UNIVERSIDADE ESTADUAL DE PONTA GROSSA
PRÓ-REITORIA DE PESQUISA E PÓS-GRADUAÇÃO
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA – DOUTORADO
ÁREA DE CONCENTRAÇÃO: DENTÍSTICA RESTAURADORA

THALITA DE PARIS MATOS BRONHOLO

AVALIAÇÃO CLÍNICA DE DIFERENTES SISTEMAS ADESIVOS E TÉCNICAS DE ADESÃO EM LESÕES CERVICAIS NÃO CARIOSAS

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Tese apresentada como pré-requisito para obtenção do título de Doutora na Universidade Estadual de Ponta Grossa, no Programa de Pós-Graduação *Stricto Sensu* em Odontologia – Área de Concentração Dentística Restauradora. Linha de Pesquisa: Pesquisa Clínica em Odontologia.

Orientador: Prof. Dr. Alessandro Dourado Loguercio

PONTA GROSSA
2021

Bronholo, Thalita de Paris Matos

B869

Avaliação clínica de diferentes sistemas adesivos e técnicas de adesão em lesões cervicais não cariosas / Thalita de Paris Matos Bronholo. Ponta Grossa, 2021.

143 f.

Tese (Doutorado em Odontologia - Área de Concentração: Dentística Restauradora), Universidade Estadual de Ponta Grossa.

Orientador: Prof. Dr. Alessandro Dourado Loguercio.

1. Estudo clínico. 2. Adesivos dentinários. 3. Condicionamento ácido do dente. I. Dourado Loguercio, Alessandro. II. Universidade Estadual de Ponta Grossa. Dentística Restauradora. III.T.

CDD: 617.6

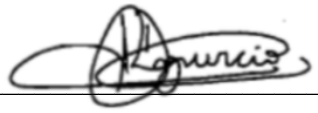
Ficha catalográfica elaborada por Maria Luzia Fernandes Bertholino dos Santos- CRB9/986

Thalita de Paris Matos Bronholo

Avaliação clínica de diferentes sistemas adesivos e técnicas de adesão em lesões cervicais não cariosas.

Tese apresentada ao Programa de Pós-graduação Stricto sensu em Odontologia da Universidade Estadual de Ponta Grossa, como requisito parcial à obtenção do título de Doutor em Odontologia, área de concentração em Dentística Restauradora linha de pesquisa de Pesquisa Clínica.

Ponta Grossa, 09 de fevereiro de 2021.



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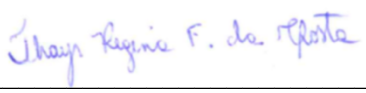

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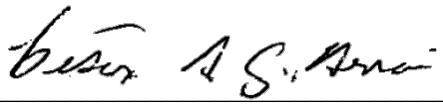

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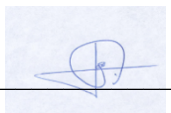

Prof. Dr. João Carlos Gomes
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Dedico este trabalho aos meus pais, Carla e Claudio, que de forma especial e carinhosa me deram força e coragem, me apoiando em todos os momentos.

“Porque sou eu que conheço os planos que tenho para vocês', diz o Senhor, 'planos de fazê-los prosperar e não de causar dano, planos de dar a vocês esperança e um futuro.”

Jeremias 29:11

AGRADECIMENTOS

A **Deus**, te agradeço pelo amor com que me conduzistes para realização desse sonho. Te agradeço pelos obstáculos enfrentados, pois com as dificuldades, amadurecemos. Obrigada pela sua companhia diária, pela paz que tenho em te seguir e te servir. O alvo está sendo alcançado, obrigada por me orientar no caminho certo.

Aos meus pais, **Claudio Jorge Vilela Matos** e **Carla Aparecida de Paris Matos**, que nunca mediram esforços em me ajudar, que me ensinaram o caminho certo, amar a Deus acima de todas as coisas. E que sempre em meio as dificuldades, suas palavras são: *"Confie no Senhor, que tudo vai dar certo"*. Obrigada por estarem ao meu lado em todos os momentos e por ser uma fortaleza verdadeira.

Ao meu esposo, **Ricardo Bronholo**, que desde o dia em que falei que um dos meus sonhos era fazer Doutorado, me apoiou, me incentivou. Obrigada por ser meu parceiro para tudo, por nunca reclamar da minha ausência, obrigada pelas palavras de conforto. Obrigada por estar comigo nos momentos mais críticos e por sempre dizer que o Senhor me fortalece. Você é resposta de oração na minha vida. Obrigada pelo seu sorriso incansável. Te amo.

Ao meu irmão, **Lincoln de Paris Matos**, que tem uma inteligência admirável, que é muito especial na minha vida e que torce por mim.

Ao meu orientador, **Alessandro Loguercio**, que desde o meu segundo ano da graduação me orientou, me ensinou, mesmo em meio a pequenas dúvidas, sempre esteve disposto a ajudar. Sou muito grata por todo ensinamento que tive nesse período, posso dizer que cresci muito. Me inspiro em seu exemplo de vida e na carreira que construiu. Obrigada pela paciência em me ensinar e pelo incentivo a ir pra frente. Espero que eu possa aprender ainda mais contigo.

A minha colega de profissão e amiga do coração **Viviane Hass**, que me ensinou tanto e que ainda me ensina a como ser um ser humano melhor, cheio de alegria e disposição. Obrigada pelos finais de semana no laboratório, pelos áudios respondendo dúvidas, por estar sempre pronta a ajudar e por orar por mim em momentos difíceis.

As **amizades** que fiz, Deus é perfeito e seus planos são perfeitos, e Ele me proporcionou lindas amizades:
Bianca Maran, **Adrieli Burey**, **Pâmela Malaquias**, **Elisama**, **Taise Alessandra Hanzen**, **Alexandra de Paula**.

Aqueles que de alguma forma me ajudaram na pesquisa, em especial a **Lujan**, **Felipe, Jullian** e **Alejandra** pela ajuda nos trabalhos.
E a todos do **Mestrado** e **Doutorado** que conheci. Obrigada por me receberem tão bem.

Ao Nino, meu gatinho fofo, que me ensinou a ter mais paciência após suas artes, mas que me trouxe muita alegria.

Aos **professores** e **funcionários** da UEPG.

A **banca presente**, pelo aceite do convite em fazer parte dela.

Por fim, agradeço a **todos** que estiveram presentes comigo neste período, me ajudando e me ensinando.

DADOS CURRICULARES

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RESUMO

Matos, T.P. **Avaliação clínica de diferentes sistemas adesivos e técnicas de adesão em lesões cervicais não cariosas.** [Tese] Doutorado em Dentística Restauradora. Ponta Grossa: Universidade Estadual de Ponta Grossa; 2021.

Objetivos: Avaliar a longo prazo diferentes técnicas de adesão, etch-and-rinse (ER), self-etch (SE) e selective enamel etch (SEE) de diferentes sistemas adesivos, convencional (CV) e universal (U), dois critérios de avaliação World Federation criteria (FDI) e United States Public Health Service (USPHS) e dois tipos de resina, flow convencional e flow modificada. **Metodologias:** Para este trabalho, foram feitos três estudos: os três ensaios clínicos randomizados (ECRs). Os ECRs foram duplo-cegos, realizado em 101 pacientes, conforme critérios de inclusão e exclusão, sendo 39, 35 e 27 em cada estudo, respectivamente. No estudo (1) foi usada a técnica ER, SEE e SE, em dentina seca e úmida, , um sistema adesivo U, avaliado pelos critérios FDI e USPHS e restaurado com resina convencional, no estudo (2) a técnica usada foi ER, dois sistemas adesivos convencionais, o critério de avaliação FDI e resina convencional, no estudo (3) foi usada a técnica adesiva SEE, um adesivo U, os critérios FDI e USPHS de avaliação e resina flow. O estudo 1 e 2 foram feitas avaliações a longo prazo de 5 anos e o estudo 3 foi feita avaliação de um ano. Os critérios de avaliação de todos os estudos seguiram os seguintes itens: retenção / fratura, adaptação marginal, coloração marginal, sensibilidade pós-operatória e recorrência de cárie. **Resultados:** No estudo (1), após 5 anos, o comportamento clínico do adesivo universal na estratégia ER foi melhor quando comparado à estratégia SE. O uso de condicionamento ácido seletivo do esmalte (SEE) é altamente recomendado para a estratégia autocondicionante. Os critérios de avaliação FDI e USPHS mostraram resultados semelhantes após 5 anos. No estudo (2) ambos os adesivos ER, Adper Single Bond 2, um adesivo contendo ácido polialquenóico, e Ambar, um adesivo contendo 10-MDP, tiveram desempenhos clínicos comparáveis e altos após 5 anos de avaliação clínica. No ECR (3) o desempenho clínico do adesivo universal associado a compósito fluido à base de ormocer ou metacrilato foi considerado promissor após um ano de avaliação clínica. Ao contrário, um compósito fluido de alta viscosidade não deve ser indicado em lesões cervicais não cariosas. **Conclusões:** A técnica ER é superior a SE, porém a técnica SE quando usado o condicionamento seletivo do esmalte (SEE) é uma opção viável. Ambos os adesivos ER, um adesivo contendo ácido polialquenóico, e um adesivo contendo MDP, tiveram desempenhos clínicos comparáveis e altos após 5 anos de avaliação clínica. Um compósito fluido de alta viscosidade não foi indicado para restaurar lesões cervicais não cariosas devido à alta perda de retenção (11,5%) após 1 ano.

Palavras-Chaves: Estudo Clínico. Adesivos Dentinários. Condicionamento Ácido do Dente.

ABSTRACT

Matos, T.P. **Clinical evaluation of different adhesive systems and adhesion techniques in non-carious cervicals. [**Thesis] Doctorate in Restorative Dentistry. Ponta Grossa: State University of Ponta Grossa; 2021.

Objectives: To evaluate different long-term adhesion techniques, being etch-and-rinse (ER), self-etch (SE) and selective enamel etch (SEE) from different adhesive systems, conventional (CV) and universal (U), two criteria World Federation Criteria (FDI) and United States Public Health Service (USPHS) and two types of resin, conventional flowable and modified flowable. **Methods:** Three studies were carried out: three randomized clinical trials (RCTs). RCTs were double-blind, performed on 101 patients, according to the inclusion and exclusion criteria, 39, 35 and 27 in each study, respectively. In study (1) the ER technique was used on dry and moist dentin, SEE and SE, a U adhesive system, evaluated by the FDI and USPHS criteria and restored with conventional resin, in study (2) the technique used was ER, a conventional adhesive system, the FDI evaluation criteria and conventional resin, in the study (3) the SEE adhesive technique, a U adhesive, the FDI and USPHS evaluation criteria and flow resin were used. Study 1 and 2 are long-term evaluations of 5 years and study 3 is a one-year evaluation. The evaluation criteria of all studies followed the following items: retention / fracture, marginal adaptation, marginal color, postoperative sensitivity and caries recurrence. **Results:** In the study (1), after 5 years, the clinical behavior of the universal adhesive in the ER strategy was better when compared to the SE strategy. The use of selective acid enamel conditioning (SEE) is highly recommended for the self-etching strategy. The FDI and USPHS evaluation criteria showed similar results after 5 years. In study (2) both ER system technique, Adper Single Bond 2, a adhevise containing polyalkenoic acid, and Ambar, a adhesive containing 10-MDP, had comparable and high clinical performances after five years of clinical evaluation. In the RCT (3), the clinical performance of the universal adhesive associated with a flowable composite based on ormocer or methacrylate was considered promising after one year of clinical evaluation. Conversely, a high viscosity fluid composite should not be indicated for non-carious cervical lesions. **Conclusions:** The ER technique is superior to SE, but the SE technique when using selective enamel conditioning (SEE) is a viable option. Both adhesives, one containing polyalkenoic acid, and other containing MDP, had comparable and high clinical performances after 5 years of clinical evaluation. A high viscosity flowable composite was not indicated to restore non-carious cervical lesions due to the high loss of retention (11.5%) after one year.

Keywords: Clinical study. Dentin Adhesives. Acid Tooth Conditioning.

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LISTA DE ABREVIATURAS E SIGLAS

AB	*Ambar*
ADA	*American Dental Association*
Bis-GMA	*Bisphenol-A-glycidyl dimethacrylate*
COEP	Comitê de Ética em Pesquisa
CONSORT	CONsolidação Padronizada de Estudos Clínicos Randomizados
ER	*Etch-and-rinse*
ERm	*Etch-and-rinse moisture*
ERd	*Etch-and-rinse dry*
FDI	*World Federation criteria*
GO	*Clinically good*
HR	*Hazard Ratio*
HV	*High viscosity*
HEMA	*2-hydroxyethyl methacrylate*
HEDMA	*1,6-hexanediol dimethacrylate*
IC	*Confidence Interval*
LCNCs	Lesão Cervical Não Cariosa
LV	*Low viscosity*
10-MDP	10-metacriloxidecil di-hidrogenofosfato
ORMOCER	Cerâmicas modificadas organicamente
ORM	*Ormocer-based flowable composite*
PAC	Copolímero de ácido polialquenóico
PO	*Clinically poor*
Rebec	Registro Brasileiro de Ensaios Clínicos
SE	*Self-etch*
SEE	*Selective Enamel Etch*
SB	*Adper Single Bond 2*
SS	*Clinically sufficient/satisfactory*
TCLE	Termo de Consentimento Livre e Esclarecido
TEGDMA	*Triethylene glycol methyl ether methacrylate*
USPHS	*United States Public Health Service*
UEPG	Universidade Estadual de Ponta Grossa

UN	*Clinically unsatisfactory*
VG	*Clinically very good*
Vs.	Versus

SUMÁRIO

1 INTRODUÇÃO

A incidência de lesões cervicais não-cariosas (LCNC) é alta, principalmente no que diz respeito à população adulta e idosa, visto que o processo de desgaste do tecido dentário é fisiológico, de progressão lenta e contínua ao longo da vida e faz parte do envelhecimento [1]. Por exemplo, nas populações de meia-idade e idosas da China, a prevalência dessas lesões foi de 76.8 e 81.3%, respectivamente [2]. Esses números podem diferir entre as populações, mas quase sempre excedem 50% [3-6]. Além de interferirem na integridade estrutural, vitalidade pulpar e aumentar a retenção de biofilme, as LCNCs podem exacerbar a sensibilidade dentária [7, 8].

As LCNCs são conhecidas por não possuírem comprometimento bacteriano, e são descritas como a perda da estrutura dentária na junção amelo-cementária [9]. Tendo em vista sua conformação reta ou angulada, sua aparência pode variar desde lesões mais superficiais à defeitos mais profundos. Além disso, podem estar presentes na face vestibular, lingual ou proximal dos dentes [1].

Apesar de sua terminologia estar sendo atualizada, sendo dividida em tensão (abfração), fricção (desgaste) e biocorrosão (degradação química, bioquímica e eletroquímica) [4], sua antiga classificação ainda é a mais utilizada, sendo ela: abfração, abrasão, atrição e erosão, as quais possuem etiologia multifatorial, influenciadas pela alimentação, ingestão de ácidos, presença de hábitos parafuncionais, estresse, interferências oclusais e desoclusões anteriores [1, 10, 11]. Além disso, sua localização também influencia, visto que há uma maior frequência em caninos (23-25%), primeiros pré-molares (23-24%) e segundos pré-molares (25-31%) [1, 12, 13].

E a hipersensibilidade dentinária pode ser descrita como uma resposta a pacientes com LCNCs, frente à diversos fatores, como estímulos térmicos, táteis, osmóticos e químicos. Provoca uma dor curta e aguda, decorrente da dentina exposta à cavidade bucal. Além disso, é definida quando não há qualquer outra forma de defeito dentário ou patologia bucal presente [14]. A ingestão de alimentos ácidos (como frutas), doces, alimentos salgados ou a exposição à estímulos frios são uma das queixas mais frequentes dos pacientes, bem como estímulos táteis (durante a escovação, por exemplo) [15, 16].

As resinas compostas são o material de escolha para o tratamento das LCNCs, como mostra um estudo feito por 178 cirurgiões-dentistas da Rede de Pesquisa em Prática Odontológica, os quais realizaram 1.301 restaurações em dentes que possuíam defeitos não-

cariosos [17, 18]. O material que une a resina composta aos dentes é o sistema adesivo, que tem se desenvolvido rapidamente devido a alta demanda na prática clínica. As duas categorias principais de sistemas adesivos são: adesivos *etch-and-rinse* (ER) e adesivos *self-etch* (SE). Os adesivos ER são divididos em dois subgrupos: ER de três e de dois passos [19, 20]. A estratégia ER de três passos é considerada o padrão ouro dos sistemas adesivos [19], porém é uma técnica sensível, e seu protocolo pode falhar com dentina úmida ou excessivamente seca [21]. Os adesivos ER de três passos foram simplificados para adesivos ER de dois passos, que combinam o primer e o adesivo em um único frasco.

Os adesivos autocondicionantes (SE) são divididos em dois subgrupos: adesivos autocondicionantes de dois e de um passo. Os adesivos SE têm menos etapas e são menos sensíveis a problemas técnicos em comparação com os adesivos ER, pois eliminam a aplicação de ácido fosfórico e o processo de enxágue [19]. Embora os sistemas ER tenham sensibilidade técnica, eles claramente têm melhor desempenho clínico do que os adesivos SE [22, 23]. Investigações relataram que o condicionamento ácido seletivo do esmalte (SEE) produziu melhor desempenho clínico [24-27].

Os fabricantes têm trabalhado rapidamente para desenvolver sistemas adesivos que garantam restaurações duradouras. A filosofia atual de simplificar o processo de aplicação, economizar tempo e eliminar o potencial de erro de várias etapas levou à fabricação de adesivos multimodo, permitindo ao clínico escolher um adesivo de acordo com seu uso. No entanto, alguns estudos indicaram que a simplificação dos adesivos ER e SE resulta na diminuição do desempenho clínico [28].

Mais recentemente, a introdução de adesivos universais permitiu usar adesivos de acordo com seu próprio julgamento para situações clínicas específicas. Os adesivos universais são baseados no conceito “frasco único” de adesivos autocondicionantes e podem ser usados em três modos diferentes (ER, SE e SEE) [29-32]. Os adesivos universais também podem aderir a vários substratos além das superfícies dos dentes, incluindo resina composta, metais, zircônia e cerâmicas à base de sílica [31]. Além disso, a adição de monômeros funcionais com potencial capacidade de adesão química à estrutura dentária pode ser benéfica em termos de durabilidade, pois garante uma adaptação íntima do substrato e dos componentes do biomaterial, evitando assim a nanoinfiltração [28]. Dois monômeros com esse potencial químico são: copolímero de ácido polialquenóico (PAC) e 10-metacriloxidecil di-hidrogenofosfato (MDP) [33, 34]. O primeiro foi usado pela primeira vez na composição de Vitrebond (3M Oral Care) e, mais recentemente, foi usado em várias formulações de adesivos do mesmo fabricante [35-37].

Devido à capacidade do PAC de se ligar quimicamente ao cálcio na hidroxiapatita, um desempenho clínico muito bom foi observado quando os adesivos ER contendo PAC são usados [23, 38-41]. Por outro lado, está bem documentado que, devido à formação de sais de 10-MDP-Ca hidroliticamente estáveis [42], a presença de MDP promove uma ligação química estável com substratos dentais [42, 43]. Apesar do uso recente, o desempenho clínico de adesivos ER contendo MDP foi avaliado e mostrou resultados muito bons [44, 45]. No entanto, até onde sabemos, apenas um ensaio clínico randomizado de curto prazo (18 meses) foi encontrado que comparou um adesivo contendo PAC e um adesivo contendo MDP, com resultados semelhantes entre os dois materiais [46].

Apesar de não resolverem o fator etiológico das lesões, as restaurações com resinas compostas são responsáveis por reestabelecer a função e a estética dos dentes, além de substituírem o tecido dental perdido, diminuírem a retenção de placa (o que consequentemente regride a incidência de lesões cariosas nessa região), restaurarem a integridade estrutural dentária e reduzirem ainda mais o desgaste [18, 47]. Porém, como nas LCNCs as restaurações são feitas na cervical dos dentes, ou muitas vezes sub-gengivalmente à esses, há uma dificuldade no controle da umidade dessa região [47-49], podendo diminuir a adesão da resina composta, juntamente à contínua distribuição de forças oclusais durante a mastigação, contrastando com o alto módulo de elasticidade do material restaurador [50-52].

Entre todos os tipos de resinas compostas disponíveis, os compósitos fluidos possuem menor carga de preenchimento e menos conteúdo de resina viscosa, o que difere dos compósitos de viscosidade regular [53-55]. Dessa forma, possuem um módulo de elasticidade 20% a 30% menor e são menos rígidos [54, 56, 57]. Assim, durante as forças mecânicas submetidas aos dentes quando estão em função, esse baixo módulo de elasticidade pode teoricamente absorver as tensões geradas durante a contração de polimerização dos compósitos [47].

Apesar de alguns estudos relatarem pouca diferença no desempenho clínico das resinas fluidas quando comparadas as de viscosidade regular em LCNCs [47, 48, 58, 59], esta ainda possui vantagem por possuir maior facilidade em sua aplicação, além de obter interfaces restauradoras com melhor adaptação marginal [47].

Os polímeros à base de metacrilato são a maioria dos compósitos fluidos apresentados no mercado, e podem conter dimetacrilato de bisglicidilo (bis-GMA), dimetacrilatos de etilenoglicol (EGDMA e TEGDMA), dimetracrilatos de uretano (UDMA) e metacrilato de hidroxietilo (HEMA). Contudo, essas resinas podem estar associadas à citotoxicidade e

genotoxicidade, incluindo alergias, disrupção de DNA, formação reduzida de dentina secundária e desregulação endócrina [60, 61].

Esses copolímeros de metacrilato, quando expostos externamente ao fluido salivar e internamente à dentina hidratada subjacente, causam sorção de água do ambiente oral [62-64], afetando negativamente as propriedades mecânicas da restauração, já que reduzem o atrito entre as cadeias [65]. Isso não só afeta a adaptação marginal das restaurações, como também sua descoloração marginal [45].

Por isso, cerâmicas modificadas organicamente, as ORMOCER®, foram criadas na intenção de superar os problemas de contração de polimerização dos compósitos convencionais, pois possuem um coeficiente de expansão térmica muito semelhante ao da estrutura dentária natural [60, 66]. Atualmente, os compostos nano-ORMOCER® resultaram a partir de uma tecnologia de matriz de silicato puro combinada com cargas nano-híbridas, a fim de substituir todas as resinas de metacrilato, além dos agentes de reticulação, os redutores de viscosidade baseados em metacrilato e os acrílicos hidrofílicos comumente usados em falhas de compósitos [67].

Embora haja resultados controversos a respeito do desempenho desse composto quando comparado ao metacrilato em restauração de dentes posteriores [68-71], estudos sobre o desempenho clínico após essas mudanças químicas em LCNCs ainda é escasso.

Portanto, os três ECRs têm como objetivo avaliar a longo prazo diferentes técnicas de adesão, seja ER, SE e selective enamel etch (SEE) de diferentes sistemas adesivos, convencional (CV) e universal (U), com dois critérios de avaliação World Federation criteria (FDI) e United States Public Health Service (USPHS) e dois tipos de resina: flow convencional e flow modificada.

2 MATERIAL E MÉTODOS

Nesta sessão será descrita a metodologia de forma resumida de cada experimento. As informações detalhadas deste item podem ser encontradas nos artigos referentes a cada experimento.

2.1 EXPERIMENTO 1

O projeto deste estudo clínico foi aprovado pelo Comitê de Ética em Pesquisa (COEP) da Universidade Estadual de Ponta Grossa através do protocolo nº 05909/11 e registrado no Registro Brasileiro de Ensaios Clínicos (ReBEC) sob o número RBR-3BF686. A metodologia detalhada deste experimento está descrita no Artigo 1 (p. 39).

2.1.1 Seleção dos Pacientes

Os sujeitos foram recrutados à medida que buscavam tratamento nas clínicas da Faculdade de Odontologia da universidade local. Nenhum anúncio foi feito para recrutamento de participantes. Os pacientes foram recrutados na ordem em que se relataram para a sessão de triagem, formando uma amostra de conveniência. Todos os voluntários assinaram um Termo de Consentimento Livre e Esclarecido (TCLE) antes de participarem do estudo (APÊNDICE A). Os participantes deveriam ter pelo menos quatro LCNCs para serem restaurados em dentes diferentes. As lesões deveriam ser não cariosas, não retentivas, mais profundas que 1 mm e envolver tanto o esmalte quanto a dentina de dentes vitais sem mobilidade. A margem cavo-superficial não pode envolver mais do que 50% do esmalte [72]. Todos os indivíduos receberam instruções de higiene oral antes da realização do tratamento operatório. Pacientes com higiene bucal extremamente precária ou em uso de dispositivos ortodônticos, periodontite grave ou crônica ou hábitos de bruxismo pesado foram excluídos do estudo, pois receberiam outros tratamentos antes da intervenção restauradora. Além disso, participantes com alergia conhecida a materiais à base de resina ou qualquer outro material utilizado neste estudo, mulheres grávidas ou amamentando, ou participantes em uso crônico de anti-inflamatórios, analgésicos e psicotrópicos não foram incluídos no estudo.

2.1.2 Cálculo do Tamanho Amostral

O cálculo do tamanho da amostra foi baseado na taxa de retenção do Adper Single Bond / Adper Single Bond Plus (3M Oral Care, St. Paul, MN, EUA), os predecessores deste adesivo universal do mesmo fabricante. A retenção foi relatada como sendo de 94% em 2 anos de acompanhamento [23, 40, 73-76]. Usando um α de 0,05, um poder de 80% e um teste bilateral, o tamanho mínimo da amostra foi de 50 restaurações em cada grupo, a fim de detectar uma diferença de 20% entre os grupos testados [77]. Neste estudo boca-dividida, foi realizada uma randomização simples no site *www.sealedenvelope.com*. Os quais foram numerados sequencialmente em envelopes opacos e selados, de forma que o operador e paciente só saberiam qual gel seria aplicado em cada hemi-arco no momento da intervenção quando o envelope fosse aberto.

2.1.3 Randomização e Ocultação da Sequência Aleatória

O processo de randomização foi realizado em tabelas geradas por computador por um membro da equipe não envolvido no protocolo de pesquisa. Os detalhes do grupo alocado foram registrados em cartões contidos em envelopes numerados sequencialmente, opacos e lacrados. Estes foram preparados por um membro da equipe que não esteve envolvido em nenhuma das fases do ensaio clínico.

A atribuição da alocação foi revelada com a abertura do envelope no dia do procedimento restaurador, o que garantiu o ocultamento da sequência aleatória. Em todos os casos, o dente com o maior número de dente FDI recebeu o tratamento descrito primeiro, enquanto o dente com o próximo número na sequência recebeu o tratamento mencionado em segundo lugar e o dente seguinte recebeu o tratamento mencionado em terceiro. Os participantes e os examinadores não tinham conhecimento da tarefa do grupo.

2.1.4 Intervenção: Procedimento Restaurador

Os mesmos dentistas calibrados envolvidos na seleção dos participantes realizaram os procedimentos restauradores. As características dos LCNCs foram avaliadas antes da colocação das restaurações e foi preenchida uma ficha com todas as informações da lesão (ANEXO C). O grau de esclerose dentinária foi avaliado de acordo com um sistema de classificação [78]

modificado por Swift et al. [79] (Tabela 4.1.1); as dimensões da lesão em milímetros (altura, largura e profundidade); e a geometria da lesão (avaliada por fotografia e classificada em <45°, 45° – 90°, 90° – 135°, > 135°) foram registradas [80]. Outras características, como a presença de faceta de desgaste de oclusão [52], também foram observadas e registradas. A sensibilidade pré-operatória também foi avaliada aplicando um jato de ar por 10 s de uma seringa odontológica colocada a 2 cm da superfície do dente (secar ao ar) e com uma sonda exploradora (toque).

Para calibrar o procedimento restaurador, o diretor do estudo colocou uma restauração de cada grupo para identificar todas as etapas envolvidas no protocolo. Em seguida, os dois operadores com mais de cinco anos de experiência clínica em odontologia operatória colocaram quatro restaurações de cada grupo em um ambiente clínico sob a supervisão do diretor do estudo. Quaisquer discrepâncias do protocolo restaurador foram identificadas e discutidas com o operador antes do início do estudo. Nesse momento, os operadores foram considerados calibrados para realizar os procedimentos restauradores. Os operadores calibrados restauraram todos os dentes sob a supervisão do diretor de estudo.

A profilaxia dentária preliminar da superfície dentária foi realizada com pedra-pomes e água antes do procedimento restaurador, seguida de enxágue e secagem. A anestesia local foi aplicada com solução de mepivacaína a 3% (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brasil) e todas as restaurações foram colocadas sob isolamento absoluto. Seguindo as diretrizes da American Dental Association (ADA) [81], os operadores não prepararam nenhuma retenção ou bisel adicional.

As LCNCs receberam o sistema Scotchbond Universal Adhesive (SU, 3M Oral Care, St. Paul, MN, EUA, também conhecido como Single Bond Universal em alguns países) aplicado em diferentes modos: uma abordagem ER, mantendo a dentina úmida (ERm) ou seco (ERd); e uma abordagem autocondicionante com (SEE) ou sem condicionamento seletivo do esmalte (SE). As composições, modos de aplicação e números de lote são descritos na Tabela 4.1.2.

No grupo ERm a dentina foi mantida visivelmente úmida, enquanto no grupo ERd a dentina foi seca ao ar por 5 s, mas não em excesso. No grupo SEE, a lesão foi seca ao ar após enxágue do ácido do esmalte. A dentina foi mantida seca em ambos os grupos SE. O adesivo foi esfregado vigorosamente em toda a superfície da dentina em todos os grupos por aproximadamente 20 s, de acordo com as recomendações do fabricante (Tabela 4.1.2), seguido

de aplicação de ar por 5s e fotopolimerização (Radii Cal, SDI , Bayswater, Victoria, Austrália) por 10 s (1000 mW / cm2).

Após a aplicação do adesivo, a resina composta Filtek Supreme Ultra (3M Oral Care, St. Paul, MN, EUA) foi usada em até três incrementos, cada um fotopolimerizado (Radii Cal, SDI, Victoria, Austrália) por 30 s. As restaurações foram concluídas imediatamente com brocas de diamante fino (KG Sorensen, Barueri, SP, Brasil). O polimento foi realizado com pontas de borracha (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein) uma semana após a colocação das restaurações.

2.1.5 Cegamento

Os avaliadores não estavam envolvidos com os procedimentos restauradores e, portanto, cegos para a atribuição do grupo. Os indivíduos também foram cegados para a atribuição de grupo em um projeto de ensaio clínico randomizado duplo-cego.

2.1.6 Avaliação Clínica

Todos os parâmetros de avaliação foram registrados em um formulário de papel padronizado (ANEXO C). O formulário de avaliação foi enviado para a equipe de pesquisa após cada observação, para que os avaliadores não pudessem saber a atribuição do grupo durante os recalls de acompanhamento. As restaurações foram avaliadas usando dois critérios: o FDI [82, 83] e os critérios USPHS (adaptado por Dalton Bittencourt et al. E Perdigão et al.) [75, 76] imediatamente após o procedimento restaurador (baseline), e após 6, 18, 36 meses e cinco anos de acompanhamento clínico.

Para qualquer um dos dois critérios, apenas as medidas clinicamente relevantes do desempenho dos adesivos foram avaliadas (Tabelas 4.1.3 e 4.1.4). O desfecho primário foi retenção / fratura, mas os seguintes desfechos secundários também foram avaliados: coloração marginal, adaptação marginal, sensibilidade pós-operatória e recorrência de cárie. A sensibilidade pós-operatória foi realizada uma semana após o procedimento restaurador, aplicando-se um jato de ar de uma seringa odontológica por 10 s a 2 cm da superfície dentária.

Essas variáveis foram classificadas de acordo com os critérios nas seguintes pontuações: (1) critérios FDI (clinicamente muito bom; clinicamente bom; clinicamente suficiente / satisfatório; clinicamente insatisfatório e clinicamente ruim) e (2) critérios USPHS (Alfa - bom,

Bravo - satisfatório e Charlie - pobre). Ambos os examinadores avaliaram todas as restaurações uma vez e de forma independente.

2.1.7 Análise Estatística

As análises estatísticas seguiram o protocolo de intenção de tratar de acordo com a sugestão do CONSORT (Consolidated Standards of Reporting Trials) [84]. Estatísticas descritivas foram usadas para descrever as distribuições dos critérios avaliados.

As taxas de sobrevida (dados de retenção / fratura) de diferentes grupos de restaurações foram calculadas pelo procedimento de Kaplan-Meier, estimando a Hazard Ratios (HR) e intervalos de confiança de 95%. O teste de log-rank foi usado para comparar as distribuições de sobrevivência dessas restaurações ($\alpha = 0,05$).

Para o resultado secundário (coloração marginal, adaptação marginal, sensibilidade pós-operatória e recorrência de cárie), em cada parâmetro geral (FDI e USPHS), as diferenças entre as classificações dos quatro grupos após 5 anos foram testadas por medidas repetidas de Friedman classificação da análise de variância ($\alpha = 0,05$). As estatísticas kappa de Cohen foram usadas para testar a concordância entre examinadores ($\alpha = 0,05$) (MedCalc Software, Versão 19.1, Ostend, Bélgica).

2.2 EXPERIMENTO 2

O projeto deste estudo clínico foi aprovado pelo COEP da UEPG através do protocolo nº protocol 14918/10. A metodologia detalhada deste experimento está descrita no Artigo 2 (p. 73-77).

2.2.1 Cálculo do Tamanho Amostral

O cálculo do tamanho da amostra foi baseado na taxa de retenção do adesivo comparativo (Adper Single Bond 2) relatado em estudos anteriores em 18-24 meses [75, 76, 85, 86]. Usando um α de 0,05, um poder de 90% e um limite de equivalência de 20%, um mínimo de 26 participantes com dois NCCL de tamanho semelhante foram necessários.

2.2.2 Seleção dos Pacientes

Um total de 51 participantes foram examinados por dois estudantes de odontologia calibrados para determinar se eles atendiam aos critérios de inclusão e exclusão (Figura 4.1.1). Os que se qualificaram para o estudo foram recrutados na ordem em que se apresentavam para a sessão de triagem, formando uma amostra de conveniência. Foram selecionados 35 voluntários e todos assinaram o TCLE antes de participarem do estudo (APÊNDICE B).

2.2.3 Randomização e Ocultação da Sequência Aleatória

Um membro da equipe não envolvido no protocolo de pesquisa realizou o processo de randomização com uma moeda que foi jogada imediatamente antes da colocação da restauração. O operador não foi cegado para a atribuição de grupo ao administrar intervenções; no entanto, os participantes e avaliadores não tinham conhecimento da atribuição do grupo.

2.2.4 Procedimento Restaurador

Todos os pacientes selecionados para este estudo receberam profilaxia dentária com pedra-pomes e água. O grau de dentina esclerótica dos NCCLs foi medido de acordo com os critérios descritos por Swift e outros (Tabela 4.2.11) [79]. As dimensões da cavidade em milímetros (altura, largura e profundidade), a geometria da cavidade (avaliada por fotografia de perfil e marcados a <45°, 45° -90 °, 90° -135° e > 135°), a presença de um antagonista e a presença de facetas de desgaste foram observadas e registradas. A sensibilidade pré-operatória também foi avaliada aplicando ar por 10 segundos a partir de uma seringa odontológica colocada a 2 cm da superfície do dente e com uma sonda exploradora. Essas características foram registradas para permitir a comparação das características básicas das cavidades dentinárias entre os grupos experimentais.

Os operadores calibrados restauraram todos os dentes sob a supervisão do diretor de estudo. Todos os participantes receberam duas restaurações, uma de cada grupo experimental, em lesões diferentes previamente selecionadas de acordo com os critérios de inclusão.

Antes dos procedimentos restauradores, os operadores anestesiaram os dentes com solução de mepivacaína a 3% (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brasil) e limparam todas as lesões com pedra-pomes e água em copo de borracha, seguido de enxágue e secagem. Em

seguida, a seleção de cores foi feita usando um guia de cores. Seguindo as diretrizes da American Dental Association (ADA) [81], nenhuma retenção ou bisel adicional foi preparado.

Um dique de borracha foi colocado e as LCNCs receberam o Adper Single Bond 2 (3M Oral Care, St. Paul, MN, EUA; também conhecido como Adper Single Bond Plus e Adper Scotchbond 1XT em alguns países) ou Ambar (FGM, Joinville , SC, Brasil) sistema adesivo, que definiu os dois grupos diferentes. As composições e modos de aplicação são descritos na Tabela 4.3.12.

Ambos os adesivos foram aplicados de acordo com as instruções do fabricante (Tabela 4.1.12). Resumidamente, a cavidade foi condicionada com ácido fosfórico 37% (CondAc 37, FGM) por 15 segundos, depois enxaguada com água por 15 segundos e seca suavemente com uma corrente de ar livre de óleo, deixando a superfície dentinária ligeiramente úmida. O adesivo foi esfregado por 10 segundos nas superfícies das cavidades e o solvente foi evaporado com um jato de ar por 20 segundos. Outra camada de adesivo foi aplicada, o solvente foi evaporado e a camada adesiva fotopolimerizada (Radii-Cal, SDI, Victoria, Austrália) por 10 segundos a 1200 mW / cm2.

Três incrementos de resina composta (Opallis, FGM) com 2 mm foram colocados, e cada um fotopolimerizado por 40 segundos. Por fim, as restaurações foram finalizadas e polidas com brocas diamantadas de grão fino (# 3195F e # 3195FF, KG Sorensen, Barueri, São Paulo, Brasil.) e discos abrasivos flexíveis (Diamond Pro, FGM).

2.2.5 Avaliação Clínica

As restaurações foram avaliadas pelo FDI critérios (Tabela 4.2.13) no início e após 6, 12, 18 e 60 meses de serviço clínico. Apenas as medidas clinicamente relevantes para avaliação do desempenho dos adesivos foram utilizadas e pontuadas (Tabela 4.2.13). O resultado clínico primário foi a retenção da restauração / fraturas, mas os seguintes resultados secundários também foram avaliados: coloração marginal, adaptação marginal, sensibilidade pós-operatória e recorrência de cárie. A avaliação da sensibilidade pós-operatória espontânea foi realizada uma semana após o procedimento restaurador. Essas variáveis foram classificadas de acordo com os critérios do FDI nos seguintes escores: clinicamente muito bom; clinicamente bom; clinicamente suficiente / satisfatório; clinicamente insatisfatório; clinicamente pobre.

2.2.6 Análise Estatística

As análises estatísticas seguiram o protocolo de intenção de tratar de acordo com a sugestão do CONSORT [84]. Estatísticas descritivas foram utilizadas para descrever as distribuições dos critérios avaliados.

As taxas de sobrevivência (dados de retenção / fratura) de diferentes grupos de restaurações foram calculadas pelo procedimento de Kaplan-Meier, estimando as razões de risco (HR) e intervalos de confiança de 95%. O teste de log-rank foi usado para comparar as distribuições de sobrevivência dessas restaurações ($\alpha = 0,05$). Para os resultados secundários (coloração marginal, adaptação marginal, sensibilidade pós-operatória e recorrência de cárie), as diferenças entre as classificações dos dois grupos após 5 anos foram testadas pela classificação de análise de variância de medidas repetidas de Friedman ($\alpha = 0,05$). As estatísticas kappa de Cohen foram usadas para testar a concordância entre examinadores. ($\alpha = 0,05$) (Statistica for Windows 7.0, StatSoft Inc., Tulsa, OK, EUA).

2.3 EXPERIMENTO 3

A descrição do desenho experimental seguiu a declaração do (CONSORT) [19]. O Comitê de Ética da Universidade Estadual de Ponta Grossa (protocolo 3.604.611; 2019) (ANEXO A) revisaram e aprovaram o protocolo e emitiram um termo de consentimento para este estudo. O consentimento informado por escrito foi obtido de todos os participantes antes do início do tratamento (APÊNDICE C). Este ensaio clínico foi registrado no REBEC, RBR-998R5B (ANEXO B).

2.3.1 Cálculo do Tamanho da Amostra

A taxa de retenção anual de compósitos fluidos em 3 anos é de aproximadamente 80% [47]. Com um α de 0,05, um poder de 90% e um ensaio de equivalência de 25%, um tamanho mínimo de amostra de 60 restaurações por grupo no pedido para detectar uma diferença de 25% entre os grupos de teste.

2.3.2 Seleção dos Pacientes

Todos os participantes foram examinados por dois estudantes de odontologia calibrados para verificar se atendiam aos critérios de inclusão e exclusão (Figura 4.3.4). As avaliações foram realizadas por meio de espelho bucal, explorador e sonda periodontal. Os participantes precisam ter boa saúde geral, ter pelo menos 18 anos, ter um nível de higiene oral aceitável e apresentar pelo menos 20 dentes em oclusão. Os participantes foram obrigados a ter pelo menos três LCNCs comparáveis (em tamanho, formato e dimensões) para serem restaurados. Essas lesões deveriam ser não retentivas, mais profundas do que 1 mm e envolver o esmalte e a dentina de dentes vitais sem mobilidade.

A margem cavo-superficial não pode envolver mais de 50% do esmalte. Pacientes com higiene bucal extremamente pobre ou usando dispositivos ortodônticos, periodontite grave ou crônica ou hábitos de bruxismo pesado foram excluídos do estudo, pois precisam receber outros tratamentos antes da intervenção restauradora. Além disso, participantes com alergia conhecida a materiais à base de resina ou qualquer outro material usado neste estudo, mulheres grávidas ou amamentando, ou participantes em uso crônico de anti-inflamatórios, analgésicos e psicotrópicos não foram incluídos no estudo.

2.3.3 Randomização e Ocultação da Sequência Aleatória

A randomização foi feita intra-individual de forma que cada sujeito ficasse com três restaurações. Esses esquemas de randomização são realizados por meio de ferramentas disponíveis no site http://www.sealenvelope.com.

Um membro da equipe não envolvido no protocolo de pesquisa realizou o processo de randomização. Os detalhes dos grupos alocados foram registrados em cartões contidos em envelopes numerados sequencialmente, opacos e lacrados. A abertura do envelope apenas no dia do procedimento restaurador garante o encobrimento da sequência aleatória. Em todos os casos, o dente com o maior número (sistema de numeração FDI) recebeu o tratamento descrito primeiro, enquanto o dente com o próximo número na sequência recebeu o tratamento mencionado em segundo lugar, com a colocação continuando de maneira semelhante até o terceiro dente.

2.3.4 Procedimento Restaurador

Todos os pacientes selecionados para este estudo receberam profilaxia dentária com pedra-pomes e água. O grau de dentina esclerótica dos NCCLs foi medido (Tabela 4.3.16). As dimensões da cavidade em milímetros (altura, largura e profundidade), a geometria da cavidade, a presença de um antagonista, e a presença de facetas de atrito foi observada e registrada (ANEXO 7.3). A sensibilidade pré-operatória também foi avaliada aplicando-se ar por 10 s a partir de uma seringa odontológica colocada a 2 cm da superfície do dente e com um explorador.

Antes dos procedimentos restauradores, os operadores anestesiaram os dentes com solução de mepivacaína a 3% (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brasil) e limparam todas as lesões com pedra-pomes e água em copo de borracha (ref # 8040RA e # 8045RA, KG Sorensen, Barueri, SP, Brasil), seguido de enxágue e secagem.

Em seguida, a seleção de cores foi feita usando um guia de cores do fabricante da resina. Dique de borracha foi colocado e o sistema adesivo universal Futurabond U (Voco) aplicado no modo autocondicionante associado ao condicionamento seletivo de esmalte foi aplicado de acordo com as orientações do fabricante em todas as cavidades. As composições, modos de aplicação e números de lote são descritos na Tabela 4.3.17. Em seguida, as cavidades foram restauradas com um dos três compósitos fluidos descritos abaixo:

- Composto fluido baseado em Ormocer (Admira Fusion Flow, Voco) foi colocado em seguido por fotopolimerização com uma irradiância de 1200 mW / cm2 (Bluephase N, Ivoclar Vivadent, Schaan, Liechtenstein) por 20 s cada.

- Compósito à base de metacrilato de baixa viscosidade (GrandioSO Flow, Voco) foi colocado conforme relatado para o compósito fluido à base de Ormocer.

- Compósito à base de metacrilato de alta viscosidade (GrandioSO Heavy Flow, Voco) foi colocado conforme relatado para o compósito fluido à base de Ormocer.

Após o preenchimento da cavidade, as restaurações foram concluídas imediatamente com brocas diamantadas finas e extrafinas nº 2200 (KG Sorensen, Barueri, SP, Brasil) e polidas com OptraPol NG (Ivoclar Vivadent, Schaan, Liechtenstein) sob refrigeração constante com água.

2.3.5 Avaliação Clínica

Os examinadores não estavam envolvidos com os procedimentos de restauração e, portanto, não tinham conhecimento da tarefa do grupo. O paciente estava cego para a atribuição de grupo em um ensaio clínico duplo-cego randomizado.

Um formulário em papel padronizado individual foi usado para cada avaliador em cada tempo de reavaliação, de modo que os avaliadores fossem mantidos cegos para as avaliações anteriores durante os recalls de acompanhamento (ANEXO D). As restaurações foram avaliadas pelos critérios da FDI e USPHS (adaptado por Bittencourt et al., 2005 e Perdigão et al., 2012) [75, 76]. O desfecho clínico primário foi a retenção / fratura da restauração, mas os seguintes desfechos secundários também foram avaliados: coloração marginal, adaptação marginal, sensibilidade pós-operatória, correspondência de cor e recorrência de cárie. A avaliação da sensibilidade pós-operatória espontânea foi realizada uma semana após o procedimento restaurador, perguntando-se ao paciente se ele sentia alguma dor durante o período.

Essas variáveis foram classificadas de acordo com os critérios do FDI em clinicamente muito bom, clinicamente bom, clinicamente suficiente / satisfatório, clinicamente insatisfatório, mas reparável, e clinicamente ruim (substituição necessária) e nos critérios USPHS em alfa, bravo e charlie. Ambos os examinadores avaliaram todas as restaurações uma vez e de forma independente. Quando ocorrem divergências durante as avaliações, é necessário chegar a um consenso antes de o participante ser dispensado.

2.3.6 Análise Estatística

As análises estatísticas seguiram o protocolo de intenção de tratar de acordo com a sugestão do CONSORT (Consolidated Standards of Reporting Trials). Estatísticas descritivas foram utilizadas para descrever as distribuições dos critérios avaliados. A análise estatística de cada item individual foi realizada para cada critério de avaliação (critérios FDI e USPHS). As diferenças nas avaliações dos três grupos em cada tempo de evocação foram comparadas duas a duas com o teste de Wilcoxon Signed Rank ($\alpha = 0,05$). Os riscos absolutos e relativos de cada critério foram calculados juntamente com o intervalo de confiança de 95%. A estatística kappa de Cohen foi usada para testar a concordância entre examinadores. Em todos os testes estatísticos, pré-fixamos o nível de significância em 5%.

3 ARTIGOS

3.1 ARTIGO 1 – FIVE-YEAR CLINICAL EVALUATION OF A UNIVERSAL ADHESIVE: A RANDOMIZED DOUBLE-BLIND TRIAL

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ABSTRACT

Objective: To evaluate the five-year clinical performance of Scotchbond Universal Adhesive (SU; 3M Oral Care, St. Paul, MN, USA) in non-carious cervical lesions (NCCLs) using two evaluation criteria.

Methods: Thirty-nine patients participated in this study. Two hundred restorations were assigned to four groups: SU-ERm: etch-and-rinse + moist dentin; SU-ERd: etch-and-rinse + dry dentin; SU-SEE: selective enamel etching; and SU-SE: self-etch. A nanofilled composite resin was placed incrementally. The restorations were evaluated at baseline and after 5 years using both the World Dental Federation (FDI) and the United States Public Health Service (USPHS) criteria. The survival rates (retention/fractures) were calculated with the Kaplan-Meier and the log-rank test. For the secondary outcomes, Friedman repeated measures analysis of variance by rank was applied (= 0.05).

Results: After 5 years the recall rate was 86%. The retention/fracture rates were 93% for Erm and ERd, 88.4% for SEE and 81.4% for SE. A significant difference was observed for SE vs. ERd and SE vs. ERm ($p = 0.01$). Also, marginal discoloration and adaptation showed significant differences with ERm and ERd resulting in fewer marginal discrepancies than SE ($p < 0.05$).
SIGNIFICANCE: After 5 years, the clinical behavior of the universal adhesive in the etch-and-rinse strategy was better when compared to the self-etch strategy. The use of selective enamel etching is highly recommended for the self-etch strategy. The FDI and USPHS evaluation criteria showed similar results after 5 years.
Keywords: Universal adhesives; Randomized clinical trial Etch-and-rinse; Self-etch; Selective enamel etching.

3.1.1 Introduction

As the life expectancy increases, the population retains their teeth longer. All forms of tooth wear have become an impor- tant issue in clinical dentistry. In contrast to carious lesions, non-carious cervical lesions (NCCLs) correspond to a loss of hard dental tissues, usually involving enamel, dentin and cementum, on the buccal surface of teeth in the vicinity of the CEJ.

The multi-factorial etiology of NCCLs has been well estab- lished in the literature [1–3]. The prevalence of NCCLs has been reported to vary from 2% to 90%, with higher prevalence in older patients [4]. More recently, a systematic review found a higher weighed prevalence of NCCLs in populations older than 30 years (53%) compared to those younger than 30 years (43%) [5]. Several clinical situations, including dentin hyper- sensitivity, possibility of pulpal exposure, patient complaining of compromised esthetics caused by the cervical lesion, and when the integrity of the tooth is threatened, would warrant restorative intervention [6].

Restoration of NCCLs with adhesive materials is challeng- ing, as dentin comprises the largest part of the bonding substrate, with sclerotic dentin present in many of these lesions. The complex morphology and composition of scle- rotic dentin make the adhesive procedure even more difficult and prone to failure [7]. In fact, restorations inserted in NCCLs have a high incidence of retention failure, marginal defects, and secondary caries, representing one of the least durable restorations [8,9].

Some technique-associated factors are also responsible for this poor outcome, including difficult isolation, insertion technique and contouring procedures [10]. As a result of these issues, NCCLs are the substrate recommended for clinical trials of dentin adhesives, as restoration loss is more likely to occur than in preparations all surrounded by enamel or prepa- rations with macro-retention.

The use of more versatile adhesive systems is appealing to clinicians. A recent generation of dental adhesive known as “universal” was launched onto the market [11–13]. The term “universal” is due to (1) the addition of resinous monomers as 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) to provide chemical bonding to hard tissue tooth and metals [14]; (2) and also to the versatility of these universal adhesives, as dentists have the opportunity to decide which strategy to use, i.e., etch-and-rinse (ER), self-etch (SE), or selective etching of enamel margins. In addition, universal adhesives can be applied on moist or dry dentin when used in the ER mode [14]. Randomized clinical trials have shown that the bonding strategy used with universal adhesives does not influence retention after 18–36 months [15–19]. Some studies showed that the ER approach resulted in better clinical performance (higher retention rate and lower marginal discoloration) [20,21]. However, a recently review of universal adhesives suggested that long-term clinical studies are needed to assess which adhesion strategy may optimize their clinical outcomes [22].

In spite of being used for the last 28 years [23], clinical stud- ies in NCCLs have reported that the ‘wet dentin’ technique does not increase the retention rate for universal adhesives when compared to dry dentin [16,20,24]. In fact, for older simplified ER adhesives, active application of the adhesive increases retention rate [25,26]. However, there are no pub- lished clinical studies over 36-month follow-up testing this hypothesis.

Therefore, the aim of this randomized double-blind clinical trial was to study the influence of different application strategies on the clinical behavior of a universal adhesive over the course of five years (Scotchbond Universal Adhesive (SU), also known as Single Bond Universal, 3M Oral Care) placed in NCCLs, using two evaluation criteria, World Dental Federation (FDI) and United States Public Health Service (USPHS) criteria. The null hypotheses tested were: (1) the retention rate of restorations of NCCLs bonded with SU do not depend on the adhesive strategy when evaluated by FDI or USPHS criteria, (2) the other secondary outcomes (marginal staining, marginal adaptation, recurrence of caries and post-operative sensitivity) of restorations of NCCLs bonded with SU do not depend on the adhesive strategy when evaluated by FDI or USPHS criteria.

3.1.2 Material and Methods

The description of the experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statements [27].

3.1.2.1 Ethics approval

The Local University (protocol 05909/11) Ethics Committees reviewed and approved the protocol and issued a consent form for this study. Written informed consent was obtained from all participants prior to starting the treatment.

3.1.2.2 Protocol registration

This clinical trial was registered in the Brazilian Registry of Clinical Trials (REBEC), a national clinical trial registry system under protocol RBR-3BF686. All participants were informed about the nature and objectives of the study

3.1.2.3 Trial design, settings and location of data collection

This was a randomized, double-blind clinical trial. The insertion phase of this study was carried out in the clinics of the School of Dentistry at the local University from January 2011 to November 2011.

3.1.2.4 Recruitment

Subjects were recruited as they sought treatment in the clinics of School of Dentistry of the local university. No advertisement was made for participant recruitment. Patients were recruited in the order in which they reported for the screening session, thus forming a sample of convenience.

3.1.2.5 Eligibility criteria

A total of 82 participants were examined by two calibrated dentists to check if the subjects met the inclusion and exclusion criteria (Fig. 4.1.1). The evaluations were performed using a mouth mirror, an explorer and a periodontal probe. Participants had to be in good general health, at least 18 years old, an acceptable oral hygiene level and present at least 20 teeth under occlusion.

Participants were required to have at least four NCCLs to be restored in different teeth. The lesions had to be non-carious, non-retentive, deeper than 1 mm and involve both the enamel and dentin of vital teeth without mobility. The cavo-surface margin could not involve more than

50% of enamel [28]. All subjects were given oral hygiene instructions before the operative treatment was performed. Patients with extremely poor oral hygiene or using orthodontic devices, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study as they would receive other treatments before restorative intervention. Also, participants with known allergy to resin-based materials or any other material used in this study, pregnant or breastfeeding women, or par- ticipants under chronic use of anti-inflammatory, analgesic, and psychotropic drugs were not be included in the study.

3.1.2.6 Sample size calculation

The sample size calculation was based on the retention rate of the simplified etch-and-rinse Adper Single Bond/Adper Single Bond Plus (3M Oral Care, St. Paul, MN, USA), the predecessors of this universal adhesive from the same manufacturer. The retention was reported to be 94% at 2-years follow-up [29–34]. Using an a of 0.05, a power of 80% and a two-sided test, the minimal sample size was 50 restorations in each group in order to detect a difference of 20% among the tested groups [35].

3.1.2.7 Randomization sequence generation and allocation concealment

The randomization process was performed using computer- generated tables by a staff member not involved in the research protocol. Details of the allocated group were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. These were prepared by a staff member who was not involved in any of the phases of the clinical trial.

The allocation assignment was revealed by opening the envelope on the day of the restorative procedure, which ensured the concealment of the random sequence. In all cases, the tooth with the highest FDI tooth number received the treatment described first, while the tooth with the next number in sequence received the treatment mentioned second and the next tooth received the treatment mentioned third. The participants and the examiners were blinded to the group assignment.

3.1.2.8 Interventions: restorative procedure

The same two calibrated dentists involved in the selection of participants carried out the restorative procedures. The fea- tures of the NCCLs were evaluated prior to the placement of the restorations. The degree of dentin sclerosis was evaluated according to an earlier scoring system [36] modified by Swift et al. [37] (Table 4.1.1); the lesion dimensions in millimeters (height, width, and depth); and the geometry of the lesion (evaluated by photograph profile and labeled at <45°, 45° -90 °, 90° -135° e > 135°) were recorded [38]. Other features, such as the presence of occlusion wear facet [39], were also observed and recorded. Pre-operative sensitivity was also evaluated by applying an air stream for 10 s from a dental syringe placed 2 cm from the tooth surface (air dry) and with an explorer (touch).

To calibrate the restorative procedure, the study director placed one restoration of each group in order to identify all steps involved in the protocol. Then, the two operators with more than five years of clinical experience in operative den- tistry placed four restorations of each group in a clinical setting under the supervision of the study director. Any discrepancies of the restorative protocol were identified and discussed with the operator prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures. The calibrated operators restored all teeth under the supervision of the study director.

A preliminary dental prophylaxis of the tooth surface was performed with pumice and water in a rubber cup prior to the restorative procedure, followed by rinsing and drying. Local anesthesia was applied with a 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil), and all restora- tions were placed under rubber dam isolation. Following the guidelines of the American Dental Association (ADA) [40] the operators did not prepare any additional retention or bevel. The NCCLs received the Scotchbond Universal Adhesive system (SU, 3M Oral Care, St. Paul, MN, USA, also known as Single Bond Universal in some countries) applied in different modes: an etch-and-rinse approach, keeping the dentin moist (ERm) or dry (ERd); and a self-etch approach with (SEE) or without selective enamel etching (SE). The compositions, application modes, and batch numbers are described in Table 4.1.2.

In the ERm group dentin was kept visibly moist, while in the ERd group dentin was air-dried for 5 s, but not overdried. In the SEE group, the lesion was air-dried after rinsing the etchant from the enamel. Dentin was kept dry in both SE groups. The adhesive was vigorously scrubbed on the entire dentin sur- face in all groups for approximately 20 s, according to the

manufacturer's recommendations (Table 4.1.2), followed by gentle air thinning for 5 s and finally light-curing (Radii Cal, SDI, Bayswater, Victoria, Australia) for 10 s (1000 mW/cm2).

After the adhesive application, the resin composite Filtek Supreme Ultra (3M Oral Care, St. Paul, MN, USA) was used in up to three increments, each one being light-cured (Radii Cal, SDI, Victoria, Australia) for 30 s. The restorations were finished immediately with fine diamond burs (KG Sorensen, Barueri, SP, Brazil). Polishing was performed with rubber points (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein) one week after placement of the restorations.

3.1.2.9 Calibration procedures for clinical evaluation

Two experienced and calibrated dentists who were not involved with the restoration procedures performed the clinical evaluation. An inter-examiner and inter-examiner agreement of at least 85% was necessary before beginning the evaluation [35].

3.1.2.10 Blinding

The examiners were not involved with the restoration proce- dures and therefore blinded to the group assignment. Subjects were also blinded to group assignment in a double-blind randomized clinical trial design.

3.1.2.11 Clinical evaluation

All evaluation parameters were recorded using a standard- ized paper case report form. The evaluation form was sent to the research staff after each observation, so that evaluators were blinded to group assignment during follow-up recalls. The restorations were evaluated using two criteria: the FDI [41,42] and the USPHS criteria (adapted by Dalton Bittencourt et al. and Perdigão et al.) [31,34] immediately after restorative procedure (baseline), and after 6, 18, 36-months and five years of clinical service.

For either of the two criteria, only the clinically relevant measures of the performance of the adhesives were evaluated (Tables 4.1.3 and 4.1.4). The primary outcome was retention/fracture, but the following secondary outcomes were also evaluated: marginal staining, marginal adaptation, post-operative sensi- tivity and recurrence of caries. The post-

operative sensitivity was performed one week after the restorative procedure, by applying an air stream from a dental syringe for 10 s at 2 cm from the tooth surface.

These variables were ranked according to the criteria in the following scores: (1) FDI criteria (clinically very good [VG]; clinically good; clinically sufficient/satisfactory; clinically unsatisfactory [UN] and clinically poor) and (2) USPHS criteria (Alfa – good, Bravo – satisfactory and Charlie – poor). Both examiners evaluated all the restorations once and indepen- dently. When disagreements occurred during the evaluations, they had to reach a consensus before the participant was dismissed. The restoration retention rates were calculated according to the ADA guidelines [40]. Cumulative failure percentage = [(PF + NF)/(PF + RR)] × 100, where PF is the number of previous failures before the current recall, NF is the number of new failures during the current recall, and RR is the number of currently recalled restorations.

3.1.2.12 Statistical analysis

The statistical analyses followed the intention-to-treat pro- tocol according to CONSORT (Consolidated Standards of Reporting Trials) suggestion [27] Descriptive statistics were used to describe the distributions of the evaluated criteria.

The survival rates (retention/fracture data) of different groups of restorations were calculated by the Kaplan–Meier procedure, estimating the Hazard Ratios (HR) and 95% confidence intervals. The log-rank test was used to compare the survival distributions of these restorations ($\alpha = 0.05$).

For the secondary outcome (marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries), in each overall parameter (FDI and USPHS), the dif- ferences between the ratings of the four groups after 5 years were tested by Friedman's repeated measures analysis of vari- ance rank ($\alpha = 0.05$). Cohen's kappa statistics were used to test the inter-examiner agreement ($\alpha = 0.05$) (MedCalc Software, Version 19.1, Ostend, Belgium).

3.1.3 Results

Forty-three out of 82 subjects were excluded from the study because they did not fulfill the inclusion criteria. Thus, a total of 39 subjects (24 male and 15 female), with a mean age of 40 years were enrolled in this study. Two hundred restorations were placed, 50 for each group.

All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 4.1.15.

The overall Cohen's Kappa statistics (0.92) showed good agreement between the examiners. All research subjects were evaluated at the baseline and at the 6 month recalls. One sub- ject did not attend the 18 months recall, four subjects did not attend the 36 months recall and two other subjects did not attend the 5-years recall. All of them had moved to another city.

3.1.3.1 Retention/fracture

All the data regarding follow-up times are depicted in Tables 4.1.6 and 4.1.7. However, only the 5-year data are described here. After 5 years of clinical evaluation, 19 restorations were lost (3 for ERm, 3 for ERd, 5 for SEE and 8 for SE). According to FDI and USPHS criteria, the 5-year retention/fracture rates (95% confidence interval) was 93% (95% CI 81.4–97.6%) for ERm, 93% (95% CI 81.4–97.6%) for ERd, 88.4% (95% CI 75.5–94.9) for SEE and 81.4% (95% CI 67.4–90.3%) for SE.

The Kaplan–Meier curves showed significant differences (Log-rank test, $p = 0.01$) among the cumulative probability of the primary endpoint, which was loss of retention/fracture (Fig. 4.1.2). The paired comparisons among the four adhesive strategies is given by the hazard ratios depicted in Table 4.1.9. Significant differences were observed for the following comparisons: SE vs. ERd (HR = 2.83; 95% CI 1.12–7.13) and SE vs. ERm (HR = 3.4; 95% CI 1.35–8.56), meaning that NCCLs receiving the SE adhesive strategy were on average 2.6 times more likely to debond/fracture than those receiving the ERm or ERd adhesive strategy at any given time (Table 4.1.9).

3.1.3.2 Marginal staining

After 5-years of clinical evaluation, 29 restorations (5 for ERm, 6 for ERd, 8 for SEE and 10 for SE) showed marginal staining under the FDI criteria (Table 4.1.6) and 18 restorations (3 for ERm, 3 for ERd, 6 for SEE and 6 for SE) for USPHS criteria (Table 4.1.7). A significant difference was found between ERm vs. SE ($p = 0.003$) and between ERd vs. SE ($p = 0.002$) groups for FDI criteria. For the USPHS criteria, there was a significant difference between ERm vs. SE ($p = 0.03$) and between ERd vs. SE groups ($p = 0.03$).

3.1.3.3 Marginal adaptation

Forty-seven restorations (11 for ERm, 10 for ERd, 9 for SEE and 17 for SE) for FDI criteria (Table 4.1.6) and, 31 restorations (8 for ERm, 6 for ERd, 7 for SEE and 10 for SE) for USPHS criteria showed some marginal discrepancy after 5-years of clinical evaluation (Table 4.1.7). For the FDI criteria, significant difference was found between ERm vs. SE ($p = 0.005$) and between ERd vs. SE ($p = 0.001$) groups. For the USPHS criteria, there was a significant difference between ERm vs. SE ($p = 0.003$) and between ERd vs. SE ($p = 0.01$) groups.

3.1.3.4 Other parameters

No restoration showed evidence of clinical problems related to recurrence of caries and post-operative sensitivity after 5 years of clinical evaluation for FDI and USPHS criteria (Tables 4.1.6 and 4.1.7).

3.1.4 Discussion

The literature covers many laboratory studies testing universal adhesives [11,43]. The performance of adhesive systems has been evaluated through clinical studies in NCCLs, especially because they provide retention, which is the most important parameter to evaluate NCCLs restorations [44]. To the extent of the authors' knowledge, this is the first long-term randomized clinical trial evaluating this specific universal adhesive.

The SU adhesive system has two potential bonding mechanism, based on: (1) Polyalkenoic acid; and (2) 10-MDP. Polycarboxylate-based adhesive materials, such as glass-ionomer cements (GIC), have been used to bond chemically to dentin and enamel since 1971 [45]. Carboxyl groups (COO–) within polyalkenoic acids replace the phosphate ions (PO_4^{3+}) in hydroxyapatite, establishing ionic bonding with Ca^{2+} [46,47]. Polyalkenoic acids interact with apatite substrates following the same adhesion-decalcification reaction [46,47]. The bonding performance of SU may result in strong, stable self-adhesion of the polyalkenoic acid co-polymer to dentin hydroxyapatite, as shown by Sezinando et al. [48] for SU. Furthermore, chemical interactions can occur through ionic bonds established by acid monomers such as 10-MDP that react with the hydroxyapatite, forming monomer-Ca salts that are stable to

degradation [46,47,49,50]. All these features help to explain the very good long-term retention rate of SU, which has also been shown in short- and medium-term clinical studies [16,17,20,24].

A few in vitro studies have questioned the chemical bonding efficacy of 10-MDP-based universal adhesives, including the partial inhibitory effect of HEMA on the interfacial nanolayering formed by 10-MDP salts on dentin [51]. And, while Yoshida et al. [52] reported the formation of nanolayering structures when SU was applied, Tian et al. showed that nanolayering was a rare finding in resin–dentin interfaces created by commercial 10-MDP-containing universal adhesives, including SU [53]. These contradicting findings warrant further studies to clarify the exact dentin bonding mechanism of 10-MDP-containing universal adhesives, including SU.

Regardless of the bonding strategy used, the present study found that a total of 19 restorations failed as a result of total or partial debonding after five years of clinical service – 3 with ERm, 3 with ERd, 5 with SEE and 8 with SE. Based on survival rate, a restoration performed with the SE strategy was on average 2.6 times more likely to debond than a restoration inserted with the ER strategy (either ERm or ERd), which leads us to reject the first null hypothesis.

The fact that simplified SE adhesives performed worse in our study is in agreement with a meta-analysis of clinical trials [54]. However, a systematic review reported a significantly lower annual failure rate for mild/ultra-mild 1-step SE adhe- sives (3.6%) than for strong 1-step SE adhesives (5.4%) [55]. In this systematic review, mild/ultra-mild 1-step SE adhesives showed a 3.6% annual failure rate, similar to the observed for SU in the self-etch strategy in the present study (3.7%) [55].

Furthermore, significant differences were observed for both marginal staining and adaptation, highlighting a poor bonding efficacy when the universal adhesive system was used in the SE strategy in comparison to ER mode, which leads us to partially reject the second null hypothesis.

In fact, a poor enamel conditioning efficacy of SE adhesives has been well-described, especially when an ultra-mild SE solution (pH S2.5) is used, due to its limited interaction with enamel [56]. One of the consequences of poor enamel etching is marginal staining. A simple way to improve the bonding of SE adhesives is to etch enamel. Although the etching pattern produced by the self-etch adhesives depends on their acidity, application time, and application mode, self-etch adhesives result in a very shallow enamel etching pattern, with reduced micro-porosities for resin infiltration [57–60]. This poorer etching ability of self-etch adhesives may

favor debonding at the margins, allowing infiltration of food stains or bacterial biofilm leading to marginal pigmentation. The benefits of previous phosphoric acid etching have been described in several in vitro studies [61–64]. More recently the use of phosphoric acid etching on enamel has also improved the performance of universal adhesives [21,32,65,66].

When SU was applied in moist (ERm) and dry (ERd) conditions in our study, similar retention rates were measured, as well as all other parameters evaluated. This similarity of results when comparing the degree of substrate moisture was not unexpected, since previous short- and medium-term clini cal trials did not report significant differences for moist versus dry bonding protocols [26,67].

Even after the concept of moist dentin having been advocated for years [26,68,69], the current literature shows that keeping the dentin moist may not have practical clinical advantages over dry bonding [67]. In addition to the difficulty of maintaining demineralized dentin moist in clinical practice, the ideal degree of moisture depends on the type of solvent in the adhesive system [70]. Since SU is an ethanol/water-based adhesive with 10–15% by weight of each [16], this amount of water would be sufficient to plasticize the collapsed collagen network, allowing both reopening and expansion of the dry dentin interfibrillar spaces for the infiltration of resinous monomers [69,70].

Moreover, the clinical performance of SU on ERd in our study suggests that if applied actively on dentin, following the respective manufacturer's instructions, moisture may have no influence on adhesion [71,72]. This adhesive application method may allow for better monomer diffusion inward, while solvents diffuse outward by the mechanical pressure applied during vigorous rubbing, and when the pressure is relieved, the adhesive solution is drawn into the collapsed collagen mesh [26].

In the present study, two clinical criteria were used to evaluate the restorations: USPHS and FDI criteria. After 5 years of clinical evaluation no difference was observed for different groups for either criteria. This is not in agreement with a recent review of clinical studies published by Marquil- lier et al. [73]. This review showed that the FDI criteria are more sensitive than the USPHS criteria [73]. However, this information was based on short- and medium-term clinical trials [15,25,32–34,74]. It is likely that longer follow-ups will detect the restoration defects more accurately, regardless of which evaluation criterion is used. Further longer-term clini- cal studies using both criteria should be carried out to test this hypothesis.

3.1.5 Conclusions

After 5 years of clinical evaluation, the clinical behavior of the universal adhesive was better in the etch-and-rinse when compared to the self-etch strategy. Therefore, if self-etch strategy was applied, it is highly recommended the use of selective enamel etching. The FDI and USPHS evaluation cri- teria showed similar results after 5 years.

Acknowledgements

This study was performed by Thalita P. Matos as partial ful- fillment of her fellowship degree at the State University of Ponta Grossa (UEPG), Ponta Grossa, PR, Brazil. This study was partially supported by the National Council for Scien- tific and Technological Development (CNPq) under grants 303332/2017-4 (AR) and 308286/2019-7 (ADL) and Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001 (TPM)

Table 4.1.1 Dentin sclerosis scale.

Dentin sclerosis scale*	
CATEGORY	**CRITERIA**
1	No sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparency
2	More sclerosis than in category 1 but less than halfway between categories 1 and 4
3	Less sclerosis than in category 4 but more than halfway between categories 1 and 4
4	Significant sclerosis present; dentin is dark yellow or even discolored (brownish); glassy appearance, with significant translucency or transparency evident

* Adapted from Swift and colleagues[33] with permission from Elsevier.

Table 4.1.2. Materials, compositions and application mode.

Adhesive systems	Composition/batch number	Application Mode (*)			
Scotchbond Universal Adhesive (3M ESPE, St Paul, MN, USA)	1. Scotchbond Universal Etchant: 34% phosphoric acid (UXT-02/Etch-01) 2. Adhesive (UXT-02/Adh-02): methacryloyloxydecyl dihydrogen phosphate, phosphate monomer, dimethacrylate resins, hydroxyethyl methacrylate, methacrylate-modified polyalkenoic acid copolymer, filler, ethanol, water, Initiators, silane.	Total-etch	Apply Etchant for 15 s Rinse for 10 s. Air dry to remove excess of water	**KEEP DENTIN MOIST**.	Apply the adhesive for 20 s with vigorous agitation. Gently air thin for 5 s. Light-cure for 10 s.
				KEEP DENTIN DRY, do not overdry.	
		Selective etching	Apply Etchant **ONLY ON ENAMEL** for 15 s Rinse for 10 s. Air dry to remove excess of water	Keep dentin dry, do not overdry.	
		Self-etch	**DO NOT USE ETCHANT**	Keep dentin dry, do not overdry	

Table 4.1.3. Word Dental Federation (FDI) criteria used for clinical evaluation [41,42].

	Esthetic Property	**Functional Properties**		**Biological Properties**	
	1. Staining margin	**2. Fractures and retention**	**3. Marginal adaptation**	**4. Postoperative (hyper-) sensitivity**	**5. Recurrence of caries**
1. Clinically very good	1.1 No marginal staining	2.1 Restoration retained, no fractures / cracks	3.1 Harmonious outline, no gaps, no discoloration.	4.1 No hypersensitivity.	5.1 No secondary or primary caries
2. Clinically good (after correction very good	1.2 Minor marginal staining, easily removable by polishing.	2.2 Small hairline crack.	3.2.1 Marginal gap (50 μm). 3.2.2 Small marginal fracture removable by polishing.	4.2 Low hypersensitivity for a limited period of time	5.2 Very small and localized demineralization. No operative treatment required
3.Clinically sufficient / satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically unacceptable.	2.3 Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity).	3.3.1 Gap < 150 μm not removable 3.3.2. Several small enamel or dentin fractures	4.3.1 Premature / slightly more intense 4.3.2 Delayed/weak sensitivity; no subjective complaints, no treatment needed.	5.3 Larger areas of demineralization, but only preventive measures necessary (dentine not exposed)

4. Clinically unsatisfactory (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement	2.4 Chipping fractures which damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration).	3.4.1 Gap > 250 µm or dentine/base exposed. 3.4.2. chip fracture damaging margins 3.4.3 Notable enamel or dentine wall fracture	4.4.1 Premature/ very intense 4.4.2 Extremely delayed/weak with subjective complaints 4.4.3 Negative Sensitivity Intervention necessary but not replacement.	5. 4 Caries with cavitation (localized and accessible and can be repaired
5. Clinically poor (replacement necessary)	1.5 Deep marginal staining not accessible for intervention.	2.5 (Partial or complete) loss of restoration.	3.5 Filling is loose but in situ.	4.5 Very intense, acute pulpitis or non vital. Endodontic treatment is necessary and restoration has to be replaced.	5.5 Deep secondary caries or exposed dentine that is not accessible for repair of restoration.
Acceptable or not acceptable (n, % and reasons	Aesthetic criteria	Functional criteria		Biological criteria	

Table 4.1.4. Modified United States Public Health Service (USPHS) criteria according to Dalton Bittencourt et al. [31] and Perdigão et al. [34].

	Marginal staining	**Retention**	**Fracture**	**Marginal adaptation**	**Postoperative sensitivity**	**Recurrence of caries**
Alfa	No discoloration along the margin	Retained	None	Restoration is continuous with existing anatomic form.	No postoperative sensitivity directly after the restorative process and during the study period	None evidence of caries contiguous with the margin
Bravo	Slight and superficial staining (removable, usually localized)	Partially retained	Small chip, but clinically acceptable	Detectable V-shaped defect in enamel only. Catches explorer going both ways.	--	--
Charlie	Deep staining cannot be polished away	Missing	Failure due to bulk restorative fracture	Detectable V-shaped defect to dentin-enamel junction	Sensitivity present at any time during the study period	Evidence of presence of caries

Table 4.1.5. Characteristics of the research subjects and the non-carious cervical lesions (NCCLs) per group.

Characteristics of research subjects	**Number of lesions**			
Gender distribution				
Male	24			
Female	15			
Age distribution (years)				
20-29	05			
30-39	12			
39-49	12			
> 49	10			
Characteristics of Class-V lesions	**Number of lesions**			
	ER*m*	ER*d*	S*EE*	SE
Shape (degree of angle)				
< 45				
45-90	14	14	12	12
90-135	34	34	38	38
> 135	02	02		
Cervico-incisal height (mm)				
< 1.5	06	03	05	07
1.5-2.5	29	36	29	30
2.5-4.0	12	10	14	12
> 4.0	03	01	02	01
Degree of sclerotic dentin				
1	20	18	17	19
2	12	14	13	10
3	12	12	09	09
4	06	06	11	12
Presence of antagonist				

Yes	50	50	50	50
No	00	00	00	00
Attrition facet				
Yes	24	22	18	26
No	26	28	32	24
Pre-operative sensitivity (spontaneous)				
Yes	50	50	50	50
No	00	00	00	00
Pre-operative sensitivity (air dry)				
Yes	24	26	30	28
No	26	24	20	22
Tooth distribution				
Anterior				
Incisor	02	02	02	02
Canines	04	08	06	08
Posterior				
Premolar	32	26	34	28
Molar	12	14	08	12
Arc distribution				
Maxillary	25	26	30	28
Mandibular	25	24	20	22

Table 4.1.6. Number of evaluated restorations for each group classified according to the World Dental Federation Criteria [41,42] in different follow-up times.

Time		**Baseline**				**06 months**				**18 months**				**36 months**				**60 months**			
FDI Criteria	***(*)***	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE
Marginal staining	VG	50	50	50	50	50	50	50	49	45	44	46	45	39	38	40	32	35	34	30	25
	GO	--	--	--	--	--	--	--	1	1	2	--	1	2	3	--	1	2	3	1	--
	SS	--	--	--	--	--	--	--	--	3	3	2	3	3	3	4	7	3	3	7	10
	UN	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Fractures and retention	VG	50	50	50	50	49	50	50	47	48	49	48	46	44	44	44	40	40	40	38	35
	GO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	1	--	--	3	1	--	1	3	1	1	1	5	3	3	5	8
Marginal adaptation	VG	50	50	50	50	34	32	29	27	29	29	30	24	33	34	33	23	29	30	29	18
	GO	--	--	--	--	16	18	21	23	18	15	18	19	8	7	8	10	7	6	3	5
	SS	--	--	--	--	--	--	--	--	1	5	--	3	3	3	3	7	4	4	6	12
	UN	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Post-operative (hyper-) sensitivity	VG	49	46	47	49	50	50	50	50	45	46	46	46	44	44	44	40	40	40	38	35
	GO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	SS	1	4	3	1	--	--	--	--	3	3	2	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Recurrence of caries	VG	50	50	50	50	50	50	50	50	48	49	48	46	44	44	44	42	40	40	38	35
	GO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

(*) VG for clinically very good; GO for clinically good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory and; PO for clinically poor.

Table 4.1.7. Number of evaluated restorations for each group classified according to the Modified United States Public Health Service (USPHS) criteria according to Dalton Bittencourt et al. [31] and Perdigão et al. [34] in different follow-up times.

Time		**Baseline**				**06 months**				**18 months**				**36 months**				**60 months**			
USPHS Criteria		ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE
Marginal staining	**Alfa**	50	50	50	50	50	50	50	49	45	46	46	43	41	41	41	33	37	37	32	29
	Bravo	--	--	--	--	--	--	--	1	3	3	2	3	3	3	3	7	2	3	1	6
	Charlie	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	1	--	5	--
Retention	**Alfa**	50	50	50	50	49	50	50	47	48	49	48	46	44	44	44	40	40	40	38	35
	Charlie	--	--	--	--	1	--	--	3	1	--	1	3	1	1	1	5	3	3	5	8
Fracture	**Alfa**	50	50	50	50	50	50	50	50	48	49	48	46	44	44	44	40	40	40	38	35
	Bravo	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
	Alfa	50	50	50	50	50	50	50	48	47	44	48	43	37	39	38	30	32	34	31	25

Marginal adaptation	**Bravo**	--	--	--	--	--	--	--	2	1	5	--	3	7	5	6	10	8	6	7	10
	Charlie	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Post-operative sensitivity	**Alfa**	49	46	47	49	50	50	50	50	45	46	46	46	44	44	44	40	40	40	38	35
	Charlie	1	4	3	1	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Recurrence of caries	**Alfa**	50	50	50	50	50	50	50	50	48	49	48	46	44	44	44	40	40	40	38	35
	Charlie	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Table 4.1.8. Absolute risk (95% CI) and relative risk (95% CI) for outcome retention for different groups after 5-years of clinical evaluation.

Properties	**Aesthetic**				**Functional**								**Biological**							
	Staining margin				**Fractures and retention**				**Marginal adaptation**				**Postoperative (hyper-) sensitivity**				**Recurrence of caries**			
	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE	ER*m*	ER*d*	SEE	SE
Acceptable	40	40	38	35	40	40	38	35	40	40	38	35	40	40	38	35	40	40	38	35
Not acceptable	00	00	00	00	3	3	5	8	00	00	00	00	00	00	00	00	00	00	00	00
Reasons					Total loss of the restorations: 19															

(*) ER*m* = Etch-and-Rinse, Moist Dentin; ER*d* = Etch-and-Rinse, Dry Dentin; SEE = Self-Etch, Selective Enamel Etching; SE = Self-Etch, No Etching

Table 4.1.9. Absolute risk (95% CI) and relative risk (95% CI) for outcome retention for different groups after 5-years of clinical evaluation.

	Absolute risk (95% CI)	Relative risk (95% CI)*
ER*m*	93.0 (81.4 – 97.6)	1.0 (0.2 – 4.7)
ER*d*	93.0 (82.4 – 97.6)	
SEE	88.4 (75.5 – 94.9)	1.7 (0.4 – 6.5)
SE	81.4 (67.4 – 90.3)	2.7 (0.7 – 9.4)

Related to group E

Table 4.1.10. Retention loss hazard ratio (95% confidence interval) for pairwise comparison of different groups.

Pairwise comparison	Hazard ratio (95%
SE vs. ER*d*	2.83 (1.12 to 7.13) *
SE vs. ER*m*	3.4 (1.35 to 8.56) *
SE vs. SEE	2.12 (0.84 to 5.35)
SEE vs. ER*d*	1.33 (0.52 to 3.35)
SEE vs. ER*m*	1.6 (0.63 to 4.03)
ER*m* vs. ER*d*	0.83 (0.33 to 2.10)

(*) Indicates groups significantly different

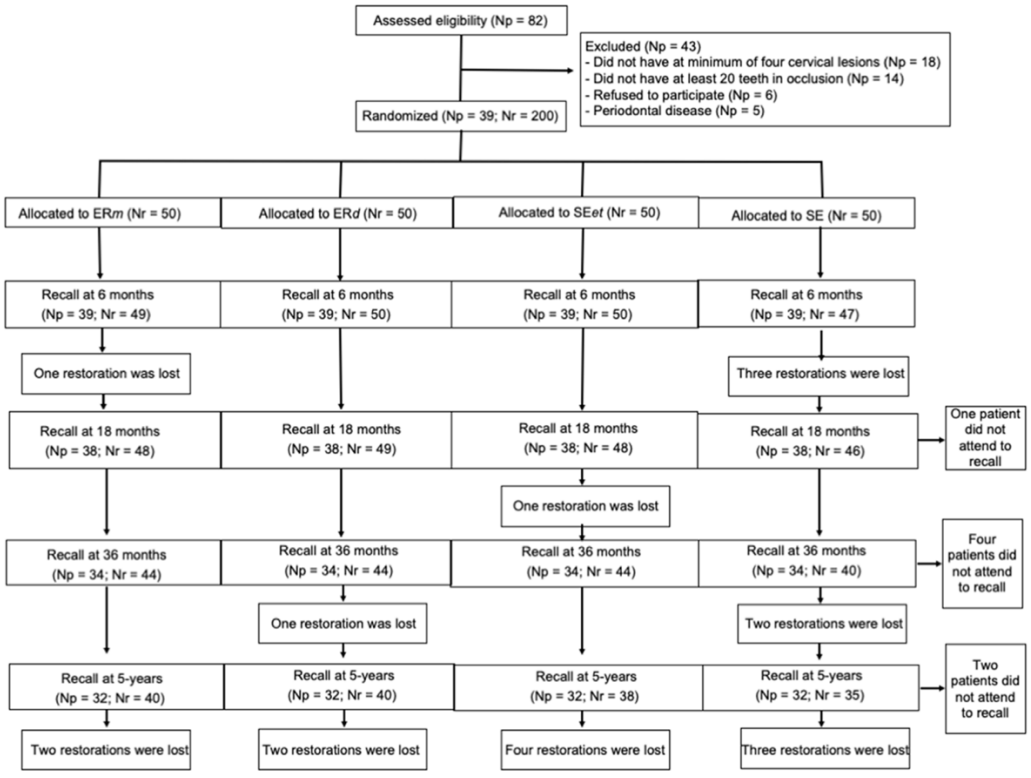

Figure 4.1.1. Flow diagram of the study phases. Np: number of patients; Nr: number of restorations

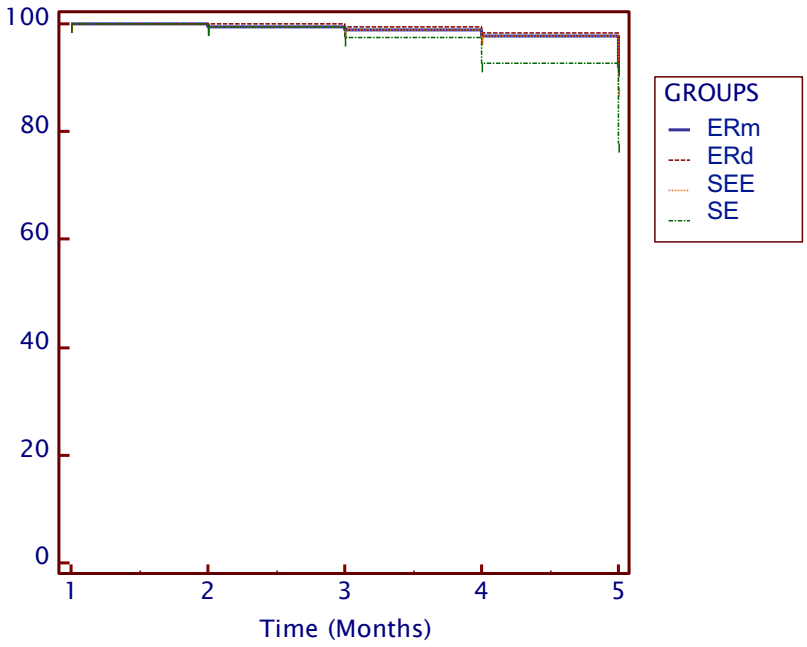

Figure 4.1.2. Survival curves for both groups (ERm: etch-and-rinse moisture; ERd: etch-and-rinse dry; SEE: selective enamel etching; SE: self-etch).

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3.2 ARTIGO 2 – FIVE-YEAR RANDOMIZED CLINICAL TRIAL ON THE PERFORMANCE OF TWO ETCH-AND-RINSE ADHESIVES IN NON-CARIOUS CERVICAL LESIONS

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ABSTRACT

Objectives: To evaluate the 5 years clinical performance of two-step etch-and-rinse adhesives in non-carious cervical lesions (NCCL).
Methods and Materials: The sample comprised 35 adults with at least two similar sized NCCL. 70 restorations were placed, according to one of the following groups: Adper Single Bond 2 (SB) and Ambar (AM). The restorations were placed incrementally using a resin composite (Opallis). The restorations were evaluated at baseline and after 6- and 18-months and 5 years. The differences in the ratings of the two materials after 6-, 18-months, and 5 years were performed with Friedman repeated measures ANOVA by rank and McNemar test for significance in each pair ($\alpha = 0.05$).
Results: Five patients did not attend the 5 years recall. No significant differences were observed between the materials for any criteria evaluated. Only four restorations (two from each material) were lost after 18-months. Thus, the retention rate for SB at 60 months were 60.0% for SB and 67.9% for AM ($p = 0.93$). After 60 month, twelve restorations (6 for SB and 6 AM) showed some loss of marginal adaptation ($p = 1.0$). Slight marginal discoloration was observed in 10 restorations (6 for SB and 4 AM; $p = 0.91$). Five restorations (2 for SB and 3 for AM) showed recurrences of caries. ($p = 1.0$).

Conclusions: Both 2-step etch-and-rinse adhesives, Adper Single Bond 2, a polyalkenoic acid-containing adhesive, and Ambar, MDP-containing adhesive, had comparable and acceptable clinical performances after 60 months of clinical evaluation.
Clinical Relevance: A polyalkenoic acid-containing adhesive and MDP-containing adhesive, had similar clinical performance.
Key-words: Randomized clinical trials, non-carious cervical lesions, adhesive systems, long-term evaluation

3.2.1 Introduction

Non-carious cervical lesion (NCCL), a frequent and challenging condition to treat, is described as the loss of hard tooth tissue at the cement–enamel junction.[1] Data from the literature regarding prevalence of NCCLs show a higher prevalence of NCCLs, ranging from 35.4%[2] up to 77.3%.[3] Besides compromising aesthetics and function, NCCLs result in dentin hypersensitivity up to 92.1%, as reported in the systematic review of prevalence studies.[4] A restorative procedure is the main way to reestablish the lost dental substrate and minimize dental sensitivity.[5]

Unfortunately, NCCLs are difficult to restore because the margins of these lesions are located in the cementum or dentin, jeopardizing moisture control and access to the gingival margins.[6] Furthermore, they present a high index of sclerotic dentin,[7, 8] which reduce bonding efficacy when compared to sound dentin.[7] Due to these adverse conditions, NCCLs are the best model to test the clinical effectiveness of adhesives.[9] Additionally, due to the presence of NCCLs in several teeth of the same patient, it is easy to compare adhesive systems in a split-mouth study design.[9, 10]

Although several adhesive strategies have been developed, one of the most used currently is the application of phosphoric acid associated with an adhesive system. This technique was launched in the mid-1980s,[11] and it was originally called “total-etch” because the enamel and dentin are etched simultaneously with phosphoric acid.[12, 13] However, the term “etch-and-rinse” has been used because it better represents the technical procedure.[14] The etch-and-rinse strategy is divided according to the number of bottles in a 2-step or 3-step system.[11] After etch-and-rinse, hydrophilic and solvent-based adhesives are applied and are responsible for infiltration into the demineralizing dentin. Afterward, the polymerization is performed and the adhesive becomes micro-mechanically bonded into dentin to form the hybrid layer.[15] However, in the etch-and-rinse adhesives, the micro-mechanical interlocking is a prerequisite for achieving a strong mechanical bond.[10]

Actually, the addition of functional monomers with the potential capacity for chemical adhesion to the tooth structure could be beneficial in terms of durability because it ensures an intimate adaptation of the substrate and biomaterial components, thereby preventing nanoleakage.[16] Two monomers with this chemical potential are polyalkenoic acid copolymer (PAC) and 10-methacryloxydecyl dihydrogen phosphate (MDP).[11, 17] The former was first used in the composition of Vitrebond (3M Oral Care) and more recently has been used in several adhesive formulations from the same manufacturer.[18-20] Due to PAC's ability to chemically bond to the calcium in hydroxyapatite, a very good clinical performance has been observed when PAC-containing etch-and-rinse adhesives are used.[21-25] On the other hand, it is well documented that, due to the formation of highly hydrolytically stable 10-MDP-Ca salts,[26] the presence of MDP promotes a stable chemical bond with dental substrates.[26, 27] Despite only recent use, the clinical performance of MDP-containing etch-and-rinse adhesives has been evaluated and has shown very good results.[28-30]

However, to the extent of the author's knowledge, only a short-term (18-month) randomized clinical trial was found that compared an adhesive containing-PAC versus an adhesive containing-MDP, with similar results between both materials.[31] Thus, the objective of this randomized clinical trial was to compare the 5-year failure rate of an adhesive containing-PAC versus an adhesive containing-MDP, with both applied in the etch-and-rinse mode, in a paired-tooth study design. The null hypothesis is that the failure rate of the composite restorations placed with both adhesive systems will be same after 60 months of clinical service.

3.2.2 Methods and Material

3.2.2.1 Study design

This was a randomized, double-blind clinical trial and it was described following the Consolidated Standards of Reporting Trials (CONSORT) statement.[33] The study was carried out in the clinic of the School of Dentistry at the local university from July, 2010 to July, 2011. All participants were informed about the nature and objectives of the study, but they were not aware of which tooth received the specific treatments under evaluation.

3.2.2.2 Participant recruitment

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for this study (protocol 14918/10). Written informed consent was obtained from all participants prior to starting the treatment.

3.2.2.3 Sample size calculation

The sample size calculation was based on the failure rate of the comparative adhesive (Adper Single Bond 2) reported in earlier studies at 18-24 months.[34] Using an α of 0.05, a power of 90%, and equivalence limit of 20%, a minimum of 26 participants with two similar-sized NCCL were required.

3.2.2.4 Eligibility criteria

A total of 51 participants were examined by two calibrated dentists to check if the subjects met the inclusion and exclusion criteria. Following these examinations, 15 subjects were excluded, and 35 were recruited after accepting the terms of the research (Figure 4.2.3). The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe.

Participants between 20 and 70 years old had to be in good general health, have an acceptable oral hygiene level, and present at least 20 teeth under occlusion. Participants were required to have at least two NCCLs to be restored in two different teeth. These lesions had to be non-carious, non-retentive, and deeper than 1 mm and had to involve both the enamel and dentin of vital teeth without mobility. The cavo-surface margin could not involve more that 50% of enamel.[37] All patients were given oral hygiene instructions before the operative treatment was performed. Patients with extremely poor oral hygiene, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study.

3.2.2.5 Randomization and allocation oncealment

The randomization process was performed by a staff member not involved in the research protocol with a coin that was tossed immediately before the restoration placement. The allocation assignments were revealed by a coin that tossed immediately before the restorative procedure to guarantee the concealment of the random sequence and prevent selection bias. The participants and the examiners were blinded to the group assignments.

3.2.2.6 Restorative procedure

All of the patients selected for this study received dental prophylaxis with a suspension of pumice and water in a rubber cup and signed an informed consent form two weeks before the restorative procedures were initiated.

The degree of sclerotic dentin from the NCCLs was measured according to the criteria described by Swift and others (Table 4.2.11).[38] The cavity dimensions in millimeters (height, width, and depth), the geometry of the cavity (evaluated by profile photograph and labeled at <45°, 45°-90°, 90°-135°, and >135°), the presence of an antagonist, and the presence of attrition facets, the distribution of enamel in cervical margin were observed and recorded. Preoperative sensitivity was also evaluated by applying air for 10 seconds from a dental syringe placed 2 cm from the tooth surface and with an explorer. These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

In order to calibrate the restoration procedure, the study director placed one restoration of each group in order to identify all steps involved in the application technique. Then the two operators, who were resident dentists with more than four years of clinical experience in operative dentistry, placed four restorations, two in each group, under the supervision of the study director in a clinical setting. The restoration failures were shown to the operators prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures.

The calibrated operators restored all teeth under the supervision of the study director. All participants received two restorations, one of each experimental group, in different lesions previously selected according to the inclusion criteria.

Before restorative procedures, the operators anesthetized the teeth with a 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil) and cleaned all lesions with pumice and water in a rubber cup, followed by rinsing and drying. Then shade selection was made using a shade guide Vita Classical e Vita System 3-D Master (VITA Zahnfabrik, Bad Säckingen, Alemanha). Following the guidelines of the American Dental Association (ADA),[39] no additional retention or bevel was prepared.

A rubber dam was placed, and then the NCCLs received the Adper Single Bond 2 (3M Oral Care, St. Paul, MN, USA; also known as Adper Single Bond Plus and Adper Scotchbond

1XT in some countries) or Ambar (FGM, Joinville, SC, Brazil) adhesive system, which defined the two different groups. The compositions and application modes are described in Table 4.2.12.

Both adhesives were applied according to the manufacturer's instructions (Table 4.2.12). Briefly, the cavity was etched with 37% phosphoric acid (CondAc 37, FGM) for 15 seconds, then rinsed with water for 15 seconds and gently dried with an oil-free air stream, leaving the dentin surface slightly moist. The adhesive was scrubbed for 10 seconds on the cavity surfaces and the solvent was evaporated with an air stream for 20 seconds. Another coat of adhesive was applied for 10 seconds, the solvent was evaporated for 20 seconds, and the adhesive layer was light-cured (Radii-Cal, SDI, Victoria, Australia) for 10 seconds at 1200 mW/cm^2.

Two or four increments of resin composite (Opallis, FGM) with less than 2 mm were placed, and each one light-cured for 40 seconds. Finally, the restorations were finished and polished using fine-grit diamond burs (#3195F and #3195FF, KG Sorensen, Barueri, São Paulo, Brazil.) and flexible abrasive disks (Diamond Pro, FGM).

3.2.2.7 Clinical evaluation

Two experienced and calibrated dentists, not involved with the restoration procedures and therefore blinded to the group assignment, performed the evaluations. For training purposes, the examiners observed 10 photographs that were representative of each score for each criterion. They evaluated 10 to 15 patients each on two consecutive days. These subjects had cervical restorations but were not part of this project. An intraexaminer and interexaminer agreement of at least 85% was necessary before beginning the evaluation.[40] After recording the parameters during evaluation using a standardized paper case report form, the evaluation paper had to be sent back to the research staff, so that evaluators were blinded to group assignment during follow-up recalls.

The restorations were evaluated by FDI [41, 42] criteria (Table 4.2.13) at baseline and after 6, 12, 18 and 60 months of clinical service. Only the clinically relevant measures for evaluation of the performance of adhesives were used and scored (Table 4.2.13). The primary clinical outcome was restoration retention/fractures, but the following secondary outcomes were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries. The evaluation of the spontaneous postoperative sensitivity was performed one week

after the restorative procedure. These variables were ranked according to the FDI criteria in the following scores: VG = clinically very good; GO = clinically good; SS = clinically sufficient/satisfactory; UN = clinically unsatisfactory; PO = clinically poor.

Both examiners evaluated all of the restorations once and independently. When disagreements occurred during the evaluations, they had to reach a consensus before the participant was dismissed.

3.2.2.8 Statistical analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT (Consolidated Standards of Reporting Trials) suggestion.[32] Descriptive statistics were used to describe the distributions of the evaluated criteria. For all outcomes (retention/fracture, marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries), the differences between the two groups' ratings after 60 months were tested by Friedman's repeated measures analysis of variance rank ($\alpha = 0.05$). Cohen's kappa statistics were used to test the inter-examiner agreement ($\alpha = 0.05$) (Statistica for Windows 7.0, StatSoft Inc., Tulsa, OK, USA).

3.2.3 Results

Thirty-five subjects (18 male and 17 female), with a mean age of 45 years, were enrolled in this study. Seventy restorations were placed (35 for each group). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 4.2.14.

The overall Cohen's Kappa statistics (0.87) showed good agreement between the examiners. All research subjects were evaluated at the baseline and in the 6, 12, and 18-month recalls. Five patients did not attend the 60-month recall because they moved to other cities (Figure1).

3.2.3.1 Retention/fracture

After 60 months, twenty-one restorations were lost (12 for Adper Single Bond 2 and 9 for Ambar; Table 4.2.15). According to ADA guidelines[35], the 60-month retention rates were

60.0% for Adper Single Bond 2 and 67.9% for Ambar. The risk ratio for both groups was 0.5 (95% CI, 0.16–1.48). The 95% CI interval of the risk ratio crosses the null value of 1, meaning the groups were not different from each other (p = 1.0). In addition, after the 60-month recall, 6 restorations for each group showed some small fractures (Table 4.2.15). No significant difference was detected between groups at the 60-month recall (p = 1.0; Table 4.2.15).

3.2.3.2 Marginal adaptation

According to the FDI criteria, after five years, 12 restorations (3 classified as “B” and 3 classified as “C” for SB and 3 classified as “B” and 3 classified as “C” for AM) showed some marginal discrepancy (Table 4.2.15). No significant difference was detected between both groups at the 60-month recall (p = 1.0; Table 4.2.15).

3.2.3.3 Marginal staining

The evaluated restorations showed a slight increase in the marginal staining after 60-month of clinical evaluation (3 classified as “B” and 3 classified as “C” for SB and 3 classified as “B” and 1 classified as “C” for AM). No significant difference was found between the groups at the 60-month recall time (p = 0.91; Table 4.2.15).

3.2.3.4 Recurrence of caries

After five years, 5 restorations (2 for Adper Single Bond 2 and 3 for Ambar) showed a small and localized demineralization around restorations that suggested recurrences of caries. No difference was observed for this parameter when both adhesives were compared (p = 1.0; Table 4.2.15).

3.2.3.5 Postoperative sensitivity

Six restorations showed post-operative sensitivity in the baseline (3 for Adper Single Bond 2 and 3 for Ambar), but this occurrence was not reported in the following recall times. No difference was observed for this parameter when both adhesives were compared (p = 1.0; Table 4.2.15).

3.2.4 Discussion

The simplification of technique in contemporary dental adhesives has occurred at the expense of an increasing incorporation of hydrophilic monomers.[10] According to a systematic review published by Peumans et al., 2004, in general, two-step etch-and-rinse adhesives perform clinically less favorably than other adhesive strategies. Two-step etch-and-rinse adhesives showed an average annual failure rate of 6.2%, that means that after 5 years of clinical evaluation, it will be expected an average failure rate of 31.0%. Therefore, some manufacturers added functional monomers, such as PAC and MDP, in their specific brands in attempt to significant improve the bonding results for simplified etch-and-rinse adhesives

For instance, Aw and others [39] compared the performance of one 3-step and two 2-step etch-and-rinse materials at 3 years and observed retention rates of 88, 81, and 90%, respectively, concluding that the materials performed similarly, regardless of the bonding strategy. An overall analysis of clinical trials that evaluated 2- and 3-step etch-and-rinse materials does not allow us to conclude the superiority of one over the other.[21,39-41] Perhaps, the addition of functional monomers, such as PAC and MDP, is responsible for the significant improvements in the bonding results for simplified etch-and-rinse adhesives.

PAC is a component of several adhesive systems by 3M Oral Care available in the market, among them is Adper Single Bond (also known as Single Bond, Scotchbond 1 and Adper Scotchbond 1 in some countries), an antecessor of Adper Single Bond 2. Initially, the rationale for the use of the PAC was to provide better moisture stability.[42] However, due to the high molecular weight of PAC, some authors indicated PAC prevents a complete infiltration of the collagen mesh, resulting in a nonuniform adhesive-dentin interface formation.[43, 44] More recently, it was observed that the carboxyl groups present in polyalkenoic acids replace the phosphate ions in hydroxyapatite, establishing ionic bonding with calcium.[20] This chemical bonding mechanism followed the same adhesion–decalcification reaction described by self-etch adhesives.[11]

Only a few years ago, Sezinando and others[20] evaluated the interaction between PAC and hydroxyapatite using high-technological spectroscopy methods. The authors showed that Adper Single Bond-containing PAC chemicals interact with hydroxyapatite, in comparison to an experimental Adper Single Bond PAC-free adhesive. It is worth mentioning, this chemical interaction depends on the abundance of PAC polar carboxyl

groups, which may provide a high affinity for binding.[20] According to the manufacturer, Adper Single Bond contains 5 to 10 wt% to PAC.[18,19] This fact should be responsible for the higher immediate and long-term bond strength values of the Adper Single Bond-containing PAC when compared to the experimental Adper Single Bond PAC-free adhesive.[18, 19]

Among the 2-step etch-and-rinse adhesives, a systematic review of in vitro bond strength studies published by De Munck and others[45] showed Adper Single Bond (described as Scotchbond 1) had a better bond strength performance. It is worth mentioning that Adper Single Bond 2 contains nanofillers, and Adper Single Bond does not. Unfortunately, the addition of nanofiller in Adper Single Bond 2 did not showed improvement in terms of bonding ability.[46] However, all of these features could be responsible for the good retention rate and lower marginal discoloration of Adper Single Bond 2 in the present study, as well as the observations in the medium and long-term clinical trial in NCCLs for their predecessor Adper Single Bond.[22-25]

Regarding the 2-step etch-and-rinse adhesive, Ambar is a nanofiller- and MDP-containing adhesive. Functional monomers have already been ranked based on their chemical bonding potentials, and 10-MDP (10-methacryloyloxydecyl dihydrogen phosphate) has been identified as capable of establishing a very intensive and stable chemical interaction with hydroxyapatite. The MDP-Ca water-insoluble salts contribute to the protection of the collagen fibers. The atomic relation of the 10-MDP molecule favors the chemical interaction.[27, 47]

Considering the chemical bonding between MDP and hydroxyapatite, dissolving the smear layer and the hydroxyapatite on the dentin surface through phosphoric acid etching, as indicated by the manufacturer of Ambar, may reduce chemical interactions mainly in the dentin surface.[48] Although this is the most plausible possibility, several in vitro studies found the resin–dentin bond strength values of MDP-containing adhesives did not diminish during water storage, even when the dentin was etched with phosphoric acid before adhesive application.[49, 50] Unfortunately, there are important open questions concerning the dentin bond durability of MDP-containing adhesives when applied in the etch-and-rinse system.

Actually, a recent study published by Hidari and others [51] evaluated the effect of phosphoric acid on dentin before the application of an MDP-containing adhesive (Clearfil Universal Bond, Kuraray, Noritake Dental, Tokyo, Japan) in comparison to an MDP-free adhesive (experimental Clearfil Universal Bond). The results showed higher immediate and

long-term degradation after artificial aging was found when a MDP-containing adhesive was used, even after phosphoric acid application. Actually, Hiraishi and others[52] speculated a certain interaction might occur between exposed collagen fibrils and MDP. On the other hand, it is more plausible the association of the methacrylate group with the long carbon spacer group effectively provides hydrophobicity,[53] and it might contribute to bond durability in vivo.[54] All of these descriptions justify the acceptable retention rate and lower marginal discoloration for Ambar adhesive observed in the present study.

In the specific case of 2-step etch-and-rinse Ambar, several in vitro studies showed an optimal laboratory performance, such as a higher degree of conversion inside the hybrid layer and immediate bond strength values, as well as, reduced water sorption and solubility and nanoleakage, similar to the Adper Single Bond 2.[55-59] Actually, it is worth mentioning that an MDP-containing Ambar adhesive showed a higher retention rate (67.9%) in comparison to a PAC-containing Adper Single Bond 2 adhesive (60.0%).

However, a closer view regarding 5 years clinical studies in non-carious cervical lesions when 2-step etch-and-rinse adhesives were evaluated, showed that, the retention rate varied from 51.5% to 77%.[39] For instance, Van Dijken and others 39 evaluated the performance of one 2-step etch-and-rinse materials and after 5 years, the retention rate of 62.3% was observed. In a recently paper published by Torres and others, after 5 years of clinical service, a retention rate of 77% was observed when one 2-step etch-and-rinse adhesive was evaluated.

Therefore, an overall analysis of clinical trials that evaluated 2-step etch-and-rinse in comparison with the results of the present study does not allow us to conclude the superiority of one over the other. This clear indicates that, no significant improvement in the clinical performance of two-step etch-and-rinse adhesives were observed when MDP (Ambar adhesive) or PAC (Adper Single Bond 2) was added.

Although the two tested adhesives have several differences in their chemistry, they share important features. The Adper Single Bond 2 and Ambar adhesive system both contain ethanol as the solvent. Usually, acetone-based systems have been reported to be more sensitive to the dentin moisture than ethanol and ethanol/water adhesives.[60] If dentin is not kept sufficiently moist, the acetone-based systems cannot infiltrate within the collagen fibrils leading to reduced bond strengths.[60] This is the mean reason for the majority of

adhesive systems available at the present moment in the market are ethanol-based systems as Adper Single Bond 2 and Ambar.

Although the two products differ in the kind of structural monomer employed, with Ambar containing urethane dimethacrylate (UDMA) and Adper Single Bond 2 containing the less flexible Bis-GMA,[31] this difference did not appear to produce important variances in the performance of either material, at least in the evaluation period.

Finally, as the FDI criteria was launched (2007) for evaluating dental restorations,[37, 38] still few publications have used it.[61, 62] However, at least two studies suggested the FDI criteria is more sensitive for identifying differences in restorations than the traditional United States Public Health Service (USPHS) criteria when evaluating restorations in NCCLs.[61, 62] This is the reason why the FDI criteria were used in the present study instead of the traditional USPHS criteria.

3.2.5 Conclusion

The present study demonstrated that both 2-step etch-and-rinse adhesives, Adper Single Bond 2, a polyalkenoic acid-containing adhesive, and Ambar, a MDP-containing adhesive, had comparable and high clinical performances after five years of clinical evaluation.

Table 4.2.11. Dentin sclerosis scale.

CATEGORY	CRITERIA
1	No sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparency
2	More sclerosis than in category 1 but less than halfway between categories 1 and 4
3	Less sclerosis than in category 4 but more than halfway between categories 1 and 4
4	Significant sclerosis present; dentin is dark yellow or even discolored (brownish); glassy appearance, with significant translucency or transparency evident

** Adapted from Swift and others[29] with permission from Elsevier.*

Table 4.2.12. Materials, compositions and application mode.

Materials (batch number)	Compositions	Application Mode (*)
Adper Single Bond 2	Acid: phosphoric acid 37% Adhesive: bisphenol glicydyl dimethacrilate, hydroxyethyl methacrylate, dimethacrylates, polyalkenoic acid copolymer, initiators, water, ethanol	1. Acid etch for 15 s; 2. Rinse with water for 15 s; 3. Dry the tooth surfaces for 5 s, but avoid excessive drying of the dentin; 4. Apply one coat of adhesive system under vigorous agitation for 10 s; 5. Evaporate the solvent for 20 s; 6. Apply a second coat of adhesive system under vigorous agitation for 10 s; 7. Evaporate the solvent for 20 s; 8. Light-cure for 10 s;
Ambar	Acid: 37% silica-thickend phosphoric acid gel Adhesive: 10-methaclyloxydecyl dihydrogen phosphate, urethane dimethacrylate, 2-hydroxyethyl metacrylate, and other hydrophilic and acid methacrylate monomers, ethanol, silaneted silica, photo-initiators, co-initiatirs, and stabilizers	

(*) According to the manufacturer`s instructions

Table 4.2.13. World Dental Federation (FDI) criteria used for clinical evaluation.

	Esthetic Property	**Functional Properties**		**Biological Properties**	
	1. Staining margin	**2. Fractures and retention**	**3. Marginal adaptation**	**4. Postoperative (hyper-) sensitivity**	**5. Recurrence of caries**
1. Clinically very good (A)	1.1 No marginal staining	2.1 Restoration retained, no fractures / cracks	3.1 Harmonious outline, no gaps, no discoloration.	4.1 No hypersensitivity.	5.1 No secondary or primary caries
2. Clinically good (B) (after correction very good	1.2 Minor marginal staining, easily removable by polishing.	2.2 Small hairline crack.	3.2.1 Marginal gap (50 µm). 3.2.2 Small marginal fracture removable by polishing.	4.2 Low hypersensitivity for a limited period of time	5.2 Very small and localized demineralization. No operative treatment required
3.Clinically sufficient / satisfactory (C) (minor shortcomings with no adverse effects but not	1.3 Moderate marginal staining, not esthetically unacceptable.	2.3 Two or more or larger hairline cracks and/or chipping (not affecting	3.3.1 Gap < 150 µm not removable 3.3.2. Several small enamel or dentin fractures	4.3.1 Premature / slightly more intense 4.3.2 Delayed/weak sensitivity; no subjective complaints, no	5.3 Larger areas of demineralization, but only preventive measures necessary (dentine not exposed)

adjustable without damage to the tooth)		the marginal integrity).		treatment needed.	
4. Clinically unsatisfactory (D) (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement	2.4 Chipping fractures which damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration).	3.4.1 Gap > 250 µm or dentine/base exposed. 3.4.2. chip fracture damaging margins 3.4.3 Notable enamel or dentine wall fracture	4.4.1 Premature/ very intense 4.4.2 Extremely delayed/weak with subjective complaints 4.4.3 Negative Sensitivity Intervention necessary but not replacement.	5. 4 Caries with cavitation (localized and accessible and can be repaired
5. Clinically poor (E) (replacement necessary)	1.5 Deep marginal staining not accessible for intervention.	2.5 (Partial or complete) loss of restoration.	3.5 Filling is loose but in situ.	4.5 Very intense, acute pulpitis or non vital. Endodontic treatment is necessary and restoration has to be replaced.	5.5 Deep secondary caries or exposed dentine that is not accessible for repair of restoration.
Acceptable or not acceptable	Aesthetic criteria	Functional criteria		Biological criteria	

(n, % and reasons	

Table 4.2.14. Characteristics of the research subjects and the non-carious cervical lesions (NCCL) per group.

Characteristics of research subjects	**Number of lesions**	
Gender distribution		
Male	18	
Female	17	
Characteristics of NCCLs lesions	**Number of lesions**	
	SB	AM
Shape (degree of angle)		
< 45	2	1
45-90	3	3
90-135	18	17
> 135	12	14
Cervico-incisal height (mm)		
< 1.5	3	3
1.5-2.5	14	17
> 2.5	18	15
Degree of sclerotic dentin		
1	28	24
2	1	5
3	5	2
4	1	4
Attrition facet		
Yes	9	10
No	26	25
Pre-operative sensitivity (spontaneous)		
Yes	16	18
No	19	
Tooth distribution		
Incisor	2	2
Canines	5	9
Premolar	25	21
Molar	3	3
Arc distribution		
Maxillary	20	24
Mandibular	15	11

Table 4.2.15. Number of evaluated restorations for each group classified according to the World Dental Federation Criteria39 in different follow-up times (6, 12, 18 and 60 months).

Time	*Baseline*			6 months		12 months		18 months		60 months	
Criteria*		** SB	AM	SB	AM	SB	AI	SB	AM	SB	AM
Fractures/Retention	VG	35	35	27	29	31	30	26	25	20	23
	GO	--	--	5	5	2	2	2	1	1	1
	SS	--	--	2	--	--		3	4	2	2
	UN	--	--	--	--	--	--		--	--	--
	PO	--	--	1	1	1	2	2	2	8	4
Marginal Adaptation	VG	35	35	34	34	29	28	24	22	17	20
	GO	--	--	--	--	4	4	3	3	3	3
	SS	--	--	--	--	--	--	4	5	3	3
	UN	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--
Marginal Staining	VG	35	35	34	34	33	32	26	26	17	22
	GO	--	--	--	--	--	--	4	3	3	3
	SS	--	--	--	--	--	--	1	1	3	1
	UN	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--
Recurrence of caries	VG	35	35	34	34	33	32	31	30	21	23
	GO	--	--	--	--	--	--	--	--	2	3
	SS	--	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--

Post-operative sensitivity	VG	32	32	34	34	33	32	31	30	23	26
	GO	3	3	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--	--

** Abbreviations: SB (Adper Single Bond 2; 3M Oral Care, St. Paul, MN, USA) and AM (Ambar; FGM, Joinville, SC, Brazil).*

*** VG for clinically very good; GO for clinically good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory and; PO for clinically poor.*

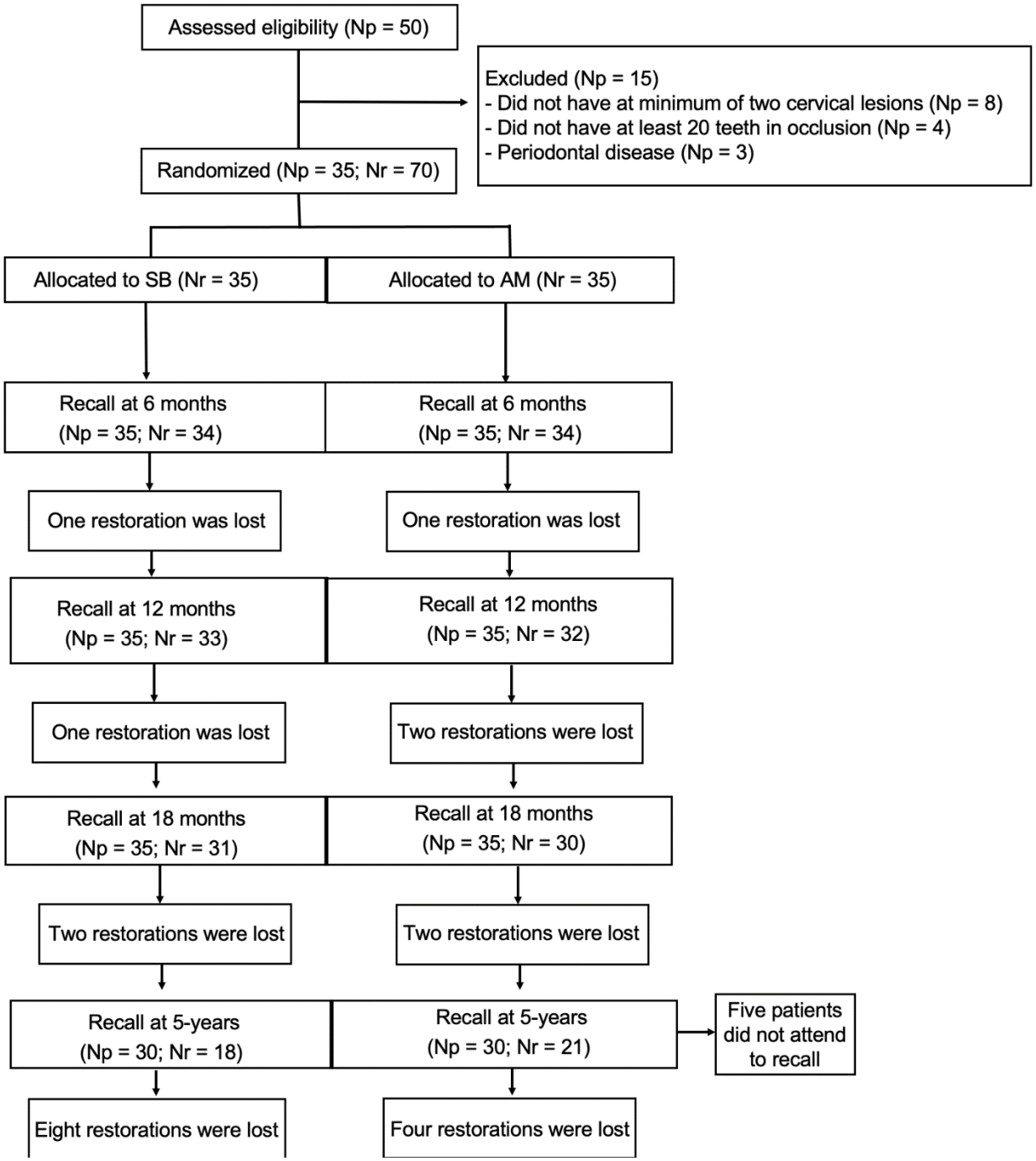

Figure 4.2.3. Flow diagram. Np: number of patients, Nr: number of restorations.

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3.3 ARTIGO 3 - CLINICAL EVALUATION OF VISCOSITY AND CHEMICAL COMPOSITION OF COMPOSITE IN NON-CARIOUS CERVICAL RESTORATIONS: 12-MONTH RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: The objective of this double-blind, randomized clinical trial was to compare the retention rates of one Ormocer-based flowable composites (ORM) versus two methacrylate-based flowable composites (LV, HV) when placed in non-carious cervical lesions (NCCLs) of adult patients.

Material and Methods: 183 restorations were performed on NCCLs using the universal adhesive Futurabond U applied in the selective enamel etching mode according to the manufacturer's directions in all cavities. Then the cavities will be restored with one out of the three flowable composites (n = 61 per group): ormocer-based flowable composite (Admira Fusion Flow, Voco, ORM), low viscosity methacrylate-based composite (GrandioSO Flow, Voco, LV) and high viscosity methacrylate-based composite (GrandioSO Heavy Flow, Voco, HV). After one year of clinical performance, these restorations were evaluated according to FDI and USPHS criteria in the following items: retention/fracture, marginal adaptation, marginal staining, postoperative sensitivity and caries recurrence.

Results: Eight restorations were lost/fractured after one year of clinical evaluation (1 in the ORM, 3 in the LV and 7 in the HV group). The retention rates for 12- months (95% confidence interval) were 98.4% (91.3%-99.7%) for the ORM group, 100% for the LV group and 88.5% (78.1%-94.3%) for the HV group, with no statistical difference identified between any pair of groups ($p > 0.05$). Five restorations presented small marginal adaptation defects at the 12-months evaluation recall, and all of them were considered clinically acceptable.

Conclusion: The clinical performance of the universal adhesive associated to ormocer-based or methacrylate-based flowable composite were found to be promise after 12-month of clinical

evaluation. Otherwise, a high viscosity flowable composite should not be indicate in non-carious cervical lesions.

Keywords: Dental bonding; Dental restoration; Clinical Trial.

3.3.1 Introduction

Non-carious cervical lesions (NCCLs) are usually described as the loss of dental structure at the cement-enamel junction that is not caused by dental caries. This type of lesion is very common in the adult population. For instance, in the middle-aged and elderly populations of China, the prevalence of these lesions was reported to be 76.8 and 81.3% respectively [1]. Such figures may differ among populations but they almost always exceed 50% [2,3]. Several risk factors such as age, location (more common in premolars, canines and second premolars), frequency of tooth brushing, bruxism and family income were found to be associated with NCCLs [4].

Data collected on placement of 1,301 restorations, due to non-carious tooth defects by 178 dentists from the Dental Practice-Based Research Network, showed that composite resins are the material of choice for the restorative treatment of these lesions in 94% of the cases [5]. The restoration with composite resins does not treat the etiology of this condition, but it replaces the lost tissue, restores the dental structural integrity, reduces further wear, can relieve dentin hypersensitivity and also improves esthetics [6].

Among all types of available composite resins, flowable composites are low viscosity restorative materials that differ from regular viscosity resin composites by having lower filler load and less viscous resin content [7]. As a result, these materials are less rigid and have an elastic modulus 20% to 30% lower than that of regular viscosity composites [8,7]. This reduced low elastic modulus can theoretically absorb the stresses generated during the polymerization shrinkage of composites and during mechanical loading in which the teeth are subjected during function [9,10].

Although one recent systematic review of clinical trials has not detected any significant difference on the retention rates of flowable or regular composite resins when placed in NCCLs [10], flowable composites carries the advantages of being user-friendly and it is very popular among clinicians [8]. Recently, a new type of flowable composite has been developed: high viscosity materials (G-aenial Universal Flo; GC, Tokyo, Japan; GrandioSO Heavy Flow, Voco, GmbH, Cuxhaven, Germany). The manufacturers claimed to have improved mechanical properties not dissimilar from regular composite restorative materials [8,11]. Although, these new flowable generations has been achieved a very well clinical performance in posterior restorations [12,13], no clinical studies were found in non-carious cervical lesions.

On the other side, the majority of the flowable composites use today continue to be based on the dimethacrylate resins introduced in the 1960s and 1970s. However, several concerns, as polymerization shrinkage and lower degree of conversion are still present. These factors associated to the water sorption leads to that leaching unreacted monomers, that may cause cytotoxicity to gingival and pulp living cell [14].

Therefore, some other alternatives were created and are available on the market. One of them are the ORganically MOdified CERamics (Ormocer). It's a combination of inorganic-organic co-polymers with inorganic silanated filler particles [15]. These restorative materials replaced all methacrylate backbone resins as well as the methacrylate-based viscosity reducers, cross linking agents and hydrophilic acrylics commonly used in composite failures [16]. However, due to several problems in handling properties, methacrylate-based monomers had to be added to the ormocer matrix of the first commercial products, diminishing the initial promising advantages [14]. This could be consider the main reason to the tendency of poor clinical performance when first generation of ormocer-based composite are compared to methacrylate-based composite in posterior restorations [15,17].

Nowadays, the pure silicate matrix technology combined with nano-hybrid fillers resulted in nano-ormocer has been showed a promise clinical performance in posterior restorations [18], the impact of such chemical changes into clinical performance of restorations placed in non-carious cervical lesions has not been evaluated yet. Therefore, the present randomized controlled trial aimed to compare the retention rates of two viscosity of methacrylate-based flowable composites, as well as ormocer-based flowable composite versus methacrylate-based flowable composites when placed in NCCLs of adult patients.

3.3.2 Material and Methods

3.3.2.1 Study design

The description of the experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement [19].

3.3.2.2 Ethics approval

The State University of Ponta Grossa (protocol 3.604.611; 2019) Ethics Committees reviewed and approved the protocol and issued a consent form for this study. Written informed consent was obtained from all participants prior to starting the treatment.

3.3.2.3 Protocol registration

This clinical trial was registered in the Brazilian Clinical Trial Registry (REBEC) RBR-998R5B.

3.3.2.4 Trial design, settings and location of data collection

This was a double-blind, split-mouth randomized controlled clinical trial. The study was performed in the clinics of the School of Dentistry of the State University of Ponta Grossa (Ponta Grossa, Paraná, Brazil) between June 2019 and November 2019.

3.3.2.5 Recruitment

Patients were recruited as they seek for treatment in the clinics of the university. Patients were recruited in the order in which they reported for screening session, forming a sample of convenience.

3.3.2.6 Eligibility criteria

All participants were examined by two calibrated dental residents to check if they met the inclusion and exclusion criteria (Figure 4.3.3). The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe. Participants need to be in good general health, be at least 18 years old, have an acceptable oral hygiene level, and present at least 20 teeth under occlusion. Participants were required to have at least three comparable NCCLs (in size, format and dimensions) to be restored. These lesions have to be non-retentive, deeper than 1 mm, and involve both the enamel and dentin of vital teeth without mobility.

The cavo-surface margin cannot involve more that 50% of enamel. Patients with extremely poor oral hygiene or using orthodontic devices, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study as they need to receive other treatments before restorative intervention. Also, participants with known allergy to resin-based materials or any other material used in this study, pregnant or breastfeeding women, or participants under chronic use of anti-inflammatory, analgesic, and psychotropic drugs were not be included in the study.

3.3.2.7 Sample size calculation

The annual retention rate of flowable composites at 3-years is approximately 80% [10]. With an α of 0.05, a power of 90%, and an equivalence trial of 25%, a minimum sample size of 60 restorations per group in order to detect a difference of 25% among the test groups.

3.3.2.8 Random sequence generation and allocation concealment

The randomization was done on an intra-individual basis so that each subject ended up with three restorations. These randomization schemes performed using tools available at the website http://www. sealedenvelope.com.

A staff member not involved in the research protocol performed the randomization process. Details of the allocated groups were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. Opening the envelope only on the day of the restorative procedure guarantee the concealment of the random sequence. In all cases, the tooth with the highest tooth number (FDI numbering system) received the treatment described first, while the tooth with the next number in sequence received the treatment mentioned second, with placement continuing in a similar manner until the third tooth.

3.3.2.9 Interventions: restorative procedure

All the patients selected for this study received dental prophylaxis with a suspension of pumice and water in a rubber cup. The degree of sclerotic dentin from the NCCLs was measured according to the criteria described by [20] (Table 4.3.16). The cavity dimensions in millimeters (height, width, and depth), the geometry of the cavity (evaluated by profile photograph and labeled at $<45^{o}$, 45^{o}-90^{o}, $90^{o}<135^{o}$, and $>135^{o}$) [21], the presence of an antagonist, and the presence of attrition facets was observed and recorded. Pre-operative sensitivity was also

evaluated by applying air for 10 s from a dental syringe placed 2 cm from the tooth surface and with an explorer. These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

To calibrate the restorative procedure, the study director placed one restoration of each group to identify all steps involved in the restorative technique. Then, other two operators, residents in the dental school - with more than five years of clinical experience placed three restorations in a clinical setting, one of each group, under the supervision of the study director. The restoration failures were shown to the operators prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures. The operators restored all teeth.

Before restorative procedures, the operators anesthetized the teeth with a 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil) and cleaned all lesions with pumice and water in a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil), followed by rinsing and drying.

Then, shade selection was made using a shade guide. Rubber dam was placed and the univeral adhesive system Futurabond U (Voco) applied in the self-etch mode associated to selective enamel etching was applied according to the manufacturer's directions in all cavities. The compositions, application modes, and batch numbers are described in Table 4.3.17. Then the cavities were restored with one out of the three flowable composites described below:

- Ormocer-based flowable composite (Admira Fusion Flow, Voco) was placed in increments of 2 mm maximum followed by light-curing with an irradiance of 1200 mW/cm^2 (Bluephase N, Ivoclar Vivadent, Schaan, Liechtenstein) for 20 s each.

- Low viscosity methacrylate-based composite (GrandioSO Flow, Voco) was placed as reported for the ormocer-based flowable composite.

- High viscosity methacrylate-based composite (GrandioSO Heavy Flow, Voco) was placed as reported for the ormocer-based flowable composite.

After cavity filling, the restorations were finished immediately with fine and extra-fine #2200 diamond burs (KG Sorensen, Barueri, SP, Brazil) and polished with OptraPol NG (Ivoclar Vivadent, Schaan, Liechtenstein) under constant water-cooling.

3.3.2.10 Blinding

The examiners were not be involved with the restoration procedures and therefore they were blinded to the group assignment. Patient was blinded to group assignment in a double-blind randomized controlled trial.

3.3.2.11 Clinical evaluation

An individual standardized paper case report form was used for each evaluator at each recall time so that evaluators were kept blinded to earlier evaluations during the follow-up recalls. The restorations was evaluated by World Federation criteria (FDI) [22,23] and the classical United States Public Health Service (USPHS) criteria (adapted by Bittencourt et al., 2005 and Perdigão et al., 2012) [24,25]. The primary clinical endpoint was restoration retention/fracture, but the following secondary endpoints were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, color match and recurrence of caries. The evaluation of the spontaneous postoperative sensitivity was performed one week after the restorative procedure by asking the patient if he experienced any pain during the period.

These variables were ranked according to FDI criteria into clinically very good, clinically good, clinically sufficient/ satisfactory, clinically unsatisfactory but repairable, and clinically poor (replacement required) [22,23] and in the USPHS criteria into alfa, bravo, and Charlie [24]. Both examiners evaluated all the restorations once and independently. When disagreements occurs during the evaluations, they had to reach a consensus before the participant was dismissed.

3.3.2.12 Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to CONSORT (Consolidated Standards of Reporting Trials) suggestion [19]. Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each individual item was performed for each evaluation criteria (FDI and USPHS criteria). The differences in the ratings of the three groups in each recall time were compared two-by-two with Wilcoxon Signed Rank test (α=0.05). The absolute and relative risks of each criterion was calculated along with the 95% confidence interval. Cohen's kappa statistics was used to test inter-examiner agreement. In all statistical tests, we preset the level of significance to 5%.

3.3.3 Results

The restorative procedures were implemented exactly as planned, and no modification was performed. Twenty five out of 52 patients examined for eligibility were not enrolled in the

study because they did not fulfill the inclusion criteria. Thus, a total of 27 subjects (12 men and 15 women) were selected. One hundred and eighty three restorations were placed: 61 for each group (Figure 4.3.5). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 4.3.18. The overall Cohen kappa statistics showed excellent agreement between the examiners during the six months (0.94) follow-up recall. All research subjects were evaluated at baseline, six and twelve-month recall and the interim results analysis are described following.

3.3.3.1 Retention/fracture

Eight restorations were lost or fractured after one year of clinical evaluation for both evaluation criteria (one for ORM and seven for HV; Tables 4.3.19 and 4.3.20). The retention rates for one year (95% confidence interval) were 98.4% (91.3%-99.7%) for the ORM group, 100% for the LV group and 88.5% (78.1%-94.3%) for the HV group, with statistical difference identified between ORM vs. HV ($p = 0.03$) and between ORM vs LV ($p = 0.01$; Tables 4.3.19 and 4.3.20).

3.3.3.2 Marginal adaptation

Five restorations were considered to have minor discrepancies in marginal adaptation at the one year recall using the FDI criteria (2 for ORM, 2 for LV and one for HV; Table 4.3.19). When USPHS criteria was used, only one restoration (LV group) showed signs of minor discrepancies in marginal adaptation. No significant difference was detected between any pair of groups at the one year recall ($p > 0.05$; Tables 4.3.19 and 4.3.20).

3.3.3.3 Marginal discoloration

Five restorations were considered to have minor discrepancies in marginal adaptation at the one year recall using the FDI criteria (1 for ORM, 1 for LV and 3 for HV; Table 4.3.19). When USPHS criteria was used, none restoration showed marginal discoloration. No significant difference was detected between any pair of groups at the one year recall ($p > 0.05$; Tables 4 and 4.3.20).

3.3.3.4 Other parameters

No restorations had postoperative sensitivity to air at the one year recall using both criteria. No restoration showed recurrence of caries after one year of clinical evaluation for FDI or USPHS criteria. Usually, the restorations showed a very good clinical performance, which can be seen in Figure 5, after one year of clinical performance.

3.3.4 Discussion

One of the objective of the present study was to compare the clinical performance to high viscosity methacrylate-based flowable composite in comparison with a low viscosity methacrylate-based flowable composite in non-carious cervical lesions. In the common sense, flowable composite has a lower filler content and higher volume of resin matrix when compared with non flowable composite [26,9]. This permits a more intimal adaptation to the cavity walls, greater flow and flexibility. Therefore, the first generation flowable composite was applied as a cavity liner or Class V restoration due to the low elastic modulus [26,9].

However, with the advent of nanotechnology, it's possible to increasing significantly the percentage of filler in the composite, maintained their handling properties (flowability). Based on this, it was possible to produce a flowable composite that has a filler content of more than 80% w/w [27], similar to regular viscosity composite materials. Actually, several studies showed that highly filled flowable composites showed mechanical properties that are comparable to those of regular viscosity composite [28,8,7,29].

Nevertheless, according to the manufacturer, both methacrylate-based (GrandioSO Flow and GrandioSO Heavy Flow) flowable composites showed high filler weight. Actually, Jager et al., evaluated the rheological properties of various flowable composites, among them, GrandioSO Flow and GrandioSO Heavy Flow. The authors showed that, although a very similar amount of filler in both materials, GrandioSO Flow showed a significant lower viscosity when compared to GrandioSO Heavy Flow. The authors described that, other factors, as the type and shape of fillers, along with the quality of silanization, probably have a greater influence here than the filler content itself, as well as previously observed for Beun [30]. It seems that, the higher viscosity of GrandioSO Heavy Flow affected their ability to 'moist' and adapt well to cavity margins and wall in non-carious cervical lesions and, consequently, significant increase

the loss of retention/fracture of GrandioSO Heavy Flow restorations after one year of clinical evaluation.

The second objective of the present study was to compare the clinical performance to low viscosity methacrylate-based flowable composite (GrandioSO Flow) in comparison with ormocer-based flowable composite (Admira Fusion Flow) in non-carious cervical restorations. As described in the introduction section, the first generation of ormocer-based composites showed a poorer long-term clinical behavior of restorations carried out with ormocer-based composites compared to methacrylate-based composites [15,17].

However, only a few number of clinical studies that evaluated both materials were found [31,32]. For instance, Celik et al. (2007) showed that, the ormocer-based flowable composite (Admira Flow, Voco) showed similar clinical performance than methacrylate-based flowable composite (Filtek Flow, 3M Oral Care, St. Paul, MN, USA) after 2-year recall rate. In other study, Dall'Orologio, Lorenzi (2014) observed none significant difference between ormocer-based flowable composite (Ceram.X Duo, Dentsply, Dentsply DeTrey, Konstanz, Germany) in comparison to methacrylate-based flowable composite (EsthetX, Dentsply) after 8 years of clinical evaluation.

These restorative materials replaced all methacrylate backbone resins as well as the methacrylate-based viscosity reducers, cross linking agents and hydrophilic acrylics commonly used in composite failures [16]. However, due to several problems in handling properties, methacrylate-based monomers had to be added to the ormocer matrix of the first commercial products, diminishing the initial promising advantages [14]. This could be consider the main reason to the controversial results when first generation of ormocer-based composite are compared to methacrylate-based composite in posterior and anterior restorations [15,17].

Of course that, as this new generation of pure silicate matrix technology combined with nano-hybrid fillers resulted in nano-ormocer, it will be expected that, a better clinical performance when compared to a methacrylate-based composite. Due to the short-term follow-up shown in the present study, it was not possible to detect any significant difference. However, future long-term evaluation need to be done to evaluate this hypothesis.

3.3.5 Conclusions

The clinical performance of a ormocer-based or low viscosity methacrylate-based flowable composite were found to be promise after 12-month of clinical evaluation.

Unfortunately, a high viscosity flowable composite did not be indicated to restore non-carious cervical lesions because the high loss of retention (11.5%) after one year.

Table 4.3.16. Dentin sclerosis scale

Dentin sclerosis scale*	
CATEGORY	**CRITERIA**
1	No sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparency
2	More sclerosis than in category 1 but less than halfway between categories 1 and 4
3	Less sclerosis than in category 4 but more than halfway between categories 1 and 4
4	Significant sclerosis present; dentin is dark yellow or even discolored (brownish); glassy appearance, with significant translucency or transparency evident

* Adapted from Swift and colleagues[20] with permission from Elsevier.

Table 4.3.17. Materials, compositions and application mode.

Materials	Composition/batch number	Application Mode (*)
Futurabond U (VOCO GmbH, Cuxhaven, Germany)	35% Phosphoric acid (Vococid): 35% Phosphoric Acid Adhesive: HEMA, Bis-GMA, HEDMA, acidic adhesive monomer (*), urethane dimethacrylate, catalyst, silica nanoparticles and ethanol	1. Apply Etchant only on enamel for 15 s (selective enamel etching) 2. Rinse for 10 s; 3. Air dry to remove excess of water 4. Keep dentin dry, do not overdry 5. Apply the adhesive for 20 s with vigorous agitation. 6. Gently air thin for 5 s. 7. Light-cure for 10 s.
GrandioSO Flow (VOCO GmbH, Cuxhaven, Germany)	Organic matrix: Bis-GMA, Bis-EMA, TEGDMA, HDDMA, canforquinone, amine and butylhydroxytoluene Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 μm) Filler content: 87% w/w	1. Placed in increments of 2 mm maximum 2. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm^2)

GrandioSO Heavy Flow (VOCO GmbH, Cuxhaven, Germany)	Organic matrix: Bis-GMA, Bis-EMA, TEGDMA, HDDMA, canforquinone, amine and butylhydroxytoluene Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-0.04 μm) Filler content: 89% w/w	1. Placed in increments of 2 mm 2. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm^2)
Admira Fusion Flow (VOCO GmbH, Cuxhaven, Germany)	Organic matrix: organically modified ceramic (Ormocer) Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 μm) Filler content: 83% w/w	1. Placed in increments of 2 mm 2. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm^2)

Abbreviations: HEMA: 2-hydroxyethyl methacrylate; Bis-GMA: Bisphenol-A-glycidyl dimethacrylate; HEDMA: 1,6-hexanediol dimethacrylate; Bis-GMA –bisphenol A-glycidyl methacrylate, Bis-GMA –bisphenol A polyethylene glycol diether dimethacrylate, TEGDMA – triethylene glycol methyl ether methacrylate, HDDMA – 1,6-hexanediol dimethacrylate,*(*) Acidic adhesive monomer in the composition of Futurabond U is* 10-MDP: 10-methacryloyloxydecyl dihydrogen phosphate according to personal communication with Dr. Martin Danebrock .

Table 4.3.18. Characteristics of the research subjects and the non-carious cervical lesions (NCCL) per group.

Characteristics of research subjects			
Gender distribution			
Male 12			
Female 15			
Age distribution (years)			
20-29 3			
30-39 2			
39-49 6			
> 49 16			
Characteristics of Class-V lesions			
	ORM	**LV**	**HV**
Shape (degree of angle)			
< 45	09	06	07
45-90	18	26	17
90-135	09	07	06
> 135	25	22	31
Cervico-incisal height (mm)			
< 1.5	13	07	10
1.5-2.5	24	21	21
2.5-4.0	19	28	24
> 4.0	04	04	05
Degree of sclerotic dentin			
1	20	18	17
2	12	14	13
3	12	12	09
4	07	07	12
Presence of antagonist			
Yes	61	61	61

No	00	00	00
Attrition facet			
Yes	16	12	11
No	45	49	50
Pre-operative sensitivity (spontaneous)			
Yes	61	61	61
No	00	00	00
Pre-operative sensitivity (air dry)			
Yes	23	23	17
No	37	38	45
Tooth distribution			
Anterior			
Incisor	16	06	09
Canines	09	14	08
Posterior			
Premolar	26	34	29
Molar	08	12	12
Arc distribution			
Maxillary	29	33	31
Mandibular	32	28	30

Table 4.3.19. Number of evaluated restorations for each group classified according to the World Dental Federation Criteria[22,23] in different follow-up times (6, 12, 18 and 60 months).

Time		Baseline			06 months			12 months		
FDI Criteria	*(*)*	ORM	LV	HV	ORM	LV	HV	ORM	LV	HV
Marginal staining	VG	61	61	61	59	60	52	59	60	51
	GO	--	--	--	1	1	2	1	1	2
	SS	--	--	--	--	--	1	--	--	1
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--
Fractures and retention	VG	61	61	61	57	60	52	57	60	51
	GO	--	--	--	1	--	1	1	--	1
	SS	--	--	--	1	--	1	1	--	1
	UN	--	--	--	1	1	1	1	1	1
	PO	--	--	--	1	--	6	1	--	7
Marginal adaptation	VG	61	61	61	60	59	54	58	59	53
	GO	--	--	--	--	1	1	2	1	1
	SS	--	--	--	--	1	--	--	1	--
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	VG	61	61	61	60	61	55	60	61	54
	GO	--	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--
Recurrence of caries	VG	61	61	61	60	61	55	60	61	54
	GO	--	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--

(*) VG for clinically very good; GO for clinically good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory and; PO for clinically poor.

Table 4.3.20. Modified United States Public Health Service (USPHS) criteria according to Bittencourt and others[24] and Perdigão and others[25].

Time		**Baseline**			**06 months**			**12 months**		
USPHS Criteria		ORM	LV	HV	ORM	LV	HV	ORM	LV	HV
Marginal staining	**Alfa**	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--
Retention	**Alfa**	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	1	--	6	1	--	7
Fracture	**Alfa**	61	61	61	58	60	53	58	60	52
	Bravo	--	--	--	2	1	2	2	1	2
	Charlie	--	--	--	--	--	--	--	--	--
Marginal adaptation	**Alfa**	61	61	61	60	60	55	60	60	54
	Bravo	--	--	--	--	1	--	--	1	--
	Charlie	--	--	--	**--**	**--**	**--**	**--**	**--**	**--**
Post-operative sensitivity	**Alfa**	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--

Recurrence of caries	**Alfa**	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--

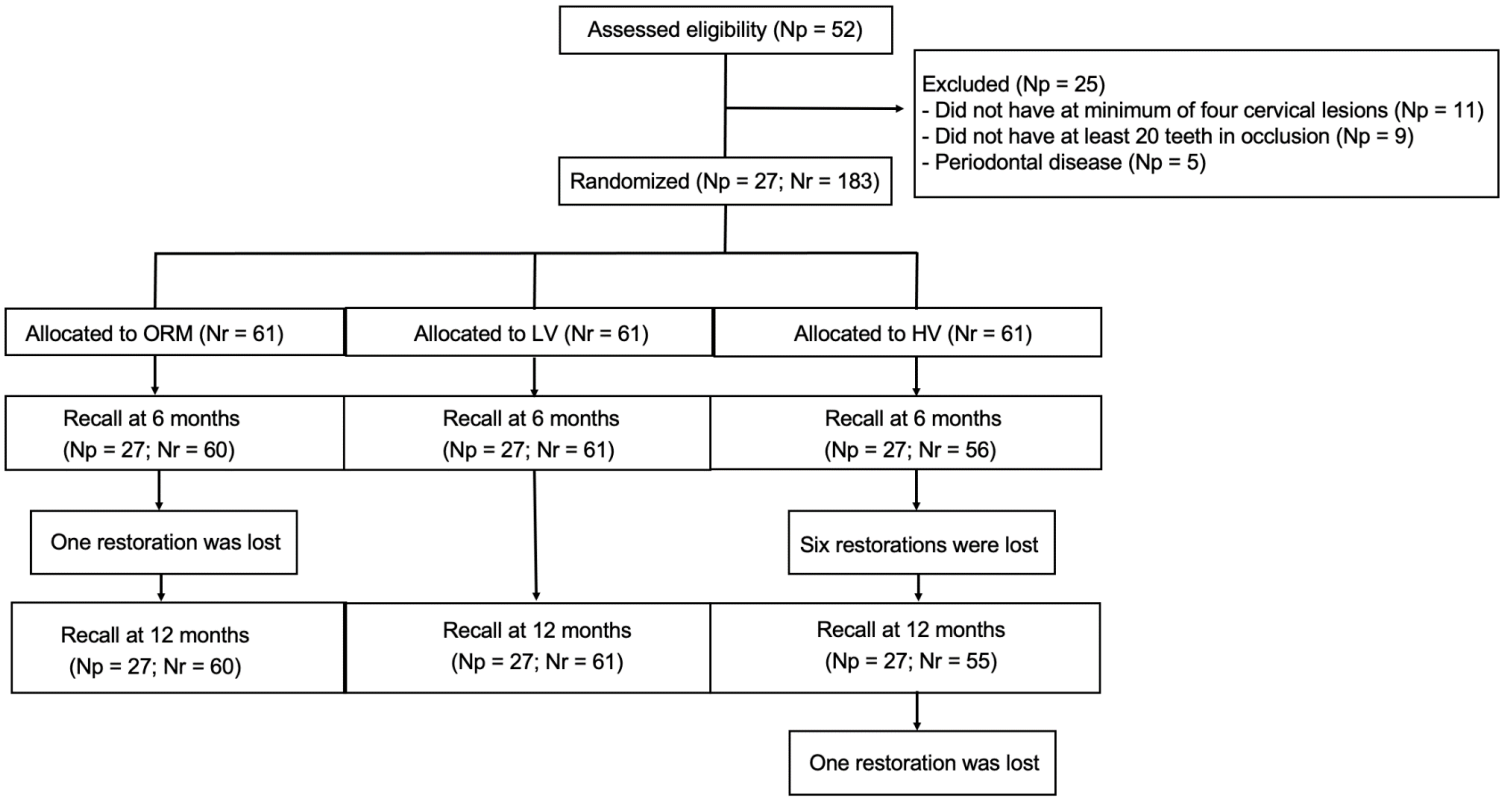

Figure 4.3.4. Flow diagram. Np: number of patients, Nr: number of restorations. ORM= ormocer-based flowable composite; LV=low viscosity methacrylate-based composite; HV= high viscosity methacrylate-based composite.

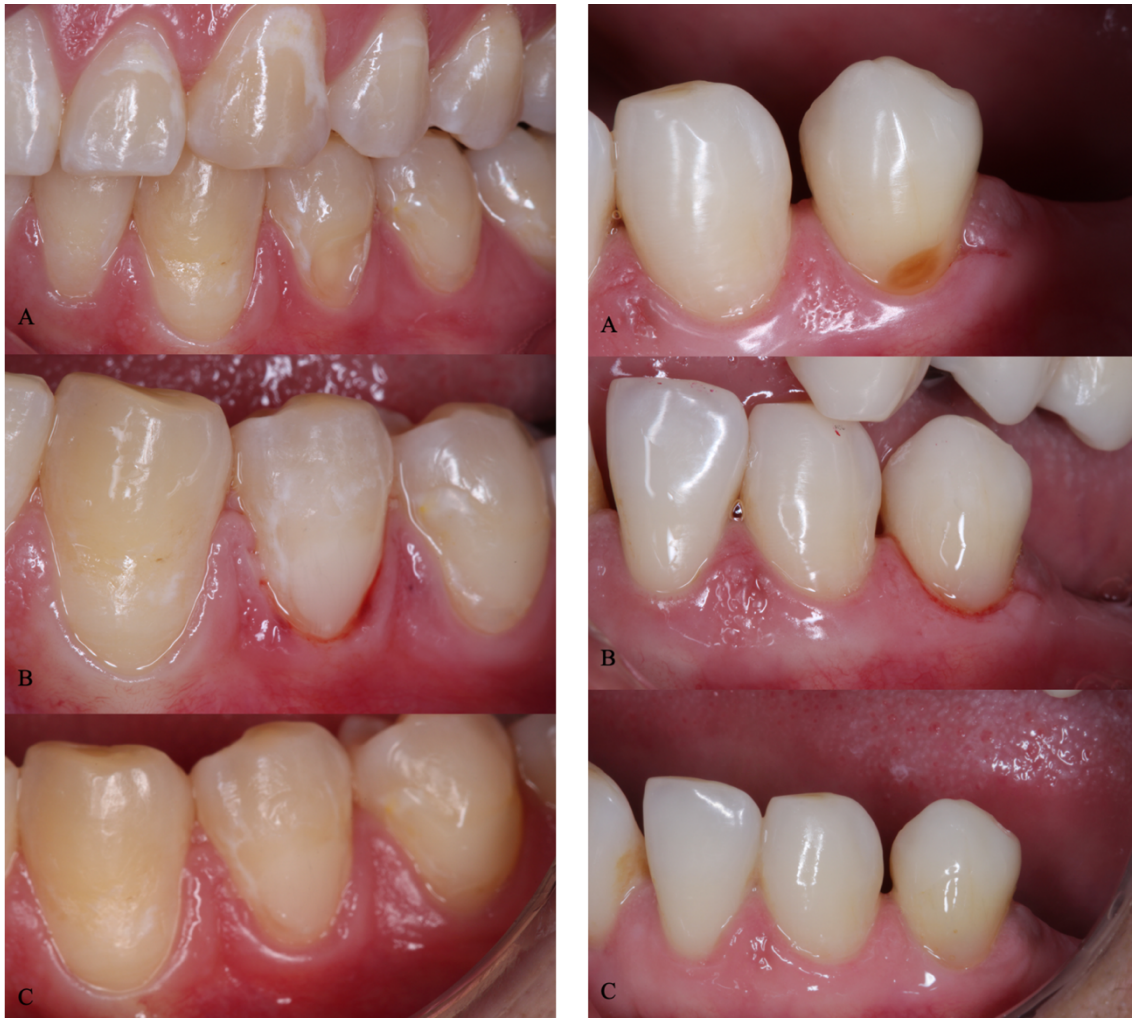

Figure 4.3.5. A: Initial aspect of non-carious cervical lesion. B: Restoration finished; Immediate aspect; Vestibular view. C: Restoration after 6-month of clinical evaluation. Vestibular view.

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4 DISCUSSÃO

O desempenho dos sistemas adesivos tem sido avaliado por meio de estudos clínicos em NCCLs, principalmente por fornecerem retenção, que é o parâmetro mais importante para avaliar restaurações de NCCLs [105]. Até onde sabemos, apresentamos dois ensaios clínicos randomizados de longo prazo avaliando este adesivo universal específico.

Um dos estudos (artigo 1) aqui apresentado descreve que o sistema adesivo SU possui dois mecanismos de ligação potenciais, baseados em: (A) ácido polialquenóico; e (B) 10-MDP. Os ácidos polialquenóicos interagem com substratos de apatita seguindo a mesma reação de adesão-descalcificação [37, 106]. O desempenho de ligação do SU pode resultar em uma auto-adesão forte e estável do copolímero de ácido polialquenóico à hidroxiapatita de dentina, conforme mostrado por Sezinando et al. [37] para SU. Interações químicas também podem ocorrer através de ligações iônicas estabelecidas por monômeros ácidos como o 10-MDP que reagem com a hidroxiapatita, formando sais monômero-Ca que são estáveis à degradação [37, 106-108]. Todas essas características ajudam a explicar a boa taxa de retenção de longo prazo de SU, que também foi demonstrada em estudos clínicos de curto e médio prazo [22, 109-111].

Independentemente da estratégia adesiva utilizada, o presente estudo (artigo 1) constatou que um total de 19 restaurações falharam como resultado de descolamento total ou parcial após cinco anos de acompanhamento clínico (3 com ERm, 3 com ERd, 5 com SEE e 8 com SE). Com base na taxa de sobrevivência, uma restauração realizada com a estratégia SE teve em média 2,6 vezes mais probabilidade de descolar do que uma restauração inserida com a estratégia ER (ERm ou ERd). O fato de que os adesivos SE simplificados tiveram pior desempenho em nosso estudo está de acordo com uma meta-análise de ensaios clínicos [112].

Uma maneira simples de melhorar a adesão dos adesivos SE é condicionar o esmalte. Embora o padrão de condicionamento produzido pelos adesivos autocondicionantes dependa de sua acidez, tempo de aplicação e modo de aplicação, os adesivos autocondicionantes resultam em um padrão de condicionamento do esmalte muito raso, com redução de micro-porosidades para infiltração de resina [113-116] . Essa menor capacidade de condicionamento dos adesivos autocondicionantes pode favorecer o descolamento nas margens, permitindo a infiltração de manchas de alimentos ou biofilme bacteriano levando à pigmentação marginal. Os benefícios do condicionamento prévio com ácido fosfórico foram descritos em vários

estudos in vitro [117-120]. Mais recentemente, o uso do condicionamento ácido fosfórico no esmalte também melhorou o desempenho dos adesivos universais [23, 45, 121, 122].

Quando o SU foi aplicado em condições úmidas (ERm) e secas (ERd) em nosso estudo (artigo 1), taxas de retenção semelhantes foram medidas, assim como todos os outros parâmetros avaliados. Essa semelhança de resultados ao comparar o grau de umidade do substrato não foi inesperada, uma vez que os ensaios clínicos anteriores de curto e médio prazo não relataram diferenças significativas para protocolos de colagem úmida versus seca [84, 85]. Mesmo depois de o conceito de dentina úmida ter sido defendido por anos [85, 123, 124], a literatura atual mostra que manter a dentina úmida pode não ter vantagens clínicas práticas sobre a adesão seca [125]. Além da dificuldade de manter a dentina desmineralizada úmida na prática clínica, o grau de umidade ideal depende do tipo de solvente do sistema adesivo [126]. Uma vez que SU é um adesivo à base de etanol / água com 10-15% em peso de cada [109], esta quantidade de água seria suficiente para plastificar a rede de colapso colapsada, permitindo a reabertura e expansão dos espaços interfibrilares de dentina seca para a infiltração de monômeros resinosos [124, 126].

Além disso, o desempenho clínico do SU no ERd em nosso estudo (artigo 1) sugere que, se aplicado ativamente na dentina, seguindo as instruções do respectivo fabricante, a umidade pode não ter influência na adesão [127, 128]. Este método de aplicação do adesivo pode permitir uma melhor difusão do monômero para dentro, enquanto os solventes se difundem para fora pela pressão mecânica aplicada durante a fricção vigorosa e, quando a pressão é aliviada, a solução adesiva é puxada para a malha de colágeno colapsada [85].

Outra questão abordada nesse trabalho (artigo 2) é a adição de monômeros funcionais, como como PAC e MDP. Eles são responsáveis pelas melhorias significativas nos resultados de adesão para adesivos ER e SE. Inicialmente, a justificativa para o uso do o PAC deveria ser por fornecer melhor estabilidade à umidade [129, 130]. No entanto, devido ao seu alto peso molecular, alguns autores indicaram que o PAC impede uma infiltração completa da malha de colágeno, resultando na formação de uma interface dentina-adesivo não uniforme [131, 132]. Mais recentemente, foi observado que os grupos carboxila presentes nos ácidos polialcenóicos substituem os íons fosfato na hidroxiapatita, estabelecendo ligação iônica com o cálcio [42, 43]. Esse mecanismo de ligação química seguiu a mesma reação de adesão-descalcificação descrita pelos adesivos autocondicionantes [33]. Vale ressaltar que essa interação química depende da abundância de grupos carboxílicos polares do PAC, que podem apresentar alta afinidade de ligação [37]. Segundo o fabricante, o SB contém 5 a 10% em peso do PAC [32]. Esse fato deve ser

responsável por os maiores valores de resistência de união imediata e de longo prazo do Adper Single Bond contendo PAC em comparação com o adesivo experimental livre de PAC Adper Single Bond [35, 36].

Em relação ao adesivo ER de dois passos, Ambar é um adesivo que contem MDP. Monômeros funcionais já foram classificados com base em seus potenciais de ligação química, e o10-MDP (10-metacriloiloxidecil di-hidrogenofosfato) foi identificado como capaz de estabelecer uma interação química muito intensa e estável com a hidroxiapatita. Os sais insolúveis em água de MDP-Ca contribuem para a proteção das fibras de colágeno. A relação atômica da molécula 10-MDP favorece a interação química [43, 133, 134].

Embora os dois adesivos testados tenham várias diferenças em sua química, eles compartilham características importantes. O Adper Single Bond 2 e o sistema adesivo Ambar contêm etanol como solvente. Comparado à água, o etanol apresenta maior pressão de vapor, o que permite melhor evaporação do solvente com secagem ao ar [135], 66 e pode ser um dos motivos para o baixo índice de falha do material apresentado neste estudo. Foi relatado que os sistemas à base de acetona são mais sensíveis à umidade da dentina do que os adesivos etanol e etanol / água [124]. Se a dentina não for mantida suficientemente úmida, os sistemas à base de acetona não podem se infiltrar nas fibrilas de colágeno, levando a uma redução da força de adesão [124].

Partindo para os tipos de resina (artigo 3), o compósito fluido tem um menor conteúdo de carga e maior volume de matriz de resina quando comparado ao compósito não escoável [89, 99]. Isso permite uma adaptação mais íntima às paredes da cavidade, maior fluxo e flexibilidade. Portanto, o compósito fluido de primeira geração foi aplicado como base de cavidade ou restauração de Classe V devido ao baixo módulo de elasticidade [89, 99].

Porém, com o advento da nanotecnologia, é possível aumentar significativamente a porcentagem de carga no compósito, mantendo suas propriedades de manuseio (fluidez). Com base nisso, foi possível produzir um compósito fluido com um teor de carga de mais de 80% p / p [136] [27], semelhante aos materiais compósitos de viscosidade regular. Na verdade, vários estudos mostraram que compósitos fluidos altamente preenchidos apresentam propriedades mecânicas que são comparáveis àquelas de compósitos de viscosidade regular [54, 88, 101, 102].

O terceiro artigo desse trabalho comparou o desempenho clínico do compósito fluido à base de metacrilato de baixa viscosidade (GrandioSO Flow) com o compósito fluido à base de

Ormocer (Admira Fusion Flow) em restaurações cervicais não cariosas. A primeira geração de compósitos à base de ormocer mostrou um comportamento clínico a longo prazo mais pobre em restaurações realizadas com compósitos à base de ormocer em comparação com compósitos à base de metacrilato [70, 71]. No entanto, apenas alguns estudos clínicos que avaliaram ambos os materiais foram encontrados [58, 104].

Esses materiais restauradores substituíram todas as resinas de estrutura de metacrilato, bem como os redutores de viscosidade à base de metacrilato, agentes de reticulação e acrílicos hidrofílicos comumente usados em falhas de compósitos [137]. No entanto, devido a vários problemas nas propriedades de manuseio, monômeros à base de metacrilato tiveram que ser adicionados à matriz ormocer dos primeiros produtos comerciais, diminuindo as vantagens iniciais promissoras [60]. Isso pode ser considerado o principal motivo para os resultados controversos quando a primeira geração do compósito à base de Ormocer é comparada ao compósito à base de metacrilato em restaurações anteriores e posteriores [70, 71] [15,17].

Por fim, como esta nova geração de tecnologia de matriz de silicato puro combinada com cargas nano-híbridas resultou em nano-ormocer, é de se esperar um melhor desempenho clínico quando comparado a um compósito à base de metacrilato. Devido a avaliação de curto prazo demonstrada no presente estudo, não foi possível detectar diferença significativa. No entanto, futuras avaliações de longo prazo precisam ser feitas para avaliar essa hipótese.

5 CONCLUSÕES

Diferentes estratégias de adesão em Adesivo Universal

(1) O comportamento clínico do adesivo universal foi melhor na técnica ER em comparação com a técnica SE.

(2) Se usar a estratégia SE, é altamente recomendável o uso de condicionamento seletivo do esmalte.

Avaliação de Adesivos Convencionais com diferentes monômeros funcionais

(3) Adesivos convencionais ER de dois passos, um adesivo contendo ácido polialquenóico, e um adesivo contendo MDP, tiveram desempenhos clínicos comparáveis e altos após 5 anos de avaliação clínica.

Comparação de um compósito fluido à base de Ormocer vs. compósito fluido à base de metacrilato

(4) O desempenho clínico de um compósito fluido à base de ormocer ou metacrilato de baixa viscosidade foi considerado promissor após um ano de avaliação clínica.

(5) Compósito fluido de alta viscosidade não é indicado para restaurar lesões cervicais não cariosas devido à alta perda de retenção (11,5%) após um ano.

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APÊNDICE A – TCLE - ARTIGO 1

Termo de Consentimento Livre e Esclarecido

Você _____,CPF___, RG___, está sendo convidado a participar da pesquisa **"Avaliação clínica de restaurações com sistema adesivo universal em lesões cervicais não-cariosas."** tendo como pesquisador responsável **Alessandro Dourado Loguercio** e como pesquisadora participante **Thalita Paris** da Universidade Estadual de Ponta Grossa. O objetivo da pesquisa é **comparar o desempenho clínico de um novo sistema adesivo, chamado universal em LCNCs.**

A sua participação no estudo será de receber as restaurações referentes aos grupos do estudo e retornar às consultas de acompanhamento nos períodos determinados para reavaliações. O voluntário não terá seus dados divulgados, os quais estarão em completo sigilo. Os resultados da pesquisa serão usados em publicações de artigos.

Após as análises você será informado dos resultados desta pesquisa da qual participa. Sua participação é voluntária, portanto não receberá recompensa ou gratificação nem pagará para participar. Será garantido o livre acesso a todas as informações e retirada de dúvidas sobre o estudo, enfim, tudo o que você queira saber antes, durante e depois da participação na pesquisa. Você poderá deixar de participar do estudo a qualquer momento, sem apresentar justificativas e, também, sem prejuízo ou perda de qualquer benefício que possa ter adquirido, tendo também todas as dúvidas esclarecidas sobre a sua participação neste trabalho. Em caso de dúvidas, você poderá entrar em contato com qualquer um dos membros da pesquisa ou com a Comissão de Ética em Pesquisa da UEPG:

Nome do pesquisador

Rua :_____ nº – Ponta Grossa /PR Telefone: _____

Nome do pesquisador

Rua :_____ nº – Ponta Grossa /PR Telefone: _____

Comitê de Ética em Pesquisa

UEPG campus Uvaranas, Bloco M, sala 25 Telefone: (42) 9115-3192.

_____

Assinatura do convidado para a pesquisa

_____ _____

Assinatura pesquisador responsável Assinatura pesquisador participante

Ponta Grossa, ___ de _____ de 2014.

APÊNDICE B – TCLE - ARTIGO 2

Termo de Consentimento Livre e Esclarecido

Você _____,CPF___, RG___, está sendo convidado a participar da pesquisa **"Avaliação clínica de restaurações com dois sistemas adesivos convencionais em lesões cervicais não-cariosas."** tendo como pesquisador responsável **Alessandro Dourado Loguercio** e como pesquisadora participante **Thalita Paris** da Universidade Estadual de Ponta Grossa. O objetivo da pesquisa é **comparar o desempenho clínico de dois sistema adesivos convencionais em lesões cervicais não cariosas.**

A sua participação no estudo será de receber as restaurações referentes aos grupos do estudo e retornar às consultas de acompanhamento nos períodos determinados para reavaliações. O voluntário não terá seus dados divulgados, os quais estarão em completo sigilo. Os resultados da pesquisa serão usados em publicações de artigos.

Após as análises você será informado dos resultados desta pesquisa da qual participa. Sua participação é voluntária, portanto não receberá recompensa ou gratificação nem pagará para participar. Será garantido o livre acesso a todas as informações e retirada de dúvidas sobre o estudo, enfim, tudo o que você queira saber antes, durante e depois da participação na pesquisa. Você poderá deixar de participar do estudo a qualquer momento, sem apresentar justificativas e, também, sem prejuízo ou perda de qualquer benefício que possa ter adquirido, tendo também todas as dúvidas esclarecidas sobre a sua participação neste trabalho. Em caso de dúvidas, você poderá entrar em contato com qualquer um dos membros da pesquisa ou com a Comissão de Ética em Pesquisa da UEPG:

Nome do pesquisador

Rua :_____ nº – Ponta Grossa /PR Telefone: _____

Nome do pesquisador

Rua :_____ nº – Ponta Grossa /PR Telefone: _____

Comitê de Ética em Pesquisa

UEPG campus Uvaranas, Bloco M, sala 25 Telefone: (42) 9115-3192.

_____

Assinatura do convidado para a pesquisa

_____ _____

Assinatura pesquisador responsável Assinatura pesquisador participante

Ponta Grossa, ___ de _____ de 2014.

APÊNDICE C – TCLE - ARTIGO 3

Termo de Consentimento Livre e Esclarecido

Você _____,CPF___, RG___, está sendo convidado a participar da pesquisa **"Avaliação clínica de resinas compostas fluidas à base de Metacrilato e O*rmocer*® em lesões cervicais não-cariosas."** tendo como pesquisador responsável **Alessandro Dourado Loguercio** e como pesquisadora participante **Thalita Paris** da Universidade Estadual de Ponta Grossa. O objetivo da pesquisa é **comparar o desempenho clínico dos novos compósitos fluidos baseados em ORMOCER® versus os baseados em metacrilato em LCNCs.**

A sua participação no estudo será de receber as restaurações referentes aos grupos do estudo e retornar às consultas de acompanhamento nos períodos determinados para reavaliações. O voluntário não terá seus dados divulgados, os quais estarão em completo sigilo. Os resultados da pesquisa serão usados em publicações de artigos.

Após as análises você será informado dos resultados desta pesquisa da qual participa. Sua participação é voluntária, portanto não receberá recompensa ou gratificação nem pagará para participar. Será garantido o livre acesso a todas as informações e retirada de dúvidas sobre o estudo, enfim, tudo o que você queira saber antes, durante e depois da participação na pesquisa. Você poderá deixar de participar do estudo a qualquer momento, sem apresentar justificativas e, também, sem prejuízo ou perda de qualquer benefício que possa ter adquirido, tendo também todas as dúvidas esclarecidas sobre a sua participação neste trabalho. Em caso de dúvidas, você poderá entrar em contato com qualquer um dos membros da pesquisa ou com a Comissão de Ética em Pesquisa da UEPG:

Nome do pesquisador

Rua :_____ nº – Ponta Grossa /PR Telefone: _____

Nome do pesquisador

Rua :_____ nº – Ponta Grossa /PR Telefone: _____

Comitê de Ética em Pesquisa

UEPG campus Uvaranas, Bloco M, sala 25 Telefone: (42) 9115-3192.

_____

Assinatura do convidado para a pesquisa

_____ _____

Assinatura pesquisador responsável Assinatura pesquisador participante

Ponta Grossa, ___ de _____ de 2019

ANEXO A - COEP

UNIVERSIDADE ESTADUAL DE PONTA GROSSA - UEPG

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação clínica de resinas compostas fluidas à base de Metacrilato e Ormocer® em lesões cervicais não-cariosas.

Pesquisador: Alessandro Dourado Loguercio

Área Temática:

Versão: 1

CAAE: 21591819.6.0000.0105

Instituição Proponente: Universidade Estadual de Ponta Grossa

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

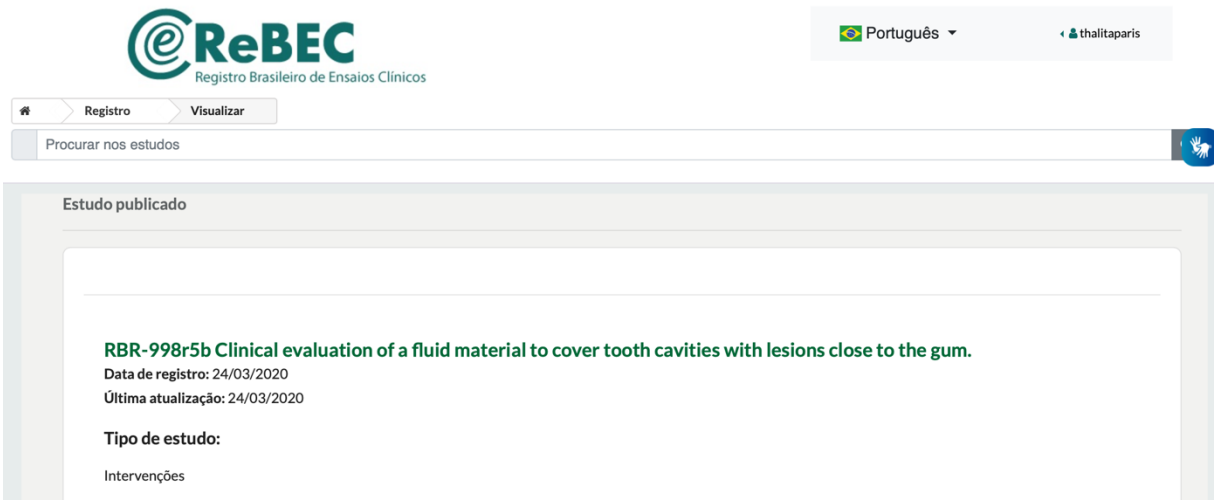
Número do Parecer: 3.604.611

Apresentação do Projeto:

Projeto de Pesquisa:

Avaliação clínica de resinas compostas fluidas à base de Metacrilato e Ormocer® em lesões cervicais não-cariosas.

ANEXO B - REBEC



ANEXO C - FICHA DE CARACTERISTICAS DA LCNC

Ficha clínica

Paciente:_____

Endereço:_____
_____

Telefone:_____

Data:

Aplicação do Adesivo: Dente Grupo Dente Grupo

____- _____ ____ - _____
____ - _____ ____ - _____
____ - _____ ____ - _____
____ - _____ ____ - _____

DENTE	GRAU DE ESCLEROSE	FACETA DE DESGASTE	PRESENÇA ANTAGONISTA	GEOMETRIA			BORDA EM ESMALTE	SENSIBILIDADE			ANGULAÇÃO DA LESÃO
				ALT.	PROF.	LARG.		AR	SONDA	ESP.	

Ficha de Retorno

Baseline	Data de retorno	Tempo de avaliação	Avaliação	Número de restaurações

Obs.: _____

ANEXO D - FICHAS DE AVALIAÇÃO CLÍNICA DA RESTAURAÇÃO

Nome Paciente: Data avaliação:

BASELINE FDI

Dente	Marginal Staining					Fractures and retention					Marginal Adaptation					Postop (hyper-) sensitivity					Recurrence of caries				
	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E

Nome Paciente: Data avaliação:

BASELINE USPHS

Dente	Marginal Staining			Retention			Fracture			Marginal Adaptation			Postoperative sensitivity			Recurrence of caries		
	A alpha	B bravo	C charlie	A alpha	B bravo	C charlie	A alpha	B bravo	C charlie	A alpha	B bravo	C charlie	A alpha	B bravo	C charlie	A alpha	B bravo	C charlie