UNIVERSIDADE ESTADUAL DO OESTE DO PARANÁ
CENTRO DE CIÊNCIAS BIOLÓGICAS E DA SAÚDE
PROGRAMA DE PÓS GRADUAÇÃO EM
ODONTOLOGIA (PPGO) - MESTRADO

RAFAELA CAROLINE MATTANA

Asperization of dental cavity to maximize the adhesion of restorations in noncarious cervical lesions (NCCL) using a universal adhesive system in the conventional mode: double blind randomized clinical trial

Cascavel – PR
2019

RAFAELA CAROLINE MATTANA

Asperization of dental cavity to maximize the adhesion of restorations in noncarious cervical lesions (NCCL) using a universal adhesive system in the conventional mode: double blind randomized clinical trial

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia, Centro de Ciências Biológicas e da Saúde, Universidade Estadual do Oeste do Paraná, como requisito parcial para obtenção do título de Mestre em Odontologia.

Área de concentração: Odontologia

Orientadora: Profª Drª Fabiana Scarparo Naufel

Cascavel – PR
2019

Ficha de identificação da obra elaborada através do Formulário de Geração Automática do Sistema de Bibliotecas da Unioeste.

Mattana, Rafaela Caroline
ASPERIZATION OF DENTAL CAVITY TO MAXIMIZE THE ADHESION OF RESTORATIONS IN NONCARIOUS CERVICAL LESIONS [NCCL] USING A UNIVERSAL ADHESIVE SYSTEM IN THE CONVENTIONAL MODE: DOUBLE BLIND RANDOMIZED CLINICAL TRIAL / Rafaela Caroline Mattana; orientador(a), Fabiana Scarparo Naufel, 2019.
32 f.

Dissertação (mestrado), Universidade Estadual do Oeste do Paraná, Campus de Cascavel, Centro de Ciências Biológicas e da Saúde, Graduação em OdontologiaPrograma de Pós-Graduação em Odontologia, 2019.

1. Adesivo. 2. Materiais dentários. I. Naufel, Fabiana Scarparo . II. Título.

unioeste
Universidade Estadual do Oeste do Paraná
Campus de Cascavel CNPJ 78680337/0002-65
Rua Universitária, 2069 - Jardim Universitário - Cx. P. 000711 - CEP 85819-110
Fone:(45) 3220-3000 - Fax:(45) 3324-4566 - Cascavel - Paraná
PARANÁ
GOVERNO DO ESTADO

RAFAELA CAROLINE MATTANA

Asperizartion of dental cavity to maximize the adhesion of restorations in non carious cervical lesions [NCCL] using a universal adhesive system in the conventional mode: double blind randomized clinical trial

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia em cumprimento parcial aos requisitos para obtenção do título de Mestra em Odontologia, área de concentração Odontclogia, linha de pesquisa Materiais Dentários Aplicados À Clínica Odontológica, APROVADO(A) pela seguinte banca examinadora:

Orientador(a) - Fabiana Scarparo Naufel

Universidade Estacual do Oeste do Paraná - Campus de Cascavel (UNIOESTE)

Biarica Medeiros Maran

Universidade Estacual do Oeste do Paraná - Campus de Cascavel (UNIOESTE)

Wagner Baseggio

Universidade Paranaense - Cascavel (UNIPAR)

Cascavel, 8 de março de 2019

Asperização da cavidade dental para maximizar adesão de restaurações em lesões cervicais não cariosas utilizando adesivo universal utilizado no modo convencional: estudo clínico, duplo cego, randomizado.

RESUMO

OBJETIVO: Este estudo clínico duplo-cego, randomizado avaliou a influência da asperização no comportamento clínico do sistema adesivo Peak® Universal Bond (Ultradent Products, USA) no modo convencional em lesões cervicais não cariosas. MATERIAIS E MÉTODOS: Um total de 92 restaurações foram alocadas em 26 pacientes em dois grupos: convencional (sem preparo) (ER) e convencional asperizado (ERa). Resina composta Forma® Plus (Ultradent Products, USA) foi utilizada de maneira incremental. As restaurações foram avaliadas nos períodos do baseline, 6 e 12 meses, utilizando os critérios preconizados pelo FDI e USPHS. Análises estatísticas foram realizadas pelos testes de Friedman e Mc Nemar (α=0.05). RESULTADOS: 13 restaurações foram perdidas aos 12 meses (6 do grupo ER, 7 do grupo ERa) ($p > 0.05$ entre os grupos). Nenhuma restauração apresentou cárie recorrente aos 12 meses. 74 restaurações apresentaram pequenas discrepâncias na adaptação marginal utilizando o critério FDI aos 12 meses (40 grupo ER, 44 grupo ERa $p > 0.05$ entre os grupos). CONCLUSÃO: A asperização antes da aplicação do Sistema adesivo Peak® Universal Bond no modo convencional não afetou o comportamento clínico das restaurações em lesões cervicais não cariosas.

Palavras chaves: adesão, sistema adesivo

Asperization of dental cavity to maximize the adhesion of restorations in noncarious cervical lesions (NCCL) using a universal adhesive system in the conventional mode: double blind randomized clinical trial

ABSTRACT

OBJECTIVE: This double-blind randomized clinical trial evaluates the influence of asperizarition on clinical behavior of Peak® Universal Bond adhesive system (Ultradent Products, USA) as etch-and-rinse (ER) in non- cariouscervical lesions (NCCLs). MATERIAL AND METHODS: A total of 92 restorations were randomly placed in 26 patients according to the following groups: Etch-and-rinse (ER) (no preparation) and etch-and-rinse and asperization (ERa). The resin composite Forma® Plus (Ultradent Products, USA) was placed incrementally. The restorations were evaluated at baseline, 6 and 12 months, using the FDI and USPHS criteria. Statistical analyses were performed using Friedman repeated-measures analysis and Mc Nemar's test (α=0.05). RESULTS: 13 restorations were lost at 12 months (6 for ER, 7 for ERa) ($p > 0.05$ between groups). No restoration showed recurrent caries lesion at 12 months. 74 restorations were considered to have minor discrepancies in marginal adaptation at the 12 month recall using the FDI criteria (40 for ER, 44 for ERa $p > 0.05$ between groups). CONCLUSION: The asperizationbefore application of Peak® Universal Bond adhesive system as etch-and-rinse didn't affect the clinical behavior of composite restorations placed in NCCLs.

Keywords: adhesion, universal adhesive

LIST OF ABBREVIATIONS

NCCL Non-Carious Cervical Lesions

ER Etch-and-rinse

ERa Etch-and-rinse and asperization

SE Self-etch

FDI International Dental Federation

USPHS United States Public Health Service

ADA American Dental Association

LIST OF TABLES

Dissertação elaborada e formatada conforme as normas das publicações científicas: Operative Dentistry

Disponível em: https://www.jopdent.com/authors/authors.php

SUMARY

1 INTRODUCTION

The adhesive systems available to dental surgeons nowadays are classified according to the treatment they offer to the dental substrate in: conventional or etch-and-rinse (ER) and self- etching (SE) systems. The first ones use phosphoric acid (10-40%) for demineralization of dental enamel and / or dentin substrates and also remove the smear layer completely, the self-etching systems, in turn, replace phosphoric acid by the hydrophilic and acid monomers included in the primer, which will partially or totally dissolve the smear layer, while generating the enamel and dentin conditioning pattern, incorporating the smear layer in the hybrid layer (1, 2, 3).

Universal adhesive systems can be used in both ER and SE strategies. From the clinical point of view, it is interesting because it allows a single product to be made either of the two adhesive strategies, and the simplification of the formulations allowed a reduction in the number of stages and the technical sensitivity (4, 5).

The adhesion to enamel in the ER technique is considered durable and effective (6, 7), because this tissue is highly mineralized (96% of hydroxyapatite crystals), presents low percentages of organic substance and water (4%), which is based on the formation of resinous projections (tags) in the interior of the selectively demineralized tissue by phosphoric acid, this process being known as mechanical bonding (6, 7, 8, 9).

In an attempt to improve dentin adhesion, some authors suggest variations in the technique of applying these adhesive systems (10) suggested to increase the time of application or to apply several adhesive layers. This approach suggests an increase in contact of the acid monomers with the surface of the enamel creating a more retentive pattern (11), report that the friction, an active application of the adhesive systems would improve adhesion by diffusing the primer. From this

(12) realized an in vitro study to evaluate the differences in the active or passive application of 3 SE adhesives with different levels of acidity in a period of 3 years, and the results showed statistical difference for the active application, mainly in dentin. The systematic review by (13) states that many factors may influence the clinical performance of Class V cavity restorations, including beveling, use of rubber dam, and asperization of the cavity to improve adhesive impregnation and hybrid layer formation.

Although laboratory tests are the initial step in assessing a number of factors in relation to the binding efficiency of adhesive systems, in vitro studies do not reflect the clinical behavior of the material (14, 15). Only in a clinical situation the actual behavior of adhesive materials

can be verified. Thus, longitudinal clinical studies play a fundamental role in proving the efficacy of adhesive systems, once multimodes adhesives have been recently introduced without clinical data to back their use (1, 3).

To assess the clinical performance of adhesive systems, noncarious cervical lesions (NCCL) are considered as models according to American Dental Association (ADA) recommendations (16, 17), due to different factors, such as: the lesion does not present mechanical retention; the retention of the restorative material will be provided exclusively by the adhesive system; the retention is evaluated in a simple way, that is, presence or absence of the restoration; restoration margins are located in enamel and dentin; these lesions are commonly located on the vestibular surface of anterior and pre-molar teeth; these lesions usually occur in several teeth, which facilitates the selection of patients and the study model to be developed (1, 18, 19).

To obtain partial approval within the ADA criteria, no more than 5% of the restorations should show marginal discoloration when patients return for evaluation in the period after 6 months. To obtain final approval, rates of fall of restorations and margins of discoloration should not exceed 10% during the eighteen months of clinical evaluation (2, 18).

The aim of this randomized clinical trial was to evaluate the effect of dental cavity asperization on adhesion of composite resin restorations in patients with NCCLs using Peak® Universal Bond (Ultradent Products, South Jordan, UT, United States) in the ER mode.

2 MATERIAL AND METHODS

2.1 Study Design

This article was prepared using the protocol established by the Consolidated Standards of Reporting Trials (20). This was a randomized double-blind clinical trial, split-mouth carried out in State University of West Paraná (UNIOESTE) from August 2017 to December 2018. All participants were informed about the nature of objectives of the study, but they were not aware of what tooth received each treatment under evaluation.

2.2 Participant Selection

The clinical investigation was approved (protocol number 59413716.8.0000.0107) by

the Scientific Review Commitee and the Commitee for the Protection of Human Participants of the State University of West Paraná (UNIOESTE). It was registered in the Brazilian Clinical Trials Registry (REBEC) under identification number RBR- 3CWRDV. Written informed consente was obtained from all participants. 26 volunteers were selected for this study (Figure 1).

2.3 Inclusion and Exclusion Criteria

A total of 35 participants were examined by two precalibretad operators to check if they met the inclusion and exclusion criteria (Figure 1). The evaluations were performed using a mouth mirror, an explorer and periodontal probe. Patients had to be at least 18 years old, have an acceptable oral hygiene, absence of periodontal disease, active caries or parafunctional habits, present at least 20 teeth under occlusion and had no removable partial dentures.

Participants were required to have at least 2 NCCLsnas it was a split-mouth study with maximum of 50% enamel margin to be restored. These lesions had to be non retentive, deeper than 1mm and involve both enamel and dentin.

2.4 Intervention: Restorative Procedure

All of the NCCLs were evaluated prior to the placement of the restorations. Te degree of sclerotic dentin was measured according to the criteria described in Table 1. The cavity dimension in millimeters (height, width and depth) and the geometry of the cavity (evaluated by profile photograph and labeled ate <45°, 45° - 90°, 90° - 135°, >135°), were also recorded. Other features as presence of antagonist and attrition facets were also observed and recorderd. Preoperative sensitivity was evalueted by applying air for 10 seconds 2 cm far from the tooth surface.

Calibrated operators restored all teeth under the supervision of the study director. All subjects received a minimum of two restorarions one of each experimental group.

The randomization process was performed using a computer-generated table by a staff member not involved in the research protocol. The allocation assignment was revealed by opening the envelope on the day of the restorative procedure. The operator was not blinded to group assignment when administering interventions; however, participants were blinded to the group assignment.

Prior to the execution of the restorations, each lesion was submitted to prophylaxis

with a rubber cup (KG Sorensen, Barueri, SP, Brazil) and local anesthesia. Rubber dam isolation was used in all cases with the use of the modified number 212 retractor clamp in its vestibular wing in order to allow a correct gingival adaptation of each case exposing the cervical margin of the lesions (Hu Friedy, Chicago IL, USA) and rubber dam (Madeitex, São Paulo, SP, Brazil). No cavity preparation was performed in group 1 – Etch-and-rinse. (ER group).

In group 2, etch-and-rinse with asperization (Era group) before the application of the adhesive system, the cavity was drilled with a spherical diamond bur FG1014 (KG Sorosen, Cotia, SP, Brazil) at high speed under refrigeration, with light pressure for 5 seconds (ERa group). Each diamond bur was used in the preparation of 10 wells and replaced for the other cavities.

The NCCLs recived the universal adhesive system following this technique: apply 37% phosphoric acid for 20s, suck, wash for 5s, and dry, drip one drop of the Peak Universal Bond into the reservoir, immerse the microbrush in the reservoir and rub the microbrush for 10s into the well, air compression for 10s, photoactivation for 10s.

Then the Forma composite resin n (Ultradent Products, USA) was used for the 2 experimental groups. This was inserted in three increments in the gingival, incisal / occlusal walls and final cover with spatula aid (Hu Friedy, Chicago, IL, USA). Each increment was photoactivated for 40 s. The immediate finishing was performed with diamond tip (KG Sorensen, São Paulo, SP, Brazil), under refrigeration and followed by the application of rubber polishing tips Astropol (Ivoclar Vivadent, Barueri, SP, Brazil). The entire procedure of finishing and polishing was performed using cotton rollers and saliva suckers to facilitate access to the cervical margin.

2.5 Sample Size Calculation

The sample calculation was calculated from the mean retention rate at 18 and 24 months of 95% of the conventional simplified adhesive Adper Single Bond/Adper Single Bond Plus (3M ESPE, St. Paul, MN, EUA), which is the predecessor of the Scotchbond Universal (3M ESPE, St. Paul, MN, EUA)(21-24).

To detect a difference of 20% between the two groups with statistical power of 80% a sample of 98 lesions was calculated in patients with at least two restorations to be treated.

2.6 Clinical evaluation

The clinical evaluation was performed by two previously calibrated evaluators, different from the operator, in order to obtain a standardization in the evaluation procedures. The evaluation method used was the one recommended by the International Dental Federation (FDI method)(Table 3) (25, 26) and the USPHS criteria (Table 4). This method is based on the evaluation of the restorations in several parameters in an increasing ordinal scale of 1 to 5.

Restoration retention was evaluated as a primary result within the functional properties. The other clinical parameters evaluated were the aesthetic properties: marginal discoloration; corresponding to the functional properties: marginal adaptation; and on biological properties: caries lesions adjacent to restoration and postoperative sensibility.

The baseline was performed shortly after the polishing of the restorations and the subsequent evaluation period of 6, 12 months. The evaluation was performed with the aid of a buccal mirror, exploratory and triple syringe (25, 26). The performance of each restoration was independently assessed by two calibrated examiners (Cohen's Kappa 85%). In the absence of agreement between the examiners, in relation to the results obtained, a discussion was held to reach a consensus, and this new evaluation was considered definitive.

The data were submitted to descriptive statistical analysis to demonstrate the frequency distributions of the clinical criteria of the FDI method evaluated. The differences in the ratings of two groups after 12 months were tested with Friedman repeated-measures analysis of variance by ranl (α=0.05), and their performance at different times was evaluated by the Mc Nemar's test (α = 0, 05).

3 RESULTS

35 patients were not enrolled in the study because they didn´t fulfill the inclusion criteria, so 26 patients were selected. The details relative to the research subjects and characteristics of the restored lesions are displayed in Table 2. All research subjects were evaluated at baseline, six month and one year recall.

3.1 Fractures and Retention

Eleven restorations were lost at 6 months (ER- 6 and ERa- 5). According to FDI (Table 5) and USPHS (Table 6) criteria, the 6 months retention rates (95% confidence interval) were 87% (75–94%) for ER, 89% (76–95%) for ERa. At 12 months thirteen restorations were lost (ER -7 and ERa-6). According to FDI and USPHS criteria, the 12 months retention rates (95% confidence interval) were 85% (73–93%) for ER; 86% (73–94%) for ERa.

When the data from the 6 months and 12 months recall in each group were compared with their baseline findings, a significant difference was found for all groups ($p < 0.05$).

When SQUACE (25, 26) was used, there no was a statistical difference among groups at the 6 months and 12 months evaluation ($p > 0.05$ Table 8).

3.2 Marginal staining

According to the FDI criteria, 74 restorations at the 6 months recall were considered to have minor discrepancies (clinically good and satisfactory) (Table 7). After 12 months, 61 restorations were considered to have minor discrepancies (clinically good and satisfactory). No significant difference was detected between any pair of groups at 6 months ($p > 0.05$). However, a significantly worse marginal staining was observed within all groups over time, after 12 months ($p < 0.05$; Tables 5), in according with FDI criteria.

No significant difference was detected between any pair of groups at 6 months and 12 months and between recall times within group when USPHS were used ($p > 0.05$; Table 6).

3.3 Marginal adaptation

According to the FDI criteria, 21 restorations at the 6 months recall were considered to have some discrepancies in marginal adaptation. After 12 months, 23 restorations were considered to have some discrepancies in marginal adaptation. Significant difference was detected between the groups at 6 months. However, a significantly worse marginal adaptation was observed within all groups over time, after 6 and 12 months ($p < 0.05$; Tables 6 and 7), in according with FDI criteria. Despite the high number of the restorations with marginal discrepancy in the FDI criteria, only three of them were considered to have clinically relevant discrepancies (clinically unsatisfactory) in the marginal adaptation even after 6 and five of them

after 12 months (Table 5).

When the USPHS criteria were used, only 3 restorations were scored as *bravo* for marginal adaptation at 6 months compared to baseline. After 12 months, 5 restorations were scored as *bravo* for marginal adaptation. No significant difference was detected between the groups at 6 and 12 months and between recall times within group ($p > 0.05$; Table 6).

3.4 Prostoperative (hyper-) sensitivity

None of the restorations showed post-operative sensitivity immediately after restorative procedures according to the FDI and USPHS criteria. After 6 months three and one restorations showed post-operative sensitivity using both the FDI and USPHS criteria, respectively; and after 12 months four and one restorations showed post-operative sensitivity using both the FDI and USPHS criteria, respectively (Tables 6 and 7).

3.5 Recurrence of caries

No restoration showed recurrent caries lesion at 6 and 12 months using both the FDI and USPHS criteria (Table 5 and 6).

3.6 General overview

When the FDI criteria for ‘acceptable’ vs. ‘not acceptable’ restorations were applied from the 6 and 12 months recall in each group were compared with their baseline findings, a significant difference was found only for fracture of restoration for all groups ($p < 0.05$; Tables 7).

4 DISCUSSION

In the present study, the influence of asperization in the adhesion of composite resin restorations in patients with non-carious cervical lesions were evaluated.

Since 2007 a new criteria for evaluating dental restorations were created, the “FDI criteria” (25, 26) tries to organize the standards of the evaluation. Although this effort, only few publications have used the FDI criteria since then(27-30). Some clinical studies uses FDIcriteria to evaluate NCCL(28, 31-34), and others uses USPHS(28, 31, 32, 35, 36). Two studies

concluded that the FDI criteria is more sensitive for detect small differences in restoraions than the USPHS criteria(28, 31).

Despite the use of two clinical evaluation criteria, the most important parameter for the evaluation of NCCL restorations has been retention rate. If the restorations are lost, all of the other criteria cannot be evaluated. In general, the clinical behavior of the adhesive at 12 months in this study, regardless of the bonding strategy stayed under the retation rates of ADA. 80% of lost restorations were performed in patients over 40 years.

Arbildo, et al. 2018 (3) wrote a systematic review and meta-analysis evaluating the adhesive strategies of universal adhesives in NCCL, using only randomized clinical trials 8 studies fulfill the inclusion criteria. The revised literature demonstrates that the conventional technique of universal adhesives results in a greater retention and absence of fractures in this kind of lesions, which wasn't demonstrated in our study.

In 2018 a similar study was developed, evaluating the influence of dentin roughening in NCCLs using a universal adhesive Tetric N-Bond Universal in both modes. A total of 192 restorations were made divided in 4 groups (ER; ER + roughness; SE and SE + roughness), and evaluated them in a period of 18 months and concluded that the roughening before the application of the adhesive didn't affect the clinical behavior of the restorations. Contrary our study, the Tetric N-Bond Universal adhesive reached ADA retation rates (37). Another double blind randomized clinical trial (33) was performed evaluating the universal adhesive Xeno Select (Dentsply) in a six-month period using FDI and USPHS criteria. 124 restoration were placed in 4 groups (ER dry dentin; ER moist dentin; SE + enamel etching and SE total), but as our study, independent of the bonding strategy Xeno Select (Dentsply) didn't fullfill ADA criteria.

Another universal adhesive studied in 2017 was Futurabond U (Voco GbmH) (34), its clinical performance was evaluated in a double-blind, randomized clinical trial in a six-month period. 200 restorations were performed in NCCLs in four groups (SE; SE+ enamel etching; ER+ dry dentin; ER + moist dentin). Evaluation followed de FDI criteria and concluded that the perfomance of the adhesive is good, and do not depend on the bonding strategy employed.

Lawson *et al.*,(35)compared the clinical performance of Scotchbond™ Universal Adhesive used in self- and total-etch modes and two-bottle Scotchbond™ Multi-purpose Adhesive in total- etch mode for NCCLs in a double blind study. A follow up period of 24 months using USPHS criteria of evaluation. The retention rates up to 24 months Scotchbond™ Universal Adhesive was equal or greater then Scotchbond™ Multi-purpose Adhesive. Loguercio, *et al.* 2015 (32) also studied the behavior of Scotchbond™ Universal Adhesive in all stratagies (ER dry; ER wet; SE+ selective enamel etching and SE) in a 36-months period,

using FDI and USPHS evaluation criteria. There was no statistical difference among bonding strategies, but when used in SE mode there were signs of degradation on the margins.

5 CONCLUSION

The asperization of the cavity before application of Peak® Universal Bond adhesive system (Ultradent Products, USA) as etch-and-rinse didn’t affect the clinical behavior of composite restorations placed in NCCLs.

At 12 months the universal adhesive Peak® Universal Bond didn't fulfill the American Dental Association criteria for full approval when using all of the bonding strategies suggested by the manufacturer.

6 ANEX

Figure 1. Adhesive system and composite resin composition.

MATERIAL	COMPOSITION
Peak® Universal Bond (Ultradent Products, Estados Unidos)	2-hydroxy ethyl methacrylate (HEMA) Methacrylated acid monomers Ethanol Chlorhexidine di-acetate
Forma® Plus (Ultradent Products, Estados Unidos)	• Monomers of Bis-GMA (Bispheno A di-Glycidyl Methacrylate), TEGDMA (Triethylene glycol dimethacrylate)

Figure 2. Flow chart

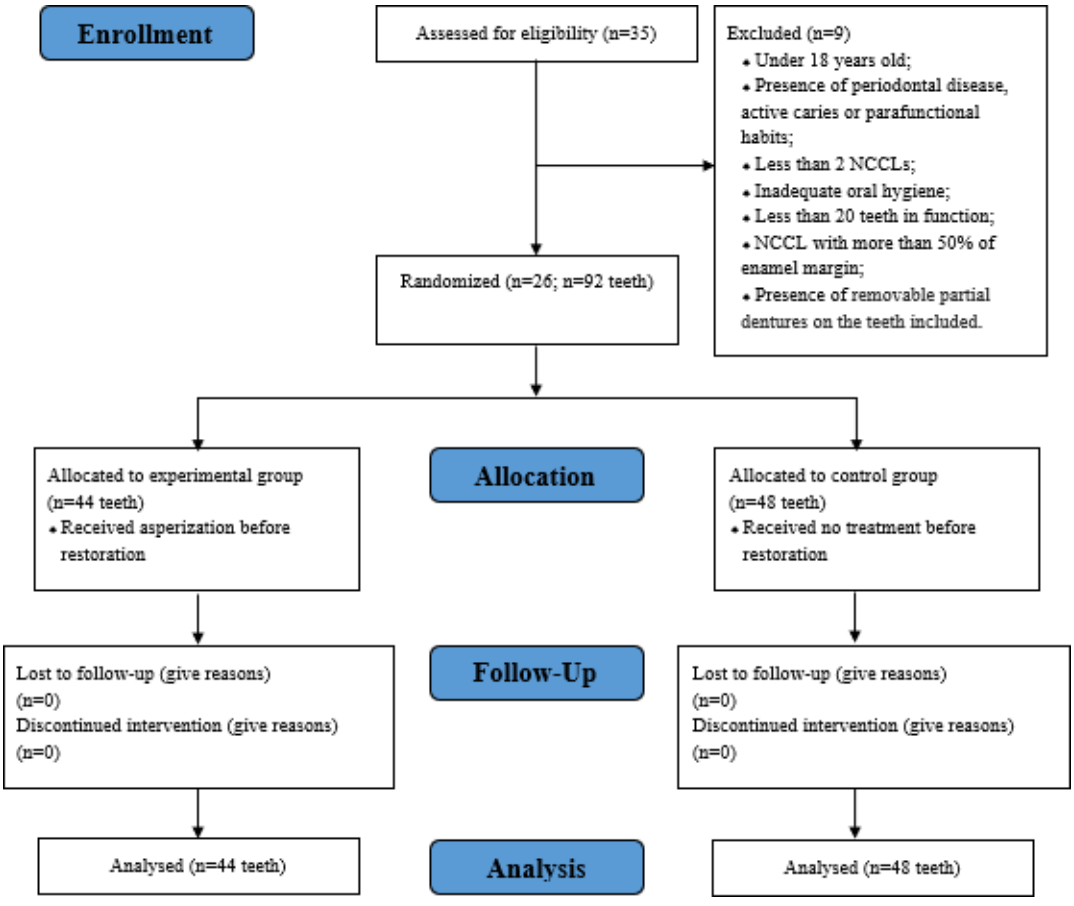

Table 1. Dentin sclerosis scale (36)

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

Table 2. Distribution of noncarious cervical lesions accordin to research subject (gender and age) and characteristic of class V lesions (shape, cervicoincisal size of the lesion, degree os sclerotic dentin, presence of antagonist, presence of attrition facets, presence of preoperative sensitivity, and tooth and arch distribution)

Characteristics of Research Subjects	**Subjects**	
Gender distribution		
Female	17	
Male	9	
Age distribution,		
18-29	2	
30-39	8	
40-49	4	
>50	11	
Race (%)		
White	92.3	
Black	7.7	
Mulatto	0.0	
Yellow	0.0	
Smoker	1	
Characteristics of Class V lesions	ER	ERa
>135	14	20
90-135	25	17
45-90	8	7
< 45	1	0
Cervico-incisal height, mm	ER	ERa
<1.5	11	7
1.5-2.5	20	20
2.5-4.0	9	6
>4.0	8	11
Degree of sclerotic dentin	ER	ERa
1	21	19
2	17	18
3	8	6
4	2	1
Presence of antagonista	ER	ERa
Yes	48	44
No	0	0
Attrition facet	ER	ERa
Yes	13	11

No	35	33
Preoperative sensitivity (spontaneous)	**ER**	**ERa**
Yes	3	3
No	45	41
Preoperative sensitivity (air dry)	**ER**	**ERa**
Yes	23	25
No	25	19
Tooth distribution	**ER**	**ERa**
Incisor	9	5
Canines	9	2
Pre molar	26	26
Molar	4	11
Arch distribution	**ER**	**ERa**
Maxillary	28	26
Mandibular	20	18

Table 3. International Dental Federation (FDI) criteria used for clinical evaluation (25, 26)

	Esthetic Property	Functional Properties	
	1. Staining Margin	2. Fractures and Retention	3. Marginal Adaptation
1. Clinically very good	1.1 No marginal staining	2.1 Restoration retained, no fractures/cracks	3.1 Harmonious outline, no gaps, no discoloration
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
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. 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 dentin/base exposed 3.4.2. Chip fracture damaging margins 3.4.3 Notable enamel or dentin wall fracture
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*

	Biological Properties	
	4. Postoperative (Hyper-) Sensitivity	5. Recurrence of Caries
1. Clinically very good	4.1 No hypersensitivity	5.1 No secondary or primary caries
2. Clinically good (after correction, very good)	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)	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 (dentin not exposed)
4. Clinically unsatisfactory (repair for prophylactic reasons)	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)	4.5 Very intense, acute pulpitis or nonvital; endodontic treatment is necessary and restoration has to be replaced	5.5 Deep secondary caries or exposed dentin that is not accessible for repair of restoration

Table 4. Modified United States Public Health Service (USPHS) (38, 39)

	Marginal Staining	Retention	Fracture
Alfa	No discoloration along the margin	Retained	None
Bravo	Slight and superficial staining (removable, usually localized)	Partially retained	Small chip, but clinically acceptable
Charlie	Deep staining cannot be polished away	Missing	Failure due to bulk restorative fracture

	Marginal Adaptation	Postoperative Sensitivity	Recurrence of Caries
Alfa	Restoration is continuous with existing anatomic form	No postoperative sensitivity directly after the restorative process and during the study period	No evidence of caries contiguous with the margin
Bravo	Detectable V-shaped defect in enamel only; catches explorer going both ways	—	—
Charlie	Detectable V-shaped defect to dentin-enamel junction	Sensitivity present at any time during the study period	Evidence of presence of caries

Table 5. Number of Evaluated Restorations for Each Experimental Group According to the Adhesive (ER [Etch-and-Rinse]; ERa [Etch-and-Rinse + asperization]) Classified According to the International Dental Federation (FDI) Criteria

FDI Criteria		Baseline		6 mo		1 yr	
		ER	ERa	ER	ERa	ER	ERa
Marginal staining	A	48	44	37	37	30	31
	B	0	0	5	2	11	7
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Fractures and retention	A	48	44	41	34	39	33
	B	0	0	1	1	1	1
	C	0	0	0	2	0	2
	D	0	0	0	2	1	2
	E	0	0	6	5	7	6
Marginal adaptation	A	48	44	30	30	28	29
	B	0	0	12	6	12	5
	C	0	0	0	2	1	3
	D	0	0	0	1	0	1
	E	0	0	0	0	0	0
Postoperative (hyper-) sensitivity	A	48	44	39	38	38	36
	B	0	0	3	0	3	1
	C	0	0	0	1	0	1
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Recurrence of caries	A	48	44	42	39	41	38
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0

Table 6. Number of Evaluated Restorations for Each Experimental Group According to the Adhesive (ER [Etch-and-Rinse]; ERa [Etch-and-Rinse + asperization]) Classified According to the Adapted United States Public Health Service (USPHS) Criteria

USPHS Criteria		Baseline		6 mo		1 yr	
		ER	ERa	ER	ERa	ER	ERa
Marginal staining	A	48	44	42	39	41	38
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
Fractures and retention	A	48	44	42	35	40	34
	B	0	0	0	4	1	4
	C	0	0	6	5	7	6
Marginal adaptation	A	48	44	42	36	40	34
	B	0	0	0	3	1	4
	C	0	0	0	0	0	0
Postoperative (hyper-) sensitivity	A	48	44	42	38	41	37
	B	0	0	0	1	0	1
	C	0	0	0	0	0	0
Recurrence of caries	A	48	44	42	39	41	38
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0

Table 7. Number of Evaluated Restorations for Each Experimental Group According to the Adhesive (ER [Etch-and-Rinse]; ERa [Etch-and-Rinse + asperization]) Classified According Acceptable and Not Acceptlable

		Group		6 mo		1 yr	
		ER	ERa	ER	ERa	ER	ERa
Marginal staining	Acceptable	48	44	42	39	41	38
	Not acceptable	0	0	0	0	0	0
	Reasons						
Fractures and retention	Acceptable	48	44	42	35	40	34
	Not acceptable	0	0	6	9	8	10
	Reasons						
Marginal adaptation	Acceptable	48	44	42	36	40	34
	Not acceptable	0	0	0	3	1	4
	Reasons						
Postoperative (hyper-) sensitivity	Acceptable	48	44	42	38	41	37
	Not acceptable	0	0	0	1	0	1
	Reasons						
Recurrence of caries	Acceptable	48	44	42	39	41	38
	Not acceptable	0	0	0	0	0	0
	Reasons						

Table 8. Number of Evaluated Restorations for Each Experimental Group According to the Adhesive Classified for Semiquantitative Score (SQUACE)

		Baseline		6 mo		1 yr	
		ER	ERa	ER	ERa	ER	ERa
Squace	Less than 10%	0	0	1	1	2	1
	Between 10% and 30%	0	0	0	2	0	2
	Between 31% and 50%	0	0	0	2	0	2

7 REFERENCES

1. De Munck Jd, Van Landuyt K, Peumans M, Poitevin A, Lambrechts P, Braem M, et al. A critical review of the durability of adhesion to tooth tissue: methods and results. Journal of dental research. 2005;84(2):118-32.

2. Perdigão J. Dentin bonding—Variables related to the clinical situation and the substrate treatment. Dental Materials. 2010;26(2):e24-e37.

3. Arbildo H, Lamas-Lara C, Cruzado-Oliva F, Rosas-Prado C, Gómez-Fuertes A, Vásquez-Rodrigo H. Comparison of the clinical effect of the adhesive strategies of universal adhesives in the treatment of non-carious cervical lesions. Systematic review and meta-analysis. Journal of Oral Research. 2018;7(5):210-22.

4. Van Meerbeek B, De Munck J, Mattar D, Van Landuyt K, Lambrechts P. Microtensile bond strengths of an etch&rinse and self-etch adhesive to enamel and dentin as a function of surface treatment. OPERATIVE DENTISTRY-UNIVERSITY OF WASHINGTON-. 2003;28(5):647-60.

5. Nagarkar S, Theis-Mahon N, Perdigão J. Universal dental adhesives: Current status, laboratory testing, and clinical performance. Journal of Biomedical Materials Research Part B: Applied Biomaterials. 2019.

6. Gwinnett A, Matsui A. A study of enamel adhesives: the physical relationship between enamel and adhesive. Archives of Oral Biology. 1967;12(12):1615-IN46.

7. Miyazaki M, Sato H, Onose H, Moore BK, Platt JA. Analysis of the enamel/adhesive resin interface with laser Raman microscopy. Operative dentistry. 2003;28(2):136-42.

8. Sadek FT, Moura SK, Ballester RY, Muench A, Cardoso PEC. The effect of long-term storage on the microleakage of composite resin restorations: qualitative and quantitative evaluation. Pesquisa Odontológica Brasileira. 2003;17(3):261-6.

9. de Souza-Zaroni WC, Delfino CS, Ciccone-Nogueira JC, Palma-Dibb RG, Corona SAM. Effect of cavity preparation method on microtensile bond strength of a self-etching primer vs phosphoric acid etchant to enamel. Journal of Materials Science: Materials in Medicine. 2007;18(10):2003-9.

10. Strydom C. Self-etching adhesives: review of adhesion to tooth structure part I. SADJ: journal of the South African Dental Association= tydskrif van die Suid-Afrikaanse Tandheelkundige Vereniging. 2004;59(10):413, 5-7, 9.

11. Jacobsen T, Söderholm K. Effect of primer solvent, primer agitation, and dentin dryness on shear bond strength to dentin. American Journal of Dentistry. 1998;11(5):225-8.

12. Loguercio AD, Raffo J, Bassani F, Balestrini H, Santo D, Do Amaral RC, et al. 24-month clinical evaluation in non-carious cervical lesions of a two-step etch-and-rinse adhesive applied using a rubbing motion. Clinical oral investigations. 2011;15(4):589-96.

13. Mahn E, Rousson V, Heintze S. Meta-analysis of the influence of bonding parameters on

the clinical outcome of tooth-colored cervical restorations. J Adhes Dent. 2015;17(5):391-403.

14. van Dijken JW, Sunnegårdh-Grönberg K, Lindberg A. Clinical long-term retention of etch-and-rinse and self-etch adhesive systems in non-carious cervical lesions: a 13 years evaluation. Dental materials. 2007;23(9):1101-7.

15. Kubo S, Kawasaki K, Yokota H, Hayashi Y. Five-year clinical evaluation of two adhesive systems in non-carious cervical lesions. Journal of Dentistry. 2006;34(2):97-105.

16. Heintze SD, Ruffieux C, Rousson V. Clinical performance of cervical restorations—a meta-analysis. dental materials. 2010;26(10):993-1000.

17. Brackett MG, Dib A, Franco G, Estrada B, Brackett WW. Two-year clinical performance of Clearfil SE and Clearfil S3 in restoration of unabraded non-carious class V lesions. Operative dentistry. 2010;35(3):273-8.

18. van Dijken JW, Pallesen U. Long-term dentin retention of etch-and-rinse and self-etch adhesives and a resin-modified glass ionomer cement in non-carious cervical lesions. Dental materials. 2008;24(7):915-22.

19. Peumans M, Kanumilli P, De Munck J, Van Landuyt K, Lambrechts P, Van Meerbeek B. Clinical effectiveness of contemporary adhesives: a systematic review of current clinical trials. Dental materials. 2005;21(9):864-81.

20. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010;8(1):18.

21. Aw TC, LEPE X, JOHNSON GH, MANCL LA. A three-year clinical evaluation of two-bottle versus one-bottle dentin adhesives. The Journal of the American Dental Association. 2005;136(3):311-22.

22. Gallo J, Burgess J, Ripps A, Walker R, Ireland E, Mercante D, et al. Three-year clinical evaluation of a compomer and a resin composite as Class V filling materials. OPERATIVE DENTISTRY-UNIVERSITY OF WASHINGTON-. 2005;30(3):275.

23. Loguercio AD, Bittencourt DD, Baratieri LN, Reis A. A 36-month evaluation of self-etch and etch-and-rinse adhesives in noncarious cervical lesions. The Journal of the American Dental Association. 2007;138(4):507-14.

24. Reis A, Loguercio A. A 36-month clinical evaluation of ethanol/water and acetone-based etch-and-rinse adhesives in non-carious cervical lesions. Operative dentistry. 2009;34(4):384-91.

25. Hickel R, Roulet J-F, Bayne S, Heintze SD, Mjoer IA, Peters M, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98--FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restorations including onlays and partial crowns. The journal of adhesive dentistry. 2007;9:121-47.

26. Hickel R, Peschke A, Tyas M, Mjör I, Bayne S, Peters M, et al. FDI World Dental

Federation: clinical criteria for the evaluation of direct and indirect restorations—update and clinical examples. Clinical oral investigations. 2010;14(4):349-66.

27. Piva F, Coelho-Souza F, editors. A deciduous teeth composite restoration clinical trial using two methods. J Dent Res Abstract; 2009.

28. Perdigão J, Kose C, Mena-Serrano A, De Paula E, Tay L, Reis A, et al. A new universal simplified adhesive: 18-month clinical evaluation. Operative dentistry. 2014;39(2):113-27.

29. Coelho-De-Souza FH, Camargo JC, Beskow T, Balestrin MD, Klein-Júnior CA, Demarco FF. A randomized double-blind clinical trial of posterior composite restorations with or without bevel: 1-year follow-up. Journal of Applied Oral Science. 2012;20(2):174-9.

30. Rodolpho PADR, Donassollo TA, Cenci MS, Loguércio AD, Moraes RR, Bronkhorst EM, et al. 22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics. Dental Materials. 2011;27(10):955-63.

31. Mena-Serrano A, Kose C, De Paula EA, Tay LY, Reis A, Loguercio AD, et al. A new universal simplified adhesive: 6-month clinical evaluation. Journal of Esthetic and Restorative Dentistry. 2013;25(1):55-69.

32. Loguercio AD, De Paula EA, Hass V, Luque-Martinez I, Reis A, Perdigão J. A new universal simplified adhesive: 36-Month randomized double-blind clinical trial. Journal of dentistry. 2015;43(9):1083-92.

33. Lopes LdS, Calazans F, Hidalgo R, Buitrago L, Gutierrez F, Reis A, et al. Six-month follow-up of cervical composite restorations placed with a new universal adhesive system: a randomized clinical trial. Operative dentistry. 2016;41(5):465-80.

34. de Albuquerque E, Warol F, Calazans F, Poubel L, Marins S, Matos T, et al. A New Universal Simplified Adhesive: 6-Month Randomized multi-center clinical trial. Rev Bras Odontol. 2017;74(4):251-60.

35. Lawson NC, Robles A, Fu C-C, Lin CP, Sawlani K, Burgess JO. Two-year clinical trial of a universal adhesive in total-etch and self-etch mode in non-carious cervical lesions. Journal of dentistry. 2015;43(10):1229-34.

36. Swift Jr E, Perdigão J, Heymann H, Wilder Jr A, Bayne S, May Jr K, et al. Eighteen- month clinical evaluation of a filled and unfilled dentin adhesive. Journal of Dentistry. 2001;29(1):1-6.

37. Loguercio AD, Luque-Martinez IV, Fuentes S, Reis A, Muñoz MA. Effect of dentin roughness on the adhesive performance in non-carious cervical lesions: A double-blind randomized clinical trial. Journal of dentistry. 2018;69:60-9.

38. Dalton Bittencourt D, Ezecelevski IG, Reis A, Van Dijken JW, Loguercio AD. An 18-months' evaluation of self-etch and etch & rinse adhesive in non-carious cervical lesions. Acta Odontologica Scandinavica. 2005;63(3):173-8.

39. Perdigão J, Dutra-Corrêa M, Saraceni C, Ciaramicoli M, Kiyan V, Queiroz C. Randomized

clinical trial of four adhesion strategies: 18-month results. Operative dentistry. 2012;37(1):3-11.