AVALIAÇÃO DE SEIS MESES DO COMPORTAMENTO CLÍNICO DE UM ADESIVO UNIVERSAL DE APLICAÇÃO “SEM ESPERA”: ESTUDO CLÍNICO RANDOMIZADO

Rossana Aboud Matos de Almeida

São Luís
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Dissertação apresentada ao Programa de Pós-Graduação em Odontologia da Universidade CEUMA para obtenção do título de Mestre em Odontologia.

Área de Concentração: Odontologia Integrada

Orientador: Profº Dr. Matheus Coelho Bandeca

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“Feliz aquele que transfere o que
sabe e aprende o que ensina.”
(Cora Coralina)

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RESUMO

Título: Avaliação de seis meses do comportamento clínico de um adesivo universal de aplicação “sem espera”: estudo clínico randomizado.

Objetivos: Avaliar o comportamento clínico de um adesivo universal de aplicação sem espera em lesões cervicais não cariosas (LCNCs).

Métodos/Materiais: Vinte e cinco pacientes participaram deste estudo. Cento e setenta e seis restaurações foram distribuídas em quatro grupos de acordo com o sistema adesivo nas estratégias de condicionamento e no tempo de espera: Prime&Bond Active (PB), aplicado na estratégia etch-and-rinse (ER) e self-etch (SE) com 20 segundos de espera e Clearfil Universal Bond Quick (CQ), aplicado na estratégia ER e SE, sem tempo de espera. Um operador experiente e calibrado confeccionou as restaurações com a resina composta (Filtek Z-350 XT), utilizando a técnica incremental. As restaurações foram avaliadas no *baseline* e após 6 meses, utilizando os critérios da Federação Dentária Intercacional (FDI) e do Serviço de Saúde Pública dos Estados Unidos (USPHS). Os dados foram analisados através dos testes de Friedman e teste de McNemar, com nível de significância de 5%.

Resultados: Cinco restaurações (3 para PB-SE e 2 para CB-SE) foram perdidas após 6 meses. Foi possível observar uma taxa de retenção de 93,2% para PB-SE, 95,5% para CQ-SE e 100% para

ambos os adesivos quando utilizada a estratégia adesiva ER ($p > 0,05$ para ambos os critérios). Dezoito restaurações mostraram algumas discrepâncias na adaptação marginal após 6 meses usando os critérios FDI (3 para PB-ER, 7 para PB-SE, 2 para CQ-ER e 6 para CU-SE), mas apenas quatro restaurações foram pontuadas como 'bravo" para adaptação marginal nos critérios USPHS (2 para PB-SE e 2 para CQ-SE; $p > 0,05$).

Conclusões: O desempenho clínico do adesivo CQ na aplicação "sem espera" foi semelhante ao adesivo PB na aplicação convencional (20 segundos), promovendo resultados bastante satisfatórios quando aplicado nas estratégias adesivas ER ou SE, após 6 meses de avaliação clínica em lesões cervicais não cariosas.

SIGNIFICADO CLÍNICO

O tempo de aplicação não influenciou no comportamento clínico do adesivo universal CQ em ambas as estratégia adesivas ER e SE, após 6 meses de avaliação clínica quando aplicado nas LCNCs.

Palavras- chave: Adesivo universal. Lesões Cervicais não Cariosas. Avaliação clínica.

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ABSTRACT

Title: Six-month clinical evaluation of a new universal adhesive applied in the “no-waiting” technique: Randomized trial

Objectives: Evaluate the clinical behavior of the universal adhesive applied in the no-waiting technique in non-carious cervical lesions (NCCLs).

Methods/Materials: Twenty-five patients participated in this study. One hundred and seventy six restorations were assigned to four groups according to the adhesive system in the conditioning strategies and in the waiting time: Prime&Bond Active (PB), applied in the etch-and-rinse strategy (ER) and self-etch (SE) with 20 seconds application and Clearfil Universal Bond Quick (CQ), applied in the ER and SE strategy, in no-waiting application. One experienced and calibrated operator made the restorations with (Filtek Z-350 XT) composite resin using the incremental technique. The restorations were evaluated at baseline and after 6 months using both the World Dental Federation (FDI) and the United States Public Health Service (USPHS) criteria. Statistical analyses were performed with Friedman repeated measures analysis of variance by rank and McNemar test for significance in each pair.

Results: Five restorations (3 for PB-SE and 2 for CB-SE) were lost after 6 months. Had a retention rate of 93.2% for PB-SE and 95.5% for CQ-SE and 100% for both adhesives when using the ER adhesive strategy ($p > 0.05$ for either criteria). Eighteen restorations showed some discrepancies in marginal adaptation at the 6-month recall using the FDI criteria (3 for PB-ER, 7 for PB-SE, 2 for CQ-ER, and 6 for CU-SE), but only four restorations were scored as ‘‘bravo’’

for marginal adaptation in the USPHS criteria (two for PB-SE and two for CQ-SE; $p > 0.05$).

Conclusions: The clinical performance of the CQ adhesive in the "no waiting" technique was similar to the PB adhesive in conventional application (20 seconds), promoting very satisfactory results when applied in the ER or SE strategy, after 6 months of clinical evaluation in non-carious cervical lesions.

CLINICAL SIGNIFICANCE

The application time did not influence the clinical behavior of the CQ universal adhesive in both adhesive strategies (ER and SE), after 6 months of clinical evaluation when applied in NCLCs.

Keywords: Universal Adhesive. Non-Carious Cervical Lesion. Clinical Trial.

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LISTAS DE ABREVIATURAS E SIGLAS

ADA	Associção Dental Americana
CONSORT	Consolidated Standards of Reporting Trials Statement
ER	Etch-and-Rinse
FDI	Federação Dentária Internacional
FDI	Federação Dentária Internacional
HEMA	Metacrilato de 2-hidroxietil
LCNCs	Lesões Cervicais Não Cariosas
MDP	10-metacriloiloxidecil di-hidrogenofosfato
ReBEC	Registro Brasileiro de Ensaios Clínicos
SE	Self-Etch
TCLE	Termo de consentimento livre esclarecido
USPHS	United States Public Health Service

SUMÁRIO

CAPÍTULO 1

Title: Six-month clinical evaluation of a new universal adhesive applied in the “no-waiting” technique: randomized trial

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ABSTRACT

Background: Evaluate the clinical behavior of the one universal adhesive applied in the “no-waiting” technique in non-carious cervical lesions (NCCLs).

Methods/Materials: Twenty-five patients participated in this study. One hundred and seventy six restorations were assigned to four groups according to the adhesive system in the conditioning strategies and in the waiting time: Prime&Bond Active (PB), applied in the etch-and-rinse strategy (ER) and self-etch (SE) with 20 seconds application and Clearfil Universal Bond Quick (CQ), applied in the ER and SE strategy), in no-waiting application. One experienced and calibrated operator made the restorations with (Filtek Z-350 XT) composite resin using the incremental technique. The restorations were evaluated at baseline and after 6 months using both the World Dental Federation (FDI) and the United States Public Health Service (USPHS) criteria. Statistical analyses were performed with Friedman repeated measures analysis of variance by rank and McNemar test for significance in each pair.

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Conclusions: The clinical performance of the CQ adhesive in the "no waiting" technique was similar to the PB adhesive in conventional application (20 seconds), promoting very satisfactory results when

applied in the ER or SE strategy, after 6 months of clinical evaluation in non-carious cervical lesions.

CLINICAL SIGNIFICANCE:
The application time did not influence the clinical behavior of the CQ universal adhesive in both adhesive strategies (ER and SE), after 6 months of clinical evaluation when applied in NCLCs.

Trial registration: This study was registered ‘retrospectively registered’ in the REBEC clinical registry under protocol RBR-5f9gps in 2019-06-06.

Keywords: Universal adhesives; non-carious cervical Lesion; clinical trial.

1.BACKGROUND

The last manufactured adhesives are called universal or multimode adhesives [1]. Manufactures have made effort to keep on the trend of simplifying techniques by providing etch-and-rinse or self-etch adhesives on enamel/dentin adhesive systems [2,3], and also to indirect materials, mainly zirconium and metals [4,5]. This versatility in terms of application is due to the addition of specific functional monomers (such as 10-methacryloyloxydecyl dihydrogen phosphate, MDP) [5]. When compared to other functional monomers, chemical bonding between MDP and dental substrate may play an important role in a stable and durable interfaces [6-8].

Several in vitro studies, in which bond durability was tested, displayed remarkable effectiveness when the universal adhesive contained 10-MDP [9-11]. Also, a closer view regarding clinical studies showed that universal adhesives attained excellent retention rate of composite restorations placed in non-carious cervical lesions using universal adhesive [12-22]. Nevertheless, when outcomes like marginal adaptation or marginal discoloration are evaluated, which is the best technique to applied universal adhesive (self-etch or etch-and-rinse) [3,20-22].

Furthermore, following the same line of simplification, recently, universal adhesives were launched in the market with a "no-waiting time" concept, in which it is possible to apply and light-cure the adhesives without waiting [23]. Manufacturers claim that the addition of a new multifunctional hydrophilic acrylamide amide monomer (also

known as rapid bond technology) [24] enhance wetting of the dentine, and therefore, reduces application time [23-25]. Recently, several studies *in vitro* testing the no-waiting in comparison with a 10 second-application mode came out with controversial results [25-28].

No waiting technique may be considered more of a marketing advantage than a real benefit, as this little time saved may be less relevant in the clinical point of view. On the other hand, it should be taken into account that a shorter application time may theoretically make its application less technique sensitive and reduce the risk of contamination in preparation [24-26]. Considering that these materials appeared as a new tendency in dental adhesion, especially because of the time and technique sensitivity optimization trend, so studies of their clinical outcomes should be deemed important.

Therefore, the objective of this double-blind, randomized clinical trial was to evaluate the clinical behavior of two universal adhesive when applied using different application techniques during 6 months of clinical evaluation. The null hypothesis tested was that universal adhesive applied according to the “no-waiting” technique bonding to non-carious cervical lesions (NCCLs) using the ER and SE strategy would result in similar retention levels over 6 months of clinical service when compared to universal adhesive applied according to the conventional application (20 seconds).

2. METHODS AND MATERIALS

2.1 Study Design

The experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement [29]. This was a randomized, double-blind clinical trial, was 'retrospectively registered' in the REBEC clinical registry under protocol RBR-5f9gps in 2019-06-06. The study was carried out in the clinic of the School of Dentistry at the Ceuma University from December 2018 to September 2019. 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.

2.2 Participant Recruitment

The Ceuma University Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for this study (protocol 3.078.493). The recruitment of participants was from December 2018 to March 2019. No type of advertisement was done in any type of media, they participants are qualified for the study were recruited in the order in which they reported for the screening session. Written informed consent was obtained from all participants prior to starting the treatment.

2.3 Sample Size Calculation

The sample size calculation was made using an online software that is available at http://www.sealedenvelope.com, based on the retention rate of universal adhesive that was reported to be

94% at 18-month follow-up (retention) [30]. Using an α of 0.05, a power of 80% and a two-sided test, the minimal sample size was 44 restorations in each group in order to detect a difference of 20% among the tested groups [31].

2.4 Eligibility Criteria

A total of 40 participants were examined by two calibrated dental students to determine if they met the inclusion and exclusion criteria (Figure 1), thus forming a convenience sample.

The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe. Participants had to be in good oral and general health, at least 18 years of age, and present with at least 20 teeth under occlusion. Participants were required to have at least four NCCLs to be restored in four 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 [32].

All patients were given oral hygiene instructions before the operative treatment was performed. Patients with extremely poor oral hygiene, severe or chronic periodontitis, xerostomia, orthodontic appliance, or heavy bruxism habits were excluded from the study.

2.5 Randomization and Allocation Concealment

A member of the study not involved in the research protocol performed the randomization process by generating the random allocation sequence, determined through the website random.org/list. Details of the allocated groups were recorded on cards contained in

sequentially numbered, opaque, sealed envelopes. The envelope was opened only on the day of the restorative procedure to reveal the allocation assignment. The operator was not blinded to the assignment of the restoration, however, the participants and evaluators were blinded to the group assignment.

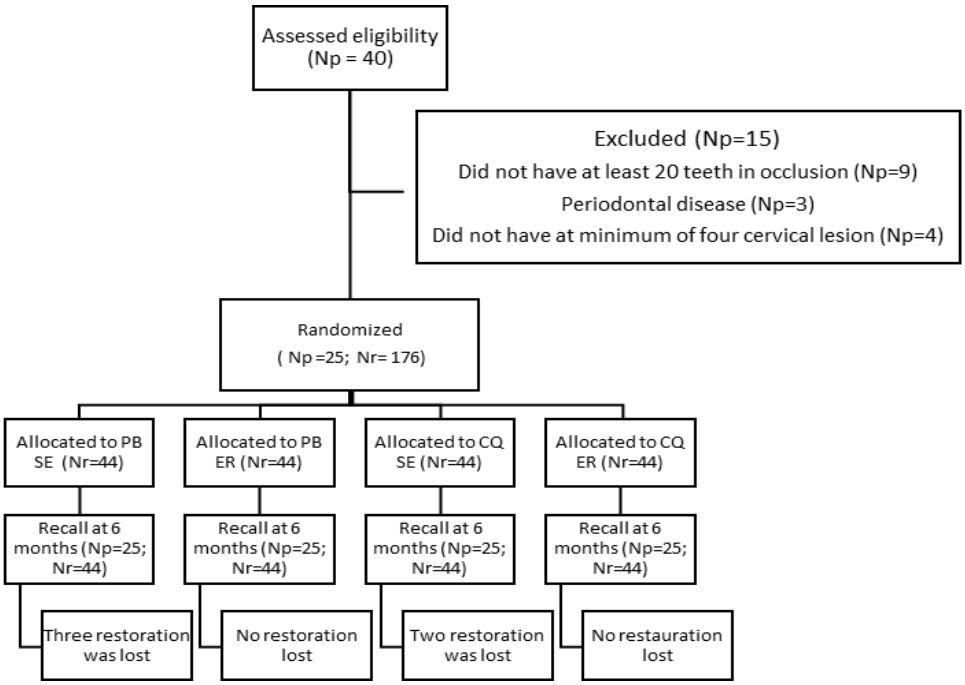

Figure 1. Participant flow diagram in the different phases of the study design. Abbreviations: Np – number of participants; Nr – number of restorations

2.6 Interventions: Restorative Procedure

All of the patients selected for this study received dental prophylaxis with a suspension of pumice and water in a rubber cup before the restorative procedures were initiated.

To evaluate the degree of sclerotic dentin from the NCCLs was used as the criteria described by Swift et al. [33] (Table 1). The cavity dimensions were measured 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

attrition facets and the antagonist were observed and recorded. Preoperative sensitivity assessment was also evaluated by exploratory probe and an air jet were used for 10 seconds and 2 cm away from the tooth surface. All NCCLs characteristics were scored to check the standardization between the experimental groups.

Table 1. Dentin sclerosis scale

Category	Criteria
1	No sclerosis present; dentin is light yellowish, with little discoloration; dentin is opaque, with little transparency
2	More sclerosis than 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 ortransparency evident

One calibrated operator, who was resident dentist with more than five years of clinical experience in operative dentistry, placed four restorations, one in each group, under the supervision of the study director in a clinical setting. All participants received a minimum of four restorations, one of each experimental group, in different lesions previously selected according to the inclusion criteria.

Before restorative procedures, shade selection was made using a shade guide. Following the guidelines of the American Dental Association (ADA) [34], no additional retention or bevel was prepared.

The tooth to be restored was isolated with cotton rolls and retraction cord (Ultrapak 000, Ultradent Prod. South Jordan, UT, USA), and then the NCCLs received the Prime&Bond Active (Dentsply Sirona, Milford, DE, USA) applied in ER and SE strategy in conventional application (20 seconds) and Clearfil Universal Bond

Quick (Kuraray, Tokyo, Japan) applied in ER or SE strategy, in no-waiting application, which defined the four different groups. The compositions, application modes, and batch numbers are described in Table 2.

After adhesive application, Filtek Z-350 XT (3M Oral Care, St. Paul, MN, USA) resin composite was used in up to three increments, each one being light cured (Valo, Ultradent Prod. South Jordan, UT, USA) for 30 seconds. The restorations were finished immediately with fine and extra-fine #2200 diamond burs (KG Sorensen, Barueri, SP, Brazil). Polishing was performed with Jiffy points (Ultradent Prod. South Jordan, UT, USA) immediately after placement of the restorations.

Table 2. Adhesive system: composition and application mode

Material/ Manufacturer/ Lot Number	Ph	Composition (*)	Manufacturer´s instruction (**)	
			Etch-and Rinse (ER)	Self-Etch (SE)
Prime&Bond Active (PB) / Dentsply Sirona; Konstanz, Germany / 1709000735	2.6	Phosphoric acid modified acrylate resins, PENTA, 10-MDP, Multifunctional acrylate, Bifunctional acrylate, Acid acrylate, Isoproponol, Water, Initiator, Stabilizer.	1.Apply Etchant for 15s 2.Rinse for 10 s. 3.Air dry to remove excess of water 4.Apply the adhesive for 20 s with vigorous agitation. 5. Gently air thin for 5 s. 6. Light-cure for 10 s. (1000Mw/cm2)	1.Apply the adhesive for 20 s with vigorous agitation. 2. Gently air thin for 5 s. 3. Light-cure for 10 s (1000Mw/cm2)
Clearfil Universal Bond Quick (CQ) / Kuraray Noritake; Tokyo, Japan / 2L0104	2.3	Bis-GMA, HEMA, 10-MDP, hydrophilic amide monomer, colloidal silica, silane coupling agent, sodium fluoride, camphorquinone, ethanol, water	1.Apply Etchant for 15 s 2.Rinse for 10 s. 3.Air dry to remove excess of water 4.Apply the adhesive with vigorous agitation. (no-waiting time) 5. Gently air thin for 5 s. 6. Light-cure for 10 s (1000Mw/cm2)	1.Apply the adhesive with vigorous agitation. (no-waiting time) 2. Gently air thin for 5 s. 3. Light-cure for 10 s (1000Mw/cm2)

(*)PENTA: dipentaerythritol pentacrylate phosphate; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate
HEMA, 2-hydroxyethyl methacrylate; Bis-GMA, 2,2 bis[4-(2-hydroxy-3-methacrylyloxy-propoxy)-phenyl] propane; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate.
(**) According to the manufacturer's instructions

2.7 Clinical Evaluation

The participants follow-up were June 2019 to September 2019. Two experienced and calibrated dentists, not involved with the restoration procedures and therefore blinded to the group assignment, evaluated restorations by FDI [35] and the classical USPHS criteria [36,37] at baseline and after 6 months of clinical service. Only the clinically relevant measures for evaluation of the performance of adhesives were used and scored (Tables 3 and 4). The primary clinical outcome was the retention/fracture, and the following secondary outcomes were marginal discoloration, marginal adaptation, dentin sensitivity and recurrent caries.

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.

These variables were ranked according to the criteria in the following scores: 1) FDI criteria (clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory, and clinically poor) and 2) USPHS criteria (alfa, bravo and charlie). Both examiners evaluated all of the restorations once and independently.

Table 3. 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	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 problems with no adverse effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically.	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 unsatisfactoy (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.	5.5 Deep secondary caries or exposed dentine that is not accessible for repair of restoration	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. Modified United States Public Health Service (USPHS)

	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

2.8 Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT (Consolidated Standards of Reporting Trials) suggestion [29]. Descriptive statistics were used to describe the distributions of the evaluated criteria. A statistical analysis was performed for each item (the retention/fracture, marginal staining, marginal adaptation, post-operative sensitivity and recurrence of caries) and for each overall parameter (FDI and USPHS). The differences between the four groups ratings after 6 months were tested by Friedman's repeated measures analysis of variance rank ($\alpha = 0.05$), and differences in the ratings of each group at baseline and after 6 months were evaluated using the McNemar test ($\alpha = 0.05$).

For the primary outcome retention, it was also calculated the

risk ratio and the relative risk of all approaches relative to the most convensional approach (ER – Prime&Bond Active). The 95% confidence interval was also reported. Cohen's kappa statistics were used to test the inter-examiner agreement. In all statistical tests, we preset the significance level at 5% (Statistical for Windows 7.0, Stat Soft Inc., Tulsa, OK, USA).

3. RESULTS

Fifteen out of 40 patients examined for eligibility were not enrolled in the study because they did not fulfil the inclusion criteria. Thus, a total of 25 subjects (13 men and 12 women) were selected. One hundred and seventy-six restorations were placed, 44 for each group (Figure 1). There was not loss patient in the 6 month evaluation.

All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 5. The overall Cohen kappa statistics showed excellent agreement between the examiners in the 6-month (0.94) follow-ups. All research subjects were evaluated at baseline and at the 6-month recall.

Retention/Fracture

Five restorations were lost or fractured after 6 months of clinical evaluation (3 for PB-SE and 2 for CQ-SE). According to both evaluation criteria, the 6-month retention rates (95% confidence interval [CI]) were 100% (92–100%) for PB-ER, 93.2% (82–98%) for

PB-SE, 100% (92–100%) for CQ-ER, and 95.5% (85–99%) for CQ-SE with no statistical difference identified between any pair of groups ($p > 0.05$; Tables 6 and 7). When the data from the 6-month results from each group were compared with the baseline findings, no significant difference was found ($p > 0.05$; Tables 6 and 7).

Marginal Adaptation

Eighteen restorations were considered to have minor discrepancies in marginal adaptation at the 6-month recall using the FDI criteria (3 for PB-ER, 7 for PB-SE, 2 for CQ-ER, and 6 for CU-SE; Table 6). When the USPHS criteria were used, four restorations were scored as ‘‘bravo’’ for marginal adaptation (two for PB-SE and two for CQ-SE; $p > 0.05$; Table 7). No significant difference was detected between any pair of groups at the 6-month recall for either evaluation criteria ($p > 0.05$; Tables 6 and 7).

Others clinical parameters

Marginal staining was not observed in any restorations at the 6-month recall using the FDI and USPHS criteria. No restorations had postoperative sensitivity at the 6-month recalls using both criteria. No restoration showed a recurrence of caries after 6 months for either criteria.

Table 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	13			
Female	12			
Age distribution (years)				
20-29	00			
30-39	09			
39-49	08			
> 49	08			
Characteristics of Class-V lesions	**Number of lesions**			
	PB-ER	**PB-SE**	**CQ-ER**	**CQ-SE**
Shape (degree of angle)				
< 45	-	-	-	-
45-90	12	11	13	12
90-135	24	22	21	21
> 135	8	11	10	11
Cervico-incisal height (mm)				
< 1.5	10	9	11	7
1.5-2.5	22	24	22	28
2.5-4.0	9	10	9	8
> 4.0	3	-	1	1
Degree of sclerotic dentin				
1	23	23	21	19
2	18	18	19	22
3	3	3	4	3
4	-	-	-	-
Presence of antagonist				
Yes	44	44	44	44
No	-	-	-	-
Attrition facet				
Yes	18	16	18	15
No	26	28	26	29
Pre-operative sensitivity (spontaneous)				
Yes	1	1	-	3
No	43	43	44	41
Pre-operative sensitivity (air dry)				
Yes	26	28	29	31
No	18	16	15	13
Pre-operative sensitivity (touch)				
Yes	25	28	28	30
No	19	16	16	14
Tooth distribution				
Anterior				
Incisor	05	05	02	04
Canines	06	04	08	07
Posterior				
Premolar	24	24	20	24
Molar	9	11	14	9

Arc distribution				
Maxillary	24	31	29	29
Mandibular	20	13	15	15

Table 6. Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria

FDI Criteria	(**)	BASELINE				6 MONTHS			
		PB-ER	PB-SE	CQ-ER	CQ-SE	PB-ER	PB-SE	CQ-ER	CQ-SE
Marginal staining	A	44	44	44	44	44	41	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--
Fractures and retention	A	44	44	44	44	44	41	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	1	--	--
	E	--	--	--	--	--	2		2
Marginal adaptation	A	44	44	44	44	41	34	42	38
	B	--	--	--	--	3	6	2	6
	C	--	--	--	--	--	1	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	A	44	44	44	44	44	42	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--
Recurrence of caries	A	44	44	44	44	44	42	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--

(*)PB-ER, Prime&Bond Active Etch-and-Rinse; PB-SE, Prime&Bond Active Self-Etch; CQ-ER, Clearfil Bond Quick Etch-and-Rinse; CQ-SE, Clearfil Bond Quick Self-Etch
(**) A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E = Clinically poor.

Table 7. Number of evaluated restorations for each experimental group (*) classified according to the Modified US Public Health Service (USPHS) criteria

USPHS Criteria	(**)	BASELINE				6 MONTHS			
		PB-ER	PB-SE	CQ-ER	CQ-SE	PB-ER	PB-SE	CQ-ER	CQ-SE
Marginal staining	A	44	44	44	44	44	41	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
Fractures and retention	A	44	44	44	44	44	41	44	42
	B	--	--	--	--	--	1	--	--
	C	--	--	--	--	--	2		2
Marginal adaptation	A	44	44	44	44	44	40	44	40
	B	--	--	--	--	--	2	--	2
	C	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	A	44	44	44	44	44	42	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
Recurrence of caries	A	44	44	44	44	44	42	44	42
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--

(*)PB-ER, Prime&Bond Active Etch-and-Rinse; PB-SE, Prime&Bond Active Self-Etch; CQ-ER, Clearfil Bond Quick Etch-and-Rinse; CQ-SE, Clearfil Bond Quick Self-Etch
(**) A = Alfa; B = Bravo; C = Charlie

4. DISCUSSION

Clinicians desire not only a reduction in the number of application steps but also quicker application time for dental adhesives and this is the major appealing for the “no-waiting” concept [24,28]. Some industries launched universal adhesives to be applied in this tecnique, one of them is the Clearfil Universal Bond Quick. The null hipotese in the present study was accepted once that, the results showed that universal adhesive applied according to the “no-waiting” technique bonding to NCCLs using the ER and SE strategy would resulted in similar retention levels over 6 months of clinical service compared to the universal adhesive applied to the

conventional application (20 seconds), whose clinical behaviour is being tested for the first time.

It is widely agreed that clinical studies in NCCLs provide great reliability for the evaluation of the performance of adhesive systems, especially because retention is the most important aspect for restoration testing in NCCLs [38]. This is considered a true endpoint, because if restorations are lost, none of the other parameters can be evaluated. The results of the present clinical trial showed a very well clinical performance of Clearfil Universal Bond Quick when applied in “no-waiting” technique in both adhesives strategies, as it obtained a retention rate of 97.8% after 6 months of clinical evaluation.

As indicated by the CQ manufacturer, besides 10-MDP, that provides a chemical interaction of bond promotion [7,39], adding the new multifunctional hydrophilic acrylamide amide monomer [24] reduced the HEMA content (2.5-10%) [40] when compared to prior adhesive generations. HEMA is a highly hydrophilic monomer that can be found in most adhesives in the market [41]. However, higher concentrations of HEMA may turn the adhesive interface susceptible to water sorption and long-term reduction of the adhesive properties [42].

In recent sudies, Kuno et al. claimed that mechanical properties are increased and water sorption is decreased in the presence of the multifunctional amide monomer, when compared to an experimental version with the same composition of CQ, but with HEMA in place of this new monomer. According to these authors

[25], the multifunctional amide monomer has a lower octanol/water partition coefficient; logPow (−0.7) than HEMA (logPow=0.3), indicating more hydrophilicity before polymerization [40], leading to a better and deeper infiltration of resin monomers into demineralized dentin and polymerize, forming a stable polymer network, producing strong micromechanical interlocking [25-27]. All these features made possible to minimize adhesive bonding time-dependency. In fact, in vitro studies showed that there were no benefits when time was increased, in terms of resin-dentin bond strength with the CQ [25,27], even after water storage [43].

Of course, it is worth to mention that Prime&Bond Active also showed a very good clinical performance in both adhesives strategies in the present study, with 96.6% of retention rate after 6 months of clinical service. These could be attributed to the fact that PB contains 10-MDP and is a HEMA-free adhesive [7,39,42]. According to the manufacturer, due to a hydrophilic core and five double-bonds per molecule, PENTA is an effective crosslinker agent and is responsible for increasing the wettability of PB. PENTA had been used in the different ‘Prime&Bond’ adhesive generations (Dentsply Sirona) and controversial results were observed when PENTA-containing adhesives are evaluated [22,44]. However, PB has showed higher resin-dentin bond strength results when compared to other universal adhesives [24,45,46].

Regarding marginal adaptation, after 6 months of clinical evaluation, more statiscal marginal discrepancies in enamel were

observed, when both universal adhesives are used in the self-etch when compared to etch-and-rinse strategy. It is well-documented that enamel etching depth is minimal when self-etch adhesive are applied, especially for mild/ultra-mild adhesives (pH = 2.3; Clearfil Universal Bond Quick and pH = 2.6; Prime&Bond Active) [47-49].

Although different clinical trials have shown that marginal discrepancies of restorations performed with universal adhesives in the self-etch mode usually develop rather rapidly [12-21], particularly when FDI criteria has been used, instead USPHS [12,13,15,19,20,44], the majority of the marginal defects are easily solved with a repolishing [50].

Finally, a 6 month-follow-up should be considered a short term evaluation and clinical trials have greater value when published after long-term follow-ups. However, recently, at least two clinical studies showed very high failure frequency after a 6- to 12-month of clinical service [44,51], that justifies the publication of these data, as this can provide clinicians with further evidence before selecting which adhesive technique could be used in their clinical offices. Future long-term follow-up studies need to be done to evaluate this hypothesis.

5. CONCLUSION

The clinical performance of the CQ adhesive in “no waiting” technique was similar to PB adhesive in conventional application, promoting rather satisfactory results when applied in the etch-and-

rinse or self-etch adhesive strategy, after 6 months of clinical evaluation in non-carious cervical lesions.

Competing interests

The authors declare that they have no conflicts of interests and the authors do not have any financial interest in the companies or products used in this study.

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APÊNDICE

Apêndice 1

METODOLOGIA DETALHADA

Desenho do estudo

O desenho do estudo foi conduzido de acordo com o Consolidated Standards of Reporting Trials (CONSORT).[29] Este estudo foi um ensaio clínico randomizado, duplo-cego, registrado no Registro Brasileiro de Ensaios Clínico (ReBEC) sob o protocolo RBR-5f9gps. O estudo foi realizado na clínica de Odontologia da universidade Ceuma de dezembro de 2018 a setembro de 2019. Todos os participantes foram informados sobre a natureza e os objetivos do estudo, mas não ficaram sabendo qual protocolo seguiu para cada dente.

Recrutamento dos participantes

O Comitê de Ética em Pesquisa do UNICEUMA revisou e aprovou o protocolo e emitiu um formulário de consentimento para este estudo (protocolo 3.078.493). Não foi feito nenhum anúncio para o recrutamento dos participantes e eles foram avaliados na ordem em que eles apareciam para a sessão de triagem, formando assim uma amostra de conveniência. Foi obtido de todos os participantes um consentimento informando por escrito antes do início do tratamento.

Cálculo amostral

O cálculo do tamanho da amostra foi feito usando um software online disponível no http://www.sealedenvelope.com, com base na taxa de retenção do adesivo universal que foi relatada em 94% em 18 meses de acompanhamento (retenção).[30] Usando um α de 0,05, poder de 80% e teste bilateral, o tamanho mínimo da amostra foi de 44 restaurações para cada grupo, a fim de detectar uma diferença de 20% entre os grupos testados.[31]

Critério de eleição

Um total de 40 participantes foram examinados para determinar se eles atendiam aos critérios de inclusão e exclusão (Figura 1). Aqueles que se qualificaram para o estudo foram recrutados na ordem em que se reportaram para a sessão de triagem, formando assim uma amostra de conveniência.

As avaliações foram realizadas com espelho bucal, explorador e sonda periodontal. Os participantes tinham que ter uma boa saúde em geral, ter pelo menos 18 anos de idade, ter um nível aceitável de higiene bucal e apresentar pelo menos 20 dentes sob oclusão. Os participantes foram obrigados a ter pelo menos quatro LCNCs em quatro diferentes dentes para serem restauradas. Essas lesões tinham que ser não cariosas, não retentivas e com profundidade superior a 1 mm e envolver o esmalte e a dentina dos dentes vitais sem mobilidade. A margem cavo-superficial não poderia envolver mais que 50% do esmalte.[32]

Todos os participantes receberam instruções de higiene bucal antes do tratamento operatório. Pacientes com higiene bucal extremamente pobre, pacientes com xerostomia, pacientes com aparelho ortodôntico e pacientes com periodontite grave ou crônica ou hábitos fortes de bruxismo foram excluídos do estudo.

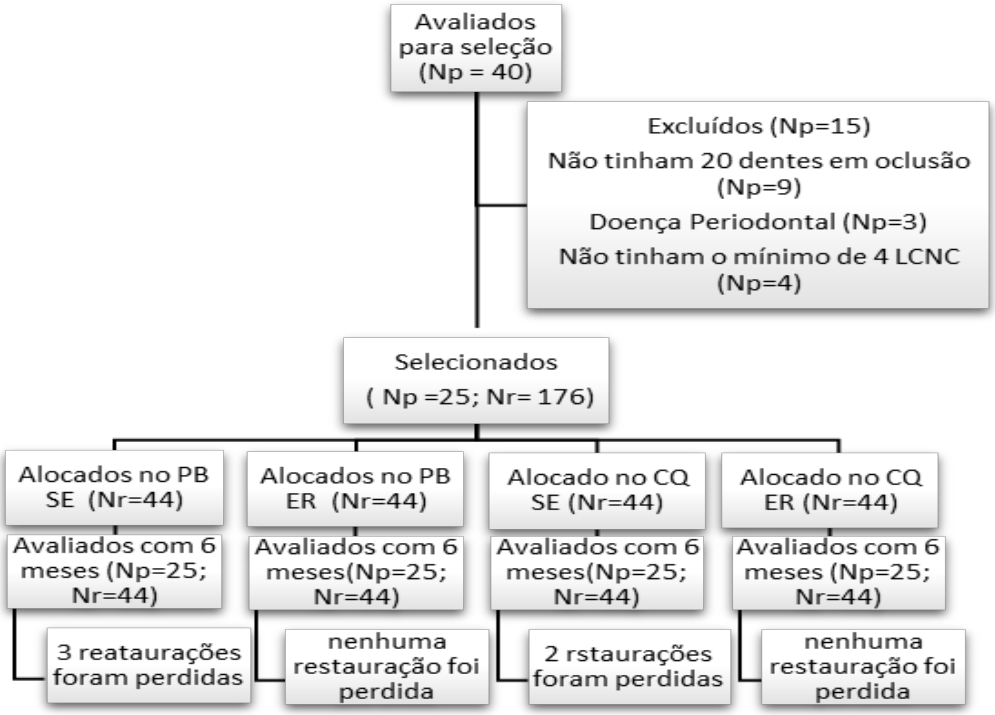


Figura 1. Fluxograma nas diferentes fases do estudo.. Np: número de pacientes, Nr: número de restaurações

Randomização e ocultação de alocação

Um membro da equipe não envolvido no protocolo de pesquisa realizou o processo de randomização (site random.org/list). Os detalhes dos grupos alocados foram registrados em cartões e posto dentro de envelopes selados e opacos. A abertura do envelope foi feita no dia do procedimento restaurador revelando a atribuição de alocação. O operador não estava cego para as intervenções, no entanto, os participantes e os avaliadores estavam cegos para a tarefa do grupo.

Intervenções: Procedimento Restaurador

Todos os pacientes selecionados para este estudo receberam profilaxia dentária com pedra-pomes e água e assinaram um termo de consentimento duas semanas antes do início dos procedimentos restauradores.

O grau de dentina esclerótica das LCNCs foi medido de acordo com os critérios descritos por Swift et al.[33] (Tabela 1). As dimensões da cavidade (altura, largura e profundidade), a geometria da cavidade (avaliada por fotografia de perfil e rotulada em <45°, 45° -90°, 90° -135° e > 135°), a presença de um antagonista e presença

de facetas de atrito foram observadas e registradas. A sensibilidade pré-operatória também foi avaliada aplicando jato de ar por 10 segundos através de uma seringa tríplice colocada a 2 cm da superfície do dente e com um explorador. Essas características foram registradas para permitir a comparação das características iniciais das cavidades dentinárias com os grupos experimentais.

Tabela 1. Escala de dentina esclerosada

Categoria	Critério
1	Nenhuma presença de esclerose (cor amarela ou esbranquiçada)
2	Mais esclerose do que na categoria 1, porém inferior a meio caminho entre as categorias 1 e 4
3	Menos esclerose do que na categoria 4, porém mais do que meio caminho entre as categorias 1 e 4
4	Significativa presença de esclerose (dentina acastanhada)

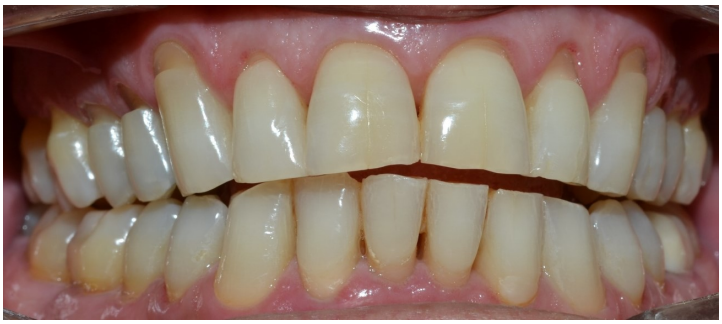


Figura 2. Aspecto inicial das LCNCs

Um operador calibrado, especialista em dentística restauradora, colocou as quatro restaurações, uma em cada grupo, sob a supervisão do diretor do estudo. Todos os participantes receberam pelo menos quatro restaurações, uma de cada grupo experimental, em diferentes lesões previamente selecionadas de acordo com os critérios de inclusão.

Antes dos procedimentos restauradores, a seleção da tonalidade era feita usando uma escala de cor. Seguindo as diretrizes da American Dental Association (ADA),[34] nenhuma retenção ou chanfro adicional foi realizado.

Os dentes que foram restaurados foram isolados com rolos de algodão e fio de retração (Ultrapak 000, Ultradent Prod., South

Jordan, UT, EUA), e as LCNCs receberam o *Clearfil Universal Bond Quick* (Kuraray, Tóquio, Japão) aplicado nas estratégias adesivas ER e SE ou *Prime&Bond Active* (Dentsply Sirona, Milford, DE, EUA) também aplicado nas mesmas estratégias ER e SE, onde definiu os quatro diferentes grupos. As composições, estratégia de aplicação e números de lote estão descritos na Tabela 2.

Tabela 2. Intervenção dos sistemas adesivos

Sistema Adesivo/ ph/	**Composição**	**Estratégia de aplicação (*)**	
		Etch-and-Rinse	**Self-Etch**
Prime&Bond Active, Dentsply, Milford, EUA / ph 2,6 / 1709000735	Diamina Bis Acrílica Água Iso-Propanol 10-MDP Proprilamina Bis Acrílica PENTA Canforoquinona HexaFluorFosfato Benzonitrila Dimetilamino Hidroquinona	1. Aplicar o ácido em esmalte e a dentina por 15s. 2. Lavar por 10s. 3. Secar gentilmente com jato de ar. 4 Aplicar o adesivo durante 20 s, com aplicação vigorosa. 5. Jato de ar moderado por 5 s para evaporar o solvente. 6. Fotopolimerizar por 10s. (1000Mw/cm2)	1. Aplicar o adesivo durante 20s, com aplicação vigorosa. 2. Jato de ar moderado por 5 s para evaporar o solvente. 3. Fotopolimerizar por 10s. (1000Mw/cm2)
Clearfil Universal Bond Quick, Kuraray, Tokyo, Japan / ph 2,2 / 2L0104	10-MDP Bisfenol-A-diglicidilmetacrilato Metacrilato de 2-hidroxietilo Monómeros de amido hidrófilico Sílica coloidal Silano Fluoreto de sódio Di-Canforoquinona Etanol Água	1. Aplicar o ácido em esmalte e dentina por 15s. 2. Lavar por 10s. 3.Secar gentilmente com jato de ar. 4.Aplicar o adesivo com agitação vigorosa. Sem tempo de espera 0s. 4. Jato de ar moderado por 5s para evaporar o solvente. 5. Fotopolimerizar por 10s. (1000Mw/cm2)	1.Aplicar o adesivo com agitação vigorosa. Sem tempo de espera 0s. 2. Jato de ar moderado por 5s para evaporar o solvente. 3. Fotopolimerizar por 10s (1000Mw/cm2)

(*) Seguido as recomendações dos fabricantes

Após a aplicação do adesivo, a resina composta Filtek Z-350 XT (3M Oral Care, St. Paul, MN, EUA) foi utilizada em até três incrementos e depois fotopolimerizada (Valo, Ultradent Prod., South Jordan, UT, EUA) por 30 segundos. As restaurações foram concluídas imediatamente com brocas diamantadas finas e extrafinas #2200 (KG Sorensen, Barueri, SP, Brasil). O polimento foi

realizado com polidores Jiffy (Ultradent Prod., South Jordan, UT, EUA) imediatamente após a colocação das restaurações.

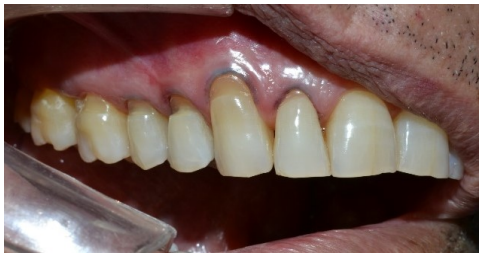


Figura 3. Inserção do fio retrator

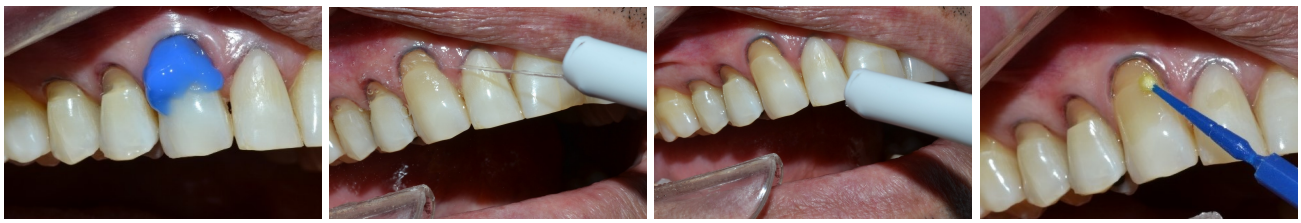


Figura 4. Sequência adesiva na estratégia ER

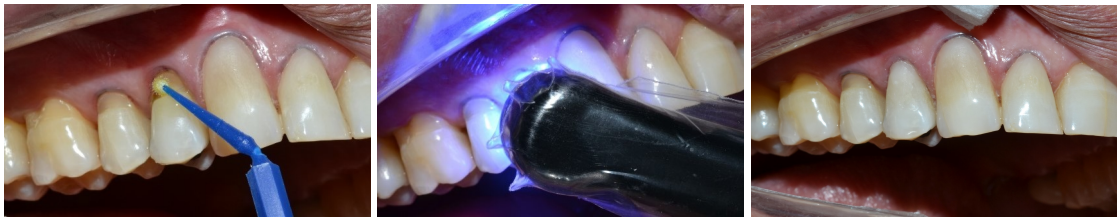


Figura 5. Sequência adesiva na estratégia SE e inserção do material restaurador

Figura 6. Sequencia de polimento com os polidores da Jiffy

Avaliação Clínica

Dois dentistas experientes e calibrados, não envolvidos nos procedimentos restauradores e, portanto, cegos para a tarefa de grupo, realizaram a avaliação. Após registrar os parâmetros durante a avaliação usando um formulário padronizado, este foi enviado de

volta à equipe de pesquisa, para que os avaliadores ficassem cegos para a atribuição de grupos durante os retornos de avaliação.

As restaurações foram avaliadas pelos critérios da FDI[35] e pelos critérios clássicos do USPHS[36,37] na linha de base e após 6 meses de realizado o procedimento. Apenas as medidas clinicamente relevantes para avaliação do desempenho dos adesivos foram utilizadas e pontuadas (Tabelas 10 e 11). O desfecho clínico primário foi retenção / fratura da restauração, mas os seguintes desfechos 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 nas seguintes pontuações: Critérios da FDI (clinicamente muito bom, clinicamente bom, clinicamente suficiente / satisfatório, clinicamente insatisfatório e clinicamente ruim) e critérios do USPHS (alfa, bravo e charlie). Ambos os examinadores avaliaram todas as restaurações independentemente. Quando ocorreram desacordos durante as avaliações, eles tiveram que chegar em um consenso antes do participante ser dispensado.

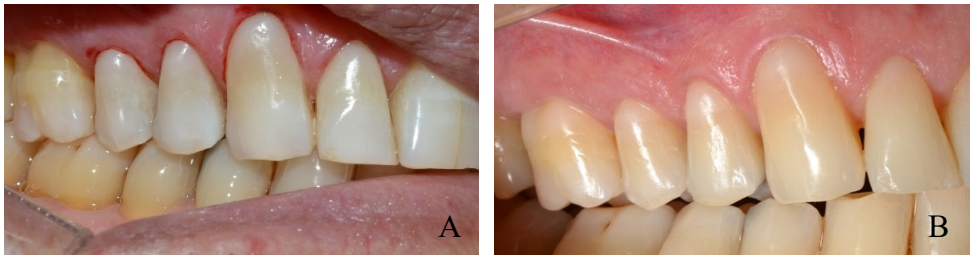


Figura 7. Avaliação imediata (A) e avaliação após 6 meses (B)

Tabela 3. Federação Dentária Internacional FDI) critérios utilizados para a avaliação clínica

	Propriedades estéticas	**Propriedades funcionais**		**Propriedades Biológicas**	
	1. Coloração Marginal	**2.Retenção/ fraturas**	**3. Adaptação marginal**	**4. Sensibilidade Pós – operatória**	**5. Recorrência de cárie**
1. Clinicamente muito bom	1.1 Sem descoloração marginal	2.1 Restauração retida, não há fraturas /fissuras	3.1 Contorno harmonioso, sem lacunas, sem descoloração	4.1 Sem sensibilidade.	5.1 Sem cárie secundária ou primária
2. Clinicamente bom (Após a correção muito bom)	1.2 Descolorações marginais pequenas, facilmente removida por meio de polimento	2.2 Pequena rachadura.	3.2.1 Fenda marginal (50 µm). 3.2.2 Pequena fratura marginal, removida por meio de polimento.	4.2 Baixa sensibilidade por um período de tempo limitado	5.2 Pequena Desmineralização, Sem necessidade de tratamento
3.Clinicamente suficiente / satisfatória (pequenas deficiências sem efeitos adversos mas não ajustável sem danos para o dente	1.3 Descoloração marginal moderada, esteticamente inaceitável.	2.3 Duas ou mais rachaduras ou maiores fissuras e / ou lascas (não afeta a integridade marginal	3.3.1 Gap <150 µm não removível 3.3.2.Várias pequenas fraturas em esmalte ou em dentina	4.3.1 Prematura / ligeiramente intensa 4.3.2 Retardada / sensibilidade fraca; sem queixas subjetivas, nenhum tratamento necessário.	5.3 Áreas de maiores desmineralização, mas apenas medidas preventivas necessárias (dentina não exposta)
4. Clinicamente insatisfatório (reparação por razões profiláticas)	1.4 Pronunciada descoloração marginal; grande intervenção necessária para a melhoria	2.4 Fraturas que prejudicam a qualidade marginal; fraturas com ou sem perda parcial (menos da metade da restauração)	3.4.1 Gap> 250 µm na dentina (exposta). 3.4.2. Lascas de fratura com margens prejudiciais 3.4.3 Notável fratura no esmalte ou na dentina	4.4.1 Prematura / muito intensa 4.4.2 Extremamente atrasada / fraca, com queixas subjetivas 4.4.3 Sensibilidade; Intervenção necessária, mas sem substituição.	5.4 Cárie com cavitação (localizada e acessível e pode ser reparada)
5. Clinicamente pobre	1.5 Descoloração marginal profunda e não acessível para a intervenção.	2.5 Perda (parcial ou completa) da restauração.	3.5 Restauração está solta	4.5, Pulpite aguda, com dor intensa ou não vital. Endodontia é necessário e a restauração tem que ser substituída.	5.5 Cáries secundárias profunda ou dentina exposta que não é acessível para reparação da restauração
Aceitável ou não aceitável (n, % e razões)	**Critérios estéticos**	**Critérios funcionais**		**Critérios biológicos**	

Tabela 4. Critérios da United States Public Health Service (USPHS) modificados de acordo com Bittencourt e Perdigão

	Coloração marginal	Retenção	Fratura	Adaptação marginal	Sensibilidade pós-operatória	Cárie recorrente
Alfa	Nenhuma descoloração ao longo da margem	Retida	Nenhuma	Restauração contínua com forma anatômica existente	Nenhuma sensibilidade pós-operatória, após o processo restaurador e durante o período de estudo	Nenhuma evidência de cárie
Bravo	Ligeira descoloração superficial (removida com polimento)	Parcialmente retida	Pequenas lascas, mas clinicamente aceitável	Detectável defeito em forma de V apenas esmalte.	...	...
Charlie	Profunda descoloração (não removida com polimento)	Ausente	Grandes fraturas na restauração	Detectável defeito em forma de V na junção esmalte-dentina	Sensibilidade presente em qualquer momento durante o período do estudo	Evidente presença de cárie

Análise Estatística

As análises estatísticas seguiram o protocolo de intenção de tratar, de acordo com a sugestão do CONSORT.[29] Estatísticas descritivas foram usadas para descrever as distribuições dos critérios avaliados. Uma análise estatística foi realizada para cada item (retenção / fratura, coloração marginal, adaptação marginal, sensibilidade pós-operatória e recorrência de cárie) e para cada parâmetro geral (FDI e USPHS). As diferenças entre as classificações dos quatro grupos após 6 meses foram testadas pela análise de medidas repetidas de Friedman na classificação de variância ($\alpha = 0,05$), e as diferenças nas classificações de cada grupo antes do procedimento e após 6 meses foram avaliadas pelo teste de McNemar ($\alpha = 0,05$).

Para a retenção das restaurações, foi calculada a taxa de risco e o risco relativo de todas as estratégias em relação à estratégia mais convencional (ER - Prime & Bond Active). O intervalo de confiança de 95% também foi relatado. As estatísticas kappa de

Cohen foram usadas para testar o acordo entre examinadores. Em todos os testes estatísticos, predefinimos o nível de significância em 5% (Statistical for Windows 7.0, Stat Soft Inc., Tulsa, OK, EUA).

APÊNDICE 2

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título do Estudo: Avaliação clínica de seis meses de um novo adesivo universal aplicado no modo “sem espera”: Estudo clínico randomizado.

Você está sedo convidado a participar de um estudo de pesquisa que se destina a avaliar a qualidade das restaurações em resina composta e a possível sensibilidade que ela pode causar. Este estudo é importante porquê vai determinar parâmetros de sucesso clínico das restaurações, e encaminhar para tratamento.

O estudo será feito da seguinte maneira: Serão realizadas restaurações em resina composta comercial e essas restaurações serão avaliadas após 24 horas e após 6 meses.

Sempre que você desejar serão fornecidos esclarecimentos sobre cada uma das etapas do estudo. A qualquer momento, você poderá recusar a continuar participando do estudo e, também, poderá retirar seu consentimento, sem que para isto sofra qualquer penalidade ou prejuízo, ou seja sem qualquer prejuízo da continuidade do seu acompanhamento médico.

Você será beneficiado pois seus dentes serão restaurados e assim removida a possibilidade de cárie, sensibilidade e exposiçao da polpa por desgaste, que se não tratada poderá levar à extração do dente, bem como será avaliado(a) após 6 meses, podendo assim prevenir novos desgastes.

Como risco, todo procedimento realizado na boca pode levar a algum grau de dor após ser realizado, pois envolve as estruturas do dente e também eventualmente pode ocorrer alguma falha e a restauração se soltar. Porém caso aconteça isso ou

qualquer outro problema, você poderá procurar nosso atedimento antes do periodo de reavaliação.

Sera garantido o sigilo quanto a sua identificação e das informações obtidas pela sua participação, exceto aos responsáveis pelo estudo, e a divulgação das mencionadas informações só será feita entre os profissionais estudiosos do assunto. Você não será identificado(a) em nenhuma publicação que possa resultar deste estudo.

Você será indenizado(a) por qualquer despesa que venha a ter com sua participação nesse estudo e, também, por todos os danos que venha a sofrer pela mesma razão, sendo que, para essas despesas estão garantidos os recursos.

_____

Pesquisador responsável

Rossana Aboud Matos de Almeida - CPF 972072503-63

Rua: Josue Montello, 1 – UNICEUMA Telefone: (98)996180199

São Luis, _____/_____/_____

_____

Assinatura do sujeito ou responsável

APÊNDICE 3

Título do Estudo: Avaliação clínica de seis meses de um novo adesivo universal aplicado no modo “sem espera”: Estudo clínico randomizado.

FICHA CLÍNICA

NOME: _____

DATA DE NASCIMENTO:_____

SEXO:_____

PROFISSÃO:_____TELEFONE:_____

ENDEREÇO:_____

EMAIL:_____

QUESTIONÁRIO DE SAÚDE GERAL- HISTÓRIA MÉDICA

1. Você se considera saudável? Sim ( ) Não ( )
2. Possui alguma doença sistêmica? Sim ( ) Não ( )

Se sim, qual?

_____

3. Possui problemas gástricos (gastrite/refluxo)?

_____

4. Já fez endoscopia? Sim ( ) Não ( ) 5. Algum diagnóstico?

_____

5. Está fazendo uso de algum medicamento? Sim ( ) Não ( )

Qual?

_____

6. Você está grávida? Sim ( ) Não ( )
7. Possui alguma alergia? Sim ( ) Não ( )
8. Já foi submetido a alguma cirurgia? Sim ( ) Não ( )
9. Tem dieta ácida (refrigerante, frutas cítricas)?

_____

QUESTIONÁRIO DE SAÚDE BUCAL

1. Você se considera saudável? Sim ( ) Não ( )

2. Possui alguma queixa específica? Sim ( ) Não ( )

Se sim, qual? _____

3. Possui algum hábito parafuncional? Sim ( ) Não ( )

( ) Ranger os dentes ( ) Apertar os dentes ( ) Morder caneta/lápis

( ) Respirar pela boca ( ) Chupar dedo/chupeta

( ) Roer unha ( ) Outro _____

4. Você fuma? Sim ( ) Não ( ) Ex-fumante? Sim ( ) Não ( )

5. Já fez tratamento ortodôntico? Sim ( ) Não ( )

Por quanto tempo? _____

6. Quantas vezes por dia escova os dentes? _____

( ) Manhã ( ) Tarde Noite ( )

7. Você usa fio dental? Sim ( ) Não ( ) Quantas vezes ao dia?_____

8. Sua gengiva costuma sangrar? Sim ( ) Não ( )

9. Sente sensibilidade nos dentes? Sim ( ) Não ( )

10. Possui dificuldade de salivação (pouca saliva)? Sim( ) Não( )

11. Sua escova é: ( ) Macia ( ) Média ( ) Dura

Declaro que os dados, inclusive cadastrais, por mim mencionados são verdadeiros. Comprometo-me a relatar qualquer alteração no meu quadro de saúde atual e durante o tratamento restaurador.

_____, _____ de _____ de 20_____

Assinatura do paciente

Categoria	Critério
1	Nenhuma presença de esclerose (cor amarela ou esbranquiçada)
2	Mais esclerose do que na categoria 1, porém inferior a meio caminho entre as categorias 1 e 4
3	Menos esclerose do que na categoria 4, porém mais do que meio caminho entre as categorias 1 e 4
4	Significativa presença de esclerose (dentina acastanhada)

- ESCALA DE DENTINA:

DENTE	1	2	3	4

- AVALIAÇÃO DA SENSIBILIDADE IMEDIATA:

Grau de Sensibilidade
0- Nenhuma
1- Leve
2- Moderada
3- Considerável
4- Severa

ANTES DO PROCEDIMENTO RESTAURADOR		DEPOIS DO PROCEDIMENTO RESTAURADOR	
DENTE	ESCALA DE DOR	DENTE	ESCALA DE DOR

- Tamanho da cavidade:

Dente	Altura	Largura	Profundidade

- Tratamento executado

DENTE	ESTRATÉGIA ADESIVA UTILIZADA	DATA

Apêndice 4

FICHA CLÍNICA DE AVALIAÇÃO

Paciente:_____
Avaliador:_____
Data:_____

Método USPHS de avaliação modificado
Período: Baseline

(A = alfa; B = bravo; C = charlie)

Dente	Cor	Descoloração Marginal	Carie recorrente	Desgaste	Adaptação marginal	Textura superficial	Sensibilidade Pré-operat.	Sensibilidade Pós-opert.	Retenção	Fratura	Outras falhas

Paciente:_____
Avaliador:_____Data:_____

Método FDI de avaliação modificado
Período: _____ meses

(A; B; C; D e E = A a C sem necessidade de reparo; D e E precisa reparo ou conserto)

Dente	Cor	Descoloração Marginal	Carie recorrente	Desgaste	Adaptação marginal	Textura superficial	PQ	PA	Retenção	Fratura	Outras falhas

ANEXO

ANEXO 1- PARECER DO COMITÊ DE ÉTICA

DADOS DO PROJETO

Título da Pesquisa: AV
CE

Pesquisador: ROSSA

Área Temática:

Versão: 2

CAAE: 00983918.5.000

Instituição Proponente

Patrocinador Principal

DADOS DO PARECER

Número do Parecer: 3

Apresentação do Proje

Os sistemas adesivos s
material restaurador à e
Alguns fabricantes lan
autocondicionante, est
chamados de universais
clínico quanto a retenç
descoloração marginal
adesivos universais Pr

restauradores, que irá s
utilizando dois critérios
USPHS. Os resultados
seguido do teste de Tuk
significância de 5%.

Objetivo da Pesquisa:

Objetivo Primario

Avaliar a estratégia ades
(Prime&Bond Active e C
Bond Quick) teve melhor

Objetivo Secundário:

• Avaliar o desempenho d
• Avaliar o desempenh
imediatamente e após
• Avaliar o desempenho d
após 6 meses.
• Avaliar o desempenho
semana e após 6 meses
• Avaliar o desempenho d

Avaliação dos Riscos e

Continuação do Parecer: 3.078.493

Comentários e Conside

Trata-se de um estudo

adequada aos objetivo

Considerações sobre o

Todos os documentos

adequados as normati

Conclusões ou Pendên

Sem pendências

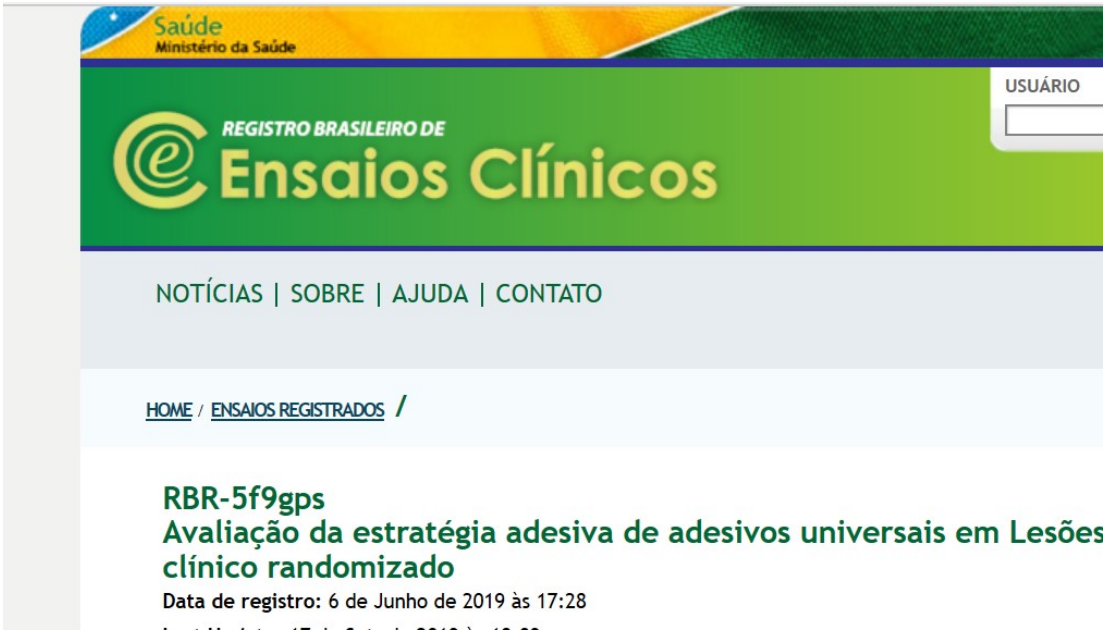
Considerações Finais a

O pesquisador deverá ap

Este parecer foi elabora

Tipo Documento	
Informações Básicas do Projeto	Pl R
Outros	co
Projeto Detalhado / Brochura Investigador	pr
Declaração de Instituição e Infraestrutura	co
Folha de Rosto	D

ANEXO 2 - REGISTRO BRASILEIRO DE ENSAIOS CLÍNICOS



ANEXO 3– NORMAS DA REVISTA

Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.

Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
  - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
  - or for non-clinical or non-research studies a description of what the article reports
- list the full names and institutional addresses for all authors
  - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study

- **Methods:** how the study was performed and statistical tests used
- **Results:** the main findings
- **Conclusions:** brief summary and potential implications
- **Trial registration:** If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration

- **Keywords**

Three to ten keywords representing the main content of the article.

- **Background**

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

- **Methods**

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

- **Results**

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

- **Discussion**

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

- **Conclusions**

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

- **List of abbreviations**

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

- # Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

- ***Ethics approval and consent to participate***

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee’s reference number if appropriate

Studies involving animals must include a statement on ethics approval and for experimental studies involving client-owned animals, authors must also include a statement on informed consent from the client or owner.

See our editorial policies for more information.

If your manuscript does not report on or involve the use of any animal or human data or tissue, please state “Not applicable” in this section.

1 References

Examples of the Vancouver reference style are shown below.

See our editorial policies for author guidance on good citation practice

Web links and URLs: All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Example reference style:

Article within a journal

Smith JJ. The world of science. Am J Sci. 1999;36:234-5.

Article within a journal (no page numbers)

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