ROSSANA ABOUD MATOS DE ALMEIDA

DESEMPENHO CLÍNICO DE UM ADESIVO UNIVERSAL UTILIZANDO DIFERENTES MODOS DE APLICAÇÃO

CLINICAL PERFORMANCE OF A UNIVERSAL ADHESIVE USING DIFFERENT APPLICATION MODES

SÃO LUÍS, 2024

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Tese apresentada ao Programa de Pós-Graduação em Odontologia da Universidade CEUMA para obtenção do título de Doutora em Odontologia.

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Orientador: Prof. Dr. Andres Felipe Millan Cardenas

Co-orientadora: Profa. Dra. Fabiana Suelen Figuerêdo de Siqueira

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Tese apresentada por Rossana Aboud Matos de Almeida

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“*Os que se encantam com a prática sem a ciência são como os timoneiros que entram no navio sem timão nem bússola, nunca tendo certeza do seu destino.”*

(Leonardo da Vinci)

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RESUMO

Recentemente, um adesivo universal foi lançado no mercado com o conceito de "sem espera", no qual é possível aplicar e fotoativar o adesivo sem esperar. O presente estudo foi dividido em dois capítulos que abordaram a avaliação do comportamento clínico de um adesivo universal de aplicação sem espera (NW) comparado a diferentes adesivos e estratégias adesivas. No experimento 1, foi avaliado o comportamento clínico de dois adesivos universais utilizando diferentes técnicas de aplicação ao longo de 18 meses de avaliação clínica em lesões cervicais não cariosas (LCNC). Foram realizadas 176 restaurações a quatro diferentes grupos: Prime&Bond Active (PB) utilizando as estratégias de condicionamento ácido (ER) e autocondicionante (SE), com aplicações de 20 segundos, e Clearfil Universal Bond Quick (CQ) utilizando as estratégias de ER e SE com a técnica NW. As restaurações foram avaliadas no início, após 6 meses e 18 meses, utilizando os critérios da Federação Dentária Internacional (FDI) e do Serviço de Saúde Pública dos Estados Unidos (USPHS). A análise de variância de medidas repetidas de Friedman e o teste de Wilcoxon foram utilizados para as análises estatísticas (α=0,05). Não foram observadas diferenças significativas entre nenhum dos grupos ou critérios após 6 meses (p>0,05). Após 18 meses, foram perdidas 10 restaurações (p>0,05) (2 com PB-ER [95,5%; IC95%: 92–100%], 4 com PB-SE [90,9%; IC95%: 82–98%], 0 com CQ-ER [100%; IC95%: 92–100%] e 4 com CQ-SE [90,9%; 82–98%]). As restaurações realizadas com a estratégia SE apresentaram mais discrepâncias marginais do que aquelas realizadas com a estratégia ER (p>0,05). Os resultados ao utilizar as estratégias CQ-SE e -ER com a técnica NW foram semelhantes àqueles ao utilizar as estratégias PB-SE e -ER para lesões cervicais não cariosas após 6 e 18 meses de avaliação clínica. No experimento 2, teve como objetivo avaliar o desempenho clínico do adesivo universal Clearfil Universal Bond Quick (CUBq) em diferentes tempos de aplicação (sem espera e com espera), comparado ao adesivo Clearfil SE Bond (CSE), em LCNCs, ao longo de 18 meses. 183 restaurações foram distribuídas aleatoriamente em três grupos com base no sistema adesivo e tempo de espera: CUBq sem tempo de espera (CUBq-NW), CUBq com tempo de espera de 20 segundos (CUBq-W) e CSE com tempo de espera de 20 segundos. As restaurações foram avaliadas após 18 meses utilizando os critérios da FDI e USPHS. As análises estatísticas envolveram a análise de variância de medidas repetidas de Friedman e os testes de Wilcoxon, com um nível de significância estabelecido em 5%. Ao longo dos 18 meses, nenhuma restauração foi perdida nos grupos testados. A avaliação da adaptação marginal indicou pequenas discrepâncias em 21 restaurações (8 CUBq-NW, 6 CUBq-W e 7 CSE). Não foram observadas diferenças significativas entre os três grupos após de 18 meses (p > 0,05). Apenas duas restaurações apresentaram descoloração marginal (1 CUBq-NW e 1 CSE). A aplicação do CUBq utilizando a técnica "com espera" ou "sem espera" demonstrou excelentes resultados clínicos em LCNCs durante o período de 18 meses, apresentando desempenho comparável ao CSE em todos os resultados avaliados.

Descritores: Adesivo Universal, Lesão cervical não cariosa, Estudo clínico, tempo de aplicação.

ALMEIDA RAM. Clinical performance of a universal adhesive using different application modes [tese]. São Luís. Universidade Ceuma; 2024.

ABSTRACT

Recently, a universal adhesive was introduced to the market with the concept of "no waiting," allowing for the application and photoactivate the adhesive without waiting. The present study was divided into two chapters that addressed the clinical evaluation of a no-wait universal adhesive (NW) compared to different adhesives and adhesive strategies. In Experiment 1, the clinical behavior of two universal adhesives over 18 months in non-carious cervical lesions (NCCLs) was evaluated. A total of 176 restorations were assigned to four different groups: Prime&Bond Active (PB) using etch-and-rinse (ER) and self-etch (SE) strategies with 20-second applications, and Clearfil Universal Bond Quick (CQ) using ER and SE strategies with the NW technique. The restorations were evaluated at baseline, 6 months, and 18 months using from the International Dental Federation (FDI) criteria and the United States Public Health Service (USPHS). Friedman's repeated measures analysis of variance and Wilcoxon test were used for statistical analyses (α=0.05). No significant differences were observed among any of the groups or criteria after 6 months ($p>0.05$). After 18 months, 10 restorations were lost ($p>0.05$) (2 with PB-ER [95.5%; 95% CI: 92–100%], 4 with PB-SE [90.9%; 95% CI: 82–98%], 0 with CQ-ER [100%; 95% CI: 92–100%], and 4 with CQ-SE [90.9%; 95% CI: 82–98%]). Restorations performed with the SE strategy showed more marginal discrepancies than those performed with the ER strategy ($p>0.05$). The results using CQ-SE and -ER strategies with the NW technique were similar to those using PB-SE and -ER strategies in standard applications for NCCLs after 6 and 18 months of clinical evaluation. In Experiment 2, the clinical performance of the universal adhesive Clearfil Universal Bond Quick (CUBq) at different application times (no waiting and with waiting) was evaluated compared to Clearfil SE Bond (CSE) in NCCLs over 18 months. A total of 183 restorations were distributed into three groups: CUBq no-wait (CUBq-NW), CUBq with a 20-second waiting time (CUBq-W), and CSE with a 20-second waiting time. The restorations were evaluated after 18 months using FDI and USPHS criteria. Statistical analyses involved Friedman's repeated measures analysis of variance and Wilcoxon tests, with a significance level set at 5%. Over the 18 months, no restorations were lost in the tested groups. Assessment of marginal adaptation indicated minor discrepancies in 21 restorations (8 CUBq-NW, 6 CUBq-W, and 7 CSE). No significant differences were observed among the three groups after the 18-month clinical evaluation ($p > 0.05$). Only two restorations showed marginal discoloration after 18 months (1 CUBq-NW and 1 CSE). Application of CUBq using the "with waiting" or "no waiting" technique demonstrated excellent clinical results in NCCLs during the 18-month follow-up period, showing comparable performance to CSE in all evaluated outcomes.

Keywords: Universal adhesives, Non-carious cervical lesion, Clinical trial, Application time

INTRODUÇÃO

A odontologia adesiva passou por um progresso notável nas últimas duas décadas, com avanços significativos na tecnologia de união desempenhando um papel fundamental[1]. Para atender à demanda dos clínicos por técnicas de união mais rápidas e menos sensíveis, foram desenvolvidos adesivos universais (AUs).[2,3] Esses AUs podem ser adaptados a várias estratégias adesivas, como condicionamento total (CT) ou autocondicionante (AC)[4,5] ou condicionamento seletivo do esmalte, que combina o condicionamento total em esmalte e autocondicionante em dentina.[6,7] Além disso, eles também podem ser utilizados em diferentes substratos indiretos.[8]

Essa versatilidade em termos de aplicação é resultado da adição de monômeros funcionais específicos, como o fosfato de dihidrogênio de 10-metacriloxidocila (10-MDP).[9] Esses monômeros interagem com os substratos dentários promovendo adesão química.[10,11] Adicionalmente, ele melhora o potencial de autocondicionamento no esmalte[12,13] e a durabilidade a longo prazo da união à dentina e ao esmalte,[11] devido à ligação iônica estável com o cálcio, formando nanoestruturas de sais de MDPCa na interface com a hidroxiapatita.[14]

Embora os AUs tenham demonstrado desempenho in vitro adequado[8, 15] e sucesso clínico,[16–18] esforços contínuos para reduzir o tempo de aplicação e diminuir a sensibilidade da técnica de aplicação, levaram ao desenvolvimento de novas tecnologias. Um exemplo é a técnica de aplicação "sem espera", que preconiza a redução do tempo de aplicação do adesivo.[19–21] O adesivo Clearfil Universal Bond Quick (CBUq) emprega esse conceito, apresentando um monômero acrilamida amida hidrofílico multifuncional (tecnologia de ligação rápida)[22] que melhora o molhamento da dentina subsuperficial, reduzindo assim o tempo de aplicação.[23,24]

A técnica "sem espera" pode ser considerada mais uma vantagem de marketing do que um benefício real, já que o pouco tempo economizado pode não ser relevante do ponto de vista clínico. No entanto, deve-se observar que um tempo de aplicação mais curto pode teoricamente tornar a aplicação menos sensível à técnica e reduzir o risco de contaminação durante a restauração.[24, 25, 27] Considerando o fato de que esses materiais surgiram como parte de uma nova

tendência de simplificação de tempo e técnica, os resultados clínicos que examinam essa tendência devem ser considerados importantes.

Recentemente, vários estudos in vitro que testaram o conceito de "sem espera" em comparação com um modo de aplicação de 10 segundos relataram resultados controversos.[25–28] Assim, ensaios clínicos que avaliem o comportamento clínico desse sistema adesivo aplicado em diferentes estratégias adesivas e diferentes técnicas de aplicação ainda são necessários.

Para isso foram feitos dois estudos clínicos randomizados. O primeiro estudo, tem como objetivo avaliar o comportamento clínico de dois adesivos universais quando aplicados em diferentes técnicas de aplicação durante 18 e 36 meses de avaliação clínica. A hipótese nula testada foi que o adesivo universal CBUq aplicado usando a técnica "sem espera" nas lesões cervicais não cariosas (LCNCs) usando as estratégias de CT e AC mostra níveis de retenção semelhantes ao longo de 18 e 36 meses de avaliação clínica em comparação com o adesivo universal Prime&Bond Active aplicado usando o tempo de aplicação padrão (20 s).

O segundo estudo, tem como objetivo avaliar o desempenho clínico do adesivo universal CBUq em diferentes tempos de aplicação (sem espera e espera) em comparação com o adesivo Clearfil SE Bond (CSE) em LCNCs após 18 meses. As hipóteses nulas do estudo são (1) CBUq aplicado com a técnica "sem espera/espera" demonstrará desempenho clínico comparável (retenção/fratura como desfecho primário) em LCNCs entre eles e quando comparado ao adesivo CSE após 18 meses de avaliação clínica e (2) CBUq usando a técnica "sem espera/espera" mostrará desempenho clínico semelhante em manchas marginais, adaptação marginal, sensibilidade pós-operatória espontânea e recorrência de cáries como resultados secundários em LCNCs entre eles e quando comparado ao adesivo CSE após 18 meses de avaliação clínica.

CAPÍTULO 1

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

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ABSTRACT

Objective: The aim of this double-blind, randomized clinical trial was to evaluate the 6- and 18-month clinical performances of a new universal adhesive applied in the “no-waiting” (NW) technique to non-carious cervical lesions (NCCLs) using two evaluation criteria. **Materials and methods:** One hundred and seventy-six restorations were assigned to four groups according to the adhesive system, adhesive strategy, and application mode: Prime&Bond Active (PB) applied using the etch-and-rinse (ER) and self-etch (SE) strategies with 20 s applications and Clearfil Universal Bond Quick (CQ) applied using the ER and SE strategies with the NW technique. The composite resin restorations were evaluated at baseline and after 6 and 18 months using the World Dental Federation (FDI) and US Public Health Service (USPHS) criteria. The Friedman repeated measures analysis of variance and Wilcoxon test were used for statistical analyses (α=0.05). **Results:** No signifcant differences were observed among any of the groups or criteria after 6 months (p>0.05). After 18 months, 10 restorations were lost (p>0.05) (2 with PB-ER [95.5%; 95%CI: 92–100%], 4 with PB-SE [90.9%; 95%CI: 82–98%], 0 with CQ-ER [100%; 95%CI: 92–100%], and 4 with CQ-SE [90.9%; 82–98%]). The restorations performed with the SE strategy showed more marginal discrepancies than those performed with the ER strategy, mainly when the FDI criteria were used (p0.05). **Conclusions:** The results when using the CQ-SE and ER strategies with the NW technique were similar to those when using the PB-SE and -ER strategies in standard applications to non-carious cervical lesions after 6 and 18 months of clinical evaluation.

Clinical relevance After 6 and 18 months, the application of Clearfil Universal Bond Quick with the “no-waiting” technique showed similar clinical performance compared to the standard application of Prime & Bond Active applied using the standard application time (20 s).

Trial registration: ClinicalTrials.gov identifier RBR-5f9gps.

Keywords: Universal adhesives. Non-carious cervical lesion. Clinical trial. Application time.

INTRODUCTION

The most recently manufactured adhesives are universal or multimodal adhesives [1]. Manufacturers have made an effort to maintain the trend of simplifying the techniques by providing etch-and-rinse or self-etch adhesives in enamel/ dentin adhesive systems, [2, 3] as well as indirect materials, mainly glass-rich ceramics, zirconia and metals [4, 5]. This versatility in terms of application is a result of the addition of specific functional monomers such as 10-metacriloxidecil dihydrogen phosphate (10-MDP) [5]. Compared with other functional monomers, the chemical bond between 10-MDP and the dental substrate may play an important role in a stable and sustainable interface [6–8].

Several in vitro studies, in which the bond durability was tested, have demonstrated remarkable effectiveness when a universal adhesive contained 10-MDP [9–11]. In addition, clinical trials have shown that universal adhesives attain an adequate retention rate for composite restorations placed in non-carious cervical lesions [12–22]. Nevertheless, when outcomes such as marginal adaptation or marginal discoloration are evaluated, the results regarding the best technique to use when applying a universal adhesive (self-etch [SE] or etch-and-rinse [ER]) are inconclusive [3, 20–22].

Furthermore, following the same line of simplification, universal adhesives were recently launched in the market with a “no-waiting” time concept, in which it is possible to apply and light-cure adhesives without waiting [23]. Manufacturers claim that the addition of a new multifunctional hydrophilic acrylamide amide monomer (also known as rapid bond technology) [24] enhances the wetting of dentine, thereby reducing the application time [23–25]. Recently, several in vitro studies that tested the “no-waiting” concept in comparison with a 10-s application mode reported controversial results [25–28].

The “no-waiting” technique may be considered more of a marketing advantage than a real benefit, as the little time saved may not be relevant from a clinical point of view. However, it should be noted that a shorter application time may theoretically make the application less technique sensitive and reduce the risk of contamination during restoration [24, 25, 27]. Considering the fact that these materials appeared as part of a new tendency of time and technique

simplification, clinical outcomes that examine this tendency should be deemed important.

Therefore, the aim of this double-blind randomized clinical trial was to evaluate the clinical behaviors of two universal adhesives when placed using different application techniques during 18 months of clinical evaluation. The null hypothesis was that the universal adhesive applied using the “no-waiting” technique for bonding to non-carious cervical lesions (NCCLs) using the ER and SE strategies would show similar retention levels over 18 months of clinical service when compared to the universal adhesive applied using the standard application time (20 s).

MATERIALS AND METHODS

Study design

The experimental design of this randomized, double-blind clinical trial followed the Consolidated Standards of Reporting Trials (CONSORT) statement [29]. Additionally, this study was registered in the Brazilian Clinical Trials Registry under the identification number RBR-5f9gps. All the procedures were performed in the clinic of the School of Dentistry at Ceuma University from September to October 2019.

The study participants were aware of the nature and aims of the research but were not informed about which tooth would receive the specific treatments under analysis.

Participant recruitment

A consent form for this study (protocol 3.078.493) was reviewed, approved, and issued by the University Ethics Committee for Investigations Involving Subjects. The participants were recruited from August 2019 to September 2019. No advertisements were used for participant recruitment. Those who qualified for the study were asked to participate in the order in which they reported to the screening session, thus forming a convenience sample. Informed written consent was obtained from all participants before starting treatment.

Sample size selection

The sample size calculation was performed using the online software http://www.sealedenvelope.com. For this purpose, the retention rate of a universal adhesive was used. Perdigão et al. [13] reported a 94% retention rate at an 18-month follow-up (retention). Therefore, using a bilateral test based on a power of 80% and statistical significance level set at 0.05, 44 restorations per group was the minimum sample size to detect a 20% group difference [30].

Eligibility criteria

Two calibrated dental students, using a mouth mirror, an explorer, and a periodontal probe, examined 39 participants to see if they met the inclusion and exclusion criteria (Fig. 1), thus constituting a convenience sample. All the participants (a) required good oral and general health, (b) were at least 18 years of age, (c) had at least 20 teeth under occlusion, and (d) had at least four non-carious cervical lesions to be restored on four separate teeth. These lesions had to have a minimum depth and extent of 1 mm and involve both enamel and dentin of vital non-mobile teeth, with at least 50% of their margins devoid of enamel [31].

Oral hygiene instructions were provided to the patients before the start of operative treatment. Inadequate oral hygiene, severe or chronic periodontitis, xerostomia, braces, or heavy bruxism habits were considered criteria for disqualification.

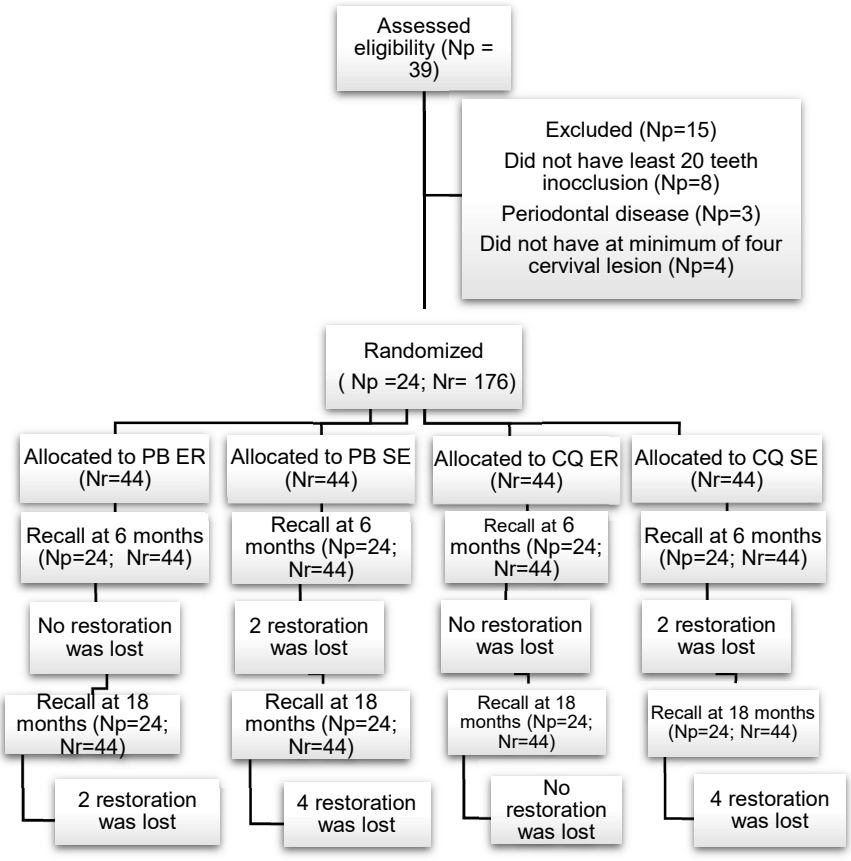

Figure 1. Participant flow diagram in the different phases of the study design. Abbreviations: Np – number of participants; Nr – number of restorations

Allocation concealment and randomization

A participant who was not involved in the research protocol performed the randomization process by generating a random allocation sequence determined through the random. org/list website. The assigned groups were deposited on cards inside sequentially numbered opaque sealed envelopes. Each envelope was opened on the day of the restorative procedure to determine the assignment. The operator was not blinded to the restorative assignment; however, the patients and evaluators were blinded to the group assignment.

Restorative procedure

Dental prophylaxis was conducted using a suspension of pumice stone and water in a rubber cup prior to the procedures. The characteristics of the non-carious cervical lesions were evaluated before the implantation of the restorations. The degree of dentin sclerosis was evaluated according to the requirements described by Swift et al. [32]. The cavity dimensions (height, width, and depth) and cavity geometry were classified as135°. All the parameters were measured in millimeters and evaluated using profile photography. The attrition and antagonist tooth wear were observed and recorded. An exploratory probe was used to assess preoperative sensitivity, and an air jet was used for 10 s, 2 cm away from the tooth surface. All the features of the non-carious cervical lesions were marked to verify the standardization between the experimental groups.

Four restorations, one per group, were placed by a calibrated operator with more than 5 years of clinical experience in operative dentistry, supervised by the study director, in a clinic. The patients received a minimum of four restorations, one from each experimental group, in different lesions previously selected according to the inclusion requirements. Neither retentions nor bevels were prepared.

The tooth to be restored was isolated using cotton rolls and a retraction cord (Ultrapak 000, Ultradent Prod. South Jordan, UT, USA), and then, the non-carious cervical lesions received the Prime&Bond Active (PB; Dentsply Sirona,

Milford, DE, USA) applied using the ER and SE strategies with the standard application (20 s) and the Clearfil Universal Bond Quick (CQ; Kuraray, Tokyo, Japan) applied using the ER and SE strategies with the “no-waiting” technique, which defined the four different groups. The compositions, application modes, and batch numbers of the adhesives used are listed in Table 1.

After the adhesive application, Filtek Z-350 XT (3 M Oral Care, St. Paul, MN, USA) resin composite was used in up to three increments, and each composite was light-cured for 30 s at an irradiance of 1000 mW/cm2 (Valo, Ultradent Prod. South Jordan, UT, USA). All the restorations were finished with fine and extra-fine diamond burs (#2200F and #2200FF, KG Sorensen, Barueri, SP, Brazil) and polished with Jiffy points (Ultradent Prod. South Jordan, UT, USA) immediately after the placement of the restorations using green, yellow, and white sequences.

Clinical evaluation

Two experienced and calibrated dentists, not involved with the restoration procedures and therefore blinded to the group assignment, evaluated all the restorations once and independently using the World Dental Federation (FDI) [33] and classical US Public Health Service (USPHS) criteria [34, 35] at the baseline and after 6 and 18 months of clinical service. In a case of disagreement between the examiners, a consensus was reached by re-examination and discussion before the patient was dismissed [13, 36, 37]. Only clinically relevant measures for evaluating the performance of the adhesives were used and scored (Tables 2 and 3). Retention/fracture considered the primary clinical outcome, while marginal discoloration, marginal adaptation, dentin sensitivity, and recurrent caries considered secondary outcomes. A properly standardized case report form was used, and immediately after the parameters were recorded during the evaluation, this document was forwarded to the research team so that the evaluators were blinded to the group task during the follow-up evaluations. These variables were categorized using the following scoring criteria: (1) FDI criteria (clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory, and clinically poor) and (2) USPHS criteria (alpha, bravo, and charlie). The evaluators assessed all the restorations simultaneously and independently.

Table 1. 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

Statistical analysis

The intention-to-treat protocol following the Consolidated Standards of Reporting Trials (CONSORT) suggestion [29] was used for statistical analyses. Descriptive statistics were used to demonstrate the influence of the evaluation criteria. A statistical analysis was performed for each item (retention/fracture, marginal discoloration, marginal adaptation, postoperative sensitivity, and caries recurrence) and for each global parameter (FDI and USPHS). After 6 and 18 months, the differences between the classifications of the four groups were tested using Friedman's repeated analysis of variance classification (α=0.05), and the differences in each group (baseline and after 6 and 18 months) were evaluated using a Wilcoxon test (α=0.05).

For the primary outcome retention, we also calculated the risk ratio and relative risk of all the approaches relative to the most traditional approach (PB-ER). A 95% confidence interval was also reported. Inter-examiner agreement was measured using the Cohen's kappa statistic. For all the statistical tests, we set a significance level of 5% (Statistical for Windows 7.0, Stat Soft Inc., Tulsa, OK, USA).

Table 2. 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	5.5 Deep secondary caries or exposed dentine that is not

				accessible for repair of restoration	accessible for repair of restoration.
Acceptable or not acceptable (n, % and reasons)	Aesthetic criteria	Functional criteria		Biological criteria	

Table 3. 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

RESULTS

Because they did not meet the inclusion criteria, 15 of the 39 patients examined for eligibility were excluded from the study. Thus, 24 individuals were selected (12 men and 12 women). One hundred and seventy-six restorations were placed, 44 in each group (Fig. 1). There was no loss of patients at the 6- and 18-month evaluations. Unfortunately, no examination results after 12 months could be obtained because of the first wave of the SARS-CoV-2 pandemic, which limited clinical examinations.

Table 4 presents all the details about the baseline related to the research subjects and characteristics of the restored lesions. The Cohen kappa statistics showed very good agreement between the examiners in the follow-ups at 6 and 18 months (0.94). All the study subjects were assessed at the baseline and follow-ups after 6 and 18 months.

Retention/fracture

The clinical evaluations after 6 months showed that five restorations were lost or fractured (three with PB-SE and two with CQ-SE). According to the evaluation criteria, the retention rates at 6 months (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-ER ($p>0.05$; Tables 6 and 7). There was no signifcant difference when the data of the results at 6 months for each group were compared with the baseline findings ($p>0.05$; Tables 5 and 6).

The clinical evaluations after 18 months showed that ten restorations were lost or fractured (two with PB-ER, four with PB-SE, and four with CQ-SE). According to the evaluation criteria, the 18-month retention rates (95% CI) were 95.5% (92–100%) with PB-ER, 90.9% (82–98%) with PB-SE, 100% (92–100%) with CQ-ER, and 90.9% (82–98%) with CQ-SE, with no statistical difference identified between any pair of groups ($p>0.05$; Tables 5 and 6). When the 18-month results for each group were compared with the baseline results, there was no significant difference ($p>0.05$; Tables 5 and 6). Table 7 shows the absolute risk of retention/ fracture for each of the groups, as well as the risk ratio in the PB-ER group. The fact that the 95% CI interval of the risk ratio crossed the null value of one meant that none of the results for the groups were different from those when using the most traditional approach of placing composites (PB-ER).

Marginal adaptation

When the FDI criteria were used for the 6-month evaluation results, 18 restorations were considered to have minor discrepancies (three with PB-ER, seven with PB-SE, two with CQ-ER, and six with CQ-SE; Table 5). Using the USPHS criteria, four restorations were scored as “bravo” (two with PB-SE and two with CQ-SE; p>0.05; Table 6). No significant differences were found between the two groups during the 6-month evaluation using the two assessment criteria (p>0.05; Tables 5 and 6).

When the FDI criteria were used for the 18-month evaluation results, 17 restorations were considered to have minor discrepancies (two with PB-ER, two with PB-SE, four with CQ-ER, and nine with CQ-SE; Table 5). A signifcant difference was detected between the CQ-ER and CQ-SE groups at the 18-month follow-up, and a signifcant difference was detected for the CQ-SE group when the baseline and 18-month evaluation results were compared (p were scored as “bravo” for marginal adaptation (three with CQ-SE; p>0.05; Table 6).

Marginal discoloration

No restoration showed marginal discoloration during the clinical evaluation after 6 months for either criterion. Sixteen restorations were considered to have small discrepancies in the evaluation after 18 months when using the FDI and USPHS criteria (one with PB-ER, five with PB-SE, two with CQ-ER, and eight with CQ-SE; Table 5). A significant difference was found between the ER and SE groups during the evaluation after 18 months. When comparing the baseline and 18-month evaluation results, a significant difference was also detected for each SE group (p0.05; Table 6).

Other clinical parameters

No postoperative sensitivity was observed in any restoration during the 6- and 18-month evaluations using the FDI and USPHS criteria. No restoration showed the recurrence of caries after 6 and 18 months for either criterion (Tables 5 and 6).

Table 4 Characteristics of the Research Subjects and the Non-carious Cervical Lesions (NCCLs) per Group

Characteristics of research subjects	Number of lesions
Gender distribution	

Male	12
Female	12
Age distribution (years)	
20-29	00
30-39	08
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 5. Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria.

FDI Criteria	(**)	BASELINE				6 MONTHS				18 MONTHS			
		PB-ER	PB-SE	CQ-ER	CQ-SE	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	41	34	42	32
	B	--	--	--	--	--	--	--	--	01	05	02	07
	C	--	--	--	--	--	--	--	--	--	--	--	01
	D	--	--	--	--	--	--	--	--	--	--	-	--
	E	--	--	--	--	--	--	--	--	--	--	--	--
Fractures and retention	A	44	44	44	44	44	41	44	42	42	39	44	40
	B	--	--	--	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	01	--	--	--	--	--	--
	E	--	--	--	--	--	02		02	02	04	--	04
Marginal adaptation	A	44	44	44	44	41	34	42	38	42	37	40	31
	B	--	--	--	--	03	06	02	06	02	02	04	06
	C	--	--	--	--	--	01	--	--	--	--	--	03
	D	--	--	--	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	A	44	44	44	44	44	42	44	42	42	39	44	39
	B	--	--	--	--	--	--	--	--	--	--	--	01
	C	--	--	--	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--	--	--	--
Recurrence of caries	A	44	44	44	44	44	42	44	42	42	39	44	40
	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 6. Number of evaluated restorations for each experimental group (*) classified according to the Modified US Public Health Service (USPHS) criteria.

USPHS Criteria	(**)	BASELINE				6 MONTHS				18 MONTHS			
		PB-ER	PB-SE	CQ-ER	CQ-SE	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	42	38	44	38
	B	--	--	--	--	--	--	--	--	--	01	--	02
	C	--	--	--	--	--	--	--	--	--	--	--	--
Fractures and retention	A	44	44	44	44	44	41	44	42	42	39	44	40
	B	--	--	--	--	--	1	--	--	--	--	--	--
	C	--	--	--	--	--	02		02	02	04	--	04
Marginal adaptation	A	44	44	44	44	44	40	44	40	42	39	44	37
	B	--	--	--	--	--	--	--	02	--	--	--	03
	C	--	--	--	--	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	A	44	44	44	44	44	42	44	42	42	39	44	40
	B	--	--	--	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--	--	--	--
Recurrence of caries	A	44	44	44	44	44	42	44	42	42	39	44	40
	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

Table 7. Absolute risk (95% CI) and relative risk (95% CI) for outcome retention/fracture for different groups after 18 months of clinical evaluation

	Absolute risk (95% CI)	Relative risk (95% CI)*
PB-ER	4.5 (1.2 - 15.1)	
PB-SE	9.1 (3.6 – 21.2)	-1.0 (-9.3 – 0.6)
CQ-ER	0.0 (0.0 - 8.0)	1.0 (0.0 – 0.0)
CQ-SE	9.1 (3.6 – 21.2)	-1.0 (-9.3 – 0.6)

(*) Related to group 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

DISCUSSION

Clinicians desire not only a reduction in the number of application steps but also quicker application times for dental adhesives, which is the major appeal of the “no-waiting” concept [24, 28]. Some industries have launched universal adhesives for applications using this technique, one of which is CQ. The null hypothesis in the present study was accepted, and the results showed that when CQ was applied with the “no-waiting” technique to non-carious cervical lesions using the ER and SE strategies, the retention levels over 18 months of clinical service were similar to those when PB was applied using the standard application method (20 s).

It is widely accepted that clinical studies on non-carious cervical lesions are very reliable when evaluating the performances of adhesive systems, especially because retention is the most important aspect when a restoration performed on an non-carious cervical lesion is evaluated [38]. This is considered a true outcome because if the restoration is lost, none of the other parameters can be evaluated. Therefore, according to the results of the present clinical trial, when applied using both adhesive strategies, when CQ was applied using the “no-waiting” technique, it showed a very good clinical performance, with retention rates of 97.8% (100% for ER and 95.5% for SE) after 6 months and 95.5% (100% for ER and 90.9% for SE) after 18 months.

As indicated by the CQ manufacturer, in addition to 10-MDP, which provides chemical interaction for bond promotion [7, 39], the addition of a new multifunctional hydrophilic acrylamide amide monomer [24] reduces the 2-hydroxyethyl methacrylate (HEMA) content (2.5–10%) [40] compared to prior generations of adhesives. HEMA is a highly hydrophilic monomer that can be found in most adhesives on the market [41]. However, higher concentrations of

HEMA may make the adhesive interface susceptible to water sorption and the long-term degradation of the adhesive properties [42].

In a recent study, Kuno et al. [25] claimed that the mechanical properties are improved, and the water sorption is decreased in the presence of a multifunctional amide monomer, when compared to an experimental version with the same composition as 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 greater hydrophilicity before polymerization [39]. Additionally, a lower octanol/water partition coefficient promotes a better and deeper infiltration of resin monomers into demineralized dentin, which, along with better polymerization, promotes the formation of a stable polymer network and induces stronger micromechanical interlocking [25–27]. All these features made it possible to minimize the adhesive bonding time dependency. In fact, in vitro studies showed that there were no benefits when the time was increased in terms of the resin–dentin bond strength with CQ [25, 27], even after water storage [43].

Of course, it is worth mentioning that PB also showed very good clinical performances with both adhesive strategies in the present study, with retention rates of 96.6% (100% for ER and 93.2% SE) after 6 months and 93.2% (95.5% for ER and 90.9% for SE) after 18 months of clinical service. This could be attributed to the fact that PB contains 10-MDP and is a HEMA-free adhesive [7, 39, 42]. According to the manufacturer, owing to its hydrophilic core and five double bonds per molecule, dipentaerythritol pentacrylate phosphate (PENTA) is an effective crosslinker agent that is responsible for increasing the wettability of PB. PENTA was used in different “Prime&Bond” adhesive generations (Dentsply Sirona), and despite the controversial results observed when previous generations of PENTA containing adhesives were evaluated [22, 44, 45], in vitro studies have shown that PB has a higher resin–dentin bond strength than other universal adhesives [24, 46, 47]. This was one of the main reasons for using this material as a control in the present study. Another factor that could explain the excellent clinical performance of PB is the application time. The manufacturer of PB recommends an application time of 20 s instead of 10 s. It is well known that a longer application time results in better bonding to dentin [48, 49].

It is worth mentioning that the literature indicates that it is necessary to use a gold standard adhesive as a control group [50]. However, because gold standard adhesives are not simple adhesives, the presence of an additional hydrophobic coat in these materials could be a source of bias in the interpretation of the results. A recently published systematic review showed that there were no randomized clinical trials of non-carious cervical lesions to support the widespread concept that some adhesives (gold standard) are better than other competitive brands available in the dental market [51].

Regarding marginal adaptation, although no significant difference was observed in the clinical evaluation after 6 months, more marginal discrepancies in the enamel were observed, as well as marginal discoloration when both universal adhesives were used with the SE strategy compared to the ER strategy in the clinical evaluation after 18 months. It is well documented that the enamel etching depth is minimal when SE adhesives are applied, especially mild/ultra-mild adhesives (pH=2.3 for CQ and pH=2.6 for PB) [52–54].

However, there were larger marginal deviations with CQ-SE than with PB-SE, particularly when using a more sensitive criterion. In fact, it is well established that extending the application time of a mild/ultra-mild universal adhesive in the SE mode may be a viable alternative to phosphoric acid enamel etching [54–57]. Thus, the “no-waiting” technique could have been responsible for the shallow etching pattern on the enamel surface, leading to the premature marginal discrepancies.

Although different clinical trials have shown that the marginal discrepancies of restorations performed with universal adhesives in the SE mode usually develop rather rapidly [12–21], particularly when FDI criteria have been instead of USPHS criteria [12, 13, 15, 19, 20, 44], most marginal defects are easily solved with repolishing [58]. In the present study, two clinical criteria were used to evaluate restorations (USPHS and FDI criteria). For more than three decades, USPHS criteria have included a practical approach to assess the clinical performance of repair materials [33, 36, 59]. However, despite some signs of clinical degradation observed by clinicians, restorations are usually classified as very good when USPHS is used, which means that this criterion is not sufficiently discriminative to detect small changes in the clinical performances of adhesive restorations [33, 60]. This was the main reason for the development of

the FDI criteria [33, 60]. Several clinical studies have shown that FDI provides a more sensitive and discriminative scale than the USPHS criteria [61]. However, despite these advantages of the FDI criteria, it was important to report the data for both criteria, mainly because several recently published clinical trials continued to use USPHS [18, 22]. Finally, an 18-month follow-up should be considered a medium-term evaluation, and clinical trials have greater value when published after a long-term follow-up. Thus, long-term monitoring studies are needed to test this hypothesis.

CONCLUSION

The clinical performance regarding the retention of CQ when using the "no-waiting" technique was similar that with the PB adhesive with the standard application, showing rather satisfactory results when applied to non-carious cervical lesions using the ER and SE strategies, as seen in clinical evaluations after 6 and 18 months.

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Declarations

Ethics approval

This clinical trial was approved (3.078.493) by the ethics and research committee of the CEUMA University. It was registered in the Brazilian Clinical Trials Registry (REBEC) under registration number RBR-5f9gps. All procedures performed on human participants obeyed the ethical standards of the institutional and/or national research committee and with the Declaration of Helsinki of 1964 and its subsequent changes or comparable ethical standards. Participants who met the eligibility criteria signed an informed consent form before enrolling in the study. Details that would reveal the identity of the subjects studied were not included.

Consent to participate

Informed consent was obtained from all individual participants included in the study.

Conflict of interest

The authors declare no competing interests

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CAPÍTULO 2

Prolonged application time effects on universal adhesives in non-carious cervical lesions: An 18-month split mouth randomized clinical trial.

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ABSTRACT

Objective: This double-blind, split mouth randomized clinical trial aimed to assess the clinical performance of Clearfil Universal Bond Quick (CBUq) universal adhesive under different application times (no waiting and waiting) compared to Clearfil SE Bond adhesive in non-carious cervical lesions (NCCLs) over 18 months. **Methods:** One hundred and eighty-three restorations were distributed randomly into three groups based on the adhesive system and waiting time: CUBq without waiting time (CUBq-NW), CUBq with a 20 s waiting time (CUBq-W), and CSE with a 20 s waiting time. After placement, restorations were evaluated after 18 months using the International Dental Federation (FDI) and United States Public Health Service (USPHS) criteria. Statistical analyses involved Friedman repeated measures analysis of variance and Wilcoxon tests, with a significance level set at 5 %. **Results:** Over the 18-month period, no restorations were lost across the tested groups. Marginal adaptation evaluation indicated minor discrepancies in 21 restorations (8 CUBq-NW, 6 CUBq-W, and 7 CSE). There were no significant differences observed among the three groups following the 18-month clinical assessment ($p > 0.05$). Only two restorations showed marginal discoloration after 18 months (1 CUBq-NW and 1 CSE). **Conclusions:** The application of Clearfil Universal Bond Quick using either the "waiting" or "no-waiting" technique exhibited excellent clinical results in NCCLs during the 18-month follow-up period, demonstrating comparable performance to Clearfil SE Bond in all assessed outcomes.

Clinical significance: The findings suggest that the new universal adhesive applied using the no-waiting technique demonstrates promising clinical performance when compared to conventional application methods.

Trial registration: ClinicalTrials.gov identifer RBR-69p7mpr.

Keywords: Non-carious cervical lesions, Adhesive, No waiting technique, FDI criteria.

1. INTRODUCTION

Adhesive dentistry has undergone a remarkable progress in the past two decades, with significant advancements in a bonding technology playing a pivotal role [1]. To meet clinicians' demand for a faster, less technique-sensitive, and more user-friendly bonding techniques, universal adhesives (UAs) have been developed [2,3]. These UAs can be adapt to various adhesive strategies, such as etch-and-rinse (E&R) or self-etch (SE) [4,5] or selective enamel etching (SEE), with SEE combining ER on enamel and SE on dentin [6,7]. Additionally, they are suitable for different indirect substrates [8].

Their versatility is significantly attributed to the incorporation of acidic functional monomers in the methacrylate formulations [6,9]. These monomers interact with dental substrates promote chemical adhesion [10,11]. Particularly, the inclusion of functional monomers, especially, 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP), enhances the self-etching potential on enamel [12,13] and improves the long-term durability of dentin and enamel bonding [11] by facilitating stable ionic bonding with calcium, forming structured nano-layers of MDPCa salts at the interface with hydroxyapatite [14].

Although UAs have demonstrated adequate in vitro performance [8, 15] and clinical success [16–18], ongoing efforts to reduce application time and enhance technique sensitivity have led to the development of new technologies. One example is a "no-waiting" technique, which advocates for reduced of adhesive application time [19–21]. Clearfil Universal Bond Quick adhesive (CBUq) employs this concept, featuring. Multifunctional hydrophilic acrylamide amide monomer (rapid bond technology) [22] that enhances subsurface dentine wetting, thereby decreasing application time [23,24].

A review of the reveals conflicting results from in vitro studies using the "no-waiting" technique with CBUq [24–27]. Despite several recent randomized clinical trials assessing the performance of CBUq in non-carious cervical lesions (NCCLs) [28–30], to extent of authors' knowledge, no previous clinical studies have compared CUBq applied in "no waiting" vs "waiting" technique.

Therefore, this double-blind randomized clinical trial aims to evaluate the clinical performance of the CBUq universal adhesive in different application times (no waiting and waiting) compared to a 2-step SE adhesive in NCCLs after 18

months. The study's null hypotheses are (1) CBUq applied with the "no waiting/waiting" technique will demonstrate comparable clinical performance (with retention/fracture as the primary outcome) in NCCLS between them and when compared to the 2- step SE adhesive after 18 months of clinical evaluation and (2) CBUq using the "no waiting/waiting" technique will show similar clinical performance in the marginal staining, marginal adaptation, spontaneous post-operative sensitivity, and recurrence of caries as secondary outcomes in NCCLS between them and when compared to 2-step SE adhesive after 18 months of clinical evaluation.

2. MATERIALS AND METHODS

2.1. Trial design

This a double-blind, split mouth and equivalent randomized controlled clinical trial was conducted between February 2021 and May 2021 at the clinics of the School of Dentistry, Ceuma University` a. The research project was submitted to evaluation by the Ethical Committee of Ceuma University` a, which approved the protocol and granted permission for the study to proceed (protocol 4.748.555). Prior to the beginning of the treatment, written informed consent was obtained from all participants.

The present study was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement [31], and the research protocol was registered at the Clinical Trial Registry under the identification number RBR-69p7mpr. No changes were performed in the protocol after trial commencement.

2.2. Participants: eligibility criteria

Two pre-calibrated dental residents conducted an examination on 45 participants to determine their eligibility for the study (Fig. 1). The evaluations were performed using an intra-oral mirror, explorer, and a periodontal probe. Participants had to be in good overall health (ASA I, a normal healthy participant; and ASA II, a participant with mild systemic disease without substantive functional limitations) [33], be older than 18 years old and less than 60 years old, a satisfactory oral hygiene level with no periodontal disease in accordance with the

Simplified Oral Hygiene Index (OHI-S) [34], and present at least 20 teeth under occlusion [35].

Participants needed to have at least three comparable NCCLs in terms of size, format, and dimensions in three different teeth that needed restoration. The NCCLs had to be non-carious, non-retentive, deeper than 1 mm and involve both the enamel and dentin of vital teeth without mobility. The cavo surface margin could not involve more than 50 % of enamel [35,36].

The study excluded individuals with extremely poor oral hygiene (OHI-S more than 3) [34], severe or chronic periodontitis (with bleeding on probing and clinical attachment loss more than 3 mm in more than four teeth) [37] heavy bruxism habits (severe masticatory muscle pain, temporomandibular joint pain, or extreme tooth wear) [38] or using orthodontic devices or removable prothesis were also excluded, as they required other treatments prior to restorative intervention. The study also did not include participants with known allergies to resin-based materials or any other materials used in the study, pregnant or breastfeeding women, or individuals who chronically took anti-inflammatory, analgesic, and psychotropic drugs [35].

2.3. Participants: settings and location

All the data were collected in the dental clinics of the Ceuma University coordinated by study director.

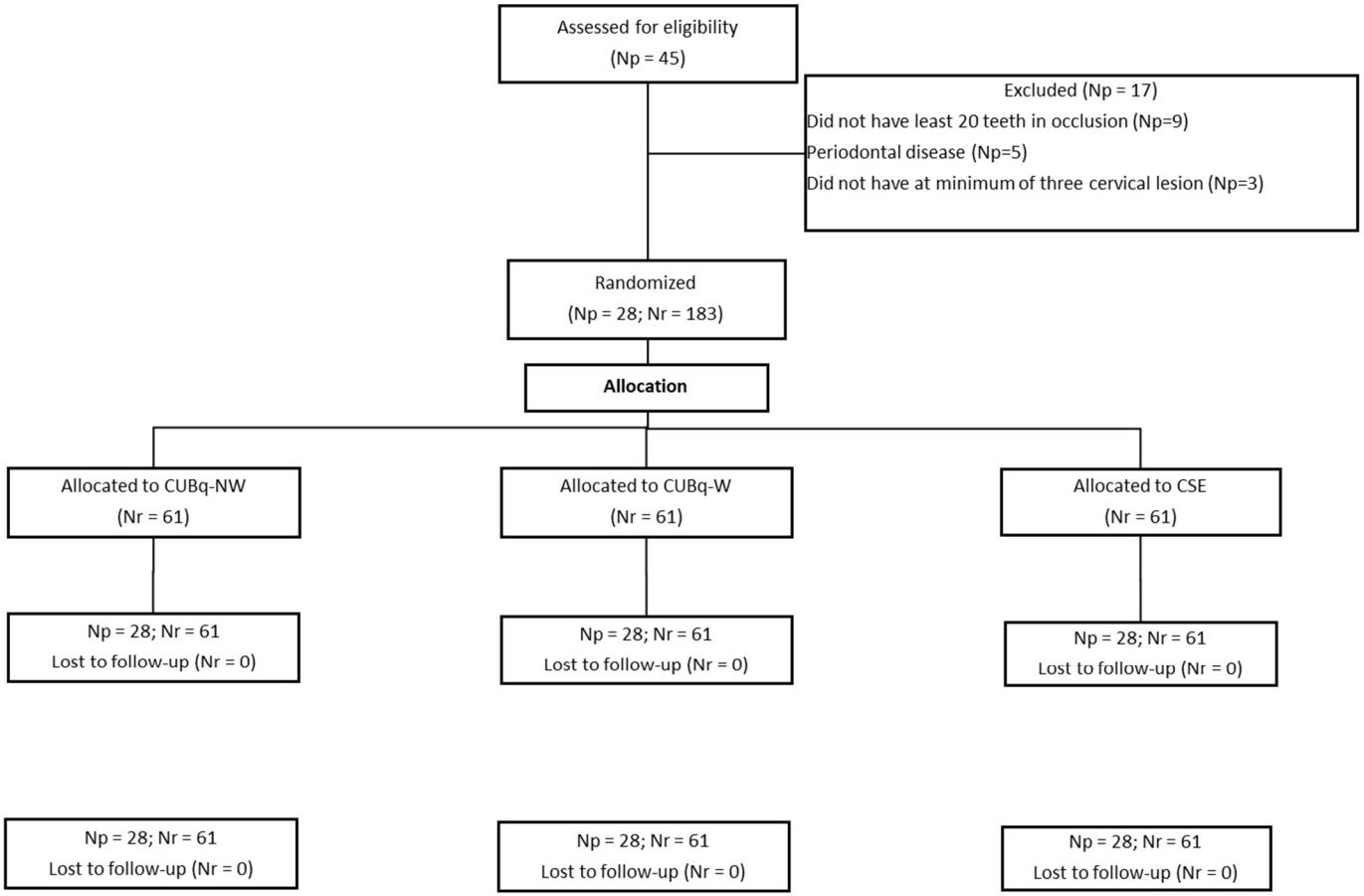

Figure 1. Participant flow diagram in the different phases of the study design. Abbreviations: Np – number of participants; Nr – number of restorations.

2.4. Interventions: characteristics of the selected teeth

Prior to the placement of the restorations, two trained and calibrated dentists involved in the selection of participants evaluated the features of all NCCLs. For this study, all participants underwent dental prophylaxis with a mixture of pumice and water in a rubber cup. The degree of sclerotic dentin from the NCCLs was assessed using the criteria outlined by Swift et al. [39]. The dimensions of the cavity, in millimeters (height), as well as its geometry (evaluated by profile photograph and labeled at 135◦) [40]. Others features, such as the presence of attrition facets and antagonist, were also observed and recorded [41]. Pre-operative sensitivity was also evaluated using an explorer (spontaneous) and by applying air for 10 s from a dental syringe placed 2 cm from the surface of the tooth (air dry). This information was collected to enable the comparison of baseline features of the dentin cavities among the experimental groups.

To standardize the restorative procedure, the study director placed one restoration from each group to identify all the steps involved in the restorative technique. Then, one experienced operator, (who specialized in esthetic dentistry and had more than 10 years of clinical practice), placed all restorations in a clinical setting, under the supervision of the study director. Restoration failures were identified and discussed with the operators prior to starting the study. Once this was done, the operators were considered calibrated to perform restorative procedures. The calibrated operators restored all teeth under the supervision of the study director.

2.5. Interventions: restorative procedure

Before starting the restorative procedures, the operators administered anesthesia using a 3 % mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil) and cleaned all lesions using pumice and water in a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil), followed by rinsing and drying. Using a shade guide, the proper shade of the resin composite was determinated, and the tooth to be restored was isolated with cotton rolls and retraction cord (Ultrapak 000, Ultradent Prod., South Jordan, UT, USA). The operators did not prepare any additional retention or bevel. To restore all NCCLs,

all the adhesives were applied using the SE mode associated with selective enamel etching, according to the techniques described below (Table 1):

"No-waiting" technique (CUBq-NW): Clearfil Universal Bond Quick (Kuraray Noritake Dental, Tokyo, Japan) universal adhesive was applied to the entire surface using a microbrush (Cavibrush, FGM Dental group, Joinville, SC, Brazil) for a minimum of 10 s with vigorous rubbing. No waiting time was required. Dried blowing mild air for 5 s, until the adhesive did not move.

Waiting technique (CUBq-W): Clearfil Universal Bond Quick (Kuraray Noritake Dental, Tokyo, Japan) universal adhesive was applied to the entire surface using a microbrush (Cavibrush, FGM Dental group, Joinville, SC, Brazil) for a minimum of 10 s with vigorous rubbing. It was waiting for 20 s. Dried blowing mild air for 5 s, until the adhesive did not move.

Clearfil SE Bond (Kuraray Noritake Dental, Tokyo, Japan): Clearfil SE Primer was applied to the entire surface using a microbrush (Cavibrush, FGM Dental group, Joinville, SC, Brazil) and rubbing for 20 s. Dried blowing mild air for 5 s until the adhesive did not move. Clearfil SE Bond was then applied.

In all groups, adhesives were light curing for 10 s, using an LED light curing unit with an irradiance of 1000 mW/cm2 (Valo, Ultradent Prod. South Jordan, UT, USA). Next, the cavities were anatomy restored with Clearfil AP-X Esthetics 2 (Kuraray Noritake Dental, Tokyo, Japan) placed in increments of up to 2 mm maximum. Each increment was light curing for 20 s at 1000 mW/cm2 (Valo, Ultradent Prod. South Jordan, UT, USA). The restorations were finished immediately using fine and extra-fine #2200 diamond burs (KG Sorensen, Barueri, SP, Brazil) and polished with Jiffy polisher (Ultradent Prod. South Jordan, UT, USA) under constant water-cooling.

Table 1. Manufacturer, batch number, composition and application mode of adhesive used.

Material/ Manufacturer/ Batch Number	pH	Composition (*)	Application mode (**)	
			Selective enamel-etch	SE-mode
Clearfil Universal Bond Quick (CUBq) / 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 37% phosphoric acid in enamel for 30 s. 2. Rinse for 30 s. 3. Air dry for 15 s.	No-waiting technique: CUBq-NW 1. Apply the adhesive with vigorous agitation (no-waiting time). 2. Gently air thin for 5 s. 3. Light cure for 10 s (1,000 mW/cm^2). Waiting technique: CUBq-W 1. Apply the adhesive with vigorous agitation for 20 s. 2. Gently air thin for 5 s. 3. Light cure for 10 s (1,000 mW/cm^2).

Clearfil SE Bond 2 (CSE) / Kuraray Noritake; Tokyo, Japan) / 9S0314	Primer: pH 2.0; Bond: pH 2.4	Primer: 10-MDP, HEMA, hydrophilic aliphatic dimethacrylate, CQ, water Bond: 10-MDP, BisGMA, HEMA, hydrophobic aliphatic dimethacrylate, CQ, initiators, accelerators, silanated colloidal silica.		1. Apply the Clearfil SE Primer for 20 s with vigorous agitation. 2. Gently air thin for 5 s. 3. Apply the Clearfil SE Bond. 4. Light cure for 10 s (1,000 mW/cm^2).

*HEMA: 2-hydroxyethyl methacrylate, Bis-GMA: 2,2 bis[4-(2-hydroxy-3- methacrylyloxy-propoxy)-phenyl] propane, 10-MDP: 10-methacryloyloxydecyl dihydrogen phosphate, CQ: camphorquinone.

** According to the manufacturer's instructio

2.6. Outcomes

Two blinded, experienced, and calibrated dental examiners (which did not participate in the restoration procedures) were responsible for the clinical evaluation. Prior to the assessment, an intra-examiner and inter-examiner agreement of no less than 85 % was necessary [42,43]. All parameters during clinical evaluation were recorded using a standardized paper case report form. The restorations were evaluated by FDI criteria [44] and United States Public Health Service (USPHS) [40] immediately after restorative procedure (baseline), and after 6, and 18-month of clinical service. The 18-month follow-up recall were realized among August to December 2022. Only the clinically relevant measures of the performance of the adhesives were evaluated.

The primary clinical outcome was restoration retention/fracture, but secondary outcome such as marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries were also evaluated. Postoperative sensitivity was assessed one week after the restorative procedure by asking the participant if they experienced any pain during that period.

The evaluated variables were ranked according to FDI criteria as clinically very good (VG), clinically good (GO), clinically sufficient/ satisfactory (SS), clinically unsatisfactory but repairable (UN), and clinically poor (PO). and in the USPHS criteria as Alfa, Bravo, and Charlie. Both examiners independently evaluated all the restorations once. In cases where discrepancies occurred during the evaluations, a consensus was required before the participant was dismissed. No changes were performed in the protocol after trial commencement.

2.7. Sample size calculation

A systematic review found that the annual fracture/failure rate for one-step self-etch adhesives in NCCLs was 4.4 %. [32] This percentage was calculated using a weighted average annual failure rate, which accounts for the non-linear progression of lost restorations. Assuming that restorations lost follow a non-linear pattern, it is predicted that the overall retention rate for these adhesives after 5 years of clinical service will be approximately 78 %. To detect a 25 % difference between test groups with an α of 0.05, power of 80 %, and a

two-sided test, a minimum sample size of 50 restorations in each group is required.

2.8. Randomization: sequence generation

Taking in account that some subjects showed more than three restorations, the randomization was performed in block size of three (to guarantee an equal number of restorations in the groups and prevent disclosure of the allocation concealment). In each block of three the same type of tooth and approximately size were consider (3 premolar, 3 molar, 3 canine or 3 incisor) per participant. The randomization process was carried out using tools found on the website (sealedenvelope.com).

2.9. Randomization: allocation concealment

Details of the allocated groups were recorded on cards and placed inside sequentially numbered, opaque, sealed envelopes. These were prepared by a staff member who was not involved in any of the phases of the clinical trial. The envelopes were only opened on the day of the restorative procedure to guarantee the concealment of the random sequence in order to prevent selection bias. Treatment was administered to the tooth with the highest FDI number first, followed by the tooth with the next number in sequence, and so on until the third tooth, with all other teeth treated in a similar method. This procedure was applied in all participants, regardless the number of restorations to be performed.

2.10. Implementation

The randomization process was carried out by a staff member who was not involved in the research protocol. The envelopes were only opened on the day of the restorative procedure to guarantee the concealment of the random sequence in order to prevent selection bias. To ensure allocation concealment, the coordinator kept the assignment schedule until all data were collected.

2.11. Blinding

This was consider a double-blind study, because participants and the examiners were blinded to the group assignment. Operator was not consider blinding because of the technical differences to application of the various materials. To avoid any potential bias, the examiners did not participate in the

restoration procedures and were therefore kept unaware of the group assignments. The participants were also kept blinded to their respective group assignment, because it is impossible for them recognize the differences between experimental groups.

2.12. Statistical analysis

The statistical analyses followed the intention-to-treat protocol recommended by CONSORT (Consolidated Standards of Reporting Trials) [31]. Descriptive statistics were used to report the distribution of the evaluated criteria [43]. A statistical analysis was performed for each item (retention/fracture, marginal discoloration, marginal adaptation, postoperative sensitivity, and caries recurrence) and for each global parameter (FDI and USPHS). After 6 and 18 months, the differences between the classifications of the three groups were tested using Friedman's repeated analysis of variance classification ($\alpha = 0.05$), and the differences in each group (baseline and after 6, 12 and 18 months) were evaluated using a Wilcoxon test ($\alpha = 0.05$).

For the primary outcome restoration retention/fracture, we also calculated the risk ratio and relative risk of all the approaches relative to the most traditional approach (Clearfil SE Bond). A 95 % confidence interval was also reported. Inter-examiner agreement was measured using the Cohen's kappa statistic. For all the statistical tests, we set a significance level of 5 % (Statistical for Windows 7.0, Stat Soft Inc., Tulsa, OK, USA).

3. RESULTS

3.1. Participant flow

Among the 45 participants initially examined for eligibility, 17 were excluded as they did not meet the inclusion criteria, resulting in the selection of 28 individuals (11 men and 17 women). In total, 183 restorations were placed, with 61 in each group (Fig. 1). The number of restorations per patient was distributed according to the following: 9 patients received 3 restorations each, 8 patients received 6 restorations each, 8 patients received 9 restorations each and 3 patients received 12 restorations each.

3.2. Recruitment

Participant were recruited as they seek for treatment in the clinics of School of Dentistry of the CEUMA university, based on their order of arrival for the screening session, resulting in a sample of convenience. The recruitment period spanned from November 2020 to December 2020. No advertisement was made for participant recruitment. The implementation took place between February 2021 and May 2021. Participants were recalled for a 6-month evaluation between August 2021 and November 2021 and for an 18-month evaluation between August 2022 and December 2022. No participants were lost during the 6- and 18-month evaluations.

3.3. Baseline data

Comprehensive details regarding baseline characteristics of the research subjects and restored lesions are provided in Table 2. Notably, no significant differences were observed between the groups for all variables ($p > 0.45$). Examiner agreement during 6 and 18 months follow-ups was strong, as the indicated by a Cohen's kappa statistics of 0.94.

3.4. Numbers analyzed

All participants were evaluated at baseline and subsequent 6- and 18-months follow-ups (Tables 3 and 4; Fig. 1).

3.5. Outcome and estimation

Regarding retention/fracture, throughout the 18-month period, no restorations were lost or experienced fractures in any of the tested groups (Tables 3 and 4).

In terms of marginal adaptation, at 18 months using FDI criteria revealed minor discrepancies in 21 restorations (8 with CUBq-NW, 6 with CUBq-W, and 7 with CSE; Table 3). Significant differences were observed within all groups when comparing baseline 6- and 18-month evaluation results ($p = 0.006$, $p = 0.02$ and $p = 0.01$, respectively; Table 3). However, no significant differences were identified among the three groups during the 18-month evaluation based on the two assessment criteria ($p > 0.05$; Tables 3 and 4). Employing the USPHS criteria, all restorations were categorized as Alpha for marginal adaptation ($p > 0.05$; Table 4). It is worth noting that, out of 21 restorations that exhibited the

same defects in marginal adaptation according to the FDI criteria, only 2 (9.5 %) were found in restorations performed on the same participants.

For the 18-month evaluation, only two restorations exhibited minor discoloration in the evaluation using the FDI and USPHS criteria (one with CUBq-NW and one with CSE; Tables 3 and 4) in different participants. No significant differences were found between groups at the 18- month follow-up ($p > 0.05$; Table 4).

Recurrence of caries was not detected in any restoration after 6 and 18 months according to either criterion (Tables 3 and 4).

3.6. Ancillary analyses

Performed analyses had been pre-specified in the protocol. No subgroup analysis was done.

3.7. Adverse events

No postoperative sensitivity were observed in any restoration during the 6- and 18-month evaluations based on FDI and USPHS criteria. Also, no others adverse events were recorded in this study.

Table 2. Characteristics of the research subjects and the non-carious cervical lesions (NCCLs) per group.

Characteristics of research subjects	**Number of lesions**			
Gender distribution				
Male	11			
Female	17			
Age distribution (years)				
20-29	02			
30-39	09			
39-49	12			
> 49	05			
Characteristics of Class-V lesions	**Number of lesions**			
	CUBq-NW	**CUBq - W**	**CSE**	**p-value**
Shape (degree of angle)				
< 45	02	02	02	0.96
45-90	41	46	45	
90-135	15	11	11	
> 135	03	02	03	
Cervico-incisal height (mm)				
< 1.5	01	04	03	0.61
1.5-2.5	32	31	27	
2.5-4.0	28	24	27	
> 4.0	-	2	04	
Degree of sclerotic dentin				
1	42	43	40	
2	17	18	20	0.99
3	02	-	01	
4	-	-	-	
Presence of antagonist				
Yes	61	61	61	

No	-	-	-	1.0
Attrition facet				
Yes	04	02	06	0.34
No	57	59	55	
Pre-operative sensitivity (spontaneous)				
Yes	00	00	00	1.0
No	61	61	61	
Pre-operative sensitivity (air dry)				
Yes	30	28	27	0.85
No	31	33	34	
Pre-operative sensitivity (touch)				
Yes	10	10	13	0.75
No	51	51	48	
Tooth distribution				
Anterior				0.42
Incisor	04	02	03	
Canines	09	07	07	
Posterior				
Premolar	31	33	27	
Molar	17	19	24	
Arc distribution				
Maxillary	33	36	32	0.75
Mandibular	28	25	29	

4. DISCUSSION

The clinical durability of bonded restorations continues to be influenced by the application strategy and degradation of the adhesive-tooth interface. The establishment of effective adhesion between different hard tissues remains a challenge for adhesive systems [18,29,30]. While a shorter application time might be desirable for clinicians, simplification can yield adverse effects, including insufficient adhesive infiltration and issues related to solvent evaporation, both on which can jeopardize the quality of adhesion [45]. In response to these challenges, manufacturers have development UAs incorporating the concept of “no-waiting” technique, aimed at minimizing waiting times during adhesive resin application, all while maintaining optimal bonding effectiveness [29].

The result of this study seem to validate the “no-waiting” concept, as similar clinical performance was observed for CBUq applied in the “no waiting” or “waiting” technique. This study is the first to directly compare these application techniques for the same commercial product. Importantly, the clinical performance was excellent, with 100 % retention/fracture rate after 18 months for both techniques, comparable to CSE, a gold-standard SE adhesive in terms of adhesive performance [1], supporting the first null hypotheses.

The manufacturer’s instructions recommend directly applying CBUq to dentin or enamel substrates, air thinning, and light-curing without waiting time (CBUq-NW). Hydrophilic monomers, like HEMA mixed with organic solvents [7–9], are known to be part of simplified adhesives such as UAs, playing a role in water evaporation and monomer diffusion on enamel and dentin surfaces [9]. However, these solvents must be eliminated before adhesive polymerization to ensure bonding durability [45]. The addition of multifunctional hydrophilic acrylamide amide monomers in CBUq facilitates faster resin monomer infiltration into demineralized dentin, allowing for the use of CBUq-NW [24].

According with same authors [24], a commercially available CUBq was compared with an experimental version, replacing the multifunctional amide monomer with HEMA. While the experimental CBUq exhibited improved bond strength with longer application time, the bond strength to dentin was not influenced by waiting time (0–40 s) when using the commercially CUBq [24].

These results are consistent with various studies suggesting that hydrophilic amide incorporation reduces time-dependent bonding performance variations [20,46–48]. Despite some conflicting immediate values results [49,50], no significant difference was observed in the adhesive performance of CBUq over time, regardless of application time [48,50].

Table 3. Number of evaluated restorations for each experimental group(*) classified according to the World Dental Federation (FDI) criteria.

FDI Criteria	(**)	BASELINE			6 MONTHS			18 MONTHS		
		CUBq-NW	CUBq - W	CSE	CUBq-NW	CUBq - W	CSE	CUBq-NW	CUBq - W	CSE
Fractures and retention	A	61	61	61	61	61	61	61	61	61
	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--
Marginal adaptation	A	61	61	61	61	61	61	53	55	54
	B	--	--	--	--	--	--	08	06	07
	C	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--
Marginal discoloration	A	61	61	61	61	61	61	60	61	60
	B	--	--	--	--	--	--	01	--	01

	C	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	A	61	61	61	61	61	61	61	61	61
	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--
Recurrence of caries	A	61	61	61	61	61	61	61	61	61
	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--	--

(*) CUBq-NW, Clearfil Universal Bond Quick - No Waiting technique; CUBq - W, Clearfil Universal Bond Quick - Waiting technique; CSE, Clearfil SE Bond.

(**) A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E= Clinically poor.

Table 4. Number of evaluated restorations for each experimental group (*) classified according to the Modified US Public Health Service (USPHS) criteria.

USPHS Criteria	**(**)**	**BASELINE**			**6 MONTHS**			**18 MONTHS**		
		CUBq-NW	CUBq - W	CSE	CUBq-NW	CUBq - W	CSE	CUBq-NW	CUBq - W	CSE
Fractures and retention	A	61	61	61	61	61	61	61	61	61
	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--
Marginal adaptation	A	61	61	61	61	61	61	61	61	61
	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--
Marginal discoloration	A	61	61	61	61	61	61	60	61	60
	B	--	--	--	--	--	--	01	--	01
	C	--	--	--	--	--	--	--	--	--
	A	61	61	61	61	61	61	61	61	61

Post-operative (hyper-) sensitivity	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--
Recurrence of caries	A	61	61	61	61	61	61	61	61	61
	B	--	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--	--

(*) CUBq-NW, Clearfil Universal Bond Quick – No Waiting technique; CUBq - W, Clearfil Universal Bond Quick - Waiting technique; CSE, Clearfil SE Bond.

(**) A = Alfa; B = Bravo; C = Charlie

Other properties of CBUq contribute to its excellent clinical results. CBUq has shown higher degrees of conversion compared to experimental CBUq [51], which is consistent with previous literature [52,53]. This can be attributed to a new integrated photoinitiator chemistry, previously used for the manufacturer in other adhesives (Kuraray Noritake), enhancing monomer conversion rates [54]. Increase conversion improves mechanical properties and reduces water sorption in CBUq [51]. While these in vitro results explain the excellent clinical outcomes, it is important to note that the clinical performance of CBUq-NW or CBUq-W was similar to CSE, an outstanding adhesive on the market [1, 32].

While CBUq and CSE have differences, they share critical characteristics. Both have a similar pH categorized as "mild" SE adhesive [55], which promotes chemical adhesion, especially with dentin [5,56]. Additionally, according to Ahmed et al. [50], both are likely to contain 10-MDP of the same quality/purity, essential for long-lasting bonding [50]. Notably, this monomer has proven successful in various ’Clearfil’ adhesive generations due to its established bond-promoting/stabilizing chemical interaction [18,47,49].

However, in comparing to previous clinical studies that assessed CBUq-NW in NCCLs restorations, differences emerged in terms of retention rates and marginal discrepancies. Specifically, de Almeida et al. [28] and Oz et al. [29] investigated CBUq-NW using various strategies (SE, ER and SEE), revealing less favorable clinical outcomes when CBUq-NW was employed in the SE strategy [28,29].

It is widely recognized that mild UAs, as CBUq, significantly enhance enamel bond strength when combined with SEE using phosphoric acid before application [20,25]. This is because mild UAs exhibit shallow conditioning pattern when compared to phosphoric acid [25,57]. Moreover, medium [58] and long-term [16] clinical studies support the superiority of the SEE strategy for mild UAs in comparison to the SE strategy in NCCLs. Consequently, the decision to implement SEE for all study groups was guided by these considerations. This choice contributed to the comparable outcomes among groups when assessing marginal adaptation and marginal discoloration, reinforcing the acceptance of the second null hypothesis by the authors.

Notably, when comparing the results of the current study with those of groups that underwent enamel etching, similar retention rates and marginal

discrepancies were observed. In fact, both de Almeida et al. [28] and Oz et al. [29] reported a 100 % retention rate after 18 and 24 months of clinical assessment when enamel etching was applied before CUBq application. In both studies, only a few restorations exhibited signs of marginal degradation [28,29]. Conversely, in another clinical evaluation of CUBq in NCCLs restorations, the authors documented a lower retention rate of 83 % after 3 years of clinical follow-up, regardless of whether enamel etching was employed or not [30]. Given the longer duration of the latter study [30], a higher number of clinical failures might be expected compared to the current and previous studies [28,29]. However, additional factors need to be considered and could contribute to explaining these differences.

Some distinctions between Peumans et al.'s study [30] and the current one warrant mention. While in the present study, involved a single experienced operator (with over 10 years of clinical experience) who placed all restorations, the previous study utilized four operators with less clinical experience (1–3 years), with one of them accounting for the majority of failures [30].

Regarding the sample composition, the current study featured a majority of participants aged between 20 and 50 years (82.1 %), whereas in the previous study, over 50 % of the participants were over 50 years old [30]. Despite lacking previous observations on the influence of age on the success or failure of restorations, age appears to impact the degree of sclerosis in the NCCLs to be restored. It is expected that in a younger population, such as in the present study, the NCCLs to be restored exhibited less sclerosis. Conversely, in the previous study, a higher proportion of NCCLs demonstrated some degree of sclerosis. Specifically, over 68 % of the NCCLs exhibited no sclerosis, while in the latter study, the majority of NCCLs (80 %) displayed some degree of sclerosis. This discrepancy partly justifies the differences observed between the two studies, as bonding to sclerotic dentin presents challenges [30].

Furthermore, in terms of secondary outcomes, the Peumans et al. study [30] similarly reported a higher number of marginal discrepancies compared to the previous one [28,29]. The authors attributed this variation to the use of FDI criteria [30], which are considered more sensitive in detecting minor changes and discrepancies in dental restorations compared to the USPHS criteria [16,59,60] used in the Oz et al. study [29]. These findings align with the results of the present

study. However, despite evaluating restorations using the same FDI criteria, the number of marginal failures documented in the previous study [30] still exceeded the results of the current study when 18-month data of the present manuscript was compared with the 1-year data of Peumans et al. study. [30]. It is important to note that the majority of these marginal discrepancies are clinically acceptable and can be addressed through refinishing and re-polishing of the restoration, as previously described, which emphasizes their lack of clinical significance [30].

However, it is worth noting that despite the recommended application method of CUB-q being "apply and no waiting," there remains some ambiguity regarding the specific duration of application as well as whether rubbing during application is necessary. As a result, the authors of the present study speculate that the divergent outcomes observed in different clinical studies evaluating CUBq may stem from slight variations in the application procedure, including factors such as the presence or absence of rubbing during application, as well as its vigor. As previously described, the adhesive was applied with vigorous rubbing at least 10 s, aligning with the approach advocated by Moritake et al. and Atalay et al. [49,61].

Considering that one of the most important causes of the generation of NCCLs is excessive toot brushing [62], in the present study, the authors provided information to all patients about the correct way to brush their teeth. However, despite being aware of the impact of oral hygiene habits, one study found that even after specific counselling sessions, no behavioral changes were observed regarding tooth brushing [63]. The impact of this educational procedure must be taken into account in future long-term follow-ups of the present study.

The authors need to acknowledge some limitations associated with the present study. One of them is the placement of more than three restorations in several patients, which may have led to a clustering effect. In fact, roughly 2/3 of the included population in this study more than three restorations. This decision was necessitated by the concerns related to the COVID-19 pandemic between November and December 2020.

While the clustering effect is a common occurrence in dental literature [16–18,29,39,41,58,60], a few studies have recommended a more complex statistical analysis [30,64]. However, in the present study, such analysis was not conducted as the majority of defects were observed in different participants.

Future studies should explore the impact of the clustering effect on the performance of non-carious cervical restorations.

Another limitation is the fact that the present study assessed the clinical performance of adhesive systems over a relatively short follow-up period of 18 months. While the results yielded promise and exhibited excellent clinical performance, it remains imperative to undertake future assessments with extended follow-up periods in order to validate these findings. Long-term investigations offer invaluable insights into the stability and endurance of dental restorations, allowing for the identification of potential complications or changes that may arise over prolonged periods of clinical service. Furthermore, lengthier follow-up periods facilitate the assessment of factors such as secondary caries, marginal discoloration, or the emergence of other adverse effects that might not be immediately evident.

5. CONCLUSION

The application of Clearfil Universal Bond Quick using both the “waiting” or “no-waiting” technique demonstrated outstanding clinical outcomes in non-carious cervical lesions during an18 months follow-up period. Notably, the clinical performance was on par with that of Clearfil SE Bond across all evaluated outcomes.

CRediT authorship contribution statement

RAB De Almeida: Methodology, Investigation. FSF Siqueira: Conceptualization, Formal analysis, Writing – original draft. Thiago Verde: Methodology, Investigation. R Naupari-Villasante: Investigation, Writing – original draft. A Reis: Supervision, Writing – review & editing. AD Loguercio: Project administration, Writing – review & editing. AFM Cardenas: Conceptualization, Project administration, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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CONSIDERAÇÕES FINAIS

No experimento 1, foram selecionados 24 indivíduos (12 homens e 12 mulheres). Foram realizadas 176 restaurações, com 44 em cada grupo. Após 6 meses, não foram observadas diferenças significativas entre nenhum dos grupos ou critérios (p>0,05). Após 18 meses, foram perdidas 10 restaurações (p>0,05) (2 com PB-ER [95,5%; IC95%: 92–100%], 4 com PB-SE [90,9%; IC95%: 82–98%], 0 com CQ-ER [100%; IC95%: 92–100%], e 4 com CQ-SE [90,9%; 82–98%]). As restaurações realizadas com a estratégia SE apresentaram mais discrepâncias marginais do que aquelas realizadas com a estratégia ER, principalmente quando os critérios da FDI foram utilizados (p0.05). Os resultados ao utilizar as estratégias CQ-SE e ER com a técnica NW foram semelhantes àqueles ao utilizar as estratégias PB-SE e -ER em aplicações padrão para lesões cervicais não cariosas após 6 e 18 meses de avaliação clínica. Após 6 e 18 meses, a aplicação do Clearfil Universal Bond Quick com a técnica "sem espera" apresentou desempenho clínico semelhante em comparação com a aplicação padrão do Prime & Bond Active aplicada usando o tempo de aplicação de 20 segundos.

No experimento 2, foram realizadas 183 restaurações, com 61 restaurações em cada grupo. O número de restaurações por paciente foi distribuído da seguinte forma: 9 pacientes receberam 3 restaurações cada, 8 pacientes receberam 6 restaurações cada, 8 pacientes receberam 9 restaurações cada e 3 pacientes receberam 12 restaurações cada. Durante o período de 18 meses, nenhuma restauração foi perdida nos grupos testados. A avaliação da adaptação marginal indicou pequenas discrepâncias em 21 restaurações (8 CUBq-NW, 6 CUBq-W e 7 CSE). Não foram observadas diferenças significativas entre os três grupos após a avaliação clínica de 18 meses (p > 0,05). Apenas duas restaurações apresentaram descoloração marginal após 18 meses (1 CUBq-NW e 1 CSE). A aplicação do Clearfil Universal Bond Quick utilizando a técnica "com espera" ou "sem espera" demonstrou excelentes resultados clínicos em LCNCs durante o período de acompanhamento de 18 meses, apresentando desempenho comparável ao Clearfil SE Bond em todos os resultados avaliados. Os achados sugerem que o novo adesivo universal aplicado usando a técnica

sem espera demonstra um desempenho clínico promissor quando comparado aos métodos de aplicação convencionais.

No entanto, ensaios clínicos que apresentem a avaliação dos desfechos com um maior tempo de avaliação ainda precisam ser realizados para esclarecer a efetividade da técnica sem espera.

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APÊNDICE

Universidade Ceuma

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

INFORMAÇÕES SOBRE A PESQUISA:

Título do Estudo: **AVALIAÇÃO DA ESTRATÉGIA ADESIVA DE ADESIVOS UNIVERSAIS EM LESÕES CERVICAIS NÃO CARIOSAS: UM ESTUDO CLÍNICO RANDOMIZADO**

Você está sendo 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, 18 e 36 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 6,18 e 36 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

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Assinatura do sujeito ou responsável

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Comitê de Ética em pesquisa da Universidade Ceuma

Rua Josué Montello 1, São Luís, MA 65075-120

INFORMAÇÕES SOBRE A PESQUISA:

Título da Pesquisa: **Avaliação clínica do Clearfil S3 bond universal quick aplicado em diferentes técnicas nas lesões cervicais não cariosas**

Você está sendo 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, 18 e 36 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 6,18 e 36 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.

_____

Assinatura do participante ou seu representante legal

_____

Pesquisador Responsável

Ms. Rossana Aboud Matos de Almeida - CPF 972072503-

63 Rua: Josue Montello, 1 – UNICEUMA Telefone:

(98)996180199

ANEXOS

CENTRO UNIVERSITÁRIO DO MARANHÃO - UNICEUMA

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO DA ESTRATÉGIA ADESIVA DE ADESIVOS UNIVERSAIS EM LESÕES CERVICAIS NÃO CARIOSAS: UM ESTUDO CLÍNICO RANDOMIZADO

Pesquisador: ROSSANA ABOUD MATOS DE ALMEIDA

Área Temática:

Versão: 2

CAAE: 00983918.5.0000.5084

Instituição Proponente: centro universitario do maranhão-uniceuma

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.078.493

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1222714.pdf	08/11/2018 11:49:01		Aceito
Outros	carta_resposta.docx	08/11/2018 11:47:39	ROSSANA ABOUD MATOS DE ALMEIDA	Aceito
Projeto Detalhado / Brochura Investigador	projeto_novo.docx	08/11/2018 11:46:24	ROSSANA ABOUD MATOS DE ALMEIDA	Aceito
Declaração de Instituição e Infraestrutura	cartadeanuencia.pdf	04/10/2018 10:36:35	ROSSANA ABOUD MATOS DE ALMEIDA	Aceito
Folha de Rosto	Documento.pdf	02/10/2018 11:50:40	ROSSANA ABOUD MATOS DE ALMEIDA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEuniversal.docx	18/09/2018 14:19:44	ROSSANA ABOUD MATOS DE ALMEIDA	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

CENTRO UNIVERSITÁRIO DO MARANHÃO - UNICEUMA

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação clínica do Clearfil S3 Universal Bond Quick aplicado em diferentes técnicas em restaurações cervicais não cariosas

Pesquisador: Andrés Felipe Millan Cardenas

Área Temática:

Versão: 1

CAAE: 45637221.0.0000.5084

Instituição Proponente: CEUMA-ASSOCIACAO DE ENSINO SUPERIOR

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.748.555

Considerações Finais a critério do CEP:

O pesquisador deverá apresentar a este CEP relatório final da pesquisa

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1678023.pdf	18/03/2021 20:33:14		Aceito
Outros	CARTA_DE_ANUENCIA_Equipe.pdf	18/03/2021 20:32:23	Andrés Felipe Millan Cardenas	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TERMO_DE_CONSENTIMENTO_LIVRE_E_ESCLARECIDO.pdf	18/03/2021 20:31:28	Andrés Felipe Millan Cardenas	Aceito
Declaração de Instituição e Infraestrutura	carta_anuencia_ies.pdf	18/03/2021 20:30:39	Andrés Felipe Millan Cardenas	Aceito
Cronograma	Cronograma.pdf	18/03/2021 20:29:59	Andrés Felipe Millan Cardenas	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_CEP.pdf	18/03/2021 20:28:47	Andrés Felipe Millan Cardenas	Aceito
Folha de Rosto	folha_de_rostro.pdf	18/03/2021 20:28:11	Andrés Felipe Millan Cardenas	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não