



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



ANDRÉ MAICO ANTUNES

ASPERIZATION OF DENTAL CAVITY TO MAXIMIZE THE ADHESION
OF COMPOSITE RESIN RESTORATIONS IN PATIENTS WITH
NONCARIOUS CERVICAL LESIONS [NCCL] USING A SELF-ETCH
ADHESIVE SYSTEM: DOUBLE BLIND RANDOMIZED CLINICAL TRIAL

Cascavel – PR

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

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Orientadora: Prof^a Dr^a Fabiana Scarparo Naufel

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“Ama-se mais o que se conquista com esforço”

Benjamin Disraeli

Asperização da cavidade dental para maximizar a adesão de restaurações de resina composta em pacientes com lesões cervicais não cariosas [LCNC] utilizando um sistema adesivo autocondicionante: estudo clínico randomizado duplo cego.

RESUMO

Objetivos: Avaliar clinicamente a longevidade de restaurações de resina composta de pacientes com lesões cervicais não-cariosas (LCNC), asperizadas para maximizar a adesão de um sistema adesivo universal utilizado no modo autocondicionante por até 12 meses.

Foi realizado um ensaio clínico randomizado duplo-cego, com boca dividida, em 31 voluntários, maiores de 18 anos, com pelo menos duas LCNCs com margem máxima de 50% de esmalte, independentemente de sua localização na arcada dentária, com higiene bucal adequada, ausência de doença periodontal, sem lesões de cárie ativas e hábitos parafuncionais, possuíam pelo menos 20 dentes em funcionamento, ausência de grampos ativos de próteses parciais removíveis nos dentes incluídos na pesquisa, totalizando 109 restaurações. Uma randomização pareada foi realizada para selecionar os dentes por paciente que fizeram parte de cada grupo experimental. Grupo 1 (SE) e grupo 2 (SEa), no grupo 2 antes da aplicação do sistema adesivo, a cavidade foi asperizada com broca diamantada esférica FG1014 (KG Sorosen, Cotia, SP, Brasil) em alta velocidade sob refrigeração com pressão suave para 5 segundos. O método de avaliação clínica utilizado foi o critério (FDI) e (USPHS). A retenção de restauração foi avaliada como o resultado primário dentro das propriedades funcionais. Os demais parâmetros clínicos avaliados, dentre as propriedades estéticas foram: descoloração marginal; correspondente às propriedades funcionais: adaptação marginal; e nas propriedades biológicas: lesão de cárie adjacente à restauração e sensibilidade pós-operatória. Os dados foram submetidos à análise estatística descritiva pelo teste de variância de Friedman ($\alpha = 0,05$) e seu desempenho em diferentes momentos será avaliado pelo teste de Mc Nemar ($\alpha = 0,05$). Resultados: 16 restaurações foram perdidas após 12 meses (6 para o grupo SE e 10 para o grupo SEa). Descoloração marginal ocorreu em 1 (SEa) e 14 (5 SE e 9 SEa) das restaurações avaliadas, respectivamente, para os critérios USPHS e FDI. Quatro restaurações (1 SE e 3 SEa) foram classificadas como bravo para adaptação marginal usando os critérios USPHS e 18 restaurações (7 SE e 11 SEa) quando os critérios de FDI foram aplicados. A sensibilidade pós-operatória foi de 2 dentes do SE ao FDI e 1 dente ao SE (USPHS), e nenhum caso de cárie recorrente foi encontrado no estudo.

Relevância Clínica: Com as limitações deste estudo concluiu-se que a asperização não melhorou os resultados de adesão à fratura e retenção.

Palavras-chaves: adesivos dentinários, infiltração dentinária, longevidade

Asperization of dental cavity to maximize the adhesion of composite resin restorations in patients with noncarious cervical lesions [NCCL] using a self-etch adhesive system: double blind randomized clinical trial

ABSTRACT

Objectives: Evaluate clinically the longevity of composite resin restorations of patients with non-carious cervical lesions (NCCL), which was asperized to maximize adhesion of a universal adhesive system used in the self-etching mode for up to 12 months.

A double-blind, split-mouth randomized clinical trial was performed on 31 volunteers, over 18 years of age, with at least two NCCLs with a maximum of 50% enamel margin, regardless of their location in the dental arch, with adequate oral hygiene, absence of periodontal disease, without active caries lesions and parafunctional habits, had at least 20 functioning teeth, absence of active staples of removable partial dentures in the teeth included in the research, totaling 109 restorations. A paired randomization was performed to select the teeth per patient that were part of each experimental group. The group 1 (SE) and group 2 (SEa), before the application of the adhesive system, the cavity was asperized with a spherical diamond bur FG1014 (KG Sorosen, Cotia, SP, Brazil) at high speed under refrigeration with soft pressure for 5 seconds. The clinical evaluation method used was (FDI) and (USPHS) criteria. Restoration retention was assessed as the primary outcome within the functional properties. The other clinical parameters evaluated, among the aesthetic properties were: marginal discoloration; corresponding to the functional properties: marginal adaptation; and on biological properties: caries lesion adjacent to restoration and postoperative sensitivity. The data were submitted to descriptive statistical analysis of variance by Friedman ($\alpha = 0.05$) and their performance at different moments will be evaluated by the Mc Nemar test ($\alpha = 0.05$). Results: 16 restorations were lost after 12 months (6 for the SE group and 10 for the SEa group). Marginal discoloration occurred in 1 (SEa) and 14 (5 SE and 9 SEa) of the restorations evaluated, respectively, for the USPHS and FDI criteria. Four restorations (1 SE and 3 SEa) were classified as bravo for marginal adaptation using the USPHS criteria and 18 restorations (7 SE and 11 SEa) when the FDI criteria were applied. Postoperative sensitivity was 2 teeth from SE to FDI and 1 tooth to SE (USPHS), and no case of recurrent caries was found in the study.

Clinical Relevance: With the limitations of this study it was concluded that the asperization didn't improve the results of adhesion to fracture and retention.

Keywords: dentin adhesives, dentin infiltration, longevity

LIST OF ABBREVIATIONS

RCT	Randomized Clinical Trial
NCCL	Non-Carious Cervical Lesions
SE	Self-etch
SEa	Self-etch Asperization
FDI	International Dental Federation
USPHS	United States Public Health Service
ADA	American Dental Association

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1. Introduction

The adhesive systems available in dentistry are classified according to the treatment they provide to the dental substrate in: conventional and self-etching systems. Nowadays, universal adhesive systems, or multi-mode adhesive systems, have been developed in dentistry, both of which can be used in either conventional or self-etching strategies. The first one use phosphoric acid (10-40%) for demineralization of dental enamel and / or dentin substrates to completely remove the smear layer, whereas the self-etching systems, in turn, replace phosphoric acid by the acid and hydrophilic monomers included in the primer, which will partially or totally dissolve the smear layer, while generating the enamel and dentin conditioning pattern, incorporating the smear layer in the hybrid layer (De Munck et al.¹ 2005, Perdigão² 2010).

From the clinical point of view, it is interesting because it allows a single product to be either of the two adhesive strategies, because it can either be used after prior acid conditioning or without the need for it, adapting clinical situation. (Marchesi et al.³ 2014, Michaud e Brown⁴ 2018, Takamizawa et al.⁵ 2016, Wagner et al.⁶ 2014).

A major challenge for adhesive systems is satisfactory adhesion in both dental substract. This is due to the variability in the morphology of each of these substrates. Enamel is a highly mineralized, consisting of 96% of mineral and 4% of organic substance and water. The inorganic content of the enamel is mainly composed of hydroxyapatite crystals and the organic matrix forming a thin network appearing between the crystals, already dentin has lower inorganic content, higher amount of collagen, moisture, presence of different substrates in the same tissue (tubules, inter- and intratubular dentin, cytoplasmic extensions, tissue fluid) and with variations related to the patient's age, pulp condition and cavity depth. (Nanci⁷ 2013).

As for the behavior of self-etching adhesives systems, although studies have been found to assert that they result in good tensile strength and demonstrate ability to control microleakage (Sadek et al.⁸ 2003, de Souza-Zaroni et al.⁹ 2007). Controversies regarding the clinical performance of these adhesive systems, especially with regard to adhesion to the enamel, since the primer does not have the same capacity of demineralization, when compared to phosphoric acid, being one of the disadvantages of the self-etching protocol is the reduction of the effectiveness of adhesion in enamel.(Perdigão et al.¹⁰ 2014)

In an attempt to improve enamel adhesion, some authors suggest variations in the application technique of these adhesive systems (Strydom¹¹ 2004) suggested to increase the time of application or to apply several adhesive layers. This approach suggests an increase in contact of the acid monomers with the surface of the enamel creating a more retentive pattern. (Jacobsen e Söderholm¹² 1998) report that friction, is an active application of the adhesive systems would improve adhesion by primer diffusion. From this (Loguercio et al.¹³ 2011) performed an in vitro study to evaluate the differences in the active or passive application of 3 self-etching adhesives with different levels of acidity in a period of 3 years, and the results showed statistical difference for the active application, mainly in dentin. The systematic review of (Mahn et al.¹⁴ 2015) states that many factors may influence the clinical performance of class V cavity restorations, including beveling, use of rubber dam and cavity asperization to improve the impregnation of the dentin adhesive system and the formation of the hybrid layer.

Although laboratory tests are the initial step in assessing the number of factors in relation to the binding efficiency of adhesive systems, in vitro studies do not reflect the clinical behavior of the material, these studies serve as indirect evidence on how the adhesive is likely to in the present study, it would be in vivo because oral conditions, such as intraoral temperature, humidity, adhesive bond fatigue, bacterial enzymes and applied forces on the teeth, do not present the possibility of being measured or precisely simulated in studies (Shah et al.¹⁵ 2014). Only in a clinical situation can the actual behavior of adhesive materials be verified. To evaluate the effectiveness of the system "universal" adhesive in their different modes of application, clinical studies should be conducted. (Perdigão et al.¹⁰ 2014)

In order to evaluate the clinical performance of adhesive systems, NCCLs are considered as models according to ADA recommendations (Heintze et al.¹⁶ 2010, Brackett et al.¹⁷ 2010), due to different factors such as: the lesion does not present mechanical retention; the retention of the restorative material will be provided exclusively by the adhesive system; the retention is evaluated in a simple way, that is, presence or absence of the restoration; restoration margins are located in enamel and dentin; these lesions are commonly located on the vestibular face of anterior and pre-molar teeth; these lesions usually occur in several teeth, which facilitates patient selection and the study model to be developed (De Munck et al.¹ 2005, Peumans et al.¹⁸ 2005).

The objective of this study was to clinically evaluate the longevity of composite resin restorations of patients with non-carious cervical lesions (NCCL), which was asperized to maximize adhesion of a universal adhesive system used in the SE mode for up to 12 months.

2. Material and Methods

2.1. Ethical approval and protocol registration

The clinical investigation was approved (protocol number 59413716.8.0000.0107) by the Scientific Review Committee and the Committee for the Protection of Human Participants of the State University of Western Paraná (UNIOESTE). It was registered in the Brazilian Clinical Trials Registry (REBEC) under identification number RBR-3CWRDV. We prepared this article using the protocol established by the Consolidated Standards of Reporting Trials (CONSORT). (Schulz et al.¹⁹ 2011).

2.2. Study design

This study was a randomized, double-blind clinical trial in which the patient and the evaluator were blinded for each patient's group assignment. The study was conducted at the Dental Clinic of the State University of Western Paraná (UNIOESTE) from August 2017 to October 2018. All participants were informed about the nature and objectives of the study but did not know which teeth received the specific treatment under evaluation.

2.3. Inclusion and Exclusion Criteria

A total of 35 participants were examined by two pre-calibrated operative dentistry to check if they met the inclusion and exclusion criteria. Participants were recruited through written advertisements placed on the university's walls. All of the volunteer participants signed an informed consent form before being enrolled in the study. Based on pre-established criteria, we selected 31 subjects who volunteered for this study (Figure 1). The participants included in the present randomized clinical trial were older 18 years old and had good general and oral health. The participants were required present at least 20 teeth under occlusion; at least two NCCL.

Participants with dental prostheses; extremely poor oral hygiene; severe or chronic periodontitis; severe bruxism; parafunctional habits; continuous use of medication that may alter the perception of pain (analgesic, anti-inflammatory); patients undergoing bleaching treatment; pregnant; were excluded.

2.4. Interventions: Restorative Procedure

Participants were examined to evaluated if they meet the inclusion and exclusion criteria by two pre-calibrated evaluators. Initial evaluations were performed using an oral clinical mirror, an explorer, and a periodontal probe.

For the calibration step, the study director F.S.N., placed a restoration of each group in order to identify all steps involved in the application technique. Then two operators who are dentists with more than 2 years of clinical experience placed two restorations of each group under the supervision of the study director in a clinical setting. At this point, operators were considered calibrated to perform the restorative procedure. The same calibrated operators restored all teeth under the supervision of the study director.

The randomization process was carried out at www.sealedenvelop.com in blocks of 2, using tables generated by the same ones made by a third person (statistic), not involved in the research protocol. The individuals selected were randomly divided into a split-mouth design to know which tooth received treatment with or without asperization. The groups distribution was recorded in sequentially numbered cards and placed in opaque and sealed envelopes. In this article, neither the participant nor the operator knew about the assignment of the groups. Once the participant is eligible for the procedure and all initial evaluations are completed, the operator would know which of two protocols to follow in the clinical procedure, immediately prior to the application of the restorative protocol, was not blinded to the when assignment group manage the interventions, because the technique of asperization requires the operator to know which technique is performing.

All subjects received a minimum of two restorations, one from each experimental group, in different cavities previously selected according to the inclusion criteria. The following materials were used in this study: Peak® Universal Bond SE adhesive system (Ultradent Products, USA) and Forma®

Plus composite resin (Ultradent Products, USA) (Table 1). Prior to the execution of the restorations, each lesion was submitted to prophylaxis with a rubber cup (KG Sorensen, Barueri, SP, Brazil). The composite resin color was selected, followed by local anesthesia. Rubber dam was used in all cases with the use of the number 212 retractor clamp modified in its vestibular wing in order to allow a correct gingival adaptation of each case exposing the cervical margin of the lesions (Hu Friedy, Chicago, IL USA) and rubber dam (Madeitex, São Paulo, SP, Brazil).

In treatment 1 (SE) no cavity preparation was performed. In the treatment 2 (SEa) prior to application of the adhesive system was performed asperization of the cavity with spherical diamond tip FG1014 (KG Sorensen, Cotia, SP, Brazil) at high speed under refrigeration, with soft pressure for 5 seconds. Each diamond bur was used in the preparation of 10 wells and replaced to make the other wells.

In the sequence both groups (SE and SEa) will receive the same adhesive procedure: Rinse the preparation and leave it moist, apply Peak SE primer by brushing for 20 seconds in dentin, dry for 3 seconds, apply the Peak Bond enamel and dentin with microbrush for 10 seconds, apply air spray at medium pressure for 10 seconds, light cure for 10 seconds.

Then the composite resin Forma® Plus was used for the 2 groups. This was inserted into the gingival, incisal / occlusal walls and final cover with spatula aid (Hu Friedy, Chicago, IL, USA). Each increment contained a maximum thickness of 2 mm and was photoactivated for 40 seconds. The immediate finishing was performed with diamond tip (KG Sorensen, São Paulo, SP, Brazil), under refrigeration and followed by the application of rubber polishing burs (Astropol, IvoclarVivadent, Liechtenstein). The entire procedure of finishing and polishing was performed under relative isolation with the use of cotton rollers and saliva suckers to facilitate access to the cervical margin (Astropol, IvoclarVivadent, Liechtenstein).

2.5. Sample Size Calculation

The sample size calculation was performed from the 18 and 24-month average retention rate of 94% of the simplified conventional adhesive Adper Single Bond / Adper Single Bond Plus (3M ESPE, St. Paul, MN, USA), which is the predecessor of (1997), "The use of a high-performance" Scotchbond Universal (3M ESPE, St. Paul, MN, USA) (Aw et al.²⁰ 2005, Gallo et al.²¹ 2005, Loguercio et al.²² 2007).

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

2.6. Clinical Evaluation

The clinical evaluation was performed by two previously calibrated evaluators, different from the operator, in order to obtain a standardization in the evaluation procedures. The clinical evaluation method recommended by the International Dental Federation (FDI method) (Table 4) recently proposed by (Hickel et al.²³ 2007, Hickel et al.²⁴ 2010). This method is based on the evaluation of the restorations in several parameters in an increasing ordinal scale of 1 to 5 and the classical USPHS criteria (Table 3) adapted by (Perdigão² 2010, Dalton Bittencourt et al.²⁵ 2005), at baseline and after 6 and 12 months of clinical service. Restoration retention was evaluated as the primary outcome within the functional properties. The other clinical parameters evaluated, among the aesthetic properties were: marginal discoloration; corresponding to the functional properties: marginal adaptation; and in the biological properties: the caries lesion adjacent to the restoration and postoperative sensitivity.

The baseline was performed shortly after the polishing of the restorations and the subsequent evaluation period of 6 and 12 months. The evaluation was performed with the aid of an oral mirror, exploratory catheter and triple syringe (Hickel et al.²³ 2007, Hickel et al.²⁴ 2010). The performance of each restoration was evaluated independently by two calibrated examiners (Cohen's Kappa 85%). In the absence of agreement between the examiners, in relation to the results obtained, a discussion was held to reach a consensus, and this new evaluation was considered definitive.

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

2.7. Statistical analysis

The statistical analyses followed the intention-to-treat protocol according to CONSORT suggestion. This protocol includes all participants in their originally randomized groups, even those who

were not able to keep their scheduled recall visits. This approach is more conservative and less open to bias.

Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each individual item was performed, as well as for each overall parameter (FDI and USPHS criteria). The differences in the ratings of the two groups after 12 months were tested with the Friedman repeated measures analysis of variance by rank ($\alpha=0.05$), and differences in the ratings of each group at baseline and after 12 months were evaluated using the McNemar test ($\alpha = 0.05$). Cohen's kappa statistic was used to test interexaminer agreement.

3. Results

Four of 35 patients were not enrolled in the study because they did not fulfill the inclusion criteria. Thus, 31 subjects were selected and 109 NCCL restorations were performed. Five patients did not return to the 6 and 12 month evaluations, being evaluated in these periods 26 patients, totalizing 88 restorations (Figure 1). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 5.

3.1. Marginal Staining

According to the FDI criteria, 76 restorations at the 6 M recall were considered to have minor discrepancies (clinically good and satisfactory). After 12 M, 71 restorations were considered to have minor discrepancies (clinically good and satisfactory). No significant difference was detected between any pair of groups at 6 M ($p > 0.05$). A significant difference was detected between any pair of groups at 12 M, the marginal staining for SE was significantly higher than those of SEa ($p = 0.0313$ and 0.0078 ; respectively, Tables 5). However, a significantly worse marginal staining was observed within all groups over time, after 12 M ($p < 0.05$; Tables 5), in according with FDI criteria. Despite the high number of the restorations with marginal discrepancy in the FDI criteria, only one of them were considered to have clinically relevant discrepancies (clinically unsatisfactory) in the marginal staining even after 6 and 12 M (Table 7).

When the USPHS criteria were used, only 1 restoration were scored as bravo for marginal

staining at 6 M compared to baseline. After 12 M, only 1 restoration were scored as bravo for marginal staining. No significant difference was detected between any pair of groups at 6 M and 12 M and between recall times within group ($p > 0.05$) (Table 6).

3.2. Fractures and Retention

Fourteen restorations were lost in the 6M evaluation. According to FDI and USPHS criteria, retention rates of 6 M (95% confidence interval) were 91% (79-96%) for SE; and 84% (71-92%) for SEa. At 12 M, twenty-one restorations were lost. According to FDI and USPHS criteria, retention rates of 12 M (95% confidence interval) were; 86% (73-94%) for SE; and 77% (63-87%) for SEa. When the 6M and 12M data in each group were compared with the baseline findings, a significant difference was found between SEa ($p < 0.05$, Tables 5 and 6), and SE group in 6M ($p > 0.05$). When SQUACE was used, there was no statistical difference between the groups in the 6 M and 12 M evaluation ($p > 0.05$; Table 8).

3.3. Marginal Adaption

According to the FDI criteria, 13 restorations at the 6 M recall were considered to have some discrepancies in marginal adaptation. After 12 M, 18 restorations were considered to have some discrepancies in marginal adaptation. Significant difference was detected between any pair of groups at 6 M, the marginal adaptation for SE was significantly higher than those of SEa ($p = 0.0313$; Table 5) and at 12 M the group SE were significantly higher than those of SEa ($p = 0.0078$, Table 5). However, a significantly worse marginal adaptation was observed within all groups over time, after 6 and 12 M ($p < 0.05$; Tables 5 and 7), in according with FDI criteria. Despite the high number of the restorations with marginal discrepancy in the FDI criteria, only two of them were considered to have clinically relevant discrepancies (clinically unsatisfactory) in the marginal adaptation even after 6 and three of them after 12 M (Table 8).

When the USPHS criteria were used, only 3 restorations were scored as bravo for marginal adaptation at 6 M compared to baseline. After 12 M, 4 restorations were scored as bravo for marginal

adaptation. No significant difference was detected between any pair of groups at 6 M and 12 M and between recall times within group ($p > 0.05$) (Table 6)

3.4. Postoperative Sensitivity

None of the restorations showed post-operative sensitivity immediately after restorative procedures according to the FDI and USPHS criteria. After 6 M two and one restorations showed post-operative sensitivity using both the FDI and USPHS criteria, respectively; and after 12 M two and one restorations showed post-operative sensitivity using both the FDI and USPHS criteria, respectively (Tables 5, 6 and 7).

3.5. Recurrence of Caries

No restoration showed recurrent caries lesion at 6 M and 12 M using both the FDI and USPHS criteria (Table 5, 6 and 7).

3.6. General overview

When the FDI criteria for ‘acceptable’ vs. ‘not acceptable’ restorations were applied from the 6 M and 12 M recall in each group were compared with their baseline findings, a significant difference was found only for fracture of restoration for all groups ($p < 0.05$; Tables 5 and 7), except to group SE at 6 M ($p > 0.05$), that is, in total 14 and 21 restorations were considered ‘not acceptable’.

4. Discussion

Even with the criteria for evaluation of dental restorations, proposed by (Hickel et al.²³ 2007, Hickel et al.²⁴ 2010), called FDI criteria, most of the clinical studies evaluating NCCL restorations, use the USPHS criteria (Perdigão et al.²⁶ 2012). A publication (Perdigão et al.¹⁰ 2014) compared the six-month clinical behavior of various adhesive strategies using criteria modified by FDI and USPHS. The results suggested that FDI criteria are more sensitive than the criteria modified by the USPHS to small variations in clinical outcomes when evaluating NCCLs restorations. This finding was corroborated in

the present study, since the marginal discrepancies were measured more frequently in the FDI criteria in relation to the USPHS criteria.

The results of the present study present a statistical difference between the groups tested when the fracture and retention parameter was used, with a greater tendency of fracture and loss of restoration to the group with surface asperization. This corroborates the study in vitro of (Phanombualert et al.²⁷ 2015) which evaluated the asperization in class V cavities performed with diamond bur and laser, obtaining greater microleakage in the group with diamond bur, which could be one of the reasons for the greater failure in the roughened group. However, it differs from the results found in another study (Zimmerli et al.²⁸ 2012) which suggests that a surface preparation (or minimum asperization) with a diamond bur is highly recommended to adhesively restore NCCL, especially from erosion.

As is often described in the literature, marginal defects generally correlate with marginal adaptation and marginal staining. Failure of the adhesive interface over time is a clinical challenge present in NCCL restorations (Farias et al.²⁹ 2015).

Contrary to this study, in a similar survey (van Dijken³⁰ 2010) where the NCCL were evaluated in roughened or not before the application of the adhesive system, the restorations of the roughened cavities had lower loss rates compared to the non-roughened cavities.

Already in accordance with the present study, regarding the retention (Dalkilic e Omurlu³¹ 2012) investigated the removal of the superficial layer of sclerotic dentine through the use of a diamond bur and did not demonstrate improvement in the retention and marginal staining of class V restorations after 24 months. On the other hand, a clinical trial demonstrated that tooth surface wear with a diamond tip before a self-etching application improved the retention rates after 8 years for adhesives used in sclerotic and non-sclerotic dentin.

An earlier study, in which the use of the diamond tip affected the bond strength in relation to the self-etching adhesive system used (Oliveira et al.³² 2003), it was observed that the shear strength of the teeth attached to Clearfil SE Bond was smaller only when the diamond tip used was thicker than the average or fine. Therefore, it may be difficult to compare the results of different studies due to differences in diamond tip marks and thickness tested.

Evaluating the One-Up Bond F nanoinfiltration by Electron Transmission Electron Microscopy (Reis et al.³³ 2004) observed a high deposition of silver grains in both the hybrid layer and the adhesive layer after storage of the specimens in water for a short period. The lattice mode of nanoinfiltration observed in these layers was attributed to the areas where water was present after the adhesive photoactivation. Thus, the residual water inside the adhesive layer can lead to incomplete polymerization of the adhesive, compromising its mechanical properties and consequently its adhesion strength, as observed in this study in some restorations in the group with surface preparations. Therefore, the quality and quantity of smear layer created by different surface preparation methods may be important factors in the use of self-etching adhesive systems, clinical factors such as type and time of conditioning (Oliveira et al.³⁴ 2012) may affect the adhesion of the restorative material to the dental.

Although the conditioning pattern produced by the self-etching adhesive systems is a function of both their acidity, time and the way of application, the self-etching systems produce a very superficial enamel conditioning with reduced micro-porosity for infiltration of the resinous monomers (Loguercio et al.³⁵ 2015, Cardenas³⁶ 2016). This lower conditioning of the self-etching systems may favor margins deterioration, allowing the infiltration of food dyes or bacterial biofilms leading to marginal pigmentation. Although a large number of marginally discrete restorations in FDI criteria were found in our results, only one of them was considered to have clinically relevant (clinically unsatisfactory) discrepancies in marginal staining even after 6 and 12 months. When the USPHS criteria were used, only 1 restoration was scored as brave for marginal staining at 6 M compared to the baseline. After 12 M, only 1 restoration was classified as brave for marginal staining. This can be a good finishing and polishing effect soon after making the restorations.

Regarding postoperative sensitivity, exposed dentin allows the movement of the dentinal fluid to stimulate the nerve fibers of the pulp, causing pain. The treatments basically involve the obliteration of the dentinal tubules, but the pain does not cease completely and is only reduced (Rosa et al.³⁷ 2014), which was also observed in this study, since the teeth presented a reduction in sensitivity. Possibly, the decrease in pain was due to obliteration of the tubules since self-etching adhesives use part of the smear layer as a binding substrate, therefore, monomer impregnated smear buffers serve as a barrier to prevent fluid change within the tubules.

In this study, we evaluated only one adhesive system, so more studies are needed on the subject and these may include the use of more self-etching adhesive systems associated with cavitation asperization, as well as other recall evaluations already planned for this same project, since they can shed light on the clinical behavior of this adhesive system over the years.

5. Conclusion

The multi-mode adhesive Peak® Universal Bond SE adhesive system (Ultradent Products, USA), in the 6 and 12 months period, was within the fracture and retention patterns according to the FDI and USPHS criteria, but when the two groups were evaluated, self-etching asperized showed inferior results for fracture and retention when compared to self-etching group.

6. References

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Table 1. Adhesive System and Composite Resin composition

Material		Composition
Adhesive System	Peak® Universal Bond SE (Ultradent Products, United States)	2-hydroxy ethyl methacrylate (HEMA) • Methacrylated acid monomers • Ethanol • Chlorhexidine di-acetate
Composite Resin	Forma® Plus (Ultradent Products, United States)	Bis-GMA monomers (Bis-Phenol A di-Glycidyl Methacrylate), TEGDMA (triethylene glycol dimethacrylate)

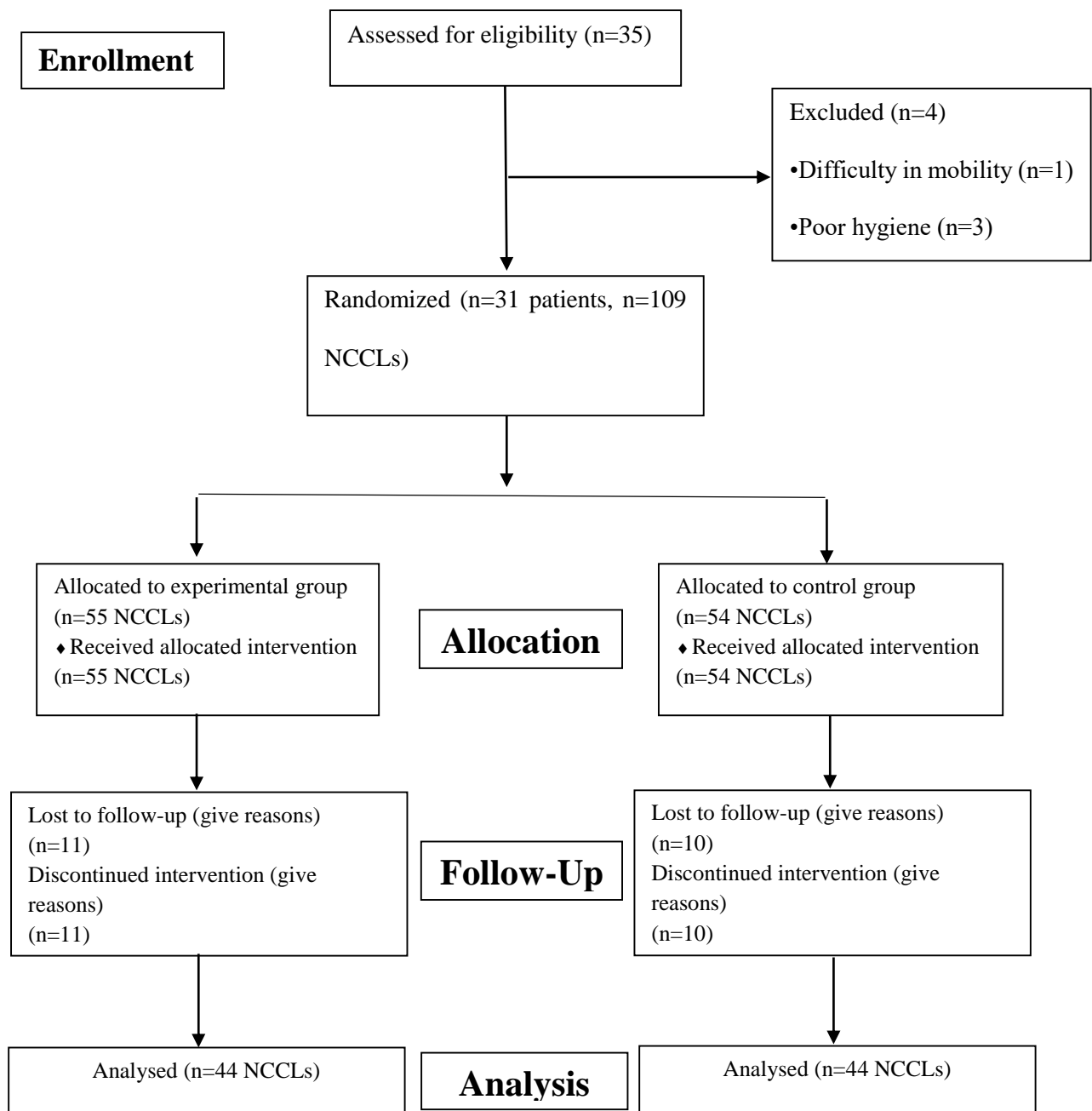
Figure 1. Flow Chart

Table 2. Baseline Characteristics of the Research

Characteristics of Research Subjects	Subjects	
Gender distribution		
Female	19	
Male	12	
Age distribution, y		
18-29	2	
30-39	10	
40-49	7	
>50	12	
Race (%)		
White	92,3	
Black	7,7	
Mulatto	0,0	
Yellow	0,0	
Smoker	1	
Risk of Caries		
Low	31	
High	0	
Characteristics of Class V lesions	SE	SEa
>135	21	22
90-135	26	25
45-90	7	8
< 45	0	0
Cervico-incisal height, mm	SE	SEa
<1.5	13	11
1.5-2.5	24	25
2.5-4.0	12	13
>4.0	5	6
Degree of sclerotic dentin	SE	SEa
1	32	31
2	14	13
3	7	9
4	1	2
Presence of antagonist	SE	SEa
Yes	54	55
No	0	0
Attrition facet	SE	SEa
Yes	16	12
No	38	43
Preoperative sensitivity (spontaneous)	SE	SEa
Yes	2	3
No	52	52

Preoperative sensitivity (air dry)	SE	SEa
Yes	35	34
No	19	21
Tooth distribution	SE	SEa
Anterior		
Incisor	8	10
Canines	10	5
Posterior		a
Pre molar	29	32
Molar	7	8
Arch distribution	SE	SEa
Maxillary	26	29
Mandibular	28	26

Table 3. Modified United States Public Health Service (USPHS) criteria according to Dalton Bittencourt and Others 10 and Perdigão and Others 11

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

Table 4. International Dental Federation (FDI) Criteria Used for Clinical Evaluation 8,9

	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 μ m) 3.2.2 Small marginal fracture removable by polishing	4.2 Low hypersensitivity for a limited period of time	5.2 Very small and localized demineralization No operative treatment required
3. Clinically sufficient/satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically unacceptable	2.3 Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity)	3.3.1 Gap ,150 μ m 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 (dentin not exposed)
4. Clinically unsatisfactory (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement	2.4 Chipping fractures, which damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration)	3.4.1 Gap .250 μ m or dentin/base exposed 3.4.2. Chip fracture damaging margins 3.4.3 Notable enamel or dentin wall fracture	4.4.1 Premature/very intense 4.4.2 Extremely delayed/weak with subjective complaints 4.4.3 Negative Sensitivity Intervention necessary but not replacement	5.4 Caries with cavitation (localized and accessible and can be repaired)

5. Clinically poor (replacement necessary)	1.5 Deep marginal staining not accessible for intervention	2.5 (Partial or complete) loss of restoration	3.5 Filling is loose but in situ	4.5 Very intense, acute pulpitis or nonvital; endodontic treatment is necessary and restoration has to be replaced	5.5 Deep secondary caries or exposed dentin that is not accessible for repair of restoration
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Table 5. Number of evaluated restorations for each group classified according to the World Dental Federation (FDI) Criteria

FDI Criteria		Baseline		6 mo		1 yr	
		SE	SEa	SE	SEa	SE	SEa
Marginal staining	A	54	55	37	34	33	25
	B	0	0	3	2	5	8
	C	0	0	0	1	0	1
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Fractures and retention	A	54	55	40	34	37	30
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	3	1	4
	E	0	0	4	7	6	10
Marginal adaptation	A	54	55	35	29	31	23
	B	0	0	5	5	6	8
	C	0	0	0	1	1	1
	D	0	0	0	2	0	2
	E	0	0	0	0	0	0
Postoperative (hyper-) sensitivity	A	54	55	38	37	36	34
	B	0	0	1	0	1	0
	C	0	0	1	0	1	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Recurrence of caries	A	54	55	40	37	38	34
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0

Table 6. Modified United States Public Health Service (USPHS) Criteria According to Dalton Bittencourt and Others and Perdigão and Others.

USPHS Criteria	Baseline		6 mo		1 yr	
	SE	SEa	SE	SEa	SE	SEa
Marginal staining	A	54	55	40	36	33
	B	0	0	0	1	0
	C	0	0	0	0	0
Fractures and retention	A	54	55	40	34	30
	B	0	0	0	3	1
	C	0	0	4	7	6
Marginal adaptation	A	54	55	40	34	37
	B	0	0	0	3	1
	C	0	0	0	0	0
Postoperative (hyper-) sensitivity	A	54	55	39	37	37
	B	0	0	1	0	1
	C	0	0	0	0	0
Recurrence of caries	A	54	55	40	37	38
	B	0	0	0	0	0
	C	0	0	0	0	0

Table 7. Restorations Acceptable or Not Acceptable According to the Federation Dental International (FDI) Criteria After 12 Months 8,9.

		Group		6 mo		1 yr	
		SE	SEa	SE	SEa	SE	SEa
Marginal staining	Acceptable	54	55	40	36	38	33
	Not acceptable	0	0	0	1	0	1
	Reasons						
Fractures and retention	Acceptable	54	55	40	34	37	30
	Not acceptable	0	0	4	10	7	14
	Reasons						
Marginal adaptation	Acceptable	54	55	40	34	37	31
	Not acceptable	0	0	0	3	1	3
	Reasons						
Postoperative (hyper-) sensitivity	Acceptable	54	55	39	37	37	34
	Not acceptable	0	0	1	0	1	0
	Reasons						
Recurrence of caries	Acceptable	54	55	40	37	38	34
	Not acceptable	0	0	0	0	0	0
	Reasons						

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

FDI Criteria		BASELINE		6 Mo		1 Yr	
		SE	SEa	SE	SEa	SE	SEa
SQUACE	Less Than 10	0	0	0	0	1	0
	Between 10% and 30%	0	0	0	0	0	1
	Between 31% and 50%	0	0	0	3	0	3