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Clinical Research

A Randomized Double-blind Clinical Trial of Dentin Surface Treatments for Composite Restorations in Noncarious Cervical Lesions: A 36-month Evaluation

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Clinical Relevance

Treating dentin surfaces with an ultrasound probe provides similar clinical performance to conventional techniques while increasing acid-etching time results in a higher risk of failure over time.

SUMMARY

Objective: This randomized, double-blind clinical trial aimed to evaluate the influence of different dentin surface treatments in noncarious cervical lesions (NCCLs).

Methods and Materials: Twenty-nine patients participated in this study. One hundred sixty-five NCCLs were selected and randomly assigned to three groups: G0 (control group) with phosphoric acid etching for 15 seconds; G1: phosphoric acid etching for 30 seconds; and G2: ultrasound probe applied for 30 seconds on the dentin surface. Class V composite resin restorations were performed (Z350, 3M ESPE, St Paul, MN, USA). The restorations were evaluated at baseline and at six, 12, 24, and 36 months according to the World Dental Federation criteria. Survival curves were obtained using the Kaplan-Meier method and the log-rank test. Comparisons between groups and times were performed using the McNemar and Chi-square tests (α=0.05).

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Results: The presence of failures due to retention was statistically different among the groups (p=0.012), and G0 and G2 showed better clinical performance than did G1. Sensitivity decreased over time in all groups. Marginal discoloration, postoperative sensitivity, and marginal adaptation were not different among the groups (p>0.05).

Conclusions: The studied dentin surface treatments showed similar clinical performance to the conventional technique at 36 months in terms of marginal discoloration, marginal adaptation, and postoperative sensitivity. In contrast, increased acid-etching time resulted in a higher risk of failure due to retention over time in composite Class V restorations.

INTRODUCTION

Noncarious cervical lesions (NCCLs) are frequently found in adults during clinical practice.[1,2] Almost a quarter of the world's population presents NCCLs, mainly in the premolars.[3] The prevalence of NCCLs has been associated with aging and tooth wear. Often, these lesions need to be restored because of sensitivity, esthetic reasons, or even to prevent further progressive loss of dental structure and to decrease plaque retention.[4,5] Treating NCCLs is often complicated because the operative field must be dry during the restorative procedure, which is clinically difficult because of the proximity of the lesion to the gingiva.[2]

In NCCLs, the critical point of adhesion is the union between the dental structure and the restorative material, especially when a cavity has poor or no retentive features.[6] Thus, to preserve the tooth structure, no dentin surface treatment is performed, or, on the contrary, numerous treatments are adopted that could vary according to the size of the cavity, the dentin substrate, and the type of restorative material to be used.[7] Studies[8,9] have investigated the effect of different dentin surface treatments on the microleakage and adhesion of composite resins in permanent teeth. A drawback of the use of composites in NCCLs might be the substantial differences in the composition of the bonding surface, since NCCLs are mainly located in the dentin, wherein bonding is more difficult to achieve than in the enamel.[9,10] NCCLs also have a high degree of sclerosis, which makes the formation of the hybrid layer on such hypermineralized dentin more difficult.[11,12] In this context, mechanical and chemical dentin surface treatments have been suggested in Class V composite restorations.[5,8-10,13-17]

Dentin surface treatments include the removal of sclerotic dentin, selective enamel etching with phosphoric acid, dentin roughening with a diamond bur, and preliminary etching with ethylenediaminetetraacetic acid.[18-21] Some clinical studies[5] have shown that these surface treatments can improve the retention rate of composites in NCCLs. Other alternative dentin treatments that could be beneficial in Class V restorations are longer durations of acid-etching application and the use of ultrasound on the dentin surface. Only *in vitro* studies have evaluated different application times of acid etching prior to composite restoration in NCCLs,[22-24] and these studies have shown contrasting results. No clinical trials have evaluated the use of ultrasound in NCCLs. Dentin surface treatments aim to increase the longevity of restorations, which is important to prevent the continued restorative cycle and preserve the dental structure and pulp vitality. Therefore, the aim of this randomized, double-blind clinical trial was to evaluate the influence of acid etching and ultrasound dentin surface treatments on the survival of composite Class V restorations. The hypothesis evaluated was that dentin surface treatments would improve the following outcomes: fracture and retention, marginal adaptation, marginal discoloration, and postoperative sensitivity.

METHODS AND MATERIALS

Sample Size Calculation

The sample size was calculated using an average annual failure rate of 6% for composite Class V restorations performed with conventional adhesive systems,[25] with 80% power and a significance level of 5%. The final sample was 28 patients to be monitored for a period of five years, considering a possible loss of 20%.

Patient Selection

The selection of patients was conducted through the dissemination of posters and distribution of pamphlets with information regarding the study in the School of Dentistry, Federal University of Pelotas, Brazil, and in basic health units located in the urban area of Pelotas. This study was approved by the local ethics committee (IRB approval process 035-2011). Patients previously diagnosed with NCCLs were scheduled for a new clinical examination to evaluate if they could be included in this study according to

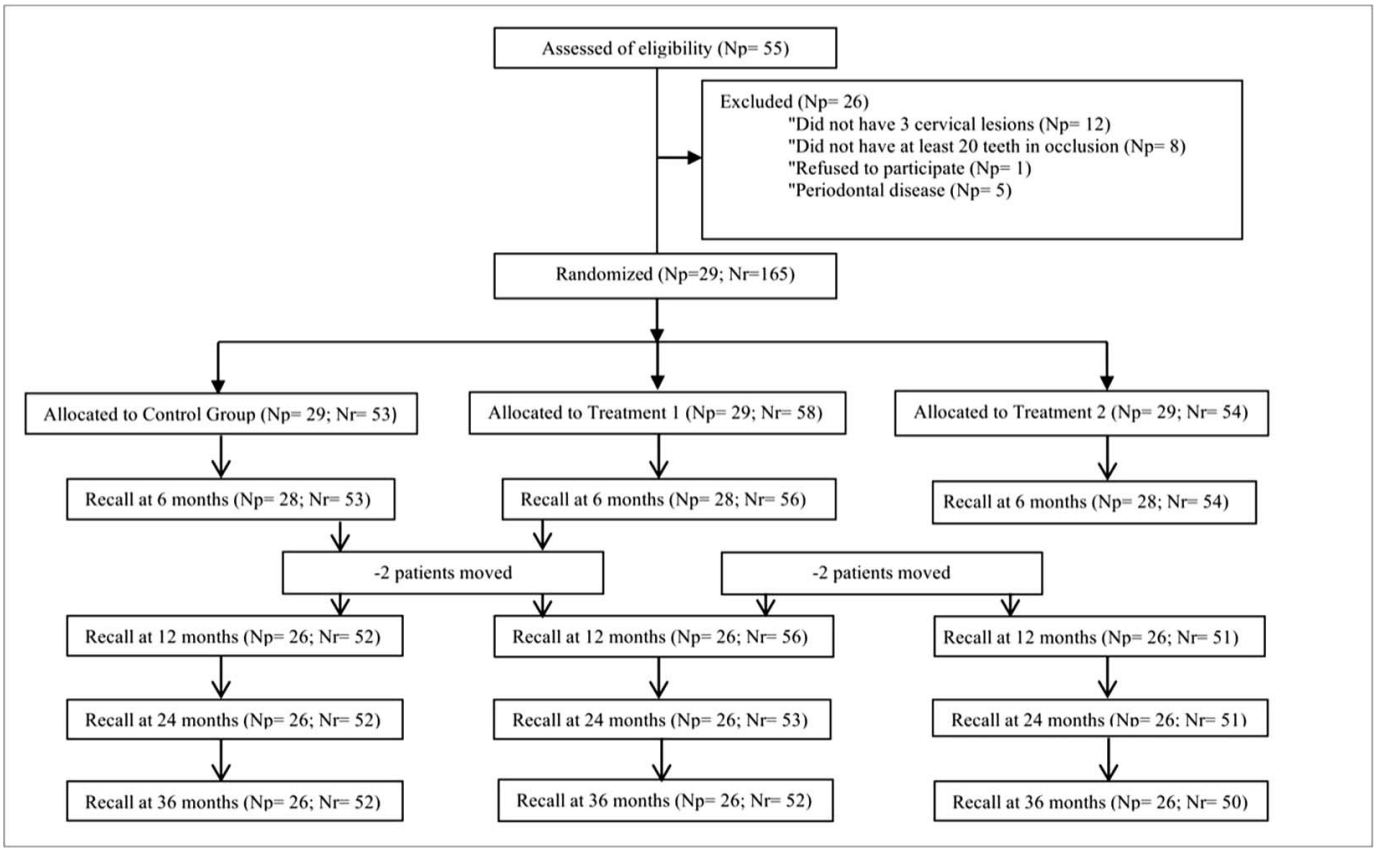

Figure 1. *Flow diagram illustrating the study stages. Np = number of patients; Nr = number of restorations.*

the inclusion and exclusion criteria. Written informed consent was obtained from all patients prior to starting the treatment. Based on preestablished criteria, we selected 29 patients for this study (Figure 1).

Eligibility Criteria

The included patients had to present at least three NCCLs on the buccal surface of vital anterior or premolar teeth. In addition, they had to present with less than 20% of visible plaque index and/or gingival bleeding index, NCCLs with no more than 3-mm probing depth, and good general health. Patients who presented with less than 20 teeth in the oral cavity; those undergoing orthodontic treatment; those with occlusion problems, with caries lesions or restorations on the buccal surface of a tooth, or with veneers or crowns; and those without antagonist teeth were excluded. Patients who met the eligibility criteria received an information letter and an informed consent form to be signed.

Training and Calibration Process

Six dentistry students enrolled in the seventh and eighth semesters participated in the training process. In the first stage of training, a two-hour lecture regarding the materials and techniques used for the removal or modification of the hypermineralized surface layer of non-carious cervical lesions was conducted. A routine detailed protocol to be instituted during the sessions was also presented. A manual containing the instructions and the protocol of clinical procedures was created and given to the students.

In the second stage of training, clinical activities regarding composite Class V restorations were performed in mannequins and in volunteers presenting NCCLs with restorative needs. These volunteers were not included in the study.

At the end of training and calibration, two operators were selected from among the six students initially enrolled to perform the restorative procedures. In addition, two assistants supported the operators and completed the medical records. The

other students were in charge of sterilization of the instruments, scheduling appointments, molding, creating photographic records, oral hygiene orientation, and periodontal treatment; all of these were among the other dental procedures offered to the patients. All of the above-mentioned steps were performed under the direct supervision of a researcher with experience in the field.

Clinical Examination

Clinical assessments were performed in the dental clinic of the Faculty of Dentistry of the Federal University of Pelotas by two previously calibrated examiners, under the supervision of a researcher responsible for the study.

The presence of NCCLs was assessed by visual inspection using a dental mirror. After confirming the presence of NCCLs, the patient's medical record containing identification data and general and dental history was completed. Dental examinations were performed using a dental mirror, a periodontal probe, dental tweezers, cotton rolls, and a dental aspirator.

For the calibration step, the study director placed one restoration within each group in order to identify all the steps involved in the application technique. Thereafter, the operators placed three restorations in each group under the supervision of the study director in a clinical setting. The restoration deficiencies were shown to the operators prior to starting the study.

The randomization process in selecting the dentin surface treatment for each NCCL in the patients was performed using identical opaque envelopes and simple selection by the blinded operators. Allocation assignment was revealed by opening the envelope at the time of the restorative procedure.

Preparation of the Patients

Four weeks before the start of the study, the patients were subjected to a prophylaxis session, which involved smoothing and polishing the supragingival tooth structure. Patients received individualized instruction for the mechanical control of dental biofilm, including guidance on brushing technique and flossing. During the monitoring period, dental support was also offered to patients involved in the study.

Clinical Protocol

Prophylaxis was conducted using a glass and rubber dam–based slurry of pumice and water. The color of the composite was selected using a shade guide (Vitapan Classical, Vita Zahnfabrik, Bad Säckingen, Germany). Local anesthesia was used if necessary before the restorative procedure.

Isolation was accomplished using a lip retractor, retraction cord #000 (Ultrapak Cord, Ultradent, South Jordan, UT, USA), cotton rolls, and a dental aspirator. Cotton rolls were positioned in the upper labial sulcus, in the lower labial sulcus, and in the sublingual region to absorb the saliva flowing mainly from the major salivary glands. The retraction cord was inserted into the gingival sulcus with the aid of a blunt spatula without excessive pressure to the periodontium. Preparation or beveling of cavosurface margins was not performed.

Teeth were randomly divided into three groups according to the techniques used to treat the hypermineralized ultra–surface layer dentin of the NCCLs, as follows:

- Control group (G0): 15-second dentin etching with phosphoric acid (protocol recommended by the manufacturer);
- Experimental group 1 (G1): 30-second etching performed with 37% phosphoric acid gel, prior to the application of the resin adhesive; and
- Experimental group 2 (G2): Ultrasound (EMS Mini Piezon) probe (Instrument B part°: DS-003A) applied for 30 seconds (vibration range from 25,000 to 32,000 pulses/s) on the hypermineralized NCCL dentin surface.

Restorative procedures were performed using a conventional adhesive system (Single Bond II, 3M ESPE, St Paul, MN, USA) and restorative nanoparticulate composite (Filtek Z350, 3M ESPE), following the manufacturer's instructions. The restorations were placed using an incremental technique with about two or three increments of the restorative composite according to the size of the NCCL using spatulas, brushes, and silicone tips for the composite resin. An LED device (Radii Cal, SDI, Victoria, Australia) with an intensity of 1200 mW/cm^2 was used for polymerization. The restoration was finished using a #12 scalpel blade and diamond and fine-grained multilaminated drills in order to remove excess material and/or improve the shape of the contour restorations. Polishing was done with silicone tips, flexible abrasive discs (Sof-Lex Pop-On, 3M ESPE), felts, and polishing discs (3M ESPE).

Clinical Evaluation

Assessment of the restorations was performed by two examiners (graduates in the field of dentistry and

Table 1: *World Dental Federation (FDI) Criteria Used for Clinical Evaluation*[49,50]

	Esthetic Property	Functional Properties		Biological Properties	
	1. Marginal Staining	**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	5.2 Very small and localized demineralization No operative treatment required
3. Clinically sufficient/ satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically unacceptable	2.3 Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity)	3.3.1 Gap < 150 μm not removable 3.3.2 Several small enamel or dentin fractures	4.3.1 Premature/ slightly more intense 4.3.2 Delayed/weak sensitivity; no subjective complaints; no treatment needed	5.3 Larger areas of demineralization, but only preventive measures necessary (dentine not exposed)
4. Clinically unsatisfactory (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement	2.4 Chipping fractures with damage to marginal quality; bulk fractures with or without partial loss (less than half of the restoration)	3.4.1 Gap >250 μm or dentine/base exposed 3.4.2 Chip fracture damaging margins 3.4.3 Notable enamel or dentine wall fracture	4.4.1 Premature/very intense 4.4.2 Extremely delayed/weak with subjective complaints 4.4.3 Negative sensitivity Intervention necessary but not replacement	5.4 Caries with cavitation (localized and accessible and can be repaired)
5. Clinically poor (replacement necessary)	1.5 Deep marginal staining, not accessible for intervention	2.5 (Partial or complete) loss of restoration	3.5 Filling is loose but *in situ*	4.5 Very intense, acute pulpitis or nonvital. Endodontic treatment is necessary and restoration has to be replaced	5.5 Deep secondary caries or exposed dentine that is not accessible for repair of restoration

different from the two operators), previously trained and calibrated with at least 80% intra- and inter-examiner kappa. In the event of a disagreement, direct clinical reevaluation of restorations or evaluation of digital photographs using the clinical criteria was performed, and discussion was conducted to reach a consensus. The examiners were blinded to the experimental groups and clinical assessment was made independently using magnification, mirror, explorer, millimeter periodontal probe, clinical tweezers, cotton rolls, and a dental aspirator. Pulp vitality was measured using cotton balls imbibed with gas jet cooling at −50°C on the surface of the teeth. Dentin sensitivity was evaluated after air jet application for three seconds at a distance of 2-3 cm from the buccal surface. Results were dichotomized as "Yes" or "No." The evaluators also referred to the digital photographs during evaluation.

Factors evaluated included pain perception sensitivity, color change and integrity of the restoration. Clinical evaluations were performed at one week (baseline) and six, 12, 24, and 36 months after the insertion of the restorations using the World Dental Federation (FDI) criteria (Table 1). Loss of restorations was considered a failure due to retention issues.

Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT suggestion.[26] This protocol includes all participants in their originally randomized groups, even those who were unable to adhere to their scheduled follow-up visits. This approach is more conservative and less open to bias. Data were tabulated, and statistical analyses were performed using the Stata 12.0 software package (Stata Corp LP, College Station, TX, USA). To report the frequency distribution of the evaluated criteria, descriptive statistics were used.

Table 2: *Dentin Sclerosis Scale*[a]

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

[a] *Adapted from Swift and others.*[27]

Survival curves were obtained using the Kaplan-Meier method and log-rank test for comparison between groups. Comparisons between groups and between study periods were performed using the McNemar test and Chi-square test, respectively, considering a significance level of 5%.

RESULTS

Descriptive Analysis

Restorations were placed between March 2011 and February 2013. The follow-ups started in July 2012 and ended in February 2016. The control and two experimental groups were placed exactly as planned without modification. One patient did not attend the six-month follow-up, and two patients did not attend the 12- and 36-month follow-ups (Figure 1). The reasons for follow-up losses were relocation from the city and loss of contact information (ie, telephone number or address).

The distribution of NCCLs in the 165 teeth of the 29 patients was almost equivalent between the maxillary and mandibular dentition. The distribution was 13.9% and 15.2% in the incisors and canines, respectively. The NCCLs were mainly localized in the premolars (ie, in more than 70% of the cases). In addition, the shape of the lesions was mostly circular (69.2%), with a diameter (64.8%) and depth of up to 2 mm (64.2%). Clinical observations based on color (Table 2)[27] showed that sclerosis was absent in more than 70% of the lesions, and the degree of sclerosis was mild or moderate in more than 28% of the lesions. Preoperative sensitivity was absent or light in more than 60% of the teeth and moderate-severe or severe in an average of 30% of teeth.

Of the 29 patients, 18 were women and 11 were men. The predominant age was between 49 and 58 years old, accounting for 42.9% of the patients, and over 82% of the patients were 37 years or older (Table 3). The main reason for restoration indicated by the patients was the limitation of lesion progression, corresponding to more than 64% of the responses, followed by esthetic dissatisfaction (42.9%) and dentin hypersensitivity (39.3%). The sample was also categorized according to smoking, daily intake of acidic beverages/foods, presence and types of harmful habits, classification of occlusion, and lateral guidance.

Table 4 shows the two experimental treatment groups and the control group at different times of evaluation of the restorations. In the control group (G0), only one failure (loss of restoration) was observed at the 36-month evaluation; G1 had a greater number of failures of restorations, at seven failures. In G2, two failures were observed at 24 months and two at 36 months. At the end of 36 months, 12 restorations lost in the three treatment groups could be aggregated.

Retention

Failure incidence increased and was statistically different at baseline and at 12, 24, and 36 months ($p<0.05$). The differences were also observed between six months and 24 and 36 months of evaluation ($p<0.05$). Loss of restorations after 36 months were more common in the mandibular (63.6%) premolars (72.7%), with lesions presenting shape angles of more than 135° (72.7%), 3- to 4-mm height (36.4%), and 1- to 2-mm depth (72.7%). No significant differences were observed between baseline and six months, between six months and 12 months, and between 12 months and 24 and 36 months.

In the control group, failure incidence was similar among the studied periods. In G1, more failures were observed at 24 and 36 months than at baseline ($p<0.05$), and the incidence was increased significantly more between 12 and 24 months than at 36 months ($p<0.05$). In G2, failure incidence increased from baseline to 36 months and between six and 36 months ($p<0.05$).

Figure 2A shows the Kaplan-Meier survival graph for failures of the composite. Failure incidence increased over time and was different among the groups (log-rank: $p=0.0124$).

Table 3: *Distribution of Noncarious Cervical Lesions (NCCLs) According to the Studied Patients (Sex and Age) and the Characteristics of Class V Lesions (Shape, Cervico-incisal Size of the Lesion, Degree of Sclerotic Dentin, Presence of Antagonists, Presence of Attrition Facets, Presence of Preoperative Sensitivity, and Tooth and Arch Distribution)*

Characteristics of Research Subjects	No. of Lesions/ Subjects	%
Gender distribution		
Male	11	37.9
Female	18	61.1
Age distribution, y		
18-29	02	6.9
30-39	07	24.1
40-49	06	20.7
>49	14	48.3
Characteristics of Class V lesions		
Shape, ° of angle		
<45	58	35.2
45-90	—	—
90-135	—	—
>135	107	64.8
Cervico-incisal height, mm		
<1.5	11	6.7
1.5-2.5	106	64.2
2.5-4.0	39	23.6
>4.0	09	5.5
Degree of sclerotic dentin		
1	111	67.3
2	39	23.6
3	15	9.1
4	—	—
Presence of antagonist		
Yes	152	92.1
No	13	7.9
Attrition facet		
Yes	—	—
No	29	100
Preoperative sensitivity (spontaneous)		
Yes	128	77.6
No	37	22.4
Preoperative sensitivity (air dry)		
Yes	110	66.7
No	55	33.3
Tooth distribution		
Anterior		
Incisor	23	13.9
Canine	25	15.2
Posterior		
Premolar	117	70.9
Arch distribution		
Maxillary	80	48.5
Mandibular	85	51.5

Marginal Staining /Marginal Discoloration

Marginal discoloration increased significantly ($p<0.001$) from baseline to all the other evaluation times (six, 12, 24, and 36 months). Marginal discoloration after 36 months was more common in the maxillary (52.5%) premolars (67.5%), with lesions presenting 1- to 2-mm height (55.3%) and depth (76.3%). In G0, G1, and G2, baseline staining increased at six, 12, 24, and 36 months ($p<0.001$). In G2, marginal discoloration increased between baseline and 36 months and between six and 36 months ($p<0.05$).

Marginal discoloration observed over the studied periods showed no differences among the groups (log-rank: $p=0.8588$) (Figure 2B). At 36 months, G2 presented more marginal discoloration than did G1 and G0, albeit with no statistical differences.

Marginal Adaptation

Marginal adaptation was not significantly different among the groups (log-rank: $p=0.1744$) (Figure 2C). The Kaplan-Meier survival graph showed that G1 maintained better marginal adaptation than did G0 and G2.

Postoperative Sensitivity

Dentin sensitivity decreased significantly between baseline and the four evaluation times: six, 12, 24, and 36 months ($p<0.001$). Comparisons between six and 36 months showed an increase in sensitivity ($p<0.001$). A similar situation occurred between 12 and 36 months and between 24 and 36 months, wherein sensitivity increased significantly ($p<0.001$). Sensitivity after 36 months was more common in the mandibular (54.5%) premolars (68.8%), with lesions

Table 4: *Number of Restorations in Each Experimental Group Classified According to the World Dental Federation (FDI) Criteria*[49,50]

Hickel Criteria[a]	Baseline			6 mo			12 mo			24 mo			36 mo		
	G0	G1	G2	G0	G1	G2	G0	G1	G2	G0	G1	G2	G0	G1	G2
1. Marginal staining															
VG	53	58	54	53	57	53	52	54	48	51	52	45	50	50	44
GO	—	—	—	—	01	01	01	04	06	02	06	09	03	08	10
SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2. Fractures and retention															
VG	53	58	54	53	56	54	53	57	50	52	54	50	52	55	50
GO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
SS	—	—	—	—	—	—	—	—	01	—	01	02	—	02	02
UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
PO	—	—	—	—	02	—	—	01	—	—	03	02	01	01	02
3. Marginal adaptation															
VG	53	58	53	53	58	52	53	57	54	53	57	53	52	58	52
GO	—	—	—	—	—	02	—	01	—	—	01	01	01	—	02
SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4. Postoperative sensitivity															
VG	53	58	54	50	57	53	51	56	51	52	58	53	51	56	52
GO	—	—	—	03	01	01	02	02	03	01	—	01	02	02	02
SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
5. Secondary caries															
VG	53	58	54	53	58	54	53	58	54	53	58	54	53	58	54
GO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—

Abbreviations: G0, control group; G1, increase the etching time; G2, ultrasound probe.
[a] *VG, clinically very good; GO, clinically good; SS, clinically sufficient/satisfactory; UN, clinically unsatisfactory; PO, poor.*

presenting shape angles of more than 135° (55.0%) and 1- to 2-mm height (55.0%) and depth (70.0%).

In G0, G1, and G2, baseline sensitivity decreased significantly at six, 12, 24, and 36 months ($p<0.001$). In G0, sensitivity was higher at 36 months than at 24 months ($p=0.04$). In G1, sensitivity was significantly higher at 36 months than at six, 12, and 24 months ($p<0.001$). In G2 as well, sensitivity was significantly higher at 36 months than at six, 12, and 24 months ($p<0.05$).

Dentin sensitivity was not different among the studied groups (log-rank: $p=0.4941$) (Figure 2D). The Kaplan-Meier survival graph suggested that sensitivity was more common in G0 than in G2 and G1. G1 had slightly fewer cases of sensitivity.

Other Parameters

No restoration had clinical problems related to the recurrence of caries at 36 months according to the FDI criteria. In addition, no adverse effects were reported by any patient regarding the treatments performed.

DISCUSSION

Previous studies[28] reported that Class V composite restorations in NCCLs have limited clinical durability. The most frequently cited reasons for possible

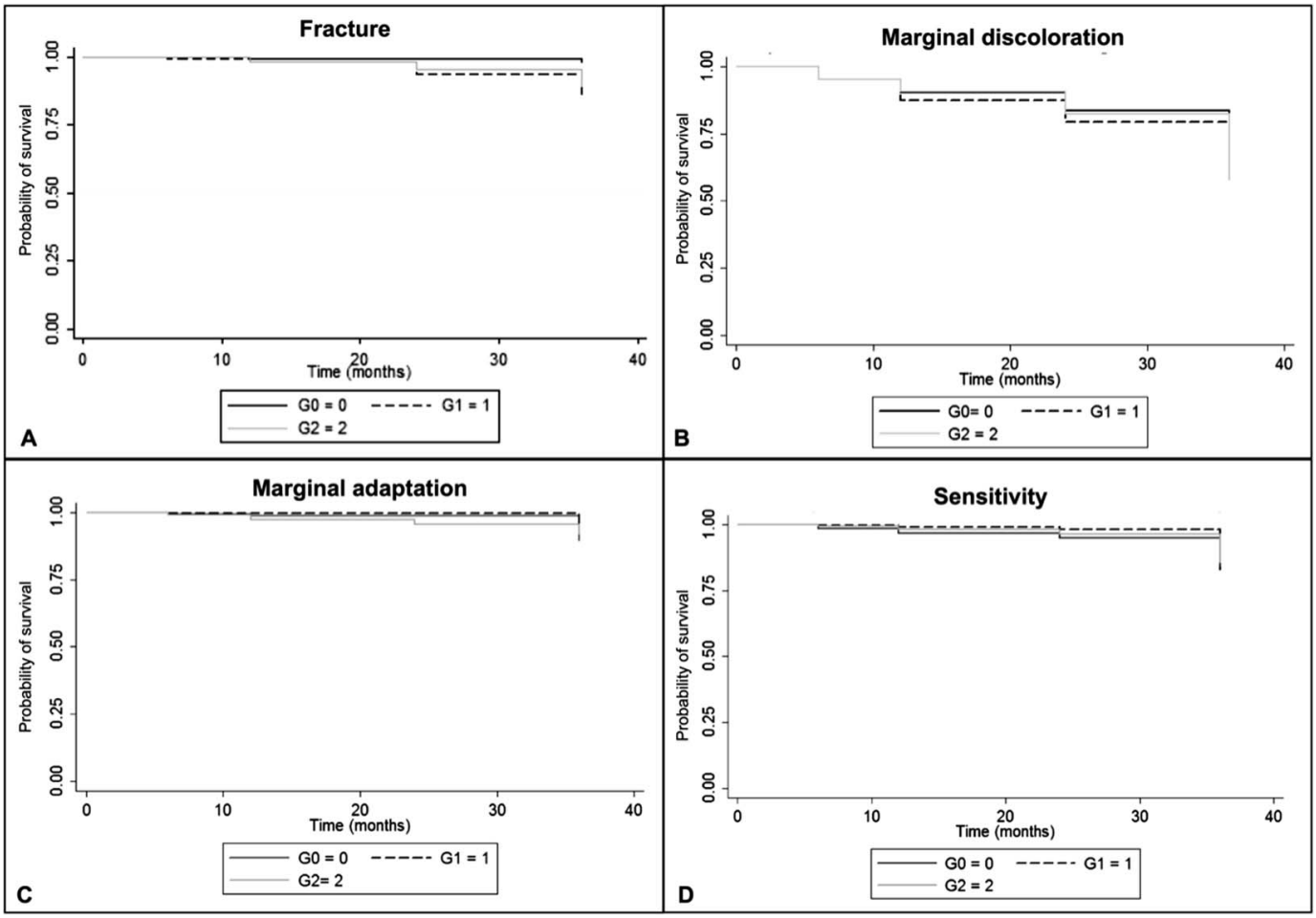

Figure 2. *Kaplan-Meier survival curves. (A) Clinical performance (failure) according to the experimental groups (log rank:* p=*0.0124). (B) Marginal discoloration according to experimental groups (log rank:* p=*0.8588). (C) Marginal adaptation according to experimental groups (log rank:* p=*0.1744). (D) Sensitivity according to experimental groups (log rank:* p=*0.4941).*

failures, even within a short period of time, included the loss of retention and poor marginal adaptation.[25,29] The loss of retention and poor marginal adaptation of the restorations performed in our study showed satisfactory long-term survival, and 12 restorations were lost, possibly because of the failure of adhesion to the substrate. The teeth exposed to a longer acid-etching time as part of the experimental dentin surface treatment showed inferior clinical performance compared with the teeth in other experimental groups. In addition, dentin surface treatment with ultrasound showed similar restoration survival to the control group after the 36-month evaluation period. Considering the aforementioned findings, our hypothesis was rejected, because the tested dentin surface treatments did not improve the survival of Class V composite restorations.

Different strategies were used in previous studies[12,30] to increase the bond strength of adhesive systems to sclerotic dentin, such as bur removal of the most superficial sclerotic dentin layer or pre-etching with phosphoric acid. There is a consensus in the literature that sclerotic dentin exhibits a low-permeability hypermineralized surface, resulting in a substrate that is less favorable for adhesion than is normal dentin,[31,32] which is a substrate usually found in NCCLs.[30] The sclerotic dentin consists of high amounts of mineral precipitates that present increased surface roughness, high surface energy, and less intercollagen infiltration; therefore, bonding to this kind of dentin was compared with bonding to a two-times etched enamel.[16] In the present study, the higher loss rate observed in the experimental group with increased acid etching could be due to the presence of nonsclerotic dentin observed in the majority of teeth. Using the recommended etching times, the thickness of the hybrid layer may change abruptly because of uneven etching.[12] This fact could

be even worse when the phosphoric acid–etching time is duplicated and may account for the controversial results observed when the etching time is duplicated in sclerotic dentin.[1,12,33] Moreover, the duplication of the phosphoric acid–etching time could cause the deepest demineralization of some intertubular and peritubular dentin, which could not be thoroughly infiltrated by resin monomers.[34]

However, the majority of restorations conducted in this study had nonsclerotic dentin, which was classified according to specific criteria for these types of lesions.[27] In these cases, a longer acid-etching time could increase the chances of degradation of collagen fibrils, compromising the bond stability over time.[35-37] Overetching, with subsequent deep demineralization, can lead to suboptimal resin impregnation and to a porous zone in the hybrid layer.[38,39] In the long term, this could compromise the durability of the bond.[34,40,41] If surface demineralization is too deep, there is a chance that the resin monomers will not diffuse to the full depth of the demineralized dentin. This would leave collagen fibers exposed and susceptible to hydrolysis, possibly weakening the bonding. Thus, it is speculated that superficial demineralization may possibly give the adhesive system a better chance to diffuse into the entire collagen network. In this context, a minimum acid-etching time of 15 seconds has been suggested by several authors,[42] with the aim to achieve an adequate bond to the normal dentin. Some *in vitro* studies[43,44] reported that increasing the etching time to 30 seconds apparently does not affect the bonding of the current hydrophilic adhesive systems to normal dentin, at least in terms of bond strength. However, in our clinical trial, a longer acid-etching time affected the retention of Class V composite restorations. In clinical practice, defining the degree and volume of sclerotic dentin is difficult, and the correct diagnosis of sclerotic dentin that will guide the clinical procedure can also be difficult.[16]

In our study, the increased etching time did not influence marginal adaptation more than it did in the other experimental groups. This possibly occurred because of better adhesion to the enamel.[16] The optical time for acid etching in an enamel substrate is 30 seconds, the time period that was used in our clinical trial. However, the presence of enamel in NCCLs and its influence on adhesion are debatable.[23] The marginal sealing ability of a restorative material in dentistry could not necessarily be correlated with caries formation, but the development of microleakage over time can influence the longevity of the restoration for esthetic reasons, especially in the visible areas of the anterior region.[45] One study[9] that evaluated bur removal of dentin and additional phosphoric acid etching before self-etch primer application showed better marginal adaptation of both self-etch adhesive systems but did not change the retention rates of Class V composite restorations.

Our study also analyzed dentin surface treatment with ultrasound for the first time. The ultrasound technique represents a noninvasive dentin surface treatment and a conservative alternative to the removal of dental tissue that would promote groove formation on the dentin surface. It is a practical, fast, and easy procedure for experienced personnel. At 36 months, ultrasound treatment presented more marginal discoloration than did increased acid etching. The absence of improvement when using ultrasound could perhaps be attributed to it not removing the hypermineralized layer of the dentin surface. This dentin surface treatment needs to be further investigated in *in vitro* studies, and especially in longitudinal clinical evaluations.

Postoperative sensitivity decreased significantly in all experimental groups from the preoperative to the postoperative stage and was stable after the 36-month evaluation period. NCCLs can limit feeding in patients because the dentin tubules are open and exposed to the buccal environment, thereby causing various degrees of sensitivity. Sensitivity in the cervical region is predominant in the premolars,[46] as was also observed in our study. This is common in NCCLs, because the exposed dentin allows the movement of dentinal fluid that stimulates the nerve fibers of the pulp, causing pain. The treatments basically involve the obliteration of dentin tubules; however, the pain does not cease completely. In fact, pain is only reduced,[46,47] as was observed in this study, since teeth presented a reduction in sensitivity. The decrease in pain was possibly due to the obliteration of the tubules promoted by the composite used to restore the lesions.

Regarding marginal discoloration, all groups showed high marginal markings over time after a six-month period. Excessive or deficient filling materials at the margin forming gaps[48] and the retention of microscopic pigments derived from colored beverages and food in the adhesive layer can increase marginal discoloration.[48] Marginal staining has been thought to be one of the first clinical signs of failure of a composite restoration.[13] However, this marginal deterioration could not be considered a clinical failure. Restorations that lack marginal adaptation or marginal discoloration were

classified as clinically good or very good in other studies,[49,50] since these defects could be easily removed by finishing and polishing.

Previous studies[49,50] have suggested the possibility of establishing criteria that predict short-term restoration failure, ranging from postoperative sensitivity to loss of restoration. According to the guidelines of the American Dental Association,[51] the performance of adhesive systems is considered satisfactory if at least 95% of the restorations are retained after six months of evaluation. In this study, the number of restorations retained through 36 months of evaluation exceeded 95%. Therefore, it is possible to obtain good clinical performance in a relatively short period of time. One study[24] compared the six-month clinical behavior of several adhesion strategies using both FDI and United States Public Health Service (USPHS)–modified criteria. The findings suggested that the FDI criteria are more sensitive than the USPHS-modified criteria to small variations in clinical outcomes when evaluating restorations of NCCLs. Thus, we used the FDI criteria to assess the clinical outcomes related to composite restorations of NCCLs.

Additionally, some limitations of this study must be addressed, because randomized clinical trials are highly controlled clinical studies that include patients with specific characteristics to answer a specific research question, which would otherwise be clinically difficult for clinicians to address. It is important to consider that the results of our clinical trial are limited to the materials and techniques tested, as well as other individual factors that could modulate the longevity of experimental treatments. In addition, evaluations with longer follow-up periods might yield different results with surface treatment in NCCLs. Moreover, single studies provide very low-quality evidence suggesting rubber dam use in dental direct restorative treatments might improve the clinical success rate of restorations.[52] Although relative isolation was used in our clinical trial, a previous study[53] indicated that no significant differences were found between the types of isolation (absolute with rubber dam or relative) in composite Class V restorations of NCCLs. Future studies that evaluate dentin surface treatments with longer follow-ups should be performed for testing other treatments strategies, such as the use of a self-etch adhesive system with ultrasound or a longer acid-etching time only in sclerotic dentin. This may lead to the optimization of the clinical procedure for Class V composite restorations. Nevertheless, it is important to consider not only the restorative materials used in NCCLs but also the development and refinement of techniques that could improve the clinical longevity of composite restorations of NCCLs.

CONCLUSIONS

The dentin surface treatments evaluated in this study, such as longer acid-etching time and ultrasound, showed similar clinical performance to the conventional adhesive procedure up to the 36-month evaluation period, when considering marginal discoloration, marginal adaptation, and postoperative sensitivity. Increasing the acid-etching time also increased the risk of failure over time. Moreover, all dentin surface treatments reduced postoperative sensitivity over time.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the UFPel. The approval code for this study is 035-2011.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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