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NaOCl Application after Acid Etching and Retention of Cervical Restorations: A 3-Year Randomized Clinical Trial

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Clinical Relevance

The cavity pretreatment with NaOCl solution seems to yield no clinical advantages for restoring NCCLs using composite resins.

SUMMARY

This study evaluated the retention of composite resin restorations in noncarious cervical lesions (NCCLs) performed with or without pretreatment with 10% NaOCl solution (deproteinization). A randomized, controlled, split-mouth, double-blinded trial was carried out. Thirty patients with at least two NCCLs were included in the study. The NCCLs were randomly allocated into two treatment groups: control (acid etching with 37% phosphoric acid + placebo solution + Adper Single Bond 2/3M Oral Care + Filtek Z350/3M Oral Care) or experimental group (acid etching with 37% phosphoric acid + 10% NaOCl solution + Adper Single Bond 2 + Filtek Z350). A calibrated examiner evaluated the restorations at baseline (1 week) and recalls (6, 12, 24, and 36 months) using the FDI criteria. The primary outcome evaluated was retention of the restorations. Data were analyzed by the Kaplan-Meier method and the log-rank test (α=0.05). After 3 years, 64 restorations were evaluated in 23 patients. The annual failure rate was 9% for the control group and 17.8% for the

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experimental group (deproteinization technique). Considering the failures and their distribution among the characteristics of the patients and NCCLs, no statistically significant differences were observed for the control and experimental treatment groups (p=0.077) or the number of teeth in the mouth (p=0.320). Restorations in the mandible (p=0.039) and premolars (p=0.013) showed significantly lower clinical survival rates. The deproteinization pretreatment with a 10% NaOCl solution did not promote additional retention of restorations in NCCLs. (clinicaltrials.gov: NCT03086720)

INTRODUCTION

Effective and stable dentin bonding is fundamental for the long-term durability of composite resin restorations, particularly when little or no marginal enamel is available.[1] In challenging restorative situations such as noncarious cervical lesions (NCCLs), loss of restoration retention is a common clinical problem.[2] Clinical studies on NCCLs restored with composite resin without mechanical retention constitute a good model for evaluating the clinical performance of adhesive restorations, since in these situations the retention of restorations relies on the bonding agent and adhesive procedure.[3-5] The prognosis of cervical restorations may also be affected by other factors, including clinical characteristics of the cervical lesion and patient-related aspects.[2,6,7]

Laboratory and clinical studies have shown that the application of phosphoric acid is not the best approach to achieve bonding to dentin,[8] especially in patients with symptomatic NCCLs. Acid etching may generate demineralized areas beneath the hybrid layer, leaving exposed collagen fibrils not impregnated by the adhesive.[9] These areas may allow access to the entry of water into the adhesive layer and cause postoperative sensitivity.[5] The exposed collagen fibrils also may undergo hydrolysis, interfering with the stability of the bonded assembly.[8] Some strategies to potentially improve dentin bonding have been proposed, especially for etch-and-rinse adhesive protocols. Inhibition of enzymatic biodegradation has been suggested; however, apart from the satisfactory laboratory evidence,[10,11] the clinical data about the contribution of this enzymatic activity to bond degradation is still unclear.[12,13]

Removal of the dentin collagen mesh exposed by acid etching could also be an optional strategy for improving bonding to dentin.[14] When the collagen mesh is removed, the adhesive interlocks with the etched hydroxyapatite without the formation of a collagen-adhesive hybrid layer. The collagen could be removed by using a deproteinization protocol, usually involving the application of sodium hypochlorite (NaOCl)[15-17]—a nonspecific proteolytic agent capable of dissolving collagen. This ability of NaOCl is influenced by the time of exposure, concentration of active chlorine, and superoxide radicals in the solution.[18,19] Many *in vitro* studies have reported stability of dentin bonding after deproteinization protocols.[18-21] Although some positive results have been reported for the deproteinization technique, other *in vitro* studies have shown that dentin pretreatment with NaOCl did not lead to better bonding results compared with the conventional adhesive technique.[22,23] Clinical investigations on the performance of restorations performed with the deproteinization technique are scarce.[14,24] Both a 2-year clinical pilot study and a 5-year clinical study concluded that NaOCl pretreatment in the restoration of NCCLs was encouraging, since it did not affect the clinical performance of NCCL restorations.[14,24] Studies have suggested that the type of adhesive system might interfere with the performance of the technique.[14] Further clinical studies are still necessary to provide results that will enable conclusions to be drawn about the *in vivo* applicability of deproteinization bonding protocols, especially considering longer follow-ups.

The deproteinization technique with NaOCl could be a significant procedure for improving the adhesive stability and restoration retention, whereas it could be yet another clinical procedure that only increases treatment time. This randomized controlled clinical trial aimed to evaluate the retention of composite resin restorations in NCCLs performed with or without pretreatment of the acid-etched dentin with a 10% NaOCl solution. The null hypothesis tested was that the deproteinization technique does not influence the failure rates after a 3-year follow-up period.

METHODS AND MATERIALS

This study is reported in accordance with the guidelines of the Consolidated Standards of Reporting Trials (CONSORT).[25]

Study Design

This study was a randomized, controlled, split-mouth, and double-blinded trial with a 3-year period of follow-up. The control group used a placebo solution, and the experimental group used 10% NaOCl solution as pretreatment after dentin acid etching and before application of the adhesive agent. In this split-mouth study, the patient and outcome evaluator were blind to the control and experimental groups. However, it was not possible to blind the operators because of the

odor of the NaOCl solution. Restorations were placed between 2011 and 2012 by 10 different operators, who were undergraduate students of a dental school, in the last year of their course, working under the supervision of an experienced clinician and researcher (AFM).

Operator Training

Theoretical and practical training minimized variation among the operators. The undergraduate students received a manual containing instructions for the application of all materials and protocols of the clinical procedures. All operators underwent preclinical demonstrative training before the study began. Afterwards, they performed cervical restorations in a number of teeth of volunteer patients, corresponding to at least 10% of the total NCCLs sample size of the study. These restorations and patients were not included in the study sample; they were treated as a part of the regular undergraduate training of the students.

Sample Size

Taking into account a rate of retention of 87% after 36 months of placing the composite resin restorations in NCCLs, and the lack of difference with the control group,[26] the sample size calculation for an equivalence trial was based on a limit of 25% difference in retention rates between the groups, at a significance level of 5% and power of 80%. Considering the loss of subjects during the follow-up period, 10% were added; thus, the final sample size was composed of 30 patients, in a study with a split-mouth design.

Recruitment and Selection of Patients

Information about the study was disseminated by distributing posters and pamphlets at the dental school. All patients who were referred to the school clinics for treatment were evaluated and treated accordingly, when necessary. The inclusion criteria for participation in the study were adults, capable of understanding the informed consent form, with at least two NCCLs in incisors, canines, or premolars, with more than 20 teeth in the mouth, and with good periodontal health. Excluded from the study were smokers, bruxers, patients with severe systemic diseases, patients undergoing orthodontic treatment, teeth without antagonists or with wear facets covering more than 50% of the incisal and/or occlusal surfaces, presence of caries or restorations in the area to be treated, visible plaque index or gingival bleeding index higher than 20%, probing depth and clinical attachment loss greater than 4 mm with bleeding on probing, and patients lacking interest in returning for follow-ups or who refused to participate.

Patients who fulfilled the eligibility criteria received an informative letter about the purpose of the study, and a term of free and informed consent [form] to be signed, confirming their voluntary interest in participating. All participants were submitted to a detailed initial clinical examination, including several criteria regarding the classification of NCCLs. The criteria for evaluating NCCLs consisted of the following parameters: cervical lesion shape ("U" or "V"), length and height of the lesion (in mm), relation of the cervical margin with the gingiva (supragingival, gingival level, or subgingival), presence of wear facets, presence and degree of dentin sclerosis (when present), dentin sensitivity, and pulp vitality.

Randomization and Blinding Procedures

Randomization was performed using MS Excel computer software by a researcher (TPC) who was not directly involved in the study at the time. A random table was used to allocate the NCCLs to each study group. The treatments (control and experimental) were allocated, considering the tooth group (incisors, canines, and premolars), for which the first tooth to be restored was randomly allocated to one treatment. In contrast, the next tooth from the same tooth group was automatically assigned to the other treatment, according to the split-mouth design. Thus, in both the groups, each patient received the same number of restorations. Ten operators (undergraduate students) performed a similar number of restorations. Each operator performed the same number of restorations in both the groups. Individual opaque sealed envelopes were used to conceal the randomization sequence, which was coded as Treatment A or Treatment B. The same clinical sequence and identical solution bottles were used for both the groups.

Clinical Procedures

Before the adhesive procedures, prophylaxis of the tooth was performed with a rubber cup and pumice-water paste. No cavity preparation or beveling of the cavosurface margin was performed. The composite resin shade was selected using the Vitapan Classical shade guide (Vita Zahnfabrik, Bad Säckingen, Germany). When necessary, local anesthesia was used. Isolation of the operative field was performed using a labial retractor, gingival retraction cord #0000 (Ultrapak Cord; Ultradent, South Jordan, UT, USA), cotton rolls, and a suction device. The dentin was etched with 37% phosphoric acid gel (Adper Scotchbond Etchant, 3M Oral Care, St. Paul, MN, USA) for 15 seconds, rinsed with air-water spray for 30 seconds, and the excess moisture was removed from dentin with absorbent

paper. For the Experimental Group, a 10% NaOCl solution (Uso Indicado Pharmacy, Pelotas, RS, Brazil) was applied with a disposable pharmaceutical syringe and remained in contact with the dentin surface for 60 seconds. The surface was rinsed with air-water spray for 30 seconds to remove all the excess NaOCl. For the control group, the same sequence was followed but using a placebo solution (water).

For both groups, the application of a two-step adhesive system (Adper Single Bond 2, 3M Oral Care) and restorative technique using a nanofilled composite resin (Filtek Z350, 3M Oral Care) were performed in accordance with the manufacturer's instructions. Each composite resin increment was cured for 20 seconds with a light-emitting diode (LED) light-curing unit (Radii-Call; SDI, Bayswater, VI, Australia) with an irradiance of 800 mW/cm^2. All the restorations were finished with #12 scalpel blades, fine and ultrafine diamond burs (KG Sorensen, Barueri, SP, Brazil) under water cooling to remove excess material and/or improve the shape and contour of the restoration. Polishing was performed with silicone tips, alumina abrasive discs (Sof-Lex Pop-On; 3M Oral Care), felt disks, and diamond polishing paste (Prisma Gloss; Dentsply Caulk, Milford, DE, USA).

Clinical Assessment

A previously trained, calibrated, and blinded examiner (MSC) who has worked as an examiner in other clinical studies carried out the clinical evaluations of restorations at baseline (1 week) and follow-up time intervals (6, 12, 24, and 36 months). Training and calibration procedures used a web-based training and calibration tool (www.ecalib.info) and clinical setting evaluations. Thirty NCCL restorations (4 patients) were reexamined 15 days later, to provide clinical intraexaminer calibration. A preevaluation intraexaminer agreement above 90% was obtained. The examiner used the criteria approved by the FDI World Dental Federation.[27] The primary outcome was retention of the restoration, and the complete loss of a restoration was considered a failure. Secondary endpoints included marginal staining, postoperative sensitivity, surface gloss, translucency, color, fracture, anatomical shape, preservation of vitality, and integrity of teeth. Each criterion was expressed in five scores—three scores for clinically acceptable restorations and two scores for unacceptable restorations (in need of repair or replacement).

Recalls

Patients were contacted by telephone and asked to attend scheduled appointments for reevaluations after 6, 12, 24, and 36 months. In case of unsuccessful telephone contact, a letter was sent to the residential address provided in the clinical record, or home visits were made by the researchers and evaluators involved in the recalls (MSC and MF). In these follow-up exams, the restorations were evaluated according to the FDI criteria, and photographic records were taken.

Statistical Analysis

Statistical analysis was performed using Stata 14.2 software (Stata Corp LP, College Station, TX, USA). Descriptive analysis was used for the variables of interest. Differences between frequencies were assessed by Fisher Exact test. Distribution and frequency data for the presence/absence of failures were measured with the Chi-square test. Survival analysis was performed using the Kaplan-Meier method, followed by the log-rank test. Unadjusted Cox regression models with shared frailty were used to verify the association between the treatments and risk of failure over time, estimating the hazard ratios (HR) and 95% confidence intervals (CI). In all analyses, α=0.05 was considered.

RESULTS

During enrollment from September 2011 to August 2012, 61 patients were assessed for eligibility: 31 did not fulfill the inclusion criteria or did not want to participate, while 30 patients (17 men, 13 women), with an average age of 49 years were included in this study, for placement of a total of 100 NCCL composite resin restorations. Details of the recruitment procedures, exclusions, losses, and the number of participants at each recall of the trial are disclosed in the study flowchart (Figure 1). After 36 months of follow-up, the average lifetime of the restorations was 2.9 years.

In Table 1, it is possible to observe the characteristics of the subjects evaluated at the last recall (36 months). Table 2 shows the features of the NCCLs. The majority of patients had between 20 and 24 teeth in the mouth, and 63.3% of the patients reported the consumption of acidic foods and/or sour drinks. However, within the sample studied, a higher number of lesions presented in patients who did not report an acidic diet (Table 3), but the difference was not statistically significant. The majority of lesions had a V wedge shape (60%), 48% had a depth below 1 mm, and 49% had a height between 1 and 3 mm. NCCLs were predominantly present in premolars (58%).

At 36 months, the annual failure rates (AFRs) were 9% for the control group and 17.8% for the experimental group (NaOCl/deproteinization technique). Kaplan-Meier survival curves for different study variables are presented in Figure 2. When observing the failures

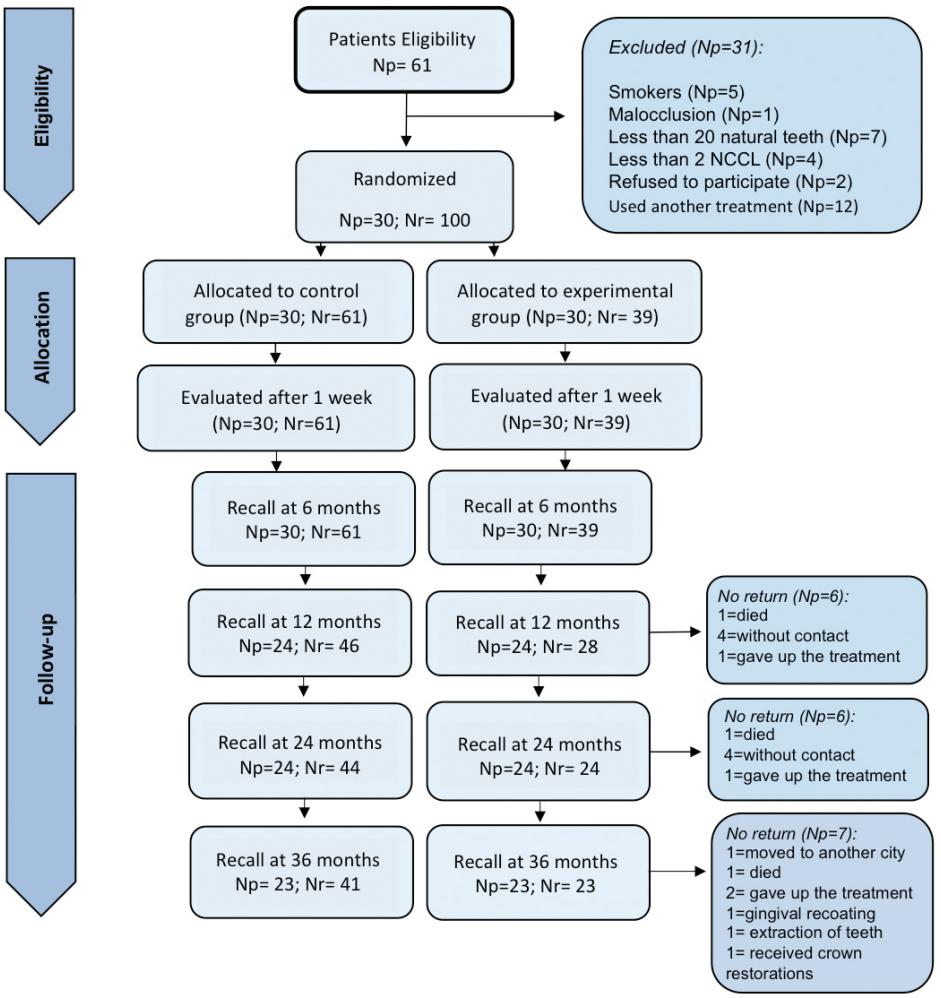

Figure 1. *Flowchart showing participants' enrollment. Abbreviations: Np, number of patients; Nr, number of restorations.*

Table 1: *Characteristics of the Subjects Included in this Study (n=30)*

Characteristic	Subdivision	N (%)
Number of teeth	20-24	17 (56.7%)
	25+	13 (43.3%)
Income	Up to 2 BMW	16 (53.3%)
	>2 BMW	14 (46.7%)
Educational level, years	Up to 8	9 (29%)
	9-11	16 (51.6%)
	>11	6 (19.4%)
Age, years	20-40	5 (15.6%)
	41-60	23 (71.9%)
	>60	4 (12.5%)
Acidic diet	Yes	19 (63.3%)
	No	11 (36.7%)

Abbreviations: BMW, Brazilian minimum monthly wage.

and their distribution among the characteristics of the patients and NCCLs, no significant differences were observed between the control and experimental groups (p=0.077, Figure 2A), or the number of teeth in the mouth (p=0.320, Figure 2C). Mandibular restorations (p=0.039, Figure 2B) and restorations in premolars (p=0.013, Figure 2D) had significantly lower clinical survival. The Cox regression analysis confirmed these results regarding the significance of the associations (Table 4). Regarding the type of treatment, there were 40% more failures in the Experimental Group (NaOCl) when compared with the control Group, but the association was not significant (p=0.075).

When the data were submitted to the Chi-square test (Table 3) to measure the quantity and percentage of data according to the presence of failure or not, no significant difference in the failure rates between the experimental and the control groups was observed (p=0.054). Table 3 presents the number and percentage

Table 2: *Characteristics of the Noncarious Cervical Lesions Restored in the Study (n=100)*

Characteristic	Subdivision	Control Group, n (%)	Experimental Group, n (%)
Tooth type	Incisor	15 (71.4%)	6 (28.6%)
	Canine	15 (71.4%)	6 (28.6%)
	Premolar	31 (53.5%)	27 (46.5%)
Dental arch	Maxilla	34 (69.4%)	15 (30.6%)
	Mandible	27 (52.9%)	24 (47%)
Lesion depth	<1 mm	28 (58.3%)	20 (41.7%)
	1-3 mm	29 (63%)	17 (37%)
	3-4 mm	1 (50%)	1 (50%)
	>4 mm	2 (100%)	0 (0%)
Lesion height	<1 mm	3 (42.9%)	4 (57.1%)
	1-3 mm	30 (61.2%)	19 (38.8%)
	3-4 mm	20 (62.5%)	12 (37.5%)
	>4 mm	4 (66.7%)	2 (33.3%)
Cavity shape	U saucer shape	26 (65%)	14 (35%)
	V wedge shape	35 (58.3%)	25 (41.7%)

of restorations for each variable studied. The variables studied, such as the patient-related variables (income, educational level, and age) and local variables (acid ingestion, depth, and height of NCCLs, cavity shape, degree of sclerosis, and restoration margin) showed no statistically significant effect on the retention of restorations. The type of the tooth and its position in the maxillary or mandibular arch seem to influence the retention of the restoration, showing that restorations in the mandible and in premolars suffered more retention failures.

With regard to tooth sensitivity, obtained by means of a questionnaire answered by the patients before and after the restorations were carried out, 37.5% of patients reported that they never had tooth sensitivity, 56.3% reported improvement in tooth sensitivity after restoration, and 6.3% of patients reported that the restored teeth remained sensitive in all of the follow-up time intervals. No patient in the NaOCl group reported sensitivity after restoration placement, while five patients in the control group (placebo) reported that the teeth remained sensitive. However, there was no difference in tooth sensitivity between the groups (p=0.270). After the 36-month follow-up period, the majority of restorations for both the groups (control and experimental) had an FDI score 1, which represents a clinically excellent result (Table 5). This finding demonstrated that the restorations remained satisfactory over time, irrespective of the treatment.

DISCUSSION

The main finding of this study was that the application of a deproteinization technique using 10% NaOCl solution after dentin acid-etching to remove the exposed collagen mesh had no positive impact on the retention of composite resin restorations in NCCLs after 3 years of clinical service. The majority of NCCL restorations remained satisfactory over time, irrespective of the treatment. The AFRs were 9% for the control group (conventional bonding technique) and 17.8% for the Experimental Group (NaOCl/deproteinization technique) after 3 years. Thus, the null hypothesis tested was accepted.

The results reported for the deproteinization technique in this clinical study were in disagreement with the positive effects reported in laboratory experiments.[18-21] Theoretically, the deproteinization technique would be able to remove the collagen mesh exposed by acid etching and make the dentin bonding assembly less prone to hydrolytic degradation or enzymatic action. However, it was reported that NaOCl could not wholly remove the collagen fibrils within clinically relevant application times[28]; thus, the bonded interface was not entirely free of collagen. Furthermore, the mismatch between acid-etched and adhesive-impregnated dentin areas may still occur in the deproteinization technique,[17] interfering with long-term bonding performance.

Results of clinical studies on the efficacy of the deproteinization technique on restoration retention are scarce, especially considering longer follow-ups.

Table 3: *Number and Percentage of Retention for Each Variable Studied (n=100)*

Variable		Survival (Retention)	Failure (Loss of Retention)	*p*-Value
Income	Up to 2 BMW	38 (74.5%)	13 (25.5%)	0.399
	>2 BMW	30 (66.7%)	15 (33.3%)	
Treatment groups	Control	47 (77%)	14 (23%)	0.054
	Experimental	23 (59%)	16 (41%)	
Educational level, years	Up to 8	21 (87.5%)	3 (12.5%)	0.187
	9-11	34 (65.4%)	18 (34.6%)	
	>11	11 (64.7%)	6 (35.3%)	
Age, years	20-40	5 (45.5%)	6 (54.5%)	0.083
	41-60	47 (70%)	21 (30%)	
	>60	16 (84.2%)	3 (15.8%)	
Acidic diet	Yes	29 (72.5%)	11 (27.5%)	0.625
	No	38 (67.9%)	18 (32.1%)	
Number of teeth	20-24	42 (62.7%)	25 (37.3%)	0.051
	25+	24 (82.8%)	5 (17.2%)	
Lesion depth	<1 mm	32 (66.7%)	16 (33.4%)	0.110
	1-3 mm	35 (76.1%)	11 (23.9%)	
	3-4 mm	0 (0%)	2 (100%)	
	>4 mm	1 (50%)	1 (50%)	
Lesion height	<1 mm	5 (71.4%)	2 (28.6%)	0.104
	1-3 mm	40 (81.6%)	9 (18.4%)	
	3-4 mm	18 (56.3%)	14 (43.7%)	
	>4 mm	4 (66.7%)	2 (33.3%)	
Tooth type	Incisor	20 (95.2%)	1 (4.8%)	0.011
	Canine	15 (71.4%)	6 (28.6%)	
	Premolar	35 (60.3%)	23 (39.7%)	
Dental arch	Maxilla	40 (81.6%)	9 (18.4%)	0.013
	Mandible	30 (58.2%)	21 (41.2%)	
Cavity shape	U saucer shape	27 (67.5%)	13 (32.5%)	0.656
	V wedge shape	43 (71.7%)	17 (28.3%)	
Dentin sclerosis	Absent	36 (76.5%)	13 (26.5%)	0.193
	Slight	17 (58.6%)	12 (41.4%)	
	Moderate	14 (82.4%)	3 (17.6%)	
	Severe	1 (33.3%)	2 (66.7%)	
Restoration margin	Supragingival	14 (53.8%)	12 (46.2%)	0.681
	Gingival level	45 (63.4%)	26 (36.6%)	
	Subgingival	2 (66.7%)	1 (33.3%)	

Abbreviations: BMW, Brazilian minimum monthly wage.

Previous studies evaluated the composite restorations of NCCLs with or without collagen removal with 10% sodium hypochlorite NaOCl[14,24]; however, they did not explore some critical local- and patient-related factors that could influence the prognosis and restoration survival rates, such as the income and educational level, type of teeth, and position of the tooth in the dental arch.[2,6,7,30]

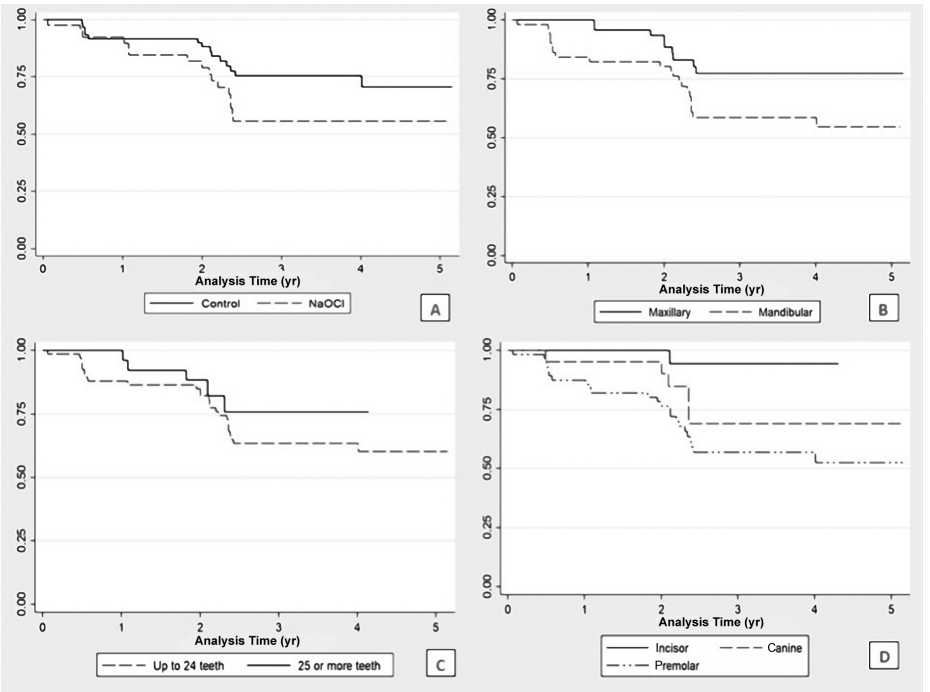

Figure 2. *Kaplan-Meier survival curves for A: type of treatment (experimental or control,* p=*0.077); B: dental arch (maxillary or mandibular,* p=*0.039); C: number of teeth in mouth (20-24 or -25 or more,* p=*0.320); and D: tooth type (incisor, canine, or premolar,* p=*0.013).*

The present findings corroborated those of previous studies showing that the adhesive procedure with a deproteinization technique, which is an extra step during the adhesive protocol, had no positive impact on the clinical service of composite restorations.[14,24] This finding indicated that there seemed to be no reason to continue testing this deproteinization technique, both *in vitro* and *in vivo*. In dental materials research, it is somewhat common to encounter contradictory findings between *in vitro* and *in vivo* studies. For instance, there has been discussion about the different mechanical results between dental restorative composite resins and ceramics observed in laboratory experiments having translated into minor effects in the clinical scenario,[29-31] which appeared to be the case here. Preclinical studies are of utmost importance in the health sciences; however, the conditions are usually far more controlled than in the clinical situation.

Table 4: *Hazard Ratios (HR) and 95% Confidence Intervals (CI) for Failure of the NCCLs Restorations According to Clinical Variablesa*

Variables	HR (95% CI)	*p*-Value
Treatment		0.075
Control - placebo	1.00	
Experimental - NaOCl	1.41 (0.97-2.05)	
Tooth type		0.046
Incisor	1.00	
Canine	5.81 (0.62-54.79)	
Premolar	10.83 (1.35-87.10)	
Position		0.027
Maxilla	1.00	
Mandible	2.68 (1.12-6.45)	
Number of teeth		0.337
20-24	1.00	
25 or more	0.53 (0.15-1.94)	

Abbreviations: NCCL, noncarious cervical lesions.
[a] *Cox regression analysis with a shared frailty factor.*

The contemporary literature has pointed out that NCCLs are probably caused by a combination of clinical factors,[32-34] which often favor a less-accurate diagnosis by dentists.[35] The shape and size of the lesions will depend on specific clinical factors. In this study, 58% of NCCLs were present in premolars, which were the teeth in which significantly more restoration failures occurred, and 60% of the total sample had a V-wedge shape. Reports on the biomechanical behavior of NCCLs have indicated that V-shaped lesions may show higher stress concentration, especially at the apex of the lesion,[32] in comparison with U-shaped lesions.[33] One study[33] showed that stresses in the depth of the lesions were distributed over a wider area for U-shaped lesions, whereas, for the V-shaped lesions, the stresses were concentrated over a narrow area. Taking all these data into account, it may be suggested that the majority of the sample in the present study was composed of lesions with poorer prognosis in terms of biomechanical behavior. However, it has also been

Table 5: *Comparison Between the Groups Considering the Restorations Remaining After 36 Months, According to the FDI Criteria Compared by Fisher's Exact Test*

General Criteria	Specific Criteria	Control Group	Experimental Group	*p*-Value
		FDI Scores (1/2/3/4/5)[a]	FDI Scores (1/2/3/4/5)[a]	
Esthetics properties	Superficial brightness	17/16/6/0/0	8/7/4/0/0	0.869
	Surface staining	20/16/3/0/0	10/5/4/0/0	0.297
	Marginal staining	5/20/13/1/0	2/12/4/1/0	0.697
	Translucency and color stability	9/16/13/1/0	5/8/6/0/0	1.000
	Anatomic form	21/13/4/1/0	8/11/0/0/0	0.185
Functional properties	Fracture	37/1/1/0/0	19/0/0/0/0	1.000
	Retention	37/1/1/2/0	19/0/0/4/0	0.281
	Marginal adaptation	14/21/4/0/0	3/16/0/0/0	0.072
	Patient perception	38/1/0/0/0	19/0/0/0/0	1.000
Biological properties	Postoperative sensitivity	35/1/3/0/0	18/1/0/0/0	0.591
	Tooth vitality	39/0/0/0/0	19/0/0/0/0	1.000

[a] *Numbers separated by slash represent the number of evaluated restorations rated for each score, according to the FDI criteria: 1. Clinically excellent; 2. Clinically good; 3. Clinically sufficient/satisfactory; 4. Clinically unsatisfactory; 5. Clinically poor.*

shown that the presence of adhesive restorations may help with generating a biomechanical behavior similar to that of sound teeth, thereby overcoming the concerns of stress concentration.[36,37] One study[38] showed that restored lesions subjected to loading at the buccal cusp tended to concentrate stresses at the gingival restorative interface. In addition, the dimension of the lesion and periodontal support status may have a significant impact on the stress distribution.[38]

A previous study evaluating the influence of tooth isolation techniques (rubber dam vs cotton roll isolation) on retention of the noncarious cervical lesion and on the occurrence/progression of gingival recession showed that the rubber dam isolation did not promote further restoration retention of NCCLs and is a risk factor for occurrence/progression of gingival recession after 5-year follow-up.[39] In the present study, the restorations were performed under cotton roll isolation. Moreover, the cotton roll isolation was effectively performed using a labial retractor, gingival retraction cord, an effective suction device, and the operator performed all clinical procedures with the help of a dental assistant. Nevertheless, moisture control may be less controlled in the mandible, in spite of all the efforts made to provide moisture-free areas for bonding. More restoration failures were observed in the mandible compared with the maxilla. A possible reason for this result may be the fact that the restorations were not placed under rubber dam isolation. The clinical relevance of this finding relies on the prognosis for restoration longevity in mandibular teeth, particularly premolars. Nevertheless, these negative results pointed out that the use of NaOCl would not only increase restoration cost and chair time but would also not provide the patient with any real clinical effect. Another clinical finding was that postoperative sensitivity was not common after restoration placement. Interestingly, only teeth in the control group remained sensitive, whereas the deproteinization technique was able to eliminate tooth sensitivity; this finding was not significant. However, if this feasible positive influence on postoperative sensitivity were to be confirmed in other studies, there are different ways to manage tooth sensitivity; and the use of NaOCl should not be encouraged for this purpose.

CONCLUSIONS

Application of 10% NaOCl solution as a deproteinization treatment after dentin acid etching and before application of a two-step adhesive in Class V NCCLs did not lead to any significant improvement in retention. The deproteinization technique did not improve any other restoration clinical parameter when compared with the conventional bonding technique for composite resins, after 3 years of clinical service. The deproteinization pretreatment seemed to yield no clinical advantages for restoring cervical lesions.

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Regulatory Statement

The Local Research Ethics Committee approved this research project (Protocol #210/2011). The study was registered in clinicaltrials.gov (NCT03086720).

Conflict of Interest

The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript. The authors of this article 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. The authors alone are responsible for the content and writing of this paper.

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