Influence of Isolation Method of the Operative Field on Gingival Damage, Patients' Preference, and Restoration Retention in Noncarious Cervical Lesions

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Clinical Relevance

The use of cotton rolls/retraction cord is as effective as rubber dam isolation for restoration of noncarious cervical lesions. In addition, patient's preference, gingival damage, or chairside time was similar for both isolation techniques.

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DOI: 10.2341/14-089-C

SUMMARY

Objectives: To evaluate the retention rates, gingival damage, and patients' preferences for adhesive restorations in noncarious cervical lesions (NCCL) associated with the use of rubber dam vs cotton rolls/retraction cord isolation.

Methods: Thirty patients having one pair of similar NCCL on opposing sides of the same arch were enrolled in this study. A total of 60 restorations were placed. In each patient one restoration was placed under rubber dam isolation (RD) using dental retainers, and the other one was placed using cotton rolls/retraction cord (CR/RC) isolation. Dental residents with more than 10 years of clinical experience restored all NCCL using the same adhesive (GO!, SDI Limited, Bayswater, Australia) and composite resin (Ice, SDI). The patients' preferences were recorded. The gingival condition

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(bleeding, gingival laceration, and gingival insertion level) was evaluated immediately after the restorative procedure and after one week. Gingival sensitivity was also assessed one week after the end of the restorative procedures. The clinical time required to perform each restoration was recorded. The performance of the restorations was assessed using the FDI criteria at baseline and six, 12, and 18 months after clinical service. All criteria evaluated were submitted to appropriate statistical analysis (α =0.05).

Results: The retention rates of the restorations at each recall time were not affected by the isolation method (p>0.05). No significant difference between isolation methods was found in regard to patients' preferences (p=0.86), gingival bleeding (p=0.57), laceration (p=0.64), insertion (p>0.52), gingival sensitivity (p=0.52), or chairside time (p=0.77).

Conclusions: The use of CR/RC was shown to be similar to the use of RD in terms of retention rates, patient's preference, gingival damage, and chairside time for adhesive restorations in NCCL.

INTRODUCTION

Nowadays, many patients demand that their dental restorations not only function well but also resemble natural teeth. It is well known that resin composite and adhesive systems are especially technique sensitive, ¹ given that proper material handling and adequate field isolation are critical for the success and longevity of the restorations.

This means that the adhesive procedures need to be performed on clean tooth surfaces without the presence of any contaminants such as intraoral humidity, saliva, and gingival/sulcular fluid or blood. ^{2,3} Contaminants have been shown to jeopardize the bonding effectiveness of adhesive systems to the dental structure. ^{4,5}

For more than a century, a rubber dam has been considered the optimal method to isolate a dental operating field. Rubber dam isolation prevents moisture contamination during the placement of direct restorations and endodontic treatments, ^{2,3,6} and most dental schools regularly teach this method. Many faculty members consider rubber dams to be an essential component of modern adhesive dentistry, ^{8,9} and many advantages have been listed elsewhere. ^{2,3}

However, the use of a rubber dam during operative dentistry procedures in a private practice is not common. 6,7,9,10 In one of the most relevant studies of rubber dam use, which involved a questionnaire completed by US general dentists, 53% of the dentists reported that they had never used a rubber dam for amalgam restorations, 45% had never used a rubber dam for anterior direct resin composites, and 39% had never used a rubber dam for posterior direct resin composites. More recently, Gilbert et al., ¹⁰ in a practice-based study, collected data on 9890 consecutive restorations done in previously unrestored tooth surfaces from 5810 patients. Most dentists (63%) in this study did not use a rubber dam for any restoration. A rubber dam was used for only 12% of restorations. Reasons for not using a rubber dam in routine practice include patient discomfort, insufficient time, technical difficulty, insufficient training, and the cost and low fees for treatment.^{6,7,9}

Ryan O'Connell² and Mala and others³ reported that almost 50% of the clinicians evaluated in a survey considered rubber dams difficult to apply, and almost 50% felt that adult patients do not like it. There is not much evidence to support the following cited claims: patient acceptance/discomfort and insufficient time, technical difficulty, insufficient training/lack of skill, and costs and fees. In fact, there are studies that support and contradict each of these claims.⁹

The influence of a rubber dam vs cotton rolls/retraction cord isolation on the performance of adhesive restorations is also the subject of controversy. Although three meta-analyses revealed no influence of the type of isolation on the survival rate of posterior composite restorations^{11,12} or that of anterior composite restoration,¹³ most of the clinical trials were observational and not prospective.¹⁰ It might be more appropriate to evaluate both methods of isolation in a prospective, split-mouth design to determine the patients' actual perceptions of both procedures.

Few clinical studies^{14,15} have attempted to address these issues for noncarious cervical lesions (NCCL), where placement of dental retainers is considered more challenging. Thus, the primary outcome of this examiner-blind, randomized clinical trial was to evaluate whether the type of isolation technique (rubber dam vs cotton rolls/retraction cord) influenced the retention rates of NCCLs bonded with a one-step, self-etch adhesive over the course of six, 12, and 18 months. As secondary outcomes, we also compared the chairside time, the gingival damage, and the patients' preferences toward the use of

Table 1:	Characteristics of Research Subjects and
	Features of the NCCLs Included in This Study for
	Both Study Groups

Characteristics of Research Subjects Patients, n Gender distribution 12 Male 12 Female 18 Age distribution, y 20-29 20-29 0 30-39 6 39-49 24 >49 30 Characteristics of Class V lesions Lesions, n Shape, ° of angle RD CR/RC <45 6 8 45-90 14 16 90-135 10 6 ≥135 10 6 2-1.5 8 6 1.5-2.5 12 16 2.5-4.0 10 6 2-4.0 0 2 Degree of sclerotic dentin 1 0 0 2 14 12 3 16 18 4 0 0 Presence of antagonist Yes 0 0 Yes 0	Both Study Groups	<i>100 111 1111</i>	o clady for
Male 12 Female 18 Age distribution, y 20-29 0 30-39 6 39-49 24 >49 30 Characteristics of Class V lesions Lesions, n Shape, ° of angle RD CR/RC <45 6 8 45-90 14 16 90-135 10 6 >135 Cervico-incisal height, mm <1.5 8 6 1.5-2.5 12 16 16 16 1.5 16 16 1.5 16 16 1.5 16 1.5 16 16 1.5 16 1.5 16 1.5 16 1.5 16 1.5 16 1.5 16 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1.8 1.6 1	Characteristics of Research Subjects	Pati	ents, n
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Age distribution, y 20-29 0 30-39 6 39-49 24 >49 30 Lestons, n Shape, ° of angle RD CR/RC <45	Male	12	
20-29 0 30-39 6 39-49 24 >49 30 Characteristics of Class V lesions Lesions, n Shape, ° of angle RD CR/RC <45	Female	18	
30-39 6 39-49 24 >49 30 Characteristics of Class V lesions Shape, ° of angle	Age distribution, y		
39-49 24 >49 30 Characteristics of Class V lesions Lesions, n Shape, ° of angle RD CR/RC <45 6 8 45-90 14 16 90-135 10 6 >135 Cervico-incisal height, mm - <1.5 8 6 1.5-2.5 12 16 2.5-4.0 10 6 >4.0 0 2 Degree of sclerotic dentin 1 0 0 2 14 12 12 3 16 18 4 0 0 Presence of antagonist 7 2 1 <	20-29	0	
Shape, ° of angle RD CR/RC <45	30-39	6	
Characteristics of Class V lesions Lesions, n Shape, ° of angle RD CR/RC <45	39-49	24	
Shape, ° of angle RD CR/RC <45	>49	30	
<45	Characteristics of Class V lesions	Les	sions, n
45-90 14 16 90-135 10 6 >135 Cervico-incisal height, mm	Shape, ° of angle	RD	CR/RC
90-135 10 6 >135 Cervico-incisal height, mm <1.5 8 6 1.5-2.5 12 16 2.5-4.0 10 6 >4.0 0 2 Degree of sclerotic dentin 1 0 0 0 2 14 12 3 16 18 4 0 0 0 Presence of antagonist Yes 30 30 No 0 0 Attrition facet Yes 0 0 No 30 30 Preoperative sensitivity (spontaneous) Yes 0 0 No 30 30 Preoperative sensitivity (air dry) Yes 18 16 No 12 14 Preoperative sensitivity (touch) Yes 16 18 No 14 12 Tooth distribution Anterior Incisor 6 2 Posterior Premolar 24 28	<45	6	8
>135 Cervico-incisal height, mm <1.5	45-90	14	16
Cervico-incisal height, mm ≤1.5 8 6 1.5-2.5 12 16 2.5-4.0 10 6 >4.0 0 2 Degree of sclerotic dentin 0 0 1 0 0 2 14 12 3 16 18 4 0 0 Presence of antagonist Ves 30 30 No 0 0 0 Attrition facet Yes 0 0 Yes 0 0 0 No 30 30 30 Preoperative sensitivity (spontaneous) Yes 0 0 No 30 30 30 Preoperative sensitivity (air dry) Yes 18 16 18 No 12 14 12 14 Preoperative sensitivity (touch) Yes 16 18 18 16 18 18 10 14 12 14 12 14 12 14 12 14 </td <td>90-135</td> <td>10</td> <td>6</td>	90-135	10	6
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>4.0 0 2 Degree of sclerotic dentin 0 0 1 0 0 2 14 12 3 16 18 4 0 0 Presence of antagonist 0 0 Yes 30 30 No 0 0 Attrition facet 0 0 Yes 0 0 No 30 30 Preoperative sensitivity (spontaneous) 0 0 No 30 30 Preoperative sensitivity (air dry) Yes 18 16 No 12 14 Preoperative sensitivity (touch) 12 14 Preoperative sensitivity (touch) 16 18 No 14 12 Tooth distribution 14 12 Anterior 1 1 1 Incisor 6 2 Posterior 24 28	1.5-2.5	12	16
Degree of sclerotic dentin 1	2.5-4.0	10	6
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2 14 12 3 16 18 4 0 0 Presence of antagonist Yes 30 30 No 0 0 Attrition facet Yes 0 0 No 30 30 Preoperative sensitivity (spontaneous) Yes 0 0 No 30 30 Preoperative sensitivity (air dry) Yes 18 16 No 12 14 Preoperative sensitivity (touch) Yes 16 18 No 14 12 Tooth distribution Anterior Incisor 6 2 Posterior Premolar 24 28	Degree of sclerotic dentin		
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No 0 0 Attrition facet 0 0 Yes 0 0 No 30 30 Preoperative sensitivity (spontaneous) 0 0 No 30 30 Preoperative sensitivity (air dry) 0 12 14 Preoperative sensitivity (touch) 12 14 Preoperative sensitivity (touch) 16 18 No 14 12 Tooth distribution 14 12 Anterior 1 1 Incisor 6 2 Posterior 24 28	Presence of antagonist		
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Yes 16 18 No 14 12 Tooth distribution Anterior Incisor 6 2 Posterior Premolar 24 28	No	12	14
No 14 12 Tooth distribution Anterior Incisor 6 2 Posterior Premolar 24 28	Preoperative sensitivity (touch)		
Tooth distribution Anterior Incisor 6 2 Posterior Premolar 24 28	Yes	16	18
Anterior Incisor 6 2 Posterior Premolar 24 28	No	14	12
Incisor 6 2 Posterior 24 28	Tooth distribution		
Posterior Premolar 24 28	Anterior		
Premolar 24 28	Incisor	6	2
	Posterior		
Molar 0 0	Premolar	24	28
	Molar	0	0

Table 1: Continued.				
Characteristics of Research Subjects Patients, n				
Arch distribution		_		
Maxillary	10	12		
Mandibular	20	18		
Abbreviations: CR/RC, cotton rolls/retraction cord; Noterical lesions; RD, rubber dam.	NCCLs, nonc	arious		

rubber dams vs cotton rolls/retraction cord isolation. The null hypothesis to be tested was that the 18-month retention rates of adhesive restorations placed in NCCLs are similar for both isolation methods.

METHODS AND MATERIALS

Patient and Lesion Selection

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and consent form for this study (protocol 6291/06). This study was reported in accordance with the Consolidated Standards of Reporting Trials statement. ¹⁶

Study Design—This was an examiner-blind, splitmouth randomized clinical trial. The study was carried out in the Clinic of the School of Dentistry at the State University of Ponta Grossa (Paraná, Brazil) from April-November 2010. We informed all participants about the nature and the objectives of the study.

Inclusion Criteria—Two calibrated dental residents screened patients to determine whether they met the study entry criteria. The qualified patients were recruited in the order in which they reported for the screening session, thus forming a convenience sample.

The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe. All participants were healthy and had at least 20 teeth. Each participant had at least one pair of similarly sized NCCLs, without undercuts. The lesions were located in the same arch but on opposing sides. All teeth selected for the study had occlusal contacts, with no more than 50% of the cavo-surface margin involving enamel. Patients must also have been willing to sign the informed consent form before starting treatment. All baseline details relative to the research subjects and the NCCLs are displayed in Table 1.

Exclusion Criteria—Patients with extremely poor oral hygiene, criteria 2 and 3 of periodontitis, ¹⁹ or with heavy bruxism habits were excluded from the

study. Patients with NCCLs exhibiting self-reported spontaneous hypersensitivity were also excluded. Of 51 patients, 21 were excluded from the study because they did not fulfill the inclusion criteria. Thus, a total of 30 subjects (12 men and 18 women), with a mean age of 45 years were enrolled in this study.

Characterization of Noncarious Cervical Lesions— The degree of sclerotic dentin was measured according to the criteria described by Swift and others. The lateral visualization of the cavity allowed the determination of the angle of the cavity (<45°; 45°-90°; 90°-135°; >135°). The gingival-incisal height of the cavity was measured using a periodontal probe. Other features such as presence of antagonist and attrition facet were also observed and recorded to allow identification of comparability of the groups at baseline (Table 1).

Before evaluation, the examiners were trained in the criteria of Swift and others²⁰ for evaluation of the sclerotic dentin and cavity angle. They observed 15-20 photographs that were representative of each score in each criterion (n=4), and the criteria were discussed with an expert. After that and on two further occasions, they evaluated 10-20 teeth that were not included in the study sample. An intraexaminer and interexaminer agreement of at least 85% was necessary before we began the evaluation.²¹

Clinical photographs were taken prior to the beginning of the treatment, at an original magnification of 1.5× using a digital camera (D70; Nikon Inc, Melville, NY, USA) with a 120-mm Medical Nikkor lens (Nikon Inc) to record the periodontal conditions. Gingival conditions (gingival insertion level and bleeding) were evaluated using the Löe and Silness Gingival Index.²² A blunt instrument, such as a periodontal probe, was used to assess the bleeding potential of the gingival tissues²² and the gingival sensitivity (yes/no). One calibrated dental resident specializing in periodontics performed this exam. Before evaluation, the examiner was trained in the criteria for the Löe and Silness Gingival Index,²² by one professor, a specialist in periodontics with more than 15 years of experience. They observed 10-20 photographs that were representative of each score. After that and on two occasions, they evaluated 10-20 teeth that were not included in the study sample. An intraexaminer and interexaminer agreement of at least 85% was necessary before we began the evaluation.²¹

Operative Procedure and Experimental Design—All patients were given oral hygiene instructions prior to the operative treatment. The same calibrat-

ed dental residents who participated in the patient screening restored all teeth under the supervision of an experienced clinician. The dental residents were clinical professors who were at the end of their doctoral courses at the School of Dentistry at the State University of Ponta Grossa (Paraná, Brazil). At the time the study was conducted, they each had clinical experience of more than 10 years.

For the calibration procedure step, the experienced clinician placed one restoration from each group to identify all restorative steps involved in the application technique. Then, each operator placed two restorations per group, also under the supervision of the experienced clinician. The restoration deficiencies were shown to the clinician prior to starting the study. Only after that were the operators considered calibrated to perform the restorative procedures.

A maximum of two restorations per patient were placed, one from each group. A total of 60 restorations were placed, with 30 for each group. In each subject, the choice of each isolation method was randomly determined by tossing a coin before the restorative intervention in order to guarantee concealment of the allocation. Both restorations were placed in the same day. The patient and the operator were not blinded to the procedure, but the examiner was.

In the RD group, the rubber dam was inserted (Madeitex, São José dos Campos, Brazil) along with the rubber dam retainer No. 212 (KG Sorensen, Barueri, Brazil). In the CR/RC group, a mouth retractor (Arc-Flex, FGM Dent Prod Ltda, Joinville, Brazil) was applied, and cotton rolls and saliva ejectors were used to keep the operative field dry. The gingival tissue of teeth from the CR/RC group was retracted with the retraction cord (Proretract, FGM Dent Prod Ltda).

After allocating the groups, the proper shade of the composite was determined using a shade selection guide (Ice Shade Guide, SDI Limited, Baywater, Australia). Both lesions were restored in the same clinical appointment, and the order of the procedure varied from patient to patient.

To determine the need for dental anesthesia, the dental retainer or retraction cord was placed and the operators asked the patient if he or she felt any discomfort. In the case of a positive answer, teeth were anesthetized (Citanest, Dentsply, Petrópolis, Brazil). In the case of a negative answer, the operative intervention continued on from that point. The lesions were cleaned with pumice and water in a rubber cup (Ref No. 8040RA and No. 8045RA, KG

Adhesive Systems	Composition	Application Mode			
Go! (SDI Limited, Bayswater, Victoria, Australia)	Phosphoric acid ester monomer; dimethacrylate monomer; monomethacrylate monomer; silicon dioxide filler; water; acetone; photoinitiators; stabilizer and sodium fluoride	 Apply first coat of adhesive to saturate all surfaces. Leave in place for 20 s. Blow with dry, high-pressure, oil-free air for 10 s to evaporate solvent. Apply second coat of adhesive to saturate all surfaces. Leave in place for 20 s. Blow with dry, high-pressure, oil-free air for 10 s to evaporate solvent. Leave surface glossy. Light-cure for 10 s with an LED light (Radii-Cal LED, SDI Limited). 			
Ice (SDI Limited, Bayswater, Victoria, Australia)	22.5% wt (39% vol) multifunctional methacrylic ester and 77.5% wt (61% vol) inorganic filler (40 nm-1.5 μ m).	 Place composite in increments of 2 mm or less. Light-cure each increment for at least 20 s using an LED light (Radii-Cal LED). 			

Sorensen, Barueri, Brazil), followed by rinsing and drying procedures. The operators did not prepare any additional retention or bevel in the NCCL, according to the guidelines of the American Dental Association.²³

The self-etch adhesive system GO! (SDI Limited) and the composite resin Ice (SDI Limited) was applied according to the manufacturer's directions (Table 2). The cavities were restored in three increments, and each one was light-cured for 20 seconds (Radii-cal, SDI Limited; 800 mW/cm²).

The restorations were finished with fine-grit diamond burs and the polishing procedure was performed with abrasive discs (Sof-Lex Pop-On discs, 3M ESPE, St Paul, MN, USA) immediately after placing the restorations. The time required for the restorative intervention from the beginning of the isolation procedure until the final polishing was recorded for both groups.

Clinical Evaluation

Patients' Preferences—Immediately after removal of each isolation method, we asked the patients about which method of isolation they preferred.

Evaluation of the Gingival Tissue Damage—Clinical photographs were taken immediately after the restorative procedure and after one week using the same parameters as for the baseline picture. The presence of gingival laceration (yes/no) was evaluated immediately after the restorative procedure and again after one week. The gingival condition (gingival insertion level and bleeding) was evaluated as described earlier only after one week of the restorative procedure. Gingival sensitivity (yes/no) after one week following the procedure was also evaluated

by asking the patient if he or she had any kind of sensitivity in the gingivae.

Performance of Adhesive Restorations—We used the FDI criteria^{24,25} to evaluate the restorations at baseline and after six, 12, and 18 months of clinical service. Only the most relevant items for testing the adhesive performance were selected (Table 3): marginal staining, fractures/retention, marginal adaptation, postoperative sensitivity, and recurrent caries.

Two experienced examiners, blinded to the group assignment, performed the follow-up examinations using a mirror and a double probe. Both examiners evaluated all the restorations once and independently. When disagreements occurred during the evaluations, they had to reach consensus.

Calibration Step—Before evaluation, the examiners were trained in the FDI criteria. 24,25 They observed 10 photographs that were representative of each score for each criterion. After that and on two occasions, they evaluated 10-15 teeth that were not included in the study sample. An intraexaminer and interexaminer agreement of at least 85% was necessary before we began the evaluation. The training was performed by one professor, a specialist in restorative dentistry with more than 15 years of clinical and research experience.

Statistical Analysis

The patients' preferences, the need for anesthesia, presence of laceration, self-report of gingival sensitivity, and the one-week gingival bleeding between the two groups were evaluated by the McNemar test.

Due to the non-normal distribution of the data from the gingival insertion level, the baseline and one-week levels for each isolation method were

Classification	Esthetic Property	Functional	Properties	Biological Properties		
	1. Staining margin	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	
Clinically good (after correction very good)	1.2 Minor marginal staining, easily removable by polishing.	2.2 Small hairline crack.	3.2.1 Marginal gap (50 µm). 3.2.2 Small marginal fracture removable by polishing.	4.2 Low hypersensitivity for a limited period of time.	5.2 Very small and localized demineralization. No operative treatment required	
3.Clinically sufficient/ satisfactory (minor 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).	$3.3.1~\text{Gap} < 150~\mu\text{m}$ not removable. $3.3.2.~\text{Several small}$ 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)	Clinically 1.4 Pronounced catisfactory (repair prophylactic major intervention		3.4.1 Gap > 250 μm 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.	

compared with each other by the Wilcoxon signed rank test. The gingival insertion level of the two groups, at each period, was also evaluated by the Wilcoxon signed rank test. The total time required for the restorative procedure was evaluated by Student *t*-test for dependent samples.

The differences in the ratings of the two groups in each recall time (six, 12, and 18 months) were tested with the Fisher exact test (α =0.05), and differences in the ratings of each recall time (six, 12, and 18 months) vs baseline findings were compared using the McNemar test (α =0.05).

RESULTS

Patients' Perceptions and Gingival Conditions

Two patients slept during the restorative procedure, and therefore they did not report any preference for the isolation methods. Fifteen and 13 patients preferred the rubber dam and cotton roll/retraction cord, respectively, and this difference was not statistically significant (p=0.86). The

total time required to perform the restoration of NCCL lesions was 20.8 ± 5.2 minutes and 21.2 ± 5.2 minutes for the RD and CR/RC groups, respectively, and this difference was not significant (p=0.77).

Approximately 70% of the patients required anesthesia, and no significant difference was observed between groups (Table 4; p=1.00). Gingival bleeding and laceration were more common for the RD group in comparison with CR/RC group; however, this difference was not significant (Table 4; p=0.57 and p=0.64, respectively). No significant difference in gingival sensitivity was reported after one week between isolation methods (Table 4; p=0.52).

The median of gingival insertion levels (mm) at baseline and at one week were similar for both isolation methods, and no significant differences between them were observed when the baseline (p=0.82) and 1-week gingival insertion levels (p=0.56) were compared with each other (Table 5).

Table 4:	Comparison of the Patient's Preference, Need for Anesthesia, Gingival Laceration, Gingival Bleeding, and Sensitivity for	
	the Study Group (%, 95% Confidence Interval [n])	l

Characteristic	RD	CR/RC	p-Value*		
Patient's preference	54 (36-71) [15]	46 (30-64) [13]	0.86		
Needed anesthesia	67 (49-81) [20]	70 (52-83) [21]	1.00		
Gingival laceration	63 (46-78) [19]	37 (22-55) [11]	0.64		
1 wk gingival bleeding	60 (42-75) [18]	47 (30-64) [14]	0.57		
1 wk gingival sensitivity	0.52				
Abbreviations: CR/RC, cotton rolls/retraction cord; RD, rubber dam.					

McNemar test.

Performance of the Adhesive Restorations

All research subjects attended the follow-up recalls. None of the patients reported postoperative sensitivity, and we did not detect caries at any of the follow-up periods.

In regard to retention, the six-month retention rates (with 95% confidence interval in parentheses) of the restorations were 93% (79%-98%) for both isolation methods, and after 12 months, 90% (74%-96%) and 86% (70%-95%), respectively, for the RD and CR/RC groups. At the 18-month recall, the retention rates were 73% (55%-86%) for the RD group and 73% (55%-86%) for the CR/RC group, with no statistical difference between any pair of groups at the six, 12, and 18-month recall (p>0.05). A significant difference was detected between the 12month and 18-month data compared with the baseline for both groups (Table 6; p < 0.05). An overall retention rate after 18 months of only 73% (55%-86%) was observed for the adhesive tested.

Only a few restorations were considered to have clinically relevant discrepancies in the item fracture (Table 6), but no significant difference was detected between any pair of groups at the six-, 12-, and 18month recall and for each group when the six-, 12-, and 18-month times were compared with baseline (p>0.05).

In regard to marginal staining and marginal adaptation, no significant difference was found between groups at each recall time and for each group when the six-, 12-, and 18-month times were compared with baseline (Table 6; p>0.05). Some clinical cases can be found in Figures 1-3.

DISCUSSION

Although one of the aims of rubber dam isolation is to protect soft tissues against physical and chemical trauma resulting from the operative procedure, 3,4 the occurrence of gingival abscess was already reported due to the retention of the rubber dam into the gingival sulcus. 26,27 In addition, the use of metallic retainer retractors in areas with a narrow width of keratinized gingiva can contribute to the occurrence of gingival recession.²⁸ Actually, both methods can cause injuries to the periodontium to some degree, although it is worth noting a high repair capacity of the gingival tissue, causing almost no pain or discomfort for the patients.²⁹

The present study observed gingival laceration and bleeding immediately after placement of the restoration, but this was not restricted to the RD group. These findings are in agreement with a recent study published by Daudt and others¹⁵ in which the authors demonstrated that the use of a rubber dam in NCCL restoration resulted in a significantly higher gingival recession only immediately after isolation; this is not statistically different from the results of the CR/RC group one week after the restorative procedure.

Table 5: Comparison	of Gingival Insertion Level Between the	e Study Groups, Median (Minimum/Maxim	num)
Groups	Median of Gingi	p-Value*	
	Baseline	1 wk After	
RD	1 (0/3)	1 (0/3)	0.78
CR/RC	1 (0/3)	1.25 (0/3)	0.48
p-Value*	0.82	0.56	
Abbreviations: CR/RC, cotton * Wilcoxon test for independe	rolls/retraction cord; RD, rubber dam. nt samples ($\alpha = 0.05$).		

Table 6: Number of Evaluated Restorations for Each Experimental Group Classified According to the World Dental Federation (FDI) Criteria^{24,25}

FDI Criteria	RD			CR/RC				
	Baseline	6-mo	12-mo	18-mo	Baseline	6-mo	12-mo	18-mo
1.Marginal staining								
VG	30	26	21	15	30	25	20	16
GO	_	2	4	4	_	2	3	4
SS	_	_	_	_	_	_	_	_
UN	_	_	_	_	_	_	_	_
PO	_	_	_	_	_	_	_	_
2. Fractures and retention								
VG	30	28	25	19	30	27	23	20
GO	_	_	_	_	_	_	_	_
SS	_	_	2	3	_	1	3	2
UN	_	2	3	8	_	2	4	8
PO	_	_	_	_	_	_	_	_
3. Marginal adaptation								
VG	30	24	20	14	30	23	19	16
GO	_	4	5	5	_	4	4	4
SS	_	_	_	_	_	_	_	_
UN	_	_	_	_	_	_	_	_
PO	_	_	_	_	_	_	_	_
4. Postoperative (hyper-) sensitivity								
VG	30	28	25	19	30	27	23	20
GO	_	_	_	_	_	_	_	_
SS	_	_	_	_	_	_	_	_
UN	_	_	_	_	_	_	_	_
PO	_	_	_	_	_	_	_	_
5. Recurrence of caries								
VG	30	28	25	19	30	27	23	20
GO	_	_	_	_	_	_	_	_
SS	_	_	_	_	_	_	_	_
UN					_		_	_
PO	_	_				_		_

Abbreviations: CR/RC, cotton rolls/retraction cord; GO for clinically good; PO for clinically poor; RD, rubber dam; VG for clinically very good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory.

This means that the damage caused by both isolation methods is reversible and not persistent; the gingival tissue can be readily repaired in a way such that fewer than half of the patients complained of pain or discomfort one week after the procedure. The gingival insertion one week after the restorative procedure was similar to the baseline for both groups, which adds evidence that the damage produced by the isolation is reversible.

Contrary to the belief that the use of rubber dam isolation is more time consuming, 6,7,9 the present study demonstrated that the time required for the placement of NCCL restorations was not affected by the choice of the isolation method. This is related to

the fact that the operators who placed the restorations in the present study are resident dentists with more than five years of clinical experience in operative dentistry. In addition, the restorations were all placed in the university environment, although there are some concerns regarding the difference between this kind of clinical trial and the results found in practice-based research.³⁰ Unfortunately, this hypothesis needs to be tested for restorations placed by operators with different levels of experience and in different environments.

The preferences of the patients for the isolation methods were similar. There is a widespread belief that RD isolation is more effective for preventing







Figure 1. Noncarious cervical lesions on upper first and second premolar (A): before and (B): after restorations and (C): at the 18 month clinical evaluation. Observe the lack of retention after 18 months for the restoration of upper second premolar (cord retraction).

contamination of the operative field. However, this was not observed in the present investigation. Regarding the adhesive performance, we expected to find a better clinical performance with the use of a rubber dam because in theory, its use provides a cleaner and contamination-free surgery field, without saliva and gingival fluid. However, the results of the present study did not prove this hypothesis, leading us to accept the null hypothesis.

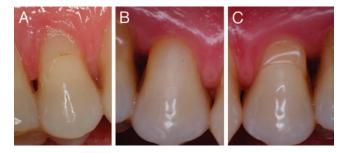


Figure 2. Noncarious cervical lesions on upper second premolar (A): before and (B):after restorations and (C): at the 18 month clinical evaluation (cord retraction). It was classified as clinically good in marginal adaptation and marginal discoloration (see enamel margin).

The results are in line with a recently published meta-analysis of NCCL clinical studies. ¹² Heintze and Rousson ¹² evaluated 105 studies, and a rubber dam was used in 47. Although the clinical success rate of restorations applied with a rubber dam

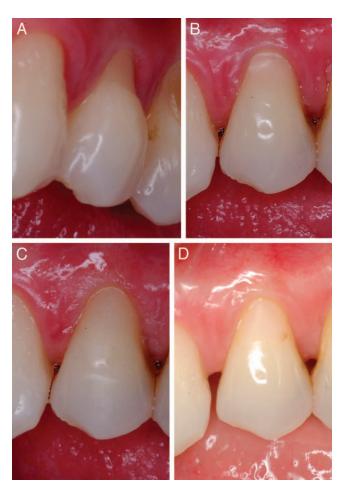


Figure 3. (A): Lateral and (B): frontal view of noncarious cervical lesions on upper first premolar before and (C): after restorations (cord retraction) and (D): at the 18 month clinical evaluation. It was classified as clinically good in the marginal discoloration (see enamel margin).

compared with cotton rolls/retraction cords showed a trend toward increased retention, the difference did not reach statistical significance. One cannot rule out the fact that experienced and trained clinicians placed the restorations in the present and in Daudt and others' study, ¹⁵ meaning that a surface free of contamination from saliva and the gingival fluid was also obtained with the CR/RC group. Again, whether this would be applicable in practice-based research, where clinicians are not extensively trained on both methods, or in other types of dental cavities, where the moisture control is more challenging, is yet to be addressed and deserves further investigation.

Previous systematic reviews of the literature have pointed out that one-step self-etch systems have higher annual failure rates than do other adhesive strategies. ^{12,31} This was also observed in laboratory studies: relatively low bond strength values to enamel and dentin were usually observed for this type of bonding strategy. ³²⁻³⁵ This is probably due to the more complex chemistry they require, because hydrophilic and hydrophobic monomers, water, solvent, and others components need to be blended in a single bonding solution. ^{36,37}

Nonetheless, the overall retention rates of the adhesive GO! in the present study were much lower than the average commonly reported by the literature for one-step self-etch adhesives. Almost 27% of the restorations debonded after a short 18-month follow-up. Although this was not the main objective of this clinical trial, it provided clinical information about a specific brand of adhesive that is clearly relevant to clinical practitioners.

In a recent laboratory study, the adhesive GO! produced the lowest microtensile bond strength values to dentin, 35,38 with a high percentage of premature failures. In addition, it was already reported that most of the teeth from the GO! group debonded completely during preparation for the microtensile bond strength test. 35,39 Under the manufacturer's instructions, a higher amount of silver nitrate was also observed in the hybrid layer produced with GO! in a previous study. 39

Hass and others³⁹ hypothesized that a less than average performance in the laboratory tests could be due to the presence of a high acetone content, which resulted in the formation of a very thin hybrid layer.⁴⁰ The thinner the adhesive layer, the more susceptible it is to polymerization inhibition by oxygen.⁴¹ In the same study, a low degree of conversion was observed inside the hybrid layer for the adhesive GO!.³⁹

Altogether, the laboratory findings suggest that the poor polymerization and bonding of this material can be related to an inadequate equilibrium among the chemicals included in the GO! formulation. For instance, GO! is a 2-hydroxyethyl methacrylate (HEMA)-free adhesive. Some research has revealed that HEMA-free one-step adhesives are prone to phase separation, which may also account for their lower bonding effectiveness. 42,43

However, one cannot omit mentioning that the quite low retention rates of the adhesive GO! in the present study were not observed in a study by Burrow and others. Those authors reported an overall retention rate of 85% after three years. Different from the present study, Burrow and others light-cured the adhesive for 20 seconds instead of the 10 seconds recommended by the manufacturer. The higher exposure time could have led to an increased degree of conversion and thus improved its clinical performance.

Another difference from both studies is that selective enamel etching was performed before adhesive application in the study by Burrow and others. 44 Although selective enamel etching has not been associated with increased retention rate but only with reduced marginal discrepancies, 45,46 this technique was only evaluated for two-step self-etch adhesives. 45,46 Perhaps for one-step adhesives, selective enamel etching may also aid in restoration retention, but this should be the focus of future investigations.

Although one might suppose that cavity preparation would increase the retention rates of the materials, we did not perform any cavity preparation in this clinical trial basically for three reasons: 1) randomized clinical trials that compare adhesive performance in cavities with or without dentin roughening did not show significant differences. ^{47,48} 2) randomized clinical trials that compared enamel beveling with no bevel also demonstrated similar findings ^{49,50}; and last, the American Dental Association guidelines for testing the adhesive performance in clinical studies does not recommend any cavity preparation. ²³

The results of this study can be generalized only to patients with low caries risk. In the present study we have excluded patients with poor oral hygiene and active caries lesions because the restoration of NCCLs would be not the priority for these patients. Other preventive measures, such as oral hygiene instructions, dental sealing, and restoration of active lesions, would have been necessary before such

patients could have met the inclusion criteria for this clinical trial.

Since the introduction of the FDI criteria, ^{24,25} few studies have attempted to compare this instrument with the traditional criteria from the United States Public Health Services (USPHS). ^{51,52} A recent study that compared both methods concluded that the FDI criteria are more sensitive than the USPHS criteria for detecting small variations in clinical outcomes, ^{51,52} and this is the reason why we used only the FDI criteria in the present study.

CONCLUSIONS

The use of cotton rolls/retraction cord was shown to be similar to the use of rubber dam isolation in terms of patient's preference, gingival damage, chairside time, and retention rates of adhesive restorations in NCCLs.

Acknowledgements

The authors would like to thank SDI Brazil for the generous donation of the restorative products employed in this study. This study was partially supported by the National Council for Scientific and Technological Development (CNPq) under grants 301937/2009-5 and 301891/2010-9.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of COEP/UEPG. The approval code for this study is 06231/09. This study was conducted at the State University of Ponta Grossa.

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.

(Accepted 28 October 2014)

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