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Effect of Pre-treatment with Chlorhexidine on the Retention of Restorations: A Randomized Controlled Trial

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This study aimed to evaluate the effect of chlorhexidine (CHX) application on etched dentin on the 6-month retention of restorations placed on non-carious cervical lesions (NCCLs). A randomized controlled split-mouth and triple blind trial was carried out. Patients (n=42) with at least two non-carious cervical lesions were included. NCCLs were randomly assigned to two groups: control (placebo solution) or test group (2% CHX solution for 60 s after acid etching and before the adhesive application). Class V restorations (n=169) were performed with an etch-and-rinse adhesive system and composite resin by 10 trained operators. A calibrated examiner evaluated the restorations at 1 week (baseline) and at 6 months using the FDI criteria. The primary outcome was retention of the restorations. The analysis of factors associated to failure of restorations was carried out by Fisher's exact test (α=0.05). After 6 months of follow-up, 3.4% (CI 95% 1.3-7.3) of the restorations failed. There was no statistically significant difference between control and CHX (p=0.920). Regarding the cavity variables, deeper (p=0.04), wider (p=0.004) and wedge-shaped (p=0.033) cavities failed more. Both treatments provided acceptable clinical performance of the restorations. The use of CHX as a adjuvant in dentin adhesion did not influence the retention of Class V restorations after 6 months of follow-up.

Key Words: chlorhexidine, MMP inhibitor, adhesive system, controlled clinical trial, dental restoration, non-carious cervical lesions.

Introduction

The ultimate goal of adhesive systems is to provide an effective and durable bond to the dental substrate increasing the longevity of restorations. However, despite all advances, the stability of this bond still presents limitations that may impair the durability of adhesive restorations in time (1). The adhesive interface degradation is attributed to a combination of hydrolytic and enzymatic degradation of collagen fibrils and degradation of the bonding resin within the hybrid layer. This degradation has been mainly associated to the presence of hydrophilic polymers in the composition of some adhesive systems (1). The degradation of the collagen component of the hybrid layer has been attributed to the action of the matrix metalloproteinase enzymes (MMPs) released from dentin (2,3).

Considering the evidence of destruction of the collagen network in human dentin by the action of MMPs, some studies examined the protective effects of MMP inhibitors on cavity preparations after acid etching and before the application of the adhesive system (2,4). MMP inhibitors could act on the dentin surface after etching and decrease the enzymatic degradation activity, increasing the stability of resin-dentin bond in time (2,5). In this context, studies have demonstrated that chlorhexidine digluconate (CHX) is an effective and non-specific MMP inhibitor that is able to prevent the enzymatic activity of metalloproteinases, mainly the MMP-2 and MMP-9 (2,6). CHX application *in vivo* (4,7) and *in vitro* (2,6) has been proposed to improve the hybrid layer integrity and to promote a more stable resin-dentin bond in time and therefore the MMP inhibition could preserve interface integrity.

CHX was proposed as a known and effective protease inhibitor based on *in vitro* and *ex vivo* studies, where the restored teeth were extracted for bond strength tests. These studies are limited to predicting the clinical success of this technique, and properly designed clinical trials should be carried out to evaluate the performance of restorative materials (8). Only a few trials were carried out to evaluate the effects of MMP inhibitors on the survival of dental restorations (9,10). Moreover, in challenging situations, as the restorative treatment of non-carious cervical lesions (NCCLs), the retention of the restorations is a common reported problem. Therefore, since the prognosis of cervical restoration may be affected by several factors, not only the adhesive procedure per se is defying, but also the clinical characteristics of the lesion and aspects related to the patient could play a role in the retention rate of restorations (11).

Based on this, the aim of this prospective randomized controlled trial was to evaluate the effect of 2% CHX

application after the etching step on the 6-month retention of restorations placed on NCCLs. The secondary aim was to evaluate the impact of the lesion and patient's characteristics on the retention of these restorations. The tested hypotheses were that the reduction of MMP activity by CHX provides better clinical performance of the restorations over time, and that factors associated to the NCCL lesions or the patient affect the performance of restorations.

Material and Methods

Ethical Considerations

The study was approved by the local Ethics Committee (protocol 210/2011), registered at clinicaltrials.gov (registration number NCT01947192) and performed according CONSORT guidelines (12). Prior to the participation in the study, all participants signed a written informed consent. All dental needs of the subjects enrolled in this study were provided by 5 undergraduate dental students, under supervision, during the whole study period, except for prosthetic rehabilitation and orthodontic treatment.

Study Design

This study was designed as a split-mouth, triple-blind (clinical evaluator, operators and patients), prospective randomized controlled clinical trial. NCCLs were randomly assigned into two different treatment groups: application of CHX (test group) or a placebo solution without CHX (control), both applied after acid etching and before the adhesive. The restorations were carried out by 10 previously trained operators (undergraduate dental students) and supervised by the main researchers (AFM, APP and MSC) from 2011 to 2012. The operators were trained with theoretical lectures and practical activities performing class V restorations. The sample selection was made by two dentists (AFM and MSC). All operators were updated and trained before the beginning of the clinical procedures by two researchers (ASM and AFM).

Sample Size

Taking into account a retention percentage of 99% after 6 months for NCCLs placed with Adper Single Bond adhesive system (13), the sample size calculation of this research was based on a 20% difference in retention rates between the groups at a significance level of 5% with a power of 80%, which resulted in a sample size of 35 patients, in a split-mouth design. Considering the dropout rate along the experimental period, a need for 40 patients was considered.

Subjects were recruited from the examination of patients under treatment at the Dental School and by announcements and advertisement posters. All who needed dental treatment of NCCLs were invited to participate. Reasons for treatment were cervical tooth sensitivity, aesthetic complaints and/or prevention of further tooth damage. The dental treatments were carried out in a Dental Clinic specific organized for treatment of noncarious cervical lesions, at the Dental School of the Federal University of Pelotas, until the sample size was obtained.

Inclusion Criteria

The following inclusion criteria were used: patients presenting at least two NCCLs in incisors, canine or premolars; patients who had more than 20 teeth present in the mouth; patients who were at least 18 years-old at the time of treatment and capable to understand and sign the written informed consent; NCCLs with at least 1 mm deep in a vital permanent incisor, canine or premolar of the maxilla and the mandible; NCCLs in the buccal surface of the teeth with an eventual small part extending interproximally; patients with good periodontal health.

Exclusion Criteria

Patients with smoking habits, bruxism, severe systemic diseases, under active orthodontic treatment and malocclusion; NCCLs tooth without the antagonist; NCCLs wear facets higher than 50% of the incisal/occlusal surface; Presence of caries or restorations in the area to be treated; Full-mouth visible plaque index (VPI) or full-mouth gingival bleeding index higher than 20%, probing depth and clinical attachment loss values exceeding 4 mm with bleeding on probing; Unwillingness to return to follow-ups or refusal to participate.

Screening of lesions was performed using a mouth mirror, an explorer and a millimeter periodontal probe. The NCCLs depth was measured by placing a probe into their deepest part, whereas the height was calculated by the distance between the most coronal to the most apical point of the cavity margins. The degrees of dentin sclerosis were identified using a scale ranked from 1 to 4 (14). Sensitivity test was measured by blowing a stream of compressed air for 3 s at a distance of 2 to 3 cm, while shielding the adjacent teeth with fingers. Tooth vitality was tested by application of an Endo-frost cold spray on the tooth and compared with the reaction of the adjacent teeth. No attempt was made to determine the etiology of the cervical lesions.

Study Groups

All of the NCCLs of consenting volunteers that fulfilled the eligibility criteria were randomly assigned to test or control groups, where the CHX was applied on dentin after the etching procedure (test group) or not (control group).

Randomization Assignment and Blinding Procedures

The randomization was carried out in a computer program (Microsoft Excel-2010) and a randomization table was used to allocate the NCCLs in each study group by random numbers. One person not directly involved with the clinical part of the study prepared this table in advance. The treatment was allocated regarding the dental group (incisors, canines and premolars), where the first tooth restored was raffled for treatment, while the next tooth from the same tooth-group was automatically assigned to the other treatment, according to the split-mouth design. The first tooth chosen followed its position in the quadrant arch. It is important to emphasize that each operator performed the same number of restorative treatments, both for control and test groups.

Opaque sealed envelopes were employed to conceal the randomization sequence. While the first randomly selected treatment was used for the lowest quadrant number, the second treatment was used for the tooth with the second lowest quadrant number (according to the FDI system). This method was repeated for every quadrant that required a cervical restoration. When an uneven number of NCCLs per patient occurred, the inequality number of lesions of one group was adjusted by restoring one more lesion with the other group in the next patient presenting uneven number of cervical lesions.

The solutions for control and test groups were put in an opaque recipient codified as Treatment A or B, respectively. That condition allowed blinding of the operators and patients, as the clinical procedure was the same for both groups.

Clinical Procedures

Before the adhesive procedures, the prophylaxis of the tooth was done and the color of the restoration was chosen (Vitapan Classical; Vita Zahnfabrik, Bad Sackingen, Germany). Whenever required, local anesthesia was given to prevent the patient having discomfort prior to the treatment. All procedures were carried out with relative isolation method and moisture control was provided using a suction device in position by an assistant during the restorative procedure and labial retractor, cotton rolls and gingival retraction cord (#000 Ultrapak Cord, Ultradent, South Jordan, UT, USA) were placed into the gingival sulcus.

There was no beveling in the cavosurface edges of NCCLs or any cavity preparation before the restorative procedures. For both groups, the restorative procedures were performed with an etch-and rinse two-step adhesive system (Adper Single Bond 2; 3M ESPE, St. Paul, MN, USA) and a nanoparticle composite resin (Filtek Z350; 3M ESPE) applied strictly following the instructions provided by the manufacturer.

After the 35% phosphoric acid (Adper Scotchbond Etchant; 3M ESPE) application for 20 s in dentin and 15 s in enamel, the cavity was dried with a dry pellet. For the control group a placebo solution (similar to the solution used for the test group but without CHX) was applied on the dentin surface for 60 s. For the test group, a 2% CHX (Manipulation Solution; Uso Indicado Pharmacy, Pelotas, RS, Brazil) was applied on dentin for 60 s. A dry pellet was used to remove the solution excess followed by the adhesive system application according to the manufacturer's instructions.

The NCCLs were restored with a direct restorative nanocomposite resin (Filtek Z350, 3M ESPE, Irvine, CA, USA) applied in at least two increments (not exceeding 2 mm thick), using a selected composite instrument (Hu-Friedy, Chicago, IL, USA). Each increment was cured for 20 s with a LED light-curing unit (Radii-Call; SDI, Bayswater, VI, Australia), intensity of 800 mW/cm^2. All restorations were finished and polished with fine and ultra-fine diamond burs (KG Sorensen, Barueri, SP, Brazil) under water-cooling, slow-speed flexible discs (Sof-Lex Pop-On, 3M ESPE), polishing paste (Diamond Excel; FGM Dental Products, Joinville, SC, Brazil) and rubber points (Enhance; Dentsply Caulk, Milford, DE, USA).

Clinical Assessment

Criteria approved by the FDI World Dental Federation were used for clinical assessment of restorations (15). The primary clinical outcome was restoration retention, considering as failure the loss of restoration. Secondary endpoints included the criteria as follows: 1) marginal adaptation, 2) marginal staining, 3) surface staining, 4) postoperative sensitivity, 5) superficial brightness, 6) translucency and color, 7) fracture, 8) anatomic form and 9) preservation of tooth vitality and integrity. Each criteria was expressed in five scores, three for acceptable and two for non-acceptable (one for reparable and one for replacement). Restorations that needed replacements were considered clinical failures, scored 5.

One previously trained and calibrated examiner who worked as examiner in other clinical trials carried out the evaluations. The examiner was blind to the interventions and not involved in their allocations or in the restorative procedures. A web-based training and calibration tool (www.ecalib.info) and clinical setting evaluation were used for training and calibration of the examiner. The clinical intra-examiner calibration was carried out with 30 Class V restorations, which were re-examined 15 days later. A pre-evaluation intra-agreement of at least 90% was obtained. Photo documentation was made pre-operatively, at baseline and at recall.

Statistical Analysis

Statistical analysis was carried out using Stata 11.0 Statistic Program (Stata Corp. LP, College Station, TX, USA). Descriptive statistics were used to describe the frequency distributions of the evaluated criteria and failures. Qualitative analysis based on the FDI criteria was analyzed independently for each of the evaluated clinical characteristics. Differences in these qualitative criteria between the treatments were analyzed using Fisher's Exact test at $p<0.05$.

Results

During enrolment from September 2011 to August 2012, 61 subjects were assessed for eligibility. Forty-two patients (20 men and 22 women) were enrolled in the study. Details of the recruitment procedures, exclusion characteristics of the patients, and the number of participants through each stage of the trial are disclosed in the flow diagram (Fig. 1). The participants were adults with a mean age of 49 years old (minimum 21 and maximum 76 years). Regarding the socioeconomic status, about half the participants came from low-income families (±U$ 700.00, two minimum monthly Brazilian wage).

As the present study had a split-mouth design, the equal distribution of the subjects into the study groups is inherent presented, thus there were no significant differences between the groups with respect to the baseline characteristics such as age, gender or family income (Table 1). In Table 2 it is possible to observe the characteristics of the noncarious cervical lesions such as height and depth of the lesion distributed in the treatment groups. Most of the NCCLs presented a height of 1 to 3 mm, with a depth around 1 mm, with the restorations placed mostly on premolars.

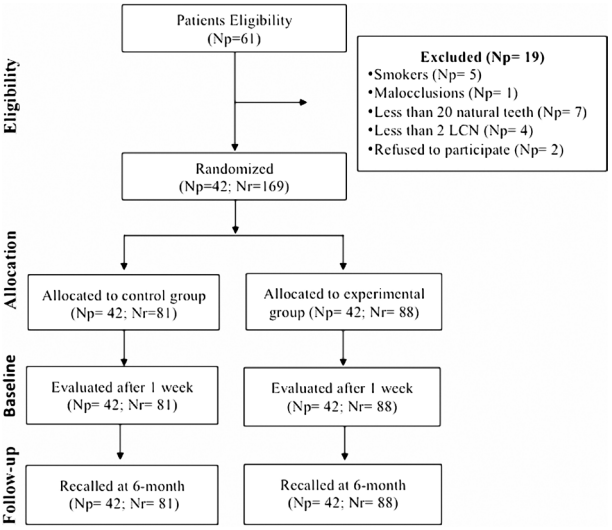

Figure 1. Flowchart showing the enrollment of the study participants. Np, number of patients. Nr, number of restorations.

A total of 169 NCCLs restorations were performed in the forty-two patients, with a median of 4.9 restorations per patient (minimum 2 and maximum 11 restorations). After 6 month after treatment all the patients returned for follow-up, representing 100% of recall response.

After 6 months of follow-up 3.4% (CI 95% 1.3 - 7.3) of the Class V restorations failed considering the primary outcome (retention – 6 restorations). Three restorations

Table 1. Baseline characteristics of the subjects included into the study groups

Characteristics	Subdivision	n [%]
Gender	Male	20 [47.6%]
	Female	22 [52.3%]
Number of teeth	<25 teeth	22 [52.3%]
	>25 teeth	20 [47.6%]
Age	20-40 years old	7 [16.6%]
	41-60 years old	29 [69.1%]
	>60 years old	6 [14.3%]
Income	<2 BMW*	20 [47.6%]
	>2 BMW*	22 [52.3%]
Educational level	<8 years	4 [9.52%]
	8 years	7 [16.6%]
	9 -10 years	4 [9.52%]
	11 years	16 [38.1%]
	12-14	4 [9.52%]
	>15 years	7 [16.6%]
Acid ingestion	Yes	26 [38.1%]
	No	16 [61.9%]

*BMW= Brazilian minimum monthly wage.

Table 2. Baseline characteristics of the non-carious cervical lesions distributed in the treatment groups

Characteristics	Subdivision	Control group n [%]	Test group n [%]
Type of teeth	Incisor	22 [48.8%]	23 [51.2%]
	Canine	14 [46.6%]	16 [53.4%]
	Premolar	50 [53.2%]	44 [46.8%]
Position	Maxillary	42 [52.5%]	38 [47.5%]
	Mandibular	43 [48.3%]	46 [51.7%]
Depth	<1 mm	42 [46.6%]	48 [53.4%]
	1 up to 3 mm	36 [50.7%]	35 [49.3%]
	3 up to 4 mm	2 [40.0%]	3 [60.0%]
	>4 mm	2 [66.6%]	1 [33.4%]
Height	<1 mm	6 [40.0%]	9 [60.0%]
	1 up to 3 mm	47 [52.8%]	42 [47.2%]
	3 up to 4 mm	26 [45.6%]	31 [54.4%]
	>4mm	3 [37.5%]	5 [62.5%]
Cavity shape	U saucer-shaped	38 [47.5%]	42 [52.5%]
	V wedge-shaped	44 [49.4%]	45 [50.6%]

Table 3. Number and percentage of retention for each studied variable

Variable		Non failure (With retention)	Failure (No retention)	p value
Income	<2 BMW	76 (100 %)	0 (0%)	p=0.123
	>2 BMW	82 (95.4%)	4 (4.6%)	
Treatment	Test	88 (98.7%)	3 (3.3%)	p=0.920
	Control	81 (96.4%)	3 (3.6%)	
Depth	<1 mm	89 (96.7%)	3 (3.3%)	p=0.024
	1 up to 3 mm	72 (98.6%)	1 (1.4%)	
	3 up to 4 mm	4 (80.0%)	1 (20.0%)	
	>4 mm	2 (66.3%)	1 (33.3%)	
Height	<1 mm	14 (93.4%)	1 (6.6%)	p=0.004
	1 3 mm	89 (100%)	0 (0%)	
	3 up to 4 mm	57 (95.0%)	3 (5.0%)	
	>4 mm	6 (75.0%)	2 (25%)	
Sensitivity	Absent	75 (97.4%)	2 (2.6%)	p=0.652
	Slight	44 (97.8%)	1 (2.2%)	
	Moderate	24 (96.0%)	1 (4.0%)	
	Severe	26 (92.8%)	2 (7.2%)	
Scleroses	Absent	114 (96.6%)	4 (3.4%)	p=1.000
	Slight	28 (96.5%)	1 (3.5%)	
	Moderate	22 (95.6%)	1 (4.4%)	
	Severe	1 (100%)	0 (0%)	
Restoration margin	Supra-gingival	45 (97.8%)	1 (2.2%)	p=0.669
	Gingival level	107 (96.4%)	4 (3.6%)	
	Subgingival	17 (94.4%)	1 (5.6%)	
Educational level	<8 years	14 (100%)	0 (0%)	p=0.079
	8 years	33 (100%)	0 (0%)	
	9-10 years	22 (91.7%)	2 (8.3%)	
	11 years	72 (98.6%)	1 (1.4%)	
	12-14	9 (90.0%)	1 (10%)	
	>15 years	19 (90.5%)	2 (9.5%)	
Cavity shape	U saucer-shaped	79 (100%)	0 (0%)	p=0.033
	V wedge-shaped	90 (93.7%)	6 (6.3%)	

from the control group (without CHX) and three restorations from the test group (with CHX) were lost. There was no statistically significant difference between control and test treatments (p=0.920). Depth (p=0.024) and height (p=0.004) of the cavity influenced the retention of the restoration. Deeper and wider cavities showed more failures than the shallow and narrow ones. The cavity configuration also influenced the retention; wedge-shaped cavities failed more than the saucer-shaped ones (p=0.033). There was no statistically significant difference for the operators for the evaluated variables (p=0.333). No statistically significant differences were detected among groups for any other evaluated criteria in the present investigation (p>0.050) (Table 3).

After the 6-month follow-up most restorations for both treatment groups presented Score 1 (clinically excellent) and 2 (clinically good) for all specific evaluated criteria (Table 4). The lost

Table 4. Comparison between the treatments considering the restorations remaining after 6 months, according to the FDI criteria compared by Fisher's Exact Test at p<0.05. Numbers separated by slash represent the number of evaluated restorations for each score, according to the FDI criteria: 1. Clinically excellent; 2. Clinically good; 3. Clinically sufficient/satisfactory; 4. Clinically unsatisfactory; 5. Clinically poor

General evaluated criteria	Specific evaluated criteria	Control treatment	Test treatment	p value
		Restoration within each score (1/2/3/4/5)	Restoration within each score (1/2/3/4/5)	
Esthetics properties	Superficial brightness	64/15/2/0/0	67/19/2/0/0	p=0.887
	Surface staining	53/22/4/1/0	59/23/5/1/0	p=0.964
	Marginal staining	49/23/7/1/0	50/29/8/1/0	p=0.734
	Translucency and color stability	34/34/10/3/0	24/52/11/1/0	p=0.092
	Anatomic form	68/12/1/0/0	76/12/0/0/0	p=0.741
Functional properties	Fracture	80/1/0/0/0	87/1/0/0/0	p=0.730
	Retention	81/0/0/0/3	88/0/0/0/3	p=0.000
	Marginal adaptation	26/47/7/1/0	39/42/7/0/0	p=0.275
	Patient perception	66/12/2/0/0	74/13/1/0/0	p=0.870
Biological properties	Postoperative sensitivity	79/2/0/0/0	84/4/0/0/0	p=0.683
	Teeth integrity	81/0/0/0/0	88/0/0/0/0	p=0.169
	Tooth vitality	81/0/0/0/0	88/0/0/0/0	p=1.000
	Periodontal	68/11/5/0/0	72/14/4/0/0	p=0.833

restorations were replaced in the same way as the first time, within the same group (control or CHX), while restorations with a score 4 (clinically unsatisfactory) were repaired.

Discussion

This study showed that while the use of CHX as a MMP inhibitor did not affect the outcome of the restorations placed in NCCLs, the factors associated with the lesion/patient characteristics might affect the performance of those restorations. While the current trend is towards simpler and faster clinical application procedures with less steps, the application of MMP inhibitor during the adhesive procedure, increasing the number of steps has shown a tendency to improve the adhesion stability with time (2,7). In the present investigation, the treatment with a MMP inhibitor did not interfere in the retention rates, partially rejecting the tested hypothesis. Despite the limitations of the short follow-up period (6-month), the present findings did not show favorable results for the tested treatment (CHX) which was comparable to the traditional treatment (control group). At 6 months, only six restorations were scored as clinically unacceptable (3.4% failure rate) due to complete debonding of three restorations of each studied group. Two other clinical trials also showed similar results after 18 and 36-month follow-ups (9,10). It is interesting to note that even with longer follow-ups that could favour the exhibition of the unfavorable clinical characteristics for the restorations, the use of MMP inhibitors seems to not improve the restorations' longevity (9,10).

It is well-established that studies involving cervical restorations should be considered to investigate adhesion effectiveness (1,16) and, in general, composite resin has been suggested as the material of choice for those restorations (11). NCCLs present clinical difficulties for restorative procedures, although even with less experienced operators, most restorations placed by dental students are considered satisfactory after long-term evaluation (17). NCCLs exhibit margins located in enamel and dentin, with sclerotic dentin commonly in the lesion area, turning into a more complex substrate for adhesion (11). In the present study the lesions were not excluded from the screening based on the proportion of margins involving enamel and dentin, neither on the degree of dentin sclerosis. In fact, the degree of sclerosis did not affect the retention rate of the Class V restorations in this study.

The retention variable is a key criterion by which clinical efficacy of tooth-resin adhesion should be estimated because it is the most obvious sign of a failed restoration since it does not depend on the examiner's subjective assessment. According to the 2001 American Dental Association guidelines, resin-based enamel-dentin adhesives achieve ´provisional acceptance` at 6 months if their retention loss in NCCLs is less than 5% without mechanical retention features, and less than 10% after 18 months (18). This is the reason why a 6-month clinical follow-up assessment was considered, with the test group fulfilling that criterion guideline. Taking into account that the sealing capacity of restorations has often been assessed by the integrity and color changes along the entire or part of the margins (15), both treatments were able to properly seal the resin-tooth interface in the assessed period.

In addition to the loss of the restoration, another criterion that could constitute an early failure at 6-month is severe post-operative sensitivity (15). However, both groups performed equally well without reporting abnormal post-operative sensitivity after the restorative procedure. Yet, the frequency of tooth sensitivity to air stimulus was reduced from before to after the restorative procedure. In part this favorable clinical benefit can be attributed to the intervention by itself (restorative procedure), and not the employed treatment (19).

According to the literature, it is not possible to determine a unique etiological factor for NCCLs, but there is an understanding that it is a multifactorial condition; however, current scientific evidence does not support an association between occlusal causes and NCCLs (20). The incidence of NCCLs ranges from 5 to 85%, and the number, size and depth of the lesions increase with patients' age (19,21). Patients that present NCCLs usually present numerous lesions and since the prognosis of cervical restoration may be significantly affected by several factors related to the material, patient and the environment, it is hard to predict the prognosis of these restorations (11). In this study, some cavity variables affected the retention of the cervical restorations regardless the treatment. The depth, height and cavity shape (configuration) definitely play a role for failure-prognostic variables, as deeper and wider lesions presented statistically more retention failure than the others. It was reported that repetitive compressive and tensile stresses caused by tooth flexure in NCCLs contribute to restoration loss due to the mechanical load applied and the resulting tensile stress is concentrated in the cervical area (22). Based on this, the larger lesions can be more affected by those stresses than the smaller cervical lesions. The characteristics of sharp angles and wedge-shapes have not yet been explained by the proposed theories (23).

The causes of the reduced longevity of Class V restorations are still weakly understood. Failures of those restorations are assigned to inadequate moisture control and also to occlusion, although systematic reviews

showed no association of NCCLs with any specific causal agent, and the role of occlusion on its pathogenesis is yet undetermined (24). Clinical studies associated tooth flexure with low retention in cervical restorations, showing that the para-axial loading movement has negative effects on the cervical restorations interface and that repetitive cyclic loadings may induce a failure in the cervical region of the restoration (25). These facts could explain the prevalence of failures for bigger (wider and deeper) restorations, which may result in more flexural movements because of their size.

A limitation of this study is the fact that longer follow-up is advised for direct restorative materials, as longer recall periods are very useful especially when a new treatment method is being tested (15). There were no significant differences in the clinical performance between the dentin treatments; however, a longer period of reevaluation is needed to substantiate the results of this study.

Within the period of 6 months, non-carious cervical restorations placed with both treatments performed equally with a success rate of 96.6%, with acceptable clinical performance. The application of CHX as a MMP inhibitor used as a coadjutant in dentin adhesion did not influence the retention of Class V restorations after 6 months of follow-up. However, factors associated to the tooth cavity configuration, such as shape and extension of the lesion affected the retention of restorations placed on NCCLs.

Resumo

O objetivo deste estudo foi avaliar o efeito da aplicação de clorexidina (CRX) em dentina condicionada na retenção de restaurações confeccionadas em lesões cervicais não-cariosas (LCNC) após 6 meses. Ensaio clínico randomizado triplo cego do tipo boca dividida foi conduzido. Pacientes (n=42) com no mínimo duas LCNC foram incluídos. LCNC foram randomizadas em dois grupos: controle (solução placebo) ou grupo teste (aplicação de CRX 2% por 60 s após o condicionamento e antes da aplicação do adesivo). Restaurações Classe V (n=169) foram realizadas com adesivo de condicionamento ácido total e resina composta, por 10 operadores treinados. Um examinador calibrado avaliou as restaurações após 1 semana (base) e 6 meses usando os critérios da FDI. O desfecho primário foi retenção das restaurações. A análise dos fatores associados à falha das restaurações foi conduzida com Teste Exato de Fisher (α=0,05). Após 6 meses de acompanhamento, 3,4% (IC 95% 1,3–7,3) das restaurações falharam. Não houve diferença estatística entre os grupos CRX e controle (p=0,920). Com relação às variáveis das cavidades, cavidades mais profundas (p=0,024), largas (p=0,004) e em formato de cunha (p=0,033) falharam mais. Ambos os tratamentos (CRX e controle) proporcionaram performance clínica aceitável das restaurações. O uso de CRX como coadjuvante na adesão à dentina não influenciou a retenção das restaurações Classe V após 6 meses de acompanhamento.

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