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ORIGINAL ARTICLE

Two-year clinical performance of a two-step etch-and-rinse adhesive in non-carious cervical lesions

Influence of subject's age and dentin etching time

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Abstract
Aim The aim of this study was to evaluate the influence of the subject's age and dentin etching time on the clinical performance of a two-step etch-and-rinse adhesive in class V non-carious cervical lesions (NCCLs).
Materials and methods Forty patients with NCCLs (classified as degrees 2 and 3 of dentin sclerosis) were enrolled in this study. The lesions were selected and assigned into two groups (n=70/group) according to the subject's age: (G1) between 21–35 years old and (G2) between 40–54 years old. Each group was randomly divided into two subgroups (n=35/group) according to dentin etching time using recommended application time (15 s) and an extended application time (30 s). A total of 140 restorations with XP Bond (Dentsply DeTrey, Germany) were placed. The composite resin Esthet X (Dentsply) was placed incrementally. All restorations were evaluated using the modified USPHS criteria. Data was analyzed by the McNemar and chi-square tests (p<0.05).
Results At the end of 2 years, 132 restorations (94.2 % recall rate) were evaluated. The 24-month retention rates (%) were 93.5 for G1(15), 97.1 for G1(30), 93.9 for G2(15), and 97.0 for G2(30). There were no statistical differences in the retention rates in each recall period among groups.
Conclusion For the selected age groups, neither the subject's age nor the etching time had any influence on the clinical performance of XP Bond adhesive in NCCLs over a 24-month period.
Clinical relevance The clinical effectiveness of the XP Bond was excellent after 2 years of clinical service. Long-term clinical evaluations are necessary to confirm this finding.

Keywords Randomized clinical trial · Acid etching · Dentin bonding · Etch and rinse · Non-carious cervical lesions

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Introduction

Non-carious cervical lesions (NCCLs) result from a pathological process where tooth wear is caused by masticatory activity, biomechanical frictional processes, acid dissolution, and biomechanical loading forces [1]. Guidelines for treatment of such lesions have been developed, and restorative procedures are sometimes needed and may be placed to relieve hypersensitivity, to prevent further tooth structure loss and to improve esthetics [2]. However, restoration of NCCLs has been a challenge for dental practitioners as failures due to lack of retention and marginal discoloration are often noticed [3].

Failures in the restoration of NCCLs normally are result of failure of the adhesive interface, which is often pretreated with phosphoric acid prior to adhesive placement. Biological and clinical factors such as relative humidity of the bonding substrate [4], caries [5], amount of dentin (vs. enamel) [6], dentin age [7], and etching time [8, 9] can affect dentin bonding and be a factor in the clinical performance of restoration of NCCLs. Moreover, sclerotic dentin, which is common in NCCLs, is a complex substrate for bonding due the presence of a hypermineralized layer on the dentin surface [10, 11]. This physiological hypermineralized layer of dentin makes it more acid-resistant and somewhat less susceptible to the conditioning steps used in the adhesive procedure [12, 13].

Increasing etching time has been suggested as a possible strategy for improving micromechanical retention of resin to hypermineralized sclerotic dentin in in vitro studies [7, 14–16]. On the other hand, some laboratory studies have showed that increased etching time had no effect on the bond strengths of adhesive systems when bonded to young versus aged dentin [6, 9, 17]. However, clinical studies [18, 19] have reported no significant differences in the retention of cervical restorations in sclerotic lesions versus non-sclerotic lesions.

Despite improvements in the formulation of contemporary dental bonding adhesives, the micromechanical interlocking has been considered as the main bonding mechanism to etched enamel and provides successful retention of composite resins. Although mechanical bonding of the composite resin to acid-etched enamel is well-established and reliable procedure, bonding to dentin seems still inferior and less predictable [20–22]. The primary mechanism for bonding to dentin with etch-and-rinse adhesives is via the removal of the dentin smear layer and surface mineral, wetting of dentin substrate by components of adhesive, and adhesive infiltration followed by entanglement of resin monomers into exposed collagen matrix in the demineralized zone [23]. Durability of dentin bonding is dependent on the adhesive's specific formulation and not only the bonding strategy. The new formulation of XP Bond (Dentsply DeTrey, Konstanz, Germany) with a tertiary butanol used as solvent yields a competitive adhesion to both enamel and dentin combined with the advantages to be more user-friendly than multiple-step bonding agents, to allow complete adhesive resin penetration under a wide range of dentin conditions and to provide chemical interaction between the adhesive and mineral apatite in the dentin [24]. Despite available literature on the effects of the etching time and subject's age on clinical performance of a two-step etch-and-rinse adhesive in NCCLs, limited information is available.

Therefore, the aim of this study was to evaluate the clinical performance of a two-step etch-and-rinse adhesive in a 24-month randomized paired-tooth clinical trial. The null hypothesis was that the dentin etching time (15 vs. 30 s) and subject's age (youngest vs. oldest age groups) do not influence the clinical performance of a two-step etch-and-rinse adhesive in NCCLs.

Materials and methods

Subjects

This study was approved by the Institutional Review Board of Federal University of Santa Catarina (094/09). Forty subjects (17 females and 23 males) with two or four NCCLs were recruited according to inclusion and exclusion criteria (Table 1). The subjects included in this study were selected from the health affairs campus of the Federal University of Santa Catarina, Brazil, who needed dental treatment of NCCLs. Selected subjects were initially evaluated using a mouth mirror, an explorer, and a periodontal probe. Prior to treatment, participants read and signed a consent form. All patients were informed about the nature and objectives of the study. Tooth vitality was examined using an ice spray applied with a small foam pellet for 2 s, and all teeth to be restored were vital. Dentin preoperative sensitivity was also measured (air stream) before and after restorative procedure. Subjects were then questioned for subjective sensitivity by using a visual analog scale (VAS) ranging from 0 to 10, on which 0 represented 'no sensitivity" and 10 "most severe sensitivity."

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Patients older than 18 years
Patients able to attend for each recall appointments
Patients with more than 20 teeth
Periodontal health
Presence of non-retentive cavities, presenting no more than 50 % of margins in enamel (cervical margins in dentin and incisal margins in enamel)
Presence of two or four non-carious cervical lesions under occlusion (2 to 3 mm in cervicoincisal height and ≥1.5 to ≤3 mm in depth)
Exclusion criteria
Pregnancy or breast-feeding
Patients using anti-inflammatory or analgesic drugs
Patients with systematic or psychological disease
Patients under orthodontic, bleaching and desensitizing therapy
Patients with heavy bruxism
Presence of class V carious lesions

The mean age of the subjects was 37.5 years (ranging between 21 to 54 years) at the start of the study. NCCLs were initially distributed into two groups (n=70) according to the subject's age (dentin age): G1—ranging in age from 21 to 35 years (mean 28 years) and G2—ranging in age from 40 to 54 years (mean 47 years). Then, the two groups were subdivided according to dentin etching time, 15 and 30 s. Therefore, NCCLs were randomly assigned into four groups consisting of 35 lesions per group. The cervical lesions to be restored from the both age groups were randomly assigned for restoration either following the recommended or extended dentin etching time. In summary, the same subject had up to four restorations performed, with different etching time applied to one tooth, in order to make an intraindividual comparison of the two etching times. For a direct comparison, each subject received up to four restorations placed in teeth pairs (one or two pairs), in which lesions of group G1(15) were paired to lesions of group G1(30) and lesions of group G2(15) were paired to lesions of group G2(30) following pairwise design. A randomized sample schedule was prepared

to minimize the effects of subject/material and to exclude possible bias on the results of the study.

Restorative procedure

A total of 140 NCCLs were restored in 40 patients by one operator. No more than four restorations per subject were performed. North Carolina Dentin Sclerosis Scale is a visual method to evaluate the degree of sclerosis [25]. Among the selected lesions, 89 % were classified as degree 2 or 3 and were equally distributed among the groups (Table 2). The lesions characteristics were also categorized in terms of cervicoincisal height (mean 2.3 mm), depth (mean 1.8 mm), and shape (47 % wedge-sharp/53 % saucer-rounded). Differences in lesion size and in other characteristics were minimal. All lesions were filled without retentive grooves or bevels. Restorative procedure was performed with cotton rolls, retraction cords, and saliva ejector in order to prevent contamination by moisture. Lesions were prepared as follows: (1) prophylaxis with plain pumice in a rubber cup and rinsed with water, (2) shade selection (VitaPan Classic, Vita Zahnfabrik; Bad Säckingen, Germany), and (3) relative isolation. For groups G1(15) and G2(15), a phosphoric acid etchant (36 %) (DeTrey Conditioner, Dentsply DeTrey, Konstanz, Germany) was applied to the enamel margins and dentin surfaces simultaneously for 15 s. After rinsing for at least 15 s, the surface was carefully dried without desiccating the dentin. The same procedure was performed for groups G1(30) and G2(30), except that dentin was etched for 30 s.

XP Bond (Dentsply DeTrey, Konstanz, Germany) was applied according to the manufacturer's instructions and light cured for 10 s (Table 3). All lesions were restored with a light-cured microhybrid resin-based composite (Esthet X, Dentsply DeTrey, Konstanz, Germany). Composite was inserted in three increments of 1.0–1.5 mm. Each increment was light cured for 20 s using a LED light-curing unit (Ultra Blue IS, DMC equipment, Brazil) with a measured light output of 600 mW/cm^2. All restorations were finished with ultrafine diamond bur and sequential flexible abrasive discs (Sof-Lex Pop-On, 3 M ESPE, St. Paul, MN, USA), and polishing with a rubber cup associated with aluminum oxide polishing pastes. After each polishing step, all restorations were thoroughly rinsed with water and air-dried before the next step, until final polishing.

Table 2 Distribution of noncarious cervical lesions according to degree of sclerotic dentin [25]

Degree of sclerotic dentin	Number of lesions			
	G1(15)	G1(30)	G2(15)	G2(30)
1	03	01	02	03
2	15	16	16	15
3	16	15	14	17
4	02	02	02	01

Clinical evaluation

Evaluations were performed by two clinicians previously calibrated and blinded for the treatments performed using a mirror and sharp explorer after teeth prophylaxis. Preoperative sensitivity and postoperative sensitivity were assessed. Sensitivity was based on the patient's response to stimuli. Stimulus was a 1-s air flow at a 1-cm distance. Restorations were evaluated immediately (within 24 h), at 7 days and after 2, 6, 12, 18, and 24 months using the University of North Carolina (UNC)-modified USPHS criteria (ratings: *alfa*, *bravo*, *charlie*) [25] for pre- and postoperative sensitivity, marginal discoloration, retention, marginal integrity, and secondary caries (Table 4). The modified USPHS criteria used in this clinical investigation have been designed to measure aesthetic qualities and functional performance of restorations [26, 27]. In case no agreement was reached, a third examiner evaluated the restoration.

Statistical analysis

Statistical analysis included McNemar's test to compare the variation of alpha ratings over time within the same group and chi-square test to compare association between groups (SPSS 17, Inc., Chicago, IL, USA). The level of significance was set at $p<0.05$. Inter-examiner reliability was assessed using weighted coefficient Cohen's kappa ($K>0.8$).

Results

At 24 months, a total of 132 restorations were available for clinical evaluation (94.2 % recall rate) (Table 5). Four patients could not be evaluated during every evaluation time due to changes in their home address and/or phone number. At the end of 6 months, the probability of restoration survival rates was 100 % for all groups.

After 24 months, the survival rates were 93.5 % for G1(15), 97.1 % for G1(30), 93.9 % for G2(15) and 97.0 % for G2(30). There was no statistically significant difference between restoration survival rates at the end of the 24-month evaluation period ($p>0.05$). Mean lesion volumes were not significantly different among the four restorative groups ($p>0.05$). No significant correlation regarding the influence of the lesion volumes on retention rate was found ($p>0.05$). Regarding marginal integrity, the percentage of restorations showing absence of marginal defects was higher in the youngest age group (G1(15)=93.5 % and G1(30)=97.1 %) than in the oldest age

Table 3 Materials used in this study

Material	Manufacturer	Compositions	Instruction for use	
De Trey Conditioner 36	Dentsply, De Trey; Konstanz, Germany	Phosphoric acid 36 % (pH <2)	Dentin/enamel etching time	
			Recommended	Apply acid etch to enamel (15 s) and dentin (15 s). Rinse thoroughly for 10 s. Blot excess water using a cotton pellet.
			Extended	Apply acid etch to enamel (15 s) and dentin (30 s). Rinse thoroughly for 10 s. Blot excess water using a cotton pellet.
XP Bond	Dentsply, De Trey; Konstanz, Germany	Primer/Bond: TCB resin, PENTA, UDMA, TEG-DMA, HEMA, CQ, functionalized nanofiller, *tert*-butyl alcohol	Apply XP Bond adhesive to etched enamel and dentin. Leave undisturbed for 20 s, and dry gently for 5 s. Light cure for 10 s.	
Esthet X	Dentsply, De Trey; Konstanz, Germany	Bis-GMA, Bis-EMA, TEGDMA, CQ, stabilizer, pigments		

TCB carboxylic acid modified dimethacrylate, *PENTA* phosphoric acid modified acrylate resin., *UDMA* urethane dimethacrylate, *TEGDMA* triethyleneglycol dimethacrylate, *HEMA* 2-hydroxyethylmethacrylate, *Bis-GMA* bisphenol A diglycidyl methacrilate; *Bis-EMA* ethoxylated bisphenol A diglycidyl methacrilate, *CQ* camphorquinone

group (G2(15)=87.9 % and G2(30)=97.0 %), although the difference was not statistically significant (p=0.348).

Sensitivity to air improved significantly for all groups from baseline to 1 week after insertion. At the end of 2 years, 6.4, 2.9, 6.1, and 6.1 % of the lesions in groups G1(15), G1(30), G2(15), and G2(30), respectively, exhibited postoperative sensitivity. The number of alpha scores for sensitivity has significantly increased from baseline to 24 months in all the experimental groups at all evaluation periods within this study (p=0.001). Regarding marginal discoloration, all restorations received alpha ratings at 24 months evaluation in groups G1(15) and G1(30). There was no marginal discoloration in groups G1(15) and G1(30) at any evaluation time. However, regardless of the subject's age, in the oldest age groups G2(15) and G2(30), some marginal discoloration was found and scored as bravo (two and four restorations, respectively) at the end of 24 months. No statistical differences were recorded for any other parameters (p>0.05).

Table 4 Modified USPHS direct evaluation criteria [25–27]

Category	Criteria
Preoperative sensitivity (air syringe)	Alpha: absent
	Charlie: present
Postoperative sensitivity (query)	Alpha: absent
	Charlie: present
Marginal discoloration (discoloration at margins)	Alpha: absent
	Bravo: superficial discoloration (localized, removable); clinically acceptable
	Charlie: deep discoloration (generalized, not removable); clinically unacceptable
Retention	Alpha: retained
	Bravo: partially retained
	Charlie: missing; clinically acceptable
Marginal integrity (adaptation)	Alpha: undetectable
	Bravo: detectable, visible crevice along the enamel margin only; clinically acceptable
	Charlie: detectable, explorer penetrates into crevice in which dentin is exposed; clinically unacceptable
Secondary caries	Alpha: absent
	Charlie: present

Table 5 Number of restorations evaluated (*N*) and percentages of restorations with alpha scores for each criterion according UNC-modified USPHS criteria at each evaluation recall

	Preoperative	7 days	2 months	6 months	12 months	18 months	24 months
G1(15): USPHS (% alpha)							
N	35	35	35	35	35	31	31
Sensitivity	0	100	100	100	100	93.6	93.6
Marginal discoloration	–	100	100	100	100	100	100
Retention	–	100	100	100	100	93.5	93.5
Marginal integrity	–	100	100	100	100	93.5	93.5
Secondary caries	–	100	100	100	100	100	100
G1(30): USPHS (% alpha)							
N	35	35	35	35	35	35	35
Sensitivity	0	88.6	94.3	100	100	97.1	97.1
Marginal discoloration	–	100	100	100	100	100	100
Retention	–	100	100	100	97.1	97.1	97.1
Marginal integrity	–	100	100	100	97.1	97.1	97.1
Secondary caries	–	100	100	100	100	100	100
G2(15): USPHS (% alpha)							
N	35	35	35	35	33	33	33
Sensitivity	33.3	93.9	93.9	93.9	93.9	93.9	93.9
Marginal discoloration	–	100	100	93.9	93.9	93.9	93.9
Retention	–	100	100	100	93.9	93.9	93.9
Marginal integrity	–	100	100	97	90.9	90.9	87.9
Secondary caries	–	100	100	100	100	100	100
G2(30): USPHS (% alpha)							
N	35	35	35	35	33	33	33
Sensitivity	15.1	100	100	100	100	93.9	93.9
Marginal discoloration	–	100	84.8	81.8	81.8	81.8	81.8
Retention	–	100	100	100	100	97	97
Marginal integrity	–	100	100	100	100	97	97
Secondary caries	–	100	100	100	100	100	100

Discussion

Clinical trials are the ultimate test to evaluate adhesive restorations longevity. This randomized clinical trial showed that after 2 years, clinical success rate of the direct resin composite adhesive restorations in NCCLs (G1 or G2) were not statistically different. Our findings indicated that the restoration retention to the NCCLs in G2 is similar to that in G1. Based on the results of the present investigation, we failed to reject the null hypothesis. The dentin etching time and subject's age did not influence the clinical performance of a two-step etch-and-rinse adhesive system in class V non-carious cervical lesions. In clinical studies, success of a material is indicated by its longevity in the oral cavity, which makes retention rates the most important evaluation criteria [28].

Dentin adhesion is not only affected by the type of adhesive system but also by the mineralization level or substrate sclerosis [9, 13, 29, 30]. As observed in several other studies, the subject's age has been reported to have an impact on the clinical adhesive effectiveness, decreasing retention rates of composite restorations in NCCLs with older patients [31, 32]. Conversely, others studies have suggested that retention is not age-dependent [33–35]. As previously described, the actual lesion stage or the time that dentin has been exposed to oral environment rather than the subject's age may play a role in bonding effectiveness of specific adhesives [36]. Regarding the actual results of this clinical trial, retention rate was high for both groups after 2 years of clinical investigation. Probability of survival rates were 93.5 % for G1(15), 97.1 % for G2(30), 93.9 % for G3(15), and 97 % for G4(30). No significant difference in retention rate was recorded between the four experimental groups ($p>0.05$), which may be explained by the number of NCCLs classified as degree 2 or 3 equally distributed among

the groups. However, hypermineralized dentin is the result of the individual tooth response to irritations like abrasive and chemical irritants and can be found in all age groups [35].

As mentioned above, a relevant modification in dentin is the process of physiological aging and it is also known that dentin mineral content increases with age [7, 9, 13]. Aged dentin is considered a substrate less receptive to adhesion [11]. Clinical evaluations showed elevated levels of failure in adhesive restorations performed in older subjects [31, 32]. For this reason, some authors suggested that increasing the length of time that the lesion area is etched would be beneficial [14, 37]. Under a laboratory perspective, increased dentin etching time can produce a deeper demineralized zone where the primer and adhesive resins may not completely fully infiltrate the demineralized dentin collagen network [38]. The discrepancy between depth of dentin demineralization and depth of resin infiltration allows the formation of nanospaces at the base and within the hybrid layer [39]. Such region of unprotected collagen fiber can be a pathway for nanoleakage and susceptible to continuous degradation from oral fluids and bacterial enzymes, thereby weakening the physical properties of the resin–dentine bond [39, 40]. Conversely, Saboia et al. [41] demonstrated complete infiltration of the demineralized dentin by the resin monomers and revealed additional chemical bonding as formation of calcium phosphate complexes derived from the phosphate esters and the mineral apatite in dentin. Kimmes et al. [42] showed that when the phosphoric acid etching time on dentin was extended to 60 s, XP Bond ranked eleventh of the 11 adhesive systems tested (eight self-etch and three total-etch). Therefore, different etching times—recommended versus extended—did not result in significant changes in dentin shear bond strength for XP Bond (27.9 and 30.5 MPa, respectively). In our study, retention did not seem to depend on whether chosen dentin etching time was 15 or 30 s. This is in corroboration with findings of in vitro studies [9, 42–44]. Our findings did not reveal any significant effect of doubling the dentin etching times recommended by the manufacturer when a two-step etch-and-rinse adhesive is used in NCCLs.

With regard to the adhesive system used in this study, XP Bond (Dentsply DeTrey), only two clinical trials, evaluating the clinical effectiveness of this total-etch adhesive in class V non-carious cervical lesions, have been published in literature [45, 46]. Blunck et al. [45] evaluated the effectiveness of XP Bond when used to restore NCCLs. It was concluded that this specific adhesive can produce an effective bond with no restoration losses at the early 6-month follow-up, which may meet the criteria for a provisional acceptance according to ADA guidelines [47]: less than 5 % failure rate after 6 months of clinical performance. In the class V clinical study of Van Dijken [46], the retention loss for XP Bond (27.1 %) was higher than the others adhesives tested after 5 years. The author concluded that XP Bond provided good initial bond strength and clinical retention acceptable low failure rates (8 %) after 2 years. Regarding the results of this clinical study, it is worth mentioning, however, that in this study, all restorations were performed in NCCLs without intentional enamel involvement. No enamel bevels were placed or other ways were used to get extra mechanical retention. The enamel incisal margin of the lesions was etched with phosphoric acid and such lesions consisted of dentin in more than 85 % of the lesion surface area. However, the combined bond to enamel margin (small amount) and to dentin (large surface inside the lesion) will not camouflage the role of the dentin bond in the clinical performance [47]. To obtain full acceptance, retention of 90 % after 18 months is required. In this study, XP Bond fulfilled both provisional and full acceptance. The major feature of this material is the presence of PENTA (dipentaerytritolpentacrylate–phosphoric acid-monomer). PENTA is an adhesion promoter that facilitates resin monomers infiltration into demineralized dentin for micromechanical interlocking and provides chemical bonding between residual hydroxyapatite from dentin and phosphate esters in the adhesive functional group, as it was demonstrated in several ultra-morphologic interface analyses [24, 41, 48].

Regarding marginal discoloration, the percentage of restorations showing no discoloration remained stable in time in the youngest age groups (100 %), but decreased slightly in the oldest age groups [G3(15)=93.9 %/G4(30)=81.8 %] after 2 years. However, this difference was not statistically significantly different. Marginal discoloration was only observed as superficial localized marginal discoloration and occurred only slightly (not significantly) more in group G4(30), six restorations (18.2 %). In all restorations, discoloration was located at the enamel margin where a small incisal marginal defect was present. These small shortcomings only have a minor effect on the restoration clinical performance, as they can be removed by refinishing and re-polishing the restoration margins [49–52].

Postoperative sensitivity was rarely noticed at the 2-year recall. In the present study, frequency of postoperative sensitivity was already low at 18 months (6 %) and remained quite stable during the 2-year study period. Increased sensitivity at baseline might have been the result of some gingival retraction and thus root exposure during restorative procedures (restoration placement and finishing), which seems to be a common finding in clinical studies [18, 25, 28, 31, 33, 36]. Two-year follow-up could provide some information about the clinical performance of bonded restorations, but this period is also too short for the development of any secondary caries. In this study, at the end of 2 years, no caries were found adjacent to the restorations. The consistent alpha ratings for all UNC-modified USPHS criteria evaluated in this current study reflect clinical effectiveness of the two-step etch-and-rinse adhesive after 2 years of clinical service when applied after different dentin etching times (15 or 30 s) in class V non-carious cervical lesions (NCCLs).

One of the limitations of this clinical investigation is that 24 months may be a short period for considerable changes to

become evident regarding the effect of subject's age and dentin etching time on the clinical performance of the two-step etch-and-rinse adhesive XP Bond. As the negative effects of the oral environment on the clinical performance of resin-based materials increase over time, further long-term clinical trials might show differences among the groups evaluated in this study.

Conclusion

According to the protocol used and evaluated age groups in this study, subject age did not influence clinical performance of adhesive restorations on NCCLs after 24 months of clinical evaluation. Extending etching time on dentin did not influence the clinical performance of the adhesive system tested.

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Conflict of interest The authors declare that they have no conflict of interest.

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