The purpose of this study was to evaluate the five-year clinical performance of a two-step self-etch adhesive in non-carious cervical sclerotic lesions with or without selective acid-etching of enamel margins. A total of 104 cervical restorations in 22 patients (46–64 years) were bonded following either self-etch approach (AdheSE non-etch) or a similar application, including selective acid-etching of enamel margins (AdheSE etch), and were restored with resin composite. The restorations were evaluated at baseline and after one, two, three and five-years (84 restorations in 19 patients) according to the USPHS criteria. Data were analyzed using McNemar’s test. Cumulative retention rates for the non-etch and etch groups were 82.6% and 86.1% respectively. No significant differences were detected in the retention rates, marginal adaptations at dentin side and secondary caries between the groups. After five-years, the clinical performance of the two-step self-etch adhesive with or without selective acid-etching of enamel margins, was acceptable.

**Keywords:** Clinical evaluation, Enamel etching, Non-carious cervical sclerotic lesions, Two-step self-etch adhesive, USPHS criteria

**INTRODUCTION**

The interactions of adhesive systems with the tooth substrates are based on the etch-and-rinse or the self-etch approaches. Most of the etch-and-rinse and self-etch adhesive systems exhibit immediate successful bonding effectiveness to dental hard tissues. Conversely, depending on the type of system, long-term in vitro evaluations have mostly resulted in dramatic decreases in bonding efficiency due to the breakdown of the tooth-restoration interface. In vitro studies have indicated that resin-dentin bonds last much longer. Recently, Van Meerbeek et al. examined the possible relationship between bond-strength tests and the clinical effectiveness of contemporary adhesive systems for non-carious cervical lesions (NCCLs) in terms of retention rates and only found a significant relationship between the aged bond strength data and the five-year clinical data. In contrast, Heintze et al. reported a significant correlation between microtensile bond strength values and marginal discoloration, although no correlations could be found between bond strength values and retention rate, clinical index or marginal integrity of cervical restorations bonded to NCCLs. On the other hand, Carvalho et al. indicated that it is questionable whether the knowledge of bonding mechanisms obtained from laboratory testing can be used to justify clinical performance of resin-dentin bonds. Therefore, clinical trials conducted on NCCLs remain the best method of evaluating the outcome of an adhesive or technique as such trials provide direct evidence about effectiveness.

As concerns have been expressed regarding the in vitro bonding effectiveness and durability of self-etch adhesives to unetched and unground enamel, and the pre-etching of enamel has been shown to enhance the bond strengths of self-etch adhesives to values that are comparable to those produced by etch-and-rinse adhesives, some clinical trials have focused on the benefits of selective enamel etching of the cavity margins prior to the application of the self-etch adhesives. After two-years of observation, cervical restorations bonded with a one-step self-etch adhesive resulted in less enamel marginal discoloration when the enamel margins were selectively etched. Similar significant differences between the etch and non-etch groups were reported in a two-year clinical study that also evaluated a one-step self-etch adhesive and in a three-year clinical study that evaluated a two-step self-etch adhesive with or without selective enamel etching. However, in the literature, the number of long-term clinical trials that provide information about the clinical performance of different types of self-etch adhesives with prior selective enamel etching is limited. Only Peumans et al. reported that even after eight-years of clinical service, a two-step self-etch adhesive showed favorable bonding efficacy to NCCLs with both approaches. Therefore, this prospective, controlled, randomized clinical trial aimed to evaluate the five-year clinical performance of the two-step self-etch adhesive AdheSE with or without selective enamel etching in sclerotic NCCLs. The null hypothesis of the study was that selective enamel etching would not have a significant influence on the clinical performance of cervical restorations that were bonded with the two-step self-etch adhesive.

**MATERIALS AND METHODS**

Patients with at least two pairs of non-carious cervical sclerotic erosion/attrition/abfraction lesions with incisal
or occlusal margins in enamel and gingival margins in dentin, with Class I occlusions without missing two or more units in the molar region, had good oral hygiene and periodontal health, and without removable prostheses were selected for the study. Patients with chronic periodontitis or heavy bruxism were excluded. Sclerotic dentin in NCCLs was visually identified according to the North Carolina Dentin Sclerosis Scale as reported by Heymann and Bayne\(^\text{17)}\) (Table 1). NCCLs with Category 3 or 4 degrees of sclerosis were included in the study. Wedge-or saucer-shaped lesions that were categorized in terms of depth with a periodontal probe (>2 mm) were selected. The patients were informed about the nature and objectives of the study and written informed consent was obtained from each participant prior to the initiation of the treatment. The Clinical Investigations Ethic Committee of Yeditepe University reviewed and approved both the consent form and the research protocol (RB approval 271). Before starting the clinical trial, in order to obtain a power of 80%, the number of restorations in each group has been calculated as 46. Taking subject dropout into account (the dropout rate of 13%, a ratio of 0.13, within the first year), the sample size per group was adjusted to 52 restorations in each group. Therefore, 14 patients with two pairs and 8 patients with three pairs of lesions (16 female and 6 male; 46–64 years; mean age 51.5 years) that meet the inclusion-exclusion criteria were included in the study. Almost the same number of anterior (incisor, canine) and posterior (premolar) lesions (54 and 50 respectively) were selected and all the teeth were then pooled. The distributions of the NCCLs according to shape, degree of sclerotic dentin, presence of pre-operative sensitivity and distribution of the teeth are described in detail in the three-year report\(^\text{15)}\). One hundred and four cervical restorations in 46 maxillary and 58 mandibular teeth (Table 2) were placed by one operator in random order (using randomization tables).

Operative procedures were performed without local anesthesia and without bevelling the enamel margins or roughening the dentin surfaces. The operating sites were isolated with cotton rolls and, when necessary, with retraction cords. Prior to bonding, the teeth were cleaned with a pumice-water slurry, using a rubber cup to remove the salivary pellicle and any remaining dental plaque. The two-step self-etch adhesive (AdheSE, Ivoclar Vivadent, Liechtenstein) was applied following two protocols: (1) the application according to the manufacturer’s instructions (i.e., the self-etch) (AdheSE non-etch, \(n=52\)); and (2) a similar application of AdheSE that included prior selective acid-etching of the enamel cavity margins with 37% phosphoric acid for 30 s (i.e., the AdheSE etch, \(n=52\)). The restorations were built up with a microhybrid resin composite (Point 4; Kerr Corporation, Orange, CA, USA) in incremental steps of 1 mm, and each step was polymerized for 40 s (PolyLux II, KaVo, Germany) at 600 mWcm\(^2\) using a QTH polymerization unit (Table 3). The restorations were finished with 40 µm and 15 µm diamond burs at high speed (Acurata, G+K Mahnhardt Dental, Thurmansbang, Germany) and water-cooled polishing discs (Sof-Lex, 3M ESPE; St. Paul, MN, USA) at low speed.

Two investigators, who were not the operator of the study, were calibrated prior to the start of the study using a set of photographs. The evaluation phase of the study began after obtaining 85% intra- and

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**Table 1  **Classification of sclerotic dentin according to North Carolina Dentin Sclerosis Scale\(^\text{15)}\)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>No sclerosis is evident, dentin is opaque, light yellow, or whitish in color with no discoloration, and little translucency or transparency is evident</td>
</tr>
<tr>
<td>Category 2</td>
<td>Irregular translucency over less than 50% of the surface area</td>
</tr>
<tr>
<td>Category 3</td>
<td>Irregular transparency or translucency over 50% of the surface area</td>
</tr>
<tr>
<td>Category 4</td>
<td>Dentin is glossy in appearance, dark yellow or slightly brownish in color, with the majority of the dentin exhibiting translucency or transparency</td>
</tr>
</tbody>
</table>

**Table 2  **Distribution of restorations

<table>
<thead>
<tr>
<th>Arch</th>
<th>Groups</th>
<th>Right quadrant (48)</th>
<th>Left quadrant (56)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Premolar (20)</td>
<td>Canine (11)</td>
</tr>
<tr>
<td>Maxilla (46)</td>
<td>Etch (25)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Non-etch (21)</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Mandible (58)</td>
<td>Etch (27)</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Non-etch (31)</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

Numbers in parenthesis represent the total number of restorations.
inter-examiner agreement in the calibration phase. The calibrated investigators were fully blinded to the adhesive procedure that was used and independently evaluated the restorations at baseline, and at one-, two-, three- and five-years according to the modified United States Public Health Service (USPHS) criteria\textsuperscript{19} (Table 4), which includes retention, marginal discoloration, secondary caries, and marginal adaptation at the enamel and dentin sides. To observe the restorations in the future, no attempts were made to remove any visible excess or stain by polishing.

Clinical evaluation of each restoration was performed using a probe and a mouth mirror under operating light. Cumulative retention failure rates for each recall were calculated according to the American Dental Association Acceptance Program Guidelines\textsuperscript{20}. Cumulative failure % = (PF+NF)/(PF+RR). PF is the number of previous failures before the current recall, NF is the number of new failures during the current recall, and RR is the number of the recalled restorations for the current recall. Post-operative sensitivity, defined as any sensitivity, pain, or discomfort (yes/no) to air delivered via a dental unit for three seconds at a distance of 2 cm from the restoration while the neighboring teeth were covered with the evaluator’s fingers, was recorded after the treatment and at each recall.

**Statistical analysis**

The differences in the USPHS criteria ratings between the etch and non-etch techniques at one-, two-, three- and five-years and the performances of the etch and non-etch groups between each evaluation period were examined using McNemar’s test at a significance level of $p=0.05$. The Cohen’s Kappa statistic was used to test the inter-examiner agreement ($p<0.05$). Clinical survival of the restorations after 5 years was determined using Kaplan-Meier analysis. The log-rank test was used to compare the survival rates of the etch and non-etch groups ($p<0.05$).

**RESULTS**

Figure 1 shows the flow diagram of the study. The number of the recalled patients and evaluated restorations at one-, two-, three- and five-years were 22 (104), 21 (100), 19 (91), 19 (84) respectively. At two-years, one patient with four restorations moved to another city. At three-years, two patients with eight restorations did not want to take part of the study anymore and at five-years, three restorations in one patient could not be evaluated due to crown treatments. At the end of five-years, 84 restorations in 19 patients were evaluated. Table 5 presents the results of the evaluations of the

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**Table 3** Materials composition and their application procedures

<table>
<thead>
<tr>
<th>Materials</th>
<th>Composition</th>
<th>Application Procedure</th>
<th>Lot</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>AdheSE</td>
<td>Primer: Mixture of dimethacrylates, phosphoric acid acrylate, water, initiators and stabilizers</td>
<td>Apply primer for 20 s and gently air-blow</td>
<td>J17817</td>
<td>Ivoclar-Vivadent; Schaan, Liechtenstein</td>
</tr>
<tr>
<td></td>
<td>Adhesive: Mixture of dimethacrylates, HEMA, highly dispersed silicon dioxide, initiators and stabilizers</td>
<td>Apply adhesive and light-cure for 10 s</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point 4</td>
<td>Resin matrix: Uncured methacrylate ester, monomers, inert mineral fillers, activators and stabilizers</td>
<td>Apply in incremental technique of 1 mm and light-cure for 40 s</td>
<td>205554</td>
<td>Kerr Corp; Orange, CA, USA</td>
</tr>
</tbody>
</table>

HEMA: hydroxyethyl methacrylate.

**Table 4** Modified USPHS criteria\textsuperscript{19}

<table>
<thead>
<tr>
<th>Category</th>
<th>Scores</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retention</td>
<td>Alpha</td>
<td>No loss of restorative material</td>
</tr>
<tr>
<td></td>
<td>Charlie</td>
<td>Any loss of restorative material</td>
</tr>
<tr>
<td>Marginal Discolouration</td>
<td>Alpha</td>
<td>No discolouration</td>
</tr>
<tr>
<td></td>
<td>Bravo</td>
<td>Discolouration without axial penetration</td>
</tr>
<tr>
<td></td>
<td>Charlie</td>
<td>Discolouration with axial penetration</td>
</tr>
<tr>
<td>Secondary Caries</td>
<td>Alpha</td>
<td>No caries present</td>
</tr>
<tr>
<td></td>
<td>Charlie</td>
<td>Caries present</td>
</tr>
<tr>
<td>Marginal Adaptation</td>
<td>Alpha</td>
<td>Closely adapted, no visible crevice</td>
</tr>
<tr>
<td></td>
<td>Bravo</td>
<td>Crevices detected without exposure of enamel and dentin, clinically acceptable</td>
</tr>
<tr>
<td></td>
<td>Charlie</td>
<td>Marginal crevice with dentin exposure, clinical failure</td>
</tr>
</tbody>
</table>
restorations that were bonded with the AdheSE non-etch and the AdheSE etch techniques at baseline and at each recall period. The Cohen’s Kappa statistic (0.89) indicated excellent agreement between the investigators, and no statistical difference was observed between their evaluations ($p > 0.05$). Loss of retention was the only reason for failure that was observed during the follow up. Cumulative retention rates for the non-etch and etch groups were 82.6% and 86.1% respectively. No significant differences between the retention rates of both groups were observed at any recall ($p > 0.05$). The cumulative survival rate of the non-etch and etch groups was presented in the Kaplan-Meier survival curve (Fig. 2). The log-rank test showed that survival functions did not differ significantly between the groups after five years ($p = 0.538$).

The number of restorations with clinically acceptable slight marginal discoloration (Bravo scores)
Due to the lack of inherent macro-mechanical retention, adhesion is the most important factor in the retention of restorations for the treatment of NCCLs. These lesions are primarily dentin lesions and contain only smaller amounts of enamel at the occlusal side. Therefore, adhesion to NCCLs is not only affected by the type of the adhesive and its application technique but also by the chemical and ultrastructural characteristics of the dentin substrate\(^9\). Some clinical trials have demonstrated that sclerotic dentin does not affect the clinical performance of adhesives\(^{4,20}\), conversely others have resulted in lower retention rates\(^{22,23}\). Therefore, in this study, the variable of dentin sclerosis was held constant by not including non-sclerotic or slightly sclerotic lesions to focus on the potential benefit of selective acid-etching of the enamel margins on the clinical performance of cervical restorations bonded with a two-step self-etch adhesive to unprepared sclerotic NCCLs.

Regarding the results of this study, the recall rate at five-years was 80.8%. The patients and the lesions were selected according to a pre-determined inclusion/exclusion criteria. Due to the difficult clinical access of the molars, cervical lesions in molars were not included however, the numbers of anterior (incisor and canine) and posterior (premolar) lesions were nearly the same (54 and 50, respectively), and all the teeth were statistically pooled. To eliminate interoperator variability, all restorations were placed by the same operator. The evaluations at each recall were performed by two investigators independently of the operator who placed the restorations, and these investigators were blind to the technique used. These factors may have reduced the bias during evaluation.

Loss of retention was the only reason for failure that was observed during the follow up. At five-years, the cumulative loss rate for the AdheSE non-etch group was 17.4% and that for the AdheSE etch group was 13.9% \((p<0.05)\). These results indicate that selective acid etching of the enamel margins on the cervical restorations in sclerotic NCCLs that were bonded with the two-step self-etch adhesive AdheSE. While some in vitro studies showed stable bonding durability after water storage for AdheSE\(^{24}\), some studies reported significant decrease in bonding effectiveness to dentin\(^{25,26}\). The loss rates observed in this clinical study are around the range of loss rates that has been reported for clinical evaluations of two-step self-etch adhesives in NCLLs at five-years\(^{3,4,27}\). Peumans et al.\(^3\) reported a 2% loss rate for Clearfil SE Bond, while van Dijken\(^4\) evaluated the same adhesive and reported a 12.7% loss rate. Conversely, Kubo et al.\(^{27}\) reported a 100% success rate with Clearfil Liner Bond II, which is the predecessor of Clearfil SE Bond. The reason for the variability between the loss rates of different adhesive systems from the same approach may be related to the chemical composition of the adhesive. The high success rate achieved with Clearfil SE Bond has been attributed to its functional monomer 10-MDP, which can chemically interact with the hydroxyapatite to create a two-fold bonding mechanism that involves both
micromechanical and chemical bonding. Conversely, the functional monomers of the intermediately strong two-step self-etch adhesive AdheSE cannot chemically bond to the calcium of the hydroxyapatite, and the retention provided is based solely on micromechanical interlocking.

At five-years, compared to the moderate sclerotic lesions (Category 3), a significantly higher loss rate was found for the severe sclerotic lesions (Category 4; 2.7% and 19.23%, respectively). Consistent with this finding, some clinical studies have found that higher degrees of sclerosis are associated with inferior bonding and retention loss. Conversely some studies have indicated that characteristics of sclerotic dentin are not significant factors for the retention of cervical restorations. The presence of a hypermineralized layer on the surface of the lesion with entrapped bacteria, denatured collagen at the bottom of the hypermineralized layer, and the high variability of tubule occlusion preclude optimal bonding to highly sclerotic dentin in NCCLs, which may lead to higher retention loss.

The null hypothesis that selective enamel etching with phosphoric acid would not have a significant influence on the clinical performance of cervical restorations was not accepted. At five-years, a significantly higher percentage of restorations in the non-etch group exhibited clinically acceptable slight marginal discolorations (Bravo scores) and clinically acceptable small marginal defects (Bravo scores) at the enamel side than in the etch group. However, in all restorations, marginal discoloration and marginal adaptation remained clinically acceptable and did not influence the retention rates of the restorations or the development of secondary caries. Similarly, a weak correlation between marginal adaptation and the clinical performance of restorations has been observed in other in vivo studies with similar study designs. In an eight-year clinical study, Peumans et al. observed a significantly higher number of restorations with clinically acceptable marginal defects at the enamel side in the non-etch group than in the etch-group. Similarly, after two-years of observation, Abdalla and Garcia-Godoy reported that a one-step self-etch adhesive resulted in less enamel marginal discoloration when the enamel was selectively etched. Moreover, using a one-step self-etch adhesive, Fron et al. noticed significant differences between the etch and non-etch groups in terms of marginal discoloration and minor marginal defects after two-years. Conversely, in terms of marginal adaptation at the dentin side, no significant differences were recorded between the etch and non-etch groups at each recall. Indeed margins at the enamel side seemed more prone to marginal degradation than margins at the dentin side, as previously mentioned in other clinical trials.

The differences in the clinical behaviors of the restorations between the etch and non-etch groups can be attributed to the differences between the micromechanical etching pattern of phosphoric acid and the self-etch adhesive AdheSE (pH: 1.7). The etching pattern created by phosphoric acid on enamel is considered to be the reference point for obtaining efficient and durable bonding in in vitro and in vivo studies. Conversely, the etching pattern created by AdheSE is shallower with subsequently reduced micromechanical retention and the marginal quality of composite restorations bonded with AdheSE was improved when phosphoric acid was applied selectively to the enamel. These findings support the results of the present study.

As is often described in the literature, marginal discoloration is typically correlated with marginal adaptation. In the present study, 73.69% (AdheSE non-etch) and 27.1% (AdheSE etch) of the restorations received Bravo scores for marginal adaptation, and 68.43% (AdheSE non-etch) and 24.3% (AdheSE etch) received Bravo scores for marginal discoloration at the enamel side. These findings provide evidence that the increase in Bravo scores for marginal adaptation is usually accompanied by an increase in Bravo scores for marginal discoloration. Indeed, the number of restorations with small marginal defects and/or superficial marginal discolorations at the enamel side increased further after one-year recall. As this study was performed without beveling the enamel cavosurface margins, which has been shown to have no significant influence on the clinical performance of cervical restorations in a meta-analysis, the increase in the number of restorations with Bravo scores for marginal discoloration in both groups might also have been caused by the accumulation of stains derived from colored beverages at the marginal step. Thus, the discolorations were small and were therefore rated as clinically acceptable.

Secondary caries is one of the main reasons for the failure of composite restorations. However, throughout the evaluation period of the present study, none of the restorations presented secondary caries. Similar observations have also been reported in several clinical trials that have evaluated different categories of adhesives in the treatment of NCCLs at five-years. The good oral hygiene and periodontal health of the patients and the accessible location of the cervical restorations for cleaning, might have contributed to this finding.

None of the restored teeth exhibited post-operative sensitivity to air at the five-year recall. The characteristics of the sclerotic dentin and the minimal or absent post-operative sensitivity produced by the two-step self-etch adhesives can be the causes of this clinical finding.

CONCLUSIONS

At five-years, the clinical effectiveness of the two-step self-etch adhesive AdheSE was acceptable. The only positive effects of selective acid-etching of the enamel margins with phosphoric acid were reduced incidences of clinically acceptable marginal discolorations and superficial marginal defects at the enamel side.
ACKNOWLEDGMENT

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REFERENCES


