

# Clinical Performance of a Two-step Self-etch Adhesive with Additional Enamel Etching in Class III Cavities

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## Clinical Relevance

This mild, two-step self-etch adhesive system showed acceptable clinical performance in Class III cavities after three years. Additional etching of the enamel margins improved the marginal quality of restorations bonded with this adhesive system.

## SUMMARY

**Objective:** This study evaluated the effect of additional enamel etching on the clinical performance of Class III composite restorations bonded

with a mild two-step self-etch adhesive system in a three-year evaluation of clinical service.

**Methods:** Using a paired-tooth study design, 38 patients received at least one pair of restorations. In each paired cavity, a mild two-step self-etch adhesive (Clearfil SE Bond) was used, either with (C-SE etch) or without additional enamel etching, using phosphoric acid (C-SE non-etch). Clearfil AP-X was used as the restorative material for all restorations. Evaluation of the restorations was performed at baseline and after six months, one year, two years and three years of clinical service in terms of retention, marginal discoloration, marginal adaptation, postoperative sensitivity and secondary caries using the modified Ryge criteria.

**Results:** A retention rate of 100% both for the C-SE non-etch and C-SE etch groups was noted. Significant differences were observed between the groups regarding the marginal discoloration

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( $p=0.001$ ) and marginal adaptation ( $p=0.002$ ) at three years. C-SE non-etch restorations revealed more small marginal defects and superficial marginal discoloration than the C-SE etch group.

**Conclusion:** Although the clinical performance of the mild two-step self-etch adhesive in Class III cavities was found acceptable after three years, additional etching of the enamel margins improved the marginal quality of this adhesive by preventing small marginal defects and superficial marginal discolorations.

## INTRODUCTION

The increasing patient demand for esthetic restorations has stimulated the development of tooth-colored restorative materials. The advances in dental materials and adhesive technology have enabled the dentist to make esthetic anterior restorations in a simple and economical way.

Using etch&rinse and self-etch adhesive systems are two main adhesion strategies in current adhesive dentistry.<sup>1</sup> The etch&rinse strategy includes an etching step, followed by the application of a primer and bonding agent. Conventional three-step etch&rinse adhesives have been reported to bond effectively to enamel and dentin.<sup>2-4</sup> However, these adhesives have some shortcomings, as it is a time-consuming procedure and there is the risk of over-etching, which may lead to a possible discrepancy between the depth of demineralization and monomer infiltration.<sup>5</sup> These shortcomings directed researchers toward developing new adhesives, leading to the eventual development of self-etch systems.

Self-etch adhesives do not require a separate "etch&rinse" phase, because they include acidic monomers that simultaneously condition and prime both enamel and dentin. Elimination of the rinsing step and partial removal of the smear layer and smear plugs with these adhesives leads to less technique-sensitive, time-consuming procedures, as well as a possible reduction of postoperative sensitivity.<sup>1</sup> Self-etch adhesives can be subdivided according to their acidity: mild ( $\text{pH} \geq 2$ ), intermediate ( $\text{pH} \approx 1.5$ ) and strong ( $\text{pH} \leq 1$ ).<sup>1,2</sup> Strong self-etch adhesives exhibit rather deep demineralization effects and lead to a bonding mechanism and ultra-morphology similar to that produced by etch&rinse adhesives. On the other hand, mild self-etch adhesives partially dissolve the dentin surface, leaving residual hydroxyapatite still attached to collagen. Therefore, specific carboxyl or phosphate groups that have chemical bonding potential to calcium can chemically interact with this residual hydroxyapatite. The combination of the chemical and mechanical bonding in mild self-etch adhesive systems may result in bonding that better resists hydrolytic breakdown and may lead to the pro-

duction of quite stable bonds.<sup>1,2</sup> Unlike bonding to dentin, concern remains regarding the enamel etching-capability of mild self-etch adhesives. While some authors reported a lower bonding effectiveness with these systems when compared to etch&rinse adhesives,<sup>2,6</sup> others have found a similar bonding effectiveness on enamel for some self-etch adhesives.<sup>7-8</sup>

Although resin composites accompanied by adhesive systems have been extensively used in Class III cavities, few clinical studies regarding their performance have been published.<sup>9-11</sup> Clinical trials regarding the performance of adhesive systems have generally been performed in non-carious Class V restorations.<sup>12-14</sup> Although non-carious Class V lesions are suitable for testing bonding effectiveness,<sup>15</sup> using other cavity designs may also give important clinical knowledge regarding margin evaluation criteria.

The current study evaluated the effect of additional etching of enamel on the clinical performance of Class III restorations bonded with a mild two-step self-etch adhesive after three years. The null hypothesis tested was that the additional etching of enamel does not improve the marginal quality of Class III cavities restored with a mild two-step self-etch adhesive.

## METHODS AND MATERIALS

### Patient and Lesion Selection

Thirty-eight patients (10 males and 28 females), ranging in age from 19 to 60 years (with a mean age of 36 years) recruited from the university hospital, were included in this paired-tooth randomized controlled clinical trial. The Committee for Medical Ethics of Suleyman Demirel University approved the study protocol. Each patient signed an informed consent form after the nature and objectives of the clinical trial had been explained at the start of the study. The gender, age, smoking habits and oral hygiene status of patients are presented in Table 1.

The inclusion/exclusion criteria were as follows:

#### Inclusion Criteria:

1. Good general health.
2. Having at least two Class III carious lesions or existing defective restorations, including proximal surfaces in permanent maxillary anterior teeth, which were asymptomatic or sensitive to cold.

#### Exclusion Criteria:

1. Absence of adjacent and antagonist teeth.
2. Severe periodontal diseases and poor oral hygiene.
3. Symptoms of pulpitis, such as spontaneous pain or sensitivity to pressure.

The mild two-step self-etch adhesive system, Clearfil SE Bond (Kuraray, Osaka, Japan), was used in the cur-

Table 1: Baseline Data Regarding the Patients Included in the Study		
	Number of Patients	Number of Fillings
<b>Gender distribution</b>		
Female	28	70
Male	10	32
<b>Age distribution (years)</b>		
20-29	12	32
30-39	13	30
40-49	6	18
50-59	6	16
60-69	1	6
<b>Smoking habits</b>		
Non-smoker	26	68
Smoker	12	34
<b>Oral hygiene</b>		
Good oral hygiene	29	72
Gingivitis and plaque	9	30
<b>Total</b>	<b>38</b>	<b>102</b>

rent study following two different protocols (Table 2). While the enamel cavity margins were additionally etched with 35% phosphoric acid (SS White, Gloucester, England) for 15 seconds prior to the application of Clearfil SE Bond in the experimental protocol (C-SE etch), Clearfil SE Bond was applied to enamel and dentin without additional etching in the control protocol (C-SE non-etch). The same restorative material (Clearfil AP-X PLT, Kuraray) was used for all restorations.

Following a paired-tooth design, a total of 51 pairs of restorations (right central incisor-left central incisor, right lateral incisor-left lateral incisor and right canine-left canine) were placed. The selection of protocol for a pair of teeth was randomized with the help of flipping a coin to select the first protocol, then the tooth on the right side received the selected protocol first. The tooth on the left side received the other protocol. Each patient received a maximum of six restorations, three per group. Table 3 shows the distribution of restorations according to their location, the liner used and the presence of preoperative sensitivity.

### Restorative Procedure

Before treatment, initial periapical radiographs were taken of the teeth to be treated. Vitality test scores of the teeth were recorded using a thermal sensitivity test. The teeth to be restored were cleaned with flour of pumice and water in a rubber cup attached to a low-speed handpiece, rinsed with water and dried with oil-free air before shade selection. The cavities were prepared and the old restorations removed using round diamond and fissure burs at high speed under water-cooling. Carious dentin was removed with hand instruments and slow-speed tungsten carbide burs. If needed to prevent patient discomfort during restorative procedures, local anesthesia was applied. Control of the excavated cavity floor was mainly conducted according to probing with a sharp explorer and evaluating the color of the underlying dentin. For untreated carious lesions, a conserva-

Table 2: Composition and Application Procedures of the Materials Used			
Material	Manufacturer	Composition	Application
Dycal (Lot #071130)	Dentsply Caulk, Konstanz, Germany	Base paste: Disalicylate ester of 1,3, butylene glycol; calcium phosphate; calcium tungstate; zinc oxide; iron oxide Catalyst paste: calcium hydroxide; ethyl toluenesulfonamide; zinc stearate; titanium dioxide; zinc oxide; iron oxide	Mix Dycal Liner components until a uniform color is achieved. Use ball-pointed Dycal Liner applicator to place it over the deep portion of the cavity in a thin layer (approximately 0.8-1 mm thickness).
35% phosphoric acid (Lot #510233)	SS White, Gloucester, England	35% phosphoric acid, thickener	Apply acid gel selectively on enamel and leave for 15 seconds; thoroughly rinse and gently air dry.
Clearfil SE Bond (Lot #41594)	Kuraray, Osaka, Japan	Primer: 10-MDP, HEMA, hydrophobic aliphatic dimethacrylate, camphorquinone, water, accelerators Bond: HEMA, BisGMA, 10-MDP, hydrophobic aliphatic dimethacrylate, colloidal silica, dl-camphorquinone, initiators, accelerators	1) Apply primer with rubbing 2) Leave in place for 20 seconds 3) Dry with air during 5 seconds 4) Apply bond 5) Gentle air-blow 6) Light cure for 10 seconds
Clearfil AP-X (Lot #41172, 41150 Shade: A2, A3, B2, XL)	Kuraray, Osaka, Japan	Barium glass, silica, colloidal silica, silicon dioxide (vol 71%, 0.1-15 µm), BisGMA, TEGDMA, photo-initiator	1) Apply in 2 mm increments 2) Light cure for 40 seconds
*BisGMA; Bisphenol-glycidyl methacrylate, HEMA; 2-hydroxyethyl methacrylate, 10-MDP; 10-methacryloyloxydecyl dihydrogen phosphate, TEGDMA; triethyleneglycol dimethacrylate.			

tive (adhesive) cavity design was used. Unlike the untreated carious lesions, the form and size of the cavities of the replaced restorations were dictated by the existing composite material rather than the carious

lesion (Table 3). A 1-2 mm enamel bevel was performed to increase the bonding area. The entire cavity margin of each restoration was located in enamel.

One experienced operator, familiar with adhesive dentistry and following the standard procedures and manufacturer's recommendations, placed all the restorations under rubber dam isolation (Dental Dams, Royal Shield, Malaysia; Clamps, Hu-Friedy, Chicago, IL, USA). Calcium hydroxide (Dycal, Dentsply/Caulk, Milford, DE, USA) was only used in deep cavities and applied directly over the deep portion of the preparation (Table 3). All the cavities were restored using a Mylar strip and wooden wedge to re-establish the anatomical shape and proximal contacts of the teeth. After cavity preparation, the adhesive (Clearfil SE Bond) was applied. In the C-SE etch group, the enamel margins were additionally etched with 35% phosphoric acid gel for 15 seconds, then thoroughly rinsed and air-dried prior to the application of Clearfil SE Bond primer (Table 2). The restorative composite (Clearfil AP-X PLT) was placed incrementally in 2-mm layers. Each layer was cured for 40 seconds using a light-curing unit (Heliolux DLX, Ivoclar Vivadent, Schaan, Liechtenstein) with a power density of 550 mW/cm<sup>2</sup>. Following removal of the Mylar strip, the proximal region of the restorations was additionally polymerized for 20 seconds. Final contouring and finishing of the restorations was performed at the same appointment using fine grit diamond burs (Edenta AG, Sankt Gallen, Switzerland) under water-cooling to remove gross excess and flexible points impregnated with silicone dioxide (Astropol, Ivoclar Vivadent) to obtain smooth surfaces. Aluminum oxide finishing strips (Dentonics Inc, Monroe, NC, USA) were used to finish and polish the proximal surfaces.

### Evaluation Procedure

Two dentists other than the operator who placed the restorations performed an independent evaluation of the teeth. The evaluators were blinded to the experimental protocol used for any Class III cavity and were calibrated prior to the study. The test of intra-examiner and inter-examiner agreement resulted in a Cohen's Kappa statistic of 0.87 and 0.91. All the restorations were evaluated at baseline and after six months, one year, two years and three years of clinical use. The restorations were examined using the modified Ryge criteria (USPHS)<sup>16-18</sup> for retention, marginal discoloration, marginal adaptation, postoperative sensitivity and secondary caries (Table 4). The

Table 3: *Baseline Data Regarding the Lesions Included in the Study*

Characteristics of the Class III Lesions	Number of Lesions	
	C-SE Non-etch	C-SE Etch
<b>Untreated/Previously Treated Lesion</b>		
Untreated carious lesion	41	43
Previously treated lesion (replacement old restoration)	10	8
<b>Tooth Distribution</b>		
Maxillary central incisor	33	33
Maxillary lateral incisor	15	15
Maxillary canine	3	3
<b>Liner</b>		
No liner	49	49
Calcium hydroxide liner	2	2
<b>Preoperative Sensitivity</b>		
No preoperative sensitivity	41	41
Yes preoperative sensitivity (air, probe)	10	10

Table 4: *Modified Ryge Criteria Rating System*<sup>16</sup>

Category and Rating	Criteria*	Evaluation Method
Retention	A: Retained B: Partially retained C: Missing	Visual: after air-drying the tooth; tactile: using a sharp probe.
Marginal adaptation	A: Undetectable crevice along the margin B: Detectable V-shaped defect in enamel only C: Detectable V-shaped defect in DEJ	Tactile: moving a sharp probe over the restorations margins.
Marginal discoloration	A: No discoloration anywhere along the margin B: Superficial staining (removable, usually localized) C: Deep staining (not removable, generalized)	Visual: after air-drying the tooth and after removing plaque (if necessary).
Secondary caries	A: No evidence of caries B: Evidence of caries along the margin of the restoration	Visual: after air-drying the tooth and after removing plaque (if necessary); tactile: using a probe (after air-drying the tooth) and using bitewing radiographs.
Postoperative sensitivity	A: No postoperative sensitivity at any time of the restorative process and during the study period B: Experience of sensitivity at any time of the restorative process and during the study period	Blowing a stream of compressed air for 3 seconds at a distance of 2-3 cm from the restoration.

\*A=Alpha; B=Bravo; C=Charlie



restorations were scored as follows: Alpha represented the ideal clinical situation; Bravo indicated that the restoration was clinically acceptable and Charlie indicated that the restoration was clinically unacceptable and the restoration had to be replaced.<sup>16</sup> When disagreement occurred during the evaluations, the restorations were re-evaluated by both dentists and a consensus was obtained.

Postoperative sensitivity was measured by blowing a stream of compressed air for three seconds at a distance of 2–3 cm from the restoration and by moving the probe over the restored tooth surface. At each recall, vitality tests were recorded.

The overall success rate was determined using the parameters of retention, marginal adaptation, marginal discoloration and secondary caries. Retention loss, severe marginal defects, discoloration that needed repair or replacement and the occurrence of caries along the restoration margins were considered to be clinical failures.<sup>19</sup>

### Statistical Analysis

The statistical analysis was processed with the SPSS 13.0 software system (SPSS Inc, Chicago, IL, USA). Differences in the ratings of the two groups after six months, one year, two years and three years were tested with the McNemar  $\chi^2$  test. The Fisher's Exact test was used to evaluate whether there were any differences between the groups in terms of the number of cavities restored due to untreated carious lesions or previously treated lesions. Differences in the occurrence of marginal discoloration between patients with good oral hygiene and patients with moderate gingival inflammation and plaque accumulation and between smokers and non-smokers were also analyzed using the Fisher's Exact test. Performance of the materials at

baseline and after six months, one year, two years and three years was analyzed using the McNemar test. For all tests, the probability level for statistical significance was  $\alpha=0.05$ .

### RESULTS

There were no significant differences between study groups in terms of the number of cavities restored due to untreated carious lesions or previously treated lesions. At the three-year follow-up, 80 of the 102 restorations were evaluated (78% recall rate). One patient (six restorations) did not attend the recall appointments after six months and seven patients (16 restorations) did not attend the three-year recall. Reasons for not being available at each recall were checked. These patients were unavailable for recall appointments because some moved away from the city and there were unknown reasons for others; however, no patient reported any negative comments for the restorative procedures done. The results for the evaluated restorations are displayed in Table 5.

**Retention:** None of the restorations presented at the three-year recall was lost, resulting in a retention rate of 100% for both the C-SE non-etch and etch groups.

**Marginal Discoloration:** While six C-SE non-etch and three C-SE etch restorations scored Bravo for marginal discoloration at one year ( $p=0.572$ ), the number of restorations showing superficial marginal discoloration (Bravo) was five for the C-SE non-etch and three for the C-SE etch groups at two years ( $p=0.486$ ). In addition, one C-SE non-etch restoration exhibited deeper, more defined marginal staining and scored Charlie (Table 5). However, the number of restorations with superficial marginal discoloration increased to 15 in the C-SE non-etch group at three years, whereas only four restorations showed superficial marginal discoloration in the

Table 5: Results for Different Parameters Evaluated in This Study. For the Modified Ryge Criteria, Data Shown is n of Examined Restorations/n of Ratings (% of ratings)

Parameter	Rating	Baseline		6 Months		1 Year		2 Years		3 Years	
		C-SE non-etch	C-SE etch	C-SE non-etch	C-SE etch	C-SE non-etch	C-SE etch	C-SE non-etch	C-SE etch	C-SE non-etch	C-SE etch
Recall rate		51/51 (100)	51/51 (100)	51/51 (100)	51/51 (100)	51/48 (94)	51/48 (94)	51/48 (94)	51/48 (94)	51/40 (78)	51/40 (78)
Retention	A	51/51 (100)	51/51 (100)	51/51 (100)	51/51 (100)	48/48 (100)	48/48 (100)	48/48 (100)	48/48 (100)	40/40 (100)	40/40 (100)
	B	—	—	—	—	—	—	—	—	—	—
	C	—	—	—	—	—	—	—	—	—	—
Marginal discoloration	A	51/51 (100)	51/51 (100)	51/47 (92)	51/50 (98)	48/42 (88)	48/45 (94)	48/42 (88)	48/45 (94)	40/25 (62)	40/36 (90)
	B	—	—	51/4 (8)	51/1 (2)	48/6 (12)	48/3 (6)	48/5 (10)	48/3 (6)	40/15 (38)	40/4 (10)
	C	—	—	—	—	—	—	48/1 (2)	—	—	—
Marginal adaptation	A	51/51 (100)	51/51 (100)	51/48 (94)	51/50 (98)	48/45 (94)	48/47 (98)	48/45 (94)	48/47 (98)	40/26 (65)	40/36 (90)
	B	—	—	51/3 (6)	51/1 (2)	48/3 (6)	48/1 (2)	48/3 (6)	48/1 (2)	40/14 (35)	40/4 (10)
	C	—	—	—	—	—	—	—	—	—	—
Postoperative sensitivity	A	51/51 (100)	51/51 (100)	51/0 (0)	51/0 (0)	48/48 (100)	48/48 (100)	48/48 (100)	48/48 (100)	40/40 (100)	40/40 (100)
	B	—	—	—	—	—	—	—	—	—	—
Secondary caries	A	51/51 (100)	51/51 (100)	51/0 (0)	51/0 (0)	48/48 (100)	48/48 (100)	48/48 (100)	48/48 (100)	40/40 (100)	40/40 (100)
	B	—	—	—	—	—	—	—	—	—	—
Overall clinical success rate		51/51 (100)	51/51 (100)	51/51 (100)	51/51 (100)	48/48 (100)	48/48 (100)	48/47 (98)	48/48 (100)	40/40 (100)	40/40 (100)

"—" indicates no change regarding this score in the study groups.

C-SE etch group. The difference between the C-SE non-etch and C-SE etch groups was statistically significant at three years ( $p=0.001$ ). No significant differences were found between patients with good oral hygiene and those with moderate gingival inflammation and plaque accumulation ( $p=0.745$  for C-SE non-etch,  $p=0.172$  for C-SE etch) and between smokers and non-smokers ( $p=0.065$  for C-SE non-etch,  $p=0.640$  for C-SE etch) in terms of the presence of marginal discoloration.

The McNemar test revealed significant differences between the baseline scores and that of the recalls in the C-SE non-etch group, while no significant differences were observed in the C-SE etch group. The number of Bravo or Charlie scored restorations in the C-SE non-etch group significantly increased after three years when compared to the baseline scores ( $p=0.031$ ).

**Marginal Adaptation:** A number of small detectable enamel marginal defects (Bravo) were observed for both groups (6% for C-SE non-etch and 2% for C-SE etch) at two years. However, the number of restorations with small detectable enamel marginal defects increased to 14 in the C-SE non-etch group at three years; whereas, this number was only four in the C-SE etch group. The difference between the C-SE non-etch and C-SE etch groups was statistically significant at three years ( $p=0.002$ ).

There were significant differences between the baseline and three-year recall in the C-SE non-etch group, while no significant differences were observed between the baseline and recall periods in the C-SE etch group. The number of Bravo restorations in the C-SE non-etch group significantly increased after three years when compared to the baseline scores ( $p=0.000$ ).

**Postoperative Sensitivity:** None of the restorations were postoperatively sensitive to air or tactile contact.

**Secondary Caries:** No secondary caries was observed after three years of clinical service.

## DISCUSSION

In the current study, the effect of additional enamel etching on the clinical performance of Class III composite restorations was evaluated in a paired-tooth randomized controlled clinical trial. The reason for studying Class III restorations was that the presence of marginal defects and discoloration as a result of using a mild self-etch adhesive could lead to pronounced aesthetic shortcomings in such restorations. In addition, there are a limited number of clinical studies regarding the performance of self-etch adhesives in Class III restorations.<sup>9-11</sup> C-SE Bond was chosen as a mild two-step self-etch adhesive because of its proven excellent performance in laboratory and clinical studies.<sup>3,7,20-21</sup> For additional etching, 35% phosphoric acid was applied to enamel margins before the application of C-SE Bond. The idea behind the current study was

that the etch&rinse approach still provides the most effective bond to enamel, and the bonding effectiveness of mild self-etch adhesives to enamel can be improved with the additional etching of enamel using phosphoric acid.

Several patients were unavailable for recall appointments because they had moved or were unreachable based on the phone numbers they provided; the recall rate of the current study at the end of three years was 78%, however, no patient reported any negative comments for the restorative procedures done.

No restorations were lost during this three-year clinical trial, resulting in a retention rate of 100% for both groups. In previous studies, 100% retention rates for C-SE were also reported at 12-36 months in Class III and Class V restorations.<sup>10,12-14</sup> That result may be attributed to its two different bonding mechanisms: micromechanical and chemical bonding. C-SE interacts with dentin and produces a hybrid layer approximately 1  $\mu\text{m}$  thick by simultaneous demineralization and infiltration of dentin with monomers, resulting in uniform and stable resin-infiltrated dentin.<sup>5</sup> Moreover, its functional monomer 10-MDP has been shown to chemically interact with residual hydroxyapatite around the exposed collagen fibrils.<sup>22</sup>

In the current study, the increase in marginal defects and marginal discoloration from baseline to three years was significant for the C-SE non-etch group; whereas, throughout the same period, no significant differences were found for the C-SE etch group. The mild self-etch adhesive system has a less stable bonding capacity to enamel, probably because of its more shallow etch pattern.<sup>23-24</sup> Previous *in vitro* studies also reported that the etching potential of mild self-etch adhesives was lower than that of phosphoric acid, and the bond strength values of mild self-etch adhesives could be improved by the adjunctive use of phosphoric acid.<sup>25-27</sup> Moreover, in a literature review regarding marginal integrity, significantly better marginal adaptation in enamel margins was indicated *in vitro* and *in vivo* with etch&rinse adhesives when compared to self-etch adhesives.<sup>28</sup> The reason for the compromised enamel marginal quality in the self-etch systems was attributed to the lack of observable resin tags.<sup>3</sup>

The increase in small enamel marginal defects over time in the C-SE non-etch group may be attributed to degradation of the bonding resin. Small marginal defects may have caused marginal discoloration as a result of microleakage through the degraded resin-tooth interface as indicated in previous clinical trials.<sup>29-31</sup> Some studies reported that etch&rinse adhesives or additional etching exhibited higher percentages of gap-free margins in enamel after thermomechanical loading when compared to two-step self-etch adhesives.<sup>3,32</sup> After fatigue loading, self-etch adhesives have been

found to be less effective when compared to etch&rinse adhesives,<sup>3,33</sup> although most of the adhesives bonded well to cut enamel prior to functional and thermal stresses.<sup>2,34</sup> It has been proposed that the presence of air voids trapped along the resin-enamel interface may cause a more rapid in-plane crack propagation in self-etch adhesive systems. On the other hand, the incorporation of resin tags in acid-etched enamel reduces crack propagation and improves fracture toughness of the interface.<sup>3</sup>

In previous studies, the clinical performance of C-SE with and without the additional etching of enamel using phosphoric acid was evaluated in Class III and Class V restorations.<sup>10,12-13,35</sup> In one study, it was reported that additional etching of the enamel margins of Class III cavities did not influence the marginal adaptation and marginal discoloration scores of C-SE Bond after a one-year clinical evaluation.<sup>10</sup> However, in three- and five-year clinical evaluations of Class V cavities, the number of small incisal enamel marginal defects gradually increased and became significantly higher in the C-SE non-etch groups when compared with the C-SE etch group at two years.<sup>13,35</sup> In the current study, although the number of small detectable enamel marginal defects and superficial marginal discoloration in the C-SE non-etch group was higher than that of the C-SE etch group at each recall, the differences between the two groups became statistically significant only at the three-year recall.

One of the reasons for the pronounced increase at the three-year recall may be attributed to operator-dependent factors. The interpretation of evaluation criteria can differ in clinical trials, especially when the deterioration is small and the staining is slight. The shortcomings of the current evaluation criteria and a need for evaluating marginal integrity and marginal discoloration in a more standardized way were emphasized and the use of new, more detailed evaluation criteria was recommended by Hickel and others.<sup>36</sup> The nutritional habits of patients, especially the frequency of consuming products that stain the teeth, may also contribute to the different results from the different studies.<sup>37</sup> In addition, differences in cavity designs and chewing forces affecting the teeth examined may be the reason for differences in the results of these studies. Although more small defects and superficial marginal discoloration in the current study were obtained in the C-SE non-etch group compared to the additionally etched group, this was not critical for the overall clinical performance of this adhesive. Similarly, problems in marginal adaptation and marginal discoloration of the self-etch adhesive system were slight in previous studies and did not affect the overall clinical performance of this adhesive.<sup>10,12-13,35</sup> However, how these criteria will be affected by time-dependent factors should be observed at further evaluation periods.

One of the other parameters evaluated in the current study was postoperative sensitivity. Twenty teeth (10 for each group) had preoperative sensitivity. Moreover, four cavities (two for each group) were relatively deep, so a calcium hydroxide liner was used over the deep portion of the preparations in these restorations. However, patients who received C-SE restorations with or without additional etching of the enamel margins reported no postoperative sensitivity. This criterion remained optimal during this three-year clinical trial. This result indicated that the dentinal tubules were adequately sealed with this mild two-step self-etch adhesive system, which is consistent with the findings that have exhibited a reduction in postoperative sensitivity with this self-etch adhesive.<sup>38-40</sup>

## CONCLUSIONS

The clinical performance of the mild two-step self-etch adhesive in Class III cavities was found acceptable after three years. Although additional etching of the enamel margins improved the marginal quality of this adhesive by preventing small marginal defects and superficial marginal discolorations, it was not critical for the overall clinical performance of this adhesive. Further recalls are planned to follow-up on the clinical performance of these restorations, because the differences between the study groups regarding marginal adaptation and discoloration might become more apparent at later periods, indicating negative environmental effects on the clinical performance of resin-based materials, which may increase with time.

## Conflict of Interest

The authors of this study declare that they have no conflict of interest.

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