Eight-year clinical evaluation of a 2-step self-etch adhesive with and without selective enamel etching

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ABSTRACT

Objectives. The objective of this randomized controlled clinical trial was to evaluate the 8-year clinical performance of a mild 2-step self-etch adhesive in non-carious Class-V lesions with and without prior selective phosphoric acid-etching of the enamel cavity margins.

Methods. A total of 100 non-carious Class-V lesions in 29 patients were restored with Clearfil AP-X (Kuraray). The composite restorations were bonded following two different approaches: (1) application of Clearfil SE (Kuraray) following a self-etch approach (control group; C-SE non-etch), (2) selective phosphoric acid-etching of the enamel cavity margins before application of Clearfil SE (experimental group; C-SE etch). The restorations were evaluated after 6 months, 1, 2, 3, 5 and 8 years of clinical service regarding their retention, marginal integrity and discoloration, caries occurrence, preservation of tooth vitality and post-operative sensitivity.

Results. The recall rate at 8 years was 76%. Only two restorations, one of the C-SE non-etch group and one of the C-SE etch group, were clinically unacceptable due to loss of retention leading to a retention rate and a clinical success rate of 97% in both groups. Aging of the restorations was characterized by an increase in the percentage of restorations with a small but clinically acceptable marginal defect (C-SE non-etch: 92%; C-SE etch: 84%) and/or a superficial marginal discoloration (C-SE non-etch: 44%; C-SE etch: 28%). At the enamel side, the presence of small marginal defects (C-SE non-etch: 86%; C-SE etch: 65%) and superficial marginal discoloration (C-SE non-etch: 11%; C-SE etch: 3%) was more frequently noticed in the control group than in the experimental group. The difference, however, was only statistically significant for the presence of superficial marginal discoloration (McNemar, \( p = 0.01 \)).

Significance. After 8 years of clinical functioning, the clinical effectiveness of Clearfil SE remained excellent, with selective acid-etching of the enamel cavity margins only having some minor positive effect on marginal integrity and absence of marginal discoloration at enamel.
1. Introduction

Several contemporary dental adhesives have been documented to provide adequate immediate bond strengths to enamel and dentin [1–5]. However, the clinical longevity of bonded restorations is still too short due to degradation of the adhesive-tooth–composite interface [3,6,7]. In laboratory circumstances, the durability of this bond is tested using different kinds of artificial aging methods like water storage, thermo-cycling, mechanical loading, degradation by enzymes and various chemical substances [3,6,7]. These in vitro durability tests give detailed information regarding the mechanisms of degradation. Although it is not correct to generalize that laboratory studies can predict the durability of the bond in clinical circumstances, there are some associations between laboratory and clinical data on bonding effectiveness. In a review article of Van Meerbeek et al. [7] a possible relationship was searched for between laboratory bond-strength data obtained in a systematic review, and the clinical retention rates collected in a systematic review on the clinical effectiveness of contemporary adhesives in non-carious Class-V lesions. A significant, quite reasonable correlation was found between the aged bond-strength data and the 5-year clinical data. The number of medium to long-term clinical trials in the literature, however, is limited. There is certainly a need for these longer-term clinical trials as they remain the ultimate way to collect scientific evidence on the clinical effectiveness of a restorative treatment.

According to a systematic literature review of non-carious Class-V clinical trials, published between 1998 and 2009, the lowest annual failure rates (expressed as retention loss) have been recorded for the glass-ionomers (2 ± 0.03%) and the so-called ‘mild’ and ‘intermediately strong’ 2-step self-etch adhesives (1.9 ± 3.3%) [7]. Among the self-etch adhesives, the mild 2-step self-etch adhesive Clearfil SE (Kuraray) is considered as the golden-standard because of its highly adequate dentin bonding effectiveness in vitro [3,5,8–13] and in vivo [14–20]. The Clearfil SE adhesive system, the primer of which has a pH 2, provides a uniform submicron hybrid layer (0.5–1 μm) with substantial hydroxyapatite crystals still protecting the collagen fibrils [1,3,8,12]. The functional monomer 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP), present in the Clearfil SE primer, has been proven to interact with this residual hydroxyapatite through primary ionic bonding [21]. The resulting calcium salts are hydrolytically stable, which contributes to the long-term durability of the resin/dentin interface [22]. Regarding the durability of the bond of Clearfil SE to dentin in vitro, most studies reported a slight decrease in dentin bonding effectiveness [4,13,23–29], while in some studies the bonding effectiveness did not change after different types of aging [30–34]. Until now, no long-term clinical trials are available in the literature that can give information about the clinical bond durability of this adhesive.

In non-carious Class-V lesions, the major part of the bonded tooth surface consists of dentin, while only at the incisal side the adhesive restorative material is bonded to enamel. Literature so far indicates that the most durable bond to enamel is obtained following an etch-and-rinse approach, signifying that the distinct enamel etch pattern created by phosphoric acid-etching is most important to achieve a durable bond to enamel [1,3,5,26]. In contrast, Clearfil SE, produces a very mild superficial etch pattern [8,12,35–38]. Although some studies reported a bond strength to ground enamel similar to that of etch-and-rinse adhesives [9,36], in most studies the bonding effectiveness to enamel was significantly lower [3,37–40]. Even though in vitro durability studies showed a stable strength to enamel over time [13,41–43], the marginal integrity of Clearfil SE to enamel deteriorated [4,23,26,32,44] resulting in increased microleakage [27,45]. Selective etching of enamel with phosphoric acid before application of the adhesive has been proposed to improve the durability of the enamel bond [8,26,35,37,38,45,46]. In 2000, we started a Class-V clinical trial to evaluate the effect of adjunctive/selective enamel etching on the clinical performance of the restorations [16,19,47]. After 5 years, we observed a significantly higher number of small marginal defects at the enamel side in the non-etch group compared to the etch group [19]. We decided to continue the follow-up of the study for a longer period to determine if this marginal deterioration will become worse with time and will negatively influence the clinical performance of the restorations.

Therefore the objective of this randomized clinical trial was to evaluate the clinical performance of the mild 2-step self-etch adhesive, Clearfil SE, in non-carious Class-V lesions after 8 years of clinical functioning. The hypothesis tested was that selective enamel etching with phosphoric acid had a significant influence on the clinical performance of Class-V restorations.

2. Materials and methods

In this clinical trial 29 patients were enrolled (mean age: 58 years, 11 males and 18 females). In each patient two or four non-carious cervical lesions were restored randomly (using randomization tables) following two experimental protocols: (1) Application of a ‘mild’ 2-step self-etch adhesive (Clearfil SE, Kuraray, Tokyo, Japan) according to the instructions of the manufacturer (C-SE non-etch). (2) Similar application of Clearfil SE, but including initial selective acid-etching of the enamel cavity margins with 40% phosphoric acid (C-SE etch) (Table 1). Clearfil AP-X (Kuraray, Tokyo, Japan) was used as restorative composite for all 100 restorations. The selection criteria and restorative procedure are described in detail in the 3-year report [16].

After 8 years of clinical service, the overall clinical success rate was recorded in terms of (1) restoration retention, (2) enamel and dentin marginal integrity, (3) marginal discoloration, (4) caries occurrence, (5) post-operative sensitivity and (6) preservation of tooth vitality by two evaluators using a pre-determined set of criteria introduced by Vanherle et al. [48]. These evaluators were not the operators and were fully blinded to the adhesive procedure that was used. The first four parameters (retention, marginal integrity, marginal discoloration and caries occurrence) were considered as the key parameters for overall clinical success, determining the ‘overall clinical success rate’. Retention loss, severe marginal defects and/or discolored that needed intervention (repair
Table 1 – Adhesive composition and application procedure.

<table>
<thead>
<tr>
<th>Adhesive Component and composition</th>
<th>Application procedure</th>
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<tbody>
<tr>
<td>Clearfil SE (Kuraray, Tokyo, Japan)</td>
<td>Primer: 10-MDP, HEMA, hydrophilic dimethacrylate, CQ, N,N-diethanol p-toludine, water</td>
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<tr>
<td></td>
<td>Apply primer for 20 s; gently air-blow</td>
</tr>
<tr>
<td></td>
<td>Adhesive: 10-MDP, Bis-GMA, HEMA, hydrophilic dimethacrylate, CQ, N,N-diethanol p-toludine, silanized colloidal silica</td>
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<tr>
<td></td>
<td>Apply adhesive and light-cure for 10 s</td>
</tr>
<tr>
<td>K-etchant (Kuraray)</td>
<td>40% phosphoric acid, thickener</td>
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<td></td>
<td>Apply etchant selectively on enamel and leave for 15 s; thoroughly rinse and gently air dry (only for C-SE etch)</td>
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Bis-GMA, bisphenol-glycidyl methacrylate; CQ, di-camphoroquinone; HEMA, hydroxyethyl methacrylate; 10-MDP, 10-methacryloxydecyl dihydrogen phosphate.

or replacement) and occurrence of caries along the restoration margins were considered as clinical failures.

Marginal integrity was evaluated using a sharp probe and a mirror. Post-operative sensitivity was measured by blowing a stream of compressed air for 3 s at a distance of 2–3 cm from the cervical restoration while shielding the adjacent teeth with fingers and by moving the probe over the restored tooth surface. Clinical photographs were taken at this recall. Any discrepancy in evaluation between the two evaluators was immediately resolved at chair side.

Statistical analysis compared on a pair-wise basis the ratings of retention, marginal integrity, marginal discoloration and overall clinical success between the experimental and the control group using the McNemar test at a significance level of 5% (p<0.05).

3. Results

The 8-year clinical data for the various parameters evaluated are summarized in Table 2.

3.1. Recall rate

The 8-year recall rate was 76%. In total, 7 patients did not attend the recall because of the following reasons: 2 patients died, 2 patients had a severe illness, 1 patient moved to another place, 1 patient would not take part at the study anymore and in 1 patient the restored teeth received crowns in function of a total rehabilitation.

3.2. Retention rate

In both groups (C-SE etch and C-SE non-etch) one restoration was lost at the 8-year recall leading to an overall retention rate of 97% (McNemar, p = 0.48).

3.3. Marginal defects

The percentage of restorations without marginal defect decreased further after 8 years of clinical functioning (C-SE etch: 16%; C-SE non-etch: 8%; p = 0.5). Only small clinically acceptable marginal defects were observed at the enamel side (C-SE etch: 65%; C-SE non-etch: 86%; p = 0.09) and at the dentin side (C-SE etch: 54%; C-SE non-etch: 62%; p = 0.57). These percentages of small marginal defects were higher in the control group but the difference was not statistically significant.

3.4. Marginal discoloration

None of the restorations showed clinically unacceptable severe marginal discoloration. Small marginal discoloration at the enamel and/or dentin side was observed in 28% of the C-SE etch restorations and 44% of the C-SE non-etch restorations (p = 0.11). The percentage of restorations with a superficial marginal discoloration at the incisal enamel margin was significantly higher in the control group (C-SE etch: 11%; C-SE non-etch: 36%; p = 0.01). At the dentin side, the difference between both groups was small and not statistically significant (C-SE etch: 22%; C-SE non-etch: 28%; p = 0.75).

3.5. Post-operative sensitivity, caries occurrence and preservation of tooth vitality

At the 8-year recall none of the restored teeth became non-vital due to the placement of the restoration. In addition, none of the restored teeth showed post-operative sensitivity or caries occurrence.

3.6. Clinical success rate

Only two restorations (one of the control group and one of the experimental group) were clinically unacceptable due to loss of retention, leading to a clinical success rate of 97% in both groups (McNemar, p = 0.48).

4. Discussion

Long-term clinical trials are the ultimate test to evaluate the longevity of adhesive restorations, however, they are scarce to find in the literature. Therefore, when adhesive restorations in a clinical trial function well and have a high retention rate in the short-term, the investigators should be encouraged to carry out the study over a longer time period. The most time-consuming step of the clinical trial is the start of the study: in particular the selection of the patients, the placement of the restorations, and the baseline evaluation demand a lot of time.
and effort. The following recall sessions take less time compared to the baseline evaluation and give valuable information regarding the longevity of the restorations. Nevertheless, there are some difficulties with long-term clinical trials. First, several current long-term clinical trials do not have an optimal study design (no control group available, no randomization, no double-blind evaluation...) [49–52] as they were started at a moment that no guidelines were recommended for the setup of a randomized controlled clinical trial [53]. Consequently, the results of these clinical trials cannot be included in a meta-analysis, by which a more objective and quantitative summary of evidence can be obtained. Another difficulty in long-term clinical trials is to obtain an adequately high recall rate in order to achieve sufficient clinical validation. In most long-term clinical trials a recall rate lower than 50% is reported [49,51,52,54,55], which may affect the outcome of these trials seriously. Guidelines are needed to implement a correction factor for these low recall rates during interpretation of the results. In addition, it should be anticipated that patients were carefully informed about the possible extension of the evaluation period of the restorations at the start of the study.

The present study is adequately randomized, provides a detailed description of the study methodology, exhibited a careful informed about the possible extension of the evaluation period of the restorations at the start of the study. Monticelli et al. [27] and Rosales-Leal [24] observed a lower bonding effectiveness was measured in most 2-step self-etch adhesive system provides a separate particle-filled hydrophobic resin, which shows a high conversion rate and is known for its excellent mechanical properties [56–60]. However, after durability testing a slight decrease in dentin bonding effectiveness was measured in most in vitro studies. Monticelli et al. [27] and Rosales-Leal [24] observed a lower sealing capacity at the dentin side after respectively water aging and thermo-cycling, while in the study of Arisu et al. [33], occlusal loading did not influence the sealing capacity. Thermo-cycling and water storage of Class-V composite restorations [4] and thermo-mechanical fatigue loading of Class-II composite restorations [23,26] bonded with Clearfil SE lead to a decrease of the percentage of continuous margins at the dentin side. Ülker et al. [29] measured a significant decrease in dentin bond strength after mechanical loading. While indirect water storage for 12 months did not influence the bond strength of Clearfil SE to dentin [30,34,61], a slight decrease in bond strength was measured after direct water storage in almost all in vitro studies with varying periods of water storage [13,25,28,61–63]. Van Landuyt et al. [13] measured a lower bond strength already after 6 months of water storage. TEM morphological evaluation of the adhesive interface showed some signs of bond degradation. A distinct de-bonding of filler particles, attributed to hydrolysis of the filler–matrix coupling from the adhesive layer, was observed at the bottom part of this adhesive layer nearest the dentin. The impaired long-term bonding was also related to failures at the bottom of the hybrid layer, most likely associated to insuffi-

<table>
<thead>
<tr>
<th>Table 2 – Evaluation results in percentage at each evaluation period.</th>
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<tr>
<td>Recall period</td>
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</tr>
<tr>
<td>Recall rate</td>
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<tr>
<td>Retention rate</td>
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<tr>
<td>Absence of marginal defects</td>
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<td>Enamel marginal defect</td>
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<td>Small enamel marginal defect</td>
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<td>Severe enamel marginal defect</td>
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<td>Dentin marginal defect</td>
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<tr>
<td>Small dentin marginal defect</td>
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<tr>
<td>Severe dentin marginal defect</td>
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<tr>
<td>Absence of marginal discoloration</td>
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<tr>
<td>Superficial localized marginal discoloration</td>
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<tr>
<td>Deep generalized restoration discoloration</td>
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<tr>
<td>Absence of sensitivity</td>
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<tr>
<td>Absence of caries occurrence</td>
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<td>Overall clinical success rate</td>
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E, Clearfil SE etch; NE, Clearfil SE non-etch; all parameters, except for recall rate, retention rate and overall clinical success rate, refer only to the retained restorations.
Fig. 1 – The cervical lesions on both upper central incisors were restored (21: C-SE etch; 11: C-SE non-etch). (a) Situation before treatment, (b) baseline, (c) 2 years: both restorations showed excellent marginal integrity and absence of marginal discoloration. (d) At the 8-year recall, only a small clinically acceptable marginal defect (arrow) was noticed on the left central incisor (21).

The only signs of degradation of the adhesive interface in this study presented as clinically acceptable small marginal defects and/or superficial marginal discoloration. Indeed, the number of restorations with a small marginal defect and/or superficial marginal discoloration at the enamel side and/or dentin side increased further since the 5-year recall. Marginal discoloration was always accompanied by the presence of a marginal defect. This was also observed in other clinical trials [66,67]. Indeed, there is evidence suggesting that the integrity of the marginal seal correlates with the occurrence of marginal discoloration [68]. These small shortcomings only have a minor effect on the clinical effectiveness of the restorations as they can be removed by refinishing and repolishing of the restoration margins. However, in most situations the effect was so minimal that this was not required (Figs. 1 and 2).

A similar phenomenon of increased marginal deterioration was noticed in the 10-year clinical trial evaluating another mild 2-step self-etch adhesive, Clearfil Liner Bond 2 [49], but also in long-term clinical trials evaluating etch-and-rinse adhesives [54,55,65]. A detailed comparison between clinical trials carried out at different universities is, however, difficult to make as evaluation of marginal integrity and marginal discoloration is not perfectly standardized.

The small marginal defects and/or superficial discoloration in the present study, were more frequently observed in the 7-year clinical trial with similar study design evaluating two 3-step etch-and-rinse adhesives, considered as the golden-standard of the adhesives, the success percentages for these adhesives (Optibond FL (Kerr): 94%; Permaquick (Ultradent): 90%) were quite similar as in the present study [65]. Hereby, we can say that the 2-step self-etch adhesive Clearfil SE has an equal long-term bonding effectiveness as these 3-step etch-and-rinse adhesives. In addition, there is a clear advantage regarding the application procedure and technique sensitivity for Clearfil SE. The critical etch-and-rinse phase is omitted, which makes the application procedure not only shorter, but also easier [5].
C-SE non-etch group than in the C-SE etch group. This difference was most obvious at the enamel side, however only statistically significant for the presence of superficial marginal discoloration. This confirms what in most in vitro durability studies was noticed namely that following the self-etch approach marginal deterioration at the enamel side was significantly more present compared when enamel was selectively etched with phosphoric acid prior to application of Clearfil SE [26,32,45]. The increased presence of small marginal defects and superficial marginal discoloration at the enamel side in this study did not influence the survival rate of the restorations or the development of secondary caries. Similarly, a weak correlation between marginal adaptation in vitro and clinical performance of the restorations was noted by several authors [44,68,69]. The fact that only clinically acceptable small marginal defects and superficial marginal discoloration were observed at the enamel side, points out that, in spite of the superficial etch pattern, the bond of Clearfil SE to enamel is quite durable. The contribution of the chemical bonding between 10-MDP and hydroxyapatite to this durable enamel bond should not be underestimated [22,37].

One has to take into account that the non-carious Class-V restoration may not be the best model for correlating results with enamel fatigue data, as this is primarily a dentin lesion, with a smaller amount of enamel at the incisal side, and the stress on the restoration margins may not be as great for Class I/II restorations. In an in vitro study of minimally invasive box-only preparations for direct composite restorations and CEREC inlays, enamel conditioning with phosphoric acid of the unveeled enamel margins negatively affected the marginal adaptation after loading compared with using the self-etch approach alone [70]. These authors hypothesize that the slightly inferior enamel bonding performance may produce less stress at the margins, resulting in fewer gaps and paramarginal enamel fractures. In a Class-II clinical trial comparing the 2-step etch-and-rinse adhesive Single Bond (3M Espe) and Clearfil SE, small marginal enamel defects occurred more often in the Clearfil SE group, however the difference was not significant [20]. From these results we can conclude that an additional acid-etching step could be considered for restorations whose retention primarily depends on a strong bond to the enamel surface, such as large Class IV or veneer restorations.

Post-operative sensitivity was not present at all at the 8-year recall. The so-called mild self-etch adhesives are assumed to cause less post-operative pain, as they use the smear layer as bonding substrate, leaving residual smear plugs that cause less dentinal fluid flow than etch-and-rinse adhesives [71]. In general, post-operative pain resolves within a short time period after placement of the composite restoration. In the present study, post-operative sensitivity was almost non-existing at baseline and after 6 months (6%). This

Fig. 2 – The cervical lesions on both mandibular premolars were restored (44: C-SE etch; 45: C-SE non-etch). (a) Situation before treatment, (b) baseline, (c) 3 years: both restorations showed small marginal defects and superficial marginal discoloration at the enamel side (arrows). (d) Both restorations were still clinically acceptable after 8 years of clinical functioning. Only small marginal defects and superficial marginal discoloration were present at the incisal enamel side and the cervical dentin side (arrows).
is in accordance with two short-term posterior composite clinical trials, in which postoperative sensitivity was rarely seen with Clearfil SE [20,44].

Finally, no caries was observed at the restoration margins of the Class-V restorations. The same observation was done in all other medium-term to long-term Class-V clinical trials evaluating other categories of adhesives [49,51–53,55,65]. Although caries recurrence is in general presented as the main reason for failure of composite restorations [72,73], the location of the Class-V restorations and the easy accessibility for cleaning would certainly have contributed to this positive result.

5. Conclusion

At 8 years, the clinical effectiveness of Clearfil SE, a mild 2-step self-etch adhesive, appeared excellent. Selective phosphoric acid-etching of the enamel margins had only some minor positive effect on secondary clinical parameters like a lower incidence of small marginal defects/discolorations at the enamel side. These clinically acceptable marginal shortcomings, however, did not require any restorative intervention at the 8-year recall.

REFERENCES


