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ORIGINAL ARTICLE

Clinical effectiveness of a one-step self-etch adhesive in non-carious cervical lesions at 2 years

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Abstract A 2-year randomized, controlled prospective study evaluated the clinical effectiveness of a one-step self-etch adhesive and a "gold-standard" three-step etch-and-rinse adhesive in non-carious Class-V lesions. The null hypothesis tested was that the one-step self-etch adhesive does perform clinically equally well as the three-step etch-and-rinse adhesive. A total of 161 lesions in 26 patients were restored with Clearfil AP-X (Kuraray). The restorations were bonded either with the "all-in-one" adhesive Clearfil S3 Bond (Kuraray) or with the three-step etch-and-rinse adhesive Optibond FL (Kerr). The restorations were evaluated at baseline and after 6 months, 1 and 2 years, regarding their retention, marginal adapation, marginal discoloration, caries occurrence, preservation of tooth vitality and post-operative sensivity. Retention loss, severe marginal defects and/or discoloration that needed intervention (repair or replacement) and the occurrence of caries were considered as clinical failures. The recall rate at 2 years was 93.8%. Only one Clearfil S3 Bond restoration was lost at the 2-year recall. All other restorations were clinically acceptable. The number of restorations with defect-free margins decreased severely during the 2-year study period (to 6.7% and 25.3% for Clearfil S3 Bond and Optibond FL, respectively). The Clearfil S3 Bond restorations presented significantly more small marginal defects at the enamel side than the Optibond FL restorations (Clearfil S3 Bond: 93.3%; Optibond FL: 73.3%; p=0.000). Superficial marginal discoloration increased in both groups (to 53.3% and 36% for Clearfil S3 Bond and Optibond FL, respectively) and was also more pronounced in the Clearfil S3 Bond group (p=0.007). After 2 years, the simplified one-step self-etch adhesive Clearfil S3 Bond and the three-step etch-and-rinse adhesive Optibond FL were clinically equally successful, even though both adhesives were characterized by progressive degradation in marginal integrity. Clearfil S3 Bond exhibited more small enamel marginal defects and superficial marginal discolorations.

Keywords Randomized clinical trial · Adhesives · One step · Self etch · Cervical lesions

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Introduction

One-step self-etch adhesives, that combine etching, priming and application of the adhesive resin into one solution, are well accepted by general practitioners [1].

The morphological features of the hybrid layer produced by these adhesives depend on the acidity of the self-etching solution [2–4].While the so-called strong one-step self-etch adhesives demineralize dentin (and enamel) relatively deep (2–3 μm), "mild" adhesives demineralize tooth substrate only superficially [5, 6]. As a result, mild self-etch adhesives typically present with a submicron hybrid layer with less pronounced resin-tag formation. The collagen fibrils in the submicron hybrid layer are not completely deprived from hydroxyapatite, which may serve as receptor for additional chemical interaction with specific carboxyl or phosphate groups of the functional

monomer included in the adhesive formulation [2, 7, 8]. However, such primary chemical bonding has so far only been proven for specific functional monomers like 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) and to a lower extent for 4-methacryloxyethyl trimellitic acid [9] as well as for polyalkenoic acids as the functional polymers within glass-ionomers [10].

The key advantages of one-step adhesives over their multi-step counterparts are their easy and fast application procedure. However, for most one-step (self-etch) adhesives, this simplified application procedure goes along with some sacrifice in bonding performance [3, 11–15]. This lower bonding efficiency has been thoroughly documented in laboratory and must be attributed to an interplay of several factors, such as low conversion rate [16, 17], reduced mechanical strength of the adhesive resin, enhanced water sorption through osmosis from the host dentin, potential phase-separation effects when the adhesive solution is low in or free of HEMA [18–20], among others. Nevertheless, a one-step self-etch adhesive that shows relatively good bonding effectiveness to enamel and dentin in vitro is Clearfil S3 Bond (Kuraray, Tokyo, Japan) [21–24]. This one-step adhesive contains the functional monomer 10-MDP, which was shown to have the most efficient chemical bonding potential of all functional monomers tested so far [9].

Laboratory testing under optimal in vitro conditions is valuable as a pre-clinical screening test of adhesive materials. However, the information on the bonding effectiveness of adhesives conducted in optimal laboratory conditions should be validated by controlled prospective clinical studies. The ultimate test method to evaluate the clinical effectiveness of dental adhesives is a non-carious Class-V clinical trial [11, 12]. Therefore, the aim of this randomized controlled trial was to evaluate the 2-year clinical effectiveness of the one-step self-etch adhesive, Clearfil S3 Bond, and the three-step etch-and-rinse adhesive, Optibond FL (Kerr, Orange, USA), in non-carious cervical Class-V lesions. The null hypothesis tested was that the one-step self-etch adhesive does perform clinically equally well as the three-step etch-and-rinse adhesive.

Materials and methods

Material selection

One hundred sixty-one cervical lesions were restored either with Clearfil S3 Bond or Optibond FL. Clearfil S3 Bond is an ultra-mild (pH≈2.7) one-component one-step self-etch adhesive. Optibond FL, an ethanol/water-based three-step etch-and-rinse adhesive, was chosen as control. Composition and application procedure of both adhesives are shown in Table 1. All lesions were restored with a universal micro-hybrid composite, Clearfil AP-X (Kuraray).

Patient and lesion selections

Study subjects were non-hospitalized patients from the university dental school who needed dental treatment of non-carious cervical lesions. Reasons for treatment were tooth sensitivity, prevention of further tooth wear, and/or aesthetic reasons. Patients with a complex medical history, severe or chronic periodontitis, extreme caries sensitivity and heavy bruxims (>50% of the tooth structure lost as a result of attrition) were excluded from the study. Lesions with caries were also not included in the study. All cervical abrasion and erosion lesions had their cervical margin in dentin and their incisal margin in enamel.

In total, 26 patients (14 females and 12 males) were involved. The age of the patients varied from 39 to 79 years (mean age, 50±8.3 years). The clinical trial was approved by the Commission for Medical Ethics of the Suleyman Demirel University (RBE 145-3029). Prior to participating in the study, all patients signed a written consent form.

The cervical lesions were typical wedge- or saucer-shaped abrasion/erosion/abfraction lesions of incisors, canines and premolars. The lesions were pre-operatively categorized in terms of shape (wedge or saucer-shaped, rounded or sharp margins), depth (≤1 or >1 mm), size (≤1.5, 1.5–2.5 and ≥2.5 mm), degree of dentin sclerosis (none, slight, moderate or severe), the presence of attrition facets on the incisal edge or occlusal cusp and the presence of pre-operative sensitivity, as is shown in Table 2.

All cervical lesions in each patient were restored. A pre-set randomization table was used to assign the adhesives, Clearfil S3 Bond and Optibond FL, to the teeth to be restored in each patient. The tooth with the highest tooth number was treated following the first adhesive listed, while the tooth with the lowest tooth number was treated using the other adhesive. In case of an uneven number of restorations in a patient, the extra tooth restored with one adhesive was compensated for by restoring one more lesion with the other adhesive in the next patient who presented with an unequal number of cervical lesions. In total, 81 lesions were restored with Clearfil S3 Bond and 80 lesions with Optibond FL. The average number of restorations per patients was six.

Restorative procedure

One specially instructed and experienced dentist from the university dental school placed all restorations. If needed to prevent patients' discomfort during restorative procedures, local anesthesia was applied. The teeth with the cervical lesions to be restored were first cleaned with a pumice-water slurry, using a rubber cup to remove the salivary pellicle

Table 1 Composition and application procedure of the adhesives used

Adhesive	Manufacturer	pH	Composition	Application procedure
Clearfil S3 Bond (lot no: 41115)	Kuraray, Tokyo, Japan	2.7	10-MDP, Bis-GMA, HEMA, DMA, CQ, ethanol, water and silanated colloidal silica	Step 1. Apply adhesive to entire surface with a disposable brush tip Step 2. Leave in place for 20 s Step 3. Dry the entire surface sufficiently by air-drying with high-pressure for more than 5 s while spreading the bond layer thinly Step 4. Light cure for 10 s
Optibond FL (lot no: 430398)	Kerr, Orange, CA, USA	Primer: 1.9	Etchant: 37.5% H_3PO_4	Step 1. Apply etchant on enamel and dentin, leave for 15 s, rinse for 15 s and dry for 5 s
		Bonding: 6.9	Primer: HEMA, GPDM, MMEP, water, ethanol, CQ and BHT Adhesive: Bis-GMA, HEMA, GDMA, CQ, ODMAB and filler (fumed SiO_2, barium aluminoborosilicat, Na_2SiF_6), coupling factor A174	Step 2. Apply primer while gently rubbing Step 3. Dry for 5 s Step 4. Apply bonding in a uniform layer Step 5. Light cure for 30 s

10-MDP 10-methacryloyloxydecyl dihydrogen phosphate, *BHT* butylhydroxytoluene, *Bis-GMA* bisphenol A diglycidyl methacrylate, *CQ* camphorquinone, *DMA* dimethacrylate, *GDMA* glycerol dimethacrylate, *GPDM* glycerol phosphate dimethacrylate, *HEMA* 2-hydroxyethyl methacrylate, *MMEP* mono-2-methacryloyloxyethyl phthalate, *ODMAB* 2-(ethylhexyl)-4-(dimethylamino)benzoate

Table 2 Pre-operative data regarding the cervical lesions treated in the study

Characteristics of the lesions	Number of the lesions	
	Clearfil S3 Bond	Optibond FL
Tooth distribution		
Maxillary anterior	18	24
Maxillary posterior	17	19
Mandibular anterior	17	18
Mandibular posterior	29	19
Shape of the lesion		
Sharply defined (shallow, <1 mm)	33	31
Sharply defined (deep, >1 mm)	24	25
Irregular rounded (shallow, <1 mm)	24	24
Irregular rounded (deep, >1 mm)	–	–
Size of the lesion		
≤1.5 mm	10	10
1.5–2.5 mm	39	42
≥2.5 mm	32	28
Occlusion and articulation		
Antagonist present	78	79
No antagonist	3	1
Wear facets		
No wear facets	3	7
Wear facets	78	73
Pre-operative sensitivity		
No pre-operative sensitivity	32	31
Pre-operative sensitivity	49	49

and any remaining dental plaque. The dentin walls of the lesion were mechanically roughened using a diamond bur (110 μm, no. 801/014, Medicept Dental, Hertfordshire, UK). A short 1–2-mm enamel bevel was prepared to increase the surface area for bonding and enhance aesthetics. Isolation of the tooth was provided by cotton rolls and a saliva aspirator, and using a transparent cervical matrix system (Contour-strip, Ivoclar/Vivadent, Schaan, Liechtenstein) fixed by wooden wedges. The adhesive systems were applied according to the manufacturers' instructions (Table 1). The composite Clearfil AP-X (Kuraray) was inserted in two or three increments from cervical to incisal to reduce polymerization shrinkage effects and to achieve effective setting upon curing using an Optilux 500 light-curing unit (Demetron LC, Kerr, Orange, CA, USA) with a light output not less than 600 mW/cm^2. Each composite layer was polymerized for 20 s. After placement of the final increment, the restoration was polymerized for 40 s. Final contouring and polishing of the restorations was performed using a fine-grit flame-shaped diamond bur (859/014XF, Micro Diamond Technologies Ltd, Afula, Israel), rubber points (Enhance, Dentsply/Caulk, Konstanz, Germany), flexible disks and finishing strips (Sof-Lex Pop-On set, 3 M ESPE, St Paul, MN, USA), and polishing paste (Enhance, Dentsply/Caulk).

Evaluation criteria and procedure

After evaluation of the restorations immediately following placement (baseline), all patients were subjected to a strict recall schedule with controls at 6 months, 1 and 2 years. The

clinical effectiveness 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. These parameters were scored by two experienced and calibrated examiners (different from the operator, and fully blinded to the adhesive used) using a modification of the predetermined set of criteria introduced by Vanherle et al. [25] (Table 3). Any discrepancy between evaluators was resolved at chairside.

The first four parameters (retention, marginal integrity, marginal discoloration and caries occurrence) were considered as principal parameters determining the "overall clinical success rate". Retention loss, severe marginal defects and/or discoloration that needed intervention (repair or replacement) and caries along the restoration margins were considered as "clinical failures" (Table 4). Clinical photographs were made pre-operatively, at baseline and at each recall.

Statistical analysis

The 2-year clinical effectiveness of both Clearfil S3 Bond and Optibond FL was compared for each of the variables that determine the overall clinical success rate (retention, marginal integrity and marginal discoloration). Since none of the restorations exhibited caries, no statistical comparison of the caries rate between the two groups was performed. A logistic regression analysis with generalized estimating equations, using a compound symmetry structure for the working correlation matrix, was used to account for the clustered data (multiple restorations per patient). The analyses were performed using the procedure PROC GENMOD in the statistical package SAS (version 9.2). Odds ratios and 95% confidence intervals were determined.

Results

The evaluation results at each evaluation period are shown in Table 4. The statistical analysis is presented in Table 5.

The overall recall rate was 93.8% at 2 year. Reasons for not attending the recall were checked: one patient (four restorations) had moved to another city and another patient (six restorations) did not want to be included in

Table 3 Definition, evaluation method and scores of the evaluation criteria employed

Evaluation criteria/definition	Evaluation method	Score
Retention rate: restorations retained in the lesions	Visually and tactilely using a probe (after air-drying the tooth)	R1: no loss of restoration R2: loss of restoration
Marginal adaptation: defect of the margin that can be felt when moving a sharp probe over the restoration margins	Tactilely by moving a sharp probe over the restoration margins	MA1: No marginal defect MA2: Small marginal defect at enamel side MA3: Severe marginal defect at enamel side MA4: Small marginal defect at dentin side MA5: Severe marginal defect at dentin side Small marginal defect (>50 and <250 μm): no intervention needed (=clinically acceptable) Severe marginal defect (>250 μm): intervention needed (=clinically unacceptable)
Marginal discoloration: discoloration along the restoration margins	Visually after air-drying the tooth and after removing plaque	MD1: No discoloration MD2: Superficial discoloration (=clinically acceptable) MD3: Deep discoloration, (=clinically unacceptable)
Caries: occurrence of caries along the restoration margins or underneath the restoration	Visually and tactilely using a probe (after air-drying the tooth)	CR1: No caries recurrence CR2: Caries recurrence
Post-operative sensitivity: thermal or tactile sensitivity	Sensitivity to air was tested by blowing a stream of compressed air for 3 s at a distance of 2–3 cm from the lesion/restoration, while shielding the adjacent teeth with fingers; tactile sensitivity was tested by moving a probe over the lesion/restoration	POS1: No sensivitity POS2: Sensitivity
Tooth vitality	Tested using a thermal sensitivity test	VI1: Vital VI2: Non-vital (retracted pulp) VI3: Non-vital (endodontic treatment) VI4: Non-vital due to restoration

Table 4 Clinical results for the different parameters evaluated (in percentage)

	Baseline		6 months		12 months		24 months	
	Clearfil S3 Bond	Optibond FL	Clearfil S3 Bond	Optibond FL	Clearfil S3 Bond	Optibond FL	Clearfil S3 Bond	Optibond FL
Number of restorations in study	81	80	78	77	78	77	75	75
Recall rate	100	100	96.3	96.3	96.3	96.3	93.8	93.8
Retention rate	100	100	100	100	98.7	100	98.7	100
Absence of marginal defects	100	100	42.3	58.4	17.9	36.4	6.7	25.3
Enamel marginal defects	0	0	55.1	37.7	79.5	62.3	93.3	73.3
Small enamel marginal defects	0	0	55.1	37.7	79.5	62.3	93.3	73.3
Severe enamel marginal defects	0	0	0	0	0	0	0	0
Dentin marginal defects	0	0	7.7	7.8	15.4	9.1	26.7	17.3
Small dentin marginal defects	0	0	7.7	7.8	15.4	9.1	26.7	17.3
Severe dentin marginal defects	0	0	0	0	0	0	0	0
Absence of marginal discoloration	100	100	89.7	96.1	64.1	79.2	46.7	64.0
Enamel marginal discoloration	0	0	9.0	2.6	30.8	19.5	48.0	33.3
Superficial localized marginal discoloration	0	0	9.0	2.6	30.8	19.5	48.0	33.3
Deep generalized marginal discoloration	0	0	0	0	0	0	0	0
Dentin marginal discoloration	0	0	1.3	1.3	9.0	1.3	18.7	8.0
Superficial localized marginal discoloration	0	0	1.3	1.3	9.0	1.3	18.7	8.0
Deep generalized marginal discoloration	0	0	0	0	0	0	0	0
Absence of caries occurrence	100	100	100	100	100	100	100	100
Sensitivity	3.7	1.3	10.3	13.0	5.1	9.1	4.0	6.7
Overall clinical success rate	100	100	100	100	98.7	100	98.7	100

All parameters, except for the recall rate, retention rate and overall clinical success rate refer only to the retained restorations

the study anymore (for a reason not related to the adhesive restoration performance).

A 100% retention rate was recorded in the Optibond FL group while one restoration of the Clearfil S3 Bond group was lost at 2 years, resulting in a retention rate of 98.7%.

Marginal integrity deteriorated after 2 years in both groups. The number of restorations with defect-free margins was lower in the Clearfil S3 Bond group (Clearfil S3 Bond: 6.7%, Optibond FL: 25.3%). The latter group presented significantly more small incisal marginal defects at the enamel side (Clearfil S3 Bond: 93.3%; Optibond FL: 73.3%; p=0.000). At the dentin margin, small marginal defects were recorded for 26.7% of the Clearfil S3 Bond restorations versus 17.3% of the Optibond FL restorations. This difference, however,

Table 5 Comparison of the 2-year key parameters for clinical success of Clearfil S3 Bond versus Optibond FL

Parameter	OR	LL	UL	p value
Retention	0.00	–	–	–
Marginal defects	4.75	2.08	10.84	0.000
Enamel marginal defects	5.06	2.18	11.75	0.000
Small enamel marginal defects	5.06	2.18	11.75	0.000
Dentin marginal defects	1.73	0.72	4.16	0.22
Small dentin marginal defects	1.73	0.72	4.16	0.22
Marginal discoloration	1.99	1.21	3.29	0.007
Superficial localized marginal discoloration	1.99	1.21	3.29	0.007
Overall clinical success rate	0.00	–	–	–

Regarding the parameters "marginal defects" and "discoloration", only the results for retained restorations were compared. The parameter "caries occurrence" was not included in the statistical comparison. No p value or OR is obtained when the number of events equals zero or is extremely low

OR odds ratio, i.e. the ratio of the odds of the event for Clearfil S3 Bond compared with the odds for Optibond FL, *LL* and *UL* lower and upper limit of the 95% confidence interval, respectively

was not statistically significant (p=0.22). All these marginal defects were rated as "small," which implies that they were clinically acceptable and that no immediate intervention was needed.

With regard to marginal discoloration, the percentage of restorations showing no marginal discoloration decreased in both groups during the 2-year study period. Marginal discoloration was only rated as superficial localized marginal discoloration at the enamel side (Clearfil S3 Bond: 48%; Optibond FL: 33.3%) and/or at the dentin side, (Clearfil S3 Bond: 18.7%; Optibond FL: 8%), and was observed significantly more in the Clearfil S3 Bond group (p=0.007).

No caries occurrence around or underneath the composite restorations could be detected in either the Clearfil S3 Bond or Optibond FL group, and no teeth became non-vital as result of the cervical restorations.

Around 60% of the restored teeth were sensitive to air or tactile contact pre-operatively. After restoring, this percentage decreased to approximately 11% after 6 months and 5% after 2 years.

Due to the retention loss of one restoration belonging to the Clearfil S3 Bond group, the overall success rate was 98.7% for Clearfil S3 Bond and 100% for Optibond FL after 2 years.

Discussion

Current trends in adhesive dentistry are directed towards the development and use of adhesives with a simple and fast application procedure. The one-step self-etch adhesives or so-called all-in-one adhesives can be considered a significant improvement in terms of ease of use, as compared with the three-step etch-and-rinse adhesives [3]. Indeed, an in vitro study by Van Landuyt et al. [3] recorded application times of 44 s for Clearfil S3 Bond and 113 s for Optibond FL.

Regarding the bonding effectiveness of the one-step self-etch adhesive Clearfil S3 Bond, some in vitro studies [3, 21, 22, 26] measured micro-tensile bond strengths to dentin and enamel similar as those recorded for some two-step self-etch adhesives (Clearfil SE Bond, Kuraray; Optibond Solo Plus Self-Etch, Kerr; Clearfil Protect Bond, Kuraray), as well as for the three-step etch-and-rinse adhesive Optibond FL (Kerr), which can be considered as a "gold standard." However, other studies reported lower bond strengths to dentin and enamel for Clearfil S3 Bond, when compared with the two-step self-etch adhesive Clearfil SE Bond and some two-step etch-and-rinse adhesives (Prime&Bond NT, Dentsply; Adper Single Bond Plus, 3M ESPE) and the three-step etch-and-rinse adhesive Optibond FL (Kerr) [13, 21, 24, 27].

Despite the importance of laboratory studies attempting to predict clinical performance of adhesives, clinical trials remain the ultimate way to collect scientific evidence on the actual clinical effectiveness of an adhesive restorative treatment. To date, the clinical performance of Clearfil S3 Bond has been studied in only a few short-term (1–3 years) clinical trials [28–32]. The present clinical study is the first one comparing the 2-year clinical performance of Clearfil S3 Bond with the three-step etch-and-rinse adhesive and so-considered gold-standard Optibond FL. In addition, this study is one of the three multi-center based studies evaluating the clinical performance of two one-step self-etch adhesives (G-Bond, GC; Clearfil S3 Bond) and the three-step etch-and-rinse control, Optibond FL [29, 33]. Such multi-center clinical studies with similar study design will facilitate to include at a later stage all results in a meta-analysis, by which a more objective and quantitative summary of evidence can be obtained [34].

Regarding the clinical success rate, there was no significant difference between the two groups at the 2-year recall; the null hypothesis was thus rejected. The overall clinical success rate in the Clearfil S3 Bond and the Optibond FL group after 2 years was 98.7% and 100%, respectively. Only one Clearfil S3 Bond restoration was clinically unacceptable due to restoration loss (retention rate=98.7%). Similar excellent success rates of 97-100% were reported in most short-term clinical trials evaluating Clearfil S3 Bond [28–31]. In the clinical trial of Brackett et al. [32], an obviously lower success rate of 81% was recorded for Clearfil S3 Bond after 2 years. According to the authors, this lower success rate was likely due to the inexperience of the operators in adhesive dentistry research and due to the fact that the enamel was left unprepared.

The excellent short-term clinical performance of Clearfil S3 Bond in the present study must most likely be attributed to the specific composition and resultant mechanical properties of this adhesive. Clearfil S3 Bond is a one-step self-etch adhesive, of which the self-etching primer contains 10-MDP as functional monomer dissolved in water. The interaction between this adhesive and bur-cut dentin presented a shallow hybrid layer of about 500 nm and absence of resin plugs, as shown in transmission electron microscopic studies [3, 13, 35]. At enamel, a tight interface was apparent without clear morphologic signs of deep tag formation [36]. 10-MDP has been rated as the most effective monomer for ionic binding to hydroxyapatite, thereby definitely contributing to the bond stability on the long term. The excellent 8-year clinical effectiveness of the precursor "mild" two-step self-etch adhesive, Clearfil SE Bond (that also contains 10-MDP), has also been attributed to the chemical adhesion potential of the

10-MDP functional monomer with tooth tissue [37]. In addition, Clearfil S3 Bond is rich in HEMA and therefore does not undergo phase-separation; it, nevertheless, has been shown to remain relatively technique sensitive since the lining composite needs to be applied and cured as soon as possible to reduce watersorption from dentin due to osmosis as much as possible [19, 38, 39]. Definitely, longer-term evaluation is needed to confirm this promising early clinical effectiveness and the eventual bond durability of Clearfil S3 Bond.

A remarkable observation in this clinical study was a progressive deterioration of marginal integrity in both groups during the 2-year study period. However, all marginal defects were small and remained clinically acceptable, as they actually do not require clinical intervention. Such small marginal defects were most frequently observed at the incisal enamel margin in both groups (Clearfil S3 Bond: 93.3%; Optibond FL: 73.3%). They were noticed significantly more in the Clearfil S3 Bond group than in the Optibond FL group. This must most likely be explained by the fact that Clearfil S3 Bond is an "ultra-mild" self-etch adhesive (pH≈2.7) that very shallowly interacts with enamel [36]. Referring to enamel bond strength data, Clearfil S3 Bond presented with a lower bonding effectiveness than several etch-and-rinse adhesives [3, 21, 27, 40]. However, among one-step adhesives Clearfil S3 Bond was recorded the highest bond strength to enamel in several laboratory studies [3, 22, 41]. The presence of 10-MDP with its unique chemical affinity to hydroxyapatite, but also the mechanical strength of this adhesive were advanced as reasons to explain this rather favorable bonding effectiveness to enamel [3, 21]. Nevertheless, the percentage of small enamel marginal defects in both groups was higher than in other Class-V clinical trials, in which both adhesives were tested, even in those with a similar study set-up [29, 33, 42]. Taking a closer look to the restorations at higher magnification, it was noticed that in most restorations the composite was placed further incisally/occlusally than the 2-mm enamel bevel. This has definitely led to bonding to uncut enamel. It is not unthinkable that this unground enamel was not conditioned sufficiently to obtain a reliable and stable bond. Especially the bond of the "ultra-mild" self-etch adhesive Clearfil S3 Bond to uncut enamel must have failed more easily and led to chipping of composite and/or more rapid development of a marginal defect.

With regard to the presence of defects at the dentin margin, 26.7% of the Clearfil S3 Bond and 17.3% of the Optibond FL restorations presented with a small cervical marginal defect. The difference between both groups was not statistically significant. The number of small defects at the dentin margin in the Optibond FL group at two years was quite similar in two other Class-V clinical trials (that evaluated Optibond FL following a similar study design) [33, 42].

Marginal discoloration was only observed as superficial and localized marginal discoloration, and occurred significantly more in the Clearfil S3 Bond group (53.3%) than in the Optibond FL group (36%). Marginal discoloration was most often observed in combination with a small marginal defect. A correlation between marginal defects and marginal discoloration was also noticed in other clinical trial reports [43]. It is important to mention that all these small marginal defects and superficial discolorations could be easily removed by refinishing and repolishing. Such repeated refinishing and repolishing at the regular check-ups in clinical practice is highly recommended in order to extend the restoration longevity.

The frequency of tooth sensitivity to air or tactile contact decreased during the 2-year study period. An obvious reduction in sensitivity (50%) was recorded for both adhesives at 6 months (Clearfil S3 Bond: 10.3%, Optibond FL: 13%). The lower frequency of tooth sensitivity at baseline was due to the fact that this parameter could not be evaluated in patients that received local anesthesia before treatment. From 6 months to 2 years, a further reduction in sensitivity to air or tactile contact was noticed in both groups. Despite that phosphoric acid used with Optibond FL removes the smear layer and renders the dentinal tubules patent, there was no difference in sensitivity between both groups.

Conclusions

Both the one-component, one-step self-etch adhesive Clearfil S3 Bond and the "gold-standard" three-step etch-and-rinse adhesive Optibond FL performed equally successful after two years of clinical service. Further long-term follow-up is needed to confirm the early promising clinical effectiveness of this one-step self-etch adhesive. Both adhesives showed a progressive degradation in marginal adaptation of the resin composite restorations. Restorations bonded with Clearfil S3 Bond exhibited significantly more small enamel marginal defects and superficial discolorations. These clinically still acceptable marginal shortcomings, however, did not require any restorative intervention.

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