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Clinical and OCT outcomes of a universal adhesive in a randomized clinical trial after 12 months

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ABSTRACT

Objectives: To assess the performance of a universal adhesive in different application modes in non-carious cervical lesions clinically and by optical coherence tomography (OCT).

Methods: 55 adult patients with three non-carious cervical lesions (NCCL) each participated in the study. Lesions were restored with Scotchbond™ Universal (SBU, 3 M) applied in the self-etch (SBU-SE) and the selective-enamel-etch mode (SBU-SEE) in combination with Filtek™ Supreme XTE (3 M). OptiBond™ FL (OFL, Kerr) was used as a control. Restorations were clinically assessed (FDI criteria) after 14 days, 6 and 12 months and in parallel imaged by OCT (interfacial adhesive defects), starting immediately after filling placement. Cumulative failure rates (CFR) and means of interfacial adhesive defect were statistically evaluated.

Results: After 12 months, CFRs were lower in the SBU groups (0.0% each) than in the OFL group (20.0%, $p = 0.001$). Clinically, small marginal fractures occurred three times more often in the SBU-SE than in the SBU-SEE group ($p = 0.001$). Immediately after filling placement and at each reassessment OCT revealed more interfacial defects at enamel interfaces for SBU/SE compared to SBU/SEE and OFL ($p_i \leq 0.044$). At dentin/cement more defects were seen with OFL compared to SBU/SE and SBU/SEE ($p_i \leq 0.001$). Before restoration loss, more interfacial defects appeared compared to remaining restorations ($p_{immediately/6M} = 0.132/0.002$).

Conclusions: Clinical evaluation and OCT imaging revealed higher interfacial integrity for SBU in both application modes compared to OFL. OCT detected interfacial bond failures prior to clinical deterioration or restoration loss.

Clinical significance: Scotchbond Universal showed an equivalent or improved bonding performance compared to the reference adhesive. Selective enamel etching is recommended. The parameter interfacial adhesive defect seems to be a valuable predictor for evaluation of adhesive restoration systems.

1. Introduction

During the last two decades, self-etching adhesive systems (SEA) became increasingly popular because of their alleged handling convenience and their expected lower susceptibility to errors. By introducing mild SEAs, a definite improvement in bonding effectiveness was noticed for the all-in-one adhesives so that more recent versions are almost competitive with proven multi-step golden standard approaches. [1] In order to create a sufficient retentive etching pattern at enamel an additional selective phosphoric-acid etching of the enamel cavity margins (SEE) is highly recommended [2–4] This was confirmed experimentally by increased enamel bond strength when a SEA was applied after enamel etching [5]as well as clinically with better marginal integrity and absence of marginal discoloration [6,7]

Since 2011, one-step self-etching systems with revised chemical compositions, the so-called multi-mode or universal adhesives (UA) were introduced into the market. According to the stated claim of manufacturers, these adhesives should be rather robust on wet and dry dentin and are indicated for use in the self-etch mode (SE) as well as in the etch-and-rinse mode (ER). Most of UA systems contain 10-MDP

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(methacryloyloxydecyl dihydrogen phosphate) [8].This functional monomer with a high etching potential [9] allows its application without a separate etching step, producing an effective ionic bond to hydroxyapatite through nano-layering [10,11]. In vitro, it has been proven that the bonding performance of UA to dentin was competitive regardless of the used application mode [12], which is also reflected by μTBS to dentin [13]. Good study results have been reported most frequently for Scotchbond Universal, which was the first marketed UA [14]. At enamel, analogous to the SEAs, additional conditioning with phosphoric acid (selective enamel etch, SEE) has been recommended for UAs [11,13,15,16]. As a consequence, the current study design focused on the self-etch compared to the selective-enamel-etch approach.

Assessments of adhesive systems vary between numerous in-vitro techniques, which are often invasive [17] and clinical trials, which primarily use clinical success criteria [3,18,19] partly combined with quantitative marginal analysis [20]. However, it remains controversial, how the results of these investigations should be discussed in relation to each other.

In one meta-analysis “some clear indications” have been advanced for a correlation of laboratory bond strength with clinical retention rates especially in Class-V restorations [21]. Further studies have described that μTBS data of adhesive systems, especially after water storage for six months, showed a “good correlation” with clinical marginal discoloration of Class V restorations at least in the short-term [22]. Thermomechanical loading in combination with long-term water storage has been found useful in forecasting the durability of the resin-dentin bond created in vivo [23] and a reduced interaction of the resin to enamel found by SEM corresponded to a decreased marginal integrity in vivo [24]. By contrast, in another meta-analysis “only a moderate correlation” between microtensile and macrotensile bond strength results and marginal discoloration was demonstrated, and “no correlation” between these in vitro tests and retention loss or marginal integrity in vivo was shown [25]. These contradictory statements suggest that the parameters used for simulating bond degradation in laboratory settings are generally not directly transferable to clinical outcomes. Therefore, the concern remains to identify parameters that may be used to forecast the effectiveness [19] and durability [23] of adhesive bonds.

Clinically the question arises, what are suitable evaluation parameters that reliable address differences between adhesive-composite restoration systems over years of function? Besides others [26] the authors of this study identified three key parameters in their previous clinical trials: retention (and fractures), marginal adaptation (MA) and marginal staining (MS). The integrity of the tooth-composite interface can be assumed as the most crucial factor determining the clinical success of composite restorations. In light of the above, the initial and the tooth-composite bond manifesting in the further course should indicate the clinical performance of restoration systems. In principle, the quantitative marginal analysis appears suitable for this question, particularly the assessment of the marginal integrity using morphological criteria like margin gap or perfect margin [20]. However, the SEM analysis is only able to assess the margins of restorations in a complex and time-consuming process.

Furthermore, there is evidence that interfacial adhesive defects existing immediately after composite restoration might substantially interfere with the clinical success of the restoration [19]. Against this background, a reliable in vivo evaluation of the tooth-composite bond integrity would be desirable starting immediately after filling. In the authors' opinion, optical coherence tomography (OCT) could provide this.

OCT is a non-destructive, non-invasive imaging method with spatial resolution in the micron range that is routinely used in ophthalmology for retina assessment and is now attracting more attention in dental research to image surface structures up to a depth of 2–2.5 mm [27–29]. Parallel to the clinical evaluation, OCT proved to be appropriate for the assessment of marginal gaps and internal interfacial adhesive defects as parameters characterizing the integrity of the tooth-composite interface [19,29]. Also, the clinical relevance of an assessment of the tooth-composite bond using quantitative margin analysis, in combination with a clinical study after 90 months, was shown [20]. The clinical performance was in accordance with the quality of the restoration margins based on SEM and OCT.

The aim of this randomized clinical study was to assess the 12-month performance of the universal adhesive Scotchbond™ Universal (SBU, 3 M Oral Care, St Paul, MN, USA) clinically and by OCT when placed in NCCLs in two application modes compared to a 3-step etch-and-rinse control adhesive, which is a widely accepted gold standard for dental adhesives. We tested the hypotheses that (1) SBU shows a lower cumulative failure rate (CFR) using the self-etch or selective-enamel etch application compared to a reference 3-step ER-adhesive, (2) interfacial adhesive defects demonstrated by OCT progress over time, and (3) OCT would show an increase of interfacial defects before detectable clinical deterioration or restoration loss.

2. Materials and methods

2.1. Study design

The randomized controlled clinical trial was approved by the local Ethics Committee with reference number 196-14-14042014 and was registered at German Clinical Trials Register #DRKS00011084 (http://www.drks.de/DRKS00011084). The study was double-blinded. The patients, the investigator (clinical assessment and OCT imaging) as well as the subsequent data evaluators were blinded with regard to the treatment modality of the participants. All adult participants were informed about the study and signed the informed consent. Three non-carious cervical lesions (NCCL) per patient were restored following a three-arm parallel design by one calibrated dentist of the department not further involved in this trial.

2.2. Study population

The current study included 55 patients aged between 43 and 84 years (mean 65 ± 20.5). This significantly exceeds the recommended minimum number of 30 restorations per study [30]. In a former clinical OCT study, it was shown that the performance of adhesive systems could be differentiated with a test power of 80% if a number of 18 pairs of restorations (pairwise comparison) is included [20]. All participants required three restorations of NCCL in incisors, canines or premolars. Criteria for inclusion were a positive pulp status (CO_2-snow) of the trial teeth and a physiological occlusal relationship with natural dentition. Patients were excluded if they had less than 20 teeth, any removable dentures, if contamination control during restoration was impossible to realize, and if a lesion communicated with pre-existing restorations. Moreover, periodontal probing depth above 4 mm at the trial teeth, alcohol and drug-dependence, pregnancy, habits and known allergies to materials used led to exclusion. The study focused on subjects with physiological chewing function without habits or massive abrasion facets on the study relevant teeth. Therefore, persons in treatment or wearing a hard plastic mouthguard were excluded. Both inclusion and exclusion were performed by the dentist who placed the restorations. The principal investigator enrolled the suitability of the study participants and created an group allocation of the lesions by a computer-generated list of random numbers.

2.3. Restorative procedure

The universal adhesive Scotchbond™ Universal (3 M Oral Care, St Paul, MN, USA) was applied in the conditioning modes self-etch and selective-enamel-etch. The adhesive system Optibond™FL (Kerr GmbH, Rastatt, Germany) served as the reference standard (ER mode). All lesion were restored with the nanocomposite Filtek™ Supreme XTE (3 M

Table 1
Randomized allocation of teeth and lesions.

	Number of restorations, n		
	Scotchbond Universal		Optibond FL
	Self-etch mode Filtek Supreme XTE	Selective-enamel mode Filtek Supreme XTE	Etch-and-rinse mode Filtek Supreme XTE
Location			
•maxilla	29	31	30
•mandible	26	24	25
Lesion borderline			
•enamel	–	–	–
•dentin	9	6	6
•mixed (enamel/dentin)	46	49	49
Lesion depth			
•shallow (< 1 mm deep)	10	6	5
•medium (1–2 mm deep)	42	46	47
•deep (> 2 mm deep)	3	3	3

Oral Care, Seefeld, Germany).

The sizes of the 165 lesions were assessed before restoration placement and varied from shallow (depth ≤ 1 mm) and medium (depth ≤ 2 mm) to deep (depth > 2 mm) equivalent to scores 2 to 4 on Smith and Knight's tooth wear index [31]. The characteristics of the teeth and lesions are shown in Table 1. The calibrated operator (P.S.) restored all teeth after placement of 12 NCCL restorations in vitro under the supervision of the primary investigator.

All restorations were placed according to the following protocol using magnifying glasses (2.5x). Lesions and surrounding tooth surfaces were cleaned with an oil-and fluoride-free cleaning paste before shade selection. After application of a retraction cord (Ultrapak, Ultradent Products, Inc., South Jordan, USA) to expose the cervical cavity margins, the hypermineralised dentin and the enamel margins were carefully roughened using a 15 µm diamond bur (Intensiv SA, Grancia, Switzerland). Contamination control, the adhesives and the filling material were applied according to manufacturer instructions (Table 2). Finally, the restorations were finished with fine-grained diamond burs (15 µm) and polished with rubber points (Shofu Dental GmbH, Ratingen, Germany).

2.4. Study outcomes

2.4.1. Clinical

All study teeth were photographed prior to restoration, after restoration and at each follow-up. After 14 days (baseline, t_1), 6 (t_2) and after 12 months (t_3) the principal investigator (M.H.) clinically evaluated the restorations according to the FDI criteria [32]. The aesthetic, functional and biological criteria were assessed visually with magnifying glasses (2.5x), by using explorers (Kit-EX: tip diameter 150 mm, 250 mm; Deppeler SA, Rolle, Switzerland), by interviewing, by CO_2-snow, by use of a visual analogue scale and by a periodontal probe (P15/11.5B6; Hu-Friedy Mfg. B.V., Rotterdam/Netherlands). Scoring ranges from 1 (very good), 2 (good, after correction very good), 3 (sufficient/satisfactory, minor shortcomings), 4 (unsatisfactory, but repairable), 5 (poor, replacement necessary) [32]. At baseline, isolated small marginal fractures which occurred in the first two weeks after filling were removed until marginal adaptation could be assessed with score 1. If restorations were rated clinically unacceptable in one of the criteria, they had to be excluded from further assessment and were repaired or replaced. The clinical endpoint includes the parameters fractures and retention, marginal adaptation (MA) and marginal staining (MS).

2.4.2. OCT imaging

In contrast to the clinical assessment which started at baseline, OCT assessment began immediately after filling placement (initially) and parallel to the clinical examination at 6 and 12 months. All restorations were 3D imaged using the spectral domain optical coherence tomography (SD-OCT, Telesto II; Thorlabs GmbH, Dachau, Germany). The principal investigator (M.H.) performed both the clinical assessment as well as the OCT imaging. The Telesto II used a superluminescent diode of center wavelength 1310 nm (± 120 nm). The axial/lateral resolution was verified by < 7.5 (air) µm/15 µm. Further technical specifications were: field of view and depth maximum 10 mm x 10 mm x 3.5 mm (air, pixels maximum 1000 × 500 × 1024), imaging speed 76 kHz, sensitivity ≤ 106 dB and A-scan average 1.

In the present conception, the OCT-system allowed the imaging of vestibular surfaces of anterior teeth and premolars. The stabilized imaging probe was positioned almost at a right angle, 30 to 35 mm from the restoration surface.

The image analysis was carried out as previously described [19]. The examiner (M.H.2) was trained and calibrated by an experienced OCT operator (P.S.). Out of the 350–400 B-scans per image stack, 25 equidistantly distributed images were used for the analysis (ImageJ 1.51 s, National Institute of Health, USA). The tooth-composite interfaces at enamel, dentin and root cement were separately evaluated by manual tracking the lengths of the specific interface and the existing adhesive defect, represented by a white line (signal), using ImageJ (ImageJ 1.51 s) [19]. The parameter "adhesive defect" was calculated for each B-scan in the following manner: length defect signal/length specific interface x 100, %. The weighted mean per group was calculated for enamel, dentin, and cement. Because of the minor percentage (2%) of the cement-composite interface compared to dentin, data of both interfaces were merged in the final calculations.

2.5. Statistical analysis

2.5.1. Clinic assessment

At each recall, the cumulative failure rates (CFR) were calculated as follows for each criterion and for the sum of all criteria (total score) [32]: failure percentage = [(Fprevious + Fcurrent) / (Fprevious + Ncurrent)] x 100. Fprevious represents the number of previous failures before the current recall examination, Fcurrent and Ncurrent represent the number of failures and the number of restorations seen in the current recall [30]. Kaplan-Meier survival curves were calculated.

McNemar test was used to prove the differences for all parameters between groups per time (horizontal testing) and within each group over time (vertical testing). The statistical analysis was performed using SPSS Statistics for Windows 23.0 (IBM Corp. Armonk, NY, USA) using McNemar test (two-sided, $\alpha = 0.05$).

2.5.2. Interfacial bond failure (OCT)

The weighted mean values of "adhesive defects" per group and time were calculated. In the case of restoration loss, the missing value was imputed from the highest value according to the respective group (missing data imputation). As the values were not generally normal distributed (Shapiro-Wilk-, Kolmogorov-Smirnov-test), the comparison between groups per time and within groups over time was based on non-parametric Friedman- and Wilcoxon-test (dependent samples). In a group with multiple retention loss, for all points in time before retention losses, the difference of bond failure was calculated between remaining and lost restorations using Kruskal-Wallis and Mann-Whitney-U-test as well as by regression analysis (mixed model). Due to the exploratory nature of this research, we generally refrained from correction for multiple testing and used raw p-values for assessing the group differences at the level of significance $\alpha = 0.05$.

For testing interpersonal reproducibility, ten restorations were randomly selected and assessed by two raters (dentin/cement-composite interface). For parameter "weighted mean of adhesive defect" rater

Table 2
Adhesive system, composition and procedure of application according to the manufacturer's recommendations.

Material	Composition	Self-etch mode	Selective enamel etch mode	Etch-and-rinse mode
Scotchbond Universal Etchant[a]	35% phosphoric acid		1. Apply etchant for 30 s on the enamel 2. Rinse with water for 20 s and dry with water- and oil-free air	
Scotchbond Universal[a]	10-MDP, HEMA, silane, dimethacrylate resins, VitrebondTM copolymer, filler, ethanol, water, initiators (LOT 552577)	1. Actively apply the adhesive to the cavity for 20 s. 2. Gently air-dry the adhesive for approximately 5 s for the solvent to evaporate. 3. Light cure for 10 s (> 1000 mW/cm^2)[1].		
Optibond FL[b]	FL primer: HEMA, GPDM, MMEP, water, ethanol, photoinitiator (CQ), BHT FL adhesive: Bis-GMA, HEMA, GPDM, GDMA, photoinitiator (CQ), ODMAB, fillers, barium aluminoborosilicate (LOT 4964258)			1. Apply etchant for 15 s (dentin 15 s, enamel 30 s) 2. rinse thoroughly for 15 s; air dry for 3 seconds (do not overdry) 3. Actively apply primer for 15 s; air dry for 5 s 4. Apply adhesive with light-brushing motion for 15 s; air thin for 3 s; light cure for 20 s (> 1000 mW/cm^2)[1]
Filtek Supreme XTE[a]	Bis-GMA, UDMA, TEGDMA, Bis-EMA, silanated silica, silanated zirconia, photoinitiators (LOT 552577)		1. Place restorative in increments 2. Light cure restorative in increments (body, enamel shades 2,0 mm, 20 s. dentin shades 1,5 mm, 40 s, > 1000 mW/cm^2)[1]	

10-MDP = methacryloyloxydecyl dihydrogen phosphate, Bis-GMA = bisphenol A diglycidyl methacrylate; bis-EMA(6)1 = (bisphenol A polyethylene glycol diether dimethacrylate); BHT = butylhydroxytoluene; CQ = camphorquinone; DMA = dimethacrylates, GDMA = glycerol dimethacrylate; GPDM = glycerol phosphate dimethacrylate; HEMA = 2-hydroxyethyl methacrylate, MEHQ = 4-methoxyphenol mono(2-methacryloyloxy) ethyl phthalate; ODMAB = 2-(ethylhexyl)-4-(dimethylamino)benzoate; TEGDMA = triethyleneglycol-dimethacrylate.

[1] Curing light check with curing radiometer (Demetron Model 100, Demetron Res. Corp., Danbury, CT, USA).

[a] 3 M Oral Care, Seefeld, Germany.

[b] Kerr GmbH, Rastatt, Germany.

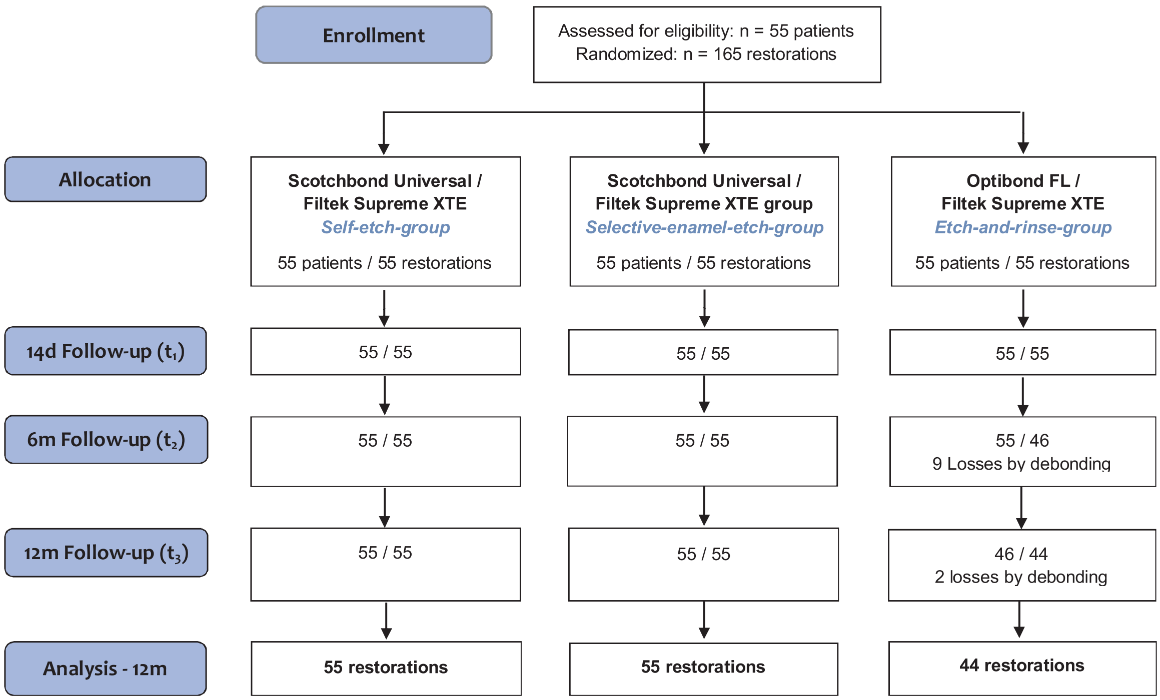

Fig. 1. CONSORT flow diagram.

2 showed a systematic deviation of - 27.4% compared to rater 1. In determining significant group differences, there was 100% agreement between the two raters (12 comparisons, Wilcoxon-test). The intrapersonal testing was done by three assessments at three randomly selected restorations each (25 B-scans), separately for the enamel- and dentin/cement-composite interface. The mean standard errors were 4.9% (enamel) or 3.9% (dentin/cement).

3. Results

3.1. Clinical assessment

After 12 months, 154 out of 165 restorations were evaluated (Fig. 1). For each recall (t_1, t_2 and t_3) the reassessment rates, aesthetic, functional and biological criteria, and CFRs from baseline to 12-month recall are summarized in Table 3. The p-values for CFR (fractures/retention score 5, as a result of retention loss), for MS, MA and corresponding to the differences between groups at each time (cross-sectional testing) and per group over the entire assessment period (longitudinal testing) are summarized in Tables 4a and 4b.

All failures resulting from a partial or total retention loss occurred in the OFL group and significantly increased after both 6 and 12 months compared to SBU-SE and SBU-SEE (Tables 3, 4a). Over time, in both SBU groups, no restoration was lost, and all restorations were scored as 1 or 2 for all parameters. In the OFL group, nine restorations were lost after six months, increased to 11 restoration losses after 12 months, resulting in an overall CFR of 20.0% (Tables 3, 4a). Cumulative survival rates were calculated (Fig. 2). After 6 and 12 months, the Kaplan-Meier curves significantly differ between each of the two SBU groups and the OFL group.

After six months there were no significant group differences for marginal staining and marginal adaptation (Table 4a). After 12 months MS significantly increased, and MA decreased in the SBU-SE group compared to SBU-SEE. In the OFL group, MS score 2 appeared more often compared to SBU-SEE, which was not the case compared to SBU-SE. MA showed no significant differences between the OFL and the SBU groups.

The restorations of all groups showed progressive marginal deterioration up to score 2, which corresponds to clinical acceptance. 23.6% of the restorations in the SBU-SE group showed a significant increased MS after 12 months compared to baseline, 43.6% showed a significant decreased MA. In the SBU-SEE group, the number of restorations with an MS rating of score 2 remained stable at a low level of 1.8%, while the number of restorations with MA score 2 increased to 14.5% (Table 4a).

Table 3
Clinical quality of the restorations from baseline to 12 months.

	SBU-SE			SBU-SEE			OFL		
	BL / 6 mo / 12 mo			BL	6 mo	12 mo	BL	6 mo	12 mo
Patients, restorations (n)	55			55	55	55	55	55	46
Reassessment rate (%)	100			100	100	100	100	100	100
Acceptable, %	100	100	100	100	100	100	100	100	100
Non acceptable, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Acceptable, % (fractures/retention)	100	100	100	100	100	100	100	83.6	80.0
Non acceptable, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	16.4[3]	20.0[3]
Acceptable, %	100	100	100	100	100	100	100	100	100
Non acceptable, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Acceptable, %	100	100	100	100	100	100	100	83.6	80.0
Non acceptable, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	16.4[3]	20.0[3]

[1]cumulative over time, [2]cumulative all criteria, [3]exclusively caused by retention loss.

Table 4a
Marginal staining, marginal adaptation (score 2) and fractures/retention (score 5). Group differences (p_i) at 6 and 12 months.

		Marginal staining score 2		Marginal adaptation score 2		Fractures/retention score 5[2]	
		6 months	12 months	6 months	12 months	6 months	12 months
SBU-SE vs. SBU-SEE	%	14.5 / 3.6	23.6 / 1.8	21.8 / 5.5	43.6 / 14.5	0.0 / 0.0	0.0 / 0.0
	p_i	0.109	**0.002**	0.125	**0.001**	n. c.	n. c.
SBU-SE vs. OFL	%	14.5 / 17.4	23.6 / 22.7	21.8 / 17.4	43.6 / 29.5	0.0 / 16.4	0.0 / 20.0
	p_i	0.791	1.000	1.000	0.664	**0.004**	**0.001**
SBU-SEE vs. OFL	%	3.6 / 17.4	1.8 / 22.7	5.5 / 17.4	14.5 / 29.5	0.0 / 16.4	0.0 / 20.0
	p_i	0.070[1]	**0.004**	0.125	0.146	**0.004**	**0.001**

Bold: significant; [1]trend; [2]retention loss, representing the cumulative failure rate; n. c.: not calculable (McNemar, 2-sided).

In the OFL group, the MS score 2 increased significantly over time to 22.7% and the MA score 2–29.5 % (Tables 4a and 4b).

3.2. OCT assessment

In Table 5 and Figs. 4, 5 the results of the OCT evaluation are presented. In all groups adhesive defects were verifiable at the enamel- and dentin/cement-composite interfaces, with group differences at each time (cross-sectional testing) and per group over the entire assessment period (longitudinal testing). The dentin/cement-composite interface predominated with a length share of 85.2% compared to enamel with 14.8%.

Enamel-composite interface (Fig. 3, Table 6)

At each time, SBU-SE showed significantly more interfacial defects compared to the other groups. OFL revealed a significantly higher level of interfacial adhesive defects than SBU-SEE after six months. After 12 months, this difference has remained as a trend. Over time, defects increased in the SBU-SE group (t_0 - t_2/t_3, t_2 - t_3), in group SBU-SEE (t_0 - t_3, t_2 - t_3) and with OFL (t_0 – t_2/t_3). Generally, the broadest distribution of the data could be observed in the SBU-SE group. There is a strong reproducibility in the group differences beginning with t_0 up to t_3.

*Dentin/*cement-*composite interface (*Fig. 4, Table 6)

Significantly less interfacial defects were observed in SBU-SEE compared to SBU-SE after 6 and 12 months. OFL showed more defects than the other groups immediately after filling placement and at 6 and 12 months ($p < 0.001$). Over time more defects appeared at t_3 compared to t_2 in all groups. SBU-SE and OFL showed increased defects after 12 months compared to t_0. Whereas OFL revealed more adhesive defects from t_0 to t_2/t_3, SBU-SEE showed fewer defects at t_2 compared to t_0. After 6 and 12 months, the broadest distribution of the data could be observed in the OFL group. Again, there is a strong reproducibility in the group differences beginning with t_0 up to t_3.

Based on these observations the following key results can be identified: SBU-SEE showed mostly less adhesive defects than SBU-SE regardless of the tooth substrate. Starting with six months, OFL revealed more defects in enamel compared to SBU-SEE and was inferior to both SBU groups at the dentin interface. In general, a progression of interfacial adhesive defects could be observed in each group over time, and the group differences for bond failures were highly reliable over time.

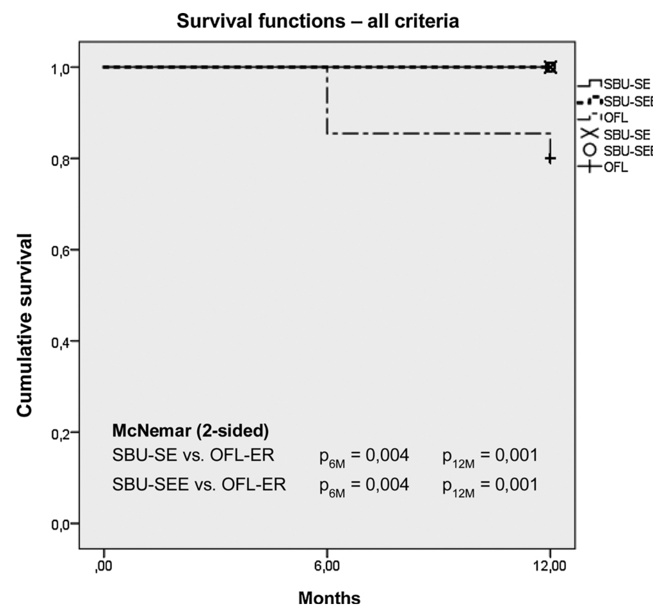

Fig. 2. Cumulative survival in the system comparison from baseline to 12 months.
(SBU – Scotchbond Universal, OFL – Optibond FL; SE – self-etch approach, SEE – selective enamel etch approach)

3.3. Clinic and OCT

The higher amount of adhesive defects at dentin interfaces (OCT) initially found in the OFL group was conforming to the higher clinical retention loss compared to SBU in both conditioning modes. Retention losses in the OFL group were clinically observed with a delay of 6 months after OCT detection of adhesive defects above average. After 12 months, this was confirmed with increased interfacial adhesive defects compared to SBU and further OFL retention losses. The progress of retention loss in this group was conforming to the steeper incline of the median compared to SBU. The higher amount of adhesive defects at six months in the SBU-SE group compared to SBU-SEE showed no clinical correlate (Fig. 4, Table 6). Starting with six months, at the enamel-composite interface, more defects were observed in the OFL group than in the SBU-SEE group, which corresponded to the clinical outcome. The

Table 4b
Changes in marginal staining, marginal adaptation (score 2) and fractures/retention (score 5) per group from baseline up to 12 months (p_i).

	Marginal staining score 2			Marginal adaptation score 2			Fractures/retention score 5[2]		
	BL vs. 6 mo	6 mo vs. 12 mo	BL vs. 12 mo	BL vs. 6 mo	6 mo vs. 12 mo	BL vs.12 mo	BL vs. 6 mo	6 mo vs. 12 mo	BL vs.12 mo
SBU-SE	0.289	0.267	**0. 022**	**< 0.001**	**< 0.023**	**< 0.001**	n. c.	n. c.	n. c.
SBU-SEE	1.000	1.000	1.000	0.250	0.180	**0.008**	n. c.	n. c.	n. c.
OFL	0.219	0.388	**0.001**	**0.008**	0.065[1]	**< 0.001**	**0.004**	0.500	**0.001**

Bold: significant; [1]trend; [2]retention loss, representing the cumulative failure rate; n. c.: not calculable (McNemar, 2-sided).

Table 5
OCT assessment regarding to marginal staining (MS) and marginal adaptation (MA). Differences of adhesive defects score 2 minus score 1 (Diff. AD) at the tooth-composite interface after 6 and 12 months and comparison of adhesive defects between restorations of score 2 vs. score 1 (p_{AD}).

	Marginal staining score 2 vs. score 1					Marginal adaptation score 2 vs. score 1				
	OCT					OCT				
		Enamel		Dentin/cement			Enamel		Dentin/cement	
		6 M	12 M	6 M	12 M		6 M	12 M	6 M	12 M
SBU- SE	Diff. AD[1]	−5.36	+ 21.65	+ 13.37	+ 1.48	Diff. AD[1]	+ 10.26	+ 24.84	−1.28	+ 0.39
	p_{AD}	0.616	0.097	**0.005**	0.973	p_{AD}	0.988	**0.003**	0.909	0.397
SBU- SEE	Diff. AD[1]	+ 9.05	- [2]	+ 13.07	−11.25	Diff. AD[1]	+ 11.59	+ 7.17	+ 8.57	−5.18
	p_{AD}	0.075	- [2]	0.065	0.145	p_{AD}	**0.001**	0.308	0.074	0.308
OFL	Diff. AD[1]	−3.16	−3.21	+ 0.59	−8.62	Diff. AD[1]	+ 0.40	−3.87	+ 4.87	−11.12
	p_{AD}	0.976	0.257	0.447	0.527	p_{AD}	0.265	0.075	0.967	0.427

Bold: significant; [1]differences of weighted mean values of adhesive defect (AD) for score 2 minus score 1; [2]score 2 no enamel interface .

initially increased amount of adhesive defects in the SBU-SE group compared to SBU-SEE and OFL was not identifiable clinically (Fig. 3, Table 6).

As retention loss was only observed for OFL, the relation to advancing interfacial adhesive defects could only be described for these restorations. At the dentin/cement-composite interface with 85.2% of total length, restorations that were lost after six months initially showed 27.3% interfacial adhesive defects compared to 19.6% on the remaining restorations ($p = 0.073$, trend). At restorations that were lost after 12 months, initially 25.2% more adhesive defects (not significant) were observed when compared to the restorations still in clinical use (19.8%, $p = 0.132$). After six months this difference became significant (77.1% vs. 32.6%, $p = 0.002$) when only the fillings were considered that have been lost after 12 months.

While OCT cannot detect MS if it is not associated with marginal gap formation, MA is partially associated with marginal gap formation. The group differences (significant or trend) in both clinical parameters MS and MA in Tables 4a (in bold) were in total agreement with the differences of the adhesive defects between the three groups, both at the enamel and dentin/cement. Again, these differences appeared 6–12 months earlier than clinically (Figs. 4, 5; Table 6). In principle, this also applies to the non-significant but clinically distinct differences. Considering restorations with clinical scores 1 vs. 2 for MS and MA, after 12 months there was no relation with interfacial gap formation (Table 5).

4. Discussion

The clinical assessment of adhesive systems on NCCLs is state of the art. Additionally, in the present study, the adhesive interface of each restoration was imaged by optical coherence tomography (OCT) at each recall in addition to the clinical findings. This analysis provides a view on the presence and development of the interfacial adhesive defects starting immediately with the filling placement that can help to explain clinical outcomes, especially when considering the individual hard

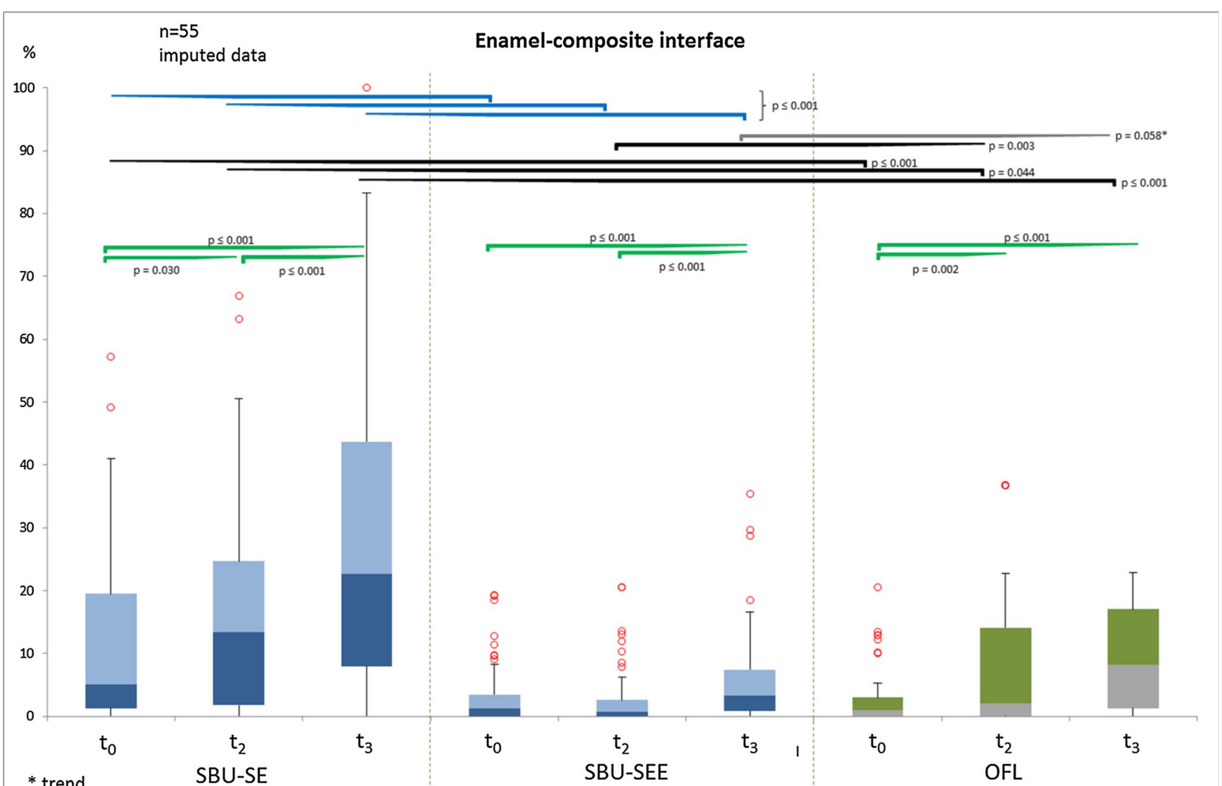

Fig. 3. Interfacial adhesive defects (%) at enamel-composite interface, immediately after filling placement (t_0), after 6 (t_2) and 12 months (t_3).

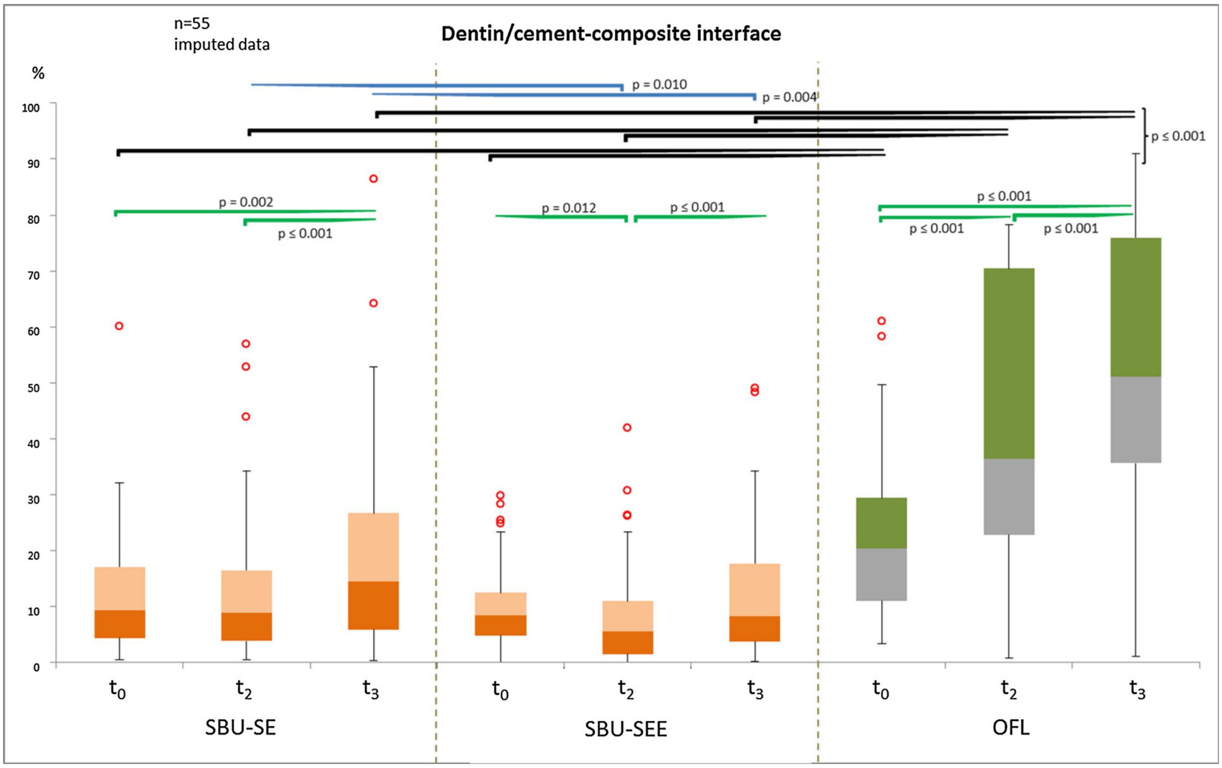

Fig. 4. Interfacial adhesive defects (%) at dentin/cement-composite interface, immediately after filling placement (t_0), after 6 (t_2) and 12 months (t_3).

tooth substances. For the first time to our knowledge, we were able to show that before restoration deterioration became clinically detectable, adhesive defects were already visible with OCT.

After 12 months Scotchbond Universal either used in the SE or SEE mode showed a higher clinical retention rate compared to the 3-step reference system Optibond FL, which means that the first alternative hypothesis can be accepted. This result is supported by significantly more extended interfacial defects to dentin/cement (OCT) compared to SBU independent of its application mode. This effect was seen immediately after restoration and remained robust up for the whole observation period. Simultaneously, faster progress of adhesive defects to dentin was observed with OFL. In the SBU groups, no clinical differences were found, but in the group SBU-SE, more defects were found with OCT, which started for enamel with t_0 and at dentin/cement with t_2. This phenomenon can be explained by the fact that clinical restorations with clinically acceptable margins often show internal debonding (Fig. 5).

Secondly, progression of interfacial defects could be confirmed in

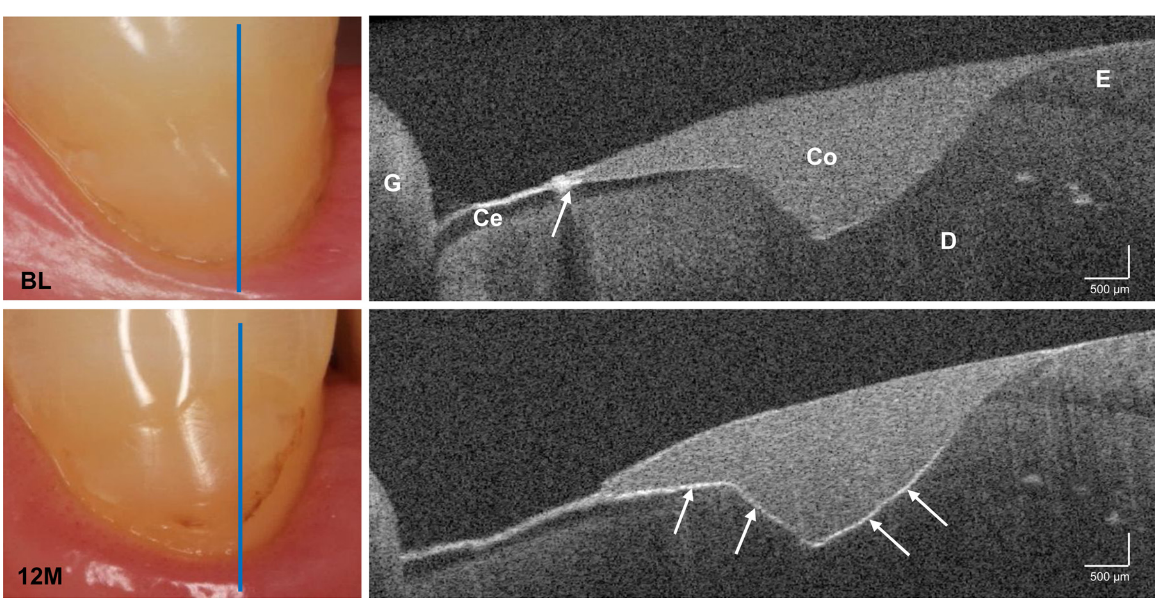

Fig. 5. Example for clinical and OCT imaging at baseline (BL) and at 12-month recall (patient 33, tooth 33, Optibond FL, enamel/dentin/cement borderline); region of OCT B-scan (vertical blue line); BL: Clinic - marginal adaptation and staining score 1 each, OCT - initial interfacial gap at dentin/cement (white arrow). 12M: Clinic - marginal adaptation and staining score 2 each, OCT - extensive interfacial gap (white arrows). Co – composite, E – enamel, D – dentin, Ce – cement, G – gingiva (The reader is referred to the web version of this article for coloured clinical images).

Table 6
Weighted mean values and standard deviation for "adhesive defect" up to 12 months.

	Enamel			Dentin/cement		
	Initial	6 months	12 moths	Initial	6 months	12 months
SBU-SE	$14.0^{a,c,i,j}$ ± 14.6	$19.2^{a,b,k,l}$ ± 17.4	$28.2^{b,c,m,n}$ ± 23.2	$11.5^{p,z}$ ± 10.8	$12.6^{q,w,B}$ ± 13.3	$19.0^{p,q,x,D}$ ± 17.5
SBU-SEE	$3.7^{d,i}$ ± 5.1	$4.3^{e,k,o}$ ± 4.9	$7.1^{d,e,m}$ ± 7.7	$10.4^{r,y}$ ± 7.2	$9.1^{r,s,w,A}$ ± 8.8	$12.5^{s,x,C}$ ± 11.1
OFL	$3.4^{f,g,j}$ ± 4.4	$7.7^{f,h,l,o}$ ± 13.8	$9.5^{g,h,n}$ ± 8.6	$20.9^{t,v,y,z}$ ± 14.0	$41.7^{t,u,A,B}$ ± 24.7	$52.8^{u,v,C,D}$ ± 26.2

Vertical and horizontal comparison: same raised letters indicate significant group differences ($p_i < 0.05$).

the OCT images. In the groups SBU-SE and OFL at the enamel, interfacial defects progress over the entire 12 months, in the group SBU-SEE this effect began with the 6-month follow-up. At dentin/cement, in the OFL group, interfacial defects progressed over the whole study period, whereas in both SBU-groups initiation was seen at the 6-month follow-up.

Additionally, the third hypothesis can be accepted. OCT showed an increase of interfacial defects before detectable clinical deterioration or retention loss. However, not all increasing defects led to restoration loss within the 12-month observation period but even initially, restorations without interfacial adhesive defects were rarely seen. Defect formation mostly started already with restoration placement and increased at different speeds up to 12 months. An increase in defects was observed, especially at enamel in the SBU-SE group and at dentin/cement in the OFL group. On enamel, the increased values for adhesive defects in the SBU-SE and OFL group over the entire period were facing the increased clinical values for marginal adaptation and marginal staining. This came into effect with time delays: after 12 months for the cross-sectional comparison and after six months for longitudinal viewing. With OCT, a difference between SBU and OFL was observed at the dentin-composite interface immediately after filling application, thus earlier and with a shift of six months compared to the clinic.

The adhesive system under study Scotchbond Universal was proved in several prospective clinical trials on NCCLs. Irrespective of the bonding strategy applied, its clinical behavior was found to be acceptable at six months [33] as well as after 18 [34] and 36 months [35]. In a further 24 months in-vivo study, SBU was evaluated on NCCLs after preparation of a 0.5 mm bevel on the occlusal margin [36]. The etch-and-rinse system Scotchbond Multi-purpose was used as a reference. A trend was shown towards increased restoration failure of the reference material compared to SBU both in the etch-and-rinse and self-etch mode ($p = 0.06$). This already suggested that SBU might be superior to classical etch-and-rinse systems.

Optibond FL was used as a control because this widely used etch-and-rinse adhesive has been a reference standard for adhesive studies for years [37,38]. In line with other studies, it can also be considered as a reference for estimating clinical failure [37–40]. Further advantageous aspects of this selection are that etching with phosphoric acid still establishes the best and most stable adhesion to the enamel and that the technique sensitivity of a classical and proven etch-and-rinse adhesive could be evaluated compared to the universal adhesive. Against this background, it was surprising that this established control adhesive performed weaker compared to the test groups and to previous studies. In clinical studies on NCCL, the failure rates of Optibond FL groups varied from 0.0% [39] up to acceptable 4% after one year [40] and 9% after five [41]. In contrast, 20% of the OFL restorations were lost after 12 months in the present study. Currently, this apparent and unexpected discrepancy from previous studies cannot be explained and should be interpreted with caution. At this time, the authors assume that the formulation of Optibond FL has not changed compared to previous studies, as no relevant information is publicly available. It should also be noted that the adhesive was used in accordance with the manufacturer's recommendations and that the dentist had many years of experience with Optibond FL as the standard adhesive and was extensively calibrated prior to this study. For Optibond FL, a sufficient micro-retention pattern is decisive for adhesion to the tooth structures. We suspect that the dentin tubules and collagen network may not have been sufficiently exposed and that the adhesive could not penetrate sufficiently into the dentin surface. The steps that can be associated with this are mechanical conditioning and surface removal with the fine-grained diamonds and the duration of phosphoric acid application (15 s). One could speculate that a slightly more aggressive pretreatment of the dentin surface on the sclerotic dentin of the NCCLs could be more advantageous with Optibond FL.

Furthermore, the clinical results were supported by the significantly increased interfacial adhesive defects in the OCT images. In a recent in vitro study, OFL was not found to be statistically different after 12 months of water storage when compared to SBU regardless of the application mode [42]. One explanation of why the present results differ from in vitro bond strength studies on Optibond FL is based on the difference of the bonding substrate. Mostly, the dentin was freshly prepared prior to adhesive application [43,44], whereas clinical studies often use NCCLs. It has to be taken into account that about 90% of the tooth tissue in NCCLs is sclerotic dentin characterized by partial or complete obliteration of the dentinal tubules and by the presence of sclerotic casts [45]. This hypermineralized surface layer affects the conditioning and hinders the monomer penetration and the resin hybridization process of the underlying dentin, making resin hybridization difficult [46]. For SEA the micro-retentive bonding to this substrate becomes very unpredictable and challenging [47]. µTBS values were significantly lower than to non-sclerotic or prepared dentin, and thermocycling had a significantly negative effect on the long-term durability of the resin-dentin bond [48]. Without removal of the hypermineralized surface layer of dentin or the application of strong acids, the use of SEA on sclerotic dentin should not lead to a sufficient bond [49].

In a meta-analysis, it was shown, that tooth composite restorations placed on roughened dentin resulted in a higher retention rate compared to unprepared dentin [50]. In the present study, the sclerotic dentin was also slightly roughened with finishing diamond burs before the application of each adhesive. However, mechanical conditioning cannot be standardized, which could potentially be a source of bias in comparison between groups. As mentioned above, one could hypothesize that the significant restoration loss in the reference group might be due to insufficient mechanical and chemical conditioning of the sclerotic dentin. In contrast, it was proven for universal adhesives that dentin roughening before application did not affect the clinical behavior of composite restorations placed in NCCLs irrespective of the acid conditioning mode used [51], which could be an indication of lower susceptibility of universal adhesives to conditioning differences.

SBU contains 10-MDP (methacryloyloxydecyl dihydrogen phosphate) as a functional monomer that has been shown to effectively form ionic bonds to hydroxyapatite [10]. Higher and more stable µTBS with reduced nanoleakage at the interfaces were demonstrated after six months of water storage [52]. A recent in vitro-study on SBU also supported the concept that a stable chemical bonding by 10-MDP to calcium (10-MDP-Ca nano-layering) is advantageous for the durability of the adhesive-dentin bond [53]. SBU in contrast to OFL seems to be more predestinated to form a stable cumulative chemical plus micromechanical bond to sclerotic dentin. The lower median increase of adhesive defects to the dentin also suggests that the cumulative chemical and micromechanical bond is more stable over time compared to the pure mechanical bond with OFL. This may explain the higher distribution of values for adhesive defects in the OFL group, which could be interpreted as a sign of higher technical sensitivity of the etch-and-rinse adhesive.

Basically, it is known, that additional H_3PO_4-gel conditioning on the prepared dentin before application of a SEA reduces the bond strength when compared to the SE approach [4]. One might speculate that overetching in SEE conditioning could negatively impact the bonding performance of universal adhesives, which in principle represent further developments of the SEAs. At first glance, the opposite results were observed in this study. Starting from 6 months, adhesive defects increased at sclerotic dentin/cement in group SBU-SE compared to SBU-SEE. A possible explanation could be that in self-etch application, less micromechanical bonding was achieved compared to in the SEE group, where unintentional acid conditioning of the dentin has resulted in a cumulation of chemical and micromechanical bonding. Therefore, it could be assumed that phosphoric acid etching of dentin might be advantageous in NCCLs if universal adhesives are used [19].

The clinical benefit of selective enamel etching before application of a SE adhesive system has been widely described. Therefore, the SBU-SEE mode was chosen as a modification of the self-etch approach since it represents the clinically more relevant application compared to the SBU-ER mode for a further developed self-etch adhesive. While the clinical retention is not significantly affected by this, an additional enamel etching [1] might improve marginal adaptation and minimize marginal staining of cervical composite restorations [3,5]. Both could also be confirmed in the present results clinically as well as by OCT with significant reduced adhesive defects after enamel etching, already visible after restoration placement. Before the application of the mild SBU (pH = 2.7), selective enamel etching is an advisable strategy to improve the bond strength to enamel [11,42,54]. In addition, a four-arm study has already been initiated which, due to the difficulty of finding volunteers with 4 equivalent lesions, has a reduced number of subjects per group (n = 22). In this study, Scotchbond Universal was additionally used in etch-and-rinse mode and the 6-month results are currently available. [19].

Another possibility to optimize the conditioning could be to prolong the application time of universal adhesives if used in SE mode. Regarding enamel, a prolonged use up to 40 s was advised to reduce the marginal deterioration [55], which could be a viable alternative to increase the etching pattern, and resin-enamel bond strength and to improve the marginal adaptation. Whether this approach also has a positive effect on dentin adhesion in NCCLs remains currently unclear.

The use of OCT in this clinical trial has made it possible to longitudinally visualize early signs of adhesive failure at the entire interface between tooth and restoration. Significant group differences detected with OCT, which are not verifiable in the clinic, show that the tomographic evaluation of composite restorations is more sensitive and more valid than the clinical evaluation. Although restorations statistically showed more interfacial adhesive defects prior to its loss, it is not possible to predict the loss for a single restoration. However, interfacial defects could be an important predictor of the clinical success of a restoration system. This was already supposed after six months of observation [19] and could be confirmed in this study. The application of OCT could thus enable shorter clinical trials and/or lower patient numbers in the future [19].Further statements are to be expected after the planned total observation time of this investigation after 36 months.

5. Conclusions

- After 12 months in vivo, clinical evaluation and OCT imaging revealed higher interfacial integrity for Scotchbond Universal in self-etch and selective-enamel-etch mode compared to the etch-and-rinse gold standard.
- Selective enamel etching is recommended prior to application of Scotchbond Universal to enhance the clinical performance.
- The OCT parameter interfacial adhesive defect seems to be a valuable predictor for evaluation of adhesive restoration systems.

Author's contributions

R. Haak contributed to conception, design, data analysis and interpretation, wrote and revised the manuscript. M. Hähnel contributed to data acquisition, analysis and interpretation, wrote the manuscript. M. Häfer and H. Schneider contributed to conception, design, data acquisition, analysis and interpretation, wrote the manuscript. K.-J. Park critically revised the manuscript. D. Ziebolz contributed to design and critically revised the manuscript. M. Rosolowski supported statistical analysis. All authors gave final approval of the work.

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The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Declaration of Competing Interest

The authors do not have any financial interest in the companies whose materials are included in this article and certify that all financial and material support for this research and work are acknowledged in the manuscript. 3 M Deutschland GmbH was consulted in defining the aim of the study but had no role in design and conduct of the study as well as in analysis and interpretation of the data.

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