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Is Optical Coherence Tomography a Potential Tool to Evaluate Marginal Adaptation of Class III/IV Composite Restorations *In Vivo*?

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Clinical Relevance

Both optical coherence tomography and scanning electron microscopy revealed partially poor marginal qualities in clinically successful composite restorations. Clinical performance cannot be successfully predicted by the extent of perfect margins.

SUMMARY

Objective: Margin analysis of Class III and IV composite restorations *in vitro* and *in vivo* occurred by scanning electron microscopy (SEM) and optical coherence tomography (OCT). The results were compared and related to clinical evaluation.

Methods and Materials: Eight Class III composite restorations were imaged *in vitro* using OCT and SEM. The margins were analyzed quantitatively. OCT signals were verified by assignment to the criteria perfect margin, gap, and positive/negative ledge. *In vivo* quantitative margin analysis of Class III/IV composite restorations made of the micro-hybrid composite Venus combined with the self-etch adhesive iBond Gluma inside (1-SE) or etch-and-rinse adhesive Gluma Comfort Bond (2-ER) (all Heraeus Kulzer) was carried out using OCT and SEM after 90 months of clinical function. The results were compared with clinical evaluation (US Public Health Service criteria; marginal integrity, marginal discoloration).

Results: *In vitro*, the correlation between OCT and SEM was high for all four margin criteria (Kendall tau b [τ_b] correlation: 0.64-0.92, $p_i \leq 0.026$), with no significant differences be-

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tween OCT and SEM ($p_i \geq 0.63$). *In vivo*, a moderate correlation was observed (τ_b: 0.38-0.45, $p_i < 0.016$). Clinically, the cumulative failure rate in the criterion marginal integrity was higher for the 1-SE group (baseline 90 M, $p = 0.011$). Similarly, OCT and SEM detected higher percentages of the criterion gap in the 1-SE group (p: 0.027/0.002), in contrast to perfect margin. Both, gap and perfect margin ranged widely between 0.0% and 88.7% (OCT) and between 0.0% and 89.0% (SEM).

Conclusion: Despite the positive selection bias after 90 months with only a few patients left, quantitative margin analysis allows for differentiation between the two adhesives at this specific date. OCT in particular offers the possibility to evaluate marginal integrity directly *in vivo*.

INTRODUCTION

The integrity of the tooth-composite interface is regarded as the most important factor determining the clinical success of composite restorations.[1–3] Thus, marginal integrity is among the most important elements when evaluating composite restorations and adhesive systems in laboratory testing and clinical trials as well as in daily clinical practice.[4–6] In order to avoid complications such as postoperative sensitivity, marginal discoloration, caries adjacent to the restoration margin, and pulpal disease, restorations should be placed with excellent marginal qualities.[3]

Numerous methods are available for laboratory testing of adhesive systems. These include bond strength testing,[3] morphologic assessments of the tooth-composite interface,[7] evaluation of marginal integrity,[4–6,8–10] evaluation of internal tooth-restoration adaptation,[4,9–11] dye penetration,[7,12] and bacterial leakage or three-dimensional (3D) assessment of restorations by micro-computed tomography.[3,13,14] Apart from marginal adaptation, these techniques are not applicable to *in vivo* conditions because of their destructive and/or invasive character. [9,11,15–17] Evaluation of marginal integrity *in vivo* can only be carried out by a few methods, such as visual examination and probing according to US Public Health Service (USPHS) criteria[18] and quantitative margin analysis using replica techniques.[6,19] Some clinical trials have combined these two methods with the detailed recording of gap formation offered by scanning electron microscopy (SEM) analysis to supplement the rather approximate clinical estimation.[4,20]

SEM analysis is widely accepted as the gold standard,[10,17,21] and is applied in numerous *in vitro* and *in vivo* studies even though it is a very technique-sensitive and time-consuming method.[9,10,20,22–24] This includes complex intermediate and partially destructive preparation steps such as producing impressions and replicas, mounting the replicas, as well as gold coating and imaging procedures under vacuum using high-energy electrons.

Besides the need for long-term clinical trials,[6,25,26] further methods for nondestructively evaluating the integrity of restoration margins and the tooth-composite interface must first be developed *in vitro*.[5,14] In addition, *in vivo* evaluation represents a particular challenge.

Optical coherence tomography (OCT) allows for depth resolved visualization of surface structures and could therefore make an important contribution to assessing restoration margins. The basic principle of the digital imaging method is that light is backscattered from areas that include structures of different refractive index, such as tooth-composite interfaces or gaps. OCT has been an established diagnostic tool in ophthalmology for years and has been implemented in other fields of medicine, such as dermatology and cardiology, over the past decade, with a first experimental application in dentistry in 1998.[27-29] OCT is based on the principle of low-coherence interferometry, which has already been described in various publications.[15,16,30–33] The method provides two-dimensional (2D) cross-sectional and 3D volumetric images, is nondestructive and noninvasive, and allows real-time imaging with high spatial resolution in the micron range. *In vitro* studies have already demonstrated the ability of OCT to provide usable images of composite restorations.[5,13,15,34,35] Structures can be imaged up to a depth of 2 to 2.5 mm due to the individual refractive indices of dental hard tissues and restoration materials. The characteristics and ability of this technique to generate high-resolution images with a handheld device make the OCT system a potential tool for assessing marginal qualities of composite restorations *in vivo*. That sparked our interest to evaluate restorations in service for a longer time period as part of a clinical study.

With regard to high esthetic demands, the reliability of the micro-hybrid composite Venus in the anterior region was evaluated in a four-year prospective clinical trial.[11] Class III/IV lesions were restored using the composite in combination with the one-step self-etch adhesive iBond Gluma inside or with the two-step etch-and-rinse adhesive Gluma Comfort Bond. After 48 months, the one-step self-etch adhesive showed inferior clinical results (USPHS criteria), since decreased marginal integrity and an increased number of dark marginal color lines (undermining marginal discoloration) were found.[11] It remained unclear as to whether the cumulative failure rates of both groups (one-step self-etch adhesive and two-step etch-and-rinse adhesive) converged or diverged. The restorations were to be reassessed after 90 months of clinical function, both clinically and using quantitative margin analysis.

The aims of the present study were as follows:

1. *In vitro* evaluation of marginal qualities of Class III and IV composite restorations using OCT compared with the established replica technique (SEM).
2. *In vivo* evaluation of Class III and IV composite restorations after 90 months of clinical function in terms of clinical failure rates and quantitative margin criteria (OCT, SEM).
   The difference between the adhesive systems was to be determined. The hypothesis was that increased numbers of clinical failures and margin gaps would occur in the group using the one-step self-etch adhesive compared with the restorations using the two-step etch-and-rinse adhesive.
3. Exploratory evaluation of the relationship between clinical outcome parameters and quantitative margin analysis.

METHODS AND MATERIALS

In Vitro

As the first part of this study, an *in vitro* investigation was performed to validate the OCT. Four unrestored, caries-free human anterior teeth extracted for periodontal reasons were included with patients' approval (local Ethics Committee protocol no. 299-10-04102010). The specimens were cleaned and stored in distilled water. Each tooth received two Class III cavity preparations (mesiobuccal, distobuccal, size $3 \times 3 \times 2$ mm each) using diamond burs (107 μm, 46 μm; Busch & Co GmbH & Co KG, Engelskirchen, Germany) under sufficient water cooling. Cavity margins were located in enamel and not beveled.

The prepared cavities (n=8) were randomly divided into two groups. The purpose was to provoke different marginal qualities, for example, marginal gaps, composite overhangs, underfilled, and perfect margins in order to evaluate them using SEM and OCT.

The first four cavities were treated with the one-step self-etch adhesive Adper Prompt L-Pop (3M Deutschland GmbH, Seefeld, Germany) according to the manufacturer's instructions, while the other four cavities were etched with 35% phosphoric acid etching gel (Vococid, Voco GmbH, Cuxhaven, Germany) to remove any smear layer. However, no adhesive was applied to encourage marginal and interfacial gaps. The nano-hybrid composite Tetric EvoCeram (Ivoclar Vivadent AG, Schaan, Liechtenstein) was used as the restoration material. Each cavity was restored using the incremental layering technique (layer thickness up to 2 mm). Each layer was light cured for 20 seconds (Bluephase, Ivoclar Vivadent AG; 1200 mW/cm^2, output determined with curing radiometer Demetron Model 100, Danbury, CT, USA). The restorations were carefully finished (finishing burs 46 μm/26 μm; Busch & Co GmbH & Co KG) and polished (CompoMaster silicone points; Shofu Dental GmbH, Ratingen, Germany) to preserve different marginal qualities.

To identify identical parts of the margins in both the SEM and OCT images, regions of interest (ROI) were defined by drilled holes along the restoration margins. Markings of a flowable composite (GrandioSO Flow, Voco GmbH) served as an additional orientation help (Figure 1). Subsequently, silicone impressions of the restored teeth were taken (polyvinylsiloxane Coltene President putty soft, President plus light body; Coltene/Whaledent AG, Altstätten, Switzerland) for fabricating epoxy replicas (Stycast 1266; Emerson & Cuming, Waterloo, Belgium). Replicas were mounted, sputter-coated with gold (20 nm, Edwards Sputter Coater S 150B; Edwards Ltd, Irvine, United Kingdom), blinded, and imaged using SEM in topography contrast at 250× magnification (20 kV, CamScan CS24; Cambridge-Scanning Com. Ltd, Cambridge, United Kingdom). The length of the criteria—perfect margin (PM), gap (G) positive ledge (PL), and negative ledge (NL) (Table 1) —was determined and expressed as a percentage of the total length of the examined restoration margin.

In addition, the restored teeth were imaged nondestructively with spectral-domain OCT (SD-OCT, 3D-volume scans, TELESTO SP 5, 1310 nm; Thorlabs GmbH, Dachau, Germany).

With this technique, the light of the SD-OCT broadband source was separated into a sample and a reference arm (Michelson interferometer configuration). The light of the sample arm was backscattered at phase boundaries between zones of different refractive index and was brought to interference

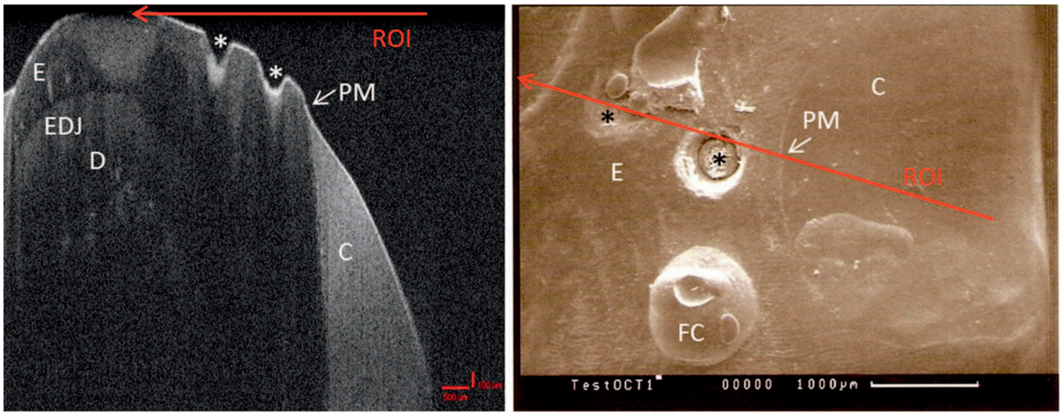

Figure 1. *Verification of OCT with SEM. Within the ROI, the OCT cross-sectional image and the SEM image can be compared. The holes (asterisks) define the ROI, the marking of flowable composite (FC) supports the orientation. C, composite restoration; D, dentin; E, enamel; EDJ, enamel-dentin junction; PM, perfect margin.*

with the unaffected light of the reference arm. The frequency of the resulting interferogram was measured, which was directly related to the depth of the scattering structure within the object. After Fourier Transform, a depth profile of the backscattering was generated (A scan). The point-by-point scanning of the OCT beam across the sample produced 2D cross-sectional images (B scans), and the line-by-line scanning produced a series of 2D images from which 3D image stacks were created.

The process of OCT imaging was as follows: the scanning probe fixed to create the right angle of light incidence, the sample tooth mounted, ROI set, focused on specimen, the surface dried using a cotton pellet to leave the surface moist with no visible water droplets (controlled hydrated condition), 2D cross-sectional imaging of ROI performed, and 3D image stack created (center wavelength 1310±107 nm, sensitivity ≤106 dB, axial/lateral resolution <7.5 [air]/15 μm, field of view maximum 9 mm × 9 mm × 2.58 mm [pixel size 700 × 700 × 512], imaging speed 91 kHz, A-scan average 1).

The OCT signals within the predefined ROI were verified by comparison with the corresponding SEM images (Figure 1). Thereafter, the OCT margin analysis was performed.

For each criterion, the number of B-scans was counted and expressed as a percentage of all available images depicting the examined restoration margin (Table 1). SEM and OCT examinations were performed by a single blinded and calibrated operator (A. S. S.-O.).

In Vivo

Materials, Selection Criteria, and Clinical Procedure—All test subjects included in the present study were participants in a long-term prospective clinical trial that started in October 2003 (local Ethics Committee, protocol no. 087/2003).[11] This trial compared the clinical performance of the one-step self-etch adhesive iBond Gluma inside (1-SE) with the two-step etch-and-rinse adhesive Gluma Comfort Bond (2-ER) in combination with the micro-hybrid composite Venus (all products by Heraeus Kulzer GmbH, Hanau, Germany).[11] At baseline (BL) of the

Table 1: *Margin Analysis Criteria (Optical Coherence Tomography and Scanning Electron Microscopy)*

Evaluation Criteria	Characterization
Perfect margin (PM)	No interruption of continuity, margin barely visible, no irregularities, no gaps or marginal openings, no marginal deficiencies
Gap (G)	Marginal opening, crevice between tooth structure and composite material
Positive ledge (PL)	Composite restoration situated on a higher level than adjacent tooth structure (eg, due to overfilling, composite excess), including overhangs
Negative ledge (NL)	Composite restoration situated on a lower level than adjacent tooth structure (eg, due to underfilling, increased wear of composite material), including chipping fractures of excess composite material if not associated with gap

prospective study, 35 patients were enrolled, age 18 to 65 years, and in need of 90 Class III (n=51) or Class IV (n=39) restorations. Fillings were placed in pairs (1-SE/2-ER) per test person and randomly assigned, in accordance with American Dental Association Guidelines (USPHS criteria).[18] Cavity preparation was defect-oriented, and enamel margins were slightly beveled. Restorations were placed under rubber dam isolation, and all products were used strictly following manufacturers' instructions. The restorations were finished and shaped with fine-grained diamond burs (15-25 μm, Intensive SA, Grancia, Switzerland) and polished with flexible silicone rubber polishing points and polishing brushes (Ivoclar Vivadent AG).

Clinical Evaluation—19 patients were included in the 90-month clinical reassessment. Each restoration was clinically scored by the principal investigator (M.H.) according to USPHS criteria,[11] focusing on marginal discoloration (MD) and marginal integrity (MI, single-blind rating alpha to delta).

To compare the results of quantitative margin analysis (SEM, OCT) and clinical evaluation, marginal integrity and marginal discoloration were selected from the USPHS criteria. The restoration-related cumulative failure rates were calculated at each recall interval for each criterion.[11]

Quantitative Margin Analysis (SEM/OCT)—Nine of the 19 patients with one restoration with each adhesive were randomly allocated to OCT and SEM analysis (approval of the local Ethics Committee, protocol no. 131-11-18042011). OCT imaging and impression taking (polyvinylsiloxane Coltene President putty soft, President plus light body) took place at the same appointment of the 90-month clinical reassessment. Epoxy resin replicas were produced (Stycast 1266), mounted and sputter coated with gold for SEM quantitative margin analysis as described in the *in vitro* part of this study (Table 1). Margin analysis by OCT and SEM used the same evaluation criteria (Table 1). Non-accessible parts of the restoration margins resulting from artifacts or a lack of clinical access were excluded, for example, when restoration margins were covered by gingiva.

All 18 restorations of the nine patients were subjected to image analysis with Fourier domain Swept-Source-OCT (SS-OCT, OCS 1300SS; Thorlabs Inc, Newton, NJ, US). The parameters of the OCT equipment were: center wavelength 1325 $\pm$ 100 nm, sensitivity 100 dB, axial/lateral resolution 12 (air)/25 μm, field of view $\leq$10 mm $\times$ 10 mm $\times$ 3 mm (pixel size 512 $\times$ 512 $\times$ 512), and imaging speed 16 kHz. After cleaning the restorations and tooth surfaces and drying by air syringe, the handheld and mechanically stabilized scanning probe was positioned at a distance of approximately 3 cm at a right angle to the restoration surface. The restoration area was brought into focus, and 2D cross-sectional images and 3D image stacks were generated within approximately six seconds. The data were saved, and the margin analysis was performed as described previously.

For testing intrapersonal reproducibility, four of the *in vivo* composite restorations (two per adhesive system) were randomly selected for three blinded reassessments of SEM and OCT images by one operator at one-week intervals. The mean percentages of marginal criteria and standard deviations were determined.

Statistical Analysis

Quantitative Margin Analysis—The parameters PM, G, PL, and NL were determined. Wilcoxon test and Kendall tau b (τ_b) were used for nonparametric comparison and measuring correlation between OCT and SEM analyses.

Clinical Evaluation—For clinical assessment of all 19 patients, the failure rates of the criteria MD (code C), MI (codes C and D), and cumulative failure rates (CFR) (BL - 90 M) were determined. Groups were compared using the McNemar test (one-sided because of a significant decrease of margin quality up to 48 months). The clinical results of the nine patients subjected to additional OCT imaging were descriptively evaluated (percentages).

Comparison of Clinical Assessment and Margin Analysis—Eighteen restorations of the nine patients were simultaneously subjected to clinical evaluation and margin analysis. The percentages of marginal criteria PM, G, PL, and NL (OCT and SEM) were listed according to the clinical ratings A, B, and C (MI and MD). The percentages of PM, G, PL, and NL of the restorations with clinical scores A, B, and C were statistically compared (Kruskal-Wallis test and Mann-Whitney U test, not normally distributed data). Accordingly, correlations between the percentage of PM, G, PL, and NL of restorations and ratings A through C of clinical outcomes MI and MD were determined (Kendall τ_b).

For a comparison between both adhesives, on the basis of the percentages of PM, G, PL, and NL (OCT, SEM), the nonparametric Wilcoxon test was made (one-sided, see previous description).

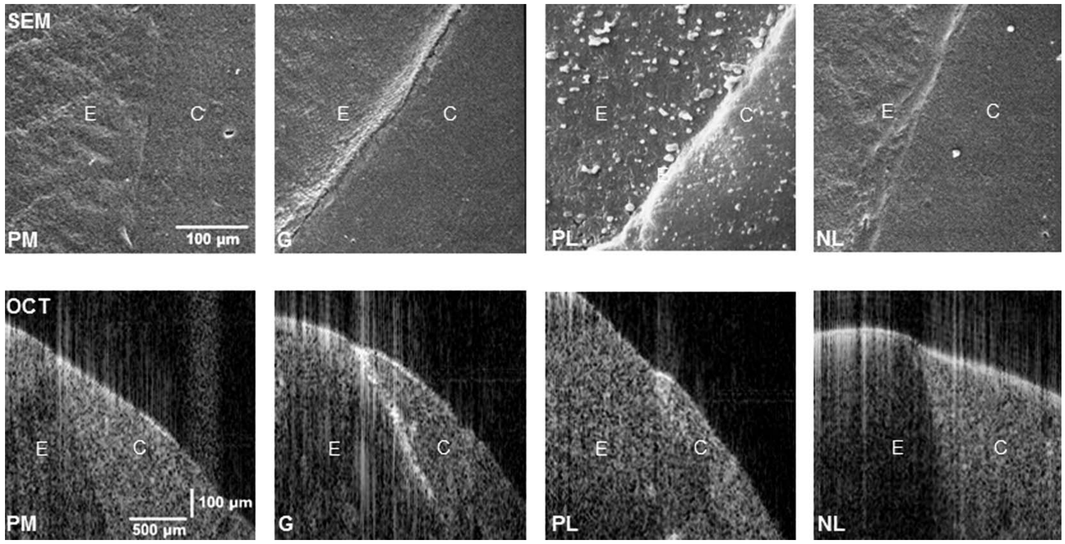

Figure 2. *Representative SEM and OCT images of a region of interest, each showing the marginal critera perfect margin (PM), gap (G), positive ledge (PL) and negative ledge (NL). C, composite; E, enamel.*

Statistical analysis was performed using SPSS 15.0 for Windows (SPSS Inc, Chicago, IL, USA) at the significance level of 0.05. Due to the exploratory nature of this research, raw *p*-values are reported, and we refrained from correction for multiple testing.

Friedman and Wilcoxon tests were used to assess the intrapersonal reproducibility of OCT and SEM margin analysis in terms of marginal criteria PM, G, PL, and NL. Means and standard deviations were calculated. Intrapersonal standard errors were 7.2% and 7.0% (OCT) or 18.4% and 4.8% (SEM) for small and large extension of the marginal criteria PM, G, PL. and NL. No significant differences between the individual reassessments were observed (p_i: 0.13-1.0).

Based on the margin analysis at 90 months, a *post hoc* calculation was carried out to estimate the power of the quantitative margin analysis by OCT and SEM with respect to parameter gap (PS-Power and Sample Size Calculation, version 3.0.43, free trial, Vanderbilt University, Nashville, TN).

RESULTS

In Vitro

It was possible to assess identical parts of the restoration margins in both the OCT B-scans and SEM images. Each of the four criteria for quantitative margin analysis could be displayed by OCT (Figure 2). The Gs between tooth hard tissue and composite restoration were shown as bright lines due to increased signal intensity in these areas. PLs and NLs were identifiable by contour changes, while PMs showed a consistent junction between tooth and restoration, distinguishable by different material brightness without additional signals at the interface (greyscale).

A strong significant correlation could be found between OCT and SEM quantitative margin analysis (τ_b PM/G/PL/NL: 0.79/0.86/0.92/0.64; p_i: 0.003-0.026, Table 2) without significant differences between both methods in all assessed criteria (p_i: 0.63-1.0).

In Vivo

Clinical Evaluation—Table 3 summarizes recall rates, reassessment rates, and cumulative failure rates with regard to the clinical criteria MD and MI from baseline to 90 months. At 90 months, 62.9% (1-SE) and 61.5% (2-ER) of the composite restorations could be reassessed. Compared with group 2-ER, in group 1-SE, the cumulative failure rate regarding to marginal integrity (restoration loss over time) was significantly enhanced (p=0.011, Table 3).

The nine subjects who received quantitative margin analysis showed the following clinical results (Table 2). In the 1-SE group, two restorations failed with MI of code C or D. One of the remaining seven restorations showed MD of code C. Thus, three of the restorations (33.3%) failed in both criteria. In the 2-ER group, no restoration failed in the criterion MI, 11.1% of restorations failed in both criteria with one of nine restorations showing MD of code C. The

Table 2: *Evaluation of Marginal Qualities of Class III and IV Composite Restorations Using SEM and OCT* In Vitro *or* In Vivo *at 90 Months Recall (Nine Restoration Pairs): Explorative Clinical Evaluation of Nine Restoration Pairs*

Margin analysis	**PM**	**G**	**PL**	**NL**
Correlation OCT – SEM, $\tau_b/(p_i)$				
In vitro	0.79 (0.006)	0.86 (0.003)	0.92 (0.003)	0.64 (0.026)
In vivo	0.38 (0.016)	0.45 (0.004)	0.44 (0.006)	0.43 (0.009)
OCT vs SEM, p_i				
In vitro	0.844	1.00	0.625	0.844
In vivo	0.812	0.516	0.018	0.980
1-SE vs 2-ER[a]; 9 pairs of restorations *in vivo*				
1-SE				
OCT	42.63	36.75[b]	10.55	8.17
SEM	38.79	38.73[c]	14.57	7.63
2-ER				
OCT	53.21	15.71	13.15	15.52
SEM	56.05	10.34	22.02	11.59
p_i				
OCT_{SEvsER}	0.190	0.027	0.348	0.064
SEM_{SEvsER}	0.080	0.002	0.065	0.064
Clinical evaluation		**Failure MI + MD, %**		
1-SE vs 2- ER; 9 pairs of restorations				
1-SE		33.3		
2-ER		11.1		
p		0.625		

Abbreviations: 1-SE, one-step self-etch adhesive iBond Gluma inside; 2-ER, two-step etch-and-rinse adhesive Gluma Comfort Bond; G, gap; MD, marginal discoloration; MI, marginal integrity; OCT, optical coherence tomography; NL, negative ledge; PL, positive ledge; PM, perfect margin; SEM, scanning electron microscopy; τ_b/(p): Kendall tau b/(p_i).
[a] *Mean values (%).*
[b] *Increase of 134% related to 15.71 (2-ER).*
[c] *Increase of 274.6% related to 10.34 (2-ER).*

displayed differences between the two groups were not statistically significant (MD: p=1.0, MI: p=0.5, sum of both criteria: p=0.625).

Quantitative margin analysis, OCT vs SEM—OCT enabled detailed imaging of restoration margins under *in vivo* conditions. Statistical analysis revealed a moderate significant correlation between OCT and SEM (τ_b PM/G/PL/NL: 0.38/0.45/0.44/0.43; $p_i<0.016$, Table 2). No significant differences could be found between both methods with regard to the criteria PM, G, and NL (p_i: 0.516-0.98, Table 2), while for PL a statistically significant difference was observed (p=0.018).

Clinical Evaluation and Quantitative Margin Analyses, Marginal Integrity—A statistically proven relationship arose from MI (clinical evaluation) and PM based on SEM (quantitative margin analysis) with a moderate significant correlation (τ_b=–0.4, p=0.034, statistical analysis). Therefore, in Table 4, merely for MI (ratings A, B, and C), the percentages of G and PM along restorations were represented. Using SEM, the B-rated restorations in Table 4 showed a significantly 39% lower mean value for PM compared with A-rated restorations (37.12% vs 61.04%, p-value of the SEM-investigation p_{SEM}: 0.016), with OCT there was a nonsignificant 19% decrease (44.22% vs 54.59%, p-value of the OCT-investigation p_{OCT}: 0.272). A stronger but nonsignificant effect resulted for G; 73% more Gs were observed by SEM analysis at B-rated restorations compared with A-rated restorations (28.92% vs 16.74%, p=0.171). OCT revealed 60% more Gs at restorations rated as B (32.00% vs 20.01%, p=0.272, Table 4). For margin criteria PL and NL, neither OCT nor SEM analysis showed a statistically proven relationship with MI (τ_b: –0.240 ... +0.160; all p-values p_i: 0.203-0.764). This was true for ratings A and B (p_i: 0.350-0.791).

Marginal Discoloration—All ratings A through C of MD showed no significant differences for PM, G, PL, NL (p_i: 0.25-1.0). In addition, no statistically significant correlations could be proven (τ_b: –0.170 ... +0.237, p: 0.201-0.881, statistical analysis).

Table 3: *Clinical Performance of iBond Gluma Inside/Venus vs Gluma Comfort Bond/Venus in the Period Baseline – 90 Months*

	iBond Gluma inside/Venus						Gluma Comfort Bond/Venus					
	Baseline	6 Months	12 Months	24 Months	48 Months	90 Months	Baseline	6 Months	12 Months	24 Months	48 Months	90 Months
Patients seen/ recalled, n	35	32/35	33/35	31/33	24/30	16/28	35	32/35	33/34	31/33	23/32	17/29
Recall response, %	100	91.4	94.3	93.9	80.0	57.1	100	91.4	97.1	93.9	71.9	58.6
Trials failed/ dropped out before, n				4	7/1	9/1			1	1/1	1/2	4/2
Trials reassessed/ recalled, n	45	41/45	42/45	39/41	30/37	22/35	45	41/45	42/44	41/43	35/42	24/39
Reassessment rate, %	100	91.1	93.3	95.1	81.1	62.9	100	91.1	95.5	95.3	83.3	61.5
Control period, months[a]		6.1 (0.89)	13.0 (1.23)	24.0 (0.72)	47.9 (0.66)	89.5 (1.41)		6.1 (1.00)	13.2 (1.38)	23.8 (0.78)	47.9 (0.82)	89.4 (1.65)
Cumulative failure rate, %, marginal discoloration	0	0	2.4	2.7	6.9	12.5	0	0	0	0	3.0	16.0
Cumulative failure rate, %, marginal integrity	0	0	7.1	14.3	20.0	41.8**	0	0	0	0	5.9	7.7**

[a] *Mean (standard deviation).*
*** Significantly different (p=0.011).*

1-SE vs 2-ER

The results of the quantitative margin analyses of 1-SE vs 2-ER are shown in Table 2.

In the 1-SE group, significantly higher percentages of Gs were detected by OCT (134.0%) and SEM (274.6%) compared with the 2-ER group (OCT: 36.75 vs 15.71, p=0.027; SEM: 38.73 vs 10.34, p=0.002). There was no statistically significant difference between the adhesive systems regarding PM, PL, and NL (p_{iOCT}/p_{iSEM}:>0.064/>0.064). In both groups, the percentages of G and PM varied considerably. Considering the values of all evaluated nine restorations in each group, G ranged between 1.3% and 88.7% with OCT and between 0.0% and 86.9% with SEM analysis, while ranges for perfect margin were between 0.0% and 88.6% (OCT) or 4.7% and 89.0% (SEM), respectively.

Test Power

Based on this margin analysis of nine pairs of restorations at 90 months and the measured group differences for G of 28.4% (SEM) or 21.0% (OCT), a *post hoc* test power of 76.60% (SEM) or 59.40% (OCT) was estimated (α=0.05). Thus, under the conditions of the actual study, a target test power of 80% would require 10 (SEM) or 13 (OCT) pairs of restorations, respectively.

Supplemental Information by OCT

OCT images provided supplemental information about inner structures of dental hard tissues and composite material (eg, enamel cracks, interfaces between composite increments, and porosities within the composite material) that remained undetected by

Table 4: *Percentages of Gaps and Perfect Margins Detected in Quantitative Margin Analysis with OCT and SEM in Comparison to Clinical Assessment Criterion Marginal Integrity (1-SE and 2-ER)*

Margin Criterion	Mean Clinical Score of Marginal Integrity		
	A	B	C[a]
Gap (G)			
OCT [%]	20.01	32.00[b]	55.71
SEM [%]	16.74	28.92[c]	41.45
Perfect margin (PM)			
OCT [%]	54.59	44.22[d]	35.24
SEM [%]	61.04**	37.12**[e]	51.87

Abbreviations: 1-SE, one-step self-etch adhesive iBond Gluma inside; 2-ER, two-step etch-and-rinse adhesive Gluma Comfort Bond; OCT, optical coherence tomography; SEM, scanning electron microscopy.
[a] *n=1.*
[b] *Increase of 60% vs 20.01.*
[c] *Increase of 73% vs 16.74.*
[d] *Decrease of 19% related to 54.59.*
e Decrease of 39% related to 61.04.
*** Significantly different (p=0.016),*

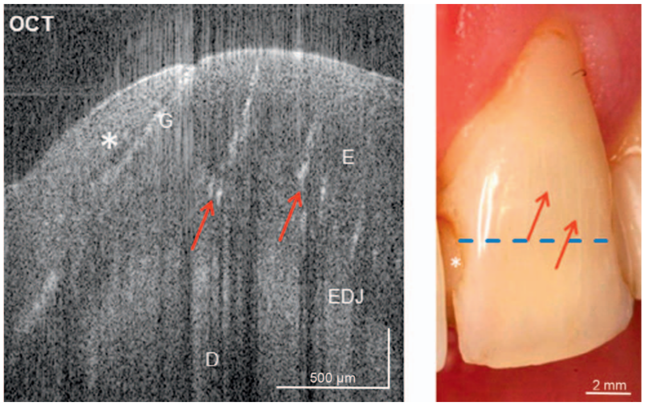

Figure 3. *OCT B-scan corresponding to the dotted blue line in the clinical image. The OCT image shows a composite restoration (*) with a marginal gap (G), which develops along the composite-enamel (E) interface. Enamel cracks (red arrows) are clearly visible. D, dentin; EDJ, enamel-dentin junction.*

SEM examination due to its limitation to visualize surface structures only. The additional findings were verified clinically (Figure 3).

DISCUSSION

OCT has been implemented in several fields of dental research in recent years from caries detection,[30] monitoring of carious lesions,[36] and remineralization processes,[32] to assessment of interfacial defects at composite restorations.[34] Features such as nondestructiveness and noninvasiveness with high-resolution imaging of dental hard tissues and composite materials distinguish OCT as a promising diagnostic tool for direct *in vivo* applications in clinical trials.[16] For example, this includes the longitudinal monitoring of surface and subsurface enamel demineralization,[37] the detection of tooth decay beneath commonly used dental sealants,[31] or the possibility of the longitudinal monitoring of the tooth-composite bond failure or the more complex assessment of composite restorations in extended clinical studies.[37]

Quantitative Margin Analysis (OCT vs SEM)

SEM in replica techniques has been typically referred to as the gold standard for quantitative margin analysis. The comparison with this technique revealed a strong correlation with OCT in *in vitro* application. *In vivo*, this decreased to a moderate correlation. Contrary to *in vitro* conditions with predefined regions of interest, it was not possible *in vivo* to ensure that identical lengths of restoration margins were evaluated. As only buccal and those interproximal margins accessible for impression taking were examined, it is conceivable that the absolute length of assessed margins differed between methods. From an OCT perspective, image acquisition is limited by the optical accessibility of tooth regions by the OCT beam. One limitation of the *in vivo* comparison is therefore that SEM analysis could have rated marginal qualities that were not rated by OCT and vice versa. This might be a potential cause of the reduced correlation between both methods *in vivo*. Moreover, it could be an explanation for the significantly higher percentages of PLs detected with SEM.

The higher spatial resolution of the SEM had no impact under the conditions of this study. The surface texture of epoxy replicas, the thickness of the deposited layer of gold, and the low 200-fold magnification used, restricted spatial resolution within the SEM images. Additional artifacts in the impressions may also affect the SEM analysis. Furthermore, OCT signaling depends on differences in refractive index, and this implies that gaps can also be recognized, even if the gap widths are below the underlying spatial resolution limit.[38]

Evaluation of Adhesive Systems

The alternative hypothesis that increased numbers of clinical failures and margin gaps occur if the one-step self-etch adhesive was used compared with the two-step etch-and-rinse system was accepted.

After the 90-month reassessment, an enhanced cumulative failure rate in the criterion marginal integrity could be demonstrated clinically in the 1-SE group (Table 3), which was also seen in the descriptive assessment of the failure in both criteria MI + MD (1-SE: 33%, 2-ER: 11%, Table 2) of the nine restorations each, which were analyzed by SEM and OCT. This corresponded with the noncumulative findings of marginal analyses revealed by both OCT and SEM at 90 months. Significantly, more marginal gaps were measured in the 1-SE group than in the 2-ER group.

Additionally, it should be pointed out that the OCT and SEM analyses reliably confirmed the group difference for the margin parameter G with the low number of nine matched pairs of composite restorations. This is noteworthy because, at the 90-month examination, restorations which were clinically successful in the long term were selectively assessed. Restorations prone to error should have been failed earlier. These facts indicate the higher power of the quantitative margin analysis (OCT, SEM) compared with clinical evaluation. Thus, OCT could be considered a reliable, noninvasive, less labor intensive, and more cost-effective alternative to SEM.

The clinical differences after 90 months complied with the data at 12 months up to the 48-month recall.[11] In this period, the MI did not always statistically significantly decrease in the 1-SE group. The discussion section of the article concluded with the open wording "one could . . . only speculate about the further divergence or convergence of the CFRs [cumulative failure rates] (between both groups)." After 90 months, it could be stated that there was no convergence regarding marginal integrity.

The results of this study substantiate the assumption that under *in vivo* conditions the margin criterion G, which reciprocally corresponds to MI, could be a quantifiable parameter to evaluate composite restoration systems, provided that the clinical protocol in all study groups is the same. The criterion PM did not permit any differentiation between adhesives or restoration systems. In this context, our answer to the commonly-asked question of "How much PM does a composite restoration need to be clinically successful?"[4] has to be: Apparently not that much. This is illustrated by the huge range of the criterion PM for OCT (0.0% to 88.6%) and SEM (4.7% to 89.0%). Furthermore, all of the 18 assessed restorations were still in function after 90 months, with no carious lesions adjacent to the restoration margins. Only one of these restorations was clinically rated C regarding MI (1-SE). Remarkably, however, this restoration could not be identified as the one with the lowest percentage of PM either by SEM or OCT. The large variance of both parameters supports the assumption that it is impossible to predict the clinical success of a restoration based on certain percentages of PMs or Gs.[10.24] Our results also tend to not confirm that the width and depth of the marginal gap could be a more decisive factor.[14]

Relationship Between Clinical Assessment and Quantitative Margin Analysis

Although for the margin criterion G a stronger effect could be observed, a statistically proven relationship could only be deduced between MI (scores A, B, and C) and PM (SEM) (Table 4). In principle, the fewer PMs present, the worse the clinical ratings. Statistical analysis could confirm this assumption for the data acquired by SEM. One reason OCT showed a smaller, nonsignificant effect could be a consequence of the difference in margins examined. Also, in future studies increased sample sizes could enhance the significance.

Regarding marginal discoloration, no statistically proven relationship could be deduced with the quantifiable margin criteria, although marginal discoloration is most commonly caused by pigment accumulation at or in marginal imperfections.[36]

Supplemental Information by OCT

As a tomographic method, OCT is able to display additional signals derived from inner structures of dental hard tissues and composite materials such as enamel cracks and interfaces between composite increments (Figure 3).[34,35,39] An OCT examination could usefully complement clinical assessment of enamel cracks and incomplete crown fractures in the future, revealing their real extent and direction, which cannot be fully assessed clinically.

Summing up, it could be stated that OCT meets the demands for applying techniques with enhanced spatial resolution in restorative dentistry.[5,14] The noninvasive nature of this method would be especially advantageous for imaging dental structures and restorations *in vivo*.

In contrast to SEM analysis, OCT offers the advantage of real-time imaging of hard tooth tissues and composite restorations, without the time-consuming and complex intermediate preparation steps that are involved in SEM analysis.[20] Additionally, OCT offers the possibility of measuring the extension of gaps at the tooth-composite interface and the imaging of inner structures of dental hard tissues and composite materials, which provides supplemental information toward the SEM examination. This could enhance clinical evaluation, especially in long-term clinical trials. There is a need for further investigation of OCT application *in vivo*, especially regarding objectivity, reliability, specificity, and sensitivity of the technique as a possible diagnostic tool in dentistry.

This study confirmed that the MI of clinically successful restorations varies significantly. Considering marginal quality as the sole or predominant criterion for clinical success is therefore not suitable to assess the long-term clinical performance of adhesive restorations.[3,10] However, the quantifiable marginal criterion G could be a useful and more predictive parameter for evaluating restoration systems. The factors affecting clinical success seem to be much more complex in structure. OCT could be, thereby, a valuable tool for diagnosing and monitoring composite restorations *in vivo*.

CONCLUSIONS

Quantitative margin analyses using SEM or OCT correspond. OCT enables both the evaluation of the margin qualities of Class III and IV composite restorations *in vitro* as well as directly *in vivo* and the generation of supplemental morphologic information about tooth surface structures.

Corresponding to clinical evaluation (*in vivo*, cumulative failure rates), quantitative margin analysis can distinguish between adhesives or restoration systems. In long-term clinical trials, cross-sectional separation of study groups might also be achievable with a small number of subjects (selection bias), even if clinical differentiation is impossible.

The margin criterion G is a suitable parameter for evaluating restoration systems.

The marginal quality of clinically successful composite restorations varies considerably. Poor marginal quality occurs in clinically successful composite restorations, indicating that a low percentage of segments with perfect margins does not successfully predict poor clinical performance.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Ethics Committee of the University of Leipzig. The approval code for this study is protocols no. 299-10-04102010, no. 087/2003, and no. 131-11-18042011.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service. and/or company that is presented in this article.

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