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Clinical and Micromorphologic 29-year Results of Posterior Composite Restorations

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Abstract

Prospective clinical studies of composite restorations revealed their safety and longevity; however, studies did not elucidate the dynamic mechanisms of deterioration caused by fractures and secondary caries. Therefore, the aims of this 29-y controlled study were 1) to follow up on the clinical behavior of posterior composite restorations annually and 2) to compare clinical outcomes with micromorphologic scanning electron microscopy features. After ethical approval, the single-arm study commenced in 1987 with 194 class I or II primary posterior composite restorations with glass ionomer cement providing pulp protection. Each restoration was evaluated annually for 15 y and then again at 29 y per the US Public Health Service–compatible Clinical, Photographic and Micromorphologic coding index, with clinical and photographic criteria for anatomic form, color matching, surface quality, wear, marginal integrity, secondary caries, and clinical acceptability. Parallel micromorphologic criteria were applied at baseline and after 1, 3, 5, 7, 10, 15, and 29 y to assess surface roughness, texture, marginal integrity, fractures, ledges, and marginal gaps with semiquantitative coding and with quantitative 3-dimensional scanning electron microscopy profilometric measurements of marginal grooves next to the enamel, grooves within the bonding zone, and ledges. Statistical analysis included the calculation of the annual failure rate and the use of Kaplan-Meier methodology and nonparametric tests. The cumulative survival rates were 91.7% (6 y), 81.6% (12 y), and 71.4% (29 y). The mean annual failure rate was 1.92%. Significant changes in the restoration-tooth interface from baseline to 5 y resulted in functional masticatory equilibrium. Clinical deterioration year by year, including micromorphologic microfractures and wear, reflected unique dynamic changes in long-term surviving restorations with very low secondary caries and fracture risks (German Network for Health Care Research VfD 29 99 003924).

Keywords: restorative dentistry, scanning electron microscopy (SEM), pulpitis, caries treatment, clinical outcomes, composite materials

Introduction

The year 2018 marks the important 110th anniversary of G. V. Black's famous text book *A Work on Operative Dentistry in Two Volumes*, intended "especially for use of students in dental schools." In the chapter "Curative Effect of Fillings," Black stated that "fillings cure purely and simply by shutting out everything from contact with dentin." He concluded that "the filling itself . . ., if it is made well and of material that is durable in the mouth, as gold or amalgam, is invulnerable; it should last a lifetime." He continues, "We make fillings that are not the best because the conditions will not allow the best operations. These are . . . fillings for temporary purposes. . . . I should say a permanent filling should practically last a lifetime" (vol. 1, pp. 193–196).

One hundred ten years later, most restorative materials last for many decades. However, tooth filling longevity, prevention of early failures, and tooth function in the long term remain an ultimate goal of material development and clinical dental research, and posterior composite restorations are particularly significant in this field. They have been clinically and micromorphologically evaluated for 3 decades (Wilson et al. 1988; Roulet et al. 1991), and their clinical safety is well established (Rezwani-Kaminski et al. 2002). Systematic reviews revealed an annual failure rate (AFR) of 2.4% after 10 y (Opdam et al. 2014) and annual AFRs of 1.5% to 2.2% after 15 y (Alvanforoush et al. 2017). Pallesen and van Dijken (2015) reported a randomized clinical study with an AFR of 1.1% after 30 y. Heck et al. (2018) found AFRs of 1.3% and 2.3% after 10 y for 2 bulk fill restorations in a randomized clinical trial. In retrospective evaluations, the 10-y AFR was 2.1%

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A supplemental appendix to this article is available online.

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(Lempel et al. 2015), and the 22-y AFRs were 1.5% (midfilled composite) and 2.2% (minifilled; Da Rosa Rodolpho et al. 2011). However, most long-term prospective clinical studies evaluating resin composite restorations contribute rather superficially to the mechanisms of secondary caries pathogenesis and fracture behavior (Lohbauer et al. 2013; Ferracane 2017).

Therefore, in vitro models and experimental studies of composite restorations are needed, the results of which will contribute to the future development of biomaterials. The introduction of the first hybrid composite materials in the 1980s was promising, but prospective longitudinal controlled clinical studies with parallel micromorphologic controls are needed to investigate the unknown secondary caries risk, the expected highly dynamic wear behavior, and the fracture risk. The main objective has been to evaluate longevity based on sensitive clinical testing and the micromorphologic determination of restoration changes.

Therefore, a combined Clinical, Photographic and Micromorphologic (CPM) coding index was introduced in 1987 for a prospective longitudinal study of a new hybrid composite material for posterior restorations. Scanning electron microscopy (SEM) replications in vivo were used to assess the dynamic behavior of filling margins and changes in the composite surface and the surrounding tooth surface. This micromorphologic semiquantitative evaluation was later supplemented by quantitative profilometric assessment with 3-dimensional (3D) SEM (Gaengler et al. 2001; Gaengler et al. 2004; Dietz et al. 2014). Therefore, the aim of the present report is to combine clinical results with a micromorphologic assessment of the dynamic behavior of composite restorations in premolars and molars over 29 y of follow-up.

Materials and Methods

The project was approved in 1987 according to the Medicinal Products Act (§14) of the Ministry of Health, Berlin, reapproved by the Ethical Committee of Jena University (3497-06/12), and registered in the German Network for Health Care Research (VfD 29 99 003924). Informed consent was obtained from all the subjects. Four calibrated clinicians were responsible for the diagnosis and primary treatment of manifest dentin carious lesions according to the protocol. No teeth with replacement fillings were included. No subject was excluded because of high caries activity. One clinician (R.M.) followed up all restorations for 29 y. One physicist (W.D.) with the clinician scored all the SEM images of all the restorations over the same 29 y. In 1987, 115 class I and 79 class II restorations in 85 premolars and 109 molars were placed in 73 adult patients aged 18 to 52 y. The present report complies with the STROBE statement (Strengthening the Reporting of Observational Studies; Vandenbroucke et al. 2007).

All posterior fillings were inserted under a rubber dam. The exposed dentin was covered with the glass ionomer cement Ketac-Bond (ESPE); the slightly beveled enamel margins were acid-etched; and a bonding agent (Universalbond; ESPE) was applied. The gingival margins of class II restorations were in the dentin in some cases, and they were not covered with cement. The composite filling material Visio-Molar X (ESPE) was incrementally inserted with curing for 60 s for each step (Elipar; ESPE). After a careful finishing of the restoration surfaces and margins, baseline clinical data were recorded, and double impressions were taken and finally replicated with resin Epon (Serva). These positive replicas were gold-sputtered and investigated under the scanning electron microscope Philips SEM 515. Standard operative procedures and 10- and 15-y results are presented elsewhere (Gaengler et al. 2001; Gaengler et al. 2004; Dietz et al. 2014).

Each restoration was clinically evaluated after 6 mo and 1 y and then annually for 15 y, with a final evaluation after 29 y per the US Public Health Service–compatible CPM index (Gaengler et al. 2001), with the C (clinical) and P (photographic) criteria for anatomic form, color matching, surface quality, wear, marginal integrity, secondary caries, and clinical acceptability. No evaluation was performed between 15 and 29 y. The micromorphologic (M) SEM criteria for surface roughness, surface texture, marginal integrity, excess material, marginal fractures, marginal ledges (loss of material), marginal gaps, and other filling imperfections (enamel fracture, bulk fracture, etc.) were used for reassessment after 1, 3, 5, 7, 10, 15, and 29 y. The profilometric 3D-SEM evaluation was performed with the 15-y samples. The SEM was equipped with a 4-quadrant solid-state backscattered electron detector (Point Electronic). The electrons of the primary beam are reflected by specimens and hit detectors surrounding the beam, simultaneously generating 4 pictures from different angles. These digital pictures were used for the computation of surface models, profilometric measurements, and topographic mapping. The software MAX 4.1 (Alicona Imaging) allowed profilometric determination of a minimal ledge depth of 0.1 µm (Dietz et al. 2014). Each restoration was stereoscopically assessed in the same 3 areas in all 8 control terms with 3 measuring lines. Therefore, replicas from baseline to 29 y were reevaluated with this new micromorphologic methodology.

Statistical Rationale

The Kolmogorov-Smirnov test was applied to evaluate the quantitative micromorphologic parameters at 6 evaluation times (baseline and 1, 5, 10, 15, and 29 y) and over the whole period for a normal distribution of the measured micrometer values. As a result, the null hypothesis of normality was clearly rejected. Consequently, the parameters were analyzed by the Friedman test as a nonparametric omnibus test of null. The significance level was conventionally set at $\alpha = 0.05$ (5%).

As the post hoc analysis to the Friedman test, the Wilcoxon signed-rank test was applied with Bonferroni adjustment to assess whether the rank sums and medians of negative ledges and marginal grooves were different between consecutive evaluation times (baseline vs. 1, 1 vs. 5, 5 vs. 10, 10 vs. 15, and 15 vs. 29 y).

The Kaplan-Meier method was used to analyze the cumulative restoration survival rate. The clinical data of the CPM index were analyzed by descriptive statistics (SPSS Statistics Premium, release 24, 64-bit version; IBM).

Table. Failures and Annual Failure Rates of Hybrid Composite Visio-Molar X Restorations over 29 y.

			Failure Due to . . ., *n* (%)			
Evaluation, y	Controlled Fillings, *n*	Total Failure Fillings, *n* (%)	Filling Fracture	Partial Filling Loss	Total Filling Loss	Secondary Caries
Baseline	194					
0.5	175	1 (0.57)	1 (0.57)			
1	167	2 (1.20)	1 (0.60)		1 (0.60)	
2	137	2 (1.46)	1 (0.73)	1 (0.73)		
3	92	2 (2.17)		2 (2.17)		
4	90	2 (2.22)		2 (2.22)		
5	69	1 (1.45)		1 (1.45)		
6	47					
7	52	4 (7.69)				4 (7.69)
8	50	1 (2.00)		1 (2.00)		
9	47	1 (2.13)				1 (2.13)
10	46					
11	42					
12	42					
13	41	2 (4.88)	1 (2.44)	1 (2.44)		
14	39					
15	37	2 (5.41)				2 (5.41)
29	29	1 (3.45)	1 (3.45)			

Total failure fillings, annual failure rate: mean = 1.92% (SD = 2.19%), median = 1.46% (interquartile range = 2.53%).

Results

Survival Distribution

After 29 y, 29 longitudinally controlled posterior restorations of 194 fillings applied in 1987 were evaluated. All the restorations in class I (25) and class II (4) were primary fillings due to dentin carious lesions. Patient dropouts accounted for 117 fillings (60.30%). Twenty-six restorations were excluded because new caries not connected to the filling developed at different sites (12 teeth) or because of prosthodontic treatment (14 teeth). Twenty-one restorations had to be replaced due to secondary caries (7 fillings), filling fractures (5 fillings), partial filling loss (8 fillings) or total filling loss (1 filling), as presented in the Table. Replacement material was amalgam in the first 5 y and later resin composite.

The cumulative survival rate according to the Kaplan-Meier method was 91.7% after 6 y, 81.6% after 12 y, and 71.4% at the end of the investigation. The mean AFR was 1.92% (SD = 2.29%) for all failed restorations. The median AFR was 1.46% (interquartile range = 2.55%; Table).

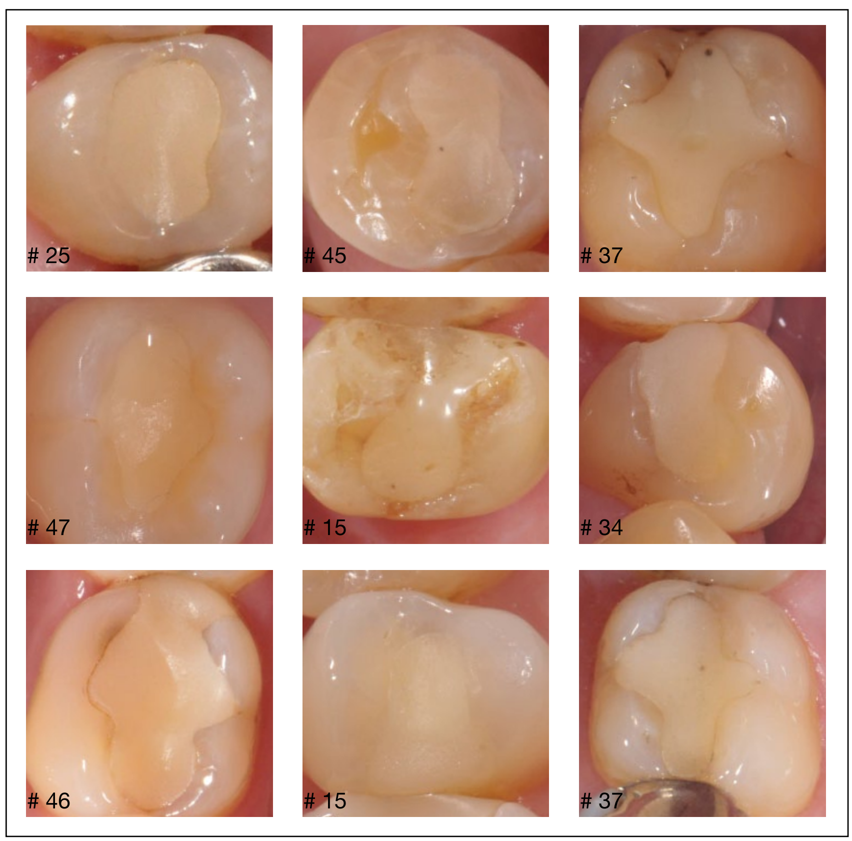

Figure 1. Clinical assessment of initial Visio-Molar X restorations after 29 y. #, tooth FDI number of molars and premolars.

Clinical Evaluation

The clinical criteria of the CPM index revealed substantial functional deterioration within the first 5 y mainly due to wear. Local loss of filling material according to individual patterns started in the third year and affected all restorations after 5 y. However, after 29 y, 23 of 29 fillings exhibited only local wear

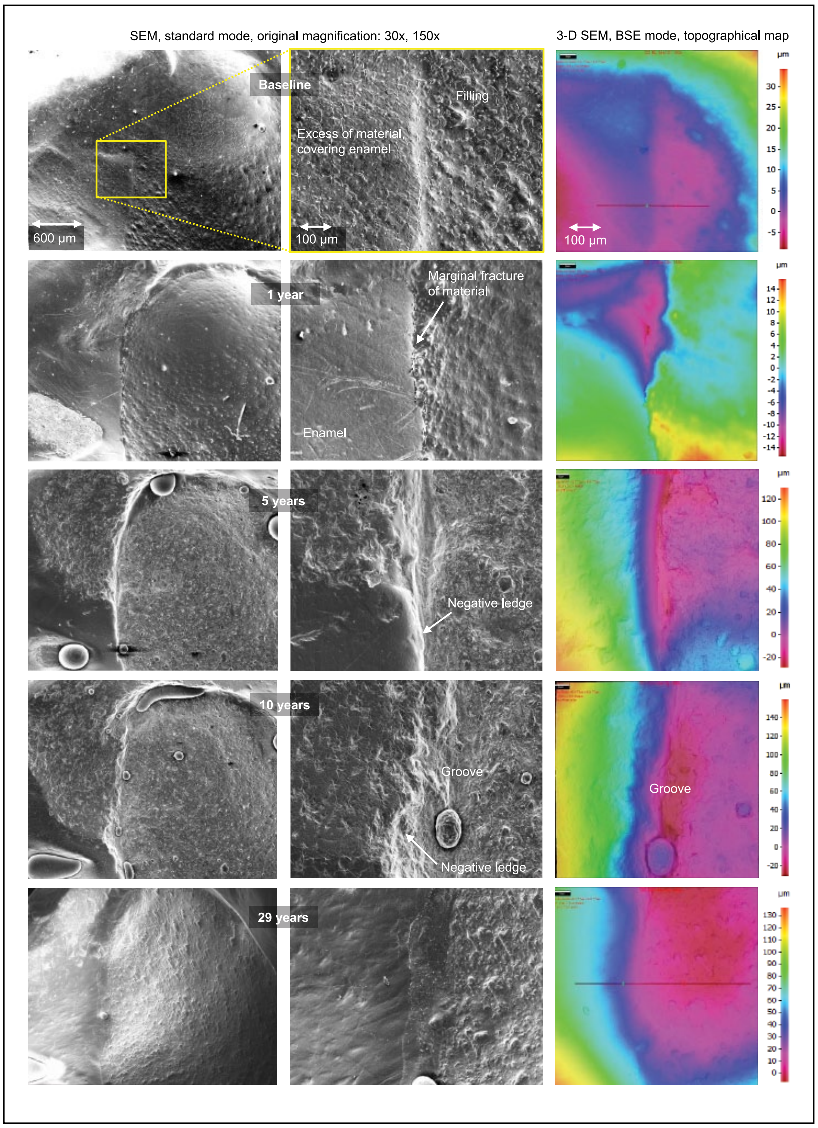

Figure 2. Micromorphologic scanning electron microscopy (SEM) assessment and topographic mapping of the filling-tooth interface for 1 molar from baseline and after 1, 5, 10, and 29 y, with a colored altitude scale ranging from −5 µm to 30 µm at baseline and 0 µm to 130 µm after 29 y, representing variable depth profiles of the whole surface. Left and middle: SEM standard mode, original magnification: 30:1, 150:1. Right: Three-dimensional (3D) SEM, backscattered electron (BSE) mode, topographic map of the filling-tooth interface, colored altitude scale, original magnification: 150:1.

with individual occlusal patterns. The percentage of restorations with seemingly perfect marginal integrity clinically changed from 100% at baseline to 31.0% after 5 y, 17.2% after 10 y, 6.9% after 15 y, and 10.3% at the end of the investigation. Negative ledges as a consequence of wear were coded only after 10 y in 51.7% of controlled fillings, 58.6% of fillings after 15 y, and 65.5% of fillings after 29 y. Very few restorations developed secondary caries: 4 fillings after 7 y, 1 after 9 y, and 2 after 15 y (Table). Figure 1 shows the photographic assessment of a sample of composite restorations at the end of the 29-y investigation.

Semiquantitative Micromorphologic Evaluation

The semiquantitative assessment of the M criteria of the CPM index showed the deterioration of restorations after 1, 3, and 5 y. At baseline, all the composite surfaces were homogeneous, yet they exhibited excess material on top of the enamel surface. This excess disappeared gradually around the circumferential margins, and after 29 y, only 1 filling exhibited excess affecting less than one-third of the circumference. Few marginal fractures were detected after 1 y; they gradually increased up to 10 y and never extended beyond one-third of the circumference. These composite layers exhibited progressive marginal fracturing until 29 y, and physiologic wear contributed to negative marginal ledges and the smooth loss of composite material (Fig. 2).

Marginal gaps rapidly increased within the first year of function in >50% of the fillings and then did not change over 29 y. Only 1 filling exhibited gaps around two-thirds of the margin. Marginal fractures, negative ledges, and marginal gaps did not contribute to secondary caries (Table).

Quantitative Micromorphologic Evaluation

The 3D-SEM-based profilometric measurements confirmed the clinical results and documented the unique features of the dynamic morphologic behavior of the filling-tooth interface. All the restorations enabled occlusal function with some or even heavy clinically unavoidable composite material excess, followed by marginal fractures, resulting in exposed enamel and ultimately rather deep marginal ledges. Figure 3 demonstrates these dynamics over 29 y, showing the formation of typical grooves between the filling body and the cavity wall. Consequently, heavy wear after 1 y with groove formation next to the enamel or with groove formation within the bonding zone for up to 5 y completely changed 10 y later, with grooves disappearing and a relatively smooth composite-tooth interface observed. The wear of the enamel and composite material contributes to an improvement of the restoration. Figure 2 shows these dynamic changes in the restored tooth surface. The different depths of marginal grooves next to enamel or within the bonding zone as compared with ledge formation are presented in Figure 4. These grooves significantly ($P < 0.05$) increased within the first year and for the next

4 y and then remained stable for the following 24 y, partly or completely disappearing. These dynamics are reproduced by ledge formation, which significantly increased within the first 5 y and then increasingly disappeared, confirming the SEM surface features (Fig. 3).

Discussion

This 29-y report summarizes the previous results after 5, 10, and 15 y (Hoyer et al. 1993; Gaengler et al. 2001; Gaengler et al. 2004; Dietz et al. 2014). Posterior dental restorations of class I and class II lesions with glass ionomer cement Ketac-Bond and hybrid composite Visio-Molar X in premolars and molars lasted for a long time, and the AFR was very low. A randomized controlled 30-y study with a follow-up every 5 y reported a cumulative survival rate of 66.7% (Pallesen and van Dijken 2015), as compared with 71.4% in the present study.

In the Copenhagen study, the overall AFR for 3 composite restorations was 0.8% to 1.4%, with 11 cases of secondary caries among 99 fillings. Again, these data match our results with 7 cases of secondary caries among 194 restorations and a mean AFR of 1.92% (median AFR = 1.46%). Six composite fractures were identified after 30 y in the Copenhagen cohort, as compared with 5 fractures identified in the present group. From a clinical perspective, secondary caries with a mean AFR of 0.90% and bulk fractures of posterior restorations with a mean AFR of 0.46% do not affect clinical safety.

Postoperative sensitivity lasting longer than 2 to 3 h indicates manifest pulpitis. We observed 4 cases of pulpitis among 194 restorations after 1 wk and 2 to 4 mo postoperatively. This very low number has been attributed to the pulp protection method with glass ionomer cement as dentin replacement material. Ketac-Bond is, according to extensive acute and chronic biocompatibility testing, clinically safe (Beer et al. 1990), and the exposure of open dentin tubules in all carious lesions (Arnold et al. 2001) to resin monomers was avoided. A retrospective study of 1 dental practice investigated the 18-y survival rate of posterior restorations with and without a glass ionomer cement base (van de Sande et al. 2015). The AFRs were 1.9% and 2.1%, respectively, reflecting no effect of the restoration technique on the survival rate.

The range of all the reported AFRs among long-term studies (15 to 22 y) has improved in the last decade (2006 to 2016) to 1.50% to 2.20%. However, the reasons for failure have shifted from high rates of secondary caries and wear to increasingly significant roles of tooth fractures, restoration fractures, and endodontic treatment (Alvanforoush et al. 2017). Our results do not support these trends, and the difference may be due to minimal invasive primary restorations in the present study as compared with larger replacement fillings in other long-term studies. The presented clinical results are also limited by the high patient dropout rate of 60.30%. Most of these patients moved to other locations far from the study center and attended other dentists. There was no access to the patient files. Another limitation was the strict inclusion criterion: Only subjects attending all recall visits (maximum, 1 missing recall) remained part of the cohort.

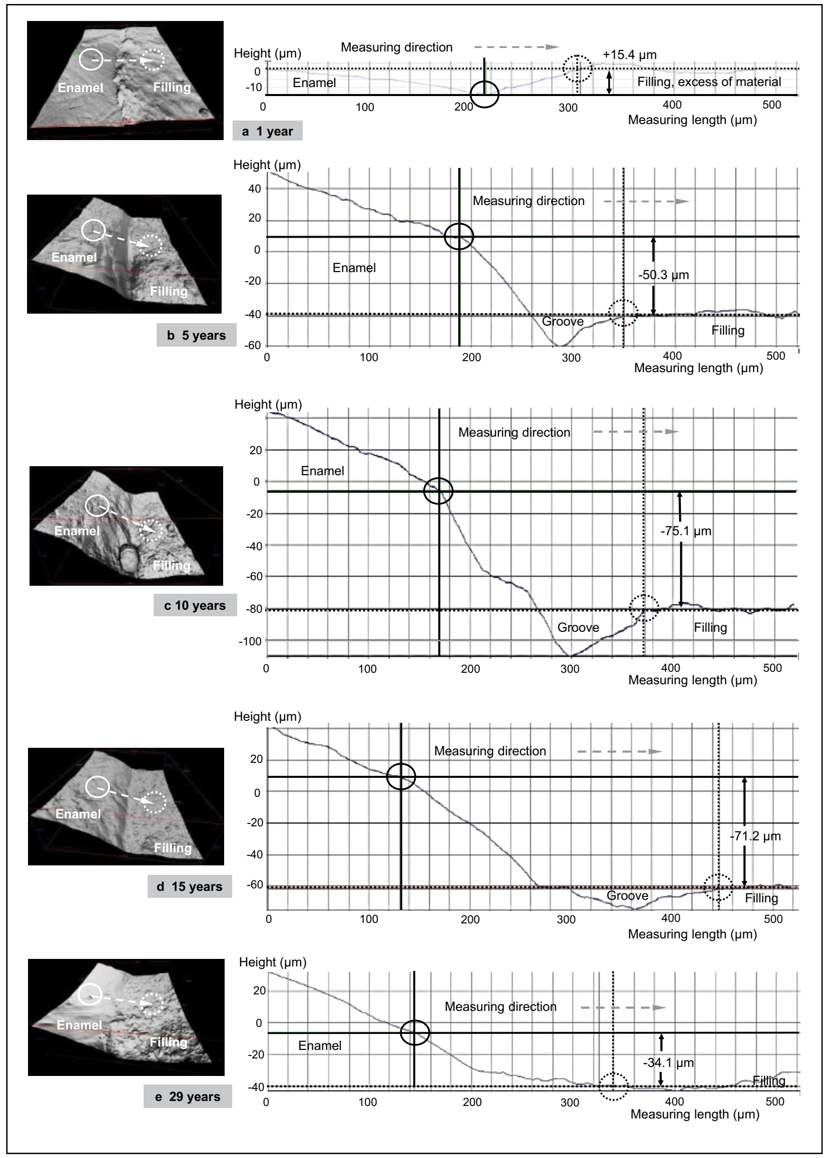

Figure 3. Marginal behavior of a posterior Visio-Molar X restoration over a period of 29 y: (**a**) 1, (**b**) 5, (**c**) 10, (**d**) 15, and (**e**) 29 y. Three-dimensional scanning electron microscopy evaluation: left, computed digital surface model of the investigated marginal area (dashed line, measuring line); right, profilometric estimation of the material loss next to the margin along the measuring line (continuous circle/line, measuring point at enamel margin; dotted circle/line, measuring point at filling surface); original magnification, 150:1.

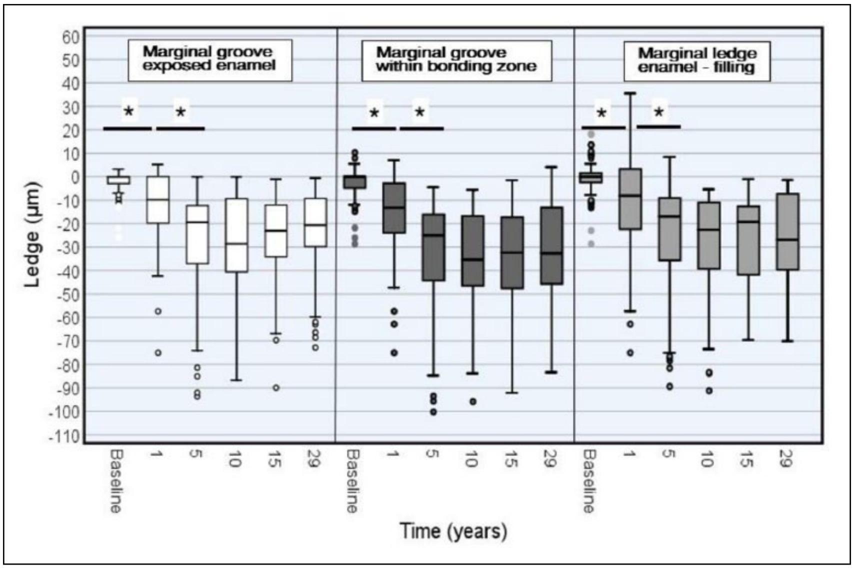

Figure 4. Statistical outcome of masticatory functional equilibrium analysis over 29 y with features of the filling-tooth interface, representing the groove formation next to the enamel and the grooves within the bonding zone, and, finally, the overall marginal ledge formation over time intervals by 3-dimensional scanning electron microscopy profilometric measurements according to Figure 3. The loss of material is represented by negative values and excess material by positive values, with zero representing the enamel margin. The line equals the median; the box represents the 1.5 interquartile range; and the error bars indicate 95% CI. Data points outside this range are marked as o (outlier values) or x (extreme values). Extreme values were not considered inaccurately measured values and were not substituted. They represent valid physical data and have high reliability. *$P < 0.05$, Friedman test.

Should composite restorations last forever? Why do they fail? Since G. V. Black's time, these have been important clinical questions, and a recently published critical review provides a promising and pragmatic answer (Demarco et al. 2017). Restorations perform favorably, and the main reasons for failure are secondary caries and fractures. A rather complex longitudinal in vivo evaluation may examine the mechanisms of failure to answer these questions. Single-arm studies contribute to the overall body of evidence and have already been included in meta-analyses (Schwendicke and Opdam 2018). The present long-term study combined annual follow-up evaluations of sensitive clinical coding with comparable semiquantitative morphologic indexing, followed by quantitative 3D-SEM profilometric measurements. This study provides insight into the marginal fracture and wear behaviors.

Wear behavior initially manifested as singular or multiple marginal fractures of very thin overlapping layers of composite material on the enamel surface. Because of the perfect color match, these layers could not be avoided under clinical conditions, and the excess composite material and subsequent microfractures were never detected in the clinical evaluations with the sensitive US Public Health Service–compatible CPM index. Masticatory function resulted in the wearing away of the microfractures and the opening of the light-cured composite microholes at the surface, which were also worn away within 12 mo. Bulk fractures were not correlated with the appearance and disappearance of marginal fractures. Bulk fractures were detected in 5 cases: 3 cases after 6 mo, 1 y, and 2 y and 2 cases after 13 and 29 y. The early bulk fractures were seemingly operator based, and the late fractures of 2 surface restorations were caused by dynamic fatigue. The micromorphologic deterioration started very early, with many microfractures around the margins, opening shallow or deep gaps and forming grooves and ledges. The typical deterioration pattern was followed by improvement due to mastication. Nevertheless, some gaps remained at the margins for 3 decades; some ledges were still deep; and there was obviously no necessity to replace imperfect restorations. These results indicate that restorative materials should not be condemned because of micromorphologic irregularities with no risk for secondary caries or bulk fractures.

The unique dynamic changes in marginal grooves at the exposed enamel walls, grooves within the bonding zone, and finally, negative marginal ledges could be detected with 3D profilometry. These clinically unknown changes occurred over the entire 29-y evaluation period. Statistical analysis indicated significant differences from baseline to 1 and 5 y. The mean depth values after 10, 15, and 29 y were not significantly different, reflecting the functional masticatory equilibrium of occlusal enamel surfaces, restoration surfaces, and the interface between them. Even in the presence of negative ledges all around the margins, abrasive forces due to chewing and attritive forces due to biting (tooth-to-tooth contact) contribute to mastication equilibrium, periodontal regeneration, and physiologic plaque control (Gaengler and Metzler 1992). Therefore, micromorphologic deterioration of the restoration surface and filling-tooth interface in the first years of service does not predict later filling failures.

In summary, this single-arm prospective, parallel, clinical, and micromorphologic evaluation of class I and class II posterior restorations with composite material as an enamel replacement and with glass ionomer cement as a dentin replacement demonstrates the unique functional behavior of early deterioration and later improvement with physiologic wear. Consequently, the survival rate is high, and the AFR is low.

Author Contributions

R. Montag, W. Dietz, T. Lang, P. Gaengler, contributed to conception, design, and data analysis, drafted and critically revised the manuscript; S. Nietzsche, B.W. Sigusch, contributed to conception, design, and data analysis, critically revised the manuscript; K. Weich, contributed to data analysis, drafted the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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