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ORIGINAL ARTICLE

Nanohybrid vs. fine hybrid composite in extended class II cavities: 8-year results

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Abstract
Objective In a controlled prospective split-mouth study, clinical behavior of two different resin composites in extended class II cavities was observed over 8 years.
Materials and methods Thirty patients received 68 direct resin composite restorations (Solobond M/Grandio, Voco—n=36; Syntac/Tetric Ceram, Ivoclar Vivadent—n=32) by one dentist in a private practice. Thirty-five percent of cavities revealed no enamel at the bottom of the proximal box, 48 % of cavities provided <0.5 mm remaining proximal enamel width. Restorations were examined according to modified US Public Health Service criteria at baseline, after 6 months, and 1, 2, 4, 6, and 8 years.
Results All patients attended the 8-year recall. The overall success rate of all restorations was 98.5 % (Kaplan–Meier survival algorithm). One Grandio restoration was lost due to bulk fracture. One Tetric Ceram restoration suffered drop out due to cusp fracture having been not related to the restoration itself. Neither restorative materials nor localization of the restorations had a significant influence on any criterion except color (darker for Grandio). Restorations in molars performed inferior compared with premolars regarding marginal integrity (4 years), restoration integrity (6, 12, 24, 48, and 96 months), and tooth integrity (12, 48, 72, and 96 months). Irrespective of the resin composite used, significant changes over time were found for all criteria evaluated in clinical examinations. Beyond the 4-year recall, marginal staining increased. Both phenomena were found earlier in molars compared with premolars. Tooth integrity significantly deteriorated because of increasing enamel cracks and chippings over time.
Conclusions Both materials performed satisfactorily over the 8-year observation period. Due to the extension of the restorations, wear was clearly visible after 8 years of clinical service.
Clinical relevance Hybrid and nanohybrid resin composites show an acceptable clinical performance after 8 years of service.

Keywords Resin composites · Nanofillers · Clinical trial · Marginal integrity · Etch and rinse · Extended lesions

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Introduction

Resin composites are today the treatment option of choice for cavitated carious lesions [1–4]. For dental biomaterials that shrink upon polymerization, durable adhesion to tooth

hard tissues is a fundamental prerequisite for clinical success [5–9]. When adhesion fails, gap formation and secondary caries affect overall clinical outcome [10–13]. There is still a difference in reliability when bonding to enamel [1, 6, 12, 14–16] is compared with dentin adhesion [8, 9, 13, 17–20], but also the latter is meanwhile clinically acceptable for appropriate sealing and low rates of postoperative hypersensitivities [4–7, 11, 12, 21, 22]. Although bonded resin composites were repeatedly reported to durably seal dentin at least with multistep adhesives [14, 17, 19, 23–25], long-term seal in class II cavities with proximal margins in dentin is still questionable. Preclinical studies utilizing chewing simulation scenarios exhibited promising results for multistep adhesives compared with simplified adhesive systems [23, 24, 26–28]. Recent results showed no influence of margin location (above vs. beneath the CEJ) in vivo [29].

However, prospective clinical long-term trials remain the ultimate instrument to elucidate this problem; on the other hand, in vitro investigations are still required in order to provide preclinical screening [17, 26, 30]. Finally, a recurrent problem with clinical trials is that after some years of clinical testing, the evaluated materials could not be in the market anymore [1, 11, 12, 15, 16, 31, 32]. Amalgam was repeatedly discussed to be superior to resin composites for restoration of extended defects or in patients with high caries risk [21, 33].

Although a few new material developments have been observed during the last decade, such as hybrid resin composites, fine hybrid resin composites, nanohybrid resin composites, purely nanofilled resin composites, and silorane-based composites, general clinical problems remained similar [34–39]. Moreover, most of the more recent clinical studies were not able to demonstrate improved clinical outcome with more innovative materials; furthermore, in most of the cases, the reports show no real long-term results compared with the present investigation [40, 41]. Also, the claim that modern nanohybrid resin composite may provide an enamel-like wear behavior has not been proven [42, 43].

The aim of this clinical trial was to investigate two different restorative material systems (i.e., adhesive and resin composite) in extended class II cavities over 8 years in order to observe differences between conventional (Tetric Ceram) and partially nanofilled (Grandio) resin composites. The null hypothesis tested was that there would be no difference between the different resin composites with their respective adhesives under investigation.

Materials and methods

Patients selected for this study met the following criteria: (1) absence of pain from the tooth to be restored, (2) possible application of rubber dam during luting of restoration, (3) no further restorations planned in other posterior teeth, (4) high level of oral hygiene, (5) absence of any active periodontal and pulpal desease, (6) restorations required in two different quadrants (split mouth design), (7) ages 18–65, and (8) no pregnancy.

The study was approved by an Ethics Committee (University Clinic Erlangen, Germany). All patients were required to give written informed consents before starting the study and agreed to participate in a recall program. Thirty patients (23 females and 7 males; mean age, 32.9 (24–59) years) with a minimum of two fillings to be replaced in different quadrants received at least two different restorations in a random decision according to recommendations of the CONSORT statement [44]. Sample size calculation was carried according to previous clinical studies [1, 12, 45]. Occluding teeth were not excluded [45].

Thirty-six Grandio fillings were bonded using an etch-and-rinse technique using Solobond M (Voco, Cuxhaven, Germany) and 32 Tetric Ceram restorations were bonded with Syntac (Ivoclar Vivadent, Schaan, Liechtenstein). All fillings (only class II, 52 MO/OD, 16 MOD or more surfaces, no cusp replacements) were re-restorations made by one dentist in a private practice (31 upper bicuspids, 12 upper molars, 14 lower bicuspids, and 11 lower molars). Reasons for replacement were caries (n=19), insufficient esthetics (n=2), and secondary caries beneath amalgam restorations (n=47). For all teeth receiving restorations, current X-rays (within 6 months of the procedure) were present. After evaluating the radiographs, 53 cavities (78 %) were treated as caries profunda. Twenty-four cavities (35 %) revealed no enamel at the floor of the proximal box, while 33 cavities (49 %) exhibited a proximal enamel width of <0.5 mm.

Table 1 Evaluated clinical codes and criteria

Modified criteria	Description	Analogous USPHS criteria
"Excellent"	Perfect	"Alpha"
"Good"	Slight deviations from ideal performance and correction possible without damage to tooth or restoration	
"Sufficient"	Few defects and correction impossible without damage to tooth or restoration. No negative effects expected	"Bravo"
"Insufficient"	Severe defects and prophylactic removal for prevention of severe failures	"Charlie"
"Poor"	Immediate replacement necessary	"Delta"

Table 2 Results of USPHS assessment for all restorations under observation

	Date of investigation (months)															
	1.2			24.4			49.2			73.3			98.2			
	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Charlie (%)
Criterion																
Surface roughness	100			99	1		93	7		82	18		78	12		
Color match	94	6		93	7		84	13	3	84	16		70	30		
Marginal integrity	44	54	2		60	40		34	66		41	59		18	82	
Integrity tooth	91	9		40	47	13	29	56	15	31	48	21	12	64	24	
Integrity restoration	93	4	3	9	41	50	1	25	74	3	34	63		15	84	1
Proximal contact	94	4	2	82	16	2	91	7	1	85	13	2	79	19	2	
Change of sensitivity	97		3	100			100			98		2	100			
Hypersensitivity	91	7	2	100			100			100			100			
Radiographic assessment	91	4	5				96	1	3							

Table 3 Results of USPHS assessment for Grandio restorations under observation

	Baseline (n=36)			2 years (n=36)			4 years (n=36)			6 years (n=36)			8 years (n=36)			
	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Charlie (%)
Criterion																
Surface roughness	100			97	3		92	8		78	22		69	31		
Color match	92	8		92	8		81	14	5	78	22		58	42		
Marginal integrity	50	47	3		53	47		36	64		39	61		19	81	
Integrity tooth	86	14		47	42	11	31	58	11	33	50	17	17	67	16	
Integrity restoration	100			11	45	44	3	28	69	3	39	58		17	80	3
Proximal contact	94	3	3	89	11		94	6		83	17			81	19	
Change of sensitivity	100			100			100			100				100		
Hypersensitivity	97	3		100			100			100				100		
Radiographic assessment	89	3	8				97	3								

All fillings were inserted in permanent vital teeth without pain symptoms. Extension for prevention was disregarded for maximal substance protection; however, the majority of restorations were previously prepared with undercuts for amalgam retention. The cavities were cut using coarse diamond burs under profuse water cooling (80 μm diamond, Komet, Lemgo, Germany), and finished with a 25-μm finishing diamond. Inner angles of the cavities were rounded and the margins were not bevelled. After cleaning and drying under rubber dam isolation (Coltene/Whaledent Inc., Altstätten, Switzerland), adhesive procedures were performed with Solobond M (two-step etch-and-rinse adhesive) and Syntac (four-step etch-and-rinse adhesive). The resin composite materials were applied into the cavity in layers of approximately 2-mm thickness and adapted to the cavity walls with a plugger. Each layer was light cured for 40 s (Elipar Trilight, 3M ESPE, Seefeld, Germany). The occlusal region was modeled as exactly as possible under intraoral conditions, avoiding visible overhangs. The light-emission window was placed as close as possible to the cavity margins. The intensity of the light was checked periodically with a radiometer (Demetron Research Corp., Danbury, CT) and was found to be constantly above 650 mW/cm^2.

As soon as polymerization was completed, the surface of the restoration was controlled for defects and corrected when necessary. Visible overhangs were removed with a scaler and the rubber dam was removed. Contacts in centric and eccentric occlusion were controlled with foils (Roeko, Langenau, Germany) and adjusted with finishing diamonds (Komet Dental, Lemgo, Germany), shaped with flexible discs (3M Dental, St. Paul, MN), super-fine discs (3M Dental) and polishing brushes (Hawe-Neos Dental, Bioggio, Switzerland). A fluoride varnish (Elmex Fluid, GABA, Lörrach, Germany) was used to complete the treatment.

At the initial recall (baseline, i.e., within 2 weeks), and after 6 months and 1, 2, 4, 6, and 8 years, all restorations were assessed according to the modified US Public Health Service criteria (Tables 1 and 2) by two independent investigators (dentists, both chairpersons) using loups with ×3.5 magnification, mirrors, probes, bitewing radiographs, impressions (Dimension Penta and Garant, 3M ESPE), and intraoral photographs. Investigators were blinded, trained, and calibrated through eight previous clinical studies and additional calibration sessions. Replicas were collected for later marginal and wear analysis (studies in preparation). Recall assessments were not performed by the clinician who initially placed the restorations.

Table 4 Results of USPHS assessment for Tetric Ceram restorations under observation

	Baseline (n=32)			2 years (n=32)			4 years (n=32)			6 years (n=32)			8 years (n=31)			
	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Alpha 1 (%)	Alpha 2 (%)	Bravo (%)	Charlie (%)
Criterion																
Surface roughness	100			100			94	6		87	13		87	13		
Color match	97	3		94	6		88	13		91	9		84	16		
Marginal integrity	37	63			69	31		31	69		44	56		16	84	
Integrity tooth	97	3		31	53	16	28	53	19	28	47	25	7	61	32	
Integrity restoration	85	9	6	6	38	56		22	78	3	28	69		13	87	
Proximal contact	94	3	3	75	22	3	88	9	3	88	9	3	77	19	3	
Change of sensitivity	94		6	100			100			97		3	100			
Hypersensitivity	84	13	3	100			100			100			100			
Radiographic assessment	94	6					94	3	3							

Table 5 Results of USPHS assessment for all restorations under observation regarding "marginal integrity" (all restorations)

Criterion	Baseline (n=68; %)	24 months (n=68; %)	48 months (n=68; %)	72 months (n=68; %)	96 months (n=67; %)
Alpha I (excellent)	44.1	0.0	2.9	0.0	0.0
Alpha II (slight defects and easily correctable)					
Negative step	8.8	44.1	29.4	38.2	14.9
Overhang	44.1	5.9	4.4	1.5	3.0
Stained overhang	1.5	10.3	0.0	1.5	0.0
Bravo (slight defects and not correctable without damage)					
Gap/negative step	1.5	16.2	22.1	11.8	29.9
Staining	0.0	23.5	41.2	47.1	52.2

Statistical appraisal was computed with SPSS for Windows XP 14.0 (SPSS inc., Chicago, IL). Statistical unit was one tooth, differences between groups were evaluated using Mann–Whitney U test, changes over time were calculated with the Friedman test (p=0.05).

Results

All patients attended the 8-year recall. One Tetric Ceram restoration failed due to cusp fracture independent of the material (drop out). The overall success rate of all restorations was 98.5 % (Kaplan–Meier survival algorithm). One Grandio restoration was lost due to bulk fracture.

Results of the clinical investigation are displayed in Tables 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, and 17. Neither restorative materials nor localization of the restorations (upper or lower jaw) had a significant influence on any criterion after 8 years (p>0.05; Mann–Whitney U test), with one exception: After 8 years of clinical service, the color of Grandio restorations was significantly darker (p <0.05; Mann–Whitney U test; Tables 3 and 4). However, restorations in molars performed inferior compared with premolars regarding marginal integrity (4 years), integrity restoration (6, 12, 24, 48, and 96 months), and integrity tooth (12, 48, 72, and 96 months; Tables 14 and 16).

Main reasons for degradation of restorative materials were chippings and cracks in molar restorations after 8 years (Table 17). Premolar restorations exhibited less tight proximal contacts after 96 months (27.3 vs. 8.7 %; Mann–Whitney U test; p<0.05). Irrespective of the resin composite used, significant changes over time were found for all criteria evaluated in clinical examinations (Friedman test; p<0.05). Marginal integrity started with a major portion of overhangs in all marginal areas until the 1-year recall and distinctly dropped afterwards (overhangs at baseline 44 %; 6 months, 65 %; 1 year, 47 %; 2 years, 6 %; 4 years, 4 %; 6 years, 3 %; and 8 years, 3 %). Beyond the 1-year recall, negative step formations were found due to wear of the resin composite (Tables 5, 6, and 7; Fig. 1c, d). Beyond the 4-year recall, marginal staining increased. Both phenomena were found earlier in molars (61 % bravo due to stained margins after 4 years, and 74 % after 8 years) compared with premolars (31 % bravo due to stained margins after 4 years and 41 % after 8 years; Table 14).

Table 6 Results of USPHS assessment for Grandio restorations regarding "marginal integrity"

Criterion	Baseline (n=36; %)	24 months (n=36; %)	48 months (n=36; %)	72 months (n=36; %)	96 months (n=36; %)
Alpha I (excellent)	50.0	0.0	0.0	0.0	0.0
Alpha II (slight defects and easily correctable)					
Negative step	5.6	38.9	27.8	33.3	16.7
Overhang	38.9	2.8	8.3	2.8	2.8
Stained overhang	2.8	11.1	0.0	2.8	0.0
Bravo (slight defects and not correctable without damage)					
Gap/negative step	2.8	19.4	25.0	8.3	30.6
Staining	0.0	27.8	38.9	52.8	50.0

Table 7 Results of USPHS assessment for Tetric Ceram restorations regarding "marginal integrity"

Criterion	Baseline (n=32; %)	24 months (n=32; %)	48 months (n=32; %)	72 months (n=32; %)	96 months (n=32; %)
Alpha I (excellent)	37.5	0.0	0.0	0.0	0.0
Alpha II (slight defects and easily correctable)					
Negative step	12.5	50.0	31.3	43.8	12.9
Overhang	50.0	9.4	0.0	0.0	3.2
Stained overhang		9.4	0.0	0.0	0.0
Bravo (slight defects and not correctable without damage)					
Gap/negative step	0.0	12.5	21.9	15.6	29.0
Staining	0.0	18.8	46.9	40.6	54.8

Tooth integrity significantly deteriorated because of increasing enamel cracks and chippings over time (9 % at baseline and 88 % after 8 years; $p<0.05$; Table 8). Enamel chippings or cracks were significantly more often observed in molars (39 % after 8 years) than in premolars (16 % bravo after 8 years; Table 15). Main reasons for decreasing "integrity restoration" were distinct wear traces (94 % after 8 years; Fig. 1c, d), cracks, and chippings of the restoration (38 % after 8 years), as well as voids having been exposed after resin composite wear (16 % after 8 years). Significantly, more cracks were detected in molar restorations (Mann–Whitney U test, $p<0.05$; Table 17).

Discussion

The most recent recommendations for clinical trials with restorative materials [32] could not be addressed in the present study, because these recommendations were published considerably after its beginning. Therefore, it was not possible to include more evaluation aspects beside well-suited protocols, such as the CONSORT statement [15, 16, 42, 44]. On the other hand, the clinical procedure, the blinded, randomized prospective approach demonstrated during the 7 years of this clinical trial that this is a good and scientifically acceptable way of conducting clinical trials. However, only maintaining a consistently high number of participants during all recall sessions allowed to draw significant conclusions regarding clinical outcome of the materials having been under investigation. The observed recall rate of almost 100 % is very good after a long time span of 8 years. In the present practice-based research attempt, this is clearly attributed to the operating dentist providing reliable patients as well as good binding to his work. The reported drop out of one Tetric Ceram restoration was due to a cusp fracture. It was not counted as failure of the restoration because the adjacent tooth suffered a similar fracture without restoration. Without appropriately realized adhesion to tooth hard tissues, clinical success with shrinking dental biomaterial is not possible [10–12, 18, 31, 43]. It is a proven fact that resin-based composites are well-suited for minimally invasive

Table 8 Results of USPHS assessment regarding "integrity tooth" (all restorations)

Criterion	Baseline (n=68; %)	24 months (n=68; %)	48 months (n=68; %)	72 months (n=68; %)	96 months (n=68; %)
Alpha I (excellent)	91.2	39.7	29.4	30.9	11.9
Alpha II (slight defects and easily correctable)					
Enamel chipping	1.5	4.4	0.0	5.9	3.0
Enamel crack	7.4	42.6	55.9	41.2	61.2
Wear	0.0	0.0	0.0	1.5	0.0
Bravo (slight defects and not correctable without damage)					
Enamel chipping	0.0	10.3	0.0	13.2	20.9
Enamel crack	0.0	2.9	14.7	5.9	3.0
Wear	0.0	0.0	0.0	1.5	0.0

Table 9 Descriptive statistics regarding "integrity tooth" (Grandio restorations).

Criterion	Baseline (*n*=36; %)	24 months (*n*=36; %)	48 months (*n*=36; %)	72 months (*n*=36; %)	96 months (*n*=36; %)
Alpha I (excellent)	86.1	47.2	30.6	33.3	16.7
Alpha II (slight defects and easily correctable)					
Enamel chipping	2.8	2.8	0.0	5.6	2.8
Enamel crack	11.1	38.9	58.3	41.7	63.9
Wear	0.0	0.0	0.0	2.8	0.0
Bravo (slight defects and not correctable without damage)					
Enamel chipping	0.0	8.3	11.1	8.3	13.9
Enamel crack	0.0	2.8	0.0	5.6	2.8
Wear	0.0	0.0	0.0	2.8	0.0

Table 10 Results of USPHS assessment for Tetric Ceram restorations regarding "integrity tooth"

Criterion	Baseline (*n*=32; %)	24 months (*n*=32; %)	48 months (*n*=32; %)	72 months (*n*=32; %)	96 months (*n*=31; %)
Alpha I (excellent)	96.9	31.3	28.1	28.1	6.5
Alpha II (slight defects and easily correctable)					
Enamel chipping	0.0	6.3	0.0	6.3	3.2
Enamel crack	3.1	46.9	53.1	40.6	58.1
Bravo (slight defects and not correctable without damage)					
Enamel chipping	0.0	12.5	18.8	18.8	29.0
Enamel crack	0.0	3.1	0.0	6.3	3.2
Wear	0.0	0.0	0.0	0.0	0.0

Table 11 Results of USPHS assessment for all restorations regarding "integrity restoration"

Criterion	Baseline (*n*=68; %)	24 months (*n*=68; %)	48 months (*n*=68; %)	72 months (*n*=68; %)	96 months (*n*=67; %)
Alpha I (excellent)	92.6	8.8	1.5	2.9	0.0
Alpha II (slight defects and easily correctable)					
Chipping	2.9	0.0	0.0	1.5	1.5
Crack	0.0	1.5	0.0	0.0	0.0
Abrasion	0.0	39.7	25.0	32.4	13.4
Roughness	1.5	0.0	0.0	0.0	0.0
Bravo (slight defects and not correctable without damage)					
Chipping	0.0	2.9	7.4	2.9	7.5
Crack probing	2.9	0.0	4.4	1.5	7.5
Abrasion	0.0	30.9	51.5	58.8	67.2
Roughness	0.0	4.4	7.4	0.0	0.0
Void	0.0	11.8	2.9	0.0	1.5
Charlie (prophylactic removal for prevention of severe failures)					
Chipping	0.0	0.0	0.0	0.0	1.5
Crack probing	0.0	0.0	0.0	0.0	0.0
Abrasion	0.0	0.0	0.0	0.0	0.0
Roughness	0.0	0.0	0.0	0.0	0.0
Void	0.0	0.0	0.0	0.0	0.0

Table 12 Results of USPHS assessment for Grandio restorations regarding "integrity restoration"

Criterion	Baseline (*n*=36; %)	24 months (*n*=36; %)	48 months (*n*=36; %)	72 months (*n*=36; %)	96 months (*n*=36; %)
Alpha I (excellent)	100.0	11.1	2.8	2.8	0.0
Alpha II (slight defects and easily correctable)					
Chipping	0.0	0.0	0.0	0.0	2.8
Crack	0.0	0.0	0.0	0.0	0.0
Abrasion	0.0	44.4	27.8	38.9	13.9
Roughness	0.0	0.0	0.0	0.0	0.0
Bravo (slight defects and not correctable without damage)					
Chipping	0.0	5.6	8.3	2.8	2.8
Crack probing	0.0	0.0	2.8	0.0	8.3
Abrasion	0.0	16.7	50.0	55.6	66.7
Roughness	0.0	5.6	8.3	0.0	0.0
Void	0.0	16.7	0.0	0.0	2.8
Charlie (prophylactic removal for prevention of severe failures)					
Chipping	0.0	0.0	0.0	0.0	2.8
Crack probing	0.0	0.0	0.0	0.0	0.0
Abrasion	0.0	0.0	0.0	0.0	0.0
Roughness	0.0	0.0	0.0	0.0	0.0
Void	0.0	0.0	0.0	0.0	0.0

primary cavities without pre-existing restoration [1, 2, 33]. However, it is still unclear how far cavities can go in terms of proximal extension [29, 34, 45]. It was repeatedly argued that resin composites may be inferior in very extended cavities and should therefore be replaced by other materials and techniques, such as amalgam or even indirect restorations [21]. Facing cavity extension, main arguments against bonded resin-based composites are secondary caries risk of and extensive wear rates after a certain amount of clinical service years [38, 39, 44, 45]. The secondary caries issue is more pronounced when proximal margins are located in dentin in class II cavities. At least from in vitro and in vivo investigations dealing with indirect ceramic inlays and onlays, it is proven that even margins extending beyond the amelocemental junction can be safely re-

Table 13 Results of USPHS assessment for Tetri Ceram restorations regarding "integrity restoration"

Criterion	Baseline (*n*=32; %)	24 months (*n*=32; %)	48 months (*n*=32; %)	72 months (*n*=32; %)	96 months (*n*=31; %)
Alpha I (excellent)	84.4	6.3	0.0	3.1	0.0
Alpha II (slight defects and easily correctable)					
Chipping	6.3	0.0	0.0	3.1	0.0
Crack	0.0	3.1	0.0	0.0	0.0
Abrasion	0.0	34.4	21.9	25.0	12.9
Roughness	3.1	0.0	0.0	0.0	0.0
Bravo (slight defects and not correctable without damage)					
Chipping	0.0	0.0	6.3	3.1	12.9
Crack probing	6.3	0.0	6.3	3.1	6.5
Abrasion	0.0	46.9	53.1	62.5	67.7
Roughness	0.0	3.1	6.3	0.0	0.0
Void	0.0	6.3	6.3	0.0	0.0

Table 14 Results of USPHS assessment of premolars vs. molars regarding "marginal integrity"

Criterion	48 months		72 months		96 months	
	Premolars (n=45; %)	Molars (n=23; %)	Premolars (n=45; %)	Molars (n=23; %)	Premolars (n=44; %)	Molars (n=23; %)
Alpha I (excellent)	2.2	4.3	0.0	0.0	0.0	0.0
Alpha II (slight defects and easily correctable)						
Negative step	40.0	8.7	44.4	26.1	18.2	8.7
Overhang	6.7	0.0	2.2	0.0	2.3	4.3
Stained overhang	0.0	0.0	2.2	0.0	0.0	0.0
Bravo (slight defects and not correctable without damage)						
Gap/negative step	20.0	26.1	8.9	17.4	38.6	13.0
Staining	31.1	60.9	42.2	56.5	40.9	73.9

No significant difference could be calculated after 72 (p=0.073) and 96 months (p=0.456) in contrast to the result after 48 months (p=0.007; Mann–Whitney U test)

stored [6, 16, 25, 44]. For class V restorations, it is similar, although 50 % of margin lengths are located in dentin here [4, 19, 20, 22]. On the other hand, proximal marginal seal in dentin-bordered cavities restored with direct resin composite restorations, this particular information is underrepresented in the literature of the field [21]. However, recent findings of Kuper et al. are promising, having shown no significant effect of proximal cavity extension below the CEJ [29]. In addition, the individual setup of the present clinical trial was mainly focusing on amalgam replacement restorations resulting in 35 % of cavities with no proximal-cervical enamel and 49 % with <0.5 mm proximal enamel width giving severe conditions to restore. Finally, even after 8 years of clinical service in stress-bearing cavities, these restorations did not reveal significantly worse clinical outcomes, and moreover, neither recurrent caries nor severe marginal staining was detected. Nevertheless, a considerable marginal deterioration was clinically detected beyond the 6-year recall. After re-evaluation of the cavity images from the treatment session, it became obvious, that larger cavities especially in molars suffered significantly larger portions of marginal staining, especially when dentin support was weak after caries excavation.

Resin-based composites have to be durably bonded for acceptable clinical outcome [5, 10, 11, 14, 31]. Restorative materials for the present study were selected after thorough in vitro testing having given promising results for both materials used, in terms of good marginal adaptation and long-term occlusal stability [24, 27, 28, 46, 49]. This safety procedure was chosen due to the problematic outcome of previous studies with materials having failed at least some preclinical screenings [15, 46, 49]. Adhesives under investigation partially required special bonding protocols, i.e. wet bonding

Table 15 Descriptive statistics of premolars vs. molars regarding "integrity tooth"

Criterion	48 months		72 months		96 months	
	Premolars (n=45; %)	Molars (n=23; %)	Premolars (n=45; %)	Molars (n=23; %)	Premolars (n=44; %)	Molars (n=23; %)
Alpha I (excellent)	37.8	13.0	42.2	8.7	18.2	0.0
Alpha II (slight defects and easily correctable)						
Enamel chipping	0.0	0.0	6.7	4.3	2.3	4.3
Enamel crack	53.3	60.9	35.6	52.2	63.6	56.5
Wear	0.0	0.0	2.2	0.0	0.0	0.0
Bravo (slight defects and not correctable without damage)						
Enamel chipping	8.9	26.1	6.7	26.1	13.6	34.8
Enamel crack	0.0	0.0	4.4	8.7	2.3	4.3
Wear	0.0	0.0	2.2	0.0	0.0	0.0

Significant differences could be calculated after 48 (p=0.013), 72 (p=0.003), and 96 months (p=0.007; Mann–Whitney U test)

Table 16 Results of USPHS assessment for premolars vs. molars regarding "integrity restoration"

Criterion	48 months		72 months		96 months	
	Premolars (n=45; %)	Molars (n=23; %)	Premolars (n=45; %)	Molars (n=23; %)	Premolars (n=44; %)	Molars (n=23; %)
Alpha I (excellent)	2.2	4.3	0.0	8.7	0.0	0.0
Alpha II (slight defects and easily correctable)						
Chipping	2.2	0.0	2.2	0.0	2.3	0.0
Crack	0.0	0.0	0.0	0.0	0.0	0.0
Roughness/abrasion	33.3	4.3	40.0	17.3	20.5	0.0
Bravo (slight defects and not correctable without damage)						
Chipping	4.4	8.7	4.4	0.0	6.8	8.7
Crack probing	4.4	4.3	2.2	0.0	6.8	8.7
Abrasion	40.0	73.9	51.1	73.9	63.6	73.9
Roughness	8.9	4.3	0.0	0.0	0.0	0.0
Void	4.4	0.0	0.0	0.0	0.0	4.3
Charlie (severe defects and prophylactic removal for prevention of severe failures)						
Chipping	0.0	0.0	0.0	0.0	0.0	4.3
Crack probing	0.0	0.0	0.0	0.0	0.0	0.0
Abrasion	0.0	0.0	0.0	0.0	0.0	0.0
Roughness	0.0	0.0	0.0	0.0	0.0	0.0
Void	0.0	0.0	0.0	0.0	0.0	0.0

No significant difference could be calculated after 72 months (p=0.085) in contrast to the result after 48 months (p=0.048) and after 96 months (p=0.007; Mann–Whitney U test)

with the acetone-based Solobond M, however, without significant clinical problems such as postoperative hypersensitivities. At beseline, Syntac produced even slightly more hypersensitivities (baseline to 6 months; 3 vs. 0 % bravo scores) but without further limitations beyond the 1-year recall. Therefore, both the internal sealing of dentin and tight dentin margins were possible with the different adhesive approaches under investigation, i.e., two- vs. four-step etch-and-rinse adhesives.

A distinct limitation in terms of clinical comparison is working with complete restorative systems (i.e., adhesive plus resin composite). This is always more complex than evaluating two adhesives with one resin composite for a smaller number of variables involved. This study was not designed to thoroughly elucidate this issue; however, promising results over the 8-year period confirm the hypothesis that both systems are clinically acceptable.

Nanofillers have been frequently incorporated into recent resin composite formulations during the last decade. Improved translucency effects for incisal esthetics and increased polishability are clear advantages

Table 17 Results of USPHS assessment for premolars vs. molars regarding "integrity restoration" after 96 months

Criterion	Crack/chipping		Abrasion		Voids	
	Premolars (n=44; %)	Molars (n=23; %)	Premolars (n=44; %)	Molars (n=23; %)	Premolars (n=44; %)	Molars (n=23; %)
Alpha I (excellent)	70.5	43.5	4.5	4.3	84.1	82.8
Alpha II (slight defects and easily correctable)	9.1	4.3	25.0	4.3	4.5	0.0
Bravo (slight defects and not correctable without damage)	20.5	47.8	70.5	91.3	11.4	17.4
Charlie (severe defects and prophylactic removal for prevention of severe failures)	0.0	4.3	0.0	0.0	0.0	0.0

In contrast to Tables 14, 15, and 16, the data are listed in relation to the subcriteria "cracks and chipping," "abrasion," and "voids" due to possible multiple ratings per criterion. Significant difference were calculated for the criterion "cracks and chippings" after 96 months (p=0.028) and "abrasion" after 48 (p=0.02) and 72 months (p=0.042; Mann–Whitney U test)

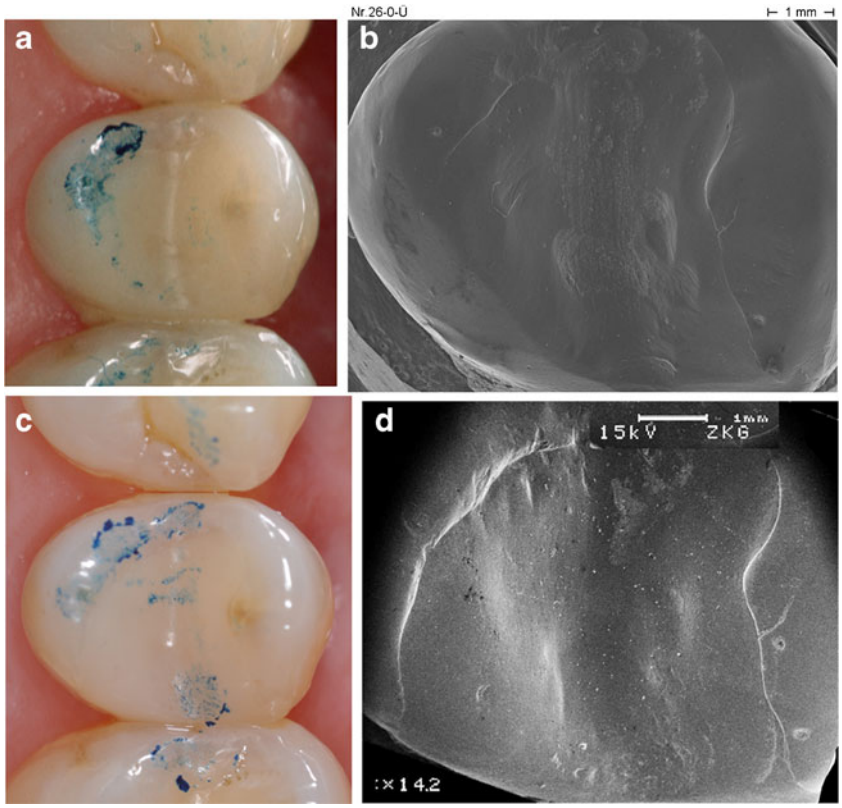

Fig. 1 **a** Clinical view of a Grandio restoration at baseline. Occlusal loading occurs mainly at the palatal cusp (blue marks). **b** Tooth of (**a**) at baseline, SEM overview. **c** Clinical view of the Grandio restoration of (**a**) after 8 years. Due to occlusal contact wear, the contact points are stronger in enamel than on the worn resin composite. **d** SEM view of (**c**). In the occlusal contact area, the material is roughened. The buccal crack of (**b**) is now longer

of this technology [12, 47, 48]. Irrespective of these more esthetic-related factors, clinical trial with this class of materials were not able to work out significantly optimized outcome or increased lifetime in vivo [12]. In the present study setup, Tetric Ceram was used classically as fine hybrid resin composite (i.e., without nanofillers); whereas, Grandio was used as one of the first resin composites with nanofiller addition to hybrid type fillers as the so-called nanohybrid resin composite [12, 34, 39]. However, the present 8-year findings could also not demonstrate superior clinical performance of nanofillers vs. conventional hybrid resin composite.

Altogether, the null hypothesis of the present investigation could not be rejected because there was no significant difference in the clinical behavior between Grandio and Tetric Ceram used for extended class II posterior restorations after 8 years of clinical service.

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Conflict of interest statement The authors declare that they have no conflict of interest.

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