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CHAPTER 5

Microhybrid vs. nanohybrid resin composites in extended cavities after 6 years.

Introduction

Although a prospective clinical trial is not an in vitro study as reflected by the topic of the present thesis, clinical data are the one and only desirable comparison tool for dental restorative materials. Moreover, they can be linked to preclinically evaluated in vitro data. Therefore, it is important to compare the presented in vitro data with clinical outcome of directly bonded dental biomaterials such as resin-based composites.

Cavitated carious lesions are today predominantly restored by use of resin composites.[1-4] Durable adhesion to tooth hard tissues still is the fundamental prerequisite for pit and fissure sealings, direct and indirect resin composites, and bonded all-ceramic restorations [5-9]. When adhesion mechanisms fail, gap formation and secondary caries corroborate clinical success of restorations [10-13].

Bonding to enamel is clinically durable at least when the etch-and-rinse approach is applied,[1,6,12,14-16] dentin still provides inferior adhesion,[8,9,13,17-20] but also clinically acceptable sealing is obtainable to limit the occurrence of postoperative hypersensitivity.[4,6,7,11,12,21,22] Although bonded resin composites have proven to durably seal dentin especially with multi-step adhesives,[14,17,19,23-25] it is still unclear whether it is possible to maintain a stable proximal seal in Class II cavities with proximal margins extending beyond the amelocemental junction. *In vitro* studies give varying results after thermomechanical loading and/or long-term storage, mostly with distinct advantages for two- or three-step adhesives compared to simplified adhesive systems.[23,24,26-28] Prospective clinical trials remain ultimate instruments, but preclinical *in vitro* investigations are still needed for experimental questions and preclinical screening.[17,26,29]

One of the most severe problems of clinical trials of dental materials is apparent: while affording acceptable results after some years of clinical service, there is a certain risk that the adhesive and/or resin composite under investigation is not in the market anymore.[1,11,12,15,16,30,31] However, it is not a matter of course that this kind of clinical trial reveals favorable results, so also catastrophic outcomes were observed when fundamental prerequisites are neglected such as hygroscopic expansion or flexural fatigue behavior.[15] And it may be still true that, e.g. amalgam, may be superior to resin composites for restoration of very extended defects,[21]

Research and development of resin-based composites during the last decade generated different subspecies of restorative materials, such as hybrid resin composites, fine hybrid resin composites, nanohybrid resin composites, or even nano resin composites (Filtek Supreme XTE, 3M ESPE, Seefeld, Germany). Especially the latter ones entered the market with claims of less polymerization shrinkage, lowered shrinkage stress and even higher wear resistance.[32-37] In most of the cases, however, a truly better clinical outcome is not proven. On the other hand, it is stated from recent in vivo results that modern nano hybrid resin composite may provide an enamel-like wear behavior.[38,39]

Therefore, 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 6 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.

Methods and Materials

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).

Thirty patients (23 female, 7 male, mean age 32.9 (24-59) years) with a minimum of two restorations to be replaced in different quadrants received at least two different restorations in a random decision according to recommendations of the CONSORT statement.[40] Thirty-six Grandio restorations were bonded with Solobond M (Voco, Cuxhaven, Germany) and 32 Tetric Ceram restorations were bonded with Syntac (Ivoclar Vivadent, Schaan, Liechtenstein). All restorations (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, 11 lower molars). Reasons for replacement were caries (n=19), insufficient esthetics (n=2), and secondary caries (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.

All restorations were inserted in permanent vital teeth without pain symptoms. An 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 (2-step etch-and-rinse adhesive) and Syntac (4-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 seconds (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., Danburg, CT, USA) and was found to be constantly above 650 mW/cm^2.

As soon as polymerization was completed, the surface of the restoration was checked 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 checked with foils (Roeko, Langenau, Germany) and adjusted with finishing diamonds (Komet Dental, Lemgo, Germany), shaped with flexible discs (3M Dental, St. Paul, USA), super-fine discs (3M Dental, St. Paul, USA) 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, 1, 2, 4, and 6 years, all restorations were assessed according to the modified United States Public Health Service (USPHS) criteria (Tables 5.1 and 5.2) by two independent investigators using loupes with x3.5 magnification, mirrors, probes, bitewing radiographs, impressions (Dimension Penta and Garant, 3M-ESPE, Seefeld, Germany), and intraoral photographs. 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.

Statistical appraisal was computed with SPSS for Windows XP 14.0 (SPSS Inc., Chicago, IL, USA). 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).

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

Table 5.1: Evaluated clinical codes and criteria.

Results

The overall success rate was 100% after 6 years of clinical service, while drop out of patients was 0%. Results of the clinical investigation are displayed in Tables 5.2-5.7. Neither restorative material nor localization of the restoration (upper or lower jaw) had a significant influence on any criterion after 6 years (p>0.05; Mann-Whitney U test). However, molar restorations performed worse than premolar restorations regarding marginal integrity (4 years), restoration integrity (6, 12, 24, 48 months), and tooth integrity (4 and 6 years; Table 5.8). Irrespective of the resin composite used, significant changes over time were found for all criteria applied in clinical

examinations (Friedman test; $p<0.05$). Marginal integrity started with a major portion of overhangs in all marginal areas having been detected until the 1-year recall and distinctly dropping afterwards (overhangs at baseline 44%; 6 months: 65%; 1 year: 47%; 2 years: 6%; 4 years: 4%; and 6 years: 3%). Beyond the 1-year recall, more and more negative step formations due to wear were detected (Table 5.5). This phenomenon was earlier seen in molars (87 % bravo after 4 years) than in premolars (51 % bravo after 4 years; Table 5.8a).

	Baseline (n=68)			2 Years (n=68)			4 Years (n=68)			6 Years (n=68)		
	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo
	[%]			[%]			[%]			[%]		
Date of investigation	**1.2 months**			**24.4 months**			**49.2 months**			**73.3 months**		
Criterion												
Surface roughness	**100**			**99**	**1**		**93**	**7**		**82**	**18**	
Color match	**94**	**6**		**93**	**7**		**84**	**13**	**3**	**84**	**16**	
Marginal integrity	**44**	**54**	**2**		**60**	**40**		**34**	**66**		**41**	**59**
Tooth Integrity	**91**	**9**		**40**	**47**	**13**	**29**	**56**	**15**	**31**	**48**	**21**
Restoration Integrity	**93**	**4**	**3**	**9**	**41**	**50**	**1**	**25**	**74**	**3**	**34**	**63**
Proximal contact	**94**	**4**	**2**	**82**	**16**	**2**	**91**	**7**	**1**	**85**	**13**	**2**
Change of sensitivity	**97**		**3**	**100**			**100**			**98**		**2**
Hyper-sensitivity	**91**	**7**	**2**	**100**			**100**			**100**		
Radiographic assessment	**91**	**4**	**5**				**96**	**1**	**3**			

Table 5.2: Descriptive statistics for all assessed restorations.

	Baseline (n=36)			2 Years (n=36)			4 Years (n=36)			6 Years (n=36)		
	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo
	[%]			[%]			[%]			[%]		
Criterion												
Surface roughness	100			97	3		92	8		78	22	
Color match	92	8		92	8		81	14	5	78	22	
Marginal integrity	50	47	3		53	47		36	64		39	61
Tooth integrity	86	14		47	42	11	31	58	11	33	50	17
Restoration integrity	100			11	45	44	3	28	69	3	39	58
Proximal contact	94	3	3	89	11		94	6		83	17	
Change of sensitivity	100			100			100			100		
Hyper-sensitivity	97	3		100			100			100		
Radiographic assessment	89	3	8				97	3				

Table 5.3: Descriptive statistics for all Grandio restorations. *

	Baseline (n=32)			2 Years (n=32)			4 Years (n=32)			6 Years (n=32)		
	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo	Alpha1	Alpha2	Bravo
	[%]			[%]			[%]			[%]		
Criterion												
Surface roughness	**100**			**100**			**94**	**6**		**87**	**13**	
Color match	**97**	**3**		**94**	**6**		**88**	**13**		**91**	**9**	
Marginal integrity	**37**	**63**			**69**	**31**		**31**	**69**		**44**	**56**
Tooth integrity	**97**	**3**		**31**	**53**	**16**	**28**	**53**	**19**	**28**	**47**	**25**
Restoration integrity	**85**	**9**	**6**	**6**	**38**	**56**		**22**	**78**	**3**	**28**	**69**
Proximal contact	**94**	**3**	**3**	**75**	**22**	**3**	**88**	**9**	**3**	**88**	**9**	**3**
Change of sensitivity	**94**		**6**	**100**			**100**			**97**		**3**
Hyper-sensitivity	**84**	**13**	**3**	**100**			**100**			**100**		
Radiographic assessment	**94**	**6**					**94**	**3**	**3**			

Table 5.4: Descriptive statistics for all Tetric Ceram restorations.

Criterion		**Baseline (n=68)**	**24 months (n=68)**	**48 months (n=68)**	**72 months (n=68)**
Alpha I Excellent		44.1 %	0.0 %	0.0 %	0.0%
Alpha II Slight defects, easily correctable	Negative step Overhang Stained overhang	8.8 % 44.1 % 1.5 %	44.1 % 5.9 % 10.3 %	29.4% 4.4% 0.0 %	38.2% 1.5% 1.5%
Bravo Slight defects, not correctable without damage	Gap / negative step Staining	1.5 % 0.0 %	16.2 % 23.5 %	23.5% 42.6%	11.8% 47.2%

Table 5.5a: Descriptive statistics regarding “marginal integrity” (all restorations).

Criterion		**Baseline (n=36)**	**24 months (n=36)**	**48 months (n=36)**	**72 months (n=36)**
Alpha I Excellent		50.0 %	0.0 %	0.0%	0.0%
Alpha II Slight defects, easily correctable	Negative step	5.6 %	38.9 %	27.8%	33.3%
	Overhang	38.9 %	2.8 %	8.3%	2.8%
	Stained overhang	2.8 %	11.1 %	0.0 %	2.8%
Bravo Slight defects, not correctable without damage	Gap / negative step	2.8 %	19.4 %	25.0%	8.3%
	Staining	0.0 %	27.8 %	38.9%	52.8%

Table 5.5b: Descriptive statistics regarding "marginal integrity" (Grandio restorations).

Criterion		**Baseline (n=32)**	**24 months (n=32)**	**48 months (n=32)**	**72 months (n=32)**
Alpha I Excellent		37.5 %	0.0 %	0.0%	0.0%
Alpha II Slight defects, easily correctable	Negative step	12.5 %	50.0 %	31.3%	43.8%
	Overhang	50.0 %	9.4 %	0.0 %	0.0 %
	Stained overhang		9.4 %	0.0 %	0.0 %
Bravo Slight defects, not correctable without damage	Gap / negative step	0.0 %	12.5 %	21.9%	15.6%
	Staining	0.0 %	18.8 %	46.9%	40.6%

Table 5.5c: Descriptive statistics regarding "marginal integrity" (Tetric Ceram restorations).

Criterion		Baseline (n=68)	24 months (n=68)	48 months (n=68)	72 months (n=68)
Alpha I Excellent		91.2 %	39.7 %	29.4%	30.9%
Alpha II Slight defects, easily correctable	Enamel chipping	1.5 %	4.4 %	0.0 %	5.9 %
	Enamel crack	7.4 %	42.6 %	55.9%	41.2%
	Wear	0.0 %	0.0 %	0.0 %	1.5 %
Bravo Slight defects, not correctable without damage	Enamel chipping	0.0 %	10.3 %	14.7%	13.2%
	Enamel crack	0.0 %	2.9 %	0.0 %	5.9 %
	Wear				1.5 %

Table 5.6a: Descriptive statistics regarding “tooth integrity” (all restorations).

Criterion		Baseline (n=36)	24 months (n=36)	48 months (n=36)	72 months (n=36)
Alpha I Excellent		86.1 %	47.2 %	30.6%	33.3%
Alpha II Slight defects, easily correctable	Enamel chipping	2.8 %	2.8 %	0.0 %	5.6 %
	Enamel crack	11.1 %	38.9 %	58.3%	41.7%
	Wear	0.0 %	0.0 %	0.0 %	2.8 %
Bravo Slight defects, not correctable without damage	Enamel chipping	0.0 %	8.3 %	11.1%	8.3 %
	Enamel crack	0.0 %	2.8 %	0.0 %	5.6 %
	Wear	0.0 %	0.0 %	0.0 %	2.8 %

Table 5.6b: Descriptive statistics regarding “tooth integrity” (Grandio restorations).

Criterion		**Baseline (n=32)**	**24 months (n=32)**	**48 months (n=32)**	**72 months (n=32)**
Alpha I Excellent		96.9 %	31.3 %	28.1%	28.1%
Alpha II Slight defects, easily correctable	Enamel chipping	0.0 %	6.3 %	0.0 %	6.3 %
	Enamel crack	3.1 %	46.9 %	53.1%	40.6%
Bravo Slight defects, not correctable without damage	Enamel chipping	0.0 %	12.5 %	18.8%	18.8%
	Enamel crack	0.0 %	3.1 %	0.0 %	6.3 %

Table 5.6c: Descriptive statistics regarding "tooth integrity" (Tetric Ceram restorations).

Criterion		**Baseline (n=68)**	**24 months (n=68)**	**48 months (n=68)**	**72 months (n=68)**
Alpha I Excellent		92.6 %	8.8 %	1.5%	2.9%
Alpha II Slight defects, easily correctable	Chipping	2.9 %	0.0 %	0.0%	1.5%
	Crack	0.0 %	1.5 %	0.0%	0.0%
	Roughness / Abrasion	1.5 %	39.7 %	25.0%	32.4%
Bravo Slight defects, not correctable without damage	Chipping	0.0 %	2.9 %	7.4%	2.9%
	Crack probing	2.9 %	0.0 %	4.4%	1.5%
	Abrasion	0.0 %	30.9 %	51.5%	58.8%
	Roughness	0.0 %	4.4 %	7.4%	0.0%
	Void	0.0 %	11.8 %	2.9%	0.0%

Table 5.7a: Descriptive statistics regarding "restoration integrity" (all restorations).

Criterion		Baseline (n=36)	24 months (n=36)	48 months (n=36)	72 months (n=36)
Alpha I Excellent		100.0 %	11.1 %	2.8%	2.8%
Alpha II Slight defects, easily correctable	Chipping	0.0 %	0.0 %	0.0 %	0.0 %
	Crack	0.0 %	0.0 %	0.0 %	0.0 %
	Roughness / Abrasion	0.0 %	44.4 %	27.8%	38.9%
Bravo Slight defects, not correctable without damage	Chipping	0.0 %	5.6 %	8.3%	2.8%
	Crack probing	0.0 %	0.0 %	2.8%	0.0 %
	Abrasion	0.0 %	16.7 %	50.0%	55.6%
	Roughness	0.0 %	5.6 %	8.3%	0.0 %
	Void	0.0 %	16.7 %	0.0%	0.0 %

Table 5.7b: Descriptive statistics regarding “restoration integrity” (Grandio restorations).

Criterion		Baseline (n=32)	24 months (n=32)	48 months (n=32)	72 months (n=32)
Alpha I Excellent		84.4 %	6.3 %	0.0 %	3.1 %
Alpha II Slight defects, easily correctable	Chipping	6.3 %	0.0 %	0.0 %	3.1 %
	Crack	0.0 %	3.1 %	0.0 %	0.0 %
	Roughness / Abrasion	3.1 %	34.4 %	21.9%	25.0%
Bravo Slight defects, not correctable without damage	Chipping	0.0 %	0.0 %	6.3%	3.1%
	Crack probing	6.3 %	0.0 %	6.3%	3.1%
	Abrasion	0.0 %	46.9 %	53.1%	62.5%
	Roughness	0.0 %	3.1 %	6.3%	0.0 %
	Void	0.0 %	6.3 %	6.3%	0.0 %

Table 5.7c: Descriptive statistics regarding “restoration integrity” (Tetric Ceram restorations).

		48 months		72 months	
Criterion		**premolars (n=45)**	**molars (n=23)**	**premolars (n=45)**	**molars (n=23)**
Alpha I Excellent		2.2 %	4.3 %	0.0 %	0.0 %
Alpha II Slight defects, easily correctable	Negative step Overhang Stained overhang	40.0% 6.7 % 0.0 %	8.7 % 0.0 % 0.0 %	44.4% 2.2 % 2.2%	26.1 % 0.0 % 0.0%
Bravo Slight defects, not correctable without damage	Gap / negative step Staining	20.0% 31.1%	26.1 % 60.9 %	8.9 % 42.2%	17.4% 56.5%

Table 5.8a: Descriptive statistics of premolars vs. molars regarding "marginal integrity". No significant difference could be calculated after 72 months (p=0.073) in contrast to the result after 48 months (p=0.007; Mann-Whitney U-test).

		48 months		72 months	
Criterion		**premolars (n=45)**	**molars (n=23)**	**premolars (n=45)**	**molars (n=23)**
Alpha I Excellent		37.8 %	13.0 %	42.2%	8.7 %
Alpha II Slight defects, easily correctable	Enamel chipping Enamel crack Wear	0.0 % 53.3% 0.0 %	0.0 % 60.9 % 0.0 %	6.7 % 35.6% 2.2%	13.0 % 52.2 % 0.0 %
Bravo Slight defects, not correctable without damage	Enamel chipping Enamel crack Wear	8.9 % 0.0 % 0.0 %	26.1 % 0.0 % 0.0 %	6.7 % 4.4 % 2.2 %	26.1 % 8.7 % 0.0 %

Table 5.8b: Descriptive statistics of premolars vs. molars regarding "tooth integrity". Significant differences could be calculated after 48 (p=0.013) and 72 months (p=0.003; Mann-Whitney U-test).

		48 months		72 months	
Criterion		**premolars (n=45)**	**molars (n=23)**	**premolars (n=45)**	**molars (n=23)**
Alpha I Excellent		2.2 %	4.3 %	0.0 %	8.7 %
Alpha II Slight defects, easily correctable	Chipping	2.2 %	0.0 %	2.2 %	0.0 %
	Crack	0.0 %	0.0 %	0.0 %	0.0 %
	Roughness / Abrasion	33.3 %	4.3 %	40.0%	17.3%
Bravo Slight defects, not correctable without damage	Chipping	4.4 %	8.7 %	4.4 %	0.0 %
	Crack probing	4.4 %	4.3 %	2.2 %	0.0 %
	Abrasion	40.0 %	73.9 %	51.1 %	73.9%
	Roughness	8.9 %	4.3 %	0.0 %	0.0 %
	Void	4.4 %	0.0 %	0.0 %	0.0 %

Table 5.8c: Descriptive statistics of premolars vs. molars regarding "restoration integrity". No significant difference was calculated after 72 months (p=0.321) in contrast to the 48 month findings (p=0.018; Mann-Whitney U-test).

Tooth integrity significantly deteriorated due to increasing enamel cracks over time ($p<0.05$; Table 5.6). Enamel chippings or cracks were significantly more frequently observed in molars (26% bravo after 4 years / 35 % bravo after 6 years) than in premolars (9% bravo after 4 years/11% bravo after 6 years). The main reasons for decreasing "restoration integrity" were visible signs of surface roughness and distinct wear traces (28% after 1 year, 75% after 2 years, 84% after 4 years, 91% after 6 years; Table 5.7). Visible wear of both materials under investigation was detectable earlier in molars (74% bravo after 4 years) than in premolars (40% bravo after 4 years; Table 5.8c, Figures 5.1 and 5.2).

Figure 5.1

Clinical view of a Grandio restoration after 6 years (upper left first premolar). A discoloration at the palatal proximal margin was detectable, probably due to a small overhang. Wear and negative step formation in the occlusal portion of the restoration was obvious. The surface appears rough.

Figure 5.2

Clinical view of a Tetric Ceram restoration after 6 years (upper right first premolar, same patient as in Figure 5.1). No discoloration was detectable clinically. Wear and negative step formation in the occlusal portion of the restoration was detectable. In the occlusal contact area of the lateral ridge, the surface show signs of surface fatigue (small cracks) and the surface appears rough.

Discussion

Fundamental prerequisites for clinical success with resin-based composites as posterior restorative material still must be met in order to achieve clinical success with this particular group of dental materials.[10-12,18,30,41] There is no doubt that resin composites are almost perfect for minimally invasive posterior cavities, however, it is to the date not fully understood how far we can go in terms of cavity extension. So it is still frequently argued that resin composites suffer some disadvantages in very

extended cavities and should therefore be replaced by other materials and techniques such as indirectly bonded restorations.[21] When large cavities need to be restored, the major objections against resin composites are the dangers of developing recurrent caries and the non-predictable wear rates over time.[42] The problem with secondary caries is even more common when proximal Class II margins are located in dentin. 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 restored.[6,16,25,42] For Class V restorations it is similar, although 50% of margin length is located in dentin.[4,19,20,22] On the other hand, proximal marginal seal in dentin-bordered cavities restored with direct resin composite restorations, is underrepresented in the literature of the field.[21] Thus, the setup of this clinical trial excluded minimally invasive cavities and was mainly restricted to amalgam replacement restorations resulting in 35% of cavities with no proximal-cervical enamel and 49% with <0.5 mm proximal enamel width. Finally, after 6 years of clinical service, these restorations did not reveal significantly worse clinical outcomes, and moreover, neither recurrent caries nor severe marginal staining was detected.
The most recent recommendations for clinical trials with restorative materials [31] could not be addressed, because these recommendations were published considerably after the beginning of the present study. Therefore, it was not possible to include more evaluation aspects among well-suited protocols such as the CONSORT statement.[15,16,40,42]

Direct and indirect resin composites as well as all-ceramic inlays have to be bonded for acceptable clinical outcome.[5,10,11,14,30] The selection of materials for this study was carried out after thorough in vitro testing with promising results for both materials used, in terms of good marginal adaptation and long-term stability,[24,27,28,43] because previous studies clearly indicated that it may be dangerous to make clinical trials with materials having failed some preclinical screenings.[15,43]

Although the different adhesives used in the present investigation required special bonding protocols, i.e. wet bonding with the acetone-based Solobond M, this obviously did not negatively influence clinical results in terms of postoperative hypersensitivities. Initially, restorations bonded with Syntac exhibited slightly more hypersensitivities (baseline to 6 months) (3% vs. 0% bravo scores), but this played

no role past the 1-year recall. Therefore, both the internal sealing of dentin and tight dentin margins were possible with both adhesives under investigation. Even so, dealing with the clinical outcome of complete restorative systems (i.e. adhesive plus resin composite) always is more complicated than evaluating two adhesives with one resin composite in order to minimize variables. This paper is not able to completely elucidate this particular problem, but the promising results over the 6-year period support the assumption that both systems are clinically acceptable.

Including nanofillers in recent resin composites is widespread in adhesive dentistry today. Major advantages are primarily enhanced translucency effects and increased polishability.[12,44,45] Irrespective of these aspects, clinical reports dealing with this class of materials exhibited no significant advantages *in vivo.*[12] In the present investigation, Tetric Ceram was used as fine hybrid resin composite (without nanofillers), and Grandio was used as one of the first resin composites with incorporated nanofillers among conventional hybrid type fillers as so-called nanohybrid resin composite.[12,32,37]

Altogether, the null hypothesis of the present investigation was confirmed because there was no difference in the clinical behavior between Grandio and Tetric Ceram used for extended Class II posterior restorations.

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