Bulk-fill Composites Compared to a Nanohybrid Composite in Class-II Cavities – A Two-year Follow-Up Study

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Purpose: To compare different concepts of direct composite restorations in class-II cavities using bulk-fill composites and a conventional composite with different layer thicknesses in a clinical study over a period of 2 years.

Materials and Methods: A low-viscosity (SDR), a high-viscosity bulk-fill (Tetric EvoCeram Bulk Fill) and a conventional nanohybrid composite (Tetric EvoCeram) were randomly assigned and placed in different layer thicknesses up to 4 mm in 160 class-II cavities in 94 patients. Restorations were clinically examined at baseline (n = 160), after 12 (n = 150) and 24 months (n = 148) and evaluated according to eight selected FDI criteria. In case of complete loss of the restoration or irreversible pulpitic symptoms, the restoration was rated as failure; repair was considered as relative failure.

Results: The materials investigated showed no significant differences regarding the FDI scores and failure rate during the entire follow-up. After 12 months, 7 failures and after 24 months a total of 8 failures were observed. After 2 years, Tetric EvoCeram Bulk Fill with a 4-mm layer thickness and SDR in combination with Tetric EvoCeram Bulk Fill with a 2-mm layer thickness exhibited a non-significant tendency towards increased hypersensitivity (FDI score 5) as compared to the reference material Tetric EvoCeram with a 2-mm layer thickness ($p = 0.051$; Kruskal-Wallis test).

Conclusion: The clinical stability of bulk-fill materials in layers up to 4 mm is comparable to nanohybrid composites after 2 years.

Keywords: bulk-fill, clinical examination, 2-year follow-up, FDI criteria.

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Dental composites are established as the filling material of choice for direct restorations in modern dentistry. Manufacturers are constantly introducing new compositions with different fillers and matrices, and several years ago, the so-called bulk-fill composites were introduced.[20] Manufacturers[24] promised time savings through faster application and better processing with a layer thickness up to 4–5 mm.[22] Some bulk-fill composites contain a new initiator, Ivocerin,[17] which is a dibenzoyl germanium derivative more reactive to light of 370–460 nm wavelength than commonly used initiators, such as camphor quinone (450–490 nm) or Lucerin TPO (up to 390 nm).[2,23,27] Bulk-fill composites which do not contain the initiator Ivocerin achieve a higher translucency due to decreased filler load and increased filler size, which enables light to penetrate into deeper layers.[4] Thus, bulk-fill composites can be placed in larger cavities with thicker layers up to 4–5 mm compared to conventional composites, using a short polymerization time (10 s) and a high light intensity (800–1000 mW/cm^2).[1,22,35]

Bulk-fill composites can be divided into two subgroups: the low-viscosity and the high-viscosity composites. The low viscosity composites have a lower filler content and have larger filler particles, resulting in lower mechanical properties. Thus, low-viscosity bulk-fill composites are only approved as a base in class-I and -II restorations and require a capping layer with conventional composites.[16] In contrast, high-viscosity bulk-fill composites exhibit a higher filler load. Due to the better mechanical properties, a capping layer is not required.[9] However, the disadvantage of high-viscosity bulk-fill composites is that the adaptation to tooth structure

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Table 1 Inclusion criteria

Signed informed consent
Indication for restorative treatment (caries, insufficient restoration) of a first or second molar
Class-II cavities
Defect size in vestibular-oral direction: at least half intercuspidal distance
Positive reaction to sensitivity test
Negative pain history
No allergy to ingredients used
Patients healthy from a medical point of view
Compliant patient
A maximum of two restorations of each material group per patient

has to be done carefully when placing the filling, which makes the process somewhat more technique sensitive.

Several studies on bulk-fill composites have been conducted which reported good results due to reduced polymerization shrinkage stress,[7,14] an adequate curing depth up to 4 mm,[31] and good bond strength, independent of the filling technique or cavity configuration.[39] However, there are few clinical studies available investigating bulk-fill composites.[10,13,38]

The aim of this study was to compare different concepts of direct composite restorations in a clinical trial. We investigated 1. the combination of a low-viscosity bulk-fill composite with a high viscosity bulk-fill capping layer; 2. a high-viscosity bulk-fill composite as a sole restorative applied in one 4-mm layer according to the manufacturer's specification; and 3. another applied like a conventional composite with maximum thickness of 2 mm; 4. a nanohybrid composite as the reference material. The observation period of the study was 2 years, as this period corresponds to the legal warranty period in Germany. To avoid influences by the adhesive, the same adhesive was used for each restoration.

MATERIAL AND METHODS

Study Design and Participants

Ninety-four patients who required class-II direct restoration of a molar and fulfilled the inclusion criteria (Table 1) were included in the study. The patients included represent a typical population found in a mid-sized city and surrounding area of about 30,000 inhabitants in the south of Germany. Four different material groups (Fig 1) were randomly assigned to the 160 cavities by drawing lots. For this purpose, 160 lots were created with 40 lots per material group. If a patient required more than one restoration, it was ensured that not more than two material groups were assigned to this patient. All 160 class-II direct restorations of the four different material groups in combination with the self-etching adhesive AdheSE Universal (Ivoclar Vivadent; Schaan, Liechtenstein) were placed by one experienced dentist in a private dental practice (Table 2). Before treatment, each patient gave written informed consent to participate in the study. The study was approved by the ethics committee of the Ludwig-Maximilians University Munich (approval number 504-16). Both dentists who participated in the study were calibrated online using the e-learning platform e-calib (University of Munich, Germany).[11]

Clinical Procedure

After non-selective caries removal or removal of the insufficient restoration, the cavities were prepared without bevels and measured accurately to 0.5 mm using a CP12 periodontal probe (Henry Schein Dental Deutschland; Langen, Germany). Cavity contamination control during the restoration process was ensured with suction devices and cotton rolls. Anatomically pre-shaped partial matrices, wooden wedges, and clamping rings were used to ensure reliable approximal contact. No liners or bases were used. For conditioning, the adhesive AdheSE Universal in self-etch technique was applied for 20 s, following dispersion with oil- and water-free compressed air and then light curing for 10 s at an intensity of 1100 mW/cm^2 (Bluephase Style, Ivoclar Vivadent). Each cavity was then filled in different layer thicknesses (specified as maximum mm layer thickness) with one of the four material combinations (Fig 1): 1. SDR (smart dentin replacement) with a 4-mm layer thickness, followed by Tetric EvoCeram Bulk Fill with a 2-mm layer thickness (SDR4TB2); 2. Tetric EvoCeram Bulk Fill with a 4-mm layer thickness (TB4); 3. Tetric EvoCeram Bulk Fill with a 2-mm layer thickness (TB2); 4. Tetric EvoCeram with a 2-mm layer thickness (TC2). Each composite layer was cured by an LED light (Bluephase Style, Ivoclar Vivadent) for 10 s (1100 mW/cm^2). The light intensity was verified once a week with a dental radiometer (Bluephase Meter, Ivoclar Vivadent) to avoid internal fluctuations during the study period. The restorations were finished by contouring and adjusting the occlusion with fine diamond burs (grain size 46 µm; Komet Dental; Lemgo, Germany) and polished with an alumina-coated urethane dimethacrylate polisher (Enhance, Dentsply Sirona; Konstanz, Germany).

Clinical Evaluation

The restorations were clinically examined by another experienced dentist immediately after placement (n = 160) as well as after 12 (n = 150) and 24 months (n = 148) according to eight selected FDI criteria, where 1 represents the best and 5 the worst rating:[11] A1 surface luster; A2a surface staining; A2b marginal staining; A3 color match and translucency; A4 esthetic anatomical form; B5 fracture of material and retention; B6 margin adaptation; C11 postoperative (hyper-) sensitivity and tooth vitality. In case of a complete loss of the restoration or irreversible pulpitic symptoms, the restoration was rated as failure (score 5). If a reparation of the restoration was required or an FDI score ≥ 4 was observed, the filling was rated as relative failure.[20]

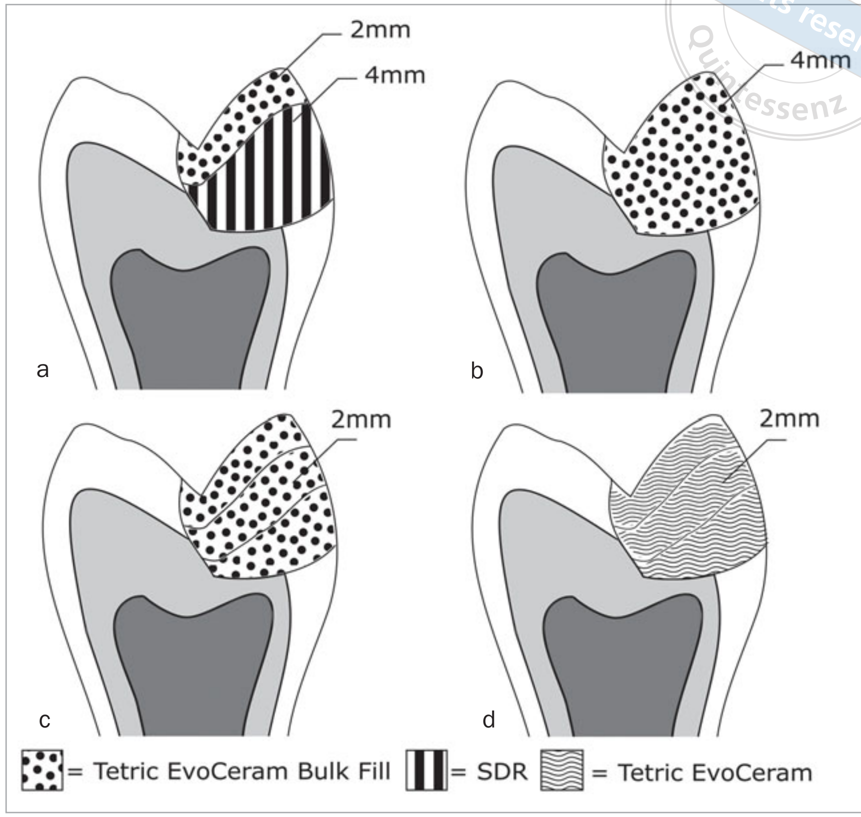

Fig 1 Materials investigated and schematic display of composite restorations. The mm values shown are the maximum layer thickness of one increment of the filling. a. Low-viscosity SDR with a layer thickness of 4 mm and a required capping layer (2 mm) with the high viscosity Tetric EvoCeram Bulk Fill; b. Tetric EvoCeram Bulk Fill with a layer thickness of 4 mm; c. Tetric EvoCeram Bulk Fill with a thickness of each layer ≤ 2 mm; d. reference material Tetric EvoCeram applied by the conventional 2-mm incremental layering technique.

Table 2 Materials, manufacturer and composition[5,21,36]

Material	Composition	Lot Nr.	Filler load	Filler size	Manufacturer
AdheSE Universal	Methacrylate: hydrophilic hydroxyethyl methacrylate (HEMA), hydrophobic decandiol, dimethacrylate (D3MA), bisphenol-A-dimethacrylate (bis-GMA), ethanol, water, highly dispersed silicon dioxide, initiators, stabilizers	S54248 T08671			Ivoclar Vivadent; Schaan, Liechtenstein
SDR	SDR patented urethane dimethacrylate, dimethacrylate, bifunctional diluting monomers, barium- and strontium aluminofluorosilicate glass (68 wt%, 45 vol%), photoinitiators, pigments	1508000660 1505000609 1605000465 1508000517 1601000662	68 wt%, 44 vol%	0.02–10 µm	Dentsply Sirona; Konstanz, Germany
Tetric EvoCeram	Dimethacrylate (16.8 wt%), prepolymers (34.0 wt%), barium glass filler, ytterbium trifluoride, mixed oxides (48.5 wt%), additives, initiators, stabilizers, pigments (< 0.8 wt%)	T09636 T09619	75.5 wt%, 54 vol%	0.04–3 µm	Ivoclar Vivadent
Tetric EvoCeram Bulk Fill	Dimethacrylate (19.7 wt%), prepolymers (17.0 wt%), barium glass fillers, ytterbium trifluorides, mixed oxides (62.5 wt%), additives, initiators, stabilizers, pigments (< 1.0% by weight)	S29569 S36152 T09619	79–86 wt%, 60–61 vol%	0.04–3 µm	Ivoclar Vivadent

Statistical Analysis

The statistical analysis was evaluated with SPSS Statistics v. 25 for Windows (SPSS/IBM; Armonk, NY, USA). Descriptive statistics were used to describe the frequency distribution of the evaluated criteria and failure rate. The Kruskal-Wallis test was used for ordinal structed data (FDI criteria) and cavity depths with a post-hoc Dunn-Bonferroni-test. Pearson's chi-squared test was chosen for nominal structured data (material groups). To analyze significant differences in the FDI score and the survival rate over the follow-

Table 3 Number and frequency of restorations at baseline and at 12- and 24-months follow-up

	Baseline	12 months	24 months
	n (%)	n (%)	n (%)
TC2	40 (100)	40 (100)	38 (95.0)
TB2	40 (100)	39 (97.5)	36 (90.0)
SDR4TB2	40 (100)	38 (95.0)	38 (95.0)
TB4	40 (100)	37 (92.5)	36 (90.0)
Total	160 (100)	154 (96.3)	148 (92.5)

TC2: Tetric EvoCeram 2 mm; TB2: Tetric EvoCeram Bulk Fill; SDR4TB2: SDR 4 mm + Tetric EvoCeram Bulk Fill 2 mm; TB4: Tetric EvoCeram Bulk Fill 2 mm.

Table 4 Depth of cavities (mean ± SD)

	Occlusal depth (mm)	Depth in the mesial proximal box (mm)	Depth in the distal proximal box (mm)
TC2	2.6 ± 0.6[a]	2.9 ± 1.8[a]	1.8 ± 2.3[a]
TB2	2.7 ± 0.7[a]	3.1 ± 1.9[a]	1.8 ± 2.2[a]
SDR4TB2	3.1 ± 0.8[b]	3.7 ± 1.8[a]	2.9 ± 2.3[a]
TB4	3.0 ± 0.7[ab]	2.8 ± 2.0[a]	2.3 ± 2.4[a]

Homogenous subgroups (α = 0.05), TC2: Tetric EvoCeram 2 mm; TB2: Tetric EvoCeram Bulk Fill; SDR4TB2: SDR 4 mm + Tetric EvoCeram Bulk Fill 2 mm; TB4: Tetric EvoCeram Bulk Fill 2 mm. Superscript lettersxx INDICATE WHAT?

Table 5 FDI rating at baseline, 12 and 24 months

		Baseline (%)		12 months (%)				24 months (%)					
Material	FDI criteria (score 1-5)	1	2	1	2	3	5	1	2	3	4	5	p-value
TC2	A1 Surface lustre	92.5	7.5	75.0	25.0	0.0	0.0	63.2	34.2	2.6	0.0	0.0	0.001
	A2a Surface staining	100.0	0.0	87.5	12.5	0.0	0.0	73.7	26.3	0.0	0.0	0.0	0.001
	A2b Marginal staining	100.0	0.0	75.0	25.0	0.0	0.0	50.0	44.7	5.3	0.0	0.0	0.001
	A3 Color match and translucency	90.0	10.0	77.5	22.5	0.0	0.0	73.7	26.3	0.0	0.0	0.0	0.007
	A4 Esthetic anatomical form	90.0	10.0	75.0	25.0	0.0	0.0	63.2	34.2	2.6	0.0	0.0	0.001
	B5 Fracture of material and retention	100.0	0.0	97.5	0.0	2.5	0.0	92.1	0.0	7.9	0.0	0.0	0.097
	B6 Marginal adaptation	100.0	0.0	85.0	15.0	0.0	0.0	71.1	26.3	2.6	0.0	0.0	0.001
	C11 Postoperative (hyper-) sensitivity and tooth vitality	100.0	0.0	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	–
TB2	A1 Surface lustre	90.0	10.0	74.4	25.6	0.0	0.0	63.9	36.1	0.0	0.0	0.0	0.009
	A2a Surface staining	100.0	0.0	82.1	15.4	2.6	0.0	80.6	16.7	2.8	0.0	0.0	0.005
	A2b Marginal staining	100.0	0.0	66.7	33.3	0.0	0.0	47.2	50.0	2.8	0.0	0.0	0.001
	A 3 Color match and translucency	80.0	20.0	66.7	33.3	0.0	0.0	61.1	38.9	0.0	0.0	0.0	0.046
	A4 Esthetic anatomical form	87.5	12.5	71.8	28.2	0.0	0.0	75.0	25.0	0.0	0.0	0.0	0.021
	B5 Fracture of material and retention	100.0	0.0	97.4	0.0	2.6	0.0	91.7	2.8	5.6	0.0	0.0	0.097
	B6 Marginal adaptation	100.0	0.0	84.6	12.8	0.0	2.6	69.4	27.8	0.0	0.0	2.8	0.001
	C11 Postoperative (hyper-) sensitivity and tooth vitality	100.0	0.0	97.4	0.0	2.6	0.0	100.0	0.0	0.0	0.0	0.0	0.368
SDR4TB2	A1 Surface lustre	90.0	10.0	75.7	24.3	0.0	0.0	55.3	42.1	2.6	0.0	0.0	0.001
	A 2 a Surface staining	100.0	0.0	81.1	13.5	5.4	0.0	81.6	13.2	2.6	2.6	0.0	0.001
	A2b Marginal staining	100.0	0.0	75.7	18.9	5.4	0.0	52.6	36.8	7.9	2.6	0.0	0.001
	A3 Color match and translucency	90.0	10.0	64.9	35.1	0.0	0.0	65.8	34.2	0.0	0.0	0.0	0.001
	A4 Esthetic anatomical form	87.5	12.5	70.3	29.7	0.0	0.0	65.8	31.6	0.0	2.6	0.0	0.001
	B5 Fracture of material and retention	100.0	0.0	100.0	0.0	0.0	0.0	97.4	0.0	0.0	2.6	0.0	0.368
	B6 Marginal adaptation	100.0	0.0	89.2	10.8	0.0	0.0	73.0	27.0	0.0	0.0	0.0	0.001
	C11 Postoperative (hyper-) sensitivity and tooth vitality	100.0	0.0	92.1	0.0	0.0	7.9	94.7	0.0	0.0	0.0	7.9	0.097
TB4	A1 Surface lustre	87.5	12.5	70.6	29.4	0.0	0.0	51.5	39.4	9.1	0.0	0.0	0.001
	A2a Surface staining	100.0	0.0	85.3	14.7	0.0	0.0	78.8	15.2	6.1	0.0	0.0	0.004
	A2b Marginal staining	100.0	0.0	61.8	38.2	0.0	0.0	36.4	60.6	3.0	0.0	0.0	0.001
	A3 Color match and translucency	77.5	22.5	64.7	32.4	2.9	0.0	60.6	39.4	0.0	0.0	0.0	0.042
	A4 Esthetic anatomical form	80.0	20.0	70.6	29.4	0.0	0.0	57.6	42.4	0.0	0.0	0.0	0.025
	B5 Fracture of material and retention	100.0	0.0	97.1	0.0	0.0	2.9	94.1	2.9	0.0	0.0	2.9	0.223
	B6 Margin adaptation	97.5	2.5	67.6	32.4	0.0	0.0	66.7	27.3	6.1	0.0	0.0	0.001
	C11 Postoperative (hyper-) sensitivity and tooth vitality	100.0	0.0	91.9	2.7	0.0	5.4	88.9	2.8	0.0	0.0	8.3	0.039

*The p-value denotes significant increase of FDI values between baseline and 24 months (Friedman test). TC2: Tetric EvoCeram 2mm; TB2: Tetric EvoCeram Bulk Fill; SDR4TB2: SDR 4 mm + Tetric EvoCeram Bulk Fill 2 mm; TB4: Tetric EvoCeram Bulk Fill 2 mm.

Table 6 Number of failures at 12 and 24 months

Material	Tooth (FDI notation)	Restoration surfaces	Month after baseline	Failure/ relative failure	Reason	FDI criteria score (criteria)	AFR in %, 12 months	AFR in %, 24 months
TC2	–	–	–	–	–	–	0	0
TB2	36	od	12	Failure	Filling loss	5 (B6)	2.6	1.4
SDR4TB2	27	mod	12	Failure	Pulpitis	5 (C11)	7.9	3.9
	26	modvp	12	Failure	Pulpitis	5 (C11)		
	37	modv	12	Failure	Pulpitis	5 (C11)		
	27	mod	24	Relative failure	Repair required	5 (A4)		
	37	mod	24	Relative failure	Repair required	5 (B5)		
TB4	47	mo	12	Failure	Filling loss	5 (B5)	8.1	5.6
	26	mo	12	Failure	Pulpitis	5 (C11)		
	26	od	12	Failure	Pulpitis	5 (C11)		
	17	mod	24	Failure	Pulpitis	5 (C11)		

AFR: Annual failure rate; A4: Esthetic anatomical form; B5: Fracture of material and retention; B6: Marginal adaptation; C11: Postoperative (hyper-) sensitivity and tooth vitality; TC2: Tetric EvoCeram 2mm; TB2: Tetric EvoCeram Bulk Fill; SDR4TB2: SDR 4 mm + Tetric EvoCeram Bulk Fill 2 mm; TB4: Tetric EvoCeram Bulk Fill 2 mm; m: mesial; d: distal; o: occlusal; v: vestibular.

up period, a Friedman test and a Kaplan Meier procedure with a log rank test was used. A p-value of 0.05 was considered significant.

RESULTS

Ninety-four patients, 64 women and 30 men, with a mean age of 30.9 years (12–69 years) participated in the study and received a total of 160 restorations. One hundred fifty-four restorations (96.3%) were re-evaluated after 12 months and 148 restorations (92.5%) after 24 months (Table 3). Table 4 summarizes the mean cavity depth of each material group. SDR4TB2 exhibited significantly greater cavity depths in occlusal region compared to TC2 and TB2. Regarding the distal and mesial cavity depths, no significant differences were observed between the material groups.

Concerning the FDI scores, there were no significant differences between the material groups investigated (Kruskal-Wallis test). However, a non-significant tendency towards increased hypersensitivity (FDI score 5) was observed for TB4 and SDR4TB2 compared to the reference material TC2 ($p = 0.051$; Kruskal-Wallis test).

Compared to baseline, there was a significant increase in FDI scores over the 24-month follow-up period for all material groups for most of the analyzed FDI criteria (Table 5). The FDI scores of the different material-groups are summarized in Table 5. After 12 months, nearly all restorations achieved scores between 1 and 3. A score of 5 (failure) was given for the following FDI criteria: marginal adaptation in 2.6% of group TB2, material fracture and retention in 2.9%, postoperative (hyper-)sensitivity and tooth vitality in 4.7% of group TB4, and postoperative (hyper-)sensitivity and tooth vitality in 7.9% of group SDR4TB2.

After 24 months, an FDI score of 4 was observed for the group SDR4TB2 for surface staining in 2.6%, marginal staining in 2.6%, esthetic anatomical form in 2.6%, and fracture of material and retention in 2.6%. Two restorations in the SDR4TB2 group with an FDI score of 4 required restoration repair and were rated as relative failure. The score 5 (5.3%) of the criterion postoperative (hyper-)sensitivity and tooth vitality in group SDR4TB2 was already given at the 12-month follow-up. Similarly, in group TB4, a score of 5 (failure) was given for the FDI criterion postoperative (hyper-)sensitivity and tooth vitality, resulting in 8.3%.

At the 24-month follow-up, group TB2 showed no more scores ≥ 4 than it did after 12 months.

After 12 and 24 months, there were no significant differences in the failure rates between the different material groups. It is noteworthy that the reference material TC2 was the only material which did not exhibit any failures (no FDI scores higher than 3) during the entire follow-up period. Table 6 summarizes the number of failures after 12 and 24 months. At the 12-month follow-up, 7 restorations (4.5%) were rated as failures due to 5 teeth with pulpitic symptoms (resulting in 4 root canal treatments and 1 extraction), and 2 lost restorations (both restorations were lost in the same patient). At the 24-month follow-up another failure was observed due to a pulpitic tooth (requiring a root canal treatment), which resulted in a total of 8 failures (5.4%). Furthermore, two restorations had to be repaired, which were counted as relative failures. The annual failure rate (AFR) dropped from 4.5% after 12 months to 2.7% after 24 months.

The Kaplan-Meier survival curve (Fig 1) displays the failure rates for all materials investigated over the period of 2 years. The log rank test showed no significant differences ($p = 0.15$) over the entire follow-up.

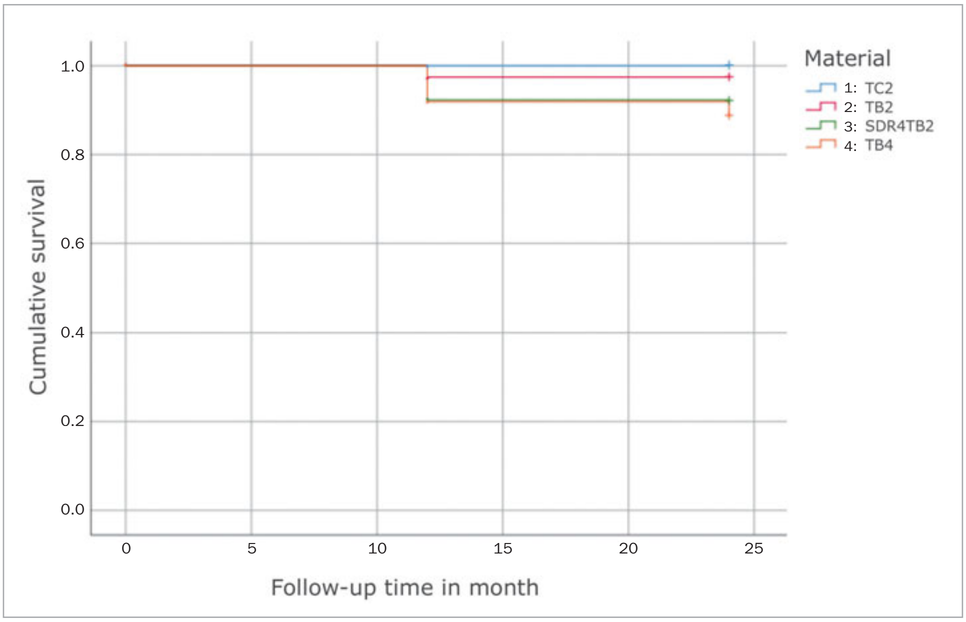

Fig 2 Kaplan-Meier survival curves for all materials investigated after 24 months. TC2: Tetric EvoCeram 2 mm; TB2: Tetric EvoCeram Bulk Fill; SDR4TB2: SDR 4 mm + Tetric EvoCeram Bulk Fill 2 mm; TB4: Tetric EvoCeram Bulk Fill 2 mm.

DISCUSSION

The aim of this study was to compare different concepts of direct composite restorations in class-II cavities. The material groups examined showed no significant differences regarding the failure rate and FDI criteria during the entire 2-year follow-up.

Until recently, the 2-mm incremental layering technique has been considered the gold standard procedure for direct posterior cavities to reduce polymerization shrinkage, achieve adequate depth of cure, as well as reducing the elution of monomers.[10,17,28,32] The introduction of bulk-fill composite materials now provides a possibility for sufficient polymerization of increments up to 4 mm thick.[10,15,16]

In this present study, the restorations were performed under isolation using cotton rolls. As previous studies have shown, absolute isolation has no significant influence on the longevity of restorations compared to isolation with cotton rolls.[30] Raskin et al[30] investigated restorations placed with rubber-dam versus cotton-roll isolation in a prospective randomized clinical trial over 10 years. They showed that the isolation modes exhibited no statistically significant differences over 10 years. These observations are in line with a systematic review by Brunthaler et al,[3] which investigated the clinical performance of posterior resin composites, and found no significant effect on the failure rate using cotton rolls vs rubber-dam.

In this study, the bulk-fill composites were applied in one increment up to 4 mm thick (TB4, SDR4TB2), as recommended by the manufacturer. The two material groups (TB4, SDR4TB2) exhibited a non-significant tendency ($p = 0.051$) towards increased hypersensitivity compared to the other two material groups with 2-mm layer thicknesses, which justifies examining this finding in more detail. Currently, polymerization shrinkage is still a weakness of resin-based composites. It can lead to debonding from the cavity walls, interfacial gap formation, and microleakage. Clinically discolored restoration margins, recurrent caries, enamel cracks and even postoperative hypersensitivity may occur.[8,19,34,40,41]

Kaisarly et al[18] proved in an in vitro study that the method of application of bulk-fill composites influenced the polymerization shrinkage. They compared SDR applied in a 4-mm layer thickness to SDR and Tetric EvoFlow applied in a 2-mm layer thickness. They found that the 4-mm technique resulted in greater shrinkage vectors and a higher debonding tendency at the cavity floor.[18] In that study, the increased polymerization shrinkage in SDR4BT2 und TB4 may have led to debonding at the restoration-tooth interface, which may explain the tendency towards the increased hypersensitivity in groups TB4 and SDR4TB2 observed in our study.

In our study, cavities treated with SDR4TB2 were significantly deeper compared to TB2 and TC2. However, these findings were only significant in the occlusal region. Furthermore, the maximum difference of the mean between the material groups was below 0.5 mm (Table 3). As the measurements were performed with a periodontal probe, differences may well lie within the measuring accuracy of the probe. Nevertheless, based on the anatomical standard dimensions of a molar (approximately 2 mm of enamel and 2.5–3 mm of dentin), a mean cavity depth in the occlusal region 3.0 ± 0.7 mm (SDR4TB2) has to be considered as deep. Thus, hypersensitivity could have occurred due to pulp irritation, regardless of the material used. However, it would be difficult to explain why hypersensitivity did not occur immediately after preparation but only later, during the follow-up. Thus, it appears more likely that, over the course of time, hypersensitivity may be the result of higher stresses caused by the polymerization shrinkage and debonding of thicker composite layers.

SDR4TB2 most frequently received the FDI scores of 4 and 5 compared to the other materials investigated (Table 5). In addition to 3 pulpitic events ("postoperative hypersensitivity and tooth vitality") described above, SDR4TB2 was the only material combination with a score of 4 for the criteria "surface staining" and "marginal staining". Surface staining depends on the ability of the material to retain pigments from the oral environment, whereas the criterion marginal staining depends on the effectiveness of dentin/enamel bonding agents as well as on the operative technique or physical parameters of the restorative material.[11] As we used the same adhesive for each restoration, the influence of the adhesive may be disregarded.

Higher rates of surface staining and marginal staining with SDR4TB2 have not been reported in previous studies, which may be due to the fact that the combination of SDR4 with a TB2 capping layer is unusual. However, we chose this combination in order to minimize the influence of different capping layers on the outcome parameters. The choice of TB2 is helpful for demonstrating the influence of the elasticity modulus of the bulk-fill material on the fatigue strength of a material. To adjust the processing properties, TB2 contains large prepolymers in addition to the common ceramic fillers and nanoparticles.[15,37] However, bonding of the prepolymers to the matrix of the composite is not as good as with inorganic fillers to the composite matrix.[6] Under occlusal loading, forces are mainly carried by the material with the higher elasticity modulus. As SDR is a low-viscosity, low elasticity modulus bulk-fill composite, the stress in the 2-mm TB2 layer within the SDR4TB2 group is higher compared to the other material groups with high-viscosity, high elasticity modulus bulk-fill composite or nanohybrid composites. Thus, increased stress may cause microcracks and filler chipping between the prepolymers and the composite matrix in the TB2 capping layer.[6] Discoloration can be embedded in these microcracks as well as in areas of "filler plucking", where fillers have been removed from the matrix by mechanical stress (score 4 for surface staining and marginal staining).[25,29]

SDR4TB2 also achieved poor results for esthetic anatomical form and fracture of material and retention (score 4). The poor results additionally support this argumentation that the capping layer (TB2) cannot compensate for the low modulus of elasticity of the underlying SDR restoration. As only a thin, 2-mm-thick capping layer is bonded to the tooth, the microcracks may even result in a break of the entire filling due to strong chewing forces (score 4 for esthetic anatomical form and fracture of material and retention, which required restoration repair).[33]

In TB2 (score 5 for marginal adaptation) and TB4 (score 5 for fracture of material and retention) one restoration was lost per group, but in the same patient. As the restorations were lost shortly after restoration placement and no material fracture was observed, handling problems during application (contamination with blood or saliva) can be suspected rather than a weakness of the material.

Study Limitations

Gender distribution in our study did not match the normal distribution of the general population. However, gender distribution was similar in all material groups investigated, with approximately 2/3 women (57%–70%) and 1/3 men (30%–43%).

In our study, the restorations were placed by one and evaluated by another experienced dentist. However, the advantage is that this approach reduces interobserver variability and makes a clinical study much more cost effective, provided the evaluator is properly trained.

In general, clinical studies of dental restorative materials distinguish between early failures (0-6 months), failures occurring over the mid-term (6 to 24 months) and late failures after two years.[12,26] Early failures are mostly a result of treatment faults (eg, post-operative hypersensitivity, loss of restoration, allergic side effects), whereas mid-term failure (marginal discoloration, discoloration/staining of material, chipping of material and or bulk fractures) and late failure (bulk fractures, tooth fractures, secondary caries, excessive wear of the material or antagonist tooth, periodontal side effects) are more attributable to material properties. Compared to other studies on the longevity of direct restorations, our study covered a mid-term follow-up period of two years and may not completely reflect the late failures.

CONCLUSION

This study showed that the 2-year outcome of bulk-fill composites are comparable to classical nanohybrid composites.

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Clinical relevance: Our study results raise the question whether a minimal time saving associated with new bulk-fill composites during the process of application justifies a potential risk of a poorer outcome.