Randomized clinical split-mouth study on a novel self-adhesive bulk-fill restorative vs. a conventional bulk-fill composite for restoration of class II cavities – results after three years

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ABSTRACT

Objectives: This randomized prospective split-mouth study evaluated the clinical performance of a novel, tooth-colored, self-adhesive bulk-fill restorative (SABF, 3M) for restoration of class II cavities as compared to a conventional bulk-fill composite (Filtek One, 3M; FOBF) over 36 months. The null-hypothesis was that both materials perform equally regarding clinical success and performance according to the FDI clinical criteria and scoring system.

Methods: 30 patients received one SABF and one FOBF restoration each. For FOBF, Scotchbond Universal (3M) was used as adhesive (self-etch mode), whereas SABF was applied without adhesive. Two blinded examiners evaluated the restorations at baseline, 24 and 36 months using FDI criteria. Data were analyzed non-parametrically (χ^2-tests; α=0.05).

Results: 29 patients were available for the 24- and 36-month examinations. Clinical success rate was 96.6% for both materials at 36-mo (one restoration failure due to secondary caries each). All other restorations revealed clinically acceptable FDI scores at all recalls. FOBF performed significantly better than SABF at all time points regarding *surface lustre* (p<0.001) and *color match and translucency* (p<0.001) and regarding *marginal staining* at 36-months (p=0.008). *Marginal staining* and *marginal adaptation* deteriorated significantly over time for both materials (both p<0.001).

Conclusions: The null-hypothesis could only partially be rejected. Both materials performed similarly regarding clinical success and performance within 36 months of clinical service, but SABF exhibited significantly inferior, but clinically fully acceptable esthetic properties as compared to FOBF. Both restorative materials showed clinically fully acceptable results over 36 months of clinical service and thus may be recommended for clinical use.

Clinical significance: The novel tooth-colored self-adhesive bulk-fill restorative exhibited clinically fully acceptable results over 36 months of clinical service, similarly to a conventional bulk-fill restorative used with a universal adhesive, but with slight shortcomings in esthetic properties. Therefore, both restorative materials may be recommended for clinical use.

1. Introduction

Resin-based composites (RBC) have become first-choice materials in dental practice for direct restoration of posterior teeth and have been extensively and successfully employed for this purpose since the late 1980s [1–6], achieving similar clinical longevity as compared to amalgam restorations, with long-term annual failure rates below 2% [5–8]. In the context of the global phase-out of amalgam following the Minamata Convention on Mercury and due to the limited access of most of the world's populations to expensive high-end dentistry, cost-effective and easy-to-use dental restorative materials with high clinical longevity and low technique sensitivity are demanded [9–12].

The introduction of high-viscosity bulk-fill RBCs already offered a considerable ease in handling as compared to conventional RBCs due to the possibility of placing larger bulks and thus avoiding the meticulous and time-consuming incremental layering technique, but these materials still require application of a separate adhesive system [11,13]. Thus, self-adhesion is a worthwhile aspect for further reducing treatment steps and facilitating handling of dental restorative materials in order to establish materials that can serve as true alternatives to amalgam [14–16]. Self-adhesive resin cements already can be considered as clinically established luting materials based on extensive investigations *in vitro* [17–19] as well as *in vivo* [20–22]. The directly emerging class of self-adhesive flowable RBCs, however, unfortunately showed insufficient clinical performance for restoration of load-bearing class I cavities [23] as well as in non-carious cervical lesions [24].

During the last few years, novel self-adhesive restoratives have been developed by different manufacturers, which exhibit better properties *in vitro* than their predecessors, and consequently may meet higher clinical restorative requirements, even for stress-bearing areas as in class II restorations [14,15,25,26]. For instance, a self-adhesive bulk-fill restorative (Surefil One™, Dentsply Sirona, Konstanz, Germany) has recently been marketed after thorough characterization *in vitro* [27–33]. This material has recently also shown acceptable short-term results in an uncontrolled practice-based clinical trial for restoration of class I, II or V cavities after up to 12 months of clinical service [34].

Another self-adhesive bulk-fill restorative (SABF; 3M Oral Care, St. Paul, MN, USA) is not yet commercially available, but has already been investigated in a randomized controlled clinical split-mouth study as compared to a conventional bulk-fill restorative (Filtek™ One Bulk Fill, FOBF; 3M Oral Care), whereby the latter was used in combination with a universal adhesive (Scotchbond™ Universal, SBU; 3M Oral Care) in self-etch mode. Over a period of 12 months, both, SABF and FOBF yielded clinically acceptable scores in all examined FDI criteria with similar clinical performance in functional and biological properties, but significantly better performance of FOBF regarding esthetic properties [25]. Despite these promising short-term results of SABF, observation periods of at least three years have been recommended for clinical assessment of direct restorative materials [35].

Therefore, the aim of this three-year follow-up investigation of a randomized controlled clinical split-mouth study was to further evaluate the clinical performance of class II restorations placed with SABF or FOBF with the latter being used in combination with the universal adhesive SBU in self-etch mode. The null-hypothesis tested was that both materials perform equally regarding clinical success and clinical performance as evaluated by the FDI clinical criteria and scoring system [35,36].

2. Material & methods

2.1. Study design

The present study is a three-year follow-up examination of a prospective controlled randomized clinical split-mouth study investigating the clinical performance of two restorative materials for restoration of class II cavities in premolars and molars, one being a novel self-adhesive dual-curing bulk-fill material (SABF), one a conventional light-curing bulk-fill RBC (Filtek™ One Bulk Fill, FOBF) applied in combination with a universal adhesive (Scotchbond™ Universal, SBU; all: 3M Oral Care, St. Paul, MN, USA) in self-etch mode. The one-year results of this study have been published earlier [25]. The sample size calculation was performed based on the results of a previous study on the clinical success rate of flowable RBCs in non-carious cervical lesions (NCCLs) [37], and has been described before in detail [25]: Assuming a type I error of 0.05, a power of 80%, and a relative risk of 0.33544, the minimum sample size for this split-mouth study was calculated to be 26 patients with two restorations each. Based on that, it was decided to recruit 30 patients for each group in order to compensate for later drop-outs during the course

of the study.

The study design followed the requirements outlined in the CONSORT 2010 statement [38] and was approved by the internal review board of the University of Regensburg (ref. 17-698-101) in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all individual participants included in the study after receiving a detailed description of the proposed treatments. The study has been registered at the German Clinical Trials Register (ref. DRKS00013564).

2.2. Patient selection

Thirty patients were recruited from the patient pool of the Department of Conservative Dentistry and Periodontology of the University Hospital Regensburg. Criteria for inclusion and exclusion have been described previously in detail [25]. In brief, patients had to be between 18 and 75 years old and in need of restorative treatment on at least two class II cavities in premolars or molars because of primary caries, secondary caries or restorations that had failed for other reasons (e.g., due to fractures or insufficient marginal adaptation). Only posterior teeth with class II cavities exhibiting antagonistic contact and at least one proximal contact were included in this study. Cavity characteristics of the included restorations have been described in detail in our previous work [25].

2.3. Clinical restorative procedures

All clinical restorative procedures were performed by three specially instructed and experienced general dentists in a standardized manner, as described previously in detail [25]. The first restoration was placed on 13.12.2017, the last restoration on 03.07.2018. Randomization of the materials (FOBF or SABF) to the respective teeth was performed by drawing a lot from an envelope prepared by the statistical advisor of this study (KAH) assigning one material to the tooth with the lower FDI number and the other to the tooth with the higher FDI number. Whenever possible, restorations were placed using rubber dam isolation; if placement of a rubber dam was not possible, moisture control and a dry operative field were accomplished using cotton rolls, parotis pads, and a saliva ejector. The tooth surface was cleaned with a slurry of pumice and the defective restoration or the carious lesion, respectively, was removed and a class II cavity was prepared. Soft carious dentin was removed with round carbide burs at low speed until firm dentin without any signs of bacterial infection was reached. If indicated, indirect pulp capping was performed with Kerr Life™ (KaVo Kerr, Brea, CA, USA). For FOBF restorations, SBU was used as an adhesive system in self-etch mode according to the instructions of the manufacturer (i.e., active application for 20 s, gentle air drying for 5 s, and light-curing for 10 s at 1250 mW/cm^2). Then, FOBF was placed in bulks of up to 4 mm and thorough light-curing was performed for 20 s per bulk from each aspect (occlusal and proximal). For SABF restorations, SABF was mixed in a capsule-mixing device (CapMix™, 3M Oral Care) for 15 s, placed in one bulk into the unconditioned cavities, and thoroughly light-cured for 20 s from each aspect (occlusal and proximal). Afterwards, restorations were finished and polished. Due to the different restorative procedures for both materials, the dentists performing the restorations could not be blinded to the materials.

2.4. Clinical examination

Clinical examinations were performed by two blinded examiners from a pool of highly trained examiners with regard to examining restorations according to the FDI clinical criteria and scoring system. All examiners from this pool had been calibrated in advance by joint assessment of restorations on photographs as well as in patients. They had not been involved in the treatment procedures, nor were they aware of the restorative material used in the individual teeth or of previous

examination scores. While our previous study reported the clinical results at baseline (BL; 1-2 weeks after restorative procedures) as well as after 6 and 12 months [25], the present study reports the results at BL, 24 months (24-mo) and 36 months (36-mo). For clinical examination of the restorations, the FDI clinical criteria and scoring system was employed [35,36], and the following criteria were selected for evaluation of the clinical performance of the restorations after up to 36-mo:

- **Esthetic properties**
  - *surface lustre* (A1)
  - *surface staining* (A2a)
  - *marginal staining* (A2b)
  - *color match and translucency* (A3)
  - *esthetic anatomical form* (A4)
- **Functional properties**
  - *fracture of material and retention* (B5)
  - *marginal adaptation* (B6)
  - *occlusal contour and wear* (B7)
- **Biological properties**
  - *postoperative (hyper-)sensitivity and tooth vitality* (C11)

- *recurrence of caries, erosion, abfraction* (C12)
- *tooth integrity (enamel cracks, tooth fractures)* (C13)
- *periodontal response* (C14)

Tooth sensitivity was investigated by means of the ice-spray test and postoperative hypersensitivities were asked from the patients. Each restoration was examined independently by both examiners. In case of disagreement between both examiners, consensus was reached by immediate joint discussion and reexamination. The relative numbers of disagreements were recorded at each examination time point.

2.5. Data analysis

Clinical success (primary outcome) was defined for restorations that are still in situ and yield exclusively clinically acceptable FDI scores (i.e., scores 1-3) in all criteria. Clinical performance (secondary outcome) was assessed according to the FDI clinical criteria and scoring system.

All FDI data for BL as well as for the 24-mo and 36-mo examinations referring to all restorations under risk until 36-mo are shown as frequency tables. For evaluating significant differences regarding primary
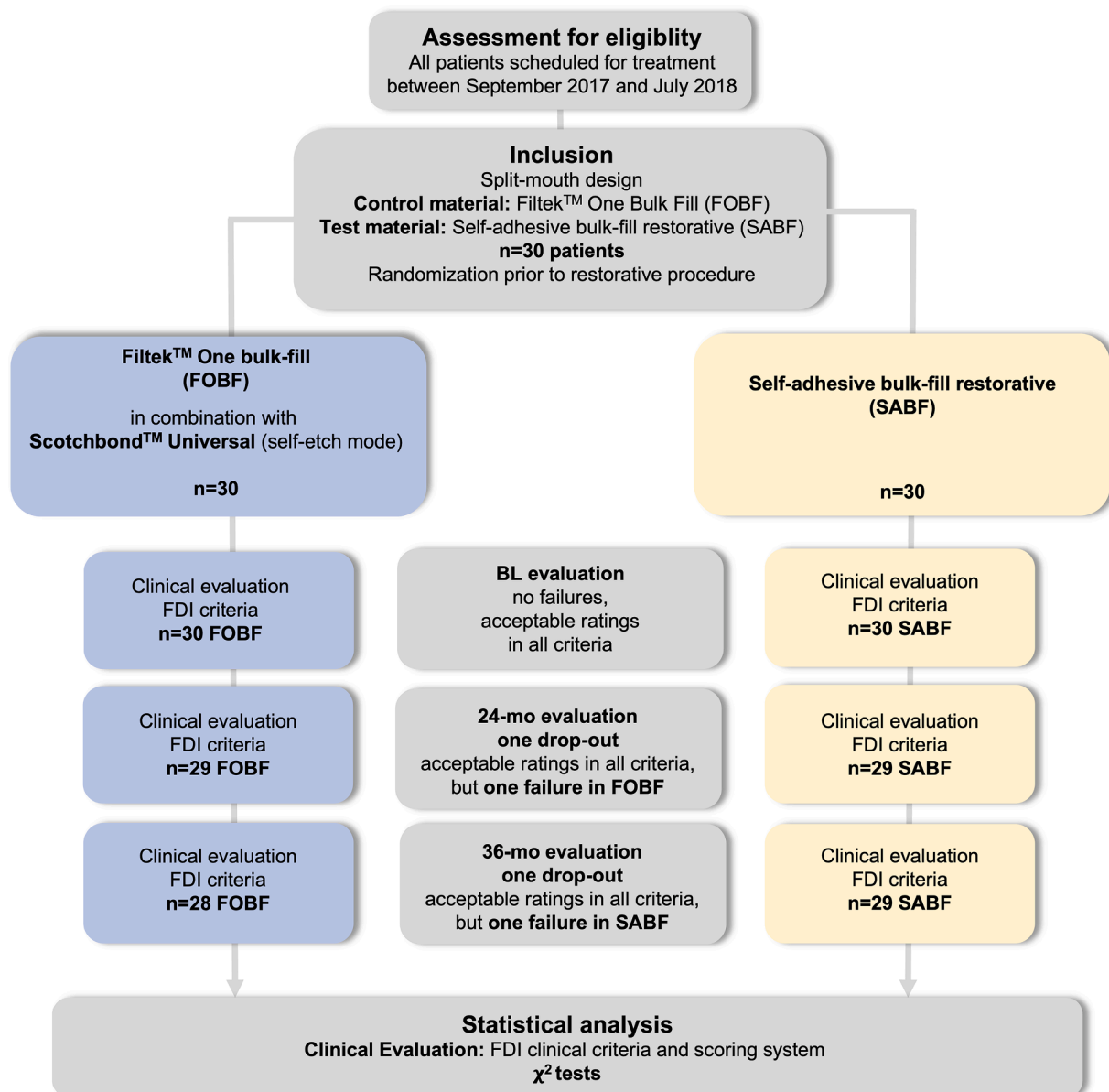

Fig. 1. Flow of participants through the stages of this study.

(clinical success) or secondary outcomes (clinical performance according to the FDI clinical criteria and scoring system) *between* both materials at an examination time point, or *within* a given material over time, pairwise χ^2 tests were applied for each single FDI criterion on a significance level of α = 0.05. All statistical analyses were performed using SPSS for Windows, version 26 (SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Recall rate

The total of 30 patients attended the examination at BL (100%). At 24-mo, 29 patients with both restorations under risk were available for clinical examination (96.7%), while one patient was not available due to restrictions associated with the COVID-19 pandemic and terminated participation prior to the 36-mo evaluation. At 36-mo, 29 patients were available for clinical examination, but one patient had experienced a failure of a FOBF restoration recorded at 24-mo, thus resulting in examination of 29 SABF restorations and 28 FOBF restorations under risk at 36-mo. Fig. 1 shows the flow of participants through the stages of this study up to 36-mo in accordance with the CONSORT 2010 statement [38].

3.2. Clinical success rate (primary outcome)

Clinical success was defined as yielding a clinically acceptable score in *all* examined FDI criteria. One failure of a FOBF restoration (score 4 in *recurrence of caries* (C12); see Fig. 2) was recorded at 24-mo and one failure of a SABF restoration (score 4 in *marginal staining* (A2b), *marginal*

adaptation (B6) and *recurrence of caries* (C12); see Fig. 3) was recorded at 36-mo. These two restorations were rated as failures, therefore leading to a clinical success rate of 96.6% for both materials at 36-mo.

3.3. Disagreements among examiners

All restorations were independently assessed by two examiners each. Among all evaluated FDI criteria in all patients, 4.4% disagreements occurred between both examiners at BL, 5.0% at 24-mo and 9.5% at 36-mo. These disagreements were immediately resolved by joint re-examination and discussion.

3.4. Clinical performance according to selected FDI criteria (secondary outcome)

3.4.1. Esthetic properties

Table 1 shows the clinical data of all restorations at all examination time points (BL, 24-mo, 36-mo) for selected criteria from the FDI *esthetic properties* panel. Although there were solely clinically acceptable scores for *surface lustre* (A1), significant differences between both materials were found at all examination time points (*p*<0.001 each), with FOBF performing significantly better than SABF. However, there was a significant deterioration in surface lustre for FOBF over time between BL and 36-mo (*p*=0.001). For *surface staining* (A2a), solely clinically acceptable scores were recorded with no significant differences between both materials, but there was a significant increase in surface staining for SABF between BL and 36-mo (*p*=0.021). With respect to *marginal staining* (A2b), there was a significant difference between both materials at 36-mo with SABF showing significantly more (*p*=0.008) marginal

Fig. 2. Depiction of FOBF restoration on tooth 47 over time, which was rated as a failure due score 4 at *recurrence of caries* (C12) adjacent to the restoration margin at 24-mo.

Note the high plaque accumulation at 12-mo and the caries adjacent to the restoration margin at 24-mo (white arrow). The caries was removed and the restoration was repaired and is still under risk at 36-mo (black asterisk depicts the repair restoration with an opaque white flowable RBC (Venus® Flow Baseliner, Kulzer, Hanau, Germany).
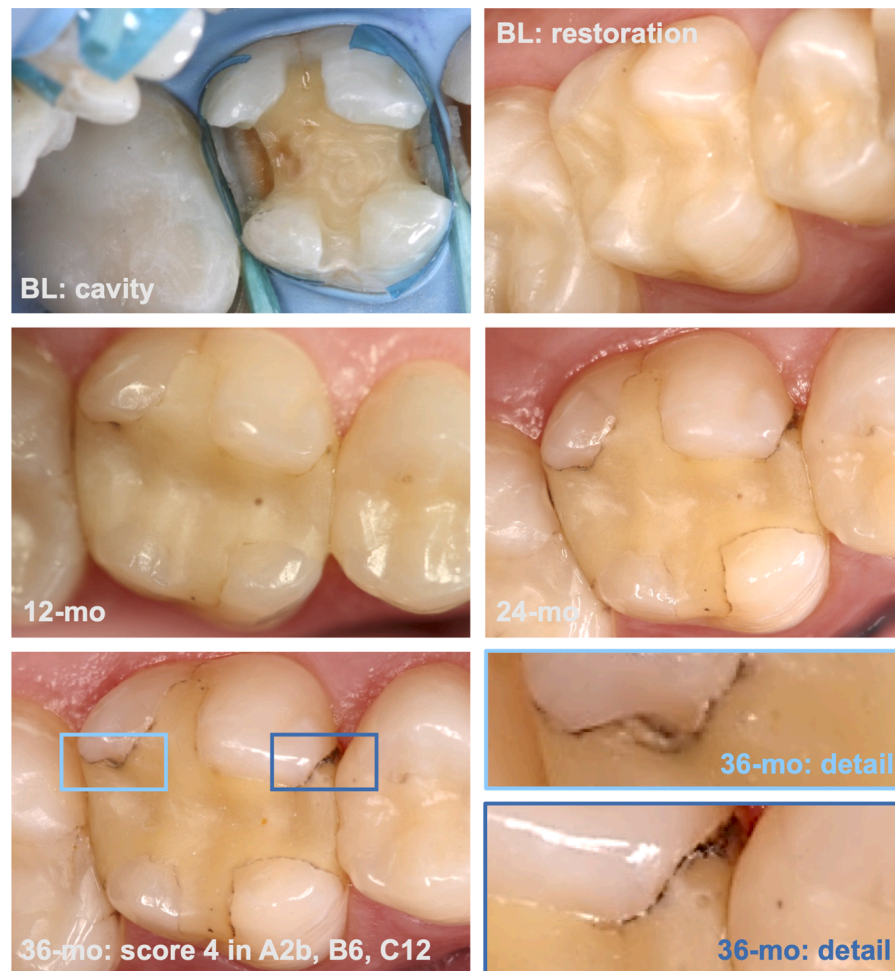
Fig. 3. Depiction of SABF restoration on tooth 16 over time, which was rated as a failure due to score 4 at *marginal staining, marginal adaptation*, and *recurrence of caries* adjacent to the restoration margin at 36-mo.
Note the increasing staining and marginal breakdown as well as caries adjacent to the restoration margin at 36-mo.

staining as compared to FOBF. Both materials revealed significant increases in marginal staining over time between BL and 24-mo (FOBF: $p<0.001$; SABF: $p=0.001$) and between BL and 36-mo ($p<0.001$ for both materials). At 36-mo one SABF restoration received a clinically unacceptable score 4, as shown in Fig. 3. Regarding *color match and translucency* (A3), FOBF performed significantly better than SABF at all examination time points ($p<0.001$). There was also a significant decrease in color match for SABF between BL and 36-mo ($p=0.002$; Fig. 4). Both materials exhibited clinically acceptable scores regarding *esthetic anatomical form* (A4) and there were no significant differences between both materials and over time. Fig. 4 shows clinical examples for differences in esthetic properties between both materials and over time.

3.4.2. Functional properties

Table 2 contains the clinical data of all restorations at the distinct examination time points (BL, 24-mo, 36-mo) for selected criteria from the FDI *functional properties* panel. With respect to *fracture of material and retention* (B5) and *occlusal contour and wear* (B7), there were solely clinically acceptable scores without any significant differences between both materials and over time. Regarding *marginal adaptation* (B6), there were no statistically significant differences between both materials. However, both materials revealed significant deterioration of marginal adaptation over time, which was recorded between BL and 24-mo for SABF ($p=0.001$) only, and between BL and 36-mo for both materials ($p<0.001$ each). At 36-mo, the same SABF restoration that was clinically unacceptable in terms of marginal staining, was also found clinically

unacceptable (score 4) with respect to marginal adaptation, as shown in Fig. 3.

3.4.3. Biological properties

Table 3 shows the clinical data of all restorations at the respective examination time points (BL, 24-mo, 36-mo) for selected criteria from the FDI *biological properties* panel. *Postoperative (hyper-)sensitivity and tooth vitality* (C11) and *tooth integrity (enamel cracks, tooth fractures)* (C13) ratings were clinically acceptable at all examination time points without any statistically significant differences between materials and over time. With respect to *recurrence of caries, erosion, abfraction* (C14), clinically acceptable scores were recorded for both materials with the exception of one case of recurrent caries at 24-mo for FOBF (see Fig. 2) and at 36-mo for SABF (see Fig. 3). These restorations were rated clinically unacceptable (score 4 each), whereby the latter being the same reported earlier as clinically unacceptable in terms of marginal staining and marginal adaptation. Regarding *periodontal response* (C14), there were no significant differences between both materials but both materials exhibited a significant deterioration between BL and 24-mo (FOBF: $p=0.001$; SABF: $p=0.002$) as well as between BL and 36-mo ($p<0.001$ each), mostly attributed to increases in score 2-ratings.

4. Discussion

To serve as a true alternative to amalgam, a restorative material should ideally combine bulk-fill and self-adhesive properties [14–16].

Table 1
Clinical data for esthetic properties according to FDI criteria.

FDI criteria	Examination time point		FOBF FDI score					SABF FDI score					Significant difference	
			1	2	3	4	5	1	2	3	4	5		
A1 surface lustre	BL	n	25	3	2	-	-	3	24	3	-	-	**<0.001**	
		%	83.3	10	6.7			10	80	10				
	24-mo	n	21	8	-	-	-	1	27	1	-	-	**<0.001**	
		%	72.4	27.6				3.4	93.2	3.4			-	-
	36-mo	n	12	16	-	-	-	-	25	4	-	-	**<0.001**	
		%	42.9	57.1					86.2	13.8			<0.001	-
A2a surface staining	BL	n	30	-	-	-	-	29	1	-	-	-	**-**	
		%	100					96.7	3.3					
	24-mo	n	29	-	-	-	-	25	3	1	-	-	**-**	
		%	100					86.3	10.3	3.4			-	-
	36-mo	n	24	4	-	-	-	20	9	-	-	-	**-**	
		%	85.7	14.3				69	31				0.032	0.005
A2b marginal staining	BL	n	30	-	-	-	-	28	2	-	-	-	**-**	
		%	100					93.3	6.7					
	24-mo	n	18	5	6	-	-	12	7	10	-	-	**-**	
		%	62.1	17.2	20.7			41.4	24.1	34.5			0.001	<0.001
	36-mo	n	14	9	5	-	-	3	13	12	1	-	**0.008**	
		%	50	32.1	17.9			10.3	44.8	41.4	3.4		<0.001	<0.001
A3 color match and translucency	BL	n	27	3	-	-	-	7	20	3	-	-	**<0.001**	
		%	90	10				23.3	66.7	10				
	24-mo	n	26	3	-	-	-	1	26	2	-	-	**<0.001**	
		%	89.7	10.3				3.4	89.9	6.7			-	-
	36-mo	n	28	-	-	-	-	1	21	7	-	-	**<0.001**	
		%	100					3.4	72.4	24.1			-	0.047
A4 esthetic anatomical form	BL	n	29	1	-	-	-	28	2	-	-	-	**-**	
		%	96.7	3.3				93.3	6.7					
	24-mo	n	28	1	-	-	-	27	2	-	-	-	**-**	
		%	96.6	3.4				93.1	6.9				-	-
	36-mo	n	28	-	-	-	-	29	-	-	-	-	**-**	
		%	100					100					-	-

Frequencies of FDI scores 1-5 (number of restorations (n) and percentages (%)) are depicted for FOBF and SABF. Clinically acceptable scores (1-3) are highlighted in green, non-acceptable scores are highlighted in orange. *p*-values show significant differences between materials at a respective examination time point in light grey, and significant differences within a material over time (BL vs. 24-mo, BL vs. 36-mo) in dark grey (FOBF left, SABF right).

Fig. 4. Exemplary depiction of differences in *surface lustre* and *color match and translucency* between both materials over time.
Top row: Mesial-occlusal-distal FOBF restoration on tooth 44 at BL, 24-mo and 36-mo.
Bottom row: Mesial-occlusal-distal SABF restoration on tooth 45 at BL, 24-mo and 36-mo.
Note the differences in surface lustre due to porosities in SABF with change to more yellowish and opaque color over time.

SABF is a tooth-colored, dual-curing, self-adhesive resin-based bulk-fill restorative, not requiring retentive cavity preparation, conditioning of enamel or dentin, or preceding application of an adhesive. SABF has shown fully satisfying short-term results after 12 months of clinical service with a survival rate of 100% and all restorations rated clinically acceptable in all examined FDI criteria [25]. Since observation periods of at least three years are recommended for clinical assessment of direct restorative materials [35], the aim of the present follow-up investigation

Table 2
Clinical data for selected functional properties according to FDI criteria.

FDI criteria	Examination time point		FOBF FDI score					SABF FDI score					Significant difference	
			1	2	3	4	5	1	2	3	4	5		
B5 fracture of material and retention	BL	n	29	-	1	-	-	29	-	1	-	-	-	
		%	96.7	3.3				96.7	3.3					
	24-mo	n	29	-	-	-	-	28	-	1	-	-	-	
		%	100					96.6	3.4				-	-
	36-mo	n	28	-	-	-	-	28	-	1	-	-	-	
		%	100					96.6	3.4				-	-
B6 marginal adaptation	BL	n	26	3	1	-	-	27	2	1	-	-	-	
		%	86.7	10	3.3			90	6.7	3.3				
	24-mo	n	21	7	1	-	-	13	14	2	-	-	-	
		%	72.4	24.2	3.4			44.8	48.3	6.9			-	0.001
	36-mo	n	5	22	1	-	-	6	19	3	1	-	-	
		%	17.9	78.6	3.6			20.7	65.5	10.3	3.4		<0.001	<0.001
B7 wear	BL	n	30	-	-	-	-	30	-	-	-	-	-	
		%	100					100						
	24-mo	n	27	1	1	-	-	28	1	-	-	-	-	
		%	93.2	3.4	3.4			96.6	3.4				-	-
	36-mo	n	27	1	-	-	-	29	-	-	-	-	-	
		%	96.4	3.6				100					-	-

Frequencies of FDI scores 1-5 (number of restorations (n) and percentages (%)) are depicted for FOBF and SABF. Clinically acceptable scores (1-3) are highlighted in green, non-acceptable scores are highlighted in orange. *p*-values show significant differences between materials at a respective examination time point in light grey, and significant differences within a material over time (BL vs. 24-mo, BL vs. 36-mo) in dark grey (FOBF left, SABF right).

of a randomized controlled clinical split-mouth study was to evaluate the clinical performance of SABF or the conventional bulk-fill RBC FOBF (used in combination with the universal adhesive SBU in self-etch mode) for restoration of class II cavities after up to 36 months. The design of the present study as a prospective, controlled, randomized clinical split-mouth study has already been discussed in detail previously [25], and followed the requirements of the 2010 CONSORT statement [38]. The use of the FDI clinical criteria and scoring system for the present study has already been discussed in our previous publication [25]. A recent study compared FDI and modified USPHS criteria for the evaluation of bulk-fill RBCs in class I and class II cavities and found differences in the criteria related to surface lustre, marginal staining, and marginal adaptation, concluding that FDI criteria allow for a more detailed evaluation of restoration in each category and thus better reflect the clinical success of the restorations [39]. Hickel *et al.* recommended not to mandatorily report all criteria but to select those with relevance for the scope of the respective study [36]. This has been followed by many authors [19,25,37,40–44], and was accordingly applied in the present study. Clinical assessment of the restorations was performed by two blinded examiners out of a pool of trained evaluators. In case of disagreements between the two examiners, both examiners reexamined the restorations and discussed till agreement was reached. The low rate of disagreements (4.4% to 9.5%) reflects the high level of experience of the examiners from using the FDI clinical criteria and scoring system in previous studies [20,25,37,43,45]. On the other hand, the higher rate of disagreements at 36-mo may result from the wider range of variations due to ageing after longer periods of clinical service as compared to BL or 12-mo, along with the possibility that a wider range of FDI scores may be applicable. Furthermore, in several criteria, the definitions for some criteria are very similar and hardly discernible (i.e., criterion *surface lustre*: score 2 "slightly dull" vs. score 3 "dull but acceptable with a film of saliva"), which can also easily result in a disagreement between examiners.

4.1. Clinical success rate (primary outcome)

The basic prerequisite for self-adhesion to dental hard tissues is that the self-adhesive material can chemically or micromechanically interact with enamel and dentin and in the latter case, especially with the smear layer [19,27]. If establishing a stable bond fails, this might result clinically in disintegration of the adhesive interface leading to post-operative hypersensitivities and marginal deterioration in the early stages of clinical service, and caries as well as bulk fractures in the long term [16, 35,46,47]. The results of the present study show that after clinical service of 36-mo both materials exhibited clinical success rates of 96.6% with just one failure of a restoration for each material. For FOBF, one restoration failed at 24-mo due to secondary caries (score 4 at *recurrence of caries*; see Fig. 2), while one SABF restoration failed at 36-mo due to clinically unacceptable marginal staining and marginal adaptation along with secondary caries (score 4 for *marginal staining, marginal adaptation and recurrence of caries*; see Fig. 3). This is in line with Hickel et al. who stated that late fractures (i.e., after 18-24 months of clinical service) mainly occur due to bulk or tooth fractures, extensive wear or due to secondary caries [35]. Despite these two failures, both materials clearly meet the requirements outlined in the former (and meanwhile no longer valid) ADA acceptance guidelines for RBCs to be used for posterior restorations which postulated that less than 10% of the restorations should yield clinically unacceptable scores (i.e., charlie ratings according to the modified USPHS criteria) after three years of clinical service [48,49]. The results of the present evaluation are also in the range of findings reported in other recent studies evaluating the clinical success of self-adhesive or conventional bulk-fill restoratives [34,50]. For instance, Rathke et al. investigated 60 restorations in class I, class II and class V cavities placed with the self-adhesive bulk-fill restorative Surefil One™ (Dentsply Sirona) in a practice-based prospective but uncontrolled study and recorded one failure of a class II restoration after 12 months, resulting in a failure rate of 2% [34]. Another recent study comparing different bulk-fill RBCs to a nanohybrid RBC for restoration

Table 3
Clinical data for selected biological properties according to FDI criteria.

FDI criteria	Examination time point		FOBF FDI score					SABF FDI score					Significant difference	
			1	2	3	4	5	1	2	3	4	5		
C11 postoperative (hyper-) sensitivity and tooth vitality	BL	n	28	2	-	-	-	27	2	1	-	-	-	
		%	93.3	6.7				90	6.7	3.3				
	24-mo	n	28	1	-	-	-	28	1	-	-	-	-	
		%	96.6	3.4				96.6	3.4				-	-
	36-mo	n	28	-	-	-	-	29	-	-	-	-	-	
		%	100					100					-	-
C12 recurrence of caries, erosion, abfraction	BL	n	29	1	-	-	-	30	-	-	-	-	-	
		%	96.7	3.3				100						
	24-mo	n	28	-	-	1	-	29	-	-	-	-	-	
		%	96.6			3.4		100					-	-
	36-mo	n	28	-	-	-	-	28	-	-	1	-	-	
		%	100					96.6			3.4		-	-
C13 tooth integrity (enamel cracks, tooth fractures)	BL	n	17	11	2	-	-	16	13	1	-	-	-	
		%	56.7	36.7	6.7			53.3	43.3	3.3				
	24-mo	n	11	18	-	-	-	12	17	-	-	-	-	
		%	37.9	62.1				41.4	58.6				-	-
	36-mo	n	16	11	1	-	-	12	17	-	-	-	-	
		%	57.1	39.3	3.6			41.4	58.6				-	-
C14 periodontal response	BL	n	16	9	5	-	-	13	10	7	-	-	-	
		%	53.3	30	16.7			43.3	33.3	23.3				
	24-mo	n	3	20	6	-	-	9	16	5	-	-	-	
		%	10.3	69	20.7			30	53.3	16.7			0.001	0.002
	36-mo	n	-	22	6	-	-	-	25	4	-	-	-	
		%		78.6	21.4				86.2	13.8			<0.001	<0.001

Frequencies of FDI scores 1-5 (number of restorations (n) and percentages (%)) are depicted for FOBF and SABF. Clinically acceptable scores (1-3) are highlighted in green, non-acceptable scores are highlighted in orange. *p*-values show significant differences between materials at a respective examination time point in light grey, and significant differences within a material over time (BL vs. 24-mo, BL vs. 36-mo) in dark grey (FOBF left, SABF right).

of 160 class II cavities recorded seven failures after 12 months and another eight failures after 24 months of clinical service, without any significant differences between the materials in terms of clinical success [50]. Yazici et al. compared the performance of a bulk-fill RBC (Tetric EvoCeram® Bulk Fill; Ivoclar Vivadent, Schaan, Liechtenstein) and a conventional RBC (Filtek™ Ultimate; 3M Oral Care) in class II restorations in a split-mouth design in 50 patients [51]. After 6 years of clinical service, there was just one restoration failure in the conventional RBC group. Despite significant degradation in terms of marginal adaptation for both groups, the restoration with the bulk-fill RBC performed significantly better with regard to marginal discoloration [51].

4.2. Clinical performance according to selected FDI Criteria (secondary outcome)

As discussed above, only those FDI criteria are reported in the present study which were considered relevant for the evaluation of load-bearing class II restorations after 36 months of clinical service.

4.2.1. Esthetic properties

SABF yielded slightly inferior esthetic properties as compared to FOBF, but within a clinically fully acceptable range, as also reported after 12 months of clinical service [25]. *Surface lustre* was found to be significantly duller for SABF as compared to FOBF at all examination time points. As discussed before, surface polishing of SABF restorations was impaired due to the presence of small voids or porosities, that may be related to the mixing procedure of the two-component material SABF [25]. While this slight dullness was obvious in SABF restorations from BL

and did not intensify over time, *surface lustre* significantly decreased in FOBF restorations over time from BL to 36-mo. This may be mainly attributed to attrition and general ageing of the restorations. Despite the shortcomings with respect to polishing and the slightly dull appearance of SABF as compared to FOBF, *surface staining* was not an issue for either material within the first 36 months of clinical service, although a significant increase was recorded for SABF over time between BL and 36-mo. Unfortunately, the study on the self-adhesive bulk-fill restorative Surefil™ One did not investigate criteria related to surface lustre or surface staining [34].

In the present investigation, both materials exhibited significantly increasing *marginal staining* over time, which was more pronounced for SABF, culminating in a significant difference between the materials at 36-mo. *Marginal staining* generally occurs in the course of clinical service due to slight degradation at the adhesive interface, leading to small imperfections or gaps in this area and accumulation of pigments within these marginal deficiencies [52–54]. In the present study, no selective enamel etching was performed with the idea of reducing working steps for both materials and using them in a simplified approach. This may have favored the occurrence of marginal discolorations [54]. The self-etching properties of a mild universal adhesive such as SBU or a self-adhesive restorative such as SABF yields inferior etching patterns in enamel as compared to phosphoric acid [14], thus potentially leading to a less intense interaction zone at the adhesive interface, favoring small imperfections along the restoration margins in the course of ongoing clinical service [54]. Accordingly, a recent clinical trial showed marginal staining significantly more often when a universal adhesive was used in self-etch than in etch-and-rinse mode for restoration of class II

cavities with a bulk-fill RBC [55].

FOBF showed mainly perfect *color match and translucency* over the whole observation period, in line with another recent clinical trial investigating FOBF in class II restorations after up to 36 months [39]. On the other hand, SABF restorations exhibited significantly inferior results in this criterion at each examination time point, but still within the clinically fully acceptable range. As for the criterion surface lustre, this difference between both materials may be attributed to the different material compositions in general. The mixing of the powder and liquid component may lead to intrinsic pores and inhomogeneities in the two-component material SABF, potentially resulting in different light transmission characteristics and explaining the more opaque and darker appearance of SABF. In the practice-based study on the self-adhesive bulk-fill restorative Surefil™ One, color match yielded 12% clinically not acceptable charlie scores according to modified USPHS criteria after 12 months of clinical service, but there was no control material [34].

In the present study, restorations with mainly perfect *esthetic anatomical forms* could be reached with both materials, FOBF and SABF, although different approaches were employed to adjust the occlusal morphology of the restorations. With SABF, subtractive procedures after light-curing of the restorations were applied to reach the final form, while FOBF restorations could be sculpted directly after placement of the material prior to light-curing, as described in detail previously [25].

4.2.2. Functional properties

Both materials exhibited clinically fully acceptable *functional properties* without any significant differences between materials. There were no catastrophic failures, bulk fractures, or extensive wear within the first 36 months of clinical service, as recorded in the criteria *fracture of material and retention* and *occlusal contour and wear*. This clearly reflects that both materials exhibited sufficient mechanical properties for restoration of load-bearing class II cavities.

Marginal adaptation is generally seen as one of the most relevant factors for clinical success of adhesively bonded restorations [52,56]. Here, a significant deterioration of both materials over time was found, starting for SABF at 24-mo and FOBF at 36-mo and mainly represented by slight steps or flashes and minor irregularities along the restoration margins at the 24-mo and 36-mo examination time points. Deterioration of marginal adaptation is usually preceded by increase in marginal staining (as also found here) indicating degradation of the adhesive interface and formation of small marginal gaps [52,53], and may be attributed to the lack of selective enamel etching in the present study [54,57], as discussed above. Accordingly, a recent systematic review stated that restorations placed with universal adhesives showed a significantly worse retention rate in NCCLs when used without additional selective enamel etching [57]. Nevertheless, the decrease in marginal adaptation observed over time in the present study may still be considered neglectable because both materials predominantly exhibited clinically acceptable scores (mainly scores 1 and 2) regarding their marginal adaptation, with the exception of one SABF restoration that failed at 36-mo (score 4 for *marginal adaptation*, see Fig. 3). Furthermore, there were no significant differences between both materials with regard to marginal adaptation over the whole study period, whereas Oz et al. reported significantly worse marginal adaptation for a self-adhesive flowable RBC in occlusal class I cavities when compared to two flowable RBCs used with universal adhesives in self-etch mode [58].

4.2.3. Biological properties

Postoperative (hyper-)sensitivity had been recorded directly after placement of one SABF restoration at BL in a few cases only but had already ceased before the 6-mo recall [25]. During the further course of the study, no clinically unacceptable postoperative hypersensitivities occurred which could have been an indicator of insufficient adhesion of the materials to dental hard tissues or loss of adhesion over time, insufficient curing depth, or presence of voids along the restoration margins.

With respect to *recurrence of caries*, two restorations were recorded as clinically not acceptable (score 4). One FOBF restoration exhibited secondary caries associated with the restoration margin at 24-mo (see Fig. 2), and was repaired using minimally invasive restoration procedures following caries removal. At 36-mo, one SABF restoration also exhibited secondary caries associated with the restoration margin along with clinically insufficient scores in marginal staining and marginal adaptation. Therefore, the whole restoration was replaced (see Fig. 3). In this regard, the handling of repairs should be discussed: In clinical practice, repair of a partially defective restoration is an approved treatment option and has been shown to increase the clinical survival of restorations, with repaired restorations lasting as long as restoration replacements [59]. However, according to the clinical study protocol of the present study and according to the original FDI criteria [35,36], repaired restorations are rated as restoration failures, even if the repair involves only a minor area of the entire restoration, which remains in function (as in the FOBF restoration failure, see Fig. 2) and could be evaluated at further recalls. Therefore, it should be taken into account for future studies that repaired restorations (score 4) are not regarded as failures but as restorations under risk, as long as it is possible to assess the restorations according to FDI criteria. The authors consider this an important aspect of discussion for application of FDI criteria in the future.

For clinical evaluation of novel dental restorative materials, it is crucial to assess *tooth integrity* and the appearance of enamel cracks or tooth fractures over time. These may occur due to water-uptake and spatial expansion of the given material, as previously observed for a variety of dental restorative materials [60–62]. Here, tooth integrity did not significantly change over time and no new cracks occurred, independent of which material was used.

Both materials exhibited significant declines in *periodontal response*, but within a fully clinically acceptable range. As discussed in our previous study [25], it was noticed that the original instructions for scoring criterion *periodontal response* can result in classifying clinically acceptable restorations as failures (score 4) simply based on clinically not relevant local fluctuations in PBI without any need of intervention (e.g., from grade 0 to grade 2). Therefore, this criterion should be amended by discriminating score 3 and score 4 ratings just by the need for intervention in terms of recontouring or polishing overhangs of a given restoration (score 3: no need for intervention; score 4: need for intervention) [25].

The null-hypothesis tested in the present study could not be rejected in all aspects: With respect to the clinical success, both materials performed equally exhibiting a clinical success rate of 96.6% after 36 months of clinical service and one restoration failure per each group. Regarding clinical performance, both restorative materials exhibited clinically acceptable scores in all examined FDI criteria (except for the failed restoration in each group). While both materials exhibited similar clinical performance in functional and biological properties, FOBF showed significantly better performance than SABF with respect to the esthetic properties *surface lustre* and *color match and translucency* at all examination time points and *marginal staining* at 36-mo. Therefore, SABF can be considered as a slightly less esthetically satisfying, but still clinically fully acceptable restorative material. There was significant deterioration along the restoration margins (*marginal staining* and *marginal adaptation*) for both materials over time, as also observed with other tooth-colored, adhesive restorative materials.

5. Conclusion

Within the limitations of this study, the novel self-adhesive bulk-fill restorative showed clinically fully acceptable results over 36 months of clinical service similarly to the bulk-fill RBC. Therefore, both materials may be recommended for clinical use, and the self-adhesive bulk-fill restorative may serve as less time-consuming alternative to conventional RBC materials that require additional use of an adhesive system.

Compliance with ethical standards

Ethical approval

All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments. The study design was approved by the internal review board of the University of Regensburg (reference: 17-698-101). The study has been registered at the German Clinical Trials Register (ref. DRKS00013564).

Informed consent

Written informed consent was obtained from all individual patients included in this study.

CRediT authorship contribution statement

Fabian Cieplik: Conceptualization, Investigation, Validation, Writing – original draft. **Karl-Anton Hiller:** Conceptualization, Formal analysis, Data curation, Writing – review & editing. **Wolfgang Buchalla:** Conceptualization, Writing – review & editing. **Marianne Federlin:** Conceptualization, Investigation, Project administration, Writing – review & editing. **Konstantin J. Scholz:** Conceptualization, Investigation, Validation, Writing – review & editing.

Declaration of Competing Interest

All authors declare that they have no conflicts of interest.

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