Randomized 3-year Clinical Evaluation of Class I and II Posterior Resin Restorations Placed with a Bulk-fill Resin Composite and a One-step Self-etching Adhesive

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Purpose: To evaluate the 3-year clinical durability of the flowable bulk-fill resin composite SDR in Class I and Class II restorations.

Materials and Methods: Thirty-eight pairs of Class I and 62 pairs of Class II restorations were placed in 44 male and 42 female patients (mean age 52.4 years). Each patient received at least two extended Class I or Class II restorations that were as similar as possible. In all cavities, a one-step self-etching adhesive (XenoV+) was applied. One of the cavities of each pair was randomly assigned to receive the flowable bulk-fill resin composite SDR in increments up to 4 mm as needed to fill the cavity 2 mm short of the occlusal cavosurface. The occlusal part was completed with an ormocer-based nanohybrid resin composite (Ceram X mono+). In the other cavity, only the resin composite CeramX mono+ was placed in 2 mm increments. The restorations were evaluated using slightly modified USPHS criteria at baseline and then annually for 3 years. Caries risk and bruxing habits of the participants were estimated.

Results: No post-operative sensitivity was reported. At the 3-year follow-up, 196 restorations – 74 Class I and 122 Class II – were evaluated. Seven restorations failed (3.6%), 4 SDR-CeramX mono+ and 3 CeramX mono+ only restorations, all of which were Class II. The main reason for failure was tooth fracture, followed by resin composite fracture. The annual failure rate (AFR) for all restorations (Class I and II) was 1.2% for the bulk-filled restorations and 1.0% for the resin composite-only restorations ($p > 0.05$). For the Class II restorations, the AFR was 2.2% and 1.6%, respectively.

Conclusion: The 4-mm bulk-fill technique showed good clinical effectiveness during the 3-year follow-up.

Keywords: bulk fill, dental restorations, clinical, composite resin, nano, posterior, self-etching adhesive.

J Adhes Dent 2015; 17: 81–88.
doi: 10.3290/j.jad.a33502

Submitted for publication: 03.08.14; accepted for publication: 10.12.14

Resin composites (RC) have gradually replaced amalgam as a restorative material during the last decade.[59] Despite its increasing use in the posterior region, several problems with resin-based materials, mainly related to the reasons for failure (recurrent caries, material and tooth fracture) still have not been solved. During curing of the resin, a network of polymers is formed, which becomes rigid due to increased cross linking of the polymer chains. Decreasing mobility of the network causes further shrinkage and results in a strain on the RC and cavity margins. The resulting stress has been associated with marginal deficiencies, enamel fractures, cuspal movement, and cracked cusps, which in turn may result in microleakage, post-operative sensitivity, and secondary caries.[1] It has been stated that posterior Class II and especially Class I cavities with a high C-factor will result in greater stresses due to a larger number of bonded surfaces.[28] However, the correlation of interfacial stress and the clinical outcome is weak, as shown in long-term follow-ups.[14,16,50] Resin composites with a lower modulus of elasticity or slower curing rate may reduce the polymerization stress.[36,60] Therefore, several modified insertion and light-curing techniques have been introduced during the past few years to decrease the marginal stress.[22,24,39,47,56,60] So far, there is no evidence that these techniques improve clinical efficacy.[22,24] Extensive efforts have also been made to develop low-shrinkage RCs by changing filler amount, size, and shape, monomer structure or

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chemistry, and by modifying the polymerization reaction.[34] Clinical data is limited, but acceptable durability was reported in two 5-year follow-up studies.[7,21]

It has been claimed that polymerization shrinkage may be decreased by the use of an incremental layering technique, horizontal or oblique, by placing the material in increments of 2 mm, followed by light curing of each layer. However, in a fininte element analysis, Versluis et al[62] concluded that the oblique layering technique instead produced the highest stresses. The use of a bulk-fill technique may result in lower shrinkage stress, but to obtain optimal conversion in deeper layers, an incremental filling technique is still required for conventional hybrid RC materials. The first marketed light-curing bulk-fill RC (QuiXfil, Dentsply DeTrey; Konstanz, Germany), a very transluscent material, showed acceptable clinical results in a 4-year randomized clinical study.[46] Recently, several new materials have been marketed within this new class of bulk-fill resin-based composites, which can be cured in layers up to 4 or 5 mm. They can be divided into two groups with different mechanical properties, the low- and high-viscosity materials.[35] As opposed to the high-viscosity materials, those with low viscosity must be covered with an occlusal layer of conventional hybrid resin RC. For the first marketed flowable bulk-fill composite resin, SDR (Dentsply DeTrey), polymerization stress was claimed to be reduced directly during curing. A polymerization modulator, a patented urethane di-methacrylate, was chemically embedded in the resin backbone, which resulted in a slower modulus development, allowing stress reduction without decreasing the conversion rate.[3,27,33,35,36,38] Moorthy et al[49] showed that Class II cavities restored with the bulk-filled SDR RC to within 2 mm of the occlusal enamel-dentin border resulted in significantly reduced cuspal deflection compared to an oblique technique. Significantly lower shrinkage stress was observed for the flowable material than for a regular methacrylate-based RC and several nanohybrid flowable RCs.[33] Only one clinical study so far has examined the clinical efficacy of the bulk-fill RCs and curing 4-mm-thick layers.[26]

Self-etching adhesives (SEA) are based on infiltration and modification of the smear layer by acidic monomers or by dissolving the smear layer and demineralizing the underlying outer layer of dentin. The bond strength and clinical performance of one-step SEAs have been questioned in the literature for many years, but recently, good clinical durability has been reported for several new products.[17,18,23,24,61] The successor of one of these SEAs, the one-step SEA XenoV, showed good short-term durability in a recent randomized clinical study.[26] In the present study, the latest version of the product (XenoV+), which is claimed to exhibit optimized application features, was tested in an extended investigation in combination with the bulk-fill SDR and an improved version of the ormocer-based nanohybrid RC Ceram X mono+.

The aim of this randomized controlled study was to intra-individually compare the clinical effectiveness of the flowable RC SDR placed in increments of 4 mm maximum (bulk fill) in large, deep Class I and Class II cavities bonded with a one-step SEA. SDR was used to fill the cavity 2 mm short of the occlusal cavosurface and was then covered with a nanohybrid RC. The SDR restoration was compared intra-individually with a restoration made only of a nanohybrid RC placed and cured with a 2-mm layering technique. The null hypothesis tested was that there would be no differences in clinical effectiveness between restorations placed with the bulk-fill RC and those without.

MATERIALS AND METHODS

From October to December 2010, all adult patients attending the Public Dental Health Service clinic at the Dental School of Umeå and a private dental clinic in Copenhagen who needed one or two pairs of similar Class I or Class II restorations were asked to participate in the follow-up. All invited patients participated in the study. No participant was excluded because of high caries activity, periodontal condition, or parafunctional habits in order to mirror the whole patient population. Pregnant patients were excluded. All patients were informed about the background of the study, which was approved by the ethics committee of the University of Umeå (Dnr 07-152M) and followed recent CONSORT and FDI recommendations.[32] Reasons for placement of the RC restorations were primary and secondary carious lesions, fracture of old fillings, or replacement for esthetic or other reasons. In order to make an intra-individual comparison possible, each patient received two or four restorations as similarly sized and located as possible. The majority of the cavities were deep and had extended sizes. There was no limitation on the thickness of the remaining cusps. The cavity pairs in each individual were randomly distributed in terms of restoration, with either the experimental or the control restoration asigned according to a predetermined scheme of randomization. The participants did not know in which cavity the experimental and control restoration were placed. In the experimental cavity, an intermediate layer of the SDR flowable RC (Dentsply DeTrey; Table 1) was placed in the deepest parts, followed by an occlusal covering layer of the nanohybrid RC Ceram X mono+ (Dentsply DeTrey; subsequently termed Ceram X). The control restoration was filled with Ceram X (RC-only restoration). All teeth were in occlusion and had at least one proximal contact with an adjacent tooth. Thirty-eight pairs of Class I and 62 pairs of Class II restorations were placed in 82 patients (44 men, 42 women) with a mean age of 52.4 years (20 to 86). The distribution of the involved experimental teeth is shown in Table 2. The sample size was calculated on the basis of previous sample size calculations performed in similarly designed studies of posterior restoration evaluations. The theoretical sample size was set to 40 restorations per group to determine significant differences in outcomes at the 95% confidence level, with an alpha value = 0.05 and 80% power. It has been possible to determine significant differences between material groups in similarly designed intra-individual comparison evaluations with this sample size in previous studies.[15,17,19] The number of participants was increased to take possible drop-outs into account.

Table 1 Resin composites and adhesive system used

Material	Composition	Type	Application steps	Manufacturer
SDR	Filler: barium-alumino-fluoro-borosilicate glass, strontium alumino-fluoro-silicate glass Matrix: modified urethane dimethacrylate resin, ethoxylated bisphenol-A dimethacrylate (EBPADMA), triethyleneglycol dimethacrylate, camphorquinone, butylated hydroxyl toluene, UV stabilizer, titanium oxide, iron oxide pigments		The SDR flow base is covered with at least 2 mm RC. Apply in 4-mm layers, light cure 20 s.	Dentsply DeTrey; Konstanz, Germany
Ceram X mono +	Filler: barium-aluminium-borosilicate glass (1.1-1.5 µm), methacrylate functionalized silicone dioxide nano filler (10 nm) Matrix: methacrylate modified polysiloxane, dimethacrylate resin, fluorescent pigment, UV stabilizer, stabilizer, camphorquinone, ethyl-4 (dimethylamino) benzoate, titanium oxide pigments, aluminium silicate pigments	Nanohybrid: 76% w/w filler, 57% v/v filler, average size of nanofillers 10 nm and nano particles 2.3 nm	Apply in 2-mm layers, light cure 20 to 30 s	Dentsply DeTrey
XenoV+		1-component one-step self-etching adhesive	Apply primer 20 s, carefully air dry for > 5 s, light cure 10 s	Dentsply DeTrey

Clinical Procedure

Existing restorations and/or caries were removed under constant water cooling. No bevels were prepared. The operative field was carefully isolated with cotton rolls and a suction device. For all Class II cavities, a thin metallic matrix was used and wedging was done carfully with wooden wedges (KerrHawe Neos; Bioggio, Switzerland). The cavities were cleaned by thoroughly rinsing with water. None of the cavities received $Ca(OH)_2$ or other base materials. Application of the one-step self-etching adhesive XenoV+ (Dentsply DeTrey; Konstanz, Germany) in both cavities was performed according to the manufacturer's instructions (Table 1). After gently agitating for 20 s, the solvent was evaporated thoroughly for at least 5 s. Curing was then performed with a well-controlled high-power curing unit (Smartlite PS, Dentsply DeTrey) for at least 10 s. For the experimental SDR restoration, the flow material was dispensed directly into the cavity from the syringe tip using slow, steady pressure, beginning at the deepest portion of the cavity and keeping the tip close to the cavity floor. The tip was gradually withdrawn as the cavity was filled. The material was available in one semi-transluscent universal shade. It was placed in bulk increments up to 4 mm as needed to fill the cavity 2 mm short of the occlusal cavosurface. After curing of the flow increment(s) for 20 s, the occlusal part of the restoration was completed using RC Ceram X. In the control cavity, the RC Ceram X was applied in 2-mm layers with an oblique layering technique, if possible. Selected resin composite instruments (Hu-Friedy; Chicago, IL, USA) were used. The pairs of restorations with each of the two restorative combinations were placed by two experienced operators (JvD, UP). After checking the occlusion/articulation and contouring with finishing diamond burs, final polishing was performed with the Shofu polishing system (Brownie, Shofu; Kyoto, Japan) and finishing strips (GC finishing strips; Tokyo, Japan).

Table 2 Distribution of the experimental restorations

Surfaces	Mandible		Maxilla		
	Premolars	Molars	Premolars	Molars	
Class I	2	25	13	36	76
Class II	33	40	19	32	124
	35	65	32	68	200

Evaluation

At baseline (immediately after placing the restorations) and after 1, 2, and 3 years the restorations were assessed by the following parameters: anatomic form, marginal adaptation, marginal discoloration, surface roughness, color match, and secondary caries by slightly modified USPHS criteria according to van Dijken (Table 3).[12] The follow-up exams were performed blindly by both operators at their clinics and at regular intervals by two calibrated evaluators. During the evaluation sessions, evaluators did not know which restorative material group the scoring concerned. For each participant, caries risk and parafunctional habits at baseline and during the follow-ups were estimated by the treating clinician by means of clinical and sociodemographic information routinely available at the annual clinical examinations, eg, incipient caries lesions, caries history, frequency and symptoms related to bruxing activity.[37,57]

Statistical Analysis

The characteristics of the restorations were described by descriptive statistics using cumulative frequency distributions of the scores. The experimental and control restorative techniques were compared intra-individually with non-parametric Friedman's two-way ANOVA.[58]

Table 3 Modified USPHS criteria for direct clinical evaluation (modified after van Dijken[12])

Category	Score		Criteria
	acceptable	unacceptable	
Anatomical form	0		The restoration is contiguous with tooth anatomy
	1		Slightly under- or over-contoured restoration; marginal ridges slightly undercontoured; contact slightly open (may be self-correcting); occlusal height reduced locally
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected
		3	Restoration is missing partially or totally; fracture of tooth structure; shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue
Marginal adaptation	0		Restoration is contiguous with existing anatomic form, explorer does not catch
	1		Explorer catches, no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin, dentin or base exposed
		4	Restoration mobile, fractured or missing
Color match	0		Very good color match
	1		Good color match
	2		Slight mismatch in color, shade or translucency
		3	Obvious mismatch, outside the normal range
		4	Gross mismatch
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2		Obvious staining cannot be polished away
		3	Gross staining
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Caries	0		No evidence of caries contiguous with the margin of the restoration
		1	Caries is evident contiguous with the margin of the restoration

Table 4 Failed class II restorations during the 3-year evaluation, tooth type, year of and reason for failure

Materials	Tooth type	Year of failure	Reason for failure
XenoV+/ SDR/ CeramX mono+	P	2	Tooth fracture
	P	2	Caries and tooth fracture
	M	2	Tooth fracture and resin composite fracture
	M	3	Caries
XenoV+/ CeramX mono+	M	1	Tooth fracture
	M	3	Tooth fracture
	M	3	Resin composite fracture

RESULTS

No postoperative symptoms were reported at baseline or at the other recalls. At three years, 196 restorations (74 Class I and 122 Class II) were evaluated. Two pairs of restorations, two Class I and two Class II cavities (drop-out rate 2%), could not be observed because one patient moved away and another died, both during the first year of the evaluation.

During the 3-year follow-up, 7 restorations (3.6%) failed, 4 SDR-CeramX mono+ and 3 CeramX mono+ only restorations. No Class I restoration failed. Two defects were observed: 1 small chip fracture which was polished and a restoration with a porosity, which was filled in. The year of and reason for failure of the failed restorations are given in Table 4. The scores at baseline and 1, 2, and 3 years for all the evaluated restorations are given as relative frequencies in Table 5. The modified USPHS scores of the Class II and Class I restorations separately are given in Tables 6 and 7, respectively. For all restorations (Class I and II), the SDR/CeramX mono+ annual failure rate (AFR) was 1.2% and the CeramX mono+ AFR was 1.0%. For the Class I restorations, the AFR was 0% in both groups. For the Class II restorations, the SDR/CeramX mono+ group showed an AFR of 2.2% and the CeramX mono+ group an AFR 1.6%. The overall differences between the two experimental restorations for the evaluated variables in both cavity classes were not significant. Six of the seven failures were observed in female participants. Eighteen participants were estimated as having high caries risk and sixteen showed mild to severe parafunctional habits during the observation period. The two carious lesions observed were found in high caries-risk participants. Four of the five fractures (cusp and material) occurred in bruxing participants. No further statistical analysis was performed due to the low failure rate.

Table 5 Scores for the evaluated XenoV+/ SDR-CeramX mono+ and XenoV+/ CeramX mono+ Class I and II restorations at baseline (n = 76 and 124), 1, 2, and 3 years (n = 74 and 122) given as relative frequencies (%)

		0	1	2	3	4
Anatomical form	XenoV+/SDR/C baseline	95.0	5.0	0	0	
	XenoV+/C baseline	98.0	2.0	0	0	
	XenoV+/SDR/C 1 year	95.0	4.0	1.0	0	
	XenoV+/C 1 year	98.0	2.0	0	0	
	XenoV+/SDR/C 2 year	94.9	2.0	0	3.1	
	XenoV+/C 2 year	94.9	4.1	0	1.0	
	XenoV+/SDR/C 3 year	94.9	2.0	0	3.1	
	XenoV+/C 3 year	97.0	0	1.0	2.0	
Marginal adaptation	XenoV+/SDR/C baseline	99.0	1.0	0	0	0
	XenoV+/C baseline	100	0	0	0	0
	XenoV+/SDR/C 1 year	97.0	2.0	0	1.0	0
	XenoV+/C 1 year	99.0	1.0	0	0	0
	XenoV+/SDR/C 2 year	92.9	4.0	0	1.0	2.1
	XenoV+/C 2 year	96.0	2.0	1.0	0	1.0
	XenoV+/SDR/C 3 year	87.8	9.1	0	0	3.1
	XenoV+/C 3 year	92.9	4.1	1.0	0	2.0
Color match	XenoV+/SDR/C baseline	60.0	38.0	2.0	0	0
	XenoV+/C baseline	65.0	33.0	2.0	0	0
	XenoV+/SDR/C 1 year	54.6	35.1	10.3	0	0
	XenoV+/C 1 year	63.3	31.6	5.1	0	0
	XenoV+/SDR/C 2 year	48.4	44.2	7.4	0	0
	XenoV+/C 2 year	54.6	39.2	6.2	0	0
	XenoV+/SDR/C 3 year	45.3	47.3	7.4	0	0
	XenoV+/C 3 year	53.7	41.1	5.2	0	0
Marginal discoloration	XenoV+/SDR/C baseline	100	0	0	0	
	XenoV+/C baseline	100	0	0	0	
	XenoV+/SDR/C 1 year	96.9	2.1	1.0	0	
	XenoV+/C 1 year	99.0	1.0	0	0	
	XenoV+/SDR/C 2 year	89.5	8.4	2.1	0	
	XenoV+/C 2 year	95.9	4.1	0	0	
	XenoV+/SDR/C 3 year	82.1	15.8	2.5	0	
	XenoV+/C 3 year	90.5	6.3	3.2	0	
Surface roughness	XenoV+/SDR/C baseline	99.0	1.0	0	0	
	XenoV+/C baseline	99.0	1.0	0	0	
	XenoV+/SDR/C 1 year	97.9	2.1	0	0	
	XenoV+/C 1 year	100	0	0	0	
	XenoV+/SDR/C 2 year	100	0	0	0	
	XenoV+/C 2 year	95.9	4.1	0	0	
	XenoV+/SDR/C 3 year	92.6	7.4	0	0	
	XenoV+/C 3 year	97.9	2.1	0	0	
Caries	XenoV+/SDR/C baseline	100	0			
	XenoV+/C baseline	100	0			
	XenoV+/SDR/C 1 year	100	0			
	XenoV+/C 1 year	100	0			
	XenoV+/SDR/C 2 year	99	1			
	XenoV+/C 2 year	100	0			
	XenoV+/SDR/C 3 year	98	2			
	XenoV+/C 3 year	100	0			

C= CeramX mono+.

Table 6 Scores at baseline (n = 124) and after 1, 2, and 3 years (n = 122) for the evaluated Class II restorations of XenoV+/ SDR-CeramX mono+ and XenoV+/ CeramX mono+ given as relative frequencies (%)

		0	1	2	3	4
Anatomical form	XenoV+/SDR/C baseline	91.9	8.1	0	0	
	XenoV+/C baseline	96.8	3.2	0	0	
	XenoV+/SDR/C 1 year	91.8	6.6	1.6	0	
	XenoV+/C 1 year	96.7	3.3	0	0	
	XenoV+/SDR/C 2 year	91.8	3.3	0	4.9	
	XenoV+/C 2 year	91.8	6.6	0	1.6	
	XenoV+/SDR/C 3 year	91.8	3.3	0	4.9	
	XenoV+/C 3 year	95.1	0	1.6	3.3	
Marginal adaptation	XenoV+/SDR/C baseline	98.4	1.6	0	0	0
	XenoV+/C baseline	100	0	0	0	0
	XenoV+/SDR/C 1 year	95.1	3.3	0	1.6	0
	XenoV+/C 1 year	98.4	1.6	0	0	0
	XenoV+/SDR/C 2 year	90.2	4.9	0	0	4.9
	XenoV+/C 2 year	93.5	3.3	1.6	0	1.6
	XenoV+/SDR/C 3 year	85.2	9.9	0	0	4.9
	XenoV+/C 3 year	88.5	6.6	1.6	0	3.3
Color match	XenoV+/SDR/C baseline	59.7	37.1	3.2	0	0
	XenoV+/C baseline	62.9	35.5	1.6	0	0
	XenoV+/SDR/C 1 year	51.6	36.7	11.7	0	0
	XenoV+/C 1 year	63.9	32.8	3.3	0	0
	XenoV+/SDR/C 2 year	48.3	44.8	6.9	0	0
	XenoV+/C 2 year	51.7	41.6	6.7	0	0
	XenoV+/SDR/C 3 year	41.4	50.0	8.6	0	0
	XenoV+/C 3 year	50.0	44.8	5.2	0	0
Marginal discoloration	XenoV+/SDR/C baseline	100	0	0	0	
	XenoV+/C baseline	100	0	0	0	
	XenoV+/SDR/C 1 year	95.0	3.3	1.7	0	
	XenoV+/C 1 year	98.4	1.6	0	0	
	XenoV+/SDR/C 2 year	84.5	12.1	3.4	0	
	XenoV+/C 2 year	93.3	6.7	0	0	
	XenoV+/SDR/C 3 year	72.4	24.1	3.5	0	
	XenoV+/C 3 year	84.5	10.3	5.2	0	
Surface roughness	XenoV+/SDR/C baseline	98.4	1.6	0	0	
	XenoV+/C baseline	98.4	1.6	0	0	
	XenoV+/SDR/C 1 year	98.3	1.7	0	0	
	XenoV+/C 1 year	100	0	0	0	
	XenoV+/SDR/C 2 year	100	0	0	0	
	XenoV+/C 2 year	96.7	3.3	0	0	
	XenoV+/SDR/C 3 year	89.7	10.3	0	0	
	XenoV+/C 3 year	96.5	3.5	0	0	
Caries	XenoV+/SDR/C baseline	100	0			
	XenoV+/C baseline	100	0			
	XenoV+/SDR/C 1 year	100	0			
	XenoV+/C 1 year	100	0			
	XenoV+/SDR/C 2 year	98.4	1.6			
	XenoV+/C 2 year	100	0			
	XenoV+/SDR/C 3 year	96.7	3.3			
	XenoV+/C 3 year	100	0			

C= CeramX mono+.

DISCUSSION

In the present randomized controlled study, restorations placed with the 4-mm layering technique using flowable bulk-fill material capped with a nanohybrid RC showed no significant difference in clinical efficacy compared to the restorations placed with a conventional 2-mm layering technique. The durability of restorations placed with the bulk-fill technique in the 3-year follow-up was clinically acceptable and confirms the results of an earlier evaluation with the predecessors of the SEA and RC used in the present study in combination with SDR.

Table 7 Scores at baseline (n = 76), 1, 2, and 3 years (n = 74) for the evaluated Class I restorations of XenoV+/ SDR-CeramX mono+ and XenoV+/ CeramX mono+ given as relative frequencies (%)

		0	1	2	3	4
Anatomical form	XenoV+/SDR/C baseline	100	0	0	0	
	XenoV+/C baseline	100	0	0	0	
	XenoV+/SDR/C 1 year	100	0	0	0	
	XenoV+/C 1 year	100	0	0	0	
	XenoV+/SDR/C 2 year	100	0	0	0	
	XenoV+/C 2 year	100	0	0	0	
	XenoV+/SDR/C 3 year	100	0	0	0	
	XenoV+/C 3 year	100	0	0	0	
Marginal adaptation	XenoV+/SDR/C baseline	100	0	0	0	0
	XenoV+/C baseline	100	0	0	0	0
	XenoV+/SDR/C 1 year	100	0	0	0	0
	XenoV+/C 1 year	100	0	0	0	0
	XenoV+/SDR/C 2 year	97.3	2.7	0	0	0
	XenoV+/C 2 year	100	0	0	0	0
	XenoV+/SDR/C 3 year	91.9	8.1	0	0	0
	XenoV+/C 3 year	100	0	0	0	0
Color match	XenoV+/SDR/C baseline	60.5	39.5	0	0	0
	XenoV+/C baseline	68.5	28.9	2.6	0	0
	XenoV+/SDR/C 1 year	59.5	32.4	8.1	0	0
	XenoV+/C 1 year	62.2	29.7	8.1	0	0
	XenoV+/SDR/C 2 year	48.7	43.2	8.1	0	0
	XenoV+/C 2 year	59.5	35.1	5.4	0	0
	XenoV+/SDR/C 3 year	51.4	43.2	5.4	0	0
	XenoV+/C 3 year	59.5	35.1	5.4	0	0
Marginal discoloration	XenoV+/SDR/C baseline	100	0	0	0	
	XenoV+/C baseline	100	0	0	0	
	XenoV+/SDR/C 1 year	100	0	0	0	
	XenoV+/C 1 year	100	0	0	0	
	XenoV+/SDR/C 2 year	97.3	2.7	0	0	
	XenoV+/C 2 year	100	0	0	0	
	XenoV+/SDR/C 3 year	97.3	2.7	0	0	
	XenoV+/C 3 year	100	0	0	0	
Surface roughness	XenoV+/SDR/C baseline	100	0	0	0	
	XenoV+/C baseline	100	0	0	0	
	XenoV+/SDR/C 1 year	97.3	2.7	0	0	
	XenoV+/C 1 year	100	0	0	0	
	XenoV+/SDR/C 2 year	100	0	0	0	
	XenoV+/C 2 year	100	0	0	0	
	XenoV+/SDR/C 3 year	97.3	2.7	0	0	
	XenoV+/C 3 year	100	0	0	0	
Caries	XenoV+/SDR/C baseline	100	0			
	XenoV+/C baseline	100	0			
	XenoV+/SDR/C 1 year	100	0			
	XenoV+/C 1 year	100	0			
	XenoV+/SDR/C 2 year	100	0			
	XenoV+/C 2 year	100	0			
	XenoV+/SDR/C 3 year	100	0			
	XenoV+/C 3 year	100	0			

C= CeramX mono+.

No difference was observed between the restorations with and without SDR. The hypothesis was therefore accepted. The results show that it is possible to use clinically thicker increments, which may certainly have advantages in many clinical situations, such as deep cavities and other sites that are difficult to reach with the curing unit.

One of the disadvantages of light-curing RCs is their limited depth of cure, with the associated risk of undercuring the bottom part of each too-thick layer. The maximum increment thickness has generally been defined as approximately 2 mm, depending on the limited penetration of light through the material.[42,43,52,55] A layering technique is therefore necessary to obtain sufficient conversion, which in turn is mandatory for obtaining acceptable physical-mechanical properties and biocompatibility of the resin-based material.[29,36,40,48] The layering technique is sensitive and bear certain risks, such as incorporating air and/or contamination between the layers. Versluis et al[62] indicated that incremental layering induced high stresses at the interfacial margins and that bulk filling should be preferred. It is crucial that bulk-fill materials possess good curing ability, otherwise inferior mechanical properties and increased monomer leakage will be the result. Several in vitro studies have confirmed that the bulk-fill material tested could be cured in 4-mm layers at irradiation times up to 20 s. This was shown by using the ISO 4049 “scrape test” as well as microhardness tests and Fourier transformed infrared spectroscopy.[3,5,7,10] Flury et al[30] stated recently that for bulk-fill materials, the ISO 4049 method overestimated depth of cure compared to that determined by Vickers hardness profiles.[30] Using Vickers hardness profiles, Alrahlah et al[2] confirmed the depth of cure claims of manufacturers of five bulk-fill RCs and showed that these materials had an acceptable post-cure depth. Variations in the depth of cure can be caused by light scattering at particle interfaces and light absorbance by photoinitiators and pigments. Ilie et al[35] explained the enhanced depth of cure of the flowable bulk-fill RC by an increased translucency due to decreased filler load and increased filler size of the material. This reduces light scattering and improves light penetration.[35] Inadequate conversion of a resin-based material will result in higher monomer leakage and decreased biocompatibility due to higher cytotoxicity. A recently published in vitro study investigated the cytotoxicity of flowable SDR by MTT assay.[53] Those authors showed that exposed cells maintained their mesenchymal phenotype, adequate viability, and no significant aptosis.[53]

In vitro studies revealed that several mechanical properties, eg, flexural strength and creep, were similar for bulk-fill RCs and nanohybrid RCs.[35,36] For other properties, such as hardness and modulus of elasticity, the bulk-fill materials were classified between the hybrid RCs and the flowable RCs.[35,36] The concern that application of thicker layers of the flowable bulk-fill material applied in deep cavities would result in increased shrinkage stress was not confirmed in vitro; in fact, the bulk-fill material revealed the lowest shrinkage stress compared to flowable and non-flowable nanohybrid and microhybrid RCs and a silorane-based RC.[33] This was confirmed by Moorthy et al,[49] who showed that the SDR base significantly reduced cuspal deflection in Class II cavities in premolars compared with a conventional RC; in that study, the prepared cavities were restored using an oblique incremental filling technique. No associated change in cervical microleakage was recorded.[49] The clinical relevance of this has to date not been shown.[16] Adequate marginal adaptation

in vitro has also been reported for the flowable base material.[9,54] We found that the 1.4% annual failure rate for the SDR restorations was not significantly different from the 1.0% for the control nanohybrid RC-only restorations. During the past few years, we have observed AFRs varying between 0.9% and 3.3% in the majority of our randomized clinical studies on posterior restorations in which different microhybrid and nanohybrid RCs and adhesive systems were evaluated; similar AFRs were found in a recent practice-based study.[20-25,41,44,51] The good clinical efficacy in the present 3-year follow-up situated the SDR flowable bulk-fill RC technique between the lower AFR materials. Catastrophic failure rates have been observed for a few restorative materials evaluated after 3 years. A hydroxyl-releasing RC showed an 8.7% AFR and a calcium aluminate cement a 24.2% AFR, indicating the necessity of 3-year follow-ups of new material groups.[15,19]

All failures in the present study were observed in Class II restorations. AFRs for the Class II restorations were therefore higher than the overall AFR, with 2.2% and 1.6%, respectively. The low failure rate of Class I restorations has been reported in many clinical investigations.[16] Comparing AFRs, recent studies state that the durability of new posterior RC restorations is the same as that reported in reviews from earlier studies around the turn of the century.[6,10,45] However, it is difficult to compare earlier studies of posterior RCs with recent ones due to the fact that the former comprised much larger numbers of Class I restorations than the latter, as shown in a current review.[25] The value of inclusion of Class I restorations in posterior RC trials should therefore be questioned.

The main reason of failure in this study was cusp fracture. This is in contrast to other studies, in which caries and/or material fracture were the main reasons for failure of RCs. Of seven failures, three were cusp fracture only and two were cusp fracture in combination with restoration fracture or caries. There are few reports in the literature describing the occurrence of tooth fractures.[31] Bader et al[4] reported the occurrence of cusp fracture to be 5 teeth per 100 adults annually. Heft et al[31] reported an incidence rate of 14 teeth with cusp/incisal edge fractures per 100 subjects per 24 months.[31] Cusp fractures are still a significant dental health problem, especially in older adults. In many cases, these are caused by the conventional preparation technique for amalgam restorations with large undercuts in posterior teeth, in order to obtain macromechanical retention.[13] A continuous occlusal loading of the weakened cusps will result initially in horizontal crack formation followed by cusp fractures. Adhesive bonding of the resin composite material to the cavity walls with amphiphilic bonding systems may alleviate this problem. In the present study, almost all included cavities were replacements of older restorations which had been placed in cavities with macromechanical retention, which increases the risk of cusp fractures. High frequencies of cusp fractures have also be observed in earlier studies of restorative materials with increased water absorption over longer periods. This resulted in increased expansion of the restorative materials, followed by crack formation in the buccal or lingual cusps and cusp fractures.[15,19] However, it can be assumed that this was not the case for the bulk-fill material used here, because we observed no failures due to cusp fractures in teeth with SDR restorations in a similar 3-year clinical follow up.[26]

CONCLUSION

The new bulk-fill technique showed acceptable clinical results and was similar to the conventional layering technique during the 3-year evaluation period. Annual failure rates were 1.0% for the conventionally filled and 1.4% for the bulk-filled restorations. Good surface characteristics, marginal adaptation, and color stability as well as a low frequency of secondary caries and resin composite fracture rate were observed.

ACKNOWLEDGMENTS

The support from the County Council of Västerbotten and Dentsply DeTrey is gratefully acknowledged.

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