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ORIGINAL ARTICLE

Clinical performance of a nanofilled resin composite with and without an intermediary layer of flowable composite: a 2-year evaluation

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Abstract The objective of this prospective clinical follow-up was to evaluate the 2-year clinical performance of a nanofilled resin composite in class II restorations. The restorations were made with and without intermediary layer of a nanofilled flowable resin composite studied in an intraindividual comparison. Each participant received at least two, as similar as possible, class II restorations of the nanofilled resin composite. One restoration of each pair (54) was chosen at random to be restored with an intermediary layer with flowable nanofilled resin composite. The other was restored without. The restorations were evaluated with slightly modified US Public Health Services criteria at baseline, 1, and 2 years. Ninety-two restorations, 46 pairs, were evaluated at 2 years. A prediction of the caries risk showed that 22 of the evaluated 48 patients were considered as high-risk patients. Two failures were observed, one in each group, resulting in a 2.2% failure rate. No statistical difference was seen between the restorations restored with and without layer of flowable resin composite. The nanofilled resin composite showed very good surface characteristics and color match, which did not change significantly during the follow-up period. The nanofilled resin composite showed a good clinical performance with a 2.2% failure rate after 2 years. No differences were observed between the restorations with and without the nanofilled flowable resin intermediary layer.

Keywords Clinical · Bonding · Flowable · Nanofiller · Posterior tooth · Sandwich

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Introduction

Concerns about the biocompatibility of amalgam made that resin composites became the first-choice restorative material for class II restorations [42]. Bonding of resinous materials to enamel is a well-established technique in operative dentistry with good clinical evidence [9]. Dentin bonding has improved since the introduction of amphiphilic adhesive systems, but their clinical durability is still not of the same quality as that of the bond to enamel [15, 16]. The mechanical and surface properties of a resin composite are influenced by many variables, for example, monomer contents, filler type, and amount and degree of polymerization. During the last years, hybrid resin composites have been used which are filled with 0.5–1-μm-sized filler particles of glass or zirconium completed with smaller amounts of microfiller particle clusters. Recently, nanofiller particles have been introduced in resin composite materials [35]. Nanotechnology is defined as the production and manipulation of materials and structures in the range of about 0.1–100 nanometers by various physical or chemical methods. Most nanohybrid resin composites contain, beside the traditional glass filler particles, as in hybrid resin composites, smaller concentrations of nanofillers and/or nanofiller clusters. These increase filler load, improve mechanical properties, and result in highly polishable surfaces. Recently, a nanofilled resin composite was marketed,

intended to improve the mechanical strength and wear resistance of hybrid resin composites and copy the high polish and polish retention of microfilled resin composites [35]. The material contains a combination of individually dispersed nanosized fillers and agglomerations of nanofiller (nanoclusters). Silica and zirconia nanoparticles are partially calcined to produce porous clusters which are infiltrated by silane prior to incorporation in the resin matrix. A lower wear and better gloss retention may be expected. Unfortunately, there is limited clinical information on the performance of nanofilled resin composite [5, 18, 19, 22]. High viscosity, sticky consistency, and difficult condensation characteristics of the material in the proximal box of posterior restorations have been indicated to result in nonoptimal cervical adaptation [8, 26]. Sandwich methods suggested did not improve the clinical durability of the proximal resin composite restoration [1, 31]. To improve placing characteristics and cervical marginal adaptation, a flowable resin composite placed at the cervical margin of the proximal box has been recommended as an intermediate layer. Their easy handling, low viscosity, increased elasticity, and wettability may result in stress-relieving properties [28, 29, 43]. Several in vitro studies showed that flowable resin composites reduce microleakage [2, 7, 20, 24, 27, 39, 44], while other studies could not confirm the improved marginal adaptation [20, 26, 34, 36, 44]. This is the first study to test the clinical effectiveness of a flowable nanofilled resin composite as intermediary layer in class II cavities.

The aim of this prospective 2-year study was to determine the clinical performance of a nanofilled resin composite in class II restorations and to study in an intraindividual comparison design the effect of a nanofilled flowable resin composite as intermediary layer in the proximal box. The hypothesis tested was that there was no difference between the nanofilled resin composite restorations with and without flowable resin composite.

Material and methods

Patient selection and clinical procedure

During a period of 12 months, all patients in need of at least two comparable class II resin composite restorations, visiting the Public Dental Health Clinic Strömsund, were asked to participate in the study. The study design was approved by the ethics committee of the University of Umeå, Sweden. Informed consent was obtained from all the participants. There were no exclusion criteria. Forty-eight patients, 21 woman and 27 men, with a mean age of 39.2 years (range 16–74) participated. In order to make an intraindividual comparison possible, each patient received at least two restorations. One with Filtek Supreme XT (3M ESPE; Table 1) and the second with an intermediate layer of the Filtek flow Supreme XT in the cervical part of the proximal box followed by Filtek Supreme XT in the other parts of the cavity. In total, 108 class II restorations were placed by two general dentists trained and calibrated for the operative procedures. Thirty-five two-surface resin composite restorations with a flowable intermediate layer and 33 without were placed in molar teeth. The corresponding numbers for premolar teeth were 19 and 21, respectively. Thirty-four restorations with a flowable intermediate resin composite layer and 27 without were placed in upper jaw. The corresponding numbers for lower jaw were 20 and 27, respectively. The majority of the cervical margins of the approximal boxes were placed in enamel. Seven restorations with and five without flowable layer had dentin-bordered margins. Reasons for placement were the replacing of existing failed restorations (41) or primary caries (67).

Except for the placement of the flowable resin composite in the cervical part of the proximal box, placed at random in one cavity in each pair, the restorative protocol was the same for both restorations. Operative procedures were

Table 1 Resin composites and bonding system used

Filtek Supreme XT	Visible light-activated nanofilled resin composite	Filler load 59 vol.% (78.5 wt.%). Dispersed filler particles nonagglomerated/nonaggregated (5–75 nm), partially calcined porous clusters (~1.3 μm) of agglomerated nanosized particles, with a primary particle size of 5–20 nm, infiltrated with silane. Bis-GMA, Bis-EMA, UDMA, and TEGDMA [35]	3M ESPE, Seefeld, Germany
Filtek flow Supreme XT	Low viscosity, visible light-activated nanofilled flowable resin composite	Zirconia/silica with an inorganic filler loading of 47% by volume and an average particle size of 1.5 μm (range 0.01 6.0 μm)	3M ESPE
Adper Scotchbond 1 XT	One-step etch-and-rinse adhesive system	Conditioner: phosphoric acid; primer/adhesive: ethanol, water, HEMA, Bis-GMA, diurethane dimethacrylate, glycerol dimethacrylate, copolymer of acrylic/itaconic acids (polyalkenoic acid copolymer), methacrylate-modified carboxylic acid	3M ESPE

performed under local anesthesia if necessary. Existing restorations and/or caries were removed under constant water cooling. A calcium hydroxide base (Kerr Life, Orange, CA, USA) was only placed in pulpa close cavity parts (<0.5 mm). No bevels were prepared. The operative field was isolated with suction device and cotton rolls. After placement of a thin metal matrix system and wooden wedges (Tofflemire matrix product; Kerr Hawes, Bioggio, Switzerland), the cavities were rinsed with water and conditioned with 38% phosphoric acid (TopDent Etsgel, Topdent, Stockholm, Sweden). Using the wet technique, the adhesive system Adper Scotchbond 1 XT (Table 1) was used in accordance with the manufacturer's recommendations. The enamel was first acid etched for 10 s, after which dentin and enamel were etched for another 5 s. The flowable resin composite Filtek flow Supreme XT was then inserted, at random in one cavity of each pair, as the first 1–1.5-mm layer in the cervical area of the proximal box. The intermediary layer was light cured for 20 s with a visible light curing unit (Lysta LCD 8838 HI-power, 800 mW/cm^2). The LCU was regularly controlled with an Optilux 100 radiometer (Kerr/Demetron, Danbury, CT, USA). The resin composite was applied in layers of maximally 2 to 3 mm with if possible an oblique layering technique. Each layer was polymerized for 20 s. Finishing was accomplished with carbide burs and polishing points under water cooling.

Evaluation

Each restoration was evaluated according to slightly modified US Public Health Services (USPHS) criteria for the following characteristics: anatomical form, marginal adaptation, color match, marginal discoloration, surface roughness, and caries [9] (Table 2). The restorations were evaluated at baseline, at 12 and 24 months by two calibrated evaluators. The caries risk for each patient at baseline was estimated by the treating clinician by means of

Table 2 Criteria for the direct clinical evaluations [9]

Category	Score		Criteria
	Acceptable	Unacceptable	
Anatomical form	0		The restoration is continuous with tooth anatomy
	1		Slightly under- or overcontoured 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 or traumatic occlusion; restoration causes pain in tooth or adjacent tissue
Marginal adaptation	0		Restoration is continuous 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

clinical and sociodemographic information which was routinely available at the annual clinical examinations, e.g., incipient caries lesions and former caries history [25, 41].

Statistical evaluation

The evaluated characteristics of the restorations, including the number of nonacceptable restorations (failures), are described by descriptive statistics by using frequency distributions of the scores. The overall clinical outcome and durability of the two restorative techniques were compared intraindividually and tested using the Friedman's two-way analysis of variance test. $p<0.05$ was considered statistically significant.

Results

Ninety-two restorations, 46 pairs, were evaluated after 2 years. Eight patients (three females, five males) with 16 restorations could not be evaluated at all recalls. The reasons for dropout were death and moving of the participants. Four of the patients reported at baseline mild postoperative sensitivity symptoms during 2 weeks for cold and air and one of the participants also for biting forces (two with flowable, two without; three molars, one premolar). Relative frequencies of the scores of the evaluated variables of the composite restorations at 2 years are shown in Table 3. Filtek Supreme XT showed very good surface characteristics and color match, which did not change significantly during the follow-up period. Two failures were observed during the follow-up. One Filtek Supreme XT restoration in a molar tooth, with a dentin-bordered cervical margin, was lost after 6 month. The second failure, in the flowable group, showed at 12 month a large chip fracture. The overall success rate at 2 years was 97.8%. No statistical significant difference in the overall survival rate between the restorations with and without intermediary flowable resin composite layer was found within the 2-year follow-up. A prediction of the caries risk showed that 22 of the evaluated 48 patients were considered as high-risk patients. Due to the short follow-up and the fact that no secondary caries was observed, no further analysis was performed.

Discussion

For most materials, laboratory investigations have served as screening model for human clinical trials. However, it was recently shown that there is a clear necessity to include clinical evaluations in the CE marking requirements of new dental restorative materials, which will provide dental patients with a higher level of protection [12, 14]. This study evaluated the 2-year clinical performance of the first

Table 3 The relative frequencies of the evaluated scores at baseline and 2 years for Filtek Supreme and Filtek Supreme/Filtek Supreme flow. *FS* Filtek Supreme, *FSflow* Filtek Supreme/Filtek Supreme flow

			0	1	2	3	4
Anatomical form	FS	Baseline	74.1	25.9	0	0	
		2 years	76.1	21.7		2.2	
	FS/FS flow	Baseline	79.6	20.4	0	0	
		2 years	73.9	23.9		2.2	
Marginal adaptation	FS	Baseline	94.5	5.5	0	0	0
		2 years	73.9	23.9			2.2
	FS/FSflow	Baseline	96.3	3.7	0	0	0
		2 years	73.9	21.7	4.4		
Color match	FS	Baseline	88.9	11.1	0	0	0
		2 years	84.8	15.2			
	FS/FSflow	Baseline	94.5	5.5	0	0	0
		2 years	93.5	6.5			
Marginal discoloration	FS	Baseline	98.1	1.9	0	0	
		2 years	89.1	10.9			
	FS/FSflow	Baseline	98.1	1.9	0	0	
		2 years	86.9	13.1			
Surface roughness	FS	Baseline	100.0	0	0	0	
		2 years	95.6	4.4			
	FS/FS flow	Baseline	100.0	0	0	0	
		2 years	100.0	0			

resin composite marketed containing only nanofillers. It disregarded the traditional microfilled resin composites which are according to the nanofiller definition also loaded with nanofiller but do contain far lower filler amounts. The additional effect of an intermediary flowable resin composite layer of the same material in the cervical part of the proximal box was also studied. The intraindividual comparison design, which has been used in several of our clinical follow-ups, made it possible to compare both restorative techniques within the same oral environments. To represent a normal clinical patient population, no patients were excluded because of high caries activity, not acceptable oral hygiene, or parafunctional habits, in contrast to other clinical evaluations including these of the investigated material [18, 33, 37]. The presence of nanoparticles and clusters in the nanofilled resin composite provide higher filler loading and distinct mechanical and physical properties compared with those of nanohybrid resin composites. A clinically satisfactory performance was reported of the nanofilled resin composite in two 1-year and one 3-year follow-ups [5, 18, 37]. However, the numbers of evaluated class II restorations in these studies were far too low to be of clinical value, 9, 14, and 18 restorations, respectively, including also class I restorations. In the last study, repaired restorations were considered functionally present and not failed. In a recent 2-year clinical evaluation, class II restorations of the nanofilled resin composite were compared in a similar intraindividual comparison with the well-known Tetric Ceram [22]. Both restorative materials showed acceptable clinical performance, and the nanofilled resin composite showed no significant difference in overall clinical performance compared to Tetric Ceram. A failure rate of 1.9% was observed for both materials after 2 years confirming the clinical performance in the present study with a clinical failure rate of 2.2%. Recently published controlled clinical longitudinal studies of hybrid resin composites showed annual failure rates varying between 1.1% and 7.0% after 2–4 years [6, 12–14, 17, 32, 40]. Tetric Ceram showed 1.9–3.3% annual failure rates, indicating a good clinical effectiveness of the nanofilled resin composite studied [12, 13]. None of the nanofiller resin composite restorations showed a nonacceptable wear pattern as evaluated by the USPHS criteria (anatomical form). However, one has to realize that this scoring system has no optimal wear evaluation method and therefore no direct conclusions can be made concerning the suggested lower wear properties of the material. More sophisticated, replica involving evaluation methods and longer evaluation periods are necessary [37]. Ernst et al. [22] reported a significant decrease in color match from at baseline 86% alpha scores to 57% at the 2-year recall of class II restorations. Efes et al. [19] evaluated class I Filtek Supreme restorations with and without flowable layer during a 2-year period. They showed only slight color changes, which confirmed our slight and nonsignificant changes of color match in both groups. Also the evaluation of Mahmoud et al. of the 37 class I nanofilled restorations showed good color stability during a 2-year follow-up [33]. In the present study, marginal discoloration was not clinical problem confirming the results of Ernst et al. [22]. In both studies, the same simplified etch-and-rinse adhesive (Scotch Bond 1) was used. Decreased marginal adaptation quality may be associated with marginal gap formation, microleakage, or secondary caries. However, no secondary caries was observed contiguous to the evaluated restorations, despite the high frequency of caries risk participants, which may indicate a good marginal seal. No secondary caries was either reported in the earlier discussed 2-year study of Ernst et al. [22]. On the other hand, one has to realize that a 2-year evaluation is far too short to observe the formation of secondary caries. This will develop mostly after 4–6 years intra-oral aging, as shown in earlier longer follow-ups [14, 17]. The operative field in the present study was isolated with cotton rolls and suction device simulating operative dental procedures in most general clinics. No difference in annual failure rate was observed compared to the study of Ernst et al. where all restorations were placed under rubber dam isolation after application of the matrix system, 1.1% and 1.0%, respectively. This confirms the nonsignificant clinical differences observed in earlier studies comparing the two isolation methods [10, 11].

Especially in box-like cavities with high configuration factor, polymerization stresses may cause cohesive and/or adhesive failures. Due to their low modulus of elasticity, flowable composites are less rigid than traditional resin composites and might absorb the stress caused by the polymerization of the final restorative composite [43]. A higher initial linear shrinkage stress was found for flowable resin composites due to the stress development being directly related to the degree of polymerization shrinkage and the materials modulus [3, 30]. A low frequency of patients with postoperative sensitivity was observed in the present study indicating a good marginal seal in both groups, confirming the results of Perdigão et al. [38] who reported that the use of flowable composite did not decrease postoperative sensitivity. The sealing effectiveness of the modified sandwich restoration has been tested extensively in vitro with controversial results. However, when the margins were located below the cementoenamel junction, none of the restorative techniques achieved a good sealing capacity [20, 23, 34]. Few clinical evaluations studied the effectiveness of the use of the intermediary flowable resin composite layer. Efes et al. [19] studied the technique in occlusal restorations and found no significant difference. Ernst et al. [21] studied the technique during 2 years in class II restorations and found no benefit. This was also

observed in our study and the hypothesis was therefore accepted.

Braga et al. [3] showed that the flexural strength of flowable resin composites varied between 4.1 and 8.2 GPa. A significant reduction of contraction stresses by the precured flowable layer could only be observed for one flowable composite. They concluded that using a flowable resin-based composite as intermediary layer is not likely to reduce the effects of polymerization shrinkage. Cadenaro et al. concluded that the use of flowable resin composites as an intermediate layer do not lead to evident stress reduction with similar risk for debonding at the interfacial margins [4]. Filtek Supreme XT Flowable Restorative exhibited the highest stress values. The material contains a less flexible and more viscous monomer Bis-EMA which is suggested to account for its high stress values recorded.

It can be concluded that nanofilled resin composite showed a good clinical performance with a 2.2% failure rate after 2 years. No differences were observed between the restorations with and without the nanofilled flowable resin intermediary layer. Longer evaluations are necessary.

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Conflict of interest The authors declare that they have no conflict of interest in the studied materials.

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