

Clinical Performance of Fiber-Reinforced Nanofilled Resin Composite in Extensively Carious Posterior Teeth of Children: 30-Month Evaluation

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Objective: To evaluate the 30-month clinical performance of a nanofilled-resin composite with or without glass-fiber layering in restorations of large cavities in posterior teeth of children. **Study Design:** A total of 71 restorations were placed in permanent molar teeth of 47 children (mean age 10.9 years) with (FRC; n=35) or without (RC; n=36) fiber layering. One operator placed all restorations. Restorations were evaluated according to the USPHS modified-Ryge criteria at baseline, 6, 12, 18, 24, and 30 months. The data were analyzed using Fisher's exact and chi-square tests and outcomes were compared using the Cochran-Q test ($p < 0.05$). **Results:** The 30-month survival rates of the restorations were 97% and 97.1% in the RC and FRC groups, respectively. Nanofilled-resin restorations with or without glass fiber-layering showed similarly high clinical performance. No differences were detected between the evaluated criteria when comparing baseline with any of the evaluation periods ($p < 0.05$). After 30 months there were no secondary caries, change in anatomical form or postoperative sensitivity. Only minor changes for marginal adaptation, marginal discoloration, color match and surface texture were observed. **Conclusion:** It was concluded that nanofilled-resin composite applied with or without glass-fiber layering showed similar and good results in large cavities of posterior permanent teeth in children over a 30-month period.

Keywords: Composite resins, Clinical study, Ryge criteria, Fiber-reinforcement, Molars

INTRODUCTION

Improvements concerning the esthetic and mechanical properties of dental resin composites have resulted in widespread use of these materials in both anterior and posterior teeth.¹ However, resin composites still have a number of limitations in posterior teeth, mainly because of problems related to technique sensitivity, polymerization shrinkage and low fracture resistance.^{1,2} Under high stress-bearing conditions, low fracture resistance may adversely affect the longevity of resin composite restorations.^{2,3} Resin-based restorations of permanent teeth have also become a routine procedure in pediatric dental clinics. However in the treatment of

extensively carious permanent molars in children, such as in direct restorations involving cusps and high-stress bearing applications, further improvements are still needed.¹⁻⁴

The mechanical properties of dental resin composites highly depend on the concentration and particle size of the filler.^{2,4-6} Thus the compressive strength, hardness, flexural strength and elastic modulus increase with the amount of inorganic fraction while the polymerization shrinkage is said to decrease.^{4,5} The most traditional dental composites for restorative purposes are hybrid and microfill types. Hybrid composites are considered to be universal composites as they can be used for anterior and posterior applications. They have excellent mechanical properties but intermediate esthetic properties.² Microfill composites were marketed to overcome the problems of poor esthetic properties but their mechanical properties are generally considered low, especially for application in regions of high occlusal force.² Nanofilled resin composites were developed recently as a universal restorative and are intended to improve the mechanical strength and wear resistance of hybrid composites with the high polish retention of microfilled resin composites.^{2,4,5,7} The material contains a combination of individually dispersed nanosized fillers and agglomerations of nanofiller (nanoclusters).⁵ Since nanofilled resin composites have reduced dimension of the particles (nanoparticles) and a wide size distribution, increased filler is achieved with the consequences of reducing the polymerization shrinkage, increasing the mechanical properties, as well as high polish properties.⁴⁻⁷ Although these materials have adequate mechanical properties, there is limited clinical information on high

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Table 1. The distribution of restorations to teeth; FRC; Nanofilled resin composite with fiber-reinforcement, RC; without fiber-reinforcement

Teeth	Group FRC	Group RC	
Upper right molar	4	4	
Upper left molar	7	10	
Lower left molar	10	12	
Lower right molar	13	9	
Total	34	35	69

stress situations. It is reported that in large preparations and especially when used to replace cusps, the fracture resistance and wear of these materials warrants attention.²

Fiber-reinforcement of resin-based composite restorations has been proposed to increase resistance of materials fracturing under high stress-bearing cavities.⁸⁻¹² Fiber-reinforced composite (FRC) is made of a polymer matrix, impregnated with fibers. The fibers allow the stresses to be distributed throughout the restoration. Since the role of the fibers is to improve the structural properties of the material by acting as crack stoppers, the FRC framework provides strength and rigidity of the composite materials.¹³⁻²⁰ The surrounding resin matrix acts to protect the fibers and fix their geometrical arrangement so that the reinforcement is supported.^{9,11}

The mechanical properties and reinforcing capacity of FRCs applied in dentistry depend on the fiber type, fiber orientation relative to load, fiber position in the restoration, impregnation of the fiber, adhesion of the fiber to the resin matrix and fiber volume fraction.^{9,10,14,15} The highest flexural strength was achieved when the fiber framework was placed on the tensile side (base) of the resin composite materials.¹⁶⁻¹⁹ Various types of fibers have been used, and the selection of fiber type is dependent on the strength required for reinforcement. Woven fibers are said to be beneficial because they can reinforce the restoration in multiple directions.^{10,20} It is claimed that the pre-impregnated woven glass fiber demonstrates the ability to withstand tensile stress and to stop crack propagation in composite material.^{9,15} Although a great deal is known about the mechanical properties, information about clinical performance with woven glass fiber-reinforcement in direct restoration of excessively carious molar teeth is lacking.

The aim of this prospective randomized double-blinded clinical study was to investigate the clinical performance of a nanofilled-resin composite applied with or without glass-fiber layering in permanent molars of children. We tested the hypothesis that using a layer of glass-fiber with the nanofilled-resin composite would improve the clinical performance of the material combination in large stress-bearing restorations of children.

MATERIALS AND METHOD

Forty-seven patients, 21 boys and 26 girls aged 8-13 years (mean age 10.9 years) with extensively carious or having insufficient restoration in the first permanent molar teeth participated in this study. All children were regular patients at the pedodontic department of the dental faculty. The study was approved by the Ethical committee of the university. The parents of the children were informed about the aim of this trial and informed written consent was obtained from all subjects. A total of 71 restorations were performed, 36 with nanofilled resin composite (RC) and 35 with Fiber-reinforced nanofilled-resin composite (FRC). In the majority of the cases, the split-mouth technique was used (48 teeth: 24 FRC, 24 RC) in which two applications (with or without glass-fiber layering) were randomly allocated to either side of the mouth by tossing a coin. In the other restorations (n= 23), the split-mouth technique was not used (with or without fiber application; n=11 and n=12 respectively). X-ray records prior to applications were used.

All the cavities were of extensive size as defined by Mount and Hume,²¹ were labelled as '4' (two or three surfaces; MOD/DO/MO) and included more than 2 surfaces or at least loss of two-thirds of one cusp. The indications for the restorations were primary caries or replacement of failed or insufficient restorations. Radiographically, 67% of lesions reached the inner half of the dentin and the rest in the outer half of the dentin. Cavities with margins below the cemento-enamel junction were excluded.

Subjects were excluded from the trial if they exhibited chronic gingivitis, rampant caries, and poor oral hygiene or were potentially unable to attend follow-up visits. Subjects that were cooperative, having no systemic disease or parafunctional habits participated in the study. Teeth with no evidence of pulpal involvement and in occlusion were included. Before treatments, the patients were given information about good dietary habits and instruction in oral hygiene.

Table 2. Resin Composites, bonding system and type of fiber used in the study:

Bis-GMA: Bisphenol-A-glycidyl dimethacrylate; TEGDMA: triethylene glycol dimethacrylate; UDMA: Urethane dimethacrylate; HEMA: 2-hydroxyethyl methacrylate; Bis-EMA: Ethoxylated bisphenol A dimethacrylate; PMMA: Polymethyl methacrylate (*) Information on the composition of composites and glass fiber was provided by the manufacturers.

Material	Manufacturer	Basic Composition *	Particle size	Filler loading (%vol)
Filtek Supreme (Nanofilled resin composite)	3M ESPE, USA	Zirconia/silica cluster filler, Bis-GMA, Bis-EMA, UDMA, TEGDMA	Nanofillers: 5-20 nm, clusters: 0.6-1.4 µm	78.5
Filtek Flow (Flowable composite)	3M ESPE, USA	Zirconia/silica, Bis-GMA, TEGDMA	1.5 µm	47
Adper Single Bond (Adhesive)	3M ESPE, USA	Silica fillers, Bis-GMA, ethanol, HEMA, water		10.5
EverStickNet (Fiber)	StickTech Ltd, Finland	PMMA, pre-impregnated bidirectional E-glass fibres		

Table 3. Criteria used for the direct clinical evaluation (A- Alfa, B- Bravo, C- Charlie).

Criterion	Score	Definition
Color match	A	The restoration matches the adjacent tooth structure in colour, shade or translucency
	B	Mismatch in color, shade or translucency between the restoration and the adjacent tooth
	C	The mismatch in color and translucency is outside the acceptable range of tooth color and translucency
Marginal discoloration	A	No discoloration anywhere along the margin between the restoration and the adjacent tooth
	B	Slight discoloration along the margin between the restoration and the adjacent tooth
	C	The discoloration penetrated along the margin of the restorative material in a pulpal direction
Marginal adaptation	A	No visible evidence of crevice along the margin
	B	Visible evidence of a crevice along the margin into which the explorer will penetrate
	C	The dentine or the base is exposed
Surface texture	A	The restoration surface is as smooth as the surrounding enamel
	B	The restoration surface is rougher than the surrounding enamel
	C	There is a crevice and fracture on the surface of the restoration
Anatomical form	A	The restoration is continuous with existing anatomical form
	B	The restoration is discontinuous with existing anatomical form, but the material is not sufficient to expose dentine or base
	C	Sufficient material lost to expose dentine or base
Secondary caries	A	No evidence of caries
	B	Evidence of caries along the margin of the restoration
Post-operative sensitivity	A	No post-operative sensitivity at any time during the restorative process and the study period
	B	Experience of sensitivity at any time during the restorative process and the study period

Clinical procedures were standardized and all teeth were restored by one operator (UC). A rubber dam was used and local anesthesia was applied in all cases. An adhesive cavity design was prepared and materials were placed according to the manufacturers' instructions. Caries detecting dye was not used. In both groups, after etching (15 seconds) adhesive was applied (Adper Single Bond, 3M ESPE USA) and light curing was performed for 20 seconds with a blue light-emitting diode (LED) (Elipar Freelight, 3M ESPE USA). Flowable resin composite (Filtek Flow 3M ESPE USA) was used as an intermediary layer in both groups. The materials used in the study are presented in Table 2.

In the FRC group, after application of a thin layer of the flowable composite resin to the cavity, a layer of woven polymer-monomer gel impregnated E-glass fiber (EverStick Net, Finland) (0.06 mm in thickness) on the unpolymerized flowable composite was condensed with a plugger and polymerized for 20 seconds using LED. The orientation of the fibers was bucco-palatal and mesio-distal. Then, nanofilled resin composite was placed to the rest of the cavity incrementally, each increment being cured for 40 seconds. Occlusion was then carefully checked with articulating paper and the restorations were contoured with fine composite finishing diamonds under water spray and finished with Sof-Lex discs (3M ESPE, USA) at the same visit (Figure 1). In the RC group, the resin composite was placed, finished and polished as in the FRC group.

Clinical Evaluation

Two blinded evaluators who were not involved in the placement of the restorations carried out the evaluation at baseline (after two weeks), and after 6, 12, 24, and 30 months using a modified USPHS-Ryge criteria (Table 3).²² Alfa and Bravo scores mean 'excellent

and clinically acceptable' results while Charlie mean 'clinically not acceptable'. Vitality testing was performed at baseline and at each subsequent evaluation. Photographs of restorations were taken prior to restoration, immediately after, and in each evaluation period (Figure 2). Cohen's Kappa scores calculated for intra-examiner and inter-examiner reliability were 0.93 and 0.97 respectively.

Statistical Analysis

Fisher's exact test was used for the effects of variables such as location, tooth type and gender. Chi-square and Fisher's exact tests were used to determine the comparisons according to USPHS criteria. The changes in each criterion during the evaluation periods were assessed using Cochran Q test at a significance level of $p < 0.05$.

RESULTS

Sixty-nine restorations in 46 patients were evaluated after 30 months with a dropout rate of 1.4%. At the end of 30 months, one patient was lost with two restorations, one from each treatment group. The distribution of restorations to teeth in terms of location and application with/without glass-fiber layering is shown in Table 1. The distribution of restorations according to gender, tooth type and jaws was not statistically different ($p > 0.05$).

Results showed no significant differences between the restorations restored with or without glass-fiber layering at the 30-month evaluation period for any of the clinical criteria. No significant differences in the evaluated criteria were detected when comparing baseline with any of the evaluation periods for both treatment groups ($p > 0.05$). All restorations were intact and all the restored teeth remained vital during the study. No post-operative sensitivity or secondary caries were recorded for any of the teeth restored throughout the

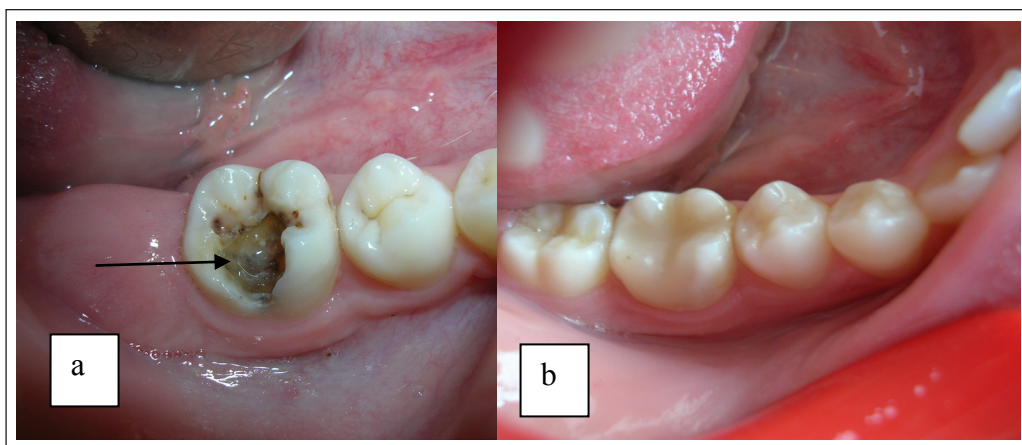


Figure 1 a) Lower right first permanent molar with a large carious lesion involving the occlusal and buccal surfaces (arrow) restored with fiber-reinforced nanofilled-resin composite b) Restored tooth after 30 months.

study period. Restorations received either Alfa or Bravo score for Ryge criteria in both treatment groups. Clinical assessment findings with respect to color match, marginal adaptation, secondary caries, surface texture, anatomical form, marginal discoloration at baseline and after 12 and 30 months are presented in Table 4.

The percentages of alpha scores for marginal discoloration, secondary caries, anatomic form loss and surface texture after the 6-month evaluation period were 100% for both treatment groups. After a one-year evaluation period, 100% of the restorations received alpha scores for secondary caries, anatomic form loss and surface texture. The restorations with Bravo scores after one-year evaluation period in the RC and FRC groups, respectively were: for marginal adaptation, 5.6 % (n=2) and 5.7 % (n=2); for color match,

2.8 % (n=1) and 2.9 % (n=1); and for marginal discoloration, 5.6 % (n=2) and 2.9 % (n=1). After 30 months, for marginal adaptation, 5.6 % (n=2) and 5.7 % (n=2); for color match, 5.7 % (n=2) and 2.9 % (n=1); for marginal discoloration, 5.6 % (n=2) and 2.9 % (n=1); and for surface texture, 2.9 % (n=1) and 2.9 % (n=2). After the 30-month evaluation period, 100% of the restorations received alpha scores for secondary caries and anatomic form in both groups. The 30-month cumulative retention rates were 97% and 97.1% in the RC and FRC groups, respectively. No statistically significant difference in the overall survival rate between the restorations with and without glass-fiber layering was found within the 30-month follow-up ($p>0.05$).

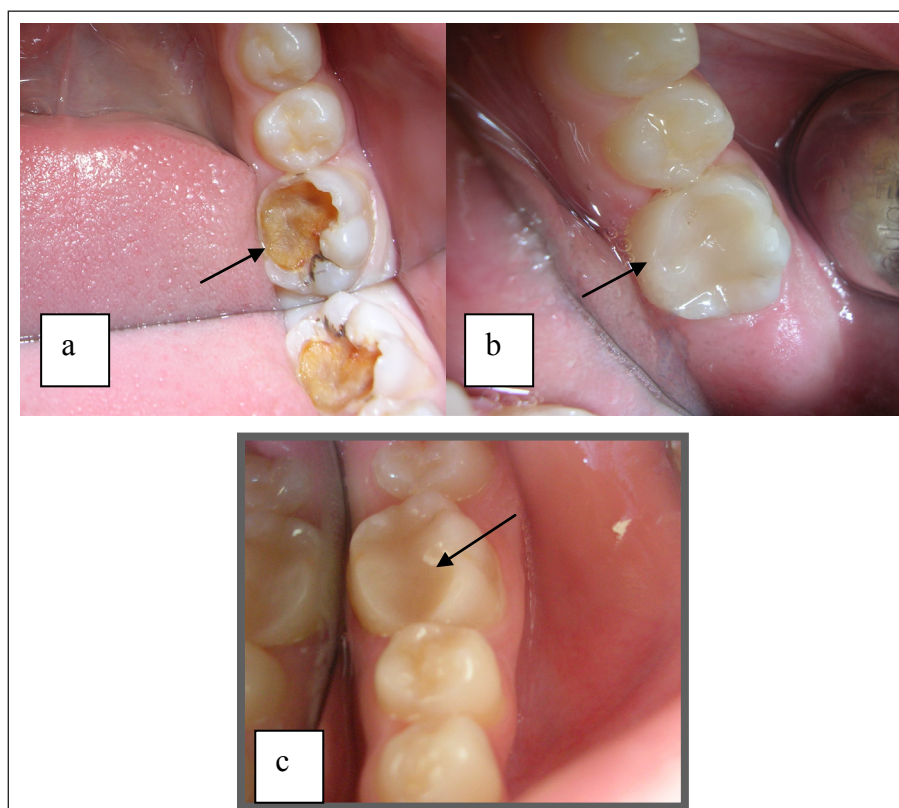


Figure 2 a) Lower right first permanent molar restored with nanofilled-resin composite b) Restored tooth after 12 months c) after 30 months.

Table 4. Results of the clinical evaluation criteria (%) at baseline, 6, 12 and 30- month follow-up (RC; Nanofilled resin composite, FRC; Fiber- reinforced resin composite). (A- Alfa, B- Bravo, C- Charlie).

		Baseline		12 months		30 months	
		RC	FRC	RC	FRC	RC	FRC
Color match	A	100	100	97.2	97.1	94.3	97.1
	B	-	-	2.8	2.9	5.7	2.9
	C	-	-	-	-	-	-
Marginal discoloration	A	100	100	94.4	97.1	94.4	97.1
	B	-	-	5.6	2.9	5.6	2.9
	C	-	-	-	-	-	-
Marginal adaptation	A	100	100	94.4	94.3	94.4	94.3
	B	-	-	5.6	5.7	5.6	5.7
	C	-	-	-	-	-	-
Surface texture	A	100	100	100	100	97.1	97.1
	B	-	-	-	-	2.9	2.9
	C	-	-	-	-	-	-
Anatomical form	A	100	100	100	100	100	100
	B	-	-	-	-	-	-
	C	-	-	-	-	-	-
Secondary caries	A	100	100	100	100	100	100
	B	-	-	-	-	-	-
Post-operative sensitivity	A	100	100	100	100	100	100
	B	-	-	-	-	-	-

DISCUSSION

In this study no significant difference was found for the clinical performance of nanofilled-resin restorations applied with or without glass fiber-layering in stress-bearing, large cavities made in posterior teeth of children after 30 months. Thus, at the 30-month evaluation, all restorations were scored Alfa for anatomical form and secondary caries formation in both the FRC and RC groups. Minor changes in some of the restorations (Bravo score) for marginal adaptation, marginal discoloration, color match and surface texture were observed in both treatment groups. Since both treatment groups showed similarly good clinical performance, the hypothesis that using glass-fiber layering with the nanofilled-resin composite would improve clinical performance and resistance to occlusal loads, was not confirmed.

Results are in accordance with reports that nanofilled-resin composites are able to resist the occlusal stresses at least as well as universal hybrid composites and exhibit good performance with sufficient clinical properties.^{7,23-27} However, it is also stated that wear resistance of these materials did not differ from microhybrid or microfill composite, and abrasive wear of the nanofilled composites was found comparable to conventional microfill composite resin materials.⁶ In a study it is stated that 'nanocluster' system in the nanofilled resin composites provided a distinct reinforcement mechanism to the resin matrix which may enhance the clinical longevity of the resin material.³⁰ However, clinical studies performed with nanofilled resin composites under high occlusal stress situations are lacking.

Previous studies have reported that superior reinforcement was achieved using fiber preforms and have suggested the use of fiber preforms in high stress-bearing restorations.^{9,10,12,15,16,19,20} Although

higher flexural strength values are obtained, results may show dissimilarity when FRC layering is applied. Factors such as fiber volume fraction, location of the fiber, and polymerization conditions may have an effect on the resultant strength values.^{13,15} No literature could be found related to the effectiveness of the woven glass fiber-reinforcement in direct restoration of stress-bearing posterior cavities. Therefore, it was not possible to compare the results.

The fibers in woven designs are divided equally in the longitudinal and transverse directions, which give composite material orthotropic mechanical properties.^{8,9,14,19} Therefore, they are suitable especially in cases where multi-direction reinforcement of the restoration is needed and the direction of load is difficult to predict.^{8,9} It is stated that the position of the FRC layer had an effect on the flexural strength of the test specimen. Thus, when fibers are placed at the direction of highest stress, partial fiber reinforcement can be enough to hinder the fracture line. The highest flexure strength was achieved when the FRC layer was located at the tensile side of the specimens.¹⁵

Fibers should be well impregnated with the polymer of the fiber composite in order to obtain a composite structure, which transfers the stresses from the polymer to the fibers. In the case of incomplete impregnation, there are voids in the polymer matrix of FRC and the mechanical properties such as flexural strength values of the FRC may be lower.¹⁷ The woven glass fiber used in this study is pre-impregnated with light-curing monomers which cross-link during polymerization of the overlying composite and formed a multiphase polymer network. A multiphase structure is called a semi-interpenetrating polymer network structure (semi-IPN). The advantages of semi-IPN are said to be easier handling of the fiber material, high strength, reduced water sorption, high flexural

strength and improved adhesion between FRC framework and veneering composite after polymerization.¹⁷

In this study, flowable resin composite was used as an intermediary layer in the restorations. It is mentioned in some studies that because of low modulus of elasticity of flowable composites they are less rigid than traditional composites and may absorb the stress caused by the polymerization of the final restorative composite.^{25,28} In addition, in vitro studies showed that flowable resin composites reduce microleakage.^{25,28} However, the effectiveness of the use of the intermediary flowable resin composite layer could not be demonstrated in some other studies.^{24,29}

Adhesive resin restorations enable the dentist to avoid using more complicated restorations in the management of extensively carious lesions in the permanent molars of children. They would also help in delaying more invasive types of treatment until the recession of the pulp horns takes place. However, difficulties in isolation of saliva or placing a direct composite may shorten the survival time of the resin restorations in young permanent dentition. In the present study, the high survival rates in the treatment groups may be due to the selection of cooperative patients.

It can be concluded that after 30-months, fiber-reinforced nanofilled-resin restorations showed good clinical performance, similar to that of the nanofilled resin composite used alone, in extensively carious cavities of posterior teeth in children.

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