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Clinical Evaluation of a Nanofilled Composite in Posterior Teeth: 12-month Results

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Clinical Relevance

Nanofilled resin composite showed excellent clinical performance, similar to microhybrid and packable composites after 12-months.

SUMMARY

This study compared the clinical performance of a nanofilled resin composite for posterior restorations with 2 microhybrid and 1 packable composite after 12 months of clinical service. Forty-two patients with at least 5 Class I or II restorations under occlusion were enrolled in this study. A total of 148 restorations were placed, 25% for each material (Filtek Supreme, Pyramid, Esthet-X or Tetric Ceram). Two calibrated operators placed all restorations, according to the manufacturers' instructions. One week later, the restorations were finished/polished. Two independent examiners evaluated the restorations at baseline and after 12 months according to the USPHS modified criteria. All patients attended the 12-month recall and 148 restorations were evaluated. Friedman repeated measures analysis of variance by rank and Wilcoxon sign-ranked test for pair-wise comparison was used for data analysis (α=0.05). All materials showed only minor modifications, and no differences were detected between their performance at baseline and after 12 months. After 1 year, the nanofilled resin composite showed similar performance to the other packable and microhybrid resin composites.

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INTRODUCTION

The majority of resin composites on the market are called universal hybrid or microhybrid resin composites. The improved esthetics provided by these materials, due to the smoother surface obtained after polish-

ing and higher wear resistance (<10 µm/year), led to their recommendation for placement in anterior and posterior teeth (Baratieri, Araujo & Monteiro, 1993). In many clinical studies, several hybrid resin composites with these characteristics showed excellent clinical performance (Leinfelder, 1995; Abdalla & Alhadainy, 1996; Schoch & others, 1999; Perdigão, Geraldelli & Hodges, 2003; Busato & others, 2001).

However, there are controversial findings regarding the performance of hybrid composites in anterior teeth. While some studies demonstrated that hybrid and microfilled composites have similar performance in esthetic cavities, others concluded that microfilled composites are the best option for anterior cavities because of their high translucency, high polish and polish retention (van Dijken, 1986; van der Veen, Pilon & Henty, 1989; Browning, Brackett & Gilpatrick, 2000; Geitel & others, 2004).

However, the degree of complexity of resin composite restoration placement and curing is blamed for perceived higher levels of secondary caries or postoperative sensitivity (Leinfelder, Bayne & Swift, 1999). In the face of these difficulties, changes in the handling characteristics of resin composites were made to improve composite placement; and several products, called packable resin composites, are available for posterior use. This category of materials is rather inhomogeneous in terms of mechanical and physical data (Ferracane, Choi & Condon, 1999; Choi & others, 2000; Abe & others, 2001) and esthetic properties (Ryba, Dunn & Murchison, 2002; Reis & others, 2003; Borges & others, 2004).

Recently, a new category of resin composites were developed and named nanofilled composites. Restorative composite systems made by the use of nanotechnology can offer high translucency, high polish and polish retention similar to that of microfilled composites while maintaining physical properties and wear equivalent to several hybrid composites (Mitra, Holmes & Wu, 2003). Unfortunately, to the extent of the authors' knowledge, there is no clinical study that has attempted to compare the performance of this new category of resin composites with other available composites for posterior use, which was the aim of this investigation.

METHODS AND MATERIALS

The research protocol was submitted to the Ethics Committee. Once the method was approved, dental students from the School of Dentistry (University of Oeste de Santa Catarina) were selected. The resin composites employed in this study were: Filtek-Supreme (3M ESPE, St Paul, MN, USA), a nanofilled resin composite; Pyramid (BISCO, Schaumburg, IL, USA), a packable resin composite and Esthet-X (Caulk-DeTrey Dentsply, Konstanz, Germany) and Tetric Ceram (Ivoclar Vivadent, Schaan, Liechtenstein) as microhybrid composites (Table 1).

Each patient required at least 5 Class I or Class II restorations. All patients had complete and normal occlusion. According to the treatment rules at the School of Dentistry, Department of Dental Materials and Operative Dentistry, University of Oeste de Santa Catarina, all patients received oral hygiene instructions before operative treatment was performed. Patients with extremely poor oral hygiene, heavy bruxism habits or periodontal problems were excluded. Most restorations replaced existing amalgams for esthetic reasons.

The restorative procedure was initiated using rubber dam isolation. The cavity design (restricted to the elimination of carious tissue) was prepared using stainless steel burs (#329, 330 and/or 245; KG Sorensen, Barueri, São Paulo, Brazil). The dentin in deeper cavities was covered with calcium hydroxide Dycal (Caulk-DeTrey) and/or glass ionomer cement Vitrebond (3M ESPE).

Randomization of the materials was performed on each patient by tossing a coin. However, interference in the randomization procedure within patients was performed in order to equally distribute materials into some important variables such as tooth type and position, restoration class and size, and occlusion in such a way that minimized the influence of those factors (Bryant & Hodge, 1994). Although all the restorations were of moderate size, as defined by Wilson, Smith and Wilson (1986), fewer than 5% of the restorations extended less than one-quarter of the way up the culpal slopes.

Table 1: *Description of Groups (materials and manufacturers)*

Groups	Materials		
	Adhesive Systems	**Resin Composites**	**Manufacturers**
(1)	Single Bond (One-bottle)	Filtek Supreme	3M ESPE, St Paul, MN, USA
(2)	One Step Plus (One-bottle)	Pyramid	BISCO, Schaumburg, IL, USA
(3)	Prime & Bond NT (One-bottle)	Esthet–X	Dentsply DeTrey GMBH Konstanz, Germany
(4)	Excite (One-bottle)	Tetric Ceram	Ivoclar Vivadent Schaan, Liechtenstein

The adhesive systems from the same manufacturer for each resin composite were employed (Table 2). The adhesive application followed the manufacturers' directions (Table 2). Placement of resin composites followed the incremental technique (2-mm thick layers). The resin composite was adapted with a flat-faced or elliptical condenser and light-cured for 40 seconds using an Optilux 501 light-curing unit (Kerr Manufacturing, Romulus, MI, USA), with a light output of 550 mW/cm^2. In Class II restorations, the adhesive system and the first increment of resin composite were applied to guarantee a better cure of the composite in the gingival margin prior to placing the pre-contoured metal matrices and wood wedges for proximal occlusal restorations (Table 3). A post-occlusal adjustment was performed with carbon paper and fine-grit diamond burs, and the

Table 2: *Composition, Application and Batch # of the Adhesives Used in This Study*

Adhesive Systems	Composition (*)	Application Mode	Batch #
1–Single Bond	1. Conditioner: 36% phosphoric acid with coloidal silica; 2. Adhesive: Bis–GMA, HEMA, dimethacrylates, polyalkenoic acid copolymer, initiator, water and ethanol.	a, b, c, d, e, f, g	3HW
2–One Step Plus	1. Conditioner: 37% phosphoric acid with coloidal silica; 2. Adhesive: Biphenyl dimethacrylate hydroxyethyl methacrylate, acetone and dental glass.	a, b, c, d, e, f, g	CE 0599
3–Prime & Bond NT	1. Conditioner: 36% phosphoric acid with coloidal silica; 2. Adhesive: PENTA, UDMA, Resin R5-62-1, T-resin, D-resin, nanofiller, cetylaminehydrofluoride and acetone.	a, b, c, d, e2, f, g1	0506001075
4–Excite	1. Conditioner: 37% phosphoric acid with coloidal silica; 2. nanofillller cetylaminehydrofluoride and ethanol adhesive.	a, b, c, d, e1, f, g1, e1, f, g1	D63059

a–acid-etch (15 seconds); b–rinse (15 seconds); c–air-dry (30 seconds); d–dentin rewetted of water; e–two coats of adhesive system, brushed for 10 seconds each; e1–one generous coat of adhesive system, brushed for 10 seconds; e2–one generous coat of adhesive system, left undisturbed for 30 seconds; f–air-dry for 10 seconds at 20 cm; g–light-activation (10 seconds with 600 mW/cm^2); g1–light-activation (20 seconds with 600 mW/cm^2)
Font: (*) Perdigão and Lopes (1999)

Table 3: *Composition of the Resin Composites Employed in This Study**

Materials	Inorganic Matrix	Organic Matrix	Batch #
1–Filtek Supreme (**)	1) Translucent shades contain a combination of a non-agglomerated/nonaggregated, 75 nm silica nanofiller, and a loosely bound agglomerate silica nanocluster consisting of agglomerates of primary silica nanoparticles of 75 nm size fillers. The cluster size range is 0.6 to 1.4 microns. The filler loading is 72.5% by weight (55% by volume). 2) All of the remaining shades contain a combination of a non-agglomerated/non-aggregated, 20 nm nanosilica filler and loosely bound agglomerated zirconia/silica nanocluster, consisting of agglomerates of primary zirconia/silica particles with size of 5-20 nm fillers. The cluster particle size range is 0.6 to 1.4 microns. The filler loading is 78.5% by weight (57% by volume)	Bis-GMA, UDMA, Bis-EMA and TEGDMA	5BC, 4AW, 4BC, 4BM, 5xC and 4CW
2–Pyramid	Pyramid Enamel: The filler loading is 65.2% by weight (48.3% by volume) (***) Pyramid Dentin: The filler loading is 75.2% by weight (60.2% by volume) (***) The particle size range of 1-15 µm (****)	Dimethacrylate of ethoxylated Bisphenol-A polycarbonated resin and TEGDMA	CE 0459 0000001743
3–Esthet-X	Barium fluoro alumino boro silicate (mean particle size <1 µm) and highly dispersed silicon dioxide (particle size 0.04 µm). The percentage by weight of total inorganic fillers is 77%, the percentage by volume is 60%	Bis-GMA-adduct, Bis-EMA and TEGDMA	CE 0120 0106201
4–Tetric Ceram	Barium glass (50.6%), Ba-Al-fluorosilicate glass (5.0%), mixed oxide (5.0%); highly dispersed silica (1.0%) and ytterbium trifluoride (17.0%). Mean particle size (0.7 µm). The percentage by volume of total inorganic fillers is 62%, the percentage by weight is 78.6%	Bis-GMA, UDMA and TEGDMA	CE 0123

Font: (*) Manufacturer's instructions; (**) Mitra & others, 2003; (***) Ferracane & others, 1999; (****) Ryba & others, 2002.

Table 4: *Modified USPHS Criteria Used*

Criteria	Code	Definition
Color Match	A	Restoration matches adjacent tooth structure in color and translucency.
	B	Mismatch is within an acceptable range of tooth color and translucency.
	C	Mismatch is outside the acceptable range.
Retention	A	Full retention.
	B	Partial retention.
	C	Restoration is lost.
Marginal Adaptation	A	Restoration closely adapted to the tooth. No crevice visible. No explorer catch at the margins, or there was a catch in one direction.
	B	Explorer catch. No visible evidence of a crevice into which the explorer could penetrate. No dentin or base visible.
	C	Explorer penetrates into a crevice that is of a depth that exposes dentin or base.
Anatomic Form	A	Restorations continuous with existing anatomic form.
	B	Restorations discontinuous with existing anatomic form but missing material not sufficient to expose dentin base.
	C	Sufficient material lost to expose dentin or base.
Surface Roughness	A	Surface of restoration is smooth.
	B	Surface of restoration is slightly rough or pitted, but can be refinished.
	C	Surface deeply pitted, irregular grooves and cannot be refinished.
	D	Surface is fractured or flaking.
Marginal Staining	A	No staining along cavosurface margin.
	B	<50% of cavosurface affected by stain (removable, usually localized).
	C	>50% of cavosurface affected by stain.
Sensitivity	A	None.
	B	Mild but bearable.
	C	Uncomfortable, but no replacement is necessary.
	D	Painful. Replacement of restoration is necessary.
Secondary Caries	A	Absent.
	C	Present.

Based on Wilson and others, 2002.

Table 5: *Number of Evaluated Restorations by Location (tooth) and Extension (class) for Each Material*

Groups	Number of Evaluated Restorations	Tooth		Class	
		Premolars	Molars	I	II
(1)	37	10	27	23	14
(2)	37	15	22	19	18
(3)	37	7	30	22	15
(4)	37	14	23	17	20
TOTAL	148	46 (31%)	102 (69%)	81 (55%)	67 (45%)

quality of the interproximal contact and cervical adaptation was checked by means of dental floss and interproximal radiographs. Finishing and polishing were carried out after 1 week, using fine-grit diamond burs (KG Sorensen, Barueri, São Paulo, Brazil) and aluminum oxide polishing paste (Kerr Manufacturing) in rubber cups on the occlusal surfaces. When necessary, abrasive strips (3M ESPE) were used in the interproximal surface.

All restorations were evaluated after 1 week (baseline) and 12 months for the following characteristics: retention, color match, interfacial staining, secondary caries, postoperative sensitivity, anatomical form, marginal adaptation or integrity and surface texture (Leinfelder, 1987). The restorations were clinically evaluated by 2 investigators (NRR and ADL) using the modified USPHS criteria as first described by Cvar and Ryge (1971) and adapted by Wilson and others (2002) (Table 4). Each examiner evaluated the restoration once and, independently, they were unaware of which material had been used, creating a double-blind study.

When disagreements arose during evaluations, the examiners had to reach a consensus. Descriptive sta-

Table 6: *Number of evaluated restorations in the items retention, anatomic form surface texture, color match, marginal adaptation, interfacial staining and postoperative sensitivity and secondary caries for each group.*

Evaluation Criteria	Scores ↓	Baseline				1 Year			
Materials →		FIL	PYR	EST	TET	FIL	PYR	EST	TET
Color Match	A	37	37	37	37	35	34	35	33
	B	--	--	--	--	02	03	02	04
	C	--	--	--	--	--	--	--	--
Retention	A	37	37	37	37	37	37	37	37
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
Marginal Adaptation	A	37	37	37	37	34	32	35	35
	B	--	--	--	--	03	05	02	02
	C	--	--	--	--	--	--	--	--
Anatomic Form	A	37	37	37	37	36	34	37	37
	B	--	--	--	--	01	03	--	--
	C	--	--	--	--	--	--	--	--
Surface Roughness	A	37	37	37	37	37	32	36	37
	B	--	--	--	--	--	05	01	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
Marginal Staining	A	37	37	37	37	37	37	37	37
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
Sensitivity	A	36	34	36	35	37	37	37	37
	B	01	03	01	02	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
Secondary Caries	A	37	37	37	37	37	37	37	37
	C	--	--	--	--	--	--	--	--

tistics were used to describe the frequency distributions of the evaluated criteria. Friedman repeated measures analysis of variance by rank and Wilcoxon sign-ranked test for pair-wise comparisons (α=0.05) were used for data analysis. The differences in the ratings by the 2 operators after 12 months were tested with Fisher's exact test (α=0.05) (Siegel, 1996). As a measurement of agreement between the examiners, Cohen's Kappa statistic was used.

RESULTS

The results are summarized in the Tables 5 and 6. In total, 148 restorations were placed in 37 patients. The distribution of the restorations was nearly similar between Class I (81) and Class II (67) cavities. Sixty-nine percent of the restorations were placed in molars (102) and 31% were placed in premolars (46). All patients attended the 1-year recall.

The Cohen's Kappa statistics (0.87) showed strong agreement between the examiners and no statistical difference was observed in their answers (p=0.76). At baseline, post-operative sensitivity was observed in 7 restorations, which disappeared in the 12-month evaluation. No secondary caries, marginal discoloration or lack of retention was observed after 1 year.

Color match and marginal adaptation were the items that received the highest number of Bravo scores (11 and 12, respectively, Figures 1 and 2). Only 4 restorations were classified as Bravo in anatomic form. Six restorations showed poor surface texture after 12 months (Figures 1 through 3). No statistical difference was observed between materials (p>0.05) and their performance at the baseline and after 1 year was statistically similar (p>0.05).

DISCUSSION

Evaluation of the composites depicted minor changes compared to the baseline. This fact is not surprising, since several studies have already shown a satisfactory performance of microhybrid composites in posterior

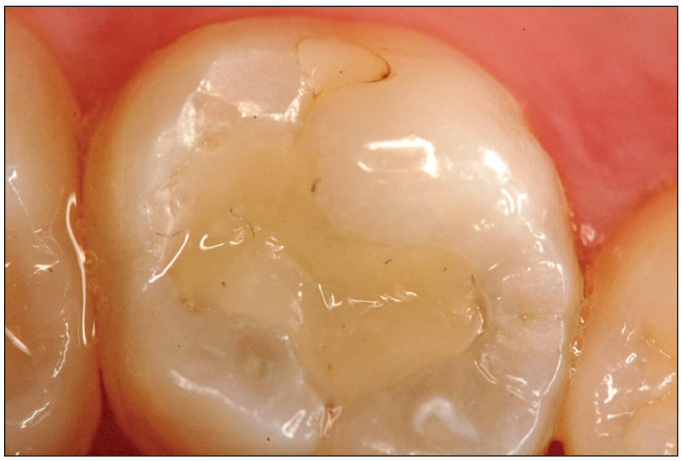

Figure 1: *Upper left first molar restored with One Step Plus adhesive system plus Pyramid resin after 1 year. Note the small fracture at the distal margin. The restoration was classified as Bravo in the item color mismatch, marginal disadaptation and surface texture.*

Figure 2: *Lower left first molar restored with Excite plus Tetric Ceram after 1 year. The surface texture and color mismatch of the restoration were classified as Bravo.*

Figure 3: *Lower right first molar restored with Prime & Bond NT and Esthet-X after 1 year. The restoration was classified as Bravo for surface texture.*

Figure 4: *Lower right second molar restored with Single Bond and Filtek Supreme after 1 year. The excellent surface texture and color match can be seen.*

teeth during initial periods of evaluation (Leinfelder, 1995; Abdalla & Alhadainy, 1996; Schoch & others, 1999; Perdigão & others, 2003).

Two microhybrid composites were evaluated in this study. Long-term clinical reports demonstrated good clinical performance of Tetric Ceram in posterior teeth, as well as its predecessor, Tetric resin composite (Wilson & others, 2000; Busato & others, 2001; Schäfers & Krantz-Schafers, 2003; Manhart & others, 2004). Although there is no long-term report on the performance of the other microhybrid composite that was evaluated (Esthet-X), short-term studies have indicated that this resin composite seems to have a promising performance in posterior teeth (Dunn & others, 2002; Perdigão & others, 2003; Türkün, 2005).

Packable resin composites arose from the progressive development of composite materials for posterior teeth. However, the packable composites available on the market have different features, mainly in the distribution and size of inorganic particles. This fact causes profound differences in the mechanical and physical properties of these composites and, therefore, their performance is material-dependent (Leinfelder & others, 1999; Ferracane & others, 1999; Choi & others, 2000; Abe & others, 2001; Abe & others, 2005).

To the extent of the authors' knowledge, no clinical study has attempted to evaluate Pyramid resin. The inorganic phase of Pyramid resin is very similar to Surefil composite (Abe & others, 2001; Sabbagh & others, 2004); therefore, some properties related to the inorganic matrix, such as surface texture characteristics (Ryba & others, 2002) and mechanical properties, are very similar to Surefil composite (Ferracane & others, 1999; Choi & others, 2000; Abe & others, 2001; Abe

& others, 2005). Although no statistical difference was observed between Pyramid and the other composites, in the surface texture item, this material had more Bravo scores after 12 months. It is likely that this is due to the higher mean particle size of this material. Materials with higher particle size, around 15 µm, tend to have lower performance in surface texture compared to materials with a mean particle size inferior to 1 µm (Loguercio & others, 2001; Yip & others, 2003; Türkün & Aktener, 2001), such as Tetric Ceram, Esthet-X and Filtek Supreme.

Irrespective of the above concerns, the packable composite Pyramid showed good performance after 1 year, which was similar to the microhybrid resins Esthet-X and Tetric Ceram (Perry & Kugel, 2000; Loguercio & others, 2001; Türkün & Aktener, 2001; Yip & others, 2003). Unfortunately, this composite was discontinued from the market and was substituted by Aelite LS packable (BISCO).

Nanofilled composites were recently released onto the market (Mitra & others, 2003). Nanotechnology is the production of functional materials and structures in the range of 0.1 to 100 nanometers by various physical and chemical methods (Mitra & others, 2003). Based on this concept, only Filtek Supreme manufacturing is based on nanotechnology composite. Other manufacturers have released some products, claiming that they are nanofilled composites. However, these new composites (Grandio [Voco], Premise [Kerr Dental], Símile [Jeneric/Pentron] and Aelite Esthetic Enamel [BISCO]) have maintained glass particles with a 1-mm mean size and have included some nano-particulated silica (Baseren, 2004). According to Farah and Powers (2003), the materials that combined glass particles, silica coloidal and nano-sized particles should be named nanohybrid composites, not nanofilled composites.

Laboratory investigations have demonstrated that Filtek Supreme can offer high translucency and high polish similar to microfilled composites, depending on the polish system (Baresen, 2004; Yap & others, 2004a; Turssi, Ferracane & Serra, 2005), while maintaining physical properties and wear equivalent to several hybrid composites (Mitra & others, 2003; Felten & others, 2003; Lu & others, 2005). Gloss and surface texture are maintained after *in vitro* aging (Yap & others, 2004b; Heintze & Forjanic, 2005; Chapman, Burgess & Mercante, 2005).

In this investigation, Filtek Supreme showed good performance in posterior teeth, which was similar to the other microhybrid and packable composites evaluated. Other clinical studies, however, have not reached similar conclusions. For example, Ernst and others (2005) compared the clinical performance of Filtek Supreme (3M ESPE) and Tetric Ceram (Vivadent) in posterior teeth after 12- and 24-months and observed that both materials were similar in all items except color match. According to the authors, Tetric Ceram had a higher percentage of color mismatch after 12 and 24 months than Filtek Supreme. In another study, Bharadwaj and others (2005) evaluated, *in vivo*, the wear of Filtek-Supreme compared with Z100 (3M-ESPE) and human enamel. The results showed that, after 1 year of clinical service, the polish of Z100 was significantly worse than Filtek Supreme, although no difference was observed between the materials in regard to wear, which was similar to human enamel.

Unfortunately, as the above studies are abstract, it is difficult to deeply analyze the experimental design and inherent variables of the studies, which could affect reliability of the data.

In regard to postoperative sensitivity or interface discoloration, a minor occurrence was found after 1 year. This finding must be related to the excellent performance of the 2-step etch&rinse adhesive system employed, as already demonstrated in other clinical investigations (Loguercio & others, 2001; Perdigão & others, 2003; 2004).

Other short-term and long-term clinical studies of nanofilled resin composites are important for predicting the longevity of materials. It is also necessary to emphasize that the timeframe for this study was not of such duration to indicate the long-term suitability of the tested materials, but it may provide an indication regarding their future performance.

CONCLUSIONS

It seems reasonable to conclude that, based on the results obtained in this study, nanofilled Filtek Supreme, the packable composite Pyramid and the 2 microhybrid composites Esthet-X and Tetric Ceram exhibited excellent clinical performance after 1 year.

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