

Clinical Evaluation of Resin-based Composites in Posterior Restorations: Two-year Results

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Clinical Relevance

Nanohybrid and low-shrinkage posterior resin composites, placed with self-etch adhesive systems in posterior teeth, showed satisfactory and similar results after two years.

SUMMARY

Objective: This study evaluated the clinical performance of a nanohybrid and a low shrinkage posterior composite in Class I and II restorations after two years.

Methods and Materials: A total of 82 Class I and Class II cavities were restored in 31 patients (10 male, 21 female) by one clinician using Grandio and Quixfil and the manufacturers' self-etch adhesives (Futura Bond and Xeno III) according

to the manufacturers' instructions. Two previously calibrated operators clinically evaluated the restorations one week after placement (baseline) and six months, one year and two years after placement using modified USPHS criteria. Statistical analysis was completed using the Pearson Chi-square and Fisher's Exact Test ($p < 0.05$).

Results: All patients attended the 12-month recall and no lack of retention was observed. With respect to color match, marginal adaptation, secondary caries and surface texture, no significant differences have been found between the two restorative materials that were tested after 12 months ($p > 0.05$). None of the restorations had shown any marginal discoloration and anatomic form loss until the end of the 12-month period. Two-year recall data demonstrated an 83.87% recall rate (26 patients). Grandio restorations showed a significant deterioration of the surface properties that demonstrated 26% Bravo scores, which are still clinically acceptable. None of the

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restorations exhibited postoperative sensitivity at any evaluation period.

Conclusions: It was concluded that nanofill (Grandio) and posterior composite (Quixfil) demonstrated acceptable clinical performance after two years. However, further evaluations are necessary for the long-term clinical performance of these materials.

INTRODUCTION

Resin-based composites have been widely used over the past decade to restore posterior teeth.^{1,2} Patient demand for tooth-colored restorations, public concerns related to mercury in dental amalgam and the desire for minimally-invasive restorations have made posterior composites an indispensable part of the restorative process. The increased conservation of healthy dental structure with resin-based composite restorations, when compared to amalgam restorations, is another significant advantage. Many clinicians have used this class of materials in posterior stress-bearing areas quite successfully for the last five to 10 years.³ However, there are some problems associated with resin-based composites in posterior teeth, including occlusal and proximal wear, marginal leakage, discoloration, polymerization shrinkage and postoperative sensitivity.⁴

As manufacturers continue to search for a tooth-colored resin-based composite material with good physical properties, the introduction of new materials has taken dentistry a step closer to the goal. These resin composites present new filler designs, a change in the organic resin, improved rheological properties, increased viscosity and reduced adherence to hand instruments.⁵⁻⁶ Recently, a new posterior composite material, Quixfil, was introduced into the dental market. The bimodal filler technology of Quixfil shows a particle distribution with two distinct peaks at 0.8 μm and 10 μm and polymerization shrinkage is stated by the manufacturer as being 1.7 vol% by the manufacturer. A longitudinal randomized clinical assessment of stress bearing Class I and II restorations showed that Quixfil exhibited good clinical results over three years.⁷

Nanocomposites are a new category of resin composites that have been developed. Restorative resin composites made by the use of nanotechnology can offer many advantages, such as reduced polymerization shrinkage, increased mechanical properties, improved optical characteristics and better gloss retention.⁸⁻¹² Additionally, wear resistance of nanocomposites has been shown, *in vitro*, to be comparable to or superior to that of microfill and microhybrid resin composites.¹²⁻¹³ Laboratory tests might provide useful information regarding the potential performance of a restorative material; however, clinical studies are important for predicting the longevity of a material in oral conditions.

Dental practitioners require scientific data from clinical studies to determine the long-term performance of resin composites in posterior teeth and to estimate the risk for patients. However, long-term results with some of these newly developed materials are lacking and remain controversial, as studies report inconsistent clinical results.¹⁴⁻¹⁵

The current study evaluated the two-year clinical performance of a nanohybrid and a low-shrinkage posterior composite in Class I and II restorations. The working hypothesis was that material properties had an influence on the clinical performance of the restorative systems.

METHODS AND MATERIALS

Patient Selection

Thirty-one patients (10 male, 21 female), requiring at least two Class I or Class II restorations, participated in the current study. The patients' ages ranged from 16 to 60 years of age (mean: 26). Patients with poor oral hygiene, severe or chronic periodontitis, heavy bruxism or a known allergic reaction against any components of the used materials were excluded from the study. Inclusion criteria were permanent premolars and molars requiring Class I and II restorations for treating primary carious lesions and at least one neighboring tooth in occlusion to the antagonistic teeth. The specific exclusion criteria included pathologic pulpal diagnosis with pain (non-vital), fractured or visibly-cracked teeth, defective restorations adjacent to or opposing the tooth, rampant caries, atypical extrinsic staining of teeth or staining of any existing tooth-colored restorations.

Patients included in the current study were selected from the Dental Clinics of Baskent University, School of Dentistry, Department of Conservative Dentistry. The protocol of this study was approved by the Baskent University Ethics Committee on Investigations Involving Human Subjects. Written informed consents were also obtained from all participants prior to treatment.

Clinical Procedures

Each patient had at least one pair of restorations. A total of 82 teeth (41 pairs) were restored with either a nanohybrid resin composite (Grandio, Voco GmbH, Cuxhaven, Germany) and its self-etch adhesive (Futurabond NR, Voco GmbH) or a low-shrinkage posterior composite (Quixfil, Denstply, Kostanz, Germany) and its self-etch adhesive (XenoIII, Dentsply) according to the manufacturers' instructions (Table 1). The distribution of materials and tooth locations were randomly determined by tossing a coin (Table 2). However, interference in the randomization procedure within patients was performed in order to equally distribute materials into some important variables, such as tooth type, tooth

Table 1: Material Descriptions, Batch Numbers and Manufacturers of the Materials Used in This Study

Material Description	Material	Chemical Composition	Manufacturer	Lot #
Dentin Bonding Agent: Light-curing self-etch bond reinforced with nanofillers	Futurabond NR	Liquid A: methacryl phosphorus acid ester and carbonic acid modified methacrylic ester Liquid B: water, ethanol, silicon pH=1.4	Voco GmbH Cuxhaven, Germany	610456
Dentin Bonding Agent Single step self-etch Fluoride releasing adhesive	XenoIII	Liquid A: HEMA, Purified Water, EthanolUrethane dimethacrylate resin, BHT, Highly dispersed silicon dioxide Liquid B: Phosphoric acid modified polymethacrylate resin, Mono fluoro phosphazene modified methacrylate resin, UDMA, BHT, Camphorquinone, Ethyl-4-dimethylaminobenzoate pH=0.4	Dentsply Caulk Milford, DE, USA	0505001099
Resin Composite Universal Light curing Nanohybrid resin composite	Grandio	87% w/w (71% volume) inorganic nano-hybrid filler, BisGMA, UDMA, TEGDMA	Voco GmbH Cuxhaven, Germany	620492
Resin Composite Posterior resin composite	Quixfil	86% by weight (66% volume) filler load UDMA, TEGDMA, Di- and trimethacrylate resins Carboxylic acid modified dimethacrylate resin, BHT UV stabilizer Camphorquinone Ethyl-4-dimethylaminobenzoate Silinated strontium aluminum sodium fluoride phosphate silcate glass	Dentsply Caulk Milford, DE, USA	0607001089
HEMA: 2-hydroxyethyl methacrylate; BHT: Butylated hydroxy toluene; TEGDMA: Triethylenglycoldimethacrylate; BisGMA: bisphenol-A-diglycidylether dimethacrylate; UDMA: Urethane dimethacrylate				

Table 2: Distribution of Materials and Tooth Locations of the Restorations

	Maxillary Arch				Mandibular Arch				
Restorative Materials	Premolar		Molar		Premolar		Molar		TOTAL
	Class I	Class II	Class I	Class II	Class I	Class II	Class I	Class II	
Quixfil		14	6	3		7	9	2	41
Grandio		11	8	5		10	3	4	41
TOTAL		25	14	8		17	12	6	
	47				35				

position and restoration class type, in such a way as to minimize the influence of those factors.

All the teeth were treated by one clinician from the research team. The teeth were prepared using conventional instruments and adhesive conservative techniques; appropriate local anesthesia was achieved pre-operatively, unless declined by the patient. Cavity preparation was limited to removal of carious tissue. The average facio-lingual width of the cavities was approximately one-third of the intercusp width. Calcium hydroxide (Dycal, Dentsply Caulk, Milford, DE, USA) was placed, where indicated, for deep cavities. No beveling was performed. The location of the

cervical margins was not recorded. For Class II restorations, the dentists used metal matrix bands (Toefflemire, Teledyne Waterpik Technologies, Newport Beach, CA, USA) and wooden wedges. Saliva isolation was accomplished with cotton rolls and saliva ejectors.

Placement of the 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 using a halogen light with a 500 mW/mm² intensity (Hi-Lux Ultra, Benlioglu, Turkey). The light output of the curing unit was monitored with a light meter (Curing Radiometer Model 100; Demetron Corp, Orange, CA, USA).

A post-occlusal adjustment was performed with carbon paper, and the quality of the interproximal contacts and cervical adaptation was checked by means of dental floss and interproximal radiographs. The restorations were finished under water-cooling with fine and super fine diamond points (KG Finishing Kit, Karensen Ltd, Brazil) and rubber polishing kits (Eveflex Polisher, EVE Ernst Vetter GmbH, Pforzheim, Germany).

Clinical Evaluation

All the restorations were clinically evaluated after one week (baseline) and six months, 12 months and two years by two investigators other than the operator who placed the restorations, using the modified USPHS criteria as first described by Cvar and Ryge¹⁶ and adapted by Wilson and others¹⁷ for retention, color matching, marginal discoloration, marginal adaptation, secondary caries, surface texture, anatomic form and postoperative sensitivity (Table 3). Bitewing radiographs were also taken. The examiners were not involved in placement of the fillings and they were unaware of the materials used in this double-blind study. When disagreement arose during evaluation, the examiners had to reach a consensus. All evaluations were carried out under a dental operating light using flat-surfaced mouth mirrors and dental explorers.

The restorations were scored as follows: Alpha represented the ideal clinical situation; Bravo was clinically acceptable and Charlie represented clinically unacceptable situations where the restoration had to be replaced. For secondary caries detection, bitewing radiographs were also taken at every recall.

Statistical Evaluation

Statistical analysis was performed using the Pearson Chi-square and Fisher's Exact Test for assessing the difference between the restorative materials ($p<.05$). Cochran's Q test was also employed for evaluating the differences between examination recalls of the same restorative material.

RESULTS

Results of the clinical evaluation comparing Quixfil and Grandio direct composite restorations at baseline, six months, 12 months and two-year follow-up with respect to color match, marginal adaptation, secondary caries and surface texture are reported in Table 4. At the end of 12 months, all of the restorations (Grandio or Quixfil) were present and a total of 82 restorations were available for clinical evaluation in 31 patients (Recall rate 100%). However, 74 restorations in 26 patients were

Table 3: Modified USPHS Evaluation Criteria

Retention	Alpha: No loss of restorative material Charlie: Any loss of restorative material
Color Match	Alpha: Matches tooth Bravo: Acceptable mismatch Charlie: Unacceptable mismatch
Marginal Discoloration	Alpha: No discoloration Bravo: Discoloration without Charlie: Discoloration with penetration in pulpal direction
Marginal Adaptation	Alpha: Closely adapted, no visible crevice Bravo: Visible crevice, explorer will penetrate Charlie: Crevice in which dentin is exposed
Secondary Caries	Alpha: No caries present Charlie: Caries present
Surface Texture	Alpha: Enamel-like surface Bravo: Surface rougher than enamel, clinically acceptable Charlie: Surface unacceptably rough
Anatomic Form	Alpha: Continuous Bravo: Slight discontinuity, clinically acceptable Charlie: Discontinuous, failure
Postoperative sensitivity	Alpha: Not present Bravo: Sensitive but diminishing in intensity Charlie: Constant sensitivity, not diminishing in intensity

evaluated at the 24-month recall (Recall rate 83.87%). At the six-month recall, all of the restorations received an Alpha score with respect to each evaluation criteria. None of the restorations presented any marginal discoloration or anatomic form loss until the end of 12 months, and none of the restorations exhibited postoperative sensitivity at any evaluation period.¹⁸

The main difference between the restorative materials (Grandio and Quixfil) at the end of 12 months was not statistically significant, demonstrating acceptable clinical performance. Nevertheless, four Grandio restorations (10%) received Bravo ratings, while 37 restorations (90%) received Alpha ratings for marginal adaptation. This difference was found to be statistically significant ($p=.018$) between baseline and 12-month recalls in terms of marginal adaptation.

At the end of 12 months, two Quixfil restorations had to be replaced due to secondary caries formation. One Grandio restoration had bulk fracture at the two-year recall.

The statistical comparison between the results at baseline and after two years of clinical service yielded a significant increase in deterioration of the surface properties for the Grandio restorations ($p=0.08$; $p<0.05$). When compared with the Quixfil restorations, the difference between Grandio and Quixfil was also statistically significant with respect to surface texture at the two-year recall ($p=0.028$; $p<0.05$). Twenty-six Grandio restorations and 34 Quixfil restorations received an Alpha rating, whereas nine Grandio and one Quixfil

Table 4: Summary of the Clinical Findings of Ryge Criteria at the End of 24 Months

		Color Match			Marginal Adaption			Secondary Caries		Surface Texture			Marginal Discoloration		
Grandio + Futura Bond	n*	A	B	C	A	B	C	A	C	A	B	C	A	B	C
Baseline	41	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)
6 months	41	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)
12 months	41	39(95%)	2(5%)	0(0%)	37(90%)	4(10%)	0(0%)	41(100%)	0(0%)	40(98%)	1(2%)	0(0%)	41(100%)	0(0%)	0(0%)
24 months	35	32(91%)	3(9%)	0(0%)	30(86%)	5(14%)	0(0%)	35(100%)	0(0%)	26(74%)	9(26%)	0(0%)	35(100%)	0(0%)	0(0%)
Quixfil + Xeno III	n*	A	B	C	A	B	C	A	C	A	B	C	A	B	C
Baseline	41	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)
6 months	41	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)
12 months	41	41(100%)	0(0%)	0(0%)	40(98%)	1(2%)	0(0%)	39(95%)	2(5%)	41(100%)	0(0%)	0(0%)	41(100%)	0(0%)	0(0%)
24 months	35	35(100%)	0(0%)	0(0%)	31(87%)	4(13%)	0(0%)	35(100%)	0(0%)	34(97%)	1(3%)	0(0%)	33(94%)	2(6%)	0(0%)

A= Alpha B= Bravo C= Charlie; the numbers in the parenthesis represents the percent value in samples

restoration received Bravo ratings with respect to surface texture.

DISCUSSION

Resin composite technology has undergone major developments over the last two decades. However, these developments have been so rapid that long-term clinical data on specific products are rarely available, because of the regular introduction of “improved” versions. *In vitro* studies might provide useful data regarding the potential performance of a material; however, such tests cannot adequately evaluate the clinical performance of a material or the handling characteristics. In addition, *in vitro* studies cannot answer questions about the *in vivo* longevity of these tooth-colored restorations.¹⁹ However, long-term results with some of these newly developed materials are lacking and remain controversial as studies report inconsistent clinical results.¹⁴⁻¹⁵ The current longitudinal randomized-controlled clinical study investigated the performance of the posterior composite, Quixfil, compared to the nanohybrid resin composite, Grandio, at two years.

While the USPHS system has served well for clinical evaluation, there are some concerns about the sensitivity of the approach in short-term clinical evaluations. The lack of sensitivity of the Ryge system to record small early changes, combined with the continually evolving clinical designs and non-standard investigator modifications of the categories, scales and reporting methods, has created a body of literature that is extremely difficult to meaningfully interpret. In many cases, the relative insensitivity of the Ryge methods during short- and medium-term clinical trials (<3-5 years) may be misinterpreted.²⁰ However, this system is still being used in clinical studies to compare those findings with previous studies that utilize the same system.

The advantages of the rubber dam are well known when performing operative procedures. These benefits

include isolation of the field and potentially improved properties of dental materials. However, in a busy practice, it is often impossible to place a rubber dam. Sometimes, cotton rolls may be the most suitable choice for isolation. Also, Raskin and others reported that there was no significant influence of moisture control on the clinical behavior of posterior resin composites.²¹ Brunthaler and others published a review surveying prospective studies on the clinical performance of posterior resin composites published between 1996 and 2002. The survey focuses on 24 *in vivo* studies, 17 of which utilized rubber dam isolation and three that did not, with four other studies not mentioning the isolation method.²²

In that same review, 16 of the studies evaluated both Class I and II restorations and only eight studies evaluated Class II restorations. However, none of these studies compared Class I and Class II restorations to each other.²² Involving both Class I and Class II restorations in a clinical research design may be challenging when comparing material performance in a follow-up study, such that marginal locations, cavity size, C factors, technical difficulties and amount of enamel available after cavity preparations may also affect the clinical performance of these restorations rather than the material itself. In future studies, it may be better if factors other than those associated with the material are standardized. This means that the results of the studies would be optimized in terms of material properties.

The first six-to-24 months appear to be the critical period for the development of deteriorations.²³ The longevity of dental restorations depends on many factors. In general, early failures, which are encountered after weeks or months, must be distinguished from late failures, which occur after several years of clinical service. Early failures are a result of severe treatment faults, selection of an incorrect indication for the restorative material or postoperative symptoms. Late failures are predominantly caused by fractures, secondary caries and wear or deterioration of the respec-

tive materials.²⁴ Mair²⁵ evaluated posterior composite restorations over a 10-year period. His data documented a wear rate decreasing after the first years.

In the current study, both of these restorative materials were used with their respective self-etch adhesive systems and demonstrated acceptable clinical performance after two years. These successful findings might be related to the relatively short- or medium-term evaluation period, which is consistent with many studies in which there were no significant differences between composite materials in early evaluation periods.²⁶⁻²⁷ The bonding of the two restorative materials was sufficient to provide adequate retention over 12 months and none of the restorations were lost. However, two Quixfil restorations failed after 12 months due to secondary caries, and these restorations were replaced.

Postoperative sensitivity seemed to be a problem related to resin composite restorations. Many studies²⁸⁻²⁹ have indicated that up to 30% of the study populations have reported postoperative sensitivity following placement of a posterior resin restoration. Self-etch primers make the smear layer part of the hybrid layer, as it dissolves the smear layer, incorporating it into the mixture of collagen fibers and resin monomers. Since the smear layer becomes an integral part of the hybrid layer, a low sensitivity response may be the outcome, which was also seen in the current study.³⁰

In regard to the clinical performance of self-etch systems, the literature contains contradictory findings, as the bonding effectiveness of these adhesives seems to be material dependent.³¹⁻³² Many self-etch systems are available on the market. They differ, among other factors, in the number of bottles, steps and acidity of the primer solution. A closer analysis of the aforementioned clinical trials³¹⁻³² reveals that self etching adhesives with good clinical performance did not belong to the group of "strong" self-etching adhesives. Instead, they belong to the group of "mild" self-etching adhesives. The pH of Futurabond NR and Xeno III is 1.4 for both, which places them in the same group.

The loss of marginal adaptation and the presence of secondary caries are predictors of the failure of posterior resin-based composites and the reason for the replacement of the restoration.²⁸ The current study revealed that two Quixfil restorations had to be replaced due to secondary caries at the 12-month recall. According to Mjör³³ and Saleh,³⁴ development of secondary caries is not only due to the material itself. Clinical environment, caries experience of patients, criteria for replacements and different handling characteristics appeared to affect clinical results. Additionally, Bernardo and others³⁵ reported that the overall risk of failure due to secondary caries was 3.5 times higher in composite restorations than in amalgam restorations.

Grandio restorations presented 10% and 14% Bravo scores between baseline and 12 to 24 months in terms of marginal adaptation, respectively, which is statistically significant. Kramer and others³⁶ found that Grandio showed 17% Bravo scores after the one-year clinical evaluation period in terms of marginal adaptation; this was in agreement with the current results. However, previous studies demonstrated that evaluation of the composites during the initial periods of evaluation depicted minor changes when compared to the baseline.³⁷⁻³⁸ However, these are only results of the Alpha-Bravo shifts, meaning that all composite restorations were still clinically acceptable and functional.

Marginal adaptation is directly influenced by the type of resin composite used.³⁹ Altering the amount and quality of the filler particles can change the esthetics and mechanical properties of restorative resin composites. Furthermore, lowering a material's viscosity by modifying the composition of the monomer system permits a higher filler load while also improving the handling properties.⁴⁰ Grandio has a filler degree of 87% w/w (71% volume) by combining spherical nanoparticles; whereas Quixfil has a filler degree of 86% by weight (66% volume) filler load, which is approximately the same.

In a previous study, Manhart and others⁴¹ evaluated the clinical performance of Quixfil for 18 months and found a significant increase in marginal discoloration with time. The three-year results of the same clinical study also demonstrated 15% marginal discoloration.⁷ While marginal defects were observed for both materials in the current study, none of the restorations showed marginal discoloration. Many of these marginal defects appeared to result from fracture of thin flashes of the resin composite material extended onto non-instrumented enamel surfaces adjacent to the cavity margins. The use of phosphoric acid etching⁴² and aggressive self-etch adhesives⁴³ may reduce the occurrence of such defects, especially in high stress-bearing areas, because of the improved enamel etching.⁴² In accordance with the current results, Abdalla and García-Godoy⁴⁴ evaluated the clinical performance of FuturaBond NR in Class V lesions and reported less deterioration in regard to marginal adaptation and marginal discoloration when an adhesive resin was applied following enamel etching.

In the current study, both of the restorative materials demonstrated acceptable color stability and surface texture. At the one-year recall, the majority of scores were Alpha. Bravo scores were recorded for only two Grandio restorations for color stability and one Grandio restoration for surface texture. However, it has been reported that changes in the surface texture and color stability of resin composite restorations could increase after one year.⁴⁵⁻⁴⁶ Likewise, the two-year results

demonstrated a statistically-increased surface texture deterioration in Grandio restorations.

It is well known that materials with rough surfaces enhance bacterial adhesion and decrease stain resistance.⁴⁷⁻⁴⁸ However, there is no positive correlation between wear and surface roughness.⁴⁹ Yazici and others documented that Grandio showed the highest roughness values when compared with a flowable, a hybrid and a polyacid modified composite, *in vitro*.⁵⁰ In clinical studies with a split-mouth design, no differences in surface roughness/texture could be found for extended Class II restorations made with Tetric Ceram and Grandio after four years of observation.³⁶ However, Heintze and others emphasized that Grandio suffered micromorphological changes due to a disintegration of the matrix and exposure of filler particles, *in vitro*.⁵¹

Grandio has a greater available range of color shades and was expected to have better color-matching ability for this material. Although Quixfil was available in one universal shade, none of the restorations showed Bravo scores at baseline. Good color match results might be related to a chameleon effect of Quixfil, blending into the tooth structure around the restoration.

Posterior composite material in the current study was found to be comparable, but not superior to the nanohybrid resin composite. Therefore, the hypothesis that differences in the composition of restorative systems had an influence on the clinical outcome was rejected. It should be noted that the time frame for this study was not of such duration as to indicate the long-term suitability of the tested materials, but it may provide an indication for detecting material-related initial clinical performance. Clinical evaluation longer than two years is necessary to make valid conclusions.

CONCLUSIONS

It was concluded that nanohybrid (Grandio) and low-shrinkage posterior composite (Quixfil) restorations demonstrated acceptable clinical performance after 24 months.

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