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Clinical Evaluation of Resin-Based Composites in Posterior Restorations: A 3-Year Study

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Key Words
Resin composite · United States Public Health Service criteria · Clinical follow-up · Posterior restoration

Abstract
Objectives: The aim of this study was to evaluate the clinical performance of a nanohybrid and a microhybrid composite in class I and II restorations after 3 years. ***Subjects and Methods:*** A total of 82 class I and class II restorations were performed in 31 patients (10 males and 21 females) using Grandio and QuiXfil with self-etch adhesives (Futurabond and Xeno III). The restorations were clinically evaluated by 2 operators 1 week after placement (baseline) and at 6 months and 1, 2, and 3 years using modified United States Public Health Service (USPHS) criteria. At the 3-year follow-up, 62 class I and class II cavities were reevaluated in 23 patients (7 males and 16 females). Statistical analysis was performed using Pearson's χ^2 and Fisher's exact tests ($p < 0.05$). ***Results:*** At the 6-month follow-up, all restorations received Alfa scores with respect to each evaluation criterion. At the 1-year follow-up, 2 QuiXfil restorations had to be replaced and Grandio restorations started to deteriorate in terms of marginal adaptation. At the end of 2 years, 9 Grandio restorations showed significant deterioration of the surface properties, demonstrating Bravo scores. At the end of 3 years, no significant differences were observed regarding color match, marginal adaptation, secondary caries, marginal discoloration, and anatomic form loss between the evaluated materials in 25 class I and 37 class II restorations. At the 3-year follow-up, Grandio restorations had 21% Bravo scores and showed significant deterioration of the surface properties, which were still clinically acceptable according to USPHS criteria. Three QuiXfil and 1 Grandio restorations were replaced because of secondary caries and loss of retention. ***Conclusions:*** Both the nanohybrid (Grandio) and the microhybrid (QuiXfil) composites were clinically functional after 3 years.

Introduction

Over the past decades, patient demand for tooth-colored restorations and the need to find alternatives to amalgam have accounted for the increased use of resin composite materials for posterior restorations [1]. Nowadays, resin composite is considered a suitable direct posterior filling material that has shown acceptable survival in clinical studies [2]. However, considerable differences in properties exist among commercial composites, e.g. in

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Table 1. Material descriptions, batch numbers, and manufacturers of the materials used in this study

Material description	Material	Chemical composition	Manufacturer	Lot No.
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, Germany	610456
Dentin-bonding agent: single-step self-etch fluoride-releasing adhesive	Xeno III	Liquid A: HEMA, purified water, ethanol urethane dimethacrylate resin, BHT, highly dispersed silicon dioxide Liquid B: phosphoric acid-modified polymethacrylate resin, monofluorophosphazene-modified methacrylate resin, UDMA, BHT, camphorquinone, ethyl-4-dimethylaminobenzoate pH = 1.4	Dentsply Caulk, Germany	0505001099
Resin composite: universal light-curing nanohybrid resin composite	Grandio	87% w/w (71% volume) inorganic nanohybrid filler, BisGMA, UDMA, TEGDMA	Voco GmbH, 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 silicate glass	Dentsply Caulk, Germany	0607001089

BHT = Butylated hydroxy toluene; BisGMA = bisphenol-A-diglycidylether dimethacrylate; HEMA = 2-hydroxyethyl methacrylate; TEGDMA = triethylenglycoldimethacryate; UDMA = urethane dimethacrylate.

terms of the filler loading level, particle morphology, and size [3]. Based on filler features, resin composites are currently classified as nanofilled, microfilled, or micro-/nanohybrid materials, with filler mass fractions varying from 42 to 85% [3]. Research and development of resin-based composites during the last decade generated different subcategories of restorative materials that include composites containing nano-sized filler particles [4, 5]. These materials are claimed to offer reduced polymerization contraction, enhanced mechanical properties, and improved esthetics [4, 5]. Nanofill composites are formulated with both nanomer and nanocluster filler particles, while nanohybrid composites are hybrid resin composites containing finely ground glass filler and nanofiller in a prepolymerized filler form [4, 5].

Recently, a new posterior microhybrid composite material, QuiXfil (Dentsply DeTrey, Konstanz, Germany), was introduced into the dental market [6]. The bimodal filler technology of QuiXfil has a particle distribution with two distinct peaks at 0.8 and 10 μm and polymerization shrinkage is stated as 1.7 vol% by the manufacturer; in a longitudinal randomized clinical assessment of stress-bearing class I and II restorations, it was claimed that QuiXfil exhibited good clinical results for up to 4 years [6].

The potential performance of a restorative material might be estimated by in vitro laboratory tests; however, clinical studies are important to predict the longevity of a material in oral conditions [7, 8]. Scientific data from clinical studies are required to determine the long-term performance of resin composites in posterior teeth and to estimate the risk for the patient. However, long-term results for some of these newly developed materials are lacking and remain controversial as studies have reported inconsistent clinical findings [9]. Hence, the purpose of the present study was to evaluate the 3-year clinical performance of a nanohybrid (Grandio) and a microhybrid (QuiXfil) composite in class I and II restorations. The null hypothesis tested that material properties had no influence on the clinical performance of the restorative systems.

Subjects and Methods

Subjects and Operative Procedures

Thirty-one patients (10 males and 21 females) who required at least 1 pair of class I or class II restorations to be filled with either nanohybrid or microhybrid restorative materials participated in this study. Twenty-four patients received 1 pair of restorations; 4 received 2 pairs, and 3 received 3 pairs. The patients' ages ranged

Table 2. Distribution of materials and tooth locations of the restorations at baseline

Restorative materials	Maxillary arch				Mandibular arch				Total
	premolar		molar		premolar		molar		
	class I	class II	class I	class II	class I	class II	class I	class II	
Grandio	–	11	8	5	–	10	3	4	41
QuiXfil	–	14	6	3	–	7	9	2	41
Subtotal	–	25	14	8	–	17	12	6	
Total	47				35				82

from 16 to 60 years. Inclusion criteria were: permanent premolars and molars that required class I or II restorations for the treatment of primary carious lesions with at least one neighboring tooth and in occlusion with antagonistic teeth. General exclusion criteria were: poor oral hygiene, severe or chronic periodontitis, heavy bruxism, and a known allergic reaction to any of the components of the materials used. Specific exclusion criteria were: a pathologic pulpal diagnosis with pain (nonvital), fractured or visibly cracked teeth, defective restorations adjacent to or opposite the tooth, rampant caries, and atypical extrinsic staining of teeth.

The patients were selected from the Department of Conservative Dentistry, Dental Clinics, School of Dentistry, Baskent University. The protocol was approved by the Baskent University Ethics Committee on Investigations Involving Human Subjects. Written informed consent was obtained from each participant prior to treatment.

At baseline, a total of 82 teeth (41 pairs) were restored with either the nanohybrid resin composite Grandio (n = 41) (Voco GmbH, Germany) and its self-etch adhesive Futurabond NR (Voco) or with the microhybrid resin composite QuiXfil (n = 41) (Dentsply De Trey, Konstanz, Germany) and its self-etch adhesive Xeno III (Dentsply, Germany) according to manufacturers' instructions (table 1). The distribution of materials and tooth locations was randomized by tossing a coin (table 2). However, interference in the randomization procedure within patients was performed in order to equally distribute the materials among important variables such as tooth type and position and restoration class type in a way that minimized the influence of those factors [10].

All teeth were treated by one dentist (K.Y.) of the research team. The teeth were prepared using conventional instruments and adhesive conservative techniques. Appropriate local anesthesia was achieved preoperatively unless declined by the patient. Cavity preparation was limited to the removal of carious tissue. The cavities were prepared on each tooth using a high-speed hand piece with air/water spray. A new bur (835R-012-4 ML; Diatech, Coltene/Whaledent AG, Switzerland) was used for every 5 teeth. The average faciolingual width of the cavities was approximately one third of the intercuspal width. Calcium hydroxide (Dycal; Dentsply De Trey) was placed where indicated for deep cavities. No beveling was performed. The location of the cervical margins was not recorded. For class II restorations, a Tofflemire retainer (Teledyne Waterpik Technologies, USA) with a steel matrix band and a wooden wedge was used to reestablish the anatomical shape and the proximal contacts of the teeth. Saliva isolation was accomplished using cotton rolls and saliva ejectors.

The 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 using a halogen light with an intensity of 500 mW/mm^2 (Hilux Ultra; Benlioglu, Turkey). The light output of the curing unit was monitored with a light meter (curing radiometer model 100; Demetron Corp., USA)

Postocclusal adjustment was made 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 during the same appointment immediately after the restorative procedures (Eveflex Polisher; EVE Ernst Vetter GmbH, Germany).

Clinical Evaluation

All restorations were clinically evaluated after 1 week (baseline), 6 months, and 1, 2, and 3 years by 2 investigators (C.C., N.A.) who were not the operator who placed the restorations. The modified United States Public Health Service (USPHS) criteria for retention, color matching, marginal discoloration, marginal adaptation, secondary caries, surface texture, anatomic form, and postoperative sensitivity were used (table 3). Bitewing radiographs were also taken. The examiners (C.C. and N.A.) were not involved in the placement of the fillings and were also unaware of the materials used in this double-blind study. Prior to the investigation, both examiners were calibrated to 100% agreement on 10 patients not included in this study. In the event of disagreement, a decision was reached by consensus. All evaluations were carried out under a dental operating light using flat-surfaced mouth mirrors and dental explorers.

Restorations were scored as follows: Alfa: the ideal clinical situation; Bravo: a clinically acceptable situation, and Charlie: a clinically unacceptable situation in which case the restoration had to be replaced. For secondary caries detection, bitewing radiographs were also taken at every follow-up.

At the end of 3 years, all patients received notification letters and phone calls for the 3-year evaluation appointment multiple times; unfortunately, 4 patients did not attend their appointment because they were performing military service and moving to another city and the authors also could not communicate with 2 of

Table 3. Modified USPHS evaluation criteria

Retention	Alfa: no loss of restorative material Charlie: any loss of restorative material
Color match	Alfa: match with the tooth Bravo: acceptable mismatch Charlie: unacceptable mismatch
Marginal discoloration	Alfa: no discoloration Bravo: discoloration without penetration in the pulpal direction Charlie: discoloration with penetration in the pulpal direction
Marginal adaptation	Alfa: closely adapted, no visible crevice Bravo: visible crevice, explorer will penetrate Charlie: crevice in which dentin is exposed
Secondary caries	Alfa: no caries present Charlie: caries present
Surface texture	Alfa: enamel-like surface Bravo: surface is rougher than the enamel, clinically acceptable Charlie: unacceptably rough surface
Anatomic form	Alfa: continuous Bravo: slightly discontinuous, clinically acceptable Charlie: discontinuous, failure
Postoperative sensitivity	Alfa: not present Bravo: sensitivity with diminishing intensity Charlie: constant sensitivity without diminishing intensity

the patients because they did not update their contact addresses (thus, a total of 10 patients were dropped from baseline). The resultant number of patients was 31, and a total of 62 restorations were evaluated after 3 years.

Statistical Analysis

Statistical analysis of the restorations was performed using Pearson's χ^2 and Fisher's exact tests to assess differences between the restorative materials ($p < 0.05$). Cochran's Q test was also used to evaluate differences between examination recalls of the same restorative material.

Results

At the 3-year follow-up, because 10 patients (20 teeth) had dropped out, the recall rate was 74.2% (table 4). One pair of restorations was evaluated in 18 patients, 2 pairs were evaluated in 2 patients, and 3 pairs were evaluated in 3 patients. The results of the clinical evaluation comparing QuiXfil and Grandio direct composite restorations at baseline, 6 months, and 1, 2, and 3 years of follow-up are reported in table 5.

At the 6-month follow-up, all restorations received Alfa scores with respect to each evaluation criterion. None of the restorations showed any marginal discoloration or anatomic form loss, and no restorations exhibited postoperative sensitivity until the end of 1 year. Nevertheless, 4 Grandio restorations received Bravo ratings while 37 restorations received Alfa ratings for marginal adaptation. This difference was found to be statistically significant ($p < 0.05$) between baseline and the 1-year follow-up in terms of marginal adaptation. At the end of 1 year, 2 QuiXfil restorations had to be replaced because of secondary caries formation.

After 2 years, no significant differences were observed with respect to color match, marginal adaptation, secondary caries, and surface texture. One Grandio restoration had a bulk fracture at the 2-year follow-up and received a Charlie score. Data demonstrated that 9 Grandio restorations showed significant deterioration of the surface properties, demonstrating Bravo scores, which are still clinically acceptable.

The statistical comparison between the results at baseline and after 3 years of clinical service showed a significant increase in deterioration of the surface texture ($p < 0.05$) for Grandio restorations. The difference between Grandio and QuiXfil was also statistically significant with respect to the surface texture parameter at the 3-year follow-up ($p < 0.05$). Twenty-one Grandio restorations and 28 QuiXfil restorations received Alfa ratings, whereas 10 Grandio and 3 QuiXfil restorations received Bravo ratings with respect to the surface texture parameter. At the end of 3 years, 1 QuiXfil restoration received a Charlie score because of secondary caries.

Overall, after 3 years, 3 QuiXfil restorations and 1 Grandio restoration were replaced because of secondary caries and loss of retention.

Discussion

Clinical assessment of the Grandio and QuiXfil materials in class I and II restorations revealed good clinical data, with predominantly Alfa scores after 3 years of clinical service. Although the overall scores corresponded to clinically acceptable conditions, when each USPHS criterion was further investigated there were some minor divergences from excellent restoration.

A loss of marginal integrity was observed for QuiXfil in our study at the 3-year follow-up, as Grandio restora-

Table 4. Distribution of materials and tooth locations of the restorations after 3 years

Restorative materials	Maxillar arch				Mandibular arch				Total
	premolar		molar		premolar		molar		
	class I	class II	class I	class II	class I	class II	class I	class II	
Grandio	–	10	8	2	–	5	3	3	31
QuiXfil	–	12	5	2	–	3	9	0	31
Subtotal	–	22	13	4	–	8	12	3	
Total	39				23				62

Table 5. Summary of the clinical findings of the modified USPHS criteria at the end of 3 years

	Baseline		6 months		1 year		2 years		3 years	
	Grandio (n = 41)	QuiXfil (n = 41)	Grandio (n = 41)	QuiXfil (n = 41)	Grandio (n = 41)	QuiXfil (n = 41)	Grandio (n = 35)	QuiXfil (n = 35)	Grandio (n = 31)	QuiXfil (n = 31)
Retention										
A	41	41	41	41	41	41	34	35	31	31
C	0	0	0	0	0	0	1	0	0	0
Color match										
A	41	41	41	41	39	41	32	35	28	31
B	0	0	0	0	2	0	3	0	3	0
C	0	0	0	0	0	0	0	0	0	0
Marginal discoloration										
A	41	41	41	41	41	41	35	33	30	28
B	0	0	0	0	0	0	0	2	1	3
C	0	0	0	0	0	0	0	0	0	0
Marginal adaptation										
A	41	41	41	41	37	40	30	31	26	27
B	0	0	0	0	4	1	5	4	5	4
C	0	0	0	0	0	0	0	0	0	0
Secondary caries										
A	41	41	41	41	41	39	35	35	31	30
C	0	0	0	0	0	2	0	0	0	1
Surface texture										
A	41	41	41	41	40	41	26	34	21	30
B	0	0	0	0	1	0	9	1	10	1
C	0	0	0	0	0	0	0	0	0	0
Anatomic form										
A	41	41	41	41	41	41	35	35	31	30
B	0	0	0	0	0	0	0	0	0	1
C	0	0	0	0	0	0	0	0	0	0
Postoperative sensitivity										
A	41	41	41	41	41	41	35	35	31	31
B	0	0	0	0	0	0	0	0	0	0
C	0	0	0	0	0	0	0	0	0	0

tions were slightly better than QuiXfil restorations. This difference could be due to the type of composite resin used, as previously reported [11]. Equally important, a loss of marginal integrity could have been caused at baseline by polymerization shrinkage or faulty adaptation of the restorative material to the cavity walls, and Bravo scores were caused by marginal openings due to adhesive failures during clinical service [6]. Many of these mar-

ginal defects appeared to result from the fracture of thin flashes of resin composite material extended on noninstrumented enamel surfaces adjacent to the cavity margins. Altering the amount and quality of the filler particles can change the esthetics and mechanical properties of restorative composite resins. Furthermore, lowering a material's viscosity by modifying the composition of the monomer system permits a higher filler load and at the same time improves the handling properties [12].

With regard to marginal discoloration criteria, the majority of the scores were Alfa. However, the relative low incidence of Bravo scores for both restorative materials may be attributed to the lack of not employment of phosphoric acid etching. Likewise, the 3-year results of another clinical study also demonstrated a 15% marginal discoloration for QuiXfil [13]. The use of phosphoric acid etching and aggressive self-etch adhesives may reduce the occurrence of such defects, especially in high-stress-bearing areas, because of the improved enamel etching [14]. With 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 [15, 16]. A more thorough analysis of the aforementioned clinical trials revealed that the self-etching adhesive with good clinical performance did not belong to the group of 'strong' self-etching adhesives but rather belonged to the group of 'mild' self-etching adhesives [15, 16]. Futurabond NR and Xeno III both have a pH of 1.4, belonging to the mild group.

The long-term performance of a restoration may also depend on the hydrophilicity and solvent type of the adhesive system used under the restorative material [17]. These parameters may promote degradation of the bond, leading to further marginal discoloration and secondary caries. Futurabond is a one-step self-etching adhesive consisting of organic acid combined with hydrophobic monomers and HEMA, all dissolved in acetone. The acetone solvent present in the Futurabond adhesive is an excellent 'water chaser', capable of avoiding residual water in dentin during its application [18]. Osorio et al. [19] demonstrated that self-etching adhesives with a pH <1 and containing water or acetone as a solvent yielded a catastrophic bond failure after 1 year of water storage [19]. Xeno III presented signs of degradation, which was plausibly triggered by hydrophilic components such as HEMA [17].

Though not statistically significant, this study revealed that 2 QuiXfil restorations had to be replaced due to secondary caries at the 1-year follow-up and 1 QuiXfil restoration had to be replaced after 3 years in separate patients. These replacements were probably done because secondary caries, fractures, and wear or deterioration of a restoration are predictors of failure of posterior resin-based composites. However, Demarco et al. [9] reported that the development of secondary caries is due not only to the material itself but also to the clinical environment; the caries experience of the patient and different handling characteristics could also affect the clinical results. Additionally, Bernardo et al. [20] 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 started presenting surface deteriorations at the 1-year follow-up in an accelerated manner until the 3-year follow-up, and the 3-year results showed a statistically increased surface texture deterioration, thereby confirming a previous report [21]. Yazici et al. [22] documented that Grandio showed the highest roughness values, which may represent rough surfaces enhancing bacterial adhesion and a decreased stain resistance compared to a flowable, a hybrid, and a polyacid modified composite in vitro. Likewise, Janus et al. [23] also reported that glass fillers of irregular forms found in Grandio protruding from the surface could explain its higher roughness values. In a clinical study with a split-mouth design, no differences in surface roughness/texture could be found for extended class II materials made with Tetric Ceram and Grandio after 4 years of observation [24]. However, Heintze et al. [25] emphasized that Grandio suffered micromorphological changes due to disintegration of the matrix and the exposure of filler particles in vitro.

Although Grandio had a greater range of available color shades, QuiXfil was available in one universal shade and none of the restorations showed Bravo scores at baseline. Good color match results might be related to the chameleon effect of QuiXfil, which blends into the tooth structure around the restoration [26]. Additionally, at the 3-year evaluation, both of the restorative materials demonstrated good color stability, except for 3 Grandio restorations scored as Bravo. The greater surface texture deterioration of Grandio may explain this result in our study.

In the current study, rubber dam isolation was not used during placement of the restorations, although it is a recommended procedure. Use of a cotton roll was preferred as it is the most suitable choice for isolation in a busy practice. Also, Raskin et al. [27] reported that there was no significant influence of moisture control on the clinical behavior of posterior resin composites. Bruntha-

ler et al. [28] published a review which is a survey of prospective studies on the clinical performance of posterior resin composites published between 1996 and 2002. The survey focused on 24 in vivo research studies. Seventeen of them utilized rubber dam isolation and 3 of them did not, and 4 other research studies included no mention of the isolation method [28].

In the present study, the microhybrid posterior composite material was found to be comparable but not superior to the nanohybrid resin composite. Therefore, we could accept the hypothesis that differences in the composition of the restorative systems had no influence on the clinical outcome, but they may provide an indication of their future performance.

Conclusion

This study showed that a nanohybrid (Grandio) and a microhybrid low-shrinkage posterior composite (QuiXfil) demonstrated acceptable clinical performances at a 3-year evaluation.

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