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ORIGINAL ARTICLE

Three-year results of a randomized controlled clinical trial of the posterior composite QuiXfil in class I and II cavities

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Abstract This longitudinal randomized controlled clinical trial evaluated direct composite restorations for clinical acceptability as posterior restoratives in single- or multi-surface cavities and provides a survey of the 3-year results. Three dentists placed 46 QuiXfil (Xeno III) and 50 Tetric Ceram (Syntac Classic) composite restorations in stress-bearing class I and II cavities in first or second molars (43 adult patients). Clinical evaluation was performed at baseline and after 3 years by two other dentists using modified US Public Health Service criteria. At the last recall period, 40 QuiXfil and 46 Tetric Ceram restorations were assessed. A total of 92.5% of QuiXfil and 97.8% of Tetric Ceram posterior composites were assessed to be clinically excellent or acceptable with predominating alpha scores. Up to the 3-year recall, three QuiXfil restorations failed because of bulk fracture, partial tooth fracture, and postoperative symptoms. One Tetric Ceram restoration was lost due to problems with tooth integrity. No significant differences between both composites could be detected at 3 years for all evaluated clinical criteria ($p>0.05$). The comparison of restoration performance with time within both groups yielded a significant increase in marginal discoloration ($p=0.007$) and deterioration of marginal integrity ($p=0.029$) for QuiXfil and significant increase in marginal discoloration ($p=0.009$) for Tetric Ceram. However, both changes were mainly effects of scoring shifts from alpha to bravo. Clinical assessment of stress-bearing QuiXfil and Tetric Ceram posterior composite restorations exhibited for both materials good clinical results with predominating alpha scores.

Keywords Composite · Molars · Clinical study · Longevity · USPHS criteria

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Introduction

The demand for direct placement esthetic restorations, even in posterior teeth, is still increasing. Patients refuse amalgam restorations mostly because of alleged adverse health effects and unaesthetic appearance. Even cast gold inlays and onlays are, despite excellent material properties and biocompatibility, more and more often declined because of esthetic considerations [14]. In return to the decreasing use of metallic conservative restorations, the frequency of direct resin-based restorations in the heavy loaded posterior region is rising.

Insufficient wear resistance resulting in loss of anatomic form and interproximal contacts with general degradation were the main problems of direct composite restorations in the 1970s and early 1980s of the last century [20]. Improvements in the filler technology and formulation of composite materials have resulted in changes in reasons for restoration replacement, let alone the increasing trend to insert composite restorations in stress-bearing areas of posterior teeth. Marginal opening with secondary caries, fracture of the restorations, marginal deterioration, and discoloration are now the principal modes of failure and reasons for limitations in the longevity of resin-based composites [1, 9, 17, 28, 29, 39].

For the restoration of class I and II lesions in posterior teeth, along with universal use hybrid composites, specially designed packable composites were introduced to meet the requirements of private practitioners for materials which should be manipulated in a more cost-effective way [19]. However, the expectations which were linked to packable composites, such as easier achievement of tight physiological proximal contacts, increase of polymerization depth, sculptability, use of metal matrix bands, etc., could either not be fulfilled or technical handling and material properties are as with regular hybrid composites [4, 5, 26]. Microfilled composites are not considered to be an adequate restorative material for heavily loaded posterior teeth; they show more fracture-related failures, especially in high-stress class II cavities, compared with hybrid composites because of their inferior mechanical properties [13].

To meet the needs of private practitioners with respect to a composite material that can be placed in posterior cavities in an economical and faster treatment technique compared to traditional hybrid composites which are placed in 2-mm increments, QuiXfil composite (Dentsply DeTrey, Konstanz, Germany) in combination with the self-etching adhesive system Xeno III (Dentsply DeTrey, Konstanz, Germany) was introduced. This 86 wt.%-filled composite is available only in one translucent shade that allows curing 4-mm material depth in 10 s with a polymerization light of minimum 800 mW/cm^2 intensity [32]. The bimodal filler technology shows a particle distribution with two distinct peaks at 0.8 and 10 µm. Shrinkage is stated 1.7 vol.% by the manufacturer. In vitro investigations concerning marginal adaptation and micro-leakage exhibited results comparable to well-established hybrid composites and respective adhesives [3, 8, 16, 24, 27].

The aim of this ongoing longitudinal randomized controlled clinical study on composite restorations was to provide a survey on the in vivo results of QuiXfil restorations in permanent molars up to 3 years compared to restorations made of Tetric Ceram (Vivadent, Schaan, FL, USA). It should be determined whether this new posterior composite showed a clinical acceptance rate comparable to a traditional hybrid composite material using the modified US Public Health Service (USPHS) scoring system.

Materials and methods

Placement of the restorations

Three dentists, experienced in adhesive restorations, placed 46 QuiXfil composite restorations in combination with the self-etching adhesive Xeno III and 50 Tetric Ceram composite restorations bonded with the etch and rinse adhesive Syntac Classic (Vivadent) in a total of 43 adults according to the manufacturers' instructions. The clinical investigation was approved by an Ethics Committee, and each patient gave written consent to participate in the study prior to treatment. Patients receiving more than one restoration received at least one restoration each with the test and the control material. A maximum of two restorations of each type were inserted into one individual. The two restorative materials were allocated to the teeth using a random design using sealed envelopes, indicating either "test group" or "control material" [15]. Only first or second molars with single (class I) and multi-surface (class II) cavities and existing antagonistic teeth that had to be treated either due to the presence of primary caries or because of the replacement of failed restorations were included in the study. Detailed inclusion and exclusion criteria for patients or teeth are as follows:

Inclusion:

- Male and female individuals at least 18 years old;
- Written consent of patients to participate in the clinical study;
- Patients with a high level of oral hygiene;
- Permanent first or second molars with restorative treatment need, with at least one neighboring tooth and being in occlusion to antagonistic teeth;
- Teeth with positive reaction to cold thermal stimulus; and
- Isthmus size of the treated cavities at least one third of the intercuspal distance.

Exclusion:

- Patients suffering from severe systemic diseases or allergies;
- Teeth with periodontal problems;
- Non-vital teeth;
- Teeth with identifiable pulpal inflammation or pain before treatment;
- Teeth formerly or now subjected to direct pulp capping; and
- Teeth with initial defects only.

Immediately prior to each restorative treatment, the patients were interviewed to determine whether the selected teeth have been giving symptoms of former hypersensitivity. Local anesthesia was used during treatment for all patients. Teeth were cleaned first with a fluoride-free prophylaxis paste and a rubber cup. All cavities were prepared with 80-µm diamond burs and finished with 25-µm grit diamond burs (Intensiv, Viganello-Lugano, Switzerland) according to common principles for direct placement adhesive restorations. Internal line and point angles were rounded and enamel margins were prepared butt-joint. Preparation was limited to the removal of decay, preserving a maximum of sound tooth structure. Enamel not supported by dentin was preserved. Only loose enamel

Table 1 Number (n) and size of evaluated direct composite restorations at the 3-year recall

	n (%)	One-surface restorations	Two-surface restorations	Three-surface restorations	Four-surface restorations
QuiXfil	40	7	19	10	4
Tetric Ceram	46	6	23	7	10

prisms were removed with finishing diamond burs. After caries removal and cavity preparation, teeth were reassessed for their continued suitability for inclusion in the trial. No liners or bases were placed; cases requiring direct pulp capping were excluded. Rubber dam was used in cases where isolation and contamination control (blood, saliva, and sulcular fluid) with suction device and cotton rolls was not considered sufficient. Cavities were limited with metal matrix bands and wooden wedges if appropriate.

Teeth restored with QuiXfil were not separately acid-etched but treated with the self-etching adhesive Xeno III. Equal amounts of liquids A and B were dispensed in a dappen dish and mixed thoroughly with a microbrush for 5 s. The activated adhesive was applied in ample amounts on enamel and dentin of the cavities (total bond) and rubbed in for at least 20 s. The solvent was evaporated with oil-free compressed air and the adhesive was light-cured for 10 s. QuiXfil composite was applied incrementally into the defects according to the manufacturer's recommendations. Each layer was light-cured separately for 10 s with a polymerization light (Elipar Highlight, 3M Espe, Seefeld, Germany) monitored at a minimum of 800 mW/cm^2 intensity.

Control cavities restored with Tetric Ceram were conditioned (total etch) with 37% phosphoric acid, enamel for approximately 30 s and dentin for a maximum of 15 s, thoroughly rinsed with water spray, followed by slightly drying the cavities with oil-free compressed air. Care was taken to avoid desiccation of the dentin, which would result in compromised bonding. Syntac Classic was applied according to the manufacturer's instructions (etch and rinse procedure on enamel and dentin) before Tetric Ceram was inserted incrementally into the cavities and light-cured.

All inserted restorations were finished with fine-grit diamond burs, polishing disks and strips (Sof-Lex, 3M, St. Paul, MN, USA), and a composite polishing kit (Enhance, Dentsply, Milford, DE, USA). High-gloss polishing was achieved with Prismagloss composite polishing paste (Dentsply) applied with a foam cup.

Evaluation of the restorations

The clinical status of the test teeth was recorded prior to restoration placement by the dentists placing the restorations. At baseline (14 days after treatment), at 3, 6, and 18 months, and at 3 years, the test teeth and the composite restorations were rated independently with mirror and probe by two other experienced dentists who were not involved with the insertion of the direct composite restorations. To eliminate bias, the assessment was done in a half-blind design where the two dentists had no preliminary information about the type of restoration they examined. At the 3-year recall, 38 of 43 patients with 40 QuiXfil restorations (87%) and 46 Tetric Ceram restorations (92%) could be evaluated (Table 1). Missing restorations were primarily caused by patient dropout, while one QuiXfil restoration had to be removed at the 18-month recall. This failed restoration is included in the number of 40 rated restorations. The criteria listed in Table 2 were assessed using modified USPHS criteria for the direct evaluation of the adhesive technique [18, 34, 37, 38]. This assessment resulted in ordinally structured data for the outcome variables (alpha=excellent result; bravo=acceptable result; charlie=replacement of the restoration for prevention; delta=unacceptable, replacement immediately necessary). When there was disagreement during an evaluation, the ultimate decision was made by forced consensus of the two examiners [7, 36]. The rating dentists were calibrated before the study by a joint examination of 20 direct composite restorations (Cohen's κ>0.65). Color photographs with marked occlusal contact points were taken [38].

Statistical evaluation

Statistical analysis was performed with the SPSS software (version 14, SPSS, Chicago, IL, USA). Inter-examiner reliability was determined by calculating Cohen's kappa

Table 2 Criteria and methods for the direct evaluation of the restorations

Criterion	Methods of evaluation
Surface texture	Visual and probe
Color match/Change of restoration color	Visual
Anatomic form of the complete surface	Visual and probe
Anatomic form at the marginal step	Visual and probe
Marginal integrity	Visual and probe
Discoloration of the margin	Visual
Integrity of the tooth	Visual and probe
Integrity of the restoration	Visual and probe
Occlusion	Visual (articulating paper)
Testing of sensitivity	Thermal testing (CO_2 ice)
Postoperative symptoms	Interviewing the patient
Patients' compliance	Interviewing the patient

value, which measures agreement between the evaluations of two raters when both are rating the same object [31]. Because the assessment of the restorations yielded clearly ordinal structured data, only nonparametric statistical procedures were used (α=0.05). The Mann–Whitney *U* test was used to explore significant differences of the 3-year results between both types of direct composite restorations for the criteria listed in Table 2 and to analyze performance differences between small and large cavities. The performance of both materials between baseline and 3 years was also analyzed statistically with the Mann–Whitney *U* test. Because of the low frequency of delta scores, Fisher's exact test was used to compute the distribution of clinically acceptable (alpha and bravo) versus unacceptable (charlie and delta) restorations.

Results

Determination of the inter-examiner reliability yielded kappa values above 0.67 for all rated criteria, except "color match" which revealed only a low initial agreement between the raters (κ=0.32).

Results of the clinical evaluation comparing QuiXfil and Tetric Ceram direct composite restorations at baseline and at 3-year follow-up are reported in Table 3. The Mann–Whitney *U* test exhibited no significant differences in any of the clinical criteria listed in Table 2 between the test material (QuiXfil) and the control (Tetric Ceram) at the 3-year recall. There was a trend for better restoration integrity in favor of Tetric Ceram, although this was not statistically significant (p=0.060). One three-surface (MOD) QuiXfil restoration failed at 18 months in a lower first molar because of bulk fracture in the mesial proximal region. One QuiXfil and Tetric Ceram restoration each had to be removed at the 3-year recall due to tooth fracture. One QuiXfil restoration failed at the 3-year follow-up because of pain symptoms (Table 4). All restorations were replaced at the respective follow-up time.

For each composite material, QuiXfil or Tetric Ceram, two classifications of cavity size were made, one- or two-surface cavities ("small cavity" group) and three or more surfaces ("large cavity" group), and statistically analyzed using the Mann–Whitney *U* test. Both Tetric Ceram and QuiXfil restorations showed no differences between the different groups of cavity size.

Table 3 QuiXfil and Tetric Ceram direct composite restorations: results of the clinical evaluation (%) at baseline and 3-year follow-up

Modified USPHS scores (%)	Baseline		3 Years			
	Alpha	Bravo	Alpha	Bravo	Charlie	Delta
QuiXfil direct composite restorations						
Surface texture	100		95	5		
Color match	100		100			
Anatomic form of the complete surface	97.8	2.2	97.5	2.5		
Anatomic form at the marginal step	97.8	2.2	90	10		
Marginal integrity	100		90	10		
Discoloration of the margin	100		85	15		
Integrity of the tooth	100		95	2.5		2.5
Integrity of the restoration	100		92.5	5		2.5
Occlusion	95.7	4.3	95	5		
Testing of sensitivity	100		100			
Postoperative symptoms	100		95	2.5		2.5
Patient's compliance	95.7	4.3	97.5	2.5		
Tetric Ceram direct composite restorations						
Surface texture	100		95.7	4.3		
Color match	96	4	97.8	2.2		
Anatomic form of the complete surface	100		97.8	2.2		
Anatomic form at the marginal step	100		93.5	6.5		
Marginal integrity	100		95.7	4.3		
Discoloration of the margin	100		87	13		
Integrity of the tooth	100		95.6	2.2		2.2
Integrity of the restoration	100		100			
Occlusion	100		100			
Testing of sensitivity	100		100			
Postoperative symptoms	100		100			
Patient's compliance	100		93.5	6.5		

The statistical comparison with the Mann–Whitney *U* test between the results at baseline and after 3 years of clinical service yielded for QuiXfil restorations a significant increase in marginal discoloration (p=0.007) and a significant deterioration of marginal integrity (p=0.029). Tetric Ceram restorations showed a significant decline for marginal discoloration (p=0.009). However, it should be noted that these effects are mainly results of alpha–bravo shifts, meaning that all composite restorations were still clinically acceptable and functional. No significant differences could be detected for all other clinical criteria.

From baseline up to 3 years, four restorations failed and were scored delta (Table 4). To analyze the clinical failure rate (distribution of charlie- and delta-scored versus alpha- and bravo-scored restorations) for QuiXfil versus Tetric Ceram restorations and small versus large cavities, 2×2 tables were created. Because of the low frequency of only four delta scores, Fisher's exact test was used. No significant differences between composite materials (p=0.257) and cavity size (p=0.456) could be detected concerning the failure rate.

Discussion

The present longitudinal randomized controlled clinical study investigated the performance of the posterior composite QuiXfil compared to the well-established hybrid composite Tetric Ceram at 3 years.

In a controlled longitudinal study, a very limited number of experienced dentists, specially trained for the specific procedure, place the restorations under almost ideal conditions. Patient population is often selected from reliable, easily available individuals (e.g., dental students, dental school staff, and faculty) with good compliance and highly motivated for oral hygiene [33]. The lesions treated are usually strictly selected and restricted to the indications of the investigated materials. Recall criteria are defined, and ideally, the calibrated recall assessments are performed by dentists different from those inserting the restorations [28]. Early detection of performance differences among tested materials (failure rate and failure mode) is the major advantage of these highly standardized longitudinal studies with strict clinical protocols.

The four-step USPHS evaluation system [35] used in the present study is the most commonly used direct method for quality control of restorations and is employed in many clinical evaluations of the performance of posterior composites, as its scores have direct clinical implications and a built-in definition of clinically acceptable restorations [6, 10, 11, 15, 21, 40, 42]. It should be mentioned that restorations scored with alpha and bravo were "clinically acceptable". Therefore, differences between alpha and bravo scores were only in degree and not in essence. Restorations rated with charlie or delta scores had experienced an essential change.

Determination of the inter-examiner reliability between the two rating dentists showed values above 0.67 for Cohen's kappa. This indicates high agreement between the examiners during assessment and supports unbiased rating [31]. As both examiners were not associated with the placement of the restorations and had no preliminary information as to what type of restoration they would evaluate, as many precautions as possible were taken to avoid unconscious operator error. A final residual bias cannot be excluded.

Up to 3 years of clinical service, all except one Tetric Ceram composite restorations showed excellent or acceptable results. With regard to QuiXfil, three restorations were lost due to bulk fracture, postoperative sensitivity, and tooth fracture, respectively. All other restorations were rated excellent or acceptable with predominating alpha scores. Statistical analysis detected no significant differences between the materials.

Loss of marginal integrity can be caused at baseline by polymerization shrinkage or faulty adaptation of the restorative material to cavity walls. Secondary bravo ratings were caused by marginal opening due to adhesive failures during clinical service. A significant increase of marginal discoloration and a deterioration of marginal integrity was found for QuiXfil after 3 years compared to baseline. Tetric Ceram restorations showed, after 3 years, significantly more marginal discoloration. Hickel et al. [15] addressed this phenomenon to appear usually in a medium time frame since insertion of the restorations.

Table 4 Reasons and time of failure of QuiXfil and Tetric Ceram restorations

Material	Tooth (FDI notation)	Restoration surfaces	Months after Baseline	USPHS score	Failure type
QuiXfil	36	mod	18	Delta	Restoration fracture
Tetric Ceram	26	modb	36	Delta	Tooth fracture
QuiXfil	36	mo	36	Delta	Tooth fracture
QuiXfil	36	mo	36	Delta	Postoperative sensitivity

A complete failure resulted in total replacement of the respective restoration

Table 5 Factors influencing the longevity of dental restorations

Patient	Dentist	Material
Oral hygiene, dietary habits	Correct indication	Strength (fractures)
Preventive measures, fluoride availability	Cavity preparation (size, type, finishing)	Fatigue/degradation
Compliance in recall	Handling and application (e.g. incremental vs. bulk placement)	Wear resistance (occlusal contact areas, contact-free areas)
Oral environment (quality of tooth structure, saliva, etc.) and systemic diseases	Curing mode (device, time, light intensity)	Bond strength, polymerization shrinkage, postoperative sensitivity
Size, shape, location of the lesion and tooth (number of surfaces, vital vs. non-vital tooth, premolar vs. molar)	Mode of finishing and polishing of the restoration	Chemical compatibility of restorative systems (DBA, composite)
Cooperation during treatment	Correct occlusion	Technique sensitivity
Bruxism/parafunctions/habits	Experience (with material and restorative technique)	Caries inhibiting effects (release of substances?)

Because of the elastic behavior and fatigue of the composite and bonding agent, negative influences of occlusal stress factors on posterior teeth may be considered to be more crucial for large restorations and molars, which are usually subjected to higher occlusal loading and stresses at the restoration–tooth interface. During clinical service this shows more effect on large restorations. For direct composite restorations, this result can also be explained by the fact that the larger the volume of composite to be polymerized, the larger the residual internal stresses in the polymerized composite even if incrementally placed. Lundin and Koch [22] found a higher failure rate for posterior composites in large cavities. Other clinical studies found a higher failure rate of posterior composite restorations in class II defects rather than in class I situations [23, 43] or better evaluation scores in premolars compared with molars [9]. In contrast to these aforementioned studies, no significant differences between large and small restorations could be detected in this study. This result is in accordance with the findings of Barone et al. [2] who found no statistical effect of restoration size on the clinical outcome of bonded composite inlays after 3 years of service.

Both materials showed a slight deterioration in marginal adaptation, with an increase of bravo scores to 4.3% for Tetric Ceram and 10% for QuiXfil concerning marginal integrity and 13% and 15% for the respective materials with regard to marginal discoloration. Especially, the increase in marginal discoloration of QuiXfil to 15% might be associated to the use of a self-etching adhesive which are discussed to have certain limitations concerning bond strength and long-term marginal seal on enamel [41]. The microretentive etch pattern on enamel of self-etching adhesives is less pronounced compared to using phosphoric acid [30].

Longevity of dental restorations is dependent upon many factors (Table 5) [12]. In general, it has to be distinguished between early failures that are encountered after weeks or few months, failures occurring in a medium time frame (6 to 24 months), and late failures after 2 years of clinical service [15]. Early failures are a result of severe treatment faults, selecting an incorrect indication for the restorative material, or postoperative symptoms. Late failures are predominantly caused by fractures of the tooth or materials' bulk fractures, secondary caries, wear or deterioration of the respective materials, and periodontal side effects [25].

The high success rate of QuiXfil (92.5%) and Tetric Ceram (97.8%) posterior composite restorations needs to be considered with regard to the period of only 3 years of clinical service. Annual failure rates are 2.5% and 0.7%, respectively. This short period results in a limited data validity that needs to be confirmed by the next follow-up investigations. The analysis of reports in the literature with regard to longitudinal clinical studies of class II posterior composite restorations demonstrates annual failure rates in a range of 0–7.0% with a mean value of 2.2% (median 1.7%) [25]. More clinically pertinent information about the long-term performance of these adhesive restorations will be published when the results of the next yearly scheduled follow-up evaluations are available.

Conclusions

Both restorative composites evaluated showed a good clinical performance in stress-bearing molar class I and II cavities of adult patients with predominating alpha scores.

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