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Clinical evaluation of the bulk fill composite QuiXfil in molar class I and II cavities: 10-year results of a RCT

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ABSTRACT

Objective. The objective of this RCT was to compare the 10-year clinical performance of QuiXfil with that of Tetric Ceram in posterior single- or multi-surface cavities.

Methods. 46 QuiXfil (Xeno III) and 50 Tetric Ceram (Syntac classic) composite restorations were placed in 14 stress bearing class I and 82 class II cavities in first or second molars. Clinical evaluation was performed at baseline and after up to 10 years by using modified US Public Health Service criteria. At the last recall period, 26 QuiXfil and 30 Tetric Ceram restorations in 11 stress bearing class I and 45 class II cavities, were assessed.

Results. Ten failed restorations were observed during the follow-up period, four Tetric Ceram restorations failed due to secondary caries (2), tooth fracture (1) and bulk fracture combined with secondary caries (1) whereas six QuiXfil restorations failed due to secondary caries (1), tooth fracture (2), secondary caries combined with restoration fracture (1), restoration fracture (1) and postoperative sensitivity (1). Fisher's exact test yielded no significant difference between both materials ($p = 0.487$).

Significance. Both materials, bulk fill QuiXfil restorations and Tetric Ceram restorations, showed highly clinical effectiveness during the 10-year follow-up.

1. Introduction

Direct composite materials are used ubiquitous for the restoration of class I and II lesions in posterior teeth. Main advantages of these restorations are conservative cavity preparations without the need for macro-mechanical retention areas and maximum preservation of healthy tooth structure and adhesive reinforcement of weak cusps. Furthermore, good esthetics in less treatment appointments are accomplished while costs are kept to a minimum compared to indirect restorative techniques [1,2]. When used within the indications and handled in accordance to the instructions of the manufactures', posterior composite restorations exhibit also an excellent clinical longevity [3–7].

Conventional hybrid composite materials are usually processed in an incremental layering technique with a layer thickness of 2 mm to overcome the problems of polymerization stress and limited depth of cure [8]. Each increment is light cured separately for 10–40 s, depending on the intensity

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of the curing device, formulation and shade/translucency of the composite material [9]. This results in a time-consuming application procedure of resin based composites that requires, for economic reasons, an adequate fee to cover the expenses [10].

At the end of the 1990s, highly-filled packable composites were introduced into the market with the expectations to render the direct adhesive technique less complicated and more cost-effective [11]. Meanwhile, packable composites do not play a relevant role anymore, as the expectations, which were linked to this special group of composite materials, such as easier achievement of tight physiological proximal contacts, increase of polymerization depth and sculptability could either not be fulfilled or technical handling and material properties were comparable to regular hybrid composites [12].

However, easier and faster placement of resin based composites is still highly demanded by general dental practitioners. The group of bulk fill composites, most of them introduced in the recent years, seems to meet the expectations from dental practitioners to provide a direct adhesive restorative material that can be manipulated faster and more convenient in the cavity [13] compared to conventional hybrid composites while still maintaining good mechanical properties – such as marginal adaptation, sealing properties, fracture strength, wear resistance – and long-term clinical success. These composites can be placed into the cavities in increments of 4 mm without prolonged curing time or using a curing device with increased irradiance [8,14]. Bulk fill composites are provided in two different viscosities [15]. High-viscosity bulk fill composites can be used to completely fill the cavities up to the occlusal surface with only one material, whereas low-viscosity bulk fill composites require a final capping layer of 2 mm by a regular hybrid composite material because of inferior mechanical properties (e.g. E-modulus and wear) due to their reduced filler load and filler composition [16–18].

QuiXfil (Dentsply DeTrey, Konstanz, Germany) was the first bulk fill composite marketed already in 2003. This high-viscosity bulk fill composite has a filler load of 86 wt.%/66 vol.% and is available in one translucent shade that allows to cure 4 mm increments in 10 s using a polymerization light of minimum 800 mW/cm^2 intensity [14]. The bimodal filler technology shows a particle distribution with two distinct peaks at 0.8 mm and 10 μm, shrinkage is claimed 1.7 vol.% by the manufacturer [19].

The aim of this longitudinal randomized controlled clinical study on two adhesive restorative systems (composite and respective bonding agent) was to provide a survey on the clinical results of QuiXfil/Xeno III restorations in permanent molars up to 10 years compared to restorations placed with Tetric Ceram/Syntac Classic (Vivadent, Schaan, Liechtenstein). Furthermore it should be determined whether the bulk fill composite QuiXfil combined with a single-step self-etch adhesive showed a clinical acceptance rate comparable to a traditional hybrid composite material combined with a three-step etch-and-rinse adhesive using the modified USPHS scoring system.

2. Method and materials

2.1. Study design and participants

The methods of restoration placement and clinical evaluation have already been published [20]. Forty-six QuiXfil (Dentsply DeTrey, Konstanz, Germany) composite restorations in combination with the self-etching adhesive Xeno III (Dentsply DeTrey, Konstanz, Germany) and fifty Tetric Ceram (Vivadent, Schaan, Liechtenstein) composite restorations bonded with the etch-and-rinse adhesive Syntac classic (Vivadent, Schaan, Liechtenstein) were randomized placed by three well trained dentists according to manufacturers' instructions.

Table 1 shows details on material composition. Each patient gave written consent to participate in the study before treatment. Ethical approval was granted by an ethics committee (Approval Number 2001-D-8473).

Patients in need of more than one restoration received at least 1 restoration with the testing material QuiXfil and one with the control material Tetric Ceram and a maximum of 2 restorations of each type. A random design was used to allocate the restorative materials to the teeth [20,21]. Eleven stress bearing class I and forty-five class II cavities could be included in the 10 year recall. Fillings had been placed either due to presence of primary caries or because of the replacement of failed restorations, in first or second molars with existing antagonistic and at least one neighboring tooth. Further inclusion and exclusion criteria for patients or teeth are shown in Table 2.

2.2. Clinical procedure

All patients received local anesthesia during treatment. Teeth were cleaned with fluoride-free prophylaxis paste and a rubber cup. To preserve a maximum of sound tooth structure, preparation was limited to the removal of caries or old insufficient restorations followed by rounding the internal line and point angles and preparation of the enamel margins with butt joint margins. Cavity preparation was carried out with 80 μm grit diamond burs and finished with 25 μm grit diamond burs (Intensiv, Viganello-Lugano, Switzerland). Cases requiring direct pulp capping were excluded. No liners or bases were used. Isolation and contamination control were carried out with suction device and cotton rolls. Rubber-dam was used in cases, where this was not considered sufficient. Metal matrix bands and wooden wedges were used when appropriate.

The self-etching adhesive Xeno III was used for QuiXfil restorations. Liquid A and B were dispensed in a dappen dish, mixed with a microbrush for 5 s and applied on enamel and dentin for 20 s. Thereafter the solvent was vaporized with oil-free compressed air and light cured for 10 s. The QuiXfil composite was incrementally applied, in layers up to 4 mm thick, according to manufacturers' recommendations. In cavities with more than 4 mm depth, a second increment was placed. Each layer was light cured for 10 s (800 mW/cm^2).

As control Tetric Ceram combined with the etch-and-rinse system Syntac classic was used to restore cavities. According to the directions of the manufacturer, enamel was etched

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