Three-and-a-half-year Clinical Evaluation of Posterior Composite Resin in Children

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ABSTRACT

Purpose: To evaluate the clinical performance of a packable composite resin (Tetric Ceram HB) for posterior restorations of children after 3.5 years, according to Ryge criteria.

Methods: Twenty five open apex molar teeth with extensive caries in 21 Iranian patients (8.2 year mean age) were restored by one operator. After caries removal, a layer of calcium hydroxide and glass ionomer base, Fuji II LC were applied. The teeth were restored using an adhesive system, Excite, and flowable composite, Tetric-Flow. The cavities were then restored incrementally with a Tetric Ceram HB. All the 25 restorations were evaluated after 3.5 years by two independent evaluators. Statistical analysis was performed using McNemar test.

Results: Surface texture for all restorations was classified as excellent. There were no evidence of secondary caries and bulk fracture in any of the restorations. Regarding the items of anatomical form and marginal integrity the statistical analysis reveled a significant difference between the baseline and recall scores respectively (P=0.031 and P=0.031).

Conclusions: It was concluded that Tertic Ceram HB exhibited excellent clinical performance after 3.5 years in the open apex first permanent molar teeth.

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Dentists often experience some problems restoring young permanent molars teeth with extensive carious lesions. Materials recommended for restoration of immature permanent teeth include amalgam, stainless steel crowns, and adhesives. Another treatment option is placement of a pin-retained amalgam or cast gold onlay restoration.[1] The problem with these treatment is increased risk of exposing the pulp due to the relative large size of the pulp and thin dentin. Stainless steel crowns are considered to be an interim treatment in childhood until replaced with a permanent crown. The procedure may reduce sound tooth surfaces, to provide adequate space for the crown. Such restorations are sometimes difficult to fit due to the clinical tooth crown's shortness and the patient's occlusion. Therefore, it may be preferred to postpone this type of treatment when some recession of the pulp horns takes place. Instead, a bonded composite resin (**CR**) restoration may be selected. This option requires minimal tooth preparation and is the least invasive treatment.[1,2] Although bonded restorations preserve the slight remaining coronal tooth structure, they are considered only a temporary restoration until the root development and apical closure is completed.[1] Most problems associated with CR restorations include secondary caries and postoperative sensitivity. The main reason why clinical success of this treatment has declined is the complexity of the composite placement and bonding procedure.[3]

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In recent years, the use of packable composite resin (**PCR**) has been increasing in operative treatments. High viscosity and consistency in PCRs improve handling characteristics that mimic that of amalgam.[4] Obtaining proper contour, finishing, and polishing, however, is more difficult than amalgam.[5] Several in vitro studies have compared mechanical properties and polymerization shrinkage of PCR to other CRs. Some researchers have noted PCR's advantages.[6] Other studies, however, have failed to document significant differences between PCR and other hybrid or reinforced microfilled composites.[5] In addition, PCRs are technique sensitive and time consuming because of incremental buildup of the restoration.[5] Controlled, independently performed clinical studies are the only basis for the manufacturers to make clinical claims. Clinical studies to test PCR, however, have not been longitudinally performed, especially in children, since these materials were introduced to the markets by 1998.

Therefore, the purpose of this study was to determine the 3½ year performance using Tetric Ceram HB (Vivadent, Schaan, Liechtenstein) packable composite resin used to restore extensive caries in open apex permanent first molars teeth.

METHODS

This study's research protocol was submitted to the Human Ethics Review Committee of the Faculty of Dentistry, Shiraz University of Medical Sciences. As the method was approved, the patients of the Pediatric Dental Clinic at the Dental School of Shiraz University, Shiraz, Iran, were selected. All patients and their parents were informed about the study. The patients received oral hygiene instruction before the operative treatment was performed. Patients with extremely poor oral hygiene, heavy bruxism habits, or periodontal problems were excluded. Clinical examinations and radiographs (periapical radiographs) were used to reveal the extent of the carious lesions on the occlusal surface of the crowns of young permanent first molars with an open apex and 0.5 to 1 mm of the remaining dentin thickness (Figure 1).

Pulp testing confirmed the teeth's vitality. All teeth had no signs of irreversible pulpal pathoses or a history of pain. Twenty-one Iranian patients (9 girls and 12 boys), with a mean age of 8.2 years, were included in this clinical trial to reconstruct 25 molars with 1 or 2 missing cusps and 1 unsupported cusp due to extended caries—approximately 1 for each case.

One operator prepared, restored, and finished 25 cavities following standard procedures and the manufacturer's directions. After obtaining adequate local anesthesia, the restorative procedures were performed with rubber dam isolation. The cavity design (restricted to the elimination of carious tissue) was prepared using fissure diamond burs (F868/016, Teez Kavan Ltd, Tehran, Iran) and no. 2 and 4 round stainless steel burs (lot no. 2427, Denver, CO, USA), without placement of bevels on either the occlusal or gingival surfaces.

A thin layer of calcium hydroxide (Dycal, Base, Dentsply, Germany) was applied to the cavity's deepest area. Then, a resin-modified glass ionomer liner (GC Fuji II LC, Tokyo, Japan) was placed to seal the dentin's depth (Figure 2). In some patients, before restoring the Class II cavities, a thin metal matrix band was held in a Tofflemire retainer (Vevey, Switzerland), adapted, and firmly wedged in the proximal area to closely adapt the matrix to the gingival margins of the preparation in order to achieve correct proximal contacts. Both the enamel and dentin were etched for 15 seconds using 35% phosphoric acid (Ultra Gel-Etch, Ultradent, South Jordan, Utah), rinsed for 15 seconds, and dried gently with a weak stream of air. The operator was careful to maintain a moist surface (wet bonding). A 2-step etch and rinse adhesive system (Excite, Vivadent) was placed in the preparation, thinned by applying a weak air stream, and light-cured for 20 seconds using a halogen light curing unit (Coltolux, Coltene, Whaledent Inc, Altstaetten, Switzerland) with a power density of 500 mW/cm^2. A thin layer of a flowable composite (Tetric-Flow, Vivadent) was placed over the dentin surface and cured. Next, the procedure was followed by applying a PCR, Tetric Ceram HB (Vivadent), using the incremental technique

Figure 1. Extensive caries in a permanent first molar with an open apex.

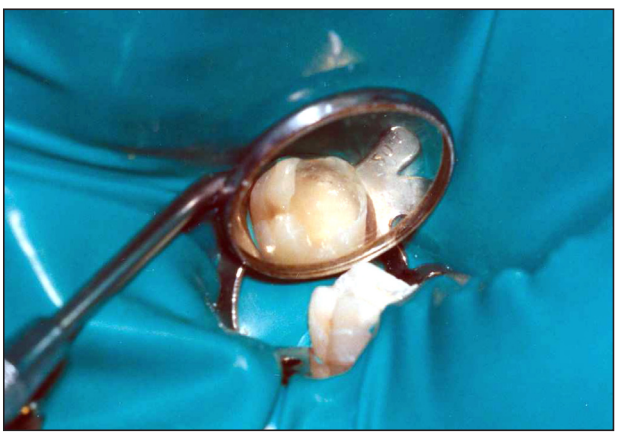

Figure 2. A layer of resin-modified glass ionomer base was placed.

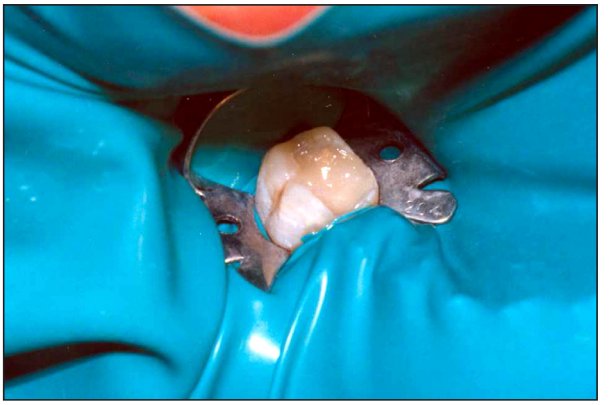

Figure 3. A first layer of packable resin composite was placed.

Figure 4. The restoration was completed with packable resin composite.

(2-mm thick layers; Figure 3). The resin composite was adapted to the cavity by a flat-faced or elliptical condenser and light-cured, 40 seconds for each increment, using a light curing unit. The light was monitored with a radiometer for adequate intensity before each restoration. Table 1 shows the materials used in this study.

After the matrices were removed from the II restorations, the proximal limits were polymerized again for 20 seconds both lingually and buccally. The occlusion was checked. All the restorations were finished using fine diamond burs (F868/018,Teez Kavan Ltd, Tehran) and polished using Sof-Lex (3M ESPE, St. Paul, Minn) and flexible aluminum oxide discs (Figure 4). A surface sealer (PermaSeal, Ultradent, South Jordan, UT, USA) was used to rebond the occlusal surface and finally cured. After finishing each restoration, a color photograph was taken. A recall program was arranged for all patients, and all restorations were evaluated approximately 3½ years after the first treatment session for the following characteristics: surface texture; anatomical form; marginal adaptation/discoloration; secondary caries; postoperative sensitivity; and bulk fracture. The restorations were clinically rated by 2 examiners using the method developed by Ryge, also known as the US Public Health Service criteria.[7]

At the follow-up appointment, periapical radiographs for detection of the secondary caries, periapical radiolucency, were taken (Figure 5), vitality tests were performed, and color photographs were taken (Figure 6). For each criterion, a score of "Alpha" was used to indicate the highest degree of clinical acceptability, scores of "Bravo" and "Charlie" to indicate progressively lessening degrees of clinical acceptability, and "Delta" to indicate that the restoration was not clinically acceptable (Table 2). When disagreement arose during evaluations, consensus evaluations were obtained between examiners.[7] We compared the baseline scores with this recall, using McNemar's test ($P<.05$).

Table 1. Composition of the Materials, Lot, and Manufacturers

Material	Composition	Lot	Product, manufacturer
Glass ionomer lining cement	• Liquid: Distilled water polyacrylic acid • Powder: (fluoro) alumino-silicate glass	0801291	GC Fuji II LC, GC Corporation, Tokyo, Japan
Excite	Mixture of dimethacrylates, alcohol, phosphonic acid acrylate, HEMA (hydroxyethyl methacrylate), SiO_2, initiators and stabilizers	E54392	Ivoclar, Vivadent, Schaan, Liechtenstein
Tetric Flow	• Organic matrix: Bis-GMA UDMA and TEGMA • Inorganic matrix: Paste of dimethacrylates, inorganic fillers, ytterbium trifluoride, • initiators, stabilizers, and pigments	E38161	Ivoclar, Vivadent Schaan, Liechtenstein
Tetric Ceram HB	• Organic matrix: Bis-GMA UDMA and decamethylendimethacrylate • Inorganic matrix: Filler percentage 80.5%. (1.0 µm) paste of dimethacrylates, inorganic fillers, ytterbium trifluoride, initiators, stabilizers, and pigments	F51109	Ivoclar, Vivadent, Schaan, Liechtenstein

RESULTS

The results are summarized in Table 3. A total of 25 restorations were placed in 21 patients. At baseline, all the restorations showed a score of "Alpha" in each of the criterion used for the study. All the patients attended the 3½-year recall appointment. After this recall period, surface textures for all restorations were classified as excellent (receiving an "Alpha" rating). Also, according to the periapical radiographs taken, there was no evidence of secondary caries in any of the restorations (receiving an "Alpha" rating). The vitality of the restored teeth did not change during the 3½ year period. None of the patients complained about postoperative sensitivity at any time during the study. No gingival inflammation or bulk fracture was observed after the 42-month recall.

Relative to marginal discoloration, 92% of the restorations received a Bravo rating and 8% received a Charlie rating. No statistical difference was detected (P=.50). For anatomical form, after 3½ years, 76% of the restorations were graded "Alpha", 16% were graded "Bravo," and only 2 were graded "Charlie". A significant difference was seen between baseline and recall (P=.031). All the margins were intact at baseline. At the end of the 3½-year review, an Alpha rating was recorded for 76% of the restorations regarding marginal integrity and 24% had been graded Bravo; a significant difference was observed (P=.031).

DISCUSSION

Composite resins were mostly used for anterior teeth and non stress bearing area. Since the introduction of CRs, developmental efforts have focused on progressing their properties so that they may serve as alternatives to amalgam in restoring posterior teeth. The improved strength, hardness, and modulus of elasticity and lower thermal conductivity of these new CRs indicate the changes.[4] Consequently, a new generation of composite resin—PCR—was introduced. PCRs are available in different features, mainly in the distribution and size of inorganic particles. This fact causes differences in the mechanical and physical properties of these composites. Therefore, their performance is material-dependent.[3,8-11] Regarding reinforcement of residual tooth structure with CRs, PCRs were used in severely compromised teeth. In this way, the cusps with 1- to 1.5-mm remaining enamel-dentin thickness could be preserved.[7] The rationale for CR curing via the incremental technique and adequate curing of each increment was that minimal shrinkage takes place within each increment. This reduced shrinkage was aided by the low cavity configuration factor, as the large free surface permits the resin to flow during polymerization.[12]

Another CR used in the present study was flowable resin. It was applied in a thin layer to all internal walls to improve composite adaptation. Tetric Flow flowable resin was chosen because of its radiopacity, which permits radiographic examination of the restoration.[13]

Furthermore, surface sealer (PermaSeal, Ultradent, South Jordan, UT, USA) was used to coat the occlusal surface. After the finishing step, microcracks were formed on the restoration's surface and below it. To minimize these harmful effects, low-viscosity monomers can be used as surface sealants, which penetrate the defects and reforce the surface layer.[14,15]

Figure 5. Follow-up periapical radiograph: The apex was closed, and there were no signs of periapical lesions.

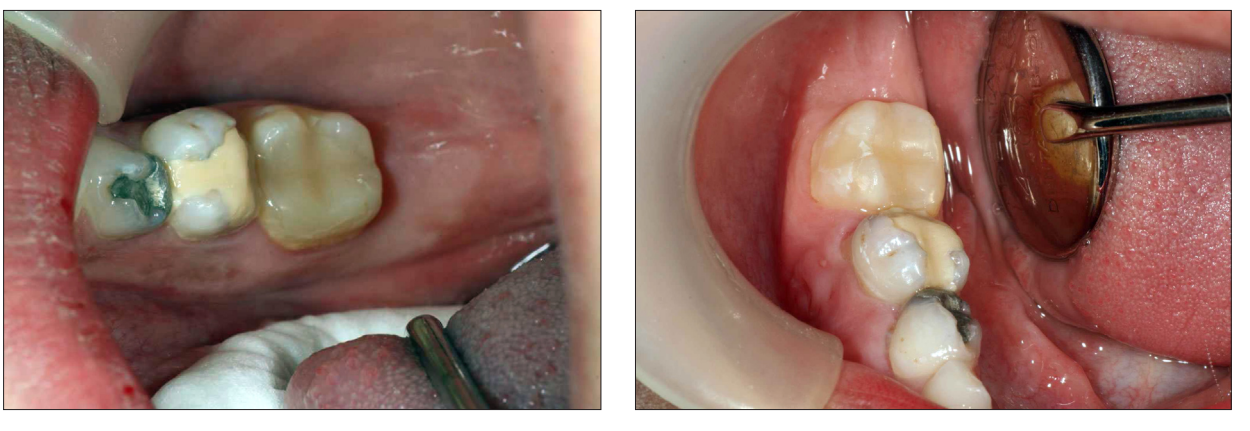

Figure 6. (a-b) Follow-up photos demonstrating slight changes in anatomic form and marginal discoloration (receiving a Bravo rating).

Table 2. Modified US Public Health Service Criteria Used for Direct Clinical Evaluation of the Restoration

Score	Alpha	Bravo	Charlie	Delta
Surface texture	Sound	Rough	—	
Anatomic form	Sound	Slight loss of material (chipping, clefts), superficial	Strong loss of material (chipping, clefts), profound	Total or partial loss of bulk
Marginal integrity (enamel)	Sound	Positive step, removable by finishing	Slight negative step, not removable, localized	Strong negative step in major parts of the margin, not removable
Marginal discoloration (enamel)	None	Slight discoloration, removable by finishing	Discoloration, localized, not removable	Strong discoloration in major parts of the margin, not removable
Secondary caries	None			Caries present
Gingival inflammation	None	Slight	Moderate	Severe
Preoperative sensitivity	None	Yes	—	—
Postoperative sensitivity	None	Moderate	Severe	—

In the current study, after the 3½-year review as compared with the baseline, approximately 92% of all restorations received a Bravo rating for marginal discoloration. These discolorations, however, were not necessarily creating gaps in margins or recurrent caries. Approximately 76% received an Alpha rating for marginal integrity. The marginal discrepancies appeared to result from the fracture of thin flashes of resin-based composite material extended onto uninstrumented or unground enamel surfaces adjacent to the preparation margins.

A slight loss of anatomic form in 16% of restorations was observed. This increased wear may be attributed to extension of a restoration because large occlusal areas are exposed to greater occlusal forces, thus reducing its wearing resistance. The more distally the tooth is positioned, the greater the wear of the restoration because the acting forces are greater. In spite of the loss of cuspal anatomic shape in some of our cases, deleterious exposure of cavity margins was not observed.

No postoperative sensitivity was experienced and reported in any of the cases during this period. Several factors may be responsible for the reduced postoperative sensitivity reported in the present study. Particular attention was paid to adapt accurate layering and curing protocols. The correct use of modern adhesive systems and excellent performance of the 2-step etch and rinse adhesive system also may contribute positively to this finding,[6] as already demonstrated in other clinical investigations.[16-18]

No difference from the baseline recordings was observed for surface textures after 3½ years. This finding may be attributed to a high quality polished surface that was not altered after 3½ years.

Also, no cuspal fracture was observed in any restorations of our study samples. This shows the importance of careful analysis and balancing the occlusion in both a static and dynamic relation. Increased resistance to occlusal load fracture may be due to high filer content (81%) in the type of composite used. In addition, the bite force is one of the components of the chewing function.[19] Some studies have confirmed that the mean bite force in children is lower than that of adults.[20-21] Also, patients with parafunctional habits were excluded from the study. Overall, none of the teeth followed had lower ratings and most ratings showed acceptable results. Some of the teeth had lost anatomical form, which is not an important defect (no threat to the pulp). The small defects on the margins in a few cases, however, were restored again.

Table 3. Clinical Evaluation of Tetric Ceram HB Posterior Composite in Permanent First Molars

Evaluation criteria	Score	Baseline (%)	3½ years (%)
Surface texture	A	25 (100)	25 (100)
	B		
Anatomic form	A	25 (100)	19 (76)
	B		4 (16)
	C		2 (8)
Marginal integrity	A	25 (100)	19 (76)
	B		6 (24)
	C		
	D		
Marginal discoloration	A	25 (100)	
	B		23 (92)
	C		2 (8)
	D		
Secondary caries	A	25 (100)	25 (100)
	D		
Preoperative sensitivity	A	25 (100)	25 (100)
	B		
Postoperative sensitivity	A	25 (100)	25 (100)
	B		
	C		
Bulk fracture	A	25 (100)	25 (100)
	B		

Several studies already have revealed a satisfactory performance of PCRs in adult teeth. Loguercio et al[6] evaluated the clinical performance of PCRs, SureFil (Dentsply Caulk, Milford, DE, USA), Filtek P60 (3M ESPE, St. Paul, MN, USA), Alert (Jeneric/Pentron, Wallingford, CT, USA), Solitaire (Heraeus Kulzer, Wehrheim, Germany) in the posterior teeth (Class I and II) vs a hybrid composite (TPH Spectrum, Dentsply Caulk, Milford, DE, USA) after 3 years. Surefil and Filtek P60 demonstrated an excellent clinical performance similar to that of hybrid resins. Alert performed the worst compared to 2 materials, and Solitaire did not fulfill the American Dental Association's acceptance criteria as a posterior restorative material. Therefore, this material is not recommended for routine use in the posterior teeth.[6] Deliperi et al.[7] assessed composite restorations with the PQ1 adhesive system (Ultradent, South Jordan, UT, USA) and Vit-1-essence (Ultradent, South Jordan, UT, USA) a microhybrid CR. This CR demonstrated excellent clinical performance for Class II cuspal coverage of direct composite restorations at completion of a 30-month evaluation.[7]

Dresch et al.[22] compared the clinical performance of a nanofilled resin composite (Filtek Supreme, 3M ESPE, St. Paul, Minn, USA) for posterior restorations with 2 microhybrids (Pyramid, Bisco Inc., Schaumburg, Ill, USA), Esthet-x Caulk, (Dentsply Caulk, Milford, De, USA), and 1 packable composite (Tetric Ceram) after 12 months. They concluded that all the composites exhibited excellent clinical performance after 1 year.[22] Also, Turkun et al[23] considered that after 2 years of clinical service, Surefil packable resin-based composite was successful in Class I and II restorations.[23] Some studies, however, have failed to document the same results and Ernst et al.[24] observed that Tetric Ceram had a higher percentage of color mismatch after 12 and 24 months vs Filtek Supreme.[24]

Overall, placement of CRs as compared to amalgam is more intricate and time-consuming and requires a more exact technique for optimal clinical results and long-term success. Careful placement, curing, proper finishing and polishing techniques, and the selection of appropriate materials are essential for the success of bonded CRs.

CONCLUSIONS

Based on this study's results, the following conclusions can be made:

1. Cases where, dentists face extensive caries in children's permanent first molars, while the apexes are open. Pulp capping has been shown to have greater long-term success than invasive treatments such as root canal therapy.
2. One of the available choices for restoring these teeth and preserving tooth structure is packable resin composite, which exhibited excellent clinical performance in a study after 3½ years and could be one of the treatment options for restoring immature permanent teeth with extensive caries in pediatric patients.
3. A long observation period is indicated, however, to substantiate the clinical performance of packable composite systems.

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