Microleakage of Ormocer-based Restorative Material in Primary Teeth: An *In Vivo* Study

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This in vivo study aimed to compare, by means of dye penetration, the microleakage values of an Ormocer-based material (Admira) and a commonly-used composite resin (Restorative Z-100) and to assess the differences in the degree of microleakage according to the cavity wall location for both tested materials. No statistically significant differences were found in the degree of microleakage between the 2 materials or the location of cavity walls. Additional preventive measures should be considered to minimize leakage since none of the restorative systems used, eliminated microleakage.
Key words: *primary teeth, Admira, Z-100, microleakage*
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In recent years, resin-based composite materials have been widely used in restorative dentistry. The popularity of these restorations has increased because of a demand for cosmetic, tooth-colored restorations and a decreased acceptance of traditional amalgam by patients with concerns about its mercury content.[1-3]

Despite recent dramatic improvements in the technology of composite resins and their adhesive systems, polymerization contraction, which occurs as the material cures, remains a major problem.[3,4] This contraction pulls the restorative material away from the cavity walls, resulting in rupture of the adhesion and the formation of marginal gaps.[5,6] These gaps cause postoperative sensitivity, discoloration and secondary caries at the restoration interface, and pulpal pathology, eventually leading to failure of the restorations.[4,7,8] Therefore, the adequacy and durability of sealing the restorative material against the tooth structure is a major consideration in the longevity of the restoration.

Several studies have documented that composite restorations have a high failure rate in primary teeth.[9-11] Kilpatrick reported a failure rate of 62% in 1993.[9] According to Fuks and colleagues, composite resin restorations are indicated for cavities in primary teeth that are expected to exfoliate within 2 years. The recommendation was based on their findings that 50% of composite restorations showed radiographic defects and required replacement after 2 years of placement.[12] The most frequently recorded types of failure were secondary caries and marginal discoloration, with loss of filling materials.[9,12]

The increased use of resin composite as the best direct esthetic restoration material has created a demand for a non-shrinking restorative material that can produce a leakage-free restoration. A new dental filling material has recentally been introduced under the name of Admira (VOCO, Gmbh, Cuxhaven, Germany). The development of this innovative material was based on Organically modified ceramic (Ormocer) materials and proven composite technology.[13]

Their manufacturer of Admira claims that its material differs from conventional composites in its outstanding biocompatibility, minimal shrinkage (less than 2% by volume), and better handling properties. The material also displays high resistance to abrasion and better esthetics, resembling that of natural teeth. Its coefficient of thermal expansion also approximates that of natural teeth. All these properties are due to the physical and chemical stability of the Ormocer structure that includes high molecular weight and a fully polymerized matrix with minimal amounts of organic resin and free monomers.[13]

Ormocer technology helps reduce polymerization shrinkage of Admira materials to an extremely low degree (up to 50% less than conventional composite resins).[13,14]

Compared with the first restorative material based on Ormocer technology (Definite; Degussa AG, Hanau, Germany) the Admira system has improved marginal integrity that is further augmented by the action of a special Ormocer adhesive with a calcium complex that enhances its bond strength on tooth structure. Here the benefits of Ormocer take effect even while applying the bonding agent.[13]

Many clinical trials have shown remarkable results

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regarding Admira's ability to seal and reduce microleakage of class II and V restorations in permanent teeth, especially on gingival margins placed in dentin or cementum.[15-17] In contrast, some studies have shown that Ormocer-based materials were associated with high leakage scores compared with conventional hybrid composites.[18,19] Both studies found that Ormocer-based materials exhibited poor marginal adaptation and showed voids between filling material and tooth interface.

Apart from the contradiction concerning the suitability of Ormocer materials to restore cavities in permanent teeth, the literature reveals no studies on the behavior of the material in restoring primary teeth. This raises the need for such a study.

The aims of this *in vivo* study were to compare, by means of dye penetration, the microleakage values of an Ormocer-based material (Admira) and a commonly-used composite resin (Restorative Z-100) in primary teeth and to assess the differences in the degree of microleakage according to the cavity-wall location of both tested materials.

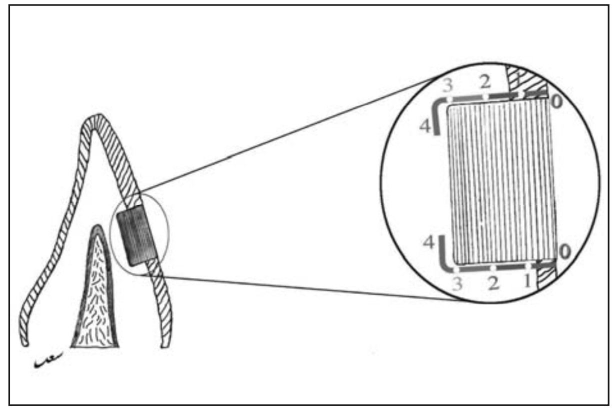

Figure 1. Schematic representation of the ranked scores (0-4) employed to analyze the extent of leakage in restoration margins. 0= no dye penetration, 1= dye penetration within 1/3 of cavity wall, 2= dye penetration within 2/3 of cavity wall, 3= dye penetration within last 1/3 of cavity wall up to the axial wall, 4= dye penetration spreading along the axial wall.

MATERIAL AND METHODS

Subjects

After the study protocol was reviewed and approved by the appropriate institutional review board, the study participants were selected from children seeking dental care in the pediatric dental clinics at King Abdulaziz University. Twenty healthy, cooperative children with an age range of 9 to 12 years were included in this study. Each selected child had at least 2 sound primary canines indicated for extraction for orthodontic reasons. A consent form was signed by the children's parents or guardians for final acceptance into the study.

Cavity preparation

Forty standardized, oval-shaped, class V cavities were prepared in the middle third of the labial surface of primary canines of the 20 children. All cavosurface margins were located on enamel surfaces and left at 90°.[20]

After profound local anesthesia and complete rubber dam isolation had been achieved, a No. 330 carbide bur mounted on a high-speed handpiece with water cooling was used for cavity preparation at the rate of 1 new bur every 5 preparations.[20] Cavity dimensions were 1.5 mm mesiodistally, 2 mm incisogingivally, and 1.5 mm deep (length of bur was used as a guide for cavity depth).[20,21] All cavity preparations were done by the same operator.

Cavity restoration

Based on a simple random design using an ideal bowel,[22] cavity in each child was selected as a control and restored with a single-bond, 1-bottle adhesive system (Restorative Z-100 composite resin; 3M Dental Products, St Paul, Minn). After the control cavity was restored, the other cavity became a test cavity and was restored with an the Admira bond, 1-bottle, Ormocer-based adhesive system and Admira Ormocer-based resin material (VOCO Gmbh, Cuxhaven, Germany). All tested materials were applied according to manufacturers' instructions and cured by the same light-curing unit (POLYlux II , KaVo Dental Gmbh, KG, Germany).

Microleakage evaluation

Using infection control precautions, we extracted all 40 teeth 4 weeks after restoration and sealed their apices immediately with sticky wax.[20,23,24] Three layers of nail varnish were applied to cover all tooth surfaces within approximately 1 mm of the restoration margins and immersed in 2% basic fuchsin dye solution for 24 hours at room temperature. Following removal from the dye solution, the teeth were cleaned, rinsed with tap water, and dried.[20]

Each tooth was sectioned labioligually through the middle of the restoration using a water-cooled diamond disc. Both halves of the sectioned tooth were then examined and scored under a stereobinocular microscope (Meiji Techno, EMZ-5TR, Japan) at a magnification of x 45 to determine the extent of dye penetration around the restoration margins.

Dye penetration at the filling-tooth interface of 80 tooth sections was scored at both incisal and gingival margins on a nonparametric, 5-point ordinal scale from 0 to 4.[25] The figure shows a schematic representation of the scoring system. If the scores from the 2 sections were different, only the higher score (denoting the most severe dye penetration) was recorded for that tooth.[20,25]

Data analysis

All statistical analyses were computed with a prepared SPSS computer program, version 10.0. The data was analyzed using the chi-square test to examine the differences in the frequency of leakage among the tested materials. The Mann-Whitney *U*-test was used to determine the significant differences of the leakage scoring between the 2 tested materials. The Wilcoxon signed rank test was used to reveal any difference in the degree of microleakage between the incisal and gingival cavity walls in the same tooth for both materials. Results were considered significant for *P*, <0.05.

RESULTS

Table 1 shows the frequency of microleakage recorded for the two tested materials. Z-100 seems to give better results than Admira. The results showed that 50% of teeth restored with Z-100 (control group) showed no dye penetration at either the incisal or the gingival wall of class V restorations (no leakage) compared with 35% of the Admira group. However, the difference was not statistically significant.

Table 2 shows the distribution of microleakage scores for tested materials at the incisal and gingival walls of the class V restorations. Mann-Whitney *U*-test analysis revealed no significant differences between Admira and Z-100 filling materials in dye penetration scores at either the incisal or the gingival wall of class V restorations. The Wilcoxon signed rank analysis also indicated no statistically significant differences in the dye penetration scores between the incisal and gingival walls for either material.

DISCUSSION

Several methods have been introduced for the evaluation of material microleakage including radioisotopes, air pressure, neutron activation analysis, pH changes, scanning electron microscopy, fluid permeability, and—the most common one—dye penetration.[7,26,27] In this study, basic fuchsin dye was selected to measure microleakage because it is easy to manipulate and is not toxic.[26] A 2% concentration was selected because the greater the concentration, the easier is the detection and classification of the degree of microleakage.[28] The split-mouth design followed in this study limited patient influence; therefore, the 2 groups of restorations were considered more comparable.[29] Some investigators prefer laboratory evaluation to study this phenomenon. However, in an *in vitro* evaluation, it is easy to standardize the model, obtain ideal adhesion, and allow thermocycling to simulate the stress caused by thermal variation (producing artificial aging).[21] In this study, an *in vivo* evaluation of microleakage was preferred as more clinically relevant because of the numerous uncontrolled variables encountered in patient treatment and the simulation of clinical conditions that are ignored in the *in vitro* studies.[25,30]

Furthermore, the artificial aging process in an *in vitro* study applies severe thermal stresses on specimens that may well exceed the temperatures to which teeth are ordinarily subjected in the oral environment. These stresses might magnify the enamel crazing initiated during cavity preparation and increase leakage after numerous immersions.[31,32] Whereas in the clinical situation, leakage can occur after a period of functioning from chemical, thermal, or mechanical stresses on the tooth-restoration interface.[25] In addition, it has been reported that occlusal loading in the form of masticatory forces promotes gap formation and marginal leakage in class V restorations because of bending of tooth structure.[33]

We consider this *in vivo* investigation of the microleakage of Ormocer-based material in primary teeth to be a pioneer study. Our data failed to prove the hypothesis that Admira filling material shows less leakage than Z-100 composite resin around the cavity margins of class V restorations in primary teeth.

Our findings are consistent with those reported by RuyaYazici *et al*, who evaluated the microleakage of class V cavities prepared in extracted permanent molars and restored with Z-100 composite resin and Admira. They concluded that no statistically significant differences in microleakage were observed between the 2 materials.[34] In a similar *in vivo* study, Koliniotou-Koumpia *et al*, using a hybrid composite resin, made a similar observation using Admira adhesive restorations, which revealed no statistically significant difference in microleakage over hybrid composite resin.[35] According to the result of a laboratory study calculating contraction rates due to shrinkage in light-cured composites, similar values were found for Admira compared with other composite resins used as controls.[36]

In contrast, Yap and Soh concluded that the polymeriza-

Table 1. Comparison of microleakage for the two tested materials.

Material \ Dye leakage	Samples without leakage	Samples with leakage	Total
Z-100 (control group)	10 (50%)	10 (50%)	20
Admira (Test group)	7 (35%)	13 (65%)	20
Chi-squared		1.8	
P-value		0.18	

Table 2. Microleakage scores for tested materials at the incisal and gingival walls of class V restorations.

	Microleakage score											
	Admira (n=20)					Z-100 (n=20)					Mann U*	Whitney p-value
Site	0	1	2	3	4	0	1	2	3	4		
Incisal	15 (75)	1 (5.0)	1 (5.0)	1 (5.0)	2 (10.0)	15 (75.0)	4 (20.0)	1 (5.0)	0 (0.0)	0 (0.0)	191	0.820
Gingival	9 (45.0)	3 (15.0)	4 (20.0)	0 (0.0)	4 (20.0)	12 (60.0)	4 (20.0)	1 (5.0)	2 (10.0)	1 (5.0)	160	0.289
Wilcoxon**			-1.628					0.103				
P-value			-1.319					0.187				

* Mann-Whitney U-test shows the differences between the two tested materials.
** Wilcoxon signed rank test shows the differences between the incisal and gingival walls.

tion shrinkage of Ormocer-based Admira was significantly lower than conventional composite resin Z-100.[14] An *in vivo* trial using Admira filling material also showed better results in microleakage of class V restorations compared with composite materials P-60, Glacier, and Ormocer-based Definite.[35]

In another study, it was found that Ormocer-based material is less capable than conventional hybrid composites in reducing contraction stresses during the early setting stage and not superior in maintaining the bond with cavity walls. The authors recorded higher contraction stresses of Ormocer-based material, along with a rapid contraction-force build-up. This phenomenon is related to the rigid matrix properties of inorganic-organic Ormocer resin. The rigidity of resin material was reported to be a result of high-molecular-weight molecules and relatively low elastic modules. All these factors may allow less flow compensation, resulting in a large amount of residual rigid contraction stress.[37]

Kournetas *et al* assessed in a laboratory experiment the marginal and internal cavity adaptation of two Ormocer-based restorative systems (Admira and Definite) and a universal hybrid resin composite (TPH Spectrum; Dentsply, Germany) combined with their respective bonding agents before and after load cycling. Both Admira and Definite exhibited a similar marginal adaptation before as well as after load cycling, which was statistically inferior compared with the hybrid resin composite system tested. Under metallographic microscope examination, the internal adaptation of both Admira and Definite was also found to be inferior to the hybrid resin, with no gap-free restorations detected, whereas all TPH restorations presented perfect adaptation. According to the authors, the inferiority seemed to be related to a defect in the bonding layer of Admira bond and Multibond, appearing as a noncontrolled thickness of the adhesive layer that could lead to nonuniform stress distribution. Additionally, this thick bonding layer may result in weakening the bond.[19]

In view of the microleakage at the different cavity walls, the results indicated no statistically significant differences in the dye penetration scores between the incisal and gingival walls for either of the tested materials. The results are in contrast to data obtained from previous studies[34,35] but consonant with others.[20]

CONCLUSIONS

Under the conditions of this *in vivo* study, it can be concluded that

1. No statistically significant differences were found in the degree of microleakage between Admira and Restorative Z-100 or the location of cavity walls.
2. None of the restorative systems used, eliminated microleakage in primary teeth.
3. Additional preventive measures should be sought to minimize leakage of tooth-colored restorative materials.

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