A Two-Year Clinical Evaluation of Glass Ionomer and Ormocer Based Fissure Sealants

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The objective of the present study provides further data comparing retention, marginal integrity and caries preventive effects of two fissure sealants (glass ionomer based; GC Fuji VII Capsule [Fuji VII] and ormocer based; Admira Seal [AS]) in children. This study was designed as a randomized single-blind clinical trial. The permanent first molars (PFMs) of 50 children, 7-13 years of age (mean age: 8.9 ± 1.3 years), were sealed with a split-mouth design. Fissure sealants applied to the PFMs according to the manufacturer's recommendations by one pediatric dentist. Clinical evaluation of the sealants was carried out to record retention, marginal integrity and presence of caries at 6, 12, 18 and 24 months after placement by the other pediatric dentist. Kaplan-Meier survival analysis and Cox's regression models were used to estimate the probability of two sealants success. **Results:** Alpha and Bravo retention and marginal integrity between fissure sealants was found similar survival rates (p>0.05). After 24 months, presence of caries was 16% for Fuji VII and 32% for AS (p<0.05). Conclusion: Fuji VII and AS exhibited similar retention and marginal integrity during 24 months. However, Fuji VII was showed better results than AS for caries preventive effect. Consequently, Fuji VII sealants may be a better choice for preventing occlusal caries.

INTRODUCTION

P it and fissure sealants were first introduced in an attempt to prevent occlusal caries by Cueto and Buonocore¹ in 1965. These materials have since been accepted as agents that are effective in the prevention of caries. The nature of the sealant material is important to the success of the fissure sealant procedure.²

Fissure sealant with glass ionomer cement was first introduced by Mclean and Wilson³ in 1974. The important advantage of using glass ionomer cement as a pit and fissure sealant is the fluoride release which results in increased resistance of the fissures to demineralization. However, researchers have demonstrated low retention rates for these materials when they are used as fissure sealants in periods between 6 months and 7 years.^{4,5} Although high percentages of lost glass ionomer sealant have been observed, this has not had a direct relationship with caries development.⁵⁻⁸ Fluoride release continues even when the sealants appear to have been lost clinically because of the remnants left at the bottom of the fissures.⁸⁻¹⁰

In 1998 a new restorative material, ormocer, which is based

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on silicon dioxide, was introduced to the market.^{11,12} Ormocers, in contrast to resin-based composites, are composed of larger monomer molecules that can reduce the effects of polymerization shrinkage, wear and leaching of monomer (the estrogenic chemical bisphenol-A).¹³⁻¹⁵ Although several previous study have evaluated microleakage or clinical properties of ormocer when they are used as a fissure sealant,¹⁶⁻²¹ no study comparing of ormocer and glass ionomer as a fissure sealant could be found in the literature.

The aim of this study was to evaluate and compare clinical success of two fissure sealants (glass ionomer based; GC Fuji VII Capsule [Fuji VII; GC, Tokyo/Japan] and ormocer based; Admira Seal [AS; Voco, Cuxhaven/Germany]) with respect to the criteria of retention, marginal integrity and the presence of caries during a 2-year period of follow-up.

MATERIALS AND METHOD

Study Design:

This study was designed as a randomized single-blind clinical trial to compare according to the USPHS clinical criteria²² (retention, marginal integrity and presence of caries) of sealants based on glass ionomer and ormocer used to seal permanent first molars [PFMs] during a 2-year period of follow-up. The study was approved by the ethics committee of the Faculty of Dentistry, Ataturk University. Each child and parent was informed of the protocol of the study, and parental informed consent was obtained before the application of fissure sealant.

50 healthy, cooperative (Frank)²³ score 3 (Positive. Acceptance of treatment; at times cautious; willingness to comply with the dentist, at times with reservation, but patient follows the dentist's directions cooperatively) or score 4 (Definitely Positive. Good rapport with the dentist, interested in the dental procedures, laughing and enjoying)]

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Material/ Manufacturer	Composition/Color	Procedure					
Vococid (Voco, Cuxhaven, Germany)	34.5% phosphoric acid gel /blue	Application: Apply for 60 s. Remove by using air-water spray.					
<i>Fuji VII</i> (GC, Tokyo, Japan)	Fluoroaluminium silicate glass, polyacrylic acid, polybasic carboxylic acid/pink	Application: Gently clean the occlusal surface with GC cavity conditioner for 10 s. Wash the surface for 20 s using air-water spray. Dry by blotting with a cotton pellet. Mix for 10 s with a capsule mixer or amalgamator. Use a brush to spread a thin film of Fuji VII capsule directly over into pits and fissure. After placement, when the material starts to lose the glossy appear- ance apply GC Fuji Varnish using a cotton pellet.					
AS (Voco, Cuxhaven, Germany)	Three-dimensionally curing inorganic –organic co-polymers as well as additive aliphatic and aromatic dimethacrylates, highly filled (54%)/opaque white	Etching: Used Vococid Application: Apply and allow penetrating for 15–20s, then light- cured for 30s.					

Table 1.	Materials used in the study	1.
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Fuji VII: Fuji VII Capsule, AS: Admira Seal

children (29 girls, 21 boys) aged 7 to 13 years (mean age: 8.9 ± 1.3 years) who were referred to the Ataturk University, Faculty of Dentistry, Department of Pediatric Dentistry, Turkey. All participants were selected by one researcher (YY). The selection criteria for the study participants were:²⁴⁻²⁶ 1. residence in the same geographical region; 2. The absence of bruxism, malocclusion, or allergy to dental resins or latex; 3. the presence of fully erupted PFMs with deep and retentive pits and fissures; 4. The presence of caries-free PFMs.

The evaluation of caries was performed using an intraoral camera (760,000 pixels, D60204449 RF System, Japan), a DIAG-NOdent device (DiagnoDent, KaVo, Biberach, Germany) and visual examination criteria of Extrand *et al.*²⁷

The plaque and debris on the occlusal surfaces were removed using a rotating brush with free flour prophylaxis paste. Images of all the PFMs were then captured using the intraoral camera and recorded on a computer for make a visual examination, compared to follow-up examination according to USPHS criteria,22 improve the accuracy of evaluations and obtain objective data. The images were evaluated according to visual examination criteria of Extrand et al 27 and the caries criteria of Francescut and Lussi28 on a 17-inch computer monitor by one researcher (CG). The researcher had been previously trained, and the scoring system was calibrated using 20 randomly selected teeth. The Kappa test was used to intra-examiner reproducibility (0.85). These teeth were chosen within the criteria required for this study. A maximum of 30 sec was allowed for the examination of each tooth. The teeth were then isolated with cotton rolls and assessed in terms of caries by the same researcher (YY) using a DIAGNOdent device for improve the accuracy of the evaluations and obtains objective data. The teeth surfaces were dry during the Diagnodent measurement. This device was calibrated using a ceramic plate and the tooth surface under investigation. Teeth that showed DIAGNOdent readings of more than 20 as a cut-off point were not included in the study, according to the instructions of the manufacturer. Two hundred PFMs from the 50 participants were included in the study (Power analysis=0.88).

Each tooth was isolated with standard cotton rolls to avoid saliva contamination and the occlusal surface was dried. Sealants with different organic structures [glass ionomer (Fuji VII) and ormocer (AS)] were performed according to manufacturer's recommendations (Table 1). All fissure sealants were applied by calibrated and experienced one author, and she was assisted by a dental nurse. A splitmouth design was used for the distribution of two fissure sealants. The method to choose which material (Fuji VII or AS) and which tooth would be sealed first (right or left mandibular molar) was randomly carried out. After successfully carrying out the sealing of the affected tooth with the appropriate sealant, the contralateral homologue tooth was sealed with the other material and the opposite quadrants were sealed with the other material to those used first. Both sealants (Fuji VII and AS) that were used in the mandibular and maxillary arch. After the application of sealants, occlusion was checked with a carbon marker. Any premature contacts were removed using a round bur. A fluoride varnish was applied to the dematerialized area that had been caused by acid-etching. Images of the sealants were then captured with the intraoral camera and recorded on the computer.

Fissure sealants were evaluated clinically by one researcher (YY) with respect to the criteria of retention, marginal integrity and presence of caries at follow-up examinations performed 6, 12, 18 and 24 months after treatment (USPHS criteria,²² Table 2). During the follow-up examinations, images of the sealants were captured using the intraoral camera. The marginal integrity of the sealants was assessed using a dental explorer. Evaluation of the retention and presence of caries was performed by matching the first and follow-up pictures of the sealants and with clinical evaluation.

Teeth with a charlie score for the retention or marginal integrity criteria, or a bravo score for the presence of caries were re-sealed or otherwise treated. They were then excluded from the study.

Statistical Analysis

The data were analyzed using the SPSS 15.0 statistics program for Windows at the 5% significance level. The difference between the

Table 2. Evaluation criteria of the sealants (USPHS)²²

Criteria	Sealant position
Retention	Alpha: Present
	Bravo: Partially present
	Charlie: Lost
Marginal integrity	Alpha: Excellent margin with no evidence of crevice
	<i>Bravo</i> : An acceptable margin with a small crevice detected
	Charlie: An unacceptable margin with larger crevice present
Presence of caries	Alpha: Absent
	Bravo: Present

ages of the participants who were treated with different types of fissure sealant was analyzed using one-way ANOVA. Intra-examiner reliability was calculated for each evaluation criterion using the Kappa statistic. Kaplan-Meier survival analysis and Cox's regression models were used to estimate the probability of two sealants success.

RESULTS

The mean kappa value for intra-examiner reliability was calculated as 0.84: 0.86 for retention, 0.82 for marginal integrity, and 0.84 for presence of caries. There was no statistically significant difference in the age of the participants between the sealant groups (P>0.05). Evaluation criteria (USPHS)²² of the sealants were shown in Table 2. The distribution of the evaluation scores of the sealants by time following treatment is shown in Table 3. Table 4 shows the clinical condition of the sealant materials during the follow-up examinations. Thirteen children were lost to the all follow-ups: they were either not interested in further participation or had moved abroad. At the end of the last clinical evaluation period, 88 of 200 sealants had successful (Fuji VII: 52/100 and AS: 36/100) (Table 4).

Retention rates [Alpha (present): 13% and 3% and Bravo (partially present): 80% and 83%] at the end of follow-up for Fuji VII and AS were 93% and 86%, respectively. For retention and marginal integrity between fissure sealants was found similar survival rates (p>0.05). Fuji VII was showed better results than AS for caries preventive effect (Table 3). After 24 months, presence of caries was 16% for Fuji VII and 32% for AS (p<0.05).

DISCUSSION

This study was compared the clinical success of glass ionomer and ormocer based two fissure sealants during 24 month in children. Our study clearly showed that Fuji VII fissure sealant was found better results than AS for caries preventive effect. However, similar survival rates were found for both retention and marginal integrity between fissure sealants.

Considering possible reasons for failure of fissure sealant, Anson *et al*²⁹ listed poor placement technique (inadequate moisture control, not sealing all pits/fissures, inadequate etching, inadequate rinsing and drying, and insufficient curing time); material wear under the forces of occlusion; non-sealant failure (extraction of tooth, proximal caries, and exfoliation); and finally, a combination of these factors. Other variables which influence sealant retention include the position of the tooth in the mouth, the skill of the operator, and

 Table 3.
 The distribution of evaluation scores of the sealants related to the follow-up periods.

Criteria	Time/S	cores	Fuji VII	AS		
	6 months	Alpha	72 (82%)	64 (73%)		
		Bravo	15 (17%)	23(26%)		
		Charlie	1(1%)	1(1%)		
	Tot	al	88 (100%)	88 (100%)		
	12	Alpha	52 (72%)	46 (64%)		
	months	Bravo	20 (28%)	26 (36%)		
		Charlie	0 (0%)	0(0%)		
Retention	Tot	al	72 (100%)	72 (100%)		
	18	Alpha	52 (76%)	46 (70%)		
	months	Bravo	16 (24%)	20 (30%)		
		Charlie	0 (0%)	0 (0%)		
	Tot	al	68(100%)	66(100%)		
	24	Alpha	9 (13%)	2 (3%)		
	months	Bravo	54 (80%)	55 (83%)		
		Charlie	5 (7%)	9 (14%)		
	Tot	al	68 (100%)	66 (100%)		
	6 months	Alpha	85 (97%)	83 (94%)		
		Bravo	3 (3%)	5 (6%)		
		Charlie	0 (0%)	0 (0%)		
	Tot	al	88(100%)	88(100%)		
	12	Alpha	68 (94%)	67 (93%)		
	months	Bravo	4 (6%)	5 (7%)		
		Charlie	0 (0%)	0 (0%)		
Marginal	Tot	al	72(100%)	72(100%)		
İntegrity	18	Alpha	66 (97%)	65 (94%)		
	months	Bravo	2 (3%)	4 (6%)		
		Charlie	0 (0%)	0 (0%)		
	Tot	al	68(100%)	66(100%)		
	24	Alpha	51 (75%)	43 (65%)		
	months	Bravo	17 (25%)	23 (35%)		
		Charlie	0 (0%)	0 (0%)		
	Tot	al	68(100%)	66(100%)		
	6 months	Alpha	85 (97%)	85 (97%)		
		Bravo	3 (3%)	3 (3%)		
	Tot	al	88(100%)	88(100%)		
	12 Alpha		70 (97%)	68 (94%)		
	months Bravo		2 (3%)	4 (6%)		
Presence	Tot	al	72(100%)	72(100%)		
of Caries			68 (100%)	66 (100%)		
	months	Bravo	0 (0%)	0 (0%)		
	Tot	al	68(100%)	66(100%)		
	24	Alpha	57 (84%)	45 (68%)		
	months Bravo		11 (16%)	21 (32%)		
	Tot	al	68(100%)	66(100%)		

Sealant Materials	Number –	Successful (months)			Failed (months)			Lost to Follow-ups (months)					
		6	12	18	24	6	12	18	24	6	12	18	24
Fuji VII	100	84	70	68	52	4	2	0	16	12	12	2	0
AS	100	84	68	66	36	4	4	0	30	12	12	2	0
Total	200	168	138	134	88	8	6	0	46	24	24	4	0

Table 4. Clinical evaluation of the sealant materials according to months

Teeth with a charlie score for the retention or marginal integrity criteria, or a bravo score for the presence of caries were evaluated as failed.

the age of the patient.³⁰ Clinical evidence suggests that sealant loss (retention failure) occurs in two phases: firstly, an initial loss due to faulty technique (such as moisture contamination), followed by a second loss associated with material wear under the forces of occlusion.31 Therefore, it seems reasonable to assume that tooth selection or technique failure at the time of sealant placement were responsible for the majority of partially retained or missing sealants within the first six months of placement. This was most likely due to inadequate moisture control. However, it has been stated that isolation by rubber dam or cotton rolls are equally effective in retention rates.^{32,33} In this study, cotton rolls were used, a technique that has been referred to as partial isolation.³³ It has been stated that absolute isolation is not necessary for the application of sealants as long as extreme care is taken to avoid salivary contamination of the etched surface.34 The factor most likely contributing to sealant failure in the present study may be inadequate moisture control. However, for retention and marginal integrity between fissure sealants was found similar survival rates (p>0.05).

Sly et al 35 demonstrated same results for Fuji VII and Fuji IX at a 12-month follow-up. Kamala and Hegde³⁶ reported that partial or complete retention of the sealant in 80% of the treated teeth in both groups (Fuji III and Fuji VII) at the one-year evaluation. Ganesh and Tandon³⁷ demonstrated that clinical retention of Fuji VII similar to resin based fissure sealant (Concise) in primary and permanent teeth during 24 month. These results were in accordance with our findings. However, other authors have showed lower total retention rates in different evaluation periods for conventional glass ionomer cement used as fissure sealant.^{3,10,38-40} This difference can be related to the properties of Fuji VII. This fissure sealant has better properties regarding superficial wear when compared to conventional glass ionomer cement. In addition, manufacturer reported that a strong and more acid resistant ion exchange layer is created when Fuji VII is applied to tooth surfaces. This 'fused' zone is a combination of glass ionomer and tooth structure and provides an effective seal and excellent protection for tooth surfaces at risk of demineralization. Fuji VII fissure sealant is high-viscosity, low solubility, reduced moisture sensitivity, a tooth-like coefficient of thermal expansion maintaining the marginal seal, releases significant levels of fluoride and easy to use.

The clinical success rate of ormocer based fissure sealant was evaluated in a few studies. Yilmaz *et al* ¹⁶ reported that retention rate is 95% (Alpha: 25% and Bravo: 70%) for AS during 24 months. Dukić *et al*.²¹ stated that total retention rate is 81.5% for AS during 12 months. These results were in accordance with our findings (%3 Alpha and 83% Bravo during 24 months.

The first and follow-up pictures of the sealants and clinical evaluation were evaluated according to the criteria of retention and presence of caries to improve the accuracy of the evaluations and obtain objective data. However, the evaluations of marginal integrity were performed using visual and tactile assessment, as in previous studies, because the marginal integrity cannot be evaluated from images of the teeth.^{24,26} In addition, earlier studies sealant retention was evaluated using visual-tactile assessment. For the present study, clinical evaluation and matching the first and follow-up pictures of the sealants was used to evaluate the retention criteria. Different evaluation ways may have contributed to difference alpha score rates.

Marginal integrity is an important criterion in the evaluation of sealants. In the evaluation of marginal integrity may be effective different organic structures, filler rates and viscosity of sealants. Although the difference was not significant, the highest alpha score rates for marginal integrity in this study were noted in free-resin and high-viscosity sealant (Fuji VII).

A partial loss of material in a sealant causes microleakage which leads to caries development under the sealing material.^{21,41-45} In the evaluation of the presence of caries statistically significant difference was found among the sealants for 24 month. Although, there were no caries lesions on these teeth at baseline, the caries was detected in 44 of the 200 PFMs by visual inspection with magnification during study (16/100 for Fuji VII and 28/100 for AS). Fractured or partially lost sealant leaves deep fissures uncovered or leaves a sharp margin that may lead to the formation of caries.² In the present study, sealant materials were only applied once. It has been stated that prevention against caries provided by sealant materials decreases over time if they are applied only once.^{25,46} In addition, a relevant factor that should be considered when glass ionomer material is studied as fissure sealant is that even after it has been clinically lost, small amounts of sealant are left on the bottom of the fissures and continue to release fluoride.^{11,12} Glass ionomer based materials release a high level of fluoride, ormocer-based sealants release only a low level.47 It has been claimed by the manufacturers that Fuji VII release six times the fluoride as compared to other glass ionomer cements and can be used as a pit and fissure sealant.⁴⁸ In this way, another kind of occlusal surface protection is provided by Fuji VII.

This study focused on the clinical effectiveness of fissure sealants that were based on glass ionomer and ormocer. Further longterm clinical studies are required in order to evaluate sealants that were based on glass ionomer and ormocer with respect to the evaluation criteria used in this study.

CONCLUSIONS

- 1. Fuji VII and AS showed similar survival rates for retention and marginal integrity.
- 2. Fuji VII showed better results than AS for caries preventive effect. Fuji VII sealants may be a better choice for preventing occlusal caries

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