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Comparison Between the Marginal Integrity of a Flowable Giomer and a Conventional Flowable Resin When Used as Sealants for Initially Demineralized Fissures. A Randomized Clinical Study.

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Abstract

Background

Dental caries is one of the most prevalent diseases. Fissure sealants have been proven to prevent the incidence or progression of dental caries provided their adequate placement and longevity.

Purpose

To investigate the marginal integrity of a bioactive resin material compared to a conventional resin-based flowable composite during management of initial carious lesion in adult population over an 18 months period.

Patient and methods

Twenty-four patients with an upper or lower molar that has an ICDAS score 1 or 2 on its occlusal surface, were selected for this study. The patienrs were divided randomly and equally into two groups. Group I was assigned to be sealed with a nano-filled giomer based sealant (Beautifil Injectable X, Shofu Dental Corp.) while Group II was assigned to be sealed with a nano-filled conventional flowable composite (Filtek z350 XT, 3m ESPE). Both sealants were applied after acid conditioning and the application of a bonding agent. The sealants were then evaluated for marginal integrity after six, twelve and eighteen months.

Results

There was a non-significant difference between the two groups. There was a significant difference regarding the marginal integrity within each group after eighteen months.

Conclusion

Both fissure sealants can successfully seal initially carious fissures. However, the marginal integrity of sealants should be evaluated periodically for repair. The nano-filled giomer flowable composite could be promising as a bioactive fissure sealant.

1. Introduction

Dental caries presents itself as one of the most prevalent diseases worldwide. The highest incidence of carious lesions in molars occurs within pits and fissures. While fissure sealants have proved to be effective to prevent the progression of such lesions, there is still fear of

recurrent attacks of dental caries that can cause the loss of marginal seal or the restoration itself[1]. Moreover, demineralized fissures can exhibit progression of the carious lesion if not properly sealed or remineralized.[2]

The medical model in caries management has been prevailing in the past few years. Actual treatment of caries is now advocated rather than the removal of potentially preservable tissues. The fact that dental structures are under a constant cycle of loss and deposition of minerals is a key to reverse initial lesions[3]. Materials containing fluoride, calcium and other minerals have been proposed for such treatment. Other theories that suggested sealing the prone areas and depriving bacteria of their essential nutrition could be a valid solution to favour mineral deposition rather than loss[4].

Fissure sealing materials can be identified in two main categories; namely flowable resins and glass ionomers. The fact that flowable resin have better mechanical properties in terms of strength and wear resistance provides an advantage of longer survival. Glass ionomers on the other hand has superior advantages in terms of fluoride release and recharge and also a chemical bond to the calcium content of tooth structures[5].

Bioactive materials aim to solve the dilemma of choices for the operators. While dentists seek to provide optimal dental care with their applied sealants, it is a difficult choice whether to choose a material to stay or to treat. These materials were proposed to provide mechanical properties close to resins and ion releasing capacities close to glass ionomers while avoiding their drawbacks of wear, solubility and faster degradation[6]. This study aimed to investigate the marginal integrity of a bioactive resin material compared to a conventional resin-based flowable composite during management of initial carious lesion in adult population over an 18 months period. The study tested the null hypothesis that no significant difference would be detected between the two materials at all intervals.

2. Materials and Methods

2.1. Materials used in this study

Two-step etch and rinse adhesive technique was used in this study; it consists of:

Acid etchant:

Scotchbond™ Universal Etchant, containing 32% phosphoric acid.

Bonding agent:

3M ESPE™ Single Bond Universal adhesive, light curing bonding agent was used.

Flowable resin composite materials:

Two different materials were used in this study.

Shofu™ Beautifil Injectable X SL flowable composite

Novel bio-active flowable resin containing nano S-PRG (Surface Pre-Reacted Glass ionomer). Self-levelling high strength flow, visible light cured, radio-opaque flowable composite.

Filtek™ Z350 XT Flowable composite

Conventional resin-based nano-filled flowable composite. A low viscosity, visible light-cured, radiopaque flowable nanocomposite (Shade A3).

Sample size

24 patients aging 18-40 years old were recruited from an outpatient clinic of a well-established hospital. Patients had maxillary or mandibular molars with initially demineralized fissures of ICDAS scores 1 or 2. The diagnosis was confirmed using a VistaCam IX device.

2.2. Ethical Considerations

All participants received information about the study, its aim, procedures, safety precautions, benefits and the expected duration of participation. The protocol of the current study was registered in (www.clinicaltrials.gov) database, with unique identification number (NCT04052802). All procedures performed in this study, involving human participants, were in accordance with the ethical standards of Research Ethics Committee of Faculty of Dentistry, Cairo University (CREC) in April, 2019 with ethical approval number (19-7-48)

2.3 Randomization and grouping

Patients were randomly assigned to either test or control group using computer generated randomization (www.random.org) which was performed by the co-supervisor. Since the study design was a randomized controlled trial where assessment of the 2 groups as two parallel groups was done, which helped to reduce the intra-individual variation.

2.4. Application of fissure sealants

The selected molars were isolated using a rubber dam and moisture was controlled by a saliva ejector and a high-volume suction. The occlusal surfaces were first cleaned by pumice and a low-speed polishing brush. The surface was then flushed using an air-water stream and dried. 32% phosphoric acid was applied to the fissures for 20 seconds followed by rinsing and drying. A microbrush was used to apply the bonding agent to the fissures followed by agitation and air-thining for 5 seconds then cured for 20 seconds. Each fissure was sealed by its corresponding resin in a continuous flow, then a brush was used to remove any

air inclusions. The resin was then cured according to the manufacturers' instructions.

2.5. Clinical Evaluation

Clinical evaluation was done immediately, after six months, twelve months and 18 months. The two assessors, who were blind to the type of material applied; evaluated all sealants independently. Materials were sufficiently similar in appearance (shade A3) to allow the examiners to be blind. The margins of all sealants were evaluated using the World Dental Federation (FDI) clinical criteria with the aid of specialized set of two blunt single ended FDI probes[7]. To classify the marginal gaps, these two special probes are available with tip diameters of 150 and 250 μm. The use of a sharp explorer for gap or caries detection is not recommended as this may lead to debonding causing a loose filling which requires replacement[8]. At each recall, clinical examinations were performed without reference to previous records. The sealants were ranked according to FDI criteria into five scores as follows; score 1: clinically very good, score 2: clinically good, score 3: clinically sufficient/ satisfactory, score 4: clinically unsatisfactory (but repairable), and score 5: clinically poor (replacement necessary)[9]. If there was any disagreement between the two investigators at each evaluation period, a consensus was reached after discussion.

2.6. Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0**. (**Armonk, NY: IBM Corp**).** Qualitative data were described using number and percent. **Mann Whitney test was used** for ordinal variables, to compare between two studied groups. **Friedman test** was used for ordinal variables to compare between more than two periods and **Post Hoc Test** (**Dunn**'s**)** for pairwise comparisons. Significance of the obtained results was judged at the 5% level.

3. Results

3.1 Intergroup comparison

A comparison between the two groups was statistically analyzed according to the measurements made by the FDI explorers as shown in table (1). The results in this study supported the null hypothesis that there is no significant difference between the two groups in terms of marginal integrity at all intervals. However, there was a significant difference between baseline and after twelve and eighteen months for group (I) and after eighteen months for group (II).

Table (1): Table showing the comparison between the GIOMER based sealant and conventional resin sealant according to FDI

FDI	Group I (n = 11)		Group II (n = 11)		p
	No.	%	No.	%	
Baseline					
Score (1)	11	100.0	11	100.0	
Score (2)	0	0.0	0	0.0	
Score (3)	0	0.0	0	0.0	1.000
Score (4)	0	0.0	0	0.0	
Score (5)	0	0.0	0	0.0	
6 months					
Score (1)	8	72.7	7	63.6	
Score (2)	3	27.3	3	27.3	
Score (3)	0	0.0	1	9.1	0.652
Score (4)	0	0.0	0	0.0	
Score (5)	0	0.0	0	0.0	
12 months					
Score (1)	4	36.4	5	45.5	
Score (2)	5	45.5	5	45.5	
Score (3)	2	18.2	1	9.1	0.606
Score (4)	0	0.0	0	0.0	
Score (5)	0	0.0	0	0.0	
18 months					
Score (1)	4	36.4	5	45.5	
Score (2)	2	18.2	2	18.2	
Score (3)	3	27.3	3	27.3	0.606
Score (4)	0	0.0	0	0.0	
Score (5)	2	18.2	1	9.1	

3.2 . Intragroup comparisons

A comparison was made for each group at different follow-up intervals according to their FDI scores as shown in table (2). The results of group (I) yielded a non-significant difference at (**p0**=0.509) between baseline and six months. Comparison between the scores at twelve months and baseline showed a statistically significant difference at (p=0.048). Comparison between the eighteen months interval and baseline was statistically significant with (p=0.003). Statistical analysis of this group at all intervals showed a statistically significant difference at (p=<0.001).

In group II, statistical comparison between baseline and the follow-up after six months showed a non-significant difference at (p=0.283). Comparison of twelve months interval to the baseline values still showed a non-significant difference at (p=0.099). After eighteen months, the values yielded a significant difference at (**p0**=0.010). Statistical comparison of this group at all intervals showed a significant difference at (p=0.002).

Table (2): Table showing the comparison between the measurements at baseline, 6 months, 12 months and 18 months according to FDI scoring in each group

FDI	Baseline		6 months		12 months		18 months		p
	No.	%	No.	%	No.	%	No.	%	
Group I (n = 11)									
Score (1)	11	100.0	8	72.7	4	36.4	4	36.4	
Score (2)	0	0.0	3	27.3	5	45.5	2	18.2	
Score (3)	0	0.0	0	0.0	2	18.2	3	27.3	<0.001*
Score (4)	0	0.0	0	0.0	0	0.0	0	0.0	
Score (5)	0	0.0	0	0.0	0	0.0	2	18.2	
p_0			0.509		0.048*		0.003*		
Group II (n = 11)									
Score (1)	11	100.0	7	63.6	5	45.5	5	45.5	
Score (2)	0	0.0	3	27.3	5	45.5	2	18.2	
Score (3)	0	0.0	1	9.1	1	9.1	3	27.3	0.002*
Score (4)	0	0.0	0	0.0	0	0.0	0	0.0	
Score (5)	0	0.0	0	0.0	0	0.0	1	9.1	
p_0			0.283		0.099		0.010*		

4. Discussion

In this study, the diagnosis of initially carious lesions was performed by the International Caries Detection and Assessment System (ICDAS-II) and then confirmed by a fluorescence-based camera (VistaCam iX). This is justified by the fact that ICDAS-II system was found to have high sensitivity but low specificity when tested[10]. To overcome the drawbacks of visual inspection, the fluorescence- based camera (VistaCam IX) was used to confirm the ICDAS-II scores[11].

The complex environment of the oral cavity renders any restorative material vulnerable to degradation. A material has to withstand masticatory forces in different directions as well as the friction produced by such activity. The diversity of fluids that exist in this environment, such as saliva, acids, buffers and different solutions introduced through diet, have different effect on restorative materials[12]. Several factors affect the reaction of each material to these stimuli, such as the type of fillers, the amount of fillers in the material, the quality of adhesion, the degree of polymerization, the mechanical strength and elastic modulus[13]. Although increasing the filler load can improve the mechanical properties of a material and increase its resistance to different stimuli, it would also result in an increase in viscosity. This would hinder the ability of a material used as a fissure sealant to effectively penetrate the fissures and create an adequate seal. The use of micro and nano-scale filler sizes can improve the mechanical properties of a material while preserving acceptable handling properties[14].

Fissure sealants applied by dental practitioners are always prone to have defects such as porosities, micro gaps, or micro cracks. Such defects seem to be unavoidable due to the limitations or the human eye to spot all the defects during application. Incorporation of air, adaptation defects or micro-cracks formed due to polymerization stress or during finishing of a restoration can all occur during restorative procedures. Such defects can then propagate causing wear and material loss[15].

The results in this study supported the null hypothesis that there is no significant difference between the two groups in terms of marginal integrity at all intervals. However, there was a significant difference between baseline and after twelve and eighteen months for group (I) and after eighteen months for group (II).

These findings were consistent with the study conducted by Askarizadeh et al., which revealed that fissure sealant margins could deteriorate over time[16]. This was explained by the fact that resin restorative materials could show a degree of water sorption and solubility over time. The disadvantage of low molecular weight (HEMA) content in the bonding agent is its degree of water uptake and solubility which could affect the marginal integrity of fissure sealants[17]. Both materials used in this study have BisGMA and TEGDMA monomers which are hydrophilic and will therefore, absorb water. Flowable resins tend to have a greater proportion of such matrix to allow them to sufficiently flow, which increases the possibility of water sorption. In addition, giomers have pre-reacted SPRG filler particles which act as fluoride releasing and recharging units, but also this increases the level of diffusing and water sorption within the material[18]. Another study comparing nano-filled sealants to micro-filled sealants also revealed similar findings stating that all fissure sealants exhibit marginal gaps that increase by time. It was explained by the fact that even after acid conditioning, some areas of enamel remain unetched which affects the quality of bonding to these areas[19].

5. Conclusion

Within the limitations of this study we can conclude that Fissure sealing is an effective and conservative treatment for initially carious fissures with ICDAS scores 1 and 2. We can also deduct that GIOMER based flowable resins are a promising alternative to conventional flowable resins when used as fissure sealants as they have the advantage of re-mineralization potentials. Continuous assessment of fissure sealants is important due to the degradation that occurs on the margins.

Authors' Contributions

A.K managed the preparation of the sample, randomization, the application of the materials and the recall for follow up and wrote the manuscript

H.T assisted in the implementation of the study and revised the manuscript

M.B was the supervisor of the study and held the randomization information

All authors have read and approved the manuscript

Informed consent

The patient accepted and signed a written informed consent to this treatment protocol.

Conflict of interest

The authors declare that they hold no competing interests.

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