

Flowable GIOMER Vs Conventional Flowable Composite For Retention And Prevention Of Caries Recurrence When Used As Sealants For Initially Demineralized Fissures. A Randomized Clinical Trial

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Abstract

Aim: to investigate the retention and potential to prevent lesion progression 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.

Methodology: Twenty-four subjects with an upper or lower molar that has an ICDAS score 1 or 2 on its occlusal surface, were selected for this study. The subjects were divided randomly and equally into two groups. Group I was assigned to be sealed with a nano-filled giomer based sealant (Beautiful 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 retention and caries progression after six, twelve and eighteen months.

Results: Most sealants remained in-situ after eighteen months. There was a non-significant difference between the two groups in terms of retention or caries progression. Only one sealant from each group progressed to ICDAS score 3.

Conclusions: Both fissure sealants can successfully seal initially carious fissures. The nano-filled giomer flowable composite could be promising as a bioactive fissure sealant.

Keywords: Fissure sealant, medical model, S-PRG fillers, resin sealant

INTRODUCTION

Dental Caries presents itself as one of the most widely spread diseases worldwide. Being a multifactorial disease, the consistent present of two factors, the host and bacteria, awaits sugars and sufficient time to complete the chain. Once the chain is complete, bacteria attached on the naturally formed pellicle on the tooth surface begins to breakdown the supplied sugar producing acids. The well supplied bacteria multiply and invites more bacterial attachment. Eventually a more acidic medium forms on the surface of enamel resulting in demineralization of the calcified tissues. Subsequently, enamel breaks down and bacteria spreads into deeper tissues and the result; dental caries.^[1]

The prevalence of dental caries began to decline since the 1970s. This was attributed to the rise of awareness which led to better oral hygiene measures and improvement of living standards. But such improvement still was not enough to eliminate the disease. A WHO report revealed that caries among 12-year-olds was moderate to high in south America and eastern Europe.^[2]

Caries occurs in pits and fissures due to their retentive nature and the difficulty in completely removing all food debris with conventional oral hygiene measures. The high incidence of carious lesions in occlusal pits and fissures of molars directed dental professionals towards the introduction of fissure sealants. Fissure sealants are materials that are applied to fill narrow pits and fissures to prevent the stagnation of food debris in such spaces.^[3]

Bio-active resin materials aim to possess the mechanical properties of resin materials in terms of higher wear resistance and dimensional stability over time. They also aim to mimic the biological activity of glass ionomers in terms of ion recharge and release. These new bio-active resin materials, with their lower particle size and better adaptability and polishability, might offer a substantial addition as

fissure sealants if they fulfil the requisities satisfactory mechanical properties of resins and of ion recharge and release of glass ionomers.^[2]

MATERIALS AND METHODS

Materials

All materials brand names, description and specifications are listed in table (3)

1. Bonding system:

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

1.1. Acid etchant:

Scotchbond™ Universal Etchant, containing 32% phosphoric acid.

1.2. Bonding agent:

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

2. Flowable resin composite materials:

Two different materials were used in this study.

2.1. 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.

2.2. Filtek™ Z350 XT Flowable composite

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

Methods

Eligibility criteria

The study included 24 patients of ages 18 to 40 years old who had initially demineralized fissures in permanent molars of the maxilla or the mandible and a good oral hygiene. Patients who had medical problems or pregnancy were excluded from the study. The study also excluded patients with bruxism or allergy of resin-based materials.

Randomization, Sequence generation and blinding

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.

The setting of the study is a single blinded study. Since blinding of the operator and the receiving patients was not applicable, the assessors and the statistician were blinded to the intervention group assigned to the patients.

Twenty-four participants selected for this study, were randomly allocated to two groups (N=12), where Group 1 (Intervention): Giomer, Beautifil Flow Plus X, Group 2 (Control): Conventional flowable resin, “Z350 XT Flowable Composite”.

Diagnosis of initial carious lesions

International caries detection and assessment system (ICDAS-II):

Selected patients were first treated with scalling and polishing procedures. Careful visual inspection of initially demineralized carious lesions was then carried out under good illumination on the clean, dry tooth surfaces with the use of a mirror and a blunt explorer. Occlusal caries lesions were detected and classified according to the International Caries Detection and Assessment System (ICDAS-II) criteria^[4].

Assessment by VistaCam iX fluorescence-based camera

The diagnosis of the selected pits and fissures was then confirmed by using the VistaCam iX fluorescence-based camera. The results were automatically interpreted by (DBSWIN, D`urrDental) software then the control ring was pressed in order to freeze the image taken by the camera. The software shows the region of the teeth that emits fluorescence and an outcome value in different colors with possible reading values from 0–5. This helps to define the caries lesions extension according to the manufacturer’s recommendation.^[5]

Material Application

Application of etch and rinse adhesive technique

The selected molars were carefully isolated with rubber dam. The occlusal surfaces of the teeth were cleaned by pumice and a polishing brush. They were then etched with 32% phosphoric acid gel for 15 seconds, rinsed thoroughly with an air/water spray for 15 seconds using a suction at the same time, then the excess water was blotted using a mini sponge to remove any trapped water. Then immediately the bonding agent was applied by a small bond brush, gentle air thinning for 5 seconds to produce a finer uniform layer, then light cured for 10 seconds with LED light cure at almost zero distance in standard mode of intensity 1200 mW/cm², according to the manufacturer’s instructions, regularly checked using a radiometer.

Application of flowable resins as fissure sealants

Both giomer filled flowable composite and conventional resin-based nano-filled flowable composite was delivered directly from the dispensing tip of its syringe into the pits and fissure. A sharp explorer was used to remove any air bubbles and obtain uniform flow of the material followed by curing for 20 seconds using LED light cure at almost zero distance. The fissure sealant was then finished and polished using a finishing and polishing kit. Finally, the occlusion was checked using an articulating paper and occlusal interferences were eliminated.

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.

Clinical assessment of sealant retention and ICDAS II score

Sealant retention was assessed visually after dryness of occlusal surfaces by air for 5 seconds. Scoring was given (n%) as complete retention (score=1), partial loss (score=2) or complete loss (score=3) [6]. The assessors examined the areas adjacent to the margins on wet and dry conditions. Scoring of the results was made according to ICDAS II criteria as they were previously calibrated.

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.

RESULTS

1. Comparison between GIOMER based resin and conventional resin according to sealant retention

1.1 Intergroup comparison

Comparison was made between the two groups according to retention. Frequencies (n) and percentages (%) of the evaluated sealants are presented in table (1). Score (1) denoted complete retention; score (2) referred to partial loss of the sealant while score (3) indicated complete loss.

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

Retention	Group I (n = 11)		Group II (n = 11)		p
	No.	%	No.	%	
Baseline					
Score (1)	11	100.0	11	100.0	1.000
Score (2)	0	0.0	0	0.0	
Score (3)	0	0.0	0	0.0	
6 months					
Score (1)	11	100.0	10	90.9	0.748
Score (2)	0	0.0	1	9.1	
Score (3)	0	0.0	0	0.0	
12 months					
Score (1)	9	81.8	9	81.8	1.000
Score (2)	2	18.2	2	18.2	
Score (3)	0	0.0	0	0.0	
18 months					
Score (1)	7	63.6	9	81.8	0.478
Score (2)	2	18.2	1	9.1	
Score (3)	2	18.2	1	9.1	

p: p value for comparing between the two studied groups

1.2. Intragroup comparisons

Intra group comparisons was made for each group using Friedman test and calculation of significance (p-value) at (5%) as shown in table (2).

Table (2): Table showing the comparison between retention scores at baseline, 6 months, 12 months and 18 months intervals in each group

Retention	Baseline		6 months		12 months		18 months		p
	No.	%	No.	%	No.	%	No.	%	
Group I (n = 11)									
Score (1)	11	100.0	11	100.0	9	81.8	7	63.6	0.073
Score (2)	0	0.0	0	0.0	2	18.2	2	18.2	
Score (3)	0	0.0	0	0.0	0	0.0	2	18.2	
Group II (n = 11)									
Score (1)	11	100.0	10	90.9	9	81.8	9	81.8	0.163
Score (2)	0	0.0	1	9.1	2	18.2	1	9.1	
Score (3)	0	0.0	0	0.0	0	0.0	1	9.1	

p: p value for comparing between the different studied periods

2. Comparison between the GIOMER based flowable resin and conventional based resin used as sealants according to ICDAS II values of the evaluated fissures

2.1. Intergroup comparison

Comparison was made between the two groups according to ICDAS II scores. Frequencies (n) and percentages (%) of the evaluated sealants are presented in table (3). ICDAS II system depends on visual scores ranging from 0 to 6. Score (0) denotes sound enamel while score (6) denotes a distinct cavity with involved dentin. The molars selected for this study had scores (1) or (2) denoting the first visual change in enamel such as opacity or discoloration visible at the entrance to the pit or fissure seen after prolonged air drying or visible when both wet and dry. Scores (3) to (6) would refer to lesion progression.

Table (3): Table showing the comparison between the GIOMER based sealant and conventional resin sealant according to ICDAS scoring

ICDAS	Group I (n = 11)		Group II (n = 11)		p
	No.	%	No.	%	
Baseline					
Score (1)	1	9.1	4	36.4	0.300
Score (2)	10	90.9	7	63.6	
Score (3)	0	0.0	0	0.0	
6 months					
Score (1)	5	45.5	3	27.3	0.478
Score (2)	6	54.5	8	72.7	
Score (3)	0	0.0	0	0.0	
12 months					
Score (1)	5	45.5	1	9.1	0.151
Score (2)	6	54.5	10	90.9	
Score (3)	0	0.0	0	0.0	
18 months					
Score (1)	5	45.5	2	18.2	0.332
Score (2)	5	45.5	8	72.7	
Score (3)	1	9.1	1	9.1	

p: p value for comparing between the two studied groups

2.2 Intragroup Comparison

ICDAS II scores analysis was done for each group at different intervals as shown in table (4).

Table (4) Table Showing the comparison between the ICDAS scoring at baseline, 6 months, 12 months and 18 months in each group

ICDAS	Baseline		6 months		12 months		18 months		p
	No.	%	No.	%	No.	%	No.	%	
Group I (n = 11)									
Score (1)	1	9.1	5	45.5	5	45.5	5	45.5	0.217
Score (2)	10	90.9	6	54.5	6	54.5	5	45.5	
Score (3)	0	0.0	0	0.0	0	0.0	1	9.1	
Group II (n = 11)									
Score (1)	4	36.4	3	27.3	1	9.1	2	18.2	0.234
Score (2)	7	63.6	8	72.7	10	90.9	8	72.7	
Score (3)	0	0.0	0	0.0	0	0.0	1	9.1	

DISCUSSION

Giomers are basically composed of surface pre-reacted glass ionomer particle fillers impregnated within a resin matrix. The production of these fillers commences with a traditional acid-base reaction between polyacrylic acid and a mixture of alumina, silica, aluminum fluoride and calcium fluoride of glass ionomer but with more water to prevent the existence of unreacted glass particles. The reaction continues for several days under pressure in a temperature up to 70 degrees Celsius. The excess water is then eliminated by freeze drying and the resultant xerogel is then milled to form PRG particles. After milling is completed the surface hydrogel is then ready for treatment. The resultant particles are either full reaction particles (FPRG) or surface reaction particles (SPRG). FPRG particles are not exposed to further treatment while SPRG particles are subjected to a silane coupling agent; γ -methacryloxypropyl trimethoxysilane^[7]. The aim of this treatment is to protect and reinforce the surface hydrogel and enhance the adhesion between the fillers and the resin matrix. The silicon dioxide layer formed by this reaction is porous, which is an important aspect to allow the diffusion of ions in both directions; from the particles to the matrix and vice versa. The particles are then dispersed in a matrix composed of BisGMA and TEGDMA which have suitable viscosities for clinical handling as well as stability in the oral environment^[8].

A nano-filled flowable resin composite (Filtek Z350 XT flowable) was used in the current study as the comparator material. As it was shown that it had reduced polymerization shrinkage which consequently improved the marginal integrity and the mechanical properties, such as tensile strength, compressive strength and resistance to fracture, due to high filler loading and distribution through nano-clusters technology^[9].

In this study, we evaluated the applied sealants for retention after six, twelve and eighteen months. The sealants were evaluated for either being totally retained, partially lost or completely lost^[10]. The results showed that the majority of sealants were totally retained at the end of the evaluation as 63.6% of the giomer sealants and 81.8% of the flowable composite sealant had total retention. The percentage of sealants that remained in situ were 81.8% for the giomer based sealant and 91.9% for the resin-based sealant. There was a non-significant difference between the two groups at all intervals. This comes in agreement with the meta-analysis conducted by Kühnisch et al.^[11], which stated an average survival rate of 83.1% for light polymerized materials used as fissure sealants. However, by the end of eighteen months, the giomer-based sealant had two partial losses and two total losses while the resin-based sealant had only one for each. This comes in agreement with the study conducted by Ercan Bekmezoğlu et al.^[12] who showed that giomer sealants had comparative retention rates with other types of sealants when used with the same technique.

However, these results were contradicted by the study conducted by Penha et al.^[13] which showed that giomer based sealants had less retention over time when compared to resin based sealants in a split-mouth study. Sharma et al.^[15] also obtained similar results when a giomer sealant was compared with a resin sealant for 12 months. Ntaoutidou et al.,^[10] also showed poor retention rates of giomer fissure sealants when used with self-etching primers. The use of an etch and rinse protocol in this study may have improved the retention of the giomer material as in previous studies, the giomer sealant was always used in combination with a self-etch primer.

In our study, fissure sealants were applied on initially carious lesions. The results in our study showed promising effects of pit and fissure sealants to arrest the ongoing process of dental caries over a period of eighteen months. Most of the teeth remained at scores 1 and 2 at all intervals of the study. Only one tooth from each group progressed to score 3 and was accompanied by sealant loss. The results came in agreement with the study performed by Tahani et al.,^[16] which evaluated caries progression after twelve months when applied on molars with ICDAS scores 0 to 2. It showed that the risk of caries progression could be three times higher when the sealant is lost and that sealant retention is essential for caries prevention to occur. Kasemkhun et al.,^[17] also revealed that the application of bonding agents under fissure sealants enhanced the retention of fissure sealants when used on initially carious lesions with scores 2 to 4. It was also concluded that this was the reason of caries arrest in such fissures as caries progress was rarely discovered after two years. Muñoz-Sandoval et al.,^[18] also tried to seal fissures with ICDAS score 3. It was stated that fissure sealing is a predictable effective treatment for non-cavitated fissures and that it can reduce the chair-time and experienced pain and fear for such cases.

On the contrary, these findings were in contradiction with the study by Berdouses et al.,^[19] which pointed that sealing carious fissures has a greater probability of sealant loss. It was also stated that those fissures would inevitably progress to cavities by time. This could be due to the different methodology used in this study as the sample size was massive, the isolation was done by cotton rolls and no adhesive was used.

The findings in our study also showed a decrease of scoring from 2 to 1 in a few samples at the six months interval of the giomer group. Although the change was not statistically significant, it could show a promising effect of such material when used as a fissure sealant. This effect did not appear to progress or change during the following check-ups. These findings could be explained by the study conducted by Salmerón-Valdés et al.,^[20] which showed that giomer fissure sealants could effectively release fluoride with the highest concentration released initially. It also showed that gomers could efficiently perform the recharge and release mechanism over time.

CONCLUSION

- 1- Fissure sealing is an effective and conservative treatment for initially carious fissures with ICDAS scores 1 and 2.
- 2- Both GIOMER based resin and conventional resin were able to prevent caries progression for a period of 18 months.
- 3- 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.

RECOMMENDATIONS

- 1- Careful examination of fissures is essential to seal initially carious fissures at early stages.
- 2- Further clinical trials are needed to distinguish the re-mineralizing effect of the novel GIOMER based sealants.

Conflict of interests

There was no conflict of interest for any of the authors

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