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One-Year Clinical Evaluation of a Glass Carbomer Fissure Sealant, a Preliminary Study

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Abstract - *Glass Carbomer® is a new generation of restorative material developed from glass-ionomer cements with possiblity of gradual mineralization into fluorapatite. The aim of this clinical trial was to investigate the retention of Glass Carbomer® fissure sealant after 12 months, in comparison to a commonly used conventional resin-based sealant. Forty-eight teeth in 24 patients [mean (SD) =8 (2.3) years] with well-delineated fissure morphology were randomly divided into two equal groups and sealed with Bis-GMA resin-based Helioseal F (group A, Ivoclar Vivadent, Liechtenstein) and Glass Carbomer (group B, Glass Carbomer® Sealant, Glass Carbomer Products, Leiden, Netherlands) using the split mouth design. Materials were placed and set according to the manufacturer's instructions using a polymerization unit Bluephase 16i (Vivadent, Liechtenstein). Complete sealant retentions in both groups were 100% and 75% after 6 and 12 months of clinical service, respectively. There were there were no secondary caries lesions in both groups after 6 months; two new carious lesions were detected in both groups after 12 months. The Mann-Whitney U test revealed no significant difference between the two groups at both evaluations points (P>0.05). Glass Carbomer® material showed a similar retention rate when compared with a resin-based sealant. Future studies are required to examine the long-term performance of Glass Carbomer® sealants.*

KEYWORDS**:** Glass Carbomer, Fluor-Hydroxyapatite, Bis-GMA resin sealant

INTRODUCTION

Pit and fissure sealants play a critical role in preventing occlusal caries in primary and permanent dentition[1]. The most commonly used sealant material is a resin composite[1-3]. Glass Ionomer Cements (GICs) also offer an alternative[4]. In order to achieve the maximum caries preventive effect on occlusal surfaces, dental sealants should have the following properties:

1. Ideal adhesion of material should be maintained during setting and function, including the challenges of both thermal and mechanical cycling.
2. Complete retention of the sealant material in the occlusal fissures in long-term depends mainly on the minimal/absence of dimensional changes.
3. Resistance to wear and fracture
4. Ease of use, including handling and placement
5. Exhibit powerful caries preventive characteristics. Inclusion of fluoride ions in the material may be beneficial on the prevention of developing carious lesions, and the remineralization of any demineralized enamel adjacent to the sealant.[3]

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GICs have different indications, providing advantages compared to classic resin-based sealant materials, including easier bonding and handling, and continuous in-vivo fluoride release[5,6]. However, previous studies have shown significantly lower retention rates compared to resin-based sealants[7,8]. In general, the mechanical properties of GICs are inferior to resin-based materials. The caries preventive properties of glass ionomer sealants are of interest to clinicians and previous studies have shown different fluoride release and preventive effects [7, 9-12]. It has been suggested that the presence of material remnants in the fissures, after the loss of the sealant, can maintain caries prevention [10, 13, 14].

Glass Carbomer® is monomer-free carbomised nano-glass restorative cement developed from traditional GIC, which contains nano-sized powder particles of fluorapatite and hydroxyapatite. The advantages of Glass Carbomer®, compared to conventional GICs, include significantly better mechanical and chemical properties[15-19] (strength, share, wear, acid resistance, and remineralization power) and command setting through the application of heat with a LED-curing device. The heat generated using a LED-curing device has been shown to accelerate the setting process of glass-ionomers[20], increase their compressive strength[21,22], and decrease microleakage formation [23]. In particular, enamel shear bond strength of Glass Carbomer material was reported to be comparable or higher than conventional GIC [24]. Additionally, there are some indications that these materials might be capable of transition into apatite and enamel like matrial [25].

The aim of the present study was to investigate the retention rate and secondary caries incidence of Glass Carbomer® fissure sealant after six and twelve months of clinical placement, and to compare that with a conventional resin-based sealant (Helioseal F).

Null hypothesis

The null hypothesis for this study had two parts.

H01: There is no difference between the retention rate of a Glass Carbomer® fissure sealant and a conventional resin-based sealant (Helioseal F) after 6 and 12 months of clinical service.

H02: There is no difference between the incidence of secondary caries after using a Glass Carbomer® fissure sealant and a conventional resin-based sealant (Helioseal F) after 6 and 12 months of clinical service.

MATERIALS AND METHODS

After ethics committee approval, informed consents were received from all parents of participating children. Twenty-four patients with an average age of 8 (2.3) years were included in the study. All molars included were fully erupted with their contra-lateral tooth present. Clinical examination, and where necessary radiographic examination, established that the molars were caries free, with the absence of mobility caused by periodontal disease, and with no evidence of hypoplasia or a history of the previous sealant application.

Application of fissure sealants

Forty-eight teeth with well-delineated fissure morphology were equally divided into two groups of 24 and sealed with either Bis-GMA resin-based Helioseal F (Group A, Ivoclar Vivadent, Liechtenstein) or Glass Carbomer® Sealant (Group B, Glass Carbomer Products, Leiden, Netherlands). The split-mouth design was used after random allocation using a random number's table. Each group consisted of 18 first and 6 second permanent molars.

Complete isolation of teeth was performed similarly in both groups using a rubber dam. In group A, the occlusal surface of each tooth was cleaned with pumice, washed and dried, and isolated. The teeth were etched for 30 seconds in group A with 37.5% phosphoric acid (Kerr Etchant, Kerr, Orange, CA, USA). Enamel was rinsed and dried for 20 seconds. The molars in group A sealed with Helioseal F and after approximately 15 seconds the sealant was cured with a polymerization light for 20 seconds. According to the manufacturer, the monomer matrix consists of Bis-GMA, urethane dimethacrylate, and triethylene glycol dimethacrylate (58.6 weight%). The fillers are highly dispersed silicon dioxide and fluorosilicate glass (40.5 weight%). Additional contents are titanium dioxide, stabilizers and catalysts (< 1 weight%).

Teeth in group B sealed with Glass Carbomer®. In group B, after cleaning with pumice, the enamel was conditioned with a dentin conditioner (Tooth cleaner; EDTA solution, Glass Carbomer Products, Leiden, Netherlands) for 20 seconds, rinsed, dried for 20 seconds and kept isolated. Subsequently, the Glass Carbomer material was applied and set with a polymerization unit curing light (60 degrees) for 60 seconds. The materials for this study were used according to the manufacturer's instructions using the polymerization unit Bluephase 16i (1600 mW/cm2, Ivoclar Vivadent, Liechtenstein).

Assessment of sealant retention and carious lesions

The evaluation criteria of Kilpatrick et al. [26] for the retention of the sealants were used. The sealant retention was classified as:

- Type 1-intact sealant
- Type 2-1/3 of sealant missing
- Type 3-2/3 of sealant missing
- Type 4-whole sealant missing.

Two calibrated investigators who previously had shown good agreement (Kappa> 0.85) in evaluating the molar occlusal surfaces evaluated all sealed surfaces. In the cases which were initially rated differently, a mutual agreement was found and recorded. The presence of new carious lesions was evaluated and recorded in two categories: 1- absent and 2- present.

The presence of Glass Carbomer® material remnants in fissures after the loss of sealant was detected with a Scanning Electron Microscope (SEM) (XL30, Philips, Eindhoven, The Netherlands). Impressions with a polyvinylsiloxane impression material of the Glass Carbomer®-sealed teeth were taken to obtain replicas of occlusal surfaces. For that purpose, the impression was taken and poured in acrylic resin (CitoFix Kit, Struers A/S, Ballerup, Denmark). The obtained replicas were analysed with SEM. The data obtained were statistically analysed using the non-parametric Mann-Whitney U test and the significance level was set at 0.05.

RESULTS

Results showed the retention rate in-group A and B was 100% after six months of clinical service (Table 1); there were no secondary caries lesions in either group (Table 2). After 12 months of clinical service, examination revealed that complete retention in both groups was 75% (Table 1) and only 2 new carious lesions was detected in each group (Table 2). The Mann-Whitney U test revealed no significant statistical difference between the groups (P>0.05) and both null hypothesis for this study were accepted.

Figure 1 shows an SEM image of a Glass Carbomer® fissure sealant material in a permanent molar. Figure 2 presents the fracture of a Glass Carbomer® sealant in the fissure. The fracture occurred within the Glass Carbomer® material. In figure 3a, a good surface adaptation of the Glass Carbomer sealant to the enamel tissue is presented. It is not possible to see the interface transition between the material and enamel. Closer examination of the structure shows many particles with a hexagonal shape. These are highlighted in figure 3b. Fluorapatite (FAP) often crystallizes in a hexagonal habit with characteristic 120 degrees angle between the faces. The results are therefore, consistent with the process of Glass Carbomer® undergoing mineralization to FAP, which may be aided by the presence of nano-crystals of FAP and hydroxyapatite that act as seeds for this process.

DISCUSSION

The present study compared a Glass Carbomer® sealant to a resin sealant material, which served as a control group, and findings were comparable to previously published investigations[11,27,28]. The Glass Carbomer® sealant showed

Table 1 *Sealant retention rate after 6 and 12 months*

Sealant material	Sealant retention after 6 months according to the evaluation criteria of Kilpatrick et al.[26]					Mann-Whitney (p value)
	1	2	3	4	Total	
Glass Carbomer, N (%)	24 (100)	0	0	0	24 (100)	1.0
Helioseal F, N (%)	24 (100)	0	0	0	24 (100)	
Total, N (%)	48 (100)	0	0	0	48 (100)	
	Sealant retention after 12 months according to the evaluation criteria of Kilpatrick et al.[26]					
	1	2	3	4	Total	
Glass Carbomer, N (%)	18 (75)	0	6 (25)	0	24 (100)	p>0.05
Helioseal F, N (%)	18 (75)	1 (4.2)	5 (20.8)	0	24 (100)	
Total, N (%)	36 (75)	1 (2.1)	11 (22.9)	0	48 (100)	

Table 2 *Incidence of new carious lesions after 6 and 12 months*

Sealant material	New carious lesions after 6 months			Mann-Whitney (p value)
	NO	Yes	Total	
Glass Carbomer, N (%)	24 (100)	0	24 (100)	1.0
Helioseal F, N (%)	24 (100)	0	24 (100)	
Total, N (%)	48 (100)	0	48 (100)	
	New carious lesions after 12 months			
	No	Yes	Total	
Glass Carbomer, N (%)	22 (91.7)	2 (8.3)	24 (100)	p>0.05
Helioseal F, N (%)	22 (91.7)	2 (8.3)	24 (100)	
Total, N (%)	44 (91.7)	4 (8.3)	48 (100)	

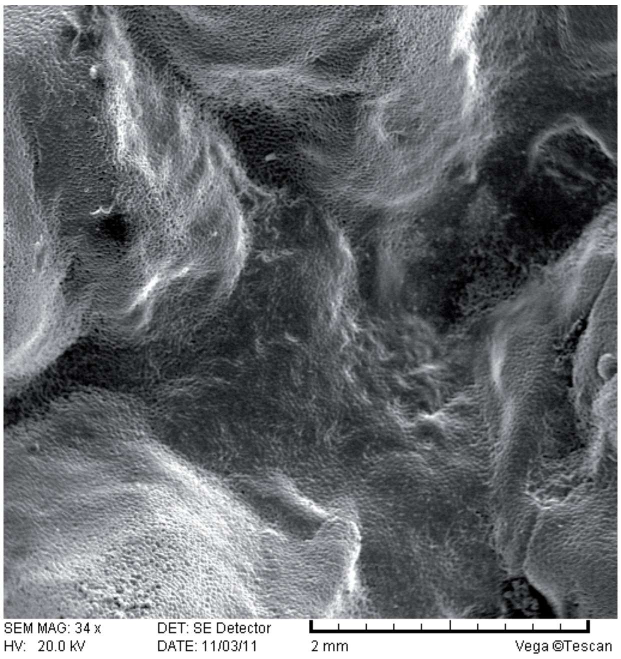

Figure 1. *Glass Carbomer fissure sealant (occlusal view)*

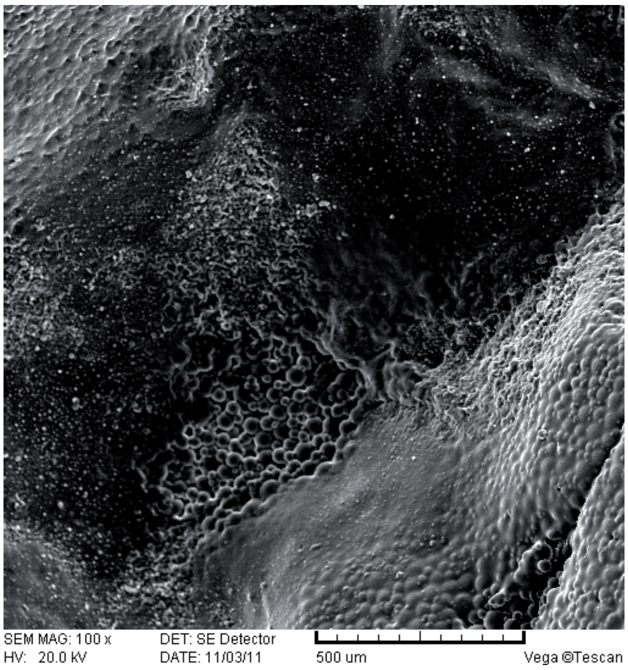

Figure 2. *Fracture of Glass Carbomer fissure sealant (Glass Carbomer left in the fissure)*

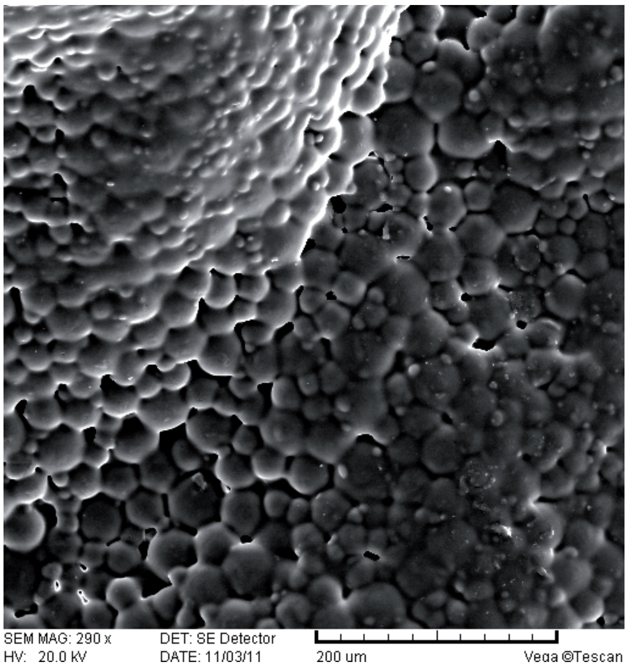

Figure 3a. *Good marginal seal of Glass Carbomer fissure sealant*

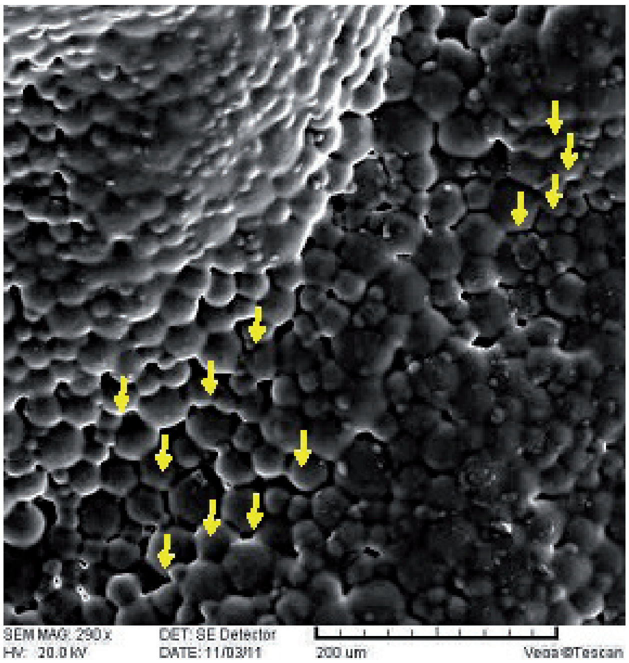

Figure 3b. *Hexagonal crystallization of fluorapatite, FAP with characteristic 120 degree angles between the faces.*

a comparable retention rate after 12 months; complete retention of Glass Carbomer® was 75% after 12 months of clinical service. The findings were comparable to the results published for conventional chemical cured glass ionomers. Of particular interest is the 2-year Finnish study in which full retention of GIC was obtained only in 26% of the sample compared with 82% of the Bis-GMA material[29]. Wide range of retention values has been reported for conventional glass ionomers. After 28 months, Poulsen et al.[6] observed a complete retention rate of less than 10% for the Fuji III glass ionomer, whereas Pardi et al.[7] observed a total retention rate of 3.5%. Weerheijm et al.[13] observed a total retention rate of 51% for Fuji IX and 15% for Fuji III after 9 months. In a recent study[30], complete retention of a glass ionomer sealant after 12 months was 30%. In the present study, the results of the incidence of the new carious lesions in the Glass Carbomer® group compared with resin sealants were not statistically different. The SEM analysis showed that fissures with a substantial loss of material have sufficient remnants of material in them that could have a caries preventive effect. A recent meta-analysis found no evidence that either material (glass ionomer and resin-based fissure sealants) was superior to the other in prevention of dental caries and both appeared to be equally suitable for clinical use as fissure sealant material[31].

A positive effect on the mechanical properties of dental composite resin materials after the application of external heat during the setting reaction has been described previously[32,33]. Algera et al.[34] and Van Duinen et al.[35] reported improved mechanical performance of a GIC when heated during setting. Kleverlaan et al.[21] demonstrated that heat application during the setting of conventional GIC can be used as a "command set" method. High-energy LED lamps generate heat (high power obtainable temperature of 60^{o} C, GCP Carboled CL-01) and are suitable to be used for "command set" purposes. The use of high-energy LED, halogen lamp or ultrasonic excitation improves the mechanical properties of the material, as heat application apparently accelerates the slow setting reaction , the first 10 min after mixing, and therefore, shortens the initial saliva sensitive phase [21]. Recent research demonstrated that heating at relatively low temperatures using light emitted from a high-energy polymerisation unit could also improve the mechanical properties as well as the shear bond strength to enamel[21, 22].

The nanotechnology in Glass Carbomer® enables a higher filler content and a lower percentage of the matrix. Nicholson and Czarnecka[36,37] suggested that application of heat evaporated part of the unbound water in the cement matrix and accelerated the chemical reaction. They show that diffusion coefficients differ slightly with the temperature. Besides the improved characteristics of Glass Carbomer®, such as anti-caries repair with the introduction of fluorhydroxyapatite and mineralisation power, the Glass Carbomer® sealant material does not contain Bisphenol-A monomers[38,39] and organic solvents (available in various bondings and coatings), which can cause health risks in children [40-42].

A possible limitation of the present preliminary study is the lack of information on the long-term performance of the Glass Carbomer® sealant used. The continuous integration of Glass Carbomer with adjacent enamel is also a matter of great interest, which can be seen after a minimum of 2-3 years in-vivo clinical service[25]. Similarly, the findings of the present study could not determine if the integration of Glass Carbomer with adjacent enamel has occurred and whether this processes materialises more over time? Answering these questions demands setting randomised clinical trials over a longer period of time, i.e., 3-5 years. However, the present data can help in sample size calculation for properly designed clinical trials with a longer evaluation period to better understand the biological processes involved in the anti-caries prevention and remineralisation.

CONCLUSION

Glass Carbomer® sealant material showed a comparable retention rate to composite resin-based sealant material over a one-year period; however, further studies are required to examine the longer-term performance of this material.

ADDRESS FOR CORRESPONDENCE

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