One year clinical trial of a glass carbomer fissure sealant
Gorseta K², Glavina D², Van Duinen R³, Skrinjaric I², Hill RG¹ and Lynch E⁴

1 Dental Physical Sciences, dental Institute, Barts and the London, Queen Mary, University of London Mile End Road London E1 4NS UK
2 Department of Pediatric and Preventive Dentistry, School of Dental Medicine, University of Zagreb, Croatia
3 former researcher Biomaterials ACTA, University of Amsterdam
4 Warwick Dentistry, University of Warwick

Abstract

Objectives. Glass Carbomer® represents a new generation of restorative material developed from glass-ionomer cements. The aim of this study was to investigate the retention of Glass Carbomer® fissure sealant after 12 months in a clinical trial, in comparison with a commonly used conventional resin-based sealant

Material and methods. After ethics committee approval, forty-eight teeth with well-delineated fissure morphology randomly divided into two groups were sealed with Glass Carbomer (Glass Carbomer® Sealant, Glass Carbomer Products, Netherlands) and Bis-GMA resin-based Helioseal F (Ivoclar Vivadent, Liechtenstein) using the split mouth design. Materials were placed and set according to manufacturer instructions using a polymerization unit Bluephase 16i (Vivadent, Liechtenstein). Teeth in group A were sealed with Helioseal F and in group B with Glass Carbomer® material using a command set.

Results. Results showed that complete sealant retentions in groups A and B were 75% after 12 months of clinical service. There were two new carious lesions in each group. The Mann-Whitney U test revealed no significant statistical difference between the two groups.

Conclusion. Glass Carbomer® material showed a comparable retention rate to a resin based sealant and can also be recommended for everyday practice. It seems that the Fluor-Hydroxyapatite incorporated in the Glass Carbomer® gives better mechanical properties. However, a long-term follow up is required to get a better understanding of the involved biological processes.

Introduction

Pit and fissure sealants undoubtedly play a critical role in preventing occlusal caries in both primary and permanent teeth.¹ The most commonly used sealant material is a resin composite.¹ ² ³ Under the generally wet conditions in the oral cavity, glass ionomer cement offers an alternative.⁴ To achieve maximum caries preventive effect on occlusal surfaces, dental sealants should have the following properties:
1. Perfect adhesion of material should be maintained not only while setting, but also during function (including the challenges of both thermal and mechanical cycling).
2. Dimensional changes of material during application should be minimal. Complete retention of the sealant material in the occlusal fissures during a long time depends to a large extent on the absence of dimensional changes.
3. Resistance to wear and fracture.
4. Ease of use including handling and placement.
5. Exhibit a powerful caries preventive effect. Inclusion of fluoride ions in the material should have a beneficial effect on the prevention of developing carious lesions, as well as the remineralization of any demineralized enamel adjacent to the sealant. Glass ionomer cements (GIC) have several advantages compared to classic resin sealant materials including: easier bonding, easy handling, and continuous fluoride release in vivo. However, a number of studies have shown significantly lower retention rates compared to resin sealants. The mechanical properties of glass ionomers in general are typically inferior to resin based materials. The question of the caries preventive effect of glass ionomer sealants is still controversial: different studies have shown different preventive effects. It was suggested that after loss of the sealant, the presence of material remnants in the fissures can maintain caries prevention.

Glass Carbomer® is a new material developed from traditional glass ionomer cements (GIC) and contains nano-sized powder particles of both fluorapatite and hydroxyapatite. The advantages of Glass Carbomer® compared to conventional GICs are significantly better mechanical and chemical properties (strength, shear, wear, acid resistance, and remineralization power) with command setting through the application of heat with a LED curing device. Glass Carbomer® is monomer free carbonised nano glass restorative cement with specially designed filler and fluoro/hydroxy apatite particles. The aim of this study was to investigate the retention rate of Glass Carbomer® fissure sealant after six and twelve months of clinical placement, in comparison to a commonly used resin-based sealant.

Material and Methods

After ethics committee approval, informed consents were received from all parents of participating children. Children with an age range of 6-16 years were included in the study. Usual to report the mean and standard error all molars included were fully erupted with their contra lateral tooth present. Clinical examination established that molars were caries free, with absence of mobility caused by periodontal disease, and with no evidence of hypoplasia or history of previous sealant application. Forty eight teeth with well-delineated fissure morphology divided into two groups were sealed with Bis-GMA resin-based Helioseal F® (Vivadent, Liechtenstein) and Glass Carbomer® Sealant (Glass Carbomer Products, Netherlands) using the split-mouth design after random allocation using a random numbers table.

Application of fissure sealant
Isolation of teeth was performed with cotton rolls and high-volume suction. In group A, the occlusal surface of each tooth was cleaned with pumice, washed and dried, and isolated with cotton wool rolls and high-volume suction. The teeth were etched for 20 seconds with 37.5% phosphoric acid (Kerr Etchant, Kerr, Orange, CA, USA). Enamel was rinsed and dried for 20 seconds following material application and polymerization. Group A consisted of 18 first and 6 second permanent molars sealed with Helioseal F® (Ivoclar Vivadent). In group B, after cleaning with pumice, the enamel was conditioned with a dentin conditioner (Tooth cleaner; EDTA solution, Glass Carbomer Products, Netherlands) for 20 seconds, rinsed, and dried for 20 seconds. Then, Glass Carbomer material was applied and command set with a LED curing light (60 degrees) for 60 seconds. Group B consisted of 18 first and 6 second permanent molars sealed with Glass Carbomer®. Materials were placed and set according to manufacturer’s instructions using the polymerization unit Bluephase 16i (Ivoclar Vivadent, Liechtenstein).
The evaluation criteria of Kilpatrick et al. 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; and type 4- whole sealant missing. Presence of new carious lesions was evaluated in two categories: 1- absent and 2- present.

The presence of Glass Carbomer® material remnants in fissures after 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 in order 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 analyzed with SEM. The data obtained were statistically analyzed using the non-parametric Mann-Whitney U test.

Results

Two investigators evaluated all sealed surfaces. In the cases which were initially rated differently, a mutual agreement was found. Results showed that 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). Results showed that complete retention in group A and B was 75% after 12 months of clinical service (Table 3). There were two new carious lesions in each group (Table 4). The Mann - Whitney U test revealed no significant statistical difference between the groups.

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 had occurred within the Glass Carbomer® material. In figure 3a 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 a lot of particles with a hexagonal habit. These are highlighted in figure 3b.

Fluorapatite (FAP), often crystallizes in a hexagonal habit with characteristic 120 degree angles 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 may act as seeds for this process.

Discussion

The results obtained in this study compared a Glass Carbomer® sealant to a resin sealant material, which served as a control group, and is comparable to other previously published results. The Glass Carbomer® material showed a very good retention rate after 12 months. Results showed that complete retention of Glass Carbomer® was 75% after 12 months of clinical service. The obtained results were better in comparison to the results published for classic (chemically cured) glass ionomers. Therefore it may be concluded that the Glass Carbomer® technology with its improved properties and characteristics are superior to existing glass ionomers for these sealants. Of particular interest is the 2-year Finnish study in which it was concluded that at the end of the clinical trial, full retention of GIC was obtained on 26% of the sample compared with 82% of the Bis-GMA material. After 28 months, Poulsen et al.6 observed a complete retention rate of less than 10% for a Fuji III glass ionomer, whereas Pardi et al.7 observed a total retention rate of 3.5%. Weerheijm et al.12 observed a total retention rate of 51% for Fuji IX and 15% for Fuji III after 9 months. In our previously published study complete retention of a glass ionomer sealant after 12 months was...
30%. In this study, the results of the incidence of the new carious lesions in the Glass Carbomer® group compared with resin sealants were not statistically significant. The SEM analysis showed that fissures with a substantial loss of material have sufficient remnants of material in the fissure that could have a caries preventive effect. The reason could be that the Glass Carbomer® material is mineralized and looks like pseudo-enamel (mineralized fluorhydroxyapatite). However, the size of our study was too small to allow for an analysis to address this question.

Some systematic reviews using meta-analysis found no evidence that either material was superior to the other in the prevention of dental caries. Therefore, both appear to be equally suitable for clinical use as fissure sealant materials.

A positive effect on the mechanical properties of dental composite resin materials after the application of external heat during the setting reaction was described by Davidson et al. and Bausch et al. Recently Algera et al. and Van Duinen et al. showed improved mechanical performance of a GIC when heated during setting. Kleverlaan et al. demonstrated that heat application during the setting of conventional GIC can be used as a “command set” method. High LED lamps with generates heat (high power obtainable temperature 60°C. i.e. GCP Carboled CL-01) are suitable to be used for “command set” purposes. Use of ultrasonic vibration and “warming up” improves the mechanical properties of the material, as raising the temperature of an exothermic reaction with an activation accelerates the reaction. It was shown that raising the temperature of the GIC can improve the shear bond strength due to rearrangement of the molecules in contact with the enamel surface. Recent research demonstrated that heating at relatively low temperatures using light emitted from a high energy polymerisation unit can also improve the mechanical properties as well as the shear bond strength to enamel.

Even at 2-3°C temperature rise measured on the surface of glass ionomer restorations before and after 60s of illumination with an infrared thermometer (PCE-889, PCE Group, Meschede, Germany) when heated with the LED (high-power, obtainable temperature 60°C) polymerisation unit, it is possible to get increased adhesion values. Heating may increase the rate of the acid-base reaction and also improve the cross-linking within the material and its overall coherence. A possible explanation may be that the nanotechnology of the material provides an increased amount of Ca2+ ions available for the bonding reaction with the enamel. The nanotechnology in Glass Carbomer® enables a higher filler content and a lower percentage of matrix. Nicholson and Czarnecka have suggested that the application of heat evaporates part of the unbound water in the cement matrix and accelerates the chemical reaction. They show that diffusion coefficients differ slightly with the temperature. Gorseta et al. and Skrinjaric et al. showed that increasing power of the LED polymerisation unit increases the mechanical properties of the GIC and Glass Carbomer® material. Besides the improved physical characteristics of Glass Carbomer® (incl. anti caries repair with the introduction of fluorhydroxy apatite and mineralisation power), the Glass Carbomer® sealant material does not contain Bisphenol-A, monomers and any other organic solvents (available in various bondings and coatings) which could cause health risks in humans with respect to childrens and pregnant women.

A long-term follow up is required to get a better understanding of the biological processes involved with respect to anti-caries prevention and the remineralisation process.

**Conclusion**

Glass Carbomer® sealant material showed a comparable retention rate to composite resin based sealant material over a one year period and can be recommended for every day practice.
References


Tables and Figures

Table 1 Sealant retention rate after 6 months

Table 2 Incidence of new carious lesions after 6 months

Table 3 Sealant retention rate after 12 months

Table 4 Incidence of new carious lesions after 12 months

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.
### Table 1 Sealant retention rate after 6 months

<table>
<thead>
<tr>
<th>Sealant material</th>
<th>Sealant retention after 6 months</th>
<th>Mann-Whitney (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 3 4 Total</td>
<td></td>
</tr>
<tr>
<td>GlassCarbomer(N) %</td>
<td>24 0 0 0 24 100</td>
<td>1.0 (NS)</td>
</tr>
<tr>
<td>Helioseal F(N) %</td>
<td>24 0 0 0 24 100</td>
<td></td>
</tr>
<tr>
<td>Total (N) %</td>
<td>48 0 0 0 48 100</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2 Incidence of new carious lesions after 6 months

<table>
<thead>
<tr>
<th>Sealant material</th>
<th>Incidence of new caries lesions after 6 months</th>
<th>Mann-Whitney (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 Total</td>
<td></td>
</tr>
<tr>
<td>GlassCarbomer(N) %</td>
<td>24 0 24 100</td>
<td>1.0 (NS)</td>
</tr>
<tr>
<td>Helioseal F(N) %</td>
<td>24 0 24 100</td>
<td></td>
</tr>
<tr>
<td>Total (N) %</td>
<td>48 0 48 100</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3 Sealant retention rate after 12 months

<table>
<thead>
<tr>
<th>Sealant material</th>
<th>Sealant retention after 12 months</th>
<th>Mann-Whitney (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 3 4 Total</td>
<td></td>
</tr>
<tr>
<td>GlassCarbomer(N) %</td>
<td>18 0 6 0 24 100</td>
<td>p&gt;0.05 (NS)</td>
</tr>
<tr>
<td>Helioseal F(N) %</td>
<td>18 1 5 0 24 100</td>
<td></td>
</tr>
<tr>
<td>Total (N) %</td>
<td>36 1 11 0 48 100</td>
<td></td>
</tr>
</tbody>
</table>

### Table 4 Incidence of new carious lesions after 12 months

<table>
<thead>
<tr>
<th>Sealant material</th>
<th>Incidence of new caries lesions after 12 months</th>
<th>Mann-Whitney (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 Total</td>
<td></td>
</tr>
<tr>
<td>GlassCarbomer(N) %</td>
<td>22 2 24 100</td>
<td>p&gt;0.05 (NS)</td>
</tr>
<tr>
<td>Helioseal F(N) %</td>
<td>22 2 24 100</td>
<td></td>
</tr>
<tr>
<td>Total (N) %</td>
<td>44 4 48 100</td>
<td></td>
</tr>
</tbody>
</table>
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.