A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealants

D Ch Dent Thesis

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By

Jennifer Mc Cafferty

Declaration

I hereby declare that this thesis has not previously been submitted for a degree at this or any other university and that it represents my own work except where duly acknowledged in the text.

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Signed: Jennie McCalling

Date: 15.10.12

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Abstract

Statement of Problem

Resin pit and fissure sealants are an effective preventative method of reducing caries in permanent molar teeth. The preventative effect is reduced because the retention of fissure sealant falls by 10-21% annually. The loss of retention on the buccal surface of mandibular molar teeth and palatal surface of the maxillary molar teeth is greater than the loss of retention on the occlusal surfaces. This high retention loss is a serious clinical problem. The teeth are once again at risk of developing caries. The time and cost implication of replacing the sealants is high and is a significant problem for the public dental health service.

Purpose

The purpose of this clinical study was to assess if the addition of an adhesive intermediate bonding agent would increase the retention of resin pit and fissure sealants on first permanent molar teeth. The study would also assess if there is a difference in retention of the sealant on occlusal, buccal or palatal surfaces by the addition of an adhesive intermediate bonding agent. The behaviour of a patient during the placement of fissure sealants can affect the ability to isolate molar teeth sufficiently to place a retentive sealant. The study assessed if the bonding agent would increase the retention of the sealant when the behaviour rating was lower.

Materials and Methods

Ethical approval was obtained from the Faculty Research Ethics Committee in Trinity College Dublin. Patients who met with the inclusion criteria were enrolled in the study and consent was obtained. Three hundred and ninety first permanent molar teeth received resin fissure sealants (Helioseal®). Half of these teeth, n=195 (test group) had an adhesive intermediate bond (ExciTE®F) added prior to the sealant application and 195 had the sealants placed without an adhesive intermediate bond (control). The age range was 5.08-15.5 years and the median age was 9 years. One trained operator placed the 390 sealants. A split mouth design was used with each patient receiving 1 or 2 bonded sealants and 1 or 2 non-bonded sealants in matching paired molar teeth. The fissure sealants were reviewed at 12 months. Two other clinicians were trained and calibrated and evaluated the retention of the fissure sealants in a blinded manner. A Cohen's kappa score was determined to assess the inter-examiner and intra-examiner reliability. Results were analysed using Fisher's exact test and a regressional model to determine statistical difference between the bonded and non-bonded sealants.

Results

Intra-examiner and inter-examiner agreement was good (Kappa score 0.81). Overall, 86% of the 390 sealants were intact at 12 month recall. The results for the paired sealants showed that 92% of the bonded sealants were intact compared to 80% of the non-bonded sealants (p=0.005 Fisher's exact test). There was no significance shown for retention of bonded versus non-bonded sealants on the occlusal surfaces (98% versus 92% respectively). A significant difference in retention of the bonded versus non-bonded sealants was observed on the buccal/palatal surfaces (92% and 81% respectively, p=0.0005). The difference between the retention of the sealants in the maxillary and mandibular arch showed that bonding had a significant beneficial effect on retention of sealants on the occlusal (p=0.03) and the palatal surface p=0.004) in maxillary molars. The bonding of sealant in the buccal pits of the mandibular molars showed no significant difference in retention (p=0.41). The behaviour of the patient significantly affected the retention of the sealants (p=0.0001) but bonding showed no significance for lower behaviour scores. A logistic regression analysis showed that the retention of pit and fissure sealants is affected by the addition of an intermediate bonding agent, the surface of the tooth and the behaviour of the patient.

Conclusions

Fissure sealants are an effective measure for caries prevention. The addition of an adhesive bonding agent significantly increases the retention of the sealants at 12 months. Overall bonded sealants were more retentive than non-bonded (92% versus 80%). This difference was significant for maxillary molars but not for mandibular molars.
The behaviour of the patient significantly affects the retention of sealants but the addition of a bonding agent does not significantly increase the retention in this circumstance.

1. Introduction

Pit and fissure sealants are a proven and effective method of preventing caries in permanent molar teeth (Ahovuo-Saloranta et al., 2008). The anatomy of pits and fissures predisposes them to stagnation of plaque which in turn leads to proliferation of cariogenic bacteria such as Streptococcus mutans leading to a carious lesion (Manton and Messer, 1995). Stagnated plaque in pit and fissure surfaces is not always eradicated through tooth brushing alone. Sealants work by changing the surface anatomy of the fissure pattern reducing the stagnation of cariogenic bacteria. The application of fissure sealants to first permanent molars has been shown to be a cost-effective measure to reduce caries and for this reason is adopted into public dental health preventative programmes for children worldwide. The caries effectiveness of fissure sealants is solely dependent on the retention of the sealant. There are several factors which affect the retention of sealants (Muller-Bolla et al., 2006). A recent proposed method of maximising the retention of fissure sealant is the addition of an adhesive bonding layer under the sealants during their placement. There are limited clinical studies in this area with mixed conclusions. If the addition of a bonding agent will maximise their retention it will increase its caries preventative effective. However, it will mean an additional step to the procedure which will have time and cost implications if it is to be introduced as part of the pubic dental health preventative programmes. This clinical study will assess the retention of fissure sealants on fully erupted, non-carious first permanent molar teeth to determine if the addition of an adhesive layer significantly improves sealant retention.

2. Literature Review

2.1 History of fissure sealants

The concept of preventing caries initiation and progression in pit and fissures of permanent molar teeth has been around for years, long before the introduction of adhesive sealant materials in the 1960s. Materials such as zinc phosphate cement and ammoniacal silver nitrate were used with poor success (Kline, 1942; Wilson, 1895). Fissure removal or odontotomy was common practice for the preventative management of pits and fissures up to the 1970s (Bodecker, 1929).

Adhesive fissure sealants began to emerge in the 1960s following the clinical research of Michael G. Buonocore. He found that the use of phosphoric acid could increase the adhesion of acrylic materials to the enamel surface of teeth (Buonocore, 1955). In this study, an 85% solution of phosphoric acid was applied for 2 minutes to bond little buttons of polymethylmethacrylate (PMMA) to incisors. He showed that, by etching the incisor, there was almost a hundred times greater retention strength of the buttons. The acid gave an opaque appearance to the enamel but it returned to a normal appearance within a few days with no indication of permanent damage to the tooth. As a result of this landmark study the *acid-etch technique* was born and remains the foundation of adhesive dentistry to this day. Soon after, further studies were carried out on the application of this technique for pit and fissure sealants in the prevention of caries (Cueto and Buonocore, 1967; Cueto, 1965). The initial study in 1965 showed retention rates of 71% at 1 year and caries prevention of 87% for permanent molars (Cueto, 1965). Follow-on studies confirmed the good retention rates of resin fissures sealants (Ismail, 1996). The early resin sealants were clear in colour but, by the mid-1970s manufacturers added titanium dioxide which made it easy to assess the sealants. More recently colour change capability has been incorporated into properties of certain sealants to facilitate review of their integrity.

By the middle of the 1980s the emphasis was on the placement of sealants to protect pit and fissure surfaces rather than fissure removal techniques and people in lower socio-economic areas should be targeted to receive sealants on first permanent molars (Graves et al., 1986). This remains the rationale for caries preventative guidelines as well as oral hygiene education and the use of fluoridated toothpaste (AAPD, 2011; HSE, 2010; Nunn et al., 2000).

2.2 Anatomy of pit and fissures of first permanent molar teeth

2.2-1 Formation of fissure pattern of molar teeth

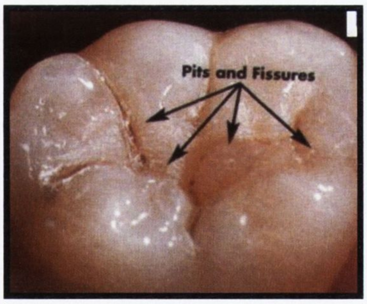
The enamel grooves and fossa are a natural development on the occlusal surface of the molars as the lobules coalesce during pre-eruptive development. Pits and fissures along the occlusal surface are a result of incomplete lobule coalescence (Nanci, 2008). The enamel of molar teeth during eruption is still maturing and is more porous and susceptible to demineralisation (Nanci, 2008). Erupting permanent molars are not in occlusion for up to a year and it can be difficult to clean. Plaque accumulation can be higher in the fissure areas during this time (Carvalho et al., 1989). Once the tooth comes into occlusion, mastication forces can change the plaque accumulation on the occlusal surfaces (Fejerskov, 2008).

2.2-2 Anatomy

The thin and narrow shape of the pits and fissures are plaque traps and the reason they have a high susceptibility to caries (Figure 2.1). Up to 50% of the caries experienced by children occurs in these areas (Ripa, 1973).

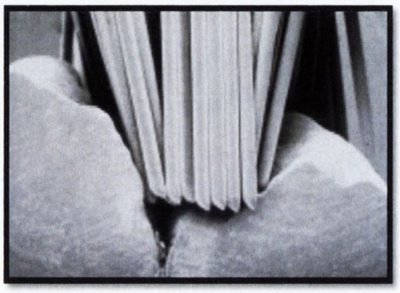
The narrow valleys of the fissures are difficult to clean. Figure 2.2 shows the cross-section of a molar tooth illustrating the difficulty in access for a toothbrush to the base of the fissures.

Figure 2.1 Pit and fissure pattern of permanent molar tooth



http://www.chandakdental.com/pit-and-fissure-sealants/

Figure 2.2 Tooth brush inability to clean fissure



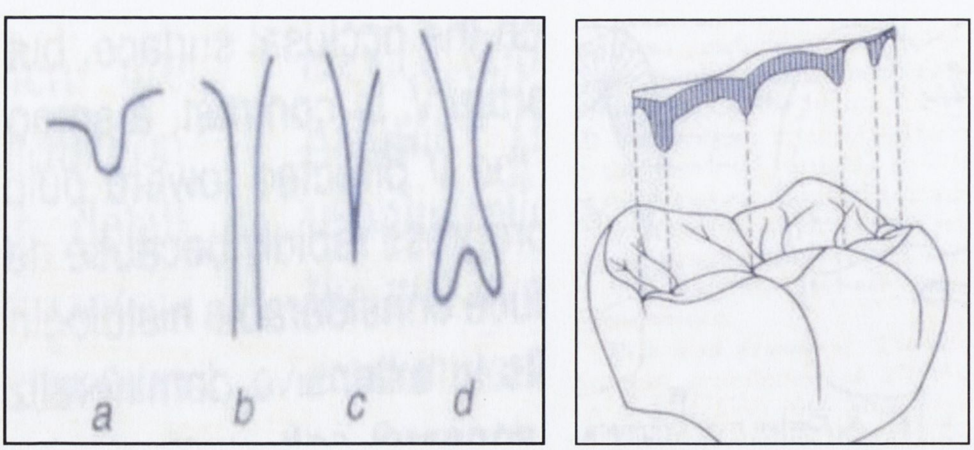
www.ivoclarvivadent.com

The shape, morphology and depth of the fissures have a role to play in caries susceptibility (Ferreira Zandona et al., 1998). In 1960 Nagano et al classified the fissure morphology of molar teeth which are described and illustrated in Table 2.1 and Figure 2.3.

Table 2.1 Fissure morphology classification (Nagano, 1960)

Fissure shape	Depth	Caries susceptibility	Site of caries initiation
V: wide open at top and narrow tip at the base	Shallow	Low	Base of fissure
U: Uniformed width throughout	Average	High	Half way up fissure
I: Uniformly very narrow	Deep	High	Top of fissure
IK: Very narrow opening with wide base	Deep	High	Top of fissure
Y: wide open at top and narrow slit extending apically at the base	Deep	High	Half way down fissure

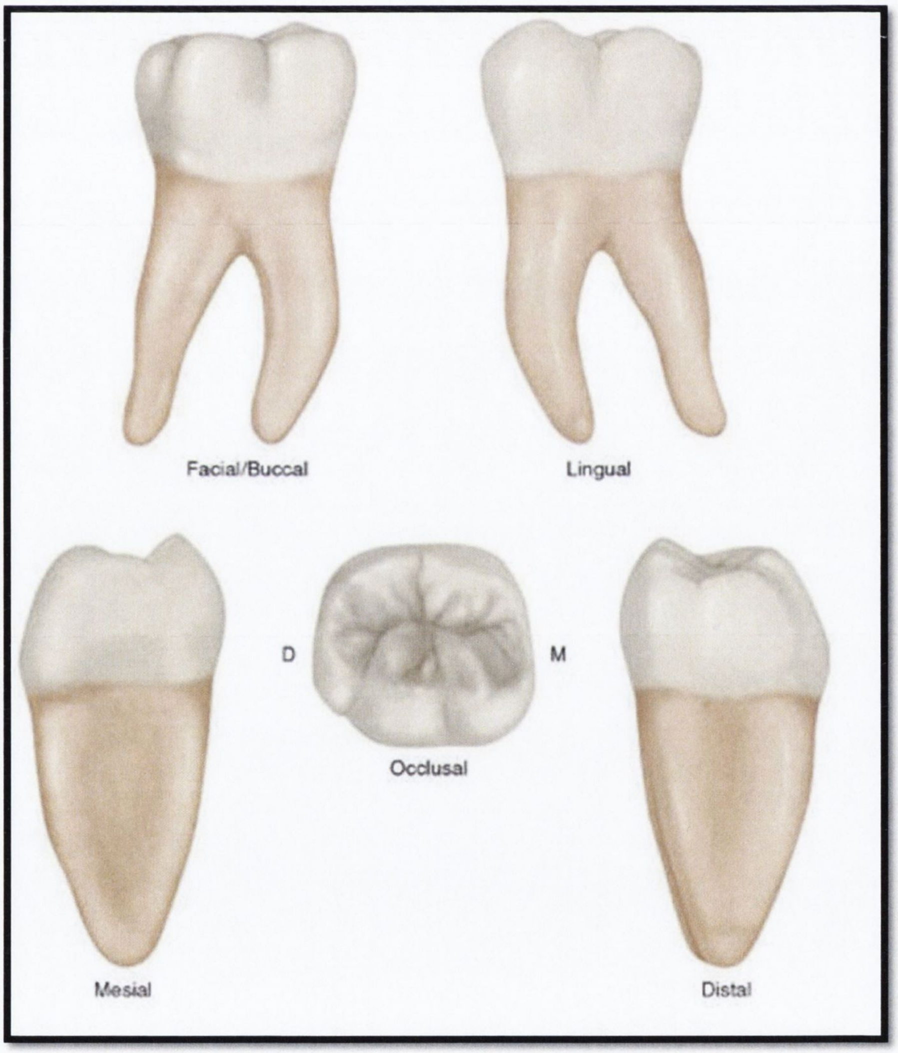
Figure 2.3 Diagram of fissure shapes (Nagano, 1960)



Mandibular first permanent molar anatomy

The mandibular first permanent molar is pentagonal in shape. The mesiodistal width is broader than the buccolingual width. The mesiodistal fissure separates the occlusal surface into a buccal and lingual area. The tooth has 5 cusps; 3 buccal cusps and 2 lingual cusps. Fissures run from the cusps to the central fossa area which gives it a cruciform pattern. The lingual cusps are bigger and more pointed than the rounded lingually inclined buccal cusps. A fissure runs down the buccal surface of the tooth between the mesiobuccal and distobuccal cusps terminating in the buccal pit, which may extend gingivally at least half the length of the crown. Mandibular first permanent molars have a mesial and distal root (Nanci, 2008) (Figure 2.4).

Figure 2.4 Anatomy of mandibular right first permanent molar

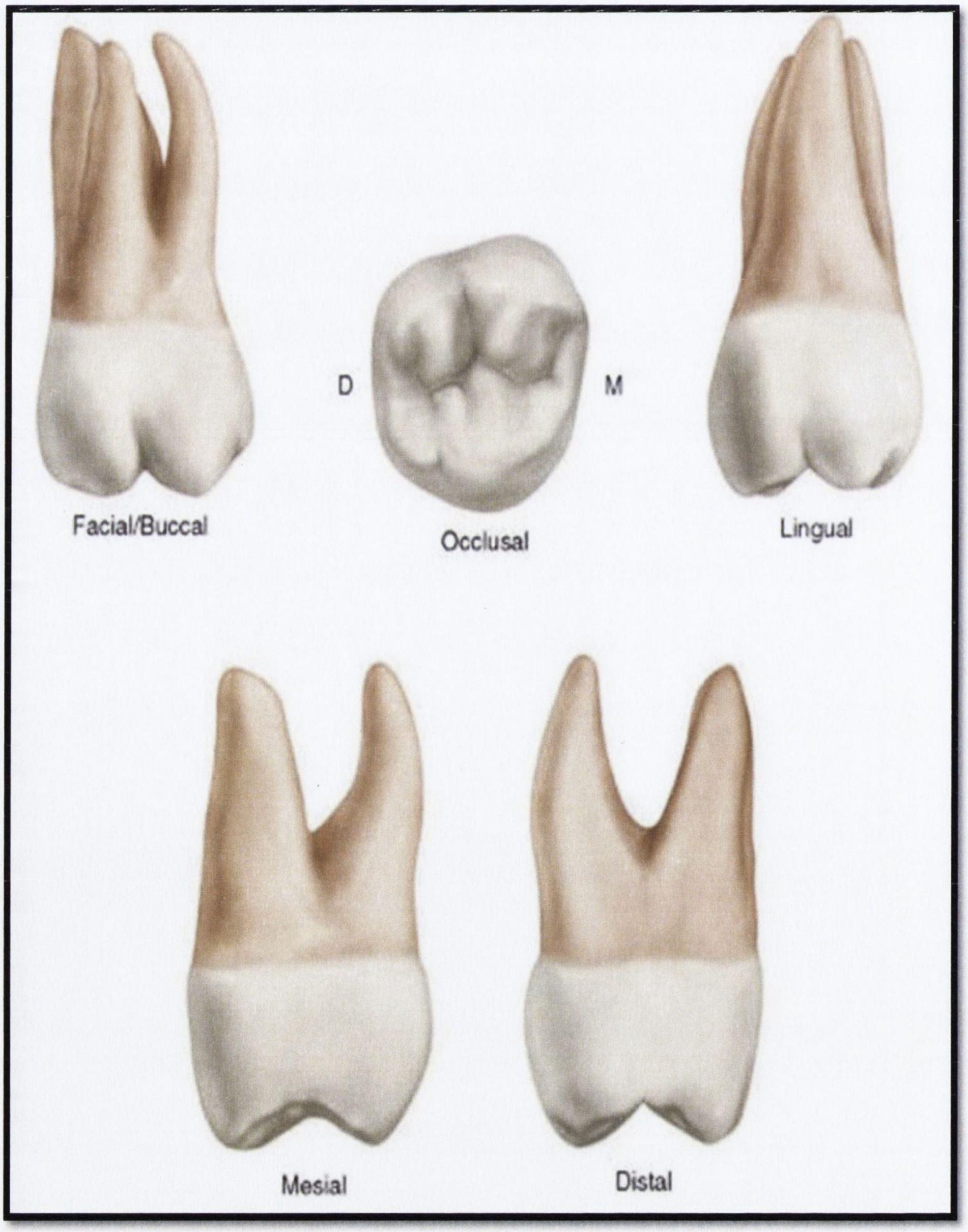


http://what-when-how.com/dental-anatomy-physiology-and-occlusion/review-of-tooth-morphology-dental-anatomy-physiology-and-occlusion-part-2/

Maxillary first permanent molar

The maxillary first permanent molar is the largest of the molar teeth with a rhomboid shape. The mesiopalatal and distobuccal angles are obtuse. The tooth has 4 cusps (mesiobuccal, mesiopalatal, distobuccal and distopalatal), in 60% of cases an additional mesiopalatal cusp is present known as the tubercule of Carabelli. The fissure pattern of these teeth is H shaped. A groove/fissure extends between the palatal cusps along the palatal surface to the midway point of the crown of the tooth. The maxillary first permanent molars have 3 roots, 2 buccal and a long palatal root (Figure 2.5) (Nanci, 2008).

Figure 2.5 Anatomy of maxillary right first permanent molar tooth



http://what-when-how.com/dental-anatomy-physiology-and-occlusion/review-of-tooth-morphology-dental-anatomy-physiology-and-occlusion-part-2/

2.3 Stages of tooth eruption

First permanent molar teeth undergo five stages of eruption (Dennison et al., 1990). These teeth usually erupt between the ages of 5-7 years of age with a mean age of emergence of 6.0-6.3 for girls and 6.3-6.5 for boys with a range varying between 5 and 8. The eruption of the first permanent molar can take up to 15 months (Ekstrand et al., 2003; Kochhar and Richardson, 1998; Leroy et al., 2003). The different stages of eruption of a molar tooth are described in Table 2.2. Resin sealants are most retentive when the tooth is fully erupted because ideal isolation is achievable during the placement of the sealant. Glass ionomer sealants can be used as intermediate sealant for partially erupted teeth in high caries risk patients as this material is less technique sensitive to moisture.

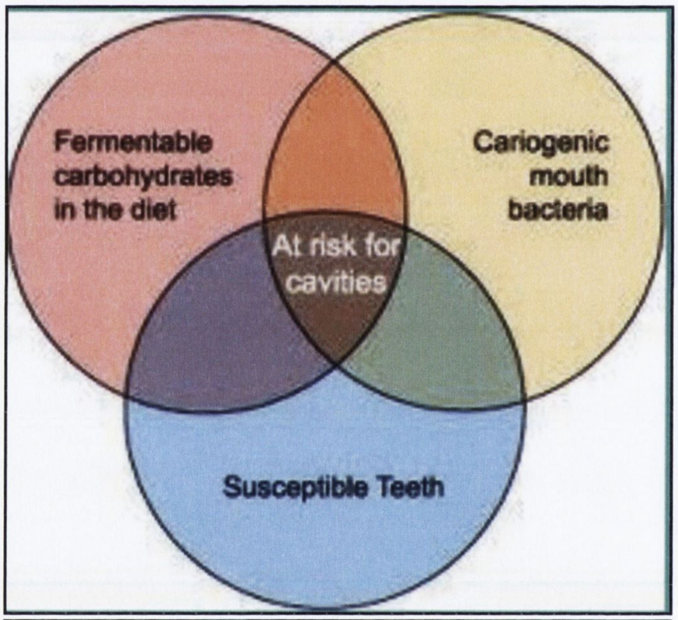
Table 2.2 Five stages of eruption of a molar tooth (Dennison et al., 1990)

Stage of eruption	Description
1.	• Not all of the cusps are visible showing through the gingiva
2.	• The occlusal surface is visible • An operculum of gingival tissue covers the distal marginal ridge • Buccal and lingual height of contour are below the gingival margin
3.	• The occlusal surface is visible • The distal marginal ridge is visible but at the same level as the gingival tissue • Buccal and lingual height of contour are below the gingival margin
4.	• The occlusal surface is visible • The distal marginal ridge is visible above the height of the gingival tissue • Buccal and lingual height of contour are below the gingival margin
5.	• The occlusal surface is visible • The distal marginal ridge is visible above the level of the gingival tissue • Buccal and lingual height of contour are above the gingival margin

2.4 Caries

The sole purpose of resin fissure sealants is to create a durable physical protective barrier over the pit and fissure surfaces of molar teeth. The barrier prevents plaque accumulation in the pit and fissure areas which could lead to a cariogenic lesion in susceptible individuals.
Dental caries is the most common chronic disease affecting children (DHHS, 2000). It is an infectious disease that results in the localised demineralisation of a tooth's surface. This process occurs when four factors are present together; time, fermentable carbohydrates, cariogenic bacteria and susceptible teeth (Figure 2.6).

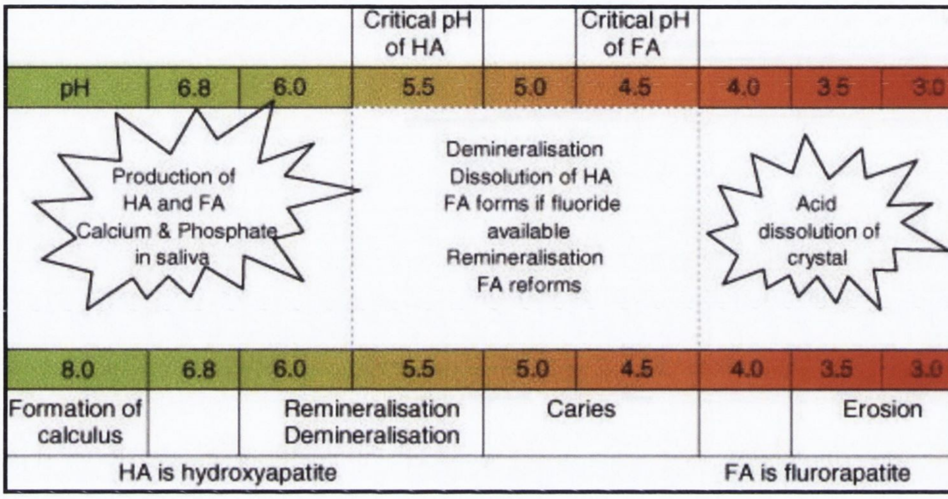
Figure 2.6 Caries Venn diagram



http://www.hesslewoodlodge.com/Diet-and-Tooth Decay%282371397%29.htm

Caries is a dynamic process of demineralisation and remineralisation caused by changes in the bacterial metabolic activity occurring in the biofilm or plaque that accumulates on the surface of teeth over time (Figure 2.7). In the presence of fermentable carbohydrates oral bacteria will produce acids that will cause a shift in the pH balance at the surface of a tooth causing mineral loss (Geddes, 1975). This shift is normally balanced by the removal of the biofilm and re-deposition of the minerals calcium, phosphate or fluoride which are present in the saliva. However, when plaque accumulates on the surface of the tooth undisturbed for a period of time the biofilm grows and the pH drops below the critical level of 5.5 allowing large concentrations of calcium and phosphate ions to be lost. Once sufficient minerals are lost the surface of the tooth becomes porous and is clinically visible as a white spot lesion. Caries progression can occur at any site on the tooth but there are certain sites which are more susceptible such as the pit and fissure areas. The white spot lesion is a reversible stage of the caries process but if left untreated will progress through the enamel into the dentine over time (Pretty, 2006; Zero et al., 2001).

Figure 2.7 Demineralisation/remineralisation equilibrium (Pretty, 2006)



http://www.dentistryatgrayhawk.com/services.html

2.4-1 Caries classification

Caries is classified in several ways. (Table 2.3 and Table 2.4).

Table 2.3 Caries classification

- Anatomical site
- Progression
- Extent of caries
- Number of tooth surfaces
- Chronology
- Black's classification
- WHO system

Table 2.4 Characteristics of Caries Classification

Anatomy	Black's (Site)	WHO (Extent)
• Occlusal (Pit and fissure caries) • Smooth surface caries • Linear enamel caries • Root caries	• Class I • Class II • Class III • Class IV • Class V • Class VI	• D1. Clinically detectable enamel lesions with intact (non-cavitated) surfaces • D2. Clinically detectable cavities limited to enamel • D3. Clinically detectable cavities in dentin • D4. Lesions extending into the pulp

2.4-2 Prevalence of caries

It is reported that the caries prevalence in industrial countries for children and adolescents has decreased since the 1970s and 1980s (Petersson and Bratthall, 1996). There are however, more recent reports that caries has increased again for these population groups in some countries (Haugejorden and Magne Birkeland, 2006).

In Ireland, the level of decay experienced by children continues to be alarmingly high in both the primary and permanent dentition despite having 71% of the public water supply fluoridated (Whelton, 2006). In comparison with the United Kingdom (Lader, 2005), the prevalence of decay in the Irish population is higher in certain age groups as shown in Table 2.5. From a global perspective the prevalence of caries is higher in children from a low socio-economic background and the severity of the decay is higher (Lader, 2005; NHANES, 2004; Whelton, 2006). Prevention of decay is therefore very important.

Table 2.5 Prevalence of decay in Ireland and UK populations(Whelton, 2006)

	5 year olds with decay	8 year olds with decay	% of 12 year olds with decay
Ireland (fluoridated)	37%	28%	54%
Ireland (non-fluoridated)	55%	25%	62%
United Kingdom (non-fluoridated)	43%	19%	43%

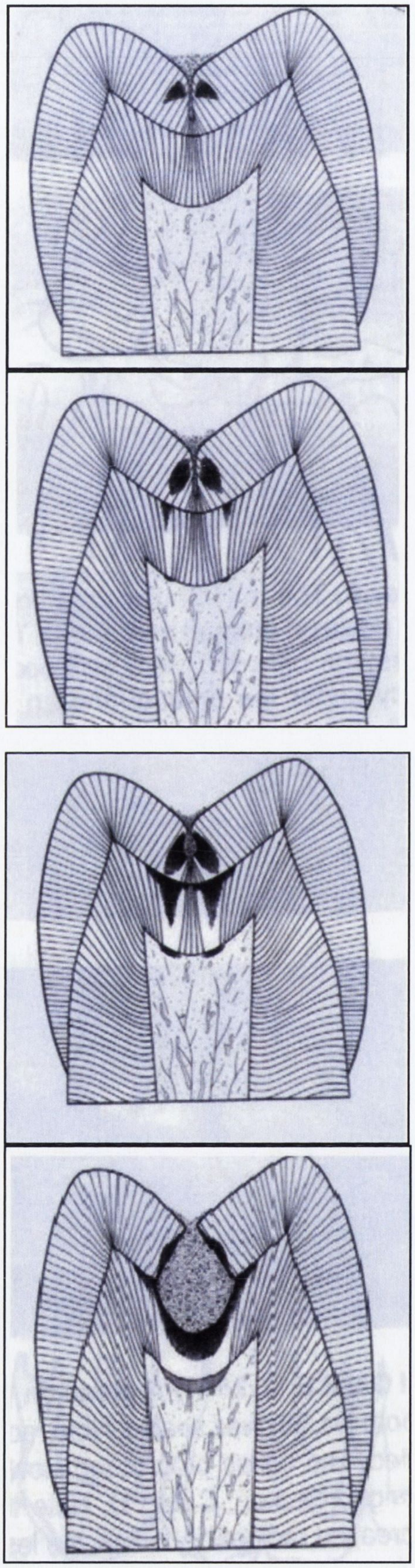
In the United States up to 42% of children in the age group of 6-19 years of age have caries affecting the permanent dentition with the prevalence of caries increasing with age. Pit and fissure surfaces accounted for 90% of the decay in this survey (NHANES, 2004). The pit and fissure surfaces of the first and second permanent molar teeth are the most common sites for caries development and therefore the rationale for placing sealants on these surfaces (Ahovuo-Saloranta et al., 2008). Irish studies show that the molar teeth in both dentitions are the most common teeth to be affected by caries (Whelton, 2006).

2.4-3 Progression

Caries initiation and progression in permanent molar teeth is most likely to occur within the first year of eruption (Vanderas et al., 2003).The main reason permanent molar teeth are more susceptible to caries progression in the post-eruption stage is because the enamel is not fully mineralised. For patients with higher caries risk factors the lesion can progress more rapidly.

The fissure areas of molar teeth can become occluded with a plaque plug early on during eruption which is not always removable with a toothbrush. The earliest colonising pathogen is Streptococcus sanguis which is shortly followed by colonisation with Streptococcus mutans. The lesion will progress through the enamel over time if left untreated as described in Figure 2.8.

Figure 2.8 Caries progression in pit and fissure surfaces (Nagano, 1960)



It is critical that fissure sealants are placed as soon as possible after eruption to create the physical barrier that will prevent a carious lesions developing (Figure 2.9). There is evidence to support the success of placing fissure sealants on early enamel lesions. The concept of sealing in caries was first reported in the early 1970s (Handelman et al., 1972). Studies have shown that sealing in early enamel lesions can decrease and arrest its progression (Bader and Shugars, 2006; Griffin et al., 2008b). The placement of sealants over an early lesion has also been shown to reduce bacterial growth (Oong et al., 2008). The guidelines are clear that sealing over early caries should only be carried out when staining is confined to the pits and fissures and there is no evidence of shadowing around the fissure which would be an indication of caries progression into the dentine. In the event that radiographs are available they should be examined for any evidence of dentine caries (Beauchamp et al., 2009; HSE, 2010).

Figure 2.9 Fissure sealant barrier

http://www.dentistryatgrayhawk.com/services.html

2.5 Types of sealants

The overall function of a sealant material is to create a lasting retentive barrier that will minimise plaque stagnation and bacterial colonization in the narrow fissure areas of molar teeth. Historically zinc phosphate cement and ammoniacal silver nitrate were used with limited success (Kline, 1942; Wilson, 1895). Nowadays glass ionomer and resin are the materials of choice for sealants.

2.5-1 Glass ionomer (GI) fissure sealants

Glass ionomer cements were first introduced by Wilson and Kent in 1972. Glass Ionomer is made up of an alkaline ion leachable, calcium and strontium aluminofluorosilicate glass powder and a water soluble acid polymer. The acid and the base combine in an acid-base reaction which creates a chemical bond with the enamel (Aboush and Jenkins, 1986).

The traditional glass ionomer material evolved to the resin modified glass ionomers (RMGI) in the 1990s. The addition of the resin improved the physical properties of the material (Croll and Nicholson, 2002).

Glass ionomer or resin modified glass ionomer sealants are indicated when isolation is not achievable to allow placement of a resin sealant (Ahovuo-Saloranta et al., 2008; Beauchamp et al., 2009; HSE, 2010). For a high caries risk patients GI/RMGI are a suitable choice when the tooth is erupting if behaviour is poor which would prohibit the placement of an effective resin sealant. The technique involved for placement of GI/RMGI sealants is quick and easy but its main short coming is its lesser retention rate than resin. Table 2.6 gives a reviews of the difference between GI and RMGI (Anusavice, 2003).

Table 2.6 Properties of Glass Ionomer and Resin Modified Glass Ionomer (Anusavice, 2003)

Glass ionomer	**Resin Modified Glass ionomer**
Application • Type I Luting • Type II Restorations • Type III Liners and bases • Type VI Fissure sealants • Type V Orthodontic brackets • Type VI Core build up	**Application** • Luting • Restorations • Liners • Fissure sealants • Orthodontic brackets • Core build up
Composition of calcium and strontium aluminofluorosilicate glass powder Silica - 41.9% Alumina - 28.6% Aluminum fluoride - 1.6% Calcium fluoride - 15.7% Sodium fluoride - 9.3% Aluminum phosphate - 3.8%	**Composition of** Fluoroaluminosilicate glass powder Silica - 41.9% Alumina - 28.6% Aluminum fluoride - 1.6% Calcium fluoride - 15.7% Sodium fluoride - 9.3% Aluminum phosphate - 3.8%

Liquid	**Liquid**
• Polyacrylic acid • Tartaric acid • Water	• Polyacrylic acid • methacrylate/ hydroxyethyl methacrylate(HEMA) monomer • Water
Setting time • 4-7 minutes • Complete setting takes 24 hours	**Setting time** • On command light activation
Advantages • Chemically bond to enamel • Release fluoride • Thermal coefficient of expansion similar to tooth **Disadvantages** • Long setting time • Poor wear resistance • Poor fracture strength • Microleakage brittle	**Advantages** • Chemically bond to enamel • Release fluoride • Thermal coefficient of expansion similar to tooth • Higher bond strength than GI **Disadvantages** • Shrinkage leading to microleakage • Viscous • Poorer retention than resin

2.5-2 Resin sealants

Resin sealants bond directly to the etched enamel surface of the pits and fissures. The resin tags form a micro-mechanical bond to the enamel. Resin sealants are the first choice for fully erupted permanents molars where adequate isolation is achievable (Ahovuo-Saloranta et al., 2008; HSE, 2010). Table 2.7 describes a review of resin sealants.

Table 2.7 Review of resin sealants

Composition The main composition of resin sealant is BIS-GMA which is a combination of Bis-phenol A and glycidyl methacrylate. Catalysts such as benzoylperoxide (auto polymerised sealants) or camphorquinone (light polymerised sealants) can be added to different resin sealants (Anusavice, 2003).
Filler particle Resin sealants are available with or without filler particles. It is important that a sealant can penetrate the fissures as deep as possible. It is not unreasonable to assume that the less viscous the resin material is the better it is at penetrating the fissures. Studies have shown that unfilled resins have a better success rate than filled resins (Barrie et al., 1990; Rock et al., 1990). Another disadvantage of filled resin sealants is that occlusal adjustments following placement is more likely than with an unfilled resin sealant (Tilliss et al., 1992).
Colour Resin sealants are available in a range of colours ranging from clear to opaque to coloured. The success rates are comparable but it is reported that the coloured or opaque sealants are easier to review (Rock et al., 1989; Simonsen, 2002; Waggoner and Siegal, 1996). One study showed that when 3 dentists review a combination of opaque and clear fissure sealants there was a 1% error rate in identifying a coloured sealants and a 23 % error rate for identifying a clear sealants (Rock et al., 1989).
Fluoride The newer generation of sealant release fluoride. Studies show that sealants with added fluoride have similar retention rates to conventional resin sealants (Lygidakis and Oulis, 1999). The presence of fluoride in the sealants has not been shown to be any more effective at caries prevention(Koch et al., 1997).
Safety Despite previous reports, patients who receive fissure sealants do not have an increased risk of oestrogen-like effects (Azarpazhooh and Main, 2008b)
Setting method Resin sealants are either self or light cured. Early studies showed that self-cured resins performed better than ultraviolet light resins. Visible light cured sealants are as good as self-cured sealants (De Craene et al., 1989)

2.6 Caries preventative effect of fissure sealants

Pit and fissure sealants prevent caries in permanent teeth. The evidence shows that resin fissure sealants reduce caries by 87% at 12 months and 60% at 48-54 months (Ahovuo-Saloranta et al., 2008). The latest Cochrane review, meta-analysis papers, systematic reviews and numerous studies with extended follow up strongly support the preventative effectiveness of fissure sealants (Ahovuo-Saloranta et al., 2008; Azarpazhooh and Main, 2008a; Mejare et al., 2003; Splieth et al., 2007; Yengopal et al., 2009). However there are conflicting reports as to which material has a higher caries preventative effect (Kuhnisch et al., 2012). The Cochrane review on the preventative effect of sealants showed that 3 studies favoured resin sealants, 2 studies favoured glass ionomer and in 3 studies there was no difference between the two materials. The study designs, number of participants, technique, teeth sealed, re-application of sealant and length of follow-up varied substantially among these 8 studies which is why no definitive conclusion could be drawn as to which material is more effective at caries prevention than the other. A review of the preventative effectiveness of the eight studies is described in Table 2.8.

Table 2.8 Caries preventative effectiveness of resin and glass ionomer sealants

Resin > glass ionomer	**Design**	**Age years**	***n***	**Reseal**	**Follow up**	**Critical appraisal**
(Songpaisan et al., 1995)	Parallel group 1st molars *GI (Fuji IX)* *Composite*	12-13	752	yes	1 Years No increase in DFS in Delton group Increase in GI group	Short follow up
(Kervanto-Seppala et al., 2008)	Split mouth 2nd molars *GI (Fuji III)* *Delton resin*	12-16	599 children	yes	3 years Resin significantly better	Not first permanent molars
(Poulsen et al., 2001)	Split mouth 1st molars *GI (Fuji III)* *Delton resin*	7	179 pairs	Not stated	3 years GI loss 90% Resin loss 10 %	Fluoride , diet, brushing unknown 35% loss to follow up
Glass ionomer > resin	**Design**	**Age years**	**n**	**Reseal**	**Follow-up**	**Critical appraisal**
(Arrow and Riordan, 1995)	Split mouth *GIC(Ketac fil)Delton resin*	7	465 pairs	Yes	44 months GI lost 62% Resin lost 100%	Allocation unclear

Glass ionomer > resin	**Design**	**Age year**	**n**	**Reseal**	**Follow-up**	**Critical appraisal**
(Beiruti et al., 2006)	Parallel group 1st molars *GI (Fuji IX)* *Composite*	7-8	360 teeth	No	5 years Caries Composite 13% GI 3%	Fluoride/ diet unknown 48% loss Isolation not ideal
Resin = glass ionomer						
(Forss and Halme, 1998)	Split mouth 1st molars *GI (Fuji III)Delton resin*	7	166 pairs	Yes	7 years GI 23.5% caries or filled Resin 16.5% caries or filled	High drop out
(Mills and Ball, 1993)	Split mouth 1st & 2nd molars *GI(Ketac silver) Resin (Delton)*	5-16	120 pairs	Not stated	1 Years No difference in caries effectiveness	Short followup High drop out
(Ganesh and Tandon, 2006)	Split mouth *GI(Fuji VII)* *Resin(Concise)*	6-7	100 pairs	Not stated	2 Years No difference in caries effectiveness	Short follow up No statistics

The ability of a fissure sealant to sustain its caries preventative effective is based on its retention to the surface of the tooth (Ripa, 1993). Studies show that resin sealants are more retentive than GI or RMGI (Beiruti et al., 2006; Poulsen et al., 2001; Poulsen et al., 2006). The ability to maximise the retention of resin sealants is the key to sustaining their caries prevention effectiveness.

2.7 Fissure sealant retention

Retention of resin fissure sealants is the single most important outcome measure to evaluate success (Kuhnisch et al., 2012). Fissure sealants provide a protective barrier between the tooth and the oral cavity therefore the longer the sealant remains intact the less likely the tooth is to develop dental caries in the pit and fissure surfaces (Ahovuo-Saloranta et al., 2008; Muller-Bolla et al., 2006; Ripa, 1993). The retention of a sealant in the majority of studies is categorised as; completely intact, partially intact or partially lost and not intact or totally lost. The most important outcome is the recorded number of sealants that remains completely intact on the tooth. (Kuhnisch et al., 2012). The studies assessing the retention of fissure sealants (glass ionomer and resin) are reviewed in table 2.9.

Table 2.9 Retention rates of fissure sealants

	Material	Design	Number	Age	Complete intact %	Partial intact %	Lost %
1 Year recall							
(Bojanini et al., 1976;	Resin *Delton*	Split mouth	173 children	6-8	91	6	3
(Charbeneau and Dennison, 1979)	Resin *Kerr*	Split mouth	229 paired teeth	5-8	79	17	4
(Sheykholeslam and Houpt, 1978)	Resin *Delton*	Split mouth	186 paired teeth	6-10	92	5	0

	Material	Design	Numbers	Age	Complete intact %	Partial intact %	Lost %
2 year recall							
(Brooks et al., 1979)	Resin *Delton*	Split mouth	152 children	5-10	84	10	6
(Charbeneau and Dennison, 1979)	Resin *Kerr*	Split mouth	193 paired teeth	5-8	71	18	11
(Sheykholeslam and Houpt, 1978)	Resin *Delton*	Split mouth	175 paired teeth	6-10	85	7	2
(Songpaisan et al., 1995)	*Glass ionomer (Fuji IX)*	Parallel group	671 children	12-13	1		
(Songpaisan et al., 1995)	*Composite resin*	Parallel group	671 children	12-13	85		
(Poulsen et al., 2001)	*Glass ionomer (Fuji III)*	Split mouth	115 children	7	9	9	82
(Poulsen et al., 2001)	*Delton resin*	Split mouth	115 children	7	80	7	13
(Ganesh and Tandon, 2006)	*Glass ionomer (Fuji VII)*	Split mouth	100 children	6-7	2	68	30
(Ganesh and Tandon, 2006)	Concise resin	Split mouth	100 children	6-7	4	66	30

	Material	Design	Number	Age	Complete intact %	Partial intact %	Lost %
(Mills and Ball, 1993)	*Glass ionomer* Ketac silver	Split mouth	59 paired teeth	5-16	83	12	6
(Mills and Ball, 1993)	*Delton resin*	Split mouth	59 paired teeth	5-16	58	17	25
3 year recall							
(Brooks et al., 1979)	Resin *Delton*	Split mouth	110 children	5-10	80	10	10
(Charbeneau and Dennison, 1979)	Resin *Kerr*	Split mouth	185 paired teeth	5-8	61	23	16
(Poulsen et al., 2001)	*Delton resin*	Split mouth	116 children	7	80	7	13
(Beiruti et al., 2006)	*Glass ionomer* *Fuji IX*	Parallel	292 teeth	7	60	N/A	N/A
(Beiruti et al., 2006)	*Composite resin VisioSeal*	Parallel	292 teeth	7	60	N/A	N/A
4 year recall							
(Charbeneau and Dennison, 1979)	Resin *Kerr*	Split mouth	185 paired teeth	5-8	52	23	11
9 year recall							
(Bravo et al., 2005)	*Resin Delton*	Cluster	82 children	N/A	39%	N/A	N/A

It is clear from the outcome of the above studies that resin sealants are more retentive than glass ionomer sealants but both materials become less retentive over time (Kuhnisch et al., 2012). The main factors that influence the retention of fissure sealants are the stage of eruption of the tooth, the behaviour of the patient and the technique. The more erupted the tooth is the greater the success of the resin sealant (Dennison et al., 1990) and the better behaved the patient is the easier it is to place a good sealant (Feigal et al., 2000). The technique for placing sealants involves multiple steps that are most effectively carried out using four handed dentistry (Griffin et al., 2008a). A study looking at the failure rate of fissure sealants placed by a dentist and a hygienist showed that the failure rate of sealants was lowest in the hygienist group (Folke et al., 2004). The evidence to support each of the steps for placing an effective sealant is described in Table 2.10.

2.7-1 Retention of resin fissure sealants on buccal/palatal surfaces

There are limited studies that assess the retention of resin sealants on the buccal surfaces of mandibular permanent molars and the palatal surface of maxillary first permanent molars. These surfaces can account for up to 40% of the caries experience of these teeth (Brown and Selwitz, 1995). The studies that are available have all reported that the failure rate is greater for buccal/palatal surfaces than for occlusal surfaces (Barrie et al., 1990; Cooney and Hardwick, 1994; Feigal et al., 2000; Futatsuki et al., 1995). In one study, after 2 years follow-up the buccal and lingual sealants were considered "completely sealed" in 35% of the sealants while 88% of the occlusal surfaces for the same teeth were considered "completely sealed" (Barrie et al., 1990).

Table 2.10 Current best practice technique for placing resin fissure sealants

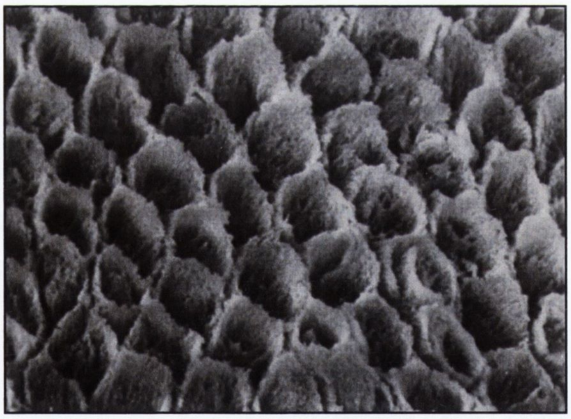
Tooth preparation	Various methods of preparing the tooth prior to sealant placement are described in the literature ranging from cleaning the surface of the tooth with a slurry of pumice and water, to air abrasion to enameloplasty. Air abrasions studies showed results yielding higher bond strength and increased tag formation to rotary cleaning with pumice. The clinical use of air abrasion systems such as Prophy-Jet are not standard practice most likely due to increased cost of the system (Brockmann et al., 1990). The use of a bur to remove the enamel is no longer common practice despite the increased retention of sealants reported (Garcia-Godoy and de Araujo, 1994). Operative intervention is not recommended by current guidelines (HSE, 2010).The use of a dry brush to pre-clean the tooth is sufficient to remove any debris that may be present (Gillcrist et al., 1998; HSE, 2010).
Etching	Buonocore originally used 85% phosphoric acid to etch the enamel. A solution of 35% is considered effective. Studies have shown that etchant placed for longer than 15 seconds do not increase retention (Chosack and Eidelman, 1988). No rinse self-etching adhesives used prior to sealant placement perform inferior to a separate etching step alone (Burbridge et al., 2007; Yazici et al., 2006)
Isolation	Studies show no difference between rubber dam or cotton roll isolation on the retention of sealants (Muller-Bolla et al., 2006). Four handed dentistry will facilitate ideal retention (Griffin et al., 2008a).
Application	Used the minimum amount of sealant necessary to cover the entire fissure pattern network while avoiding creating bubbles (HSE, 2010).
Polymerisation	UV light polymerising sealants are no longer on the market but the retention rate at 24 months was 60%. Self-curing resin sealants have a reported retention rate of 79% at 2 years and up to 65.4% retention at 20 years. The retention of light polymerised sealants at 2 years is 77.8%. The addition of fluoride to light polymerised sealants have a retention of 79.1 % at 2 years (Kuhnisch et al., 2012). Light activation resin is a command set which is more clinically time efficient. The light source be placed as close to the tooth as possible. It should be assessed for correct intensity emissions regularly (HSE, 2010)

2.8 Adhesive bonding

The addition of a bonding agent after the etchant phase of fissure sealant placement has been investigated as a means of increasing retention. Laboratory and limited clinical studies have been carried out in this area. The results are conflicting and no concrete conclusion can be drawn to recommend this additional step as an effective means of increasing fissure sealant retention.

Adhesive bonding to tooth structure is a mechanism that involves the removal of minerals from the surface layer of the enamel or dentine which creates porosities. This occurs through the etching process (Figure 2.10). The porosities are replaced by an adhesive resin monomer which forms a micromechanical lock into the surface of the tooth. Commonly used bonding resins are Bowen's resin (Bis-GMA) and Urethane Dimethacrylate (UDMA). Bis-GMA and UDMA are hydrophobic monomers that allow resin based composites to adhere to them. These resins are now refined by the addition of triethylene glycol dimethacrylate (TEGDMA) or Hydroxyethyl Methacrylate (HEMA) to change the flow and hydrophilicity of the material (Summitt, 2006).

Figure 2.10 Etched enamel with visible porosities



http://doctorspiller.com/Composites/bonding.htm

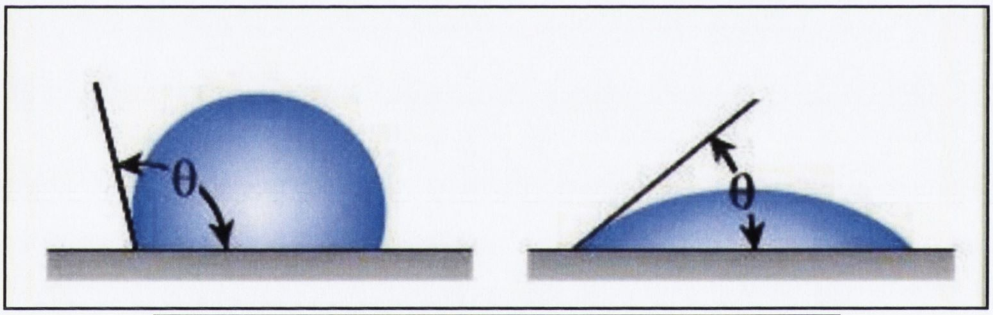
Enamel is a very smooth, highly mineralised substance with approximately 95% of it being hydroxyapatite. When the tooth is etched a very fine roughening takes place because of preferential etching of areas of lower mineral content around and inside the enamel prisms. Nowadays current etchants are about 30-40% phosphoric acid and they are applied for 15-20 seconds. This etching action has two effects;

1. It increases the surface energy and surface area of the tooth.

2. It allows the potential for a material to flow into these areas and set.

Increasing the surface energy of the enamel allows materials to form a lower contact angle with the surface of the tooth and therefore flow better. It increases the "wettability" of the surface (Figure 2.11). This greater flow allows the liquid resin to penetrate in between the partially etched enamel prisms. Since etching also increases the surface area of the tooth there is also more of the tooth to bond to after etching. The high surface energy allows the liquid into the little crevices formed by the etching and is drawn up into the small, etched cavities by capillary action. Once this liquid has set (either by auto-cure originally or now photo-activation) a plastic resin layer is now intertwined with the roughened, etched enamel. This produces an extremely strong bond, which is very durable. Bond strengths of about 20 MPa have usually been reported from experimental data (Gilpatrick et al., 1991). The success of this bond is due to the inorganic nature of enamel, which remains very stable and does not contain a lot of water or organic material. This allows even hydrophobic resins into the micro-cavities and permits effective bonding (Summitt, 2006).

Figure 2.11 Etching causes an increase in the wettability of a surface



http://www.ramehart.com/newsletters/2011-11_news.htm

2.8-1 Dentine bonding

Although dentine bonding is not directly involved in the presented thesis it is necessary to explain the reasoning behind the traditional use of an intermediate bonding agent.

Unlike enamel, which has a very high surface energy, dentine has quite a low surface energy and is not as mineralised a tissue as enamel. It contains about 70% hydoxyapatite, 12% water and 18% organic material, which is mainly type 1 collagen. Therefore trying to get hydrophobic resins, such as Bis-GMA, to form a bond with this hydrated material was a challenging problem. Furthermore cutting dentine with instruments produced a squashed layer of compacted debris called the "smear layer". This needed to be removed to allow effective penetration of the resin (Brannstrom and Astrom, 1972).

Etching the dentine with various forms of acids could remove the smear layer and demineralise the dentine but this would expose the collagen fibrils of the dentine. The drying of the surfaces causes the fibrils to collapse and prevent infiltration of the resin. In order for effective dentine bonding an intermediate hybrid layer was required to adhere to the dentine collagen on one side and the resin material on the other side. A number of early attempts were made at dentine bonding using just a hydrophobic resin and they failed to form a workable bond. Over the years a number of different methods were produced and this led to the so-called *Generational Classification* (Summitt, 2006).

2.8-2 Adhesive bonding Generation Classification

First and **Second Generation** adhesives saw the development of the first bi-functional monomers. These molecules contained a hydrophobic end and a hydrophilic end, which allowed bonding to occur to both a hydrophobic resin and a hydrophilic substrate like dentine. These generations however had not embraced the concept of acid etching the dentine as it was thought to be harmful to the pulp.

Third Generation adhesive systems involved dentine conditioning or etching. Various acids or agents such as EDTA, Maleic or Citric Acid were used to open the dentinal tubules and allow micromechanical retention to occur. Agents such as MDP and 4-META were developed to allow bi-functional bonding to the dentine and resin.

Fourth Generation adhesive systems refined the techniques and materials involved and used a three step etch and rinse technique. 30-40% Phosphoric acid was applied on dentine for a slightly shorter time than enamel and the dentinal smear layer removed. A separate primer was applied to the dentine and this contained the bi-functional monomers to penetrate into the tubules and allow dispersion among the collagen fibrils. Then an adhesive layer of unfilled/lightly filled resin was applied over the primed surface and polymerized. Therefore a Hybrid layer was formed at the dentine-resin interface. This system remains the gold standard in today's bonding systems giving the best and most durable bond strengths Systems such as All-bond 2, Optibond FL (Kerr) and Scotchbond Multi-Purpose are examples of 4^{th} generation systems.

Fifth Generation adhesives aimed to try and shorten the sequence of steps involved and combined primers and resin adhesive into one bottle. Although not as good in laboratory tests as 4^{th} generation systems they nonetheless produce very predictable bonds and are very popular clinically. Examples of these systems include Optibond Solo (Kerr), Prime and Bond (Dentsply), Excite (Ivoclar). This is the type of bond used in this study.

Sixth Generation adhesives tried to simplify the steps even further and use self-etch adhesives that etch and bond the smear layer. This is a 2-step system that uses two components in separate bottles. Two-step self-etch systems use an etchant and primer that are in one bottle and the bond in a separate bottle (Clearfil SE bond, Kuraray). One-step systems use a conditioner, primer and adhesive in two separate bottles that are mixed together and applied onto the tooth in one step (Adper Prompt L-Pop, 3M).

Seventh Generation adhesives tried to achieve the ultimate in simplification by incorporating the conditioner, primer and adhesive in a one bottle, one step system. Examples of this include Clearfil S^3 Bond (Kuraray) or iBond (Heraeus).

A number of problems have been identified in the literature with the simplified versions – 6^{th} and 7^{th} generations. The presence of a weak acid in some of the conditioners has led to concerns about effective etching of enamel. Also the hydrophilic nature of these materials which are applied in one step has led to concerns about the durability of the bond as well as the fact that the overall bond strengths are not as good as the 4^{th} and 5^{th} generation systems(De Munck et al., 2005; Summitt, 2006).

From a clinical perspective the different generations are classified as follows; (De Munck et al., 2005; Van Meerbeek et al., 2003).

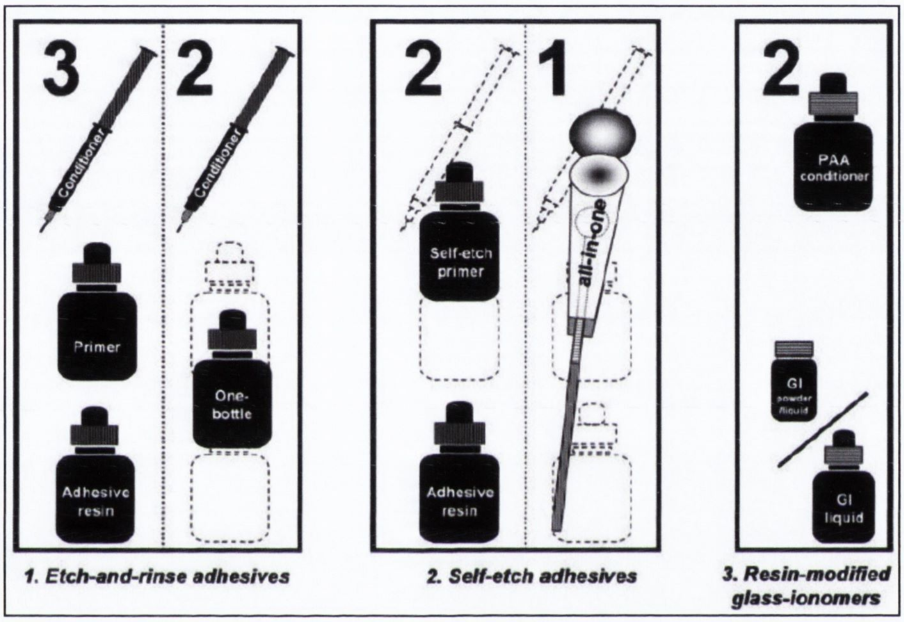
1. Etch and Rinse Adhesive
2. Self-Etch Adhesives
3. Glass ionomer adhesives

The Etch-and-Rinse Adhesives (*4^{th} and 5^{th} generation*) can be ethanol, acetone or water based. The water based adhesive systems such as Scotchbond Multipurpose Primer are less effective than the acetone or ethanol adhesives (Swift et al., 1998). Studies have shown that the ethanol based Etch and Rinse Adhesives are considered the gold standard hydrophilic adhesive system to use. The three step technique out performs the two step technique in relation to bond strength, thermo-cycling and water storage but in vivo studies indicate good durability for both techniques. (Van Meerbeek et al., 2003).

Self-Etch Adhesives, in particular the "all in one" system were designed to reduce clinical time but both laboratory and clinical studies show poor performance in durability for the "all in one" self-etch system (De Munck et al., 2005).

Glass ionomer adhesives remain the only material that can chemically interact with the surface of a tooth. Pre-treatment with a polyalkenoic gives glass ionomer both a mechanical retention and chemical adhesion (De Munck et al., 2005). A summary of the three adhesive systems is illustrated in Figure 2.12.

Figure 2.12 Adhesive systems classification (De Munck et al., 2005)



2.10 Dental Adhesives and fissure sealants

As fissure sealants only involve acid etched enamel there should not be a problem with bonding. However in recent years interest has grown in the idea of using dentine bonding agents to try and improve the retention of sealants. The rationale behind this has been two-fold:

Firstly the anatomy of the fissure patterns can vary. Deep fissure patterns can retain organic debris with high moisture content. The moisture content remains even after etching and air drying and pushes away the hydrophobic unfilled resin of the fissure sealant and prevents penetration into the deeper areas of the fissure (Summitt, 2006).

Secondly the practical application of fissure sealants rarely involves the use of rubber dam so the inherent high humidity of the oral cavity will result in some degree of moisture being present when cotton wool rolls isolation is used. Also child co-operation is a major factor in the success of fissure sealants and the possibility of accidental contamination is high during the procedure.

2.11 Rationale for the use of an intermediate bonding agent in the fissure sealant technique

A dentine bonding agent could theoretically improve the bonding of fissure sealants in a number of ways.

It could allow deeper penetration of the resin adhesive into the fissure pattern and access a greater surface area for bonding which in turn could decrease microleakage and increase bond strength of the sealant.

Some of the 4^{th} and 5^{th} generation bonding systems use solvents/carriers that are like water chasers. Acetone based systems can displace water from the etched enamel and aid in formation of the resin tags. Acetone is however highly volatile and can evaporate easily. An alternative to acetone is ethanol based carriers and they can also chase water but are a little more stable at room temperature.

Overall the intermediate bonding layer could increase the retention of fissure sealants.

One of the earliest studies on this topic showed that when a bonding agent was applied to saliva contaminated etched enamel before resin sealant application it had similar bond strength to a resin sealant placed on uncontaminated etched enamel (Thomson et al., 1981). This concept was also supported by an *in vitro* study that used the bonding agent Scotchbond on 500 bovine incisors. The results showed that the use of a bonding agent over contaminated etched enamel had the similar bond strength to a sealant placed on non-contaminated etched enamel. The study also concluded that on uncontaminated surfaces the bond strength of the sealant with an additional bonding layer was significantly greater ($p < 0.001$) than the bond strength of the sealant placed on etched enamel (Hitt and Feigal, 1992).

The microleakage of contaminated bonded sealants is reported as significantly less ($p<0.0001$) than contaminated non-bonded sealants in *in vitro* studies (Cehreli and Gungor, 2008; Hebling and Feigal, 2000). The use of an etch and rinse type adhesive showed the greatest bond strength and least microleakage in primary teeth *in vitro* (Tulunoglu et al., 1999). A more recent *in vitro* study concluded that a separate etching step is necessary to minimise microleakage and that self-etch adhesive have high levels of microleakage and should not be used in the clinical placement of sealants (Perdigao et al., 2011). The flow of resin into fissures of teeth has been shown to be increased with the use of a bonding agent (Symons et al., 1996).

When the concept of bonding sealants was investigated in a clinical setting the results are conflicting. The study designs, participant numbers, operator numbers, type of bonding system used, technique, teeth sealed, statistical analysis all varied. Few studies gave a breakdown of the differences in retention of the sealant surfaces that were bonded and not bonded.

One of the earliest *in vivo* studies was a 2 year clinical study. It concluded that the retention of fissure sealants placed under contaminated salivary conditions was greater when a bonding agent (Scotchbond) was used. The study numbers were very small ($n = 20$ children) and no statistical significance was reported (Feigal et al., 1993).

Another 2 year clinical study assessing the difference in retention between bonding sealants and not bonding resin sealants concluded that there was no difference between the 2 techniques (Boksman et al., 1993). Two light cured resin sealants (Concise Sealant and Prisma Shield Sealant) were assessed for retention with and without the use of two separate bonding agents (Scotchbond and Prisma Universal Bond). Paired permanent molar, premolar and incisor teeth were included in the study. The age of the participants is not given. At 2 year follow up from which the conclusions were drawn 55 % of the original 402 teeth were reviewed. The breakdown of which teeth were reviewed is not specified. The results are shown in Table 2.11 There was no statistical analysis carried out.

Table 2.11 Results (Boksman et al., 1993)

	Concise	Concise + Scotchbond	Prisma	Prisma + Prisma Universal bond
Retention % 2 year	84	77	77	77

The largest study with the longest follow up assessing the effect of bonding agents on the retention of sealants was carried out on 165 patients and 1058 surfaces (Feigal et al., 2000). A split mouth design was carried out on first and second molar teeth. Four trained operators placed the sealants with assistance and used cotton roll isolation. The different bonding agents were applied and air dried and then the sealant (Fluoroshield) placed immediately over the air thinned bonding agent. The tooth was then light cured for 40 seconds. Participants were divided into 5 groups each receiving a different bonding adhesive as the test group (Table 2.12).

Table 2.12 Study breakdown (Feigal et al., 2000)

Group	**Number participants**	**Paired teeth**	**Adhesive system**	**Number of bottles**	**Follow-up years**
1	65	130	Tenure primer	2	5
2	43	86	Scotch Bond Mulitpurpose primer	2	5
3	21	42	Prime & Bond	1	3
4	21	42	Single Bond	1	3
5	15	30	Tenure Quik	1	3

Variables that affect the retention were analysed using Cox regression analysis and the results were as follows;

- The earlier the eruption of the tooth the increased rate of retention loss.
- 1 bottle or 5th generation bonding agents had the greatest protective effect for both the occlusal and non occlusal surface.
- 1 bottle systems had a higher success on the buccal/lingual surfaces.
- The behaviour had a detrimental effect to retention.
- Scotchbond Multipurpose bond primer had a detrimental effect to retention.
- Maxillary sealants failure rates were higher than for mandibular sealants.

Although the overall numbers in this study appear high when it is broken down into each group the numbers are low except for the first group which had 130 paired teeth as seen in Table 2.12. The statistical analysis looked at estimated survival (Kaplan-Meier estimates) and variable that influenced sealant failures. The exact retention rates of each group were not given.

A recent split mouth study concluded that bonding sealants does not increase retention at 2 year recall. This study had substantial numbers (156 paired teeth). They used an Etch-and-Rinse adhesive system, Scotchbond Multipurpose Primer (water based adhesive). There were multiple operators and the difference in retention rate between occlusal and buccal/palatal surfaces was not analysed. The bonding agent was light-polymerised prior to sealant placement. (Mascarenhas et al., 2008). After 2 years 64% of bonded sealants were retained and 68% of the non-bonded sealants were retained. In the discussion the author recognises that the use of a water based adhesive (Scotchbond Multipurpose primer) may be the reason for the poor success of the bonded sealants. Feigal's earlier study had shown that Scotchbond Multipurpose primer had a detrimental effect on sealant survival (Feigal et al., 2000).

Similarly another clinical study by Pinar et al 2005 also concluded that the placement of a bonding agent does not significantly increase its retention at 2 year follow up. The retention rates were 79% for the bonded group and 75% for the non-bonded group. This was again a split mouth study using an Etch and Rinse bonding agent One Coat Bond, Coltene/Whaledent (water based adhesive) which was light polymerised before sealant placement. Only 88 teeth (44 pairs) were analysed at 24 months which is very low. There is no reference to the difference in occlusal, buccal or palatal surfaces. There is no reference to examiner training or calibration (Pinar et al., 2005). It seemed that poor results were shown for water based adhesives therefore the use of an ethanol based adhesive with a more stringent study design would be required to assess if the most clinically successful adhesive system would improve sealant retention.

If the addition of an adhesive bonding layer can significantly increase the retention of resin sealants then fewer patients will develop caries. However, if a clinical study can categorically show that the retention rate of bonded fissure sealants is significantly better the traditional method it should become the gold standard for the placement of resin sealant.

2.12 Aims and Objectives

Study Aims

To determine if the retention of fissure sealants on first permanent molar teeth is improved by the addition of an adhesive bonding layer before the sealant is applied.

To assess if the behaviour of the patient during the placement of fissure sealants affects the retention of the sealant.

Study Objectives

To compare the retention of fissure sealants of first permanent molars when an intermediate bonding agent is added.

To compare the difference in retention of the sealants on the occlusal, buccal and palatal surfaces.

To compare the effect of patient behaviour on the retention of sealants.

Null Hypothesis

There will be no difference in retention of fissure sealants of first permanent molars sealed with an intermediate bond layer compared to first permanent molars sealed without an intermediate bond layer

The retention of the fissure sealants will not be affected by the patient's behaviour

3. Materials and Methods

3.1 Study population, Consent & Confidentiality

3.1-1 Study Population

The study population were healthy male and female children identified via the Department of Public and Child Dental Health and the Health Service Executive (HSE) school screening clinics in the Cornmarket and Malahide area of Co. Dublin. The age range was aged between 5-16 years. The children were already treatment planned for fissure sealants of their first permanent molars. The study period was from December 2010 to March 2012.

3.1-2 Inclusion and exclusion criteria

The inclusion criteria were specific for both the patient and the teeth involved. Table 3.1 specifies the inclusion and exclusion criteria used to select participants. All patients who met the inclusion criteria were eligible for participation.

Table 3.1 Inclusion and exclusion criteria

	Inclusion Criteria	**Exclusion Criteria**
Patient	• Fit and Healthy (ASA I / II) • Male or female • Age 5 -16 years • Informed Consent	• ASA*≥ III • Informed consent not achieved
Tooth	• Fully erupted first permanent molars • Non- carious • Opposing tooth present • Fissure sealants of first permanent molar indicated on treatment pl	• Partially erupted • Caries present • Restoration present • Opposing tooth absent • No functional cusp on opposing tooth • Developmental defect

3.1-3 Permission and consent

Ethical approval was attained from the Faculty Research Ethics Committee in Trinity College Dublin in April 2010 (Appendix 7.1).

A gate keeper was appointed in the administration office of the Department of Public and Child Dental Health and in the HSE clinic in Cornmarket and Malahide, Dublin. Each potential participant and their parent or guardians were approached by the gatekeeper or a member of the study team. The study was explained and an initial request to participate was sought. Information leaflets with details and illustrations of the study were given to the participant and parent or guardian (Appendix 7.2). Each participant's parent or guardians were advised to contact the gatekeeper in their area if they wished to participate in the study. At a subsequent visit, at least a week after information leaflets were distributed, informed consent was obtained using a consent and assent form (Appendix 7.3). The consent form was signed by the participant's parent or guardian and a member of the study team. This was achieved prior to commencement of the treatment.

3.1-4 Confidentiality

Children were allocated a participant number for identification reasons. All of the consent forms, examiner training sheets and data collection forms were stored in a locked cupboard. Computerised records were stored on a password-protected computer. All information relating to the study was only accessible to the study team.

3.2 Armamentarium

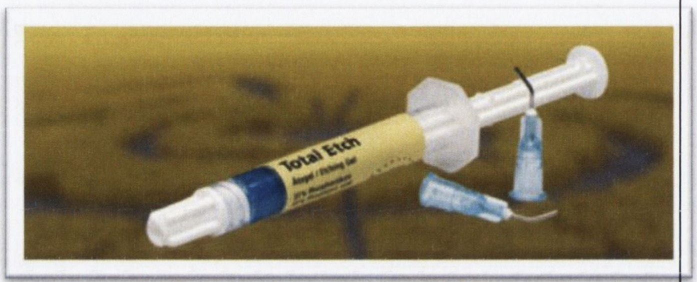
Ivoclar Vivadent etchant, bond and fissure sealant were used in this study.

3.2-1 Etchant

A commercially available gel etchant was used in this study (See Table 3.2)

Total Etch (Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan, Principality of Liechtenstein).

Table 3.2 Properties of Total Etch

ivoclar vivadent: passion vision innovation	
Composition	• 37% phosphoric acid • Polyvinyl alcohol • Pigments
Shade	• Blue
Viscosity	• Medium
Indications	• Enamel etch technique applied for • Composite restoration • Fissure sealants • Adhesive cementation crowns/veneers • Splinting/ brackets
Contraindications	• Allergy to material ingredient • Dry isolation not achievable
Cost per 2g syringe	• €11.19
CE Mark	• CE 0123
Warning	• Phosphoric acid is **corrosive**, avoid contact with eyes, skin and mucosa • Eye protection recommended
Storage	• 2-28 °C • Refrigeration will increase the viscosity

3.2-2 Bonding agent

A commercially available adhesive was used in this study. (See Table 3.3)

ExciTE®F light cure total etch adhesive (Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan, Principality of Liechtenstein).

Table 3.3 Properties of ExciTE®F light cure total etch adhesive

	ExciTE® F LIGHT-CURING TOTAL-ETCH ADHESIVE
Composition	• Phosphonic acid acrylate • HEMA • Silicone dioxide • Initiators and stabilizers • Potassium fluoride • Alcohol
Light curing	• Light intensity >500mW/cm^2
Viscosity	• Low
Indications	• Adhesive for light cured composites
Contraindications	• Allergy to material ingredient • Dry isolation not achievable
Cost per bottle	• €47
CE Mark	• CE 0123
Warning	• ExciTE F is an irritant, avoid contact with eyes, skin and mucosa • Eye protection recommended
Storage	• 2-28 °C

3.2-3 Fissure sealant

A commercially available light curing resin based fissure sealant was used in this study (see Table 3.4).

Helioseal® (Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan, Principality of Liechtenstein).

Table 3.4 Properties of Helioseal® light cured resin based fissure sealant

	ivoclar vivadent: passion vision innovation Helioseal®
Composition	• Bis-GMA (60%) • Triethylene glycol dimethacrylate (40 %) • Titanium dioxide opaquer • Stabilizers • Catalysts; camphorquinone (initiates polymerisation)
Shade	• Opaque
Viscosity	• Low
Indications	• Seal pit and fissures
Contraindications	• Allergy to material ingredient • Dry isolation not achievable
Cost per 8g bottle	• €43.69
CE Mark	• CE 0123
ADA	• ANSI/ADA Spec. No 39,Type 2

3.2-4 Additional materials and instruments

3.2-4-1 Prophy

- Prophylaxis bristle brushes (Henry Schein®, Melville, N.Y. USA).
- Conventional hand piece (Figure 3.1).

3.2-4-2 Isolation

- Cotton rolls, No. 2 roll (10mm) (Henry Schein®, Melville, N.Y. USA) Figure 3.2.
- Dry Tips®, Large (Mölnlycke Health Care, Box 130 80SE-402 52 Gothenburg, Sweden) Figure 3.2.

3.2-4-3 Light curing devices

Starlight Pro (Mectron France, Surgitech Sarl, 3706 rue de Franche Comte, 39220 Bois d'Amont, France) see Table 3.5 and Figure 3.3.

Table 3.5 Characteristics of Starlight Pro light curing device

Size (L x Ø in mm)	198 x 22,5
Weight	105g
Light source	5W LED with patented optical focusing
Light intensity	Ø 8 mm light guide > 1.200 mW/cm^2
Wavelength range	440-480 nm
Fibreglass light guide	Sterilised at 135°C

3.2-4-4 Miscellaneous

- Microbrushes, *Microbrush Plus*™, regular size (Figure 3.4).
- Periodontal probe (DE Healthcare Instruments, Henry Schein Dental suppliers, Melville, N.Y. USA) (Figure 3.5).
- Saliva ejector and high volume suction tips, (Figure 3.6)

Figure 3.1 Prophy instruments

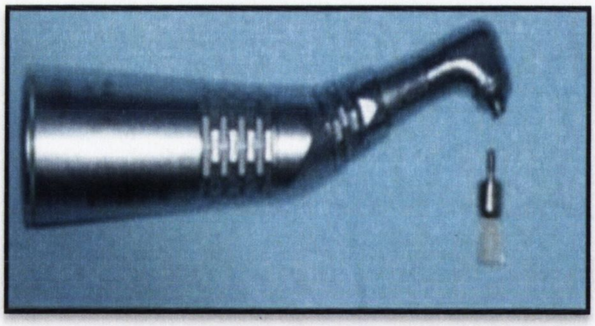


Figure 3.2 Isolation

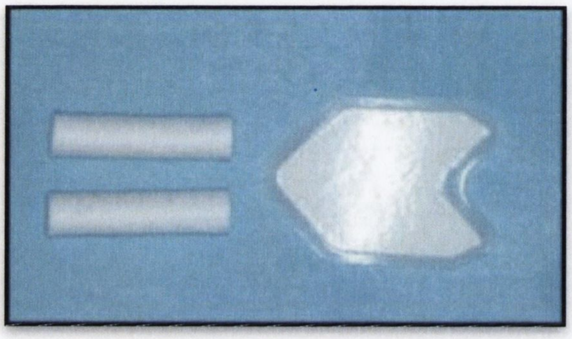


Figure 3.3 Light curing device

Figure 3.4 Microbrushes

Figure 3.5 Probe for sealant

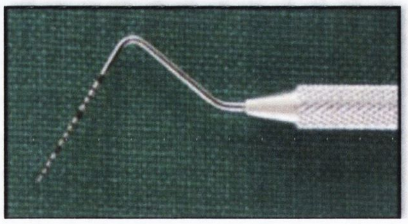
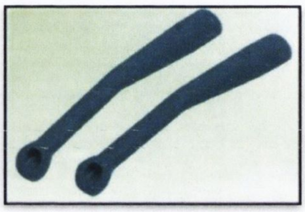


Figure 3.6 Suction devices



3.3 Study design

A randomised split mouth design was used. Paired, fully erupted, maxillary or mandibular first permanent molars were selected for fissure sealants as they would be exposed to the same oral environment and similar occlusal forces. The matching arch paired first permanent molars were randomly designated to receive a bonded sealant (Study group) or a conventional sealant (Control group). The right first permanent molar was fissure sealed first by the operator. The decision to place a bonded or conventional sealant was decided by a coin toss. The type of sealant placed on each tooth was recorded on a data collection sheet (Appendix 7.4). The behaviour of the child was scored at the end of treatment based on the Frankl behaviour scale (Appendix 7.5). Each child was reviewed 12 months after the sealants were placed.

3.4 Clinical technique

3.4-1 Prophylaxis

The occlusal, buccal, palatal or lingual pit and fissure surfaces of the first permanent molar were cleaned with a dry bristle rotary brush for 20 seconds to remove plaque and debris (Figure 3.7).

3.4-2 Isolation

- **Maxillary first permanent molars**; a large Dry Tip was placed in the buccal sulcus along with a cotton roll. The saliva ejector was positioned palatally. The pit and fissures of the tooth were air dried for 5 seconds to remove saliva.

- **Mandibular first permanent molar;** a large Dry Tip was placed in the buccal sulcus along with a cotton roll buccal and lingual to the tooth. The saliva ejector was positioned lingually and the pit and fissures of the tooth air dried for 5 seconds to remove saliva (Figure 3.8).

Figure 3.7 Prophylaxis of tooth

Figure 3.8 Isolation of tooth

3.4-3 Etchant

Total etch was applied to the pit and fissure surface of the tooth for 30 seconds. The etchant was removed using water and air from the 3 in 1 handpiece and the high volume suction until the tooth appeared frosted (Figure 3.9). Cotton rolls were replaced if the operator felt there was an indication to maintain isolation. If salivary contamination occurred the procedure started from the beginning.

Figure 3.9 Etching Procedure

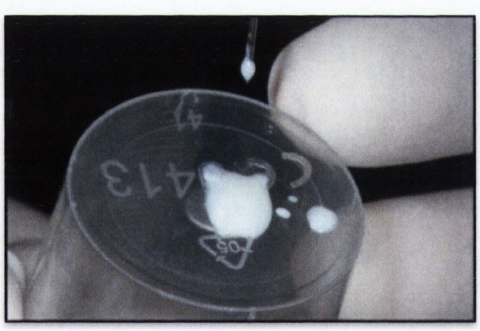
3.4-4 Adhesive layer

The bottle of ExciTE F was agitated for 10 seconds immediately before use. If the tooth was selected for bonding a thin layer of ExciTE F was applied to the pit and fissure surface of the tooth with a microbrush. The adhesive was applied as per the manufacturer guidelines but it was not light cured (Appendix 7.6).

3.4-5 Fissure sealant

The bottle of Helioseal fissure sealant was agitated for 10 seconds immediately before use as per the manufacturer guidelines (Appendix 7.7). Using the tip of a periodontal probe Helioseal was drawn through the pit and fissure of the occlusal, buccal and palatal surfaces of the tooth (Figure 3.10).

Figure 3.10 Sealant application



3.4-6 Light curing

The light cure lip was placed as close as possible to the tooth surface and activated for 40 seconds. A protective light shield was used over the light source (Figure 3.11).

Figure 3.11 Light polymerisation of the sealant

3.4-7 Post placement assessment

Using a periodontal probe the newly placed sealants were checked for retention. No occlusal adjustment was performed (Figure 3.12). If the sealants had any defects at this time the sealant was replaced and a record of replacement was recorded.

Figure 3.12 Post placement assessment

3.5 Operator

One trained operator with experience in paediatric dentistry performed treatment in all the participants. Training included placement of fissure sealants on typodont teeth on a number of occasions prior to commencement of the study. The operator followed a custom designed operator manual to ensure the fissure sealants were placed in a similar manner for each participant (Appendix 7.8).

3.6 Examiners

Two examiners with experience in paediatric dentistry reviewed the fissure sealants. As the paired fissure sealants clinically appeared the same, it was possible for the examiners to review the sealants in a blinded manner.

3.7 Training and calibration

The two examiners were trained and calibrated on 3 separate occasions with a minimum of one week between training and calibration (World Health Organisation, Oral Health Survey, Basic Methods). The training involved both examiners assessing the same first permanent molars and completing a clinical result sheet (Appendix 7.9). The retention of the fissure sealants was checked with a probe to see if the sealant could be removed. The calibration exercises were custom designed for the study using Microsoft® Office Power Point. The presentations contained clinical pictures of fissure sealants which were, (0) present, (1) partially present or (2) not present. The examiners completed a result sheet (Appendix 7.10) and the data from these sheets were inputted to a Microsoft® Office Excel spreadsheet. The results were used to determine the examiners inter and intra-examiner agreement.

3.8 Review interval

The participants were recalled 12 months after the fissure sealants were placed.

3.9 Clinical outcome data

At the review appointment each tooth surface in the study had a visual and tactile assessment of its retention. The assessment was performed by one of the trained, calibrated and blinded examiners (Feigal et al 1993). The variables for the clinical outcomes were recorded and scored on a data collection sheet (Appendix 7.11). If any of the sealants were not intact at the review visit arrangements were made to have the sealants repaired or replaced at the earliest possible appointment.

3.10 Statistical evaluation

The data in this study were recorded on Microsoft Excel 2007 (Microsoft® Inc., Redmond, WA,USA). The descriptive results were illustrated graphically using Microsoft® Excel 2007. The statistical analysis was performed using statistical software GraphPad InStat 3.0. Inter and intra examiner calibration was analysed using Cohen's kappa test.

3.11 Prospective power calculation

- Effect size: 0.3
- Type 1 error: 0.05
- Power CI: 0.95
- DF (Degree of Freedom): 2

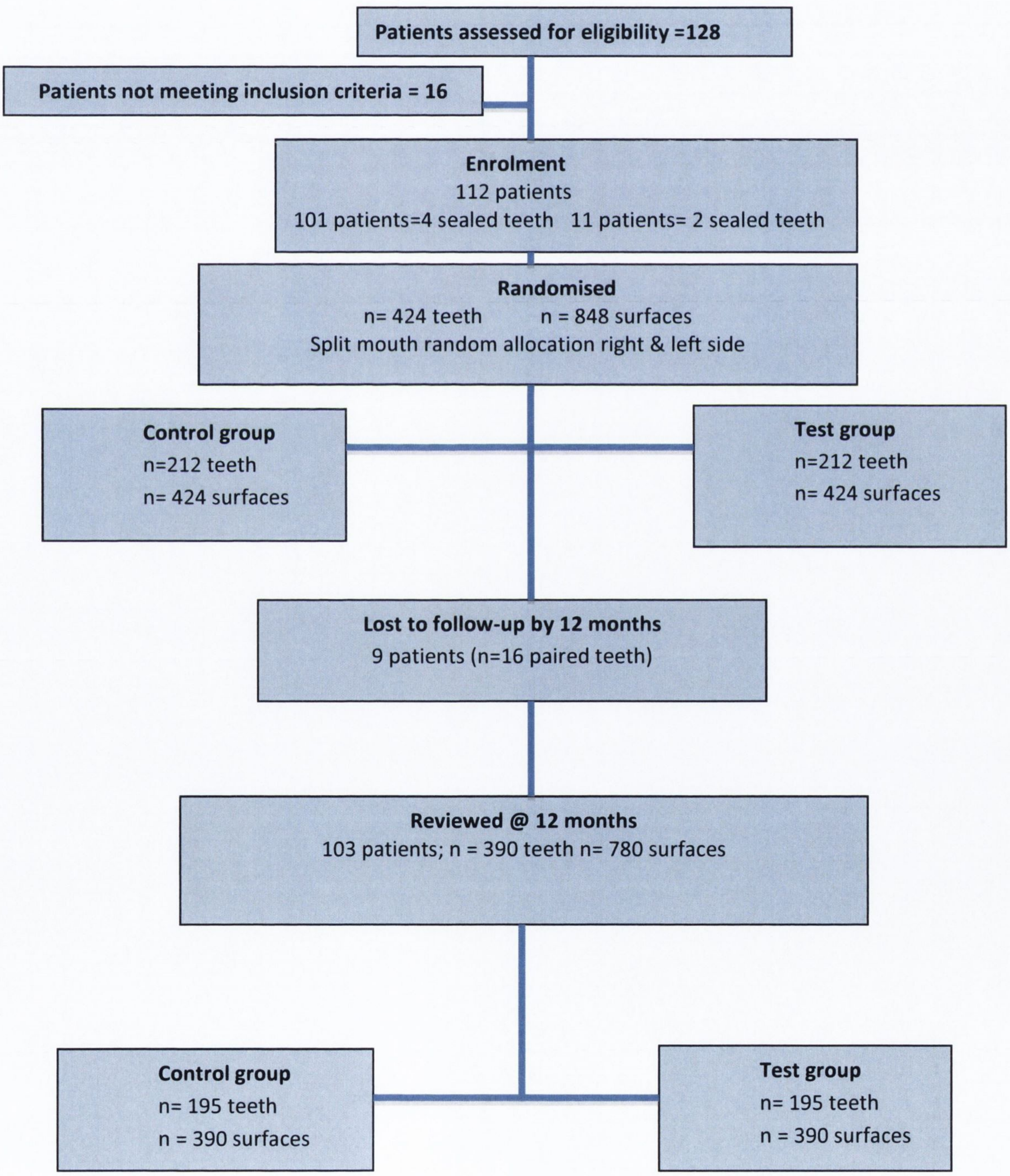
Power calculation is 172 paired teeth

4. Results

4.1 CONSORT diagram

A diagram to show the flow of the participants through each of the stages of the study is shown in Figure 4.1.

Figure 4.1 CONSORT flow chart of participants during the study



4.2 Descriptive Data

The study population were children identified via the Department of Public and Child Dental Health in the Dublin Dental University Hospital (DDUH) and from the Health Service Executive (HSE) school screening clinics in the Dublin areas of Cornmarket and Malahide. Figure 4.2 shows the breakdown of patient identification. The study period was from December 2010 to March 2012. A total of 112 patients with 424 fully erupted first permanent molars were eligible for inclusion in the study. The 112 patients received 424 fissure sealants on 848 surfaces of first permanent molars.

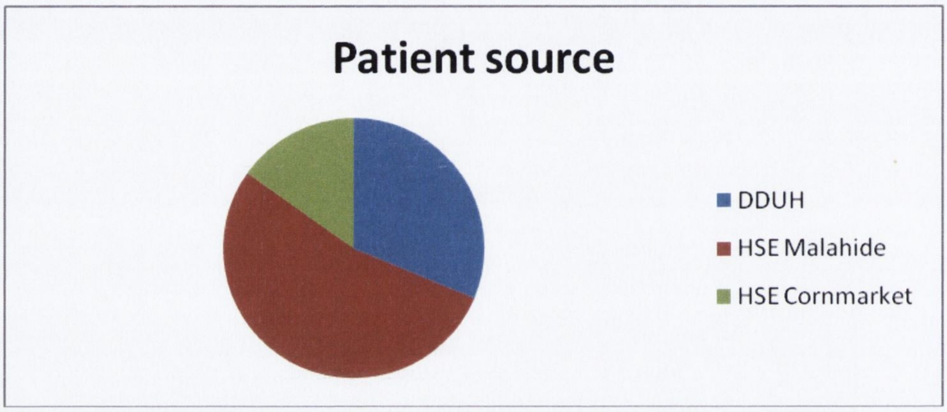


Figure 4.2 Patient Source

At the 12 month recall, 9 patients with 32 fissure sealed first permanent molars were lost to follow-up, of which four patients had immigrated with their families and five patients failed to attend recall appointments and were not contactable via post or telephone. The following figures and tables represent the data for the 103 patients with 390 sealed first permanent molars that were included for final analysis.

Gender distribution

Table 4.1 and Figure 4.3 show the gender distribution included in the study.

Table 4.1 Gender distribution

	Number	Percentage
Males	45	44%
Females	58	56%

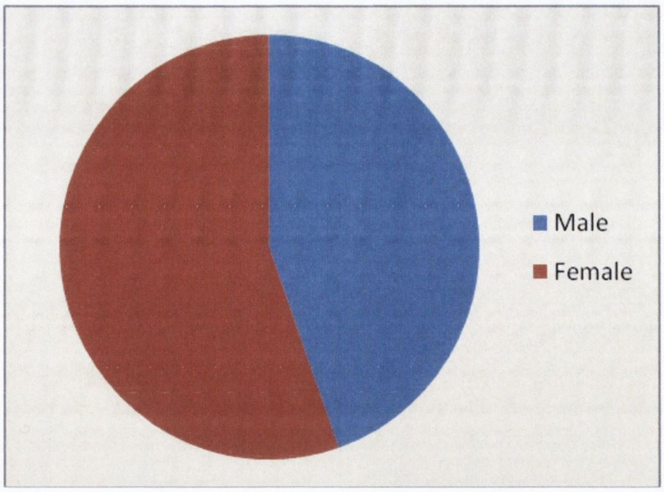


Figure 4.3 Gender distribution

Age distribution

The mean age was 8.31 years with a range of 5.08-15.5 years. The median was 9 years of age. Figure 4.4 shows the age distribution among the study participants.

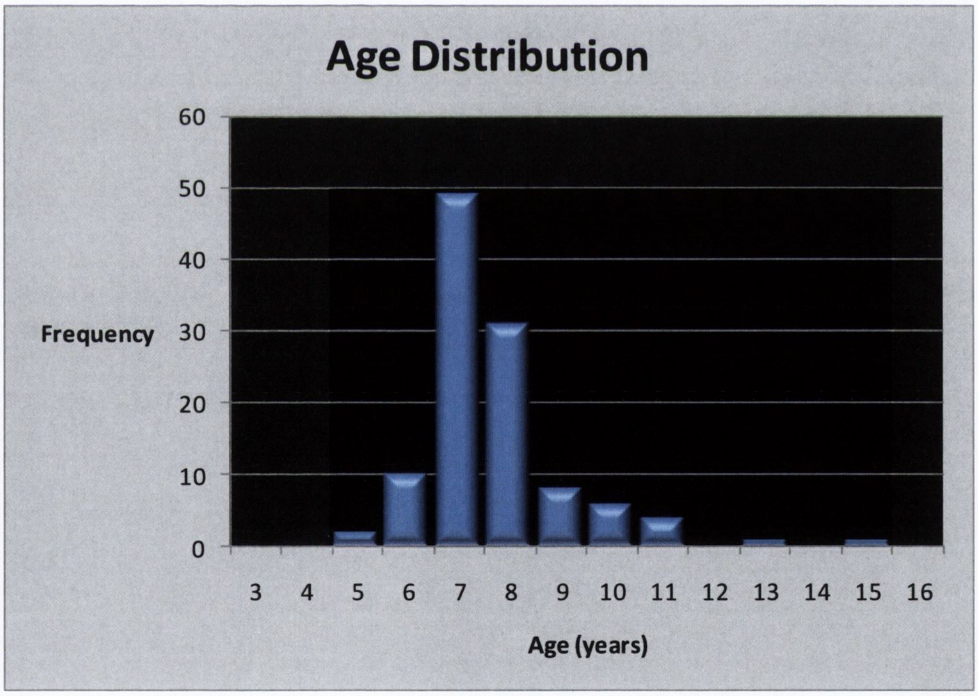


Figure 4.4 Distribution of age among the study participants

4.3 Behaviour distribution

The Frankl behaviour scale was used to grade the participant's behaviour. The operator assigned an overall single grade for the patient's behaviour at the end of treatment. Table 4.2 and Figure 4.5 shows the distribution of behaviour in the study group.

Table 4.2 Behaviour distribution

Frankl score	Number of participants	Percentage
1	0	0%
2	2	2%
3	32	31%
4	69	67%

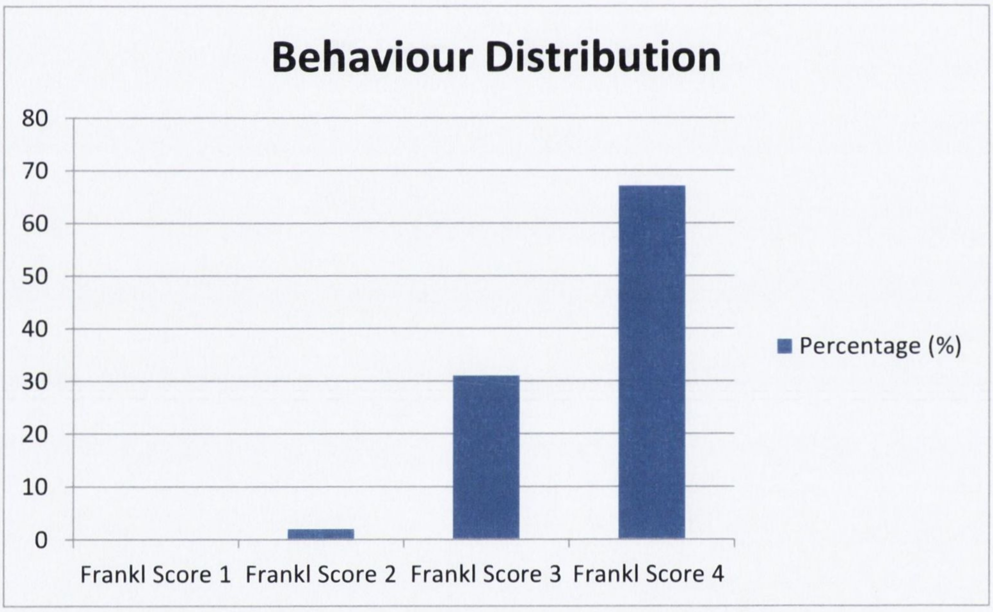


Figure 4.5 Behaviour distribution

4.4 Distribution of fissure sealants

A total of 390 first permanent molar teeth received fissure sealants. The surfaces of the teeth were analysed at 12 month recall for retention of the sealant. The 390 teeth were divided into paired right and left first permanent molars (195 pairs). Table 4.3 and Figure 4.6 show the distribution of fissure sealant placement between the maxillary and mandibular first permanent molars (FPM's).

Table 4.3 Distribution of fissure sealant

	Maxillary FPM's	Mandibular FPM's	Total Teeth
Total	194	196	**(390)**
Control	97	98	**(195)**
Test / Bonded	97	98	**(195)**

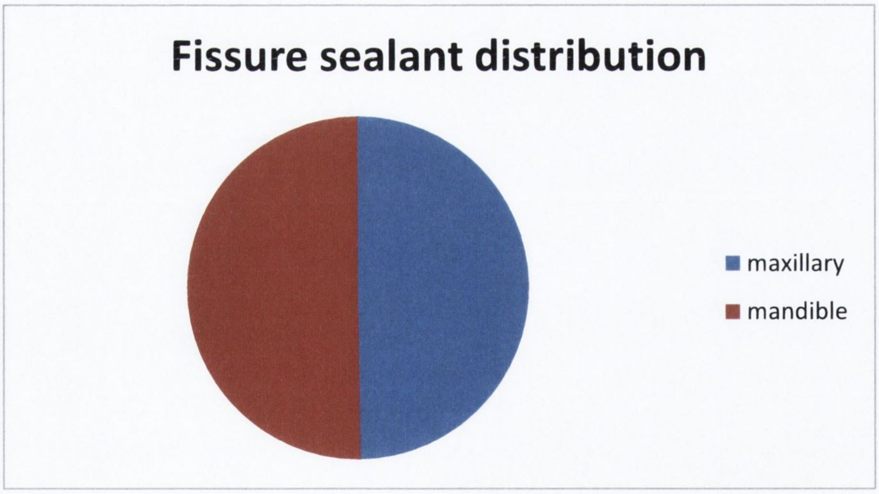


Figure 4.6 Distribution of fissure sealants

Ninety two patients received 4 fissure sealants on all first permanent molars. Eleven patients received 2 fissure sealants on paired first permanent molars Figure 4.7 shows the breakdown of the number of sealants patients received.

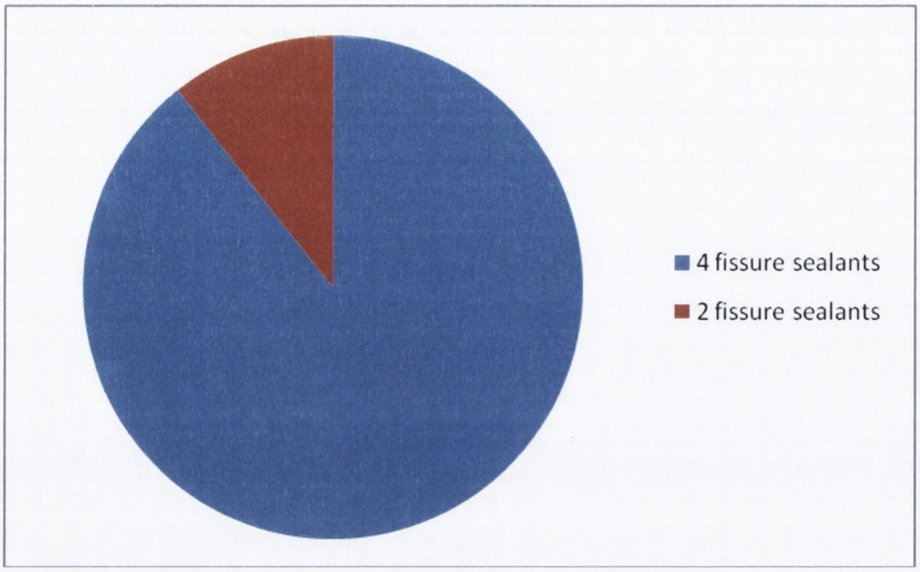


Figure 4.7 Distribution of the number of fissure sealants per patient

4.5 Clinical Parameters

4.5-1 Examiner Calibration

Two examiners were trained and calibrated and one of the examiners was used to assess the fissure sealant retention at the review visit. By having 2 calibrated examiners, it was possible to have one of the examiners available on different days for the review appointments. Cohen's kappa test values were obtained to evaluate the intra-examiner and inter-examiner agreement. Table 4.4 shows the significance of the kappa scores according to the *World Health Organisation, Oral Health Survey, Basic Method.*

Table 4.4 Cohen's kappa Score Chart

Score	Relevance
0.4- 0.6	Moderate agreement
0.6-0.8	Substantial agreement
>0.8	Good agreement
1	Total agreement

The results of examiner calibration are shown in Table 4.5 and Table 4.6.

Table 4.5 Cohen's kappa value for inter-examiner agreement

	Kappa score
Visual retention	0.81
Clinical retention	0.81

Table 4.6 Cohen's kappa value for intra-examiner agreement

Clinical variable	Kappa score Examiner 1 (EK)	Kappa score Examiner 2 (KF)
Visual retention	0.92	0.84

4.6 Retention results

4.6-1 Overall retention

At the 12 month review 85.9% of the 390 fissure sealants were intact, 4.1% were partially intact and 10% were lost. The retention rate of intact sealants on the occlusal surfaces of the first permanent molars was 95.6%. The retention rate of intact sealants on the buccal/palatal surfaces was 86.6% (Table 4.7 and Figure 4.8).

Table 4.7 Overall retention of 390 fissure sealants

Retention score	Total	Total %	Occlusal	Occlusal %	Buccal/ palatal	Buccal/ palatal %
Intact	335	85.90	373	95.64	338	86.67
Partially intact	16	4.10	15	3.85	1	0.26
Not intact	39	10	2	0.51	51	13.08
Total	390	100%	390	100%	390	100%

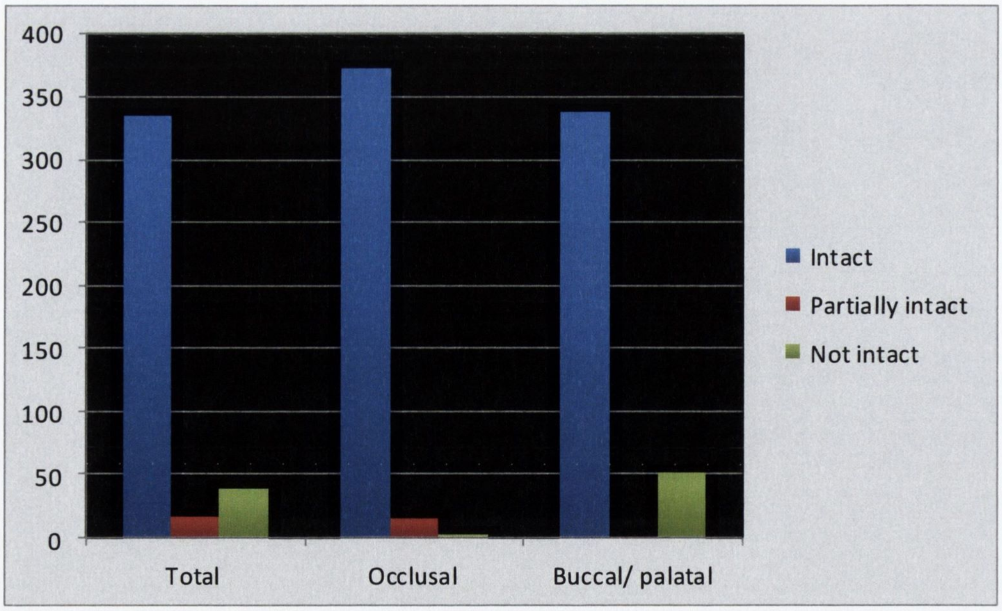


Figure 4.8 Overall retention of 390 fissure sealants

4.6-2 Overall comparison of bonded and control groups

At 12 month recall 92.31% of the bonded sealants were intact while 79.49% of the control sealants were intact (Table 4.8 and Figure 4.9).

Fisher's exact test showed a **statistically significant** difference between the bonded fissure sealants and the control fissure sealants (p=0.0005).

Table 4.8 Overall comparison of bonded and control groups

Retention score	Bonded	Control	Bonded %	Control %
Overall	*195*	*195*	*100%*	*100%*
Intact	**180**	**155**	**92.31**	**79.49**
Partially intact	**2**	**14**	**1.03**	**7.18**
Not intact	**13**	**26**	**6.67**	**13.33**

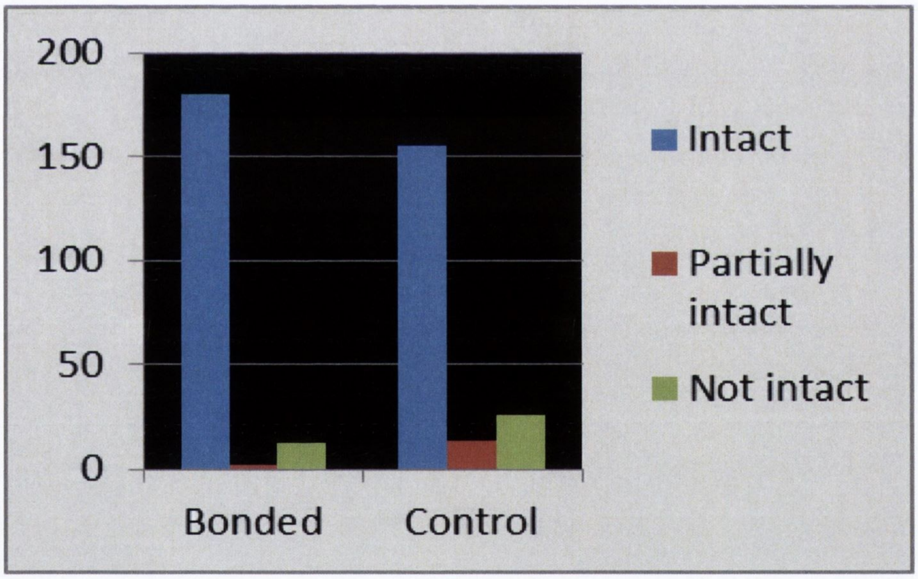


Figure 4.9 Overall comparison of bonded and control groups

4.6-3 Comparison of bonded and control groups for occlusal surfaces

At the 12 month recall 98.46% of the bonded occlusal surfaces were intact and 92.82% of the control occlusal surfaces were intact (Table 4.9 and Figure 4.10).

Fisher's exact test showed **no statistical difference** between the bonded occlusal surfaces and the control occlusal surfaces (p=0.0869)

Table 4.9 Comparison of bonded and control groups for occlusal surfaces

Retention score	Bonded	Control	Bonded %	Control %
Occlusal surface	*195*	*195*	*100%*	*100%*
Intact	**192**	**181**	**98.46**	**92.82**
Partially intact	**2**	**13**	**1.03**	**6.67**
Not intact	**1**	**1**	**0.51**	**0.51**

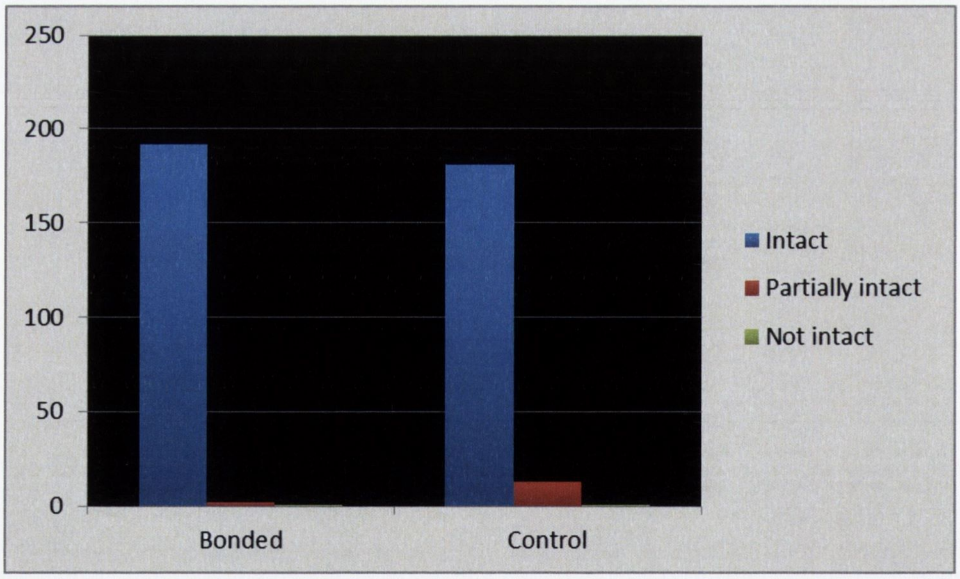


Figure 4.10 Comparison of bonded and control groups for occlusal surfaces

4.6-4 Comparison of bonded and control groups for buccal/palatal surfaces

At the 12 month recall 91.79% of the bonded buccal/palatal surfaces were intact and 81.54% of the control buccal/palatal surfaces were intact(Table 4.10 and Figure 4.11).

Fisher's exact test showed **statistical difference** between the bonded buccal/palatal surfaces and the control buccal/palatal surfaces (p=0.0005).

Table 4.10 Comparison of bonded and control groups for buccal/palatal surfaces

Retention score	Bonded	Control	Bonded %	Control %
Buccal/ palatal surface	*195*	*195*	*100%*	*100%*
Intact	**179**	**159**	**91.79**	**81.54**
Partially intact	**0**	**1**	**0.00**	**0.51**
Not intact	**16**	**35**	**8.21**	**17.95**

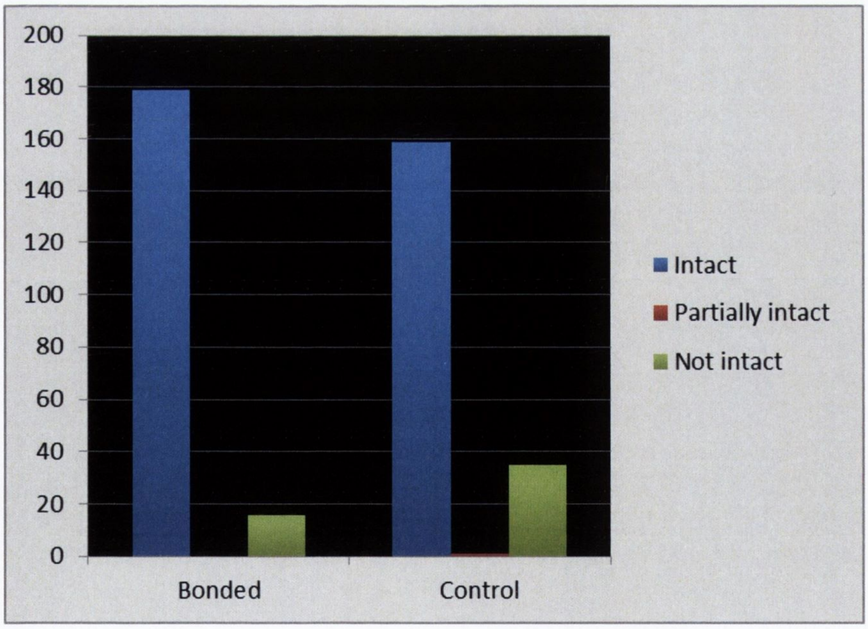


Figure 4.11 Comparison of bonded and control groups for buccal/palatal surfaces

4.6-5 Difference in retention between the maxillary and mandibular study sealant and surfaces

In the maxilla the retention of the bonded sealants was 95.88% and 75.26% for the conventional sealants (p>0.0001). The retention of the sealant on the occlusal surface of the maxillary molars was 100% for the bonded and 93% for the conventional sealants (p=0.03). The number of sealants intact on the palatal surfaces was 94.8 % for the bonded group and 76.26% for the conventional group (p=0.0004).

In the mandible the presence of an intermediate bonding agent did not have a significant effect on the retention of the sealants on either the occlusal or buccal surfaces of mandibular molars.

Table 4.11 Difference in retention between the maxillary and mandibular study sealants and surfaces

	Maxilla Bonded	Maxilla Control	Mandible Bonded	Mandible Control
1. Sealants	**%**	**%**	**%**	**%**
Intact	**95.88**	**75.26**	**88.78**	**83.67**
Partially intact	**0**	**6.19**	**2.04**	**8.16**
Not intact	**4.12**	**18.56**	**9.18**	**8.16**
2. Surfaces				
A) Occlusal				
Intact	**100**	**93.81**	**96.94**	**91.84**
Partially intact	**0**	**0**	**2.04**	**7.14**
Not intact	**0**	**6.19**	**1.02**	**1.02**
B) Palatal/ Buccal				
Intact	**94.85**	**76.29**	**88.73**	**86.73**
Partially intact	**0**	**0**	**1.02**	**1.02**
Not intact	**5.15**	**23.71**	**12.24**	**12.24**

4.7 Behaviour Results

The behaviour results showed that the better the patient's behaviour (Score 4) the greater the likelihood of having intact sealants at 12 months (Figure 4.12). Children with behaviour score 4 (n=139 pairs) had a retention of 94%. Children with score 3 (n=52 pairs) had a retention of 67% retention. Only 2 children scored 2 (n=4 paired teeth) and the retention was 25%.

Chi square test showed that the behaviour has a significant effect on retention of the sealants ($p < 0.0001$) in both the bonded and control group.

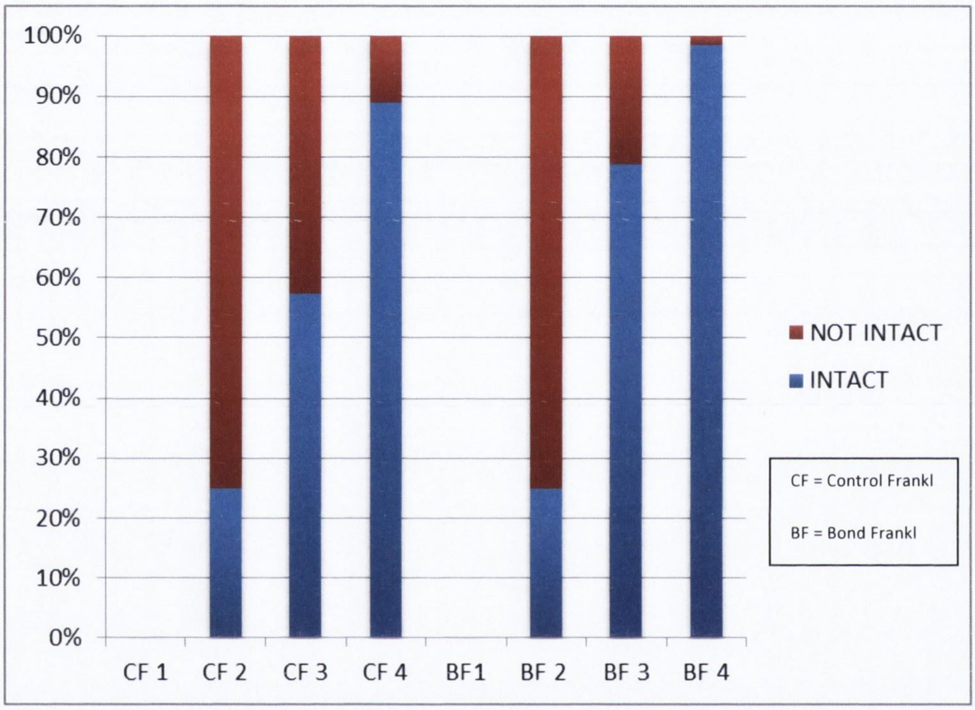


Figure 4.12 Effect of Behaviour on retention

4.8 Ages effect on retention

The mean age of the participants was 8.31. The retention of sealants in the 5-6 age group (n= 35 pairs) was 96%. For the age group 7-8 years (n= 144 pairs) the retention of sealants was 84%. The last age group was patients greater than 9 years old (n=16 pairs) the retention was 84%.

4.9 Logistic regression analysis

A logistic regression analysis was carried out to see if different variables had an effect on the retention. The results below show that an intermediate bonding agent, the surface of the tooth and the behaviour of the patient have a significant effect on the retention of resin fissure sealants Table 4.12.

Table 4.12 Logistic regression analysis

Source	Number of parameters	Degree of Freedom	L-R ChiSquare	Prob>ChiSq
Test/control	1	1	18.342812	<.0001
Behave	2	2	84.7958165	<.0001
surface	1	1	39.316289	<.0001

5. Discussion

The retention of a permanent molar fissure sealant is the fundamental key to maximising its caries prevention effectiveness (Kuhnisch et al., 2012). The reason the retention fails is due to the loss of bond strength between the sealant and the tooth interface. The factors that influence the retention of a resin sealant are the stage of eruption of the tooth, the behaviour of the patient and the technique used to place the sealant.

Studies show the more erupted the molar tooth is the greater the retention of the sealant (Dennison et al., 1990). The behaviour of the child has been shown to have a negative effect which is not surprising given the importance of isolation (Feigal et al., 2000).

The current gold standard for placing a fissure sealant is to clean the surface of the tooth with a dry brush, isolate with cotton rolls, place acid etch for 15 seconds, rinse and dry the tooth until it appears frosted and then place a thin coat of resin sealant along the fissure pattern and finally light cure the resin with an appropriate light source according to the manufacturer's guidelines (HSE, 2010).

A novel technique for increasing the retention of resin sealants is to add an intermediate bonding layer under the sealant (Feigal et al., 1993; Feigal et al., 2000). There are few clinical studies in this area and the results are conflicting (Feigal et al., 2000; Mascarenhas et al., 2008; Pinar et al., 2005). Based on previous studies which assessed the retention of resin sealants on occlusal, buccal and palatal surfaces a prospective power calculation was carried out (Barrie et al., 1990; Bojanini et al., 1976; Charbeneau and Dennison, 1979; Sheykholeslam and Houpt, 1978). It was estimated that 172 paired teeth would be required to show 80% clinical importance.

This study used a prospective, randomised-controlled, split mouth design to assess if an intermediate bonding agent increased the retention of resin fissure sealants. The study assessed if the intermediate bonding agent increased retention when the patient's behaviour scores were lower.

A total of 390 teeth and 780 surfaces (195 pairs) in 103 patients were analysed at 12 months. It was our aim to enrol as many participants as possible and have a greater number than the largest previous similar clinical study of 312 teeth (Mascarenhas et al., 2008). A review period of 12 months after the placement of the sealant was chosen to mirror the recommended recall interval of sealants advised by current public health guidelines (HSE, 2010).

The patients were recruited from 3 areas to provide participants representative of a range of economic backgrounds. The first group was from within the Dublin Dental University Hospital and would be representative of a mixed socio-economic background (35 patients). The second (17 patients) and third group (60 patients) were from the Health Service Executive (HSE) school screenings of second class children (7-8 years). The second group was from the Cornmarket area of Dublin which would be a representative of a low socio-economic area and the third group was from Malahide in north county Dublin which is a representative of moderate to high socio-economic background.

There was a dropout of 9 patients. Five children had immigrated with their families and 4 failed to attend follow up appointments despite several efforts to contact by phone and post. The drop rate was low mostly in part to the benefit of arranging review appointments of several children within the same class and area via the HSE dental service.

The materials chosen in this study are commercially available and were chosen for a number of reasons. The adhesive system ExciTE®F (Ivoclar vivadent) is a one bottle, fifth generation Etch and Rinse Adhesive system. Its clinical success is higher than other systems such as self-etch adhesives (De Munck et al., 2005). The use of a self-etch adhesive in a similarly designed study to this study showed that the retention rate of sealants placed with a self-etch adhesive was less than the retention of sealants placed without the adhesive (Burbridge et al., 2007). The adhesive bond in this study is ethanol based. Alternative Etch and Rinse Adhesive systems are available that are acetone or water based but their clinical performance is reportedly not as good. (De Munck et al., 2005; Swift et al., 1998). A 3-step or 4th generation Etch and Rinse adhesive system would have been the system with the greatest clinical success to choose but for practicality reason a 2-step system was chosen to reduce clinical time. The durability of the 5th generation adhesives such as ExciTE® is shown to be clinically very acceptable.

The resin fissure sealant Helioseal® was used in this study. It is an unfilled, light polymerising, opaque sealant with good reported clinical success. It is also the most common fissure sealant used in the Dublin Dental University Hospital.

The method for tooth preparation, isolation and application of the sealant itself were all chosen based on current evidence (Muller-Bolla et al., 2006).

The 12 month results of the study showed overall retention of the 390 sealants was 86%. The occlusal retention was 96% which is above the yearly reported average of between 79-92% (Charbeneau and Dennison, 1979; Sheykholeslam and Houpt, 1978). The retention of the buccal and palatal sealants was 87%. There are no studies available with 1 year retention figures for buccal and palatal surfaces but there is a 2 year study that showed than only 35% of sealants on the buccal/palatal surfaces were considered completely sealed (Barrie et al., 1990).

The retention of the bonded sealants was 92% and the retention of the conventional sealants was 79% at 12 month recall. The results showed that there is a statistical significance in the retention of the bonded sealants compared to conventional sealants (p=0.0005). This is a very important clinical finding. It is clear from this result that there is sufficient evidence to support the recommendation of the addition of a bonding agent to increase fissure sealant retention.

As it is reported that the retention of sealants on the buccal and palatal surfaces is lower than the occlusal surfaces these surfaces were analysed separately. The results for the occlusal surfaces showed retention of 98.4% for the bonded sealants and 92.8% for the conventional sealants. Although the difference is not statistically significant the retention is higher than previous studies (Charbeneau and Dennison, 1979; Sheykholeslam and Houpt, 1978).

For an operator the occlusal surfaces of molar teeth are most likely the easier of the 2 surfaces to visualise when placing sealants. In this study an operator manual with a controlled sealant placement technique was used. All of the teeth were fully erupted so the extent of the occlusal fissure pattern was above gingival level. These 2 factors would explain the higher than average retention is observed at 12 months in both groups and the reason there is no significant difference in retention on this surface by the use of an intermediate bonding agent. In addition the operator was experienced dentist using 4 handed dentistry which also improves isolation.

The results of this study showed that the use of an intermediate bonding agent on the buccal/palatal surface of permanent molar teeth is significantly better than the conventional method of sealant application.

The results for the buccal/palatal sealant surfaces had 91.7% retention for the bonded buccal/palatal sealant surfaces and 81.54% for the conventional buccal/palatal surface sealants. This was statistically significant (p=0.0005). There are very few clinical studies that have specifically looked at the effect an intermediate bonding agent has on the retention of buccal/ palatal surface sealants. The results of this study are in agreement with previous findings in another study (Barrie et al., 1990; Feigal et al., 2000).

The effect of the bonding on the sealant retention in the maxillary and mandibular arches was also analysed separately. There are few clinical studies that assessed this potential difference (Feigal et al., 2000; Going et al., 1977). In the maxilla, the retention of the bonded sealants was 95.88% and 75.26% for the conventional sealants, a highly significant difference ($p>0.0001$). The occlusal maxillary retention was 100% for the bonded and 93% for the conventional sealants, this also showed statistical significance ($p=0.03$). A much bigger difference was observed in the palatal surfaces with 94.8 % of the bonded palatal surfaces retained and 76.26% of the conventional palatal surfaces retained with a significance of ($p=0.0004$). The maxillary occlusal retention is greater than the yearly average of 90% for both groups and again is a reflection of the stringent clinical protocol on a surface that is above the gingival level.

The maxillary results show that an intermediate bonding agent significantly increases the retention both on the occlusal and the palatal surfaces. The reason the maxillary surfaces have a higher failure rate in the conventional group could be attributed to visualisation of these surfaces. Indirect vision using a mouth mirror is routinely used and isolation of the palatal side of the tooth is difficult, therefore the potential for salivary contamination is high for maxillary molar teeth. The intermediate bonding agent is potentially more forgiving of moisture contamination as reported in previous *in vitro* and clinical studies (Feigal et al., 1993; Feigal and Quelhas, 2003; Thomson et al., 1981).

In the mandible the overall retention of the bonded sealants was 88.7% and 83.6 % for the conventional sealants. The occlusal surface retention was 96.9 % for the bonded group and 91 .84% for the conventional group. The buccal retention was 88.73 % for the bonded group and 86.73% for the control group. No statistical significance was shown in the buccal or occlusal surfaces of mandibular first permanent molars ($p= 0.41$). When resin sealants are placed on mandibular molars cotton rolls are positioned either side of the tooth so the isolation is optimum to keep the tooth uncontaminated. Etch and resin is placed with direct vision and gravity could facilitate easier flow of the sealant material.

The results of this study are in contrast to other studies of similar design which were assessing the retention effectiveness of an intermediate bonding agent (Mascarenhas et al., 2008; Pinar et al., 2005). Both of these studies concluded there was no increase in retention in the bonded groups. The main difference with these 2 studies is the adhesive system. Although they used an Etch and Rinse system it was water based which is clinically less successful (Feigal et al., 2000; Swift et al., 1998) than an ethanol based system as used in this study. In these 2 studies the adhesive layer was light cured before the sealant was applied. This predisposes to shrinkage differential between the bond and adhesive which could lead to bonding failure between the adhesive and sealant interface. In this study the adhesive was air thinned and light cured after the sealant was applied to allow maximum flow and interlocking of the 2 compatible materials which would set at the same rate maximising the bond strength.

The study by Feigal (Feigal et al., 2000) support the results of this study however there are differences in the study design and the statistical analysis. They grouped multiple variables (patient, tooth and bonding system variables) that may have an influence on the failure rate of sealants and analysed all of the variables together. The study concluded that the use of an intermediate bonding agent improved the retention of resin sealants. The exact difference in retention between the bonded and non-bonded groups is not given. In our study a direct comparison between bonded and non-bonded sealants, surfaces and arches was carried out and variables were analysed independently. There is no other study that has similar breakdown of the variables that were able to identify significant retention differences of resin sealants by the addition of an intermediate adhesive layer.

In this study, the behaviour of the participants was assessed and the results unsurprisingly showed that the better the behaviour the more sealants that were significantly intact. The majority of the study group scored a behaviour of 4 which is the best possible behaviour (n=139 pairs). The retention of sealants in this group intact was 94%. In the second group where the behaviour score was 3 (n=52 pairs) the retention was 67%. In the final group, behaviour score 2 (n=4 pairs) which is representative of patients who were cooperatively challenging during sealant placement the retention was a very low 25%. The use of an intermediate bonding agent did not show a significant difference between the bonded and non-bonded group as the behaviour was considered worse. This is a reflection of the lower numbers in group 2 (behaviour score 3 n= 52 pairs) and group 3 (behaviour score 2 n=4 pairs) compared to group 1 (behaviour score 4 n= 139). Use of an intermediate bonding layer will not increase retention where poor behaviour impedes good isolation.

The age of the younger patients did not negatively impact the retention rate of the sealants. In fact the opposite was observed. For children in the 5-6 age group (n=35 pairs), the retention of sealants was 96%. The retention rate in the 7-8 age group (n=144 pairs) and >9 age group (n=16 pairs) was

84% for both. This was a surprising as it would be expected that the technique would be more acceptable in older children.

The main limitation of this study is the short follow up period of 12 months since we know there is a progressive loss of sealants over time. At one year we have shown that an intermediate bonding agent increases the retention of resin fissure sealants and that the effect is significant for maxillary molars and not mandibular molars. It would be of interest to see the difference in retention at 2 and 3 year follow up to determine whether the trend at 12 months continues or if bonding on occlusal and mandibular buccal areas may also benefit from bonded sealants over time. Another limitation to the study was in the patient selection. A select sample of children already treatment planned for resin sealants were chosen to gain access to large numbers of patients who require fissure sealants in a system where recall visits were facilitated. This selection may have biased the sample eliminating children with existing caries or developmental defects in their teeth. Caries risk of the participating individuals and caries preventative fractions were not planned in this study and would be useful in any future studies.

We report the success rate of an ethanol based bonding agent and this has improved overall retention rates of sealants. Until further research shows otherwise, our results suggest that an ethanol based adhesive be used rather than water based due to our higher success rates.

From the results the trend indicates that sealants placed with an intermediate bonding agent are more retentive than the conventional method for occlusal, palatal and buccal surfaces in the maxilla and mandible, particularly on the palatal and occlusal surfaces of the maxillary molars. Bonding does not significantly improve retention in mandibular molars. This is likely not only to be a reflection of the short follow up period but also related the regimental technique protocol which was adopted by the operator for the placement of the sealants.

A very high retention rate was identified on the palatal surface of the maxillary first permanent molars for bonded sealants 92 % compared to 74 % for the conventional group ($p= 0.0001$). Such a high significance at such a short time interval suggests it is an extremely relevant finding, suggesting that an intermediate adhesive layer should always be considered prior to sealing the palatal grooves of the maxillary molars.

The results of this study would suggest that an intermediate bonding agent is advantageous to improving the retention of resin fissure sealants especially for maxillary first permanent molar. The routine use of an intermediate bonding agent has cost implication in both a public and private setting (a bottle of adhesive is approximately €90-100). However a cost benefit analysis may show that this cost is far less than replacement of maxillary sealants over time.

This study showed the efficacy of adhesive bonding agent at increasing the retention of resin fissure sealants in a very controlled environment. Repeating this study in the public dental service using multiple operators would give a more accurate result of the effectiveness of this added step in increasing the retention of fissure sealants.

Given the difficulty with visualising and isolating the maxillary first permanent molar it could be recommended that an intermediate bonding agent be used to increase fissure sealant retention.

6. Conclusion

Fissure sealants are an effective measure for caries prevention. The addition of an adhesive bonding agent significantly increases the retention of the sealants at 12 months. Overall bonded sealants were more retentive than non-bonded (92% versus 80%) in this study. This difference was significant for maxillary molars but not for mandibular molars.

The use of a 4th or 5th generation bonding agent (ethanol based) is recommended. Bonded sealants on the palatal surface shows more benefit (p=0.004) than the occlusal surface (p=0.03).

The effect of an intermediate bonding agent on the retention of mandibular resin sealants showed no significant difference for the occlusal or buccal surfaces.

The study showed that the retention of resin fissure sealants is significantly affected by a patient's behaviour p=0.001 and the effect of an intermediate bonding agent had no significant effect.

Longer recall of this study is necessary to see if the intermediate bonding agent has a significant effect on the retention of the sealants. More research in this area is necessary to show further comparison. These studies should include different adhesive bonding agents.

7. Appendices

Appendix 7.1 Ethical Approval

THE UNIVERSITY OF DUBLIN
TRINITY COLLEGE

SCHOOL OF MEDICINE
FACULTY OF HEALTH SCIENCES

Trinity College, Dublin 2, Ireland
Tel: +353 1 896 1476
Fax: +353 1 671 3956
email: medicine@tcd.ie

Professor Dermot Kelleher, MD, FRCPI, FRCP, F Med Sci
Head of School of Medicine
Vice Provost for Medical Affairs

Ms Fedelma McNamara
School Administrator

email: medschadmin@tcd.ie

Ms Jennifer McCafferty,
Dublin Dental School,
Lincoln Place,
D 2

Thursday, 9th September, 2010

Study: A ramdomised control trial of the effectiveness of an intermediate bonding agent on the retention of fissure sealants

Dear Applicant (s),

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in May 2010, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely

Prof. Orla Sheils
Chairperson
Faculty of Health Sciences Ethics Committee

Cc
Dr Anne O'Connell
Dublin Dental School,
Lincoln Place,
D 2

PUBLIC AND CHILD DENTAL HEALTH
13 SEP 2010

Schools of the Faculty: Medicine, Dental Science, Nursing and Midwifery, Pharmacy and Pharmaceutical Sciences

Appendix 7.2 Patient Information Leaflet

Information Sheet Page 1

Information Sheet for Participant and Parent

A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealants

Introduction

Your child requires sealants on their first permanent "adult" molar teeth at the back of their mouth. These teeth usually erupt between 5-7 years of age. Decay can occur on the pits and grooves of these teeth if food debris and bacteria stagnate in these areas. The pit and fissure areas are difficult to clean properly with a toothbrush. Placing sealants on these teeth will make them less likely to get decay.

Fissure sealants are particularly important for children who have had decay or cavities in their primary or baby teeth. Generally sealants will stay on teeth for a number of years but sometimes the sealant can break off because it did not stick properly during its placement or the tooth was not properly dry before the sealant was placed. A common cause of sealant failure is lack of moisture control which can occur if the tooth is not fully erupted or if the child becomes uncooperative during the placement of the sealant.

In this study we are going to add a layer of bonding liquid between the tooth and the sealant after it is roughened to see if this will help hold the sealant in place for a longer period of time. Your child may need 2 to 4 sealants. We will be placing a seal on one side using the conventional method and placing a seal with the added bond layer on the other side. We hope to find out if there is a difference in retention of the sealants by using the extra bonding layer.

1

Information Sheet Page 2

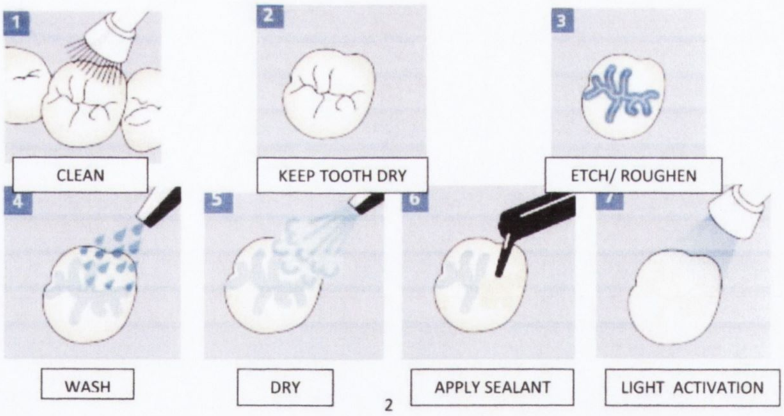
Who are the researchers and who will be treating my child?

There are 4 researchers in this study, all of whom are qualified dentists. One of the researchers is a paediatric postgraduate student in the Dublin Dental University Hospital who will be placing the sealants. This researcher is, Dr. Jennifer Mc Cafferty who is also the main researcher for this study. Dr. Evelina Kratunova, and Dr. Kirsten FitzGearld will be examiners for this study and will be reviewing your child at scheduled recall appointments. Dr Anne O' Connell is the research supervisor.

What does this involve?

- Firstly, the dentist will examine the tooth. This will involve cleaning the tooth with a dry bristle brush like an electric toothbrush.
- If matching first permanent molar teeth are suitable on the top or bottom jaw the dentist will proceed to place a conventional sealant on one side and seal the other side over an added bonding layer as illustrated in steps 1-7.
- After the sealant is placed the dentist will assign a grade as to how cooperative your child was during the treatment using a behavioural scale.

Procedure



2

Information Sheet Page 3

BEFORE SEALANT PLACED

AFTER SEALANT PLACED

What happens after the study?

Your child will be monitored by staff of the Paediatric Department in the Dublin Dental School and Hospital.

Where will this treatment take place?

Your child will have their sealants placed and reviewed in the following location ticked below:

1. Dublin Dental Hospital ☐
2. HSE clinic, Malahide Co. Dublin ☐
3. **What are the benefits?**

The benefits of placing sealants are that your child's first adult molar teeth will be protected from decay. The added bond layer may increase the life span of the sealant.

Are there risks involved?

The same sealant material will be placed on your child's teeth but the technique for placing the sealant is different. Any of the sealants may chip off or break during the study period. If this happens we will arrange to replace the sealant as soon as possible.

Information Sheet Page 4

What happens if my child already has decay in their first permanent teeth?

Your child is already treatment planned to have fissure sealants but If, the examiner suspects following assessment of the teeth that there is decay present we will advise you to attend a dentist either through the hospital, the health service clinics or a private dentist. Your child will no longer be participating in this study.

Do I have to take part?

No, if you do not have to take part in this study. If you decide you do not want your child to take part in study we will still carry out conventional sealants on your child's teeth as planned. It will not affect your right to treatment.

Can I withdraw my child from the study?

Yes, you can decide to withdraw your child from the study at any point even if you have been involved at the start. If your child is withdrawn from the study you will not be denied any treatment your child is due to have carried out in the dental hospital.

Confidentiality

Your child's identity will at all times remain confidential. His or her name will not be published and will not be disclosed to anyone outside the study group. Your child will be identified by a study number. The dentists involved in this study are the only people who will have access to your child's records. Any computerised information will be stored on a password-protected computer with restricted access. The data from the study will be kept for 5 years after the study is completed. The information will not be used for any further unrelated studies without your permission.

Access to Data

The data that is collected in relation to your child will be available for you to see at any time by asking the dentists involved in the study.

4

Information Sheet Page 5

Compensation

Your dentists are covered by standard malpractice insurance. Nothing in this document restricts or curtails your rights.

Stopping the study

The dentist may stop your participation in this study at any time without your consent

Permission

This study has been approved by the Dublin Dental University Hospital, Trinity College Dublin and the Faculty of Health Science.

Use of the data

The results of this study will be presented as part of a thesis in the primary researcher's (Dr. Jennifer Mc Cafferty) Doctorate Degree. It is also hoped that the findings will be published in a suitable dental journal or in a lecture format so that other dentists can benefit from this information.

Further Information

You can get further information or answers to your queries about the study, your participation in the study and your rights from:

- Dr. Jennifer Mc Cafferty, Department of Public and Child Dental Health, Dublin Dental School and Hospital, Lincoln Place, Dublin 2. Telephone: (01)6127303
- Dr. Anne O Connell, Department of Public and Child Dental Health, Dublin Dental School and Hospital, Lincoln Place, Dublin 2. Telephone: (01)6127303

5

Information Sheet Page 6

Once you have read this information leaflet take time to think about and if you wish your child to participate you will need to contact the following:

1. **Dental Hospital patient please contact:**

- Ms Annemarie Boon in the Department of Public and Child Dental Health, Dublin Dental School University Hospital, Lincoln Place, Dublin 2. Telephone: (01)6127303.

2. **Students of City Quay, Gloucester Street or Mater Dei, Basin Lane please contact:**

- Dr. Coleen O Neill at the HSE dental clinic, 10 Cornmarket, Dublin 2 Telephone:(01) 645 5411

3. **Students attending Malahide primary schools please contact:**

- Mrs. Gay Donnelly at the HSE dental clinic in Malahide, Tel: (01) 8450256

You will need to wait at least a week before you contact the relevant clinic. An appointment will then be arranged for your child to participate in this study.

6

Appendix 7.3 Consent and Assent forms

Consent form page 1

Consent Form

Participants name______________

A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealant

This study and this consent form have been explained to me by a member of the research team.

I am aware that my child requires fissure sealants placed on his/her back permanent teeth (first permanent molars). I understand that one of the sealants will be done in the traditional manner and the other sealant will have an added layer to see if this will hold the sealant in place for longer.

I agree that data will be collected on the outcome of these fissure sealants and used in this study.

I give my permission for the data from my child's treatment to be included in the overall findings of this research that will be published in a relevant dental journal.

The dentist, who is a researcher and will be placing the sealants on my child's teeth has explained the procedure to me clearly and has answered any question I have about it. I am aware of what will happen if I agree to take part in this study.

I have read the consent form, or it has been read to me. I freely and voluntarily agree for my child to take part in this research study without prejudice to my ethical or legal rights. I have received a copy of this consent form.

Consent form page 2

I understand that I may withdraw my child from participating in this study at any time and it will not affect any further treatment.

Participant's Name:______________________

Parent's Name: ______________________

Parent's Signature: ______________________

Date: __________

Statement of investigator's responsibility:

I have explained the nature, purpose, procedure, benefits and risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered any questions.

I believe the participant and the parent of the participant understands my explanation and has given their consent to participate in the study freely.

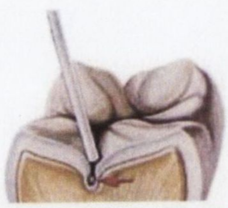
Dentist (Researcher) Signature: ______________________

Date: ____________

Assent form page 1

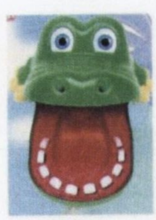
Assent Form

Today you will be having paint put on your back teeth to keep them strong and healthy.



A tooth before it is painted

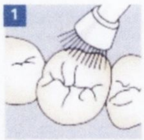
A tooth after it is painted



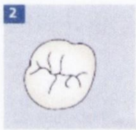
Assent form page 2

Once you are sitting back comfortably in the chair a light will go on over your head and you will be asked to open big a wide like a crocodile so your teeth can be counted.

This is how the paint will be put on your tooth.

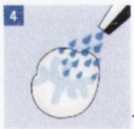


The dentist will wash your tooth by gently blowing some water and air on it. The person helping the dentist will use a suction tip which is like a little hoover to take the water away.



A piece of cotton roll will be placed beside your tooth to keep it dry so the paint can stick to your tooth properly. The cotton roll will feel soft and spongy like a pillow.

A blue gel will be placed on your tooth for 15 seconds.

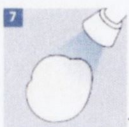


The blue liquid will then be washed away with the water.

Assent Form Page 3

The dentist will gently blow air on the tooth to dry it.

The paint is then placed on the top of your tooth.



To make the paint dry quickly the dentist will place a special light over your tooth. When you hear 4 beeps the paint is dry and the dentist will remove the cotton roll.


If you have anything you would like ask before the tooth painting starts please ask the dentist.

If there is something wrong while the dentist is painting your tooth please put up your hand high so the dentist knows there is something bothering you.

Appendix 7.4 Procedure Sheet

A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealants

Participant Name:____________________

Study Number:____

Date:________

Please tick sealant technique for appropriate tooth:

Tooth Number	16	26	36	46
Etch + Sealant				
Etch + Bond +Sealant				

Behaviour Rating:

Behaviour score	1	2	3	4

Operator:____________________

1

Appendix 7.5 Frankl behaviour scale

Scale	Behaviour
1.	Completely uncooperative, crying, very difficult to make any progress
2.	Uncooperative, very reluctant to listen or respond to questions, some progress is possible
3.	Cooperative, but somewhat reluctant
4.	Completely cooperative and even enjoys the experience

Appendix 7.6 Manufacturer guidelines for the application of bonding agent

ExciTE® F

Brugsanvisning
Käyttöohje
Bruksveiledning
Productinformatie
Οδηγίες χρήσης
Kullanım Talimatları
Инструкция по применению
Instructions for Use
Gebrauchsinformation
Mode d'emploi
Istruzioni per l'uso
Instrucciones de uso
Instruções de Uso
Bruksanvisning

- Dentalt adhæsiv med fluoridfrigivelse
- Fluoridia vapauttava hammasasidosaine
- Dentalt adhesiv med frisettelse av fluorid
- Tandheelkundig adhesief met afgifte van fluoride
- Οδοντιατρικός συγκολλητικός παράγοντας με απελευθέρωση φθορίου
- Flor salan dental adeziv
- Стоматологический адгезив, выделяющий фтор
- Dental adhesive with fluoride release
- Dentaladhäsiv mit Fluoridfreisetzung
- Adhésif dentaire libérant du fluor
- Adesivo dentale a cessione di ioni fluoro
- Adhesivo dental con liberación de flúor
- Adesivo dental com liberação de flúor
- Dental adhesiv med fluoravgivning

CE 0123

ivoclar vivadent: clinical

English

Instructions for Use

Description
ExciTE® F is a light-curing, nano-filled, fluoride-releasing, single-component adhesive for dentin and enamel bonding in conjunction with the total-etch technique.

Composition
ExciTE F contains phosphonic acid acrylate, HEMA, dimethacrylate, highly dispersed silicone dioxide, initiators, stabilizers and potassium fluoride in an alcohol solution.

Indication
- Adhesive for direct light-curing and dual-curing composite and compomer restorations
- Adhesive for indirect all-ceramic and composite restorations (inlays, onlays, veneers; only light-curing)

Contraindication
- Do not use ExciTE F if a patient is known to be allergic to any of the material's ingredients or if the stipulated working technique cannot be employed.
- ExciTE F must not be used in combination with purely self-curing composite materials. Dual-curing materials always have to be light-activated.
- Do not use ExciTE F for direct pulp capping.

Side effects
In rare cases, ingredients of ExciTE F may cause sensitization. In such cases, the product should cease to be used.

Interactions
Materials containing eugenol or clove oil may inhibit the polymerization of ExciTE F.

Application
Direct restorations
1. A dry operating field must be ensured. Ideally, a rubber dam should be placed (e.g. OptraDam® Plus).

2. In very deep cavities, areas close to the pulp should be selectively coated with a calcium hydroxide liner (e.g. ApexCal®) and subsequently covered with a pressure-resistant cement (glass ionomer cement, e.g. Vivaglass® Liner).
3. Apply phosphoric acid gel (e.g. Total Etch) to the prepared enamel and then flow the etchant onto the prepared dentin. The etchant should be left to react on the enamel for 15-30 seconds and on the dentin for 10-15 seconds. Following this, remove all etchant gel with a vigorous water spray for at least 5 seconds. Excess moisture should be removed leaving the dentin surface with a glossy wet appearance (wet bonding). This can be done with either an air gun, a dry brush, a foam pellet or other lint-free absorbents.
   Do not overdry the dentin!
4. **Use of the different delivery forms**
   ExciTE F is available in bottles, the VivaPen® and Soft Touch™ Single-Dose vessels.

Appendix 7.7 Manufacturer guidelines for the application of the fissure sealant

Step-by-step application procedure
Shake the Helioseal bottle well before use. Open the bottle only immediately before use to prevent premature polymerization by light.

1. Thoroughly clean the enamel surface to be sealed.
2. Isolate the working field, preferably with a rubber dam.
3. Apply an etching gel, e.g. Email Preparator blue, and let it react for 30 to 60 sec.
4. Rinse thoroughly.
5. Dry with water- and oil-free air. The etched enamel should have a mat white appearance. Avoid contamination of the etched surface with saliva.
6. Apply Helioseal directly with the disposable cannula or a brush, and disperse.
7. Wait for approx. 15 sec. Then cure the sealant with a suitable polymerization light (e.g. Astralis) for 20 sec.
8. Check seal and occlusion.

Recommendation
We recommend subsequent fluoride application (e.g. Fluor Protector) to provide optimum protection after sealing.

Warning
Avoid contact of unpolymerized material with skin/mucous membrane or eyes. Unpolymerized Helioseal may cause slight irritations and, in rare cases, may lead to a sensitization against met-hacrylates.

Storage
- Close Helioseal bottle immediately after use.
- Store material at 2–28 °C (36–82 °F).
- Shelf life: see date of expiration.
- Do not use the material after the indicated date of expiration.

Keep out of the reach of children
For use in dentistry only.

Manufacturer
Ivoclar Vivadent AG.
FL-9494 Schaan

Date information prepared
12/2002

This material has been developed solely for use in dentistry. Processing should be carried out strictly according to the Instructions for Use. Liability cannot be accepted for damages resulting from failure to observe the Instructions or the stipulated area of application. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in the Instructions. Descriptions and data constitute no warranty of attributes and are not binding.

Appendix 7.8 Operator Manual

A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealants

OPERATOR MANUAL

STEP	PROCEDURE
1.	Randomisation of the tooth and sealant technique by the use of a coin toss
2.	Clean tooth with a dry bristle brush on a conventional handpiece for 20 seconds
3.	**Isolation:** Maxillary molar: tooth to be isolated with cotton roll and dry tip placed buccally and saliva ejector lingually Mandibular molar: tooth is isolated with cotton rolls placed buccally and lingually and dry tip and saliva ejector
4.	Using a microbrush apply Total Etch (37% phosphoric acid) to cover the entire fissure pattern of the tooth and leave for 30 seconds
5.	Wash the etchant off the tooth with compressed air and water from the 3 in 1 tip using the high volume suction for 10 seconds
6.	Use the high volume suction to removed excess moisture in the lingual cotton roll then replace this cotton roll using a college tweezers.
7.	Dry the tooth for 10 seconds with compressed air until the tooth surface appears frosted
8.	Bottles of ExciTE F bonding agent and Helioseal fissure sealant agitated for 10 seconds immediately before use
9.	Place 1 drop of Excite F bonding agent and 2 drops of Healioseal fissure sealant placed on separate dappen dishes immediately before application
10.	Using a microbrush apply ExciTE F to the fissure surface of the tooth. Air thin for 5 seconds. (Study group only)
11.	For both the study and control group apply drops of Helioseal fissure sealant using the tip of the periodontal probe along though the fissure pattern of the tooth. Light cure for 40 seconds
12.	Remove cotton roll, dry tip and saliva ejector and check sealant for retention with a probe. Repeat steps if defect detected

Appendix 7.9 Examiner calibration sheet

A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealants

Jennifer Mc Cafferty

Clinical Examiner Result Sheet

Examiner Name : ______________________________

Date: _____

		VISUAL ASSESSMENT			TACTILE ASSESSMENT	
Patient name	**Sealant Tooth No**	**0 = PRESENT**	**1= PARTIALLY PRESENT**	**2 = NOT PRESENT**	**0= INTACT**	**1= NOT INTACT**
	1.					
	2.					
	3.					
	4.					
	5.					
	6.					
	7.					
	8.					
	9.					
	10.					
	11.					
	12.					
	13.					
	14.					
	15.					
	16.					
	17.					
	18.					
	19.					
	20.					
	21.					
	22.					
	23.					
	24.					
	25.					
	26.					
	27.					
	28.					
	29.					
	30.					
	31.					
	32.					

Appendix 7.10 Examiner calibration sheet

A Randomised Control Trial of the Effectiveness of an Intermediate Bonding Agent on the Retention of Fissure Sealants

Jennifer Mc Cafferty

Examiner Result Sheet

Examiner Name : ______________________________

Date: _____

Score	0 = PRESENT	1= PARTIALLY PRESENT	2 = NOT PRESENT
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
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Appendix 7.11 Result Sheet

A Randomised Control Trial of the Effectiveness of an
Intermediate Bonding Agent on the Retention of Fissure Sealants

Result Sheet

Participant name:____________

Examiner:_________

Date: _____

		Visual Assessment				Tactile Assessment	
Tooth		0 = Present	1= Partially present	2 = Not present		0= Intact	1= Not intact
16 occlusal 16 Palatal							
26 occlusal 26 palatal							
36 occlusal 36 buccal							
46 occlusal 46 buccal							

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