

3.4 CLINICAL STUDIES

3.4.1 Glass-Ionomer Cement

McLean and Willson recommended the use of glass-ionomer cement for fissure sealing and fissure filling in 1974. This recommendation was based on their 2 year clinical study. ASPA II, a glass-ionomer cement, formulated at the Laboratory of the Government Chemist, London, was used to seal 279 posterior teeth in patients aged between 9 to 16 years. Out of these, 250 teeth were available for examination after one year. The method has been discussed in Section 3.2.1. In view of the rapid failure of some fissure sealants, (Parkhouse, Winter 1971), the importance of this study was attached to establishing whether the glass-ionomer cement ASPA was retained in fissures for any length of time before it could be considered clinically viable and recommended for extensive clinical trials. Therefore, the study was limited to ascertain whether a long term physicochemical bond between cement and enamel appeared to exist clinically and whether any significant erosion of cement took place.

In addition, both clinical and radiographic examinations were made at yearly intervals to establish whether any secondary caries had occurred. No attempt was made to assess whether any statistically significant difference in occlusal caries rate occurred between treated and untreated teeth, since it was considered that the number of teeth examined after the first year was too small to draw any conclusions.

The condition of ASPA sealants was assessed at 1 year and 2 years. The sealants were divided into 3 categories: fissures fully sealed; fissures partially sealed; sealant lost. However, in some cases, surface of the sealant was lost just in the area where there was overbuilding of the orifice of the fissure, but where the bulk of cement still remained in the fissure. These restorations were still classed as partially sealed in order to avoid bias. The result of these studies are summarised in the following tables (Tables 7, 8).

It can be seen that percentage of fissures that remained fully sealed after 1 year is high (84%). Only 10 per cent of sealants were lost after one year and only 4 per cent further after 2 years. The incidence of occlusal caries was very small and occurred only when the sealant was lost.

McLean and Wilson (1974) concluded this study with the following recommendations.

- (1) Glass-ionomer cement was only suitable as fissure sealants where the pit or fissure orifice exceeds 100 μm .
- (2) The two-mix technique described in Section 3.2.1 should be followed for deep cement penetration.
- (3) Fissures or pits below 100 μm in size could only be treated if cement is overbuilt above the orifice.

Table 7. Condition of ASPA fissure sealant after 1 year

Teeth	No. of teeth	Fissures fully sealed		Fissures partly sealed		Sealant lost	
		No.	Per cent	No.	Per cent	No.	Per cent
Premolars	60	49	82	3	5	8	13
Molars	83	71	86	6	7	6	7
TOTALS	143	120	84	8	6	14	10

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(Source: McLean, Wilson 1974)

Table 8. Condition of ASPA fissure sealant after 2 years

Teeth	No. of teeth	Fissures fully sealed		Fissures partly sealed		Sealant lost	
		No.	Per cent	No.	Per cent	No.	Per cent
Premolars	56	41	73	4	7	11	20
Molars	82	66	80	7	9	9	11
TOTALS	138	107	78	11	8	20	14

(Source: McLean, Wilson 1974)

- (4) Early contamination of this sealant by moisture would weaken the poly (acrylate) matrix resulting in rapid wear with loss of cement. Therefore, protection by cavity varnish was essential.

Williams and Winter (1976) carried out a 2 year comparable clinical trial between 4 different fissure sealants and Nuva Seal. They used ASPA II, epoxyelite 9075, Espe 717 and Espe 71729. Their technique of placement of glass-ionomer cement has been discussed in Section 3.2.1.

A total of 105 teeth (245 pits) were sealed with ASPA II. The patients were reviewed at 6, 12, 18 and 24 months. Although the retention of ASPA II was lower than other materials, they found that there was no difference in the incidence of caries in pits and fissures between ASPA II and Nuva Seal. They attribute the failure of glass-ionomer cement retention to the following important factors.

- (1) Use of phosphoric acid for etching enamel for glass-ionomer cement.
- (2) Cement was not protected by varnish.
- (3) Two-mix technique described by McLean and Wilson (1974) was not followed.

Williams, Price and Winter (1978) repeated the 2 year clinical trial using ASPA IV, a glass-ionomer cement with smaller particle size than ASPA II. Three fissure sealants Nuva Seal, ASPA IV and Concise were compared. ASPA IV was applied with 2-mix technique and

was protected by varnish. The teeth were conditioned by 50 per cent citric acid for ASPA IV. ASPA IV and Nuva Seal were applied to 406 teeth in 216 children of mean age 11.4 years at the time of application. The results show that after 2 years in 175 patients reviewed at that time, 298 (47.1 per cent) out of 633 pits retained ASPA IV and 81 (12.8 per cent) pits were carious, compared with 343 (54.2 per cent) pits still retaining Nuva Seal, 105 (16.6 per cent) carious. The test showed Concise to be significantly better in reducing caries than Nuva Seal or ASPA ($p = 0.001$) and that ASPA and Nuva Seal were not significantly different in their cariostatic properties.

Williams and Winter (1981) reviewed this study for the fourth year evaluation and noted some interesting results. Despite the high initial loss of ASPA, at the end of 4 years retention of ASPA was slightly higher (35.4 per cent) as compared to Nuva Seal (34.4 per cent). When these results were compared to 2-year results, it was evident that there had been an additional loss of 11.7 per cent and 19.8 per cent for ASPA and Nuva-Seal, respectively. Another difference between these 2 materials was shown in caries increment scores, with a minute increase in caries incidence for pits sealed with ASPA of only 0.3 per cent, (from 12.8 per cent at 2 years to 13.1 per cent at 4 years), compared with a 2.5 per cent increase in caries incidence in teeth sealed with Nuva Seal (16.6 per cent at 2 years to 19.1 per cent at 4 years). At 4 years there was a significant difference of 6 per cent ($p < 0.01$) in caries incidence between these 2 materials. These results showed

a probability of leachable fluoride continuing its cariostatic actions on teeth several years after the cement had disappeared macroscopically from the enamel surface. There was also a net gain of 29 pits for ASPA over Nuva-Seal and the per cent effectiveness was 31.2 per cent. Williams and Winter concluded that overall ASPA performed better than Nuva Seal.

Mount and Makinson (1978) used ASPA, a glass-ionomer cement as a fissure sealant on 19 teeth, and for other restorative uses on 117 teeth. Only one failure was recorded which was due to faulty technique.

A recent 3 year study by Shimokobe, Komatsu, Kawakami and Hirota (1986) was aimed to evaluate clinically the glass-ionomer cement applied for pits and fissures and to make further improvements for its clinical use. Some 222 children having lower first molars erupted on both sides were selected. Either the left or right molar had sealant applied. The other molar with no sealant was used as a control. The glass-ionomer cement specially formulated for sealant and resin sealant, Delton, was used. Teeth for glass-ionomer cement were prepared by cleaning them with a brush cone: in low speed and water spray. The cement was then applied. Use of protective varnish against water contamination for the glass-ionomer cement is not mentioned by these authors. Delton was applied following manufacturer's instructions. The caries incidence of glass-ionomer cement and Delton were 4.9, 3.6% after 6 months; 14.6, 10.7% after 12 months; 37.6, 25.0% after 24 months; 61.1, 43.2% after 36 months, respectively.

In any of these periods, Delton showed lower caries incidence. Delton was retained even after 36 months, while glass-ionomer cement disappeared in 6 months. But the per cent effectiveness (McCune et al 1973) of glass-ionomer cement was 62.8% after 12 months, and 43.9% after 24 months. This suggests that the cement has an effect on caries prevention even after it disappears. The authors have now improved the mechanical properties of the cement to prolong its retention period and are now conducting clinical trials again (Shimokobe et al 1986).

Data regarding clinical studies of glass-ionomer cement used as pit and fissure sealant is scarce. Availability of newer and improved glass-ionomer cements with modified properties indicate that this material is worthy of further clinical studies and may be considered in any preventive dentistry programmes.

3.4.2 Conventional Pit and Fissure Sealants

Several clinical trials have been carried out to demonstrate the retention and per cent caries reduction of pit and fissure sealants. These have been reviewed at 1 to 10 year intervals. They show a varied pattern of sealant retention and related caries reduction (Table 9).

(a) Occlusal Caries Reduction

Clinical studies of the caries inhibition provided by sealants have usually been done using a half-mouth design, i.e. a caries-free tooth (or teeth) on one side of a child's mouth is treated with sealant while the same

tooth on the opposite side of the mouth is untreated and serves as a control (Charbeneau 1982). In this manner, both treated and untreated teeth, being in the same mouth, are subjected to the same potential caries attack and the only difference between the two is the presence of a sealant. In most clinical trials, the sealant application is carried out only at the initial visit and then the children are recalled at yearly intervals. At the recall examination, the teeth are checked for caries. The treated teeth are also examined for the presence of sealant. If the occlusal surface is completely sealed at the recall visit, it is presumed that the surface is caries free.

Caries reductions from 1 to 10 years after the sealant placement have been documented. Most studies have found occlusal caries reduction from 60 to 100% in the first two years after the sealant application. It can also be noticed, interestingly, the caries reduction from 37-60 per cent after 5 years of sealant application. These results are summarised in Table 9. These results are from single sealant application trials, therefore, illustrate the dramatic effectiveness of sealants. Charbeneau and Dennison (1985) have reported 26 per cent caries reduction after ten years of chemically cured sealant application.

(b) Retention Rate

At recall, treated teeth are examined visually, as well as with the tip of an explorer, in order to determine whether any pit and fissure sealants are present. Also, whether all the pits and fissures are completely covered

and that the sealant can not be dislodged. Three conditions may exist at the recall:

- (1) pits and fissures may be completely covered by the sealant;
- (2) pits and fissures may be partially covered by the sealant indicating partial loss of sealant material;
- (3) pits and fissures sealants completely lost.

Since occlusal surfaces with sealant covering all of the pits and fissures should enjoy virtual protection against caries, only completely covered teeth are listed. Most studies listed in Table 9 show 70-99 per cent retention after 1-2 years of sealant application. Charbeneau and Dennison (1985) reported 36.5 per cent retention of chemically cured sealant after ten years of application.

(c) Other Studies

Charbeneau (1982), while reviewing data from a 4 year study of Charbeneau and Dennison (1979), suggested that over a four-year period, typically 8 per cent retreatment is necessary per year, a programme, he stated, which would be 100 per cent effective in caries prevention over the 4-year period.

Unlike fluoride preparations, conventional sealants contain no additives to reduce dental caries. The success of a sealant therapy, therefore, lies in the sealant's ability to be retained on the tooth surface and physically

act as a barrier between the fissure system and the oral environment. Success or failure, therefore, is determined by the operator's clinical skill and conditions in the oral cavity which exist at the time the sealant is placed, as well as the properties of the material itself.

Rock and Bradnock (1981) have reported the effect of operator variability on the retention of fissures sealant in a 3 year study. Significant differences were found between levels of resin retention produced by 2 operators (63% and 28% after 3 years). Several other studies have also reported that the retention rates of sealants applied by similarly trained operators can vary significantly (Leake, Martinello 1976; Leske et al 1976; Rock, Gordon, Bradnock 1978; Rock, Evans 1983).

In some studies where the success has been poor, investigators have reported difficulty in obtaining moisture control (Burt et al 1977; Stephen et al 1976). The principal intraoral factors which affect the operator's ability to sufficiently dry a tooth are the position of the tooth in the mouth, and its degree of eruption. Thus sealant retention has been found to be better for the more anterior premolars than for the most posterior molars (Going et al 1976; Horowitz et al 1974; Richardson et al 1977; Rock 1972, 1973; Burt 1975a) and better for older rather than younger patients (Rock, Bradnock 1981). In addition, sealant retention was found to be better for lower teeth compared to upper teeth; this may relate to the use of direct vision and lack of adverse gravity flow

of the sealant when treating teeth in the mandibular arch (Harris et al 1976; Leske et al 1976).

Table 9. Occlusal caries reduction and retention of the pit and fissure sealants on permanent teeth, results: 1-10 years after application

Study	Type of permanent teeth	Method of cure*	Complete retention (%)	Occlusal caries reduction (%)
<u>One year after sealant application</u>				
Buonocore (1970)	Premolars 1st and 2nd molars	UV	99	100
Rock (1973)	Premolars 1st and 2nd molars	UV	86	100
Rock, Evans (1982)	1st molars 1st molars	Chem VL	76 75	99 99
Houpt, Sheykholeslam (1978)	1st molars	Chem	94	91
Bojanini et al (1976)	1st molars	Chem	92	90
Bagramian et al (1976)	Premolars 1st and 2nd molars	UV	NA	84+
Charbeneau et al (1977)	1st molars	Chem	79	83
McCune et al (1973)	Premolars 1st and 2nd molars	UV	88	81-85§

(Continued)

Table 4. (Continued)

Study	Type of permanent teeth	Method of cure*	Complete retention (%)	Occlusal caries reduction (%)
Rock (1973)	Premolars 1st and 2nd molars	Chem	53	81
Thylstrup, Poulsen (1976)	1st molars	Chem	73	70
Rock (1972)	Premolars 1st and 2nd molars	UV	54	65
Gourley (1974)	Premolars 1st and 2nd molars	UV	87	65
<u>One and a half years after sealant application</u>				
Meurman et al (1975)	1st molars	UV	88	88
Charbeneau et al (1977)	1st molars	Chem	76	76
<u>Two years after sealant application</u>				
Buonocore (1971)	Premolars 1st and 2nd molars	UV	87	99
Rock (1974)	Premolars 1st and 2nd molars	UV	80	99

(Continued)

Table 4. (Continued)

Study	Type of permanent teeth	Method of cure*	Complete retention (%)	Occlusal caries reduction (%)
Sheykholeslam, Houpt (1978)	1st molars	Chem	85	88
Rock (1974)	Premolars 1st and 2nd molars	Chem	52	84
Bagramian et al (1977)	Premolars 1st and 2nd molars	UV	NA	77-74†**
Horowitz et al (1974)	Premolars 1st and 2nd molars	UV	73	67
Gourley (1975)	Premolars 1st and 2nd molars	UV	78	58
Going et al (1976)	Premolars 1st and 2nd molars	UV	69	55
Tylstrup, Poulsen (1978)	1st molars	Chem	60	50
Higson (1976)	1st molars	UV	3	23
Burt et al (1977)	Premolars 1st and 2nd molars	UV	27	14

(Continued)

Table 4. (Continued)

Study	Type of permanent teeth	Method of cure*	Complete retention (%)	Occlusal caries reduction (%)
<u>Three years after sealant application</u>				
McCune et al (1979)	1st molars	Chem	88	85
Houpt, Shey (1979)	1st molars	Chem	77	78
Bagramian et al (1978)	Premolars 1st and 2nd molars	UV	NA	73†
Rock (1977)	Premolars 1st and 2nd molars	UV	70	68
Brooks et al (1979)	1st molars	Chem UV	80 60	65 36
<u>Four years after sealant application</u>				
Houpt, Shey (1983)	1st molars	Chem	73	72
Mertz-Fairhurst et al (1981)	1st molars	Chem	72	62
Richardson et al (1980)	1st molars	Chem	69	62
Charbeneau, Dennison (1979)	1st molars	Chem	52	54
Horowitz et al (1976)	Premolars 1st and 2nd molars	UV	50	45

(Continued)

Table 4. (Continued)

Study	Type of permanent teeth	Method of cure*	Complete retention (%)	Occlusal caries reduction (%)
Going et al (1977)	Premolars 1st and 2nd molars	UV	50	43
Leaké, Martinello (1976)	1st molars	UV	22	22
Mertz-Fairhurst et al (1981)	1st molars	UV	35	14
<u>Five years after sealant application</u>				
Meurman et al (1978)	1st molars	UV	60	60
Richardson et al (1981)	Premolars 1st and 2nd molars	UV	19	58
Gibson et al (1982)	1st molars	Chem	67	51
Horowitz et al (1977)	Premolars 1st and 2nd molars	UV	42	37
<u>Six years after sealant application</u>				
Haupt, Shey (1983)	1st molars	Chem	58	56
Mertz-Fairhurst et al (1982)	1st molars 1st molars	Chem UV	68 37	55 8

(Continued)

Table 4. (Continued)

Study	Type of permanent teeth	Method of cure*	Complete retention (%)	Occlusal caries reduction (%)
<u>Seven years after sealant application</u>				
Mertz-Fairhurst et al (1984)	1st molars	Chem UV	66 31	55 12
<u>Ten years after sealant application</u>				
Charbeneau, Dennison (1985)	1st molars	Chem	37	26

* Chem - Chemically cured sealants

UV - Ultraviolet light cured sealants

VL - Visible light cured sealants

† Sealant and topical fluoride treatment provided to children in this group; sealants reapplied if lost

§ Two examiners

** 6th and 1st grade children, respectively

4. FACTORS IN THE DESIGN AND EVALUATION OF A CLINICAL STUDY

The following sections discuss the factors relevant to the design, conduct and evaluation of a comparative study of a glass-ionomer cement used as a pit and fissure sealant and conventional pit and fissure sealants.

4.1 SELECTION OF MATERIALS

Earlier studies regarding the use of glass-ionomer cement were focused on ASPA, a glass-ionomer cement developed in the Laboratory of the Government Chemist, London. ASPA apparently suffered from a number of clinical drawbacks which limited its acceptance for clinical use (Atkinson, Pearson 1985). Prosser, Powis, Brant and Wilson (1984) studied physical properties of 15 commercially available "conventional" (available in powder and liquid form) and water hardening filling and luting glass-ionomer cements. Ketac-Fil (Espe GmbH, Germany) and Hy-bond (Shofu Dental Manufacturing Co., Japan) proved to be better in all the glass-ionomer cements, although all the 8 filling type glass-ionomer cements fulfilled the requirements of the British Standard Specification (BS 6091:1981) Glass Ionomer Cements. They listed the various properties in the following table (Table 10).

Table 10. Properties of filling glass-ionomer cements

Property	Conventional						Water-hardening					
	BS 6039 limits	LGC Aspa X	De Trey Aspa	Fuji ionomer type II	Shofu Hy-bond filling	Espe Ketac-Fil	LGC Aspa V	De Trey Chemfil	Espe Chelon	LGC Aspa V	De Trey Chemfil	Espe Chelon
Powder/liquid ratio (g/ml)	-	2.0	3.0	2.75	3.2	-	7.2	6.8	6.7	7.2	6.8	6.7
Consistency disc diam. (mm)	-	29	33	34	26	29	28	18	36	28	18	36
Rheometer working time, 23°C (min)	-	2.4	2.7	3.8	1.3	1.7	3.0	1.5	2.7	3.0	1.5	2.7
Indentation working time, 23°C (min)	1.75 min	2.25	5.0	5.0	2.75	2.75	5.75	2.0	3.5	5.75	2.0	3.5
Setting time, 37°C (min)	5.0 max	3.5	4.25	3.75	3.8	3.0	4.7	2.75	3.75	4.7	2.75	3.75
Compressive strength, 125 min		141	140	174	195	185	147	161	178	147	161	178
Diametral tensile, strength 24 h (MPa)	-	9.0	14.0	13.5	12.7	19.3	12.8	17.4	16.0	12.8	17.4	16.0
Flexural strength, 24 h (MPa)	-	30.0	9.8	8.9	12.7	30.3	25.7	19.5	13.5	25.7	19.5	13.5
Creep, 24 h	-	0.33	0.25	0.32	0.17	0.21	0.22	0.19	0.23	0.22	0.19	0.23
Water-leachable material, 7 min (%)	-	1.04	2.10	1.90	0.76	0.29	2.12	0.90	0.36	2.12	0.90	0.36
Water-leachable material, 1 h (%)	0.7 max	0.32	0.30	0.70	0.13	0.13	0.55	0.28	0.16	0.55	0.28	0.16
Opacity, C _{0.7}	0.35-0.90	0.44	0.85	0.69	0.74	0.61	0.84	0.70	0.75	0.84	0.70	0.75

(Source: Prosser et al 1984)

Use of Ketac-Fil (Espe GmbH, Germany) is suggested for the purpose of this study because of its following superior properties.

- (a) It is recommended for pit and fissure sealing by the manufacturers (Espe, GmbH).
- (b) It is available in convenient encapsulated form (applic capsule) which can be activated in the amalgamator for 10 seconds and the material is then ready for use. This capsule can be loaded in the applic applicator, a convenient tool, for dispensing the cement in the fissures and pits with ease, accuracy and pressure (Mount 1982).
- (c) When mixed it gives a reasonably thick consistency. Although it is not as thick as Chem-Fil (De Trey) and it is not as thin as Chelon (Espe) (Table 10).
- (d) It has a reasonable working time of 2.75 minutes (Table 10).
- (e) It sets earlier (3 min at 37°C) rendering the cement less susceptible to water or moisture contamination.
- (f) It is the least susceptible to moisture contamination, thereby allowing the dentist to finish the restoration earlier with less risk of early water contamination. (This is measured by water leachable materials using a seven minute curve, giving the indication of the susceptibility of the cement to early contamination by moisture. Values for Ketac-Fil were 0.29 per cent after 7 minutes and 0.13 per cent after 1 hour, whereas the values for ASPA V were 2.12 per cent

and 0.55 per cent).

- (g) It has a higher compressive strength than most other glass ionomer cements, 185 MPa after 24 hours (only Hybond has higher compressive strength than Ketac-Fil, 195 MPa after 24 hours).
- (h) It has the highest diametral tensile strength (19.3 MPa after 24 hours) and the highest flexural strength (30.3 MPa after 24 hours) than all the other glass-ionomer cements.
- (i) It has reasonably low creep and low opacity.
- (j) It has better hardness as compared to Fuji II and Chem-Fil II glass-ionomer cements (Gerdtz, Duke, Norling 1985).

In addition, it also exhibits all the favourable properties of a glass-ionomer cement, such as fluoride release, physicochemical bonding to the tooth substance, biocompatibility with oral tissues and pulp, abrasion resistance.

It is, therefore, suggested that Ketac-Fil should be used for the purpose of pit and fissure sealing.

4.1.2 Conventional Pit and Fissure Sealant

Because ultraviolet light activated sealants were the first to receive extensive clinical testing, at one time there were more published reports on this type of material than of chemically initiated systems. The ultraviolet light activated material had also been tested in

trials of greater duration. Now, however, the number of reports of chemically initiated sealants has increased and both types of sealants have been tested in studies lasting up to seven years. It now appears that the chemically initiated sealants out-perform the ultraviolet light cured sealants (Ripa 1985, 1983). In a seven year study which directly compared the caries inhibitory capabilities of the two sealant types, Brooks and co-workers (1979) and Mertz-Fairhurst and coworkers (1981, 1982, 1984) reported that a chemically initiated sealant (Delton) provided superior caries protection than that of an ultraviolet light cured sealant (Nuva Seal). Therefore, for the purpose of this study, the use of Delton (Johnson and Johnson Ltd) is recommended.

4.2 SELECTION OF METHOD OF USE

4.2.1 Glass-Ionomer Cement

From the review of literature, it appears that the technique advocated by Craig (1984), that is being followed in the Pedodontic clinic of the University of Sydney (Section 3.2.1), takes into account the properties and the related care for the use of glass-ionomer cement for pit and fissure sealing. This technique is easy to learn, standardised and can be applied when using Ketac-Fil (Espe, GmbH) glass-ionomer cement. It is therefore suggested that this method may be used for the purpose of this study. Following are the steps of this method (for details refer to Section 3.2.1).

- (1) Preparation of foil and stomahesive wafer for isolation of the sealant.
- (2) Tooth isolation with Garmer's clamps and absorbent pads or rubber dam.
- (3) Tooth cleaning with water and pumice slurry, followed by 10 seconds with Hydrogen peroxide (3%).
- (4) Washing and drying of teeth.
- (5) Activation of Ketac-Fil capsule for 10 seconds in the amalgamator.
- (6) Placement of Ketac-Fil with applier on the fissures and pits.
- (7) Material covered with precut foil and stomahesive wafer and pressure application with finger.

- (8) Removal of isolation (rubber dam, Garmer's clamps or absorbent pads) and patient is asked to bite on the wafer for 10 seconds.
- (9) Wafer readapted for initial setting period of 4 minutes. (In these four minutes, the other side may be sealed).
- (10) Reisolation of tooth, wafer/foil removed, cement covered with varnish and tooth occlusion is checked then and any high spots removed with a round bur.
- (11) Revarnishing of the surface.
- (12) Placement of a small piece of stomahesive wafer.
- (13) Contralateral teeth then sealed with conventional sealant.
- (14) Patient is then discharged, with follow-up instructions.

This method helps ensure proper isolation, correct technique and maximum protection from water or moisture contamination.

4.2.2 Conventional Pit and Fissure Sealants

Although a small variation of techniques is seen by the review of literature, the main technique for the use of conventional pit and fissure sealants has remained the same. It is suggested that the method described by the manufacturers of the selected material, Delton, may be used for the conventional sealants to rule out chances and biases. The detailed general technique is covered in Section 3.2.2 and the investigators are referred to it.

4.3 SELECTION OF PATIENTS AND TEETH

All the deep pits and fissures that are not well coalesced in newly erupted permanent teeth need pit and fissure sealing. The 2 to 3 years immediately following tooth eruption is the period of greatest vulnerability to pit and fissure decay. Thus, the earlier the sealant is applied the greater the degree of protection provided (Disney, Bohannan 1984).

Møller (1975) suggested, considering caries progression pattern and rate, that the proper age groups for pit and fissure sealing are the following:

- (a) 3 years (all primary molars erupted)
- (b) 6 years (1st permanent molars erupted)
- (c) 9-10 years (possibly premolars erupted)
- (d) 11-12 years (second premolars erupted).

Deep pits and fissures are especially susceptible to the development of caries; they are virtually impossible to clean, they harbour bacteria and are the sites with developmental weakness or frank enamel defects. On the other hand, teeth with shallow occlusal anatomy and well coalesced fissures and pits rarely develop pit and fissure caries.

Various workers have used various codings for the identification of different types of fissures and pits present and have laid criteria to select the pits and fissures for their study. Following are some of the examples:

(a) Buonocore MG (1970)

- 0 = unstained, explorer does not catch
- 1 = stained pit or fissure, but explorer does not catch
- 2 = stained or unstained, explorer catches something, but without sticking or penetrating.

All these conditions were considered caries free and were included in the study.

(b) Burt, Berman, Silverstone (1977)

- 0 = unstained fissure, explorer can not be admitted
- 1 = fissure stained or probe catches in fissure with moderate pressure
- 2 = visually obvious caries or softness detectable with explorer at the base of a stained fissure.

Of these, code 0 and 1 were considered to be caries free and were included in the study. Those with code 2 were carious and were excluded from study.

(c) Rock (1977)

- 1 = caries free, no stain and no areas easily caught by explorer
- 2 = caries free, stained but no pitted areas
- 3 = caries free, pitted areas, demonstrable with explorer, may or may not be stained
- 4 = objectively demonstrable caries or sites filled

- 5 = objectively demonstrable caries on the medial or distal surface of the tooth
- 6 = tooth unerupted or exfoliated.

1, 2, 3 were included, but 4, 5, 6 were excluded from the study.

(d) Leake and Martinello (1976)

- 0 = definite fissure - relatively smooth with no stain
- 1 = definite fissure - relatively smooth with no stain
- 2 = definite fissure - light catch of explorer with no stain
- 3 = definite fissure - light catch of explorer with stain
- 4 = definite fissure - catch supports the end of explorer.

Teeth rated 0, 1, 2, 3 and with no proximal decay were included in the study.

(e) Higson (1976)

- C0 = no sign of caries
- C1 = Thin known line at the base of fissure, no breakdown of visible changes in the walls of fissure.
- C2 = One or both of the following:
thick brown line at the base of the fissure,
while change in the walls of the fissure.
No breakdown of enamel.

C3 = Breakdown in the walls of the fissure, with break in enamel or shadow or opacity beneath enamel of less than 1.5 mm measured across the fissure.

C0 and C1 were considered caries free, C2 and above were scored carious.

(f) Brooks et al (1976)

Criteria for presence of caries:

- 1 = catch and softness
- 2 = catch and opacity
- 3 = catch and etching or white spot
- 4 = softness, with clinically obvious loss of tooth structure.

These were excluded from the study, but teeth with dark stain and catch without any evidence of decalcification were pronounced sound.

Thus, it can be seen, although the sealed carious lesions do not progress and that bacteria covered under an intact sealant do not survive (Going et al 1978; Handelman et al 1981), the obvious carious teeth or those carious teeth detected with explorer were not used in the study. It has also been suggested that if small incipient carious lesions are found, caries can be removed and combined cavity filling and sealing can be done (Mertz-Fairhurst, Schuster, Fairhurst 1986) which will successfully check the caries progression and arrest the lesion.

Review of this available literature indicates that certain criteria for selection of patients and teeth have to be laid before the commencement of study.

(1) Children with all first permanent molars erupted (age 6-8 years) may be included in the study. It is important to note that the first permanent molars are the most susceptible teeth to caries attack. Certain criteria that apply to the selection of these teeth are:

(1.1) Pits and fissures on the selected 1st molars should be deep and narrow. They may be stained or unstained but should not be carious. The presence of caries may be demonstrated by the tip of the sharp explorer which "sticks" in the lesion.

Many investigators have encountered difficulties in accurately deciding whether or not caries is present in the fissure, using visual or tactile methods. The findings of Miller and Hobson (1956) have indicated that when a probe inserted with light pressure in the pit or a fissure became stuck and required a definite pull for removal, there was some degree of caries present in 70 per cent of the cases. Roydhouse and Richardson (1972) suggest that probe-catching in the fissures may be due to the physical characteristics of the fissure. Rock (1974) argues that the weakness in the identification of early occlusal caries on the evidence of a probe lies in the fact that it is not certain that the absence of "stickiness" means that the depth of the fissures are sound. In a deep, narrow fissure, the probe may fail to enter and caries could be

present.

Although it has been shown that the decay sealed under the sealant fails to progress and gets arrested, for the purpose of this study it is suggested that pits and fissures in which a probe or an explorer sticks may be eliminated from the study.

Radiographs may be taken to demonstrate the presence of caries. Rock (1974) states that with radiographs, 5 to 51 per cent additional lesions could be detected.

(1.2) Molars with proximal decay should be excluded from the study. An accurate assessment of sealant retention can not be made in sites with approximo occlusal restorations at re-examination. It is also impossible to determine if the sealant had been successful or unsuccessful. The occlusal surface may have been restored solely because of early intervention in the restorative treatment of approximal decay, or it may have been decayed itself (Horowitz et al 1977; Horowitz, Heifetz, McCune 1974).

(1.3) Persons with molars having very shallow and wide open fissures with no caries evidence in the mouth may be excluded from the study. These persons are less likely to develop caries in the teeth and sealant placement would be a waste of time and money in these cases.

Additionally, selection of patients may be done by a single examiner to avoid interexaminer bias. Standardised instruments should be used for caries detection.

With regard to radiographs, the technique should be standardised to give an accurate assessment at the beginning stage and follow-up stages in evaluation.

It is very important that all the examinations for the selection of teeth should be carried out under well lighted conditions using a dental mirror, a sharp explorer and an air syringe to dry the field.

4.4 SELECTION OF CONTROL AND EXPERIMENTAL GROUPS, PATIENTS, TEETH AND NUMBER IN THE GROUP

4.4.1 Selection of Control and Experimental Groups, Patients, Teeth

Effectiveness of sealants have already been demonstrated by various researchers (refer Section 3.4.2). Therefore, it would not be necessary to have a control group of patients for sealant study. Moreover, for studying the differences between retention of 2 different sealants, it would be necessary to place them in a similar environment. Half mouth design has normally been adopted for this type of study. Thus, in a similar environment, the eligible contralateral pair of caries free molars are treated with glass-ionomer cement, the other pair with a conventional pit and fissure sealant. The 1st tooth to be sealed is identified, then material is decided by a coin toss to give a random sample. The contralateral tooth in the opposing arch is then sealed with the same material (e.g. 16, 36). The remaining teeth (24, 46) are then sealed with the material to be compared.

As discussed in the last section, children aged between 6-8 years may be selected for this study. It would be preferable that this study may be carried out in a hospital situation or institution because it would then be easier to follow up these cases systematically over a period of time. After selection of subject to be included in the study, the following guidelines must be followed (Adopted from American Dental Association, Council on

Dental Research 1979).

Guidelines for the use of human subjects in dental research

I. Basic principles of ethics in research involving human subjects.

- (1) Any research involving human subjects must be based upon scientific principles that offer a sound rationale for the research. The justification of research should be supported by findings obtained from laboratory or animal experimentation, scientifically established facts or findings from other clinical studies.
- (2) Research involving human subjects should be conducted by or be under the supervision of clinical investigators who are scientifically qualified and experienced. The principal investigator and the sponsoring institution or organisation are responsible for the conduct of all personnel in connection with an investigation.
- (3) Research involving human subjects should be carried out only if the rights and welfare of the participants are adequately protected. All reasonable efforts should be made to reduce possible risks to the participants and the risks must be outweighed by the benefits to be derived or by the importance of knowledge that will be gained.

- (4) The informed consent of subjects who participate in a study must be obtained by methods that are adequate and appropriate. Informed consent should be obtained in writing from a subject or the subject's parents, guardian, or authorised representative only after the study and the risks involved have been fully explained (Example forms attached, Tables 11, 12, 13, pages 122-124). If the participants are children who have reached an age of discretion, their assent should be obtained in addition to the consent of the adults responsible for them.

All basic elements of informed consent should be in writing and should minimally consist of:

- (a) A general description in lay terms of the study and its purpose followed by a fair and clear explanation of all examination and treatment procedures to be followed, including an identification of those that are experimental.
- (b) An explanation of why the subjects have been invited to participate and an assurance that the identity or particular findings will be held confidential by the investigator.
- (c) A description of any known attendant discomfort or risks that are reasonable to expect.

- (d) A disclosure of appropriate alternative procedures or treatments that might be advantageous for the subject in lieu of participation.
- (e) A description of the benefits that are reasonable to expect.
- (f) An offer to answer any inquiries concerning the study prior to its inception, or during its course. The explanatory form should contain the name, title and telephone number of the principal investigator, or his or her designee for the convenience and protection of the persons who may have questions about the study before it begins or during the course.
- (g) An instruction that the subject is free to decline participation, withdraw consent or discontinue participation in the project or activity at any time without prejudice.

The written agreement entered into by the subject should contain no exculpatory language through which the subject waives or appears to waive any legal rights or releases the institution, group, or individual or its agents from liabilities from negligence. Other items that should be contained in the informed consent document include: clear statements of whether any subjects will be deprived of the usual treatment or be asked to withhold usual practices, a description of any costs or compen-

sations to the subjects, the likelihood or chance that a subject will receive an ineffective treatment (if a placebo or untreated control group is used) and clear statement that an affirmative response and signature indicate a decision to participate.

In essence, these American Dental Association guidelines for prospective study participants or those responsible for them should be provided with sufficient, comprehensive, written information about a research project and the attendant procedures to enable them to make a rationally exercised decision about participation. Participation must truly be voluntary and not coercive in any way.

When a study is a part of research on preventive measures: (a) the investigator has the responsibility of informing subjects or those responsible, of any existing oral conditions. Even when there are no provisions for treating subjects in a study, subjects have the right to be informed of the conditions that may affect their health or well being and should be encouraged to seek required treatment and to continue routine dental care; (b) participants, their families when appropriate, and pertinent, institutional and health officials should be informed of a study's important findings; (c) these persons should be informed of the extent and probable duration of the protection received by the treated subjects.

Other considerations are as follows:

- (a) Radiographs should be taken in a clinical study only when they are essential to the purpose of the study. Adequate protection from radiation should be afforded both the participants and the personnel who expose radiographs. Every effort should be made to optimise the radiographic efficiency, i.e. obtaining maximum radiographic information with minimum patient exposure. Diagnostic information from radiographs, reproductions or duplications of radiographs or duplicate films should be made available to the subject's personal dentist on request.
- (b) The subjects must clearly understand that the examinations that are a part of a clinical study are not a substitute for the usual examinations they may receive from their personal dentists.

4.4.2 Number in the Group

It is impossible for an investigator to study efficacy of sealants in an entire population of children. It is, therefore, essential to draw a smaller sample from the population, collect data and statistically analyse it and then apply the findings to the population. The sample should be representative of populations and its size must be sufficient to permit inclusion of all possible characteristics of the universe (Miller 1985).

The aim for the efficacy of pit and fissure sealants should be 100% in retention as well as the caries reduction, but our past knowledge shows sealant retention from 18 to 99 per cent and caries reduction from 65 to

100 per cent after one year of sealant placement (Table Section 3.4.2). It is generally seen that the sealants are 85% effective after one year of placement (National Institutes of Health, 1984). It is expected that the glass-ionomer cement, Ketac-Fil, with its improved qualities, would clinically perform at least 10% better than the conventional sealants. Any proposed study should therefore have sufficient numbers in groups to enable a statistical significant difference in performance to be shown. A 10% improvement in retention rates could be considered of clinical value.

All the previous studies cited from the literature have taken a 5% level of statistical significance for their results, a level accepted generally in the dental field. Therefore, an appropriate statistical significance in this study at 5% level of significance at 95% power of test, the sample size estimated for this study to show an absolute difference between a success rate of 85% for conventional sealants and 95% success for glass-ionomer cement would be 219 teeth in each group (derived from Table 14.3a in Chilton 1982).

Table 11. Example of a consent form for a fissure sealant study

Title of Project

Pit and fissure sealant study

Name(s) of Chief Investigator(s)

General Purposes, Methods and Demands

see attached page

Possible Risks, Inconvenience and Discomforts

see attached page

I have been asked to allow my child to participate in the above research study, and given my consent by signing this form on the understanding that:

1. The research study will be carried out in a manner conforming with the principles set out by the National Health and Medical Research Council, which appear on the overleaf.
2. I comprehend the general purpose, methods, demands and possible risks, inconvenience or discomforts of the study.
3. If I do not volunteer my child to participate in the research study, he/she can still receive appropriate treatment for his/her condition.
4. In giving my consent, I acknowledge that my child's participation in this research study is voluntary and that he/she may withdraw at any time.

Signature: _____ Date: _____

by subject, if over 18 years, otherwise by Guardian or next friend.

Witnessed by: _____

of: _____

Table 12. National Health and Medical Research Council:
Statement on Human Experimentation (October 1976)

NOTICE TO PARTICIPANTS

Research projects approved by the Hospitals are to conform to the principles set out in the National Health and Medical Research Council's "Statement on Human Experimentation". The latest statement approved in October 1976 is reproduced below:

STATEMENT ON HUMAN EXPERIMENTATION

The collection of data from planned experimentation on human beings is desirable for the advancement of knowledge necessary for improving human welfare. Experiments range from those undertaken as part of patient care to those undertaken either on patients or on healthy subjects for the purpose of contributing to knowledge, and include investigations on human behaviour. Investigators have ethical and legal responsibilities towards their subjects and should therefore observe the following principles:-

1. The research must conform to generally accepted moral and scientific principles.
2. The investigator after careful consideration and appropriate consultation must be satisfied that the possible advantage to be gained from the work justifies any discomfort or risks involved.
3. Whenever possible, the research should be based on prior laboratory and animal experiments.
4. The investigator must be mindful at all times of his duty towards the individual subject of the research respecting his personality, rights, wishes, beliefs, consent and freedom.
5. The research should be conducted only by suitably qualified persons with appropriate clinical competence having available facilities for the proper conduct of the work and for dealing with emergencies.
6. New therapeutic or experimental procedures which are at the stage of early evaluation and which may have long-term effects should not be undertaken unless appropriate provision has been made for long-term care and observation.
7. Before research is undertaken, the subject, his legal guardian or next friend shall have given free consent. To this end the investigator is responsible for providing the subject, his legal guardian or next friend, at his level of comprehension, with sufficient information about the purposes, methods, demands, risks, inconvenience and discomforts of the study. If at all possible, consent shall be obtained in writing.
8. The subject, his guardian or next friend must be free at any time to withdraw consent to further participation.
9. The investigator must discontinue or modify the research if, during the course of the experiment, it becomes apparent that continuation may be harmful.

Table 13: Example of an Information Letter: Fissure Sealant Study

PIT AND FISSURE SEALANT STUDY

Dear Parent of _____

You may be aware that dentists often coat the deep pits and grooves on the biting surfaces of newly erupted molar teeth in children, in an attempt to prevent decay from occurring in these difficult-to-clean areas. The materials used for this procedure are called Fissure Sealants.

A dental filling material currently used extensively to fill children's teeth, is to be tested for its suitability as a fissure sealant. The study will involve the coating of the biting surface of an upper and lower molar tooth on one side of the child's mouth; the corresponding molar teeth on the opposite side will be coated with a fissure sealant already in common usage.

The retention of these two materials on the tooth surface will then be measured over a period of 6, 12, 24 and 36 months.

We would like to emphasise that:

The coating of tooth surface with a fissure sealant is a well accepted dental treatment and is of proven benefit in preventing decay.

The material being tested as a fissure sealant is also extensively used for filling teeth and considered safe for prolonged retention in the mouth.

There will be no injections or drilling of teeth as part of the study.

The risks of taking part in the study will be no different from those entailed in routine dental treatment.

4.5 CONDUCT OF STUDY

4.5.1 Standardization of Technique

The technique to be followed in a study needs to be standardized for very important reasons such as, (a) to eliminate or reduce operator variability, (b) to ensure that the experimental conditions are similar for all study groups.

The methods for the pit and fissure sealing by using conventional sealants and glass-ionomer cements have been standardized and have been discussed in Section 4.2. The operators must practise and master these techniques before the commencement of study.

Some special aspects related to materials must be remembered, for example, when using the glass-ionomer cement, special attention should be given to prevention of water contamination during and after placement of material. With conventional pit and fissure sealant, a dryness of field before placement should be ensured. Contamination of etched tooth surface should be avoided and if contaminated, the etched surface should be re-etched for 10 seconds with phosphoric acid.

The number of operators should be limited to a minimum (1 or 2) to ensure elimination of bias; reduce interoperator variability. The operators should be available for subsequent follow-up evaluations.

In longitudinal studies, the effect of drop-outs could seriously affect the results, therefore, there must be a logical explanation of how this eventuality can be handled, for example, all the patients should be well informed of the duration and follow-up of the study. A larger sample, than that calculated with statistical aids, may be utilized.

4.5.2 Criteria for Teeth Selection

The following criteria for teeth selection may be adopted.

- (a) All the subjects selected for the study should be between age 6-8 years and should have all their first permanent molars erupted.
- (b) This study is limited to the first permanent molars only. Brooke et al (1979) suggests that the use of first permanent molars provides a simplified study design for data analysis, reduced chances of errors in application and recording, and permits simpler and faster follow-up evaluations, in addition to serving as a stringent test for retention of a sealant.
- (c) All the first permanent molars should comply with the following criteria. This criteria should be tested with the use of a sharp explorer and mirror, and radiographs (only if necessary).
 - (i) There should be no evidence of caries on occlusal or proximal surfaces of these molars.

(ii) Stained fissures or pits are not necessarily indicative of the presence of caries. Therefore, all stained or unstained deep pits and fissures which are not "sticky" must be included.

(iii) Caries free subjects with their 1st permanent molars having shallow and wide, well coalesced self-cleaning fissures and pits should be excluded from the study.

4.5.3 Initial Evaluation

After the sealants have been placed, an initial evaluation must be carried out by the investigator. The purpose of this evaluation is to check the sealant status, to record the relevant data and to issue instructions to the patient. Initial evaluation must be carried out in well lighted conditions with a sharp explorer and a dental mirror.

1. Sealant Status: Each sealant should be checked with the explorer for its retention before allowing the subjects to leave. Any loose or detached sealants should be replaced immediately.
2. Recording the Data: Table 14 shows an example of a data collection and analysis sheet. Data collected in this fashion can be directly transferred to a computer. This will facilitate the analysis after the subsequent follow-ups. Other relevant variables such as the degree of cooperation and isolation method

Table 14. (Continued)

EVALUATION (CODES 1, 2, 3, 4, 5, 6)	1 BASELINE	2 INITIAL	3 SIX MONTH	4 ONE YEAR	5 TWO YEAR	6 THREE YEAR
CARIES STATUS WITH TYPE OF MATERIAL USED						
16						
26						
36						
46						
(Caries absent - 0, Caries present - 1) (KETAC-FIL - 1, DELTON - 2)						
DEGREE OF COOPERATION						
(Cooperative - 1, Noncooperative - 2)						
ISOLATION						
(Rubber dam - 1, Garmer's clamps and cotton rolls - 2)						
OTHER RECORDS						
PHOTOGRAPHS						
CASTS						
RADIOGRAPHS						
(Not taken - 0, Taken - 1)						

should be recorded. The same sheet for recording can be utilized for subsequent follow-ups. Photographic records and dental stone replica (casts) may be made. These can be used to judge the degree of retention of materials at the subsequent follow-up.

3. Instructions to the Patients

- (a) Patients should be forewarned about the possibility of sealant loss and subsequent development of dental caries. They should also be informed that should any caries develop, it would be restored with amalgam.
- (b) Patients are requested to inform their personal dentists regarding this study.
- (c) All the patients must be told to report if:
 - (i) there is any post-operative problem;
 - (ii) the sealant is lost or caries develops;
 - (iii) there is any change of address or telephone number;
 - (iv) it is not possible to attend the follow-up appointment so that another appointment can be allocated.
- (d) A letter containing these instructions and the dates of follow-up evaluation appointment should be given to each patient.

In addition to these instructions, phone calls or written reminders (if no phone) prior to the evaluation date should be made to help ensure the 100% presence of all the patients at each follow-up.

4.5.4 Follow-Up Evaluation

The main purpose of the follow-up evaluation is to collect data, at different intervals, on the retention of sealants and their effectiveness as shown in caries reduction which can subsequently be analysed to indicate the success or failure of the research project. All the subjects must be recalled for examination at the 6 months, 1 year, 2 year, 3 year intervals.

4.5.4.1 Six months evaluation

Although the six month sealant examination is not a sufficient period to judge the efficacy of sealants, it is nevertheless essential to check retention or early loss of any sealants. It would also give indications of any difficulties which may be encountered in subsequent follow-up examinations, fall out rate (patients) and to familiarise patients with these recall examinations. All the sealants must be checked for retention status and caries status. The examinations must be carried out by the same persons who carried out the sealant placements, under the same well lighted conditions with a sharp explorer and dental mirror. Radiographs should not be taken at this examination. None of the lost sealants are replaced, but any carious teeth must be filled, and these teeth should be categorised as sealant completely lost or caries present for the subsequent follow-up.

Each individual tooth (1st molar) is checked for:

(a) Sealant Status

Code 1 - Sealant completely intact - recorded when the sealant is detected in all of the occlusal fissures and pits (as placed), either visually or by explorer with moderate pressure.

Code 2 - Sealant partially lost - recorded when sealant is detectable in only some parts of occlusal pits and fissures.

Code 3 - Sealant completely lost - recorded when the examiner is unable to observe any presence of sealant after a close visual/tactile examination. It is important to avoid scratching and damaging the enamel with the sharp probe.

(b) Caries Status

Code 0 - Caries absent - no visual or demonstrable caries on the sealant site.

Code 1 - Caries present - demonstrable caries present on the sealant site.

This data is recorded on patient's study records sheet (Table 14) and transferred to computer for storage and later analysis.

4.5.4.2 One year follow-up

There is a lot of data available in the literature regarding the retention rates of the sealants and per cent caries reduction. All the principles applied to the six months evaluation remain the same for subsequent evaluations. Use of radiographs for the presence or absence of dental

caries may be included at this evaluation. If the study casts are made at the initial evaluation, they may be repeated at this stage to demonstrate any changes in the sealants. It is necessary that the same examiners should carry out this evaluation. All the data is recorded on patient's record sheet (Table 14) and transferred to the computer.

Follow-ups may be carried out at the 2nd and 3rd year after sealant application. At all these follow-ups, data may be analysed as described in 4.5.6 to demonstrate any significant differences appearing between the Ketac-Fil and Delton; in their performance.

4.5.5 Presentation of Results

The data which is collected and transferred to computer can be analysed for the sealant retention and the caries status. This can be presented in the following manner.

4.5.5.1 Sealant status

Sealant retention by the tooth and material used can be first summarised and presented as shown in Table 15.

This data can be then further analysed to indicate variations, if any, in the degree of retention of these two sealants in different arches or on different sides of the patient's mouth (Table 16).

Table 15. Retention of a sealant by tooth and sealant type

FOLLOW-UP	Tooth		KETAC-FIL SEALANT STATUS			DELTON SEALANT STATUS		
	Type	Number	Completely present	Partially present	Completely lost	Completely present	Partially present	Completely lost
SIX MONTHS	16							
	26							
	36							
	46							
	T							
ONE YEAR	16							
	26							
	36							
	46							
	T							
TWO YEAR	16							
	26							
	36							
	46							
	T							
THREE YEAR	16							
	26							
	36							
	46							
	T							

Table 16. Degree of retention of Ketac-Fil and Delton by arches and sides of the patient

FOLLOW-UPS MATERIAL	Base line	Six month	One year	Two year	Three year
Ketac-Fil Arch total 16 + 26 36 + 46 Side total 16 + 36 26 + 46 TOTAL KETAC-FIL					
Delton Arch total 16 + 26 36 + 46 Side total 16 + 36 26 + 46 TOTAL DELTON					
TOTAL SEALANTS					

The degree of retentiveness of these sealants can be finally summarised in the form shown in Table 17.

4.5.5.2 Caries status

The data recorded on Table 14 may be analysed for caries status and presented in the form shown in Table 18.

Table 17. Degree of retentiveness of sealants

Time since application	Number of teeth examined	Ketac-Fil		Delton	
		Completely present	Partially present	Completely lost	Partially present
6 months		Completely present	Partially present	Completely lost	Partially present
1 year					
2 years					
3 years					Completely lost

Table 18. Caries status by tooth and sealant type

Follow-up time	Tooth		Ketac-Fil Caries Status			Tooth		Delton Caries Status		
	Type	No.	Caries No.	Absent %	Caries Present %	Type	No.	Caries No.	Absent %	Caries Present %
SIX MONTHS	16					16				
	26					26				
	36					36				
	46					46				
	Total					Total				
ONE YEAR	16					16				
	26					26				
	36					36				
	46					46				
	Total					Total				
TWO YEARS	16					16				
	26					26				
	36					36				
	46					46				
	Total					Total				
THREE YEARS	16					16				
	26					26				
	36					36				
	46					46				
	Total					Total				

4.5.6 Analysis of Results

All the data which is collected at 6 months, one year, two year and three year follow-up should be analysed to determine if there are any differences in the performance of these two materials.

(a) Retention of sealants by type of material used

Complete retention of sealants can be found out by using the following formula:

$$\text{Retention (\%)} \text{ of Ketac-Fil or Delton} = \frac{\text{(Type) Sealant completely retained}}{\text{Total (Type) sealant placed}} \times 100$$

This formula can be similarly applied to all the data to find per cent retention (complete or partial) or per cent loss of a particular material. These figures can be further analysed for any significant difference in the performance of these materials.

(b) Comparison of per cent retention (complete or partial) and loss of Ketac-Fil to that of Delton.

Since this data is a qualitative data, it can be expressed in the following 2 x 3 contingency table.

Consider H_0 = (null hypothesis) as there is no difference in these percentages from the expected percentages.

CONDITION TYPE	Completely present	Partially lost	Completely lost	TOTAL
KETAC-FIL	a	b	c	a+b+c
DELTON	d	e	f	d+e+f
TOTAL	a+d	b+e	c+f	a+b+c+d+e+f

For this contingency table, with 2 rows and 3 columns, degree of freedom

$$df = (N_R - 1)(N_C - 1) = (2 - 1) \times (3 - 1) = 1 \times 2 = 2$$

The formula for expected frequencies is as follows:

$$E = (F_R \times F_C) / F_T$$

where F_R = total frequency of the row
 F_C = total frequency of the column
 F_T = total frequency of all outcome.

Thus

$$E_a = \frac{(a+b+c)(a+d)}{a+b+c+d+e+f}$$

$$E_b = \frac{(a+b+c)(b+e)}{a+b+c+d+e+f}$$

$$E_c = \frac{(a+b+c)(c+f)}{a+b+c+d+e+f}$$

$$E_d = \frac{(d+e+f)(a+d)}{a+b+c+d+e+f}$$

$$E_e = \frac{(d+e+f)(b+e)}{a+b+c+d+e+f}$$

$$E_f = \frac{(d+e+f)(c+f)}{a+b+c+d+e+f}$$

Then this data is used to calculate the value of χ^2

Cell	O	E	(O-E)	(O-E) ²	(O-E) ² /E
a	a	E _a	(a-E _a)	(a-E _a) ²	(a-E _a) ² /E _a
b	b	E _b	(b-E _b)	(b-E _b) ²	(b-E _b) ² /E _b
c	c	E _c	(c-E _c)	(c-E _c) ²	(c-E _c) ² /E _c
d	d	E _d	(d-E _d)	(d-E _d) ²	(d-E _d) ² /E _d
e	e	E _e	(e-E _e)	(e-E _e) ²	(e-E _e) ² /E _e
f	f	E _f	(f-E _f)	(f-E _f) ²	(f-E _f) ² /E _f
					$\Sigma = \chi^2$

Therefore χ^2 can be found as

$$\chi^2 = \Sigma [(O-E)^2/E]$$

Then refer to the table of chi square at $df = 2$ and find the probability for this value χ^2 . If this probability is more than $P = 0.05$, conclude that there is no statistical significance in the different retention rates for the two materials (accept H_0), but if the probability for value χ^2 is less than $P = 0.05$, then conclude that the different rates for the two materials are statistically significant. [Note: $P = 0.05$ is the most commonly used level of significance in the dental field.]

(c) If overall individual retention rates (complete retention, partial loss, complete loss) of Ketac-Fil and that of Delton are observed by the χ^2 test to be significantly different, then the individual components can be further tested by "t" test to test the statistical significance of differences observed.

For example:

To compare,

complete retention rate of Ketac-Fil = a

complete retention rate of Delton = b

level of significance taken at P = 0.05

difference (a - b) = c

H_0 (null hypothesis) = there is no

difference between a and b, i.e. a = b

Standard error of percentage $SE_a = \sqrt{p_a q_a / N_a}$

where p_a = percentage retention of Ketac-Fil

$q_a = (100 - p_a)$

N_a = total number of teeth sealed with Ketac-Fil

Standard error of percentage $SE_b = \sqrt{p_b q_b / N_b}$

where p_b = percentage retention of Delton

$q_b = (100 - p_b)$

N_b = total number of teeth sealed with Delton.

To find,

Standard error of difference between Ketac-Fil and Delton

$$SE_{diff} = \sqrt{SE_a^2 + SE_b^2}$$

Degrees of freedom $df = (N - 1)$

where N represents total number of teeth sealed with Ketac-Fil and Delton.

$$(N = N_a + N_b)$$

For $P = 0.05$ at $df = (N - 1)$

critical value of "t" can be found for t-table (t_{crit})

Calculating the "t" value for the difference between complete retention percentages of Ketac-Fil and Delton

$$t_{calc} = \frac{a - b}{SE_{diff}} = \frac{c}{SE_{diff}}$$

If the calculated value for "t" exceeds the critical value for "t", the hypothesis ($a = b$) is rejected and then one concludes that the difference between the complete retention of Ketac-Fil and that of Delton is significant and one that is extremely unlikely to be due to chance. However, if the calculated value for "t" exceeds the critical value for "t", the hypothesis ($a = b$) is accepted and then one concludes that the difference between the complete retention of Ketac-Fil and that of Delton is not significant and one that is due to chance alone.

All the retention and loss rates can thus be similarly tested for the statistical significance of difference between materials. These tests must be carried out after each follow-up evaluation.

(d) The relationship of the degree of retention or loss can be similarly compared to other variables, such as:

(i) interarch or side differences, (ii) degree of patient cooperation, (iii) isolation techniques, and (iv) interoperator variability, by using "chi square" and/or "t" tests.

Further details concerning statistical analysis are contained in textbooks on statistics, such as those referred to by the writer in this section; Chilton (1982), Miller (1981).

5. DISCUSSION

Today, in many countries, dental caries is largely a disease of pits and fissures as opposed to lesions on smooth tooth surfaces. The National Dental Caries Survey, USA (1979-80) showed that only 16% of the caries experience of 5 to 17 year old children occurred in approximal surfaces (smooth) but 84% involved surfaces with pits and fissures (National Institute of Health 1984). Repeated observation has shown that a child who is born and raised in an area with natural or artificial fluoridation will experience 50 per cent less caries than equivalent non-fluoridated subjects (Stephen, Strong 1985). However, Baker-Dirks, Houwink and Kwant (1961) showed most protection (approximately 75 per cent) is confined to smooth surfaces, only 25-30 per cent being obtained in the stagnation sites of the grooved pit and fissure areas where pH values below pH 4 may occur due to formation of acid of bacterial origin (Sandham, Onose 1976). Even fluoridated enamel is susceptible to this degree of acid attack, hence the concept of fissure sealing evolved whereby a plastic resin would be applied to these caries-susceptible surfaces.

Various sealants have been tried successfully. These include filled or unfilled, self-curing or photo-curing resins. Initial studies regarding fissure sealants showed poor retention rates. The whole concept of fissure sealing was, therefore, questioned as to whether (a) sealant systems were faulty; (b) techniques of

application were faulty; or (c) the erupting first permanent molar could actually be sealed given the hostile intra-oral environment and immaturity of patients in which these teeth were erupting (Stephen, Sutherland, Trainer 1976). It was only when laboratory studies showed the light output from early polymerising sources was often inadequate and some early sealants absorbed UV light, that the poor results of the early studies could be explained in part by inadequate polymerisation of resins (Stephen, Strang 1985). In addition, adequate post etch washing (Adipranato, Beach, Hardwick 1975) and drying (Young et al 1975) were proved to be more important than the etchant concentration. Enamel sealant bond strength testing (Young et al 1975) showed that provided between 30 to 50 per cent w/w H_3PO_4 (phosphoric acid) was used for etching, early predictions relating to etchant concentration which had been based purely on histological observation (Silverstone 1974) were invalid.

Sealants have now been shown to be very effective in the prevention of decay on the occlusal pits and fissures. The effectiveness of dental sealants in the prevention of tooth decay has been demonstrated in a variety of research findings covering a span of 16 years. It has also been shown that caries protection is 100% in pits and fissures that remained completely sealed. Complete retention rates after one year are 85% or better and after five years are at least 50%. These trials have shown that a close correlation exists between retention of sealants and their effectiveness, regardless of how the

latter is defined and measured (Refer to Section 3.4.2).

In spite of the success of sealants their utilization by the members of the dental profession is limited. Silverstone (1982b) attributes this to the following reasons:

- (1) They are not convinced that research data justifies sealant use.
- (2) They believe that sealants are lost too often.
- (3) They have a difficulty in motivating patients and parents in accepting the technique and justifying a fair fee.
- (4) They are afraid of sealing caries.
- (5) They believe that they can place amalgam restorations in the same amount of time, for the same fee, with better and lasting results.

Since a vast amount of research in this field has ruled out these beliefs, Silverstone (1982b) feels the need for educating the profession about the sealants and need for further research, for better and better materials.

Gift and Frew (1986) investigated the changes in sealant use by the dentists in the United States. Their study shows a definite increase of 20% more dentists who are using sealants, from 38% in 1974 to 58% in 1982.

Glass-ionomer cements, invented by Wilson and Kent in 1972, justify their use in pit and fissure sealing by various useful properties they exhibit. These include physicochemical bonding to the tooth structure, bio-

compatibility to oral tissues, ability to release fluoride which renders them advantages of fluorides such an antimicrobial properties and producing acid resistant enamel surfaces; abrasion and wear resistance and aesthetic acceptability. In addition, the glass-ionomer cements are now available in a convenient encapsulated form rendering them easy to use. Although their use for pit and fissure sealing has been advocated long ago (McLean, Wilson 1974), there have been very few controlled comparative studies that have been carried out. Therefore, this study of glass-ionomer cement (Ketac-Fil) and conventional sealants has been suggested.

It is expected that due to the ability of glass-ionomer cement to chemically adhere to the tooth surface, it would be retained longer than conventional sealants. It would release fluoride and render the adjacent enamel less susceptible to acid attack from bacterial plaque even if the sealant is partially lost.

The time for placement for pit and fissure sealing is very important. The treatment is especially effective when pits and fissures of teeth are sealed soon after the eruption; the time when the teeth are most prone to develop dental caries. Once the tooth ages in the mouth and post eruptive enamel maturation takes place, it would be less susceptible to decay. Glass-ionomer cements, due to their added advantage of fluoride release, are expected to aid the post eruptive enamel maturation.

Although pit and fissure sealants have been tested comprehensively and are shown to be effective against

dental caries, there is always room for newer materials, such as the glass-ionomer cement, which with its additional properties may prove to be more effective and easy to use. The ideal aim for any study related to fissure sealants should be to obtain 100% success in retention, as well as 100% effectiveness against dental caries in those occlusal surfaces which benefit least from community water fluoridation.

Retention and effectiveness of sealants depends on the following factors:

- (a) Use of a proper technique.
- (b) Selection of patients and teeth.
- (c) Operator variability.
- (d) Choice of materials.

(a) Use of Proper Technique

It is necessary to adhere to a proper technique for the material chosen. Usually, a commercially available material is well-tested by the manufacturers before it is made available. Materials usually have a recommended technique for placement which should be followed. Alterations of such techniques should only be done if the new technique is being tested for its efficacy by the operator or variation has been tested by research and is well documented. Specific aspects of techniques for the use of fissure sealants are isolation and moisture control, preparation of tooth surfaces, and moisture control during and after setting. For a conventional pit and fissure sealant after a proper isolation, the teeth are cleaned

with a pumice slurry not containing any oils, such as glycerine, or fluorides. It is thought, but not confirmed, that the presence of these agents may contaminate the tooth surface and adversely influence enamel conditioning and subsequent bond strength between the sealant and tooth surface. This prophylaxis is very important because it has been shown to increase the bond strength.

Acid etching of tooth surfaces is an essential step for conventional sealants because the micropores formed on the enamel surface host the resinous tags and provide a mechanical retention to the sealant. Drying the teeth thoroughly after washing off the acid is necessary as the water may interfere in the mechanical bonding of sealant to the tooth surface. Conventional sealants do not need moisture control after their setting (complete polymerisation) takes place.

Glass-ionomer cement bonds chemically as well as mechanically with the tooth surface. Prophylaxis of the tooth surface is not an essential step in this procedure to obtain adequate bond strength. However, washing the surface with 3% hydrogen peroxide or conditioning the surface with polyacrylic acid, tannic acid or dodicin is recommended since it has been shown to increase the bond strength between the cement and tooth surface. The most essential step for glass-ionomer cements is the moisture control necessary during and after initial setting, and until the final set of material is reached. Various agents have been tried with varied success, such as water-proof varnish, petroleum jelly, cocoa butter, grease, and

stomahesive wafers. Earl, Hume and Mount (1985) studied the effect of different surface treatments (varnishes, petroleum jelly, cocoa butter, ethyl cyanoacrylate) on the water movements across the glass-ionomer cement surface and concluded that petroleum jelly and Y-sol when thickly applied and the De Frey, Fuji, Ketac and nail varnish when properly placed gave a reasonable degree of protection against the movement of water across the surface of newly placed glass-ionomer cement. Placement of varnish covered with a piece of stomahesive wafer would give optimum moisture control.

(b) Selection of Patients and Teeth

As previously stated, teeth should be sealed as soon after they erupt in the mouth. An age group of 6-8 years is recommended for study because patients would be expected to have all four first permanent molars erupted. Any tooth that has remained caries free for four or more years is less likely to become carious and is not recommended for sealing (Ripa 1985). Ripa (1985) also has described tooth-oriented criteria for the use of sealants. These criteria are based primarily upon a visual-tactile inspection of the pits and fissures of the teeth whose proximal surfaces are sound and upon other considerations. The dried pit and fissure surface is first evaluated using a mirror and explorer. Status of the tooth surface will be either carious, have questionable caries or be sound. Frank caries is easily recognized as a break in the continuity of the enamel, with softness, and usually with

discolouration. Surfaces diagnosed as carious are not to be sealed. They must be restored. A questionable diagnosis is one in which the operator can not make a definite decision that the tooth surface is carious or sound. The explorer tip sticks in the tooth fissure or a pit. But other evidence of caries such as softness felt by the tip of the explorer or a white halo of undermining demineralization is lacking. The "stickiness" may be caused by the explorer tip wedging between the sound walls of a narrow fissure. Because the surface has not been diagnosed as carious, a restoration is inappropriate. However, since the sticky area can easily trap bacteria and food particles, and since cleaning can be difficult, these areas should be considered to have a heightened level of caries susceptibility. Previously, treatment of these fissures and pits consisted of "watching" them. This was a euphemism which meant that they were not at that time indicated for restoration, but after observing them over a time if they decayed they could then be restored. This approach was acceptable because dentistry then lacked an appropriate treatment for these pits and fissures.

Today, an approach of "watchful waiting" can be substituted by sealing these questionable tooth surfaces. This approach is justified since it has been shown that if a diagnostic error occurs and caries is inadvertently sealed, the lesion will not progress but instead should arrest (Silverstone 1986, Ripa 1985). The principal diagnostic criteria for a sound pit or fissure is that the enamel surface is hard and resistant to penetration by an explorer.

If there is a minute break in the integrity of the enamel surface, but the area is hard, the surface is considered to have an inactive or arrested lesion and it is treated as sound. A sound or caries-free pit or fissure may be sealed based upon considerations of occlusal morphology, tooth age, status of proximal surfaces, and general caries activity in the mouth. These considerations are listed in Table 19.

(c) Operator Variability

Retention and effectiveness of a sealant depends on the operator's ability, practice and background. Therefore, an operator must practise the procedure and master it. Use of the glass-ionomer cement does not involve a long tedious procedure and is easy to place.

(d) Choice of Material

It is possible that the glass-ionomer cement would prove to be a better fissure sealant since it bonds physicochemically with tooth structure, releases fluoride and is easy to use. 'Ketac-Fil' is even easier to use since it is available in an encapsulated form. Conventional sealants are effective as long as they remain firmly adhered to tooth surfaces. Conventional sealants do not contain any active ingredients. Their preventive function is achieved by their adhering to the enamel surface and physically occluding the pits and fissures from the rest of the oral environment. As long as the sealant remains intact, caries should not develop beneath it. This is

Table 19. Tooth oriented indications and contraindications for the use of pit and fissure sealants

Surface diagnosis	Clinical considerations	Do seal	Do not seal
Carious	Occlusal anatomy	If pits or fissures are separated by transverse ridge, a sound pit or fissure may be sealed	Carious pits or fissures
Questionable	Status of proximal surface(s) General caries activity	Sound Many occlusal lesions; few proximal lesions	Carious Many proximal lesions
Sound	Occlusal morphology Tooth age Status of proximal surface(s) General caries activity	Deep, narrow pits and fissures Recently erupted teeth Sound Many occlusal lesions; few proximal lesions	Broad well-coalesced pits and fissures Teeth caries-free for four years or longer Carious Many proximal lesions

(Source: Ripa 1985)

because of the intimate bond between the sealant and etched enamel surface which prevents significant marginal leakage. Thus the longevity of a sealant on the tooth, i.e. its retention, is important because more surfaces in which sealant completely occludes the pits and fissures should not decay. In this context, retention is a prime determinant of sealant success.

Glass-ionomer cements release fluoride, which is shown to be acquired by the adjacent enamel. Complete retention of glass-ionomer cement when used as a pit and fissure sealant may not be necessary for their continued effectiveness against dental caries.

A comparative study between the glass-ionomer cements and conventional sealants is proposed. The proposed period of study is a three year evaluation. The retention rates may be compared at the yearly intervals. A one year period is too small to comment on dental caries. Therefore, the study should be evaluated at 2, and 3 years after sealant placement.

A 100 per cent success in prevention of caries can be achieved from sealants if they are periodically checked and all the lost sealants are replaced.

The proposed comparative study of glass-ionomer cements and conventional pit and fissure sealants may show a practical and more effective direction for caries prevention.

6. CONCLUSIONS

In this thesis the glass-ionomer cements and the conventional pit and fissure sealants have been compared for their properties and effectiveness as pit and fissure sealants through a comprehensive literature review, from which it was concluded that:

1. The glass-ionomer cements are basically composed of a reaction product of a polyalkenoic acid, a homo- or co-polymer of acrylic acid and an ion leachable aluminosilicate glass. The conventional sealants are basically made up of a common base, Bis-GMA, which may be unfilled or filled with quartz or lithium aluminium silicate fillers.
2. Glass-ionomer cements set by the reaction between the polyacrylic acid and the glasses. When these are mixed together, the glass is attacked by the acid and Al^{+++} , Ca^{++} , Na^{+} ions are liberated as is fluoride, probably in the form of complexes. Calcium and eventually Aluminium polysalts form, which crosslink the polyion chains. The salts hydrate to form a gel matrix which surrounds the unreacted glass particles. Thus the set cement consists of an agglomeration of untreated powder particles surrounded by a silica gel which is held together in an amorphous matrix of hydrated calcium and aluminium polysalts. Conventional sealants which are basically unpolymerised systems of Bis-GMA oligomers, set by polymerisation reaction.

This polymerisation can be chemically activated or photoactivated.

3. Glass-ionomer cements bond physicochemically to the tooth structure. They form ionic bonds with enamel through multiplicity of -COOH groups which they contain and these carboxyl groups form a hydrogen linkage to enamel apatite. Conventional pit and fissure sealants bond mechanically to the pre-conditioned tooth surface by the formation of resinous tags which extend into the microporosity formed by the acid etching.
4. Set glass-ionomer cements and set conventional pit and fissure sealants are biocompatible and very well tolerated by oral tissues.
5. Since glasses used in glass ionomer cements are high in fluoride content, they release fluoride which can be acquired by the adjacent enamel rendering it less susceptible to acid dissolution. None of the commercially available Bis-GMA pit and fissure sealants are capable of releasing fluoride.
6. Glass-ionomer cements exhibit antimicrobial properties through their release of fluoride ions. Conventional pit and fissure sealants do not possess antimicrobial properties. They prevent decay by acting as a physical barrier between the oral cavity and the depth of fissures and pits.

7. Studies regarding the retention of glass-ionomer cement are very few. They concentrate on ASPA, which was the first glass-ionomer cement, made available by the Laboratory of the Government Chemist, London. Despite low retention rates, these studies do show a reasonable reduction in dental caries. This could be attributed to the fluoride release which continues its effect even after the cement is macroscopically lost from the pits and fissures.

Conventional pit and fissure sealants have been comprehensively studied for their retention and have shown retention rates of 60 to 100% in the first 2 years and 37-60 per cent after 5 years.
8. Glass-ionomer cements are reasonably abrasion resistant and resistant to acid erosion. Studies on the wear of conventional sealants have been inconclusive, but a study of Jensen et al (1985) has shown no difference between wear of filled or unfilled resins.
9. To be effective, pit and fissure sealants must be placed as soon as possible after the tooth erupts in the oral cavity.
10. Data regarding effectiveness of glass-ionomer cements against caries is limited. Conventional sealants have been shown to demonstrate a significant caries reduction.

The factors that have been determined to be of relevance for a proposed comparative study between a glass-ionomer cement and a conventional pit and fissure sealant are as follows:

- (1) The encapsulated glass-ionomer cement, Ketac-Fil and chemically polymerising conventional sealant Delton would be suitable materials for the purpose of this study.
- (2) The method recommended by Craig (1984) may be used for the placement of Ketac-Fil. Manufacturer's directions may be followed for the placement of Delton.
- (3) A minimum sample of 400 first permanent molars in 100 children aged between 6-8 years would need to be selected. Contralateral teeth within each patient are then sealed either with glass-ionomer cement or conventional sealant to provide similar environmental conditions.
- (4) First permanent molars selected for study should meet the following criteria:
 - (a) All four first permanent molars should be erupted and present in the mouth.
 - (b) There should be no evidence of caries on the occlusal, as well as the proximal surfaces of these molars.
 - (c) Molars with shallow and wide fissures and with no evidence of caries in the mouth should be excluded from the study.

- (5) All the sealed molars may be examined at 6 months, one year, two year and three year intervals to determine retention of sealants and caries development. The results then should be compared for any differences in performance between these two materials; and the performance of other materials as described in the literature.

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