EVALUATION OF RESIN-BASED FISSURE SEALANTS PLACED UNDER FIELD CONDITIONS

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ABSTRACT

BACKGROUND: The application of dental sealants is a recommended procedure to prevent and control dental caries. However, despite strong evidence for the safety and effectiveness of dental sealants, their use still remains low, especially among children from lower socio-economic communities. The World Health Organization (WHO), Centres for Disease Control and Prevention (CDC) and the Association of State and Territorial Dental Directors (ASTDD) strongly endorse the implementation of school based dental sealant programmes as a community-based preventive strategy to increase sealant use and reduce dental caries. However, in the WHO African Region, oral health is seen as a very low priority and this is compounded by limited technical and managerial resources. The availability of human resources and equipment are crucial for the successful placement of dental sealants. A gap in the research literature was identified for determining the effectiveness of fissure sealants placed under field conditions.

AIM: To evaluate the caries preventive effect as well as retention status of a resin-based fissure sealant that was placed under field conditions as part of a school based sealant programme.

METHODOLOGY: A cross-sectional comparative study was conducted at two primary schools in close proximity of each other in the same low socio-economic area in Beaufort West, South Africa. The study population consisted of grade two children between the ages of 7-9 years who had fully erupted first permanent molar teeth. The case group consisted of 100 learners who received dental sealants on caries-free first permanent molar teeth 12 months earlier. The control group consisted of a random selection of the same number of learners from the adjacent school. Dental caries on the occlusal surfaces of the first permanent molar teeth was detected by making use of the decayed (D) portion of the decayed, missing and filled tooth (DMFT) score, while a separate diagnosis distinguished between cavitated and non-cavitated lesions. Sealant retention was determined by a calibrated examiner who was not involved in the placement of the sealants.

RESULTS: The response rate of the study was 80.0% (n=100) and 78.9% (n=356) of the fissure sealants that were originally placed were evaluated. When the sealants were placed in 2013, 52.0% of the children were female and at the 12 month follow-up, 51.3% were female. The average age of the female children at follow-up was 8 years and 4 months (99.9 months) and 8 years and 5 months (101.8 months) for the males. The standard deviation of the gender profiles differed by 1 month only and implies an equal distribution of age between female and male children throughout the study. Just less than ten per cent (7.8%) of the sealants were fully intact at the 12 month follow-up examination and 91% were totally lost, which is a higher sealant loss rate than what is generally reported on in the literature. Of the 7.8% fully retained sealants, a statistically significant proportion (p=0.044) were found on the mandibular molar teeth. The caries incidence rate in the sealed group was 7.1% versus 9.1% in the control group. Relative risk (RR) calculations was slightly lower for the sealed (RR=0.79) than the unsealed (RR=1.02) teeth.

CONCLUSION: The study showed a 2% lower caries prevalence rate on the occlusal surfaces of the sealed versus the unsealed teeth. However, this does not represent a statistically significant finding (P=0.39). The study also showed a low retention rate for the resin-based sealants placed under field conditions (12 month retention rate of 7.8%). The results from this study has therefore shown that resin-based fissure sealants placed on grade 1 learners under field conditions appear to be not ideal in preventing the onset of dental caries on the occlusal surfaces of the first permanent molar teeth.

DECLARATION

I, Carl Edzard Potgieter (Student No. 2656280), the undersigned, hereby declare that this dissertation is my own original work except where indicated in acknowledgements and references. It is being submitted in partial fulfilment for the degree (MSc) in Community Dentistry at the Faculty of Dentistry, University of the Western Cape. It has not been previously submitted in part or its entirety towards and other degree or examination at any other university.

Signature: _____ Date: _____

DEDICATION

This work is dedicated to my beautiful wife, Ronèl, whose love and patience knows no boundaries. Thank you for taking care of the household and our three wonderful children while I was (always) pre-occupied with this Master's Degree.

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CHAPTER 1

1.1 Introduction

The prevention of dental caries is very important from a public health point of view (Ahovuo-Saloranta *et al.* 2013). The World Health Organization (WHO) considers fissure sealants as one of the most effective primary preventive measures to ensure the complete protection and total preservation of the occlusal surfaces of posterior teeth. It is also recognized as one of the most effective and least invasive procedures to prevent and control dental caries (Condò et al. 2013).

The rationale behind fissure sealants stems from the fact that the sealing material creates a protective mechanical barrier that prevents the micro-organisms of bacterial plaque to stagnate, proliferate and damage the healthy tooth structure underneath (Ahovuo-Saloranta *et al.* 2013). With about 90% of carious lesions originating in the pits and fissures on the occlusal surfaces of posterior teeth, fissure sealants have proven to be very effective in reducing the incidence of dental caries on these surfaces (Ahovuo-Saloranta *et al.* 2013; Condò *et al.* 2013; Azarpazhooh & Main, 2008b). For optimal protection of the occlusal surfaces of the first permanent molar teeth, fissure sealants should be placed as soon as possible after eruption of the teeth (Virtanen et al. 2003). The importance of early placement of fissure sealants were highlighted by Lalloo & Turton (2008) who showed that the likelihood of developing dental caries was significantly higher amongst children who did not receive fissure sealants within their first year of schooling (the year when a child turns seven in South Africa) as opposed to children who did receive fissure sealants during this time.

However, despite overwhelming evidence for the safety, effectiveness and cost-effectiveness of fissure sealants, its use still remain low (Zadik & Bechor, 2008; CDC, 2005). Fissure sealant utilisation was found to be statistically lower among school children from lower socio-economic backgrounds. These include children whose parents are unemployed, uneducated, who lives in low-cost housing and who attend public schools (Al-Agili *et al.* 2012; Ayo-Yusuf *et al.* 2011). These disparities has also resulted in a social inequality in sealant utilisation as the children who seems to be most in need of sealants are least likely of receiving them (Dye *et al.* 2007). In South Africa, where more than 80% of the population are dependent on the state for their oral health services (van Wyk & van Wyk, 2004) dental public health treatment data have shown a significant increase in the number of tooth

extraction procedures and fewer restorations and fissure sealants being done (Lalloo & Turton, 2008).

School-based fissure sealant programmes (SBFSP) have shown to increase sealant usage, especially among children from lower socio-economic backgrounds. This is because SBFSP can target low-income children who are less likely than their wealthier counterparts to receive preventive services and to have a regular source of care (U.S. Department of Health and Human Services, 2000). With 90% of carious lesions in children to go untreated (Thorpe, 2006), it is fair to assume that current oral health systems do not ensure that children receive timely restorations once they get cavities. Untreated dental caries furthermore negatively affects general quality of life by having a serious impact on the child's well-being and ability to fulfil desired socio-economic functions. It usually results in pain and sepsis and can negatively affect a child's dietary intake and aggravate undernutrition because of the inability to masticate (Thorpe, 2006). Children who are not exposed to fissure sealants would therefore be at risk of a higher morbidity, more pain and sepsis, malnutrition and the need for more extensive dental treatment (Aleksejūnienė et al. 2010). In cases where children is able to get the tooth restored, it comes at a steep financial price as the restoration of one tooth was found to be 12 times more expensive than a fissure sealant (Griffen *et al*. 2002). A focus on SBFSP is therefore justified by the lack of on-going access to care, the higher likelihood that a cavity would not be restored promptly and the cost-saving attributes of fissure sealants.

There is however, a clear distinction to be made between the placement of fissure sealants in a school-based setting vs. at a dental practice. The successful placement of fissure sealants is dependent on the availability of sufficient human and technical resources (Aleksejūnienė *et al.* 2010; Gooch *et al.* 2009). Obviously, a dental clinic setting can offer a better control of caries risk management, clinical procedures, choice of materials, patient recall, and compliance as opposed to a school-based setting (Aleksejūnienė *et al.* 2010). A gap in the research literature was subsequently identified by the Cochrane Collaboration pertaining to the effectiveness of fissure sealants placed "in other conditions" (Ahovuo-Saloranta *et al.* 2013).

1.2 Motivation for the present study

In lower socio-economic communities, it is often difficult for children to go to a dental clinic for treatment. Time, finances, availability of transport and long distances are real-world challenges faced by many South African children on a daily basis. With more than 80% of the South African population being dependent on the state for their oral health services (van Wyk & van Wyk, 2004), these difficulties result in many children foregoing preventive and/or curative treatment. It also leads to a high number of untreated carious lesions among school learners (van Wyk & van Wyk, 2010). On account of this, many children only seek care due to pain and sepsis and in a public health setting the most common treatment option is extraction of the tooth (Lalloo & Turton, 2008). Dental public health treatment data have shown a significant increase in the number of tooth extraction procedures and fewer restorations and fissure sealants being done (Lalloo & Turton, 2008).

With more than 70% of dental caries in South African school children to go untreated (van Wyk & van Wyk, 2010), the dental profession needs to revisit the way in which population-based caries preventive programmes are implemented. If the majority of school children are unable to visit the dental team at clinics, it may be more useful to take prevention to children at the schools. It would therefore be difficult to disagree with the statement that oral health practitioners in the public sector should make every effort to try and improve the accessibility of vulnerable children to caries preventive services. However, one also needs to ensure that these efforts are in fact effective in terms of its outcome and effect on the target population. This is what lies at the heart of this study.

1.3 Background to the study

In 2013, 356 fissure sealants were placed on 100 grade one learners attending the J.D. Crawford primary school in Beaufort West, South Africa. J.D. Crawford primary school is situated in a low socio-economic part of Beaufort West. Placement of the sealants was done as part of a primary school preventive programme driven by staff from the local primary health dental clinic. When the sealants were placed, it was not done as part of the present study. Seeing that transportation of the children to the dental clinic was problematic, the dentist committed to go to the primary school and do the fissure sealants there instead. This was done in an effort to increase accessibility as well as sealant usage among children from a low socio-economic area and thereby ensuring that these children could also benefit from the caries preventive properties of fissure sealants.

Without reaching out to these children, the chances were very slim of them visiting the nearest clinic to have fissure sealants placed on their teeth.

However, there were two major obstacles to overcome: 1) the dentist had to work in a non-clinical low resourced environment without the aid of a dental assistant. Reaching out to the school meant that the children had to be treated in the school staff room under natural light, seated on a fold-up dental chair, with no compressed air or suction available. 2) Although these conditions were generally more favourable for the placement of glass ionomer (GI) fissure sealants (Emmerling Munoz & Carver Silva, 2013), a resin-based (RB) fissure sealant was the only one available to the dentist. The dentist therefore never had a choice of which material to use. The only choice was whether to reach out to these children with whatever resources were available, or not.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

Dental caries is the most common non-communicable disease in the world (Goldman *et al.* 2008). It has a negative impact on the quality of life, economic productivity and development of individuals (Sheiham, 2006). It therefore comes as no surprise that dental caries is still regarded as a major public health concern (Ahovuo-Saloranta *et al.* 2013). Although significant reductions in the prevalence of dental caries were experienced during the 1970's and 1980's (Bratthall *et al.* 1996), newer studies reported on "alarming increases" in global dental caries since the beginning of the 21st century (Bagramian *et al.* 2009). These increases were found to be mostly in lower socio-economic groups, new immigrants and children. It was also found that almost 90% of carious lesions in children were untreated (Thorpe, 2006).

This high percentage of untreated dental caries can therefore be seen as evidence that current oral health systems are failing to prevent and appropriately treat dental caries in children (Thorpe, 2006). Although the application of fissure sealants is recognized as one of the most effective and least invasive procedures to prevent and control dental caries (Ahovuo-Saloranta *et al.* 2013; Condò *et al.* 2013; Azarpazhooh & Main, 2008b), its usage still remain low (Zadik & Bechor, 2008; CDC, 2005).

The World Health Organisation (WHO), Centers for Disease Control and Prevention (CDC) and the Association of State and Territorial Dental Directors (ASTDD) have subsequently endorsed the implementation of school based fissure sealant programmes (SBFSP) as a community-based preventive strategy to increase sealant use and reduce the incidence of dental caries among school children (Ahovuo-Saloranta *et al.* 2013; Condò *et al.* 2013; Azarpazhooh & Main, 2008b).

This literature review will start with an overview of the most commonly used fissure sealants and continue with a discussion on matters relating to the effectiveness of fissure sealants and how it can be measured. It will also include sections pertaining to the safety and cost-effectiveness of fissure sealants, utilization of fissure sealants and the role that school-based fissure sealant programmes can play in caries prevention. The last section will focus on the

methodologies used throughout the literature to evaluate the effectiveness of fissure sealants placed in field conditions.

2.2 Commonly used fissure sealant materials

The most commonly used fissure sealants today are resin-based (RB) and glass-ionomer (GI) based sealants. RB fissure sealants seal pits and fissures through micro-retention, which is created through the establishment of resin tags after an acid etching process of the enamel surface (Quinonez *et al.* 2005). In contrast to RB fissure sealants, GI sealants do not bind to the enamel surface through micro-retention, but rather through a weaker chemical reaction resulting from an ion exchange process (Frencken & Holmgren, 1999).

Successful placement of RB sealants are very technique sensitive and requires an absolute dry field of placement until polymerization is complete. Proper isolation techniques are therefore crucial for the placement of a successful RB fissure sealant. For this type of sealant, salivary contamination during placement is the most common reason of failure (Emmerling Munoz & Carver Silva, 2013). Successful placement of RB fissure sealants can be enhanced by proper isolation of the teeth, by placing the sealants only after complete eruption of a tooth (i.e. once there is no gingival tissue on the crown) and by following good operator techniques and protocols.

On the contrary, successful placement of GI sealants are not so technique sensitive. This can mainly be ascribed to the hydrophylic properties of GI sealants which mean that they do not require an absolute dry field of placement to be successful (Lindemeyer, 2007). In fact, when a GI sealant is placed, some authors have even suggested that one can press the sealant onto the occlusal surface of the tooth with a saliva-moistened finger without compromising the quality of the sealant (Emmerling Munoz & Carver Silva, 2013). Glass ionomer sealants also contain fluoride ions which is released and taken up by the tooth enamel. This assists in remineralization of the enamel and thus renders the tooth structure less susceptible to demineralization (Lindemeyer, 2007). Furthermore, Pardi *et al* (2003) have noted that even after glass ionomer sealants appear to have been lost from the tooth surface, some small amounts can still be found in the pits and fissures and release fluoride to help remineralise the tooth enamel.

2.3 Indicators for success [retention vs incidence]

The first clinical evidence for the effectiveness of fissure sealants was based on split mouth study designs whereby caries occurrence was compared between sealed and unsealed teeth (Rock & Anderson, 1982). The overwhelming positive correlation between fissure sealants and caries reductions have subsequently resulted in the use of unsealed control groups in further clinical trials to become ethically unacceptable (Locker *et al.* 2003). Clinical studies then started to use different sealant materials and/or the use of sealant techniques as their new controls (Muller-Bolla *et al.* 2006). This direct comparison of the different materials and their placement techniques slowly resulted in sealant retention rates, instead of caries prevention rates, to become the main outcome of many fissure sealant studies. An inter-category misinterpretation of sealant retention as a "beneficial factor" in dental caries prevention has resulted in sealant retention to be mistakenly regarded as a "valid surrogate endpoint" (clinical measurement or physical sign) for determining fissure sealant effectiveness (Mickenautsch & Yengopal, 2013b).

After being supported by regression results of retention rate studies, it was highlighted as obvious that (RB) fissure sealants could only prevent the onset of dental caries while still present on the tooth surface (Rock & Anderson, 1982). Liebenburg (1994) and Weintraub & Bart (1987) found it self-evident that if any prophylactic benefit were to be accrued because of the use of fissure sealants, the sealants had to be completely intact on the tooth surface. The obvious conclusion was then made that since caries did not develop while the sealant remained intact on the tooth, the length of time that the sealant stayed intact on the tooth was a justifiable method to be used as a surrogate measure of the sealant's effectiveness in preventing the onset of dental caries (Muller-Bolla *et al.* 2006; Locker *et al.* 2003). It was then declared on behalf of the American Dental Association Council of Scientific Affairs (Beauchamp *et al.* 2008) that the retention rate of fissure sealants can be taken as an acceptable surrogate for caries prevention. This also prompted Künish *et al.* (2012) to declare that "intact sealant" was the leading fissure sealant criterion today.

For this reason, many studies were conducted and reported on the retention rates of RB and GI fissure sealants. The results were consistent that RB fissure sealants yielded higher retention rates than GI sealants (Ahovuo-Saloranta *et al.* 2013; Azarpazhooh & Main, 2008b; Muller-Bolla *et al.* 2006). For instance, Condò *et al.* (2013) reported that RB fissure sealants had a 69.6% total sealant retention after 12 months, compared to 31.3% for GI sealants after

the same period. Large differences in the retention rate of RB sealants have also been reported on, ranging from 2% - 80% (Azarpazhooh & Main, 2008b). The highest retention rate for RB sealants was achieved after the operative field was isolated with a rubber dam. In these conditions, a total retention rate of 77.3% was recorded (Condò *et al.* 2013). It was also found that the use of an adhesive system with a RB sealant did not increase the value of total retention rate over a 12 month period, which was found to be 56% (Condò *et al.* 2013). Because total sealant "intactness" is widely regarded as a main criterion for RB sealant effectiveness, maintenance (recall and replacing) of RB fissure sealant programmes was advocated as an important component of such a programme (Mejare *et al.* 2003).

However, recent papers by Mickenautsch & Yengopal (2013a; 2013b) suggest that, although complete retention of fissure sealants has indeed been established as a beneficial factor for the prevention of dental caries, it appears not to be a sufficiently accurate predictor of caries development. They argued that for complete sealant retention (or loss thereof) to be a valid surrogate endpoint (clinical measure or physical sign) it would need to fulfil the following two criteria: 1) there needs to be a direct association with caries absence (or caries occurrence) on sealed teeth and 2) an independence of its ratio to caries from the type of sealant material used. They reported that although the risk of losing complete retention of the sealant material was more than twice as high for GI sealants than for RB sealants (0.84 versus 0.36 respectively), the mean risk for caries occurrence was similar (0.12 versus 0.12) (Mickenautsch & Yengopal, 2013a). Condò *et al.* (2013) also reported that, despite RB sealants having a higher retention rate than GI sealants, no significant difference was found in the caries incidence rate between the two sealant materials after 12 months. This might partly be explained by the continuous release of fluoride of the GI materials and by the permanence of micro-particle tags of material in the pits and fissures of the teeth (Beauchamp *et al.* 2008; Griffen *et al.* 2009; Baseggio *et al.* 2010).

Therefore, although RB sealants are superior to GI sealants in terms of sealant retention (Poulsen *et al.* 2001; Muller-Bolla *et al.* 2006), there was no clear benefit of one type of sealant over the other in terms of caries prevention (Ahovuo-Saloranta *et al.* 2013). It can therefore be argued that, while for RB fissure sealants, the retention rate might still be seen as a "beneficial factor" to achieve caries reduction, the same cannot be assumed for GI sealants. Caries manifestation should always remain the main focus and valid endpoint in clinical fissure sealant trials (Mickenautsch & Yengopal, 2013b).

2.4 Caries preventive effect of fissure sealants

The effectiveness of fissure sealants in preventing dental caries has also been well established by randomized clinical trials (Ahovuo-Saloranta et al. 2004; Mejare et al. 2003). Recent systematic reviews also concluded that fissure sealants are effective in delaying the onset of dental caries (Condò et al. 2013, Ahovuo-Saloranta et al. 2013; Bagramian et al. 2009). It is however, important to note that fissure sealants do not eliminate dental caries, but rather predictably reduce the occurrence thereof (Gooch et al. 2009).

Fissure sealants have been shown to reduce the caries incidence rate on the occlusal surfaces of molar teeth to as low as 2.5% after 12 months (Condò et al. 2013). A meta-analysis of a one-time placement of auto-polymerized sealants on permanent molars in children found that the sealants reduced dental caries by 78% at one year and 59% at four or more years of follow-up (Llodra et al. 1993). In a different clinical trial, fissure sealants have also shown to reduce the incidence of dental caries on the occlusal surfaces of molar teeth from 40% to 6%. In another group of children, the placement of fissure sealants reduced the percentage of carious teeth from 70% to 19% over a 2 year period (Condò et al. 2013).

Fissure sealants also have very good long term results in preventing the incidence of dental caries. Bravo et al. (2005) reported that 76.6% of teeth that were not sealed developed dental caries after 9 years as opposed to only 26.6% of teeth that received fissure sealants. A 15 year follow up of another study also revealed a reduction in dental caries of 54% among teeth that received fissure sealants (Jodkowska, 2008). Azarpazhooh & Main (2008b) also commented on reductions in dental caries of up to 50% on teeth that were sealed (with any type of sealant) when compared with placebo controls.

2.5 Safety of fissure sealants

A recent increase in the use of composite restorations and sealants in dentistry has highlighted the possible release of some resin monomers, especially bis-DMA that can lead to the formation of 2,2-bis[4-hydroxyphenol]propane or BPA (Azarpazhooh & Main, 2008a). In the manufacturing process of polycarbonate plastic resins (the basis of fissure sealants), an acidic catalyzation of phenol and acetone have shown to lead to the formation of BPA. *In vivo*, BPA was found to form a bond to oestrogen receptors of cells at sub-toxic concentrations and studies have shown that the oestrogen-like properties of BPA can lead to impaired development, as well as compromised health and reproductive systems in wildlife (Topari *et al.* 1996). Furthermore, there are also reports in the literature that BPA and bis-DMA can stimulate the proliferation of certain breast cancer cells (Olea *et al.* 1996).

Although fissure sealants typically do not contain BPA itself, it does contain the monomers that are derived from BPA. These monomers are called bis-GMA and bis-DMA. While bis-GMA was found to be stable to various hydrolytic conditions and therefore do not convert to BPA, it is the bis-DMA in certain sealants and composites that can hydrolize and convert to BPA (Arenholt-Bindslev *et al.* 1999).

When resin-based dental restorations or sealants are placed on the teeth, the material is subjected to an in-situ polymerization of the monomers. It is at this stage where concerns were raised about the possible release of the potentially harmful monomers from the resin into the salivary fluid of the oral cavity (Azarpazhooh & Main, 2008a). Although, in some cases, low levels of BPA were detected in intro-oral saliva after the placement of certain sealants, it was found to be present for a very short time only (less than 3 hours) (Olea *et al.* 1996; Arenholt-Bindslev *et al.* 1999; Fung *et al.* 2000). In the cases where BPA was detected in the saliva, no BPA levels could however be found in the bloodstream. The absence of systemic absorption of BPA has therefore led to the conclusion that fissure sealants do not pose any health threats to human beings (Azarpazhooh & Main, 2008a). This is a very important finding as it gives one complete reassurance from an ethical point of view that fissure sealants are in fact safe to use on patients.

2.6 Cost-effectiveness of fissure sealants

When the cost-effectiveness of a preventive intervention like fissure sealants is evaluated, there are many factors that need to be considered. Direct costs associated with the delivery of fissure sealants include costs involved in procuring the material, administration and costs involved in quality assurance. Indirect costs are just as important to consider and involves costs incurred by the patient/recipient themselves for receiving the intervention. These can include travel time and time off work and/or school (Griffen *et al.* 2002).

The total cost associated with the placement of the sealants should then be considered against the benefits that sealants offer. Such benefits include reductions of the caries incidence rates, which in turn leads to a reduction in the number of future dental visits as the need for dental restorations decrease. There is also the added bonus of an improvement in the quality of life that is associated with lower incidence of dental caries (Azarpazhooh & Main, 2008b). In a retrospective cohort study of children, Weintraub *et al.* (2001) compared the likelihood of need for restorative treatments and associated expenditures for first permanent molars with and without fissure sealants. They came to the conclusion that unsealed molars were almost 3 times more likely to receive further dental treatment than sealed molars (22.2% vs. 7.9%). This was similar to the finding of Lalloo & Turton (2008) that children who did not receive fissure sealants during their first year of school (the year when they turn seven) were significantly more likely to experience dental caries after 1 year compared to children who did receive fissure sealants.

Griffen *et al.* (2002) further analysed the cost-effectiveness of three different sealant delivery strategies. The first strategy was to seal all (SA) the first permanent molar teeth of the target group irrespective of caries risk (population approach). The second strategy was to assess the children according to caries risk and then only seal the molars of children in the high risk group (risk based sealant or RBS). The third strategy was to seal none (SN) of the teeth, but rather wait and carry out a restorative procedure later on, if necessary. At the time of this study, the baseline cost of providing a sealant was $27.00 per sealant versus $73.77 per one surface amalgam. They concluded that the second strategy (RBS) was the most cost-effective strategy.

However, while the 'high risk' strategy seems to be a commonly adopted approach for the prevention of dental caries, the low accuracy of methods used to properly identify these 'high risk' children have been used as a major critique against this approach (Batchelor & Sheiham, 2006). The critique seemed to hold value since it was concluded that no predictive model had been able to correctly identify those (high risk) individuals who will get the highest future caries increments (Van Palenstein Helderman *et al.* 2001). Batchelor & Sheiham (2006) furthermore added that changes in the average caries experience within a population were not limited to specific sub-groups but rather occurred throughout the whole population. Their finding that 94% of new lesions occurred in individuals who were considered to be at low risk can be seen as further evidence of the inability of caries predictive models to correctly identify where future caries increments is most likely to happen. This critique on the high-risk approach is based on the concept that the largest "…burden of ill health comes more from the many who are exposed to low inconspicuous risk than from the few who face an obvious problem" (Rose, 1993).

The question however, still remains: which approach to fissure sealant application is more effective? Bagramian *et al.* (2009) reported on "alarming increases" in global dental caries since the beginning of the 21st century. These increases highlight the need for an effective caries preventive strategy to be implemented (fissure sealants is recognized as one of the most effective and least invasive procedures to prevent and control dental caries (Ahovuo-Saloranta et al. 2013; Condò et al. 2013; Azarpazhooh & Main, 2008b)). Thorpe (2006) also reported that these increases were mainly found in lower socio-economic groups, immigrants and children. This implicates a socio-demographic context which is linked to the "alarming increases" in dental caries in the 21st century. Burt (2005) similarly argued that geographic targeting of caries preventive programmes should be used in conjunction with a population based approach. He furthermore stated that geographic targeting is simply another form of a directed population approach. Geographic targeting indicates an approach that is based on socio-demographic or epidemiologic data to identify groups as opposed to screening for individuals who may benefit from an intervention (Watt, 2005). The finding of Batchelor & Sheiham (2006) that 94% of new carious lesions were found on individuals who were not classified as being at high risk for caries development can be seen as evidence that a high risk approach may not be the most effective approach and that a population approach (coupled with geographic targeting) might prove to be the strategy that will prevent the most future carious lesions.

2.7 Fissure sealant utilization

Fissure sealant utilisation varies worldwide. It is highest in countries with comprehensive oral health care systems where fissure sealants are offered for free. This was found in some northern European countries where fissure sealant coverage was in excess of 50% (Ekstrand *et al.* 2007). In the United States of America, the utilisation of fissure sealants was found to be much lower with only 29% of 6-11 year olds and a slightly higher 37% of 12-15 year old children having at least one sealed permanent tooth (CDC, 2005). In Greece, only 8% of 12- and 15 year olds had at least one permanent tooth sealed (Oulis *et al.* 2011). This was comparable to Saudi Arabia where only 9% of grade three and grade eight learners had at least one sealed permanent molar (Al Agili *et al.* 2012). In South Africa, only 3.5% of 12 year olds had been exposed to fissure sealants (Ayo-Yusuf *et al.* 2011).

Fissure sealant utilisation was found to be statistically lower among school children from lower socio-economic backgrounds (Al-Agili *et al.* 2012; Ayo-Yusuf *et al.* 2011). These include children whose parents were unemployed (Ayo-Yusuf *et al.* 2011), had a lower level of education (Al Agili *et al.* 2012), who lived in low-cost housing and attended public schools (Al Agili *et al.* 2012).

Fissure sealant utilization was also found to be much lower among children who did not make regular use of oral health services, but only came to see the dentist when in pain (Ayo-Yusuf *et al.* 2011; Oulis *et al.* 2011). It is therefore quite surprising that, despite the effectiveness, cost-effectiveness and safety of fissure sealants, its usage still remained low (Zadik & Bechor, 2008; CDC, 2005).

One of the reasons for the low usage of fissure sealants was the concern of many dentists about sealing over clinical caries (Aleksejūnienė *et al.* 2010). However, contemporary protocols for the treatment of dental caries support sealing over active non-cavitated occlusal carious lesions (Griffen *et al.* 2008a; Feigal, 2002; Wellbury *et al.* 2004). Griffen *et al.* (2008a) reported that, on an annual basis, only 2.6% of non-cavitated carious lesions that were sealed had progressed to deeper caries. The placement of fissure sealants on teeth with non-cavitated carious lesions was also associated with a 71% reduction in progression to cavitated lesions after 5 years. Non-cavitated carious lesions are defined as lesions with no discontinuity or break in the integrity of the enamel surface (Griffen *et al.* 2008a). *In vivo* evidence have furthermore shown that viable organisms under properly placed sealants have either been reduced or eliminated (Oong *et al.* 2008), which obviously prevents any further

progression of the carious lesion and consequently resulted in an arrested carious tooth (Mertz-Fairhurst *et al.* 1986).

The placement of a fissure sealant over a carious lesion can therefore be considered a better treatment option than the alternatives of dental neglect or extraction of the tooth (Ismael, 1996). Moreover, even if fissure sealant programmes serve only to delay rather than prevent the need for restorative care, there is still a substantial benefit to be gained since it has been shown that the half-life of restorations is considerably greater if the child is older than nine years when the restoration is placed (Walls *et al.* 1985).

The literature has shown that not only can fissure sealants be placed on incipient carious lesions, but also on tooth surfaces where there is doubt about the caries status. Azarpazhooh & Main (2008b) reported that fissure sealants can safely be placed on teeth with early, non-cavitated carious lesions. Available evidence consistently indicates that the overall incidence of dental caries in permanent molars is lower among children who received fissure sealants compared with the incidence in similar children who did not (Gooch *et al.* 2009).

In fact, the caries preventive/delaying effect (Gooch *et al.* 2009) of fissure sealants were found to be so effective that Bakhshandeh *et al.* (2012) conducted a study to assess the possibility of arresting occlusal dental caries in adults by fissure sealants alone. 60 Resin based sealants and 12 composite restorations were made on 52 adult patients. These patients were referred for restorative treatment by senior lecturers at the School of Dentistry in Copenhagen, Denmark. After a mean follow-up period of 33 months, 7 sealants were repaired or replaced due to failure and only 3 were restored due to caries progression. This study has shown that the majority of lesions of the referred lesions were successfully arrested by sealants. The results from this study again demonstrated the caries preventive effect of fissure sealants and might even be used to promote the idea of sealing occlusal carious lesions in adults. However, the authors also stated that a longer observation period is needed for final conclusions to be made (Bakhshandeh *et al.* 2012).

2.8 School based fissure sealant programmes

There are strong recommendations in the literature for the placement of fissure sealants as part of an overall strategy to prevent the onset of dental caries on the molar teeth of children (Azarpazhooh & Main, 2008b). Recommendations furthermore provide for the placement of fissure sealants on all permanent molar teeth without cavitation within the target group (i.e., permanent molar teeth that are free of caries, permanent molar teeth that have deep pit and fissure morphology, permanent molar teeth with "sticky" fissures, or permanent molar teeth with stained grooves). Fissures sealants should be placed as soon after eruption as isolation can be achieved, but should not be placed on partially erupted teeth or teeth with cavitation or caries of the dentin. It is therefore recommended that fissure sealants be placed on first and second molar teeth within 4 years after eruption (Azarpazhooh & Main, 2008b), preferably within the first year (Lalloo & Turton, 2008).

Unfortunately, racial, ethnic and economic disparities persist resulting in inequalities in oral health status, access and receipt of preventive services (Tomar & Reeves, 2009). An inequality in sealant use has been identified in children who are most in need of fissure sealants, but are at a disadvantage of receiving it. Children from low-income families were found to be almost twice as likely to develop dental caries in their permanent teeth as opposed to children from higher-income families (28% vs. 16%). Nonetheless, only about one in five children, or 20%, from low-income families receives dental sealants. This proportion is notably less than the 40% of children from families with incomes greater than two times the poverty threshold who receives dental sealants (Dye *et al.* 2007).

School-based fissure sealant programmes (SBFSP) have shown to be an important intervention to increase sealant use and reduce dental caries (U.S. Department of Health and Human Services, 2000), especially among vulnerable children who are less likely to receive preventive care (CDC, 2001a). A systematic review of published scientific studies concluded that school-based fissure sealant programmes can reduce the incidence of occlusal caries on molar teeth by up to 60% (U.S. Department of Health and Human Services, 2000).

By targeting schools that serve children in lower socio-economic communities, SBFSP can therefore be very effective in addressing the socio-economic inequalities in sealant usage (Gooch *et al.* 2009). It can similarly be used to reduce or even eliminate racial disparities pertaining to fissure sealant usage through selective targeting of schools (CDC, 2001a).

A recent meta-analysis reported that teeth with fully or partially lost sealants were not at a higher risk of developing caries than teeth that were never sealed (Griffen *et al.* 2009). Thus, children from low-income families, who are more likely to move between schools than their higher income counterparts (Shachter, 2004) will not be placed at a higher risk of developing caries because they missed planned opportunities for sealant reapplication through SBFSP.

2.9 Clinical versus school setting

There are notable differences between the recommendations for sealant use in clinical versus school settings. First is the approach to caries risk assessment. Whereas clinicians in a clinical setting assess caries risk at the level of the patient or the tooth, SBFSP clinicians must also consider the risk at the level of the school and/or population (Gooch *et al.* 2009). Because children from lower socio-economic families and communities are at a higher risk of developing dental caries, all children who participate in a SBFSP should receive fissure sealants routinely as a primary preventive measure. Such an approach is similar to what Burt (2005) described as geographic targeting in conjunction with a population based approach and should be done without individual caries risk assessments in order to avoid stigmatization (Gooch *et al.* 2009).

The second major difference between the placement of fissure sealants in a school-based versus clinical setting is the context in which the sealants are placed. Important distinctions exist relating to the availability of diagnostic and treatment resources between a school-based and clinical setting. Clinical care settings typically include comprehensive diagnostic and treatment resources, whereas in the context of SBFSP resources are usually limited to those necessary for successful sealant placement and retention (Gooch *et al.* 2009). Obviously, a better control of caries risk management, clinical procedures, choice of materials, patient recall, and compliance can be assured in a dental practice (clinical setting) than in a school-based environment (Aleksejūnienė *et al.* 2010).The choice of sealant material (RB versus GI) is therefore an important factor that might have a serious impact on the overall success of the SBFSP.

2.10 Methodological issues

2.10.1 Placement of fissure sealants

The basis for the clinical effectiveness of fissure sealants lies in the proper use of the materials and the respect for each clinical step in the application process (Condò *et al.* 2013). SBFSP imply the placement of fissure sealants at the school itself (U.S. Department of Health and Human Services, 2000). Hence, for such projects in which suboptimal conditions may occur, it is important to employ the most practical and pragmatic methodology for securing sealant effectiveness (Aleksejūnienė *et al.* 2010).

The essential steps in the placement of fissure sealants include cleaning pits and fissures, acid etching tooth surfaces and maintaining a dry field while the sealant is placed and cured (Beauchamp *et al.* 2008). However, although most dental sealant manufacturers direct the operators to clean the tooth surface prior to acid etching, none of them actually specify a particular method of cleaning the tooth surface (Gooch *et al.* 2009). This might be due to the finding that no significant differences were observed between surfaces cleaned with a hand piece and prophylaxis brush with prophypaste and those cleaned with a dry toothbrush alone (Gray *et al.* 2009; Griffen *et al.* 2008b; Muller-Bolla *et al.* 2006; Gilchrist *et al.* 1998). Tooth cleaning with a dry tooth brush alone therefore seems to be the most practical and simplified approach for teeth cleaning in a SBFSP (Aleksejūnienė et al. 2010).

Sealant application involves strict attention to detail and dry field isolation throughout the procedure (Simonsen, 2002). Saliva contamination is the most commonly reported reason for RB sealant failure (Azarpazhooh & Main, 2008b) with a total failure rate of around 60% (Seeman *et al.* 2005). In addition, RB sealants were found to be ineffective in saliva contaminated sites, regardless of prior etching or not (Silverstone *et al.* 1985). Although practitioners admit that rubber dam isolation is best (Waggoner & Siegal, 1996), it is hardly ever used during sealant placement (Gray & Paterson, 1998). Obvious disadvantages of the rubber dam isolation are discomfort during a dam clamp placement, the need for a local anaesthetic, difficulty in placing a clamp onto a partially erupted tooth, and an increase in the cost and need for sterilization of the armamentarium (Waggoner & Siegal, 1996).

Clinical studies comparing isolation using either a rubber dam or a cotton roll (with the aid of a suction system) found no differences in RB sealant retention and caries prevention (Francis *et al.* 2008). Thus, proper isolation with cotton rolls in conjunction with a suction system should be adequate in sealant placement (Simonsen, 2002). However, to ensure acceptable quality of cotton roll isolation and of overall performance in sealant placement in community settings, four-handed dentistry is needed (Griffen *et al.* 2008b; Waggoner & Siegal, 1996). The four-handed placement technique (placement of sealants by a primary operator with the assistance of a second person) is associated with a 9 percentage point increase in sealant retention over the two-handed placement technique (placement of sealants by a single operator) (Griffen *et al.* 2008b). The four-handed placement technique is furthermore advised with one operator taking control of the field isolation with cotton rolls supplemented by portable water and a suction system, while the other performs the steps of the sealant placement protocol (Aleksejūnienė *et al.* 2010).

Saliva contamination is hard to avoid in a young patient (Feigal *et al.* 2000). The protective effect of bonding materials in saliva-contaminated surfaces was subsequently of particular research interest. Quite surprisingly, the results have shown that the usage of a bonding agent did not increase retention rate (Pinar *et al.* 2005), but only increased both the time and the cost of the sealant application (Simonsen, 2002). Self-etching adhesives have similarly raised a particular interest in research as they do not require rinsing or changing of cotton rolls (Fuks & Kupietzky, 2007) and could potentially be desirable for application of fissure sealants under field conditions. However, clinical studies have shown that the bonding of available self-etching adhesives to enamel is inferior to that achieved with total etch systems, and therefore not recommended in sealant placement (Hara *et al.* 1999).

The overall success of a SBFSP is therefore highly dependent on the choice of material and subsequent adherence to the placement criteria (Condò *et al.* 2013; Aleksejūnienė *et al.* 2010). In cases where saliva contamination is least likely to occur, such as in a clinical setting with the use of the four-handed placement technique, the choice of either a RB or GI sealant seems to be warranted. However, in cases where saliva contamination is likely to be a high risk factor, such as in the context and setting of the present study, a GI sealant material would ideally have been the preferred material of choice (Emmerling Munoz & Carver Silva, 2013; Lindemeyer, 2007).

2.10.2 Evaluation of dental caries

In 2001, a systematic review concluded that the relative accuracy of methods used to identify carious lesions could not be determined from the available studies (National Institutes of Health, 2001). Although many systematic reviews accepted the visual or visual/tactile inspection as a valid standard for caries detection (Bader *et al.* 2002) newer studies have suggested that the use of a sharp explorer under pressure could introduce a pathway for caries progression (Kuhnish *et al.* 2007). Therefore, based on reviews of the best available evidence and on contemporary caries detection criteria, international caries researchers are now more inclined to support visual assessment alone as a more appropriate caries assessment method for detecting the presence of surface cavitation and/or signs of dentinal caries (Pitts, 2004).

The World Health Organization (WHO, 2013) recommends that a clinical examination for dental caries should be conducted with a plane mouth mirror. The use of radiography and fibreoptics is not recommended in field studies as they are impractical to use under field conditions. The examination should proceed in an orderly manner from one tooth to the other, thereby ensuring that a systematic approach is being followed at all times. Considerable care should be taken to identify tooth-coloured restorations, as they might be extremely difficult to detect with a visual examination (WHO, 2013).

A tooth is considered sound if it shows no evidence of treated or untreated clinical caries. The preceding stages of cavitation are excluded as they cannot be reliably identified under most field conditions. Thus, a crown with the following defects, in the absence of other positive criteria, should be coded as sound:

- white or chalky spots; discoloured or rough spots that are not soft to touch with a metal community periodontal index (CPI) probe. The CPI probe is a specially designed lightweight metal probe featuring, among others, a rounded ball tip instead of a sharp ended tip;
- stained enamel pits or fissures that do not have visible cavitation or softening of the floor or walls detectable with a CPI probe;
- dark, shiny, hard, pitted areas of enamel in a tooth showing signs of moderate to severe enamel fluorosis;
- lesions that, on the basis of their distribution or history, or on examination, appear to be due to abrasion (WHO, 2013).

Caries should be recorded as present when a lesion in a pit or fissure, or on a smooth tooth surface, has an unmistakable cavity, undermined enamel, or a detectably softened floor or wall. A tooth with a temporary filling, or one which is sealed but also decayed, should also be included in this category. In cases where the crown of a tooth has been destroyed by caries and only the root is left, the caries is judged to have originated in the crown and is therefore scored as carious also. The CPI probe should be used to confirm visual evidence of caries on the tooth surface(s). Where any doubt exists, caries should not be recorded as present (WHO, 2013).

2.10.3 Study design

In most studies where prevalence or retention outcomes were evaluated, the investigators made use of a cross sectional study design (Al Agili *et al.* 2012; Oulis *et al.* 2011; Ekstrand *et al.* 2007). Inclusion criteria for most of the systematic reviews on fissure sealant retention and caries experience was for a study period of at least 12 months (Ahovuo-Saloranta *et al.* 2013; Beiruti *et al.* 2006).

2.11 Summary

Fissure sealants are one of the most effective primary preventive measures for ensuring complete protection and total preservation of the occlusal surfaces of posterior molar teeth (Condò *et al.* 2013). Protection and preservation of the occlusal surfaces of posterior teeth is important because 90% of carious lesions come from the deep pits and fissures in them (Beauchamp *et al.* 2008). Fissure sealants have subsequently been proven, through numerous systematic reviews and randomized clinical trials, to be extremely effective in reducing the incidence of caries on these surfaces (Ahovuo-Saloranta *et al.* 2013; Condò *et al.* 2013; Azarpazhooh & Main, 2008b).

Although some studies suggested that the prevention of fissure sealants were mainly due to the retention rate of the sealants over time (Kühnish *et al.* 2012; Ahovuo-Saloranta *et al.* 2004), newer evidence now suggests that the caries preventive efficacy of fissure sealants may not be inferred from the established retention rates (Lalloo & Turton, 2008).

Consequently, the effectiveness of fissure sealants in preventing the onset of dental caries may therefore not be approved or dismissed on the basis of retention rates (Mickenautsch & Yengopal, 2011). In support of this notion is the finding that, although RB sealants showed superior retention rates over GI sealants (Muller-Bolla *et al.* 2006; Poulsen *et al.* 2001), no clear benefit could be established between the two in terms of caries prevention (Ahovuo-Saloranta *et al.* 2013).

The published evidence shows that RB and GI sealants show equivalence in terms of clinical efficacy for caries prevention. This suggests that both materials offer similar caries prevention benefit. It is thus important that clinicians and oral health planners of fissure sealant programmes consider factors such as context (the child), setting (school versus clinic), follow-up (if available resources allow for annual follow-ups where retention can be assessed and RB fissure sealants be replaced, otherwise GI sealants should be the material of choice) and isolation (non-ideal isolation methods should favour the use of GI sealants rather than RB ones) before deciding on which material is best to use in a proposed programme.

Evidence-based practices have also dismissed (Azarpazhooh & Main, 2008a) the speculative notion that fissure sealants can cause any harm by producing oestrogen-like effects as well as stimulating the proliferation of certain breast cancer-like cells (Topari *et al.* 1996; Olea *et al.* 1996). Today, it is generally accepted that fissure sealants do not pose any health threats to human beings and can safely be placed on children (Azarpazhooh & Main, 2008a).

The cost-effectiveness of fissure sealants has also been well established throughout the literature. It is estimated that teeth that did not receive fissure sealants were almost 3 times more likely to receive further dental treatment than sealed molars (Weintraub *et al.* 2001). In addition, the most cost-effective way of delivering fissure sealants were found to be through a publicly funded school-based fissure sealant programme (Bertrand *et al.* 2011).

It is therefore quite surprising that, despite the evidence for the safety of fissure sealants, its cost-effectiveness as well as its effectiveness in reducing the incidence of dental caries, its usage still remained low (Zadik & Bechor, 2008; CDC, 2005). Fissure sealant utilization was furthermore found to be significantly lower among school children from lower socio-economic backgrounds (Al-Agili *et al.* 2012; Ayo-Yusuf *et al.* 2011). These disparities has resulted in a social inequality in sealant utilisation as the children who seems to be mostly in need of it were least likely of receiving them (Dye *et al.* 2007).

Burt's (2005) proposal of a geographic targeting of caries preventive programmes in conjunction with a population based (seal all) approach can subsequently be seen as a very good alternative in terms of trying to eradicate the social inequalities that currently exist in fissure sealant utilization. This approach indicates a caries preventive programme that is based on socio-demographic data to identify groups as opposed to individuals who may benefit from the programme (Watt, 2005).

However, school-based fissure sealant programmes have shown to be very effective in increasing dental sealant utilization, especially among children from lower socio-economic backgrounds. (U.S. Department of Health and Human Services, 2000). Nevertheless, a clear distinction exists between the application of fissure sealants in a school-based setting as opposed to a dental practice (Aleksejūnienė *et al.* 2010). In their review on the use of fissure sealants for the prevention of dental caries, the Cochrane Collaboration revealed that, although fissure sealants are effective in the prevention of dental caries, information on the magnitude of the benefit of sealing teeth in "other conditions" is scarce (Ahovuo-Saloranta *et al.* 2013).

CHAPTER 3

AIM & OBJECTIVES

3.1 AIM

To evaluate the caries preventive effect as well as retention status of resin-based fissure sealants placed under field conditions.

3.2 OBJECTIVES

- To determine the caries status on the occlusal surfaces of first permanent molar teeth that was sealed with a resin-based fissure sealant 12 months earlier;

- To determine the caries status on the occlusal surfaces of the first permanent molar teeth of children (control) who did not receive fissure sealants;

- To determine the retention status of the fissure sealants that was placed 12 months earlier.

CHAPTER 4

METHODOLOGY

4.1 Definition of terms

Caries preventive effect: The absence of surface cavitation, i.e. a break or discontinuity of the enamel surface caused by loss of tooth substance (Radike, 1968); the absence of an "unmistakable cavity" (WHO, 1997).

Under field conditions: Placed at a location other than a dental clinic.

4.2 Background to the study

The study is concerned with the evaluation of a school based fissure sealant programme that was driven by a dentist from the local primary health dental clinic. In 2013, 356 fissure sealants were placed on all (n=100) the grade one learners attending the J.D. Crawford primary school in Beaufort West, South Africa, irrespective of their caries risk or oral health status. J.D. Crawford primary school is situated in a low socio-economic part of Beaufort West. Placement of the sealants was done as part of a primary school preventive programme driven by staff from the local primary dental clinic. Placement criteria included that a child needed to be in grade 1. Fissure sealants were then placed on all fully erupted and caries free first permanent molar teeth. When the sealants were placed, it was not done as part of the present study.

Seeing that transportation of these children to the dental clinic was problematic, the dentist committed to go to the primary school and do the fissure sealants there instead. This was done in an effort to increase access and sealant usage among children from a low socio-economic area and thereby ensuring that these children could also benefit from the caries preventive properties of fissure sealants. Without reaching out to these children, chances are very slim of them coming to the nearest clinic for having fissure sealants placed on their teeth.

The sealants were placed at the local primary school, under natural light, without the assistance of a dental nurse (two handed technique). Children were seated on a fold-up dental chair, with no compressed air or suction available. The occlusal surfaces of the targeted teeth were cleaned with wet cotton wool pellets and dried with dry cotton wool pellets. Isolation was achieved by placing cotton rolls lingually and buccally of the targeted teeth. The cleaned occlusal surfaces were conditioned by using the self-etch Adper-L-Pop system by 3M ESPE. The self-etching liquid was applied with the brushes that comes standard with the system and was cured with a cordless curing light for 30 seconds. There was no water rinsing or air drying of the occlusal surfaces. Clinpro® fissure sealant (3M ESPE) was applied onto the conditioned occlusal pits and fissures, manipulated with the brush tip to free potential air bubbles and cured for 30 seconds. No rotary instruments were available and therefore no occlusal adjustments were made at the time of placement.

The use of a RB fissure sealant under aforementioned conditions was not made by choice, but by necessity: the RB Clinpro® (3M ESPE) sealant was the only fissure sealant available to the dentist (the only one available on the RT 296 Dental Consumables contract). The choice was therefore not which material to use, but rather whether to reach out to these children with whatever resources were available, or not.

4.3 Study design

This was a cross-sectional comparative study. For the purposes of the study, a control school was chosen on the basis of being in close proximity of J.D. Crawford primary school in the same socio-economic area. Because of resource constraints at the time of sealant placement, the control school did not form part of the primary school preventive programme during 2013. It is also important to highlight that, when the sealants were placed during 2013, it was not done as part of the original research project. The children in the control school were in grade 1 at the time of the fissure sealant programme being implemented in the J.D. Crawford primary school. The socio-economic status and oral hygiene practices of the children in J.D. Crawford and A.H. Barnard primary schools were assumed to be similar because children from both schools came from the same area.

4.4 Study sites

The two study sites consist of the two primary schools in Beaufort West: J.D. Crawford and A.H. Barnard Primary Schools. These schools are in close proximity of each other in the same socio-economic area.

4.5 Study population

Children in grade two, between the ages of 7-9 years old with fully erupted first permanent molar teeth who attended J.D. Crawford or A.H. Barnard Primary Schools.

4.6 Study Sample

Cases: 80 of the original 100 (80%) grade one learners were available for follow up 12 months after the fissure sealants were placed.

Controls: 80 grade two learners from A.H. Barnard school that did not have any sealants placed on their first permanent molar teeth. A systematic cluster sampling process was undertaken to identify the control group. Matching was done until the control group consisted of the same amount as well as male: female ratio as the case group.

4.7 Measurements

A structured data capture sheet was the method chosen for collecting the data in this study (Appendix 1). The data capture sheet was designed to ensure that it suited the aim and objectives of the study, was clear, simple, unambiguous, minimized potential errors from the researcher and coder and enabled efficient, meaningful analysis of the acquired data.

Dental caries was clinically detected and noted on the data sheet by making use of a visual inspection according to the regulations as set out by the WHO (2013). According to this method, caries were positively recorded when a lesion in a pit or fissure on the occlusal surface of the affected tooth had an “unmistakable cavity”. As per the WHO (2013) criteria, a CPI or round-ended probe was furthermore used to confirm the visual evidence of caries on the affected tooth.

Table 1: Coding of the caries status on the occlusal surface of first permanent molar teeth

CODE	CONDITION/STATUS
0	Sound
1	Caries
2	Filled & decayed
3	Filled, no decay
4	Missing due to caries
5	Missing any other reason
6	Sealant, varnish
7	Bridge abutment or special crown
8	Unerupted tooth
9	Excluded tooth

Sealant retention status was evaluated and noted on the data sheet by making use of the evaluation criteria for sealant retention as described by Frencken *et al.* (1998) (see Table 2).

Table 2: Evaluation criteria for sealant retention

SCORE	CRITERIA
0	Present, good seal
1	Present partly, visible pits and/ or fissures are free of active caries; no sealant needed
2	Present partly, visible pits and/ or fissures show signs of active caries; treatment is needed
3	Not present, pits and/ or fissures show no signs of (active) caries; no treatment is needed
4	Not present, pits and/ or fissures show signs of active caries; treatment is needed
9	Unable to diagnose

Caries absent: 0, 1, 3; caries present: 2, 4; retention: 0, 1, 2; no retention: 3, 4.

4.8 Establishing contacts

Access to the participants of the study was made initially by letter to the participating school principals and parents. English and Afrikaans versions of the letter were made available, as this is the two predominant languages in the area (Appendix 2). An introduction of the researcher, the basic aim and objectives of the study, what participating in the study would involve and how long the examination would take were explained. It was emphasized that strict confidentiality would be maintained at all times and that the results of the study would be presented in a manner that ensured anonymity. Once signed informed consent (Appendix 3) was received for each child, arrangements were made for the clinical examinations to be carried out at a time convenient to the participants and schools.

4.9 Standardisation and calibration

The objectives of the standardization and calibration exercises are to:

- Ensure uniform interpretation, understanding and application of the criteria for caries detection and sealant retention;
  Ensure that the examiner could examine consistently to a standard.

Prior to the clinical dental evaluations, the examiner was calibrated on a group of pre-selected children who possessed the same characteristics to be assessed in the main study in order to assess intra-examiner agreement. The kappa statistic was 0.9083 (Appendix 4).

4.10 Validity and reliability

The author was the only investigator involved in the gathering and interpretation of the data, thereby assuring the standardised recording of all the information presented. Re-examination of part of the sample was untenable due to serious time constraints. The researcher acknowledges that this could have impacted on the reliability and validity of the study data and has listed this as one of the limitations of this study.

4.11 Data collection

On the days of the examinations, children with signed, informed consent forms (Appendix 3) were examined in the school personnel room. The children had to brush their teeth before being examined. The examination was done by the examiner (who was not involved in the placement of the sealants) who whore a Heine II Surgical headlight for proper illumination and making use of a mouth mirror and dental probe. The examiner also used a mobile 3-in-1 air syringe for proper drying of the tooth surfaces. The children were seated on a fold-up dental chair.

For each child, the following data was recorded on the data capture sheet: Name, age, gender, caries status of the occlusal surface of the first permanent molar teeth and the sealant retention status where necessary.

4.12 Statistical analysis of data

The collected data from the dental examination and data capture sheets was recorded and captured on a Microsoft Excel spread sheet. While basic descriptive analysis was done by using the Microsoft Excel environment, further statistical analysis was done by Professor Stefan Maritz by making use of the statistical computing program called "R" (R Core Team, 2013). Several statistical tests were carried out to determine significant differences between different elements of the captured data. The level of significance was set at 0.05. The Relative Risk (RR) was computed using the Cochrane Software (version 5.2) program for absence and/or caries presence at the end of the observation period (12 months).

4.13 Ethical considerations

The protocol was submitted for ethical approval and approved by the University of the Western Cape Faculty and University Research Ethics Committee (Appendix 5). Informed consent was obtained from the principal of each participating school and the parents or guardians of the children involved. It was emphasized that strict confidentiality would be maintained at all times and that the parents or guardians could withdraw their child at any time without being penalized.

All grade 2 learners of the relevant schools received instructions on good oral health behaviour as well as a dental screening, toothpaste and a toothbrush. Children with further treatment needs were referred to the nearest clinic to have the necessary treatment done. They will all receive fissure sealants when they attend the dental clinic with their referral letters from the study.

4.14 Limitations

The researcher acknowledges that the sample size and lack of scientific sample size calculations, control group identification and the validity and reliability of the data collected (no re-examination of the target groups have been carried out due to time constraints) can all be seen as potential sources of bias in the present study.

CHAPTER 5

RESULTS

5.1 Response rate

356 Fissure sealants were placed on 100 children as part of a school-based fissure sealant programme during 2013. When the follow up examination was done 12 months later, 80 children had signed informed consent forms and were included in the study. A total number of 281 sealants were then re-examined. The response rate in terms of fissure sealants was therefore 78.9% and 80% in terms of the number of children.

5.2 Demography

When the sealants were placed in 2013, 52 of the children were female and 48 male. At the 12 month follow-up, 41 or 51.3% of the respondents were female and 39 or 48.8% were male (see Figure 1).

FIGURE 1: Demographic distribution of children according to gender

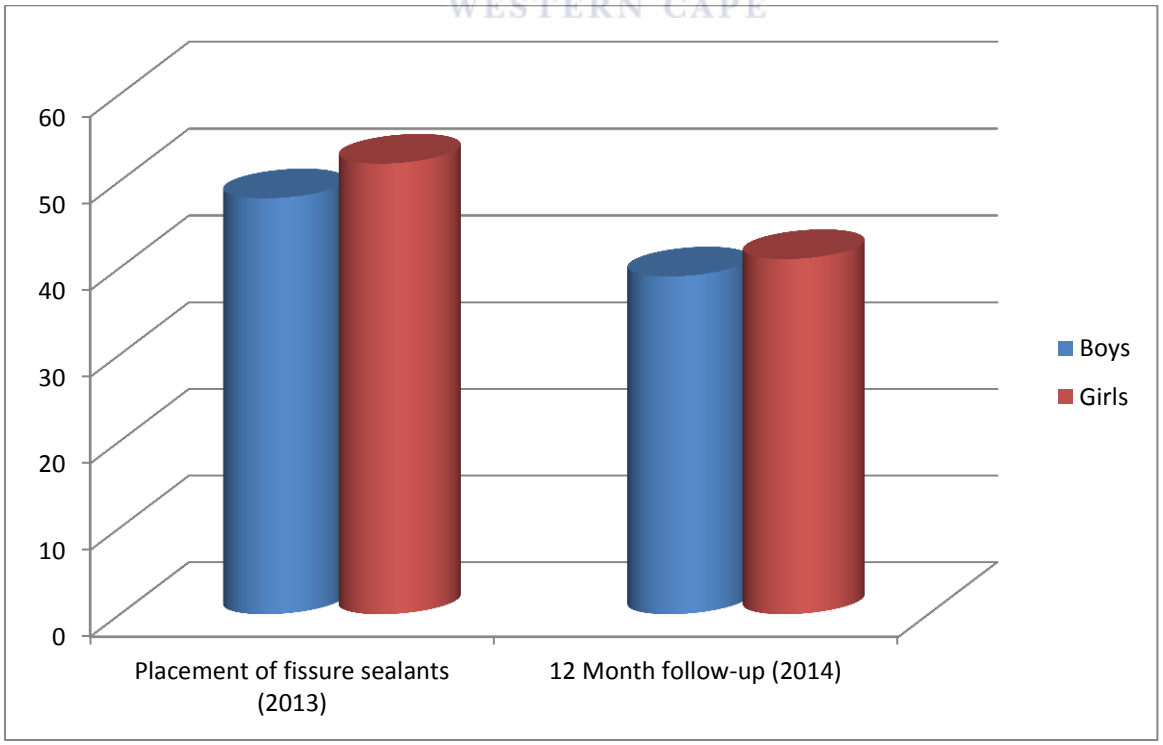


Table 3: Age statistics by gender at 12 month follow-up (in months)

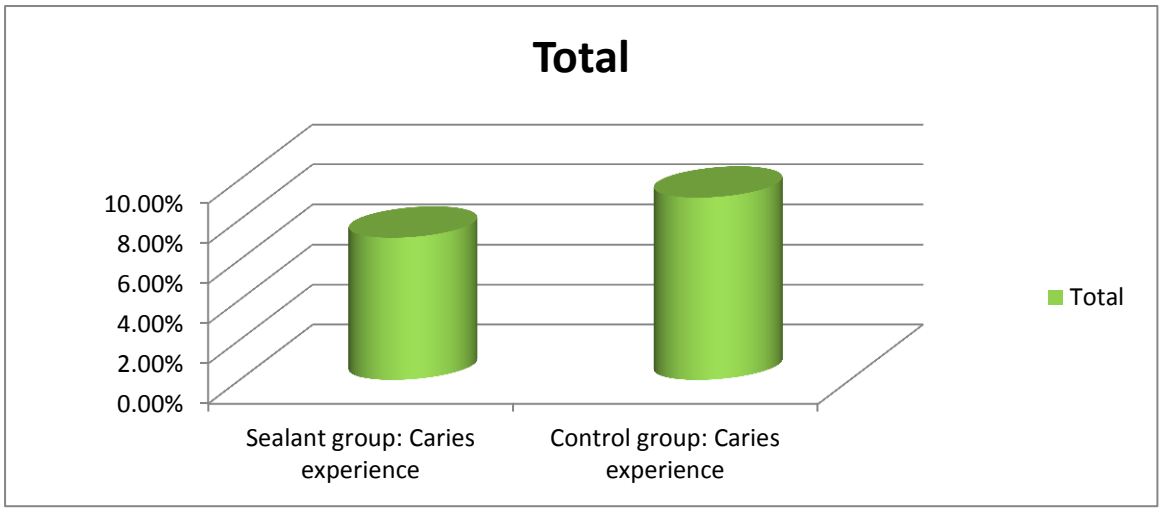
GENDER	NUMBER	MEAN	STD. DEVIATION	LOWER BOUNDARY OF 95% CONFIDENCE INTERVAL	UPPER BOUNDARY OF 95% CONFIDENCE INTERVAL
FEMALE	41	99.9	5.0	94	116
MALE	39	101.8	5.1	94	113

The average age of the female children was 8 years and 4 months (99.9 months) and 8 years and 5 months (101.8 months) for the males. The standard deviation of the gender profiles differ by 1 month only and therefore imply an equal distribution of age between female and male children. The 95% confidence interval is fairly wide (22 months for the female group and 19 months for the male group), on account of the relatively small sample size.

5.3 General caries experience at 12 month follow-up

Out of the 281 teeth that were sealed, 20 of them were classified as being carious at 12 month follow up (7.1%). From the control group, 29 out of the 320 teeth that were evaluated were classified as carious (9.1%). The association between caries incidence on sealed vs. unsealed teeth was found not to be significant (P=0.39).

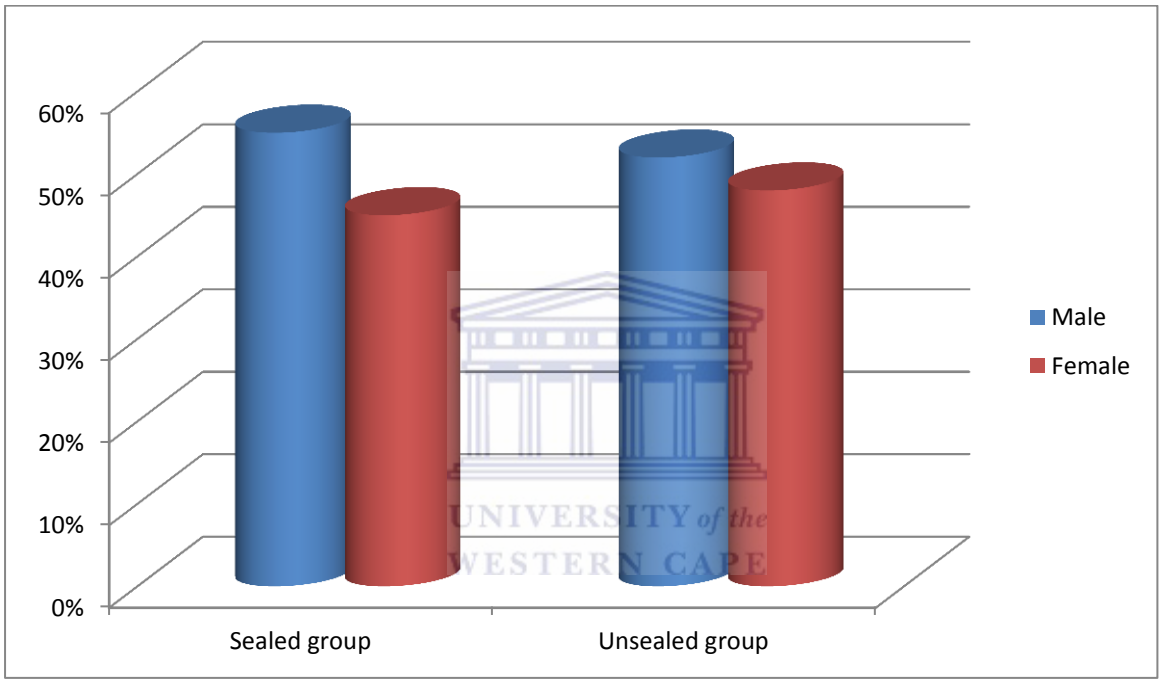
FIGURE 2: Caries experience at 12 month follow-up:



5.4 Caries incidence by gender

In the sealed group, 55% (11 out of 20) of the carious teeth were found in males and 45% (9 out of 20) in females. The unsealed group showed a rather similar pattern with 52% (15 out of the 29) of the carious teeth found in males and 48% (14 out of the 29) of the carious teeth to be found in females. The association between caries incidence in male versus female subjects was also not significant (P=0.6864).

Figure 3: Caries incidence by gender



5.5 Caries prevalence by tooth number

Tooth numbers 36 and 46 (mandibular molars) showed a greater number of carious lesions than tooth numbers 16 and 26 (maxillary molars) (Table 4). However, by pooling the results for tooth 36 and tooth 46, and then the results for tooth 16 and tooth 26, and by applying a paired t-test, the result turned out to be not statistically significant (P=0.159).

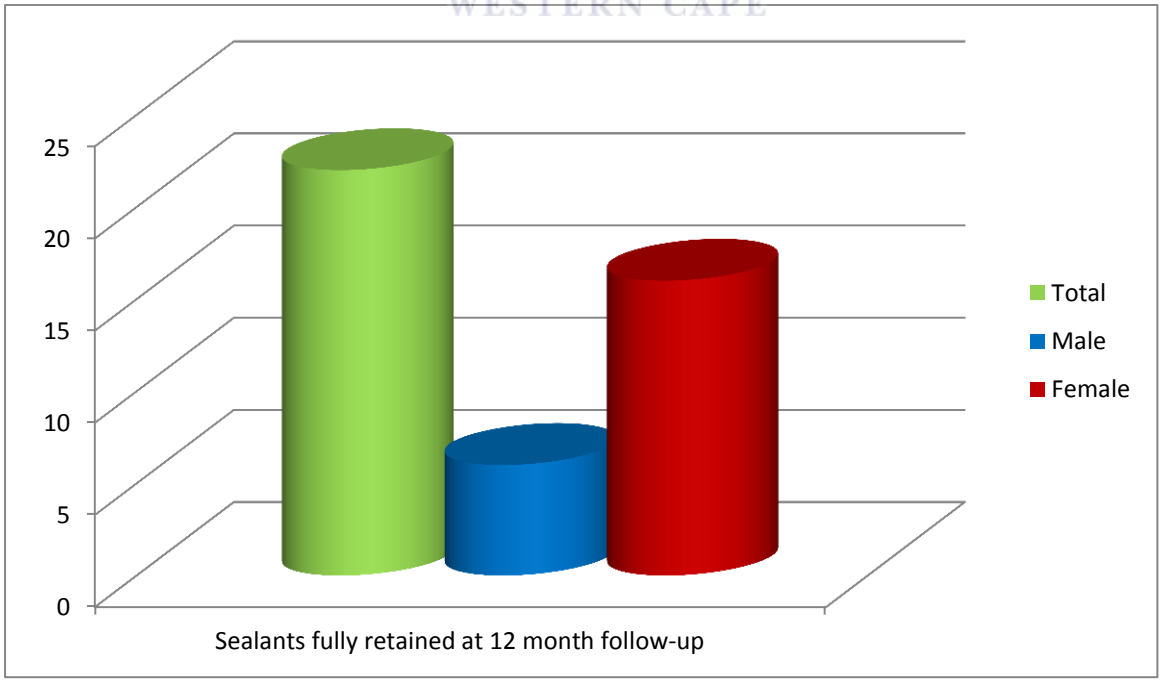
Table 4: Caries prevalence per tooth number at 12 month follow-up:

TOOTH NUMBER	PERCENTAGE CARIES
16	3.1
26	3.0
36	12.3
46	5.2

5.6 General sealant retention at 12 month follow-up

As far as sealant retention is concerned, only 22 (7.8%) of the 281 sealants that were placed were still fully intact at 12 month follow-up. This means that 256, or 91%, of the total amount of sealants placed were lost. Of the 22 sealants that were present at 12 month follow-up, 16 (73%) were in females and only 6 (27%) in the male group. 3 Of the 281 teeth that were sealed had already been extracted due to dental caries at the 12 month follow-up, all 3 belonging to the male group.

FIGURE 4: Sealant retention at 12 month follow-up according to gender



5.7 Sealant retention by tooth number

Sealant retention was also higher among tooth numbers 36 and 46 (mandibular molars) than among tooth numbers 16 and 26 (maxillary molars) (Table 5). However, by pooling the results for tooth 36 and tooth 46, and then the results for tooth 16 and tooth 26, and then applying a paired t-test , the results turned out to be significant (P=0.044).

Table 5: Sealant retention percentage per tooth number

TOOTH NUMBER	SEALANT RETENTION PERCENTAGE
16	4.7
26	4.5
36	11.0
46	10.4

TABLE 6: Contingency table displaying the 12 month follow-up results

No. of teeth		Caries		TOTAL
		Yes	No	
Fissure sealants	Yes	20	261	281
	No	29	291	320

TABLE 7: Fissure sealant versus no fissure sealant caries absence at 12 month follow-up

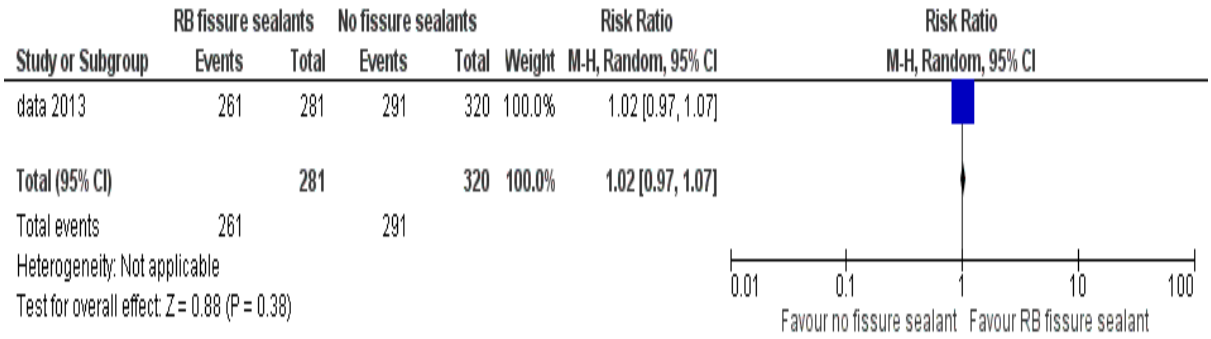
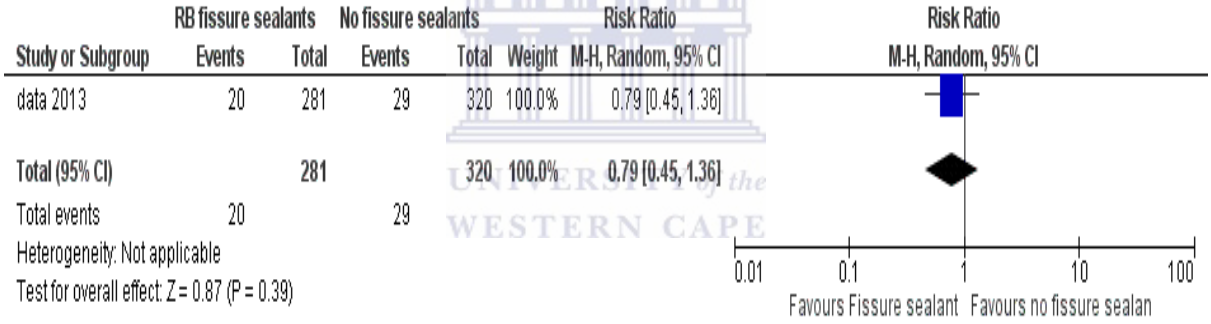


TABLE 8: Fissure sealant versus no fissure sealant caries present at 12 month follow-up



From tables 7 and 8 it is clear that for both outcomes (caries absence and caries present) there is no significance in both analyses (P=0.39). Although the respective risk ratios of 1.02 and 0.79 showed a slightly lower risk of developing dental caries in the sealed group, the general trend was not significant (P=0.39).

CHAPTER 6
DISCUSSION

6.1 Introduction

Fissure sealant use is an important strategy in the prevention of dental caries. They act as a physical barrier thereby preventing oral bacteria and dietary carbohydrates from aggregating within the deep pits and fissures on the occlusal surfaces of molar teeth. The physical barrier prevents the development of acidic conditions which result in dental caries (Nikiforuk, 1985). Nearly all carious lesions are found in the pits and fissures in the occlusal surface of posterior molar teeth (Beauchamp *et al.* 2008). Racial, ethnic and economic disparities have been identified as children who are most likely to benefit from the caries preventive effect of fissure sealants seem to be less likely to receive these interventions (Tomar & Reeves, 2009).

A 12 month follow-up of fissure sealants in the present study was relevant since the maximum loss of sealants usually occurs within the first 12 months after placement. Under normal conditions, sealant retention has been found to decrease annually by 5%-10% (Feigal, 1998). Clinical evidence suggests that sealant loss occurs in two ways. There is an initial loss due to faulty technique (such as moisture contamination), followed by a second form of loss associated with material wear under the forces of occlusion (Nikiforuk, 1985). Faulty technique may lead to earlier loss of sealants as opposed to occlusal wear (Dhar & Tandon, 2000). However, although sealant failures within the first 12 months can be attributed to a lack of proper isolation methods (Subramanium *et al.* 2008), a difference in diet, dental health awareness, and the use of indigenous oral hygiene practices could also be attributed to early loss of sealants (Dhar & Chen, 2012).

This chapter discusses the findings of the present study that sought to evaluate the caries preventive effect as well as sealant retention of a resin based fissure sealant that was placed as part of a school-based fissure sealant programme. What makes this study unique is the fact that the fissure sealants were placed under field conditions.

6.2 Response rate

In the present study, the response rate in terms of the number of children at 12 month follow-up was 80%. This also represented a response rate of 78.9% in terms of the number of fissure sealants at 12 month follow-up. The 12 month response rate in similar studies was high, as is evident by the 100% response rate recorded by Dhar & Chen (2012) as well as 89.2% recorded by Subramanium *et al.* (2008). The researcher acknowledges that ideally one would like to account for the exact numbers approached and those unavailable or declining. Although a response rate of 80% is still regarded as an acceptable outcome in epidemiological studies (Joubert & Ehrlich, 2007), the 20% loss to follow-up can be seen as a possible source of bias in the present study.

6.3 Sample size

In the evaluation of fissure sealant retention status and caries preventive effects the sample sizes differ greatly. While some studies worked with groups as small as 17 (Bhatia *et al.* 2012) and 25 (Dhar & Chen, 2012), Subramanium *et al.* (2008) worked with a sample size of 107 children. The sample size of 100 in the present study represent all the grade 1 learners who had 1 or more non-carious, fully erupted first permanent molar tooth/teeth at the time of sealant placement in 2013. This study is based on a programme that was already implemented. It was therefore not possible to perform study sample size calculations and the researcher also acknowledges this as a limitation to the study.

6.4 Age of fissure sealant placement

Fissure sealants are recommended to be placed as soon after eruption as proper isolation of the permanent molar teeth can be achieved. It is therefore contra-indicated to place fissure sealants on teeth that are not fully erupted. Fissure sealants are also recommended to be placed on children within 4 years after eruption (Azarpazhooh & Main, 2008b), but preferably within the first year after eruption (Lalloo & Turton, 2008). The first permanent molar teeth usually erupt between the ages of 6 and 7 years (ADA, 2006). Fissure sealants should therefore be placed on children aged between 6 to 8 years and 10 to 12 years, depending on when the teeth were fully erupted.

In the present study, the average age of the female children were 7 years and 4 months with a standard deviation of 5 months when the sealants were placed and 7 years and 5 months with standard deviation of 5.1 months for the male children. The sealants were placed on fully erupted and caries free teeth only and well within the recommended age group.

6.5 Caries preventive effect

As far as the development of caries is concerned, it is important to keep in mind that fissure sealants do not eliminate dental caries, but rather predictably reduce the onset thereof (Condò *et al.* 2013; Gooch *et al.* 2009). Because the fissure sealants in the present study were placed on caries-free teeth, all the cases of caries detected at 12 month follow-up were classified as "incidence" cases. Per definition, incidence cases imply the number of new cases developed during a specified time (MedlinePlus, 2015).

The present study showed a caries incidence rate of 7.1% in the sealed group. This was higher than the average of 2.5% as described by Condò *et al.* (2013) after 12 months. However, in the literature review of Condò *et al.* (2013), all the fissure sealants were placed in a clinic setting and not under field conditions as in the present study. The fact that a RB sealant was used in the present study, under conditions which is theoretically more favourable to GI sealants, could also have had an effect on the higher than expected caries incidence rate on the sealed teeth.

The caries incidence rate of the unsealed group in the present study was 9.1%. The present study therefore showed a 2% reduction in the 12 month incidence rate of dental caries between the sealed and unsealed groups. This reduction related to a risk ratio of 0.79, which indicates that the children who did receive fissure sealants were at a slightly lower risk of developing dental caries. However, there was no statistical significance between the sealed and unsealed groups with regard to caries prevalence at 12 month follow up (P=0.39). Reductions in the incidence rate of dental caries between sealed and unsealed teeth vary substantially throughout the literature. Condò *et al.* (2013) reported on variations in these reduction rates ranging from 40% to 6%. The reduction rate in the present study (2%) was outside this reported range. One explanation for this might again have been because of the fact that a RB sealant was placed under field conditions in a low resourced environment which was theoretically more suitable for GI sealants.

The low reduction rate in the present study therefore suggests that in suboptimal settings (i.e. under field conditions) RB sealants should be used with caution. However, if RB sealants are placed in such conditions, it is recommended that the four-handed technique should be applied and follow-up of the sealants be done.

6.6 Sealant retention rate

The present study showed that only 7.8% of the RB sealants were fully intact at the 12 month follow-up. Although this falls within the reported range of 2%-80% (Azarpazhooh & Main, 2008b), total retention rates of RB fissure sealants at 12 month follow-up is generally higher than 7.8%. Bhatia *et al.* (2012) reported on total retention rates of 17.6% and 23.5% while Dhar & Chen (2012) reported on a total retention rate of 24% for RB sealants at 12 month follow-up.

The total loss of sealants in the present study was high at 91%. Dhar & Chen (2012) reported that only 48% of the RB sealants showed a total loss at 12 month follow-up. This was similar to the 46% total loss reported by Subramanium *et al.* (2008). The high sealant loss in the present study might be attributed to saliva contamination, seeing that no mobile suction unit was available when the sealants were placed. This, together with the fact that a RB sealant material was used (hence a very technique sensitive material (Emmerling Munoz & Carver Silva, 2013)) could arguably have been the main reasons for this higher-than-normal sealant loss rate. Application technique and isolation of the operative field is critical in the determination of the clinical success of RB sealant retention rates (Condò *et al.* 2013). It is thus clear that in field conditions where less than ideal conditions exist, the choice of material is critical to the success of the fissure sealant programme. The very low retention rate at 12 months achieved with the RB sealant materials suggest that this is not an ideal material to use under these conditions especially when one considers that RB sealants are only protective whilst they remain bonded onto the tooth surface (Künish *et al.* 2012; Rock & Anderson, 1982), GIC sealants however, still offer a protective benefit in cases where they may be partially or totally lost (Lindemeyer, 2007; Pardi *et al.* 2003).

Yazici *et al.* (2006) analysed how a technique of preparing the surface enamel through acid-etching increases the value of total retention of a RB sealant to a year. In the present study, options for preparation of the surface enamel were limited because the sealants were placed under field conditions without the availability of a dental assistant and a water/air syringe. The operator tried to compensate for this by preparing the surface enamel with a self-etch adhesive system that does not require any rinsing. However, the use of adhesive systems, whether it be Total-Etch or Self-Etch, does not increase the value of total retention to 12 months for RB sealants (Condò *et al.* 2013).

The results of this study has shown that under field conditions, and among children, RB sealants appear to be not ideal in offering the caries protective effect needed as the retention rate after only 12 months was only 7.8%. When one takes into account the context (a young child), setting (under field conditions), follow-up (or lack thereof) and isolation challenges (saliva contamination) that is associated with a school based fissure sealant programme, there is a definite case to be made that oral health providers should at least be able to have the choice as to which material to use under such conditions.

6.7 Statistical significant result

The present study showed only one statistically significant finding. Although statistical analysis of the data showed that the percentage of retained sealants on the different tooth numbers (16, 26, 36 and 46) was low, it was however greater for tooth numbers 36 and 46 compared to tooth numbers 16 and 26. By pooling the results for teeth 36 and 46, and then the results for teeth 16 and 26, and applying a paired t-test, the difference in sealant retention for teeth 36 and 46 versus teeth 16 and 26 was statistically significant ($p=0.044$). In other words, teeth numbers 36 and 46 had a statistically significant higher percentage of retained sealants than teeth numbers 16 and 26. This was consistent with the finding of Morgan *et al.* (2005) and Deery *et al.* (2001) that higher success rates was demonstrated for fissure sealants placed on mandibular teeth and mesial sites, than on maxillary teeth and distal sites. Deery *et al.* (2001) furthermore argued that this might be due to direct vision, gravity flow of the resin, and generally well-defined pits and fissures in mandibular teeth. It is also noted that a longer follow-up period in the present study could have shown different results.

6.8 Limitations

This study is based on a programme that was already implemented before the onset of the study. The researcher was therefore unable to follow a scientific sampling process as all the grade 1 learners who received fissure sealants and had signed consent forms took part in the study. The study forms part of the Masters Degree in Dental Public Health from the University of the Western Cape and subsequently imposed a certain time frame to which the researcher had to adhere to. Resin based fissure sealants were the only ones available to the dentist at the time of fissure sealant placement and this resulted in a lack of a control group who received an alternative intervention (glass ionomer sealants). Time constraints that applied to the researcher also resulted in a lack of intra-examiner reliability and validity as re-examination of a part of the study population were not achieved. The researcher therefore acknowledges that the above-mentioned factors can all be interpreted as potential sources of bias in the present study.

CHAPTER 7

CONCLUSION

Although the risk ratio of 0.79 indicates a slightly lower risk of the sealed teeth for developing dental caries, the overall results from this study concluded that there was no statistical significance in caries incidence between the sealed and unsealed teeth (P=0.39).

Sealant loss was also higher than what is generally reported on in the literature. One therefore has to conclude that the placement of RB fissure sealants under sub-optimal conditions in the field appears not to be beneficial in reducing the incidence of dental caries.

RECOMMENDATION

These results have highlighted the need for proper material choice to be considered when fissure sealants are placed under field conditions. If the placement of sealants under field conditions occurs where no follow-up is being planned, there is no doubt that GI sealants must be considered. If a follow-up is being planned and sufficient resources are available to ensure proper saliva control, then the use of a RB sealant under field conditions can be considered.

The poor retention rates in the present study suggest that, under field conditions, a RB sealant may not be the appropriate material to use in a school based fissure sealant programme. It can similarly be used as motivation for local health authorities to ensure that both RB and GI sealant materials are available to oral health practitioners in the public sector. The availability of both these materials would then enable dentists and oral hygienists to play a crucial role in reducing the racial, ethnic and economic disparities that currently exist in oral health status and receipt of oral health preventive services (Tomar & Reeves, 2009).

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APPENDICES

Appendix 1: Data capture sheet

PROVINCIAL GOVERNMENT: WESTERN CAPE

ORAL HEALTH SURVEY FORM

[For 6 year old & 12 year old learners]

School Name	Pt. No.

NAME: Examiner No.	

CLINIC: Clinic Code	

Age	
Gender (1 = Female, 2 = Male)	
Grade	

Name	

Date of Examination						
	Y	Y	M	M	D	D

CARIES STATUS AND TREATMENT NEEDS

	18	17	16	55 15	54 14	53 13	52 12	51 11	61 21	62 22	63 23	64 24	65 25	26	27	28
Status																
Treatment																
Status																
Treatment																
	48	47	46	45 85	44 84	43 83	42 82	41 81	31 71	32 72	33 73	34 74	35 75	36	37	38

STATUS		
Permanent tooth		**Primary tooth**
0	Sound	A
1	Decayed	B
2	Filled & decayed	C
3	Filled, no decay	D
4	Missing due to caries	E
5	Missing any other reason	
6	Sealant, varnish	F
7	Bridge abutment or special crown	
8	Unerupted tooth	
9	Excluded tooth	

TREATMENT	
0	None
1	Caries arrest. or sealant care
2	1 Surface filling
3	2 or more surface filling
4	Crown or bridge abutment
5	Bridge element
6	Pulp care
7	Extraction
8	Need for other care
9	Specify .....

Fissure Status

If caries is present, indicate with an "x" if caries could have been prevented on that tooth by a fissure sealant

17	16	26	27
47	46	36	37

Fissure Sealant Retention Status	
0	Present, good seal
1	Present partly, fissures free of caries, no sealant needed
2	Present partly, fissures have active caries, treatment needed
3	Not Present, fissures free of caries, no sealant needed
4	Not Present, fissures have caries, treatment needed
9	Unable to diagnose

17	16	26	27
47	46	36	37

Appendix 2: Information sheet, in both English and Afrikaans

DEPARTMENT OF HEALTH

CENTRAL KAROO DISTRICT

DR. C.E. POTGIETER
B.Ch.D. (US); PDD (UWC)

t: 023 414 8200
e-mail: carl.potgieter@westerncape.gov.za

INFORMATION SHEET FOR PARENTS

TITLE OF STUDY: EVALUATION OF RESIN-BASED FISSURE SEALANTS PLACED UNDER FIELD CONDITIONS

By

DR CARL POTGIETER

Purpose of the Study. As part of the requirements for the M.Sc. (Master's) degree in Dental Public Health at the University of the Western Cape (UWC), I have to carry out a research study. The study is concerned with the high amount of rotten teeth in our primary school children and is looking at a way to try and reduce this high number of rotten teeth (also called dental caries).

What will the study involve? The study will involve the examination of valuation of the 4 teeth in your child's mouth that received fissure sealants 12 months ago.

Why have you been asked to take part? You have been asked because you are in the age group and school that has had fissure sealant treatment.

Do you have to take part? No. If you feel uncertain whether or not your child should participate, we will respect your decision. However, should you agree to let your child be part of this study and later on wish to withdraw your child, it is also in order as you can withdraw your child from this study at any time.

Will your participation in the study be kept confidential? YES. At no stage in the study will we use any names and no references will be made to you or your child.

What will happen to the results? The results will be presented in a thesis. No individual names will be mentioned. The thesis will be seen by my supervisor, an internal and an external examiner. The study may also be published in a scientific research journal.

What are the possible disadvantages of taking part? None, except that your child will be subjected to an oral examination using only a dental mouth mirror and probe at the school.

What if there is a problem? If any other dental problems are observed during the examination, your child will receive a referral letter to the nearest dental clinic to have the problem examined and managed.

Who has reviewed this study? The Faculty and University Research Ethics Committees.

DEPARTEMENT VAN GESONDHEID

SENTRAAL KAROO DISTRIK

DR. C.E. POTGIETER t: 023 414 8200
B.Ch.D. (US); PDD (UWC) e-mail: carl.potgieter@westerncape.gov.za

INLIGTING AAN OUERS

TITEL VAN STUDIE: EVALUASIE VAN 'N HARS-GEBASEERDE FISUURSEEL WAT ONER VELD KONDISIES GEPLAAS WAS.

Die studie word gedoen deur

DR CARL POTGIETER

Doel van die studie: As deel van die vereistes vir die M.Sc. (Meesters) grad in Publieke Mondgesondheid by die Universiteit van die Wes Kaap (UWK) moet ek a navorsingstudie onderneem. Die studie is gemoeid met die hoë vlakke van vrot tande onder ons laerskool leerlinge en word gedoen om 'n manier te vind om hierdie hoë vlakke te verlaag (vrot plekke op tande word ook tandkaries genoem).

Wat behels die studie: Die studie behels 'n evaluasie van die 4 tande in u kind se mond wat 12 maande tevore met die fisuurseel materiaal geseël was.

Hoekom word jy gevra om deel te neem aan die studie? Jy word gevra omdat jy in dieselfde ouderdomsgroep en skool is waar fisuursele geplaas was.

Moet jy deelneem aan die studie? Nee. Indien u onseker voel of u kind moet deelneem aan die studies al ons u gevoel ten volle respekteer. Indien u egter instem dat u kind mag deelneem aan die studie, maar later voel u wil eerder u kind onttrek, sal ons u besluit weereens respekteer sienende dat u u kind ter enige tyd van die studie mag onttrek, sonder enige gevolge.

Sal jou deelname aan die studie konfidensieel wees? JA. Die studie is nie gemoeid metdie name van die kinders nie. Daarom word hulle name glad nie in die studie gebruik nie en ook geen verwysing na spesifieke individue nie.

Wat word van die resultate van die studie? Die resultate gaan in ‘n tesis vervat word. Geen individue se name sal genoem word nie. Die tesis gaan deur my toesighouer (by die universiteit), ‘n interne en ‘n eksterne eksaminator gesien word. Die studie mag ook in ‘n wetenskaplike joernaal publiseer word.

Wat is die moontlike nadele om deel te neem aan die studie? Daar is geen. Al wat gaan gebeur is dat daar ‘n binnemondse ondersoek op u kind gedoen gaan word waardeur slegs ‘n mond spieeltjie en stomp punt instrument gebruik gaan word.

Appendix 3: Informed consent letter

UNIVERSITY OF THE WESTERN CAPE

FACULTY OF DENTISTRY

INFORMED CONSENT FOR ORAL EXAMINATION

May 2014

Dear Parent

I am a Master's student in the Department of Community Dentistry from the Faculty of Dentistry, University of the Western Cape. I am carrying out a study to look at how whether the sealants we placed in your child's mouth last year are still in place on the tooth. To do this I would need to examine your child's mouth and look at those teeth. We are doing this to see if there are ways in which we can improve the way we place these fillings and whether they have done their job in preventing tooth decay. In addition, we may also take photographs.

The procedure will take 5-10 minutes. There are no risks associated with this study and there should be no discomfort during the examination, and the child will not feel any pain. If we require photographs, we will take photographs of the teeth ONLY and no-one will be able to see your child's face on the photographs or recognise him or her. All information obtained will be strictly confidential.

You are completely free to allow your child to take part in the study. If you decide that you do not want your child to be part of the study, this will not be held against you or your child. If you would like your child to take part in the study, please sign the form below to allow us to proceed with the oral examination. If you would like to withdraw your child or the child would like to withdraw from the study at any point or for any reason, they are free to do so and no questions will be asked. If you have any questions or queries or would like more information about the study please contact me Dr Carl Potgieter on telephone number (021) 937 3148 ; fax (021) 931 2287; e-mail suenaidoo@uwc.ac.za or after hours on (021) 686 2720.

Yours sincerely

Dr Carl Potgieter

I have read the information sheet and I understand what is required of my child to participate in the study and I agree to allow my child to participate in this study.

Name: ....

(in block letters) (Signature)

Date: .....

Witness 1: . ……..

Witness 2: ……

Appendix 4: Kappa Statistic for Fissure Sealants

Kappa Statistic for Fissue Sealants

Pt No.	Gold Sound + Exam Sound (a)	Gold Sound + Exam Defective (b)	Gold Defective + Exam Sound (c)	Gold Defective + Exam Defective (d)	Total
Pt 1	2			2	4
Pt 2	3			1	4
Pt 3	1			3	4
Pt 4	4				4
Pt 5	4				4
Pt 6	4				4
Pt 7	4				4
Pt 8	4				4
Pt 9	3		1		4
Pt 10	4	0			4
Pt 11					0
Pt 12					0
Pt 13					0
Pt 14					0
Pt 15					0
Total	33	0	1	6	

Total Number of Teeth

Dentist no:		Gold Standard: Sound	Gold Standard: Defective	
1	Sound	33	1	34
	Defective	0	6	6
		33	7	40

Proportions

Dentist no:		Gold Standard: Sound	Gold Standard: Defective	
1	Sound	0.83	0.03	0.85
	Defective	0.00	0.15	0.15
		0.83	0.18	1.00

Observed	0.9750
Expected	0.7275
Kappa:	**0.9083**

Kappa	Agreement
>0.8	Good
0.6 - 0.8	Substantial
0.4 - 0.599	Moderate

Agreement between Gold Standard and Dentist 1 is Good

Certified by: _____

Dr RB Barrie

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Appendix 5: Ethics Approval

Date: 26th September 2014

For Attention: Dr Carl Potgieter
Department of Community Dentistry

Faculty of Dentistry

Tygerberg Campus

Dear Dr Potgieter

STUDY PROJECT: Evaluation of resin-based fissure sealants placed under field conditions

PROJECT REGISTRATION NUMBER: 14/8/13

ETHICS: Approved

At a meeting of the Senate Research Committee held on Friday 26th September 2014 the above-mentioned project was approved. This project is therefore now registered and you can proceed with the study. Please quote the above-mentioned project title and registration number in all further correspondence. Please carefully read the Standards and Guidance for Researchers below before carrying out your study.

Patients participating in a research project at the Tygerberg and Mitchells Plain Oral Health Centres will not be treated free of charge as the Provincial Administration of the Western Cape does not support research financially.

Due to the heavy workload auxiliary staff of the Oral Health Centres cannot offer assistance with research projects.

Yours sincerely

Professor Sudeshni Naidoo

Deputy Dean: Research