Success Rate of Prepared and Unprepared Sealants in Children with Low and Moderate-high Caries Risk

by

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Abstract

This retrospective study's aim was to examine the success rate of prepared and unprepared sealants at different ages of placement, and to determine if caries risk played a role in the sealants' success. Data was collected from 1,173 first molars subjects from a private pediatric dental clinic (Children's Dental World, Winnipeg, Manitoba). These were categorized based on initial treatment types (unprepared sealants (55%), prepared sealants (38%), and non-treated (7%)), and then further analyzed by their initial caries risk (low (27%) or moderate-high (73%)). Treatment failure and success were assessed at 12-months and 24-months post-treatment. Overall, in a 24-month period, both sealant methods were found to be highly successful with an overall average of 97% at 12-months and 93% at 24-months. The prepared sealants method statistically did not have significantly more failures (3.24% and 4.31%) than unprepared sealants (3.67% and 2.71%) at both recall periods. There were more failures for the sealants when placed at age 5, 6, and 7 years (5.54% and 5.88%) at 12-months and 24-months. Initial and change in caries risk status did not seem to have an impact on the overall success rate of sealants. The highest success rate for sealed molars was found when subjects consistently remained at low caries risk over the 24-month period (Group 1 97.60%) but it was found to be statistically insignificant. Overall, both sealant methods are highly successful in preventing occlusal caries on first permanent molars, regardless of caries risk.

Introduction

With major advancements in dental research in recent years, one would assume caries would soon become history. Despite the decline of caries prevalence in developed countries, occlusal caries still remain a major contributor of oral health problems in children and adolescents, comprising 80-90% of total caries[1-7].

Occlusal caries can easily develop on a newly erupted molar, where susceptible narrow, deep fissures facilitate the retention of bacteria, nutrients, and debris necessary for the development of decay[8-10]. Once carious decay is established on a tooth, the costly cycle of restorations and eminent tooth loss begins[11, 12]. Therefore, the most beneficial and cost effective way to treat caries is through prevention[3, 13-15]. A strict oral hygiene regime, topical and systemic fluoride, xylitol use, and diet counseling are only effective in preventing smooth-surface caries[1, 12, 13, 16-18]. Dental sealant is the only proven, successful preventive method that is able to penetrate into the deep pits and fissures of a molar to prevent occlusal caries from developing[17, 19-21].

Dental sealants have been proven to be highly effective since their introduction by Buoncore in 1955[1, 2, 12, 22-25]. Applying dental sealants is a minimally invasive procedure that does not require any removal of tooth structure or preparation[23, 26]. The main objective of the placement of sealants is to cover the pits and fissures, shielding them from bacteria and debris and thus preventing caries development[1, 8, 12, 20, 23]. This technique has

been well investigated over the last 70 years, but many practitioners still express doubts concerning their long-term effectiveness and durability[14, 26-29].

The original technique used acid etching and bonding of a high viscosity acrylic resin and did not involve the removal of any decay prior to sealant application[4, 8, 20, 23]. The main concern in relation to the effectiveness of unprepared sealants is their retention on the tooth surface. Studies have shown that retention decreases over time and is affected by many factors such as moisture control, choice of sealant material, and the use of a bonding agent[1, 4, 24, 26, 30-32]. The rationale to have good sealant retention is that complete or partial loss of the sealant re-exposes the susceptible occlusal area to caries development by creating a non-cleansable surface, thereby increasing microleakage and promoting decay[1, 2, 12, 33]. However, recent evidence showed that sealant loss did not increase the risk, as compared to teeth that had never been sealed[33-36]. Therefore, the necessity for absolute long-term retention is in question.

To increase retention and prevent caries progression in teeth with incipient decay, new sealant materials and techniques have been explored. There are several types of prepared sealants depending on the extent and depth of the cavity preparation[8, 24, 37]. Amongst these, Simonsen is the pioneer for the preventive resin restoration (PRR), or prepared sealant technique[8, 12, 20, 38]. Prepared sealant arose from the principle need to remove the diseased tooth structure prior to the placement of the restorative material since sealing over caries could lead to progression of decay under the restoration and eventual tooth loss[8, 12]. The major benefit of the procedure is the minimally invasive

removal of caries whilst preserving tooth-structure, and simultaneously offering preventive effects of a sealant[8, 10, 32, 39, 40]. However, recent studies have shown incipient caries removal to be unnecessary prior to sealant placement since the procedure can arrest their progression[22, 33, 41-43].

Both unprepared and prepared sealants have been proven to be effective in preventing occlusal caries and they are highly retentive over time, as indicated by many Cochrane reviews and meta-analyses[1, 2, 44]. Based on the procedure and results from in-vitro studies[39, 45-47], prepared sealants, theoretically, should have better retention and success when compared to unprepared sealants because of the increased bonding surface and better penetration of sealant material into the fissure after mechanical preparation. One would also assume prepared sealants in high-caries risk patients should be highly beneficial in preventing occlusal caries due to the proposed higher level of retention. The few studies that have investigated the efficacy of unprepared sealants in patients with high- versus low- caries risks have had contradictory results[11, 25, 48-50], but there are fewer studies that investigate the success rate of prepared sealants in preventing occlusal caries in high caries risk populations[37, 51]. Therefore, it is important to design and carry out a study to address the clinical efficacy of unprepared sealants compared to prepared sealants in preventing occlusal caries in children with increased caries risk.

Literature Review

Occlusal Caries Development

With major advancements in preventive dentistry in recent years, one would assume caries would soon become history. While the introduction of fluoridation greatly decreased the number of smooth and proximal surface caries, occlusal pits and fissure caries did not show this trend[6, 18]. Occlusal caries still remain a major contributor of oral health problems in children and adolescents, comprising 80 to 90 percent of total caries[1-7]. The majority of these are found in the pits and fissure surfaces of the first and second permanent molars[3, 52].

Occlusal caries can easily develop in a newly erupted molar where susceptible fissure anatomy facilitates the retention of bacteria, nutrients, and debris necessary for decay to develop[8-10]. In addition, current knowledge on occlusal caries initiation on young permanent molars indicates that the tooth's functional usage also plays a role in plaque accumulation, in addition to the susceptible fissure anatomy[9, 10]. Plaque can easily accumulate on the cuspal inclines and deep fissures of the occlusal surface of a newly erupting molar that lacks mechanical cleansing from chewing, and the caries progression has been shown to decrease once the tooth is in functional occlusion[9]. Therefore, children around the ages of 5 to 7 years, with erupting molars are at an increased risk of occlusal caries.

For the erupted tooth, further compounding the problem of regular plaque retention is the inaccessibility of the narrow fissure to saliva and toothbrush bristle necessary for mechanical plaque removal[8, 10]. The thin enamel at the base of the fissure and close proximity to dentin allows for easy caries development and dentinal penetration[8, 10]. Ultimately, the more plaque and debris that is retained on the occlusal surface of the tooth, the higher the chance of caries development. Regardless, once carious decay is established on a tooth, the costly cycle of restorations and eminent tooth loss begins[11, 12]. Therefore, the most cost effective way to treat any caries is through prevention[3, 15, 29].

Management of Occlusal Caries: true means of prevention

Prevention is the most important step in caries disease management[16, 53]. A strict oral hygiene regime, fluoride supplementation, topical fluoride application, water fluoridation, xylitol use, and diet counseling are all evidence-based methods to help prevent caries[1, 12, 16-18, 54, 55]. Unfortunately, due to the etiology of occlusal caries, this standard caries prevention regime is not sufficient to prevent caries that will manifest in the deep fissures where cleansing and penetration of preventive agent is insufficient[2, 3].

Dental sealant application is an effective evidence-based means of preventing occlusal caries from initiation and/or progression within the fissures and pits [1, 5, 17, 19-21]. Dental sealant involves bonding a high-viscosity resin on the caries-free occlusal surface that does not require any removal of tooth structure or local anesthesia[23]. A Cochrane review found that dental sealants on permanent molars reduced caries up to 48 months when compared to having no sealants[1]. Another review found that sealants reduced the

incidence of caries by 85 percent after the first year of placement, and 57 percent at 48 to 54 months post-treatment[2]. This technique was extensively researched and updated over the last 70 years and evolved over time to also treat teeth with minor caries, giving rise to the prepared and unprepared dental sealant categories[12, 20].

Unprepared Dental Sealants

Unprepared dental sealant is a minimally invasive restorative procedure on caries-free molars that did not require any removal of tooth structure or local anesthesia[23]. The main objective of the placement of any sealants is to cover the non-cleansible pits and fissure anatomy, shielding them from bacteria and debris, thus preventing caries development[1, 23]. The original technique used acid etching and bonding of a high viscosity resin material without any mechanical preparation[8, 12]. Several systematic reviews and meta-analyses throughout the years have indicated that unprepared sealants are effective in preventing the initiation and progression of dental caries[1, 2, 5, 25, 44]. As shown in one meta-analysis, the overall long-term effectiveness of autopolymerised fissure sealants in preventing dental decay was 71% [44]. Numerous well-designed clinical studies on the long-term retention of sealants showed that with appropriate recall and maintenance, there is a high success rate of up to 80 to 90 percent after 10 or more years[38, 40, 56].

Since the effects of sealants are experienced by covering of the pits and fissures, one would assume that the loss of sealant material would re-expose the tooth to the risk of occlusal caries. Investigation on how to maximize retention of sealants on a tooth brought on a new onslaught of studies addressing this concern. There are several factors that can

contribute to retention[57], 1. sealant material, 2. moisture isolation, 3. use of bonding agent, and 4. removal of debris prior to placement.

Sealant Material:

The use of resin-based and glass ionomer-based sealants have been extensively researched by multiple systematic reviews and clinical trials[22, 26, 58-62]. Based on numerous Cochrane reviews by Ahovuo et al. [1, 2], and many meta-analyses and clinical studies, it has been demonstrated that resin-based sealant material provides better long-term retention rates than glass ionomer-based sealants[10, 19, 30, 63]. The current recommendations from the American Academy of Pediatric Dentistry (AAPD) advocate resin-based sealant material as the first choice for all permanent molars[64]. However, with lower long-term retention rates, the use of glass ionomer-based sealants have been suggested to be used as an "interim or transitional" sealant when resin-based sealants cannot be placed due to compromised moisture control[5, 58, 64]. This can be particularly useful in erupting molars where caries risk is high and resin sealant placement is not possible due to moisture contamination.

Moisture Isolation:

According to the systematic review by Muller-Bolla et al. [31], rubberdam isolation of the tooth is an important aspect of the success of light-cured resin sealant placement. Techniques to achieve moisture control other than the use of rubberdam have been investigated over the years[12, 65]. A systematic review showed that cotton-roll isolation

was the most common technique utilized when placing light cured resin-based sealants[31]. Other systems that have proven to be effective are Isolite™ and VacuEjector™ [66, 67]. Although an additional material expense, these systems ensure moisture control and efficiency while reducing procedure time[66, 67]. The most cost-effective and convenient way to isolate and obtain high retention rates is the use of the four-handed technique[65]. AAPD currently advises the placement of resin-based sealants in a moisture-controlled environment aided by rubberdam or the four-handed technique[64].

Use of Bonding Agent:

Resin-based sealant placement requires a bonding agent to ensure retention and decrease microleakage[68-71]. Many studies have explored the significant effects of different bonding systems on retention rates[68, 69, 72, 73]. Feigal et al.[74] suggested the use of ethanol or acetone-based primer-bond system over the two-bottle system or water-based primers for increasing retention of dental sealants. A recent randomized clinical trial reaffirmed the higher sealant retention success with the use of ethanol-based single bottle bonding agent[70]. The trade-off for using a bonding system to increase retention is the cost of time and material expense for this extra step before sealant placement. Several systematic reviews and trial studies investigate sealant retention with the self-etch bonding system such as L-Pop Prompt™ [68, 74] to eliminate this extra step. While some studies found that self-etch bonding agents may not provide the same level of retention as the total etch technique[68, 70], others have found similar retention rates of the self-etch system compared to the total-etch group[4]. The AAPD 2014 Guideline on Restorative Dentistry recommends

the use of a "low-viscosity hydrophilic material bonding layer as part of or under the actual sealant" for better long-term retention and effectiveness[64].

Prophylaxis and Mechanical Enameloplasty:

The original concept of mechanical tooth debridement began around 1983 when studies showed an increase of sealant retention following mechanical preparation using a #1 slow-speed round bur to remove plaque, organic debris and surface enamel from the fissure prior to the total-etch sealant technique[40, 75, 76]. This technique, coined "enameloplasty", gave rise to the concept of prepared sealant[8]. The higher retention success can be contributed to minute widening and deepening of the fissure anatomy along with the removal of debris resulting in an increased penetration of etchant, bond, and sealant material[45]. There is also an increase in sealant thickness (due to the removal of enamel surface), which counteracts loss and wear[39, 45-47, 76]. However, many recent studies showed that mechanical preparation to the enamel has no impact on the fissure penetrability, microleakage, or retention of sealants[5, 35, 63, 75, 77, 78]. In addition, partial or complete loss of sealant did not increase a tooth's caries risk. Current literature and the AAPD no longer support enameloplasty and even suggest that the physical removal of tooth structure may instead lead to an increased caries risk if sealant were lost[11, 63, 64].

Cleaning the tooth surface from plaque and debris would improve the adherence of the resin and bond material on the tooth. The general removal of plaque and debris prior to sealant placement can be done through air-abrasion, toothbrush prophylaxis, or hand-piece prophylaxis[26]. Toothbrush prophylaxis is more educational, but time-consuming

and less preferred than handpiece prophylaxis. However, it does not remove any enamel structure. According to systematic reviews, toothbrush prophylaxis yields equivalent or higher success than hand-piece prophylaxis[31, 33, 79]. The AAPD changed its recommendation of limited enameloplasty[57] to no mechanical preparation in its 2014 guideline[64].

Other factors that affect retention:

Other significant factors that affect the retention of sealants include patient's behaviour, operator variables, enamel alteration, age of patient, time of placement, and arch[27, 67, 69, 70]. Dentist often defer sealants treatment based on the clinical intuition that a patient of a certain young age or poor behaviour would decrease sealant's retention if they were placed[69]. Patient behaviour has a definite impact on sealants placement and effective isolation, and there are no studies to date that look at how behaviour and saliva control affect sealant success[69, 70]. Enamel alteration, such as hypoplasia, can affect the adhesion of the sealant material[80]. Depending on the eruption stage and location of sealant on the molars, such as the distal-lingual groove of the maxillary molar, isolation can be difficult, hence affecting retention [52, 69, 70]. The manner of the patient occlusion also affects the wear and retention the sealant[70].

Prepared Sealants: preventive resin restorations

Prepared sealants, also known as preventive resin restorations (PRR), arose from an amalgamation of the goals of resin-adhesive technology, arresting active caries, and

minimally invasive treatment[8, 12, 20, 26]. In the 1970's, dental sealants were introduced for teeth without caries lesions, while the preventive resin restorative technique was being developed as a result of the need to remove minimal amounts of diseased tooth structure and restore the tooth without extending into a class-1 cavity preparation[12, 32]. Although similar to a sealant with enameloplasty, the major differences for preventive resin restoration are the removal of caries, the need to etch-bond, and placement of a composite or flowable resin instead of the sealant material[12, 32].

According to Simonsen[8], there are three types of PRR preparation, depending on the extent and depth of the cavity preparation. A Type 1 PRR preparation uses air abrasion or a small round bur to remove superficial amounts of enamel before placement of sealant[20]. A Type 2 PRR preparation involves cutting deeper into the enamel and restoration with a flowable resin material with a bonding agent. A type 3 PRR preparation involves restoration with composite resin for structural restoration, and topped with flowable resin to seal the pits and fissures[8]. Type 1 PRR is indistinguishable from the conventional sealant with enameloplasty, and most Type 1 PRRs are classified as unprepared sealants[8]. While there are many studies on unprepared sealants, prepared sealants have not been as widely investigated[24, 26, 32, 37, 81]. The major benefit of this procedure is that it allows minimal caries removal whilst preserving sound tooth-structure, increasing retention, decreasing microleakage, and simultaneously offering preventive effects of an unprepared sealant[8, 20, 32, 45].

Results from recent studies have shown opposing evidence to the prepared sealant therapy. Mertz-Fairhurst et al.[42] found a good level of success for teeth that had have resin sealant covering occlusal caries for over 9 years. Increasingly, sealants are now being place directly over incipient caries to prevent caries progression[33, 82]. Oong et al.[43] showed a 71.8% decrease in the number of viable bacteria within the lesion following sealant application, due to decreased access to nutrients from the oral environment. Furthermore, numerous studies have shown an arrest of the progression of dental lesion with application of sealants alone[4, 22, 41, 42], leading some to question the necessity of caries removal prior to sealant placement. The AAPD guidelines currently support sealing of non-cavitated enamel lesions based on this long-term evidence[64].

Regardless of the numerous studies showing caries arrest, the ultimate question of possible lesion reactivation remains since the 'seal' of any restoration cannot be certain forever[10, 49]. The decision as to sealing or removing incipient caries should be based on whether the lesion resides in the enamel or dentin, as suggested by Simonsen[20]. Simonsen also recommended designing long-term clinical studies to elucidate this debate.

Caries Risk Assessment and Management

Dental sealants were extensively studied since their introduction, and are critical components in a caries management regime[16, 53]. The American Academy of Pediatric Dentistry currently advocates individualized caries management protocols and treatment plans based on the patients' specific caries risk levels, age, and compliance with preventive strategies[13, 50, 58, 64, 83]. There are many predictors for caries risk, as well as studies that

attempt to determine the clinical indicators for sealant placement as it relates to caries risk[10, 21, 48, 59]. However, the best predictor of future caries is still past caries experience[53, 84-86]. Raadal et al. found a strong correlation between primary molar caries history and fissure caries in the first permanent molar[87]. Due to the previously mentioned higher caries risk in newly erupted molars, placement of sealant is recommended on teeth shortly after erupting into occlusion, around age 5 to 7 years, to maximize preventive effects and cost savings[9]. However, caries risk assessment is a continuous process and patients should be assessed for sealants-based caries risk and needs with time[5, 19, 53, 64, 83]. Furthermore, current AAPD recommendations are to place sealants in all permanent molars with deep fissure anatomy or developmental defects that are at risk for the development of caries[53, 58, 64].

Current Evidence that Investigates Sealants with Caries Risk Considerations

Both unprepared and prepared sealants have proven to be effective in preventing occlusal caries[1, 26, 40]. Based on the evidence of success, one must assume that any sealants in high caries risk patients should be highly beneficial in preventing occlusal caries. Few studies have investigated the efficacy of unprepared sealants in patients with high versus low caries risk, with contradictory results[11, 21, 25, 48-50, 57]. Moreover, there are fewer quality studies that look at the success rate of prepared sealants in preventing occlusal caries in higher caries risk populations[25, 37, 51]. For this reason, it would be important to design a study that addresses the clinical efficacy of unprepared sealants compared to prepared sealants in preventing occlusal caries in children with increased caries risk.

Objectives

The objectives of this study were as follows:

1. To assess success rate of sealants at ages 5, 6, 7, 8, 9, and 10.
2. To assess whether the 2 types of sealant methods have different success rates when placed at different ages, between 5, 6, 7, 8, 9, and 10 years.
3. To assess whether initial caries history has an effect on the success rate of the two methods of sealant techniques in preventing occlusal caries within a 2-year period.
4. To assess whether the change in caries risk from initial placement to 2 years post-treatment has any effect on the success rate at the end of the study.

Hypothesis

The null hypothesis is that there is no difference in success rates between prepared and unprepared sealants in preventing occlusal caries in first permanent molars regardless of initial caries risk or age of treatment. The alternative hypothesis is that low initial caries risk will increase the success rate of both methods. It was also expected that the prepared sealants would be a more successful method in preventing occlusal caries when compared to unprepared sealants, regardless of risk factors and age.

Materials and Methods

The study proposal was submitted to the University of Manitoba's Research Ethics Board (REB) where it was reviewed, and approved on January 14, 2014, for retrospective data review (Ethics #:HS17017).

Sample Selection

The patients selected for this retrospective study were identified by analyzing dental records of children who had received unprepared and/or prepared sealant treatments at a private pediatric specialty dental clinic (Children's Dental World - CDW) in Winnipeg, Manitoba. Originally, patients were also going to be selected from the University of Manitoba Graduate Pediatric Dental Clinic (Winnipeg, MB), but the clinic did not have a sufficient number of patients who had completed treatment and attended a minimum of 24 months of follow-up appointments. Approximately 5,000 patient records with prepared and unprepared sealants placed from the years 2009 to 2014 were selected from the computer data-based Dentrix™, however, the computer program cannot separate the data based on treatment age or on which tooth treatment was performed. In order to select a sufficient amount of data for each age group the investigators wanted to examine, the principle investigator performed a manual initial screening of all charts with both sealant treatments to exclude all that did not meet the inclusion criteria.

The inclusion criteria consisted of patients who:

1. received treatment on erupted first permanent first molars treated with the prepared or unprepared sealant technique;
2. were between 5 and 10 years of age at the time of treatment;
3. had no previous restorations on the permanent molar teeth prior to treatment;
4. returned for at least 2 yearly recall appointments after their initial treatment.

The exclusion criteria consisted of patients who:

1. had pre-existing enamel or dental defects;
2. had banded molars;
3. had insufficient data (patient with inadequate dental records 2 years prior to treatment);
4. had insufficient follow-up (patients who did not return for 2 yearly recall appointments after sealant treatment was initiated);
5. had special health care needs.

After the initial screening, the patients were categorized into one of eight groups based on treatment age (5, 6, 7, 8, 9, and 10 years) and treatment type (unprepared and prepared sealants). Each age included up to 11 months and 30-31 days of the respective patient's age. This age range was choosen because it is the period when a permanent first molar tooth would be most susceptible to occlusal caries up to 4 years following eruption of the tooth. Ages 5 and 6 years were combined into one group as this is the age when permanent first molars erupt. Ages 9 and 10 were combined into a single group because this age respresents up to 4 years following the eruption of the first permanent molar. Ages 7 and 8

were not combined as they represent the two or three years following the eruption of the first permanent molars. For each group of ages 5/6, 7, 8, and 9/10 years, required data was collected on a data-collecting sheet (Appendix A) by selecting every third patient from the list that had been arranged in alphabetical order by age. If the tooth or subject sample was not eligible, the next patient on the list was selected. Due to the number of treated patients aged 9 and 10 years, all subjects were included in the sample for that age group. This process was repeated until the desired sample size was reached. Each subject was assigned a unique identifier to protect the patient's identity. The list of patient identifiers with their corresponding study number was recorded into a Microsoft Excel data file and stored on the secured data server in order to protect the privacy of each patient.

Determination of Sample Size

An initial power analysis was performed by the statistician to acquire an estimate of the number of subjects required for this study. Based on a generous estimation, the minimum requirement needed to identify a significant difference was 145 unique subjects in each group. After the initial screening, only 645 patients met the inclusion criteria. A decision was made to use individual tooth as subject for the study in an attempt to meet the desired sample size. After initial data analysis, we question if the size of our sample pool is large enough to generate results for adequate statistically analysis. For this reason, we increased the sample size, however the differences between the different treatment groups remained to be very small. Overall, the obtained data from this study was sufficient for an exploratory analysis that provided answers to the clinically significant questions.

Recall Assessment

After the initial demographic and treatment information was collected, information on the status of the treated or untreated teeth was recorded at two points in time. The first point in time was the recall appointment at 12-months post-treatment, and the second point in time was the recall appointment at 24-months post-treatment. The status of the treated or untreated tooth was assessed and recorded as follows:

- *No retreatment required (2)* – sealed teeth that are intact. This was considered to be a successful treatment outcome.
- *Need retreatment (3, 4, 5)* – these teeth required either monitoring of sealant due to marginal leakage such as staining (3), partial/complete sealant loss that required re-sealing (4), or placement of a class 1 restoration due to occlusal caries (5). This was considered to be failure of treatment.
- *No initial treatment (0)* – teeth that did not receive any restorative treatment and continued to remain untreated.
- *Requiring treatment (1)* - sealant or restoration was placed on teeth that were not initially treated.

In addition, investigators also collected information on patients' caries status at each recall by determining whether the patients acquired caries in teeth other than the permanent molars. If so, their caries risk status at the recall period changed. Treated teeth that received any retreatment (3, 4, 5) or untreated teeth that required treatment (1) at the 12-month recall were not followed any further for the 24-month follow-up; hence, these

teeth were removed from the 24-month follow-up count. Any teeth that acquired interproximal caries at any time were also excluded.

Selection Criteria for Treatment Success or Failure

In this study, sealant success was defined as when the sealant remained on the tooth intact and without signs of marginal leakage, full or partial loss of sealant, or occlusal caries. Sealant failure was defined by the presence of occlusal caries that required a class 1 restoration after initial sealant placement or failure of sealants that might/might not have required a retreatment. Teeth that acquired interproximal caries on the treated tooth after initial treatment were excluded from the study. Standard radiographic and clinical diagnostic criteria were used to detect interproximal caries at follow-up appointments.

Selection Criteria for Categorizing Caries Risk

To be categorized as low caries risk (1) in this study, patients must have been caries-free a minimum of 24 months prior to initial treatment. Patients with caries history within 24 months were classified as having moderate-to-high caries risk (2). We grouped moderate and high caries risk patients to compare any increased caries risk with low caries risk patients and the effects it may have on the treatment outcome. Patients who acquired caries on teeth other than the tooth treated after initial prepared or unprepared sealant placement were re-classified as increased risk. Patients who had increased caries risk and did not present with caries for 24 months were reclassified as low caries risk.

Standardized Protocols for Unprepared and Prepared Sealant Placement

For unprepared sealant placement: Sealants were placed on first permanent molars with deep pits and fissures and no incipient caries. Unprepared sealants were placed with very little or no mechanical preparation on the tooth, followed by acid etching (Etch-Rite™ 38% phosphoric acid gel, Pulpdent), placement of a bonding agent (Heliobond™, Ivoclar Vivadent), and placement of sealant material (Clinipro Sealant, 3M ESPE). Rubberdam or 4-handed cotton roll moisture isolation was used.

For prepared sealant placement: Prepared sealants were placed on first permanent molars with stained deep pits and fissures, and/or incipient decay. Prepared sealant placement required minimal tooth preparation to remove incipient decay and/or discoloration, acid etching (Etch-Rite™ 38% phosphoric acid gel, Pulpdent), placement of bonding agent (Heliobond™, Ivoclar Vivadent), and placement of a flowable resin material (Revolution Formula 2 Flowable Light Cure Composite, Kerr). Rubberdam or 4-handed cotton roll moisture isolation was used.

Restorative materials used: The restorative materials used for the prepared and unprepared sealants was the same, and consistent within the private practice clinic since 2009.

Multiple operators: Although different operators placed the unprepared and prepared sealants at the site investigated, they had been using the same methodology for sealants and examination since joining the dental practice. Therefore, having multiple operators in this study would have had minimal impact on the outcomes.

Statistical Analysis

The principle investigator used Microsoft Excel to performed data entry and initial distribution analysis. For all statistical analyses, a p-value of 0.05 or 0.10 and a 95% confidence interval were used. A statistician from the University of Manitoba Biostatics Unit performed the statistical analysis using SPSS 20.0 for Windows. Since the sample collected consisted of multiple subjects/teeth from the same patients, it was important that the statistical model take this potential inter-subject correlation into account. In order to model the probability of failure as a function of treatment while taking into account this potential within-subject correlation, the generalized estimating equations approach (GEE) was used to test whether the difference in failure rates between the two treatment methods was of statistical significance. The investigators also used the Fisher's Exact Test as a more conventional, simpler method to test for significance between the groups when looking at whether change in initial caries risk had any effect on treatment failure. The investigators chose to ignore the inter-subject correlation in favour of testing for significance in this set of data.

Results

General Sample Distribution

A total of 1,173 teeth from 317 unique subjects were sampled (Table 1). This sample was distributed between four age groups; ages 5 and 6 (26.60%), age 7 (28.99), age 8 (24.38) and ages 9 and 10 (20.03%). Generally, the total sample was also evenly distributed between males (50.64%) and females (49.36%), as well as within the age groups (Table 1).

TABLE 1 Distribution of Sample

	Age 5/6	Age 7	Age 8	Age 9/10	Total
Total # teeth	312 (26.60%)	340 (28.99%)	286 (24.38%)	235 (20.03%)	1173
Female	181 (58.01%)	151 (44.41%)	153 (53.50%)	109 (46.38%)	594 (50.64%)
Male	131 (41.99%)	189 (55.59%)	133 (46.50%)	126 (53.62%)	579 (49.36%)

Distribution of Initial Treatment and Caries Risk

Samples from ages 9 and 10 were combined because there were not as many prepared or unprepared sealant treatments performed in these age groups. Samples from ages 5 and 6 were combined to give a better picture of prepared and unprepared sealants placed when the tooth was beginning to erupt. Since eruption of the permanent molars can vary between the ages of 5 and 6, they were randomly sampled and combined into one

group to achieve appropriate sample size. The majority of the prepared and unprepared sealants were placed by ages 7 and 8.

TABLE 2a Distribution of Initial Treatment and Caries Risk in the Sample

	Age 5/6	Age 7	Age 8	Age 9/10	Total
Initial Treatments					
total prepared sealants	149 (47.76%)	172 (50.59%)	174 (60.84%)	154 (65.53%)	649 (55.33%)
total unprepared sealants	140 (44.87%)	139 (40.88%)	101 (35.31%)	62 (26.38%)	442 (37.68%)
total with no treatment	23 (7.37%)	29 (8.53%)	11 (3.85%)	19 (8.09%)	82 (6.99%)
Initial Caries Risk					
Mod/High Risk	255 (81.73%)	259 (76.18%)	198 (69.23%)	148 (62.98%)	860 (73.32%)
Low Risk	57 (18.27%)	81 (23.82%)	88 (30.77%)	87 (37.02%)	313 (26.68%)

Of these subjects, 55.33% of first permanent molars received prepared sealants, 37.68% received unprepared sealants, and 6.99% did not receive any treatment because they were not deemed to be necessary at the time (Table 2a). Looking at Table 2a, the proportion of teeth receiving prepared sealants seemed to have increased with age; the number of prepared sealants increased from 47.76% at ages 5 and 6 to 65.53% at ages 9 and 10 (Table 2a). Meanwhile, the proportion of teeth receiving unprepared sealants

seemed to have decreased with age; the number of unprepared sealants decreased from 44.87% at ages 5 and 6 to 26.38% at ages 9 and 10 (Table 2a). The proportion of teeth receiving no treatment was relatively similar between each age group (Table 2a).

TABLE 2b Distribution of Initial Treatment and Caries Risk in the Sample

		age 5/6	age 7	age 8	age 9/10	Total
Initial tx	mod-high initial caries risk					
	Prepared Sealant	135 (43.27%)	120 (35.29%)	122 (42.66%)	99 (42.13%)	476 (55.34%)
	Unprepared Sealant	99 (31.73%)	111 (32.65%)	70 (24.48%)	43 (18.30%)	323 (37.56%)
	No Initial Treatment	21 (6.73%)	28 (8.24%)	6 (2.10%)	6 (2.55%)	61 (7.09%)
	total	255 (81.73%)	259 (76.18%)	198 (69.23%)	148 (62.98%)	860 (100%)
Initial tx	low initial caries risk					
	Prepared Sealant	14 (4.49%)	52 (15.29%)	52 (18.18%)	55 (23.40%)	173 (55.27%)
	Unprepared Sealant	41 (13.14%)	28 (8.24%)	31 (10.84%)	19 (8.09%)	119 (38.02%)
	No Initial Treatment	2 (0.64%)	1 (0.29%)	5 (1.75%)	13 (5.53%)	21 (6.71%)
	total	57 (18.27%)	81 (23.82%)	88 (30.77%)	87 (37.02%)	313 (100%)

Initial caries risk was categorized by determining whether the patients had any caries diagnosed within 24 months prior to sealant treatments. The subjects were

classified as having moderate-high initial caries risk (2) if they had detectable caries on any teeth other than the first permanent molar within 24 months prior to sealant placement. They were considered low initial caries risk (1) if they did not have any detectable caries within 24 months prior to treatment. The total number of teeth having moderate-high initial caries risk at the time of sealant placement was 73.32%, while 26.68% of teeth had low initial caries risk category.

The investigators also wanted to look at the initial treatment and age groups to determine if there were any differences in distribution when caries risk was moderate-high or low. The proportion of prepared sealants, unprepared sealants, and those with no treatment in the moderate-high group (55.34%, 37.56%, 7.09%) and low initial caries risk group (55.27%, 38.02%, 6.71%) appeared to be consistent. While the number prepared sealants placed in the patients with moderate-high initial caries was fairly well distributed across the age groups, there appeared to be an increasing trend for this treatment when patients were at the low initial caries risk from ages 5 and 6 (4.49%) to ages 9 and 10 (23.40%) (Table 2b). For the unprepared sealants, there was a general decreasing trend for ages 5 and 6 to ages 9 and 10 in patients with both moderate-high (31.73% → 18.30%) or low initial caries risk (13.4% → 8.09%) (Table 2b).

Notably, there was a higher number of teeth with no initial treatment in the moderate-high risk group at ages 5 and 6 (6.73%) and age 7 (8.24%), as compared to the other age groups in the same risk category (2.10% and 2.55% respectively) (Table 2b). However, the reverse was true for the low initial caries risk category, where there were

more teeth with no initial treatment in groups age 8 (1.75%) and 9 and 10 (5.53%) in the low initial caries risk category (Table 2b).

Recall Assessment

Following initial sealant placement, data was collected on the status of the sealants at 12 months and 24 months post-treatment.

At 12-Month Recall

At 12 months following initial sealant placement, the majority of the treated molars (96.88%) did not require any retreatment (Table 3a). This was found to be consistent between the different age groups (94.46-98.18%) (Table 3a). A very small proportion of treated molars failed (need retreatment 3, 4, 5). Approximately 3.12% of the total number of treated molars required retreatment, including replacement of sealant, watch on a defective sealant, or a replacement with a class 1 restoration (Table 3a). A greater number of teeth failed treatment in the ages 5 and 6 group (5.54%%), when compared to the other age groups (Table 3a).

TABLE 3a Distribution of Outcomes at 12 Month Recall

	Age 5/6	Age 7	Age 8	Age 9/10	Total
At 12-Month Recall					
no retreatment (2)	273 (94.46%)	302 (97.11%)	270 (98.18%)	212 (98.15%)	1057 (96.88%)
needs retreatment (3,4,5)	16 (5.54%)	9 (2.89%)	5 (1.82%)	4 (1.85%)	34 (3.12%)
no initial treatment (0)	15 (65.22%)	23 (79.31%)	7 (63.64%)	14 (73.68%)	59 (71.95%)
requiring treatment (1)	8 (34.78%)	6 (20.69%)	4 (36.36%)	5 (26.32%)	23 (28.05%)

Looking at molars with no initial sealant treatment, 28.05% of the total untreated molars required placement of a sealant or restoration at 12-months (Table 3a). The proportion of teeth requiring treatment appeared to be similarly distributed amongst the age groups, ranging from 20.69% to 36.36% (Table 3a).

Overall, there were slightly fewer total failure/retreatment with initial unprepared sealants (2.94% of total unprepared sealants placed) than with prepared sealants (3.24% of total prepared sealants placed) (Table 3b). Notably, the group of ages 5 and 6 with prepared sealants (3.53%) seemed to require more retreatment when compared to the other groups (0.85%-1.40%) (Table 3b).

TABLE 3b General Distribution of Initial Treatment Groups Within Retreatment Outcomes at 12-Month Follow Up

	At 12-Month Recall	Age 5/6	Age 7	Age 8	Age 9/10	Total
Initial tx	Retreatment (3,4,5)					
	Prepared Sealant	11 (8.15%)	4 (%)	4 (1.40%)	2 (0.85%)	21 (3.24%)
	Unprepared Sealant	5 (5.05%)	5 (4.50%)	1 (0.35%)	2 (0.85%)	13 (2.94%)
	total	**16 (5.54%)**	**9 (2.89%)**	**5 (1.82%)**	**4 (1.85%)**	**34 (3.12%)**

A GEE model was used to test for statistical significance between prepared and unprepared sealants' efficacy. Due to the size of the sample, there was no significant difference in failure or success between the two sealant treatments at 12-months post-treatment (p-value = 0.8815) (Table 3c). Although there was no statistical significant difference, the investigators will further explore the distribution of failure/success within each group to determine if there was anything of value to add to future studies.

TABLE 3c P-value from Generalized Estimating Equation Model for Prepared and Unprepared Sealants at 12-Months

Analysis of GEE Parameters Estimate						
Empirical Standard Error Estimates						
Parameter	**Estimate**	**Standard Error**	**95% confidence interval**		**Z**	**Pr > |Z|**
Intercept	-3.5406	0.7979	-5.1045	-1.9767	-4.44	<0.0001
Initial Tx	0.0716	0.4799	-0.8690	1.0121	0.15	**0.8815**

At 24-Month Recall

At 24 months following initial sealant placement, the majority of the treated sample (93.22%) did not require any retreatment (Table 4a). There was an increasing trend of

success/no retreatment as the age of placement increased from ages 5 and 6 to ages 9 and 10 (88.58 → 96.76%) (Table 4a). Although the success/no retreatment outcome was lower than those at 12-months post-treatment (average 96.88%) (Table 3a), the results still indicate that both treatments were highly retentive and protective over a 24-month period.

TABLE 4a Distribution of Retreatment Outcome at 24-Month Recall

	Age 5/6	Age 7	Age 8	Age 9/10	Total
At 24-Month Recall					
no retreatment (2)	256 (88.58%)	291 (93.57%)	261 (94.91%)	209 (96.76%)	1017 (93.22%)
need retreatment (3,4,5)	17 (5.88%)	11 (3.54%)	9 (3.27%)	3 (1.38%)	40 (3.67%)
no initial treatment (0)	13 (56.52%)	12 (41.38%)	3 (27.27%)	12 (63.16%)	40 (48.78%)
requiring treatment (1)	2 (8.70%)	11 (37.93%)	4 (36.36%)	2 (10.53%)	19 (23.17%)

Approximately 3.67% of treated molars required retreatment at 24-months post-treatment, including placement of a sealant, replacement of sealant, watch on a defective sealant, or replacement with a class 1 restoration (Table 4a). This was slightly more than the number of retreated teeth at 12-months post-treatment (3.12%) (Table 3a). There was a decreasing trend in the failure/retreatment rate as age of placement increased from ages 5 and 6 to ages 9 and 10 (5.88% →1.38%) (Table 4a). Interestingly, these rates were similar to those at the 12-month follow-up (Table 3a).

Slightly more non-treated teeth required treatment at 24-months (29.27%) (Table 4a) as compared to 12-months (28.05%) (Table 3a). There were more untreated teeth that required treatment from age 7 (37.93%) and age 8 (36.36%) than other age groups (Table 4a).

TABLE 4b General Distribution of Initial Treatment Groups Within Retreatment Outcomes at 24-Month Follow Up

	At 24-month Recall	**Age 5/6**	**Age 7**	**Age 8**	**Age 9/10**	**Total**
Initial tx	Retreatment (3,4,5)					
	Prepared Sealant	14 (9.40%)	8 (4.65%)	4 (2.30%)	2 (1.30%)	28 (4.31%)
	Unprepared Sealant	3 (2.14%)	3 (2.16%)	5 (4.95%)	1 (1.61%)	12 (2.71%)
	Total	**17 (5.88%)**	**11 (3.54%)**	**9 (3.27%)**	**3 (1.38%)**	**40 (3.67%)**

Looking at the distribution of the two different sealant methods that required retreatment at 24-months post-treatment, there appeared to be more prepared sealants requiring retreatment than unprepared sealants (4.31% vs 2.71%) (Table 4b). There also appeared to be more failure/retreatment required for molars with prepared sealants at 24-months post-treatment (4.31%) (Table 4b) than 12-months post-treatment (3.24%) (Table 3b). This rate seemed to be similar for molars treated with unprepared sealants (2.71% at 24-months vs. 2.94% at 12-months) (Table 4b, 3b).

Ages 5 and 6 had the highest proportion of total treated molars that required retreatment (5.88%) at 24-month recall as compared to other age groups (Table 4b). More specifically, the prepared sealants placed at ages 5 and 6 (9.40%) seemed to require more retreatment when compared to the other age groups (1.30-4.65%) (Table 4b). There was a slight decreasing trend of failure/retreatment in the prepared sealant group from ages 5 and 6 (9.40%) to ages 9 and 10 (1.30%) (Table 4b). For the unprepared sealants, there did not appear to be any specific trend observed. In summary, unprepared sealants seemed to have a higher failure rate than prepared sealants, especially when placed at ages 5 and 6.

TABLE 4c P-value from Generalized Estimating Equation Model for Prepared and Unprepared Sealants at 24-Months

Analysis of GEE Parameters Estimate						
Empirical Standard Error Estimates						
Parameter	**Estimate**	**Standard Error**	**95% confidence interval**		**Z**	**Pr > |Z|**
Intercept	-4.1442	0.7445	-5.6033	-2.6851	-5.57	<0.0001
Initial Tx	0.5395	0.4254	-0.2942	1.3732	1.27	**0.2047**

A GEE model was used to test for statistical significance between prepared and unprepared sealants' efficacy at 24-month recall. Again, due to the numbers, there was no significant difference in failure or success between the two sealant treatments at 24 months post-treatment (p-value = 0.2047) (Table 4c).

Initial Caries Risk Effects on Success and Failure Rate

In order to assess whether initial caries risk had any role in the success and failure between the two treatment methods, the data was separated into moderate-high and low

initial caries risk categories. The investigators were then able to further investigate each treatment method within the risk category at 12-months and 24-months post-treatment. It is important to note that failed treatment/retreatment outcomes at 12-months post-treatment did not carry forward to the count at 24-months post-treatment.

Success Between Treatments at Different Initial Caries Risk

Treatment success at moderate-high initial caries risk was slightly higher than low initial caries risk at 12-months post-treatment (97% vs 96.58%), and very similar at 24-months post-treatment (93.12% vs. 93.49%) (Table 5a). There were no specific trends observed between each age group for all categories.

At 12-months post-treatment, the total success of unprepared sealants at moderate-high initial caries risk (97.83%) was only slightly higher than that of the prepared sealants (96.22%) (Table 5a), however, the opposite was true when initial caries risk was low. Prepared sealants (98.27%) were more successful than unprepared sealants (94.12%) in the low initial caries risk category at 12-months post-treatment (Table 5a).

TABLE 5a Percentages of Treatment Success of Prepared and Unprepared Sealants Separated by Initial Caries Risk at 12- and 24-Months Post-Treatment

	Age 5/6	Age 7	Age 8	Age 9/10	Total
At 12-month Recall					
No Retreatment (2)					
Mod-high initial caries risk					
Prepared Sealant	124	117	120	97	458
	(91.85%)	(97.50%)	(98.36%)	(97.98%)	(96.22%)
Unprepared Sealant	97	110	69	41	317
	(97.98%)	(99.10%)	(98.57%)	(95.35%)	(97.83%)
Total	221	227	189	138	**775**
	(94.44%)	(98.27%)	(98.43%)	(97.18%)	**(97.00%)**
Low initial Caries Risk					
Prepared Sealant	14	51	50	55	170
	(100%)	(98.08%)	(96.15%)	(100%)	(98.27%)
Unprepared Sealant	38	24	31	19	112
	(92.68%)	(85.71%)	(100%)	(100%)	(94.12%)
Total	52	75	81	74	**282**
	(94.55%)	(93.75%)	(97.59%)	(100%)	**(96.58%)**
At 24-month Recall					
No Retreatment (2)					
Mod-high initial caries risk					
Prepared Sealant	110	110	118	96	434
	(81.48%)	(91.67%)	(96.72%)	(96.97%)	(91.17%)
Unprepared Sealant	96	109	65	40	310
	(96.97%)	(98.20%)	(92.86%)	(93.02%)	(95.98%)
Total	206	219	183	136	**744**
	(88.03%)	(94.81%)	(95.31%)	(95.77%)	**(93.12%)**
Low initial Caries Risk					
Prepared Sealant	14	50	48	54	166
	(100%)	(96.15%)	(92.31%)	(98.18%)	(95.95%)
Unprepared Sealant	36	22	30	19	107
	(87.80%)	(78.57%)	(96.77%)	(100%)	(89.91%)
Total	50	72	78	73	**273**
	(90.91%)	(90.00%)	(93.96%)	(98.65%)	**(93.49%)**

At 24-months post-treatment, this trend was more pronounced. The success of unprepared sealants at moderate-high initial caries risk (95.98%) was higher than that of the prepared sealants (91.17%) (Table 5a). Prepared sealants (95.95%) were more successful than unprepared sealants (89.91%) in the low initial caries risk category at 24-months post-treatment (Table 5a).

Failure Between Treatments at Different Initial Caries Risk

Treatment failure at moderate-high initial caries risk was very slightly lower than that of low initial caries risk at 12-months post-treatment (3% vs 3.42%), while the reverse was true at 24-months post-treatment (3.88% vs. 3.08%) (Table 5b). The failure rate seemed to be similar for all initial risk categories at 12- and 24-months post-treatment (around 3-3.88%) (Table 5b).

At 12-months post-treatment, there was a higher failure rate of prepared sealants at moderate-high initial caries risk (3.78%) compared to that of the unprepared sealants (1.86%) (Table 5b). While the reverse was true when initial caries risk was low. The total unprepared sealants (5.88%) failed more often than the total prepared sealants (1.73%) in the low initial caries risk category at 12-months post-treatment (Table 5b). There was no observable trend for each age group, however, prepared sealants placed at ages 5 and 6 with moderate-high initial caries risk appeared to have the highest failure percentage at 12-months post-treatment (8.15%) (Table 5b). While unprepared sealants placed at age 7 with low initial caries risk had a failure rate of 14.28%, this number might not be reliable due to limited total unprepared sealants within this group (Table 5b).

TABLE 5b Percentages of Treatment Failure of Prepared and Unprepared Sealants Separated by Initial Caries Risk at 12- and 24-Months Post-Treatment

	Age 5/6	Age 7	Age 8	Age 9/10	Total
At 12-month Recall					
Retreatment (3,4,5)					
Mod-high initial caries risk					
Prepared Sealant	11	3	2	2	18
	(8.15%)	(2.50%)	(1.64%)	(2.02%)	(3.78%)
Unprepared Sealant	2	1	1	2	6
	(2.02%)	(0.90%)	(1.43%)	(4.65%)	(1.86%)
Total	13	4	3	4	24
	(5.56%)	(1.73%)	(1.56%)	(2.81%)	(3.00%)
Low initial Caries Risk					
Prepared Sealant	0	1	2	0	3
	(0%)	(1.92%)	(3.85%)	(0%)	(1.73%)
Unprepared Sealant	3	4	0	0	7
	(7.32%)	(14.28%)	(0%)	(0%)	(5.88%)
Total	3	5	2	0	10
	(5.45%)	(6.25%)	(2.41%)	(0%)	(3.42%)
At 24-month Recall					
Retreatment (3,4,5)					
Mod-high initial caries risk					
Prepared Sealant	14	7	2	1	24
	(10.37%)	(5.83%)	(1.64%)	(%)	(5.04%)
Unprepared Sealant	1	1	4	1	7
	(1.04%)	(0.90%)	(5.71%)	(%)	(2.17%)
Total	15	8	6	2	31
	(6.41%)	(3.46%)	(3.13%)	(%)	(3.88%)
Low initial Caries Risk					
Prepared Sealant	0	1	2	1	4
	(0%)	(1.92%)	(3.85%)	(1.82%)	(2.31%)
Unprepared Sealant	2	2	1	0	5
	(4.88%)	(7.14%)	(3.23%)	(0%)	(4.20%)
Total	2	3	3	1	9
	(3.64%)	(3.75%)	(3.61%)	(1.35%)	(3.08%)

At 24-months post-treatment, this trend was again more pronounced. The total failure of prepared sealants at moderate-high initial caries risk (5.04%) was higher than that of the unprepared sealants (2.17%) (Table 5b). The unprepared treatment (4.20%) had a higher failure rate than the prepared method (2.31%) in the low initial caries risk category at 24-months post-treatment (Table 5b). For prepared sealants placed in teeth

with moderate-high initial caries risk, there was noticeably higher failure rate for those placed at ages 5 and 6 (10.37%) and age 7 (5.83%) when compared to other age groups (Table 5b). The reverse was true for unprepared sealants in the same category. There were slightly more failures for the unprepared sealants placed at age 8 (5.71%) and ages 9 and 10 (2.33%) compared to the younger age groups with moderate-high initial caries risk (Table 5b). There were no observable trends between the age groups for the low initial caries risk category at this recall period. It was notable that were more failures for unprepared sealants with low initial caries risk placed at ages 5 and 6 (4.88%) and age 7 (7.14%) than at other age group of the same category (Table 5b). However, the reliability of the number of the low initial caries risk group was questionable due to limited initial totals of the categories.

Treatment on Initially Non-Treated Teeth

At 12-months follow-up, more molars required treatment if they had moderate-high caries risk previously compared to low initial caries risk (34.43% requiring treatment with moderate-high risk versus 9.52% requiring treatment with low risk) (Table 5c). The same trend was found at the 24-month recall, where 24.59% of molars required treatment in the moderate-high caries risk compared to 19.05% at low initial caries risk (Table 5c). However, it was interesting to note that for the low caries risk group at both recall periods, untreated molars in ages 5 and 6 and age 7 did not require treatment (Table 5c).

TABLE 5c Percentages of No Treatment Requiring Treatment Separated by Initial Caries Risk at 12- and 24-Months Post-Treatment

	Age 5/6	Age 7	Age 8	Age 9/10	Total
At 12-month Recall					
Mod-high initial caries risk					
No Treatment (0)	13	22	3	2	40
	(61.90%)	(78.57%)	(50.00%)	(33.33%)	(65.57%)
Need Treatment (1)	8	6	3	4	21
	(38.09%)	(21.43%)	(50.00%)	(66.67%)	(34.43%)
Low initial Caries Risk					
No Treatment (0)	2	1	4	12	19
	(100%)	(100%)	(80.00%)	(92.31%)	(90.48%)
Need Treatment (1)	0	0	1	1	2
	(0%)	(0%)	(20.00%)	(7.69%)	(9.52%)
At 24-month Recall					
Mod-high initial caries risk					
No Treatment (0)	11	11	1	2	25
	(52.38%)	(39.28%)	(16.67%)	(33.33%)	(40.98%)
Need Treatment (1)	2	11	2	0	15
	(9.52%%)	(39.28%)	(33.33%)	(0%)	(24.59%)
Low initial Caries Risk					
No Treatment (0)	2	1	2	10	15
	(100%)	(100%)	(40.00%)	(76.92%)	(71.43%)
Need Treatment (1)	0	0	2	2	4
	(0%)	(0%)	(40.00%)	(15.38%)	(19.05%)

Changes in Caries Risk

The investigators were interested in determining if any changes in the initial caries risk status at the 24-month recall had any influence on the overall treatment outcome. Caries risk status was categorized at 24-months post-treatment if patients did not have any caries in the previous 12-month period.

TABLE 6a Distribution of Treatment Outcome of the Sealant Technique at 24-months Recall Stratified by Change in Initial Caries Risk

Change in Caries Risk at Initial Treatment → 24-Months Recall	Status at 24-Month Recall		
	No Retreatment (2)	**Retreatment (3,4,5)**	**Total**
Group 1 Low risk (1) → Low risk (1)	244 (97.60%)	6 (2.40%)	***250***
Group 2 Low risk (1) → Mod-High risk (2)	35 (92.11%)	3 (7.89%)	***38***
Group 3 Mod-High risk (2) → Low risk (1)	585 (94.76%)	21 (3.47%)	***606***
Group 4 Mod-High risk (2) → Mod-High risk (2)	181 (94.76%)	10 (5.24%)	***191***
Total	**1045**	**40**	**1085**

Comparing the different groups, all seemed to have a very high success rate, ranging from 97.60% to 92.11% (Table 6a). The group that appears to have the lowest failure/retreatment frequency was patients with low caries risk before and after the treatment (Group 1 at 2.40%) (Table 6a). Interestingly, patients with low initial caries risk had the highest retreatment rate (Group 2 at 7.89%) if the patient's caries risk change to moderate-high at 24 months (Table 6a). The total number of subjects in this group was very limited because it is rare for a patient to have change from low to high risk. Patients with moderate-high caries risk had the second highest retreatment rate (Group 4 at 5.24%) if they remained at high caries risk (Table 5a). However, there was no statistically significance between the groups (p-value = 0.1763) (Table 5b).

TABLE 6b Fisher Exact Test for Change in Initial Caries Risk

Fisher Exact Test	
Table Probability (P)	9.090E-0.4
Pr ≤ P	0.1763

Discussion

This study's aim was to examine the success rate of prepared and unprepared sealants at different ages of placement, and to determine if caries risk played a role in their success. A retrospective chart review was performed on the data collected from 1,173 first molars subjects from a private pediatric dental clinic (Children's Dental World, Winnipeg, Manitoba). These were categorized into unprepared sealants [1], prepared sealants [2], and non-treated [0] subjects, and further analyzed by their initial caries risk, low [1] or moderate-high [2]. Treatment failure and success were assessed at 12-months and 24-months post-treatment. Overall, in a 24-month period, both sealant methods were found to be highly successful. The prepared sealants method had more failures than unprepared sealants at both recall periods. More specifically, there were more failures for the prepared sealants placed at a younger age. Unprepared sealants were more successful than prepared sealants for patients with moderate-high initial caries risk, and the reverse was true for molars with low initial caries risk. The highest success rate was found for sealed molars that started with low initial caries risk and remained at low caries risk over the 24-month period. Overall, both sealants methods were found to be highly successful on first permanent molars in preventing occlusal caries.

A number of systematic reviews focus on the success of preventing caries in sealants, but do not specify whether prepared or unprepared sealants were used[1, 2, 22, 31, 44]. Very few quality studies on prepared sealants exist[25], and even fewer studies that compare both techniques[17, 37]. Despite in vitro studies that have shown that

enameloplasty does improve retention[39, 47, 57, 63, 76], some in vivo studies showed otherwise[37, 75]. Additionally, previous concerns with the need to increase retention through enameloplasty were unfounded because partial or complete loss of sealant and lack of post-treatment follow-up did not necessarily increase caries risk in previously sealed molars[11, 33, 43].

The AAPD recently changed its guidelines on enameloplasty prior to sealant placement, following studies showing that incipient caries do not need to be removed prior to sealant placement[22, 33, 42, 82, 88]. However, the ultimate debate still remains whether sealed caries would become reactivated following restoration failure. This study was designed to compare unprepared and prepared sealant methods to see if there was a difference in efficacy between the two methods in terms of age of placement and caries risk. No significant differences in success rates between the two methods were found.

Preference of Prepared Sealants over Unprepared Sealants

While collecting the data for this study, the principle examiner noticed that at the site investigated, proportionately more prepared sealants were being placed than unprepared sealants (649 versus 442 subjects respectively in Table 2a). Interestingly, a larger proportion of sealants were placed in moderate-high caries risk individuals compared to low caries risk individuals. The investigators believed the reason for more prepared sealants being placed was due to the high caries risk patient population in this pediatric specialty practice. High caries risk patients were also more likely to exhibit incipient caries that would indicate enameloplasty prior to sealant placement, based on the

recommendations of previous AAPD guidelines[57]. This made it very difficult to match the sample size for each age group, as some age groups did not have a sufficient number of sealants for the purpose of this study. The numbers of prepared sealants used are expected to change in the future, as the American Academy of Pediatric Dentistry (AAPD) recently changed its guidelines discouraging the removal of incipient decay prior to sealant placement[64].

The investigators found that majority of the sealants were placed at ages 5 and 6, and age 7, and there were proportionately fewer sealants being placed at ages 9 and 10. This discrepancy can be explained by newly erupted molars that were considered more susceptible to caries and would indicate sealant placement within 3 to 4 years post-eruption[9, 10]. Furthermore, the placement of prepared sealants appeared to have increased with older patients, as more prepared sealants were placed in these patients, while the opposite trend was seen for unprepared sealants. The investigators postulated that the clinical choice of prepared and unprepared sealant placement at different ages depends on the presence of incipient caries. Chances of incipient caries in a newly erupted tooth with low initial caries risk is low, and therefore, unprepared sealants were more likely being placed at ages 5 and 6, at low initial caries risk category. The benefits of sealants decreases with age and they may have been placed in older patients that displayed signs of incipient caries that necessitated removal. This can be clearly observed when comparing the number of prepared and unprepared sealants placed at ages 9 and 10 in both initial caries risk group (Table 2b).

Due to the disproportionate demographics and limited patient pool, the ability to do an analysis for statistical significance was restricted. However, the investigators' observations gave insight and an exploratory analysis to the questions and future studies

Unprepared and Prepared Sealants Are Protective

The retention rates for both unprepared and prepared sealants in this study were comparable with previous studies, 84% to 100% over 2.5 years[12, 24, 44, 56, 89]. For this study, the investigators considered any marginal staining, full or partial loss of sealant, or occlusal caries to be an indication of failure. Other studies showed that a loss of sealant did not place a tooth at higher risk of developing caries, when compared to unsealed teeth[11, 33]. If the investigators included only occlusal caries as failure, there would have been very little to no failure in this study. Comparing the success rate at 12-months and 24-months post-treatment, showed them to be very similar with very minimal retreatment rate per recall period. This is consistent with previous reports of sealants having 80% to 90% success rate after 10 or more years[38, 40, 56]. The present study also found that changing to a higher caries risk from low initial risk over the 24-month period decreased the success rate when compared to other groups that were at lower risk, however the retention rate was still above 90%. Therefore, both sealant methods are highly protective in first permanent molars regardless of caries risk or age of placement.

Prepared Sealant Has Higher Failure Rate Than Unprepared Sealants

Since the proportion of success is high for both treatment methods, the investigators wanted to further explore whether there was a difference in the failure pattern for each

sealant method. Prepared sealants were found to have a higher failure rate than unprepared sealants, for both follow-ups post-treatment. Looking at the distribution of treated molars that required retreatment at the different ages at 12- and 24-months post-treatment, prepared sealants placed at ages 5 and 6 were shown to have the highest failure percentage (Table 3b and 4b). This could be due to a number of factors that affect sealant retention, such as sealant material, moisture isolation, use of a bonding agent, tooth debridement, patient's behaviour, operator variables, enamel alteration, time of placement, and location of tooth in the arch[1, 2, 30, 31, 36, 64, 65, 69-71, 75, 90, 91].

With any retrospective study, there are limitations to the control of these variables, however, the investigators can account for a few of these variables. The restorative materials used for both sealant methods were consistent for the entire practice and study period at the pediatric specialty office where the investigation took place. Although there were multiple operators involved in the diagnosis and sealants placement, the practitioners were consistent with the same method of diagnosis and sealant placement since joining the practice. Furthermore, numerous operators may have been involved in a single patient's sealant treatment and diagnosis, thereby making the sampling of operator variable more random. When looking at the low failure rate, the investigators can be fairly sure that operator variable is probably negligible. As well, the investigators excluded children with special-health care needs and molars with hypoplastic enamel, which may have increased the likelihood of failure.

The investigators suspected that one of the reasons for the observed increased failure rate for prepared sealants when placed at ages 5 and 6, and age 7, was the child's behaviour and tooth location. According to Feigal et al., poor cooperation can compromise moisture isolation and can cause poor retention of sealant at 12-months, irrespective of the bonding agent used[69, 70]. Young children and those who had previous restorative treatments were more likely to have poorer behaviour and to lack the attention span required for the extra procedures involved with prepared sealants. However, the investigators were unable to collect the child's behaviour rating during data collection due to inconsistent recording. Another reason for increased failure of prepared sealants might have been the location of the tooth in the arch, as it has been shown that maxillary molars tend to have a higher failure rate, especially on the palatal surfaces[70]. However, the investigators did not examine tooth location and failure rate in this study. Armed with this information, the investigators would encourage practitioners to actively monitor sealants for failure when placed in younger patients, especially around ages 5, 6, and 7. As well, the investigators would recommend that future studies look further to account for the location of the tooth being treated and the behaviour of the patient.

Influence of Caries Risk in Success/Failure of Sealant Placement

It was rather unexpected that unprepared sealants had a lower retreatment rate than prepared sealants. The investigators wanted to further explore whether prepared or unprepared sealants were more successful when placed in moderate or high caries risk individuals, as compared to low caries risk. Children with early childhood caries have higher risk in developing future caries compared to low caries risk children[84, 86], therefore,

sealants are considered the most cost-effective method, especially for patients with increased caries risk[5, 50, 53].

The investigators previously anticipated that prepared sealants would be more successful and have a lower failure rate in teeth with moderate-high caries risk, since previous studies on enameloplasty indicated higher retention with mechanical preparations[39, 47, 63]. The results from the present study showed that unprepared sealants had slightly lower retreatment outcomes than prepared sealants when placed on teeth, and especially on teeth with moderate-high initial caries risk at 12-months and 24-months post-treatment. However, prepared sealants were more successful when placed in low-risk molars when compared to unprepared sealants.

To explain the differences in failure rates observed between the treatments at different caries risk groups, the investigators looked further into the differences between the age groups. There was proportionally more failure/retreatment observed with prepared sealants placed at ages 5 and 6, and age 7 in the moderate-high caries risk category, while there was proportionately more failure for unprepared sealants placed at age 5 & 6, and age 7 with low caries risk. This observation was consistently observed at 12-months and 24-months post-treatment. This data did not show any significant conclusion in terms of whether caries risk was correlated with the success rate of the two treatment modalities. Again, the investigators postulated this increased failure rate for both treatment modalities to behavioural discrepancies and moisture isolation issues, since children with moderate-high caries risk are more likely to have worsened behaviour due to

previous restorative experiences. Unfortunately, the investigators did not incorporate behaviour rating into their data analyses. When looking at the increased failure rate for the unprepared sealants in the low-caries risk category, the investigators were reminded of the importance of assessing age in relation to behaviour and moisture control prior to any type of sealant placement.

Since there were no significant differences between the success rates of the two treatment modalities being affected by initial caries risk, the investigators were interested in knowing if the change in caries risk would instead have an impact the success/failure of sealants. The majority of the patients remained in their initial caries risk category throughout the 24-month period. The investigators found that sealant success was higher in patients who were of low caries risk 24-months post-treatment, as compared to being moderate-high caries risk. Despite having the lowest overall sealant success when compared to other groups, patients who converted to high caries risk from initial low caries risk were still found to have an overall sealant success of 92.11% (Table 6a). This suggests that changes in caries risk might have some impact on the success of sealants, however, the protective effects of sealants remains high.

A number of studies explored caries risk to determine if it is more cost effective for sealant to be placed in a particular risk group to prevent occlusal caries. Many studies recommended sealants to be placed on high caries risk children[3, 4, 8, 21, 49, 50, 57, 83, 89]. A systematic review by Mejare et al.[25] found a lack of quality studies that looked at the influence of caries risk on the effectiveness of sealants, although studies have shown that

sealant retention is lower for high caries risk regardless of other factors[11, 37, 59]. This method was still proven to be highly effective in preventing occlusal caries in high risk groups[11, 48]. Data from the present study did not show a significant difference in failure given the difference in caries risk, but were still suggestive of a high success rate of sealants at higher caries risk. Since caries risk can change over time, the investigators believe that placement of sealant can be protective regardless of caries risk, as suggested by Leskinen et al.[21], and is a valid recommendation in an effort to prevent caries.

Study Limitations

There are a number of limitations to this study. The first limitation is sampling. Since there were very few studies that investigated the differences between prepared and unprepared sealants, the investigators were unable to do a fair power estimation of sample size needed. Since the success rates were very high for prepared and unprepared sealants, a very large sample size is required in order to show clinical significance. The disproportion of sealants placed at different ages also created difficulty in terms of matching the sample size for each age group. Also, a limited numbers of sealants were placed in low caries risk individuals, perhaps due to the larger high-risk population at the sampling location. The investigators did not have a large enough sample size at the site of investigation to match each age group with each caries risk category for each treatment studied.

Another limitation to the present study is the classification of caries risk. The investigators classified moderate-high caries risk when patients had caries within 24

months prior to treatment, and low caries risk when patients had no caries within 24 months prior to treatment. The investigators classified moderate and high caries risk in one group, as the sample size would have been limited if the moderate risk group were to be excluded. The clinical effects of the caries risk between the low and moderate-high groups might have been too small to see a true difference. This could have contributed to the reason to why the investigators were unable to see the treatment difference between the risk groups.

A similar study by Hevinga et al.[51] showed that sealant failed more often in patients with a high restoration profile (high dfmt score). For this study, the investigators used only past caries experience to determine caries risk, which may not have been a true assessment for the actual caries risk. Caries risk assessment is a complex process and takes into account many factors that can play into the caries development and management[13, 16, 48, 53]. Other studies have used stage of tooth function, surface anatomy, fluoride history, plaque load, socioeconomic status, et cetera, to assess caries risk[10, 69]. The investigators were originally planning to use patient's oral hygiene status as part of determining patient's caries risk, however, they were unable to use the oral hygiene variable due to inconsistent records. Although past caries experience is the best predictor for caries, it might not have been a sufficient index for an accurate comparison.

The investigators postulated that patient's age and behaviour in relation to moisture control during treatment was the major indicator for sealant failure in this study, however, they did not collect data on patient's behaviour due to inconsistent record of ratings. They

did not further investigate the location of the failed sealed tooth in the arch because the small failure sample did not provide any appreciable data. It should be noted that a large proportion of the sealants placed at ages 5 and 6, and age 7 were completed when patients were under general anesthesia, and therefore, the true failure rate might be underestimated in this study.

Future Studies

To overcome the sampling problem, the investigators recommend a power calculation based on the information from this study, and using multiple sites and general and specialty practices to generate a better, more well-distributed sample representing the Manitoba population. For a better clinical definition of caries risk, future studies should incorporate additional factors, such as fluoride use, social economic background, compliance, et cetera, for a full comprehensive assessment of caries risk. Also, excluding the moderate risk group by selectively comparing only patients with caries 12-months prior to sealant placement to those who did not have caries for 24-months will perhaps allow investigators to determine the true effects of caries risk. Knowing that ages 5, 6, and 7 had increased sealant failure rates, the investigators suggest further study into the effects of behaviour and tooth location on the success rate of sealants.

Given the current recommendations on placement of sealants over incipient caries, ideally, investigators should design future studies to examine the longevity and long-term consequences of this new protocol. It would be interesting to explore how successful these sealants are in patients with high caries risk over time. Also, it would be beneficial to

compare the rate of caries development and progression of these unprepared sealants placed in young patients with challenging treatment behaviour. Due to the inability to control various important variables in a retrospective study, and low failure rate of sealants, the investigators recommend designing a large-scale, longitudinal, randomized controlled trial of split-mouth design to look at the performance of this new sealant recommendation in the years to come.

Conclusion

In summary, the present study confirms the high level of success of sealants in preventing occlusal caries development in first permanent molars. The investigators found that prepared sealants at a younger age and moderate-high caries risk have a higher failure rate than unprepared sealants in the same category. The investigators postulate that young age and poor behaviour play an important role in the determination of sealant failure. The results from the study showed that initial caries risk was not correlated with the success rate of prepared and unprepared sealants. However, maintenance of lower caries risk at 24-months post-treatment was found to have the highest sealant success when compared to subjects having high caries risk at 24-months follow-up. Future studies should place emphasis on the longitudinal effects of age and behaviour in sealants placed over incipient caries.

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Appendix 1 – Data Collection/Capture Sheet

Participant Unique Code Number: _____ (do not use a personal identifier)
Tooth #: _____
Study #: _____ (Participant Unique Code – Tooth #)

Data Collection/Capture Sheet

(To be used with Master List)

Protocol Title: Success Rate of Prepared and Non-Prepared Sealant in Children with Low and High Caries Risk

Date of Data Collection (DD/MM/YY): _____

Data to be collected on paper: Yes ☒ No ☐

Data to be entered directly into computer spread sheet Yes ☒ No ☐

Data Elements to be collected:

Demographic data and identifiers

1. Age (MM/YY): _____
2. Birthdate (DD/MM/YY): _____
3. Gender (f-1; m-2): _____

Data elements from chart or database

Treatment Details:

Assess if the treated tooth have interproximal caries that was undetected during the initial treatment appointment (If yes, data collection will stop since this is an exclusion criteria.

4. Identify type of treatment provided: _____ (none – 0, sealant – 1, PRR – 2)
5. Date when treatment was performed: _____ (DD/MM/YY)
6. Age when treatment was performed: _____ (MM/YY)
7. Identify tooth treated: _____ (#16 – 1; #26 – 2; #36 – 3; #46 – 4)

Patient's initial caries risk assessment:

8. Oral Hygiene at Initial Treatment: _____ (poor/fair -1, good - 2)
9. Patient had caries in less than 24 months prior to initial placement of sealant/PRR: No – 1 ☐ Yes – 2 ☐ (No – 1 (low risk) /yes – 2 (high/moderate risk))

At 12-month recall:

To assess success/failure of treatment:

10. Identify status of tooth at 12-month: _____ (no treatment required on untreated tooth – 0; need to place sealant/PRR on untreated tooth – 1; intact previous sealant/PRR not requiring treatment – 2, watch/observe previous sealant/PRR with stains – 3, loss of sealant/PRR that require retreatment – 4, class 1 caries or restoration – 5)

11. Date when re-treatment/restoration was done: _____ (DD/MM/YY)

To assess if the interproximal caries developed on the treated tooth is independent from treatment performed:

12. At this recall exam, does patient have interproximal caries on the treated tooth that require a class 2 restoration? No – 1 ☐ Yes – 2 ☐

To assess change in caries risk status:

13. Does the patient have new carious lesion other than the treated tooth in the last 12 months. No – 1 ☐ Yes – 2 ☐

At 24-month recall:

To assess success/failure of treatment:

14. Identify status of tooth at next 12 month: _____ (no treatment required on untreated tooth – 0; need to place sealant/PRR on untreated tooth – 1; intact previous sealant/PRR not requiring treatment – 2, watch/observe previous sealant/PRR with stains – 3, loss of sealant/PRR that require retreatment – 4, class 1 caries or restoration – 5)

15. Date when re-treatment/restoration was done: _____ (DD/MM/YY)

To assess if the interproximal caries developed on the treated tooth is independent from treatment performed:

16. At this recall exam, does patient have interproximal caries on the treated tooth that require a class 2 restoration? No – 1 ☐ Yes – 2 ☐

To assess change in caries risk status:

17. Does the patient have new carious lesion other than the treated tooth in the last 12 months since the last recall. No – 1 ☐ Yes – 2 ☐