รายงานวิจัยฉบับสมบูรณ์

โครงการวิจัย

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A randomized controlled trial of using an intermediate bonding layer on the retention of sealants placed on pit and fissures enamel caries

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ชื่อเรื่อง : การวิจัยทางคลินิกแบบสุ่มและมีกลุ่มควบคุมด้วยการใช้สารยึดติดทางทันตกรรมต่อการยึดติดของการเคลือบรอยผุผิวเคลือบฟันบริเวณหลุมร่องฟัน
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ลิขสิทธิ์ : มหาวิทยาลัยรังสิต

บทคัดย่อ

รายงานการวิจัย เรื่อง การวิจัยทางคลินิกแบบสุ่มและมีกลุ่มควบคุมด้วยการใช้สารยึดติดทางทันตกรรมต่อการยึดติดของการเคลือบรอยผุผิวเคลือบฟันบริเวณหลุมร่องฟัน เป็นวิจัยพัฒนาเชิงทดลองที่มุ่งศึกษาว่าการใช้สารยึดติดทางทันตกรรมช่วยเพิ่มประสิทธิภาพในการยึดติดของวัสดุเคลือบหลุมร่องฟันบนรอยผุผิวเคลือบฟันบริเวณหลุมร่องฟันหรือไม่ โดยเป็นการทดลองในเด็กจำนวน 40 คน อายุเฉลี่ย 11 ปี 3 เดือน ซึ่งมีคู่ฟันกรามแท้ที่มีรอยผุผิวเคลือบฟันบริเวณหลุมร่องฟันในระดับ ICDAS และตำแหน่งเดียวกัน ทันตแพทย์ผู้มีประสบการณ์ 1 คน ทำการเคลือบรอยผุบริเวณหลุมร่องฟันด้วยวัสดุเคลือบหลุมร่องฟันชนิดเรซิน *(3M ESPE Clinpro™)* ในฟันกรามแท้ 96 ซี่ โดยใช้การศึกษาแบบแบ่งส่วนช่องปาก กลุ่มศึกษา 48 ซี่ใช้วัสดุเคลือบหลุมร่องฟันชนิดเรซินร่วมกับการใช้สารยึดติดทางทันตกรรมชนิดเอทานอล *(OptiBond™ Solo Plus)* กลุ่มควบคุม 48 ซี่ใช้การเคลือบหลุมร่องฟันโดยไม่ใช้สารยึดติดทางทันตกรรม ทำการติดตามผลการยึดติดทุกช่วง 6 เดือน โดยผู้ตรวจสอบ 2 คนที่ไม่ทราบข้อมูลของการทดลอง *(Kappa =0.80)* และวิเคราะห์ผลโดยสถิติ McNemar

ผลการติดตามการรักษาระยะเวลา 6 เดือน (ค่าเฉลี่ย 6 เดือน 30 วัน) พบว่าฟันที่ได้รับการเคลือบรอยผุ 46 คู่ (92 ซี่) ได้รับการประเมิน และพบว่ากลุ่มที่ได้รับการเคลือบรอยผุโดยการใช้สารยึดติดทางทันตกรรมร่วมด้วยมีการยึดติดที่ดีกว่า ร้อยละ 93.48 เป็นการยึดติดอย่างสมบูรณ์ และร้อยละ 6.52 เป็นการยึดติดแบบไม่สมบูรณ์ กลุ่มที่ไม่ใช้สารยึดติดทางทันตกรรม ร้อยละ 34.79 เป็นการยึดติดอย่างสมบูรณ์ และร้อยละ 65.21 เป็นการยึดติดแบบไม่สมบูรณ์ โดยพบว่าการยึดติดของทั้งสองกลุ่มมีความแตกต่างกันที่ระดับนัยสำคัญ 0.00 ดังนั้นการใช้สารยึดติดทางทันตกรรมชนิดเอทานอล ดูเหมือนว่าจะช่วยเพิ่มประสิทธิการในการยึดติดอย่างไรก็ตามควรมีการติดตามผลการศึกษาในระยะยาว

Title : A randomized controlled trial of using an intermediate bonding layer on the retention of sealants placed on pit and fissures enamel caries

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ABSTRACT

Research report's title "A randomized controlled trial of using an intermediate bonding layer on the retention of sealants placed on pit and fissures enamel caries" was a split-mouth randomized study that study to assess whether an adhesive bonding agent improve the retention of sealant placed on pit-and-fissures enamel caries.

The data were collected from forty children *(mean age = 11.3 years)* who had paired of permanent molars with pit-and-fissures enamel caries in the same ICDAS code *(mode of baseline ICDAS code = 2)* and same location were recruited. One experienced operator placed resin-based sealant *(3M ESPE Clinpro™)* on 96 permanent molars using a randomized split-mouth design. The test group; bonded caries sealing (n=48) had an ethanol-based bonding agent *(OptiBond™ Solo Plus)* placed as intermediate adhesive layer, and no bonding agent was used in control group; conventional caries sealing group (n=48). The retention of sealants were reviewed in 6-month-interval by two blinded examiners *(Kappa = 0.80)* and analyzed by using McNemar's test.

The results show that after 6 months, the mean time between after sealant placement and review was 6 months and 30 days, 46 pairs of caries sealed teeth (92 teeth) were available for examination. Teeth with bonded caries sealing group showed a better retention; 93.48% were completely sealed and 6.52% were incompletely sealed, teeth in conventional sealing group revealed 34.79% completely sealed and 65.21% incompletely sealed. The differences in sealant retention between both groups were statistically significant *(p=0.00)*.

Thus, the using of an ethanol-based bonding agent as intermediate adhesive layer of resin-based sealant placed on pit-and-fissures enamel caries seems to improve the sealant retention and showed significantly better retention than conventional technique at 6-months. Thus, a longer period of follow up should be performed and investigated.

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Finally, I would like to express my appreciation to my family for their unconditional support and encouragement to pursue me interests. Thank you so much.

Sukrit Poonsuk

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LIST OF ABBREVIATIONS

%	Percentage
ICDAS	International Caries Detection and Assessment System
RCT	Randomised Controlled Trial
OR	Odds Ratio
CI	Confidence Interval
H_0	Null hypothesis
H_1	Alternative hypothesis
p	Probability
P	Complete retention of sealant
1-β	Power of test
α	Confidence level
TM	Trademark
n	Numbers of subject

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CHAPTER 1

INTRODUCTION

Introduction and background

The occlusal surfaces of molar teeth consist of grooves, intersegment grooves, and fossae which are classically termed as “pit and fissures system.” These areas are the predilection of plaque accumulation and are protected from mechanical cleaning, notably from tongue and cheek movement and also from tooth brushing; therefore these occlusal surfaces are the plaque stagnation area. (Meyer-Lueckel, Paris, & Ekstrand, 2013) Undoubtedly, caries process most often develops in the pit and fissures system of occlusal surfaces. (Carvalho, Ekstrand, & Thylstrup, 1989)

Pit-fissures-caries sealing has been described as the placement of a sealant material over the carious lesion or demineralized enamel at pit and fissures system, which micromechanically bonds to the tooth preventing the access of cariogenic bacteria to their source of nutrients and further demineralization.(Meyer-Lueckel et al., 2013) The evidence-based clinical recommendations for use of pit-fissure-sealants recommended that sealants can prevent the progression of early non-cavitated carious lesions.(Beauchamp et al., 2009) A meta-analysis showed that placement of pit-and-fissure sealants significantly reduces the percentage of caries progression in non-cavitated carious lesions. (Griffin, Oong, et al., 2008) There were no findings that bacteria increase under the placement of sealant over existing caries. The placement of sealant over caries could lower the number of viable bacteria by at least 100-fold and reduce the number of lesions with any viable bacteria by fifty percent. (Oong, Griffin, Kohn, Gooch, & Caufield, 2008) In consistent with the classic study of Mertz-fairhurst and colleaques supported that it is possible to use sealants to arrest the progression of caries process. (Mertz-Fairhurst, Curtis, Ergle, Rueggeberg, & Adair, 1998) Moreover, a systematic review of randomized controlled trial for the use of sealants recommended that sealants are also effective in reducing progression of noncavitated carious lesions at occlusal pit and fissures system. (Wright et al., 2016) Recent trends in the management of dental caries, there have been a lot of evidences to support that early stage of pit-and-fissures caries should be managed more conservatively with sealants. They can potentially preserve tooth structure and lower the likelihood of future complex restorations.

The evidence regarding sealant material concluded that resin-based sealants are the first choice of material for both preventive sealant and pit-fissures-caries sealing.(Beauchamp et al., 2009) One meta-analysis showed the high retention rates of resin-based sealants compared to glass-ionomer

-cement-based and compomer sealants. The visible light-polymerizing resin-based sealants are recommended for clinical use because of their faster and less error-prone clinical application. (Kühnisch, Mansmann, Heinrich-Weltzien, & Hickel, 2012)

The success of pit-fissures-caries sealing or preventive sealant treatment has been measured mainly as the retention rate of sealant.(Simonsen, 1991) The goal is to make sealant penetration as complete as possible. There are many factors related to the penetration and the retention of resin-based sealant.(Muller-Bolla, gerier, Tardieu, Velly, & Antom-archi, 2006) (Beauchamp et al., 2009) which include the macroscopic structure of pit and fissures system, the microscopic structure of enamel, the cleaning of fissure prior to sealant placement, the dryness of tooth surface, the technique of moisture control, the etching system & technique, cooperation of the patient and position of the tooth.

One systematic review concluded that etch-and-rinse systems produce significantly higher bond strengths than self-etching systems.(Beauchamp et al., 2009) In consistent with another recent systematic review also concluded that the retention rate of sealant placed on occlusal surfaces following the use of etch-and-rinse system showed higher retention rate than sealant applied in the self-etching system.(Botton et al., 2016) Therefore, the etch-and-rinse system is the goal standard for the application of resin-based-sealant. Previous study had shown that the etching times of 15 seconds for the etch-and-rinse technique is sufficient to produce the required etch-pattern for bond strength of resin-based sealant and the usual recommendation for rinsing is 20 to 30 seconds (Tendon, Kumari, & Udupa, 1989) However, the exact rinse time is probably not as important as ensuring that the rinse is thoroughly enough to remove all of the etchant from the surface. (Waggoner & Siegal, 1996)

In an in vitro study about the ability of resin-based sealant on the different–macroscopic structures of pit-fissure-system, they concluded that shallow fissures present significantly smaller unfilled area of sealant than deep fissures. This is due to the fact that shallow fissures have a significantly wider entrance angle, whereas the deep fissures have narrow entrance angles which will lead to incomplete removal of organic substances and hinder the optimal etching and sealing ability. (Celiberti & Lussi, 2007)

In the study of Burrow and colleagues found that the microscopic structure of enamel forming at the pit and fissures system was a prismless structure. These prismless enamel crystals exhibit unidirectional orientation and are densely arranged. When this structure was etched, the result created was a relatively uniform dissolution with limited porosity and resin penetration. Hence, the failure to

achieve a satisfactory bond of fissure sealants may be due to the lack of tag formation following etching. (Burrow, Burrow, & Makinson, 2001)

A systematic review and meta-analysis in 2016 concluded that the use of adhesive systems beneath pit and fissures sealant can increase the retention of resin-based sealant. Also, when adhesive systems are used, the etch-and-rinse adhesives are preferable. (Bagherian, Shirazi, & Sadeghi, 2016) With regard to bonding agent placement before sealant placement, there is a randomized clinical trial that suggests that acetone or ethanol solvent based primers (low viscosity hydrophillic bonding agent), especially the single bottle system, enhanced the retention of sealants. (Feigal et al., 2000) Moreover, a recent well controlled randomized clinical trial revealed that an ethanol-based single component bonding agent significantly increased the retention of resin-based sealants particularly on the surfaces that were easily lost. (McCafferty & O'Connell, 2016)

Use of an intermediate bonding agent had been shown to be positive results in retention before placing a resin-based sealant in salivary contaminated enamel.(Feigal, Hitt, & Splieth, 1993) Another clinically studied for hypomineralized enamel in permanent molars also found substantially increased resin-based sealant retention compared with acid etching alone. (Lygidakis, Dimou, & Stamatak, 2009) However, the disadvantages of using a bonding agent are increased chair time and added cost. (Simonsen, 2002)

Pit-fissures-enamel caries lesion is a complex microscopic structure of enamel crystal which described as prismless crystal. As mentioned earlier, the prismless enamel is the etched resistance zone. Thus, this zone inhibited resin tag development. (Burrow et al., 2001) (Celiberti & Lussi, 2007) The histological appearance of demineralized enamel also has complexity because of the consequence from demineralized-remineralized process. A fluoride-rich acid-resistant mineral is formed on the surface of the pit-fissures-enamel caries lesion which reducing its porosity and increasing more resistant to subsequent acid challenges. In an in vivo study revealed that the surface of white spot carious lesion was apparently much more acid-resistant (at least approximately 2 times) than the areas of sound enamel. (Iijima & Takagi, 2000) When scanned with an electron microscope, the demineralized enamel that was etched by 30% phosphoric acid appears more elevated than surrounding sound enamel which suggests that it has a higher acid resistance. (Lee, Shey, & Cobb, 1995) This complex characteristic of pit-fissure-caries may also be an obstacle for the penetration of 37% phosphoric acid, the conditioner and sealant materials.

The retention rates of sealants placed on pit-and-fissures carious teeth were somewhat different in various clinical studies depended on sealant types, clinical criteria to assessing retention, and their research methodology.(Gibson & Richardson, 1980; Handelman, Leverett, Espeland, & Curzon, 1987; Soto-Rojas et al., 2012)

In vitro study of Paris and colleagues evaluated a comparison of the conventional resin-based sealant (fissure sealing) and the low viscosity resin (resin infiltration) penetration into the pit-fissures-caries lesions. The result revealed that conventional resin based sealant penetrated superficially into pit-fissures-caries lesions with ICDAS-code 2, while, low viscosity resins (resin infiltrants) were penetrated significantly deeper than that of conventional resin-based sealant. (Paris, Lausch, Selje, Dörfer, & Meyer-Lue, 2014) A recent study has investigated in vitro the tensile bond strength of resin-based sealant to enamel after a cariogenic challenge using three different boning protocols: etching only, total-etch adhesive, and a self-etching adhesive system. They concluded that the total-etch adhesive is significantly highest tensile bond strength with incipient enamel caries. (Kalra, Suprabha, Rao, Shenoy, & Lewis, 2015)

In this study, the researchers have been interesting in the long-term retention rates of resin-based sealant on pit and fissures enamel caries. As of today, there have no clinical study about using the bonding agent as an intermediate adhesive layer to improve the retention of pit and fissures caries sealing.

Objective

This research was a randomized clinical trial. The aim was to evaluate the retention of light curing resin-based sealant on pit-fissures enamel caries sealing with the placement of a single-component alcohol-based etch-and-rinse bonding agent as an intermediate adhesive layer.

Research question

The specific research question was: Is there a difference between the two techniques (the conventional technique of resin-based sealant VS the conventional technique plus with the placement of bonding agent as an intermediate adhesive layer) with regard to retention of sealant following its placement on pit-fissures- enamel caries of permanent molar teeth?

Research hypothesis:

H_0: The use of a bonding agent as an intermediate adhesive layer will not be statistically significant improves the retention rate of resin-based sealant on pit-fissures caries sealing.

($P_{test} = P_{control}$; P = complete retention of sealant)

H_1: The use of a bonding agent as an intermediate adhesive layer will be statistically significant improves the retention rate of resin-based sealant on pit-fissures caries sealing. ($P_{test} \neq P_{control}$; P = complete retention of sealant)

Research conceptual framework:

Population: Patients who attend to receive comprehensive dental treatment at pediatric dental clinic.

Sample: A patient who has a paired of permanent molars teeth with active and pit-fissures enamel caries (ICDAS code 2 or 3).

Independent variable: The technique of sealant placement.

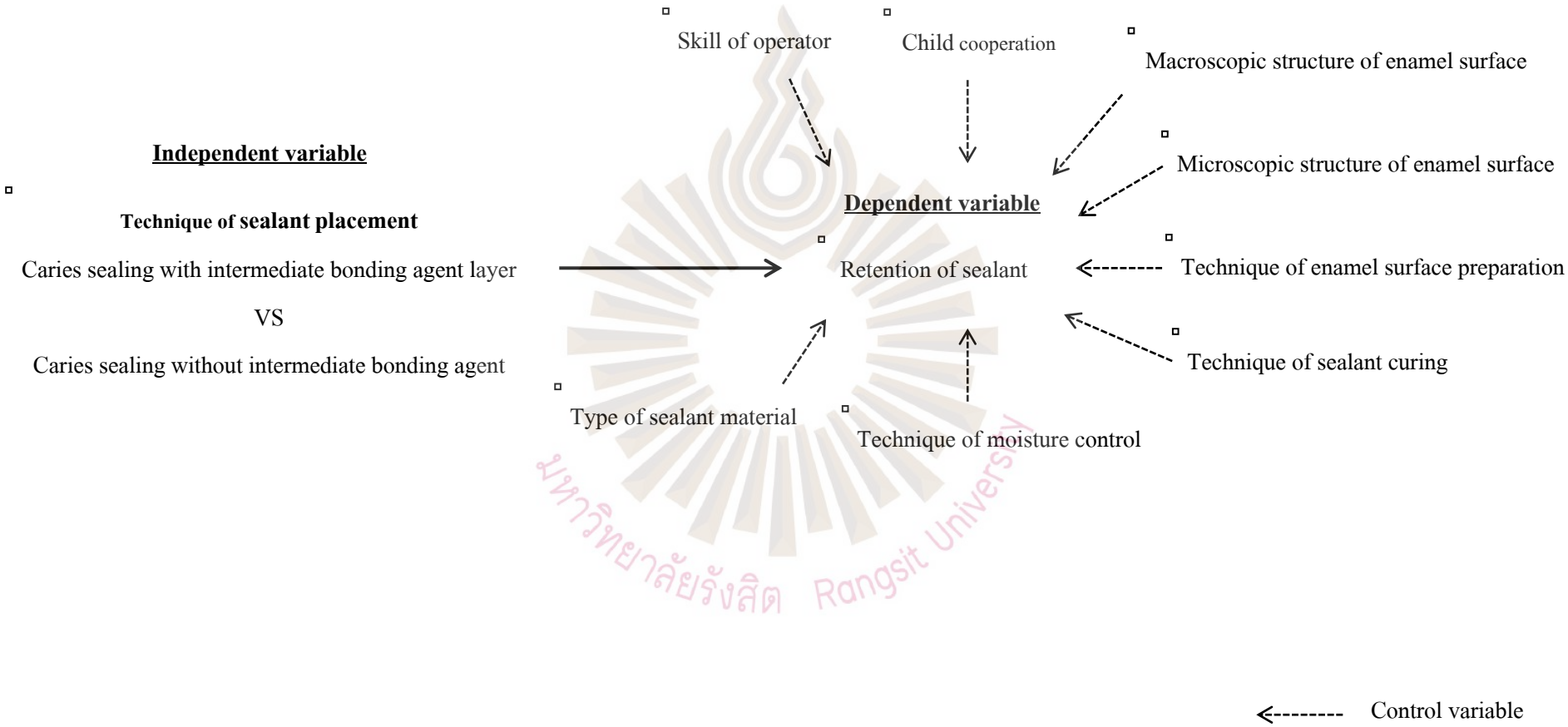
Dependent variable: The retention of sealant.

Interval of study: This research began on 1st January 2018 through 31st October 2018. First six-month clinical evaluation was examined and reported.

Expected benefits:

This research was a scientific data to support the pit-fissures caries management by improving the effectiveness of pit-fissures caries sealing technique.

Figure 1 Research conceptual framework



CHAPTER 2

REVIEW LITERATURE

1. Type of Sealant

In a meta-analysis, studied clinical retention of pit and fissures sealants in relation to observation time and material type. (Kühnisch et al., 2012) A total of 146 articles included information about sealant retention, with a minimum observation time of 2 years. These publications were analyzed to determine the retention rates of the various materials studied (UV-light-, light- and auto-polymerizing resin-based sealants, fluoride-releasing materials, compomers, flowable composites and glass-ionomer-cement-based sealants). As part of the systematic review, 98 clinical reports and 12 field trial reports were identified. Auto-polymerizing sealants had the longest observation time (up to 20years) and were found to have a 5-year retention rate of 64.7% (95%CI = 57.1–73.1%), which was estimated from the meta-analysis model. Resin-based light-polymerizing sealants and fluoride-releasing products showed similar 5-year retention rates (83.8%, 95%CI = 54.9–94.7% and 69.9%, 95%CI = 51.5–86.5%, respectively) for completely retained sealants. In contrast to these high retention rates, poor retention rates were documented for UV-light-polymerizing materials, compomers and glass-ionomer-cement-based sealants (5-year retention rates were <19.3%). Retention rates for UV-light-polymerizing materials, compomers, and glass- ionomer-cement-based sealants were classified as inferior.

According to the systematic review in 2006 revealed that visible- light sealants (83.8%), fluoride-releasing materials (69.9%), and auto-polymerizing sealants (64.7%) all had a good retention rate after 5 years. Based on an assessment of more recent studies, however, auto- and light-polymerizing materials appear to have a similar performance, but there may be a slight advantage of using light-polymerizing sealants. Indeed, the faster and less error-prone clinical application of light-polymerizing resin-based materials (i.e., immediate polymerization after application and reduced integration of air bubbles during the mixing procedure), makes them the preferred choice for daily dental practice.

Based on the present meta-analysis, we concluded that resin-based sealants (light and auto-polymerizing sealants and fluoride-releasing materials) can be recommended for clinical applications. Nevertheless, light-polymerizing resin- based sealants are preferable for daily practice because of their superior longevity and the low risk for errors during the procedure. Glass-ionomer-cement-based

sealants and compomers are associated with considerably lower retention rates than conventional resin- based sealants; thus, they are not recommended for routine clinical use in dental practice.

Resin-based sealants can be classified in a number of different ways, typically polymerization method, filled or unfilled, colored or clear, and color-changing upon polymerization and moisture tolerant. The majority of resin-based materials cure or polymerize by a free radical reaction with the reaction being initiated by a tertiary amine (the so-called chemically cured, auto curing or self-curing materials) or by initiating free radical generation with a visible light curing device. While there are certain differences in the properties of the cured resins and in clinical technique when using these two classes of material, both self-cure and light-cure sealants appear to provide equivalent clinical effectiveness when applied to etched dry enamel.(Simonsen, 1991)

In March of 1977, the first colored sealant (3M's Concise White Sealant) was introduced to the US market. There are clear advantages to a color as long as it is esthetically acceptable. It is easier to see the sealant during application, and it is much faster to assess retention with a white sealant than with a clear sealant at later time intervals. Also, documentation of retention is much easier over long time periods with a colored sealant.(Simonsen, 1991)

Sealant are often available as clear or opaque white. The advantages to an opaque sealant are that it is easy to see during application and easy to monitor its retention at a recall visit. Assessment of a clear sealant requires tactile exploration of the sealed surface. One study that examined the visibility to clear and opaque sealant found that the error rate for identifying and opaque sealant was less than 2% whereas for clear resin it was nearly 23%. Moreover, the most common error for the examiners was to incorrectly identify a clear resin sealant on a tooth that had not been treated. (Rock, Potts, Marchment, Clayton-Smith, & Galuszka, 1989)

Two newer material are available that have color properties. Clinpro (3M ESPE, St. Paul, Minn.) is a sealant that is pink upon application and turns white when cured. This color change provides no clinical advantage and has been describes as a "perceives marketing benefit." (Simonsen, 2002)

Sealant products come in a variety of material, visible light-polymerized, auto polymerizing, but these have largely been replaced by visible light-curing sealant. The benefits of light-cured versus chemical-cured sealants are the following: (1) the sealant material sets in 10-20 seconds versus 1 to 22 minutes; (2) no mixing of resin is required, eliminating the incorporation of air bubble; (3) the viscosity of the sealant remains constant during infiltration of etched enamel pores; and (4) the sealant material

does not set until it is light activated. However, studies have shown similar retention rate and similar strengths. (Ripa, 1993)

Pit and fissure sealants also can be classified as filled or unfilled, and the findings of clinical trials indicate that unfilled sealant performs better than filled sealants. (Barrie, Stephen, & Kay, 1990)Penetration, an important yet poorly recognized factor in sealant application and retention, is inversely proportional to the viscosity. Thus, it could be reasoned that an unfilled resin will penetrate deeper into the fissure system, and, therefore, perhaps be better retained. In a study comparing unfilled and filled sealant as well as gel or liquid etchant after the same time in the mouth, an unfilled light-cured resin was significantly better retained than a filled light-cured resin. The use of etchant in gel form was as effective as liquid etching.(Rock, Weatherill, & Anderson, 1990)

In a study of 58 children, half were sealed with PrismaShield (a filled sealant) (DENTSPLY Caulk, Milford, DE), and the others with the unfilled Concise White Sealant (3M ESPE, St. Paul, Minn), by a community dental service hygienist. In comparing PrismaShield and Concise after 2 years, 81% of PrismaShield sealant was completely retained, compared with 88% of the unfilled Concise White Sealant. (Barrie et al., 1990)

In addition to the aforementioned disadvantage of lack of equivalent penetration of the filled sealants (or flowable resins, as they are also called), another disadvantage is occlusal adjustment. Unfilled sealant will abrade rapidly, probably within 24 to 48 hours, if it is left in occlusion with an opposing cusp tip.(Simonsen, 1978)

2. The sealing pit-fissures-enamel caries by resin based sealant

In recent study 2017, Study of sealants for preventing and arresting pit-and-fissures occlusal caries in primary and permanent molars. (Wright et al., 2016)

The purpose of this review was to summarize the available evidence regarding the effect of dental sealants for the prevention of pit-and-fissures occlusal caries in primary and permanent molars on children, adolescents, and adults from the general population who did or did not have a history of carious lesions and who had either a sound occlusal surface or a noncavitated carious lesion in primary and permanent molars compared with a control without sealants, with fluoride varnishes, or with another head-to-head comparison. For studies in this review are parallel and split-mouth randomized controlled trial (RCTs). Effective of intervention by comparison of sealant versus nonuse of sealalnt. For the 2- to 3-year follow-up, participants who received sealants reduced their risk of developing new

carious lesions by 76% (odds ratio [OR], 0.24; 95% confidence interval [CI], 0.19-0.30; P < .00001) and follow-up in 4-7 year to participants who received sealants had a reduction in the risk of developing new carious lesions by 79% (OR, 0.21; 95% CI, 0.10-0.44; P < .0001) and follow up of 7 or more years, participants who received sealants had a reduction in the risk of developing new carious lesions by 85% (OR, 0.15; 95% CI, 0.08-0.27; P < .00001) These follow up have compared with participants who did not receive sealants.

In a recent meta-analysis that examined the effectiveness of sealant in preventing progression of carious lesion found that the mean annual percentage of non cavitated lesions that has been sealed and still progressed was only 2.6% versus 12.6% of unsealed early, noncavitated lesions.(Griffin, Oong, et al., 2008)

Mertz-Fairhurst and coworkers published a classic study in 1998 in which they examined the cariostatic effect of seal restorations after 10 years. One of the treatment groups included teeth with frank, cavitated lesion in which the only preparation provided was placing a 1-mm wide bevel in sound enamel around the margin of lesion.The carious tooth structure was not removed. The teeth was restored with the following technique: etch,prime,bond,place composite, and then place sealant over the restoration. Of the 85 teeth available for follow-up at 10 years, only 12 of these teeth had failed. Although this article does not advocate sealing over frank, dentinal caries, it does highlight the power of the coronol seal. (Mertz-Fairhurst et al., 1998)

Review of evidence-based clinical recommendation for the use of pit and fissure sealant (Beauchamp et al., 2009) In data from 2004, 42% of children and young adults aged 6 to 19 years had dental caries (decayed or filled) in their permanent teeth.

Evidence regarding sealants for caries prevention. Placement of resin-based sealants on the permanent molars of children and adolescents is effective for caries reduction. Sealants are effective in reducing occlusal caries incidence in permanent first molars of children, with caries reductions of 76.3% at 4 years, when sealants were reapplied as needed. (Beauchamp et al., 2009)

Conclusion of evidence-based clinical recommendation for the use of pit and fissure sealant can be used effectively apprroach to prevent primary caries , the sealant also are an effective secondary prevention and sealant placement over early (noncavitated) lesion.

Review of the effect of dental sealants on bacteria levels in caries lesion that examine the effects of sealants on bacteria levels within caries lesion under dental sealants of permanent molar. Method uesd to measure the effect of sealants on bacteria levels, they used the log10 reduction in mean total

viable bacteria counts (= log10 mean VBC_{SEALED} – log10 mean $VBC_{NOTSEALED}$, where a log10 mean VBC value of 6 equals 1 × 106 , or 1,000,000 CFU) between sealed and not-sealed caries and the percentage reduction in the proportion of samples with viable bacteria counts greater than zero. To measure activity for total bacteria, Streptococcus mutans and lactobacilli as primary cariogens in pit-and-fissure caries ad whether the difference in meanVBC for sealed and unsealed teeth was significant ($P < .05$). (Oong et al., 2008)

In conclusion that sealants significantly reduced bacteria level in carious lesion (cavitated lesion).These finding support those of recent meta-analysis that sealants prevented caries progression and found that when sealants are retained, and thus access to fermentable substrates is blocked, bacteria do not appear capable of exerting their cariogenic potential.

Review of the effective of sealants in managing caries lesion. This meta-analysis examined the effectiveness of sealants in preventing caries progression in sealed permanent teeth. This study used a random-effects model to estimate percentage reduction in the probability of caries progression in sealed vs. unsealed carious teeth. In vivo studies that compared caries progression or bacteria levels in permanent teeth that did and did not receive sealant. The annualized progression rates for cavitated lesions would be 19.4% (sealed) and 59.3% (not-sealed). The percentage of noncavitated lesions progressing would be 2.6% (sealed) and 12.6% (not-sealed). Alternatively, if we classified all teeth in the Going study as non-cavitated, then the median annualized progression rates for non-cavitated lesions would be 2.9% (sealed) and 13.6% (not-sealed), respectively. Another RCT found that the mean depth change in caries lesions was significantly lower in the sealed group than in the not-sealed group (Griffin, Oong, et al., 2008)

3. Factors related to retention of sealant

Factors related to sealant retention were reported in many clinical studies which included the cleaning and dryness of tooth, the technique of moisture control, the etching system and technique, cooperation of a patient and position of teeth in mouth.

The cleaning and dryness of tooth, many studies have looked at different methods of enamel surface preparation prior to acid etching and sealant application. The accepted application technique for pit and fissure sealant application in the early years consisted of cleaning the enamel surface to be treated with a pumice and water mixture using a rotary brush. Some operators would simply use a pointed dry bristle brush, perhaps followed by dragging an explorer tine through the fissure anatomy,

rather than using any pumice (avoiding any fluoride or oil-based commercial pumice, paste and dentifrices mix so as not to leave any oily residue on the enamel surface which may hinder etching of the enamel surface and their possible effect on the bond strength between the etched tooth surface and sealant material).

In one study, split-mouth design that the teeth had been cleaned using a brush attached to a rotary instrument with fluoridated prophy paste, versus dry brushing. A the tooth-cleaning technique of dry brushing with a toothbrush as a preparatory step in the sealant procedure yielded high clinical sealant retention at 12 months. This retention was comparable to that observed with rotary instrumentation. Dry brushing with a toothbrush may be an equivalent alternative to mechanical cleaning with prophylactic paste. This absence of significant difference of retention rate between the two study groups could be due to the cleaning effect of acid etching prior to sealant application. (Gillcrist, Vaughan, Plumlee, & Wade, 1998) A double-blind clinical trial study that comparing mechanical cleaning using pumice with no cleaning does not have any clinical interest because it was proved that both have negative effects on bonding. (Donan & Ball, 1988)

In a recent systematic review of controlled clinical trials that compared surface cleaning methods directly (surfaces cleaned with a handpiece and prophylaxis brush with pumice, compared to surfaces cleaned simply by running an explorer along the fissures and cleaning with an air-water syringe) found no difference in sealant retention. (Muller-Bolla et al., 2006) Similarly, in a comparison of the effects of supervised toothbrushing versus handpiece prophylaxis on the retention of sealants. A review considering the best available evidence compared two surface-cleaning methods and found no difference in long term (five-year) sealant retention, as least higher rates of retention were evident in the toothbrush prophylaxis groups at the end of the first year after sealant placement. In the first study, researchers found no difference in retention of sealants between surfaces cleaned mechanically with pumice and those cleaned with air-water spray and a probe. In the other study, there was no difference in retention between surfaces mechanically cleaned with prophylaxis paste on a handpiece and those cleaned by dry brushing. Gray et al. showed that a supervised cleaning by the patient was at least as effective in terms of retention of the sealant as a traditional handpiece prophylaxis. (Gray, Griffin, Malvitz, & Gooch, 2009) It is possible that some prophylaxis pastes marketed in the 1970s and 1980s contained oils or other substances that interfered with bonding. It also is possible that residual paste or pumice within pits and fissures after prophylaxis and etching could reduce retention of sealants. (Buonocore, Matsui, & Gwinnett, 1968)

The technique of moisture control, the isolation of the tooth from contamination by saliva is one the most important aspects of sealant placement because the total clinical procedure corresponds to a technique which is sensitive in that saliva contamination after the acid etching stage prevents the formation of tags and thereby the mechanical retention of the resin. (Locker, Jokovic, & Kay, 2003)

In one study of pit-and-fissure sealant was applied to 523 teeth in school children using either cotton rolls or a VacEjector for isolation. After a minimum of six months, the patients were recalled and the retention of the sealants was evaluated. No significant difference in sealant retention was found between the two isolation methods. (Wood, Saravia, & Farrington, 1989) A four year clinical trial study was to evaluate the retention of fissure sealants, cotton rolls isolation versus rubber dam isolation with cleaning of occlusal surface using a bristle brush showed the following success rates of full retention 81% and 91% cotton rolls or rubber dam and there was no statistically significant difference. (Lygidakis, Oulis, & Christodoulidis, 1994) Maintenance of a dry field is much simplified with a four-handed procedure, but a technique using a combined mouth prop, light source and high-volume suction device as a preventive procedure to prevent sealant failure. A study by Griffin et al. had examined four-handed delivery of sealants determined that it is associated with an increased retention rate. In comparison to two-handed dentistry, four-handed delivery is associated with a 9% increase in the retention rate. (Griffin, Jones, Gray, Malvitz, & Gooch, 2008)

Moreover, the study of sealant retention in the 49 paired sites after 6 months. Complete retention was observed in 32 or 65% of the sites sealed with rubber dam and in 34 or 69% of the sites sealed using the cotton roll technique. The paired sites sealed using cotton roll technique showed better retention than when a rubber dam. The difference in retention between the two techniques was not statistically significant when tested using McNemar's test for paired observations. Thus, the use of rubber dam when sealing pits and fissures in primary molars of pre-schoolchildren does not appear to increase sealant retention. Equally good results were obtained with the careful use of cotton roll and saliva ejector for moisture control. (Poulsen & Peltoniemi, 1979)

The majority of sealant application involves strict attention to detail and dry field isolation throughout the procedure. Although practitioners admit that rubber dam isolation is best, they do not use this type of isolation (i.e., a survey of over 1,000 pediatric dentists found that they preferred cotton roll isolation over a rubber dam). Obvious disadvantages of the rubber dam isolation are discomfort during a dam clamp placement, the need for a local anesthetic, difficulty in placing a clamp onto a partially erupted tooth, and an increase in the cost and need for sterilization of the armamentarium.

Moreover, clinical studies comparing isolation using either a rubber dam or a cotton roll found no differences in sealant retention and caries : thus, proper isolation with cotton rolls should be adequate in sealant placement. The choice of cotton roll over rubber dam isolation will also lead to better patient management and saves time. To ensure the quality of the cotton roll isolation and of overall performance in sealant placement in community settings, four-handed dentistry is needed, so students should work in pairs. (Aleksejuniene, Brondani, Pattanaporn, & Brukiene, 2010)

The etching system and technique, a recent systematic review concluded that the retention rate of sealant placed on occlusal surfaces following the use of self-etching system show lower retention rate than sealant applied in the etch-and-rinse system. (Botton et al., 2016) The etch-and-rinse system is the goal standard for the application of resin-based-sealant. Previous studied have shown etching times of 15 seconds for the etch-and-rinse technique is sufficient to produce the required etch-pattern for bond strength of resin-based sealant and the usual recommendation for rinsing is 20 to 30 seconds. (Tendon et al., 1989) However, the exact rinse time is probably not as important as ensuring that rinse is through enough to remove all of the etchant from the surface. (Waggoner & Siegal, 1996) The aim of this study was to evaluate the effect of saliva contamination and re-etching time. There were no significant differences between all tested groups ($p>0.05$); therefore, the tested hypothesis must be accepted. Contamination for either 30 or 60 seconds did not affect the bond strength of the sealant to enamel, regardless of the re-etching procedure. When enamel was contaminated for 30s, there was a tendency of the bond strength to return to control values when re-etching was performed for 5 or 15 seconds. Such tendency was not observed when enamel was contaminated for 60s. (Mascarenhas, Nazar, Al-Mutawaa, & Soparkar, 2008)

Cooperation of a patient, the purpose of this 10-year, retrospective, cohort study was to evaluate the success of permanent molar sealants. Cumulative survival probability for 10 years in this practice was 87%, using Kaplan Meier analyses. The factors associated with an increased risk of failure included: age (P<.001); dmft (P<.003); no fluoride (P<.001); dentist (P<.001); and registered dental assistant (P<.001). Behavior showed a slightly higher risk of failure that approached significance. Age and dmft were highly significant, with slight increased risk of failure. (Folke, Walton, & Feigal, 2004 Sep-Oct) Interestingly, the assess the clinical benefits of this sealant program by comparing caries experience of a group of participants and nonparticipants and evaluate the retention rates of occlusal sealants in children. The patient's age at the initial visit appeared to be the only factor that influenced retention and children who participated in the sealant program had significantly lower (P<.016)

permanent first molar DMFT scores than children who did not participate in this public health program. (Dorantes et al., 2005 May-Jun)

A randomized clinical trial of an adhesive bonding agent increases the retention of resin fissure sealants on first permanent molars, the effect of the child's behavior on the retention of the sealants was also assessed. Results showed that the higher the participant's behavior score (Frank Behavior Rating Scale), the greater number of intact sealants recorded at 12 months and behavior of the patient significantly affected the retention of fissure sealants (P = 0.0001). The majority of children (94%) had a behavior score of four and were very cooperative. Children with behavior score of three had lower sealant retention (67%), and the two participants with behavior score of two had only 25% sealants intact after 1 year. (McCafferty & O'Connell, 2016)

The position of teeth in mouth. The study of the half-mouth technique, a pit and fissure sealant was applied to the permanent first molars of 200 children between 6 and 8 years of age. Complete retention of sealant at 12, 24, and 36 months after application was 91.6%, 88.9%, and 87.5%, respectively. Partial retention of sealant was 5.8%, 7.1%, and 8.5% at the same intervals. Total loss of sealant was 2.5% at 12 months and 4.0% for both 24 and 36 months. No statistically significant difference in complete retention, partial retention and total loss retention between maxillary and mandibular molars was noticed at 12, 24 and 36 months. (McCune, Bojanini, & Abodeely, 1979 Oct)

4. Adhesive system

The fundamental principle of bonding to enamel and dentin is essentially based on an exchange process, in which minerals removed from dental hard tissues are replaced by resin monomers that upon polymerization become micromechanically interlocked in created porosities. (Meerbeek, Landuyt, & Munch, 2006; Meerbeek et al., 2003) This process involves two phases. One phase consists of removing calcium phosphates by which microporosities are exposed at both enamel and dentin. Then the hybridization phase involves infiltration and polymerization of resin within the created surface microporosities. This results is micro-mechanical interlocking and believed to be a prerequisite to get good bonding, the potential benefit of additional chemical interaction between functional monomers and tooth substrate components has recently gained new attention. (Meerbeek et al., 2003)Without doubt, this micromechanical interlocking of multiple, tiny resin tags within the acid-etched enamel surface are still today provides the best achievable bond to enamel.(Meerbeek et al., 2003) It not only

effectively seals the restoration margins in the long term, but also protects the more vulnerable bond to dentin against degradation.

Despite the major difference in the manner of etching between etch-and-rinse and self-etch adhesives, the other fundamental steps for adhesion, namely the 'priming' and actual 'bonding' phase, can be either separate or combined. (Munch et al., 2003) Etch-and-rinse adhesives require either two or three steps depending on whether the primer and bonding agent are separated or combined in a single bottle. Similarly, self-etch adhesives can be either one- or two-step systems depending on whether the self-etching/primer solution is separated from the bonding agent or combined with it. (Meerbeek & Yoshida, 2013) The latter enables a single application procedure of a so-called 'all-in-one' adhesive.

Etch-and-Rinse approach technique still most effective approach to achieving efficient and stable bonding to enamel. However, dentin etching exposed network of collagen that is nearly completely demineralized of hydroxyapatite (calcium phosphates) should be considered. Most critical in this technique is step of primer. When an acetone-based adhesive is used, the highly technique-sensitive "wet-bonding" technique is mandatory (Tay &others, 1996). Otherwise, gentle post-conditioning air-drying of acid etch dentin (and enamel) following a "dry-bonding" technique still guarantees effective bonding when a water/ethanol-based adhesive is used (Van Meerbeek & others, 1996, 1998).

From the traditional three-step etch-and-rinse adhesives, simplified two-step adhesive have been developed that combine the primer and the adhesive resin into one single solution. Despite presenting a more friendly technique, these simplified adhesives tend to perform in an inferior manner when compared to their three-step counterparts. (Cardoso et al., 2011)

Self-etch approach is different from their etch-and-rinse counterparts, self-etch adhesives do not require a separate etching step, as they contain acidic monomers that simultaneously etch and prime the dental substrate. Due to such acidic characteristics, self-etch adhesives are able to dissolve the smear layer and demineralize the underlying dentine/enamel. (Tay, Sano, Carvalho, Pashley, & Pashley, 2000)

It no longer needs an etch and rinse phase, which not only decrease clinical application time, but also significantly reduce technique-sensitivity or the risk of making errors during application and manipulation. Another important advantage of the self-etch approach is that infiltration of resin occurs simultaneously with self-etching process, by which the risk of discrepancy between both processes is low and non-existent. However, the long-term effects of incorporating dissolved hydroxyapatite crystals and residual smear layer remnants within the bond. The resultant interfacial structure also becomes

more hydrophilic and more prone to hydrolytic degeneration (Tay & others, 2002a; Tay, Pashley & Yoshiyama, 2002b). This technique involves either two- or one-step application procedure. The self-etch effect should be associated with to monomers to which one or more carboxylic or phosphate acid groups are grafted (Van Meerbeek & others, 2001a).

5. Retention and effectiveness of dental sealant

The clinical effectiveness of a colored pit and fissure sealant at 36 months was show the complete retention for permanent teeth was 94.4% and for primary teeth, 94.6%. There is no difference in retention was found when the etch time for primary molars was varied (60 or 120 seconds). The sealant used was found for protecting occlusal, buccal, and lingual pits and fissures against caries. The white color of pit and fissure sealant in which produce by the addition of 1% titanium dioxide gives this sealant several advantages to be visually confirmed at application and easily checked on recall (Simonsen, 1980)

Another study of 5 years retention and effectiveness of a single application of an adhesive sealant in preventing occlusal caries in Kalispell, Montana. They used single applications of and pit and fissure adhesive sealant and were made to the teeth and five years later, it has been reported that 42% of the sites initially sealed retained all the sealant. However, 93% of the sites from which sealant was only partly lost were free of caries. These findings show that when the sealant is partly or totally retained, it is effective in preventing caries. (Horowitz, Heifetz, & Poulsen, 1977)

However, in the clinical study of 15 years of pit and fissure sealant retention rate found that one of the study reported of about 80 percent of the sealed pit and fissures sealant retention over 10 years and no caries was found. (Simonsen, 1987) (Wendt & Koch, 1988)

The study of retention and effectiveness of dental sealant in clinically assesses in the long term period of 15 years after single application of a colored pit and fissure sealant to four permanent first molar in children. The report status of a test and control group of children 15 years after a single application of pit and fissure sealant and the other group without sealant application on all permanent first molars, was retrospectively being selected on the basic of age, gender, fluoridated residence living area and a health plan membership. The group of 200 patients was randomly selected, who received pit and fissure sealant at Group Health Medical Center in Bloomington, Minnesota, between Feb. 1and Aug. 31,1976. The material being used was auto cured Concise White Sealant (3M Company, Dental Products Division) by a single operator and one trained assistant in a fully equipped operatory room.

(Radike, 1968)

Complete retention. This category did not analyze the amount of sealant wear as all sealants will show wear after 15 years in vivo. If some areas were uncovered as a result of sealant wear, the sealant could still be classified as completely present, if no sealant bulk loss were present. But if any pit or fissure was exposed as a result of sealant wear or loss, it could not be classified as completely present.

Partial retention. The sealant is present, but as a result of either wear, or loss of the material, in the part of a previously sealed pit or fissure, or both, has been exposed.

Missing. No trace of sealant can be detected. For the maxillary molars, the palatal, occlusal (distal) and occlusal (mesial) surfaces were analyzed separately. For the mandibular molars, the occlusal surface was examined. Buccal surfaces of mandibular molars were not scored because many of the surfaces were smooth and difficult to assess. Even if sealant had been applied, many surfaces would not fit into the partially present category as no pits or fissures were exposed.

In conclusion, fifteen years after the single application of the sealant, it was completely retained at 15 years on 27.6 percent and 35.4 percent partially retained. None of the partially retained sealant surfaces were carious. The sealant was completely missing on 10.9 percent of the surfaces, and 26 percent of the surfaces either had been restored or were carious. The comparison of sealant group and a group without sealant shows that the 15 years after the single application of a pit and fissure sealant, only 31.3 percent were carious or restored. In the group without sealant, 17.2 percent of the surfaces were sound, whereas 82.8 percent were carious or restored.

In assessing sealant retention in this study was majority depend on the advantage of the white color resin sealant. This color makes sealant retention easier to assess and and possibility of accurate documentation of sealant retention over time to the use of photographs. The sealant was safe and effective despite only with the study of one application at the beginning of the 15-year trial period. Thus, in routine dental health care, multiple applications or reapplied of fit and fissure sealant in partial loss of sealant would suggests the 100 percent caries prevention in pit and fissure surfaces. (Simonsen, 1987)

6. Effect of bonding agents on the retention and microleakage of resin-based sealants

A systematic review and meta-analysis have shown that the use of adhesive systems beneath fissure sealants can increase the retention of fissure sealants. Furthermore, compared to other adhesive systems, the use of etch-and-rinse systems are preferable.(Bagherian et al., 2016)

Hitt and Feigal 1992 were the first to report the benefit of adding an adhesive system between etched enamel and sealant as a way of optimizing bond strength in the presence of moisture and salivary contamination. Their study investigated bond strength in vitro, when a bonding agent was used beneath sealants under varied conditions of contamination. Under conditions of humidity or intact saliva, sealant alone showed a significant reduction in bond strength ($P < 0.001$).(Hitt & Feigal, 1992)

Boksman and colleagues 1993 found that sealants used with a bonding agent had a higher retention rate at 6 months but did not have an increase in retention rate after two years, compared to sealants alone. (Boksman 1993) On the contrary, the two-year clinical study by Feigal et al. 1993 supported the use of primer and bonding under sealant to enhance sealant retention. Even on enamel contaminated by saliva, the retention of sealant used in conjunction with two component etch-and-rinse bonding agent (Scotchbond ^{TM}) was better than sealant alone on dry enamel.(Feigal et al., 1993)

Moreover, Hebling and Feigal 2000 studied the influence of three different adhesives (Scotchbond™ Universal DCA, Single bond^{TM}, Prime&Bond 2.1^{R}) as an intermediate layer between sealant and saliva-contaminated enamel. This study evaluated the reduction of sealant microleakage under a stereomicroscope and scanning electron microscope. Sealants placed on contaminated enamel with no bonding agent and air drying showed the most extensive microleakage (94.27%). Conversely, all bonding agent groups showed less than 6.79% leakage, which is a significant reduction in microleakage ($P<0.0001$).(Hebling & Feigal, 2000)

Nogourani and colleagues 2012 found that 2-step etch-and-rinse adhesive system (fifth generation) and both one and two step self-etching adhesive systems (sixth generation) increased the success rate of fissure sealant retention in a one-year clinical study of newly-erupted maxillary molars. The results supported the use of these two bonding agents in pit-and-fissure sealants under both isolated and contaminated conditions. Furthermore, the study found that self-etch systems seemed less sensitive to moisture contamination.(Nogourani, Janghorbani, Khadem, Jadidi, & Jalali, 2012)

Bhat and colleagues 2013 clinically evaluated sealant retention and development of caries in moisture-tolerant resin-based sealant, conventional resin-based sealant with and without a bonding agent, and Glass Ionomer Cement Sealant in young permanent teeth over a period of one year.

Conventional resin-based sealant used in conjunction with a bonding agent performed the best having the least dislodgement of sealant and no evidence of caries. Its performance was followed by moisture-tolerant resin-based sealant, conventional resin-based sealant, and Glass Ionomer sealant, respectively. The difference in the mean scores between the four groups was found to be statistically significant ($P < 0.001$) (Bhat, Konde, Raj, & Kumar, 2013)

Mc Cafferty and O' Connell 2016 found that the addition of an ethanol-based, fifth-generation adhesive system beneath fissure sealants significantly increased the retention of sealants. The main finding of this study was the statistically significant improvement in retention of an ethanol-based bonding agent compared to conventional sealants in first permanent molars at one year ($P=0.0005$). (McCafferty & O'Connell, 2016)

In 2013, Karaman and colleagues found that the retention rates for sealants in the Solobond M two-step etch-and-rinse adhesive group were significantly higher than those in the Futurabond NR one-step self-etch adhesive group in forty-eight months of evaluation ($p<0.05$). (Karaman et al., 2013)

From a randomized control clinical trial of Aman and colleagues 2015 also compared total-etch adhesive to self-etch (seventh generation) adhesive in sealant retention after 6 months. The result showed a significant difference ($P<0.001$) where a higher proportion of complete retention was seen in total-etch (Odds ratio=3.7). (Aman, Khan, Salim, & Farid, 2015)

Apart from the study in normal enamel, Lygidakis and colleagues 2009 evaluated the retention rate of fissure sealants applied to hypomineralised molars (MIH) with occlusal enamel opacities, using a single bottle adhesive system (One-step) versus using the conventional etch and seal technique after 4 years. It appears that the highest retention rate was found in the two-step etch and rinse single-bottle adhesive system (fifth generation) with a 70.2% full retention rate after the 4-year period, while no fissure sealant was completely lost on any samples. (Lygidakis et al., 2009)

Because of the extent and depth of the etching pattern should influence the bonding performance of an adhesive, as enamel bonding is primarily based on micromechanical interlocking of a low-viscosity resin into microporosities.(Hannig, Bock, Bott, & W, 2002) However, the depth of the enamel surface removed during the etching procedure can be affected by many factors, such as the type and concentration of acid, the duration of etching, and the chemical composition of the surface. (Bates, Retief, Jamison, & Denys, 1982) It has been demonstrated that the application of a one-step self-etch adhesive did not create a deep enamel etching pattern compared to those of phosphoric acid. Moreover, the hydrophilic monomers present in the bonding agents increase the surface wetting and resin

penetration. Thus, the use of etch-and-rinse single component alcohol-based bonding agent placement before sealant application appears to be the most appropriate bonding agent in maximizing the retention of sealant.

CHAPTER 3

RESEARCH METHODOLOGY

This research was approved by the Research Ethics Committee, Research Institute of Rangsit University, Thailand. Written, informed consent obtained from guardians prior to the study. All subjects were recruited from regular patients attending the pediatric dental clinic of Rangsit Dental College.

Subjects, participants, and intervention

Sample selection

Inclusion criteria

1. A child patient who had paired, fully erupted, maxillary or mandibular permanent molars with pit-fissures-enamel caries. All pit-fissures-caries lesions were classified as ICDAS-code 2 up to ICDAS-code 3 and active lesions following the International Caries Classification and Management System(ICDAS, 2017): *(As shown in figure A)*
   - *ICDAS-code 2* is the distinct visual changes in enamel seen as a carious opacity or visible discoloration (white spot lesion and/or brown carious discoloration) not consistent with clinical appearance of sound enamel and which show no evidence of surface breakdown or underlying dentine shadow.
   - *ICDAS-code 3* is a white or brown spot lesion with localized enamel breakdown, without visible dentine exposure or an underlying dentine shadow.
   - Signs of active lesions of enamel caries have been described as surfaces of enamel are whitish/yellowish and opaque with loss of luster, feeling rough when the tip of the ball-ended probe is moved gently across the surface. Lesions are in plaque stagnation area.
2. A child patient who was able to cooperate for sealant procedure.

Exclusion criteria

1. A permanent molar tooth with distinct cavity or discolored enamel with underlying dentine shadow.
2. A permanent molar tooth with other enamel defects such as hypominerlized enamel, amelogenesis imperfecta, erosion, and fluorosis.
3. A child who tended not to be sufficiently cooperative to allow sealant placement.
4. A child patient with known acrylate allergies.

Sample recruitment and assignment

A randomized split-mouth study design was used. The cooperative patients present of paired (contra-lateral), fully erupted, maxillary or mandibular permanent molars with the same ICDAS-code and location of pits-fissures-caries was selected for pits-fissures-caries sealing by an experienced pediatric dentist. Two bitewing radiographs were obtained and interpreted for the diagnosis of no radiographic signs of dentinal caries. Each paired of samples was exposed to the same environment and similar occlusal force.

Location and ICDAS-code of caries lesions were recorded on a data collection sheet and the type of intervention on each sample was also recorded. *(As shown in Appendix A)*

The matching arch-paired permanent molars were randomly assigned to receive a bonded sealant placement (test group) or a conventional sealant placement (control group). Left molar was always the first tooth for sealant placement. Randomization of the technique of sealant placement was carried out using a coin toss by the research assistant on the day of treatment.

Operators

One experienced pediatric dentist and well-trained four-handed-sealant performing dental assistants performed sealant treatment to all subjects.

Intervention regarding with the technique of sealant placement

1. **Cleaning pit and fissures system:** all surfaces of permanent molars were thoroughly cleaned with a dry bristle rotary brush *(As shown in figure B)* to remove plaque and debris from pit-fissures-system. Rinse thoroughly with water.
2. **Moisture control:** Isolation of the permanent molars were achieved by 2x2 gauze rolls *(As shown in figure C)* and four-handed dentistry technique with saliva ejection device and high volume evacuation. The pit and fissures of the tooth were dried with oil and water free air for 5 seconds to remove water and saliva.
3. **Enamel surface conditioning:** 37.5% phosphoric acid ***(Kerr Gel Etchant™****, as shown in figure D)* was applied to the pit and fissures surface of each tooth for 15 seconds with microbrush. *(As shown in Figure E)* Thoroughly rinse with air/water spray to remove etchant. Remove rinse water with suction. If saliva contacts the etched surface, re-etch for 5 seconds

and rinse. Thoroughly dry etched surface with clean, oil-free air. The dry etched enamel surfaces should appear as a matte frosty white.

4. **Sealant placement:**

   - **Control group (conventional caries sealing)**: after etching enamel surfaces of the teeth in control group, they were immediately applied with opaque unfilled visible light-curing resin-based sealant *(**3M ESPE Clinpro™**, as shown in figure F)* using a micro-brush. Stirring the sealant with the micro-brush during sealant placement to eliminate any possible bubble. Cure the sealant by exposing it to visible light (wave length 450-470 nanometers) from a light curing unit *(**Demi plus model, Kerr™**, as shown in figure G)*. A 20 seconds exposure needed for each surface. The tip of the light was held as closely as possible to sealant, without actually touching the sealant. When set the sealants formed a hard, opaque film, off-white in color with a slight surface inhibition. The thin sticky films on the surface of sealants were wiped with a moist cotton pellet. Occlusion was checked and adjusted as required by a using the cured resin finisher *(**Enchance™**, as shown in figure H)*

Test group (bonded caries sealing): the teeth in study group had an adhesive layer of bonding agent *(**OptiBond™ Solo Plus, Kerr**, as shown in figure I). OptiBond™ Solo Plus* was used in this study which is low viscous fluid nonvolatile monomer and has barium glass filler particle incorporated. The specific monomer is 2-Hydroxy ethyl methacrylate, dissolved in ethanol solvent.(Cardoso et al., 2011) According to the guide for using of OptiBond™ *Solo Plus* adhesive system has recommended that uncured monomer may cause contact dermatitis. Person should avoid contacting with skin, eyes, and soft tissue. In case of contact with skin or eyes, wash thoroughly with water. There were two well designed clinical studies that ethanol solvent based bonding agent, as part of or under sealant. The hazards were not reported from these studies(Feigal et al., 2000; McCafferty & O'Connell, 2016). OptiBond™ Solo Plus was applied to the etched enamel surfaces with a microbrush for 15 seconds using light brushing motion. The bonding agent was thinned out by using an air syringe for 3 seconds. Photopolymerization was done for 5 seconds. Sealants *(**3M ESPE Clinpro™**)* were immediately applied through pit and fissures system. The applied sealants were cured for 20 seconds. *(As shown in figure J)* Individual light-curing of the intermediate bonding agent layer and the sealant was applied following the protocol of a previous study. (Torres et al., 2005)

CHAPTER 4

RESULTS

Baseline data

The study flow diagram was shown in figure1. A total of 40 subjects were recruited to this study, 21 were male and 19 were female. The mean age of subjects was 11 years 3 months (range = 7 years 8 months - 16 years 8 months). Thirty-two and 8 subjects had one pair and two pairs of permanent molars with the same ICDAS code and location of pit-and-fissures enamel respectively. All caries lesions did not show radiographically dentinal caries.

Forty-eight pairs of permanent molars with pit-and-fissures enamel caries that classified as ICDAS code 2 or 3 were sealed with a resin-based sealant by a well experienced operator. The mode of ICDAS code was 2. Twenty-nine pairs were maxillary teeth and 19 pairs were mandibular teeth. Forty-eight test teeth sealed with using bonding agent as intermediate adhesive layer; 48 control teeth sealed without using bonding agent.

Sealant retention at first 6-month-review

The mean time between placement and review was 6 months 30 days (range = 5 months 29 days - 8 months 3 days).

Two subjects who had one pair of caries sealed teeth (4 teeth) failed to attend follow-up. The remaining 38 subjects with 92 caries sealed teeth were reviewed at 6 months and included in statistical analysis. Good intra-examiner and inter-examiner agreement was achieved (Kappa's coefficient of 0.80).

At the 6-month-review; 64.13% of all caries sealing teeth included sealant placed with bonding agent and sealant placed without bonding agent were completely sealed. 35.86% of which were incompletely sealed. Caries sealed teeth in test group (sealant placement with bonding agent) presented a better retention, 93.48% were completely sealed and 6.52% were incompletely sealed. Control group (sealant placed without bonding agent) showed 34.79% were completely sealed and 65.21% were incompletely sealed (Chart 1). There were thirty-three previously caries sealed teeth were categorized as incompletely sealed teeth. There was a previously caries sealed tooth with incompletely sealed that showed the caries progression. This caries progressive tooth was managed by a minimal restoration.

The results in the retention of sealant placed on pit-and-fissures enamel caries between bonded sealing and conventional sealing were shown in Table 1. These results were analyzed by McNemar test using IBM SPSS software, version 20 and revealed statistically significant (p=0.00).

Figure 2 The study flow diagram

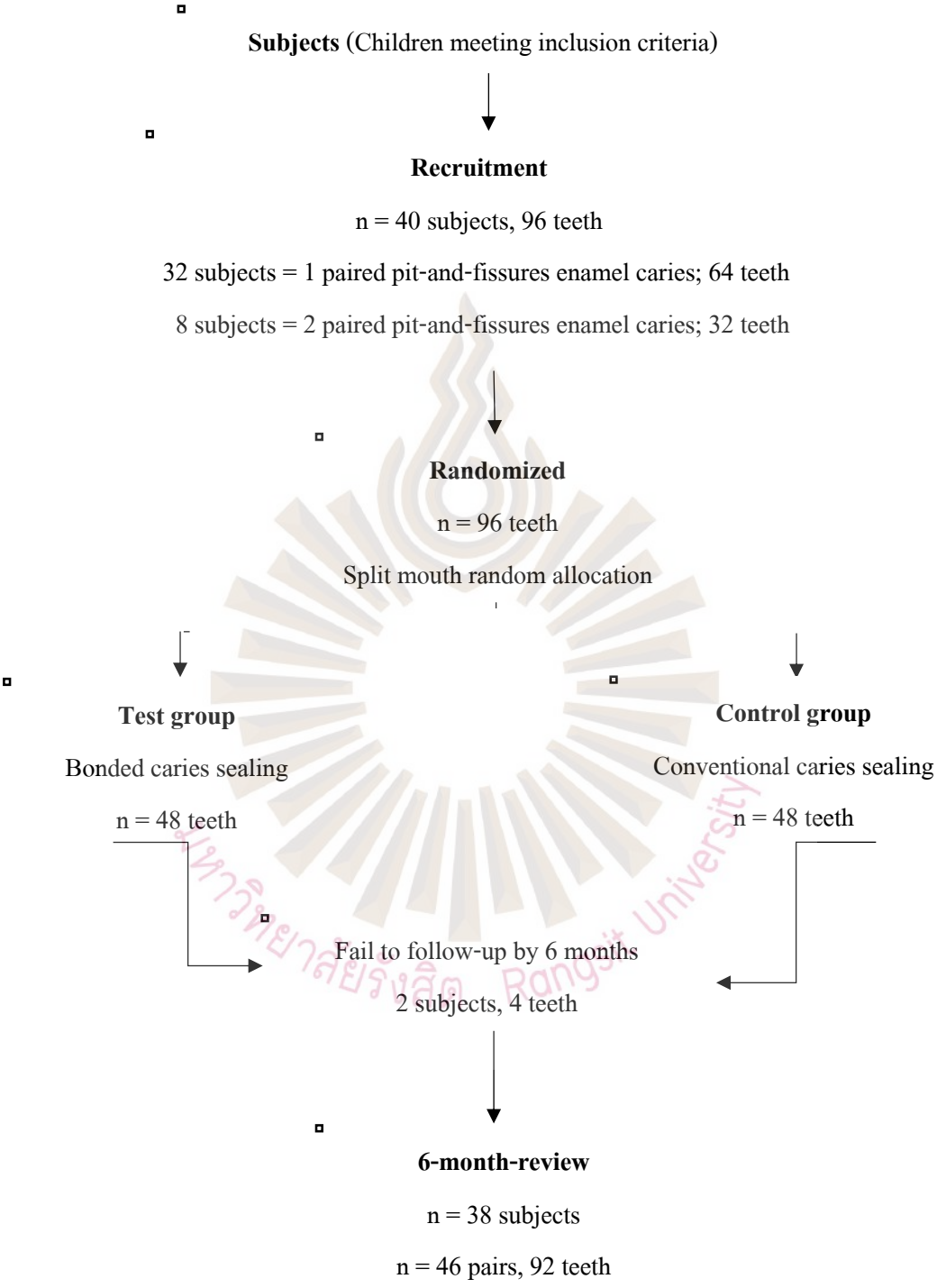
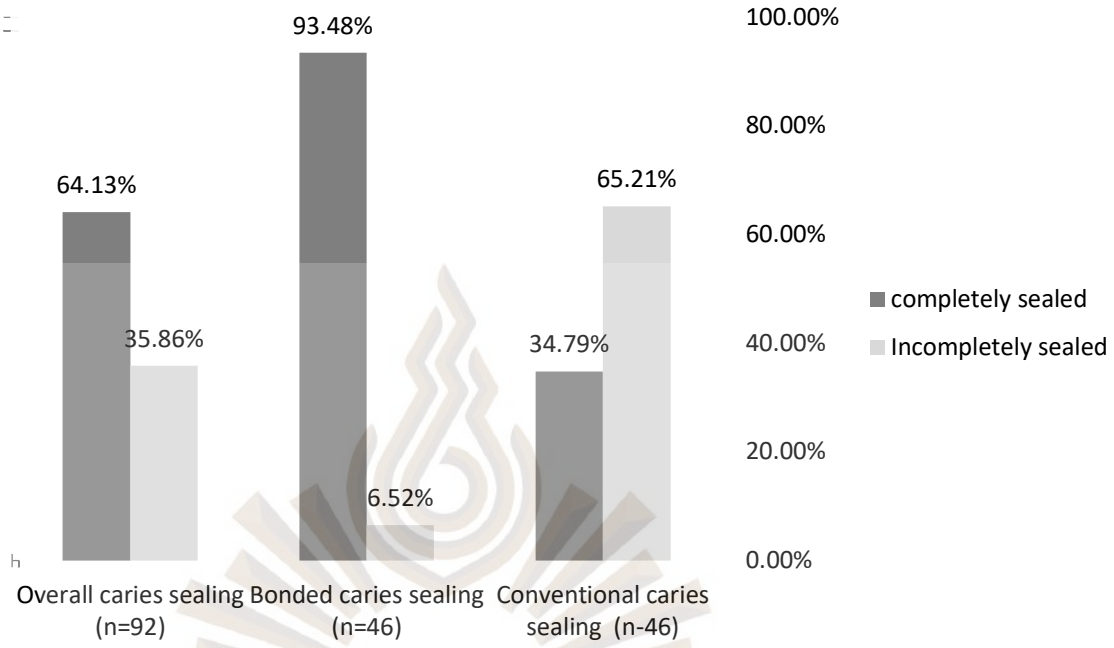


Chart 1 Percentage of sealant retention in overall caries sealing, bonded caries sealing, and conventional caries sealing.



n = number of caries sealed teeth

Table 1 Retention of sealant placed on pit-and-fissure enamel caries between bonded caries sealing and conventional caries sealing.

	Conventional caries sealing		
Bonded caries sealing	Completely sealed (n)	Incompletely sealed (n)	Total
Completely sealed	16	27	43
Incompletely sealed	0	3	3
Total	16	30	46

n = number of caries sealed teeth

CHAPTER 5

DISCUSSION AND CONCLUSION

The contemporary in caries management is to move away from the surgical model (to excise and replace diseased tooth tissue) towards a preventive approach aiming to control the initiation and progression of the diseases process throughout a person's lifetime. Therefore, the clinical researcher has to assess the effectiveness of products and strategies focusing to control the caries process and prevent the progression of diseases into advanced stage that needs to be restored. Likewise, the treatment strategies for initial occlusal caries lesions have gradually changed during the past decades from surgical treatment towards non-surgical treatment.(Pitts, 2004) The caries progression can be arrested by sealing with sealants.(Bakhshandeh, Qvist, & Ekstrand, 2012; Beauchamp et al., 2009 ; Griffin, Oong, et al., 2008).

Thirty-three previously caries sealed teeth in sealants with bonding agent and without bonding agent that categorized as incompletely sealed were reexamined for caries progression. There was only one surface of an incompletely sealed tooth (1.1% of 92 previously caries sealed teeth) that progress clinically from active non-cavitated lesion to active cavitated lesion and need to be restored. The rest of the previously caries sealed teeth that categorized as incompletely sealed (98.9 % of 92 previously caries sealed teeth) had no caries progression, therefore sealant were resealed. This result was consistent with a meta-analysis which reported that there were only 2.6% of caries progression and concluded that the placement of pit-and-fissure sealants significantly reduces the percentage of caries progression in non-cavitated carious lesions.(Griffin, Oong, et al., 2008) Though in this study, the clinical researcher could not evaluate clinically for caries progression in previously caries sealed teeth with completely sealed but we can assume that the caries beneath the sealant do not progress as long as the sealant is intact and tight.(Handelman, 1982; Mertz-Fairhurst et al., 1998) This finding supports the contemporary caries management which recommends that immediate surgical treatment of initial stage of pit-and-fissures caries may not be necessary. Thus, clinicians can consider sealing these lesions or can simply wait and monitor them for signs of active progression. The approach focusing on prevention and nonsurgical management (e.g. sealant) are particularly engaging, since they could potentially preserve the tooth structure and lower the likelihood of future complex restoration. The retention rates of sealants placed on pit-and-fissures carious teeth were somewhat

different in various clinical studies depended on sealant types, clinical criteria to assessing retention, and their research methodology. One previous clinical study reported that the retention rates of sealants (included both UV-polymerized and autopolymerized materials) for carious tooth surfaces are similar to sound tooth surfaces. The retention rates of carious sealed surfaces were 76.3% and 64.0%, respectively, at the 1-year and 2-year follow up.(Handelman et al., 1987) Another study reported the 1-year retention rates of resin-based-autopolymerized sealants placed on noncavitated carious lesions are 89.6% which have similar retention rates with sound teeth.(Gibson & Richardson, 1980) The other study has reported that the retention rates of resin-based-light-polymerized sealants placed on incipient pit-and-fissures caries are 94.2%, 71.3%, and 55.6%, respectively, at the 1-year, 2-year, and 4-year follow up. These differences might be the result of the different criteria to assessing retention. (Soto-Rojas et al., 2012) In this study revealed the first-6-month-retention of resin-based-light-polymerized sealants placed on pit-and-fissures enamel caries (mode of ICDAS code was 2) in permanent molars, was 64.1 % of overall caries sealed teeth. It was not surprising that the retention of sealant placed on pit-and-fissure enamel caries is still different from previous studies. One possible reason is that our study used the technique of four-handed sealant placement instead of rubber dam isolation. However, there was a study examined four-handed delivery of sealants and concluded that it associated with increasing retention of resin-based sealant.(Griffin, Jones, et al., 2008) Another possible reason is that our study used the stringent clinical criteria to assess retention of sealant; partial loss sealants and total loss sealants were grouped together as incompletely sealed teeth Thus, the retention of resin-based sealant placed on pit and fissures enamel caries in our study is lower than other caries sealing studies, while, the general acceptance of sealant retention was 90-95 % at first year (the 5% to 10% sealant loss per year) when placed on caries-free permanent molars.(Feigal, 1998)

It is well accepted that pit-fissures-enamel caries lesions are complex microscopic structures of enamel crystals which described as prismless crystals. The prismless crystals are the acid-etched resistance zone. (Celiberti & Lussi, 2007; Iijima & Takagi, 2000; Lee et al., 1995) When this structure was etched, the result created was a relatively uniform dissolution with limited porosity and resin penetration. Hence, the failure to achieve a satisfactory retention of sealants may be due to the lack of tag formation following etching. (Burrow et al., 2001) Our investigated objective of this clinical study was to improve the penetration and the retention of resin-based sealant placed on pit-and-fissures enamel caries. The main result of our study showed that the retention of a bonded sealant placed on pit-and-fissures enamel caries at 6 months had significant improvement over conventional sealants (p =

0.00); as a result the use of an ethanol-based bonding agent as intermediate bonding layer can be used to increase sealant retention of pit-and-fissures caries sealing in permanent molars. This is similar to the clinical study that recommend using an ethanol-based bonding agent to significantly increase the retention of resin-based sealant particularly for the easily sealant lost surfaces (McCafferty & O'Connell, 2016); and clinically resulted for mild hypomineralized enamel of permanent molars.(Lygidakis et al., 2009) Moreover, this main result was supported by a previously in vitro study which revealed that using bonding agent significantly had highest tensile bond strength when placed on incipient pit-and-fissures caries.(Kalra et al., 2015)

However, there was an unwanted result in our study; the retention of sealant placed on the 3 pairs of permanent molars with pit-and-fissures enamel carious lesions did not completely retained in both bonded sealant placement and conventional sealant placement. The clinical researchers had observed that the baseline carious lesions of these caries sealed teeth which were ICDAS code 2 with dark brown or black in color and plaque stagnated areas. It could be assumed that these carious lesions had underwent demineralized-remineralized process several times.(Meyer-Lueckel et al., 2013) It is well known that, the fluoride-rich acid resistant mineral is formed on the surfaces which reducing its porosity and increasing more resistant to subsequent acid challenge. This complex characteristic of these surfaces may also be an obstacle for the penetration of 37% phosphoric acid and sealant.(Iijima & Takagi, 2000; Lee et al., 1995)

The present study seems to show positive effect on the retention of sealant placement when using a bonding agent as intermediate bonding layer. The curing protocol in our study followed the technique of individual light-curing on the intermediate bonding agent layer and the sealant which was used in the study of Torres et al.(Torres et al., 2005) From our point of view, this curing protocol might consider to be less efficient in the aspect of chair time as suggested by Simonsen.(Simonsen, 2002) However in one study, reported that their operators tended to prefer fewer steps and less chair time when performing sealant placement.(Burbridge, Nugent, & Deery, 2007) While another previously clinical study of bonded sealant using simultaneous curing of both materials also showed the positive result in the retention of sealant placed on sound permanent molars.(McCafferty & O'Connell, 2016) Therefore, more future research will be benefit to improve this disadvantage of the additional chair time curing technique when using bonding agent as intermediate bonding layer in sealant placement on pit-and-fissures enamel caries.

In conclusion, the using of an ethanol-based bonding agent as intermediate adhesive layer of resin-based sealant placed on pit-and-fissures enamel caries seems to improve in sealant retention and showed significantly better retention than conventional technique at 6-months. The caries progression was low for caries sealed teeth with and without bonding agent. Thus, a longer period of follow up should be performed and investigated.

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APPENDICES

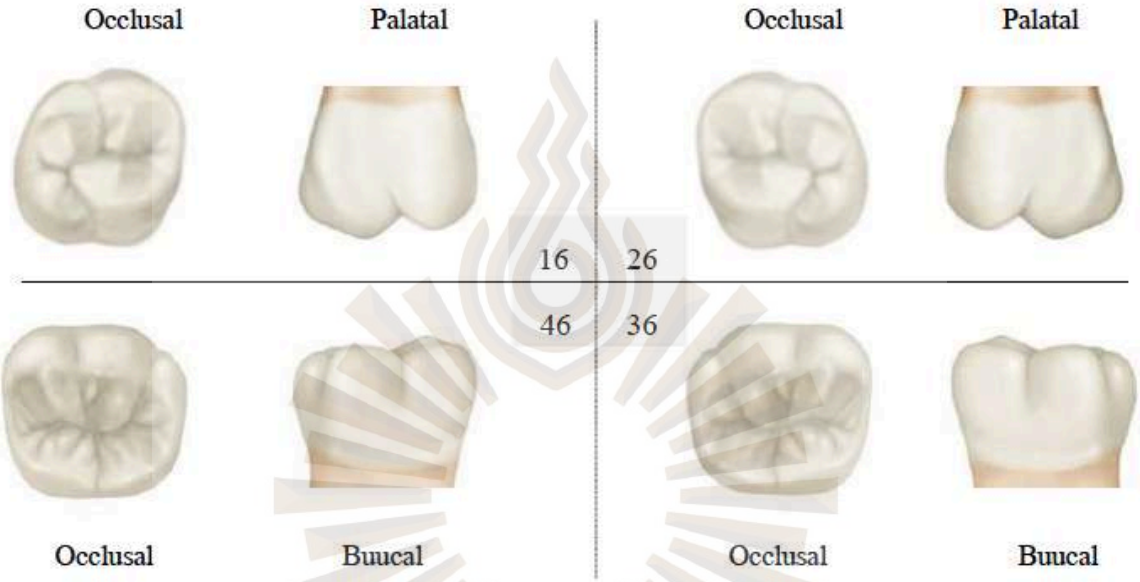
DATACOLLECTION SHEET

Data collection sheet

No……..

Date: First visit……

Patient's name: …… HN: ……



Red = carious lesion

Pit & Fissure Sealant	Control			Test		
	Tooth ……			Tooth ……		
Recall	Intact	Partial loss	Total loss	Intact	Partial loss	Total loss
6 months (…./…./….)						
1 year (…./…./….)						
2 years (…./…./….)						
3 years (…./…./….)						
4 years (…./…./….)						
Total						

CONTINGENCY TABLE

	Test group (Bonded sealant)	Control group (Conventional sealant)	SUM
Complete Retention	A	B	A+B
Incomplete Retention	C	D	C+D
SUM	A+C	B+D	N

A = Numbers of samples which are bonded sealant with complete retention.

B = Numbers of samples which are conventional sealant with complete retention.

C = Numbers of samples which are bonded sealant with incomplete retention.

D = Numbers of samples which are conventional sealant with incomplete retention.

SAMPLE SIZE COLLECTION

Formula for calculation: (Lemeshow, Hosmer, Klar, & Lwanga, 1990)

P = Proportion of annual retention rate of sealant on hypomineralized enamel

$P_{\text{bonded sealant placement}} = 1$

$P_{\text{conventional sealant placement}} = 0.79$

$Z\alpha = 1.645, Z\beta = 0.84$

$$n = 2P(1-P)(Z\alpha + Z\beta)^2 / (P_1 - P_2)^2$$

$$n = (2 \times 0.895)(1-0.895)(1.645+0.84)^2 / (1- 0.79)^2$$

$$n = 26.317$$

The sample size will be adjusted 20% of loss follow up, therefore we will need 31 cases in our study.

หนังสือแสดงความยินยอมการเข้าร่วมโครงการวิจัย

อาสาสมัครผู้เข้าร่วมโครงการวิจัยเป็นผู้ที่ยังไม่บรรลุนิติภาวะ (อายุต่ำกว่า 15 ปี)

การวิจัยเรื่อง การวิจัยทางคลินิกแบบสุ่มและมีกลุ่มควบคุมด้วยการใช้สารยึดติดทางทันตกรรมต่อการยึดติดของวิธีการเคลือบรอยโรคฟันผุบริเวณหลุมร่องฟัน

วันให้คำยินยอม วันที่……..…เดือน……พ.ศ…….

ข้าพเจ้า(นาย/นาง/นางสาว)…….

▫ เป็นบิดา/ มารดา โดยชอบธรรม

▫ มีความสัมพันธ์เป็น……(เด็กชาย/เด็กหญิง) ……

อยู่บ้านเลขที่……ซอย……ถนน……..…แขวง/ตำบล……..…เขต/อำเภอ…..……

จังหวัด……รหัสไปรษณีย์……บัตรประชาชน/ข้าราชการเลขที่……..……

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการวิจัยหรือจากยาที่ใช้ รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียด และมีความเข้าใจดีแล้ว ซึ่งผู้วิจัยได้ตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบัง ซ่อนเร้น จนข้าพเจ้าพอใจและยินยอมให้ผู้เยาว์ของข้าพเจ้าเข้าร่วมโครงการนี้โดยสมัครใจ

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมการวิจัยนี้เมื่อใดก็ได้ ถ้าข้าพเจ้าโดยผู้เยาว์ของต้องการ ข้าพเจ้าไม่เสียสิทธิใดๆ ที่จะได้รับ และที่จะเกิดขึ้นตามมาในโอกาสต่อไป ผู้วิจัยรับรองว่าจะเก็บข้อมูล เฉพาะเกี่ยวกับผู้เยาว์ของข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย ผู้วิจัยรับรองว่าหากผู้เยาว์ของข้าพเจ้าได้รับผลกระทบใด ที่มีสาเหตุจากการวิจัยดังกล่าวผู้เยาว์ของข้าพเจ้าจะได้รับการชดเชยจากผู้วิจัยไม่ต่ำกว่ามาตรฐานขั้นต่ำโดยทั่วไปหรือตามมาตรฐานสากล อาสาสมัครสามารถติดต่อผู้วิจัยได้ที่ คณะทันตะแพทยศาสตร์ มหาวิทยาลัยรังสิต 52/347 ต.หลักหก อ.เมือง จ.ปทุมธานี รหัสไปรษณีย์ 12000 เบอร์ติดต่อ 0-2997-2200 ต่อ 4319, 4323, 4315, 4317 หรือ 087-7109329 (ตลอด 24 ชั่วโมง)

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โดยผู้ที่รับผิดชอบเรื่องนี้คือ อาจารย์ ทันตแพทย์ สุกริช พูลสุข

- ข้าพเจ้ายินยอมให้ผู้กำกับดูแลการวิจัย ผู้ตรวจสอบ คณะกรรมการจริยธรรมการวิจัยในคน และคณะกรรมการที่เกี่ยวข้องกับการควบคุมยาสามารถเข้าไปตรวจสอบบันทึกข้อมูลทางการแพทย์ผู้เยาว์ของข้าพเจ้าเพื่อเป็นการยืนยันถึงขั้นตอนโครงการวิจัยทางคลินิกโดยไม่ล่วงละเมิดข้อมูลของอาสาสมัครตามกรอบที่กฎหมายและกฎระเบียบได้อนุญาตไว้
- ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ
- ข้าพเจ้าไม่สามารถอ่านหนังสือได้ ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ข้าพเจ้าได้รับสำเนาเอกสารใบยินยอมที่ลงนามและลงวันที่ เก็บไว้แล้ว 1 ฉบับ

ลงนาม ..... ผู้ปกครอง

( )

ลงนาม ..... ผู้วิจัย

( )

ลงนาม .....พยาน

( )

ลงนาม .....พยาน

( )

คำชี้แจงโครงการวิจัยแก่ผู้ยินยอมตนเข้าร่วมการวิจัย (สำหรับผู้ปกครอง)

1. การวิจัยเรื่อง

การวิจัยทางคลินิกแบบสุ่มและมีกลุ่มควบคุมด้วยการใช้สารยึดติดทางทันตกรรม ต่อการเพิ่มการยึดติดของวิธีการเคลือบรอยโรคฟันผุบนหลุมร่องฟัน

2. เหตุผลที่ต้องทำวิจัย

เนื่องจากในปัจจุบันการเคลือบหลุมร่องฟันด้วยสารเคลือบหลุมร่องฟันชนิดเรซินเป็นวิธีการที่นำมาใช้รักษารอยโรคฟันผุระยะเริ่มต้นบริเวณหลุมร่องฟัน ปัจจัยหนึ่งที่สำคัญต่อความสำเร็จในการรักษาคือการยึดติดของวัสดุเคลือบหลุมร่องฟัน การศึกษานี้จึงหาวิธีการเพิ่มการยึดติดโดยการใช้สารยึดติดทางทันต-กรรมเพื่อเพิ่มประสิทธิภาพในการยึดติด

3. วัตถุประสงค์

เพื่อประเมินการยึดติดของการเคลือบรอยผุโดยการใช้สารยึดติดทางทันตกรรมเป็นตัวกลางในการยึดติดของวัสดุเคลือบหลุมร่องฟัน

4. วิธีการวิจัย

เป็นการคัดเลือกกลุ่มตัวอย่างในเด็กที่มีรอยโรคฟันผุที่ฟันกรามแท้อย่างน้อย 1 คู่ซึ่งมีความจำเป็นที่จะต้องได้รับการรักษาเพื่อยับยั้งการลุกลามของรอยโรคฟันผุ

วิธีการวิจัยจะทำการเคลือบรอยผุด้วยวัสดุเคลือบหลุมร่องฟัน โดยฟันซี่หนึ่งจะได้รับการเคลือบด้วยวัสดุเคลือบหลุมร่องฟันชนิดเรซินตามวิธีการปกติ และฟันอีกซี่หนึ่งจะเคลือบรอยผุด้วยวัสดุเคลือบหลุมร่องฟันชนิดเรซินชนิดเดียวกันร่วมกับการใช้สารยึดติดทางทันตกรรม โดยจะติดตามผลการรักษาทุก 6 เดือน ตามเวลานัดหมายเพื่อตรวจสุขภาพฟันประจำทุก 6 เดือน

5. ระยะเวลาในการวิจัย

ระยะเวลาในการวิจัยจะมีการติดตามทุกๆ 6 เดือน หลังจากวันแรกที่ผู้เข้าร่วมโครงการมาทำการวิจัย เป็นระยะเวลาสูงสุด 2 ปี

6. ประโยชน์ที่จะได้รับ

ถ้าผลของการศึกษาวิจัยพบว่า มีการเพิ่มการยึดติดของวัสดุเคลือบหลุมร่องฟันโดยการใช้สารยึดติดทางทันตกรรมเป็นตัวกลางในการยึดติด จะเป็นการช่วยเพิ่มประสิทธิภาพในการรักษารอยโรคฟันผุระยะเริ่มต้นบริเวณหลุมร่องฟัน สามารถยับยั้งลุกลามของรอยโรคฟันผุได้อย่างมีประสิทธิภาพ และลดโอกาสในการกรอกำจัดรอยผุ เป็นการรักษาโครงสร้างที่ดีของฟันไว้

7. ข้อเสี่ยงที่อาจจะเกิดขึ้นและการป้องกันและแก้ไข

วิธีการเคลือบรอยผุด้วยวัสดุเคลือบหลุมร่องฟันเป็นวิธีการที่ง่าย ไม่มีการกรอตัดเพื่อกำจัดรอยผุจึงไม่ก่อให้เกิดการเจ็บปวดใดๆ แต่ต้องการความร่วมมือของผู้ป่วยเด็กเพื่อการควบคุมน้ำลายระหว่างการรักษา

การเคลือบหลุมร่องฟัน มีระดับความเสี่ยงน้อยมาก วัสดุเคลือบหลุมร่องฟัน และสารยึดติดทางทันตกรรมที่นำมาใช้ในการรักษาเป็นวัสดุที่ถูกนำมาใช้รักษาในคน มาเป็นระยะเวลานานได้อย่างปลอดภัย โดยผู้ทำการศึกษาวิจัยจะให้การรักษาตามมาตรฐานทางวิชาการ และข้อแนะนำการใช้งานของวัสดุตามคำแนะนำของผู้ผลิต

8. การรักษาความลับ

ข้อมูลทั้งหมดจะนำไปใช้เพื่อการศึกษาวิจัยเท่านั้น โดยจะไม่มีการนำไปเปิดเผยให้กับบุคคลอื่น และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย ผู้วิจัยรับรองว่าหากผู้เยาว์ของข้าพเจ้าได้รับผลกระทบใดๆ ที่มีสาเหตุจากการวิจัยดังกล่าวผู้เยาว์ของข้าพเจ้า จะได้รับการชดเชยจากผู้วิจัยไม่ต่ำกว่ามาตรฐานขั้นต่ำโดยทั่วไปหรือตามมาตรฐานสากล

9. สิทธิของผู้เข้าร่วมโครงการ

ผู้เข้าร่วมโครงการสามารถที่จะถอนตัวจากโครงการได้ตลอดเวลาโดยไม่มีเงื่อนไข และไม่จำเป็นต้องใช้เหตุผล โดยจะไม่กระทบต่อการรักษาที่พึงได้รับตามปกติ

10. ข้อพิจารณาด้านจริยธรรม

ผู้เข้าร่วมโครงการจะถูกจัดให้ได้รับการรักษาโดยปราศจากอคติใดๆ และผู้เข้าร่วมโครงการทุกคนจะได้รับข้อมูลเบื้องต้นก่อนการรักษา

เอกสารคำอธิบาย/คำชี้แจงโครงการแก่อาสาสมัคร

คำชี้แจงโครงการวิจัยแก่ผู้ยินยอมตนเข้าร่วมการวิจัย (สำหรับเด็ก)

การวิจัยเรื่อง การวิจัยทางคลินิกแบบสุ่มและมีกลุ่มควบคุมด้วยการใช้สารยึดติดทางทันตกรรม ต่อการเพิ่มการยึดติดของวิธีการเคลือบรอยโรคฟันผุบนหลุมร่องฟัน

ชื่อผู้วิจัย อ.ทพ. สุกริช พูลสุข

ชื่อผู้ช่วยงานวิจัย ทพญ. ลิลินดา ศรีสุนทรไท

นทพ. กุสุมา ทรงผาสุข รหัสนักศึกษา 5406960

นทพ .ดวงหทัย พรหมมิน รหัสนักศึกษา 5505755

นทพ. พีรดา ทรงถาวรทวี รหัสนักศึกษา 5505845

นทพ .สุพิชชา หรั่งทอง รหัสนักศึกษา 5505864

นทพ .ธนัชชา เกิดศรี รหัสนักศึกษา 5506066

ที่อยู่

คณะทันตแพทยศาสตร์ มหาวิทยาลัยรังสิต 52/347 ต.หลักหก อ.เมือง จ.ปทุมธานี รหัสไปรษณีย์ 12000 เบอร์ติดต่อ 0-2997-2200 ต่อ 4319, 4323, 4315, 4317 หรือ 087-7109329 (ตลอด 24 ชั่วโมง)

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วัตถุประสงค์

เพื่อประเมินการยึดติดของสารเคลือบหลุมร่องฟันโดยการใช้สารยึดติดทางทันตกรรมเป็นตัวกลางในการยึดติดบนหลุมร่องฟัน

วิธีการศึกษา

หลังจากผู้ปกครองของเด็กตกลงให้นักเรียนเข้าร่วมโครงการวิจัยและลงนามในเอกสารยินยอมแล้ว

1. เด็กจะได้รับการการบอกถึง

“ ฟันกรามแท้ที่มีรอยโรคฟันผุ หมอจะเคลือบปิดหลุมร่องฟันให้ เพื่อป้องกันไม่ให้เชื้อโรคไปเกาะติดได้ง่ายและป้องกันการลุกลามของฟันผุ” โดยหมอจะทำการขัดฟันด้วยแปรงขัดฟันและล้างน้ำทำความสะอาดฟัน จากนั้นจะกันน้ำลายด้วยผ้าก๊อซ แล้วทาสีม่วงให้กับฟัน ล้างสีม่วงออกเป่าลมให้ฟันแห้งแล้วจึงทาสีชมพูเคลือบปิดหลุมและร่องฟัน ฉายแสงสีฟ้าเพื่อให้สีชมพูแข็ง และเปลี่ยนเป็นสีขาว ”

2. เด็กจะได้รับการเคลือบหลุมร่องฟัน ใช้เวลาประมาณ 15 นาที

CERTIFICATE OF APPROVAL ETHICAL COMMITTEE OF RESEARCH INSTITUTE OF RANGSIT UNIVERSITY

Certificate of Approval

Ethical Committee of Research Institute of Rangsit University

1. Title of Project	A randomized controlled trial on the use of intermediate bonding agent for the retention of pit and fissures caries sealing
2. Principle Investigator	Sukrit Poonsuk
3. Affiliation	Faculty of Dental Medicine, Rangsit University
4. Project Number	RSEC 67/2560
5. Date of Approval	January 1, 2018 - October 31, 2018

The prior mentioned documents have been reviewed and approved by Ethical Committee of Research Institute of Rangsit University based on the Declaration of Helsinki and Good Clinical Practice

Signature.....

(Associate Professor Dr. Kanda Wongwailikhit)

Chairman, Ethical Committee

Figure 3 Pit and fissures enamel caries lesion, Pit and fissures caries sealing

Figure 4 Dry bristle rotary brush

Figure 5 2x2 gauze rolls

Figure 6 Kerr Gel Etchant™

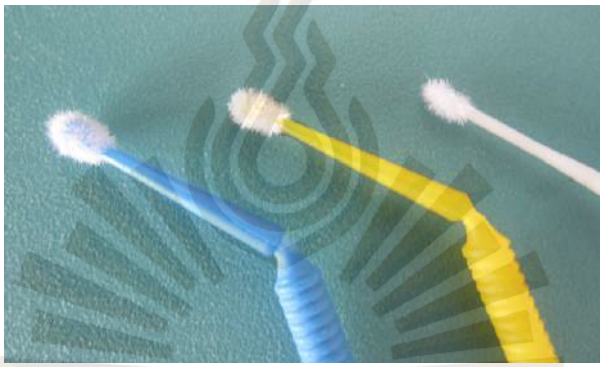


Figure 7 Microbrush

Figure 8 3M ESPE Clinpro™

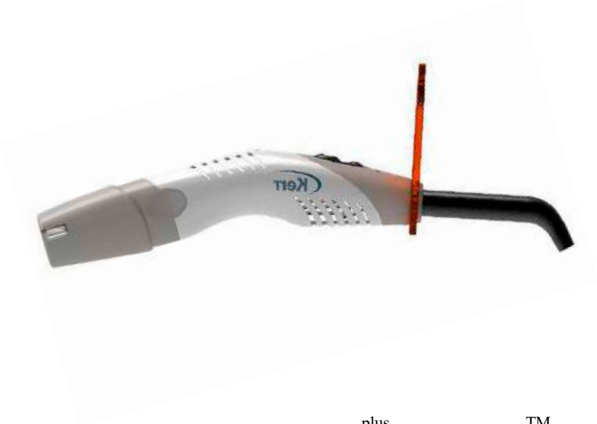


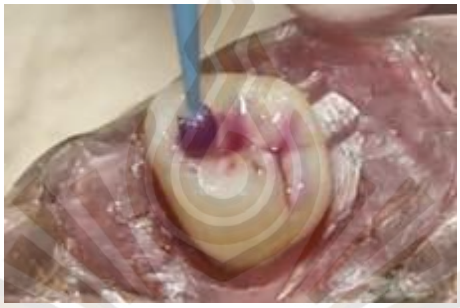
Figure 9 Demi[plus]model, Kerr[TM]

Figure 10 Enchance[TM]

Figure 11 OptiBond[TM] Solo Plus, Kerr

Figure 12 The treatment procedures of test group

Thoroughly cleaned pit and fissures with a dry bristle rotary brush.



Applied 37.5% phosphoric acid (Kerr Gel Etchant™) to the pit and fissures.

The dry etched enamel appears as a matte frosty white.

Applied bonding agent (OptiBond™ Solo Plus, Kerr) to the etched enamel.

CURRICULUM VITAE

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