Original Article

Comparative Evaluation Of Clinical Performance Of Giomer Based And Hydrophilic Resin Based Pit And Fissure Sealant In Primary Molars: A Split Mouth Clinical Trial

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Abstract

Aim: The current in vivo study is done to compare the retention, marginal staining, marginal integrity, and development of new carious lesions between a hydrophilic resin-based sealant and a giomer-based pit and fissure sealant on primary molars.**Study Design:**180 primary molars from 45 participants are taken into consideration in this randomised clinical investigation. 90 primary molars were sealed with Beautisealant (Group 1) and the other 90 primary molars were sealed with Embrace Wet Bond sealant (Group 2). To evaluate the clinical performance Modified USPHS criteria will be used and applied immediately following sealant application, at 3, 6, and 12 months. The entire set of data was gathered, enteredinto MS Excel, and examined with SPSS 16.0. The parameters of clinical evaluation were compared using the Fisher's exact test and the Pearson Chi-Square test.**Result:** At the end of 12 months, 75.9% of group 2 primary molars still had sealants in place, compared to 26.2 percent of group 1, which is statistically significant (p.001). **Conclusion:** Hydrophilic sealants may be employed as efficient fissure sealants, particularly in children who are at high risk for tooth decay, overly salivate, are physically and intellectually challenged, have partially erupted molars, and for children enrolled in community care programs.

Keywords: Children Dentistry, Primary molars, Pits and Fissures,Hydrophobic sealants, Hydrophilic sealants, Retention.

Introduction

Pits and fissures are regarded as the one factor that contributes the most to the development of occlusal caries.[1]Children's high prevalence and quick development of occlusal caries are most likely caused by several factors, including the deep pits and fissures to house bacteria and nutrients as well as the near proximity of their bases to the dentinoenamel junction.Due to surface tension, salivary access to the fissures is restricted, thus inhibiting remineralization and decreasing the efficacy of fluoride, contributing to the high incidence of occlusal caries.[2]Pit and fissure sealants are materials that are placed in the occlusal pits and fissures of teeth that are prone to dental caries. These materials produce a micromechanically bonded barrier coating, preventing caries-causing bacteria from accessing their source of nutrients.[3]Various factors determine the effectiveness of sealants for caries prevention such as child's cooperation (moisture control), timing of sealant placement and long term retention.[4]Retention depends upon morphology of pit and fissures, adequate isolation, conditioning of enamel, application techniques, particular material characteristics like adequate adhesion.[5]The properties required for an ideal fissure sealant include biocompatibility, anticariogenicity, adequate bond strength, good marginal integrity, resistance to abrasion and wear and cost effectiveness.[6]

Routinely used pit and fissure sealants incorporate either the classical acid etch technique or priming (acetone, distilled water, carboxylic acid monomer and phosphoric acid monomer), both requiring an absolute isolation for the entire treatment.In the self-etch approach, the etching and priming steps are combined into a single step procedure, without the need for washing. This reduces the chair side time and technique sensitivity, especially for uncooperative children.

Recently, some modifications were made in chemical formulation of sealants and one amongst them is giomer based pit and fissure sealant. These materials don't contain monomers and bis-GMA, which are predominantly hydrophobic in nature and require a dry atmosphere. To get around the need for a dry field, many authors advise using them with hydrophilic bonding agents. The bonding agents, however, significantly lengthen the process and raise the cost.

A complete dry field is prerequisite for creation of an effective bond and the applications of sealants are equally technique sensitive.[7]Isolating the area is difficult task especially in case of pediatric patients. Until now only moisture tolerant sealants were glass ionomer due to its ionic bonding rather than micromechanical retention with an acid-etched enamel surface.[8]

In view of the above, another recent advancement is Embrace wet bond, a moisture tolerant resin-based sealant with water miscible technology which requires much less dry field. It is based on hydrophilic resin chemistry, mixing di-tri and multifunctional acrylate monomers into anovel acid integrating chemistry, and is free of Bis GMA and Bisphenol A. The material is acidic when activated, and because it is no longer impacted by water in the cured condition, it has a neutral pH and very little water solubility.

Moisture control is much emphasized in pediatric dentistry; a biomaterial providing an overall effective treatment is preferred and recommended. Using this impetus, we have designed this in-vivo study to evaluate the clinical performance of two materials i.e. hydrophobic giomer based pit and fissure sealant (BeautiSealant Shofu, Japan) and hydrophilic resin based sealant (Embrace wet bond, Pulpdent USA).

Material and methods

This study was conducted in the Department of Pediatric and Preventive Dentistry of two institutions of Ghaziabad.

Prior to the study, approval was taken by the ethical committee. Informed consent was obtained from each subject's parents/guardians before enrolling them in the study. 3to 5 years old healthy childrenhaving both left and right primary molars with no sign of occlusal caries, hypocalfication or developmental anomaly were included in the study.Uncooperative patient, Unerupted / partially erupted on the contralateral side, patients having any chronic medical diseases or receiving long term medication such as drugs affecting the salivary flow and patient allergic to any restorative material were excluded from the study.

This study was designed as randomized split mouth clinical trial. 45children having both left and right 2ndprimary molars from either arch were taken to receive two types of pit and fissure sealants (Embrace wet bond, Pulpdent USA and Beautisealant Shofu, Japan). Thus, a total of 180 sealant applications were done. Patients were recalled at 3-, 6- and 12-months intervaland were inspected and explored to check for retention (Criteria by Tonn and Ryge 1982), development of carious lesion, marginal integrityand marginal staining according to the Modified United States Public Health Services (USPHS) criteria[9] by a different trained observer. The evaluator was blinded to the type of sealant applied.

Time in seconds for each sealant application was recorded by the operator, using the digital stopwatch, beginning from the placement of rubber dam for isolation till the end of the curing cycle.

The selected tooth was cleaned with slurry of pumice and a rubber cup, rinsed and then dried; isolation was carried out using rubber dam and adequate suctioning to maintain a dry operating field followed by sealant placement by a single operator.

Group 1: Teeth sealed with Beautisealant

Adequate amount of primer was first dispensed onto V-DISH, which was available in the company kit after following the same procedure as above for cleaning and drying the teeth. A fine micro-brush was used to apply the primer on the enamel surface of pits and fissures. It was left undisturbed for at least 10 seconds, followed by gentle air drying to avoid dispersion of primer.The sealant was then applied directly from the syringe into the pit and fissures slowly and steadily and light cured for 20 seconds as per manufacturer's instructions. Occlusion was checked and reduced as per the patient comfort.

Group 2: Teeth sealed with Embrace wet bond

37% phosphoric acid etchant was applied on the occlusal surface directly with the syringe for 30 seconds. The tooth was washed for 15 seconds and then air dried for 5 seconds. A white frosted appearance on the enamel confirmed adequate etching. Embrace wet bond sealant was then applied to the pits and fissures according to the manufacturer's instructions. The sealant was cured for 20 seconds using LED light curing unit. Occlusion was checked using articulating paper and extra material was reduced with slow speed finishing burs.

Hypothesis that was considered for the study:

1. There is no significant difference in retention of Beautisealant (Shofu, Japan) and Embrace wet bond (Pulpdent, USA) pit and fissure sealant.
2. There is no significant difference in time of application of both pit and fissure sealants.
3. There is no significant difference in development of carious lesion of both pit and fissure sealants.
4. There is no significant difference in marginal integrity of both pit and fissure sealants.

Statistical analysis

All the data was collected and entered in MS excel and analyzed using SPSS 16.0 for windows (SPSS Inc, Chicago, IL, USA, 2001). Student t-test was used to compare the application time. Pearson Chi-Square test and Fisher's exact test was used to compare the other parameters of clinical evaluation. Level of significance was set at 5%.

Results

This study was performed on 45 children with a mean age of 4.57±0.594 years; out of which 22 were girls and 23 were boys. Two patients were excluded at the six-month and three at the twelve-month follow-up. Thus a total of 160primary molars were evaluated in a split-mouth design.

The Embrace wet bond group presented significantly higher retention of sealants than the Beautisealant group. 100% of complete retention of sealants was seen at 3 and 6 months follow up.At 12 months follow up it was 76.2% (Table 1).

Table 1- Comparision of sealant retention at 3, 6 and 12 months in both groups

		BeautiSealant N (%)	Embrace wetbond N (%)	P-Value
3 months	Retention of Sealant	80(100.0%)	80(100.0%)	Retention at 3 months is constant.
	Loss of Sealant	0(0%)	0(0%)	
6 months	Retention of Sealant	76(95.0%)	80(100.0%)	P value>0.05
	Loss of Sealant	4 (5.0%)	0(0%)	
12 months	Retention of Sealant	21(26.2%)	61(76.2%)	P value<0.001***
	Loss of Sealant	59 (73.8%)	19(23.8%)	

The presence of marginal staining of Beautisealantat 3 months follow up was 10.0%and no marginal staining was evident in cases of Embrace wet bond. At 6 months follow up marginal staining seen in both the groups were 15.0% and 2.5%; at 12 months follow up were 26.2% and 63.8% respectively.Statistically significant difference was observed between the two groups at 12 month follow up.

At 3 months follow up development of new carious lesion in both the groups were0% where as at 12 months follow up, it was 13.75% and 15.0% respectively. However, the difference was not statistically significant (P > 0.05).(Table 2)

Table 2- Comparison of development of carious lesion at 3, 6 and 12months of both the sealants

		BeautiSealant N (%)	Embrace wetbond N (%)	P-Value
3 months	Presence	0(0%)	0(0%)	Caries at 3 months is constant
6 months	Presence	10(12.5%)	12(15.0%)	P value>0.05 by Fisher's Exact Test
12 months	Presence	11(13.75%)	12(15.0%)	P value>0.05 by Fisher's Exact Test

*Significant P<0.05, **strong significant P<0.01, ***Highly significant P<0.001, ^Not significant P>0.05

In Embrace wet bond group marginal integrity was found to be significantly more in comparision to Beautisealant which was 60.2% at 12 months follow up.

Mean application time for BeautiSealant was 2.58 ± .498 minutes and for Embrace wet bond was 4.04 ± .236 minutes which was significantly higher due to conventional total-etch technique.

While the hypothesis 1, 2 and 4 was rejected and Hypothesis 3 wasaccepted.

Discussion

Dental caries is one of the most prevalent and common dental problem affecting most of the children in India.[10] The occlusal surfaces of the teeth usually have deep pits and fissures which provide a good environment for demineralization with minimal salivary access and make them caries prone. Caries incidence in occlusal surfaces of molars is 56-70% in children within age of 5 to 17 years.[11] Some of the factors that favor occlusal caries are time, substrate, micro-organisms and tooth, the eruption stage or functional use of the tooth and its specific anatomy.[12]

The principal application for fissure sealants is the prevention of pit and fissure caries.[13] The ability of sealants to prevent caries relies on the creation of a seal that keeps nutrients from getting to the microflora in pits and fissures. About eight times more fragile than smooth surfaces are pits and fissures.[14] Because of this, proper sealant placement and retention are essential. The currently available hydrophobic resin-based sealants are extremely technique-sensitive and influenced by a variety of factors, such as patient compliance, operator variability, and operating field contamination.[15]Due to the clinical procedure's great sensitivity to moisture, one main disadvantage of sealing fissures is that it is challenging to etch partially erupted molars.

Thus, the present study evaluated the retention of giomer based sealant which incorporates self etching primer (group1) and hydrophilic resin-based sealant which is moisture tolerant (group2). “Beautisealant” is a fluoride releasing sealant and provides a safer, simpler and more predictable system that completely eliminates the need for conventional phosphoric acid etch while assuring a durable bond to the tooth structure. It is filled with S-PRG (Surface Pre-Reacted Glass) filler where a stable glass ionomer phase is formed to provide the benefits of fluoride. The S-PRG filler is based on fluoroboroaluminosilicate glass, UDMA, TEGDMA, micro fumed silica. The self-etching primer contains acetone, distilled water, carboxylic acid monomer and phosphoric acid monomer.[7]
For the first time, "Embrace Wet Bond" is hydrophilic in nature and has unique properties such as Resin Acid – Integrated Network [R.A.I.N.], margin free and hydro-balanced, continuous fluoride release, water activated and pH controlled, water miscible, and tooth protection from micro leakage. Both chemical and micromechanical processes are involved in the bonding to the tooth structure.[16]

It is also free of Bisphenol A (BPA), which means that Bis-GMA is not present. According to Amir Azarpazhooh and Patricia A. Main (2008)[17], Bis-GMA has the capacity to connect with oestrogen receptors at subtoxic quantities, which could have dangerous effects. It was discovered that the development, health, and reproductive systems were impaired when done in vitro.

Clinical evaluation by both visual and tactile examination was carried out to check for the retention of sealant materials at 3, 6 and 12 months. The USPHS criteria were utilised to evaluate the retention of the sealant.In this study, clinical evaluation at 12 months revealed that 61 teeth in Group 2 (Embrace Wet Bond) had retained their sealant, compared to 21 teeth in Group 1 (26.2%). (Beautisealant). The aforementioned finding was determined to be statistically significant (p=0.001). In the current study, there was a decline of retention over time in both groups.

In light of the numerous instances of self-etching bonding materials that have been documented, it would appear that the traditional etch-and-rinse approach and the usage of a new hydrophilic fissure sealer would be preferable in order to maintain adhesion qualities in the presence of minute moistures[18]. Because self-etch materials have less adhesive properties than etch-and-rinse materials, applying self-etch bonding material as the adhesive agent of fissure sealant material to teeth is a cautious procedure that should be done with frequent patient follow-ups. Another more compelling explanation for the present study's success is that these materials produce hybrid layers with higher-quality, longer resin outgrowths and better and more regular etching patterns than the standard acid-etch and rinse procedure.

These findings are in accordance with study done byRatnaditya Aet al (2015) who evaluated two pit and fissure sealants and concluded that complete retention of Embrace wet bond was 67.9% at 12 months follow up.[14]Güçyetmez T et al (2017)compared retention of two sealants for 15 months, embrace wet bond was found to be more successful.[18,19]In 2017, a study by Nahid A et al showed 62.5% retention rate of Embrace wet bond at 12 months follow up.[20]
In terms of development of carious lesion, in the present study, at 12 months follow up presence of carious lesion in Group 1 (Beautisealant) and Group 2 (Embrace wet bond) were 13.75% and 15.0% respectively. No statistical significant difference was observed between the two groups. Pit and fissure sealant application is quite successful in avoiding caries in young children, and the reduction of caries development is more correlated with the quality of sealant retention than with the material's composition.

According to SU HR et al, phosphoric acid etching sealant and one-step etching adhesives have equal clinical anticariogenic effects.[21] VM Preetha et al. compared the antibacterial properties of two fluoride-releasing and a non fluoride-releasing pit and fissure sealants and showed that fluoride released by the sealant was able to produce an inhibitory effect against Streptococcus mutans and Lactobacillus acidophilus and concluded that the three factors - etching, sealing and antibacterial activity of fluoride are together almost a guarantee to inhibit the cariogenic bacteria under the sealants.[22]

An important parameter in the evaluation of the clinical success of sealant materials is the marginal adaptation, mainly at the sealant margin. In the present study, at 12 months follow no visible evidence of crevice along the periphery (Alpha) in Group 1 (BeautiSealant) and Group 2 (Embrace wet bond) were 20% and 60.2% respectively. The reason being, etching procedures might increase adhesion to enamel of sealant materials, allowing better marginal adaptation. The presence of a marginal gap can lead to marginal staining, which can be considered the first sign of sealant failure.

Marginal fissures occur due to polymerization shrinkage, which in turn is related to cavity geometry, quality of adhesion, curing process and the visco-elastic properties of the materials. Resins with high modulus of elasticity undergo high polymerization shrinkage, resulting in breakdown of the enamel-sealant micro-mechanical union. Moreover, depending on the size of the orifice and the support offered by the cuspal inclines, a potential weakness may occur in the sealant, and its loss might re-expose the fissure. The thermal expansion coefficient of sealants is significantly different from that of enamel, and the mechanics of expansion and contraction of teeth are different from those of sealants. These factors also contribute to microleakage and marginal fissure formation.

In a study done on molars of children aged 7 to 10 years old, Deshpande A et al. evaluated the retention rate, marginal integrity, and marginal discoloration of two different sealants using rubber dam isolation. They came to the conclusion that fissure sealants with total-etch were superior to self-etch adhesives in terms of marginal integrity and anatomical form.[23] In contrast, Azam Nahvi et al. evaluated microleakage in self-etch fissure sealants and conventional fissure sealants with total-etch or self-etch adhesive and concluded that the microleakage caused when using self-etch fissure sealant was not different from that caused by the use of the conventional method.

Conclusion

To conclude, hydrophilic sealants may be used as efficient pit and fissure sealants, particularly in children who are physically or mentally challenged,uncooperative, or have molars that have only partially erupted. The use of an improved hydrophilic resin technology as a fissure sealant should be promoted because of the ease of application, reduction in operating time, and the adherence of these materials to moist teeth favours their placement. Because of these benefits, Embrace Wet Bond Sealant is a good choice for community care programs. However, given the different methods of both hydrophilic and hydrophobic sealants that are currently available, they should be evaluated and monitored for longer periods of time in the future.

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