Journal of Chemical Health Risks

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JCHR (2024) 14(6), 1949-1960 | ISSN:2251-6727

"Comparative Evaluation of Clinical Efficacy of Pit and Fissure Sealants Combined with Enamel Deproteinization V/S Intermediate Bonding: An in Vivo Study"

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(Received: 16 September 2024 Revised: 11 October 2024 Accepted: 11 December 2024)

KEYWORDS

Caries, Deproteinization, Fissures, Sealants, Tooth

ABSTRACT:

Background : Dental caries is still the most common chronic childhood disease and the primary cause of tooth loss. Pit and fissure sealants (PFS) are one of the most effective non-invasive approaches to prevent and/or arrest occlusal caries in high caries risk children and in deep, retentive pits and fissures. Sodium hypochlorite is a non-invasive technique, that has been used in endodontics due to its antibacterial effects and capability to dissolve and remove organic smear layer from the root canal space without doing any harm to tooth structure.

Aims and Objectives : To Evaluate the clinical efficacy of Pit and Fissure Sealants with Enamel Deproteinization and clinical efficacy of Pit and Fissure Sealants with Intermediate Bonding and to Compare both on permanent first molars.

Materials and Methods: 35 children, age 6-9 years were enrolled into the study. 70 teeth were divided into two group in 35 children each. Group I (35teeth) –Enamel Deproteinization, Acid Etching and application of Pit and Fissure Sealant. Group II (35 teeth) - Acid Etching, application of Bonding agent and application of Pit and Fissure Sealant. The sealed teeth were clinically evaluated at 3,6 and 9 months of interval to assess marginal integrity and gross fracture around the sealant.

Results : The results showed that most of the restorations exhibited acceptable clinical performance in all the clinical parameter at the end of 9 months. Thus, it can be concluded that both the method individually can be used to increase the clinical efficacy of the pit and fissure sealant. The data obtained at 3 months, 6 months and 9 months intervals was tabulated or marginal integrity and gross fracture of pit and fissure sealants using USPHS criteria and statistically compared using the Chi-square test of significance for group 1 and group 2. The result obtained for both the group was a statistically non-significant for the frequencies

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obtained ($p>0.05$) at all time intervals.

Conclusion : Both the method individually can be used to increase the clinical efficacy of the pit and fissure sealant.

INTRODUCTION

Dental caries is a bacterially based disease that progresses when acid produced by bacterial action on dietary fermentable carbohydrates, diffuses into the tooth and dissolves the mineral (demineralisation).[1] Caries on occlusal and buccal/ lingual surfaces account for almost 90% of caries experienced in children and adolescents.[2] Pits and fissures have variations in their appearance in cross section. They were described based on the alphabetical description of shape.[3] Pit and fissure sealants (PFS) are one of the most effective non-invasive approaches to prevent and/or arrest occlusal caries in high caries risk children and in deep, retentive pits and fissures (PF).[4]

Pit and fissure sealants were introduced and based on the pioneering studies reported by Buonocore on acid etching, which improved the adhesion of resin materials to tooth structure.[5] Enamel etching converts the smooth enamel surface into an irregular surface with a high surface energy (72 dynes/cm) more than twice that of unetched enamel.[6] However, Hobson et al found that the topographic quality of enamel etching with phosphoric acid (H_3PO_4) was not accomplished over the total adhesion surface.[7] H_3PO_4 acts only on the mineralized part of enamel but doesn't eliminate the organic material which compromises less than 1%.[8] For this reason, various invasive and non invasive techniques such as sodium hypochlorite (NaOCl) deproteinization have been suggested.[9]

The concept of enamel deproteinization for clinical use was first introduced by Espinosa et al in 2008. These authors demonstrated that removing organic content from an enamel surface with 5.25% sodium hypochlorite (NaOCl) as a deproteinizing agent prior to phosphoric acid etching doubled the enamel's retentive surface significantly, from 48.8% to 94.47% and increased Type-I and Type-II etch patterns which is good for ideal bonding.[7]

This split mouth study with the teeth receiving deproteinization in one group and bonding agent application in the other is used to determine whether the increased retention of the sealant is because of deproteinization or due to the presence of intermediate bonding layer.

AIM & OBJECTIVES

To Evaluate the clinical efficacy of Pit and Fissure Sealants with Enamel Deproteinization and clinical efficacy of Pit and Fissure Sealants with Intermediate Bonding and to Compare both on permanent first molars.

Objectives : To Evaluate the clinical efficacy of Pit and Fissure Sealants with Enamel Deproteinization. To Evaluate the clinical efficacy of Pit and Fissure Sealants with Intermediate Bonding. To Compare the clinical efficacy of Pit and Fissure Sealants with Enamel Deproteinization to clinical efficacy of Pit and Fissure Sealants with Intermediate Bonding

MATERIALS AND METHODS

Study design and site

The present study was a prospective double-blind, split mouth, parallel group, randomized study conducted in Department of Pediatric and Preventive Dentistry, RUHS College of Dental Sciences and hospital, Jaipur, in a children aged 6-9 years during a period of two year.

Ethical Considerations

The procedure and its possible discomfort and benefits were explained to the guardian of the children involved and their written consent was obtained prior to the procedure. An approval from ethical committee of RUHS College of Dental Sciences was taken to carry out this study.

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Sample size determination

Sample size was determined using the expected proportion of event / outcome in each group values of which are estimated from literature & using the formula

$$n = \frac{\left(Z_\alpha + Z_\beta\right)^2 \lfloor p\,(1-p) + q\,(1-q) \rfloor}{(p-q)^2}$$

Where Z_α is the z variate of alpha error i.e. a constant with value 1.96, Z_β i.e. a constant with value 0.84. p, q are proportions of the variable, values of which are taken from the parent article.

Approximate estimates:

1. 80% power

2. Type I error to be 5%

3. Type II error to be 20%

4. Difference in proportions between the groups to be 0.22

Substituting the values,

$$n = \frac{(1.96 + 0.84)^2 \lfloor 0.21 \rfloor}{(0.22)^2}$$

A minimum of 28 subjects per group completing the study would be giving a good external validity to the present study

For follow-up studies, to avoid loss by loss to follow up / attrition, consider recruiting 5-25% more subjects so that even after attrition, we would be able to achieve the required minimum sample size.

So, taking into consideration the attrition to be 15%

$$n = \frac{N}{(1-0.85)}$$

$$n = \frac{28}{(1-0.85)}$$

= 32.94

Approximately 33 subjects per group should be recruited for the study.

Inclusion criteria:

1. Age of the patient was between 6 and 9 years (Both boys and girls).

2. Presence of deep fissures and pits in recently erupted permanent first mandibular molars, where the occlusal surface of tooth was fully visible.

3. Evidence of an acceptable home dental cleaning regimen.

4. Patient cooperation and acceptance for the treatment.

5. Absence of class I clinical carious lesion.

6. No prior dental therapy.

7. No fluoride mouth rinse program practiced in the school.

8. Consent by the subject/ parents/guardians

Exclusion Criteria:

1. History of any medical condition that might interfere with the study.

2. Long-term regimen of medication that could affect the salivary flow and diet modification.

3. History of any adverse reaction to any of the restorative materials used.

4. History of abnormal parafunctional activity.

5. Heavy occlusal contacts on the teeth to be restored.

6. Patients undergoing fluoride application regimen.

7. Highly uncooperative child.

Thus 70 teeth were divided into two group in 35 children each.

- Group I(35teeth) - Enamel Deproteinization, Acid Etching and application of Pit and Fissure Sealant.
- Group II (35 teeth) - Acid Etching,

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application of Bonding agent and application of Pit and Fissure Sealant.

Blinding

The present study was double blinded as the participants were unaware to the material used in the study. In addition, the analyser and the statistician were also blinded to randomization and the procedure of allotting the material to the children.

The analyser was only involved in baseline and follow-up of the restorative treatment. The operator could not be blinded because of the difference in the method used.

Materials used in the study

I. Cleaning powder-Non-fluoridated pumice

II. Pit and fissure sealant - Helioseal F Plus

III. Etchant-mail preparatory etching gel(Ivoclar Vivadent)containing37% phosphoric acid

IV. Bonding Agent -Tetric N-Bond Adhesive(Ivoclar Vivadent)

V. Deproteinizing agent - Sodiumhypochlorite5.25%(PRIME dental products)

VI. Vaseline

Methodology

70 sound permanent mandibular first molar from 35 patients were involved in this study. The teeth selected were divided into two groups randomly and procedures were carried out as follow:

Group I (35teeth)-

- Tooth selected was examined using mouth mirror and explorer under dental operating light to identify sound occlusal surface.
- Tooth was cleaned using non-fluoridated pumice powder mixed with normal saline with slow speed rotating brush and cup mounted on contra angled micro motor handpiece for gross debris removal, then rinsed and dried.
- Isolation was done using rubber dam.
- The enamel surface was pre-treated with 5.25% NaOCl (PRIME dental products) applied with a sterile cotton pellet for 60 seconds, rinsed with sterile water, dried for 10 seconds.
- Emailpreparatoretchinggel(IvoclarVivadent)wasappliedwithasyringetipfor 15-30 seconds, rinsed with water for 10-20 seconds, then dried for an additional 10 seconds using oil free air.
- The tooth surface was checked for opaque, matt-white, frosty appearance to confirm etching.
- Conventional resin-based sealant (Helioseal F Plus) was applied to all the pits and fissures of occlusal surface using the disposable applicator tip and then cured for 20-30 sec. per surface.
- Once the material was cured, pits and fissures were examined with an explorer to make certain that-

- There were no voids.
- All pits and fissures were cured and covered with sealant.
- Sealant application was checked for occlusal interference with articulating paper.

GroupII (35teeth) –

- Tooth selected was examined using mouth mirror and explorer under dental operating light to identify sound occlusal surface.
- Tooth was cleaned using non-fluoridated pumice powder mixed with normal saline with slow speed rotating brush and cup mounted on contra angled micro motor handpiece for gross debris removal, then rinsed and dried.

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- Isolation was done using rubber dam.
- Email preparatory etching gel (IvoclarVivadent)was applied with a syringe tip for 15-30 seconds, rinsed with water for 10-20 seconds, then dried for an additional 10 seconds using oil free air (chip blower)
- The tooth surface was checked for opaque, matt-white, frosty appearance to confirm etching.
- Application of the bonding agent - Tetric N-Bond adhesive (IvoclarVivadent) was done with a disposable tip and the tooth was light cured for 20 seconds.
- Conventional resin-based sealant (Helioseal F Plus) was applied to all the pitsand fissures of occlusal surface using the disposable applicator tip and then cured for 20-30 sec. per surface.
- Once the material was cured, pits and fissures were examined with an explorer to make certain that-

- There were no voids
- All pits and fissures were covered with sealant and cured.
- Sealant application was checked for occlusal interference with articulating paper.

Evaluation

Patient were recalled for evaluation in-

1) 3 months
2) 6 months
3) 9 months

In follow up appointments, the respective treated tooth was evaluated using. The US Public Health Service criteria (modified Ryge's criteria)

Statistical Analysis

All data were entered into a computer by giving coding system, proofed for entry errors

- Data obtained was compiled on a MS Office Excel Sheet (v2019,Microsoft Redmond Campus, Redmond, Washington, United States).
- Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM).
- Inter group comparison (2groups) was done using t test.
- Comparison of frequencies of categories of variables with groups was done using chi square test.

For all the statistical tests, $p<0.05$ was considered to be statistically significant,

OBSERVATION AND RESULT

The present study was conducted on 35 children of aged 6 to 9 years who follows the criteria indicated for Pit and fissure sealant.

The mean age the study group was 7.00 with a standard deviation of 0.840. (Table 1)

	N	Minimum	Maximum	Mean	Std. Deviation
Age	35	6	9	7.00	.840

Table 1: Table showing mean age of the subjects

Intra group comparison

The data was obtained at 3 months, 6 months and 9 months intervals. The results were tabulated for marginal integrity and gross fracture of pit and fissure sealants using USPHS criteria. And statistically compared using the Chi-square test of significance

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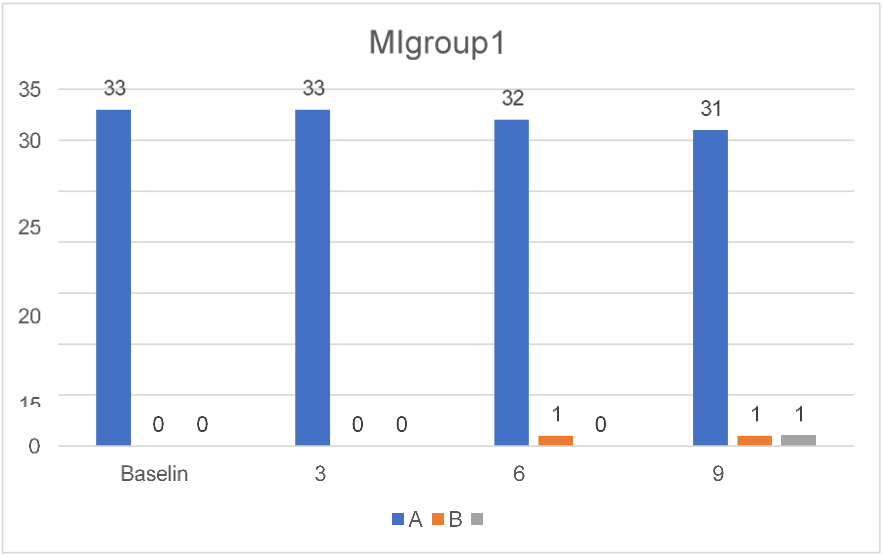
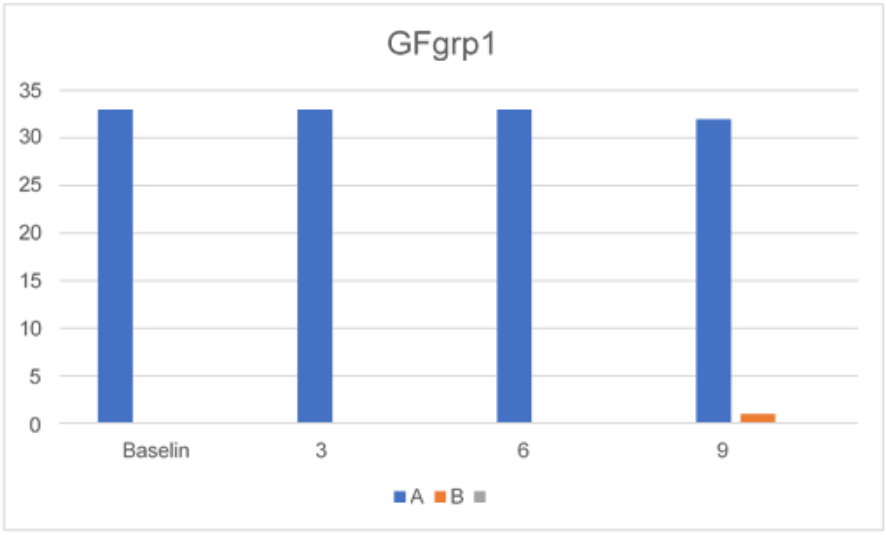
Group1–Enamel Deproteinization.

1. *Marginal integrity :* The comparison of MI at baseline, 3 ,6 and 9 month is given in Graph 1. A gap was detected between the sealant and the tooth surface by the tip of an explorer in 1 sample at 6 months and 1 sample at 9 month. The explorer penetrates crevice defect which extended to the dento - enamel junction in 1 sample at 9 month. According to chi square test, there was a statistically non-significant difference seen for the frequencies between the time intervals (p>0.01) for Marginal Integrity in Group 1.



Graph1: Intra group comparison of Marginal Integrity of group1*time

2. *Gross fracture:* The comparison of GF at baseline, 3 ,6 and 9 month is given in Graph 2. In 1 sample at 9 months Sealant was partially lost. According to chi square test, there was a statistically non-significant difference seen for the frequencies between the time intervals (p>0.01) for GF in Group 1.



Graph 2: Intra group comparison of GF for group1*time

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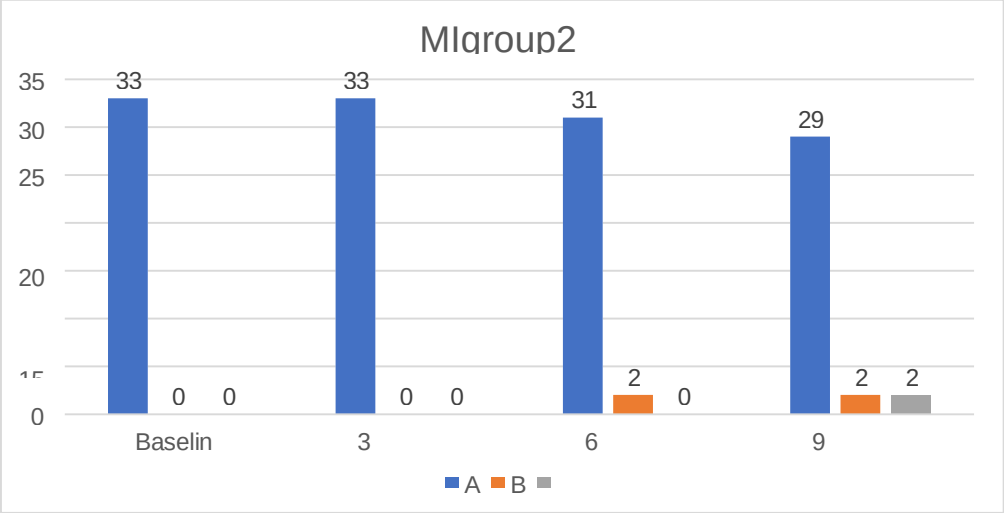
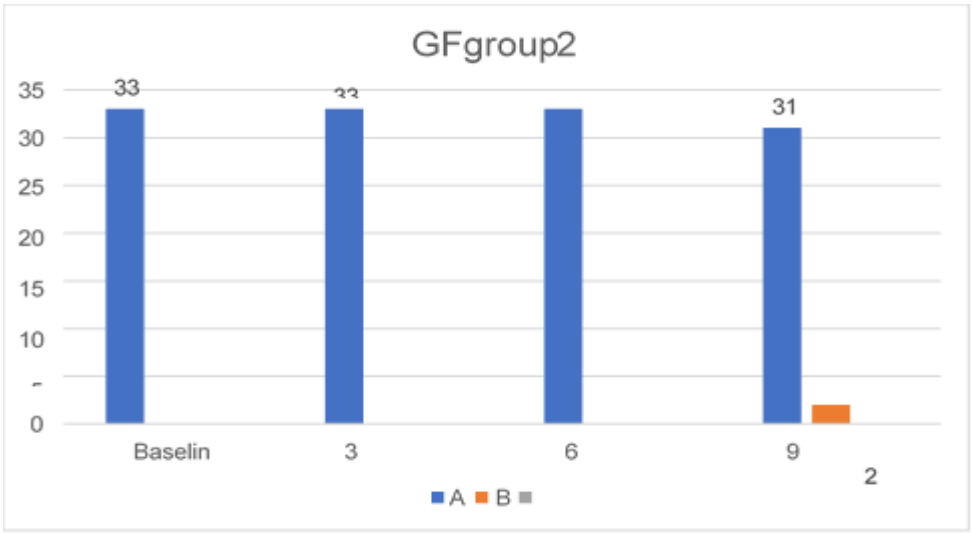
Group 2 –Intermediate Bonding.

1. *Marginal integrity :* The comparison of MI at baseline, 3, 6 and 9 month is given in Graph 3. A gap was detected between the sealant and the tooth surface by the tip of an explorer in 2 samples at 6 months and 2 samples at9 months. The explorer penetrates crevice defect which extended to the dento-enamel junction in 2 sample at 9 months. According to chi square test, there was a statistically non-significant difference seen for the frequencies between the time intervals (p>0.01) for MI in Group 2.



Graph3:Intra group comparison of MI for group2*time

1. *Gross fracture:* The comparison of GF at baseline, 3, 6 and 9 month is given Graph 4. In 2 samples at 9 months, sealant was partially lost. According to chi square test, there was a statistically non-significant difference seen for the frequencies between the time intervals (p>0.01) for GF in Group 2.



Graph4: Intra group comparison of GF for group2* time

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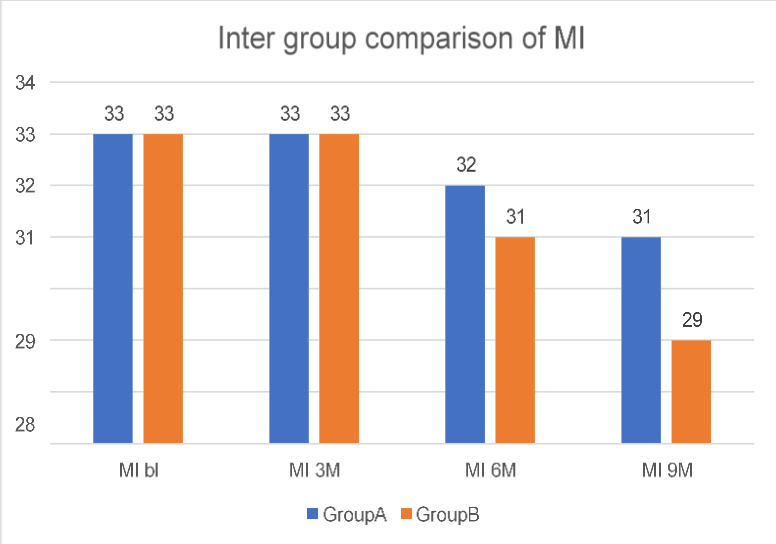
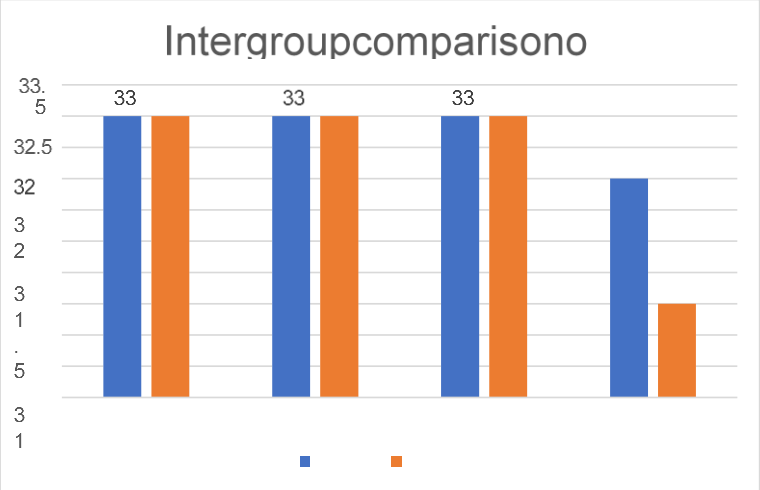
Inter group comparison

The data obtained at 3 months, 6months and 9 months intervals was tabulated for marginal integrity, cavo surface marginal discoloration, and gross fracture of pit and fissure sealants using USPHS criteria and statistically compared using the Chi-square test of significance for group 1andgroup2 (Graph 5 & 6). The result obtained for both the group was a statistically non-significant for the frequencies obtained ($p>0.05$) at all time intervals.



Graph5: Inter group comparison of MI Between Group 1and 2*time



Graph6 : Inter group comparison of GF Between group1 and 2*time

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DISCUSSION

The development of pit and fissure sealants was based on the discovery that etching enamel with phosphoric acid increased the retention of resin restorative materials and improved marginal integrity considerably. The initial studies evaluating the effects of acid-etching on enamel were performed by Buonocore in 1955.[10]

The required properties of an ideal fissure sealant includes biocompatibility, adequate bond strength, anti cariogenecity, resistance to wear and abrasion, good marginal integrity and cost effectiveness. Occlusal anatomy of the teeth also has the role in the success rates of pit and fissure sealants.[11] The effectiveness of sealant may be associated with certain technical problems during its application that includes tissue management and salivary contamination.[12,13] Therefore, for efficient valuation of the sealant based on their properties, rubber dam was used during the procedure of this study, reducing the possibility of faulty technique and inadequate isolation condition

The efficacy of sealant in the prevention of caries has been associated with the degree and duration of the retention of sealant. The need for sealant placement should be reassessed during periodic preventive care, being repaired and replaced as needed. Unfortunately, after all these years, we continue to face adhesive failures and engage in repetitive dentistry.[14]

Hence, this study was carried to evaluate the clinical efficacy of the sealant when placed following enamel deproteinization and intermediate bonding on mandibular first permanent molar by using modified USPHS (United States Public Health Service) criteria for marginal integrity and gross fracture at baseline, 3, 6 and 9 month. The sample size calculated for the study was 35 teeth per group, 2 patient did not come for follow up for 9 months. So a total of 33 patients with66 restorations were followed up till 9 months.

Enamel deproteinization was done using 5.25% sodium hypochlorite solution (PRIME dental products).Bonding agent used was Tetric®N-Bond (Ivoclar Vivadent),a light-curing, nano-filled single-component adhesive used in conjunction with the total etch technique. The use of nano-fillers ensures the formation of a homogeneous layer and improved adhesion to the tooth structure.[15]

Sealant used was Helioseal F Plus (Ivoclar Vivadent), a light-curing, white- shaded fissure sealant featuring fluoride release. In addition to easy and accurate placement, Helioseal F Plus is fluoride releasing, which is a must for good preventive caries control.[15]

Resin composite is the most commonly used sealant material.[16] The caries- preventive effect of resin-based sealants depends on the sealing of pits and fissures through micro retention in tags created by the acid etching of enamel.[17]

Dental enamel consists of 96% of inorganic matter and organic matter is less than 1% out of which less than half part contains protein.[18] Phosphoric acid acts mostly on the mineralized part i.e. inorganic portion of the enamel surface but it does not eliminate the organic material. Due to this outer organic layer, phosphoric acid is prevented to etch the surface of enamel efficiently, that results in variable pattern and a deceptive surface of enamel for bonding.[19] So, it is mandatory to remove the organic part from the enamel surface to improve the quality of pattern of etching, which gave rise to the enamel deproteinization concept.[8]

Literature shows that the enamel deproteinization technique with sodium hypochlorite is an effective way to remove organic material on the occlusal enamel surfaces of teeth.[20] Thus, this could be a boon to the retention rates of the sealant applied to the treated enamel.

In this study, enamel deproteinization was done using 5.25% NaOCl (PRIME dental products) for 60sec. before enamel etching (Email preparator etching gel, Ivoclar Vivadent) and then sealant was placed. The clinical efficacy was evaluated at 3, 6, and 9 month intervals.

The assessment of the marginal integrity was done by visual inspection using mouth mirror and explorer, with that 32 samples at 6 month and 31

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samples at 9 months shows their intact margins. (Graph 1). The number of sample present with the intact margin wassufficientandtheintactmarginsshowthelongevityofanyrestoration so, the retention of the sealant with enamel deproteinization followed by enamel etching can be achieved with intact margin.

In a study by Kielbassa et al. it was reported that through liquefaction of organic materials by NaOCl the quality of etching pattern will be improved which increases the retention of the sealent.[21]

The assessment of the gross fracture was done visually with the help of mouth mirror, sealant was intact and fully retained up to 6 month and 1 sample at 9 month was partially retained with some portion of the restoration still intact (Graph 2). Sealant fracture and marginal fissure formation eventually contribute to microleakage, that ultimately leads to failure of the restoration.

Ayman et al stated that though NaOCl has a lower etching ability, it deproteinizes and increases the surface and give a chance to the etching material to penetrate more deeply creating Type 2 etching pattern and also increasing bond strength, and fracture resistance of the sealant.[22]

There was a statistically non-significant difference seen for the frequencies between the time intervals ($p>0.01$) in group 1 for marginal integrity and gross fracture, showing that Enamel deproteinization before acid etching increases the clinical efficacy of the sealant material.

A study by Ekambaram et al stated that deproteinization could hold a positive future for obtaining improved fissure sealant adhesion to defective enamel surfaces. The surface morphology of moderate and severe hypomineralized enamel after acid etching showed ill-defined enamel rods and inter-rod substances with a poor etching pattern.[23]

A research study by Botton G et al, found that Occlusal sealants applied with self-etch systems show lower retention throughout time than sealants applied in the conventional approach, regardless of the use of adhesive systems.[24]

In this study, adhesive (Tetric N-Bond adhesive system) was applied by using applicator tip and light cured for20 sec., after acid etching and sealant (Helioseal F Plus) was placed. The tooth was isolated using rubber dam for efficient evaluation of the sealant based on their properties, reducing the possibility of faulty technique and inadequate isolation condition.

There was a statistically non-significant difference seen for the frequencies between the time intervals ($p>0.01$) in group 2 for marginal integrity and gross fracture.

Based on the results observed in this study, in which control of saliva and isolation was done, the use of bonding agent as an intermediary layer between enamel and sealant did not affect sealant success with no significant difference in its clinical efficacy. It seems that the success of a sealant is related to whether the sealant is applied under optimal conditions.

Lussi and Duangthip also showed that use of a bonding agent in situations where there is saliva contamination is beneficial for microleakage reduction with increase in retention of the sealant.[25]

In another research, Pinar et al. assessed the clinical performance of sealants with and without a bonding agent and showed that the placement of bonding under the fissure sealant did not affect the clinical success of the sealant.[26]

According to the result obtained on intergroup comparison between both the group of this study, the clinical efficacy of the sealant was almost equivalent for both the group. Enamel deproteinization group showed some better result at 9 months then intermediate bonding group. However, the difference was not statistically significant between both the groups.

However, all the restorations done in the study using enamel deproteinization and intermediate bonding showed clinically acceptable outcomes upto 9 months. It is important to follow up these restorations for a longer period to better analyse the clinical performance of the materials.

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CONCLUSION

Within the limitations of this study, the following conclusions can be drawn:

1. The concept of enamel deproteinization with 5.25% sodium hypochlorite can be applied to the occlusal surfaces of newly erupted permanent molars as this can remove the organic layer from its surface and will increase the etching patterns that are favourable for a good bond between the tooth and the sealant.

2. The concept of using bonding agent with pit and fissure sealant in situations where there is saliva contamination, can significantly enhance the retention of pit and fissure sealants.

3. Enamel deproteinization and intermediate bonding layer with enamel etching can help to improve the clinical efficacy of pit and fissure sealants in children. The result from the data obtained was statistically insignificant on comparing both the group at different time interval.

4. Long-term clinical trials are certainly needed because they remain the ultimate way to collect scientific evidence on the clinical effectiveness of restorative treatments.

SUMMARY

The present study was conducted in the Department of Paediatric and Preventive Dentistry, RUHS College of Dental Sciences, Jaipur to evaluate and comparethe clinical efficacy of sealant using Enamel Deproteinization and Intermediate bonding.

A total of 35 children aged 6-9 years, having bilateral non carious permanent first molars were selected foe study. After obtaining an informed consent from the parent/guardian, the 70 teeth were divided into 2 groups based on the method randomly allocated to each tooth.

Group1: Sealant with Enamel Deproteinization

Group 2 : Sealant with Intermediate bonding

Most of the restorations exhibited acceptable clinical performance in all the clinical parameter at the end of 9 months. Thus, it can be concluded that both the method individually can be used to increase the clinical efficacy of the pit and fissure sealant.

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