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ASSESSMENT OF THE DURABILITY AND PRESENCE OF CARIES OF THREE DIFFERENT TYPES OF PIT AND FISSURE SEALANTS IN YOUNG PERMANENT FIRST MOLARS: A PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Objectives: This study was performed to evaluate the clinical durability and presence of caries of three different types of pit and fissure sealants in young permanent first mandibular molars in children aged between 6-8 years. **Subjects and methods**: A total of 54 children with first permanent molars were randomly assigned to three groups (n=18): Group (A): "Embrace Wet-Bond"; hydrophilic pit and fissure sealant.Group (B)"Helioseal-F"; hydrophobic pit and fissure sealant. Group (C): "Fisseal"; flowable composite pit and fissure sealant. Clinical evaluations of marginal integrity, marginal discoloration, and retention after sealant placement were carried out at 3, 6, 9, and 12 months. **Results**: the results revealed significant difference between the all studied groups in regard to marginal integrity, and marginal discoloration after 3,6, and 9 months of follow-up periods and non-statistically significant difference at12 months. **Conclusion**: the use of fissure sealant provides clinical outcomes for caries prevention in the young permanent mandibular molars.

KEYWORDS: Pit-and-fissure sealant, Embrace Wet-Bond, Helioseal, Fisseal flowable composite.

INTRODUCTION

Dental caries is a multifactorial disease that develops when the bacterial biofilm's composition changes, causing an imbalance between the processes of demineralization and remineralization and manifesting as the development of caries lesions in both primary and permanent dentitions. Dental caries is still regarded as a major global burden that has a negative impact on people's health and quality of life even in the 21st century [(1)].

Pit and fissure sealants are materials that are placed within the occlusal pits and fissures of teeth that are prone to caries. This creates a protective barrier that is micromechanically linked and prevents caries-causing bacteria from accessing their source of nutrition. By creating a barrier between the tooth surface and the oral environment, pit and fissure sealants have been shown to be a successful approach for lowering the rate of occlusal caries on permanent posterior teeth. Today, resin-based compounds with high retention rates make up the majority of sealant materials utilized [(1)].

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The applicability of flowable restorative systems in dentistry has increased, mainly because of their beneficial properties which include low viscosity, low modulus of elasticity and easy handling. Bis-GMA based pit and fissure sealant materials such as Helioseal "non-fluoridated, filled resin-based material" and Fisseal "fluoridated, unfilled resin-based material", may form a micromechanically bonded layer over the tooth surface, thus cutting the access of caries producing bacteria from their source of nutrient [(2)]. However, they are clinically limited by the difficulties inherent in the use of resins in a moist environment because they are Bis-GMA based materials, which are primarily hydrophobic in nature and require a dry field. The wet-bonding have many advantages such as; less technique sensitive, tooth-integrating, superior marginal seal, smooth margins, and better retention [(3)].

Embrace Wet-Bond sealant is a unique moisture-tolerant resin-based sealant that contains no Bis-GMA and no Bisphenol A and uses hydrophilic resin chemistry. Embrace Wet-Bond incorporates di-tri and multifunctional acrylate monomers into an advanced acid-integrating chemistry that is activated by moisture. Embrace Wet-Bond has proven to be a substance that is less viscous, produces longer resin tags, displays less microleakage, demonstrates more marginal adaptability, and penetrates fractures with exceptional efficiency when compared to conventional Bis-GMA-based sealants [(4)].

The rationale for the use of sealants as a preventive intervention is the high prevalence of pit and fissure caries. When applied to deep, caries-prone fissures, pit, and fissure sealants penetrate and protect the vulnerable areas from the oral environment. Obtaining a retentive surface area for bonding that is clean and dry at the time of sealant installation is important for the appropriate retention of a resin-based sealant [(5)]. The research so far is limited to the individual product evaluation, and very few studies have compared the clinical abilities of these commercially available products. Thus, the present study was designed to clinically evaluate and compare the durability and evidence of caries of three commercially available pit and fissure sealants; Embrace Wet-Bond, Helioseal-F, and Fisseal over a period of 12 months.

SUBJECTS AND METHODS

Study design: a prospective comparative clinical study.

Study setting and population: This clinical study was performed on children aged between 6-8 years. The children with at least one fully erupted young first permanent mandibular molar without carious lesions were selected from patients attending the outpatient clinic of Pedodontics and Oral Health Department, Faculty of Dental Medicine, Al-Azhar University (Cairo, Boys) and enrolled in this study. This study involved a total of 54 fully erupted young first permanent molar without carious lesions.

Inclusion criteria: Age range from (6-8) years. Non-cavitated deep/retentive pit and fissures in molars. Stained or minimal decalcified appearance of pits and fissures in molars. Permanent first molars without any carious lesions. Parents and patients' acceptance and cooperation.

Exclusion criteria: Enamel hypoplasia. Bad oral hygiene. The occlusal surface of molars having shallow pit and fissures, which are self-cleansing in the oral cavity for more than 4 years. Clinically detectable caries in molars. Molars that partially erupted or cannot be isolated adequately. Previously placed sealants or restorations on molar teeth.

Ethical consideration:

This study was conducted after approval of Ethical Committee, Faculty of Dental Medicine, Al-Azhar University (Boys, Cairo) with approval reference No. (571/3254).

Patient consent:

Before starting of this study, all selected children and his/her parent's/caregiver were informed about all the procedure used in this clinical study (in respect to the application of tooth decay preventive methods). Then, each parent's/care giver was signed

an informed consent having details about the whole clinical procedure, (appendix A).

Sample size calculation:

Sample size calculation was based on the previous study of Singh et al [6], mean score for pit and fissure sealant retention between different sealant materials. Using G*power version 3.0.10 to calculate sample size based on effect size =1.683, 2-tailed test, α error =0.05 and power = 80.0%, the total calculated sample size will be 18 in each group.

Subject grouping:

The involved children in the present study were randomly divided into three equal groups. A total of 54 young first permanent molars were properly diagnosed, selected, and randomly assigned to three groups (n=18) based on the type of fissures sealant material used as follow: **Group (A)**: "Embrace Wet-Bond"; hydrophilic pit and fissure sealant. **Group (B):** "Helioseal-F"; hydrophobic pit and fissure sealant. **Group (C):** "Fisseal"; flowable composite pit and fissure sealant.

Intervention procedures:

A complete medical history and personal data was obtained from parents of every selected child. After that, dental examination using visual and tactile examination methods by a single examiner for any young first permanent mandibular molars without caries, and with deep and retentive pit and fissures. The clinical examination was performed before beginning of any operative procedures for each enrolled subject to assess the tooth condition and to ensure proper case selection [7].

Sealing procedure:

Oral prophylaxis and isolation: [1,7]

- The procedure began by oral prophylaxis of the patient.
- Later, pit and fissure surfaces were cleaned using employing soft brushes with a low-speed hand piece (W&H, Bürmoos, Austria).
- After thorough rinsing, proper isolation was maintained using rubber dam.

Sealant application: [3,6,7]

- The occlusal surface of each tooth was dried and etched with 37% phosphoric acid gel and rinsed thoroughly for 15 seconds**.**
- If salivary contamination occurred, the etching process was repeated .
- After rinsing, the teeth were softly dried with a cotton pellet to leave the tooth moist . Prior to the sealant material being applied, the occlusal surface of the teeth was still somewhat damp and looked glossy and shiny.
- A frosty white appearance indicated proper etching.
- Then, **for groups (B and C);** the bonding agent was applied on the etched tooth surface and was cured with light-emitting diode (LED) dental light-curing unit for 20 seconds (Monitex BlueLex 105, Monitex Industerial Co., Garden City, Idaho, USA).
- However, **for groups (A);** bonding agent was not applied to the teeth which were to be filled with "Embrace Wet-Bond" sealant.
- Then, one layer of each resin-based sealant was applied using a special applicator with a light brushing motion, on the occlusal surface of each tooth with respective sealants.
- After that, the sealant was light-cured with LED dental light-curing unit for 20 seconds.

Evaluation of Sealant After Placement:

- After placement of sealant, the occlusion was checked using articulating paper then any high points were trimmed using the finishing bur.
- The immediate retention was verified with an explorer.
- Children were instructed not to eat or drink for 30 min.

Observation:

- Post-sealing clinical evaluations were performed by a single examiner, in the same dental office, in similar conditions.
- The clinical evaluation of sealants was done by experienced pedodontist (Co-supervisor) with the aid of dental explorer no. 5 and intraoral mirror [6].
- Clinical evaluations of marginal integrity, marginal discoloration, and retention after sealant placement were carried out at 3, 6, 9, and 12 months.
- Evaluation of marginal integrity, marginal discoloration, were carried out according to Ryge and Synder's criteria [8].

Score 0: Lack of discoloration.

Score 1: Margin discoloration.

Score 2: Discoloration under the sealant.

Data management and analysis:

- The collected data during the study were tabulated and statistically analyzed using the ANOVA test; using SPSS version 22. Qualitative data were presented as number and percent. ANOVA and Mann Whitney U tests for continuous variables. Pearson and spearman correlation were used to correlate between continuous variables. The P-values < 0.05 were accepted as statistically significant.

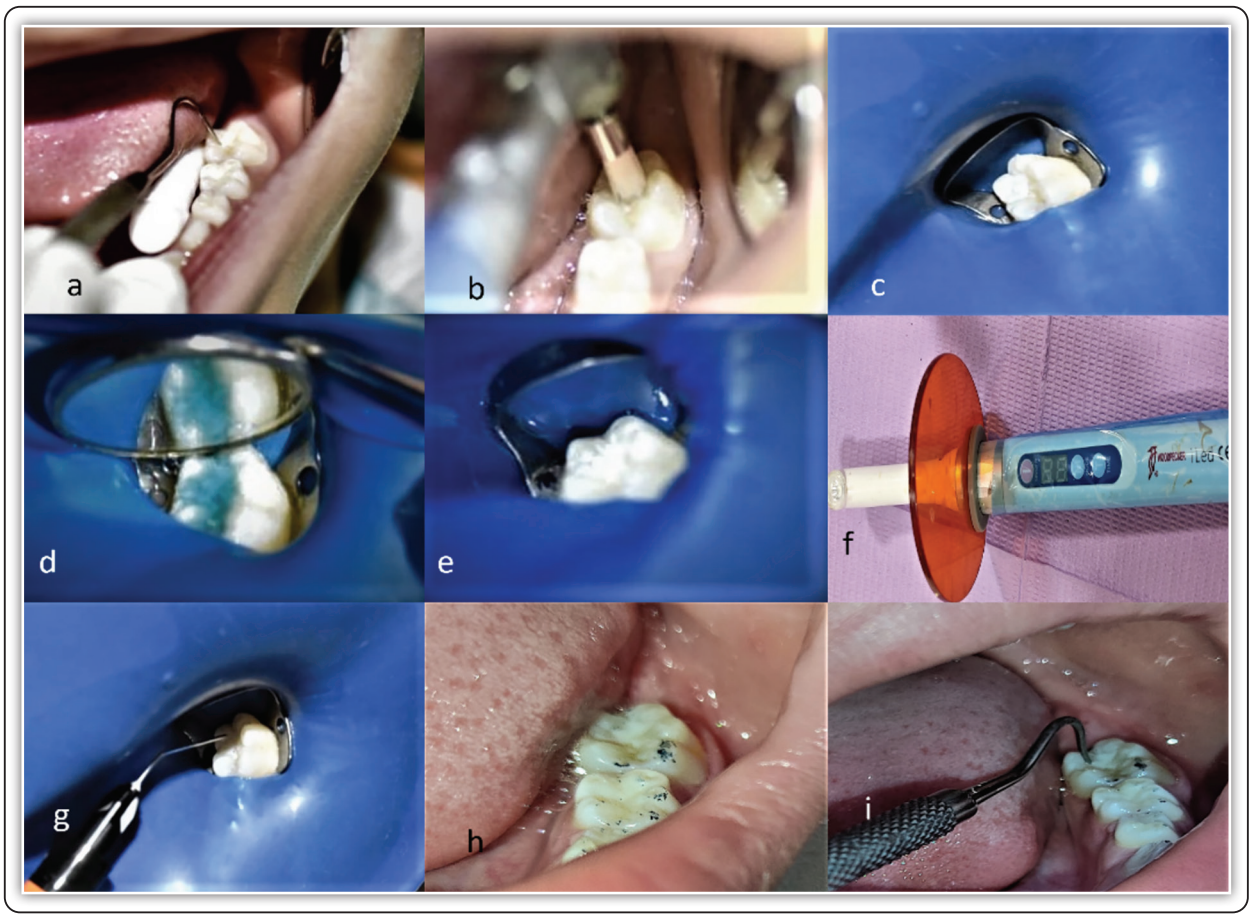

FIG (1) a, Clinical examination, b, Oral prophylaxis procedures, c, Isolation of the tooth, d, etching of the occlusal surface, e, A frosty white appearance of the tooth after etching, f, LED dental light-curing unit, g, Application of sealant, h, Occlusion examination using articulating paper, I, Examination of retention using an explorer.

RESULTS

Marginal integrity among the all-tested groups:

Regarding marginal integrity, after 3-months, all tested sealant showed statistically significant difference (P=0.002), after 6-months (P=0.007), after 9-months (P=0.044), and after 12-months **non-**statistically significant difference (P=0.4336) **Table (1).**

Marginal discoloration among the all tested groups:

Regarding marginal discoloration, after 3-months, all tested sealant showed statistically significant difference (P=0.001), after 6-months (P=0.006), after 9-months (P=0.025), and after 12-months **non-**statistically significant difference(P=0.111). **Table (2)**

TABLE (1) Marginal integrity among the all-tested groups at all follow-up periods:

Variables		3-months	6-months	9-months	12-months	W-score	P-value
Group A	**Score 0**	18 (100%)	17 (94.44%)	15 (83.33%)	13 (72.22%)	0.7506	0.0027 *
	Score 1	0 (0%)	1 (5.56%)	2 (11.11%)	3 (16.67%)		
	Score 2	0 (0%)	0 (0%)	1 (5.56%)	2 (11.11%)		
Group B	**Score 0**	16 (88.89)	14 (77.78%)	11 (61.11%)	8 (44.44%)	0.893	0.1315 ns
	Score 1	2 (11.11%)	3 (16.67%)	4 (22.22%)	6 (33.33%)		
	Score 2	0 (0%)	1 (5.56%)	3 (16.67%)	4 (22.22%)		
Group C	**Score 0**	17 (94.44%)	15 (83.33%)	13 (72.22%)	10 (55.56%)	0.838	0.0268*
	Score 1	1 (5.56%)	2 (11.11%)	4 (22.22%)	6 (33.33%)		
	Score 2	0 (0%)	1 (5.56%)	1 (5.56%)	2 (11.11%)		
P-value		0.00257*	0.0078*	0.0442*	0.4336 ns		
W-score		0.6888	0.7453	0.824	0.9215		

**; significant at p < 0.05. ; non-significant at p >0.05. ns= non-significant.*

TABLE (2) Marginal discoloration among the all tested groups at all follow-up periods:

Variables		3-months	6-months	9-months	12-months	W-score	P-value
Group A	**Score 0**	18 (100%)	18 (100%)	16 (88.89)	14 (77.78%)	0.717	0.00125*
	Score 1	0 (0%)	0 (0%)	2 (11.11%)	3 (16.67%)		
	Score 2	0 (0%)	0 (0%)	0 (0%)	1 (5.56%)		
Group B	**Score 0**	17 (94.44%)	15 (83.33%)	13 (72.22%)	10 (55.56%)	0.853	0.0407*
	Score 1	1 (5.56%)	3 (16.67%)	4 (22.22%)	5 (27.78%)		
	Score 2	0 (0%)	0 (0%)	1 (5.56%)	3 (16.67%)		
Group C	**Score 0**	18 (100%)	16 (88.89)	14 (77.78%)	12 (66.67%)	0.826	0.0190*
	Score 1	0 (0%)	2 (11.11%)	3 (16.67%)	4 (22.22%)		
	Score 2	0 (0%)	0 (0%)	1 (5.56%)	2 (11.11%)		
P-value		0.0011*	0.0061*	0.0253*	0.1119 ns		
W-score		0.644	0.733	0.8	0.864		

**; significant at p < 0.05. ; non-significant at p >0.05. ns= non-significant.*

Retention and caries evaluation among the all-tested groups:

Regarding sealant retention and caries, after 3-months, all tested sealant showed statistically significant difference (P<0.001), after 6-months (P<0.001), after 9-months (P=0.005), and after 12-months (P=0.006).

TABLE (3) Retention and caries evaluation among the all tested groups at all follow-up periods:

Variables		3-months	6-months	9-months	12-months	W-score	P-value
Group A	Score 0	18 (100%)	17 (94.44%)	15 (83.33%)	13 (72.22%)	0.612	0.0000*
	Score 1	0 (0%)	1 (5.56%)	3 (16.67%)	4 (22.22%)		
	Score 2	0 (0%)	0 (0%)	0 (0%)	1 (5.56%)		
	Score 3	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
	Score 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
Group B	Score 0	16 (88.89)	14 (77.78%)	11 (61.11%)	8 (44.44%)	0.755	0.0002*
	Score 1	2 (11.11%)	4 (22.22%)	5 (27.78%)	7 (38.89%)		
	Score 2	0 (0%)	0 (0%)	2 (11.11%)	3 (16.67%)		
	Score 3	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
	Score 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
Group C	Score 0	17 (94.44%)	15 (83.33%)	13 (72.22%)	10 (55.56%)	0.694	0.0000*
	Score 1	1 (5.56%)	3 (16.67%)	4 (22.22%)	7 (38.89%)		
	Score 2	0 (0%)	0 (0%)	1 (5.56%)	1 (5.56%)		
	Score 3	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
	Score 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
P-value		<0.0001*	<0.0001	0.005*	0.006*		
W-score		0.553	0.628	0.733	0.819		

**; significant at p < 0.05. ; non-significant at p >0.05. ns= non-significant.*

DISCUSSION

In the present study, sealants were evaluated at every 3-month interval, i.e., at 3rd, 6th, 9th, and 12th month to ensure the complete retention of the sealants and provide the necessary treatment, if required, as early as possible [8]. At the different follow-up periods in the present study the results showed that, the "Embrace-Wetbond" sealant performed better than (Helioseal-F) and flowable resin composite sealant (Fisseal) in terms of all the tested characteristics (marginal integrity, discoloration, retention and caries prevention) i.e. the "Embrace-Wetbond" sealant has better clinical durability and caries prevention ability when compared to the two other tested sealants. The reason behind this can be attributed to the presence of less filler content in the "Embrace-Wetbond" sealant materials which makes them less viscose, thus making them more penetrable into the pit and fissure areas when compared to the two other tested sealants [7,9].

Another probable reason for this difference in findings may be sited to the greater tensile strength of "Embrace-Wetbond" sealant compared to the

other resin cements. Also, "Embrace-Wetbond" sealant has less viscosity, forms longer resin tags, and provides good marginal adaptation and access well into deep grooves compared to Bis-GMA-based sealants [7].

The results of the present study in relation to marginal integrity revealed that the "Embrace-Wetbond" sealant showed the significant best marginal integrity among other groups . This could be attributed to the different organic structures and filler rates between the "Embrace-Wetbond" sealant which is non Bis-GMA-based sealant (hydrophilic sealant) and the two other Bis-GMA-based sealants (hydrophobic sealants)[7,10]. Additionally, the "Embrace-Wetbond" sealant has good marginal adaptation due to its lower filler content, less viscosity, and its ability to forms longer resin tags, and its better ability to penetrate into the deep grooves compared to Bis-GMA-based sealants [7,9].

A restoration discolors at its margins due to marginal breakdown, inviting plaque and leading to the penetration of oral fluids causing microleakage and secondary caries [11]. The results in relation to marginal discoloration showed the "Embrace-Wetbond" sealant had exhibited the least marginal discoloration when compared to the two other Bis-GMA-based sealants at the different follow-up periods during this study. Thus, the marginal integrity of the "Embrace-Wetbond" sealant would be one of the main factors determining the efficacy and longevity of the sealing material [12]. Moreover, the hydrophilic compound hydroxyethyl methacrylate, an important ingredient in EW, helps in greater water sorption. This enables to have better bonding to the tooth structure in the presence of moisture and thus majorly contributing to the lack of marginal discoloration in comparison to the other sealing agents [13].

Additionally, the results of this study showed a statistically significant difference between the tested sealants in regard for retention. The "Embrace-Wetbond" sealant showed a considerably higher retention rate than the two other Bis-GMA-based sealants. This could be attributed also to the hydrophilicity the "Embrace-Wetbond" sealant which resulted in good marginal adaptation, as well as, it's the lower filler content which resulted in its lower viscosity, and its ability to forms longer resin tags, and its better ability to penetrate into the deep grooves of when compared to the other sealants [7,9].

The results of this study also showed that the flowable resin composite (Fisseal) has the significant higher marginal integrity, less discoloration, and retention when compared to the (Helioseal-F). This could be related to the ease of application the flowable resin composite (Fisseal), in addition to its good flow, less air bubble incorporation and increased working time [14]. Moreover, the increased retention the flowable resin composite (Fisseal) which observed in this study could be related to the use of an adhesive which increases its cost and time[14].

However, the low retention rate of Helioseal–F is related to calcium fluoride which is formed rapidly thereby reducing its sealing to enamel surface[14]. Moreover, the presence of higher fillers content makes its viscosity higher by decreasing its penetrability[15]. However, flowable resin composite (Fisseal) contains pre-polymerized filler with fluoride release particles which have better polishability, mechanical properties, ease of handling and flow, thus allowing deeper penetration into the fissures[13,14].

However, at the end of the 12-month evaluation, it was seen that there was no statistically significant difference between the all three tested group regarding to the marginal integrity and discoloration of sealants. This because it is a known fact that as the time progresses, the sealant material starts deteriorating due to the masticatory forces [8]. Also, it was reported that the loss of sealing material over time is mainly due to abrasion, masticatory forces and marginal infiltration as a secondary outcome of inaccurate moisture control [7].

Although there were no carious lesions on the study teeth at baseline, and 3-months, and caries initiation was detected after 9-months and 12-months in the two Bis-GMA-based sealants groups (Helioseal–F and Fisseal) during the study, while, in "Embrace-Wetbond" sealant there was initiation of caries at the end of the 12 months. There was statistically significant difference found among the fissure sealant for retention and caries evaluation. These results may be related to the results of marginal integrity and retention of the different sealants in the present study. This because the fractured or partially lost fissure sealants leave deep fissures uncovered or a sharp margin that may lead to the formation of caries [10]. Also, the results of the present study showed that regard to presence of caries all of the three tested sealants showed a relatively high caries preventive ability. This could be attributed to the fact that the incorporation of fluoride into the enamel underlying or adjacent to the sealant increases the resistance to demineralization[10]. However, the difference in caries preventive ability in the present study could be explained by, while all resin-based sealants release different levels of fluoride, Bis-GMA-based sealants release only a low level [10].

CONCLUSION

The use of Embrace Wet-Bond fissure sealant provides better clinical durability and clinical outcomes for caries prevention than the Bis-GMA-based sealants. The use of Fisseal flowable composite fissure sealant provides better clinical durability and clinical outcomes for caries prevention than the Helioseal-F hydrophobic fissure sealant. The use of Helioseal-F hydrophobic fissure sealant provides the lower clinical durability and clinical outcomes for caries prevention. Generally, the use of fissure sealant provides clinical outcomes for caries prevention in the young permanent mandibular molars.

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