

Assessment of Clinical Success of Three Sealants: Embrace-WetBond, Clinpro, and Helioseal-F in Permanent Molars: An *In Vivo* Study

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ABSTRACT

Purpose: To evaluate and compare marginal integrity, marginal discoloration, and retention rates of Embrace-WetBond (EW), Helioseal-F (HF), and Clinpro (CL) sealants in permanent molars.

Materials and methods: Sealants were applied on 90 permanent mandibular molars in 48 children aged 6–14 years with deep pit and fissures, and evaluation of these sealants was performed using Ryge and Synder's criteria at 0, 2, 4, 6, 8, and 12 months.

Results: Embrace-WetBond showed maximum marginal integrity (83.3%) as compared to CL (73.3%) and HF (60%) at the end of 12 months. Lack of marginal discoloration was highest in EW (93.3%) as compared to CL (76.7%) and HF (80%) at the end of 12 months. Embrace-WetBond showed highest retention (96.7%) as compared to CL (80%) and HF (73.3%) at the end of 12 months. The results were, however, statistically insignificant ($p > 0.05$).

Conclusion: Embrace-WetBond sealant is better than CL and HF in terms of retention.

Keywords: Marginal integrity, Permanent molars, Pit and fissure sealants, Retention rate.

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INTRODUCTION

Pits and fissures are defects of cuspal odontogenesis. These provide a suitable site for the retention of food and microorganisms. Thus, contributing to the development of poor oral hygiene, early enamel demineralization, and ending to an invasive occlusal caries.¹ In order to counteract these deleterious effects, pit and fissure sealant materials were introduced.

According to Simonsen RJ (1978), pit and fissure sealants are the materials that are introduced into the occlusal pits and fissures of caries-susceptible teeth. They form a micromechanically bonded layer over the tooth surface, thus cutting the access of caries producing bacteria from their source of nutrients.¹

The clinical effectiveness of fissure sealants is directly associated with their retention. Retention depends on the morphology of pits and fissures, adequate isolation during the placement, and proper conditioning of enamel.²

In order to improve the physical properties of sealants, manufacturers have added fluorides, filler particles, and colors to resin material. The sealant that has fillers in it is Helioseal-F (HF). The sealant that is unfilled and changes its color during polymerization is Clinpro (CL).³

The major drawback of these sealants is sensitivity to moisture, which ultimately leads to failure in the retention of the sealant.⁴ Therefore, a sealant which has good retention abilities with improved physical properties and a good moisture tolerance would be a material of choice.⁵

Embrace-WetBond (EW) is a unique moisture-tolerant, resin-based sealant, which can bond to a relatively wet surface of tooth without compromising the retention ability of the sealant. A unique hydrophilic and hydrophobic balance is created in case of EW sealant as it does not contain the main moisture-sensitive materials like bisphenol A-glycidyl methacrylate (Bis-GMA) or bisphenol-A.⁶

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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 marginal integrity, marginal discoloration, and the retention abilities of three commercially available pit and fissure sealants, viz; moisture-tolerant fissure sealant (EW), resin-based filled sealant (HF), and unfilled (CL) sealant material over a period of 12 months.

MATERIALS AND METHODS

This clinical study was done on a sample of 48 children aged between 6 years and 14 years. Ethical approval was obtained from the institutional ethical committee before the conduction of the study. The purpose of the study was explained to the parents/guardians of the children, and written informed consent was taken

for their willing participation in the study. This study was conducted from January 2017 to May 2018, with the last date of inclusion of the sample into study on May 18, 2017.

A list of all the schools running in the study area was obtained from the city municipal corporation office. Lottery system of sampling was done to select five schools, and the children between 6 years and 14 years were screened by a single examiner using mouth mirror and a dental explorer for the presence of deep pit and fissures on the mandibular permanent first molar. Prior permission was obtained from the concerned school authorities before the examination of the children. A total of 120 children were screened, of which 48 children who met the selection criteria were selected for the study (Consort Flowchart 1). Sample size was determined after consulting the data of the previous publication of similar nature. Following selection criteria was set before the selection of the final sample;

Inclusion Criteria

- Questionable pits and fissures in permanent mandibular first molar with age of child ranging from 6 to 10 years.
- Questionable pits and fissures in permanent mandibular second molar with age of child ranging from 11 to 14 years.
- Noncavitated deep pit and fissures in molars.
- Molars with caries-free proximal surfaces.
- Stained or minimal decalcified appearance of pits and fissures in molars.

Exclusion Criteria

- 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 cannot be isolated adequately.
- Previously placed sealants or restorations on molar teeth.
- Uncooperative children.

A total sample of 90 teeth (first and second lower permanent molars) in 48 children were divided into three groups equally using simple random method of sampling (Consort Flowchart 1).

- Group I ($n = 30$) – Teeth sealed with CL (3M ESPE, USA).
- Group II ($n = 30$) – Teeth sealed with HF (Ivoclar Vivadent, Liechtenstein).
- Group III ($n = 30$) – Teeth sealed with EW (Pulpdent, USA).

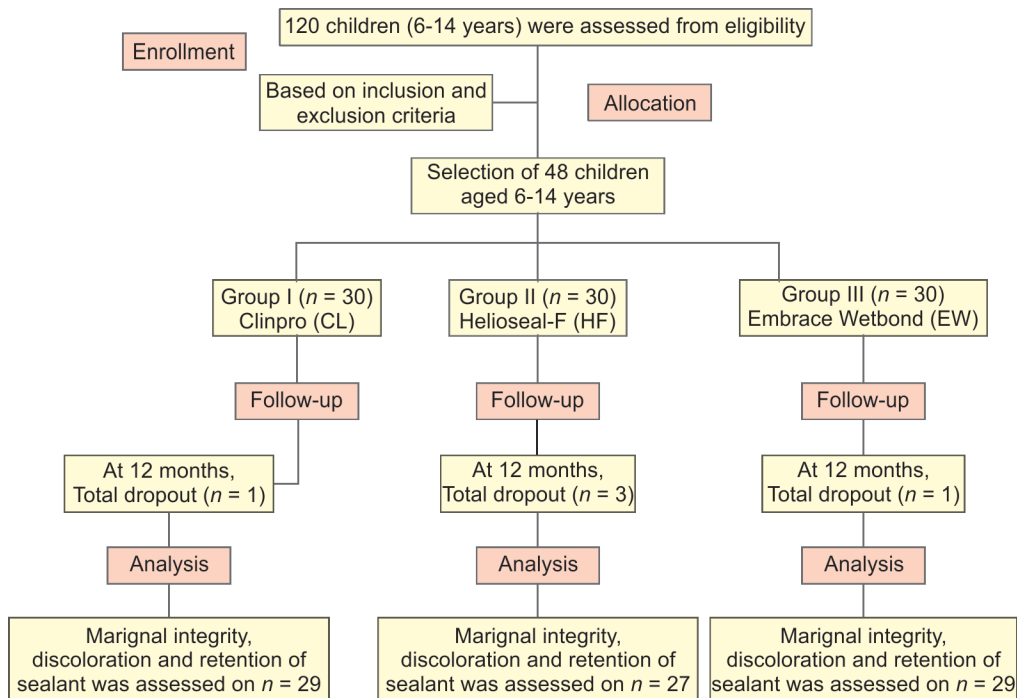
Procedure

The procedure began by oral prophylaxis of the patient. Later, pit and fissure surfaces were cleaned with slurry of pumice and a bristle brush. After thorough rinsing, proper isolation was maintained using cotton rolls and suction tip.²

The occlusal surface of each tooth was dried and etched with 37% phosphoric acid (Eco-Etch; Ivoclar Vivadent, Inc. Schaan, Liechtenstein) and rinsed thoroughly for 30 seconds. If salivary contamination occurred, the surface was re-etched. A frosty white appearance indicated proper etching. Then the bonding agent (Ivoclar Vivadent Inc. Schaan, Liechtenstein) was applied on the etched tooth surface and was cured with light cure unit with an intensity of 500 mW/cm² for 20 seconds (Ultralite 500EW). However, bonding agent was not applied to the teeth which were to be filled with EW sealant. The occlusal surface of each tooth was then applied with respective sealants and light cured for 20 seconds using the same light cure unit. Sealant CL changed its color from pink to white after polymerization.

After the restoration, the occlusion was checked for any high points using articulating paper; and if any found, they were trimmed using the finishing bur. Clinical evaluations of marginal integrity, marginal discoloration, and retention after sealant placement were carried out by the World Health Organization probe at 2, 4, 6, 8, 10, and 12 months according to Ryge and Synder's criteria (1973) (Table 1).⁶ The clinical evaluation was done by the experienced pedodontist and the sample groups were

Flowchart 1: Consort flowchart of study



concealed to the examiner in order to overcome the evaluation bias by the examiner (ITT Analysis). Data collected were sorted and were tabulated in Microsoft excel 2007 and the data were further amended to statistical analysis using the SPSS software version 23.0 (IBM Corporation, Armonk, New York, USA). Chi-square test and one-way analysis of variance test were used to compare the different sealant materials. The *p* values < 0.05 were accepted as statistically significant.

RESULTS

Of the 48 children, 42 children received two different sealants on two teeth, and 6 children received a single sealant on only one

tooth. Thus, a total of 90 teeth were sealed with CL, EW, and HF at baseline. The children who did not turn for the follow-up were excluded from the study. All the children turned up for second month evaluation. At 4th and 10th month evaluation, two teeth filled with HF were excluded from the study owing to refusal to continue the study. Similarly, from the sixth month evaluation, 1 teeth filled with CL was excluded from the study as the child met with an accident. And at the 12th month, one child with HF and EW sealants could not be evaluated since he had relocated to another city. Therefore, the total number of teeth evaluated per group at the end of 12 months was CL (29), EW (29), and HF (27) same is shown in Table 2.

Table 1: Ryge and Synder's criteria for clinical evaluation of pit and fissure sealant

Marginal integrity	Alfa (A)	Existent contour continuity
	Bravo (B)	Existent contour discontinuity less than 50%
	Charlie (C)	Existent contour discontinuity greater than 50%
Marginal discoloration	Alfa (A)	Lack of discoloration
	Bravo (B)	Margin discoloration
	Charlie (C)	Discoloration under the sealant
Retention	Alfa (A)	Total retention
	Bravo (B)	Partial retention with partial exposure of one fissure without the risk of caries
	Charlie (C)	Partial retention with exposure of one or more fissures with the risk of caries
	Delta (D)	Complete sealant loss

Comparison of the marginal integrity of three different sealants at 2, 4, 6, 8, 10, and 12 months is shown in Table 2. At the 12-month interval, maximum cases of existent contour continuity (A) were seen in EW sealant group, with 83.3% incidence in comparison to the CL and HeliOSEAL sealants with 73.3% and 60.0% incidence, respectively. No significant difference was observed in the marginal integrity for the different time intervals and for the different scores of Embrace and CL sealants, except in case of HeliOSEAL where the *p* value was significant.

Table 3 represents the comparison of the marginal discoloration of three different sealants at different time intervals. The *p* value of CL, EW, and HF is 0.801, 0.986, and 0.964, respectively, indicating no statistical significant difference for the marginal discoloration in all the three groups at different time intervals for the different scores. At 12 months, EW (93.3%) showed highest percentage of lack of discoloration followed by HF (80%) and CL (76.7%).

Comparison of the retention of three different sealants at 2, 4, 6, 8, 10, and 12 months is depicted in Table 4. Total retention (A) of the sealant at all the periods was appreciated for EW with 96.7% of retention rate; whereas in CL and HF groups, the total retention was appreciated at the end of 12 months in 80.0% and 73.3% cases, respectively. However, individual groups showed no significant

Table 2: Comparison of the marginal integrity of different sealants

Sealant	Month	Marginal integrity						<i>p</i> value
		A		B		C		
		<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	
Clinpro sealant	2	29	96.7	1	3.3	0	0.0	0.37
	4	29	96.7	1	3.3	0	0.0	
	6	26	86.7	3	10.0	0	0.0	
	8	26	86.7	3	10.0	0	0.0	
	10	23	76.7	5	16.7	1	3.3	
	12	22	73.3	6	20.0	1	3.3	
Embrace sealant	2	30	100.0	0	0.0	0	0.0	0.967
	4	30	100.0	0	0.0	0	0.0	
	6	27	90.0	3	10.0	0	0.0	
	8	27	90.0	3	10.0	0	0.0	
	10	26	86.7	4	13.3	0	0.0	
	12	25	83.3	4	13.3	0	0.0	
HeliOSEAL sealant	2	30	100.0	0	0.0	0	0.0	0.005*
	4	29	96.7	0	0.0	0	0.0	
	6	28	93.3	1	3.3	0	0.0	
	8	27	93.3	1	3.3	0	0.0	
	10	21	70.0	7	23.3	0	0.0	
	12	18	60.0	9	30.3	0	0.0	

*Significant at 5% level of significance (*p* < 0.05)

Table 3: Comparison of the marginal discoloration of different sealants

Sealant	Month	Marginal discoloration						p value
		A		B		C		
		n	(%)	n	(%)	n	(%)	
Clinpro sealant	2	30	100.0	0	0.0	0	0.0	0.801
	4	29	96.7	1	3.3	0	0.0	
	6	26	86.7	3	10.0	0	0.0	
	8	25	83.3	4	13.3	0	0.0	
	10	25	83.3	4	13.3	0	0.0	
	12	23	76.7	6	20.0	0	0.0	
Embrace sealant	2	30	100.0	0	0.0	0	0.0	0.986
	4	30	100.0	0	0.0	0	0.0	
	6	30	100.0	0	0.0	0	0.0	
	8	30	100.0	0	0.0	0	0.0	
	10	29	96.7	1	3.3	0	0.0	
	12	28	93.3	1	3.3	0	0.0	
Helioseal sealant	2	30	100.0	0	0.0	0	0.0	0.964
	4	28	93.3	1	3.3	0	0.0	
	6	28	93.3	1	3.3	0	0.0	
	8	28	93.3	1	3.3	0	0.0	
	10	27	90.0	1	3.3	0	0.0	
	12	24	80.0	3	10.0	0	0.0	

Table 4: Comparison of the retention of different sealants

Sealant	Month	Retention								p value
		A		B		C		D		
		n	(%)	n	(%)	n	(%)	n	(%)	
Clinpro sealant	2	30	100.0	0	0.0	0	0.0	0	0.0	0.925
	4	29	96.7	1	3.3	0	0.0	0	0.0	
	6	26	86.7	3	10.0	0	0.0	0	0.0	
	8	26	86.7	3	10.0	0	0.0	0	0.0	
	10	25	83.3	4	13.3	0	0.0	0	0.0	
	12	24	80.0	4	13.3	1	3.3	0	0.0	
Embrace sealant	2	30	100.0	0	0.0	0	0.0	0	0.0	1.000
	4	30	100.0	0	0.0	0	0.0	0	0.0	
	6	30	100.0	0	0.0	0	0.0	0	0.0	
	8	30	100.0	0	0.0	0	0.0	0	0.0	
	10	30	100.0	0	0.0	0	0.0	0	0.0	
	12	29	96.7	0	0.0	0	0.0	0	0.0	
Helioseal sealant	2	30	100.0	0	0.0	0	0.0	0	0.0	0.998
	4	27	90.0	2	6.7	0	0.0	0	0.0	
	6	27	90.0	2	6.7	0	0.0	0	0.0	
	8	26	86.7	3	10.0	0	0.0	0	0.0	
	10	25	83.3	3	10.0	0	0.0	0	0.0	
	12	22	73.3	5	16.7	0	0.0	0	0.0	

difference in the retention rate at different time intervals, and the *p* value for the same is 0.925, 1.000 and 0.998 for CL, EW, and HF, respectively.

DISCUSSION

The basis for the caries-preventive effect of sealants is the formation of a barrier that averts nutrients in the oral cavity from reaching the microorganisms present in the fissures.⁶

Occlusal fissures are eight times more susceptible to caries than are smooth surfaces. Risk of occlusal caries is more in the first 4 years following tooth eruption.⁷

Buonocore⁸ introduced the concept of conditioning the enamel with phosphoric acid and showed that resin materials can bond to the tooth surface by micromechanical adhesion. Cueto and Buonocore, first outlined the sealing of pits and fissures with an adhesive resin and its subsequent role in caries prevention.⁹ Hitt and

Feigl first elaborated the advantages of adding a dentin bonding agent between the etched enamel and sealant.¹⁰

Helioseal-F is a Bis-GMA and filler containing tooth color sealant. Fillers in this particular material include fluorosilicate glass that releases fluoride ions over a period of time.¹¹ The high viscosity of this material due to the added fillers aids in stability and homogeneity of the sealant.¹²

Clinpro is a Bis-GMA containing, pink, visible light cure, fluoride-releasing sealant which changes its color to white after polymerization. They possess superior wear resistance and better retention compared to filled sealants.⁴ In comparison to HF, CL has got better penetrability into the pit and fissures as the filler content in CL is less than that of the HF.¹² Approximate filler content of CL is 16%, whereas in HF it is 43% by weight.

Embrace-WetBond is a recently developed sealant, which micromechanically and chemically bonds to slightly moist tooth surfaces.⁶ The clinical performance of the material relies on the type of sealant used.³ The successful bonding of resin sealant to enamel requires adequate conditioning of enamel. In the present study, 37% phosphoric acid gel (Ivoclar Vivadent) was used with an etching time of 30 seconds.¹⁴ Etching helps sealant to extend deeply into the enamel by forming micropores and manifesting strong micromechanical bond.^{2,13}

In this study, after etching, the bonding agent Tetric N-Bond was applied on the tooth surface before the placement of sealant. The utilization of bonding agent beneath the sealants on etched enamel surface was done to increase the bond strength, reduce microleakage, and intensify the flow of resins into fissures.¹⁵

In this study, sealants were evaluated at every 2-month interval, i.e., at 2nd, 4th, 6th, 8th, 10th, and 12th month to ensure the complete retention of the sealants and provide the necessary treatment, if required, as early as possible.

At the end of the 12-month evaluation, it was seen that Group EW performed better than CL and HF in terms of all the physical characteristics. It is a known fact that as the time progresses, the sealant material starts deteriorating due to the masticatory forces.¹⁶ At the 12-month time period, the deterioration of all the three restorative materials was appreciated. Nevertheless, the teeth sealed with EW (83.3%) showed less wear and tear in comparison to other CL (73.3%) and HF (60%). The results were in accordance with the findings of the similar study done by Reddy et al.² The reason behind this can be attributed to the presence of less filler content in the newer sealant materials which makes them less viscous, thus making them more penetrable into the pit and fissure areas.¹²

Another probable reason for this difference in findings may be sited to the greater tensile strength of Embrace compared to the other resin cements. Also, EW has less viscosity, forms longer resin tags, and provides good marginal adaptation and access well into deep grooves compared to bis-GMA sealants.

The results in relation to marginal discoloration showed that group EW had exhibited the least marginal discoloration, with 93.3% of the sealant surfaces remaining intact. Whereas groups HF and CL showed 80% and 76.7% of nondiscolored sealant surfaces, respectively. Similar findings were appreciated in the earlier study done by Ninawe et al. who found 86.7% of marginal discoloration in HF group.¹¹ 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 Thus, the marginal integrity would be one of the main factors determining the efficacy and longevity of the sealing material.¹⁶ 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.⁷

In the present study, the HF group (73.3%) demonstrated smallest retention rate at the end of 12 months in comparison to EW group (96.7%) and CL group (80%). However, the difference noted was not statistically significant. This was in accordance with earlier studies done by Reddy et al. and Askarizadeh et al. who had compared resin-based filled and unfilled sealants. Accordingly, both the authors reported insignificant difference between HF and CL groups and between HF and EW groups, respectively.^{2,7}

However, contrasting results have been reported by Schlueter et al. who found significant lower retention of EW (27%) group in comparison to HF (92%) group at the end of 1 year. This difference in the results might be attributed to the difference in the duration of etching prior to the application of the sealant material.⁵

The sealants free of filler provided greater flowability into enamel than sealants with microfiller.¹⁷ And this might be the reason behind the insignificant difference in the clinical success of the different sealant materials.^{4,14,18}

Embrace is less technically sensitive in comparison to helioseal because of its hydrophilic property. Embrace is acidic before curing and after light curing, it has a neutral pH with physicochemical properties like those of the conventional sealants.

Thus, in cases of difficult isolation (uncooperative patients, those with physical or mental disabilities, semierupted molars, etc.), Embrace is the sealant of choice.⁷

The use of bonding agent in the current study was overall noncontributory toward the result. This finding was in accordance with the reports by Srinivasan et al. who undertook the randomized clinical trial study on microleakage of repaired fissure sealants.¹⁹

In the current study, the sealants like EW, placed without employing bonding agent and etching the teeth with phosphoric acid demonstrated the utmost retention. This might be due to the fact that etching of the enamel not only removes the smear layer efficiently but also generates microporosities for the strong mechanical bond of the sealants. Despite the trend of self-etch adhesives, etching with phosphoric acid is still considered as the gold standard against which new materials are tested.^{15,20}

Although the study evaluated the parameters related to marginal integrity, marginal discoloration, and the retention rate for 12 months' period, it fails to provide the long-term evaluation of the retention rate of these sealants. Thus, the study further carries the scope to evaluate the said parameters for the longer duration.

CONCLUSION

Embrace-WetBond showed better clinical success when compared to CL and HF sealants mainly because of its moisture-tolerance capacity. Embrace-WetBond pit and fissure sealant can be the choice of material in cases where the moisture control is a critical issue.

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ITT ANALYSIS

Out of **48 children**,

42 children—two different sealants on two tooth

6 children—single sealant on only one tooth.

Thus a total of **90 teeth** were sealed with CL, EW and HF at baseline.

The children who did not turn for the follow-up were excluded from the study.

At 2nd month—No exclusion

At 4th month—one tooth filled with HF was excluded from the study owing to refusal to continue the study.

At 6th month—one tooth filled with CL was excluded from the study as the child met with an accident.

10th month—one tooth filled with HF was excluded from the study owing to refusal to continue the study.

And at 12th month—1 child with HF and EW sealant could not be evaluated since he had relocated to another city.

Total number of tooth evaluated per group at the end of 12 months was CL (29), EW(29), HF(27).