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Retention and remineralization effect of moisture tolerant resin-based sealant and glass ionomer sealant on non-cavitated pit and fissure caries: Randomized controlled clinical trial

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ABSTRACT

Introduction/objectives: Pit and fissure sealants are an essential part of preventive dentistry and should be adopted as a crucial part of the minimally invasive dentistry due to their profound benefit to our patients.

Methods: The study design is a single-blind, split-mouth, randomized controlled clinical trial. Forty patients between age 6–9 were selected. First permanent molars' occlusal surfaces with scores of 1, or 2 according to the International Caries Detection and Assessment System II (ICDAS II) and with scores between 14–30 by using DIAGNOdent device (Kavo®, Biberach, Germany) were selected and readings recorded. One side of the mouth was randomly chosen to have either the moisture tolerant resin sealant or the glass ionomer sealant placed, and then the second material was placed on the other side. The retention of these materials was analyzed at 3 and 6 months. The sealants were then removed and DIAGNOdent readings were subsequently taken.

Results: After three months, full retention was found in 38/40 (95%) teeth in Group A (Embrace™ WetBond™) and 35/40 (87.5%) teeth in Group B (Fuji TRIAGE®). Additionally, no sealant suffered a total loss in group A, whereas, three sealants were totally lost (7.5%) in group B. The difference in sealant retention in two groups in this period was not found to be statistically significant ($P > 0.05$).

At six months, full retention was found in Group A 34/40 (85%) and 25/40 (62.5%) in Group B. Also, the partial loss in Group A was 2/40 (5%) whereas in Group B 7/40 (17.5%). Also, the total loss was 4/40 (10%) and 8/40 (20%) in Group A and B, respectively. The difference in sealant retention in two groups after six months follow-up was found statistically significant ($P < 0.05$).

The initial mean values of DIAGNOdent readings were 22.42 and 22.8 in Group A and Group B, respectively. After six months, DIAGNOdent mean values revealed a drop in both groups, and this difference was statistically significant. Nevertheless, when Group A was compared to Group B in terms of remineralization effect, the differences were found not to be statistically significant ($p > 0.05$).

Conclusions: Within the limitation of this study, we affirmed that occlusal caries lesions, which is restrictive to enamel and in need of surgical intervention, can be arrested clinically by sealing the lesion with both a hydrophilic resin sealant and glass ionomer sealant materials. Embrace™ WetBond™ showed superiority over the glass ionomer sealant tested in retention after six months follow up.

1. Introduction

Pits and fissures can be at high risk for dental caries since their morphology provides a great environment to plaque growth, and a haven for bacterial growth, while sealing pits and fissure has been recommended as an essential method for preventing occlusal caries [1]. Many pre-treatment procedures have been tested to improve the success rates of sealant application, such as using Erbium YAG laser, brush with pumice slurry application, rotary bur instrumentation, air polishing, air abrasion, and longer etching times [1,2].

Retention and marginal integration of the placed sealant is the primary measure of its success and has been shown to contribute to a decreased incidence of caries in pit and fissure areas [3]. However, many dental professionals have not adopted this vital preventive

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procedure. One reported reason is the perceived lack of longevity of the materials used [4]. Typical resin-based sealants are perceived to have a higher retention rate as compared to glass ionomer sealants. However, evidence shows that resin-based sealants have a limited survival rate due to their hydrophobic characteristics. Their passive nature and the challenges associated with their application in a moist environment, especially for use in partially erupted permanent molars, also lends to the reduction in its use in the clinical setting [5]. Traditional resin-based materials can act as a physical barrier and can prevent the maturation of newly erupted dentition. The passivity of these resin-based sealants fails to contribute to the protection and potential healing of the pits and fissures to which they are applied.

In contrast, GIC sealants which have been shown to have lower retention rates compared to the hydrophobic resin-based sealants have been shown to reduce the incidence of caries as compared to traditional resin sealants [6]. The abilities to allow ion transfer enables GIC materials to form a continuous interface with the tooth structure and increase of calcium and phosphorus in the surface layer [7]. This data indicates that it is vital for our materials to have dynamic, active and not passive behavior in the oral environment and are very attractive in dentistry due to the benefit of fluoride release from materials [8].

The development of bioactive hydrophilic resin sealant materials with the ability to provide ion transfer while maintaining their physical properties has provided an added potential to improve outcomes with our patients. They can offer higher retention and effective sealant results since they are active materials, which would be beneficial in the maturation of newly erupted teeth and be less technique-sensitive then typical resins in the moist oral environment [9].

The capability of these bioactive hydrophilic resin materials to be retentive and to remineralization caries-effected pit and fissures equal to or better than that of GIC sealants, however, not yet been compared. This study aims to evaluate the clinical retention, and remineralization ability in occlusal pit and fissure caries affected permanent first molar in 6 to 9-year-old children when sealed with both GIC sealants and bioactive moisture-tolerant resin sealants.

2. Material and methods

Ethical approval to conduct this study was obtained from the Ethical committee of Damascus University, Faculty of Dentistry. Written Informed consents that describe the purpose and scope of this study have been signed by parents or guardians of all children included in this study

The study design is a single blind, split-mouth, randomized controlled clinical trial.

This study was registered in clinical trials registry (Trial Id: ACTRN12618001940268).

2.1. Sample size determination

Sample size was calculated using g-power 3.1 software. The significance level was set at 0.05 and the power of the study was set to be 0.80.

Based on a previous study [10], it was estimated that 68 teeth/34 participants were required to demonstrate an effect size (0.4) in the average proportion of remineralized incipient pit and fissure caries.

The sample size was increased to 80 teeth/40 patients, to avoid the negative effect of the possible dropout rate.

2.2. Inclusion criteria

The recruitment process began in the early September 2018 and follow-ups were at 3 and 6 months respectively after initial placement of test materials. 40 Participants were selected from patients attending Pedodontic Department at the Faculty of Dentistry, Damascus University that matched the following Inclusion criteria:

Table 1
ICDAS II codes and criteria.

Codes	Criteria
0	Sound tooth surface
1	First visual change in enamel
2	Distinct visual change in enamel
3	Enamel breakdown, no dentine visible
4	Underlying dentinal shadow
5	Distinct cavity with visible dentine
6	Extensive distinct cavity with visible dentine

2.3. Patient related criteria

1) Cooperative Children aged from 6 to 9 years old.
2) Healthy patients with no history of previous systematic diseases that can affect their oral health.

2.4. Tooth related criteria

1) Both mandibular-symmetric first permanent molars are fully erupted.
2) First permanent molars' occlusal surfaces show scores of 1, or 2 according to the International Caries Detection and Assessment System II (ICDAS II) (Table 1) and show scores between 14–30 by using DIAGNOdent device (Kavo®, Biberach, Germany) (Table 2) [11].

Exclusion criteria: uncooperative children, children with mental and/or physical disorders; teeth suffer from proximal caries, developmental defects, cavitation, hypoplasia and teeth with sealant or restoration.

2.5. Allocation method

The participants and their parents were blinded to each treatment. The randomization units were (left or right) and (Treatment A or Treatment B). Two opaque envelops were used in this allocation method, and each participant has got two draws, one from each envelope.

2.6. Research protocol

An experienced investigator screened all possible candidates for inclusion and exclusion criteria. Patients that meet inclusion criteria received bitewing radiographs taken to rule out proximal caries. Then thorough oral prophylaxis was conducted using bristle brush and pumice paste.

Occlusal surfaces of mandibular first permanent molars were assessed by a visual method and scored according to ICDAS criteria. All teeth screened in the prospective candidate needed to be accessed at ICDAS 1, or 2, for the patient to advance into the study.

Next, the teeth of those prospective candidates were evaluated using the DIAGNOdent™ device (Kavo Dental). Measurements were done after drying the teeth with air flow and isolating teeth by cotton rolls after calibration of the DIAGNOdent™ device with a ceramic standard was done. Evaluation of the occlusal surface was accomplished by first

Table 2
The Lussi and Helwing classification for DIAGNOdent values.

Values	Diagnosis
0-13	sound dental tissue
14-20	lesions detected in outer half of enamel
21-29	Lesion detected in inner half of enamel
30 or <	lesions detected in the dentin

measuring the sound buccal surface of the examined teeth and then moving upward toward the occlusal surface. This was repeated three times before Baseline values for each tooth were recorded. The peak value of the three evaluations was then recorded as the baseline value for this tooth. When one of the teeth in the potential candidate failed to get a score between 14–30, the patient was excluded from the study.

During the first visit after selection, standard oral-hygiene training was provided to the children. They were asked to brush their teeth in the instructed way two times a day. At the next visit, selected participants drew from two opaque envelopes. The First draw was to determine on which side the treatment would be done first (right or left). The Second draw was to determine which type of sealant would be applied on the selected side (Group A or Group B). Before the application of pit and fissure sealants, another oral prophylaxis was conducted. The tooth surfaces were then rinsed with water and dried. After that, isolation of the tooth was done using cotton rolls and saliva ejector.

In Group A, teeth were sealed with Embrace™ WetBond™ Sealant (Pulpdent Corporation, Watertown, Mass., USA) following the manufacturer's instructions. The occlusal surface was dried using compressed air, followed by acid etching with 37 percent phosphoric acid gel for 20 s (Total Etch, Ivoclar-Vivadent, Schaan, Liechtenstein). Then, teeth were rinsed with water for approximately 30 s. Excess moisture was removed from the tooth surface using cotton pellets, but the tooth still lightly moist, glossy, or shiny. Embrace WetBond sealant was applied to the pits and fissures with a small applicator tip attached to the syringe. The sealant was light-cured for 20 s using a visible light-curing unit.

In Group B, teeth were sealed with Fuji TRIAGE® (GC, Tokyo, Japan) following the manufacturer's instructions. The occlusal surface was dried using compressed air, followed by applying Cavity Conditioner (GC, Tokyo, Japan) for approximately 15 s. The tooth was rinsed with water for approximately 15 s. After rinsing the tooth was dried by air flow and cotton pellets. A Fuji Triage® capsule was mixed in an amalgamator for 10 s. Then the capsule was inserted into the GC capsule applicator (GC, Tokyo, Japan) and was triggered and applied to pits and fissures on the selected tooth surface. After 2 and a half minutes (setting time for Fuji TRIAGE®), petroleum gel was wiped on the sealant surface.

The chemical composition of treatment materials is presented in Table 3.

2.7. Outcome measurement

The follow-up recalls were conducted after 3 and 6 months for all participants. Two calibrated investigators evaluated retention and remineralization effect of the applied sealants. The participants and their sealants were examined for retention at 3 and six month follow up appointments using a dental explorer following Simonsen's criteria score: [12]

The retention was scored as follows:

0 = sealant completely retained; 1 = sealant partially lost or 2 = sealant completely lost. (Oulis and Berdouses)

At the six month recall appointment and after completing the retention evaluation as described above, the sealants were removed using an air abrasion device (Rondoflex-plus 2013 Kavo®, Biberach, Germany). Once the sealants were removed, remineralization assessment was conducted using DIAGNOdent device using the same technique that was used at baseline measurements.

2.8. Statistical analysis

The intra and inter-examiner DIAGNOdent values were assessed using Cohen's Kappa statistic test. The Wilcoxon Signed-Rank Test evaluated the difference between the initial and sixth month DIAGNOdent values. Kolmogorov Smirnov test was done to test the normality distribution. The retention assessment of the fissure sealants of two groups was analyzed using the Mann-Whitney U Test. All statistical analyses were conducted using SPSS 25.0 for Windows (SPSS Inc. Chicago, IL, USA).

3. Results

The intra-observer agreement between the two examiners was 0.85 and 0.88. The inter-observer agreement was 0.83 for Cohen's Kappa.

Forty patients were enrolled in this study which equated to 80 permanent mandibular first molars randomized into two groups. Fig. 1 illustrates the cohorts in this study.

Table 4 contains the results of sealant retention comparing Embrace™ WetBond™ and Fuji Triage® after three and six months.

Of the total number of sealants, full retention occurred in 38/40 (95%) teeth in Group A (Embrace™ WetBond™) and 35/40 (87.5%) teeth in Group B (Fuji TRIAGE®) at the end of 3 months. Also, no sealant suffered from a total loss in group A, whereas, three sealants were lost (7.5%) in Group B. However, the difference in sealant retention in two groups in this period was not found to be statistically significant ($P > 0.05$).

At six months, full retention occurred in Group A 34/40 (85%) and 25/40 (62.5%) in group B. Also, the partial loss in group A was 2/40 (5%) whereas in group B 7/40 (17.5%). Also, the total loss was 4/40 (10%) and 8/40 (20%) in group A and B, respectively. The difference in sealant retention in two groups after six months follow-up was found statistically significant ($P < 0.05$).

The initial mean values of DIAGNOdent™ readings were 22.42 and 22.8 in group A and group B, respectively. After six months, DIAGNOdent™ mean values revealed a drop in both groups, indicating a remineralization effect. This difference was statistically significant. Nevertheless, the results comparing Group A and Group B in terms of the remineralization effect, the differences were found not to be statistically significant ($p > 0.05$) (Table 5).

4. Discussion

It is a known fact that pit and fissures on the occlusal surfaces of teeth are more vulnerable than the smooth surface for carious lesions initiation [13]. The complex morphology and the lack of salivary access to pit and fissure areas are the main factors behind the high incidence of pit and fissure caries since it makes a pit and fissures a perfect site for the retention of the dental plaque [14]. The ability of pit and fissure sealants to be effectively retained is an important clinical component of the success of pit and fissure sealants in preventing caries formation [15].

Resin-based sealants are commonly used. However, they have significant drawbacks: they are technique sensitive to moisture and can fail with the contamination of the operation field [16]. Glass ionomer sealants are considered to be an acceptable alternative to resin sealants

Table 3
Composition of materials used in the study.

Material	Composition
Embrace WetBond	Light cure resin filled with glass particles Hydrophilic dimethacrylic esters resin-based
FUJI TRIAGE®	Glass ionomer, alimunofluorosilicate glass, polyacrylic acid, distilled water, polybase carboxylic acid

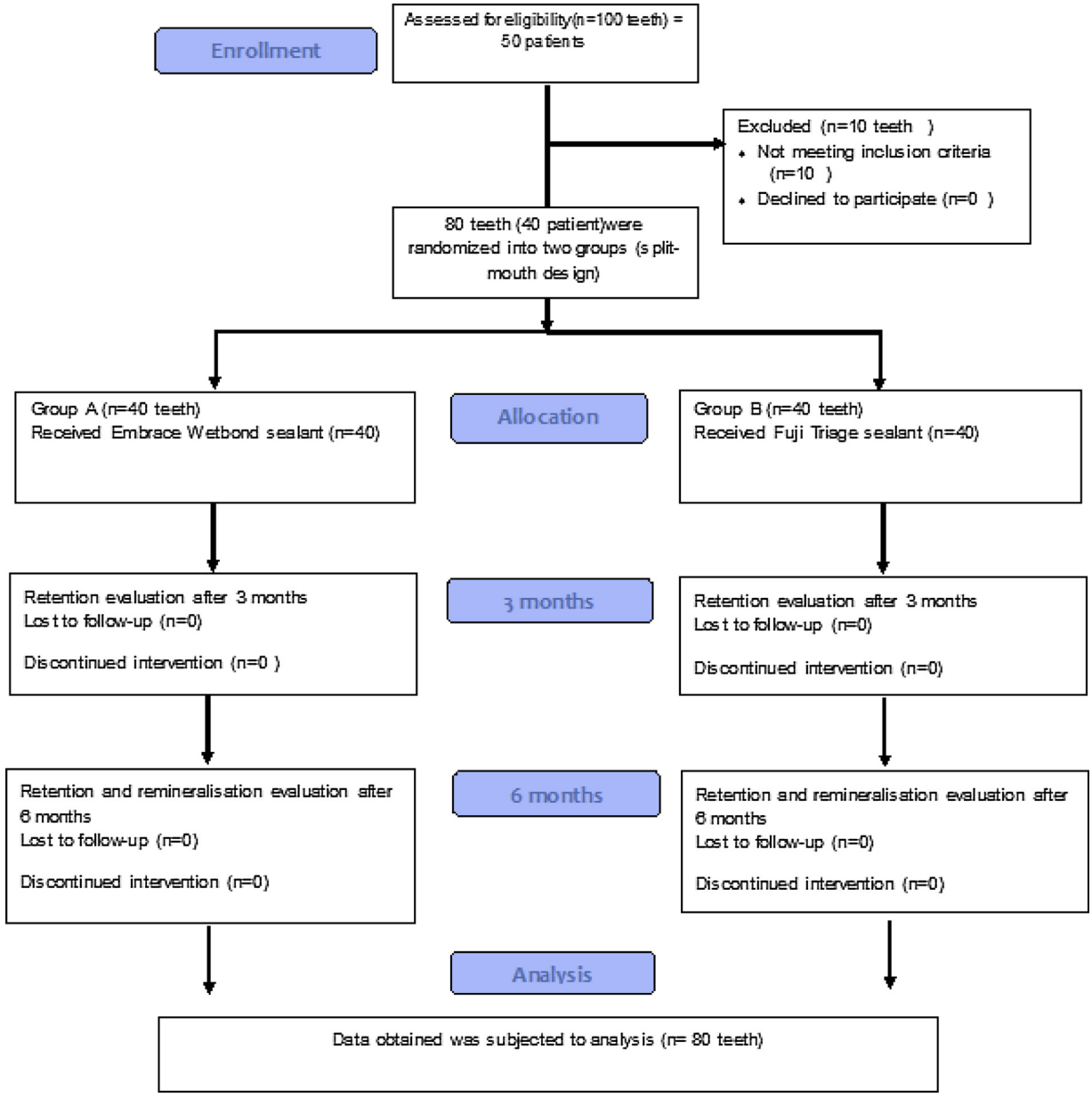

Fig. 1. Consort diagram for the study.

Table 4
Comparison of sealant retention rates.

Evaluation	Sealant retention	Group A (n = 40), n = (%)	Group B(n = 40), n = (%)	Significant
3 months	full retention	38 (95)	35 (87.5)	P = 0.216
	Partial retention	2 (5)	2 (5)	
	full loss	0 (0)	3 (7.5)	
6 months	full retention	34 (85)	25 (62.5)	P = 0.04*
	Partial retention	2 (5)	7 (17.5)	
	full loss	4 (10)	8 (20)	

* Significantly different (P < 0.05).

Table 5
Comparison of DIAGNOdent values.

DIAGNOdent	Group A Mean (Std.)	Group B Mean (Std.)	Result Between two group after 6 months P = 0.608
Initial value	22.8(2.68)	22.42(2.74)	
6.month value	21.02(3.14)	21.47(3.6)	
Result	P = 0.001*	P = 0.044*	

* Significantly different (P < 0.05).

owing to their high fluoride release, moisture-friendly features on top of that, and the application of glass ionomer is less troublesome because of its hydrophilic nature. On the other hand, Conversely, the main disadvantage of glass ionomer sealants is its poor retention [17].

Although the retention values of GI-based pit and fissure sealants are lower than those of the resin-based ones, their caries-preventing effects are more effective than other types. These materials have high fluoride release, and the glass ionomer particles have been shown to remain in the bottom of fissures [27,30]. Frencken and Wolke reported that remnants of high-viscosity glass ionomer materials are retained and block the deeper parts of pits and fissures even after the sealant appears to have disappeared clinically, thus continuing its caries-preventive effect [31].

Recently, hydrophilic resin-based technology has been developed which incorporates a moisture-tolerant feature. One of these products is Embrace ™ WetBond™ sealant. It is a self-priming, self-adhesive and is reported to be less technique sensitive due to its hydrophilic resin technology. It is reported to provide continuous fluoride release [18]. Bonding to the tooth structure appears to be both chemical and micromechanical [33–35]. Embrace™ WetBond™ sealants unique moisture-tolerant resin-based sealant that is activated by moisture [32]. When placed and activated by moisture, the material is acidic, and when cured, it is no longer affected by water and, as a result, the cured material has a neutral pH and very low water solubility [33]. In vitro studies on Embrace™ WetBond™ have shown that the material is less viscous, forms long resin tags, and shows less microleakage, superior marginal adaptation, and excellent penetration into fissures as compared to conventional Bis-GMA-based sealants.

A split-mouth design is the most effective method to determine the clinical effectiveness of different products with the same clinical applications settings (if applicable) to avoid confounding factors [19]. Furthermore, mandibular first permanent molars were chosen in a majority of studies to assess the retention of pit and fissure sealants since it is easier to observe them than other teeth [10].

In 2016, a guideline panel convened by the American Dental Association Council on Scientific Affairs and the American Academy of Pediatric Dentistry identified the retention and the remineralization capacity of pit and fissure sealants on incipient caries as a needed research area for the generation of more evidence on pit and fissure sealants [20]. That call for action provided the incentive and the rationale for the present study.

DIAGNOdent™ was selected as a mechanism to determine remineralization since it was shown by Patil et al. [21] to be an effective mechanism to measure both demineralization and remineralization of tested samples. Other studies [38,39] have also shown that this mechanism can monitor de- and remineralization in early lesions. Mendes et al. [40]. Indicated that laser fluorescence was not able to detect remineralization their in-situ work. However, the experimental model used involved the use of an experimental remineralizing solution and water. This study, with the use of an in-vivo split-mouth environment and the application of beneficial remineralizing reservoir materials such as glass ionomer and the hydrophilic, ion releasing sealants, provided a realistic outcome that displays the ability to remineralize and detect that change with laser fluorescence. Calibration of the evaluators and the instrument is also essential. The same mode of calibration in studies must be employed by all evaluators when using laser fluorescence measurements in longitudinal caries monitoring [39]. These criteria were employed in this study.

Most studies have used Simonsen criteria for evaluation of sealants for its simplicity, and It encompasses scoring criteria for sealant retention on the surface of the teeth [18,22,23]. In the assessment of the results of this study, when the 3rd- and 6th-month retention values were statistically compared, the Fuji-Triage® (Group B) group was found to have lower retention values; however, when its initial and 6th-month DIAGNOdent values were statistically compared, the remineralization values were found to be similar to the remineralization values of Embrace™ WetBond™ group.

In the present study, the 6^{th}-month clinical evaluation showed that full retention was seen in 85% of sealants in group A (Embrace™ WetBond™) and 62.5% of sealants in group B (Fuji-Triage®). The difference between the two groups' retention values was observed to be statistically significant ($P < 0.05$), which is in agreement with previous studies. Bhat et al. found that the glass ionomer sealant was lost in almost 65% of the teeth as compared to only 10% of moisture-tolerant sealant after six months [18]. Ratnaditya et al., found retention rate of Embrace WetBond sealant to be 83% after six months [24]. The lower retention values of glass ionomer sealant could be attributed to the low wear resistance to occlusal forces [25].

Several studies reported that retention rates for the glass ionomer sealants could be as low as 2–10% [26,27]. These studies findings are inconsistent with our resluts. A possible explanation for these contrary findings could be related to the use of Cavity Conditioner in this study with the glass ionomer sealant. This product contains polyacrylic acid, which produces a chelation reaction with the calcium of the enamel, thus providing a hybrid layer for the glass ionomer to establish a more stable bonding surface. The conditioner also acts as a wetting agent [27].

Remineralization assessment was done using the DIAGNOdent™ device twice during the study; First before the application of the sealant, and then after 6 months. Both sealant types were removed before the second evaluation to reduce the probability of false-positive diagnoses with DIAGNOdent™ due to intrinsic autofluorescence of sealant fillers and opacifying agents [28].

The removal process of sealants was done using air abrasion device (Rondoflex 2013 Kavo®, Biberach, Germany) with 27 μm aluminum oxide powder. It has been shown that removal of old composite restoration and sealant could be safely done with air abrasion [29]. Several studies of this air-abrasion technique have shown that it does not inflict any distress on enamel structure, especially when lower particle sizes were used [36,37].

To the best of our knowledge, there have been no In-vivo studies evaluating the remineralization effectiveness of Embrace WetBond™ sealant in comparison to Fuji Triage sealant. The result from the present study shows both groups were able to remineralize incipient caries as outlined in Table [5]. However, there was no significant difference between glass ionomer sealant and Embrace™ WetBond ™ sealant in the remineralization effect.

The limitations of the study include a comparatively limited follow-up span of six months for the evaluation of retention and remineralization. Also, only the participants were blinded from knowing which material was applied whereas the investigator couldn't be blinded during the process of application and assessment due to the different technique required for application and the different texture and color of both materials.

5. Conclusion

Within the limitation of this study, we affirmed that occlusal caries lesions, which is restrictive to enamel and in need of surgical intervention, can be arrested clinically by sealing the lesion with both a hydrophilic resin sealant and glass ionomer sealant materials. Embrace™ WetBond™ showed superiority over the glass ionomer sealant tested in retention after six months follow up.

Declaration of interest

None.

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