**Retention and Remineralization effect of moisture tolerant resin-based sealant and glass ionomer sealant on non-Cavitated Incipient Pit and Fissure Caries: Randomized clinical study.**

**Material and methods:**

Ethical approval to conduct this study will be obtained from the Ethical committee of Damascus university, Faculty of dentistry. Written Informed consents that describe the purpose and scope of this study will be signed by parents or guardians of all children included in this study.

The study design will be a single blind, split-mouth, randomized clinical trial.

**Sample size**

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 two-sample t-test, 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.

Sample size will be raised to 80 teeth/40 patients to avoid the negative effect of the possible drop rate.

**Inclusion criteria**

40 Participants will be selected from patients attending Pedodontics department at the faculty of dentistry, Damascus University that match the following Inclusion criteria:

Patient related criteria:

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

Teeth 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(table 2).

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

**Allocation method**

The randomization units will be (left or right) and (Treatment A or Treatment B). Two opaque envelops will be used in this allocation method and each participant will get two draws, one from each envelope.

Participants and their parents will be blinded what treatment A or treatment B stands for.

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| 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 (not cavitated into dentine) |
| 5 | Distinct cavity with visible dentine |
| 6 | Extensive distinct cavity with visible dentine |

**Research protocol**An experienced investigator will screen all possible candidates for inclusion and exclusion criteria. Patients that meet inclusion criteria will be seated on a dental unit and bite wing radiographs will be taken to rule out proximal caries. Then a thorough oral prophylaxis will be conducted using a bristle brush and pumice paste.

Occlusal surfaces of mandibular first permanent molars will be assessed by a visual and tactile method and scored according to ICDAS criteria. If one of the teeth failed to score 1, or 2, the patient will be excluded.

After that, Teeth will be diagnosed using DIAGNOdent device (Kavo, Germany). Measurements will be done after drying the teeth with air flow and isolating them by cotton rolls. First of all, calibration with a ceramic standard will be done, then baseline values for each tooth will be recorded by measuring the sound buccal surface of the examined teeth then moving upward toward the occlusal surface. After probing the whole occlusal surface, the procedure will be repeated three times. At the end, the peak value will be recorded as the baseline value for this tooth. If one of the teeth failed to get a score between 14-30, the patient will be excluded.

No treatment will be provided in the first visit. A standard oral-hygiene training will be provided to the children. They will be asked to brush their teeth in the instructed way two times a day.

At the next visit, selected participants will draw from two opaque envelopes. The first draw will be to determine on which side the treatment will take apart first (Right or left). The Second draw will be to determine which type of the sealant will be applied on the selected side (group A or group B).

Before the application of pit and fissure sealants, another oral prophylaxis will be conducted then tooth surface will be rinsed with water. After that, isolation of the tooth will be done using cotton rolls and saliva ejector.

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

In group B, teeth will be sealed with Fuji Triage (GC, Tokyo, Japan) following the manufacturer’s instructions. The occlusal surface will be dried using compressed air, followed by applying Cavity conditioner (GC, Tokyo, Japan) for approximately 15 seconds. Then, tooth will be rinsed with water for approximately 15 seconds. Tooth surface will be blot dried by air flow and cotton pellets. Fuji Triage capsule will be mixed by an amalgamator for 10 seconds. Then the capsule will be inserted into the GC capsule applicator (GC, Tokyo, Japan) and will be 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 will be wiped on the sealant surface.

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

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| 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 |

**Outcome measurement**

The follow up recalls will be conducted after 3 and 6 months for all participants. Retention and remineralization effect of the applied sealants will be evaluated by two calibrated investigators.

Each sealant will be examined for retention at 3 and 6 months follow up recalls using a dental explorer following the criteria score: 0 = sealant completely retained; 1 = sealant partially lost or 2 = sealant completely lost. (Oulis and Berdouses)

At the second recall and after retention evaluation, sealants will be removed using an air abrasion device (Rondoflex-plus 360

Kavo®, Biberach, Germany).

After that, Remineralization assessment will be conducted using DIAGNOdent device using the same technique that was used at baseline measurements.

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| Table 3: Composition of materials used in the study | |
| Material | composition |
| Embrace WetBond sealant | Light cure resin filled  with glass particles Hydrophilic dimethacrylic  esters resin-based |
| FUJI TRIAGE | Glassionomer, alimunofluorosilicate glass, polyacrylic acid, distilled water, polybase carboxylic acid |