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Original Article

RETENTION RATE AND CARIES PREVENTIVE EFFECT OF GIOMER-BASED FISSURE SEALANT VERSUS RESIN-BASED FISSURE SEALANT IN PATIENTS WITH NON-CAVITATED PITS AND FISSURES IN PERMANENT MOLARS OVER ONE YEAR: A RANDOMIZED CLINICAL TRIAL.

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Abstract

Aim: This study was conducted to clinically assess the retention rate and caries inhibition potential of self etch giomer-based sealant compared to total etch resin-based sealant in permanent molars with non-cavitated carious fissures over one year.

Subjects and methods: A total of 30 participants with non-cavitated carious fissures were randomly separated into two groups (n=15): Group (1) received self-etch giomer-based BeautiSealant® while Group (2) received total-etch resin-based UltraSeal XT™ plus. Sealant retention was evaluated using visual-tactile examination while VistaCam iX Proof fluorescent camera was used for caries progression detection at baseline, after 3, 6 and 12 months. Chi-Squared test was used in the statistical analysis.

Results: Regarding sealant retention and caries progression, no statistically significant differences were found across various follow-up durations between the two materials.

Conclusion: Both self-etch giomer-based and total-etch resin-based sealants showed similar clinical performance and caries preventive effect after 12 months of follow-up.

Clinical Significance: Self-etch giomer-based and total-etch resin-based sealants are highly recommended to be used in permanent molars with non-cavitated carious fissures.

Keywords: giomer, fissure sealant, retention rate, caries preventive effect, permanent molars.

Introduction

Oral problems, particularly dental caries, and periodontal disease are directly correlated with everyday habits. To avoid these oral disorders at an early stage, health-promoting practices such as limiting sugar consumption, brushing teeth efficiently and regularly, using dental floss, and seeing a dentist on a regular basis should be followed [1].

Fissures of molars are more liable to caries initiation and greater plaque buildup than smooth surfaces because of their morphological complexity [2]. Thus, Fissure sealants were developed to create a barrier that restricts the aggregation of food debris, preventing caries development and stopping caries process [3].

The ADA suggests using fissure sealants for caries prevention [4]. The clinician's skills have a crucial impact in the prognosis of sealant treatment [5]. Recurrent caries frequently arises around sealed pits and fissures because of either microleakage that is caused by polymerization shrinkage or partial detachment of the sealant [6].

In clinical practice, resin-based sealants are often utilized because of their improved stability under occlusal stresses, promising retention rates and longevity. Retention of resin sealants is based on micromechanical bonding between enamel and resin so acid etching prior to their application is recommended [7]. Commercial sealants that release fluoride include a soluble fluoride salt or a glass filler capable of fluoride ion release. Several in vitro investigations have confirmed the ability of these sealants to stop the process of demineralization via fluoride release [8].

The pre-reacted glass ionomer filler technique involves fluoro-aluminosilicate glass particles that have undergone a reaction with polyacrylic acid before being integrated into resin. So, a novel hybrid material (giomer) was created to integrate the mechanical properties and micro-mechanical adhesion of resin composites with the caries inhibitory impact of glass ionomer. Giomer based fissure sealant releases large amounts of ions because of its glass-ionomer phase. Fissure sealants incorporating surface pre-reacted glass-ionomer fillers and used with a self-etch primer can preserve enamel integrity with absence of the tags caused by acid etching [9].

The purpose of this clinical trial was to assess the null hypothesis that giomer-based sealant will demonstrate a retention rate and caries inhibition potential equivalent to that of the conventional resin-based sealant. Notably, as of now, no clinical trials have been released for publication evaluating the caries inhibition potential of giomer-based sealant when assessed by VistaCam iX proof.

Subjects and Methods

This trial was performed at Cairo University's Faculty of Dentistry and registered at www.clinicaltrials.gov. The identification number was NCT05336162. The trial was created as a randomized, double-blinded, two-parallel-arms with a 1:1 allocation ratio.

Medical recipients between 16-22 years old having deep non-cavitated carious fissures in permanent molars were included. By visual tactile examination method, eligible pits and fissures had ICDAS-II codes 1 and 2 and by VistaCamiX proof, they gave readings > 0.9 and < 2. Patients with uncooperative behavior that might hinder the isolation techniques and medically compromised were excluded. Teeth with ICDAS-II codes 3, 4, 5 and 6 were excluded. Partially erupted teeth and teeth with developmental and formative pathosis weren't included.

Medical recipients visiting the clinic of the Conservative department at the Faculty of Dentistry, Cairo University, underwent screening two months before the study intervention. Caries detection was confirmed using VistaCam iX Proof fluorescence camera. Teeth were isolated, dried, and images captured. Results were categorized using numerical values (0 to 3) and teeth with scores not within the included range were excluded. Out of 50 screened patients, 30 met the inclusion criteria, and written consent was obtained. Figure 1 illustrates the participant flow in the study.

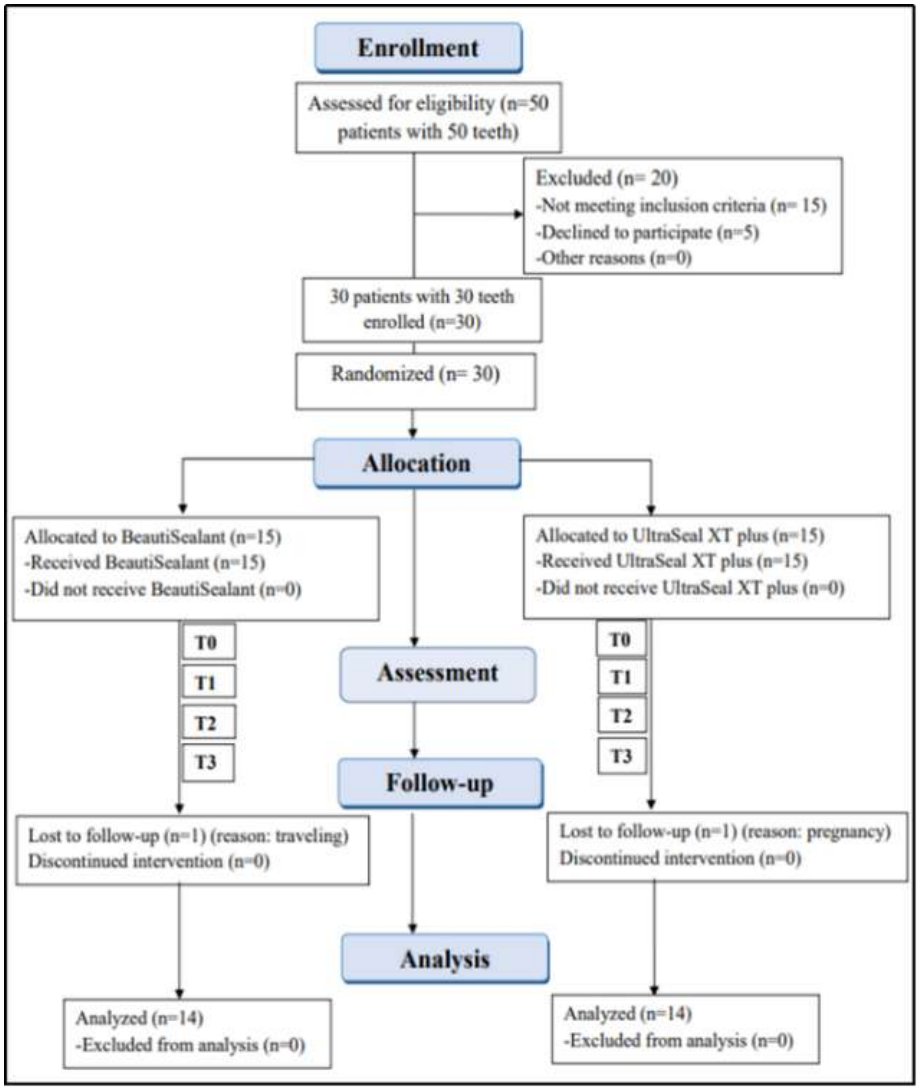

Figure (1): Flow Diagram following CONSORT guidelines

The study used simple randomization for teeth, assigning numbers from 1:30 to either intervention or control groups using (www.randomization.com). Participants received envelopes with treatment group codes. The trial was double-blind, concealing material assignment from patients and assessors. Operators were not fully blinded due to variations in application protocols.

Permanent molars with non-cavitated carious fissures were sealed using either BeautiSealant®, (Shofu, Japan) or UltraSeal XT™ plus (Ultradent™, USA). BeautiSealant® is a Light-cured, giomer-based sealant with the ability to release and recharge fluoride. It was used with BeautiSealant® self etch primer. UltraSeal XT™ plus is a Light-cured, filled, resin-based sealant with the ability to release fluoride. It was used with Power Etching™ phosphoric acid etchant gel.

Clinical procedures:

Field preparation:

Isolation of teeth was done with a heavy rubber dam sheet (Sanctuary Dental Dam, Malaysia) and stabilized by molar clamps (KSK dentech, Japan).

Pre-operative Assessment:

The teeth were cleaned off from plaque with a rotating brush on a slow speed handpiece and pumice slurry (PEDRA POMES®, Brazil). The

teeth were flushed with an air-water spray to remove any pumice residue [10]. The teeth were re-evaluated by VistaCamiX proof after biofilm removal, to make certain that the readings were not affected by the biofilm to avoid false positive readings [11].

Sealant application:

Both sealants were applied following the instructions provided by the manufacturers.

Giomer-based BeautiSealant® application (Intervention group):

The BeautiSealant self-etch primer was applied on the enamel of the fissures using a 1.0mm super fine microbrush (Cotisen®, China) then air blown for three seconds to create a thin bonding layer. The BeautiSealant paste was applied into the fissures using a dispensing syringe tip. The paste was light-cured using light curing device (DTE O-Light II,Woodpecker, China) with light intensity ≥ 1000 mW/cm2 and wavelength of 440-490 nm, for 10 seconds.

Resin-based UltraSeal XT™ plus application (Control application):

Starting with the application of BM4 Power Etching for 30 seconds on the enamel surface of fissures using a dispensing syringe tip. Rinsing of the etchant followed by drying using oil and water free air from an air-water syringe. Dry etched enamel surface was inspected for the chalky white appearance [12]. The UltraSeal XT™ plus fissure sealant was placed and light cured as mentioned with the intervention.

Occlusal adjustments, finishing and polishing:

AccuFilm® II (Parkell®, USA) , a 40 nm articulating paper , was used to assess occlusion and any premature contact was removed with yellow coded finishing diamond stones (MANI, Japan). One-step composite polisher (OneGloss®, Shofu, Japan) was used for polishing.

Outcome assessment:

Fissure sealants were assessed for retention and progression of caries and documented by two trained assessors immediately after application, after 3, 6 and 12 months in evaluation charts. Retention was evaluated using visual-tactile examination. Teeth were air-dried and assessed under a dental operating light, using mirrors and blunt dental explorers [13]. Scores for retention were: fully retentive when the sealant was completely present, partially lost when a portion of the sealant was lost and totally lost when there was no evidence for the sealant. Caries progression was evaluated in areas of lost sealant at each recall appointment using VistaCamiX proof fluorescence camera (Dürr Dental, Germany). The scores were compared to assess caries progression either; A: no caries progression or B: caries progression. A spacer was employed with each tooth to make the distance uniform between the camera tip and the tooth [11].

Statistical analysis:

Medcalc software, version 19 for Windows (MedCalc Software Ltd, Ostend, Belgium) was used to analyze the data. The comparisons between the interventions were conducted using the Chi-Squared test ($P \leq 0.05$). The comparisons within each intervention were performed using the Chi-Squared test ($P \leq 0.0083$). The clinical significance was assessed using relative risk. A confidence level of 95% with 80% power was applied. All tests were two-tailed.

Results

Retention:

Between the two materials, no statistically significant differences were found across various follow-up durations: baseline, 3 months, 6 months, and 12 months ($P = 1.0000$, $P = 1.0000$, $P = 0.1485$, and $P = 0.2673$, respectively). Within the BeautiSealant group, a statistically significant difference was observed among different follow-up durations ($P = 0.0038$*). Regarding the UltraSeal XT sealant group, no statistically significant difference was noted among different follow-up durations ($P = 0.1037$). Regarding retention after 12 months, there was a 75% higher risk of failure for BeautiSealant compared to UltraSeal XT (RR= 1.7500(95% CI 0.6568 to 4.6628; P =0.2630)).

Caries progression:

Between the two materials, no statistically significant differences were observed across different follow-up durations: baseline, 3 months, 6 months, and 12 months (P = 1.0000). Within the BeautiSealant group, no statistically significant difference was found among different follow-up durations (P = 0.9970). Similarly, regarding the UltraSeal XT group, no statistically significant difference was observed among different follow-up durations (P = 0.9970). No difference in the risk of caries progression after 12 months between BeautiSealant sealant and UltraSeal XT sealant was found (RR = 1.0000, 95% CI 0.02119 to 47.1867; P = 1.0000).

Discussion

The goal of this study was to clinically assess the retention rate and caries inhibition potential with the use of self etch giomer-based BeautiSealant® compared to total etch resin-based UltraSeal XT™ plus in permanent molars with non-cavitated carious pits and fissures.

Evaluation of sealant retention was done at baseline, 3, 6 and 12 months using visual-tactile examination which is convenient and highly valid [13]. Caries progression in areas where the sealant was partially or totally lost was evaluated using VistaCam iX proof fluorescence camera. The camera provides a quantitative analysis of dental caries with high sensitivity for demineralization in enamel and dentin [11]. It also has a high accuracy in detecting incipient carious lesions [14]. The VistaCam can only assess the surfaces underlying the clear transparent sealants whereas in opaque sealants this process is not applicable as the opacifiers like titanium dioxide that are present in these sealants can interfere with the fluorescence produced by the camera and attenuate it giving false positive and false negative results [15]. Both sealants used in this study were opaque, so evaluation of caries progression was done with partially and totally lost sealants.

In the current study, in-terms of retention, the comparison between both sealants has demonstrated that there is no statistically significant difference across various follow-up durations. Despite the different application protocols, both comparator and intervention performed equally in terms of retention, thus the null hypothesis is accepted. This was in agreement with a study performed by Coelho et al. [16], who attributed the results to the occlusal maturity of the treated molars and the good clinical visualization of the erupted teeth during treatment. However, in the current study, UltraSeal XT™ plus performed clinically better than BeautiSealant® which revealed 75% more risk for failure regarding retention after 12 months. This could be explained by the insufficient etching ability of BeautiSealant Primer® and the greater resistance of the aprismatic enamel. Many of self-etch adhesives do not have the same acidity as phosphoric acid [17].

In terms of caries progression, the comparison between both sealants has demonstrated that there is no statistically significant difference across various follow-up durations which led to acceptance of the second null hypothesis. This was in agreement with a study performed by Jhingan et al. [18], who attributed the results to the effect of the released ions from both sealants.

The caries inhibition potential of BeautiSealant® depends upon the surface pre-reacted glass ionomer filler (S-PRG). The S-PRG filler is a tiny glass particle composed of three layers; a Silicon dioxide coating then a pre-reacted glass ionomer phase and eventually a glass core. The S-PRG filler is obtained by drizzling poly-acrylic acid that permeates the outermost layer and produces an acid-base interaction involving the fluoro-aluminosilicate core. S-PRG filler secretes six ions: fluoride, borate, strontium, sodium, silicate, and aluminum ions. The amounts of these ions released from S-PRG filler are higher than those released from the unreacted fillers of conventional GIC. Fluoride ions have the ability to strengthen the tooth by forming fluorapatite crystals. Strontium improves the resistance of teeth to acid attacks by transforming hydroxyapatite to strontium-apatite. The borate ions have a buffer capacity and allow remineralization. The released strontium and sodium ions promote acid buffering. These six ions can restrict the growth of streptococcus mutans leading to prevention of

caries [19]. Although the BeautiSealant® was partially or totally lost in some cases in the current study, the caries did not progress in agreement with a study performed by Kotsanos et al. [17] in which the caries preventive effect of BeautiSealant® was attributed to the S-PRG remnants in the depth of fissures after sealant loss.

In terms of UltraSeal XT™ plus, the caries preventive effect relies on its fluoride-releasing ability [20]. Fluoride has a strong affinity to exchange hydroxyl ions that are present in hydroxyapatite and form fluorapatite. The way fluoride and calcium ions interact is much stronger than that of hydroxyl and calcium ions enhancing durability of the crystal lattice and reducing dissolvability in acidic conditions 21. Fluoride can disturb the bacterial metabolism and adhesion to the enamel. It can also diffuse into the bacterial cell and inhibit bacterial enzymes such as enolase [22]. Although the UltraSeal XT™ plus was partially or totally lost in some cases in the current study, the caries was arrested which was similar to a research conducted by Safari et al. [23] in which the caries inhibition potential of fluoride-releasing resin-based fissure sealant was attributed to the remnant of the fissure sealant within the depths of fissures along with the increased concentrations of fluoride on enamel.

To the best of our knowledge, this trial was the first to evaluate the caries inhibition potential of a giomer fissure sealant using the VistaCam iX proof. Results of the current study cannot be generalized as only one type of resin-based sealants was tested. Further well-designed randomized controlled trials involving increased sample sizes and prolonged follow-up duration are advised to validate the results.

Conclusion :

1) Self-etch giomer-based and total-etch resin-based fissure sealants had similar retention rates when used to seal non-cavitated carious fissures in permanent molars along one year follow-up.

2) Caries inhibition potential of giomer-based fissure sealant was comparable to the fluoride releasing resin-based fissure sealant.

3) Both giomer-based and resin-based fissure sealants have acceptable clinical performance.

Conflict of Interest:

No conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 31/5/2022, approval number: 6522.

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