

Microcavitated (ICDAS 3) carious lesion arrest with resin or glass ionomer sealants in first permanent molars: A randomized controlled trial

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ABSTRACT

Objectives: Although there is some consensus that carious lesions in early stages (non-cavitated) could be treated using sealants, neither the type of materials nor their use in lesions with localized enamel breakdown (microcavitated) has been reported. To compare the efficacy of resin or glass ionomer (GI) sealants in arresting microcavitated carious lesions (ICDAS 3) in first permanent molars.

Materials and methods: A double-blinded randomized controlled clinical trial was conducted in 41 healthy 6 to 11-year-old children. At the baseline examination, each subject had at least one carious lesion classified as ICDAS 3 on the first permanent molar. One hundred fifty-one lesions were randomized into: Group 1: resin sealants (76 lesions) and Group 2: GI sealant (75 lesions). Carious lesion progression was assessed clinically and radiographically. Progression and retention failure were the outcomes used for group comparisons at p-value < 0.05.

Results: After a two-year follow-up, only one lesion progressed to ICDAS 5, without statistically significant differences between the groups ($\chi^2(1) = 0.90$, $p = 0.53$). Radiographically, 100 lesions (98%) were arrested and 2 (2%) showed radiographic progression, without differences between groups ($\chi^2(1) = 0.93$, $p = 0.93$). At 2 years, complete retention was observed in 77% of the resin-based and in 83% of the GI sealants, without statistical differences between type of sealant ($\chi^2(1) = 0.71$, $p = 0.48$). The multilevel mixed model demonstrated that location and type of sealant did not affect retention rates ($\chi^2(1) = 24.98$, $p < 0.001$).

Conclusion: Sealing ICDAS 3 carious lesions in permanent molars appears to be effective in arresting lesions after a two-year follow-up. Clinicaltrials.gov: RCTICDAS3/2015.

Clinical significance: Minimally invasive approaches for carious lesion management have been promoted. Using sealants for the treatment of microcavitated lesions (ICDAS 3) appears predictable in the routine practice, without predilection for resin or glass ionomer materials. In addition to preserving tooth structure, this strategy reduces chair-time, dental fear and costs, and increases coverage to dental care.

1. Introduction

The minimal intervention dentistry (MID) approach is a practice intended to preserve dental structures and restore form and function, keeping operative interventions at a minimum level [1]. As part of this approach, minimally invasive treatment (MIT) of dental carious lesions implies conservative techniques to stop lesion progression, protecting, at the same time, the maximal amount of dental tissues. These techniques are intended to maintain health, function and esthetics [1–3]. In addition, MIT reduces the potentially deleterious consequences of using more aggressive conventional treatments that may affect health and integrity of the pulpal tissue. In a world experiencing an accelerated aging process, with longer life expectancies than ever before, preventive and conservative approaches for managing dental caries will

facilitate the preservation of the "biological asset" [4]. This asset is represented by the dental tissues, which are expected to remain functional through the life-cycle.

One of the main strategies for the MIT of carious lesions is the use of sealants. Several studies have indicated that carious lesions located below a sealant have a very low progression rate [5,6]. Sealing non-cavitated carious lesions has been reported as effective in arresting occlusal lesions of permanent teeth in children, adolescents and adults [7]. Non-cavitated lesions treated with sealants have demonstrated an average annual progression of 2.6% versus 12.6% for unsealed lesions [8]. However, these clinically successful procedures require an intact sealant [6]. A systematic review showed that resin-based sealants can stop non-cavitated lesion progression, but the authors suggested that more clinical trials with longer follow-up periods should be carried out

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to increase the scientific value of the findings [9].

Despite the evidence available for non-cavitated lesions, the use of resin sealants as treatment for microcavitated carious lesions (i.e. ICDAS code 3) has only been limitedly reported [10]. The use of sealants can create an effective barrier between the external oral environment and the dental biofilm within the body of the initially cavitated lesions. Under a MIT philosophy, sealant placement can replace traditional restorative treatments, minimizing unnecessary tissue removal during operative procedures and preserving tooth structures.

There is controversial evidence regarding whether the type of sealant material affects the outcomes of the conservative procedures for carious lesion management [11]. It has been discussed that conventional glass ionomer (GI) sealants used as treatment for non-cavitated occlusal lesions may not be sufficiently effective to arrest lesion progression [12], mainly due to its low mechanical properties [13]. On the other hand, it has been argued that resin-based sealants are technically sensitive and an appropriate clinical technique is a key aspect to achieve clinical success [14]. Resin-based sealants applied under liquid contamination from fluids can create adhesive failure, compromising retention [15]. Thus, when total humidity control is not possible, GI may be a suitable alternative to replace resin-based sealants, as GI has good hydrophilic characteristics [16]. A recent systematic review found fifteen studies comparing the preventive role of GI and resin-based sealants, concluding that there is not enough evidence to establish the superiority of either of the two materials [17] and a study of 13 years of follow-up to evaluate the preventive effect of GI concluded that GI sealants may be long-term caries-protective [18]. Hence, the aim of the present study was to compare carious lesions progression and material retention between resin-based and GI sealants, for the management of ICDAS 3 occlusal carious lesions in schoolchildren.

2. Materials and methods

2.1. Trial design and ethical considerations

A randomized controlled clinical study (RCT) was designed in children between 6 and 12 years of age who attended the dental clinics of the University of Talca, Talca, Chile. The study protocol was approved by the Scientific Ethics Committee of the University of Talca (Number: 2015-075-RG). Parents or legal guardians signed an informed consent form that authorized the participation of their children in the study. Additionally, each child signed an assent form. If the lesions progressed, professional dental treatment was provided at the time of detection. The study has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The study protocol was registered at Clinicaltrials.gov: RCTICDAS3/2015.

2.2. Sample size

To calculate sample size, the Granmo v.7 software (Barcelona, Spain) was used with an alpha error of 0.05 and a beta error of 0.2 in a bilateral contrast. Differences between the study groups were estimated to be around 25% based on a previously published study [12], with equally distributed number of teeth in both groups. A 20% drop-out rate was anticipated. Thus, 74 lesions were needed in each group to conduct regression models.

2.3. Participants and recruitment

The age of the participants ranged between 6 and 12 years (mean 9.1 years, SD 1.4). Participants were systemically healthy and had at least one ICDAS 3 lesion on the occlusal surface of the first permanent molar (FPM). Children with semi-erupted FPM, enamel defects (hypoplasia, hypocalcifications, fluorosis), periodontal diseases (except gingivitis), orthodontic appliances or those under medication, were

excluded from the study. Once the consent and the assent forms were signed, children were examined and those who met the inclusion criteria were selected to participate in the study. The recruitment phase occurred between April and May 2015. All the examinations and treatments were carried out by a single dentist, specialist in pediatric dentistry. Thus, 41 children who had 151 ICDAS 3 lesions were selected and enrolled in the RCT. A calibration on ICDAS criteria was conducted [19] and the intra and inter-examiner Kappa values were calculated against an expert and certified dentist on ICDAS, who acted as the gold-standard examiner. Kappa value was 0.9 in both, intra and inter-examiner agreements, which is considered as an “almost perfect agreement” [20]. Prior to the dental examination, participants were invited to brush their teeth under supervision. Standardized Bite-wing radiographs were obtained. To standardize the radiographs, a customized positioning system was used (X-ray Holder, DMG, Hamburg, Germany), with the aid of a bite registration material (Occlufast, Badia Polesine, Italy). X-ray films were scanned using the Roviscan system (Posdion, Seoul, Korea) and digitized on a computer using the WiseScan300 program. Participants received oral hygiene instruction in each control, but no other intervention. Characteristics for the carious lesions included are presented in Table 1.

2.4. Clinical procedures, by intervention group

All the lesions were randomized to either treatment group through a software (www.random.org). Treatment groups were: resin-based sealant (n = 76; Clinpro Sealant, 3M ESPE, St. Paul, MN, USA) and GI sealant (n = 75; EQUIA Fil, GC, Tokyo, Japan). If a child had one lesion, the assigned treatment arm was randomized. When the participant had 2 lesions, they received both types of sealing material, randomizing the treatment. In case the participant had 3 lesions, they received both types of sealants and the third was randomized to either arm. When the child had 4 lesions, 2 sealants of each type were placed, each of them randomized to each tooth. The random allocation sequence was generated by the first author, who assigned participants to the interventions. Two dental students who participated in the study, but not authored the paper, enrolled all participants.

An especially designed clinical record was used to register all data. Treatments were performed by a single operator, who was not blinded due to the different clinical presentations and application techniques of the materials, in a single application and according to the manufacturer's instructions, briefly: teeth were isolated with cotton rolls and carious lesions were cleaned with a cotton swab dampened with water and air-dried. Before sealant application, in the resin-based sealant group, the occlusal enamel was etched with 37% orthophosphoric acid for 15 s, then rinsed for 30 s with water and air-dried for 15 s. Sealant was placed uniformly and polymerized with a light curing lamp for 20 s at 1 cm from the tooth surface. Sealant integrity was checked using a dental probe. If pores were detected, additional material was applied.

For the ICDAS 3 lesions sealed with GI, enamel was conditioned

Table 1

Characteristics for the carious lesions included; number of lesions and percentage of the total.

Variables	Resin Sealant (n = 76)	Glass Ionomer Sealant (n = 75)	p-value
Tooth position			
Lower	45 (59.2%)	32 (42.7 %)	0.04
Upper	31 (40.8 %)	43 (57.3 %)	
Surface			
Occlusal	41 (53.9%)	42 (56.0%)	0.32
Lingual	19 (25.0%)	12 (16.0%)	
Buccal	16 (21.1%)	21 (28.0%)	

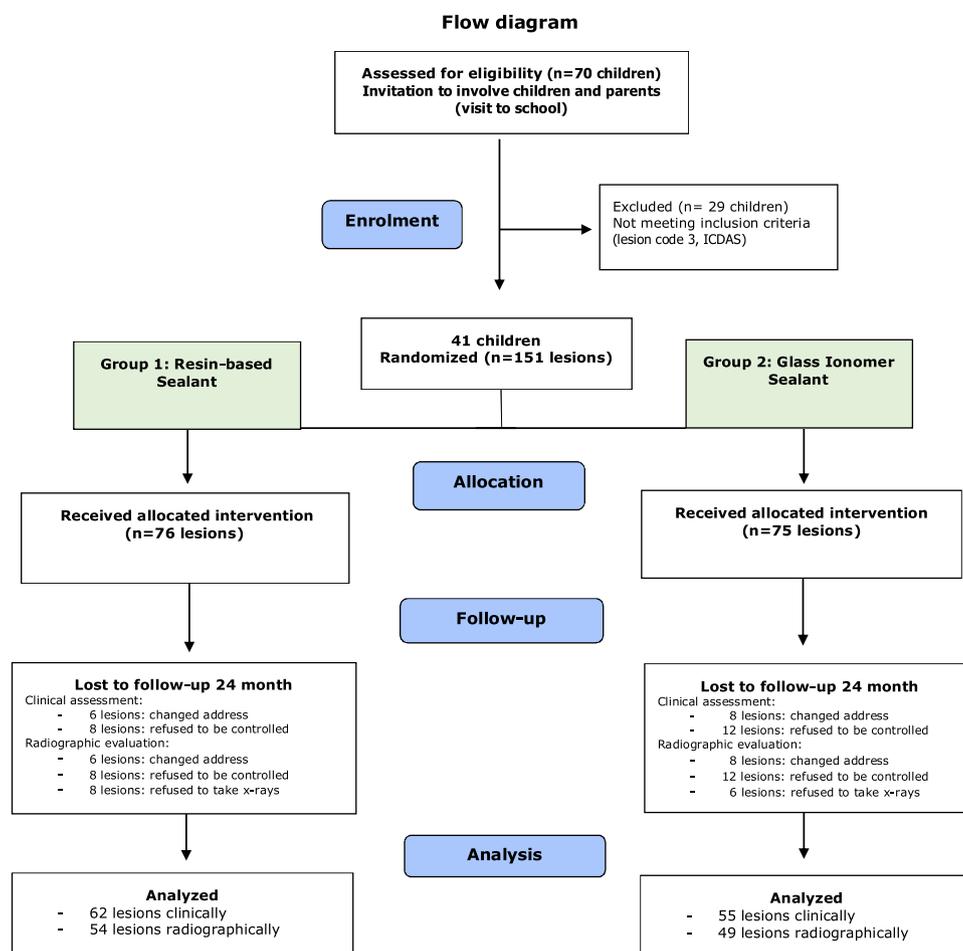


Fig. 1. Flow diagram: A CONSORT flow diagram showing: number of subjects, number of lesions, study groups, clinical and radiographic evaluations of both study arms.

with polyacrylic acid using a fine brush, rubbing it over the lesion for 15 s, washed with a moisturized cotton ball for 5 s and air-dried for 5 s. The commercial presentation of the GI used was capsules, which had to be mechanically mixed for 10 s. Once mixed, an applying tip was placed to the capsule and dispensed from bottom to top of the pits and fissures. GI sealant was compressed against the tooth by digital pressure for 2 min. Excess of material was then removed with manual cutting instruments and a probe, without the aid of rotatory instruments. Occlusion was checked, and sealant surface was cleaned and protected with EQUIA Coat and polymerized for 20 s. For both materials, occlusion was adjusted and the location of the restoration on the occlusal surface was registered on the clinical record.

2.5. Assessments and outcomes

Subjects were evaluated twice, at 12 months and 24 months after the beginning of the study. Lesion progression was assessed, along with the retention and integrity of the materials. Each sealant was evaluated clinically and radiographically.

2.5.1. Clinical evaluation

Each sealed surface was evaluated by a single examiner in a standardized way, following the sequence below:

Material Retention

- Successful: carious lesions, pits and fissures completely covered by the material.
- Failure: carious lesions, pits and fissures partially or totally visible.

Lesion progression: A lesion was considered to have progressed if the original ICADS 3 code changed to a greater code (ICADS 4, 5 or 6).

- Code 1: Progression
- Code 2: No progression

2.5.2. Radiographic evaluation

Radiographs taken during the baseline examination and after 24 months were compared to determine carious lesion progression during the follow-up period. This evaluation was conducted by a single trained radiologist who was blinded to the study arm of the lesion. This procedure was performed in a dark room with a viewing box and a magnifying glass. When a radiolucent area was larger than that registered at baseline, the lesion was categorized as “radiographic progression”. On the other hand, when no change or the radiolucent area decreased in comparison with the baseline radiographs, lesions were categorized as “No radiographic progression”.

2.6. Statistical analysis

Descriptive information regarding the study categories was included. The bivariate analysis, of the relationship between the type of sealants with the progression of the lesions and the retention of the material at 24 months, involved Fisher’s exact statistical test. A mixed bivariate binary regression model was performed to evaluate the risk of the sealants to suffer retention failures. A mixed multivariate binary model was also computed to evaluate the main effects and interactions of sealant type and tooth surface under treatment (i.e., buccal and

others), upon the retention of the material. These mixed models were performed using Generalized Estimated Equations (GEE) to compensate the fact that teeth were selected as the observational unit and randomized. Some patients had more than one tooth treated. The GEE applies as a multilevel modelling approach for categorical variables. Patients were considered as level 1 and teeth as level 2 variable of the analysis. Additional multilevel models were unfeasible due to small number of clinical and radiographic failures. p-values < 0.05% were considered significant. Data were analyzed using SPSS v24 (IBM, NY, USA).

3. Results

Of the 151 lesions included in the study, 77.4% (n = 117) were evaluated clinically and 67.5% (n = 102) were evaluated radiographically at the 24-month assessment. Lesions lost to follow were due to subject's change of address or refusal to take control radiographs (Fig. 1). The group of GI sealants had more losses, both clinical and radiographically, compared to the resin-based group.

Only one of the lesions treated with resin-based sealants progressed clinically (1.6%) to Code 5, without statistically significant differences between the groups ($\chi^2(1) = 0.90, p = 0.53$). No lesion from the GI group showed signs of clinical progression. Similarly, 1.9% (n = 1) and 2.0% (n = 1) showed radiographic progression in the resin-based and GI group, respectively. This difference lacked statistical significance ($\chi^2(1) = 0.93, p = 0.93$) (Table 2).

After 24 months, complete retention was observed in 77.4% (n = 48) of the resin and in 83.6% (n = 46) of the GI sealants. There was a trend for a better retention of the GI sealants (OR = 1.49), without statistically significant differences between the materials ($\chi^2(1) = 0.71, p = 0.48$) (Table 3). Location in the arch, sex and age of the participant did not demonstrate any statistically significant relationship with the radiographic or clinical success of the sealants (data not shown). The multilevel binary regression model was statistically significant ($\chi^2(1) = 24.98, p < 0.001$) and demonstrated that the type of material and tooth surface did not influence sealant retention. Similarly, the interaction between the type of material and tooth surface did not result in significant risk values. Sealants placed in the buccal surface showed a non-statistically significant trend for increased risk of retention failure compared to those placed in occlusal or lingual surfaces (Table 4).

4. Discussion

Treatment strategies used for managing carious lesions have been changing considerably during the last years. These strategies have moved from operative and restorative interventions to a non-operative and minimally invasive management which aims at the preservation of the tooth structure throughout the life-cycle [4]. One of the techniques advocated for the non-operative management of carious lesions is the use of sealants over non-cavitated lesions [8]. Despite recent

Table 2
Clinical and radiographic results after 24 months of follow-up.

Clinical assessment	Success n = 116 (99%)	Failure n = 1(1%)	Risk	95%CI	p-value
Resin sealant	61 (98.4)	1 (1.6%)	1		
GI sealant	55 (100)	0 (0%)	0.98	0.95-1.02	0.53
	$\chi^2(1) = 0.90$				
Radiographic assessment	No lesion progression n = 100 (98%)	Lesion progression n = 2 (2%)	Risk	95%CI	p-value
Resin sealant	53 (98.1)	1 (1.9)	1		
GI sealant	47 (98.0)	1 (2.0)	0.89	0.06-14.4	0.93
	$\chi^2(1) = 0.93$				

Table 3
Clinical sealant retention results after 24-month assessments.

Materials	Success n = 94 (80.3%)	Failure n = 23 (19.7%)	Risk	95%CI	p-value
Resin sealant	48 (77.4%)	14 (22.6%)	1.49		
GI sealant	46 (83.6%)	9 (16.4%)	1	0.59-3.78	0.48
	$\chi^2(1) = 0.71$				

Table 4
Multilevel binary regression model testing the influence of material and surface upon the retention failure of the sealant after a 24-month assessment.

Multilevel model	Beta	Standard error	Risk	95%CI	p-value
Material					
Resin sealant	1	1	1		
GI sealant	0.26	0.68	0.77	0.2-2.9	0.71
Surface					
Occlusal	1	1	1		
Buccal	0.66	0.93	1.93	0.3-11.9	0.48
Lingual	0.05	0.93	1.10	0.2-6.6	0.96
Material*Surface					
Others	1	1	1		
Resin*Buccal	0.77	1.17	2.16	0.2-21.6	0.51
GI*Buccal	1.37	1.11	3.95	0.4-35.2	0.22
Wald $\chi^2(1) = 24.98, p < 0.001$					

recommendations from the American Dental Association and the American Academy of Pediatric Dentistry on using sealants over non-cavitated lesions [21], the present study was carried out with the idea of extending the indication for this type of procedure on localized enamel breakdown, without visible dentin exposure (ICDAS 3), for which there is no evidence available. This approach appears as an attractive way to minimize intervention and to preserve tooth structure, according to the principles of the MID and the MIT for carious lesions.

The results of this research showed that after 24 months, clinical progression of carious lesion treated with sealant was minimal, regardless of the type of material used. Only one lesion showed clinical progression in the resin sealant group. Radiographic assessments showed a progression of 1.9% of total lesions treated with resin sealant and 2.0% with GI. Similar findings have been reported in non-cavitated lesions at 12 months [14]. The authors, however, concluded that the follow-up may be too short to provide the clinician with enough evidence. Herein, we extend the observation period up to 2 years. It has been stated that clinical efficacy of sealing for arresting carious lesions depends on the complete retention of the material [5,6,14]. Conversely, the present study showed no progression when the sealant was partially or completely dislodged, which is consistent with previous studies conducted in cavitated primary molars reaching the outer half of dentin [22]. The study showed 64.7% of clinical success at 18 months in the arrest of occlusal cavitated lesions, lower than our study sealing microcavitated lesions. Also, our results are in line with those reported previously in a study of 7–10 year-old children where carious lesions were managed with resin sealant with at least 2 permanent molars with ICDAS lesions scored up to 4 and radiographically less than halfway through the dentin [10]. Their results showed that sealants were 100% effective at 12 months and 86% at 44 months in the management of occlusal lesions. There was low radiographic progression of 1% at 12 months, 3% at 24 months and 9% at 44 months. Furthermore, Borges et al, 2012 found 11.5% progression in non-cavitated lesions when the sealant was dislodged at the 12-month follow-up [6].

There are studies showing that sealed carious lesions have a lower progression than unsealed lesions. One study showed that, after 5 years, sealing in deep pits and fissures or with early enamel caries, only 10.8% of sealed lesions had progressed compared to 51.8% of unsealed lesions [23]. Also, another study conducted on non-cavitated lesions with resin sealants found that after one year, 96% of the untreated lesions

progressed compared to 3.8% of the sealed lesions [14].

On the other hand, evidence for the use of GI sealants on carious lesions is scarce. Indeed, only one study refers to the therapeutic use of GI sealants in 51 teeth with clinically non-cavitated occlusal caries radiographically located beneath the enamel-dentine junction. Although no differences were clinically detected, the results showed 11.1% of radiographic progression compared to 50% of untreated lesions [12]. On the best of the authors' knowledge, this is the first clinical trial for the use of sealants as treatment for microcavitated caries lesions, that is, lesions with clinical loss of continuity of the enamel (enamel breakdown, as described in ICDAS 3 lesions). The use of sealants in this situation can replace the traditional restoration, preserving dental structure and delaying or eliminating the need for operative procedures.

The most plausible explanation for the results observed is that sealants may interrupt the nutritional supply for the active infiltrating biofilms within dentin, impairing bacterial growth and subsequently, lesion progression [24–26]. Despite these promising results, regular professional monitoring is necessary to assure long-term clinical success.

Although the apparently high predictability of sealing microcavitated lesions in arresting lesion progression, retention continues to be a challenge. Indeed, the retention rate for either material used was relatively low with about 20% failure after 2 years, but without progression. A non-significant higher retention for GI over resin sealants was observed, with 83.6% and 77.4%, respectively. From a clinical point of view, whether these numbers for retention rates are considered acceptable or not may be debatable, but still mandates periodic control and clinical supervision. Reasons for sealant loss or fracture over time, in the absence of lesion progression, may derive from several sources. Furthermore, the irregular shapes of the lesion margins could alter sealant penetration and interlocking. Enamel quality of a previously acid-attacked tissue by bacterial acids may compromise optimal adhesion [27]. The presence of a dental biofilm that could remain at the bottom of the pit and fissure of the microcavitated lesion could reduce the adaptation of the sealants. Previous studies have shown that demineralized and cavitated surfaces can decrease the longevity of the sealant, since microleakage occurs more frequently around sealed carious lesions than healthy sealed surfaces. An *in vitro* study compared the microleakage and penetration depth of the resin sealant between cavitated fissures and healthy surfaces [27]. The results of previous studies showed that there was no microleakage or differences in the penetration of the sealant. This controversy and the lack of evidence available warrants further research on the topic, mainly clinical trials.

Furthermore, we decided not to use any disinfectant before placing the sealants in the cavities. It has been argued that the use of, for example, 2% chlorhexidine solution would increase restoration survival. The existent literature, however, has failed to show this protective effect. Indeed, a 5-year follow up of ART restorations concluded that disinfecting an ART cavity with a 2% chlorhexidine solution is unnecessary, as it does not increase survival when compared to a non-disinfected cavity [28].

As abovementioned, evidence is inconclusive with respect to the type of material to be used for sealing non-cavitated lesions and even less for cavitated or microcavitated lesions. Most of the studies available report favorable results for arresting non-cavitated lesions using resin sealants [5,6]. Our results, nonetheless, evidenced no differences in clinical progression when GI and resin sealants were compared. We do not concur to the conclusion from a previous study [12], stating that GI sealant may not be effective enough to arrest non-cavitated occlusal carious lesion, for our study showed comparable results. Moreover, some studies have reported a cariostatic effect of GI sealants derived from its property of up-taking fluoride from the environment and releasing it around the restoration [29,30]. The latter has not been consistently shown in clinical trials. Interestingly, however, one study demonstrated that when a GI sealant is placed over the pits and fissures

and then dislodged, there are remains of the material at the bottom of the fissures, which also allows the release of fluoride in the enamel and mechanically block the depth of the fissure [31,32]. This phenomenon would combine the mechanical effect of the sealant with the remineralizing and the putative antibacterial activity of fluoride [33]. Although not significant, GI showed higher retention rates than the resin sealants (Table 3). We speculate that this could be the result of the high viscosity of the GI cement, the digital pressure applied that allow deep penetration of the material and the altered adhesion of the resin sealant in a natural microcavity, with remains of biofilm and unsupported enamel.

Despite the use of standardized bite registries for the radiographic assessment of the lesions, we acknowledge some limitations with the technique, as participants were in the process of tooth replacement and bone growth, so, some distortion of the records may have occurred. Hence, certain considerations must be taken in future studies with children of this age. In our study, radiographic assessment was carried out by a trained and expert radiologist, which reduces operator-derived bias. Furthermore, Bite-wing radiographs for occlusal lesions is not the canonical way to control lesion progression, but it is still an acceptable technique that has been used in similar studies evaluating occlusal lesions [34]. Radiographic subtraction has been successfully used in different studies of occlusal lesions [34], but in the present study, the depth of the lesions preclude the use of this technique, as many lesions were restricted to enamel. Thus, regardless of the inherent limitations of any technique, periodical radiographic monitoring of the lesions is compulsory to ensure clinical success and failure control. Follow-up is not restricted to radiographic control, but also to clinical examination of marginal integrity and material retention [5].

This conservative approach of sealing microcavitated carious lesions, under the scope MID, has several advantages over the traditional restorative management of the lesions, including: a patient-friendly procedure used without the need for anesthetics, lower costs and higher access to treatment, and the preservation of the “biological asset” [4] throughout the life-cycle, avoiding the cycle of restorations or the so called “restorative death spiral” [35].

5. Conclusions

The use of therapeutic sealants appears to be effective in arresting progression of microcavitated lesions (ICADS 3), without noticeable differences between resin and GI sealants.

Since clinical sound evidence supporting the use of this type of therapeutic approach is rather weak, further studies, with longer follow-up are strongly suggested.

Declaration of Competing Interest

None.

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