


## Alternative of Lower-Cost Glass-Ionomer Sealant in the Prevention of Caries Lesions in Brazilian Children


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### Abstract

**Objective:** To compare retention, preventive effectiveness and longevity of two different high-viscosity glass-ionomer sealants Ketac Molar<sup>®</sup> and Maxxion R<sup>®</sup> in the sealing of erupting and out-of-occlusion first permanent molar in children aged 5-7 years. **Material and Methods:** Children with past caries experience with healthy erupting first permanent molar were included in the study. Teeth 16 and 46 were sealed with Ketac Molar<sup>®</sup> and teeth 26 and 36 were sealed with Maxxion R<sup>®</sup>. After 8 months, the retention of sealants was evaluated using the following criteria: total retention; presence of sealant in two thirds of the occlusal surface; presence of sealant in one third of the surface; and total absence of the sealant. **Results:** Statistical difference between materials was observed, and Ketac Molar<sup>®</sup> retention was superior to that of Maxxion R<sup>®</sup> ( $p < 0.05$ ). Regarding the development of caries in sealed first permanent molar, none of the teeth sealed with Ketac Molar<sup>®</sup> or Maxxion R<sup>®</sup> developed caries lesion. **Conclusion:** Ketac Molar<sup>®</sup> retention is significantly superior to that of Maxxion R<sup>®</sup>, but the preventive effectiveness in the development of carious lesions is similar for both, which is extremely interesting for the field of public health, since the cost of the material is significantly lower.

**Keywords:** Dental Caries; Dental Materials; Pit and Fissure Sealants; Dentition, Permanent.

## Introduction

Caries disease has been affecting humanity since prehistory. However, the profile of this disease has changed due to changes in the habits and behavior of the population [1,2]. Dental caries can be described as a dynamic process, which occurs along bacterial deposits due to the fermentation of food substrates resulting in the production of organic acids. These acids cause changes in the balance between dental surface and the plaque fluid, causing mineral loss over time [3].

In recent decades, a drop in dental caries rates in both developed and developing countries, as is the case of Brazil, has been observed [4]. Several factors are pointed out as possible causes for the disease decline: application of sealants, addition of fluoride to the public supply water, large-scale use of fluoridated dentifrices [2,5], changes in the pattern and amount of sugar consumption associated with the improvement in the quality of life conditions and greater comprehensiveness of oral health promotion and education actions. However, dental caries remains a major public health problem, especially in childhood, both in Brazil and in most of the world [6]. The disease distribution is not homogeneous, and some populations show dental caries polarization [7].

Based on scientific evidence, the application of caries prevention agents in children, such as pit and fissure sealants is indicated [8-10]. Thus, when sealants are properly applied, they are highly effective in preventing caries in the region of pits and fissures [11]. Considering children aged 5-7 years, the use of sealant is a very interesting preventive measure due to the eruption of the first permanent molars [12]. During the eruption of first molars, there is greater susceptibility to caries, since these teeth present immature enamel rich in calcium carbonate, which is more soluble in acidic medium. In addition, before reaching the occlusal plane, the erupting tooth is more prone to biofilm accumulation [13]. In this way, preventive measures in this age group become relevant.

There are, on the market today, resin-based and glass-ionomer sealants. The factors that determine the best choice are mainly the humidity of the site and the stage of tooth eruption. While resin-based sealants require excellent moisture control, which is difficult at the stage of tooth eruption, glass ionomer-based materials have lower moisture sensitivity and the advantage of releasing fluoride, which benefits the remineralization of dental structures, reducing mineral loss [8]. Although ionomer-based sealants have lower retention index when compared to resin-based sealants, the preventive effect is similar [14].

Although the technique of sealing pits and fissures has proven to be efficient in the prevention of caries on occlusal surface [15], in vivo studies that consider materials developed in Brazil, that is, with more accessible market values for the sealing of erupting first permanent molars are still necessary [9,16,17]. There are several ionomer-based sealants from different manufacturers in the Brazilian market, which require clinical studies to evaluate their performance and especially their insertion in public health.

Therefore, the objective of this study was to compare retention, preventive effectiveness and longevity of two different high-viscosity glass-ionomer sealants in the sealing of erupting and out-of-occlusion first permanent molar in children aged 5-7 years.

## Material and Methods

### Study Type and Sample

This is a longitudinal clinical trial. Children aged 5-7 years who attended the public education network of the municipality of São José dos Ausentes, RS, Brazil, were selected. The city is located in the state of Rio Grande do Sul, 236 km away from the state capital. According to the last census carried out in the year 2018 18, the city population was 3,509 inhabitants and HDI was 0.663 according to IBGE in the year 2010 19. The public supply water is fluorinated and has between 0.6 and 0.9 ppmF / L.

The study sample consisted of children aged 5-7 years of both genders attended at Basic Health Unit (UBS) of the municipality of São José dos Ausentes, Brazil. All children enrolled in municipal elementary schools at this age group were invited to participate in the study.

### Inclusion and Exclusion Criteria

Inclusion criteria were: children with past caries experience, free and informed consent signed by parents or guardians and with the first permanent molar under eruption process, with at least two thirds of the occlusal surface being exposed and out of occlusion. Children with permanent first molars in occlusion or with caries were excluded.

The sample of children aged 5-7 years was composed of 92 students. Of these, 89 obtained parental consent to participate in the study, but only 63 met the inclusion criteria. Six children gave up, so that the total number of children attended was 57 and the total number of teeth evaluated was 228.

### Experimental Design

A sample where the defined experimental unit was the tooth was used, with elements 16 and 46 sealed with Ketac Molar Easy Mix (3M ESPE Dental Products, St. Paul, MN, USA) and elements 26 and 36 with Maxxion R (FGM Produtos Odontológicos, Joinville, SC, Brazil).

### Clinical Examination

Clinical examination was performed in a dental office at the Basic Health Unit. Intraoral exams followed a systematic approach after prophylaxis with Robson toothbrush, pumice stone and water, with washing and drying of dental surfaces with triple syringe. The diagnosis of caries disease was visual using the International Caries Detection and Assessment System (ICDAS) index and performed with the aid of mirror, compressed air and suction.

The ICDAS index considers both cavitated and non-cavitated caries lesions. Surfaces were classified according to scores: 0 - no change in the enamel translucency after drying for 5 seconds; 1 - opacity visible after drying for 5 seconds; 2 - opacity visible even in the presence of moisture; 3 - cavity located in opaque or pigmented enamel; 4 - shading of the underlying dentin; 5 - cavity in opaque or pigmented enamel with exposure of the underlying dentin; 6 - cavity in opaque or

pigmented enamel with exposure of the underlying dentin, involving more than half of the surface [11]. This classification was performed by a single previously calibrated examiner ( $Kappa = 0.843$ ).

Prior to sealant application, children had their first erupting molars classified as [20]: stage 2 - the entire occlusal surface of the tooth emerges through the gingiva, but gingival operculum extends over the distal marginal ridge; or stage 3 - the entire occlusal surface is exposed and does not contain gingival operculum, but the distal gingival tissue is adjacent and at the height of the distal marginal ridge.

Children also had a clinical record containing data such as: name, age, caries index according to the ICDAS criterion [11], presence or absence of clinically visible biofilm on the vestibular face of the upper incisors and socio-economic conditions.

### Sealant Application

Children were submitted to the application of ionomer-based sealant in dental offices. Sealants used were spatulated according to manufacturers' instructions, applied on molars with the fingerprint technique and protected with vaseline. All children were screened and attended by a single dentist, who strictly followed biosafety standards.

Sealed teeth were reexamined after 8 months of application to evaluate retention and effectiveness in occlusal caries prevention in the first permanent erupting molars. Sealants were evaluated for retention and effectiveness in preventing caries lesions in erupting molars. The following criterion was used to evaluate sealant retention: TR - total retention; PR1 - presence of sealant in two thirds of the occlusal surface; PR2 - presence of sealant in one third of the occlusal surface; PT - absence of sealant on the occlusal surface [21]. Surfaces that have lost the sealant were evaluated for the presence of caries according to the ICDAS criterion.

### Statistical Analysis

Data were tested for normality by the Lilliefors test and were not normal. For the comparison of groups regarding the retention of sealants, considering the different eruption stages, the non-parametric Mann-Whitney test was used. The presence or absence of clinically visible biofilm on the vestibular face of the upper incisors and the socioeconomic conditions were evaluated by descriptive statistics. The significance level of the statistical analysis was 5%.

### Ethical Aspects

This study was approved by the Ethics Research Committee of the São Leopoldo Mandic School of Dentistry (Protocol No. 039306/2015). Data were collected after consent from parents or guardians of participants through the Informed Consent Form.

### Results

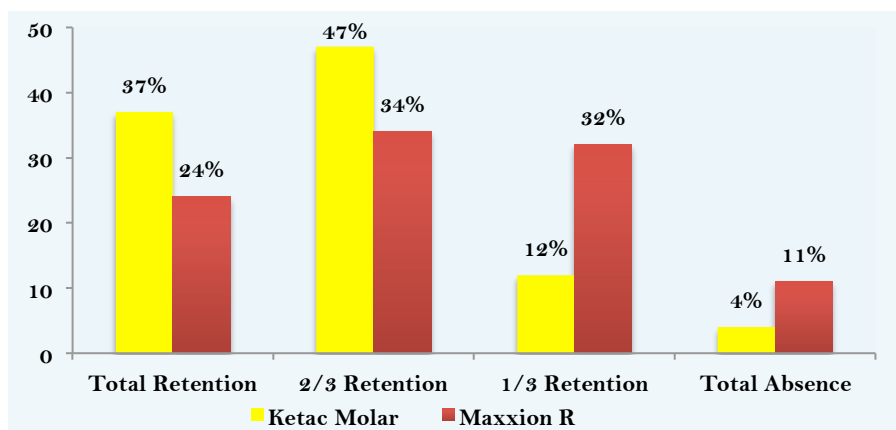
According to clinical examination, the following results are shown in Table 1.

**Table 1. Prevalence of the worst ICDAS score per child.**

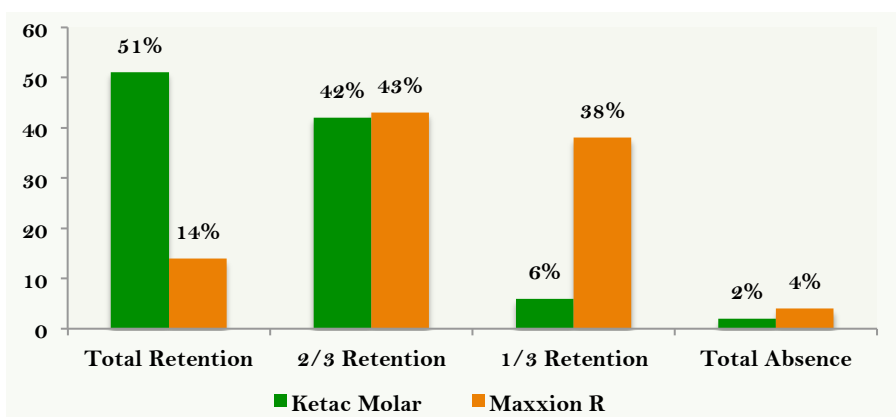
| Scores According to ICDAS | Prevalence |
|---------------------------|------------|
| Score 0                   | 28%        |
| Score 1                   | 23%        |
| Score 2                   | 12%        |
| Score 3                   | 11%        |
| Score 4                   | 16%        |
| Score 5                   | 7%         |
| Score 6                   | 4%         |

Also during clinical examination, the presence of bacterial biofilm and the stages of eruption of the first permanent molars were evaluated. The presence of bacterial plaque was verified in 47%, while 38% of the first permanent molars were in Stage 2 of eruption and 62% in stage 3.

The comparison of the retention of sealants considering the different materials and different stages of tooth eruption after eight months of follow-up is described in Figures 1 and 2 for stage 2 and 3 of tooth eruption.



**Figure 1. Retention of sealants in molars at stage 2 of tooth eruption after eight months of follow-up.**



**Figure 2. Retention of sealants in molars at stage 3 of tooth eruption after eight months of follow-up.**

Significant difference was observed between materials when used on stage 2 ( $p = 0.0190$ ) and stage 3 ( $p < 0.0001$ ) of tooth eruption. Thus, the performance of Ketac Molar® was superior to

Maxxion R® after eight months of follow-up, regardless of stage of tooth eruption. Regarding the caries-preventive effect of both materials, no caries lesion development was observed in any sealed tooth, regardless of material used after 8 months of follow-up.

## Discussion

The main objective of this study was to test a lower-cost material compared to Ketac Molar® and to show that they present similar preventive actions, being relevant information in terms of public health. Thus, this study draws the attention of the public sector to an effective preventive option, with significantly lower cost.

During the last few decades, scientific researches have provided data for a better understanding of the dental caries process. There was an increase in knowledge of the demineralization/remineralization mechanism, the progression of caries lesion, the role of bacteria and fluoride. All this information allowed that oral health care could be more focused on prevention [22-24].

On the other hand, in developing countries, a large part of the population remains without access to any type of dental care. Often, treatment is only performed when the only option is tooth extraction [25]. Several factors contribute to this outcome: insufficient financial resources in Public Health, impossibility of access to private dentistry, need for sophisticated equipment and materials. In this context, alternatives to provide dental care to a greater number of people have been searched.

Higher risk of developing occlusal caries is related to the stage of tooth eruption, since biofilm accumulation on the dental surface in this period is more evident, hygiene is impaired due to the child's lack of motor ability and dental enamel not yet reached post-eruptive maturation [26-28].

Sealants are isolated physical barriers that protect teeth from the oral environment, avoiding the accumulation of dental plaque and the onset of caries lesion progression in the enamel of pits and fissures [29-31]. Sealants came from the need to facilitate hygiene by sealing pits and fissures in permanent molars, because the phase of eruption of permanent molars is a period of clinical concern, since the enamel of molars is still immature, poor hygiene (below the occlusal plane) and anatomy of pits and fissures that favor food accumulation [32].

Due to these criteria, we decided to perform sealing during the period of eruption of permanent molars. In addition, erupting molars were also emphasized in this work because they have immature enamel and are susceptible to caries disease, as previously mentioned [33]. Thus, a conservative approach was adopted, i.e., ionomer-based sealants applied to pits and fissures to prevent dental caries.

The present study aimed at performing a preventive procedure that is easy to perform and well accepted by children, as previously reported [34], in which sealants have been used as part of the prevention program control and indicated with professional supervision [35-37], since the benefit of the glass-ionomer sealant is increased by the association of fluorine with its formula. Fluorine acts directly in the remineralization process, favoring remineralization and reducing demineralization.

Good sealing performance was achieved with high viscosity ionomer-based materials. Sealants were evaluated in a period of eight months of follow-up, where the degree of retention of these sealants was evaluated and sealing with Ketac Molar<sup>®</sup> was shown to be superior. Regarding the characteristics of glass-ionomer cements, the type of adhesion is an important feature to indicate its use. It presents chemical bond to the dental structure resulting from the chelation of carboxyl groups of polyacids with calcium present in the enamel apatite [38]. As for retention, it is known that the retention index presented has been satisfactory, but it still presents failures due to the properties of the material [35]. Sealing with glass-ionomer cement in this study presented difference in retention and great success in prevention, since no caries developed even when the sealant was lost. It was also shown that sealants have obtained excellent results in the prevention of permanent erupting molars in children at high risk for caries [36,37].

In vivo longitudinal clinical trials using nationally produced GICs are few [39,40] and the present study compared the Brazilian Maxxion R<sup>®</sup> material with the gold standard Ketac Molar<sup>®</sup> and verified that Ketac Molar<sup>®</sup> had much better result regarding the retention of the material when evaluated six and eight months after application. Unlike this study, which presented better results for one of the materials analyzed, a study carried out in Latvia analyzed for two years the sealing of class I cavities with Chem-Flex<sup>™</sup> glass ionomer. The results were successful for both materials (92.5% test material and 94.9% control) [41].

In the present research, success was obtained with regard to the prevention of caries in sealed molars. The sealing of pits and fissures is effective in the prevention of dental caries in occlusal surfaces [42]. It is known that the sealant creates a physical barrier between the occlusal surface and the oral environment, thereby preventing the progression of the disease. For patients who do not respond to treatment based on the control of disease activity and have carious lesions on other surfaces, the sealing of pits and fissures is indicated [43]. However, when teeth reach the occlusal plane, regardless of type or depth of fissures, biofilm disorganization, physiological sealing and probable loss of material will easily occur.

The inclusion criterion of this study was the stage of tooth eruption [20], where only patients at stage 2 and stage 3 of tooth eruption participated in the study. Sealing with high-viscosity GIC in newly erupted molars decreased the chances of carious lesions by 50% [44]. As in this study, total success in prevention was obtained, in which no sealed tooth developed caries lesion.

A previous study compared the clinical performance of two ionomer-based sealants in the sealing of freshly erupted permanent molars, conventional Vidrion<sup>®</sup> and high-viscosity GIC ChemFlex<sup>®</sup> and observed no statistical difference between them when retention was evaluated [45]. Other authors compared GIC modified by Vitremer resin<sup>®</sup> with conventional GIC Ketac-Bond<sup>®</sup> and found higher retention and preventive efficacy in the group where molars were sealed with Vitremer<sup>®</sup> due to the fact that it contains resin-based components, favoring its adhesion to the dental structure [46].



Unlike results obtained in this study, some authors observed that Ketac Molar® ionomer-based sealant presented behavior similar to others in relation to retention [47], and can be used for occlusal sealing with the digital pressure technique, since these materials are considered gold standard. Recent systematic review showed reduction of caries lesions in teeth sealed with GIC when compared to molars that did not receive the treatment [48].

High-viscosity ionomer-based sealants tested in this study showed difference in clinical performance when retention was evaluated after eight months, considering their stage of eruption. However, the most important result was regarding the preventive effectiveness of both materials, since both showed excellent result in caries prevention. Data have shown that the indication of sealant in erupting molars is correct when considering its preventive effect. Literature shows that large part of clinical evaluation studies involving ionomer-based sealants report lower adherence over time [49]. A review with meta-analysis has shown that although there are few studies in literature evaluating the retention and efficacy of ionomer-based sealants, these materials showed good preventive effect. Despite showing lower adhesion to the dental structure and lower visual retention in clinical trials, GIC shows release of fluoride on the tooth surface, and material particles are found in fissures even after the material is not visible on the surface [48,51,52], justifying its use as sealant of pits and fissures.

Some limitations in the present study should be highlighted: a laboratory study can control important clinical variables, such as moisture, better visualization of the entire dental region (different from clinical trials). Pediatric dentistry presents limitations in the use of sealants as preventative material on the surface of molars due to the difficulty of maintaining the oral environment dry during treatment, which decreases the success in the retention of sealants [28,50,52]. Therefore, further studies should improve methodologies to obtain increasingly accurate and effective results, since clinical trials are difficult to perform, mainly because they involve humans.

In addition, Maxxion R® has shown to be easily introduced in public health, since it has low cost, easy application and feasibility to be used in the field, that is, in school.

## Conclusion

Sealing of erupting molars with high-viscosity glass ionomer-based Ketac Molar® had superior retention compared to Maxxion R® on occlusal surfaces of permanent molars at different stages of tooth eruption after eight months of follow-up, suggesting satisfactory clinical performance. However, the preventive effectiveness in the development of caries lesions was similar for both materials, confirming the good clinical performance of ionomer-based sealing.

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**Conflict of Interest:** The authors declare no conflicts of interest.



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