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ORIGINAL ARTICLE

Performance of Preventive Methods Applied to the Occlusal Surface of Primary Teeth: A Randomized Clinical Study

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Abstract

Objective: To evaluate the clinical performance of three preventive materials on the occlusal surfaces of primary molars over a 36-month period. **Material and Methods:** The study was conducted with a split-mouth design involving four experimental groups: G1 – resin-modified glass ionomer cement (Vitremer®); G2 - resin sealant (Alpha Seal Light®); G3 - silver diamine fluoride (Cariostatic®); and G4 - control group without material. Thirty-two children aged 36 to 60 months, attending a pediatric clinic, with a deft index ≥ 1 and four primary second molars participated in the study. The material retention was evaluated in G1 and G2, and the presence of incipient caries was evaluated in all groups. Data were submitted to the Wilcoxon test and survival test ($\alpha = 5\%$). **Results:** At three, six, 12, 24 and 36 months, G2 exhibited greater material loss (maximum loss: 44%) in comparison to G1 (maximum loss: 35%), but this difference did not achieve statistical significance ($p = 0.214$). The highest incidence of incipient caries occurred in G3 (20%), but no significant differences were found between groups at any evaluation time ($p = 0.154$). **Conclusion:** There were no statistically significant differences between the evaluated products regarding material retention and dental caries, although there was more material loss in teeth that received the Alpha Seal® sealant resin, and a greater number of carious lesions in the Cariostatic® group (silver diamine fluoride).

Keywords: Pit and Fissure Sealants; Tooth, Deciduous; Dental Caries.

Introduction

The reduction in the incidence of dental caries among the young population in recent years is not related to changes in eating habits or frequency of sugar intake, but to improved oral hygiene [1], daily dose of fluoride and sealing of occlusal tooth surfaces [2,3]. However, the incidence of dental caries on occlusal surfaces remains high, with pits and fissures representing 80 to 90% of dental caries experience in childhood and adolescence [4]. Occlusal surfaces represent only 12.5% of the permanent dentition, but account for approximately 50% of dental caries in schoolchildren [5].

Data for the primary dentition are similar. Some authors reported that primary molars account for approximately 60% of caries experience in children aged two to three years, and the occlusal surfaces are the most affected structures in this process [3]. Indeed, occlusal surfaces are highly susceptible to the development of dental caries due to their specific anatomical shape, which includes grooves and pits that facilitate the accumulation of food remnants and provide a favorable niche for caries. This situation is further aggravated by the difficulty to brush this region, due to the poor motor skills found in children [6].

Inadequate oral hygiene, poor motor skills and a sugar-rich diet compromise the satisfactory implementation of sealing procedures in young children [6]. Due to these drawbacks, it is necessary to employ caries control methods to minimize the incidence and progression of this condition on occlusal surfaces [7], such as sealing of pits and fissures and the use of fluoridated products. A proper diagnosis, knowledge regarding the properties of materials employed, determination of caries risk, sealant application at the appropriate time and caries control with periodic checkups are fundamental to the success of preventive treatment [8,9].

According to the literature, the use of sealants (resin sealants, glass ionomer cement or resin-modified glass ionomer cement) on permanent molars is considered effective, safe and feasible for the reduction of occlusal caries in schoolchildren [10-12]. However, there are few reports addressing preventive methods for children at high risk of tooth decay who are susceptible to the development of occlusal caries after the eruption of the primary first and second molars [6,13,14].

Occlusal sealants are fluid resins able to seep into pits and fissures and penetrate the micropores of acid-etched enamel, to physically isolate the occlusal surfaces [15] and maintain dental health in the most exposed area [16]. The preventive effect is directly dependent on the sealant retention in pits and fissures [1].

Materials with glass ionomer cement have demonstrated good results despite the lower degree of retention. The fluoride release and consequent remineralizing capacity are among the advantages of such materials for sealing of occlusal surfaces [6].

Silver diamine fluoride (SDF) is another caries control agent widely used to prevent caries in pits and fissures. SDF has preventive and cariostatic properties, seals dentinal tubules, is inexpensive, easy to apply and can be used on a large scale [17]. SDF is especially indicated for the treatment of primary molars in primary care for children with high caries risk who participate in educational/preventive programs [18].

Due to the diversity of materials for dental caries prevention, longitudinal clinical studies are needed to evaluate the effectiveness of such materials. Thus, the present prospective study evaluated the clinical performance of a resin sealant, resin-modified glass-ionomer cement and silver diamine fluoride on primary second molars in patients at high risk for dental caries, with periodic evaluations up to 36 months after the sealing procedure.

Material and Methods

The standardized protocol of the CONSORT Statement was used to report the present clinical trial [19].

Ethical Aspects

This study was approved by the Institutional Review Board of Maringá State University, Brazil, under Process no. 34047814.0.0000.0104. Legal caretakers were informed on the study objectives and procedures and agreed with participation of their children by signing an informed consent form, in compliance with Resolution 196/96 of the Brazilian National Health Council.

Sample and Data Collection

This study was conducted on a convenience sample of thirty-two male and female children, recruited from the pediatric clinic of the Iguaçu primary care unit in the city of Maringá, state of Paraná, Brazil. The inclusion criteria were age 36 to 60 months, positive attitude toward treatment, decay factors and deft index equal to or greater than 1, complete primary dentition with healthy primary second molars, and restorative treatment completed at the time of occlusal sealing. Evaluations were conducted three, six, 12, 24 and 36 months after the sealing procedures. All data were recorded on standardized clinical charts.

Selection of the tooth and material to be applied was randomized in each child. Thus, each second molar (55, 65, 75 and 85) received a different treatment: the first tooth received resin-modified glass ionomer cement (Vitremer®, 3M do Brasil, Sumaré, SP, Brazil); the second received a resin sealant (Alpha Seal Light®, Nova DFL Produtos Odontológicos, Rio de Janeiro, RJ, Brazil); the third received silver diamine fluoride (Cariostatic®, Inodon Odontologia, Porto Alegre, RS, Brazil); and the fourth tooth received no material, serving as control (Table 1). The alternation was observed in all children in the study, to include all materials and all teeth in the arch, adding up to 30 teeth in each study group

Table 1. Experimental groups.

Groups	Brand Name	Activation	Composition	Manufacturer
G1 - Resin-modified glass ionomer cement	Vitremer®	Light	Powder: Fluoroaluminosilicate glass, potassium persulfate, ascorbic acid Liquid: 50% polycarboxylic acid copolymer, 20% HEMA, water, 13% carboxylic acid copolymer	3M Dental Products St. Paul, MN, USA
G2 - Resin Sealant	Alpha Seal Light®	Light	Bis-GMA Tegdma, 2,6 DI, urethan, B200P, benzyl dimethyl ketal, camphorquinone and quantacure EHA	DFL, Rio de Janeiro, RJ, Brazil

G3 - Silver Fluoride Diamine	Cariostatic®	-	Ammonium hydroxide, silver nitrate, sodium hydroxide, hydrofluoric acid and aqueous vehicle	Inodon, Porto Alegre, RS, Brazil
G4 - Control	-	-	-	-

To ensure the accuracy of data, the application of materials and periodic evaluations were performed by a single dentist previously submitted to training exercises. An assistant contributed to the application procedure and was previously familiar with the proportions and handling of materials.

Clinical Phase

Preliminary Procedures

Socioeconomic data, medical history, dental history and dietary habits were obtained from clinical records at the pediatric clinic. After dying the crowns with basic fuchsine solution (Chemical Industry Modern and Trade, Barueri, São Paulo, Brazil), the researcher quantified initial bacterial plaque on the labial surface using the modified Greene & Vermillion Index (1964). Professional cleaning was then performed, followed by drying the teeth and determination of decayed, extracted and filled primary teeth (initial deft index).

With the oral environment completely dried, cotton roll isolation was used and a saliva suction tip was positioned. The occlusal pits and fissures were etched with 37% phosphoric acid (Condac 37%, FGM Dental Products, Joinville, SC, Brazil) for 15 seconds, followed by rinsing for 30 seconds and drying of the occlusal surface (groups 1 and 2) [20].

Application of Materials

Resin-modified glass ionomer cement (Vitremer®)

One drop of liquid was added to ½ scoop of powder to obtain a more fluid mixture and facilitate penetration into the pits and fissures [20]. The material was carefully applied using a microbrush until pits and fissures were covered. Light curing was then performed for 40 seconds. The material was subsequently protected with a thin layer of finishing gloss, which was light cured for 20 seconds.

Light cured resin sealant (Alpha Seal Light®)

A microbrush was used to apply the material to the occlusal surface until covering all pits and fissures, followed by light curing for 40 seconds. The surface was then rubbed with a cotton pellet and verified for complete coverage.

Silver diamine fluoride (Cariostatic® 10%)

Following prophylaxis and cotton roll isolation, the material was gently rubbed into the pits and fissures using cotton pellets and a medical forceps, and maintained free of contamination for three minutes, following by rinsing with water for 30 seconds.

With this material, quarterly reapplication was performed using the same procedure as the first application. For the other materials (Vitremer® and Alpha Seal Light®), the technique was performed only once.

Clinical Evaluation

The examiner first underwent a training exercise for proper evaluation of the retention of materials, as well as presence of dental caries. Evaluations were performed at three, six 12, 24 and 36 months. Prior to the evaluations, the Greene & Vermillion Index was determined, followed by professional prophylaxis and determination of the deft index. The qualitative evaluation consisted of visual and tactile clinical examinations with cotton roll isolation with the aid of a dental probe, dental mirror and air-water syringe under reflected light.

The material retention was evaluated using the criteria proposed by Ryde & Snyder (1973) and classified as complete retention, partial retention or complete material loss [21]. Only teeth that received the glass ionomer cement and resin sealant were evaluated for material retention. Dental caries was analyzed in the four study groups (glass ionomer cement, resin sealant, silver diamine fluoride and control) using the following classifications: absence of decay, active white spot (incipient caries without cavitation), cavitation in dentin, and marginal discoloration.

Statistical Analysis

Data were entered into a database and analyzed using the SPSS program for Windows (Version 22.0, IBM Corp., Armonk, NY, USA). Descriptive analysis was performed for gender, age, whether children brushed their own teeth, whether children performed flossing and whether children ingested cariogenic foods between meals. The initial deft index and the index after 36 months of follow-up were submitted to the Kolmogov-Smirnov normality test and analyzed using the nonparametric Wilcoxon test, at a significance level of 5% ($p < 0.05$). Data during the clinical follow-up were evaluated using a survival test (McNemar test) for determination of the retained material and incidence of caries over time.

Results

The initial sample comprised 32 children (13 girls and 19 boys; mean age five years), totaling 128 primary second molars. The loss of one patient occurred at 24 months, when the individual no longer responded to the evaluator's contact attempts. Thus, the response rate at the end of 36 months was 96.8%.

The deft index values after 36 months of follow-up (median: 2.00; SD: ± 2.15) were significantly higher than the initial values (median: 1.00; SD: ± 1.23) ($p < 0.001$), demonstrating the high risk of the sample with regard to tooth decay. In the material survival analysis, Vitremer® demonstrated higher percentage of retention at all evaluation times (3, 6, 12, 24 and 36 months) in comparison to Alpha Seal®. After 36 months, 65% of teeth sealed with Vitremer® exhibited efficient

sealing, whereas only 56% of teeth sealed with Alpha Seal® contained material. However, this difference did not achieve statistical significance (p = 0.214) (Table 2).

Table 2. Performance of sealants regarding retention over time (N = 64).

Groups	Failure	Sample Loss	Survival Analysis	95% CI	p-value*
Vitremer					
3 months	1	0	0.96		
6 months	2	0	0.90		
12 months	4	0	0.78	24.6-32.4	
24 months	4	1	0.65		
36 months	0	0	0.65		0.214
Alphaseal					
3 months	4	0	0.87		
6 months	2	0	0.81	20.8-30.1	
12 months	4	0	0.68		
24 months	4	1	0.56		
36 months	0	0	0.56		

*McNemar test for survival analysis (log rank).

In the survival analysis regarding the emergence of tooth decay, no statistically significant differences were found between Vitremer®, Alphaseal®, Cariostatic® and control groups (p = 0.154). However, the Cariostatic® group had the highest number of incipient carious lesions over time, with only 80% of teeth free of caries at the end of 36 months in comparison to 87% in the control group. The Vitremer® and Alphaseal® groups only exhibited carious lesions after 36 months, ending the period with 93% and 96% of teeth free of decay, respectively (Table 3).

Table 3. Performance of sealants regarding the evidence of incipient carious lesions over time (N=128).

Groups	Failure	Sample Loss	Survival Analysis	95% CI	p-value*
Vitremer					
3 months	0	0	1.0		
6 months	0	0	1.0		
12 months	0	0	1.0	36.0-36.0	
24 months	0	1	1.0		
36 months	2	0	0.93		
Alphaseal					
3 months	0	0	1.0		
6 months	0	0	1.0	36.0-36.0	
12 months	0	0	1.0		
24 months	0	1	1.0		
36 months	1	0	0.96		
Cariostatic					
3 months	1	0	0.96		0.154
6 months	1	0	0.93		
12 months	1	0	0.90	29.1-35.8	
24 months	2	1	0.85		
36 months	1	0	0.80		
Control					
3 months	0	0	1.0		
6 months	2	0	0.93		
12 months	0	0	0.93	30.7-36.7	
24 months	1	1	0.90		
36 months	1	0	0.87		

*McNemar test for survival analysis (log rank).

Discussion

Few studies have reported the importance of preventive measures for primary molars in children with early childhood caries. This is the first investigation to evaluate the preventive effect of a resin sealant, resin-modified glass ionomer cement and silver diamine fluoride on primary second molars in patients at high risk of dental caries. Thirty-six months after the procedures, the Alpha Seal® group exhibited lower clinical success, with a retention rate of 56% in comparison to the 65% rate in the Vitremer® group.

Some authors report that the preventive effect of sealing materials is given by adhesion to the enamel surface, which forms a barrier that protects the pits and fissures on the occlusal surface of molars [22,23]. Thus, retention is fundamental to determine the clinical success of a given material [24]. In the present study, the group that received glass ionomer cement exhibited one more carious lesion in comparison to the group that received the resin sealant. The loss of material may predispose occlusal fissures to demineralization cycles and consequent appearance of new carious lesions, which could be prevented by sealant reapplication where necessary [8,25,26].

After a 36-month evaluation, spme authors found that the resin Fluorshield® sealant achieved significantly better results than the resin-modified glass ionomer cement Vitremer® regarding material retention and caries reduction [10]. They concluded that glass ionomer cement could be used as a temporary material at the time of eruption or when patients are at high risk of dental caries. After a six-month evaluation following the sealing of permanent teeth, the resin sealant Fluorshield® showed better retention rates in comparison to resin-modified glass ionomer cement Vitremer®, but pointed out that both materials were effective at preventing tooth decay [26]. Adequate results are achieved by proper application of the material, since the use of resin-based sealants requires a contaminant-free, dried environment for complete bonding to enamel. Thus, depending on the child's age, compliance or degree of tooth eruption, the material may not reach its maximum retention capacity.

The literature also presents divergent data regarding the preventive effect of resin sealants and glass ionomer cement. In a previous study conducted, resin sealants had a mean retention rate of 83.8% and glass ionomer sealants had retention rates of only 19.3% over a five-year follow-up period [27]. The authors concluded that the lack of adhesion to enamel was the main reason for the low glass ionomer retention rates.

All four groups tested had cases of tooth decay, without statistically significant differences, although the incidence was very low. The Alpha Seal® resin group developed carious lesion in one tooth; the glass ionomer cement group developed caries in two; the group that received silver diamine fluoride (Cariostatic®) developed six carious lesions, and four teeth with a total of six lesions were found in the control group. Some authors exhibited similar findings, reporting no statistically significant difference regarding the development of caries among molars sealed with high viscosity glass ionomer cement and a resin sealant [28].

The literature reports the use of silver diamine fluoride as an additional option for preventive treatment on occlusal surfaces. According to researchers, this product forms a chemical seal with obliteration of dentinal tubules, and the resulting materials - calcium fluoride, silver phosphate and silver proteinate - covering both organic and inorganic parts [29-31]. In a 24-month study addressing decay on 1491 molars, it was found the resin sealant Clinpro® achieved better results in comparison to silver diamine fluoride at a concentration of 38% [32]. A similar result was found in the present investigation when comparing the number of carious lesions in teeth sealed with the resin sealant Alpha Seal® or Vitremer® to those sealed with silver diamine fluoride.

The antimicrobial action of silver diamine fluoride depends directly on the concentration [33]. The concentration of this substance in products available in Brazil is 10, 12, 30 or 38%. Thus, further studies are needed using products with higher concentration, since the product evaluated in the present investigation (Cariostatic®, Inodon Odontologia) contains 10% (100 mg per mm3), which may have influenced the lower performance of the material and the higher number of carious lesions.

Researchers indicate that the appearance of caries on sealed teeth can be attributed to problems such as inadequate isolation of the operative field, excessive masticatory force and inadequate patient compliance [6,14]. In the present study, the presence of caries was identified thirty-six months after sealant application, which may have been due to an incorrect initial diagnosis at the time of selection, since the morphology of the irregular occlusal surface favors plaque retention and the development of caries in both permanent and primary teeth. Visual observation was used to detect lesions on occlusal surfaces, and it is not easy to determine the different shades of brown or black along the fissures. Thus, estimating the activity of occlusal lesions on enamel using the visual method is a difficult task [10].

Difficulties were faced when applying the materials due to the young age of patients as well as the single application of sealants. However, the clinical results were quite satisfactory, with high success rates in terms of preventive potential. Despite the higher final deft index in comparison to the index at study onset, the primary second molars continued to be sound and the vast majority came closer to natural exfoliation, thereby completing their lifecycle and maintaining space for the permanent successors.

All materials evaluated in the present investigation achieved satisfactory results regarding both retention and prevention against the development of caries. However, considering the diversity of preventive materials and the importance of treatment of cavities and occlusal fissures for the maintenance of oral health, the clinical judgment of the dentist is paramount for indication of the most appropriate material, taking into account the patient's basic needs. Sealants constitute a relevant aspect of preventive dentistry, along with the periodic application of fluoride, adequate oral hygiene, proper diet and periodic checkups.

Conclusions

1) No statistically significant differences were found between products regarding the material retention, although more material loss occurred in teeth that received the sealant resin Alpha Seal®;
2) No statistically significant differences were found between he products evaluated regarding tooth decay (incidence of incipient caries), although Cariostatic® (silver diamine fluoride) had a greater number of carious lesions;
3) The fluoride materials were effective as a preventive method for the occlusal surfaces of primary molars in children at high caries risk, and should be indicated as a treatment option in educational and preventive programs in early childhood.

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