Effectiveness of a Glass Ionomer Cement Used as a Pit and Fissure Sealant in Recently Erupted Permanent first Molars

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ABSTRACT

Purpose: This study's purpose was to evaluate the caries-preventive effect of a glass ionomer cement (**GIC**) used as an occlusal sealant on recently erupted permanent first molars.
Methods: A double-blind, randomized, controlled, clinical trial was undertaken that included 36 5- to 8-year-olds (and 92 permanent first molars) who were randomly allocated to the test group (GIC) or the control group (auto-polymerized resin-based sealant [**RBS**]). The Mann-Whitney test was used to compare the number of new carious or filled occlusal surfaces in the 2 groups.
Results: After 6 months, 1 occlusal surface in the test group and 2 occlusal surfaces in the control group showed carious lesions (P=.15). In the fifth year of follow-up, 2 occlusal surfaces in the test group and 7 occlusal surfaces in the control group were filled or carious (P=.42), and the mean number of sealed surfaces that became carious or filled was 0.2 (95% confidence interval [CI]=0.02-0.70) for the GIC-sealed teeth and 0.6 (95% CI=0.20-1.30) for the RBS-sealed teeth (P=.30).
Conclusion: High-viscosity glass ionomer cement can provide some level of protection against dental caries when used as a dental sealant in newly erupted permanent first molars.
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Dental caries lesions occur in areas where biofilms were allowed to remain for a relatively long period of time. This is why occlusal surfaces are particularly at risk until molars come into functional occlusion.[1] A number of measures are available to control occlusal caries, including: intensive patient education and professional tooth-cleaning[2]; application of silver diamine fluoride every 6 months[3]; and placement of dental sealants.[4] Resin-based sealants (**RBSs**) change the occlusal morphology by forming a micromechanically-bonded resin layer that functions as a physical barrier between the enamel surface and the oral environment.[4,5] RBSs are considered highly effective in preventing dental decay on permanent first molars,[6] and the sealant benefit is increased by placement on surfaces judged to be at high risk or on surfaces that already exhibit incipient carious lesions.[7]

Clinical studies have shown that long-term success of resin-based dental sealants is dependent on their retention to the tooth surface.[5,8] The most important factor associated with decreased sealant retention is contamination of the tooth with saliva after acid etching.[8] It has been suggested that the use of a hydrophilic bonding material under a RBS applied in a moist environment could yield a bond strength equivalent to the bond strength obtained when a RBS is

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applied directly to clean, etched enamel. This enhances sealant retention when proper tooth isolation is not possible.[4,8,9] Nevertheless, before adopting the use of adhesive agents prior to the application of RBS, clinicians should consider that they tend to increase the time and cost of the sealant application procedure.[4]

Glass ionomer cements (GICs) have the ability to chemically bond to dental enamel, are less hydrophobic than RBSs, and release fluoride, thus offering an alternative to resin-based sealants in situations where there is a high chance of moisture contamination during sealant application (ie, uncooperative children and permanent molars not fully erupted).[10] It has been hypothesized that, despite a high rate of macroscopic sealant loss, GICs have a caries-preventive effect. This is because the material that remains at the bottom of the pits and fissures may act as a rechargeable, slow-release fluoride deposit.[11,12] Conventional self-hardening GICs are difficult to handle and have poor wear resistance and fracture strength. High-viscosity GICs (ie, Fuji IX, GC America, Alsip, IL, and Ketac Molar, 3M ESPE, St. Paul, Minn), however, developed for the atraumatic restorative technique (ART), have much improved physical properties[13], and Class I restorations on occlusal surfaces of permanent molars with the high-viscosity GIC showed a significantly better survival rate than those with the previous generations of GIC.[14]

This study's purpose was to evaluate the caries-preventive effect of a high-viscosity glass ionomer cement (Fuji IX) used as an occlusal sealant in recently erupted permanent first molars. We hypothesized that teeth that were sealed with GIC would develop fewer caries lesions than teeth that were not. The main outcome measure was thus the number of new carious and filled sealed occlusal surfaces after 6 months and 5 years of follow-up.

METHODS

This randomized, controlled, clinical trial was carried out in the Department of Pediatric Dentistry, Rio de Janeiro State University, Rio de Janeiro, RJ, Brazil, from 1998 to 2004. Prior to the start of the study, ethical approval was obtained from the Ethics Committee of Pedro Ernesto Hospital, Rio de Janeiro State University, and only children whose parents gave written, informed consent were enrolled. Overall, 36 6- to 8-year-olds, with at least 1 permanent first molar erupted and 2 or more primary molars decayed, filled, or extracted due to caries, participated in the study. The children were randomly allocated to the test group (GIC; Fuji IX) or to the control group (RBS; Delton, Dentsply International, York, Pa), using a list of random numbers. Each patient and caregiver was unaware as to which group each child was assigned.

Figure 1. Glass ionomer sealant immediately after placement.

Figure 2. Resin-based sealant immediately after placement.

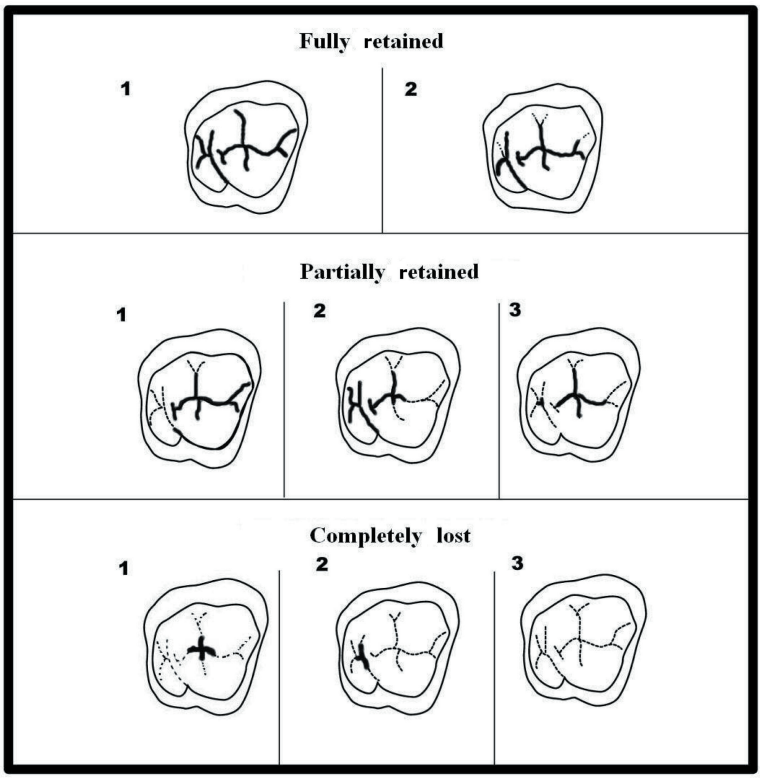

Figure 3. Criteria used for sealant retention assessment in the permanent maxillary molars.

At baseline, oral exams and bitewing X rays were undertaken to record the children's dental caries experience. Their caretakers were interviewed to provide data about socioeconomic status, fluoride exposure, and oral hygiene practices. The participants were also given oral hygiene instructions and dietary counseling. Those who had dental care needs were referred to the pediatric dental clinic for appropriate restorative and surgical treatment.

All the permanent first molars that presented a sound occlusal surface or occlusal caries at the D_1 level (noncavitated enamel lesion) entered the study (N=92). The sealants were placed by graduate students without the support of a chairside assistant (Figures 1 and 2), and it was not possible to blind operators to treatment allocation because of the obvious differences between RBS and GIC placement techniques.[15,16]

SEALANT PLACEMENT

The RBSs were placed according to the technique described by Waggoner and Siegal.[15] The occlusal surface was cleaned using a bristle brush and pumice and rinsed thoroughly with water for 30 seconds. The tooth was isolated with cotton rolls, and the occlusal surface was etched with 37% phosphoric acid for 30 seconds. The acid was removed by rinsing for 30 seconds, and the tooth was air-dried until the occlusal surface was dull white. The sealant was applied using a disposable dispenser, and the material was left undisturbed until its final set. Next, the sealant surface was wiped with a wet cotton roll and inspected with a dental explorer for complete coverage and absence of bubbles. Occlusion was checked with articulation paper and, when necessary, adjustments were made with composite finishing burs.

Glass ionomer sealants were placed according to the ART procedure developed by the World Health Organization.[16] The occlusal surface was cleaned using a toothbrush and explorer. The tooth was isolated with cotton rolls, and the occlusal surface was conditioned with diluted GIC liquid for 15 seconds and washed and dried with cotton roll pellets. The GIC (Fuji IX) was hand mixed according to the manufacturer's instructions and applied on the occlusal surface with an applier instrument, slightly overfilling the pits and fissures. The mixed GIC was pressed into the pits and fissures with a petroleum-jelly-coated index finger for 30 seconds. Excess material was removed with a carving instrument, and the sealant was coated with Fuji varnish. Children were instructed not to eat for at least 1 hour.

SEALANT EVALUATION

Participants were re-examined to assess sealant retention and occlusal caries incidence 6 and 60 months after the sealants had been placed. The exams were performed with the aid of artificial light, a dental mirror, and explorer after the teeth had been cleaned with a toothbrush and dried with compressed air for 5 seconds. Bitewing X rays were also taken. The examiners were blinded to the subject's allocation group. At the 6-month follow-up, the oral exams were done independently by 2 dentists. In case of disagreement, consensus was achieved by discussion. At the 5-year follow-up, the oral exams were performed by 1 trained and calibrated examiner whose interexaminer reliability was established by the repeated evaluation, within a 1-week interval, of 26 occlusal surfaces of children not included in the study. The interexaminer reliability for caries diagnosis and sealant retention measured by the Kappa coefficient was 1.0 and 0.86, respectively. Sealants were classified as completely lost, partially retained, and fully retained according to the extension of pits and fissures still covered by GIC or resin upon examination (Figures 3 and 4). Occlusal surfaces were considered carious if they showed a cavity that had clearly penetrated the dentin or if a radiolucency in dentin could be seen on the bitewing X ray.

STATISTICAL ANALYSIS

The data were entered into a database using Epiinfo 6.04 (Centers for Disease Control and Prevention, Atlanta, Ga) and analyzed using Stata 7.0 (Stata Corp., College Station, Texas). The data were first examined using simple descriptive statistics. Comparisons between the test and control groups were then made using t, Fisher's exact, and Mann-Whitney tests. The level of significance was set at $P<.05$.

RESULTS

The mean age of the 36 children in the study was 6.8 years (±0.98 SD). Most of them were of low socioeconomic status: half of the mothers had completed only elementary school, and 61% of the families had a monthly income of less than 4 times the minimum wage (approximately $450 US). The test and control groups had the same number of participants and a similar mean age, but the mean dmfs score (number of decayed, missing, and filled surfaces in primary teeth) was higher in the GIC group than in the RBS group (Mann-Whitney test; *P*=.76; Table 1). All participants reported brushing their teeth daily, 11% reported using dental floss regularly, and 67% usually had a dental check-up once a year.

All 92 teeth included in the study (46 teeth in each group) were evaluated 6 months after sealant application. The GIC sealant showed a higher retention rate than the resin-based sealant, and 3 teeth showed occlusal dentin caries: 1 in the test group and 2 in the control group. The carious tooth sealed with GIC had a partially retained sealant, and of the carious teeth sealed with RBS, 1 showed a completely lost sealant and the other showed a partially retained sealant. None of the 52 teeth with a fully retained sealant developed a caries lesion (Table 2).

Five years after sealant application, the children were called in for another dental examination. Twenty children (56%) with 49 teeth included in the study (21 teeth in the test group and 28 teeth in the control group) attended. The mean number of decayed, missing, and filled surfaces (DMFS) in the permanent dentition was 2.2 and 1.6 for the test group and control group children, respectively. Clinical and radiographic exams showed that 9 sealants had failed: 7 in the control group and 2 in the test group (Fisher's exact test; *P*=.27; Table 2). The retention rate was higher for the GIC sealant than for the RBS. The mean number of decayed and filled sealed occlusal surfaces was 0.6 (95% CI=0.20-1.30) for the control group and 0.2 (95% CI=0.02-0.70) for the test group (Mann-Whitney test; *P*=.30). The percentage of children with new decayed permanent first molars was higher in the control group (22%) than in the test group (11%; Fisher's exact test; *P*=.66).

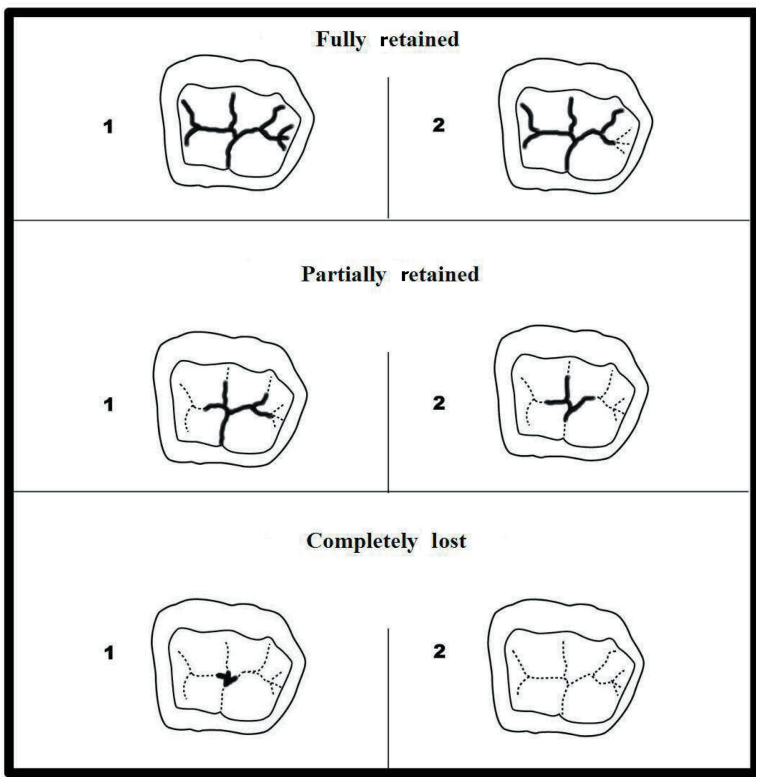

Figure 4. Criteria used for sealant retention assessment in the permanent mandibular molars.

DISCUSSION

This clinical trial was developed to evaluate the caries-preventive effect of GIC used as a dental sealant on occlusal surfaces of recently erupted permanent first molars. To improve the trial's efficiency, only high caries-risk children (ie, of low socioeconomic status and having past caries experiences in deciduous teeth) were included.[17] This should be considered before extrapolating the results to individuals in a different population.

This study's key strengths are: random allocation of participants; parallel-group design; careful training and calibration of examiners; blinding of examiners and participants to treatment allocation; use of standardized criteria for the assessment of sealant retention; and choice of a true outcome measure (ie, dentin caries) instead of a surrogate endpoint (ie, sealant retention or discoloration).

At baseline, the test and control groups had similar age and gender distributions. Despite having mothers with a higher education level and reporting a higher frequency of fluoride toothpaste use, test group children had a higher, though not statistically significant, mean dmfs than control group children. The difference in caries experience between the 2 groups could still be noticed at the end of the follow-up period, and test group children showed a slightly higher mean DMFS than control group children. Nevertheless, both the number of dentin occlusal caries lesions after 6 months and the number of occlusal restorations and new occlusal caries lesions after 5 years was lower in GIC-sealed molars than in RBS-sealed molars. This is an important finding because, since sealing with GIC is a simple, patient, and user-friendly procedure that does not require sophisticated and expensive dental equipment, its widespread use can help increase access to preventive dental care for children in developing countries where resources are scarce.[18]

The proportion of fully retained, high-viscosity GIC sealants found in the present study (29%) after 5 years of follow-up was higher than the proportion of fully retained occlusal sealants reported in previous studies that used conventional GIC. Using Fuji III (GC America), Poulsen et al[19] obtained less than 10% of complete retention

Table 1. Main Characteristics of the Test (Glass Ionomer Cement [GIC]) and Control (Resin-based Sealant [RBS]) Groups at Baseline and at the Final Examination, After 5 Years of Follow-up

Characteristics	Baseline		Final examination	
	GIC group N=18	RBS group N=18	GIC group N=10	RBS group N=10
Initial dmfs	16.5 (95% CI*= 10.60-22.40)	13.3 (95% CI= 8.50-8.10)	10.9 (95% CI= 7.10-14.60)	13.9 (95% CI= 6.50-28.30)
DMFS	--	--	2.2 (95% CI= 0.20-4.20)	1.6 (95% CI= 0.50-2.70)
Age	6.6 (95% CI= 6.10-7.00)	7.0 (95% CI= 6.50-7.50)	12.0 (95% CI= 11.50-12.50)	11.9 (95% CI= 11.10-12.70)
Gender				
Female	10 (56)	12 (67)	7 (70)	3 (30)
Male	8 (44)	6 (33)	3 (30)	7 (70)
Use of fluoride toothpaste				
Yes	17 (94)	16 (89)	10 (100)	9 (90)
No	0	0	0	0
No information	1 (6)	2 (11)	0	1 (10)
Mother's education				
<8th grade	6 (33)	7 (39)	3 (30)	4 (40)
8th grade	5 (28)	3 (17)	3 (10)	1 (10)
High school	4 (22)	4 (22)	2 (20)	2 (20)
Terciary, college	2 (11)	2 (11)	2 (20)	2 (20)
No information	1 (6)	2 (11)	0	1 (10)

** CI=confidence interval*

after 28 to 39 months of follow-up, whereas Boskman et al[20] found that only 2% of the sealants were completely retained after 5 years. On the other hand, Ho et al[21] and Frencken et al,[22] who also used Fuji IX (GC America) reported that 66% and 71% of the fully and partially retained sealants survived after 2 and 3 years, respectively. Since GIC sealants act more as a fluoride reservoir than as a physical barrier to bacterial adhesion and colonization, it is possible that a partially retained GIC sealant continues to offer caries protection whereas a partially retained RBS does not. Overall, these findings suggest that, contrary to what used to happen with conventional GICs, high-viscosity GICs—when applied using the "press-finger" technique of the ART approach—may penetrate into the pits and fissures of permanent molars and remain adhered long enough to provide a clinically important benefit to the patient.

An unexpected finding of this study was the low complete retention rate of the RBS (21%), since previous studies had shown higher figures.[6] This is probably due to the fact that only newly erupted molars of young children were included in the present study. The incomplete eruption of these teeth, along with the children's lack of cooperation, may have led to saliva contamination during sealant application, thereby decreasing the mechanical bonding between RBS and dental enamel and substantially compromising sealant retention. The dental literature confirms that RBSs present lower retention rates in younger subjects.[19,23-25] The fact that the operators worked without the support of a chairside assistant may also have contributed to this outcome.

The high attrition rate is this study's main limitation. Most dropouts occurred because patients could not be reached, either because they had moved or because their phones had been disconnected. The baseline characteristics of the subjects who left the study were compared with those of the subjects who remained. The former had a higher dmfs, were less likely to perform tooth-brushing under parental supervision and belonged to families with lower mean monthly income. This suggests that at the beginning of the study the children effectively examined at the fifth year of follow-up were likely to be less vulnerable to dental caries than those not examined because they dropped out. Other factors possibly associated with the development of dental caries (ie, consumption of sweets or snacks and professional fluoride applications) were not assessed. Also, it is important to point out that the lower incidence of occlusal caries in the GIC group may have been produced by a combination of factors.

The caries-preventive effect of GIC sealants has been demonstrated previously by a number of researchers,[24,26-29] but 2 systematic reviews recently published[6,30] concluded, however, that there is still no evidence that, when used on the occlusal surfaces of permanent molars, either GIC or resin-based sealants reduce caries incidence more effectively. Therefore, more well-designed, randomized, clinical trials addressing the effectiveness of GIC as a dental sealant are still required.

CONCLUSION

High-viscosity glass ionomer cement can provide some level of protection against dental caries when used as a dental sealant in situations where it is not possible to adequately isolate the tooth from saliva contamination during sealant application (ie, incompletely erupted teeth or uncooperative children) and when complete GIC sealant retention may not be necessary for its caries preventive effect.

Table 2. Sealant Retention and Presence of Dentin Caries or Restoration in the Test (Glass Ionomer Cement Sealant [GIC]) and Control (Resin-based Sealant [RBS]) Groups, After 6 Months and 5 Years of Follow-up

Follow-up period	Group	Retention rate			Presence of dentin caries or restoration		Total
		Completely lost N (%)	Partially retained N (%)	Fully retained N (%)	Yes N (%)	No N (%)	
6 mos	GIC	3 (7)	14 (30)	29 (63)	1 (2)	45 (98)	46 (100)
	RBS	8 (17)	15 (33)	23 (50)	2 (4)	44 (96)	46 (100)
	Total	**11 (12)**	**29 (32)**	**52 (56)**	**3 (3)**	**89 (97)**	**92 (100)**
5 ys	GIC	9 (42)	6 (29)	6 (29)	2 (10)	19 (90)	21 (100)
	RBS	16 (58)	6 (21)	6 (21)	7 (25)	21 (75)	28 (100)
	Total	**25 (50)**	**12 (25)**	**12 (25)**	**9 (18)**	**40 (82)**	**49 (100)**

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