

A 48-month randomized controlled trial of caries prevention effect of a one-time application of glass ionomer sealant versus resin sealant

Eda HAZNEDAROĞLU¹, Şirin GÜNER², Canan DUMAN¹ and Ali MENTEŞ¹

¹ Department of Pediatric Dentistry, Faculty of Dentistry, Marmara University, Basibuyuk Campus, Basibuyuk, 34854, Maltepe-Istanbul, Turkey

² Department of Pediatric Dentistry, Faculty of Dentistry, Trakya University, Balkan Campus, 22030 Edirne, Turkey

Corresponding author, Eda HAZNEDAROĞLU; E-mail: ehaznedaroglu@marmara.edu.tr

The aim of this study was to compare the caries prevention effectiveness, retention rates and the level of fluoride of saliva of a glass-ionomer sealant (GIS) with that of a resin-based sealant (RS). Eighty GIS and 80RS were placed on the first permanent molars in 40 children aged 7–10 years. Children were re-examined at 6, 12, 24, 36 and 48 months after the procedure. Saliva samples were collected before the sealant was applied and again at each appointment, and fluoride levels were measured. After 48 months, occlusal caries were seen in 4 and 12 teeth in GIS and RS groups respectively. There was a statistically significant difference in the fluoride levels of saliva between baseline and up to 12th month in GIS group. GISs presented effective prevention of caries development, even though the failure rate is higher when compared to the RSs. An increased salivary fluoride level due to GISs might be an additive effect on the prevention of dental caries.

Keywords: Fissure sealant, Fluoride, Glass ionomer, Randomized trial, Resin

INTRODUCTION

Dental caries remain widespread worldwide, despite routine prevention methods¹. Pit-and-fissure sealants are effective in preventing caries on an individual level and as a public health measure for at-risk populations²⁻⁴. The two most common materials used for sealing pits and fissures are resins and glass-ionomers. Systematic reviews and meta-analyses have shown that both glass-ionomer sealants (GISs) and resin-based sealants (RSs) are capable of preventing the development of caries^{5,6}. The longevity of resin-based sealants is higher than that of low- and medium-viscosity glass-ionomer-based materials⁷; however, glass-ionomer cement (GIC) is not as sensitive to moisture as resin-based sealants⁸. Additionally, the use of GIC significantly reduced the incidence of caries⁹, perhaps due to its release of fluoride (F)¹⁰. In contrast, other studies have indicated that, for the permanent teeth of children and adolescents, resin-based sealants are more effective than GIC at reducing caries at 24 to 44 months after implementation¹¹⁻¹⁴. Thus, there is conflicting evidence as to whether GIC may reduce the prevalence of caries in children's permanent teeth^{9,12,15-17}.

When molars are in an eruption process, moisture control is not possible. Thus, GICs, as interim sealants, are highly beneficial in newly erupted teeth when the risk of caries is highest. However, for fully erupted molars, GICs show a lower success rate¹⁸. It has been suggested that the gold standard in caries prevention through sealant administration should not be based on physical outcomes, but rather on biological outcomes. Such biological outcomes are measured in relation to the absence of caries in pits and fissures after applying sealant⁵.

Even where GISs clinically appear to have been

totally lost, there remain small particles of material attached to the enamel of the occlusal fissures¹⁴. The establishment of a fluoride reservoir might be expected to contribute to caries prevention and to make the effectiveness of glass ionomer materials as sealants less dependent on the long-term retention of the material. Slow release of fluoride from restorative materials and a specially designed slow-release device have also been reported to induce remineralization¹⁹. A low level of fluoride in saliva has been shown to prevent and reverse caries by preventing demineralization and enhancing remineralization^{19,20}. Fluoride concentrations as low as 0.02–0.06 ppm has been shown to enhance remineralization after enamel specimens were subjected to *in vitro* demineralization¹⁹. Rajtboriraks *et al.* reported *in-vivo* fluoride release of sealants up to one month and it is more beneficial if the sealant can increase the fluoride level in the oral environment²¹. So, long term follow up studies were needed to evaluate caries prevention of GIS related to its fluoride release.

The purpose of this randomized clinical trial was to compare the effectiveness of caries prevention, retention rates and level of fluoride of saliva of an RS to that of a GIS in fully erupted molars. Sealants were placed on occlusal pits and fissures in permanent molars of children with a high incidence of caries over a 4-year period.

MATERIALS AND METHODS

Sample size and study design

This trial was a prospective randomized, controlled, parallel-group clinical study. The observation period was 48 months, and the study was performed in the Pediatric Dentistry Department, Dental Faculty, Marmara University, Istanbul, Turkey.

Prior to this study, and based on the results of an earlier trial for which the primary outcome was retention, a power analysis was conducted by an independent statistician (RK, ARK-Company of Statistical Consultant)¹⁾. The overall power was calculated to be 0.8 and the minimally important difference between the groups was calculated as 2.5–15.4% at a level of significance of 0.05, which produced a required number of 20 teeth (5 subjects) for each group. Thus, a total of 40 participants (20 girls and 20 boys), aged 7–10 years were enrolled in the randomized clinical trial.

The study design was approved by the Ethics Committee of the School of Medicine, University of Marmara (Approval number: B.30.2.MAR.0.01.02/AEK/635). ClinicalTrials.gov ID number is NCT02063815 and name of trial registry is “A Trial of Caries Prevention Effect of Fissure Sealants”.

Children whose four first permanent molars were fully erupted and cavity free and who had a mean number of decay and filled primary teeth (dft) index ≥ 2 were included in this study. Children with any systemic diseases, motor problems, or a dft index ≤ 1 were excluded from the study. For standardization, oral hygiene training and nutritional counselling were given to all study participants, along with toothpaste containing 1,450-ppm fluoride. Dental history of the patients showed low brushing habits and low fluoride in the drinking water.

Written informed consent was obtained from the parents or guardians of all children in the study.

In total, 120 children (aged 7–10) who attended the Department of Pediatric Dentistry, Marmara University, were examined by two experienced clinicians (D1 and D2) and 40 children with no decay in the first permanent molars were assessed by visual examination (clinically) and confirmed with a laser fluorescent device (DIAGNOdent pen, Kavo, Germany; Fig. 1). Before assessment, tooth surfaces were cleaned with a handpiece, air dried and examined visually. Then the DIAGNOdent device was calibrated; tip A was used for fissure surfaces. The measurement was performed with the tip contacting the tooth surface at a right angle. Teeth were measured three times using the maximum setting, and the average DIAGNOdent values were recorded²²⁾. Teeth with a score < 13 using the laser fluorescent device were included in the study²²⁾.

This study was a randomized controlled trial, with sealants clustered in each child. Block randomization was used to ensure balance. Accordingly, this was a small clinical trial of $n < 100$. One of the clinical examiners (D2) was involved in the random sequence generation and the allocation concealment steps and was not involved in the sealant implementation step.

The participants and parents were blinded to the dental materials; the sealant implementation step was performed by D1 (D1 was assisted by D3), who could not be blinded due to differences in the sealants and their application protocols. All dentists were experienced with both sealant methods and were further instructed before the study.

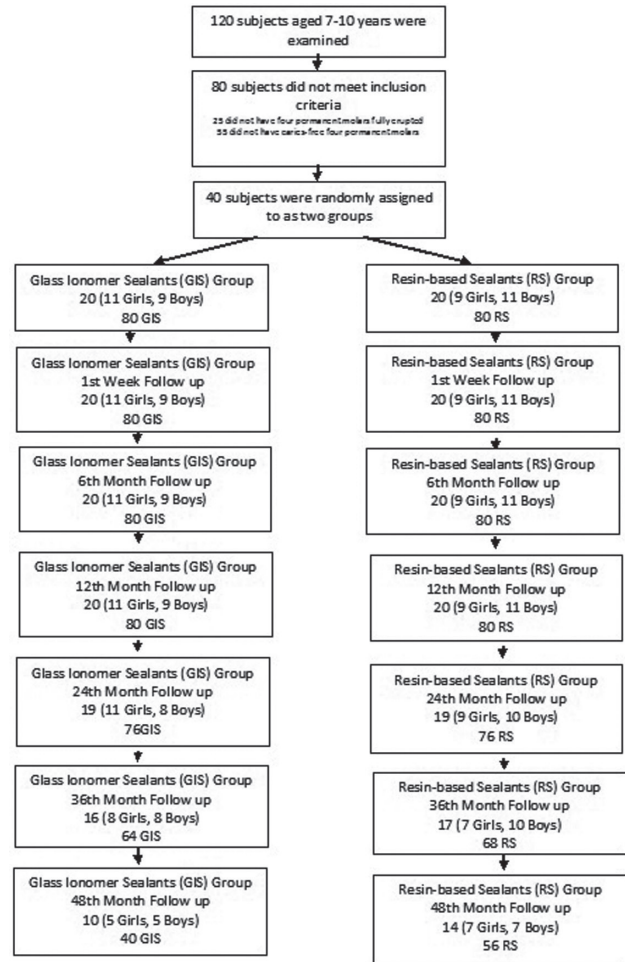


Fig. 1 Participant flow.

Intervention

All sealants were applied to a patient's teeth during the same appointment. In total, 80 glass ionomer (Fuji Triage[®], GC Europe) and 80 resin-based (Ultrasal XT[®], Ultradent, USA) fissure sealants were applied to the first permanent molars of 40 children in a randomized fashion. Fuji Triage[®] is a conventional glass ionomer cement, produced especially for fissure protection. The major advantage of using Fuji Triage[®] over other GICs is the fluoride release by the sealant, which is considered to be the highest among all GICs²³⁾. Teams of two pediatric dentists (D1 and D3) performed the procedures (one assisting the other), with sealants being applied within 3 months of the caries examination.

1. GIS application

Teeth were isolated with cotton rolls. To remove salivary pellicle and plaque, the occlusal surfaces were cleaned with a fluoride-free pumice paste using a bristle brush. The tooth surface was then rinsed to remove the prophylactic paste and air dried. Following drying, 20% polyacrylic acid (Cavity Conditioner, GC Europe) was

applied for 10 s and then removed using air-water spray. Finally, the tooth was air dried gently for 10 s. The GIC was applied to the pits and fissures on the occlusal surface using a gloved finger according to Frencken and Wolke²⁴. Next, a varnish (G Coat, GC Europe) was applied and cured (CromaluxE-Plus, Mega Physik, Rastatt, Germany) according to the manufacturer's instructions. The occlusal contacts were assessed, and if necessary, adjustments were made using a finishing bur, followed by a second application of varnish and curing. Participants were instructed to not eat for at least 1 h following the procedure.

2. RS application

Teeth were isolated with cotton rolls. To remove salivary pellicle and plaque, the occlusal surfaces were cleaned with a fluoride-free pumice paste using a bristle brush. The tooth surface was then rinsed to remove the prophylactic paste and air-dried. Following drying, the tooth surface was etched with 37% phosphoric acid (UltraEtch® Ultradent) for 15 s, rinsed with air-water spray for 15 s, and then air dried for ~5 s until the etched enamel gave a chalky appearance. Resin sealant was applied and cured according to the manufacturer's instructions. The occlusal contacts were assessed, and if necessary, adjustments were made using a finishing bur.

All patients were called for recall appointments and all sealed teeth were re-examined in the same pediatric dentistry department after 6, 12, 24, 36, and 48 months by two experienced and calibrated pediatric dentists (D3 (until 12 months), D4 (all periods)) and scored using the following system: 1, total sealant retention, 2, partial loss (any loss of material), and 3, total loss. All dentists are experienced and working in the same department. They were not blinded because GIC and resin-based sealants are different and can be readily recognized. Tooth surfaces were cleaned with a hand-piece. In the case of partial sealant loss, a caries evaluation was performed only by visual inspection. DIAGNOdent pen was not used for those teeth. In the case of total sealant loss, a meticulous caries evaluation was performed visually in a dental setting with proper illumination, air drying and a blind explorer. Visible cavitation, changes in tooth color (opacity) or anamnestic information indicating pulpal symptoms were recorded. Caries was detected visually for opacity, defects at the margin, or softness by an explorer. Then, further diagnose was initiated using the DIAGNOdent-pen for those teeth. Scores higher than 20 and 30 were recorded as enamel and dentin caries, respectively²². In case of dentin caries detection, composite restorations were applied to those teeth.

Saliva sample collection

Patients were requested to avoid brushing their teeth the morning of saliva collection. Saliva samples were collected at least twelve hours after toothbrushing. To obtain baseline fluoride levels, unstimulated saliva

was collected prior to the sealant's being applied. After sealant application, saliva samples were collected again, followed by additional collections at 6, 12, 24, 36, and 48 months. All samples were frozen at -80°C until fluoride analysis.

All decayed teeth were treated within six months of sealant application; however, fluoride-releasing materials were avoided so as not to influence the salivary fluoride level.

Fluoride analysis

Fluoride levels were measured using the ion selective electrode (Orion 960900 Fluoride Combination Electrode, Thermo Scientific, USA) according to manufacturer's instructions.

Outcome measure

The main outcome measure was the number of caries, the retention rates, new caries lesion in sealed teeth and the salivary fluoride level after 48 months.

Statistical analysis

Data were analyzed using the NCSS (Number Cruncher Statistical System) 2007 statistical software (Utah, USA). The χ^2 test was used to evaluate differences in retention rates among the different sealants and new caries for each evaluation period.

Kaplan-Meier survival analysis was used to compare the sealants, followed by the log-rank test to check the differences among survival curves (comparing the groups). Any loss of sealant was considered a failure. A two-way ANOVA for repeated measures (considering the time frame intervals and fluoride levels) was performed with *post hoc* pairwise comparison tests. A *p*-value of <0.05 was considered significant with 95% confidence intervals.

RESULTS

In total, 120 participants were screened, and 40 met the inclusion criteria. Participant ages ranged from 7 to 10 years, with a mean of 8.32 ± 1.7 years. Participants were randomly assigned to the two study groups. A flowchart of the study is presented in Fig. 1. The mean dft scores were 6.5 ± 4.26 and 5.15 ± 2.25 for the GIS and RS groups, respectively, prior to the study; they were not statistically significantly different ($p=0.1102$).

All carious primary teeth were restored, and all subjects remained a part of the study for 12 months with 100% follow-up. After 48 months, 96 sealants in 24 patients were available for the final evaluation. The retention rates are shown in Table 1 and RS group was found to be statistically significant from GIS group in each time frame (Table 1).

Sealant survival is shown in Fig. 2. Partial loss of sealant was considered a failure and the cumulative sealant retention (full) rate over 48 months was 27.6% for RS and 10.8% for GIS. The difference was statistically significant (log rank=58.40, $p=0.0001$, 95% CI; Fig. 2).

Table 2 shows the incidence of caries in teeth where

sealants were partial or total lost. Caries did not develop in any teeth during the first 24 months after treatment.

DIAGNOdent pen values were between 21 and 29 for all carious teeth in the GIS group whereas they were between 21 and 29 for five teeth and greater than 30 for seven teeth in the RS group at 48 months. 12 cases of total loss were observed in the RS group, and dentine caries occurred in 7 (58.3%) of those teeth. Since those 7 teeth were diagnosed as dentin caries in 4 patients, occlusal composite restorations were applied to those teeth. No restoration was applied to any GIS group.

Salivary fluoride levels (ppm) of both groups at different time intervals are shown in Table 3. Pairwise comparisons of the groups revealed that there was a statistically significant difference in the fluoride levels of saliva between baseline and after treatment, first week, 6th month and 12th month in GIS group ($p=0.0001$).

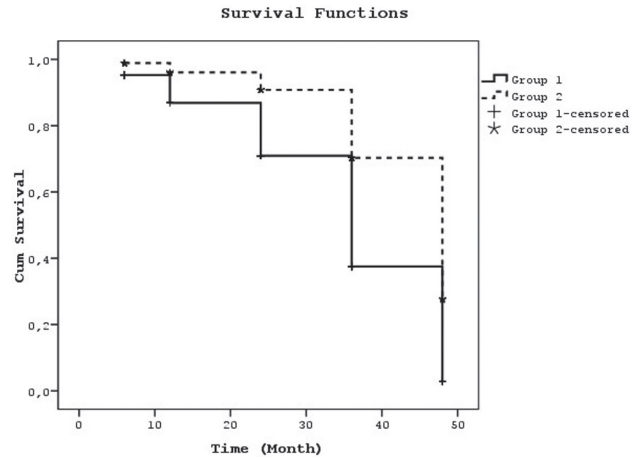


Fig. 2 Cumulated proportions of sealant retention over 48 months in the two groups, Group 1 (GIS) and Group 2 (RS) (Partial loss of sealant was considered as failure) Log Rank: 58.40. $p=0.0001$, 95% (CI).

Table 1 Distribution of sealant retention rates

Evaluation ^a	6 Months		12 Months		24 Months		36 Months		48 Months	
	GIS	RS	GIS	RS	GIS	RS	GIS	RS	GIS	RS
1 (No, (%))	64 (80)	76 (95)	57 (71.25)	72 (90)	43 (56.58)	65 (85.53)	15 (23.44)	40 (58.82)	3 (7.5)	22 (39.29)
2 (No, (%))	15 (18.75)	4 (5)	22 (27.5)	8 (10)	32 (42.11)	11 (14.47)	44 (68.75)	28 (41.18)	27 (67.5)	22 (39.29)
3 (No, (%))	1 (1.25)	0	1 (1.25)	0	1 (1.32)	0	5 (7.81)	0	10 (25.00)	12 (21.43)
Total No.	80	80	80	80	76	76	64	68	40	56
<i>p</i>	0.005257*		0.003032*		0.000032*		0.000000*		0.000000*	

^a=1, Completely retained; 2, partial loss; 3, total loss

* Significance difference= $p<0.05$

Table 2 Number of patients and occurrence of caries

	Groups	Patients		Teeth		<i>p</i>
		Present (no (%))	Drop out (no (%))	Sound (no (%))	Decayed (no (%))	
6 Months	GIS	20 (100)	0	80 (100)	0	—
	RS	20 (100)	0	80 (100)	0	
12 Months	GIS	20 (100)	0	80 (100)	0	—
	RS	20 (100)	0	80 (100)	0	
24 Months	GIS	19 (95)	1 (5)	76 (95)	0	—
	RS	19 (95)	1 (5)	76 (95)	0	
36 Months	GIS	16 (80)	4 (20)	63 (98.4)	1 (1.6)	0.303
	RS	17 (85)	3 (15)	68 (100)	0	
48 Months	GIS	10 (50)	10 (50)	36 (90)	4 (10)	0.141
	RS	14 (70)	6 (30)	44 (78.6)	12 (21.4)	

Table 3 Mean \pm SD of salivary fluoride levels (ppm) at different time intervals

Groups	Baseline	After sealant	6 months	12 months	24 months	36 months	48 months
GISs	0.002 \pm 0.002	3.849 \pm 1.562	0.154 \pm 0.087	0.125 \pm 0.052	0.025 \pm 0.027	0.016 \pm 0.024	0.009 \pm 0.007
RSs	0.014 \pm 0.040	0.043 \pm 0.126	0.059 \pm 0.052	0.052 \pm 0.037	0.011 \pm 0.015	0.010 \pm 0.008	0.006 \pm 0.002
<i>p</i>	0.218	0.0001	0.0001	0.0001	0.033	0.386	0.162

DISCUSSION

This randomized clinical study compared caries prevention using a conventional RS (Ultrasal XT[®]) and a GIS (Fuji Triage[®]) on occlusal pits and fissures over a 48-month period in a group of children with a high incidence of caries. The level of salivary fluoride was also evaluated.

Many clinical trials have been published comparing the effects of resin-based sealants and glass-ionomer sealants on caries prevention. Systematic reviews and meta-analyses have shown that both GIS and RS are capable of preventing the development of caries^{5,6}. Nevertheless, the routine clinical use of a glass ionomer sealant is still unreliable because of poor retention¹⁸.

Many authors have considered GIC unsuitable for sealing pits and fissures because of their low physical characteristics^{7,24}. Although GIC may not be observed in a pit or fissure, the material may still remain and prevent caries from forming^{25,26}. The Cochrane Review³ estimated that the caries-preventative effect of sealants ranges from 87% at 12 months to 60% at 48-54 months; however, this effect relies on adequate retention of the sealant. According to Guler and Yilmaz²⁷, Fuji VII[®] and Admira Seal[®] exhibited similar retention and marginal integrity during a 24-month period; however, Fuji VII was more effective than Admira Seal[®] for preventing caries. Sly *et al.*²⁸ showed that Fuji VII and Fuji IX performed the same after a 12-month follow-up. Moreover, Kamala and Hegde²⁹ reported that both Fuji III[®] and Fuji VII[®] exhibited partial or complete retention in 80% of patients at the 1-year evaluation. These results are consistent with our findings. Also, consistent with other studies, this study observed lower long-term total retention rates for GIS compared with resin sealants^{13,30}.

In our study, the highest rate of sealant loss was seen at 48 months in both groups. After 48 months, 96 sealants in 24 patients were available for evaluation. The total retention rates were 7.5 and 40.0% in the GIS and RS groups, respectively, and the total and partial retention rates were 75 and 78.6%, respectively. Similar to the study of Hesse *et al.*³¹ in our study, partial loss of sealant was considered a failure. The cumulative sealant retention (full) rate over 48 months was 27.6% for the RS and 10.8% for the GIS in this study. The difference was statistically significant (log rank=58.40, *p*=0.0001, 95% CI). Although five instances of total loss were observed after 36 months in the GIS group, only

one case of enamel caries was observed in that group. This study showed that, although the retention rate was statistically higher in the RS group, no caries developed in teeth with partial GIS loss after 48 months and no dentine caries developed in teeth that with total GIS loss after 48 months. DIAGNOdent pen values were between 21 and 29 for all carious teeth in the GIS group whereas they were between 21 and 29 for five teeth and greater than 30 for seven teeth in the RS group.

Twelve cases of total loss were observed in the RS group, and dentine caries occurred in 7 (58.3%) of those teeth. Since those 7 teeth were diagnosed as dentin caries in 4 patients, occlusal composite restorations were applied to those teeth. No restoration was applied to any GIS group. Similar to our results, Liu *et al.*³² showed that although the retention of resin sealant was better than that of the ART GIS, their preventative effectiveness against caries in permanent molars did not differ significantly over 24 months³². One study showed that GIS was four times as effective in preventing the development of caries in pits and fissures even with sealant loss compared to composite resin sealants over a 1- to 3-year period³³. Other *in vitro* studies have shown that GIS materials improve enamel strength in fissures^{33,34}.

Glass ionomer sealants should be called 'fluoride depot cements' because they slowly release fluoride³⁵. A combination of sealant and fluoride is predicted to have an additive effect on the prevention of dental caries, which is beneficial, as the sealant increases salivary fluoride levels²¹. Most sealant studies have used a half-mouth design in which the teeth on one side of the mouth were treated, while the contralateral teeth remained unsealed³⁶. This study did not use the half-mouth design because one aim of the study was to compare the level of salivary fluoride in the two groups. We expected that in the case of salivary fluoride levels being increased in one of the groups, there would be a protective effect against caries.

In our study, pairwise comparisons of the groups revealed that there were statistically significant differences in fluoride levels in saliva between baseline and after treatment, at months 6, 12 in the GIS group (*p*=0.0001). The salivary fluoride levels were higher in the GIS group during the first 48 months; however, this difference was not significant after month 24. Similarly, saliva fluoride levels were not significantly higher than those at baseline in either group. *In-vitro* studies have confirmed that glass-ionomer cements can act as

rechargeable reservoirs, distributing a continuous low level of fluoride due to uptake from fluoridated solutions, dentifrices and mouthwashes^{10,34}. Factors including the components of saliva, the acquired pellicle, pH, and ion concentration that might have decreased fluoride diffusion from the sealant were not analyzed³⁷. Moreover, additional fluoride sources, including toothpaste or diet, were available to participants and might have affected the levels of fluoride.

Rubber dam isolation is ideal but cotton roll isolation is most commonly used; however, either is equally effective in terms of retention rates¹⁸. In this study, cotton rolls were used, a technique that has been referred to as partial isolation. Absolute isolation may not be necessary for the application of sealants as long as extreme care is taken to avoid salivary contamination of the etched surface¹⁸.

Choosing between a resin sealant and a glass ionomer sealant will be strongly influenced by clinical considerations, including the prevalence or risk of caries in the child. In this study, the prevalence of caries in the participants was high compared with previous studies^{27,32,38,39} and the GIS group performed better than the RS group in preventing caries.

Our study had some limitations. Specifically, other factors that might have an effect on the prevalence of caries were not evaluated and the dropout rate was higher than expected. Our study presents a dropout of 40% (Baseline children=40 and 48-months evaluation=24 children). Due to the multifactorial etiology of dental caries, predicting the onset of new caries lesions is difficult. Oral hygiene training and nutritional counselling were given to all study participants, along with toothpaste containing 1,450-ppm fluoride at each appointment. However, the patients' homecare could not be controlled.

In conclusion, the GIS used showed comparable efficacy in the prevention of caries development, although the failure rate was higher than with the RS. An increased salivary fluoride level seen in this study due to GISs might be an additive effect on the prevention of dental caries. Thus, the routine clinical use of a glass ionomer sealant may be reliable.

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