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A One-Year Evaluation of a Free Fissure Sealant Program

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Abstract

Statement of Problem: Pit and fissure sealant therapy has been approved as an effective measure in the prevention of occlusal dental caries. Resin based materials are the most common materials used worldwide. A variety of resin based fissure sealants are produced and used. Most of them have been presented with ideal results in research environment. However, their effectiveness in the real life, especially in a mass application program such as Iran's oral health reform plan is not clear.

Objectives: To evaluate the longevity of different fissure sealant applied in Iran's oral health reform plan in Fars Province (south of Iran) after one year.

Materials and Methods: Seven counties were selected. One hundred 6- to 8-year-old school children who had undergone fissure sealant therapy in spring 2015 were randomly selected from each county. Their first molars were examined to evaluate the status of the fissure sealants which were applied one year ago. Data on the type/brand of fissure sealant materials, type and experience of clinicians who applied them, existence of a chair-side assistant, and whether the children were caries-free at the time of fissure sealant application were collected from the existing reports.

Results: Data of 1974 teeth from 598 children were used for the final analysis. The effects of type/brand of the material was significant on the final results and remained significant ($p < 0.001$) after adjustments for the level of fluoride, urban/rural area, upper/lower jaw, type of clinician who applied the sealant, existence of a chair-side assistant, and child's gender, age, and being caries-free.

Conclusions: Many factors affect the success rate of a fissure sealant therapy program. The type/brand of the material remained significantly related to the success rate of the fissure sealant even after adjustments for other influencing factors. In this study, Clinpro™ Sealant (3M/ESPE, USA) showed better longevity after one year of application.

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Introduction

It is well recognized that a higher prevalence of dental caries start from pits and fissures, compared to the smooth surfaces. In children, about 90 percent of decays of the permanent teeth start from pits and fissures. And a considerable number of them remain in these surfaces for the person's life [1,2].

Fissure sealant (FS) therapy was introduced in the 1960s and has been widely used since then [2,3]. Resin based sealants are more commonly used currently. The preventive effects of resin based pit and fissure sealants have been demonstrated in several studies [1,4]. They can reduce the occurrence of tooth decay by more than 50% in the first through five years after the application when each tooth is sealed only once with no follow up treatment. In cases that the sealed teeth are regularly (annually for instance) examined and the defected or lost fissure sealants are renewed, the chance of caries could be reduced by 75% up to four years [5].

With all proven preventive benefits of fissure sealant therapy, it is still difficult to convince people to request their dentist to perform it, or accept their dentist's suggestion for it. Unfortunately consumers, health service providers (such as health ministry), and health insurers all resist paying for preventive oral care [6,7] . However, in Iran, an oral care program was established in 2015 as part of the national health reform plan which started in 2014 [8,9]. In this program, the state health system was obliged to provide oral health prevention services to all primary school children through primary care trusts. It included regular oral examinations, oral hygiene instruction, scaling and cleaning teeth, fluoride therapy, and application of fissure sealants [9].

Although the effectiveness of pit and fissure sealants is well established, most studies confirming that have been conducted in an ideal environment. This means the method of application has been closely supervised in such an environment. However, the results of mass application of sealants, when several children are called and treated in a day, might be different [10]. In the new program in Iran, parents do not pay for sealants, and in some cases they are not even given enough information about sealing their children's teeth. Therefore, it is possible to think that the results of sealant therapy might not be as good as what is seen in both in-vitro and in-vivo experimental conditions.

It is understandable that FS material would gradually fade away by both physical (mastication forces) and chemical means. However, good evidence is available showing that, if properly applied, FS should remain on the tooth surface (covering pits and fissures in an acceptable condition) for several years [11].

One of the main reasons for early loss of FS is contamination of the tooth surface with saliva during FS application [12]. This is of special importance as FS is usually applied to children's (who might be less cooperative) teeth which might not be fully erupted [13]. Apart from that, the most important factor related to the success rate of FS in the first year of application is the type/brand of the material [11,14]. As mentioned above, the fissure sealant materials are usually tested either in factory laboratories or in the most ideal clinical environment. But how would they work under the real life conditions?

The current study was, therefore, designed and conducted to evaluate the success rate of the fissure sealants applied to the first permanent molars of six to eight year old school children of Fars province (south of Iran) under the health reform plan after one year of application. The main objective of this study was to test the efficacy of different fissure sealant materials in such conditions.

Materials and Methods

The free fissure sealant program started in the early 2015 as a national program targeting the primary school children in Iran. In Fars province, south of Iran, 28 counties (cities/towns plus their politically related villages) plus Shiraz (the capital city of Fars province) participated in the program. Shiraz and six randomly selected counties were included in the current study. Three counties were selected by simple randomization from those with low or optimal level of fluoride in water. Three other counties were selected from areas with high (> 1.5 ppm) level of fluoride in the tap water. Shiraz was added to the low/optimal fluoride level group. Therefore, seven counties were assessed in this study.

In each county, a list of 6- to 8-year-old children who received free fissure sealant therapy during spring 2015 was obtained from the existing documents, which were prepared for a report to the Ministry of Health. In each county, 50 children were selected from the urban and 50 from the rural areas. Stratified random sampling (educational zone, sex, school, pupil) was used for samples selection from the city of Shiraz and its rural areas. A simple randomization

was used in the other six counties.

Those children with at least one of their first permanent molars undergoing fissure sealant therapy in the reports were included. Information on children's age and sex, type of residential area (rural/urban), dental health status, type of fissure sealant, method of application, type of the clinician who applied the fissure sealant, and existence of a chair-side assistant was obtained from the records. The types of clinicians were as follows: dental hygienist, recently graduated dentist in their vocational training (VT), dentists with less than five years of experience (not in their VT), and dentists with more experience.

A general dental practitioner was invited to the study from each of seven areas. They were trained and calibrated to act as examiners for this study. Examinations took place in spring 2016, approximately one year after the FS application. The selected children were examined in their schools using disposable gloves, mirrors and tongue blades. A head light was used in adjunct with the natural classroom lights. Occlusal surfaces of their teeth were taken into account only. The condition of the first molars, which had FS applied to them one year ago, was registered as: sound with good FS in place, sound with partial FS, sound with defected FS, sound with no FS, decayed with FS, decayed with no FS, and filled. Those with full coverage, such as a stainless steel crown, were considered as filled.

For some analysis, tooth condition was transformed into a binary variable of successful and failed. For this purpose, only those teeth that were sound and had a good FS in place were considered successful.

Those children who did not attend the examination session for any reason, had changed their school, and had undergone fixed orthodontic treatment were excluded. The examiners were allowed to mark a tooth as "questionable" if they could not reach a definite diagnosis about the condition of the tooth. The questionable teeth were also excluded from the final analysis. All information were gathered and kept highly confidential.

SPSS statistical software (version 20) was used for data entry and analysis. Each examined tooth was considered as an independent sample during analysis. Frequency and percentage of each type of tooth condition was calculated. The condition of the examined teeth was compared between urban and rural areas, areas with low/optimal and high levels of fluoride in water, boys and girls, caries-free children and those with caries in their other teeth at the time of FS application, upper and lower teeth, existence and absence of a chair-side assistant, type of clinician, and type/brand of fissure sealant, using a Chi-square test. The relationship between children's age at which an FS was placed with the success rate of FS was assessed using an ANOVA test. Logistic regression was used to assess the independent effect of the brand of the material on the outcome.

Results

Data of 1974 teeth from 598 children were used for the final analysis. As it was mentioned above, each tooth was considered as an independent sample. Demographic variables of the samples are presented in Table 1. About 60% of the examined teeth were from counties with low or optimal level of fluoride in water and the other 40% were from areas with high fluoride level (> 1.5 ppm). Only 13.6% of the examined teeth were in children who were reported as caries-free at the time of the fissure sealant application. More than half (52.6%) of the fissure sealants were conducted by general dental practitioners in their compulsory vocational training. Relatively good proportions were seen in other factors such as urban/rural area, gender, upper/lower jaw, and existence of chair-side assistance at the time of FS application.

Six types of fissure sealants were used. Each of them was used for between 13.4 and 20.2 percent of the examined teeth (Table 2). The condition of the examined teeth, at the time of examination (which was around one year after the fissure sealant application), is presented in Table 3. Only 47% (N = 927) of the examined teeth had a good fissure sealant in place. This means less than half of the teeth reported to be sealed were still in good shape and condition. None of the examined teeth was extracted.

There was a significant difference in the results based on the type of the clinicians who applied the fissure sealant ($p < 0.001$). If we consider the teeth with a good fissure sealant in place with no decay in their occlusal surface as successful, dentists with less than five years of experience who were not in their compulsory VT had the highest success rate (64%). That is while the dental hygienists had the lowest rate (34.6%). On the other hand, dental hygienists had the highest number of teeth with no detectable fissure sealant (sound with no FS + decayed with no FS = 57.3%). Dentists with more than five years of experience had the highest percentage of the teeth which

Table 1: Demographic characteristics of the included teeth (N=1972)

Variable	Value	Frequency	Percentage
Level of fluoride	Low/optimal	1183	59.9
	High	791	40.1
Area	Rural	886	44.9
	Urban	1088	55.1
Gender	Boy	1051	53.2
	Girl	923	46.8
Caries free (at the time of FS application)	No	1702	86.2
	Yes	268	13.6
	Not recorded	7	0.2
Jaw	Upper	945	47.9
	Lower	1029	52.1
Existence of a chaireside assistance	Yes	937	47.5
	No	1037	52.5
Type of clinician	Dentist in VT	1039	52.6
	Dentist with < 5 years of experience	203	10.3
	Dentist with > 5 years of Experience	444	22.5
	Dental hygienist	288	14.6

Table 2: Types of fissure sealant material used and the number of teeth treated with each of them

Fissure sealant material	Manufacturer	Number of teeth treated with	% of teeth treated with
Master-Dent™ Pit and Fissure Sealant- light curing- Opaque	Dentonics (USA)	360	18.2
Seal-Rite™ Pit and Fissure Sealant	Pulpdent Corporation (USA)	286	14.5
Wet-Bond™ Pit and Fissure Sealant	Pulpdent Corporation (USA)	264	13.4
Eco-S™ Pit and Fissure Sealant	Vericom Co. Ltd. (Korea)	398	20.2
Seal-It	Spident Co. Ltd. (Korea)	368	18.6
Clinpro™ Sealant	3M ESPE Co. (USA)	298	15.1
Total	--	1974	100

Table 3: Condition of the teeth when examined one year after fissure sealant application (N=1974)

Code	Condition of teeth	Number of teeth	% of teeth
1	Sound with good FS in place	927	47.0
2	Sound with partial FS in place	116	5.9
3	Sound with defected FS	129	6.5
4	Sound with no FS detected	597	30.2
5	Decayed with partial or defected FS	33	1.7
6	Decayed with no FS detected	115	5.8
7	Filled	57	2.9
8	Extracted	None	0

were filled (4.7%) (Table 4).

There was also a significant difference in the results between those in low/optimal level of fluoride and those in high level of fluoride in their water ($p < 0.001$). A higher percentage of sound teeth with good FS in place (55.2% vs. 41.4%) and a lower percentage of filled teeth (1.5% vs. 3.8%) were seen in areas with high level of fluoride. The difference between rural and urban areas was also statistically significant ($p < 0.001$). There was a markedly lower percentage of sound with good FS teeth (44.1% vs. 49.3%) and markedly lower percentage of filled teeth (0.9% vs. 4.5%) in those from rural areas.

In terms of being caries-free at the time of fissure sealant therapy, there was a significantly higher percentage of sound with good FS (59.3% vs. 45.1%) and significantly lower percentage of sound with no FS (20.5% vs. 31.7%) in caries-free children, compared with others ($p < 0.001$). It seemed that the upper jaw teeth were more likely to remain sound. There was a higher percentage of sound with good FS (53.4% vs. 41.0%), a lower percentage of decay with no FS (2.9% vs. 8.6%), and a lower number of filled teeth (2.0% vs. 3.7%) in the upper jaws ($p < 0.001$).

When a chair-side assistant was available, a higher number of sound with good FS, a higher number of sound with partial FS, a higher number of sound with defected FS, and much lower numbers of sound with no FS, and decay with no FS were seen ($p < 0.001$).

In terms of the effects of types of fissure sealant material, percentage of successful results (sound with good FS in place) was much higher when Clinpro™ (3M ESPE, USA) was used (67.4%). This was significantly higher than the success rate of between 38 and 51 percent in other types ($p < 0.001$). Moreover, the percentage of sound with no FS was several folds higher in any other material (22%-45%) when compared with 9.7% in Clinpro™ Sealant ($p < 0.001$). Clinpro™ was among lower percentages in other failed cases, too (Table 5).

Among other types, Pulpdent's conventional Seal-Rite™ (USA), which uses a dry bond system, had one of the highest percentages of sound with partial FS, and the highest percentage in two other failed tooth conditions: sound with the defected FS and filled teeth. Pulpdent's Wet-BondTM (USA) showed the highest proportion of decayed teeth with no FS, Masterdent and Spident had high numbers of sound with no FS.

To make sure that the differences in the results of using different materials are truly related to the type/brand of FS, the effects of other factors were eliminated by adjusting through using a logistic regression modeling. It was revealed that the difference between the six types of FS was independent from the other factors ($p < 0.001$), although they remained significant in the equation (Table 6). The effect of the type of area (urban/rural) was reversed in the regression model, showing that those living in rural areas had a better chance of success in FS after adjustments for other factors.

Discussions

Iran's Health Reform Plan started in 2014. It initially targeted the tertiary care in hospitals to make sure everybody enjoys a better quality treatment in hospitals with less out of pocket costs. All Iranians were offered a health insurance regardless of their working status. This was happening for the first time in Iran [8,9]. Considering the high costs of this plan and the fact that no previous Iranian government allocated such budget to health, it was regarded as "Rouhani Care" in global media referring to Iran president's heed towards better health insurance coverage [15,16].

Attention to primary care was added to Iran's Health Reform Plan one year after its start date. Regarding the oral health care, the plan focused mainly on preventive measures which were officially introduced in April 2015. Children in primary schools were placed as the target group. They were offered oral examination, oral hygiene instruction, fluoride therapy, extraction of infected teeth, and fissure sealant therapy free of charge. The latter was done by either dentists or dental hygienists in a mass application in which several (or even a whole class of) children were taken to a dental setting in a single day and fissure sealants were applied to all their eligible teeth. As one may predict, quality of services might fall in such mass service provision. The objective of the current study was, therefore, to evaluate the effectiveness of fissure sealant application in such non-ideal conditions. It was designed to see what types of fissure sealant materials were used in this program and to compare their effectiveness in such conditions. As different materials were used in different places, it was necessary to observe and adjust for other affecting variables such as the level of fluoride in the area's water, children's gender and age, rural or urban area of living, upper or lower jaw

Table 4: Condition of the examined teeth by the type of clinician applying the fissure sealant around one year ago

Type of clinician who applied the FS		Present tooth condition							Total
		sound with good FS	Sound with partial FS	Sound with defected FS	Sound with no FS	Decayed with FS	Decayed with no FS	Filled	
Clinician who applied the FS	Dentist in V	476 (45.8%)	67 (6.4%)	77 (7.4%)	305 (29.4%)	12 (1.2%)	71 (6.8%)	31 (3.0%)	1039 (100.0%)
	Dentist with less experience	130 (64.0%)	19 (9.4%)	9 (4.4%)	37 (18.2%)	2 (1.0%)	2 (1.0%)	4 (2.0%)	203 (100.0%)
	Dentist with more experience	227 (51.1%)	21 (4.7%)	27 (6.1%)	104 (23.4%)	16 (3.6%)	28 (6.3%)	21 (4.7%)	444 (100.0%)
	Dental hygienist	94 (32.6%)	9 (3.1%)	16 (5.6%)	151 (52.4%)	3 (1.0%)	14 (4.9%)	1 (0.3%)	288 (100.0%)
Total		927 (47.0%)	116 (5.9%)	129 (6.5%)	597 (30.2%)	33 (1.7%)	115 (5.8%)	57 (2.9%)	1974 (100.0%)

Table 5: Condition of the examined teeth by the type/brand of the fissure sealant material used

		Present tooth condition							Present tooth condition
		sound with good FS	Sound with partial FS	Sound with defected FS	Sound with no FS	Decayed with FS	Decayed with no FS	Filled	
FS material	Master-Dent™	145	14	17	161	2	18	3	360
		40.3%	3.9%	4.7%	44.7%	0.6%	5.0%	0.8%	100.0%
	Seal-Rite™	116	20	40	79	2	13	16	286
		40.6%	7.0%	14.0%	27.6%	0.7%	4.5%	5.6%	100.0%
	Embrace Wet-Bond™	119	14	8	83	4	30	6	264
		45.1%	5.3%	3.0%	31.4%	1.5%	11.4%	2.3%	100.0%
	Eco-S™	204	28	27	88	14	22	15	398
		51.3%	7.0%	6.8%	22.1%	3.5%	5.5%	3.8%	100.0%
	Seal-It™	142	25	14	157	9	16	5	368
		38.6%	6.8%	3.8%	42.7%	2.4%	4.3%	1.4%	100.0%
	Clinpro™	201	15	23	29	2	16	12	298
		67.4%	5.0%	7.7%	9.7%	0.7%	5.4%	4.0%	100.0%
	Total	927	116	129	597	33	115	57	1974
		47.0%	5.9%	6.5%	30.2%	1.7%	5.8%	2.9%	100.0%

Table 6: Effects of all the studied variables on success rate of FS before and after adjustments

Variable		Tooth condition*		p-value before adjustments	OR*** (95% C.I)	*p*-value after adjustments
		Success**	Failure			
Age		6.86±0.86	6.71 ± 0.81	<0.001	0.849 (0.753-0.957)	0.007
Level of fluoride	High	55.2%	44.8%	<0.001	1	--
	Low/ optimal	41.4%	58.6%		0.45 (0.35-0.54)	<0.001
Type of area	Urban	49.3%	50.7%	<0.001	1	--
	Rural	44.1%	55.9%		2.14 (1.60-2.86)	<0.001
Existance of a chair-side assisstant	Yes	56.5%	43.5%	<0.001	1	--
	No	38.4%	61.4%		0.44 (0.33-0.57)	<0.001
Child's sex	Girl	43.0%	57.0%	<0.001	1	--
	Boy	50.4%	49.6%		1.35 (1.11-1.64)	0.003
Jaw	Lower	41.0%	59%	<0.001	1	--
	Upper	53.4%	46.4%		1.71 (1.41-2.08)	<0.001
Caries free status	Yes	59.3%	40.7%	<0.001	1	--
	No	45.1%	54.9%		0.57 (0.43-0.77)	<0.001
Type of clinician	Dental Hygienist	32.6%	67.4%	<0.001	1	--
	Dentist in VT	45.8%	51.2%		1.47 (1.05-2.04)	0.024
	Dentist with <5y experience	64.0%	36.0%		2.41 (1.57-3.70)	<0.001
	Dentist with >5y experience	51.1%	48.9%		1.60 (1.04-2.44)	0.031
Type of FS material	Clinpro™	67.4%	32.6%	<0.001	1	--
	Masterdent™	40.3%	59.7%		0.30 (0.20-0.43)	<0.001
	Seal-Rite™	40.6%	59.4%		0.47 (0.32-0.69)	<0.001
	Wet-Bond™	45.1%	54.9%		0.45 (0.31-0.66)	<0.001
	Eco-S™	51.3%	48.7%		0.55 (0.39-0.79)	0.001
	Seal-It™	38.6%	61.4%		0.41 (0.29-0.59)	<0.001

*Tooth condition at the examination date (about one year after FS application). Age was described using mean±SD and categorical variables were described using rate(%)
"**Sound teeth with acceptable FS in place" was considered success. Other conditions were considered failure.
***Adjusted Odds Ratio using a logistic regression model.

teeth, the type and experience of those who applied the FS, presence of a chair-side assistant, and if the children were caries-free at the time of fissure sealant application.

It was found that less than half (47.0%) of the teeth reported to have fissure sealant were sound and had intact or acceptable FS in place one year after application. It is better to say that these teeth "were sound" not "remained sound" at the time of examination, as we could not be sure if all of the examined teeth were sound at the time of fissure sealant teeth. Some clinicians might have applied fissure sealant to the teeth that were questionable or had dental caries in their initial phase either by mistake or with the hope that the FS could stop or postpone the caries progress [17].

Three main types of material are available for sealing pits and fissures: resins, glass-inomers and poly-acid modified resin composites (compomers), which are a combination of the first two. To date, the resin-based pit and fissure materials are still the most widely used material, which have also showed the highest effectiveness even in comparison with the newer types of material [5,18]. In the current study, six different materials were found being used for FS application, and all of them were resin-based.

One of the findings of this study was that when a wet bond system was used for FS application (Embrace Wet-Bond™ – Pulpdent- USA), a high number of decayed teeth with no FS were reported. This could be due to the inappropriate placement of FS, which in turn could be considered as a result of the applicant being unfamiliar with this system. Some other studies have also reported similar findings [19].

It was found that near five percent of the examined teeth were filled. That was just around one year after FS application. These were either filled during one year between FS application and the examination date which could be filled instead of FS application at the time of program, or were wrongly reported as having sealed while they were filled before. As this was a retrospective study, there was no way to distinguish between the three possibilities.

Many previous studies on FS reported much higher success rate [1,20]. A study by Ismail and Gagnon (1995) was one the first studies that evaluated an FS program in field. They reported that only 2.5% of the sealed teeth needed filling after one year [21]. However, in the current study 2.9% of the sealed teeth were already filled after one year; the other 7.5% of the teeth were found having caries and, therefore, should have been filled. In another study by Heller et al., 8% of the sealed teeth had or needed filling after five years of FS application [22]. This is almost equal to the percentage of the teeth which had or needed filling just one year after FS application in the current study.

One of the reasons for low success rate of FS reported in the current study could be the possibility of application of fluoride varnish right before FS application. Both fluoride therapy and FS were parts of the oral health reform program. Thus, it is assumed that some clinicians had possibly applied fluoride and FS in the same visit. It is argued that the reaction of fluoride with the enamel would add to the enamel's resistance to acids, and therefore, lowers the resin bond to the tooth surface [23,24]. Data on the possible concurrency of fluoride and FS therapies were not obtained in this study.

Another fact worth mentioning is the possibility of over-reporting the number of FS application by clinicians in the Iran's current program. False reporting could happen in any similar community program. However, the high rate of sound teeth with no FS in this study should ring the bells. A quality and quantity control would be necessary if the policy makers would really intend to continue this program and lower the DMFT in future. Even by considering all limitations of the FS program and limitations of this study, the results of Clinpro™ (3M ESPE – USA) were much better than the others; however, the difference could neither be ignored nor be related to the limitations.

Based on the findings of the current study, it seems that the teeth sealed in the oral health reform program in 2015 need to be reevaluated and either get filled or sealed again. Nevertheless, it is a global finding that repeating FS application would increase its success rate by both increasing the rate of the existence of a good FS on tooth surface after any specific period of time and decreasing the caries rate [25,26].

Conclusions

In this study, it was shown that several factors affect the success rate of a fissure sealant therapy program in schoolchildren. The type of material used in such program plays a vital role which is independent from other affecting factors. In this study, resin-based fissure sealant material made by 3M/ESPE, USA (Clinpro™) showed higher longevity and retention than other five materials.

Conflict of Interest: None declared.

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