

Original Article

Time of Application of Fluoride Varnish versus Resin-Based Fissure Sealant in Newly Erupted Permanent Molars in Group of Egyptian Children: A Randomized Clinical Trial.

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Abstract

Aim: This study aims to determine the application time of fluoride varnish (FV) versus resin-based fissure sealant (RBS) required to prevent caries in newly erupted permanent molars in a group of Egyptian children. Subjects and methods: This is a randomized clinical trial with two arms, parallel groups, and allocation-blinded. The total number of participants was 182, with ages ranging from 6 to 8 years. The participants were randomly assigned to one of two groups: RBS as a control and FV as an intervention. The participants were treated by 2 post-graduate students (91 teeth in each part. In part 1, (45) teeth were in the FV group, and (46) teeth were in the RBS group. Of the 91 teeth only 89 teeth completed the follow-up at 6 and 12 months. Outcomes measured were the time of application which was calculated by a stopwatch.

Results: The results revealed that at the time of application, the base time results showed that FV had a significantly lower application time than RBS ($p < 0.001$). While the difference after 6 and 12 months was not statistically significant ($p > 0.05$). The odds ratio for treatment unacceptability in the FV group was 0.31, indicating that the odds of treatment unacceptability in the FV group were not statistically inferior to those in the RBS group. **Conclusion:** The results of our trial demonstrated no significant difference between FV and RBS in caries prevention and the time of application for FV was shorter than RBS. Due to its lower cost, shorter time, and simplicity, we recommend the use of FV as a preventive material in dental public health programs, but RBS in a private dental clinic. Both FV and RBS were acceptable for children.

Keywords: Fluoride Varnish, Children, Fissure Sealant, Time.

I. INTRODUCTION

Dental decay is the most chronic disease and prevalent dental problem, as it can lead to pain, infection, and difficulty eating. Caries ranges from demineralization to loss of tooth structure or complete destruction of the crown. This is a dynamic and active caries process characterized by

distinct periods of destruction and repair (Kazemina et al., 2020).

The first permanent molar (FPM) is of main importance for dentition and tooth development, and early loss from tooth decay affects the subsequent dental health of children. Due to the high incidence of caries in FPM, it must be sealed

to prevent the development & growth of plaque & bacteria in the grooves (Aldossary *et al.*, 2018).

Fissure sealants (FS) or fluoride varnish (FV) can be applied to the teeth to prevent caries. A dental sealant is a one-time application of a coating consisting of an adhesive substance such as glass ionomer or resin, which is applied to the tooth surface. It protects teeth from acid by sealing off the grooves that tend to accumulate food (Kashbouret *al.*, 2020).

A randomized clinical trial by **Mattar *et al.*** was conducted in 2021 to compare FS chair time & patients' preference by using 3 different isolation techniques. Three isolation techniques (rubber dam isolation, isolite system, & cotton roll isolation). The age of Participants was 6:15 years & requiring 4 sealants on the first or second PMs. Chair times for the isolite system, rubber dam isolation, and cotton roll isolation were 248.14, 255.89, and 243.29 seconds, respectively. In conclusion, there were no significant differences in sealant time application between the 3 isolation techniques. But, cotton roll isolation was the most preferred technique by the participants (Mattar *et al.*, 2021).

Hawkins *et al.* conducted a study to compare the application time of foam and varnish. The FV technique took less time than the foam (5.81 vs 7.86 min; $P < 0.001$). However, the greatest difference was he was a child aged 3–6 years (5.22 vs 8.61 min, $P < 0.001$). These results support the use of FV in caries prevention programs (Hawkins *et al.*, 2004).

On the other hand, FV is a paste that includes quantities of fluoride, a mineral that is naturally found in teeth to save them from harm as it facilitates the remineralization process that reduces the appearance of new carious lesions. Application of FV should be done by dentist two to four times a year (Kashbour *et al.*, 2020).

However, the FV has a higher fluoride concentration than gels, foams, rinses, and pastes, sodium fluoride (NaF) Varnish is less hazardous to children as less of it is ingested during the application, due to its short setting time and low dose used. Children should be especially careful

because of toxicity and sickness (Mahalakshmi and Ajai, 2021).

Therefore, the objective of the current trial was to determine the time of application of FV versus RBS for the prevention of dental caries in newly erupted PMs in a Group of Egyptian Children.

II. SUBJECTS AND METHODS

This study was a randomized controlled clinical trial performed in the outpatient diagnostic clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University. The total number of participants 182 participants, were selected from the outpatient clinic. The participants were randomly assigned to one of two groups: RBS as a control and FV as an intervention. The participants were treated by 2 post-graduate students (91) teeth in each part. In part 1, (45) teeth were in the FV group, and (46) teeth were in the RBS group.

Inclusion criteria comprised: newly fully erupted FPM in children aged 6–8, healthy children with no physical or mental disorders, and no sex predilection was determined. While exclusion criteria involved: children with dental decay in enamel, history of pain or swelling, or parents refusing their children's participation in the trial.

Sample size was calculated based on the results of **Arruda *et al.*** (Arruda *et al.*, 2012). The predicted sample size (n) was found to be a total of (152) teeth, i.e. (78) teeth per group. It was increased by 20% to account for possible dropouts, for a total of 182 teeth 91 teeth for intervention group FV & 91 teeth for control group RBS. So in this trial (part 1), 91 teeth were enrolled in this study 45 teeth in FV group & 46 teeth in RBS group. Sample size calculation was performed using PS software version 3.0 for Windows.

Stopwatch was selected as the measurement method for time of application in this investigation (Kiran, 2020). Assessment and collection of the outcome were done at treatment visit (baseline), 6 and 12 months clinically (using

DFS, calculate the time of application with stopwatch).

The FS was evaluated visually and tactically, and an attempt was made to dislodge it with a probe. Any deficiencies in the material were repaired to ensure an intact sealant surface (Chestnutt *et al.*, 2017).

Statistical analysis

Categorical data were presented as frequency and percentage values and were analyzed using Fisher's exact test. Numerical data were presented as mean and standard deviation values and were explored for normality by using Shapiro-Wilk test. Non-parametric numerical data (DFS score and time of application) were analyzed using Mann-Whitney U test for intergroup comparisons. The significance level was set at $p < 0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.1.3 for Windows (Core Team, 2023).

III. RESULTS

This study was conducted on 182 child that were randomly allocated to both tested groups (i.e. 91 teeth in FV group and 91 teeth in RBS group). This part of the study was contained 91 teeth 45 cases in FV group and 46 cases in RBS group.

Demographic data for both groups were presented in **Table (1)** and **Figures (1)** and **(2)**. There was 25(47.2%) males and 20(52.6%) females in FV group, while in RBS group there was 28(52.8%) males and 18(47.4%) females. The mean age in the FV was (7.40 ± 0.73) years, while in RBS it was (7.22 ± 0.63) years. There was no statistical significant difference between both groups regarding demographic data ($p > 0.05$).

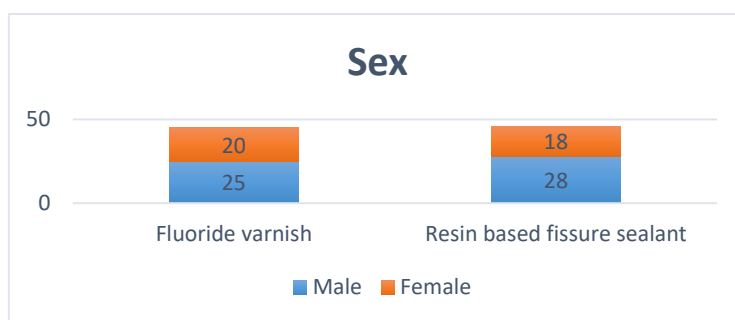
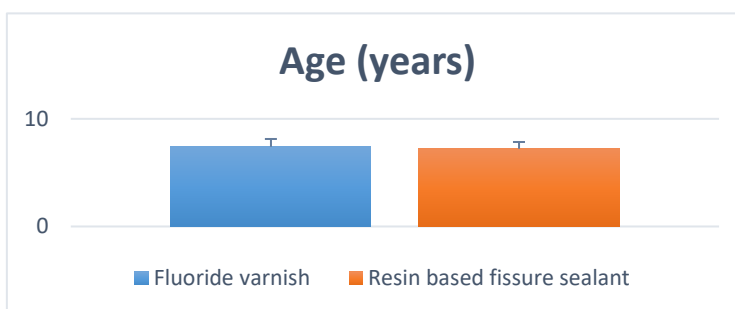
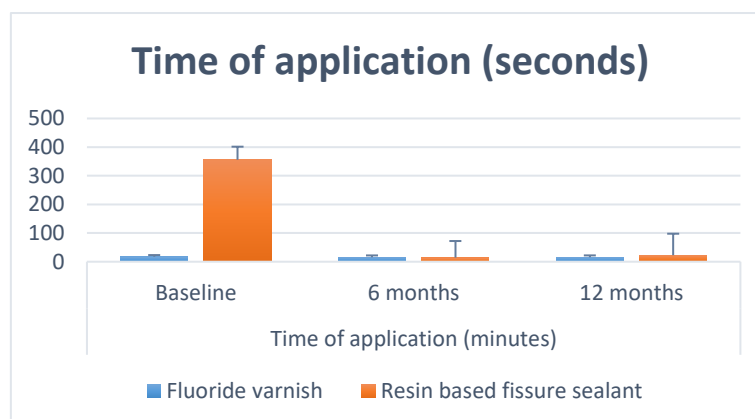
Mean & standard deviation (SD) values of time of application (seconds) for different groups were described in **Table (2)** and **Figure (3)**. At baseline & after 12 months, results showed that FV to have significantly lower application time than resin based fissure sealant ($p < 0.001$). While after 6 months they showed FV to have a significantly higher application time ($p < 0.001$). For all intervals, a 10% of the resin sealant group mean was used as the null hypothesis value (i.e. 10% inferiority margin) and the effect size was large ($r > 0.5$).

Table (1): Demographic Data of study sample for both groups

Parameter		Fluoride varnish	Resin based fissure sealant	p-value
Sex	Male	n	25	0.607
		%	47.2%	
	Female	n	20	
		%	52.6%	
Age	Mean±SD	7.40±0.73	7.22±0.63	0.203

Table (2): Mean & standard deviation (SD) values of time of application (seconds) for both groups.

Interval	Time of application (seconds)		Mean difference 95% CI	p-value	Effect size (r)
	(mean±SD)				
	Fluoride varnish	Resin based fissure sealant			
Baseline	17.58±5.55	355.74±45.74	338.16 (324.49:351.84)	<0.001*	0.86
6 months	15.37±6.55	14.24±58.02	1.13 (- 16.20:18.47)	<0.001*	0.03
12 months	15.49±6.58	22.61±75.14	7.12 (- 15.28:29.52)	<0.001*	0.13

**Figure (1):** Bar chart showing gender distribution**Figure (2):** Bar chart showing mean and standard deviation values (error bars) for age (years)**Figure (3):** Bar chart showing mean and standard deviation values (error bars) for time of application (seconds) in both group

IV. DISCUSSION

This study compared two preventive materials, RBS and FV to find out if FV could be applied within as a less time alternative to RBS with more acceptability from patients and parents. A dental sealant is a one-time application of a coating consisting of an adhesive substance as glass ionomer or resin which is applied to tooth surface. It protects teeth from acid by sealing off the grooves that tend to accumulate food. The most common sealant is RBS (Kashbour et al., 2020).

Also, according to the review 2021, (Baik et al., 2021) FV should be applied 2 to 4 times per year. In our study the application of FV was two applications per year each 6 months. This review is coincide with our study.

In the current study, the application of FV period was one year, and we plan to carry out follow-ups after trial termination for a longer period if feasible. the patients were recalled at 6 months and 1 year after the treatment to assess caries using DFS (Arruda et al., 2012), calculate the time of application with stopwatch and questionnaire for parents to measure acceptability and adverse effect (Chestnutt et al., 2017).

In the current study the time of application for FV & RBS respectively at Baseline (17.58 ± 5.55 & 355.74 ± 45.74 second), after 6 months (15.37 ± 6.55 & 14.24 ± 58.02 second) and after 12 months 15.49 ± 6.58 & 22.61 ± 75.14 second). The base time results showed that FV had a significantly lower application time than RBS ($p < 0.001$). While the difference after 12 months was not statistically significant ($p > 0.05$). So FV was statistically inferior to RBS regarding time of application. There were no previous trial about the time of application for FV & RBS.

V. CONCLUSION

Based on this study, the following can be concluded:

- Both fluoride varnish & resin based sealant are acceptable for children aged 6:8 years.

- The time of application for fluoride varnish is lesser than resin based sealant.

VI. RECOMMENDATIONS

Additional investigations are needed to assess the time of application due to the lack of studies concerned with time.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on:26\1\2021, approval number:(7121).

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