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# Remineralization Assessment of Early Childhood Caries using QLF-D: A Randomized Clinical Trial

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#### **Abstract**

**Objectives**: The aim of this study was to assess remineralization effects after applying fluoride varnish on children with white spot in maxillary and mandibular anterior teeth using quantitative light-induced fluorescence. **Methods/Statistical Analysis**: 56 participants (2–5 years old) were randomly divided into the Fluor protector group (n=28) and the FluorDose group (n=28). An oral examination was performed at baseline, and QLF-D was used for observations on early caries lesion. After applying the assigned fluoride varnish, QLF-D images were reacquired after 2 and 4 weeks. Data were analyzed using one-way ANOVA and t-test with PASW statistics 18.0 (SPSS Inc., Chicago, IL, USA). **Findings**: Both groups showed a significant decrease in  $\Delta F$  value from baseline to after 4 weeks (p < 0.05), at which time, Groups I and II showed a decrease of 5.88% and 1.71%, respectively. There was not statistically significant difference between group I and group II. According to QLF-D scores (0, 1, and 2), all groups showed the highest remineralization rate at score 2 after 2 weeks fluoride application. In the results from after 4 weeks, Group I showed the highest remineralization rate at score 2 (13.2%), while Group II showed the highest remineralization rate at score 1 (9.96%). **Improvements/Applications**: Viscosity and concentration of the fluoride varnish showed that not to affect the remineralization effect. QLF-D is thought to be useful device in observation of early carious lesion in ECC.

**Keywords:** Early childhood caries, Fluoride varnish, QLF-D, Remineralization, White spot

#### 1. Introduction

Early childhood caries (ECC) refers to dental caries that occur among children under the age of 6, and the areas where it most commonly occurs are the labial surface of maxillary primary anterior teeth, maxillary primary canines, and the buccal surface of maxillary and mandibular primary molars. ECC progresses at a faster rate than the type of dental caries that appear in adults, and thus, it is important to detect early and treat ECC<sup>1,2</sup>. The best care for ECC can be viewed as remineralization of white spot.

The enamel surface of white spot maintains a relatively healthy state, but there is loss of minerals in the area. The demineralized areas are seen as a white-colored, dried state<sup>3</sup>. When remineralization is induced on the demineralized enamel, the progression of demineralization stops and recovery back to original state is possible<sup>4</sup>. Clinically, the most widely used treatment for remineralization is topical fluoride therapy<sup>5</sup>. The mechanism of fluoride in caries prevention is well-known as ability to promoting remineralization, increasing the acid resistance, and anti-microbial activity<sup>6</sup>. Fluoride varnish containing 5%

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NaF is a material that is used widely in pediatric dentistry since it can be applied easily and safely on children during their primary dentition stage<sup>7</sup>. Moreover, early discovery and diagnosis are important for successful treatment of white spot. For clinical diagnosis of caries, dentists use visual and tactile test and radiographic images8. However, these methods are dependent on subjective individual judgment, which can cause significant differences between examiners. Furthermore, white spot is difficult for clinicians to detect. Because of these reasons, methods for accurately and objectively detecting caries early on are continuing to be developed. QLF is one of the caries diagnostic equipment recognized as being clinically applicable. This method uses the fluorescence that emanates when blue visible light of 405 nm is illuminated on the tooth surface to display the fluorescence loss of the minerals as a  $\Delta F$  value<sup>9</sup>. Moreover, it can discover early caries and assess the degree of caries progression. In<sup>10,11</sup> proved the clinical applicability of QLF. Recently, a second generation QLF-D that combines QLF with high-resolution DSLR has been developed. QLF-D made improvements on the filter using the same principle as conventional QLF. Compared to conventional QLF,

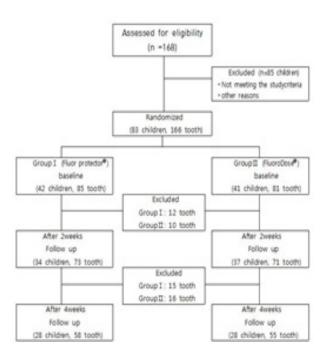
QLF-D shows color that is closer to the actual tooth color. Moreover, it is also capable of detecting red fluorescence generated by porphyrin, a metabolite secreted by bacteria inside the oral cavity. QLF-D can not only diagnose white spot, but can also easily identify dental plaque, calculus, and even microleakage from dental restoration<sup>12</sup>. Also, invitro study showed that the QLF-D could be useful for the evaluation of the remineralisation effect in artificial caries lesion<sup>13</sup>. Therefore, the purpose of this in vivo study was to evaluate the effects of remineralization of fluoride varnish in early childhood caries using QLF-D.

## 2. Material and Methods

The present study was a randomized clinical trial that was conducted after an approval from the Institutional Review Board at Namseoul University (IRB No. NSU-140526-4).

#### 2.1 Participants

A total of 168 children, younger than 6 years, who were in kindergarten were recruited. Of these, 83 children with at least 1 white spot in the primary anterior teeth



**Figure 1.** The diagram depicting the study design.

on QLF-D analysis results were selected as the study participants. The diagnostic criteria for white spot were set to an  $\Delta F$  value -0.5–-26.0 based on the guidelines outlining the tooth quality and QLF score according to a  $\Delta F$  value at the 2011 International Conference on QLF (ICQ) and QLF scores of 0–2 points from the 2010 study by . During the 4 weeks of the study period, 27 children dropped out or were excluded, which resulted in a total of 56 children (113 teeth) completing the study Figure 1.

The inclusion criteria were as follows:

- · Children under 6 years old
- · Children should have 1 or more white spot
- · Children without any mental disorders or systemic diseases
- · Children without mental or physical disabilities
- · Children whose parent(s) agreed to participant in the study

The exclusion criteria were as follows:

- · Children with clearly diminished cooperation
- · Children with severe dental phobia
- · Children with an allergic reaction to fluoride

#### 2.2 Treatment Protocol

The present study was conducted for a total of 4 weeks with same examinations performed at baseline, 2 weeks, and 4 weeks. The treatment protocol was explained to all participants and consent forms were obtained from them. One dentist and one dental hygienist performed QLF-D imaging and oral examinations. The children with white spot in the maxillary and mandibular primary anterior teeth were randomly allocated into two groups, after which two different types of fluoride varnishes with viscosity and concentrations were applied, one type to each group Table 1. Fluoride varnishes were applied one time each to Group I (Fluor protector, Ivoclar Vivadent, Liechtenstein) and Group II (FluoroDose, Centrix Inc., USA) by the dental hygienist, following the manufacturers' protocol. After 2 weeks, QLF-D images were acquired to look for white spot in the participants. At that time, images were acquired after removal dental plaque by tooth brushing for accurate observation of caries lesions. After 4 weeks, the same procedures as during the second visit were performed. The QLF-D imaging equipment used was QLF-D Biluminator™2 (Inspektor Research Systems by, Amsterdam, Netherlands) and the images were acquired in person a single researcher. Imaging was performed in a darkroom with interference from light completely blocked and the camera settings when using white light were ISO 1600, shutter speed 1/60s, aperture value (AV) 16.0, small-fine image size, and manual white balance. When using blue light, the settings were ISO 1600, shutter speed 1/30s, AV 5.6, small-fine image size, and white balance daylight. The acquired images were analyzed by an image analysis program, QA2 version 1.23, to calculate the remineralization rate as  $\Delta F$  value that exhibits the depth of the lesion. The concept of remineralization rate referenced a study by14.

Table 1. Fluoride varnish products used in this study

Product	Fluor protector	FluoroDose	
Fluoride content	0.4 mg	6.75 mg	
Package	0.4 ml	0.3 ml	
ppm F	1,000	22,600	
Characteristics	Liquid	glutinousness	

#### 2.3 Statistical Analysis

The present study used SPSS Version 20.0 (Statistical Package for the Social Sciences, IBM, USA), with statistical significance level set to 95%. The differences in  $\Delta F$  values between before and after fluoride varnish application for both groups were analyzed paired t-tests, while the between-group differences was carried out using independent t-tests. Moreover, the differences in remineralization rates according to QLF scores were analyzed using the one-way ANOVA.

#### 3. Results

#### 3.1 General characteristics

The general characteristics of the participants are shown in Table 2. Among the included 56 children, 27 were boys

and 29 were girls (mean age: 3.88 years). The dft index of boys and girls was 3.11 and 2.83, respectively (mean 2.96).

# 3.2 Changes in Lesion Depth after Fluoride Varnish Application

 $\Delta F$  values analyzed at 2 and 4 weeks after applying the fluoride varnishes are shown in Table 3. The analysis was performed per tooth and not per child. After the fluoride varnish application, the depth of caries lesion decreased slightly, but  $\Delta F$  values after 2 weeks did not show statistically significant differences. However, both groups showed a statistically significant decrease in  $\Delta F$  values after 4 weeks (p < 0.05). The remineralization rate after 4 weeks in Groups I and II was 5.88% and 1.71%, respectively, with no significant difference between the two groups.

Table 2. General characteristics of this study subjects

Classification	Group 1 n = 28	Group 2 n = 28	Total n = 56
Sex (M/F)	11/17	16/12	27/29
Age (Mean ± SD)	$4.07 \pm 0.09$	$3.68 \pm 0.90$	$3.88 \pm 0.91$
dft index (Mean ± SD)	4.14 ± 3.12	1.79 ± 2.18	2.96 ± 2.92

**Table 3.**  $\Delta F$  value at baseline, 2 weeks and 4 weeks after applying fluoride varnish

Group	N	Baseline	2 weeks	4 weeks	·p	
		M (SD)	M (SD)	M (SD)		
	58	-11.95 (5.65)	-11.57 (5.32)	-10.89 (4.83)	0.024	
	55	-11.98 (4.72)	-11.94 (4.55)	-11.40 (4.19)	0.044	
р		0.977	0.694	0.547		

N = number of teeth

p-value was obtained by independent sample t-test (p < 0.05)

<sup>\*</sup>p-value was obtained by repeated measure ANOVA (p < 0.05)

#### 3.3 Remineralization Rate by QLF Score

Remineralization rates for both groups according to QLF scores (0, 1, and 2) are shown in Table 4. The QLF scores were based on the results from a study by, which divided the initial  $\Delta F$  before fluoride varnish application into three intervals. When the score was 1, the remineralization rate for Group 1 after 2 and 4 weeks was 5.68% and 12.85%, respectively, and 0.75% and 9.96%, respectively, for Group II. When the score was 2, which had the deepest lesion depth ( $-26 \le \Delta F \le -18.5$ ), the remineralization rate after 2 weeks was 8.23% and 7.45% in Groups I and II, respectively, showing no statistically significant intergroup difference. Moreover, the highest remineralization rate of 13.72% was seen in Group I after 4 weeks. Both groups did not show statistically significant differences in remineralization rates by QLF score intervals (p < 0.05).

# 4. Conclusion

Early discovery of caries lesions and remineralization treatments are that much more important, because dental caries progress much faster in primary teeth. The QLF-D is a non-invasive diagnostic that can help in the early diagnosis of white spot and quantitatively assess the progression of lesions<sup>15-17</sup>. The present study used QLF-D on children, under 6 years old, who had white spot, for comparing the remineralization effects of fluoride varnishes. QLF-D was used to assess the remineralization rates by  $\Delta F$  values at 2 and 4 weeks after a single application of fluoride varnish. The total number of participants was 56; their mean age was 3.88 years; and the mean dft index was 2.96 (boys: 3.11, girls: 2.83). The fluoride varnishes used as the study materials were Fluor protector and FluoroDose, which offer improvements over existing varnish applications in that they are less sticky and have coloration similar to natural teeth. Previous study<sup>18</sup> proved that Fluor protector was caries lesion preventative and had remineralization effects, also a study by 19 reported Fluor protector was capable of reducing white spot. In-vitro study<sup>20</sup> when remineralization rate of FluoroDose was compared to other fluoride agents, FluoroDose showed a relatively higher remineralization rate of 37.54% at 7

**Table 4.** Recovery rate according to the QLF score after 2 weeks and 4 weeks

Time	QLF Score Group	0	1	2	. p*
		$-12 \le \Delta F \le -0.5$	$-18 \le \Delta F \le$ $-12.5$	$-26 \leqq \Delta F \leqq -18.5$	
2 weeks		-3.13 (17.25)	5.68 (9.40)	8.23 (9.64)	0.038
		-6.22 (29.09)	0.75 (12.57)	7.45 (5.61)	0.301
	р	0.626	0.166	0.861	
4 weeks		-0.89 (16.41)	12.85 (12.72)	13.72 (11.27)	0.003
		-6.72 (24.01)	9.96 (14.85)	6.61 (6.42)	0.013
	р	0.29	0.50	0.19	

p-value was obtained by independent sample t-tests (p < 0.05)

<sup>\*</sup>p-value was obtained by one-way ANOVA (p < 0.05)

days after the application. The results in the present study showed Fluor protector having a slightly higher remineralization rate than FluoroDose, but since there were no statistically significant differences between the groups, it was determined that the viscosity and concentration of fluoride varnishes did not affect dental caries remineralization. Previous study also reported that the duration and number of fluoride application had an influence on remineralization, rather than the concentration of fluoride<sup>21</sup>. Moreover, the present study also showed that both fluoride varnishes showed a decrease in caries lesion depth at 4 weeks after fluoride application. When 2% NaF was applied, there was no change in hardness up to 2 weeks, but microhardness increased significantly from 3 weeks. Those results were similar to our results, and it is believed that long-term observational studies on the remineralization effects of fluoride varnishes are needed in the further study. In their in vivo study, proposed the QLF score system for the first time, which took into account the relationship between  $\Delta F$  value and actual state of tooth quality. The QLF score uses a  $\Delta F$  value of -12.5 as the reference in assessing healthy enamel and enamel undergoing initial changes for determining the treatment for caries lesions. A previous study showed that baseline  $\Delta F$  value is a factor that influences lesion recovery and that the critical point of  $\Delta F$  value was -14.5. Moreover, lesions with baseline  $\Delta F$  value of  $-20 \le \Delta F \le$ -10 showed a recovery rate of approximately 30%, whereas lesions in the interval with  $\Delta F$  value of -10  $\leq$  showed a pattern of no recovery. Based on these previous studies, the present study confirmed whether there were differences in the remineralization rates of fluoride varnishes according to lesion depth. QLF scores were divided into 3 intervals according to  $\Delta F$  values;  $-12 \leq \Delta F \leq -0.5$  (score 0), -18 $\leq$ ∆F $\leq$ -12.5 (score 1), and -26 $\leq$ ∆F $\leq$ -18.5 (score 2). Analysis of differences based on these intervals demonstrated that both Fluor protector and FluoroDose showed a slight increase in remineralization rate in intervals with baseline  $\Delta F$  values of  $-18 \le \Delta F \le -12.5$  and -26≦ $\Delta$ F≦-18.5. In contrast, the interval with  $\Delta$ F value of -12≦∆F≦-0.5 showed a decrease in remineralization rate, with no differences in remineralization effects between the two products. Therefore, it was confirmed that remineralization effects appeared when baseline  $\Delta F$  value corresponded to score 1 or higher. A limitation in the present study was that fluoride varnishes were applied only once for assessment of remineralization effects, and thus, the appropriate number of applications could not be tested. In further studies, a wide range of fluoride varnish application cycles and greater number of applications should be included to find the optimal fluoride application point. Moreover, the present study assessed only two types of fluoride varnishes, it would be necessary to assess the remineralization effects of all commercially available fluoride varnishes in proposing clinical guidelines.

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