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Clinical evaluation of PRG Barrier coat versus fluoride varnish on the color improvement of white spot lesions in permanent teeth of children: A randomized controlled trial

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Abstract

Background: White spot lesions (WSLs) are common in dentistry, and remineralizing agents like fluoride are used to prevent, treat, and improve their color. Surface pre-reacted glass filler (S-PRG filler) barrier coat material has been developed as an alternative to fluoride treatment. This study aims to evaluate the clinical effectiveness of S-PRG barrier coat material versus fluoride varnish in remineralizing and color-improving the white spot lesions in children's permanent anterior teeth in addition to patients' anxiety following treatment.

Methods: Patients were randomly selected and divided into two groups; each group contained 44 WSLs lesions: group (A) received Giomer varnish with (S-PRG) surface-prereacted glass-ionomer (PRG Barrier Coat, SHOFU) filler. On the other hand, group (B) received 5% NaF fluoride varnish (Clinpro white varnish, 3M). The WSLs were assessed clinically using a spectrophotometer (VITA Easyshade ®) by two experienced assessors at Baseline, after one, three, and six months. 'Participants' anxiety in response to the treatment was assessed immediately after application of the varnish using the facial visual scale. For every test, the mean and standard deviation have been calculated for every group. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to examine the normality of the data; the results revealed a non-parametric (non-normal) distribution.

Results: There was no statistically significant difference in the values of **ΔE and ΔE00** between base line-one month, three months, and six months groups where (p=0.461) in both groups. Comparing the results of the two groups to each other, There was a statistically significant difference in ΔE and ΔE00 of Baseline to 1-month values of S-PRG where ΔEab (7.72) and ΔE00 (6.61) and Fluoride varnish where ΔEab (11.96) and ΔE00 (8.38) where (p=0.003). No statistically significant difference could be found between S-PRG and Fluoride varnish where (p=0.655) concerning the 'Participants' anxiety.

Conclusion: Within the study's limitations, PRG Barrier Coat resulted in more improved enamel color than the fluoride varnish one month after application, though not to the required level of esthetics. The color difference between the Baseline and the three-time intervals did not significantly improve when using both materials. Both techniques for applying varnish were deemed suitable by the patients.

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1 Introduction

White spot lesions are a frequent clinical situation in dentistry; their prevalence has been rising, with a frequency between 10% and 49% recently [1]. Patients receiving fixed orthodontic treatment have reportedly experienced it more frequently. However, many epidemiological studies have revealed that their prevalence varies widely, ranging from 2% to 97% [2-6]. White spot lesions are signs of demineralization behind a layer of highly mineralized, undamaged enamel. They may or may not result in caries formation, and they can also be caused by other etiologies; including fluorosis, hypomineralization/hypomaturation, and hypoplasia, which can present functional and aesthetic challenges. Several pathogeneses contribute to it, but plaque buildup over time is the main one. Other factors that affect it include diet, genetic disorders, and variations in the levels of certain elements in saliva, such as phosphate, fluoride, and calcium [7-9].

The white color appearance is because of the variations in refractive indices between healthy enamel areas and demineralized ones; this difference in refractive index affects the translucency of enamel, leading to the appearance of a milky white lesion [7, 10]. To determine the depth and scope of the lesions, visual and photographic inspection have historically been the diagnostic techniques used for white spot lesions. Alternatively, new methods have emerged recently, including microradiography, microcomputed tomography, and fluorescence [9].

Although it is crucial to get an accurate diagnosis since white spot lesions can have a variety of etiologies, the therapeutic method for treating it remains the same [9,11]. The best course of action for treating white spot lesions is minimal intervention, which should begin with remineralization treatments to stop the disease's progression and rebuild the strength and function of the enamel, then proceed with teeth whitening, microabrasion, and resin infiltration if needed[8,12].

Numerous types of remineralizing agents have been used clinically. Topical fluoride-based treatment has been the first choice for many clinicians as it plays an essential role in enamel repair, it converts the hydroxyapatite into fluorapatite which is more resistant to acid attack, enhances remineralization process by binding calcium and phosphate ions forming new fluorapatite crystals, inhibit the activity of acid-producing bacteria and fluoride ion retaining on plaque surface as well as hard and soft dental tissues which enhances the remineralization process [13].

However, the fluoride concentration, whether through increased fluoride intake from other sources or not applying the suitable amount of fluoride to each case, might put the patient at risk for fluorosis development. Another important drawback is the questionable fluoride's capability to reverse the prior mineral loss completely. In profound lesions, the remineralization may not take place in the lesion body's deeper regions. For these reasons, the creation and application of remineralizing agents is required in order to either supplement fluoride in its effectiveness or even ultimately replace it [14].

A lot of dental products are being developed as; Nano-hydroxyapatite, calcium phosphate and bio-active glass in order to replace fluoride treatment. Surface pre-reacted glass filler (S-PRG filler) barrier coat material was released as an alternative. It is a bioactive material where the six distinct ions Aluminum, Borate, Fluoride, Silicate, Sodium, and Strontium are released by the S-PRG filler. These released ions can act together through different mechanisms to preserve the tooth's structure; as its ability to buffer acids, which prevents demineralization, the antibacterial effect promoted by borate ions decreasing biofilm formation, and through reducing the critical pH by strontium apatite and fluorapatite formation [15].

Several in vitro studies comparing and evaluating the remineralizing effect of fluoride varnishes versus (S-PRG filler) containing barrier coat material on extracted tooth structure have been done, while few clinical trials have been applied to assess their results in the actual dental environment [16-18].

Gaber E. et al., (2023) conducted a study to evaluate the impact of resin infiltration of ICON material against PRG Barrier Coat coating material (PRG) in terms of improving the carious lesion status of WSL in adult patients immediately, three months, six months, and after one year. It was determined that infiltration of icon resin is a therapeutically effective treatment for demineralized WSLs. The PRG Barrier Coat is not effective for treating WSLs, however, it can be used for a brief period of time as a preventative measure and to slow the advancement of caries [19].

In order to compare the remineralizing effects of varnishes with varying concentrations of S-PRG filler to sodium fluoride on enamel caries lesions, Moecke SE et al., 2022 conducted a study where they discovered that varnish containing 40% of S-PRG fillers was more effective than the typical 5% NaF-based product and could be used as a substitute for fluoride for the remineralization of initial enamel caries [15].

Using color-matching stickers and digital camera photos, Wakamatsu, N. et al. (2018) investigated the buccal surfaces of seven children, age range between 8 to 15 years, who had WSLs. After applying the PRG Barrier Coat, WSLs were measured using imaging software every three months for up to a year, and the results were compared to baseline values. It was determined that

periodic fluoride application combined with the use of PRG Barrier Coat could enhance the positive remineralization effects on WSLs [20].

This study aims to evaluate the clinical effectiveness of S-PRG barrier coat material versus fluoride varnish (Clinpro White varnish) in remineralizing and color-improving the white spot lesions in children's permanent anterior teeth in addition to patients' anxiety following treatment.

The null hypothesis states that there is not a significant difference between the fluoride varnish (which is what Clinpro White Varnish contains) and the S-PRG filler barrier coat material in terms of remineralizing and improving color.

2 Materials and Methods

2.1 Study setting and ethical approval

The study was conducted at the clinic of the Department of Pediatric Dentistry, Faculty of Dentistry, October University for Modern Sciences and Arts between March 2023 and January 2024. The research protocol and the informed consent form were assessed and approved by the Ethical Committee of Scientific Research in the Faculty of Dentistry, October University for Modern Sciences and Arts, with approval number (REC-D 262-3). The trial was then registered on the clinicaltrials.gov, (Identifier: NCT05775250) on 7/3/2023.

2.2 Study design

The current study is a double-blinded randomized controlled clinical trial, having two arms parallel design with a 1:1 allocation ratio. The study design followed the (CONSORT 2010 Flow Diagram) shown in (**Fig.1**)

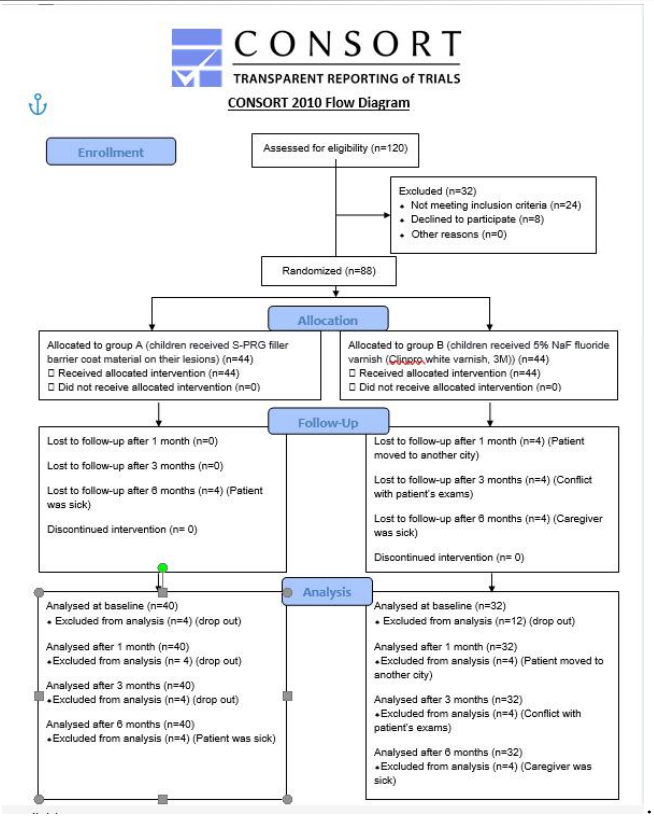


Figure 1. CONSORT 2010 Flow Diagram

2.3 Eligibility criteria

The eligible participants have been recruited in this study according to the following criteria: the inclusion criteria involved both male and female patients aged from 8-14 years having WSLs in permanent anterior teeth, children with good general and oral health, and 'haven't used any remineralizing agent in the former three months except the standard toothpaste. The WSL index Gorelick et al., (1982) was used during the evaluation and recruitment of the eligible participants. Only those who had scores one or two had been recruited in this study. Score one represented mild cases with WSLs that included less than 1/3 of the surface without surface disruption, while score two represented moderate cases in which WSLs included more than 1/3 of the surface with a roughened surface that did not require restoration [21]. However, the exclusion criteria included patients having caries or restorations in the labial surface, extrinsic or intrinsic stains, patients under active orthodontic treatment, and uncooperative patients.

2.4 Sample size calculation

Sample size calculation was estimated using the results of a clinical trial that compared the color change of white spot lesions in children treated with Icon® resin infiltration versus those treated with Clinpro™ XT varnish [22]. They reported that the mean ± SD of color change in the Icon resin infiltration group was 9.66 ± 1.42, while in the ClinPro X varnish group, it was 10.59 ± 1.21.

Using the higher SD value, we estimated that the sample size should minimally be (38 lesions) in every group to enable rejection of the null hypothesis with 80% power at α = 0.05 level using ' 'Student's t-test for independent samples. The sample size was increased by 15% (44 lesions) in each group to compensate for the possible dropout rate during the follow-up period. The PS Power and Sample Size Calculations software, version 3.1.2 for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA), was used to calculate the sample size.

2.5 Recruitment

All participants who fulfilled the eligibility criteria were recruited (48 hours before the varnish application) from the Pediatric Dentistry Department outpatient clinic, Faculty of Dentistry, October University for Modern Sciences and Arts. Participants were divided into two groups: Group A: children received S-PRG filler barrier coat material (PRG Barrier Coat, SHOFU) on their lesions and,

Group B: children received 5% NaF fluoride varnish (Clinpro white varnish, 3M) on their lesion.

All the caregivers of the eligible participants who agreed to participate in the current study and commit to the follow-up appointments had read and signed the informed consent that explained all the steps, benefits, and risks included in the study. All participants were given proper oral hygiene instructions before treatment and they were instructed to use fluoridated toothpaste twice daily.

2.6 Allocation of participants

2.6.1 Randomization and allocation concealment

Computer-generated simple randomization was done using (Randomness and Integrity Services Ltd http:// www. random. org). The random sequence generator randomly assigned the participants to the experimental or the control group with an allocation ratio of 1:1.

2.6.2 Blinding

The current study is a double-blinded trial. The participants and outcome assessors were blinded; however, the operator could not be blinded because of the differences in the packaging and manipulation between the two products.

2.7 Treatment protocol

All the products evaluated in this study, their description, manufacturer names, and lot numbers have been stated in **Table 1.**

Table 1. Products, description, lot numbers, and 'manufacturers' names

products	Description	Lot numbers	Manufacturer
S-PRG filler barrier coat material	A light-cured tooth-surface coating material containing surface pre-reacted glass-ionomer (PRG) filler	062101	SHOFU INC.
Clinpro™ white varnish	5% NaF fluoride varnish	NE99731	3M ESPE

2.7.1 Participants' preparation and application of the varnish

Before application of the varnish, teeth were cleaned using a prophylaxis polishing paste (Prophy Paste, PSP Dental Co. Ltd.) with a low-speed cone brush in a contra-angle low-speed handpiece. It was then dried with air and isolated using cotton rolls.

2.7.2 Application of the varnish

In the S-PRG group, S-PRG filler barrier coat material (PRG Barrier Coat, SHOFU) was administrated once. According to the manufacturer's instructions, a drop of the active was mixed with the base using the attached brush. After isolation with cotton rolls, the brush was used to smear the WSLs with the mix. It was kept undisturbed for at least three seconds, then cured for 10 seconds using the visible-light curing unit (Elipar™ LED Curing Light, 3M Gulf Ltd.).

In the fluoride varnish group, 5% NaF fluoride varnish (Clinpro white varnish, 3M) was administrated once. Following the instructions of the manufacturer, the package was unpacked, and the application guide was used to display the contents and mixed to avoid the separation of sodium fluoride components. After isolation, a thin layer of the varnish coated the WSLs in the labial surfaces, while the proximal surfaces were covered with dental floss. The participants were asked to keep their mouths closed to allow the varnish to set in the presence of saliva. Rinsing or suction was not allowed immediately after the application of the varnish. The participants have been asked to avoid consumption of rough and viscid food or hot drinks for two hours after application of the varnish. For the rest of that day, participants were asked to eat soft food and, stop tooth brushing or flossing.

2.8 Outcome assessment and follow-up protocol

The WSLs had been assessed clinically by two experienced assessors at baseline, after one, three, and six months. The primary outcome of this study was ΔE (the differences in color perception). It has been assessed using a spectrophotometer (VITA Easyshade® Advance 4.0, VITA Zahnfabrik, Bad Sackingen, Germany) at the

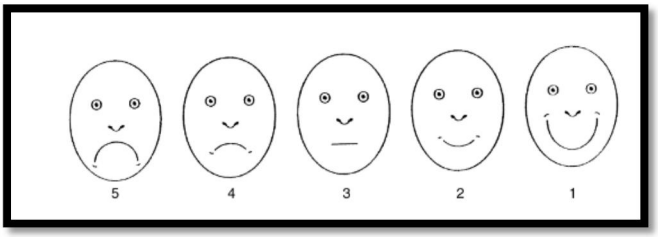
baseline and, follow-up periods [23].

According to the manufacturer instruction, of the spectrophotometer that was calibrated, and an infection control shield was applied to the probe tip before assessment of each patient. During assessment, the probe tip has been applied and held steady perpendicular to the surface of the enamel lesion then the measurement button has been pressed until two rapid "beeps" have been heard indicating that the measurement was complete. The values of the measurement was displayed as CIELAB parameters (L*a*b* values) L* denoted the tooth lightness, a* indicated hues change across the redgreen axis, while b* represented the hues difference across the yellow-blue axis. Accordingly, ΔE has been calculated and recorded by the next equation [23].

$\Delta E = [(\Delta L^*)2 + (\Delta a^*)2 + (\Delta b^*)2]^{1/2}$

The secondary outcome involved the measurement of ΔE 2000 as is the latest formula used to evaluate color differences. It aimed to correct the differences between the measurement results and visual evaluations, as it was a weakness in the L*a*b* color space. The calculation depended on the lightness difference ΔL*, saturation difference ΔC*, and hue difference ΔH*, with correction using weighing coefficients (SL, SC, and SH) and constants called parametric coefficients (kL, kC, and kH), as follows.

Figure 2. The Facial Image Scale



$$\Delta E_{00} = \sqrt{\left(\frac{\Delta L`}{k_L \cdot S_L}\right)^2 + \left(\frac{\Delta C`}{k_C \cdot S_C}\right)^2 + \left(\frac{\Delta H`}{k_H \cdot S_H}\right)^2 + \left(R_T\left(\frac{\Delta C`}{k_C \cdot S_C}\right)\left(\frac{\Delta H`}{k_H \cdot S_H}\right)\right)}$$

Where

$$L` = L^* \qquad a` = a^*(1+G) \qquad G=0.5\left(1-\sqrt{\frac{\bar{C}^*_{ab}{}^7}{\bar{C}^*_{ab}{}^7+25^7}}\right)$$

$$b` = b^* \qquad C` = \sqrt{(a`)^2+(b`)^2} \qquad h` = \tan^{-1}\left(\frac{b`}{a`}\right)$$

The weighting coefficients SL, SC, and SH are calculated as follows.

$$S_L = 1+\frac{0.015(\bar{L}`-50)^2}{\sqrt{20+(\bar{L}`-50)^2}} \qquad S_C = 1+0.045\bar{C}` \qquad S_H = 1+0.015\bar{C}`T$$

$$T = 1-0.17\cos(\bar{h}`-30)+0.24\cos(2\bar{h}`)+0.32\cos(3\bar{h}`+6)-0.20\cos(4\bar{h}`-63)$$

The rotation factor RT is calculated as follows. (The hue angle and θ are in degrees.)

$$R_T = -\sin(2\Delta\theta)R_C \qquad \Delta\theta = 30\exp\left(-\left(\frac{\bar{h}`-275}{25}\right)^2\right)$$

$$R_C = 2\sqrt{\frac{\bar{C}`^7}{\bar{C}`^7+25^7}}$$

Note 1: The bar over the values represented the average values for the two colors.

Note 2: The parametric coefficients kL, kC, and kH may fluctuate following the actual measurement conditions, but all three are set to one under the regular settings stated for CIE 2000.

The tertiary outcome involved Participants' anxiety in response to the treatment. It was assessed immediately after the application of the varnish using the facial visual scale [24]. The Facial Image Scale comprises five pictures representing faces arranged from very happy to very unhappy as shown in (**Fig. 2**).

Participants had been requested to select a picture that represented their feelings at that time. The scale was listed by recording one to the very happy and five to the very unhappy face. Intraoral photographs have been taken using iPhone 13 Pro Max at the baseline and at the end of the follow-up period.

2.9 Statistical analysis

Statistical analysis was done using IBM® SPSS® Statistics Version 20 for Windows. The mean and standard deviation values were measured for both groups. The significance level was set at $P \leq 0.05$. Data had been inspected for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data revealed a non-parametric (not-normal) distribution. The Mann-Whitney test was used to compare both groups in non-related samples. Friedman test compared more than two groups in related samples. Wilcoxon test compared both groups in related samples.

3 Results

3.1 Baseline data and recruitment

Forty-four WSLs present in 11 patients have been treated using S-PRG filler barrier coat material in the S-PRG group, while 44 WSLs of 11 patients received NaF fluoride varnish

in the fluoride varnish group. After six months, one patient (4 WSLs) in the S-PRG group was lost to follow-up, while three patients (12 WSLs) in the fluoride varnish group were lost to follow-up; one patient after one month, one after three months, and another one after six months. The flow diagram is presented in (**Fig.1**) CONSORT flow diagram.

3.2 Comparison of color changes between the two groups:

3.2.1 ΔE:

3.2.1.1 Effect of time within each group:

In both groups, there was not any statistically significant difference between the baseline and all the following visits (after 1m,3m, and 6m) where the *p*-value for S-PRG, Fluoride varnish was (*p*=0.461), (*p*=0.315) respectively. Presented in **Table 2.**

3.2.1.2 Relation between groups:

Over the six-month follow-up time, there was a statistically significant difference between (S-PRG) and (Fluoride varnish) where (*p*=0.003) when comparing between baseline and 1m, while there was not any statistically significant difference between the groups when comparing baseline to 3m and 6m where (*p*=0.065) and, (*p*=0.847) respectively. Presented in **Table 2.**

Table 2. The mean, and standard deviation (SD) values of ΔE of both groups.

Variables	ΔE								
	S-PRG				Fluoride varnish				p val
	Mean	Std error	SD	Median	Mean	Std error	SD	Median	
Baseline and 1m	7.72	0.67	4.22	7.76	11.96	1.31	7.39	10.78	0.00
Baseline and 3m	8.91	0.69	4.38	8.96	11.67	1.05	5.92	9.75	0.06 s
Baseline and 6m	9.30	0.86	5.42	8.49	11.14	1.42	8.06	8.39	0.84 s
p-value	0.461ns				0.315ns				

3.2.2 ΔE 2000:

3.2.2.1 Effect of time:

In both groups, there was not any statistically significant difference between the baseline and all the following visits (after 1m, 3m, and 6m) where the *p*-value for S-PRG, Fluoride varnish was (*p*=0.910), (*p*=0.296) respectively. Presented in **Table 3.**

3.2.2.2 Relation between groups

During the six-month observation time, there was a statistically significant difference between (S-PRG) and (Fluoride varnish) where (*p*=0.014) when comparing between baseline and 1m, while there was not any statistically significant difference between the groups when comparing baseline to 3m and 6m where (*p*=0.058) and, (*p*=0.986) respectively. Introduced in **Table 3.**

Table 3. The mean, and standard deviation (SD) values of ΔE 2000 of both groups.

Variables	ΔE 2000								
	S-PRG				Fluoride varnish				p-value
	Mean	Std error	SD	Median	Mean	Std error	SD	Median	
Baseline and 1m	6.61	0.58	4.88	4.99	8.38	1.08	6.13	7.04	0.014*
Baseline and 3m	6.97	0.49	4.15	5.78	8.13	0.84	4.77	7.16	0.058ns
Baseline and 6m	6.96	0.62	5.26	5.86	7.79	1.17	6.60	5.57	0.986ns
p-value	0.910ns				0.296ns				

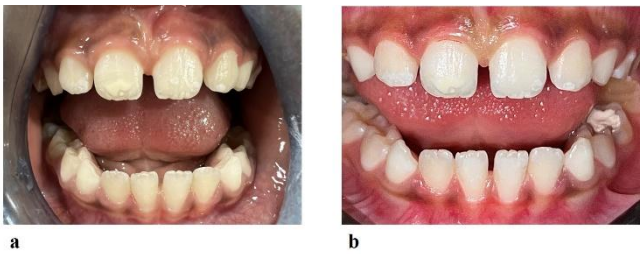
3.3 Patients' anxiety:

There was not any statistically significant difference between both groups where (*p*=0.655). Presented in **Table 4.**

Table 4. The mean, standard deviation (SD) values of anxiety of both groups.

Variables	Anxiety			
	Mean	Std error	SD	Median
S-PRG	1.27	0.14	0.47	1.00
Fluoride varnish	1.36	0.15	0.50	1.00
p-value	0.655ns			

A clinical case from the S-PRG Group at baseline and the end of the follow-up period is presented in **(Fig. 3).**



a b

Figure 3. Clinical case from the S-PRG Group. **Figure 3a.** Baseline**, Figure 3b.** After 6 months**.**

Another clinical case from the fluoride varnish Group is presented at baseline and at the end of the follow-up period in **(Fig. 4).**

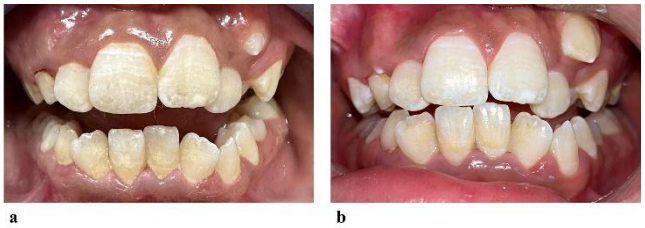


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Figure 4. Clinical case from the fluoride varnish Group**. Figure 4a.** Baseline, **Figure 4b**. After 6 months**.**

4 Discussion

White spot lesions (WSLs) are the first sign to clinically appear in dental enamel before the stage of cavitation; they are distinguished by subsurface demineralization regions that occur under an intact enamel surface. The affected area has less mineral content, impairs the enamel's translucent quality and gives the area an opaque white appearance. Keep in mind that for demineralization to be evident, it must be at least 300–500 μm deep [25,26].

Increasingly more patients seek aesthetic care from dental experts these days, even minor flaws like WSL may be viewed by the patient as a disqualifying issue in the context of smile aesthetics [27]. Consequently, remineralizing agents are used to either treat or prevent white spot lesions. Fluoride applications (such as varnishes, gels, or creams) can be used as remineralizing agents in the office or at home to support good oral hygiene.

The use of remineralizing agents, such as dental sealants, glass ionomer and composites independent of patient compliance, could be an additional choice [25].
The efficiency of various remineralizing agents is somewhat debatable, and most earlier studies have assessed the effectiveness of remineralizing agents in vitro. Therefore, research must examine the newer remineralizing agents under various conditions because of their ongoing development and a shortage of in vivo investigations [28]. The goal of the current study was to compare and contrast two distinct approaches treating white spot lesions, each with a unique mechanism of action; fluoride varnishes since fluoride is considered the cornerstone of remineralization in dentistry, and PRG barrier coat as a new promising remineralizing material.

Dental varnish is a coating material that coats teeth to form a film, allowing for a relatively regulated release of the active ingredient as well as a simple and dependable topical treatment. The primary determinant of the product's efficacy is the type and concentration of the active component. The concentration of sodium fluoride that is most frequently used in literature is 5%, which is why it was chosen for our study [15].

A prior study investigated the prevalence of WSLs in 1130 patients, age range between two to 18, who came to the pediatric dentistry department at Asahi University Hospital for dental recall exams. In deciduous dentition, 7.9% of individuals had carious lesions before cavitation; in mixed dentition, it was 11.9%; and in permanent dentition, it was 14.1%, accordingly, the age range chosen in this study was eight to 14 of permanent anterior teeth, as these findings indicated that early intervention for caries lesions on young permanent teeth is required to stop demineralization [29].

This research used a VITA Easyshade® guide spectrophotometer to measure color. Because instrumental readings may be produced more quickly, are objective, and can be quantified, instrumental color analysis may be superior to visual color determination [25]. Spectrophotometers are some of the most versatile, practical, and accurate instruments for matching of color; they measure a specimen's spectral reflectance or transmittance curve and help determine surface color [30].
Given that the ΔEab* values for perceptible and acceptable color differences varied in size and were chromaticity-dependent, Recently, CIEDE2000 (Δ*E00*) a novel formula for color differences based on CIELAB including chroma and hue functions was created to enable more precise color differentiation [19]. so, both (ΔEab)* and (Δ*E00*) were calculated in this study.

The results of this study were partially in agreement with the null hypothesis that stated that there would not be a significant difference in the remineralizing effect of the S-PRG filler barrier coat material compared to the fluoride varnish (Clinpro white varnish contains) since there was a significant difference between the fluoride and S-PRG at the time interval between the Baseline and 1 month.

The S-PRG filler barrier coat material had significantly lower ΔEab (7.72) and ΔE00 (6.61) than that of the fluoride varnish, where ΔEab (11.96) and ΔE00 (8.38); this might be attributed to; fluoride varnishes forming a thin, firm varnish layer that adhered to the enamel after application, yet due to the complex oral environment and movement produced by the tongue, buccal muscles, saliva wash, mastication and dental hygiene practices, a fluoride varnish is likely to be removed quickly [25]. However, pre-reacted glass-ionomer (PRG) technology was used to develop the S-PRG Barrier Coat (Shofu Inc., Kyoto, Japan), a tooth-surface coating material that, in contrast to earlier technologies, can coat the entire tooth surface and is anticipated to have a major impact on preventing dental caries. Measurements of the number of ions released in previous studies revealed the continuous, sustained release of six ions, including the antibacterial B and the acid-resistant Sr and F [31-35]. Nevertheless, there was no discernible ion release from the material lacking the S-PRG filler. This result implied that the ion release from this material depends on the S-PRG filler. Furthermore, it is believed that the 15-μm film of the S-PRG Barrier Coat reduces the likelihood of shedding and fracturing. The risk of cavitation and discoloration increases when a covering material breaks because a step is formed between the affected area and the tooth surface [31].

Nonetheless, the S-PRG Barrier Coat has a minimal risk of cavitation because it hardly fractures and demonstrates a smooth transition between the tooth surface and the film [31]. Many ions are also believed to have a role in S-PRG's buffering ability. The hypothesis that acidity is neutralized by borate ions generated from S-PRG was the subject of Hiraishi et al.'s investigation [36]. Ogawa Y et al work also revealed the composition of the S-PRG solutions, primarily aqueous B(OH)3 with adsorbed negatively charged B(OH)4 - ions on the surfaces of dentin and enamel. The pH rises when acid is used up during the conversion of tetrahedral to trihedral boron [37].

Additionally, it has been found that in both materials there was no statistical difference in the values of ΔEab or ΔE00 in the three-time intervals; Baseline and one month, three months, and six months. Several factors could explain this: De- and remineralization are complicated processes involving multiple simultaneous processes. The process of remineralization involves taking calcium (Ca), phosphate (P) (and occasionally fluoride) ions from slightly supersaturated saliva and moving them to demineralized locations where remineralization takes place. However, processes of demineralization and degradation occur concurrently. Therefore, in order to eventually build up the enamel, the remineralization rate needs to be higher than the demineralization rate. The high concentration of substances such as sodium, pyrophosphate, (glyco) proteins, peptides, (bi)carbonate, and related chemicals is another factor that affects in-vivo mineralization. via reducing the availability of P and Ca ions to the remineralization site, these ions and macromolecules may hinder the apatite remineralization process. These locations are present in enamel, where the crystals are partially covered with proteinaceous material, which means that just a portion of the surface is remineralized. These areas with a high organic content can also be found in lesions, where mineralization rates could be twice as slow as in vitro [14].

Even though earlier research has demonstrated that conventional fluoride and S-PRG varnishes can encourage the remineralization of white spot lesions, the deposition of minerals on the outside layer rather than the lesion's body, in which case the newly formed top layer that is highly mineralized might be preventing mineral ions from diffusing into the deepest parts of the lesion. This deposition leaves an outer layer that is highly mineralized, which is thought to slow down the demineralization process by keeping acids from penetrating deeper into the enamel. Additionally, it might stop mineral ions from penetrating the lesion body and restrict enamel recrystallization to the subsurface zone. This may help explain why the treatment ultimately did not improve the color of WSLs through remineralization [38].

This is in agreement with A 2023 study by Gaber E. et al. who evaluated the effectiveness of resin infiltration of Icon material versus PRG Barrier Coat coating material in improving carious lesion status of white scaly lenticular lesions (WSL) in adult patients. The study found that infiltration of icon resin is a therapeutically effective treatment for demineralized WSLs, while PRG Barrier Coat is not effective for treating WSLs but can be used as a preventative measure. He explained this by the glass ionomers' internal acid-base reactions resulting in voids and fractures. The acidic environment may impact the material's integrity, which could cause the coating layer to dissolve. Furthermore, the material's hydrophilic component demonstrated water sorption capabilities. Water sorption and dissolution may cause the material's degradation [19].

Even after remineralization agents, WSLs frequently remain detectable on many radiographs and clinical settings. This occurs because the lesion's deepest area continues to diffuse light differently and has the lowest potential for remineralization. Thus, some internal opacity will persist even if the white area becomes shiny, smooth, and hard (and therefore inactive) [37]. This could be proved in our study by the fact that neither dental caries nor cavitations appeared after the application of either varnishs after 6 months, despite opaqueness in the treated teeth, indicating that the teeth were remineralized and that dental caries was avoided in this region [31].

Midway through the observation period, the S-PRG Barrier Coat was not reapplied, nor was tooth surface polishing done following application. The material's ease-of-removal property is supposed to make it possible to reapply a coat, which could be a suitable approach to cope with discoloration and increase the remineralization rate [31].

Prior research has demonstrated that the severity of lesions determines the recovery rate and that treatment effectiveness requires longer than six months [39,40].

These outcomes correlated with a 12-week clinical trial conducted by Güçlü, Zeynep Aslı, et al. to assess the effects of sodium fluoride varnish regimes at 5% and 10% CPP-ACP on the regression of non-orthodontic white spot lesions (WSLs). Most WSLs in the groups treated with fluoride varnish and control showed no change in appearance [41].

However, it disagreed with a study by Singh, S., et al. on 45 participants aged 16 to 25 with at least one post-orthodontic WSL. The study found that applying fluoride varnish and using fluoride toothpaste twice a day for six months significantly reduced the severity of WSLs [42]; this might be due to the use of fluoride toothpaste twice a day in conjugation with the varnish,

which was not done in our study. As well as a study done by Wakamatsu N. et al. where WSLs were treated with PRG Barrier Coat, and for a maximum of one year, the areas of the WSLs were measured using imaging software every three months and compared to baseline values. Compared to the baseline, significant differences were seen over the whole trial period. During the trial period, no teeth with cavities needed to be restored. Based on the results of the current study, the PRG Barrier Coat could be a helpful substance for WSL remineralization that meets patients' satisfaction following treatment with no adverse side effects [29].

High dental anxiety in children has resulted in poor oral hygiene, periodontal diseases, and dental caries due to neglected oral healthcare. Additionally, children with underlying dental anxiety will be uncooperative, making dental treatment challenging for pediatric dentists. Any modification to the process or nature of dental care can have an impact on how patients behave and accept the care, starting with the patient's pre-visit preparation, the amount of time they spend in the waiting room, the assistants and the dentist's attitudes, and the materials or techniques used during the appointment. We wanted to find out if there were any differences between the two materials in terms of patients' acceptance of the application steps. No statistically significant difference was found between S-PRG and Fluoride varnish where (p=0.655) concerning the Participants' anxiety [43].

Limitation of Study

One of the study's limitations was the absence of laser fluorescence and quantitative light-induced fluorescence for evaluating WSLs. These technologies could have offered an even better way to assess WSLs and, in turn, the most appropriate treatment plan regarding the number of applications and time intervals. Unfortunately, we could not incorporate these technologies into our experiment due to financial constraints.

Furthermore, a larger sample size would have allowed for higher precision. Moreover, additional research is needed on the length of an acceptable period. Better stain prevention may also result from transferring meals and beverages indicated in supplemental documents that may cause staining to foods and beverages that kids are likely to eat and from explaining these guidelines.

5 Conclusion

Since the best course of action for treating white spot lesions is minimal intervention, which should begin with remineralization treatments to stop the progression of the disease and rebuild the strength and function of enamel, it can be concluded that both used materials can be effectively applied, with the preference of the S-PRG Barrier Coat which has shown better results after one month interval, though not to the required level of esthetics which will require more investigation regarding the time and number of applications. The patients found both varnish application methods to be satisfactory

Authors' Contributions

The authors confirm contribution to the paper as follows: study conception and design, manuscript writing and concepts design in addition to conducting the research and investigation process: Naglaa Ezzeldin. Dina Wahied; managed data collection, manuscript writing, Provision of study materials, reagents, materials and computing resources, or other analysis tools. Rasha Atef; analysis and interpretation of results, design and definition of intellectual content. Shereen Shaaban Mustafa; draft manuscript preparation, development and design of methodology. All authors reviewed the results and approved the final version of the manuscript.

Conflict of interest

The authors declare that they hold no competing interests.

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