Clinical evaluation of white spot lesions treated by surface pre-reacted glass filler coating material in comparison with Icon resin infiltration by laser fluorescence: A randomized controlled trial

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Abstract

Objective: White spots are one of the initial sign of dental caries. Resin infiltration and remineralization are used to prevent white spot lesions (WSL) cavitation. Mineral deposition depends on the equilibrium between demineralization and remineralization, which may occur as a natural repair mechanism. This study aimed to compare the effect of PRG Barrier Coat coating material (PRG) against resin infiltration of Icon material in improving the carious lesion state of WSLs over 1

year. **Clinical Considerations:** The efficacy of fluroboro-aluminosilicate glass surface coating with S-PRG fillers and Icon resin infiltration in improving the esthetic appearance (masking) and caries lesion state of WSLs immediately, after 3 months, after 6 months, and after 1 year among adult patients. Laser fluorescence was used to compare the two materials to evaluate caries progression. The PRG Barrier Coat group showed an immediate significant improvement in laser fluorescence device (LF) scores in demineralization progress and inhibition of caries progression with a significant improved effect. **Conclusions:** Icon resin infiltration is a clinically successful treatment for demineralized WSLs. The PRG Barrier Coat is useful for a short time as a control of caries progression and prevention protocol, but not for the treatment of WSLs.

Clinical Significance:S-PRG Barrier Coat is a clinically successful strategy for the inhibition of caries and improvement of remineralization.

Keywords; White spot lesions, ICON, S-PRG, Remineralization, Masking color, Laser Fluorescence, Initial caries.

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Introduction

Dental caries are an infectious microbial disease that affects most people all over the world [(1)]. Tooth decay is initiated by the decomposition of minerals and disintegration of the dental tissue matrix. The loss of subsurface minerals from intracrystalline spaces leads to an optical phenomenon known as white spot lesions (WSLs) [(2)]. Early detection of demineralization using recent diagnostic tools is helpful in eliminating the progress of the decay process. Remineralization plays a helpful role in the management and reduction of early caries. The WSLs have two layers: the outermost surface layer, which is relatively intact, mineral rich, and softer

than the sound enamel and subsurface layer (body of the lesion), where the dissolution occurs mainly, which is porous and has low mineral content [(3).]

There are two aspects of WSLs treatment: a noninvasive technique using remineralization and a minimally invasive technique using resin infiltration to improve esthetics [(4)]. The latest strategy is to treat noncavitated caries noninvasively, which is the most conservative approach, and preserves the tooth structure through remineralization and reduction of bacterial adhesion to decrease the progression of caries, eventually improving strength, function, and esthetics [(5)].

Fluoride is the gold standard for blocking demineralization cycles. However, after fluoride varnish application, the outer layer may become saturated with more minerals, thereby reducing ion diffusion to the deepest layer[(6)]. Several remineralizing agents have been used to deposit calcium and phosphate minerals in enamel that resemble hydroxyapatite; however, the crystalline deposition of minerals does not mimic natural deposition [(7)].

Bioactive ingredients with the power of remineralization in the deep area of the body of the lesion were used. A fluoroboro-aluminosilicate glass surface-coated S-PRG filler barrier coat was used to remineralize the WSLs [(8)]. S-PRG pretreats fluorobooro-aluminosilicate glass with polyacrylic acid and water to recharge and release the fluoride. Additionally, releasing more types of ions aids biofilm suppression and decreases bacterial adhesion and the buffering capacity of acids and enhances remineralization [(9)].

Another treatment option is the micro-invasive resin infiltration technique, which includes resin infiltration that fills enamel pores. Consequently, the resin diffuses through capillary interactions, forming a mechanical barrier and preventing demineralization and bacterial acids penetration[(10)].

The detection of initial demineralization as early as possible is preferred by routine checks. Noninvasive treatment of WSLs helps stop cavitation and caries progression [(11)]. Laser fluorescence is important for detecting the first sign of subsurface demineralization and monitoring over time. Therefore, the DIAGNOdent laser fluorescence device was used to quantify mineral loss in lesions and detect changes in caries[(12)]. Laser fluorescence devices are highly sensitive for diagnosing demineralization of hard tooth structures and mineral loss using digital numbers (1–99) which indicate the stage of caries and cavitation[(13)].

In our study, we compared two different lines of treatment of WSLs: noninvasive remineralization technique (PRG Barrier Coat) and micro-invasive resin infiltration technique (Icon) in the ability to improve the caries lesion state (LF scores) of WSLs over 1 year in adult patients. The null hypothesis was that the carious lesion state of WSLs would not improve after using a resin coating material containing S-PRG fillers or Icon resin infiltration.

Materials and methods

I. Materials

Two materials were used in this study

1. Icon resin infiltration (DMG, Hamburg, Germany): It comprised of three steps: Icon etch, Icon dry, and Icon infiltrant.
2. The PRG Barrier Coat Mini-Kit (Shofu Inc., Kyoto, Japan) consists of PRG Barrier Coat active and base containers.

II. Methods

II.1. Study design

It is a single-center, double-blinded (assessor and patient), two parallel armed randomized control clinical trials with an equal allocation ratio (1:1) for the

comparison of Icon resin infiltration and PRG Barrier Coat (PRG) effects on WSLs. DIAGNOdent pen (Kavo, Biberach, Germany) laser fluorescence device scores (LF) were used to evaluate progress or suppression over time. The Consolidated Standards of Reporting Trails statement has been reported in randomized controlled trials references [(14)].

II.2. Ethical approval and consent form

This RCT was approved by the Institutional Ethics Committee of the Faculty of Dental Medicine, Al-Azhar University (No.350/466/08/10/19). Detailed information was discussed with the patients to be aware of the benefits, and they signed a consent form to include and participate in this study (in regional language) before the start of the study. This RCT was conducted in boys at the Faculty of Dental Medicine, Al-Azhar University, Cairo-boys branch at the period time from 1/1/2021 to 18/11/2022.

II.3. Sample Size

Based on a previous clinical study [(15)] a sample size of 15 in each group was the effective size of the sample for the experimental and control groups, with a significance level (α) of 0.05 and a power of 80%. The mean and standard deviation of the color of the Icon at baseline were 33.2 ± 17.33 and for the control group and 17.95 ± 6.26% for the experimental group. On this basis, we estimated an increase in the total number 20 in each group to compensate for loss during follow-up.

II.4. Eligibility criteria

The maxillary anterior teeth of patients with WSLs were selected at the time of regular dental visits to outpatient clinics. Clinical selection was conducted by a single examiner using a mirror, a periodontal probe, and an airway syringe. The inclusion criteria were as follows: adult patients aged 20–40 years, patients with at

least two maxillary anterior teeth with buccal WSLs, and mild and moderate WSLs according to Gorelick's scale [16]. Exclusion criteria were cavitated lesions, stains (such as tetracycline staining) on the anterior teeth, application of remineralizing agents or restoration with glass ionomer in the past 3 months [17], and current participation in another study.

II.5. Clinical examination of WSLs

The WSLs were clinically evaluated after professional dental prophylaxis. The same clinician performed the initial clinical examination of the WSLs to avoid intra-examiner errors, using Gorelick's scale under the light of the dental unit directly after drying the teeth with compressed air for 5 seconds. Scores for lesions 1 and 2 were also considered. This was confirmed by using an LF device. Fluorescence scores (11–20) of WSLs were considered to indicate outer half enamel caries (initial demineralization) [18].

II.6. Assessment of caries lesion state

The demineralization state of the WSLs was assessed using LF to monitor lesions over time. Prior to the demineralization state measurements, all teeth with WSLs were scaled and polished with a prophylactic non-fluoridated pumice paste. The data were recorded at baseline (T0). Calibration was performed with each tip change and for each new patient according to the manufacturer's instructions.

II.7. Grouping

The total number of 40 non-cavitated WSLs in permanent maxillary anterior teeth were collected from 20 patients, each patient had two WSLs, and were randomly assigned into two equal main groups (n=20) according to the type of materials used in the WSLs treatment: control group (Icon) and intervention group (PRG).

II.8. Randomization, Allocation, and blinding

Randomization was performed by asking patients to choose the sealed envelope of the material. Randomization depended on two interrelated aspects: sequence generation and allocation concealment.

The two main groups of teeth were divided and each patient received both treatments: right (R) and left (L). The treatment option was randomly allocated by patients who selected a sealed envelope with (L Icon, R PRG) or (R Icon, L PRG) written inside. The participants and assessors were blinded to the material assignment, whereas the operator was not blinded owing to the difference in the application protocol of the materials used.

II.9. Materials application

The teeth with WSLs were isolated using a rubber dam system (Sanctuary Dental Dam 6X6). Teflon tape was used to protect the adjacent tooth from the effects of acids used. The materials were applied in accordance with the manufacturer's instructions. To be standardized, one clinician applied all materials.

A. PRG Barrier Coat:

One of the base containers was broken off, and one drop of activator was added to the base container and mixed in the base container using a disposable brush. The mixture was applied to the WSLs, left undisturbed for more than 3 s, and then light-cured for 10 s. The uncured layer was removed by gently rubbing the surface with an adhesive microbrush.

B. Resin infiltration (ICON)**:**

In the first step, the WSLs surface layer was etched with 15% hydrochloric acid gel (Icon–Etch) for 2 min. The etched area was washed for 30 s using water spray, followed by drying with compressed air for 10 s. In the second step, an ample

amount of 99% ethanol (Icon -Dry) was applied to the etched area and allowed to stand for 30 s. The lesion was then dried thoroughly with compressed air for 10 s. In the last step, the Icon resin infiltrate was applied for 3 min to allow penetration, and the excess resin was removed using dental floss. The Icon resin infiltrate was light-cured for 40 s using a light-emitting diode (LED Elipar, 3M ESPE, USA). A second layer of Icon was applied for 1 min and light-cured for 40 s. Finally, the Icon treated WSLs were polished.

II.10. Patient instructions

Patients were instructed to brush the day after treatment using an Oral-B soft-texture brush (Procter & Gamble, USA) with fluoride toothpaste (Crest Cavity Protection, 1,100 ppm F) twice a day and prohibited from using other fluoridated products.

II.11. Outcomes and follow-up

The primary outcome: was a change in fluorescence scores at 3, 6, and 12 months for all treatment groups.

The secondary outcome: was to compare fluorescence values between the treatment groups.

The endpoint: was that the durability and effect of Icon and PRG on WSLs by clinical evaluation by using the LF device to assess the state of the carious lesion.

At every follow-up visit before the assessments, the treated teeth were polished with fluoride-free polishing paste. Subsequently, the treated WSLs were evaluated postoperatively by the same operator using the LF device at the following time intervals; T1, immediately after treatment; T2, after 3 months; T3, after 6 months; and T4, after 12 months.

II.12. Statistical analyses

Statistical analyses were performed using SPSS version 21 (Statistical Procedures Companion, Chicago, IL, USA). The Kolmogorov–Smirnov test was used to verify the normality of the data distribution. To compare the effects of the two materials at different follow-up periods, a one-way ANOVA test was used. For multiple comparisons within the two groups, post-hoc Tukey's test was performed within each group, and the two intervals were compared. The P-value was set at $P \leq 0.05$.

Results

I. Baseline data (Patient allocation and follow-up)

After 6 months, one patient was lost to follow-up because of difficulty in transportation as he moved to another city. The remaining 19 patients and their treated WSLs were evaluated. After 12 months, three patients did not attend follow-up as they transferred to other clinics and chose to restore the WSLs because the patients wanted a more esthetic appearance of WSLs and chose the filling treatment. The remaining 16 patients and their treated WSLs were evaluated. The trial flow diagram is shown in (**Figure 1)**. No unfavorable side-effects (such as pain, sensitivity, or cavitation) were observed. No clinically obvious effects, such as alteration of gingival tissue or loss of vitality, were observed in either of the two groups.

II. Intragroup comparison of PRG

II. A. PRG Barrier Coat

The statistical analysis of the LF scores of PRG showed that; the difference was statistically significant in immediate and 3 months follow-up period as indicated by the ANOVA test ($P<0.00001$). However, there were nonsignificant differences in 6-months ($P=0.2605$) and 12-months ($P=0.97039$). The post hoc Tukey test

showed a significant increase in the mean value of the LF scores of PRG with time. The higher mean of LF scores was recorded at the baseline. Then, it decreased immediately after application, and after that, it increased respectively with time from 3-month to 12-month. The data is summarized in **(Table 1)** and **(Figure 2).**

Figure 1: The flowchart diagram showing patient flow during the trial.

Table 1: Effect of PRG Barrier Coat LF scores of WSL at different periods.

Variable	Baseline	Immediate	3-months	6-months	12-months	P-value
PRG (Mean± SD)	15.80±2.62^{A}	2.87±1.51 ^{C}	5.07±2.58 ^{B}	14.07±1.38 ^{A}	15.27±3.08^{A}	<0.00001*

*; significant at $P < 0.05$.
Different uppercase letters mean statistically significant.
(SD) standard deviations

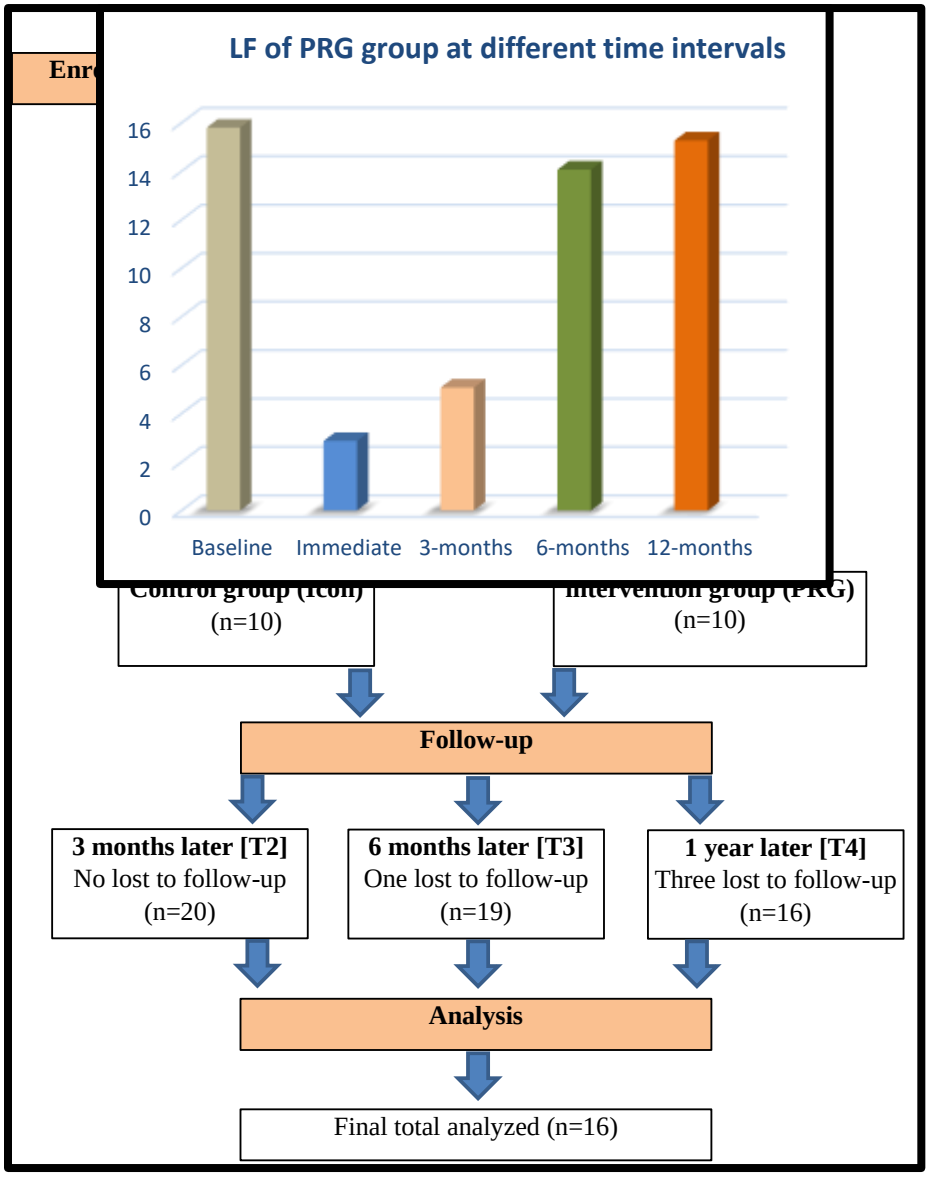

Figure 2: Bar chart representing the effect of PRG Barrier Coat on caries lesion state scores of WSL at different periods

*II. B. Resin infiltration (*Icon*)*

The statistical analysis of the LF scores of Icon showed that; the difference was statistically significant in all follow-up periods as indicated by the ANOVA test ($P<0.00001$). The post hoc Tukey test showed a significant increase in the mean value LF scores of Icon with time. The higher mean LF scores were recorded at the

baseline. Then, it decreased immediately after application, and after that, it increased respectively with time from 3-month to 12-month. The data is summarized in **(Table 2)** and **(Figure 3)**

III. Intergroup comparison of both materials

The comparison of LF scores at the different time intervals of follow-up is indicated by the ANOVA test and is summarized in **(Table 3)** and **(Figure 4)**. Statistical analysis of LF scores between the two groups at baseline, immediately after material application, and after 3-months showed that there were no significant differences (P >0.05). There was a significant difference in the LF scores between the Icon and PRG groups at 6-months and 12-months (P <0.05)**.**

Table 2: Effect of Icon on LF scores of WSLs at different periods

Variable	Baseline	Immediate	3-months	6-months	12-months	P-value
ICON (Mean± SD)	15.47 ± 2.64^{A}	2.47 ± 0.83^{E}	4.60 ± 1.06^{D}	8.67 ± 1.49^{C}	11.13 ± 1.24^{B}	<0.00001*

*; significant at P < 0.05.
Different uppercase letters mean statistically significant.

(SD) standard deviations

Figure 3: Bar chart representing the effect of Icon on caries lesion state scores of WSL at different periods

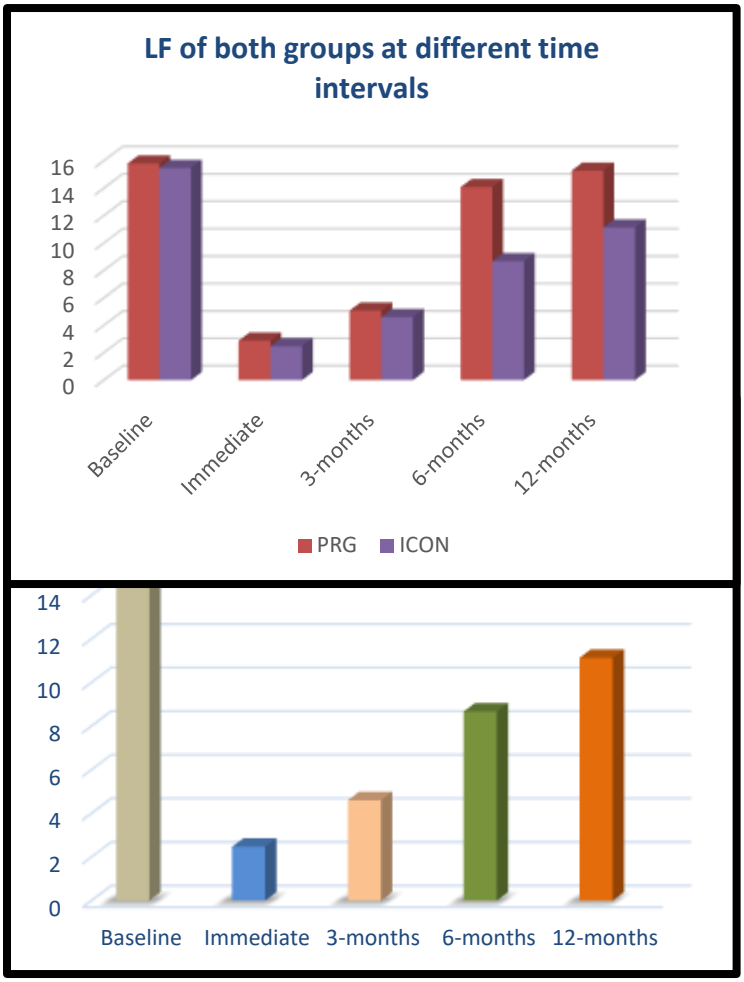

Table 3: Comparison of LF scores among both groups at different time intervals.

Variable	PRG (Mean ± SD)	ICON (Mean ± SD)	P-value
Baseline	15.80±2.62	15.47±2.64	0.5543 ns
Immediate	2.87±1.51	2.47±0.83	0.0515 ns
3-months	5.07±2.58	4.60±1.06	0.5811 ns
6-months	14.07 ± 1.38^{A}	8.67 ± 1.49^{B}	<0.00001*
12-months	15.27 ± 3.08^{A}	11.13 ± 1.24^{B}	<0.00001*

*; significant at P < 0.05. ns; non- significant P > 0.05.
Different uppercase letters mean statistically significant.

Figure 4: Bar chart representing the comparison of caries lesion state scores among the two groups at different time intervals

Discussion

WSLs are optical phenomena because the pores within the body of the lesion may appear clinically owing to differences in the refractive index of sound enamel (1.62) and porous enamel (1.12) that is filled with air or water [19]. The light which shines on the tooth are reflected, scattered, or deflected to appear as opaque white spots, which may compromise esthetics if present in the esthetic zone and may progress to cavitated lesions if not adequately managed [20]. Intervention with restoration of initial enamel lesions requires enamel removal extending to the subsurface zone and demineralized penetration into dentin, which results in unfavorable damage to the tooth structure [21].

There was a high correlation between visual findings and LF. Although it is an accurate measure for the detection of initial carious lesions, it can also be used for demineralization quantification to monitor changes in WSLs [22]. In addition, LF can be used as a prevention protocol objective by comparing it with visual examination [23]. Visual examination depends on the skill of the operator and

experience of the assessment. Despite its low reliability, reproducibility, and sensitivity, it is highly recommended for high-specificity characterization [24].

The Icon group showed an immediate significant decrease in LF scores at all follow-up periods. This could be due to the resin filling the intracrystalline spaces in the subsurface lesions, thereby sealing the pores. After polymerization, Icon prevents the acid pathway from infiltrating demineralized body lesions and slows the progression of caries [7]. These results are consistent with **those reported by Knösel et al** [25] and **Ciftci et al** [26].

Before the application of Icon, etching was performed with 15% HCL for 2 min, according to the manufacturer's instructions, to remove the highly mineralized surface layer and provide accessibility infiltration of subsurface lesions. Then, Icon-Dry was applied to evaporate water from the pores to enable the resin to infiltrate and soak the pores by capillary diffusion and increase the surface free energy [27].

Furthermore, the micro-invasive resin infiltration concept is based on filling the body lesion pores with resins via capillary action by the application of low viscosity, unfilled, low-resin to the WSLs. This can prevent further lesion progression by blocking the diffusion paths of cariogenic acids [28], occludes diffusion pathways for cariogenic acids, and immediately causes caries progression to slow or even arrest.

In addition, the microhardness of the WSLs increased with the occlusion of the pathway for dissolved minerals and resin infiltration owing to the uniform complex of TEGDMA resin and crystal minerals. The interaction with hydroxyapatite improved mechanical strength, stopped caries progression, and improved esthetic appearance [29].

However, our findings disagree with **Markowitz** and **Carey**, [30] who found no difference between LF readings of sound enamel and artificial demineralized enamel. They explained the treatment of WSLs using an Icon mask color, and the laser device read the fluorescence obtained from the bacterial porphyrin. They did not recommend the use of laser fluorescence in studies that used artificially created WSLs.

In the PRG group, our results showed an immediate improvement and a significant improvement in LF scores after 3 months, indicating a healthy condition. This may be due to the formation of a polymeric physical film barrier against caries-causing microorganisms [31]. Moreover, this may be due to effective hermetic sealing, which acts as a mechanical barrier to suppress the ingress of acid without degrading the enamel acid suppression of antibacterial and mineral effect on releasing ions, bringing pH values closer to neutral [32]. These results are consistent with **those of Örtengren et al** [33]**,** who found that the application of S-PRG significantly diminished plaque accumulation over 90 days with buffering capacity.

Another reason is that PRG creates a mechanical barrier film to microorganisms on the enamel surface, thereby halting incipient lesions and preventing cavitation. In addition, ionic activity protects the surface against demineralization [34].

Above all, the effect of the six ions released from the S-PRG fillers inhibits the demineralization of enamel by acid buffering and antibacterial activity. The acid neutralization effect was strongly accelerated by sodium, strontium, and aluminum. Strontium interacts with hydroxyapatite to form stronger acid-resistant strontioapatite. The antimicrobial effect was mainly promoted by boron ions. A reduction in bacterial growth on the tooth surface by ions was released [35].

After 1 year, a significant increase in LF scores was found in the PRG group. This could be attributed to the internal acid-base reactions of the glass ionomers, leading to voids and cracks. The acidic environment may affect the integrity of the material and may lead to partial dissolution of the coating layer [(36)]. In addition, the hydrophilic component of the material exhibited water-sorption properties. Degradation of the material could be due to water sorption and dissolution [(37)].

These explanations are consistent with **those of Nascimento et al** [(38)]**,** who found that fluoride-releasing coating material had the most staining discoloration even after 1 week. They explained that the water sorption properties could be attributed to weakening of the material.

Moreover, surface irregularities due to the degradation of the material over time allow bacteria to survive for a longer time. Irregularities preserve bacteria in contact with the tooth despite brushing. Charging of fluoride and its release from PRG over time inhibits bacterial growth [(39)].

Otherwise, Giomers need to absorb water to maintain the fluoride release and recharge properties of the glass ionomer cements. Material durability may be reduced by water sorption, which has a negative effect on bond and mechanical properties [(40)].

In addition, there was a significant increase in LF scores in the Icon group over time, which may be due to the loss of the outer shell due to acid conditioning and the degradation effect of the material over time. This allows bacteria to continue the demineralization process, making the lesion prone to progression [(41)]. This finding was in accordance with the results of **Baafif et** al, **[(17)]** who found significant differences between baseline and all follow up intervals in LF scores at the 3, 6,12

month follow-up. This may be due to the dissolution or degradation of the material in oral fluids after long periods.

Likewise, the degradation of the resin maybe due to the increased number of pores that allow acid penetration, caries progression, and insufficient resin-filled porosities [42].

In contrast to our results, a study by **Gözetici et al.** [15] found no significant differences were observed between 3 and 6 months in the Icon group. They explained that the result might have been due to improved brushing habits and professional tooth cleaning at the beginning of the study.

In the comparison between the two groups, there were significant differences in the 6- and 12-months periods with improved effects of Icon compared to PRG according to LF scores. The results of Icon showed significantly greater penetration than that of S-PRG. This could be because a fluoride-rich outer layer or hyper-mineralized enamel might prevent penetration of S-PRG [43]. Therefore, it was hypothesized that the PRG coating material did not improve the carious lesion state of WSLs, in comparison to Icon, over a period of 1 year.

Indeed, demineralized outer enamel in the S PRG leads to shallower pores with low bond and decreased penetration compared to Icon [44]. Similarly, it was observed in a previous study that the longer the resin tags of a sealant, the lesser the nanoleakage and, consequently, the better its sealing ability [45]. Furthermore, the penetration depth of sealants into WSLs plays an important role in controlling caries lesion progression [46]. Moreover, etching increases enamel porosity and wettability, allowing the penetration of low-viscosity resin [47].

These explanations are consistent with those reported by Hagag et al, who compared the penetration depth of two resin-based materials, Icon and a self-etch

adhesive, in WSLs. They observed that the highest penetration depth was recorded in the Icon group. They explained that self-etch is not suitable for removing the surface layer of enamel lesions while increasing the surface area and pores, and the dissolution of the surface layer of the WSLs [(48)].

Additionally, the infiltration technique creates a diffusion barrier inside the enamel lesion, which strengthens the demineralized enamel with the resin matrix, preventing cavitation by controlling caries progression. Therefore, the resin infiltrated layer should prevent further wear and cavitation. In contrast to the application of coatings, a diffusion barrier remains on the enamel surface as a covering resin coating [(49)].

Our results are in agreement with **those of Rohym et al**, [(28)] who compared the clinical performance of a fluoride-releasing coating material versus Icon in the treatment of WSLs using LF. They found that the LF scores significantly increased at 6 and 12 months for the coating group more than for the Icon group, with degradation of material over time.

According to the filler content, S PRG had fillers, whereas Icon was filler-free. The penetration power of low-viscosity S-PRG was lower than that of highly viscous Icon [(50)]. In fact, the shallow depth of the S PRG did not penetrate the micropores, whereas the resin infiltrated as it was unfilled [(51)].

Moreover, our findings are in agreement with **those of Sharma et al.,** who compared fluoride-rich releasing and Giomer-based sealants. The fluoride-rich group showed a significant increase in retention at 1 year compared to the Giomer group. They explained that the mechanical retention of sealants is the direct result of resin penetration into the micropores from etching to form micromechanical tags [(52)].

This result disagreed with **that of Wakamatsu et al.,** who found esthetic improvement and reduction in WSLs after 1 year. They explained that all the subjects used the same brush and brushing motion with a professional fluoride application (Acidulated Phosphate Fluoride gel). This helps to increase the remineralization of WSLs [(53)].

The limitation of our study was the improvement in S PRG remineralization and fluoride release, which led to a cross effect on ICON.

Our suggestion that total enamel conditioning before PRG application would improve wetting and penetration for self-etching and bioactive effects should be evaluated in future clinical studies.

Conclusions

Within the limitation of this study the conclusion may be

1- S-PRG surface coating material gives an immediate effective treatment in WSLs.
2- Icon provides a clinical esthetic improvement of WSLs.
3- S-PRG had a better effect on the control of caries progression and LASER fluorescence score than ICON.
4- Icon resin infiltration is more clinical successful.
5- Icon and S-PRG showed acceptable results in inhibition of Enamel demineralization.

conflict of interest
The authors declare no conflict of interest.

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The authors do not have any financial interests in the companies whose materials are included in this article.

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Declaration;

Ethical approval and consent; Full Ethical approval was obtained from the Faculty of Dental Medicine, Al-Azhar University Ethics Committee (no.350/466/08/10/19). Informed consent was obtained from all subjects with complete clarification of the nature of the study and they signed a consent form (in regional language) before the start of the study. All participants were of legal age and signed consent forms (there was no need for written consent from parents/guardians). All procedures were performed in accordance with the guidelines and regulations of the Ethical Committee of the Faculty of Dental Medicine, Al-Azhar University

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