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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Research Article

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Abstract

Objective: White spots become one of the initial signs of dental caries. Resin infiltration and remineralization was used to prevent WSLs cavitation. Deposition of minerals depends on the equilibrium between demineralization and remineralization which may happen as a natural repair mechanism. The aim of this study is to compare the effect of PRG Barrier Coat coating material (PRG) against the resin infiltration ICON material in improving the caries lesion state of the WSLs along 1 year.

Clinical Considerations: the efficacy of fluoroboro-aluminosilicate Glass surface coating S-PRG fillers and ICON resin infiltration in the ability to improve the aesthetic appearance (masking) and caries lesion state of the 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 the caries progression. PRG Barrier Coat group showed immediate significant improvement in LF scores in demineralization progress and inhibition of caries progression with a significant improved effect.

Conclusions: Resin infiltration ICON is more clinical successful treatment for demineralized WSLs. PRG Barrier Coat is useful for short time as control of caries progression and prevention protocol not for treatment of WSLs.

Clinical Significance: S-PRG Barrier Coat was clinically successful strategy in inhibition of caries and improve remineralization.

Introduction

Dental caries is an infectious microbial disease that affects most people all over the world \(^{(1)}\). Tooth decay initiated with decomposition of mineral and disintegration of dental tissue matrix. The loss of subsurface minerals of enamel from intracrystalline spaces led to an optical phenomenon getting what called white spot lesions (WSLs) \(^{(2)}\). Early detection of demineralization by recent diagnostic tools is helpful in elimination of the progress of the decay process. Remineralization has a helpful role in the management and reduction of early caries. The WSLs have two layers: outermost surface layer which relatively intact, mineral rich, softer than sound enamel and subsurface layer (body of the lesion) where the dissolution occurs mainly on it, which is porous and has low mineral content \(^{(3)}\).

There are two aspects of treating WSLs; noninvasive technique by remineralization and by minimally invasive technique to improve esthetic by resin infiltration \(^{(4)}\). The latest strategy is treating a non-cavitated caries noninvasively, which is the most conservative approach and preserves the tooth structure through remineralization and reduction of bacterial adhesion to decrease progression of caries that will eventually improve strength, function and esthetics \(^{(5)}\).

Fluoride application was the gold stander for blocking the cycle of demineralization. However, after fluoride varnish application, the outer layer may be saturated with more minerals, so, reduce the diffusion of ions to the deepest layer\(^{(6)}\). Several remineralizing agent was used to deposition of calcium / phosphate...
minerals in enamel resembling the hydroxyapatite, however, the crystalline deposition of minerals does not mimic the natural one (7).

Bioactive ingredients with the power of remineralization at the deep area of the body of lesion was used. Fluoroboro-aluminosilicate Glass surface coating S-PRG fillers barrier coat was used to remineralize WSLs (8). S-PRG pretreated fluoroboro-aluminosilicate glass with polyacrylic acid and water to recharge and release fluoride. Additionally, releasing more types of ions this aid in biofilm suppression, decrease adhesion of bacteria. buffering capacity of acids and enhances remineralization (9).

Another treatment option is micro-invasive resin infiltration technique, which include resin infiltration, that fills the enamel pores. Consequently, allow resin to diffuse by capillary interactions forming a mechanical barrier, prevent demineralization and bacterial acids penetration (10).

Above all, detection of initial demineralization as early as possible is preferred by routine check. Noninvasive treatment to WSLs helps to stop cavitation and caries progression (11). Laser Fluorescence is important to detect the first sign of subsurface demineralization and monitoring over-time. Therefore, DIAGNOdent laser fluorescence device was used to quantify mineral loss in lesions and allow detection of any change of caries (12). Laser fluorescence device is highly sensitive to diagnose demineralization of hard tooth structure and mineral loss by digital number from (1–99) which indicate the stage of caries and cavitation (13).

In our study, we choose to comparatively evaluate two different lines of treatment of WSLs: noninvasive remineralization technique (PRG Barrier Coat) against micro-invasive resin infiltration technique (Icon) in the ability to improve caries lesion state (LF scores) of the WSLs along 1 year among adult patients. The hypothesis was that the resin coating material containing S-PRG fillers would clinically improve the caries lesion state of WSLs, in comparison to Icon, over a period of one year. And the null hypothesis was The caries lesion state of WSLs will not improve after using the resin coating material containing S-PRG fillers or Icon resin infiltration.

**Materials And Methods**

Two materials were used in this study

1. Icon resin infiltration (DMG, Hamburg, Germany): It comprised 3 steps for resin infiltration; icon etch, icon dry and icon infiltrant.

2. PRG Barrier Coat Mini-Kit (Shofu Inc., Kyoto, Japan): It consists of PRG Barrier Coat active and base containers.

**Study design**

It is a single centered, double blinded (assessor and patient); two parallel armed randomized control clinical trial with an equal allocation ratio (1:1) for the comparing of Icon resin infiltration and PRG Barrier
Coat (PRG) effect on WSLs. DIAGNOdent pen (Kavo, Biberach, Germany) laser fluorescence device scores (LF) were used to evaluate the progress or suppression over-time. CONSOTR (Consolidated Standards of Reporting Trails) statement was reported on this randomized controlled trials references (14).

**Ethical approval and consent form:**

This RCT was approved by the institutional Ethics Committee at the Faculty of Dental Medicine, Al-Azhar University Ethics Committee (No.350/466/08/10/19). A detailed information was discussed with patients to be aware with the benefits and signed a consent form to include and participate in this study (in regional language) before the start of the study. This RCT study was held in the Faculty of Dental Medicine, Al-Azhar University, Cairo, boys. The trial was registered at https://clinicaltrials.gov with a given number (NCT05550116 22/09/2022).

**Sample Size**

Based on the previous clinical study (15) the sample size of 15 in each group was effective size of sample for the experimental and control groups with significance level ($\alpha$) of 0.05 and power 80%. Means and standard deviation of color of icon at baseline was $33.2 \pm 17.33$ and for control group was $17.95 \pm 6.26$. On this basis we estimate to increase the total number 20 in each group to compensate for losses during follow up.

**Eligibility criteria**

Patients with WSLs on their maxillary anterior teeth were selected at the time of their regular dental visits in the outpatient clinics. Clinical selection was conducted using a mirror, periodontal probe, and airway syringe by a single examiner. Inclusion criteria were as follows: adult patients aged 20–40 years, each patient had 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 (as tetracycline staining) on anterior teeth, application of remineralizing agents or restoration with glass ionomer the past three months (17), and current participation in another study.

**Clinical examination of WSLs**

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

**Assessment of caries lesion state:**

Assessing demineralization state of WSLs was done by LF to monitoring the lesion by time. Prior to demineralization state measurements, all teeth with WSLs were scaled and polished with a prophylaxis
non-fluoridated pumice paste (Kemdent Flour of Pumice, ADP Ltd, Swindon, UK) by using a rubber prophylaxis cup (Skylun, Chancheng District, Foshan, China) at a low-speed handpiece, and finally, rinsed with water. Data were recorded at baseline before treatment (T0).

Calibration performed routinely with each tip change and for each new patient according to the manufacturer's instructions by following steps: pressing (Menu) key once followed by the (Enter) button. A small zero will appear in the display followed by a large zero. The display then changed to a letter and two-digit number (70 in this device), and the unit will emit an audible tone, when the tone begins gently place the tip on the calibration disc at 90-degree angle holding steady. When the tone stops, calibration is completed, and the unit is ready to use. The two-digit number displayed during calibration should match the calibration number printed on the circular calibration disc (70 in this device).

Enrollment of patients:

We examined 45 patients, 10 patients do not accept participate in the trial and 15 patients did not meet the inclusion criteria (cavitation/chipping adjacent to WSLs / did not present at least 2 WSLs with LF score 11-20). Finally, 20 patients were matching the inclusion criteria and take part in this study. All participants signed the consent form (no need for written consent from the parents/ guardians).

Grouping:

Total number of (40) non-cavitated WSLs in permanent maxillary anterior teeth collected from (20) patients, each patient has 2 WSLs, and randomly assigned into 2 equal main groups (n=20) according to the type of materials used in WSLs treatment, control group (Icon) and intervention group (PRG).

Randomization:

Randomization was done by asking the patient to choose a sealed envelope of the material. Randomization depended on two interrelated aspects: Sequence generation, and allocation concealment.

Allocation and blinding

Two main groups of teeth were divided, and every patient received both treatments, right (R) and left (L). Randomly allocated the treatment option by patients which select the sealed envelope with written inside (L Icon, R PRG) or (R Icon, L PRG). At the clinic had his code number and randomly select an opaque envelope. Firstly, the patient ensure recruitment in the trial and knew the benefits to ensure the allocation concealment. After that, the code was released to patients and service began which took place after all baseline measurement had been completed.

The Participants and assessors were blinded to the material assignment while the operator was not blinded due to the difference in the application protocol of the used materials.

Materials application
Rubber dam applied to get better isolation, protect the gingiva, and ensure the best treatment result possible, the teeth with WSLs were isolated using rubber dam system (Sanctuary Dental Dam 6X6). Teflon tape used to protect the adjacent tooth from the effect of acids used. The material applied according to the manufactures’ instructions. To be standardized one clinician apply all materials.

**PRG Barrier Coat (Figure 1);**

It consists of eight Base containers and Active. One of the base containers broken off, one drop of activator was added to the base container and then mixed in the base container using disposable brush provided. The mixture was applied on the WSLs, leave undisturbed for more than 3 seconds, cured for 10 seconds by light cure. The uncured layer was removed by gently rubbing the surface with adhesive micro brush.

**Resin infiltration (ICON);**

The first step, WSLs surface layer was etched with 15% hydrochloric acid gel (Icon -Etch) for 2 minutes (Figure 2). Then, washing the etched area for 30 seconds using water spray, followed by drying with compressed air for ten seconds. The second step was application ample amount of 99% ethanol (Icon -Dry) to the etched area and let set for 30 seconds and then the lesion dried thoroughly with compressed air for ten seconds. The last step 3 minutes application of ICON resin infiltrate to allow penetration and the excess was removed with dental floss. ICON resin infiltrate was light cured for 40 seconds with a Light emitting diode (LED Elipar, 3M ESPE, USA). Then, a second layer of Icon was applied for one minute and light cure for 40 second. Finally, the treated WSLs polished to finish the surface to a smooth luster and avoid discoloration by food stains.

**Patient instruction**

Patients were instructed to brush the day after treatment using a brush Oral-B soft-texture (Procter&Gamble, US) with fluoride toothpaste (Crest Cavity Protection, 1100 ppm F) twice a day and prohibit other fluoridated products.

**Outcomes and follow-up**

**The primary outcome:** change in fluorescence scores at 3 months, 6 months, and 12 months for all treatment groups. **The secondary outcome:** comparison of fluorescence values within the treatment groups. **The endpoint:** the durability and effect of Icon, and PRG on WSLs were clinically evaluated by LF device to assess the caries lesion state.

At every follow up visit before the assessments, the treated teeth were polished with fluoride-free polishing paste using a rubber cup, then, a lip retractor was inserted. After that, the teeth were air dried for 5 seconds. The DIAGNOdent pen was calibrated according to the manufacturer’s instructions prior to any assessment. The treated WSLs were evaluated post-operatively by the same operator at the following time intervals; immediately T1 after treatment, T2 three months later, T3 six months later and T4 twelve 12 months later.
Statistical analysis was performed using SPSS statistical version 21 (Statistical Procedures Companion, Chicago, IL, USA). To verify the normality of distribution of data Kolmogorov-Smirnov test were used. For comparison of the effect of the two materials one-way ANOVA test was used immediately T1 after treatment, T2 three months later, T3 six months later and T4 twelve 12 months. For multiple comparisons within the two groups post hoc Tukey test, within each group, and compared the two intervals. The P-value Significance level was set at \( P \leq 0.05 \).

**Results**

**Baseline data (Patient allocation and follow-up)**

All 20 patients which included in this study were called by phone to come for assessment within the first week of the start of 3-6-12 months periods. After 6 months one patient was lost to follow-up due to difficulty with transportation, as he moved to another city. The remaining 19 patients came, and the treated WSLs were evaluated. While after 12 months three patients did not come to follow-up as they transferred to other clinics as they choose restoring the WSLs, because the patients wanted the more esthetically appearance of WSLs and they choose the filling treatment. The remaining 16 patients came, and the treated WSLs were evaluated. The trial flow diagram is shown in (Figure 3). No unfavored side effects (as pain, sensitivity, or cavitation) were observed. Literally, no Clinically obvious effects as, alteration of gingival tissue, vitality loss in the 2 groups.

**Intragroup comparison of PRG (Table 1):**

The statistical analysis of the LF scores of PRG showed a statistically significant difference in immediate and 3 months follow-up period as indicated by the ANOVA test (\( P < 0.00001 \)). However, there were a nonsignificant difference 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 ± SD) of LF scores was recorded at the baseline (16.73±2.09). Then, it decreased immediately after application to (2.00±0.85), and after that, it increased respectively with time (4.71±1.14), (10.06±0.79), and (13.20±1.57) from 3-month to 12-month (Figure 4).

**Intragroup comparison of Icon (Table 2):**

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 of the caries lesion state scores of Icon with time. The higher mean and standard deviation (Mean ± SD) of the LF scores was recorded at the baseline (15.47±2.64). Then, it decreased immediately after application to (2.47±0.83), and after that, it increased respectively with time (4.60±1.06), (8.67±1.49), and (11.13±1.24) from 3-month to 12 month. (Figure 5)

**Intragroup comparison of both materials:**
The comparison of LF scores at various time intervals of follow-up is indicated by the ANOVA test and summarized in (Table 3). The statistical analysis of LF scores among the two groups at baseline, immediately after materials application, and after 3-months showed that; there were insignificant differences between them as (P > 0.05). A significant difference in LF scores between the Icon and PRG groups at 6-months and 12-months (P < 0.05). (Figure 6).

The result image of two treatments: a Preoperative photo (Figure 7), after immediate treatment of both material (Figure 8) and twelve 12 months later final result image (Figure 9).

Discussion

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

There was a high correlation between visual findings and LF. Although, it is accurate measure of detecting initial carious lesion, it can be used for demineralization quantification to monitor changes with WSLs (22). Also, LF can be used prevention protocols objective by comparing to the visual examination (23). The visual examination dependent on the skills of operator and experience of assessment. It is highly recommended as high specificity characterization, despite, its low reliability, reproducibility and sensitivity (24).

In this randomized and controlled clinical study, changes in WSLs were evaluated after applying Icon resin infiltrate and PRG fluoride releasing coating material, over 12-months. WSLs were evaluated by LF measurements.

Icon group showed immediate significant decrease LF scores and in all follow-up periods. This could be due to the resin filled the intracrystalline spaces in subsurface lesion, thus sealing the pores. ICON after polymerization prevent the acid pathway to infiltrate in the demineralized body lesion and slow progression of caries (7). These results were in cope with Knösel et al. (25) and Ciftci et al (26).

Before application of Icon, etching with 15% HCL for 2 minutes, according to manufactures instructions, to remove the highly mineralized surface layer to give accessibility infiltration of subsurface lesions. Then, apply (Icon -Dry) to evaporate water from porosities to enable the resin to infiltrate and soak the pores by capillary diffusion and increasing the surface free energy (27).

Furthermore, the micro-invasive resin infiltration concept based on fills the body lesion pores with resins, via capillary action by application of low viscosity, unfilled, low resin to the WSLs. It can prevent further
lesion progression by blocking the diffusion paths for cariogenic acids \(^{(28)}\).

occludes diffusion pathways for cariogenic acids and immediately causing caries progression to slow down or even be arrested

As well as the microhardness of WSLs increased with occlusion of pathway for dissolved minerals and resin infiltration due to a uniform complex of TEGDMA resin and crystals minerals. The interaction with hydroxyapatite improved the mechanical strengths, stop caries progression and aesthetic appearance \(^{(29)}\).

On the other hand, our finding disagreed with **Markowitz K & Carey K**, \(^{(30)}\) they found that there is no difference between LF readings of sound enamel and artificial demineralized enamel. They explained the treatment of WSLs by Icon mask color and the laser device read the fluorescence obtained from bacterial porphyrin. They do not recommend using laser fluorescence in studies which using artificial created WSLs.

Regarding to PRG group our results showed immediate and after 3-months significant improvement in LF scores giving healthy condition. This may be due to the formation of polymeric physical film barrier to the caries causing microorganisms \(^{(31)}\). Moreover, this may be due the effective hermetic sealing which act as a mechanical barrier to suppress the ingress of acid without degrading of enamel surface upon application, and the material compositions which having the ability to recharge fluoride and release other ions, as aluminum, borate, silicate, sodium and strontium, to protect enamel by acid suppression of antibacterial and mineral effect on releasing ions, bringing pH values closer to neutral \(^{(32)}\). These results agreed with **Örtengren, et al.** \(^{(33)}\), that found the application of S PRG significantly diminish accumulation of plaque over ninety days with buffering capacity.

Another reason, the PRG make mechanical barrier film to the microorganisms in the enamel surface thereby halting incipient lesions and preventing cavitation. Also with ionic activity that make covering on the surface against demineralization procedure \(^{(34)}\).

Above all, the effect of released six ions from S-PRG fillers inhibit the demineralization of enamel by acid buffering and antibacterial activity. The acid neutralization effect is strongly accelerated by sodium, strontium, and aluminum. The strontium interacts with hydroxyapatite to form a stronger acid resistant strontioapatite. The antimicrobial effect mainly promoted by boron ions. Reduction of bacterial growth on tooth surface by ions released \(^{(35)}\).

After 1 year, an increase in LF scores in PRG group significantly was found. This could be attributed to the internal acid base reactions for glass ionomers lead to voids and cracks. The acidic environment may affect the integrity of material and may lead to partial dissolution of coating layer \(^{(36)}\). Also, the hydrophilic component in the material gave water sorption properties. Degradation of the material could be due to the water sorption and dissolution \(^{(37)}\).

These explanations meet with **Nascimento PL et al.** \(^{(38)}\), who found fluoride releasing coating material had the most staining discoloration even in one week. They explained that water sorption properties may be
attributed to weaken the material.

Moreover, surface irregularities due to degradation of the material over time act as a room for bacteria and survive for more time. Irregularities preserve bacteria to be in contact with tooth despite of brushing. Charging of fluoride and release from PRG by time inhibit bacterial growth\(^ {\text{39}}\).

Otherwise, Giomers have the need to absorb water to maintain fluoride release and recharge properties of glass-ionomer cements. The material durability may be reduced by water sorption that have negative effect on bond and mechanical properties\(^ {\text{40}}\).

Also, there were significant increase in the LF scores in ICON group by time, this may be due to lose of the outer shell as acid conditioning and the degradation effect of the material over time. This allows entrance of the bacteria to continue the demineralization process, making the lesion prone to progression\(^ {\text{41}}\). This finding was in accordance with Baafif et al.,\(^ {\text{17}}\) who found significant differences between baseline, and all follow up intervals LF scores at the 3, 6,12 month follow up. Their explanation may be due to dissolution or degradation of the material in oral fluids after long periods.

Likewise, the degradation of resin maybe due to the increase numbers of pores that allow acid penetration and caries progression and insufficiently resin filled porosities\(^ {\text{42}}\).

In contrast to our results, a study by Gözetici, et al.,\(^ {\text{15}}\) who found there was no significant differences were observed between 3 and 6 months in Icon group according to LF scores. Their explanation was that the result might be due to improved brushing habits and professional tooth cleaning at the beginning of the study.

In comparison between the two groups there were significant difference in 6- and 12-months periods with improved effect of Icon rather than PRG according to LF scores. These results of Icon showed significantly greater penetration than S PRG. This could be due to fluoride rich outer layer or hyper mineralized enamel might prevent penetration of S PRG\(^ {\text{43}}\). So, the hypothesis was rejected that as the PRG coating material did not improve the caries lesion state of WSLs, in comparison to Icon, over a period of one year.

Indeed, S PRG demineralized outer enamel lead to a shallower pores with low bond and decreased penetration than ICON\(^ {\text{44}}\). Similarly, It was observed in previous study, the longer the resin tags of a sealant the lesser is the nanoleakage and consequently the better is its sealing ability\(^ {\text{45}}\). Also, the depth of penetration of sealants into WSLs plays an important role in the control of caries lesion progression\(^ {\text{46}}\). Moreover, etching increase the enamel porosity and wettability to allow for the penetration of the low-viscosity resin\(^ {\text{47}}\).

These explanations meet the same results found with Hagag N et al .who compared the depth of penetration of two resin-based materials Icon and self-etch adhesive in WSLs. They found that the highest penetration depth was recorded in Icon group. They explained that the self-etch is not suitable to remove
the surface layer of enamel lesions while making more surface area and pores plus the dissolution of the surface layer of the WSLs (48).

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

Our results in agreement with Rohym et al (28) who compared the clinical performance of fluoride releasing coating material versus Icon in treatment of WSLs by LF. They found in LF scores significantly increase in 6 and 12 months for coating group more than Icon as degradation of material by time.

According to fillers content the S PRG has fillers while Icon is fillers-free. Power of penetration of low viscous S PRG is lower than high viscous ICON (50). In fact, the shallow depth of S PRG did not penetrated in microporosities while, resin infiltrate as it is unfilled (51).

Moreover, our finding in agreement with Sharma et al., who compared a fluoride rich releasing sealant and Giomer based sealants. The fluoride rich were significantly increase in retention at 1 year than Giomer. They explained that the mechanical retention of sealants is the direct result of resin penetration into micropores from etching to form micromechanical tags (52).

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

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

Our suggestion that totals enamel conditioning prior PRG application would improve wetting and penetration for self-etching, and bioactive effects, which deserves to be evaluated in future clinical studies.

Conclusions

Within the limitation of this study the conclusion may be

1. S-PRG surface coating material give immediate effective treatment in WSLs.
2. ICON have a clinical esthetic improvement of WSLs.
3. S-PRG has a better effect in 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.
Declarations

**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 about the nature of the study and signed a consent form (in regional language) before the start of the study. All participants were of legal age and signed their consent forms (no need for written consent from the parents/ guardians). All methods were carried out in accordance with the guidelines and regulations of Ethical Committee of Faculty of Dental Medicine, Al-Azhar University

**Consent to publish:** not applicable

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**Conflicts of Interest:** The authors declare no conflict of interest.

**Author Contributions:** Conceptualization, Ahmed Gamal ELdeen El Maslout and Wakwak M A.; methodology, Gabr E H and Wakwak M A.; investigation, Gabr E H Wakwak M A. and Ahmed Gamal Eldeen El Maslout; writing original draft preparation Gabr E H, Ahmed Gamal ELdeen El Maslout and Wakwak M A. writing—review and editing, Gabr E H and Wakwak M A.

**Data Availability Statement:** Available on request The datasets generated and analyzed during the current study are not publicly available due [Governmental and institutional prohibition by Law Unless an agreement upon request ] but are available from the corresponding author on reasonable request.

**Acknowledgement/ Disclosure Statement:** The authors have no financial interest with the material from companies in this trial.

References


Tables

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (Mean± SD)</th>
<th>Immediate</th>
<th>3-months</th>
<th>6-months</th>
<th>12-months</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRG</td>
<td>15.80±2.62A</td>
<td>2.87±1.51C</td>
<td>5.07±2.58B</td>
<td>14.07±1.38A</td>
<td>15.27±3.08A</td>
<td>&lt;0.00001*</td>
</tr>
</tbody>
</table>

*; significant at P < 0.05.

Different uppercase letters mean statistically significant.

(SD) standard deviations

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (Mean± SD)</th>
<th>Immediate</th>
<th>3-months</th>
<th>6-months</th>
<th>12-months</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Icon</td>
<td>15.47±2.64A</td>
<td>2.47±0.83E</td>
<td>4.60±1.06D</td>
<td>8.67±1.49C</td>
<td>11.13±1.24B</td>
<td>&lt;0.00001*</td>
</tr>
</tbody>
</table>

*; significant at P < 0.05.

Different uppercase letters mean statistically significant.

(SD) standard deviations

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>PRG (Mean ± SD)</th>
<th>ICON (Mean ± SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>15.80±2.62</td>
<td>15.47±2.64</td>
<td>0.5543 ns</td>
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<tr>
<td>Immediate</td>
<td>2.87±1.51</td>
<td>2.47±0.83</td>
<td>0.0515 ns</td>
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<tr>
<td>3-months</td>
<td>5.07±2.58</td>
<td>4.60±1.06</td>
<td>0.5811 ns</td>
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<tr>
<td>6-months</td>
<td>14.07±1.38A</td>
<td>8.67±1.49B</td>
<td>&lt;0.00001*</td>
</tr>
<tr>
<td>12-months</td>
<td>15.27±3.08A</td>
<td>11.13±1.24B</td>
<td>0.00001*</td>
</tr>
</tbody>
</table>

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

(SD) standard deviations

**Figures**

![Image](image_url)

**Figure 1**

Application of PRG Barrier Coat
Figure 2

Application of Icon-Etch
Figure 3

The flow diagram of the study
Figure 4

Bar chart representing the effect of PRG Barrier Coat on caries lesion state scores of WSL at different periods
Figure 5

Bar chart representing the effect of Icon on caries lesion state scores of WSL at different periods
Figure 6

Bar chart representing the comparison of caries lesion state scores among the two groups at different time intervals.
Figure 7

Preoperative photo with rubber dam applied showing WSLs on the labial surface of anterior teeth.

Figure 8

Immediately postoperative image with Icon applied on upper right central while PRG applied on upper left central.
Figure 9

1 year follow-up image showing complete preservation of esthetic enhancement of anterior teeth.