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ORIGINAL ARTICLE

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One Year Clinical Evaluation of White Spot Lesions with Newly Introduced Resin Modified Glass-Ionomer in Comparison to Resin Infiltration in Anterior Teeth: a split mouth randomized controlled clinical trial from Egypt

Avaliação clínica de um ano de lesões de mancha branca com iônomo de vidro modificado por resina recentemente introduzido em comparação à infiltração de resina em dentes anteriores: um ensaio clínico controlado randomizado de boca dividida do Egito

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ABSTRACT

Objective: to compare the clinical performance of newly introduced resin modified glass ionomer varnish (Clinpro™ XT) versus resin infiltration in treatment of post-orthodontic white spot lesions. **Material and Methods:** Six participants (70 teeth) were enrolled with post-orthodontic white spot lesions. Randomization was performed according to patient selection for the sealed envelope containing which half will receive the control (resin infiltration (ICON, DMG) and the other will receive the intervention (resin modified glass-ionomer cement varnish (Clinpro™ XT, 3M)). Follow up was done after 1 day, 1 week, 1 month, and 3 months, 6 months and 12 months. The color was assessed by spectrophotometer while the degree of demineralization was measured by Diagnodent pen 2910. Patient satisfaction was assessed using (VAS) Visual analogue scale **Results:** Regarding color change, significant improvement in lightness for ICON group, while Clinpro™ XT group, the change was insignificant. The demineralization data revealed significant decrease in demineralization with resin infiltration after immediate application. Clinpro™ XT showed also significant decrease after immediate assessment and significant increase in demineralization in 6 and 12 months. **Conclusion:** Resin infiltration can be considered more as an alternative treatment rather than fluoride varnish. Clinpro™ XTis considered as a preventive protocol, provided that renewal application is needed after 3 months.

KEYWORDS

3M Resin cement; Resin cements; Glass ionomer cements; Fluorides; Follow up studies; Glass ionomer.

RESUMO

Objetivo: comparar o desempenho clínico do recém-introduzido verniz de ionômero de vidro modificado por resina (Clinpro ™ XT) com a infiltração de resina no tratamento de lesões de manchas brancas pós-ortodônticas. **Material e Métodos:** Seis participantes (70 dentes) foram inscritos com lesões pós-ortodônticas de manchas brancas. A randomização foi realizada de acordo com a seleção do paciente para o envelope lacrado contendo qual metade receberá o controle (infiltração de resina (ICON, DMG) e a outra metade receberá a intervenção (verniz de cimento de ionômero de vidro modificado por resina (Clinpro ™ XT, 3M)). O acompanhamento foi feito após 1 dia, 1 semana, 1 mês e 3 meses, 6 meses e 12 meses. A cor foi avaliada por espectrofotômetro, enquanto o grau de desmineralização foi medido pela caneta Diagnodent 2910. A satisfação do paciente foi avaliada usando (VAS) Escala visual analógica. **Resultados:** Em relação à mudança de cor, houve uma melhora significativa na luminosidade para o grupo ICON, enquanto o grupo Clinpro ™ XT, a mudança foi insignificante. Os dados de desmineralização revelaram diminuição significativa da desmineralização com infiltração de resina após a aplicação imediata. O grupo Clinpro ™ XT também mostrou diminuição significativa após avaliação imediata e aumento significativo na desmineralização em 6 e 12 meses. **Conclusão:** A infiltração de resina pode ser considerada mais como uma alternativa de tratamento do que o verniz fluoretado. O Clinpro ™ XT é considerado um protocolo preventivo, uma vez que a renovação é necessária após 3 meses.

PALAVRAS-CHAVE

Cimento de resina 3M; Cimentos de resina; Cimentos de ionômero de vidro; Fluoretos; Estudos de acompanhamento; Ionômero de vidro.

INTRODUCTION

White spot lesions (WSLs) are one of the most undesired iatrogenic side-effects of orthodontic treatments. Labial surface demineralization has been reported to occur in up to 96% of individuals involving multibracket appliances. [1,2] It has been seen as early as four weeks after the beginning of this treatment. [3]

It was reported that presence of complex structure in orthodontic brackets makes their periphery an amenable site for the retention of bacterial plaque accumulation, increased difficulty in maintaining oral hygiene and modification of the quantity and quality of oral microbiota after appliance placement. [4] Several studies have reported a significant increase in the prevalence and severity of tooth demineralization in patients during orthodontic treatment. [5–7]

White spot lesions have a whitish chalky appearance due to an optical phenomenon caused by mineral loss in the surface and sub-surface that alters the refractive index and increases the scattering of light in the affected area resulting in greater visual enamel opacity. [8] This unaesthetic aspect can be physiologically diminished by time through remineralization of the surface by diminishing areas that retained the plaque and because of enhancing local hygiene. The ion exchange between saliva and enamel causes the superficial surface area to beremineralized. In some cases, unaesthetic chalky white appearance remains permanently. [9]

Treatment modalities aiming to mask the chalky white lesions and making them less visible have been developed over the years. The most recent modality is based on the application of unfilled, low viscosity infiltrate resin to the affected lesion. [10] It has the advantage of preventing further lesion progression under demineralizing conditions compared to no treatment. [11] So, it fills the gap between prevention and restoration that is found in many in-vitro studies. [12] However, few studies evaluated white spot lesion masking with resin infiltration and not the long-term color stability of the treatment that could affect the patient satisfaction when used in esthetic areas.

On the other side, the traditional strategy for treating white spots was to remineralize incipient lesions with the use of fluorides. [13]. Remineralization process involves diffusion of phosphate and calcium into subsurface lesion to restore the lost tooth structure. [14] Fluoride increase the percentage of mineral deposition that helps to reharden the softened tooth structure, but still controversy about improving the milky color of the porous enamel or only reharden the surface layer and less effect on appearance.

Recently introduced highly filled, resin-modified glass ionomer-based light-curable fluoride varnish (Clinpro™ XT), the manufacture claims that it enhances the white spot lesion and provides a site-specific fluoride releasing coating for more than 6 months while traditional varnish sustains only four months.[10]

In the current literature, no Randomized Controlled Trials (RCTs) have evaluated the clinical performance of resin modified glass ionomer fluoride varnish versus resin infiltration, regarding degree of demineralization and esthetic behavior. This study would in turn affect selection of suitable material that consequently would benefit in treating the white spot lesions of post-orthodontic patients.

MATERIALS AND METHODS

Sample Size and esthics

The aim of this study is to compare color changes in patients complaining from white

discoloration in anterior teeth using Clinpro™ XT Varnish and ICON. The standard deviation of Icon was 2.8. The expected difference between 2 groups was 1.9, So it was needed to study 35 teeth in each group to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis was 0.05. [15]

Study Design

In a randomized controlled split mouth design, 6 participants (72 teeth) were enrolled with six upper and six lower anterior post-orthodontic white spot lesions. [Minimum 3 months of orthodontic debonding.]

Randomization was performed according to patient selection for the sealed envelope containing which half will receive the control (resin infiltration (ICON, DMG) and the other will receive the intervention (resin modified glass-ionomer cement varnish (Clinpro™ XT, 3M).Follow up was done after 1 day, 1 week, 1 month, and 3 months, 6 months and 12 months. (Figure 1)

This randomized controlled clinical trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT) Statement. [16] The CONSORT statement is an international consensus guide and checklist to improve reports on randomized controlled trials (RCT) reference. This study was approved by the Ethics in Human Research Committee of the faculty of Dentistry, Cairo University. Full protocol was published online in clinicaltrial.gov to avoid repetition and keep the integrity of the research work, with protocol number of NCT02912741.

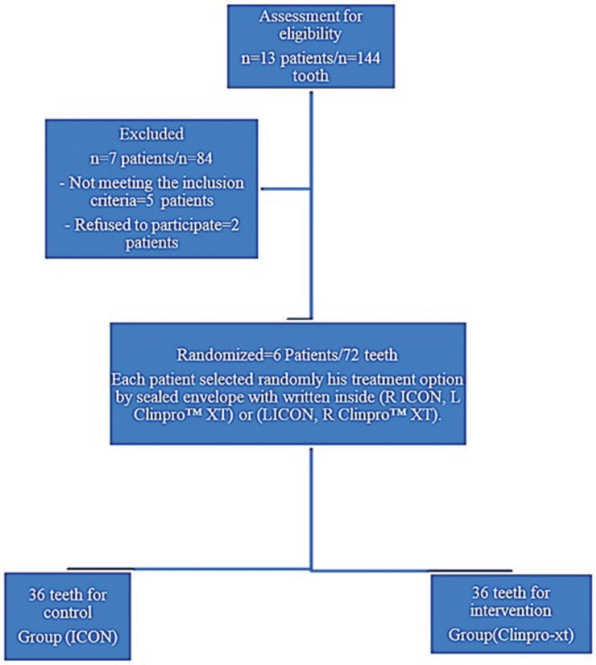

Figure 1 - Flow chart for the experimental design.

Setting, participants and recruitment

The Study took place at the outpatient clinic of Conservative Dentistry department in Faculty of Dentistry, Cairo University. Patients (age ranged from 15-25 years old) were recruited from the outpatient clinic of the Conservative department, Faculty of Dentistry, Cairo University. Each patient was informed of the nature of the study, consented to participate and signed a consent form. Inclusion and exclusion criteria used for enrollment of patients and investigated teeth are listed below.

Sequence generation, allocation and blinding

Patients were enrolled with six upper and lower anterior post-orthodontic white spot lesions. Teeth were divided into two groups: 35 for control (ICON) and other: 35 for intervention (Clinpro™ XT), that every patient will receive both treatments :(R) represent the right side or (L) represent the left side. Each patient selected randomly his treatment option by sealed envelope with written inside (R ICON, L Clinpro™ XT) or (LICON, R Clinpro™ XT).

At the setting place, patient had his number code and selected randomly between opaque sealed envelopes. Allocation concealment was ensured, as the service did not release the code until the patient had been recruited into the trial, that took place after all baseline measurement had been completed.

Satisfaction Assessment (VAS scale):

First, the patient was asked for his satisfaction by visual analogue scale (0-100mm), 0 score refer to not satisfied at all, while 100 score refer to totally satisfied for both upper anterior and lower anterior teeth. By instructing to look-into a mirror and assess each quadrant alone then the patient rated his satisfaction by making a vertical mark on the 100-mm line. The measurement in millimeters was converted to the same number of points ranging from 0 to 100 points. The exact question was "What is your degree of satisfaction at present?" This was done with each side of arch. [17] The patient was informed for repeating the same test after treatment is ended in the follow up periods.

Lightness assessment:

The colorimetric parameters of the white spot lesions for upper and lower anterior teeth, were assessed using an intraoral spectrophotometer (VITA Easyshade V, VITA Zahnfabrik, Bad Säckingen, Germany),

The device was set to assess degree of lightness "L" within ranges from 0 (black) to 100 (white). The lower L* values suggest the better masking effect and the color less white closer to the tooth structure. This assessment was done by selecting the Single tooth & Bleaching mode according to the manufactures' instructions for (VitaEasy shade V). [18] According to the manufactures' instructions, the area of the lesion was measured until two successive measurements report the same shade. Sound Adjacent enamel was recorded for each tooth as baseline data. Δ L Lightness change value= L* of WSLs- L *(baseline of normal tooth)

Assessment of Demineralization:

Assessing white spot lesions state for anterior upper and lower teeth, was done using Diagnodent pen 2910 (KaVo, Biberach an der Riss, Germany) to record the progression in the lesion area by time. It is based on usinga Diode laser with 655nm wavelength and power less than 1 mW. Laser is emitted from tip/sensor and detects back-scattered fluorescence from the tooth dental surface [19]. This laser light is absorbed by metabolites of intraoral bacteria that emit a red fluorescence. This fluorescence which is reflected by dental surface is indicated as a number-scores ranges: a reading between 0 and 10 indicates healthy enamel, between 11 and 20 suggests initial demineralization, between 21 and 30 means considerable demineralization, and greater than 30 indicates dental caries. This number offers the possibility to monitor lesion behavior. [20]

Data were recorded after application of the material: immediately, after 1 day, 1 week, 1month, 3 months, 6 months and 1 year.

Materials application

The teeth were polished with non-fluoridated pumice paste, using a low speed handpiece to remove the debris layer, and washed with water stream. Then, rubber dam isolation (Sanctuary Dental Dam 6X6) was done.

Application of each material was done according to the manufactures' instructions:

Resin infiltration (Control)

The surface layer of the WSLs was etched with 15% hydrochloric acid for 2 min to expose outer layer of the lesion body [21]. Then, lesion was washed for 30 seconds using water spray, followed by drying with compressed air.

Then, ethanol was applied for 30 sec followed by air drying. The resin infiltrate (ICON®- Infiltrate; DMG, Hamburg, Germany) was placed for 3 min to allow penetration and the excess was removed with dental floss. After

that, the resin infiltrate was light-cured for 40 s using a Light emitting diode (LED) (Woodpecker, 1200mW/cm^2, S/N H12020837B, China). That was followed byan application of a second layer of Icon-Infiltrate, for an additional minute and finally light-cured for 40 s.

Clinpro™ XTvarnish application (Intervention)

37% of phosphoric acid gel was applied on WSLs surface for 15 s for enamel etching. Then, lesion was washed with water spray followed by air drying for 5 s.

The material (paste/ liquid) were mixed for 15 seconds to obtain a smooth consistency and glossy appearance. The mixture was applied to the enamel surface using brush, in a thin layer and light-cured for 20 seconds.

Following these clinical procedures, each patient was informed to eat soft, non- abrasive diet and to not use a toothbrush on the same day of treatment. Patients were instructed to brush twice daily the following day with (Oral-B toothbrush, Procter&Gamble, US) with non-fluoridated toothpaste (Miswak, Dabur, India) to exclude the effect of the fluoridated tooth paste on remineralization progress.

Statistical analysis

Data were represented as mean and standard deviation and P value was set 0.05. The comparison between two treatment groups at different follow up periods was performed usingIndependent T-test regarding lightness and VAS. One-Way ANOVA test was performed to compare between upper and lower arches within the same treatment group followed by Tukey`s Post Hock test for multiple comparisons. The degree of demineralization using diagno-pen,exploration of normality of the data was performed using Kolmogorov-Smirnov/Shapiro-Wilk normality tests. Mann-Whitney U test performed to detect the level of significance between each group. Comparison between follow up periods within the same group was performed by Friedman`s ANOVA test. Statistical analysis was performed with SPSS 20® (Statistical Package for social science, IBM, USA), Graph Pad Prism®** Graph Pad Technologies, USA and Microsoft Excel 2016 (Microsoft Co-operation, USA.)

RESULTS

Lightness assessment

There was a significant improvement in lightness for ICON group after immediate application of the material in both upper and lower teeth. For Clinpro™ XT group, there was an insignificant change in lightness for upper and lower teeth in all follow up periods. Significant differences were found between both materials in all follow up periods. (Figure 2) (Table I)

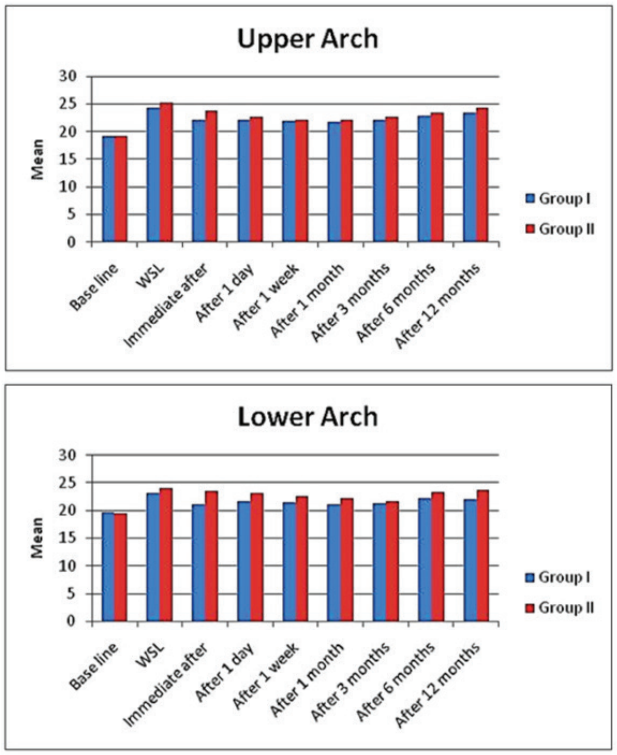

Figure 2 - Bar charts represent means of both groups at different follow up periods in upper and lower arches regarding Δ L.

Table I - Statistical Analysis showing comparison between two groups (ICON and Clinpro-xt)for Δ L regarding all follow up periods in, a. upper arch b. lower arch.

a. upper arch		Base line	WSL	After	1D	1W	1M	3M	6M	12M
ICON	Mean	19.2	24.4	22.1	22.2	21.9	21.8	22.2	22.9	23.4
	SD	1.3	2.7	1.5	0.9	1.3	0.9	0.7	1.3	1.7
Clinpro-xt	Mean	19.2	25.2	23.7	22.6	22.2	22.2	22.6	23.5	24.3
	SD	2.5	2.4	1.7	0.8	1.3	0.7	0.6	1.1	1.3
P Value		1.0	0.1	0.001 *	0.05 *	0.01 *	0.04 *	0.01 *	0.04 *	0.01 *

b. lower arch		Base line	WSL	After	1D	1W	1M	3M	6M	12M
ICON	Mean	19.7	23.2	21.1	21.7	21.5	21.2	21.3	22.2	22.1
	SD	1.4	2.1	2.1	1.7	1.6	0.9	0.8	2.1	1.2
Clinpro-xt	Mean	19.5	24.2	23.5	23.2	22.6	22.2	21.7	23.3	23.7
	SD	1.6	3.1	1.8	2.1	2.1	1.4	0.9	2.2	2.7
P Value		0.5	0.18	0.001*	0.001*	0.01 *	0.0001*	0.05 *	0.03 *	0.002 *

M: Mean, SD: Standard Deviation, P: Probability level. *significant difference.

Assessment of demineralization

Upper teeth and lower teeth revealed significant decrease in demineralization degree with resin infiltration after immediate application and kept stable. Clinpro™ XT showed also significant decrease in demineralization degree after immediate assessment. However, a significant increase in demineralization degree was found after 6 and 12 months. Insignificant difference was found between ICON andClinpro-xt in all follow up periods except in 6 and12 months (Figure 3) (Table II)

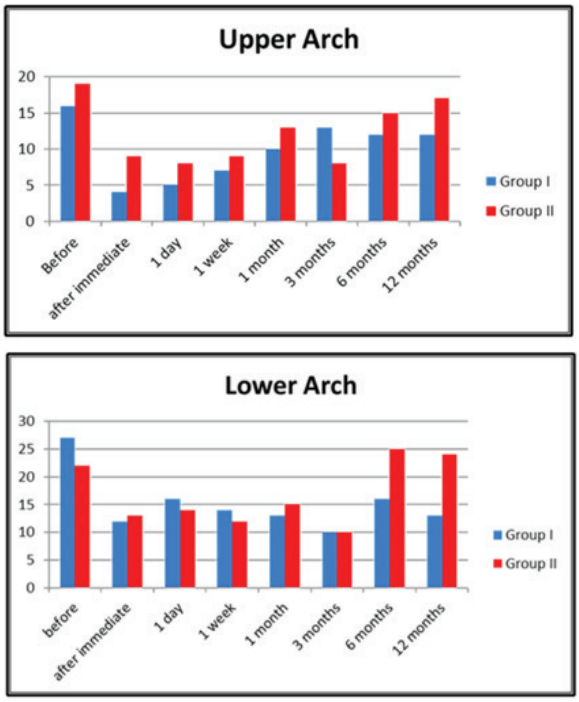

Figure 3 - Bar charts represent comparison between two groups for upper and lower arches regarding demineralization progress through all follow up periods.

Table II - Statistical analysis showing comparison for demineralization degree between two groups (ICON and Clinpro-xt) in, regarding all follow up periods a. upper arch, b. lower arch.

a. upper arch	Group I (ICON)		Group II (Clinpro-xt)		P value
	M	SD	M	SD	
Before	27	25	22	19	0.3
After immediate	12	13	13	7	0.6
1 day	16	19	14	10	0.5
1 week	14	8	12	8	0.2
1 month	13	12	15	8	0.4
3 months	10	7	10	7	0.9
6 months	16	13	25	18	0.01*
12 months	13	7	24	19	0.002*

a. upper arch	Group I (ICON)		Group II (Clinpro-xt)		P value
	M	SD	M	SD	
Before	16	24	19	14	0.5
After immediate	4	5	9	15	0.06
1 day	5	9	8	17	0.3
1 week	7	8	9	8	0.3
1 month	10	11	13	15	0.4
3 months	13	17	8	9	0.1
6 months	12	14	15	13	0.3
12 months	12	12	17	20	0.2

M: Mean, SD: Standard Deviation, P: Probability level. *significant difference.

Satisfaction assessment

Significant increase in satisfaction was found after immediate application of ICON and significant decrease in 12-month for both upper and lower arches. Clinpro™ XT showed significant increase after immediate application followed by significant decline. Significant difference was found between both materials in all follow up periods. (Figure 4) (Table III). The differences between upper and lower teeth were explained in tables I, II, III.

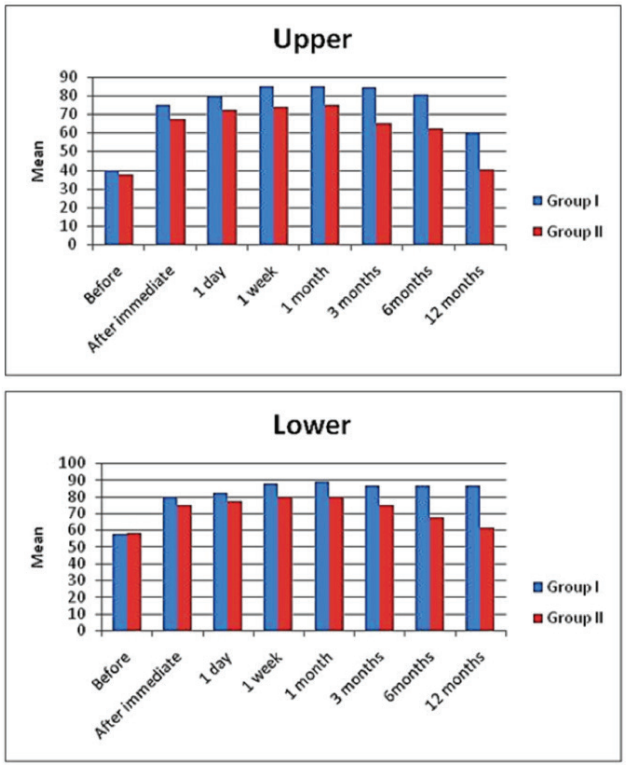

Figure 4 - Bar charts represent VAS comparison in upper and lower arches.

Table III - Statistical analysis showing comparison between group I (Icon) & group II (Clinpro XT) in VAS regarding all follow up periods in:a. upper arch, b. lower arch.

a. Upper	ICON		Clinpro-xt		P value
	M	SD	M	SD	
Before	40	7.1	37.5	10.9	0.2
After immediate	75	15	67.5	17.	0.05 *
1 day	79.25	15.1	72.5	13.2	0.05*
1 week	85	8.7	73.75	17.1	0.0008*
1 month	85	3.5	75	15	0.0003 *
3 months	84.6	4.3	65	15	0.0001 *
6 months	80.7	7.1	62.5	7.8	0.0001 *
12 months	60.3	8.9	40.2	9.8	0.0044*

b. Lower	ICON		Clinpro-xt		P value
	M	SD	M	SD	
Before	57.5	4.3	58.5	4.3	0.4
After immediate	80	6.1	75	10.6	0.01 *
1 day	82.3	10.6	77.5	10.1	0.05*
1 week	87.8	14.6	80	12.2	0.04 *
1 month	88.75	2.2	80	12.2	0.0001 *
3 months	86.25	2.2	75	8.7	0.0001 *
6 months	86.25	2.2	67.5	10.9	0.0001 *
12 months	86.25	2.2	61.25	8.9	0.000 *

M: Mean, SD: Standard Deviation, P: Probability level. *significant difference.

DISCUSSION

White spot lesion is an optical phenomenon due to subsurface tissue loss. The concept is based on changes in light scattering within the lesions as sound enamel has refractive index (RI) of 1.62. The microporosities of enamel carious lesions are filled with either a watery medium (RI 1.33) or air (RI 1.0). The difference in refractive indices between the enamel crystals and medium inside the porosities makes the light scattering that results in a whitish opaque appearance of these lesions. Infiltration the carious lesions with resin (RI 1.52) are in contrast to the watery medium which cannot evaporate and is similar to the apatite crystals. [11].

Color assessment was done using a VITA Easyshade® guide spectrophotometer. The instrumental color analysis offers a potential advantage over visual color determination because instrumental readings are objective, rapid and can be quantified. Spectrophotometers are among the most accurate, flexible, and useful instruments for color matching.[22] Color measurements were quantified in terms of the coordinate value L* which established by the Commision international de l'Eclariage (CIE), that locates the color of an object in a three-dimensional color space. We only captured the L* value because the objective of this study was to evaluate the masking effect of WSLs based on the lightness scale. The L* represents the degree of lightness within ranges from 0 (black) to 100 (white). The higher the L* value the whiter the lesion, which means the higher degree of demineralization. The lower L* values suggest the better masking effect and the color closer to the tooth structure. [18]

Prior to resin infiltrant was applied, 15% hydrochloric acid to promote erosion of the surface layer (less than 30 μm of demineralized enamel) and allow the penetration of resin infiltration into the lesion body. This etching procedure possibly interferes with the surface color by removing minerals from the enamel. Then, application of (ICON-Dry; Ethanol) was done for removing water remnants inside micro-porosities. By capillary forces action, the infiltrate which a highly fluid resin, penetrates the enamel lesions and blocks the diffusion paths for cariogenic acids, subsequently promotes the early arrest of caries. [19] Icon creates a diffusion barrier inside the lesion by replacing lost minerals with resin. This concept closes the gap between preventive therapies and corrective restorations. [20,11]

Significant improvement after immediate application was found (decreased Δ L lightness change value). This may be due to the entrance of the resin matrix into the microporosities of enamel caries lesions that decreased the difference in refractive indices between porosities (RI) 1.0 and enamel which has refractive index (RI) 1.62 to be (RI) 1.4. [18] the same cause for on-spot effect of resin infiltration. The incomplete masking of the lesions that might be attributed to other factors play role in improving the mask effect (lesion and infiltration depth, lesion activity, complete or incomplete infiltration, polymerization shrinkage). [23] It was explained that 15% HCl is most suitable for removing approximately 40 μm of the hypermineralized surface layer which becomes quite thicker in inactive lesions, make incomplete conditioning. [21] It was proposed to repeat eroding the surface layer several times to completely remove it and consequently tonsure the deep penetration of infiltrates. As resin infiltration concept was developed from the basis of micro-invasive concept repetition of HCl erosion was thought to be studied further, thus in this study the manufacturer's recommendation was strictly followed. Our results were in agreement with previous studies. [20,22]

In contrast to Ou et al.[24], they explained that, regardless of infiltration depth, the enamel surface and most of the carious lesion bodies were filled with infiltration resin matrix, resulting in nearly the same light reflectivity and performance for color measurement.

At one year of follow up period, a statistically significant increase in lightness; this could be attributed to the resin composition of the material with properties influenced by water. Water may promote a variety of chemical and physical processes that create biological concerns as well as produce deleterious effects on the structure and function of the polymer matrix itself. [25] Effect of water was in indirect way by the hydrolytic degradation effect reducing the optical properties and clinical performance.

Resinous materials are susceptible to extrinsic and intrinsic pigmentation over the

course of time, degradation and wear which is influenced by the rate of water absorption of the material and degree of polymer conversion of the monomers. [26]

A recent study done by Arslan et al. [27] was in agreements with this study. They explained the cause due to presence of TEGDMA containing polymer which is responsible for its superior infiltration ability, cause water sorption and solubility properties. This monomer is highly hydrophilic and may undergo degradation in oral environment, reducing clinical performance. These findings were also in accordance with Inagaki et al. and Altarabulsi et al., [28,29] who found statistical significant decline in color or resin infiltration after 12 month follow up.

In opposite to Knösel et al. [15], who found no significant changes after 24 months with acceptable esthetic results. This was due to early infiltration following debonding. In addition to Cazzollaet al. [30], he explained the effectiveness of the material that carious lesions with a severity not greater than D1* the ICDAS (International Caries Detection Assessment System), will give best results.

Lower anterior teeth results showed statistically significant change in lightness after immediate application giving better improvement but the lesion was still visible, this could be due to the shallower lesion depth found in mandibular teeth due to saliva role and proximity to salivary glands as reported in the vivo study by Chapman et al. [31]

Regarding Clinpro-xt, non-statistical significant change in lightness for upper and lower anterior teeth occurred, this could be due to the erosion protocol for the white spot lesion by application of 37% of phosphoric acid (15 s) that incapable of removing the outermost hypermineralized layer to allow penetration of the material and the thick consistency of the material due to presence of (Bis-GMA network) produced thicker layers leaving voids inside the lesion does not match the refractive index of the sound enamel. These explanations meet the same results found with Meyer-Lueckel et al. [32] , Vianna et al. [10]

The detection of demineralization degree using quantitative light fluorescence method is much more sensitive than direct visualization. It was evident that using this method is useful clinical adjunct in diagnosis and follow up monitoring in orthodontic patients. [33] DIAGNOdent is an effective tool for evaluating decalcification. It has high specificity for lesions in the outer half of the enamel. [34] It was found a correlation of 0.76 between the DIAGNOdent scores and incipient enamel lesion depths. [35] Also, it has been reported to have excellent reliability indicating consistent performance that make it suitable for longitudinal monitoring of carious lesions and aid clinical decision making with respect to management of orthodontically induced surface lesions. [36] It is sensitive enough to detect small changes in carious lesions over time. Recently, it was concluded that, DIAGNOdent could be used to assess the efficacy of fluoride varnish in preventing white spot lesion. [37]

ICON Group showed immediate significant decrease for both upper and lower teeth. This may be due to infiltrated micropores with resin that inhibit caries progression through mechanical blockage.Also, these results were in accordance to Yuan et al. [38] and Poggio et al. [39]

Clinpro™ XT light-curable fluoride varnish (LCFV) possibly provides a burst of fluoride released during the first few days after placement, and long-term sustained fluoride release over the life of the coating. The fluoride resides in fluoroaluminosilicate glass particles: reaction at the surface provides the immediate release, while the interior provides a reservoir of fluoride for sustained release. Clinpro™ XT Varnish is a resin-modified glass ionomer material that can

release F, Ca, and P, and recharge with fluoride-containing toothpaste and mouth rinse.F ion release from fluoro-aluminosilicateglass might act to form fluoroapatite, with the result that enamel demineralization would be inhibited. In addition, released Ca and P ions might inhibit local demineralization by their buffering effect and enhance remineralization, compared with other coating materials.

Application of Clinpro™ XT is also preceded by acid etching with 37% phosphoric acid for etching the outer-most mineralized layer allow material penetration inside the lesion.[40] It also contains calcium glycerophosphate, which can provide calciumandphosphate release over the life of the coating 3–6 months. [37]

Significant decrease in demineralization degree was found after immediate application for upper and lower teeth. This could be due to formation of mechanical barrier. This finding was in accordance with Sohn et al. [41].Also, Bozza et al, [42] explained more by the effect of fluoride, calcium, phosphate released from varnish.

Then, significant increase in demineralization condition in 6 and 12 months follow up was noted. This could be due to degradation of the material by time and the rougher surface. Poggio et al. [39], stated that the rougher surfaces absorb more salivary proteins and, consequently, more bacteria. In addition to decline in concentration of fluoride, as the bacterial content increases by decreasing the fluoride concentration. [43, 44] Moreover, recharge of fluoride by tooth paste is absent in this study. Our results were in agreements with Shahet al. ,Mehta et al., and Alsayed et al. [40, 45,46], voids and cracks have been attributed to the continuous internal acid-base reactions known for glass ionomers and could also be due to the effect of the acidic environment on the integrity of material.

According to the manufacture claim, Clinpro-xt offers protection through more fluoride release in both the short term (releases more fluoride over a 24-hour period) and the long term (over 6 months longer than other coatings) and this product has a high filler content imparts wear resistance that can resist up to 5000 strokes of brushing. Within the ambit of this study, these claims could not be verified, and future histological studies must be conducted to verify them. Mehta et al. [45], agreed with our concern.

Depending on the concept about the very superficial WSLs completely disappear by remineralization, thus they were excluded from this study, as they do not need any further treatment. This reason why was a period of 3months post orthodontic patients were selected, to allow the remineralization process to take place. [15]

Degree of demineralization was found different in upper teeth (Higher demineralization or deeper in depth) than lower teeth (shallower). This might be due to effect of saliva. (Ogaard B 1989)[3]. (Treatment was randomized in split mouth (right & left sides) to ensure that material will have different behavior on Shallow and deeper WSLs

A split-mouth study design creates divisions within the mouth of patients who constitute the experimental units randomly assigned to treatments [47]. This kind of study design is very popular in dentistry, particularly in the fields of orthodontics and periodontics. In a split-mouth study design, the subjects have the both control and experimental materials, thus eliminating inter-subject variability and increasing the power of the study compared to a design where a subject (whole mouth) is assigned to a treatment [48].

Patients were advised not to have any form of external fluoride supplement and were asked to refrain from any fluoride rinses and any form of fluoride treatment for the entire

duration of the study to reduce the bias, only non- fluoridated tooth-paste used twice daily.

Despite the inherent subjectivity in valuing outcomes of white spot lesions treatment, most studies have been focused on the physical properties and effectiveness of resin infiltration and ignored the perceptions of patients. For ICON group statistically significant increase was found in satisfaction after immediate application of the material. This was in accordance with Mahran et al. [49]. It was stated that this could be due to the camouflage effect of the material. Also, they found non- significant change after 3months and 6 months showing stability for 6 months as our findings. Decline occurred after 12 months, this was due to the change in optical properties after degradation of resinous material in composition. [26]

For Clinpro-xt, upper and lower anterior teeth showed statistically significant improvement in score immediate after application of the material although the white lesion was still detectable, Also, a statistically significant decline in satisfaction of the patients after 3 and 12 months.

In comparison between both groups in both upper and lower anterior teeth regarding the VAS scale, there was a non-statistically significant difference between WSLs before the application of the material. This gave us a good point for qualitative comparison of the material behavior toward satisfaction. Results for all follow up periods had a statistically significant improved effect of resin infiltration rather than resin modified glass ionomer varnish (Clinpro™ XT).

The limitation of our study was the questionable cross-effect of fluoride released From clinpro-xt on the other ICON segment. This might lead to improvement of demineralization inhibition

CONCLUSION

Concerning enhancement of esthetics, resin infiltration should be considered more as an alternative treatment rather than fluoride varnish. Clinpro™ XT is considered as a preventive protocol, provided that renewal application is needed after 3 months.

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