Original Article

Resin Infiltration Technique and Fluoride Varnish on White Spot Lesions in Children: Preliminary Findings of a Randomized Clinical Trial

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Abstract

Aim: To clinically assess the efficacy of resin infiltration versus fluoride varnish for arresting white spot lesions (WSLs) on permanent teeth in children. **Subjects and Methods:** Among the children referred to the our University, Faculty of Dentistry, Department of Pediatric Dentistry, 23 aged between 8–14 with 81 anterior WSLs were included in the study. The participants were randomly assigned to either the resin infiltration group or the fluoride varnish group. WSLs were assessed using a laser fluorescence device (DIAGNOdent pen, Kavo, Germany) and were characterized at baseline, immediately following resin infiltration application and at a 6-month follow-up. For the statistical analyses, the IBM SPSS Statistics 22 (IBM SPSS, Turkey) program was used to assess the findings of the study. **Results:** Participant retention was 100% at 6 months. There was no significant difference between the two groups when baseline DIAGNOdent (DD) values were compared ($P > 0.05$). The reduction in 6-month follow-up DD values were statistically significant in both groups relative to baseline values. The 6-month values of the resin infiltration group were statistically lower than those of the fluoride varnish group ($P = 0.028$, $P < 0.05$). **Conclusions:** Resin infiltration and fluoride varnish are clinically feasible and efficacious methods for the treatment of anterior WSLs. The inhibition of caries progression by resin infiltration should now be considered an alternative to fluoride treatment.

Keywords: *Children, fluoride varnish, resin infiltration technique, white spot lesions*

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Introduction

Dental caries is one of the most common diseases of the hard tissues of the teeth in children; it originates from interactions between cariogenic bacteria in dental plaque, fermentable carbohydrates (primarily sugars), and an imbalance in the process of demineralization and remineralization over time.[1] The first clinical sign of enamel caries is a white spot lesion (WSL) or initial caries lesion, which is defined as subsurface enamel porosity from carious demineralization that presents itself as a milky-white opacity when located on smooth surfaces.[2] These lesions are demineralized surfaces that are restricted to enamel and are non-cavitated. They have a more porous subsurface than sound enamel. WSL is the earliest stage of the caries process, and at this stage, it can be arrested or remineralized.[3] The non-invasive or minimally invasive interventions for these lesions are of great importance for the prevention of extensive tooth destruction caused by the progression of caries and for reducing treatment duration and cost.[4] In addition, anxiety toward dental drilling is a severe problem in dental practice and leads to avoidance behavior, particularly in children. Routine operative treatment is challenging to perform and may require special behavior management.[5]

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To date, the efficacy of several different methods in the treatment of WSLs has been investigated.[4,6] Great attention has been devoted to the non-invasive treatment of WSLs with the use of topical fluoride agents (e.g., toothpaste, fluoride containing mouth rinse, gel, and varnish) associated with diet and good oral hygiene to promote lesion remineralization.[7] Remineralization, the natural repair process for non-cavitated lesions, relies on calcium and phosphate ions, assisted by fluoride, to rebuild a new surface on existing crystal remnants in subsurface lesions remaining after demineralization.[8] Fluoride ions incorporate into remineralizing enamel/dentin, changing carbonated apatite to a fluoroapatite-like form that is more acid-tolerant and imparts additional acid resistance to the hard tissues.[9]

Fluoride plays a key role in the prevention and control of dental caries. However, this approach is not always successful, as it requires sufficient compliance of the patient and a change of harmful habits, with many of the patients abandoning the treatment before completion.[10]

Caries resin infiltration represents a new concept in dentistry, offering beneficial clinical applicability for clinicians and high acceptance by patients; such infiltration is effective in arresting smooth-surface enamel lesions in randomized and controlled clinical trials[11-13] and is an alternative approach to treat early caries lesions that are not expected to remineralize or arrest by non-invasive measures when the infiltration is performed with low-viscosity light-curing resins (i.e., so-called infiltrants). This technique aims to fill the intercrystalline spaces within the lesion body, which act as diffusion pathways for acids and dissolved minerals, thus sealing the lesion without a covering resin coat. After polymerization, the infiltrant occludes diffusion pathways for cariogenic acids and dissolved minerals.[14,15] From the available *in vitro*, *in vivo,* and *in situ* studies, it seems convincing that the RI of enamel lesions is effective in arresting and stabilizing the progress of WSLs.[16,17] This technique is considered micro-invasive and may bridge the gap between the non-invasive and minimally invasive treatment of WSLs, postponing the need for a restoration as long as possible.[18]

As this technique is relatively new, there is a lack of data on its outcomes in children. The aim of this current study was to clinically assess the efficacy of the resin-infiltration (RI) technique versus fluoride varnish (FV) for arresting the WSLs on permanent teeth in children.

Subjects and Methods

The study was approved by the Clinical Research Ethics Committee of Medical School (protocol number: C-02). Informed written consent was obtained from the children's parents or guardians prior to their enrolment in the study, according to the ethical guidelines of the 2008 declaration of Helsinki.

Participant selection

Children with WSLs on their maxillary anterior teeth were selected at the time of their regular dental visits in the Pediatric Dental Clinic at our University, Dentistry Faculty, Department of Pediatric Dentistry. Clinical selection was conducted using a mouth mirror, periodontal probe, and airway syringe by a single examiner. Inclusion criteria were as follows: the presence of at least one active smooth-surface WSL on permanent anterior teeth with DIAGNOdent (DD) results between 6 and 20 [D1 and D2, Table 1]; age between 8 and 14 years; and informed consent. Exclusion criteria were as follows: had orthodontic treatment; current participation in another study; and long-term systemic illness or withholding informed consent.

From 108 screened participants, 23 children with 81 teeth met the inclusion criteria, gave their informed consent and were enrolled in the study. Children that presented other needs for dental treatment were referred to treatment, and all participants were instructed regarding general oral hygiene and dietary habits.

Treatment

Before treatment, teeth were cleaned and rinsed thoroughly, and the surfaces of test sites were examined using DD according to the manufacturer's instructions. The device was calibrated before each surface to be analyzed. Baseline readings for each tooth were obtained by placing the probe on sound tooth structure. Three measurements were taken, and the mean was considered a final baseline value. Only teeth that scored D1 and D2 were included in this study.

Following examination with DD, two parallel groups were defined according to the active treatment received: RI (Icon®, Dental Milestones Guaranteed-DMG, Hamburg, Germany) and FV (5% sodium fluoride) (Clinpro™ White Varnish (3M UNITEK, Monrovia, CA, USA) groups. The participants were randomly allocated to each group using an electronic random number generator. Treatments were performed by a single trained investigator.

Treatment procedures

Resin infiltration

The lip retractor, cotton roll, and a gum shield were applied to achieve dry working conditions. The RI technique was performed according to the manufacturer's instructions. A 15% hydrochloric acid gel (ICON-Etch, DMG, Hamburg, Germany) was applied on the surface layer of enamel for 120s. Subsequently, the etching gel was thoroughly washed away for 30s using a water spray and dried. The lesion was desiccated using ethanol (99%; ICON-Dry, DMG) for 30s followed by air drying. A low-viscosity resin (ICON-Infiltrant, DMG) was applied to the enamel surface and allowed to penetrate inside for 3 minutes. Excessive material was wiped away using a cotton roll from the surface before light curing. After light curing for 40s with an intensity of 1200–1350 mW/cm^2 (GC D-Light Duo LED Curing Light, Tokyo; Japan), the application of infiltrant resin was repeated once for 1 minute and light cured for 40s. Finally, the roughened enamel surface was polished using composite resin polishing discs (Sof-lex, 3M ESPE, Saint Paul, MN, USA).

Fluoride varnish

Tooth surfaces were cleaned thoroughly and isolated with cotton rolls. According to the manufacturer's instructions, the unit-dose packages were opened, and the contents were dispensed onto the application guide and mixed to avoid the separation of sodium fluoride components. A thin coat of varnish was applied, and proximal areas were coated with dental floss. The patient was instructed to close his or her mouth to set the varnish in the presence of saliva and not to rinse or apply suction immediately after application. Children were advised to avoid eating hard and sticky foods or drinking hot beverages for the next 2 hours, to consume a soft diet, and to avoid brushing and flossing for the rest of the day.

Follow-up examination

In the RI group, the first DD examination was performed just after the RI treatment of treated surfaces, and the second was performed after 6 months. DD values were recorded as previously described. In the FV group, DD examination was performed only after 6 months. The examination with DD was repeated by a clinical investigator who was experienced, calibrated (k-value = 0.84) and blinded regarding the treatment group allocation of the teeth. The investigators attended a training and calibration session prior to the study. The collected data were subjected to statistical analysis.

Statistical analyses

For the statistical analyses, the IBM SPSS Statistics 22 (IBM SPSS, Turkey) program was used while assessing the findings of the study. The distribution of the parameters was evaluated by the Shapiro-Wilk test, and it was determined that the parameters were not normally distributed. The Mann-Whitney U test was, thus, used to compare the two groups of parameters. The Friedman test was used to evaluate changes in time for the RI group, and the Bonferroni correction and Wilcoxon signed-rank tests were used for intra-group comparisons. The significance level was taken as $P = 0.008$. The Wilcoxon signed-rank test was used in the intra-group comparison of the fluoride group. The overall significance of the study was assessed at $P < 0.05$.

Results

There was no loss of subjects from the beginning to the follow-up exclusion. Children did not report any complaints or unwanted side effects. Clinically, no unwanted effects, such as loss of vitality, staining, or gingival alterations were observed in either of the two groups.

The mean age of the children was 10.78 ± 2.08 years, with 10/23 (43%) females and 13/23 (57%) males. Twelve children with 45 teeth were allocated to the RI group, and 11 children with 36 teeth were allocated to the FV group.

Table 2 shows the evaluation of DD values in the RI group over time. There was a statistically significant difference ($P = 0.001$; $P < 0.05$) between the baseline, post-treatment, and 6-month follow-up values. The Bonferroni-corrected and Wilcoxon signed-rank tests were used to determine the period from which the significance was attributed. The level of significance was accepted as 0.008 (0.05/6 = 0.008). The reductions in the DD values post-treatment ($P = 0.001$) and at the 6-month follow-up ($P = 0.001$) were statistically significant relative to baseline values ($P < 0.008$). There were no detectable differences between post-treatment and 6-month follow-up DD values ($P > 0.05$). In the FV group, the 6-month follow-up DD values were significantly reduced relative to the baseline values ($P = 0.007$; $P < 0.05$) [Table 3].

Table 4 shows the evaluation of the baseline and 6-month DD values of the RI and FV groups. There were no significant differences between the two groups when baseline DD values were compared ($P > 0.05$). The 6-month follow-up DD values of the FV group were significantly higher

Table 1: Manufacturer's cut-off points for DIAGNOdent used in this study

Score	Fluorescence values	Clinical criteria
D0	0-5	No demineralization
D1	6-14	Outer enamel demineralization
D2	15-20	Inner enamel demineralization
D3	21-99	Dentin demineralization

Table 2: Evaluation of DIAGNOdent values in resin infiltration group over time

DIAGNODent values	Resin infiltration (mean±SD)
Baseline	12.96±4.22 (12)
Post-treatment	6.09±3.53 (6)
6th month	5.96±3.38 (5)
P	0.001*

Friedman test: **P*<0.05. SD=Standard deviation

Table 3: Evaluation of DIAGNOdent values in fluoride varnish group over time

DIAGNODent values	Fluoride varnish (mean±SD)
Baseline	10.86±5.49 (11)
6th month	8.50±5.07 (7)
P	0.007*

Wilcoxon signed test: **P*<0.05. SD=Standard deviation

Table 4: Evaluation of baseline and 6th month DIAGNOdent values of resin infiltration and fluoride varnish groups

DIAGNOdent values	Mean±SD		*P*
	Resin infiltration	Fluoride varnish	
Baseline	12.96±4.22 (12)	10.86±5.49 (11)	0.052
6th month	5.96±3.38 (5)	8.50±5.07 (7)	0.028*
Differences between baseline and 6th month	7.0±3.67 (7)	2.36±4.67 (3)	0.001*

Mann–Whitney U test: **P*<0.05. SD=Standard deviation

than those of the RI group ($P = 0.028$, $P < 0.05$). The RI group showed a statistically significant decrease in the amount of reduction in the 6-month DD values relative to the baseline values of the FV group ($P = 0.001$, $P < 0.05$).

Discussion

In this study, children with similar socio-economic backgrounds and hygiene practices were chosen to minimize the effect of any other etiological factors on the progression and regression of incipient lesions. The children who had WSLs on permanent anterior teeth or had orthodontic treatment were excluded from the study to avoid the risk of surplus etching during the bonding of braces and/or possible harmful effects on enamel during the debonding procedure. DD was used to monitor the remineralization of WSLs in this study. DD is a simple, clinically relevant and dependable tool for monitoring the progression and regression of WSLs following different therapies as described in a previous study.[19]

The present study was performed to determine the efficacy of the RI technique and FV on WSLs in children. Use of fluoride is a non-invasive choice for treating WSLs. If the varnish on the tooth surface is retained for a prolonged period, increased fluoride concentrations produce deposits of calcium-fluoride-like material. Fluoride from this calcium fluoride material, which is deposited in the pores and cariogenic sites in enamel, can gradually diffuse into the overlying dental plaque or underlying enamel. Cariogenic sites specifically absorb fluoride and subsequently release it for a certain period of time. Fluoride release can prevent demineralization and promote the remineralization of early WSLs.[20] Varnishes are also relatively easy to apply and are well tolerated, making them particularly well suited for children. Therefore, the varnish form of fluoride was selected for this study.

Naidu *et al*. reported a 40% reduction in the number of WSLs after 3-month follow-up FV application.[19] Similarly, another report confirmed that FV application was effective in reversing and arresting active enamel lesions, and therefore, reduced the need for restorative intervention.[21]

In the present study, in the FV group, it was found that the DD values of WSLs were significantly reduced from baseline to the end of 6 months. These findings were in accordance with previous studies, which reported significant remineralization of early enamel lesions with 5% sodium FV.[21,22]

In the present study, the application of FV was performed only at the first treatment appointment to reflect the usual clinical application of the FV in children and was not repeated until the 6-month follow-up. This application is different from that of previous studies, in which repeated FV applications were performed over a short period of time.[7,19]

The RI concept aims to arrest incipient enamel caries lesions (as opposed to removing them) and obstruct the diffusion pathways for acids and dissolved minerals in the enamel.[23] Consistent with this assertion, the results of this study show that RI significantly reduced the DD values post-treatment and at the 6-month follow-up from the baseline values of WSLs.

The results of previous studies that agree with this study indicate that RI is effective and minimally invasive and that this approach has advantages over other options for the treatment of WSLs.[15,16] Microabrasion, which has been used for the reduction of WSLs, removes up to 360 μm of the demineralized enamel.[24] In comparison, etching with 15% hydrochloric acid, as used in this study, has been shown to remove approximately 40 μm of the hypermineralized surface layer,[25] exposing the lesion body and allowing the resin to penetrate into the lesion body.[14] High-concentration fluoride treatment is contraindicated, as this approach enhances the remineralization of the superficial layer of the lesion, accelerating the arrest of remineralization in the subsurface portion of the WSLs.[26] Traditional resin-based composite restorations, veneers and crowns require the removal of enamel, and these treatment options are invasive and can pose challenges, particularly in children.

A further advantage of this technique is that unlike fluoride, infiltrant resin can improve color, even in deeper lesions, because the resin penetrates deeper lesions; the effect appears immediately after treatment.[5,27]

When the efficacy of the RI technique and fluoride treatment on WSLs were compared, the results of this study showed that the RI group showed a statistically significant decrease in the amount of reduction in the 6-month DD values relative to the baseline values in the FV group. In a recent study, the effectiveness of RI in conjunction with FV treatment versus FV treatment alone on facial smooth-surface caries lesions in children was clinically evaluated. The authors reported superior reduction in lesion progression for RI in conjunction with FV treatment than FV treatment alone.[28] In this study, RI treatment alone was found to be superior to FV treatment.

Our findings are also in agreement with a recent *in vitro* study that compared the effect of RI and FV (5% NaF) on enamel surface properties, in which the authors also found that the surface microhardness in surfaces treated by RI was significantly higher than that in surfaces treated by FV.[29] RI has been shown to significantly increase microhardness and reduce the mineral loss of bovine enamel after a demineralization challenge. The low-viscous light-curing resin infuses into the enamel and creates a diffusion barrier within it, thus occluding pathways for acid entry into the enamel. In contrast, the FV may create a relatively shallow layer coating.[30] It is important to note that the lesion body did not remineralize to the same level as the surface zone after fluoride application.[31] In this study, the reduction in DD values in the FV group was lower, possibly because the detection signal of DD comes from the body of the lesion, which cannot be completely remineralized.[32]

Conclusions

RI and FV are clinically feasible and efficacious methods for the treatment of anterior WSLs. RI reduced lesion progression in a single visit and provided continuity for follow-up intervals of 6 months. The inhibition of caries progression by RI should be considered an alternative to topical fluoride treatment.

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Conflicts of interest

There are no conflicts of interest.

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