



The efficacy of 38% silver diamine fluoride in preventing orthodontic white spots: a split-mouth randomized controlled trial

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Abstract

AIM. White spot lesions represent a negative and common adverse effect of fixed orthodontics. The research tried to establish the effectiveness of isolated use of 38% silver diamine fluoride in prevention of active white spot lesions during debonding of orthodontic appliances. The study was a randomized, split-mouth controlled, placebo-controlled, and a double-blind study.

MATERIALS AND METHODS. Split-mouthed randomized, double-blind, placebo-controlled trial was applied. Thirty teenagers (mean age 15.2 ± 1.8 years), whose bilateral active lesions on the anterior teeth occurred after debonding and had a minimum of two active white spots lesions on the anterior teeth were enrolled. Randomly, the lesions were divided in regards to treatment, whereby one time use was done with 38% silver diamine fluoride (experimental), or placebo solution (control).

RESULTS. The general finding was the stabilization of the lesions with a hard and smooth feel with a sense of touch upon examination after the assessment period, one- and three-months follow-ups. The alteration in the laser fluorescence (DIAGNOdent) scores and aesthetical satisfaction with patients were secondary outcomes. Silver diamine fluoride group had considerably variable arrestment rates than the placebo group at the three months follow-ups (93.3 and 16.7 respectively, $p < 0.001$). The mean scores (DIAGNOdent) in the silver diamine fluoride group were very low (32.1–18.4) than in the placebo group (30.8–36.9) ($p = 0.001$). It was determined that the patient satisfaction in reference to the black stain after the usage of SDF was insignificant; its mean value was 2.8 out of 10.

CONCLUSIONS. 38% silver diamine fluoride used as a single application on an individual patient is fairly effective in the prevention of white spots lesions associated with orthodontics, although its acceptance is low due to its staining effect. Silver diamine fluoride is an aesthetically problematic good solution that can be applied to treat the post-orthodontic white space lesions especially in patients with a high risk of caries.

Keywords: silver diamine fluoride, white spot lesions, orthodontics, minimally invasive dentistry, caries arrest, randomized controlled trial

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Эффективность 38% диаминфторида серебра в профилактике белых пятен эмали при ортодонтическом лечении: рандомизированное контролируемое исследование с разделением по половинам зубного ряда (split-mouth)

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Резюме

ЦЕЛЬ. Белые пятна эмали (White Spot Lesions, WSLs) являются частым и неблагоприятным осложнением несъемной ортодонтической аппаратуры. Исследование направлено на оценку эффективности изолированного применения 38% диаминфторида серебра (Silver Diamine Fluoride, SDF) для профилактики активных белых пятен эмали после снятия ортодонтических конструкций. Проведено рандо-

мизированное, контролируемое исследование с разделением по половинам зубного ряда, плацебо-контролем и двойным ослеплением.

МАТЕРИАЛЫ И МЕТОДЫ. В исследование включены 30 подростков (средний возраст $15,2 \pm 1,8$ года), у которых после снятия ортодонтической аппаратуры выявлялись двусторонние активные поражения передних зубов, при наличии минимум двух активных белых пятен. Случайным образом поражения распределялись на две группы: однократное применение 38% диаминфторида серебра (экспериментальная группа) или плацебо-раствора (контроль).

РЕЗУЛЬТАТЫ. Основным результатом было стабилизирование поражений, проявляющееся плотной и гладкой поверхностью при зондировании через 1 и 3 месяца наблюдения. Вторичными исходами являлись изменения показателей лазерной флуоресценции (DIAGNOdent) и эстетическая удовлетворенность пациентов. В группе диаминфторида серебра показатели остановки процесса через 3 месяца были значительно выше по сравнению с плацебо (93,3% и 16,7% соответственно; $p < 0,001$). Средние значения DIAGNOdent в группе диаминфторида серебра были существенно ниже (32,1–18,4) по сравнению с контрольной группой (30,8–36,9) ($p = 0,001$). Удовлетворенность пациентов, связанная с появлением темного окрашивания после применения диаминфторида серебра, была низкой и составила в среднем 2,8 из 10.

ВЫВОДЫ. Однократное применение 38% диаминфторида серебра является эффективным методом профилактики белых пятен эмали, ассоциированных с ортодонтическим лечением. Однако его широкое использование ограничено эстетическим побочным эффектом в виде окрашивания тканей зуба. Диаминфторид серебра может рассматриваться как клинически значимое решение для пациентов высокого кариес-риска при постортодонтических поражениях эмали.

Ключевые слова: диаминфторид серебра, белые пятна эмали, ортодонтия, минимально инвазивная стоматология, остановка кариеса, рандомизированное контролируемое исследование

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INTRODUCTION

The finalization of the fixed orthodontic treatment is a significant achievement to the patients, which results to the acquisition of a superior connection of the occlusiveness and a rise in the aesthetics of the face. However, the appearance of white spot lesions (WSLs) which are the most frequent and the most evident iatrogenic complication of treatment is likely to mar such successful result [1]. WSLs are the clinical symptoms of the caries process first, and they are presented in the form of opaque and white spots on the enamel surface due to the demineralization of the subsurface. This is because the oral environments promoted by local microclimate of fixed appliances are challenging, which promotes the growth of plaque and allows the proliferation of the niche zones of acidogenic bacteria to induce a sustained loss of pH at the enamel surface [2]. It is very high and WSLs prevalence is reported to be as high as 70% of the orthodontic patients, which equates to high clinical burden, and it leaves the patients dissatisfied after the procedure was performed [3; 4].

The traditional management concept of WSLs has been on remineralization and prevention of further demineralization. They include the use of high-concentration fluoride varnishes, use of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) and rigorous oral hygiene education [5; 6]. Though these methods are likely to be effective, their efficacy is very erratic and highly dependent on the long-term adherence of patients- a variable that cannot always be predicted particularly in adolescent groups [7]. Consequently, re-

gardless of preventive therapy, the lesions which fail to heal or persist are still large and leave physicians with a limited number of options not being invasive when the lesions have already been demineralized.

The Silver Diamine Fluoride (SDF) has been revived in the present version of minimal invasive dentistry in the past years. It is a clear, liquid and 25% silver 5% fluoride agent that has been broadly established as an extremely proficient and non-invasive agent in arresting cavitated carious lesions in primary teeth and in special needs populations [8; 9]. The mechanism of action is two-fold and potent: the silver ions possess an intense antibacterial effect due to damage to the cell walls and inhibition of the essential enzymes, and the fluoride ions provoke the remineralization and formation of the protective layer on the surface of the lesion of fluoroapatite and silver phosphate [10; 11]. It has been demonstrated to be highly effective in systematic reviews and meta-analyses of which one of them led to caries arrestment in the majority of cases [12; 13].

This was a good evidence base of cavitated lesions although the use of SDF in early non-cavitated orthodontic induced WSLs immediately after debonding is a relatively new area of research and under-studied. The fact that SDF may be a clean, once-only therapy of these widespread lesions is enormous. In its pre-eminence is its greatest drawback, however, that it leaves the carious tissue permanently stained black, which is a major turnoff against its application, especially on anterior teeth that are highly visible [14; 15]. This is a marker of successful lesion arrestment, and, at that,

it creates a cosmetic dilemma of monumental magnitude to the patients and the clinicians.

Therefore, there is an urgent need to find high-quality evidence to evaluate the clinical effectiveness of SDF versus its aesthetic implications on the orthodontic patients. The main hypothesis of this split-mouth randomized controlled trial was to strictly test the hypothesis that a single application of 38% SDF is superior to placebo in arresting active WSLs following the removal of fixed orthodontic appliances. The other aim was to find the level of patient satisfaction with the resulting aesthetic outcome and it was quantitative.

MATERIALS AND METHODS

Methodology and research subjects

It was a prospective split-mouth, random, controlled placebo, double-blind and split-mouth clinical trial done as per the Consolidated Standards of Reporting Trials (CONSORT). In Baghdad University, the College of Dentistry, ethical consent was taken. All the participants and their guardians were informed to give informed consent and assent.

The sample size was 30 participants, 16 being females and 14 males (15.2 ± 1.8 years). The target group was recruited in an orthodontic clinic (January 2024–June 2024). The inclusion criteria were as follows: (1) patients of 12–16 years old and had completed a full course of fixed orthodontic treatment; (2) had at least 2 active and non-cavitated WSLs [International Caries Detection and Assessment System (ICDAS) code 2] and were bilaterally located in symmetrically placed front teeth (between canine and canine teeth). The exclusion criteria included: (1) history of known hypersensitivity to silver; (2) already had cavitated lesions (ICDAS 3 or above), enamel hypoplasia, or fluorosis; (3) contraindication with medical conditions to normal dental care.

Calculation of sample size

Power analysis using the G*Power software (3.1.9.7) was used. The alpha (α) error probability of 0.05 and the power ($1 - \beta$) of research test led to the sample size requirement of $n = 30$ pairs of lesions as shown in a pilot study and the literature [16].

Randomization and concealment

The qualifying WSLs were assessed following the debonding and the professional prophylaxis. The patients were selected at random in the Test and in the other lesion Control group (38% SDF, Advantage Arresttm, Elevate Oral Care and the placebo: a fluoride-free, colored aqueous solution respectively).

Trial assignment was made by a computer-based list with randomization and assigned in sequentially numbered envelopes. This was done by merely one operator who was not involved in the results analysis. No one, especially the patients, and the outcome assessor, were aware of the group allocations.

Intervention

The tooth was isolated using cotton rollers, dried using air in five seconds and a microbrush was immersed in the respective solution, and directed to the lesion in sixty seconds, as recommended by the manufacturer. Any excess solution was cleared using dry microbrush.

Performance indicators

Baseline measurements, one-month measurements, and three months measurements were implemented:

1. Major outcome: lesion arrest. Lesions were evaluated on the basis of a blind, sharp sickle explorer. An arrested lesion was hard and smooth to feel. A stretchy or elastic lesion was referred to as active [17].

2. Secondary review: laser fluorescence. A DIAGNOdent Pen (KaVo), the caries mineral status was identified through an established technique of measuring caries activity [18]. The maximum distance was the distance between the lesion site and the place.

3. Patient acceptance. Three months post-treatment, patients used a Visual Analog Scale (VAS) to rank their satisfaction with the appearance of the treated lesions with 0 (unsatisfied with the appearance of the treatment site entirely) to 10 (satisfied with the appearance of the treatment site entirely) [19].

Data examination

The SPSS Statistics version 28.0 was used to analyze the data. The main result was analyzed with the help of the McNemar test. The scores of DIAGNOdent were evaluated using repeated-measures ANOVA and paired *t*-tests to determine the changes in the values. The approach that was used to analyze the patient VAS scores was the paired *t*-test. A *p*-value that was lower than the value of 0.05 was regarded as significant.

RESULTS

Lesion arrestment

The summary of the clinical arrestment rates is presented in Table 1. At the one-month follow-up, the group of SDF at the time of arrest (86.7) was much higher on average as compared to the placebo group (10.0) ($p < 0.001$). After 3 months of follow-up, lesions in SDF group (28 out of 30 lesions) were arrested as opposed to 5 out of 30 lesions in the placebo group ($p < 0.001$).

Table 1. Lesion arrestment rates

Таблица 1. Показатели остановки кариозных поражений

Group	Baseline [Active lesion]	One Month [Arrested lesion]	Three Months [Arrested lesion]
SDF	30/30 (100%)	26/30 (86.7%)	28/30 (93.3%)
Placebo	30/30 (100%)	3/30 (10.0%)	5/30 (16.7%)

DIAGNOdent evaluations

Table 2 presents the shift in the mineral structure as recorded by DIAGNOdent. The baseline scores of the SDF condition and placebo were not significantly different ($p = 0.42$). The three-month observation showed significant and consistent improvement in the mean scores in the SDF group, which was an indicator of remineralization. Instead, there was a significant rise in the scores in the placebo group which reflected lesion progression.

Table 2. Time-Dependent average DIAGNOdent Scores (Standard Deviation)

Таблица 2. Средние значения показателя DIAGNOdent в динамике (стандартное отклонение)

Group	At baseline	One month	Three month	p-value (within group)
SDF	32.1 (4.5)	21.3 (5.1)	18.4 (4.8)	< 0.001
Placebo	30.8 (5.2)	33.9 (5.8)	36.9 (6.5)	< 0.001
p-value (among groups)	0.42	< 0.001	< 0.001	–

Patient acceptance

This aesthetic result was much more unacceptable to the patients who received SDF lesions. The mean score of VAS satisfaction in the SDF group was 2.8 ± 1.5 , and the placebo group was 7.1 ± 1.8 ($p < 0.001$).

DISCUSSION

The results of the randomized controlled trial present the strong Level I data that indicate that single application of 38% SDF is an outstanding method to prevent active white spots lesions during the post-orthodontic period. The 93.3% in the SDF group at the 3 months follow of arrest is not only statistically significant but also clinically significant which is a tremendous improvement compared to the low natural arrestment rate at placebo. This finding agrees with the literature available on the effectiveness of SDF to prevent cavitated dentinal caries in the primary teeth because the systematic studies have demonstrated equal success rates [12; 20]. The effectiveness of SDF being rapid and 86.7% of the lesions being solved in such a short time frame of only a month, proves that the treatment can be highly effective in clinical cases where a significant number of lesions is involved.

The objective data of DIAGNOdent readings that are quantifiable give the additional evidence on the mechanism of action of SDF. The large and steady decrease in the values of fluorescence in SDF group mean the gradual increase in enamel density and mineral structure, and the development of a hypermineralized, sclerotic surface layer [11; 16]. This hardened layer is an additional physical barrier against cariogenic microorganisms besides it being more resistant to being exposed to acid. The gradual increase of the scores of DIAGNOdent in the placebo group justifies the continuation of cariogenic issues despite the orthodontics treatment. It implies that such premature lesions are highly likely to proceed with further demineralization and result in cavita-

tion without such a powerful and definite intervention as SDF and can be reinforced by the long-term follow-ups of the WSLs [17].

The most interesting and intricate result of this study is that the outstanding clinical effectiveness and the significantly low patient acceptability vary significantly. The average satisfaction of 2.8/10 on the lesions treated with SDF compared to 7.1/10 on the lesions treated with the placebo is an obvious and significant treatment issue. The aesthetic tradeoff is what builds the greatest challenge to the broad application of SDF on visible surfaces, as widely reported in literature [14; 15]. The emergence of black discoloration is impossible to correlate with the chemical reaction of silver ions with decalcified tissue, which may be provided as the visual indication of stagnant lesion. This presents a big and weighty appraisal decision on both the clinician and the patient: Is the short-term gain of high-efficacy and instantaneous caries arrest worth the cosmetic opportunity cost in the long term? According to the current clinical practice recommendations, a collaborative decision-making process should be used to attain such a decision [18]. It would be better used in high-risk patients of caries, where the treatment of the disease is necessary, lesions on less conspicuous surfaces, or when the conditions of access to restorative treatment are low.

This study has some constraints. The three months follow-up period of this research is insufficient since it merely shows the short-term effects but fails to determine the long-term sustainability of the results. Moreover, it fails to put into consideration several mitigating measures that may be implemented in case of stains. Future studies ought to focus more on longitudinal research studies based on a long follow-up. Combination therapies, which can preserve the efficacy of SDF and improve aesthetics, need to be investigated.

Adding potassium iodide (KI) immediately after the addition of SDF to lower the staining by the new silver iodide, that is less coloured, is controversial [19; 21]. The second option which can be taken is through the repetition of the SDF, which will prevent the lesion and then resin glass ionomer will be applied to cover the discolouration and provide the support to the porous enamel [22; 23]. Studies on these protocols would potentially reveal the maximum potential of SDF in aesthetically sensitive regions.

CONCLUSION

Single therapy 38% of silver diamine fluoride is highly good and effective in the prevention of the active lesions of the white spot following an orthodontic treatment. Their application on conspicuous anterior teeth is however much restricted because of a low acceptance of the product by the patients as a result of black staining. Thus, SDF can be regarded as a helpful tool in minimally invasive dentistry but it has to be thought out and it should be applied only when the caries arrest needs to be prioritized over the aesthetics or on the non-visible surfaces. The future research can be concentrated on the ways of how SDF therapy can be less stained and more aesthetic.

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AUTHOR'S CONTRIBUTION

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