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Research Protocol

Dentistry Section

Effect of Curing Light on Crown Discolouration of Restored Primary Teeth Following Silver Diamine Fluoride and Potassium Iodide Application: An In-vivo Study Protocol

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ABSTRACT

Introduction: Dental caries treatment has evolved from surgical methods to Minimal Intervention Dentistry (MID), which focuses on preserving tooth structure and utilising biological methods. Silver Diamine Fluoride (SDF) is a notable approach with strong antibacterial properties that prevent the growth of caries. Researchers have explored a method involving SDF, potassium iodide solution and Glass Ionomer Cement (GIC), which has shown minimal impact on caries-arresting effectiveness while enhancing the darkening of demineralised tooth surfaces.

Need of the study: By assessing the discolouration levels in primary teeth, the present study seeks to elucidate the potential role of curing light in exacerbating or mitigating discolouration. The findings will provide valuable insights into optimising restorative protocols to minimise discolouration and enhance aesthetic outcomes in paediatric dental practice, ultimately improving patient satisfaction and treatment efficacy.

Aim: To investigate the impact of curing light exposure on crown discolouration in primary teeth treated with SDF and potassium iodide.

Materials and Methods: An experimental study will be conducted in the Department of Paediatric and Preventive Dentistry at Sharad Pawar Dental College and Hospital, Maharashtra, India, from March 2025 to August 2025. The study will involve four groups: Group I, Group II, Group III and Group IV. Participants will be divided as follows: Group I will receive one drop of SDF applied to the carious tooth surface. Group II will receive one drop of SDF combined with potassium iodide. Group III will receive a drop of SDF solution. Group IV will receive a drop of SDF combined with potassium iodide. All groups will undergo curing treatment for 20 seconds. Follow-up appointments will be scheduled at one, three and six months to assess the progress of the treated tooth and evaluate the need for additional applications. Three time points will be used for color assessments: T0 (immediately after treatment) T1 (three months) T2 (six months). A dental spectrophotometer will be used to measure the color of the dentin surface adjacent to the restoration. Descriptive statistics and frequency distribution will be performed. An Analysis of Variance (ANOVA) test will be conducted for intergroup comparisons at $p<0.05$.

Keywords: Dental caries, Minimally invasive dentistry, Paediatric dentistry, Remineralisation

INTRODUCTION

The treatment approach for dental caries has evolved and advanced significantly over the past century. Previously, it was managed through a strictly surgical "drill and fill" method based on the principles of "extension for prevention" and G.V. Black's cavity designs. In recent years, with increasing knowledge and advancements, the concept of MID has emerged. MID emphasises the preservation of naturally occurring tooth structures and adopts a biologic approach toward the management of carious lesions.

The use of SDF, a compound introduced into dental practice by Nishino M et al., in 1969 for its ability to arrest dental caries, aligns with this modern trend [1].

SDF exhibits a high level of antibacterial activity, effectively destroying cariogenic bacteria and preventing the formation of multi-species biofilms on tooth surfaces. A 38% concentration of SDF is commonly applied topically to help prevent and arrest the progression of dental caries [2]. In modern dentistry, it is typically used as a preventive measure every six months or annually [3].

Following SDF application, silver deposition occurs, which darkens the affected area of the tooth. This takes place on both demineralised or decayed enamel and dentin. The deeper layers of the lesion become densely remineralised, with increased levels of calcium and phosphate, thereby protecting the collagen within the dentin of the arrested cavity. The resulting stain on the demineralised tissue is permanent and serves as a visible indicator of caries arrest [4]. The black stain appears within two minutes of application and may intensify over the following six hours [5].

To address this staining effect, a modified SDF treatment method has been developed involving the application of GIC after rinsing with a saturated Potassium Iodide (KI) solution (10% KI). Studies have shown that this approach has only a minimal impact on SDF's effectiveness in arresting caries [2,3]. When the SDF/KI precipitates are adequately washed before cement application [2], the bond strength of glass ionomer restoratives to dentin remains satisfactory. However, if the precipitates are not thoroughly rinsed, the bonding strength is significantly reduced [6]. Furthermore, the darkening of demineralised and carious tooth surfaces treated with SDF is enhanced when exposed to a curing light. The use of a curing light promotes additional silver precipitation within the affected dentin, increases its hardness and limits the penetration of SDF into sound dentin [4].

REVIEW OF LITERATURE

Zhao IS et al. studied the effects of KI and SDF on secondary caries prevention and tooth discolouration in GIC restorations using 30 premolars. The specimens were divided into three groups: Group I (SDF + KI), Group II (SDF) and Group III (no treatment). After exposure to a cariogenic biofilm challenge, demineralisation was evaluated using Fourier Transform Infrared Spectroscopy (FTIR) and micro Computed Tomography (micro-CT), while colour changes were assessed using the Commission Internationale de l'Éclairage

(CIELAB) colour system. Results showed significant differences in amide I-to-hydrogen phosphate ratios ($p<0.001$), with Group II showing the best outcomes. The study concluded that although SDF + KI reduced secondary caries compared to no treatment, it was less effective than SDF alone. Some staining was observed at the restoration margins, though it was less pronounced than that seen with SDF treatment alone [2].

Detsomboonrat P et al., studied 24 extracted teeth with carious lesions and categorised them into six groups: SDF only, SDF + 7.5% KI, SDF + 10% KI, SDF + 15% KI, SDF + 20% KI and SDF + saturated KI. The KI solution was applied immediately after SDF application. Tooth images were analysed for colour measurements at different time intervals. The study found a dose-dependent reduction in black staining following KI application, except in the saturated group. It concluded that KI application reduces black staining in a dose-dependent manner [6].

The effects of SDF therapy on primary teeth with untreated caries were investigated by Crystal Y.O. et al., in a study involving five groups of twenty-four teeth:

1. SDF application for one minute,
2. SDF application for ten seconds followed by twenty seconds of Light-Emitting Diode (LED) exposure,
3. SDF application for ten seconds,
4. Untreated and
5. Untreated with LED exposure.

X-ray spectroscopy and electron imaging were used to measure silver penetration. Groups 4 and 5 showed no silver deposition, while Groups 1 and 2 exhibited significantly higher silver penetration than Group 3 ($p<0.001$). The study concluded that silver penetration was enhanced when SDF was applied for ten seconds followed by twenty seconds of LED exposure, comparable to the effect of a one-minute SDF treatment [4].

To evaluate the effects of KI and SDF, Nguyen V. et al. treated ten groups of teeth. Colour measurements and visual examinations were performed to assess colour changes. The findings showed that after four weeks, all KI-treated groups exhibited little to no staining. The study found that applying SDF and KI to both carious and healthy teeth resulted in minimal or no darkening, especially when combined with glass ionomer (self-cure), resin-modified glass ionomer, composite, or when no restorative material was used [5]. Hence the present study is to investigate the impact of curing light exposure on crown discolouration in primary teeth treated with SDF and KI.

Primary objectives: To evaluate the extent of discolouration in primary teeth treated with:

- SDF,
- SDF combined with KI,
- SDF with LED curing light and
- SDF combined with potassium iodide and LED curing light-measured immediately after treatment, at three months and at six months.

Secondary objectives: To perform a comparative analysis of discolouration among the four groups (SDF, SDF + KI, SDF + LED curing light for 20 seconds and SDF + KI + LED curing light for 20 seconds) over time, highlighting the effects of adjunctive treatments (KI and LED curing light) on the degree of discolouration.

Null Hypothesis (H_0): There is no significant difference in the extent of discolouration of primary teeth treated with SDF, SDF combined with KI and SDF with LED curing light across different treatment groups or time intervals (immediate, 3 months and 6 months).

Alternative Hypothesis (H_1): There is a significant difference in the extent of discolouration of primary teeth among the treatment groups (SDF, SDF with KI and SDF with LED curing light) and/or across time intervals (immediate, 3 months and 6 months).

MATERIALS AND METHODS

The present in-vivo study will be conducted in the Department of Paediatric and Preventive Dentistry, Sharad Pawar Dental College and Hospital, Maharashtra, India, from March 2025 to August 2025. Ethical approval for the research project has been granted by the Institutional Ethics Committee (Ref. No. DMIHER(DU)/IEC/2024/297). Parents and children participating in the study will be informed about the study protocol and written informed consent will be obtained from the parents.

Inclusion criteria: The study will include children aged three to eight years with dental caries classified as D1 or D2 according to the American Dental Association classification. Only healthy children without systemic illness will be considered. The selected teeth must show no signs of pulpal exposure.

Exclusion criteria: Children will be excluded if they have known allergies to SDF or KI, developmental dental defects, extensive decay, pulp involvement, or non-restorable teeth. Those taking medications that could affect tooth colour or structure, or who have received SDF or similar treatments within the past six months, will also be excluded.

Sample size calculation: The sample size will be determined using the following formula:

Group 2 mean ≈ 624.3 µm

- Group 3 mean ≈ 141.5 µm
- Standard deviations approximated from IQRs:

  $SD_2 \approx 906.5$

  $SD_2 \approx 138.7$
- Pooled SD (approximation):

$$SD_{pooled} = \sqrt{\frac{906.5^2 + 138.7^2}{2}} = \sqrt{\frac{821738 + 19242}{2}} \approx \sqrt{420490} \approx 648.45$$

- α=0.05, so $Z1-\alpha/2$=1.96
- Power = 80%, so $Z1-\beta$=0.84
- Effect size = Δ=624.3–141.5=482.8

  Sample size formula :

$$n = \left\lceil \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \cdot 2 \cdot SD^2}{\Delta^2} \right\rceil$$

$$n = \left\lceil \frac{(1.96 + 0.84)^2 \cdot 2 \cdot (648.45)^2}{(482.8)^2} \right\rceil = \frac{7.84 \cdot 2 \cdot 420490}{233096} = \frac{6595632}{233096} \approx 28.3$$

$$\Rightarrow \boxed{n \approx 29 \text{ per group}}$$

- Sample size per group: 29

Study Procedure

Participants will be comfortably positioned in the dental chair and the procedure will be clearly explained to them. Any doubts or concerns will be addressed before beginning treatment. To ensure proper isolation and dryness of the teeth being treated, cotton rolls will be used.

The tooth surface will first be cleaned, followed by air abrasion to remove debris and plaque. After cleaning, the surface will be thoroughly rinsed with water and dried with air to prepare for treatment [Table/Fig-1] [7].

Caries depth category	D1	D2	D3
Radiographic presentation of the approximal surfaces of Dentin	Radiolucency extend to the dentino-enamel junction or outer one-third of the dentin.	Radiolucency extends into the middle one-third of the dentin.	Radiolucency extends into the inner one-third or the dentin.

[Table/Fig-1]: Caries depth categories [7].
D1: Early dentin caries; D2: Moderate dentin caries; D3: Deep dentin caries

Participants will then be randomly divided into four groups:

Group I: One drop of SDF will be applied to the carious tooth surface using an applicator tip, ensuring complete coverage of the affected area and left in place for one minute.

Group II: One drop of SDF combined with potassium iodide will be applied in the same manner and left for one minute.

Group III: A drop of SDF solution will be applied to the carious tooth surface using an applicator tip, ensuring complete coverage. This group will then receive curing light exposure for 20 seconds.

Group IV: A drop of SDF combined with potassium iodide solution will be applied in the same way, followed by curing light exposure for 20 seconds.

Care will be taken to avoid contact with surrounding soft tissues to prevent staining.

Participants will be instructed not to eat or drink for at least 30 minutes following the application to allow the SDF solution to adequately penetrate and adhere to the tooth structure.

Follow-Up and colour assessment: Follow-up appointments will be scheduled at one month, three months and six months to assess the progress of the treated tooth and determine if additional applications are required.

Colour assessments will be performed at three time points:

- T_0: Immediately after treatment
- T_1: Three months after treatment
- T_2: Six months after treatment

A dental spectrophotometer will be used to measure the colour of the dentin surface adjacent to the restoration. Colour will be assessed according to the CIELAB colour system, which evaluates three parameters:

- For lightness (0=black, 100=white)
- For red (+a) to green (-a)
- For yellow (+b) to blue (-b)

The spectrophotometer will be calibrated according to the manufacturer's instructions. Each measurement will be taken three times by a single operator and the average values will be recorded. Variations in colour over time will then be calculated [8].

Outcomes

Primary outcome: The extent of discolouration in primary teeth treated with SDF, SDF combined with KI and SDF with LED curing light, measured immediately after treatment, at three months and at six months.

Secondary outcome: Comparative analysis of discolouration among the treatment groups over time, focusing on the impact of adjunctive treatments (KI and LED curing light) on the degree of discolouration.

STATISTICAL ANALYSIS

Data will be analysed using G*Power statistics to determine statistical significance. The results of the outcome variables will be presented using descriptive statistics and frequency distribution. Data will be analysed using the Statistical Package for the Social Sciences (SPSS), Version 23. ANOVA test will be performed to compare intergroup differences, with a significance level set at $p<0.05$. Upon completion of the research, the data will be disseminated by publishing the findings in a peer-reviewed scientific journal.

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