

# Potential discolouration of silver diamine fluoride versus silver diamine fluoride/potassium iodide in primary teeth: a randomised clinical study

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## Key points

Based on the results of our study, both silver diamine fluoride and silver diamine fluoride/potassium iodide were effective in arresting carious lesions in primary anterior teeth, but the application of potassium iodide didn't prevent the discolouration caused by silver diamine fluoride application.

No adverse events were reported with either materials.

Although parents/guardians perceived discolouration, they were open to compromise aesthetics in favour of using a less invasive approach.

## Abstract

**Aim** This study aimed to evaluate the potential discolouration and carious lesion arresting effect of silver diamine fluoride (SDF) and silver diamine fluoride/potassium iodide (SDF/KI) in the treatment of carious primary teeth.

**Materials and method** A total of 30 carious primary canines were randomly assigned to treatment groups where Group I was treated with SDF while Group II was treated with SDF/KI. Caries arrest was assessed based on consistency and stability of lesion size while the discolouration of treated lesions was assessed digitally using a VITA Easyshade spectrophotometer.

**Results** Both treatments demonstrated 100% efficacy in arresting active caries lesions. Regarding discolouration, the total colour difference represented by delta E ( $\Delta E$ ) was  $16.45 \pm 5.69$  for Group I compared to  $9.54 \pm 3.09$  for Group II immediately post-operative, with a statistically significant difference ( $p = 0.003$ ). Both groups showed similar values at 1, 3, 6 and 12 months after the treatment, with no statistically significant difference. No incidence of serious adverse effects related to either treatment and the majority of parents/guardians were satisfied with both treatments compromising their child's aesthetic appearance.

**Conclusions** Both SDF and SDF/KI are effective in arresting carious lesions in primary teeth but in terms of the discolouration potential, the use of KI significantly reduced the discolouration caused by SDF immediately post-operatively. Unfortunately, marked discolouration was recorded in the subsequent follow-up visits, compromising the aesthetic outcome.

## Introduction

Dental caries has been recognised as a major public health problem and one of the most frequent chronic diseases impacting humans worldwide, affecting 60–90% of schoolchildren.<sup>1</sup> In children from families from a low-income background, the majority of carious lesions were left untreated due

to cost and limited availability or access to dental services. For these reasons, the severity of the disease increases, which leads to pain, expense and a decreased quality of life for the affected children and their families.<sup>2</sup>

In this context, there was a great interest in simple, effective, accessible, affordable and safe treatments to halt the progress of carious lesions. Among these treatments is silver diamine fluoride (SDF), which can be used as the best strategy to control the burden of dental caries in children around the world.<sup>3</sup>

The Food and Drug Administration authorised the use of SDF as a dentine hypersensitivity agent in 2014 and acknowledged its off-label use for caries arrest and prevention in the United States, the

United Kingdom and Thailand.<sup>1</sup> Moreover, the American Dental Association and American Association of Paediatric Dentistry support its off-label usage in a comprehensive caries management programme to arrest cavitated caries lesions in primary teeth.<sup>4</sup>

Clinically, there are a multitude of benefits associated with the application of SDF in the clinical management of caries. One such benefit is the simple and relatively painless application that allow it to be widely used in special conditions, such as early childhood caries, paediatric patients with additional needs and patients with behavioural or medical issues impeding conventional therapy. Another major advantage is its cost-effectiveness, where small volumes (25  $\mu$ L) of SDF can be used to treat up to five teeth.

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Thus, dentists can offer dental treatment to those who cannot afford or access regular dental care.<sup>5</sup>

The black discolouration of carious enamel and dentin that resulted from the application of SDF may limit its use. Because the discolouration affects the aesthetic appearance of the tooth, many parents/guardians may oppose treatment, making the dentist hesitant of proposing it as a treatment option.<sup>6</sup>

In an attempt to minimise the black discolouration, the use of a potassium iodide (KI) solution after SDF application has been suggested. Unfortunately, there is insufficient evidence to demonstrate its effectiveness in reducing tooth discolouration, so clinical studies with a long period of observation are still needed.<sup>5,7</sup> Our study aimed to evaluate the potential discolouration and carious lesion arresting effect after application of SDF versus SDF/KI in the treatment of carious primary anterior teeth.

## Materials and methods

### Study design

This was a split-mouth, randomised, controlled, clinical study conducted to evaluate the potential discolouration and carious lesion arresting effect after application of SDF versus SDF/KI in the treatment of carious primary anterior teeth. The Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed to ensure the reporting of this clinical study.<sup>8</sup>

### Sample size

The power and sample size calculations programme (Sealed Envelope Ltd, 2012) was used to calculate the sample size.<sup>9</sup> The continuous outcome superiority trial power calculator is available online at <https://www.sealedenvelope.com/power/continuous-superiority/>. Based on the results of Nguyen *et al.*,<sup>10</sup> a total sample size of 30 patients was calculated, with an 80% chance of detecting an increase in the mean lightness values from 53.6 in the control group to 71.3 in the experimental group, at a 5% level of significance and a 35% dropout rate.

### Ethical aspects

The current research was carried out in compliance with the Helsinki Declaration.<sup>11</sup> Ethical approval was obtained from the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University.

After a comprehensive explanation of the treatment procedure, benefits and possible complications, informed consent was obtained by the children's parent/guardian.

This study has been registered on [clinicaltrials.gov](https://clinicaltrials.gov) under the title 'Staining potential and caries arresting effect of silver diamine fluoride/potassium iodide and silver diamine fluoride' with the identifier NCT04196829.

### Study setting

Children were recruited from the outpatient clinic of the paediatric dentistry and dental public health department and they were carefully assessed for eligibility to participate in the study.

### Inclusion criteria

- Children aged from 3–6 years old
- Children with bilateral carious primary canines
- Active carious lesions which have International Caries Detection and Assessment System (ICDAS)<sup>12</sup> code 4 or 5.

### Exclusion criteria

- Children with spontaneous pain or any signs of pulpal infection
- Children having any clinical or radiographic signs of periapical infection
- Active carious lesions which have ICDAS codes other than 4 or 5
- Children which have sensitivity to silver or other heavy metal ions
- Children which have any gingival or perioral ulceration or stomatitis.

### Randomisation and allocation concealment

Owing to the split-mouth study design, randomisation was performed to assign right side carious canines to one of the treatment modalities using a sealed envelope, while the left side carious canines were assigned to the opposite group automatically, with a 1:1 allocation ratio dividing the 30 carious primary canines into two equal groups with 15 teeth in each group as follows:

- Group I (n = 15): teeth treated with SDF (e-SDF, Kids e-Dental, India. One bottle [3.25 mL] containing 38% SDF)
- Group II (n = 15): teeth treated with SDF/KI (Riva Star, SDI, Bayswater, Australia. Two bottles – a silver bottle [1.5 mL] containing 38% silver fluoride in an ammonia solution and a green bottle [3.0 mL] containing KI solution).

### Blinding

The child participants and their legal guardians, the outcomes assessors and the statistician were blinded.

### Baseline clinical examination

Participants' personal, medical and dental histories were obtained at the baseline examination. Through meticulous visual inspection of the carious lesion, the state of carious lesions was recorded and scored according to the ICDAS using a ball-ended World Health Organisation probe with gentle force.

The colour of the carious lesion was assessed digitally using a VITA Easyshade spectrophotometer after being calibrated in accordance with the manufacturer's instructions to assess the baseline shade of the carious lesion before treatment. A single operator replicated the L\*, a\* and b\* values three times and the average values were recorded. The L\* axis represented lightness ranging from black (0) to white (100), the a\* axis ranging from red (+a\*) to green (-a\*), and the b\* axis ranging from yellow (+b\*) to blue (-b\*).

### Clinical procedure

In Group I, the gingival tissue in the anterior area was protected with petroleum jelly and the affected tooth surface was gently cleaned and dried with cotton gauze. Using a micro brush, the affected tooth surface was coated with a 38% SDF solution. Moisture control was maintained for at least one minute after SDF placement using a gentle flow of compressed air to allow for absorption, then excess SDF was removed using cotton gauze.

In Group II, the application of SDF was carried out in the same manner as in Group I, followed by the immediate application of the KI solution using a separate micro brush, saturated with KI solution, until the precipitate went from yellow to white and then clear.

The colour of the treated carious lesion was recorded immediately post-operatively using a digital VITA Easyshade spectrophotometer to calculate the delta E ( $\Delta E$ ) value that defines the total colour difference. Then, children were instructed to avoid rinsing, eating and drinking for one hour after treatment. All children were recalled back after 1, 3, 6, 9 and 12 months to assess treatment outcomes.

### Outcomes

- Discolouration of the carious lesion was assessed digitally using  $\Delta E$  as follows:  

$$\Delta E = ([\Delta L]^2 + [\Delta a]^2 + [\Delta b]^2)$$

- Carious lesion arrest was judged based on:
  - The stability in the size of the carious lesion, evaluated using the ICDAS index, into stable or progressing
  - The consistency of the lesion was evaluated upon gentle probing using a ball-ended World Health Organisation probe into soft or hard
- Evaluation of the presence or absence of adverse events observed or complaints from either parents/guardians or the children, including pain, transient gingival swelling and gingival bleaching
- Parent/guardian satisfaction for SDF treatment was recorded using a detailed questionnaire.<sup>13</sup>

### Statistical analysis

Quantitative data were represented as mean and standard deviation (mean  $\pm$  SD) values and the t-test was used to assess the

significant differences. Qualitative data were described as frequencies and percentages and the chi-square test was used to assess the significant differences. The p-value was considered statistically significant if  $\leq 0.05$ . The IBM SPSS Statistics (22.0) software package for Microsoft Windows was used to conduct the statistical analysis.

### Results

The flow of patients throughout the study, as demonstrated in Figure 1, showed that 13 patients with 26 carious lesions completed the 12-month study period, while only two subjects with four carious lesions failed to complete the entire follow-up period. Due to the COVID-19 lockdown, patients couldn't attend the clinic for follow-up at nine months.

Patients who participated in the present study were aged between 4–6 years, with a mean age of  $5.33 \pm 0.64$  years, while the distribution of sexes was 60% boys and 40% girls. At the baseline examination by ICDAS classification, 60% scored 4 and 40% scored 5.

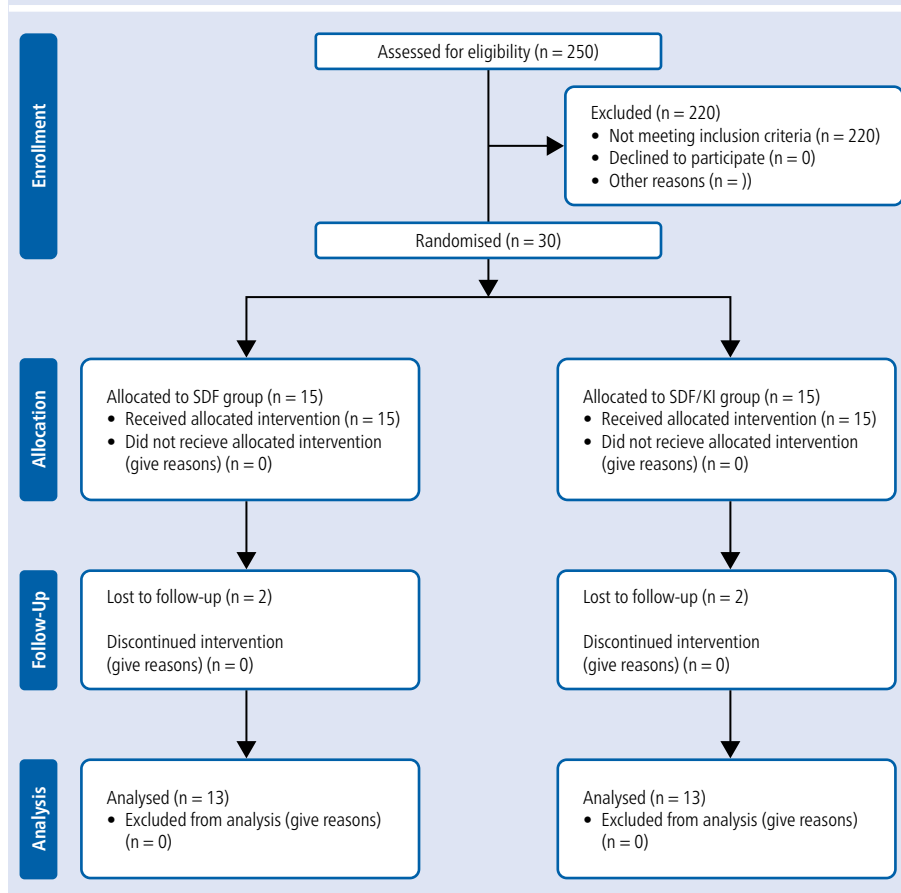
Regarding the discolouration of treated carious lesions, the colour parameter that changed the most in both groups was  $\Delta L$ , which represented a greater darkening of the teeth. With a p-value of 0.006, there was a statistically significant difference between the two groups immediately after the treatment, while no statistically significant differences were found at 1, 3, 6 and 12 months, as shown in Table 1.

Regarding the  $\Delta E$  values among both groups, Group I recorded higher values immediately after treatment in comparison to Group II, with a statistically significant difference ( $p = 0.003$ ). Both groups showed similar values at 1, 3, 6 and 12 months after the treatment with no statistically significant difference, as shown in Table 2.

When comparing  $\Delta E$  at different time intervals, both groups showed a progressive increase in  $\Delta E$  throughout the entire follow-up period, with only a statistically significant difference between the immediate post-operative and one month ( $p = 5.6E-08$  for Group I and  $p = 1.1E-07$  for Group II).

Assessment of the effect of both treatments in arresting carious lesions has relied on the tactile evaluation of lesion consistency and the employment of the ICDAS codes to evaluate the stability of the lesion size.

**Fig. 1** Participant flow diagram through the randomised clinical trial according to CONSORT guidelines



**Table 1** Mean and standard deviation (mean  $\pm$  SD) values for  $\Delta L$  representing lightness difference in both groups

Time interval	Group I	Group II	P-value between groups
	Mean $\pm$ SD	Mean $\pm$ SD	
Immediate post-operative – baseline	-13.76 $\pm$ 5.72	-6.84 $\pm$ 3.98	0.006*
One month – baseline	-28.14 $\pm$ 6.02	-24.31 $\pm$ 5.81	0.165
Three months – baseline	-29.84 $\pm$ 7.35	-25.81 $\pm$ 9.29	0.312
Six months – baseline	-31.23 $\pm$ 6.94	-27.63 $\pm$ 6.21	0.293
Twelve months – baseline	-35.35 $\pm$ 4.56	-31.50 $\pm$ 7.52	0.236

Key:  
\* = significant ( $p \leq 0.05$ )  
Non-significant =  $p > 0.05$

In both groups, all the treated teeth were considered arrested at the 6- and 12-month follow-up periods, as shown in Figure 2.

Concerning adverse events observed or complained about from either parents/guardians or children, only one case (7.7%) in Group I complained of pain and transient gingival swelling, while gingival bleaching was observed in 23.1% and 15.4% in Group I and II, respectively, with no statistically significant difference ( $p = 0.30782$ ).

Regarding parental satisfaction with treatment, most parents/guardians agreed or strongly agreed about the ease of application, the painlessness of the process and the taste of both materials, while 84.6% in Group I and 69.2% in Group II weren't comfortable with the discoloration of teeth, as shown in Figure 3.

### Discussion

SDF was proposed as an alternative treatment for caries prevention and arrest because it is simple, relatively painless and affordable, as well as conforming to the concept of minimally invasive dentistry. As a result, treating caries lesions with SDF appears to be particularly appropriate for younger, less compliant and socially vulnerable children.<sup>14</sup>

The discoloration that follows SDF application has significantly diminished its use in paediatric and adult patients. One of the proposed methods for preventing this adverse side effect is the application of KI immediately after SDF.<sup>15</sup>

Unfortunately, there is conflicting evidence regarding the effect of SDF/KI on tooth colour.

*In vitro* studies on both primary and permanent teeth showed that KI was effective in preventing tooth discolouration, while a clinical study on root caries in the older population found no effect.<sup>15</sup> Moreover, only a single clinical trial with six months of follow-up revealed a 25% reduction in the incidence of discolouration following KI application, owing to the scarcity of studies that evaluate the effect of SDF with KI and its methodological limitations.<sup>16,17</sup> The present study aimed to evaluate the potential discolouration and carious lesion arresting effect after application of SDF versus SDF/KI in the treatment of carious primary anterior teeth.

The current study demonstrated 100% efficacy of both treatments in arresting all active caries lesions where all lesions were hard and stable in size. These findings were in accordance with previous studies and can be attributed to the high silver and fluoride ion concentrations, the synergic effect of these ions and its increased alkalinity.<sup>1,13,18,19</sup>

The silver component interacts with the sulphhydryl groups of proteins and DNA from the microorganisms, interfering in the bacterial metabolism and causing its destruction and inhibiting the formation of biofilm. Additionally, the silver salts formed on the dentin surface block the dentinal tubules, reducing tooth sensitivity and contributing to forming a very resistant dentin outer layer.<sup>1,20,21</sup>

The fluoride component of the SDF reacts with calcium phosphate and hydroxyapatite to form fluorapatite and calcium fluoride, which improves the acid resistance, mineral density and hardness of the carious dentin, which is consistent with dentin remineralisation.<sup>22</sup>

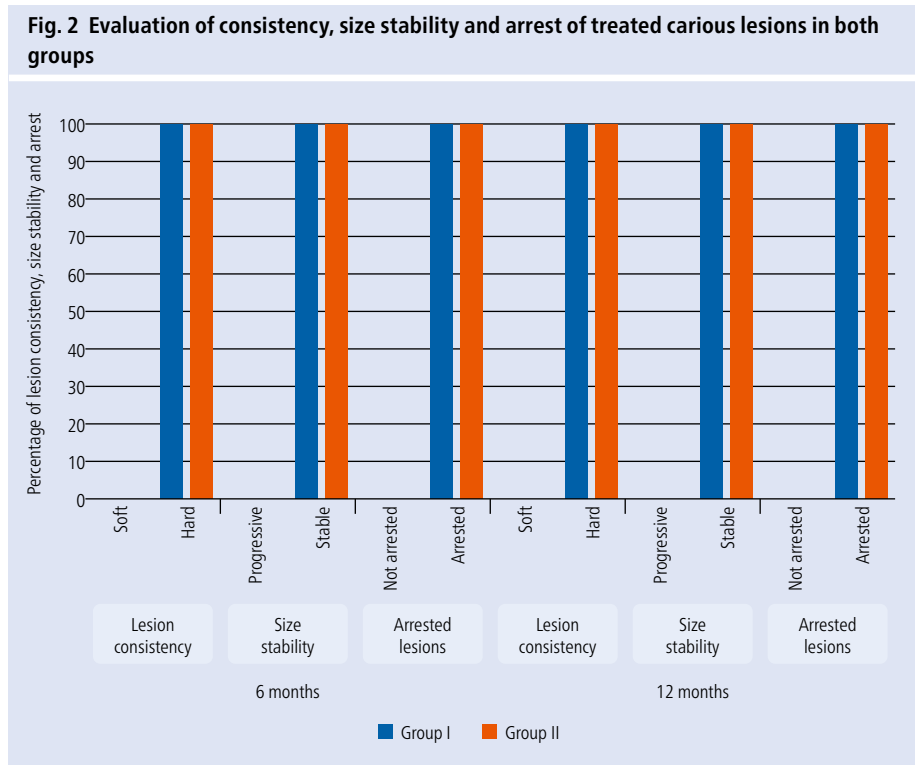
Additionally, SDF inhibits the breakdown of the exposed collagen matrix, owing to the high concentration of silver which inhibits matrix metalloproteinases and cysteine cathepsins. This is very important, as the collagen network provides the scaffold for the new remineralisation cores.<sup>22,23</sup>

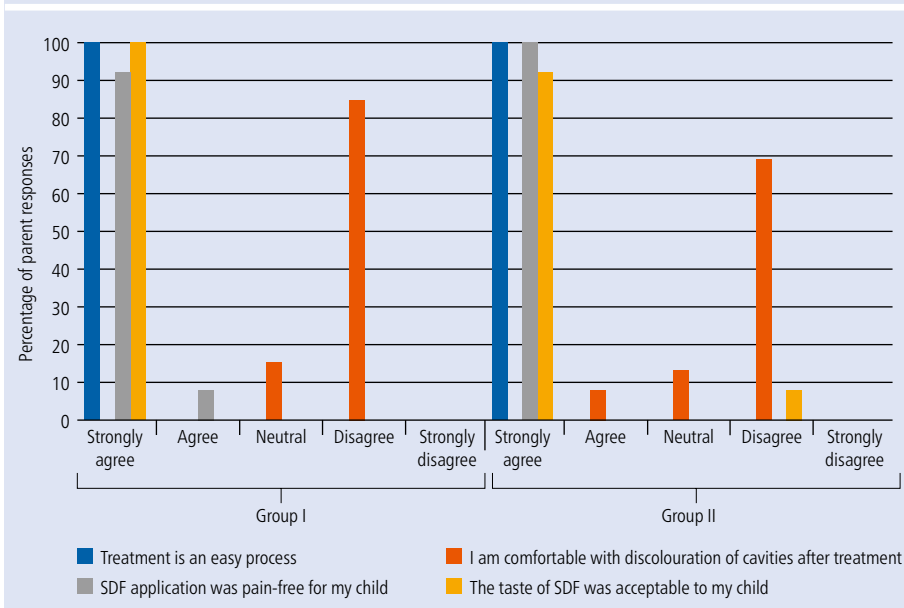
The evaluation of discolouration was done using a digital VITA Easyshade spectrophotometer. VITA Easyshade measures the complex colour of tooth structure numerically, where the  $L^*$ ,  $a^*$  and  $b^*$  colour system was used to elucidate each colour three-dimensionally in space. This device has shown high reliability and reproducibility, eliminating the problems of subjectivity in colour assessment by giving quantitative values to calculate the  $\Delta E$  value that defines the total colour difference between the final and baseline values.<sup>7,24,25</sup>

**Table 2 Mean, and standard deviation (mean  $\pm$  SD) values for  $\Delta E$  representing the total colour difference in both groups**

Time interval	Group I	Group II	P-value between groups
	Mean $\pm$ SD	Mean $\pm$ SD	
Immediate post-operative	16.45 $\pm$ 5.69	9.54 $\pm$ 3.09	0.003*
One month	35.84 $\pm$ 3.94	33.75 $\pm$ 8.50	0.489
Three months	37.85 $\pm$ 9.08	36.42 $\pm$ 7.87	0.717
Six months	40.29 $\pm$ 10.11	39.72 $\pm$ 6.63	0.896
Twelve months	45.24 $\pm$ 6.94	44.65 $\pm$ 5.80	0.857

Key:  
\* = significant ( $p \leq 0.05$ )  
Non-significant =  $p > 0.05$



**Fig. 3** The distribution of parental satisfaction for treatment in both groups

Immediately after the application of both materials, both groups showed a degree of discolouration represented by a mean  $\Delta E$  value equal to  $16.45 \pm 5.69$  for Group I and  $9.54 \pm 3.09$  for Group II, which was in agreement with previous studies.<sup>7,26,27</sup>

This finding can be attributed to black precipitate formed on the surface of carious dentine because of the reaction of unreacted silver ions on the partially denatured collagen, where the excess unreacted silver ions precipitated as silver sulphide, inducing discolouration.<sup>27,28</sup>

In both groups, the degree of discolouration increased markedly at one-month follow-up, represented by the progressive increase in mean  $\Delta E$  value by  $35.84 \pm 3.94$  in Group I and  $33.75 \pm 8.50$  in Group II, with a statistically significant difference between the immediate post-operative and one-month follow-up ( $p = 5.6E-08$  in Group I and a  $p = 1.1E-07$  in Group II). The difference in mean  $\Delta E$  value between 1, 3, 6 and 12 months wasn't statistically significant in both groups.

This finding can be linked to the fact that metallic silver was formed by the reaction of SDF and hydroxyapatite and its production was accelerated when exposed to light and high temperatures that eventually increase the brown-black appearance of the carious lesion over time.<sup>24,27,28,29</sup>

When discolouration was compared in both groups immediately post-operatively, Group I showed more discolouration, represented by a higher mean  $\Delta L$  value ( $-13.76 \pm 5.72$ ), compared to Group II ( $-6.84 \pm 3.98$ ), with a

statistically significant difference ( $p = 0.006$ ) and a higher mean  $\Delta E$  value ( $16.45 \pm 5.69$ ) compared to Group II ( $9.54 \pm 3.09$ ), with a statistically significant difference ( $p = 0.003$ ), which was in agreement with previous studies.<sup>26,27,28,29</sup>

The ability of KI in reducing the discolouration caused by SDF can be justified through reaction with the free silver ions, producing a creamy white precipitate of silver iodide.<sup>27,28</sup>

On the contrary, both groups showed a similar degree of discolouration represented by mean  $\Delta E$  values equal to  $35.84 \pm 3.94$ ,  $37.85 \pm 9.08$ ,  $40.29 \pm 10.11$  and  $45.24 \pm 6.94$  at 1, 3, 6 and 12 months, respectively, for Group I, and mean  $\Delta E$  values equal to  $33.75 \pm 8.50$ ,  $36.42 \pm 7.87$ ,  $39.72 \pm 6.63$  and  $44.65 \pm 5.80$  at 1, 3, 6 and 12 months, respectively, for Group II. There was no statistically significant difference between groups at 1, 3, 6 and 12 months, with a  $p$ -value of 0.489, 0.717, 0.896 and 0.857, respectively.

These findings were in accordance with several studies<sup>2,16,17,26,30</sup> that reported the ability of KI to improve initial aesthetic appearance after SDF application. However, after time, KI does not seem to result in any significant difference in discolouration. This can be attributed to the fact that silver iodide, which is formed upon the application of KI following SDF, is a photosensitive material that can dissociate into silver and iodine when exposed to light.<sup>15,29</sup>

No incidence of serious adverse effects related to both treatments occurred during the whole study period. Oral pain, transient

gum swelling and gum bleaching were seldom reported in the present study, which were in accordance with previous studies reporting no major side effects among children.<sup>20,31,32</sup> This finding can be attributed to the diffusion of SDF onto surrounding tissues, resulting in temporary irritation of gingiva that subsided within days.<sup>17</sup>

The majority of parents/guardians in the present survey were satisfied with both treatments in terms of ease of application, painlessness of the process and material taste compromising their child's aesthetic appearance. These findings were in accordance with several studies<sup>13,18,33</sup> and can be attributed to the fact that parents/guardians may perceive the discolouration from SDF in anterior teeth as being unaesthetic, but most parents/guardians are open to compromise aesthetics in favour of using a less invasive approach, especially when the child's co-operation becomes a barrier for traditional treatment to avoid the possibility of their children having to undergo sedation or general anaesthesia.<sup>3,28</sup>

Since parents/guardians may not have other affordable options for treating and alleviating pain in their children, the simplicity and cost-effectiveness of SDF make it a very favourable treatment for children of lower socioeconomic status.<sup>6</sup>

## Conclusions

Based on the results of our study, both SDF and SDF/KI were effective in arresting carious lesions in primary anterior teeth but the application of KI didn't prevent the discolouration caused by SDF application. No adverse events were reported with both materials. Although parents/guardians perceived the discolouration, they were open to compromising aesthetics in favour of using a less invasive approach.

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### Ethics declaration

This study was approved by the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University with approval number 19-12-23. The research was carried out in accordance with the Declaration of Helsinki. Written informed consent to participate was obtained from the children's parents/guardians.



The authors have no relevant financial or non-financial interests to disclose.

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#### Author contributions

Mariam M. Mohsen and Yasmin M. Yousry contributed to the study's conception and design, material preparation, data collection and analysis. The first draft of the manuscript was written by Mariam Mohsen and Yasmin Yousry contributed. Both authors read and approved the final manuscript.

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