



Clinical and Radiographic Evaluation of Silver Diamine Fluoride and Potassium Iodide Using Smart Technique in Primary Molars: An In-Vivo Study

Dr. Nikita Bhure, Dr. Nagarathna PJ, Dr Sagar Bhure, Dr. Nabila Naaz Sheikh, Dr. Nancy Singh

MDS, MDS, Professor, MDS, MDS, MDS

Aureus Institute of Medical Sciences, Nagpur, Chhattisgarh Dental College and Research Institute, Rajnandgaon, Aureus Institute of Medical Sciences, Pediatric dental practitioner, Nagpur , Pediatric dental practitioner, Lucknow

Abstract

Objective:

To evaluate and compare the cariostatic effect and discoloration caused by 38% Silver Diamine Fluoride with and without potassium iodide clinically and radiographically in primary molars.

Material & Methods:

45 healthy children aged 6 years with distant cavitation were selected for the study. Children were grouped as teeth treated with 38% silver diamine fluoride, treated with 38% silver diamine fluoride with 10% Potassium Iodide, and the control group. All groups were restored with glass ionomer cement. Clinical and radiographic evaluation of cariostatic effect and discoloration for 1, 6, and 12 months was done.

Results:

The Silver Diamine Fluoride group had more arrested lesions (93.33%) compared to 38% silver diamine fluoride and 10% Potassium Iodide (86.66 %) at 12 months with no significant difference in the first month ($p=.103$) but a significant difference in the cariostatic effect of 38% silver diamine fluoride and 10% Potassium Iodide was found at 6 and 12 months i.e. ($p=0.044$ and $p=.004$) respectively. The mean value

parameter for discoloration denoted as ΔE indicates high statistical differences between the groups. (p=0.000)

Conclusion:

Annual topical application of 38% silver diamine fluoride was more effective in arresting dental caries than 38% silver diamine fluoride and 10% Potassium Iodide.

Keywords: Potassium Iodide, Silver Diamine Fluoride, SMART Technique, Discoloration.

Introduction

Silver diamine fluoride (SDF) is used as a topically applied cariostatic agent.^[1] The use of ammonical silver fluoride for the arrest of dental caries was pioneered by Dr Nishino and Yamaga in Japan, who developed it to combine the actions of F^- and Ag^+ and led to the approval of the first SDF product, Saforide (Bee Brand Medico Dental Co, Ltd, Osaka, Japan) in 1970.^[2] Silver diamine fluoride (SDF) has been used for more than 25 years.^[3] 38% SDF has been utilized for decades in various countries, including China, Japan, Germany, Nepal, Brazil, Argentina, New Zealand, and Australia, to arrest caries.^[4] Which got its Food and Drug Administration approval in October 2016, found to be very promising in Minimal Intervention Dentistry (MID).

However, a significant disadvantage of SDF use is that black staining on teeth, can cause aesthetic concern for patients and parents.^[5] To alleviate this effect and increase patient acceptance, the application of a saturated solution of potassium iodide (KI) immediately after SDF has been suggested. It is postulated that KI prevents staining through the precipitation of excess silver ions as white silver iodide. Supersaturated solutions of KI have been tested as a second step after SDF treatment.^[6] It is desired that the effectiveness of SDF in arresting caries should not be affected or minimally affected by the application of KI.^[7] However, there is an insufficient study in primary teeth to support the claim and it is not practical to leave gross cavitations open while implementing SDF arrest procedures. In addition, it may not be possible for the patient to return for dental care for multiple SDF treatments and subsequent restoration.

In either case, we define SMART as "Silver Modified Atraumatic Restorative Treatment" because SDF is applied and immediately restored with conventional GIC (self-curing) at the same appointment. Glass ionomer Cement is used as a material for placement of dental restorations and is known to release fluoride,

which can help to remineralize the carious lesion.^[8] The Arrest of Caries Techniques (ACT) presents a set of appropriate oral healthcare technologies for disadvantaged communities. Caries arresting treatment aims to halt or slow down caries progression and is a practical solution to minimize children's discomfort and problems due to caries. These techniques aim to arrest decay but do not aim to restore the damaged tooth structure.^[9] Clinical Studies regarding the effectiveness of the KI with SDF in arresting dental caries are scanty. Hence, this field of study was conducted to assess clinically and radiographically the effectiveness of silver diamine fluoride and potassium iodide on primary molars in preschool children with dental caries.

Materials & Methods:

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, Chhattisgarh Dental College and Research Institute on 45 children under the age group of 6 years who reported to the department were selected with Parent/guardian consent. Approval from the Institutional Ethical Committee was obtained. Healthy children with no history of spontaneous pain exhibited extensive caries characterized by distinct cavitations exposing visible dentin. (C+/-) [According to the International Caries Classification and Management System 2019, (ICCMS)]^[10] was included. Teeth with previous restoration, unrestorable teeth, presence of any clinical signs (fistula, swelling, or any abnormal tooth mobility), presence of any radiographic findings such as inter-radicular or periapical radiolucency, thickening of periodontal space, internal or external root resorption, history of silver allergy, mucositis, and ulcerations were excluded from the study.

TYPE OF STUDY: Randomized clinical trial.

Selected children were randomly allocated into **Group 1:** 38% silver diamine fluoride (SDF), the teeth were isolated using cotton rolls, and petroleum jelly was applied to gingival and mucosal surfaces. The status of the dentine caries lesions was assessed by visual inspection and aided by tactile detection using a ball-end probe. Soft debris in the cavity was removed so, as to reduce the bacterial load of the carious lesion. The 38% silver diamine fluoride solution (Fagamine®) was applied using a disposable micro brush applicator directly to the tooth surface for 2 minutes. SDF was thoroughly air-dried from the tooth after application. Following the procedure, conventional 3M keta molar glass ionomer cement (GIC) restoration was done. **Group 2:** 10% Potassium Iodide (KI)- 38 % silver diamine was applied the same as group 1, and immediately 10% potassium iodide (KI) (Lugol's Solution®, Product code: 38195) was applied using a

disposable micro brush applicator. Initially, a white precipitate tends to form then repeat the KI application until the precipitate turns colorless or no more white precipitation is formed. The teeth were washed and air-dried, followed by GIC restoration. **Group 3:** Control group, only GIC restorative treatment was performed.

The children were instructed not to eat or drink for at least 1 hour and proper oral hygiene instructions were given to all of them. The follow-up examinations were carried out at 1, 6, and 12 months for evaluation of cariostatic effect and discoloration in primary teeth. On recall, radiographic evaluation of the cariostatic effect was examined using KODAK RVG-6100 systems with pediatric Sensor Size-0 with a standardized paralleling technique. Technical specifications include active area dimensions - 17 x 22 mm (374 mm), matrix dimensions (pixels) - 900 x 1200 mm (1.08 million), and X-ray tube voltage of 60 to 90 kV. The images were processed in a digital reader pre-set CS dental imaging software. The distance between the X-ray source to the skin and the exposure time (0.35 seconds) were the same for all cases throughout the study. To measure carious lesion depth, pre-calibration of the same image from processing software was set in default mode, and the carious lesion depth was assessed in millimetres. A straight line was drawn between the center of the carious lesion up to the deepest part of the pulp, which was then materialized by a straight line drawn using the measurement tool. The same equipment and measurement criteria were used in all the examinations by a single observer. (Figure 1)

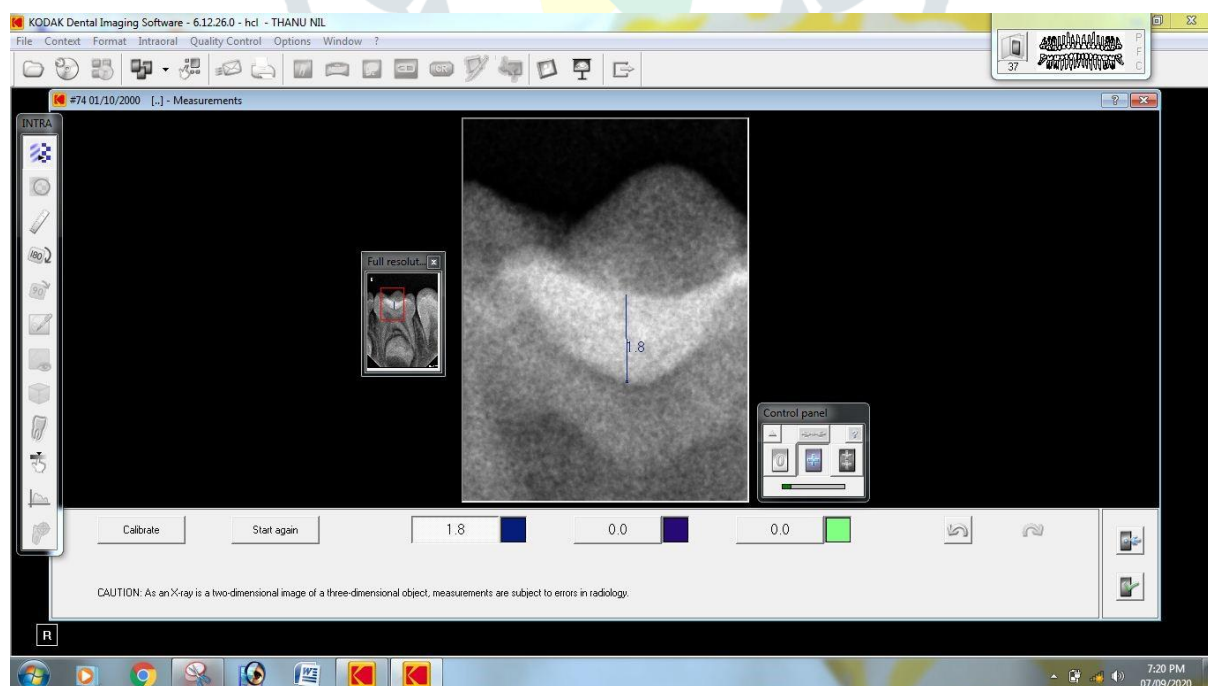


Figure 1:- Radiological evaluation of carious lesion depth, with KODAK RVG-6100

To assess the discoloration, all the teeth were photographed immediately after treatment and subsequently at the 1st, 6th, and 12th months. The A1601- F1s high-resolution digital camera which features a 13-megapixel digital camera sensor with F/2.2 aperture, 8x optical zoom, and phase detection autofocus to provide images in 1080p high definition was used to capture all the images. This allows for more light to enter and enhances its sensitivity. Each tooth's color was measured using a colorlab™ sensor, version 1.2 (Vilka Studios) available on the Google Play Store and IOS Store online. (Figure 2) The color lab sensor contains 118 color systems with over 112000 colors built by default; it blocks out ambient light and provides its own calibrated light source using standard 45/0° measurement. The device provides color readouts in CIELAB [6] and calculates color differences. L value and ΔE values were recorded (Figure 3) and compared among the groups.

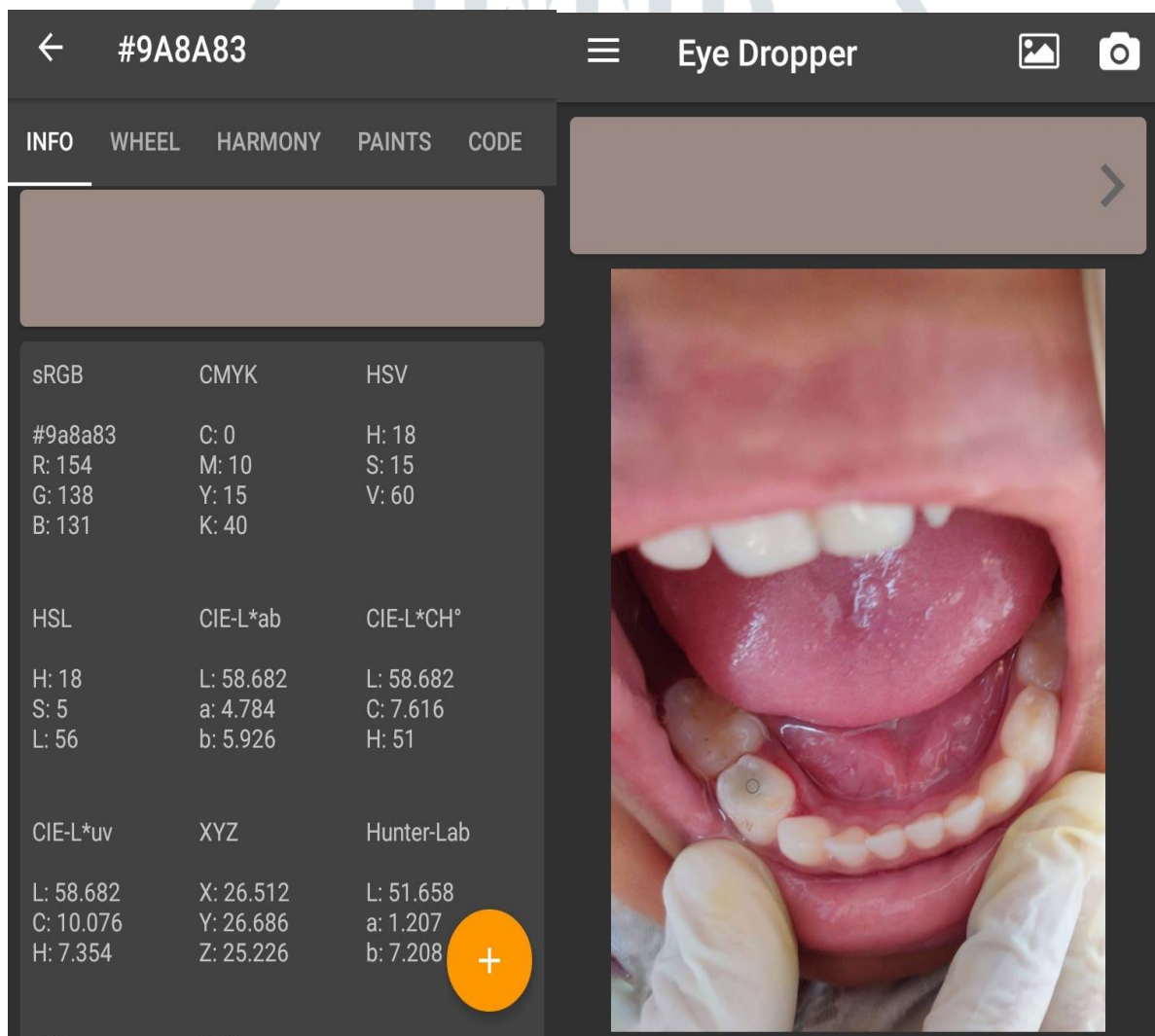


Figure 2:- CIE L*a*b* measurement using color lab™ sensor, version 1.2 Vilka

ΔE (CIE L*a*b units)	Visual Detection
0-1	No visible difference
1-2	The color difference is not noticeable to an untrained eye
2-3.5	Color differences may be noticeable to an untrained eye
3.5-5	Obvious shade difference when colors are compared side by side
≤ 6	The cutoff value for commercially reproducible colors
> 6	Different colors

Figure 3:- Commonly accepted color difference perceptibility

Data obtained was compiled systematically in a Microsoft Excel spreadsheet and analyzed using the Software Statistical Package for Social Sciences (SPSS) 21.0 version. Firstly, the Saprio Wilk test was done to check the data were normally distributed throughout all the groups. Following the analysis, the Pearson correlation coefficient (95%CI) was used to evaluate the correlation between the three groups, considering with significant p-value ($p < 0.05$). Similarly, a Paired t-test was used within all the groups to evaluate parameters included in the study individually for every group. For the multiple comparisons between the groups by independent t-test and one-way Analysis of variance (ONE WAY ANOVA) were used for statistical analysis with $p < 0.05$ as a level of significance.

Result

The study group was randomly divided into Silver Diamine Fluoride, Silver Diamine Fluoride with Potassium Iodide, and the control group. Distribution, mean, standard deviation, percentage, frequency, inter-comparison, and analysis were done to evaluate among study groups.

The mean value score for carious depth among study groups was 1.7356, 1.7000, and 1.5422 during 1 month, 6 months, and 12 months. (Table 1, Graph 1) Intergroup comparison between the groups showed 6.323, 9.260, and 19.390 during 1 month, 6 months, and 12 months indicating no significant difference in the first month ($p = .103$) but a significant difference was found in 6 and 12 months as ($p = .044$) and ($p = 0.004$) respectively. The results of our study showed that the Silver Diamine Fluoride group had more arrested lesions (93.33%) compared to SDF + Potassium Iodide (86.66 %) at 12 months with no significant difference in the first month ($p = .103$) but a statistically significant difference in the cariostatic effect of SDF + Potassium Iodide was found at 6 and 12 months i.e. ($p = 0.044$ and $p = .004$) respectively. (Table 2)

The mean value score for L value among study groups was 74.7280, 79.1966, and 76.0203 during 1 month, 6 months, and 12 months. (Table 3, Graph 2) Intergroup comparison between SDF, SDF+KI, and control group about L value: The mean square score for CIELAB within study groups was 18.571, 16.842, and 445.485. Test of significance ($p = 000$, $.000$, and $.005$) respectively indicating highly statistically significant differences among all the groups in 1 month, 6 months, and 12 months. (Table 4)

The mean value parameter for ΔE between SDF, SDF+ KI, and the control group was found to be 4.040, 1.553, and 0.500 respectively, with mean SD to be 0.5221, 0.2642, and 0.2104. ($p=0.000$) indicates high statistical differences between all groups. (Table 5, Graph 3)

Discussion

As an alternative, non-invasive method of topical application of 38% Silver Diamine Fluoride (SDF) adopts a modern conservative approach to managing dental caries specifically affecting high-risk populations.^[11] The anti-cariogenic mechanism of SDF is two-fold, with direct actions on bacteria and teeth. Laboratory studies have illustrated that the silver ions in the SDF can inhibit and eliminate cariogenic bacteria by interfering with the structure and function of bacterial nucleic acids and proteins. Both fluoride and silver ions contained in SDF appear to have the ability to inhibit the formation of cariogenic biofilms. Silver ion antibacterial action is threefold, penetrating and destroying bacteria cell wall structures, inhibiting enzymatic activity thus influencing metabolic processes, and inhibiting the replication of bacterial DNA. Furthermore, silver ions penetrate enamel up to a depth of 25 microns forming silver protein conjugates that enhance the resistance of carious dentine to acid and enzymatic breakdown.^[12] In addition, SDF treatment can increase the micro-hardness of carious lesions in dentine and the mineral density of carious lesions in enamel.^[13]

Our finding on the cariostatic efficacy of Silver Diamine Fluoride supports a study conducted by, Chu et al (2002)^[5] who compared the use of annual application of 38% SDF and 5% sodium fluoride (NaF) varnish. The caries arrest of SDF and NaF was $>96\%$ and $>70\%$ respectively. Duangthip et al (2016).^[14] compared three applications of 5% NaF varnish and a single 30% SDF application. The study found that a single application of SDF was significantly more effective at arresting caries than NaF. In this study, the mean arrested lesions in SDF and SDF + KI group reached the maximum at 1 month and a reduction at 6 and 12 months was observed. Silver diamine fluoride was applied annually and that might be the reason for the

decrease in the number of arrested lesions at 6 and 12th months. Though there are no documented recommendations for the frequency of SDF applications. A clinical trial, by Yee et al. (2009) ^[15], showed 38% silver diamine fluoride was more effective in arresting caries than 12% silver diamine fluoride. In disparity, Fung et al. (2016) ^[16] designed a study in China on primary dentition and concluded that SDF is more effective in arresting dentin caries in the primary teeth of preschool children at 38% concentration than 12% concentration and when applied bi-annually rather than annually.

Application time in clinical studies has not shown any correlation to the clinical outcome. Therefore, a 2-minute application time of SDF was found to show successful caries arrest in children. Similarly, Zhi Q h (2012) ^[17] stated that allowing 1-3 minutes for the silver diamine fluoride to soak into and react with a cavitated lesion is thought to show definite success. The simplicity of the SDF application might have contributed to its higher acceptability.^[18]

Digital radiography has become an alternative to analog radiography because of its advantages, including the fact that the image is accurate and can be improved with the appropriate software. ^[19, 20] The measurements of cariostatic lesions in the study were performed using the KODAK 6100 RVG system with an electronic ruler from the deepest spot corresponding to the bottom of the cavity after the excavation of caries.

The main reason for digitally analyzing the measurements of cariostatic lesions in our study supports the valid statement by Valizadeh et al (2015) ^[21] he attempted to design software to determine the depth of the decay in a more precise manner. A clinical study by Maria D Basso (2015) ^[22] reveals that the length of primary teeth estimated by in vivo and ex vivo studies using digital radiographs was found to be like the actual tooth length. However, it is possible to determine primary tooth length in digital radiography using on-screen measurements with a reasonable degree of accuracy and less radiation exposure.

The decayed tooth structure will darken as the caries lesions arrest after the application of SDF. So, a promising approach to applying a saturated solution of KI has been suggested after SDF to reduce color changes. All teeth treated with only SDF showed darkening, regardless of the restorative material used and the teeth that received the KI treatment were lighter than those that only received the SDF treatment. The L value of study groups was found as follows: SDF > SDF + KI > Control group. So, the commonly accepted color difference perceptibility for ΔE derived from CIELAB was found to show (0-1)- no visible difference

for the control group, (3.5-5)- Obvious shade difference when colors were compared side by side for SDF and (1-2)- A color difference not noticeable to the untrained eye for SDF+KI. This indicates a darkening in SDF-treated teeth, with minimal changes for KI and control groups at 1, 6, and 12 months.

The suggested explanation for our finding is that the silver ions from the SDF solution will react with the iodide ions from the KI solution to form silver iodide. It was reported that the application of SDF + KI to dentine surfaces before the placement of GIC restorations did not affect the bond strength of GIC to dentine [7] and did not adversely interfere with the fluoride uptake into the adjacent demineralized dentine.[23] Placement of SDF and a glass ionomer cement (GIC) sealant/restoration during the same appointment to limit access to fermentable carbohydrates and improve chances of SDF caries arrest.[24]

In our study, SDF with KI prevented secondary caries formation around GIC restorations, but it was not as effective as SDF when used alone. This finding suggests that KI is influencing the effectiveness of SDF in preventing the formation of secondary caries. The reason is that the application of KI solution might reduce the number of active silver ions.

Thus, it is clear from our study that KI affects the cariostatic activity of SDF; hence, a better material should be used along with SDF to achieve cariostatic and aesthetic acceptability at the same time. A study by Mahmoud Sayed (2018) [25] on the evaluation of the effect of Glutathione (GSH) biomolecule on the reduction of enamel and dentin discoloration after the application of 38% silver diamine fluoride solution (SDF), showed an insignificant color change over time and GSH did minimize color changes, especially on enamel and to a lesser extent on dentin. The studies found washing and air-drying the SDF/KI precipitate increases the bond strength to GIC significantly.[26] If SDF and KI are to be used, the precipitate must be washed and air-dried thoroughly before the application of the adhesive system or material. The use of a conditioning agent or acid etch post-application of SDF/KI may further improve bond strength.

The technique presented will combine the advantages of three proven principles:

- 1) The antibacterial and remineralizing effects of SDF causing caries arrest [27,28]
- 2) Partial/incomplete caries removal on deep caries lesions approaching a vital and asymptomatic pulp [29,30] and
- 3) Proper placement of a chemically sealed and bonded GIC restoration. [24]

Conclusion:

Annual topical application of 38% silver diamine fluoride solution was more effective in arresting dental caries. SDF + KI treatment caused a perceptible staining at the restoration margin, but the intensity was less than that with purely SDF treatment.

When SDF application is followed with a GIC restoration, the combination is a durable treatment of choice that synergizes caries arrest, fluoride release, and cleanability. SDF treatment is an efficient, simple, quick, and safe method in the management of caries in young and uncooperative children. The risk of cross-infection is extremely low. So, further studies are required as an alternative to Potassium Iodide, as it showed a reduction in the efficacy of 38% Silver Diamine Fluoride.

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Table1: Overall mean scores of cariostatic effect, among the groups.

Month	Group	Mean	Std.Deviation	Std.Error
1st month	SDF	1.8600	.26673	.06887
	SDF+KI	1.5733	.49203	.12704
	Control group	1.7733	.30347	.07836
	Total	1.7356	.37909	.05651
6thmonth	SDF	1.8600	.26673	.06887
	SDF+KI	1.4667	.63770	.16465
	Control group	1.7733	.30347	.07836
	Total	1.7000	.45875	.06839
12thmonth	SDF	1.7533	.54885	.14171
	SDF+KI	1.1000	.82289	.21247
	Control group	1.7733	.30347	.07836
	Total	1.5422	.66383	.09896

Table2: Inter-group comparison of cariostatic effect among study groups

Months	Group type	Sum of Squares	Mean Square	Sig.
1st month	Between Groups	.648	.324	.103
	Within Groups	5.675	.135	
	Total	6.323		
6thmonth	Between Groups	1.281	.641	.044 *
	Within Groups	7.979	.190	
	Total	9.260		
12thmonth	Between Groups	4.403	2.202	.004 *
	Within Groups	14.987	.357	
	Total	19.390		

*Indicates a significant value

Table3: Mean value of L, among the Groups.

Month	Group	Mean	Std. Deviation	Std.error
1st month	SDF	53.2611	5.30750	1.37039
	SDF+KI	80.3252	4.24914	1.09712
	Controlgroup	90.5976	3.08031	.79533
	Total	74.7280	16.47310	2.45566
6thmonth	SDF	62.0563	4.94014	1.27554
	SDF+KI	84.5254	4.05942	1.04814
	Controlgroup	91.0082	3.10497	.80170
	Total	79.1966	13.17096	1.96341
12thmonth	SDF	66.8875	4.13832	1.06851
	SDF+KI	69.6222	36.17922	9.34143
	Controlgroup	91.5513	3.22368	.83235
	Total	76.0203	23.44903	3.49558

Table4: Inter-group comparison of L among study group

Month	Group type	Df	Mean Square	F	Sig.
1st month	Between Groups	2	5579.994	300.468	.000*
	Within Groups	42	18.571		
	Total	44			
6thmonth	Between Groups	2	3462.758	205.608	.000*
	Within Groups	42	16.842		
	Total	44			
12thmonth	Between Groups	2	2741.680	6.154	.005*
	Within Groups	42	445.485		
	Total	44			

*Indicates a significant value

Table5: Mean dependent variation of Δ E among study groups.

Groups	Mean	Std. Deviation	Std. Error	sig.
SDF	4.040	.5221	.1348	.000*
KI	1.553	.2642	.0682	
Controlgroup	.500	.2104	.0543	
Total	2.031	1.5414	.2298	

*Indicates a significant value

