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Assessment of Parental Perception and Clinical Efficacy of Silver Diamine Fluoride (SDF) Application in Primary Dentition: A Prospective Study

Amina Sultan[1,b], *Simran Uppal*[2,a,*], Maryam Siddiqui[1,c], Barsha Priya Deka[3,d], Abhishek Mehta[4,e], Akanksha Juneja[1,f]

[1]*Department of Pediatric & Preventive Dentistry, Faculty of Dentistry, Jamia Millia Islamia, New Delhi.*
[2]*Faculty of Dentistry, Jamia Millia Islamia, New Delhi.*
[3]*NIHR Project Core, Faculty of Dentistry, Jamia Millia Islamia, New Delhi.*
[4]*Department of Public Health Dentistry, Faculty of Dentistry, Jamia Millia Islamia, New Delhi.*
**Corresponding author*

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ABSTRACT

Objectives: Silver diamine fluoride (SDF) is a promising, cost-effective treatment for caries arrest. Despite its clinical efficacy, concerns regarding tooth discolouration and limited data on parental acceptance in India highlight the need for further research. Aim: To evaluate the clinical effectiveness of 38% SDF in arresting caries in primary teeth and assess parental perceptions of the treatment post-application.

Materials and Methods: A non-randomized, prospective, single-arm clinical study was conducted on 107 children aged 1–10 years with at least one carious lesion (ICDAS scores 3–6) in primary dentition. SDF application was done at baseline and during follow-up evaluations, which were done at 2 weeks and 3 months. A questionnaire assessed parental perceptions, including time efficiency, comfort, pain, taste, and satisfaction post-application. Clinical outcomes, including lesion colour, texture, and pain, were evaluated by an independent dentist. Chi square test was used to assess the association between parental perception and variables like age, gender and tooth position.

Results: Parental satisfaction was high, with 71% of them rating the treatment as comfortable and 48.5% finding the taste acceptable. Clinical outcomes revealed significant improvements in lesion texture, with 93.4% of lesions becoming hard after 3 months. Lesion colour transitioned predominantly to black (93.4%), indicating remineralization. Pain and sensitivity significantly decreased over time, and most (86%) reported no pain during treatment.

Conclusions: These findings demonstrated Silver Diamine Fluoride effectiveness in reducing pain and enhancing lesion remineralization. Given the study's findings, integrating SDF therapy into routine paediatric dental care can significantly improve caries management, particularly in underserved communities.

Keywords: Children, caries arrest, early childhood caries (ECC), silver diamine fluoride (SDF), parental acceptability.

[a] asultan@jmi.ac.in 0000-0001-5245-4416
[b] simranuppal2142@gmail.com 0000-0002-1755-1058
[c] dr.maryamsiddiqui@gmail.com 0000-0003-2819-4567
[d] nihrproject.jmi@gmail.com 0000-0002-2750-8571
[e] amehta@jmi.ac.in 0000-0002-9192-7615
[f] ajuneja@jmi.ac.in 0000-0003-4127-1133

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Introduction

The Global Burden of Disease (GBD) study (2021) has provided updated insights into the prevalence of dental caries in both deciduous and permanent dentition, highlighting significant regional disparities and trends over the past three decades. While the total number of affected cases remained largely unchanged from 1990 to 2021, the burden was disproportionately high amongst children under five years of age. It was observed that the African region experienced a 93.9% increase in prevalent cases, while the Eastern Mediterranean reported a 34.1% rise.[1] India currently lacks a comprehensive national oral health policy to address widespread dental health concerns. Few systematic reviews have reported that over 50% of children are affected by dental caries, with prevalence rates ranging from 50.84% to 62.41%. The overall prevalence of dental caries amongst children aged 3 to 18 years is estimated to be 52%.[2,3] Despite having a well-established Primary Health care system, dental services are inaccessible and unaffordable. Most patients had to bear the cost of dental procedures from their pocket, as we lack the facilities of government or private dental health insurance.[4]

The management of dental caries in uncooperative children, especially those with special health care needs, can be challenging and may necessitate treatment under sedation or general anaesthesia, which not only increases the financial burden but also carries the risk of systemic complications.[5,6] To alleviate the burden of dental caries in young children and mitigate the serious ramifications of untreated decay, identifying an effective, cost-efficient treatment method is crucial. Among various fluoride-based treatments, silver diamine fluoride (SDF) has emerged as a promising cariostatic agent for both primary and permanent dentition,[7] with even more potency than

Fluoride varnishes and Atraumatic Restorative Treatment (ART).[8]

The U.S. Food and Drug Administration (FDA) has even recognized SDF as a "breakthrough therapy" for caries arrest and prevention, while the American Academy of Paediatric Dentistry (AAPD) endorses its use in caries prevention.[9,10] Since its discovery in 1960, dental professionals in China, Australia, Brazil, and Argentina have been using SDF to control dental decay in primary teeth, occlusal caries in developing permanent molars and root caries in geriatric patients.[11]Additionally, recent randomized controlled trials conducted in Hong Kong demonstrated that SDF an reduce carious lesions in children when applied biannually at a concentration of 38%.[12] Further, it has proven effective in alleviating pain due to dentinal hypersensitivity.[13] Its ease of application, cost-effectiveness, minimal training requirements, minimal adverse reactions, and non-invasive nature make it a viable alternative for treating uncooperative patients. With 70% of India's population living in rural or low-income areas, SDF could serve as an accessible treatment option for many. However, despite its benefits, parental acceptance of SDF treatment is limited due to concerns about the resulting permanent black staining on teeth.[4,14] Further, we need more clinical data to thoroughly assess the efficacy of SDF in arresting dental caries and determine the optimum concentration and frequency of SDF applications to formulate standard guidelines.

There is limited data available that has focused on understanding the views and acceptance of SDF in the Indian paediatric population. Only a few researchers have focused specifically on parents' perceptions of SDF treatment in terms of aesthetics, highlighting a gap in understanding this aspect of acceptance. Thus, this study aimed to evaluate the clinical efficacy of 38% SDF in arresting dental caries in primary teeth as well as the parental and children's perception related to this therapy. The null hypotheses were :(i) SDF treatment is not clinically effective in arresting dental caries in the primary dentition, and (ii) SDF therapy did not fulfil the parental expectation of a successful dental treatment involving aesthetics and comfort. Alternative hypothesis was that the above statements were false. By addressing both the clinical efficacy and the perception of this innovative treatment, the findings of this study could contribute to improved management strategies for ECC and enhancehealth outcomes for vulnerable paediatric populations around the world.

Materials and Methods

A non-randomized, prospective, single-arm clinical study was conducted on children in the mixed dentition period who underwent SDFapplications in their carious teeth. Overall, 107 children received SDF therapy.

Eligibility Criteria and Recruitment of Participants into the Study

The dentist explained SDF therapy to the parents, showed them pre- and post-treatment photographs of clinical cases for assessment, and only recruited patients willing to undergo the procedure. The paediatric patients recruited were healthy without any medical comorbidity, accompanied by parents, and willing to participate voluntarily. The inclusion criteria involved paediatric dental patients with at least one carious lesion in the primary teeth which was clinically and radiographically detectable. Hence, lesions with the ICDAS scores of 3,4,5,or 6 according to ICDAS (International Caries Detection and Assessment System) specifications were selected for SDF therapy.[15] Pre-operative periapical radiographs(IOPA) were taken at the start of the study to rule out any pulpal involvement of the teeth or any peri-radicular pathology. Teeth with signs and symptoms of pulpitis were excluded. We also excluded children with developmental dental anomalies like amelogenesis imperfecta or dentinogenesis imperfecta and with a known history of allergies or sensitivities to any dental materials, any metal and silver or uncooperative patients in first appointment. The duration of the study was 12 months.

Sample Size Calculation:

The sample size for this study was determined using G-Power 3.1.9.7 software. A Chi-Square goodness of fit test was selected to compare proportions between groups. The calculation was performed using an effect size (w) of 0.262, an alpha error probability (α) of 0.05 and a statistical power (1 – β) of 0.080. The degree of freedom (df) was set to 1. Based on these parameters, the total required sample size was estimated to be 115 participants. The non-centrality parameter (λ) was 7.894 and the chi–square value was 3.841. The actual computed power for this sample size was 0.802, confirming that the study design meets the required statistical rigor. A p-value <0.05 was considered statistically significant for hypothesis testing.

Ethical Issues and Consent

Before the commencement of the recording of the questionnaire and SDF application, informed consent was obtained from the child's parent or guardian. Ethical clearance to conduct the study was taken from the Institutional Ethics Committee. [8/5/232/JMI/IEC/2019]

SDF Application Procedure

The SDF applications were done according to the manufacturer's instructions and American Academy of Paediatric Dentistry (AAPD) chair-side guidelines.[16] Before the treatment, only gross debris was removed from the carious lesions. The lips and surrounding mucosa were coated with petroleum jelly to prevent unnecessary discolouration during the SDF treatment. To optimize SDF's effectiveness in arresting caries,38% SDF (e SDF) was topically applied carefully on the dried surface of the selected carious tooth surfaces under isolation with cotton rolls and suction. The SDF was applied with a micro brush or the applicator tip and allowed to be absorbed for up to 2 minutes and the excess was removed with cotton or gauze. Parents were instructed not to allow the child to drink or eat anything for approximately 1 hour after the SDF application. The patients were put on review and

asked to report after 2 weeks (2nd visit) and 3 months (3rd Visit). Following the clinical evaluation, on 2nd and 3rd visits, a re-application of 38% SDF was done on the previously treated carious lesions demonstrating no abnormal clinical signs of pathology. Keeping the patient's cooperation in mind, the Tell-Show-Do technique was pursued before the treatment, and for the sake of standardization, all three SDF- applications were done by only one trained dentist for every participant.

Data Collection

A post-treatment questionnaire was prepared for this study which had 2 sections.

Section 1- Post-treatment parents' perceptions

After recording the demographic details of the child and his/her parents, questions were asked related to parents' views and children acceptability of SDF therapy following the application. The parents were asked to rate their dental experience with SDF therapy. The purpose was to assess whether SDF application was a comfortable, pain-free process for the child, taste of SDF was acceptable to the child and whether this therapy fulfilled their expectation of a successful dental treatment.

Section 2- Clinical Examination Post-SDF application

Here we recorded the clinical findings of the carious lesions following SDF applications. To eliminate bias, a previously trained dentist who was not involved in SDF application, evaluated the surfaces of the treated teeth by visual and tactile inspection using a mouth mirror and a Community Periodontal Index (CPI) periodontal probe. The clinical assessment criteria were according to a previous study on SDF efficacy.[17] The effectiveness of SDF was determined by clinically examining the treated teeth surfaces for the colour (Brown, Yellow, and Black), texture of treated carious lesions (Soft, Hard, and Chalky) and the presence or absence of pain and infection. This dentist recorded clinical findings related to texture, colour, and pain on the day of the first application and after subsequent re-applications during the second and third visits, which took place at two-week and three-month intervals, respectively.

Post-operative Considerations

The treatment was deemed successful if the patient did not report any pain and the treated caries were hard and black in colour with no signs of infection or active caries. Whereas, if there were clinical manifestations of infection, constant pain between the scheduled appointments and treated caries was yellow and soft on probing even after 3rd application at 3-month intervals, or the patient missed the recall appointment, the therapy was regarded unsuccessful. In these instances, the patients underwent dental interventions like restorations, pulp capping, pulpectomy or extraction according to the dental need.

Data Analysis

The statistical analysis for the study was done using IBM SPSS version 21. The power analysis was performed to determine the appropriate sample size for the study. Descriptive statistics were utilized to summarize the demographic characteristics of study participants. Statistical significance for the association between the gender, age group and tooth position with respect to SDF application was tested using Pearson's Chi-square test. The level of significance was kept at $p < 0.05$.

Results

This study was involved SDF application of 61 primary anterior teeth and 46 primary molars of 107 participants, with a modest disparity between males (n = 40, 37%) and females (n = 67, 63%). Most participants (n = 53, 49.5%) were within the 1-4 years age group, while the remaining 50 (46.7%) were in the 5-8 years age group. A small proportion (n = 1; 3.7%) belonged to the 9-10 years age group.

Gender and age- wise comparison of the parental and participants' perceptions related to the application of SDF was done. The results showed that most of the parents of female participants felt that it was a little less time-consuming compared to the other treatment, but numbers were not showing statistically significant difference between these variables. When asked about the comfort of the SDF treatment compared with the traditional treatment both the male and female participants largely reported being "comfortable". While comfort levels showed slight variation across age groups, these differences were not statistically significant. The majority (86%) of the positive participants reported "no pain" during the treatment. No significant age or gender-based differences were observed in terms of reporting of pain. In terms of taste acceptance of SDF, a very small number of participants (5.6%) rated it as "highly unacceptable". More females (49.2%) were comfortable with the taste of SDF although the difference was not statistically significant. Satisfaction levels with the treatment of SDF were generally high as most of the participants and parents were "completely" satisfied with the treatment. The difference between age groups was not statistically significant. (Table 1-2)

Clinical efficacy (colour, texture, and presence/absence of pain and sensitivity) of SDF therapy was evaluated at 2 weeks and 3 months. We checked the association of locations of carious lesions (anterior or posterior region) with the effect of SDF therapy. Regarding complaints of pain and sensitivity, the change over time was not significant. Majority of the participants did not report any pain on the day of first application (87.8%) and after three months of treatment (93.3%). The colour of treated lesions changed significantly over time. Initially, a portion of the lesions were brown, but this percentage decreased notably after two weeks showing a significant association in lesion colour over time. A highly significant association was observed in the texture of the treated lesions. On the day of application, 32 (29.9%) lesions were soft, which decreased further to 8.4% (n = 9) after two weeks. Conversely, the percentage of lesions classified as hard increased over time (93.4%). A chalky texture was observed in a small percentage of lesions initially which decreased substantially by three months

(Table 3). Regarding the association of SDF application and location of carious lesions, pain and sensitivity reduced notably, showing complete resolution in 95% of primary anterior teeth and 89.1% in primary molars by 3 months. Lesion colour transitioned predominantly to black in 93.4% of carious lesions, indicating remineralization.

Texture increased substantially by 3 months with 91.3% primary molars -91.3% and 95% anterior teeth showed hard consistency. These findings demonstrate the treatment's effectiveness in reducing sensitivity and enhancing lesion remineralization. (Table 4)

Table 1. Association of participant's gender with the treatment of SDF

Variables		Gender			Significance
		Male	Female	Total	
		N (%)	N (%)	N (%)	
1. Time consumption	Little more	2 (5%)	4 (5.9%)	6 (5.6%)	X^2 - 0.24 p-value 0.80
	Little less	30 (75%)	52 (77.6%)	82 (77%)	
	No difference	8 (20%)	11 (16.4%)	19 (17.7%)	
	Very uncomfortable	4 (10%)	3 (4.4%)	7 (6.5%)	
2. Comfortness compared to traditional treatment	Uncomfortable	1 (2.5%)	4 (5.9%)	5 (.6%)	X^2 - 2.10 p-value 0.55
	Comfortable	29 (72.5%)	47 (70.14%)	76 (71%)	
	Very comfortable	6 (15%)	13 (19.4%)	19 (17.7%)	
3. Experience of pain & sensitivity	No Pain	35 (87.5%)	58 (86.56%)	93 (86%)	X^2 - 0.02 p-value 0.98
	Little pain	4 (10%)	7 (10.4%)	11 (10.2%)	
	Intense pain	1 (2.5%)	2 (2.9%)	3 (2.8%)	
4. Level of taste acceptance of SDF of the child	Highly unacceptable	4 (10%)	2 (2.9%)	6 (5.6%)	X^2 - 2.36 p-value 0.30
	Slightly unacceptable	17 (42.5%)	32 (47.7%)	49 (45.7%)	
	Highly acceptable	19 (47.5%)	33 (49.2%)	52 (48.5%)	
5. Satisfaction of the treatment	Completely	14 (35%)	22 (32.8%)	36 (33.6%)	X^2 - 0.68 p-value 0.71
	Mostly	18 (45%)	35 (52.2%)	53 (349.5)	
	Slightly unacceptable	8 (20%)	10 (14.9%)	18 (16.8%)	
Total		40 (37.38%)	67 (62.6%)	107 (100%)	

Table 2. Association of participant's age groups with the treatment of SDF

Variables		Age Groups				Significance
		1-4 years	5-8 years	9-10 years	Total	
		N (%)	N (%)	N (%)	N (%)	
1. Time Consumption	Little more	6 (11.3%)	11(22%)	1 (25%)	18 (16.8%)	X^2 - 2.78 p-value 0.60
	Little less	24 (45.2%)	22 (44%)	2 (50%)	48 (44.8%)	
	No difference	23 (43.3%)	17 (34%)	1 (25%)	41 (38.3%)	
	Very uncomfortable	2 (3.77%)	2 (4%)	1 (25%)	5 (4.6%)	
2. Comfortness compared to traditional treatment	Uncomfortable	1 (1.88%)	1 (2%)	1 (25%)	3 (5.6%)	X^2 - 12.32 p-value 0.05
	Comfortable	26 (49%)	21 (42%)	1 (25%)	48 (44.8%)	
	Very comfortable	24 (45%)	26 (52%)	1 (25%)	51 (47.6%)	
3. Experience of pain & sensitivity	No Pain	27 (50.9%)	26 (25%)	2 (50%)	55 (51.4%)	X^2 - 7.71 p-value 0.10
	Little pain	25 (47.16%)	23 (46%)	1 (25%)	49 (45.7%)	
	Intense pain	1 (1.88%)	1 (2%)	1 (25%)	3 (2.8%)	
4. Level of taste acceptance of SDF of the child	Highly unacceptable	7 (13.2%)	6 (12%)	1 (25%)	14 (13%)	X^2 - 1.92 p-value 0.74
	Slightly unacceptable	25 (47.16%)	19 (38%)	1 (25%)	45 (42%)	
	Highly acceptable	21 (39.6%)	25 (50%)	2 (50%)	48 (44.8%)	
5. Satisfaction of the treatment	Completely	16 (30.18%)	25 (50%)	2 (50%)	43 (40.1%)	X^2 - 6.59 p-value 0.15
	Mostly	28 (52.83%)	22 (44%)	1 (25%)	51 (38.3%)	
	Slightly unacceptable	9 (16.98%)	3 (6%)	1 (25%)	13 (12.1%)	
Total		53 (49.5%)	50 (46.7%)	4 (3.7%)	107 (100%)	

**X2 = Chi-Square value, significance at p-value <0.05*

Table 3. Association of SDF application on the first day and follow up

Variables		On the day of application		2 weeks later		3 months later		Significance
		N	%	N	%	N	%	
1. Pain/Sensitivity	Present	14	13.08%	9	8.41%	7	6.54%	X^2- 2.87 p-value 0.24
	Absent	93	86.92%	98	90.6%	100	93.46%	
2. Colour	Brown	44	41.12%	23	21.5%	4	3.74%	X^2 - 75.94 p-value 0.00001
	Yellow	19	17.76%	3	2.80%	3	2.80%	
	Black	44	41.12 %	81	75.70%	100	94.46%	
3. Texture of treated carious lesion	Soft	31	28.97%	9	8.41%	5	4.67%	X^2 - 37.35 p-value 0.00001
	Hard	67	62.62%	92	85.96%	100	93.46%	
	Chalky	9	8.41%	6	5.61%	2	1.87%	

**X2 = Chi-Square value, significance at p-value <0.05*

Table 4. Association of location of carious lesion [Anterior and Posterior teeth] with SDF application

Variables		Anterior Teeth			Posterior Teeth			Significance
		On the day of application n (%)	2 weeks later n (%)	3 months later n (%)	On the day of application n (%)	2 weeks later n (%)	3 months later n (%)	
1. Pain/ Sensitivity	Present	6 (9.8%)	5 (8.1%)	3 (4.9%)	8 (17.3%)	4 (8.6%)	4 (8.6%)	X^2 – 5.08 p-value 0.41
	Absent	55 (90.1%)	56 (91.80%)	58 (95%)	38 (82.61%)	42 (91.3%)	42 (91.31%)	
2. Colour	Brown	26 (42.6%)	13 (21.31%)	3 (4.9%)	18 (39.1%)	10 (21.74%)	1 (2.1%)	X^2 – 77.37 p-value 0.00001
	Yellow	12 (19.6%)	2 (3.28%)	1 (1.6%)	7 (15.2%)	1 (2.17%)	2 (4.3%)	
	Black	23 (37.7%)	46 (75.41%)	57 (93.4%)	21 (45.6%)	35 (76.09%)	43 (93.4%)	
3. Texture of treated carious lesion	Soft	15 (24.5%)	5 (8.20%)	2 (3.2%)	16 (34.7%)	4 (15.2%)	3 (6.5%)	X^2 – 41.41 p-value 0.00001
	Hard	42 (68.8%)	52 (85.25%)	58 (95%)	25 (54.3%)	40 (86.96%)	42 (91.3%)	
	Chalky	4 (6.5%)	4 (6.56%)	1 (1.6%)	5 (10.8%)	2 (4.35%)	1 (2.1%)	
TOTAL		61			46			

**X2 = Chi-Square value, significance at p-value <0.05*

Discussion

Both the null hypothesis postulated before the initiation of this study can be rejected and alternative hypothesis is accepted as the application of SDF effectively enhances the remineralization of lesions, leading to the arrest of dental caries in primary teeth. Most patients and their parents were satisfied with SDF therapy-related parameters such as comfort, taste, and aesthetics. The primary drawback of Silver Diamine Fluoride (SDF) therapy is the potential for black discolouration after application. This concern is significant because it raises parents' anxieties about aesthetics, particularly concerning front teeth.[18] Many authors have also found that primary anterior teeth have lesser parental acceptance of SDF application than posterior teeth when aesthetics are concerned.[19,20,21] In our study, most parents expressed satisfaction with SDF therapy, with 41% being "completely satisfied" and 39% "mostly satisfied." Many parents found the SDF process slightly less time-consuming than traditional treatments, and approximately 45% of patients reported that the taste of SDF was “highly acceptable.” No significant gender disparity was observed. Similar observations of parental acceptability to taste and discolouration were reported in previous studies.[17,22] In addition, Clemens et al.,[17] reported that 70.0% of the parents felt SDF application was pain-free. A randomized controlled study reported that parental acceptance increased time, rising from 1.4% at baseline to 4.5% at 30 months follow-up.[23]

In the current study, a highly significant association was observed in the texture of the treated lesions with time and number of applications. At the 3-months follow-up, we observed that majority of carious lesions had turned black in colour and developed a hard texture, confirming SDF’s remineralizing effect, consistent with findings from previous studies.[17,22] We have noted that the colour of treated lesions changed significantly over time both in the anterior teeth and in primary molars. Initially, a small number of the lesions were brown , but this percentage decreased notably after two weeks demonstrating a significant association in lesion colour over time.In the current study, only two carious lesions remained yellow, and five lesions exhibited soft consistency upon exploration, even after three applications at three-month intervals similar to the results obtained by other researchers.[24, 25] Chaurasiya et al.[26] reported that five lesions were brown and soft at the end of three months and thus considered not arrested, while Caroline et al.[24] reported 89.6% arrested carious lesions 3 months post SDF application. Another study by Yılmaz et al.,[25] demonstrated the greater remineralization effect of

38% SDF on the dentin of primary molars as compared to 5% NaF varnish.

SDF application can quickly relieve pain in teeth with severe caries by occluding the dentinal tubules of the exposed dentine surface. It occurs through the formation of deposits and the precipitation of proteins resulting from SDF interaction.[27] In our study more than 90% of carious lesion treated with SDF were found to have hard texture after 3 months period signifying an arrest of dental caries. These findings are similar to previous studies where researchers reported significant caries arrest in almost all carious teeth within three months following the application of 38% SDF, without any signs of pain or infection. Also, parents reported being comfortable with the taste, appearance, and technique.[17,22,27] Buldur et al.[22] documented 100% caries arrest in anterior teeth and 84.6% in posterior teeth, while Shrivastava et al.[28] reported 80% caries arrest at the first recall, increasing to 93.3% at 3 months. The present study's findings corroborated the efficacy of silver diamine fluoride (SDF) in arresting active carious lesions and parental satisfaction with this therapy. Based on these results, we can safely acknowledge that SDF therapy can halt the progression of active carious lesions in primary teeth.

Limitations of the current study include a relatively small sample size and age range, which may limit the generalizability of these findings. The follow-up period was also shorter, which may not be sufficient to evaluate the long-term efficacy of SDF therapy. Moreover, there might have been parental biases in satisfaction reporting. The lack of a control group or alternative treatment options limited this study's ability to compare the efficacy of SDF directly with other interventions. Nevertheless, this study addresses clinical outcomes and psychosocial factors related to SDF application, thus demonstrating its effectiveness, acceptance, and practicality as a minimally invasive approach in paediatric dentistry. Further research with longer-term follow-ups and standardized application protocols is recommended to optimize the use of SDF and address its limitations more comprehensively.

Conclusions

Parental and patient acceptability was generally positive, with a high percentage reporting satisfaction with the treatment outcomes of SDF with the only limitation of blackish discoloration of treated lesions. These findings demonstrate the treatment's effectiveness in reducing sensitivity and enhancing lesion remineralization. Given the study's findings, integrating SDF therapy into routine paediatric dental care can significantly improve caries management, particularly in underserved communities.

Conflicts of Interest Statement

There are no conflicts of interest.

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