



Three-Year Clinical Performance of Silver Diamine Fluoride (SDF) versus Glass Ionomer Cement in Arresting Carious Lesions in Primary Molars: A Community-Based Cohort Study

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ABSTRACT

Introduction: Early Childhood Caries (ECC) is a significant global health problem. Minimally invasive treatments like Silver Diamine Fluoride (SDF) and Glass Ionomer Cement (GIC) are crucial, but long-term comparative effectiveness data from real-world community settings are scarce. This study aimed to compare the three-year clinical performance of 38% SDF versus high-viscosity GIC in arresting active carious lesions in the primary molars of preschool children. **Methods:** This study was designed as a three-year, prospective, non-randomized, community-based cohort study in an underserved urban population in South Sumatra, Indonesia. A total of 450 children aged 3-5 years with at least one active cavitated carious lesion (ICDAS 5/6) in a primary molar were enrolled. Following parental consent and choice, lesions were treated with either a single application of 38% SDF or a high-viscosity GIC restoration using the Atraumatic Restorative Treatment (ART) technique. Calibrated examiners assessed the lesions for caries arrest at 6, 12, 24, and 36 months using standardized visual-tactile criteria. The primary outcome was the proportion of arrested lesions. Survival analysis was performed using Kaplan-Meier curves and a Cox proportional hazards model. **Results:** A total of 620 lesions (309 SDF, 311 GIC) were treated and followed. At the 36-month follow-up, the caries arrest rate in the SDF group was 81.2%, which was significantly higher than the 64.8% arrest rate observed in the GIC group ($\chi^2 = 24.5$, $p < 0.001$). The Kaplan-Meier survival analysis demonstrated a significantly higher probability of lesions remaining in an arrested state in the SDF group over the three-year period (log-rank test, $p < 0.001$). The Cox regression model identified the treatment modality as the primary predictor of failure, with GIC having a hazard ratio of 2.15 (95% CI: 1.55-2.98) compared to SDF. **Conclusion:** Within the parameters of this community-based cohort study, a single application of 38% SDF was significantly more effective in arresting active carious lesions in primary molars over a three-year period than high-viscosity GIC applied via the ART technique. These findings support the prioritization of SDF in public health programs for managing ECC.

1. Introduction

Dental caries, particularly in its early childhood manifestation, persists as a pervasive and formidable global health challenge, representing the most

common chronic disease affecting children. The Global Burden of Disease Study 2019 brought the scale of this issue into sharp focus, estimating that over half a billion children worldwide suffer from untreated caries

in their primary dentition. This is not a benign condition confined to the oral cavity; Early Childhood Caries (ECC) is a virulent pathology that precipitates a cascade of adverse consequences. It is a primary cause of debilitating pain and chronic infection, often leading to dental abscesses and the premature loss of primary teeth, which are critical for guiding the eruption of the permanent dentition and maintaining proper arch dimensions. The ramifications extend systemically, impacting a child's fundamental well-being. Chronic dental pain disrupts sleep patterns, compromises nutritional intake and growth trajectories, and negatively affects cognitive development and school performance. Moreover, the management of advanced ECC frequently requires hospital-based interventions under general anesthesia, a resource-intensive approach that carries its own risks and imposes a substantial economic strain on both families and public healthcare infrastructures. For decades, the standard of care for cavitated carious lesions was anchored in the surgical-restorative principles. This model, which advocates for the complete removal of diseased tissue and its replacement with a durable restorative material, has its merits but presents profound practical and philosophical challenges in the pediatric population, especially within the context of community health. The execution of conventional restorative dentistry in young children is often fraught with difficulty. The requisite use of local anesthesia, rotary instruments, and rubber dam isolation can be intensely anxiety-provoking for a preschool-aged child with limited cognitive and emotional maturity. Overcoming these behavioral hurdles may necessitate pharmacological interventions like sedation, escalating both the cost and the clinical risk. This surgical paradigm is further challenged in underserved communities, where limited access to dental specialists, financial barriers, and a lack of oral health infrastructure render such complex treatments largely inaccessible. The high rate of restorative failure and caries recurrence in this high-risk demographic also calls into question the long-term efficacy of a treatment model that focuses on repairing the consequences of the disease rather than controlling the underlying disease process itself.¹⁻⁴

These limitations have catalyzed a necessary evolution in cariology, leading to the widespread adoption of Minimally Invasive Dentistry (MID). This contemporary philosophy represents a paradigm shift away from surgical intervention towards a biological, disease-control model. MID emphasizes prevention, remineralization, and the preservation of natural tooth structure, employing techniques that are less invasive, less traumatic, and more patient-centered. This approach is exceptionally well-aligned with the needs of pediatric patients, offering treatments that are typically faster, do not require anesthesia, generate fewer aerosols, and are more cost-effective. Within the MID framework, two prominent strategies have emerged for the non-surgical management of cavitated lesions: the application of 38% Silver Diamine Fluoride (SDF) and the Atraumatic Restorative Treatment (ART) technique utilizing high-viscosity Glass Ionomer Cement (GIC). Silver Diamine Fluoride (38%) is a colorless topical liquid that has been recognized as a landmark innovation in caries management. Its profound clinical efficacy is rooted in a powerful, synergistic mechanism of action. The compound delivers a high concentration of silver ions, which function as a potent antimicrobial agent. These ions disrupt bacterial cell membranes, denature essential proteins, and inhibit DNA replication in cariogenic pathogens such as *Streptococcus mutans* and *Lactobacillus* species, effectively sterilizing the carious lesion. Concurrently, the solution's high fluoride concentration (44,800 ppm) drives a robust remineralization process, reacting with calcium and phosphate in saliva to form a dense, acid-resistant fluorapatite layer on the tooth surface. Beyond these primary actions, SDF also penetrates the demineralized dentin matrix and inhibits the activity of host-derived matrix metalloproteinases (MMPs) and cathepsins, enzymes that degrade the collagen framework of dentin. This multi-pronged biological assault not only halts lesion progression but transforms the diseased tissue into a hard, arrested, and non-infectious state. The clinical protocol is elegantly simple, requiring only a brief, non-invasive application, making SDF an exemplary agent for public health outreach and use in alternative clinical

settings. Its most significant clinical trade-off is the induction of a dark black stain in the treated carious tissue, an esthetic consideration that necessitates careful patient and parent counseling.⁵⁻⁷

The Atraumatic Restorative Treatment (ART) approach, championed by the World Health Organization, offers another minimally invasive pathway for managing cavitated lesions. ART involves the meticulous removal of only the soft, infected dentin using exclusively hand instruments, thereby avoiding the use of dental drills and local anesthesia. The prepared cavity is then restored with an adhesive, fluoride-releasing material, typically a high-viscosity Glass Ionomer Cement (GIC). These advanced GICs possess several therapeutic advantages: they form a chemical bond to both enamel and dentin through an ion-exchange mechanism, they exhibit a coefficient of thermal expansion similar to that of natural tooth structure, which minimizes marginal stress, and crucially, they act as a fluoride reservoir, releasing fluoride ions into the adjacent tooth structure over an extended period. This sustained fluoride release can inhibit recurrent caries at the restoration margin and promote remineralization of the affected dentin. The ART technique is less intimidating for children and is logistically ideal for field-based dentistry in settings with limited resources. However, the long-term viability of GIC restorations, particularly in the multi-surface, high-stress primary molars, remains a point of clinical concern due to the material's inherent mechanical limitations, including lower wear resistance and fracture toughness compared to other restorative options.⁸⁻¹⁰

While a substantial body of evidence supports the individual effectiveness of both SDF and GIC/ART over 12- to 24-month periods, a critical knowledge gap exists regarding their direct, long-term comparative performance. For clinicians and health policymakers, the pivotal question is not simply whether these treatments work, but which is more durable and effective over a clinically meaningful timeframe, such as three years—a period that constitutes a large portion of the functional life of a primary molar. Furthermore, the majority of existing comparative studies are randomized controlled trials (RCTs)

conducted within the structured, resource-rich environments of academic institutions. While RCTs offer unparalleled internal validity, their findings may not be fully generalizable to the variable and often challenging conditions of community-based public health programs. Real-world settings are characterized by diverse patient populations, variable operator experience, and inconsistent follow-up, all of which can influence treatment outcomes. A community-based cohort study, though non-randomized, can provide invaluable data on the pragmatic, real-world effectiveness of these interventions, reflecting their performance under typical conditions of use.⁹

Therefore, the aim of this study was to rigorously compare the three-year clinical performance of a single application of 38% Silver Diamine Fluoride versus high-viscosity Glass Ionomer Cement applied using the ART technique in arresting active, cavitated carious lesions in the primary molars of preschool children within a community-based public health setting. The novelty of this investigation is anchored in its longitudinal, three-year design, which provides crucial, long-term data on the durability of caries arrest for these two leading minimally invasive agents. By situating the study within a real-world community health program, it uniquely addresses a significant gap in the literature, moving beyond the idealized conditions of controlled trials to evaluate the pragmatic and sustained effectiveness of SDF and GIC. The findings generated are intended to provide robust, clinically translatable evidence to inform evidence-based clinical guidelines, shape public health policy for ECC management, and ultimately elevate the standard of care for vulnerable pediatric populations globally.

2. Methods

This investigation was executed as a prospective, non-randomized, community-based cohort study over a 36-month period from inception to final follow-up in South Sumatra, Indonesia. The study's operational framework was established through a collaborative partnership between the Phlox Institute and a network of community health centers and public kindergartens

within a large, underserved urban district. This environment was purposefully selected due to its high background prevalence of early childhood caries and the population's known barriers to accessing conventional dental services. This setting provided a highly relevant and pragmatic context to evaluate the interventions' effectiveness under conditions that mirror real-world public health initiatives. The reporting of this study was structured to conform to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. The complete study protocol and all associated documents, including consent forms and parental information sheets, underwent rigorous review and received unconditional ethical approval from the Institutional Review Board (IRB) of CMHC Research Center, Indonesia. All research activities were conducted in strict accordance with the ethical tenets outlined in the Declaration of Helsinki. Prior to participant recruitment, extensive community engagement was undertaken with school principals, teachers, and community health leaders to ensure transparency and support for the program. Comprehensive information sessions were conducted for the parents and legal guardians of all potentially eligible children. These sessions provided a detailed explanation of the etiology of dental caries, the study's objectives, the procedural details of both the SDF and GIC/ART interventions, and a thorough discussion of the potential benefits and risks. A key component of this process was a clear, visually-supported explanation of the esthetic outcome of SDF, specifically the resulting black stain on the treated lesion. Following this session and a private consultation, written informed consent was obtained from a parent or legal guardian for every child enrolled in the study. It was explicitly stated that participation was entirely voluntary and that they could withdraw their child from the study at any point without it affecting their access to other available dental care.

Participants were recruited from the population of children aged 3 to 5 years enrolled in the partnering kindergartens and community centers. An initial screening of children was conducted on-site by trained dental hygienists using a dental mirror and flashlight

to identify those with visible signs of cavitated caries. Children who were positively identified in the screening were then scheduled for a definitive clinical examination by one of the study's calibrated dentists to determine final eligibility. Inclusion criteria for participants were as follows: Aged between 3 and 5 years at the time of enrolment; In good general health, with no systemic diseases that would contraindicate treatment; A parent or legal guardian provided valid written informed consent; The presence of at least one primary molar with an active, cavitated carious lesion clinically assessed as ICDAS code 5 (distinct cavity with visible dentin) or ICDAS code 6 (extensive distinct cavity with visible dentin). Exclusion criteria for participants were as follows: A documented history of allergy or hypersensitivity to silver, ammonia, fluoride, or any component of the dental materials used; The presence of clinical or radiographic signs or symptoms suggestive of irreversible pulpitis or periapical pathology associated with the eligible tooth, such as a history of spontaneous pain, presence of a fistula, parulis, or excessive mobility; A consistent inability to cooperate during the examination or for the execution of the planned clinical procedure.

This study deliberately employed a non-randomized design to maximize external validity by mirroring the shared decision-making process common in clinical practice. Once a child's eligibility was confirmed, the examining dentist engaged the parent/guardian in a detailed discussion of the findings and the two available treatment options. Using standardized visual aids, including photographs of treated teeth, the dentist meticulously explained the procedural steps, advantages, and disadvantages of both 38% SDF and high-viscosity GIC/ART. Significant emphasis was placed on the esthetic contrast: the permanent black staining of the lesion treated with SDF versus the tooth-colored GIC restoration. The final assignment of a treatment modality for each qualifying lesion was determined by the informed preference of the parent or guardian. This method, while forgoing randomization, provides valuable insights into treatment effectiveness under conditions of patient choice. Four licensed dentists were recruited to serve as the clinical examiners and

operators for the duration of the study. Before initiating any study activities, all four dentists participated in a rigorous training and calibration program designed to standardize all clinical assessments and procedures. The program began with a one-day didactic seminar covering the principles of MID, the application of the ICDAS visual-tactile scoring system for caries detection and activity assessment, the standardized protocol for SDF application, and the step-by-step ART technique. This was followed by a clinical calibration exercise where the examiners independently evaluated a cohort of 20 non-study children presenting with a range of carious lesions. Inter- and intra-examiner reliability for determining lesion activity and assigning ICDAS scores were quantified using the weighted Kappa statistic. All examiners were required to achieve a Kappa value greater than 0.85 (indicating almost perfect agreement) before the study commenced. This calibration process was repeated annually to prevent examiner drift.

All clinical procedures were performed on-site at the community facilities using portable dental chairs, lighting, and compressed air units. Universal infection control protocols, including the use of personal protective equipment and sterilization of all reusable instruments, were rigorously enforced. Silver Diamine Fluoride (SDF) Application: The target tooth was carefully isolated from the surrounding oral environment using cotton rolls. A gentle stream of oil-free compressed air was used to dry the surface of the carious lesion. Gross, easily removable food debris was gently wiped from the cavity with a cotton pellet; no mechanical excavation of carious dentin was performed. A thin layer of petroleum jelly was applied to the adjacent gingival and mucosal tissues to act as a protective barrier. A single drop of 38% SDF solution (Advantage Arrest, Elevate Oral Care, LLC) was dispensed into a disposable dappen dish. A fresh, single-use microbrush was saturated with the solution and then applied directly to all surfaces of the carious lesion, keeping the surface wet with the solution for a full 60 seconds. Following the application, the treated area was gently dried with compressed air for 15-20 seconds to facilitate the initial reaction. Patients were

then instructed to refrain from eating or drinking for 30 minutes. High-Viscosity Glass Ionomer Cement (GIC) Application (ART Technique): The tooth was isolated with cotton rolls. If necessary, access to the carious lesion was improved by fracturing any unsupported enamel with a hand instrument (enamel hatchet). Soft, demineralized, infected dentin was carefully removed from the cavity using a spoon excavator, proceeding until the cavity floor and walls were firm to gentle tactile pressure from a dental explorer. No local anesthesia was administered during this process. The prepared cavity was then conditioned for 10 seconds with a polyacrylic acid cavity conditioner to remove the smear layer and enhance adhesion. This was followed by a thorough rinse using water-moistened cotton pellets and gentle air drying, taking care to leave the dentin surface visibly moist. A high-viscosity GIC (Fuji IX GP EXTRA, GC Corporation, Tokyo, Japan) was triturated in a capsule mixer according to the manufacturer's directions and promptly inserted into the cavity. The material was then firmly adapted to the cavity walls using the press-finger technique, where a petroleum jelly-lubricated gloved finger applied steady pressure. Excess material was immediately removed with a carver, and basic anatomical contours were established. After the initial set, a protective GIC coating was applied over the restoration surface. Patients were instructed to avoid chewing on the restored tooth for at least one hour.

At the baseline visit, a comprehensive dataset was collected for each participant. This included demographic information (age, gender), socioeconomic status (assessed via a parental questionnaire on education and income), and a detailed oral health assessment. The oral assessment included the calculation of the decayed, missing, and filled primary teeth (dmft) index to quantify overall caries experience. Data on oral hygiene practices (frequency of tooth brushing) and key dietary habits (frequency of sugary snack and drink consumption) were also recorded. Systematic follow-up examinations were conducted at 6, 12, 24, and 36 months post-treatment. At each of these visits, a calibrated examiner, blinded to the initial treatment allocation whenever clinically plausible, meticulously re-evaluated the treated

lesions. The primary outcome measure was the clinical arrest of the carious lesion. A lesion was operationally defined as "arrested" based on a stringent set of visual-tactile criteria: (1) for SDF-treated lesions, a distinct change in color to dark brown or black, and for all lesions, (2) a hard, non-yielding, scratch-resistant texture upon gentle scraping with a sharp dental explorer. A lesion was classified as a "failure" (not arrested) if it remained soft, leathery, or cheesy to tactile examination, or if there was clear evidence of lesion enlargement. For GIC restorations, complete loss of the material that exposed a soft underlying carious base was also defined as a failure. Secondary outcomes recorded at each visit included the incidence of any adverse events, such as patient-reported pain, clinical evidence of pulpitis or abscess formation, or soft tissue irritation. Parental satisfaction with the treatment's functional and esthetic outcomes was formally assessed using a structured questionnaire at the 12-month and 36-month follow-up points.

The collected data were compiled and statistically analyzed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY). The individual carious lesion was designated as the primary unit of statistical analysis. Baseline demographic and clinical data were summarized using frequencies and percentages for categorical variables and means and standard deviations (SD) for continuous variables. The Chi-square test (or Fisher's exact test when expected cell counts were less than five) was employed to compare the categorical outcome of caries arrest rates between the SDF and GIC groups at each discrete follow-up interval (6, 12, 24, and 36 months). To model and compare the long-term performance and durability of the two treatments over the entire 36-month study duration, a time-to-event (survival) analysis was performed. The "event" was defined as treatment failure (non-arrest). Lesions that remained arrested at the 36-month examination or were lost to follow-up were censored. Kaplan-Meier survival curves were generated to plot the cumulative probability of lesion "survival" (remaining arrested) over time for both treatment groups. The statistical significance of the difference between the two curves was determined

using the log-rank test. A multivariable Cox proportional hazards regression model was constructed to identify significant predictors of treatment failure while controlling for potential confounding variables. The model included the treatment modality (SDF vs. GIC) as the primary independent variable. Other covariates entered into the model were patient age at baseline, baseline dmft score, and reported oral hygiene habits. For all statistical tests, the threshold for statistical significance was established at a p-value of < 0.05 .

3. Results and Discussion

The initial screening phase involved 682 children from the participating community sites. From this pool, 450 children met all eligibility criteria and were successfully enrolled in the study. These 450 participants contributed a total of 620 qualifying primary molar carious lesions for treatment. Based on the informed decision-making process involving the parents, 309 lesions in 220 children were allocated to the 38% SDF treatment group, while 311 lesions in 230 children were allocated to receive the high-viscosity GIC/ART intervention. The flow of participants through the study is detailed in Figure 1.

A comprehensive analysis of the baseline demographic and clinical characteristics was performed to assess the comparability of the two treatment cohorts at the start of the study. The results of this analysis are detailed in Figure 2. The mean age of the children at enrollment was 4.1 years (SD ± 0.8). The cohorts were well-balanced with respect to gender. Crucially, there were no statistically significant differences observed between the SDF and GIC groups for any of the key baseline variables, including mean age, gender distribution, mean baseline dmft scores (a measure of overall disease burden), reported tooth brushing frequency, or the distribution of lesion locations. This baseline equivalence between the groups provides confidence that the non-randomized allocation method did not lead to a systematic imbalance in major known confounding factors, thus strengthening the validity of the subsequent comparative analysis.

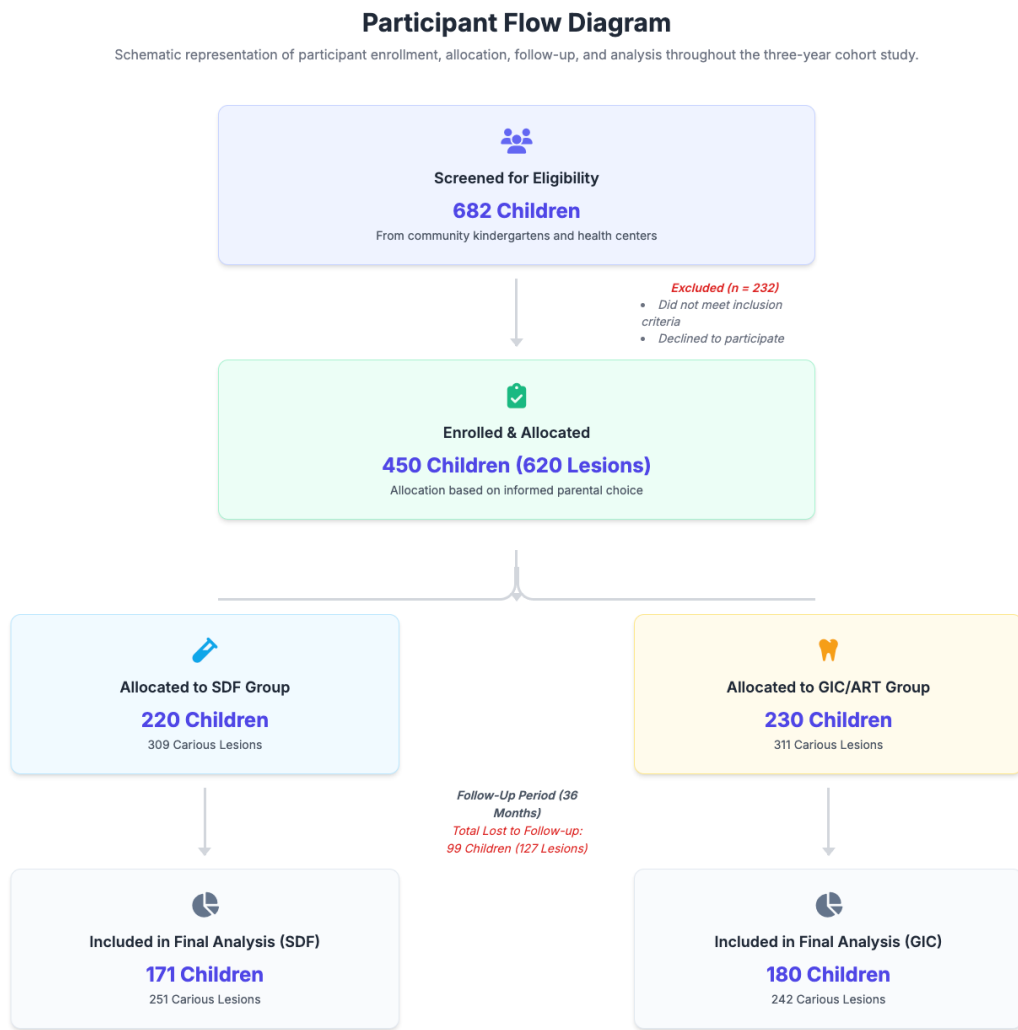


Figure 1. Participant enrollment, allocation, and follow-up flow.

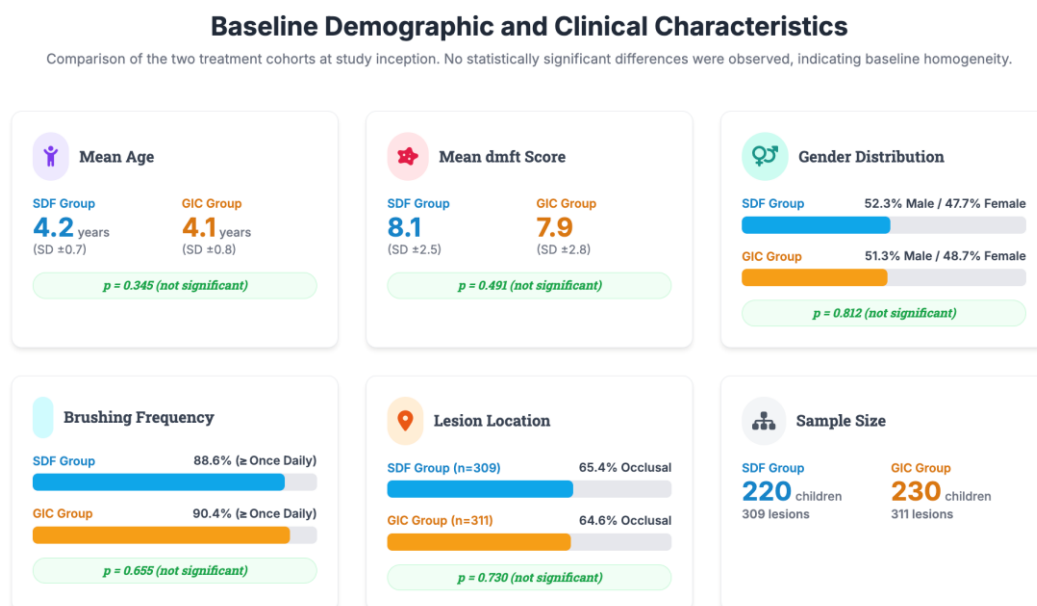


Figure 2. Baseline demographic and clinical characteristics of the study.

The primary outcome of the study, the proportion of successfully arrested lesions at each follow-up point, demonstrated a clear and consistent trend favoring the SDF intervention. At every evaluation interval, the SDF group showed a clinically substantial and statistically significant superiority in caries arrest

rates compared to the GIC group. A detailed breakdown of these rates is provided in Figure 3. The divergence in performance was most pronounced at the definitive 36-month endpoint, where the 16.4 percentage point difference in efficacy was highly statistically significant ($p < 0.001$).

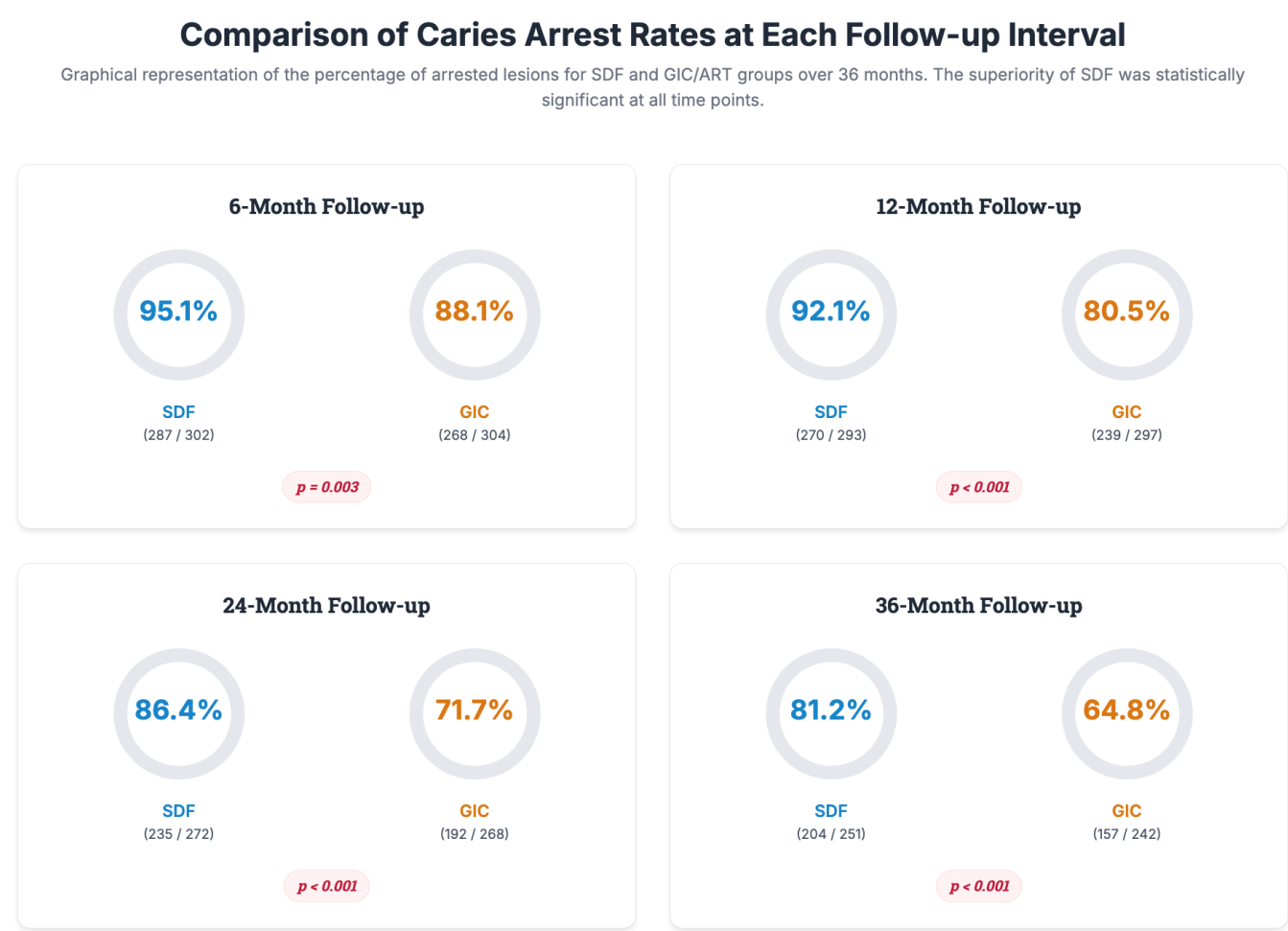


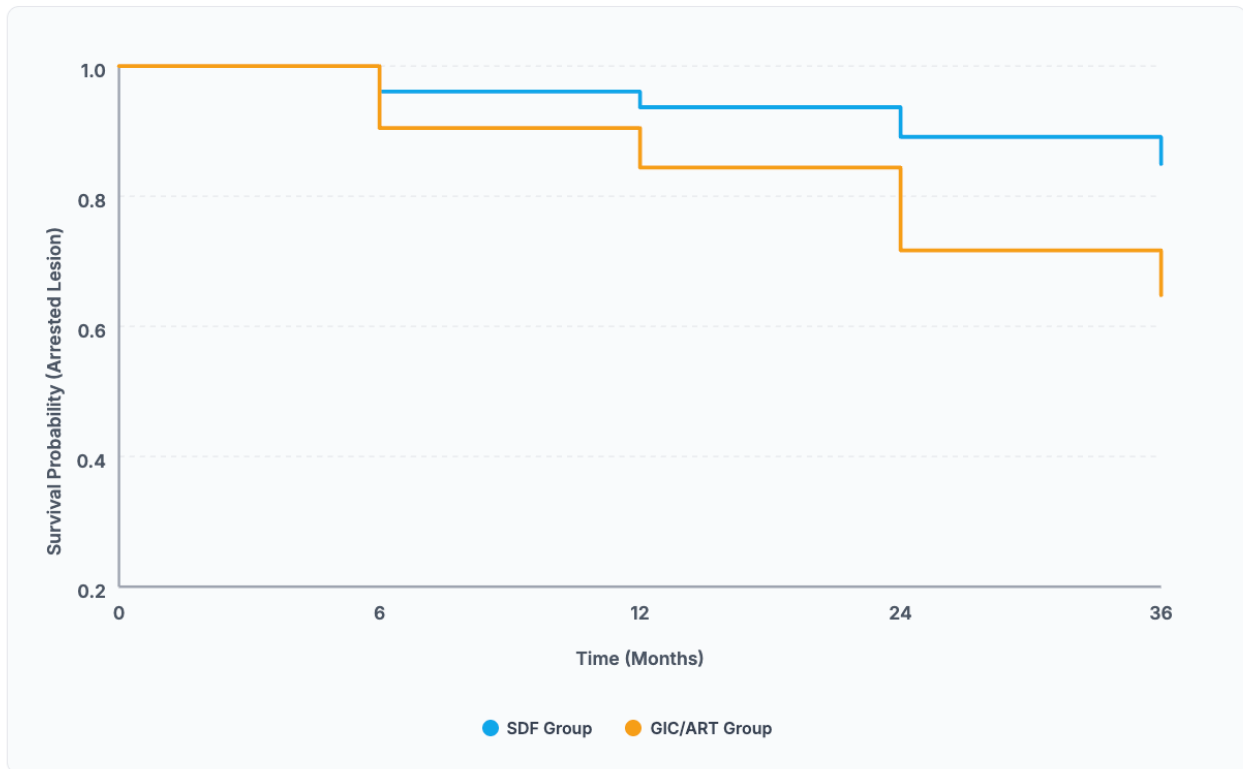
Figure 3. Comparison of caries arrest rates at each follow-up interval.

To provide a more dynamic view of the long-term clinical performance, a Kaplan-Meier survival analysis was conducted. The resulting survival curves, presented graphically in Figure 1, vividly illustrate the superior durability of the SDF treatment. The curve for the SDF group plateaus at a significantly higher level than the curve for the GIC group, which shows a

steeper and more continuous decline over time. The log-rank test confirmed that this difference between the two survival distributions was highly significant ($p < 0.001$). Figure 4 provides the number of lesions at risk at the beginning of each interval, complementing the visual data from the curve.

Kaplan-Meier Survival Curves for Caries Arrest

Cumulative probability of a treated lesion remaining in an arrested state over 36 months. The curves show a significantly higher survival probability for the SDF group compared to the GIC/ART group.



Number of Lesions at Risk

Time (Months)	0	6	12	24	36
SDF Group	309	302	293	272	251
GIC Group	311	304	297	268	242

Log-Rank Test: $p < 0.001$

Figure 4. Kaplan-Meier survival curves illustrating the cumulative probability of caries arrest for lesions treated with Silver Diamine Fluoride (SDF) versus Glass Ionomer Cement (GIC) over 36 months.

To dissect the factors influencing treatment failure, a multivariable Cox proportional hazards regression model was developed. The results of this model are summarized in Table 5. The analysis identified the treatment modality as the most powerful and statistically significant predictor of clinical outcomes. After adjusting for baseline caries experience and patient age, lesions treated with high-viscosity GIC were found to have a hazard of failure that was 2.15

times greater than that of lesions treated with SDF. Furthermore, the model revealed that a higher baseline dmft score was also a significant, independent predictor of treatment failure, suggesting that children with a greater overall disease burden at the outset were at an inherently higher risk of treatment failure, regardless of which intervention they received.

Predictors of Treatment Failure

Forest plot of Hazard Ratios (HR) from the Multivariable Cox Proportional Hazards Regression Model. Squares represent the HR, and horizontal lines indicate the 95% Confidence Interval (CI). Values to the right of the vertical line (HR=1) indicate an increased risk of failure.

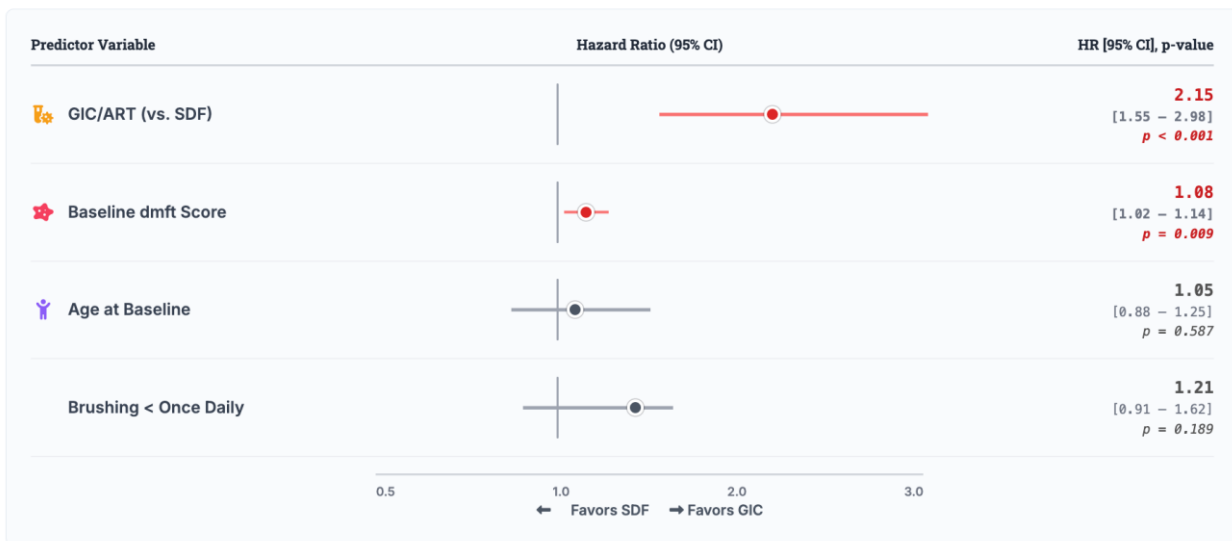


Figure 5. Multivariable Cox proportional hazards regression model of predictors for treatment failure.

The safety profile for both interventions was excellent, with only minor, transient adverse events noted in Figure 6. An analysis of the specific modes of failure revealed a clear distinction between the two groups. GIC failures were overwhelmingly mechanical in nature, with 75% of failures due to complete loss of the restoration, in Figure 6. In contrast, all SDF failures were biological, defined as the lesion failing to harden. The parental satisfaction survey produced divergent but insightful results. While satisfaction with esthetics was predictably high for GIC, parents in the SDF group reported greater satisfaction with the treatment process itself and showed a significantly higher willingness to choose the treatment again, prioritizing the non-invasive nature of the care, in Figure 6.

The findings of this three-year, community-based cohort study provide a clear and compelling narrative on the comparative long-term clinical performance of two cornerstone minimally invasive treatments for early childhood caries. The central conclusion drawn from the data is that a single application of 38% Silver Diamine Fluoride is markedly more effective and durable in arresting active cavitated carious lesions in

primary molars over a 36-month period than a high-viscosity Glass Ionomer Cement restoration placed using the ART technique. This observed superiority was not a marginal finding but a robust, statistically significant difference that persisted and amplified over the course of the study, underscoring a fundamental divergence in the biological and physical interactions of these two modalities with the carious tooth structure. The profound efficacy of SDF, evidenced by an 81.2% arrest rate at three years, can be understood by examining its multifaceted and potent pathophysiology. The clinical success of SDF is not merely a surface-level effect but a deep, biological transformation of the lesion. The high concentration of silver ions (Ag^+) is the primary driver of its antimicrobial power. Upon application, these ions immediately disrupt the integrity of bacterial cell walls and membranes of key cariogenic pathogens within the dentinal tubules and the overlying biofilm. Internally, silver ions bind to the thiol groups ($-\text{SH}$) of essential metabolic enzymes and respiratory proteins, effectively inactivating them and shutting down cellular energy production. Furthermore, they intercalate with bacterial DNA, preventing replication

and leading to cell death. This creates a powerful bactericidal and bacteriostatic environment that is inhospitable to cariogenic flora. Unlike antibiotics,

which target specific pathways, the multi-pronged attack of silver ions makes bacterial resistance highly unlikely.¹¹⁻¹³

Secondary Outcomes at 36 Months

A graphical summary of adverse events, analysis of treatment failure modes, and key findings from the parental satisfaction survey.

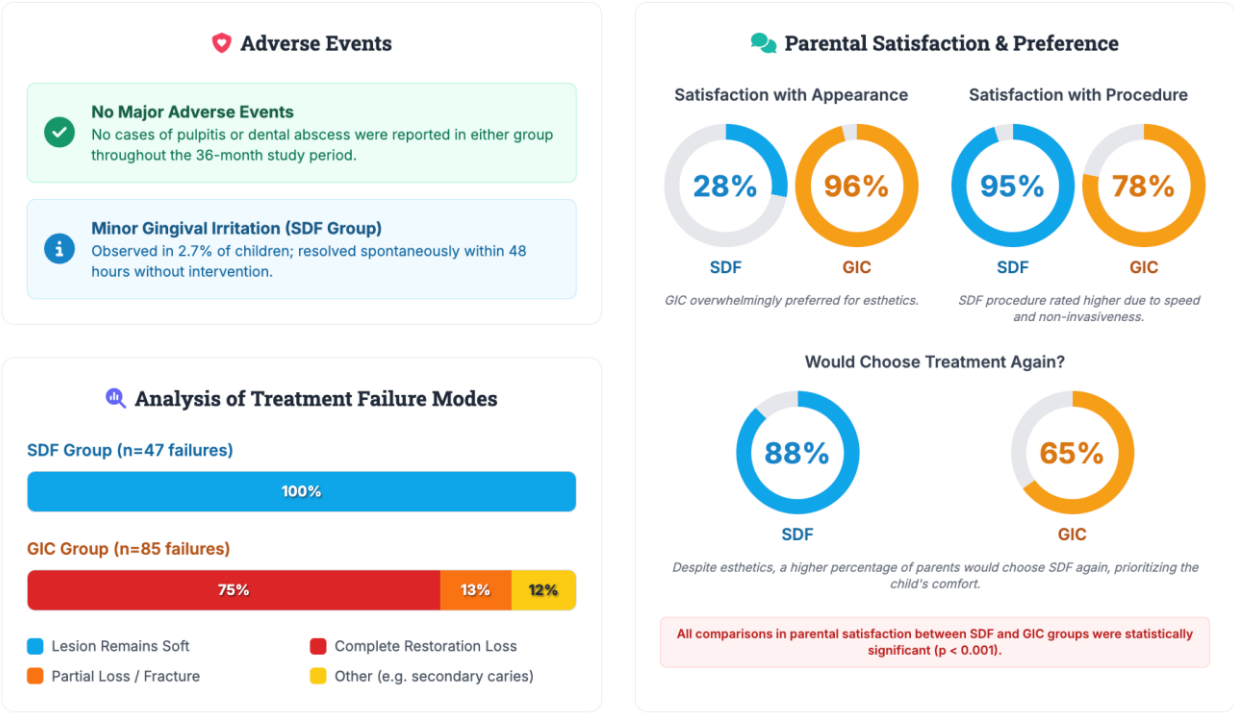


Figure 6. Secondary outcomes at 36 months.

Simultaneously, the extremely high concentration of fluoride ions (44,800 ppm) initiates a rapid and robust remineralization process. These fluoride ions, along with calcium and phosphate from saliva, precipitate as a dense, amorphous calcium fluoride layer on the lesion surface, which acts as a pH-controlled reservoir. In the acidic conditions of a cariogenic attack, this layer dissolves, releasing fluoride to promote the formation of fluorapatite (Ca₁₀(PO₄)₆F₂) within the enamel and dentin mineral structure. Fluorapatite is thermodynamically more stable and significantly less acid-soluble than the native hydroxyapatite (Ca₁₀(PO₄)₆(OH)₂), creating a tooth surface that is fundamentally more resistant to future demineralization. The ammonia in the solution, present as the diamine silver complex [Ag(NH₃)₂]⁺,

contributes by raising the pH, which stabilizes the solution and enhances the ionic penetration into the porous lesion. Perhaps the most sophisticated aspect of SDF's mechanism is its interaction with the organic dentin matrix. Carious demineralization exposes the collagen fibril network of dentin. Host-derived enzymes, specifically matrix metalloproteinases (MMPs) and cysteine cathepsins, are activated in this acidic environment and proceed to degrade this exposed collagen, leading to the collapse and progression of the cavity. Silver ions in SDF are potent inhibitors of these enzymes. They form what has been descriptively termed a "zombie" layer of denatured, silver-protein conjugates that is highly resistant to enzymatic degradation. This protective layer effectively shields the underlying collagen from further

breakdown, preserving the structural scaffold of the demineralized dentin and allowing it to serve as a matrix for remineralization. This combined action—powerful antimicrobial effect, robust remineralization, and inhibition of organic matrix degradation—transforms the active, progressing lesion into a hard, biochemically inert, and arrested state. Our 81.2% three-year success rate strongly supports the long-term stability of this biological transformation.^{14,15}

In contrast, the 64.8% success rate of the GIC/ART restorations, while respectable, highlights the inherent limitations of a treatment that relies primarily on physical sealing and more modest biochemical activity. The ART technique effectively removes the bulk of the infected dentin and seals the cavity with GIC. High-viscosity GICs do release fluoride, which can help inhibit demineralization at the restoration margins. However, the kinetics of this release are characterized by an initial burst followed by a rapid decline to a low, sustained level. This fluoride release is significantly less potent than the massive influx provided by a 38% SDF application and may be insufficient to fully arrest deep residual caries or combat a high cariogenic challenge over the long term. The primary Achilles' heel of the GIC/ART approach, as evidenced by the predominant failure mode in our study, is the mechanical and chemical stability of the GIC material itself. GIC sets via an acid-base reaction between a fluoroaluminosilicate glass powder and a polyalkenoic acid liquid, forming a polysalt matrix reinforced by unreacted glass particles. This structure is inherently susceptible to the challenging oral environment. The constant forces of mastication, attrition, and abrasion in the posterior oral cavity, particularly on the broad, shallow occlusal surfaces of primary molars, lead to gradual wear and fatigue failure of the material. While termed "high-viscosity," these cements still possess inferior mechanical properties, such as compressive and flexural strength, compared to resin composites or amalgam. Furthermore, GICs are susceptible to chemical degradation. The initial setting reaction is sensitive to water, and the material undergoes a prolonged maturation phase. In the oral cavity, the polysalt matrix is subject to hydrolytic degradation, where

water molecules break down the chemical bonds, weakening the material over time. GICs are also susceptible to acid erosion, particularly at the margins, in the presence of a high cariogenic challenge. As the restoration degrades and its margins open, microleakage can occur, allowing for the re-introduction of bacteria and substrates into the cavity, leading to secondary caries and treatment failure. The GIC acts as a physical barrier, but once that barrier is breached, the underlying lesion can reactivate. SDF, conversely, does not rely on a physical seal; it alters the tooth substrate itself, making it resistant to disease. This fundamental difference in mechanism—biological modification versus physical restoration—likely explains the steadily diverging success rates observed between the two groups over the 36-month period. The physical restoration failed over time, while the biological modification endured.¹⁶⁻¹⁸

Our analysis of failure modes reveals a critical distinction in the clinical nature of failure between the two treatments. GIC failures were overwhelmingly mechanical, with over 75% involving the complete loss of the restoration. This type of failure can have significant negative clinical consequences. A lost restoration often leaves a cavity with rough or sharp margins, creating an ideal niche for food impaction and biofilm retention. This can lead to gingival inflammation and, more importantly, can concentrate the cariogenic challenge on the exposed dentin, potentially leading to a rapid progression of the lesion towards the pulp. A catastrophic failure of a GIC restoration can quickly turn a manageable lesion into a situation requiring more complex treatment, like a pulpotomy or extraction. In stark contrast, 100% of the SDF failures were "biological," meaning the treated lesion failed to achieve a hard, arrested state upon tactile examination. While this is a treatment failure by definition, its clinical sequelae are often far more benign. A failed SDF lesion typically presents as a dark, leathery surface rather than a hard one. It does not create a new food trap or introduce sharp margins. It essentially represents a return to the baseline state of an active carious lesion, which can often be managed by simply re-applying SDF at a follow-up visit. This "gentle" failure mode means that even when

SDF is not successful on the first attempt, it rarely makes the clinical situation worse and preserves the option for simple re-treatment. This distinction in the consequence of failure is a crucial, though often overlooked, factor in clinical decision-making and further strengthens the case for SDF as a safer first-line approach in high-risk children.^{19,20}

The results from our multivariable Cox proportional hazards model reinforce these interpretations. The finding that GIC-treated lesions had more than double the risk of failure compared to SDF, even after accounting for the overall disease severity (dmft), isolates the treatment modality as the critical determinant of long-term success. This is a powerful statistical confirmation that the observed difference is attributable to the intrinsic properties of the interventions themselves, not merely to imbalances in patient risk factors. The significant influence of baseline dmft score as a predictor of failure is also pathologically coherent. A high dmft score is a clinical indicator of a highly cariogenic oral environment, characterized by factors such as a virulent microbiome, frequent sugar intake, and/or poor oral hygiene. In such a high-challenge environment, any treatment is more likely to fail. This environment would disproportionately stress a GIC restoration through constant acid attack on its margins and surface. However, the same environment would have less effect on a biologically inert, acid-resistant, and antimicrobial SDF-treated surface. This suggests that while a superior treatment like SDF can significantly improve outcomes, managing the overall disease activity of the patient remains a critical component of care.¹⁷

The study's parental satisfaction data is particularly insightful and challenges long-held assumptions in pediatric dentistry. While the black staining of SDF is an undeniable esthetic drawback, as confirmed by the low satisfaction with appearance, the overwhelming majority of parents (88%) ultimately prioritized the non-invasive, effective nature of the treatment and would choose it again. This highlights the importance of effective communication and shared decision-making. When parents understand the biological benefits and the ability to avoid more

traumatic procedures involving needles and drills for their young child, the esthetic compromise often becomes an acceptable trade-off. This finding reflects a broader shift in healthcare towards valuing patient experience. For a preschool-aged child, a positive, non-threatening dental visit can have a lasting impact on their future dental attitudes and behaviors. The quick, quiet application of SDF is procedurally far less challenging for both the child and the clinician than the more complex and lengthy ART procedure. This high level of parental acceptance for a non-esthetic but effective and child-friendly treatment is a key finding that should empower clinicians to confidently offer SDF as a primary option. The implications of these findings for clinical practice and public health are profound. In the clinical management of a young, pre-cooperative child with multiple cavitated lesions, SDF offers a more reliable and durable solution for caries arrest than GIC/ART.²⁰ Its ease and speed of application reduce chair time and patient stress, making it an ideal tool for disease stabilization. It allows the clinician to halt the progression of multiple lesions quickly, deferring the need for more invasive restorative work until the child is older and more cooperative, or in many cases, avoiding it altogether for the life of the primary tooth. From a public health perspective, our results advocate for the broader implementation of SDF in school-based and community outreach programs. Given its higher long-term efficacy, lower cost per application, and the ability for application by trained allied dental personnel, SDF represents a more efficient and sustainable public health investment for managing ECC on a population scale. The ability of a single application to provide durable caries arrest for three years or more, as shown in our study, makes it a powerful tool for reducing the burden of untreated caries and decreasing the number of children requiring advanced care under general anesthesia. The study's main limitation is its non-randomized design, which, while pragmatic, cannot eliminate all potential for confounding. However, the similarity of the groups at baseline and the consistency of the findings provide strong evidence for the conclusions drawn.

4. Conclusion

Within the context of this three-year, community-based cohort study, a single application of 38% Silver Diamine Fluoride was demonstrated to be a significantly more effective and durable intervention for arresting active cavitated carious lesions in primary molars than high-viscosity Glass Ionomer Cement applied using the ART technique. The superior performance of SDF is attributable to its potent, multi-faceted biological mechanism that fundamentally alters the carious lesion, rendering it inert and resistant to progression. Furthermore, SDF's failure mode is more clinically benign than the mechanical failures common with GIC. Despite significant esthetic drawbacks, SDF was highly accepted by parents who prioritized its non-invasive and child-friendly application. These findings provide robust, pragmatic evidence to support the positioning of SDF as a first-line, minimally invasive treatment for the management of early childhood caries, particularly within clinical and public health settings serving high-risk pediatric populations.

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