Comparative evaluation of silver diamine fluoride versus glass ionomer cement in arresting dental caries in permanent first molars of 6–9-year-old children: a randomized controlled trial

[1]Dr. Preetha G, [2]Dr. Ayush Garg, [3]Dr. Gagandeep Kaur Chahal

[1] MDS, Department OF Conservative Dentistry AND Endodontics College address with pincode
Madha Dental College and Hospital , Madha Nagar , Kundratur , Chennai 600069
Email id ganesan.preetha@gmail.com
[2]Lecturer Desh Bhagat Dental College, Desh Bhagat University
Ayushgarg3120@gmail.com
Orcid id 0009-0003-2191-635X
[3]Professor, Department of Prosthodontics, National Dental College Derra Bassi, Punjab, India

Corresponding Author
Dr. Preetha G
MDS, Department OF Conservative Dentistry AND Endodontics College address with pincode
Madha Dental College and Hospital , Madha Nagar , Kundratur , Chennai 600069

ABSTRACT

Background: Dental caries of the permanent first molar remains the single most prevalent untreated oral condition in children worldwide[1] and disproportionately affects the permanent first molar because of its early eruption, complex occlusal morphology, and prolonged period of post-eruptive enamel maturation.[2,3] Silver diamine fluoride (SDF) and glass ionomer cement (GIC) are the two most widely used non- and minimally-invasive agents for arresting cavitated dentinal caries in children, yet head-to-head randomized evidence comparing them specifically in permanent first molars of 6-9-year-old children remains limited.

Objective: To compare the clinical and radiographic effectiveness of 38% SDF versus high-viscosity GIC in arresting active dentinal caries in permanent first molars of children aged 6-9 years, and to compare retreatment need, tooth/restoration survival, patient/parental acceptability, and safety between the two interventions.

Materials and Methods: A two-arm, parallel-group, single-centre randomized controlled trial (superiority design) will be conducted in accordance with the CONSORT 2010 statement.[18] Children aged 6-9 years with at least one permanent first molar presenting active, cavitated, non-symptomatic dentinal caries (Nyvad activity criteria[19] scores 4/5, or ICDAS-II ≥ 4) will be randomly allocated 1:1 to receive either biannual topical application of 38% SDF or a single-visit high-viscosity GIC restoration placed using an atraumatic restorative treatment (ART)-based protocol. The primary outcome is the proportion of lesions clinically arrested at 12 months. Secondary outcomes include radiographic lesion progression/arrest, need for retreatment, restoration/lesion survival (Kaplan-Meier analysis), parental acceptability of appearance (including SDF-associated black staining), chair-side time, and adverse events. Sample size, randomization, blinding, and the statistical analysis plan are pre-specified (see Materials and Methods).

Results: This protocol-stage manuscript is submitted with the study data collection [not yet started / ongoing / completed but not yet analysed delete as applicable]. Numerical results (participant flow, baseline characteristics, arrest rates, effect sizes, confidence intervals, and exact p-values) will be inserted here once the trial dataset is available and analysed according to the pre-specified plan. No results are reported in this version to avoid presenting fabricated or assumed data.

Conclusion: The conclusion will state, strictly on the basis of the trial's own findings, whether SDF and GIC produced comparable, superior, or inferior caries-arrest outcomes in this population, framed with the appropriate effect size and 95% confidence interval.

Keywords: Silver diamine fluoride; Glass ionomer cement; Dental caries; Caries arrest; Permanent first molar; Randomized controlled trial; Children; Minimally invasive dentistry.

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INTRODUCTION

Untreated dental caries of the permanent dentition is the most prevalent of the 371 diseases and injuries assessed in the Global Burden of Disease Study 2021, accounting for an estimated 2.24 billion prevalent cases worldwide.[1] In children transitioning into the mixed dentition, the permanent first molar is disproportionately vulnerable: it erupts as early as five to six years of age, often before caries-preventive behaviours are established, presents a deeply fissured occlusal morphology that is difficult to clean, and undergoes a prolonged period of post-eruptive enamel maturation during which it is at heightened risk of rapid cavitation.[2,3] Cross-sectional data from early permanent dentition cohorts confirm that the first permanent molar carries a disproportionate share of the total caries burden compared with other permanent teeth erupting at the same age.[2]

For decades, the default response to a cavitated lesion was operative removal of carious tissue and restoration, typically requiring local anaesthesia, rotary instrumentation, and a cooperative child. This approach is difficult to deliver at population scale, is poorly tolerated by many young or anxious children, and does nothing to arrest disease in other affected or at-risk surfaces. Professional bodies have consequently shifted toward non-surgical and minimally invasive caries-management strategies as first-line options, particularly in young, pre-cooperative, or high-caries-risk children.[4] Large pragmatic school-based trials have confirmed that non-restorative regimens built around topical silver and fluoride agents can meaningfully reduce the prevalence of untreated decay at population level.[5]

Silver diamine fluoride is a colourless-to-pale-yellow alkaline aqueous solution combining the antibacterial action of silver with the remineralizing action of fluoride. Mechanistically, silver ions are bactericidal against cariogenic organisms including Streptococcus mutans and inhibit cariogenic biofilm formation, while fluoride promotes precipitation of calcium fluoride and, ultimately, fluorapatite a mineral phase substantially more acid-resistant than native hydroxyapatite.[6] SDF additionally inhibits host- and bacteria-derived proteolytic enzymes (matrix metalloproteinases and cysteine cathepsins), thereby protecting the exposed dentinal collagen matrix from degradation and contributing to the characteristic hardening of arrested lesions.[6,7] These combined actions make SDF a genuinely non-invasive option: it requires no cavity preparation, can be applied in under a minute per surface, and needs minimal cooperation from the child.[4]

Glass ionomer cement, by contrast, is a restorative material that chemically bonds to enamel and dentine via an acid-base reaction between fluoroaluminosilicate glass and polyalkenoic acid. Beyond its restorative role, GIC is inherently cariostatic: it takes up and releases fluoride in a sustained, rechargeable manner, producing a fluoride-rich zone at the tooth-material interface that inhibits demineralisation and is bacteriostatic toward cariogenic flora.[8] These properties, together with technique tolerance in a moist field, underpin its central role in the World Health Organization's atraumatic restorative treatment (ART) approach, which uses hand instruments alone to remove frankly carious, softened dentine before sealing the cavity with a high-viscosity GIC an approach specifically designed for settings and patients in whom conventional rotary restorative care is not feasible.[9]

Direct comparative evidence between SDF and GIC exists, but is concentrated in primary teeth and in populations other than the specific 6-9-year age band with erupting/newly erupted permanent first molars. The original randomized trial by Zhi et al. compared SDF and GIC for arresting dentinal caries in preschool children's primary teeth and remains the most frequently cited head-to-head comparison in the field.[10] Mendiratta et al. subsequently compared SDF against GIC combined with fluoride varnish in permanent posterior teeth of intellectually disabled patients, reporting comparable six-month arrest rates between arms.[11] Closer to the present population, Baraka et al. conducted a twelve-month randomized trial in exactly the 6- to 9-year age range, comparing SDF (with and without potassium iodide) against resin-modified GIC as an indirect pulp-capping strategy in deep carious permanent first molars, and reported clinical and radiographic outcomes at three, six, and twelve months.[12] A recent systematic review specifically addressing SDF for coronal caries arrest in children and adolescents, including permanent first molars, has highlighted substantial heterogeneity in application protocols and comparator materials across the existing trials, and has called for further well-designed, adequately powered randomized trials in this population.[13] Similarly, a contemporary randomized trial in 6-9-year-olds compared SDF against a fluoride varnish (rather than GIC) for managing molars affected by molar-incisor hypomineralisation, again underscoring how few trials isolate GIC as the direct comparator to SDF in this specific age and tooth group.[14]

A recognised drawback of SDF is the irreversible black staining it produces in arrested lesions, caused by the precipitation of silver phosphate and metallic silver within the demineralised dentine.[6] Survey-based and scoping-review evidence indicates that parents generally find this staining more acceptable on posterior than anterior teeth, and that acceptability is strongly context-dependent rising when the alternative is a more invasive or behaviourally demanding treatment such as

sedation or general anaesthesia.[15,16] Because the permanent first molar is a posterior tooth, it sits within the zone of relatively higher parental tolerance for staining, but this assumption has rarely been tested directly in a comparative trial against an aesthetically neutral alternative such as GIC.[15,16]

Taken together, the existing literature establishes that both SDF and GIC are biologically plausible and independently effective caries-arresting strategies, and that early evidence from mixed populations (preschool primary teeth,[10] intellectually disabled patients,[11] indirect pulp-capping cohorts[12]) suggests broadly comparable effectiveness. However, a dedicated, adequately powered, CONSORT-compliant randomized controlled trial evaluating SDF against GIC as stand-alone caries-arresting interventions rather than as pulp-capping bases or in atypical populations specifically in permanent first molars of 6-9-year-old children, incorporating radiographic outcomes, retreatment/survival analysis, and parental acceptability of SDF-associated staining, has not been reported. This trial is designed to close that gap.

AIM AND OBJECTIVES

Aim

To compare the effectiveness of 38% silver diamine fluoride and high-viscosity glass ionomer cement in arresting active dentinal caries in permanent first molars of children aged 6-9 years.

Primary objective

To compare the proportion of carious lesions clinically arrested at 12 months following treatment with SDF versus GIC.

Secondary objectives

To compare radiographic evidence of lesion arrest/progression between the two groups at 6 and 12 months.

To compare the cumulative need for retreatment and restoration/lesion survival between groups over the follow-up period.

To compare parental/child acceptability, including tolerance of SDF-associated black staining, and chair-side treatment time and feasibility between the two interventions.

To document and compare adverse effects and complications associated with each intervention.

MATERIALS AND METHODS

Study design

This will be a single-centre, two-arm, parallel-group, randomized controlled superiority trial with a 1:1 allocation ratio, conducted and reported in accordance with the CONSORT 2010 statement and its extensions for dental/oral health trials.[18] Given the visible nature of SDF-induced black staining, full participant/operator blinding is not feasible; the trial will therefore employ single-blinding of the outcome assessor(s) and of the statistician, as detailed under Randomization and allocation below.

Study setting

Study population

Children aged 6 to 9 years (inclusive) attending the outpatient paediatric dentistry clinic (and any affiliated school dental health programme) with at least one permanent first molar exhibiting active, cavitated dentinal caries will be screened for eligibility. Where a child has more than one eligible molar, [the single most severely affected molar will be selected as the index tooth for randomization / all eligible molars within a child will be entered and analysed using a clustering-adjusted model to be finalised by the investigators] to avoid unit-of-analysis error, consistent with the statistical approach described below.

Eligibility criteria

Inclusion criteria

Children aged 6-9 years at the time of enrolment, of either sex, in good general health (ASA I).

Presence of at least one permanent first molar with active, cavitated dentinal caries, accessible to visual-tactile examination, corresponding to Nyvad activity score 4 or 5[19] (or, where the Nyvad system is not adopted, ICDAS-II code ≥ 4).

Lesion asymptomatic, with no clinical or radiographic evidence of pulpal involvement, spontaneous pain, sinus tract, or pathological mobility.

Tooth accessible for topical application/restoration under standard operatory conditions without requiring sedation.

Parent/legal guardian willing and able to provide written informed consent, and child able to provide assent as age-appropriate.

Willingness and ability to attend all scheduled follow-up visits over the 12-month study period.

Exclusion criteria

Clinical or radiographic signs of pulpal involvement, periapical pathology, or need for pulp therapy/extraction.

Known hypersensitivity/allergy to silver compounds or to any component of the GIC used.

Systemic conditions or medications contraindicating routine outpatient dental procedures.

Children with special health-care needs where behavioural cooperation would necessitate pharmacological behaviour management (these children merit dedicated study and are excluded

here to preserve a homogeneous, generalisable 6-9-year cohort).
Prior restoration or SDF application on the index tooth.

Sample size calculation
Sample size was estimated for a two-sided test of the difference between two independent proportions (caries-arrest rate at 12 months), using the standard formula:
n (per group) $= [(Z\alpha/2 + Z\beta)^2 \times \{ p_1(1-p_1) + p_2(1-p_2) \}] / (p_1 - p_2)^2$
where p_1 and p_2 are the anticipated 12-month arrest rates in the SDF and GIC groups respectively, $Z\alpha/2 = 1.96$ for a two-sided α of 0.05, and $Z\beta = 0.84$ for 80% power (or 1.28 for 90% power, at the investigators' discretion).

Randomization and allocation
Eligible molars/children will be randomly allocated 1:1 to the SDF or GIC group using a computer-generated random allocation sequence (e.g. random number generator in [SPSS / R / www.randomization.com to be specified]), with permuted blocks of randomly varying size (e.g. blocks of 4 and 6) to maintain balance while limiting predictability. Where more than one molar per child is randomized, randomization will be stratified or clustered appropriately to preserve independence assumptions (see Statistical analysis). Allocation concealment will be achieved using sequentially numbered, opaque, sealed envelopes prepared by an investigator not involved in enrolment or treatment, or via a centralised web/telephone randomization service if available. The envelope will be opened only after baseline examination and informed consent/assent are complete. Because SDF produces a visible black staining that is not replicated by GIC, blinding of the operator and, in most cases, the parent/child is not achievable; however, (i) baseline caries assessment will be performed and recorded before group allocation is revealed, (ii) radiographic outcome assessment will be performed by an examiner blinded to group allocation wherever technically feasible (e.g. by cropping/masking identifying information on digital radiographs), and (iii) the statistician analysing the outcome data will remain blinded to group identity (coded as Group A/B) until the primary analysis is locked, consistent with CONSORT recommendations for trials in which full blinding is not possible.[18]

Intervention: Silver Diamine Fluoride
Following isolation with cotton rolls and gentle removal of superficial plaque/debris, 38% SDF solution (approximately 2.24-2.35 F− mg/dose, depending on the commercial preparation used [product name/manufacturer to be specified]) will be applied to the cavitated lesion using a micro-applicator brush for a minimum contact time of 60 seconds, followed by gentle air-drying. Surrounding gingiva and soft tissue will be protected with petroleum jelly or an equivalent barrier to avoid inadvertent staining. No cavity preparation or carious tissue removal will precede application, consistent with the non-invasive rationale for SDF use. Application will be repeated at the 6-month follow-up visit (biannual regimen), in keeping with current clinical guidance,[4] with additional reapplication at any visit where the lesion is judged clinically active (soft, not fully arrested) on re-examination. Parents/guardians will be counselled in advance, both verbally and in writing, about the expected permanent black discolouration of the treated lesion, as part of the informed-consent process.

Comparator: Glass Ionomer Cement
The comparator molar will be restored in a single visit using a high-viscosity, encapsulated glass ionomer cement ([product name/manufacturer to be specified]) placed according to a standard atraumatic restorative treatment (ART)-based protocol: isolation with cotton rolls, removal of only frankly carious, softened peripheral and superficial dentine using hand excavators (no rotary instrumentation), cavity conditioning per manufacturer instructions, and incremental placement of the GIC with digital/finger-pressure adaptation and, where indicated, a co-applied fissure sealant technique over adjacent susceptible pits and fissures. No local anaesthesia will ordinarily be required. Restorations will be finished and checked for occlusal interference at the same visit. No further active treatment of the restored surface is planned unless clinical failure (see Outcome measures) is identified at follow-up, at which point retreatment will be provided and recorded as a secondary-outcome event.

Clinical examination and caries assessment
All clinical examinations will be performed under adequate illumination using a mouth mirror and a Community Periodontal Index of Treatment Needs (CPITN)-type ball-ended probe (used only for tactile confirmation of surface texture, not to induce cavitation), after the tooth surface has been cleaned and dried. Lesion activity/severity will be scored using the Nyvad visual-tactile caries activity criteria, which classify surfaces from sound through non-cavitated active/inactive lesions to cavitated active/inactive (arrested) lesions and have demonstrated high reproducibility in both primary and permanent dentitions.[19] Two calibrated examiners will conduct baseline and follow-up assessments; inter- and intra-examiner reliability will be established before the trial begins on a convenience sample of [n to be specified] teeth, with a target weighted kappa of ≥ 0.80 required

before an examiner is permitted to enrol/assess study participants.

Outcome measures

Primary outcome

Clinical caries arrest at 12 months, defined as conversion of the index lesion to a hard, shiny/leathery, Nyvad-inactive (arrested) surface on visual-tactile examination (for SDF-treated lesions, arrest is additionally supported by, but not solely dependent on, the presence of the characteristic black discolouration).[19] Lesions in the GIC group will be classified as arrested if the restoration remains intact with no clinical or radiographic evidence of recurrent/residual active caries at the margins.

Secondary outcomes

Radiographic outcome: change in radiolucency/lesion depth on standardized bitewing or periapical radiographs at baseline, 6, and 12 months, scored by a blinded examiner using a pre-specified ordinal radiographic scale (e.g. no change / partial arrest / complete arrest / progression), following methodology comparable to prior SDF radiographic outcome studies in permanent molars.[20]

Need for retreatment: any re-intervention on the index tooth (repeat SDF application beyond the planned biannual schedule due to non-arrest, or replacement/repair of the GIC restoration) will be recorded as a time-to-event outcome.

Tooth/restoration survival: analysed using Kaplan-Meier survival curves with failure defined as loss of caries arrest (SDF group) or restoration failure requiring replacement (GIC group), compared between groups using the log-rank test.

Patient/parental acceptability: parent-reported acceptability of tooth appearance (including tolerance of black staining in the SDF group) and child-reported comfort/anxiety, using a structured, previously validated questionnaire [instrument to be specified, e.g. an adapted Parental Perceptions of Silver Diamine Fluoride Dental Colour Changes questionnaire], administered at the treatment visit and at 12 months.

Chair-side treatment time and feasibility: total operator time (minutes) from isolation to completion of the procedure, and any need for behaviour-management adjuncts.

Adverse effects/complications: any pain, soft-tissue irritation/staining, allergic reaction, or other adverse event, graded for severity and relatedness to treatment.

Follow-up schedule

Table: 1. Planned follow-up schedule and assessments

Visit	Time point	Assessments performed
Visit 1	Baseline (Day 0)	Screening, consent/assent, baseline clinical (Nyvad/ICDAS-II) and radiographic assessment, randomization, intervention delivered
Visit 2	3 months (±2 weeks)	Clinical caries-activity assessment; adverse-event review
Visit 3	6 months (±2 weeks)	Clinical + radiographic assessment; second SDF application (SDF group); parental-acceptability questionnaire; adverse-event review
Visit 4	12 months (±2 weeks)	Clinical + radiographic assessment (primary and secondary outcomes); parental-acceptability questionnaire; adverse-event review; study exit

Data collection

All clinical, radiographic, and questionnaire data will be recorded on a pre-piloted, structured case-report form (paper or electronic [to be specified]) by examiners blinded to treatment allocation wherever methodologically possible. Data will be entered into a password-protected electronic database with a proportion [e.g. 10%] of entries independently double-checked for accuracy. Unique, de-identified participant codes will be used throughout; the key linking codes to identifiable information will be held separately by the principal investigator in accordance with the data-management plan approved by the Institutional Ethics Committee.

Statistical analysis

Analysis will follow a pre-specified statistical analysis plan and will be conducted on an intention-to-treat basis, with a supportive per-protocol analysis. Continuous variables (e.g. age, chair-side time) will be summarised as mean ± standard deviation or median (interquartile range) as distribution dictates, and compared between groups using the independent-samples t-test or Mann-Whitney U test as appropriate. Categorical variables (e.g. sex, arrest status) will be summarised as frequencies and percentages and compared using the chi-square test or Fisher's exact test where expected cell counts are small. The primary outcome (12-month arrest rate) will be compared between groups using the chi-square/Fisher's exact test, with the between-group risk difference, relative risk, and corresponding 95% confidence intervals reported alongside the exact p-value; a two-sided $p < 0.05$ will be considered statistically significant. Where more

than one molar per child is included, a generalized estimating equations (GEE) or mixed-effects logistic regression approach will be used to account for within-child clustering. Time-to-retreatment/failure will be analysed using Kaplan-Meier survival curves compared with the log-rank test, with hazard ratios (95% CI) derived from Cox proportional-hazards regression. All analyses will be performed using [SPSS version XX / R version X.X.X to be specified], and effect sizes (e.g. Cohen's h for proportions, or the number needed to treat) will be reported alongside p-values wherever informative.

RESULTS

Participant flow

A CONSORT 2010 flow diagram[18] (Figure 1) should be constructed summarising the numbers of children assessed for eligibility, excluded (with reasons), randomized, allocated to each intervention, followed up at each time point, lost to follow-up/discontinued (with reasons), and analysed for the primary outcome.

Figure 1. CONSORT participant flow diagram (template)

Stage	SDF group	GIC group
Assessed for eligibility, n	[n]	[n]
Excluded (did not meet criteria / declined), n	[n]	[n]
Randomized, n	[n]	[n]
Received allocated intervention, n	[n]	[n]
Lost to follow-up by 12 months, n (reasons)	[n; reasons]	[n; reasons]
Discontinued intervention, n (reasons)	[n; reasons]	[n; reasons]
Analysed for primary outcome (ITT), n	[n]	[n]

Baseline characteristics

Table 2. Baseline demographic and clinical characteristics of participants (template)

Characteristic	SDF group (n = [ ])	GIC group (n = [ ])	p-value
Age, years, mean ± SD	[ ]	[ ]	[ ]
Sex, male / female, n (%)	[ ]	[ ]	[ ]
Index tooth (46/16/26/36), n (%)	[ ]	[ ]	[ ]
Baseline lesion severity (Nyvad score), n (%)	[ ]	[ ]	[ ]
Baseline dmft/DMFT, mean ± SD	[ ]	[ ]	[ ]
Socio-economic status category, n (%)	[ ]	[ ]	[ ]

Primary outcome

Table 3. Twelve-month caries-arrest rate by treatment group (template)

Outcome	SDF group	GIC group	Risk difference (95% CI)	p-value
Lesions arrested at 12 months, n/N (%)	[ ]	[ ]	[ ]	[ ]

Secondary outcomes

Table 4. Secondary outcomes by treatment group (template)

Outcome	SDF group	GIC group	p-value
Radiographic arrest at 12 months, n/N (%)	[ ]	[ ]	[ ]
Retreatment required, n/N (%)	[ ]	[ ]	[ ]
12-month survival (Kaplan-Meier), %	[ ]	[ ]	[log-rank p =]
Parental acceptability score, mean ± SD	[ ]	[ ]	[ ]
Chair-side time, minutes, mean ± SD	[ ]	[ ]	[ ]

Adverse effects or complications

Narrative and/or tabulated summary of all recorded adverse events by group (e.g. transient soft-tissue staining, mucosal irritation, pain on application/placement), including severity grading and relatedness to the intervention.

Statistical analysis (results)

Confirmation that the analysis was conducted exactly as pre-specified in the Materials and Methods (or documented description of, and justification for, any deviation), together with the software/version used.

Tables and figures

Tables 1-4 and Figure 1 above are provided as structural templates consistent with the journal's requirement that all tables and figures be embedded in the text, in increasing numerical order, and cited at the appropriate point in the narrative. High-resolution clinical and radiographic images (pre- and post-treatment) for representative cases in each group should be added as additional numbered figures once available, with the corresponding underlying chart data supplied in spreadsheet (Excel) format as required by the journal's checklist.

DISCUSSION

Principal findings

Once the trial is complete, this paragraph should open with a concise, one- to two-sentence statement of the headline comparative finding (e.g. whether SDF and GIC produced statistically comparable, or significantly different, 12-month arrest rates), quoting the effect size and 95% confidence interval established in the Results, without extrapolating beyond what the data show.

Comparison with previous studies

Regardless of the direction of the eventual finding, the result should be interpreted against a heterogeneous existing evidence base. Zhi et al.'s foundational trial compared SDF and GIC in preschool children's primary teeth and remains the most widely cited direct comparison of the two materials, though its findings cannot be assumed to generalise to permanent first molars in older children.[10] Mendiratta et al. found SDF to be statistically comparable to GIC combined with fluoride varnish for arresting caries in permanent posterior teeth of intellectually disabled patients at six months, although their population differed substantially in behavioural and risk-factor profile from a general 6-9-year-old cohort.[11] Most relevantly, Baraka et al.'s twelve-month trial, conducted in exactly the 6-9-year age range in permanent first molars, compared SDF (with and without potassium iodide) against resin-modified GIC as an indirect pulp-capping base beneath a composite restoration a materially different clinical scenario from the present trial's comparison of SDF used non-restoratively against GIC used as a stand-alone ART-style restoration, but nonetheless the closest existing population-and-tooth match.[12,20] A recent systematic review of SDF for coronal caries arrest in children and adolescents highlighted wide variability in application regimen, comparator, and outcome definition across the available trials, a heterogeneity that the present trial's pre-registered, CONSORT-aligned protocol is designed to reduce.[13] The present findings should be discussed explicitly against each of these comparator studies' reported arrest rates, follow-up duration, and population characteristics once available.

Biological and clinical explanation

Any observed difference, or lack of difference, in arrest rates is biologically plausible in either direction. SDF's mechanism direct bactericidal action, dentinal collagen protection, and fluorapatite formation acts on the lesion in situ without removing carious tissue, which may permit more rapid onset of arrest but leaves the lesion surface unrestored and therefore potentially more plaque-retentive over time if reapplication lapses.[6,7] GIC, by removing only the softened peripheral dentine and then sealing the cavity, physically excludes the oral biofilm from the lesion surface while its sustained fluoride release continues to promote remineralisation at the restoration margins; its cariostatic action is therefore contingent on marginal integrity being maintained.[8] Any difference in the two materials' arrest rates, retreatment need, or survival in this trial's population should be interpreted with reference to these distinct, complementary mechanisms rather than treated as evidence that one material is categorically superior to the other.

Clinical implications

Both interventions sit within a broader shift toward minimally invasive, non-surgical caries management endorsed by paediatric dentistry professional guidance, particularly for young or behaviourally challenging children in whom conventional operative care is difficult to deliver.[4,5] A pragmatic, tooth-specific comparison of SDF and GIC in exactly the population in which the permanent first molar is most vulnerable six- to nine-year-olds is intended to give clinicians and public-health planners tooth-specific, age-specific evidence on which to base first-line treatment selection, particularly in resource-limited or outreach/school-based settings where chair time, cost, and number of visits are practical constraints.[5,9]

Strengths

Randomized, CONSORT-compliant design with pre-specified primary and secondary outcomes, sample-size justification, and a pre-registered statistical analysis plan.[18]

Use of the validated Nyvad caries-activity criteria for a reproducible, activity-based (rather than purely morphological) definition of arrest.[19]

Inclusion of radiographic, survival/retreatment, and parental-acceptability outcomes alongside the primary clinical endpoint, providing a more complete effectiveness picture than clinical arrest rate alone.

A population and tooth group (6-9-year-olds, permanent first molars) that is under-represented in

the existing head-to-head SDF-versus-GIC literature, which has concentrated on primary teeth or atypical patient groups.[10,11]

Limitations

Full participant and operator blinding is not achievable because SDF produces visible black staining that GIC does not; this is mitigated, but not eliminated, by blinded radiographic assessment and a blinded statistician.

Single-centre design may limit generalisability to other populations, water-fluoridation contexts, and caries-risk profiles; multi-centre replication would strengthen external validity.

A 12-month follow-up, while consistent with comparable published trials,[10,11,12] may not fully capture longer-term restoration survival or late reversal of arrest; extended follow-up is recommended (see Recommendations).

As with any pragmatic clinical trial, loss to follow-up and protocol deviations may affect the precision of intention-to-treat estimates; anticipated attrition has been incorporated into the sample-size calculation, but actual attrition and its potential for bias must be reported transparently in the final results.

CONCLUSION

A single-paragraph conclusion should be inserted once the trial is complete, stating strictly what the data demonstrated (e.g. “SDF and GIC produced statistically comparable/non-comparable 12-month caries-arrest rates in permanent first molars of 6-9-year-old children, with [specific secondary-outcome differences]”), without generalising beyond the study's design, population, or follow-up duration.

RECOMMENDATIONS/FUTURE IMPLICATIONS

Multi-centre trials across differing caries-risk and water-fluoridation contexts are recommended to strengthen generalisability of any comparative effect observed.

Longer-term follow-up (24-36 months) would clarify durability of arrest and long-term restoration survival, consistent with follow-up durations used in comparable primary-tooth trials.[17,23]

Future trials could incorporate potassium-iodide-modified SDF or nanosilver-fluoride alternatives, both of which have been explored specifically to reduce the aesthetic burden of black staining while preserving antibacterial and remineralising activity, and could be compared against both SDF and GIC in a three-arm design.[12,25]

Formal cost-effectiveness and chair-time analyses alongside clinical outcomes would help translate any comparative effectiveness finding into public-health and health-system recommendations for school-based and outreach caries-control programmes.[25,26]

Systematic, routine monitoring and reporting of adverse effects should continue to be incorporated into all SDF and GIC trials, building on existing safety-focused systematic reviews.[27]

REFERENCES

1. GBD 2021 Oral Disorders Collaborators. Trends in the global, regional, and national burden of oral conditions from 1990 to 2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet. 2025;405(10482):897-910. doi:10.1016/S0140-6736(24)02811-3.
2. Gudipaneni RK, Alkuwaykibi AS, Ganji KK, Bandela V, Karobari MI, Hsiao CY, et al. Assessment of caries diagnostic thresholds of DMFT, ICDAS II and CAST in the estimation of caries prevalence rate in first permanent molars in early permanent dentition - a cross-sectional study. BMC Oral Health. 2022;22(1):133. doi:10.1186/s12903-022-02134-0.
3. Braga MM, Mendes FM, De Benedetto MS, Imparato JC. Effect of silver diammine fluoride on incipient caries lesions in erupting permanent first molars: a pilot study. J Dent Child (Chic). 2009;76(1):28-33.
4. Crystal YO, Marghalani AA, Ureles SD, Wright JT, Sulyanto R, Divaris K, et al. Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs. Pediatr Dent. 2017;39(5):135-145.
5. Ruff RR, Barry-Godín T, Niederman R. Effect of silver diamine fluoride on caries arrest and prevention: the CariedAway school-based randomized clinical trial. JAMA Netw Open. 2023;6(4):e2255458. doi:10.1001/jamanetworkopen.2022.55458.
6. Zhao IS, Gao SS, Hiraishi N, Burrow MF, Duangthip D, Mei ML, et al. Mechanisms of silver diamine fluoride on arresting caries: a literature review. Int Dent J. 2018;68(2):67-76. doi:10.1111/idj.12320.
7. Mei ML, Lo ECM, Chu CH. Arresting dentine caries with silver diamine fluoride: what's behind it? J Dent Res. 2018;97(7):751-758. doi:10.1177/0022034518774783.
8. Nicholson JW, Sidhu SK, Czarnecka B. Fluoride exchange by glass-ionomer dental cements and its clinical effects: a review. Biomater Investig Dent. 2023;10(1). doi:10.1080/26415275.2023.2244982.
9. Sidhu SK, Nicholson JW. Glass Ionomer Cement. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. Bookshelf ID: NBK582145.

10. Zhi QH, Lo EC, Lin HC. Randomized clinical trial on effectiveness of silver diamine fluoride and glass ionomer in arresting dentine caries in preschool children. J Dent. 2012;40(11):962-967. doi:10.1016/j.jdent.2012.08.002.
11. Mendiratta M, Manjunath BC, Kumar A, Yadav V, Shyam R, Wig M. Effectiveness of silver diamine fluoride and glass ionomer cement combined with fluoride varnish in arresting dental caries among intellectually disabled individuals: a randomized controlled trial. Spec Care Dentist. 2021;41(5):544-552. doi:10.1111/scd.12607.
12. Baraka M, Tekeya M, Bakry NS, Fontana M. Twelve-month randomized controlled trial of 38% silver diamine fluoride with or without potassium iodide in indirect pulp capping of young permanent molars. J Am Dent Assoc. 2022;153(12):1121-1133. doi:10.1016/j.adaj.2022.08.008.
13. Vishwanathaiah S, Patil S, et al. Effectiveness of silver diamine fluoride (SDF) in arresting coronal dental caries in children and adolescents: a systematic review. J Clin Pediatr Dent. 2024;48(4). doi:10.22514/jocpd.2024.101.
14. Al-Nerabieah Z, AlKhouli M, Dashash M. Preventive efficacy of 38% silver diamine fluoride and CPP-ACP fluoride varnish on molars affected by molar incisor hypomineralization in children: a randomized controlled trial. F1000Res. 2024;12:1052. doi:10.12688/f1000research.136653.3.
15. Crystal YO, Janal MN, Hamilton DS, Niederman R. Parental perceptions and acceptance of silver diamine fluoride staining. J Am Dent Assoc. 2017;148(7):510-518.
16. Magno MB, da Silva LP, Ferreira DM, Barja-Fidalgo F, Fonseca-Gonçalves A. Aesthetic perception, acceptability and satisfaction in the treatment of caries lesions with silver diamine fluoride: a scoping review. Int J Paediatr Dent. 2019;29(3):257-266.
17. Llodra JC, Rodriguez A, Ferrer B, Menardia V, Ramos T, Morato M. Efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molars of schoolchildren: 36-month clinical trial. J Dent Res. 2005;84(8):721-724.
18. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC Med. 2010;8:18. doi:10.1186/1741-7015-8-18.
19. Nyvad B, Baelum V. Nyvad criteria for caries lesion activity and severity assessment: a validated approach for clinical management and research. Caries Res. 2018;52(5):397-405.
20. Baraka M, Cevidanes L, Tekeya M, Bakry N, Ruellas A, Botero T, et al. Three-dimensional assessment of radiographic changes after indirect pulp capping using silver diamine fluoride with or without potassium iodide in young permanent teeth (12-month RCT). Caries Res. 2023;57(2):177-188. doi:10.1159/000529893.
21. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-2194.
22. Hafiz Z, Allam R, Almazyad B, Bedaiwi A, Alotaibi A, Almubrad A. Effectiveness of silver diamine fluoride in arresting caries in primary and early mixed dentition: a systematic review. Children (Basel). 2022;9(9):1289. doi:10.3390/children9091289.
23. Vollú AL, Rodrigues GF, Rougemont Teixeira RV, Cruz LR, Dos Santos Massa G, de Lima Moreira JP, et al. Efficacy of 30% silver diamine fluoride compared to atraumatic restorative treatment on dentine caries arrestment in primary molars of preschool children: a 12-month parallel randomized controlled clinical trial. J Dent. 2019; 88:103165. doi: 10.1016/j.jdent.2019.07.003.
24. Nanda S, et al. Systematic review - adverse effects of silver diamine fluoride. J Dent Sci. 2022;7(4).
25. Quritum M, Abdella A, Amer H, El Desouky LM, El Tantawi M. Effectiveness of nanosilver fluoride and silver diamine fluoride in arresting early childhood caries: a randomized controlled clinical trial. BMC Oral Health. 2024;24(1):701. doi:10.1186/s12903-024-04406-3.
26. Ramakrishna SP, Ramchandra MW, Sachin MC, Kiran MA, Harp . To ascertain effectiveness of pre-sterilization cleaning of endodontic instruments before placement in glass bead sterilizer – An in vitro study [Internet]. IP Indian J Conserv Endod. 2016.
27. Kapoor P, Singh H, Ghai GS, Ghai GK. Perception of Pain and Discomfort from Three Types of Orthodontic Separators. Indian Journal of Dental Sciences. 2013 Oct 1;5(4).