SAMPLE 04 | CLINICAL TRIAL SUMMARY & CRITICAL APPRAISAL

Silver Diamine Fluoride vs Fluoride Varnish for Early Caries in First Permanent Molars

Randomized controlled trial | Pediatric dentistry / caries management

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Key findings

- At six months, 59 of 67 teeth treated with silver diamine fluoride (SDF) plus potassium iodide (KI) reached ICDAS 0 (88.1%), compared with 40 of 61 teeth treated with fluoride varnish (FV) (65.6%): an absolute difference of 22.5 percentage points ($p < 0.001$; reviewer-calculated 95% CI 7.9 to 36.3, unadjusted for clustering).
- SDF + KI was delivered in one session; FV required four weekly applications.
- Clinically interesting, but only two randomized clusters, a reduced analyzed sample, per-protocol analysis, incompletely reported blinding and short follow-up limit certainty and generalizability.

Background

First permanent molars may be vulnerable to caries during eruption. This 2026 randomized controlled trial compared 38% silver diamine fluoride (SDF) followed by potassium iodide (KI) with 5% sodium fluoride varnish for arresting early occlusal caries lesions in first permanent molars in children.

Study design and outcome

The trial included 165 children aged 6–12 years from two primary schools in Brazil. Of 660 first permanent molars assessed, 139 teeth with active early lesions entered the treatment comparison: 73 in the SDF group and 66 in the FV group. At six months, 128 teeth were re-evaluated: 67 in the SDF group and 61 in the FV group.

Caries severity was assessed using the International Caries Detection and Assessment System (ICDAS), a visual clinical scoring system. The primary outcome was defined as a transition from baseline ICDAS 1 or 2 to ICDAS 0 at six months. ICDAS 0 indicates a clinically sound surface with no visual evidence of caries on examination. This is a clinical visual outcome, not a radiographic endpoint or evidence of long-term lesion stability.

The SDF group received 38% SDF followed by KI in one session. The FV group received 5% sodium fluoride varnish in four weekly sessions.

Key results

At six months, 59 of 67 SDF-treated teeth (88.1%) reached ICDAS 0, compared with 40 of 61 FV-treated teeth (65.6%). The absolute difference was approximately 22.5 percentage points ($p < 0.001$).

The report does not provide a confidence interval or relative effect estimate. For context, the reviewer calculated the following from the reported counts (Newcombe method for the risk difference; log method for the risk ratio):

Measure	Estimate	95% CI
Risk difference	22.5 percentage points	7.9 to 36.3
Risk ratio	1.34	1.10 to 1.64

These are the reviewer's own calculations, not values reported by the authors. They treat teeth as independent and do not account for clustering by school, so the true uncertainty is likely wider than shown. They are offered as an indication of precision, not as a corrected analysis.

The study reported no statistically significant association between eruption stage and treatment outcome ($p = 0.99$). However, 86.2% of assessed molars were at eruption stage 4, so the evidence for partially erupted molars was limited. The absence of a statistically significant association should not be interpreted as proof that treatment effects are equivalent across eruption stages.

SAMPLE 04 | CRITICAL APPRAISAL

Clinical interpretation and limitations

What makes the result clinically interesting?

A higher proportion of teeth reached ICDAS 0 at six months after one SDF + KI session than after four weekly FV applications. This difference in treatment burden may be relevant in pediatric and public-health settings where repeated attendance is difficult. However, the result should be interpreted in the context of the study's design and follow-up period.

Blinding and outcome assessment

The article describes the trial as single-blind, but the accessible report does not clearly identify who was blinded. It also reports that clinical assessments and treatments were performed by a single calibrated researcher. Because the primary outcome relied on visual ICDAS assessment, incomplete reporting of the blinding procedure leaves uncertainty about the potential for assessment bias; it does not, by itself, establish that bias occurred.

Important limitations

- **Reduced sample.** The calculated minimum sample was 212 teeth, but 139 eligible teeth with ICDAS 1–2 lesions entered the comparison and 128 were re-evaluated at six months. The authors attributed the reduced sample mainly to a lower-than-expected prevalence of active early lesions.
- **Clustering.** Randomization was performed at school level with only two clusters, while the analysis was conducted at tooth level. The authors state that cluster effects were not adjusted for because only two schools were included. The independence of observations is therefore uncertain, and the reported p-value should be interpreted cautiously.
- **Per-protocol analysis and attrition.** Eleven of 139 teeth (about 8%) were lost to follow-up: 6 in the SDF group (8.2%) and 5 in the FV group (7.6%). Loss was small and similar between groups, but the per-protocol analysis may still introduce bias if completion is related to prognosis, treatment or outcome. The authors assumed that losses were missing at random and unrelated to intervention or clinical outcome; this cannot be verified from the reported data alone.
- **Baseline imbalance and eruption stage.** Mean age differed between groups at baseline (7.84 years in the SDF group vs 8.41 years in the FV group; $p = 0.033$). In addition, 86.2% of assessed molars were at eruption stage 4, limiting the evidence for less-erupted molars.

Staining and acceptability

Potassium iodide was used after SDF to minimize potential silver-related staining or gray discoloration. However, staining, adverse effects, and patient or parent acceptability were not reported as separate clinical outcomes in the results available for this review. The trial therefore does not establish how the two strategies compare on these patient-centered outcomes.

Interpretation

In this study, a single application of 38% SDF + KI was associated with a 22.5-percentage-point higher proportion of teeth reaching ICDAS 0 at six months than four weekly applications of 5% fluoride varnish. The finding is clinically interesting, particularly given the difference in treatment burden. However, the small number of randomized clusters, reduced analyzed sample, per-protocol analysis, incompletely described blinding and limited representation of partially erupted molars warrant caution. The results should not be generalized beyond the studied population and follow-up period without further evidence.

Implications for practice and research

These findings alone are not sufficient to change practice. Larger multi-site trials with adequate numbers of clusters, clearly reported blinding, intention-to-treat analysis, follow-up beyond six months, and reporting of staining and parent acceptability would be needed before the observed difference could be considered robust.

Source study

Andrade RSE, Piovesan ETA, de Queiroz IQD, Azevedo TDPL, Costa VPP, Bezerra ACB. Effectiveness of silver diamine fluoride and fluoride varnish in arresting caries lesions in permanent molars: A randomized controlled trial. *Journal of Dentistry*. 2026;169:106647. doi:10.1016/j.jdent.2026.106647.

Portfolio note: Prepared as a professional medical-writing sample demonstrating clinical-trial interpretation and critical appraisal. This document is not a clinical protocol or individualized dental advice. Confidence intervals and attrition figures are the author's own calculations from the reported counts.