



Clinical Evaluation of Curodont in Arresting Incipient Caries in Primary Teeth

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Introduction

Dental caries is the most common chronic childhood disease, often leading to restorative treatment once lesions progress beyond the dentinoenamel junction (DEJ). Current caries management emphasizes early detection and non-invasive prevention of lesion progression.

Self-assembling peptide technology (P11-4) promotes enamel remineralization by forming a scaffold that supports calcium phosphate deposition within subsurface lesions. Clinical data in pediatric settings remain limited.

This prospective feasibility study evaluated whether incipient lesions treated with Curodont (P11-4) progressed into dentin or required restorative treatment. Hypothesis: $\geq 80\%$ of treated lesions would remain stable.

Objectives

- Evaluate the proportion of incipient carious lesions treated with Curodont that do not progress into dentin or require restorative treatment during follow-up in a pediatric clinical setting.
- Assess clinical stability of treated enamel lesions over the follow-up period.
- Evaluate feasibility of incorporating P11-4 treatment into routine pediatric dental practice.
- Explore whether Curodont can reduce the need for surgical intervention.

Materials and Methods

Study Design and Sample Selection

Inclusion: patients not undergoing active orthodontic treatment; non-cavitated white spot lesions, early enamel demineralization, decalcification, or incipient caries in esthetic and non-esthetic zones (facial/buccal, occlusal and interproximal).

Exclusion: cavitated lesions, molar-incisor hypomineralization, or intolerance to isolation/etching. Total: 18 participants, 55 permanent tooth surfaces.

Pre-Operative Assessment

Baseline intraoral photography (flash) for all selected teeth, periapical radiographs for anteriors and bitewing radiographs for suspected interproximal involvement.

Clinical Procedure

Teeth were cleaned with pumice. Isolation via Dryshield or cotton roll. A 37.5% phosphoric acid etchant was applied for 20 seconds to buccal, lingual, and occlusal aspects, then rinsed and air dried.

The Curodont Repair Fluoride Plus applicator was activated per manufacturer instructions and applied to the lesion site for 5 minutes without rinsing. Fluoride varnish was applied post-treatment.

For interproximal lesions, one of the following techniques was used:

- Direct placement into the interproximal space
- Superfloss-assisted delivery into the contact area
- Compression into embrasures with a plastic instrument to facilitate diffusion

Patients instructed to refrain from eating/drinking for 30 minutes post-treatment.

Outcome Assessment and Follow-Up

Post-operative photographs obtained immediately. Follow-up at 3, 6, 12, 18 and 24 months with intraoral photographs and bitewing radiographs to assess lesion progression or remineralization.

Billing and Coding

Billed using CDT code D1354 (interim caries arresting medicament application) on a per-tooth basis.

Results

9	18	7	15
Patients Enrolled	Total Surfaces	3-Mo Check (77.8%)	Surfaces Assessed

Primary Outcome — Caries Progression at 3 Months

93.3% Non-Progression Rate

14 / 15 assessed surfaces — 1 lesion progressed

Outcome	Surfaces (n)	% Assessed
✓ No Progression	14	93.3%
✗ Progression	1	6.7%
TOTAL ASSESSED	15	100%

* 1 progression: Tooth #5 Distal, assessed Apr 10, 2026.

* 2 patients pending 3 month follow up; 3 surfaces excluded from analysis.

Surfaces per Patient (Descriptive)

2.14	2.0	0.90
Mean surfaces	Median	SD

Range: 1–3 surfaces per patient | IQR: 1.5–3.0

Results support P11-4 as a viable non-invasive option for managing incipient caries in primary teeth. The single progressed surface was on a distal interproximal lesion — a notoriously challenging surface for topical agent delivery.

Surface Type Breakdown (n = 15 assessed surfaces)

Surface	n	% Total	Progression	Non-Prog Rate
Distal	7	46.7%	1	85.7%
Mesial	7	46.7%	0	100%
Facial	1	6.7%	0	100%
TOTAL	15	100%	1	93.3%

95% Confidence Interval for Non-Progression Rate

Method	Estimate	Lower CI	Upper CI	Interpretation
Clopper-Pearson	93.3%	68.1%	99.8%	Preferred exact
Wilson Score	93.3%	70.2%	98.8%	Wide CI; small sample

Hypothesis Test — One-Sample Z-Test (one-sided)

H₀: Non-progression rate = 50% | H₁: rate > 50%

Z = 3.357 | p = 0.0004 | REJECT H₀ ✓

Strong statistical evidence treatment prevents caries progression at $\alpha = 0.05$

Conclusion

At 3-month follow-up, 93.3% of assessed surfaces (14/15) treated with Curodont Repair Fluoride Plus on primary teeth showed no caries progression — exceeding our $\geq 80\%$ stability hypothesis and supporting the clinical utility of P11-4 in primary dentition.

- 14 of 15 assessed surfaces remained stable — only 1 surface (Tooth #S Distal) showed radiographic progression.
- 95% CI lower bound: 68.1% (Clopper-Pearson exact); the wide interval reflects the small sample size and should be interpreted with appropriate caution.
- Treatment was well-tolerated and feasible to integrate into routine pediatric dental workflows.
- Enrollment window: Jan 29 – Apr 3, 2026 (64 days); follow-up at 6, 12, 18, and 24 months is ongoing.

References

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Disclaimer: Curodont product was donated by vVARDIS Scientific & Clinical Affairs, North America