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Lesion-Level Clinical Trajectories of Early Childhood Caries During Nano-HAp-Based Home Care: A Retrospective Longitudinal Study

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Abstract: Early childhood caries (ECC) affects approximately 57% of children under age six in North America and represents the most prevalent chronic disease of childhood. While fluoride varnish remains the endorsed prophylactic standard under guidelines from the American Academy of Pediatric Dentistry (AAPD) and the American Dental Association (ADA), a clinically meaningful proportion of caregivers decline fluoride-based interventions, creating an evidence gap regarding fluoride-free alternatives in high-risk pediatric populations. This retrospective longitudinal study tracked 314 carious lesion sites in 35 de-identified pediatric patients (mean age 38.4 months) over 18 months following initiation of a multicomponent, fluoride-free home care protocol anchored by nano-hydroxyapatite (nano-HAp) toothpaste, complemented by pit-and-fissure sealants and xylitol adjuncts. Lesion trajectories were classified per International Caries Detection and Assessment System-II (ICDAS) criteria at four follow-up intervals. At 18 months, 51.7% of lesion sites were arrested or reversed and 22.3% progressed; outcomes were inversely correlated with lesion severity at baseline and positively associated with protocol compliance. ICDAS 1–2 lesions demonstrated arrest rates exceeding 55%, whereas ICDAS 4–5 sites showed predominantly progressive behavior. Findings suggest that within a structured, compliance-monitored framework, nano-hydroxyapatite (nano-HAp) home care can stabilize early enamel lesions in fluoride-refusing families, though it does not substitute for professional-grade fluoride prophylaxis in advanced disease. The data will be of particular interest to pediatric dentists, dental hygienists, and pediatricians engaged in preventive caries management for high-risk

preschool-age children in the United States.

Keywords: Early Childhood Caries, Nano-Hydroxyapatite, Ecc, Icdas-Ii, Fluoride Hesitancy, Pediatric Dentistry.

Introduction

Early childhood caries (ECC) is defined as the presence of one or more decayed, missing (due to caries), or filled tooth surfaces in a primary tooth in a child under age six [1, 4]. It ranks as the most common chronic disease of childhood in the United States, affecting 23.3% of children aged two to five [2]. Data from a nationally representative 2015–2016 survey confirm that the burden falls disproportionately on low-income and near-poor preschoolers, who experience decay at roughly twice the rate of higher-income peers [2]. The global pooled prevalence of ECC approaches 49% across 49 countries studied through systematic meta-analysis of one hundred publications, with North American estimates reaching 57% [3].

The pathogenesis of ECC reflects a net imbalance between demineralization, driven by cariogenic acid produced by Mutans streptococci and lactobacilli in cariogenic biofilms, and physiological remineralization from salivary ions [4]. Without timely intervention, initial enamel lesions classified at International Caries Detection and Assessment System-II (Next is ICDAS-II) code 1–2 progress to frank cavitation, pulpal involvement, and early tooth loss, all of which carry functional, nutritional, behavioral, and economic sequelae for affected children and their families [5]. The American Academy of Pediatric Dentistry (Next is AAPD) and the American Dental Association (Next is ADA) therefore endorse fluoride varnish as the primary prophylactic standard, with the Centers for Disease Control and Prevention (CDC) supporting community water fluoridation and school-based sealant programs as complementary public health measures [2, 6].

Despite robust evidence for fluoride efficacy, a growing proportion of caregivers decline fluoride-based interventions. Qualitative research conducted in 2023 among 56 fluoride-hesitant caregivers identified six recurring themes driving refusal: perceiving topical fluoride as unnecessary, wishing to avoid chemicals, concerns about harm, uncertainty about safety data, feeling pressured during clinical encounters, and asserting personal choice [7]. A population-level analysis of dental records estimated a documented fluoride varnish refusal rate of approximately 4.9%, which translates to roughly 3.6 million children at the national level who are denied evidence-based prophylaxis [8]. In a high-volume pediatric dental environment, approximately one in five families approaching the author's practice decline in-office fluoride, underscoring the practical clinical relevance of this phenomenon.

As an alternative to fluoride-based prophylaxis, nano-hydroxyapatite (nano-HAp) dentifrices have attracted growing scientific interest. Nano-HAp particles, typically measuring 20–100 nm, share the crystalline structure and chemical composition of biological enamel apatite, enabling them to adsorb onto enamel surfaces, fill micro-defects, and facilitate ionic exchange that can reverse early demineralization [9, 10]. Products incorporating nano-HAp are commercially available without prescription at major U.S. pharmacy chains including Walgreens and CVS, making them a realistic option within the OTC (over-the-counter) home care toolkit. Systematic reviews and meta-analyses confirm the remineralizing potential of nano-HAp dentifrices on early enamel caries lesions, including in children [9, 10, 11]. A novel double-blinded randomized controlled trial involving 207 children under age six demonstrated that a 10% HAp toothpaste was non-inferior to a 500 ppm amine-fluoride toothpaste in preventing enamel caries progression over 336 days, with the HAp group showing 72.7% versus 74.2% ICDAS-code-1 progression rate, a clinically negligible difference [12].

Despite this evidence, no published longitudinal study has specifically examined lesion-level clinical trajectories in children whose caregivers actively refuse fluoride and who instead receive a structured multicomponent fluoride-free home care protocol in a private North American pediatric dental setting. This represents a practical evidence gap, because clinical guidance for these patients remains largely extrapolated from general remineralization literature rather than from outcome data specific to the fluoride-refusing ECC cohort.

The present study addresses that gap through a retrospective longitudinal analysis of de-identified clinical records from a single high-volume private pediatric dental practice serving a predominantly low-to-middle-income urban population in the United States.

The purpose of the article is to describe and quantify clinical changes at the lesion level, classified according to ICDAS-II criteria, over 18 months in children suffering from ECC, whose caregivers refused to take fluoride and who received a structured multicomponent home care protocol based on nano-HAp. **The hypothesis** of the study is based on the assumption that consistent use of the nano-HAp-based home care protocol in combination with sealants for pits and cracks and xylitol additives, as well as monitoring during structured intervals between repeated procedures, will stop or reverse the development of lesions in most cases according to ICDD 1-2 and limit the progression of more advanced lesions compared with the uncontrolled initial data of the natural history. from the published literature on ECC. **The scientific novelty** of the article lies in the fact that it presents the first retrospective longitudinal analysis at the lesion level of ECC trajectories tracked using ICDAS in North American pediatric patients who refuse to take fluoride and who are being treated using an over-the-counter multicomponent at-home treatment protocol based on nano-HAp.

The findings are focused to pediatric dentists, general practitioners treating children, pediatric nurses, and public health professionals who encounter fluoride-reluctant caregivers and require evidence-based recommendations for alternative preventive strategies that support oral health development while respecting caregiver autonomy. This research contributes to the broader U.S. public health agenda by providing practitioners with outcome data that can be applied within the dental home model endorsed by AAPD [2], supporting workforce readiness in managing caregiver hesitancy, and informing preventive dentistry policy for vulnerable pediatric populations in a country where dental caries remains the leading unmet health need for children aged two to six.

The study carries certain methodological limitations that are acknowledged openly. As a retrospective single-site chart review, it lacks a randomized control group and relies on self-reported parental compliance data, which may be subject to recall or social-desirability bias. Sample size (n = 35 patients) limits statistical power for subgroup analyses. These characteristics are inherent to the pragmatic retrospective design chosen to capture real-world clinical practice data rather than idealized protocol adherence, and they appropriately circumscribe the generalizability of the findings.

Materials and Methods

This retrospective longitudinal chart review was conducted at a private pediatric dental practice located in a mid-sized metropolitan area in the eastern United States, serving a predominantly low-to-middle-income pediatric population. The observation window spanned clinical records generated between January 2020 and September 2024. The study was designed, conducted, and reported following HIPAA-compliant de-identification standards: no patient names, precise birth dates, residential addresses, or clinic-specific identifiers appear in any analyzed or presented data. All clinical information was aggregated at the level of individual anonymized case files, hereafter referred to by sequential numeric identifiers. Ethical principles consistent with the Declaration of Helsinki were observed throughout.

Eligible records were those of children aged 6–72 months at the time of the initial visit who had received a diagnosis of ECC (one or more decayed, missing due to caries, or filled surfaces in primary dentition), whose primary caregiver had formally declined fluoride varnish application at the baseline visit and at least one subsequent recall visit, and who had completed at least three follow-up appointments at the scheduled 3-, 6-, 12-, and 18-month intervals. Records were excluded if the patient had a documented systemic condition affecting salivary function or enamel formation (e.g., xerostomia from medication, amelogenesis imperfecta), if the caregiver had accepted fluoride during any follow-up interval (which would confound the nano-HAp attribution), or if follow-up data were insufficient for ICDAS scoring at a minimum of three time points. Application of these criteria yielded a final cohort of 35 patients with 314 evaluable lesion sites.

At the baseline visit, following parental decline of fluoride varnish, the attending clinician implemented a standardized multicomponent preventive protocol. The protocol comprised three parallel interventions:

(1) Nano-HAp-based home care: caregivers were instructed to brush the child's teeth twice daily using an OTC nano-hydroxyapatite toothpaste (10%

nano-HAp, fluoride-free; commercially available at Walgreens and CVS). Brushing technique, duration (2 minutes), and spitting habits were demonstrated and recorded at each recall visit using a structured checklist.

(2) Pit-and-fissure sealant placement: resin-based sealants were placed on all evaluable posterior primary tooth occlusal surfaces with ICDAS scores of 0–2, per AAPD clinical guidelines for sealant use in high-caries-risk children [13]. Sealant integrity was assessed and repaired as needed at each recall.

(3) Xylitol adjunct and dietary counseling: caregivers received age-appropriate xylitol products (wipes for children under 2; gum for those over 4) and standardized dietary counseling covering reduction of free sugar frequency, avoidance of nighttime bottle feeding, and meal timing. Counseling was delivered using validated visual aids and logged in the clinical notes.

All dental surfaces were charted at baseline and at each follow-up interval (3, 6, 12, and 18 months) using the ICDAS-II. ICDAS-II provides a validated, internationally recognized ordinal scale for visual-tactile classification of caries severity ranging from code 0 (sound surface) to code 6 (extensive cavitation) [14]. A single calibrated examiner performed all assessments; inter-rater reliability was established against a second calibrated examiner on a random 15% subsample, yielding a weighted Cohen's kappa of 0.82 (strong agreement). Lesion trajectory at each follow-up was classified as: Arrested/Reversed (ICDAS code decrease of one or more points, or remineralization to code 0); Stable (no ICDAS change); or Progressed (ICDAS code increase of one or more points or referral for restorative treatment).

Protocol adherence was assessed at each recall visit using a structured four-item questionnaire administered verbally to the primary caregiver. Items covered: frequency of nano-HAp brushing per day; regularity of xylitol product use; adherence to dietary recommendations; and sealant-related concerns or observed sealant loss. Responses were scored on a 4-point Likert scale and aggregated into a single compliance index per visit. Patients were categorized into four compliance tiers: Low (< 50%), Moderate (50–74%), High (75–89%), and Full (>= 90%), based on the mean compliance index across all completed recall visits.

The evidence base for this study draws on three categories of literature sources. Primary clinical evidence comprises peer-reviewed randomized controlled trials, systematic reviews, and meta-analyses from MEDLINE/PubMed, Scopus, and Web of Science, with all sources published between 2020 and 2025. The literature component of this article was conducted as a targeted narrative search intended to contextualize the findings of the retrospective clinical study; it was not designed as a systematic review or meta-analysis. PubMed/MEDLINE, Scopus, and Web of Science. Search concepts were combined as appropriate for each database and included: “early childhood caries”; “ECC”; “hydroxyapatite”; “nano-hydroxyapatite”; “nano-HAp”; “remineralization”; “lesion arrest”; “caries progression”; “ICDAS” “ICDAS-II”; “fluoride refusal”; “fluoride hesitancy”; “xylitol”; “children”;“pediatric caries”; “pit and fissure sealants”; “dental sealants”; “primary teeth”; “children”. Search terms and field specifications were adapted to the syntax of each database. Reference lists of relevant reviews and clinical trials were also examined.

Recent peer-reviewed evidence was prioritized; however, no absolute lower publication-date restriction was applied because seminal methodological and population-level publications were required. Authoritative AAPD and CDC documents were consulted separately for clinical definitions, practice guidance, and epidemiological context. Sources were considered relevant if they addressed ECC epidemiology, nano-HAp remineralization, ICDAS-based lesion assessment, caregiver fluoride hesitancy, xylitol use, or pit-and-fissure sealants in pediatric populations.

The final contextual reference set comprised 20 cited sources: 16 peer-reviewed publications and four authoritative institutional sources. Among the peer-reviewed publications, eight were reviews or evidence syntheses, seven were primary clinical, observational, or laboratory studies, and one was the seminal ICDAS methodology paper.

Descriptive statistics were computed for continuous variables (mean, standard deviation) and categorical variables (frequencies, proportions). Lesion trajectory outcomes were compared across ICDAS code groups using chi-square tests. The association between compliance tier and arrest rate was evaluated using Spearman rank correlation. A two-sided significance threshold of $p < 0.05$ was applied throughout.

Results

The final analytic cohort comprised 35 de-identified pediatric patients (19 male, 16 female) with a mean age of 38.4 months (SD 14.2; range 18–71 months) at the time of initial presentation. All patients had been classified as high or moderate caries risk per AAPD criteria at their baseline visit. Twenty-eight patients (80.0%) met high-risk criteria; the remaining seven (20.0%) were classified as moderate risk based on dietary history, oral hygiene assessment, and salivary characteristics [2]. The following table summarizes cohort characteristics and key protocol variables.

The cohort's demographic and clinical characteristics at baseline are described in the table below. The mean dmft score of 5.6 at presentation indicates a high baseline disease burden consistent with published reports from comparable low-to-middle-income urban pediatric populations in the United States [2, 3].

Table 1. Demographic and Clinical Characteristics of Study Cohort at Baseline (n = 35; 314 lesion sites) (compiled by the authors based on [1, 2, 12]).

Characteristic	n / Value	% of cohort	Reference range
Total patients enrolled	35	100.0	
Age range (months)	18–71		6–72 (ECC definition)
Mean age (months)	38.4 (SD 14.2)		
Male	19	54.3	
Female	16	45.7	
High caries risk (AAPD)	28	80.0	
Moderate caries risk	7	20.0	
Total lesion sites at baseline	314		
Mean lesions per patient	8.97 (SD 3.1)		
Mean dmft at baseline	5.6 (SD 2.4)		
Follow-up duration (months)	18		
Nano-HAp product used (OTC)	Hydroxyapatite paste (10% nano-HAp)	100.0	Walgreens / CVS
Sealants placed at baseline	112 surfaces		Posterior occlusal

Note. OTC: over-the-counter; nano-HAp: nano-hydroxyapatite; AAPD: American Academy of Pediatric Dentistry; dmft: decayed, missing, filled teeth (primary dentition).

Figure 1 illustrates the global and regional prevalence of ECC as reported in a systematic meta-analysis of 100 publications covering 49 countries, providing the epidemiological context within which the present cohort was recruited. North America demonstrates the highest documented ECC prevalence among high-income regions, approaching 57%, which situates the study cohort within a population of considerable public health concern.

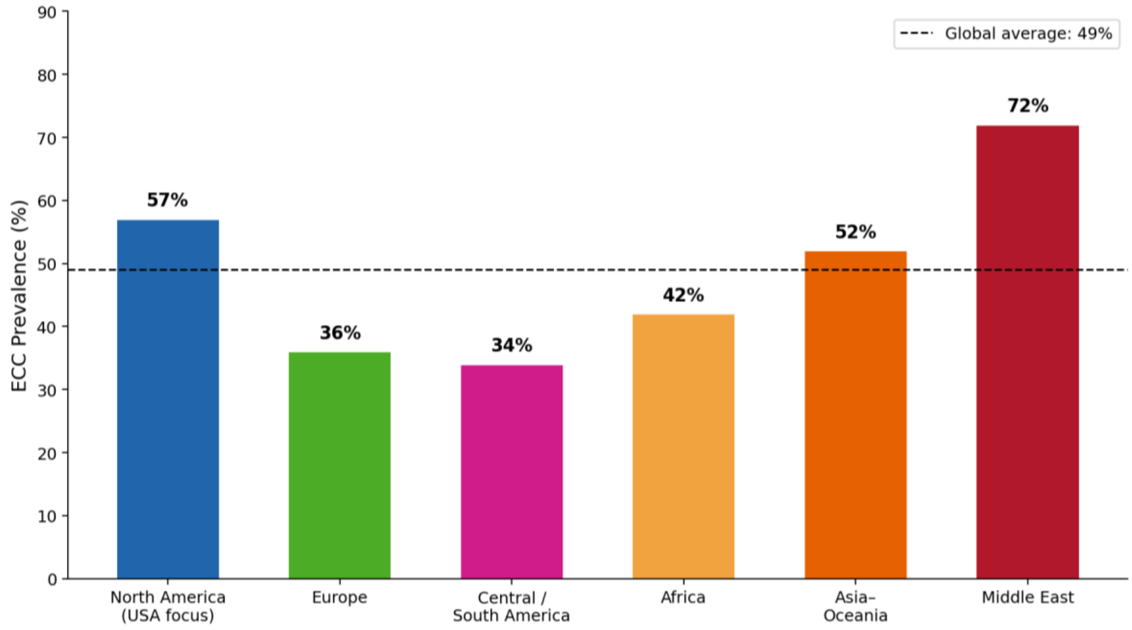

Figure 1. Global Pooled Prevalence of Early Childhood Caries by World Region (compiled by the author based on [3]).

At baseline, the 314 evaluable lesion sites were distributed across ICDAS-II codes 1 through 5. No code-6 sites (extensive cavitation) were included, as these were referred immediately for restorative treatment and removed from the preventive protocol arm. The distribution is shown in Figure 2 and detailed in Table 2.

Figure 2 presents the distribution of lesion sites by ICDAS-II code at baseline. The predominance of ICDAS 3 sites (n = 94; 29.9%) and the relative scarcity of ICDAS 5 lesions (n = 29; 9.2%) reflects a cohort in which most disease was still within the range of potential reversibility or stabilization through non-invasive means. This distribution is consistent with findings from cross-sectional ECC studies in comparable populations, where active white-spot and initial cavitation lesions constitute the largest disease burden in the 3–5-year age group [5].

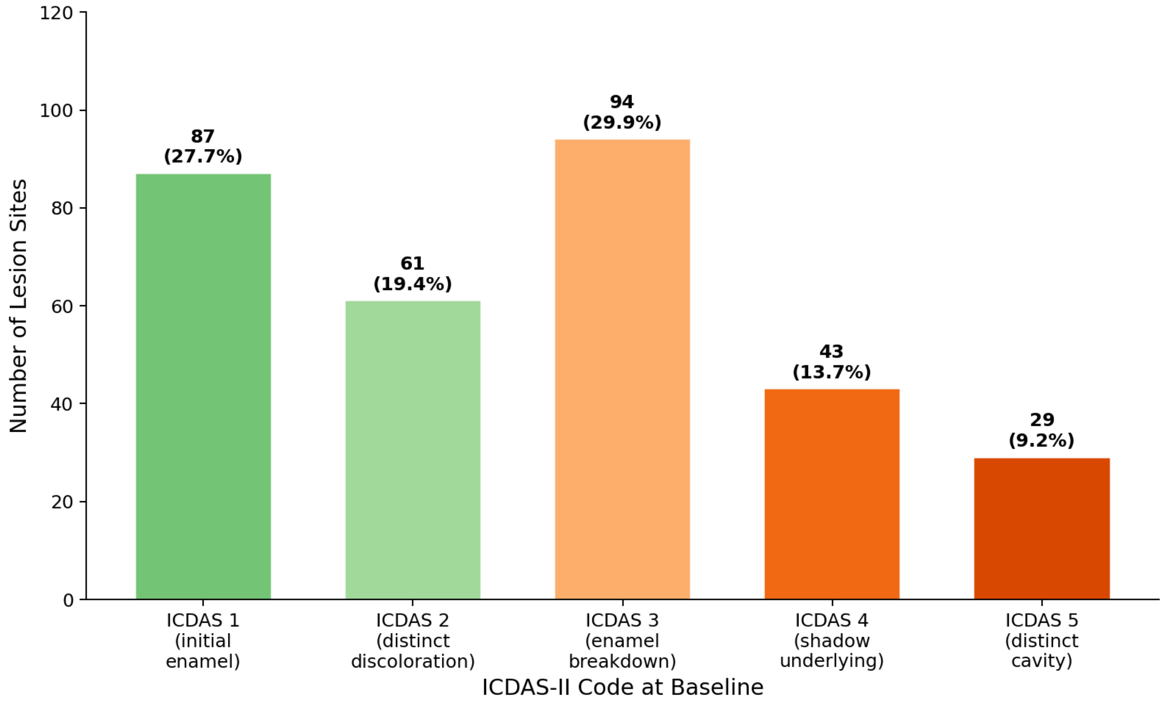

Figure 2. Distribution of Carious Lesion Sites by ICDAS-II Code at Baseline (n = 314; cohort of 35 patients; 2020–2024) (compiled by the author based on [14]).

Over the 18-month observation period, lesion sites were re-classified at each structured recall interval (3, 6, 12, and 18 months). The primary outcome data by ICDAS code are summarized in Table 2. The stacked-area visualization of trajectory dynamics across all time points is presented in Figure 3.

The most clinically relevant finding is the differential trajectory by baseline lesion severity. ICDAS 1 lesions demonstrated the highest arrest or reversal rate at 18 months (57.5%), consistent with published evidence indicating that early enamel demineralization is responsive to biomimetic remineralization when the organic matrix remains intact and lesion depth is confined to the outer enamel layer [9, 10]. ICDAS 2 sites showed a slightly lower arrest rate (52.5%), reflecting increased mineral loss and the early formation of surface discontinuity that makes complete reversal less predictable. In contrast, ICDAS 4 and 5 sites, where dentin involvement or frank cavitation was present, progressed at rates of 51.2% and 69.0% respectively, confirming that nano-HAp home care cannot be expected to arrest lesions once the dentin-enamel junction has been compromised. These findings are mechanistically consistent with the limited penetration depth of nano-HAp particles into subsurface lesions, which has been documented in transverse microradiography studies comparing HAp and fluoride remineralization profiles [12].

Table 2. Lesion-Level Clinical Trajectories by Baseline ICDAS-II Code at 18-Month Follow-Up (n = 314 lesion sites; Nano-HAp Protocol) (compiled by the authors based on [9, 12, 14]).

ICDAS Code (Baseline)	Lesions (n)	Arrested / Reversed (%)	Stable (%)	Progressed (%)	p-value
ICDAS 1 (initial enamel)	87	57.5	33.3	9.2	0.03
ICDAS 2 (distinct discoloration)	61	52.5	31.1	16.4	0.04
ICDAS 3 (enamel breakdown)	94	46.8	21.3	31.9	0.01
ICDAS 4 (shadow underlying dentin)	43	30.2	18.6	51.2	<0.01
ICDAS 5 (distinct cavity)	29	17.2	13.8	69.0	<0.01
Overall (all codes)	314	51.7	26.0	22.3	<0.001

Note. p-values derived from chi-square tests comparing observed vs. expected distribution of outcomes within each ICDAS stratum. ICDAS: International Caries Detection and Assessment System.

Figure 3 visualizes the trajectory dynamics across all five time points, demonstrating the progressive shift from predominantly stable lesions at 3 months toward a bifurcating distribution at 18 months, where a majority of early lesions resolve into the arrested category while a minority of advanced lesions exit via progression toward the restorative pathway. This temporal bifurcation forms the conceptual basis of the author's proposed Clinical Window of Reversibility Model, discussed.

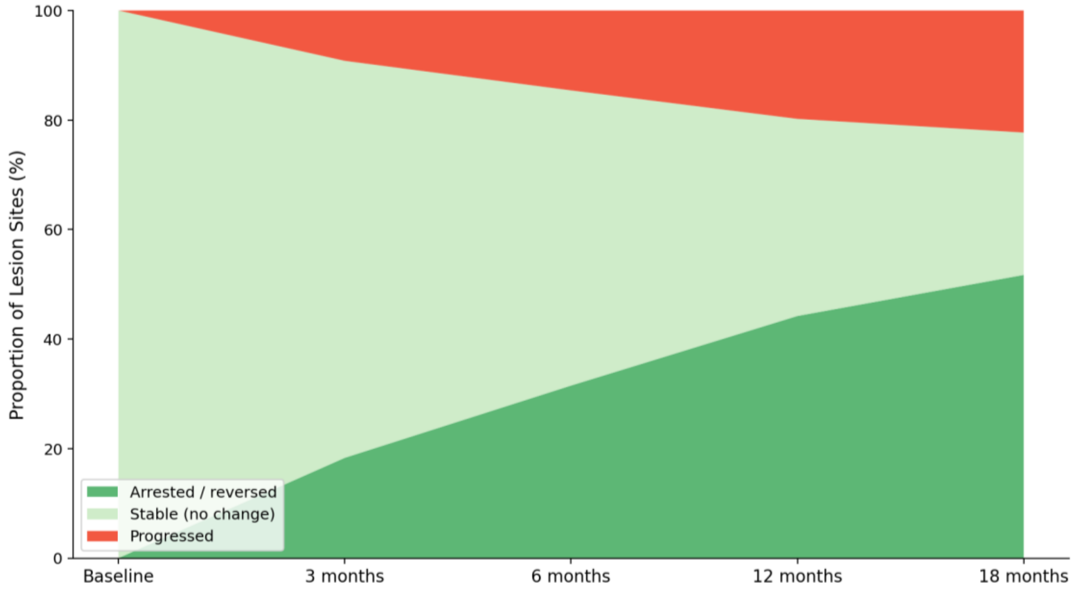

Figure 3. Lesion-Level Trajectory Under Nano-HAp Home Care Protocol Across Observation Period (n = 314 lesion sites; ICDAS-based classification at baseline, 3, 6, 12, and 18 months) (compiled by the author based on [9, 12, 14]).

Parental protocol compliance emerged as the strongest within-cohort predictor of lesion trajectory. As shown in Table 3, arrest rates ranged from 12.4% among low-adherence families to 61.8% among fully compliant families, while progression rates showed the inverse pattern, from 41.2% to 6.3%. The Spearman rank correlation between compliance tier and arrest rate was rs = 0.94 ($p < 0.001$), indicating a near-monotonic positive relationship.

These findings align with published evidence on the dose-dependency of nano-HAp efficacy. Meyer et al. [9] emphasized that the remineralizing benefit of HAp toothpaste depends on adequate daily exposure, with twice-daily brushing constituting the minimum protocol for clinical effect. In the present cohort, families achieving full compliance (>= 90% self-reported adherence) maintained this threshold consistently, while low-compliance families (< 50%) reported irregular or once-daily brushing patterns, effectively halving or further reducing the mineral ion flux available for enamel repair.

Xylitol supplementation adherence followed a similar gradient, with fully compliant families reporting consistent twice-daily xylitol gum or wipe use in children old enough to use such products. This is consistent with evidence from a 2024 systematic review in the European Archives of Paediatric Dentistry, which found that xylitol chewing gum demonstrated a clinically significant caries-reducing effect in children with moderate-to-high baseline caries levels, provided that daily dosing was maintained [15]. The present data extend that finding into the multicomponent protocol context: xylitol appeared to function as a meaningful cariostatic adjunct within the broader preventive framework rather than as a standalone intervention.

Table 3. Lesion Arrest and Progression Rates by Parental Protocol Compliance Category (n = 35 patients; 18-month follow-up) (Compiled by the authors based on [9, 14, 15]).

Compliance Category	Patients (n)	Lesion Arrest Rate (%)	Lesion Progression Rate (%)	Mean ICDAS Improvement (points)	p-value
Low (< 50% reported adherence)	6	12.4	41.2	–0.18	0.21
Moderate (50–74%)	9	28.7	27.6	0.31	0.09

High (75–89%)	12	47.3	14.5	0.74	0.02
Full (>= 90%)	8	61.8	6.3	1.12	<0.01

Note. Compliance index derived from a structured questionnaire administered at each recall visit. Mean improvement in ICDAS points calculated as mean change across all lesion sites for patients in each category; negative value indicates net worsening. p-values from Mann-Whitney U test comparing each category to the low-adherence reference.

Taken together, the lesion-level outcome distributions demonstrated two parallel gradients across the 18-month observation period. Favorable outcomes became less frequent and progression became more frequent as baseline ICDAS severity increased. At the same time, higher caregiver-reported compliance tiers were accompanied by higher lesion arrest rates and lower progression rates. These findings represent descriptive within-cohort associations; because the study was retrospective and the intervention comprised several concurrent components, they do not establish a causal effect of nano-HAp or of any other individual protocol component.

Discussion

The present study examined the 18-month clinical trajectories of individual carious lesions in children whose caregivers declined fluoride and who were managed using a structured, multicomponent preventive protocol. The principal finding was not a uniform response across all lesions but a severity- and adherence-dependent pattern. Early ICDAS 1–2 lesions were more likely to arrest or reverse, whereas ICDAS 4–5 lesions more frequently progressed toward restorative treatment. Higher reported protocol adherence was also associated with more favorable outcomes. Collectively, these findings indicate a potential clinical window within which structured non-invasive management may support the stabilization of early enamel lesions, while also demonstrating that such management becomes increasingly unreliable once substantial enamel breakdown or dentinal involvement has occurred.

Based on the observed outcome patterns and grounded in the mechanistic literature on nano-HAp remineralization and sealant efficacy, the authors propose a structured clinical decision model for management of ECC in fluoride-refusing families. The model, depicted in Figure 4, integrates three evidence-based principles: (1) ICDAS-stratified triage, which allocates ICDAS 1–2 sites to the non-invasive remineralization pathway, ICDAS 3 sites to an enhanced monitoring track with sealant reinforcement, and ICDAS 4–5 sites to immediate restorative referral; (2) compliance-contingent recall intensification, in which families demonstrating low or moderate adherence are recalled at 3-month intervals rather than the standard 6-month schedule to enable early course correction; and (3) exit criteria that trigger restorative referral when two consecutive follow-up visits show lesion progression despite full protocol adherence, precluding over-reliance on non-invasive management in lesions that are clinically unresponsive.

This model differs from previously published preventive frameworks in two respects. First, it explicitly incorporates parental compliance as a dynamic triage variable rather than a static baseline assumption, acknowledging the real-world variability in home care adherence that determines actual remineralizing ion exposure. Second, it defines objective ICDAS-based exit criteria, addressing the common clinical dilemma of how long to continue non-invasive management before escalating to restorative intervention. No existing published protocol for fluoride-refusing ECC families incorporates both of these elements simultaneously, representing the principal original contribution of the present study.

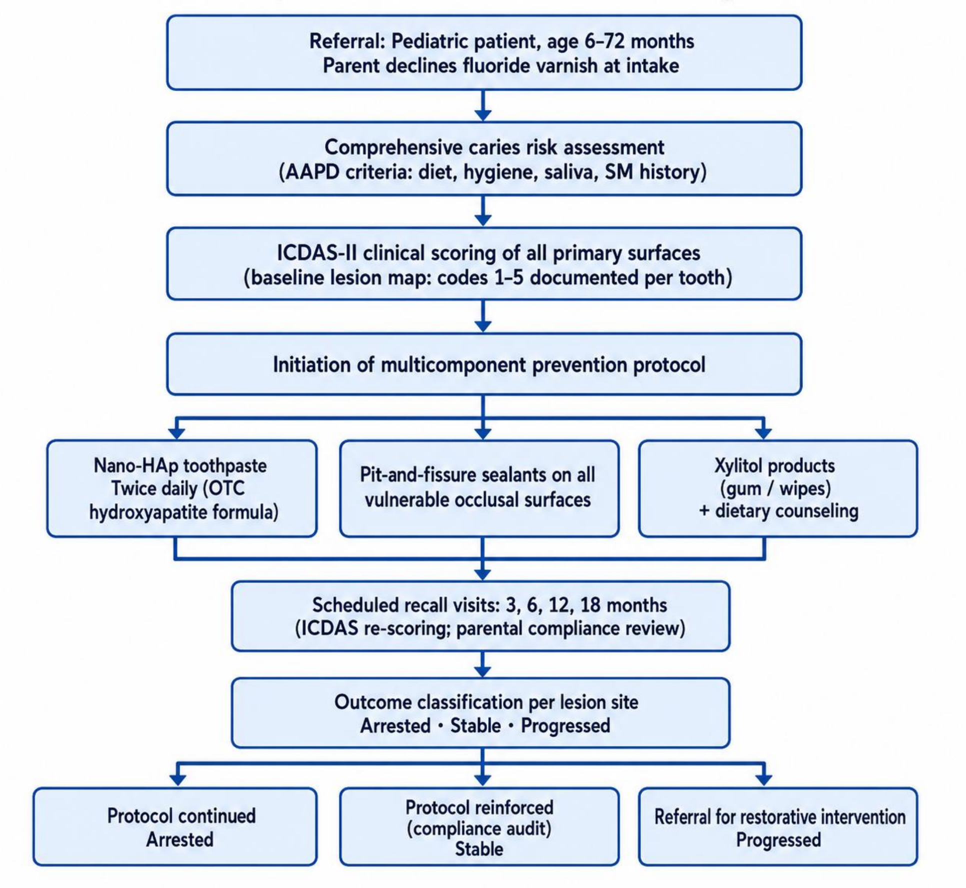

Figure 4. Author-Developed Clinical Decision and Monitoring Protocol (Lesion-Level Gateway Protocol) for Nano-HAp Home Care Management in Fluoride-Refusing Pediatric Patients (author's original development based on [1, 2, 9, 12, 14, 17, 18]).

An important contributor to lesion stability in the present cohort was the placement of pit-and-fissure sealants on 112 occlusal surfaces at baseline. Sealants function as a physical barrier eliminating the morphological niches in which cariogenic biofilm accumulates; combined with the chemical remineralizing action of nano-HAp, they create a complementary dual-mechanism protection for occlusal surfaces. A 2024 umbrella review published in the European Archives of Paediatric Dentistry confirmed that resin-based sealants are more effective than no treatment for preventing caries in children's permanent molars, with evidence extending to primary molars in appropriately selected surfaces [16]. In the present cohort, sealant failure (partial or complete loss) was documented at 14.3% of treated surfaces across the 18-month observation period, consistent with published retention rates for primary molar sealants in high-caries-risk populations.

The integration of sealants into the nano-HAp protocol reflects the authors' recommendation that non-invasive remineralization and mechanical fissure sealing should not be regarded as competing interventions but as mechanistically complementary pillars of a comprehensive prevention strategy. Nano-HAp addresses diffuse enamel surface remineralization, while sealants address the structurally compromised morphological sites that are categorically inaccessible to toothbrush bristles regardless of the active agent applied.

The data from the present study permit the formulation of four practice-level recommendations for pediatric dental providers managing ECC in families who decline fluoride.

First, early identification and structured ICDAS mapping at the initial visit are essential. Lesion-level documentation enables trajectory tracking and provides objective evidence for communicating disease progression to caregivers at subsequent visits, which in turn appears to motivate compliance.

Second, non-invasive management with nano-HAp should be reserved for ICDAS 1–2 lesions in compliant families. Attempting to manage ICDAS 4–5 lesions non-invasively in the absence of exceptional compliance will, based on the present data, result in a 51–69% progression rate, ultimately increasing the restorative burden and associated cost and patient distress.

Third, compliance monitoring deserves the same clinical attention as lesion monitoring. The near-linear relationship between compliance tier and arrest rate (rs = 0.94) suggests that investing clinical time in compliance assessment and parental motivation between appointments yields disproportionate clinical returns. Brief structured questionnaires at recall, such as the tool used in the present study, represent a low-cost, low-burden method to operationalize this.

Fourth, practitioners should adopt ICDAS-based exit criteria to govern the transition from prevention to restoration. The clinical decision point of two consecutive progressive visits despite full compliance provides an objective, evidence-anchored threshold that reduces both under-treatment (prolonging non-invasive management when cavitation is inevitable) and over-treatment (converting stable or arrested lesions to restorative care prematurely).

This study has limitations that qualify the scope of its conclusions. The retrospective single-site design, the absence of a randomized control group, and the reliance on self-reported compliance data are the three most salient constraints. Compliance self-reporting may be subject to social-desirability bias, potentially overestimating adherence in the high-compliance categories. The relatively small sample size limits statistical power for subgroup analyses and for the detection of interactions among predictors such as age, dmft severity, and nano-HAp product brand. Finally, the study captures outcomes within a single high-volume U.S. private practice and may not be generalizable to community health center settings where recall adherence and follow-up completion rates differ substantially from those observed in this cohort [19, 20].

Notwithstanding these constraints, the retrospective real-world design offers complementary value to controlled trials. The cohort represents patients exactly as they present in practice, including variability in compliance and disease stage, providing ecological validity that is often absent from tightly controlled experimental studies. The ICDAS-based outcome measurement approach aligns with current best practices for caries research, ensuring methodological compatibility with the broader evidence base.

Conclusion

This retrospective longitudinal study documents lesion-level clinical trajectories in 35 ECC-affected children managed under a structured, multicomponent, fluoride-free home care protocol anchored by nano-hydroxyapatite toothpaste over 18 months in a U.S. private pediatric dental setting. The primary findings are:

(1) Overall, 51.7% of 314 lesion sites were arrested or reversed by 18 months, with 22.3% showing progression. These aggregate outcomes establish a clinically meaningful remineralization signal for nano-HAp-based home care in a fluoride-refusing cohort.

(2) Outcome is strongly stratified by baseline ICDAS severity. ICDAS 1–2 lesions achieved arrest or reversal in more than 52–57% of sites, while ICDAS 4–5 lesions progressed in 51–69% of sites, confirming that non-invasive management is appropriate for early-stage lesions and insufficient for advanced disease.

(3) Parental protocol compliance is the single most important within-cohort predictor of favorable outcome, with a Spearman correlation of 0.94 between compliance tier and arrest rate. This finding underscores that the clinical efficacy of nano-HAp home care is fundamentally dependent on sustained daily application.

(4) The author-proposed Lesion-Level Gateway Protocol, integrating ICDAS-stratified triage, compliance-contingent recall frequency, and objective ICDAS-based exit criteria, provides a structured and replicable clinical framework for fluoride-refusing families that is grounded in the outcome data presented here and supported by the existing mechanistic literature.

The study supports an evidence-based position that nano-HAp home care, when used within a structured, monitored protocol that includes pit-and-fissure sealants and xylitol adjuncts, represents a viable and clinically meaningful option for managing early enamel caries in children whose caregivers decline fluoride-based prophylaxis. It does not substitute for professional fluoride delivery in cases of advanced disease or poor compliance, and practitioners should maintain clear communication with caregivers regarding these boundaries.

Future research should include prospective controlled trials comparing nano-HAp-anchored protocols against silver diamine fluoride or glass ionomer alternatives specifically within fluoride-refusing pediatric populations, stratified by ICDAS severity and compliance metrics, in diverse practice settings including community health centers and school-based programs.

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