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Review
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Factors contributing to failed pediatric dental appointments: A scoping review

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Highlights

Children depend on caregivers for dental care access, increasing vulnerability to missed appointments. Identifying barriers is essential to support families and improve pediatric dental attendance.

This scoping review included nine studies and found that children from families using public insurance experience the highest rates of missed pediatric dental appointments.

Findings support targeted outreach for publicly insured families, including reminders, flexible scheduling, transportation support, and policy actions to reduce access inequities.

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Abstract

Children are uniquely dependent on caregivers to access health care services, including dental appointments. Reviewing existing literature to identify barriers to care may help highlight at-risk populations and inform strategies to improve appointment attendance and overall access to pediatric dental care. The aim of this scoping review was to identify key factors contributing to missed or failed pediatric dental appointments. A comprehensive literature search was conducted across PubMed, CINAHL, MEDLINE, and Scopus using controlled vocabulary and free-text terms related to pediatric dental care and appointment attendance. Eligible studies were peer-reviewed, published in English after 2000, conducted in the United States, and focused exclusively on missed pediatric dental appointments as the primary outcome. Nine studies were included in the review, each examining barriers to accessing pediatric dental care. Recurrent factors associated with missed appointments were identified across studies. Five studies reported higher nonattendance among populations utilizing Medicaid, four identified longer wait times between scheduling and appointments, three reported racial disparities, and two cited a prior history of no-show appointments as a significant predictor. Missed pediatric dental appointments are consistently associated with lower socioeconomic status and related social determinants of health. Families utilizing public health insurance, including Medicaid for dental care or transportation, experience higher rates of appointment failure. Additional risk factors include children with special health care needs, unconfirmed appointments or caregiver forgetfulness, and logistical challenges such as transportation barriers and limited job flexibility.

Keywords: Appointment and Schedules; Health Services Accessibility; Medicaid; Pediatric Dentistry; Social Determinants of Health

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INTRODUCTION

Dental caries, or tooth decay, is the leading chronic condition found in children.[1] Despite its prevalence, it is also the most neglected health issue in this population.[2] The American Academy of Pediatric Dentistry recommends that children establish a dental home no later than 12 months of age and attend regular recall appointments every 3-6 months, depending on caries risk.[3] Because of the anatomy of primary teeth, children are uniquely vulnerable to oral disease, which can have lasting effects both physically and psychologically.[4] Untreated dental caries can lead to several adverse systemic health effects, including but not limited to pain, infection, swelling, exacerbation of existing health conditions, and even death.[5]

Children are uniquely vulnerable to oral health disparities because of their dependence on caregivers to facilitate access to health care.[6] Factors such as the caregiver's level of education, ability to take time off work, transportation availability, and insurance eligibility all contribute to whether children receive timely and adequate dental care, which can lead to disparities in oral health outcomes.[1]

Social determinants of health are non-medical factors that historically have large impacts on health outcomes.[7] Large medical organizations such as the American Academy of Pediatric Dentistry recognize the influence of social factors on children's oral health and how social barriers can have direct clinical outcomes on the lives of children.[8] These barriers can disproportionately affect children from low-income families, communities with limited access to dental professionals, and populations that face other systemic challenges.[1] This reliance on caregivers, combined with the intricacies of socioeconomic challenges faced by families, creates substantial barriers to care. It is well established in existing literature that people and communities with low socioeconomic status suffer worse oral health outcomes than their middle- or high-socioeconomic counterparts.[1] While there are public programs that exist, such as Medicaid for insurance or transportation, the Ronald McDonald house for shelter close to hospitals, and the Children's Health Insurance Program (CHIP) to help with some barriers, circumstances are often multifactorial in nature and providing mere coverage is not necessarily adequate in mitigating all barriers to addressing oral health care.

Targeting factors and populations at risk for missed appointments can help us efficiently and effectively create programs that are tailored to fit the problem. Identifying patterns or common obstacles to care can help to identify possible local or federal programs to help combat lack of access to care as a whole.

The objective of this scoping review is to understand significant factors cited for missed pediatric dental appointments. Firstly, to identify trends in the current body of literature. Secondly, to discover potential gaps in knowledge. Finally, to establish characteristics of target populations for intervention.

METHODS

A comprehensive literature database search was performed to find all relevant literature on missed pediatric dental appointments. The database search strategy was developed by a health science librarian in consultation with the project team. Studies were identified by the librarian developing and running searches in MEDLINE, PsycInfo, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Scopus, and Cumulative Index to Nursing and Allied Health Literature (CINHAL). Gray literature resources were also searched. Only studies published in English were included. No filters were used in the search.

Studies conducted outside the United States and before 2000 were excluded. The search strategy was written for Ovid MEDLINE and translated using each database's syntax, controlled vocabulary, and search fields. MeSH terms and text words were used for the search concepts of dental appointments or dental scheduling, pediatrics, children, failed appointments, missed appointments, cancelled appointments, no-shows, and their synonyms. All databases and gray literature resources were searched on August 30, 2024. This review captures research published in the temporal framework leading up to this search review. A draft search strategy was then reviewed by a second librarian. Full search strategies are available here: https://osf.io/ju9wz/

Of the 2056 studies imported for review, 357 were excluded for duplication. Of the 1699 remaining, 54 were included for full-text review. To be considered for inclusion, the study had to be peer-reviewed with data collected and published in English before 2000 in the United States. The research had to exclusively focus on pediatric dental appointment attendance or failed attendance as the target subject of the study. The research had to have children as the target population being studied. Studies were excluded if they were published before 2000, conducted outside of the United States, written in a language other than English and conducted in an adult population or mixed adult/pediatric population. From the articles included, data were extracted and independently evaluated by two pediatric dentists. If there was a discrepancy in decision-making, a third pediatric dentist served as the tiebreaker. Ultimately, data from nine studies were extracted for inclusion (Figure 1).

RESULTS

In this scoping review, nine articles[9-17] were identified that addressed commonly cited factors and populations for missed pediatric dental appointments (Table 1). In the studies included, populations with racial predilections, low socioeconomic groups, communities utilizing public insurance, families with social or transportation issues, and appointments scheduled a length of time before the date of service were factors that all contributed to higher rates of missed pediatric dental care opportunities. Of the nine articles included, five determined that populations utilizing public insurance had the highest rates of missed care opportunities. In other words, populations whose children qualified for state or federal insurance had an increased likelihood of no-show dental appointments.

Most of the studies included in this scoping review found correlations between populations utilizing public insurance (Medicaid) and missed care opportunities in the pediatric dental population. Based on eligibility criteria for public insurances, the vast majority of the population they serve is below the Federal Poverty Level in their respective areas. This is consistent with existing literature, which suggests that there exists a relationship between missed care and children in low-income or low-socioeconomic families.

The study by Alrayyes et al. [9] found that from January 2019 to November 2019, patients scheduled for moderate sedation with one or more decayed, missing, or filled primary teeth (DMFT) due to caries failed appointments more often with unconfirmed appointments, history of no-show, or long wait times. Interestingly, families with children who had nine or more DMFT presented to their appointments at a higher rate. One might think that children with fewer caries present more frequently and reliably to their dental appointments, but this inverse shift could be due to the guardian's perceived acuity of their child's dental status.

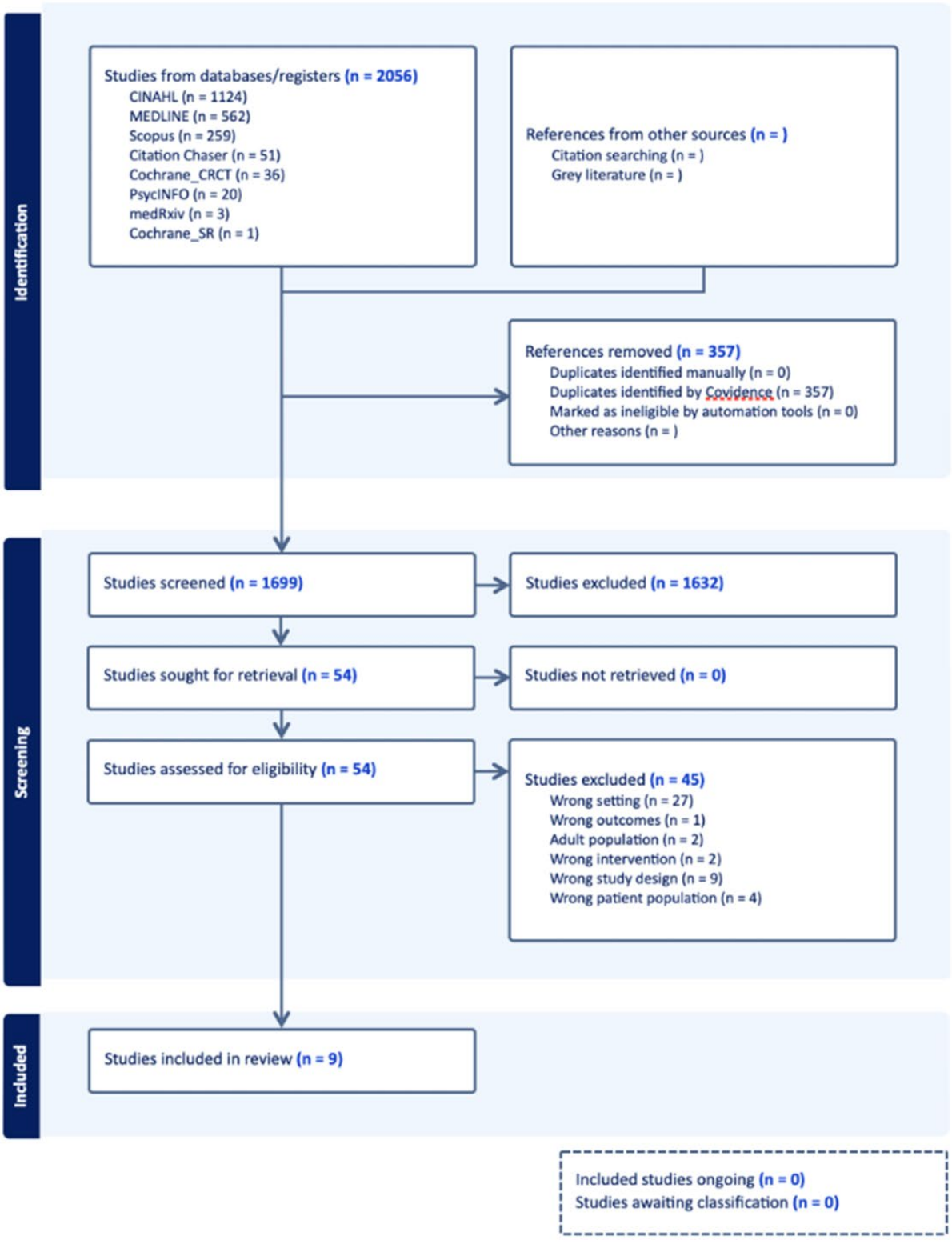

Figure 1. PRISMA diagram

Table 1. Details regarding articles selected for inclusion in the study

Citation	Study Design	Results	Limitations
Alrayyes SM, Capezio N, Kratunova E, LeHew CW, Alapati S. Factors associated with moderate sedation attendance at a university-based pediatric dental clinic. *J Dent Educ* 2021;85(12):1821-1827. doi: 10.1002/jdd.12749.[9]	Cross-sectional study	Appointment confirmation and DMFT score ≥ 9 had positive correlation with attendance, while no-show history and longer waiting time had negative impact on attendance.	Did not evaluate parental level of education or employment
Butler J, Leary K, Qian F, Lesch A. Comparison of failed and kept general anesthesia appointments in a pediatric dental clinic. *J Dent Child (Chic)* 2021;88(3):173-179.[10]	Cross-sectional retrospective chart review	Patients seen for emergency care between consultation and treatment appointments and with longer waiting time for appointment had higher rates of missed appointments.	Relied on patient survey and opinion, limited by changing nature of history and physical examination appointments by hospital protocols and academic environment
Casaverde NB, Douglass JM. The effect of care coordination on pediatric dental patient attendance. *J Dent Child (Chic)* 2007;74(2):124-129.[11]	Retrospective chart review	Patients without care coordination, with high caries scores, poor behavior, longer waiting times between appointments, history of no-show, and lack of serviceable phone had higher rates of missed care.	Limited detail and information included, limited period assessed
Christensen AA, Lugo RA, Yamashiro DK. The effect of confirmation calls on appointment-keeping behavior of patients in a children's hospital dental clinic. *Pediatr Dent* 2001;23(6):495-498.[12]	Randomized controlled trial	In private insurance group, confirmation calls resulted in statistically significant increase in appointment attendance.	Not all confirmation calls are considered successful contact
Discepolo K, Melvin P, Ghazarians M, Tennermann N, Ward VL. Socioeconomic and clinical demography of dental missed care opportunities. *JDR Clin Trans Res* 2023;8(4):356-366. doi: 10.1177/2380084422110479.[13]	Retrospective cohort study	Multivariable logistic regression estimated increased missed care opportunities in Black/non-Hispanic and Hispanic populations, patients with no/public insurance, complex medical conditions, appointments scheduled during COVID-19 pandemic, long waiting times between appointments, children from neighborhoods of high social vulnerability.	Patients with zip codes missing from chart excluded from study, orthodontic and limited examination appointments excluded

Table 1. Details regarding articles selected for inclusion in the study (continued)

Citation	Study Design	Results	Limitations
Emhardt JR, Yepes JF, Vinson LA, Jones JE, Emhardt JD, Kozlowski DC, Eckert GJ, Maupome G. Significant factors related to failed pediatric dental general anesthesia appointments at a hospital-based residency program. *Pediatr Dent* 2017;39(3):197-202.[14]	Cross-sectional study	Statistically significant rate of missed care opportunities in Black populations, self-pay patients, appointments scheduled later in the day, patients who travel > 60 miles for appointment, snowfall > 0.5 inches, and decreased temperature.	n/a
Goldman K, Aldosari MA, Discepolo K. Missed dental care appointments in an urban safety net hospital. *Journal of the California Dental Association* 2022;50(8):473-479. doi: 10.1080/19424396.2022.12224328.[15]	Cross-sectional	Hispanic and Black populations, public insurance patients, patients living in low-income neighborhoods, and those living within 10 miles of the hospital showed increased percentages of no-show rates.	Small sample size, single hospital in the Northeast (limited generalizability)
Mathu-Muju KR, Li HF, Hicks J, Nash DA, Kaplan A, Bush HM. Identifying demographic variables related to failed dental appointments in a university hospital-based residency program. *Pediatr Dent* 2014;36(4):296-301.[16]	Retrospective chart review	Self-pay patients, children older than 6 years of age, and rural residents were statistically more likely to fail appointments.	Appointment attendance evaluated by percentage, not raw data
Ogawa JT, Kiang J, Watts DJ, Hirway P, Lewis C. Oral health and dental clinic attendance in pediatric refugees. *Pediatr Dent* 2019;41(1):31-34.[17]	Retrospective Chart Review	Children aged 13-18 years and refugees had higher rates of missed appointments.	Selection bias due to retrospective nature of study

The study by Butler et al. [10] showed that within failed appointments, 82.6% had public aid (Medicaid) and 47.7% had special health care needs. The most common reason for failed appointments was child illness. In addition, patients who were seen for emergent dental issues between initial consultation and sedation appointments were more likely to fail than patients who were not seen. Additionally, this paper found that the mean and median days from initial consultation to surgery date were significantly higher for those who missed appointments. In other words, families who had longer wait times to be scheduled for treatment had higher rates of no-show appointments.

The study done by Casaverde et al.[11] proposed utilizing care coordinators to help families with the logistics of attending their children's appointments. Care coordinators are able to set appointment reminders, arrange home visits, arrange transportation and babysitting during scheduled appointments, and refer to other medical/social/educational services as needed. Children scheduled at the University of Connecticut/Burgdorf Dental Clinic for nitrous oxide or oral sedation appointments between May 2003 to May 2004 were assessed.

Of the variables analyzed, only a previous history of no-show appointments had a statistically significant association with appointment attendance. The study also found that children with lower DMFT and higher behavioral scores had a higher rate of presentation for dental appointments, which contradicts directly with the previously mentioned paper. With the implementation of care coordinators, appointment attendance rates increased from 52% to 59%, which was not statistically significant.

DISCUSSION

When considering families at risk of missing pediatric dental appointments, it is important to identify those individuals to make selective decisions regarding how to best help or provide support. Future investigations into programs that have helped to lower appointment nonattendance may be useful to inform public health policies and programs moving forward.

To address the commonly cited factor of forgetfulness, widespread implementation of appointment reminder systems, such as text messages or automated calls, may be imperative in reminding families of upcoming appointments.[18] Ideally, this would give families ample time to coordinate logistics and request support, such as the need for transportation or childcare during appointments. This intervention would be relatively easy to implement in community health centers, hospitals, and private practices alike.

Other factors frequently cited for missed dental appointments included history of no-show, certain racial groups, social issues, and transportation barriers. The difficulty in implementing support programs for specific members of society is discovering parameters or eligibility criteria that allow these at-risk populations to be identified.[19] Targeting patients who have a history of no-shows for intervention such as reminder phone calls can be a way to consolidate resources while effectively reducing no-show rates.[19] Appointment attendance positively affects reimbursement, which helps support the financial aspect of providing care and holding appointment times for patients who may have poor utilization and therefore a lost care opportunity and non-billable time.[19] Sorting a patient population by zip code, for example, to identify underserved areas may be a good start, but patients may have address changes, incorrect information listed, or other social issues that make this methodology ineffective. Additional parameters must be identified to accurately represent the patient's geographical location and everyday settings to accurately implement programs for at-risk communities.

Based on the literature, children who were seen in an emergency department setting to address an acute dental issue also had higher rates of failed appointments.[10] Especially in private practices, having complete access to a child's medical records across health care facilities in not always possible as private dental practices often operate in isolation from system-wide electronic health care record systems. Since practitioners cannot view which children have had their acute needs met, they are not able to reach out to families to make a compelling case for why non-acute issues must also be addressed before worsening of the dental problems. Holistic and complete chart reviews of children across health care databases are critical to obtaining a thorough history of every single patient.

Ultimately, more research must be done to identify these at-risks populations before widespread change can be implemented and policy can be created to target intervention. Filtering patients in a database by race, zip code, history of no-show appointments, or immigration status may be a good start to identify patients who require extra support to attend their appointments. Implementing a questionnaire for parents to complete may also have desired effects of identifying families with social issues, but those

who believe they will not qualify may not take the time to complete these surveys.

Because of parameters set during our search, the findings are relevant to the United States only. Though other countries must face barriers to oral health care for the pediatric population, a hypothesis may be made that federal support or parental knowledge of oral health care may be substantially different than that of the United States. It would be valuable to assess whether patterns of missed care opportunities observed here are the same as those in other countries. Additionally, the body of literature specifically related to missed pediatric dental care appointments is limited. Because of the lack of standardized measurement tools as well as differing contexts of the missed appointments (outpatient clinic, sedation, general anesthesia), it was challenging to compare results, which limit the generalizability of the findings. Most of the study designs were observational in nature; however, there was methodological heterogeneity across the studies making comparison and synthesis across results challenging. Finally, publication bias must always be considered in scoping reviews as literature that has statistically significant and positive findings is typically published to be available for inclusion for review. Therefore, trends in the literature noted may be inflated to include studies that had pertinently positive findings.

CONCLUSIONS

Studies have shown a correlation between lower socioeconomic status families and higher adverse health outcomes and missed appointments. Barriers to care fall into general groupings of socioeconomic barriers, logistical difficulties, and health-related complications.

Future research on this subject may explore the rate of attendance to restorative and operative appointments versus elective appointments (orthodontics), social support to address social determinants of health that may impact appointment adherence and incentive programs that positively enforce appointment attendance.

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Effectiveness of non-fluoride agents in combination with fluorides for dental caries prevention: A systematic review and meta-analysis

Tony Jose ✉

Highlights

- Combining fluoride with agents like chlorhexidine, CPP-ACP, povidone iodine, or herbal products may improve remineralization and antimicrobial effects in prevention.
- Meta-analysis showed fluoride combined with non-fluoride agents, especially CPP-ACP, reduced caries activity and lesion area more effectively short term than fluoride alone.
- Non-fluoride remineralizing agents may support fluoride-based caries management, but long-term multicenter randomized trials are needed to confirm lasting benefits.

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Abstract

Although fluoride has been known as anti-caries agents for many years, its usage is associated with some side-effects. Owing to antimicrobial and remineralization-enhancing properties, non-fluoride agents such as chlorhexidine, povidone iodine, casein phosphopeptide-amorphous calcium phosphate (CPP-ACP), and various herbal products have gained attention as remineralization strategies for the prevention and management of dental caries. The present study aimed to evaluate the effectiveness of combined therapy using topical fluoride (TF) with these non-fluoride agents over TF monotherapy for the prevention of dental caries. Following PRISMA guidelines, a literature search was conducted across PubMed, ScienceDirect, SpringerLink, Wiley Online Library and Google Scholar for studies published between 2005 and 2025. Articles that evaluated the use of non-fluoride agents (chlorhexidine, CPP-ACP, povidone iodine, herbal products) in combination with fluoride-containing products were included. Totally, 21 articles were included in the review and 17 articles were included in the meta-analysis. Most of the reviewed studies used CPP-ACP as non-fluoride remineralizing agents, while only few used povidone iodine and chlorhexidine. Findings revealed that fluoride, when used in combination with non-fluoride agents, was significantly more effective than fluoride monotherapy in reducing caries activity in less than two months and at three months in both primary and permanent teeth. Additionally, this combination therapy resulted in a significant reduction in lesion area after three months of treatment. However, no statistically significant difference was observed between fluoride combination therapy and fluoride monotherapy with respect to caries increment in either the short-term or long-term follow-up. Fluoride, when combined with non-fluoride agents, particularly CPP-ACP, showed better remineralization potential compared with fluoride alone, particularly in the short-term basis. These findings support the adjunctive use of such combinations in caries management; however, further long-term, multicenter RCTs are warranted to confirm their clinical durability and sustained effectiveness.

Keywords: Chlorhexidine, CPP-ACP; Dental Caries; Fluoride; Povidone Iodine

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INTRODUCTION

Human teeth are primarily composed of hydroxyapatite.[1] In its biological form, hydroxyapatite contains carbonate (CO_3^{2-}) and hydrogen phosphate (HPO_4^{2-}) ions, which increase its solubility[2–4] and make it more susceptible to demineralization, especially when exposed to sugary and acidic foods.[5] Dental caries develop when sugars are metabolized by acidogenic bacteria into organic acids, leading to demineralization of enamel.[6] Although remineralization can occur naturally via saliva, caries progress when demineralization exceeds remineralization over time.[7] Early-stage caries appear as non-cavitated white spot lesions (WSLs), which can worsen into cavitated lesions, if left untreated.[8] Dental decay is a global public health concern and the most common chronic disease affecting people of all ages.[9–11] Hence, early diagnosis and proper treatment are essential for effective management of this global oral health problem.[8]

Fluoride has been reported as an anti-caries agent over two centuries, particularly in developed countries.[12,13] It can replace hydroxide ions of tooth enamel to form fluorapatite, which is more resistant to acid dissolution.[14] Today, fluoride is a common ingredient in toothpastes, mouthwashes, and dental varnishes, administered both topically and systemically.[15] Fluoride's primary action is topical, enhancing remineralization and reducing enamel demineralization.[16] While topical use is safe, excessive ingestion, especially in children under six who often lack adequate swallowing control, can lead to fluorosis or gastrointestinal issues.[17–19] Moreover, emerging fluoride resistance in cariogenic bacteria[20,21] has prompted researchers in exploring combination therapies for improved prevention.

In this context, non-fluoride agents, such as chlorhexidine, povidone iodine (PI), casein phosphopeptide-amorphous calcium phosphate (CPP-ACP), and various herbal products, have gained attention for their antimicrobial and remineralization-enhancing properties. Studies have shown that a varnish containing chlorhexidine and fluoride arrested root caries among older adults.[22] Similarly, a varnish combining PI and sodium fluoride (NaF) proved more effective than NaF alone in preventing dental caries in children.[23] One derivative of milk protein, termed as CPP-ACP, is recognized for its ability to enhance remineralization and is increasingly used in non-invasive treatments for early enamel lesions.[24] Herbal formulations are also being incorporated into oral care due to their natural antimicrobial potential.[25] The rationale for combining topical fluorides with these non-fluoride agents lies in their potential synergistic effects, i.e., enhancing caries prevention while possibly reducing the risks associated with fluoride overuse.

While several systematic reviews and meta-analyses have examined the efficacy of combination therapies, many have focused exclusively on pediatric populations and have yielded mixed and inconclusive results. For example, two systematic reviews[26,27] concluded that combined therapies were effective, but the findings were limited to children. In contrast, one study[28] reported that fluoride alone outperformed a combination of fluoride and CPP-ACP in managing white spot lesions (WSLs), while another study[29] found no significant difference between monotherapy and combination therapy for early smooth-surface caries. Moreover, previous meta-analyses have typically assessed only one type of non-fluoride agent, lacking a broader comparative approach. Therefore, a comprehensive systematic review and meta-analysis are warranted to evaluate the overall effectiveness of various combination therapies across diverse populations and clinical outcomes.

The present study aimed to systematically review and identify studies that compared the effectiveness of combined therapy using topical fluoride with non-fluoride agents (such as povidone-iodine, chlorhexidine, CPP-ACP, or herbal products) versus topical fluoride monotherapy in the prevention of dental caries. The extracted data were subsequently subjected to meta-analysis to assess whether combination therapy demonstrates superior clinical outcomes in terms of dental caries incidence, salivary bacterial counts, lesion area, and remineralization potential across various follow-up durations. By consolidating the available data, this review will provide a comprehensive evaluation of the comparative effectiveness of fluoride monotherapy and combination regimens in the prevention and management of caries.

METHODS

The guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[30] were adhered to in this systematic review and meta-analysis. The PRISMA checklist for the present work is available in Supplementary Table 1.

PICO Framework

The Population, Intervention, Comparison/Control, and Outcome (PICO) framework was used to formulate the following research question:

"Does the combination of non-fluoride agents with fluoride enhance the effectiveness of dental caries prevention compared with fluoride monotherapy alone?"

For this study, the population comprised patients (both children and adults) diagnosed with dental caries or identified as being at higher risk of caries. The intervention of interest was the combined therapy involving fluoride agents used in conjunction with non-fluoride agents (chlorhexidine, CPP-ACP, povidone iodine, herbal products). The comparator was fluoride monotherapy. The outcomes assessed included increment of dental caries, remineralization potential measured using fluorescence-based method values (QLF and LF), lesion area, and bacterial count.

Selection Criteria

The inclusion criteria for the study were as follows: (1) Studies involving patients (both adult and children) diagnosed with dental caries or identified as being at higher risk of caries; (2) Studies that evaluated the use of non-fluoride agents (chlorhexidine, CPP-ACP, povidone iodine, herbal products) in combination with fluoride-containing products or herbal products compared with fluoride; (3) Studies focusing on the prevention or management of dental caries, including remineralization and/or demineralization processes along with the caries continuum and antibacterial effects; (4) Studies that included randomized controlled trials (RCTs), observational studies, and clinical trials conducted on human teeth and; (5) Studies published in peer-reviewed journals between 2005 and 2025.

The exclusion criteria included: (1) Systematic reviews, case reports, conference abstracts, posters, and book chapters; (2) Studies that focused on nanoparticles, herbal extracts, or other natural products (e.g., probiotics), or studies that used non-fluoride agents without combination with fluoride; (3) Studies that investigated non-fluoride products other than chlorhexidine, CPP-ACP, povidone iodine, or herbal products; (4) Studies that included oral health education interventions as a strategy for managing dental caries; and (5) Studies that addressed oral conditions (such as dental erosion, gingivitis, or dental plaque) without a direct association with caries prevention.

Search Strategy

Five electronic databases, namely, PubMed, ScienceDirect, Wiley Online Library, Springer, and Google Scholar, were used to screen articles. Besides electronic databases, an extensive manual search was done within the references lists of selected studies and review articles to find eligible records. The following keywords identified from prior research were used to search the databases for relevant articles: "fluorides", "fluoride treatment", "chlorhexidine", "chlorhexidine varnish", "povidone-iodine", "casein phosphopeptide amorphous calcium phosphate", "CPP-ACP", "caseins", "herbal mouthwash", "herbal mouthrinse", "dental caries", "tooth decay", "dental plaque", "Lactobacillus", and "Streptococcus". Logical combinations of appropriate keywords and Medical Subject Headings (MeSH) terms were applied using Boolean operators for conducting the search. Supplementary Table S1 provides comprehensive details on electronic databases, search terms, filters, and number of results retrieved.

Study Selection and Data Screening Process

The study selection involved a systematic search across multiple databases, including PubMed, Wiley Online Library, ScienceDirect, SpringerLink, and Google Scholar, using pre-specified search terms. Initially, titles and abstracts of the retrieved articles were screened to exclude irrelevant studies that did not address the research question. Duplicate entries and redundant publications were also removed during this stage. Full-text versions of the shortlisted articles were then obtained and evaluated against a set of predefined inclusion and exclusion criteria. To facilitate structured organization and subsequent analysis, all references from the selected studies were systematically documented in an Excel spreadsheet.

Two researchers independently searched and screened the articles, and any discrepancies that arose were resolved through consultation with a third researcher.

Data Extraction

Relevant data were extracted from each included study independently by two researchers, covering various aspects such as study details (first author's name, year of publication, and the country), patients' characteristics (total number of participants, age of sample population, type of teeth affected), compounds used in experimental and control groups, follow-up period and outcomes measurements (DIAGNOdent scores, QLF indices, mean values of lesion area and indices of caries, such as ICDAS, EDI, DMFT/S). Disagreements, if any, were settled by a third researcher. Following this extraction process, the data were subjected to a quantitative analysis.

Outcome Measurement

For the comparative evaluation of caries-preventive effectiveness between fluoride monotherapy and combination therapy, outcome measures were categorized into primary and secondary. The primary outcomes focused on remineralization potential, which was evaluated using changes in mean DIAGNOdent scores and quantitative light-induced fluorescence (QLF) radiance values. These outcomes were assessed at short-term follow-up periods of less than two months and at three months post-intervention. Secondary outcomes examined caries progression in terms of reduction in lesion area and caries increment after treatment. Lesion area reduction was recorded at three months while the mean increment in dental caries was recorded at longer follow-up intervals of 6, 12, and 24 months. Studies investigating the use of herbal mouthrinses in combination with fluoride were not identified in the available literature and were therefore not included in the analysis.

Risk of Bias Assessment

The risk of bias in the included randomized studies was assessed using the revised Cochrane Risk-of-Bias tool (RoB 2).[31] This tool evaluates five key domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective outcome reporting. Studies were classified as having a *low risk of bias* when more than half of the assessed domains were judged to be at low risk, whereas a *high risk of bias* was assigned when at least two domains were rated as high risk. The assessment was independently conducted by two reviewers, and any disagreements were resolved through consultation with a third investigator.

Statistical Analysis

The meta-analysis was performed using RevMan software (v5.4, The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). Standardized mean differences (SMDs) were calculated for individual and pooled statistics. The corresponding 95% confidence intervals (CIs) were estimated using the restricted maximum-likelihood estimator. Meta-analysis was conducted utilizing the fixed-effect and random-effect models as and where required. Heterogeneity was quantified using I^2 statistic, which was classified as (i) I^2 = 0%–25% referring to no heterogeneity (ii) I^2 = 25%–50% as moderate heterogeneity, (iii) I^2 = 50%–75% as high heterogeneity, and (iv) I^2 = 75%–100% extreme heterogeneity. Statistical significance was determined by a probability value of < 0.05. Forest plots were applied to display the measured effect sizes with their 95% CIs for all studies included. Publication bias was assessed through funnel plots.

RESULTS

Literature Screening

Following PRISMA guidelines, the study selection, evaluation and synthesis process was meticulously documented. Figure 1 illustrates the flowchart of the review process. A total of 495 articles were retrieved, with contributions from PubMed (206 articles), ScienceDirect (211), SpringerLink (29 articles), Wiley Online Library (46), and Google Scholar (3). After removing three duplicate records, 439 articles were excluded after the screening of title and abstract due to irrelevance. Fifty-three studies underwent manual screening and 32 full-text articles that did not satisfy all eligibility criteria were removed. Finally, 21 studies were included in the qualitative analysis and 17 articles were considered for meta-analysis. However, studies investigating the usage of herbal mouthrinses in combination with fluoride were not identified in the available literature using the specified search terms. Therefore, only studies evaluating CPP-ACP, chlorhexidine, or povidone iodine in combination with fluoride were included in the analysis.

Risk of Bias Assessment

The risk of bias of the included studies was assessed using the Cochrane Risk of Bias 2 tool and the results are summarized in Table 1. With respect to the randomization process, several studies were judged to be at low risk of bias; however, a number of trials showed some concerns or a high risk due to inadequate reporting or lack of allocation concealment. Bias arising from deviations from the intended interventions was generally assessed as low across most studies. In contrast, bias arising from missing outcome data was frequently rated as high risk, as many trials reported incomplete follow-up or did not clearly explain whether missing data were related to the true outcome. The domain assessing outcome measurement was largely judged to be at low risk, reflecting the use

of standardized and validated assessment methods, although a few studies raised some concerns. Bias in the selection of the reported results was predominantly assessed as low risk. Overall, only a limited number of studies were classified as having a low risk of bias, while the majority were rated as high risk, primarily driven by concerns related to missing outcome data and, in some cases, deficiencies in the randomization process.

The risk of bias of the included studies was assessed using the Cochrane Risk of Bias 2 (ROB 2) tool and is presented in Table 1. With respect to the randomization process, several studies were judged as low risk; however, a number of trials showed some concerns or high risk due to inadequate reporting or lack of allocation concealment.

Bias due to deviations from intended interventions was generally low across most studies. In contrast, bias arising from missing outcome data was frequently rated as high risk, as many trials reported incomplete follow-up or did not clearly explain whether missingness was related to the true outcome. The domain assessing measurement of the outcome was largely judged as low risk, reflecting the use of standardized and validated assessment methods, although a few studies showed some concerns. Bias in the selection of the reported result was predominantly low risk. Overall, only a limited number of studies were judged as low risk of bias, while the majority were rated as high risk, primarily driven by concerns related to missing outcome data and, in some cases, the randomization process.

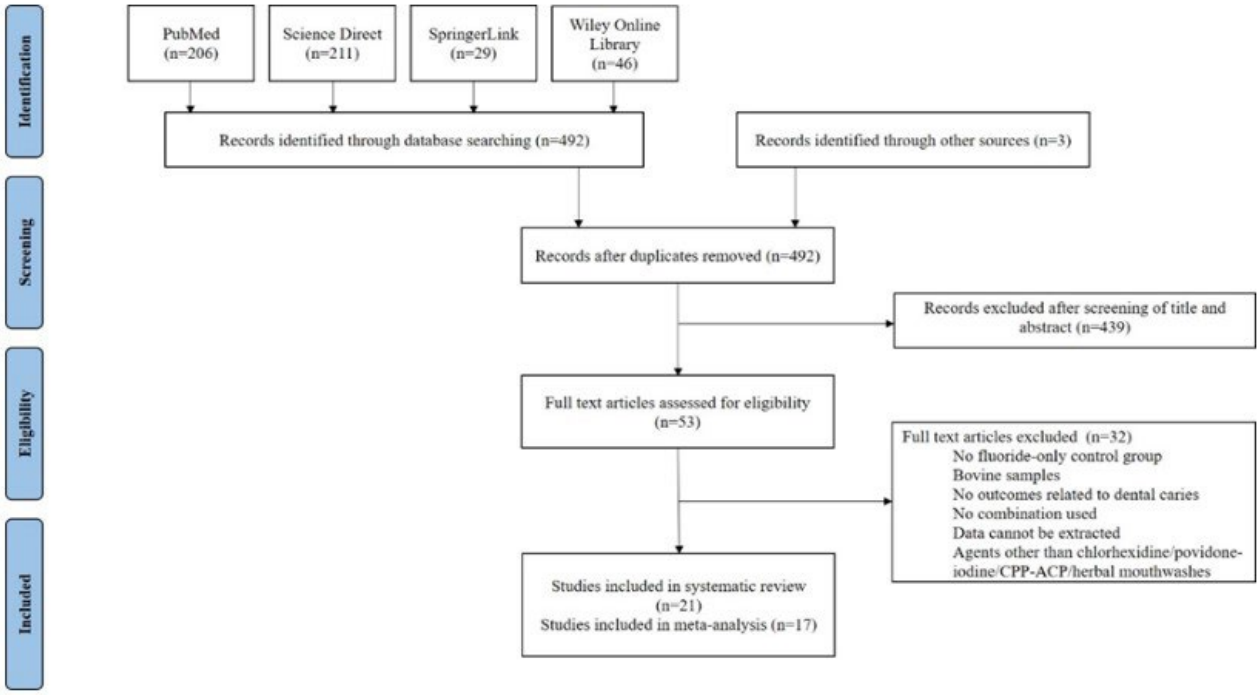

Figure 1. PRISMA 2020 flow diagram illustrating the study selection process in the systematic review and meta-analysis

Table 1. Risk of bias assessment

Study ID	Randomization process	Deviation from the intended intervention	Missing outcome data	Measure of the outcome	Selection of the reported result	Overall bias
Bobu (2019)	!	+	+	+	+	!
Yazicioğlu (2017)	!	+	+	+	+	!
Singh (2016)	+	+	-	+	+	-
Mendes (2018)	+	+	-	+	+	-
Lena (2015)	+	+	+	+	+	+
Esparza-Villalpand (2021)	+	+	-	+	+	-
Mekky (2021)	+	+	+	+	+	+
Güçlü (2016)	+	+	!	+	+	!
Al Batayneh (2019)	+	+	-	+	+	-
Beerens (2018)	+	+	-	+	+	-
Park (2022)	-	+	+	+	+	-
Bröchner (2011)	+	+	-	+	+	-
Beerens (2010)	+	+	-	+	+	-
Zhan (2006)	-	+	!	+	+	-
Pukallus (2013)	+	+	-	+	+	-
Sundell (2013)	-	+	-	+	+	-
Sitthisettapong (2012)	+	+	-	+	+	-
Milogram (2021)	+	+	-	+	+	-
	+	Low risk	!	Some concerns	-	High risk

Study Characteristics

The main characteristics of the studies included in this review are presented in Table 2. A total of 21 studies published between 2005 and 2022 were included in this review. The population age ranged from 2 to 79 years. Studies were performed across diverse geographical regions including Romania,[32] Turkey,[33,34] India,[35,36] Brazil,[37] Spain,[38] Mexico,[39] Egypt,[40] Jordan,[41,42] The Netherlands,[43,44] Denmark,[45] Germany,[22] USA,[46] Australia,[47] Sweden,[48] Thailand,[49] Micronesia,[23] and Saudi Arabia.[50] Most studies (n = 11) were conducted on primary dentition particularly in younger populations, although several (n = 7) focused on permanent teeth.

All patients had caries lesions that were treated with either fluoride monotherapy (control group) or combination therapy (combined with non-fluoride agents) (experimental group). In most studies (n = 14), CPP-ACP either alone or in

combination with fluoride (CPP-ACFP) were used as remineralizing agents, in concentrations ranging from 0.2% to 10%. Apart from CPP-ACP, four studies used 10% povidone iodine,[23,35,46,50] whereas three studies used chlorhexidine[22,47,48] as non-fluoride agents to manage caries lesions. Studies using herbal mouthrinses in combination with fluoride were not identified in the available literature and were therefore not included in the analysis. All participants in the experimental group were administered with these non-fluoride agents alongside fluoridated dentifrices (similar to the control group). Participants in the control group underwent conventional fluoride-based regimens, including sodium fluoride (NaF) mouthrinse, varnish, dentifrice, or acidulated phosphate fluoride (APF) gel, while a few of them were given placebo or fluoride-free control pastes. Outcomes were predominantly assessed in terms of caries activity, lesion progression or regression, bacterial counts, and lesion area, with follow-up durations varying considerably from 10 days[39] to as long as 24 months.[23,47,48]

Synthesis of Results

Primary Outcome: Remineralization Potential

A total of 185 patients in the experimental group and 216 patients in the control group from four included studies were compared for reductions in caries activity based on DIAGNOdent (laser fluorescence) scores. The pooled analysis across all studies showed a significant overall benefit of fluoride and non-fluoride combined therapy compared with fluoride monotherapy at follow-up periods of less than two months (SMD = −0.60; 95% CI: −0.93 to −0.28; p = 0.0003), with moderate heterogeneity (I^2 = 55%, p = 0.05) (Figure 2). Subgroup analysis demonstrated that in primary teeth, the combination of fluoride and non-fluoride interventions resulted in a significant reduction in caries activity compared with fluoride controls (SMD = −0.84; 95% CI: −1.44 to −0.25; p = 0.005; I^2 = 71%, p = 0.06). In permanent teeth, the effect of combination intervention was also significant but of smaller magnitude (SMD = −0.44; 95% CI: −0.80 to −0.09; p = 0.01, I^2 = 31%, p = 0.22).

Figure 3 depicts that all studies were distributed symmetrically around the pooled SMD, indicating no publication bias. Subgroup analysis demonstrated no significant difference in caries activity between "non-F+F" and "F" groups when CPP-ACP was used as a non-fluoride agent (SMD = 0.24; 95% CI: −0.30 to 0.78; p > 0.05). Heterogeneity was not significant among the pooled studies (I^2 = 59%; p = 0.12). Similarly, the pooled analysis showed no significant effect between the two groups when CPP-ACFP was used (SMD = −0.46; 95% CI: −1.04 to 0.11; p = 0.12; I^2 = 43%, p > 0.05) (Figure 4). Overall, the pooled analysis across all studies showed no significant benefits in experimental group in less than two months of treatment (SMD = −0.12; 95% CI: −0.60 to 0.36; p > 0.05; I^2 = 69%, p = 0.01).

Figure 5 depicts that all studies were distributed symmetrically around the pooled SMD, indicating no publication bias. After three months of treatment, a significant reduction in DIAGNOdent scores was observed when fluoride was used in combination with CPP-ACP or CPP-ACFP (SMD = −0.28; 95% CI: −0.52 to −0.04; p < 0.05), with no heterogeneity (I^2 = 2%, p = 0.39) (Figure 6). Subgroup analysis revealed that patients who used CPP-ACFP as non-fluoride agent along with fluoride had significantly lowered DIAGNOdent scores compared to fluoride controls (SMD = −0.41; 95% CI: −0.75 to −0.08; p = 0.02), with no heterogeneity (I^2 = 0%, p = 0.38). However, no significant difference was found between the two groups when CPP-ACP was used in "non-F+F" group (SMD = −0.14; 95% CI: −0495 to 0.21; p > 0.05; I^2 = 0%, p = 0.33).

Table 2. Characteristics of included studies

First Author (Year)	Country	Sample Size	Age of Participants	Affected Teeth	Experimental Group	Control Group	Outcomes Measurement	Follow-up period
Bobu (2019)	Romania	86	21 to 26 yrs	permanent teeth	(10% CPP-ACP + 0.2% NaF) + fluoride dentifrice (1450 ppm F)	(0.05% NaF mouthrinse) + fluoride dentifrice (1450 ppm F)	caries activity	1, 2 and 3 months
Yazicioğlu (2017)	Turkey	109	18 to 30 yrs	permanent teeth (smooth surfaces)	(10% CPP-ACP + 900 ppm F) + fluoride dentifrice (1450 ppm F)	fluoride dentifrice (1450 ppm F)	caries activity	1 month
		176		permanent teeth (occlusal surfaces)	(10% CPP-ACP+ 900 ppm F) + fluoride dentifrice (1450 ppm F)	fluoride dentifrice (1450 ppm F)	caries activity	
Singh (2016)	India	28	16 to 25 yrs	permanent teeth	(10% CPP-ACP + 900 ppm F) + fluoride dentifrice (1000 ppm F)	fluoride dentifrice (1000 ppm F)	caries activity	1, 3 and 6 months
		27		permanent teeth	(10% CPP-ACP + 900 ppm F) + fluoride dentifrice (1000 ppm F)	fluoride varnish (5% NaF) + fluoride dentifrice (1000 ppm F)	caries activity	
Mendes (2018)	Brazil	18	5 to 13 yrs	permanent teeth	10% CPP-ACP + 900 ppm NaF	fluoride dentifrice (1450 ppm F)	caries activity	1 and 3 months
		18		permanent teeth	10% CPP-ACP + 900 ppm NaF	1.23% APF gel	caries activity	

Table 2. Characteristics of included studies (continued)

First Author (Year)	Country	Sample Size	Age of Participants	Affected Teeth	Experimental Group	Control Group	Outcomes Measurement	Follow-up period
Lena (2015)	Spain	111	6 to 14 yrs	permanent teeth	(10% CPP-ACP + 900 ppm NaF) + fluoride dentifrice (1100 ppm F)	5% NaF + fluoride dentifrice (1100 ppm F)	caries activity	1, 2 and 3 months
		119		permanent teeth	(10% CPP-ACP) + fluoride dentifrice (1100 ppm F)	5% NaF + fluoride dentifrice (1100 ppm F)	caries activity	
Esparza-Villalpand (2021)	Mexico	84	3 to 7 yrs	primary teeth	(10% CPP-ACP + 900 ppm NaF) + fluoride dentifrice (1450 ppm F)	fluoride dentifrice (1450 ppm F)	caries activity	10, 21 days
Mekky (2021)	Egypt	44	3 to 5 yrs	primary teeth	2% CPP-ACP + 5% NaF	5% NaF	caries activity	1.5, 4.5, 7.5 months
Güçlü (2016)	Turkey	11	8 to 15 yrs	permanent teeth	10% CPP-ACP + fluoride dentifrice (1450 ppm F) + 5% NaF	fluoride dentifrice (1450 ppm F) + 5% NaF	caries activity	3 months
Al-Batayneh (2019)	Jordan	79	4 to 5 yrs	primary teeth	10% CPP–ACP + fluoride dentifrice (500 ppm F)	fluoride dentifrice (500 ppm F)	changes in caries lesions, lesion area	3 and 6 months
Al-Batayneh (2017)	Jordan	54	extracted teeth	primary teeth	10% CPP–ACP + fluoride dentifrice (500 ppm F)	fluoride dentifrice (500 ppm F)	changes in caries lesions	10 weeks

Table 2. Characteristics of included studies (continued)

First Author (Year)	Country	Sample Size	Age of Participants	Affected Teeth	Experimental Group	Control Group	Outcomes Measurement	Follow-up period
Beerens (2018)	The Netherlands	51	12 to 19 yrs	not specified	(0.2% CPP-ACP + 900 ppm NaF) once a day + fluoride dentifrice	Ultradent (fluoride-free control paste once a day + calcium) + fluoride dentifrice	changes in caries lesions, bacterial count, lesion area	6 weeks, 3, 6 and 12 months
Park (2022)	Germany	38	60 to 79 yrs	permanent teeth	0.3% CHX + Ammonium fluoride (1400 ppm F)	NaF (22,600 ppm F)	changes in caries lesions	2 weeks, 6 and 12 months
Bröchner (2011)	Denmark	50	Not mentioned	not specified	10% CPP–ACP + fluoride dentifrice (1,100 ppm F)	fluoride dentifrice (1,100 ppm F)	changes in caries lesions, lesion area	1 month
Beerens (2010)	The Netherlands	54	12 to 19 yrs	not specified	0.2% CPP-ACP + 900 ppm NaF + fluoride dentifrice	(fluoride-free control paste + calcium) + fluoridated dentifrice	changes in caries lesions, lesion area	6 weeks, 3 months
Zhan (2006)	USA	22	2 to 6 yrs	primary teeth	10% Povidone iodine + 1.23% APF gel	1.23% APF gel	dental caries increment, bacterial count	12 months
Pukallus (2013)	Australia	199	2 to 4 yrs	primary teeth	0.12% CHX gel + fluoride dentifrice (304% fluoride)	fluoride dentifrice (304% fluoride)	dental caries increment	24 months

Table 2. Characteristics of included studies (continued)

First Author (Year)	Country	Sample Size	Age of Participants	Affected Teeth	Experimental Group	Control Group	Outcomes Measurement	Follow-up period
Sundell (2013)	Sweden	78	2 to 5 yrs	primary teeth	1% CHX gel + fluoride varnish + fluoride dentifrice (250 ppm F)	fluoride varnish + fluoride dentifrice (250 ppm F)	dental caries increment	24 months
		83			1% CHX gel + fluoride varnish + fluoride dentifrice (250 ppm F)	0.2% sodium fluoride gel + fluoride varnish + fluoride dentifrice (250 ppm F)	dental caries increment	
Sitthisettapong (2012)	Thailand	296	2½ and 3½ yrs	primary teeth	10% CPP-ACP + fluoride dentifrice	Placebo + fluoride dentifrice	dental caries increment	6 and 12 months
Parsa (2021)	India	200	4 to 7 yrs	primary teeth	10% Povidone iodine + fluoride varnish (2% NaF)	fluoride varnish (2% NaF)	dental caries increment	6 and 12 months
Milogram (2021)	Micronesia	273	49 to 84 months	primary teeth	10% Povidone iodine + 5.0% NaF	5.0% NaF	dental caries increment	12 months
		262			10% Povidone iodine + 5.0% NaF	5.0% NaF	dental caries increment	24 months
El-Houseiny (2005)	Saudi Arabia	54	4-6 years	primary teeth	10% Povidone iodine + 1.23% APF gel	1.23% APF gel	dental caries increment	6 and 12 months

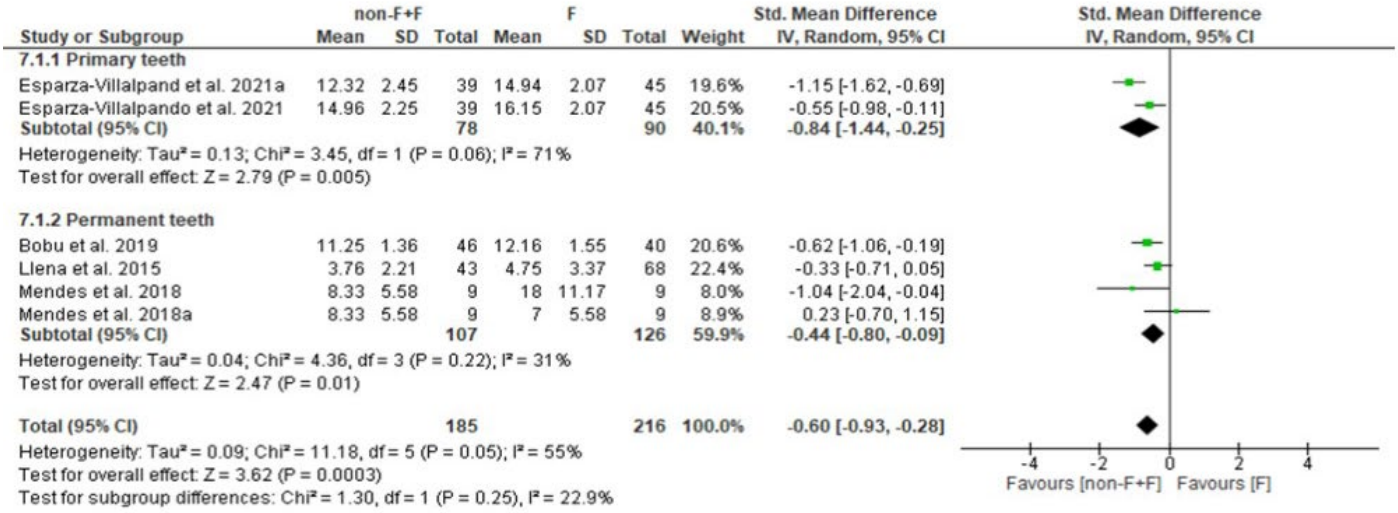

Figure 2. Forest plot comparing the effect of fluoride monotherapy versus fluoride combined with non-fluoride agents on caries activity (DIAGNOdent scores) in primary and permanent teeth at short-term follow-up (< 2 months)

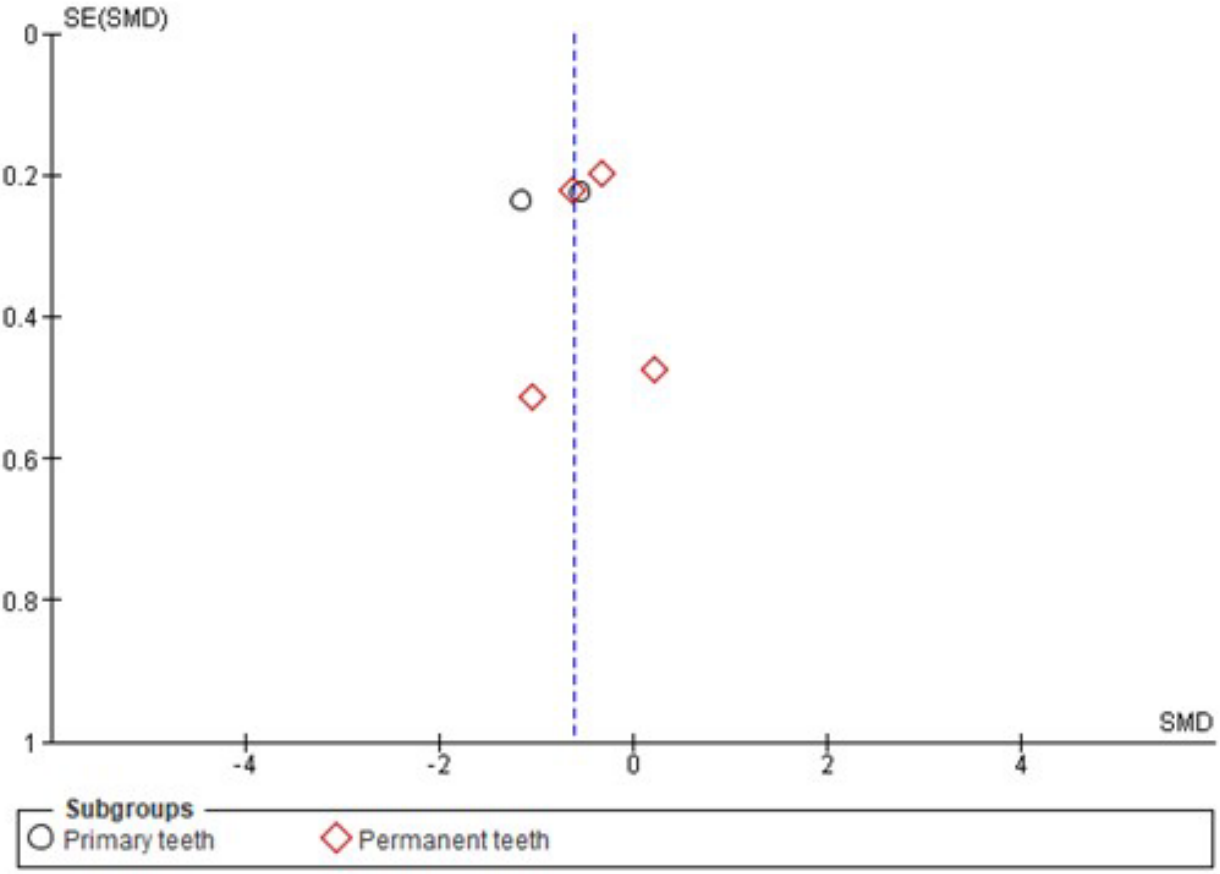

Figure 3. Funnel plot assessing publication bias for studies reporting DIAGNOdent-based caries activity outcomes at < 2 months

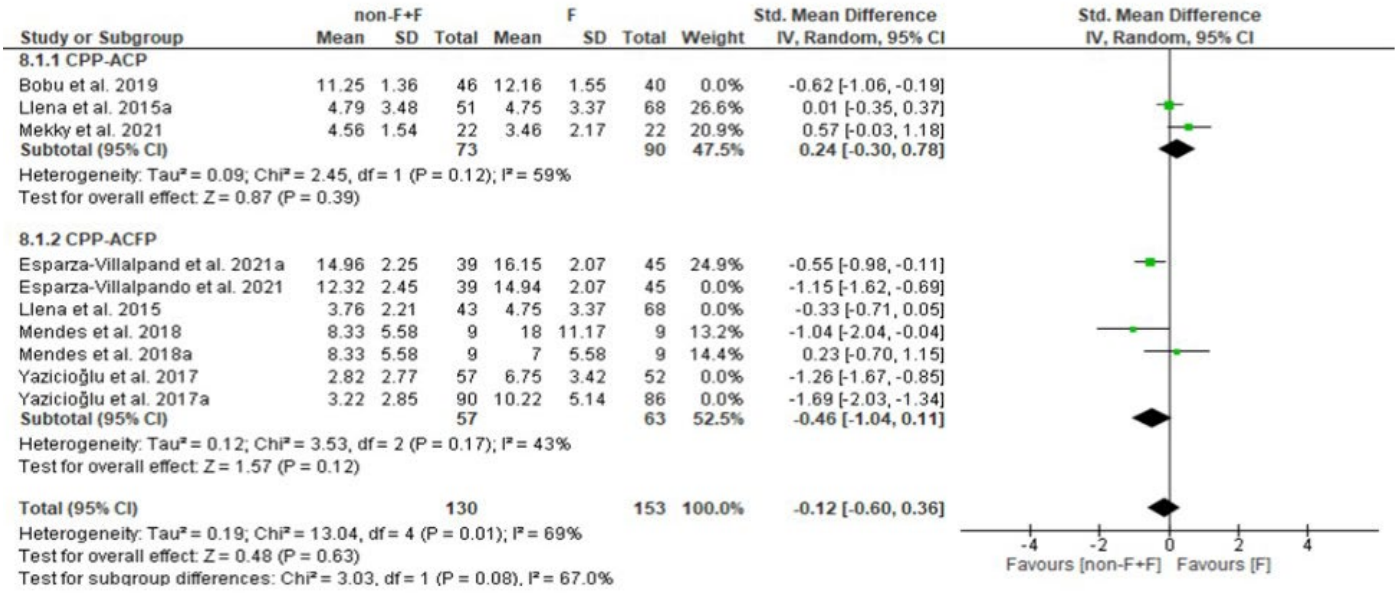

Figure 4. Forest plot presenting subgroup analysis by type of non-fluoride adjunct (CPP-ACP and CPP-ACFP) for caries activity measured using DIAGNOdent at < 2 months

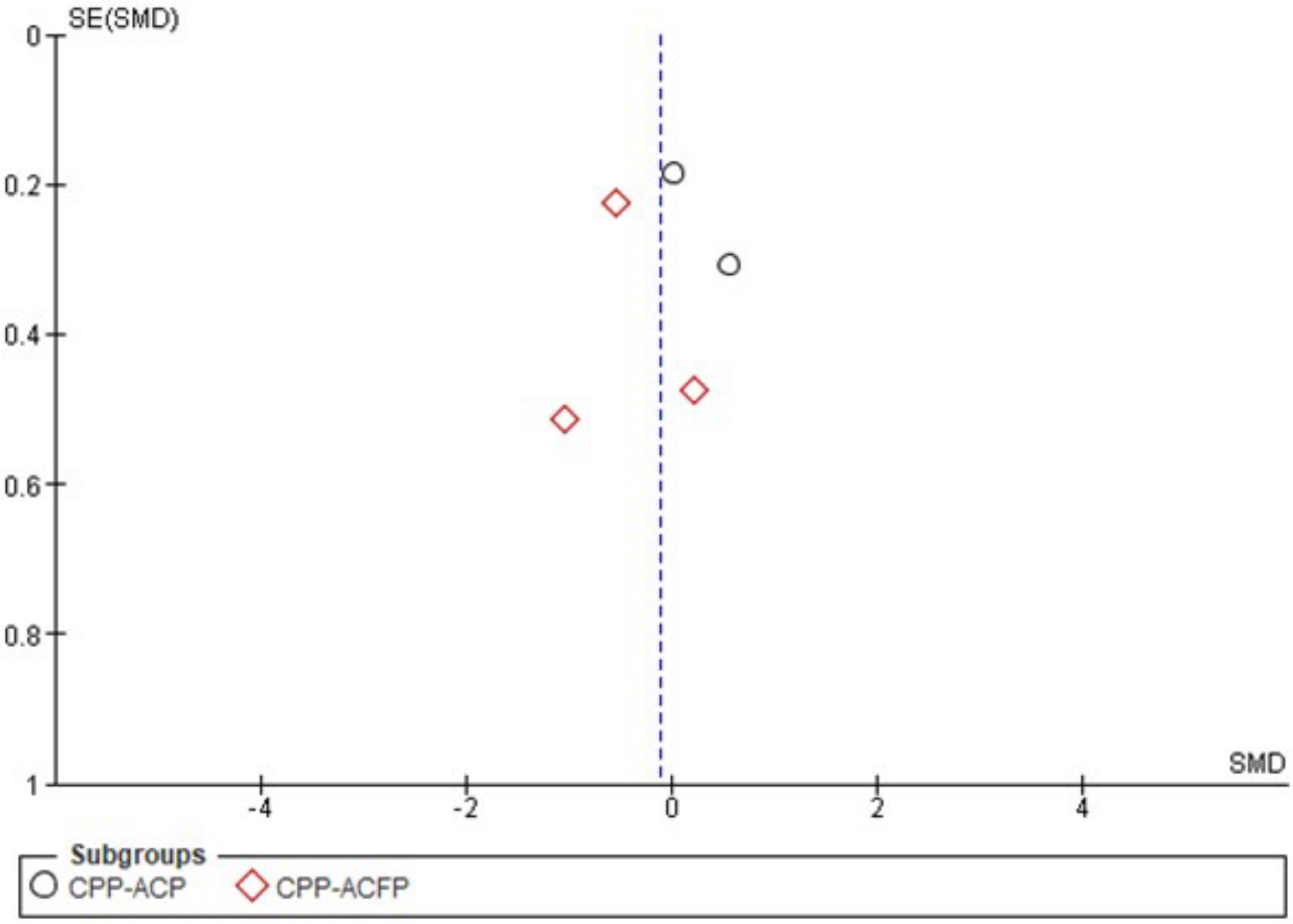

Figure 5. Funnel plot evaluating publication bias for subgroup analyses of DIAGNOdent outcomes at < 2 months

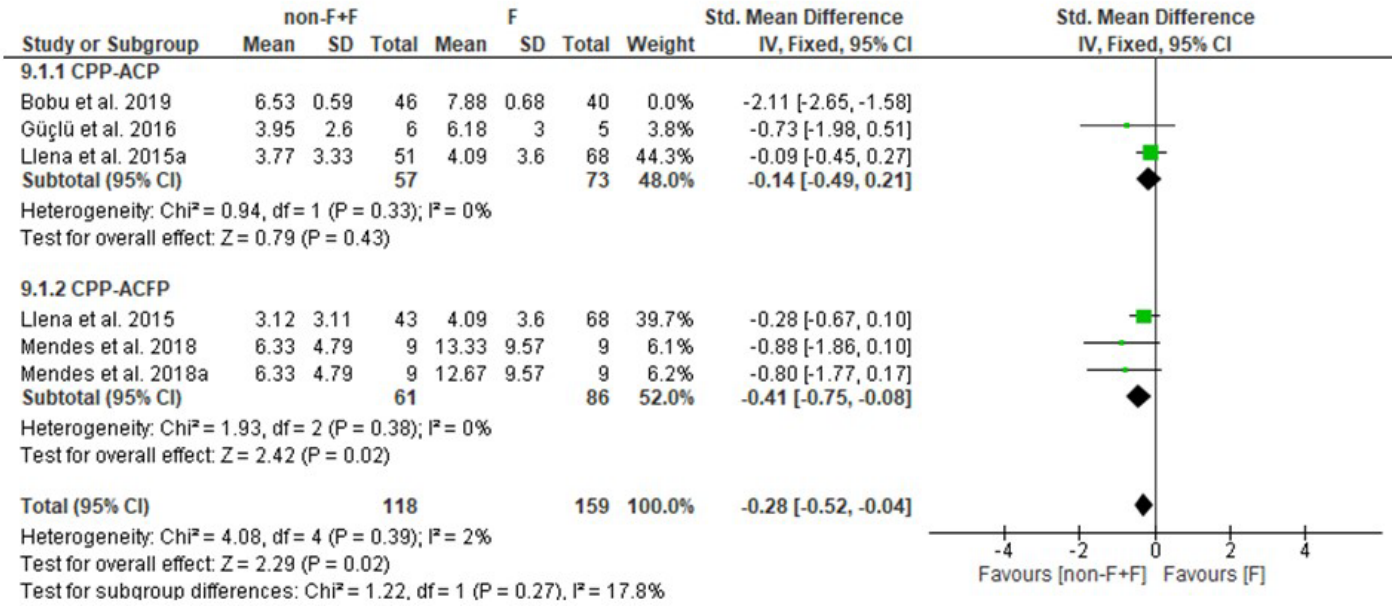

Figure 6. Forest plot presenting subgroup analysis by type of non-fluoride adjunct (CPP-ACP and CPP-ACFP) for caries activity measured using DIAGNOdent at 3-month follow-up

A symmetrical distribution of studies around the pooled effect estimates in the funnel plot indicated no apparent publication bias (Figure 7).

A total of three studies reported changes in caries lesions in 184 teeth based on QLF readings after three months of treatment. The pooled analysis across all studies showed no significant lesion changes when fluoride was used alone or in combination with non-fluoride agents (SMD = 0.22; 95% CI: −0.08 to 0.51; p > 0.05). Heterogeneity was not significant among the pooled studies (I^2 = 36%; p = 0.21) (Figure 8).

Figure 9 depicts that all studies were distributed symmetrically around the pooled SMD, indicating no publication bias.

Secondary Outcome: Reduction in Lesion Area

A total of 89 patients in the experimental group and 95 patients in the control group were compared for mean reduction in lesion area in the three studies included. The pooled analysis showed a significant difference in the outcomes between the two groups favoring combined therapy (SMD = −0.31; 95% CI: −0.60 to −0.02; p < 0.05). There was no heterogeneity among the pooled studies (I^2 = 0%, p = 0.98) (Figure 10).

Figure 11 depicts that all studies were distributed symmetrically around the pooled SMD, indicating no publication bias.

Secondary Outcome: Dental Caries Increment

Overall, the pooled analysis across all studies showed no significant difference in caries increment among patients undergoing fluoride monotherapy and combined therapy after 6 months (SMD = −0.06; 95% CI: −0.23 to 0.11, p > 0.05; I^2 = 10%, p = 0.33), 12 months (SMD = 0.10; 95% CI: −0.23 to 0.04, p > 0.05; I^2 = 23%, p = 0.27), and 24 months (SMD = 0.07; 95% CI: −0.09 to 0.23, p > 0.05; I^2 = 0%, p = 0.74) of treatment (Figure 12).

Figure 13 depicts that all studies were distributed symmetrically around the pooled SMD, indicating no publication bias.

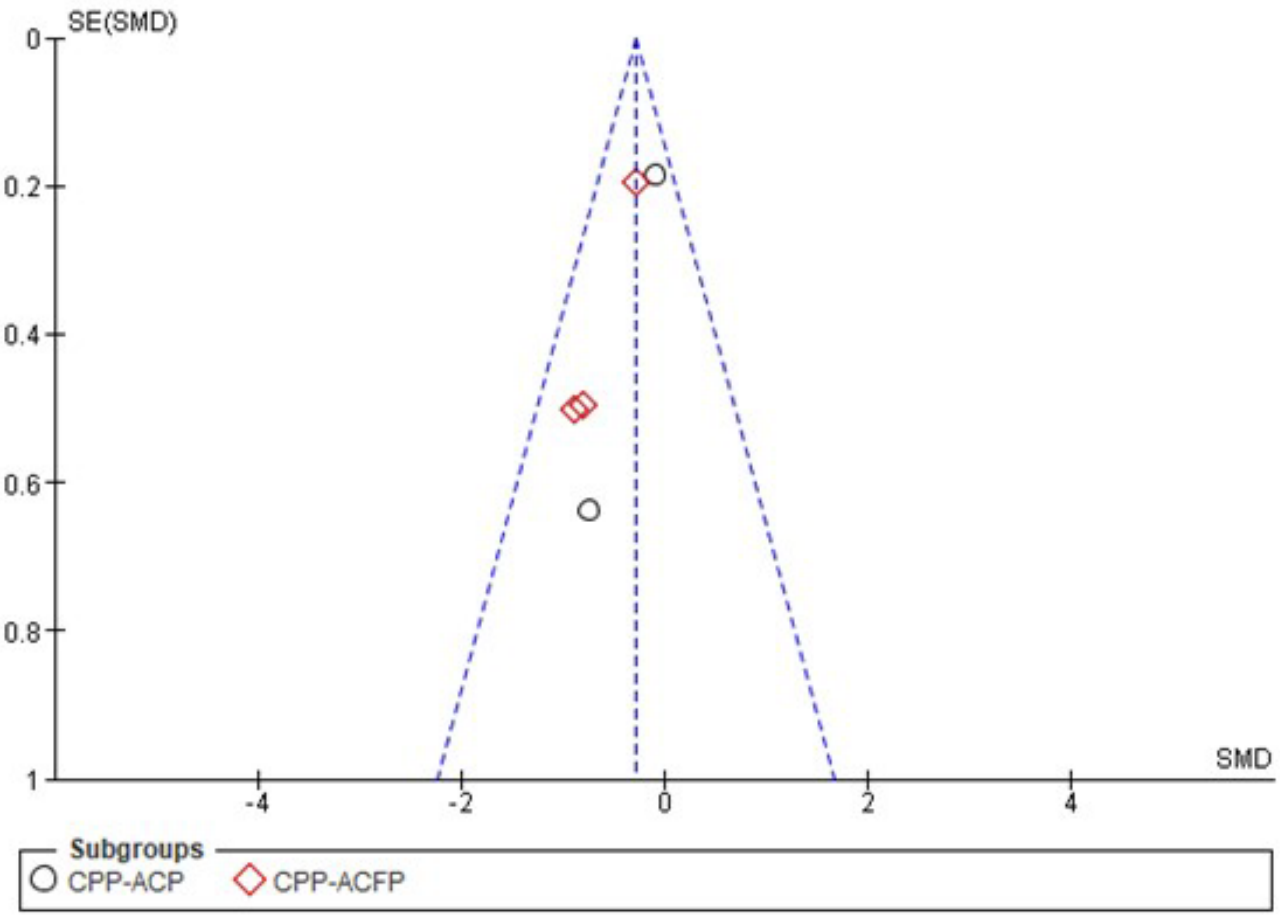

Figure 7. Funnel plot assessing publication bias for subgroup analyses of DIAGNOdent outcomes at 3-month follow-up

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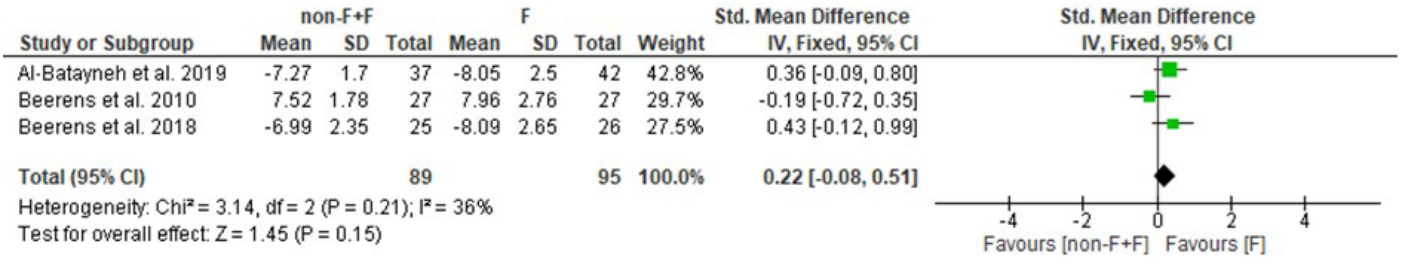

Figure 8. Forest plot comparing changes in lesion characteristics based on quantitative light-induced fluorescence (QLF) values at 3 months post-treatment between fluoride monotherapy and combination therapy

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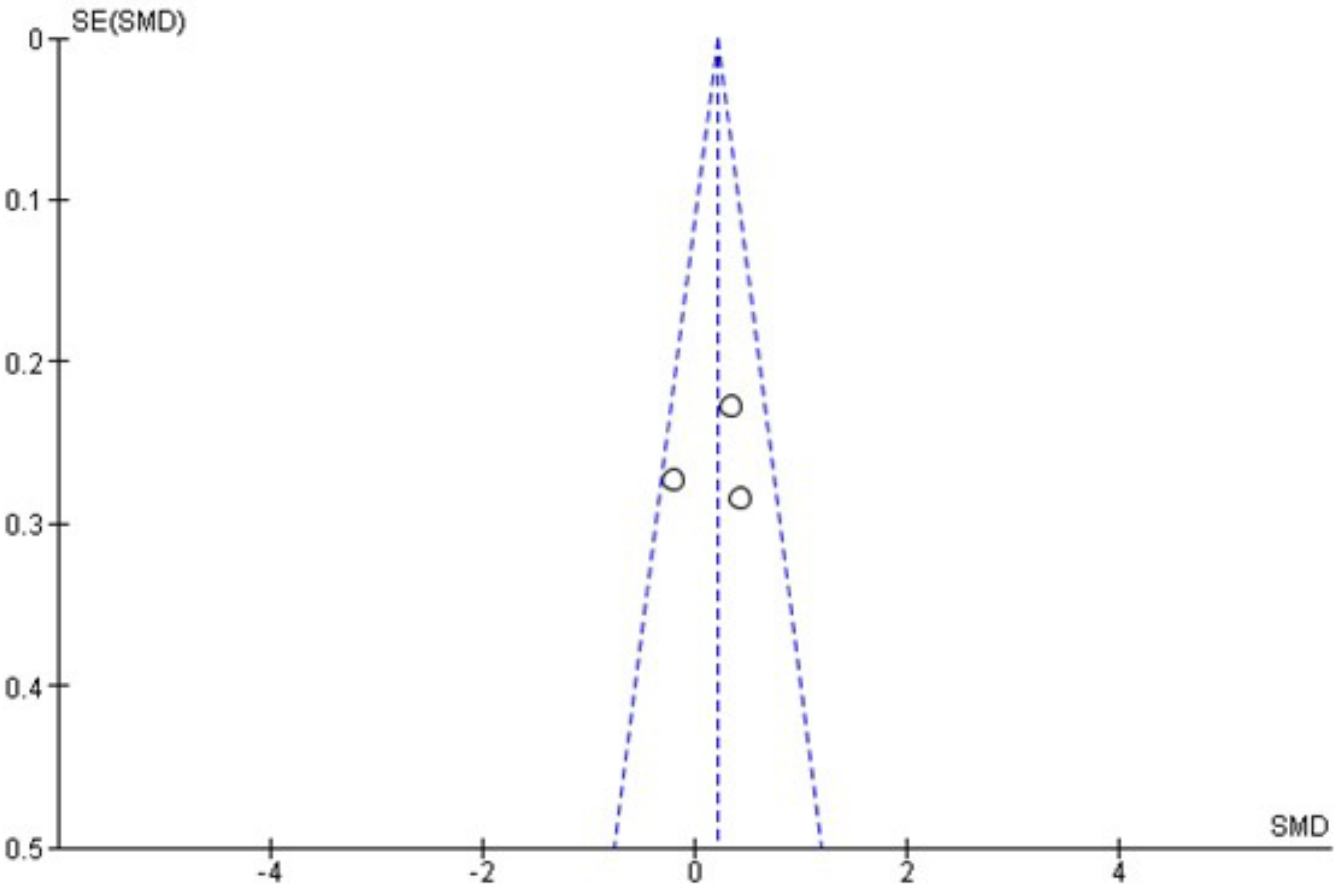

Figure 9. Funnel plot evaluating potential publication bias for QLF-based lesion change outcomes at 3 months

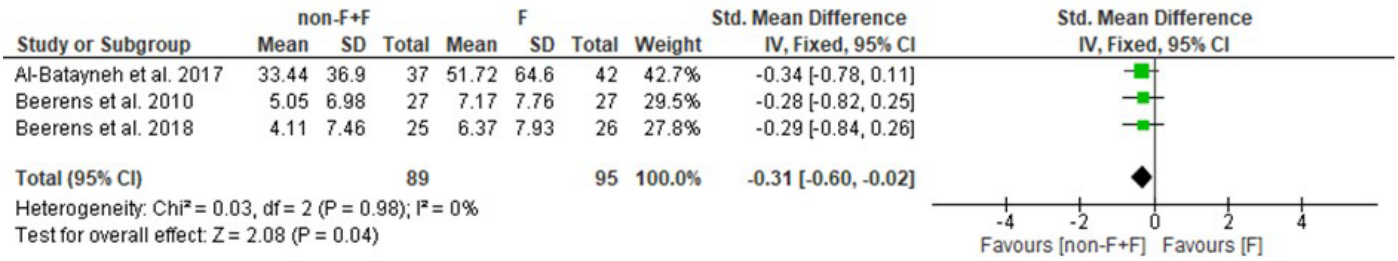

Figure 10. Forest plot demonstrating the effect of combination therapy versus fluoride monotherapy on lesion area reduction at 3 months

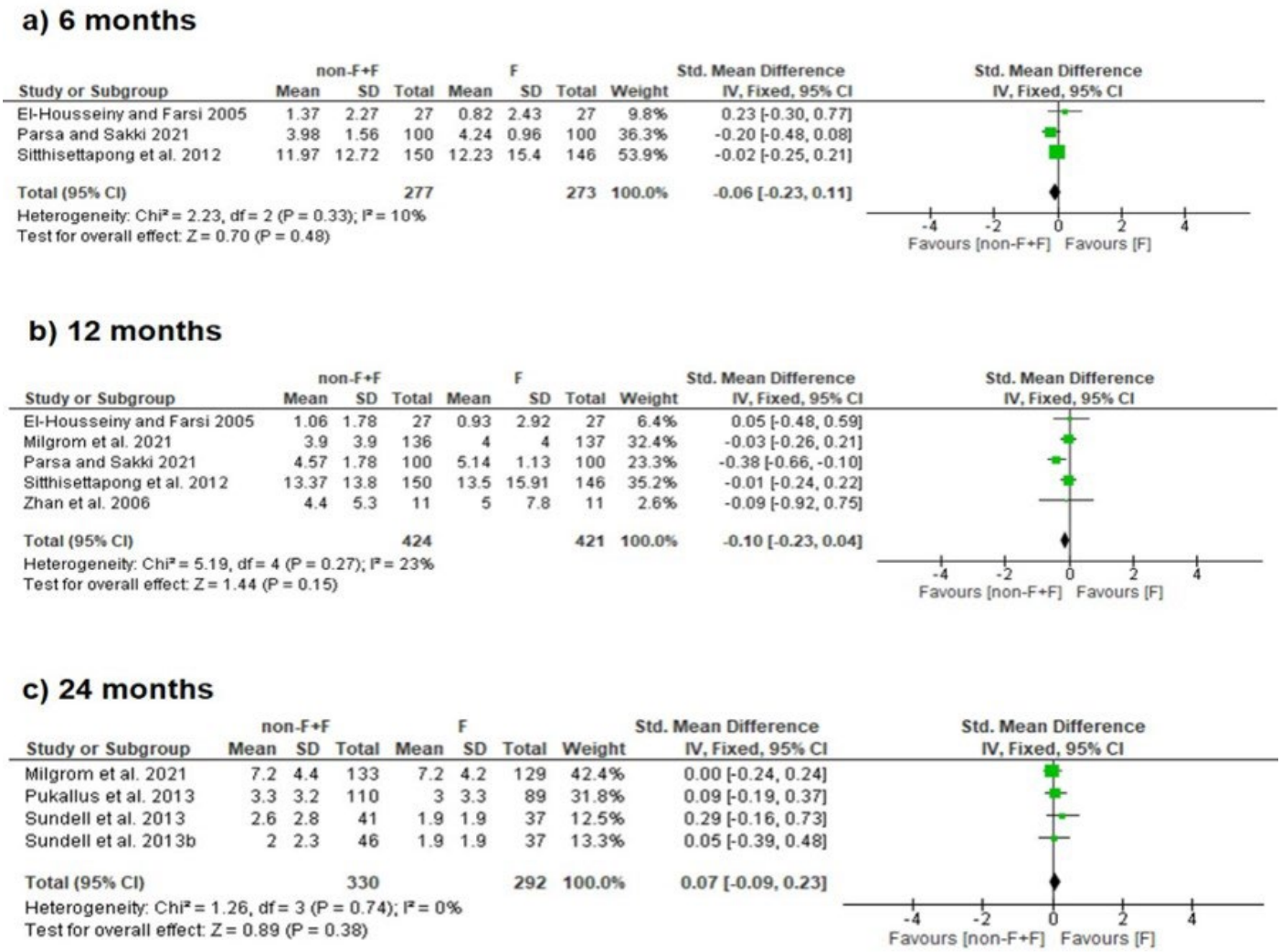

Figure 11. Funnel plot assessing publication bias for lesion area reduction outcomes at 3 months

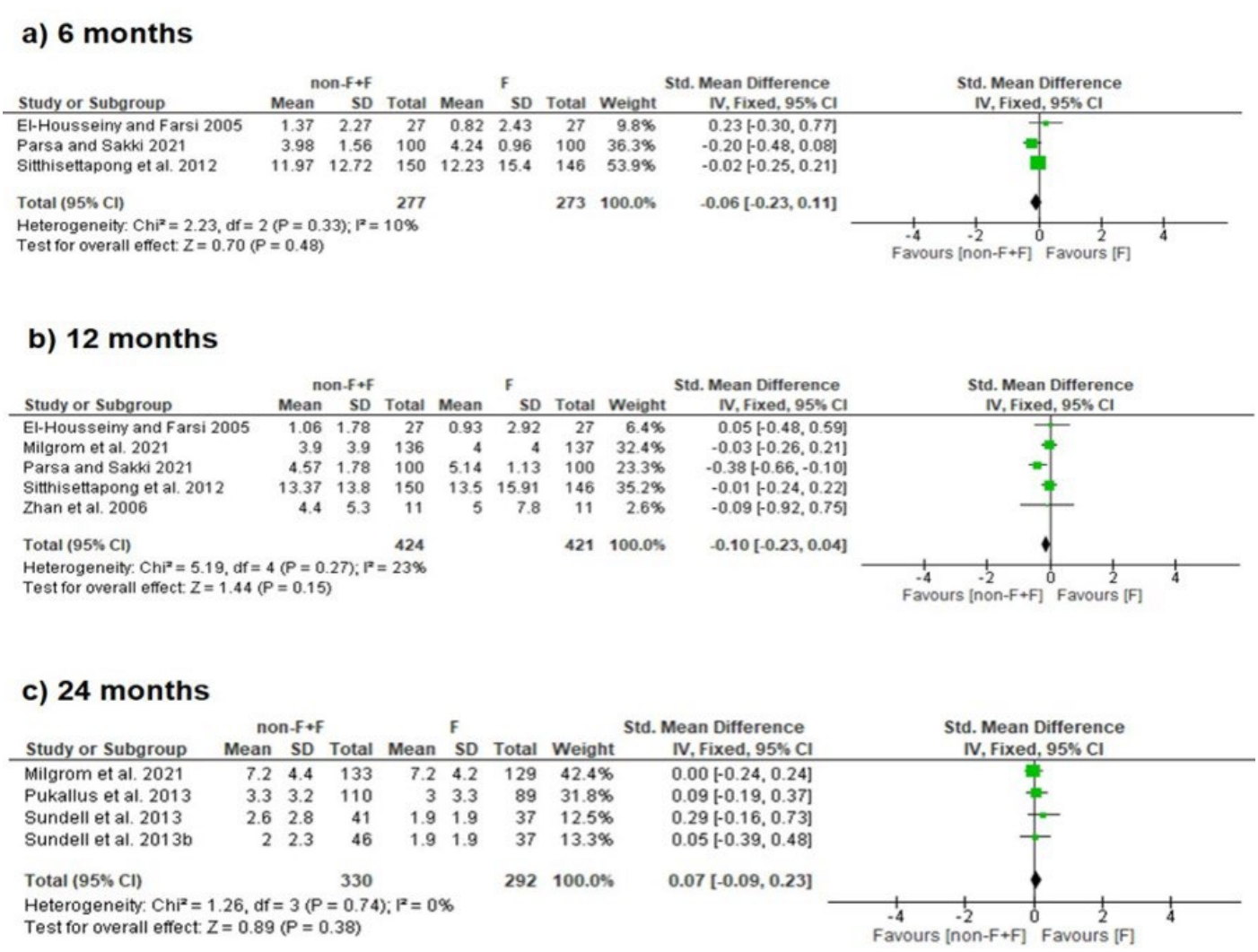

Figure 12. Forest plot comparing dental caries increment between fluoride monotherapy and combination therapy across different long-term follow-up periods (6, 12, and 24 months)

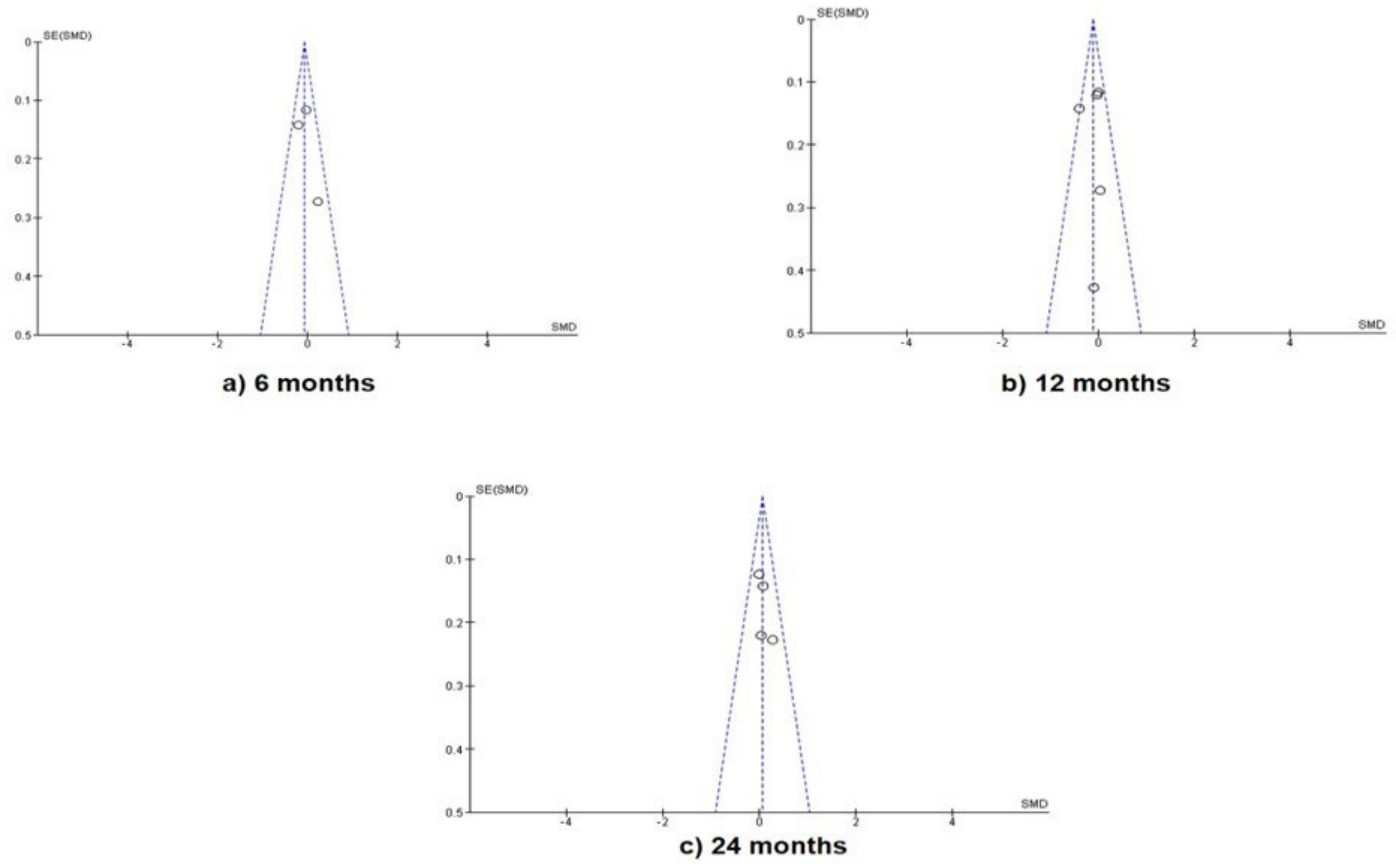

Figure 13. Funnel plots assessing publication bias for long-term caries increment outcomes at different post-treatment timepoints

DISCUSSION

The present systematic review and meta-analysis synthesized available evidence from RCTs to evaluate the effectiveness of fluoride combined with non-fluoride adjunctive agents compared with fluoride monotherapy in the management of dental caries. Outcomes were primarily evaluated through fluorescence-based detection methods, including laser fluorescence (DIAGNOdent) and QLF, both of which are widely accepted as sensitive tools for monitoring changes in the mineralization of enamel. Laser fluorescence techniques, such as DIAGNOdent, have been extensively used to measure the remineralization potential of dental products by detecting changes in fluorescence that correspond to mineral loss or gain. Previous research has shown that decreases in DIAGNOdent values after treatment indicate successful remineralization and lesion arrest, confirming the utility of this method in short-term clinical trials.[51,52] Similarly, QLF provides a non-destructive and reproducible approach for the quantification of lesion area and fluorescence loss,[53] enabling detection of early, subclinical mineral changes in enamel surfaces. Both techniques offer valuable insights into early remineralization dynamics that are difficult to capture with purely clinical measures. However, these methods provide indirect surrogate outcomes and do not directly measure long-term caries prevention or cavitation.

The pooled analysis revealed that combination therapy, particularly with CPP-ACP, was associated with significantly greater short-term improvements in remineralization potential and reductions in lesion area compared to fluoride alone at follow-up periods of less than two months

and three months of treatment. These findings suggest that adjunctive agents may enhance the early biochemical and physicochemical effects of fluoride in controlling caries activity and supporting remineralization in the short-term basis. Fluoride remains the cornerstone of caries prevention and management, with a history of over two centuries of use.[12,13] Its primary mechanism of action involves enhancing the deposition of calcium and phosphate ions during remineralization, resulting in the formation of fluoridated hydroxyapatite crystals that are more resistant to subsequent acid dissolution.[14,16] While bioavailable calcium and phosphate are typically supplied by saliva, their availability may be compromised by individual lifestyle, diet, or salivary function.[54] This limitation provides the rationale for combining fluoride with calcium- and phosphate-containing formulations, to further suppress demineralization and enhance remineralization.[55]

CPP-ACP has emerged as an important biomimetic agent in this context. CPP-ACP stabilizes calcium and phosphate ions in an amorphous, bioavailable state and maintains high concentrations of these ions in close proximity to enamel lesions.[56,57] This mechanism not only facilitates mineral deposition but also buffers fluctuations in the oral environment, reducing the risk of repeated demineralization. When used along with fluoride, the complex is capable of delivering calcium, phosphate, and fluoride ions simultaneously at the lesion site. Studies have shown that this synergistic action may promote the formation of enamel-like mineral phases and enhance lesion repair.[58,59] This is in consistent with the subgroup findings of the present review where CPP-ACP when used along with fluoride, demonstrated significant reductions in caries activity, highlighting the importance of fluoride incorporation along with the complex. Overall, these mechanisms align with the observed short-term remineralization benefits rather than durable caries prevention.

An important observation of this meta-analysis is the differential effect between primary and permanent dentition. The subgroup analysis revealed that combination therapy conferred greater short-term benefits in primary teeth, with effect sizes nearly twice as large as those seen in permanent teeth. This may be attributable to the structural differences between primary and permanent enamel, including thinner enamel, lower mineral content and higher porosity of primary teeth.[60,61] In permanent teeth, although combination therapy demonstrated significant benefits, the effect was smaller, suggesting that enamel maturity and exposure history may reduce the magnitude of benefit.

Despite favorable short-term outcomes, no significant differences were noticed between fluoride monotherapy and combination therapy for long-term caries increment at 6-24 months. This finding suggests that while adjunctive agents may accelerate early remineralization or reduce fluorescence-detected lesion activity, these short-term improvements do not translate into sustained reductions in new caries formation. One possible methodological explanation lies in the nature of the outcome measures. Short-term benefits were primarily detected using fluorescence-based techniques (e.g., DIAGNOdent, QLF), which are sensitive to early mineral changes but represent surrogate markers rather than definitive clinical endpoints, such as cavitation or caries incidence. These methods may capture transient mineral gains that are not maintained over time in real-world conditions. On the other hand, previous research indicated that the combination of povidone iodine and topical fluoride was more effective in preventing new lesions, particularly in permanent teeth among children aged 1-12 years, but the quality of evidence was rated very low.[27] Evidence also suggests that chlorhexidine and povidone iodine can help in caries prevention.

Chlorhexidine, though primarily recognized for its antimicrobial activity, can contribute to remineralization by inhibiting collagen degradation in dentin and facilitating mineral deposition along with collagen fibrils.[62] Similarly, povidone-iodine acts as an antimicrobial agent that reduces cariogenic *Streptococcus mutans* populations and limits acid production, thereby indirectly helping caries prevention.[27,63,64] Although agents such as chlorhexidine and povidone-iodine possess antimicrobial properties and may indirectly support caries control, the present study showed a lack of long-term effectiveness of these agents in caries prevention. This time-dependent discrepancy may reflect the influence of broader behavioral, dietary, and environmental factors on caries progression that cannot be fully mitigated by topical agents alone. From a clinical perspective, caries is a multifactorial disease influenced by behavioral, dietary, and environmental determinants that extend beyond the localized effects of topical agents. Unhealthy dietary habits, such as frequent consumption of sugary food, fast foods, or salty snacks, can directly increase the incidence of caries and indirectly promote cariogenic biofilm formation.[65,66] Longitudinal evidence indicates that improved diet quality reduces caries experience, while frequent snacking, consumption of sour milk products and salty snacks, and eating behaviors like food fussiness increase caries risk in children and adolescents.[67] Addictive behaviors including tobacco and alcohol use further alter oral biofilm ecology, indirectly accelerating caries progression.[65] Environmental influences, including neighborhood disadvantage and exposure to passive smoking, are also associated with higher increments of caries, underscoring the broader social determinants of oral health.[68] Therefore, the lack of sustained long-term benefits of adjunctive agents in the present analysis suggests that modifying the oral microenvironment alone may be insufficient to counteract persistent behavioral and environmental risk factors. Taken together, the study highlights the need to interpret short-term remineralization benefits cautiously and emphasizes the importance of long-term clinical endpoints in future trials.

This study has several limitations that should be acknowledged. First, most included studies evaluated CPP-ACP or CPP-ACFP in combination with fluoride, while evidence for other non-fluoride agents such as chlorhexidine and povidone-iodine was limited, and no studies evaluating the use of herbal products in combination with fluoride were identified. As a result, the findings of this meta-analysis largely reflect the effectiveness of CPP-ACP–based combination therapies, which restricts the generalizability of the results to other adjunctive agents. Second, a considerable level of heterogeneity was observed among the included studies. In addition to variations in the study design, participant age groups, and intervention protocols, there was considerable variability in fluoride concentrations and delivery methods, ranging from low-dose dentifrices to high-concentration professional applications. This variability has important clinical implications, particularly in pediatric populations where fluoride dosage must be carefully balanced against the risk of dental fluorosis and unintended ingestion. Differences in fluoride potency may have influenced treatment effects, making it difficult to attribute observed benefits solely to adjunctive agents. Consequently, the generalizability of the findings to standardized and age-appropriate clinical protocols may be limited. Third, the search strategy did not extend to certain major databases, such as Scopus and Web of Science. As a result, it is possible that some relevant studies were not captured, potentially influencing the comprehensiveness of the review. Finally, many of the included studies relied on fluorescence-based methods, such as laser or quantitative light-induced fluorescence, which provide indirect estimates of

remineralization potential rather than direct clinical confirmation of lesion prevention.

Clinical Implications for Pediatric Dentistry

The findings of this review have particular relevance for pediatric dental practice. Subgroup analysis indicated that combination therapy demonstrated greater short-term remineralization benefits in primary teeth compared to permanent teeth. This may be attributed to the structural characteristics of primary enamel, which is thinner, more porous, and less mineralized, making it more responsive to remineralization interventions but also more susceptible to rapid caries progression. Therefore, early non-invasive management strategies are especially critical in pediatric population.

The enhanced short-term effects observed with CPP-ACP combination suggest potential value in managing non-cavitated lesions and white spot lesions in children. However, the absence of a consistent long-term reduction in caries increment highlights that adjunctive topical therapies should not replace comprehensive preventive strategies. In pediatric patients, caries progression is strongly influenced by dietary habits, feeding practices, oral hygiene behavior, and caregiver supervision. Additionally, variability in fluoride concentration across included studies has important safety implications in children. Since excessive fluoride ingestion during enamel development increases the risk of dental fluorosis, careful consideration of fluoride dosage, frequency of application, and supervision during home use remains essential. The benefits of combination therapy must therefore be balanced with age-appropriate fluoride recommendations.

CONCLUSIONS

The present systematic review and meta-analysis evaluated the effectiveness of non-fluoride adjunctive agents used in combination with fluoride compared with fluoride monotherapy for the prevention and management of dental caries. A total of 21 studies from different countries, involving children, adolescents, and adults across primary and permanent dentitions, were included. The review primarily evaluated short-term remineralization outcomes using fluorescence-based methods and long-term caries increment as a clinical endpoint. The pooled results indicated that the combination therapy, particularly fluoride used with CPP-ACP, demonstrated enhanced short-term remineralization and greater reduction in early lesion activity compared with fluoride alone. These benefits were primarily observed in fluorescence-based outcomes within short follow-up periods, supporting the potential role of combination therapy in the management of early caries lesions. However, current evidence did not demonstrate a consistent long-term advantage of combination therapy over fluoride monotherapy in reducing caries increment at extended follow-up periods (6-24 months). Therefore, while adjunctive agents may offer additional benefits in early lesion management, especially in high-risk groups such as children and young adults, their sustained effectiveness in long-term caries prevention is not currently supported by robust clinical evidence. Given that most included studies relied on surrogate fluorescence-based outcomes and that CPP-ACP–based formulations constituted the majority of interventions evaluated, the generalizability of these findings to other adjunctive agents and long-term clinical outcomes remains limited. Future studies should focus on standardized protocols, larger sample sizes, and longer follow-up durations to confirm the long-term clinical effectiveness of non-fluoride-based adjuncts. Direct clinical endpoints, such as cavitation or lesion arrest, should be prioritized over fluorescence-based measures to better guide clinical practice and public health policy.

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Clinical effectiveness of pediatric rotary instrumentation systems in pulpectomy of primary teeth: A systematic review

Faten Balloumi ✉

Highlights

- Pediatric rotary instrumentation may reduce chairside time and improve clinical efficiency during pulpectomy of primary teeth.
- Rotary systems generally demonstrated favorable outcomes regarding postoperative pain, instrumentation time, and obturation quality.
- Further well-designed multicenter studies are needed to establish evidence-based recommendations for pediatric rotary instrumentation.

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Abstract

The aim of this systematic review was to compare the efficiency of pediatric rotary systems used in the pulpectomy of primary teeth. The research protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO). An electronic search was conducted across four databases: PubMed via MEDLINE, the Cochrane Central Register of Controlled Trials, ScienceDirect, and the Wiley Online Library using search equations formulated through combinations of keywords and Boolean operators. Reference management was performed using Zotero. Of the 128 records initially identified, 30 studies met the inclusion criteria. An additional 21 studies were included through manual searching of the reference lists of the selected articles. Consequently, a total of 51 studies were included in the present systematic review. The quality assessment was performed using the RoB 2 tool, and the overall risk of bias was judged to be low. The latest generations of the Kedo-S pediatric rotary systems, namely Kedo-S Plus, Kedo-S Square, and Kedo-SG Blue, were the most frequently investigated systems and generally demonstrated favorable outcomes, including reduced postoperative pain and bacterial load, shorter chairside time, improved obturation quality, and higher clinical success rates. WaveOne Gold and XP-Endo Shaper systems also showed promising efficiency; however, evidence regarding their performance remains limited. Comparisons of rotary techniques suggested that reciprocating motion may be associated with reduced chairside time and enhanced obturation quality. Nevertheless, heterogeneity among studies, inconsistent evaluation methods, and the predominance of studies conducted in India may limit the generalizability of the findings. In addition, important in vitro pulpectomy parameters, such as canal trajectory preservation and debris extrusion, were not assessed. Therefore, further well-designed multicenter clinical and in vitro studies comparing multiple pediatric rotary systems are required to establish definitive clinical recommendations.

Keywords: Dental Pulp Cavity; Endodontics; Obturation; Pain, Postoperative; Pulpectomy; Root Canal Preparation; Tooth, Deciduous

INTRODUCTION

Premature loss of primary teeth is the most critical issue in pediatric dentistry practice since it results in various troubles damaging both aesthetics and oral functions of the child.[1] Pulpectomy is a pulp therapy aiming to retain primary teeth with irreversibly pulp involvement until their physiological exfoliation. Compared to extraction, pulpectomy offers multiple advantages since it preserves arch space and its integrity, saves speech and chewing abilities, garantees a normal eruption of succedaneas permanent teeth and maintains the aesthetic appearance of the child ensuring his normal psychological development. In the other hand, it prevents crowding and tongue deformating habits. Also, this therapetic procedure eliminates the inflammation or the infection of the affected pulp and prevents its further spread which retains the primary teeth in a healthy condition.[2- 3]

The success of such a procedure ultimately depends on the quality of the chemo mechanical preparation of the canals.[4] In fact, root canal instrumentation aims to the clean and shape the canal system by removing the infected content of the pulp chamber without damaging the integrity of the root canal. Furthermore, this mechanical preparation must facilitate the propagation of the irrigation solution until the apical third of the root ensuring a total desinfection of the root canal system and guide its tridimentionnal filling by creating a continuous tapered preparation.[3] In fact, two factors shoud be considerd so as to garantee a perfect root canal preparation : the instrument used and the technique employed. Considering the technique, multiple ones was suggested including the coronoapical and the apicocoronal techniques.[3] Regarding the instrument used, Stainless steel instruments have been conventionally used. Hand instrumentation is associated with multiple prejudices such as uneven preparation, iatrogenic lateral perforation, ledge formation, zipping, canal transportation, instrument fracture and apical blockage.[5-6- 7] In addition, being a time-consuming procedure, it lengthens the dental appointement and may affect his behavior.[4-1] Thus, since the duration of dental appointment has a huge impact on the child's behavior, rotary instrumentation made a substantial rise in the releam of pediatric dentistry.

Rotary file systems were invented in order to overcome the disadvantages of the conventional approach. Ni-Ti rotary files were first described in primary teeth by Barr et al. in 2000 and ever since, the use of use of rotary instrumentation has been developed in pediatric endodontics.[4] Barr et al. admited that the use of rotary instrumentation in deciduous teeth pulpectomy reduces the overall time needed for root canal preparation and obturation, facilitates the root canal access, and garantees more predictable and consistently dense fills.[8] Also, in comparison to manual files, rotary file sytems garantee the preservation of the anatomical form of primary teeth, prevent procedural errors such as instrument fracture and allow an easier dental practice with less practionner fatigue.[3-7] These benefits of rotary instrumentation go back to the greater flexibility and shape memory of Ni-Ti of which rotary file systems are made.[9]

Various rotary systems have been invented over the years. At the beggining, NiTi files used for root canal treatment of permanent teeth were integrated with a modified sequence to be used in deciduous teeth ; This includes Protaper, M2, and K3.In one hand, ProTaper Next was introduced in 2000 and made of MWire NiTi and had a distinctive design allowing to enhance the flexibility and cyclic fatigue resistance.[7] In the other hand, Mtwo rotary system consists in 4 instruments with inactive tips and is characterized with a more shaping ability, more cleaning efficiency in curved root canals, and highest cyclic fatigue resistance in apical abrupt curvatures, when compared with other rotary systems.[10-11] Moreover, K3 NiTi rotary file system was designed by Dr. John McSpadden in 2002 and it consists in 5 files with different sizes,

used from the largest to the smallest.[12] However, the increasing length and taper of these files limited their use in pedodontics and launched the need of a unique rotary file with an adjusted length and taper.[13] From here, the Kedo rotary file was first introduced in 2017 by Jeevanandan G who recommended this exclusive rotary file system as an effective time gaining method to debride uneven walls of primary root canals and to guarantee a predictable and uniform root canal fill.[6] These individualised files are characterized with a variably variable taper (VV) ensuring both flexibility and efficiency. Kedo-S, Kedo-SG and Kedo-SH was launched as a result of the continious progression of the Kedo pediatric rotary file. Kedo-SG blue rotary file consists of D1, E1, and U1 files, while Kedo-SH hand file consists of P1, P2, and P3 stainless steel files and D1, E1, and U1 nickel–titanium files.[3] Whilst, a single file system called Kedo-S Square was the latest version of it. Kedo-S Square is composed of two files : A1 is used in the anterior canals, whereas P1 is used for posterior canals.[4] The above mentioned systems are used with a continuous motion. In contrast, other rotary file systems were manifactured to be used with a reciprocating motion : The NiTi reciprocating systems including WaveOne and Reciproc, which have been adopted by Dr. Yared.[14] WaveOne is a one file reciprocating system that has been introduced by Dentsply Maillefer in 2011.[14] In fact, it consists of a single file of three sizes : small (for fine canals), primary (for the majority of canals), and large (for large canals).[15] From the other side, Reciproc is a single-file NiTi system consisting of three files, including the R25, R40, and R50.[14]

This systematic review aimed to compare the clinical effectiveness of the different commercially available rotary file systems and to deduce the one or ones that ensure(s) the highest effeciency. This comparison included all the clinical parameters of the pulpectomy procedure and made the manual approach as a reference.

METHODS

This systematic review followed the PRISMA guidelines. The research question was formulated based on the PICO system (Population : children ; Intervention : pulpectomy of primary teeth ; Comparison : success of the pulpectomy ; Outcome : the most effective rotary system) and it was the following : Which rotary system(s) should we choose when performing pulpectomy of primary teeth in children ?

The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) under the following record : CRD42024621231 and the electronic research was carried out through four databases (Pubmed, Cochrane library, ScienceDirect, and Wiley Online library) using different equations which were formulated by the combination of keywords (rotary system, primary teeth, instrumentation, root canal preparation, postoperative pain, root canal treatment, pulpectomy, obturation) and the boolean operatores (AND, OR, NOT).

The electronic search was conducted between November and December 2024 and led to the obtaining of 328 references and the management of references was performed using Zotero. After duplicata removal 268 references remained. The title screening of the remaining references against the eligibility criteria resulted in the remain of 103 references which were screened by their abstracts. Thirty articles made it up until to last step. The examination of the references lists of the included articles of step 2 resulted in the addition of 42 articles. Thus, 72 references were subjected to the full-text reading and 21 of them were excluded. A complementary search through Google Scholar was conducted and added no relevent reference. Accordingly, this systematic review was made of 51 articles (Figure 1). Owing to clinical and statistical heterogeneity of the included studies, meta-analysis wasn't feasible.

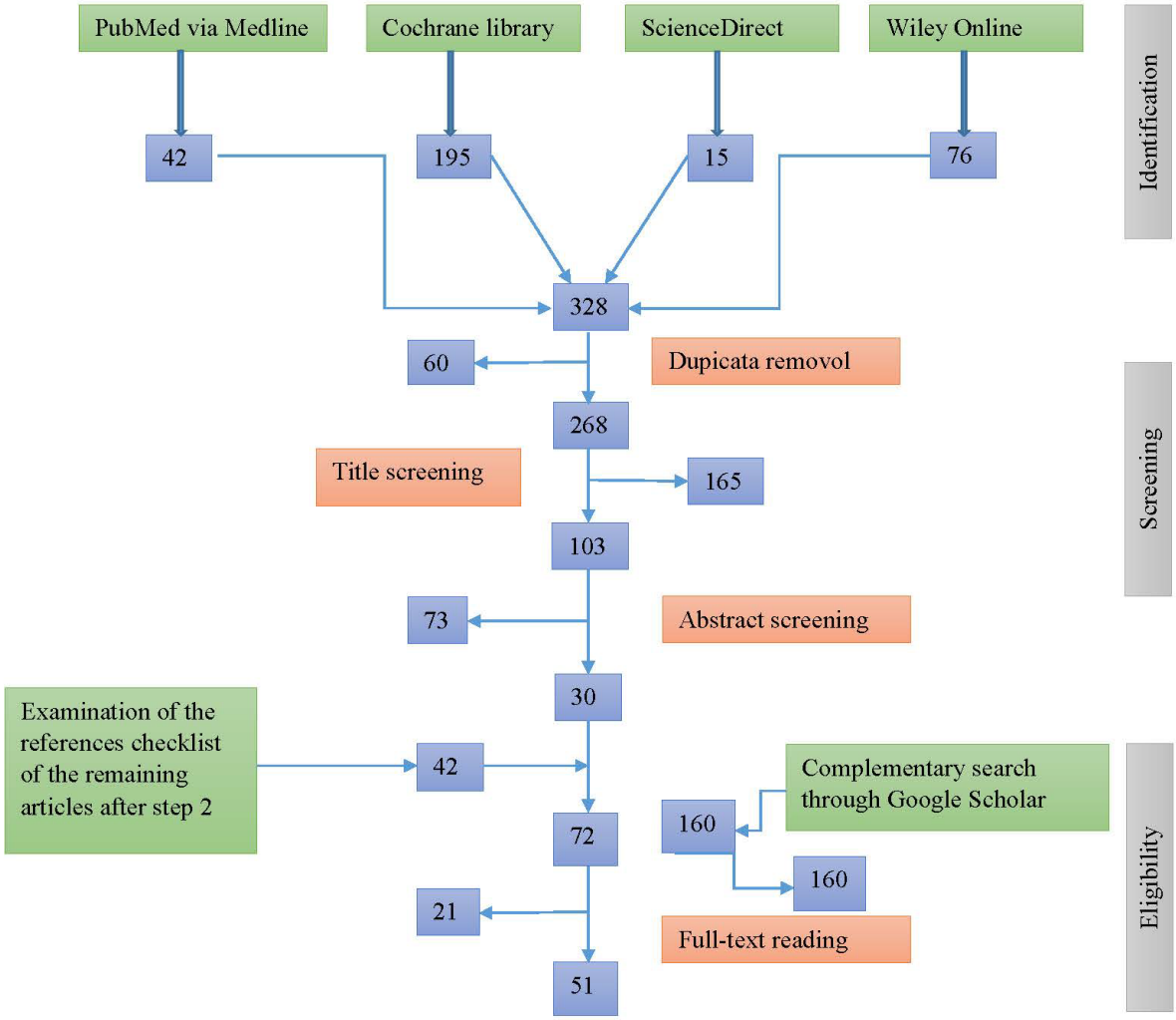

Figure 1. Search strategy chart flow

The eligibility criteria applied for this systematic review are the following :

Inclusion Criteria

- Rondomized controlled trials (RCT) and clinical studies ;

- Articles published between 2014 and 2024 ;

- Articles written in English ;

- Studies performed on Human children ;

- studies performed on primary teeth ;

- Studies focusing on the efficiency of rotary systems in root canal treatment of primary teeth.

Non-Inclusion Criteria

-Systematic reviews and meta analysis, cohort studies, in vitro studies, case reports, posters and communications sessions, books and book chapiters, abstracts ;

-Studies performed on Human adults or animals ;

-Studies performed on permanent teeth ;

-Articles written in language other than English ;

-Articles published before 2014 ;

-Studies not assessing the efficiency of rotary systems in root canal treatment of primary teeth.

Cohort studies weren't included in this systematic review since the comparative evaluation of rotary pediatric systems focused on clinical parameters that essentially require immediate assessment.

RESULTS

Fifty one articles were included in the present systematic review. Based on the country where the study was performed, 36 studies were carried out in India, 4 in Egypt, 4 in Brazil, 2 in Iran, 1 in Mexico, 1 in Saudi Arabia, 1 in Syria, 1 in Turkey, and 1 in Thailand.

Regarding the year of publication, 3 studies were published in 2014, 1 in 2015, 4 in 2017, 4 in 2018, 5 in 2019, 9 in 2020, 9 in 2021, 5 in 2022, 9 in 2023 and 2 in 2024. Thus 67% of the included studies were published in the past 5 years.

Considering the type of study performed, 8 out of 51 were clinical studies while 43 were rondomised controlled trials. The following primary teeth pulpectomy related factors were evaluated by the included studies : post-operative pain, mean microbial load, instrumentation and obturation times, complications during instrumentation, quality of obturation, success rate, patient's behavior, and operator's percpective.

Each included study assessed one or more of the up mentioned criteria and compared either between the manual and rotary instrumentation or between rotary file systems. The present systematic review assessed each factor apart and aimed to nominate the rotary system which demonstrates the highest efficiency considering the different evaluated criteria.

Postoperative Pain (P.O.P)

Seventeen studies assessed this factor (Table 1).

Cleaning Efficacy (C.E)

Four studies out 51 focused on this factor (Table 2).

Instrumentation Time (I.T)

Thirty five studies focused on this criteria and evocated a number of rotary file sytems (Table 3).

Obturation Time (O.T)

Only 10 studies were interested in this criteria (Table 4).

Obturation Quality (O.Q)

This factor was also assessed by 35 studies (Table 5).

Complications during Instrumentation (C.I)

Only one study evaluated this parameter (Table 6).

Success Rate (S.R)

This parameter was assessed by 8 studies out of 51 (Table 7).

Child's Behavior (C.B)

Three studies highlighted this clinical factor (Table 8).

Operator's perspective (O.P)

Only one study focused on this criteria (Table 9).

Tables 10–12 show comparative summaries of manual, rotary, continuous, and reciprocating instrumentation systems according to different evaluated clinical and procedural parameters.

Risk of BiasAssessment

Cochrane risk-of-bias tool for randomized trials (RoB 2) was used for the quality assessment of the included studies (Table 13).

Table 1. Postoperative pain assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Alnassar I et al.	-Hand files ; -ProTaper Next rotary system ; -WaveOne rotary system.	- Hand instrumentation demonstrated a significantly higher postoperative pain compared to rotary instrumentation at 6, 12 and 24 H postoperatively ; - No postoperative pain difference between ProTaper Next and WaveOne rotary systems	-Difference between manual and rotary instrumentation : Significant ; -Difference between the two rotary systems : Not significant.	ProTaper Next rotary system & WaveOne rotary system
EL-Desouky SS et al.	-Hand files ; - Kedo-S Square rotary system ; - Fanta AF Baby rotary system.	- The use of hand files was associated with a significantly higher postoperative pain as compared to kedo-S Square rotary system and Fanta AF Baby rotary system.	- Difference between manual and rotary instrumentation : Significant.	Kedo-S Square rotary system & Fanta AF Baby rotary system
Govindaraju L et al. (2018)	-Hand K-files ; - Kedo-S rotary system ; - ProTaper rotary file system.	-The use of Kedo-S rotary file the pain perception was statistically lower when compared to ProTaper rotary file system and hand K-files.	-Difference between manual and rotary instrumentation : Significant ; -Difference between the two rotary systems : Significant.	Kedo-S rotary system
Moudgalya MS et al.	-Hand files ; -Kedo-S files ; -K-Flex rotary files.	-Kedo-S files and K-Flex rotary files showed a significantly less postoperative pain compard to hand files while the difference between Kedo-S system and K-Flex system in reducing post-operative pain wasn't significant.	-Difference between manual and rotary instrumentation : Significant ; -Difference between the two rotary systems : Not significant.	Kedo-S system & K-Flex system
Topçuoğlu G et al.	-Hand K files ; - Revo-S rotary file system.	-Pulpectomy with hand K files resulted in significantly higher pain intensity when compared to pulpectomy done by Revo-S rotary file system, at 6,12, 24 and 48 H postoperatively. This difference wasn't significant at 72 H and one week post-treatment.	- Difference between manual and rotary instrumentation : Significant.	Revo-S rotary file system

Table 1. Postoperative pain assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Panchal V et al (2019)	-Hand K files ; -Hand H files ; - Kedo-S rotary system.	- Instrumentation with Kedo-S rotary system was associated with significantly less post-operative pain at 6 and 12 h post-operatively, in comparison to hand K and H files ; -At 6 h, instrumentation with K- file showed significantly less post-operative pain as compared to H-file which was not significant at 12 H ; -At 24, 48 and 72 h interval there was no significant difference in the post-operative pain between Kedo-S rotary system, hand K-files and hand H-file	- Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary system
Nair M et al.	- Hand k-files ; -Kedo S rotary files ; - Mtwo rotary files.	-Rotary instrumentation using Kedo S files and Mtwo files caused, at 6 H postoperatively, significantly less post-operative pain when compared to hand k-files instrumentation. This difference wasn't significant at 12, 24 and 72H postoperatively. Precisely, The least post-operative pain was recorded with Mtwo files followed by Kedo-S files followed by hand k files	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Mtwo rotary files ++ Kedo S rotary files +
Jeevanandan G et al. (2020)	- Manual NiTi-K flex files - Kedo-S rotary system ; - Reciprocating NiTi-K flex files	-At 6 and 12 h post-operatively, Kedo-S rotary system showed significantly the least post-operative pain followed by manual NiTi-K flex files followed by reciprocating NiTi-K flex files which demonstrated significantly the highest post-operative pain.	- Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary system
Jeevanandan G et al. (2021)	-Hand K-files ; - Kedo-SH hand files -Kedo-SG Blue rotary system.	- Kedo-SG Blue rotary system showed a significantly less post-operative pain followed by hand K-files and Kedo-SH hand files.	- Difference between manual and rotary instrumentation : Significant.	Kedo-SG Blue rotary system

Table 1. Postoperative pain assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Tyagi R et al.	- Hand NiTi-K flex files ; - Pro AF Baby Gold rotary system ; - WaveOne reciprocating system.	-At 6H, hand NiTi-K flex files showed significantly the highest mean post-operative pain followed by Pro AF Baby Gold rotary system followed by WaveOne reciprocating system which demonstrated the least post-operative pain. This difference wasn't significant at 24, 72 H and one week postoperatively. -The difference between Pro AF Baby Gold and WaveOne reciprocating rotary system wasn't significant at 6, 24, 72 H and one week postoperatively	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	WaveOne reciprocating system
Lakshmanan L et al.	-Hand K-files ; -Kedo-S rotary system ; - Kedo-S Square rotary system.	-At 6 H postoperatively, hand K-files showed significantly the highest post-operative pain followed by Kedo-S rotary system, followed by Kedo-S Square rotary system which showed the least intensity of postoperative pain. However, this difference wasn't significant at 12 and 24 H post treatment.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Kedo-S rotary system+ Kedo-S Square rotary system++
Divya S et al.	-Hand K-files ; -Kedo-S rotary system ; -K3 rotary file systems	-No significant difference between hand K-files, Kedo-S and K3 rotary file systems at 6, 12, 24 and 48 H postoperatively -No pain was percepted at 72 H regardless the instrumentation technique.	- Difference between manual and rotary instrumentation : Not significant ; - Difference between the two rotary systems : Not significant.	_
Marques RPS et al.	-Hand K files ; - WaveOne Gold reciprocating system.	-No differences in relation to discomfort and late postoperative pain between the manual instrumentation (hand k files) and the reciprocating rotary instrumentation (WaveOne Gold reciprocating system).	- Difference between manual and rotary instrumentation : Not significant.	_

Table 1. Postoperative pain assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Elheeny AAH et al. (2023)	- Hyflex EDM : continuous rotation motion ; - Reciproc R25 : reciprocating rotation motion.	-No statistically significant difference regarding both, postoperative pain incidence and intensity and postoperative analgesics intake between the continuous (Hyflex EDM) and reciprocating (Reciproc R25) rotation motions	- Difference between the two rotary systems (continuous vs reciprocating roation motion) : Not significant.	_
Elheeny AAH et al. (2022)	- OneShape rotary system ; - WaveOne Gold reciprocating system.	- No significant difference in the pain experience between OneShape rotary system and WaveOne Gold reciprocating system.	- Difference between the two rotary systems (continuous vs reciprocating roation motion) : Not significant.	_
Thakur B et al.	- Manual k-files ; XP-endo Shaper rotary system ; - Kedo-SG Blue rotary system.	- XP-endo Shaper rotary system was associated with significantly less postoperative pain compared to rotary pediatric Kedo-SG Blue and manual k-files at 6 and 12 H. Also, XP-endo Shaper rotary system showed no pain after 6 H post-operative and and was associated with the least percentage of patients who needed analgesics.	-Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	XP-endo Shaper rotary system
Barasuol JC et al.	- Hand K-files ; - ProDesign Logic rotary file system.	- No association was found between the type of instrumentation and post-operative pain, or analgesic medication intake after the endodontic treatment.	Difference between manual and rotary instrumentation : Not significant.	_

Table 2. Cleaning efficacy assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Jeevanandan G et al.	- Hand K files ; - Kedo S Plus ; - Kedo S Square NiTi rotary files.	-Significant reduction of the microbial amount with the use of Kedo S Plus, Kedo S Square NiTi rotary files and hand K files. Though, Kedo S plus rotary system had the best potentiel of bacterial reduction.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	Kedo S plus
Subramanyam D et al.	- Kedo S rotary files ; - Hand K files	- Greater reduction of bacterial load with Kedo S rotary files in comparison to hand K files. However, the difference wasn't statistically significant.	Difference between manual and rotary instrumentation : Not significant.	Kedo S rotary files
Lakshmanan L et al. (2022)	- Hand H files ; -Hand K files ; -Kedo-S Square rotary files.	-Although the difference wasn't statistically significant, the Kedo-S Square rotary files demonstrated a better reduction of the bacterial count when compared to hand H files and hand K files.	Difference between manual and rotary instrumentation : Not significant.	Kedo-S Square rotary files
Moudgalya MS et al.	- Hand files ; - Rotary K-Flex files ; - Kedo-S files.	- Kedo-S files and rotary K-Flex files showed a significantly better efficiency in reducing bacterial load compared to hand files. Moreover, the authors found Kedo-S rotary file system was significanlty more efficient compared to K-Flex rotary system.	-Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S rotary file system

Table 3. Instrumentation time assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Morankar R et al.	- Hand K files ; - Hyflex CM NiTi rotary files.	-Pulpectomy with hand K files resulted in a significantly higher instrumentation time than Hyflex CM NiTi rotary files.	Difference between manual and rotary instrumentation : Significant.	Hyflex CM NiTi rotary system
Amorim AC et al.	- Hand K files ; - Hyflex EDM rotary files.	- Significantly longer instrumentation time with the manual instrumenration using hand K files compared to the rotary one using Hyflex EDM rotary files.	Difference between manual and rotary instrumentation : Significant.	Hyflex EDM rotary system
Kaushik M et al.	- Manual H files ; - Hyflex CM rotary system ; - Flexicon X7 rotary system.	- Instrumentation time of primary molars with Flexicon X7 rotary system was significantly less as compared to the Hyflex CM rotary system and manual H files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Flexicon X7 rotary system
Dinesh Kumar et al.	- Hand k files ; - Kedo-S Square rotary files.	- Significantly less instrumentation time with the pediatric rotary Kedo-S Square files compared to the hand k files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S Square rotary system
EL-Desouky SS et al.	- Manual k files - Fanta AF Baby rotary system ; - Kedo S-Square rotary system	- Kedo S-Square rotary system demonstrated a significantly lower instrumentation time followed by Fanta AF Baby rotary system and manual k files.	-Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo S-Square rotary system
Durairaj BA et al.	- Manual k files ; - Kedo-S Square rotary files.	- Significantly less instrumentation time with Kedo-S Square files as compared to manual k files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S Square rotary system

Table 3. Instrumentation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Jeevanandan G et al.	- Hand k files ; - Hand H files ; - Kedo-S Square rotary system.	- Kedo-S Square rotary system was associated with significantly the least instrumentation time followed by hand k files followed by hand H files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S Square rotary system
Govindaraju L et al. (2018)	- Hand K-files ; - Protaper rotary file system ; - Kedo-S rotary file system.	- Instrumentation time was significantly lower with the use of Kedo-S rotary file system compared to the Protaper rotary file system and the hand K-files.	-Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S rotary file system
Kumar A et al.	- Hand K files ; - ProTaper rotary file system.	- The mean instrumentation time was significantly less with the rotary instrumentation using ProTaper rotary file system compared to the manual instrumentation with hand K files.	Difference between manual and rotary instrumentation : Significant.	ProTaper rotary file system
Krishna DR et al.	- Hand H-files ; - Mtwo rotary files.	- The mean instrumentation time was significantly less with Mtwo files when compared with H-files.	Difference between manual and rotary instrumentation : Significant.	Mtwo rotary system
Mokhtari N et al.	- Hand K files - Mtwo rotary system.	- Mtwo rotary system showed a significantly less instrumentation time compared to the manual instrumentation using hand K files.	Difference between manual and rotary instrumentation : Significant.	Mtwo rotary system
Govindaraju L et al. (2017)	- Hand K files ; - Mtwo rotary system ; - ProTaper rotary system.	- The rotary instrumentation through the use of Mtwo and ProTaper rotary systems, resulted in a significantly lower instrumentation time compared to the manual instrumentation with hand K files. -There was no significant difference between Mtwo and Protaper rotary systems.	-Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Mtwo rotary system & ProTaper rotary system.

Table 3. Instrumentation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Govindaraju L et al. (2017)	- Hand K files - K3 rotary system ; - Protaper rotary system.	-Protaper rotary system showed a significantly less instrumentation time followed by K3 rotary system followed by hand K files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Protaper rotary system
Babaji P et al.	-Manual K files ; -K3 rotary files.	-The K3 rotary files showed a significantly less instrumentation time compared to the manual K files.	Difference between manual and rotary instrumentation : Significant.	K3 rotary system
Vieyra JP et al.	- Hand K files ; - ProTaper rotary files ; -Light Speed LSX rotary system	-Light Speed LSX rotary system showed a significanlty less instrumentation time followed by ProTaper files followed by the hand K files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Light Speed LSX rotary system
Barasuol JC et al.	- Hand K-files ; - ProDesign Logic rotary file system.	-ProDesign Logic rotary file system showed a significantly less instrumentation time compared to hand K-files.	Difference between manual and rotary instrumentation : Significant.	ProDesign Logic rotary file system
Marques RPS et al.	- Manual K-files ; - WaveOne Gold reciprocating system.	-WaveOne Gold reciprocating system showed a significantly less instrumentation time than the manual K-files.	Difference between manual and rotary instrumentation : Significant.	WaveOne Gold reciprocating system
Boonchoo K et al.	- Hand K files ; - WaveOne Gold rotary system.	-The single reciprocating file WaveOne Gold rotary system demonstrated a significantly shorter instrumentation time than the stainless steel hand K files.	Difference between manual and rotary instrumentation : Significant.	WaveOne Gold rotary system

Table 3. Instrumentation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Tyagi R et al.	-Hand K-flex files ; - Pro-AF Baby Gold rotary system ; - WaveOne reciprocating system.	-Hand K-flex files was associated with a significantly higher instrumentation time when compared with Pro-AF Baby Gold rotary system and WaveOne reciprocating system. -WaveOne reciprocating system showed a less instrumenation time than Pro AF Baby Gold rotary system, but the difference between them two wasn't significant.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	WaveOne reciprocating system
Jeepalyam S et al.	- Prime-Pedo rotary system ; - Kedo-SG Blue rotary system.	- Significantly less instrumentation time with Kedo-SG Blue rotary system compared to Prime-Pedo rotary system.	- Difference between the two rotary systems : Significant.	Kedo-SG Blue rotary system
Preethy NA et al.	- Hand K files ; - ProTaper Gold rotary system ; - Kedo-SG Blue rotary system.	- Kedo-SG Blue rotary system was associated with significantly less instrumentation time as compared to hand K files. -Instrumentation time with Kedo-SG Blue rotary system was lower than that with ProTaper Gold rotary system but the difference wasn't significant.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Kedo-SG Blue rotary system
Shetty B et al.	- NiTi K-flex hand files ; - Pro AF Baby Gold rotary system ; -Kedo-SG Blue rotary system	- The use of Kedo-SG blue rotary system resulted in significantly the least instrumentation time followed by the Pro AF Baby Gold followed th NiTi K-flex hand files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-SG Blue rotary system

Table 3. Instrumentation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Priyadarshini P et al.	- Hand K-files ; - Kedo-SH manual files ; - Kedo-S rotary system ; - Kedo-SG Blue rotary system	- The mean instrumentation time was significantly less with the use of rotary Kedo-SG Blue file system followed by Kedo-S, Kedo-SH manual files and hand K-files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-SG Blue rotary system
Kohli A et al.	- Prime Pedo rotary system ; - Pro-AF-Baby Gold rotary system ; - Kedo-SG Blue rotary system.	- Although the difference wasn't significant, Kedo-SG Blue rotary system showed the least instrumentation time followed by Pro-AF-Baby Gold followed by Prime Pedo rotary system.	Difference between rotary systems : Not significant.	Kedo-SG Blue rotary system
Sruthi S et al.	- Reciprocating hand K-files ; - Kedo-SH hand files ; - Kedo-SG Blue rotary system.	- Kedo-SG Blue rotary system showed a highly significant reduction in the instrumentation time followed by Kedo-SH hand files and reciprocating hand K-files.	Difference between manual and rotary instrumentation : Significant.	Kedo-SG Blue rotary system
Moudgalya MS et al.	- Hand K files ; - Rotary k-Flex files ; - Kedo-S rotary system.	- Kedo-S rotary system showed significantly the lowest instrumentation time followed by rotary k-Flex files followed by the hand K files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S rotary system
Panchal V et al. (2019)	- Hand K-files ; - Hand H-files ; - Kedo-S rotary system.	- Kedo-S rotary system showed the least instrumentation time compared to hand K-files and hand H-files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary system

Table 3. Instrumentation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Lakshmanan L et al. (2020)	- Hand K files ; - Reciprocating K files ; - Kedo-S rotary file system.	- Kedo-S rotary file system showed significantly the least instrumentation time compared to the reciprocating K files and hand K files, while the reciprocating K files showed significantly the highest instrumentation time when compared to the two others root canal preparation techniques.	Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary file system
Jeevanandan G et al. (2018)	- Hand K-files ; - Kedo-S paediatric rotary files.	- The mean instrumentation time using Kedo-S paediatric rotary files was significantly less than that using hand K-files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary system
Shah HS et al.	- Hand K files ; - Pro-AF rotary files ; - Kedo-S rotary files.	-Kedo-S rotary files demonstrated significantly the least instrumentation time followed by Pro-AF rotary files followed by hand K files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S rotary system
Girish Babu KL et al.	- Manual K files ; - Kedo-S rotary system ; - Hero Shaper rotary file.	- Kedo-S and Hero Shaper rotary file systems showed a significantly less instrumentation time as compared to manual K files. Whereas, the difference wasn't significant between the two rotary systems.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Kedo-S rotary system & Hero Shaper rotary system
Juliet S et al.	- Kedo-S rotary system ; - ProTaper rotary system ; - RaCe rotary system.	- RaCe rotary file system showed significantly less instrumentation time followed by ProTaper rotary file system followed by Kedo-S rotary file system ; -The difference between the three rotary systems was significant.	Difference between rotary systems : Significant	RaCe rotary system

Table 3. Instrumentation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Pawar BA et al.	- Hand K files ; - Kedo-S rotary system ; - XP-endo Shaper rotary system.	- XP-endo Shaper rotary system was associated with a significantly shorter instrumentation time compared to Kedo-S rotary system and hand K files which resulted in the longest time for root canal preparation.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	XP-endo Shaper rotary system
Makarem A et al.	- Hand H files ; -FM (FlexMaster) rotary system.	- FM (FlexMaster) rotary system showed a significantly less instrumentation time compared to hand H files.	Difference between manual and rotary instrumentation : Significant.	FM (FlexMaster) rotary system
Lakshmanan L et al. (2023)	- Manual K-files ; - Kedo-S file system ; - Kedo-S Square file system.	- Kedo-S Square file system showed significantly the least instrumentation time followed by Kedo-S file system followed by manual K-files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S Square file system
Gomes G et al.	-Hand K files ; - ProTaper rotary system.	- There was no significant difference regarding the instrumentation time between hand (hand K files) and rotary (ProTaper rotary system) instrumentation techniques.	Difference between manual and rotary instrumentation : Not significant.	–

Table 4. Obturation time assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Morankar R et al.	- Hand K files ; - Hyflex CM NiTi rotary files.	- The difference wasn't significant between the manual (hand K files) and the rotary (Hyflex CM NiTi rotary files) instrumentation, considering the filling time.	Difference between manual and rotary instrumentation : Not significant.	_
Boonchoo K et al.	- Hand K files ; -WaveOne Gold rotary system.	- There was no significant difference between hand K files and WaveOne Gold rotary system regarding obturation time.	Difference between manual and rotary instrumentation : Not significant.	_
Gomes G et al.	- Hand K files ; - ProTpaer rotary system.	- The difference wasn't significant between ProTpaer rotary system and hand K files, regarding the obturation time.	Difference between manual and rotary instrumentation : Not significant.	_
Makarem A et al.	- H hand files ; - FlexMaster rotary files.	- No significant difference between the FlexMaster rotary files and H hand files in terms of obturation time.	Difference between manual and rotary instrumentation : Not significant.	_
Kumar A et al.	- Hand K files ; - ProTaper rotary file system.	- Although the difference wasn't statistically significant, the mean obturation time was found to be less in the rotary instrumentation (ProTaper rotary file system) compared to the manual instrumentation (hand K files).	Difference between manual and rotary instrumentation : Not significant.	ProTaper rotary file system
Babaji P et al.	- Manual K files ; - K3 rotary files.	- The difference was significant when manual K files were compared to K3 rotary files.	Difference between manual and rotary instrumentation : Significant.	K3 rotary system
Jeepalyam S et al.	- Prime-Pedo rotary system ; - Kedo-SG Blue rotary system.	- Kedo-SG Blue rotary system showed a significantly less obturation time compared to Prime-Pedo rotary system.	Difference between the two rotary systems : Significant.	Kedo-SG Blue rotary system

Table 4. Obturation time assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Shah HS et al.	- Manual K files ; - Kedo-S rotary system ; -Pro AF Baby Gold rotary file system.	- Kedo-S and Pro AF Baby Gold rotary file systems showed significantly less obturation time compared to manual K files. - Although the least timing taken for obturation was the following instrumentation using Pro-AF rotary system, the difference with Kedo-S rotary system wasn't significant.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Pro AF Baby Gold rotary file system.
Girish Babu KL ey al.	- Manual K files ; - Kedo-S rotary system ; - Hero Shaper rotary system.	- Kedo-S and Hero Shaper rotary file systems showed a significantly less obturation time as compared to manual K files. - Hero Shaper rotary file system showed less obturation time than Kedo-S rotary file system but the difference wasn't significant.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	Hero Shaper rotary file system
Tyagi R et al.	- Hand K-flex files ; - WaveOne rotary sytem ; - Pro-AF Baby Gold reciprocating rotary system	- Significantly higher obturation time with the use of hand K-flex files as compared to WaveOne and Pro-AF Baby Gold rotary systems. - WaveOne reciprocating rotary system showed a less obturation time than Pro AF Baby Gold rotary system. Though, the difference wasn't significant.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Not significant.	WaveOne reciprocating rotary sytem

Table 5. Obturation quality assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Morankar R et al.	- Hand K files ; - Hyflex CM NiTi rotary files.	- No significant difference regarding the filling quality between the manual (hand K files) and rotary instrumentation (Hyflex CM NiTi rotary files).	Difference between manual and rotary instrumentation : Not significant.	_
Amorim AC et al.	- Manual K files ; - Hyflex EDM rotary files.	- No significant difference between the manual K files and rotary instrumentation (Hyflex EDM rotary files) in terms of quality of root filling.	Difference between manual and rotary instrumentation : Not significant.	_
Kaushik M et al.	- Manual H files ; - Flexicon X7 and Hyflex CM rotary files.	- No significant difference regarding the quality of obturation was found between manual H files and Flexicon X7 and Hyflex CM rotary files	Difference between manual and rotary instrumentation : Not significant.	_
Barasuol JC et al.	- Hand K files ; -ProDesign Logic rotary file system.	- No difference regarding the apical limit of the obturation, was observed between hand K files and ProDesign Logic rotary file system.	Difference between manual and rotary instrumentation : Not significant.	_
Durairaj BA et al.	- Manual K files - Kedo-S Square rotary files.	- No significant difference between the Kedo-S Square files and the manual K files based on the quality of obturation.	Difference between manual and rotary instrumentation : Not significant.	_
Govindaraju L et al.	- Hand K-files ; - ProTaper rotary system ; - Kedo-S rotary file systems.	- No statistically significant difference considering the quality of obturation between hand k-files, ProTaper, and Kedo-S rotary file systems.	- Difference between manual and rotary instrumentation : Not significant ; - Difference between the two rotary systems : Not significant.	_
Preethy NA et al.	- Manual K files ; - ProTaper Gold rotary files ; - Kedo-SG blue rotary files.	- There was no statistically significant difference in terms of obturation quality between manual K files, ProTaper Gold rotary files, and Kedo-SG blue rotary files.	- Difference between manual and rotary instrumentation : Not significant ; - Difference between the two rotary systems : Not significant.	_

Table 5. Obturation quality assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Sruthi S et al.	- Kedo-SH hand files ; - Reciprocating hand K-files ; - Kedo-SG Blue rotary system.	- No significant differences were noted between Kedo-SG Blue rotary system, Kedo-SH hand files and reciprocating hand K-files.	Difference between manual and rotary instrumentation : Not significant.	_
Marques RPS et al.	- Hand K files ; - WaveOne Gold rotary system.	- No differences were observed in relation to quality of root canal filling between hand instrumentation with K files and reciprocating rotary instrumentation using WaveOne Gold rotary system.	Difference between manual and rotary instrumentation : Not significant.	_
Mokhtari N et al.	- Manual K files ; - Mtwo rotary system.	- No differences were observed in relation to quality of root canal filling between manual K files and Mtwo rotary files.	Difference between manual and rotary instrumentation : Not significant.	_
Govindaraju L et al. (2017)	- Hand K files ; - Mtwo rotary system ; - Protaper rotary system.	- No significant difference between hand K files, Mtwo and Protaper rotary files.	Difference between manual and rotary instrumentation : Not significant.	_
Kumar A et al.	- Hand K files ; - ProTaper rotary system.	- Hand K files and ProTaper rotary files showed a similar percentage of optimally filled canals. Whereas, under fills were more noticed in manual instrumentaion and over fills were more observed in rotary instrumentation.	Difference between manual and rotary instrumentation : Not significant.	_

Table 5. Obturation quality assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
EL-Desouky SS et al.	- Manual K files - Fanta AF Baby rotary system ; - Kedo-S Square rotary system.	- Kedo-S Square rotary system was associated with a significantly greater number of optimally filled teeth followed by Fanta AF Baby rotary system and manual k files.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S Square rotary system
Denish Kumar et al.	- Manual K files - Kedo-S Square rotary system.	- Significantly better obturation quality with the rotary Kedo-S Square files compared to hand k files.	Difference between the two rotary systems : Significant.	Kedo-S Square rotary system
Jeevanandan G et al. (2020)	- Hand K files ; - Hand H files ; - Kedo-S Square rotary file system.	- Kedo-S Square rotary file system showed significantly the highest number of optimally filled canals compared to hand K and H files. - Kedo-S Square rotary system was associated with significantly the highest number of overfilled canals.	Difference between manual and rotary instrumentation : Significant.	Kedo-S Square rotary file system
Lakshmanan L et al. (2023)	- Hand K files ; - Kedo-S file system ; - Kedo-S Square file system.	- Kedo-S Square file system demonstrated the highest percentage of optimally filled canals followed by Kedo-S file system followed by hand K files, but the difference wasn't significant. As well, regarding the presence of voids, the difference wasn't significant.	Difference between manual and rotary instrumentation : Not significant ; - Difference between the two rotary systems : Not significant.	Kedo-S Square file system
Panchal V et al.	- Hand K-files ; - Hand H-files ; - Kedo-S rotary system.	- Significantly higher number of optimally filled canals with Kedo-S rotary system compared to hand K-files and hand H-files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary system
Jeevanandan G et al. (2018)	- Hand K files ; - Kedo-S rotary file system.	-Kedo-S rotary file system showed a significantly higher number of optimally filled canals and lower number of under and over filled canals as compared to hand K files.	Difference between manual and rotary instrumentation : Significant.	Kedo-S rotary system

Table 5. Obturation quality assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Divya S et al.	- Hand K-file ; - K3 rotary file system ; - Kedo-S rotary sytem.	- Kedo-S file showed significantly the least underfilled canals and had, but not significantly, the highest percentage of optimally filled canals compared to hand K files and K3 rotary system.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S rotary sytem
Moudgalya MS et al.	- Hand files ; - Rotary K-Flex files ; - Kedo-S rotary system.	- Regarding the apical seal, Kedo-S and rotary K-Flex files showed similar efficiency and they were significantly more efficient in obtaining apical seal than hand files. As well, Kedo-S files showed significantly the least scores of voids, followed by rotary K-Flex files, whereas, hand K files showed significantly the highest number of canals with voids.	- Difference between manual and rotary instrumentation : Significant ; - Difference between the two rotary systems : Significant.	Kedo-S rotary system
Lakshmanan L et al. (2020)	- Hand K files ; - Reciprocating K files ; -Kedo-S files.	- Although the difference wasn't significant, the highest optimal fillings were noted with Kedo-S files followed by hand K files followed by reciprocating K files. However, Kedo-S showed the highest over fills while reciprocating K files showed the highest percentage of under fills.	Difference between manual and rotary instrumentation : Not significant.	Kedo-S rotary system
Juliet S et al.	- ProTaper rotary file system ; - RaCe rotary file system ; - Kedo-S rotary file system.	- Kedo-S rotary file system showed a better obturation quality with a maximal number of optimal fills and minimal percentage of under fills and over fills followed by ProTaper rotary file system followed by RaCe rotary file system.	Difference between the rotary systems : Not significant.	Kedo-S rotary system

Table 5. Obturation quality assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Girish Babu KL et al.	- Manual K files ; - Kedo-S rotary system ; - Hero Shaper rotary file system.	- Kedo-S and Hero Shaper rotary file systems showed a significantly better obturation quality as compared to manual K files. Also, when compared to Kedo-S rotary file system, Hero Shaper rotary file system showed more optimal fills, less under fills but more over fills. Though, the difference wasn't significant.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	Hero Shaper rotary file system
Jeepalyam S et al.	- Prime-Pedo rotary system ; - Kedo-SG Blue rotary system.	- Although the difference wasn't significant, Kedo-SG Blue rotary system demonstrated a higher number of optimally filled canals compared to Prime-Pedo rotary system.	Difference between the two rotary systems : Not significant.	Kedo-SG Blue rotary system
Kohli A et al.	- Pro-AF-Baby Gold rotary system ; - Prime Pedo rotary system. - Kedo-SG Blue rotary system.	- Kedo-SG Blue rotary system showed, but not significantly, the highest number of optimally filled canals and the lowest number of underfilled canals as compared to Pro-AF-Baby Gold rotary system and Prime Pedo rotary system.	Difference between the rotary systems : Not significant.	Kedo-SG Blue rotary system
Katge F et al.	- Hand H files ; - Protaper Universal rotary system ; - Prime Pedo rotary system.	- Prime Pedo rotary system showed significantly higher number of optimally filled canals as compared to Protaper Universal rotary system and H files in mesial canals. Regarding voids, the authors reported that Prime Pedo and Protaper Universal rotary files displayed significantly less number of voids in obturation as compared to hand H files.	-Difference between manual and rotary instrumentation : Significant ; -Difference between the two rotary systems : Significant.	Prime Pedo rotary system

Table 5. Obturation quality assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Shah HS et al.	- Hand K files ; - Kedo-S rotary files ; - Pro-AF Baby Gold rotary files.	- Pro-AF Baby Gold files showed, but not significantly, the maximum number of optimal obturations with the least number of voids followed by Kedo-S rotary files followed by hand K files.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	Pro-AF Baby Gold rotary system
Govindaraju L et al. (2017)	- Hand K files ; -Protaper rotary system ; - K3 rotary file system.	- Despite the difference wasn't significant, the highest number of optimally filled canals were noticed with the K3 rotary file system followed Protaper rotary system followed by hand K files.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	K3 rotary file system
Babaji P et al.	- Hand K fils ; -K3 rotary system.	- K3 rotary system was associated with significantly higher percentage of optimally filled canals and lower percentage of under and over fills compared to hand K fils.	Difference between manual and rotary instrumentation : Significant.	K3 rotary system
Shetty B et al.	- Hand K-files ; -Pro AF Baby Gold rotary system ; -Kedo-SG blue rotary system.	-Although the difference wasn't significant, Kedo-SG blue was associated with the highest number of optimally filled canals followed by hand K-files followed by Pro AF Baby Gold rotary system. -Hand K-files showed the highest number of overfilled canals. Regarding voids, Pro AF Baby Gold demonstrated the least amount of voids followed by hand k-files within the use of Kedo-SG blue was associated with the highest number of voids.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	Kedo-SG blue rotary system & Pro AF Baby Gold rotary system

Table 5. Obturation quality assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Priyadarshini P et al.	- Kedo-SH manual files ; - Hand K-files ; -Kedo-S rotary system ; - Kedo-SG Blue file system.	- Kedo-SG Blue file system demonstrated a high statistically significant level of optimal quality of obturation followed by Kedo-SH manual files, Kedo-S rotary system, and hand K-files.	-Difference between manual and rotary instrumentation : Significant ; -Difference between the two rotary systems : Significant.	Kedo-SG Blue file system
Jeevanandan G et al. (2021)	- Hand K-files ; - Kedo-SH hand files ; - Kedo-SG Blue pediatric rotary system.	- Kedo-SG Blue pediatric rotary system showed a significantly better obturation quality followed by Kedo-SH hand files followed by hand K-files.	Difference between manual and rotary instrumentation : Significant.	Kedo-SG Blue rotary system
Boonchoo K et al.	- Hand K files ; - WaveOne Gold rotary system.	- In mesial canals, WaveOne Gold rotary system showed a significantly higher percentage of overfilled canals compared to hand K files which showed a significantly higher percentage of under fills. - There was no significant difference between them in distal canals	Difference between manual and rotary instrumentation : Significant.	–
Pawar BA et al.	- Hand K files ; - Kedo-S rotary system ; - XP-endo Shaper rotary system.	- XP-endo Shaper rotary system showed a significantly higher number of optimally filled canals and lower number of under and overfilled canals compared to Kedo-S rotary system and hand K files.	-Difference between manual and rotary instrumentation : Significant ; -Difference between the two rotary systems : Significant.	XP-endo Shaper rotary system
Makarem A et al.	- Hand H files ; - FlexMaster rotary system.	- FlexMaster rotary system showed a significantly better obturation quality in terms of both obturation extent and form in comparison to the hand H files.	Difference between manual and rotary instrumentation : Significant.	FlexMaster rotary system

Table 6. Complication during instrumentation assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Morankar R et al.	- Hand K files - Hyflex CM NiTi rotary file system.	-There were two cases of instrumental fracture encountered with Hyflex CM NiTi rotary file system versus none observed with hand K files. Though, the difference wasn't significant.	Difference between manual and rotary instrumentation : Not significant.	Hand K files

Table 7. Success rate assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Morankar R et al.	- Hand K files ; - Hyflex CM NiTi rotary file system.	-Although the difference wasn't significant, the clinical success rate was higher with hand K files as compared to Hyflex CM NiTi rotary file system. -Radiographic success rate was higher, but not significantly, with Hyflex CM NiTi rotary file system	Difference between manual and rotary instrumentation : Not significant.	– –
Kumar A et al.	- Hand K files ; - ProTaper rotary file system.	- Manual instrumentation with hand K files demonstarted a better clinical success rate than the rotary instrumentation with ProTaper rotary file system, but the difference wasn't significant.	Difference between manual and rotary instrumentation : Not significant.	Hand K files
Elheeny AA et al. (2015)	- Manual K files ; - RaCe rotary system.	- RaCe rotary system exhibited higher success rate percentage over ProTaper rotary system and manual K files. Though, the difference wasn't significant.	Difference between manual and rotary instrumentation : Not significant.	RaCe rotary system
Girish Babu KL et al.	- Manual K files - Hero Shaper rotary file system ; - Kedo-S rotary file system.	- Clinical success rate was considered as 100% for Kedo-S rotary file system, Hero Shaper rotary file system and manual K files. Whereas, the highest radiographic success was observed with Hero Shaper rotary file system, followed by Kedo-S rotary file system followed by manual K files. - The two- year-follow up revealed no significant difference between these three instrumental techniques.	Difference between manual and rotary instrumentation : Not significant ; - Difference between the two rotary systems : Not significant	Hero Shaper rotary file system
Amorim AC et al.	- Hand K files ; - Hyflex EDM rotary files.	- No difference between the manual technique using hand K files and the rotary technique using Hyflex EDM rotary files in terms of both clinical and radiographic success.	Difference between manual and rotary instrumentation : Not significant.	–

Table 7. Success rate assessment by the included studies (continued)

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Marques RPS et al.	- Hand K files ; - WaveOne Gold reciprocating system.	-Similar success rate was observed for both manual (hand K files) and reciprocating (WaveOne Gold reciprocating system) techniques.	Difference between manual and rotary instrumentation : Not significant.	_
Boonchoo K et al.	- Hand K files ; - WaveOne Gold rotary system.	- No significant difference between hand K files and WaveOne Gold rotary system at 6 and 12 months post operatively regarding both clinical and radiographic success rate.	Difference between manual and rotary instrumentation : Not significant.	_
Vieyra JP et al.	- Hand K files ; - Light Speed LSX rotary system ; - ProTaper file rotary system.	- No difference was found between the rotary (Light Speed LSX and ProTaper file rotary systems) and manual (hand K files) instrumentation considering both clinical and radiographic success rate.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	_

Table 8. Child's behavior assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Krishna DR et al.	- Manual H files ; - Mtwo rotary files.	- Young patients significantly preferred manual H files over Mtwo rotary files.	Difference between manual and rotary instrumentation : Significant.	Manual H files
Barasuol JC et al.	- Hand K files ; - ProDesign Logic rotary file system.	- There was no association between the type of instrumentation and participant behavior when compared hand K files to ProDesign Logic rotary file system.	Difference between manual and rotary instrumentation : Not significant.	_
Tyagi R et al.	- Hand NiTi-K flex ; - Pro AF Baby Gold rotary system ; - WaveOne reciprocating system.	- No statistically significant difference between pre-operative and post-operative child's behavior was noticed when comparing hand NiTi-K flex, Pro AF Baby Gold rotary system and WaveOne reciprocating system.	-Difference between manual and rotary instrumentation : Not significant ; -Difference between the two rotary systems : Not significant.	_

Table 9. Operator's perspective assessment by the included studies

Study	Compared instruments	Findings	Significance	Effective rotary instrument
Krishna DR et al.	- Manual H-files ; - Mtwo rotary files.	- Operators preferred Mtwo rotary files over manual H-files. However, the difference wasn't significant.	Difference between manual and rotary instrumentation : Not significant.	Mtwo rotary system

Table 10. Recaputilative table demonstrating the comparison between manual instrumentation and rotary instrumentation based on the different evaluating parameters

	P.O.P	C.E	I.T	O.T	O.Q	S.R	C.I	O.P	C.B
Rotary instrumentation	+	+	+	+	+	=	-	+	-
Hand Instrumentation	-	-	-	-	-	=	+	-	+

* + : Effective ; - : Not effective ; = : Equally effective ; _ : Not mentioned

Table 11. Recaputilative table demonstrating the comparison between rotary systems based on the differents evaluating parameters

	P.O.P	C.E	I.T	O.T	O.Q	S.R	C.I	O.P	C.B
Kedo-S plus	_	++	_	_	_	_	_	_	_
Kedo-S Square	++	+	++	_	++	_	_	_	_
Kedo-SG Blue	+	_	++	++	++	_	_	_	_
Kedo-S	+	++	+	+	+	+	_	_	_
ProDesign Logic	_	_	+	_	-		_	_	=
WaveOne Gold	++	_	++	+	-	-	_	_	=
Light Speed LSX	_	_	++	_	_	-	_	_	_
Pro AF Baby Gold	+	_	+	+	+	_	_	_	=
Fanta AF Baby rotary	+	_	+	_	-	_	_	_	_
Mtwo	+	_	+	_	-		_	+	-
Hyflex CM NiTi	_	_	+	-	-	-	-	_	_

* ++ : Most effective ; + : Effective ; - : Not effective ; = : Equally effective ; _ : Not mentioned

Table 11. Recaputilative table demonstrating the comparison between rotary systems based on the differents evaluating parameters (continued)

	P.O.P	C.E	I.T	O.T	O.Q	S.R	C.I	O.P	C.B
Hyflex EDM	+	_	+	_	-	-	_	_	_
FlexMaster	_	_	+	-	+		_	_	_
Hero Shaper	_	_	+	+	+	++	_	_	_
K3	-	_	+	+	+	_	_	_	_
Prime Pedo	_	_	-	-	+	_	_	_	_
ProTaper	+	_	+	-	-	-	_	_	_
Flexicon X7	_	_	++	_	-	_	_	_	_
K-Flex	+	+	-	_	+	_	_	_	_
XP-endo Shaper	++	_	++	_	++	_	_	_	_
Revo-S	+	_	_	_	_	_	_	_	_
Reciproc R25	+	_	_	_	_	_	_	_	_
OneShape	+	_	_	_	_	_	_	_	_
RaCe rotary system	_	_	+	_	-	++	_	_	_

* ++ : Most effective ; + : Effective ; - : Not effective ; = : Equally effective ; _ : Not mentioned

Table 12. Recaputilative table showing the comparison between continuous and reciprocating motion used in rotary instrumentation

	P.O.P	C.E	I.T	O.T	O.Q	S.R	C.I	O.P	C.B
Continuous motion	=	_	-	-	_	_	_	_	=
Reciprocating motion	=	_	+	+	_	_	_	_	=

* + : Effective ; - : Not effective ; = : Equally effective ; _ : Not mentioned

Table 13. Quality assessment of the included studies based on the RoB 2 tool

	D1	D2	D3	D4	D5	Overall	Explanation
Morankar R et al.							–
Jeevanandan G et al. (2023)							The significance of difference in bacterial load reduction between rotary files wasn't assessed.
Dinesh kumar et al.							The quality of obturation assessment was only based on the extent of fill while the presence of voids wasn't reported.
Alnassar I et al.							The pain assessment was performed by parents.
Amorim AC et al.							The randomization process wasn't clearly described. The quality of obturation assessment was only based on the extent of fill and the presence of voids wasn't reported. Small sample size.
Subramanyam D et al.							Small sample size.
EL-Desouky SS et al.							The quality of obturation assessment was only based on the extent of fill and the presence of voids wasn't reported. The evaluator of postoperative pain wasn't mentioned.
Jeepalyam S et al.							The quality of obturation assessment was only based on the extent of fill and the presence of voids wasn't reported. Small sample size.
Durairaj BA et al.							Samll sample size.
Lakshmanan L et al. (2022)							Small sample size.
Elheeny AAH et al. (2023)							–
Kaushik M et al.							The assessor of the quality of obturation wasn't blinded to the instrumentation technique. The presence of voids wasn't evaluated.

Table 13. Quality assessment of the included studies based on the RoB 2 tool (continued)

	D1	D2	D3	D4	D5	Overall	Explanation
Krishna DR et al.							Small sample size. The evaluator of the main outcome wasn't blinded.
Panchal V, Jeevanandan G, and Subramanian EM (2019)							The evaluation of instrumentation time wasn't blinded. The presence of voids wasn't evaluated.
Divya S et al.							The assessment of postoperative pain wasn't blinded. The presence of voids wasn't evaluated. Small sample size.
Jeevanandan G et al. (2020)							Small sample size. The presenceof voids wasn't evaluated.
Govindaraju L et al. (2018)							The presence of voids wasn't evaluated. Small sample size.
Preethy NA et al.							The presence of voids wasn't evaluated. Small sample size.
Shetty B et al.							Small sample size. The measurement tool of the instrumentation time wasnt' mentioned.
Moudgalya MS et al.							The assessors of results weren't mentioned. Postoperative pain was evaluated by parents.
Barasuol JC et al.							–
Elheeny AAH et al. (2022)							–
Marques RPS et al.							–
Mokhtari N et al.							The objectives and results of the trial weren't well-defined. The measurement tools of all the parameters weren't mentioned. The assessers of parameters weren't mentioned.

Table 13. Quality assessment of the included studies based on the RoB 2 tool (continued)

	D1	D2	D3	D4	D5	Overall	Explanation
Thakur B et al.							–
Topçuoğlu G et al.							–
Kumar A et al.							Small sample size. The presence of voids wasn't evaluated. The assessers of parameters weren't mentioned.
Boonchoo K et al.							The measurement tools of parameters weren't mentioned The presence of voids wasn't reported. Small sample size.
Panchal V et al. (2019)							Postoperative pain assessment by phone calls. The presence of voids wasn't evaluated
Priyadarshini P et al.							
Kohli A et al.							The presence of voids wasn't reported.
Sruthi S et al.							The presence of voids wasn't reported. Small sample size.
Govindaraju L et al. (2017)							Small sample size. The presence of voids wasn't reported.
Nair M et al.							The pain assessment wasn't blinded.
Lakshmanan L et al. (2020)							Small sample size. The presence of voids wasn't reported.
Lakshmanan L et al. (2023)							Small sample size.
Katge F et al.							Small sample size.

Table 13. Quality assessment of the included studies based on the RoB 2 tool (continued)

	D1	D2	D3	D4	D5	Overall	Explanation
Gomes G et al.							Very small sample size (8 primary teeth).
Pawar BA et al.							The presence of voids wasn't evaluated. The instrumentation time assessment wasn't blinded. Significance difference between instrumentation techniques wasn't reported.
Jeevanandan G et al. (2018)							The presence of voids wasn't evaluated.
Makarem et al.							Small sample size. The evaluator of chair side time wasn't mentioned.
Govindaraju L et al. (2017)							The presence of voids wasn't evaluated. Small sample size.
Babaji P et al.							The evaluators of the parameters weren't mentioned. The measurement tools of all parameters weren't mentioned. The presence of voids wasn't evaluated.
Vieyra JP et al.							The evaluation of parameters wasn't blinded. Small sample size.
Shah HS et al.							Small sample size. The evaluator of instrumentation and obturation time wasn't mentioned.
Elheeny A et al. (2015)							The evaluator of success rate wasn't mentioned.
Girish Babu KL et al.							The presence of voids wasn't evaluated.
Juliet S et al.							Small sample size. The presence of voids wasn't evaluated.

Table 13. Quality assessment of the included studies based on the RoB 2 tool (continued)

	D1	D2	D3	D4	D5	Overall	Explanation
Jeevanandan G et al. (2020)							–
Jeevanandan G et al. (2021)							Small sample size. The presence of voids wasn't evaluated.
Tyagi R et al.							The evaluator of postoperative pain wasn't mentioned. The measurement tool of instrumentation time wasn't mentioned.

Domains

D1: Bias arising from the randomization process

D2: Bias due to deviations from intended interventions

D3: Bias due to missing outcome data

D4: Bias in measurement of the outcome

D5: Bias in selection of the reported result

Judgement

Low risk

Some concerns

High risk

DISCUSSION

Pulpectomy is considered the treatment of choice for primary teeth with severe pulpal involvement, as it aims to preserve deciduous teeth until their physiological exfoliation. This ensures the maintenance of essential oral functions, including mastication and phonation, preserves esthetics, and prevents the development of deleterious oral habits. The introduction of nickel–titanium (NiTi) alloys enabled the use of rotary instrumentation in pulpally involved teeth, first reported by Barr et al. in 2000. Since then, numerous rotary systems have been developed specifically for pulpectomy in primary teeth.[60]

This systematic review aimed to compare different rotary file systems used for pulpectomy in primary teeth and to identify the most reliable system for clinical use. The evaluation focused on key clinical parameters, including postoperative pain, cleaning efficacy, instrumentation time, obturation time and quality, success rate, practitioner's preference, child behavior, and intraoperative complications. An efficient rotary system should minimize postoperative pain and analgesic intake, reduce chairside time to enhance patient cooperation, prevent instrument fracture, provide optimal cleaning and shaping, achieve high-quality obturation, ensure a high success rate, and be preferred by both clinicians and patients.

Postoperative pain is a critical outcome in pediatric endodontics, as it can significantly influence a child's future dental behavior.[57] Pain was assessed using a four-point pain intensity scale categorizing pain as none, slight, moderate, or severe.[16] The findings of this systematic review indicate that rotary instrumentation is more effective than manual instrumentation in reducing postoperative pain, in agreement with the umbrella review conducted by Swaminathan et al.[61] Among the rotary systems evaluated, Kedo-S Square, WaveOne Gold, and XP-Endo Shaper demonstrated superior performance in minimizing postoperative pain.[16-24-37-30] When comparing continuous rotation and reciprocating motion, no

significant difference in pain reduction was observed.[28]

The primary objective of pulpectomy in primary teeth is the elimination of intracanal microorganisms to prevent reinfection and promote periradicular tissue healing, thereby reducing postoperative discomfort.[33] Rotary instrumentation demonstrated superior cleaning efficacy compared to hand files. When rotary systems were compared with each other, Kedo-S Plus and Kedo-S showed the most favorable cleaning outcomes.[9-32-18]

Chairside time, defined as the duration required for canal preparation and obturation, is a crucial factor in pediatric dentistry. Reducing treatment time helps alleviate anxiety, improves cooperation, and decreases operator fatigue, particularly when managing uncooperative children.[43-18] The present review demonstrated that rotary instrumentation significantly reduced chairside time compared to manual techniques, consistent with the findings of Faghihian et al.[62] Rotary systems such as Kedo-S Square, Kedo-SG Blue, WaveOne Gold, LightSpeed LSX, Flexicon X7, and XP-Endo Shaper were associated with short treatment times.[35-16-36-4-37-26-24-44-45-46-47-1-3-54-25] Furthermore, reciprocating motion resulted in shorter chairside time than continuous rotation.[24]

Obturation quality is a decisive factor in the success of root canal treatment.[35] Rotary instrumentation was associated with superior obturation quality, a finding also supported by Faghihian et al.[62] and Swaminathan et al.[61] In this contexte, Kedo-S Square, Kedo-SG Blue and XP-Endo Shaper exhibited superior obturation quality.[54_4-37-25-44-1-46-47-23]

Regarding overall success rates, most studies reported comparable outcomes between hand and rotary instrumentation.[2-34-27-43-26] However, when comparing rotary systems, RaCe and Hero Shaper demonstrated higher success rates.[59-52] Success was evaluated both clinically and radiographically.

Clinically, success was defined by the absence of pain, tenderness to percussion, gingival swelling, sinus tract formation, or abnormal mobility.[2] Radiographic success was characterized by the absence of increased or new radiolucencies and the absence of pathological internal or external root resorption.[2]

Instrument fracture was the most commonly reported complication associated with rotary instrumentation, although it was noted in only one study.[2] Instrument separation is multifactorial and may be minimized by limiting instrument reuse and ensuring adequate operator experience.[2]

From the practitioner's perspective, rotary instrumentation was generally preferred, with the Mtwo rotary system favored over hand files.[34] Regarding child behavior, one study[38] reported a preference for manual instrumentation, whereas two others[31-24] found no association between behavior and instrumentation type. Continuous and reciprocating motions showed comparable behavioral outcomes.[24]

This systematic review has several strengths. It is the first to compare not only manual and rotary pulpectomy techniques in primary teeth but also a wide range of currently available rotary systems. Additionally, it included a substantial number of high-quality clinical studies evaluating multiple clinical parameters.

However, several limitations must be acknowledged. The heterogeneity of the included studies prevented the performance of a meta-analysis, as individual studies evaluated different outcomes and rotary systems. In addition, a considerable proportion of the included studies were characterized by small sample sizes, which may adversely affect the statistical power and overall reliability of their findings. Another limitation of the present review is that most of the included studies evaluated variants of the Kedo-S rotary system, potentially leading to an overrepresentation of its performance and

introducing the risk of performance overestimation. Furthermore, the review focused exclusively on clinical parameters related to pulpectomy procedures. Some of these outcomes are inherently subjective, being dependent on either practitioner assessment or patient-reported measures, while others reflect only short-term follow-up periods. Collectively, these factors preclude the formulation of definitive conclusions.

Additionally, the quality assessment identified a moderate risk of bias across the included studies, raising further concerns regarding the reliability and internal validity of the reported outcomes.

Moreover, a large proportion of the included studies (36 out of 51) were conducted in India, emphasizing the need for multicentric research. Future studies should aim to include a broader range of rotary systems and evaluate a wider array of clinical parameters. Finally, the exclusion of in vitro studies limited the assessment of additional objective variables such as apical debris extrusion and the ability of rotary systems to maintain the original canal anatomy during instrumentation.

CONCLUSIONS

Considering the heterogeneity of the included studies and the lack of standardized and objective assessment of pulpectomy parameters, identifying a single pediatric rotary file system that consistently fulfilled all evaluated criteria was not feasible. Nevertheless, this systematic review emphasizes the need for future multicentric studies with standardized methodologies that simultaneously evaluate a broader range of rotary systems. Such studies should integrate both clinical and in vitro parameters to provide more robust and comprehensive evidence to guide clinical decision-making in pediatric endodontics.

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Comparative evaluation of sucrose solution, ice application, and topical anesthetic gel for pain control during local anesthetic administration in children: A randomized clinical trial

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Highlights

- Pain during local anesthetic injections remains a major challenge affecting cooperation and anxiety in pediatric dental patients.
- Sucrose combined with topical anesthetic provided the greatest reduction in pain perception and physiologic stress responses.
- Simple, low-cost adjuncts such as sucrose and ice may improve comfort and cooperation during pediatric dental injections.

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Abstract

Aim: Discomfort during local anesthetic administration remains a concern in pediatric dentistry, with topical anesthetics providing limited benefit. Although sucrose and cryotherapy are promising adjuncts, comparative evidence on their effectiveness, alone or combined, is still limited. This study aimed to evaluate and compare the effectiveness of sucrose solution, ice, and topical anesthetic gel alone and in combination for reducing pain during dental injections in children aged 7 to 12 years. **Methods:** A randomized clinical study was conducted on 100 healthy, cooperative children requiring maxillary local anesthesia. Participants were assigned to five groups: Group I (30% sucrose solution), Group II (ice application), Group III (ice + topical anesthetic gel), Group IV (30% sucrose solution + topical anesthetic gel), Group V (topical anesthetic gel only). Pain perception was assessed using the Wong-Baker Facial Pain Rating Scale (WBFPRS), Visual Analog Scale (VAS), Face, Legs, Activity, Cry, Consolability scale (FLACC), and Sound, Eye, Motor scale (SEM). Physiological responses, including pulse rate and oxygen saturation (SpO_2), were recorded at three intervals. **Results:** Statistically significant intergroup differences were observed for pain perception and physiological parameters ($p < 0.001$). The lowest pain scores on WBFPRS and FLACC, along with the most stable pulse rate and oxygen saturation during injection, were observed in the sucrose plus topical anesthetic group. Ice combined with topical anesthetic also demonstrated significant analgesic benefit, whereas topical anesthetic alone resulted in the highest pain and stress responses. **Conclusions:** The combined use of sucrose solution and topical anesthetic gel was the most effective intervention for reducing pain perception and physiological stress during local anesthetic injections in children. Ice application with topical anesthetic gel also provided measurable benefit. Sucrose is a simple, low-cost, non-pharmacological adjunct that improves comfort in pediatric dental procedures.

Keywords: Anesthesia, Local; Dental Injection; Pain Measurement; Pediatric Dentistry; Topical Anesthetics

INTRODUCTION

Effective pain management is a cornerstone of pediatric dental care, as it plays a crucial role in reducing anxiety, improving cooperation, and ensuring successful treatment outcomes. To achieve adequate pain control, the administration of local anesthesia is frequently necessary. Local anesthesia injections often trigger anxiety and disruptive behavior in young patients, affecting cooperation and procedural success.[1] Effective pain prevention can improve a child's cooperation by fostering trust between the dentist and the child while also reducing fear and anxiety during current and future dental visits.[2]

Several techniques have been suggested to reduce pain caused by the administration of local anesthesia, including topical anesthetic, gels or sprays, the distraction method, warming the anesthetic solution, regulation of the injection rate, buffering the anesthetic agent, counter stimulation, and local precooling with refrigerant spray.[3-4.]

A number of studies have also reported the success of orally administered sweet-tasting solutions for the management of neonatal pain in the clinical setting.[5-6] Administration of oral sucrose solution before immunization showed a significant reduction in pain as compared to the application of topical local anesthetics.[7] Recent pediatric dental trials have demonstrated that oral sucrose significantly reduces needle-related pain in children beyond infancy, including school-aged populations, supporting its clinical applicability in children aged 7–12 years.[8] There is a paucity of clinical research assessing the effectiveness of sucrose and its combination with other non-pharmacological agents for pain control during local anesthesia in pediatric dental patients, especially using both subjective and physiological parameters.

Therefore, this study aimed to evaluate and compare the analgesic effectiveness of sucrose, ice, and their combinations with topical anesthetic gel during local anesthesia administration in children aged 7 to 12. The null hypothesis stated that there would be no difference in pain perception among the five intervention groups.

METHODS

A randomized, controlled, single-blind clinical trial was conducted, where the examiner recording the pain assessment scores was blinded to the group allocation to minimize observer bias, to compare the efficacy of sucrose solution, ice application, topical anesthetic gel, and combination in reducing the pain related to dental injection across children aged 7–12 years.

This randomized clinical trial was conducted in accordance with the CONSORT 2010 guidelines for the reporting of randomized trials. The study was conducted in the Department of Pediatric and Preventive Dentistry. The Institutional Research and Ethical Board of the University approved all aspects of this research. (IREB/2021/PEDO/09). The sample size was calculated using G*Power software (version 3.1.9.7, Heinrich Heine University, Düsseldorf, Germany) based on effect sizes reported in previous studies such as Ghaderi et al.[9] which demonstrated moderate analgesic effects for pre-cooling interventions. Using a one-way ANOVA model with an effect size of 0.40, $\alpha = 0.05$, and a higher desired statistical power of 90%, the required sample size was 85 participants.

To allow equal allocation across the five intervention groups and to slightly exceed the required power, the sample size was rounded up to 100 participants (20 per group). This ensured balanced group distribution and improved statistical precision. This larger sample size also helped account for potential data loss.

Inclusion and Exclusion Criteria

Children aged 7–12 years who were systemically healthy, cooperative (Frankl behavior ratings III or

IV), and mentally capable of effective communication were included in the study. Only maxillary primary molars indicated for extraction or pulp therapy were considered, provided there was no history of infection, swelling, abscess, or radiographic evidence of periapical pathology or soft-tissue inflammation at the injection site.

Children were excluded if they were medically compromised or had a history of systemic, mental, or physical disorders, known allergy to lidocaine, or previous painful dental experiences. Those undergoing emergency dental treatment or demonstrating uncooperative behavior (Frankl behavior ratings I or II) were also excluded.

Grouping and Interventions

Participants were randomly allocated into five groups using simple randomization with opaque, sealed envelopes, each receiving different pre-treatment interventions prior to local anesthesia administration via the infiltration technique(Figure 1). Group I received 30% sucrose solution only. Group II received ice application only. Group III received a combination of ice application and topical anesthetic gel. Group IV received a combination of 30% sucrose solution and topical anesthetic gel. Group V received topical anesthetic gel and served as the comparison group. Interventions were standardized across all participants, and each child received only the allocated treatment before local anesthetic administration. The study procedure was explained to the parents, from whom informed written and oral consent was obtained. An anesthetic cartridge containing 2% lignocaine with 1:80,000 adrenaline was used (Lignospan Special; Septodont, Saint-Maur-des-Fossés, France).

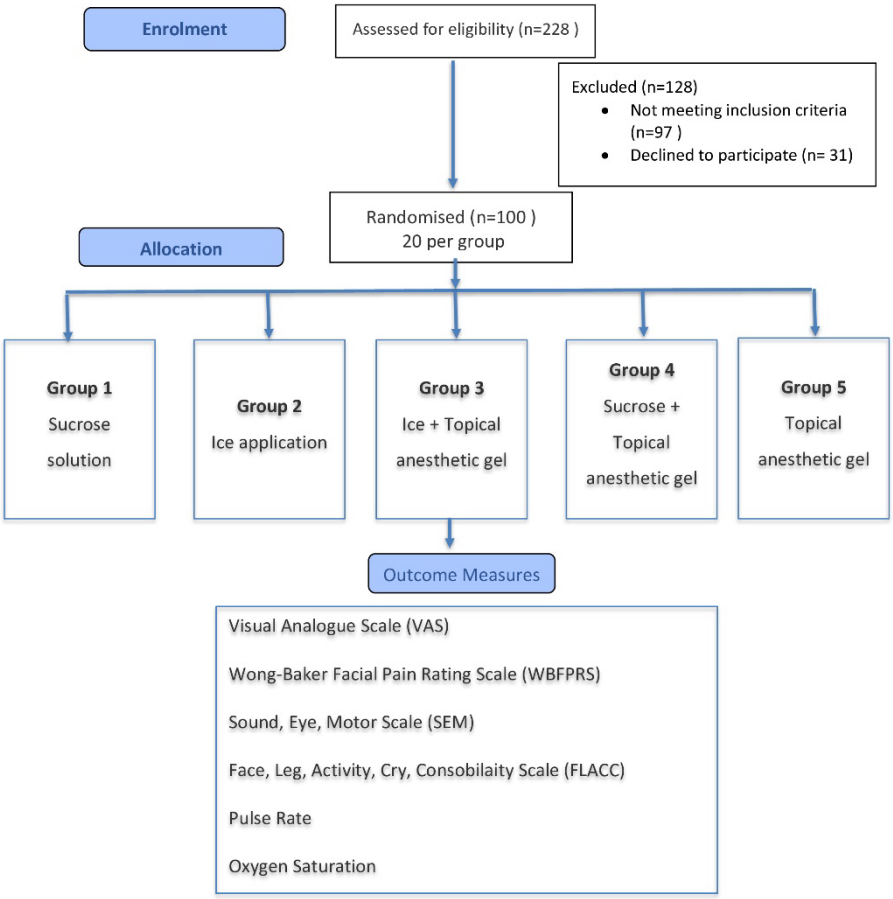

Figure 1. Flowchart illustrating the randomized allocation of pain control interventions in children

All participants in the study received an infiltration injection of 1.8 ml of 2% lidocaine hydrochloride containing 1:80,000 epinephrine. (Lignospan Special; Septodont, Saint-Maur-des-Fossés, France) This standard dosage was administered to ensure effective local anesthesia during the dental procedure. To promote cooperation and minimize anxiety, the tell–show–do behavior management technique was consistently employed for all participants.

Group I (30% Sucrose Solution Only)

Children were given 5 mL of freshly prepared 30% sucrose solution (30 g sucrose dissolved in 100 mL distilled water) using a sterile oral syringe. They were instructed to swish the solution in their mouth for 1 minute and then expectorate. Local anesthesia Lignospan Special (2% lidocaine with 1:80,000 epinephrine; Septodont, Saint-Maur-des-Fossés, France) was administered immediately after.

Group II (Ice Application Only):

A clean, sterilized ice stick was applied directly to the injection site on the buccal mucosa using gauze. Ice was applied with light pressure for 1 minute. Local anesthesia Lignospan Special (2% lidocaine with 1:80,000 epinephrine; Septodont, Saint-Maur-des-Fossés, France) was then administered.

Group III (Ice + Topical Anesthetic Gel):

Ice was applied to the buccal mucosa at the injection site for 1 minute as described above. After drying the area, Lignospan® Gel (5% lignocaine, Septodont, France) was applied topically using a cotton applicator and left in place for 1 minute before administration of local anesthesia Lignospan Special (2% lidocaine with 1:80,000 epinephrine; Septodont, Saint-Maur-des-Fossés, France).

Group IV (Sucrose Solution + Topical Anesthetic Gel)

The mucosa was first dried, and 5% lignocaine topical anesthetic gel Lignospan® Gel (5% lignocaine, Septodont, France) was applied to the injection site and allowed to act for 1 minute**.** Immediately afterward, the child was given 5 mL of 30% sucrose solution to swish for 1 minute and then expectorate**.** Local anesthesia Lignospan Special (2% lidocaine with 1:80,000 epinephrine; Septodont, Saint-Maur-des-Fossés, France) was administered immediately after these steps.

Group V (Topical Anesthetic Gel Only)

Lignospan® Gel (5% lignocaine, Septodont, France) was applied directly to the dried injection site and left for 1 minute before administering the local anesthetic Lignospan Special (2% lidocaine with 1:80,000 epinephrine; Septodont, Saint-Maur-des-Fossés, France).

Pain perception and physiological responses were assessed using a combination of validated subjective, behavioral, and physiological tools to ensure comprehensive pain evaluation. In this single-blind study, the independent outcome assessor who recorded all pain scores and physiological measurements was blinded to group allocation, while operator blinding was not feasible because the interventions were visibly distinguishable. Subjective pain was assessed using the Wong–Baker Facial Pain Rating Scale (WBFPRS), a self-report measure in which children select one of six facial expressions that represent increasing pain intensity from 0 ("no hurt") to 10 ("hurts worst").[10] Behavioral pain responses were evaluated using two validated observational scales. The FLACC scale assesses five behavioral domains: Face, Legs, Activity, Cry, and Consolability. Each domain is scored from 0 to 2, producing a total score ranging from 0 to 10, with higher scores indicating greater distress.[11] The Sound, Eye, Motor (SEM) scale captures immediate behavioral reactions to pain by rating

vocal response, eye activity, and motor movement. Each category is scored from 0 to 3, giving a total score between 0 and 9. In addition to these subjective and behavioral tools, physiological indicators such as pulse rate and oxygen saturation (SpO_2) were recorded using a calibrated pulse oximeter (Dr. Morepen PO-08, New Delhi, India) because changes in autonomic parameters are known to accompany discomfort and anxiety during dental procedures.

All measurements were systematically recorded at three critical time points: before the injection (preoperative), during the injection, and after the injection (postoperative), to capture dynamic changes in pain perception and physiological response throughout the procedure.

Statistical Analysis

All data were analyzed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). The normality of data distribution was assessed using the Shapiro–Wilk test.

The Kruskal–Wallis test was used to compare pain scores (VAS, WBFPRS, FLACC, SEM) across the five intervention groups. For within-subject comparisons of SpO_2 and pulse rate across three time intervals (pre-operative, during injection, and post-operative), repeated measures ANOVA was employed. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 228 children were assessed for eligibility; 97 did not meet the inclusion criteria and 31 declined to participate. The remaining 100 eligible, cooperative children aged 7–12 years (mean age: 7.0 ± 0.8 years) were enrolled and randomly allocated into five intervention groups (n = 20 each).The gender distribution included 49 males and 51 females. Baseline demographic characteristics, including age and gender, were comparable across all groups, confirming group homogeneity (Table 1).

Table 1. Baseline demographic characteristics of participants across study groups

Demographic Parameter	Overall	Group I	Group II	Group III	Group IV	Group V	Test statistic	p-value	Effect Size
Age (Mean ± SD)	7.0 ± 0.8	8 ± 0.7	9 ± 0.7	7.4 ± 0.3	8.5 ± 0.4	8.2 ± 0.6	F(4,95)=22.14	<0.001	$\eta^2 = 0.48$
Gender – Male/Female	49/ 51	10/10	12/8	9/11	11/9	7/13	$\chi^2 = 2.96$	0.564	Cramer's V = 0.17

ANOVA: Analysis of variance; χ^2: Chi-square test; η^2: Eta squared; Cramer's V: Measure of association for categorical variables; $p < 0.05$ was considered statistically significant.

Pain Perception Assessment

Pain perception was evaluated using multiple validated scales. Analysis of Visual Analog Scale (VAS) scores revealed a statistically significant difference among the five groups (p = 0.016). Group III (ice + topical anesthetic gel) exhibited the lowest mean VAS score (3.26 ± 0.99), indicating the greatest analgesic effect. In contrast, Group V (topical anesthetic gel alone) showed the highest mean pain score (4.74 ± 1.91), followed by Group IV (sucrose + topical anesthetic gel) with a mean of 4.32 ± 1.20 (Table 2).

Similar trends were observed with the Wong-Baker Facial Rating Scale (WBFPRS), where intergroup differences were statistically significant (p = 0.042). Group IV demonstrated the lowest mean WBFPRS score (3.05 ± 1.46), while Group V recorded the highest (4.84 ± 2.08), suggesting increased discomfort in children who received topical anesthetic gel alone (Table 3).

Table 2. Comparison of Visual Analog Scale (VAS) pain scores among study groups

Group	Mean ± SD	95% CI	Median (IQR)	p-value
Group I	4.21 ± 1.47[a]	3.53 – 4.92	4 (4–6)	
Group II	3.58 ± 0.84[a]	2.93 – 4.28	4 (4–4)	
Group III	3.26 ± 0.99[b]	2.64 – 3.96	4 (2–4)	
Group IV	4.32 ± 1.20[a]	3.63 – 5.03	4 (4–5)	
Group V	4.74 ± 1.91[a]	4.04 – 5.44	4 (4–6)	0.016*

*Kruskal–Wallis test; Superscript letters (a, b) indicate statistically significant differences between groups based on post hoc analysis; groups sharing the same superscript do not differ significantly. $p < 0.05$ was considered statistically significant

Table 3. Comparison of Wong–Baker Faces Pain Rating Scale (WBFPRS) scores among study groups

Group	Mean ± SD	95% CI	Median (IQR)	p-value
Group I	3.95 ± 1.40[b]	3.34 – 4.56	4 (3–5)	
Group II	3.53 ± 0.92[b]	3.13 – 3.93	4 (3–5)	
Group III	3.11 ± 1.21[b]	2.58 – 3.64	3 (2–4)	
Group IV	3.05 ± 1.46[b]	2.41 – 3.69	3 (2–4)	
Group V	4.84 ± 2.08[c]	3.93 – 5.75	5 (4–6)	0.042*

*: Kruskal–Wallis test; Superscript letters (b, c) indicate statistically significant differences between groups based on post hoc analysis; groups sharing the same superscript do not differ significantly. $p < 0.05$ was considered statistically significant

The FLACC behavioral pain scores also varied significantly among the groups ($p = 0.001$). Group III recorded the lowest mean FLACC score (1.89 ± 1.17), reflecting minimal observed pain behaviors. Conversely, Group V reported the highest score (4.84 ± 2.08), followed by Group I (sucrose alone), reinforcing the superior efficacy of combination approaches (Table 4).

Assessment using the Sound, Eye, Motor (SEM) scale showed no statistically significant differences across groups ($p = 1.000$). Mean SEM scores ranged from 3.05 ± 1.21 in Group III to 4.21 ± 1.47 in Group V, suggesting a similar pattern to other pain measures, though without statistical significance (Table 5).

Physiological Parameters

Hemodynamic responses were evaluated by monitoring pulse rate and oxygen saturation (SpO_2) at three intervals: preoperative (T0), intraoperative (T1), and postoperative (T2). Pulse rate varied significantly among groups at all time points ($p < 0.001$). Group III showed the most stable cardiovascular response, with minimal intraoperative elevation, while Group V exhibited the highest rise during injection (Table 6).

Table 4. Comparison of FLACC pain scores among study groups

Group	Mean ± SD	95% CI	Estimated Median	Estimated IQR	p-value
Group I	3.89 ± 1.40[c]	3.28 – 4.50	3.9	1.89	
Group II	3.47 ± 0.92[b]	3.07 – 3.87	3.5	1.24	
Group III	1.89 ± 1.17[a]	1.38 – 2.40	1.9	1.58	
Group IV	3.05 ± 1.21[b]	2.52 – 3.58	3.1	1.63	
Group V	4.84 ± 2.08[c]	3.93 – 5.75	4.8	2.81	0.001*

*: Kruskal–Wallis test; Superscript letters (b, c) indicate statistically significant differences between groups based on post hoc analysis; groups sharing the same superscript do not differ significantly. $p < 0.05$ was considered statistically significant

Table 5. Comparison of Sound, Eye, Motor (SEM) pain scores among study groups

Group	Mean ± SD	95% CI	Median (IQR)	p-value
Group I	3.89 ± 1.40	3.28 – 4.50	4 (3–5)	
Group II	3.47 ± 0.92	3.07 – 3.87	3 (2–4)	
Group III	3.05 ± 1.21	2.52 – 3.58	3 (2–4)	
Group IV	3.26 ± 0.99	2.83 – 3.69	3 (2–4)	
Group V	4.21 ± 1.47	3.57 – 4.85	4 (3–5)	1.000 (N.S)

*: Kruskal–Wallis test ($p < 0.05$); $p < 0.05$ was considered statistically significant. No significant (N.S.) intergroup differences were observed

Table 6. Intergroup comparison of pulse rate (beats per minute) at preoperative, intraoperative, and postoperative stages

Groups	Group I	Group II	Group III	Group IV	Group V	p-Value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Pre-op	86.77 ± 5.99[c]	79.08 ± 5.46[b]	76.85± 5.30[a]	77.96± 5.38[b]	86.47 ± 5.97[c]	<0.001
During	95.00 ± 6.56[c]	86.65 ± 5.98[b]	79.58± 5.49[a]	83.11± 5.73[b]	96.07 ± 6.63[c]	<0.001
Post-op	87.04 ± 6.01[c]	81.22 ± 5.60[b]	73.28± 5.06[a]	77.24± 5.33[b]	87.19 ± 6.02[c]	<0.001

Pulse rate was compared across groups and time points using repeated-measures analysis of variance (ANOVA). Post hoc pairwise comparisons were performed to assess intergroup differences at each time point. Superscript letters (a, b, c) indicate statistically significant differences between groups within the same time point; groups sharing the same superscript do not differ significantly. $p < 0.05$ was considered statistically significant

Oxygen saturation levels also differed significantly between groups ($p < 0.001$). Group III maintained the highest SpO_2 readings during and after the procedure, whereas Group V demonstrated the lowest saturation levels intraoperatively, further indicating heightened physiological stress (Table 7).

DISCUSSION

Pain during local anesthesia is a major concern in pediatric dentistry due to its association with fear, anxiety, and future dental avoidance. This study's findings suggest that both sucrose solution and ice, when combined with topical anesthetic, significantly reduced pain perception compared to using any single method.

The results align with findings from Ghaderi *et al.*[9] who demonstrated that precooling the injection site significantly reduces pain behaviors during local anesthesia, supporting the effectiveness of ice in modulating nociceptive transmission. Vafaei et al.[12] also reported that different injection-site preparation methods produce distinct effects on children's pain perception and behavioral responses, emphasizing that sensory-based interventions can meaningfully influence facial expression, withdrawal, and vocalization patterns consistent with the lower FLACC and physiological responses observed in our combination groups. Similarly, oral sucrose has been shown to reduce pain by triggering the release of endogenous opioids, offering analgesic effects similar to morphine.[7,5,13] Ratnaparkhi et al.[14] reported that oral sucrose significantly reduced pain perception during local anesthetic injections in children aged 3–9 years, supporting our observation that sucrose combined with topical anesthetic produced lower behavioral and physiological stress responses than topical anesthetic alone. While sucrose is well established in neonatal analgesia, its efficacy in older children during dental procedures is still emerging.

This study provides compelling evidence for the dual action mechanism. Pain signals are rapidly transmitted via the myelinated A-delta fibers and the non-myelinated C-fibers which are the slow-conducting fibers. As the tissue temperature decreases, the nerve conduction velocity also decreases in both A-delta and C-fibers. Thus, a fall in skin temperature tends to increase the pain threshold in an individual.[15-16]

Ice decreases nerve conduction velocity by reducing the local temperature, leading to an increased pain threshold via inhibition of A-delta and C-fiber transmission.[17] Local cooling is also believed to slow or eliminate pain signal transmission[18] and to retard neuromuscular transmission.[19] In addition, cooling muscle tissue reduces its tone via a reduction in the activity of muscular spindles.[19]

Sucrose stimulates taste receptors that trigger endogenous endorphin release, resulting in behavioral calming and reduced nociceptive processing.[20] Sucrose is said to reduce pain sensation when administered orally and not via gastric lavage.[21] Following the consumption of sweet substances, an increase in endogenous β-endorphin activity was observed in both rat brains and human plasma.[22,23]

These noninvasive, low-cost, and easily administered methods showed substantial effectiveness in clinical settings. Group IV (sucrose + topical anesthetic gel) offered the most consistent reduction across both subjective and objective measures of pain and physiological stress. This suggests that combining gustatory and topical anesthetic approaches can optimize patient comfort during injection procedures.

The findings underscore the importance of multimodal pain management strategies in pediatric dentistry, supporting the inclusion of pre-treatment with sucrose or ice as part of standard protocols, especially in anxious or first-time patients.

Table 7. Intergroup comparison of oxygen saturation at preoperative, intraoperative, and postoperative stages

Groups	Group I	Group II	Group III	Group IV	Group V	p-Value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Pre-op	94.35 ± 1.79[c]	93.57 ± 1.78[c]	96.75 ± 1.84[a]	95.15 ± 1.81[b]	95.09 ± 1.81[b]	<0.001
During	90.51 ± 1.54[c]	90.19 ± 1.53[c]	96.16 ± 1.63[a]	93.17 ± 1.58[b]	88.97 ± 1.51[b]	<0.001
Post-op	94.23 ± 1.5[c]	95.42 ± 1.53[c]	97.29 ± 1.56[a]	96.35 ± 1.54[b]	96.01 ± 1.54[b]	<0.001

Oxygen saturation was compared across groups and time points using repeated-measures analysis of variance (ANOVA). Post hoc pairwise comparisons were performed to assess intergroup differences at each time point. Superscript letters (a, b, c) denote statistically significant pairwise comparisons; identical superscripts indicate no significant difference. Repeated-measures ANOVA was performed to evaluate differences across groups and timepoints ($p < 0.001$)

Although SEM scores did not differ significantly among the groups, this finding should be interpreted considering several influencing factors. The SEM scale, while useful for observing sound, eye, and motor reactions, is less sensitive to subtle variations in pain behavior than validated tools such as the FLACC scale[11] and is more susceptible to observer variability because responses may be brief and influenced by momentary anxiety or movement unrelated to pain. Developmental differences within the 7–12-year age range may have further reduced variability, as younger children tend to express discomfort through more overt behaviors while older children demonstrate greater emotional regulation and may underreport pain.[24] Procedural heterogeneity may also have contributed; extractions are perceived as more invasive and anxiety-provoking than pulp therapy, which can heighten behavioral or physiological responses.[25] These combined factors may explain why the SEM scale did not discriminate effectively among intervention groups, even when other pain measures showed clearer differences.

Variability in prior dental experience may also have influenced outcomes. Although children with clearly unpleasant or painful past treatments were excluded, the study did not differentiate between dental-naïve children and those with neutral or positive experiences. Even non-painful prior encounters can shape expectations, coping behavior, and baseline anxiety during treatment, potentially affecting both behavioral and physiological responses. Together with age-related differences, differences in procedure type, and the inherent limitations of the SEM scale, this residual variability may have contributed to within-group overlap and the non-significant findings for SEM scores. Future studies may benefit from stratifying by procedure type, ensuring tighter age matching, incorporating more sensitive behavioral or physiological pain measures, and documenting prior dental experiences more comprehensively.

The modest sample size per group of 20 may limit the statistical power to detect subtle differences, particularly in subjective outcomes like the SEM scale. Although the sample size was adequately powered, the age distribution was not entirely homogeneous, which may have introduced residual confounding despite randomization. Stratified or block randomization in future research could help ensure age-balanced allocation.

Operator blinding was not feasible because the interventions were visibly distinct, creating the possibility of subtle performance bias. Approaches such as double-dummy designs or using separate operators for intervention delivery and anesthesia administration may enhance blinding.

Pain assessment relied on self-report and behavioral scales, which are inherently subjective and may be influenced by anxiety, temperament, or prior medical experiences. Including objective physiological markers such as salivary cortisol could strengthen the validity of pain measurement. The study captured pain responses during a single clinical encounter and does not address the longer-term impact on dental anxiety, behavior at subsequent visits, or recall of procedural pain. Longitudinal follow-up studies are needed to determine whether these analgesic approaches provide sustained benefits.

CONCLUSIONS

It is a well-known challenge to ensure pain-free local anesthesia delivery in children. However, the use of simple non-pharmacological methods such as ice application can significantly improve patient comfort. The present study showed that ice, especially when combined with topical anesthetic gel, provides superior pain control and more stable physiological responses compared to topical anesthetic alone. Additionally, sucrose, when used alone or in combination, also demonstrated measurable benefits in reducing pain perception, suggesting its potential as a practical, safe, and palatable alternative to enhance analgesia during pediatric dental procedures. Ice and sucrose thus emerge as effective adjuncts to improve cooperation and reduce distress during local anesthesia administration in children.

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Factors that affect the duration of dental treatment in children during general anaesthesia

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Highlights

- Accurate prediction of treatment duration under general anaesthesia is important to improve operating room efficiency and patient safety in children.
- Less experienced dentists required longer operative times, while the tooth-specific calculation tool closely predicted actual treatment duration.
- Improved treatment planning may enhance clinical efficiency and support safer paediatric dental care under general anaesthesia.

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Abstract

Aim: This study aimed to evaluate the dentist's experience, types of procedures performed, and secondary factors that may affect dental treatment in paediatric patients under general anaesthesia (GA). **Methods:** A retrospective cohort study of paediatric patients who underwent dental treatment under general anaesthesia at Baskent University Hospital between 2016 and 2020 was carried out. Patient demographic data were collected, the planned and applied treatment procedures were noted, and the operating times were recorded. Using a newly developed calculation tool, estimated procedure times were calculated for the planned treatments. Years of work as a specialist were recorded to analyse the impact of operator experience. **Results**: The mean age of the patients was 5.29 years (±1.94 SD), and 58.8% were male. Statistically significant differences were observed in procedure times when comparing patients with and without systemic diseases. Additionally, dentists with 5 years of experience or less required significantly longer procedure times under general anaesthesia compared to those with 6 to 10 years of experience ($p=0.003$) and those with more than 10 years of experience ($p<0.001$). However, no significant difference was found between the groups with 6 to 10 years of experience and those with over 10 years of experience ($p=0.144$). In the obese patient group, dentists with 5 years of experience or less had significantly longer procedure durations than more experienced dentists ($p=0.047$). **Conclusions**: Dentists' experience positively affected the duration of the procedure and the preferred type of procedure performed under GA. A new tool was developed to estimate treatment durations under GA.

Keywords: Body Mass Index; Dental Health; General Anaesthesia; Paediatric Dentistry

INTRODUCTION

Some paediatric patients may need dental treatment under general anaesthesia (GA), which is a safe and convenient procedure for dentists and patients.[1] The American Academy of Pediatric Dentistry (AAPD) recommends GA for paediatric dental patients who are unable to cooperate; those who are extremely fearful, anxious, or uncommunicative; those who have complex medical/physical/mental conditions; those who can benefit from GA, protecting them from psychological trauma and reducing medical risks; and those who require immediate comprehensive dental rehabilitation.[2] An operating room (OR) is often considered the most appropriate setting for providing such care to patients with complex medical conditions. [3,4] In some cases, anaesthesiologic requirements are not fully considered, and dental care under GA has been reported to be more cost-effective than repeated outpatient restorative visits.[5] It has been recommended that safe and efficient completion of dental treatment under GA requires specialized training, knowledge, adaptability, and techniques beyond routine practice, in addition to adherence to established protocols and guidelines.[1,6] Paediatric dentists are trained to recognize the need for hospital-based dental treatment and work with an anaesthesia team to provide optimal patient care.[3]

It was reported that the average waiting time for complex dental care for children in pain is 28 days for GA, and without pain, the waiting time for GA is 71 days.[7] Thus, there are substantial increases in the number of patients seeking care and the length of time that children must wait for treatment. Although this is because of insufficient resources in some cases, it is still concerning.[7] It has been reported that the reason for the long waiting times for treatment under general anaesthesia is the high number of patients with medical needs other than dental treatments in the operating rooms, the lack of personnel, the high number of patient-related cancellations, and the insufficient use of time in the operating room.[3,8-10] Improvements in the use of the operating room for paediatric dental procedures will increase the number of patients who can receive treatment, reduce waiting times, prevent delays in dental treatment in children, reduce the use of analgesics and antibiotics, and increase patients' quality of life.[11]

Despite the increasing demand for paediatric dental treatment under general anaesthesia, accurate prediction of operative time remains challenging. Existing studies have mainly evaluated procedural types or patient characteristics separately, and most estimation approaches rely on generalized or quadrant-based calculations that may overlook the cumulative impact of multiple procedures performed on individual teeth.[8] This limitation may contribute to inefficient operating room scheduling, prolonged anaesthesia exposure, and increased waiting times for treatment.[3,7] Therefore, a comprehensive model that simultaneously considers operator experience, patient-related factors, and tooth-specific procedural details is needed to improve time prediction and optimize clinical workflow in paediatric dental GA settings.

Another concern about the dental treatments performed under general anaesthesia is the safety of the procedures.[12] Recently, the US Food and Drug Administration (FDA) reported that exposure to certain sedatives and general anaesthetics might affect the brain development of children under 3 years of age, especially for procedures longer than 3 hours.[12] For several years, there has been debate about its effects on brain development.[13] Additionally, recent studies revealed an increased risk associated with prolonged dental procedures under general anaesthesia. This underscores the critical importance of predicting procedure time.[14] Previous studies have analysed the duration of dental procedures and surgeries provided to

paediatric patients under general anaesthesia, but no studies have evaluated dentists' experience, and no study has introduced a practical, procedure-based calculation tool for estimating treatment durations under GA in paediatric dentistry.[14-17]

This study aimed to investigate the GA time utilized for dental procedures for paediatric patients to improve the planning of OR scheduling and to better understand the GA time requirements through a retrospective cohort study. For these purposes, it was planned to assess the relationship between dentists' experience and GA duration in paediatric dental procedures. Correspondingly effects of patient factors—including systemic disease, ASA classification, BMI, and radiographic assessment—on procedure time were evaluated. Finally, we have developed and tested a new calculation tool designed to predict procedure durations more accurately than the existing quadrant-based methods. By combining operator-related, patient-related, and procedural variables, this study aims to improve OR scheduling efficiency, optimize clinical workflow, and contribute to safer, more predictable paediatric dental care under GA.

METHODS

This retrospective cohort study was approved by the Baskent University Institutional Review Board and Ethics Committee (Project no: D-KA20/45) on 08/01/2021. The study population comprised all paediatric GA cases, including those with ASA grades of 1, 2, and 3, from January 2016 to December 2020. GA for complete dental treatment was deemed necessary when children were unable to cooperate or had physical or mental impairments that inhibited cooperation, based on the expert opinion of the treating dentist. Informed consent was not deemed necessary for this de-identified retrospective study. Patients scheduled for combination cases involving nondental services and those with prolonged bleeding time and allergic reactions during the procedure were excluded from the study; no additional exclusion criteria were applied. A total of 23 patients were excluded from the study because of eligibility criteria. A total of 400 subjects met the study requirements. In our clinical routine, the guardian of the patient who is scheduled for general anaesthesia selects the dentist. This choice is made in the reception area, independent of the dentist.

The following data were recorded for descriptive statistics: age, sex, weight, height, BMI, American Society of Anesthesiologists (ASA) Physical Status Classification System status, systemic diagnoses, number of teeth treated, planned and applied dental treatments and their estimated operation times, and dental operator experience. The duration of dental cases was obtained from anaesthesia and surgical records. The following times were recorded: (1) the patient's presentation in the OR; (2) when the patient was "anaesthesia ready"; (3) the beginning of the dental operation; (4) the completion of the dental operation; and (5) the completion of anaesthesia (patient's arrival in a post-anaesthesia care unit (PACU)). The duration of the operation was considered the time elapsed (in minutes) from the start of the dentist's actions to when the last dental manipulation was finished.

The time estimates for scheduling dental procedures under the GA were calculated using a modified version of the previously described guidelines (Table 1).[18] The difference between the actual and estimated processing times was calculated using plus and minus values. A single dental examiner collected all dental and medical records. Inconsistencies identified during data collection were resolved by cross-checking electronic and paper records. Any discrepancies not resolved in this manner were excluded from the case study.

Table 1. Estimating case time.[18]

Procedure	Time (mins)
Primary dentition:	
1 posterior tooth restoration	7.5
1 anterior tooth restoration	5
Pulpotomy	5
Anterior teeth pulpectomy	10
1 anterior tooth extraction	1
1 posterior tooth extraction	2
Stainless steel crown	5
Strip crown	7
Fissure sealant	3
Restorations of severely crowded teeth	+5*
Permanent dentition:	
1 posterior tooth restoration	10
1 anterior tooth restoration	10
1 anterior tooth extraction	5
1 posterior tooth extraction	7
Fissure sealant	3
Restorations of severely crowded teeth	+10*

Example: Restorations for 4 primary posterior teeth for 2 of them pulpotomy and 1 stainless steel crown and 2 anterior primary teeth and 1 permanent molar teeth would require (4×7.5)+(2×5)+(1 × 5)+(2x5)+(1x10)=65 minutes dentist operator time.* Additional time for severely crowded teeth

The dental diagnosis was made based on radiographic findings when the patient cooperated sufficiently to allow them; otherwise, it was based solely on visual data. In our study, the total number of procedures varied across all the cases, resulting in differences in procedure times. However, calculations were performed on a per-procedure basis. In addition, it was determined whether the teeth were permanent or primary, and teeth that had undergone restorative or preventive pulp treatment or had been extracted were recorded. To analyse the impact of the operator's experience, the number of years for which the person had worked as a specialist was taken as a basis. All procedures were performed in accordance with the ethical standards of the institutional and national research ethics committees.

Statistical analyses of the data were performed using the Statistical Package for the Social Sciences (SPSS) version 25.0. Quantitative data were summarized as the mean, median, standard deviation, and interquartile range (IQR), whereas qualitative data were collected as numbers and percentages. The Kolmogorov–Smirnov test was used to test whether the data were normally distributed, and the homogeneity of variances was evaluated with Levene's test. The Mann–Whitney U test was used to assess dental procedure times by the presence of systemic diagnoses and radiography. One-way ANOVA and the Kruskal–Wallis test were used to evaluate the duration of dental procedure according to the age group, ASA classification, physician experience, and BMI.

RESULTS

This study revealed 400 patients who underwent treatment under general anaesthesia; 58.8% of the patients were male (n = 235), and 41.3% were female (n = 165). The patients' mean age was 5.29 ± 1.94 years (1.42 to 15.42 years). The following age categories were used: Group I: 17- to 47-month-old patients (n=96, 24%); Group II: 48- to 59-month-old patients (n=84, 21%); Group III: 60- to 71-month-old patients (n=106, 26.5%); Group IV: 72- to 83-month-old patients (n=53, 13.3%); and Group V: patients who were at least 84 months old (n=61, 15.3%). The mean and median durations of GA were 69.42 and 65 minutes, respectively, and the durations ranged from 15 to more than 165 minutes. When the distribution of dental treatment times applied under general anaesthesia was examined according to age group, no statistically significant difference was found (p=0.934) (Table 2).

Table 2. Descriptive features and distribution of predicted and actual treatment durations in minutes.

		Predicted times (min)			Actual treatment times (min)		
	n* (%)	Mean±SD	Median (IQR)	p	Mean±SD	Median (IQR)	p
Age Groups							
[17-47] months	96 (24.0)	74.28±30.23	70.50 (43)	.001KW	68.07±25.97	65 (34)	.934KW
[48-59] months	84 (21.0)	83.73±26.85	81.25 (37)		71.49±25.46	65 (39)	
[60-71] months	106 (26.5)	73.87±23.05	71.50 (26)		69.43±24.95	65 (35)	
[72-83] months	53 (13.3)	72.35±22.32	72 (28)		67.49±23.66	60 (25)	
84+ months	61 (15.3)	60.78±23.22	62 (30)		70.33±26.35	65 (40)	
BMI							
Underweight (<5p)	56 (14.0)	78.61±24.88	73 (31)	.387KW	69.32±22.19	62.50 (34)	.363KW
Healthy weight (5p-85p)	162 (40.5)	73.98±26.98	71 (33)		68.02±22.82	65 (35)	
Overweight (85p-95p)	22 (5.5)	66.91±20.08	66 (30)		61.14±24.44	60 (21)	
Obesity (>95p)	42 (10.5)	73.79±29.71	68 (43)		71.19±27.18	70 (36)	
Radiography							
Yes	329 (82.3)	73.56±25.71	71 (32)	.361U	68.73±24.71	65 (35)	.411U
No	71 (17.8)	75.15±29.89	79 (37)		72.61±27.67	70 (40)	
Systemic Diagnoses							
Yes	99 (24.8)	65.61±24.54	63 (34)	.001U	64.01±23.21	60 (30)	.011U
No	301 (75.2)	76.58±26.54	74 (31)		71.20±25.70	70 (40)	
Systemic Diagnoses							
Cardiological disorders	36 (41.0)	61.35±27.37	61 (38)	.417F	63.25±22.71	60 (24)	.140KW
Metabolic diseases	26 (29.5)	65.10±24.37	61.25 (33)		55.19±18.99	60 (23)	
Nervous system diseases	26 (29.5)	69.90±22.06	76.50 (34)		70.38±25.41	60 (41)	

n*: Number of patients, Min: Minutes; U: Mann-Whitney U Test, F: One-way ANOVA Test, KW: Kruskal-Wallis Test

The ASA classifications were distributed as follows: ASA I (ASA 1: healthy patients) (n=308; 77%), ASA II (ASA 2: mild to moderate systemic disease) (n=74; 18.5%), and ASA III (ASA 3: severe systemic disease) (n=17; 4.3%). The most prevalent systemic diagnoses corresponded to "cardiological disorders" (n=43 patients; 10.5%) and "metabolic diseases" (n=33 patients; 8.1%), followed by "nervous system diseases" (n=32 patients; 7.8%). A statistically significant difference was observed when comparing the actual and predicted procedure times for patients with and without systemic disease (p=0.011 and p=0.001, respectively). In addition, no difference was observed when the patients were examined according to the type of systemic disease (p>0.05).

When the number of years of work as a specialist in paediatric dentistry was examined, three groups were formed. The first group had 5 years of experience or less (n=150), the second group had 6–10 years of experience (n=137), and the third group had > 10 years of experience (n=113). When the duration of treatment under GA was examined according to dentist experience, years of professional experience were found to result in statistically significant differences. According to the results of the Mann–Whitney U test with Bonferroni correction for multiple comparisons, a significantly longer duration of the actual procedure was needed for the dentists who had less than 5 years of experience compared with dentists who had 6–10 years of experience or more (p=0.003). It was also observed that there was a significant difference (p<0.001) between dentists with less than 5 years of experience and those with more than 11 years of experience. However, there was no significant difference between specialists in Paediatric Dentistry with 6–10 years of experience and those with 11 or more years of experience (p=0.144).

Patients were considered overweight or obese based on their BMI and age-related predictive growth charts from the Centers for Disease Control and Prevention.[19] Based on these criteria, 56 patients (14%) were underweight, 22 patients (5.5%) were overweight, and 42 patients (10.5%) were obese. When the duration of the treatments applied under general anaesthesia was examined according to the BMI, it was observed that there was no statistically significant difference between the predicted procedure times and the actual procedure times (p=0.387 and p=363, respectively). When the duration of the procedures performed according to the experience of the paediatric dentist was examined only in the patient group defined as obese, it was observed that there was a statistically significant difference (longer operating duration) in the group of physicians with 5 years of experience or less (Table 3) (Figure 1).

While the planning of treatments to be applied under general anaesthesia was performed according to radiographic evaluations for 329 patients, only visual examination methods were used for 71 patients because radiographs could not be obtained. There was no significant difference in terms of the predicted times and actual treatment times according to the previous diagnoses based on the radiographic findings (p=0.361 and p=0.411, respectively). However, in the patient group in which dental procedures were performed under general anaesthesia without previous radiographic diagnoses, it was observed that the actual procedure duration was longer than the predicted duration calculated according to the applied procedures (Table 2).

In all the evaluated groups, the combination of two dental treatment modalities—surgical (primary and permanent tooth extraction) and restorative—was the most common. The frequencies of the treatment modalities applied were similar for all groups. The frequency of application of stainless-steel crowns and fissure sealants is given in Table 4.

Table 3. Actual and predicted time distribution according to physician experience and patients' body mass index.

		Predicted times (in minutes)			Actual treatment times (in minutes)		
	n	Mean±SD	Median (IQR)	p	Mean±SD	Median (IQR)	p
Dentists Experience							
5 years and less	150	75.29±26.42	74.25 (33)	.420KW	76.73±25.78	75 (30)	<.001KW
6-10 years	137	73.63±27.23	72 (34)		67.75±26.87	60 (45)	
11 years and more	113	72.17±25.69	69 (30)		61.73±19.47	61.73 (30)	
Underweight patients (<5p)				.861KW			.246KW
5 years and less dentists	25	77.70±26.37	70 (37)		75.60±24.08	70 (40)	
6-10 years dentists	16	78.94±27.34	73 (43)		66.69±19.52	60 (24)	
11 years and more dentists	15	79.77±20.86	76 (26)		61.67±19.79	60 (30)	
Healthy weight patients (5p-85p)	58	73.84±27.62	76 (35)	.737KW	71.98±24.39	67.50 (35)	.135KW
5 years and less dentists	48	75.31±26.28	71.75 (29)		68.75±24.94	65 (40)	
6-10 years dentists	56	72.99±27.32	69.75 (31)		63.30±18.35	60 (25)	
11 years and more dentists				.796KW			.460KW
Overweight patients (85p-95p)	7	66.00±16.44	69.50 (32)		74.29±31.94	60 (70)	
5 years and less dentists	8	62.63±23.19	66.25 (41)		60.00±14.64	57.50 (20)	
6-10 years dentists	7	72.71±21.18	62 (32)		49.29±21.30	50 (35)	
11 years and more dentists							
Obesity (>95p)							
5 years and less dentists	17	79.21±26.88	74 (36)	.212KW	83.82±26.90	75 (45)	.047KW
6-10 years dentists	17	74.68±32.98	65 (50)		64.71±24.78	70 (45)	
11 years and more dentists	8	60.38±27.40	55.50 (34)		58.13±24.19	55 (28)	

n*: Number of patients; KW: Kruskal-Wallis Test

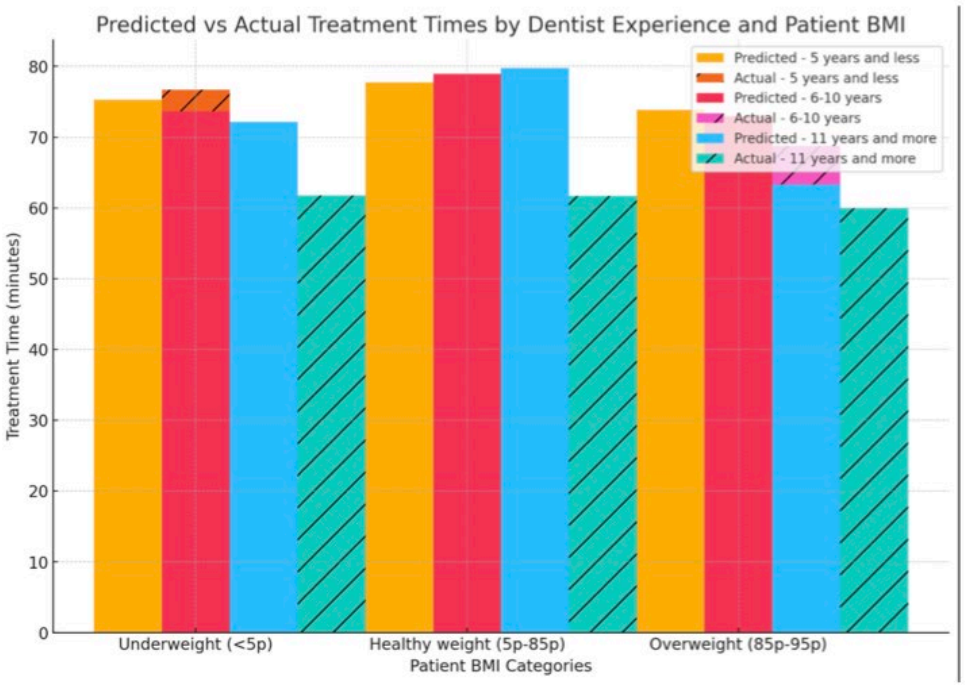

Figure 1. Comparison of predicted and actual treatment times by dentist experience and patient BMI category

Table 4. Distribution of stainless-steel crown and fissure sealant applications.

	Stainless-steel crown	Fissure sealant
Dentists Experience	n	n
5 years and less	36	46
6-10 years	110	18
11 years and more	28	7
Age Groups of the patients		
[17-47] months	51	0
[48-59] months	30	4
[60-71] months	55	24
[72-83] months	27	17
84+ months	11	26
BMI of the patients		
Underweight (<5p)	35	19
Healthy weight (5p-85p)	84	31
Overweight (85p-95p)	8	5
Obesity (>95p)	12	2

n*: number of dental procedures

DISCUSSION

The demand for dental treatment under GA continues to increase in patients with special needs who are unable to cooperate, extremely fearful, anxious, or uncommunicative.[1,20] Currently, no universally accepted protocols exist for dental treatment performed under GA.[1] Completing full-mouth rehabilitation in a single GA session is advantageous for patients and families compared to multi-session treatments.[20] However, predicting serious adverse events during prolonged procedures remains challenging, supporting recommendations for hospital-based dental treatment in such cases.[14,21,22]

Although the FDA has issued warnings regarding possible adverse effects of anaesthetics and sedatives—such as oxygen desaturation or hypotension—especially in procedures longer than 3 hours, [12] studies have reported no severe complications in paediatric dental GA.[6] Efficient OR time use remains a priority,[14] and predicting procedure duration before treatment begins is essential.[1] Foley et al. [8] evaluated "lost" OR time and reported no significant difference between experienced and trainee providers. In contrast, our study revealed that dentists with ≤5 years of experience had significantly longer operative times than those with 6–10 or ≥11 years of experience did, while no difference was observed between the two more experienced groups. These findings support previous findings that operator experience reduces treatment duration.[23] In our data, stainless steel crowns were more often placed by dentists with 6–10 years of experience, whereas fissure sealants—a preventive measure—were more frequently applied by less experienced dentists, possibly reflecting differences in training approaches.

Permanent tooth extractions under GA were relatively infrequent compared with primary tooth extractions, consistent with prior research.[17] Stainless steel crowns were more common in

younger age groups, whereas the use of fissure sealant was low across all ages. Similar to earlier studies, age influenced the type of procedures performed.[24] Longer-than-expected treatment times in older children, especially those with special needs, may be because of more complex permanent tooth care, examination difficulties, or additional conditions such as periodontal disease or impacted teeth.[17,18,25]

Some studies have reported no difference in GA duration between patients with and without systemic or developmental conditions, whereas others have reported fewer restorative procedures for children with disabilities.[26] In addition to operator-related variables, several patient-related characteristics may influence the duration of dental treatment under general anaesthesia. Systemic health status, BMI, radiographic availability, and cooperation level can alter both treatment complexity and intraoperative decision-making. In medically compromised children, treatment plans are often simplified to minimize anaesthetic exposure, which may explain the shorter procedure durations observed in this group.[27–29] Conversely, the absence of preoperative radiographs may lead to unexpected intraoperative findings, requiring additional interventions and prolonging the operative time, as radiographic assessment has been shown to improve diagnostic accuracy and treatment planning.[28,29] Similarly, obese patients may present limited oral access and positioning challenges that can increase operative time, particularly when managed by less experienced clinicians.[6] These findings emphasize that patient-related factors interact with operator experience and should be considered collectively when estimating GA duration.

Dentists often plan simpler treatments for special healthcare needs (SHCN) patients to improve prognosis and reduce GA time.[27–29] Our results are in line with those of Forsyth et al.[18], who reported shorter actual and predicted procedure times in medically complex patients compared with healthy ones. This may reflect a more aggressive approach to completing essential treatment quickly. Additionally, certain systemic conditions may influence procedure time; for example, hypoplastic-hypomineralized teeth are frequent in transplant patients because of intensive drug use.[30,31] Due to the retrospective nature of our study, we could not assess the time per restoration for these teeth; however, prospective research could address this issue.

The mean treatment duration in our study (69.42 min) was comparable to that reported by Ibrahim et al.[15] and Arabovis et al.[16] When radiographs were unavailable—often in younger patients or those with neurological conditions—actual procedure time exceeded predictions. These findings support previous findings that radiographs improve diagnostic accuracy compared to visual inspection alone.[28,29] The absence of radiographs likely led to intraoperative findings that required unplanned procedures, thereby extending the GA time.

Although BMI did not significantly affect procedure time, obese patients treated by less experienced dentists required longer durations. This may be due to limited oral access, the need for additional preparation time, and anaesthesia adjustments, which require advanced clinical skills.[6]

Time estimates were calculated using a tool adapted from a study by Forsyth et al.[18] Unlike previous quadrant-based estimation methods, the calculation tool used in this study adopts a tooth-specific approach that accounts for the exact number and type of procedures performed. This allows a more individualized estimation of operative time, particularly in complex full-mouth rehabilitation cases frequently encountered under GA.[18] From a clinical perspective, such precise time estimation may support more efficient operating room scheduling, reduce unexpected overtime, and limit prolonged anaesthetic

exposure, which has been associated with potential safety concerns in paediatric patients undergoing longer procedures.[12,14] Therefore, the proposed model provides not only methodological novelty but also practical clinical relevance for optimizing OR efficiency and improving patient safety. By shifting from a quadrant-based approach to a tooth-specific approach, we achieved closer alignment between the predicted and actual times. This method accounts for multiple procedures per quadrant and allows for additional time in complex cases. Prospective studies should refine the model by incorporating variables such as lesion extent, dental anomalies, and dmfs/DMFS scores.

The retrospective design limited data collection on factors such as caries activity, periodontal health, and oral hygiene, which may influence the duration of GA. Another limitation of this study is that the experience and workflow integration of auxiliary dental staff, such as dental assistants, were not evaluated. Operative efficiency under general anaesthesia is not determined solely by the dentist's experience; effective coordination between the clinician and assisting personnel influences instrument handling, patient positioning, and overall procedural flow. Even highly experienced clinicians may require longer operative times when working with inexperienced assistants, whereas well-trained support staff may contribute to shorter and more efficient procedures. Previous studies evaluating operating room efficiency in paediatric dental general anaesthesia settings have emphasized that team organization and workflow dynamics can affect operative time utilization and scheduling efficiency.[8,21] Therefore, future prospective studies should include the experience level and team dynamics of auxiliary staff to provide a more comprehensive prediction model for treatment duration under general anaesthesia.

CONCLUSIONS

The duration of paediatric dental procedures under GA is influenced by both operator and patient factors. Less experienced dentists (<5 years) required significantly longer treatment times, particularly in obese patients, whereas those with systemic diseases generally had shorter durations because of more conservative treatment planning. The absence of radiographic evaluation was associated with longer-than-expected procedures, highlighting the importance of accurate preoperative assessment.

The tooth-specific calculation tool developed in this study provided procedure time estimates that closely matched actual durations and represented a practical improvement over previous quadrant-based models. Its adoption in OR scheduling could enhance efficiency, reduce anaesthesia exposure, and improve patient throughput.

In terms of clinical recommendations, complex or time-sensitive cases under GA should be assigned to more experienced operators, radiographic assessments should be used whenever possible to increase planning accuracy, and targeted training for the management of obese paediatric patients under GA should be provided.

Future prospective studies should validate this calculation tool in diverse clinical settings and integrate additional oral health variables to further improve prediction accuracy.

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Comparative evaluation of staining and micro-shear bond strength of silver diamine fluoride, silver diamine fluoride with potassium iodide, and ammonium hexafluorosilicate on primary teeth: An in-vitro study

Tanya Sinha[1] ✉, Praveen Kumar S Bali[2], Bharath KP[3], Mallikarjuna K[4], Patil Disha[5], Poornima Parameshwarappa[6]

Highlights

- The study compared color stability and bond strength of silver diamine fluoride (SDF), SDF with potassium iodide, and ammonium hexafluorosilicate on primary teeth.
- SDF and SDF with potassium iodide caused severe discoloration, while ammonium hexafluorosilicate showed better color stability and higher bond strength.
- Ammonium hexafluorosilicate may be a preferable alternative in primary teeth where esthetics and composite bonding are clinically important.

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Abstract

Aim: To compare and evaluate the staining and micro-shear bond strength of composite resin following the application of silver diamine fluoride, silver diamine fluoride with potassium iodide, and ammonium hexafluorosilicate on primary teeth. **Methods**: Forty-five extracted human primary teeth were divided into three groups (n = 15) according to the surface treatment received: silver diamine fluoride, silver diamine fluoride with potassium iodide, and ammonium hexafluorosilicate. Color changes were measured at baseline, 5 minutes, 7 days, and 30 days using spectrophotometry. Following surface treatment, composite resin was bonded, and the specimens were subjected to thermocycling. Micro-shear bond strength was then evaluated using a universal testing machine. The statistical significance was set at $p< 0.05$. Repeated measures ANOVA and Post Hoc Tukey HSD test was performed. **Results:** Teeth treated with ammonium hexafluorosilicate demonstrated the least discoloration and the highest lightness values at 30 days. Silver diamine fluoride with potassium iodide exhibited the greatest color change compared to silver diamine fluoride. Micro-shear bond strength was significantly higher in the ammonium hexafluorosilicate group compared to both silver diamine fluoride and silver diamine fluoride with potassium iodide ($p < 0.05$). **Conclusions**: Ammonium hexafluorosilicate exhibited superior color stability and higher micro-shear bond strength compared to silver diamine fluoride and silver diamine fluoride with potassium iodide, indicating its potential as a more aesthetic and durable alternative in pediatric restorative treatments.

Keywords: Dental Bonding; Potassium Iodide; Silver Diamine Fluoride; Tooth Deciduous; Tooth Discoloration

INTRODUCTION

Silver diamine fluoride (SDF) is an effective and widely used tooth preservation technique in paediatric dentistry; however, its major drawback is the characteristic black discoloration of treated lesions, which results in poor patient and parental acceptability.[1] To overcome this limitation, potassium iodide (KI) has been used adjunctively to reduce caries discoloration, while ammonium hexafluorosilicate (AHF) has emerged as a more promising alternative with comparable caries-arresting potential and improved aesthetics.

Silver diamine fluoride (SDF) is a topical fluoride agent composed of silver, ammonia and fluoride ions commonly used in 38% concentration containing 44,800ppm fluoride.[2] It exhibits potent antimicrobial, promotes remineralization, and inhibits collagen degradation within dentin. Its unique "zombie effect" enables dead bacteria to additionally kill surrounding microorganisms. One drop contains 0.025 ml and around 2.24 mg of fluoride. One drop is sufficient to treat five teeth.[3] Despite its effectiveness, SDF treatment results in black staining of carious lesions due to silver precipitation.

To enhance the aesthetics of the SDF-treated teeth, potassium iodide (KI) is used as it forms a white precipitate and temporarily decreases the discolouration. It can however lower the anti-caries potential with time due to the lowered available silver ions.[5,6] Although KI has been shown to be useful in controlling the initial discoloration, its effect in the long- term aesthetics is debatable.[7]

Ammonium hexafluorosilicate (AHF) is a stain-free alternative to SDF and contains ammonium, silicon, and fluoride ions. It enhances fluoride uptake, promotes hydroxyapatite formation, and occludes dentinal tubules with silica-calcium phosphate precipitates.[8,9] Due to its improved resistance against demineralization and less staining potential, it is a promising candidate in aesthetic, non-invasive dental care in kids.[10,11]

This study aimed to compare and evaluate staining potential and micro shear bond strength of Silver Diamine Fluoride (SDF), Silver Diamine Fluoride with potassium iodide (SDF + KI), and AHF on primary teeth. The null hypothesis tested was that no significant difference in the change of colour and microshear bond strength of composite to teeth after treatment with silver diamine fluoride, silver diamine fluoride with potassium iodide and ammonium hexafluorosilicate.

METHODS

Ethical Approval and Study Design

The research protocol received formal approval from the Institutional Ethics Committee (Institutional Ethics Committee, College of Dental Sciences, Davangere, Karnataka, India (ID: CODS/IEC/23/2022-23).

Inclusion & Exclusion Criteria

Forty-five extracted carious primary teeth were collected with ICDAS II scores 4 & 5 without involving the pulp chamber, teeth without fractures or developmental defects were included in the study. Teeth with developmental defects, fractures, deep caries involving the pulp chamber, teeth with restorations were excluded from the study.

Sample Size Calculation

The sample size was determined using the formula $n = Z^2\sigma^2/e^2$, with variance estimates obtained from previous study of similar design. Substituting these values in the formula, for a 95% confidence interval and 80% power, the sample size estimated was 15 per group. Thereby, the total sample size was 45. The samples were randomly allocated into three groups (n = 15): Group A—38% Silver diamine fluoride (SDF) Gel (Kedo®, Chennai, India); Group B—38% Silver diamine fluoride Gel followed by 10% potassium iodide (SDF+KI)

(Kedo®, Chennai, India); and Group C—Ammonium hexafluorosilicate (AHF) (Otto Chemie Pvt. Ltd., Mumbai, India).

Specimen Preparation

A total of 45 teeth were cleaned and debris were removed from the surface of the teeth using a spoon excavator. The teeth were sectioned at the cementoenamel junction and the roots were removed and the remaining teeth material were embedded into the acrylic. The cusps were flattened using a diamond disc to obtain a standardized carious surface.

Colour Analysis

Baseline colour measurements were recorded prior to agent application. A dab of Silver diamine fluoride gel (SDF) and silver diamine fluoride gel with potassium iodide (SDF+KI) were carried and applied using microbrush applicators for 1 minute each, whereas ammonium hexafluorosilicate (AHF) was prepared as a 0.476 mol/L solution and applied for 3 minutes using a cotton swab. The specimens were then thoroughly rinsed and stored in artificial saliva. Colour change was evaluated visually and instrumentally using the CIE L*a*b* colour system at 5 minutes, 1 week, and 1month post-application. Instrumental colour measurements were obtained using a spectrophotometer (Konica Minolta CM-5, Konica Minolta Inc., Japan).

Specimen Preparation for Micro-shear Bond Strength

45 dentin slices measuring 2 mm in thickness and 0.8 mm in width were made using Bainpol VT (Single Disc Table Top Grinder/Polisher) under water coolant and embedded in acrylic resin. Following application of the respective agents, composite resin (D-tech Compomax composite restorative kit) was bonded using a silicone mould (2 mm height × 0.8 mm diameter).

Micro-shear Bond Strength

The specimens were stored in artificial saliva at 37 °C for 24 hours and then subjected to 1000 thermocycles (Holmarc Thermocycler Model HO-THC-01) between 5 °C and 55 °C. Micro-shear bond strength testing was performed using a universal testing machine (Instron Universal Testing Machine e-3000) with a knife-edge loading head at a crosshead speed of 1 mm/min until bond failure.

RESULTS

AHF consistently exhibited the least reduction in lightness (L), whereas silver diamine fluoride (SDF) showed greatest darkening over time, which was more pronounced at the 30th day ($p < 0.001$), indicating significant discoloration. As shown in Table 1**,** AHF initially demonstrated the highest red values along the red-green axis (a*). Both SDF and SDF+KI showed progressive shift toward green with greatest reduction observed in the SDF+KI group at 30 days ($p = 0.018$). Along the yellow-blue axis (b*), AHF initially exhibited the highest yellow values, while both SDF and SDF+KI showed marked yellow fading, with SDF demonstrating a shift toward blue- grey hues over time. Notably, at 30 days, AHF showed partial recovery of yellow values, resulting in higher b* values compared to the other groups.

Total colour change, by ΔE values, indicated SDF +KI exhibited the greatest change (ΔE = 10.541), followed by SDF, suggesting clinically perceptible staining. AHF demonstrated a moderate ΔE (6.117) indicating improved colour stability. The difference in colour change SDF-treated groups and AHF was found to be statistically significant ($p < 0.05$), confirming greater long- term staining associated with SDF and SDF+KI.

Post-hoc Tukey analysis revealed significant intergroup differences as shown in Table 2. Both SDF and SDF+KI exhibited greater darkening and colour shifts towards green and blue compared to AHF. In contrast, AHF consistently showed better colour preservation at 30 days, supporting its potential as a more aesthetic caries- arresting agent in paediatric dentistry. With respect to microshear bond strength as shown in Table 3 and 4, AHF demonstrated significantly high values (10.86 MPa) compared to SDF (5.09 MPa) and SDF+KI (4.30 MPa), with no statistically significant difference between the latter two groups.

These findings indicate that, in addition to superior colour stability, AHF provides enhanced bonding performance, highlighting its potential as a promising alternative to conventional silver-based caries arresting agents. Post hoc tukey test also shows significant change in microshear bond strength with AHF having highest strength followed by SDF+KI and SDF.

Table 1. Multiple comparison of mean difference in L*, A* & B* values at baseline, 5 mins, 7th day and 30th day after application of agents

Measurement	Group Name	N	Mean	SD	p value
Baseline L*	SDF-BL	15	63.297	6.106	0.231
	SDF+KI-BL	15	65.505	4.723	
	AHF-BL	15	66.393	2.927	
Baseline A*	SDF-BL	15	2.964	1.068	0.016*
	SDF+KI-BL	15	2.981	1.119	
	AHF-BL	15	4.153	1.237	
Baseline B*	SDF-BL	15	5.270	1.417	0.005*
	SDF+KI-BL	15	6.184	1.803	
	AHF-BL	15	7.297	1.655	
5 min L*	SDF-BL	15	62.379	5.071	0.351
	SDF+KI-BL	15	62.975	4.495	
	AHF-BL	15	64.326	2.663	
5 min A*	SDF-BL	15	2.471	1.152	<0.001*
	SDF+KI-BL	15	1.929	0.790	
	AHF-BL	15	4.199	1.256	
5 min B*	SDF-BL	15	4.530	1.592	0.006*
	SDF+KI-BL	15	5.668	2.139	
	AHF-BL	15	6.879	2.008	

Table 1. Multiple comparison of mean difference in L*, A* & B* values at baseline, 5 mins, 7th day and 30th day after application of agents (continued)

Measurement	Group Name	N	Mean	SD	p value
7th day L*	SDF-BL	15	58.847	3.465	0.281
	SDF+KI-BL	15	60.254	3.285	
	AHF-BL	15	60.793	3.109	
7th day A*	SDF-BL	15	2.128	0.524	0.635
	SDF+KI-BL	15	2.354	0.761	
	AHF-BL	15	2.278	1.250	
7th day B*	SDF-BL	15	2.226	1.165	0.003*
	SDF+KI-BL	15	3.869	1.144	
	AHF-BL	15	3.179	1.652	
30th day L*	SDF-BL	15	55.001	1.943	<0.001*
	SDF+KI-BL	15	56.243	3.253	
	AHF-BL	15	63.856	3.567	
30th day A*	SDF-BL	15	1.187	0.334	0.018*
	SDF+KI-BL	15	0.811	0.521	
	AHF-BL	15	1.555	0.867	
30th day B*	SDF-BL	15	1.358	0.703	<0.001*
	SDF+KI-BL	15	1.865	0.414	
	AHF-BL	15	5.113	2.078	
Baseline-5min Delta E	SDF-BL	15	2.653	1.108	0.186
	SDF+KI-BL	15	3.635	1.846	
	AHF-BL	15	3.303	1.779	
Baseline-7th day Delta E	SDF-BL	15	5.895	2.859	0.157
	SDF+KI-BL	15	6.002	2.948	
	AHF-BL	15	7.847	3.029	
Baseline-30th day Delta E	SDF-BL	15	9.845	4.754	0.002*
	SDF+KI-BL	15	10.541	4.050	
	AHF-BL	15	6.117	2.523	

*; Repeated measures ANOVA test, $p<0.05$; SD: standard deviation; SDF: silver diamine fluoride; SDF+KI: silver diamine fluoride with potassium iodide; AHF: ammonium hexafluorosilicate

Table 2. Post Hoc Tests (Tukey) for comparison of L*, A* & B* at different time intervals between different groups

Measurement	Comparison	Mean Difference	P value
Baseline A*	SDF-BL vs AHF-BL	-1.19	0.018*
	SDF+KI-BL vs AHF-BL	-1.17	0.020*
Baseline B*	SDF-BL vs AHF-BL	-2.03	0.004*
5 min A*	SDF-BL vs AHF-BL	-1.73	<0.001*
	SDF+KI-BL vs AHF-BL	-2.27	<0.001*
5 min B*	SDF-BL vs AHF-BL	-2.35	0.005*
7th day B*	SDF-BL vs SDF+KI-BL	-1.64	0.005*
30th day L*	SDF-BL vs AHF-BL	-8.85	<0.001*
	SDF+KI-BL vs AHF-BL	-7.61	<0.001*
30th day A*	SDF+KI-BL vs AHF-BL	-0.744	0.005*
30th day B*	SDF-BL vs AHF-BL	-3.76	<0.001*
	SDF+KI-BL vs AHF-BL	-3.25	<0.001*
Baseline-30th day Delta E	SDF-BL vs AHF-BL	3.73	0.032*
	SDF+KI-BL vs AHF-BL	4.42	0.009*

*; post hoc tukey test, p<0.05; SD: standard deviation; SDF: silver diamine fluoride; SDF+KI: silver diamine fluoride with potassium iodide; AHF: ammonium hexafluorosilicate.

Table 3. Comparison of microshear bond strength of different groups after application of different agents

Variable	Group	N	Mean	SD	SE	P value
Maximum Force [N]	SDF	10	15.66	5.02	1.586	<0.001*
	SDF + KI	10	13.63	4.37	1.381	
	AHF	10	32.46	10.44	3.302	
Microshear bond strength at Max Force [MPa]	SDF	10	5.09	1.67	0.527	<0.001*
	SDF + KI	10	4.30	1.27	0.402	
	AHF	10	10.86	3.30	1.045	

*; Repeated measures ANOVA test, p<0.05; SD: standard deviation; SDF: silver diamine fluoride; SDF+KI: silver diamine fluoride with potassium iodide; AHF: ammonium hexafluorosilicate

DISCUSSION

The present study aimed to evaluate and compare the discoloration and micro-shear bond strength of three caries-arresting agents -silver diamine fluoride (SDF), silver diamine fluoride with potassium iodide (SDF+KI), and ammonium hexafluorosilicate (AHF)- on primary teeth. The findings confirmed that SDF produced the greatest degree of staining, which increased progressively over time. This observation is consistent with reports by Gupte et al. and Karaduran et al., who attributed the characteristic dark staining associated with SDF to the conversion of silver ions into insoluble compounds such as silver phosphate, which darken upon exposure to light.[12,13] This aesthetic limitation represents a significant drawback, particularly when SDF is used in anterior teeth.

Potassium iodide has been advocated as an adjunct to SDF to mitigate discoloration by forming a white or yellowish precipitate of silver iodide. However, the present study demonstrated that SDF+KI specimens continued to exhibit marked staining at 30 days, suggesting that the masking effect of KI is transient. This finding aligns with studies by Aly et al., Hamdy, and Nguyen et al., which reported that silver iodide is photosensitive and gradually darkens with light and environmental exposure. [2, 14]

In contrast, ammonium hexafluorosilicate exhibited superior colour stability, minimal staining, and the highest micro-shear bond strength among all groups. These findings are in agreement with observations by Gelmboldt and Hosoya, who reported that AHF does not produce dark precipitates due to the absence of silver ions, thereby offering improved aesthetic outcomes.[8,13,14] Additionally, AHF facilitates the formation of calcium fluoride–like precipitates that enhance remineralization without adversely affecting tooth colour, which may explain the higher bond strength observed in the present study, as also reported by Suge et al.[15] The favourable interaction of AHF with adhesive systems may be attributed to its non-interference with dentinal bonding substrates, unlike silver-based agents.

Furthermore, the reduced bond strength observed in the SDF and SDF+KI groups may be attributed to residual silver compounds interfering with adhesive penetration and hybrid layer formation. This observation is supported by studies conducted by Knight et al., Lutgen et al., and Aboulsaood, who reported compromised bond strength due to silver deposition on dentin surfaces when adhesive protocols were not optimized.[16,17,18] Interestingly, previous studies have demonstrated improved bonding outcomes with delayed bonding or adjunctive surface treatments such as laser preconditioning.

In summary, although SDF and SDF+KI remain effective caries-arresting agents, their clinical use is limited by aesthetic concerns and reduced bond strength. Ammonium hexafluorosilicate, on the other hand, demonstrated favourable aesthetic and mechanical properties, suggesting its potential as a promising alternative, particularly in anterior teeth and aesthetically sensitive areas in children. Nevertheless, as this was an in-vitro study, further long-term clinical investigations are required to validate these findings under dynamic oral conditions involving saliva, mastication, and biofilm formation.

The present study has certain limitations that should be considered while interpreting the results. As this was an in-vitro investigation, the findings may not completely reflect the clinical behaviour of the tested agents under dynamic oral conditions involving saliva, masticatory forces, biofilm formation and dietary staining. The evaluation period was limited to 30 days; therefore, long term colour stability and durability of the bond strength could not be assessed. Additionally, extracted

primary teeth were used, which lack pulpal pressure and biological responses that may influence agent penetration and adhesive interaction in vivo. Only one adhesive system and composite resin were evaluated and different restorative materials may yield varying outcomes. Despite these limitations, the study provides valuable preliminary evidence regarding the aesthetic and bonding performance of ammonium hexafluorosilicate compared to silver-based caries arresting agents.

CONCLUSIONS

This study has demonstrated that silver diamine fluoride (SDF) produces black staining that is too pronounced to be used in the anterior or aesthetic critical areas. It also demonstrated that SDF exhibits the lowest micro-shear bond strength that depicts the augmented risk of fracture of composite restoration.

Silver diamine fluoride/potassium iodide (SDF + KI) on the other reduced discoloration to a small extent through silver iodide precipitation but stain remained after a long period. Mechanical advantage was not significantly higher than SDF and micro shear bond strength was not reinforced.

Ammonium hexafluorosilicate had maintained natural enamel colour with minimal visible discoloration, demonstrating superior aesthetic stability over the study period. Maximum micro-shear bond strength indicated good bond strength to composite and high level of durability of the restoration.

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Effect of different children's toothpastes on compomer surface roughness: An in vitro study

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Highlights

- The type of toothpaste used in pediatric patients may influence the surface integrity of restorative materials.
- Reduced surface roughness may contribute to decreased plaque accumulation and lower risk of secondary caries.
- The use of herbal- and fluoride-containing toothpastes may improve the long-term durability and aesthetic stability of restorations.

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Abstract

Aim: To compare the effects of different children's toothpastes on the surface roughness (Ra) of compomer materials under conditions simulating one year of toothbrushing. **Methods:** A total of 80 disc-shaped specimens prepared from a Dentsply Sirona compomer material were polished and randomly assigned to five groups (n = 16): control (distilled water), Sensodyne Pronamel Kids, Chicka Chicka, The Humble Co. Kids, and Weleda Kids. Baseline surface roughness (Ra) values were recorded using a profilometer. Toothbrushing was performed using a brushing simulation in accordance with ISO standards, and post-brushing Ra measurements were obtained under identical conditions. Data distribution was assessed using the Shapiro–Wilk test. Intergroup comparisons were conducted with the Kruskal–Wallis test, followed by the Dunn–Bonferroni post hoc test when appropriate, while intragroup comparisons were performed using the Wilcoxon test. The primary outcome variable was defined as ΔRa ($\alpha = 0.05$). **Results:** No statistically significant differences were observed among the groups in terms of absolute Ra values at baseline or after brushing ($p > 0.05$). In all groups, Ra values showed a significant increase after brushing in intragroup analyses ($p < 0.001$). A significant difference was detected among the groups with respect to ΔRa values ($p < 0.001$). Post hoc analyses revealed that the increase in ΔRa was significantly higher in the Sensodyne Pronamel and Chicka Chicka groups compared with the control, The Humble Co. Kids, and Weleda Kids groups. **Conclusions:** Toothbrushing increased the surface roughness of compomer materials in all groups, with toothpaste formulation playing a determining role in this change. The Humble Co. Kids and Weleda Kids groups demonstrated more limited surface alterations in compomer restorations, as indicated by lower ΔRa values.

Keywords: Compomers; Surface Properties; Toothbrushing; Toothpaste

INTRODUCTION

Dental caries is a major health problem affecting individuals of all age groups. Therefore, ensuring effective oral hygiene during childhood, removing dental plaque that leads to caries, and preventing enamel demineralization constitute the fundamental goals of preventive dentistry.[1, 2] Dental plaque is one of the primary etiological factors in the initiation and progression of caries and periodontal diseases. Toothbrushing, which constitutes a fundamental component of daily oral care, enables the mechanical removal of dental plaque.[3, 4] Toothpastes are among the most important therapeutic components of daily oral hygiene and are one of the most commonly used dental products.[5]

Toothpastes contain numerous components in their formulations, each serving different functions. Among these, abrasive agents may consist of various materials such as hydrated silica, calcium pyrophosphate, dicalcium phosphate dihydrate, sodium metaphosphate, perlite, sodium bicarbonate, zirconium silicate, pumice powder, aluminum oxide, calcium carbonate, and nano-hydroxyapatite. Abrasive particles contribute not only through their mechanical action but also by facilitating the removal of extrinsic surface stains. However, increased abrasivity may result in undesirable surface roughness on enamel, soft tissues, and various restorative materials. The abrasivity of a toothpaste is closely related not only to the amount used but also to the particle size, shape, and chemical properties of the abrasive components.[6]

The abrasivity of a toothpaste is generally expressed by the Relative Dentin Abrasivity (RDA) value, which is the most widely accepted method for defining toothpaste abrasivity. The International Organization for Standardization (ISO) has established an upper RDA limit of 250 for adult toothpastes.[7, 8] However, to date, no internationally defined RDA limit has been established for children's toothpastes.[9]

In recent years, increasing awareness regarding the potential effects of chemical ingredients has led to growing interest in herbal-based toothpastes.[10] Owing to their antimicrobial, anti-inflammatory, and antioxidant properties, herbal extracts may play a supportive role in the prevention of dental caries and periodontal diseases.[11,12] Currently, many children's toothpastes—both conventional and herbal formulations—contain fluoride, aiming to provide effective protection against dental caries. An ideal children's toothpaste formulation should aim to maximize fluoride bioavailability, minimize abrasivity, and ensure user tolerance through an acceptable flavor.[13]

Both herbal and conventional toothpastes are readily accessible and widely used in daily clinical practice. Since fluoride plays a critical role in caries prevention, only fluoride-containing toothpastes were included in this study to ensure clinical relevance. The selected toothpastes differed in terms of their active ingredients, abrasive systems, and formulation characteristics.

Herbal toothpastes are characterized by plant-based formulations, the use of milder surfactants, and generally silica-based abrasive systems, which may influence their interaction with restorative materials. For example, Weleda Kids (Weleda AG, Germany) toothpaste contains Calendula officinalis extract and plant-derived oil components, whereas The Humble Co. Kids (The Humble Co., Sweden) toothpaste includes biologically active components such as erythritol, aloe vera, and xylitol. In contrast, conventional formulations may incorporate more pronounced cleaning and abrasive systems. In this context, Sensodyne Pronamel Kids (Haleon, UK) represents a formulation known for its erosion-protective properties, whereas Chicka Chicka Kids (Kundal, South Korea) contains botanical components such as Camellia (tea) extract, mint extract, and broccoli extract, as well as abrasive

agents including hydrated silica and sodium bicarbonate.

Surface roughness of restorative materials may change following toothbrushing, and increased surface roughness may promote plaque accumulation. A smoother surface can reduce plaque retention and surface staining, thereby improving both the longevity and esthetics of restorations.[14]

Compomer is a restorative material developed specifically for pediatric dentistry and is particularly susceptible to surface alterations associated with long-term toothbrushing and toothpaste use. Surface roughening of compomer materials may adversely affect esthetics and increase plaque retention, ultimately reducing the lifespan of the restoration.[15] Therefore, evaluating the long-term effects of children's toothpastes with different fluoride-containing formulations on compomer surfaces is of considerable importance for the clinical success of pediatric restorations.

The aim of this in vitro study was to evaluate the surface roughness induced on compomer materials by different children's toothpastes under conditions simulating one year of toothbrushing, using a profilometer. The null hypothesis (H_0) tested in this study was that toothbrushing with different children's toothpastes would not result in a statistically significant difference in surface roughness (Ra) of compomer materials.

METHODS

Sample Size Determination

A power analysis was performed to determine the required sample size. The sample size calculation was based on a type I error rate of 5% ($\alpha = 0.05$), an effect size of 0.40, and a statistical power of 80% ($1-\beta = 0.80$). Accordingly, a total of 80 compomer specimens were prepared, with at least 16 specimens allocated to each group.

Specimen Preparation

Dyract XP compomer material (Dentsply Sirona, Dyract XP, Compomer, 2025, York, PA, USA) was used in this study. Compomer discs were fabricated using standardized stainless steel molds with a diameter of 10 mm and a thickness of 2 mm. A glass slide was placed over the molds to ensure surface flatness, prevent air bubble formation, and remove excess material. The specimens were polymerized for 20 seconds using an LED light-curing unit (3M ESPE, Elipar S10, light-curing unit, 2025, St. Paul, MN, USA) in accordance with the manufacturer's instructions.

Surface Standardization

To obtain a standardized compomer surface, all specimens were sequentially polished under water using 600-, 800-, and 1200-grit silicon carbide abrasive papers. Following polishing, the specimens were rinsed with distilled water and air-dried.

Baseline Surface Roughness Measurement

Baseline surface roughness (Ra) values of all specimens were measured using a profilometer (Mahr GmbH, Perthometer M2, Profilometer, 2025, Göttingen, Germany) at the Central Laboratory of Ankara University Faculty of Dentistry. Three measurements were obtained from different locations on each specimen, and the mean value was recorded as the baseline Ra. Measurements were performed with a cut-off length of 0.25 mm, a tracing length of 0.8 mm, and three repeated surface scans. Measurement areas were marked to ensure that post-brushing measurements were obtained from the same locations.

Group Allocation

After completion of baseline surface roughness measurements, specimens were randomized into

five groups (n = 16 per group) using a computer-generated randomization method. The compositions of the toothpastes used are presented in Table 1. The groups were defined as follows:

(1) control group (brushing with distilled water), (2) Sensodyne Pronamel Kids toothpaste (Haleon, fluoride toothpaste, 2025, UK), (3) Chicka Chicka Kids toothpaste (Kundal, fluoride toothpaste, 2025, South Korea), (4) The Humble Co. Kids toothpaste (The Humble Co., herbal fluoride toothpaste, 2025, Sweden), and (5) Weleda Kids toothpaste (Weleda AG, herbal fluoride toothpaste, 2025, Germany).

Toothbrushing Procedure

The toothbrushing procedure was performed using a toothbrushing simulator (Lua Instruments 3median B12, Toothbrushing Simulator, 2025, Türkiye, Serial No: DT250514) (Figure 1). Medium-bristle nylon brush heads compatible with electric toothbrushes (Procter & Gamble, Oral-B White series, toothbrush head, 2025, USA) were used. The bristle structure, stiffness, and physical properties of the brush heads were consistent with the criteria defined in ISO 11609:2017.[16]

Table 1. Ingredient characteristics and manufacturer information of the children's toothpastes used in the study

Product (Brand – Country)	Fluoride (ppm)	Abrasive Agents	Herbal/Natural Ingredients	Other Ingredients
Sensodyne Pronamel Kids (GSK – UK)	1450 ppm NaF	Hydrated Silica	—	Aqua, Sorbitol, Glycerin, PEG-6, Cocamidopropyl Betaine, Xanthan Gum, Flavor, Sodium Saccharin, Sucralose, Titanium Dioxide, Sodium Hydroxide, Limonene
Chicka Chicka Kids (Kundal – South Korea)	1450 ppm NaF	Hydrated Silica, Sodium Bicarbonate	Camellia (tea) extract, mint extract, broccoli extract, mixed botanical extracts (CBHC-C)	Glycerin, Aqua, Lauryl Glucoside (plant-derived surfactant), Xylitol, low-acidity ethanol (70%), Steviol Glycosides (natural sweetener), Sodium Carboxymethyl Cellulose (thickener), Flavor
The Humble Co. Kids (Sweden)	1000 ppm NaF	Hydrated Silica	Erythritol, *Aloe barbadensis* leaf juice, Xylitol, Cellulose gum, Disodium Cocoyl Glutamate, Lauryl Glucoside, Rebaudioside A	Glycerin, Aqua, Hydroxyapatite, Flavor, Potassium Citrate, Citric Acid, Sodium Benzoate, Potassium Sorbate
Weleda Kids (Germany)	1000 ppm NaF	Silica	*Calendula officinalis* flower extract, *Prunus amygdalus dulcis* (sweet almond) oil, esculin	Glycerin, Aqua, Flavor, Limonene

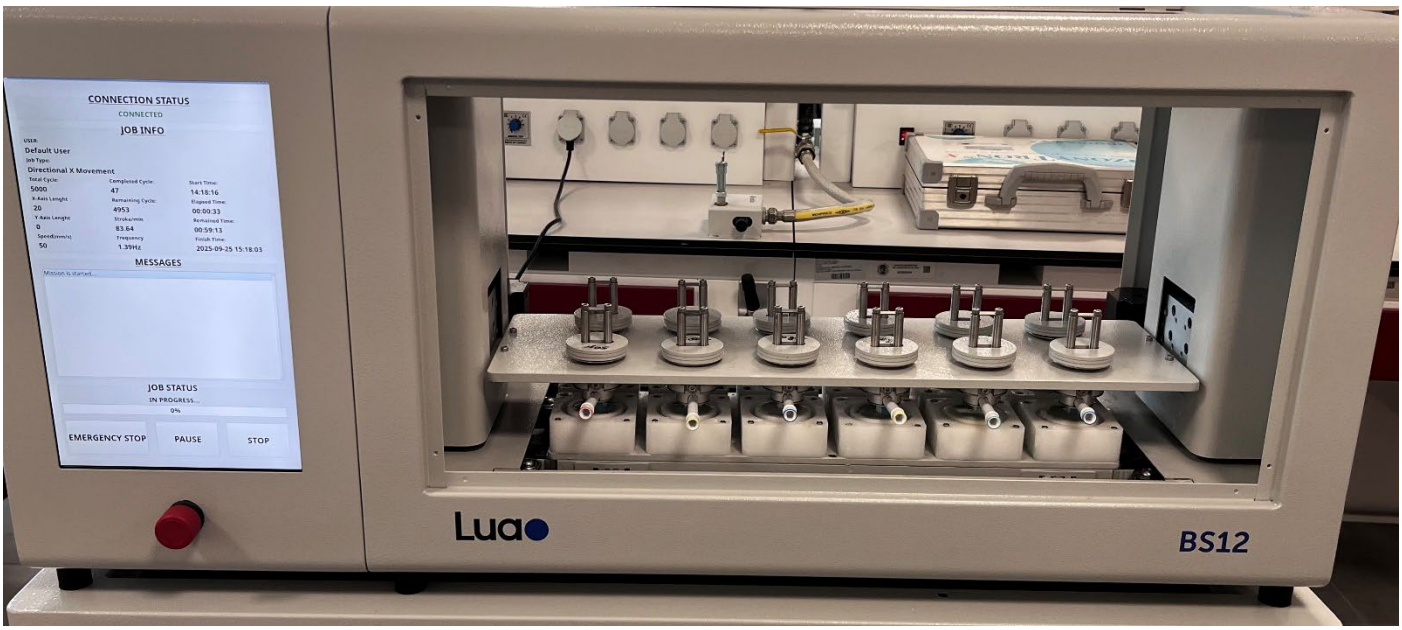

Figure 1. Toothbrushing simulator (Lua Instruments 3median B12, Serial No: DT250514, Türkiye)

The brushing force of the simulator was set at 2.5 ± 0.2 N, and 10,000 brushing cycles were applied to the compomer surfaces to simulate approximately one year of toothbrushing. A toothpaste slurry was prepared by mixing 25 g of toothpaste with 40 mL of distilled water. To minimize variability associated with bristle deformation, brush heads were replaced every 2,500 cycles, corresponding to the clinical recommendation of replacing a toothbrush every three months. The procedure was performed in a continuous manner without predefined rest intervals between brushing cycles, with interruptions occurring only during toothbrush replacement. All other parameters, including brushing force, frequency, and duration, were kept constant throughout the experiment. All brushing procedures were conducted using a linear back-and-forth motion at a constant speed of 50 mm/s, while maintaining constant contact pressure and cycle length throughout the experiment.

Post-Brushing Surface Roughness Measurement

Following the toothbrushing procedure, the specimens were carefully rinsed with distilled water and gently air-dried. Post-brushing surface roughness (Ra) values were then determined using the same profilometer device and measurement parameters as those used for the baseline measurements. All measurements were performed under identical environmental conditions, and the obtained data were recorded for analysis.

Statistical Analysis

All data obtained in the study were analyzed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics for continuous variables were presented as mean ± standard deviation (SD) and median (minimum–maximum). Data distribution was assessed using the Shapiro–Wilk test, and nonparametric tests were applied when the assumption of normality was not met.

The Kruskal–Wallis H test was used to compare baseline (Ra_before) and post-brushing (Ra_after) surface roughness values among groups. For variables showing statistically significant differences, pairwise comparisons were performed using the Dunn post hoc test with Bonferroni correction.

Intragroup comparisons between pre- and post-brushing values were conducted using the Wilcoxon signed-rank test. To evaluate the net effect of toothpastes on surface roughness, the variable ΔRa was calculated as (Ra_after − Ra_before), and these difference values were compared among groups using the Kruskal–Wallis test. Statistical significance was set at $p < 0.05$. Effect sizes were calculated as $r = |z|/\sqrt{n}$ for intragroup analyses and epsilon-squared (ε^2) for intergroup comparisons.

RESULTS

In this study, the effect of toothbrushing on the surface roughness of compomer materials was evaluated based on the change in Ra values between pre- and post-brushing measurements (ΔRa = Ra_after − Ra_before). At baseline, no statistically significant difference was observed among the groups in terms of Ra values (Kruskal–Wallis $H = 2.11$; $p = 0.715$).

According to intragroup comparisons using the Wilcoxon signed-rank test, post-brushing Ra values in the control group were found to be significantly higher than baseline values ($p < 0.001$). Similarly, statistically significant increases in Ra values after brushing were observed in the Sensodyne Pronamel Kids, Chicka Chicka Kids, The Humble Co. Kids, and Weleda Kids groups ($p < 0.001$, $p = 0.003$, $p < 0.001$, and $p < 0.001$, respectively).

Intergroup comparison of ΔRa values revealed a statistically significant difference among the groups, with a large effect size (Kruskal–Wallis $H = 26.2$; $\varepsilon^2 = 0.30$; $p < 0.001$). Post hoc Dunn–Bonferroni analyses demonstrated that the Sensodyne Pronamel Kids and Chicka Chicka Kids groups exhibited significantly higher ΔRa values compared with the control group. In addition, these two groups showed significantly greater ΔRa values than the The Humble Co. Kids and Weleda Kids groups. No statistically significant difference in ΔRa values was found between the Sensodyne Pronamel Kids and Chicka Chicka Kids groups. Likewise, no significant differences were observed among the control, The Humble Co. Kids, and Weleda Kids groups, indicating similar levels of surface roughness change.

Baseline and post-brushing Ra values for each group are presented in Table 2, while intergroup comparisons of ΔRa values are shown in Table 3. The visual distribution of median ΔRa values across groups is illustrated in Figure 2.

DISCUSSION

Despite the wide variety of toothpastes currently available for children, the number of studies investigating their effects on enamel and restorative materials remains limited.[9, 17–22] The effects of different fluoride-containing children's toothpastes on the surface roughness of compomer materials were evaluated under a toothbrushing simulation performed in accordance with ISO standards. Most existing studies have focused on the effects of children's toothpastes on glass ionomer cements or primary tooth enamel.[9, 17, 18, 19] Previous research has reported that compomer materials may exhibit increased surface roughness and material loss following toothbrushing.[23] However, no studies were identified that specifically evaluated the effects of herbal-based children's toothpastes on compomer surfaces, making direct comparison with the present findings difficult.

According to ISO/TR 14569-1:2007, brushing forces applied in toothbrushing wear tests should reflect physiological forces used under clinical conditions. Brushing forces ranging from 0.5 to 2.5 N have been reported to represent clinical toothbrushing conditions. Accordingly, the brushing force of 2.5 N selected in the present study falls within physiological limits and was considered appropriate for clinic conditions.[14,24,25]

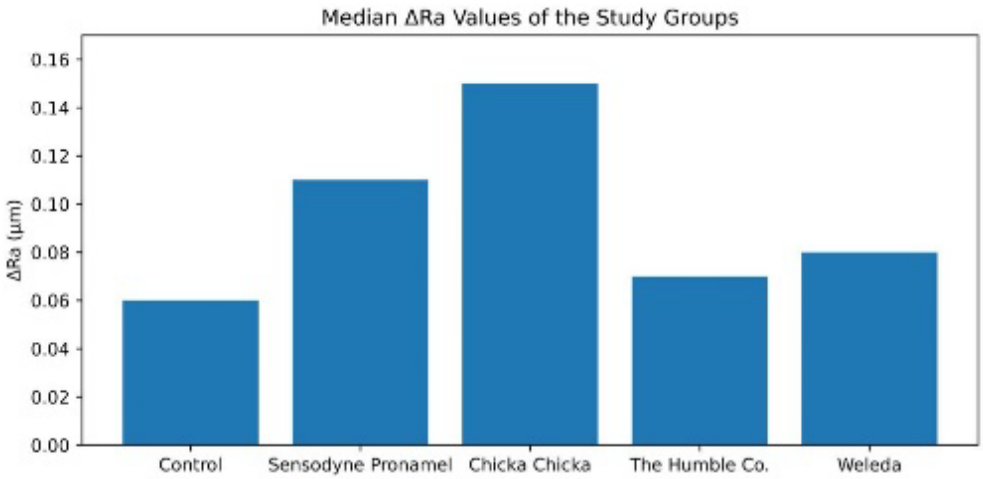

Figure 2. Comparison of median ΔRa values among the study groups

Table 2. Baseline and post-brushing Ra values of the study groups

Group	n	Ra Before, Median (Min–Max)	Ra After, Median (Min–Max)
Control (Distilled Water)	16	0.40 (0.21–0.81)	0.45 (0.28–0.87)
Sensodyne Pronamel Kids	16	0.35 (0.21–0.73)	0.46 (0.31–0.93)
Chicka Chicka Kids	16	0.31 (0.17–0.94)	0.64 (0.28–1.29)
The Humble Co. Kids	16	0.45 (0.21–0.96)	0.52 (0.28–1.03)
Weleda Kids	16	0.34 (0.22–0.90)	0.42 (0.30–1.01)

Data are presented as median (minimum–maximum); Ra: surface roughness (µm); Intragroup comparisons between baseline and post-brushing Ra values were performed using the Wilcoxon signed-rank test

Table 3. Intergroup comparison of ΔRa values

Group	ΔRa (Median, µm)
Chicka Chicka Kids	0.15[a]
Sensodyne Pronamel Kids	0.11[a]
Weleda Kids	0.08[b]
The Humble Co. Kids	0.07[b]
Control	0.06[b]

Intergroup differences in ΔRa values were evaluated using the Kruskal–Wallis test ($H = 26.2$; $p < 0.001$), followed by Dunn–Bonferroni post hoc analysis for pairwise comparisons. Different superscript letters ([a], [b]) indicate statistically significant differences between groups, while identical superscripts indicate no significant difference (Bonferroni-adjusted $p < 0.05$).

The application of 10,000 brushing cycles is a commonly used parameter in in vitro studies evaluating surface roughness of restorative materials and has been reported to simulate approximately one year of clinical toothbrushing.[14, 26–28]

In line with ISO 11609 and commonly reported protocols in the literature, toothpaste slurries were prepared by mixing 25 g of toothpaste with 40 mL of distilled water.[16, 29, 30] This standardized ratio allows for a comparable assessment of the abrasive effects of different toothpaste formulations.

The absence of statistically significant differences among baseline Ra values for compomer specimens indicates that the groups were homogeneous in terms of surface characteristics prior to the experimental procedures and that the observed post-brushing changes were attributable to the brushing process and the properties of the toothpastes used. An increasing trend in Ra values was observed in all groups following toothbrushing, with even the control group (brushing without toothpaste) showing a significant increase in surface roughness. This finding is consistent with previous studies reporting that mechanical toothbrushing alone can alter compomer surface topography and lead to surface degradation and matting in resin-based materials.[23,28,31] In addition, wear of toothbrush bristles has been reported to contribute to increased surface roughness.[32] Therefore, brush heads were replaced every 2,500 cycles in the present study to minimize this effect.

The main factors determining surface changes during toothbrushing include the mechanical action of the toothbrush, the abrasivity profile of the toothpaste, and the structural characteristics of the restorative material.[30, 33, 34] The observation that ΔRa values were significant even in the control group highlights the baseline effect of mechanical brushing. For this reason, the use of ΔRa as an outcome variable is essential for accurately evaluating the net effect of toothpastes, and intergroup comparisons in the present study were therefore based on this parameter.

Although Chicka Chicka Kids toothpaste contains botanical ingredients, it is not marketed as an herbal toothpaste. In the present study, significantly higher ΔRa values were observed in the Chicka Chicka Kids group compared with the control, The Humble Co. Kids, and Weleda Kids groups, indicating that this toothpaste may induce more pronounced surface alterations on compomer materials. Although a precise comparison of abrasivity was not possible due to the lack of detailed RDA information for this product, this finding underscores the importance of formulation-related surface effects. Previous studies have reported that toothpastes with higher abrasive potential or whitening properties can significantly increase surface roughness of resin-based restorative materials.[34, 35]

Although statistically significant increases in post-brushing Ra values were observed in The Humble Co. Kids and Weleda Kids groups, their median ΔRa values were lower than those of the Chicka Chicka Kids and Sensodyne Pronamel Kids groups and were closer to those of the control group. The predominantly herbal composition of these products may be associated with more limited surface alterations. Herbal extracts, natural thickeners such as alginates, and oil-based components present in these formulations may reduce friction between abrasive particles and the surface during brushing, resulting in a gentler cleaning profile. In particular, ingredients such as *Calendula officinalis* flower extract, sweet almond oil, and alginate in Weleda Kids toothpaste may have contributed to this effect.

The literature suggests that the morphology and surface charge of hydrated silica particles may result in a more controlled surface interaction with resin-based materials and that formulations with low-to-moderate abrasivity profiles may limit

increases in surface roughness.[15, 30, 33] Although all groups except Weleda Kids contained hydrated silica, differences in ΔRa values may be related to variations in particle shape, size, and fineness of abrasive derivatives.[28]

In the Sensodyne Pronamel Kids group, ΔRa values were significantly higher than those observed in the Weleda Kids and The Humble Co. Kids groups, while no statistically significant difference was detected when compared with the Chicka Chicka Kids group, despite numerically lower values. This finding may reflect the balance between abrasive-cleaning efficacy and the effect of fluoride on surface modification in the Sensodyne Pronamel Kids formulation. The moderate ΔRa values observed suggest that this toothpaste may provide a balanced cleaning–abrasion profile on compomer surfaces. Indeed, such formulations have been recommended in the literature, particularly for individuals at risk of enamel erosion.[30, 33]

It is well established that exceeding the critical surface roughness threshold (~0.2 μm) increases the risk of plaque retention and discoloration.[26] Therefore, the use of toothpastes with lower abrasivity profiles may represent a clinically rational approach for the maintenance of compomer restorations in pediatric patients. The more limited ΔRa values observed in The Humble Co. Kids and Weleda Kids groups suggest that these products may offer potential advantages in this regard. However, the clinical relevance of these findings should be confirmed through in vivo studies.

The main limitations of this study include the inability of in vitro conditions to fully replicate the dynamic oral environment, such as the presence of saliva, biofilm formation, and fluctuations in pH and temperature. Additional limitations include the evaluation of only one compomer material, the assessment of a limited number of commercially available children's toothpastes, and the lack of precise RDA data for all tested products. Compomer material was selected due to its widespread use in pediatric dentistry. Future studies should evaluate a broader range of compomer and composite systems, include toothpastes with known RDA values, and incorporate advanced surface analysis techniques such as SEM, AFM, three-dimensional profilometry, gloss, and color measurements in addition to surface roughness.[34–37]

CONCLUSIONS

This study demonstrated that different children's toothpaste formulations may exert varying effects on the surface roughness of compomer materials. While the Chicka Chicka Kids and Sensodyne Pronamel Kids groups exhibited higher ΔRa values, more limited surface alterations were observed in The Humble Co. Kids and Weleda Kids groups. These findings suggest that formulation characteristics of children's toothpastes—particularly the type of surfactants and abrasive systems—may influence the surface integrity of compomer restorations. Nevertheless, long-term in vivo studies are required to confirm these results under clinical conditions.

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