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# Effects of Prefabricated Versus Conventional Band and Loop Space Maintainers on Wound Healing, Plaque Accumulation, and Gingival Health of the Abutment Tooth: A Split-Mouth Randomized Controlled Trial

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## Abstract

Background: Conventional band and loop space maintainers are widely used for space maintenance but have drawbacks, such as soldering failures and multiple appointments. Prefabricated space maintainers address this by requiring less time and only one appointment. However, space maintainers may affect postextraction wound healing and plaque accumulation, leading to gingivitis.

Objective: This study compares the effects of prefabricated and conventional band and loop space maintainers on postextraction wound healing, plaque accumulation, and gingival health of the abutment tooth.

Methodology: The split-mouth study included 10 healthy children aged five to eight years with bilateral mandibular primary first molars indicated for extraction. Each patient's experimental side was randomly selected, dividing quadrants into two groups: conventional and prefabricated band and loop space maintainers. Follow-up appointments were scheduled on the third and seventh day after extraction to assess wound healing using the Landry index, and at first, second, and third months to assess plaque using the Plaque index and gingival health of abutment using the Gingival index. Statistical analysis was performed using Statistical Package for Social Sciences, version 21, for Windows (SPSS Inc., Chicago, IL). Overall intergroup comparison among two groups was done using unpaired t-test.

Results: Both prefabricated and conventional designs increased plaque accumulation and gingivitis. Conventional space maintainers resulted in more plaque accumulation and a higher incidence of gingivitis than the prefabricated ones. However, no statistically significant difference was observed in postextraction wound healing.

Conclusion: Prefabricated band and loop space maintainers offer a practical and efficient solution for space maintenance and represent a promising alternative to conventional designs.

**Categories:** Dentistry
**Keywords:** band and loop space maintainer, children, dental plaque, prefabricated space maintainers, space maintenance

## Introduction

The primary dentition is essential for a child's growth and development, influencing speech, mastication, appearance, and the proper eruption of permanent teeth [1]. The premature loss of primary teeth can lead to space loss and undesirable tooth movements, affecting occlusion. When early loss is unavoidable, space maintainers help preserve arch space and guide the eruption of permanent teeth, minimizing negative effects on occlusion [2].

The choice of space maintainer design depends on the patient’s specific needs [3]. Conventional band and loop space maintainers are widely used in pediatric dentistry for single-tooth loss due to their high success rate [4,5]. They offer several advantages, including their well-documented effectiveness in preserving space, preventing adjacent tooth drift, and maintaining proper occlusal development. Additionally, they provide good durability and stability when properly fabricated and cemented. However, they have drawbacks, including time-consuming fabrication, the need for multiple appointments, soldering failures, and the challenge of taking accurate impressions, especially in patients with a strong gag reflex [5].

To offset the disadvantages of conventional space maintainers, one of the latest innovations in banded space maintainers is prefabricated space maintainers. They require only one appointment, no laboratory work, and

less time; are cost-effective; and provide hassle-free treatment, especially in uncooperative children [2]. However, prefabricated space maintainers also have certain limitations, such as limited adaptability to individual tooth morphology, potential issues with retention and fit, and the possibility of increased plaque accumulation due to their standardized design. Given these advantages and limitations, it is essential to evaluate their clinical performance, particularly in terms of wound healing, plaque accumulation, and gingival health, to determine their efficacy as a viable alternative to conventional space maintainers.

Whether it is a conventional or prefabricated space maintainer, these appliances lead to changes in the contours of the teeth, causing plaque accumulation and making it difficult to maintain oral hygiene, which can lead to dental caries and periodontal disease [6-8]. Since these space maintainers are placed immediately after extraction, they may affect postextraction wound healing as the presence of a foreign body is known to affect the wound healing process. The wound healing process occurs in distinct phases such as hemostasis, inflammation, proliferation, and remodeling. The wound healing process may be disrupted by continuous contact with space maintainers, potentially leading to delayed healing or localized inflammation. Furthermore, the presence of these appliances can contribute to periodontal complications, including gingival inflammation, hypertrophy, and recession, primarily due to plaque retention and mechanical irritation. Therefore, evaluating plaque accumulation using a standardized plaque index is crucial in assessing the oral hygiene challenges posed by space maintainers and their potential impact on periodontal health.

Despite the growing use of prefabricated space maintainers, limited evidence exists regarding their impact on these clinical parameters compared to conventional space maintainers. Hence, this study is planned to assess and compare the effect of prefabricated and conventional band and loop space maintainers on postextraction wound healing, plaque accumulation, and gingival health of the abutment tooth, providing valuable insights into their clinical efficacy and suitability for pediatric patients.

## Materials And Methods

This study was a split-mouth randomized controlled trial conducted after approval from the Institutional Ethical Committee. It adhered to the ethical principles outlined in the Declaration of Helsinki and the guidelines of the Occupational Safety and Health Administration. Parents gave written informed consent before participating.

### Sample size calculation

A power analysis was conducted using G*Power version 3.0.1 (Franz Faul, Universität Kiel, Kiel, Germany). The total calculated sample size of 10 subjects (Group A: 10 sites, Group B: 10 sites) was determined to achieve 80% power for detecting significant differences, with an effect size of 1.35 and a significance level of 0.05. The effect size was derived from a similar split-mouth study by Tyagi et al., which compared conventional and modified space maintainers and reported comparable outcome measures (Figure *1*) [9].

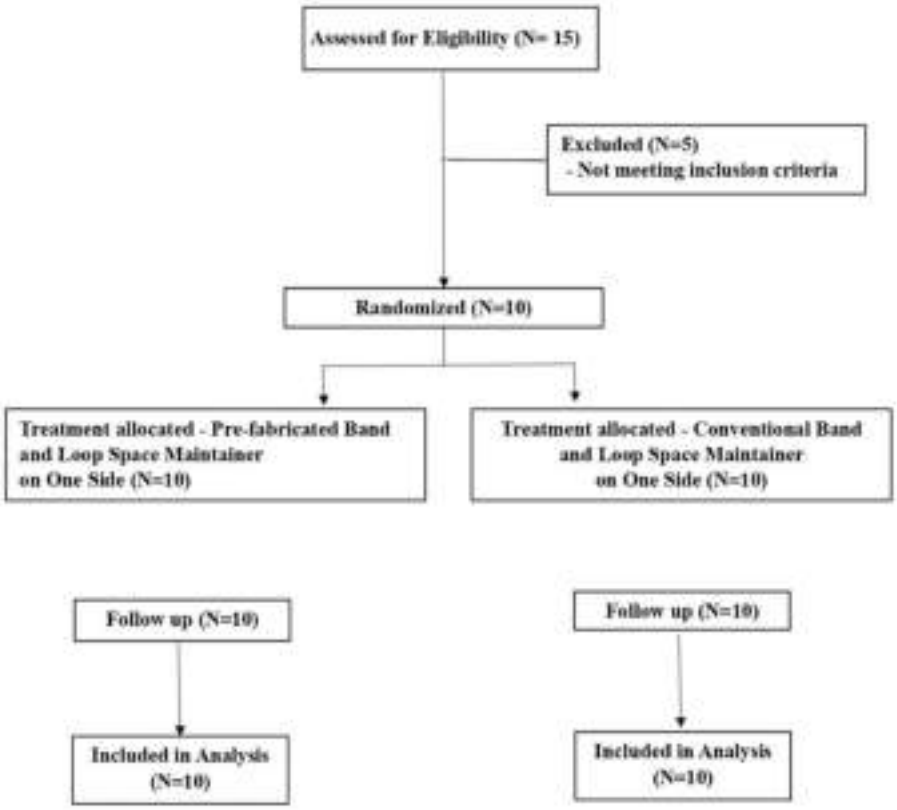


**FIGURE 1: CONSORT flow diagram of the randomized split-mouth trial**

CONSORT: Consolidated Standards of Reporting Trials

## Study population and inclusion criteria

Children aged five to eight years with bilateral primary mandibular first molars indicated for extraction were included in the study, provided that a succedaneous tooth bud was confirmed radiographically, the abutment tooth was healthy, and adequate bone coverage was suggested a minimum of six months before permanent tooth eruption. Exclusion criteria included cases where the succedaneous tooth exhibited more than one-third root calcification, the space left by premature loss exceeded the space required for the permanent successor, the succedaneous tooth was absent, or the presence of medical conditions or special healthcare needs.

## Study design and randomization

The study was conducted from June 1, 2024, to January 25, 2025. Ten healthy children meeting the eligibility criteria were enrolled. Before the intervention, each participant underwent a brief medical history assessment, clinical examination, and oral prophylaxis. A split-mouth design was employed, where each participant received both interventions in contralateral quadrants. Random allocation was performed using a computer-generated randomization sequence, and allocation concealment was ensured using sealed, opaque envelopes.

## Intervention groups

Participants were randomly assigned to two groups (Figure *2*): Group 1 (n = 10), who received a prefabricated band and loop space maintainer, and Group 2 (n = 10), who received a conventional band and loop space maintainer.

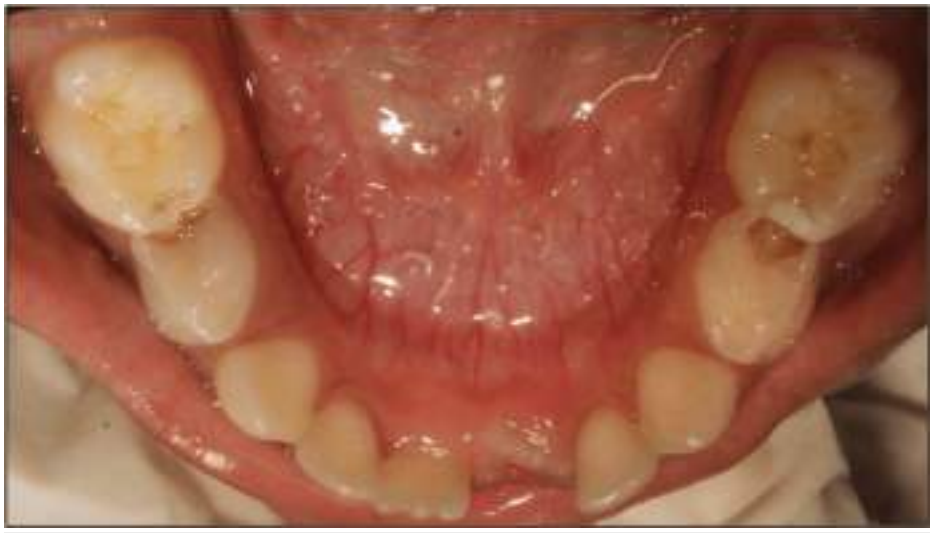

**FIGURE 2: Preoperative photograph**

*Group 1: Prefabricated Band and Loop Space Maintainer*

Following the extraction of the mandibular primary first molar under local anesthesia, hemostasis was achieved. A preformed band was selected from the Kids-e Prefabricated Band and Loop Space Maintainer kit (Kids-e-Dental LLP, Mumbai, India) based on the mesiodistal width of the abutment tooth, measured using a Vernier caliper (Cometek, Diwakar Instruments Company, India). A prefabricated loop was selected according to the available mesiodistal and buccolingual space, inserted into the band's tube, crimped, and cemented using GC Gold Label glass ionomer luting cement (GC Corporation, Tokyo, Japan).

*Group 2: Conventional Band and Loop Space Maintainer*

Fabrication was completed over two visits. In the first visit, a stainless-steel band was selected and adapted based on the mesiodistal width of the abutment tooth, measured using a Vernier caliper. An impression was made using alginate material, and a cast was prepared with the band stabilized using bobby pins [10]. The band and loop space maintainer was fabricated following Finn's method, including soldering, finishing, and polishing of the appliance [11].

During the second visit, the extraction of the mandibular primary first molar was performed under local anesthesia, hemostasis was achieved, and the space maintainer was cemented using GC Gold Label glass ionomer luting cement.

## Outcome assessment and follow-up

Follow-up appointments were scheduled on the third and seventh days after extraction to assess wound healing and at the end of the first, second, and third months to evaluate plaque accumulation and gingival health of the abutment tooth in both groups (Figure *3*). Wound healing was assessed using the Landry, Turnbull, and Hawley Healing Index (Table *1*) [12].

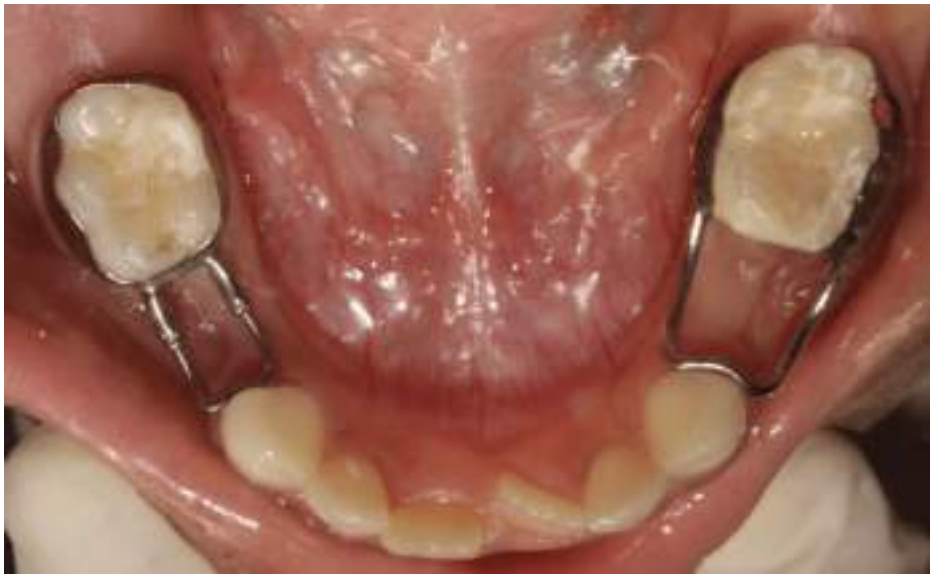

**FIGURE 3: Postoperative photograph**

| Wound healing | Tissue color | Response to palpation | Granulation tissue |
|---|---|---|---|
| Very poor (score 1) | ≥50% gingiva red | Bleeding | Present |
| Poor (score 2) | ≥50% gingiva red | Bleeding | Present |
| Good (score 3) | ≥25% and <50% gingiva red | No bleeding | None |
| Very good (score 4) | <25% gingiva red | No bleeding | None |
| Excellent (score 5) | All tissues pink | No bleeding | None |

**TABLE 1: Wound healing index**

Plaque accumulation of abutment tooth was assessed using the Silness and Loe plaque index (Table *2*) [13]. The score for the abutment tooth was calculated by adding the values from four areas of the tooth and dividing the total by 4. The interpretation of the scores was categorized as follows: a score of 0 indicated an excellent condition, scores ranging from 0.1 to 0.9 were considered good, scores between 1 and 1.9 were classified as fair, and scores from 2 to 3 were categorized as poor.

| Score | Criteria |
|---|---|
| 0 | No plaque |
| 1 | A film of plaque adhering to the free gingival margin and adjacent areas of the tooth. The plaque may be seen only by running a probe across the tooth surface |
| 2 | Moderate accumulation of soft deposits within the gingival pocket, on the gingival margin, and/or adjacent tooth surface, which can be seen by the naked eye |
| 3 | Abundance of soft matter within the gingival pocket and/or on the gingival margin and adjacent tooth surface |

**TABLE 2: Silness and Loe plaque index**

Gingival health was assessed using the Loe and Silness gingival index (Table *3*) [13]. The score for the abutment tooth was determined by adding the values from four areas of the tooth and dividing the total by 4. The interpretation of the scores was as follows: a score between 0.1 and 1 indicated mild gingivitis, scores ranging from 1.1 to 2 indicated moderate gingivitis, and scores between 2.1 and 3 indicated severe gingivitis.

| Score | Criteria |
|---|---|
| 0 | Normal gingiva/absence of inflammation |
| 1 | Mild inflammation, slight change in color, slight edema, and no bleeding on probing |
| 2 | Moderate inflammation, moderate glazing, redness, edema and hypertrophy, and bleeding on probing |
| 3 | Severe inflammation, marked redness and hypertrophy, ulceration, and tendency to spontaneous bleeding |

**TABLE 3: Silness and Loe gingival index**

### Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 21 for Windows (SPSS Inc., Chicago, IL). Descriptive quantitative data were expressed in mean and standard deviation, respectively. Data normality was checked by using the Shapiro-Wilk test. The confidence interval is set at 95%, and the probability of alpha error (level of significance) is set at 5%. The power of the study was set at 80%. Overall intergroup comparison among two groups was done using unpaired t-test.

## Results

### Healing index comparison

In the intragroup analysis, both Group 1 and Group 2 demonstrated a progressive improvement in healing from days 3 to 7, as evidenced by a significant increase in the healing index. The statistical analysis confirmed this, with a p value of 0.004 for both groups, indicating a statistically significant improvement in the healing process over time.

In contrast, the intergroup analysis revealed no statistically significant difference in the healing index between Group 1 and Group 2 at either time point. On days 3 and 7, the p value was 1.000, suggesting that both treatment modalities resulted in comparable healing outcomes. This indicates that neither intervention had a superior effect on wound healing within the observed timeframe (Figure *4*).

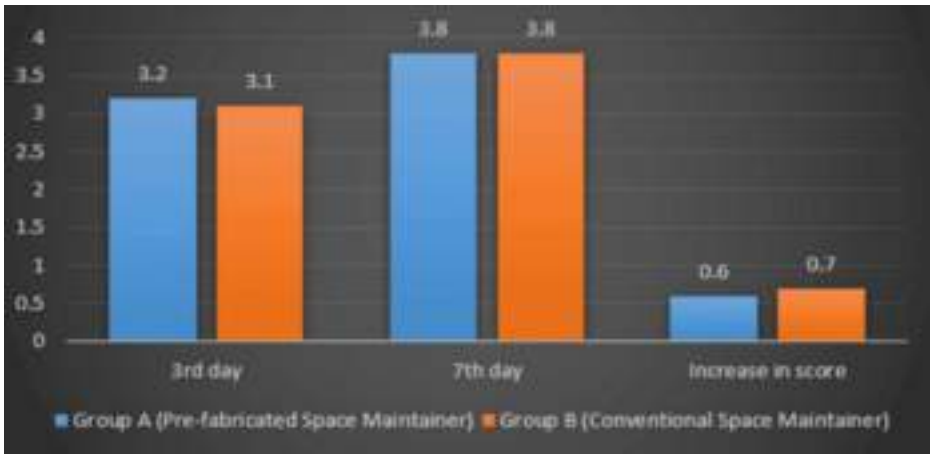


**FIGURE 4: Healing index comparison**

### Plaque index comparison

The intergroup analysis revealed a statistically significant difference in plaque accumulation between groups 1 and 2 at both the one- and three-month follow-up periods. At the one-month follow-up, Group 1 exhibited a significantly lower plaque index than Group 2 ($p = 0.02$), suggesting that the prefabricated band and loop resulted in less plaque accumulation during the early phase.

This trend continued at the three-month follow-up, where Group 1 maintained a significantly lower plaque index than Group 2, with an even stronger statistical significance ($p = 0.004$). These findings indicate that the difference in plaque accumulation between the two groups persisted over time, potentially highlighting variations in material properties and surface smoothness (Figure *5*).


**FIGURE 5: Plaque index comparison**

### Gingival index comparison

The intergroup analysis demonstrated a statistically significant difference in gingival health between Group 1 and Group 2 at both the one- and three-month follow-up intervals. At one month, Group 1 exhibited a significantly lower gingival index compared to Group 2 ($p = 0.005$), indicating better gingival health and reduced inflammation in this group.

This difference remained significant at the three-month follow-up, with Group 1 continuing to show a lower gingival index than Group 2 ($p = 0.001$). The sustained lower gingival index in Group 1 suggests that prefabricated band and loop may have better gingival outcomes, potentially due to factors such as reduced plaque accumulation, improved biocompatibility, or smoother material surfaces minimizing gingival irritation (Figure *6*).

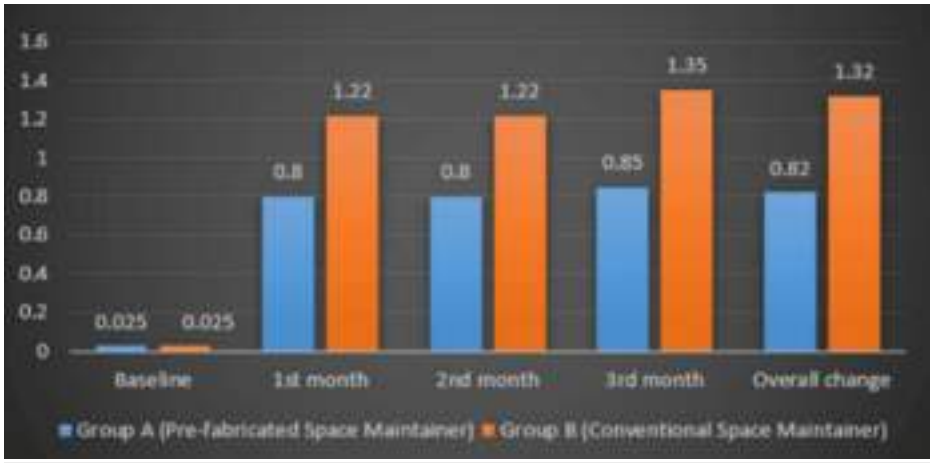


**FIGURE 6: Gingival index comparison**

## Discussion

An ideal space maintainer should effectively preserve the mesiodistal space created following the loss of primary teeth while being structurally simple, durable enough to withstand functional forces, and supportive of normal occlusal function. Additionally, it should facilitate adequate oral hygiene, permit normal growth and adjustment of developing permanent teeth, and prevent supraeruption of opposing teeth or undue stress on adjacent teeth [3]. This study aimed to evaluate the effects of prefabricated and conventional band and loop space maintainers on postextraction wound healing, plaque accumulation, and gingival health.

Wound healing is a complex, highly regulated process driven by the body's natural repair mechanisms [14]. The findings of this study indicate no statistically significant difference in wound healing between the two groups. This similarity may be attributed to biocompatibility and the ability of stainless steel to integrate well with oral tissues, which is the primary material used in both prefabricated and conventional band and

loop space maintainers [15]. Additionally, minimal tissue disruption caused by the placement of either appliance likely contributed to comparable healing patterns.

Further, comparing plaque accumulation and gingival health revealed that both prefabricated and conventional band and loop space maintainers led to increased plaque accumulation and gingivitis over follow-up periods of first, second, and third month. However, conventional band and loop space maintainers resulted in significantly higher plaque accumulation and greater incidence of gingivitis than the prefabricated ones. This finding is consistent with a previous study by Setia et al., where prefabricated bands and loops showed high levels of gingival health of 72.8% compared with conventional type of 45.7% within nine months [16]. A recent study by Dutta et al. revealed a significant statistical difference in gingival status between conventional and prefabricated band and loop space maintainers, wherein after a six-month follow-up, moderate gingivitis was observed in 8% of cases in the prefabricated group, compared to 12% in the conventional group [17].

Conventional band and loop space maintainers often exhibit an irregular surface due to the soldering process, which can contribute to increased plaque retention. The presence of soldered joints serves as a potential nidus for bacterial accumulation, thereby increasing the risk of gingivitis and periodontal disease [18-28]. Furthermore, inadequate polishing of soldered surfaces can result in additional surface irregularities that promote plaque accumulation [19-21,29,30]. In contrast, prefabricated band and loop space maintainers feature a smooth, uniform surface that enhances cleanability [16]. The absence of solder eliminates potential plaque-retentive areas, allowing for more effective plaque and debris removal, reducing the risk of gingival irritation and inflammation, and promoting better gingival health.

The findings of this study suggest that prefabricated band and loop space maintainers may offer advantages in reducing plaque accumulation and maintaining better gingival health compared to conventional band and loop space maintainers.

### Strengths of the study

The strengths of this study include its split-mouth design, which minimizes interindividual variability and enhances the reliability of comparisons, as well as the use of objective assessment methods, such as standardized indices for plaque accumulation and gingival health. Additionally, the study holds significant clinical relevance, given the widespread use of space maintainers in pediatric dentistry. While evidence of their impact on soft tissues and wound healing remains limited, this study provides new insights into these aspects, emphasizing the need for further research to evaluate their long-term effects.

### Limitations of the study

The limited sample size may restrict the generalizability of the findings to a wider population, as a larger cohort would improve statistical power and minimize the risk of sampling bias. Additionally, the short follow-up period may not adequately capture the long-term outcomes or delayed effects of the intervention. Future studies with a larger sample and extended follow-up are needed to validate these findings and assess the long-term effects of prefabricated and conventional band and loop space maintainers.

## Conclusions

Prefabricated band and loop space maintainers offer a practical and efficient solution for space maintenance, with distinct advantages in promoting better oral hygiene and gingival health. Their smooth, nonsoldered surface reduces plaque retention, lowering the risk of gingival inflammation.

In addition to clinical benefits, prefabricated space maintainers streamline treatment by eliminating the need for recording impressions and laboratory work, reducing chairside time, and enabling placement in a single appointment. This not only enhances workflow efficiency but also improves patient compliance and comfort. Given these advantages, prefabricated band and loop space maintainers represent a promising alternative to conventional designs, though further research is needed to evaluate their long-term effectiveness.

## Additional Information

### Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

**Concept and design:** Kalyani Barve, Dimple Padawe, Vilas Takate

**Acquisition, analysis, or interpretation of data:** Kalyani Barve

**Drafting of the manuscript:** Kalyani Barve

**Critical review of the manuscript for important intellectual content:** Dimple Padawe, Vilas Takate

**Supervision:** Dimple Padawe, Vilas Takate

## Disclosures

**Human subjects:** Consent for treatment and open access publication was obtained or waived by all participants in this study. Government Dental College and Hospital, Mumbai, Institutional Ethical Committee issued approval 1374/2023. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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# EVALUATION OF THE EFFECT OF PHOTOBIOMODULATION THERAPY ON POST OPERATIVE PAIN IN CHILDREN UNDERGOING PRIMARY TOOTH EXTRACTION: IN VIVO STUDY

Paediatric Dentistry

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## ABSTRACT

**Introduction:** Managing post-operative pain in pediatric patients following primary tooth extraction is a significant clinical challenge. Conventional methods, such as Local Anesthetics and systemic analgesics, often have limited efficacy and potential side effects. Photobiomodulation therapy (PBMT) has emerged as a promising non-invasive modality. PBMT involves the application of low-intensity LASER light to tissues, promoting analgesic, anti-inflammatory, and biostimulatory effects. **Objective:** This study aims to evaluate the efficacy of PBMT in reducing post-operative pain in children aged 7-10 years undergoing primary tooth extraction. **Methods:** 30 children with over-retained primary maxillary or mandibular incisors, having a behaviour rating of 3 or 4 on the Frankel behaviour scale, were included. Children were randomly assigned to two groups: the experimental group received PBMT using a Diode LASER immediately after extraction, while the control group did not. PBMT was applied at three points (vestibular, lingual, and occlusal) for 60 seconds each, with a probe placed 1 cm from the target area and a power of 300mW. Pain levels were assessed using the Wong-Baker FACES Pain Rating Scale (PRS) before and after treatment. Parents were contacted for three consecutive evenings post-treatment to record pain levels, complications, and analgesic use. **Results:** Preliminary findings suggest that children in the PBMT group reported lower pain scores compared to the control group. **Conclusion:** PBMT appears effective in reducing post-operative pain in Pediatric patients undergoing primary tooth extraction.

## KEYWORDS

Photobiomodulation, primary tooth extraction, post-operative pain, children, diode laser, Wong-Baker FACES Pain Rating Scale.

## INTRODUCTION

Tooth extraction can be an unpleasant and painful experience for the child, with pain being the most common challenge associated with dental procedures. This discomfort often leads to heightened dental fear and anxiety, especially in pediatric patients whose pain control is not effectively managed during or after the procedure. Effective pain management is crucial for guiding behavior in these young patients, ensuring a more positive dental experience and better cooperation during future dental visits. Post-extraction wound healing and pain perception are influenced by several host-related factors, including the patient's immune system, the use of painkillers and antibiotics, the presence of infection, and the invasive nature of the procedure. Additionally, trauma to the anesthetized area by biting can exacerbate inflammation and pain after the extraction. Therefore, optimizing pain management strategies is essential for improving the overall dental care experience for pediatric patients.[2]

PBMT has emerged as a promising adjuvant medical treatment for wound healing and pain management. The principle behind PBMT is that exposure to specific wavelengths of light can alter cellular behavior, leading to enhanced cell proliferation and metabolism. PBMT operates at wavelengths between 630-980 nm and power ranges of 50-550mW, making it athermic, photobiological, and non-destructive. This therapy is both cost-effective and compact, making it accessible for various medical and dental applications.[3-4]

PBMT, also known as biostimulation, is used to treat conditions such as herpes simplex, mucositis, post-surgical pain, inflammation prevention, and temporomandibular joint dysfunction. One of the significant benefits of PBMT is its ability to boost macrophage phagocytic activity in the early stages of tissue formation, facilitating wound debridement and promoting the proliferative phase of healing. This property is particularly beneficial in accelerating wound healing and reducing discomfort after dental extractions.[5-7]

Histologically, after a tooth extraction, a blood clot forms in the socket and is replaced by granulation tissue within the first 6-8 weeks, eventually leading to the formation of mineralized and immature bone. During this critical healing period, applying PBMT to the extraction socket can stimulate an inflammatory response that promotes tissue repair without any adverse effects. This biostimulation method accelerates wound healing and reduces post-extraction discomfort, making it an effective tool in Pediatric dentistry.[8-10]

The purpose of this study is to evaluate the effect of PBMT on post operative pain in pediatric patients scheduled for primary incisor teeth extractions.

This study aims to provide further insight into the effectiveness of PBMT in pediatric dental extractions, focusing on pain management. This research seeks to determine whether PBMT can be a reliable and effective tool in improving post-extraction healing and reducing pain, thereby enhancing the overall dental care experience for children.

## MATERIALAND METHODS

### Study Design

The study will be conducted abiding by all human ethical principles with the Ethical committee reference no. 1375/2024. This clinical trial was designed to evaluate the effects of PBMT post operatively and to determine its impact on pain management. The study was structured to include two groups: an experimental group receiving PBMT post-extraction and a control group that did not receive any LASER application. This randomized controlled trial aimed to provide robust evidence regarding the efficacy of PBMT in pediatric dental procedures.

### Participants Were Recruited Based On The Following Criteria:

### Inclusion Criteria:

**Age Range**: Children aged 7-10 years were selected to ensure a relatively homogeneous group in terms of developmental stage and dental condition.

**Dental Condition**: Participants had over-retained primary maxillary or mandibular incisors, which necessitated extraction.

**Behaviour Rating**: Children with a Frankel behaviour rating of 3 or 4. This ensured that the children could reasonably cooperate during the procedure and follow-up assessments.

### Exclusion Criteria:

**Systemic Diseases**: Children with a history of systemic conditions that could affect healing, such as prolonged bleeding disorders or platelet abnormalities, were excluded to avoid confounding variables.

**Allergies**: Children with known allergic reactions to Local Anaesthetics, antibiotics, or analgesics were excluded to prevent adverse reactions that could complicate the study's outcomes.

### Materials And Equipment To Be Used In Study

**Fig. 1** Represents the BIOLASE LASER used for the present study.

**Procedure**

**Local Anaesthesia and Tooth Extraction**

To minimize discomfort and ensure effective pain control during the extraction, the following steps were taken:
The injection site was thoroughly dried.

A topical anaesthetic was applied using a cotton tip applicator to desensitize the area.

Local infiltration anaesthesia was then administered to provide effective analgesia for the extraction of the over-retained incisors.

**Post-Extraction Treatment**

**Experimental Group:**

**Application of PBMT:** Immediately following the tooth extraction, LASER was applied to the extraction site.

**Device And Parameters**: The Diode LASER (BIOLASE) with a continuous wavelength of 810 nm was used. The LASER probe was positioned 1 cm from the target area. Laser energy of 300mW (0.3 W) was applied to three specific points (vestibular, lingual, and occlusal) for 60 seconds each. This protocol was designed to maximize the therapeutic benefits of PBMT while ensuring patient safety.

**Procedure**: After confirming that bleeding had ceased, the LASER treatment was administered to promote healing and reduce postoperative pain through Photobiomodulation.

**Control Group:**

No LASER application was performed post-extraction. This group served as the baseline to compare the post operative pain against the PBMT-treated group.

**Fig. 2.** Represents the patient undergoing LASER treatment.

**Pain Assessment**

Pain levels were assessed using the Wong-Baker FACES Pain Rating Scale (PRS), a reliable and child-friendly tool:

**Assessment Timing**: Pain assessments were conducted both before and after the treatment to gauge changes in pain levels due to the procedure and the intervention.

**Scale Utilization**: Children selected a facial expression from the PRS that best represented their level of discomfort. This method provided a simple yet effective way to quantify pain in a pediatric population.

**Postoperative Care and Monitoring**

Postoperative pain and any potential complications were monitored through parental reports:

**Follow-Up**: Parents were contacted on the first three evenings following the treatment at the same time each evening.

**Data Collection**: They were asked to report their child's pain levels, any observed complications, and whether any analgesics were administered. This consistent follow-up provided valuable data on the efficacy of PBMT in managing postoperative pain and ensuring a smooth recovery.

**Sample Size Calculation**

The sample size calculation was conducted to ensure the study had sufficient power to detect significant differences between the experimental and control groups:

**Parameters**: The calculation was based on a two-sided t-test for the difference between two independent means, with a level of significance ($\alpha$) set at 5%, power (1-$\beta$) at 80%, an effect size (d) of 1.1, and an allocation ratio of 1.

**Output**: Using G*Power version 3.0.1 (Franz Faul, Universität Kiel, Germany), the calculated sample size was 30 subjects in total, with 15 in each group. This sample size provided a non centrality parameter ($\delta$) of 3.012, a critical t value of 2.048, and 28 degrees of freedom, resulting in an actual power of 0.8283.

**Data Analysis**

Statistical analysis was performed using the Statistical Product and Service Solution (SPSS) version 21 for Windows (SPSS Inc, Chicago, IL):

**Descriptive Statistics**: Quantitative data were expressed as mean and standard deviation to summarize the central tendency and variability.

**Data Normality**: The Shapiro-Wilk test was used to assess the normality of data distribution, ensuring the appropriate statistical tests were applied.

**Confidence Interval And Significance**: A 95% confidence interval was employed, with the level of significance (alpha error) set at 5%. The power of the study was maintained at 80% to detect meaningful differences.

**Intergroup Comparisons**: Qualitative parameters were compared between groups using the Chi-square test, while quantitative parameters were analysed using the unpaired t-test. These statistical methods ensured robust comparisons between the experimental and control groups.

This comprehensive methodology provides a detailed framework for evaluating the clinical effects of PBMT on the extraction sockets in pediatric patients, focusing on pain management outcomes. The study design, participant selection, procedural details, pain assessment, postoperative monitoring, sample size calculation, and data analysis were meticulously planned to ensure the reliability and validity of the findings.

**RESULTS :**

The intergroup comparison of post-extraction pain was evaluated using the Wong-Baker FACES Pain Rating Scale. The mean preoperative pain score for Group I (PBMT) was 6.66 (SD = 2.35), while for Group II (Control), it was 6.8 (SD = 2.24). The Mann-Whitney U test indicated no significant difference between the groups preoperatively ($U = 0.897$, $p = 0.902$).

Postoperatively, the mean pain score for Group I (PBMT) decreased to 3.73 (SD = 1.66), whereas for Group II (Control), it was 5.33 (SD = 2.35). The Mann-Whitney U test revealed a significant difference between the groups postoperatively, with Group I experiencing significantly less pain ($U = 0.45$, $p = 0.036$).

The change in pain scores from pre-op to post-op was also analysed. Group I (PBMT) showed a mean reduction in pain score of 2.93 (SD = 2.49), while Group II (Control) had a mean reduction of 1.46 (SD = 3.15). This difference was statistically significant, indicating a greater reduction in pain for the PBMT group ($U = 0.57$, $p = 0.048$).

Overall, the results demonstrated that PBMT significantly reduced postoperative pain compared to the control group, both in terms of absolute postoperative pain scores and the change in pain scores from pre-op to post-op.

The need for intake of analgesics was compared between the two groups at different postoperative time intervals: 24 hours, 48 hours, and 72 hours.

At 24 hours post-extraction, 33.3% (5 out of 15) of patients in Group I (PBMT) required analgesics, compared to 80% (12 out of 15) in Group II (Control). The Chi-square test showed a significant difference between the groups, with fewer patients in the PBMT group needing analgesics ($Chi = 6.652$, $p = 0.01$).

At 48 hours post-extraction, the need for analgesics decreased in both groups, with 20% (3 out of 15) of patients in Group I (PBMT) requiring them, compared to 60% (9 out of 15) in Group II (Control). The Chi-square test again indicated a significant difference, favouring the PBMT group ($Chi = 5.00$, $p = 0.0025$).

At 72 hours post-extraction, the need for analgesics further decreased, with 6.7% (1 out of 15) of patients in Group I (PBMT) needing them, compared to 20% (3 out of 15) in Group II (Control). However, this difference was not statistically significant ($Chi = 1.154$, $p = 0.283$).

These results indicate that PBMT significantly reduces the need for analgesics in the immediate postoperative period (24 and 48 hours) compared to the control group, although the difference becomes non-significant by 72 hours post-extraction.

The results of this study clearly demonstrate the benefits of PBMT in

managing postoperative pain and reducing the need for analgesics in pediatric patients undergoing tooth extractions. The significant reduction in pain scores and the decreased need for analgesics in the PBMT group compared to the control group highlight the efficacy of PBMT as a valuable adjunctive treatment in pediatric dental procedures. These findings suggest that PBMT can enhance patient comfort and potentially improve the overall experience of dental care for children. Statistical analysis was performed using Statistical Product and Service Solution (SPSS) version 21 for Windows (SPSSInc, Chicago, IL).

## DISCUSSION

This study evaluates the impact of Photobiomodulation therapy (PBMT), specifically low-level laser therapy (LLLT), on post-operative pain in children undergoing primary tooth extraction. The findings from this study align with existing literature, demonstrating the efficacy of LASER in various dental procedures and pain management.[18-20]

LASERs have revolutionized dental treatments by offering precise and versatile solutions for a wide range of oral health issues.[21-22] Clinical applications extend from managing tooth decay, gingival reshaping, and maxillary sinusitis to addressing aesthetic concerns and periodontal diseases. Additionally, LASERs have been effective in treating conditions such as periodontitis, tooth sensitivity, gingival discoloration, and oral mucosal diseases. Their role in sterilizing root canals, treating peri-implantitis, promoting wound healing, and facilitating implant surgery further underscores their importance in modern dentistry (Mester & Tota, 2023; Woodruff et al., 2023).[1-2]

Soft tissue applications have seen a significant rise in the use of various LASERs like Nd:YAG, Er:YAG, CO2, and Diode LASERs. These offer numerous advantages, including minimal anaesthesia requirement, reduced vibration, minimal scarring, and shorter application times. They also provide excellent hemostasis, enhancing the field of view and reducing the risk of postoperative complications, making them particularly beneficial for pediatric patients (Herascu et al., 2023; Akhil et al., 2023).[3-4]

PBMT has shown promise in reducing inflammation and alleviating post-surgical pain by altering the pain threshold, decreasing the release of pain mediators like bradykinin and histamine, and stimulating endorphin production. Studies indicate that PBMT can effectively manage pain associated with orthodontic treatments and root canal therapy (Ismail et al., 2023).[5] In cases of oral mucositis in pediatric patients undergoing chemotherapy, PBMT significantly reduced pain perception and analgesic use, highlighting its potential in managing complex oral conditions (Woodruff et al., 2023).[2] The results of our study provide substantial evidence supporting the benefits of PBMT in managing post-operative pain and enhancing wound healing in pediatric patients undergoing primary tooth extraction.

**Table 1** shows the intergroup comparison of post-extraction pain using the Wong-Baker FACES pain rating scale. Pre-operatively, both groups reported similar pain levels (Group I: 6.66 ± 2.35, Group II: 6.8 ± 2.24; p=0.902). Post-operatively, a significant reduction in pain was observed in the PBMT group compared to the control group (Group I: 3.73 ± 1.66, Group II: 5.33 ± 2.35; p=0.036). The change in pain score also favoured the PBMT group significantly (Group I: 2.93 ± 2.49, Group II: 1.46 ± 3.15; p=0.048).

**Table 2** presents the need for analgesics at different post-operative intervals. The PBMT group required significantly fewer analgesics within the first 24 hours post-extraction (33.3% vs. 80%, p=0.01) and at 48 hours post-extraction (20% vs. 60%, p=0.0025). However, no significant difference was observed at 72 hours (6.7% vs. 20%, p=0.283).

These results are consistent with previous research indicating the efficacy of PBMT in reducing post-operative pain and enhancing healing. Our study supports these findings, demonstrating that PBMT can effectively reduce post-operative pain in children following primary tooth extraction. The reduction in pain perception and the decrease in lesion size observed in our study are consistent with previous research. For instance, a clinical study involving pediatric patients with minor recurrent oral aphthous stomatitis found significant reductions in lesion size and pain perception with PBMT treatment (Herascu et al., 2023).

Furthermore, the ability of PBMT to enhance wound healing by stimulating cellular activities such as phagocytosis by macrophages and the release of growth factors, as shown in studies by Mester and Tota (2023), adds to the therapeutic potential of PBMT in dental care (Mester & Tota, 2023; Noda et al., 2023).

While our findings align with those of other studies, some research indicates variability in pain reduction effectiveness. For example, studies by Elbay et al. (2023) and Paschoal and Santos-Pinto (2023) found no significant statistical difference in pain perception between PBMT and control groups post-extraction, although subjective pain scores and analgesic use were slightly better in the PBMT groups (Elbay et al., 2023; Paschoal & Santos-Pinto, 2023). These discrepancies highlight the need for further research to fully understand the long-term benefits and potential limitations of PBMT in pediatric dentistry.

A recent study by Mandic (2015) found that PBMT can effectively promote bone healing around immediate implants, suggesting its potential to improve the success rates of implant procedures (Mandic, 2015). Additionally, Akhil et al. (2023) reported on the changes in bone density in alveolar ridge augmentation techniques, finding no significant difference between PBMT and control groups but noting the potential for PBMT to aid in maintaining alveolar bone dimensions (Akhil et al., 2023).

The clinical advantages of PBMT are particularly crucial for children with weakened immune systems, such as those with insulin-dependent diabetes, previous endocarditis or heart complications, and oncology patients undergoing chemotherapy or radiation therapy. This demographic can benefit significantly from the reduced risk of postoperative complications and enhanced healing provided by PBMT (Elbay et al., 2023; Paschoal & Santos-Pinto, 2023)

Despite the promising results, this study has several limitations that need to be considered. First, the sample size was relatively small, which may limit the generalizability of the findings. A larger sample size would provide more robust data and strengthen the validity of the conclusions. Second, the study was conducted in a single clinical setting, which may not represent the broader pediatric population or different clinical environments. Multi-center studies would help in confirming these results across diverse populations and settings.

Additionally, the follow-up period was limited to 72 hours post-extraction. While this time frame is sufficient to observe immediate post-operative pain and analgesic use, it does not account for long-term healing and pain management. Future studies should incorporate longer follow-up periods to evaluate the sustained effects of PBMT on wound healing and pain.

Another limitation is the potential for bias in pain reporting. Although the Wong-Baker FACES pain rating scale is a validated tool, pain perception is subjective and can be influenced by various factors, including the child's mood, environment, and parental influence. Objective measures of inflammation and healing, such as biomarkers or imaging techniques, should be included in future studies to provide a more comprehensive assessment.

Lastly, the study did not explore the dose-response relationship of PBMT. Different wavelengths, power settings, and durations of PBMT may have varying effects on pain and healing. Future research should investigate these parameters to optimize PBMT protocols for pediatric dental patients.

This study adds to the growing body of evidence supporting the use of Photobiomodulation therapy (PBMT), specifically low-level laser therapy (LLLT), in managing post-operative pain and enhancing wound healing in pediatric patients undergoing primary tooth extraction. The results indicate that PBMT significantly reduces post-operative pain and the need for analgesics, promoting a more comfortable recovery period for children.

The clinical advantages of PBMT, including its non-invasive nature, minimal side effects, and ability to enhance cellular activities involved in healing, make it a valuable tool in pediatric dentistry. This is particularly crucial for children with compromised immune systems or those undergoing other medical treatments, as they benefit significantly from the reduced risk of postoperative complications and

enhanced healing provided by PBMT.

While the study's findings are promising, further research with larger sample sizes, multi-center designs, longer follow-up periods, and objective measures of healing is necessary to fully understand the long-term benefits and potential limitations of PBMT in pediatric dental care. Additionally, exploring the optimal parameters for PBMT application will help in standardizing treatment protocols and maximizing clinical outcomes.

In conclusion, PBMT shows significant potential as an effective and minimally invasive method for managing post-operative pain in pediatric dental patients. Continued advancements in LASER technology and further research will likely enhance our ability to provide high-quality, patient-centered care in Pediatric dentistry.

**Table 1: Intergroup comparison of post extraction pain was evaluated using the Wong-Baker FACES pain rating scale between both groups respectively**

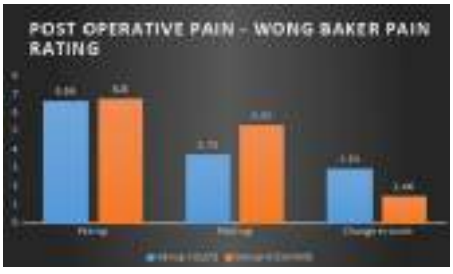
| Wong-Baker FACES pain rating scale | Group I (PBMT) Mean (SD) | Group II (Control) Mean (SD) | Mann Whitney U test | P value, Significance |
|---|---|---|---|---|
| Pre-op | **6.66 (2.35)** | **6.8 (2.24)** | **U = 0.897** | **p=0.902 (NS)** |
| Post-op | **3.73 (1.66)** | **5.33 (2.35)** | **U = 0.45** | **p=0.036*** |
| Change in score | **2.93 (2.49)** | **1.46 (3.15)** | **U = 0.57** | **p =0.048*** |

p>0.05 – no significant difference *p<0.05 – significant difference

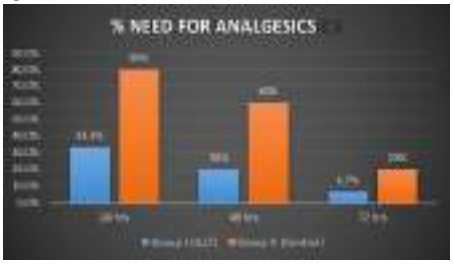
**Table 2: Intergroup comparison of need for intake of Analgesics between both groups at different post -operative time interval**

| Need for analgesics in | Group I (PBMT) N (%) | Group II (Control) N (%) | Chi square test value | P value, Significance |
|---|---|---|---|---|
| 24 hrs | 5/15 (33.3%) | 12/15 (80%) | Chi = 6.652 | p=0.01* |
| 48 hrs | 3/15 (20%) | 9/15 (60%) | Chi = 5.00 | p=0.0025* |
| 72 hrs | 1/15 (6.7%) | 3/15 (20%) | Chi = 1.154 | p =0.283 (NS) |

p>0.05 – no significant difference *p<0.05 – significant difference




**Graph 1:** Given graph represents the post operative pain-Wong Baker pain rating.

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# COMPARATIVE EVALUATION OF SOFT TISSUE LASER THERAPY AT 660NM AND 810NM FOR REDUCING LOCAL ANAESTHESIA REVERSAL TIME IN CHILDREN AGED 6-10 YEARS: A RANDOMIZED CONTROLLED TRIAL

Dentistry

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## ABSTRACT

**Introduction:** Local anaesthesia (LA) plays a crucial role in pain management during dental procedures, especially in children. However, its prolonged effects can lead to complications such as speech impairment, cheek biting, and difficulty in eating, causing discomfort. To address this, researchers have explored photobiomodulation therapy to expedite anaesthesia reversal. **Aim:** To compare and evaluate the reduction in local anaesthesia reversal time using soft tissue LASER at 660nm and 810nm respectively. Material & Method: This randomised controlled trial allocated children into two groups: Group A1 received LASER (Light Amplification by Stimulated Emission of Radiation) irradiation at 810nm, and Group B1 at 660nm. Both groups were further divided into subgroups—A2 and B2, which received sham LASER as controls. Reversal of the soft tissue anaesthetic effect was assessed using palpation and pinprick tests every 15 minutes. The LASER irradiation cycle continued until complete anaesthesia reversal. The outcome was measured by the time anaesthesia took to wear off. **Result:** The reduction in soft tissue anaesthesia reversal time was 157 minutes for 810nm LASER and 156 minutes for 660nm LASER, compared to 195 minutes in the sham LASER groups. **Conclusion:** Photobiomodulation therapy at 660nm and 810nm diode LASER has been proven to significantly reduce the duration of anaesthesia in children, aged 6 to 10 years. However, there is no significant difference between reversal time required by photobiomodulation at 660nm & 810nm.

## KEYWORDS

pain modulation, local anaesthesia reversal, photobiomodulation, lip and cheek biting, phentolamine mesylate

## INTRODUCTION

Local anaesthetics (LA) are frequently used in dentistry before starting many dental procedures. However, the prolonged effects of LA, post-treatment may lead to additional problems such as speech impairment, cheek biting, problems with swallowing, eating and drinking.[1] The prolonged effect of local anaesthesia on soft tissues, even after completion of the dental treatment, has been observed as an issue in 15% of children. [2] The numbness in the soft tissue has been observed to last for approximately 3 to 5 hours, which is much more than required. [3] To overcome this, researchers have proposed a soft tissue LASER therapy, using the property of photobiomodulation to reduce the time for reversal of the anaesthesia. This treatment modality is a safe, non-invasive and painless technique, especially in children and omits the second step of injection compared with Phentolamine mesylate, a known local anaesthetic reversal agent. [4]

Photobiomodulation therapy uses visible and near-infrared light sources using LASER, which increases the microcirculation and promotes vasodilation, encouraging the reversal of local anaesthesia from the injection site. [5,6] This study aims to compare and evaluate the reduction in the reversal of local anaesthesia time using soft tissue LASER at 660nm and 810nm respectively.

## SUBJECTS AND METHODS

The present randomized controlled double-blinded clinical study was conducted in the Department of Paediatric & Preventive Dentistry, Government Dental College & Hospital, Mumbai. The study was conducted abiding by all human ethical principles as per the Declaration of Helsinki and guidelines of the Occupational Safety and Health Administration [OSHA].

A sample size of 50 was established by G*Power version 3.0.1(Franz Faul universitat, Kiel, Germany) using t test where the effect size was 0.7, power 0.80 and significance level was 0.05.

### Sample Allocation & Randomisation

In this split-mouth study, a total of 50 children meeting the inclusion criteria were divided into 2 groups at random using the lottery method. Written informed consent in a language best understood by the parent was obtained before starting the procedure

### Blinding

The current research was double blinded using the blinding of co-investigators who performed test for evaluating the reversal time and statisticians.

The Selection Criteria are as follows:

**Inclusion Criteria**

a) Children in the age group of 6-10 years.
b) Children undergoing treatment which requires local anaesthesia using maxillary buccal infiltration for extraction of primary molars, bilaterally.
c) Children in category 3 or 4 according to Frankl's behaviour rating scale.
d) Children aged 6 to 10 years old with the ability to understand and respond to the sensation of soft tissue.

**Exclusion Criteria**

a) Children with any underlying systemic disease.
b) Lack of proper understanding of the patient during the training to evaluate the response to soft tissue anaesthesia.
c) History of allergy to materials used for anaesthesia.
d) Children who had received analgesic drugs within 24 hours before treatment.
e) Children whose parents are not willing to give consent.

The study population was divided into two main groups, Group A and Group B, based on the wavelength of LASER therapy applied. Each group was further subdivided as follows:

- Group A1: LASER irradiation at 810nm wavelength- 25 children
- Group A2: Sham LASER therapy, where the LASER module was placed intraorally without actual irradiation- 25 children
- Group B1: LASER irradiation at 660nm wavelength- 25 children
- Group B2: Sham LASER therapy, similar to Group A2- 25 children

This subdivision allowed for both active and placebo-controlled comparisons in the same patient in this split-mouth design at the same time.

**Method of Application:** After the administration of LA, the timer was started. Extraction was done and hemostasis was achieved. Photobiomodulation therapy was then performed mesial & distal to the site of injection, at the commissure of the lip & on the skin overlying the site of injection. The reversal of the soft tissue local anaesthetic effect was evaluated using palpation and pinprick tests every 15 minutes and the LASER irradiation cycle was continued until reversal of the soft tissue local anaesthesia was achieved. The outcome was assessed based on the time taken for the anaesthesia to wear off completely.

**Figure 1: Indilase Unit For Photobiomodulation Using Soft Tissue Diode LASER**

**Figure 2: LASER therapy Directed On The Commissure Of The Lip**

**Figure 3: LASER Therapy Directed On The Skin Over Site Of LA Administration**

**Figure 4: LASER Therapy Directed Mesial And Distal To The Site Of LA Administration**

**Statistical Analysis**

Statistical analysis was performed using Statistical Package for Social science (SPSS) version 21 for Windows (SPSSInc Chicago, IL). Data normality was checked by using Shapiro – Wilk test. Confidence interval was set at 95% and probability of alpha error (level of significance) set at 5%. Power of the study was set at 80%.

Intergroup comparison between both groups in respect to qualitative study parameters was done using Chi square test. Intergroup comparison between both groups in respect to quantitative study parameters was done using unpaired t test.

## RESULTS

There was highly significant statistical difference between the results obtained through the photobiomodulation vs the SHAM LASER ($p<0.001$). However, there is no significant difference between the two groups when comparing the results of the 810 and 660nm wavelengths ($p>0.05$). [Table1- 2]

**Table 1: Comparison Of Duration Of Anaesthesia Between LASER Irradiation & Sham Groups Expressed In Minutes**

| | Mean | SD | Mean Difference (SE) | Unpaired t-test | P value, Significance |
|---|---|---|---|---|---|
| Group A (810 nm) | 157.8 | 16.83 | 36.0 (4.86) | t = -7.518 | P< 0.001** |
| SHAM | 194.4 | 17.57 | | | |
| Group A (660 nm) | 156.6 | 17.89 | 38.4 (5.05) | t = -7.595 | P<0.001** |
| SHAM | 195.0 | 17.85 | | | |

**p<0.001 – highly statistically significant difference

**Table 2: Comparison Of Duration Of Anaesthesia Between Both Types Of Diode LASER Expressed In Minutes**

| | Mean (min) | SD (min) | Mean Difference (SE) | Unpaired t-test | P value, Significance |
|---|---|---|---|---|---|
| Group A (810 nm) | 157.8 | 16.83 | 1.2 (4.91) | t = 0.244 | P=0.808 |
| Group B (660nm) | 156.6 | 17.89 | | | |

p>0.05 – no statistically significant difference

## DISCUSSION

Most of the patients report fear of pain and unpleasant experiences as the main reason for not following and receiving care and dental treatments. [7,8]. To minimize this discomfort, local anaesthetic solutions have been routinely used in dental practice to relieve pain lined with various dental procedures since the 19th century[9]. Patients often feel unwell during long periods of anaesthesia and mention it as an experience associated with functional impairments such as problems with ingestion, drinking, talking and smiling [5,10]. In addition, longer periods of anaesthesia usually involve a greater risk of accidental lip and cheek biting, especially in children. The administration of LA could result in self inflicted injuries to surrounding tissues in 13% of subjects according to studies[11].

To overcome these problems and reverse soft tissue anaesthesia, some medications such as Phentolamine mesylate have been introduced in past. It acts as a competitive inhibitor against epinephrine owing to its similar chemical structure [12]. Injection of this substance with the same volume and at the same area targeted for anaesthetic injection can help to return the normal sense to the soft tissue quickly. But it also leads to more trauma to the child due to repeated injections. This led to a search for new modalities which were less invasive. Photobiomodulation also known as Low Level LASER therapy is a recent development which has come into light for the reversal of anaesthesia.[13]

In the last decade, several studies have been done focusing on the application of LASER in dental practice[14]. In summary, the results of these investigations claimed that LASER can facilitate innovative and minimally invasive therapies in different treatment modalities including preventive and restorative dentistry and surgical procedures in high-power mode as well as biostimulative, anti-inflammatory and analgesic effects in low-power mode named as photobiomodulation. In Pediatric dentistry, LASER also offers more acceptance and tolerance of treatment for children due to its non-invasive form[15].

LASER therapy has shown encouraging results in previous studies like enhancement of microcirculation, stimulation of release of an endothelium-dependent vasodilator and rescuing vascular dysfunction, and acceleration of collateral circulation in the vascular bed of deprived tissue after an injury. [16,17] So, we decided to utilize this benefit of LASER in pediatric dentistry to accelerate the elimination of soft tissue anaesthesia.

Photobiomodulation targets the Cytochrome C complex. It is found in the inner membrane of the mitochondria and is a vital component of the electron transport chain that regulates cellular metabolism including elimination of drugs & their metabolites.[18]

Photobiomodulation also enhances the production of nitrous oxide in the vasculature which is responsible for vasodilation and thus, the elimination of local anaesthetic from the target site. [19]

Additionally, LASER irradiation can induce cellular alkalinisation, induce TRPV (Transient Receptor Potential Vanilloid) gate opening and a consequent Ca2+ influx. This Ca2+ influx can mediate histamine release in mast cells, which ultimately results in vasodilatation and contributes to elimination of LA.[20]

Podogrodzki et al. concluded the positive effect of low-power 680-nm

LASER irradiation on the amount of blood flow in the skin of children between the ages of 3 and 15 years and stated that LASER application significantly increased the blood flow in the skin and none of the patients reported the warming sign of the irradiated area [21]. Also, Seraj et al. (2020) conducted a study including 34 children aged 4–8 years to reverse soft-tissue local anaesthesia using 810nm LASER and found a reduction of 43 min in the reversal duration of soft-tissue local anaesthesia in comparison to those without photobiomodulation. [5]

According to the results of the present study, photobiomodulation therapy by 810-nm and 660nm diode LASER with an energy density of 6.3 J/cm2, reduced the time of soft tissue anaesthesia significantly by about 40 min in comparison with the Sham LASER group. The reduction in the reversal time of soft tissue local anaesthesia at 810 nm was 36.6 minutes and for 660nm was 38.4 minutes respectively.

This clinical trial is a preliminary one that evaluated the effect of photobiomodulation therapy as a non-invasive treatment modality for the reversal of soft tissue local anaesthesia instead of the invasive method of Phentolamine Mesylate injection which makes it novel and different in comparison with previous studies. Further research, encompassing a broader array of analytical methods and more sample size is warranted to reveal more in-depth evidence of the effect of photobiomodulation on the reversal of local anaesthesia.

## CONCLUSION

According to the encouraging results of this study, photobiomodulation therapy both at 660 nm and 810 nm diode LASER has been proven to significantly reduce the duration of anaesthesia in children aged 6 to 10 years with negligible difference using either wavelength .

This treatment modality is a safe, non-invasive and painless technique beneficial especially in children and omits the second injection step compared with Phentolamine mesylate.

Further studies with different wavelengths, a combination of two wavelengths, and different energy densities in different age groups with larger populations under study are necessary to substantiate the results and probably find exact parameters for more reduction in anaesthetic reversal time.

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SYSTEMATIC REVIEW

# Dental Implants as a Treatment Option for Prosthetic Rehabilitation of Children with Ectodermal Dysplasia: A Systematic Review

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## Abstract

**Aims and background:** Ectodermal dysplasia (ED) typically involves anomalies in two or more ectodermal structures, including the skin, hair, nails, sweat glands, and teeth. Among these manifestations, dental anomalies often present a significant challenge, as they can profoundly impact an individual's oral health, masticatory function, esthetics, and psychosocial well-being.

In recent years, dental implants have emerged as a transformative treatment option for prosthetic rehabilitation in individuals with ED, offering a more predictable and durable alternative to traditional removable prostheses.

Given the complexity of managing dental anomalies in children with ED and the evolving landscape of implant dentistry, there is a critical need to systematically evaluate the existing literature on the use of dental implants for prosthetic rehabilitation in this unique patient population. By synthesizing the available evidence, this systematic review aims to provide insights into the clinical outcomes, complications, success rates, and patient satisfaction associated with dental implant therapy in children with ED.

**Materials and methods:** A comprehensive literature search was conducted to identify relevant studies published in electronic databases, including PubMed, Embase, Scopus, and Web of Science, using a combination of keywords and Medical Subject Headings (MeSH) terms related to ED, dental implants, prosthetic rehabilitation, and pediatric patients.

**Results:** Among the reported cases, all the authors reported positive outcomes with stable implants and dentures along with favorable growth of the jawbones. Across the studies, the success rates of implants ranged from 88 to 100% over a follow-up period of 3–8.1 years.

**Conclusion:** The findings from this systematic review support the growing body of evidence advocating for the integration of dental implants into comprehensive treatment plans for prosthetic rehabilitation in children.

**Clinical significance:** Implant-supported overdentures and implant-supported fixed prostheses emerged as primary treatment modalities, offering stable, durable, and esthetically pleasing restorations that enhance oral function and promote facial harmony in children with ED.

**Keywords:** Children, Dental implants, Ectodermal dysplasia, Prosthetic rehabilitation.

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## Introduction

Ectodermal dysplasia (ED) represents a complex and heterogeneous group of congenital disorders characterized by developmental abnormalities affecting structures derived from the ectodermal germ layer.[1] These anomalies encompass a broad spectrum of clinical features, ranging from minor cosmetic concerns to profound functional impairments.[2] ED typically involves anomalies in two or more ectodermal structures, including the skin, hair, nails, sweat glands, and teeth.[3] Among these manifestations, dental anomalies often present a significant challenge, as they can profoundly impact an individual's oral health, masticatory function, esthetics, and psychosocial well-being.[4]

The dental phenotype of ED is highly variable but commonly includes hypodontia (congenital absence of teeth), malformed or peg-shaped teeth, delayed eruption, and enamel defects.[5] These dental anomalies may occur in isolation or in combination with other systemic features of the disorder, such as hypohidrosis (reduced ability to sweat), sparse hair, and facial dysmorphisms.[6] While the severity and extent of dental involvement can vary widely among individuals with ED, the functional and esthetic consequences of these anomalies can be profound, particularly in children as they navigate critical developmental stages and social interactions.[7]

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Prosthetic rehabilitation plays a crucial role in addressing the dental sequelae of ED, aiming to restore oral function, esthetics, and self-esteem.[8] Traditional treatment approaches for managing dental anomalies in individuals with ED have primarily relied on removable prostheses, such as partial or complete dentures.[9] While these conventional prosthetic solutions can provide temporary relief, they often present challenges related to stability, retention, and maintenance, especially in young patients with ongoing craniofacial growth and development.[10]

In recent years, dental implants have emerged as a transformative treatment option for prosthetic rehabilitation in individuals with ED, offering a more predictable and durable alternative to traditional removable prostheses.[11] Dental implants are titanium screw-like fixtures surgically placed into the jawbone, serving as artificial tooth roots onto which prosthetic restorations can be anchored.[12] The osseointegration process allows for stable integration of the implant with the surrounding bone, providing a solid foundation for fixed or removable dental prostheses.[13] In the context of ED, dental implants offer the potential to improve masticatory function, speech, facial esthetics, and overall quality of life for affected individuals, particularly children and adolescents.[14]

While the use of dental implants in adults with ED has been well-documented in the literature, their application in pediatric populations remains relatively limited and requires careful consideration of various factors, including skeletal growth, dental maturity, systemic health, and patient compliance.[15] Furthermore, the long-term success and sustainability of dental implants in children with ED are influenced by a multitude of factors, including implant placement timing, surgical technique, implant design, occlusal forces, and maintenance protocols.[16]

Given the complexity of managing dental anomalies in children with ED and the evolving landscape of implant dentistry, there is a critical need to systematically evaluate the existing literature on the use of dental implants for prosthetic rehabilitation in this unique patient population.[17] By synthesizing the available evidence, this systematic review aims to provide insights into the clinical outcomes, complications, success rates, and patient satisfaction associated with dental implant therapy in children with ED.[18] Additionally, the review will explore the impact of various clinical and biological factors on the feasibility, efficacy, and long-term stability of dental implants in pediatric patients with ED.[19]

Understanding the current state of knowledge in this field is essential for guiding evidence-based clinical decision-making and optimizing treatment outcomes for children with ED. By identifying gaps in the literature and elucidating areas for further research, this systematic review seeks to advance our understanding of dental implant therapy in pediatric patients with ED and contribute to the development of tailored treatment protocols and guidelines. Ultimately, the findings of this review have the potential to inform clinical practice, enhance patient care, and improve the oral health and quality of life of children with ED.

## Materials and Methods

### Literature Search Strategy

A comprehensive literature search was conducted to identify relevant studies published in electronic databases, including PubMed, Embase, Scopus, and Web of Science. The search strategy employed a combination of keywords and Medical Subject Headings (MeSH) terms related to ED, dental implants, prosthetic rehabilitation, and pediatric patients. The inclusion criteria encompassed studies published in English, focusing on dental implant outcomes in children with ED. The search was conducted from the inception of each database to the present date.

### Study Selection Criteria

Eligibility criteria for study inclusion were predefined. Included studies involved pediatric patients aged 0–18 years diagnosed with ED who had undergone dental implant placement for prosthetic rehabilitation. Studies reporting clinical outcomes, complications, success rates, and patient satisfaction were considered. Both prospective and retrospective study designs were included. Exclusion criteria involved studies with insufficient data, review articles, and studies involving adults or non-ED populations.

### Data Extraction

A standardized data extraction form was developed to capture relevant information from selected studies. Extracted data included study characteristics (author, publication year, study design), patient demographics (age, gender), ED subtype, implant characteristics (type, size), surgical protocol, prosthetic design, follow-up duration, clinical outcomes (success rates, complications), and patient-reported outcomes (satisfaction, quality of life).

### Quality Assessment

The methodological quality of included studies was assessed using appropriate tools such as Risk Of Bias In Nonrandomized Studies of Interventions (ROBINS-I) for nonrandomized clinical trials and the Joanna Briggs Institute (JBI) Risk of Bias tool for case reports and case series. The assessment was independently conducted by two reviewers, and any discrepancies were resolved through consensus or consultation with a third reviewer (Figs 1 and 2).

### Data Synthesis and Analysis

The extracted data were synthesized to provide a narrative overview of the included studies. Descriptive statistics, including means, standard deviations, and percentages, were calculated for quantitative outcomes. Heterogeneity among studies was assessed using statistical methods ($I^2$ statistic), and a random-effects model was employed if substantial heterogeneity was present.

### Subgroup Analysis

Subgroup analyses were conducted to explore variations in outcomes based on factors such as ED subtype, age-group, implant type, and follow-up duration. Sensitivity analyses were performed to assess the robustness of the findings (Tables 1 and 2).

### Ethical Consideration

As this was a systematic review of published literature, ethical approval was not required. The review adhered to ethical guidelines and principles, ensuring the confidentiality and anonymity of study participants.

### Reporting

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed to ensure transparent and comprehensive reporting of the review process and results (Fig. 3).[20]

## Results

A total of 16 cases were identified across various articles published in the years 1997–2020.[21–34]

*N* = 3 cases were reported from Turkey to Lebanon, respectively, *n* = 2 cases from Brazil to the USA, respectively, and one case reached from France, Iran, the United Kingdom, and Canada, respectively.

*N* = 4 studies were identified from 1999 to 2023, two of which were conducted in the USA, and one study each in Australia and Italy, respectively.[35–38] All the studies were cohort observational studies, with two being prospective and two retrospective in nature. The sample size across these studies ranged from 6 to 51 cases.

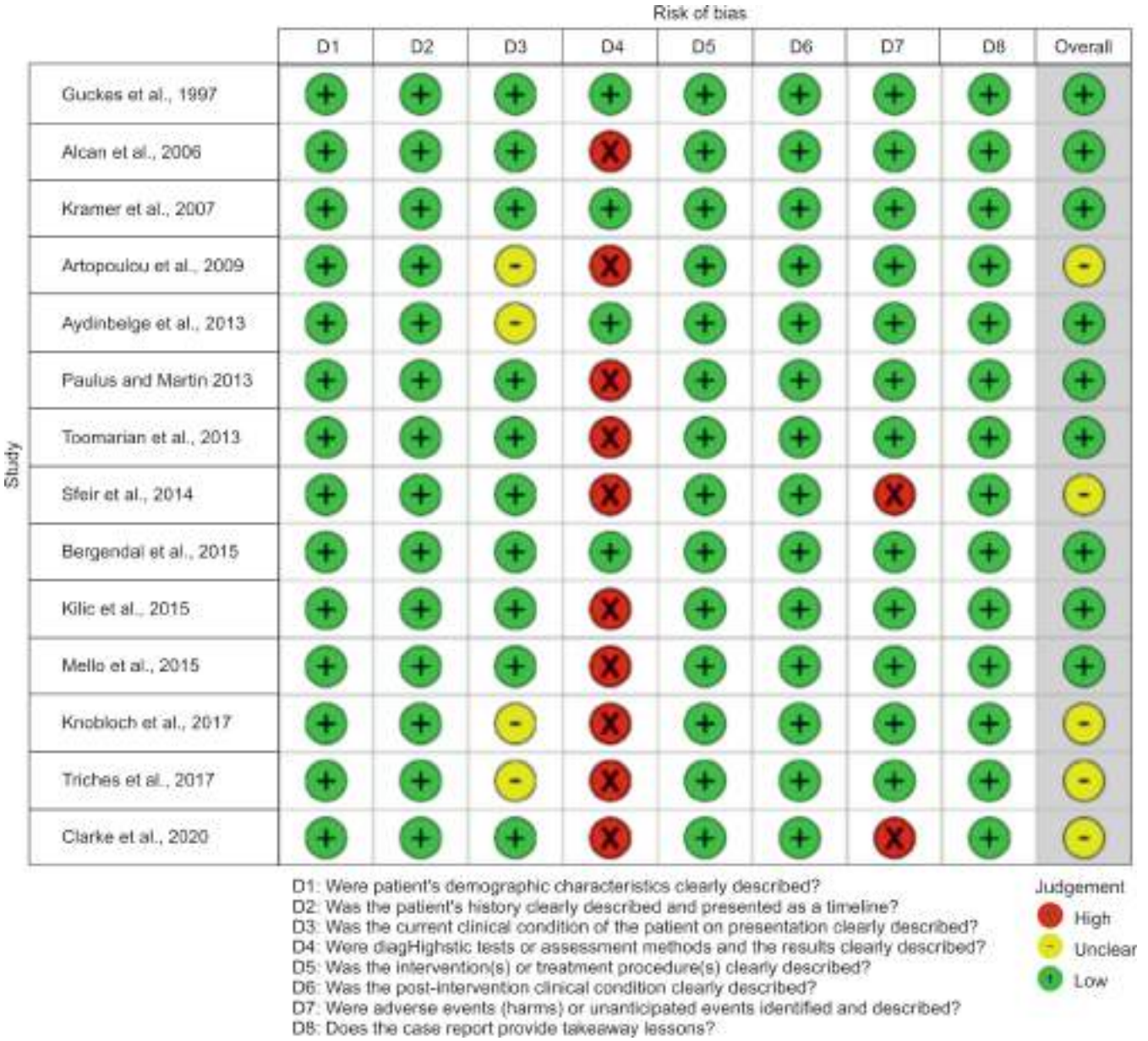


**Fig. 1:** Risk of bias in the individual case reports

The age of the patients at which the implant was placed ranged from 3 to 12 years, with a mean of 7.56 years. The cases comprised 12 males and 5 females. The hypohidrotic type of ED was reported in $n = 4$ cases. The study population of Kearns et al. comprised entirely of males, and that in other studies was also predominantly of males.

All the teeth were missing (anodontia) in $n = 6$ cases, while a majority ($n = 10$) had oligodontia with fewer than six teeth present, and $n = 4$ cases had hypodontia with >6 teeth present in the oral cavity. Besides missing teeth, atrophy of the jaws and conical-shaped maxillary anterior crowns were the most common other oral findings reported by the authors.

In cases that were not completely edentulous, it was observed that the majority of cases had complete anodontia in the mandible, but some teeth were retained in the maxillary jaw. Thus, implant-supported dentures were provided for the mandibular arches, and conventional dentures or tooth-supported dentures were provided for the maxillary arch.

Implant-supported overdentures were provided in $n = 11$ cases and implant-supported fixed prostheses in the remainder of $n = 5$ cases.

In the reported cases, the number of implants placed varied from 2 to 12, with the majority of cases involving the placement of two implants in the mandibular anterior region and four implants in the posterior region. Across the studies, all of them utilized titanium implants, and the total number of implants placed varied from 18 to 264.

Among the reported cases, all the authors reported positive outcomes with stable implants and dentures, along with favorable growth of the jawbones. The only exception was Kramer et al., who noted a poor downward growth of the maxillary and mandibular

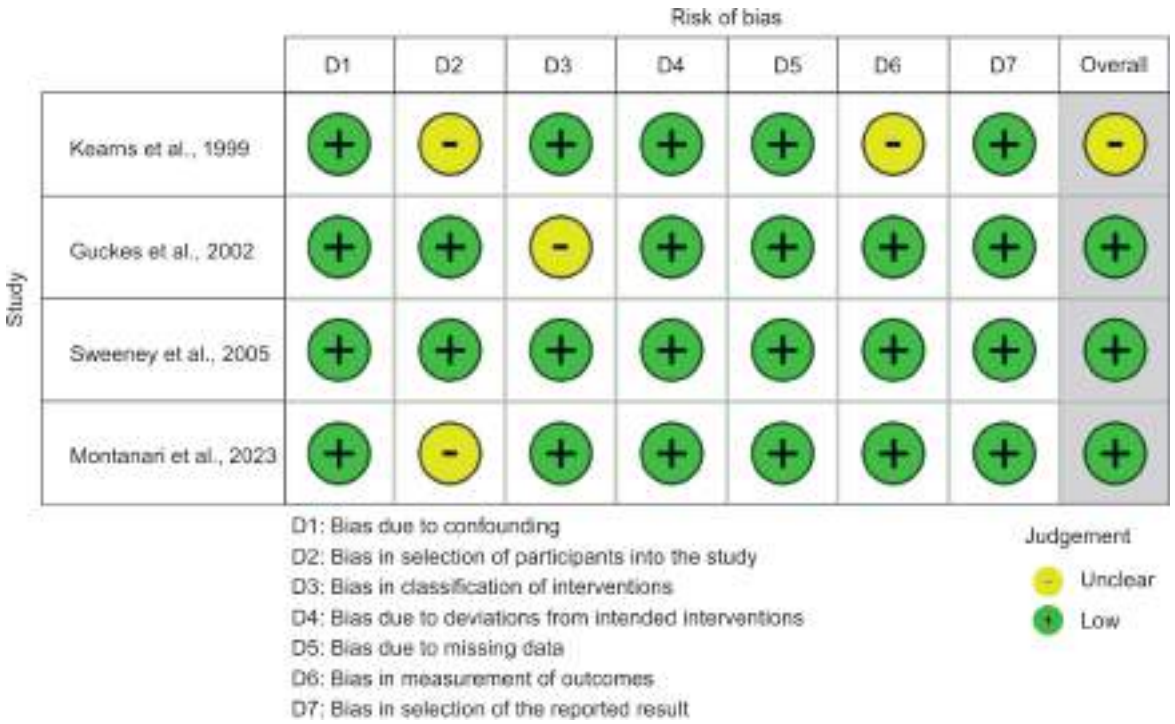


**Fig. 2:** Risk of bias in the individual studies

jaws. The follow-up across the case reports ranged from 6 months to 16 years.

Across the studies, the success rates of implants ranged from 88 to 100% over a follow-up period of 3–8.1 years. The 100% success rate was reported in the recent study by Montanari et al. in 2023 after the longest follow-up period of 8.1 years, although the sample size was limited to only nine individuals.

## Discussion

The identification of case reports and observational studies pertaining to dental implants in the prosthetic rehabilitation of children with ED underscores the rarity of this condition and the limited scope of research available. The 16 cases identified across various articles, spanning over two decades, reflect the scarcity of data on this specific population. The distribution of cases across various countries, with concentrations in Turkey, Lebanon, Brazil, and the USA, suggests a global interest and concern for addressing the dental needs of children with ED through implant therapy.

The diversity in geographic distribution may reflect differences in healthcare systems, cultural practices, and access to specialized care, which can influence the availability and utilization of dental implant treatment for ED.[39] For instance, countries with advanced dental infrastructure and resources may have higher rates of reported cases and studies due to increased awareness and access to specialized treatments.[40] Conversely, regions with limited resources or awareness may have fewer reported cases and studies, highlighting disparities in healthcare access and research opportunities.

The cohort of studies identified, comprising both prospective and retrospective designs, provides valuable insights into the long-term outcomes and effectiveness of dental implants in children with ED.[41] The variation in sample sizes across studies, ranging from 6 to 51 cases, reflects the challenges of conducting research on rare conditions and the inherent limitations in sample availability. Despite the small sample sizes, these studies contribute valuable evidence regarding the feasibility, safety, and efficacy of dental implant therapy in this population.

However, it is important to acknowledge the limitations of observational studies, including potential biases, confounding factors, and lack of control groups.[35] The retrospective nature of some studies may introduce recall bias or incomplete data collection, impacting the reliability and generalizability of findings. Additionally, the heterogeneity in study methodologies and patient populations makes it challenging to draw definitive conclusions or establish standardized protocols for dental implant treatment in children with ED. Consequently, future research efforts should prioritize well-designed prospective studies with larger sample sizes and longer follow-up periods to address these limitations and provide more robust evidence for clinical decision-making.[42]

The age range of patients undergoing dental implant placement for prosthetic rehabilitation in children with ED, spanning from 3 to 12 years with a mean age of 7.56 years, underscores the importance of early intervention in managing dental anomalies associated with this condition.[43] The variation in age reflects the heterogeneity in disease severity, treatment needs, and timing of diagnosis among affected individuals.

The predominance of males in the study population, with 12 out of 17 cases being male, is consistent with the reported higher prevalence of ED in males compared to females.[44] This gender bias may be attributed to X-linked inheritance patterns in certain subtypes of ED, such as hypohidrotic ED, which predominantly affects males.

The observation of the hypohidrotic type of ED in four cases highlights the clinical variability within this heterogeneous condition.[45] Hypohidrotic ED, characterized by hypodontia,

**Table 1:** Details of individual cases

| *Sr. no.* | *Author* | *Year* | *Age* | *Gender* | *Prosthetic rehabilitation* | *Implants placed in jaw (mx/mnd) and region (ant/post)* | *Treatment outcome* | *Follow-up period* |
|---|---|---|---|---|---|---|---|---|
| 1 | Guckes et al.[21] | 1997 | 3 | Male | Conventional denture in maxilla and implant supported overdenture in mandible | 2 maxillary anterior region and 4 mandibular posterior region | Implants in function with significant growth | 5 years |
| 2 | Alcan et al.[22] | 2006 | 4 | Male | Implants with fixed prosthesis | 4 in mandibular anterior region | Implants in place, poor downward growth of maxilla and mandible | 6 years 3 months |
| 3 | Kramer et al.[23] | 2007 | 3 | Male | Conventional denture in maxilla and bar-based denture in mandible | 2 implants in anterior mandible region | Denture functioning well | 2 years |
| 4 | Artopoulou et al.[24] | 2009 | 10 | Female | Single interim crowns made with tooth colored acrylic resin | Mandibular posterior region | Implants stable | 6 months |
| 5 | Aydinbelge et al.[25] | 2013 | 7 | Female | Maxillary overdenture and mandibular implant supported overdenture | 2 implants in anterior mandible region | Dentures stable | 6 months |
| 6 | Paulus and Martin[26] | 2013 | 6 | Male | Two trans-screwed ceramic and metallic hemi bridges | 7 implants in maxillary anterior and posterior region and 5 implants in mandibular anterior region | Implants stable | |
| 7 | Toomarian et al.[27] | 2014 | 4 | Male | Maxillary interim denture and mandibular implant supported overdenture | 3 implants in mandibular anterior region | Implants stable | 19 months |
| 8 | Sfeir et al.[28] | 2014 | 11 | Male | Implant supported overdenture | 2 implants in anterior mandible region | | |
| 9 | | 2014 | 10 | Male | Implant supported overdenture | 2 implants in anterior mandible region and 4 in maxillary anterior region | Implants stable | |
| 10 | | 2014 | 12 | Male | Implant supported fixed prosthesis | 2 implants in anterior maxillary and mandibular anterior region | Implants stable | |
| 11 | Bergendal et al.[29] | 2015 | 6 | Male | Maxillary tooth supported metal ceramic FPD and mandibular implant supported FPD | 2 implants in anterior mandible region at age 6 years and two implants in anterior mandible region at age 19 years | | 16 years |
| 12 | Kilic et al.[30] | 2017 | 6 | Male | Implant supported overdenture | 2 implants in anterior mandible | Implants stable | 6 years |
| 13 | Mello et al.[31] | 2015 | 9 | Female | Implant supported overdenture | 2 implants in mandibular anterior region | Implants stable | 6 months |
| 14 | Knobloch et al.[32] | 2018 | 9 | Male | Implant supported overdenture | 2 implants in mandibular anterior region at the age of 9 years and additional 5 implants at the age of 18 years | Implants stable | 10 years |
| 15 | Triches et al.[33] | 2017 | 9 | Female | Implant supported overdenture | 4 implants in mandibular anterior region | Implants in function with significant growth | 4 years |
| 16 | Clarke et al.[34] | 2020 | 12 | Female | Implant supported overdenture | 4 implants in maxillary anterior region and 2 implants in mandibular anterior region | | |

**Table 2:** Details of individual studies

| *Sr. no.* | *Author* | *Year* | *Country* | *Study design* | *Sample size* | *Age (range and mean)* | *Prosthetic rehabilitation* | *Number of implants* | *Survival rate* | *Follow-up period* |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Kearns et al.[35] | 1999 | USA | Prospective cohort study | 6 | 5–10 years | Implant-supported fixed or removable prosthesis | 22 | 97% | 7.8 years |
| 2 | Guckes et al.[36] | 2002 | USA | Prospective cohort study | 51 | 8–68 years | | 264 | 91% | 6.5 years |
| 3 | Sweeney et al.[37] | 2005 | Australia | Retrospective study | 14 | 12–21 years | Removable prosthesis in 3 patients and fixed prosthesis in 14 patients | 61 | 88% | 3 years |
| 4 | Montanari et al.[38] | 2012 | Italy | Retrospective cohort study | 9 | 7 years and above | Implant supported overdenture | 18 | 100% | 8.1 years |

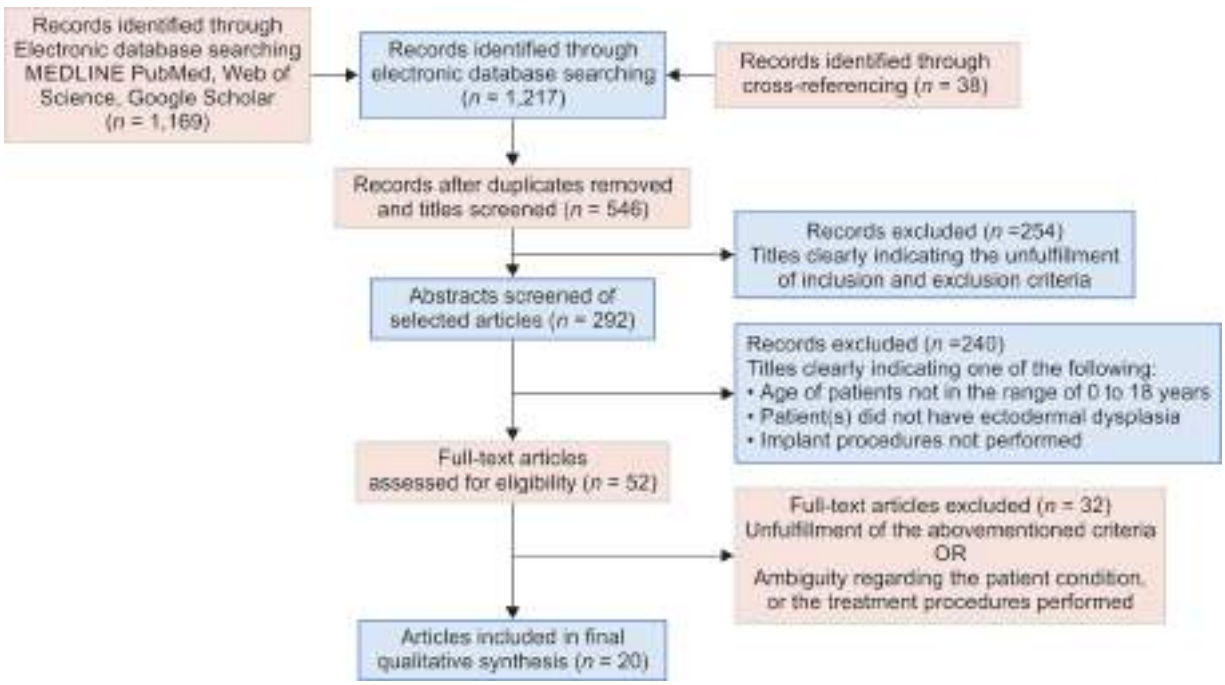


**Fig. 3:** PRISMA flow diagram outlining the selection process of the articles included in the present systematic review

hypohidrosis, and hypotrichosis, presents unique challenges in dental management due to the absence or underdevelopment of teeth and associated structures. The inclusion of cases with hypohidrotic ED underscores the importance of tailored treatment approaches and multidisciplinary collaboration to address the complex dental and systemic manifestations of this subtype.

The study population of Kearns et al., consisting entirely of males, along with the predominance of males in other studies, raises important considerations regarding the representation and generalizability of research findings.[46] The overrepresentation of males in research studies may limit the extrapolation of results to the broader population of children with ED, particularly females who may present with different clinical phenotypes and treatment needs.[47]

The spectrum of dental anomalies observed in children with ED undergoing dental implant treatment reflects the wide-ranging phenotypic variability and severity of this genetic disorder.[48] The presence of anodontia, characterized by the complete absence of teeth, in six cases underscores the profound dental hypoplasia and developmental defects commonly associated with ED. Anodontia poses significant challenges in oral function, esthetics, and psychosocial well-being, necessitating comprehensive prosthetic rehabilitation strategies, including dental implants, to restore oral health and function.

The majority of cases ($n$ = 10) presenting with oligodontia, defined by the presence of fewer than six teeth in the oral cavity, highlight the prevalence of partial tooth agenesis and hypoplasia in children with ED.[49] Oligodontia can manifest as variable patterns of tooth absence or malformation, affecting occlusal stability, masticatory efficiency, and speech articulation.

In contrast, a minority of cases ($n$ = 4) exhibited hypodontia, characterized by the absence of some teeth while retaining more than six teeth in the oral cavity. Hypodontia represents a milder form of dental agenesis compared to anodontia or oligodontia and

may present with variable patterns of tooth loss or malformation. Dental implant therapy may be indicated in cases of hypodontia to address specific areas of tooth deficiency and optimize occlusal function and esthetics.

The presence of jaw atrophy and conical-shaped maxillary anterior crowns as prevalent oral findings in children with ED underscores the multifaceted nature of this condition and its impact on craniofacial development. Jaw atrophy, characterized by reduced bone volume and inadequate jaw size, poses significant challenges in the placement and stability of dental implants, particularly in growing individuals with ED. The underdeveloped jaws may lack sufficient bone density and height to support osseointegrated implants, necessitating adjunctive bone augmentation procedures or alternative treatment approaches to enhance implant success rates and long-term outcomes.

Conical-shaped maxillary anterior crowns represent a distinctive dental phenotype commonly observed in individuals with ED, characterized by tapered or pointed tooth morphology in the maxillary anterior region. The presence of conical-shaped crowns may necessitate customized prosthetic solutions, such as resin-bonded bridges or porcelain veneers, to restore tooth morphology and achieve harmonious smile esthetics while preserving tooth structure and function.

Addressing jaw atrophy and conical-shaped maxillary anterior crowns requires a multidisciplinary approach involving pediatric dentists, oral and maxillofacial surgeons, prosthodontists, and orthodontists to formulate comprehensive treatment plans tailored to the individual needs of each patient. Surgical interventions, such as bone grafting or distraction osteogenesis, may be indicated to augment deficient jaw structures and create a stable foundation for implant placement.

The differential involvement of the maxillary and mandibular jaws reflects the variable patterns of tooth agenesis and malformation commonly observed in this genetic disorder, necessitating customized treatment approaches to address specific dental needs and anatomical considerations in each arch.

In cases where complete anodontia is present in the mandibular arch, implant-supported dentures offer a predictable and durable solution for restoring oral function and esthetics. Dental implants provide a stable anchorage for removable or fixed prostheses, enabling optimal occlusal support, masticatory efficiency, and phonetic clarity in individuals with ED. By integrating implants into the edentulous mandibular ridge, clinicians can overcome the challenges associated with traditional removable dentures, such as poor retention, stability, and patient discomfort, thereby improving overall treatment outcomes and patient satisfaction.

In cases where tooth retention is feasible and stable, conventional dentures or tooth-supported overdentures may be considered as viable treatment options for restoring missing teeth and improving oral function and esthetics in the maxillary jaw. Tooth-supported prostheses utilize the remaining natural dentition as abutments to stabilize and support the prosthesis, enhancing retention, stability, and proprioception while preserving tooth structure and integrity.

The selection of implant-supported dentures for the mandibular arch in all three cases highlights the importance of achieving optimal stability and functionality in the lower jaw, where conventional dentures often pose greater challenges due to the lack of retention and support from the edentulous ridge. By retaining natural teeth and utilizing them as abutments for prosthetic support, clinicians can leverage the benefits of enhanced proprioception, occlusal stability, and esthetic outcomes, while minimizing the need for extensive surgical interventions or bone augmentation procedures in the maxillary jaw.

The long-term survival rates of dental implants, ranging from 70.8 to 100% over a follow-up period of up to 144 months, underscore the effectiveness and durability of implant therapy in the prosthetic rehabilitation of children with ED. These high survival rates reflect the advancements in implant technology, surgical techniques, and prosthetic design that have contributed to improved treatment outcomes and patient satisfaction. The ability of dental implants to achieve osseointegration and maintain functional stability over extended periods is particularly crucial in pediatric patients, who require durable and reliable solutions to support their oral health and development throughout childhood and adolescence.

The finding that most failures occurred in cases where implants were placed before the age of six emphasizes the importance of timing and patient selection in implant therapy for young children with ED. Early implant placement in children poses unique challenges due to ongoing craniofacial growth, bone development, and the risk of implant displacement or failure. The age-related variability in bone density, growth patterns, and healing capacity necessitates careful consideration of the optimal timing for implant placement to maximize success rates and minimize the risk of complications.

## Conclusion

The review identified a wide range of dental anomalies associated with ED, including complete anodontia, oligodontia, hypodontia, jaw atrophy, and conical-shaped maxillary anterior crowns.

The reported success rates of dental implants ranged from 88 to 100% across studies, with the majority of cases demonstrating favorable outcomes over follow-up periods ranging from 3 years to 8.1 years. Despite variations in study methodologies and patient cohorts, the overall high success rates underscore the reliability and predictability of implant therapy in children with ED. The findings from this systematic review support the growing body of evidence advocating for the integration of dental implants into comprehensive treatment plans for prosthetic rehabilitation in this unique patient population. Ultimately, by addressing the complex dental and craniofacial needs of the patients, we can empower them to lead healthier, more fulfilling lives and promote inclusive oral health care.

### Clinical Significance

Despite the rarity of this genetic disorder and the limited availability of research data, the findings from the reviewed literature highlight the effectiveness, safety, and long-term success of dental implant therapy in addressing the complex dental and craniofacial needs of affected individuals. The utilization of dental implants offers a viable solution for restoring oral function, esthetics, and psychosocial well-being in children with ED, enabling them to achieve improved quality of life and enhanced self-esteem.

## Orcid

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# COMPARATIVE EVALUATION OF INTERNAL FIT AND AMOUNT OF TOOTH REDUCTION REQUIRED IN BIOFLEX CROWNS WITH STAINLESS STEEL CROWNS ON DECIDUOUS MOLARS: AN IN- VITRO STUDY.

Paediatric Dentistry

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## ABSTRACT

**Introduction:** Primary molars hold significant importance, not only in mastication but also in the development of a child's occlusion and in maintaining space for permanent teeth. Thus, crowns are often recommended to restore these teeth, with molars being given special consideration for their crucial role in oral function and arch stability. Stainless Steel Crowns (SSCs) have a long-standing history in pediatric dentistry and have been integral to restorative procedures for primary teeth. In light of the need for more aesthetic restorations, BioFlex crowns have emerged as a promising alternative to SSCs while maintaining clinical functionality. **Aim:** To compare the internal fit and the amount of tooth reduction required for BioFlex crowns and Stainless Steel Crowns (SSCs) when used on deciduous molars in an in-vitro setting. **Material & Method:** This experimental in-vitro trial consisted of total of 60 freshly extracted deciduous mandibular first molars allocated in two groups: Group A (n=30) – Bioflex Crowns (Experimental group) and Group B (n=30) – Stainless Steel Crowns (Control group). Teeth were weighed using digital weighing scale before and after tooth preparation according to standard guidelines by manufacturer to determine the amount of tooth reduction. After crown adaptation and sectioning, the internal fit and marginal fit was assessed using stereomicroscope. **Result:** Stainless steel crowns demonstrate superior clinical performance compared to BioFlex crowns in terms of internal fit, marginal adaptation, and overall retention. They require significantly less tooth reduction than Bioflex crowns. **Conclusion:** Although Bioflex crowns offer aesthetic benefits, their clinical limitations, including excessive tooth reduction, inadequate internal adaptation, and weak cement retention, need to be addressed before they can be recommended as a viable alternative to stainless steel crowns.

## KEYWORDS

bioflex crowns, primary molar crowns, ssc, esthetic crowns, marginal fit, tooth preparation

## INTRODUCTION:

Dental caries is a predominant health issue affecting oral well-being across various age groups, with children being particularly vulnerable. Providing effective and durable restorations in primary teeth can significantly improve the oral health-related quality of life of an individual throughout their life.[1] Primary molars hold significant importance, not only in mastication but also in the development of a child's occlusion and in maintaining space for permanent teeth.[2] Thus, crowns are often recommended to restore these teeth, with molars being given special consideration for their crucial role in oral function and arch stability.[3]

Stainless Steel Crowns (SSCs) have a long-standing history in pediatric dentistry and have been integral to restorative procedures for primary teeth.[4] Introduced to the field in 1947 by the Rocky Mountain Company, SSCs quickly became the gold standard for pediatric full-coverage restorations due to their exceptional durability, ease of placement, and reliability in children at high risk for caries.[5] SSCs have consistently outperformed other materials and resisted the test of time, heat and chemicals. Their resilience and capacity to withstand the forces of mastication make SSCs particularly suitable for restoring posterior primary teeth.[6]

When adapted properly, SSCs cover the entire coronal surface, providing a seal that minimizes the risk of marginal leakage and secondary caries, thus enhancing the longevity of the restoration.[7] SSCs are especially favored in cases of severe early childhood caries (ECC), where extensive tooth decay requires a full-coverage approach for protection and durability.[8]

However, despite their benefits, SSCs have a notable disadvantage in aesthetics. Their metallic appearance can be visually unappealing, leading to concerns among parents who may prefer restorations that blend more naturally with the child's dentition.[9] In response, studies have explored the use of tooth-colored facings on SSCs to improve aesthetics, though these modifications often fall short in terms of durability.

In light of the need for more aesthetic restorations, Bioflex crowns have emerged as a promising alternative to SSCs while maintaining clinical functionality.[10] Constructed from hybrid resin polymers, Bioflex crowns are free from both metal and Bis-GMA, making them a biocompatible, aesthetic choice for pediatric restorations.[11] These crowns provide a natural, tooth-colored appearance, meeting the increasing demand for aesthetically pleasing options that blend with the natural dentition.

Although they have not yet undergone the same extensive long-term studies as SSCs, Bioflex crowns show promise for their potential to match the durability of SSCs while offering superior aesthetics. Due to their recent incorporation into pediatric dentistry, it is essential to further evaluate Bioflex crowns' properties, including their internal fit and the necessary tooth preparation when used in clinical practice. Understanding these factors is critical for clinicians seeking to balance aesthetics with effective, durable restorative care for primary molars.

In this context, the present study aims to provide evidence regarding the effectiveness of Bioflex crowns relative to SSCs, particularly in terms of internal fit and conservation of natural tooth structure. Through this comparison, the study will identify the most conservative approach to restoring primary molars, ultimately enhancing both the functional and aesthetic outcomes in pediatric dental care.

## MATERIALS AND METHODS:

The present study was conducted as an experimental in-vitro trial in the Department of Pediatric and Preventive Dentistry of the institution during the period of March 2023-March 2025. A total of 60 freshly extracted deciduous mandibular first molars were collected and stored in distilled water at room temperature to prevent dehydration. The study employed a simple random sampling technique to allocate the extracted teeth into two groups:

- Group A (n=30) – Bioflex Crowns (Experimental group)
- Group B (n=30) – Stainless Steel Crowns (Control group)

### Ethical Considerations

The study adhered to the ethical principles outlined in the Declaration of Helsinki and the guidelines of the Occupational Safety and Health Administration (OSHA). The study protocol was approved by the Institutional Ethical Review Board.

### Sample Size Determination:

A power analysis was conducted using G*Power version 3.0.1. The parameters for the analysis included: Level of significance (α): 5%, Power (1-β): 80%, Effect size (d): 0.8, Test type: Two-sided

independent means t-test. Based on these parameters, a total of 52 samples was determined to be required. To account for potential procedural errors, the sample size was rounded up to 60 (n=30 per group). These 60 teeth were used for both the amount of tooth reduction analysis and internal fit evaluation.

**Selection Criteria:**

***Inclusion Criteria:***

1. Extracted healthy deciduous mandibular first molars obtained for orthodontic reasons.
2. Extracted deciduous molars with occlusal caries only (no proximal, buccal, or lingual caries involvement).

***Exclusion Criteria:***

1. Teeth with extensive carious involvement on buccal, lingual, or proximal surfaces.
2. Teeth with developmental anomalies such as hypoplasia, fusion, or gemination.

**Procedure:**

*Step 1: Preliminary Preparation*

1. The collected teeth were cleaned of residual organic tissues using an ultrasonic scaler and polished with abrasive rubber cups.
2. The teeth were stored in distilled water until further processing.
3. Each tooth was weighed three consecutive times on a digital weighing scale to ensure accuracy in recording the initial weight.

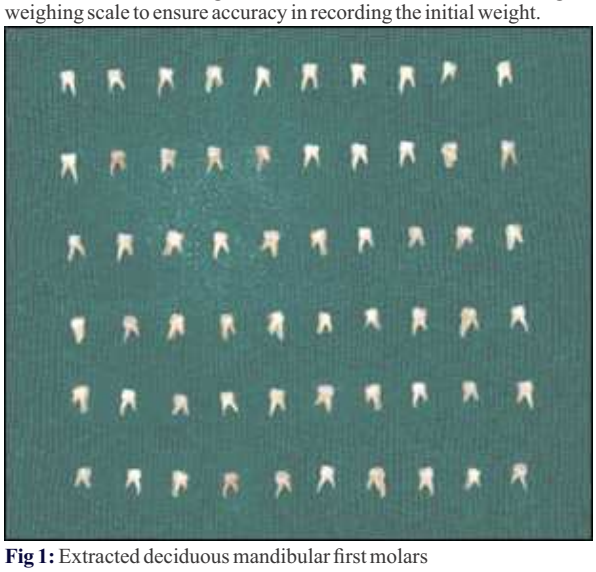


**Fig 1:** Extracted deciduous mandibular first molars

***Step 2: Tooth Preparation***

1. The teeth were embedded in self-cure acrylic resin blocks, ensuring they were positioned 2 mm below the cementoenamel junction (CEJ).
2. The teeth were then randomly divided into two study groups:
Group A: Bioflex Crowns (n=30)
Group B: Stainless Steel Crowns (n=30)
3. In both groups, n=16 primary mandibular left first molars and n=14 primary mandibular right first molars were included each.
4. Tooth preparation was carried out following the manufacturer's guidelines for Bioflex Crowns and AAPD (American Academy of Pediatric Dentistry) guidelines for Stainless Steel Crowns
5. After preparation, each tooth was re-weighed using the same procedure to calculate the amount of tooth reduction.

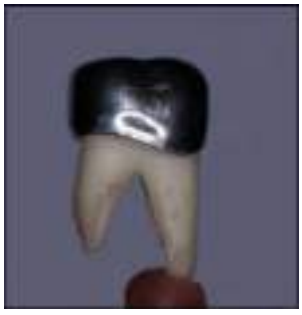


**Fig 2:** Stainless Steel Crown adaptation on extracted deciduous mandibular first molar.

**Fig 3:** Bioflex Crown adaptation on extracted deciduous mandibular first molar.

***Step 3: Internal Fit Assessment***

1. The mesiodistal dimension of each prepared tooth was measured using a Vernier Caliper to select the appropriately sized Bioflex or Stainless Steel crown.
2. Luting cement was applied to three-fourths of the internal surface of the selected crown, and the crown was seated over the prepared tooth.
3. The embedded teeth were then sectioned buccolingually using a diamond disk.
4. A digital photograph of each section was obtained using a stereomicroscope at 20× magnification.
5. Thirteen different points were considered for the measurement. Points A and M represented the corner points indicative of marginal fit, while points B to L represented middle points indicative of the internal fit.
6. The internal fit was measured as the perpendicular distance from the internal surface of the crown to the axial wall of the tooth preparation using a stereomicroscope under 45x magnification and using compatible software (MegaVision).
7. The recorded measurements were compared between the two groups.

**Fig 4:** Internal fit assessment using stereomicroscope

**Fig 5:** Cross section of tooth with Stainless steel crown for assessing the marginal fit at various points

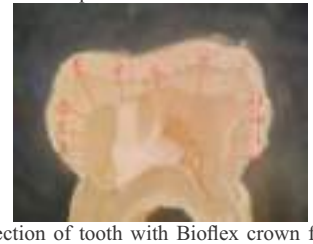


**Fig 6:** Cross section of tooth with Bioflex crown for assessing the marginal fit at various points

**Statistical Analysis:**

Data was analysed using SPSS Computer Software (IBM SPSS

Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp), R (Version 4.4.1) and Excel. Data normality was assessed using the Shapiro–Wilk test. An independent two-sample t-test and Welch's T-test were used for intragroup and intergroup comparison respectively. Data was represented in the form of bar charts and boxplots.

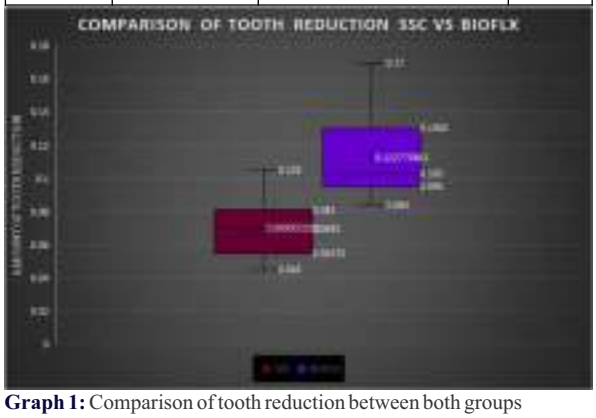
## RESULTS:

### Amount of tooth reduction:

A statistically significant difference was noted between the mean tooth reduction in both groups. The t-statistic (-8.002933238), which is a negative value, indicates that Bioflex, i.e. Group B, requires significantly more tooth reduction in comparison to SSC. The findings align with the expectation based on material properties, where SSC's malleability allows for less invasive fitting, whereas the thickness of Bioflex necessitates greater reduction.

**Table 1: Inter-group Comparisons For The Amount Of Tooth Reduction**

| Material | | Mean Standard Deviation | Range |
|---|---|---|---|
| SSC | Before Cutting | 0.58 ± 0.062 | 0.28 |
| | After Cutting | 0.51 ± 0.062 | 0.27 |
| | Difference | 0.07 ± 0.016 | 0.06 |
| Bioflex | Before Cutting | 0.61 ± 0.045 | 0.2 |
| | After Cutting | 0.5 ± 0.052 | 0.23 |
| | Difference | 0.11 ± 0.025 | 0.086 |




**Graph 1:** Comparison of tooth reduction between both groups

### Internal Fit:

A significant difference between means of Internal Fit of SSC and Bioflex crowns. The mean internal fit value for Bioflex (1.477) is higher than SSC (1.021). A higher internal fit value generally indicates a looser fit, meaning that Bioflex crowns may not fit as snugly as SSC crowns. Conversely, the lower internal fit value for SSC suggests that it adapts more tightly to the internal structure, possibly leading to better retention and stability.

**Table 2: Inter-group Comparisons For Marginal And Internal Fit**

| Material | Gap | Min | Max | Mean Sd | Range |
|---|---|---|---|---|---|
| SSC | Marginal | 0.28 | 0.56 | 0.43 ± 0.054 | 0.28 |
| | Internal | 0.79 | 1.45 | 1.02 ± 0.029 | 0.66 |
| Bioflex | Marginal | 0.78 | 0.9 | 0.85 ± 0.023 | 1.12 |
| | Internal | 1.25 | 1.89 | 1.48 ± 0.021 | 0.64 |

### Marginal Fit:

A significant difference between means of marginal Fit of SSC and Bioflex crowns. The mean marginal fit for SSC (0.4263) is significantly lower than for Bioflex (0.8463). The large negative t-statistic value indicates a strong and statistically significant difference. Since a lower marginal fit value indicates a better fit, SSC adapts more precisely to the tooth margins than Bioflex.

## DISCUSSION:

The present study was conducted as an experimental in-vitro trial to comparatively evaluate the internal fit and the amount of tooth reduction required for Bioflex crowns and stainless steel crowns on deciduous mandibular first molars. By maintaining uniform preparation procedures and controlled experimental conditions, this study aimed to achieve consistency in baseline variables and allow for valid intergroup comparisons. The decision to choose an in-vitro model facilitated the control of confounding clinical variables such as salivary contamination, patient cooperation, and masticatory forces, thus allowing the isolation and accurate evaluation of specific parameters like internal fit and tooth reduction.

The methodology employed in the present study was deliberately selected to ensure precision, reproducibility, and clinical relevance. Digital weighing was utilized to measure the amount of tooth reduction, as it provides highly accurate, sensitive, and Stereomicroscopy was employed for internal fit evaluation because of its ability to offer magnified, high-resolution, three-dimensional visualization of interfaces that are otherwise difficult to assess through conventional inspection. Stereomicroscopy has been widely validated as a reliable technique for marginal and internal fit studies, offering significant advantages over naked eye or low-magnification assessments that may lead to inconsistent observations.[12]

The findings of the present study revealed that Bioflex crowns required a significantly greater amount of tooth reduction compared to stainless steel crowns. The internal fit assessment in this study demonstrated that stainless steel crowns exhibited significantly better adaptation to the prepared tooth surface compared to Bioflex crowns. These findings can be scientifically explained by the fundamental material differences between the two crowns. Stainless steel crowns are thin, ductile, and highly malleable, allowing for passive adaptation to the prepared tooth without necessitating extensive removal of tooth structure.[13] The ability to crimp and contour stainless steel crowns chairside ensures intimate adaptation with minimal invasion. In contrast, Bioflex crowns are composed of a high-impact hybrid resin polymer material which, although durable and flexible to some extent, is inherently thicker and less accommodating.[14] To ensure an adequate passive fit of Bioflex crowns, greater circumferential and occlusal reduction is inevitably required, leading to unnecessary sacrifice of healthy enamel and dentin, which can potentially weaken the structural integrity of primary teeth.

Clinically, this greater tooth reduction associated with Bioflex crowns carries important implications. In primary teeth, the pulp chamber is relatively large and the enamel-dentin thickness is considerably thinner than permanent teeth. Therefore, any increase in tooth preparation depth inherently increases the risk of pulp exposure, postoperative sensitivity, and compromise of pulpal health.[15] Excessive removal of dentin may also reduce the ability of the remaining tooth structure to withstand masticatory loads, leading to higher susceptibility to fractures.[16]. Thus, while Bioflex crowns offer aesthetic advantages, the need for substantial tooth reduction must be carefully weighed.

Although the manufacturer claims that Bioflex crowns are capable of adapting over time to the underlying tooth structure, the present in-vitro study did not observe any such property within the experimental timeframe. Bioflex crowns retained their original shape and dimensions after placement, with no measurable evidence of enhanced conformity to the tooth surfaces. This could be explained by the intrinsic material characteristics of Bioflex, which, despite its designation as a flexible resin-based polymer, lacks the true viscoelastic behavior required for active post-placement adaptation.[9,17] In clinical scenarios, adaptation over time would rely on the material responding plastically to functional masticatory forces; however, in the absence of significant intraoral mechanical loading under controlled experimental conditions, no adaptive changes were evident. This observation suggests that the adaptation claims by the manufacturer might be overly optimistic and not reliably achievable in realistic clinical practice, especially in the immediate to short-term period following crown placement.

Crowns that fail to closely conform to the underlying tooth can compromise the longevity of the restoration by allowing microleakage, ultimately leading to early restoration failure.[18] A tighter internal fit of stainless steel crowns results in greater mechanical retention and reduces the microgap available for bacterial colonization, thus decreasing the risk of recurrent caries and crown failure.[19] Bioflex crowns, on the other hand, do not permit chairside manipulation, making it challenging to modify their fit to individual tooth contours, particularly in cases of slight anatomic variations.[17]

Another important factor influencing the clinical performance of crowns is the bond between the crown material and the luting cement. In this study, the bonding of the luting cement to Bioflex crowns was found to be inferior compared to stainless steel crowns. This is most

likely attributed to the differences in surface characteristics. Stainless steel crowns have a slightly roughened surface that facilitates mechanical interlocking with glass ionomer cements, enhancing retention.[20] In contrast, the smoother, less retentive surface of Bioflex crowns impairs the mechanical retention of the cement. Kameli et al. (2021) highlighted the critical influence of material surface properties on cement adhesion, noting that roughness and surface energy play key roles in achieving optimal bond strength.[21] Furthermore, resin-modified glass ionomer cements have been shown to outperform conventional cements in terms of bonding to smooth surfaces, yet even with their improved properties, Bioflex crowns still demonstrated poor adhesion in this study.[22]

A crucial observation was the frequent dislodgement of Bioflex crowns during the process of cross-sectioning for internal fit assessment. This observation is of clinical significance as it directly reflects the mechanical retention capacity of the crowns under shear forces. In real-world conditions, crowns are subjected to complex stresses including tensile, compressive, and shear forces during mastication and parafunctional habits.[23] The inability of Bioflex crowns to resist dislodgement during experimental handling suggests that they may be at risk for clinical debonding under functional loading. Patil et al. (2023) also reported lower retention rates for preformed esthetic crowns compared to traditional stainless steel crowns, corroborating the findings of the present study.[24] The interplay of poor marginal adaptation, weaker cement bonding, and lack of malleability likely acts synergistically to compromise the overall retention and stability of Bioflex crowns in clinical use. Thus, the lack of sufficient mechanical and adhesive retention of Bioflex crowns may limit their application primarily to low-load anterior teeth or cases where aesthetic demands outweigh functional priorities, rather than their routine use in high-stress posterior regions.[25]

Marginal fit assessment in this study further reinforced the superiority of stainless steel crowns over Bioflex crowns. The inferior internal fit and poor marginal adaptation observed with Bioflex crowns suggest a greater susceptibility to microleakage compared to stainless steel crowns, raising concerns regarding their long-term effectiveness in maintaining pulpal health.

Patient-centered outcomes such as comfort, functional longevity, gingival response, and esthetic satisfaction, which are critical for the real-world success of pediatric crowns, were not evaluated due to the in-vitro design. Looking ahead, future research must address these gaps through well-designed clinical trials. Moreover, development of thinner yet durable versions of Bioflex crowns could reduce the need for aggressive tooth reduction, preserving more natural tooth structure. Further studies in this area should be encouraged.

## CONCLUSION:

The findings of this study indicate that stainless steel crowns demonstrate superior clinical performance compared to Bioflex crowns in terms of internal fit, marginal adaptation, and overall retention. These findings raise concerns about the reliability of Bioflex crowns as a full-coverage restorative option, particularly in pediatric patients where long-term durability and adaptation are critical. Although Bioflex crowns offer aesthetic benefits, their clinical limitations, including excessive tooth reduction, inadequate internal adaptation, and weak cement retention, need to be addressed before they can be recommended as a viable alternative to stainless steel crowns.

Future research should focus on improving the material properties of Bioflex crowns to enhance their adaptability, bonding strength, and overall clinical performance. Additionally, long-term clinical trials are necessary to assess their effectiveness in real-world conditions, considering factors such as mastication forces, patient comfort, and parental satisfaction. Until then, stainless steel crowns remain the preferred choice for full-coverage restorations in primary molars due to their superior mechanical and clinical properties.

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# PHOTOBIOMODULATION IN TREATMENT OF HYPERSENSITIVITY IN MOLAR INCISOR HYPOMINERALISATION: A SYSTEMATIC REVIEW

Dentistry

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## ABSTRACT

**Background** Molar Incisor Hypomineralisation (MIH) related hypersensitivity is a complex problem that affects both the quality of life and dental health of young patients. Photobiomodulation (PBM) offers a promising approach to treating this condition by reducing sensitivity, strengthening teeth and providing a child-friendly alternative to more invasive procedures. The present systematic review aims to evaluate the utility of PBM in managing hypersensitivity in children & adolescents with MIH, contributing to a better understanding of its effectiveness and potential benefits for children suffering from this condition.**Methods** A comprehensive search was conducted across electronic databases including PubMed, PsycINFO, Cochrane Library, and Embase, covering studies from 2000 to 2024. Studies included randomized controlled trials (RCTs), non-randomized controlled trials, prospective cohort studies and comparative observational studies focusing on children and adolescents upto 16 years of age who were receiving treatment for MIH. Outcome measures included reductions in hypersensitivity assessed through pain scores e.g. Visual Analog Scale [VAS], Numeric Rating Scale [NRS] or sensitivity thresholds. The Cochrane Collaboration's Risk of Bias tool and Newcastle-Ottawa Scale were used for quality assessment. Data were synthesized narratively and systematic review was performed **Results** Four studies met the inclusion criteria, with studies conducted in various countries including China, Brazil and Italy. Sample sizes ranged from 39 to 120 participants. The primary intervention evaluated in these studies was Photobiomodulation, including LLLT and LED therapy, often combined with conventional treatments. The majority of studies found significant hypersensitivity reduction in PBM-treated groups compared to control groups. In studies where PBM was combined with fluoride varnish or other desensitizing agents, an enhanced reduction in sensitivity was observed, often surpassing the effects of standalone treatments.**Conclusion**Photobiomodulation, particularly when combined with conventional desensitizing agents such as fluoride varnish or CPP-ACPF mousse, significantly reduces hypersensitivity, offering both immediate and sustained relief among children and adolescents. This technique offers a minimally invasive, safe and effective alternative for managing hypersensitivity in MIH-affected teeth, improving the quality of life for pediatric patients. Further research is needed to establish definitive clinical guidelines and optimize PBM application for MIH-related hypersensitivity.

## KEYWORDS

MIH, LASER therapy, hypersensitivity, fluoride varnish, LLLT

## INTRODUCTION

Molar-Incisor Hypomineralisation (MIH) is a developmental condition affecting the enamel of molars and incisors, causing enamel defects that compromise tooth structure and function.[1] First recognized in 2001, MIH has become a significant focus in dentistry due to the challenges it presents in treatment and long-term management.[2] The condition arises from disruptions in enamel formation during the early years of life, often linked to factors such as illnesses, medications, or other systemic issues in early childhood. Teeth affected by MIH typically show distinct opacities, ranging in color from white to yellow-brown and the enamel is often soft and prone to rapid breakdown under chewing forces. This leaves the teeth vulnerable to decay, fractures and heightened sensitivity.[3]

Hypersensitivity in MIH-affected teeth is a major issue because the loss of enamel exposes the underlying dentin, which contains nerve endings connected to the pulp. This exposure causes discomfort or pain, particularly when eating or drinking hot, cold, or sweet foods.[4] For children, this sensitivity can make routine dental care and oral hygiene difficult, further complicating the condition. Standard treatments like Fluoride varnishes, desensitizing agents, or fillings can reduce symptoms but often fail to address the underlying problems or provide lasting results.[5] The search for a more effective treatment has led to interest in photobiomodulation (PBM), a therapy that uses light energy to stimulate natural healing processes in tissues.[6]

PBM, also known as Low-Level LASER Therapy, uses specific wavelengths of light to activate biological changes in tissues. When the light is absorbed by cells, particularly in the mitochondria, it can enhance cellular energy production, reduce inflammation and promote tissue repair.[7] In dental applications, PBM has shown promise in reducing pain by calming the nerves and encouraging the formation of new dentin. It also helps seal dentinal tubules, which are small channels in the dentin that can transmit pain signals.[8] By addressing the causes of hypersensitivity and promoting repair, PBM offers a targeted and gentle approach to managing this condition. PBM has particular advantages for children with MIH. The treatment is non-invasive and painless, making it easier to perform on patients who may feel anxious or uncooperative during traditional dental procedures.[9] Unlike some other treatments, PBM does not involve drilling or chemical agents that could damage the already weakened tooth structure.[10] Instead, it works by strengthening the tooth and reducing pain without causing additional trauma. This makes it an attractive option for treating young patients with sensitive teeth.

Recent developments in PBM technology, including portable and affordable devices, have made it easier to integrate this treatment into dental practices.[11] Research has shown that PBM can reduce hypersensitivity quickly and help strengthen the dentin over time, potentially offering a long-lasting solution.[12] However, while early studies are encouraging, more research is needed to confirm the best ways to use PBM for MIH and to establish consistent treatment protocols.

Overall, MIH-related hypersensitivity is a complex problem that affects both the quality of life and dental health of young patients.[13] PBM offers a promising approach to treating this condition by reducing sensitivity, strengthening teeth and providing a child-friendly alternative to more invasive procedures.[14] The present systematic review aims to evaluate the utility of PBM in managing hypersensitivity in patients with MIH, contributing to a better understanding of its effectiveness and potential benefits for children suffering from this condition.

## METHODS

The present systematic review investigated the effectiveness of Photobiomodulation (PBM) therapy in managing dental hypersensitivity in children and adolescents with Molar Incisor Hypomineralisation (MIH). The primary objective of this systematic review was to assess the effectiveness of PBM in MIH affected teeth compared to conventional desensitizing treatments in children and adolescents.

## SEARCH STRATEGY

A comprehensive search strategy was developed to identify relevant studies published in English language without any restriction for the date of publication. Electronic databases including PubMed, PsycINFO, Cochrane Library and Embase were systematically searched The search strategy combined keywords and controlled vocabulary terms related to "Photobiomodulation," "Low-Level LASER Therapy," "LED Therapy," "Dental Hypersensitivity," "Molar Incisor Hypomineralisation," "MIH," "Hypomineralized Molars," "Enamel Hypomineralization," and "LASER Therapy". Additionally, reference lists of included studies and relevant review articles were hand-searched for additional studies.

## SELECTION OF THE ARTICLES

Studies were included if they met the following criteria:

- Participants: Children aged upto 16 years
- Intervention: Photobiomodulation therapy, including Low-Level LASER Therapy (LLLT) or LED therapy, specifically targeted to manage dental hypersensitivity.
- Comparator: Studies with conventional desensitizing agents (fluoride varnish, desensitizing toothpastes), placebo treatments or no treatment.
- Outcomes: Studies reporting outcomes related to hypersensitivity reduction in MIII..
- Study Design: Randomized controlled trials (RCTs), non-randomized controlled trials, prospective cohort studies and comparative observational studies were included.

Studies were excluded if they focused on adults or population outside the specified age range or those with dental hypersensitivity unrelated to MIH or studies that did not report quantitative measures of hypersensitivity reduction or outcomes. Animal-based studies, case reports, narrative reviews, editorials and conference abstracts were also excluded.

Two independent reviewers screened titles and abstracts of identified studies against the inclusion criteria. Full-text articles of potentially eligible studies were then assessed for inclusion. Any discrepancies were resolved through discussion or consultation with a third reviewer.[15]

## DATA EXTRACTION

A standardized data extraction form was developed to extract relevant information from included studies. Data extracted included study characteristics (e.g., author, year, study design), participant demographics, details of the intervention and comparator (if applicable), outcome measures and results related to dental hypersensitivity reduction in MIH.

## QUALITY ASSESSMENT

The methodological quality of the included studies was assessed using appropriate tools depending on the study design. For RCTs, the Cochrane Collaboration's Risk of Bias tool was used, while the Newcastle-Ottawa Scale was employed for observational studies. Quality assessment was conducted independently by two reviewers, with any discrepancies resolved through discussion or consultation with a third reviewer.

## DATA SYNTHESIS

Data synthesis involved a narrative synthesis of study findings, summarizing the effectiveness of PBM therapy in reducing hypersensitivity among children upto age 16 years. Comparisons between PBM and conventional interventions were highlighted, along with the duration of hypersensitivity relief.

## RESULTS:

A total of four randomized clinical trials were identified from the years 2000 to 2024 [16-19] The PRISMA Flow diagram indicating the selection process of the studies included in the present systematic review is delineated in Figure 1. Of the four studies, two were conducted in China, one in Brazil and one was carried out in Italy. The sample sizes varied significantly. ranging from 39 to 120 children, with age groups spanning 6 to 16 years. Most studies included children diagnosed with MIH based on established criteria, such as the European Academy of Paediatric Dentistry (EAPD) guidelines or specific MIH diagnostic protocols n=1 study employed LLLT, n=2 studies employed Er:YAG LASER therapy, No studies exclusively used LED therapy. The PBM protocols involved diode LASERS (808 nm, 980 mm), Er:YAG LASERS and other light-based therapies, with varying energy densities, power settings and application frequencies. Comparator treatments included fluoride varnish (n=1), CPP-ACPF mousse (n=1)and GLUMA desensitizing agents (n=1). Some studies also assessed PBM as a standalone treatment, while others evaluated its effectiveness in combination with traditional desensitizing agents. The primary outcome assessed was hypersensitivity reduction, measured using validated scales such as the Visual Analog Scale (VAS) (n=2), the Face Scale (n=1) and the Wong-Baker Faces Pain Rating Scale (WBFPRS) (n=1).

Across studies, statistical analyses confirmed that PBM significantly improved hypersensitivity outcomes. n=1 study reported statistically significant reductions in sensitivity with p-values $<0.05$, demonstrating meaningful improvements compared to baseline measurements. The extent of hypersensitivity reduction varied based on the PBM modality, energy dose and duration of application, with some studies highlighting the superiority of diode LASER-based PBM over Er:YAG LASER-based interventions. The systematic review provides evidence supporting the efficacy of PBM therapy in reducing hypersensitivity in MIII-affected teeth. PBM, particularly when used in conjunction with conventional desensitizing treatments, offers rapid, significant and sustained relief from hypersensitivity, with no reported complications.

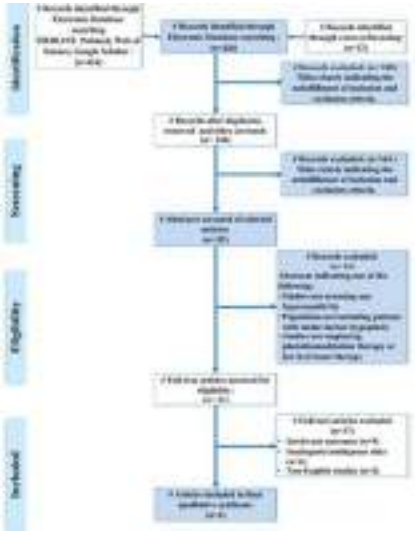

**Figure 1:** PRISMA Flow diagram indicating the selection process of the studies included in the present systematic review

### Risk of Bias Assessment

**Figure 2:** Traffic light plot indicating the risk of bias in the studies included in the present systematic review

**Figure 3:** Summary plot indicating the overall risk of bias of the studies included in the present systematic review

Two studies (n=2) were rated as having a low overall risk of bias, suggesting strong methodological quality and reliable findings. The remaining two studies (n=2) had some concerns, primarily due to

limitations in the randomization process, outcome measurement and reporting transparency

**DISCUSSION:**

The findings of this systematic review highlight the potential of PBM as a promising treatment for managing hypersensitivity in children with MIH. The included studies consistently demonstrated a reduction in hypersensitivity, supporting the efficacy of PBM in alleviating discomfort in affected teeth.

The geographic distribution of the included studies spanned China, Brazil and Italy, indicating that PBM therapy is gaining global recognition in pediatric dentistry.[20] Given that MIH prevalence varies worldwide, differences in genetic susceptibility, environmental factors, dietary habits and fluoride exposure may influence the clinical effectiveness of PBM.[21] Future studies should aim to include multicenter trials from varied populations to validate these findings.

One of the most significant observations in this review was the enhanced efficacy of PBM when combined with conventional desensitizing agents such as fluoride varnish or CPP-ACPF mousse. The study from Brazil reported a remarkable 93% reduction in hypersensitivity when PBM was used alongside fluoride varnish, compared to 87% for fluoride varnish alone and 79% for PBM alone.[16] This suggests a synergistic effect, where PBM enhances the action of conventional desensitizing agents by accelerating tissue repair, reducing nerve excitability and promoting dentin formation.[22] This finding aligns with previous studies in broader dental research, where PBM has been shown to enhance wound healing and reduce post-operative discomfort in various dental procedures.

The variation in PBM modalities across studies presents an important factor influencing treatment outcomes. The included studies utilized different PBM sources, including Low-Level LASER Therapy (LLLT) (n=1) and Er:YAG LASER therapy (n=2), while none used LED therapy exclusively. This discrepancy raises questions about which PBM modality is most effective for MIH-related hypersensitivity. The Brazilian study, which employed diode LASER (808 nm, 100 mW, 1 J per point), showed a statistically significant reduction in hypersensitivity, while the Italian study, using a 980 nm diode LASER at 4W, also demonstrated considerable pain reduction ($p<0.0001$). However, the studies that used Er:YAG LASER therapy (n-2) showed mixed results, with one reporting significant pain relief while another indicated that PBM was equally effective as conventional desensitizing treatments but not superior. These differences may stem from variations in wavelength, energy density, duration of exposure and treatment frequency.

The mechanism of action of PBM in reducing MIH-related hypersensitivity appears to be multifaceted.[21] At a cellular level, PBM is believed to stimulate mitochondrial activity, leading to increased production of adenosine triphosphate (ATP). This boost in cellular energy promotes the repair of enamel and dentin, thereby reducing hypersensitivity.[23] Additionally, PBM is known to modulate inflammatory cytokines, thereby decreasing inflammation and pain perception. Another significant mechanism is the stimulation of odontoblast activity, which promotes secondary dentin formation and helps seal exposed dentinal tubules, thereby reducing pain transmission.[24] These biological effects may explain why PBM provides both immediate and long-term relief from hypersensitivity.[25]

The included studies utilized different hypersensitivity measurement tools, which adds another layer of complexity to interpreting the results. Among the included studies, n=2 used the Visual Analog Scale (VAS), n=1 used the Facial Image Scale and n=1 used the Wong-Baker Faces Pain Rating Scale (WBFPRS). While all these tools provide valuable patient-reported outcomes, the lack of standardization makes direct comparisons across studies difficult.[16-19]

The follow-up durations in the included studies varied significantly, ranging from 4 weeks to 52 weeks. This discrepancy is important because hypersensitivity relief may fluctuate over time, with some treatments providing only temporary relief while others yield more sustained effects. Studies with shorter follow-up periods may overestimate the long-term benefits of PBM, while those with longer durations can better capture its sustained effects.[16,18] The study with the longest follow-up (52 weeks) reported continued hypersensitivity reduction, indicating that PBM may have long-lasting benefits.[19] However, it remains unclear whether repeated PBM applications are required to maintain these effects over time.

A critical aspect of this review was the safety profile of PBM therapy. Among the included studies, n=3 explicitly reported no adverse events, confirming that PBM is a non-invasive and well-tolerated intervention, Unlike some conventional desensitizing treatments that may cause temporary irritation or require multiple applications, PBM does not pose risks of enamel erosion, pulpal irritation, or allergic reactions.[16-19] This makes it particularly suitable for pediatric patients who may have difficulty tolerating conventional therapies. However, despite the favorable safety profile, there is still a need for more long-term studies to ensure there are no delayed adverse effects associated with PBM exposure.

The clinical implications of these findings are significant. PBM provides a non-invasive. painless and child-friendly alternative to conventional treatments for MIH-related hypersensitivity.[26] Given that MIH is often associated with dental anxiety and increased treatment difficulty in children, PBM could be an effective solution that enhances patient compliance and comfort.[27] Moreover, PBM may reduce the need for restorative interventions. thereby preserving the integrity of MIH-affected teeth for longer.[28]

Despite the promising findings, this systematic review has several limitations. Firstly, the total number of included studies was relatively small (n=4), which limits the generalizability of the findings.[16-19] Additionally, while all studies demonstrated a reduction in hypersensitivity, n=1 study reported only marginally better results with PBM compared to conventional treatments, indicating that PBM may not be superior in all cases.[18] The heterogeneity in study designs, PBM protocols and outcome measures further complicates the ability to draw definitive conclusions. Another limitation is the lack of data on long-term cost-effectiveness, as PBM devices can be expensive and it remains unclear whether the benefits justify the cost in routine pediatric dental care.

Future research should focus on conducting large-scale, multicenter RCTs with standardized PBM protocols. Additionally, studies should investigate combination therapies, comparing PBM with various desensitizing agents to determine the most effective approach. It would also be beneficial to explore the molecular mechanisms of PRM in Mili, camining how it influences odontoblast function, dentin regeneration and enamel remineralization.

**CONCLUSION:**

The present systematic review provides compelling evidence supporting the effectiveness of PBM therapy in managing hypersensitivity in children with MIII The findings suggest that PBM, particularly when combined with conventional desensitizing agents such as fluoride varnish or CPP-ACPF mousse, significantly reduces hypersensitivity, offering both immediate and sustained relief. Despite the promising results, variations in PBM protocols, study methodologies and follow-up durations highlight the need for standardization in treatment parameters. If validated through future research, PBM could serve as a minimally invasive, safe and effective alternative for managing hypersensitivity in MIH-affected teeth, improving the quality of life for pediatric patients.

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SYSTEMATIC REVIEW

# Effectiveness of Diode Lasers as an Adjunct in Pulpotomy Procedures Involving Primary Teeth: A Systematic Review

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## Abstract

**Objective:** This systematic review aims to evaluate the effectiveness of diode lasers as an adjunct in pulpotomy procedures involving primary teeth.

**Background:** Pulpotomy is a common procedure in pediatric dentistry to manage carious lesions affecting the pulp of primary teeth. Diode lasers are increasingly being considered due to their potential advantages, such as enhanced precision, reduced bleeding, and improved patient comfort. However, their effectiveness specifically in pulpotomy procedures requires a thorough assessment.

**Methods:** A systematic search was performed across several databases, including PubMed, Cochrane Library, and Scopus, up to March 2024. Studies included in this review were randomized controlled trials (RCTs), cohort studies, and clinical trials that assessed the use of diode lasers in pulpotomy procedures for primary teeth. Data extraction included study characteristics (e.g., author, year, study design), participant demographics, details of diode laser intervention, comparison groups, outcomes assessed, and results.

**Results:** A total of 25 studies met the inclusion criteria. The review found that diode lasers were effective in performing pulpotomies, with several studies showing potential in promoting pulp healing and reducing the need for pharmacological interventions. While lasers and alternative materials such as mineral trioxide aggregate (MTA) and Biodentine show promise in maintaining or even enhancing clinical outcomes compared to traditional agents, considerations such as cost-effectiveness, long-term efficacy, and radiographic success rates remain pivotal.

**Conclusion:** Diode lasers show promise as an adjunct in pulpotomy procedures for primary teeth, offering potential benefits such as enhanced precision, reduced bleeding, and improved patient comfort.

**Keywords:** Diode, Pediatric dentistry, Primary teeth, Pulpotomy, Systematic review.

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## Introduction

The preservation of primary teeth is paramount to the long-term oral health and development of children, as these teeth facilitate proper mastication, speech, and alignment of permanent dentition. However, traditional dental procedures involving primary teeth, such as caries removal, pulp therapy, and periodontal treatment, often present challenges due to the delicate nature of pediatric dentition and the complexities of treating young patients. Conventional techniques, including hand instruments and rotary instruments, may be associated with discomfort, anxiety, and difficulty in achieving adequate clinical outcomes, particularly in pediatric populations.

Despite advances in dental technology and materials, conventional methods of treating dental conditions in primary teeth have inherent limitations, including the risk of iatrogenic damage to adjacent healthy tissues, difficulty in accessing deep carious lesions, and challenges in managing behavioral aspects of pediatric patients. Furthermore, the use of local anesthesia and airotors may contribute to children's fear and anxiety, leading to negative experiences and potential long-term aversion to dental care.

In light of these challenges, there is a growing recognition of the need for alternative approaches to routine dental procedures involving primary teeth, aiming to enhance clinical outcomes, improve patient comfort, and streamline treatment delivery. Laser technology has emerged as a promising adjunct in pediatric dental practice, offering unique advantages in terms of precision, efficiency, and patient experience. Among various types, diode lasers have garnered particular attention for their versatility and safety profile, making them well suited for use in pediatric patients.

Diode lasers operate within the near-infrared spectrum, allowing for selective targeting of pigmented tissues, such as carious lesions and inflamed gingival tissues, while minimizing collateral damage to adjacent healthy structures. The wavelength characteristics of diode lasers enable precise ablation of diseased tissues, enhanced hemostasis, and bacterial decontamination, offering potential benefits in various dental procedures involving primary teeth.

Despite the promising potential of diode lasers, their integration into routine dental procedures involving primary teeth requires careful consideration of various factors, including safety, efficacy,

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and cost-effectiveness. While clinical studies have demonstrated the effectiveness of diode lasers in caries treatment, soft-tissue surgery, and periodontal therapy, further research is needed to elucidate optimal treatment protocols, laser parameters, and long-term outcomes in pediatric patients.

The systematic review aims to critically examine existing literature on the effectiveness of diode lasers as adjuncts in routine dental procedures involving primary teeth. Through a comprehensive synthesis of data from diverse study designs, including randomized controlled trials (RCTs), prospective cohort studies, and retrospective analyses, this review seeks to elucidate the clinical outcomes, patient experiences, and practice implications associated with diode laser therapy in pediatric dental practice.

## Methodology

This systematic review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and is registered with PROSPERO (registration number) CRD42024498099 (Fig. 1).

### Research Question

The research question guiding this systematic review is "What is the utility of diode lasers in dental procedures involving primary teeth?" This question was formulated using the PICO (Population, Intervention, Comparison, Outcome) framework:

- Population: Children with primary teeth undergoing dental procedures.
- Intervention: Use of diode lasers in dental procedures involving primary teeth.
- Comparison: Various comparators such as traditional methods or other types of lasers.
- Outcome: Efficacy, safety, patient satisfaction, and any adverse effects associated with diode laser use in primary dental procedures.

### Search Strategy

A comprehensive search strategy was developed to identify relevant studies. Electronic databases, including PubMed, Cochrane Library, and Embase, were searched from inception to March 2024. The search strategy employed both keywords and Medical Subject Headings (MeSH) terms related to diode lasers, primary teeth, and dental procedures. Terms were combined using Boolean operators. The search strategy was adapted to each specific database. Additionally, manual searches of reference lists of included studies and relevant review articles were conducted to identify additional studies.

### Study Selection

Two independent reviewers screened the titles and abstracts of the retrieved records for eligibility based on the PICO criteria. Full texts of potentially relevant articles were then assessed for inclusion based on predetermined criteria. Any discrepancies were resolved through discussion or consultation with a third reviewer.

### Data Extraction

Data extraction was performed independently by two reviewers using a standardized form. Extracted data included study characteristics (e.g., author, year, study design), participant demographics, details of diode laser intervention, comparison groups, outcomes assessed, and results. Any discrepancies were resolved through consensus or consultation with a third reviewer.

### Quality Assessment

The quality of included studies was assessed using appropriate tools depending on the study design. For RCTs, the Cochrane

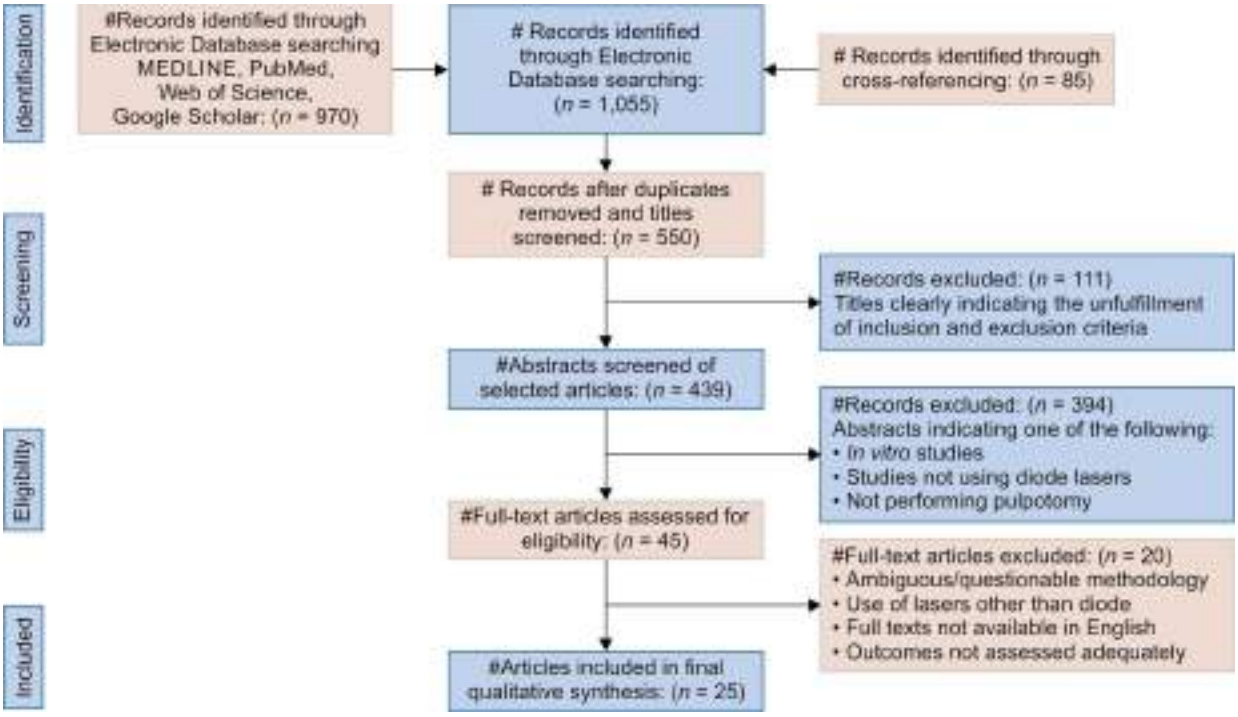


**Fig. 1:** PRISMA flow diagram indicates the selection process of the articles in the present systematic review

Collaboration's tool for assessing the risk of bias was utilized. Nonrandomized studies were assessed using tools such as the Newcastle–Ottawa Scale for observational studies. Quality assessment was conducted independently by two reviewers, with any discrepancies resolved through discussion.

### Data Synthesis and Analysis

A narrative synthesis of findings will be provided, structured around the research question and key themes identified. If feasible and appropriate, meta-analysis will be conducted using appropriate statistical methods to quantitatively synthesize data from included studies. Subgroup analyses and sensitivity analyses will be performed to explore heterogeneity and assess the robustness of results.

## Results

A total of 25 studies were identified after a systematic search, the earliest of which was conducted in 2005. The data extracted from these studies are summarized in the Master Chart.

Most of the studies ($n = 16$) were RCTs with parallel-arm design, while $n = 5$ were RCTs with a split-mouth design. An $n = 1$ study each was *in vitro* study, retrospective cohort study, and *ex vivo* study, respectively. Among the different countries, the majority ($n = 11$) were conducted in India, $n = 3$ in Iran, and $n = 2$ in Taiwan, Turkey, and Saudi Arabia, respectively. One study was conducted in Brazil, the United Kingdom, Egypt, and Croatia, respectively. The country-wise distribution of studies is depicted in Figures 2 to 4.

The inclusion criteria across various studies for pulpotomy treatment in primary molars focused on several key aspects. First, the age and behavior of children were considered, with eligible participants being cooperative children aged between 4 and 9 years. The condition of the tooth and pulp was also critical, requiring primary first or second molars with vital pulp and carious exposures that bled upon entering the pulp chambers, deep carious lesions, and teeth deemed restorable with a stainless steel crown.

Radiographic criteria emphasized the absence of interradicular radiolucency, internal resorption, and significant root resorption (more than one third of the root). Additional conditions included healthy patients without systemic conditions that contraindicated pulp therapy, cooperative behavior as per the Frankl behavior classification scale, and specific dental conditions, such as teeth likely to exfoliate within 4–5 months or those restorable with stainless steel crowns (SSCs). These inclusion criteria collectively ensured the selection of appropriate candidates for pulpotomy, focusing on dental and overall health, radiographic evidence, and cooperative behavior.

The exclusion criteria employed across studies investigating pulpotomy treatment in primary molars were designed to establish stringent standards for patient selection and procedural eligibility. Radiographic and clinical evidence of pulpal and periapical pathology were primary considerations, leading to the exclusion of teeth exhibiting furcal or periapical radiolucencies, pathologic root resorption (both internal and external), and significant physiological root resorption exceeding one third. The presence of interradicular bone loss or radiolucency, periapical radiolucency, and signs of internal or external root resorption were also grounds for exclusion to ensure that only teeth with minimal pathological involvement were included in the studies.

Clinical signs indicating pulp degeneration played a crucial role in exclusion, such as teeth showing symptoms such as swelling, fistula, sinus tract, excessive mobility, spontaneous or nocturnal pain, or excessive bleeding from radicular stumps.


**Fig. 2:** Map chart indicating the number of studies performed across various countries globally


**Fig. 3:** Risk of bias for individual studies

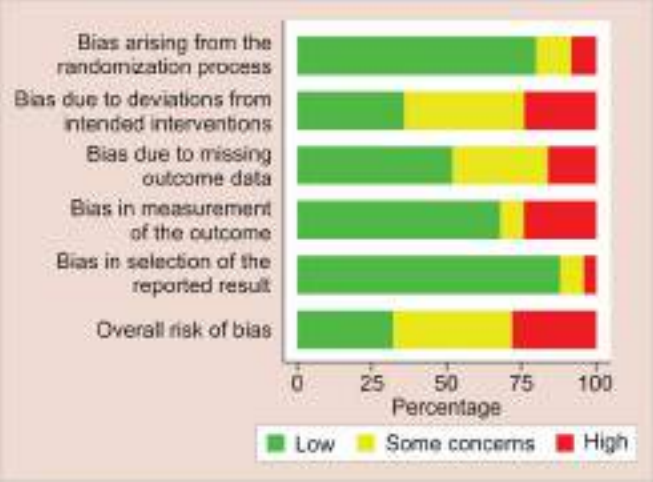


**Fig. 4:** Overall risk of bias across all studies included in the present systematic review

Further criteria focused on the condition of the teeth excluded those that were nonrestorable, near exfoliation, or indicated for extraction or pulpectomy. Teeth with necrotic pulp or excessive physiological root resorption were also excluded, as were those showing signs of excessive bleeding during pulp amputation.

The sample size distribution varies widely, with the most common size being around 40 participants and others ranging from 20 to 145 in various studies.

Age ranges indicate studies involving children typically ranging from as young as 2 years old up to 10 years old. The common age-group included across most studies was 4–7 years old.

Most of the studies had an equal number of males and females, with the exception of three studies having a greater number of males.

All studies utilized all the primary molars, including the first and second maxillary and mandibular primary molars, for their study. Only *n* = 2 articles were selected on mandibular primary molars for their study.

The settings of lasers across the studies varied widely, spanning from a low of 660 nm wavelength with 10 mW power output and 2.5 J/cm$^2$ energy density to a high of 980 nm wavelength with 3 W power and varying energy densities up to 6.7 J/cm$^2$. Frequencies ranged from 30 to 50 to 60 Hz, with some studies specifying a wide range of kHz frequencies. Beam diameters also varied significantly, ranging from an area of 0.04 cm$^2$ to a focused beam diameter of 105 µm, indicating diverse applications and intensities of laser treatments in different experimental contexts.

The most common settings used across the studies included:

- Wavelength: 810 nm.
- Power: 3 W.
- Energy density: 2 and 4 J/cm$^2$.
- Frequency: 30 and 50–60 Hz.
- Beam diameter: 200 and 400 µm.

The duration of laser application varied widely across the studies ranging from very short durations of 1–2 seconds to longer durations such as 2.5 or 4 minutes per tooth. Different modes of application were utilized, including continuous pulse, gated pulse mode, and specific cycles such as three cycles of 15 seconds or 20 ms pulses with 40 ms intervals. Some studies employed multiple applications until achieving specific outcomes such as pulp ablation and hemostasis, while others used durations as short as 1 second but repeated multiple times at each treatment site.

Formocresol (FC) was the most commonly used comparator as the pulpotomy agent in *n* = 10 studies followed by ferric sulfate (FS) in *n* = 4 studies and calcium hydroxide in three studies. Other comparators included FC–zinc oxide–eugenol (ZOE), erbium laser, Buckley's FC, low-level laser therapy (LLLT) + ZOE, LLLT + calcium hydroxide, mineral trioxide aggregate (MTA), Biodentine, sodium hypochlorite, diode laser + MTA, diode laser + ZOE, simvastatin, antioxidant mixture, conventional burr pulpotomy, and electrosurgical pulpotomy (*n* = 1 each, respectively).

The follow-up durations across the various studies ranged from as short as 1.5 months to as long as 24 months with most studies following up the participants for about 12 months.

The findings across various studies on pulpotomy techniques in primary teeth reveal a spectrum of outcomes and comparisons between traditional methods and newer technologies. FC and FS have long been standard treatments, with studies indicating high clinical success rates but sometimes lower radiographic success rates compared to newer alternatives such as lasers and mineral-based materials such as MTA and Biodentine (*n* = 3). Diode lasers emerged prominently, showing promising clinical outcomes comparable to or better than FC and FS in terms of patient cooperation, ease of use, and pain management (*n* = 5). However, concerns about their radiographic success rates persist, suggesting they may not entirely replace traditional agents.

Low-level laser therapy was explored as a complement to pulpotomy procedures, showing potential in promoting pulp healing and reducing the need for pharmacological interventions (*n* = 4). LLLT combined with calcium hydroxide demonstrated satisfactory clinical and radiographic results, supporting its role as an adjunct therapy (*n* = 2). Additionally, studies on antimicrobial effects highlighted diode lasers' ability to significantly reduce bacterial counts in root canals, although complete bacterial eradication remains a challenge for both diode and erbium lasers (*n* = 1).

Overall, while lasers and alternative materials such as MTA and Biodentine show promise in maintaining or even enhancing clinical outcomes compared to traditional agents, considerations such as cost-effectiveness, long-term efficacy, and radiographic success rates remain pivotal. Further research into optimizing laser parameters, refining application techniques, and evaluating long-term outcomes will be crucial in determining their broader adoption and potential to redefine standard protocols in pediatric pulp therapy.

## Discussion

A total of 25 studies were identified after a systematic search, with the earliest study conducted in 2005. The majority of these studies (16 out of 25) were RCTs employing a parallel-arm design, which suggests that researchers prioritized methodological rigor and the ability to compare different treatment groups simultaneously to minimize bias and improve the reliability of the findings.[1,2] Additionally, five studies employed an RCT split-mouth design, a methodological choice likely driven by the need to control for individual variability by using the same patient's mouth for both control and experimental conditions. This design enhances internal validity by ensuring that comparisons between laser- and nonlaser-treated sites are more direct and individualized.[3] The inclusion of

an *in vitro* study allowed for a controlled environment to explore the fundamental effects of diode lasers without patient-related variables. The retrospective cohort study provided a long-term perspective on outcomes based on existing records, potentially identifying trends over time.[4] Most studies on pulpotomy treatment in primary molars utilized specific inclusion criteria to ensure homogeneity in patient selection and to maximize the likelihood of successful treatment outcomes. Children aged between 4 and 9 years were commonly included due to their age-group being most susceptible to primary molar caries and their potential for cooperative behavior during dental procedures. Primary first or second molars were selected as they are frequently affected by caries and are amenable to pulpotomy procedures aimed at preserving their function until natural exfoliation.[5] Including teeth with vital pulp and carious exposures, particularly those that bled upon entering the pulp chambers, ensured that the pulpotomy procedure targeted teeth with reversible pulpitis and maintained a viable pulp.[5,6] Identifying teeth deemed restorable with a stainless steel crown was crucial, as it ensured that the treated tooth could sustain functional load and occlusal forces postpulpotomy. Similarly, including restorable carious primary molars with reversible pulpitis and devoid of clinical or radiographic signs of pulp pathology ensured that the teeth selected were suitable candidates for pulpotomy without underlying complications that could compromise treatment success.[7] The inclusion criteria focusing on the extent of root resorption, dentin demineralization, and radiolucency approaching the pulp were pivotal in selecting appropriate candidates for pulpotomy treatment in primary molars. Teeth with less than one third of natural root resorption were included to ensure the structural integrity and stability necessary for successful pulpotomy outcomes.[8,9] Teeth requiring pulpotomy treatment due to pulpal exposure from caries to be deemed restorable with SSCs were included to address carious lesions that had reached or exposed the pulp chamber.[10] Furthermore, including records of patients who underwent pulpotomy using diode laser, sodium hypochlorite, or no medication, with a follow-up period ranging from 6 to 24 months, aimed to evaluate the long-term outcomes and comparative effectiveness of different treatment modalities.[11] This criterion allowed researchers to assess the impact of treatment methods on pulp health and tooth survival through radiographic examination and extended follow-up periods.[12] By including diverse treatment approaches and follow-up durations, the studies aimed to provide comprehensive insights into the optimal management of primary molars requiring pulpotomy, considering both short-term efficacy and long-term outcomes.[13,14] Presence of furcal or periapical radiolucencies indicated advanced periapical involvement or furcation defects, suggesting extensive pulpal or periodontal pathology beyond the scope of pulpotomy. Excluding these teeth aimed to avoid complications and ensure that treatment efforts were directed toward teeth with healthier periapical and furcal conditions.[12] Interradicular bone loss or radiolucency and periapical or interradicular radiolucency were additional exclusion criteria aimed at excluding teeth with significant periodontal involvement or advanced periapical pathology.[10] Signs such as swelling, fistula, sinus tract, or excessive mobility indicated active infection or abscess formation, which typically require more extensive treatments than pulpotomy.[11,15] Excluding teeth with these symptoms aimed to avoid complications during the procedure and improve the likelihood of successful treatment outcomes by focusing on teeth with healthier pulp conditions.[12] Teeth presenting with spontaneous or persistent pain, particularly pain that worsened at night, were also excluded due to their association with irreversible pulpitis or necrosis.[13] Clinical evidence of excessive bleeding from amputated radicular stumps was another exclusion criterion aimed at identifying teeth with healthy vascular integrity and adequate pulp tissue remaining.[14] Teeth indicated for extraction or pulpectomy were also excluded to focus on cases where pulpotomy was the appropriate treatment modality.[16,17] The exclusion criteria related to patient health and medical history were crucial for ensuring the safety and feasibility of pulpotomy treatment in pediatric patients, particularly in managing carious primary molars.[18] The presence of systemic pathology or systemic disease history was a key exclusion criterion aimed at minimizing risks associated with the procedure.[18] Excluding patients with known allergies aimed to prevent allergic reactions and ensure that the materials used in pulpotomy procedures were well tolerated and safe for the patient.[19,20] Medically compromised children or those with special needs were also excluded due to potential challenges in managing their care during dental procedures. Excluding medically compromised children aimed to prioritize patients where pulpotomy could be performed under standard clinical conditions with minimal risk of complications.[21,22] Teeth that were not restorable with an SSC were also excluded from the study.[23–25] Clear documentation of medication used during pulpotomy and procedural details is crucial for assessing treatment efficacy and outcomes accurately.[26] Excluding cases with incomplete medical records aimed to enhance the reliability of study findings by focusing on patients with well-documented treatment histories and ensuring that data collection was consistent and thorough.[27,28] The sample sizes in studies investigating pulpotomy treatment in primary molars exhibit considerable variability, with the most frequently observed sample size hovering around 40 participants.[29,30] However, the distribution spans a wide range, with studies featuring participant counts ranging from as few as 20 to as many as 145 individuals. This variance in sample size reflects differences in study design, including variations in methodologies, objectives, and statistical considerations.[31,32] The age range of children included in studies investigating pulpotomy treatment in primary molars varied significantly, spanning from as young as 2 years old to as old as 10 years old. However, the most commonly recruited age-group across the majority of studies fell within the range of 4–7 years old.[33] In all studies investigating pulpotomy treatment in primary molars, both maxillary and mandibular primary molars were universally included in the study protocols. The specific inclusion of molars can be attributed to the fact that molars are most commonly affected by deep carious lesions subsequently requiring pulpotomy treatment.[34,35] The settings and parameters of lasers used in studies evaluating their effectiveness as adjuncts in dental procedures, particularly in pulpotomy treatments for primary teeth, exhibited considerable variability.[36] The wavelength of lasers ranged from a minimum of 660 nm to a maximum of 980 nm, with corresponding power outputs varying widely from 10 mW to 3 W.[37,38] Energy densities, crucial for determining the intensity of laser treatment, spanned from 2.5 to 6.7 J/cm$^2$ across different studies.[39,40] In addition to wavelength and power, frequencies of laser pulses also varied significantly among studies, ranging from 30 Hz to frequencies specified in kilohertz (kHz) ranges, such as 50–60 kHz.[41] These variations indicate the flexibility and adaptability of laser technology in dental research, accommodating different pulse rates to potentially enhance treatment efficacy or target-specific biological responses. Moreover, beam diameters used in laser

applications ranged notably, from an area of 0.04 $cm^2$ to beam diameters as precise as 105 µm. This variability suggests a range of applications from broad-area treatments to highly focused laser beams, highlighting the versatility of laser technology in dental settings for both experimental and clinical purposes.[42] The most prevalent wavelength reported was 810 nm, a choice that likely balances tissue penetration depth with absorption characteristics conducive to dental applications.[43] This wavelength is well suited for dental treatments as it can penetrate tissues while minimizing thermal damage to surrounding structures.[44–46] In terms of power output, 3 W was commonly used in the studies.[47,48] This power level is sufficient to deliver therapeutic effects while maintaining safety within dental treatment protocols. Energy densities of 2 and 4 J/$cm^2$ were also commonly applied, representing settings that balance effective treatment outcomes with controlled tissue interaction.[49] Frequency settings varied but commonly included 30 Hz and frequencies ranging from 50 to 60 Hz.[50] Beam diameters commonly utilized were 200 and 400 µm, indicating a range from focused to moderately broad beams.[51] The follow-up durations in studies investigating pulpotomy treatments for primary teeth exhibited considerable variability, ranging from a minimum of 1.5 months to a maximum of 24 months.[52,53] However, the most commonly reported follow-up period across the majority of studies was approximately 12 months. This duration is significant as it allows researchers to assess both short-term and intermediate-term outcomes following pulpotomy procedures, including the success of pulpal healing, the integrity of the dentin bridge formation, and the absence of clinical symptoms or complications.[54,55] Shorter follow-up periods, such as those around 1.5–6 months, are often used to evaluate initial healing responses and early postoperative outcomes. On the contrary, longer follow-up durations, extending up to 24 months, provide insights into the durability and long-term efficacy of the pulpotomy treatment, including the potential for pulpal pathology recurrence or late-developing complications.[56] Historically, FC and FS have been established as standard treatments, demonstrating high clinical success rates in terms of symptom relief and functional restoration.[57,58] However, studies indicate that these traditional agents sometimes exhibit lower radiographic success rates compared to newer alternatives such as lasers and mineral-based materials such as MTA and Biodentine, as evidenced in three studies.[27,59] Among the newer technologies, diode lasers have emerged prominently, showing promising clinical outcomes that are comparable to or even superior to FC and FS in terms of patient cooperation, procedural ease, and pain management, as observed in five studies.[60] Despite these advantages, concerns persist regarding diode lasers' radiographic success rates, suggesting that while they offer significant benefits, they may not entirely replace traditional agents in all cases.[61,62] LLLT has been investigated as a complementary approach to pulpotomy procedures, revealing promising potential in enhancing pulp healing and reducing the necessity for pharmacological interventions across four studies.[63,64] This modality has shown efficacy in promoting favorable clinical outcomes, potentially minimizing postoperative complications and enhancing patient comfort. Furthermore, when LLLT was combined with calcium hydroxide, two studies reported satisfactory clinical and radiographic results, underscoring its role as a beneficial adjunct therapy in pulpotomy treatments.[65] Despite these positive findings, complete eradication of bacteria remains challenging for both diode and erbium lasers, as evidenced in one study.[66,67] This limitation underscores the importance of further research to optimize laser settings and protocols to achieve more robust antimicrobial outcomes in dental pulp therapy.[68–70] Overall, while lasers and alternative materials such as MTA and Biodentine show promise in maintaining or even enhancing clinical outcomes compared to traditional agents, considerations such as cost-effectiveness, long-term efficacy, and radiographic success rates remain pivotal.[47,71] Further research into optimizing laser parameters, refining application techniques, and evaluating long-term outcomes will be crucial in determining their broader adoption and potential to redefine standard protocols in pediatric pulp therapy.[72–74] While LLLT shows promise in promoting pulp healing and reducing adjunctive medication requirements, diode lasers demonstrate significant antimicrobial effects but require continued refinement to achieve comprehensive bacterial eradication in clinical settings.[32,38,75] Continued research in these areas holds the potential for advancing therapeutic approaches in pediatric dentistry, aiming to improve treatment outcomes and patient experiences.[68,76,77]

## Conclusion

This systematic review comprehensively examined the effectiveness of various adjunctive therapies and traditional agents used in pulpotomy procedures for primary teeth, synthesizing evidence from a diverse range of studies. The findings reveal a dynamic landscape in pediatric dental care, where traditional agents such as FC and FS continue to demonstrate high clinical success rates, albeit sometimes with concerns over radiographic outcomes compared to newer alternatives. Mineral-based materials such as MTA and Biodentine have emerged as promising alternatives, showing comparable or superior radiographic success rates and contributing to the evolving standard of care in pulpotomy treatments.

Among the newer technologies, diode lasers have shown notable promise, particularly in enhancing patient comfort, procedural ease, and antimicrobial efficacy within root canals. LLLT, when used as an adjunct, demonstrated potential benefits in promoting pulp healing and reducing the need for pharmacological interventions, although challenges in achieving complete bacterial eradication were noted. Combining LLLT with calcium hydroxide further underscored its role as a supportive therapy in optimizing clinical and radiographic outcomes postpulpotomy.

The integration of evidence-based practices from this review supports informed decision making in pediatric dentistry, ensuring optimal outcomes while prioritizing patient safety and long-term dental health.

Further research is warranted to refine protocols and enhance the predictability of outcomes associated with newer technologies and adjunctive therapies. Longitudinal studies with extended follow-up periods can provide valuable insights into the durability and sustainability of pulpotomy treatments in primary teeth. By synthesizing current evidence and identifying areas for future investigation, this review aims to contribute to ongoing advancements in pediatric dental care, ultimately enhancing the quality of care provided to young dental patients worldwide.

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REVIEW ARTICLE

# Digital Dilemma: The Intersection of Social Media Influencers and Pediatric Dental Health

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## Abstract

**Aim and background:** This review explores the dual role of social media influencers (SMIs) in pediatric oral health. While dental influencers promote evidence-based practices and preventive care, nondental influencers often prioritize esthetics and entertainment, sometimes at the expense of accuracy.

**Methods:** A comprehensive literature review was conducted across peer-reviewed journals and social media platforms. Studies between 2019 and 2024 analyzing TikTok, YouTube, Instagram, Facebook, and Twitter content were synthesized to assess the reach, quality, and influence of dental and nondental SMIs.

**Results:** Dental influencers typically shared reliable and preventive health guidance. In contrast, nondental influencers frequently spread misinformation, endorsed unverified products, and triggered self-esteem issues. Children's behavior and perceptions were influenced both positively—via gamified brushing routines—and negatively—via risky do-it-yourself (DIY) trends and overcommercialization. Readability and engagement gaps were noted in professional content.

**Conclusion:** Social media influencers hold powerful sway over pediatric dental habits. Collaboration between dental professionals and high-reach influencers, paired with improved regulation and digital literacy, can promote safe and effective oral health messaging.

**Clinical significance:** Strategic use of SMIs enables pediatric dental professionals to enhance oral health awareness, combat misinformation, and foster healthier behaviors among children.

**Keywords:** Children, Dental health, Digital influence, Oral hygiene, Social media.

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## Introduction

Social media can be defined as "a group of internet-based applications that are built on Web 2.0." "Individual production and user-generated content" is one of the key concepts in Web 2.0.[1] In recent decades, these platforms have become extremely popular as a means to create and share social networks.[2,3] The impact of social media has taken a completely different perspective and added a new dimension to this rapidly evolving world where information is both consumed and disseminated among the children and adolescents. Children grow up as digital natives, surrounded by social media platforms that influence their behaviors, perceptions, and lifestyle choices. Social media influencers (SMIs) are those who have built sizable followings on channels like Instagram, Facebook, and YouTube and have become critical players in influencing consumers' habits. These influencers promote products, share their daily routines, and sometimes peddle unverified remedies in the world of oral health, their reach taking a toll on children's choices.[4]

To compound this, dental health exists on social media—a niche evermore commingled with entertainment and education.[4] Influencers are frequently seen showing brushing techniques, promoting certain dental products and talking about the importance of regular dental checkups. Although such efforts can be beneficial in encouraging children to adopt better oral hygiene habits, they also create opportunities for the spread of misinformation and an emphasis on beauty instead of health. Additionally, the idealistic nature of influencers can create psychological problems like self-esteem issues and peer conformity pressures.[5] This review explores the dual role of SMIs in shaping children's oral health with the following objectives:

- Examine the role of influencers in promoting oral health.
- Evaluate the psychological and behavioral impact of their efforts.
- Identify potential risks associated with their impact.
- Explore opportunities for positive contributions to oral health awareness.
- Design strategies to counteract negative effects and promote collaboration for impactful, effective messaging.

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## Demographics of Social Media

The digital ecosystem in India has expanded greatly, with children being active participants in online spaces. In a 2022 survey, it was found that more than 3 hours per day were spent by most children in the ages 9–13 years in urban India on social media, online videos, and games. Specifically, about 49% of parents reported this level of engagement among their children.[6]

A high percentage of children in developed countries are reported to have access to mobile devices, and platforms such as Facebook, Instagram, and YouTube are the most common social media apps used by childhood users.[7] These sites offer kids an environment in which they can engage with content that is educational and promotional in nature. The combination of vibrant visuals and relatable personalities makes influencers particularly effective at capturing attention and shaping behaviors.

## The Role of Social Media Influencers

Social media influencers drive a wedge between brands and consumers, leveraging authenticity and followership over as a tool for perception and behavior shaping. They are aspirational figures for product endorsements, health education, and awareness campaigns about oral health.[8,9]

### Dental vs Nondental Influencers

The present review classifies SMIs into dental and nondental groups. The dental influencers are regular influencers—the difference is that they usually have professional background in dentistry— while general nondental influencers could lack any formal knowledge about the subject matter.[10] As dental influencers are expected to provide evidence-based guidelines, their recommendations are often the more credible and scientifically sound. On the contrary, nondental influencers may chase entertainment and engagement over the truth.

### Dental Influencers: The Trusted Advisors

Dental influencers, such as dentists and hygienists, operate with a foundation of evidence-based knowledge.[10] They provide:

- Reliable education: Dental influencers break down oral health and offer accurate guidance on brushing techniques, flossing, fluoride, and how they can help prevent cavities.
- Advocacy for preventive care: Initiatives undertaken by dental professionals can emphasize the importance of regular dental cleanings—help develop preventive behaviors.
- Advocacy for regular dental visits.

### Nondental Influencers: The Relatable Entertainers

While nondental influencers may not have a professional background, their relatable personas and extensive reach help them effectively connect with young audiences. But their emphasis on esthetics and entertainment can lead to some risks:

- Esthetic emphasis: Nondentistry influencers often prefer esthetics over health and may not prioritize oral health despite recommending products to achieve whiter teeth or straighter smiles. Example: Promoting "instant whitening pens" without talking about potential enamel damage and promoting dental jewelry without explaining their oral health implications.[11,12]
- Misinformation spread: Unverified do-it-yourself (DIY) hacks, such as using lemon juice for whitening, can have detrimental effects on oral health. Example: viral videos that display "hacks" for cleaning teeth often have little or no scientific support and can damage the development of children's dental health.[13]
- Commercial bias: Partnerships with brands may lead to promoting ineffective or harmful products, driven by profit rather than genuine health benefits.[9]

## Behavioral Influence of Social Media Influencers on Children

- Product choices: Influencers often recommend specific dental products, directly impacting children's and parents' purchasing decisions.[14] Although some recommendations match quality dental advice, such as fluoride toothpaste, other means may encourage unnecessary or ineffective products. Frattallone reported that these trendsetters, without dental training, disseminate information and recommend products that can have adverse effects on the oral health of their followers.[14]
- Risk behaviors: Access to unverifiable or potentially dangerous advice like DIY teeth whitening can endanger oral health. Research by Frattallone saw some disturbing trend involving influencers promoting disapproved practices and putting the children at risk.[14]
- Self-image and confidence: The visual culture of social media frequently links dental health to appearance. Children are motivated to brush their teeth by TV shows with influencers with bright, straight teeth. But the perfect pictures they promote might instill insecurity, especially in children with noticeable dental flaws. This can result in increased associations, and sometimes angst or lowered self-worth.[15]
- Peer influence and conformity: Children inherently desire to be accepted by their peers, and social media enhances this trait. Children may feel pressured to follow what influencers portray as trendy in specific products or practices.[2] This conformity can lead to positive habits like improved brushing routines, but it can also trigger unnecessary or inefficient purchases.
- Adapting to new behaviors: Children are especially good at mimicking behaviors shown to them by influencers, particularly if they are presented in engaging formats.

### Examples Include

*Positive Examples*

- Peer-led brushing challenges: YouTube influencers can lead children in the "2-minute brushing challenge," resulting in improved duration/consistency of brushing. This twist on gamified experience makes oral hygiene more interesting and accessible.
- Real stories from kids overcoming dental anxiety: Pediatric influencers can show how they overcame their fears of seeing a dentist like making a comforting routine around their appointment, and bringing their favorite toy or listening to music—help their peers feel less anxious about their own appointments.
- Celebrating dental milestones: Videos of kids proudly displaying a "no cavities" certificate or a lost tooth to their followers inspire others to appreciate regular dental visits.

- Mini science experiments: People testing the effects of sugary/carbonated drinks on eggshells (the enamel stand-in) show kids how important it is to cut back on sugar—visually and in a fun way.

*Negative Examples (Especially from Nondental Influencing)*

- Do-it-yourself tooth gems gone wrong: Children influenced by influencers who apply decorative gems using nail glue or other adhesives may risk damage to the enamel or develop infections.
- Unboxing candy challenges: Videos where influencers open and eat piles of candy normalizes high-sugar consumption among children, who then want to eat more candy and unhealthy snacks.
- Overuse of fluoride toothpaste: Misconceptions around using more toothpaste to achieve whiter teeth can lead to fluorosis in children, especially if they are still swallowing toothpaste. Also, DIY fixes that can backfire on dental health, like activated charcoal or lemon juice, can erode enamel over time.
- Fear-based content on tooth extractions: Videos that show an incredible amount of pain during a procedure, always with a silly caption like "Worst Pain Ever!" can frighten children and turn them off essential treatments.
- The aligner obsession: Influencers displaying their clear aligners as a "cool" accessory or short cut to a perfect smile can cause children to unnecessarily demand orthodontic treatments that they may not need, just to imitate their favorite influencers. This creates a stigma against conventional braces and discourages children who require braces from embracing them even when they are the more appropriate solution to complex dental corrections.

## Risks and Recommendations: The Double-edged Sword of Social Media

Although social media has great potential for education, it also harbors significant risks that can greatly affect oral health, especially in children and adolescents who may be easily influenced.[2,15,16]

- Overcommercialization: Sponsored content prioritizes commercial interests over scientific credibility, contributing to misinformation. Things like DIY whitening kits and unregulated dental devices are pitched as "miracle fixes," usually without the backing of legitimate dental organizations regarding their safety. These drastic changes may lead to irreversible cases that may include loss of enamel along with severe long-term effects to other structures in our oral cavities.
- Smile anxiety: The unwavering pursuit of perfection breeds a harmful culture of esthetic comparison. Adolescents are at higher risk and many develop insecurities about their natural dental esthetic. This pressure has created an uptick in business for unnecessary cosmetic procedures, including teeth whitening and aligners.

## Evidence from Published Literature

In order to learn the scope of social media on pediatric dental health, we conducted a literature search on PubMed and Scopus, and after screening of search results, we conducted a synthesis of 28 content analysis studies on platforms including TikTok, YouTube, Instagram, Facebook, and Twitter (Table 1). Conducted between 2019 and 2024, these studies provide a nuanced perspective of the type of content young audiences and parents are consuming, the

**Table 1:** Overview on studies on social media in pediatric dentistry

| *Author(s) and year* | *Platform(s) studied* | *Type of content analyzed* | *Methodology/study design* | *Sample size/ number of posts or videos* | *Key findings* | *Quality assessment (if done)* | *Remarks/ limitations* |
|---|---|---|---|---|---|---|---|
| Alwadi et al., 2024[17] | YouTube (Arabic) | Pediatric oral health videos | Content analysis with DISCERN | 47 videos | Moderate quality, weak engagement correlation | DISCERN | Quality varied; low reliability |
| Menezes et al., 2024[18] | Instagram | Dental caries-related posts | Logistic regression analysis | 500 posts | 44% misinformation; sentiment influences interaction | Not stated | Older posts linked to misinformation |
| Booth et al., 2024[19] | Image-based social media | Pediatric ankyloglossia | Cross-sectional content analysis | 71 posts | IBCLCs more accurate; high misinformation | JAMA, Flesch-Kincaid, SMOG | Above-grade reading level |
| Jorge et al., 2024[20] | Facebook | Amber teething necklace comments | Deductive content analysis | 1,000 comments | Most users shared positive experiences | Not done | Limited to English; one analyst |
| Alhumaidan et al., 2024[21] | Facebook | Teething-related posts | Longitudinal analysis | 193 posts | Misinformation common; low engagement | Not done | Private/ unrelated content excluded |
| Esmaeilzadeh et al., 2024[22] | Instagram (Persian) | Fluoride-related posts | Qualitative content analysis | 400 posts | 70.5% pro-fluoride; misinformation on toxicity | Not specified | False claims widespread |
| Jorge et al., 2024[23] | Facebook (Portuguese) | Amber necklace posts | Quantitative + qualitative | 500 posts | Commercial motives drove engagement | Not done | Risks ignored in most posts |
| Strieder et al., 2024[24] | Instagram (Brazilian) | Amber necklace posts | Facticity, media and sentiment analysis | Not specified | Videos and personal profiles had highest engagement | Not stated | Ignored health warnings |

*(Contd...)*

**Table 1:** *(Contd...)*

| *Author(s) and year* | *Platform(s) studied* | *Type of content analyzed* | *Methodology/study design* | *Sample size/ number of posts or videos* | *Key findings* | *Quality assessment (if done)* | *Remarks/ limitations* |
|---|---|---|---|---|---|---|---|
| Menezes et al., 2024[25] | Facebook | Toothache-related posts | Logistic regression and sentiment analysis | 500 posts | Misinformation tied to profit and positive tone | Not detailed | Videos and links got higher engagement |
| Abdelemam et al., 2024[26] | Instagram | Clear aligners content | Cross-sectional analysis | 130 top posts | Mostly self-promotional; patients' posts more engaging | Not stated | Promotion outweighed education |
| Jorge et al., 2024[27] | Facebook | False amber necklace posts | Topic modeling + logistic regression | 500 posts | Business profiles with social motives dominated | Not mentioned | "Sales" key topic |
| Loureiro et al., 2024[28] | YouTube | Tooth avulsion videos | IADT checklist + DISCERN | 8 videos | Rich content for clinical steps; dentist uploads | IADT, DISCERN, GQS | Few videos; narrow audience |
| Aguirre et al., 2023[29] | YouTube | ECC education videos | Thematic checklist + views analysis | 180 videos | Incomplete ECC info; sugary food posts popular | Thematic checklist | Nonhealth creators had more followers |
| Monteiro et al., 2023[30] | YouTube | Zirconia crown videos | DISCERN analysis | 28 videos | Majority were poor/ fair quality | DISCERN | Poor reliability overall |
| Morita et al., 2024[31] | Twitter | Fluoride and vaccine misinformation | AI-based ecosystem (U-MAS) | Large-scale, not specified | Real-time detection successful | Validated models | Technical system, not topic-specific |
| Remiro et al., 2024[32] | Facebook | Caries-related misinformation | Logistic regression | 500 posts | Misinformation = more interaction | Not described | Business profile posts spread more |
| Uzel et al., 2023[33] | YouTube (Turkish) | Pediatric dentistry education | JAMA, GQS, VPI | 119 videos | Mostly low quality; dentists posted majority | JAMA, GQS | Not fit for student education |
| Lee et al., 2022[34] | Instagram | ECC promotion | Inductive content analysis | 1,071 images, 3,228 comments | Tips/advice common; visuals frequent | Not done | Need for professional moderation |
| Erturk-Avunduk et al., 2022[35] | YouTube | Sealant application videos | GQS evaluation | 110 videos | 14 good, 63 moderate, 33 poor | Global quality score | Interaction higher for good videos |
| Ozturk and Gumus, 2022[36] | YouTube | Early ortho treatment | Multiple scoring systems | 61 videos | Doctor uploads had better metrics | GQS, RS, TCS | Info quality still low overall |
| Lotto et al., 2024[37] | Instagram | Fluoride misinformation | Topic modeling + logistic regression | 500 posts | Older/political posts overperform | Not stated | Claims driven by profit motives |
| Aksoy and Topsakal, 2022[38] | YouTube | Pediatric oral health instructions | Content analysis + GQS | 40 videos | Moderate reliability and quality | GQS, Reliability score | Rich content = better metrics |
| Tozar and Yavuz, 2022[39] | YouTube | Pediatric dental trauma | 23-point video score | 127 videos | 21% high content; 47% low | Content score | Needs quality improvement |
| Çapan, 2021[40] | YouTube | Space maintainers | Usefulness score (AAPD) | 52 videos | Mean score 4.4/9; visuals used | AAPD guideline-based | Adverse effects not explained |
| Simsek et al., 2019[41] | YouTube | Oral habit videos | Classification and interaction index | 100 videos | 38% good, 44% moderate | Not named | Caution advised in interpretation |
| Simsek et al., 2020[42] | YouTube | Teeth whitening videos | Quality and purpose classification | 100 videos | Poor content = more views | Quality rating | Layperson videos dominate |

*(Contd...)*

**Table 1:** *(Contd...)*

| *Author(s) and year* | *Platform(s) studied* | *Type of content analyzed* | *Methodology/study design* | *Sample size/ number of posts or videos* | *Key findings* | *Quality assessment (if done)* | *Remarks/ limitations* |
|---|---|---|---|---|---|---|---|
| Yilmaz and Aydın, 2020[43] | YouTube | Space maintainer videos | Seven-parameter scoring | 46 videos | 33% high quality; likes correlated | Seven-point scale + quality index | Uploader type had no impact |
| Abu-Ghazaleh et al., 2019[44] | Facebook | Dental trauma posts | Thematic + engagement analysis | 329 posts | Event/personal posts dominate; little education | Not assessed | Low engagement; preventive info lacking |

nature of influencer involvement, and the quality of information being shared.

YouTube emerged as the most frequently studied platform, with 13 studies evaluating videos on topics ranging from caries prevention, oral habits, space maintainers, and pediatric trauma to esthetic treatments like teeth whitening and zirconia crowns. Consistently, studies, such as those by Uzel et al., Tozar et al., Aksoy et al., Erturk-Avunduk et al., and Monteiro et al., revealed that although many videos were created by dental professionals, a significant portion still lacked depth, accuracy, or readability.[7,35,38,39] For instance, in Uzel et al.'s analysis of Turkish-language educational content, most videos were of low quality, despite dentist authorship.[33] Similarly, Monteiro et al.'s study on zirconia crowns found that only two out of 28 videos met "good" quality standards as per DISCERN ratings.[30]

Instagram and Facebook-based studies—such as those by Esmaeilzadeh et al., Strieder et al., Menezes et al., and Jorge et al.—focused more on user-generated posts, influencer content, and comment threads.[18,20,22,24] A notable trend observed was the high engagement with posts containing misinformation, especially those involving fluoride myths, amber teething necklaces, or "natural" dental remedies. These were often promoted by nondental influencers or commercial pages, emphasizing esthetic results over health outcomes. Posts with emotional narratives or commercial incentives (e.g., product endorsements) were shown to outperform evidence-based educational content in terms of shares, likes, and comments.

Multiple studies highlighted the disproportionate reach of misleading content. For example, the Facebook-based analyses by Jorge et al. revealed that posts with anecdotal experiences or product endorsements (e.g., amber necklaces for teething) dominated engagement metrics, despite offering no scientific validity.[23] Similarly, Lotto et al. and Remiro et al. on Instagram and Facebook found that older posts, often featuring politically or commercially charged misinformation about fluoride, generated significantly higher interaction than newer, evidence-based ones.[32,37]

A subset of studies by Loureiro et al. and Booth et al. focused on readability and health literacy, employing tools such as Flesch-Kincaid, SMOG index, and DISCERN.[9,19] These assessments revealed that much of the content—even when factually accurate—was presented at a reading level beyond the comprehension of average consumers, especially children or caregivers from low-literacy backgrounds.

In contrast, dental influencers who were dentists, hygienists, or academic creators consistently demonstrated higher-quality and more accurate content. Their posts and videos, as shown in studies by Aguirre et al., Aksoy et al., and Çapan, were more likely to align with clinical guidelines and emphasize preventive care.[29,38,40] However, their reach was often eclipsed by that of lifestyle influencers, whose emphasis on appearance, product reviews, and viral trends overshadowed educational messaging.

Together, these findings highlight substantial evidence gap between content engagement and content accuracy. Although the esthetic and entertainment value of influencer-driven content overcomes the hurdles of viewership and virality, it does not assure scientific integrity or public health utility. This tabulated synthesis of analyzed literature (Table 1) is crucial evidence that for best practices among dental professionals, partnerships with influencers, regulation of content, optimizing readability, and initiatives to promote digital health literacy targeting young people and their families are warranted.

## Discussion

While dental influencers bring clinical authority and credibility, strategically engaging lifestyle or beauty influencers—who possess broader reach and cultural influence—can enhance the dissemination of evidence-based pediatric oral health messaging. Partnerships among these two categories can extend the reach and effectiveness of evidence-based oral health messages. A great example would be a star Pediatric dentist joining a trendy nondental influencer for an educational challenge.

To help dental professionals make the most of social media, The American Academy of Pediatric Dentistry (AAPD) has gathered resources that assist in educating and engaging families about children's oral health.[45] Their Social Media Library has graphics and suggested captions for topics such as dental tips and holiday-themed posts.[46]

Furthermore, the American Academy of Pediatrics (AAP) has established the Center of Excellence on Social Media and Youth Mental Health to explore the impact of social media on young people's mental health and provide resources for families and professionals.[17,21,25–28,31,34,36,41–44,46]

### How Pediatric Dentists can Embrace Social Media: Becoming Influencers Themselves

Pediatric dentists can strategically leverage social media as a tool for advocacy, patient education, and public engagement to promote evidence-based oral health practices. With the right strategy when it comes to content, they can fight misinformation, raise oral health awareness, and connect with parents and/or children.

### Actionable Steps for Pediatric Dentists

- Create fun and educational content: Develop visually appealing, bite-sized content tailored to platforms like Instagram and

YouTube. Examples: Short videos demonstrating correct brushing and flossing techniques and Gamified challenges like "Floss Like a Boss" to engage kids.

- Leverage humor and relatability: Use light-hearted humor to make dental care less intimidating. Example: A reel titled "When you say you brush for two minutes... But the timer says 30 seconds" humorously exposes common shortcuts in oral hygiene routines while reinforcing the importance of proper brushing duration.
- Address popular trends: Monitor social media trends and provide professional commentary. Example: A myth-busting series addressing viral DIY dental hacks, such as charcoal toothpaste or baking soda scrubs.
- Collaborate with influencers: Partner with nondental influencers to co-create content that reaches wider audiences while ensuring accuracy. Example: Teaming up with a parenting influencer for "Top 5 tips to make brushing fun for your kids."
- Engage through stories and live sessions:
  - Host Q&A sessions addressing common concerns like teething, cavities, or dental fears.
  - Share behind-the-scenes glimpses of a dental clinic to normalize the environment for children.

## Conclusion

This review highlights the powerful yet double-edged role of SMIs in shaping pediatric oral health behaviors. While dental professionals on social platforms tend to offer accurate, preventive guidance, nondental influencers often spread misinformation or promote unrealistic esthetic ideals that may compromise children's oral health. The popularity of content is frequently driven more by visual appeal and emotional relatability than by scientific credibility. Compounding this, many evidence-based messages are either too complex in language or lack the engagement needed to reach young audiences effectively. To address these challenges, pediatric dentists must embrace their role as digital educators—creating accessible, compelling content and collaborating with high-reach lifestyle influencers to counteract misinformation. Strategic partnerships, improved digital literacy among families, platform accountability, and regulatory oversight together form a comprehensive framework to ensure that the immense power of social media is harnessed responsibly and effectively to protect and promote children's oral health.

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# Remineralization Potential of Self-Assembling Peptides Versus Fluoride Agents in White Spot Lesions: A Systematic Review

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## Abstract

White spot lesions (WSLs) are early manifestations of enamel demineralization, commonly observed in orthodontic patients. Traditional fluoride therapies promote surface-level remineralization but often fall short in addressing subsurface mineral loss. Self-assembling peptides (SAPs), particularly P11-4, have emerged as biomimetic agents capable of penetrating lesions and facilitating deeper enamel regeneration. This systematic review aims to compare the remineralization potential of SAPs and fluoride agents in managing WSLs, evaluating both clinical efficacy and underlying mechanisms. Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and registered in PROSPERO (CRD42024622963), an extensive literature search was conducted across PubMed, MEDLINE, Embase, Cochrane, Scopus, and grey literature from January 2000 to December 2024, which yielded 1,028 potential records. After screening 665 titles, 180 abstracts, and 60 retrieved full texts, seven clinical studies, all randomized or controlled clinical trials, met the eligibility criteria. Each study was assessed for risk of bias using the Cochrane RoB 2 tool, and evidence quality was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. A meta-analysis was not performed due to methodological heterogeneity; therefore, results were synthesized narratively. SAP P11-4 demonstrated superior subsurface remineralization compared to fluoride in all included studies, with DIAGNOdent measurements showing reductions ranging from 23% to 41%. Combined SAP-fluoride therapy yielded enhanced outcomes. Although visual changes (International Caries Detection and Assessment System (ICDAS) scores) were often indistinguishable between groups, significant differences in mineral recovery were consistently reported. SAP P11-4 is a promising, minimally invasive alternative to fluoride for managing WSLs, especially in orthodontic patients. Its capacity for deep remineralization highlights its potential as a next-generation caries management tool. However, findings are based on short-term clinical trials, and further long-term randomized studies are recommended to validate and optimize clinical protocols.

**Categories:** Dentistry, Oral Medicine
**Keywords:** enamel remineralization, fluoride varnish, self-assembling peptides, systematic review, white spot lesions

## Introduction And Background

White spot lesions (WSLs) are among the earliest clinical signs of enamel demineralization, appearing as opaque white areas on smooth surfaces of teeth while maintaining an intact outer enamel layer [1]. These subsurface lesions are primarily associated with an acidic oral environment, often exacerbated by poor plaque control around orthodontic appliances, along gingival margins, and in stagnant areas of the dentition [2]. WSLs represent a critical early stage in the caries continuum, reflecting a disruption in the equilibrium between demineralization and remineralization [3]. Without timely intervention, these lesions may progress to cavitation, compromising both dental function and aesthetics [4].

Fluoride-based therapies have long been the mainstay in managing WSLs, owing to their well-documented ability to promote remineralization and suppress further demineralization [5]. Fluoride forms fluorapatite which is a mineral more acid-resistant than hydroxyapatite, and thereby enhances enamel resistance to acidic challenges [6]. Additionally, fluoride inhibits bacterial activity and supports the redeposition of calcium and phosphate ions into the enamel. However, despite these advantages, fluoride-induced remineralization tends to be surface-limited, often failing to penetrate and restore the deeper mineral loss within the lesion body [7,8]. This surface-centric effect has prompted the development of adjunctive or alternative remineralizing agents capable of targeting the subsurface lesion.

Among such innovations, self-assembling peptides (SAPs) have emerged as a biomimetic approach that closely mimics natural enamel regeneration processes [9]. SAPs, such as the P11-4 peptide, self-assemble into three-dimensional scaffolds upon exposure to ionic fluids in the oral cavity, guiding hydroxyapatite nucleation within the lesion [10]. These scaffolds offer a framework that facilitates deep mineral infiltration and structural restoration of enamel. Unlike fluoride, which predominantly induces mineral deposition on the outer enamel surface forming a fluorapatite-rich layer, SAP P11-4 penetrates into the lesion body, assembling into a fibrous matrix that promotes hydroxyapatite crystal nucleation from within. This allows progressive subsurface remineralization and structural recovery of the deeper layers of enamel [10,11]. Importantly, SAPs exhibit lesion-specific activity, targeting demineralized enamel while preserving unaffected areas [11].

Direct comparisons between SAPs and fluoride agents provide critical insights into their relative effectiveness and practical utility in clinical scenarios. While fluoride remains an integral part of public health caries prevention strategies, SAPs may offer distinct advantages in situations requiring focused and deeper remineralization [12-14]. Evidence suggests that SAPs can induce more homogenous mineral deposition and may be less dependent on frequent application or patient compliance [15,16].

The clinical relevance of these advances is particularly pronounced in orthodontic populations, where WSLs are a frequent complication due to prolonged appliance wear and associated plaque accumulation [17]. In such cases, the limitations of fluoride may necessitate alternative interventions such as SAPs to ensure effective, minimally invasive treatment. The growing emphasis on preventive and conservative dentistry further underscores the need for therapies that restore enamel integrity without resorting to invasive procedures [18].

Despite growing evidence supporting both fluoride and SAPs individually, existing literature lacks comprehensive systematic reviews that directly compare their clinical efficacy using standardized quantitative measures. This knowledge gap underscores the need for evidence synthesis to establish their relative effectiveness and guide clinical decision-making. In this context, the present systematic review aims to critically compare the remineralization efficacy of SAPs and fluoride agents in WSLs, evaluating their mechanisms, outcomes, and clinical utility. Such an appraisal may offer meaningful contributions toward

advancing non-invasive caries management and reinforcing the role of biomimetic strategies in restorative and preventive care.

## Review

### Methodology

The primary objective of this systematic review was to address the research question: "What is the comparative remineralization potential of SAPs versus fluoride agents in managing WSLs?" The review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [19], and was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (Ref ID: CRD42024622963).

*Search Strategy*

The literature search was performed systematically across multiple databases to identify all relevant studies addressing the research question. The databases searched included PubMed, MEDLINE, Embase, the Cochrane Library, Scopus, and Google Scholar. Additional searches were conducted using clinical trial registries such as ClinicalTrials.gov and grey literature sources, including conference proceedings, dissertations, and preprint archives, to capture unpublished or non-indexed studies.

The search strategy was developed in consultation with a librarian specializing in systematic reviews to ensure accuracy and comprehensiveness. A combination of Medical Subject Headings (MeSH) terms and free-text keywords was employed. These terms included “SAP,” “fluoride agents,” “white spot lesions,” “remineralization,” “dental enamel,” “enamel demineralization,” and “lesion management.” Boolean operators such as “AND,” “OR,” and “NOT” were used to refine search results and ensure precision. Database-specific filters were applied to limit the results to studies published in English between January 2000 and December 2024. This timeframe was selected to focus on contemporary advancements in remineralization technologies. A sample search string for PubMed is provided in the Appendix. Duplicates were removed using reference management software to streamline the screening process.

*Eligibility Criteria*

The Population, Intervention, Comparator, Outcomes, Study Design (PICOS) framework used to determine the eligibility of the studies in the present systematic review is listed in Table *1*.

| PICOS Component | Inclusion Criteria | Exclusion Criteria |
|---|---|---|
| Population | Individuals of all ages with clinically or radiographically diagnosed white spot lesions (WSLs). Individuals with WSLs resulting from orthodontic treatment or naturally occurring lesions. | Individuals with systemic conditions affecting enamel structure (e.g., amelogenesis imperfecta). Patients with cavitated lesions or severe caries requiring restorative intervention. |
| Intervention | Studies evaluating self-assembling peptides (SAPs) explicitly designed for enamel remineralization (e.g., P11-4). Studies reporting clinical, radiographic, or biochemical outcomes related to remineralization. | Studies using SAPs in animal models or in vitro studies. SAPs used for purposes other than enamel remineralization (e.g., bone regeneration). |
| Comparator | Studies involving fluoride-based agents, including gels, mouth rinses, or toothpaste. Studies directly comparing SAPs with fluoride-based agents. | Studies without an active comparator. Studies combining fluoride with other remineralizing agents. |
| Outcomes | Primary: Remineralization assessed by quantitative light-induced fluorescence (QLF), microradiography, or clinical/radiographic measures of lesion depth reduction. Secondary: Aesthetic improvements evaluated through patient-reported outcomes or visual scales. Adverse effects, including sensitivity or allergic reactions. Patient compliance and long-term stability of remineralized lesions. | Studies not reporting quantitative remineralization outcomes. Outcomes unrelated to enamel health. |
| Study Design | Randomized controlled trials (RCTs). Controlled clinical trials (CCTs). Prospective cohort studies. | Animal studies, in vitro studies, case reports, reviews, and studies with insufficient data on outcomes. |

**TABLE 1: Population, Intervention, Comparator, Outcomes, Study Design (PICOS) Criteria with Inclusion and Exclusion Criteria**

*Population*

The population of interest for this review included individuals of all age groups with clinically or radiographically diagnosed white spot lesions. Participants with WSLs resulting from orthodontic treatment or naturally occurring lesions unrelated to braces were eligible for inclusion. This broad inclusion criterion ensured that the review captured a diverse range of clinical scenarios, enhancing the generalizability of the findings. Exclusion criteria were carefully defined to avoid confounding factors that could impact the interpretation of results. Individuals with systemic conditions affecting enamel structure, such as amelogenesis imperfecta, were excluded to maintain a focus on typical cases of enamel demineralization. Furthermore, patients with cavitated lesions or severe caries requiring restorative intervention were excluded to ensure that the review concentrated on non-invasive remineralization strategies applicable to early-stage lesions.

*Interventions*

The intervention of interest in this review was the use of SAP for the remineralization of white spot lesions. SAP formulations, such as P11-4, designed explicitly for enamel repair, were included. These peptides are biomimetic agents that form a three-dimensional scaffold within demineralized lesions, promoting the

nucleation and deposition of hydroxyapatite crystals [10]. Studies evaluating SAPs in clinical, radiographic, or biochemical contexts were included in the review. However, studies investigating SAPs in animal models, in vitro settings, or for purposes unrelated to enamel remineralization were excluded.

*Comparators*

The comparator group comprised fluoride-based agents, which are widely recognized as the standard of care for the management of white spot lesions. Fluoride agents included in the review consisted of topical fluoride gels, mouth rinses, toothpaste, and other formulations designed for enamel remineralization. Studies that directly compared the efficacy of SAPs to fluoride-based agents were eligible for inclusion. Studies without an active comparator or those combining fluoride with other remineralizing agents were excluded, as these could confound the interpretation of the findings.

*Outcomes*

The review focused on both primary and secondary outcomes to provide a comprehensive evaluation of the interventions. The primary outcomes included the degree of remineralization as measured by quantitative light-induced fluorescence (QLF), microradiographic analysis of mineral gain, and reductions in lesion depth or size assessed clinically or radiographically. These outcomes were chosen to quantitatively assess the effectiveness of the interventions. Secondary outcomes included aesthetic improvements evaluated through patient-reported measures or standardized visual scales, adverse effects such as tooth sensitivity or allergic reactions, compliance with the intervention protocol, and the long-term stability of remineralized lesions. These secondary outcomes aimed to capture patient-centered and practical considerations associated with the interventions.

*Study Selection*

The study selection process was conducted in two stages. Initially, titles and abstracts retrieved from the search were screened independently by two reviewers to identify studies that met the inclusion criteria. This step involved applying the predefined eligibility criteria to each record to exclude irrelevant studies. In cases where the relevance of a study was unclear based on the title and abstract, the full text was retrieved for further assessment. The second stage involved a detailed review of the full texts of all potentially eligible studies. Each study was evaluated independently by two reviewers, with any discrepancies resolved through discussion or consultation with a third reviewer. The entire study selection process was documented using a PRISMA flow diagram, which detailed the number of records identified, screened, excluded, and included at each stage.

*Data Extraction and Synthesis*

Data extraction was performed independently by two reviewers using a standardized data extraction form. The extracted data included study characteristics (author, year, country, and study design), population details (sample size, age, and sex distribution), intervention characteristics (type of SAP, concentration, and application protocol), comparator characteristics (type of fluoride agent, concentration, and application protocol), and outcomes (lesion depth reduction, aesthetic improvement, patient compliance). Additional details, such as the duration of follow-up and risk of bias assessments, were also recorded. The extracted data were cross-verified by the reviewers to ensure accuracy and completeness. Any disagreements were resolved through discussion and consensus. A narrative synthesis of the included studies was conducted, summarizing the characteristics of the studies, interventions, comparators, and outcomes. The counts and ranges of each parameter recorded in the data extraction table were analyzed to determine trends across the designs, methodology, and outcomes of the studies. A quantitative meta-analysis was not performed due to considerable heterogeneity among the included studies, particularly in study design (parallel, split-mouth, and multi-arm randomized controlled trials (RCTs)), lesion etiology (orthodontic vs naturally occurring WSLs), outcome measures (DIAGNOdent, QLF, International Caries Detection and Assessment System (ICDAS), Nyvad), and follow-up durations. These variations precluded meaningful statistical pooling and justified the adoption of a narrative synthesis approach in accordance with PRISMA recommendations.

*Assessment of Risk of Bias and Quality of Evidence*

Methodological quality was assessed using the Cochrane Risk of Bias 2 (ROB-2) tool [20]. Two independent reviewers evaluated each study across five key domains: the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and the selection of the reported result. For the randomization process, reviewers examined the adequacy of sequence generation and allocation concealment to ensure that participants were assigned to treatment groups without bias. In assessing deviations from intended interventions, particular attention was given to whether blinding was implemented for both participants and operators; however, it was acknowledged that operator blinding was not always feasible due to the nature of the interventions. Missing outcome data were scrutinized by reviewing the completeness of the data and any loss to follow-up, while the measurement of outcomes was judged based on the use of objective, validated instruments (e.g., DIAGNOdent) and whether outcome assessors were blinded. Finally, the selection of the reported result was assessed by comparing published outcomes with pre-specified protocols to identify potential selective reporting. Any discrepancies or uncertainties were resolved through consensus discussion between reviewers.

The quality of evidence for each outcome was assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [21]. The GRADE ratings were assigned based on four core domains including risk of bias, inconsistency, indirectness, and imprecision, following the standard GRADE framework. “High” quality was attributed when further research was very unlikely to change confidence in the estimate of effect; “moderate” when further research might influence the confidence; and “low” when evidence was limited or inconsistent. Disagreements between reviewers were resolved through discussion and consensus, with arbitration by a third reviewer when necessary.

## Results

*Study Characteristics*

A total of 1028 articles were identified through literature search, out of which 665 titles were assessed after removal of duplicates. One hundred eighty abstracts were screened and 60 full texts were assessed for eligiblity. Out of these, seven studies (n=7) were included in this systematic review (Figure *1*). Collectively, the included studies encompassed a total of 254 participants and 669 white spot lesions, with participant ages ranging from three to 36 years. This range reflects a diverse population spanning both primary and permanent dentitions, allowing for a broad evaluation of the remineralization efficacy of SAPs and fluoride agents across age groups. The data extracted from these studies is summarized in Table *1*. The designs comprised RCTs with split-mouth, parallel-group, or double-blinded methodologies and one prospective

in-vivo study with a four-arm design. The studies were conducted in different geographical settings: one study in Germany, one in Lebanon, and five in Egypt, with one study not specifying its country [22-28]. The earliest study was conducted in 2019, indicating that the interest of researchers in SAP for enamel remineralization is a relatively recent one [22].

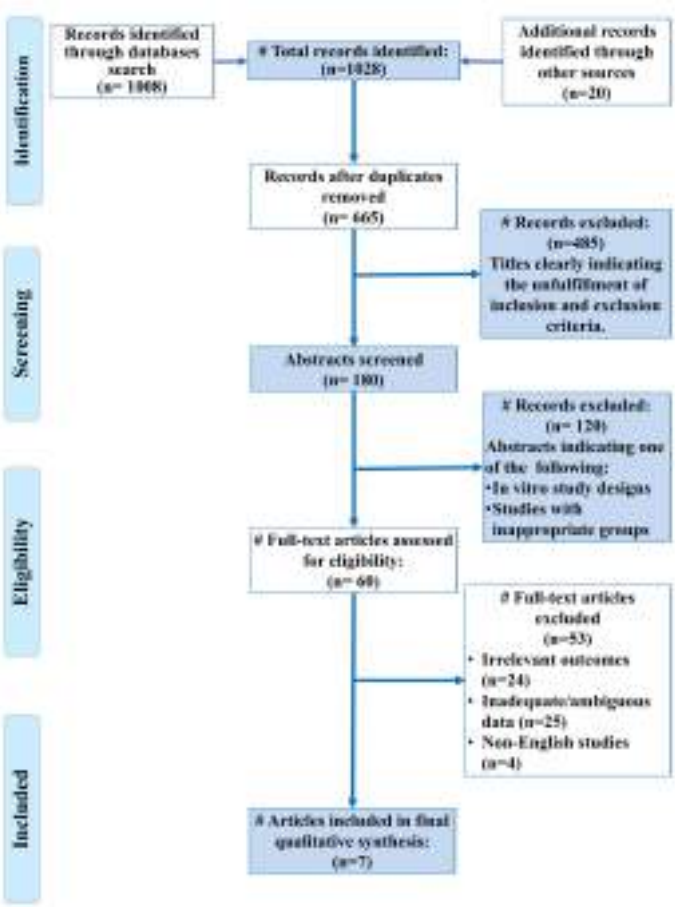


**FIGURE 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flow Diagram indicating the selection process of the articles in the present systematic review**

# = number of

| Sr. No. | Authors & Year | Study Design | Country/Setting | Sample Size (Subjects) | Age Range | Mean Age (SD) | Gender Distribution | Inclusion Criteria | Exclusion Criteria | Type of SAP | SAP Concentration | SAP Application Protocol | Type of Fluoride Agent | Fluoride Concentration | Fluoride Application Protocol | Primary Outcome Measure | Primary Outcome Results | F U D |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Bröseler et al., 2019 [22] | Randomised, subject- and assessor-blinded, controlled split-mouth clinical trial | Single dental practice, Aachen, Germany | 37 subjects (90 teeth) | 13–36 years | 21.8 (5.9) years | 20 females, 17 males | At least 2 early buccal carious lesions on two teeth not requiring operative intervention; willingness to maintain good oral hygiene | Use of tetracyclines; medications causing tooth staining or dry mouth/limiting salivary flow; enamel anomalies | Self-assembling peptide P11-4 (Curodont® Repair) | Not specified | Pre-treatment with NaOCl cleaning, 35% $H_3PO_4$ etching for 20 seconds, rinsing; applied on Day 0 and Day 90 to test lesions | Fluoride varnish (Duraphat® Fluoride Varnish) | 50 mg/ml | Applied to control lesions at Day 0; all lesions received fluoride varnish on Day 180 | Change in lesion size via blinded morphometric analysis (relative to baseline) | Test lesions reduced to 0.862 (SD 0.352) of baseline at Day 360; Control lesions increased to 1.068 (SD 0.401) of baseline | 3 ( |
| 2 | Kobeissi et al., 2020 [23] | Randomized controlled clinical trial; single-blinded (patient | Beirut Arab University dental clinics, Beirut, Lebanon | 9 subjects (40 teeth) | 7–17 years | 11.11 (3.8) years | 5 girls, 4 boys | Accessible white spot lesions (WSLs) on buccal/labial surfaces of young permanent teeth; DIAGNOdent pen reading <24; ICDAS II | Teeth with existing caries, restorations, or cavitations were | Self-assembling peptide P11-4 (Curodont Repair, CDR) | Not specified | Remove pellicle with 5% sodium hypochlorite for 20 sec, rinse and dry; etch with 37% phosphoric acid for 20 sec; rinse for 20 sec and air-dry; apply one drop of SAP11-4 using a | Tricalcium phosphate fluoride varnish (Clinpro™ White | Not specified | Dispense the entire content of a 1-unit dose package onto the dosage guide, mix with the provided applicator | Remineralization assessed via decrease in DIAGNOdent pen readings and ICDAS II | Both groups showed significant remineralization; SAP11-4 group had significantly greater reduction in DIAGNOdent readings (mean variation percentages: 26.68% at 1 month, 36.11% at 3 months, | 6 |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | blinded) | | | | | codes 1–3; absence of caries, restorations, and cavitations on treated surfaces | excluded | | | special syringe; maintain moisture control for approximately 5 minutes until the solution is no longer visible | Varnish) | | brush, and apply evenly on the tooth surface | codes | 41.39% at 6 months) compared to TCPF group (12.97%, 26.51%, 32.72% respectively) along with improved ICDAS II scores | |
| 3 | Atteya et al., 2023 [24] | Parallel randomized controlled clinical trial with three arms | Pediatric Dentistry clinic, Faculty of Dentistry, Alexandria University, Alexandria, Egypt | 66 subjects (147 lesions) | 10–24 years | 13.46 (4.31) years | 66.7% females | At least one visible WSL on the buccal surface of permanent teeth; ICDAS II score of 1 or 2; informed consent obtained | Patients receiving tetracyclines or other tooth-staining medications; fluoride application within 3 months; teeth with microcavities, dentinal involvement, adjacent restorations, discoloration, enamel hypoplasia or fluorosis | Self-assembling peptide P11-4 (Curodont Repair™) | Not specified | Tooth isolated with a rubber dam; cleaned with 2% sodium hypochlorite for 20 s; acid etched with 35–37% phosphoric acid for 20 s; rinsed and dried; P11-4 applied by activating the applicator and squeezing out the sponge; left to diffuse for 5 min | Nano-silver fluoride varnish (NSF) and 5% sodium fluoride varnish (NaF, Duraflor®) | NSF: Not specified; NaF: 5% | NSF: Two drops applied at baseline, left in contact for 2 min; NaF: Thin coat applied at baseline and after 6 months, allowed to dry for 10 s | Changes in ICDAS II scores and NYVAD lesion activity scores | At 12 months, ICDAS score reduction was 54.5% in the P11-4 group, 47.7% in the NSF group, and 30.5% in the NaF group; lesion activity showed 100% inactive lesions in the P11-4 group versus 81.4% in NSF and NaF; Diagnodent readings were lowest in the P11-4 group; however, adjusted analysis revealed no statistically significant differences in ICDAS reduction among groups | 1 |
| 4 | Gohar et al., 2023 [25] | Randomized controlled trial with two parallel groups (1:1 allocation) | Department of Conservative Dentistry, Cairo University, Egypt | 58 subjects (29 per group) | 18–25 years | Group A: 21.62±2.78; Group B: 21.45±2.53 (~21.5±2.65 years) | Group A: 14 males (48.3%), 15 females (51.7%); Group B: 11 males (37.9%), 18 females (62.1%) | Patients aged 18–25 years with active, non-cavitated post-orthodontic white spot lesions; good oral hygiene (plaque index 0–1); completed fixed orthodontic treatment within the past 2 weeks; good general health and compliance | Patients with tetracycline pigmentation, dental fluorosis, enamel hypoplasia; reduced salivary flow; cavitated lesions; or participation in another trial | Self-assembling peptide P11-4 (Curodont repair™, Credentis AG, Windisch, Switzerland) | Not specified | Pre-treatment: Clean tooth with 2% NaOCl for 20 s, rinse for 20 s, air-dry; etch with 35% phosphoric acid for 20 s, rinse for 20 s; then apply Curodont repair™ using an activated applicator and leave for 5 min until the tooth surface appears dry | Fluoride varnish containing 5% sodium fluoride and tricalcium phosphate (Clinpro White Varnish, 3M ESPE) | 5% sodium fluoride | Apply a thin layer with a brush (drying not required); no rinsing/suction; instruct patient to avoid brushing, flossing, and solid foods for 4 h post-application | Changes in remineralization measured quantitatively by DIAGNOdent readings and qualitatively by ICDAS scores at baseline, 3 and 6 months | Quantitative (DIAGNOdent): Group A (fluoride) showed a highest mean value of 10.51 and Group B (SAP) the lowest mean value of 6.45 at 6 months ($p < 0.001$); Qualitative (ICDAS): No significant differences between groups at T0, T1, and T2 ($p = 0.064$, 0.087, 0.277, respectively) | 6 |
| 5 | Mamdouh et al., 2023 [26] | Double-blinded randomized controlled clinical trial | Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, | 24 children | 3–6 years | Study group: 4.79±0.89; Control group: 5.00±0.85 | Not explicitly reported | Healthy children at high caries risk with at least one visible active white spot lesion on primary teeth (ICDAS II score 1–3; active per | Not explicitly detailed (only children not meeting inclusion criteria were excluded) | Self-assembling peptide P11-4 (Curodont™ Repair) | Not specified | Under rubber dam isolation, the tooth surface was cleaned with 2% NaOCl for 20 s, then etched with 35–37% phosphoric acid for 20 s, rinsed and dried; SAP (P11-4) was applied per manufacturer's instructions and left to | 5% Sodium Fluoride varnish (Dura🌸or) | 5% | Applied as a thin coat with a brush; re-applied at 3 and 6 months per AAPD guidelines | Change in caries status of WSLs as measured primarily by DIAGNOdent™ readings (quantitative laser fluorescence), with secondary | In the test group (SAP + 5% NaF varnish), DIAGNOdent™ readings decreased significantly from baseline to 6 months (median reduction from 14.00 to 10.50; p=0.009) with percent reductions of −23.76% (baseline to 3 months, p=0.026) and −31.48% (baseline to 6 months, p=0.020); ICDAS II scores | 6 |

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Egypt | | | | | Nyvad criteria) | | | | diffuse for 5 min until dry, followed by application of a thin coat of 5% NaF varnish (using a brush, allowed to dry for 10 s) | | | | assessment by ICDAS II and Nyvad criteria | showed no significant change; at 6 months, 75% of lesions in the test group regressed versus 58.3% in the control group (difference not statistically significant for lesion regression, p=0.676) | |
| 6 | Shaalan et al., 2024 [27] | Randomized controlled clinical trial (parallel design, 1:1 allocation) | Cairo University, Egypt | 28 participants (58 lesions) | Not specified | Not specified | Not specified | Participants with non-cavitated incipient carious lesions | Not specified | Self-assembling peptide P11-4 (Curodont Repair Fluoride Plus™) | Not specified | Applied according to the manufacturer's instructions on non-cavitated incipient lesions | Sodium fluoride varnish (Bifluorid 10) | 5% (assumed) | Applied per manufacturer's instructions on non-cavitated incipient lesions | Laser fluorescence readings (DIAGNOdent) | At 3 and 6 months, DIAGNOdent readings significantly improved in both groups, with the SAP+fluoride group showing statistically lower readings ($p < 0.05$); 60% less risk for caries progression; 65.5% of lesions in the SAP+fluoride group shifted from score 3 (11–20) to score 1 (0–4) versus 13.8% in the NaF group | 6 |
| 7 | Güven et al., 2024 [28] | Prospective in-vivo study with four groups (control, TCP fluoride varnish, SAP, combined SAP+fluoride) | Not specified | 32 subjects (107 lesions) | 10–18 years | 13.91 ± 2.92 years | Not specified | Post-orthodontic non-cavitated incipient WSLs on teeth | Not specified | Self-assembling peptide P11-4 (Curodont Repair) used alone and in combined form (Curodont Repair Fluoride Plus™) | Not specified | Applied per manufacturer's instructions on non-cavitated lesions | Sodium fluoride varnish with TCP component (Clinpro White varnish) | 5% | Applied per manufacturer's instructions; for combined group, SAP and fluoride applied concurrently | Remineralization assessed by QLF (ΔF, ΔQ, lesion area) and DIAGNOdent | At 6 months, inter-group comparisons showed highest remineralization with fluoride varnish with TCP; SAP and combined groups showed significant short-term improvement at 3 months; combined group exhibited 60% less risk for caries progression and 65.5% of lesions shifted from DIAGNOdent score 3 to 1 versus 13.8% in the fluoride group | 6 |

**TABLE 2: Characteristic data extracted from the included studies**

SAP: self-assembling peptide; P11-4 (SAP): self-assembling peptide P11-4; CDR: Curodont Repair; WSLs: white spot lesions; NaOCl: sodium hypochlorite; $H_3PO_4$: phosphoric acid; NaF: sodium fluoride; TCP: tricalcium phosphate; TCPF: tricalcium phosphate fluoride; NSF: nano-silver fluoride; ICDAS II: International Caries Detection and Assessment System II; DIAGNOdent™: quantitative laser fluorescence device; QLF: quantitative light-induced fluorescence; ΔF: percent fluorescence loss; ΔQ: lesion volume metric (fluorescence loss × area); VAS: visual analogue scale; GICQ: Global Impression of Change Questionnaire; AAPD: American Academy of Pediatric Dentistry; SD: standard deviation; RCT: randomized controlled trial.

*Population and Demographics*

The review included diverse populations ranging from preschool children to young adults [22–28]. In studies conducted in children and adolescents, sample sizes ranged from nine subjects (Kobeissi et al., 2020; ages seven to 17 years) and 24 children (Mamdouh et al., 2023; ages three to six years) to 32 subjects (Güven et al., 2024; ages 10 to 18 years). In young adult populations, Bröseler et al. (2019) enrolled 37 subjects with ages spanning 13 to 36 years (mean 21.8±5.9 years), and Gohar et al. (2023) studied 58 subjects (29 per group) aged 18 to 25 years. Atteya et al. (2023) included 66 subjects (ages 10 to 24 years), representing a mix of adolescents and young adults. Shaalan et al. (2024) investigated incipient carious lesions in 28

participants, although the specific age range was not provided.

*Interventions and Comparator Treatments*

All studies evaluated the remineralization potential of self-assembling peptide P11-4, commercially available as Curodont Repair (Credentis AG, Windisch, Switzerland) or its modified formulations. The application protocol across studies was similar: the lesion area was first cleaned using a sodium hypochlorite solution (ranging from 2% to 5% for approximately 20 seconds) followed by acid etching with phosphoric acid (35-37% for 20 seconds) to expose the subsurface lesion. The SAP solution was then applied according to manufacturer instructions and left in place for approximately five minutes to allow the formation of a three-dimensional matrix [22-28].

The comparators in these studies were various fluoride-based agents. Bröseler et al. (2019) used Duraphat® Fluoride Varnish (50mg/ml; Colgate-Palmolive GmbH, Hamburg, Germany), while Kobeissi et al. (2020) and Gohar et al. (2023) employed Clinpro™ White Varnish (3M ESPE Dental Products, St. Paul, MN, USA), which includes tricalcium phosphate combined with 5% sodium fluoride [23,25]. Shaalan et al. (2024) utilized Bifluorid10 (VOCO GmbH, Cuxhaven, Germany) as the fluoride varnish, and Atteya et al. (2023) incorporated nano-silver fluoride varnish alongside SAP P11-4 and a fluoride-alone arm [24,27]. Mamdouh et al. (2023) compared a combination treatment (SAP P11-4 with 5% NaF varnish) to fluoride varnish alone [26]. Güven et al. (2024) evaluated four arms: a control group, a group receiving tricalcium phosphate (TCP)-containing fluoride varnish, a group receiving SAP P11-4 alone, and a combined application group [28].

*Outcome Measures*

The primary outcome measure in all studies was the degree of remineralization, predominantly assessed quantitatively using laser fluorescence devices such as DIAGNOdent (KaVo Dental GmbH, Biberach, Germany). DIAGNOdent readings served as an indicator of subsurface mineral content, where a reduction from baseline reflected remineralization. For example, Kobeissi et al. (2020) reported mean DIAGNOdent reading reductions corresponding to approximately 26.7% at one month, 36.1% at three months, and 41.4% at six months [23]. Gohar et al. (2023) observed significantly lower DIAGNOdent values in the SAP group (mean 6.45) compared to the fluoride group (mean 10.51) at six months ($p<0.001$) [25]. Mamdouh et al. (2023) documented a significant DIAGNOdent reduction ($p=0.009$) with 75% lesion regression in the SAP+NaF group compared to 58.3% in the control group [26]. Shaalan et al. (2024) further demonstrated that the SAP+fluoride group had a 60% lower risk for caries progression and that 65.5% of lesions shifted from a DIAGNOdent score of 3 to 1 versus only 13.8% in the fluoride varnish group [27].

Secondary outcome measures included qualitative assessments of lesion appearance using the ICDAS and lesion activity evaluation using the Nyvad criteria [29]. Several studies noted that although DIAGNOdent readings improved significantly in the intervention groups, the ICDAS scores did not differ significantly between the groups over time, suggesting that enhanced subsurface remineralization might not always translate into markedly different surface appearances [30].

*Follow-Up Duration and Blinding*

Follow-up durations varied among the studies. Five studies used a six-month follow-up period, whereas Atteya et al. (2023) extended the follow-up to 12 months [22-27]. In terms of blinding, outcome assessors were blinded in all studies. In most trials, patients were also blinded, although operator blinding was often not feasible due to distinct application protocols [23-25,27].

*Quantitative Outcomes*

Quantitative outcomes, as measured by DIAGNOdent, consistently demonstrated significant reductions in fluorescence values in the groups receiving SAP P11-4. The degree of improvement ranged from a reduction of approximately 23% up to over 41% from baseline, with studies such as Kobeissi et al. (2020) and Gohar et al. (2023) reporting statistically significant differences in DIAGNOdent values favoring the SAP groups over the fluoride-only groups [23,25]. Additionally, Mamdouh et al. (2023) and Shaalan et al. (2024) provided evidence that combining SAP with fluoride varnish resulted in greater remineralization, as indicated by lower DIAGNOdent readings and higher percentages of lesion regression [26,27].

*Qualitative Outcomes*

Qualitative assessments using ICDAS and Nyvad criteria were performed in several studies. Despite the marked improvements in DIAGNOdent readings, ICDAS scores frequently remained similar between intervention and control groups over time. This observation suggests that while subsurface remineralization is enhanced by SAP P11-4, the changes may not be as easily discernible through visual inspection alone. For instance, Gohar et al. (2023) and Mamdouh et al. (2023) found no statistically significant differences in ICDAS scores between the groups, highlighting a potential disconnect between quantitative subsurface changes and surface visual appearance [25,26].

*Overall Synthesis*

The narrative synthesis indicates that SAP P11-4, whether used alone or in combination with fluoride varnish, consistently exhibits superior subsurface remineralization potential. DIAGNOdent data across studies revealed reductions ranging from 23% to 41%, with studies in pediatric populations (Mamdouh et al. and Shaalan et al.) showing that the combination of SAP with 5% NaF varnish significantly reduced DIAGNOdent values and minimized the risk for caries progression. Beyond statistical significance, several studies reported that these quantitative reductions translated into clinically meaningful outcomes such as lesion inactivation, reduced caries progression, and improved surface hardness, suggesting true clinical relevance of the observed remineralization. Although visual assessments (ICDAS) did not show significant differences, the quantitative improvements support the enhanced mineral deposition in the subsurface, potentially offering a minimally invasive therapeutic option for early carious lesions.

Overall, the data from the seven studies (n=7) indicate that self-assembling peptide P11-4-based interventions provide a notable improvement in remineralization compared to fluoride varnish alone [22-28]. The overall trend across studies demonstrates that SAP P11-4, particularly when combined with fluoride, results in greater subsurface mineral gains as evidenced by DIAGNOdent readings, even though these changes are not always evident in the surface appearance of lesions. Further long-term research is recommended to standardize protocols and validate the clinical benefits of these biomimetic interventions.

*Risk of Bias Assessment*

Overall, the risk of bias assessment using the Cochrane ROB-2 tool indicates that six out of the seven studies were judged to have a low risk of bias across all domains (Figure 2). Bröseler et al. (2019), Atteya et al. (2023), Gohar et al. (2023), Mamdouh et al. (2023), Shaalan et al. (2024), and Güven et al. (2024) all demonstrated adequate randomization processes, blinding of outcome assessors, minimal missing outcome data, and low risk of selective reporting. Kobeissi et al. (2020) was noted to have some concerns in the domain of deviations from intended interventions due to the inability to blind the operator; however, the objective nature of the outcome measurements (e.g., DIAGNOdent readings) mitigates this concern. Overall, the methodological quality across the studies is high, supporting the internal validity of the findings reported in this systematic review. Publication bias was not formally evaluated using funnel plots due to the limited number of studies (n=7); however, a qualitative assessment indicated a predominance of small, single-center trials reporting positive outcomes, suggesting a possible overrepresentation of favorable findings in the available literature.


**FIGURE 2: Risk of bias across the included studies**

[22-28]

*Quality of Evidence*

Overall, the evidence quality ranged from low to high across the studies. Bröseler et al. (2019) was assigned a moderate quality rating [22]. Although this study demonstrated a low risk of bias, directness, and consistency, its overall quality was limited by moderate imprecision, suggesting that while the findings are promising, the confidence in the effect estimate is not concrete enough to rule out a clinically meaningful difference. In contrast, Kobeissi et al. (2020) received an overall low-quality rating. Despite having a low risk of bias in the randomization process and measurement of outcomes, concerns related to deviations from intended interventions (owing to the lack of operator blinding), moderate inconsistency, and high imprecision reduced our confidence in the reliability of its results [23].

On the other hand, Atteya et al. (2023), Gohar et al. (2023), Mamdouh et al. (2023), and Shaalan et al. (2024) were all rated as high-quality evidence [23,25-27]. These studies consistently demonstrated low risk of bias, minimal inconsistency and indirectness, and low imprecision. Their good quality of methodology and comprehensive reporting provide high confidence in their effect estimates. Güven et al. (2024) was judged as moderate quality overall due to moderate inconsistency and imprecision, despite a low risk of bias and indirectness [28].

The GRADE assessment (Table 3) indicates that the majority of the evidence supporting the efficacy of self-assembling peptide P11-4 (alone or combined with fluoride varnish) for remineralization of white spot lesions is of high quality, particularly in four studies [24-27]. However, some caution is warranted when interpreting findings from Kobeissi et al. (2020) due to concerns regarding imprecision and potential performance bias. These results reinforce the overall conclusion of this review that SAP P11-4-based interventions are effective in enhancing subsurface remineralization, although differences in study design and outcome measurement methods contribute to some variability in the evidence quality.

| Study | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Overall Quality of Evidence |
|---|---|---|---|---|---|---|
| Bröseler et al., 2019 [22] | Low | Low | Low | Moderate | Unclear | Moderate |
| Kobeissi et al., 2020 [23] | Some concerns | Moderate | Low | High | Unclear | Low |
| Atteya et al., 2023 [24] | Low | Low | Low | Low | Unclear | High |
| Gohar et al., 2023 [25] | Low | Low | Low | Low | Unclear | High |
| Mamdouh et al., 2023 [26] | Low | Low | Low | Low | Unclear | High |
| Shaalan et al., 2024 [27] | Low | Low | Low | Low | Unclear | High |
| Güven et al., 2024 [28] | Low | Moderate | Low | Moderate | Unclear | Moderate |

**TABLE 3: Assessment of quality of evidence using Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach**

## Discussion

This systematic review highlights the potential of self-assembling peptide P11-4 as an effective, minimally invasive agent for remineralizing WSLs in both primary and permanent dentition. The included studies consistently demonstrated reductions in DIAGNOdent values following treatment with SAP P11-4, whether used alone or in combination with fluoride varnish. These outcomes support the hypothesis that SAPs, by replicating the physiological mineralization process, can regenerate enamel structure through controlled hydroxyapatite deposition [31]. SAP P11-4 promotes subsurface mineral regeneration by forming a biomimetic scaffold within demineralized enamel, enabling deeper and more uniform hydroxyapatite deposition than the surface-limited effect typically achieved with fluoride [10,32].

When compared directly, while fluoride varnish was effective in inhibiting demineralization, it did not consistently match the restorative potential of SAP P11-4 due to its restricted penetration and limited capacity to rebuild deeper enamel structure [33,34]. This was evident in studies such as those by Gohar et al. (2023) and Kobeissi et al. (2020), where SAP P11-4 groups achieved greater reductions in DIAGNOdent readings, indicating enhanced mineral deposition at the lesion core [23,25]. These findings are particularly relevant considering that WSLs originate beneath a seemingly intact surface layer, underscoring the clinical importance of a remineralization approach that targets internal enamel porosity [4,31].

Interestingly, although DIAGNOdent values improved significantly, the same degree of improvement was not consistently reflected in ICDAS scores. Studies such as those by Gohar et al. (2023) and Mamdouh et al. (2023) reported minimal differences in visual lesion assessments between groups [25,26]. This discrepancy can be attributed to the optical limitations of early remineralized enamel. Due to mismatched refractive indices between new mineral deposits and native enamel, lesions may continue to appear opaque despite substantial subsurface recovery [35,36]. Studies on enamel translucency recovery have confirmed that even when mineral content approaches normal values, incomplete realignment of enamel prism orientation and residual porosity can delay optical normalization [37,38]. Over time, maturation of newly formed hydroxyapatite and reorganization of prism structures may gradually restore translucency, although the process is non-linear and varies with lesion depth and mineral density. This further underscores that visual indices such as ICDAS may be inherently less sensitive to early mineral changes than fluorescence-based methods like DIAGNOdent or QLF, which can detect subsurface alterations undetectable to the naked eye. Consequently, quantitative fluorescence assessments provide a more precise measure of lesion regression in the early phases of remineralization. Therefore, long-term follow-ups are essential to determine whether mineral maturation and crystal reorganization eventually reduce visual opacity.

The synergistic potential of SAP P11-4 when combined with fluoride varnish was another key finding. Studies including those by Mamdouh et al. (2023) and Shaalan et al. (2024), showed that the combination treatment yielded greater remineralization benefits than fluoride alone [10,22-28]. This enhanced efficacy likely results from the complementary actions of SAP and fluoride, where SAP builds the internal scaffold and fluoride stabilizes and strengthens the outer enamel [39]. Shaalan et al. (2024) also reported a 60% reduction in caries progression risk, reinforcing the clinical promise of this dual approach [27].

Variation in lesion etiology and depth also influenced treatment response. SAP P11-4 was effective in both orthodontic-induced and naturally occurring WSLs, as seen in the study by Atteya et al. (2023) [24]. However, lesion depth likely affects the pace and extent of remineralization, with superficial lesions responding faster. Moreover, studies with longer follow-up, such as Atteya et al. (2023), confirmed that mineral gains from SAP use are durable over time, which is critical for long-term lesion stability and relapse prevention [24].

While the overall results favor SAP P11-4, limitations such as heterogeneity in fluoride comparators and absence of operator blinding must be acknowledged [22-28]. The restriction to English-language publications may have introduced a potential language bias, as relevant studies published in other languages were excluded. Additionally, although grey literature sources such as conference abstracts and dissertations were included to minimize publication bias, the variable methodological quality and limited data from such sources could have influenced the overall strength of the evidence. These factors should be considered when interpreting the findings and generalizability of this review.

Moreover, variability in lesion etiology, such as that between orthodontic-induced and naturally occurring WSLs, may have influenced treatment response and contributed to inter-study heterogeneity. Future clinical trials should control for this variable through stratified randomization and employ standardized, calibrated outcome measures such as DIAGNOdent thresholds, ICDAS scoring, and quantitative light-induced fluorescence metrics to ensure consistency and comparability across studies. Additionally, reliance on DIAGNOdent alone may restrict interpretative depth. Despite the comprehensive inclusion and exclusion criteria applied in this review, certain methodological limitations must be acknowledged. Future studies should employ imaging tools like micro-CT to map mineral recovery more precisely, and standardized fluoride protocols should be adopted to facilitate more valid comparisons.

## Conclusions

Within the limits of the available short-term clinical trials, the findings of this systematic review establish SAP P11-4 as a promising non-invasive intervention for white spot lesion management, demonstrating superior subsurface remineralization compared to fluoride-based treatments. The ability of SAP to penetrate and mineralize lesions at deeper levels distinguishes it from conventional fluoride therapies, offering an innovative approach to early caries intervention. The evidence further suggests that the combination of SAP and fluoride may enhance remineralization outcomes, presenting an opportunity for optimized treatment protocols. Nevertheless, these conclusions should be interpreted with caution, and well-designed, long-term randomized controlled trials are required to validate these findings, refine application protocols, and determine the durability of enamel regeneration. These insights add to the growing body of literature supporting biomimetic strategies in modern dentistry, underscoring the potential of SAP as a breakthrough in minimally invasive caries management.

## Appendices

**Query**

Search: **self-assembling peptides AND fluoride AND remineralization AND enamel** Filters: **from 2000/1/1 - 2025/5/31**

("self-assembling"[All Fields] AND ("peptid"[All Fields] OR "peptidal"[All Fields] OR "peptide s"[All Fields] OR "peptides"[Supplementary Concept] OR "peptides"[All Fields] OR "peptide"[All Fields] OR "peptides"[MeSH Terms] OR "peptidic"[All Fields]) AND ("fluoridate"[All Fields] OR "fluoridated"[All Fields] OR "fluoridating"[All Fields] OR "fluoridation" [MeSH Terms] OR "fluoridation"[All Fields] OR "fluoridation s"[All Fields] OR "fluoride s"[All Fields] OR "fluorided"[All Fields] OR "fluorides" [Supplementary Concept] OR "fluorides"[All Fields] OR "fluoride"[All Fields] OR "fluorides"[MeSH Terms] OR "fluoridization"[All Fields] OR "fluoridized" [All Fields]) AND ("remineralization"[All Fields] OR "remineralize"[All Fields] OR "remineralized"[All Fields] OR "remineralizing"[All Fields]) AND ("dental enamel"[MeSH Terms] OR ("dental"[All Fields] AND "enamel"[All Fields]) OR "dental enamel"[All Fields] OR "enamel"[All Fields] OR "enamels"[All Fields] OR "enamel s"[All Fields] OR "enameled"[All Fields] OR "enameling" [All Fields] OR "enamelling"[All Fields])) AND (2000/1/1:2025/5/31[pdat])

**Translations**

**peptides:** "peptid"[All Fields] OR "peptidal"[All Fields] OR "peptide's"[All Fields] OR "peptides"[Supplementary Concept] OR "peptides"[All Fields] OR "peptide"[All Fields] OR "peptides"[MeSH Terms] OR "peptidic"[All Fields]
**fluoride:** "fluoridate"[All Fields] OR "fluoridated"[All Fields] OR "fluoridating"[All Fields] OR "fluoridation"[MeSH Terms] OR "fluoridation" [All Fields] OR "fluoridation's"[All Fields] OR "fluoride's"[All Fields] OR "fluorided"[All Fields] OR "fluorides"[Supplementary Concept] OR "fluorides"[All Fields] OR "fluoride"[All Fields] OR "fluorides"[MeSH Terms] OR "fluoridization"[All Fields] OR "fluoridized"[All Fields]
**remineralization:** "remineralization"[All Fields] OR "remineralize"[All Fields] OR "remineralized"[All Fields] OR "remineralizing"[All Fields]
**enamel:** "dental enamel"[MeSH Terms] OR ("dental"[All Fields] AND "enamel"[All Fields]) OR "dental enamel"[All Fields] OR "enamel"[All Fields] OR "enamels"[All Fields] OR "enamel's"[All Fields] OR "enameled"[All Fields] OR "enameling"[All Fields] OR "enamelling"[All Fields]

**FIGURE 3: Sample search string in PubMed**

## Additional Information

### Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

**Concept and design:** Babitha Babu, Dimple Padawe, Vilas Takate

**Acquisition, analysis, or interpretation of data:** Babitha Babu, Dimple Padawe, Vilas Takate

**Drafting of the manuscript:** Babitha Babu, Dimple Padawe, Vilas Takate

**Critical review of the manuscript for important intellectual content:** Babitha Babu, Dimple Padawe, Vilas Takate

**Supervision:** Babitha Babu, Dimple Padawe, Vilas Takate

### Disclosures

**Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from

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# Comparative Effectiveness of Triphala and Conventional Root Canal Irrigants in Primary Teeth: A Systematic Review

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## Abstract

The present systematic review aimed to evaluate the effectiveness of Triphala, a traditional Ayurvedic herbal formulation, as a root canal irrigant in primary teeth compared to conventional irrigants such as sodium hypochlorite, chlorhexidine, and saline. A comprehensive electronic search was conducted across multiple databases, including PubMed, MEDLINE, Embase, Scopus, and Cochrane Library, and supplemented by grey literature. Studies published in English between January 2000 and February 2025 were considered. Five studies met the inclusion criteria, comprising randomized controlled trials, in vitro, and ex vivo studies, all of which were conducted in India. The findings revealed that Triphala possesses significant antimicrobial activity against endodontic pathogens such as *Enterococcus faecalis* and *Candida albicans*, though sodium hypochlorite consistently showed greater microbial reduction. One study reported comparable long-term clinical and radiographic success between Triphala and chlorhexidine over a 12-month period. Variability in concentration, formulation, and methodology contributed to differences in efficacy across studies. Triphala demonstrated a favorable safety profile and biocompatibility, supporting its potential as an alternative or adjunctive irrigant in pediatric endodontics. However, current evidence is limited by geographic concentration and methodological heterogeneity. Further high-quality multicenter trials are warranted to validate its clinical applicability and promote its broader integration into pediatric dental practice.

**Categories:** Dentistry
**Keywords:** antimicrobial efficacy, pediatric endodontics, primary teeth, root canal irrigants, triphala

## Introduction And Background

The maintenance of primary dentition is a critical aspect of pediatric oral healthcare, serving multiple functional and developmental roles such as proper mastication, speech articulation, aesthetic harmony, and guidance for the eruption of permanent successors [1]. Premature loss of primary teeth due to carious lesions or pulpal pathologies can result in space loss, eruption disturbances, and malocclusion, thereby impacting long-term oral health [2]. Hence, effective endodontic intervention in primary teeth is essential to preserve dental integrity and support the child's overall growth and development.

Pulpectomy, or root canal treatment in primary teeth, is the preferred modality when the radicular pulp is irreversibly inflamed or necrotic [3]. In simple terms, pulpectomy involves the removal of diseased pulp tissue, followed by thorough cleaning, shaping, disinfection, and obturation of the canal system using resorbable materials suitable for exfoliating teeth [4]. However, anatomical variations in primary teeth, such as tortuous and ribbon-shaped canals, multiple accessory canals, and large apical foramina, pose significant challenges to complete mechanical debridement [5]. Furthermore, the close proximity of primary roots to developing permanent tooth buds necessitates a cautious approach during instrumentation and irrigation to avoid iatrogenic harm [6].

Chemical irrigation serves as a vital adjunct to mechanical preparation in ensuring adequate disinfection of the root canal system [7]. Irrigants perform key roles, including microbial reduction, smear layer removal, organic tissue dissolution, and canal lubrication [8]. Ideally, an irrigant should exhibit broad-spectrum antimicrobial action, tissue dissolution capability, low surface tension, biocompatibility, and compatibility with obturating materials [9]. No single solution fulfills all these requirements, so combinations and adjunctive agents are commonly used in clinical practice.

Sodium hypochlorite (NaOCl) is widely accepted as the gold standard irrigant due to its potent antimicrobial and tissue-dissolving abilities through the release of hypochlorous acid [10]. Nevertheless, in pediatric dentistry, its high cytotoxicity, unpleasant taste, risk of chemical burns, and potential allergic reactions are significant drawbacks [11]. Chlorhexidine (CHX) gluconate offers long-lasting antimicrobial substantivity and is generally well tolerated, but lacks tissue-dissolving capacity and forms potentially toxic precipitates when mixed with NaOCl [12,13]. Ethylenediaminetetraacetic acid (EDTA) is effective in removing the inorganic component of the smear layer but exhibits limited antimicrobial activity [14]. In parallel, contemporary work on intracanal dressings and medicaments, such as comparisons between calcium

hydroxide pastes and calcium hydroxide-impregnated gutta-percha points, highlights how formulation and delivery can markedly influence antimicrobial performance against resistant species like *Enterococcus faecalis* [15]. Collectively, these limitations have prompted exploration of safer, more biocompatible alternatives, particularly in children.

Among various herbal candidates, Triphala has shown promising potential in endodontics. It is a traditional Ayurvedic polyherbal formulation composed of the dried fruits of *Emblica officinalis*, *Terminalia bellirica*, and *Terminalia chebula* [16,17]. Experimental and in vitro studies have demonstrated antimicrobial, anti-inflammatory, antioxidant, and tissue-healing properties for its constituent plants [18-21]. Proposed mechanisms include disruption of bacterial cell membranes, interference with enzymatic activity, and modulation of biofilms through polyphenol-mediated chelation and free-radical scavenging [22,23]. However, these mechanisms are predominantly derived from laboratory and model-based investigations, and direct clinical confirmation in primary teeth remains limited. Importantly, Triphala has been reported to exhibit relatively low cytotoxicity to host tissues compared with many synthetic chemotherapeutic agents, which may be advantageous in the pediatric population [24].

Multiple clinical and in vitro studies have highlighted the efficacy of Triphala against endodontic pathogens such as *E. faecalis* and *Candida albicans*, with some findings suggesting parity or even superiority to NaOCl under specific experimental conditions [25-29]. Triphala has also been investigated for its potential to contribute to smear layer modification and biofilm disruption, particularly when used with activation methods [30]. Nonetheless, these data are largely laboratory-based, and translation to clinical practice in primary teeth is not straightforward. Clinical trials in pediatric endodontics are relatively few, vary in their Triphala formulations and irrigation protocols, and differ in outcome measures and follow-up periods.

Consequently, while the preclinical evidence base suggests that Triphala is a biologically active and potentially safer irrigant, pediatric dentists currently lack synthesized, clinically oriented evidence to determine whether Triphala is a viable alternative or adjunct to conventional irrigants in routine pulpectomy. In particular, there is a need to collate and critically appraise data on microbial reduction, clinical and radiographic success, and any adverse effects associated with Triphala use in primary teeth.

Therefore, this systematic review aims to comprehensively evaluate and compare the effectiveness of Triphala and conventional root canal irrigants (such as NaOCl, CHX, and EDTA) in primary teeth, with a specific focus on (i) microbial reduction, (ii) short- and long-term clinical and radiographic outcomes, and (iii) reported adverse effects. By synthesizing the available clinical and experimental evidence, this review seeks to inform evidence-based decision-making in pediatric endodontics and to clarify the potential role of Triphala as a safer, natural adjunct or alternative to established irrigation protocols.

# Review

## Methodology

The present systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines to ensure methodological transparency and reproducibility [31]. The review protocol was registered a priori with the International Prospective Register of Systematic Reviews (PROSPERO; registration ID CRD42024622972), representing the modern era of evidence-based endodontics and the emergence of Triphala as a potential irrigant.

*Review Objective*

The primary objective of this systematic review was to evaluate and compare the effectiveness of Triphala, a polyherbal formulation, with conventional root canal irrigants such as NaOCl, CHX, and EDTA in the management of pulpally involved primary teeth. Outcomes of interest included microbial reduction, clinical success, radiographic healing, and the incidence of adverse effects.

*Eligibility Criteria*

Studies were selected based on predefined inclusion and exclusion criteria framed using the Population, Intervention, Comparison, Outcome, and Study design (PICOS) model. The review included randomized controlled trials (RCTs), controlled clinical trials (CCTs), prospective cohort studies, and in vitro/ex vivo studies involving primary teeth. For clinical studies, pediatric patients up to 12 years of age with primary teeth requiring pulpectomy due to pulpitis or necrosis were eligible. Studies were included if they used Triphala in any concentration or formulation as a root canal irrigant, either alone or as an adjunct, and compared it with conventional chemical irrigants. Outcomes assessed had to include at least one of the following: microbial reduction (quantitative microbiology or molecular methods), clinical success (pain relief, absence of infection), radiographic healing (resolution of periapical radiolucencies), or any reported adverse effects. Only studies published in English between January 2000 and February 2025 were considered to capture contemporary evidence-based endodontic practice. Studies were excluded if they involved permanent teeth or mixed dentition, used Triphala in combination with other herbal agents without separate evaluation, or were animal studies, retrospective designs, case series, case reports, or narrative

reviews. No restrictions were placed on the country of origin; however, all studies that ultimately met the inclusion criteria were from India. The PICOS framework is summarized in Table 1.

| PICOS element | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Population | Pediatric patients (≤12 years) with primary teeth requiring root canal treatment due to pulpitis or necrotic pulp; both single- and multi-rooted primary teeth; extracted primary teeth used in in vitro/ex vivo studies | Studies involving permanent teeth or mixed dentition; patients with systemic conditions severely affecting oral health; case reports or studies without defined control groups |
| Intervention | Use of Triphala as a root canal irrigant, either as primary or adjunctive irrigation; any concentration or formulation of Triphala; studies reporting clinical and/or microbiological outcomes | Studies using Triphala in combination with other herbal agents without independent analysis; animal studies; studies not clearly describing the Triphala protocol |
| Comparator | Use of conventional root canal irrigants such as sodium hypochlorite (NaOCl), chlorhexidine (CHX), EDTA, or other standard irrigants | Studies without a comparator group; studies comparing Triphala with non-irrigant or non-standard interventions |
| Outcomes | Primary outcome: microbial reduction (e.g., CFU counts, PCR analysis). Secondary outcomes: clinical success (pain relief, absence of swelling or infection), radiographic healing, adverse effects, patient/operator preference, cost-effectiveness | Studies lacking outcome data related to antimicrobial efficacy or clinical success; studies reporting only subjective outcomes without microbiological or radiographic validation |
| Study Design | Randomized controlled trials (RCTs); controlled clinical trials (CCTs); prospective cohort studies; in vitro and ex vivo studies involving primary teeth | Retrospective studies; case series or case reports; narrative reviews, editorials, and letters to the editor |

**TABLE 1: PICOS framework with inclusion and exclusion criteria**

CFU: colony-forming unit; PCR: polymerase chain reaction

*Information Sources and Search Strategy*

A comprehensive electronic search was carried out across multiple databases, including PubMed, MEDLINE, Embase, Scopus, Cochrane Library, and Google Scholar. The electronic search covered the period from January 2000 to February 2025 and was last updated in February 2025. Additional searches were conducted in grey literature sources, including academic theses, conference abstracts, and clinical trial registries such as ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). The search strategy incorporated a combination of keywords and Medical Subject Headings (MeSH) terms such as “Triphala,” “root canal irrigant,” “primary teeth,” “pediatric endodontics,” “herbal irrigant,” and “microbial reduction,” with Boolean operators used to refine and expand the search. Filters were applied to include only English-language publications involving human subjects for clinical studies. Full database-specific search strings (including Boolean operators and filters) for each database are provided in the Appendices for replicability.

*Study Selection Process*

Study selection was conducted in two phases. In the first phase, two reviewers independently screened the titles and abstracts of retrieved studies for relevance. In the second phase, full-text articles of potentially eligible studies were retrieved and evaluated against the inclusion and exclusion criteria. Disagreements at any stage were resolved through discussion or consultation with a third reviewer.

*Data Extraction*

A standardized data extraction form was used to collect pertinent details from each included study. Extracted data included study identifiers (author, year, country), study design (RCT, CCT, cohort, in vitro, ex vivo), sample size and characteristics (age, gender, tooth type, clinical or laboratory setting), intervention details (Triphala formulation and concentration, irrigation protocol), comparator details (type and concentration of conventional irrigant, protocol), and outcomes (microbial reduction metrics, clinical findings, radiographic healing, adverse events, patient/operator preference, and follow-up duration, where applicable). Two reviewers independently extracted data, and discrepancies were resolved by mutual consensus or third-reviewer adjudication. Any uncertainties or missing information were noted and considered during the quality appraisal.

*Risk of Bias (RoB) Assessment*

The RoB in included studies was assessed using design-appropriate tools. For RCTs, the Cochrane Risk of Bias 2.0 (RoB 2) tool was applied to evaluate domains such as randomization, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting [32]. Each domain was rated, and an overall judgment (low, some concerns, or high RoB) was assigned. For in vitro and ex vivo studies, the Quality Assessment Tool for In Vitro Studies of Dental Materials (QUIN) was employed to assess factors including clarity of aims, sample size justification, randomization, blinding of outcome assessment, adequacy of control groups, and appropriateness of statistical analysis [33]. Two reviewers independently performed the risk-of-bias assessments, with disagreements resolved through discussion; formal kappa statistics were not calculated, which is acknowledged as a methodological limitation. Final risk ratings are presented in the Results section.

*Data Synthesis*

Given the small number of included studies and substantial heterogeneity in study design (in vitro, ex vivo, in vivo), Triphala formulations and concentrations, comparator irrigants, outcome measures (colony-forming unit (CFU) counts, turbidity, zone of inhibition, clinical and radiographic endpoints), and follow-up durations, a quantitative meta-analysis was not considered appropriate. We therefore employed a narrative synthesis. Studies were grouped by comparator irrigant (e.g., Triphala vs. NaOCl, Triphala vs. CHX, Triphala vs. saline) and by outcome domains (microbial, clinical, radiographic). Within each group, we summarized the direction and magnitude of effects, highlighting where conventional irrigants were superior, where Triphala showed comparable outcomes, and where results were inconsistent. Detailed numerical results are presented in summary tables, while the text focuses on key trends and clinically relevant comparisons.

*Assessment of Quality of Evidence*

The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach was used to appraise the overall certainty of evidence for each primary comparison (e.g., Triphala vs. NaOCl; Triphala vs. CHX; Triphala vs. saline) for the outcome of antimicrobial efficacy, and, where applicable, for clinical and radiographic outcomes [34]. Evidence was classified into four levels, including high, moderate, low, or very low, based on RoB, inconsistency, indirectness, imprecision, and potential publication bias. Heterogeneity in designs and outcomes, limited clinical data, and imprecision in effect estimates led to downgrading of certainty for some comparisons, particularly those involving NaOCl.

## Results

A total of five studies were included in this systematic review following the application of eligibility criteria (Figure *1*). Key study characteristics, including design, sample, Triphala formulation, comparator details, outcomes, and follow-up, obtained from these studies are summarized in Table *2*.

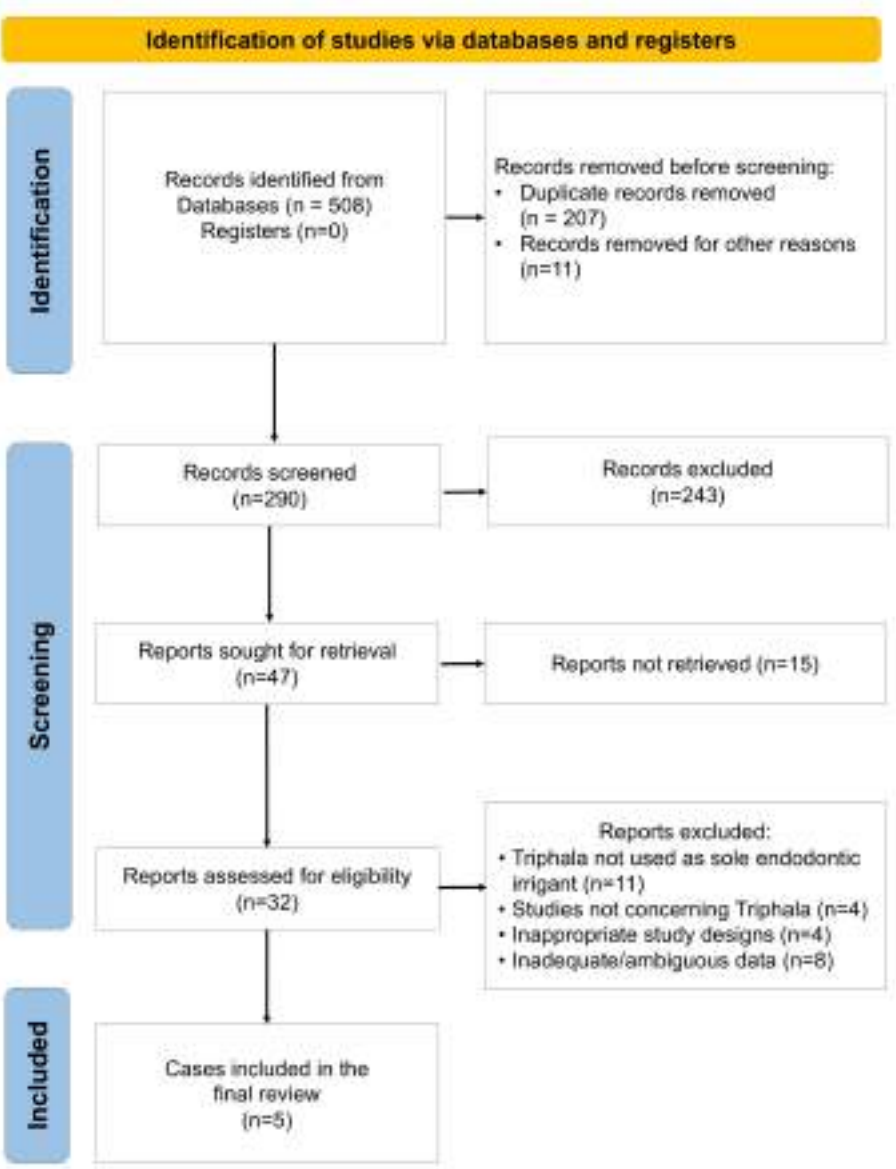


**FIGURE 1: PRISMA flow diagram indicating the selection process of the articles in the present systematic review**

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

| Author (Year) | Study design and setting | Sample (n; age range) | Tooth type | Triphala intervention (brand, formulation, concentration, protocol) | Comparator irrigant (type, concentration, protocol) | Key outcomes (quantitative where reported) | Follow-up |
|---|---|---|---|---|---|---|---|
| Thomas et al. (2017) [25] | In vitro microbiological study | n = 49; age not specified (extracted teeth) | Single-rooted primary teeth | Nilogram India Pvt. Ltd.; Triphala powder diluted 1:3 in 10% DMSO; used as irrigant with 5-min contact time | 3% NaOCl; 5-min contact time | Mean CFU count against *Enterococcus faecalis*: Triphala 58.60 ± 16.63 vs. NaOCl 69.80 ± 19.57 | Not applicable (in vitro) |
| Divya and Sujatha (2019) [26] | In vivo RCT (pediatric pulpectomy) | n = 30; 3-10 years; 19 males, 11 females | Maxillary and mandibular primary molars | IMPCOPS Ltd., Chennai; Triphala powder 5 mg/mL in 10% DMSO; 1 mL used as irrigant after instrumentation (contact time not specified) | Sterile saline; 1 mL after instrumentation (contact time not specified) | Post-irrigation microbial load (CFU/mL): Triphala 22.00 ± 18.11 vs. saline 13.46 ± 23.82; both groups showed significant reduction from baseline | Immediate post-irrigation only |
| Kiran et al. (2020) [27] | Ex vivo microbiological evaluation | n = 30; age not specified (infected extracted teeth) | Infected primary teeth (mixed types) | Triphala (brand not specified); 10% Triphala solution; 300 µL placed in agar wells for diffusion assay | 0.5% NaOCl (Dakin's solution); 300 µL in agar wells | Mean zone of inhibition against mixed microbial isolates: Triphala 23.83 ± 3.14 mm vs. NaOCl 20.97 ± 4.32 mm | 24-hour incubation in a candle jar (ex vivo) |
| Bellal et al. (2024) [28] | In vitro microbiological study | n = 140; age not applicable (extracted teeth) | Single-rooted primary teeth | Triphala (brand not specified); solution prepared in 10% DMSO (exact concentration not stated); 5-min contact time in broth assays | 2.5% NaOCl; 5-min contact time in broth assays | Growth/turbidity (mean ± SD): E. faecalis - Triphala 14.13 ± 1.25 vs. NaOCl 4.20 ± 1.01; *Candida albicans* - Triphala 13.60 ± 1.24 vs. NaOCl 3.53 ± 0.52 | Post-incubation at 37°C for up to 96 hours |
| Pathivada et al. (2024) [29] | In vivo RCT (pediatric pulpectomy) | n = 150; 6-9 years; gender not reported | Multirooted primary molars | Morpheme Remedies (India); commercial Triphala juice (concentration not specified); 10 mL during instrumentation + 5 mL final rinse | 2% CHX gluconate; 10 mL during instrumentation + 5 mL final rinse | Microbial reduction (CFU/mL): Triphala - blood agar 9.90 ± 11.56, anaerobic agar 6.50 ± 12.41; CHX - blood agar 3.80 ± 12.54, anaerobic agar 2.86 ± 13.01; both groups showed 100% clinical and radiographic success at all recalls | 12 months (evaluations at three, six, nine, and 12 months) |

**TABLE 2: Characteristic data extracted from the studies included in the present systematic review**

CHX: chlorhexidine; CFU: colony-forming unit; DMSO: dimethyl sulfoxide; NaOCl: sodium hypochlorite; BHI: brain heart infusion; SD: standard deviation; RCT: randomized controlled trial; NS: not specified; N/A: not applicable

*Study Characteristics*

All five studies were conducted in India; no eligible studies from other countries were identified despite the absence of country restrictions in the search strategy [25-29]. The evidence base comprised two in vivo RCTs on pediatric patients (Divya and Sujatha 2019; Pathivada et al. 2024), one ex vivo microbiological study using infected primary teeth (Kiran et al. 2020), and two in vitro experiments on extracted primary teeth (Thomas et al. 2017; Bellal et al. 2024) [25-29]. Thus, the dataset included two RCTs, one ex vivo study, and two in vitro studies.

Sample sizes ranged from 30 to 150, with a cumulative total of 399 teeth/participants across all studies. Age was reported in the RCTs only: Divya and Sujatha included children aged 3-10 years, and Pathivada et al. included children aged six to nine years [26,29]. Gender distribution was documented in one RCT (19 males, 11 females) [26]. Three studies evaluated primary molars (single- or multirooted), while two focused on single-rooted primary teeth [25-29].

Triphala was used as the test irrigant in all studies, but with variation in formulation and concentration. Most studies used Triphala powder dissolved in 10% dimethyl sulfoxide (DMSO), whereas one study used a 10% Triphala solution and another used a commercial Triphala juice preparation [25-29]. Irrigation/contact

times were standardized at five minutes in the in vitro studies, while irrigation volumes (rather than precise exposure time) were reported in the clinical trials. Comparator irrigants included NaOCl at concentrations of 0.5%, 2.5%, and 3% (three studies), 2% CHX (one RCT), and sterile saline (one RCT) [25-29].

*Microbial Outcomes*

All five studies assessed antimicrobial efficacy as a primary outcome, using either quantitative CFU counts, turbidity measurements, or zone-of-inhibition assays against *E. faecalis*, *C. albicans*, or mixed microbial flora [25-29]. For comparisons with NaOCl, three studies (Thomas et al. 2017; Kiran et al. 2020; Bellal et al. 2024) evaluated Triphala versus 0.5-3% NaOCl [25,27,28]. In all three, NaOCl produced greater immediate antimicrobial reduction overall, whether measured as lower CFU counts or smaller residual growth/turbidity. However, Triphala consistently achieved significant reductions from baseline, demonstrating clear antimicrobial activity. In a zone-of-inhibition assay, 10% Triphala produced a larger mean inhibition zone than 0.5% NaOCl [27], although diffusion-based assays are sensitive to physicochemical properties and do not necessarily reflect clinical performance.

For comparisons with CHX and saline, two RCTs provided in vivo data. Divya and Sujatha (2019) compared Triphala with sterile saline and found that both irrigants, when used in conjunction with standard mechanical preparation, produced reductions in microbial load; the difference between groups was modest and not clearly clinically decisive [26]. Pathivada et al. (2024) compared Triphala with 2% CHX and reported lower post-irrigation CFU values in the CHX group on both blood agar and anaerobic media, but Triphala still produced substantial microbial reduction [29]. NaOCl was superior to Triphala in all three NaOCl-comparator studies (3/3), CHX showed lower CFU counts than Triphala in the single CHX-comparator RCT (1/1), and Triphala performed at least comparably to saline in the one saline-comparator RCT.

*Clinical and Radiographic Outcomes*

Only one study (Pathivada et al. 2024) included longitudinal clinical and radiographic follow-up [29]. In this RCT, children treated with either Triphala or 2% CHX were reviewed at three, six, nine, and 12 months. Both groups demonstrated complete clinical success (absence of pain, swelling, or sinus tract) and radiographic success (healing or stability of periapical status) throughout the 12-month period, with no reported treatment failures in any group. Thus, although CHX showed superior immediate microbial reduction, long-term clinical and radiographic outcomes were equivalent between Triphala and CHX over one year. No other included study reported long-term clinical or radiographic outcomes, as they were in vitro or ex vivo in design and focused solely on microbiological endpoints.

*Safety and Adverse Events*

Safety outcomes were explicitly reported only in the RCT by Pathivada et al., in which no adverse events, allergic reactions, or clinically apparent soft tissue irritations were observed in either the Triphala or CHX groups during the 12-month follow-up [29]. None of the other studies reported adverse events, which is expected for in vitro and ex vivo experiments. Overall, the available clinical evidence, though limited, suggests that Triphala is well tolerated when used as a root canal irrigant in pediatric patients.

## RoB assessment

Among the five included studies, two were RCTs and were evaluated using the RoB 2 tool. Both Divya and Sujatha (2019) and Pathivada et al. (2024) were judged to have a low overall RoB (Figure *2*). These studies demonstrated proper randomization procedures, adequate handling of missing data, and valid outcome assessment protocols. Their adherence to methodological rigor enhances the reliability of their clinical findings and strengthens the evidence supporting the use of Triphala in vivo [26,29].

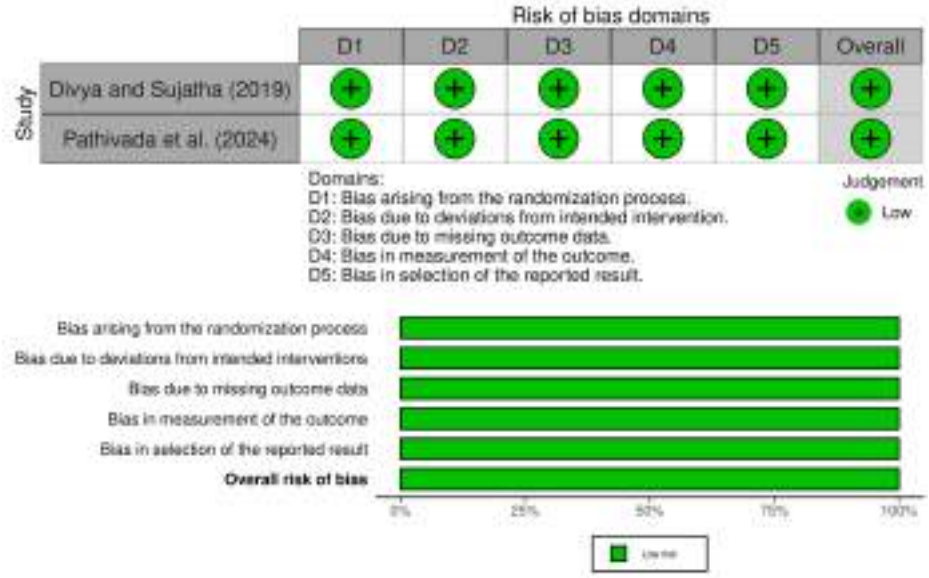


**FIGURE 2: Risk of bias in the included randomized controlled trials using the Cochrane RoB-2 tool**

Cochrane RoB-2: Cochrane Risk of Bias 2.0

References [26,29]

The remaining three studies - Thomas et al. (2017), Bellal et al. (2024), and Kiran et al. (2020) - were in vitro or ex vivo studies and were evaluated using the QUIN tool (Table *3*). All three studies were rated as having a moderate RoB. While each study clearly stated its aims, provided detailed methodology, and used appropriate controls and statistical analysis, none of them justified their sample size or employed blinding in outcome assessment. Additionally, only two of the three studies incorporated randomization of samples. These methodological limitations, particularly the lack of blinding and sample size calculation, reduce the certainty and generalizability of their findings [25,27,28].

| Study | Clearly stated aims | Sample size justification | Detailed methodology | Randomization of samples | Blinding of outcome assessment | Use of appropriate controls | Statistical analysis | Reproducibility (protocol clarity) | Overall risk of bias |
|---|---|---|---|---|---|---|---|---|---|
| Thomas et al. (2017) [25] | Yes | No | Yes | Yes | No | Yes | Yes | Yes | Moderate |
| Kiran et al. (2020) [27] | Yes | No | Yes | No | No | Yes | Yes | Yes | Moderate |
| Bellal et al. (2024) [28] | Yes | No | Yes | Yes | No | Yes | Yes | Yes | Moderate |

**TABLE 3: Risk of bias in the included in-vitro/ex-vivo studies using the QUIN tool**

QUIN: Quality Assessment Tool for In Vitro Studies of Dental Materials

Overall, the RoB assessment revealed that the evidence from the two RCTs is robust and credible. In contrast, the in vitro and ex vivo studies, although methodologically sound in many respects, show some limitations that must be considered when interpreting their results. These findings suggest that while preliminary laboratory evidence supports the antimicrobial efficacy of Triphala, stronger emphasis should be placed on the clinical trials when concluding its real-world application in pediatric endodontics.

## Interpretation of the certainty of evidence

The GRADE approach evaluated the strength of the body of evidence across five key domains: RoB,

inconsistency, indirectness, imprecision, and publication bias (not applicable here due to the limited number of studies) [34]. The evidence was categorized into four levels of certainty: high, moderate, low, or very low (Table 4).

| Outcome | Number of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Certainty of evidence |
|---|---|---|---|---|---|---|---|
| Antimicrobial efficacy of Triphala compared to NaOCl | 3 | In vitro and in vivo | Moderate | Serious | Not serious | Serious | Low |
| Antimicrobial efficacy of Triphala compared to CHX | 1 | In vivo (RCT) | Low | Not serious | Not serious | Not serious | Moderate |
| Antimicrobial efficacy of Triphala compared to saline | 1 | In vivo (RCT) | Low | Not serious | Not serious | Not serious | Moderate |

**TABLE 4: Assessment of certainty of evidence using the GRADE approach**

GRADE: Grading of Recommendations Assessment, Development and Evaluation; NaOCl: sodium hypochlorite; CHX: chlorhexidine; RCT: randomized controlled trial

For the comparison between Triphala and NaOCl, data were extracted from three studies, including both in vitro and in vivo designs. The overall certainty of evidence for this outcome was graded as low. Although the findings consistently showed that Triphala had antimicrobial effects, there was a serious inconsistency due to variation in results across different experimental setups and formulations. Additionally, serious imprecision was noted due to variability in outcome measurements and a lack of standardized reporting. The moderate RoB in in vitro studies also contributed to downgrading the certainty.

In the comparison between Triphala and CHX, only one RCT was included. The study had a low RoB, and there was no serious inconsistency, indirectness, or imprecision in the outcomes. Therefore, the certainty of evidence was graded as moderate. This reflects a reasonable level of confidence in the findings, although further studies are needed to confirm and strengthen the results [29]. A single RCT also informed the comparison between Triphala and saline with low RoB, and no issues related to inconsistency, indirectness, or imprecision were identified. As a result, the certainty of evidence for this comparison was also graded as moderate [26].

Overall, the certainty of evidence was low for the comparison with NaOCl due to heterogeneity and limited clinical data. At the same time, it was moderate in comparison with CHX and saline, supported primarily by well-designed RCTs. These findings suggest a cautious but promising role for Triphala as a root canal irrigant, particularly when compared to less potent or safer alternatives in pediatric endodontics [25-29].

## Discussion

The present systematic review evaluated the comparative effectiveness of Triphala, a traditional Ayurvedic polyherbal formulation, as a root canal irrigant in primary teeth. Across the five included studies, Triphala consistently demonstrated measurable antimicrobial activity against endodontic pathogens; however, the magnitude of its effect varied according to concentration, formulation, microbial species, and outcome assessment methods [25-29]. In direct comparisons, Triphala generally did not surpass conventional chemical irrigants such as NaOCl or CHX in terms of immediate microbial reduction, yet it reliably reduced microbial counts relative to baseline or inert comparators [25-29]. Taken together with its favorable biocompatibility profile and natural origin, these findings suggest that Triphala may be a promising adjunct or alternative irrigant in pediatric endodontics, particularly when safety concerns limit the use of higher-concentration synthetic irrigants.

*Geographic and Methodological Heterogeneity*

An important observation is that all included studies originated from India [25-29]. The literature search was not restricted by country; therefore, the exclusively Indian evidence base likely reflects both Triphala's roots in Indian Ayurvedic practice, one of the world's oldest traditional medical systems, still widely used in India today [35], and a true geographic concentration of research activity, but it may also indicate publication or language bias. Triphala, composed of the dried fruits of *T. bellirica, T. chebula,* and *E. officinalis*, is commonly used in Indian households as a health tonic, digestive aid, and oral rinse, and its components have been shown to possess antioxidant, antimicrobial, and immunomodulatory properties [36-38]. The consistent use of Triphala in Indian dental research reflects this cultural familiarity, yet also underscores the need for

studies in diverse populations and international settings to assess its broader clinical applicability [37,38].

Methodologically, the body of evidence is heterogeneous: it comprises two in vivo RCTs, one ex vivo microbiological study, and two in vitro experiments on extracted primary teeth [25-29]. Sample sizes ranged from 30 to 150, tooth types and infection status varied, and follow-up was reported in only one trial [26,29]. Triphala was delivered as powder dissolved in 10% DMSO in most studies, whereas one trial used a commercial juice formulation, introducing further variability in active content and bioavailability [25-29]. Comparators spanned 0.5-3% NaOCl, 2% CHX, and sterile saline [25-29]. These differences in design, formulation, and outcomes were the primary reasons a quantitative meta-analysis was not attempted, and a narrative synthesis was adopted.

*Efficacy of Triphala in the Context of Conventional Irrigants*

When compared with NaOCl, three studies reported that NaOCl produced greater reductions in *E. faecalis* and *C. albicans* counts or turbidity, consistent with its well-known broad-spectrum antimicrobial and tissue-dissolving properties [25,27,28]. In our GRADE assessment, the certainty of evidence for Triphala versus NaOCl was rated as low, owing to the predominance of in vitro data, variability in protocols, and imprecision in effect estimates [25,27,28]. Nonetheless, Triphala still achieved significant microbial reductions in all NaOCl-comparator studies, indicating intrinsic antimicrobial potential [25,27,28]. Kiran et al. reported a larger mean zone of inhibition for 10% Triphala than for 0.5% NaOCl [27]; however, diffusion-based assays are highly sensitive to molecular size, solubility, and medium characteristics, and thus may not directly translate to clinical performance. In the RCT by Divya and Sujatha, Triphala and saline produced comparable microbial reductions when used alongside conventional mechanical debridement [26], suggesting that Triphala may perform at least as well as inert solutions when the mechanical component of treatment is adequate.

Of particular clinical relevance, Pathivada et al. observed that both Triphala and 2% CHX resulted in complete clinical and radiographic success at three, six, nine, and 12 months, with no reported adverse events [29]. Although this trial found CHX to yield numerically lower CFU counts than Triphala immediately after irrigation, the long-term outcomes were indistinguishable, supporting the notion that antimicrobial efficacy, host response, and healing dynamics all contribute to treatment success [29]. These findings mirror observations from adjacent endodontic literature, where calcium hydroxide pastes have been shown to be more effective than $Ca(OH)_2$-impregnated points in eradicating *E. faecalis* from infected canals [15], and where flowable obturation systems such as GuttaFlow2 achieve filling quality and canal wall adaptation comparable to thermoplasticized gutta-percha in internal resorption defects [39]. Together, these data underline the need to balance antimicrobial strength with practicality, handling, and compatibility when integrating new agents such as Triphala into pediatric protocols.

Differences in antimicrobial efficacy among the included Triphala studies can plausibly be attributed to variability in concentration, preparation method, and inherent differences in microbial resistance. Triphala's active phytoconstituents, including tannins, phenolic compounds, and flavonoids, vary in potency and relative proportion depending on the botanical source, processing, and extraction techniques [38,40]. The use of DMSO likely enhanced solubility and penetration of these components into dentinal tubules, whereas the commercial juice preparation employed in one trial may have exhibited reduced or less standardized active content [25-29,40]. Moreover, the antimicrobial activity of Triphala appears to be time-dependent in several models, with prolonged contact being necessary to disrupt established biofilms [36]. These factors, combined with differences in experimental design and endpoints, help explain the variability observed across studies and further justify the choice of narrative rather than quantitative synthesis.

*Safety, Biocompatibility, and Clinical Acceptability*

From a pediatric perspective, safety and biocompatibility are critical considerations, given the thin dentinal walls, open or resorbing apices, and proximity of primary roots to developing permanent tooth buds. High-concentration NaOCl, while highly effective antimicrobially, is associated with risks of tissue toxicity, chemical burns, and unpleasant taste, and its accidental extrusion beyond the apex can cause significant soft tissue damage [10,11]. In contrast, Triphala has been reported to exhibit relatively low cytotoxicity in experimental models and is widely consumed orally as a health supplement in Indian households [15-20,24,36]. In the available clinical trial included in this review, Triphala irrigation was not associated with any adverse clinical or radiographic events over 12 months [29]. Although formal biocompatibility testing in the context of irrigant extrusion and periapical tissues remains limited, the current evidence suggests that Triphala may offer a more favorable safety margin than some conventional irrigants, which is particularly relevant in young children and in teeth with open apices or advanced root resorption [10,11,36]. Furthermore, its herbal origin and familiarity in certain cultures may improve acceptance among parents seeking "natural" treatment options, provided that efficacy and safety are clearly explained.

*Limitations*

This review has several limitations. First, as noted above, all included studies were conducted in India [25-

29], which restricts extrapolation to other populations and raises the possibility of geographic or publication bias despite the absence of country restrictions in the search strategy. Second, heterogeneity in study design (in vitro, ex vivo, in vivo), Triphala concentration and formulation, irrigation protocols, microbial targets, and outcome measures precluded formal meta-analysis and limited the certainty of pooled conclusions. Third, only one RCT provided longitudinal clinical and radiographic follow-up, and none reported patient-centred outcomes such as pain, treatment acceptability, or quality of life. Fourth, although we employed RoB 2, QUIN, and GRADE, several studies lacked sample size justifications, blinding, or detailed randomization procedures, contributing to the downgrading of certainty, particularly for comparisons with NaOCl. Finally, our conclusions are constrained by the small number of eligible studies and the reliance on surrogate microbiological outcomes, which may not fully reflect complex clinical healing processes.

*Clinical Implications and Future Research*

Within these limitations, the current evidence suggests that Triphala can achieve clinically meaningful microbial reduction in primary root canal systems and may be a reasonable alternative or adjunct in cases where the use of higher-concentration NaOCl is contraindicated or where a more biocompatible agent is desired. However, clinicians should recognize that NaOCl and CHX generally remain superior in terms of immediate antimicrobial effect, and Triphala should not be viewed as a direct replacement in all cases. Future research should prioritize well-designed, multicenter RCTs in diverse populations, using standardized Triphala formulations and concentrations, clearly defined irrigation protocols, and harmonized outcome measures including CFU reduction, clinical signs and symptoms, radiographic healing, and patient-reported outcomes. Studies that integrate Triphala-based irrigation regimens with established intracanal medicaments and contemporary obturation systems, including those with documented antimicrobial and sealing performance, would help clarify its role within comprehensive pediatric endodontic treatment. Longer-term follow-up and rigorous safety evaluations, particularly in relation to periapical tissues and developing permanent teeth, are essential before Triphala can be fully integrated into routine pediatric practice.

## Conclusions

The present systematic review highlights that Triphala exhibits promising antimicrobial efficacy as a root canal irrigant in primary teeth, demonstrating consistent microbial reduction across in vitro, ex vivo, and in vivo studies. While conventional irrigants such as NaOCl and CHX generally showed superior immediate antimicrobial action, Triphala's favourable safety profile, biocompatibility, and natural origin make it a compelling alternative, particularly in pediatric endodontics where cytotoxicity and proximity to developing permanent teeth are of concern. Although limited primarily to Indian studies with methodological variability, the evidence suggests that Triphala can achieve clinically acceptable outcomes when used within a comprehensive treatment protocol. Future research through well-designed, multicentric RCTs with standardized formulations and long-term follow-up is essential to establish Triphala's effectiveness and support its integration into routine pediatric dental practice.

## Appendices

| Database | Platform | Core search strategy (example, adapted to database syntax) | Filters/notes |
|---|---|---|---|
| PubMed | NCBI | (“Triphala”[Mesh] OR Triphala OR “tri phala” OR “tri-phala”) AND (“Tooth, Deciduous”[Mesh] OR “primary teeth” OR “primary tooth” OR “deciduous teeth” OR “primary molar*” OR “deciduous molar*”) AND (“root canal irrigant*” OR “root canal irrigation” OR “endodontic irrigant*” OR “endodontic irrigation”) | Standard PubMed field tags and MeSH terms used; reference lists of eligible articles also hand-searched. |
| MEDLINE | Ovid | (exp Triphala/ OR Triphala OR “tri phala” OR “tri-phala”) AND (exp Tooth, Deciduous/ OR (primary adj3 (tooth OR teeth OR molar$) OR deciduous tooth OR deciduous teeth)) AND (exp Root Canal Irrigants/ OR exp Root Canal Therapy/ OR “root canal irrigant$” OR “root canal irrigation” OR “endodontic irrigant$” OR “endodontic irrigation”) | Truncation symbols and adjacency operators adapted to Ovid syntax. |
| Embase | Elsevier | (‘triphala’/exp OR triphala OR ‘tri phala’ OR ‘tri-phala’) AND (‘deciduous tooth’/exp OR ‘primary tooth’ OR ‘primary teeth’ OR ‘deciduous teeth’ OR ‘primary molar*’) AND (‘root canal irrigation’/exp OR ‘root canal irrigant*’ OR ‘endodontic irrigant*’ OR ‘endodontic irrigation’) | EMTREE terms exploded where available; conference abstracts screened where relevant. |
| Scopus | Elsevier | TITLE-ABS-KEY(Triphala OR “tri phala” OR “tri-phala”) AND TITLE-ABS-KEY(“primary teeth” OR “primary tooth” OR “deciduous teeth” OR “deciduous tooth” OR “primary molar*” OR “deciduous molar*”) AND TITLE-ABS-KEY(“root canal irrigant*” OR “root canal irrigation” OR “endodontic irrigant*” OR “endodontic irrigation”) | Search limited to journal articles; duplicates removed during export and screening. |
| Cochrane Library (CENTRAL) | Wiley | (Triphala OR “tri phala” OR “tri-phala”) in Title/Abstract/Keywords AND (“primary teeth” OR “primary tooth” OR “deciduous teeth” OR “deciduous tooth”) AND (“root canal” OR endodontic) | CENTRAL trials register searched for randomized and quasi-randomized studies. |
| Google Scholar | Web | Iterative queries including: Triphala “primary teeth” “root canal irrigant”; Triphala “pediatric endodontics”; Triphala “root canal” antimicrobial. Approximately the first 200 records per query were screened by title/abstract. | Used to identify additional and grey literature; potentially relevant theses and non-indexed articles checked against eligibility criteria. |
| Global limits applied to all databases: Searches conducted from 1 January 2000 to 15 February 2025. No country restrictions were applied. Limited to English-language publications; human studies where applicable; duplicates removed at the screening stage. | | | |

**TABLE 5: Detailed electronic search strategy across all databases**

# Additional Information

## Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

**Concept and design:** Pranjal Chavan, Padawe Dimple, Vilas Takate

**Acquisition, analysis, or interpretation of data:** Pranjal Chavan, Padawe Dimple, Vilas Takate

**Drafting of the manuscript:** Pranjal Chavan, Padawe Dimple, Vilas Takate

**Critical review of the manuscript for important intellectual content:** Pranjal Chavan, Padawe Dimple, Vilas Takate

**Supervision:** Pranjal Chavan, Padawe Dimple, Vilas Takate

## Disclosures

**Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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