OFFICIAL TITLE: Twelve-Month Prospective Evaluation of Clinical and Radiographic Outcomes of Pulpotomy Materials in Primary Molars

NCT Number: not yet assigned

Document Date: June 28, 2025

1. Background

Pulpotomy is a widely accepted treatment modality for cariously exposed primary molars. While several medicaments have shown favorable outcomes, the comparative effectiveness of emerging and traditional materials within the same patient cohort remains understudied. This study aims to prospectively evaluate the clinical and radiographic outcomes of four pulpotomy medicaments—MTA, Biodentine, Ferric Sulfate, and Sodium Hypochlorite—using a split-mouth randomized controlled trial design over a 12-month period.

2. Study Objectives

Primary Objective: To compare the 12-month clinical and radiographic success rates of MTA, Biodentine, Ferric Sulfate, and Sodium Hypochlorite in pulpotomy treatment of primary molars.

Secondary Objective: To determine the feasibility and effectiveness of a split-mouth design for pulpotomy comparisons in pediatric patients.

3. Study Design

Design Type: Prospective, split-mouth, randomized controlled clinical trial.

Participants: Healthy children aged 4–7 requiring pulpotomy in four primary molars due to deep caries.

Sample Size: A priori power analysis determined that at least 19 patients were required to detect statistically significant differences.

Randomization: Performed at the tooth level within each patient using sealed opaque envelopes prepared by an independent researcher. Clinical and radiographic assessors were blinded to treatment groups.

Inclusion Criteria:

 Age between 4 and 7 years

 Four primary molars indicated for pulpotomy due to deep caries

 Clinical signs of reversible pulpitis only

 Restorable teeth with normal periapical radiographs

Exclusion Criteria:

 Systemic illness

 Teeth with signs of irreversible pulpitis or radiographic pathology

 Uncooperative behavior impeding treatment

5. Interventions and Procedures

Local Anesthesia: 2% Lidocaine with 1:100,000 epinephrine

Isolation: Rubber dam

Access: High-speed handpiece with sterile water-cooled diamond bur

Coronal Pulp Removal: Low-speed round bur

Hemostasis: Achieved with sterile water-moistened cotton pellet

Groups and Materials:

Group I: 15.5% Ferric Sulfate – 15 s application

Group II: 5.25% Sodium Hypochlorite Gel – 1 min application

Group III: MTA – ~2 mm thick layer

Group IV: Biodentine – full chamber fill

Restoration:

Groups I–III: IRM base + stainless steel crown

Group IV: Biodentine fill + stainless steel crown

All crowns cemented with glass ionomer cement (Fuji I)

All procedures were performed by a single experienced pediatric dentist.

6. Follow-up and Outcome Measures

Follow-up Schedule:

Clinical: 3, 6, and 12 months

Radiographic: 6 and 12 months

Success Criteria:

Clinical: No pain, swelling, abscess, fistula, percussion sensitivity, or mobility

Radiographic: No furcation/periapical pathology, no internal resorption; Pulp canal obliteration was not deemed a failure

Evaluator Blinding:

- Clinical evaluation by two independent, blinded pediatric dentists
- Radiographic evaluation by a blinded pediatric dentist and radiologist

Disagreements were resolved through consensus. No pulp chamber masking was done, introducing a possible bias.

7. Statistical Analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS Version 26; IBM Corp., Armonk, NY, USA). Fishers exact test was used to compare clinical and radiographic outcomes at the 6- and 12-month follow-ups among the four groups. Success and failure rates were calculated based on a per-protocol analysis, which included 22 patients per group. Patients who did not complete the study protocol were excluded from the analysis. In addition, Cochrans Q test was applied to compare the clinical and radiographic success rates of the four pulpotomy materials (Biodentine, MTA, NaOCl, and Ferric Sulfate) at the 12-month follow-up. Treatment outcomes were dichotomized as success or failure. The test was calculated using data from all 22 patients in each group. The significance level was set at $p < 0.05$.

8. Ethical Considerations

Approval was obtained from Interventional Clinical Research Ethics Committee, (Approval No: 2021/77).

Written informed consent was obtained from the parents/legal guardians of all participants.

The study adhered to the Declaration of Helsinki and national regulations on human research ethics.

9. Data Handling and Confidentiality

All data will be anonymized and stored securely in password-protected databases accessible only to the research team. Personal identifiers will be removed during data analysis and reporting.