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Pulp Therapy Outcomes in Primary Molars Using Locally Available Materials: A Clinical Trial in Resource-Constrained Settings

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Abstract

The management of pulpal pathology in primary molars presents significant challenges in resource-constrained settings where access to conventional endodontic materials remains limited. This clinical trial investigated the efficacy of locally available materials for pulp therapy in primary molars, comparing their clinical and radiographic outcomes against standard treatment protocols. A prospective randomized clinical trial was conducted involving 180 children aged 4-9 years presenting with deep carious lesions in primary molars requiring pulp therapy. Participants were randomly allocated into three treatment groups: Group A received conventional formocresol pulpotomy, Group B received pulpotomy with locally prepared zinc oxide-eugenol paste, and Group C underwent pulpectomy using a modified zinc oxide-based root canal filling material. Clinical and radiographic evaluations were performed at 3, 6, and 12-month intervals. The primary outcome measures included clinical success (absence of pain, swelling, and pathologic mobility) and radiographic success (absence of internal or external resorption, furcation radiolucency, and periapical pathology). Results demonstrated that locally available materials achieved comparable success rates to conventional materials, with Group A showing 88.3% success, Group B demonstrating 85.0% success, and Group C exhibiting 83.3% success at 12-month follow-up, with no statistically significant differences between groups ($p > 0.05$). These findings suggest that locally available materials can serve as viable alternatives for pulp therapy in primary molars, particularly in settings where access to commercial endodontic products is limited. The study provides evidence-based support for adapting treatment protocols to local resource availability without compromising clinical outcomes, thereby improving access to essential pediatric dental care in underserved populations.

Keywords: Pulp therapy, primary molars, resource-constrained settings, locally available materials, pulpotomy, pulpectomy, pediatric dentistry

1. Introduction

The preservation of primary dentition represents a fundamental objective in pediatric dentistry, serving critical functions in maintaining space for permanent successors, facilitating proper mastication, supporting normal speech development, and contributing to psychological well-being through aesthetic considerations. When primary teeth are affected by deep carious lesions extending into pulp tissue, intervention becomes necessary to prevent

premature tooth loss and its associated sequelae, including space loss, impaired masticatory function, and potential psychological impacts on developing children. Pulp therapy in primary teeth encompasses various treatment modalities, ranging from indirect pulp capping and direct pulp capping to pulpotomy and pulpectomy procedures, each indicated based on the extent of pulpal involvement and the tooth's proximity to natural exfoliation.

The selection of appropriate materials for pulp therapy procedures in primary teeth has evolved considerably over the past several decades, driven by advances in understanding pulp biology, concerns regarding material biocompatibility, and the development of novel bioactive materials. Traditional materials such as formocresol, despite their widespread historical use and demonstrated clinical success, have faced increasing scrutiny due to potential systemic toxicity concerns and the classification of formaldehyde as a probable human carcinogen by international health organizations. This has prompted the dental community to explore alternative materials including ferric sulfate, mineral trioxide aggregate, calcium hydroxide, and various bioactive compounds, many of which have demonstrated favorable outcomes in controlled clinical studies conducted primarily in well-resourced healthcare environments.

However, the implementation of evidence-based pulp therapy protocols faces substantial challenges in resource-constrained settings, where financial limitations, supply chain disruptions, lack of infrastructure, and restricted access to specialized dental materials create significant barriers to optimal patient care. According to the World Health Organization, approximately 2.3 billion people worldwide suffer from untreated dental caries in permanent teeth, with an even higher prevalence in primary dentition, particularly affecting populations in low- and middle-income countries where access to preventive and restorative dental services remains severely limited. In these contexts, dental practitioners often must adapt treatment approaches to available resources, sometimes relying on locally sourced or improvised materials when conventional endodontic products are unavailable or economically prohibitive for the patient population served.

The concept of utilizing locally available materials for dental treatment is not entirely novel, as various traditional medicine systems have historically employed natural substances with antimicrobial and therapeutic properties for oral health management. However, the systematic evaluation of these materials through rigorous clinical trials remains limited, creating a gap between clinical practice necessitated by resource constraints and the evidence base required to support such practices through peer-reviewed scientific literature. This research gap is particularly concerning given that treatment decisions in resource-limited settings often rely on anecdotal experience rather than robust clinical evidence, potentially compromising patient outcomes and professional standards of care.

Recent research has begun to address this evidence gap by investigating alternative materials that are more accessible, affordable, and sustainable for use in resource-constrained environments. Studies examining materials such as turmeric, propolis, Aloe vera, and various plant-based compounds have shown promising antimicrobial and anti-inflammatory properties that could theoretically support their use in pulp therapy applications. Additionally,

modifications to conventional materials or simplified preparation techniques that reduce costs while maintaining clinical efficacy represent another avenue for improving treatment accessibility. However, many of these investigations have been conducted primarily through in vitro studies or small-scale clinical observations, necessitating larger, well-designed clinical trials to establish definitive evidence regarding their safety and effectiveness in pediatric populations.

The present study was designed to address this critical knowledge gap by conducting a prospective randomized clinical trial comparing outcomes of pulp therapy procedures in primary molars using locally available materials against conventional treatment protocols in a resource-constrained clinical setting. The research aims to provide evidence-based guidance for dental practitioners working in similar environments, potentially expanding treatment options while maintaining acceptable standards of care. By systematically evaluating clinical and radiographic outcomes over a 12-month follow-up period, this investigation seeks to determine whether locally available materials can achieve success rates comparable to conventional materials, thereby supporting their potential integration into clinical practice guidelines for resource-limited settings. Furthermore, the study explores the practical feasibility, cost-effectiveness, and patient acceptance of alternative treatment approaches, considering not only clinical outcomes but also the broader implications for healthcare delivery and access to essential dental services in underserved populations.

2. Literature Review

2.1 Pulp Therapy in Primary Teeth: Fundamental Principles

The biological rationale for pulp therapy in primary teeth is grounded in the unique anatomical and physiological characteristics that distinguish primary dentition from permanent teeth. Primary tooth pulp exhibits greater vascularity, higher cellular content, and more pronounced reparative capacity compared to permanent teeth, features that theoretically enhance healing potential following conservative pulp treatment procedures. However, these same characteristics also contribute to more rapid progression of pulpal pathology when bacterial invasion occurs, necessitating timely intervention to prevent irreversible damage and tooth loss. The decision-making process for selecting appropriate pulp therapy procedures depends on accurate diagnosis of pulp status, typically categorized as normal, reversibly inflamed, irreversibly inflamed, or necrotic, each requiring distinct treatment approaches.

Pulpotomy procedures, involving the removal of coronal pulp tissue while preserving vital radicular pulp, represent the most commonly performed pulp therapy technique in primary molars with reversible pulpal inflammation confined to the coronal portion. The success of pulpotomy treatment relies heavily on the medicament placed over the radicular pulp stumps, which must provide antimicrobial action, promote healing, and potentially stimulate formation of a dentinal bridge while avoiding toxicity to residual pulp tissue or surrounding structures. Formocresol, introduced by Sweet in 1930, became the gold standard pulpotomy medicament for decades, with numerous studies reporting success rates ranging from 70% to

98% at various follow-up intervals. The material's mechanism of action involves fixation of tissue proteins in the superficial layers of radicular pulp, creating a zone of devitalized tissue that theoretically prevents bacterial penetration while the deeper pulp tissues remain vital and functional.

Despite its widespread historical use, formocresol has generated considerable controversy within the dental community due to concerns about potential systemic distribution, mutagenicity, and carcinogenicity. Research has demonstrated that formaldehyde, the active component of formocresol, can be detected systemically following pulpotomy procedures, raising questions about cumulative exposure risks, particularly in children requiring multiple pulpotomies. The International Agency for Research on Cancer classified formaldehyde as a Group 1 carcinogen in 2004, based primarily on evidence linking occupational exposure to nasopharyngeal cancer, prompting many countries to restrict or discontinue its use in dental applications. This regulatory environment has accelerated the search for alternative pulpotomy medicaments that can provide comparable clinical success without the associated safety concerns.

Mineral trioxide aggregate has emerged as a leading alternative to formocresol, demonstrating excellent biocompatibility, sealing ability, and capacity to stimulate hard tissue formation. Multiple systematic reviews and meta-analyses have concluded that MTA pulpotomy achieves success rates equal to or exceeding formocresol, with some studies suggesting superior long-term outcomes. However, the high cost of MTA, ranging from $30 to $50 per application in developed countries and representing even greater relative expense in resource-constrained settings, combined with technical challenges related to its handling characteristics and prolonged setting time, have limited its widespread adoption, particularly in economically disadvantaged populations. This cost-benefit disparity creates a significant equity issue in pediatric dental care, where children in resource-rich environments have access to advanced biomaterials while those in resource-poor settings continue to rely on older, potentially problematic alternatives or receive no treatment at all.

2.2 Challenges in Resource-Constrained Settings

The delivery of pediatric dental services in resource-constrained settings faces multifaceted challenges extending beyond simple material availability to encompass infrastructure limitations, workforce shortages, financial barriers, and cultural factors that collectively impede access to care. A comprehensive analysis by the World Health Organization identified that low- and middle-income countries typically have fewer than one dentist per 10,000 population, compared to ratios of one dentist per 1,000-2,000 population in high-income countries, resulting in severe capacity constraints for providing even basic dental services. This workforce shortage is often compounded by geographic maldistribution, with dental professionals concentrated in urban centers while rural and remote populations face extreme access barriers requiring travel distances and costs that are prohibitive for many families.

Infrastructure deficits represent another critical constraint, as many health facilities in resource-limited settings lack consistent electricity supply, running water, sterilization equipment, and proper waste disposal systems that are essential for maintaining infection control standards during dental procedures. The absence of reliable cold chain storage affects the availability of materials requiring refrigeration, while inadequate waste management infrastructure creates challenges for disposing of potentially hazardous materials in accordance with environmental and safety regulations. These infrastructural limitations necessitate adaptation of clinical protocols to accommodate available resources, often requiring practitioners to make difficult choices between ideal treatment approaches and practically feasible alternatives.

Economic barriers operate at multiple levels, affecting both healthcare systems and individual patients. At the system level, limited healthcare budgets in resource-constrained countries result in inadequate allocation of funds for dental services, which are often viewed as lower priority compared to medical conditions perceived as more immediately life-threatening. This underfunding translates to insufficient procurement of dental materials, equipment, and supplies, forcing clinics to operate with minimal inventory and limiting treatment options available to practitioners. At the patient level, out-of-pocket costs for dental care represent a substantial financial burden for families living in poverty, with even modest fees for materials and services potentially exceeding daily or weekly household income. Studies conducted in various resource-limited settings have documented that cost considerations frequently result in treatment delays, incomplete treatment courses, or selection of extraction rather than tooth-preserving procedures, perpetuating cycles of poor oral health.

The supply chain for dental materials in resource-constrained settings presents additional complexities, with importation of specialized products subject to customs delays, storage requirements, expiration concerns, and dependency on international suppliers who may not prioritize small-volume markets. This creates vulnerability to supply disruptions that can leave clinics without essential materials for extended periods, forcing cancellation of scheduled procedures and contributing to patient frustration and loss of confidence in the healthcare system. Local manufacturing of dental materials remains extremely limited in most resource-constrained countries, reflecting both the technical complexity of pharmaceutical-grade production and the relatively small market size that makes such investments economically challenging.

2.3 Locally Available Materials: Evidence and Potential

The exploration of locally available materials for dental applications represents a convergent evolution of traditional medicine practices and modern scientific investigation, seeking to identify compounds that combine cultural acceptability, local availability, affordability, and demonstrable therapeutic efficacy. Numerous plant-based materials have been investigated for their potential antimicrobial, anti-inflammatory, and tissue-healing properties relevant to pulp therapy applications. Turmeric (Curcuma longa), widely available across South and Southeast Asia, contains curcumin, a polyphenolic compound with well-documented anti-inflammatory and antimicrobial properties that have been explored in various dental

applications. Studies have demonstrated that curcumin exhibits antibacterial activity against oral pathogens including Streptococcus mutans and Enterococcus faecalis, suggesting potential utility in endodontic applications.

Propolis, a resinous mixture produced by honeybees from botanical sources, has attracted significant research attention due to its broad-spectrum antimicrobial activity, anti-inflammatory effects, and capacity to promote tissue healing. The composition of propolis varies based on local flora, but typically includes flavonoids, phenolic acids, and aromatic compounds that contribute to its therapeutic properties. Several studies have investigated propolis as a pulpotomy medicament in primary teeth, with results suggesting clinical and radiographic success rates comparable to formocresol in short-term follow-up periods. However, the standardization of propolis preparations remains challenging due to compositional variability, and long-term clinical data remain limited.

Zinc oxide-eugenol has been utilized in dentistry for over a century, valued for its antimicrobial properties, obtundent effect on pulp tissue, and ability to form a hard mass suitable for temporary or permanent restorations. The material's widespread availability, low cost, and familiarity to dental practitioners make it an attractive option for resource-constrained settings. While primarily used as a temporary filling material or as a component of root canal sealers in permanent teeth, various formulations of zinc oxide-eugenol have been investigated for pulpotomy and pulpectomy procedures in primary teeth. Research suggests that when properly formulated and applied, zinc oxide-eugenol can achieve acceptable clinical outcomes, though success rates in some studies have been somewhat lower than those reported for MTA or formocresol.

Calcium hydroxide, though commercially available as a dental material, can be prepared relatively simply from locally available calcium oxide (quicklime) and represents another potential option for resource-constrained settings. The material's high pH creates an antimicrobial environment and stimulates hard tissue formation, properties that have supported its use in various endodontic applications. However, calcium hydroxide pulpotomy in primary teeth has shown variable outcomes in clinical studies, with some research reporting success rates below those of formocresol or MTA, potentially related to the material's gradual resorption and inability to provide a permanent seal over radicular pulp tissue.

Natural products such as Aloe vera, green tea polyphenols, and various essential oils have also been investigated for potential dental applications, demonstrating antimicrobial and anti-inflammatory properties in laboratory studies. However, the transition from promising in vitro results to validated clinical applications requires rigorous evaluation through well-designed clinical trials, an area where research remains notably deficient for most alternative materials. The existing evidence base consists primarily of small pilot studies, case series, and short-term follow-up data, with few investigations providing the level of evidence required to support definitive clinical recommendations.

2.4 Clinical Trial Methodology in Pediatric Dentistry

The design and implementation of clinical trials in pediatric populations present unique methodological challenges that must be carefully addressed to ensure valid, reliable results while protecting the welfare of child participants. Ethical considerations assume paramount importance when conducting research involving children, requiring robust informed consent processes that respect parental authority while also soliciting age-appropriate assent from child participants. The principle of clinical equipoise—genuine uncertainty within the expert medical community about the relative merits of treatment alternatives—must be clearly established to justify randomization of children to different treatment arms, ensuring that no participants are knowingly assigned to inferior treatment.

Sample size determination in pediatric dental clinical trials must account for multiple factors including expected success rates, minimum detectable differences considered clinically meaningful, statistical power requirements, and anticipated loss to follow-up. Power analysis typically assumes success rates for standard treatments based on existing literature, then calculates the sample size needed to detect specified differences with adequate statistical confidence. In the context of pulp therapy trials, success rates for conventional treatments generally range from 70% to 95% depending on the specific procedure, material, and follow-up duration, requiring sample sizes typically ranging from 30 to 60 participants per treatment group to detect differences of 15-20% with 80% power.

Randomization procedures must be carefully designed to minimize selection bias while remaining practical to implement in clinical settings. Simple randomization through coin tosses or random number tables is straightforward but can result in imbalanced group sizes, particularly with smaller sample sizes. Block randomization ensures balanced allocation across treatment groups and can incorporate stratification for important prognostic factors such as tooth type, extent of carious involvement, or patient age. Allocation concealment, maintaining the treatment assignment unknown to the recruiting clinician until the point of randomization, represents a critical safeguard against selection bias, often implemented through sealed opaque envelopes or centralized randomization services.

Blinding in dental clinical trials presents particular challenges due to the difficulty of concealing treatment assignments from practitioners performing procedures that involve distinctly different materials or techniques. However, blinding of outcome assessors—the clinicians evaluating treatment success at follow-up examinations—is typically feasible and important for minimizing detection bias. Blinding of participants and parents represents another layer of protection against bias, though complete blinding may not always be possible depending on the nature of the interventions being compared. Studies should clearly report the level of blinding achieved and any instances where blinding was compromised, allowing readers to assess potential for bias in the results.

Follow-up protocols must balance the need for comprehensive outcome assessment against practical considerations of participant burden and resource constraints. In pulp therapy research, outcome evaluation typically includes both clinical assessment (presence or absence

of pain, swelling, sinus tract formation, pathologic mobility) and radiographic assessment (presence or absence of internal resorption, external resorption, furcation involvement, periapical pathology). The timing of follow-up assessments varies across studies but commonly includes evaluations at 3, 6, and 12 months, with some investigations extending follow-up to 24 months or until natural exfoliation of treated teeth. Longer follow-up periods provide more definitive evidence of treatment durability but also increase loss to follow-up and associated threats to validity.

3. Materials and Methods

3.1 Study Design and Setting

This prospective randomized clinical trial was conducted at the Department of Pediatric Dentistry, District Hospital Dental Clinic, serving a predominantly rural population in a resource-constrained setting where access to specialized dental materials is limited and patient populations face significant economic barriers to healthcare access. The study received ethical approval from the Institutional Review Board prior to participant recruitment (Protocol Number: IRB-2023-PED-047), with all procedures conducted in accordance with the Declaration of Helsinki principles for research involving human subjects. The trial was registered with the Clinical Trials Registry (Registration Number: CTRI/2023/08/056432) prior to enrollment of the first participant, ensuring transparency and accountability in the research process.

The clinical facility where the study was conducted represents a typical resource-constrained environment, operating with basic dental equipment including standard dental units, hand instruments, slow-speed handpieces, and conventional radiographic equipment. The clinic serves a catchment population of approximately 200,000 individuals, predominantly from agricultural communities with limited financial resources and variable health literacy. Patient care is provided by general dental practitioners who manage a wide range of oral health conditions with limited access to specialized referral services or advanced materials. This setting was deliberately chosen to ensure that study findings would be relevant to similar resource-constrained environments facing comparable challenges in delivering pediatric dental care.

3.2 Participant Selection and Randomization

Participant recruitment occurred over a 12-month period from August 2023 to July 2024, with children attending the dental clinic for routine care or presenting with dental complaints screened for potential eligibility. Inclusion criteria were carefully defined to identify appropriate candidates for pulp therapy while ensuring participant safety and study validity. Children aged 4 to 9 years presenting with primary molars having deep carious lesions with pulpal involvement, as evidenced by either pulpal exposure during caries excavation or clinical symptoms suggestive of reversible pulpitis, were considered for inclusion. Additional inclusion requirements specified that teeth must have at least two-thirds of root length remaining as assessed radiographically, demonstrating that sufficient time remained before

natural exfoliation to allow meaningful evaluation of treatment outcomes. Parents or legal guardians were required to provide written informed consent, and children aged 7 years or older provided verbal assent after age-appropriate explanation of study procedures.

Exclusion criteria were designed to eliminate cases where alternative diagnoses or complicating factors would confound outcome assessment or place participants at unacceptable risk. Children with systemic conditions affecting healing capacity or immune function, including uncontrolled diabetes mellitus, immunodeficiency disorders, or ongoing immunosuppressive therapy, were excluded from participation. Teeth with clinical or radiographic evidence of irreversible pulpitis or pulp necrosis, including presence of spontaneous pain, night pain, soft tissue swelling or sinus tract formation, excessive tooth mobility beyond physiologic limits, or radiographic evidence of furcation or periapical pathology, internal or external root resorption, or less than two-thirds root length remaining, were deemed unsuitable for the pulp therapy procedures under investigation. Children with known allergies to any of the materials being evaluated, those who had received antibiotics within the two weeks preceding treatment, or those whose parents or guardians were unable to commit to follow-up visits were also excluded to minimize confounding variables and ensure adequate outcome assessment.

Following determination of eligibility and completion of the informed consent process, participants were randomly allocated to one of three treatment groups using computer-generated random number sequences with permuted block randomization (block size of 6) to ensure balanced distribution across groups. Group A received conventional formocresol pulpotomy using diluted formocresol (1:5 dilution) as the pulp medicament, representing the traditional standard of care in the study setting. Group B received pulpotomy with locally prepared zinc oxide-eugenol paste as the pulp medicament, formulated according to a standardized protocol using pharmaceutical-grade zinc oxide powder and eugenol oil available through local suppliers. Group C underwent pulpectomy procedures using a modified zinc oxide-based root canal filling material prepared by mixing zinc oxide powder with eugenol and calcium hydroxide powder in specified proportions to create a paste with appropriate handling characteristics and radiopacity.

Allocation concealment was maintained through the use of sequentially numbered, opaque, sealed envelopes prepared by a research assistant not involved in patient care or outcome assessment. Envelopes were opened only after completion of caries excavation and confirmation of pulpal exposure, at which point the specific pulp therapy protocol was initiated according to the assigned treatment group. While complete blinding of the treating clinician was not feasible due to the distinct nature of the materials and procedures, outcome assessors conducting follow-up evaluations were blinded to treatment allocation, with treating clinicians instructed not to discuss treatment specifics with assessing clinicians or record treatment group assignments in locations accessible to outcome evaluators.

3.3 Treatment Protocols

All treatment procedures were performed by two calibrated pediatric dental practitioners with at least five years of clinical experience, following standardized protocols developed specifically for this study. Calibration sessions were conducted prior to study initiation to ensure consistency in technique and decision-making across operators. Treatment sessions were conducted under local anesthesia using 2% lignocaine with 1:100,000 epinephrine, administered via inferior alveolar nerve block for mandibular teeth or maxillary infiltration for maxillary teeth. Rubber dam isolation was employed in all cases to maintain a dry operating field and prevent contamination with oral fluids. Carious tissue was excavated using slow-speed round burs with copious water irrigation, proceeding from the periphery toward the pulp to minimize risk of inadvertent pulp exposure.

For Group A participants assigned to conventional formocresol pulpotomy, treatment proceeded according to the following protocol. After pulp exposure was identified during caries excavation, the roof of the pulp chamber was removed using a high-speed fissure bur with water spray, exposing radicular pulp stumps. Coronal pulp tissue was removed using sharp excavators, and hemorrhage from radicular pulp stumps was controlled using moist cotton pellets with gentle pressure. Once hemostasis was achieved, indicating presumptively healthy radicular pulp tissue capable of healing, a cotton pellet moistened with 1:5 diluted formocresol was placed in contact with radicular pulp stumps for five minutes. Following removal of the medicated cotton pellet, a layer of zinc oxide-eugenol base material was placed over the pulp stumps, and the tooth was restored with stainless steel crown cemented with glass ionomer cement. The selection of stainless steel crowns rather than conventional filling materials reflects clinical best practice for pulpotomized primary molars, providing superior durability and protection against future fracture.

For Group B participants assigned to locally prepared zinc oxide-eugenol pulpotomy, the initial steps of caries excavation, deroofing of the pulp chamber, and coronal pulp amputation were identical to Group A. However, instead of formocresol application, a thick paste of zinc oxide-eugenol was prepared by mixing pharmaceutical-grade zinc oxide powder with eugenol on a glass slab using a stainless steel spatula until a firm, putty-like consistency was achieved. This paste was carefully placed directly over the radicular pulp stumps using a small amalgam plugger, applying gentle pressure to achieve adaptation to the pulp chamber floor while avoiding excessive pressure that might force material into root canals. A layer of zinc oxide-eugenol cement of thinner consistency was then placed over the initial paste layer, and the tooth was restored with a stainless steel crown cemented with glass ionomer cement, following the same final restoration protocol as Group A.

For Group C participants assigned to pulpectomy with modified zinc oxide-based root canal filling, treatment protocols were necessarily more extensive due to the need for complete pulp tissue removal and root canal filling. After caries excavation and pulp exposure, the pulp chamber was accessed and coronal pulp tissue removed as described for pulpotomy procedures. Root canal orifices were identified and negotiated using small barbed broaches and K-files, with working length determined by subtracting 2 millimeters from the

radiographic root length to avoid overfilling beyond the apex. Root canals were instrumented using hand files with copious irrigation using normal saline, as sodium hypochlorite irrigation was not employed due to safety concerns regarding use of this material in primary teeth and potential for toxicity if inadvertently expressed beyond the apex. Following completion of instrumentation, canals were dried using paper points and then filled with the modified zinc oxide-based paste. This filling material was prepared by mixing zinc oxide powder, eugenol, and calcium hydroxide powder in a ratio of 5:2:1 by weight, creating a paste that could be introduced into canals using lentulo spirals or carefully packed using hand instruments. Following root canal filling, a layer of zinc oxide-eugenol base was placed over the pulp chamber floor, and teeth were restored with stainless steel crowns as described for the other treatment groups.

3.4 Outcome Assessment and Follow-up

Primary outcome measures consisted of clinical success and radiographic success evaluated at 3, 6, and 12-month intervals following treatment. Clinical evaluation at each follow-up visit included comprehensive assessment documented on standardized case report forms. Clinical success was defined as absence of all the following adverse findings: spontaneous pain reported by patient or parent, pain on percussion detected during clinical examination, soft tissue swelling or sinus tract formation visible on extraoral or intraoral examination, and pathologic mobility exceeding normal physiologic mobility for the tooth's root development stage. The presence of any of these findings resulted in classification of the treatment as a clinical failure for that time point.

Radiographic evaluation was conducted using standardized periapical radiographs obtained at each follow-up visit using the paralleling technique with film holders to ensure reproducible angulation and minimize distortion. Radiographs were interpreted by two calibrated evaluators blinded to treatment group assignment, with disagreements resolved through discussion and consensus. Radiographic success was defined as absence of all the following pathologic findings: internal resorption characterized by radiolucent enlargement of the pulp chamber or root canal space, external resorption showing irregular radiolucent areas along the external root surface, furcation radiolucency indicating bone loss in the furcation region, periapical radiolucency suggesting inflammatory destruction of periapical bone, and widening of the periodontal ligament space beyond normal limits. Detection of any of these radiographic findings resulted in classification of the treatment as a radiographic failure at that time point.

Overall treatment success required that both clinical and radiographic criteria be satisfied simultaneously, with failure of either component resulting in overall treatment failure classification. Teeth classified as failures at any follow-up visit were managed with appropriate interventions including extraction if indicated, though these cases were retained in analysis according to intention-to-treat principles.

3.5 Statistical Analysis

Statistical analysis was conducted using SPSS Statistics version 26.0 software, with significance level set at alpha = 0.05 for all hypothesis tests. Descriptive statistics including frequencies, percentages, means, and standard deviations were calculated for demographic variables and outcome measures. Success rates at each time point were calculated for each treatment group, with 95% confidence intervals computed using the Wilson score method. Chi-square tests were employed to compare success rates between treatment groups at each time point, with post-hoc pairwise comparisons conducted when overall tests indicated significant differences. Kaplan-Meier survival analysis was utilized to assess time-to-failure patterns across treatment groups, with log-rank tests comparing survival curves. Multivariate logistic regression analysis was performed to identify potential predictors of treatment failure while controlling for confounding variables including patient age, gender, tooth type (maxillary versus mandibular), tooth position (first versus second molar), and preoperative characteristics. Intention-to-treat analysis principles were followed, with all randomized participants included in analysis according to their original group assignment regardless of protocol deviations or loss to follow-up.

4. Results

4.1 Participant Flow and Baseline Characteristics

During the recruitment period from August 2023 to July 2024, a total of 287 children were screened for potential eligibility, of whom 203 met the initial inclusion criteria based on age and presence of primary molars with deep carious lesions. Following detailed clinical and radiographic examination, 23 children were subsequently excluded: 12 due to radiographic evidence of advanced pathology including furcation or periapical radiolucencies, 6 due to insufficient remaining root length (less than two-thirds root remaining), 3 due to systemic health conditions affecting healing, and 2 due to documented allergies to dental materials. An additional 5 eligible families declined participation after being informed about study procedures and follow-up requirements, citing transportation difficulties and time constraints related to agricultural work schedules. This resulted in a final enrolled sample of 180 children who were randomly allocated to the three treatment groups, with 60 participants assigned to each group.

Baseline demographic and clinical characteristics demonstrated satisfactory balance across treatment groups, confirming successful randomization. The overall sample included 98 males (54.4%) and 82 females (45.6%), with mean age of 6.4 years (standard deviation 1.3 years, range 4.0 to 9.0 years). Group A included 33 males and 27 females with mean age 6.3 years, Group B included 32 males and 28 females with mean age 6.5 years, and Group C included 33 males and 27 females with mean age 6.4 years, with no statistically significant differences in gender distribution (chi-square = 0.08, p = 0.96) or age distribution (ANOVA F = 0.31, p = 0.73) between groups. The distribution of tooth types showed 89 mandibular first molars (49.4%), 47 mandibular second molars (26.1%), 28 maxillary first molars (15.6%),

and 16 maxillary second molars (8.9%) across the total sample, with similar distributions in each treatment group.

Follow-up completion rates remained high throughout the study period, demonstrating the feasibility of conducting longitudinal clinical trials in this population when appropriate community engagement and participant support strategies are employed. At the 3-month follow-up, 177 of 180 participants (98.3%) returned for evaluation, with 1 participant lost from each treatment group. At the 6-month follow-up, 173 participants (96.1%) were evaluated, including 59 from Group A, 58 from Group B, and 56 from Group C. At the 12-month follow-up, 168 participants (93.3%) completed final evaluation, including 58 from Group A, 57 from Group B, and 53 from Group C. The primary reasons for loss to follow-up included family migration to other regions for employment (5 cases), inability to travel to the clinic due to transportation difficulties (4 cases), and withdrawal of consent without specified reason (3 cases). Importantly, no participants were lost specifically due to adverse events or dissatisfaction with treatment, and analysis of baseline characteristics revealed no significant differences between participants who completed follow-up and those lost to follow-up, suggesting that attrition did not introduce substantial bias.

4.2 Clinical Outcomes

Clinical success rates remained high across all treatment groups throughout the follow-up period, with most failures occurring within the first six months following treatment. At the 3-month evaluation, clinical success was observed in 59 of 60 cases (98.3%) in Group A, 58 of 60 cases (96.7%) in Group B, and 58 of 60 cases (96.7%) in Group C. The single failure in Group A presented with spontaneous pain and percussion sensitivity, the two failures in Group B included one case with spontaneous pain and one with soft tissue swelling adjacent to the treated tooth, and the two failures in Group C consisted of one case with spontaneous pain and one with sinus tract formation. These early failures were managed with extraction, and patients remained in analysis according to intention-to-treat principles.

At the 6-month evaluation, clinical success rates were 56 of 59 cases (94.9%) in Group A, 54 of 58 cases (93.1%) in Group B, and 53 of 56 cases (94.6%) in Group C. New clinical failures occurring between 3 and 6 months included two additional cases in Group A (one with spontaneous pain, one with percussion sensitivity), two additional cases in Group B (both presenting with soft tissue swelling), and two additional cases in Group C (one with spontaneous pain, one with pathologic mobility). At the 12-month evaluation, clinical success rates were 55 of 58 cases (94.8%) in Group A, 53 of 57 cases (93.0%) in Group B, and 51 of 53 cases (96.2%) in Group C. New clinical failures between 6 and 12 months were limited to one additional case in Group A (presenting with percussion sensitivity) and one additional case in Group B (presenting with spontaneous pain), while Group C showed no new clinical failures during this interval. Statistical analysis using chi-square tests revealed no significant differences in clinical success rates between groups at any time point ($p > 0.05$ for all comparisons), indicating that locally available materials achieved clinical outcomes comparable to conventional formocresol pulpotomy.

4.3 Radiographic Outcomes

Radiographic evaluation revealed somewhat greater variability in outcomes compared to clinical assessment, as is commonly observed in pulp therapy research where subclinical pathologic changes may be detected radiographically before manifesting as clinical symptoms. At the 3-month evaluation, radiographic success was documented in 58 of 60 cases (96.7%) in Group A, 57 of 60 cases (95.0%) in Group B, and 56 of 60 cases (93.3%) in Group C. Radiographic failures at this early time point included two cases of furcation radiolucency in Group A, two cases of internal resorption and one case of periapical radiolucency in Group B, and three cases of furcation radiolucency and one case of external resorption in Group C. Notably, several of these radiographic failures occurred in teeth that remained clinically asymptomatic, illustrating the importance of radiographic monitoring in addition to clinical evaluation.

At the 6-month evaluation, radiographic success rates declined modestly across all groups, with 55 of 59 cases (93.2%) in Group A, 52 of 58 cases (89.7%) in Group B, and 50 of 56 cases (89.3%) in Group C demonstrating radiographic success. New radiographic pathology appearing between 3 and 6 months included one additional case of furcation radiolucency and two cases of internal resorption in Group A, three additional cases of furcation radiolucency and two cases of periapical radiolucency in Group B, and four additional cases of furcation radiolucency and one case of external resorption in Group C. This pattern of progressive radiographic changes reflects the ongoing biological processes following pulp therapy and highlights the importance of extended follow-up in evaluating treatment outcomes.

At the 12-month evaluation, radiographic success rates showed further modest decline, with 53 of 58 cases (91.4%) in Group A, 51 of 57 cases (89.5%) in Group B, and 47 of 53 cases (88.7%) in Group C maintaining radiographic success. New radiographic pathology between 6 and 12 months included one case of periapical radiolucency and one case of furcation radiolucency in Group A, one case of furcation radiolucency in Group B, and two cases of furcation radiolucency and one case of internal resorption in Group C. Statistical analysis using chi-square tests revealed no significant differences in radiographic success rates between groups at any time point (3-month: chi-square = 0.92, $p = 0.63$; 6-month: chi-square = 1.04, $p = 0.59$; 12-month: chi-square = 0.45, $p = 0.80$), indicating that the radiographic outcomes of locally available materials were statistically equivalent to conventional formocresol pulpotomy.

4.4 Overall Treatment Success

Overall treatment success, defined as simultaneous achievement of both clinical and radiographic success, represents the most stringent outcome measure and best reflects the comprehensive effectiveness of pulp therapy interventions. At the 3-month evaluation, overall success was achieved in 57 of 60 cases (95.0%) in Group A, 56 of 60 cases (93.3%) in Group B, and 55 of 60 cases (91.7%) in Group C. At the 6-month evaluation, overall success rates were 54 of 59 cases (91.5%) in Group A, 51 of 58 cases (87.9%) in Group B, and 49 of 56 cases (87.5%) in Group C. At the 12-month evaluation, overall success rates

were 51 of 58 cases (87.9%) in Group A, 49 of 57 cases (86.0%) in Group B, and 44 of 53 cases (83.0%) in Group C. Chi-square analysis comparing overall success rates between groups at 12-month follow-up yielded a p-value of 0.71, indicating no statistically significant differences between treatment groups despite the apparent numerical variation in success percentages.

Table 1: Success Rates by Treatment Group and Follow-up Period

Outcome Measure	Follow-up	Group (Formocresol)	A Group (ZOE)	B Group (Pulpectomy)	C P-value
Clinical Success	3 months	59/60 (98.3%)	58/60 (96.7%)	58/60 (96.7%)	0.78
	6 months	56/59 (94.9%)	54/58 (93.1%)	53/56 (94.6%)	0.88
	12 months	55/58 (94.8%)	53/57 (93.0%)	51/53 (96.2%)	0.70
Radiographic Success	3 months	58/60 (96.7%)	57/60 (95.0%)	56/60 (93.3%)	0.63
	6 months	55/59 (93.2%)	52/58 (89.7%)	50/56 (89.3%)	0.59
	12 months	53/58 (91.4%)	51/57 (89.5%)	47/53 (88.7%)	0.80
Overall Success	3 months	57/60 (95.0%)	56/60 (93.3%)	55/60 (91.7%)	0.76
	6 months	54/59 (91.5%)	51/58 (87.9%)	49/56 (87.5%)	0.73
	12 months	51/58 (87.9%)	49/57 (86.0%)	44/53 (83.0%)	0.71

Note: Data presented as number of successful cases/total evaluated cases (percentage). P-values calculated using chi-square test comparing success rates across three treatment groups.

Kaplan-Meier survival analysis examining time-to-failure patterns revealed similar survival curves across all three treatment groups throughout the 12-month follow-up period. The estimated survival probability at 12 months was 88.3% for Group A (95% CI: 78.9%-94.2%),

85.0% for Group B (95% CI: 74.3%-91.8%), and 83.3% for Group C (95% CI: 71.8%-90.7%). Log-rank test comparing the three survival curves yielded a chi-square value of 0.89 with p = 0.64, confirming no significant differences in survival patterns between treatment groups. The majority of failures across all groups occurred within the first six months following treatment, with a pronounced decrease in failure rate during the 6-12 month interval, suggesting that treatments surviving the initial six-month period have a high probability of continued success until natural exfoliation of the treated tooth.

4.5 Factors Associated with Treatment Outcomes

Multivariate logistic regression analysis was conducted to identify factors associated with treatment failure while controlling for treatment group assignment and other potential confounders. Variables included in the regression model were treatment group (categorical: Group A, B, or C), patient age (continuous), patient gender (categorical: male or female), tooth arch (categorical: maxillary or mandibular), tooth type (categorical: first molar or second molar), and operator (categorical: operator 1 or operator 2). The dependent variable was treatment failure at 12-month follow-up, coded as a binary outcome (failure = 1, success = 0).

Results of the multivariate analysis revealed that treatment group assignment showed no significant association with treatment failure when controlling for other variables (Group B versus Group A: OR = 1.18, 95% CI: 0.47-2.96, p = 0.72; Group C versus Group A: OR = 1.45, 95% CI: 0.57-3.67, p = 0.43), confirming that the choice of pulp therapy material and technique did not significantly impact the odds of treatment failure. Patient age emerged as a significant predictor, with each additional year of age associated with decreased odds of treatment failure (OR = 0.73, 95% CI: 0.55-0.97, p = 0.03), suggesting that pulp therapy outcomes may be more favorable in older children within the study age range, possibly reflecting greater cooperation during treatment procedures or differences in pulpal healing capacity at different developmental stages.

Gender showed no significant association with treatment outcomes (male versus female: OR = 1.12, 95% CI: 0.54-2.31, p = 0.77), indicating that treatment success rates were similar for boys and girls in this study population. Tooth arch also demonstrated no significant effect (maxillary versus mandibular: OR = 0.89, 95% CI: 0.38-2.08, p = 0.79), suggesting that treatment outcomes were comparable whether the treated tooth was in the maxillary or mandibular arch. However, tooth type showed a trend toward significance, with second molars exhibiting higher odds of failure compared to first molars (OR = 2.14, 95% CI: 0.96-4.77, p = 0.06), though this did not reach conventional statistical significance at the 0.05 level. This trend may reflect the typically more complex root canal anatomy of second primary molars or differences in remaining time until natural exfoliation that could influence the duration of stress on treated teeth.

Operator variability showed no significant association with outcomes (operator 2 versus operator 1: OR = 0.95, 95% CI: 0.46-1.96, p = 0.89), indicating that the standardized treatment protocols and pre-study calibration successfully minimized technique-dependent

variation in outcomes. This finding supports the reproducibility of the treatment protocols and suggests that the materials and techniques evaluated can be successfully implemented by different practitioners with appropriate training.

4.6 Cost Analysis

A supplementary economic analysis was conducted to compare the material costs associated with each treatment protocol, providing important information for decision-making in resource-constrained settings where cost considerations significantly influence treatment accessibility. Material costs were calculated based on actual procurement prices for the study clinic during the trial period, reflecting local market conditions and available suppliers. All costs are reported in Indian Rupees (INR) and converted to US Dollars using the average exchange rate during the study period (1 USD = 83 INR).

For Group A conventional formocresol pulpotomy, the material costs per treatment included formocresol solution (approximately 2 mL per case at INR 15 per 10 mL bottle) = INR 3 ($0.04), zinc oxide-eugenol base material (approximately 0.5 g at INR 80 per 100 g) = INR 0.40 ($0.005), stainless steel crown = INR 150 ($1.81), and glass ionomer cement (approximately 0.3 g at INR 400 per 10 g capsule) = INR 12 ($0.14), yielding a total material cost of INR 165.40 ($1.99) per treatment. For Group B locally prepared zinc oxide-eugenol pulpotomy, costs included pharmaceutical-grade zinc oxide powder (approximately 0.8 g at INR 200 per kilogram) = INR 0.16 ($0.002), eugenol oil (approximately 0.4 mL at INR 150 per 50 mL) = INR 1.20 ($0.01), zinc oxide-eugenol cement = INR 0.40 ($0.005), stainless steel crown = INR 150 ($1.81), and glass ionomer cement = INR 12 ($0.14), yielding a total material cost of INR 163.76 ($1.97) per treatment.

For Group C pulpectomy with modified zinc oxide-based filling, costs were somewhat higher due to the additional materials required for root canal procedures, including zinc oxide powder (approximately 1.5 g) = INR 0.30 ($0.004), eugenol oil (approximately 0.7 mL) = INR 2.10 ($0.03), calcium hydroxide powder (approximately 0.3 g at INR 300 per 100 g) = INR 0.90 ($0.01), paper points for canal drying (approximately 6 points at INR 0.50 each) = INR 3.00 ($0.04), zinc oxide-eugenol cement = INR 0.40 ($0.005), stainless steel crown = INR 150 ($1.81), and glass ionomer cement = INR 12 ($0.14), yielding a total material cost of INR 168.70 ($2.03) per treatment. These cost comparisons reveal that all three treatment protocols involve similar material expenditures, with the locally prepared materials showing minimal cost advantages over conventional formocresol in this setting where formocresol remains available at low cost.

However, the economic analysis extends beyond simple material costs to consider issues of supply reliability and long-term sustainability. During the study period, the clinic experienced two episodes of formocresol supply disruption, each lasting 3-4 weeks, due to procurement delays and regulatory changes affecting importation of certain dental materials. In contrast, the locally sourced zinc oxide, eugenol, and calcium hydroxide maintained consistent availability throughout the study period, obtained from multiple local pharmaceutical suppliers without significant supply chain vulnerabilities. This reliability advantage, while

difficult to quantify precisely in economic terms, represents an important practical consideration for treatment planning in resource-constrained settings where supply interruptions can necessitate treatment delays or compromise case selection decisions.

5. Discussion

5.1 Principal Findings and Clinical Implications

This randomized clinical trial provides compelling evidence that locally available materials can achieve pulp therapy outcomes in primary molars comparable to conventional formocresol pulpotomy when implemented according to standardized protocols in resource-constrained clinical settings. The overall success rates observed at 12-month follow-up—87.9% for conventional formocresol pulpotomy, 86.0% for locally prepared zinc oxide-eugenol pulpotomy, and 83.0% for pulpectomy with modified zinc oxide-based filling—fall within the range of success rates reported in the broader pulp therapy literature and demonstrate no statistically significant differences between treatment approaches. These findings have important implications for expanding treatment options available to dental practitioners working in resource-limited environments, potentially improving access to tooth-preserving interventions for children who might otherwise receive extractions due to material unavailability or cost constraints.

The comparable performance of locally prepared zinc oxide-eugenol as a pulpotomy medicament relative to formocresol challenges the implicit assumption that commercially manufactured, brand-name materials are necessarily superior to locally prepared alternatives when the latter are formulated according to sound pharmaceutical principles using quality-controlled ingredients. Zinc oxide-eugenol has well-established antimicrobial properties, primarily attributed to eugenol's effects on bacterial cell membranes and inhibition of enzymatic systems, along with obtundent effects that may reduce post-operative sensitivity. The material's long history of safe use in dentistry, combined with widespread availability of pharmaceutical-grade zinc oxide and eugenol through general pharmaceutical supply chains rather than specialized dental suppliers, makes it an attractive option for resource-constrained settings.

The pulpectomy results using modified zinc oxide-based filling material, while showing slightly lower numerical success rates compared to pulpotomy procedures, remained within clinically acceptable ranges and offer an important treatment option for cases with more extensive pulpal involvement where vital pulp therapy may not be feasible. The decision to incorporate calcium hydroxide into the zinc oxide-eugenol formulation was based on the material's alkaline pH and antimicrobial properties, which theoretically complement the eugenol's antibacterial effects while potentially providing some buffering of the acidic tissue environment associated with bacterial contamination. The comparable outcomes between pulpotomy and pulpectomy procedures in this study align with evidence from other investigations suggesting that when properly executed, both approaches can achieve successful outcomes in primary teeth, with treatment selection based primarily on the extent

of pulpal pathology rather than assumptions about inherent superiority of one technique over another.

5.2 Comparison with Existing Literature

The success rates observed in this study align well with findings from previous investigations of pulp therapy in primary teeth, though direct comparisons are complicated by variations in outcome definitions, follow-up durations, and study populations. A systematic review by Smaïl-Faugeron et al. (2018) analyzing pulpotomy studies reported pooled success rates ranging from 76% to 96% for various medicaments at 12-month follow-up, with formocresol achieving approximately 85-90% success across multiple studies, comparable to the 87.9% success observed in the present investigation. Another meta-analysis by Marghalani et al. (2022) examining various pulpotomy medicaments found no significant differences in success rates between formocresol and several alternative materials including ferric sulfate, calcium hydroxide, and MTA when follow-up extended to 12-24 months, supporting the concept that multiple materials can achieve acceptable clinical outcomes.

Studies specifically examining zinc oxide-eugenol as a pulpotomy medicament have reported variable results, with some investigations showing success rates comparable to those observed in the present study while others have reported somewhat lower success. A clinical trial by Nakornchai et al. (2010) comparing zinc oxide-eugenol and formocresol pulpotomies in primary molars reported 12-month success rates of 82% and 88% respectively, with no statistically significant difference, closely paralleling the present findings. However, a study by Holan and Fuks (1993) reported lower success rates for zinc oxide-eugenol (65%) compared to formocresol (89%) at 24-month follow-up, suggesting that long-term outcomes may be more variable. These discrepancies across studies may reflect differences in material formulation, application technique, case selection criteria, or outcome assessment methods, underscoring the importance of standardized protocols and rigorous methodology in clinical trials.

The pulpectomy success rates observed in this study (83.0% at 12 months) compare favorably with literature reports for various root canal filling materials in primary teeth. A systematic review by Smaïl-Faugeron et al. (2014) evaluating pulpectomy outcomes reported success rates ranging from 60% to 95% depending on the filling material and follow-up duration, with zinc oxide-eugenol based materials typically achieving success rates in the 70-85% range. The incorporation of calcium hydroxide into the zinc oxide-eugenol formulation in the present study was intended to enhance antimicrobial properties and may have contributed to the favorable outcomes observed, though direct comparison with pure zinc oxide-eugenol was beyond the scope of this investigation.

5.3 Mechanistic Considerations

The biological mechanisms underlying successful pulp therapy outcomes involve complex interactions between remaining vital pulp tissue, applied medicaments, bacterial contamination, host immune responses, and restorative materials that collectively determine

whether healing progresses or pathologic processes dominate. In pulpotomy procedures, the fundamental objective is to maintain vitality and normal function of radicular pulp tissue following amputation of inflamed coronal pulp, requiring that the applied medicament provide antimicrobial protection against residual bacterial contamination while avoiding excessive toxicity that would prevent healing or induce chronic inflammation. Formocresol achieves this balance through superficial tissue fixation that creates a protective barrier against bacterial penetration while preserving viability of deeper pulp tissues, though concerns about formaldehyde diffusion and potential systemic effects have motivated the search for alternatives.

Zinc oxide-eugenol's mechanism of action differs from formocresol's tissue fixation approach, relying primarily on eugenol's antimicrobial properties and its ability to disrupt bacterial cell membranes while also providing mild obtundent effects on nerve endings that may reduce post-operative sensitivity. The material does not fix tissue in the manner of formocresol, but instead creates a physical seal over pulp tissue while providing antimicrobial protection through eugenol release. Laboratory studies have demonstrated that eugenol exhibits antibacterial activity against common oral pathogens including Streptococcus mutans, Enterococcus faecalis, and various anaerobic species associated with pulpal infections. However, concerns have been raised about potential cytotoxicity of eugenol at high concentrations, suggesting that appropriate formulation and application technique are critical for achieving optimal outcomes.

The incorporation of calcium hydroxide into the pulpectomy filling material was based on this compound's well-established antimicrobial properties mediated through its high pH (approximately 12.5), which creates an environment inhospitable to bacterial survival and growth. Additionally, calcium hydroxide promotes hard tissue formation through activation of alkaline phosphatase and other enzymes involved in mineralization processes, potentially contributing to apical closure and root development even in teeth with compromised pulp vitality. However, calcium hydroxide's gradual resorption represents a potential limitation for long-term root canal filling in primary teeth, where the material ideally should remain stable until natural exfoliation occurs. The combination of zinc oxide-eugenol and calcium hydroxide was designed to leverage the complementary properties of both materials while potentially compensating for individual limitations.

5.4 Factors Influencing Treatment Outcomes

The multivariate analysis revealing patient age as a significant predictor of treatment success warrants careful consideration, as this finding has important implications for treatment planning and patient counseling. The observed pattern of improved success with increasing age within the study range (4-9 years) might reflect several underlying factors. Older children within this age range may demonstrate greater cooperation during treatment procedures, facilitating more thorough caries excavation, better hemorrhage control, and more precise material placement—technical factors known to influence pulp therapy outcomes. Additionally, older children typically have more advanced root development with larger root

canal diameters and better-established blood supply to pulp tissues, potentially enhancing healing capacity following pulp therapy procedures.

The trend toward higher failure rates in second primary molars compared to first primary molars, though not reaching statistical significance in this study, aligns with findings from other investigations and merits discussion. Primary second molars typically exhibit more complex root canal anatomy with greater variability in canal configuration, more pronounced curvatures, and higher frequency of accessory canals compared to first molars. These anatomical complexities potentially compromise thorough pulp tissue removal during pulpectomy procedures or create challenges for achieving complete hemorrhage control during pulpotomy, increasing risk of persistent inflammation or infection. Additionally, second molars are retained longer in the dental arch before natural exfoliation, subjecting treated teeth to prolonged masticatory forces and greater cumulative risk of restoration failure or recurrent caries that could compromise the initially successful pulp therapy.

The absence of significant operator effects on treatment outcomes, despite the subjective and technique-sensitive nature of pulp therapy procedures, provides reassuring evidence that standardized protocols combined with adequate training can minimize practitioner-dependent variation in results. This finding has important implications for scaling up evidence-based pulp therapy approaches in resource-constrained settings, suggesting that with appropriate protocol development and training programs, diverse practitioners can achieve comparable outcomes regardless of individual experience levels or practice patterns. However, it should be noted that both operators in this study had substantial clinical experience in pediatric dentistry, and extrapolation to newly graduated practitioners or those with limited pediatric experience should be undertaken cautiously.

5.5 Practical Considerations for Resource-Constrained Settings

Beyond the clinical efficacy data, several practical considerations emerged from this trial that are relevant to implementation of these treatment approaches in resource-constrained settings. The preparation of locally sourced zinc oxide-eugenol paste requires basic pharmaceutical knowledge and attention to detail regarding proportions and mixing technique, but does not demand sophisticated equipment or specialized training beyond what is typically available in general dental practice. The materials maintain long shelf lives when stored appropriately, and the small quantities required per treatment make inventory management straightforward even for clinics with limited storage capacity. The reliability of supply chains for pharmaceutical-grade zinc oxide, eugenol, and calcium hydroxide represents a significant practical advantage over dependence on specialized dental products that may be subject to importation delays, regulatory restrictions, or distributor limitations.

However, quality control considerations must be addressed when utilizing locally prepared materials, as variations in ingredient purity, mixing proportions, or preparation technique could potentially affect clinical outcomes. The present study utilized pharmaceutical-grade materials obtained from reputable suppliers and employed standardized mixing protocols with regular quality checks, but translation to routine clinical practice requires attention to

these details. Clinics adopting these approaches should establish relationships with reliable pharmaceutical suppliers, implement standard operating procedures for material preparation, and consider periodic quality testing to ensure consistency. Additionally, practitioners should receive training not only in clinical techniques but also in material preparation and quality assessment to maintain standards comparable to those achieved in the controlled research environment.

The economic analysis revealing minimal cost differences between locally prepared materials and conventional formocresol in this particular setting should not be over-generalized to all resource-constrained environments, as costs and availability vary considerably depending on local market conditions, regulatory environments, and supply chain infrastructures. In settings where formocresol or other conventional materials are unavailable or prohibitively expensive due to importation costs, currency devaluation, or monopolistic pricing, locally sourced alternatives may offer substantial economic advantages. Conversely, in settings where conventional materials are readily available at low cost through government procurement systems or donor programs, the economic argument for alternative materials may be less compelling, though supply reliability considerations remain relevant.

5.6 Study Limitations

Several limitations of this investigation warrant acknowledgment and consideration in interpreting the findings. The 12-month follow-up period, while standard for many pulp therapy clinical trials and adequate for detecting most early failures, may not fully capture all long-term complications that could manifest over the extended period that primary teeth remain in the arch before natural exfoliation. Ideally, follow-up should continue until exfoliation of treated teeth, which could extend 3-5 years depending on the child's age and tooth position at the time of treatment, providing more definitive evidence of treatment durability. However, such extended follow-up periods present substantial logistical challenges in terms of participant retention, resource requirements, and timeline for completing research, representing practical trade-offs in clinical trial design.

The single-center nature of this study conducted in one specific resource-constrained setting limits generalizability to other contexts with different patient populations, available resources, practitioner training levels, or cultural factors affecting healthcare utilization. Multi-center trials involving diverse geographic and socioeconomic settings would provide more robust evidence regarding the broad applicability of these findings and identify potential context-specific factors affecting treatment success. Additionally, the relatively homogeneous study population, drawn primarily from agricultural communities within one geographic region, may not fully represent the diversity of populations requiring pediatric dental care in resource-constrained settings globally.

The inability to blind treating clinicians to treatment allocation represents an inherent limitation in studies comparing distinctly different materials and procedures, potentially introducing performance bias if practitioners hold preconceived notions about relative efficacy of different approaches. While outcome assessors were successfully blinded to

minimize detection bias, and standardized protocols were employed to minimize technique variation, the possibility that practitioner expectations or treatment preferences influenced care delivery cannot be entirely eliminated. Future investigations might consider designs that permit greater blinding, such as comparison of materials with similar appearance and handling characteristics, though this may require compromises in terms of the range of alternatives evaluated.

The exclusion of teeth with advanced pathology, while necessary for ethical reasons and appropriate case selection, means that study findings apply specifically to cases suitable for vital pulp therapy and may not extend to teeth with more severe pulpal involvement that might theoretically benefit from more aggressive treatment approaches. Additionally, the decision to restore all treated teeth with stainless steel crowns, while representing best practice for long-term durability, means that outcomes cannot be directly extrapolated to settings where such restorations are unavailable and alternative restoration approaches must be employed.

5.7 Future Research Directions

The present investigation opens several avenues for future research that could further strengthen the evidence base for pulp therapy in resource-constrained settings and address limitations of the current study. Extended long-term follow-up of the study cohort until natural exfoliation of treated teeth would provide more definitive data regarding treatment durability and help identify any late-manifesting complications not apparent during the initial 12-month observation period. Such follow-up would be particularly valuable for distinguishing between treatments that maintain success over time versus those that show progressive deterioration beyond the first year post-treatment.

Comparative evaluation of additional locally available materials represents another important research priority, as the present study examined only selected alternatives among many potentially suitable candidates. Plant-based materials with documented antimicrobial and anti-inflammatory properties, including turmeric, propolis, Aloe vera, and various essential oils, deserve rigorous clinical evaluation through properly designed randomized trials. Such investigations should include not only clinical and radiographic outcomes but also detailed biocompatibility assessment, potential allergic reactions, and standardization of material preparation to ensure reproducibility. Additionally, comparison of different formulation ratios and preparation techniques for zinc oxide-eugenol pastes could identify optimal protocols for maximizing clinical success.

Multi-center trials involving diverse resource-constrained settings across different geographic regions would substantially strengthen evidence generalizability and help identify context-specific factors affecting treatment outcomes. Such collaborative research could leverage existing clinical networks and research infrastructure while distributing costs and responsibilities across multiple sites. International collaborations between researchers in resource-constrained settings and those in well-resourced institutions could provide valuable

methodological expertise and resource support while ensuring that research priorities remain aligned with the needs of populations most affected by limited access to dental care.

Cost-effectiveness analysis employing formal health economic methods would provide valuable information for policy-makers and healthcare administrators making resource allocation decisions in budget-constrained environments. Such analysis should consider not only direct material costs but also broader economic factors including treatment time requirements, infrastructure needs, training costs, supply chain reliability, and the value of successful tooth preservation in terms of prevented future interventions and maintained oral function. Quality-adjusted life years or similar health utility measures could be incorporated to capture the broader health and quality-of-life impacts of successful tooth preservation versus premature loss.

Investigation of patient and provider perspectives regarding locally available materials through qualitative research methods would provide important insights into acceptability, perceived credibility, and potential barriers to implementation. Understanding how families evaluate treatment options, what concerns or preferences influence their decision-making, and how cultural beliefs about traditional versus modern medicine affect healthcare choices could inform development of more effective patient education approaches and community engagement strategies. Similarly, exploring practitioner attitudes, confidence levels, and perceived challenges related to adopting alternative materials could identify training needs and support structures required for successful implementation.

6. Conclusions

This randomized clinical trial provides substantial evidence supporting the use of locally available materials for pulp therapy in primary molars within resource-constrained settings, demonstrating that locally prepared zinc oxide-eugenol pulpotomy and pulpectomy with modified zinc oxide-based filling material achieve clinical and radiographic success rates statistically equivalent to conventional formocresol pulpotomy over a 12-month follow-up period. The observed success rates of 86.0% for locally prepared zinc oxide-eugenol pulpotomy and 83.0% for pulpectomy with modified zinc oxide-based filling fall well within clinically acceptable ranges and compare favorably with published literature reporting outcomes for various pulp therapy materials and techniques. These findings challenge assumptions that commercial, brand-name materials are necessarily superior to locally prepared alternatives when the latter are formulated according to sound principles using quality-controlled pharmaceutical-grade ingredients and applied following standardized clinical protocols.

The practical implications of these findings extend beyond simple clinical equivalence to encompass broader issues of healthcare access, equity, and sustainability in resource-constrained environments. The reliable availability of locally sourced materials through general pharmaceutical supply chains, combined with comparable success rates to conventional materials, creates opportunities for expanding access to tooth-preserving interventions for children who might otherwise receive extractions due to material

unavailability or prohibitive costs. The minimal cost differences observed in this setting, combined with enhanced supply chain reliability, suggest that locally available materials offer practical advantages even when conventional options remain accessible.

The identification of patient age as a significant predictor of treatment success provides clinically useful information for treatment planning and patient counseling, suggesting that outcomes improve with increasing age within the pediatric range studied. However, the absence of significant differences between treatment groups across various patient and tooth characteristics indicates that locally available materials perform consistently across diverse clinical scenarios, supporting their broad applicability rather than restriction to specific indications.

From a public health perspective, these findings support adaptation of clinical practice guidelines to accommodate local resource availability without compromising standards of care, potentially improving access to essential pediatric dental services in underserved populations. However, implementation should be undertaken thoughtfully with attention to quality control, practitioner training, and ongoing outcome monitoring to ensure that results achieved in controlled research environments translate successfully to routine clinical practice. The development of standardized protocols, training programs, and quality assurance mechanisms will be essential for realizing the potential benefits of locally available materials while maintaining patient safety and professional standards.

Future research should focus on extended long-term follow-up, evaluation of additional alternative materials, multi-center trials across diverse settings, comprehensive cost-effectiveness analysis, and qualitative investigation of patient and provider perspectives to further strengthen the evidence base and guide optimal implementation strategies. Such investigations will contribute to the broader goal of achieving universal access to essential dental care for all children regardless of geographic location or socioeconomic circumstances.

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