

ABSTRACT

The objective of this single-arm clinical study was to assess the clinical success of the Lesion Sterilization and Tissue Repair (LSTR) technique for the management of necrotic primary molars in children in Pennsylvania, United States, over a 12-month follow-up period. Children aged 4–10 years presenting with primary molars exhibiting signs of pulpal necrosis—including pain on mastication, spontaneous pain, draining sinus tract, fistula, or abscess—were recruited. Eligible teeth received LSTR therapy using a triple-antibiotic paste pulpotomy. Clinical success was defined as tooth retention without pain at 12 months following treatment. Thirty-three primary posterior teeth were included. Of these, 16 teeth demonstrated clinical success (48%). Twelve teeth (36%) were lost to follow-up before the 12-month evaluation, and five teeth (15%) were classified as treatment failures. Given the anatomical and behavioral challenges associated with root canal therapy in primary dentition—including thin dentinal walls, root divergence, physiologic resorption, and limited patient cooperation—LSTR represents a viable alternative to traditional pulpectomy. For primary teeth exhibiting signs of irreversible pulpitis or necrosis, LSTR may offer a conservative treatment option that avoids premature extraction. Appropriate informed consent and careful management of parental expectations remain essential components of care.

INTRODUCTION

Dental caries remains the most prevalent chronic disease of childhood, affecting 21.4% of children aged 2–5 years and 50.5% of children aged 6–11 years in the United States.¹ When left untreated, carious lesions may progress to irreversible pulpitis, pulpal necrosis, dentoalveolar abscess, and potentially life-threatening complications.

Management of pulpal necrosis in primary molars presents a significant clinical challenge. Conventional pulpectomy, while considered the standard of care, is technically demanding due to anatomical complexities inherent to the primary dentition, including thin dentinal walls, divergent root morphology, accessory canals, and progressive physiologic root resorption.² These factors, compounded by limited patient cooperation in young children, can render complete mechanical debridement of the root canal system impractical. Early loss of primary teeth carries its own consequences, including space loss, ectopic eruption, and functional or speech impairment.³

Lesion Sterilization and Tissue Repair (LSTR) is a biologically driven alternative in which a triple antibiotic paste—comprising metronidazole, ciprofloxacin, and clindamycin—is applied to the pulp chamber to eliminate polymicrobial infection and facilitate periapical tissue repair without full root canal instrumentation.⁴ Per the 2025–2026 American Academy of Pediatric Dentistry (AAPD) guidelines, LSTR should be chosen over pulpectomy in primary teeth with significant root resorption, or to retain teeth for up to 12 months that would otherwise be extracted.⁵

Comparative studies have demonstrated clinical success rates of LSTR comparable to conventional pulpectomy with ZOE at 12 months (86.4% vs. 90.9%), with LSTR requiring significantly less chair time (61.4 min vs. 145.1 min, $P < 0.001$).⁶ A systematic review comparing LSTR to Vitapex likewise found equivalent clinical success at 12 months, supporting LSTR as a viable minimally invasive alternative.⁷

Despite this promising evidence base, published clinical data on LSTR outcomes in North American pediatric populations remain limited. This study aimed to evaluate the 12-month clinical success of LSTR therapy in children aged 4–10 years presenting with necrotic primary molars at St. Christopher's Hospital for Children in Philadelphia, Pennsylvania.

MATERIALS AND METHODS

This prospective, single-arm clinical evaluation was conducted at St. Christopher's Hospital for Children in Philadelphia, PA. The protocol received Institutional Review Board approval (IRB #1907007269), originally in 2020 and modified in 2025 to include additional co-investigators. This ongoing study currently targets a final enrollment of 50 teeth with comprehensive 12-month follow-up data.

Participants included pediatric patients aged 4–10 years, categorized as ASA Class I or II, and exhibiting cooperative behavior (Frankl Behavior Rating 3–4).

Inclusion Criteria:

Primary molars with deep caries approximating the pulp.
Clinical diagnosis of pulpal necrosis (spontaneous/nocturnal pain, pain on mastication, intraoral abscess, or draining fistula).
Radiographic evidence of periapical or furcation radiolucencies.
Presence of a succedaneous tooth with less than 2/3 root resorption.

Exclusion Criteria:

Allergy to any component of the antibiotic paste.
Excessive internal or external root resorption (>3/4 of the root structure).
Proximity to natural exfoliation or perforated pulpal floor.
High risk for infective endocarditis or significant pathologic mobility (Grade 2+).

Treatment Protocol (LSTR):

Isolation was strictly maintained using a rubber dam or IsoDry. After complete caries excavation, the pulp chamber was accessed and irrigated with chlorhexidine. A round bur was utilized to create a specific medication cavity at each canal orifice.

The medication used was a 3Mix-MP alternate paste, specifically compounded by the St. Christopher's internal pharmacy:

3Mix-MP Alternate Paste Composition

| Component | Concentration | Function |
|---------------|---------------|---|
| Metronidazole | 30% | Targets obligate anaerobes |
| Ciprofloxacin | 30% | Broad-spectrum bactericidal |
| Clindamycin | 30% | Targets Gram-positive and anaerobic cocci |
| Iodoform | 10% | Radio-opacifier and antimicrobial enhancement |

*Data compiled from internal pharmacy, St. Christopher's Hospital for Children, Philadelphia, PA.

Fig. 1: Alternate Paste composition

The paste was deposited into each orifice reservoir, and the access was sealed with Fuji II LC. Final restoration consisted of a stainless-steel crown cemented with Glass Ionomer Cement (GIC).

Follow-Up and Success Criteria:

Clinical and radiographic evaluations were performed at 1, 3, 6, and 12 months. Each recall included a periapical radiograph to monitor for healing or progression of pathology.

Success was defined as:

Clinical: Tooth retention without pain, absence of soft tissue pathology (fistula/swelling), and normal function.
Radiographic: Reduction or stabilization of periapical/furcation radiolucencies and absence of new pathological progression.

RESULTS

In this ongoing study, 33 primary posterior teeth in children aged 4–10 years received LSTR therapy. Clinical success was defined as tooth retention without pain, absence of soft tissue pathology, and no radiographic progression at 12 months.

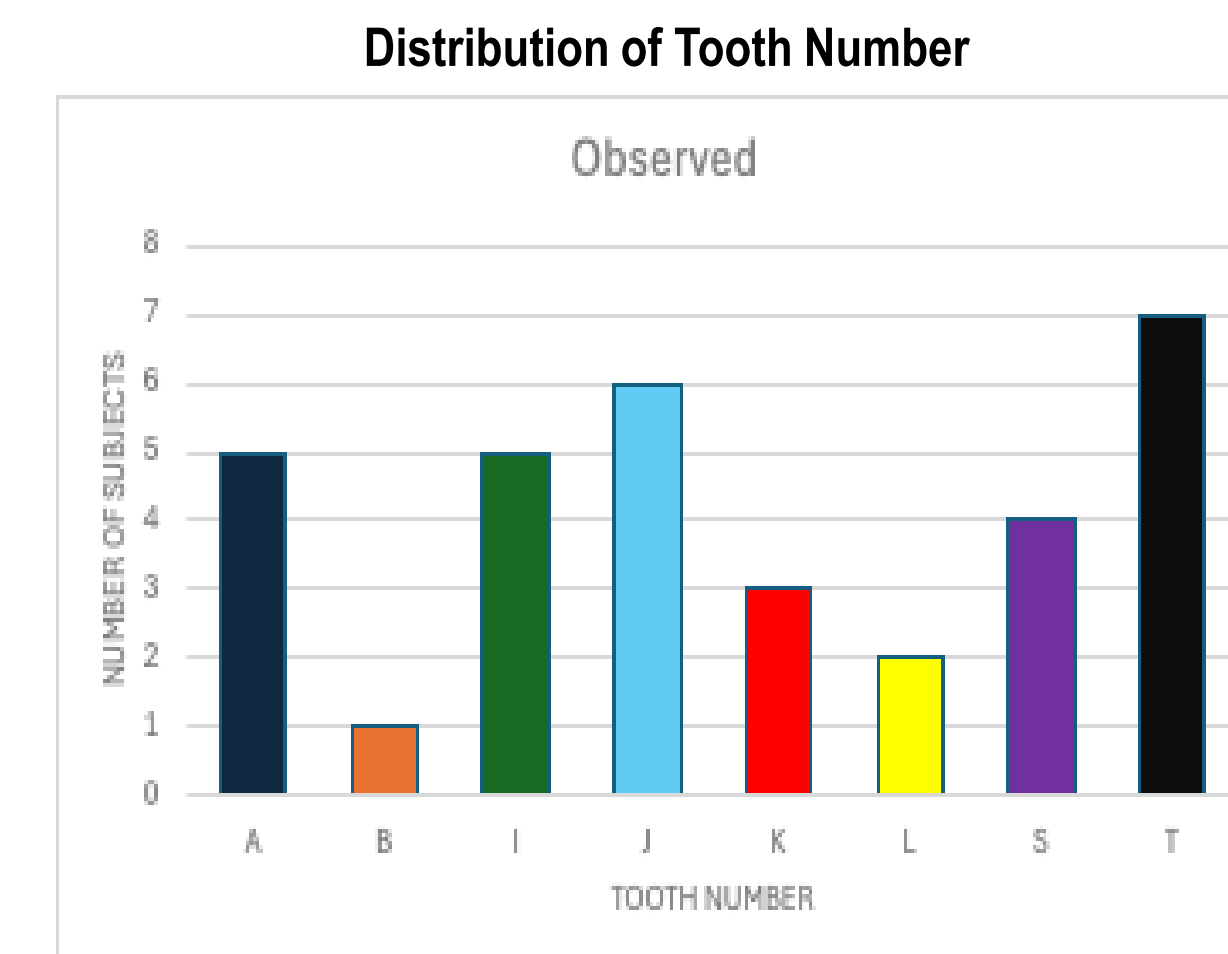


Fig 2: Distribution of treated teeth with LSTR

The majority of cases were symptomatic, with pain and abscess formation being the most prevalent indicators for LSTR treatment. Specifically, 30.3% (n=10) of subjects presented with pain alone, while another 30.3% (n=10) exhibited a combination of both pain and abscess. Abscess formation in the absence of other clinical symptoms was noted in 24.2% (n=8) of the cases. Only a small fraction of the sample showed signs of pathologic mobility, with one subject (3.0%) presenting with mobility and pain, and no subjects presenting with mobility alone or mobility combined with an abscess. Notably, 12.1% (n=4) of the teeth were asymptomatic, identified only through radiographic signs. These findings underscore the significant clinical burden—primarily infection and discomfort—characterizing the teeth selected for this LSTR intervention.

| Sign/Symptom at Initial Presentation | # of Subjects |
|--------------------------------------|-----------------|
| Radiographic Signs Only | 4 |
| Abscess Only | 8 |
| Pain Only | 10 |
| Pain + Abscess | 10 |
| Pathologic Mobility + Abscess | 0 |
| Pathologic Mobility + Pain | 1 |
| Pathologic Mobility Only | 0 |
| TOTAL | 33 Teeth |

Fig 3: Presented signs and symptoms prior to treatment

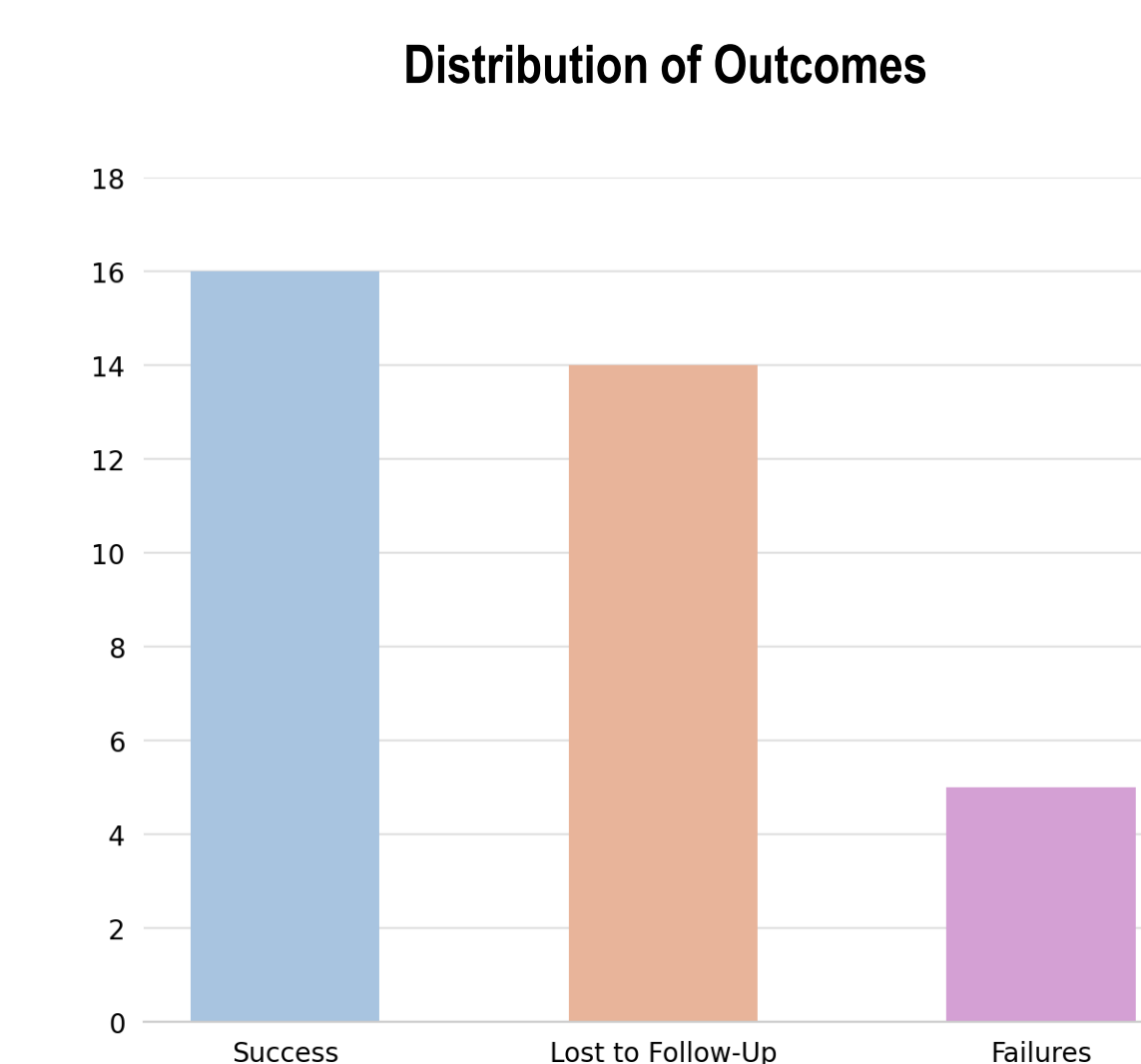


Fig 4: Distribution of outcomes of study

At the 12-month follow-up, clinical success was observed in 16 teeth (48%). Twelve teeth (36%) were lost to follow-up prior to the 12-month evaluation. Treatment failure requiring extraction occurred in 5 teeth (15%). Notably, among teeth that were followed for at least 6 months, a 100% success rate was observed with no concerning clinical signs.

Follow-Up to Failure

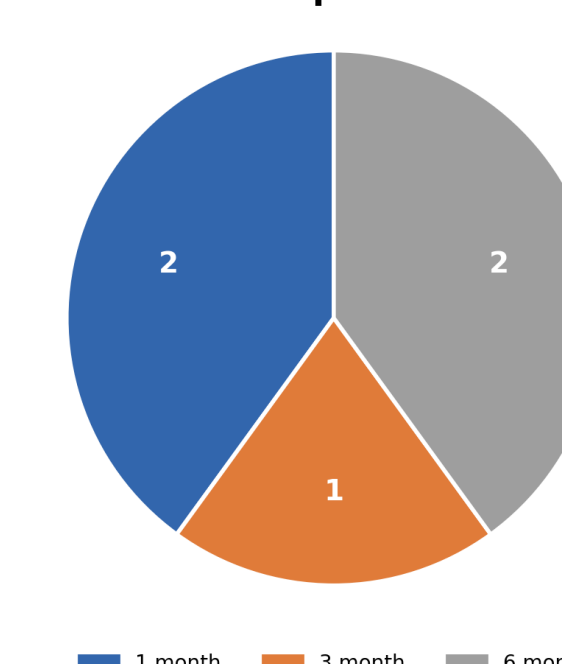


Fig 5: Pie chart of different failure categories

Treatment failures occurred at multiple time points and were associated with different clinical findings. At 1 month, all failures (n=2) were due to pain. At 3 months, one failure was attributed to abscess formation. By 6 months, failures (n=2) were associated with worsening radiographic findings or loss of the crown or medication. No specific tooth type or initial presenting symptom was found to be predictive of treatment failure.

DISCUSSION

This ongoing study presents promising early data on LSTR as a pulp therapy alternative for primary posterior teeth, with several findings warranting attention.

The clinical profile of included teeth reflects real-world practice: the majority presented with pain, abscess, or both, confirming that LSTR is being applied to teeth with significant pulpal and periradicular involvement. The small subset of asymptomatic teeth identified radiographically highlights the role of routine imaging in identifying occult pathology amenable to early intervention.

The 48% clinical success rate at 12 months must be interpreted with caution given the substantial loss to follow-up (36%). When restricted to teeth with at least 6 months of documented follow-up, a 100% success rate was observed — a finding that suggests LSTR may be highly effective when patients remain engaged in care. The loss-to-follow-up rate likely reflects the realities of pediatric populations, where compliance, caregiver engagement, and scheduling barriers are well-documented challenges rather than true treatment failure.

Treatment failures were distributed across early, mid, and later time points and were associated with different clinical presentations — early failures driven by pain, later ones by radiographic deterioration or loss of the restorative seal. This temporal pattern suggests that different failure mechanisms may be operative at different stages, and that close monitoring at 1 and 3 months may be particularly important for identifying at-risk cases early. Notably, neither tooth type nor initial presenting symptom predicted failure, which limits the ability to risk-stratify patients preoperatively and underscores the need for consistent follow-up regardless of presentation.

These findings align with existing literature suggesting that LSTR can achieve meaningful clinical success in primary teeth, particularly in settings where pulpectomy may be technically challenging or when patient cooperation is limited. The high attrition rate remains a significant limitation and will be addressed as the study continues to enroll and follow participants. Future analyses with larger sample sizes and more complete follow-up data will be essential to establish more definitive efficacy estimates and to explore predictors of success and failure.

CONCLUSION

In this real-world clinical evaluation, LSTR was investigated as an alternative treatment modality for necrotic primary molars, yielding a clinical success rate of 48% at 12 months (16/33 teeth). Analysis of the cohort revealed that early outcomes were crucial predictors of long-term prognosis: all teeth remaining stable at the 6-month follow-up demonstrated 100% ultimate clinical success, suggesting that stability in this critical early window indicates a positive prognosis. Conversely, the vast majority of failures occurred within the first 3 months post-procedure, typically presenting with pain or abscess formation, highlighting the need for careful early monitoring. Crucially, the analysis indicated that no specific tooth type (e.g., first vs. second molar) or specific initial presenting symptom pattern (e.g., pain, abscess, or asymptomatic) was predictive of treatment failure, reinforcing that patient and procedural factors may be equally impactful variables.

Based on these results, LSTR remains a viable, time-efficient alternative to pulpectomy, particularly in challenging clinical situations such as advanced root resorption where conventional treatment is not possible, or in cases involving limited patient cooperation where reduced chair time is paramount. However, several critical limitations must be considered. The current data set is preliminary with a small sample size (n=33). Furthermore, the exceptionally high rate of loss to follow-up (36%) significantly limits our ability to draw reliable conclusions about long-term sustainability beyond 12 months. Additional confounding factors may include unblinded outcome assessment (susceptible to observer bias), potential inter-examiner variability in diagnosis, and unanalyzed patient behavioral factors which may contribute to poor isolation or secondary restoration loss, confounding the failure analysis.

To address these challenges, continued enrollment toward our target of 50 teeth with complete 12-month follow-up is already underway. Future large-scale, prospective randomized controlled trials comparing LSTR directly to standard pulpectomy in North American populations are urgently warranted to validate these preliminary findings. Furthermore, implementing more robust structured recall protocols and improved parental education is essential to minimize loss to follow-up and optimize overall patient outcomes for this promising technique.

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