LESION STERILISATION AND TISSUE REPAIR ANTIBIOTIC PASTE VERSUS ZINC OXIDE AND EUGENOL PULPECTOMY FOR TREATMENT OF PRIMARY MOLARS WITH PULP NECROSIS

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INTRODUCTION:

Severe carious lesions on primary teeth frequently lead to infectious changes in the dental pulp, due to the thinner and more porous calcified dentin and the reduced protective ability of the dentin-pulp complexes. The main diagnoses of dental pulp disorders encompassed chronic hypertrophy, purulent gangrenous variants, and necrotic forms[1]. Pulpal infections occur more rapidly in primary teeth due to their distinct form and structure compared to permanent teeth[2]. Teeth that are pathological, have considerable surface deterioration, lack sufficient bone support, and demonstrate extensive root resorption are frequently considered for extraction. The premature loss of teeth results in several complications, including the displacement of neighboring teeth, interruption of the normal eruption sequence, insufficient room for permanent teeth, alterations in speech, and diminished usefulness[3,4]. TA substitute to extraction is endodontic treatment, sometimes known as pulpectomy. Pulpectomy of necrotic primary molars is a considerable challenge in juvenile dental clinics. The intricacy of root canal anatomy and the protracted duration of therapy are the principal concerns. Moreover, endodontic therapy in juvenile patients requires their cooperation. The increased challenge in detecting root resorption limits the precise determination of the actual working length[5].

Simpler methods utilizing antibiotic pastes have been recommended in mainstream clinical practice due to the limitations of primary tooth root canal preparation. Without preparing the canal, these pastes are placed to the pulp chamber floor[3]. Necrotic primary teeth have been treated with zinc oxide and eugenol (ZOE) paste since 1930. Radiopacity, tissue compatibility, and antibacterial properties define ZOE paste. ZOE endodontics provides outstanding radiological and clinical results5. A new, less-invasive, more effective approach may give physicians and patients hope. Lesion sterilization and tissue repair (LSTR) supports numerous therapeutic uses. The goal is to eliminate pulp germs with a simpler way. The LSTR treatment technique focused on restoring primary teeth with a particular antibiotic combination. Antibacterial paste targets several microorganisms. The LSTR approach validated on major teeth with multiple roots yielded good prognostic findings. This reduces or eliminates clinical and radiographic symptoms without preventing permanent tooth formation1. When extraction or pulpectomy is not possible due to a poor prognosis, lesion sterilization and tissue healing are ideal[4–8]. In one research, the effectiveness of ZOE pulpectomy and LSTR antibiotic paste

in treating necrotic primary molars was examined. After six months, the effectiveness in terms of overall success was 23 (52.3%) in ZOE and 32 (72.7%) in LSTR[5].

The management of necrotic primary teeth remains a subject of debate, with no established consensus on the optimal endodontic procedure or restorative material. This study is designed to compare the effectiveness of ZOE pulpectomy with the LSTR technique using a triple antibiotic paste in primary molars affected by pulp necrosis. The findings aim to identify the superior treatment approach, thereby enhancing tooth retention and minimizing the risk of early tooth loss and postoperative complications.

OBJECTIVE:

To compare the efficacy of lesion sterilization and tissue repair antibiotic paste versus ZnO and Eugenol pulpectomy for treatment of Primary molars with Pulp Necrosis

OPERATIONAL DEFINITION:

Pulp Necrosis: will be identified radiographically by the presence of a radiolucent area in the furcation or periapical region, loss of lamina dura, or widening of the periodontal ligament space on intraoral periapical radiographs.

Efficacy: Each tooth will be labeled with its overall success, which will include only those who passed both clinical and radiographic examinations after six months. Clinical success will be defined as the absence of nasal tract edema and/or peeling. Radiographic success criteria will include the initial radiolucent region being missing, reduced in size, or completely vanishing, as well as the lack of any new radiolucency.

HYPOTHESIS:

Null Hypothesis

There is no difference in the efficacy of LSTR antibiotic paste versus ZOE for treatment of Primary molars with Pulp Necrosis.

Alternate Hypothesis

There is a difference in the efficacy of LST antibiotic paste versus ZOE for treatment of Primary molars with Pulp Necrosis

MATERIAL AND METHODS:

Study design: Randomized Controlled Trial.

Study setting: Department of Operative Dentistry, MTH, Faisalabad.

Duration of study: 1 year after synopsis approval

Sample size: By using WHO calculator for two proportions at

Significance level (α)	=	5%
Power of test	=	80%
Proportion in Group A(p1)	=	72.70%[5]
Proportion in Group B (p2)	=	52.30%[5]
Sample size	=	180 (90 in each group)

Sampling Technique: Non-Probability Consecutive Sampling.

SAMPLE SELECTION

Inclusion criteria:

- Children of both genders
- 4 years and 10 years
- Pulp necrosis in mandibular primary molars with minimum of 2/3 of the roots
- Consent from Parents/Guardian of children.
- Sufficient crown structure for restoration.

Exclusion criteria:

- Children who have a physical or mental change.
- Involving systemic illnesses.
- History of allergy to drugs being utilized
- Antibiotics use within three months
- Teeth with aberrant root resorption or pulp canal obliteration on periapical radiography

Data collection procedure:

After receiving ethical permission from CPSP and The University of Faisalabad's ERB, this project will start. Once their guardians have given their verbal approval, eligible patients will be registered. Pulp necrosis will be diagnosed using a predetermined operational definition. Using a straightforward random table, patients will be divided into two groups at random. The lead researcher will carry out every process. We'll employ standard behavior control strategies. Local anesthesia will be administered after topical anesthetic (2% lignocaine gel). Following rubber dam isolation, normal procedures will be used to remove soft caries and open the access.

- Group A (LSTR): After chamber irrigation with 3% NaOCl and drying, CTZ paste (chloramphenicol, tetracycline, zinc oxide mixed with eugenol) will be prepared from encapsulated powders and applied to the pulp chamber. The cavity will be restored with resin-modified glass ionomer cement.
- Group B (ZOE Pulpectomy): Following working length determination via radiograph, canal debridement will be performed using K-files and 3% NaOCl. ZOE paste will be prepared from encapsulated ZnO mixed with eugenol and placed manually in canals, 2 mm short of the apex. Final restoration will be with resin-modified glass ionomer.

At six months, patients will have a clinical and radiological evaluation. By collecting the patients' mobile numbers, follow-up will be guaranteed. After six months, efficacy will be noted in both clinical and radiographic studies. The lack of nasal tract edema and/or peeling will be considered a clinical success. Success in radiography will be determined by whether the original radiolucent region is gone, shrinks in size, or vanishes completely, as well as by if no new radiolucency appears.

Data analysis:

SPSS version 25.0 will be used to analyze the data. Frequencies and percentages will be used to display categorical factors such gender, radiolucency, edema, root resorption, tooth mobility, and treatment effectiveness. The mean ± standard deviation will be used to represent the continuous variable, age. The effectiveness of the two groups' treatments will be compared using the Chi-square test. To manage their impact, stratification will be carried out for effect modifiers such as age, gender, and bone crypt involvement. A p-value of less than 0.05 will be regarded as statistically significant in the post-stratification chi-square test.

References:

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DATA COLLECTION PROFORMA

"LESION STERILISATION AND TISSUE REPAIR ANTIBIOTIC PASTE VERSUS ZINC OXIDE AND EUGENOL PULPECTOMY FOR TREATMENT OF PRIMARY MOLARS WITH PULP NECROSIS"

Case No: Hospital Registration: Date:

ID: Age: Gender: M □ F □

Group: Group A/Group B

		Pre-Operative		24 Hours		3 Months		6 Months	
		Yes	No	Yes	No	Yes	No	Yes	No
CLINICAL	Mobility								
	Sinus tract/Abscess								
	Clinical success								

		Pre-Operative		24 Hours		3Months		6 Months	
		Yes	No	Yes	No	Yes	No	Yes	No
RADIOGRAPHIC	Furcation radiolucency								
	Peri-apical radiolucency								
	Radiographic success								

Key:

Yes	↑ = Increase
No	↓ = Decrease ↔ = Stable A= Absent

Main Outcome Variable

Total Efficacy: Yes/No