

# Clinical and radiographic evaluation of polyantibiotic paste and metapex for pulp therapy in primary molars

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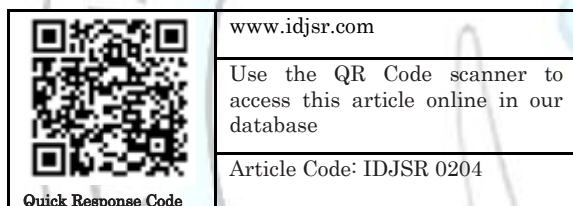
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## Abstract

**Aim:** To compare the clinical and radiographic success of polyantibiotic paste and Metapex for pulp therapy of primary molars.

**Methods:** A prospective single-blind randomized design comprising a total of thirty pulpally involved primary molars from 27 healthy children aged 3–8 years and were treated with Group A (containing Neosporine, Bacitrecin Polymyxin B; Ornidazole, Nodifloxacin) and Group B. For polyantibiotic paste LSTR (‘Lesion sterilization and tissue repair therapy) was used and for Metapex conventional pulpectomy method was used. The outcome was compared using a Z-test with a significance level of 0.05.

**Results:** Group A and Group B showed 100% and 96% clinical success respectively after 3 months. Considering the radiographic findings at the end of 3months, no statistically significant difference (P=0.36665) was found between the two groups.

**Conclusions:** It can be concluded that both polyantibiotic paste and Metapex can be used as a medicament for pulp therapy in primary teeth with poor prognosis. However, long term clinical studies should

be carried out to evaluate the clinical efficacy of the material used.

**Key words:** Polyantibiotic paste; Metapex; Primary teeth; Pulp therapy; Calcium hydroxide

## Introduction

Preservation of the primary tooth is the best space maintenance for its successor, if resolution of the pathological process can be achieved. However, the complex morphology of the root canal system in deciduous teeth makes it difficult to achieve proper cleansing by mechanical instrumentation and irrigation of the canals (1). So, in order to increase the success rate of the endodontic treatment, substances with antimicrobial properties are frequently used as root canal filling materials in primary teeth.

Metapex is a pre-mixed calcium hydroxide and iodoform paste that has an advantage of being a resorbable material and hence preferable in primary teeth. When extruded into furcal or apical areas, it can either be diffused away or resorbed in part by macrophages, in as short a time as 1 or 2 weeks and causes no foreign body reaction(1,2).

A mixture of antibacterial drugs can sterilize carious lesions, necrotic pulps, and infected root dentine of primary teeth. Repair of damaged tissues can be expected if lesions are disinfected (4). Lesion Sterilization and Tissue Repair Therapy (LSTR) or Non Instrumental Endodontic Treatment (NIET) developed by The Cariology Research Unit of the Niigata University. It is a new biologic approaches in the treatment of carious lesions with or without pulpal and periapical involvement using a mixture of antibiotics. LSTR has no mechanical instrumentation. This prevents too much enlargement of root canals and unnecessary irritation of periapical tissues. It also reduces chair time and requires only one treatment visit. Clinical success of antibacterial drugs paste using 3mix comprising of metronidazole, ciprofloxacin, and minocycline has been reported in various studies. However, literature regarding polyantibiotic paste containing Neosporine, Bacitrecin & Polymyxin B(Neosporin<sup>R</sup>antibiotic ointment); Ornidazole (Metrogyl<sup>R</sup>Gel) & Nodifloxacin (Nadibact Cream) used in this study is scarce(3,4).

Hence, this prospective single-blinded randomized study was designed to compare polyantibiotic paste and Metapex for pulp therapy of poor prognosis primary molars.

### Materials and Method

The sample consisted of thirty primary molars with poor prognosis from 27 children aged 3–8 years after obtaining informed consent. Ethical clearance was taken from the Ethical Committee of Govt. Dental College and Hospital, Jaipur.

#### Inclusion Criteria:

1. The presence of gingival abscess,
2. Fistula opening, or clinical mobility;
3. Evidence of pathologic external or internal root resorption,
4. Furcation, or periapical radiolucency on the radiographs; or
5. Pulpotomized tooth failure.

#### Exclusion Criteria:

1. Non-restorable teeth or
2. Teeth with excessive root resorption involving more than half of the root
3. Pulpal floor perforation,
4. Patients with medical problems or history of drug allergy to any study drugs.

Teeth were divided randomly into two groups.

Group A- Test Group (Polyantibiotic Paste)

Group B – Control Group (Metapex)

Local anaesthesia was administered, using Lignocaine HCL 2% with Adrenaline 1: 80,000 (Xylum-A, Regain Laboratories). Pre-operative periapical radiographs were taken for both groups. The tooth was isolated with a rubber dam (Fig-1). Treatment procedure for both the groups were performed by single operator (5).

#### Procedure for the Group A

**Preparation of Polyantibiotic paste.** Equal quantity (0.2ml) of all the medicaments i.e combination of Neosporine, Bacitracin & Polymyxin B (Neosporin<sup>R</sup> antibiotic ointment); Ornidazole (Metrogyl<sup>R</sup> Gel) and Nodifloxacin (Nadibact Cream) were taken and mixed on a glass slab for 30seconds to prepare a homogenous paste.

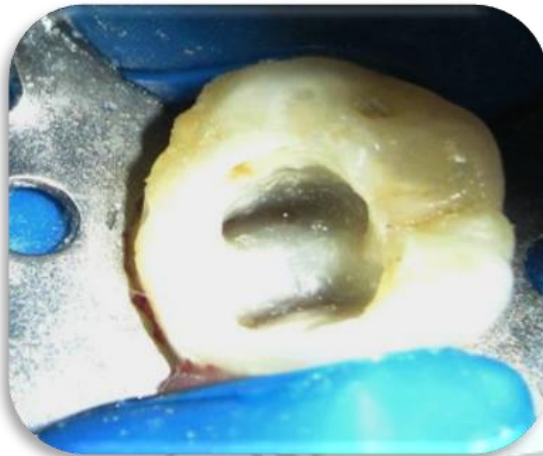
**Group A:** After access opening with a fissure bur in a high-speed handpiece, necrotic pulp tissue was removed using a sterile sharp spoon excavator (Fig. 2) and irrigated with 5% sodium hypochlorite (NaOCl). Haemorrhage, if present, was controlled by applying sterile cotton pellets moistened with 10% NaOCl against the pulp stumps and maintained for 1 min. Then the root canal orifice was enlarged using Gates-Glidden drill (No1) (Fig.-2) and the cavity was irrigated with

normal saline. The access cavity was then dried with cotton pellets. The polyantibiotic paste was placed on the orifices of root canals and pulpal floor, followed by placement of light cured glass-ionomer cement (Vitrebond<sup>TM</sup>; 3M ESPE). The teeth were restored with preformed stainless steel crowns. (Fig-3) Postoperative periapical radiographs were taken.

**Group B** Access cavity was prepared and necrotic pulp tissue was removed using a spoon excavator and barbed broaches from pulp chamber and root canal. The root length was determined using a diagnostic radiograph. Each canal was enlarged to two or three instrument sizes greater than the first filed 2–3 mm short of the radiographic apex. Copious irrigations with 5% NaOCl and normal saline were carried out in order to aid in removing debris. The canals were dried with sterile paper points and Metapex was filled in directly by a pre-packed syringe. Premixed zinc oxide-eugenol (Coltosol) was used to fill the pulp chamber and the teeth were restored with stainless steel crowns after 1 week. If the canals had excessive bleeding or pus exudates, they were dried with paper points and filled with Calcium hydroxide paste prepared by mixing Calcium hydroxide with distilled water to a creamy consistency. At a subsequent appointment (7–14 days after medication), if no signs or symptoms of inflammation were exhibited, the canals were irrigated with 5% NaOCl and dried with paper points before filling with Metapex. Postoperative periapical radiographs were taken.



**Fig. 1: Intra-oral view of 85 after rubber dam application**



**Fig. 2: Enlarged Root canal Orifices for proper application of polyantibiotic paste**



**Fig. 3: Intra-oral view of 85afterstainless steel crown placement.**

**Results**

After pulp therapy, clinical and radiographic evaluations were performed after 1 week and 3 months. Blinded clinical evaluations were performed by the operator (5).

**Clinical criteria for success:** Patients who had initial pain, gingival abscesses, fistula openings, or abnormal mobility were completely free of clinical signs and symptoms(5).

**Radiographic criteria for success:** Static or reduced size of bifurcation / periapical radiolucency, no progression of pathologic external root resorption, no progression of internal root resorption, and no newly formed radiographic lesions(5). The success rate of both groups at 3 months was determined by statistical analysis with a **Z-test** for the proportion of both groups. A P-value <0.05 was considered statistically significant. Pre - and postoperative clinical and radiographic examinations are shown in Table 1.

**Postoperative clinical findings:** Teeth in both the groups were clinically evaluated after 1 week, postoperatively. At this time, no symptoms were reported in any of the treated teeth. At 3 months, both groups showed 100% clinical success. Regarding clinical success, no statistically significant (P=1) difference was found between the two groups (Table 2).

**Postoperative radiographic findings:** Postoperative radiographic success of both groups is shown in Table 2. Considering the radiographic findings at the end of 3 months, no statistically significant differences (P=0.3665) were found between group A and group B.

**TABLES**

**Clinical & Radiographic examination before & after treatment**

SIGN & SYMPTOMS	PREOPERATIVE (n=30)		POSTOPERATIVE (n=30)	
	P.A.P	Metapex	P.A.P	Metapex
Spontaneous pain	15	12	0	0
Gingival swelling	5	7	0	0
Sinus opening	7	5	0	0
Abnormal mobility	4	2	0	0
Pain to percussion	14	15	0	0
Bifurcation radiolucency	12	14	10	9
Periapical radiolucency	5	7	3	4
External resorption	8	6	2	2
<b>Internal resorption</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>

Clinical & Radiographic success rate after 3 months

Results	P.A.P	Number % Metapex	P- Value
CLINICAL SUCCESS	15/15 (100)	15/15 (100)	1.000
RADIOGRAPHIC SUCCESS	13/15(87)	14/15(93)	0.3665

Discussion

The lack of treatment of a deciduous tooth with irreversible pulpitis or pulpal necrosis can cause damage to the succedaneous tooth (e.g., enamel hypomineralization or hypoplasia) (6) and produce negative impacts on the child’s oral health related quality of life (e.g., pain, missed school days and difficulty in chewing) (7). Therefore, teeth presenting these conditions should be extracted or subjected to root canal treatment (1). Various techniques for the endodontic treatment of deciduous teeth have been described (8).

In the present study the clinical and radiographic success of polyantibiotic paste and Metapex for pulp therapy of primary molars was compared. In the present study no statistically significant difference was observed between both groups in clinical and radiographic follow-up. Result showed high clinical success with both the treatment techniques. This is in accordance with favourable findings described in previous studies (3, 4).

Takushige et al. evaluated the efficacy of poly-antibiotic paste comprising of ciprofloxacin, metronidazole, and minocycline, on the clinical outcome of “Lesion Sterilization and Tissue Repair,” LSTR, therapy in primary teeth with periradicular lesions and concluded that primary teeth with periradicular lesions with or without physiologic root resorption were treated successfully by the LSTR endodontic therapy. (4)

The systemic administration of antibiotics relies on patient compliance with the dosing regimens followed by absorption through the gastro-intestinal tract and distribution via the circulatory system to bring the drug to the infected site. Hence, the infected area requires a normal blood supply which is no longer the case for teeth with necrotic pulps and for teeth without pulp tissue. Therefore, local application of antibiotics within the root canal system may be a more effective mode for delivering the drug (9).

In present study local application of antibiotics was done with mixture of Neomycin, Polymyxin B, Ornidazole and Nadifloxacin present in commercially available ointments & creams for endodontic therapy of primary molars. Metronidazole should be the first drug of choice because it has a wide bactericidal spectrum against anaerobes (10), which are common in oral sites. However, it has been found that some bacteria in

lesions were resistant to metronidazole and, thus, other antibacterial drugs, Neomycin, PolymyxinB were mixed with metronidazole in an effort to eliminate all the bacteria. Extensive in vitro and in situ studies have been conducted showing the mixed drugs to be effective against oral bacteria (11).

Septomixine forte®(a combination of dexamethasone, tyrothricin and both polymyxin and neomycin sulphate)was found to be the most effective antibiotic paste against E. faecalis and A. israelii commonly found in endodontic infections.(12)

Here in present study Neomycin, Polymyxin B was used to eliminate E. faecalis which is mainly responsible for endodontic failure.

Tang et al. (2004) suggested that Neomycin is bactericidal against Gram-negative bacilli but it is ineffective against Bacteroides and related species, as well as against fungi. Polymyxin B sulphate is ineffective against Gram-positive bacteria, and it has been demonstrated that a routine 1-week application of Septomixine Forte was not effective in inhibiting residual intracanal bacterial growth between appointments(13).So a wide spectrum antibiotic e.g. Nadifloxacin has also been added in the paste.

The instrumentation of root canal is performed with caution; otherwise it force contaminants and toxic by-products into the periapical tissues, causing possible injury to the underlying permanent tooth bud (14). The root canal treatment without mechanical instrumentation may be more advantageous, especially in teeth with preoperative root resorption. For primary teeth, the presence of accessory canals, porosity, and permeability in the pulpal floor region indicate a probable connection between pulpal and periodontal tissues. Polyantibiotic paste can easily distribute through these regions and induce a sterile zone, expected to promote tissue repair. Prabhakar et. al. Evaluated the success of 3Mix using two techniques: only the necrotic coronal pulp was removed, and both necrotic coronal as well as accessible radicular pulp tissue were extirpated. Their results showed no statistically significant difference(15). Thus, they concluded that radicular pulp tissue removal may not be necessary.

The success rate of polyantibiotic paste was found to be equal that of Metapex but the sample size included could not establish significance. Because of the high antibacterial effectiveness and non-instrumentation technique, polyantibiotic paste may be more suitable in

cases of poor prognosis. Another clinical advantage of this is less chair-side time and more economic. Nevertheless, similarly to the root canal materials, we will not it is not advisable to use polyantibiotic paste in a child at risk of infective endocarditis. Also, the potential sequelae of this treatment should be considered such as the risk of damage to the successor or cyst formation if a focus of chronic infection is left. Neomycin can produce ototoxicity or nephrotoxicity if it is absorbed systemically. For these reasons, further studies with larger sample size and long follow-up period need to be conducted.

## Conclusions

Polyantibiotic paste and Metapex can be used as pulp therapy agents in pulpally involved primary teeth. The simple and short procedures of polyantibiotic paste may be superior to other materials used for pulp therapy in children. Yet, further studies with longer follow-up periods are necessary to evaluate if polyantibiotic paste causes any harmful effects on the permanent succedaneous tooth.

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