Original Article

In Search of a Novel Substitute: Clinical and Radiological Success of Lesion Sterilization and Tissue Repair with Modified 3Mix-MP Antibiotic Paste and Conventional Pulpectomy for Primary Molars with Pulp Involvement with 18 Months Follow-up

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Abstract

Objectives: The aim of this study was to evaluate the clinical and radiographic success of zinc oxide (ZnO)-ozonated oil, modified 3Mix antibiotic paste, and vitapex in the treatment of primary molars requiring pulpectomy. **Methods:** Sixty-four primary molars of forty-three healthy children aged between 4 and 8 years with primary molars requiring root canal procedure were treated with ZnO-ozonated oil, modified 3Mix-MP antibiotic paste, and vitapex. Clinical follow up was done at 1, 6,12 months and 18 months while radiographical follow-up was done at 6,12 and 18 months, respectively. **Results:** The results showed that the clinical success rates of ZnO-ozonated oil, modified 3Mix-MP paste and vitapex were 95.5%,89.5% and 100% respectively and radiographical success rates were 94.4%,80.95% and 100% respectively after 18 months period of observation. **Conclusion:** The overall success rates of ZnO-ozonated oil, vitapex and modified 3Mix antibiotic paste were comparable.

Keywords: *lesion sterilization and tissue repair, modified 3Mix-MP paste, pulpectomy; zinc oxide-ozonated oil, vitapex,clinical and radiological follow-up*

Introduction

Endodontic treatment in primary teeth is aimed primarily to remove all bacterial infection by endodontic instrumentation and proper irrigation and to obturate the root canals with a filling material. The success of pulpectomy also determined by resolution of the clinical and radiological signs and symptoms, normal exfoliation of treated primary tooth, and unimpeded eruption of succedaneous tooth. Hence, longer follow-up period is required for evaluation of the success of endodontic treatment in primary molars.[1]

Due to complexity, tortuous course and the irregularity of the root canals, and danger of injury to the permanent tooth bud in the deciduous dentition, the biomechanical preparation is not as well established as in permanent teeth. The prognosis of endodontic treatment in deciduous teeth is determined by the qualities of the paste used for filling. An ideal root canal filling material should has following properties (a) it should resorb at the same rate as the primary teeth and can be eliminated easily if accidentally extruded beyond apex. (b) it should be noninflammatory ,nonirritating to permanent tooth germ and antiseptic in nature (c) it should be radiopaque, easy to handle, cost-effective, nonstaining to the tooth (d)it should be able to seal the canal properly and set under wet conditions.[2]

The commonly used materials for primary root canal fillings are non-reinforced zinc oxide (ZnO) eugenol, iodoform-based pastes (KRI), and a combination of iodoform paste and calcium hydroxide (Vitapex, Endoflas).[3-6] Problems reported in ZnO eugenol were slow resorption, irritation to periapical tissues, necrosis of bone and cementum and alteration in the path of eruption of succedaneous teeth. Iodoform pastes were also reported to cause allergic reactions.[7-11] Vitapex (calcium hydroxide with iodoform in oily vehicle) is considered a nearly ideal root canal filling material for primary teeth with high clinical and radiographic success rates.[12-15]

How to cite this article: Doneria D, Thakur S, Singhal P, Chauhan D, Keshav K, Uppal A. In search of a novel substitute: Clinical and radiological success of lesion sterilization and tissue repair with modified 3mix-mp antibiotic paste and conventional pulpectomy for primary molars with pulp involvement with 18 months follow-up. Contemp Clin Dent 2017;8:514-21.

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Access this article online

Website: www.contempclindent.org

DOI: 10.4103/ccd.ccd_47_17

Quick Response Code:

However, its faster resorption than the root of primary tooth produces a hollow area in the root canals which is popularly known as "hollow tube effect" which can act as nidus for bacteria.[16,17]

This led to search for a novel substitute as obturating material. In search of newer material, it was also reported that ozonated oil with ZnO has the potential to be used as obturating material in primary teeth.[18] Studies showed that ozone in aqueous form shows essentially no toxicity to oral cells *in vitro* and has high antimicrobial power without the development of drug resistance.[19-22]

A relatively new biologic approach, lesion sterilization, and tissue repair therapy (LSTR) were introduced in the treatment of carious lesions with or without pulpal and periapical involvement using a mixture of three broad spectrum antibiotics, namely, metronidazole, ciprofloxacin, and minocycline (3Mix).[23-25] Modification of 3Mix by using cefaclor in place of minocycline and ornidazole in place of metronidazole has better clinical results.[26,27] The rationale of LSTR is that mixture of three antibiotics (3Mix) can sterilize necrotic pulps and infected root dentine of primary teeth. Repair of damaged tissues can be expected if lesions are disinfected. In the primary dentition, LSTR has shown high rate of clinical success as a substitute for pulpectomy.[28,29] However, radiographic success is questionable in long-term follow-up.[30]

In the research to find an ideal obturating material or alternate treatment option for tooth requiring pulpectomy, the present *in vivo* study was undertaken to evaluate and compare clinical and radiographic success of ZnO with ozonated oil, vitapex, and modified 3Mix-MP as root canal filling materials for primary tooth.

Methods

The study consisted of patients in the age group of 4–8 years, attending the Outpatient Department of Pediatric and Preventive Dentistry, Himachal Pradesh Government Dental College and Hospital, Shimla. Ethical approval from the Institutional Ethical Committee and consent from the parents/guardians were obtained. The criteria for selection of teeth include first and second primary molars (maxillary and mandibular) showing that one or more signs and symptoms indicating pulpectomy are required**:** (a) Spontaneous pain or tender to percussion, (b) Deep carious with pulp exposure, (c) Uncontrolled hemorrhage after removal of coronal pulp tissue, (d) Presence of chronic apical abscess or sinus tract, and (e) The tooth should be restorable and radiographic characteristics: (a) Coronal-radiographic evidence of a deep carious lesion or lesion approximating pulp and (b) Radicular – (i) discontinuity of lamina dura and (ii) Furcation involvement less than or equal to half of shortest root in vertical dimension.

The teeth were excluded when nonrestorable or presented with physiologic root resorption more than a third of its length or if they had the presence of obliteration of the root canal, excessive internal resorption, internal calcifications, perforation into the bifurcation, or any underlying dentigerous cysts. Patients with any systemic illness or with previous history of allergy to the antibiotics used in the study were also excluded.

Clinical and radiographic information before treatment was recorded by an operator. The enrollment of teeth to either group was done randomly by envelope draw method.

Proper local anesthesia was administered, using lignocaine 2% with 1:200,000 epinephrine (Becain-ADR, H. P., India). The tooth was isolated with a rubber dam. All treatments were performed by same operator.

Clinical procedure for zinc oxide-ozonated oil and vitapex

Proper access cavity was made using a large round bur. Pulp was removed initially with spoon excavator, and further radicular pulp was removed with fine H-file along with repeated irrigation with 1% sodium hypochlorite and saline. The root length was determined using diagnostic radiograph. The biomechanical preparation was done using H-files (21 mm) in pull back motion. Simultaneously, irrigation was done using 1% sodium hypochlorite[31] and normal saline. Each canal was enlarged to two or three instrument size greater than the first file used. After drying the pulp cavity using cotton pellets and paper points, vitapex (Neo dental co., Tokyo, Japan) which is supplied in a prepacked polypropylene syringe was transported directly to the canals. While for ZnO-ozonated oil, the root canals were filled with the freshly mixed ZnO powder (DPI, Mumbai, India) (0.2 g, arsenic free) and ozonated castor oil (0.007 cc Ozonil, Ozone Forum of India, Mumbai, India) using motor driven lentulo spirals. Clearly underfilled canals were refilled again and overfilled teeth were excluded from the sample. After obturation of the root canals, the cavity was filled with glass ionomer cement in the same visit. The patient recalled after 15 days, and final restoration was done with stainless steel crowns using standard technique.

Clinical procedure for 3Mix MP paste

Preparation of modified 3Mix MP paste

The chemotherapeutic agents used were ornidazole tablets 500 mg (Ornida, Aristo pharmaceuticals, India), ciprofloxacin tablets 500 mg (Ciplox®, Alchemist Ltd., India), and cefaclor tablets 250 mg (Distaclor™ DT, Baroque pharmaceuticals, India). After the removal of enteric coating of tablets with the help of B.P blade, the drugs are pulverized into fine powder using sterilized mortar pestle. The powered drugs were kept separately in amber-colored air tight containers. The fine powder was used up within a month. 3Mix-MP paste was freshly prepared for each use. The same amount of each powdered drug (1:1:1) was mixed to form modified 3Mix powder.

One part of propylene glycol (P) and the same volume of macrogol (M) were mixed to make MP. For standard preparation, one part of MP and 7 parts of modified 3Mix powder were mixed.

Placement of modified 3Mix-MP in cavity

After chamber access with a straight fissure bur, necrotic pulp tissue was removed using a sterile sharp spoon excavator and accessible radicular pulp was also extirpated and irrigation with 1% sodium hypochlorite was done. The canals orifices were enlarged using round bur to form medication cavity which was 1 mm in diameter and 2 mm in depth) [Figure 1].[28] Modified 3Mix-MP was then placed into medication cavity. After the placement of modified 3Mix-MP paste, the cavity was filled with GIC restoration in the same visit, and final restoration was done with stainless steel crown.

Clinical and radiographic evaluation

After treatment, clinical evaluation was done at 1, 6, 12 and 18 months while radiographic evaluations were performed at 6,12 and 18 months. The preoperative and follow- up radiographs are shown in Figures 2-4 for the three groups. Blinded clinical evaluations were performed by the operator. The radiographic evaluations were carried out by two coinvestigators. The intraexaminer reliability and interexaminer reliability of the first and the second coinvestigators were calculated by Cohen's kappa statistic, i.e., 0.90 and. 867, respectively, which indicates excellent level of agreement. The criteria for clinical success include the absence of pain, presence of healthy soft tissue, and absence of abnormal mobility. The criteria for radiographic success include static/reduction in size of intra-radicular radiolucency, evidence of bone regeneration/continuity of lamina dura, and the absence of internal/external resorption. The treatment was judged to be successful when both clinical and radiographic criteria were fulfilled. The success rate of all three groups at 6,12 and 18 months was determined by statistical analysis with a Z-test for the proportion of the groups. P value < 0.05 was considered statistically significant.

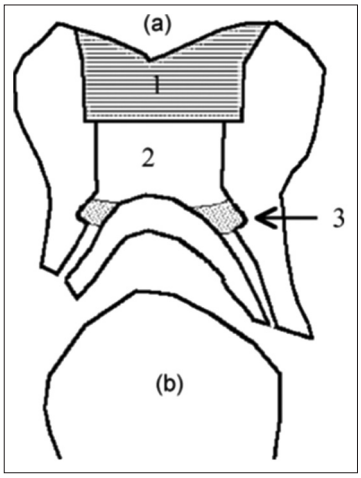


Figure 1: Lesion sterilization and tissue repair for deciduous teeth (a) deciduous teeth with physiologic root resorption (b) the succedaneous permanent teeth (1 and 2) final restoration by glass ionomer cement (3) 3Mix-MP in the prepared medication cavity (1 mm diameter and 2 mm depth)[28]

Results

Distribution of tooth type in the sample is shown in Table 1. Before treatment, the majority of the teeth in three groups presented with pain or tenderness to percussion. Preoperative, postoperative, and followup clinical examinations at 1, 6, 12 and 18 months are shown in Table 2a and b. Preoperative radiological evaluation

Table 1: Distribution of sample in the study

Tooth type	Zinc oxide-ozonated oil (*n*=20)	Modified 3Mix -MP paste (*n*=24)	Vitapex (*n*=20)
First molars			
Upper	2	8	4
Lower	6	4	6
Second molars			
Upper	3	4	1
Lower	9	8	9

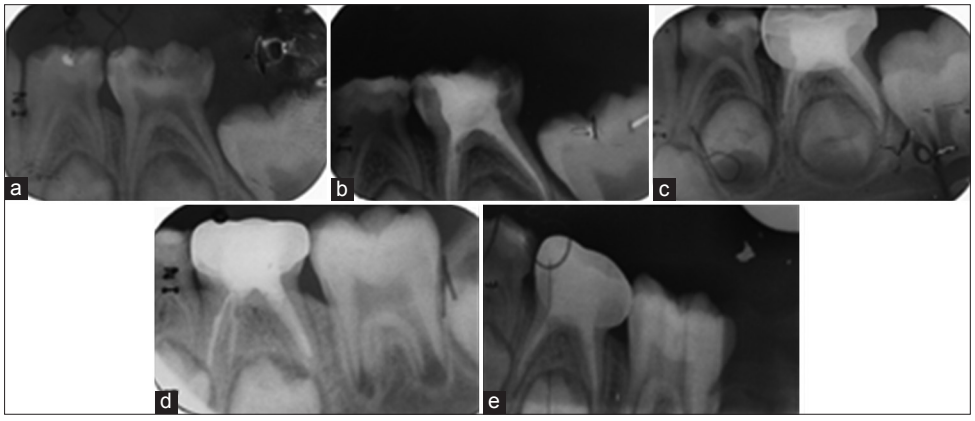


Figure 2: 75 treated with ZnO-ozonated oil as obturating material after pulectomy (radiographic success). (a) Preoperative (b)postoperative (c) After 6months (d) after 12 months (e) after 18 months

and postoperative radiographic followup at 6. 12 and 18 months are shown in Table 3a and b.

Postoperative clinical findings

All teeth of three groups were clinically checked at 1 month postoperatively. At this time, no pain, abscess, and mobility were reported but 9 teeth showed pain on percussion among total 64 treated teeth. At 6 and 12 months, ZnO-ozonated oil and vitapex groups showed 100% clinical success while modified 3Mix-MP paste (LSTR therapy) showed 95.5% of clinical success. One tooth was presented with symptoms of pain, abscess, and mobility in modified 3Mix-MP paste at 6 months. Retreatment was done for this tooth and symptoms subsided, but at 12 months, this tooth presented with abscess and mobility and poor prognosis so extraction was done followed by space maintainers. In 18 months follow up, 6 teeth were excluded due to drop out or teeth exfoliation. Among 58 left out teeth, 55 teeth revealed excellent clinical signs of success with absence of any pain or sensitivity or signs of mobility, fistula, swelling, or inflammation of the gingival tissue surrounding the tooth. One tooth in group ZnO-ozonated oil presented with pain and mobility and 2 teeth with modified 3Mix-MP paste presented with mobility. No statistically significant difference between the three groups was observed for the clinical success at 6, 12 and 18 months as shown in Graph 1-3.

Postoperative radiological findings

An attempt has been made to follow up the cases clinically as well as radiographically for a satisfactory period of 18 months to provide uniqueness to the present study. For the three groups- ZnO-ozonated oil, modified 3Mix-MP paste and vitapex groups, the radiological success was 100%, 83.3% and 100% at 6 months , 100%, 79.2 and 100% at 12 months and 94.4%, 80.9 % and 100% at 18 months respectively. Considering the radiographic findings at the end of 6,12 months statistically significant differences were found between three groups (P = 0.029 and 0.011, respectively) while at 18 months, no statistically significant differences were found between three groups (P = 0.396). More specifically, internal

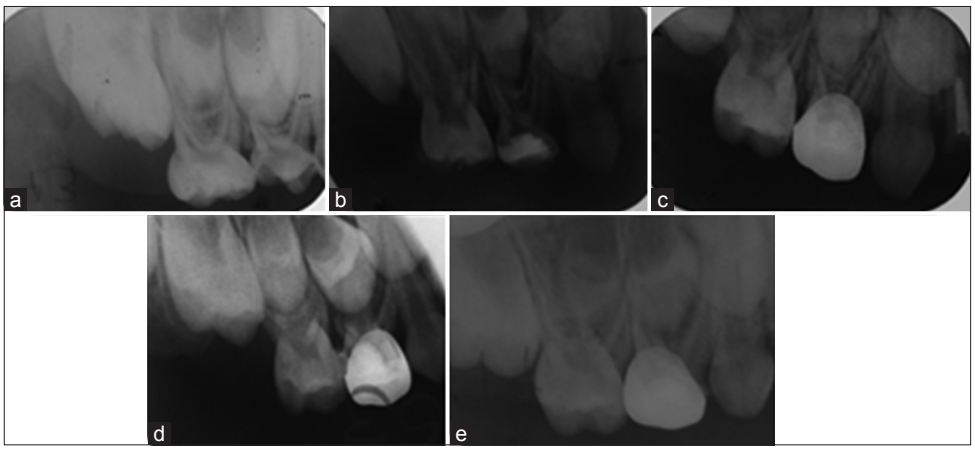


Figure 3: 54 treated with modified 3Mix-MP paste after lesion sterilization and tissue repair therapy (radiographic success). (a) Preoperative (b)postoperative, (c) After 6months (d) after 12 months (e) After 18 months

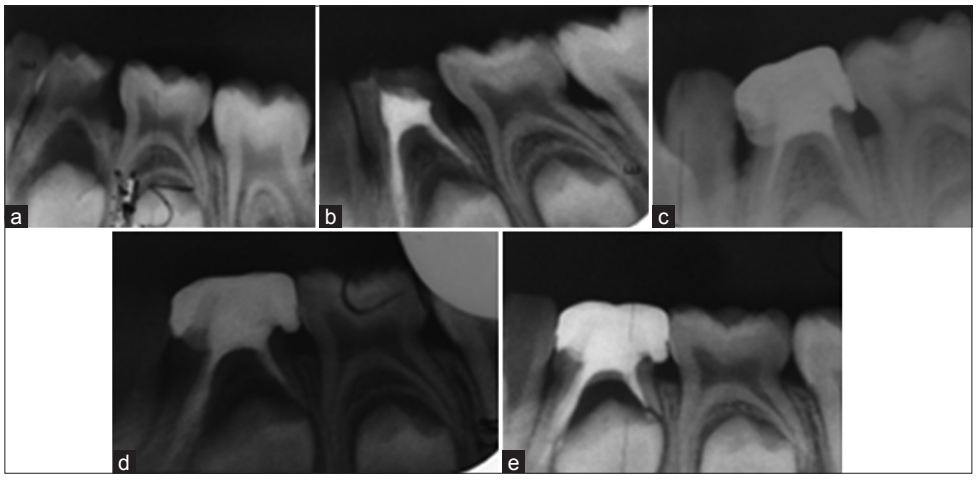


Figure 4: 75 treated with vitapex as obturating material after pulpectomy (radiographic success) (a) Preoperative (b)postoperative (c) After 6 months (d) after 12 months (e) After 18 months

Table 2a: Clinical evaluation preoperative and postoperative at 1 and 6 months

Signs and symptoms	Preoperative			Postoperative					
				1 month			6 months		
	Group 1 *n*=20(%)	Group 2 *n*=24(%)	Group 3 *n*=20(%)	Group 1 *n*=20(%)	Group 2 *n*=24(%)	Group 3 *n*=20(%)	Group 1 *n*=20(%)	Group 2 *n*=24(%)	Group 3 *n*=20(%)
Pain	18 (90)	21 (87.5)	18 (90)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.2)	0 (0)
Abscess	7 (35)	9 (37.5)	4 (20)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.2)	0 (0)
Mobility	7 (35)	8 (33.3)	4 (20)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.2)	0 (0)
Pain on percussion	20 (100)	23 (95.8)	20 (100)	3 (15)	4 (16.6)	2 (10)	0 (0)	1 (4.2)	0 (0)
Lymphadenopathy	1 (5)	2 (8.3)	1 (5)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)

n: No of primary teeth

Table 2b: Clinical evaluation postoperative at 12 and 18 months

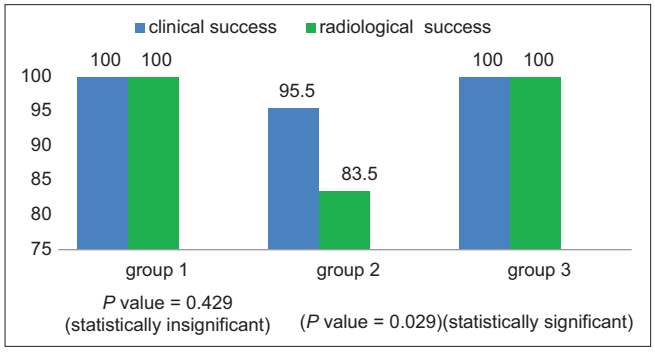
Signs and symptoms	Postoperative					
	12 months			18 months		
	Group 1 *n*=20(%)	Group 2 *n*=24(%)	Group 3 *n*=20(%)	Group 1 *n*=18(%)	Group 2 *n*=21(%)	Group 3 *n*=19(%)
Pain	0 (0)	0 (0)	0 (0)	1 (5.5)	0 (0)	0 (0)
Abscess	0 (0)	1 (4.2)	0 (0)	0 (0)	0 (0)	0 (0)
Mobility	0 (0)	1 (4.2)	0 (0)	1 (5.5)	2 (9.5)	0 (0)
Pain on percussion	0 (0)	1 (4.2)	0 (0)	0 (0)	0 (0)	0 (0)
Lymphadenopathy	0 (0)	1 (4.2)	0 (0)	0 (0)	0 (0)	0 (0)

n: No of primary teeth

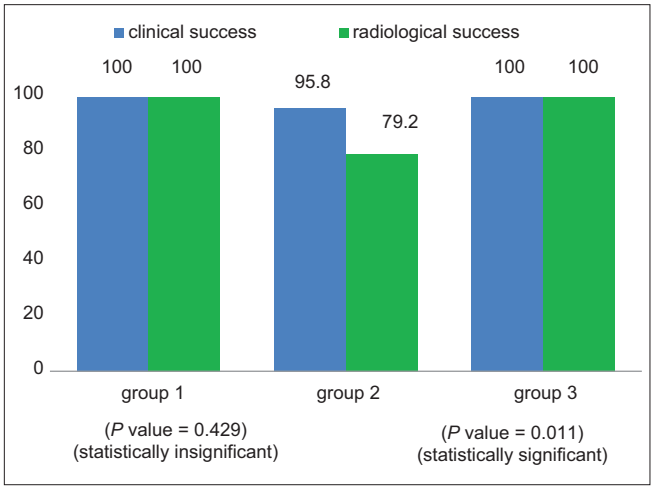
Table 3a: Radiographic evaluation preoperative and at 6 months

Radiographic findings	Preoperative			Postoperative 6 months		
	Group 1 (*n*=20), *n* (%)	Group 2 (*n*=24), *n* (%)	Group 3 (*n*=20), *n* (%)	Group 1 (*n*=20), *n* (%)	Group 2 (*n*=24), *n* (%)	Group 3 (*n*=20), *n* (%)
Interradicular radiolucency present (preoperative/remains static after 6 months)	16 (80)	24 (100)	17 (85)	0	2 (8.3)	0
Decrease in interradicular radiolucency after treatment	-	-	-	16 (80)	18 (87.5)	17 (85)
Increase in interradicular radiolucency after treatment	-	-	-	0	1 (12.5)	0
Internal resorption	0	0	0	0	3 (12.5)	0

n: Number of primary teeth



Graph 1: Clinical and radiological success at 6 months



Graph 2: Clinical and radiological success at 12 months

resorption was observed in three of the teeth treated with modified 3Mix-MP paste at 6-month recall [Figure 5]. Among these three reported failures, two teeth showed

internal resorption which confined to the tooth and did not show any clinical symptoms which showed no further increase in the resorption area at 12 months and 18 months. While one tooth among reported failures showed internal resorption, increase in interradicular radiolucency [Figure 6] and presented with clinical symptoms of abscess and mobility at 12 months, was extracted and followed by space maintainer. At 18 months, two more teeth presented with increase in radiolucency with mobility.

Discussion

An attempt has been made to follow up the cases clinically as well as radiographically for a satisfactory period of 18 months to provide uniqueness to the present study. This study examined the clinical and radiographic success rate of ZnO-ozonated oil, modified 3Mix-MP paste for root canal treatment of pulpally involved primary molars compared with widely used materials such as vitapex. In search of newer material, researchers drew attention toward ozone as it has potent antimicrobial action and is biocompatible for oral cells. Ozonated water and olive oil have the capacity to entrap and then release oxygen/ozone, an ideal delivery system. In reaction to oils, ozone breaks the double bonds between carbon atoms of lipid molecules, producing oxygenated compounds such as hydroperoxides and polyperoxides which account for its action.[32] In endodontics, few studies have focused on the use of ozone as an intracanal medicament and as an irrigant.[21,22]

The search of dental literature showed only one published study by Chandra *et al*. (2014) in which ZnO with ozonated oil was evaluated as filling materials for root canal treatment in primary teeth.[18] In our study, ZnO and ozonated oil mixture was used as obturating material in one group. The clinical success rate of 100% at 6 and 12 months in our study is in accordance with Chandra *et al*. (2014) The radiological success rate of 100% in our study at 6 and 12 months is slightly more than that reported by Chandra *et al*., i.e. 96.7% and 93.3% at 6 and 12 months, respectively. However, at 18 months, the radiological success rate is 94.4%.

In the present study, vitapex was used for obturation in primary molars. The overall clinical and radiological success rate at 18 months is 100%, which was in accordance with

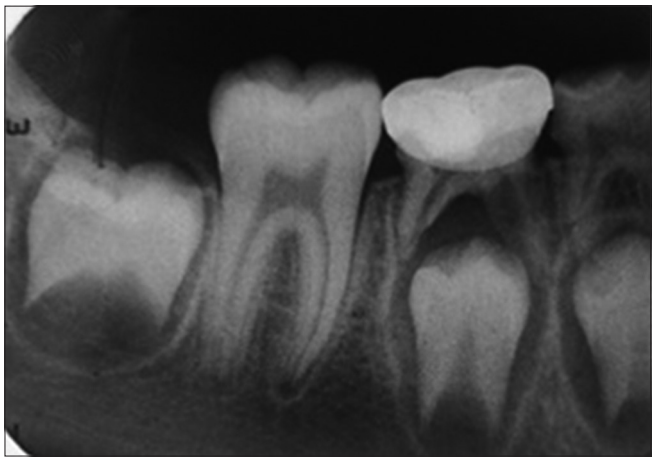
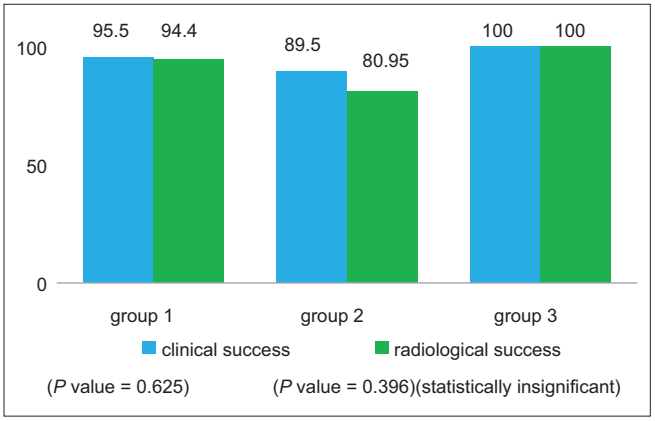


Figure 5: Eighty-five showing internal resorption after 12 months



Graph 3: Clinical and radiographic success at 18 months

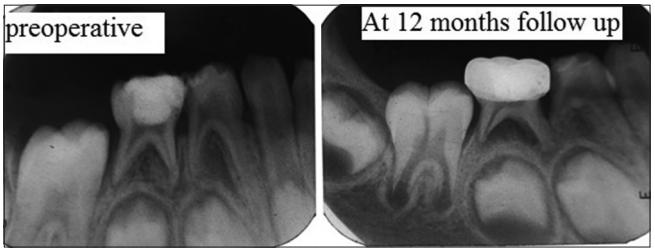


Figure 6: Radiographic failure in modified 3Mix-MP paste group

Table 3b: Radiographic evaluation at 12 and 18 months

Radiographic findings	Postoperative					
	12 months			18 months		
	Group 1 (*n*=20), *n*(%)	Group 2 (*n*=24), *n* (%)	Group 3 (*n*=20), *n* (%)	Group 1 (*n*=18), *n* (%)	Group 2 (*n*=21), *n* (%)	Group 3 (*n*=19), *n* (%)
Interradicular radiolucency present (static after 12 and 18 months)	0	1 (4.2)	0	0	1 (4.7)	0
Decrease in interradicular radiolucency after treatment	16 (80)	18 (75)	17 (85)	17 (94.4)	16 (76.19)	17 (89.4)
Increase in interradicular radiolucency after treatment	0	2 (8.3)	0	1 (5.5)	2 (9.5)	0
Internal resorption	0	3 (12.5)	0	0	2 (9.5)	0

n: Number of primary teeth

and comparable with the studies reported by Mortazavi and Mesbahi,[33] Ozalp,[4] Trairatvorakul *et al*.,[34] Nakornchai *et al*.,[35] and Pramila *et al*.[36] in the literature. However, the radiological success rate that was reported by Nakornchai *et al*.,[35] i.e., 56% was very less which can be due to poor prognosis sample selected in their study.

Due to several anatomic complications, long-term successful outcome of conventional pulpectomy procedure in necrotic or abscessed primary teeth has been reported in literature up to 85%.[37,38] Hence, the use of such procedure should have a convenient alternative with comparable or better success rate. The cariology research unit of the School of Dentistry, Niigata University, Niigata, Niigata Prefecture, Japan, developed the concept of LSTR therapy in 1990. Extensive *in vitro* and *in situ* studies have shown that the mixture (3-Mix) of metronidazole, ciprofloxacin, and minocycline is effective against oral bacteria, including those in the endodontic lesions of primary teeth.[24-26] Cruz *et al*.[39] showed that the addition of propylene glycol and macrogol (MP) as a carrier vehicle greatly improved the penetration ability of these medications.

Newer drug combinations were also used by replacing minocycline with drugs having the same antibacterial spectrum, for example, amoxicillin, cefaclor, cefroxadine, fosfomycin or rokitamycin,[24,26] clindamycin,[40] and metronidazole with ornidazole[27] and tinidazole.[41] Minocycline can cause discoloration of tooth and ornidazole showed better results than metronidazole.[28] Hence, we modified 3Mix-MP mixture by substituting metronidazole and minocycline, ornidazole and cefaclor, respectively, with macrogol and propylene glycol as vehicle. In our study, modified 3Mix-MP paste was used and 1 clinical failure was observed at 6 months evaluation and 4 failures were observed radiologically. Furthermore, at 12 months, there was 1 clinical failure and 5 radiological failures noted on evaluation. At 18 months, two teeth more presented with clinical as well as radiological failures. The overall clinical success rate at 18 months is 89.5%, which was in accordance and comparable with Prabhakar *et al*.[29] and Pinky *et al*.[27]. Prabhakar *et al*.[29] compared pulpotomy and pulpectomy techniques in LSTR in Group A and Group B, respectively, and reported 93.3% clinical success rate for Group A while 100% for Group B. Pinky *et al*.[27] compared 3Mix and modified 3Mix in Group 1 and Group 2, respectively, and reported clinical success rates of 90% and 100%, respectively. The radiological success rate of 79.2% is comparable with Nakornchai *et al*.[35] However, it is lesser than as reported by Prabhakar *et al*.[29] and Pinky *et al*.[27] but higher than that of Agarwal *et al*.[42] and Trairatvorakul *et al*.[31] (2012). Studies reported earlier on LSTR in primary teeth showed variation in success rates due to differences in sample selection, evaluation criteria, and techniques employed for LSTR.

In our study, internal resorption and increase in intraradicular radiolucency were found to be the most common causes of radiologic failure in LSTR group with modified 3Mix antibiotic paste. Previous investigations have also reported increase in radiolucency and internal résorption as the most frequent postoperative radiological failures observed in primary molars after LSTR.[27,29,30] Trairatvorakul *et al*. reported the overall success rates for conventional pulpectomy were higher (89%)[34] than the overall success rates of 3Mix-MP NIET (36.7%).[31] However, results with 3Mix-MP with radicular pulp extirpation yielded comparable success (83.3%)[29] which are in accordance with our study.

Within the three groups, the clinical success of ZnO-ozonated oil group and vitapex group were comparable at 6, 12 and 18 months while for LSTR group, it was 89.5% which was slightly lesser with statistically no significant difference ($P < 0.429$). Radiologically, success rates for ZnO-ozonated oil group and vitapex group were 94 and 100% at 18 months. However, in LSTR group, the success rates were 89.5% and 80.9% at 18 months respectively. These results were statistically insignificant ($P < 0.396$).

In the present study, although all three materials have shown clinically good results, further studies with a larger sample size with a longer period of follow-up is required. Investigations are also required to understand the reaction of periapical tissues to drugs as well as the amount of drug absorption into the systemic circulation. Ultrastructural, histological, and microleakage studies may be helpful to further determine the suitability of ZnO-ozonated oil in future pulpectomy studies.

Conclusion

Within the limits of the present *in vivo* study, we conclude that all three materials used in ZnO-ozonated oil, modified 3Mix-MP, and vitapex can be used effectively as pulpectomy agents in deciduous teeth. It can also concluded that ZnO-ozonated oil can be safely and successfully used as a new obturating material in primary teeth, and modified 3Mix-MP antibiotic treatment can be a substitute of conventional root canal treatment in primary molars.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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