Clinical evaluation of 3Mix and Vitapex[®] as treatment options for pulpally involved primary molars

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Objective. The aim of this study was to compare the clinical and radiographic success of 3Mix and Vitapex[®] for root canal treatment of pulpally involved primary molars.

Methods. Fifty teeth from 37 healthy children aged 3–8 years with pulpally involved primary molars needing root canal procedures were treated with 3Mix or Vitapex[®] before restoration with stainless steel crowns. The research employed a prospective single-blinded randomized design. The subjects were followed up clinically and radio-graphically at 6 and 12 months, respectively. The

outcome was compared using a Z-test with a significance level of 0.05.

Results. Both groups showed 100% and 96% clinical success at 6 and 12 months, respectively. At 6 months, radiographic success of 3Mix and Vitapex[®] was 84% and 80%, respectively, and at 12 months, radiographic success of 3Mix and Vitapex[®] was 76% and 56%, respectively. Considering the radiographic findings at the end of 6 and 12 months, no statistically significant differences were found between the two groups (P = 0.356 and 0.068, respectively).

Conclusion. 3Mix and Vitapex[®] can be used as a root canal treatment agent in pulpally involved primary teeth.

Introduction

Pulpally involved primary teeth with excessive external root resorption, internal root resorption, or extensive bone loss were reported to render the prognosis less favourable and contraindicated for root canal treatment¹. In young children, early removal of primary teeth is not recommended due to aberration of the arch length, resulting in a mesial drift of the permanent teeth and consequent malocclusion. Some authors have advocated the extraction of poor prognosis teeth and placement of space maintainers. Yet, these appliances have some disadvantages in terms of function and oral hygiene care¹. Preservation of the primary tooth is the best space maintenance for its successor, if resolution of the pathological process can be achieved. Root canal treatment may be an alternative choice.

Assoc. Prof. Siriruk Nakornchai, Department of Pediatric Dentistry, Faculty of Dentistry, Mahidol University, Bangkok, Thailand 10400. E-mail: dtsnk@mucc.mahidol.ac.th Mobile phone 66-89772-3011 Fax 66-2203-6450 Vitapex[®] (Neo Dental Chemical Products Co., Ltd, Tokyo, Japan) is a pre-mixed calcium hydroxide and iodoform paste that claims to be a nearly ideal root canal filling material for primary teeth. The advantage of Vitapex[®] as a resorbable material is obvious. 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^{2,3}. Many authors have reported favourable results with Vitapex[®] for root canal filling of primary teeth with a success rate ranging from 96% to 100%^{2,4,5}. Yet, the intraradicular resorption of Vitapex[®] in the follow-up period was observed. Even though they did not show any clinical nor radiographical problems, early resorption of Vitapex[®] in root canals may stop disinfection and become a hollow tube for bacteria to induce re-infection^{5,6}. Although Vitapex[®] showed good biocompatibility, this material had low antibacterial effect when compared with other root canal filling materials for primary teeth^{7,8}.

Lesion Sterilization and Tissue Repair Therapy (LSTR) or Non Instrumental Endodontic Treatment (NIET) endodontic treatment are

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new biologic approaches in the treatment of carious lesions with or without pulpal and periapical involvement using a mixture of three antibiotics: namely, metronidazole, ciprofloxacin, and minocycline. A mixture of three antibacterial drugs (3Mix) can sterilize carious lesions, necrotic pulps, and infected root dentine of primary teeth⁹⁻¹¹. Repair of damaged tissues can be expected if lesions are disinfected¹². LSTR has no mechanical instrumentation. This prevents too much enlargement of root canals and unnecessary irritation of periapical tissues^{9,13}. It also reduces chair time and requires only one treatment visit. Clinical success of 3Mix has been reported in a few studies^{12,14}.

To date, there have been limited clinical studies of 3Mix in primary root canal treatments. This prospective single-blinded randomized clinical trial was designed to compare 3Mix and Vitapex[®] for root canal treatment of poor prognosis primary teeth.

Methods

The research protocol and informed consent form were reviewed and approved by the Committee on Human Rights Related to Human Experimentation, Mahidol University, Bangkok, Thailand. The samples consisted of 50 poor prognosis primary molars from 37 children aged 3–8 years after obtaining informed consent from their parents. The criteria for case selection in the study were: the presence of gingival abscesses, fistula openings, or clinical mobility; evidence of pathologic external or internal root resorption, furcation, or periapical radiolucency on the radiographs; or pulpotomized tooth failure. The teeth were excluded when they were not restorable or if they had excessive root resorption involving more than half of the root or pulpal floor perforation. Patients with medical problems or history of drug allergy to metronidazole, ciprofloxacin, or minocycline were also excluded. Clinical and radiographic information before treatment was recorded by an operator. The intra-examiner reliability for clinical and radiographic examination was calculated by Cohen's kappa statistic (1 and 0.97, respectively). The assignment of teeth to either group was performed randomly by the toss of a coin. Proper local anaesthesia was administered, using Mepivacaine HCl 2% with Adrenaline 1 : 100,000 (Septodont, Saint-Maur-der-Fosse's Cedex, France). The tooth was isolated with a rubber dam. All treatments were performed by one operator.

Procedure for the experimental group (3Mix)

Preparation of 3Mix. The enteric coating of metronidazole (Flagyl[®], Sanofi-Aventis, Thailand), ciprofloxacin (Ciprobay[®], Bayer, Germany), and minocycline (Minocin[®], Wyeth, China) was removed. The tablets were pulverized using a mortar and pestle. The powdered antibiotics were stored and sealed in airtight containers separately from moisture and light. The same amount of each drug powder (1 : 1 : 1) was mixed together. After that, the mixed drugs were combined with macrogol and propylene glycol (MP) (Vidhyasom Co., Ltd, Bangkok, Thailand) to form an ointment. Unused 3Mix-MP was discarded at the end of the office hour.

Clinical procedure of LSTR. After chamber access with a fissure bur in a high-speed handpiece, necrotic pulp tissue was removed using a sterile sharp spoon excavator (Fig. 1a) and irrigated with 2.5% 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. The cavity was then dried with cotton pellets. The 3Mix-MP was placed on the orifices of root canals and pulpal floor (Fig. 1b), then covered with light cured glass-ionomer cement (VitrebondTM; 3M ESPE) (Fig. 1c). The teeth were immediately restored with preformed metal crowns (stainless steel crowns) and cemented with glass-ionomer cement (GC Corporation, Tokyo, Japan) (Fig. 1d).

Procedure of the control group (Vitapex[®]). The pulp chamber was opened and necrotic pulp tissue was removed using a spoon excavator and barbed broaches. The root length was determined using a diagnostic radiograph. A rubber stop was placed appropriately on



Fig. 1. Procedure of root canal treatment using 3Mix: (a) removing of caries and coronal pulp tissues; (b) applying of 3Mix-MP at orifices; (c) covering 3Mix-MP with light cured GICs; (d) restoring with stainless steel crown.

the number 15 K-file. Filing was carried out approximately 2-3 mm short of the radiographic apex. Each canal was enlarged to two or three instrument sizes greater than the first file. Copious irrigations with 2.5% NaOCl were carried out between the uses of each instrument in order to aid in removing debris as much as possible. The canals were dried with sterile paper points and Vitapex[®] was filled in directly by a pre-packed syringe. Fortified zinc oxide-eugenol (IRM; Dentsply[®], Milford, Delaware, USA) was used to fill the pulp chamber and the teeth were restored with stainless steel crowns. If the canals had excessive bleeding or pus exudates, they were dried with paper points. Calcium hydroxide (The Faculty of Dentistry, Mahidol University, Thailand) was mixed with distilled water to a creamy consistency. The paste was filled in the root canals with a lentulo spiral. At a subsequent appointment (7–14 days after medication), if no signs or symptoms of inflammation were exhibited, the canals were irrigated with 2.5% NaOCl and dried before filling. If signs or symptoms of inflammation were presented in the subsequent appointment, the canals were recleaned and remedicated and the root canal filling procedure was postponed. Postoperative periapical radiographs were taken to assess the adequacy of fillings. The root fillings were categorized with regard to length in relation to the radiographic apex. Groups of length determination were 0–2 mm (adequate), shorter than 2 mm from the radiographic apex (underfilled), and overfilled. A tooth was categorized as overfilled even if other roots were filled short or adequate.

Clinical and radiographic evaluation. After root canal treatment, clinical radiographic evaluations were performed at 6 and 12 months. Blinded clinical evaluations were performed by the operator. The radiographic evaluations were carried out using the same standard view box previously calibrated by two co-investigators. The intra-examiner reliability of the first and the second co-investigators was calculated by Cohen's kappa statistic (0.89 and 1, respectively). The evaluations of the two co-investigators were standardized to determine inter-examiner reliability by independently analysing radiographs of 20 primary molars. Cohen's kappa statistic

indicated excellent reproducibility between the two co-investigators with a measurement agreement of 0.89. Clinically, the criteria for success were that patients who had initial pain, gingival abscesses, fistula openings, or abnormal mobility were completely free of clinical signs and symptoms. The radiographic success criteria were 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. If calcified metamorphosis occurred, it was noted but not regarded as a treatment failure. The success rate of both groups at 6 and 12 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.

 Table 1. Distribution of root canal treatment in primary molars by tooth type.

	Number				
Tooth type	3Mix (<i>n</i> = 25)	Vitapex [®] (<i>n</i> = 25)			
First molars					
Upper	2	0			
Lower	7	8			
Second molars					
Upper	1	1			
Lower	15	16			

Results

Each group comprised 25 poor prognosis primary molars. Distribution of tooth type is shown in Table 1. Before treatment, the majority of the teeth in both groups presented with pain or tenderness to percussion. Pre- and postoperative clinical and radiographic examinations are shown in Table 2. In the 3Mix group, all teeth had complete treatment in one visit. In the Vitapex[®] group, a one-visit root canal procedure was undertaken in 14 of the 25 teeth. The remaining teeth were treated in two visits due to a great deal of gingival swelling and discharge.

Postoperative clinical findings

All teeth of both groups were clinically checked at 1 week, postoperatively. At this time, no symptoms were reported in any of the treated teeth. At 6 months, both groups showed 100% clinical success. All cases revealed excellent clinical signs of success and no patient complained of pain or sensitivity after the treatment. No teeth showed signs of mobility, fistula, swelling, or inflammation of the gingival tissue surrounding the tooth. At 12 months, one tooth in each group presented with a gingival abscess. Regarding clinical success, no difference was found between the two groups (Table 3).

Table 2. Clinical and radiographic examination before and after treatment at 6 and 12 months.

	Preoperative n = 25 (%)		6 months		12 months	
	3Mix	Vitapex [®]	3Mix	Vitapex [®]	3Mix	Vitapex [®]
Signs and symptoms						
Spontaneous pain	22 (88)	25 (100)	0 (0)	0 (0)	0 (0)	1 (4)
Gingival swelling	4 (16)	6 (24)	0 (0)	0 (0)	1 (4)	1 (4)
Sinus opening	3 (12)	2 (8)	0 (0)	0 (0)	1 (4)	0 (0)
Abnormal mobility	2 (8)	5 (20)	0 (0)	0 (0)	0 (0)	0 (0)
Pain to percussion	19 (76)	22 (88)	0 (0)	0 (0)	0 (0)	1 (4)
Radiographic findings						
Bifurcation radiolucency	18 (72)	19 (76)	2 (8)	3 (12)	4 (16)	11 (44)
Periapical radiolucency	16 (64)	14 (56)	2 (8)	5 (20)	5 (20)	9 (36)
External resorption	12 (48)	7 (28)	1 (4)	4 (32)	2 (8)	8 (32)
Internal resorption	4 (16)	1 (4)	2 (8)	0 (0)	1 (4)	0 (0)
Calcified metamorphosis	0 (0)	0 (0)	0 (0)	0 (0)	2 (8)	0 (0)

	Follow-up period (months)	Number (%		
Results		3Mix (n = 25)	Vitapex [®] (n = 25)	<i>P</i> -value
Clinical success	6	25/25 (100)	25/25 (100)	1.0000
	12	24/25 (96)	24/25 (96)	1.0000
Radiographic success	6	21/25 (84)	20/25 (80)	0.3557
	12	19/25 (76)	14/25 (56)	0.0681

Table 3. Clinical and radiographic success rates of 3Mix and Vitapex[®] root canal treatment at 6 and 12 months.

Postoperative radiographic findings

Radiographic assessment of the extent of root canal filling immediately after treatment in the Vitapex[®] group revealed that 3 of the 25 teeth were adequately filled, 19 teeth were overfilled, and 3 teeth were underfilled. At the end of follow-up period, 14 teeth of the Vitapex[®] group showed partial resorption of filling in the root canals. Postoperative radiographic success of both groups is shown in Table 3. Bone regeneration was found in both groups (Figs 2 and 3). Considering the radiographic findings at the end of 6 and 12 months, no statistically significant differences were found between the 3Mix and Vitapex[®] groups (P =0.356 and 0.068, respectively). More specifically, internal resorption was observed in two of the teeth treated with 3Mix at 6-month recall (Fig. 4). At 12 months, these teeth showed calcification in the resorption area. Nevertheless, one more tooth presented with internal resorption at that time. These internal resorptions were confined to the tooth and did not show any clinical symptoms.

Discussion

This study examined the clinical and radiographic success rate of 3Mix for root canal treatment of pulpally involved primary molars compared with widely used materials like Vitapex[®]. Our result showed no statistically significant difference between both groups in clinical and radiographic follow-up. The samples represented a wide spectrum of pathosis, mostly, poor prognosis cases. Yet, some teeth with internal resorption are vital and might have a better prognosis than a tooth with a necrotic pulp. Our result showed high clinical



Fig. 2. Preoperative and postoperative radiographs of a mandibular second primary molar treated with 3Mix. (a) Preoperative: loss of lamina dura, furcation radiolucency. (b) Radiograph taken 6 months postoperatively showing improvement of furcation radiolucency with bone regeneration. (c) Radiograph taken 12 months postoperatively showing further improvement of the lesion, lamina dura intact.

success. This confirms favourable findings described by previous studies^{2,4,5,12,14}. In general, the root canals of poor prognosis teeth are resorbed by pathologic condition. The instrumentation of root canal had to be performed with caution; otherwise this would force contaminants and toxic by-products into the periapical tissues, causing possible injury to the underlying permanent tooth bud¹⁵. Even though, the root canal instrumentation was performed 2-3 mm short of the apex, mostly overfilled root canals were found in our study. Yet, the extruded material disappeared completely at 6-month follow-up. The rapid elimination of extruded Vitapex[®] can be considered as one of the most important advantages. The root canal treatments without

Fig. 3. Preoperative and postoperative radiographs of a mandibular second primary molar treated with Vitapex[®]. (a) Preoperative: periapical and furcation radiolucency. (b) Immediate postoperative: Length of fill is long, exceeding into the bicuspid tooth follicle. (c) Radiograph taken 6 months postoperatively showing improvement of furcation radiolucency with bone regeneration, extra-radicular excess of paste has been completely resorbed. (d) Radiograph taken 12 months postoperatively showing further improvement of the lesion.





Fig. 4. Postoperative radiographs of a mandibular first primary molar treated with 3Mix and revealed internal root resorption. (a) Immediately after postoperation: no internal root resorption. (b) Six-month recall, note internal resorption of distal root (arrowhead). (c) Twelve-month recall, canal calcification at the resorption area (arrowhead).

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. 3Mix can easily distribute through these regions and induce a sterile zone, which is expected to promote tissue repair. Furthermore, propylene glycol and macrogol were used as a drug vehicle in this study. Propylene glycol was found to be an excellent compound to carry 3Mix into the entire dentin and through the dentinal tubules, thus 3Mix could kill all the bacteria in the lesions¹⁶. Prabhakar et al.¹⁴ 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 difference¹⁴. Thus, radicular pulp tissue removal may not be necessary.

The slight difference between the results of this study and those of previous investigations of 3Mix may be related to the difference in the methods and the sample criterion. Takushige *et al.*¹² and Prabhakar *et al.*¹⁴ used a composite resin for final restoration in root canal-treated teeth. In this study, the teeth were restored with stainless steel crowns, which are widely used as standard material

for extended carious primary teeth and pulptreated teeth. Furthermore, they enlarged the root canal orifices to build a medication cavity before applying mixed drugs. To simplify the technique, the medication cavity was not prepared in this study.

On the contrary, radiographic success of the Vitapex[®] group in this study was less than those of previous studies^{2,4,5}. It might be due to the poor prognosis samples. Holan and Fuks¹⁷ suggested that success differences may be related to the pathologic condition of the tooth prior to treatment rather than to the filling technique per se. Coll and Sadrian reported that pulpectomy-treated teeth with minimal or no preoperative root resorption had a significantly higher success rate than those with excessive root resorption. The degree of preoperative root resorption seemed to be the most important radiographic diagnostic criterion in determining whether a pulpectomy will likely succeed¹⁸. Not surprisingly, the success rate of poor prognosis teeth in this study was less than in previous reports. In this study, 14 of the 25 samples used calcium hydroxide as root canal dressing material. This material is a strong alkaline substance with high pH (approximately 12.5), thus providing bactericidal effect. Intracanal medication could improve the treatment outcome; however, the success rate of the Vitapex[®] group was comparable with 3Mix group. At 12-month recall, two teeth that had internal root resorption at the first follow-up period presented calcification at the resorption area. Yet, one more tooth had internal resorption at that time. Internal resorption is a common response of the pulp to chronic inflammation and active only if part of the pulp remains vital. Internal resorption can be transient or progressive¹⁹. In this study, 3Mix was used as pulp dressing material following removal of the coronal pulp as in pulpotomy procedures. Severe bleeding is always found in chronically inflamed radicular pulp removal. Schroder claimed that internal resorption depended on the presence of an extra-pulpal blood clot on the wound surface that interfered with the healing of pulpotomized tooth. The author also suggested that preventing blood clot formation might mini-

mize the chances for chronic inflammation and internal resorption²⁰. In the 3Mix group, haemorrhage was controlled by placing a cotton pellet saturated with 10% NaOCl as an effective haemostatic agent. This agent is not toxic to pulpal tissue and does not interfere with pulpal healing. In addition, it does aid in the removal of the clot and stops haemorrhage that compromises pulp healing^{21,22}. Although the cause of internal resorption is unknown, Smith et al. classified internal resorption as a radiographic success when it did not reach the bone. They claimed that as this radiographic finding does not involve osseous changes, it would not affect the permanent successors. Internal resorption was regarded as a failure only if the process reached the root's outer surface, thereby inducing an inflammatory process in the periodontal ligament and the surrounding bone. The authors found evidence of calcification in the area of internal resorption at the follow-up period²³. Both calcific metamorphosis and internal resorption are the result of odontoblastic and odontoclastic activities. This gives the comparatively higher radiographic success rate of our study. The radiographic success rate of the 3Mix group would then change from 84% to 92% and 76% to 80% at 6- and 12-month follow-up period, respectively. In this study, we chose to observe teeth displaying internal resorption instead of extracting these teeth as failures.

The success rate of 3Mix tended to be higher than that of Vitapex[®] but the sample size presented could not establish significance. Because of the high antibacterial effectiveness and noninstrumentation technique, 3Mix may be more suitable in cases of poor prognosis. Another clinical advantage of 3Mix-MP is less chair time. Nevertheless, similarly to the root canal materials, we would not advocate this 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. In addition, localized minocycline staining of the permanent tooth bud may occur due to an excellent distribution of 3Mix-MP. For this reason, further studies need to be conducted.

Conclusions

Both 3Mix-MP and Vitapex[®] can be used as a root canal treatment agent in pulpally involved primary teeth. The simple and short procedures of 3Mix may be superior to other materials used for root canal treatment in children. Yet, further studies with longer follow-up periods are necessary to evaluate if any effects on the permanent succedaneous tooth.

- What this paper adds
- Both 3Mix-MP and Vitapex[®] can be used as a root canal treatment agent in pulpally involved primary teeth at 12-month follow-up period.
- The use of 3Mix-MP may be an optional treatment for poor prognosis primary teeth.

Why this paper is important for paediatric dentists

• The simple and short procedures of 3Mix may be superior to other materials used for root canal treatments in pulpally involved primary teeth.

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