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Comparison of zinc oxide and eugenol, and Vitapex for root canal treatment of necrotic primary teeth

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Summary. *Objectives.* The aims of this study were to evaluate iodoform base materials for root canal treatment of necrotic primary teeth, and to compare them with traditionally used zinc oxide and eugenol (ZOE).

Sample and Methods. Zinc oxide and eugenol and Vitapex (a premixed calcium hydroxide and iodoform paste) were compared for root canal treatment in 52 necrotic primary teeth in two groups of children with a mean age of 5 years and 8·4 months. All the patients were followed-up clinically and radiographically 3 months and 10–16 months postoperatively.

Results. The overall success rates of Vitapex and ZOE were 100% and 78·5%, respectively. Using Fisher's Exact Test, the difference was statistically significant ($P < 0·05$).

Conclusion. Both ZOE and Vitapex gave encouraging results. Vitapex, however, can be used more safely whenever there is a doubt about the patient's return for follow-up.

Introduction

Root canal therapy was advocated as early as 1932 as a method for retaining those primary teeth which would otherwise be lost [1]. Zinc oxide and eugenol (ZOE) paste was the first root canal filling material to be recommended for primary teeth, as described by Sweet in 1930. Since then, several authors have reported moderate to high success rates in preserving chronically infected teeth using this material [2].

An ideal root canal filling material for primary teeth must have several properties, such as resorbing at a rate similar to that of the primary root, being harmless to the periapical tissues and permanent tooth germ, resorbing readily if pressed beyond the apex, and being strongly antiseptic. It should easily fill the root canals, adhere to the walls of the canal, not be susceptible to shrinkage, be easily removed if necessary, be radiopaque and not discolour the tooth. It also should not set to a hard mass which could deflect an erupting succedaneous tooth [3,4].

However, according to several studies, ZOE fails to meet many of these criteria; for example, there are many reports about the slow rate of resorption of ZOE cement in the canals [5]. When forced beyond the apex, there is a risk of deflection of erupting succedaneous teeth because of its hardness [6]. It also has only limited antibacterial action [7,8]. Because of these shortcomings, the use of an iodoform base or $Ca(OH)_2$-containing materials as substitutes for ZOE has received attention in recent years [9–13]. In contrast to ZOE, these more modern materials are more easily resorbed from the periapical area and cause no foreign body reaction. They also have potent germicidal properties. Many of them resorb in synchrony with primary roots, can be easily forced into the pulp canals and accessory canals, and have no undesirable effect on succedaneous teeth [14,15]. Among such materials, a relatively new compound, which is a premixed calcium hydroxide and iodoform paste (Vitapex), is claimed to be a nearly ideal root canal filling material for primary teeth [1]. Because there have been only

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limited controlled human studies on this subject, a prospective clinical trial was designed to compare ZOE and Vitapex for root canal treatment of necrotic primary teeth in children.

Methods

The sample consisted of 58 non-vital primary teeth, including 23 maxillary and 30 mandibular primary molars, and five anterior teeth. One tooth per child was selected for the study. A thorough clinical evaluation as well as periapical radiography were performed at the first visit. The criteria for selection of the teeth included in the study were: the presence of soft-tissue abscesses or sinus tracts around the tooth; evidence of pathologic processes on the radiographs, ranging from slight thinning of the trabecular pattern to large areas of radiolucency in the furcation and/or periapical region; or little or no pulp tissue remaining when the pulp chamber was entered. Teeth were excluded when they were not restorable or if they had a perforated pulpal floor. Patients with significant medical problems were also excluded, as were teeth with evidence of internal or external root resorption involving more than one-third of the root length.

Treatment for each of the teeth involved was carried out over two visits. At the first appointment, a complete pulpotomy was performed. Efforts were made to remove all necrotic tissue from the pulp chamber using a sharp spoon excavator before irrigation with normal saline. A formocresol-moistened cotton pledget was then placed in the pulp chamber and sealed with zonalin (Zinc-Oxide BP, Zinc Acetate, Eugenol BP, Associated Dental Products Ltd, Kemdent Works, Wiltshire, UK) as temporary restoration. At the second visit, which was usually 1–2 weeks later, and before entering to the root canals, the length of the tooth from the mesial or distal cusp to the apex of the root was measured on the radiograph. Based on the measurement, a rubber stop was placed appropriately on the K-file. Each canal was enlarged to two or three instrument sizes greater than the first file. In primary molars, preparation usually started with a number 15 file. In anterior teeth, preparation begin with as large a file as dictated by the size of the canal. Filing was carried out approximately 1–2 mm short of the radiographic apex. Copious irrigation with sterile saline was carried out between the use of each instrument in order to aid in removing as much debris as possible. The pulp chamber was finally dried with suitably sized cotton pellets and the pulp canals with appropriately sized sterile paper points. Only in the case of an acute alveolar abscess was an antibiotic prescribed at the first visit.

In 29 of the primary molars where the pulp was necrotic as a result of caries and three anterior teeth which were non-vital following trauma, ZOE paste was used as the root canal filling material. In the remaining cases (24 primary molars and two anterior teeth), which were all non-vital as a result of caries, Vitapex was used to fill the root canals. The teeth were randomly treated with either ZOE (Zinc Oxide BP, Eugenol BP, Associated Dental Products Ltd) or Vitapex (prefilled syringe with 0·5 g paste, Dia Dent Co., Tokyo, Japan).

A random number table was used for randomization of cases to treatment using ZOE or Vitapex as the root canal medicament.

In the ZOE group, a homogenous and thin mix of ZOE paste (without setting accelerators) was prepared and paper points covered with the material were used to coat the root canal walls. Following this, a thick mix of the treatment paste was prepared and pushed into the root canals with a suitable root canal finger plugger and moistened cotton pellets.

In the Vitapex group, the premixed paste was packaged in a syringe with a number of disposable tips. The tip of these disposable nozzles proved too thick for use in the narrow root canals of primary molars, however, and therefore, the material was carried into the canals with the use of endodontic finger pluggers and moistened cotton pellets in the same way as for ZOE paste.

When the root canals were judged to be well filled, periapical radiographs were taken to assess the adequacy of fillings. The findings were recorded in the patient's chart as being short, complete or long fills. Following root canal fillings, all of the posterior teeth were restored with silver amalgam and the anterior ones with composite resin filling materials. All the patients were placed on a recall programme, and were followed clinically and radiographically 3 months and 10–16 months postoperatively.

Clinically, the criteria for success were that patients who had presented initially with or without evidence of pain, fistula, intraoral swelling, extraoral swelling or abnormal mobility were completely free of clinical signs and symptoms at the 10–16-month follow-up.

The radiographic criteria for success were that the patients who showed evidence of bone radiolucency in their preoperative radiographs demonstrated evidence of a reduction in the size of the radiolucent area at the 10–16 month follow-up, and patients without any evidence of a radiolucent area at the start of treatment showed no newly formed radiolucency after 10–16 months.

In those patients without evidence of aberrations in the normal path of the eruption of the successor tooth at the initial visit, there should be no evidence of deflection of the succedaneous tooth after 10–16 months. The comparison of the overall success rate between the two groups of patients was carried out using Fisher's Exact Test. *P*-values of $< 0{\cdot}05$ were considered statistically significant.

Results

Fifty-eight children (26 girls and 32 boys) aged between 3 and 13 years were randomly selected and provided with treatment in this clinical trial. The mean ages of the patients in the ZOE and Vitapex groups were $5{\cdot}8 \pm 1{\cdot}9$ and $5{\cdot}6 \pm 1{\cdot}12$ years, respectively. Positive preoperative clinical and radiographic findings for all the patients included in the study are presented in Table 1. None of the succedaneous teeth which were evaluated by preoperative radiographs of all patients in both groups showed any evidence of deflection in the normal path of eruption at the first appointment.

The findings of the immediate postoperative radiographs of the treated teeth are presented in Table 2. Of the 58 original patients selected and treated at the beginning of the study, 52 returned for follow-up. The remaining six patients had either moved from the area, or changed their addresses and/or phone numbers, and contact was lost. Therefore, the information presented here relates to the 52 patients who attended a follow-up appointment. After a 3-month period, clinical signs and symptoms of pain, fistula, and intraoral and extraoral swelling had disappeared completely in all cases of both groups. Of those patients and teeth showing evidence of abnormal mobility at the initial visit, 50·3% in the ZOE group and 78·4% in the Vitapex group were recorded as without abnormal mobility at the first follow-up visit. Some 48·6% of the cases in the ZOE group and 77·8% of the Vitapex group with evidence of pathological change in the preoperative radiographs demonstrated regeneration and reduction in the size of the area of radiolucency after 3 months. In none of the patients in either group was there evidence of deviation from the normal path of eruption after 3 months. In all cases in the ZOE group who had been recorded postoperatively as long fill, particles of extruded material were still evident after 3 months. In the Vitapex group, there was no evidence of extruded filling material in cases of overfill at the 3-month follow-up (Fig. 1). As at the first follow-up visit, none of the patients in either group showed any evidence of pain, fistula, or intraoral or extraoral swelling at the second follow-up appointment. The results of the 10–16-month clinical and radiographic evaluations of patients who had abnormal mobility and bone radiolucency preoperatively are presented in Tables 3 and 4, respectively. As shown, the number of cases with preoperative abnormal mobility or bone radiolucency who were recorded as having no abnormal mobility or having an improvement in bone radiolucency was greater at the second follow-up than in the first for both groups of the patients.

Table 1. Positive preoperative clinical and radiographic findings.

Variable	Pain	Fistula	Intraoral swelling	Extraoral swelling	Abnormal mobility	Bone radiolucency
Number	51	25	21	12	32	38
Percentage	87·9	43·1	36·2	20·6	55·1	65·5

Table 2. Immediate postoperative radiographic evaluation of root canal treated teeth with either zinc oxide and eugenol (ZOE), or Vitapex.

Root canal filling materials	Short fill		Complete fill		Long fill	
	Number	Percentage	Number	Percentage	Number	Percentage
ZOE	10	31·2	15	46·8	7	21·8
Vitapex	3	11·5	13	50	10	38·4

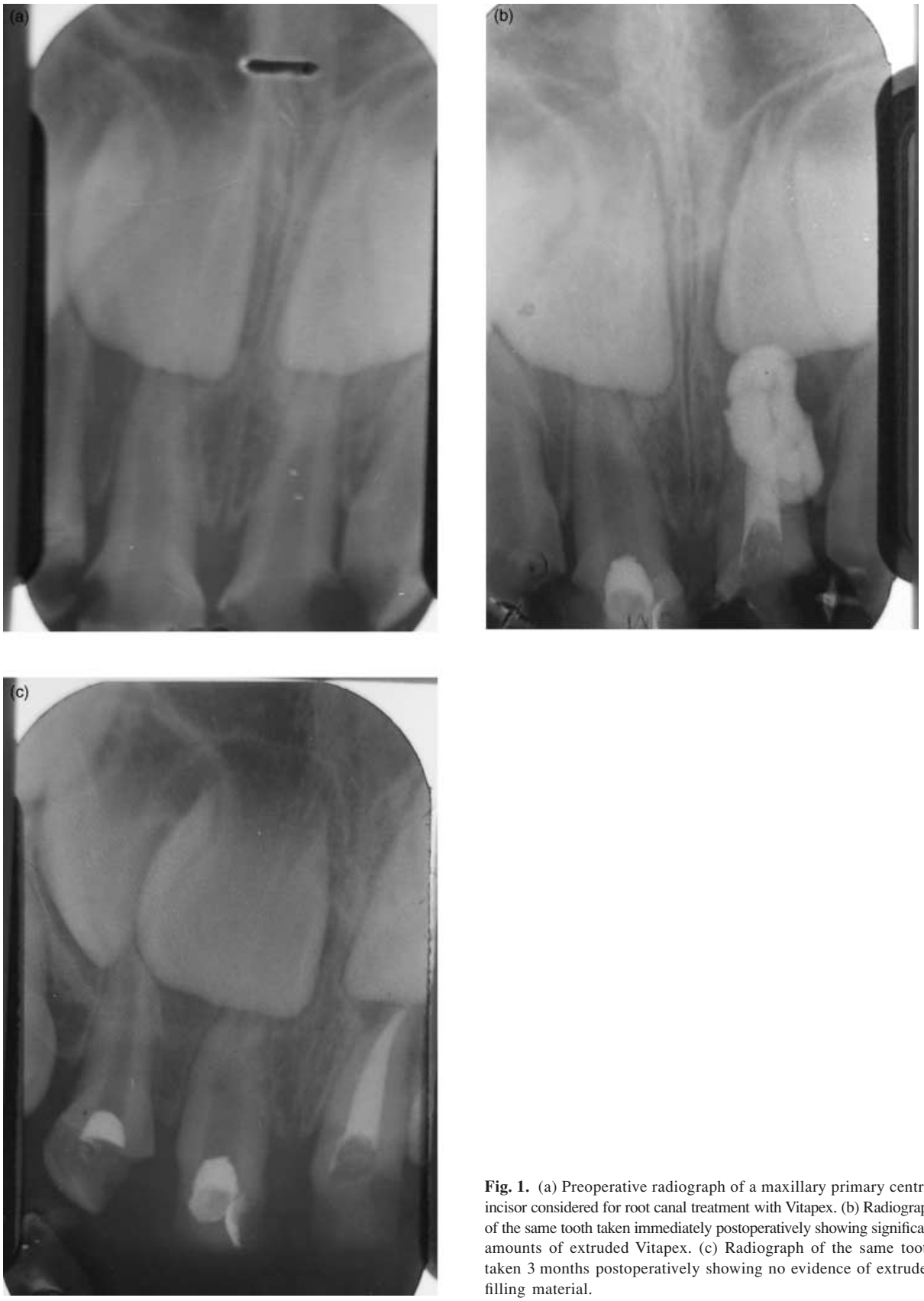

Fig. 1. (a) Preoperative radiograph of a maxillary primary central incisor considered for root canal treatment with Vitapex. (b) Radiograph of the same tooth taken immediately postoperatively showing significant amounts of extruded Vitapex. (c) Radiograph of the same tooth taken 3 months postoperatively showing no evidence of extruded filling material.

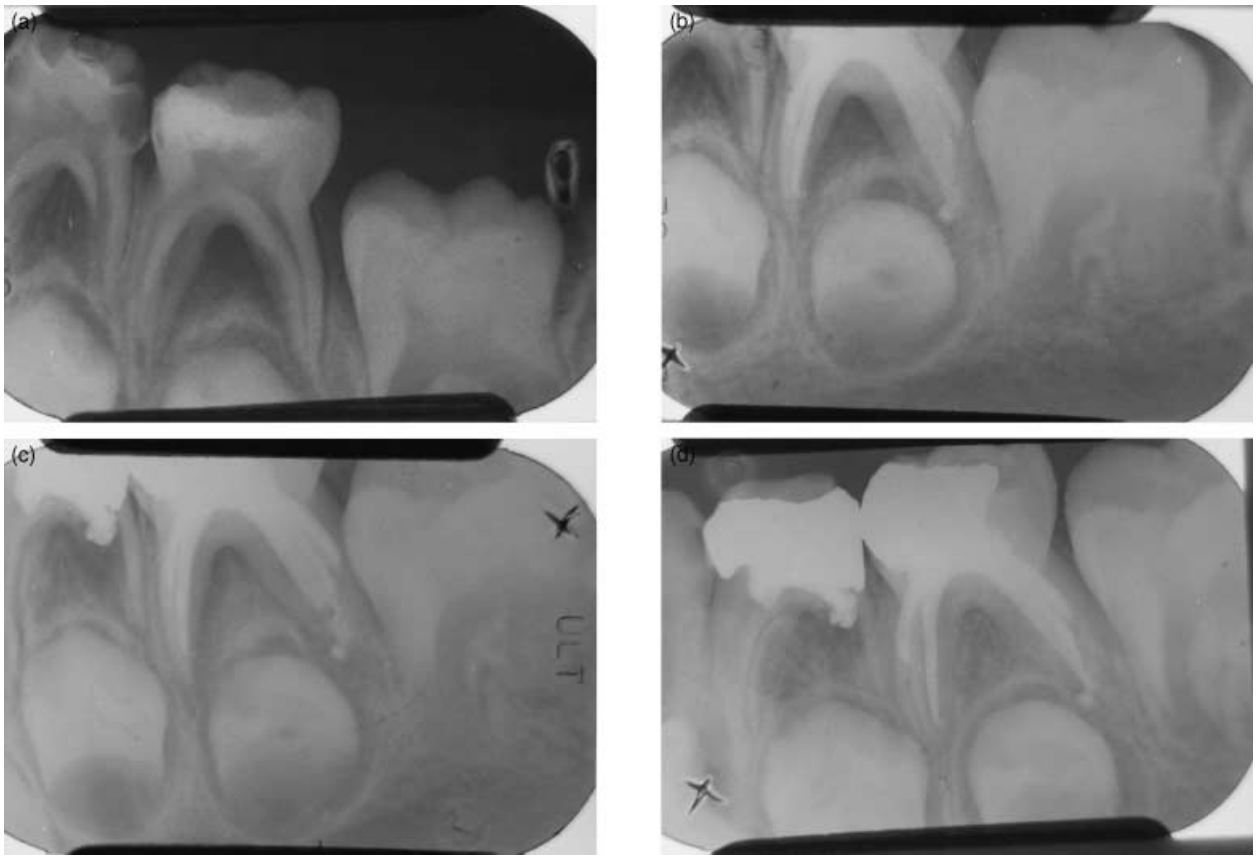

Fig. 2. (a) Preoperative radiograph of a mandibular second primary molar considered for root canal treatment with zinc oxide and eugenol. (b) Radiograph taken immediately postoperatively. (c) Radiograph taken 3 months postoperatively showing improvement of furcation radiolucency. (d) Radiograph taken 12 months postoperatively showing further improvement of the lesion.

Table 3. Clinical evaluation of patients with preoperative abnormal mobility 10–16 months after root canal treatment with either zinc oxide and eugenol (ZOE), or Vitapex.

Root canal filling materials	No abnormal mobility		Abnormal mobility	
	Number	Percentage	Number	Percentage
ZOE	15	78·9	4	21·05
Vitapex	13	100	0	0

Table 4. Radiographic evaluation of patients with preoperative bone radiolucency 10–16 months after root canal treatment with either zinc oxide and eugenol (ZOE), or Vitapex.

Root canal filling materials	Improvement in bone radiolucency		No change in bone radiolucency	
	Number	Percentage	Number	Percentage
ZOE	12	75	4	25
Vitapex	12	100	0	0

This was indicative of progressive improvement in all the treated teeth (Fig. 2). In two of the patients in the ZOE group, deflection from the normal path of eruption was diagnosed in the successor tooth after 10–16 months without any such evidence being found preoperatively (Fig. 3). In none of the teeth with preoperative bone radiolucency was this condition recorded as becoming worse at the follow-up appointments and none had newly formed lesions at the 10–16 month follow-up in either group of patients. Contrary to the Vitapex group, in which complete resorption of extruded material was noted as early as 3 months, particles of extruded ZOE were not significantly changed in size even after 10–16 months (Fig. 4).

According to the results and considering the criteria for success in this study, the overall success rate (clinical and radiographic) was 100% for Vitapex and 78·5% for ZOE at the 10–16 month follow-up period. The difference in success was statistically significant (Fisher's Exact Test, $P = 0{\cdot}015$).

Discussion

Several investigators agree that total removal of the pulp tissue from the root canals of primary teeth

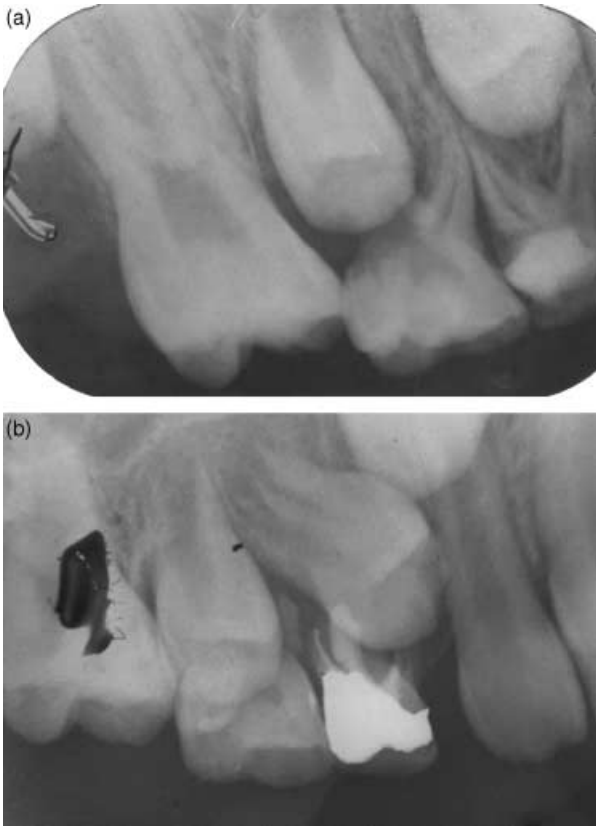

Fig. 3. (a) Preoperative radiograph of a maxillary first primary molar considered for root canal treatment with zinc oxide and eugenol. (b) Radiograph of the same tooth taken 10 months postoperatively showing deflection of the successor tooth, which was not evident in (a), the preoperative radiograph.

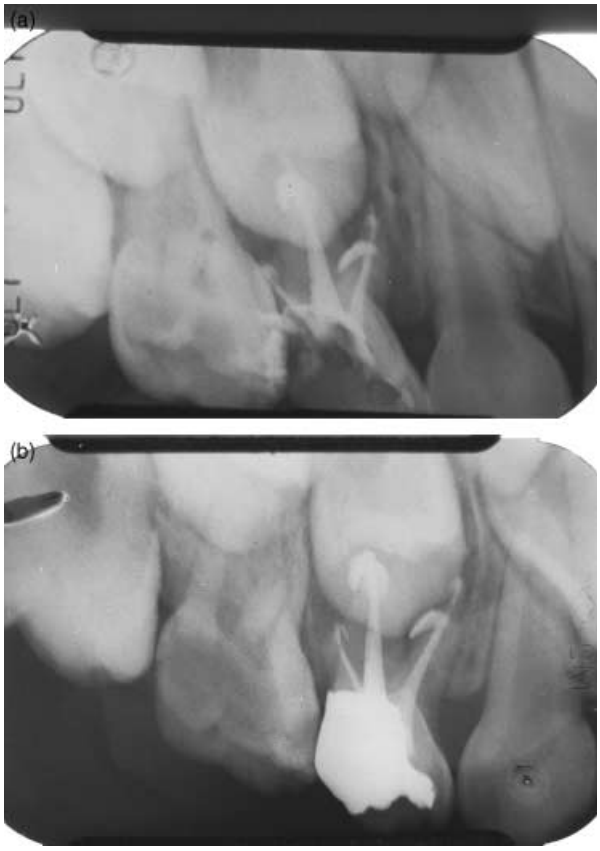

Fig. 4. (a) Radiograph of a maxillary first primary molar treated with zinc oxide and eugenol (ZOE) taken immediately postoperatively. (b) Radiograph of the same tooth taken 10 months postoperatively showing particles of extruded ZOE without a significant reduction in size.

cannot be achieved because of their complex and variable morphology. It is also difficult to eliminate the wide range of organisms, which are often present in infected primary root canals [15–18]. Thus, the particular quality of the paste used for filling determines the prognosis in the endodontic treatment of infected primary teeth [2,19].

The results of the present study suggest that root canal treatment of necrotic primary teeth with either ZOE or Vitapex as a root canal filling material is a successful procedure. This does not conform with the reports of Massler, Brauer and other researchers, who claimed that root canal treatment of non-vital primary teeth is inappropriate because of the difficulty in cleaning the root canals effectively [20,21].

The overall success rate of 78·5% achieved in the ZOE group of patients is nearly consistent with the results of Gould, Coll *et al*., Flaitz *et al*. and Yacobi *et al*., who independently advocated the use of ZOE for root canal treatment of necrotic primary teeth and reported success rates ranging from 76% to 84% after an average follow-up of 28 months [18,22–24]. The slight difference between the results of this study and those of previous investigators may be related to the difference in the number of cases and also the length of follow-up.

All the cases in the Vitapex group were clinically and radiographically successful after 10–16 months, a result that is in agreement with those of Fuchino [27] and Nurko & Garcia-Godoy [13], who reported the suitability and the high success rate of calcium hydroxide for the root canal treatment of non-vital primary teeth. The high level of success in both the ZOE and Vitapex groups can be partly related to the minimal amount of preoperative root resorption of the cases. This is consistent with the work of Coll & Sadrian, who reported that pulpectomy-treated teeth with minimal or no preoperative root resorption

had a significantly higher success rate than those with excessive root resorption [6]. In all of the patients in the ZOE group with extruded material beyond the apex, particles of ZOE were radiographically evident and without any significant reduction in size even after 10–16 months. These findings are consistent with the reports of Barker & Lockett [28], Spedding [25] and Fuks & Eidelman [5], who stated that extruded ZOE resisted resorption and took months or even years to resorb. Observing two cases of deflected succedaneous teeth in the ZOE group after 10–16 months confirmed the speculations of Ranly & Garcia-Godoy regarding deflections of the developing permanent tooth buds [29].

Contrary to the findings in the ZOE group, no evidence of remaining particles was seen after 3 months in patients from the Vitapex group in whom filling material had been extruded, suggesting that the extruded filling material had been completely resorbed. This is in agreement with the work of Nurko & Garcia-Godoy [13], who suggested that resorption of extruded Vitapex took from 1–2 weeks to 2–3 months. Contrary to the findings of Machida [1], however, there was no evidence of Vitapex within the root canals being resorbed in any of the patients in this study during the 10–16-month follow-up period. It is probable that the rapid elimination of extruded Vitapex and the fact that it does not set to a hard mass can be considered as one of the most important advantages of Vitapex over ZOE. One of the main purposes of treating and retaining a necrotic primary tooth is to maintain space for the eruption of the succedaneous tooth in a proper position, promoting normal development of occlusion. Therefore, if deflection of the successor tooth occurs following treatment of the predecessor, little is gained from such a treatment. Immediate postoperative radiographs showed that the number of short fills was greater in the ZOE group, contrary to the higher number of long fills and complete fills in the Vitapex group. This may be because of the thinner consistency of Vitapex in comparison to ZOE. This premixed paste may more easily flow into the narrow and tortuous root canals of primary molars, and reach the apex or even beyond. Similar to the results of Fuchino & Nishino, it was found that calcium hydroxide paste could be easily applied during the treatment procedure and was also easily evaluated on radiographs because of its radiopacity [26,27]. No significant difference was found between the two materials regarding the ease of insertion of the material or the radiopacity, however. It may be assumed that the higher success of Vitapex in comparison to ZOE may be related to the two main characteristics of this paste: (1) Unlike ZOE, Vitapex can be rapidly eliminated from periapical tissues and does not set to a hard mass, and therefore, the probability of deflection in successor tooth is minimized. (2) It also appears that the two main components of Vitapex (calcium hydroxide and iodoform) are responsible for its higher antibacterial properties. These two points may help to explain the difference between the success rates of ZOE and Vitapex seen in this study.

Conclusions

In conclusion, the results of this study show that Vitapex may be significantly more successful than ZOE as a filling material following pulpectomy in necrotic non-vital primary teeth. Material extruded through the apex was resorbed more successfully without loss of the root filling itself. Vitapex appears to be a suitable alternative for ZOE as a root canal filling material for primary teeth.

Résumé. *Objectifs*. Evaluer des matériaux de traitement canalaire à base d'iodoforme dans le traitement de dents temporaires nécrosées et les comparer au traditionnel oxyde de zinc eugénol (ZOE).
Echantillon et méthodes. ZOE et Vitapex (une pâte prémixée à base d'hydroxyde de calcium et de iodoforme) ont été comparés dans le traitement canalaire de 52 dents temporaires nécrosées, au sein de deux groupes d'enfants d'âge moyen 5 ans et 8,4 mois. Tous les patients ont été suivis cliniquement et radiographiquement à 3 mois et 10–16 mois post-opératoires.
Resultats. Le taux de succès de Vitapex était de 100% et de 78,5% pour ZOE. La différence était statistiquement significative en utilisant le test exact de Fisher.
Conclusion. ZOE et Vitapex ont donné des résultats encourageants. Cependant, Vitapex pourrait être utilisé avec plus de sécurité en cas de doute sur le retour du patient lors du suivi.

Zusammenfassung. *Ziele*. Evaluation von Materialien auf Jodoformbasis für Wurzelkanalfüllung bei Milchzähnen nach Pulpanekrose im Vergleich zu konventionellen Zinkoxid Eugenol (ZOE) Füllungen.
Stichprobe und Methode. ZOE und Vitapex (eine kommerziell erhältliche Paste mit Jodoform und Calciumhydroxid) wurden verglichen zur Wurzelkanalfüllung von 53 nekrotischen Milchzähnen in

zwei Gruppen von Kindern mit einem mittleren Alter von 5 Jahren und 8 Monaten. Alle patienten wurden klinisch und röntgenologisch nachuntersucht 3 Monate sowie 10–16 Monate nach der Behandlung. *Ergebnisse*. Die Erfolgsrate war bei Vitapex 100% im Vergleich zu ZOE von 78.5%. Unter Verwendung eines exakten Tests nach Fisher war der Unterschied statistisch signifikant. ($p < 0.05$).
Schlussfolgerung. Sowohl ZOE als auch Vitapex zeigten gute Ergebnisse. Falls Zweifel an der Wiedervorstellung der Patienten für Kontrolluntersuchungen bestehen, könnte Vitapex sicherer sein.

Resumen. *Objetivos*. Evaluar los materiales de base yodofórmicos para el tratamiento del conducto radicular y compararlos con el óxido de cinc y eugenol (OZE), usado tradicionalmente.
Muestra y métodos. En dos grupos de niños con una edad media de 5 años y 8,4 meses, se compararon el OZE y el Vitapex (una premezcla de hidróxido de calcio y pasta yodofórmica) para el tratamiento del conducto radicular de 52 dientes temporales necróticos. Todos los pacientes fueron seguidos clínica y radiográficamente en el postoperatorio a los 3 meses y 10–16 meses. *Resultados*. El porcentaje de éxito global fue del 100% para el Vitapex comparado con el valor del 78,5% obtenido para el OZE. La diferencia fue estadísticamente significativa ($p < 0,05$), usando el test exacto de Fisher. *Conclusión*. Tanto el OZE como el Vitapex dieron resultados esperanzadores. Sin embargo, el Vitapex podría ofrecer más seguridad en caso de duda sobre el regreso del paciente en el seguimiento.

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