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How does zinc oxide-eugenol compare to ferric sulphate as a pulpotomy material?

Keywords: pulpotomy; zinc oxide-eugenol; ferric sulphate; paediatric dentistry

SUMMARY

This study compared the clinical and radiographic responses after 3 months to a sterile compression technique with zinc oxide-eugenol or 15.5% ferric sulphate in 145 pulpotomised primary teeth in 30 children. In both groups of teeth the success rate was 100%. These short-term results suggest that either technique may be used.

OPSOMMING

In hierdie studie word die kliniese en radiologiese reaksie na 3 maande op 'n steriele kompressietegniek met 'n sinkoksied-eugenol of 15.5% ferrisulfaat in 145 gepulpotimiseerde primêre tande van 30 kinders vergelyk. In albei groepe is 100% sukses behaal. Hierdie korttermyn resultate dui daarop dat beide tegnieke gebruik mag word.

Introduction

Pulpotomy in paediatric dentistry has a long clinical history. Because of the ability of injured pulpal tissue to heal, dentists have tried various techniques and materials to preserve its vitality whenever possible. In pulpotomy, only the coronal part of the pulp tissue is removed to leave the residual vital, radicular pulp tissue intact, which is either preserved or stimulated to repair and regenerate, depending on the technique and material used.

Pulp therapy in primary teeth differs from similar treatment in permanent teeth because the root canals of primary teeth are more complex than those in permanent teeth, having lateral canals that often link with each other, making removal of tissue in them very difficult. Also, the developing permanent teeth are below their predecessors. It is important to use a pulpotomy material that is biocompatible and which does not interfere with the exfoliation of the primary teeth or with the eruption of the underlying permanent teeth.

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Formocresol was the first pulpotomy material to produce good clinical results (Buckley, 1904). It is a bactericidal agent that also fixes, or mummifies the residual radicular pulp tissue (Nunn, Smeaton and Gilroy, 1996). While it is a reliable pulpotomy material (Avram and Pulver, 1989; Morawa *et al.*, 1975), it has cytotoxic effects (Kettey and Goodman, 1991; Ranly and Horn, 1987; Ranly 1985), and mutagenic and carcinogenic risks (Judd and Kenny, 1987; Goldmacher and Thilley, 1983; Lewis and Chestner, 1981) which is important since it is absorbed and distributed systemically from the pulpotomy sites (Rusmah and Rahim, 1992; Pashley *et al.*, 1980; Myers *et al.*, 1978). Because of its potentially harmful effects, formocresol is no longer regarded as an ideal material to use in pulpotomies (Nunn, Smeaton and Gilroy, 1996; Kettey and Goodman, 1991; Judd and Kenny, 1987).

Glutaraldehyde has been shown to be a better pulp fixative than formocresol (Ranly and Lazzari, 1983; Davis, Myers and Switkes, 1982). It is more self-limiting in penetration because of cross-linking properties and its larger molecular size (Rusmah and Rahim, 1992; Ranly and Lazzari, 1983); it is also less antigenic and cytotoxic than formocresol (Ranly, Horn and Hubbard, 1989; Wemes *et al.*, 1982), but it is still absorbed and distributed systematically (Ranly *et al.*, 1989), although most of the absorbed dose is said to be eliminated within 3 days (Myers *et al.*, 1986). Generally, the success rate is not as high as reported for formocresol pulpotomy (Tsai, Su and Tseng, 1993; Fuks *et al.*, 1990).

Calcium hydroxide, with its high pH and its ability to stimulate tissue repair and to induce the formation of reparative dentine formation, has also been used as a pulpotomy material (Cvek *et al.*, 1987; Guo and Messer, 1976; Heithersay, 1975). The stimulus evoked by calcium hydroxide is delicately balanced between one of repair and one of resorption (Cvek *et al.*, 1987), thus many pulpotomised teeth treated with calcium hydroxide end up with internal resorption. Although it is considered a safe material when compared with formocresol, owing to its high failure rate, there are no strong arguments for its use in primary tooth pulpotomies (Gruythuysen and Smits, 1995; Schroder, 1978).

A non-aldehyde chemical, ferric sulphate, a powerful haemostatic agent, has received attention recently as a pulpotomy agent (Fuks *et al.*, 1997). Landau and Johnsen (1988) first tested this material as pulpotomy agent in monkeys, and observed a histological response superior to that in pulps treated with calcium hydroxide after 60 days. This was followed by a clinical study (Fei, Udin and Johnson, 1991) which showed a successful pulpotomy with ferric sulphate in 28 out of 29 teeth after 12 months. In another clinical study, Buskin (1995) showed a 100% clinical success rate after 3 months in 38 teeth treated with 15.5% ferric sulphate. Although both clinical studies have shown high success rates, the samples sizes were relatively small and the observation periods were short.

Recently, several other pulpotomy methods have been proposed, e.g. feracrylum (Prabhu and Munshi, 1997), electrofulguration (Fishman *et al.*, 1996), argon laser (Wilkerson, Hill and Arcoria, 1996) and bone morphogenetic protein (Ranly, 1994), but these methods are not yet accepted and some are expensive.

Zinc oxide-eugenol is the most widely used base material in pulpotomies, but earlier studies have revealed some negative effects when it is placed directly onto pulp tissue (Magnusson and Schroder, 1981). More recently, Fuks *et al.* (1991) demonstrated equally favourably histological tissue responses to zinc oxide-eugenol and glutaraldehyde pulpotomies in baboon teeth. Other supporters of the technique are Croll and Killian (1992), who described a zinc oxide-eugenol pulpotomy technique which they claimed to be 'most valuable and reliable in clinical use over the past 20 years', but regrettably provided no statistics to support this. These reports of good tissue response to zinc oxide-eugenol question the need for a fixative in pulpotomies, even one with few deleterious effects such as glutaraldehyde.

If a non-fixative is to be used, ferric sulphate pulpotomy is promising although not yet generally accepted since there are only two reported studies in children (Buskin, 1995; Fei *et al.*, 1991). Zinc oxide-eugenol is a well-accepted material in clinical dentistry and is known to be safe when used in humans. Zinc oxide-eugenol pulpotomy, however, has only been reported in animal studies as a control material (Fishman *et al.*, 1996; Fuks *et al.*, 1991; Lloyd, Seale and Wilson, 1988). There are no publication on the clinical outcome of the technique in children. Although there have been varying interpretations of the histological responses of the pulpal tissues to zinc oxide-eugenol, animal research (Fuks *et al.*, 1991) has shown that with careful case selection and proper manipulation of the material, it may perform just as well as glutaraldehyde.

The aim of this study was to compare the clinical success of ferric sulphate and zinc oxide-eugenol pulpotomies.

Materials and methods

After ethical approval by the university's Committee for Research on Human Subjects, informed consent was obtained from children and their parents to participate in the study. The children, aged between two and nine years, required at least two pulpotomies of primary teeth on each side of the mouth to allow a paired design for intra-person comparison.

Teeth were included in the study according to clinical and radiographic criteria. Clinically there had to be no fistulae, no excessive mobility, no tenderness to percussion and sufficient remaining tooth to allow restoration. Radiographic criteria were a carious exposure of the pulp, no internal or external resorption, no calcific pulpal degeneration, and no inter-radicular or periapical radiolucencies.

All the children in the study required general anaesthesia because of the extensive treatment that they needed. In both materials groups, the current standard pulpotomy technique at the University of the Witwatersrand Dental School was used as follows: After placement of rubber dam, caries was removed using a sterile round carbide bur (#6) before deroofing of the pulp chamber under continuous water irrigation. The coronal pulpal tissues were removed with a slow-running sterile round bar, followed immediately by a copious sterile physiological saline rinse using a 20 ml syringe and 15 gauge needle.

At this stage, haemostasis was achieved by two methods. In one group of teeth 15.5% ferric sulphate (Astringedent, Ultradent Products Inc., South Jordan, Utah, USA) was gently applied to the pulpal stumps with the applicator (Dento-infusor) supplied by the

manufacturer. If bleeding persisted, there was a second application. In the second (zinc oxide-eugenol) group light pressure was applied with sterile cotton pellets on the cut pulp.

Once haemostasis had been achieved, a thick mix of pure zinc oxide-eugenol paste (3M Dental Products, St Paul, Minnesota, USA) was placed into the pulp chamber in both groups and allowed to set. For the final restoration, either amalgam restorations (Oralloy Magicaps, Coltene, Maiwah, New Jersey, USA) or stainless steel crowns (Ion Ni-Chro crowns, 3M Dental Products, St Paul, Minnesota, USA) were placed.

The number of teeth requiring pulpotomies was not always equal on both sides of the mouth, so a perfect paired experimental design was not possible for all patients. Since ferric sulphate is the current standard procedure for pulpotomies at the university's dental school, it was decided, on ethical grounds, that the side of the mouth with more teeth needing pulpotomies would be assigned to the 15.5% ferric sulphate group, and the opposite side would receive the zinc oxide-eugenol treatment. All parents were requested to contact the operator if pain developed during the post-operative period.

Bite wing radiographs (DF54, 2 cm X 3 cm intraoral film) of the study teeth, which included the primary tooth apices, were taken pre-operatively, postoperatively and at the follow-up visit using a 70kV X-ray machine, and with patients wearing protective lead aprons.

The study design required postoperative evaluation to be done 3 months after the pulpotomy. The operator who had done the pulpotomy did the clinical assessment. Teeth were judged clinically successful if there was no pain or tenderness to percussion, swelling, fistulae, or furcation involvement. The pain or tenderness to percussion was measured as either present or absent, after gently tapping the tooth with the back of an intraoral mirror. Furcal involvement was assessed with a periodontal probe. Radiographic evaluation was made by three other dentists, blind to the treatment used, who discussed each radiograph to reach a consensus. Radiographic success required a normal periodontal ligament, absence of internal or external root resorption, and no intraradicular or periapical radiolucency.

Statistical analysis was planned as follows: The University of the Witwatersrand's Sun SPARCcentre 2000 computer running in UNIX would be used with SAS (1990) to apply a linear-logistic analysis. Pain, furcal and periapical radiolucencies would be the dependent variables, and child, jaw side and treatment materials would be the independent variables. The critical level of statistical significance was set at $P < 0.05$.

Results

In order to obtain 30 children at the 3-month follow-up, 41 children had to be included in the study. Eleven did not return for a follow-up visit. No parents contacted the operator to report pain.

A total of 145 pulpotomies were performed in the 30 children (18 girls, 12 boys). The childrens' ages ranged from 2.2 years to 9.7 years, with a mean age of 5.9 years (SD 2.0, Table I). There was a mean of 4.8 pulpotomies per child. The number of pulpotomies performed at each age is shown in Table II.

Table I. **Numbers of children by age and gender, and percentage of sample**

Age	Female		Male		Total	
(years)	*N*	%	*N*	%	*N*	%
2	2	6.7	0	0	2	6.7
3	2	6.7	2	6.7	4	13.3
4	1	3.3	4	13.3	5	16.7
5	3	10.0	1	3.3	4	13.3
6	3	10.0	1	3.3	4	13.3
7	5	16.7	3	10.0	8	26.7
8	0	0	0	0	0	0
9	2	6.7	1	3.3	3	10.0
Total	18	60	12	40	30	100

Table II. **Number of pulpotomies by age and gender, and percentage of all pulpotomies**

Age	Female		Male		Total	
(years)	*N*	%	*N*	%	*N*	%
2	9	6.2	0	0	9	6.2
3	15	10.3	8	5.5	23	15.9
4	4	2.8	16	11.0	20	13.8
5	10	6.9	4	2.8	14	9.7
6	19	13.1	6	4.1	25	17.2
7	22	15.2	19	13.1	41	28.3
8	0	0	0	0	0	0
9	7	4.8	6	4.1	13	8.9
Total	86	40.7	59	40.7	145	100

The distribution of teeth treated is shown in Table III. Of the 145 pulpotomised teeth, 74 were on the right side and 71 on the left; 76 teeth were in the ferric sulphate group and 69 teeth were in the zinc oxide-eugenol group. Eighteen teeth that required pulpotomies were anterior teeth, 127 were posterior teeth. The tooth with the highest frequency of pulpotomies was tooth 74 (20 pulpotomies), followed in descending order by tooth 84 (18), 54 (17), 64 and 75 (16 each), 85 (15), 55 (12), and 65 (11). A total of 76 mandibular molars had pulpotomies performed compared with 56 maxillary molars.

Table III. **Number of pulpotomies by tooth and material, and percentage of all pulpotomies**

Tooth	Ferric sulphate		Zinc oxide-eugenol		Total	
	N	%	*N*	%	*N*	%
51	1	0.7	5	3.5	6	4.2
52	1	0.7	3	2.1	4	2.8
53	1	0.7	0	0	1	0.7
54	10	6.7	7	4.8	17	11.7
55	6	4.1	6	4.1	12	8.2
61	3	2.1	1	0.7	4	2.8
62	3	2.1	1	0.7	4	2.8
63	0	0	0	0	0	0
64	6	4.1	10	6.9	16	11.0
65	7	4.8	4	2.8	11	7.6
71	0	0	0	0	0	0
72	0	0	0	0	0	0
73	0	0	0	0	0	0
74	11	7.6	9	6.2	20	13.8
75	8	5.5	8	5.5	16	11.0
81	0	0	0	0	0	0
82	0	0	0	0	0	0
83	1	0.7	0	0	1	0.7
84	10	6.9	8	5.5	18	12.4
85	8	5.5	7	4.8	15	10.3
Total	76	52.4	69	47.6	145	100

All the teeth in the study, whether in the ferric sulphate or zinc oxide-eugenol groups, were judged to be clinically and radiographically successful. Due to the clear outcome no statistical analysis was required. A typical example of 3-month postoperative radiograph of a zinc-oxide pulpotomy after a carious exposure of the pulp is shown in Fig. 1.

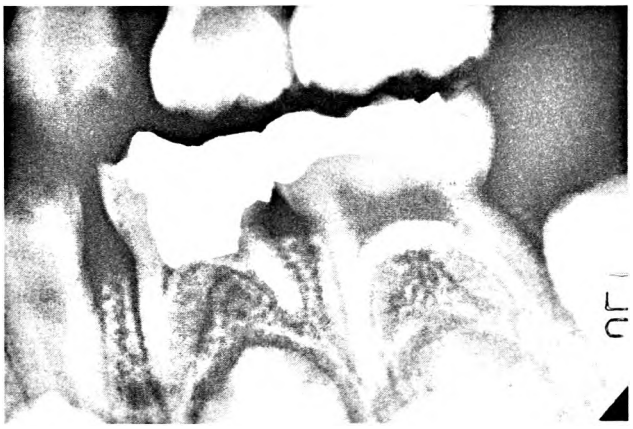

Fig. 1. A bite-wing radiograph at the 3-month recall visit showing tooth 74 with a zinc oxide-eugenol pulpotomy and amalgam restoration.

Discussion

The main objective of the pulpotomy in primary teeth is to retain the tooth in the dental arch until normal resorption and exfoliation occurs. To realise this any pulpotomy medicament must produce clinical and radiographic success as was measured in the current study. All the pulpotomies in this study were successful at 3 months, with no differences between the ferric sulphate and the zinc oxide-eugenol methods.

Although the time to achieve haemostasis after pulpal amputation was not recorded, haemostasis appeared to be achieved sooner with ferric sulphate (approximately 5 minutes), than when the residual pulp stumps were gently compressed with a sterile cotton pellet (about 2-3 minutes longer than ferric sulphate).

When pulpotomy success should be assessed in primary teeth has not been defined in the dental literature. Assessment time periods in published pulpotomy studies have varied considerably, from 2 to 12 months or even longer (Cotes *et al.*, 1997; Fuks *et al.*, 1997; Fishman *et al.*, 1996; Buskin, 1995; Fei *et al.*, 1991; Laundau and Johnsen, 1988; Magnusson and Schroder, 1981). Ideally, the longer the follow-up period the better the chance for pathology to manifest. However, choice of timing is influenced by the likelihood of tooth exfoliation, which depends on the age of presentation of the child and the tooth concerned, as well as the likelihood of patient return for assessment of the treatment. The 3-month follow-up period chosen for the present study was based on clinical experience, because if a pulpotomy is going to fail it should become evident within 3 months.

This study has shown excellent clinical and radiographic results for both 15.5% ferric sulphate and zinc oxide-eugenol as pulpotomy medicaments. The high succcess rate of both materials in this study agrees with the results of previous studies by Fuks *et al.* (1997), Fishman *et al.*, (1996), Buskin (1995) and Fei *et al.*, (1991). The successful clinical and radiographic results also correlate with the histological findings of Fuks *et al.*, (1991) and Landau and Johnsen (1988) which showed little inflammation and no abscess formation in the pulpal tissues treated with both materials.

Both materials used in the present study are readily available to any general dental practitioner. Ferric sulphate is the more expensive of the two, has a limited shelf life and is recommended to be used with a special applicator. It is commonly used by dentists for haemostasis before taking impressions. Zinc oxide-eugenol is one of the most widely used dental materials, is inexpensive and has a very long shelf life.

The current investigation, however, was a short-term study with a 3-month follow-up period. According to the guidelines used in treating paediatric patients at the University of the Witwatersrand Dental School and based on other published work (Mathewson *et al.*, 1982; Kennedy and Kapala, 1980), one of the criteria for considering pulpotomy is an expected lifespan of the treated tooth of 18 months. Therefore, a longer observation period of up to 18 months would be ideal to evaluate any long-term detrimental effects.

Conclusion

Both 15.5% ferric sulphate and zinc oxide-eugenol are good alternative pulpotomy medicaments to formocresol or glutaraldehyde. Final choice of pulpotomy technique is up to the individual clinician. In the context of a Third World situation or in rural areas where material availability is a problem, the zinc oxide-eugenol pulpotomy technique is recommended because it involves one material less, reduces the pulpotomy cost but achieves the same result as 15.5% ferric sulphate.

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