

Comparative evaluation of zinc oxide-eugenol and zinc oxide with *Neem* oil in root canal treatment of primary teeth: Split-mouth study with 12 months follow-up

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Abstract

Background: Various root canal filling materials are used to preserve pulp tissue involved carious the primary tooth. A single material that fulfills all the requirements of an ideal root canal filling material for primary teeth is yet unavailable. Hence, this study was initiated to evaluate clinically and radiographically, the efficacy of two obturating materials – zinc oxide eugenol (ZOE) and zinc oxide mixed with *Neem* oil (ZON) for 12 months. **Aims:** To assess the success rate of a mixture of zinc oxide and neem oil in comparison to zinc oxide-eugenol paste, as an obturating material in primary molars. To compare the efficacy of ZON as an obturating material at the various time interval of 3, 6, 9, and 12 months postoperatively. **Materials and methods:** This split-mouth, double-blind study was performed on 24 children aged 5–7 years, who presented with bilaterally infected primary molars. Total 48 infected primary molars were divided into two groups for pulpectomy followed by obturation with ZOE and ZON, respectively. Randomization with the chit-pick method, for the control and experimental drug, was performed. A follow-up for 12 months was performed. The Chi-square test was used for inter-group comparison and the Z test was used for the analysis of data over a period of time. **Results:** Overall clinical findings in this study revealed 91.7% results in ZOE compared with 100% results in the ZON group. The radiographical findings revealed 91.7% results in ZOE compared with 100% success in the ZON group. **Conclusion:** ZON demonstrated excellent effectiveness as an obturating material in the 12-month follow-up period as compared to ZOE in primary teeth. The efficacy elicited in this study could be a basis to recommend ZON as herbal alternative obturation material.

Keywords: *Neem* oil, obturating materials, primary teeth, pulpectomy, zinc oxide-eugenol

Introduction

The pediatric dentist strives to save every deciduous tooth considered vital for the complete functioning of the child patients' dental arch. The widely used approach of pulpectomy of deciduous molar teeth is considered as a balanced treatment approach to ensure the retention of these teeth till either natural shedding or on occasions of prolonged retention. Hence, this serves as a specialized treatment modality for primary teeth with irreversible pulpal diseases or nonvital radicular pulp with or without associated infection.^[1] The model obturation material must entail qualities such as antibacterial, resorbable at the same rate of the root, and harmless to periapical tissues and the developing tooth bud. Additionally, it must effortlessly fill the canals, adhere to the walls, not shrink, must readily resorb if extruded beyond the apex, be easily removed if necessary, be radiopaque, and causes no discoloration of the tooth.^[2-4]

The predominantly utilized materials presently, for primary root canal fillings are zinc oxide-eugenol (ZOE), iodoform and calcium hydroxide-based pastes, and endoflas.^[5,6] The periapical irritant effects of eugenol, are recognized.^[7] Further, the allergic reactions to iodine among individuals and discoloration caused by iodoform-based pastes are widely researched.^[8,9] Reports of few studies, demonstrating periapical irritation by iodoform pastes.^[10] and the bismuth in iodoform paste may lead to encephalopathy when used

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as wound dressing for head and neck surgery are cause for concern.^[11]

Unfortunately, none of the commercially available materials satisfy all the ideal criteria and the side-effects of synthetic materials is a valid concern. This has prompted a search for herbal alternatives. *Azadirachta indica* A. Juss (*A. indica*), commonly known as *Neem*, has attracted worldwide importance in recent years, owing to its wide range of medicinal properties, for example, anti-bacterial, anti-fungal, anti-viral, anti-oxidant, anti-ulcer, and anti-inflammatory.^[12]

Very few studies show the application of herbal materials as an obturating agent. To cite the limited research in this context, where propolis has been used in pulpotomy^[13,14] as well as pulpectomy^[15] and *Aloe vera* (*Aloe barbadensis* miller) gel used as an obturating material in the primary dentition.^[16] Studies have shown that neem extract has better antimicrobial properties than *Aloe vera*^[17] and propolis extracts.^[18] This study intended to evaluate the efficacy of a mixture of zinc oxide and neem oil when compared to ZOE paste, as an obturating material in primary molars.

Materials and methods

The present longitudinal study was conducted to assess the effectiveness of zinc oxide mixed with neem (ZON) compared to ZOE paste, as an obturating material in primary molars. A total of 200 patients were examined [Figure 1] and 24 children were selected based on inclusion criteria [Table 1] and after obtaining written informed consent from the parents. A split-mouth study was performed on 24 children aged 5–7 years, who presented with bilaterally infected primary molars. Total 48 infected primary molars were divided into two groups for pulpectomy followed by obturation with ZOE and ZON, respectively. Split-mouth, double-blind technique was used. Control drug and experimental drug were obturated by simple chit pick randomization method. All children were followed up for over 12 months.

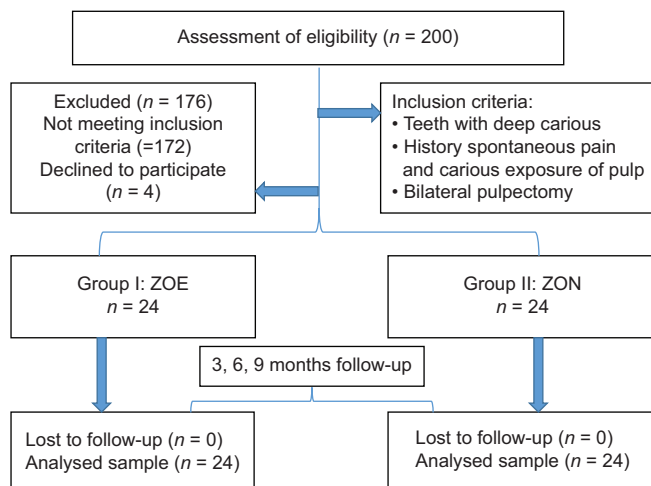


Figure 1: Consort chart

Selection criteria

The clinical and radiographic criteria are presented in Table 1.

The case distribution:

- Group I (24 teeth): Zinc oxide powder mixed with eugenol oil (ZOE)
- Group II (24 teeth): Zinc oxide powder mixed with pure neem oil (ZON).

Preparation of zinc-oxide and neem oil mixture

Zinc oxide powder (Prime Dental Pvt. Ltd. Thane, Maharashtra, India) and 100% neem oil (Deve Herbes, New-Delhi, India) were mixed on a glass slab with the help of a stainless-steel spatula, in mixing ratio of 1:3 as same as zinc oxide and eugenol. The method followed to manipulate ZON paste demonstrated the initial setting time established at 8 min –10 min where the consistency of the mixture was semi solid and final setting into hard mass at 24 h. The mixture also demonstrated no leaching when tested at hourly intervals for 24 h.

Methodology

Local anesthesia for the selected tooth to be treated was achieved followed by isolation with rubber dam. A straight-line access to root canals was achieved depending on the extent of the lesion. Coronal pulp was removed with a spoon excavator. This was followed by chemo-mechanical preparation that was carried out using K files and irrigating solutions (saline, 2% V-concept) to remove the necrotic pulp tissue. All the canals were dried using paper points. The canals were then obturated with medicines (ZOE) group-I and (ZON) group-II. Immediate postobturation radiographs were taken. A final restoration with stainless steel crowns was performed.

Patients were recalled after 3, 6, 9 and 12 months and evaluated according to the clinical and radiographic criteria. The treatment was deemed successful when the following criteria were fulfilled: absence of pain, tenderness to percussion, gingival inflammation/sinus tract, and mobility. Visual analog scale was used for the assessment of pain. Cases which demonstrated signs of failure (pain and gingival inflammation) were treated with local pus drainage, analgesic, and antibiotics. No retreatment was performed.

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Clinical criteria	
Children aged 5–7 years with infected primary molars bilaterally	Children who had nonrestorable teeth
History of spontaneous pain with deep carious lesion	
Radiographic criteria	
Adequate alveolar bone support	Teeth with <2/3 root
Absence of internal resorption, absence of external pathologic resorption	Teeth with radiographically evident inter-radicular and peri-radicular radiolucencies

Results

A total of 48 primary molars were endodontically treated among 24 children in the age group of 5–7 years, who had bilaterally infected primary molars. The selected teeth were divided into two groups of 24 teeth and were obturated with the group I and group II, respectively.

The patients were examined for clinical and radiographic findings before the procedure. Majority of the teeth presented with pain or tenderness to percussion, preoperatively. The follow-up examination revealed a marked improvement in the terms of clinical factors in both groups. [Table 2] Incidence of pain was seen in 75% and 70.8% of patients in group-I and group-II preoperatively.

Pain was observed in two patients in group I after 12 months. While 100% relief in pain (highly significant [$P < 0.001^{**}$]) was observed in group-II. A statistically highly significant difference present in the pain perception when both groups were compared at various time periods ($P < 0.001^{**}$) was noted.

The presence of tenderness on percussion was found in one case of group-I at 3, 6 months postoperatively while no case reported tenderness on percussion in group-II.

Intergroup comparison showed a statistically high significance difference. ($P < 0.001^{**}$). When individual groups were compared for various time intervals; there was no statistically significant difference present.

Inter-radicular radiolucency was absent in all the cases before the start of the study. Radiographic examination was carried out at 3, 6, 9 and 12 months intervals. Development of radiolucency was observed in two cases of the ZOE group at 3 and 6 months follow-up, respectively. While in group-II showing one case of inter-radicular radiolucency at 3 months follow-up was found. This has demonstrated the decrease of radiolucency at 12 months of follow-up. There was no statistically significant difference in between the groups [Table 3].

Overall clinical effectiveness achieved in this study was 91.7% in group-I compared with 100% in group-II. Overall radiographic effectiveness achieved in this study was 91.7% in group-I compared with 100% in group-II [Table 4].

Discussion

At present, numerous materials (ZOE, calcium hydroxide, calcium hydroxide with iodoform paste, KRI paste, maisto's paste, walkhoff's paste, etc.) have been tested for their efficiency

Table 2: Group I and Group II clinical findings

Follow up period	Pain		Mobility		Sinus		Tender on percussion	
	Group-I (n %)	Group-II (n %)	Group-I (n %)	Group-II (n %)	Group-I (n %)	Group-II (n %)	Group-I (n %)	Group-II (n %)
Preoperative	75%	70.8%	0	0	0	0	16.7%	25%
Postoperative (months)								
3	4.2%	4.2%	4.2%	0	0	0	4.2%	0
6	4.2%	4.2%	0	0	4.2%	4.2%	4.2%	0
9	4.2%	0	0	0	4.2%	0	0	0
12	8.3%	0	0	0	4.2%	0	0	0
Z test	2.454 ($P < 0.001^{**}$)	2.309 ($P < 0.001^{**}$)	0.144 ($P > 0.05$) NS	0.000 ($P > 0.05$) NS	0.144 ($P > 0.05$) NS	0.144 ($P > 0.05$) NS	0.433 ($P > 0.05$) NS	0.866 ($P > 0.05$) NS
Chi-square test	128.60 ($P < 0.001^{**}$)		9.038 (0.443) NS		4.103 ($P > 0.05$) NS		34.737 ($P < 0.001^{**}$)	

****** $P < 0.001$: Highly statistically significant difference. NS: Not significant

Table 3: Comparison of inter-radicular radiolucency in group I and group II, preoperatively, 3, 6, 9 and 12 months postoperatively

Duration	Number of teeth	Group I			Group II		
		Present/ increase, n (%)	Absent/ no change n (%)	Decrease n (%)	Present n (%)	Absent n (%)	Decrease n (%)
Preoperative	24	0	24 (100)	0	0	24 (100)	0
Postoperative (months)							
3	24	1 (4.2)	23 (95.8)	0	1 (4.2)	23 (95.8)	0
6	24	1 (4.2)	22 (91.7)	1 (4.2)	0	23 (95.8)	1 (4.2)
9	24	1 (4.2)	22 (91.7)	1 (4.2)	0	23 (95.8)	1 (4.2)
12	24	0	22 (91.7)	2 (8.3)	0	24 (100)	0
Z test			0.144 ($P > 0.05$) NS			0.000 ($P > 0.05$) NS	
Chi-Square test					13.594 ($P > 0.05$) NS		

NS: Not significant

Table 4: Overall success rate

Success parameter	Group I (months)				Group II (months)				Significant
	3, n (%)	6, n (%)	9, n (%)	12, n (%)	3, n (%)	6, n (%)	9, n (%)	12, n (%)	
Clinical success	23 (95.8)	23 (95.8)	23 (95.8)	22 (91.7)	24 (100)	24 (100)	24 (100)	24 (100)	0.588 (NS)
Radiographic success	23 (95.8)	22 (91.7)	22 (91.7)	22 (91.7)	23 (95.8)	23 (95.8)	23 (95.8)	24 (100)	0.214 (NS)

NS: Not significant

as obturating agents, but none exhibit the requisite properties for an ideal obturating material.^[19] Success rates reported with ZOE cement by various authors are as follows: 82.3%,^[20] 82.5%,^[21] and 86.1%.^[22] Chawla *et al.* used a mixture of calcium hydroxide and zinc oxide as a root canal filling material, but this material was depleted from the canals earlier than the physiologic root resorption.^[23] Recent studies with endoflas a root canal material demonstrated success rates ranging from 54.8% to 100%.^[6] Search for an ideal obturating material which meets all the requirements is a continued venture.

Neem oil is a herbal and naturally found material. The chemical constituents present in it are part of the physiological functions of living flora, and hence, they are believed to have better compatibility with the human body.^[24] Every part of the tree has been used in traditional medicine for household remedies.^[25] It is active against *Klebsiella*, *staphylococcus*, and *serratia* species. It is also active against *streptococcus mutans* and *streptococcus faecalis*.^[26] Prasad *et al.*^[27] demonstrated antimicrobial action of neem against *Candida albicans*, *Enterococcus faecalis-in vitro*. This study has opened perspectives for its use as root canal irrigant. Furthermore, Chatterjee *et al.*^[28] evaluated antigingivitis and antiplaque effect of neem mouth rinse on plaque-induced gingivitis-*in vivo*, and demonstrated the higher efficacy of neem mouthrinse in reducing periodontal indices compared to chlorhexidine. Thus, the antimicrobial property of neem was established in root canal irrigants and mouthwashes.^[18,27] However, research regarding the incorporation of neem in obturating material is scarce.

To improve the properties and effectiveness, various additions to ZOE have been attempted, but the addition of these compounds neither increased the success rate nor made the material more resorbable as compared to ZOE alone. Eugenol also acts as an irritant in the periapical region and when mixed with zinc oxide powder, it sets as a hard mass. Whereas zinc-oxide powder, if mixed with neem oil, provides the following advantages: Nonirritant to soft tissue, biocompatible to human periodontal ligament fibroblasts,^[28] sufficient working time, with primary setting time 4–6 h, its ease of placement, etc. Hence, this study has explored the combination of zinc-oxide powder with neem oil to ascertain its efficacy as an obturation material in primary teeth.

A highly statistically significant difference ($P < 0.001^{**}$) was seen between the two groups at postoperative 12 months follow-up for pain and tenderness. There were no obvious failures in the ZON group. In contrast, the ZOE group displayed

one case with postoperative pain; tender on percussion, gingival swelling, and mobility 2 weeks post-obturation, and incomplete healing until the 12-month follow-up.

The results of the present study are comparable to Holan and Fuks (1993)^[29] who reported an efficacy of 84% with KRI paste as compared to 65% with ZOE. Reddy and Fernandes^[30] have reported 100% effectiveness with the use of Maisto's paste and 80% with ZOE. Nadkarni and Damle (2000)^[31] have reported 94.28% efficacy with the use of calcium hydroxide and 88.57% efficacy with the use of ZOE after 9 months. Mortazavi and Mesbahi (2004) reported success rate (clinical and radiographic) was 100% for vitapex and 78.5% for ZOE at the 10 – 16-month follow-up period for root canal treatment of necrotic primary teeth).^[32]

Other research performed with additives to zinc oxide, comparable to the present study are, Al-Ostwani, *et al.*^[15] reported the new ZOP paste (zinc oxide with *propolis*) achieved clinical success rate of 93.8% and radiographic success rate of 62.5% after 12 months, while ZOE achieved clinical success rate 87.5% and radiographic success rate 56.3% after 12 months. Another study by Rahman and Christiano^[33] concluded that ZOP has lower antibacterial effectiveness on the *Enterococcus faecalis* than ZOE. Gupta *et al.*^[34] showed that zinc oxide propolis had greater clinical success and its resorbability was similar to that of compared endoflas, metapex and ZOE. Navaneet *et al.*^[35] found that the formulations obtained by incorporating *Triphala* (combination of fruits of *Emblica officinalis* Gaertn., *Terminalia chebula* Retz., and *Terminalia bellirica* Roxb.), *Aloevera* (*Aloe barbadensis* miller), *Tulsi* (*Ocimum sanctum* Linn) in zinc oxide exhibited substantial antimicrobial activity when compared to ZOE alone.

The present research has assessed the ZON as an obturating material in infected primary molars and observed excellent success rate over 12 months period. However, the implication of the healing process of neem on resorptive furcation pathology in abscessed primary teeth is one of the future prospectives to explore. Hence, further research would be advocated to explore and analyze the effects of these materials with long-term follow-up.

Conclusion

Overall clinical findings in this study reveal 91.7% efficacy in zinc oxide eugenol (ZOE) compared with 100% effectiveness in the zinc oxide neem oil (ZON) group. Overall radiographic findings in this study reveal 91.7% success in ZOE compared with 100% success in the zinc oxide with neem oil group. The present investigation indicated that reduction in clinical

signs and symptoms and healing of furcation radiolucency as evidenced by resolution or arrest of radiolucency was present with both the materials (ZOE and ZON) used. However, a gradual but almost complete reduction in preoperative signs and symptoms was observed with zinc oxide with neem oil. The findings of the present investigations indicate that ZON could be used as an alternative to ZOE as an obturation material.

This study was done with a 12-month evaluation period, hence a long-term follow-up to establish adverse effects if any, as well as radiological improvements especially, furcation and apical change appropriately is required. Furthermore, clinical and histological studies with longer follow-up till the period of tooth exfoliation to ascertain the efficacy of this novel treatment modalities are recommended.

Ethical approval

The study protocol was approved by the institution review board-Ethical committee of Narsinhbhai Patel dental college and hospital, SPU, Visnagar. We do not have CTRI registration.

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Conflicts of interest

There are no conflicts of interest.

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