



Clinical and Radiographic evaluation of mixture of Zinc Oxide powder and Nanohydroxyapatite as an obturating material in primary molars

Avaliação clínica e radiográfica da associação do pó de óxido de zinco com nanohidroxiapatita como um material obturador utilizado em primeiros molares

Pratyusha KOTTAPALLI¹, Ghanashyam Prasad MADU¹, Naga Radhakrishna AMBATTI¹, Deepthi BOLLA¹, Venkata Sandeep RAYALA¹, V.K.Raviteja NARRA¹

1 – Pedodontics and Preventive Dentistry – St. Joseph Dental College – Eluru – Andhra Pradesh – India.

ABSTRACT

Pulpectomy is the treatment alternative in rescuing the pulpally involved carious primary teeth. Various obturating materials are being used to conserve an infected deciduous dentition. The present study documents the use of a novel obturating material in primary molars due to the disadvantages associated with of the currently used materials. **Objective:** To evaluate clinically and radiographically the success rate of the mixture of zinc oxide powder and nanohydroxyapatite with saline as an obturating material in primary molars and also to compare its efficiency with Endoflas. **Material and Methods:** Thirty pulpectomy indicated primary molars were randomly divided into two equal groups; Group I (mixture of zinc oxide powder and nanohydroxyapatite with saline) and Group II (Endoflas FS). The teeth were evaluated using various clinical and radiographic criteria at 3, 6 and 9-month intervals. The obtained results were statistically analyzed ($P < 0.05$). **Results:** The overall present study findings revealed 100% clinical success in both the groups. Whereas radiographically, success reported was 66% for Group I and 100% for Group II at the end of 9 months follow-up. The difference in the radiographic success rate between the two groups was statistically significant ($P < 0.05$). **Conclusion:** Endoflas FS had demonstrated high success rate both clinically and radiographically when compared to the novel combination of a mixture of zinc oxide powder and nanohydroxyapatite with saline as obturating material.

KEYWORDS

Endoflas; Mixture of zinc oxide and nanohydroxyapatite; Obturating material; Pulpectomy; Primary molars; Endoflas.

RESUMO

Pulpectomia é uma alternativa de tratamento que visa resgatar polpas envolvidas em processos cariosos de dentes decíduos. Vários materiais obturadores estão sendo usados para conservar a dentição decídua infectada. O presente estudo relata o uso de um novo material obturador em molares decíduos devido às desvantagens dos materiais atualmente utilizados. **Objetivo:** Avaliar clínica e radiograficamente a taxa de sucesso da mistura de pó de óxido de zinco e nanohidroxiapatita como material obturador em molares decíduos e também comparar sua eficiência com Endoflash. **Material e Métodos:** Trinta molares decíduos que foram indicados para pulpectomias foram divididos aleatoriamente em dois grupos iguais; Grupo I (mistura de pó de óxido de zinco e nanohidroxiapatita) e Grupo II (Endoflash). Os dentes foram avaliados utilizando vários critérios clínicos e radiográficos em intervalos de 3, 6 e 9 meses. Os resultados obtidos foram analisados estatisticamente ($P < 0,05$). **Resultados:** Os achados gerais do presente estudo revelaram sucesso clínico de 100% em ambos os grupos. Enquanto que radiograficamente, o sucesso relatado foi de 66% para o Grupo I e 100% para o Grupo II ao final de 9 meses de acompanhamento. A diferença na taxa de sucesso radiográfico entre os dois grupos foi estatisticamente significante ($P < 0,05$). **Conclusão:** O Endoflas demonstrou alta taxa de sucesso tanto clínica como radiograficamente quando comparado à nova combinação de pó de óxido de zinco e nanohidroxiapatita como material obturador.

PALAVRAS-CHAVE

Endoflas; Mistura de pó de óxido de zinco e nanohidroxiapatita; Material obturador; Pulpectomia; Molares decíduos.

INTRODUCTION

Maintenance of the integrity and health of the teeth and their supporting tissues was the primary goal of pulp therapy [1]. Pulpectomy helps to preserve a pulpally involved carious primary tooth by abolishing bacteria and their products and also ensures hermetic seal of the root canals thereby allowing the primary teeth to fulfill its function until normal exfoliation can occur without harming the successor or affecting the health of the individual [2].

Endoflas FS, which is a mixture of calcium hydroxide, zinc oxide eugenol and iodoform, had a high success rate and can be considered to be an effective root canal filling material in primary teeth due to its healing ability, bone regeneration characteristics and its resorption of excess material without washing within the roots [2].

The most commonly used pulpectomy medicaments in primary endodontics include Zinc oxide eugenol, Calcium hydroxide, iodoform and their combinations. But due to associated drawbacks like toxicity, reduced anti-microbial activity, over retention or easy resorption, the currently available commercial materials being used do not satisfy all the requirements of an ideal pulpectomy medicament. In dentistry, the current trend is towards the use of biomaterials like hydroxyapatite [3].

Hydroxyapatite has attained much interest in recent times as a biomaterial because it is the main biomineral component which is found in human hard tissues, i.e. tooth and bone and also due to its similarity in crystallography and chemical composition to that of human hard tissue [4]. Hydroxyapatite has a wide range of applications due to its outstanding properties like biocompatibility, bioactivity, osteoconductivity, nontoxicity and noninflammatory nature [4].

The present study was undertaken to evaluate the clinical and radiographical performance of a hydroxyapatite-based pulpectomy medicament ie; mixture of zinc oxide powder and nanohydroxyapatite with

saline and also to compare its success rate with Endoflas FS.

MATERIALS AND METHODS

Thirty decayed primary molars that were indicated for pulpectomy in children with age ranges from 4-10 years were selected for the study. Parents/guardians were informed about the study and consent was obtained before commencement of any procedure. The permission of the Ethical committee of the institute (protocol#CEC/034/14-17) was obtained prior to the initiation of the study.

The teeth with following signs and symptoms such as history of spontaneous pain, presence of 2/3rd of root, presence of swelling, nonvital teeth and tenderness on percussion were included in the study. Teeth showing internal/external resorption and extreme mobility, grossly decayed teeth and teeth with pathological lesion extending to the tooth germ of the successor's tooth were excluded from the study.

A single visit pulpectomy was carried out and all the pulpectomies were performed by a single investigator. Following the step-back biomechanical preparation, using K-files (Dentsply, Maillefer, Switzerland) with alternating 1% sodium hypochlorite and normal saline irrigation, the teeth were randomly divided into 2 groups of 15 each based on the obturating material being used. Group I – mixture of zinc oxide powder (DPI, Mumbai, India) and nanohydroxyapatite (Sigma – Aldrich, Saint Louis, USA) with saline, Group II – Endoflas FS (Sanlor and Cia. S. En C. S., Colombia). Obturation was done by incremental technique.

Preparation of Zinc oxide and Nanohydroxyapatite mixture (Group I):

Zinc oxide powder and nanohydroxyapatite powder were taken in 2:1 ratio and were mixed with saline on a glass slab with the help of a stainless steel spatula.

For all the 30 primary molars post obturation restoration was done with Glass ionomer cement followed by a stainless steel crown (3M-ESPE, St. Paul, MN, USA). The radiographic assessment was made to verify the quality and extent of filling. The teeth were evaluated using various clinical and radiographic criteria at 3, 6 and 9 months interval.

Clinical criteria for evaluation at 3, 6 and 9 months [2]

Presence or absence of pain, tenderness on percussion, swelling and mobility.

Radiographic criteria for evaluation at 3, 6 and 9 months [2]

Resorption of overpushed material (if any), resorption of material with the physiologic root resorption, deviated path of eruption of succedaneous teeth.

The obtained results were compiled and subjected to statistical analysis using the chi-square test, SPSS version 20 software.

RESULTS

The preoperative and postoperative clinical signs and symptoms were tabulated (Table 1). Statistically significant difference ($P = 0.0001$) was seen between the preoperative and postoperative clinical signs and symptoms in both the Groups at postoperative 3, 6 and 9 months. There were no extractions or failures in both the Groups. There was complete clinical success of 100% in both the Groups.

Radiographically when the teeth were assessed for changes in the inter-radicular radiolucency a success of 66.66% was observed for Group I whereas 100% success without any occurrence of inter-radicular radiolucency at the end of 9 months was observed in Group II (Table 2).

Table 1 - Comparison of clinical findings for Groups I & II.

Follow-up period	Pain		Mobility		Swelling		Tenderness on percussion	
	Group I n %	Group I n %	Group I n %	Group I n %	Group I n %	Group I n %	Group I n %	
Pre-operative	11 73.33%	12 80%	0 0%	0 0%	0 0%	0 0%	0 0%	
Post-operative								
3 months	0	0	0	0	0	0	0	
6 months	0	0	0	0	0	0	0	
9 months	0	0	0	0	0	0	0	
P value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	

Table 2 - Comparison of radiographical findings for Groups I & II.

Radio-logical findings	Group I – ZINC OXIDE AND NANO-HYDROXYAPATITE			Group II – ENDOFLAS FS		
	N	(%)		N	(%)	
Pre-Operative	N	(%)		N	(%)	
Furcation Radiolucency	2	13%		0	0%	
Post-Operative	3 months	6 months	9 months	3 months	6 months	9 months
Furcation Radiolucency decrease in size	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%
increase in size	4 26%	5 33.33%	5 33.33%	0 0%	0 0%	0 0%
Deviated path of eruption of succedaneous teeth	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%

Radiographic assessment of the overfilled material in Group I revealed that out of the 4 overfilled canals, complete resorption of the excess material was observed in 4 overfilled canals at the end of the 3rd-month follow-up. Whereas in Group II out of four canals, complete resorption occurred in two canals at 3rd-month follow-up and other two canals at the end of 6th-month follow-up. There was no deviated path of eruption of succedaneous teeth noted in both the groups (Table 3).

In Group I, the resorption of the filling material was equal to the physiological resorption of the root in 80% of the cases, in two cases (i.e 13.3%) resorption of root less than filling material and in one case (i.e 6.6%) resorption of root was more than filling material. Whereas 100% correlation between the resorption of the filling material and the physiological resorption of the root was noted in Group II (Table 4).

The overall clinical and radiographic findings in this study revealed 100% clinical success in both the groups. Whereas, radiographically success reported was 66.66% with Group I, 100% with Group II at the end of 9 months follow-up. The difference in the radiographic success rate between the two was statistically significant ($P < 0.05$) (Table 5).

Table 3 - Comparison of Group I and Group II with respect to resorption of overfilled material.

Fate of overfilled material	3 months		6 months n=0		9 months n=0	
	Resorbed	Not Resorbed	Resorbed	Not Resorbed	Resorbed	Not Resorbed
GROUP I n=4	4	0	0	0	0	0
GROUP II n=4	2	2	2	0	0	0

Table 4 - Comparison of postoperative relative resorption of filling material with respect to root resorption for Groups I and II.

Resorption of filling material with respect to root resorption	3 months		6 months		9 months	
	Group I N %	Group II N %	Group I N %	Group II N %	Group I N %	Group II N %
Resorption of root greater than filling material	1 (6.6%)	0 (0%)	1 (6.6%)	0 (0%)	1 (6.6%)	0 (0%)
Resorption of root equal to filling material	14 (93.3%)	15 (100%)	12 (80%)	15 (100%)	12 (80%)	12 (100%)
Resorption of root less than filling material	0 (0%)	0 (0%)	2 (13.3%)	0 (0%)	2 (13.3%)	0 (0%)

Table 5 - Comparison of overall success for Groups I & II.

Success parameters	Group I – ZINC OXIDE AND NANOHYDROXYAPATITE						Group II – ENDOFLAS FS					
	3 months		6 months		9 months		3 months		6 months		9 months	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Radiological Success	11	74%	10	66.66%	10	66.66%	15	100%	15	100%	15	100%
Clinical success	15	100%	15	100%	15	100%	15	100%	15	100%	15	100%

DISCUSSION

As the natural teeth act as the best space maintainer, preservation of primary teeth until their normal exfoliation is the main goal of pulp therapy in primary teeth and also preserving the primary teeth helps in esthetics, phonetics, mastication and social acceptance [1]. Endoflas, a relatively recent material is a mixture of Calcium hydroxide, Zinc oxide eugenol and Iodoform [5]. The success of Endoflas was cited in many studies. In a study by Ramar K, Murgara J (2010) they observed a much higher success rate with Endoflas (95%) compared to other materials and also reported healing ability, bone regeneration characteristics and resorption of excess endoflas without washing within the roots [2].

Alaa O Al-Ostwani (2016) evaluated four different root canal fillings in primary molars i.e. zinc oxide and propolis (ZOP), Endoflas, Metapex paste, and ZOE paste after considering the clinical and radiographic outcome they concluded that Endoflas had good efficacy as a root-canal filling for nonvital primary teeth [6]. Endoflas possesses most of the qualities of an ideal obturation material, but the disadvantage of this material is its eugenol content which causes periapical irritation [5]. Hence, in the present study hydroxyapatite based pulpectomy medicament which was a mixture of zinc oxide and nanohydroxyapatite was used to evaluate its success as an obturating material in primary teeth. This new combination [zinc oxide and nanohydroxyapatite] was more biocompatible as it was mixed with saline thereby totally eliminating the eugenol which is an irritant.

With the development of nanotechnology, a major impact on materials science has been noted. In this century, the production of materials with nanostructures has gained much attention for adsorption, catalytic, biomaterials and optical applications [4]. Hydroxyapatite when in nanoparticle size is similar to tooth crystals, so the resorption of zinc oxide and nanohydroxyapatite paste will be in tune to that of the physiological resorption of the roots of deciduous tooth. Hydroxyapatite is more compatible with the surrounding cells and tissues owing to its neutral pH [3].

In the present study, nanohydroxyapatite was chosen as an obturation material because it is biocompatible, non-toxic, safe to periapical tissues in the event of extrusion and capable of undergoing resorption [3]. The properties of non-toxic nature and biocompatibility of nanohydroxyapatite has been evident in many in-vivo and in-vitro studies [3]. The healing ability of hydroxyapatite, when exploited for the purpose of pulp capping and pulpotomy studies, suggested that hydroxyapatite induced dentinogenic effect in the pulp cells of experimental animals [7-10].

Jeeva et al (2014) compared the cytotoxicity and anti-microbial activity of three pulpectomy medicaments-Zinc oxide eugenol, Metapex and Chitra HAP – Fil in-vitro and concluded that cytotoxicity and antimicrobial activity of both Zinc oxide eugenol and Metapex failed to qualify as acceptable pulpectomy medicaments. The prime ingredient in the Chitra HAP-Fil paste is hydroxyapatite nanoparticle gel (65%) which is the basic mineral content of human bone and teeth. The rest of the paste is commercial pure Iodoform (32%) which imparts antibacterial property to the paste. The gelling agent (alginate) – 3% (including 0.2% surfactant) binds with the calcium ions in the hydroxyapatite. The paste is toxicologically safe and provided in premixed 1 ml syringe, so that it can be delivered into the canals using disposable tips.[3]

Chitra HAP-Fil is seen to outshine both these materials against which it was evaluated,

as it has reasonably acceptable levels of cytotoxicity as well as antimicrobial activity [3]. On analyzing all the factors, it was found that Chitra HAP-Fil apparently satisfies all the ideal requirements for a pulpectomy material proving its capability as a promising ideal pulpectomy material [3]. But the reason for not using Chitra HAP-Fil in the present study was the unavailability of this formulation commercially.

With the evidence from animal studies and in-vitro studies, Nanohydroxyapatite was used as a successful pulpotomy medicament in comparison to 2% glutaraldehyde in human primary molars by Adlakha VK in 2009 [11] and as a direct pulp capping agent by Swarup SJ (2014), nanohydroxyapatite had proved its ability to produce complete dentinal bridges with favorable cellular and vascular responses when compared to mineral trioxide aggregate and calcium hydroxide [12]. Thus, considering the success of nanohydroxyapatite in various dental applications made us propose a new direction for its use as root canal filler in deciduous teeth.

Grenho L et al (2013) analyzed the antibacterial effect of nanohydroxyapatite after addition of ZnO in composites and concluded that antibacterial activity increased with decreasing ZnO particle size and also with increasing concentration. Biofilm formation tests revealed that the nano HA-ZnO composites exhibit a strong effect against the common pathogens *S. Aureus* and *E. Coli* [13]. This positive finding prompted us to evaluate the clinical efficacy of this mixture of Zinc Oxide and nanohydroxyapatite as pulpectomy medicament.

The pulpectomy procedure was followed by placement of stainless steel crown on all the teeth to prevent microleakage and ensure the success of the treatment. This is in support of previous studies which state that the success rate of teeth restored with a permanent restoration (stainless steel crown or amalgam filling) was significantly higher than those teeth left with a temporary filing [14,15].

The success of Endoflas was reported by different authors and the present study results

were in agreement with previous studies which showed 100% success rate both clinically and radiographically [5]. Whereas novel combination ie; Zinc oxide and nanohydroxyapatite showed clinical and radiographic success rate of 100% and 66.66% respectively after a follow-up of 9 months. The experimental material ie; Zinc oxide and nanohydroxyapatite couldn't be compared to previous study results as in all probability this was the first in vivo study to explore its efficacy as an obturating material in primary teeth.

The hypothesized reasons for the failure of the novel combination of Zinc oxide and nanohydroxyapatite include the grainy consistency of the mixed cement which resulted in short-fill or voids in few canals, less working time and also shrinkage of material within the canal that can be attributed to the vehicle saline as it is watery in consistency unlike eugenol which is oil-based. Another potential disadvantage of Zinc oxide and nanohydroxyapatite was the difficulty in delivering the material into the root canals due to the consistency of the mixed cement and also lack of lubricant which prevented the optimal fill of the root canals in few teeth.

The early resorption of the material within the canal might result in 'hollow tube' where the tissue fluid containing bacteria can fill the space in the unfilled or empty canals to induce reinfection. This infection will shift the pH-value to acidic, dissolving root dentin and cementum thus initiating the resorptive process. This inflammation also causes the transformation of undifferentiated cells of connective pulpal tissue into giant multinuclear cells, which are responsible for the resorption process [16].

The limitation of the present study includes smaller sample size, hence further clinical trails with a larger sample size are recommended with a suitable oil-based liquid component preferably herbal-based other than eugenol as a vehicle to this novel combination of Zinc oxide and Nanohydroxyapatite to test its credibility as obturating material in primary teeth.

CONCLUSION

From the present study, Endoflas had demonstrated high success rate both clinically and radiographically when compared to the novel combination of zinc oxide powder and nanohydroxyapatite as obturating material. But further clinical trials with longer follow-ups are recommended to support this result.

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Naga Radhakrishna Ambati
(Corresponding address)

Pedodontics and Preventive Dentistry – St. Joseph Dental College
Eluru – Andhra Pradesh – Duggirala, Pin: 534003, India
drradhakrishna27@gmail.com

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