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Comparative Study of Calcium Phosphate versus Formocresol in Pulp Treatment of Primary Teeth

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ABSTRACT

Purpose: To clinically and radiographically evaluate the postoperative treatment outcome of Calcium Phosphate cement (CPC) and formocresol (FC) materials in pulpotomy treatment of primary teeth. **Materials and method:** 75 Primary molars in 25 patients were chosen according to specific criteria. Teeth were divided depending on the pulpotomy material into 3 groups: Group I (Calcium phosphate with physiologic saline pre-cleaning group), Group II (Calcium phosphate with Sodium hypochlorite pre-cleaning group) and Group III (formocresol). This was followed by clinical follow up after 1, 6 and 12 months. In addition, Periapical radiographs were collected post-operatively, 6 and 12 months visits. **Results:** The results showed no statistically significant difference in the cumulative clinical success between all three groups over 1, 6 and 12 months of study. For teeth to be successful clinically, they should be free from pain, swelling of pulpal origin, do not have any sinus tract or tenderness to percussion and no pathological mobility. Radiographic assessment also demonstrated no cumulative significant difference between groups ($p \leq 0.05$). Radiographically successful teeth were free from internal resorption, pathologic external resorption, periapical or interradicular radiolucency and changes in the periodontal ligament space. **Conclusion:** Calcium Phosphate as a pulpotomy material was observed to be a valuable alternative to regularly used formocresol with greater biocompatibility, mouldability, and osteoconductivity.

KEYWORDS

Calcium phosphate, Primary teeth, Pulpotomy, Formocresol

INTRODUCTION

The high susceptibility of the vital dental pulp to be invaded by various types of bacteria from the microbial oral flora has been a

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debate. As a result, bacterial infections of the pulp due to either dental caries or traumatic injuries of the deciduous dentition would continue to remain a treatment challenge in pediatric dentistry. Vital pulpotomy is the advisable treatment when infection is localized to the exposure site with a healthy pulp tissue. So, the coronal pulp is removed and the radicular pulp tissues remain. Pulpotomy is considered the treatment of choice in primary teeth that have asymptomatic carious exposures, it is performed to prevent the immature teeth loss, and hence preserve the various functions of deciduous teeth [1].

Hypothetically, there are different pulpotomy materials available to treat the radicular pulp of human deciduous teeth; however, Formocresol stays the 'gold standard' for Pulpotomy in human primary teeth at a 1: 5 dilution. The reason for this is the high success results of Formocresol on both clinical and radiographic aspects. However, the high formaldehyde content that interface with vascularized connective tissue within the dental pulps of children, obviously renders to its high toxicity carcinogenicity and mutagenicity [2, 3].

Some substitutes must be found out to avoid the Formocresol drawbacks. One of these alternatives for pulpotomy is the calcium phosphate cement material (CPC), recently it has a high level of attention from different researchers due to it is chemically similar to human hard tissues both bone and teeth. [4, 5].

The calcium phosphate cement material (CPC) has some advantages over other materials such as the biocompatibility, osteoconductivity and mouldability. Likewise, they are not toxic, nor immunogenic and do not have any mutagenic or cancer-causing potential. Besides, CPC fulfills the important characteristics of a pulpotomy material that has been suggested to be suitable for pulp treatments, it falls in the class of hydraulic cements that work though self-hardening to hydroxyapatite (HA), the bone mineral. [6, 7]. For these reasons, the main goal of this study was to evaluate and compare the clinical and radiographical success of CPCs and FC on pulpotomy treatment in primary molars.

MATERIALS AND METHODS

This study was accomplished in the outpatient clinic of Pedodontics Department, Faculty of Dental Medicine for Girls, Al-Azhar University. Research Ethics Committee approval with code **(REC-PE-21-11)** was obtained from Faculty of Dental Medicine for Girls, Al-Azhar University.

Assuming an alpha (α) level of 0.05 (5%) and a Beta (β) level of 0.20 (20%) i.e. power=80% and an effect size (w) of (0.37); the predicted sample size (n) was a total of (75) samples i.e. (25) for each group. Sample size calculation was performed using G*Power version 3.1.9.2.

In the current study 25 patients having 75 teeth were included, they fulfilled the following criteria; age from 4-8 years old, patient and parent cooperation, absence of any systemic disease that can contraindicate pulp therapy, having at least 3 primary molars that have caries with nearly equal carious involvement that will possibly require pulpotomy [8].

The chosen teeth had specific common criteria; asymptomatic carious teeth, restorability using chrome steel crowns, no pathologic indications of pulpal contamination or tooth looseness, no sinus tract or swelling in soft tissue, vital pulp without pus secretion following pulpal entry and reaching adequate hemostasis of the radicular pulp following pressure with a sterile cotton pellet**.** Radiographically teeth should be without interradicular radiolucency, no loss of lamina dura, absence of internal or external root resorption and no change in the periodontal ligament area [9].

After taking detailed medical and dental history, clinical and radiographic examinations were done. Preoperative periapical radiographs of the teeth chosen for treatment were obtained using a standardized paralleling system that utilizes an

exposure time of 0.4 seconds. For achieving this technique, the following tools were utilized: an X ay machine set at 70Kvp, an XCP posterior film holder, Intra oral sensor size 0, 8mA and a digital x-ray system (Vista scan Dental Perio, Durr Dental AG, Bietigheim, Germany).

Technique of vital pulpotomy: [10]

The teeth of choice were anesthetized by Mepecaine - L (Alexandria Co. For Pharmaceuticals, Egypt).Patients were permitted to stay for 10 min before pulpotomy treatment, for effective isolation rubber dam was used. Removal of caries with a sterile #330 rapid pear-molded carbide bur with coolants followed by access to a pulp chamber.

When confirming pulp exposure, the roof of the pulp was removed with a clean high speed round bur #4 along with water spray. Coronal pulp removal was accomplished with a clean sharp, large sized spoon excavator and the cavity was refined by a high speed fissure bur. Hemostasis was primarily done using little cotton pellet dampened in saline with pressure for 2-3 minutes. Teeth that showed excessive bleeding were exempted from this study. For the clinical and radiographic evaluation the teeth were equally divided into 3 groups:

Group I Calcium phosphate cement with physiologic saline cleansing group (25 primary molar). The pulp stumps of 25 primary teeth were washed with physiologic saline. After control of hemorrhage, the radicular pulps were topped with a thin putty consistency of calcium phosphate cement (CPC) (SIGMA-ALDRICH, USA). Then, a thick, homogeneous mix of zinc oxide and eugenol paste (ZOE) (Zinconol ® Prevest Dent Pro, Digiana, Jammu, India) was added to cover the pulp stumps of the teeth (Figure 1).

Group II Calcium phosphate cement with Sodium hypochlorite cleansing group (25 primary molars). The pulp stumps of 25 primary teeth were irrigated with 5% NaOCl for 30s, pulp tissues were then topped with a thin putty consistency of calcium phosphate cement 3:1 powder/liquid ratio to make a 2mm CPC layer over pulp stumps, which then covered with zinc oxide and eugenol paste (Figure 2).

Group III Formocresol group (25 primary molars) positive control group. The pulp stumps of primary teeth were dressed with a cotton pellet damped with formocresol (Prevest Dent Pro, Digiana, Jammu, India) for 5 min. Which then followed by covering the pulp stumps of teeth with the zinc oxide eugenol paste, the blend was compacted against the site of interest with a wet cotton pellet (Figure 3).

All teeth were then restored with fortified glass Ionomer restoration (GIC) (EQUIA™Fil GC corporation, Tokyo, Japan, ALSIP, IL60803) followed by stainless steel crowns (3M ESPE St Paul, USA) cemented to teeth by using glass ionomer cement (PROMEDICA Dental Material GmbH Domagkser, 31. 24537 Germany). A periapical radiograph was taken post operatively. Patients were told to contact the specialist if any unfavorable signs or side effects happened between follow up visits.

Patients were reviewed for clinical examination after 1, 6 and 12 months, for examining any signs and symptoms in the treated teeth. The clinical assessments were accomplished at each follow up visit, data were recorded in a patient evaluation form. Clinical success criteria were considered, teeth should be painless, have no swelling of pulpal origin, no sinus tract or pathological looseness and no percussion tenderness. Periapical radiographs also were taken for all treated teeth at 6 and 12 months follow up visits. For teeth to be successful radiographically, they should be free from internal resorption, pathologic external resorption, interradicular or periapical radiolucency and any increase in the periodontal ligament space [11].

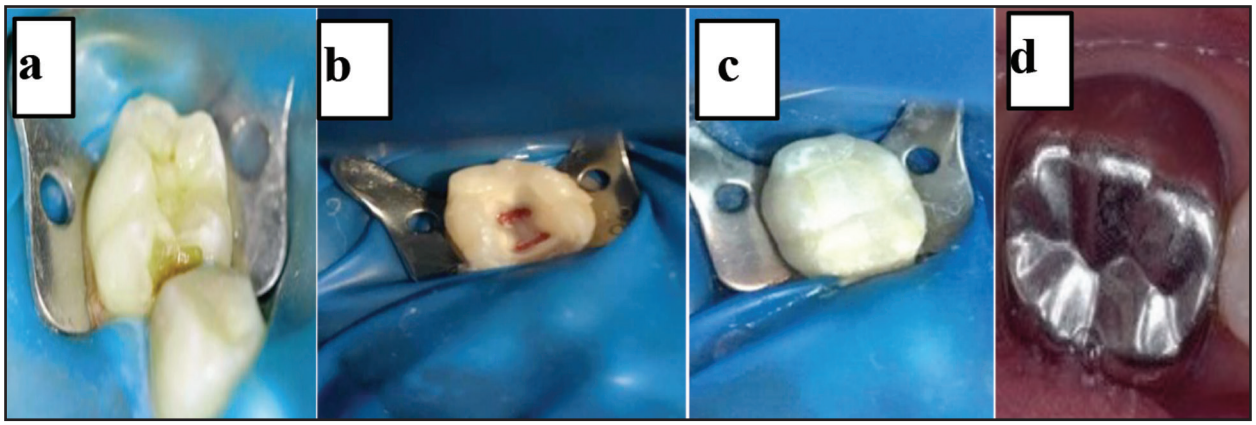

Figure (1) a) Preoperative photo; b) Pulpotomy with saline cleansing; c) After application of CPC, ZOE and GIC; c) Postoperative photo.

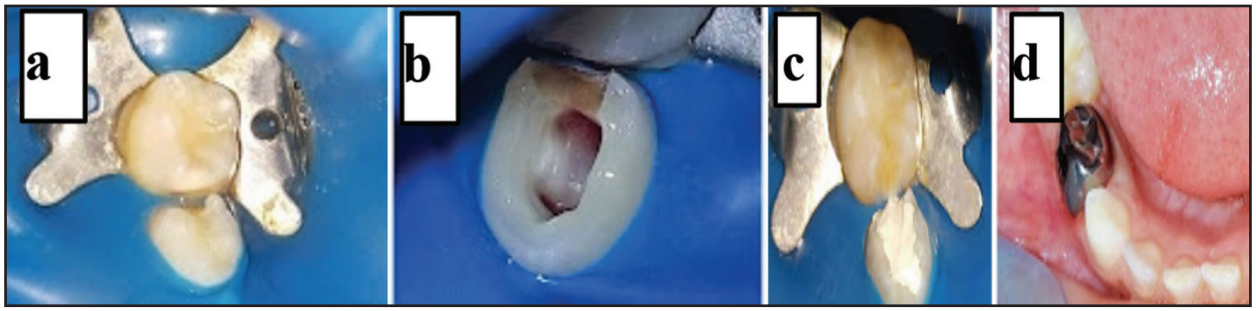

Figure (2) a) Preoperative photo; b)pulpotomy with NAOCL cleansing; c) after application of CPC, ZOE and GIC; c) Postoperative photo.

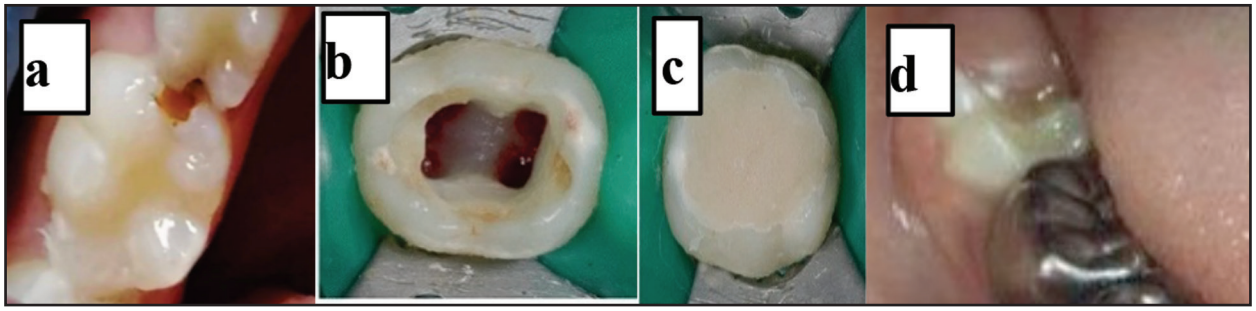

Figure (3) a) Preoperative photo; b) formocresol pulpotomy; c) after application of ZOE and GIC; d) postoperative photo.

RESULTS

Statistical Analysis:

Statistical analysis was then performed utilizing an economically accessible programming program (SPSS 18; SPSS, Chicago, IL, USA).

Data were expressed as numbers and percentages which were compared within and between groups using chi square test. Microsoft excel was used for generation of representative figures. The level of significance was set at $P \leq 0.05$.

Clinical results:

At one month, all clinical signs were absent in all groups at one month, with no significant difference between groups (p=1). Cumulative clinical success was 100% in all groups at one month.

At 6 months, restoration was intact in all groups at 6 months, with no significant difference between groups (p=1). Spontaneous pain was found in 4% of cases in group I, but was absent in group II and group III, with no significant difference between groups (p=0.36). Mobility was found in 4% of cases in group I and group II, but was absent in group III, with no significant difference between groups (p=0.60). Swelling was found in 4% of cases in group III, but was absent in group I and group II, with no significant difference between groups (p=0.36).

Fistula was absent in all groups and tenderness to percussion was found in 4% of cases in group II, but was absent in group I and group III, with no significant difference between groups (p=0.36). Cumulative clinical success at 6 months was 92% in group I&II, but was 96% in group III, with no significant difference between groups (p=0.81), (Table 1).

At 12 months, Restoration was intact group II, but was present in 4% of cases of group I and III at 12 months, with no significant difference between groups (p=0.60). Spontaneous pain was found in 4% of cases in group I and group II, but was absent in group III, with no significant difference between groups (p=0.60). Mobility was found in 8% of cases in group I and group II, but was absent in group III, with no significant difference between groups (p=0.33). Swelling was found in 4% of cases in group III, but was absent in group I and group II, with no significant difference between groups (p=0.36).

Fistula was absent in all groups and tenderness to percussion was found in 4% of cases all groups, with no significant difference between groups (p=1). Cumulative clinical success at 12 months was 80% in group I, 88% in group II and 92% in group III, with no significant difference between groups (p=0.446), (Table 2).

Radiographic results:

At 6 months, internal resorption was absent in group III, but was present in 4% of cases of group I and II at 6 months, with no significant difference between groups (p=0.60). External resorption and Inter-radicular bone resorption were absent in all groups. Widened periodontal ligament and periapical radiolucency were found in 4% of cases in all groups, with no significant difference between groups (p=1). Radiographic success was 88 % in group I, 88% in group II and 92% in group III, with no significant difference between groups (p=0.87), (Table 3).

Table (1) *Comparison of Clinical evaluation results in different groups at 6 months (chi square test)*

Clinical evaluation	Gp I		Gp II		Gp III		X2	P
	N (25)	%	N (25)	%	N (25)	%		
Restoration wasn't intact	0	0	0	0	0	0	0	1ns
Spontaneous pain	1	4	0	0	0	0	2.03	0.363ns
Mobility	1	4	1	4	0	0	1.03	0.60ns
Swelling	0	0	0	0	1	4	2.03	0.363ns
Fistula	0	0	0	0	0	0	0	1ns
Tenderness to percussion	0	0	1	4	0	0	2.03	0.363ns
Cumulative clinical success	23	92	23	92	24	96	0.43	0.81ns

*Significance level p≤0.05, *significant, ns=non-significant*

Table (2) *Comparison of Clinical evaluation results in different groups at 12 months (chi square test)*

Clinical evaluation	Gp I		Gp II		Gp III		X^2	P
	N (25)	%	N (25)	%	N (25)	%		
Restoration wasn't intact	1	4	0	0	1	4	1.03	0.60ns
Spontaneous pain	1	4	1*	4	0	0	1.03	0.60ns
Mobility	2	8	2	8	0	0	2.11	0.35ns
Swelling	0	0	0	0	*1	4	2.03	0.363ns
Fistula	0	0	0	0	0	0	0	1ns
Tenderness to percussion	1	4	1*	4	*1	4	0	1ns
Cumulative clinical success	20	80	22	88	23	92	1.62	0.446ns

*Significance level p≤0.05, *significant, ns=non-significant*

Table (3) *Comparison of Radiographic evaluation results in different groups at 6 months (chi square test)*

Radiographic evaluation (6 months)	GpI		GpII		Gp III		X^2	P
	N (25)	%	N (25)	%	N (25)	%		
Internal root resorption	1	4	1	4	0	0	1.03	0.60ns
External root resorption	0	0	0	0	0	0	0	1ns
Widened periodontal ligament	1	4	1	4	1	4	0	1ns
Periapical radiolucency	1	4	1	4	1	4	0	1ns
Inter-radicular bone resorption	0	0	0	0	0	0	0	1ns
Radiographic success	22	88	22	88	23	92	0.28	0.87ns
Clinical &Radiographic success	20	80	20	80	22	88	0.74	0.69ns

*P-value significance level p≤0.05, *significant, ns=non-significant*

At 12 Months, Internal resorption was absent in group III, but was present in 4% of cases of group I and II at 12 months, with no significant difference between groups (p=0.60). External resorption was absent in all groups. Widened periodontal ligament was found in 8% of cases in all groups, with no significant difference between groups (p=1). Periapical radiolucency was foud in 8% in group I, in comparison to 4% in group II &III, with no significant difference between groups (p=0.77).

Inter-radicular bone resorption was absent in group II& III, but was present in 4% of cases of group I, with no significant difference between groups (p=0.36). Radiographic success was 76 % in group I, 84% in group II and 88% in group III, with no significant difference between groups (p=0.52), (Table 4).

Table (4)*Comparison of Radiographic evaluation results in different groups at 12 months (Chi square test)*

Radiographic evaluation (12 months)	GpI		GpII		Gp III		X^2	P
	N (25)	%	N (25)	%	N (25)	%		
Internal root resorption	1	4	1	4	0	0	1.03	0.60ns
External root resorption	0	0	0	0	0	0	0	1ns
Widened periodontal ligament	2	8	2	8	2	8	0	1ns
Periapical radiolucency	2	8	1	4	1	4	0.53	0.77ns
Inter-radicular bone resorption	1	4	0	0	0	0	2.03	0.36ns
Radiographic success	19	76	21	84	22	88	1.3	0.52ns
Clinical &Radiographic success	14	56	18	72	20	80	3.51	0.17ns

*P-value significant at p≤ 0.05, * significant, ns= non-significant.*

DISCUSSION

A relatively recent alternative medicament for pulpotomy is the calcium phosphate cement (CPC). It has been used as a novel bone substitute in different clinical routes including dentistry and orthopedics. Researchers used CPC in animal pulp capping, periodontal therapeutic as well as root canal treatments and in implant surgeries [4, 12].

Formocresol is still consumed by 92.4% of pediatric dentists as the standard therapeutic agent for primary teeth pulpotomies. The reason for this is its simplicity to use, economically suitable, and it has a high clinical success. In addition, it has a bactericidal and devitalizing results. [2, 13].

The study was conducted by split mouth technique; the goal of this technique was to exclude other differences between patients from the treatment comparisons. This is done through having within-patient comparisons rather than between-patients comparison, decreasing the error associated with the experiments, thereby obtaining a more powerful statistical test[14]. Radiographic examination was performed using a standardized paralleling technique to prevent vertical dimension distortion and to provide an image that is easily reproducible, also a digital sensor was utilized for less radiation dose and to prevent errors in processing. [15].

In this study, the age of patients ranged from 4 to 8 years. Avoidance of children under 4years of age from the study was due to their limited cooperativeness which is usually improved by 6-7 years. Children more than 8years were additionally avoided because of the likelihood of physiologic root resorption (>3/4 of root). A past study on pulpotomy treatment has been directed in the comparative age group [16].

In Calcium phosphate with physiologic saline cleansing group, all clinical signs of failure were absent after one month. However, at 6 months, one case showed spontaneous pain, and one case showed mobility. At 12 months, restoration wasn`t intact in one patient, in another patient there was spontaneous pain, one with tenderness to percussion, and two showed mobility at the end of that period. The overall clinical success was 100% at 1 month, 92% at 6 months and 80% at one year.

The high percentage of clinical success matched the results of other study which reported 100% success rate at 70 days follow-up period, this high percentage of success might be credited to CPC gave progressively great outcomes in pulpal irritation [2]. These results contradict a past results report which

showed at 6, 9, 12 months, total clinical success rates of 72%, 73%, and decreased to 52.6% at 12 months [17].

Regarding the radiographic evaluation in CPC group, at 6 months, one case showed Internal root resorption, one case with widened periodontal ligament and one with periapical radiolucency in a lower second primary molar. At 9 months, one case demonstrated inner root resorption, 2 cases indicated extended periodontal space, 2 cases showed periapical radiolucency and one case with inter-radicular bone resorption. The total success in radiographic results showed 88% at a half year and 76% at a year, these findings were less successful than formocresol ones, however, the difference was statistically insignificant.

There were limited investigations done to assess the relative radiographic success of CPC pulpotomy as compared to the formocresol till date. Nevertheless, these results are in disagreement with another previous study which reported radiographic evaluation with total success rate of 47.4% at 12 months [4].Similarly, In the second group, despite being statistically insignificant, there was a slight positive effect of the sodium hypochlorite on the rate of both clinical and radiographic success after 12 months follow up [18, 19].

In Formocresol group, clinical success was 100% at one month, 96% at 6 months and 92% at 9 months which showed that time had no statistically significant effect on the overall cumulative clinical success. Regarding the radiographic evaluation, there was absence of all radiographic signs of failure at 96%, at 6 months and 88% at 12 month which proved that there was no significant effect of time on the overall radiographic success [20].

CONCLUSION

Calcium phosphate cement was found to be an acceptable alternative pulpotomy agent Also, unlike formocresol, CPCs have the mix of biocompatibility, osteoconductivity and mouldability. Besides, they are non-harmful, non-immunogenic and do not have any mutagenic or cancer-causing potential. In regards to pulpotomy cleansing materials, there was no significant difference observed between the NaOCl and physiologic saline.

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RECOMMENDATIONS

More clinical, radiographical and histological studies with bigger sample size and longer follow up periods are required to study the effect of CPC on the long run.

CONFLICT OF INTEREST

There was no conflict of interest.

FUNDING

No funding has been received for this study.

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