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CLINICAL, RADIOGRAPHICAL AND HISTOLOGICAL ASSESSMENT OF PULPOTEC PULPTOMY IN VITAL PRIMARY TEETH

Ahmed Shafeek Mahmoud Eid [1*], Alaa Aldeen Abd Allah[2], Alaa Nabil Abass[3]

ABSTRACT

Objectives: To evaluate the effect of Pulpotec clinically, radiographically and histologically on the pulpotomized primary teeth. **Subjects and methods**: Study was carried out on sixty primary teeth scheduled for extraction for orthodontic purpose, divided into two equal groups of 30 primary teeth in each one. Group (A): Thirty primary teeth will receive Formacresol pulpotomy. Group (B): 30 primary teeth will receive Pulpotec pulpotomy. All pulpotomized primary molars in the present study were restored with SSCs. All pulpotomized teeth were followed up clinically and radiographically at day 1, 1.5 month, and 3 months. At the 3 months follow-up period, the treated teeth were extracted for histological examination of the pulp. **Results:** Pulpotec pulpotomy group showed increased children percentage by 10% with pain, tenderness to percussion, swelling, partial loss of lamina dura and widening of periodontal ligament space from 1.5 month to 3 months. Regarding Formacresol pulpotomy group, there was increased children percentage by 30% with pain, tenderness to percussion, swelling, partial loss of lamina dura, widening of periodontal ligament space from 1 day to 3 months and increased children percentage by 3-13% with abscess, fistula, mobility and periapical radiolucency from 1.5 month to 3 months. Regarding histological results, there was a statistically non-significant difference in children percentage. **Conclusion:** Pulpotec can be used as reliable alternative to Formacresol for the pulpotomy procedures in primary teeth.

KEY WORDS: keywords: primary teeth, pulptomy, Pulpotec, Formacresol.

INTRODUCTION

Oral health is a major public health issue that affects all population groups. Poor oral health during childhood is directly related to poor oral health outcomes in childhood and adulthood, as people are prone to tooth decay throughout their lives [(1)].

Tooth decay is the most common chronic disease affecting a significant portion of the world's population, including around 60 to 90% of school children and the vast majority of adults. Caries occurs due to the demineralization of the tooth structure by organic acids, which are formed by oral bacteria, which are present in the dental plaque through the anaerobic metabolism of food sugars [(2)].

An increased prevalence of tooth decay appears to occur in people of low socioeconomic status. In deciduous teeth, caries is an important predictor for the future development of caries in permanent teeth. Therefore, tooth decay in children is expected to be a growing public health burden [(3)].

1. Masters Candidate, Ministry of Health, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University.
2. Associate Professor, Pedodontics and Oral Health Department, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University
3. Lecturer of Pedodontics and Oral Health, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University.

• ***Corresponding author*:** ahmed.shafeew.374@gmail.com

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Healthy primary teeth are given space for their permanent successors, which develop in the jaw below. Their premature loss through tooth decay or injury often leads to loss of space for their successors and can lead to problems with crowding in the permanent dentition [4].

The treatment of pulp-affected teeth in primary teeth and immature permanent teeth poses particular challenges. There is general agreement that the pulp in primary teeth has a high potential for repair. However, there are questions about the techniques and materials that offer the highest percentage of success [5].

Pulpotomy is one of the most frequently used treatment methods to preserve deciduous teeth that have been infected by caries. Pulpotomy is performed on a deciduous tooth with extensive caries but no evidence of radicular pathology when caries removal results in carious or mechanical pulp exposure. It is conservative therapy performed to remove inflamed coronal pulp tissue, followed by the application of an effective and compatible bactericidal drug [6].

Various materials have been used to perform pulpotomies of deciduous teeth. Formacresol (FC) is a popular material of choice for pulpotomy procedures on deciduous teeth because of its ease of use and excellent clinical success. Concerns about the FC pulpotomy have been expressed due to inflammation and necrosis, cytotoxicity, systemic disorders, mutagenic, carcinogenic potential, and immunological response [7].

Zinc Oxide Eugenol (ZO/E) is one of the materials used as a pulp bandage after FC pulpotomy. It offers analgesic properties and a strong antibacterial effect against staphylococci, micrococci, bacillus and enterobacteria for more than 30 days. In addition, ZO / E provides an effective seal, which limits micro-leaks and subsequent recurring infections [8].

However, various toxic effects have been reported when ZO / E is applied directly to the pulp due to the irritating effects of eugenol, so the eugenol component of the paste has been linked to claims of failure of primary molar pulpotomy [9, 10].

Pulpotec has proven to be a potential material for biodental applications due to its unique properties such as bioactivity, antimicrobial effect, biocompatibility and compatibility with other materials. The Pulpotec-based materials have been extensively studied for a variety of dental applications [11]. The aim of the present study was to investigate the effect of Pulpotec clinically, radiographically and histologically on pulpotomized deciduous teeth.

SUBJECTS AND METHODS

This study was controlled clinical trial and was carried out on sixty primary teeth that were indicated for extraction. Thirty primary teeth were assigned to be treated with Formacresol, and an equal number with Pulpotec pulpotomies.

Ethical consideration

The study was accepted ethically with EC Ref No.91/103/22/04/19, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University. Signed informed consent was done from the parents of each child before beginning the study.

Inclusion criteria:

The teeth scheduled for extraction for orthodontic purpose at the age range of 7 to 8 years. The teeth were sound or carious without any clinical signs and symptoms denoting an infected pulp. Absence of any clinical and radiographic infection, evidence of pulpal degeneration such as pain on percussion, history of swelling or sinus tracts. Also there must be no abnormal radiographic signs of internal or external resorption and no furcation radiolucency. The teeth were obtained from healthy patients free of any systemic diseases that may contraindicate pulp therapy.

Exclusion criteria:

Any allergic history of any component of Pulpotec material, uncooperative children and handicapped children.

Sample size calculation: sample size of 30 in each group has an 80% power to detect an increase in survival proportion of 0.283 with a significance level (alpha) of 0.05 (two-tailed). In 80% (the power) of those experiments, the P value will be less than 0.05 (two-tailed) so the results will be deemed "statistically significant". In the remaining 20% of the experiments, the increase in survival proportion will be deemed "not statistically significant". Report created by GraphPad StatMate 2.00.

Assessment:

The outcome of success or failure is determined by the following clinical, radiographical and histological criteria.

Clinical criteria: [12]

Presence of any signs such as spontaneous or nocturnal pain, tenderness to percussion or palpation, abscess, swelling, fistula and pathologic mobility was definitively indicative of clinical failure.

Radiographical criteria: [12]

Lamina dura of the pulpotomized teeth, examined on high quality periapical radiographs were compared with their radiographs before treatment. Observation of partial loss of the lamina dura or widening of the periodontal membrane space was recorded as a radiographical failure.

Presence of any sign of pathologic external or internal root resorption as well as periapical or interradicular radiolucency was definitively demonstrative of radiographical failure.

Histological criteria:

The criteria previously established by Hosterd et al, 1981[13] and Fuks et al, 1997 [14] as follows:

0: None or mild vital pulp, absence of inflammation or a few inflammatory cells limited to the pulpotomy site.

1: Moderate inflammation evident below the pulpotomy site but limited to the coronal third of the radicular pulp.

2: Severe inflammation and circulatory disturbances affecting most of the pulp (including partial necrosis).

3: Necrosis.

4: Periradicular or interradicular abscess.

5: Abscess including pathological root resorption.

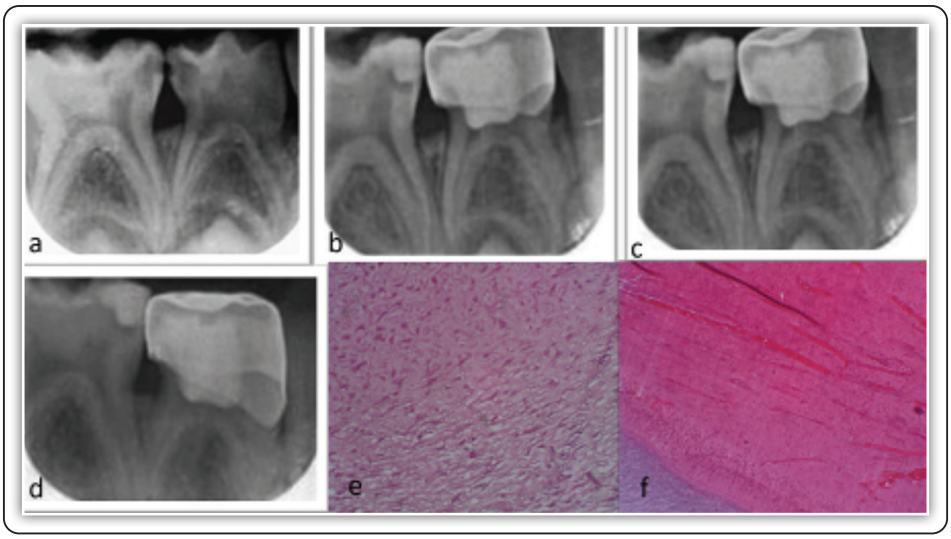

FIG (1) Pulpotec application pulpotomy for primary molar of girl 7.5 years old, a-Preoperative; b-After 24hours; c-After 6weeks; d-After 3months; e- Three months after Pulpotec pulpotomy: fibrosis of dental pulp with mild inflammatory infiltration (H&E X400); f-Three months after Pulpotec pulpotomy: almost normal pulp architecture. However, dilatation & congestion of blood capillaries is evident (H&E X200).

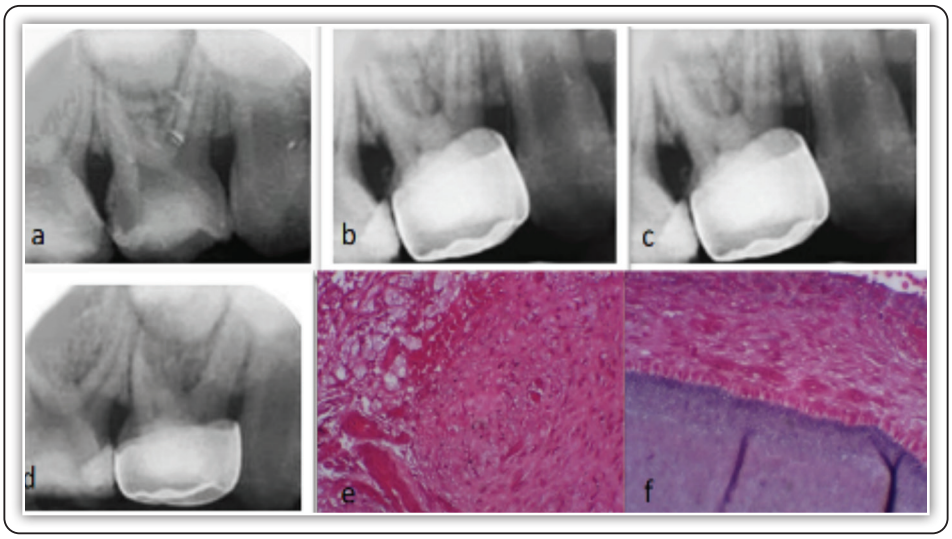

FIG (2) Formacresol application pulpotomy for primary molar of girl 7 years old, a-Preoperative; b-After 24hours; c-After 6weeks; d-After 3months; e- Three months after Formacresol pulpotomy: Inflammatory cells infiltration intermingling with fibrous tissue. Dilatation & congestion of blood capillaries (H&E X400); f- Three months after Formacresol pulpotomy: abnormal architecture of dental pulp, extensive amount of fibrosis in conjunction with inflammatory cells infiltration and vascular congestion (H&E X400).

Statistical analysis of the data:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level. The used tests were 1 - Chi-square test for categorical variables, to compare between different groups.2 - Fisher's Exact or Monte Carlo Correction for chi-square when more than 20% of the cells have expected count less than 5.3 - Cochran's test for binary qualitative variables, to compare between more than two periods with Post Hoc Test (Dunn's) for pairwise comparisons. 4 - Student t-test for normally distributed quantitative variables, to compare between two studied groups.

RESULTS

In the present study, Pulpotec pulpotomy group showed increase in the percentage of children with pain, tenderness to percussion, swelling, partial loss of lamina dura and widening of periodontal ligament space by 10% from 1.5 months to 3 months. For Formacresol pulpotomy group, the percentage was higher with pain, tenderness to percussion, swelling, partial loss of lamina dura and widening of periodontal ligament space by 30% with the same intervals. 3 to 13% of Formacresol pulpotomy group showed signs of abscess, fistula, mobility, and periapical radiolucency at 1.5 months to 3 months.

Clinically, the success rate of Pulpotec and formacresol obtained in this study at 3 months was 90% for Pulpotec and 70% for Formacresol. In the present study, at day 1, 1.5 months and 3 months, there was a statistically non-significant difference between groups regarding children percentage with pain, tenderness to percussion, abscess, swelling, fistula, mobility, partial loss of the lamina dura, widening of periodontal ligament space, internal/ external resorption, furcal/ periapical radiolucency and histological results.

TABLE (1): Comparison between the two studied groups according to pain, tenderness to percussion and abscess

		Pulpotec pulpotomy (n = 30)	Formocresol pulpotomy (n = 30)	χ^2	p
Pain	**1 Day**				
	AB	30 (100.0%)	28 (93.3%)	2.069	$^{FE}p=$ 0.492
	PT	0 (0.0%)	2 (6.7%)		
	1.5 month				
	AB	30 (100.0%)	27 (90.0%)	3.158	$^{FE}p=$ 0.237
	PT	0 (0.0%)	3 (10.0%)		
	3 month				
	AB	27 (90.0%)	21 (70.0%)	3.750	0.053
	PT	3 (10.0%)	9 (30.0%)		
Tenderness to percussion	**1 Day**				
	AB	30 (100.0%)	29 (96.7%)	1.017	$^{FE}p=$ 1.000
	PT	0 (0.0%)	1 (3.3%)		
	1.5 month				
	AB	30 (100.0%)	28 (93.3%)	2.069	$^{FE}p=$ 0.492
	PT	0 (0.0%)	2 (6.7%)		
	3 month				
	AB	27 (90.0%)	20 (66.7%)	4.812*	0.028*
	PT	3 (10.0%)	10 (33.3%)		
Abscess	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	3 month				
	AB	30 (100.0%)	29 (96.7%)	1.017	$^{FE}p=$ 1.000
	PT	0 (0.0%)	1 (3.3%)		

x^2: **Chi square test** *FE*: **Fisher Exact**

p: p value for comparing between the studied groups

**: Statistically significant at p ≤ 0.05*

TABLE (2): Comparison between the two studied groups according to swelling, fistula and mobility

		Pulpotec pulpotomy (n = 30)	Formocresol pulpotomy (n = 30)	χ^2	p
Swelling	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	3 month				
	AB	27 (90.0%)	21 (70.0%)	3.750	0.053
	PT	3 (10.0%)	9 (30.0%)		
Fistula	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	3 month				
	AB	30 (100.0%)	29 (96.7%)	1.017	$^{FE}p=$ 1.000
	PT	0 (0.0%)	1 (3.3%)		
Mobility	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	3 month				
	AB	30 (100.0%)	28 (93.3%)	2.069	$^{FE}p=$ 0.492
	PT	0 (0.0%)	2 (6.7%)		

x^2: **Chi square test** *FE*: **Fisher Exact**

p: p value for comparing between the studied groups

TABLE (3): Comparison between the two studied groups according to partial loss of the lamina dura, widening of periodontal ligament space, internal/external resorption and furcal/ periapical radiolucency

		Pulpotec pulpotomy (n = 30)	Formocresol pulpotomy (n = 30)	χ^2	p
Partial loss of the lamina Dura	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	29 (96.7%)	1.017	FEp= 1.000
	PT	0 (0.0%)	1 (3.3%)		
	3 month				
	AB	27 (90.0%)	21 (70.0%)	3.750	0.053
	PT	3 (10.0%)	9 (30.0%)		
Widening of periodontal ligament space	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	28 (93.3%)	2.069	FEp= 0.492
	PT	0 (0.0%)	2 (6.7%)		
	3 month				
	AB	27 (90.0%)	21 (70.0%)	3.750	0.053
	PT	3 (10.0%)	9 (30.0%)		
Internal/external resorption	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	3 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
Furcal/ periapical radiolucency	**1 Day**				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	1.5 month				
	AB	30 (100.0%)	30 (100.0%)	00.0	NS
	PT	0 (0.0%)	0 (0.0%)		
	3 month				
	AB	30 (100.0%)	26 (86.7%)	4.286	FEp= 0.112
	PT	0 (0.0%)	4 (13.3%)		

x^2: **Chi square test** *FE*: **Fisher Exact**

p: p value for comparing between the studied groups

**: Statistically significant at p ≤ 0.05*

TABLE (4): Comparison between the two studied groups according to histologic results.

	Pulpotec pulpotomy (n = 30)	Formocresol pulpotomy (n = 30)	χ^2	MCp
Histologic				
1	14 (46.7%)	6 (26.7%)	3.654	0.293
2	13 (43.3%)	15 (50.0%)		
3	3 (10.0%)	8 (20.0%)		
4	0 (0.0%)	1 (3.3%)		

x^2: **Chi square test** *MC:* **Monte Carlo**

p: p value for comparing between the studied groups

DISCUSSION

An important goal in pediatric dentistry is to keep the deciduous dentition intact until the permanent successors break through. A high proportion of deep carious lesions in deciduous teeth is associated with pulp exposure. The removal of the infected coronal pulp tissue (pulpotomy) is one of the treatment methods used. In order to improve the treatment, fix the pulp tissue and maintain its vitality, the surface of the pulp is covered with a therapeutic agent. Over the years, many materials have been researched that can be used as drugs for pulpotomy. Formacresol is considered the "gold standard" and was first used by Sweet (1930) for pulpotomy with a success rate of 97% [15, 16].

The thought led to the development of materials like Pulpotec, which was used in this study due to the reported adverse effects of Formacresol like potential carcinogenicity, immune sensitization, mutagenicity and cytotoxicity.

Pulpotec (PD) is a radiopaque, non-absorbable material for the simple, fast and long-term treatment of the pulpotomy of vital molars. The vitality of the remaining radicular pulp after treatment with Pulpotec is undisputed. Pulpotec is commercially available as a resin cement that contains polyoxymethylene, iodoform, dexamethasone acetate,

formaldehyde, phenol, guaiacol and additives. It works by mummifying the pulp stump at the chamber-canal interface, while the structure of the underlying pulp is preserved [17].

The aim of the present study was to investigate the effect of Pulpotec clinically, radiologically and histologically on pulpotomized primary teeth. In the present study, Formacresol was selected as the control group and Pulpotec was chosen as the experimental one due to its anti-inflammatory properties[18].

For this study, children between the ages of 7 and 8 years were selected. This age group was selected considering the lack of cooperation in the younger age children and the physiological root resorption in the older ones.

In the present study, Pulpotec pulpotomy group showed increased children percentage by 10% with pain, tenderness to percussion, swelling, partial loss of lamina dura and widening of periodontal ligament space from1.5 month to 3 months. Regarding Formacresol pulpotomy group, there was increased children percentage by 30% with pain, tenderness to percussion, swelling, partial loss of lamina dura, widening of periodontal ligament space from 1 day to 3 months and increased children percentage by 3-13 % with abscess, fistula, mobility and periapical radiolucency from 1.5 months to 3 months. Clinically, the success rate of Pulpotec and Formacresol obtained in this study at 3 months was 90% for Pulpotec and 70% for Formacresol.

Pulpotec has the advantage of having clinical success even in cases with a little residual blood in the pulp chamber when used as a pulpotomy medicament. The results of Pulpotec are in agreement with Donskaya and Dedeyan's [19] clinical trials using Pulpotec as pulpotomy medicament that reported easiness and simplicity with success rate 100% at 3 months and 6 months follow-up periods.

In the present study, at day 1, 1.5 month, and 3 months, there was a statistically non-significant difference between groups regarding children percentage with clinical, radiographical and histological results. Hence, Pulpotec can be used as alternative pulpotomy agent to Formacresol in primary teeth. These results are in agreement with Bhawna et al., [20] evaluated and compared the radiographic and clinical success of Formacresol, Pulpotec as pulpotomy medicaments in primary molars. At the end of 6 months, clinical success was 100% for all groups. Whereas radiographic success was 96.7% for Formacresol and 100% for Pulpotec group. This study showed that Pulpotec used for primary teeth pulpotomy has good success rates on follow-up; and hence can be used as alternatives to formacresol.

A histological evaluation study by Satygo after using Pulpotec for pulpotomy procedures showed three zones adjacent to the pulp-cement interface that resembles formacresol. Although Pulpotec and Formacresol showed similar histological findings, Pulpotec is advisable over Formacresol due to the minimal formaldehyde concentration in Pulpotec compared to Formacresol [17].

The present study shows that the clinical, radiographical and histological success rates of Pulpotec are higher than that of Formacresol for primary molars over a 3 month period. Hence it can be concluded that Pulpotec can be used as reliable alternative to Formacresol for the pulpotomy procedures in primary teeth. However, further clinical, radiographical and histological researches are suggested with a longer follow up period and a larger sample size to draw a definitive conclusion.

CONCLUSION

It can be concluded that: 1. Pulpotec used for primary teeth pulpotomy has good success rates on follow-up. 2.Pulpotec can be used as reliable alternative to Formacresol for the pulpotomy procedures in primary teeth.

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