A clinical and histopathological evaluation of different pulpotomy agents in primary teeth

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Abstract

The purpose of this investigation is to compare the response of primary teeth clinically and histopathologically to vital pulp therapy using formocresol (FC), Ferric sulfate (FS), and Pulpotec (PD).

A total of 60 primary molars were treated in 43 children aged 7-9 years. Twenty primary molars received FC, and an equal number received FS, and PD by random selection. Clinical evaluations were performed at 3 and 6 months recall for the whole samples. Histopathological evaluations were carried at 6 months for the teeth indicated for extraction (total 30) as part of the orthodontic treatment. Statistical analysis using Z-test was performed on the data to determine significant differences between the groups.

Three and six months results showed a highly significant difference ($P< 0.01$) between the tested materials in most clinical findings, while histopathologically after 6-months in the FC group mild inflammation was seen in two cases, severe inflammation in three cases, necrosis in two, and abscess in one case. In the FS group mild in one case, severe in three cases, necrosis in one case, and abscess in two cases, finally in PD group mild inflammation was seen in one case, severe in one case, necrosis in one case, with no abscess formation in any case. Clinical and histopathological evaluations showed that Pulpotec (PD) can be considered as a replacement for FC and FS.

Key words: pulpotomy, formocresol, ferric sulfate, pulpotec.

Introduction

Pulpotomy is a universally accepted treatment of odontitis in primary and permanent teeth that involves the amputation of the infected or affected coronal pulp with keeping of viable root pulp [(1)]. Preservation of the periodontium intact is the main purpose of this method ,which is based upon the significant resilience of the root pulp to various effects, and is determined by the features of histological structure[(2)].

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The use of formocresol for pulpotomy procedure in primary teeth was supported by several studies [3,4,], but because of its systemic and local side effects, it may be essential to use alternative techniques and materials [5].

Ferric sulfate is proposed as a pulpotomy agent on the theory that its mechanism of controlling hemorrhage might minimize the chances for inflammation believed by some investigators to be associated with physiologic clot formation[6]. Even though high clinical success rates have been found using formocresol and ferric sulfate, it has been shown that both produce severe inflammatory responses histologically [7,8]. Haghgou and Abbasi [9], found that severe and moderate inflammation have been seen in about 50% of the cases treated with either foromocresol or ferric sulfate, and pulp necrosis in 40 % of formocresol pulpotomy. A study conducted by Salako et al [8] showed pulpal necrosis with formocresol and pulpal destruction with ferric sulfate pulpotomies performed on rat molars. Recent studies have revealed that the pulp has a great capacity for healing, this has led us to investigate the possibilities of perfecting a filling material capable of compensating for the inconveniences mentioned in the above studies and also generating the cicatrization of the radicular pulp and its perenniality with the help of substances which would initially ensure antisepsis and hemostasis and then the maintenance of long term antisepsis and impermeability by means of good volumetric stability [10]. Pulpotec (PD) is a filling paste for simple, rapid and long term treatment by pulpotomy of vital molars, both permanent and deciduous. The addition of pharmacological constituents ensures an aseptic treatment, induces cicatrization of the pulpal stump at the chamber-canal interface, whilst maintaining the structure of the underlying pulp. The efficiency and the properties of «PD» Pulpotec are substantiated by a radiographic file compiled on the basis of results of over 300 pulpotomies performed with Pulpotec and monitored for periods of 3 to 13 years[11].

This study was conducted to compare the clinical and histopathological response of primary molars to vital pulp therapy using formocresol, ferric sulfate, and pulpotec

Material and Methods

A total of 43 males & females patients aged 7-9 years were selected from those treated at AL-Razzi medical centre, with one or more carious primary molars (total= 60 teeth), where removal of dental caries will produce a vital pulp exposure. All patients had moderate to severe pain, and a vital pulp. There was no medical contraindication for dental treatment in the subjects. Twenty teeth were assigned to be treated with formocresol, and an equal number with ferric sulfate and pulpotec pulpotomies. In this clinical study, 30 teeth previously scheduled for extraction for orthodontic purpose, and then to be subjected to the histopathological evaluation of pulpal response. Prior to the participation in this investigation informed consent was signed by all subjects and their parents after a thorough explanation of the possible benefits, procedures, and risks. A surgically clean technique should be used because of the possible pain or discomfort

each case was anesthetized followed by access cavity preparation under rubber dam, all remaining dental caries was removed, and the overhanging enamel was planed back to provide good access to coronal pulp, the entire roof of the pulp chamber was removed with a sterile fissure bur. The coronal pulpal tissue was then removed using a sterile slow-speed round bur #6. Hemostasis was achieved using a saline-moistened cotton pallet placed over the orifices of the canals. The formocresol technique was completed during a single appointment, when the hemorrhage is controlled readily and the pulp stumps appear normal, the pulp chamber is dried with sterile cotton pellets, a pellet of cotton moistened with a (1:5) concentration of Buckley's formocresol (PD, Switzerland) and blotted on sterile gauze to remove the excess is placed in contact with the pulp stumps and is allowed to remain for (5) minutes, when the pulp stump became black instead of red, freshly prepared thick pulpotomy paste prepared by mixing one drop of formocresol + one drop of eugenol + Zinc oxide powder (PD, Switzkerland) placed over the pulp stumps. Then cement base applied on it (PD, Switzerland), the tooth is then restored with amalgam filling material (SDI/ Austria).

The ferric sulfate (FS) pulpotomy procedure was done similar to the FC pulpotomy but instead of formocresol as a capping material ,a 15.5% FS solution in an aqueous vehicle (Astringedent, Ultradent Products Inc,Utah) was gently applied on the pulp stump for 10-15 seconds with the syringe applicator supplied by the manufacture. An air-water syringe was used to flush the pulp chamber with water, if the homeostasis was achieved, the pulp chamber was sealed with fortified zinc oxide-euogenol mixture supplied in premeasured capsules (Dentsply Caulk, Milford, Del) , the molars were then immediately restored with amalgam as a final restoration[(12)].

Treatment of pulpitis by method of vital amputation using pulpotec was provided in two visits. In the first visit pulpotomy was performed in the usual way, after removal of the coronal pulp tissue Pulpotec liquid was mixed with Pulpotec powder (PD, Switzerland) and blend to obtain required thick, creamy consistency of the paste, the paste was then inserted into the pulp-chamber with a large sized paste filler. The presence of small quantities of blood does not affect the efficiency of Pulpotec ,the cavity was air-dried prior to the application of the paste, and then sealed with a temporary cement. Place a cotton roll between the 2 dental arches and request the patient to bite progressively but firmly , so that the Pulpotec paste clings to the walls of the pulp-cavity as well as to the root-canal orifices. Setting time of Pulpotec is approximately 7 hours.

During the second visit approximately 8-10 days later, the treatment was completed by setting the final tight obturation with amalgam, which placed on the Pulpotec, possibly leaving a thin intermediary layer of temporary cement to insulate Pulpotec from the final obturation material[(13)].

Clinical evaluations were carried out at 3 and 6 months, treated teeth were inspected for any sign or symptom including report of pain, presence of gingival swelling, mobility, tenderness to percussion, and draining fistula.

Histopathological evaluations were carried out at 6 months for the teeth indicated for extraction as part of orthodontic treatment (30 teeth), these teeth were divided into three groups of 10 teeth for each type of pulpotomy treatment and fixed in 10% neutral buffered formalin, decalcified in 10% formic acid for 5-6 weeks and embedded in paraffin wax (Fig. 1) in the department of histopathology –College of Dentistry-Baghdad University. Then sections of 5 mm were cut and stained with Hematoxylin and Eosin according to the method of Brown &Brenn[14]. Sections of the pulpal tissue of each tooth which were limited to the middle third of the radicular pulp were evaluated by light microscopy for pulpal inflammation (mild and severe), presence of necrosis, and abscess. Data were analyzed using a Z-test (percentage test) to perform comparisons between the groups .

Results

All patients (43 males and females aged 7-9 years) were available for recall at 3 and 6 months. In the FC group after 3 months the pain was presented in three cases, the picture is nearly the same in FS group with two cases, while no case reported this complain in PD group (Table 1). The data collected from patients at 6 months recall indicated that fistula was detected in four cases treated with FC compared to one case in the FS and PD groups. The assessments of the other clinical signs were also more in FC group than in teeth treated with FS and PD at 3 and 6 months. Tenderness to percussion was observed in three cases with FC and FS groups, but one in the PD group at 3 months, the number of cases presented this clinical finding became higher at 6 months.

Statistically high significant difference was seen ($P < 0.01$) in clinical observations of pain, swelling, mobility, percussion, and draining fistula between 3 and 6 months for all the tested groups except for mobility in PD no significant difference ($P > 0.05$) was detected (Table2)

Using the Z-test no significant differences were found between FC and FS at 3 months for percussion and fistula (Table 3), while the difference was highly significant for the rest of the clinical findings, at 6 months there were highly significant differences between the two groups in all clinical observations except of swelling.

Table (4) illustrated the comparison of subjects treated with FC and those with PD, the differences were highly significant for the recorded observations at 3 and 6 months, with no significant difference for mobility and fistula at 3 months.

Concerning the cases treated with FS and those with PD, data analysis revealed that differences were highly significant during the both tested periods, with no significant difference noticed for fistula at 6 months (Table 5).

The histopathological evaluation demonstrated that the inflammations (mild and severe) in the PD group and necrosis were less than that of FC and FS after 6 months follow- up (Table 6). The histopathological picture of mild inflammation showed the

infiltration of minute amounts of inflammatory cells (polymorphonuclear leucocyts) with capillary dilation (in FC group two cases, FS and PD one case), while in the cases that showed severe inflammation (Fig.3), there was a dense infiltration of polymorphonuclear leucocytes and capillary proliferation (in FC and FS groups three cases with one case in PD group), pulp necrosis was observed in two cases in FC group and one case in FS and PD groups in which the cells were characterized by opaque protoplasm with disappearance of intracellular details, the pulpal tissue in the cases of abscess was replaced by microabscess that showed disintegrating polymorphonuclear leucocytes accompanied by vessel dilation and accumulation of exudate where suppuration has occurred (in FC group one case and in FS two cases) . Normal pulp did not show any histopathological changes (Fig. 2). The Z-test demonstrated highly significant differences for all the findings between the groups, except between FC &FS for the severe inflammation, and between FS &PD for mild inflammation and necrosis the differences were non significant (Table 7).

Discussion

Many private practitioners today view that the ultimate goal for a pulpotomy is to maintain the primary tooth with no clinical signs or symptoms until the permanent successors erupt, with no harm occurring to the permanent successors. In this study, ferric sulfate (FS) pulpotomy has resulted in outcomes nearly similar to those of (FC) pulotomy in primary molars, these findings are compatible to that found by Fuks et al & Ibricevic et al [7,15] .The high number of the clinical and histpathological findings following FC may be attributed to pulpal inflammatory response and cytotoxicity of formocresol[16]. However, many clinicians continue to perform the formocresol pulpotomy because it produces predictable outcomes, materials are readily available, and the technique is simple[5]. The results revealed that ferric sulfate also had harm effects on the radicular pulp tissue this is due to the fact that FS produces hemostasis at the amputated pulp stumps by mechanically sealing cut blood vessels, this leaves vital pulp tissue in contact with ZOE which causes a moderate to severe inflammatory responses with resulting acute inflammation and necrosis[17]. Varagas and Packham[18] found that teeth treated with formocresol and Ferric sulfate had a high incidence of premature loss due to severe pulpal inflammation, resorption or abscess formation leading to pain, swelling, and space loss, our histopathological findings also shown that both produce inflammatory responses in the form of mild to dense infiltration of inflammatory cells (polymorphonuclear leucocytes) with vessel dilation and abscess formation that responsible for pain, swelling, tenderness to percussion, and draining fistula.

The researches undertaken demonstrates high levels of effectiveness in the modern dental preparations under examination, namely pulpotec, for sealing the pulp stumps of teeth treated for pulpitis by the vital pulpotomy method. Clinical trials provided by Dedeyan and Donkaya [13] have shown absence of pains at all patients without exception

after use of pulpotec. Even if the pain syndrome was found evident at diagnostics of pulpitis it was completely arrested after depositioning of the first portion of the preparation. No complaints were lodged by patients either in the intervals between visits to clinic or during the dynamic observation. No swelling of gum in the area of the treated tooth was detected during the given period (4-6) months, no evidence of a fistula and no mobility of a tooth 6 months after the treatment, the results of these clinical trials were in agreement with our results 3 months after the treatment, but disagree with those at 6 months. The study presented here is unique in that it is the first randomized clinical trial compare FC, FS and PD pulpotomy for primary molars in Iraq. Based on the data of the current study, formocresol and ferric sulfate produce equivalent outcomes which met the Casas and Ibricevic investigations[12,15], and pulpotec produces more favorable outcomes, it seems that the potential use of this material could successfully eliminate side effects associated with FC and FS in pulpotomy procedure for primary teeth.

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Figure (1): Samples imbedded in paraffin wax

Table (1): Clinical findings seen at the 3-months and 6-months follow-up for cases of formocresol(FC), ferric sulfate(FS), and pulpotec(PD).

Clinical findings	FC		FS		PD	
	3 months	6 months	3 months	6 months	3 months	6 months
Pain	3	6	2	5	0	1
Gingival swelling	1	2	0	2	0	1
Mobility	0	3	1	2	0	0
Tenderness to percussion	3	7	3	5	1	3
Fistula	0	4	0	1	0	1
No. of cases	20	20	20	20	20	20

Table (2): Z-test (percentage test) result between 3 months & 6 months for each group

Groups	Clinical findings	Z-test	Z-tab(5%)	Z-tab(1%)	Sig.
FC	Pain	22.72	1.96	2.33	H.S
	Gingival swelling	12.01			H.S
	Mobility	36.02			H.S
	Tenderness to percussion	29.21			H.S
	Fistula	42.16			H.S
FS	Pain	17.71	1.96	2.33	H.S
	Gingival swelling	29.02			H.S
	Mobility	12.03			H.S
	Tenderness to percussion	15.81			H.S
	Fistula	20.25			H.S
PD	Pain	20.25	1.96	2.33	H.S
	Gingival swelling	20.25			H.S
	Mobility	0.00			N.S
	Tenderness to percussion	21.08			H.S
	Fistula	20.25			H.S

N.S :Non Significant at level $P > 0.05$.
H.S :Highly Significant at level $P < 0.01$.

Table (3) Z-test (percentage test) result in 3 and 6-months follow up of the different clinical findings between FC & FS

	Clinical findings	Z-test	Z-tab(5%)	Z-tab(1%)	Sig.
3 Months	Pain	9.56	1.96	2.33	H.S
	Gingival swelling	20.25			H.S
	Mobility	20.25			H.S
	Tenderness to percussion	0.00			N.S
	Fistula	0.00			N.S
6 Months	Pain	14.61	1.96	2.33	H.S
	Gingival swelling	0.00			N.S
	Mobility	9.56			H.S
	Tenderness to percussion	13.80			H.S
	Fistula	28.69			H.S

N.S :Non Significant at level $P > 0.05$.
H.S :Highly Significant at level $P < 0.01$.

Table (4) Z-test (percentage test) result in 3 and 6- months follow-up of the different clinical findings between FC & PD

	Clinical findings	Z-test	Z-tab(5%)	Z-tab(1%)	Sig.
3 Months	Pain	36.02	1.96	2.33	H.S
	Gingival swelling	20.25			H.S
	Mobility	0.00			N.S
	Tenderness to percussion	21.08			H.S
	Fistula	0.00			N.S
6 Months	Pain	41.16	1.96	2.33	H.S
	Gingival swelling	12.01			H.S
	Mobility	36.02			H.S
	Tenderness to percussion	29.21			H.S
	Fistula	28.69			H.S

N.S :Non Significant at level $P > 0.05$.
H.S :Highly Significant at level $P < 0.01$.

Table (5): Z-test (percentage test) result in the 3 and 6-month follow-up of the different clinical findings between FS & PD

	Clinical findings	Z-test	Z-tab(5%)	Z-tab(1%)	Sig.
3 Months	Pain	12.01	1.96	2.33	H.S
	Gingival swelling	20.25			H.S
	Mobility	20.25			H.S
	Tenderness to percussion	21.08			H.S
	Fistula	20.25			H.S
6 Months	Pain	28.69	1.96	2.33	H.S
	Gingival swelling	12.01			H.S
	Mobility	29.02			H.S
	Tenderness to percussion	15.81			H.S
	Fistula	0.00			N.S

N.S :Non Significant at level $P > 0.05$.
H.S :Highly Significant at level $P < 0.01$.

Table (6): histopathological findings seen at the 6-months follow-up for cases of formocresol(FC), ferric sulfate(FS), and pulpotec(PD).

Histopathological findings	FC	FS	PD
Mild inflammation	2	1	1
Severe inflammation	3	3	1
Necrosis	2	1	1
Abscess	1	2	0
No. of cases	10	10	10

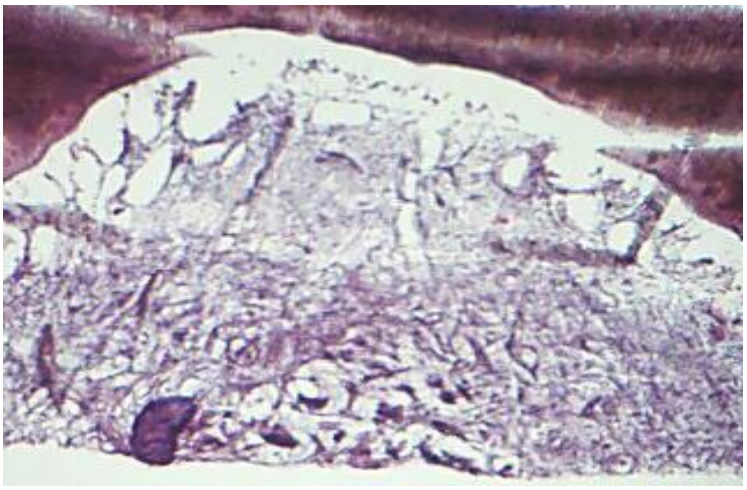

Figure (2): Normal pulpal tissue with normal capillary and no histopathological changes

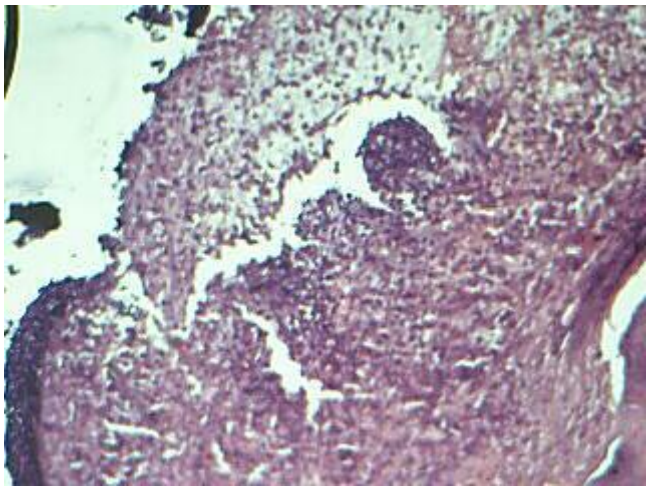

Figure (3): severe inflammation of the pulp with dense infiltration of polymorphonuclear cells

Table (7): Z-test (percentage test) result in the 6-months follow-up of the histopathological findings between groups

Groups	Histopathological findings	Z-test	Z-tab(5%)	Z-tab(1%)	Sig.
FC&FS	Mild inflammation	12.01	1.96	2.33	H.S
	Severe inflammation	0.00			N.S
	Necrosis	12.03			H.S
	Abscess	12.01			H.S
FC&PD	Mild inflammation	12.01	1.96	2.33	H.S
	Severe inflammation	21.08			H.S
	Necrosis	12.03			H.S
	Abscess	20.25			H.S
FS&PD	Mild inflammation	0.00	1.96	2.33	N.S
	Severe inflammation	21.08			H.S
	Necrosis	0.00			N.S
	Abscess	29.02			H.S

N.S :Non Significant at level $P > 0.05$.
H.S :Highly Significant at level $P < 0.01$.

تقييم سريري و نسيج مرضي للأسنان اللبنية باستعمال عدة مواد لعملية تحنيط لب السن

إنّ الهدف من هذا البحث هو مقارنة استجابة الأسنان اللبنية سريرياً ونسيج مرضياً لعملية تحنيط لب السن الحي واستعمال مادة الفورموكريزول ،مادة الفريك سلفيت،ومادة البلبوتيك.

شملت الدراسة للأسنان ٦٠ طاحن لبني من مجموع ٤٣ طفل تتراوح أعمارهم بين ٧-٩ سنوات. قسمت الاسنان الى ثلاثة مجموعات، المجموعة الاولى تضمنت ٢٠ طاحن لبني عولج بمادة الفورموكريزول، والمجموعة الثانية ٢٠ طاحن لبني عولج بمادة الفريك سلفيت، والمجموعة الثالثة ٢٠ طاحن لبني عولج بمادة البلبوتيك تم اختيارالمجاميع عشوائياً.

جميع الحالات قيمت سريرياً بعد ٣ و ٦ أشهر متابعة،أمّا التقييم النسيج مرضي فقد تم بعد ٦ أشهر للأسنان التي تحتاج إلى قلع كجزء من المعالجة التقويمية.

أظهرت النتائج السريرية عند ٣و٦ أشهر متابعة فروق معنوية كبيرة بين المواد المختبرة، أما النتائج النسيجية بعد ٦ أشهر فقد أظهرت:-حالتي التهاب طفيف، ٣ حالات التهاب شديد، حالتين موت اللب، وحالة واحدة خراج من مجموع ١٠ حالات لمجموعة الفورموكريزول. أمّا مجموعة الفريك سلفيت فكانت حالة واحدة أظهرت التهاب طفيف ، ٣حالت التهاب شديد، حالة واحدة موت اللب، وحالتين خراج من مجموع ١٠ حالات أيضاً، و أخيراً مجموعة البلبوتيك فكانت حالة واحدة التهاب طفيف، حالة واحدة التهاب شديد، حالة واحدة موت اللب ولم تظهر أي حالة خراج.

أظهرت النتائج السريرية والنسيج مرضية أنّ مادة البلبوتيك يمكن اعتمادها كبديل عن مادتي الفورموكريزول والفريك سلفيت لعملية تحنيط لب السن.

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