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CLINICAL AND RADIOGRAPHIC EVALUATION OF BIODENTINE VERSUS FORMOCRESOL IN VITAL PULPOTOMY OF PRIMARY MOLARS (A RANDOMIZED CONTROL CLINICAL TRIAL)

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ABSTRACT

Background: The main objective of pulp therapy is to preserve the integrity and health of the teeth and their supporting tissues, as well as to maintain the pulp vitality. Formocresol (FC) is that fixing agent which is considered as gold standard and used as pulpotomy medicament for primary teeth for decades. Several concerns had been reported about the use of FC. These concerns push new medicaments to be used for pulpotomy purposes. Among these medicaments is Biodentine (BD).

Aim of the study: To compare FC and BD clinically and radiographically when used for pulpotomy of vital primary molars.

Study Design : A randomized control clinical trial (split mouth and double blind) was conducted on 43 (4-6 years-old) children with decayed vital mandibular primary molars which were treated by pulpotomy using both medicaments . All treated teeth were followed for one year (at 3, 6, 9 and 12 months clinically and at 6 and 12 months radiographically).

Results: BD showed 100% clinical and radiographic success at all follow up timing, however FC showed 85.4% and 78% radiographic success at 6 and 12 months follow up period . By clinical evaluation FC showed 95.1% success at the end of follow up period with no significant difference.

Conclusions: BD as a pulpotomy medicament showed 100% clinical and radiographic success with no statistically significant difference with FC clinically. However a statistically significant difference was recorded between both medicaments regarding their radiographic success rate where BD was superior.

KEY WORDS: Pulpotomy, Primary Teeth , Formocresol, Biodentin, Success rate

INTRODUCTION

Treatment of primary teeth with vital pulp exposure is a topic of great interest in the field of pediatric dentistry.

The main objective of pulp therapy is to preserve the integrity and health of the teeth and their supporting tissues, and to maintain the vitality of the pulp [1,2].

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Pulpotomy of primary teeth is defined as amputation of the coronal pulp and treatment of the remaining vital radicular portion with a long term clinically successful medicament. An ideal medicament used for pulpotomy should have a bactericidal effect, enhance healing of the radicular pulp tissue, biocompatible and does not interfere with physiologic root resorption [3].

A wide range of medicaments and techniques have been used for pulpotomy purposes with different modes of action including formcresol (FC), ferric sulfate, calcium hydroxide, laser application, electro surgery and MTA [4-8] .

FC is that devitalizing and fixing agent which was introduced to dentistry since 1904 with full concentration of Buckley's formula (19% formaldehyde, 35% cresol, and 15% glycerin in distilled water). These concentrations were proved to be toxic to connective tissue cells [3,9].

A five times diluted formula of Buckley's formocresol, was suggested and used since 1968, it was concluded that formocresol in this concentration does not interfere with prolonged recovery of connective tissue, and might suppress the inflammatory response [10].

Although its high success rate, availability and cost effectiveness, the use of formocresol in dental treatment was a matter of considerable debate because of its possible mutagenic, carcinogenic and toxic effects. a study have claimed that FC is "likely no longer suitable for use in Dentistry" and "should be abandoned" up to the limit that the International Agency for Research on Cancer classified medicaments containing formaldehyde as carcinogenic and should not be used for humans in June 2004 [11].

More over, in European Union countries all dental products containing formaldehyde have been withdrawn from the dental market [12].

However a considerable number of other studies showed no evidence of significant risks of using formocresol in pulp therapy for primary teeth, also the American Academy of Pediatric Dentistry still recommend its use for pulp therapy and still used and taught in many dental schools worldwide [5, 9,13].

As a result of this debate about FC, other medicaments had been raised and used for pulpotomy. Among them, calcium silicate based cements which were used in pulp therapy techniques such as pulp capping and apexogenesis. These medicaments have good sealing ability and biocompatibility [14, 15].

Mineral trioxide aggregate (MTA) was introduced in 1993 as a root end filling material [16] .It has been suggested as a bio regenerative and bio inductive material with a very high success rate that could be comparable to FC or even superior. So it has been used in pulpotomy procedures since 2001[17] as concluded from a systematic review and a meta-analysis of randomized clinical trials [7].

But MTA has some drawbacks such as its difficulty in handling, prolonged setting time, tooth discoloration and low cost effectiveness [18-20].

Biodentine (BD) was introduced to dentistry, manufactured by Septodont and it has been available since 2010. It is considered as dentine substitute and a high-purity calcium silicate based material formed of powder and liquid [21]. Biodentine powder is mainly composed of tricalcium silicate, calcium carbonate and zirconium oxides while the liquid contains calcium chloride as the setting accelerator and water reducing agent [22].

BD has been used first in endodontic field due to its promising physical properties, perfect sealing ability, ease of manipulation and short setting time in addition to very important findings that it does not cause tooth discoloration [23,24] as well as excellent bactericidal effect due to its high alkalinity (pH = 12) [25,26].

Biodentine and MTA were compared as pulpotomy agents for primary teeth. Clinical and radiographic evaluations were performed with 100% success for both of the MTA and Biodentine groups

or with a minor superiority of MTA that was none significant [27-29].

A randomized, split-mouth, double-blind, controlled clinical trial was carried out to compare clinical and radiographic success rates of biodentine versus form cresol in pulpotomy of primary molars. After six months follow up period the results showed an equal success rate of 100% [26].

Clinical studies comparing biodentine and formocresol success rates in pulpotomy of human primary teeth are scarce. The purpose of this clinical study was to compare the clinical and radiographic success rate of biodentine with that of formocresol for pulpotomy of human primary molars over a period of one year.

MATERIALS AND METHODS

Study design

Randomized clinical trial, double blinded using split mouth technique.

Study setting

This study was carried out in Pediatric Dentistry Department-Faculty of Dentistry-Cairo University-Egypt.

Patients

Patients recruited for this study were selected according to the following criteria:

- Healthy children between 4 and 6 years of age with two matched bilateral deep carious primary mandibular first or second molars.
- No evident clinical symptoms of pulpal necrosis or pulp degeneration such as pain on percussion, spontaneous pain, history of swelling or presence of sinus tract.
- No pathologic or physiologic mobility.
- No radiographic evidence of internal and external resorption, pulp stone, and interradicular or periapical lesions (Preoperative radiograph).
- The remaining tooth structure would be restorable with a stainless steel crown.
- Bleeding time after amputation of the coronal pulp tissue was within normal limits (5 minutes).

Sample size calculation

Using sealedenvelop.com, [30] the online sample calculator, sample size was calculated assuming the null hypothesis that biodentine and formocresol have an average success rate of 95,99 % and 87.8 % respectively [26, 31,32,33]. Thus planning a binary outcome non inferiority trial with a difference of 8.19 %, then 76 primary molars (38 per group) are required to be 90% sure that the upper limit of a one-sided 95% confidence interval will exclude a difference in favor of the standard group of more than 10% [34].

With an estimation of 10% annual dropout, sample size was set to 86 primary molars (43 per group) [35].

Forty three children with the matching criteria of patient selection were included in this study.

Research Ethics Committee approval was obtained from Faculty of Dentistry Cairo University. Detailed treatment plan and procedures were explained to the parents and informed written consent s were obtained before practical work.

Randomization

Using 4 times folded papers in which one of the tested materials was written (43 paper for each material) contained in a closed white envelops (43 envelop in each one folded paper of each tested materials were placed), the selected two matched bilateral deep carious primary mandibular molars were randomly allocated to one of the tested materials.

When guardians agreed for their child to participate in the trial, an envelope was drowned and patient personal data was written on it.

At the time of treatment of the first tooth in each patient, one of the folded papers was taken from the envelope and the type of the dressing material was recorded.

Trial participants and outcome assessors were blinded to the type of materials used in each tooth.

Clinical treatment

1- Preoperative photographs and radiographs were recorded for all selected cases as base line data (fig. 1)

2- Local anesthesia was given at the side of the tooth selected for treatment.

3- Then the teeth were isolated using rubber dam.

4- Dental caries was removed with a slow-speed round bur No.5, before pulpal exposure. The entire roof of the pulp chamber was then removed using round bur No.5 mounted in a water-cooled high speed turbine. The coronal pulp was amputated using a sharp spoon excavator and the pulp chamber was irrigated with a light flow of normal saline. Moistened cotton pellets were placed over the pulp stumps, and high pressure was applied (1-5 min). When the cotton pellets were removed homeostasis was apparent.

5- If bleeding was not controlled within 5 minutes the case had been excluded from the study.

6- application of tested materials:

a) Formocresol group:

sterile cotton pellets were placed in a solution of 1:5 diluted Buckley's formocresol (Buckley's Formocresol, Sultan Healthcare) and immediately blotted dry on sterile gauze. The cotton pellet was placed directly over the radicular pulp stumps and left for 5 minutes. It was then removed and pulp stumps were covered with zinc oxide eugenol (ZOE) paste (DPI, Mumbai, India). The cavity was filled with thick mix of zinc oxide and egenol (fig. 2).

b- Biodentine group:

Biodentine capsule was gently tapped on a hard surface (to diffuse powder); five drops of liquid from the single dose dispenser were poured into the capsule which was placed in a triturator for 30 sec. The mixture of biodentine was then introduced into the pulp chamber using amalgam carrier, The cavity was filled with Glass ionomer cement (Riva self cure, SDI, Australia) (fig. 3).

In both groups teeth were restored with stainless steel crowns (3M, ESPE, Unitek, United States). Cemented with glass ionomer cement (GC Fuji I, GC America, Alsip, IL, USA). An immediate postoperative radiograph using periapical film size 2 (Speed D Film, Kodak, United States) was taken (fig 4).

Follow up protocol:

The children were recalled for clinical evaluation at 3, 6, 9 and 12 months and for radiographic evaluation at 6 and 12 months.

Evaluation of the trial outcomes:

a) clinical evaluation:

Treatment was considered clinically successful when there was absence of spontaneous or nocturnal pain, abscess, fistula or pathologic mobility.

b) Radiographic evaluation:

Treatment was considered radiographically successful when there was absence of periapical or inter-radicular radiolucency, external or internal root resorption or calcific metamorphosis in the radicular pulp canal.

Treatment was considered as a failure when one or more of the previously mentioned signs was detected. Time for teeth with pulpotomy failure was defined as the time elapsed between treatment and the first visit in which pathologic finding was detected.

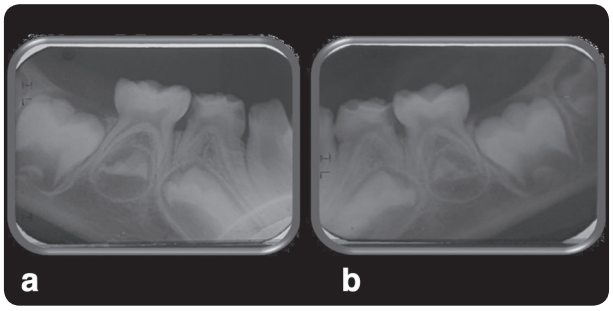

Fig. 1: Preoperative radiographs for primary molar to be treated with biodentine (a) and formocresol (b).

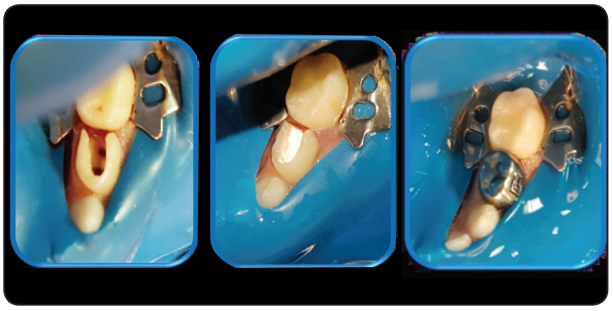

Fig. 2: Formocresol pulpotomy.

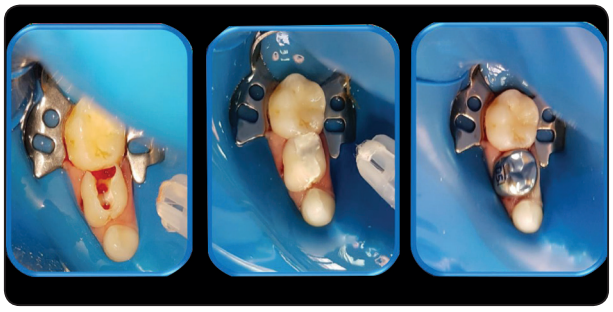

Fig. 3: Biodentine pulpotom

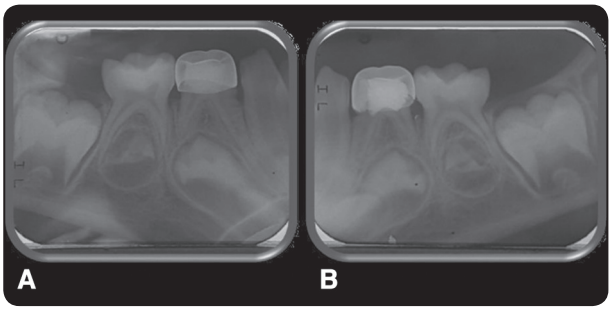

Fig. 4: Immediate Postoperative radiographs for primary molar treated with biodentine (a) and formocresol (b).

Radiographic evaluation was done by two blinded assessors independently.

The inter examiner agreements was calculated using Kappa scores.

- Data were collected and statistically analyzed.

RESULTS

43 children (both boys and girls whom ages ranged from 4 to 6 years old) with bilateral deeply decayed mandibular primary molars were participated in this study , where 86 primary molars were classified into two groups .One of them included 43 primary molars which were treated by biodentine (test group) while the other was the contralateral 43 primary molar and were treated by our gold standard FC (control group).

These children were followed up for one year with 3 months interval (at 3,6,9 and 12 months) clinically, while at 6 and 12 months radiographically. At the beginning of the follow up 2 cases were dropped out and excluded from the total number of children ,so the authors completed this study with 41 till the end of the follow up period.

Clinical Evaluation:

At 3 months the whole cases (41) showed 100% clinical success with both materials (biodentine and formocresol) . Two cases of mobility were recorded in the FC group one of them at 6 and the other at 12 months follow up period with a percentage of success 95.1% and failure 4.9% . On the other hand biodentine showed 100% clinical success till the end of follow up period but with no statistically significant difference (table 1 fig. 5) .

TABLE (1) Descriptive statistics and results of Wilcoxon signed rank test for comparison between clinical success in the two groups

Time	Criteria	Formocresol (n = 41)		Biodentine (n = 41)		*P*-value
		n (41)	%	n (41)	%	
3 months	Pain	0/41	0	0/41	0	NC†
	Abscess or fistula	0/41	0	0/41	0	NC†
	Mobility	0/41	0	0/41	0	NC†
Clinical evaluation		41/41	100	41/41	100	NC†
6 months	Pain	0/41	0	0/41	0	NC†
	Abscess or fistula	0/41	0	0/41	0	NC†
	Mobility	1/41	2.4	0/41	0	0.317
Clinical evaluation	Success	40/41	97.6	41/41	100	0.317
	Failure	1/41	2.4	0/41	0	
9 months	Pain	0/41	0	0/41	0	NC†
	Abscess or fistula	0/41	0	0/41	0	NC†
	Mobility	1/41	2.4	0/41	0	0.317
Clinical evaluation	Success	40/41	97.6	41/41	100	0.317
	Failure	1/41	2.4	0/41	0	
12 months	Pain	0/41	0	0/41	0	NC†
	Abscess or fistula	0/41	0	0/41	0	NC†
	Mobility	2/41	4.9	0/41	0	0.157
Clinical evaluation	Success	39/41	95.1	41/41	100	0.157
	Failure	2/41	4.9	0/41	0	

: Significant at P ≤ 0.05, NC†: Not Computed because the variable is constant

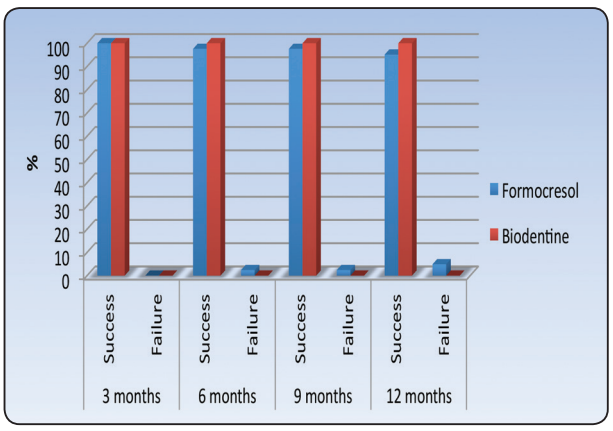

Fig. (5): Bar chart representing comparison between clinical success in the two groups

Radiographic Evaluation:

By comparing the radiographic success in both groups the results of this study showed that at 6 months FC showed 85.4% radiographic success and 14.6% radiographic failure (6 cases 2 of them represented with radiolucency and 4 with internal root resorption). By time and at the end of follow up period the success rate of FC decreased to reach 78% and failure 22% as the number of cases with radiolucency increased to be 3 and the resorption cases increased to be 6 .However BD showed 100 % radiographic success with a statistically significant difference where p- value was 0.014 and 0.003 at 6 and 12 months consecutively (table 2, fig. 6,7,8).

TABLE (2) Descriptive statistics and results of Wilcoxon signed rank test for comparison between radiographic success in the two groups.

Time	Criteria	Formocresol (n = 41)		Biodentine (n = 41)		*P*-value
		N	%	N	%	
6 months	Radiolucency	2/41	4.9	0/41	0	0.157
	Resorption	4/41	9.8	0/41	0	0.046*
	Calcific metamorphosis	0/41	0	0/41	0	NC†
Radiographic evaluation	Success	35/41	85.4	41/41	100	0.014*
	Failure	6/41	14.6	0/41	0	
12 months	Radiolucency	3/41	7.3	0/41	0	0.083
	Resorption	6/41	14.6	0/41	0	0.014*
	Calcific metamorphosis	0/41	0	0/41	0	NC†
Radiographic evaluation	Success	32/41	78	41/41	100	
	Failure	9/41	22	0/41	0	0.003*

: Significant at P ≤ 0.05, NC†: Not Computed because the variable is constant

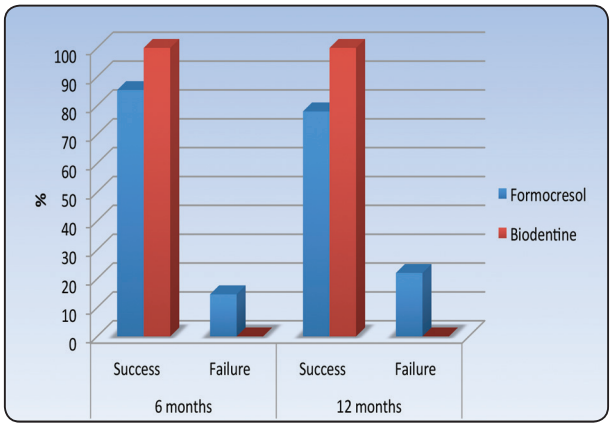

Fig. (6): Bar chart representing comparison between radiographic success in the two groups

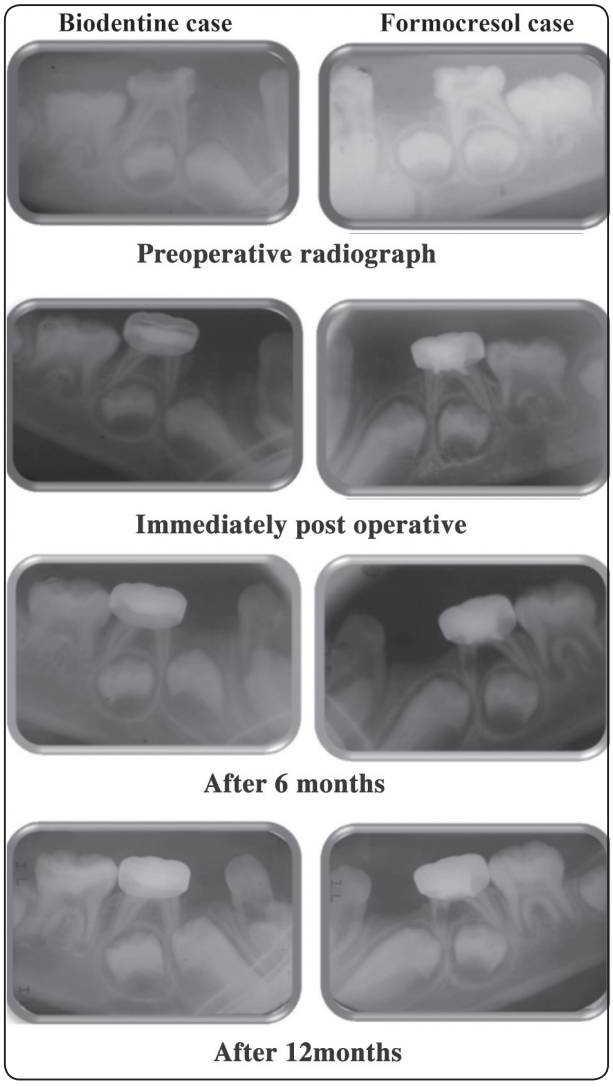

Fig. (7) Radiographic progress over a period of 12 months for primary molars treated with formocresol or biodentine

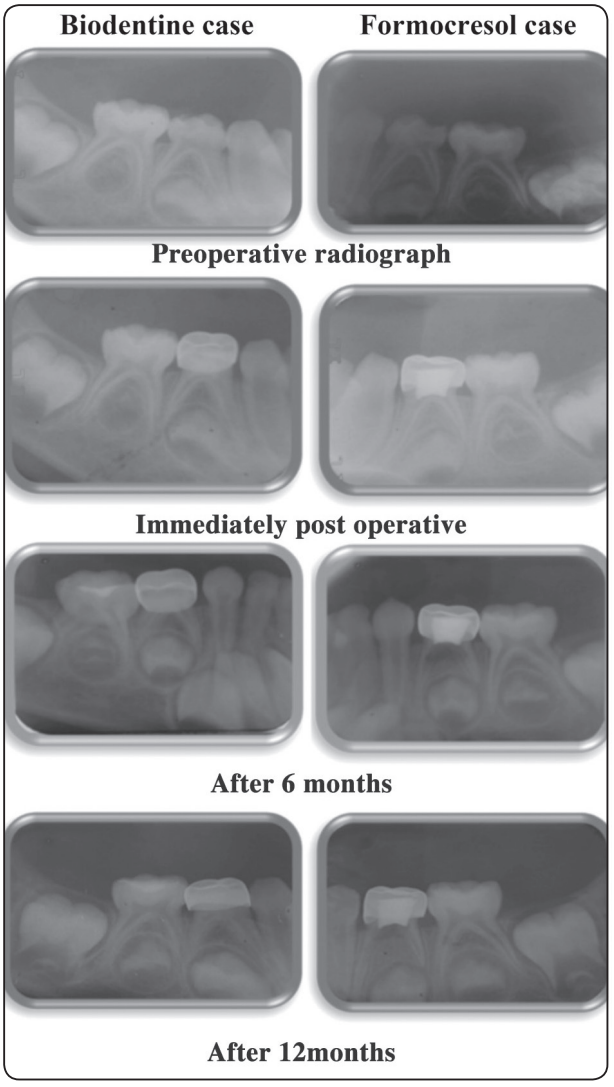

Fig. (8) Radiographic progress of another case over a period of 12 months for primary molars treated with formocresol or biodentine.

DISCUSSION

Pulpotomy is one of the most important and accepted techniques used for treatment of asymptomatic primary teeth with carious pulp exposure [36].

FC is a pulpotomy medicament used for devitalization of vital pulp tissues with a great bactericidal effect and very high recorded success rates [14,18] in addition to its availability and coast effectiveness so, it is considered as a gold standard, still used and officially taught in many dental schools [13].

As a result of the concerns about the safety of FC by several authors [13,14,18,37] alternative materials have been introduced to the dental market with higher safety properties. Among these materials are MTA and BD.

In this study the authors compared FC as a gold standard versus BD for pulpotomy of vital primary molars in an attempt to find a safer medicament to be used as an alternative to FC bearing in mind the safety and general health of children.

In the present study 4 to 6 years old children were involved in order to be more co-operative with easier behavior management as well as to conduct the study on primary molars away from the age of normal physiologic root resorption.

Split mouth technique was applied in order to standardize the general conditions of the child, dietary habits, oral hygiene practices, immune response and tissue reactions, in addition to the availability of the child to follow up and evaluate the success rates of both materials [27].

The mandibular molars were treated in this study as they are usually more accessible for practical work as well as their radiographic interpretation is much more easier without superimposition which enables the investigators to identify any radiographic changes [38].

All selected primary molars were pulpotomized using either FC or BD , then covered by stainless steel crowns as they were proved to be the most durable, protective and long standing restorations [26,39].

All treated primary molars were evaluated for clinical success rate at 3,6,9,12 months. While radiographic evaluation was done after 6 and 12 months.

Two cases were dropped out of the total number (43) with a percentage of 4.7 % while 41 cases were highly committed and completed their follow up till the end of 12 months. These two cases were not able to attend the follow up appointments due to difficulty in transportation and inconvenient time for their parents to bring them. Also it was observed that some dental patients once they were pain relieved, they did not come for follow up.

By comparing both materials the results of this study showed that there was no statistical difference regarding the clinical success rates during all follow up periods. BD showed 100% clinical success rate while FC showed 100%, 97.6%, 97.6% and 95.1% clinical success at 3, 6, 9, and 12 months respectively (table 1 fig. 5).

FC showed two cases of pathologic mobility one of them at 6 months and the other at 12 months follow up. These results were supported by Farsi et al [40] and Carrotte and Waterhouse[41] who explained this unfavorable response on the bases that when FC comes in direct contact with vital pulp for five minuets , this time is very short to produce complete fixation leaving the pulp in a state of chronic inflammation which results in pathologic mobility. Waterhouse et al [42] and Vargas and Packham [43] explained the occurrence of pathologic mobility due to the chronic irritation of the pulp tissues from the eugenol content of the freshly prepared zinc oxide eugenol paste which may result in internal and or external root resorption.

On the other hand the results of this study showed that there was a statistical significant difference between FC and BD treated cases regarding radiographic success rates. BD showed 100% radiographic success rate during the whole follow up period. While FC showed 85.4% and 78% success rate at 6 and 12 months follow up respectively (table 2 fig.6).

Two cases of radiographic failure with FC (radiolucency in the furcation area) were recorded at 6 months, this number increased to three cases at 12 months follow up. This results goes in agreement with Berger[44] and Magnusson[45] who attributed the furcation involvement to the smaller molecular size of FC so it can penetrate into the furcation area through the accessory pulp canal and the very thin and permeable pulpal floor causing such inflammatory response. This finding was also supported by other studies [14, 43, 46, 47, 48].

Another four cases of radiographic failure with FC (internal and or external root resorption) were recorded at 6 months follow up. This number increased to six cases at 12 months follow up. This result goes in line with the opinion of Berger [44] and Magnusson [45] who found that in FC pulpotomy there is an internal root resorption with or without external root resorption . They also reported that the percentage of failure with FC pulpotomy increased with time.

The presence of internal root resorption was attributed to the eugenol content of the capping material which can lead to certain vascular changes that may result in chronic inflammation with the formation of granulation tissue and differentiation of osteoclast – like odontoclasts that act on the inner wall of the root leaving internal resorption [49].

No calcific metamorphosis was seen radiographically during the follow up period neither with FC nor BD cases. This finding goes in agreement with Haval et al [49]. Meanwhile this finding was a source of debate between the researchers being considered as a failure due to deviation from the normal structure of the pulp tissue to calcific metamorphosis [42,46,47,48] while other researchers considered calcific metamorphosis as an extra activity of odontoblast like cells that retain their vitality and continue their role in dentin formation in an attempt to repair and heal after a stimulus [50-52].

High success rates of BD seen in this study both clinically and radiographically are in agreement with the previous studies done on primary molars [30, 53,54]. Attempts to preserve pulp vitality of the remaining pulp tissues of the primary teeth treated with pulpotmy seems to be more successful both clinically and radiographically.

CONCLUSIONS

According to the results of this study, the following conclusions could be withdrawn :

1- BD (as a pulpotomy agent) showed 100% clinical and radiographic success, however FC showed more clinical than radiographic success through out one year follow up .

2- No statistical significant difference was recorded by comparing FC and BD regarding their clinical success, however BD was superior.

3- Statistical significant difference was recorded by comparing both materials regarding their radiographic success where FC showed more radiographic failure which increased by time.

RECOMMENDATIONS

According to the results of this clinical study we can recommend:

1- The use of BD as a pulpotomy agent in an attempt to avoid the drawbacks of FC.

2- More clinical and histological studies with longer follow up period.

3- More studies should be conducted in our developing countries to evaluate the cost effectiveness of BD.

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