

# Clinical Assessment of Pulp Therapy for Primary Molars Performed Under General Anesthesia, Using Two Pulpotomy Agents-A Retrospective Cohort Study

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**Abstract** The aim of this retrospective study is to clinically and radiographically assess the ferric sulfate and tricalcium silicate (Biodentine™) pulpotomies. The study consisted a total of 25 children- 9 girls and 16 boys aged between 3-6 yrs. From the patients' medical records we determined that 35 primary molars were pulpotomied with Biodentine™ and 65 were pulpotomied with ferric sulfate (FS). Patients were recalled in the post-op 6<sup>th</sup> month for clinical examination and in the post-op 12<sup>th</sup> month for both clinical and radiographic examination. While a statistically significant difference was found between the factors of age, gender and pulpotomy agents ( $P<0,05$ ), no statistically significant difference was found between the jaw and teeth types ( $P>0,05$ ). As a result, recently developed tricalcium silicate based agents (Biodentine™) can be used as an alternative to FS in pulpotomy.

**Keywords:** ferric sulfate, Tricalcium silicate, Biodentine™, pulpotomy of the primary teeth, general anesthesia, early childhood caries

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## 1. Introduction

Pulpotomy is an endodontic treatment option for keeping the vitality and the functions of the radicular pulp by the amputation of the infected coronal pulp with the objective of retaining the carious primary teeth until the natural exfoliation. [1] The quest for ideal pulp-dressing agent has always been a subject of considerable debate since the pulpotomy was first defined by Atkinson in dentistry in 1866 and various researches are still conducted for an ideal medication. [2]

In recent years, several materials have been used for pulpotomy and pulpotomies were classified in three major categories as; devitalizing, preserving and regenerating in accordance with the agents' effects on the pulp. [3] It is a common view that a pulp dressing material should be bactericidal, protecting root pulp, promoting healing and not harming the pulp and periradicular tissues. [4] Unlike the Portland cement in Mineral Trioxide Aggregate (MTA), Tricalcium Silicate based dental materials are developed by in-vitro synthesis of the high-purity raw materials. One of those materials, Biodentine™ (BD), has become a commercially available dentine substitute. [5] Due to the effects of tricalcium silicate based cements on the proliferation and odontogenic differentiation of human dental pulp cells, they were considered to be ideal capping materials in the primary dentition. [6]

In this study, we aimed to compare the clinical and radiographic success of BD, a highly recommended-new

material for pulp amputations with FS, which is a frequently used medication in current amputation therapies.

## 2. Materials and Methods

### 2.1. Sample Collection and Ethical Consideration

This study consists of patients who received pulp therapy for primary teeth under General Anesthesia (GA) in Ataturk University Faculty of Dentistry Department of Pediatric Dentistry between January 2013 and February 2014. Approval of Ataturk University Faculty of Dentistry Ethics Committee was obtained for the collection of personal data and records (18.12.2014/36).

We reached the study participants' personal data through "evaluation forms of the pediatric patients treated under protective immobilization, N<sub>2</sub>O/O<sub>2</sub> and GA" in the archive records. Patients were treated by a pediatric dentist with 20 years of experience.

An age less than 71 months and no systemic disease that may adversely affect the success of treatment were used as the selection criteria to determine the pediatric patients. In accordance with their dates of previous dental treatment obtained from the recorded forms, the patients were recalled after six months and one year retrospectively and they were radiographically followed-up. 16 children (a total of 41 teeth) were excluded from the study since they were inaccessible by phone or lost during follow-up.

Parents volunteered to participate in the study were informed about the dental examinations and evaluations, and their written approvals were obtained. Pulpotomies for 100 primary teeth (61 primary first and 39 secondary molars) in a total of 25 children (9 girls and 16 boys) were evaluated. Treatment records of the participants revealed that two type of pulpotomy agents had been used; Ferric Sulphate- Zinc Oxide Eugenol cement (FS-ZOE) and Biodentine (BD).

## 2.2. Pulpotomy Procedures

In regard to the information given by the pediatric dentist who performed the pulpotomy procedures, all patients evaluated in the study had received pulpotomy therapies under GA and after the removal of the carious tissues from the teeth, pulp chambers had been breached with a  $\square$  330-carbide bur under continuous water spray.

Coronal pulp tissue was removed with a round bur on a slow-speed hand-piece and hemostasis was achieved by the application of a saline-wet cotton pellet for 3-5 min. After achieving hemostasis the chosen dressing-material was placed.

Following 15-sec application of 20% FS, ViscoStat<sup>®</sup> (Ultradent Products Inc, Salt Lake City, Utah, USA) to some teeth as amputation agent, FS was rinsed off with 2cc isotonic saline solution. After the access cavities were dried with sterile pellets, Pele Tim<sup>®</sup> (Voco GmbH-Germany), ZOE (Sultan Chemist Inc, Englewood, NJ-USA) was placed.

BD (Septodont, Saint-Maur-des-Fosses, France) was prepared in accordance with the manufacturer's instructions for use -5 drops of liquid were poured into one capsule and mixed on a rotating mixing device for 30 sec- and placed into the pulp chamber.

In all teeth, the amputation materials were covered with glass ionomer cement [Ionofil Molar AC (Voco, Cuxhaven, Germany)] followed by Stainless Steel Crown (SSC) restorations (3M ESPE, Seefeld, Germany) cemented with Meron Plus AC (Voco, Cuxhaven, Germany)

## 2.3. Collection of Data, Clinical and Radiologic Follow-Ups

By searching the archive records, patients matching inclusion criteria who had undergone pulpotomies were identified and informed about the study by phone, and the acceptors were invited to department of pediatric dentistry. Nothing but the clinical examination findings of the participating patients were recorded at the 6<sup>th</sup> month while their clinical and radiologic assessments were made at the 12<sup>th</sup> month. All periapical X-ray images used for radiographical assessment were taken using the same unit (IRIX70E, Trophy ETX, France) and by the same pediatric dentist.

## 2.4. Clinical Success/Failure Assessment Criteria

- Spontaneous pain, palpation, and percussion sensitivity
- Edema, fistula, and abnormal mobility
- Lymphadenopathy in the corresponding node locations

## 2.5. Radiologic Success/Failure Assessment Criteria

- Existence or non-existence of radiolucency in the periapical and furcation regions
- Presence or absence of internal or external root resorption
- Expanded or non-expanded periodontal ligament

Association with the results of clinical and radiologic evaluations, the teeth in which any of the aforementioned criteria were observed, have been judged as failure while calcific metamorphosis haven't been not assessed as failure.

## 2.6. Statistical Analysis

The data were processed using SPSS version 18.0 (SPSS Inc., Chicago, IL, USA) using the  $\chi^2$  test. The significance level was set to be  $p < 0.05$ . Additionally, the relationship between dependent and independent variables were examined.

## 3. Results

Pulp amputation therapies performed 12 months ago with BD and FS-ZOE for 100 primary molars in a total of 25 children (9 girls and 16 boys) were clinically and radiographically evaluated in this study. Distribution of the number of the agents used in the amputation procedures by the age, gender and medication type is given in Table 1. BD was used in 35 pulpotomies of 100 teeth studied, and 65 teeth were amputated with FS-ZOE.

**Table 1. Distribution of the pulpotomied teeth by the age, gender and type of medicament**

Age	Pulpotomy Medicaments				Total
	BD		FS-ZOE		
	Female	Male	Female	Male	
3	5	4	-	4	13
4	-	12	7	14	33
5	-	4	19	10	33
6	5	5	3	8	21
<b>Total</b>	10	25	29	36	100

Distribution of the pulpotomied teeth by the arch locations is given in Table 2.

No statistically significant difference was found in the assessment of maxillary and mandibular first and second primary molars in regard to the success rate criteria ( $P < 0.05$ ), ( $\chi^2$ : 0,253).

Clinical and radiographic success rates of primary molars treated by pulpotomy using BD and FS-ZOE after a follow-up period ranging from 6 to 12 months are presented in Table 3.

Since no clinical pulpotomy failures such as, abscess/swelling in vestibular sulcus, unremarkable soft tissue, draining fistula, sensitivity to percussion and palpation, spontaneous pain, mobility and lymphadenopathy have been observed in any teeth, we did not provide their distributions. However, distribution of radiographic failures is presented since they have been recorded independently. Distribution of radiographic failure types by the medicaments used in pulpotomy is given in Table 4.

Table 2. Distribution of the pulpotomied teeth by the arch locations

		Maxillary First Molar	Maxillary Second Molar	Mandibular First Molar	Mandibular Second Molar	Total
Age	6	6	3	8	4	21
	5	8	6	11	8	33
	4	7	5	13	8	33
	3	3	2	5	3	13
Gender	Female	13	5	15	10	43
	Male	11	11	22	13	57
Material	BD	9	6	14	6	35
	FS-ZOE	15	10	23	17	65
Success Criteria	Successful	19	15	26	16	76
	Unsuccessful	5	1	11	7	24
Total		24	16	37	23	100

Table 3. Clinical and radiographic success rates of primary molars treated by pulpotomy using BD and FS-ZOE after a follow-up period of 6-12 months

Medicament	Clinical success rate- n(%)		Radiographic success rate- n(%)
	6 mo	12 mo	12 mo
BD	35(100)	35(100)	34(97.1)
FS-ZOE	65(100)	65(100)	42(64.6)

Table 4. Distribution of radiographic failure types by the medicaments

Radiographic Failures	Medicaments		Total
	BD	FS-ZOE	
Furcational radiolucency	-	2	2
Internal resorption	1	16	17
External resorption	-	5	5
Total	1	23	24

Radiographic failures have been observed in 24 out of 100 studied teeth. All failure types presented in Table 4 have occurred in different teeth. We observed frequent internal resorptions. Nonetheless, calcific metamorphosis which was seen in a total of 36 teeth, 21 in BD and 15 in FS-ZOE group was not included in Table 4 since we did not assess it as a failure.

Distribution of the age, gender, arch, tooth and material factors by the success rates was obtained in accordance with the outcomes of the clinical and radiographic assessments. Distribution of these factors by the success rates and the results of chi-square analysis ( $\chi^2$ ) were presented in Table 5.

Table 5. Radiographic success rates by age, gender, tooth types, locations and types of medicament

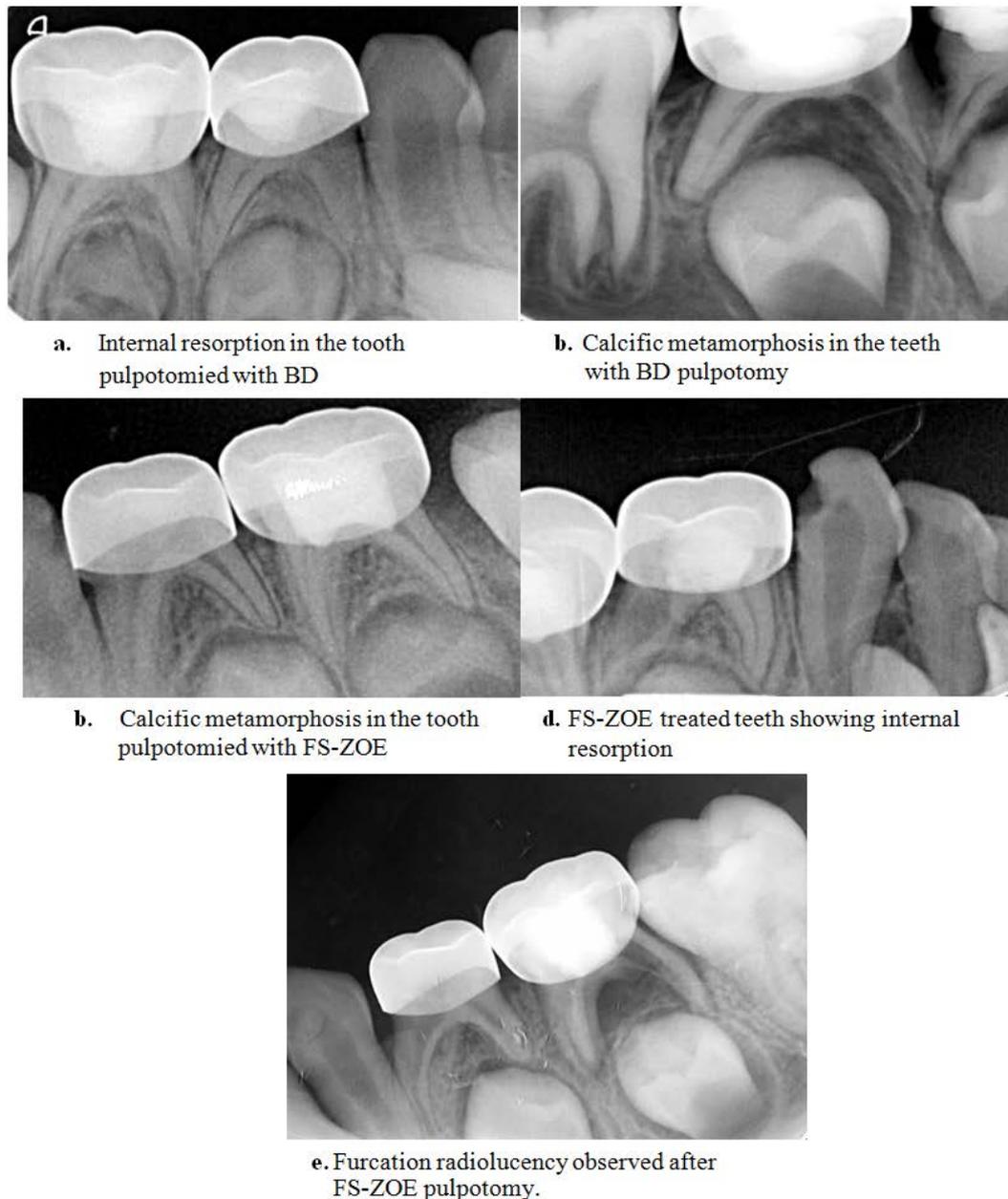
Variable	Success n (%)	Total	P
Age	6	17(81)	.023
	5	19(56)	
	4	29(88)	
	3	11(85)	
Gender	Male	28(65)	.027
	Female	48(84)	
Arch Location	Maxilla	42(70)	.085
	Mandible	34(85)	
Tooth type	First molar	45(74)	.514
	Second molar	31(80)	
Medicament	BD	34(97)	*.000
	FS-ZOE	42(65)	
Total	76	100	

\*Indicating a statistically significant difference between two treatment groups by  $\chi^2$  test with  $p < 0.05$ .

Table 6. Multiple logistic regression analysis for factors associated with treatment

Variable	B	S.E	Wald	df	Sig	Exp(B)#
Age			4.367	4	.224	
3						1
4	.739	1.152				2.095
5	-.750	1.048				.473
6	-.226	1.174				.798
Gender	-.596	.598	.994	2	.319	
Male						1
Female						.551
Arch Type	1.262	.608	4.305	2	.038	
Maxilla						1
Mandible						3.534
Tooth Type	.545	.577	.893	2	.345	
First Molar						1
Second Molar						1.725
Material	-2.91	1.105	6.377	2	.012*	
BD						1
FS+ZOE						.061
Constant	3.242	1.353	5.745		.017	25.590

\*  $p < 0.05$ .



**Figure 1.** Periapical radiographs of cases after a follow-up period of 12 months; **a.** Internal resorption in the tooth pulpotomied with BD **b.** Calcific metamorphosis in the teeth with BD pulpotomy **c.** Calcific metamorphosis in the tooth pulpotomied with FS-ZOE **d.** FS-ZOE treated teeth showing internal resorption **e.** Furcation radiolucency observed after FS-ZOE pulpotomy.

The statistical analyses of the factors by the outcomes, given in [Table 5](#) are as follows; no statistically significant differences between the groups by age, gender, arch and tooth types were found ( $P>0.05$ ), whereas the differences between the pulpotomy agents were found to be statistically significant in regard to the outcomes of radiographic evaluation of the materials (medicaments) ( $P<0.05$ ).

Additionally, multivariate logistic regression was performed in our study for the analysis of factors associated with the success/failure of treatment.

(Success)  $Y=f(\text{Age, gender, arch type, tooth type, material})$

The results of the logistic regression for factors associated with treatment are shown in [Table 6](#).

Periapical radiographies of the cases showed the symptoms of internal resorption, calcific metamorphosis, and furcational radiolucency 12 months after the treatment are shown in [Figure 1](#).

## 4. Discussion

Due to the dentin structure of primary teeth, pulpotomy has frequently become a therapeutic option for the treatment of deep dentinal carious lesions. From past to present, so many dressing materials have been tried (Formocreasol-FC, FS, glutaraldehyde, Calcium Hydroxide, MTA) and MTA, FS, FC have found to be the most successful and popular materials among the others. [7] Among them, popularity of FC temporally decreased because of its some negative effects such as; cytotoxicity, mutagenicity, potential carcinogenicity, systemic spread, and necrosis leading the researches search for new agents, which can be safely used in children. [8,9]

We know that just like MTA, Biodentine which is a newly developed tricalcium silicate-based medicament, can also be applied directly on the pulp tissue and thus, it

stimulates the hard-tissue formation by sustaining the vitality of the pulp [10].

In our clinic, BD and FS+ZOE are frequently used for the pulpotomy of primary teeth. The reasons for the preference of BD over the other materials are; capability of penetrating into dentine tubules, potential of restoring the mechanical properties of the teeth with excessive tissue loss, and more practical clinic use as compare to MTA. Due to its ease of application, and clinical and radiographic success reported in the dental literature FS-ZOE, is another choice as amputation material.

Many studies conducted divulge that, radiologic success rates have been found to be lower than the clinical rates. [37,38] Thus following pulpotomy, the necessity for radiologic follow-ups gains importance.

Camp and Fuks reported that the follow-up examinations after the endodontic therapies were essential. [3] In one of their studies, Peng et al [6] remarked that there was no recommended follow-up period for the pulpotomies performed in the primary teeth.

Although the long-term follow-up examinations are important for assessing the success rate of dressing material in regard to the treatment period, lost-to-follow-ups and missed appointments due to the prolonged times adversely affect the success/fail evaluation rates of the clinical studies. In their study, Casas et al stated that only 29 of the 130 amputated pulps could have been followed-up for 3 years. [12]

12-month clinic and radiologic follow-ups of the 3-6 years old healthy children who were previously treated under GA were planned in our study, and the patients ready for clinical examinations and X-Ray screenings were included.

Although the number of the pulpotomies performed under GA was higher, a follow-up loss occurred in the study due to the exclusion of the children who were not cooperative during the clinical examinations and X-Ray imaging stages.

It has been suggested that the systemic diseases may lessen the regeneration potential of the pulp tissue and degenerated odontoblasts may lead to new dentinal formation disorders. [13] Children with the systemic diseases were excluded in our study since they might decrease the regeneration capacity and affect the success rate of treatment.

Guelman et al [14] reported that there is no significant relation between the success rates of the pulpotomies and the age factor in the patients <>6. The initiation period of physiological root resorption was manifested as 6 years for primary first molars and 8 years for primary second molars in "Kronfeld's Chronology of Dental Development". [15] Osteoclastic activity begins with the initiation of the root resorption. [16] For deciding the amputation therapy, resorption must not exceed 2/3 of the root length on the radiographs. We thought that the physiological root resorption was not extensive enough to contraindicate the pulpotomy, since the followed patients were 3-6 years old in our study. The age factor was found to be statistically significant in affecting the success rate of the pulp amputation therapy. We think that this is associated with the more BD use in the more successful age groups.

Similar failure rates have been observed for both girls and boys in the researches studying the gender influence

on the success rate. No statistically significant difference has been found also in our study.

Relationship between the success rate of the pulpotomy and arch location has been researched and more failure rates have been observed in the mandible. [14,18] The reason for observing less pulpotomy failure rates in the maxilla was reported as; the difficult assessment of the radiographs due to the superimposing images of maxillary sinuses and underlying permanent teeth germs with the roots of the primary molars. [19] Although there was no significant difference between the failure rates of pulp amputation therapies performed in maxilla and mandible in our study, pulpotomy failure rate in maxillary primary molars was found to be higher than the rate of mandibular primary molars as observed also in the other studies.

We observed a 100% clinical success rate for both medicaments. Similar to our study, in their researches assessing the clinical success rate of amputations with FS; Fei et al [20] observed a 100% success rate at the end of 12 months, Markovic et al [21] observed 89% at the end of 18 months, and Huth et al [22] observed 100% at the end of 24 months.

Smith et al [23] observed a 74-80% success rate in their radiologic evaluation of FS amputation therapies at the end of a 19-month follow-up. Additionally, they reported that radiographic success rate decreased over time in FS pulpotomies.

Researchers remarked that after the pulpotomies performed with FS, eugenol might lead to a histamine increase in the pulpal blood flow, vasodilation, common inflammatory response and consequently lead to internal resorption due to the direct contact of eugenol with the pulp tissue because of the hydrolysis of the directly applied ZOE [24,25,26].

It has been reported that internal resorptions might be observed more frequently after the FS pulpotomies, since there was only a metal-protein membrane between the dental pulp and eugenol. [23] Various studies have revealed that following the amputation therapies, in cases where it was used as a base material, ZOE acted like a barrier reducing the survival chance of the bacteria that could infiltrate into the pulp [27,28].

We determined a 97% success rate of BD in the 12-month radiographic follow-ups of BD and FS medications used in our study while observing a 65% FS rate. A significant difference was found between the success rates of the agents in the statistical analysis.

Although we observed a lower success rate of FS agent in comparison to other studies, this was very close to those obtained by Smith et al. [23] According to Logistical regression analyses, BD was found to be 0.06 times more successful than FS in our study.

Post-pulpotomy external resorption is the process by which the bacterial toxins or lesions in the root pulp infiltrate into the periodontal ligament through the dentinal tubules, breakdown and absorb the cementum & alveolar bone tissues [29].

Casas et al [30] observed symptoms of external resorption up to 33% after the pulp amputation therapies performed with FS. We detected external resorption in 5 of the teeth pulpotomied with FS (8%) while seeing no external resorption in the BD pulpotomied group.

Neamatollahi et al [31] performed pulp amputation therapies for 135 primary molars of the children aged between 3-6 with FC, FS and MTA and assessed the clinical and radiographic results of the 12-month follow-up of these teeth. They mainly encountered with the calcific metamorphosis in radiographic assessments and the rates of incidence were determined as; 65 % in FC, 64.1% in FS, and 56.1% in MTA groups respectively.

Compared to their study, 60% calcific metamorphosis rate seen in BD group of our research is sharing similarity with their MTA group. On the contrary, in our study, 23% rate of calcific metamorphosis incidence observed in FS group is significantly lower than that of Neamatollahi et al [31]. Farsi et al [32] stated that the calcific metamorphosis was initiated with the stimulation of odontoblastic activity in the teeth which received pulp amputation therapy and in this case, the pulp has maintained its vitality. Peterson et al [33] enunciated that calcific metamorphosis was not a fail criteria and its treatment should be the following-up of the teeth until the exfoliation. Thus like several other researches, [34,35,36] our study did not judge the calcific metamorphosis as a fail criteria.

Owing to its higher clinical and radiologic success rates observed in 12-month follow-ups, we believe that BD may be used as a pulpotomy medicament for the primary teeth. However, long-term follow-ups are necessary to recommend it.

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