

Efficacy of orthoMTA, retroMTA and ferric sulphate as pulpotomy agents in primary molars: A randomized clinical trial

Purpose

The purpose of this study is to evaluate the clinical and radiographic success rates of RetroMTA, OrthoMTA, and ferric sulfate as pulpotomy agents in primary molars.

Materials and Methods

Ninety-six primary second molars from 32 children aged 5 to 9 years were enrolled in this study. The teeth were randomly divided into three groups based on the pulpotomy agent used: O-MTA, R-MTA, and FS. Clinical and radiographic follow-up examinations were conducted at 3, 6, 9, and 18 months postoperatively.

Results

At the end of the study period, 84 teeth were evaluated. The clinical success rates were 75% for FS, 96.4% for O-MTA, and 92.8% for R-MTA groups. In the radiographic analysis, the success rates at the 18-month follow-up period were 50% for FS, 85.8% for O-MTA, and 82.2% for R-MTA groups. According to the Chi-square test and Kaplan-Meier survival analysis, there was a statistically significant difference among the success rates and survival probabilities of the groups ($p < 0.05$).

Conclusion

OrthoMTA and RetroMTA demonstrated better treatment outcomes for pulpotomy of primary second molars than ferric sulfate at the 18-month follow-up period.

Keywords: Pulpotomy, primary teeth, ferric sulphate, mineral trioxide aggregate, zinc oxide eugenol cement

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Introduction

Pulpotomy is a treatment procedure used in pediatric dentistry for asymptomatic cariously exposed teeth with a healthy radicular pulp. The success of pulpotomy relies on completely removing the infected coronal part and covering the remaining healthy pulp tissue with a suitable agent (1). The choice of material plays a significant role in the success of pulpotomy, along with accurately diagnosing the infected dental pulp. An ideal material for pulpotomy should provide a hermetic seal, antibacterial efficacy, compatibility with physiological exfoliation, and support healing of the radicular pulp (2,3). Various materials have been used in pulpotomy procedures to promote the devitalization, preservation, or regeneration of the pulp tissue. Formocresol, previously a commonly preferred material, has been replaced by ferric sulfate (FS) and Mineral Trioxide Aggregate (MTA) due to its toxic and mutagenic effects (4,5).

Ferric sulphate (FS) has also been used as a pulpotomy agent because of its high survival rates. A ferric ion-protein complex occurs when the FS contact with the blood, and seals the cut vessels and prevent the consti-

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tution of blood clot (6). The success rate of ferric sulphate has been reported from 81% to 97% in the previous studies (4-7). Although, it has high clinical success rate, there are studies that it may create moderate to severe inflammatory responses lead to internal resorption (7).

Mineral trioxide aggregate (MTA) has been widely recommended for various endodontic procedures in humans. Numerous studies have reported its high clinical success rate, making it an ideal material for pulpotomy (8-10). MTA promotes dentin bridge formation and maintains normal pulp histology. Unlike ferric sulfate, calcium hydroxide, or formocresol, MTA does not result in internal resorption, which is commonly observed in teeth treated with those materials. While studies have demonstrated the high clinical and radiographic performance of MTA in endodontic treatment of primary teeth, ongoing research aims to improve its physical, mechanical, and biological properties (11). Consequently, different materials have been introduced for use in primary molar pulpotomies. OrthoMTA, designed specifically for orthograde root canal filling, exhibits excellent sealing ability in root canals and dentinal tubules, low expansion rate, and ease of application (12,13). RetroMTA, a newly developed MTA material free of heavy metals, offers a shorter setting time (11,14). However, limited clinical studies have compared the success rates of OrthoMTA and RetroMTA as pulpotomy agents for primary molars (11). Thus, there is a need for randomized controlled trials to assess the clinical and radiographic success rates, survival times, and time-related failures of these newly developed materials. The null hypothesis tested in this study was that there would be no differences in the clinical and radiographic success and survival rates among the RetroMTA, OrthoMTA and FS in primary molar pulpotomies.

Materials and Methods

Ethical approval

This randomized controlled clinical trial was reviewed and approved by the Ethics Committee of Aydin Adnan Menderes University Faculty of Dentistry (Approval reference:2018/047) and conducted in accordance with the guidelines of the Declaration of Helsinki between June 2017 and July 2018. The trial was designed in accordance with the 2010 Consolidated Standards of Reporting Clinical Trials statement and registered (Protocol Registration Receipt NCT03718676) at <http://www.clinicaltrials.gov>.

Sample size

The sample size was calculated considering 95% power and a significance level of .05 (effect size=0.40) according to the outcomes of the study by Goyal *et al.* (15). As a result, 96 teeth from 32 patients were included for three groups (n=32).

Participants and study design

The participants referred to the Aydin Adnan Menderes University Faculty of Dentistry between 5-9 years of age were assessed for eligibility. The details are presented in the Consolidated Standards of Reporting Trials Flow diagram

(Figure 1). The trial protocol was explained in details and participants/caregivers signed written informed consent. The inclusion criteria were as follows: Systemically healthy children between 5-9 years of age with three second primary molars indicated for pulpotomy. Carious or mechanical exposure of pulp in symptom free vital primary molars. presence of pulp degeneration and (Pulp canal obliteration, periodontal ligament widening, periapical and furcal radiolucency, and internal/external root resorption) physiologic resorption of less than one third of the root.

The exclusion criteria of the study were as follows: having any known systemic chronic diseases, allergy to local anesthetic agents, uncooperative children for routine dental treatment, presence of spontaneous pain and mobility, fistula formation, gingival redness and swelling, sensitivity to percussion test, not eligible for restoration with a preformed metal crown.

Clinical procedure and study outcomes

The same investigator performed the procedures at the Aydin Adnan Menderes University Faculty of Dentistry Department of Pediatric Dentistry. The three second molars of each patient were randomly assigned, using a table of random numbers, either the group as follows: FS (Group FS, n=32), O-MTA (Group O-MTA, n=32) and R-MTA (Group R-MTA, n=32).

After administration of local anesthesia (Ultracain DS, Aventis Pharma, Istanbul, Turkiye), teeth were isolated with the rubber dam. Coronal access was obtained with a high speed bur mounted in an airator with water spray following caries removal. The coronal pulp removal was performed by low speed instrument and continuous water spray. The cavity was then rinsed with steril serum and a wet cotton

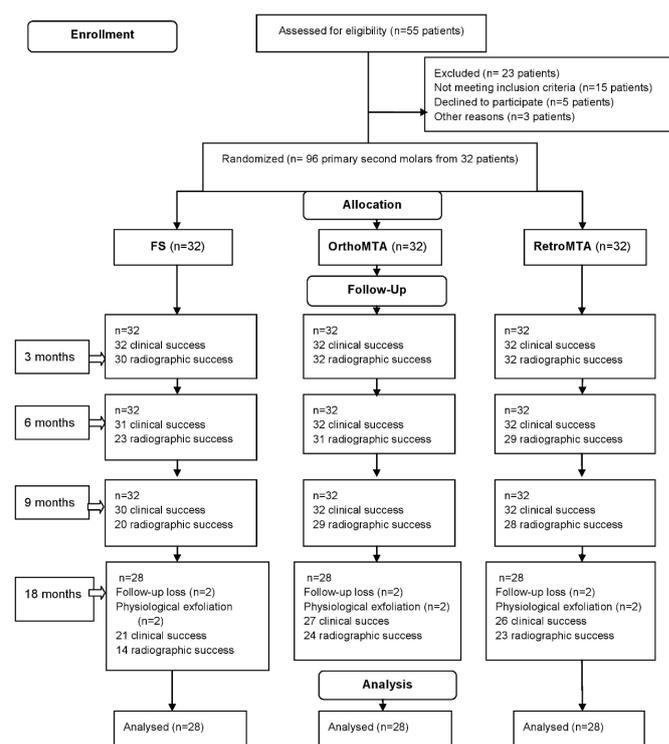


Figure 1. The CONSORT flow chart of the patients and second primary molars included in this study.

pellet was placed on pulp stumps for five minutes to achieve hemostasis. If bleeding didn't stop at this stage, the tooth was excluded from study. The teeth included the study were treated as described below depending on the type of pulpotomy agent.

Group Ferric Sulphate (FS)

A 15.5 % ferric sulphate moistened cotton pellet (ViscoStat, Ultradent, South Jordan, USA) was applied to the pulp stumps for 15 seconds. After irrigation, zinc oxide eugenol (Cavex Zocem, Cavex, Netherlands) base placed on radicular pulp stumps. The whole cavity was filled up with a glass ionomer cement (Ahfill, AHL, Tonbridge, UK). Final restoration was performed using preformed metal crowns (Kids crown, Shin Heung, Republic of Korea) at the same visit.

Group OrthoMTA (O-MTA) and RetroMTA (R-MTA)

OrthoMTA (OrthoMTA, BioMTA, Daejeon, Korea) and RetroMTA (RetroMTA, BioMTA, Daejeon, Korea) was prepared as recommended by their respective manufacturers' instructions and placed over the pulp stumps. The whole cavities were filled up with a glass ionomer cement. Preformed metal crowns were used for the restorations of pulpotomized teeth (Kids crown®, Shin Heung, Republic of Korea) at the same visit. The crowns were cemented with a glass ionomer based adhesive prepared according to the manufacturer's recommendations.

Follow-up

The teeth were examined clinically and radiographically at 3, 6, 9, and 18 months postoperatively. In case there was no spontaneous pain, pathologic mobility, swelling, fistula, and gingival inflammation such teeth were signed to case report form as clinical success. The postoperative radiographs were evaluated independently by two investigators. The presence of internal/external root resorption, periapical/furcal radiolucency and pulp canal obliteration was recorded as radiographic failure.

Statistical analysis

The data were evaluated using SPSS 20.0 (Statistical Package for the Social Sciences, Inc. Chicago, IL, USA) software. Inter-examiner agreement was calculated for the radiographic assessment using Cohen's Kappa test. Categorical data were

analysed by Chi-square test and a multiple comparison post-test, with statistical significance set at $p < 0.05$. Log-rank tests were conducted to compare the survival rate of the groups. Graphical representations of survival rates were produced for groups using the Kaplan-Meier method.

Results

A total of 96 teeth were pulpotted in 32 children (16 girls and 16 boys) in the study. The mean age of the patients was 6.3 ± 1.2 years. Flow chart of this study is presented in Figure 1. All teeth were evaluated without any drop-out at 3-, 6-, and 9-month follow-up periods; whereas, at the 18 month 12 molars could not be evaluated as a result of two patients drop-outs and physiologic exfoliation of molars in two patients. The kappa value was high (0.93) and showed strong inter-examiner agreement.

Clinical findings

After 6 months of follow up, one clinical failure had occurred in FS group presenting a fistula. Two molars from FS group showed fistula at the 9-month follow-up. Clinical failure was not observed in O-MTA and R-MTA group during 9-month follow-up period. There were no statistically significant differences between the clinical success rates of the groups in 3, 6, and 9- month follow-up period (Table 2).

After 18-month follow-up period 7, 1 and 2 molars showed clinical failure in FS, O-MTA and R-MTA groups respective-

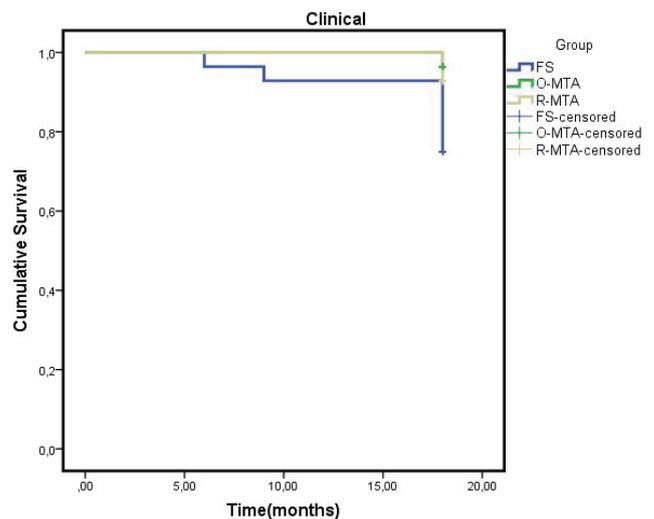


Figure 2. Clinical cumulative survival analysis of the groups.

Table 1. Clinical success and failure rates for ferric sulphate, OrthoMTA and retroMTA at 3-, 6-, 9-, and 18-month follow-up periods.

	3 months		6 months		9 months		18 months	
	(+) n (%)	(-) n (%)	(+) n (%)	(-) n (%)	(+) n (%)	(-) n (%)	(+) n (%)	(-) n (%)
FS	32(100) ^a	0(0)	31(96.9) ^a	1(3.1)	30(93.7) ^a	2(6.3)	21(75) ^a	7(25)
O-MTA	32(100) ^a	0(0)	32(100) ^a	0(0)	32(100) ^a	0(0)	27(96.4) ^b	1(0)
R-MTA	32(100) ^a	0(0)	32(100) ^a	0(0)	32(100) ^a	0(0)	26(92.8) ^b	2(7.2)
p value	-		0.36		0.13		0.03	

(+) = Success, (-) = Failure, * $p < 0.05$ = Statistically significant. Different superscript letters mean significant differences between groups at 3-, 6-, 9- and 18-month follow-up periods.

ly. Four teeth from FS group, one tooth from O-MTA group and one tooth from R-MTA group showed gingival inflammation. 3 teeth from FS group and one tooth from R-MTA group showed fistula formation. The clinical success rates of the groups were 75%, 96.4%, and 92.8% for FS, O-MTA and R-MTA groups, respectively. The differences between the clinical success rates of the groups were statistically significant at the end of 18-month follow-up time ($p < 0.05$) (Table 2). There were significant differences in 18-month clinical survival probabilities of the groups ($p < 0.05$) [Log-rank (Mantel-Cox): $\chi^2 = 7.30$; $df = 2$; $p = 0.02$] (Figure 2).

Radiographic findings

The radiographic success rates were 50%, 85.8 % and 82.2% for the FS, O-MTA and R-MTA groups respectively at the end of 18-month follow-up time. There were statistically significant differences between the radiographic success rates of the groups at 6, 9 and 18 month follow-up periods ($p < 0.05$) (Table 2). In FS group root resorptions were observed in two teeth at 3-month follow-up time. At 6-month follow-up time two additional teeth had root resorptions, five teeth had periapical or furcal radiolucency and four teeth had root resorptions. At 9-month follow-up two additional teeth had root resorptions, one additional tooth had periapical or furcal radiolucency. At 18-month follow-up one additional tooth had periapical or furcal radiolucency (Table 3). In O-MTA group there was pulp canal obliteration in one tooth at 6-month follow-up. At 9-month follow-up one additional tooth had pulp canal obliteration and, one tooth had periapical or furcal radiolucency. At 18-month follow-up one additional tooth had periapical or furcal radiolucency (Table 3). In R-MTA group, one tooth had root resorption, one tooth had furcation radiolucency and one tooth had widen-

ing of periodontal ligament at 6-month follow-up period. At 9-month follow-up one tooth had pulp canal obliteration. At 18-month follow-up one additional tooth had pulp canal obliteration (Table 3). There were significant differences in 18-months radiographic survival probabilities of the groups ($p < 0.05$) [Log-rank (Mantel-Cox): $\chi^2 = 20.3$; $df = 2$; $p = 0.001$] (Figure 3).

Discussion

This randomized controlled clinical trial aimed to evaluate the clinical and radiographic success rates of two different mineral trioxide aggregate (MTA) materials, OrthoMTA and RetroMTA, as well as ferric sulfate (FS) in primary second

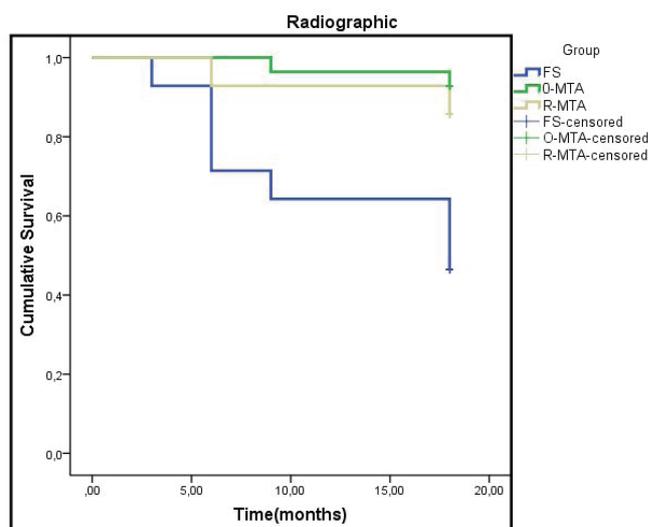


Figure 3. Radiographic cumulative survival analysis of the groups.

Table 2. Radiographic success and failure rates for ferric sulphate, OrthoMTA and RetroMTA pulpotomies at 3-, 6-, 9-, and 18-month follow-up periods.

	3 months		6 months		9 months		18 months	
	(+) n(%)	(-) n(%)	(+) n(%)	(-) n(%)	(+) n(%)	(-) n(%)	(+) n(%)	(-) n(%)
FS	30(93.7) ^a	2(6.3)	23(71.9) ^a	9(18.1) ^a	20(62.5) ^a	12(37.5)	14(50) ^a	14(50)
O-MTA	32(100) ^a	0(0)	31(96.9) ^b	1(3.1) ^b	29(90.6) ^b	3(9.4)	24(85.8) ^b	4(14.2)
R-MTA	32(100) ^a	0(0)	29(90.6) ^b	3(9.4) ^b	28(87.5) ^b	4(12.5)	23(82.2) ^b	5(17.8)
p value	0,13		0,02*		0,00*		0.002*	

(+) = Success, (-) = Failure; * $p < 0.05$ = Statistically significant. Different superscript letters mean significant differences between groups at 3-, 6-, 9- and 18-months follow-up periods.

Table 3. Distribution of the radiographic changes of the groups at 3, 6, 9 and 18 month follow-up periods.

Groups	FS					O-MTA					R-MTA				
	3	6	9	18	Total	3	6	9	18	Total	3	6	9	18	Total
PR or FR	0	5	1	1	7	0	0	1	1	2	0	1	0	0	1
RR	2	2	2	0	6	0	0	0	0	0	0	1	0	0	1
WPL	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1
PCO	0	0	0	1	1	0	1	1	0	2	0	0	1	1	2

Abbreviations: PR or FR, periapical radiolucency or furcal radiolucency; RR, root resorption; WPL, widening of periodontal ligament; PCO, pulp canal obliteration.

molars over an 18-month follow-up period. The study findings demonstrated that OrthoMTA and RetroMTA exhibited significantly higher clinical and radiographic success rates compared to FS. FS is commonly used as a hemostatic agent in pulpotomy treatment for primary molars to prevent clot formation, which is known to contribute to treatment failure (16,17). Previous studies have reported that the most common radiographic failure associated with FS is internal root resorption (18,19). The presence of internal resorption is believed to be caused by the irritant effect of zinc oxide eugenol, a base material used with FS, which can trigger chronic inflammation (20,21). Insufficient hemorrhage control, pulpal inflammation, bacterial infiltration, and failed restorations have also been identified as contributing factors to internal resorption (21).

Numerous studies have evaluated the clinical and radiographic success rates of MTA and FS. For example, Peng *et al.* (22) reported clinical success rates for FS ranging from 78% to 100% and radiographic success rates ranging from 42% to 97%. Cordell *et al.* (23) demonstrated an 86.6% clinical success rate for FS, while MTA achieved 100% clinical success. Junqueira *et al.* (24) observed 100% clinical success rates for both MTA and FS pulpotomies at the end of an 18-month follow-up period. In a study by Goyal *et al.* (15), clinical failures in the FS group at the six-month mark included fistula formation in 9.1% of cases and tooth mobility in 27.3% of cases. Similarly, fistula formation was observed in the FS group at the six- and nine-month follow-ups in the present study, with additional cases noted at the nine- and 18-month marks. During the nine-month follow-up period, both the OrthoMTA and RetroMTA groups showed no clinical failures, consistent with existing literature (25-27). However, at the 18-month follow-up, one case of gingival inflammation was observed in each MTA group, while two cases of fistula formation were noted in the RetroMTA group. The clinical success rates at the 18-month follow-up period were 75% for FS, 96.4% for OrthoMTA, and 92.8% for RetroMTA. The similar clinical success rates between the two MTA materials in this study may be attributed to their comparable antibacterial activity against endodontic bacteria (28). The lower success rate observed in the FS group in this study could be related to misdiagnosis of the pulp status, presence of radicular pulp infection, or irritation caused by the zinc oxide eugenol cement used as a base material in the FS group (29).

Studies have reported radiographic success rates of MTA ranging from 94% to 100% over follow-up periods ranging from 12 to 74 months (30). Olatosi *et al.* (26) found a radiographic success rate of 96% for MTA at the 12-month follow-up. Godhi *et al.* (31) followed MTA pulpotomies for 36 months and reported a 100% radiographic success rate. Kang *et al.* (11) evaluated the radiographic success of pulpotomies using ProRoot MTA, OrthoMTA, and RetroMTA in 143 children and reported success rates of 100%, 94.7%, and 94.7% respectively at the 12-month follow-up. Kim *et al.* (32) reported similar success rates for RetroMTA, OrthoMTA, and ProRoot MTA over an 84-month period. Lin and Lin (33) found that the radiographic success rate of FS was lower than that of MTA and NaOCl at the 24-month follow-up. Cordell *et al.* (23) stated that FS had a radiographic success rate of 60%, while MTA showed a 100% radiographic success rate at the 12-month follow-up.

In the present study, when evaluating the radiographic success of pulpotomy materials at the end of 18 months, the success rates were 50% for FS, 92.9% for O-MTA, and 89.3% for R-MTA groups. The lower success rates observed in this study, compared to previous studies, may be mainly due to the assessment criteria used in this study, where pulp canal obliteration was considered a failure. Pulp canal obliteration is a commonly observed radiographic finding in MTA pulpotomies. There are different opinions in the literature regarding the evaluation of pulpal canal obliteration (calcific metamorphosis). Some studies have reported that pulp canal obliteration occurs as a result of odontoblastic activity and is considered a sign of pulp vitality, therefore not indicative of failure (34,35). Waterhouse *et al.* (36) histologically evaluated pulpotomized and extracted primary molars due to clinical failure and found intracanal calcifications in the extracted teeth. Hence, in the present study, pulp canal obliteration was considered a failure. Farsi *et al.* (35) reported an obliteration rate of 5.4% in MTA pulpotomies at the 24-month follow-up. Kusum *et al.* (27) reported pulp canal calcification in 20% of cases after nine months of follow-up. In our study, pulp canal obliteration was observed in one tooth in the FS group, two in the O-MTA group, and two in the R-MTA group at the 18-month follow-up.

Studies have shown that internal root resorption occurs as a result of chronic pulpitis and is commonly found in teeth with necrotic pulp (37). However, there is no consensus in the literature regarding the inclusion of internal resorption as a failure criterion in the radiographic evaluation of pulpotomy therapy. For example, Holan *et al.* (38) did not consider internal resorption as a failure criterion, while other studies have included it (20, 39, 40). In line with the literature, this study considered internal resorption as a radiographic failure criterion. The frequency of internal resorption was higher in the FS group compared to the MTA groups. Despite the absence of clinical symptoms in teeth with internal resorption, they were monitored throughout the study. Additionally, periapical radiolucency or furcation radiolucency was more common in the FS group. It is important to note that this study had limitations, including a small sample size and a short follow-up period.

Conclusion

Within the limitations of this prospective trial, it can be stated that orthoMTA and retroMTA materials used in this study are more likely to demonstrate superior outcomes in terms of clinical and radiographic evaluations compared to FS at the 18-month follow-up period.

Türkçe özet: Süt azı dişlerinde pulpotomi ajanı olarak OrthoMTA, RetroMTA ve Ferric sülfatın etkinliği: Randomize klinik çalışma. Amaç: Bu çalışmanın amacı, süt azı dişi pulpotomilerinde OrthoMTA, RetroMTA, ve Ferric sülfatın klinik ve radyografik başarı oranlarının değerlendirilmesidir. Gereç ve Yöntem: Çalışma için 5-9 yaş arası 32 çocuğun 96 adet süt ikinci azı dişi seçildi. Dişler pulpotomi materyaline göre rastgele üç eşit gruba ayrıldı: O-MTA, R-MTA ve FS. Klinik ve radyografik takip muayeneleri operasyon sonrası 3, 6, 9 ve 18. aylarda yapıldı. Bulgular: Çalışma süresinin sonunda toplam 84 diş değerlendirildi. Bu çalışmada klinik başarı oranı FS, O-MTA ve R-MTA grupları için sırasıyla %75, %96,4 ve %92,8 olarak belirlenmiştir. Takip süresinin sonunda, FS, O-MTA, R-MTA grupları sırasıyla %50, %85,8 ve %82,2 radyografik başarı göster-

miştir. Ki-kare testi ve Kaplan-Meier sağkalım analizine göre grupların başarı oranları ve sağkalım olasılıkları arasında istatistiksel olarak anlamlı fark bulunmuştur ($p < 0.05$). Sonuç: OrthoMTA ve RetroMTA onsekiz aylık takip süresinin sonunda, süt azı dişlerinin pulpotomilerinde klinik ve radyografik olarak ferrik sülfattan daha başarılı bulunmuştur. Anahtar Kelimeler: Pulpotomi, süt dişi, ferrik sülfat, mineral trioksit agregat, çinko oksit öjenol siman

Ethics Committee Approval: This randomized controlled clinical trial was reviewed and approved by the Ethics Committee of Aydın Adnan Menderes University Faculty of Dentistry (Approval reference:2018/047).

Informed Consent: Parents provided written informed consent.

Peer-review: Externally peer-reviewed.

Author contributions: SY, SK participated in designing the study. SY, SK participated in generating the data for the study. SY, SK participated in gathering the data for the study. SY, SK participated in the analysis of the data. SY, SK wrote the majority of the original draft of the paper. SY, SK participated in writing the paper. SY, SK have had access to all of the raw data of the study. SY, SK have reviewed the pertinent raw data on which the results and conclusions of this study are based. SY, SK have approved the final version of this paper. SY, SK guarantee that all individuals who meet the Journal's authorship criteria are included as authors of this paper.

Conflict of Interest: The authors declared that they have no conflict of interest.

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