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Official Publication of Istanbul University Faculty of Dentistry

Eur Oral Res 2025; 59(1): 53-57

Original research

Comparison of calcium silicate-based materials in pulpotomies of primary molars: a randomized clinical trial

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Purpose
The primary objective of this investigation is to evaluate the clinical and radiographic findings of mineral trioxide aggregate (MTA) and Biodentine (BD) as pulpotomy agents in primary molars.

Materials and Methods
Two hundred primary molars (N=200) were treated with pulpotomy. Clinical and radiographic outcomes, including both successes and failures, were documented throughout a 36-month follow-up period. Statistical analyses were performed using the Fisher Exact, McNemar, and Chi-Square tests.

Results
No statistically significant differences in success rates were found between the 1-, 3-, 6-, 24-, and 36-month assessments for each material when evaluated independently. However, at the twelfth month, the clinical and radiographic success rates for MTA (98% and 92%, respectively) were significantly higher than those for BD (90% and 80%, respectively) with a p-value of less than 0.05.

Conclusion
In this study, MTA demonstrated greater success than BD at 36 months. Nevertheless, higher quality randomized controlled trials with longer follow-up periods are necessary to obtain more reliable results.

Keywords: *Tricalcium silicate, mineral trioxide aggregate, pulpotomy, primary teethv*

Introduction

Pulpotomy stands as the preferred method of treatment for asymptomatic primary molars where caries has approximated the pulp (1). Pulpotomy involves the surgical removal of the coronal pulp followed by the application of a pulp-dressing agent to preserve the vitality of the remaining radicular pulp tissue (2). Pulpotomy can be classified based on the following treatment objectives: preservation, devitalization, and regeneration (3). An ideal pulpotomy medicament should effectively eliminate bacteria while being compatible with the biological environment to promote healing and minimize any negative effects on the patient's oral health. Additionally, it should facilitate root pulp healing while aligning with the natural physiological process of root resorption (4).

Formocresol (FC) is suggested as the ideal dressing agent in pulpotomy procedures by the American Academy of Pediatric Dentistry, despite concerns regarding its potential mutagenic and toxic effects (2,3). FC continues to be widely recognized and upheld as the gold standard against which all new materials, including calcium hydroxide, ferric sulfate, and glutaraldehyde, are compared (2).

The search for newer pulpotomy materials is ongoing. The objective of preserving pulp tissue has been replaced by the pursuit of regeneration

Presented at: *This article has been presented in FDI World Dental Congress, Madrid, Spain, in August 2017.*

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Received: 14 October 2022
Revised: 28 March 2023
Accepted: 19 December 2023

DOI: 10.26650/eor.20241189015

How to cite: *Koruyucu M, İlisulu SC, Yardımcı S, Seymen F. Comparison of calcium silicate-based materials in pulpotomies of primary molars: a randomized clinical trial. Eur Oral Res 2025; 59(1): 54-58.* DOI: 10.26650/eor.20241189015

due to improvements in biocompatibility and bioinductivity of the materials. MTA and BD have been developed for these purposes (3). MTA has the ability to seal and stimulate hard tissue formation. Its biocompatibility enables its widespread use in pediatric dentistry. BD also has high biocompatibility combined with bioactivity, thanks to calcium silicate's improved properties, including rapid setting time and high strength (2).

The primary objective of this investigation is to evaluate, both clinically and radiographically, the success of two pulpotomy medicaments: Pro-Root White MTA and BD in primary molars. The null hypothesis is that there are no significant differences between MTA and BD in radiographic and clinical outcomes.

Material and Methods

Ethical statement

This randomized clinical trial was conducted from 2013 to 2016, with the study protocol receiving approval from the Ethics Committee of Istanbul University, Medical Faculty (file number: 2012/1742-1302). The research strictly adhered to the Declaration of Helsinki. The study was registered at ClinicalTrials.gov (NCT03395496), and meticulous adherence to the 2010 Consolidated Standards of Reporting Trials Statement was observed in the study design. Additionally, the study design followed the guidelines outlined in the CONSORT 2010 Statement for reporting parallel group randomized trials (5).

Study design

The patients who participated in this study were attending the Pediatric Dentistry clinic. The possible discomforts, risks, and benefits of the procedures were explained to the participants and their families. Before participating in the study, the parents gave their informed consent. Eligible participants were between 6 and 12 years of age (mean age 10 ±1.62). All patients were healthy and had one or two primary molars in need of pulpotomy treatment. Clinical and radiographic examinations were systematically performed to ensure compliance with the specified inclusion criteria.

Inclusion criterion

The inclusion criteria for teeth selection included the following parameters: teeth had to demonstrate extensive caries, teeth must radiographically demonstrate the existence of 2/3 of the root length, and there must be adequate tooth structure to be restored. Additionally, there should be no radiographic or clinical evidence of pulp pathology (such as spontaneous pain, tenderness to percussion or palpation, swelling, sinus tract, pathologic mobility, etc.). This study excluded teeth without permanent successors.

Sample size estimation

The sample size was calculated to have 80% power at a 5% level of statistical significance with a 10% level of difference between the groups, necessitating 71 teeth in each group. A total of 213 primary molars (108 molars in Group I and 105 molars in Group II) were included from 106 children. Thirteen teeth were excluded from the study due to uncontrolled pulp bleeding (Figure 1).

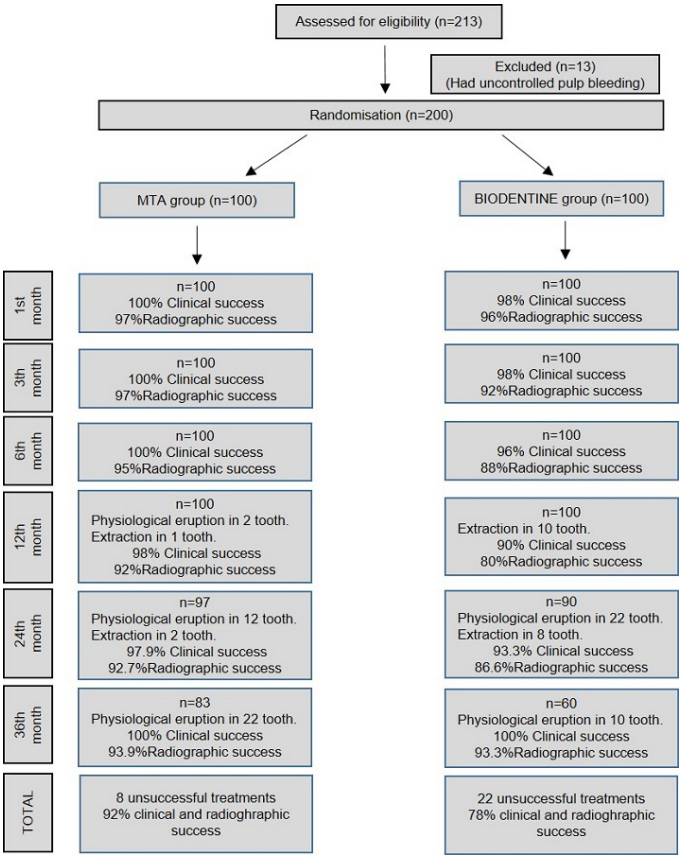

Figure 1. *Flow chart of the clinical and radiographic success of the materials.*

Pulpotomy protocols

Pulpotomy procedures were conducted following the application of local anesthesia and rubber dam isolation to ensure patient comfort and procedural precision. Caries removal and coronal access were performed using a high-speed bur with water spray to expose the pulp chamber. Patients were excluded from the study if hemostasis was not achieved within 3 minutes after placing a sterile cotton pellet gently against the amputated pulp, indicating a potential infection of the pulp tissue within the canal.

Two different pulpotomy medicaments were applied according to the manufacturer's instructions for 200 primary molars. Group I: Pro-Root MTA (Dentsply Tulsa Dental Specialties, Johnson City, U.S.) was formulated by combining three parts of powder with one part of water to achieve a putty-like texture. The prepared mixture was then inserted into the pulp chamber and gently condensed using a dampened cotton pellet. Following this, a glass ionomer base material was applied over the MTA. Group II: BD (Septodont, Saint Maur des Fosses, France) powder in the capsule was mixed with five drops of liquid in a triturator (4200 rpm) for 30 seconds. The resulting mixture was placed in the pulp chamber and left to set entirely, which took roughly 12 minutes. Permanent restoration was carried out during the same session.

After the pulpotomies, all molars were restored using amalgam materials. Clinical and radiographic assessments

were conducted during follow-up visits at 1, 3, 6, 12, and 36 months. In cases where a patient missed or cancelled a session, a new follow-up examination was rescheduled. Experienced pediatric dentists, unaware of the patients' assigned treatment groups, conducted the clinical examinations.

Treatment follow-up

A pulpotomized tooth was deemed clinically successful if there were no signs of swelling, pain, fistula, gingival inflammation, or pathologic mobility. A paralleling technique with a film holder (Rinn XCP; Dentsply, Elgin, U.S.) was used to capture the preoperative and control periapical radiographs. An automatic processor (Velopex® Intra-X Medivance Instruments, London, U.K.) was used to process the radiographs, which were then inspected and evaluated under optimal illumination. Radiographic examinations were performed by two experienced pediatric dentists. Each control was evaluated independently. Physiological eruption was considered a success. For intra-examiner reproducibility of radiographic assessment, 10% of the radiographs were re-evaluated after 2 weeks. The intra-examiner kappa value was determined to be 0.90.

Statistical analysis

Statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS, IBM Corporation, Version 21.0; Armonk, NY, USA) software. Group differences were assessed using Fisher's Exact Test, Student t-test, Shapiro-Wilk Test, McNemar Test, and Chi-square statistical tests. The significance level was set at $p<0.05$.

Results

As there were statistical differences between the two materials, null hypothesis was rejected. A total of 200 pulpotomized primary molars were evaluated in this study. Figure 1 shows a flow chart of the included pulpotomized teeth. The mean ages (± SD) were 9.82 ± 1.43 years for the MTA group and 10.18 ± 1.77 years for the Biodentine (BD) group, with no statistically significant difference between them (p=0.116).

Clinical findings for the two materials were significantly different at the 12-month follow-up (p=0.037). In the Biodentine group, statistically significant differences were observed between the 1st and 12th months (p=0.008), 3rd and 12th months (p=0.008), 3rd and 24th months (p=0.031), 6th and 12th months (p=0.031), and 24th and 36th months (p=0.031). No significant differences were noted between these timepoints in the MTA group (Table 1).

A significant difference in radiographic findings was also noted between the materials at the 12-month follow-up (p=0.025). In the Biodentine group, significant differences were found between the 1st and 6th months (p=0.08), 1st and 12th months (p=0.01), 1st and 24th months (p=0.02), 3rd and 12th months (p=0.01), 3rd and 24th months (p=0.02), 6th and 12th months (p=0.08), and 6th and 24th months (p=0.08). There was no statistically significant difference between these timepoints in the MTA group (Table 2).

Clinical evaluation at 6 months showed success rates of 100% for the MTA group and 98-96% for the Bioden-

Table 1. *Statistical analysis of the clinical success of the materials.*

Duration	Group I (MTA)	Group II (BD)	[1]p
	n (%)	n (%)	
1st month	100 (100%)	98 (98%)	[1]*0.497*
3th month	100 (100%)	98 (98%)	[1]*0.497*
6th month	100 (100%)	96 (96%)	[1]*0.121*
12th month	98 (98%)	90 (90%)	[2]*0.037**
24th month	95 (97.9%)	84 (93.3%)	[1]*0.157*
36th month	83 (100%)	60 (100%)	-
1-3 months [3]p	*1.000*	*1.000*	
1-6 months [3]p	*1.000*	*0.500*	
1-12 months [3]p	*0.500*	*0.008**	
1-24 months [3]p	*0.500*	*0.289*	
1-36 months [3]p	*1.000*	*1.000*	
3-6 months [3]p	*1.000*	*0.500*	
3-12 months [3]p	*0.500*	*0.008**	
3-24 months [3]p	*0.500*	*0.031**	
3-36 months [3]p	*1.000*	*1.000*	
6-12 months [3]p	*0.500*	*0.031**	
6-24 months [3]p	*0.500*	*0.289*	
6-36 months [3]p	*1.000*	*1.000*	
12-24 months [3]p	*1.000*	*1.000*	
12-36 months [3]p	*0.500*	*1.000*	
24-36 months [3]p	*0.500*	*0.031**	

*[1]Fisher Exact's test, [2]Continuity (Yates), [3]McNemar test, *p<0.05*

Table 2. *Statistical analysis of the radiographic success of the materials.*

Duration	Group I (MTA)	Group II (BD)	[1]p
	n (%)	n (%)	
1st month	97 (97%)	96 (96%)	[1]*1.000*
3th month	97 (97%)	92 (92%)	[2]*0.215*
6th month	95 (95%)	88 (88%)	[2]*0.128*
12th month	92 (92%)	80 (80%)	[2]*0.025**
24th month	90 (92.8%)	78 (86.7%)	[2]*0.254*
36th month	78 (94%)	56 (93.3%)	[1]*1.000*
1-3 months [3]p	*1.000*	*0.125*	
1-6 months [3]p	*0.500*	*0.008**	
1-12 months [3]p	*0.063*	*0.001**	
1-24 months [3]p	*0.063*	*0.002**	
1-36 months [3]p	*0.250*	*0.125*	
3-6 months [3]p	*0.500*	*0.125*	
3-12 months [3]p	*0.063*	*0.001**	
3-24 months [3]p	*0.063*	*0.002**	
3-36 months [3]p	*0.250*	*0.125*	
6-12 months [3]p	*0.250*	*0.008**	
6-24 months [3]p	*0.250*	*0.008**	
6-36 months [3]p	*1.000*	*0.500*	
12-24 months [3]p	*1.000*	*0.500*	
12-36 months [3]p	*1.000*	*1.000*	
24-36 months [3]p	*1.000*	*1.000*	

*[1]Fisher Exact's test, [2]Continuity (Yates), [3]McNemar test, *p<0.05*

tine group (Table 1). Radiographic evaluation at 6 months showed success rates of 97-95% for the MTA group and 96-88% for the Biodentine group (Table 2). After the eruption and extraction of the teeth, the success rates started to decrease. When the total success rates of the groups were compared after 36 months, a statistically significant difference was found (p=0.010) (Table 3).

Table 3. *Statistical analysis of the total success of the materials.*

Total Success	Group I (MTA)	Group II (BD)	[1]p
	n (%)	n (%)	
Successul	92 (92%)	78 (78%)	*0.010**
Unsuccessful	8 (8%)	22 (22%)	

*Continuity (Yates), *p<0.05*

Discussion

This preliminary randomized clinical trial assessed the clinical and radiographic performance rates of pulpotomies using either MTA or BD in primary molars. Both groups demonstrated clinical and radiographic success, with a significant difference in success rates found at the 36-month follow-up.

Clinical research has centered on comparing various pulpotomy agents. Many studies examining pulpotomy materials have employed FC and Ferric sulfate (FS) as control medicaments, consistently concluding that these materials yield comparable results (1-3, 6-10).

After a Cochrane review, it was concluded that no pulpotomy medicament or technique produces better results than another. Studies comparing FC and MTA in pulpotomy treatment in primary teeth showed that MTA is a better pulpotomy agent than FC (11). Fuks (2008) reviewed multiple randomized clinical trials comparing MTA and FC and recommended MTA as an alternative to FC because it showed better results in all cases (12). A recent meta-analysis examining the clinical effects of MTA and FC in primary molar pulpotomies included thirty clinical trials across seven databases. It concluded that MTA is a more promising agent, with a success rate of 95% compared to FC's success rate of 87% (2,13).

Following these findings, MTA was chosen as the control material. In previous studies, the success rates of MTA as a pulpotomy material have varied between 66-100% (1,3,4,7-10,12-23). Similar radiographic and clinical success rates of MTA pulpotomy were observed in our study (92-100%).

El-Meligy *et al.* (2016) compared the clinical and radiographic success rates of BD and FC as pulpotomy agents in primary teeth. The success rate for BD was reported as 100%, while that of FC was 94% at the 6-month follow-up (6). Carıkçıoglu *et al.* (2017) defined the clinical and radiographic success rates of BD and FS. The success rates were 97.1% for BD and 64.6% for FS-ZOE between 6 to 12 months (24).

Juneja and Kulkarni (2017) compared FC, MTA, and BD in their randomized controlled clinical trial. After follow-ups at 12 and 18 months, they noticed significant differences in clinical outcomes between FC, MTA, and BD. Radiographic outcomes were also significantly different between FC and MTA at 6, 12, and 18 months. They showed that MTA has a superior success rate (100%) to BD (86.7%) and that BD has a superior success rate to FC (73.3%) at the 18-month follow-up (3). Güven *et al.* (2017) conducted a clinical and radiographic comparison of calcium silicate-based materials (Pro-Root MTA, MTA-P, BD) and FS in primary molar pulpotomies. After 24 months, the total success rates for the PR-MTA, MTA-P, BD, and FS groups were reported as 93.1%, 86.2%, 82.75%, and 75.86%, respectively (4).

In another study, Kusum *et al.* (2015) evaluated MTA, BD, and propolis in primary dentition pulpotomies. MTA and BD were found to be more successful than propolis, both clinically and radiographically, at the 9-month follow-up (20). Niranjani *et al.* (2015) compared the success of pulpotomy outcomes using MTA, lasers, and BD. The results showed that MTA offers the best outcome as a pulpotomy agent, though the comparison of MTA, BD, and Laser was not statistically significant at the 6-month follow-up (21).

Cuadros-Fernandez *et al.* (2016) also evaluated the MTA and BD materials. The clinical success rate for MTA was 95.3%, and 97.5% for BD at 6 months. The clinical success rates at 12 months were 97.4% for MTA and 100% for BD. The radiographic success rate was 100% in both groups at 6 months and 97.4% in the MTA group and 94.9% in the BD group at 12 months (2). Bani et al. (2017) compared BD and MTA. The clinical success rate was 100% in both the MTA and BD groups at 6 months, 96.9% in both groups at 12 months, 96.9% in both groups at 18 months, and 96.8% in both groups at 24 months. The radiographic success rate was 100% in both groups at 6 months, 96.9% in both groups at 12 months, 90.6% in MTA and 93.8% in BD at 18 months, and 87.1% in MTA and 93.6% in BD at 24 months (19).

Comparing these two studies with our research, Bani *et al.*'s (2017) clinical findings are similar to ours in that MTA was clinically more successful than BD at the 6-, 12-, and 24-month follow-ups. Interestingly, their radiographic success rate was higher for BD at 24 months. In contrast, Cuadros-Fernandez *et al.* (2016) showed better clinical outcomes with BD at the 6- and 12-month follow-ups; however, at the 12-month follow-up, MTA was more successful radiographically. Clinically and radiographically, MTA was found to be more successful than BD in all months (2). Many studies have shown that radiographic success rates are lower than clinical success rates, aligning with the findings of the current study (2,3,19,20,24,25). Thus, it is important and necessary to perform radiographic follow-ups after pulpotomies.

This study constitutes a long-term clinical investigation with a substantial sample size and an extended follow-up period. It is essential to interpret the study findings in the context of certain limitations inherent in the study design. A significant constraint is the utilization of amalgam for coronal restoration. Financial constraints precluded the availability of stainless steel crowns, compelling the authors to employ amalgam restorations in all pulpotomies. To mitigate potential inconsistencies arising from disparate restorations, teeth exhibiting extensive structural loss that requires extensive restorations were deliberately excluded from the study.

Conclusion

Within the limitations of this clinical study, it can be concluded that MTA exhibits a higher overall success rate compared to BD at the 36-month follow-up for pulpotomies in

primary molars. However, to substantiate these findings, further high-quality randomized controlled trials with extended follow-up periods are necessary.

Türkçe özet: *Süt azı dişi pulpotomilerinde kalsiyum silikat esaslı malzemelerin karşılaştırılması: randomize bir klinik çalışma. Amaç: Bu çalışmanın amacı, süt azı dişleri için pulpotomi ajanları olarak mineral trioksit agregat (MTA) ve Biodentine (BD) materyallerini klinik ve radyografik olarak karşılaştırmaktır. Hastalar ve Yöntem: Toplam 200 süt azı dişine pulpotomi tedavisi uygulandı. 36 aylık takiplerde klinik ve radyografik başarı ve başarısızlıklar kaydedildi. Gruplar arasındaki farklar Fisher Exact, McNemar ve Chi-Square testleri kullanılarak istatistiksel olarak analiz edildi. Bulgular: Materyaller kendi içinde değerlendirildiği birinci, üçüncü, altıncı, yirmi dördüncü ve otuz altıncı aylar arasında başarı oranlarında istatistiksel olarak anlamlı bir fark yoktu. On ikinci ayda MTA materyalinin klinik ve radyografik başarı oranları (sırasıyla %98 ve %92), BD materyalinden (sırasıyla %90 ve %80) istatistiksel olarak anlamlı bulundu (p<0.05).Sonuç: 36 ayın sonunda MTA materyali BD'den daha başarılı bulundu. Bununla birlikte, güvenilir sonuçlar için daha uzun takip süreli yüksek kaliteli randomize kontrollü çalışmalara ihtiyaç duyulmaktadır. Anahtar Kelimeler: trikalsiyum silikat; mineral trioxide aggregat; pulpotomi; süt dişleri*

Ethics Committee Approval: The study protocol has been approved by Research Ethics Committee of Istanbul University, Medical Faculty (project number: 2012/1742-1302)

Informed Consent: Participants' parents or legal guardians provided informed consents.

Peer-review: Externally peer-reviewed.

Author contributions: MK contributed to the design of the study, while MK, SCI, and SY were involved in data generation. Additionally, MK and FS participated in data collection and analysis. MK and SCI primarily authored the initial draft of the paper, with MK contributing to the writing process. MK had access to all raw data, and MK, FS reviewed the relevant raw data supporting the study's results and conclusions. MK, SCI, SY, and FS collectively approved the final version of the paper, ensuring adherence to the journal's authorship criteria.

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

Financial Disclosure: The authors declared that they have received no financial support.

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