Objectives: Pulpotomy is the common therapy for cariously exposed pulps in symptom-free primary molar teeth. For many years, researchers have searched for an ideal material that allows regeneration of the residual pulp. The purpose of this study was to evaluate the efficacy of mineral trioxide aggregate (MTA), Biodentine as a pulpotomy medicament in primary teeth, both clinically and radiographically.

Materials and Methods: A total of 25 children (50 human primary molar teeth) aged between 5 and 9 years were selected in this randomized clinical study. The patients were randomly assigned to receive the pulpotomy medicaments in either Group 1: MTA or Group 2: Biodentine. All pulpotomized teeth were restored with stainless steel crowns and evaluated clinically and radiologically at 1, 3, 6 and 12 months. Statistical analysis using Mann–Whitney U test and Fisher's exact test, and chi-square test was performed to determine the significant differences between the groups.

Results: Clinical and radiological success rates were 96 and 80% in Group 1 and 96 and 60% in Group 2, respectively. There were no significant differences between the groups (P > 0.05). The radiographic success rates decreased in the controls, but there were no significant differences.

Conclusion: Biodentine showed similar clinical and radiographic results as MTA in the 12-month evaluation and can be safely used as a pulpotomy medicament.

Keywords: Biodentine, mineral trioxide aggregate, pulpotomy.
clinical studies in humans, MTA should be considered the new gold standard for pulp-capping treatment.\cite{7,10,11} However, the material has some shortcomings, such as difficulties in manipulation, long setting time, high cost, and tooth discoloration.\cite{9,12} Biodentine, which is a new calcium silicate-based material with active biosilicate technology, was developed to overcome the shortcomings of MTA. Biodentine can be used in crowns and roots where MTA is used because of its dentine-like mechanical properties.\cite{12-15} It has favorable effects on vital pulp cells and stimulates tertiary dentine formation.\cite{12-17} Biodentine is composed of powder and liquid. The powder part includes tricalcium silicate, dicalcium silicate (3 CaO SiO$_2$ and 2 CaO SiO$_2$), and calcium carbonate (CaCO$_3$). Zirconium dioxide (ZrO$_2$) is present as a contrast substance and calcium chloride present as liquid (CaCl$_2$·2H$_2$O) to obtain rapid setting time and high strength.\cite{13,14}

Both MTA and Biodentine can be used as pulpotomy medicaments and a few studies have investigated the clinical and radiological effects of MTA and Biodentine. Therefore, the aim of this study was to evaluate and compare the clinical and radiological success of MTA and Biodentine pulpotomies in human primary teeth in a 12-month follow-up.

**Materials and Methods**

Ethical approval for this study was obtained from the Cumhuriyet University Clinical Research Ethics Committee (2014–04/46) and the study was conducted at the Faculty of Dentistry, Department of Pediatric Dentistry, Cumhuriyet University. The clinical procedure, associated risks, and benefits were fully explained to the parents of the participants and written consent to participate was obtained before the procedure.

**Sample size calculation**

Sample size was performed under the assumption of studies that have resemble to our study.\cite{2,18,19} Accepting $\alpha = 0.05$, $\beta = 0.20$, $(1-\beta) = 0.80$ a total of 50 subjects are necessary (25 in MTA group and 25 in Biodentine group). The power of test was found 0.8063. The study was performed on 50 first and second primary carious molar teeth of 25 patients (12 female, 13 male) aged between 5 and 9 years (in the mind of starting root resorption age according to Logan and Kronfeld)\cite{20} assigned into two groups that included MTA and Biodentine, allocating 25 teeth in each group using simple lottery method.

Intra- and extraoral examinations of patients were performed before the treatment and their initial radiologic examinations were performed.

Patients who had no disease, such as congenital or rheumatic heart disease, leukemia, allergic reactions to substances, such as local anesthetics and latex, who did not require general anesthesia and sedation, and who had good individual and family cooperation were included in the study.

The teeth requiring pulpotomy were selected based on the inclusion criteria: deep cavity lesions that exposed vital pulp during the removal of caries; no history of spontaneous or nocturnal pain; absence of clinical symptoms such as swelling, fistula, tenderness of the percussion or palpation, pathologic mobility; those in which hemostasis was achieved within 5 minutes during clinical procedure; and the presence of two-thirds of the root length radiographically. No radiographic evidence of pulp degeneration, such as internal or external root resorption, furcal radiolucency, intraradicular or periapical bone destruction, or pulp stones.

The 50 teeth that were considered according to the above-mentioned criteria were randomized into two study groups. In the first group, MTA pulpotomy was performed on 25 teeth and Biodentine pulpotomy was performed on the rest in the second group.

**Treatment procedures**

After performing topical anesthesia by lidocaine spray, regional anesthesia was administered by Maxicaine D-S (Maxicaine, Vem İlaç, Ankara, Turkey). All cavity lesions were removed and an access cavity was prepared under the isolation of rubber dam. A low-speed sterile round bur (No.12, No.18) and excavator were used for removing coronal pulp. Sterile cotton pellets moistened with sterile saline were placed over the pulp stumps and light pressure was applied for 5 minutes. All pulpotomy procedures were performed by same pediatric dentist.

**MTA pulpotomy**

After hemostasis, MTA was prepared according to the manufacturer's instructions by mixing MTA powder with distilled water in a 3:1 ratio and pulp stumps were covered. The MTA condensed lightly with a moistened cotton pellet. Resin-modified glass ionomer cement (Vitrebond 3M ESPE, Seefeld, Germany) was placed to fill the pulp chamber. The teeth were restored with stainless steel crowns (3M ESPE, Dental Products, St. Paul, MN, USA) and cemented with glass ionomer cement (Meron® Voco, Cuxhaven, Germany). Pulpotomy procedure for MTA group can be seen in [Figures 1a-f].

**Biodentine pulpotomy**

After hemostasis, Biodentine (Septodont, Saint Maur des Fosse's, France) was mixed according to the manufacturer’s instructions and applied. First, the Biodentine capsule was struck gently on a solid surface.
to mix the powder inside. It was then mixed with 5 droplets of liquid for 30 seconds using a triturator. The Biodentine mixture was condensed to the pulp stumps using an amalgam carrier and moistened cotton pellet. The cavity was filled with Biodentine and then restored by using a stainless steel crown and cemented with glass ionomer cement. Pulpotomy procedure for Biodentine group can be seen in [Figure 2a-f].

**Evaluation of pulpotomy treatment and stainless steel crown (SSC) application**

After applying SSC, the first radiographs were taken and the patients were recalled for clinical and radiographic evaluation after 1, 3, 6 and 12 months. Clinical and radiological evaluations were performed independently by two experienced pediatric dentists. The teeth were considered successful if they had no symptoms of palpation–percussion sensitivity, spontaneous pain, hot–cold sensitivity, presence of fistula-swelling, pathologic mobility, internal–external resorption, periapical/interradicular bone destruction, disintegration of the lamina dura, enlargement of the periodontal space, and radiological calcific metamorphosis.

**Statistical analysis**

Study data were entered in SPSS (22.0) and the Mann–Whitney U test, Fisher’s exact chi-square test were performed. A $P$ value <0.05 was considered statistically significant.

**RESULTS**

In the present study, 25 children (female = 12, male = 13) and 50 teeth (1st primary molar = 27, 2nd primary molar = 23) were included. The mean age was 7.36 ± 1.25 years. Age, gender, and pulpotomy treatment types of the groups are presented in [Table 1].

**Clinical evaluation**

There was no statistically significant difference between clinical success rates in months 1, 3, 6 and 12 ($P > 0.05$) [Table 2]. The Kappa index obtained was 1.0 for clinical evaluation. In MTA group, one tooth was extracted due to fistula formation at month 12. In Biodentine group, one tooth was extracted due to fistula formation at month 12. Clinical failures are presented in [Table 3].

**Radiological evaluation**

The success rates are presented in [Table 4]. The Kappa index obtained was 0.87–1 for radiological evaluation. Radiological failures are presented in [Table 5].

In the radiological evaluation, the success rates were 100% in both groups at the end of the 1st month.

At the end of month 3, there were no statistically differences between the groups ($P = 0.240$). The success rate was 92% (n = 23) in MTA group and 80% (n = 20) in the Biodentine group. A total of 4% (n = 1) disintegration of the lamina dura and 4% (n = 1) interradicular or periapical bone destruction were observed in the MTA group. And 4% (n = 1) external resorption, 8% (n = 2) interradicular or periapical bone destruction, and 4% (n = 1) disintegration of the lamina dura were observed in Biodentine group.

![Figure 1: (a) Preoperative clinical appearance of 2nd mandibular primary molar tooth, (b) preoperative radiological appearance of 2nd mandibular primary molar tooth, (c) providing hemostasis, (d) condensation of mineral trioxide aggregate, (e) restoration with SCC, (f) first radiograph after treatment](image)

**Table 1: Age, gender, and the type of teeth of patients**

<table>
<thead>
<tr>
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<th>MTA n=25</th>
<th>BIODENTINE n=25</th>
<th>Total n=25</th>
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<tr>
<td><strong>Age</strong></td>
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</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>12</td>
<td>24</td>
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<tr>
<td><strong>Tooth</strong></td>
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<tr>
<td>First primary molar</td>
<td>12</td>
<td>15</td>
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<td>Second primary molar</td>
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</table>
In the radiological evaluation at month 6, the success rates were 84% for MTA group and 68% for Biodentine group and there no statistically differences between the groups (P = 0.199). While 84% (n = 21) of cases were completely successful, cases had 4% (n = 1) external root resorption, 8% (n = 2) interradicular or periapical bone destruction, and 4% (n = 1) enlargement of periodontal space in MTA group.

The radiological evaluation showed 68% (n = 17) success rate in the Biodentine group at the end of 6th month. A total of 4% (n = 1) external root resorption, 4% (n = 1) external root resorption and bone destruction between the periapical and interroot regions, 16% (n = 4) interroot regions and interradicular or periapical bone destruction, 8% (n = 2) disintegration of the lamina dura were observed.

The success rates were 80 and 60% for MTA and Biodentine groups at the end of 12th month, respectively, and there no statistically significant differences between the groups (P = 0.060). One tooth was extracted due to fistula formation; therefore, the total evaluation was performed on 24 teeth in MTA group. And 80% (n = 20) teeth were determined to be successful and 4% (n = 1) external root resorption and 12% (n = 3) interradicular or periapical bone destruction were observed. In Biodentine group, 4% (n = 1) external root resorption, 4% (n = 1) external root resorption and bone destruction between interradicular and periapical regions, 24% (n = 6) bone destruction between periapical and interradicular regions and 8% (n = 2) disintegration of the lamina dura continuity were observed.
Pulpotomy treatment is a routine treatment for symptom-free primary molar teeth that have been exposed with caries. During the pulpotomy procedure, infected or affected coronal pulp is amputated and the vital radicular pulp tissue surface is covered with a pulp-capping agent that promotes healing. Pulpotomy may be performed by non-pharmacotherapeutic approaches such as electrosurgery and laser treatment. Pharmacotherapeutic approaches may also be used, such as various medicaments and biological materials, including formocresol, ferric sulphate glutaraldehyde, calcium hydroxide, and MTA. [15]

The latest material for this purpose was bioactive calcium-silicate-based material (Biodentine), which was recently introduced by Septodont and could conciliate high mechanical properties with excellent biocompatibility and has bioactive behavior. [13] With enhanced properties, Biodentine can be used with the same clinical indications as MTA. [16,17] There are few studies reported in the literature that compare the clinical and radiological efficiency of MTA and Biodentine in human primary teeth. Nowicka et al. [19] evaluated human pulp tissue responses when capped with Biodentine and MTA in the third molar teeth and reported that there was no statistically significant difference between pulp responses.

Kusum et al. [22] evaluated MTA, Biodentine and Propolis as pulpotomy medicaments in their study. They reported that success rates were 100% for MTA, 100% for Biodentine, and 84% for Propolis clinically, whereas they were 92% for MTA, 80% for Biodentine, and 72% for Propolis, radiologically. They indicated that although there was no difference between MTA and Biodentine, both of them were significantly different from Propolis; thus, Biodentine may be used safely as a pulpotomy material.

Niranjani et al. [23] compared MTA, Biodentine and laser in their pulpotomy study and reported that the highest success rate was in MTA group; however, there was no statistically significant difference between the groups.

Cuadros-Fernandez et al. [24] compared MTA and Biodentine and reported that the clinical success rate of Biodentine was 97% and MTA was 92%; radiological success rates were 95 and 97%, respectively. They also reported that there was no significant difference between the success rates of materials.

The results of this clinical study showed a clinical success rate of 96% and radiological success rate of 80% for the MTA group and a clinical success rate of 96% and radiological success rate of 60% for the Biodentine group. There were no statistically significant differences between the groups both clinically and radiologically (P > 0.05). The results were in agreement with Kusum, Niranjani, and Cuadros-Fernandez et al. [22,24]

There were two clinical failures, one in MTA group and one in Biodentine group. The failures may be associated with misdiagnosis, iatrogenic errors, poorly adapted SSC, and leakage from these SSC.

There were 5 failures in MTA group and 10 failures in Biodentine group, but these cases were followed and they did not show clinical failure. The reasons for radiological failures should be histologically evaluated, which is one of the shortcomings of the study.

MTA showed higher success rates than Biodentine both clinically and radiologically. The higher success rates of MTA can be explained by it being a biocompatible material, its high sealing ability and possessing a pH of approximately 11–12.

Both MTA and Biodentine are tricalcium silicate-based materials and they are biocompatible materials for pulp tissue. [13,25,26] When compared to MTA, Biodentine has advantages, such as being easy-to-manipulate, high viscosity, short setting time, and superior mechanical properties; however, it is not as radiopaque as MTA.
and required triturator and an additional time period for it.

**CONCLUSION**

According to the results of this study, both MTA and Biodentine can be used as pulpotomy agents, but more long-term studies with larger samples size are required.

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**Conflicts of interest**

There are no conflicts of interest.

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