Abstract

Background: Clinical research examining the use of mineral trioxide aggregate (MTA) as an apical barrier material are limited, and no studies have so far examined the clinical performance of BioAggregate as apical barrier material in nonvital immature teeth.

Aim: This study was aimed to provide a comparative evaluation of the clinical and radiographic success of MTA and BioAggregate as an apical barrier material in children with traumatized nonvital, immature permanent maxillary incisors.

Subjects and Methods: A total of 26 maxillary incisor teeth in 20 children aged 7–11 were chosen for this study. Teeth were randomly divided into two groups according to the material to be applied, and the apical barrier was performed. Following treatment, for 24-month, teeth were clinically and radiographically evaluated once every 3- and 6-month, respectively.

Results: All teeth treated with MTA and BioAggregate were clinically and radiographically successful throughout the 24-month follow-up period.

Conclusions: Similar success was achieved in the apical barrier that using BioAggregate and MTA. BioAggregate would be considered suitable materials for apical barrier technique and can be used as an alternative to MTA.

Key words: Apical barrier, BioAggregate, mineral trioxide aggregate

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Introduction

Completion of root development and apex closure occurs from 1 to 4 years after the emergence of the tooth in the oral cavity.[1] In teeth with an open apex, proper root filling cannot be achieved if endodontic treatment is needed as a result of dental trauma or caries.[1-3] Thus, the clinician is faced with the challenge of creating an apical stop or constriction in order to achieve a hermetically sealed root-canal filling.[4]

Various treatment options exist to manage nonvital immature teeth which include apexification, apical barrier technique, and regenerative endodontic procedures.[2-3]

Up to now, mineral trioxide aggregate (MTA) has been popularly employed as a suitable material in apical barrier technique,[2-11] as it combines good tissue biocompatibility, low solubility, ability to induce mineralized tissue formation, and bacteriostatic action with favorable sealing ability.[2,5,12] Despite these excellent properties, MTA also possesses several undesirable characteristics such as long setting time,[12] difficulties in manipulation and insertion,[13] high costs,[14] and potential of discoloration.[7,8] In order to overcome these limitations, various alternative formulations have been developed.
Recently, a modified version of MTA, the calcium silicate-based nanoparticles sized bioceramic BioAggregate (DiaRoot BioAggregate, Innovative BioCeramix Inc., Vancouver, BC, Canada) has emerged on the dental market.[15] Unlike MTA, BioAggregate does not contain aluminum oxide and bismuth oxide.[15,16] Recent studies reported that BioAggregate is more biocompatible,[17-19] better-sealing ability,[20,21] higher fracture,[22] and acidic resistance[23] than MTA.

In light of the information presented above, BioAggregate represents a reasonable alternative to MTA for apical barrier material in nonvital immature teeth. However, to our knowledge, no published study has investigated the clinical performance of BioAggregate as an apical barrier material in nonvital immature teeth. Therefore, the aim of this study was to evaluate and compare the clinical and radiographical success of MTA and BioAggregate as an apical barrier material in children with traumatized nonvital, immature permanent maxillary incisors.

Subject selection
The study population consisted of good general healthy (having no history of systemic diseases or hospitalization) and cooperative children applying for treatment at the Department of Pediatric Dentistry, Faculty of Dentistry, Ondokuz Mayis University, Samsun, Turkey from November 2009 to December 2010. This clinical pilot study was approved by the Clinical Research Ethics Council (2009/3), and informed consent was obtained from the parents of all study participants.

Medical and dental histories were obtained during the initial evaluation of each patient, and clinical and radiographic examinations were performed to assess tooth vitality. The following clinical signs and symptoms were recorded: Acute pain, need for analgesics for pain control, tenderness to percussion, tenderness to palpation, sinus tract, a bad taste in the mouth, discoloration, luxation injury, and crown fracture. Clinical examinations also included electric pulp testing (Digitest, Parkell Electronics Division, Farmingdale, USA) and cold stimulation testing (Chloroethyl, Wehr, Baden, Germany). Radiographic examinations were conducted using an anterior film holder and periapical radiographs (Digitest, Parkell Electronics Division, Farmingdale, USA) and cold stimulation testing (Chloroethyl, Wehr, Baden, Germany). Radiographic examinations were performed to assess tooth vitality. Following clinical and radiographic examinations, 26 immature incisor teeth with evidence of pulp necrosis as a result of previous dental trauma in 20 children aged 7–11 were selected for inclusion in this study. Inclusion and exclusion criteria are given in Table 1.

Treatment procedures
All treatment procedures were performed by the same pediatric dentist (NT) using the same protocol. In the first appointment, local anesthesia (Ultracaine DS-Fort Ampul, Sanoft Aventis Ilaclari Ltd. Sti., Istanbul, Turkey) was administered, and teeth were isolated with a rubber dam (Ash Rubber Dam Kit, Dentsply International Inc., Milford, USA). A round diamond bur (801H016, Hager and Meisinger GmbH, Heisingen, Germany) was used to prepare an appropriate access cavity to allow removal of all necrotic tissue. The necrotic pulp was extirpated and working length was determined from a radiograph taken with a film holder. Canals were prepared to 2 mm short of the radiographic apex with K-files (Diadent Group International Inc., Canada) using a gentle, circumferential motion, and copious irrigation with 2.5% sodium hypochlorite to maximize cleansing and minimize dentin removal. After biomechanical preparation, canals were irrigated using a sterile saline solution and dried with sterile paper points (Spident, SPI Dental Mfg. Inc., Korea). Calcium hydroxide (Ca(OH)\textsubscript{2}) paste (Kalsin, Aktu Tic., İzmir, Turkey) was placed in the canal using a lentulo spiral (Mani Inc., Tochigi, Japan), and a radiograph was exposed to determine the degree of the Ca(OH)\textsubscript{2} filling. If found to be adequate, the endodontic access cavity was sealed with cotton pellets and reinforced with zinc oxide eugenol cement (IRM, Dentsply International Inc., Milford, USA).

Patients were recalled for a second appointment after 7 days, at which time the root-canal was re-accessed, the Ca(OH)\textsubscript{2} dressing was removed with reamers and the canal was irrigated with ethylenediaminetraacetic acid followed by 2.5% sodium hypochlorite. After minor instrumentation, canals were irrigated with sterile saline solution and dried with sterile paper points. Teeth were then randomly divided into treatment groups (n = 13) for apical barrier with MTA or BioAggregate (randomization was achieved by coin throwing). Patients were blinded to the type of materials used. Materials were mixed in line with the manufacturers’ instructions, inserted into the apical third of the root-canal using a carrier, and gently condensed using pluggers premeasured to 4 mm short of the working length. A conventional periapical radiograph was taken to confirm the appropriate placement of the material, a cotton pellet moistened with sterile water was placed over the apical plug, followed by a dry cotton pellet, and the endodontic access cavity was sealed with IRM.

After 4 days, patients were recalled for a third appointment. The cotton pellets were removed, and a reamer was used to check the apical plug for set and hardness. Canals were then obturated with Gutta-percha (Spident, SPI Dental
and a resin-based root-canal sealer (AH Plus, Dentsply, Konstanz, Germany) using the lateral condensation technique. If the apical plug hardness was unsatisfactory, procedures were repeated, and the final obturation was delayed to a later visit. Once obturation was completed, a periapical radiograph taken was used to evaluate the root filling. After the root-canal filling was determined to be adequate, teeth were restored with glass-ionomer liner material (Fuji IX, GC Corporation, Tokyo, Japan) and composite resin (Grandio, Voco, Cuxhaven, Germany).

Clinical and radiographic examinations
All preoperative, immediate postoperative, and recall radiographs were taken with a beam guiding device using the paralleling technique. All radiographic films were exposed and processed conventionally under similar conditions and analyzed under standardized conditions (darkened room, magnification).

Clinical and radiographic evaluations were performed by two different investigators (NT and SB). Kappa-Cohen test used for examiner calibration showed complete agreement between the two investigators.

Following treatment, study participants were recalled at 3-month intervals for the 24-month follow-up period. The following clinical parameters were assessed:

- Pain or discomfort at any time following root-canal obturation
- Use of any analgesics for pain relief
- Tenderness to palpation or obvious signs of abscess formation (sinus tract, etc.)
- Tenderness to percussion.

Treatment was recorded as a clinical failure if any of the above parameters were met. The following radiographic parameters were also assessed once every 6-month:

- Normal periodontal ligament space
- Reduction in the size of the periapical lesion as compared to preoperative radiographs
- No evidence of inflammatory external root resorption.

Treatment was recorded as a radiographical success when all three of the above parameters were met. In cases where a locally widened periodontal ligament space remained after healing of an extensive periapical lesion, this defect was considered to be scar tissue rather than a sign of persisting disease, and in such situations, apical barrier material was classified as a success. In cases where no reduction was observed in the size of the periapical radiolucency, the success of apical barrier materials were deemed inconclusive. Radiographical evidence of failure included enlargement of an existing periapical lesion, the formation of a new lesion after placement of the root filling, and signs of root resorption or hypercementosis.

Statistical analysis
Statistical analysis was performed using the SPSS 12.0 software program (SPSS Inc, Chicago, IL, USA) with the level of significance set at 0.05. Intra-examiner calibration was measured using Kappa-Cohen test.

Results
This study was conducted with 26 incisor teeth in 20 healthy and cooperative children (10 girls, 10 boys) aged 7–11 years (mean age: 8.7 ± 1.5 years; mean age of girls: 8.50 ± 1.72 years; mean age of boys: 8.90 ± 1.1). The demographic and baseline data for each group are presented in Table 2. 26 teeth included in this study were evaluated for the 24-month

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<td>Restorable tooth</td>
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<td>Possibility of rubber-dam isolation</td>
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<td>Root formation at stage 8 (two-thirds of root completed) or 9 (root almost completed-open apex), in according to Nolla[24]</td>
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<td>Nonvital immature permanent incisor requiring endodontic therapy</td>
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<td><strong>Exclusion criteria</strong></td>
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<td>Pathological external or internal root resorption</td>
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<td>Horizontal or vertical root fracture</td>
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<td>Pulp calcification</td>
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<td>Ankylosis</td>
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<th>Table 2: Demographic and baseline characteristics for each group</th>
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<td><strong>MTA (n=13)</strong></td>
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MTA=Mineral trioxide aggregate

![Figure 1: Radiographs of tooth 11 treated with mineral trioxide aggregate](image_url)
(a) Preoperative radiograph (b) Postoperative radiograph (c) 12-month follow-up (d) 24-month follow-up
follow-up period. No patients were lost during the follow-up period. The clinical and radiographic findings for each group at follow-up period are given in Tables 3 and 4, respectively.

Among the 26 teeth included in this study, the following symptoms were observed: Enamel fractures, 4 teeth; non-complicated crown fractures, 3 teeth; complicated crown fractures, 13 teeth; luxation injuries, 6 teeth; acute pain, 12 teeth; sensitivity to percussion, 19 teeth; sensitivity to palpation, 8 teeth; preoperative apical abscesses, 4 teeth; sinus tract, 6 teeth; preoperative radiographic periapical lesions, 17 teeth (8 teeth in MTA group and 9 teeth in BioAggregate group); the root formation at Stage 8, 19 teeth (9 teeth in MTA group and 10 teeth in BioAggregate group) the root formation at Stage 9, 7 teeth (4 teeth in MTA group and 3 teeth in BioAggregate group).

All teeth in both the MTA and BioAggregate groups were rated clinically and radiographically successful throughout the 24-month follow-up period. This finding of the present study cannot be evaluated as statistically because of the success in all teeth [Figures 1 and 2]. Interestingly, the coronal discoloration was coincidentally observed in 2 teeth (15.39%) from the MTA group in the 6-month follow-up [Figure 3], but no teeth in the BioAggregate group. No bleaching was performed to discolored teeth until the end of the study.

**Discussion**

The management of dental trauma to immature permanent teeth in young children can be challenging. As a result of dental trauma, these teeth may become nonvital, which leads to arrested root development. Root-canal treatment at this time is a significant challenge, because of the thin and
Tuloglu and Bayrak: Apical barrier technique in immature teeth

Although MTA has been the material most frequently used in apical barrier technique,[2,6] due to its disadvantages,[7,8,12–14] necessitate more ideal apical barrier materials, with adequate biological and mechanical properties. Recently, a new calcium silicate-based bioceramic material, BioAggregate, has been introduced with the intention of preserving the properties and clinical applications of MTA without its negative characteristics. BioAggregate is composed of tricalcium silicate, dicalcium silicate, tantalum pentoxide, calcium phosphate monobasic, hydroxyapatite, and amorphous silicon dioxide.[15,16] BioAggregate is also aluminum-free content, a fact that contributes to its greater biocompatibility with a periradicular tissue.[16] Moreover, the various advantages of BioAggregate include ease of application and manipulation; working time is more than 5 min and convenient setting time,[15] higher fracture strength,[22] and better sealing ability[20,21] than MTA. Despite these advantages of BioAggregate, to our knowledge, there have not yet been any clinical researches examining the use of BioAggregate in apical barrier techniques. Therefore, this clinical pilot study aimed to evaluate and compare the clinical and radiographic success of MTA and BioAggregate when used as an apical barrier material in traumatized nonvital, immature permanent incisors.

This clinical pilot study was carried out on a relatively small sample of nonvital, immature teeth (26 teeth in 20 children) over a relatively short follow-up period (24-month). In this regard, the limitations in terms of collecting a sample of nonvital teeth with open apices that meet the inclusion criteria should be kept in mind. Moreover, whereas a larger sample size would allow for the identification of statistical differences between materials, the design of the present study (i.e. small sample size and relatively short follow-up period) is consistent with other apexification studies in the literature.[6,7,9]

Simon et al.[10] examined the radiographic success of MTA when used as an apical barrier material on 57 immature permanent incisors over a follow-up period ranging from 6 to 36 months and reported reductions in preexisting periapical lesions in 81% of cases. Moore et al.[8] compared ProRoot MTA and MTA Angelus as an apical barrier material and found clinical and radiographic success rates of 95.5% for both materials. Another study evaluated apical barrier formation of 17 nonvital immature permanent incisors using MTA and found clinical and radiographic success rates of 94.1% and 76.5%, respectively.[7] A retrospective study by Mente et al.[11] assessing healing of immature teeth treated with MTA apical barriers found successful healing in 84% of cases. El-Meligy and Avery[9] demonstrated a clinical and radiographic success rate of 100% with MTA, which was found to be a suitable replacement for Ca(OH)₂ in apexification treatment. Overall, a review of clinical studies indicates that clinical and radiographic success rates of apical barrier formation with MTA range from 81% to 100% and 76–95%, respectively.[4,7,11] In line with these findings, the present study showed that all teeth treated using MTA was clinically and radiographically successful over the course of 24-month of follow-up. With regard to BioAggregate, given that the literature contains no previous reports on apical barrier formation using BioAggregate, no comparisons can be made with the clinical and radiographic success rates of apical barrier formation with this material found in the present study.

Tooth discoloration is an important aesthetic concern in young patients. Studies by Sarris et al.[7] and Moore et al.[8] found coronal discoloration in 11.8% and 22.7% of cases, respectively, following the placement of MTA as an apical barrier material. In the present study, coronal discoloration was coincidentally observed in 2 teeth (15.39%) treated with MTA, whereas no coronal discoloration was observed among teeth treated with BioAggregate. Discoloration caused by MTA has been attributed to the metal oxides (e.g. Bi₂O₃, Al₂O₃, FeO) contained in the material.[23,29] Unlike MTA, BioAggregate contains no metal oxides,[16] which could explain the lack of coronal discoloration in the BioAggregate group in the present study. Additional in vitro and in vivo studies are needed to provide a more definitive determination of the cause of discoloration with MTA and BioAggregate.
Conclusions

This study found excellent clinical and radiographic results when either MTA or BioAggregate is used as an apical barrier material in children with traumatized nonvital, immature permanent maxillary incisors. Within the limitation of this study, BioAggregate can be considered a possible alternative to the MTA. However, MTA still remains as one of the important materials used in apical barrier technique. Further clinical studies with larger sample sizes and longer follow-up periods are required to find the best apical barrier material in dental practice.

Acknowledgments

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References

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