

# Treatment Outcome of Mineral Trioxide Aggregate in Open Apex Teeth

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## Abstract

**Introduction:** This cohort study is the second phase of a previously reported trial. The primary aim was to assess the outcome of the treatment of teeth with open apices managed by the orthograde placement of mineral trioxide aggregate (MTA) apical plugs. The secondary goal was to identify potential outcome factors for this kind of treatment with a larger sample size and longer follow-up periods than in the first phase of the project.

**Methods:** Two hundred twenty-one patients who had been treated between 2000 and 2010 were contacted for follow-up examination 12–128 months after treatment (median, 21 months). At the time of treatment, these patients presented a total of 252 teeth with open apices caused by apical root resorption or excessive apical enlargement or with immature apices. Treatment was performed by supervised undergraduate students (12% of teeth), general dentists (49%), and dentists whose practice was limited to endodontics (39%). The investigated outcome relied on clinical and radiographic criteria and was dichotomized as healed or diseased.

**Results:** Of 252 examined teeth (88% recall rate), 90% were healed. Teeth with and without preoperative periapical radiolucencies demonstrated healed rates of 85% and 96%, respectively. Forty-five percent of the teeth (113/252) were followed up at least 2 years later and 21% (53/252) at least 4 years later. Univariate survival analyses identified 4 prognostic factors: preoperative apical periodontitis, the experience of the treatment providers, the number of treatment sessions, and the apical extrusion of MTA. Multiple regression analyses confirmed an increased risk of disease for teeth with preoperative apical periodontitis (hazard ratio = 4.59; 95% confidence interval, 1.57–13.4;  $P = .005$ ). In addition, the experience of the treatment provider was found to influence the outcome (hazard ratio = 0.25; 95% confidence interval, 0.09–0.75;  $P = .03$ ).

**Conclusions:** Orthograde placement of MTA apical plugs appears to be a promising treatment option for teeth with open apices. The healed rates for such teeth were high in this study, even after follow-up periods of

more than 4 years. The presence of preoperative apical periodontitis was identified as an important prognostic factor. (*J Endod* 2013;39:20–26)

## Key Words

Long-term results, mineral trioxide aggregate, MTA, open apex, treatment outcome

Mineral trioxide aggregate (MTA) is a root canal repair material that was developed at the beginning of the 1990s at Loma Linda University in California. In early 2000, MTA (ProRoot MTA; Dentsply-Maillefer, Ballaigues, Switzerland) was introduced in Europe.

Endodontists were particularly interested in investigating the much advertised biocompatibility of MTA, which has since been confirmed in many *in vitro* and *in vivo* studies (1). It also displayed good sealing properties with regard to bacterial leakage (2–4). A recently published literature review by Torabinejad and Parirokh (5) summarized the results of most of the studies on the biocompatibility and sealing abilities of MTA.

The biocompatibility of MTA and its satisfactory sealing ability in the presence of moisture, including blood (6), are properties that support its successful application for the orthograde obturation of nonvital teeth with open apices. Several animal studies (7–9) and the first clinical studies (10–15) on the use of MTA as an apical barrier for teeth with necrotic pulps and open apices are now available. Although these studies provide useful insight, their value as a reliable assessment of the long-term prognosis for this treatment option is limited. The actual number of cases reported is small, and the follow-up periods were generally too short. The study by Mente et al (12) is the article that resulted from phase I of this study project. In phase I, 84% of the 56 teeth examined were healed. Teeth with or without preoperative periapical radiolucencies exhibited healed rates of 100% and 78%, respectively. None of the analyzed potential outcome factors showed a significant effect on the outcome (12). These results suggested that the study was underpowered, highlighting the problems of earlier studies as described above. A power calculation performed after phase I indicated that 170 teeth would be needed for phase II. The aim of this second phase of the project was 2-fold: to elicit the outcome of the treatment of teeth with open apices managed by the orthograde placement of MTA apical plugs and to reinvestigate the potential outcome predictors with a larger sample size than that used in phase I.

## Materials and Methods

### Inclusion and Exclusion Criteria

The study protocol of phase II of this project was approved by the Ethics Committee of the University of Heidelberg (Ref. 095/2010). This is a historical cohort

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0099-2399/\$ - see front matter

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<http://dx.doi.org/10.1016/j.joen.2012.10.007>

study (retrospective in treatment with a prospective follow-up assessment of outcomes). Subjects for the study were identified from among patients who received endodontic treatment with orthograde placement of MTA plugs at the Department of Conservative Dentistry at the University Hospital of Heidelberg from December 2000–October 2010. To evaluate as many long-term results as possible, all the patients involved in phase I were recalled for another follow-up examination in phase II.

The inclusion criteria for this historical cohort study were as follows:

1. Teeth in which chronic apical periodontitis had led to apical root resorption
2. Teeth in which the apical constriction had been inadvertently enlarged as a result of overinstrumentation
3. Immature pulpless teeth with incomplete root formation
4. Teeth with apical root resorption after trauma

In all groups, the diameter of the apical foramen was clinically confirmed to exceed at least that of an ISO size 40 file. Subjects with compromised immune status, who were pregnant at the time of follow-up, who declined to participate in the study, or who had incomplete pretreatment or intratreatment records were excluded. Teeth with longitudinal root fracture or a periodontal-endodontic lesion (on the day of endodontic treatment) were also excluded from the study. The interval between the endodontic treatment and the last follow-up examination was at least 1 year (with a tolerance of 14 days).

## Recruitment of Patients

Subjects who met the inclusion criteria (221 patients) were contacted by mail and subsequently by phone and were invited to attend the follow-up examinations. All potential participants were mailed detailed information about the study. On the day of the follow-up examination, the patients were again given a detailed explanatory information sheet and were asked to sign a declaration of informed consent to participation in the study. Clinical and radiographic follow-up examinations were undertaken after written informed consent had been provided.

## Calibration

**Clinical Calibration.** In phase I of this study project (12), the follow-up examinations were performed by 2 investigators who were clinically calibrated by independently examining 21 patients on 1 day. This calibration displayed a high level of consensus with regard to probing depth (99.4%), attachment loss (99.5%), furcation involvement (99.0%), tooth mobility (98.8%), and type of restoration (99.0%). There was no discrepancy in the results of the cold and percussion tests or in the quality of restorations recorded by both examiners for the 21 patients examined (12). In light of the very high reliability regarding all clinical parameters that had already been established, no further calibration on patients was undertaken for phase II of this study project. Because of the much larger number of patients in phase II and the associated increase to 4 investigators, it would not have been reasonable to expect the patients to undergo a 4-fold calibration in 1 day by all the investigators.

**Radiographic Calibration.** One examiner (T.P.) was also designated to carry out all the radiographic interpretations of intraoral periapical views. Before evaluating the study radiographs, this examiner (T.P.) was calibrated with the periapical index (PAI) calibration kit with 100 periapical radiographs (16). Intraexaminer reliability and interexaminer agreement with the calibration kit's gold standard were assessed by using Cohen's kappa.

## Endodontic Treatment Intervention

Supervised undergraduate students (ST) treated 30 teeth (12%), general dentists (GD) treated 124 teeth (49%), and dentists whose practice was limited to endodontics (EN) and who had routinely performed the MTA apical plug technique for at least 2 years (EN) treated 98 teeth (39%). All treatment providers used a dental operating microscope when applying the MTA apical plug. The EN group performed the entire root canal treatment with the aid of a dental operating microscope (Zeiss, Oberkochen, Germany). In all cases in which the treatment was performed by undergraduate students (ST), the MTA apical plug was applied by an endodontically experienced supervisor, whereas the remaining root canal treatment (cleaning, shaping, and obturation) was executed by the student.

The methodology of the cleaning and shaping procedures, as well as the step-by-step procedure of the placement of the MTA apical plug followed by the backfill of the space coronal to the MTA plug, has been described in detail in the previous report on phase I of this study project (12).

## Preoperative and Intraoperative Data

Preoperative and intraoperative information pertaining to clinical variables was gathered from the patients' records and radiographs and entered into a specifically designed database. Preoperative data included age, gender, tooth location, number of roots, clinical signs and symptoms, response to cold testing, tooth mobility, probing depths (6 per tooth) and attachment loss, furcation involvement, sinus tract, periapical radiolucency, signs of apical root resorption, and previous root canal filling. Intraoperative data included date of treatment completion, number of treatment sessions, cleaning and shaping technique, root canal filling technique, complications, temporary seal, MTA extrusion, and experience of the treatment provider.

## Follow-up Examination

The follow-up examinations were performed by 4 designated examiners (M.L., M.O., D.P., T.P.) and carried out at different time intervals that ranged from 12–128 months after treatment. The presence of clinical signs and symptoms, response to cold testing (carbon dioxide snow), tooth mobility, type and quality of restoration, probing of pocket depths and attachment loss, furcation involvement, and presence of a sinus tract were recorded and entered in a structured recall form that was specially designed for this study.

The quality of the coronal restoration was assessed both clinically (visual inspection with mirror and explorer) and radiographically by evaluating signs of restoration breakdown or caries. The main purpose of this was to judge whether bacteria penetration into the root canal system of the tooth might be expected. Periapical radiographs were assessed as described below. Signs of apical root resorption or extrusion of MTA were recorded, and the images were forwarded to the calibrated examiner for PAI-based interpretation.

## Outcome Assessment

Radiographs were coded, stored, and subsequently assessed by the designated examiners. Preoperative, post-treatment, and follow-up radiographs were examined independently in a random sequence. They were evaluated in a darkened room by using an illuminated viewer box (Kentzler-Kaschner Dental GmbH, Ellwangen, Germany) with  $\times 2$  magnification. Radiographs were evaluated by a PAI-calibrated examiner (T.P.) with several years of clinical experience. Multirrooted teeth were assessed according to the highest scored root.

Outcomes were assessed on the basis of the clinical and radiographic findings. A case was classified as healed when the PAI score

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