INTRODUCTION

Traumatic dental injury in children can result in pulp necrosis and subsequent arrest of root maturation (1). These nonvital immature permanent teeth have thin dentinal walls and wide-open apices. The absence of an apical stop to support conventional obturation is the principal concern. Therefore, it is highly desirable to induce apical root-end closure. Traditionally calcium hydroxide apexification has been advocated to induce root maturation with increased root length and thickness. However, the intended outcome is not achieved predictably and an intraradicular post cannot be placed after this procedure (3).

Mineral trioxide aggregate (MTA) as a root-end barrier material has been widely recommended for the successful management of a tooth with an open apex. It has an excellent sealing ability, tissue compatibility and bio-inductive properties (4, 5). The technique for MTA apical barrier placement involves chemo-mechanical preparation, inter-appointment dressing with a suitable...
intracanal medicament and subsequent placement of an MTA apical plug, either in a single or two-step procedure (6, 7). The thickness of the MTA apical barrier has been extensively researched, and it has been documented that a 4mm plug is sufficient for an adequate apical seal (8).

Immature teeth with open-apices have incompletely formed root with irregular apical dentinal walls (9). MTA apical barriers placed up to the radiographic root-end in these teeth, can result in overfill and a less favourable outcome may ensue (10). It is common for case series and prospective studies to place MTA apical barrier up to the radiographic root end (11, 12). The present preliminary clinical study aimed to evaluate the effect of the apical extent of MTA apical barrier on periapical healing of a non-vital immature permanent incisor tooth with an open apex.

**MATERIALS AND METHODS**

**Subject enrolment**

The institutional research Ethics Committee approved the study protocol (Ref. No. IESC/T-422/26-08-2015, RT-25/2015) following the principles of Helsinki (version 2008).

**Inclusion and exclusion criteria**

Healthy participants of either gender in the age group of 8-18 year requiring nonsurgical endodontic therapy in bilateral permanent maxillary central incisor teeth with a diagnosis of pulp necrosis and asymptomatic apical periodontitis exhibiting radiographic periapical index (PAI) score ≥3 (13) and associated Cvek’s stage 4 of root development (14) were enrolled between July 2015 and December 2017. Radiographic examination was carried using a size-1.5 CMOS RVG sensor (EzSensor Classic™, VaTech, Korea) exposed by paralleling cone technique at standardized X-ray operating parameters (70 kV, 7mA, and 0.12s). Teeth with extensive bone loss, a history of previous endodontic intervention, and non-restorable teeth were excluded. Verbal information regarding the study aim, associated procedures, and written bilingual patient information sheet was provided. Written informed consent was obtained from either of the parent or legal guardian.

**Sample selection and randomization method**

In the absence of related literature and since this was a preliminary clinical study, a convenience sample size comprising of six participants with traumatized bilateral nonvital immature permanent maxillary central incisor teeth (n=12) were selected for a split-mouth study design. In each subject, the bilateral nonvital immature permanent maxillary central incisor teeth were randomly assigned using permuted block randomization to either group I (n=6, MTA apical barrier up to the radiographic root-end) or group II (n=6, MTA apical barrier 2 mm short of the radiographic root-end). The participants were blinded to the treatment allocation.

**Interventions**

**Nonsurgical endodontic therapy**

It was performed by a single operator (KT). A standardized two-visit protocol was followed. The tooth was anaesthetized with 2% lignocaine with 1:200,000 adrenaline (LOX 2%, Neon Laboratories Ltd., Mumbai, India). The access cavity was prepared under rubber dam isolation using a sterile round carbide bur (Dentsply Maillefer, Ballaigues, Switzerland). The canal terminus was determined and working length (WL) at that position was opted for with an electronic apex locator (Tri Auto-ZX, J Morita USA) operated as per manufacturer’s recommendations and confirmed radiographically. In case of discrepancy between the measured WL, the radiographic WL was taken as the final (15). Minimal mechanical instrumentation of the canal was carried out with ISO K-files (Dentsply Maillefer, Ballaigues, Switzerland). The entire instrumentation was supplemented with copious irrigation of the canal with 5.25 % sodium hypochlorite (NaOCl) (PRIME Dental Products Pvt. Limited, Pune, Maharashtra, India). The canal was irrigated with 17% Ethylenediaminetetraacetic acid (EDTA) (Largal ultra Septodont, Codex, France) for 1 minute and the final flush was carried out with distilled water. To limit extrusion of the irrigant in the periapical area, the Endovac irrigation delivery system (EndoVac™ system; Kerr Dental, Orange, CA, USA) was used. The canal was dried with a sterile absorbent paper points (Dentsply Maillefer, Ballaigues, Switzerland), and an intracanal medicament of calcium hydroxide slurry was placed with a lentulo spiral (Dentsply Maillefer, Ballaigues, Switzerland). The access cavity was restored with Cavit™ G (3M ESPE Dental AG, Seefeld/Oberbay, Germany). The patients were recalled at a one-week interval. The root canal was re-accessed following the above endodontic protocol. Calcium hydroxide was removed with 10 ml each sequential irrigation of 17% EDTA and 5.25% NaOCl solution. This was aided with ultrasonic activation (16). If there was a persistent discharge from the root canal, another dressing of calcium hydroxide slurry was placed until a dry canal was obtained. Two teeth required additional calcium hydroxide intracanal medication. Subsequently, an MTA (White ProRoot® MTA, Dentsply Maillefer, Ballaigues, Switzerland) apical barrier was placed.

**MTA apical barrier**

To serve as an internal matrix for placement of the MTA apical barrier, sterile resorbable collagen sponge was sized into a suitable piece. In Group I, the rubber stopper of the hand plunger was adjusted up to established WL, and collagen pellet was placed flush to the radiographic root end. In Group II, the rubber stopper of the hand plunger was adjusted 2 mm short of the established WL and was used to place the collagen pellet short of the radiographic root end. MTA powder was mixed as per the manufacturer’s recommendation. It was carried into the root canal in increments using the Dovgan MTA carrier (Dentsply Maillefer, Wey bridge, UK) and condensed with Schilder pluggers (Dentsply Caulk, Milford, USA) until an appropriate thickness of 4 mm was achieved. A moist cotton pellet was placed over it. To confirm the correct placement of the MTA apical plug, a digital intraoral periapical radiograph was exposed at standardized parameters (70 kV, 7mA, and 0.12s) on a size-1.5 CMOS RVG sensor (EzSensor Classic™, VaTech, Korea). The access cavity was restored with Cavit™ G (3M ESPE Dental AG, Seefeld/Oberbay, Germany). The patient was recalled after twenty-four hours. The tooth was re-accessed under aseptic conditions. The setting of the MTA was confirmed. Obturation was performed using an AH plus® sealer (Dentsply DeTreY GmbH, Konstanz, Germany) and Calamus®
Dual thermoplastic injection system (Dentsply Maillefer, Ballaigues, Switzerland). The access cavity was sealed with an Optra Bond® All in one (Dentsply DeTrey GmbH, Konstanz, Germany) and composite resin material (Ceram.X® SphereTEC™ one Composite, Dentsply DeTrey GmbH, Konstanz, Germany).

**Clinical evaluation**
The cases were evaluated clinically at twelve and twenty-four months. Tenderness to palpation, percussion, mobility, pus discharge, and the absence or presence of sinus were noted and compared with previous records.

**Radiographic evaluation**
The pre and twenty-four months post-operative PAI scores of the teeth were radiographically evaluated (Figs. 1-3) and compared by two trained endodontist who were blinded to the study objectives and methodology. The examiners repeated the scoring after the one-month interval. Inter-rater and intra-rater agreement scores were calculated using Cohen’s kappa analysis. The scores were 0.818 and 0.83, respectively.

**Statistical analysis**
The data collected was entered in Microsoft Excel and subjected to statistical analysis using Statistical Package for Social Sciences (IBM SPSS Inc., version 20.0, Chicago, IL, USA). The level of significance was fixed at 5% and P≤0.05 was considered statistically significant. Kolmogorov-Smirnov test and Shapiro-Wilks test were employed to test the normality of data. The categorical data were represented in frequency (n)/percentages (%). Mann Whitney U test, Kruskal Wallis and post hoc analysis was performed for quantitative variables.

**RESULTS**
No case was lost to follow up at the end of the observation period of twenty-four months. All patients reported no symptoms associated to the teeth in question, suggesting that the treatment was successful. In this study, the PAI score was considered as an ordinal scale. They were dichotomized as healed, PAI scores <3 or non-healed, PAI scores ≥3. On inter-group comparison between the frequency distribution of baseline

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**Figure 1.** (a) Preoperative intraoral periapical radiograph of teeth #11 and #21 with non-blunderbuss canal and open apex associated PAI scores of 5 and 4 respectively. (b) Immediate postoperative intraoral periapical radiograph of tooth #21 showing MTA apical barrier 2 mm short and tooth #11 showing MTA apical barrier up to radiographic root end. (c) & (d) Follow up intraoral periapical radiograph exhibiting resolution of the periapical lesion at 12 and 24 months

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**Figure 2.** (a) Preoperative intraoral periapical radiograph of teeth #11 and #21 with non-blunderbuss canal and open apex associated PAI scores of 5 and 5 respectively. (c) Immediate postoperative intraoral periapical radiograph of tooth #11 showing MTA apical barrier 2 mm short of radiographic root end and tooth #21 showing MTA apical barrier up to radiographic root end. (c) & (d) Follow up intraoral periapical radiograph exhibiting resolution of the periapical lesion at 12 and 24 months
Beyond the confines of the root-end was considered as an open apex. This type of root canal is an indication for an MTA apical barrier.

MTA has diverse clinical applications (19) and has been extensively used for apical barrier formation in a nonvital tooth with an immature apex (20, 21). In retrospective studies, the clinical and radiographic outcome of teeth treated by MTA apical barrier placement, a success rate of 90-93% was observed. This method produces a predictable apical barrier, reduces treatment time, and is an evidence-based technique for the management of permanent nonvital tooth with an open apex (22, 23). The thickness of the MTA apical barrier has been extensively evaluated, and a 4 mm MTA apical barrier is ideal for preventing bacterial leakage (24). Hence the same thickness was preferred.

The results of the present study demonstrated that despite placing MTA apical barrier up to the radiographic root end periapical healing was evident in all the teeth and there was no significant difference (P=1.0). At 24 months follow up interval, on inter-group comparison between the proportion of teeth healed and non-healed (radiographic), no statistically significant difference was observed (P=1.0) (Table 1). This study reported a 100% success rate with a complete resolution of periapical radiolucency in both the groups.

**DISCUSSION**

This study was aimed to determine the optimal apical extent of the MTA apical barrier in a nonvital immature permanent anterior tooth with an open apex. Based on the results of this study, it was observed that there was no influence on treatment outcome (i.e. healing of apical periodontitis) between the two treatment protocols.

The definition of open apex varies according to the authors (17, 18). In this study, the anterior maxillary tooth that had radiographic evidence of non-blunderbuss canal (Cvek’s stage 4) and in which an ISO size #80 K file could passively pass beyond the confines of the root-end was considered as an open apex. This type of root canal is an indication for an MTA apical barrier.

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**TABLE 1.** Demographic profile, clinical and radiographic outcome

| Case | Age (Years) | Gender | Tooth no. | Demographic profile and radiographic outcome | Outcome 24 months |
|------|-------------|--------|-----------|-------------------------------------------|-------------------|
|      |             |        |           | Radiographic postoperative PAI score        | Clinical          |
| 1    | 14          | M      | 11*       | 5                                         | 1                 | Asymptomatic      |
| 2    | 15          | M      | 11*       | 3                                         | 1                 | Asymptomatic      |
| 3    | 10          | M      | 21*       | 4                                         | 1                 | Asymptomatic      |
| 4    | 17          | M      | 11*       | 3                                         | 1                 | Asymptomatic      |
| 5    | 14          | F      | 21*       | 5                                         | 1                 | Asymptomatic      |
| 6    | 18          | M      | 21*       | 4                                         | 1                 | Asymptomatic      |

*MTA placed up to the radiographic root end, **MTA placed 2 mm short of the radiographic root end*
CONCLUSION

In a nonvital immature permanent anterior tooth, MTA apical plug can be placed either at or 2 mm short of the radiographic root end.

Disclosures

Conflict of interest: Authors declared no conflict of interest.

Ethics Committee Approval: The institutional research Ethics Committee approved the study protocol (Ref. No. IESC/T-422/26-08-2015, RT-25/2015) following the principles of Helsinki (version 2008).

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