Effect of Different Apical Preparation Sizes on Outcome of Primary Endodontic Treatment: A Randomized Controlled Trial

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Abstract

Introduction: The study was designed as a randomized controlled trial to evaluate the effect of the apical preparation size in relation to the first apical binding file (FABF) on the outcome of primary endodontic treatment in mandibular first molars. **Methods:** One hundred sixty-seven patients met the inclusion criteria. They were randomly allocated to 5 different endodontic treatment groups (ie, A, B, C, D, and E) in which canals were enlarged to 2, 3, 4, 5, and 6 sizes larger than the FABF, respectively. One hundred twenty-nine patients were evaluated at the 12-month follow-up. The primary outcome measure was the change in periapical radiolucency as assessed by periapical index (PAI) scores. The clinical finding constituted the secondary outcome measure. **Results:** A statistically significant reduction in PAI scores was observed in all groups ($P < .001$). The proportion of successfully healed cases increased with an increase in the apical preparation size with 48%, 71.43%, 80%, 84.61%, and 92% successful healing observed in groups A to E, respectively. However, statistical analysis revealed that only group A showed significantly less improvement than other groups ($P < .05$). No significant difference was observed between the rest of the groups. Regression analysis revealed a significant and positive association between the master apical preparation size and an improvement in PAI scores ($\beta = 0.037$, $P = .001$). **Conclusions:** The enlargement of the canal to 3 sizes larger than the FABF is adequate, and further enlargement does not provide any additional benefit during endodontic treatment. *(J Endod 2012;38:1309–1315)*

Key Words

Apical periodontitis, apical preparation size, endodontic treatment, first apical binding file, periapical healing, periapical index

Root canal treatment may be defined as the combination of mechanical instrumentation of the root canal system, its chemical debridement, and filling with an inert material designed to maintain or restore the health of the periradicular tissue (1). The primary objective of the entire procedure is to eliminate microorganisms and pathologic debris from the root canal system and to prevent its reinfection (2, 3). Although it may not be justified to play up the role of any 1 step, mechanical instrumentation accompanied by irrigation may be considered as the most essential component that aids in achieving this objective (4, 5). However, studies have observed that the current instrumentation and irrigation techniques are not completely effective in the elimination of debris and bacteria from the apical third. The difficulty in the removal of bacterial debris from the apical third has been attributed to the narrow canal space, the complex canal morphology, inadequate flushing of irrigants, and variation in the diameter of the root canal (6).

The enlargement of the apical area has been advocated to ensure an adequate depth of penetration of the irrigant for better cleansing (7). However, the extent of apical enlargement required is a matter of debate. Preparation to larger apical sizes has been suggested by its protagonists to be the most efficacious way of cleaning and disinfecting the canals. Larger apical preparations allow better removal of infected dentin (8), enhance the flushing action of irrigants in the apical region (9), and significantly reduce the bacterial load in the canal system (10–13). Enlargement to different apical sizes, including #30 (14) and #40 (15), has been suggested for the effective removal of debris from the canal. Similarly, various preparation sizes of #45 (2, 16) and #60 to #80 (8) have been shown to significantly reduce the bacterial load during endodontic treatment. Contrary to these findings, Yared and Dagher (17) have reported a #25 file to be as efficient as a #40 file for reducing residual microorganisms.

The traditional approach involves the preparation of the root canal to 3 sizes larger than the first apical binding file (FABF) (18). However, the effectiveness of this approach in ensuring uniform and sufficient removal of dentin from all regions of the canal wall has been questioned (19). Recommendations based on morphometric studies of the apical region of the root canals indicate that it may be inadequate (20–22). Although some studies (21, 22) have recommended enlargement ranging from 6 to 8 sizes larger than the FABF, others (20) have shown that canals in multirooted teeth may necessitate enlargement to a minimum size of #60 to fully instrument the apical region.

The drawbacks of larger apical preparation sizes include undesirable deviation from the original shape of the canal; weakening of the root; and procedural complications like ledge formation, transportation, and perforations (23, 24). The conservation of tooth structure and the prevention of the extrusion of obturating materials have been

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cited as primary advantages of minimal apical enlargements (25, 26). Yu and Schilder (27) proposed that the final preparation should have a continuous taper with the smallest possible apical foramen. Buchanan (28) suggested that apical preparation should be performed to the minimum size possible; thus, preparation to size 20 was sufficient in most of the cases encountered.

To the best of our knowledge, to date there are only 3 studies (29–31) analyzing the effect of the apical size of canal preparation on the treatment outcome, and these too are retrospective in nature. Of these, although 2 (29, 31) suggested a decrease in the success rate with an increase in the apical preparation size, the third study (30) could not find any difference in success with varying apical preparation sizes.

Thus, the debate on the effect of apical enlargement on the success in endodontic treatment remains unsettled. Although randomized controlled trials are regarded as the gold standard in clinical research, no such study has been conducted in this regard to date. Thus, it was believed that a well-designed, prospective study was required to shed light on this contentious issue.

The objective of this randomized clinical trial was to evaluate the effect of different apical preparation sizes on the outcome of primary root canal treatment in mandibular first molars. The null hypothesis tested was that there is no effect of apical enlargement on the success of root canal treatment.

Materials and Methods

This study was approved by the Institutional Review Board of Pandit Bhagwat Dayal Sharma University of Health Sciences, Rohtak, India. Study subjects were recruited from the pool of patients referred to the Department of Conservative Dentistry and Endodontics of Post Graduate Institute of Dental Sciences for initial nonsurgical root canal treatment between June 2009 and January 2011. Mature permanent mandibular first molars having pulpal necrosis as confirmed by a negative response to cold and electric pulp tests and radiographic evidence of apical periodontitis (minimum size $\geq$2 mm $\times$ 2 mm) were included in this study. Patients were excluded if they were younger than 18 years of age, pregnant, diabetic, immunocompromised, had a positive history of antibiotic use within the past month or required antibiotic premedication for dental treatment (including infective endocarditis or prosthetic joint prophylaxis), or had teeth that had been previously accessed and with procedural error.

Once eligibility was confirmed, the patients were informed of the study design, the clinical procedure involved, and the associated risks. They were also ensured that root canal treatment would be performed regardless of whether or not they decided to participate in the study. Once the patient agreed to participate, verbal and written consent was obtained, and the patient was randomly assigned to 1 of the 5 designated groups. Randomization was developed to eliminate any bias on the part of the investigators and to balance the number of patients between the treatment protocol types. Using an equal proportion randomization allocation ratio, 1 of the investigators (A.G.) created envelopes that contained concealed assignment codes that were assigned sequentially to eligible patients. It was ensured that neither the primary investigator nor the patient was aware of the treatment protocol assigned before completing the consent process.

Assuming a fairly normal distribution of the samples, the minimum sample size required for comparing the means of ordinal data was determined using the Karlsson method (32). The change in the periapical index (PAI) scores observed after 12 months was the primary outcome measure of our study. With power = 0.90, $P < .05$, and the minimum clinically significant mean difference between groups set at 0.50 units (standard deviation $\pm$ 0.50 unit) while using the PAI (33), a minimum sample size of 21 subjects per group was required to adequately show a difference in success. To compensate for the expected attrition in the patient pool over the period of time, a decision was made to enroll at least 30 subjects in each group.

Clinical Procedure

The principal investigator (H.R.S.) conducted all preliminary consultations and examinations followed by treatment using a standardized protocol. A supervising faculty member verified all the clinical and radiographic findings. After the administration of local anesthesia (2% lidocaine with 1:100,000 epinephrine), caries were excavated, and the access cavity was prepared under rubber dam isolation. The coronal part of the canals were initially enlarged using Gates-Glidden drills (Dentsply Maillefer, Tulsa, OK) to achieve a straight-line access to the apical third of each root. During the procedure, irrigation was performed with 3% sodium hypochlorite (NaOCl; Sainsburryple, London, UK) using a 27-G endodontic syringe (Monoject; Sherwood Davis & Geck, St Louis, MO). The working length was determined with the help of an electronic apex locator (Root ZX; J Morita, Irvine, CA) and confirmed with straight and angled radiographs. Canals were then prepared using the step-back technique with 0.02 taper ISO stainless steel hand files with each successively larger file placed 0.5 mm coronal to the previous one.

The master apical file (MAF) size for each canal was set at 2, 3, 4, 5, and 6 sizes larger than the first file to bind at the working length in groups A, B, C, D, and E, respectively. The canals were enlarged to their intended sizes accompanied by irrigation with 5 mL 3% NaOCl after each instrumentation cycle. Canal patency was ensured by passing a #10 stainless steel file approximately 0.5 to 1.0 mm beyond the working length. Once the canals had been enlarged, they were irrigated with 5 mL 17% EDTA (Prevest Denpro Limited, Jammu, India) for 1 minute followed by a final wash with 5 mL 3% NaOCl. After drying with sterile absorbent points, the canals were filled with paste made by mixing calcium hydroxide powder (Roth International Ltd, Chicago, IL) with 2% chlorhexidine liquid (ICPA Health Products Limited, Ankleshwar, India) using a lentulo spiral. The tooth was then temporarily restored with Intermediate Restorative Material (Dentsply Ltd, Weybridge, UK). The patient was recalled after 1 week. At the next appointment, the paste was removed with the help of Hedstroem files (Dentsply Maillefer, Tulsa, OK) and copious irrigation with 3% NaOCl followed by a final rinse of 5.0 mL 17% EDTA and 5.0 mL 3% NaOCl. The canals were then inspected under a dental operating microscope to confirm removal of the paste and obturated with gutta-percha and a zinc oxide eugenol–based sealer using lateral condensation technique. After obturation, the access cavity was restored with amalgam. An immediate postoperative radiograph was taken using preset exposure parameters with a Rinn paralleling device (Dentsply Ltd). Ektaspeed Plus E speed film (Kodak Ltd, Hemel Hempstead, United Kingdom) was used and processed manually.

Follow-up examinations were performed every 3 months until 12 months after the procedure and consisted of history taking and clinical and radiographic examinations. The same exposure parameters as at the time of the initial examination were used to obtain periapical radiographs at the follow-up visits.

Assessment of Treatment Outcome

The change observed in periapical radiolucency at the 12-month follow-up visit was used to assess the primary treatment outcome. The criteria for the clinical success of the treatment, which was taken as the secondary outcome measure, included the absence of pain and