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

Hans Raj Saini, MDS, Sanjay Tewari, MDS, Pankaj Sangwan, MDS, Jigyasa Duhan, MDS, and Alpa Gupta, MDS

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

From the Post Graduate Institute of Dental Sciences, Rohtak, Haryana, India.

Address requests for reprints to Dr Sanjay Tewari, Post Graduate Institute of Dental Sciences, Rohtak, Haryana 124001, India. E-mail address: tewarisanjayrohtak@yahoo.co.in

0099-2399/$ - see front matter

http://dx.doi.org/10.1016/j.joen.2012.06.024

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

TABLE 1. PAI Scoring*

PAI score	Description of radiographic findings
1	Normal periapical structures
2	Small changes in bone structure
3	Changes in bone structure with some mineral loss
4	Periodontitis with well-defined radiolucent area
5	Severe periodontitis with exacerbating features

*PAI scoring as shown suggested by Ørstavik et al (33).

tenderness to percussion/palpation, the absence of sinus or any associated soft-tissue swelling, tooth mobility of grade 1 or less, and no deterioration in periodontal probing depth as compared with baseline measurements. The periapical status, as observed on radiographs, was assessed by 3 examiners (S.T., J.D., and P.S.) using the PAI score (33) presented in Table 1. Because our study involved multirooted teeth, it was decided to register the least favorable of the scores given to individual roots as the final score of the tooth. During both the clinical and radiographic assessment, it was ensured that the examiners had no knowledge of the patients' treatment protocol or baseline presentation.

To assess intrarater agreement, the examiners repeated the entire exercise with radiographs after 1 month. Intrarater and interrater reliability was determined by Cohen Kappa interrater analysis. Values of kappa from 0.40 to 0.59 are considered moderate, 0.60 to 0.79 substantial, and 0.80 to 1.00 outstanding agreement (34). After completion of the exercise, the examiners met to discuss any ambiguity in scores until a consensus was reached. The scores obtained after the consensus were used for the final analysis. Once the records were completed, clinical and radiographic findings at the follow-up visits were compared with those documented at the time of the preoperative examination. Furthermore, data extracted from the PAI was converted into a nominal scale by considering teeth with PAI score $\leq$2 as healed and PAI $\geq$3 as not healed. The proportion of teeth falling in each group was calculated.

Statistical Analysis

The Kruskal-Wallis test followed by the Mann-Whitney U test and the chi-square test were used to evaluate the difference between groups at baseline and follow-up for ordinal data and dichotomous data, respectively. The Wilcoxon signed rank test was applied for the evaluation of change in the PAI score for each group from baseline to the 12-month follow-up. Multiple linear regression was applied to find out the effect of age, sex, smoking, the initial apical binding file size, and MAF size on the periapical healing. All statistical analysis was performed with an alpha value of 0.05 using 2-tailed analysis. Because almost all teeth were symptom free at the 12-month follow-up, clinical findings were recorded but not analyzed statistically.

Results

After a thorough examination, 167 patients were included at the beginning of the study; 37 patients were lost to follow-up. There was 1 treatment failure at the follow-up period of 3 months in group E when the patient presented with a complaint of pus discharge. A sinus tract was detected on examination, and surgical intervention was considered for further management of the case. At the end of the study, 129 patients were examined with 25, 28, 25, 26, and 25 patients in groups A to E, respectively (Fig. 1). Demographic characteristics for each group (age and sex) are listed in Table 2. An analysis of demographic data revealed no statistical difference between groups with respect to age and sex. Intra- and interrater kappa reliability scores ranged from 0.76 to 0.82.

The mean PAI scores for groups A, B, C, D, and E were 4.68, 4.82, 4.72, 4.77, and 4.84 at the immediate postoperative examination and 2.60, 2.14, 1.88, 2.04, and 1.92 at the 12-month follow-up, respectively. A statistically significant decrease in the PAI score was observed in all the groups from the immediate postoperative examination to the 12-month follow-up ($P < .001$). Improvement (a reduction in the PAI score) was observed in 100% of cases in all the groups. Canal preparation with a 2-size apical enlargement depicted a significantly lower reduction in the mean PAI score than the rest of the groups ($P <$ .05), whereas no significant differences in the reduction in the mean PAI scores was observed between groups B, C, D, and E ($P > .05$) (Table 3). The proportion of successfully healed cases increased with the increase in the apical preparation size with 48%, 71.43%, 80%, 84.61%, and 92% successful healing observed in groups A, B, C, D, and E, respectively. However, the chi-square test revealed a statistically significant difference in the proportion of healed/not healed cases only in group A (Table 4). Regression analysis revealed a significant association of the success rate with the master apical preparation size, whereas no association was observed with age, sex, smoking, and initial apical binding file (Table 5). With the exception of the 1 treatment failure mentioned previously, there were no abnormal clinical findings in any of the groups at the follow-up examination.

Discussion

The present study was designed as a randomized controlled trial to evaluate the effect of the apical preparation size on the success of endodontic treatment. Although an effort was made to homogenize the study groups to the best extent possible, there are several known and unknown factors that could have influenced the results. For example, smoking has been stated to have an influence on healing (35). This factor was not controlled at the time of recruitment in the study. However, contrary to the popular belief, our study did not show any link between smoking and healing. Also, although the size of periapical radiolucency was not controlled, the difference between the sizes in various groups was found to be insignificant. Thus, the potential confounding of results by the preoperative size of the periapical lesion could be ignored. Setzer et al (36) observed that only certain preoperative periodontal conditions including attachment loss can be considered to significantly affect the prognosis of endodontic treatment, whereas Gillen et al (37) observed that the chances of healing of apical periodontitis increased with both adequate root canal filling and restoration. To control these factors, the present study recruited only molars with pocket depths within 4 mm; the quality of the coronal as well as the apical seal obtained by the principal investigator was within the acceptable standards as verified by the supervising staff. Although a recent study (38) did not find an association between FcγRIIIA gene polymorphism with posttreatment apical periodontitis, the authors stated that the tissue response may vary between individuals as a result of genetic polymorphism, thus making some cases more prone to poor outcome compared with others.

It has been suggested that longer follow-up periods may be required when evaluating changes in periapical region after endodontic treatment because the probability of success increases over time (39). However, it has also been shown that most of the radiographic changes are apparent within the first year and that the "late failures," which are relatively uncommon, do not have any significant influence on the overall evaluation of periapical health in a study (40). Longer periods of follow-up pose a problem because clinical studies evaluating the outcome of treatment methods are typically demanding financially and suffer from attrition in the patient pool over time (41).

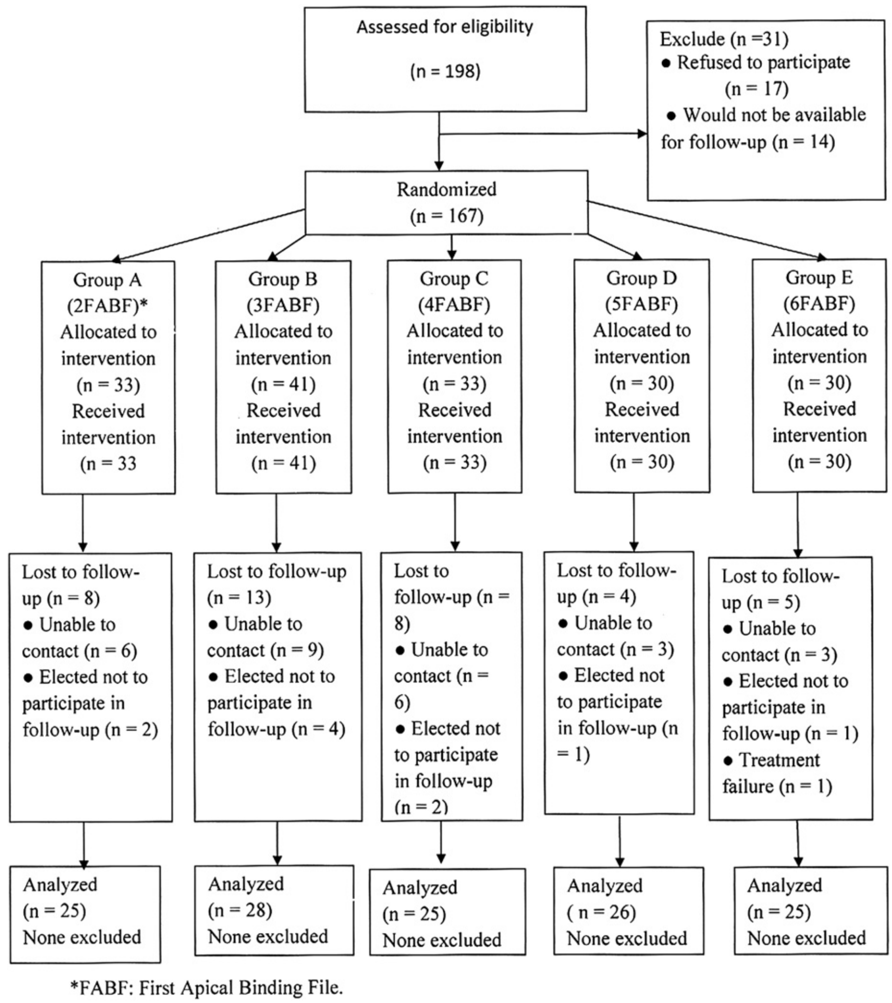

Figure 1. Consolidated Standards of Reporting Trials flowchart.

"Success" in studies is a relative term and subject to the interpretation of the researcher (42). A search of the literature concerning endodontic success will reveal numerous criteria used. Although several studies have used tooth survival as a sole success criteria (43, 44), others have evaluated it clinically and radiographically, either individually or in combination. These criteria too have been applied either rigorously (39, 41) or liberally (42, 43, 45) depending on the examiner. This may explain the wide variation in "success" observed in different studies. In our study, we used the PAI score for radiographic evaluation with a requirement of a periapical radiolucent area with size $\geq 2 \times 2$ mm in all the individual teeth, corresponding to an initial PAI score ≥ 3.

PAI scoring is a fairly error-free, reproducible, and objective system based on the correlation of reference radiographs with histologic diagnosis (33). However, it suffers from 1 potential limitation; it is susceptible to observer variation (46). To overcome this limitation, the radiographs were examined for scoring at 2 separate occasions after which the intrarater and interrater reliability was calculated. Furthermore, in case of disagreement, only the scores obtained with consensus were included for analysis. In this study, intra- and interrater kappa reliability scores ranged from 0.76 to 0.82, suggesting moderate to outstanding consensus.

TABLE 2. Demographic Characteristics

Groups	Male/female	Age (y)
A	12/13	Mean = 33 (range, 18–72)
B	13/15	Mean = 28 (range, 18–53)
C	13/12	Mean = 30 (range, 18–63)
D	16/10	Mean = 27 (range, 18–62)
E	11/14	Mean = 25 (range, 18–40)
Total	65/64	Mean age = 28.6

We attempted to analyze success in more than 1 way. First, we considered PAI as an ordinal scale and compared the improvement in scores observed in each group. Second, we divided the teeth in each group on the basis of a healed/not healed dichotomous outcome. Either way, the statistical analysis revealed similar results. An increase in the success rate observed with an increase in the apical preparation size may be explained by the increased cleanliness of the canal walls and the reduced bacterial load observed with an increase in the apical preparation size *in vitro* (47, 48). However, investigations have also reported that no technique or apical enlargement is capable of completely cleaning the root canals. The fact that most of the cases still heal clinically despite incomplete elimination of debris and bacteria indicates that only an optimum reduction in the 2 may be required to allow healing to occur. However, the definition of this "optimum" is still obscure.

Recent *in vitro* studies have recommended enlargements almost to 6 to 8 sizes larger than the first binding file to obtain complete circumferential cutting of all the canal walls (21, 22). Our study, on the contrary, showed that once the canal had been enlarged to 3

TABLE 3. The PAI Score at the Immediate Postoperative and 12-month Evaluation for Groups A to E

Groups	Baseline PAI score (mean ± standard deviation)	12-month PAI score (mean ± standard deviation)	Change in PAI score with 95% confidence interval
Group A[a] (n = 25)	4.68 ± 0.47	2.60 ± 0.87	2.08 (1.79–2.369)
Group B[b] (n = 28)	4.82 ± 0.40	2.14 ± 0.89	2.68 (2.44–3.00)
Group C[b] (n = 25)	4.72 ± 0.46	1.88 ± 0.73	2.84 (2.55–3.12)
Group D[b] (n = 26)	4.77 ± 0.43	2.04 ± 0.66	2.73 (2.56–3.03)
Group E[b] (n = 25)	4.84 ± 0.37	1.92 ± 0.76	2.92 (2.63–3.20)

The same superscript letters indicate no statistically significant difference at a significance level of $P = .05$.

sizes larger than the FABF, any further increase in preparation size led to only an insignificant increase in the success rate. The success achieved here with smaller apical preparations may be explained on the basis of 3 factors:

1. Use of intracanal medicament, which may have helped in achieving optimum disinfection of canals without the requirement of enlargement to larger sizes
2. Decreased shear stresses observed with larger canal sizes leading to a reduction in debridement efficacy of the irrigant (49)
3. Penetration depth of the irrigating needle, which has been shown to be an important factor governing intracanal microbial control (9)

Studies have also shown that the canal size along with the diameter of the irrigating needle and the depths of its penetration significantly affect the removal of debris from the root canal system (9, 49–51). A study using radiopaque liquids has shown that the apical penetration of the irrigants is only 1 mm beyond the needle tip (50). It is pertinent to note here that we used a 27-G needle for irrigation whose external diameter corresponds to an ISO 40 file and hence can penetrate to 1 to 2 mm short of the apex only in canals enlarged with the step-back technique to a minimum apical size of 30. Thus, a minimum enlargement to size 30 must have been necessary for adequate penetration of the needle into the canal to ensure optimal cleaning of the apical region. This was found to be the average preparation size of canals enlarged 3 times the FABF. Once the threshold for this size was crossed, the efficacy would not differ significantly as was evident in later groups. Although many studies (9, 50, 51) have recommended larger apical preparations for better flushing in the apical third, it must be noted that these experimental works used 23- to 25-G needles for irrigation, which would require larger preparations to reach the apical third. This is further confirmed in a study (52) in which adequate irrigation in the apical region was observed with a 27-G needle in 30 size canals, whereas larger preparations to sizes of 45 and 50 were essential for similar results with 25- or 23-G needles, respectively. Our results are supported by a study that found that apical instrumentation to a #30 size file with a 0.06 coronal taper is as effective as a #35 file for the removal of debris and the smear layer from the apical portion of the root canals (14). It is interesting to note that the authors used a 27-G needle for irrigation, as was the case in this study. A classic study (53) evaluating the influence of the method of canal preparation on the quality of obturation reported that step-back preparations, as used in the present study, showed significantly lesser leakage as compared with standardized preparations. They suggested that preparations with size and taper that allowed the spreader to penetrate to within 1 mm of the working length promoted better sealing of gutta-percha with lateral compaction compared with those which permitted only limited spreader penetration.

The results of *in vivo* studies can be expected to deviate from those of *in vitro* studies on account of several other known and unknown factors that come into play in *in vivo* studies and are absent in *in vitro* studies. Thus, the *in vitro* studies primarily serve to provide a direction for further *in vivo* evaluation, and caution must be exercised before applying their results in clinical situations. As noted earlier, overzealous enlargements may also adversely affect the mechanical properties of root canal–treated teeth (23, 24) and cause complications; hence, they must be avoided.

Our results are contrary to the findings of previous studies that evaluated the effect of the apical size of canal preparation on treatment outcome to date (29–31). Strindberg (29) reported that the success rate of endodontic treatment decreased with an increase in apical size preparation. Although Hoskinson et al (31) did not specify the tooth type with particular size enlargement, they too reported a decrease in the success rate with an increase in the MAF size. However, the study could not find any significant effect of the MAF size on treatment outcome. Furthermore, the distribution of teeth for each enlargement size was not uniform. In contrast, Kerekes and Tronstad (30) found no difference in success rates between roots enlarged to sizes 20 to 40 and those enlarged up to sizes 45 to 100 where success rates of 90% and 91% were observed. However, these results must be interpreted with caution because the tooth type in the 2 groups were distinctly different; the first consisted mainly of roots with 2 canals as well as the buccal roots of maxillary premolars and molars, whereas canals with only 1 root were included in the second group.

The studies conducted by Strindberg (29), Kerekes and Tronstad (30), and Hoskinson et al (31) were all retrospective in nature, and none of these studied the effect of enlargement on success as a primary objective. Retrospective studies suffer from serious shortcomings because they are subject to various forms of bias that may distort their outcomes. Because most of the data are obtained by the researcher before the study is designed, bias can occur during case selection as well as evaluation of the outcome measures (54). The stratification of studies according to the level of evidence (55) assigns such studies

TABLE 4. The Proportion of Teeth Healed and Not Healed in Each Group at the 12-month Evaluation

Groups	Healed (PAI ≤2) (%)	Not healed PAI ≥3 (%)	Improved (%)
Group A[a] (n = 25)	48 (n = 12)	52 (n = 13)	100
Group B[b] (n = 28)	71.43 (n = 20)	28.57 (n = 8)	100
Group C[b] (n = 25)	80 (n = 20)	20 (n = 5)	100
Group D[b] (n = 26)	84.61 (n = 22)	15.38 (n = 4)	100
Group E[b] (n = 25)	92 (n = 23)	8 (n = 2)	100

The same superscript letters indicate no statistically significant difference at a significance level of $P = .05$.

TABLE 5. Multiple Linear Regression to Determine the Association of Dependent Factors with an Improvement Observed in the PAI Score

Determinants	Unstandardized coefficients β	Standard error	Standardized coefficients	Significance value
Constant	1.290	.663		.054
FABF	−.008	.028	−.024	.787
MAF	.037	.010	.323	.000*
Age	.003	.006	.044	.627
Sex	.202	.154	.130	.193
Smoker	−.160	.196	−.080	.417

Adjusted R^2 = 0.078.

*Significant at P < .05.

(29–31) a lowest level of evidence (level 5). The randomized clinical trial conducted here has the highest level of evidence (level 1) and hence is a more meaningful approach to addressing this issue.

Finally, the limitations of the present study should be taken into consideration. These limitations include the smaller sample size, drop-outs, and the use of radiographic criteria for determining the healing rate. Also, more reliable techniques like cone-beam computed tomography scanning may be used to evaluate treatment outcomes because it has been reported to detect more periapical lesions compared with periapical radiographs (56). Long-term studies with a larger sample size may help in confirming the suggested relationship. On the one hand, many studies have associated bacterial reduction with a particular number of file size, it is not practical to recommend a particular file size that ensures better bacterial/debris removal in clinical practice. On the other hand, recommendation for enlargement in accordance with FABF is more practical because the size of the apical binding file varies from case to case. Within the limits of this study, it is concluded that apical enlargement to 3 sizes larger than the FABF is adequate, and any further enlargement may not provide any additional benefit for the long-term prognosis of endodontic treatment.

Acknowledgments

The authors deny any conflicts of interest related to this study.

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