Effect of apical clearing technique on the treatment outcome of teeth with asymptomatic apical periodontitis: A randomized clinical trial

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Abstract

Aim: This study aims to compare the periapical healing of teeth with asymptomatic apical periodontitis treated either by conventional apical preparation (CAP) or apical clearing technique (ACT).

Materials and Methods: Twenty subjects with bilateral nonvital similar teeth exhibiting comparable periapical index (PAI) score were enrolled and randomly allocated. Group I (CAP, n = 20): Apical preparation three sizes greater (master apical file [MAF]) than the first binding file at the established working length. Group II (ACT, n = 20): Apical preparation three sizes greater than the MAF that was followed by dry reaming. Root canal therapy was accomplished in single-visit for all the teeth. They were pursued radiographically at 3, 6, 9 and 12 months. Pre- and post-treatment PAI scores were compared. To ascertain the proportion of healed teeth between the two groups, McNemar Chi-square test was applied.

Results: At 3, 6, and 9 months’ time interval the proportion of healed teeth for Group II (ACT) was greater in comparison to Group I (CAP) (P < 0.05). However, at 12 months follow-up period this difference was not significant (P = 0.08).

Conclusion: ACT enhanced the healing kinetics. However, the long-term (12 months) radiographic outcome was similar for either technique.

Keywords: Apical clearing technique; apical size; conventional apical preparation

INTRODUCTION

Etiology of apical periodontitis can be attributed to direct incursion of microbes or their noxious metabolic by-products emanating from the root canal system into the periapical tissues. Its pathogenesis involves activation of the innate and adaptive immune system coupled with sensory nerve response in the periapical tissues. Clinically, it manifests itself as either symptomatic or asymptomatic apical periodontitis. Elimination of the inciting irritants from the root canal can result in resolution of this disease process. In the hierarchy of treatment modalities, nonsurgical endodontic treatment (NSET) is given preference for the management of apical periodontitis. It is based on firm biological and mechanical tenets and involves thorough chemomechanical preparation followed by three-dimensional obturation of the root canal system.[1] NSET has a success rate of 73–86% in teeth with apical periodontitis.[2] The major cause cited for its failure is the persistence of intracanal bacteria, especially in the apical third of the root canal system.[3] Two hallmark features of this region are its variability and unpredictability. This part harbors complexities such as ramifications, fins, deltas, and webs which act as a cul-de-sac for bacteria.
Thorough instrumentation of the apical region is a critical component of cleaning and shaping. The conventional approach entails enlarging the apical constriction three sizes larger (master apical file [MAF]) than the first apical binding file.

In teeth with apical periodontitis, intracanal bacteria can penetrate the apical dentinal tubules up to a depth of 500 μm. Theoretically, if the first apical binding file is an ISO size 20, with conventional apical preparation (CAP) the final apical size would be ISO size 35. This may be insufficient to eradicate the deeply embedded bacteria from the root canal and thus compromising the dynamics of healing. The mean time taken to achieve radiographic periapical healing by CAP is 12 months. This implies that a tooth may be considered for permanent restoration only after elapse of this period. Such a schedule is difficult to follow in everyday clinical practice because both the dentist and patient are eager to finish the case with a permanent restoration as soon as possible. Therefore, a treatment protocol that may allow for enhanced healing kinetics may be of clinical advantage.

Apical clearing technique (ACT) involves the sequential use of files two to four sizes larger than the MAF at the established working length and this is followed by dry reaming. The primary perceived advantage is the removal of the deeper infected dentin and compacted debris. Till date, no clinical study has established the efficacy of ACT or otherwise for the management of teeth with asymptomatic apical periodontitis.

The hypothesis of the present study was that the ACT in comparison to CAP would result in superior treatment outcome.

**MATERIALS AND METHODS**

**Sample size and case selection**
To attain the radiographic periapical healing with CAP, a period of 10 ± 2 months is required. Assuming that the ACT can achieve the same in 5 ± 2 months, keeping the confidence level at 95%, power at 90% and in addition considering dropouts, 20 healthy subjects of either gender between the age group of 15 and 35 years with asymptomatic, nonvital bilateral similar teeth with no previous endodontic intervention exhibiting comparable periapical index (PAI) score were enrolled. Twenty study subjects that fulfilled the above-mentioned inclusion criteria's were recruited from the patient's pool referred for nonsurgical root canal treatment to the specialty clinic of the department. Ethical clearance from the Institute Research Ethics Committee was obtained. All the procedures were performed under local anesthesia.

**Treatment protocol**
Tooth was anesthetized (LOX 2%, Neon Lab Limited, Mumbai, Maharashtra, India) and under rubber dam isolation, access to the pulp chamber was achieved. It was refined with start-X ultrasonic tips (Dentsply Maillefer, Ballaigues, Switzerland) and cleansed with distilled water. The root canal was prepared in a standard crown-down technique with 0.02 taper NiTi flex K hand file (Dentsply Maillefer, Ballaigues, Switzerland). The electronic working length (Raypex 6® Apex Locator, VDW GmbH, Munich, Germany) was established and confirmed radiographically.

Based on the type of apical preparation, 40 teeth (twenty subjects) were equally distributed using block randomization method. Accordingly, for Group I (CAP, n = 20) apical preparation three size larger (MAF) than the first apical binding file was performed. For Group II (ACT, n = 20) MAF was determined and apical preparation three size larger (Final apical file [FAF]) than that was executed. This was followed by dry reaming which entailed placing the FAF to the established working length and rotating it clockwise at 360°. The irrigation protocol for either group involved the use of freshly prepared 5.25% sodium hypochlorite (Dentpro, Mohali, India) and 15% ethylenediamine tetraacetic acid (Septodont, Codex, France). This was followed by photactivitated disinfection (PAD™ red system, Denfotex Light Systems Ltd., Fife, United Kingdom). Obturation was accomplished with AH Plus® sealer (Dentsply DeTrey GmbH, Konstanz, Germany) and Calamus dual thermoplastic injection system (Dentsply Maillefer, Ballaigues, Switzerland). Teeth were restored with FulFil Extra Universal Composite (Dentsply DeTrey GmbH, Konstanz, Germany). The entire procedure was accomplished in single-sitting.

**Radiographic assessment**
Pre- and post-treatment digital intraoral periapical radiographs were exposed on a size-2 CMOS RVG sensor (Kodak RVG 5100 Digital Radiography System, Eastman Kodak Company, Minneapolis, France) held in a positioning device (Rinn XCP-ORA, Dentsply Int. Inc., New York, USA). A customized polyvinyl siloxane bite block was used to standardize the horizontal angulars. Two trained endodontists who were blinded to the study objectives and methodology were requested to interpret the radiographs. PAI scoring system was applied to assess the size of the periapical lesion at baseline and follow-up interval [3, 6, 9 and 12 months; Figure 2A and B]. To assess intrarater agreement, the examiners repeated the entire exercise with radiographs after one month. Intrarater and intrarater reliability was determined by kappa analysis. The data extracted from the PAI scores was converted into a
nominal scale by considering teeth with PAI score <3 as healed and PAI ≥3 as not healed. The proportion of healed teeth in each group was determined [Table 1].

**Statistical analysis**

Statistical tests were performed using the Stata 11.0 software (Stata Corp, College Station, Texas, USA). To ascertain the proportion of healed teeth between the two groups, McNemar Chi-square test was applied.

**RESULTS**

Twenty patients were included in the beginning of the trial; two patients were lost to follow-up [Figure 1]. No patient reported any adverse experience during the investigation.

Intra- and inter-rater kappa reliability scores ranged from 0.82 to 0.86. This highlights an outstanding agreement.\(^{[9]}\)

At 3, 6, and 9 months’ time interval, the proportion of healed teeth for Group II was greater in comparison to Group I \((P < 0.05)\). However, at twelve month follow-up period this difference was not significant \([P = 0.08, \text{ Table 1}]\).

**DISCUSSION**

Limited literature is available on ACT. Hence, to generate the highest level of evidence, a well-designed randomized clinical trial was conceptualized and undertaken. Although age and gender have not been significantly associated with the potential for healing after nonsurgical endodontic
The tissue response may vary between individuals as a result of genetic polymorphism, thus making some cases more prone to poor outcome. To negate the host response of unlike individuals, bilateral teeth in the same subject were included in this study. A multi-rooted in comparison to the single rooted tooth with apical periodontitis has a lower probability of complete healing. Pathology of the maxilla resolves faster than the corresponding mandibular lesion due to the presence of the extensive vascular network. Furthermore, lesion of the anterior segment of either jaw exhibits accelerated healing due to the proximity of the buccal and lingual plates. Considering these facts, similar teeth of akin maxillofacial bone and anteroposterior segment were compared.

Randomization during subject selection was performed by the “block method.” This guaranteed a balance in sample size and ensured equal treatment allocation within each block. Moreover to eliminate the “patient bias,” the subjects were kept blinded. On a radiograph, the size of the periapical lesion was assessed with PAI scoring system. In the present study, the baseline mean PAI scores for Group I, II were 3.6 and 3.55 respectively with $P = 0.329$. Hence, the preoperative periapical lesion sizes were comparable across both groups. Clinical studies with extended follow-up periods pose a risk of patient attrition. Subsequent to nonsurgical endodontic treatment (NSET), a follow-up of 1 year is sufficient as most of the radiographic changes are apparent within this time frame, and the “late failures” which are relatively uncommon do not have any significant influence on the overall outcome of a study. Presuming that apical clearing would result in radiographic healing as early as 5 ± 2 months a follow-up period of 3, 6, 9 and 12 months was preferred over 6, 12, and 18 months. A recall rate of 90% was achieved which further strengthened the results.

The aim of NSET is to prevent or cure apical periodontitis. The outcome of any intervention should be related to “healing.” In this study, the postoperative PAI scores were converted into a nominal scale by considering teeth with PAI score <3 as healed and PAI score ≥3 as not healed. At 3, 6 and 9 months’ time interval, the proportion of healed teeth were higher for Group II (ACT) in comparison to Group I (CAP) ($P <0.05$).
In long-standing infection, microorganisms can penetrate the dentinal tubules to varied depths. These intra-tubular organisms remain protected from conventional chemomechanical preparation. Deeper dentin removal appears to be the key method for decreasing the bacterial load. In Group II, ACT involved apical preparation two to four sizes larger than the MAF which possibly allowed for the accomplishment of the above objective. Final apical reaming which is the concluding step of ACT aids in the removal of the infected dentin chips compacted in the apical area that can hinder disinfection and obturation. Yadav et al. conducted a study to determine the effect of apical clearing and foramen widening on apical ramifications and bacterial load in root canals and found it to be effective in removing apical ramifications and results in a decrease in colony forming units. On the contrary, conventional approach entails enlarging the apical constriction three sizes larger (MAF) than the first apical binding file. This is based on the presumption that this initial file gauges the apical canal diameter and by using three successively larger files to the same working length, the layer of heavily infected dentine can be removed. However, there is no evidence to substantiate the above-mentioned fact. In addition, since majority of the canals are oval in shape, the validity of this approach is debatable. These combined could be the plausible reasons for enhanced healing with ACT.

However, at 12 months follow-up period, the difference between the proportion of healed teeth was not significant across both groups (P = 0.08), i.e., teeth treated by CAP healed albeit taking a longer duration. This could be credited to the effective irrigation and enhanced disinfection achieved with PAD. Khademi et al. conducted an ex-vivo study to determine the instrumentation size required for the effective penetration of irrigants and elimination of debris and smear layer from the apical third of the root canals. They concluded that a size 30 file was sufficient. This is achievable with CAP.

Prolonged healing process raises the possibility that the activated macrophages in the lesion may maintain their status quo long after the initial cause of their stimulation has been eliminated. The presence of these cells for extended period in tissues results in persistence of their osteoclastic and inhibition of the fibroblastic activity. This can hinder connective tissue and bone repair. Curtailing the healing period can result in faster rehabilitation of the tooth with a permanent definitive prosthesis thus preventing the prolonged use of temporary restorations that may leak and allow recontamination of the obturated root canal. Hence, an enhanced rate of periradicular healing is definitely desirable.

Within the limitations of the present study the obtained results sustained the hypothesis. Longitudinal studies with larger sample size are required to positively substantiate these findings and also evaluate the efficacy of ACT for re-treatment cases.

**CONCLUSION**

ACT enhanced the healing kinetics. However, the long-term (12 months) radiographic outcome was similar for either technique.

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**Conflicts of interest**

There are no conflicts of interest.

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