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Comparative Evaluation of Apical Debris Extrusion during Root Canal Preparation using Three Different Rotary File Systems: A Study Protocol

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Apical extrusion of debris leads to postoperative inflammation and endodontic failure.
Objectives: To comparatively evaluate debris extrusion by using Trunatomy rotary files, 2 shape, ProTaper next rotary files.
Methodology: Sixty Extracted single rooted human premolar teeth will be included in the study. After access opening, canal patency will be established by 15 K-file till the apical foramen followed by determination of working length by visual method. Now the samples will be divided into 3 groups: Group1: Trunatomy, Group 2: 2 shape file, Group 3: ProTaper Next files. Following this the manufacturer's instructions will be followed for the instrumentation. During instrumentation, extruded debris and irrigants will be collected into the preweighed test tubes. Following this, these tubes will be stored in an incubator at the temperature of 70°C for next 5 days. To evaluate the resultant weight of extruded debris, these test tubes will be weighed.
Expected Results: Trunatomy rotary file system is expected to produce less debris than 2 shape, ProTaper Next file system.

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Conclusion: This study would be helpful for clinicians to choose better and efficient file system for instrumentation which produce comparatively less debris extrusion further reducing the chances of endodontic flareup.

Keywords: Apical extrusion; debris; Trunatomy; 2 shape; ProTaper Next.

1. INTRODUCTION

The success of endodontics is based on thorough debridement, disinfection, and obturation in three dimension. A complete root canal debridement by instrumentation and irrigants is the critical step in endodontic management [1]. During the root canal instrumentation dentine chips, necrotic tissue, microbes, intracanal irrigants, pulp tissue fragments may extrude from apical foramen leading to the pain or flare-up [2].

Flare up is “acute exacerbation of periradicular pathosis after an initiation or in the continuation of the root canal treatment within few hours or days and it is of sufficient severity requiring an emergency unscheduled treatment” [3]. The factors leading to the inter appointment flare-ups can be chemical, mechanical, as well as microbial injury to the pulp or the periapical tissues [4].

Irrespective of various techniques with the instruments used, biomechanical preparation of canal leads to extrusion of the debris into periradicular tissues even while maintaining canal preparation short of apical terminus [5]. This leads to extrusion causing induction of pain and/or edema because of the inflammatory response. According to reports, these undesired consequences occur between 1.4% and 16% of the time. Chapman et al was first to document extrusion of infectious material from the root canal in between the instrumentation [6]. The evaluation of debris which are extruded apically in between instrumentation were first quantified by Vande Visse and Brilliant [7].

It is reported that the in-and-out instrumentation motion produces more apically extruded debris than the rotational motion since rotary instruments were having an ability of pulling the debris into the flutes of the instrument, which pushes the debris out of canal in coronally. Studies have proven that various changes in NiTi rotary design have been done to reduce the debris extrusion. Still, no method or technology had been proven to be full proof in preventing debris periapically, only the extent varies.

Recently, Trunatomy file system (Dentsply Sirona) is introduced which has a special 0.8mm NiTi heat treated wire, instead of the 1.2 mm NiTi wire [8]. The file has Off-centered parallelogram cross-section design, with an improved flexibility and the cyclic fatigue resistance, slim design, superior canal-centering ability.

Micromega offers 2 shape file system of continuous rotation. These are heat-treated by T Wire technology [9]. It has asymmetrical triangular cross section causing reduction in the risk of instrument fracture and increasing the efficacy for brushing movements which leads to effective selective cleaning.

ProTaper Next (Dentsply Sirona), works on a traditional continuing rotational motion. These are manufactured from the M-wire technology having a rectangular off-centered cross-section ,ensuring only two-point contact with canal wall at a given time [10]. Due to these characteristics, canals are cleaned efficiently and have increased strength and reduced lateral and apical compaction of debris.

So, the study’s purpose is “to compare the amount of debris extruded apically using Trunatomy , 2 shape, ProTaper Next rotary file systems”.

1.1 Aim

To evaluate and compare the apical extrusion of debris during biomechanical preparation using three different rotary systems

1. Trunatomy file system (Dentsply Sirona)
2. 2 shape (Micromega)
3. Protaper Next (Dentsply Sirona)

1.2 Objectives

1. To evaluate debris extrusion by using Trunatomy rotary files.
2. To evaluate debris extrusion by using 2 Shape rotary files.
3. To evaluate debris extrusion by using ProTaper Next rotary files.

4. To compare debris extrusion by using Trunatomy, 2 shape, ProTaper Next rotary files.

2. MATERIALS AND METHODS

2.1 Sources of Data

The study will be conducted in Sharad Pawar Dental College, In Department Of Conservative Dentistry And Endodontic in 60 extracted premolars.

2.2 Statistical Analysis

Based on the result of previous studies, sample size is calculated by using the formula :-

$$n = (Z_\alpha + Z_\beta)^2(\delta_1^2 + \delta_2^2/K) / \Delta^2$$

Where Z_α = is the level of significance at 5% i.e. 95% confidence interval = 1.96
Z_β = is the power of test = 80% = 0.84
δ1 = SD of mean debris in Protaper =0.00024
δ2 = SD of mean debris in Revo –S = 0.00018
Δ = Difference between 2 groups

So by above formula sample size will be 60. Thus each group will have a sample of 20.

= 20 Samples needed in each group

The mean of the dry weight of extruded debris will statistically analyzed by using SPSS, version 12. For the intergroup comparison Chi square test ,One way Anova test, Post hoc Tukey test will be used.

2.3 Study Design

In this study, a total of 60 samples will be divided into three groups:

The groups are as follows:

Group 1. 20 samples with Trunatomy file system (Dentsply Sirona)

Group 2. 20 samples 2 shape (Micromega)

Group 3. 20 samples Protaper Next (Dentsply Sirona)

2.4 Inclusion Criteria

60 freshly extracted single rooted mandibular premolars that will be extracted for orthodontic reason with the fully formed apices. Teeth with single root canal and apical foramen with root curvature between 0° and 20° (Schneider's method) which will be confirmed with mesiodistal and buccolingual radiographs will be used for this investigation. The presence for the single canal will be confirmed by the radiographs which are taken in buccal and proximal direction.

2.5 Exclusion Criteria

- Fractured teeth
- Teeth with tooth resorption
- Teeth having root caries
- Teeth having calcified canals and/or bifurcated/trifurcated root canals
- Previous endodontic treatment

2.6 Materials

- 60 freshly extracted mandibular premolars
- Irrigation needle
- Distilled water
- EDTA Gel (Prime Dental)
- Test tubes
- Trunatomy files (Dentsply Sirona)
- 2 shape files (Micromega)
- Protaper next files (Dentsply Sirona)
- Endomotor
- Electronic microbalance 0.00001mg accuracy
- Incubator

STEP: 1] The teeth will be cleaned for the soft-tissue remnants and debris ,followed by storing in the distilled water. Using high-speed diamond disks, all teeth will be measured for tooth length and decoronated for a standard tooth length of 16 mm. Afterwards, access cavities will be prepared in all sample teeth [11]. The working length will be evaluated by a size 10 K-file, until it will be visible at the apical foramen followed by subtraction of 1 mm from the measurement. The minor constriction size will be standardized, and any tooth where the size 15 K-file is extruded beyond apical foramen will be excluded

STEP: 2] The experimental model which is designated by Myers and Montgomery method [12] will be used in this study. The test tubes with separated stoppers will be used in the study. The flower arrangement foam will be placed in tube for simulation of the slight resistance of periradicular tissues. On every stopper, a hole will be created and each tooth will be cemented up to CEJ and open ended 25-G needle will be inserted on the side of the tube stopper, acting

Chart 1. Three groups each containing 20 samples

GROUPS	File system	Sample size
Group 1	Trunatomy file system (Dentsply Sirona)	20
Group 2	2 Shape (Micromega)	20
Group 3	ProTaper Next (Dentsply Sirona)	20

as a drainage canula to maintains pressure inside and outside of the tube. The electronic microbalance having accuracy of 0.00001g used for measurement of the preliminary weights of the test tubes. The mean value for all the three successive weights for each tube will be calculated.

STEP: 3] Based on to the rotary file used for the biomechanical preparation, the sample teeth will be divided randomly into three groups with 20 each.

STEP: 4] All the instrumentations will be performed using a 16:1 gear reduction handpiece powered by a torque-controlled electric motor (X-Smart motor, Dentsply, Maillefer, Switzerland; Europe) at speed of **300 rpm and 2 Ncm torque.**

After every time the instrument is withdrawn from the canal, 1ml of distilled water will then be used. We will then perform irrigation with an in-and-out motion of the syringe using a irrigation needle placed up to 3 mm of the working length. Here, maximum volume of irrigant for each group is limited to 8ml. The apex to be prepared till #25 file for each instrumentation technique.

STEP: 5] Once instrumentation is finished, root canal irrigation with the 2ml of final irrigation with distilled water. After instrumentation the needle, stopper, and the sample tooth will be separated from test tube after chemo mechanical root canal preparation. The external tip of the tooth will be irrigated using 2 ml distilled water.

STEP: 6] After that these samples will be kept in an incubator at the temperature of 70°C for 5 days for the evaporation of distilled water before calculating the weight of the dried debris. Using an electrical analytical balance, the final weight of the tubes containing the extruded debris will be determined. The mean value of the consecutive three weights for each tube will be calculated. On subtraction of the weight of empty tubes with foam from the tubes containing extruded debris, the dry weight of extruded debris will be calculated.

3. EXPECTED RESULTS

Trunatomy rotary file system are expected to give better results than 2 Shape, ProTaper Next file system.

4. DISCUSSION

Apically extruded debris following root canal treatment leads to postoperative complications – like the inflammation, the postoperative pain, and delay in periapical healing. Additionally, debris extruded during treatment are responsible for persistent apical area inflammation. Hence, decrease in a debris extrusion is necessary for reduction in postoperative complications.

In this study, periapically extruded debris will be collected on the basis of broadly accepted experimental setup of “Myers and Montgomery”. Although this study cannot mimic the vital periradicular tissues, the technique allows comparing in between the file systems. As a irrigant distilled water was used for avoiding any possible increase in debris weight due to crystallization of sodium hypochlorite.

In the study conducted by Paramasivam Vivekanandhan et al. on the periapical debris extrusion in between the root canal instrumentation of by use of two rotary and one reciprocating Ni-Ti systems in sixty extracted mandibular premolars. Protaper, Revo-S and WaveOne file system were used. Statistical analysis was done using GraphPad prism version 6 and unpaired t-test was used for the intergroup comparison. This study concluded that less debris extrusion was associated with the Revo-S file compared to Protaper and WaveOne file [13].

In another study conducted by Fatih Cakici et al. compared the quantity of periapically extruded debris following the root canal instrumentation by use of four various instrumentation systems in eighty human mandibular molar teeth. “ProTaper Gold, ProTaper Next, ProTaper Universal, and RECIPROC” were used. The data analysis was done by SPSS. For comparison of the mean value of debris, one-way variance analysis with

the post-hoc Tukey's test was used. This study concluded that PTU was related with considerably greater extruded debris compared to the PTG, PTN, and RECIPROC, while amongst the RECIPROC and PTN no major difference was found [14].

In study performed by Ami R Patel et al on quantitative analysis of periapically extruded debris in between the root canal procedure by using three various instrumentation systems. For this study, mesiobuccal canal of freshly extracted ninety mature mandibular molars were selected. WaveOne Gold, SAF, and Hyflex EDM file systems are used [15]. The statistic comparison in debris extrusion was analyzed with the post hoc Tukey test. This study concluded that SAFs extrudes comparatively less debris amount than that of WOG and HEDM [16].

There is a need of further studies for assessment of the extrusion of debris along with intracanal irrigants. Further in vivo studies are also needed for evaluating the post instrumentation pain with these instrumentation systems.

5. CONCLUSION

This study aims for evaluation and comparison of the apical extrused debris during biomechanical preparation using Trunatomy ; 2 shape ; Protaper Next rotary file systems.

6. LIMITATIONS

The results which will be obtained cannot be generalized for teeth with severely curved canals, multiple roots, open apices, incomplete root development.

The study will not assess the correlation of debris extrusion with various irrigation systems, the reassessment of apical dentinal plug, histopathological correlation of periapical inflammation with apical debris extrusion.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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