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COMPARATIVE ASSESSMENT OF APICALLY EXTRUDED DEBRIS USING PROTAPER NEXT, HYFLEX CM AND EDGEFILE X7 NICKEL TITANIUM INSTRUMENTS (AN IN VITRO STUDY)

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ABSTRACT

Aim: To compare the amount of debris extruded after the use of three endodontic NiTi engine driven systems; Protaper Next, Hyflex CM and EdgeFile X7 rotary files.

Material and Methods: A total number of 42 freshly extracted human premolars were selected. Teeth were randomly divided into three equal groups (14 teeth each group) according to type of Ni-Ti rotary file system; (A) Protaper Next, (B) Hyflex CM and (C) EdgeFile X7. Standard Access cavity prepared and checked for patency using K file #10 and #15. Root canal instrumentation on the single canal lower premolars was done. Debris was collected after root canal instrumentation in pre-weighed Eppendorf tubes. The tubes were weighed 2 times on the analytical balance. First weight: Before instrumentation. Second weight: After evaporation of moisture and irrigant and incubation. Welch test was used for inter-group comparison.

Results: No statistically significant difference was detected in the amounts of debris extrusion among the three groups

Conclusion: All the tested endodontic rotary instruments caused apical extrusion of debris.

KEYWORDS: Debris Extrusion; EdgeFile X7; HyFlex CM; Protaper Next, Rotary Instrumentation.

INTRODUCTION

During root canal preparation, necrotic pulp tissue, pulp fragments, microorganisms, may be extruded into the periradicular area despite of strict control on the root canal length. The apical extrusion of infected debris causes disruption of the balance between host defense and microbial virulence resulting in attacks of flare-ups 1. Literature has reported that non-contaminated dentin and pulp tissue as well, can trigger an inflammatory reaction when forced apically during mechanical instrumentation.

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All root canal preparation techniques cause to some degree apical extrusion of debris; nevertheless, the amount of debris pushed apically varies according to the preparation technique 2. Rotary instruments behave differently in terms of apical extrusion of debris due to the variation in their design in terms of radial lands, taper, flute design, materials used and kinematics 3, 4.

Major advances in the manufacturing and metallurgy of rotary instruments have led to the introduction of various systems with novel designs over the past years. The ProTaper Next (PTN) (Dentsply-Maillefer, Ballaigues, Switzerland) rotary system is a member of the fifth generation of NiTi files. It is fabricated with M-Wire using novel heat treatment process 5. PTN is designed to operate with the center of rotation located off-center, to produce a mechanical wave of motion that travels along the length of the working part, reducing the engagement of the file to the dentin. The offset design of the instrument improves the flexibility as well as debris removal 6.

The HyFlex CM multiple-file system (Coltene-Whaledent, Cuyahoga Falls,OH, USA) is manufactured from Controlled Memory (CM) wire that had undergone thermo-mechanical surface treatment, improving the fatigue resistance performance of the file 7. That unique design feature of the CM instruments provided higher flexibility and enables the instruments to maintain the original canal anatomy, thereby minimizing the risk of transportation as well as enhancing the safety during instrumentation

EdgeFile X7 instruments (EF) (Edge Endo; Albuquerque, New Mexico, United States) is manufactured by a proprietary process called FireWire, which is a combination of heat treatment and cryogenic applications that increases the flexibility and fracture resistance 8.

The aim of the present study was to compare the performance of the Protaper Next, Hyflex CM and EdgeFile X7 files in terms of the amount of the apical debris extrusion produced during endodontic treatment. The null hypothesis is that there would be no statistically significant difference among the tested groups in terms of the amount of apically extruded debris

MATERIALS AND METHODS

Sample size calculation

By adopting an alpha level of (0.05) a beta of (0.2) i.e. power=80% and an effect size (f) of (0.498) calculated based on the results of **Tanalp, Jale, et al. 9**; the predicted sample size was a total of (42) samples. Sample size calculation was performed using G*Power version

1- Sample selection and preparation

Freshly extracted human permanent single rooted intact mandibular premolars were collected from the clinic of the Department of oral and maxillofacial surgery, Faculty of Oral and Dental Medicine, Future University. Mandibular premolar teeth were extracted due to periodontal and prosthetic reasons. Teeth were cleaned from outer debris with ultrasonic then disinfected by sodium hypochlorite for 30 minutes and stored in saline solution for use.

The selected teeth met the criteria of no root caries, no internal or external resorption, no root canal calcification, no pulp stones, single canal and completely formed apices. The curvatures of the selected samples were measured by using Schneider method 10. Teeth that possess a curvature between 0 and 10 degrees were only included in the study.

The teeth were decoronated at the cemento-enamel junction using high-speed hand piece. Root canals were checked for patency to exclude teeth with root canal calcification or pulp stones. The working length was then established using #15 K-file (Mani, Japan) seen through the apex. The working length was calculated as 1 mm shorter than this length.

2- Sample Classification

The experimental samples were divided into 3 main groups: Group I: Protaper Next (n=14), Group II: Hyflex CM (n=14) and Group III: EdgeFile X7 (n=14) for evaluation of apically extruded debris.

3- Method of evaluation

A modified version of the experimental model described by Myers and Montgomery 11 was used to assess the amount apically extruded debris. Empty Eppendorf tubes were sterilized, numbered and weighed using an analytical balance three times and average weight was calculated (W1). Then, a hot instrument was used to create a hole in the stopper of the Eppendorf tubes. External root surface was covered with double layer of nail polish except for 1 mm around the apical foramen. Roots were inserted into these holes under pressure and a 27-gauge bent needle that was inserted alongside the stopper to balance the air pressure. The whole apparatus was then assembled into a glass vial and the vial was covered with aluminum foil. After instrumentation and irrigation, separated stopper with the root were removed from the pre-weighed Eppendorff tube, the external root surface was flushed with 1 mL distilled water to collect debris adhering to external root surface. Then, the vials were placed in the incubator at 65^{o} C for 3 days with placement of Calcium Chloride inside the incubator to ensure moisture removal. The apically extruded debris collected in the pre-weighed Eppendorf tubes were weighed again (W2) after instrumentation and evaporation of moisture and irrigant. The amount of apically extruded debris was determined by subtracting the average weight of the pre-weighed Eppendorf tubes from the average weight of Eppendorf tubes containing the dried debris obtained from three consecutive measurements (W2 -W1). All measurements were done using analytical balance.

The root canals of the 3 groups were mechanically prepared using ProTaper Next, Hyflex CM and EdgeFile X7 rotary instruments, respectively. The crown-down technique was used during the shaping procedure according to the manufacturer protocol utilizing a torque-controlled endodontic motor (X-Smart, Dentsply Maillefer)

Group I: ProTaper Next (n=14): The root canals were prepared using the ProTaper Next rotary system with gentle in and out motion (300 rpm /2 Ncm). The instrumentation sequences were X1 (17/04), X2 (25/06), and X3 (30/075). All instruments were used till the working length.

Group II: Hyflex CM(n=14): The root canals were prepared using HyFlex CM instruments proceeding in the canals (500 rpm/ 2.5 Ncm) with sequence file (25/08), file (20/04), file (25/06), and file (30/04). All instruments were used at the working length.

Group III: EdgeFile X7(n=14): The root canals were prepared using EdgeFile X7 according to the manufacturer instructions. Files were operated (300 rpm/ 3Ncm) in the following sequence: file (17/ 04), file (20/04), file (25/04), and file (30/04) until the full working length.

All canals were irrigated with 1mL of distilled water between each successive file with 30-gauge needle tips (NaviTip, Ultradent, South Jordan, UT, USA) 2mm short from the working length. For each root canal, 1 set of instruments was used then discarded after use.

Statistical analysis:

Numerical data was represented as mean and standard deviation (SD) values. Shapiro-Wilk's test was used to test for normality. Homogeneity of variances was tested using Levene's test. One-way ANOVA test was used to analyze intergroup comparison. The significance level was set at $p<0.05$ within all tests.

RESULTS

Results of intergroup comparisons presented in table (1) showed that there was no significant difference between different groups (p=0.070). The highest mean value of extruded debris was found in Hyflex CM group (0.004±0.004), followed by Protaper Next (0.003±0.002), while the lowest value

was found in EdgeEndo X7 group (0.002±0.001). Mean values of extruded debris (gm) in different groups were presented in figure (1).

TABLE (1): Mean and standard deviation (SD) values for extruded debris (gm) in different groups

Extruded debris (gm) (Mean±SD)			p-value
Protaper Next	**Hyflex**	**Edge**	
0.003±0.002	0.004±0.004	0.002±0.001	**0.070ns**

ns; non-significant (p>0.05)

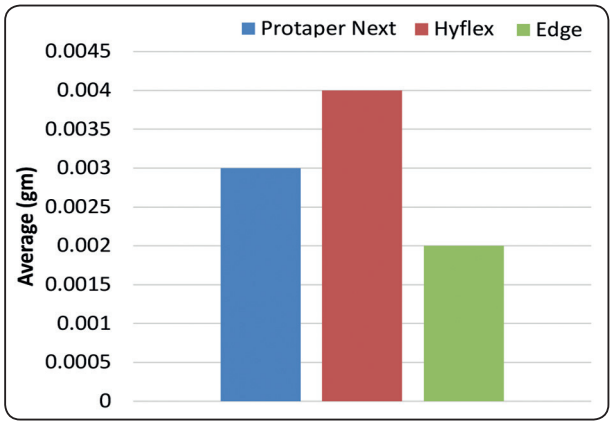

Fig. (1) Bar chart showing average extruded debris (gm) in different group

DISCUSSION

A significant complication which is undesirable for both the patient and the practitioner is the inter appointment flare-ups that occur as a sequelae of apical extrusion during root canal treatment. When debris is pushed out of apical foramina, it will result in an Ag-Ab reaction. This reaction will generate an acute inflammatory reaction in the periapical tissues, and cause damage to the cell membrane causing prostaglandins release, and ultimately pain for patient [12, 13]. Thus, reduction in debris extrusion during canal preparation will lessen the postoperative pain after endodontic treatment [14].

In this study, three different NiTi rotary systems were evaluated in terms of apically extruded debris using a commonly accepted methodology 11. This methodology has been previously used and generally accepted **(Kocak et al. [4], Burklein & Schafer [15], Ghivari et al. [16], Burklein et al. [17])**. The main drawback of the method is the inability to mimic vital periapical tissues 18.

At the present study, ProTaper Next rotary file system was used as the control group since the design of its apical portion and its off-centered rectangular cross section lead to debris removal in a coronal direction resulting in less debris extrusion **Kocak [14], Ozsu [19]** and **Cicek [20].**

On the other hand, the other two rotary file systems, HyFlex CM and EdgeEndo X7 were selected as they possess enhanced flexibility when compared to conventional Ni-Ti instruments. The reason for selecting single-rooted teeth having single canals and low curvatures was to reduce the complications arising during the mechanical preparation of severely curved root canals.

In the present study, standardization was applied by using the same methodology of Reddy and Hicks [21] regarding the master apical size selection. Whereas, the final apical preparation diameter was set at size 30 for all the tested groups for standardization purpose which is an essential requirement for comparison of debris extrusion of different root canal instruments [22].

The selection of the irrigant has an impact on the quantitative values of the extruded debris. It might seem more logical to select an irrigant routinely used during endodontic procedures, such as NaOCl, as it reflects precisely the clinical conditions. Nonetheless, sodium crystals are inseparable from debris and might adversely affect the reliability of the experimental methodology. Thus, distilled water was used as an irrigant to avoid false weight measurements resulting from possible crystallization of sodium hypochlorite irrigant [18].

The results of this study showed that all instrumentation systems produced extruded debris with different values that were in agreement with other studies [15, 16, 23, 24] who found that all the instrumentation techniques extruded debris apically. According to the results obtained, there was no significant difference between Protaper Next, Hyflex CM and EdgeEndo X7 systems in terms of mean weight of apically extruded debris. Differences in the results between the three rotary systems may be caused by the instrumentation technique, technical skills or the cross-sectional designs of the instrument [15].

The PTN is an excellent rotary file system which is thermo-mechanical processed resulting in a reported increased flexibility and very few reports indicate apical extrusion of debris after its clinical usage. It has off-centered rectangular cross section that gives the file a snakelike motion through the root canal. The high cutting efficiency reduces the shaping time. This can be the main advantage of the file and may lead to least debris extrusion [25]. Another explanation of this finding was that PTN causes less debris extrusion due to its metallurgy. The presences of martensitic phase in NiTi alloy (M wire) ensure a reduced amount of apical extrusion at a similar torque than austenitic NiTi alloy. These metallurgical properties provide less stiffness and reduced restoring force to the instruments that could justify the reduced amounts of debris extrusion after root canal preparation [26, 27]; hence, it was used as one of the instrumentation techniques for the present study.

HyFlex CM rotary system present the recent metallurgy technology presented as the CM wire which contains a smaller percentage of nickel than other systems [28]. **Kocak et al** [29] and **Labbaf** [30] demonstrated that Hyflex files produced less debris extrusion as, unwinding the spirals of HyFlex rotary system occurs during instrumentation. This phenomenon may lead to decrease in the cutting cleaning ability of the instrument. As a result, production of the dentinal chips and debris were decreased.

EdgeEndo X7 showed high flexibility due to the small parabolic cross-section, the surface electropolishing and the thermal treatment [31]. The thermal treatment results in an increased flexibility, where the file maintains the canal curvature well and causes less canal transportation. Maintaining the canal curvature has been shown to result in less iatrogenic defects and thus reduced potential to create and extrude debris [32]. Also, EdgeEndo X7 possesses a variable helical angle reducing the screwing in effect, **Koch et al.** [33] stated that files with constant helical angle allow debris to accumulate and varying the helical angle enhances removal of debris more efficiently.

It has to be mentioned that the results of this study should not be directly correlated to clinical situations. No attempt was made to simulate the presence of vital pulp or periapical tissues, and an *in vivo* model might give different results, as periapical tissues may serve as a natural barrier, inhibiting debris extrusion. Results differ greatly with the positive and negative pressure at the apex, 34 as well as with normal or pathological periapical tissues. Furthermore, this study was limited to teeth with mature roots. Results cannot be applied to teeth with immature apices.

The null hypothesis was accepted as the results of this study showed that, there was no significant difference in the amount of apical extruded debris among the tested groups.

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