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Evaluation of Apically Extruded Debris During Root Canal Preparation Using ProTaper Ultimate and ProTaper Gold: An *Ex Vivo* Study

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ABSTRACT

Objective: To assess the extruded debris apically by the ProTaper Ultimate rotary nickel-titanium files compared to the ProTaper Gold files on preparing the mesiobuccal root canals of mandibular molars.

Methods: Thirty mandibular molars with mesial canals showing Vertucci Type-IV configuration and curvatures ranging between 20° to 40° were selected and divided into two groups per the rotary files used for root canal shaping (n=15). Myers and Montgomery's methodology was adopted for the collection of debris. The average weight of the collected dried debris was recorded and statistically analyzed using the independent t-test at a significance level of ($p<0.05$) after log transformation.

Results: The ProTaper Ultimate showed significantly less debris extruded (2.35±0.65 mg) than ProTaper Gold (3.25±0.47 mg) ($p=0.001$).

Conclusion: ProTaper Ultimate can efficiently prepare curved root canals with the minimal amount of apical debris extruded compared to ProTaper Gold.

Keywords: Apical debris extrusion, nickel-titanium, postoperative pain, ProTaper Gold, ProTaper Ultimate, root canal preparation

HIGHLIGHTS

- ProTaper Ultimate can efficiently prepare curved root canals with less debris extruded apically compared to ProTaper Gold.
- Apical debris extrusion during root canal shaping is inevitable.
- ProTaper Ultimate files might cause less postoperative pain compared to ProTaper Gold files.

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INTRODUCTION

The long-term success of conventional root canal treatment depends on the quality of each procedural step performed. Proper coronal access cavity preparation allows for straight-line access to the initial canal curvature (1), which in turn helps achieving thorough disinfection of the root canal system (2). Various rotary nickel-titanium files are used to enlarge and clean the root canal; however, this instrumentation will unintentionally lead to debris extrusion apically (3). These debris harbour bacterial cells, necrotic pulpal tissues, intracanal medicaments, irrigants, and dentinal cutting debris (4). These apically extruded debris can elicit an inflammatory response and are considered one of the major causes of interoperative flare-ups (5). Several factors influence the quantity of extruded debris (6). Nevertheless, no existing instruments or preparation techniques can totally prevent debris extrusion (7).

One of the major design features of the recent rotary nickel-titanium files is the flute and pitch design to help moving the debris in a coronal rather than an apical direction (6). Several improvements have been made to the recently launched rotary nickel-titanium files in order to facilitate and shorten the shaping procedures as well as preserve the precious radicular dentine and minimized the apical debris extrusion.

The ProTaper Gold system (PTG) was launched following the same basic fundamental design features of its predecessor, the ProTaper Universal, maintaining the progressive taper as well as the convex triangular cross-section (8). It is a thermally treated multifile system that operates in continuous rotation demonstrating improved cutting efficiency and less stress accumulation due to less contact with the radicular dentine (8, 9).

A recently introduced rotary system from the ProTaper series is the ProTaper Ultimate (PTUT). It also shows the unique progressive taper feature, being fixed from D1 to D3, and then gradually decreasing starting from D4 till the D16. This design helps create the ProTaper ultimate deep shape, which is claimed to allow for conservative canal preparation and less debris extrusion (10).

To the knowledge of the authors, only one research evaluated the apical debris extrusion by the ProTaper Ultimate files in single-rooted mandibular premolars with moderate curvature (11). Another study investigated the effect of the temperature of the irrigant on the apical debris extrusion by ProTaper Ultimate files (12). Therefore, this study aimed to compare and evaluate the ProTaper Ultimate and ProTaper Gold rotary files in terms of apical debris extrusion in preparing mandibular mesiobuccal canals. The null hypothesis tested was that there would be no difference in the amount of apically extruded debris between the two rotary nickel-titanium file systems tested in preparing mandibular mesiobuccal canals.

MATERIALS AND METHODS

Study Design and Ethical Approval

This study was designed as an *ex vivo* comparative study with an approval number of "IRB/COD/STD/32/June-2022".

Sample Size Calculation and Selection

A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that no difference would be found between tested groups regarding the weight of apically extruded debris. By adopting alpha (α) and beta (β) levels of (0.05) (i.e., power = 95%), and effect size (d) of (3.62) calculated based on the results of Sinha et al. (13), the minimal total required sample size (n) was found to be (n=18) samples (i.e., 9 samples per group). Sample size calculation was performed using R statistical analysis software version 4.3.2 for Windows (The R Foundation, Auckland, New Zealand).

Thirty freshly extracted mandibular molars were used. Inclusion criteria were intact mandibular first and second molars with fully developed apices, mesial root with two separate canals (mesiobuccal and mesiolingual), mesial root with curvature angles ranging from 20°–40° according to Schneider's method (14) and curvature radius less than 6 mm, and narrow canals; which cannot accommodate files larger than #15 K-file (Mani Inc., Takenzawa, Japan) loosely. The exclusion criteria were previously endodontically treated mesiobuccal canals, calcified canals, root resorption, and canals showing no apical patency or developmental abnormalities.

Sample Preparation and Classification

The teeth were cleaned from debris and soft tissues using an ultrasonic device (Acteon, Norwich, England). In order to achieve a standard root canal length of 16 mm, decoronation was performed using a diamond disk (Kerr, Detroit, MI, USA). The mesial roots were separated at the furcation area with a diamond disk (15).

The mesiobuccal canals were localized, and negotiated using manual stainless steel K-files size 8 (Mani Inc., Takenzawa, Japan). A dental operating microscope (Global Surgical Corporation, Saint Louis, MO, USA) was used at a magnification of 8X to properly and accurately determine the working length for the root canal shaping procedures by deducting 1 mm from the tooth length (15, 16). K-file #10 was used to ensure canal patency. Periapical radiographs were exposed mesiodistally and buccolingually to ensure the presence of a separate mesiobuccal canal [Vertucci type IV (17)]. All canals were manually prepared using small stainless steel K-files till they could accommodate a size 10 K-file to the working length. All roots were labeled with numbers from one to 30. A computer algorithm was generated from (https://www.random.org) in order to achieve randomization of the samples into two equal groups (n=15).

Apparatus Setup and Root Canal Instrumentation

An analytic balance scale (Analytical balance standard plus, Kartuska, Poland) with an accuracy of 10–4g was used to weigh the 30 empty Eppendorf tubes separately after being labeled three times (18). Afterward, the tubes were placed into the glass vials, and a round hole was created in the tube lid. The root sample was inserted up to the level of the cementoenamel junction and fixed with a flowable composite (3M ESPE, Bayem, Germany) to seal the gap between the lid and root. An irrigating needle tip of a gauge of 27-G (Ultradent, South Jordan, UT, USA) was inserted for pressure equalization. Aluminum foil was used to cover the apparatus during the instrumentation phase as shown in (Fig. 1) (19).

A size 15 K-file was used for glide path creation initially. Both rotary file systems tested were used with speed and torque settings as recommended by the manufacturer. The Endo MateTC2 endodontic motor (NSK, Tokyo, Japan) was set to a continuous rotation with standardization of speed at 350 rpm, and torque setting at 2.5 N/cm. For the PTUT group, the following file sequence was used; Slider, Shaper, F1, and F2. For the PTG group, the following file sequence was used; S1, S2, F1, and F2. Each set of files was used to prepare only one canal and then discarded.

During root canal preparation, a slight in-and-out movement, following the canal anatomy passively with minimal

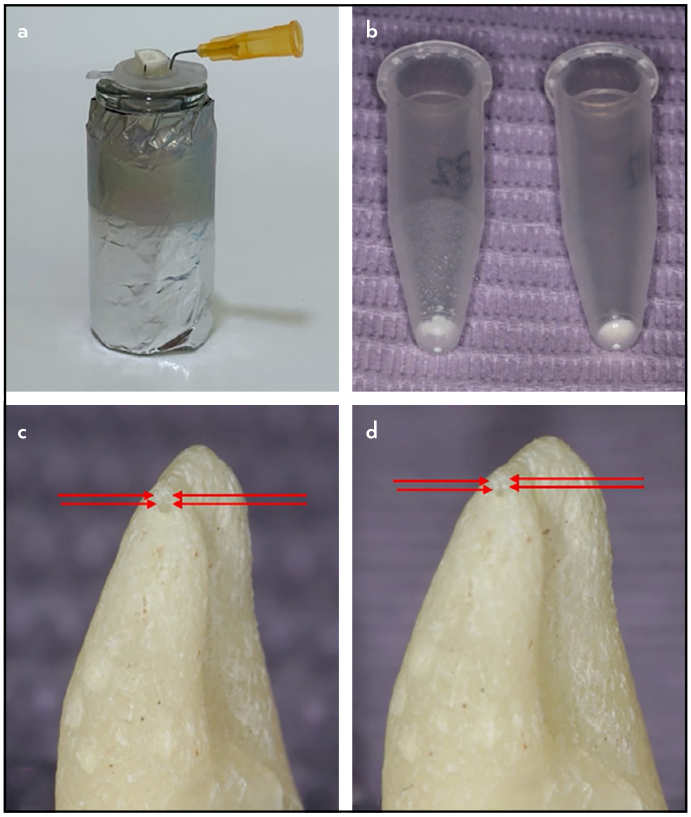

Figure 1. Photomicrograph of the methodology adopted, (a) apparatus assembly; (b) dried extruded debris; (c) mesiobuccal root tip before instrumentation; (d) mesiobuccal root tip with debris extruded through the apical foramen after instrumentation, red arrows pointing to the apical foramen

apical pressure, in a gentle pecking motion till reaching the determined working length. Apical patency was maintained throughout the procedural steps.

Irrigation Protocol

An open-ended NaviTip 29 G (Ultradent, South Jordan, UT, USA) was used to irrigate the root canals during the procedure using room-temperature distilled water. The irrigating tip was placed 2 mm shorter than the working length. The volume of the irrigant was kept constant throughout the procedure, being 10 mL per root canal. Irrigation was performed between every two successive files and the following three pecks using the same file. Washing of the root canal was performed using one millilitre of distilled water after completion of the shaping process. This final wash helps in collecting any residual debris (19).

Final Weight Calculation

Before the final weight calculation, all the tubes were removed from the glass vials and placed in an incubator for five days at 70°C. This incubation period allows all samples to totally dry out removing any remnants of water in the specimens which will affect the final weight later (19). The tubes were weighted thrice and the average was recorded. Then, the weight of extruded debris was calculated as the difference between the pre-and post-weights.

All teeth were prepared by the first author. In order to eliminate bias, the last author was kept blinded to the sample grouping and was responsible for the weighing of the samples before and after instrumentation. The biostatistician was blinded to the sample grouping as well.

TABLE 1. Descriptive statistics for the weight of extruded debris in mg

Group	Mean	95% CI		SD	Min	Max
		Lower	Upper			
Protaper Gold	28.51	21.68	35.35	13.51	13.57	59.83
Protaper Ultimate	12.56	8.96	16.16	7.12	2.80	28.63

CI: Confidence interval, SD: Standard deviation, Min: Minimum, Max: Maximum

TABLE 2. Intergroup comparisons, mean±standard deviation values of log weight of debris

Log weight of extruded debris (mg) (mean±SD)		Mean difference (95% CI)	t-value	p
Protaper Gold	Protaper Ultimate			
3.25±0.47	2.35±0.65	0.89 (0.47:1.32)	**4.29**	**<0.001***

*: Significant (p<0.05). SD: Standard deviation, CI: Confidence interval

Statistical Analysis

Descriptive statistics were calculated. Data were positively skewed and failed to follow normal distribution. Therefore, log-transformation of the data was calculated to achieve normality. The independent t-test was used to compare between the two test groups with a significance of ($p<0.05$). The statistical analysis was performed using R statistical analysis software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Descriptive statistics for the debris weight are presented in Table 1. Intergroup comparisons of the log weight of extruded debris are presented in Table 2. The amount of extruded debris in Protaper Gold samples 3.25±0.47 mg was significantly higher than that of the Protaper Ultimate 2.35±0.65 mg ($p<0.001$).

DISCUSSION

Apical debris extrusion can be described as an undesired consequence during root canal instrumentation. These apically extruded debris is one of the aetiological factors for postoperative endodontic pain as well as interoperative flare-ups. Care should be taken during the shaping of the root canals to minimize if not avoid debris extrusion apically (8, 20, 21).

The root canal preparation technique, the motion adopted, the master apical file diameter, the working length, and the different design features of the files influence the amount of extruded debris apically (22). Studies have examined the effects of changing the angles of reciprocation (23), pre-flaring (24, 25), glide path (3, 26, 27) different glide path systems (19), and the taper (28) on apical extrusion. Irrigating solution, volume, technique, needle, and activation method also greatly influence the extruded debris apically (29–32).

For any recently launched rotary nickel-titanium file system in the market, meticulous assessment and evaluation of its potential to extrude debris apically while shaping the root canals should be performed. Therefore, the current study evaluated the recently launched Protaper Ultimate file system in terms of debris extrusion.

Three dimensionally-printed resin teeth were used in a previous study (33) due to the difficulty of standardizing the morphology of natural teeth such as type, curvature of the canals, and apical diameter. In this study, natural human teeth were used to simulate clinical situations better and mimic the physiological structures of dentine, and to avoid softening of the resin which occurs during preparation (34). Post-endodontic pain levels and inter-appointment flare-ups were recorded to be statistically significantly higher in molar teeth due to the more complex anatomical structure of the root canal system compared to anteriors and premolars; therefore, curved mandibular MB canals were used (35, 36).

To prevent crystallization of the debris, sodium hypochlorite solution was not applied in this study as an irrigating solution (18, 20). Distilled water was used instead with a fixed volume of irrigant used per canal for standardization of samples.

PTUT group extruded quantitatively less debris compared to the PTG group with a statistically significant difference (p=0.001); therefore, the null hypothesis was rejected. This can be explained by several key factors. The improved file design of PTUT might enhance debris removal efficiency. The files have a rhomboid cross-sectional design in the terminal 3 millimeters, and then it changes to a parallelogram cross-section at D4 till D16 (10). This allows for specifically adjusting the cutting efficiency of each part of the file. This can lead to reduced stresses during cutting and increased space available for debris removal. Moreover, the improved cross-sectional design, coupled with optimized fluting and tapering patterns might reduce the risk of debris being pushed apically while maintaining flexibility, by ensuring that debris is effectively moved coronally away from the apex (11). This conservative taper design helps in preserving more tooth structure while still providing efficient cleaning and shaping.

Additionally, PTUT Finishers files show a fixed taper in the apical three millimeters, which then decreases gradually from D4 to D16. This creates what the manufacturer claims is the "deep shape" of the PTUT, which helps to keep the irrigant confined within the clearance spaces and reduce the amount of apically extruded debris (10).

Furthermore, the sequence of files in the PTUT system is also designed to shape the canal progressively, minimizing debris compaction. Additionally, the presence of Slider files helps pre-shape the canal, further reducing debris generation during the use of larger shaping and finishing files (37). Another factor is the alternating off-set machining process which decreases the contact with the surface to be cut, providing better flexibility and more clearance space (10).

The superior results of the PTUT are aligned with those obtained by AlOmari et al. (12), who concluded that PTUT is the superior system in terms of reducing apical extrusion. This superiority was also attributed to the file's unique design.

On the other hand, the results of this study contradict those of Eskibaglar et al. (11), who documented that the PTUT system extruded more debris than TRN and VDW.R. This contradiction might be due to different speed and torque settings, the diameter of the files tested, and file design. Additionally, the sample selected for the aforementioned study consisted of single-rooted, straight premolars, as opposed to the curved mesiobuccal roots of mandibular molars used in our study.

The undesirable performance of the PTG in this study yielding more debris follows those results obtained earlier by Cakici et al. (38), who documented similar undesirable performance of PTG yielding more debris than the ProTaper Next rotary nickel-titanium files. On the contrary, Çırakoglu et al. (39), stated that PTG was superior to ProTaper Next in terms of debris extrusion. This contradiction could be explained based on the different methodology adopted in both studies as they did not instrument the same type of teeth, and they used different root canal irrigant during the shaping procedure of the root canal.

Similarly, Karatas et al. (40) found that PTG was superior to the ProTaper Universal rotary nickel-titanium files as well. This can be attributed to the operator's skills or the type of samples used, with the potential to result in less debris extrusion. Furthermore, Ali et al. (16), stated that PTG and ProTaper Next did not show any difference. Although PTG and ProTaper Next have different cross-sections, convex triangular and rectangular, they attributed their similar performance to the same kinematics used, which is the continuous rotation.

Limitations of the current study include the *ex vivo* experimental design where the absence of necrotic tissues or vital pulp tissue within lateral canals and apical ramifications can impact the results. Absence of periapical tissues which act as a barrier against apical debris extrusion in addition to lack of host tissue reactions might also affect the study results. In addition to standardizing the curvature range which makes generalization of the results impossible (20).

CONCLUSION

Under the experimental conditions of this *ex vivo* study, it can be concluded that apical debris extrusion can occur in both files systems. However, PTUT outperformed the PTG extruding less apical debris. Further clinical studies to evaluate the impact of apical debris extrusion on flare-ups and postoperative discomfort are recommended. Further studies evaluating the performance of the recently launched PTUT file system in terms of cyclic fatigue resistance, torsional fatigue resistance, shaping ability, and cleaning ability are needed.

Disclosures

Ethics Committee Approval: The study was approved by the Gulf Medical University Institutional Review Board (no: IRB/COD/STD/32, date: 01/06/2022).

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