In Vitro Evaluation of Apical Debris Extrusion Using Different Rotary File Systems in Extracted Mandibular Premolars

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ABSTRACT
Objectives
This in vitro study aimed to compare the amount of apically extruded debris generated during root canal preparation using three contemporary nickel–titanium file systems with different design features and kinematics: TruNatomy, HyFlex EDM, and WaveOne Gold.

Methods
Eighty-seven extracted single-rooted mandibular premolars were randomly assigned to three groups (n = 29). Canal preparation was performed according to the manufacturers' instructions for each system. Irrigation was standardized using 10 mL of distilled water per canal. Apically extruded debris was collected in pre-weighed Eppendorf tubes, dried at 70 °C for 5 days, and weighed using an analytical balance. Statistical analysis was performed using one-way ANOVA with appropriate post hoc tests or the Kruskal–Wallis test, depending on data distribution. The significance level was set at $P < 0.05$.

Results
A statistically significant difference in the amount of apically extruded debris was observed among the groups ($P < 0.001$). TruNatomy produced significantly less debris (mean ± SD: 0.018 ± 0.006 g) compared with HyFlex EDM (mean ± SD: 0.031 ± 0.006 g) and WaveOne Gold (mean ± SD: 0.027 ± 0.008 g). No significant difference was detected between the HyFlex EDM and WaveOne Gold systems ($P > 0.05$).

Conclusion
Within the limitations of this in vitro model, apical debris extrusion differed among rotary systems with distinct design characteristics and kinematics. TruNatomy was associated with lower debris extrusion than HyFlex EDM and WaveOne Gold under standardized laboratory conditions. These findings should be interpreted as comparative experimental data, as periapical tissue resistance and clinical irrigation dynamics were not simulated.

Keywords: Apical debris extrusion; Root canal preparation; Nickel–titanium instruments; TruNatomy; WaveOne Gold; HyFlex EDM

INTRODUCTION
Effective root canal treatment necessitates the thorough cleaning of the canal system, both mechanically and chemically, utilizing endodontic files in conjunction with appropriate irrigation solutions. Yet, during canal shaping, a certain amount of irrigant, debris, necrotic tissue, or even microorganisms and their by-products may unintentionally pass through the apex and reach the periapical tissues. This situation may result from the instrumentation techniques used and may contribute to postoperative inflammation as well as compromise treatment outcomes.[1] Apical extrusion has been associated with postoperative inflammation and pain in clinical settings. The spread of bacteria and their by-products into the periradicular region may cause acute inflammation and pain, and in addition, it may lead to flare-ups and delayed healing. However, the extent and severity of this response may vary depending on the amount and virulence of extruded microorganisms as well as host-related defense mechanisms.[2]

Preservation of root anatomy during canal preparation is of great importance. Extensive research in the literature has indicated that employing stainless-steel files during the shaping process may lead to issues such as a reduction in working length, apical transportation, and the formation of ledges.[3–5] Stainless-steel files possess greater stiffness and lower flexibility than nickel-titanium instruments. Particularly in curved canals, they tend to straighten within the canal, which may result in working length reduction, apical transportation, and ledge formation.[6] The nickel-titanium (NiTi) rotary file systems, which are prevalently employed in root canal procedures, have played a crucial role in mitigating complications due to their exceptional flexibility characteristics.[7] Their improved shaping ability preserves the original canal anatomy more predictably, reduces procedural errors, and enhances the overall quality of canal cleaning. From both the clinician's and the patient's perspective, another advantage is the increased comfort of the treatment experience resulting from the shorter procedure time.[8]

Various tools and techniques have been devised for the purpose of shaping the root canal system. All instruments and methods used may cause varying amounts of root canal debris to be extruded beyond the apical region.[9] It has been reported that the debris and residues extruded from the root canal are caused by the different mechanical properties of the endodontic file systems used.[10] The wide variety of endodontic instruments available today has led researchers to investigate the factors that may influence the frequency and severity of this occurrence. Among these factors are the shape, size, mode of use (manual or motor-driven), metallurgical structure, and kinematic motion of the instrument.[11]

The file systems used in root canal preparation are continuously being improved. Manufacturers claim that their newly developed instruments are more durable, flexible, and efficient. Even though new file systems are made to address the limitations of earlier designs, they still tend to cause a certain amount of debris extrusion beyond the apex. Systems that reduce apical debris extrusion may be advantageous in experimental comparisons aimed at understanding instrument-related factors under standardized conditions.

TruNatomy, HyFlex EDM, and WaveOne Gold represent contemporary NiTi file systems with distinct design characteristics and kinematic motions. This study conducted a comparative analysis of rotary file systems to assess their impact on the quantity of apically extruded debris under standardized experimental conditions. It was hypothesized that differences in file design and motion could result in varying degrees of debris extrusion. Accordingly, the null hypothesis tested was that no significant difference would be observed among the TruNatomy, HyFlex EDM, and WaveOne Gold systems with respect to apical debris extrusion.

METHODS

Ethics and Sample Collection

This study was ethically approved by the Ethics Committee of Kahramanmaraş Sütçü İmam University, Medical Research Board (Decision No: 08, Session: 2024/27, Date: October 14, 2024). The study was conducted between October 21, 2024, and March 24, 2025. All experimental procedures, including root canal instrumentation and debris collection, were performed by a single researcher to ensure methodological standardization and eliminate inter-examiner variability. Extracted teeth were collected anonymously, and no patient-identifiable data were used in this study. The extracted teeth were stored in physiological saline solution at 4 °C and used within 3 months. This in vitro study was reported in accordance with the PRILE 2021 guidelines for laboratory studies in endodontology.

Sample Size Determination

The determination of the sample size for this study was conducted through power analysis. The alpha error level was set at $\alpha = 0.05$, the beta error level at $\beta = 0.20$ (power = 80%), and the effect size was calculated as 0.34, based on apical debris values reported in similar studies.[12,13] In this study, 87 single-rooted mandibular premolar teeth (n = 29 per group) were extracted due to periodontal, prosthetic, or orthodontic indications. The root surfaces were meticulously cleaned of soft tissues and calculus using periodontal curettes.

Tooth Selection Criteria

Subsequently, radiographic images were obtained in both mesiodistal and buccolingual orientations. Specimens exhibiting calcification or multiple canals were excluded from the study (Figure 1). Teeth that had previous root canal treatment, open apices, calcified canals, root surface caries, resorption, cracks, or crown–root fractures, as well as teeth with more than one root canal, were not included. All selected teeth were stored in physiological saline throughout the study period. Only extracted mandibular premolars with fully formed apices and root canal curvature of less than 10° (straight canals) were included in the study.

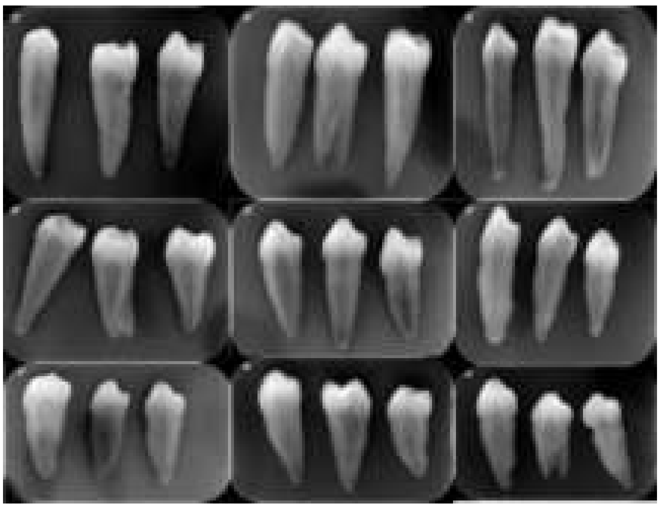


Figure 1: Radiographs were obtained in mesiodistal and buccolingual directions, and specimens with calcification or multiple canals were excluded.

Randomization and Blinding

The teeth were randomly distributed into three groups, with 29 specimens in each group (n = 29). Randomization was performed using a computer-generated random sequence. The examiner responsible for measuring debris weight was blinded to group allocation (İ.B.).

Experimental Setup for Debris Collection

In this study, the experimental setup described by Myers and Montgomery[14] was used to compare the HyFlex EDM, TruNatomy, and WaveOne Gold rotary file systems in terms of apical debris extrusion. The Eppendorf tubes used in the study were numbered sequentially. For the experimental setup, the caps of 87 Eppendorf tubes were modified. Openings large enough to allow the samples to pass through were created in the caps using a heated hand instrument. The teeth were inserted through these openings and secured to the caps using flowable composite resin. The modified caps were then placed onto the pre-weighed Eppendorf tubes after removing their original caps. The initial weight of each tube was measured three times using a precision balance with an accuracy of 10^{-4} g (Pioneer, Ohaus, USA), and the average value was recorded. All procedures were executed under controlled laboratory conditions, specifically at a temperature of 22 ± 1 °C and a humidity level of 50 ± 5%. The assembled apparatus (Figure 2) was inspected for any leakage prior to canal preparation. This arrangement ensured that the pre-weighed tubes remained stable throughout the experimental procedure. A 27-gauge syringe needle was inserted through the cap and into the tube to equilibrate the internal and external air pressure. The Eppendorf tube-tooth assembly, designed to obscure the operator's view of expelled debris and irrigation solution, was placed within dark-colored bottles. Furthermore, to prevent fluid and debris that might extrude coronally from leaking into the tube, the remaining tube-tooth was sealed with a rubber dam (Figure 2).

Figure 2: Final experimental setup using the Eppendorf tube system for the collection of apically extruded debris.

Working Length Determination and Pre-flaring

In each tooth group, access cavities were meticulously prepared using a diamond round bur attached to an air turbine handpiece, with water cooling employed throughout the process. To establish the working length, a #15 K-file was introduced into the canal until the tip of the file was observable at the apical foramen, at which point a rubber stop was positioned at the coronal reference point. To ensure standardization, the #15 K-file was advanced slowly until the file tip became just visible at the apical foramen. No intentional extension beyond the foramen was allowed. The same operator performed all working length determinations using the same protocol for all specimens, thereby minimizing variability in the extent of file protrusion beyond the apical foramen. The definitive working length was calculated by deducting 1 mm from the observed measurement. Pre-flaring procedures were performed in all samples using hand K-files up to size #20 at the determined working length.

Root Canal Preparation Protocols
All preparations were performed using an endodontic motor (Ai-Motor, Woodpecker, Muenster, Germany) in accordance with the parameters recommended by the manufacturers (Figure 3).

Group 1: TruNatomy (Dentsply Sirona, Maillefer, Ballaigues, Switzerland) – Shaping was performed on 29 samples using the TruNatomy (26.04 Prime) file with rotational motion at a speed of 500 rpm and a torque of 1.5 N·cm.

Group 2: HyFlex EDM (Colténe/Whaledent, Altstätten, Switzerland) – Shaping was performed on 29 teeth using the HyFlex EDM (size 25, variable taper) file in rotational mode at a speed of 400 rpm and a torque of 2.5 N·cm.

Group 3: WaveOne Gold (Dentsply Sirona, Maillefer, Ballaigues, Switzerland) – Shaping was performed on 29 samples using the WaveOne Gold (25.07 Primary) file in reciprocating motion, with 150 degrees counterclockwise (CCW) and 30 degrees clockwise (CW) rotation.

Figure 3: Endodontic motor (Ai-Motor, Woodpecker, Muenster, Germany) used for root canal preparation according to the manufacturers' recommended settings.

Each rotary file was replaced with a new one after being used in a maximum of two canals. During canal preparation, a total of 10 mL of distilled water was used as the irrigant for each specimen. Irrigation was delivered using a 27-gauge side-vented needle placed 2 mm short of the working length. The insertion depth was measured and standardized for each specimen using an endodontic ruler.

Debris Collection and Measurement
After shaping, the Eppendorf caps were opened, and the debris on the root surface was directed into the tube, washed with 1 mL of distilled water, and collected in the tube. This process also transferred any debris adhering to the root surface into the tube. The tubes were then placed in a dry oven with their caps open and incubated at 70 °C for 5 days until the liquid inside completely evaporated. After the liquid evaporated, the tubes were weighed three times using a 10^{-4} g scale (Pioneer, Ohaus, USA), and the average values were recorded. The extruded debris was calculated as the difference between the initial weight of the tube and the weight of the tube containing debris after drying.

Statistical Analysis
In quantitative data, one-way analysis of variance (ANOVA) was applied to compare three or more independent groups for variables that followed a normal distribution. Tukey's HSD or Tamhane's T2 post hoc tests were used for multiple comparisons. For variables that did not follow a normal distribution, comparisons of three or more independent groups were performed using the Kruskal–Wallis H test; for pairwise comparisons, the Dunn–Šidák post hoc method was used. For qualitative variables, distributional differences between groups were assessed using the chi-square (χ^2) test and Fisher's exact test. The level of statistical significance was set at $P < 0.05$, and exact P values are reported in accordance with the journal guidelines. Data analysis was performed using Jamovi and IBM SPSS Statistics (v22) software.

RESULTS

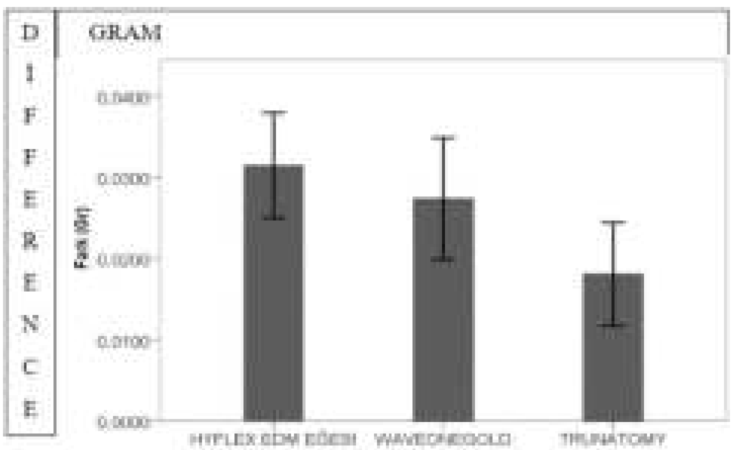
In this study, a statistically significant difference was found among the groups in terms of the weight of apically extruded debris (P < 0.05). According to the results, the lowest amount of apical debris extrusion was observed in the TruNatomy group, while higher debris weights were recorded in the HyFlex EDM and WaveOne Gold groups (Table 1).

Table 1: Amount of apically extruded debris by group

Group	Amount of Debris (g) (Mean ± SD)
TruNatomy	0.018 ± 0.006
HyFlex EDM	0.031 ± 0.006
WaveOne Gold	0.027 ± 0.008

After the Tukey HSD test, it was determined that the amount of extruded debris in the HyFlex EDM and WaveOne Gold groups was significantly higher than that in the TruNatomy group (Figure 3). However, no statistically significant difference was found between the HyFlex EDM and WaveOne Gold file systems (P > 0.05).

Accordingly, the amount of extruded debris ranked from highest to lowest as follows: HyFlex EDM, WaveOne Gold, and TruNatomy (Table 2). Overall, statistically significant differences were observed between TruNatomy and both HyFlex EDM and WaveOne Gold, whereas no significant difference was detected between the HyFlex EDM and WaveOne Gold systems.



DISCUSSION

Findings: The null hypothesis, which posited that there would be no significant differences in the apically extruded debris among the three file systems, was rejected. Statistical analysis revealed a significant difference in the quantity of extruded debris among the groups, as determined by one-way ANOVA ($F = 29.581$, $P < 0.001$). The HyFlex EDM group exhibited the highest mean amount of extruded debris (0.031 ± 0.006 g), followed by the WaveOne Gold group (0.027 ± 0.008 g), while the TruNatomy group demonstrated the lowest values (0.018 ± 0.006 g). Post hoc analysis confirmed that both HyFlex EDM and WaveOne Gold extruded significantly more debris than TruNatomy, while no difference was observed between HyFlex EDM and WaveOne Gold.

Implications: This study aimed to investigate the influence of different rotary file systems on the extrusion of debris during root canal preparation. The apical extrusion of debris is known to contribute to postoperative inflammatory responses in clinical practice. The present findings indicate that even modest differences in instrument design and kinematic motion can influence the magnitude of apical debris extrusion. Accordingly, instrument-related factors may influence debris extrusion patterns under standardized experimental conditions.[7] It has been reported that debris, irrigants, and microorganisms extruded through the apical foramen may disrupt the equilibrium between microbial load and host defense mechanisms, thereby predisposing patients to postoperative pain and flare-ups.[15–17] Accordingly, apical debris extrusion represents not only a mechanical phenomenon but also a biologically relevant event. In the present study, differences in debris extrusion among rotary file systems were evaluated as a laboratory-based surrogate parameter rather than as a direct predictor of clinical outcomes. Using flexible rotary file systems with lower taper values and narrower cross-sectional designs may reduce apical pressure and facilitate coronal debris transportation.[18] Such design characteristics appear particularly relevant in contemporary minimally invasive shaping concepts. Among the systems evaluated, the TruNatomy system generated the least amount of apically extruded debris. Its high flexibility, reduced taper, and minimally invasive design likely decreased apical compaction forces and promoted coronal debris removal. Previous studies have similarly reported that the heat-treated NiTi alloy and narrow cross-sectional geometry of TruNatomy may contribute to reduced debris extrusion.[19] Recent in vitro and clinical investigations have also reported lower debris extrusion and postoperative pain scores associated with TruNatomy use.[20,21] However, postoperative flare-up risk is multifactorial and depends on patient-related, microbial, irrigant-related, and procedural variables; therefore, direct clinical extrapolation from in vitro findings should be made with caution.

Among the systems evaluated, TruNatomy and HyFlex EDM operate with continuous rotation, whereas WaveOne Gold utilizes reciprocating kinematics. These differences in motion patterns and design features may partly explain variations in debris extrusion observed across studies. Several investigations have compared apical debris extrusion among contemporary file systems. Çırakoğlu et al. reported significantly lower extrusion with TruNatomy compared with ProTaper-based systems, attributing this effect to differences in kinematics, cross-sectional design, and taper.[22] The present findings are consistent with these observations. Similarly, Karataş et al. demonstrated that WaveOne Gold produced less debris extrusion than earlier-generation systems operating with continuous rotation.[23] The intermediate extrusion values observed for WaveOne Gold in the present study align with these reports. Studies by Djuric et al. and Mustafa et al. further emphasize that apical debris extrusion is influenced by a complex interaction between instrument design, motion pattern, and preparation sequence.[24,25]

The consistently lower extrusion associated with TruNatomy across multiple experimental models supports the hypothesis that minimally invasive design principles may play a role in reducing apical debris transport. Taken together, both the literature and the present findings indicate that apical debris extrusion is governed by multiple interacting factors, including instrument taper, cross-sectional geometry, metallurgical properties, and kinematic motion. Standardization of experimental models remains essential for meaningful comparisons among contemporary systems.

Trade-Offs: The main strengths of this study include strict standardization of experimental procedures, blinded debris collection, and direct comparison of three contemporary file systems under identical conditions. These methodological features enhance the reliability and comparability of the findings.

The limitations of this study should also be acknowledged. The in vitro design does not replicate periapical tissue resistance or clinical irrigation dynamics, and the use of single-rooted premolars limits generalizability to more complex canal anatomies.

Within these limitations, the present study provides comparative experimental data on how instrument design and kinematic motion influence apical debris extrusion under standardized laboratory conditions.

Take-Home: Although all tested instrumentation systems resulted in apical debris extrusion, HyFlex EDM generated the highest amount, WaveOne Gold demonstrated intermediate values, and TruNatomy produced the lowest.

Expectations for Future Research: Future studies should focus on evaluating apical debris extrusion under clinical conditions and investigating its relationship with postoperative pain and periapical healing.

Recommendations: Within the limitations of this in vitro study, instrumentation systems producing less apical debris extrusion, such as TruNatomy, may be preferred to minimize potential postoperative complications.

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DECLARATIONS

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Data availability: Data are available from the corresponding author upon reasonable request.

AI declaration: Generative AI (ChatGPT, OpenAI) was used to refine wording, enhance readability, assist in summarizing long sections, and provide structural suggestions. No AI tool was used to generate scientific data, interpret results, or create original content. The author(s) reviewed and edited all text and take full responsibility for the final version.

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