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ORIGINAL ARTICLE

Comparative analysis of debris extrusion and instrumentation time among various endodontic file systems: an in vitro study

ABSTRACT

Aim: *Debris extrusion during endodontic procedures, characterized by the unintended displacement of root canal debris, poses significant clinical challenges, potentially leading to postoperative pain and infection. In this study, we aimed to evaluate the differences in debris extrusion and instrumentation time among various endodontic file systems.*
Methodology*: 120 mandibular first molars were included in the study, with 15 specimens in each group: Protaper Next, HyFlex CM, HyFlex EDM, WaveOne Gold, Reciproc Blue, Trunatomy, PTUltimate, and Rmotion. Both debris extrusion and instrumentation time for these systems were assessed. Descriptive analyses were performed, and statistical comparisons were made using the Kruskal-Wallis test (p<0.05).*
Results*: Protaper Next and HyFlex CM exhibited significantly higher mean debris extrusion compared to other systems. On the other hand, the remaining systems, showed lower mean debris extrusion. HyFlex CM was the most time-consuming, while WaveOne Gold, R-Motion, and Reciproc Blue were among the quickest. HyFlex EDM demonstrated a balanced performance, being efficient in both debris extrusion and time.*
Conclusions*: The findings suggest that while some systems significantly minimize debris extrusion and reduce instrumentation time, the choice of an endodontic file system should be guided by specific clinical conditions and operator preference based on our comparative analysis.*

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Introduction

Debris extrusion during endodontic procedures, defined as the unintentional displacement of root canal debris including bacteria and necrotic tissue beyond the apical foramen, is a critical concern due to its potential to cause inflammation and subsequent infection of periapical tissues (1). Studying debris extrusion from different endodontic files helps identify file designs and usage protocols associated with minimal extrusion. This not only mitigates the risk of periapical tissue damage but also contributes to improving the overall success rate of endodontic procedures (2).

The inherent variability in root canal anatomy, coupled with the diverse designs and materials of endodontic files, contributes to the complexity of debris extrusion. Nevertheless, gaining an understanding of how these factors influence debris extrusion is pivotal in identifying the most effective file designs and usage protocols. Such insights can significantly enhance the success rates of endodontic procedures (3, 4).

Despite numerous studies on debris extrusion in endodontics, most of them have focused on specific systems, given the multitude available in the market (5-7). However, as mentioned earlier, debris extrusion is a multifactorial phenomenon, and research methodologies vary considerably across the literature. Therefore, the primary aim of this research is to incorporate a diverse range of endodontic systems, encompassing both rotary and reciprocating systems, to enable impartial comparisons. This approach seeks to mitigate the methodological discrepancies that often impede the synthesis of systematic reviews in this field (8). The study will investigate the extent of debris extrusion and the time required for instrumentation with various endodontic file systems, including ProtaperNext, HyFlex CM, HyFlex EDM, WaveOne Gold, Reciproc Blue, Trunatomy, PTUltimate, and Rmotion. The null hypothesis posits that there is no statistically significant difference in debris extrusion and instrumentation time among the evaluated endodontic systems.

Material and Methods

The manuscript of this laboratory study has been written according to Preferred Reporting Items for Laboratory studies in Endodontology (PRILE) 2021 guidelines (9). After obtaining approval from the local Research Ethics Committee (opinion no. 5.731.282), the study included 120 mandibular first molars extracted for various reasons. Inclusion criteria were as follows: teeth with fully developed roots displaying separate foramina, curvature angles ranging between 15 to 20 degrees (10), absence of calcifications, resorption, or prior endodontic treatment, and an initial apical canal diameter equivalent to that of a #15 K-file (Maillefer Corp, Ballaigues, Switzerland). Subsequently, these teeth were meticulously disinfected through immersion in a 0.5% chloramine-T trihydrate solution for a duration of one week.

To ensure consistent initial conditions across all samples, the diameter of the mesiobuccal canal was standardized using a #15 K-file (Dentsply Maillefer, Ballaigues, Switzerland). Each file was gently inserted into the canal until it snugly fit within, and its tip was visible at the apical foramen. This process was conducted under the magnification of a dental operating microscope at 12.5x (Stemi 508; Carl Zeiss, Jena, Germany), which ensured precise visualization and placement. The working length (WL) for each canal was then established as 1 mm short of this measurement to maintain uniformity in measurement criteria across all specimens.

To further standardize the sample selection, only canals that met these specified criteria were included in the study. Any canal that did not fit these requirements was excluded and replaced with another specimen that matched the standardized conditions. Additionally, the study included a radiographic verification step to confirm the uniformity of canal configuration prior to the instrumentation procedures. All teeth were radiographed in both the buccolingual and mesiodistal dimensions using a CDR Elite digital radiographic sensor (Schick Technologies), ensuring that all specimens adhered to a consistent anatomical baseline. This step was critical for addressing potential variability in root canal anatomy and minimizing its impact on the study outcomes. In this study, the standardization of the canal was specifically focused on the mesiobuccal aspect due to the exclusive instrumentation of this canal.

The sample size calculation was conducted using G*Power 3.1.9.4 software, developed by Heinrich-Heine-Universität Düsseldorf, Germany. The primary outcome of interest was the quantity of debris extruded. In accordance with a previous study by Mustafa et al. (11) the study aimed to detect a difference of 0.0018 between groups. With a standard error of 0.00165, a power of 0.80, and a significance level of 0.05, the calculated sample size necessary for the study would be 15 specimens per group.

Conventional access cavities were prepared by sectioning the crowns at the cementoenamel junction using a round diamond bur (Horico Dental Hpf; Ringleb, Berlin, Germany) attached to a low-speed handpiece driven by a micromotor, all while maintaining water cooling. This process yielded specimens measuring 13 mm in length, a measurement confirmed using a digital caliper (500 series, DIN 862; Mitutoyo, São Paulo, SP, Brazil).

Randomization

The specimens were subjected to random allocation using the Random Allocation Software, version 1.0.0, into eight distinct experimental groups, each consisting of 15 specimens. These allocations were made based on the specific instrumentation systems employed, which included ProtaperNext, HyFlex CM, HyFlex EDM, WaveOne Gold, Reciproc Blue, Trunatomy, PTUltimate, and Rmotion.

Instrumentation

Within the Protaper Next group, an X1 (17.04) PTN file (Dentsply Maillefer, Ballaigues, Switzerland) was employed in rotary motion, operating at a speed of 300 rpm with a torque of 2 N·cm. This instrument underwent three in-and-out movements (pecks), each having a stroke amplitude of 3 mm, in every third of the canal (cervical, middle, and apical) until it reached the WL, which was set at 1 mm short of the apical foramen. The same sequence was replicated using an X2 (25.06) instrument. For the HyFlex EDM group, the OneFile instrument (25/~, variable taper) from the Hyflex EDM rotary system (Coltène, Altstätten, Switzerland) was utilized in rotary motion, functioning at a speed of 500 rpm with a torque of 2.5 N·cm. This instrument underwent the same type of motion with a similar amplitude and WL as that used for the X1 instrument in the PTN group.

For the HyFlex CM group, the instrumentation sequence was unique due to the absence of a 25.06 taper instrument. The protocol was as follows: A 25.08 instrument was initially used for cervical preparation, given its 19 mm length. This was alternated with a manual #10 file, with odontometry performed intermittently. Subsequently, instruments with specifications 20.04, 25.04, and 20.06 were used in sequence. Although this may seem unconventional, it was done this way to avoid using a 30.04 instrument, which would deviate significantly from the apical standard set by the other instruments.

In the WaveOne Gold group, the Primary file (25.07) from the WaveOne Gold system (Dentsply Maillefer, Ballaigues, Switzerland) was employed in reciprocating motion. This involved three in-and-out movements (pecks) with a stroke amplitude of 3 mm in the cervical, middle, and apical thirds of the canal, and this motion continued until the WL was reached.

In the Reciproc Blue group, the R25 instrument (25.08) from the Reciproc Blue system (VDW GmbH, Munich, Germany) was utilized in the same fashion as described for the WaveOne Gold group. The procedure involved the use of the Reciproc program on the motor.

For the Trunatomy group, the Trunatomy files were used in rotary motion, operating at a speed of 500 rpm with a torque of 1.5 Ncm. The instrumentation sequence began

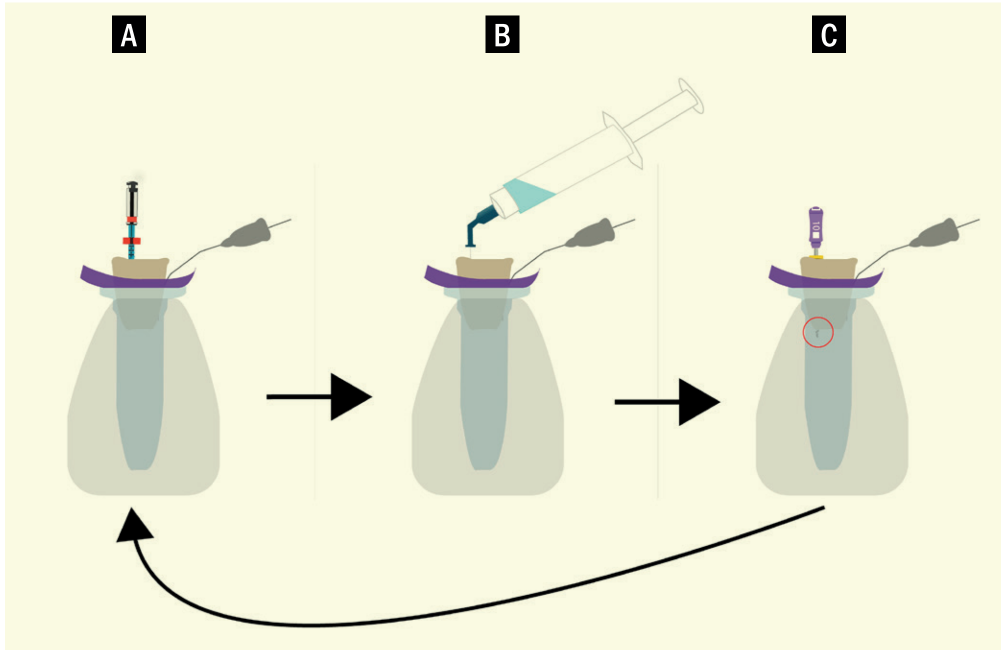

Figure 1
Illustration of the instrumentation protocol.
A) An example of instrumentation using Reciproc Blue file;
B) the irrigation protocol following every 3 in-and-out movements or one-third of root instrumentation;
C) utilization of #10 K-type file extended 1mm beyond the apex for patency verification, with the red circle indicating the 1 mm extension beyond the apex.

with an orifice modifier (20.08) until reaching half the WL, followed by the use of a glider (17.02), small (20.04), and prime (26.04) instruments, all the way to the WL. For the ProTaper Ultimate group, the instrumentation sequence began with a Slider 16.04, followed by a Shaper 20.04. Subsequent instruments used were F1 20.07 and F2 25.08. It is important to note that the diameter of these files is 1.0 mm, unlike the 1.2 mm diameter commonly found in other instruments.

For the RMotion group, a #25 file with a .06 taper was used. The instrument was employed in the same manner as the WaveOne file, utilizing the WaveOne program on the motor for the procedure. The instruments were operated using an X-Smart Plus motor (Dentsply Maillefer, Ballaigues, Switzerland), with adjustments made for each specific system. It's important to note that, regardless of the system used, each instrument was dedicated to preparing a single root canal and was subsequently discarded. The mesiolingual canals remained untouched and did not undergo any instrumentation or irrigation during the entire experimental process. All canals were instrumented by a single operator to ensure consistency throughout the experimental procedures. The operator was an experienced endodontist with extensive clinical expertise and several published articles in the field. Given the operator's familiarity with both rotary and reciprocating techniques, no additional specific training was conducted prior to the experiment. This proficiency minimized variability due to operator influence.

During the instrumentation process, the specimens received irrigation with 3 mL of double-distilled water, administered using a side-vented needle (29G NaviTip; Ultradent Products Inc, South Jordan, UT) at intervals of every three in-and-out movements or after one-third of the root was instrumented. Following each movement and irrigation cycle, foramen patency was confirmed by using a #10 K-file that extended 1 mm beyond the foramen in all experimental groups (Figure 1).

Upon the completion of the instrumentation, a final irrigation was carried out using 1 mL of double-distilled water, without exceeding a total of 10 mL of irrigant, which was standardized for all specimens. Subsequently, the canals were aspirated using a capillary tip (Ultradent, South Jordan, UT) and then dried using paper points provided by the respective manufacturer of each system.

Manufacture of the apparatus for collecting and weighing extruded debris:
The amount of apically extruded debris after instrumentation was quantified according to the method proposed by Myers & Montgomery (12), and modified by other authors (5, 13). In all experimental groups, the Eppendorf tubes were placed in an incubator (Model EL–14; Odontobras, São Paulo, Brazil) and maintained at a consistent temperature of 70 °C for a continuous duration of 5 days. This period allowed for the complete evaporation of the double-distilled water from inside the Eppendorf tubes. Subsequently, each Eppendorf tube underwent three separate weightings on the same precision balance that was initially used. The average weight from these three measurements was recorded as the final weight of the Eppendorf tube, now containing the extruded debris. The calculation of the dry weight of the extruded debris (in grams) was achieved by subtracting the initial weight (that of the empty tube) from the final weight.

Evaluation of actual instrumentation time:
The instrumentation procedure for each specimen was meticulously timed using a digital stopwatch (Seiko, Japan). The timer was initiated when the instrument was put into motion inside the root canal and ceased when the instrument was withdrawn, providing the precise instrumentation time for each case.

Statistical analysis
The results obtained for debris weight and instrumentation time underwent statistical analysis using the software Jamovi v1.6.21 (https://www.jamovi.org). It's important to note that the Shapiro-Wilk test indicated a rejection of the assumption of data normality for both the quantity of extruded debris and the actual instrumentation time. Descriptive analyses were conducted, and the subsequent statistical analysis was carried out utilizing the Kruskal-Wallis test.

Results

Regarding debris extrusion, ProtaperNext and HyFlex CM are significantly different from the other file systems ($p<0.05$), showing the highest mean values. In contrast, HyFlex EDM, WaveOne Gold, Reciproc Blue, Trunatomy, PTUltimate, and Rmotion have significantly lower mean values of debris extrusion (figure 2 and table 1). In terms of instrumentation time, the data reveal that ProtaperNext, HyFlex CM, Trunatomy, and PTUltimate required longer times ($p<0.05$). Conversely, HyFlex EDM, WaveOne Gold, Reciproc Blue, and Rmotion showed significantly shorter instrumentation times ($p<0.05$). All numerical data and statistical differences between the groups are described in Table 1.

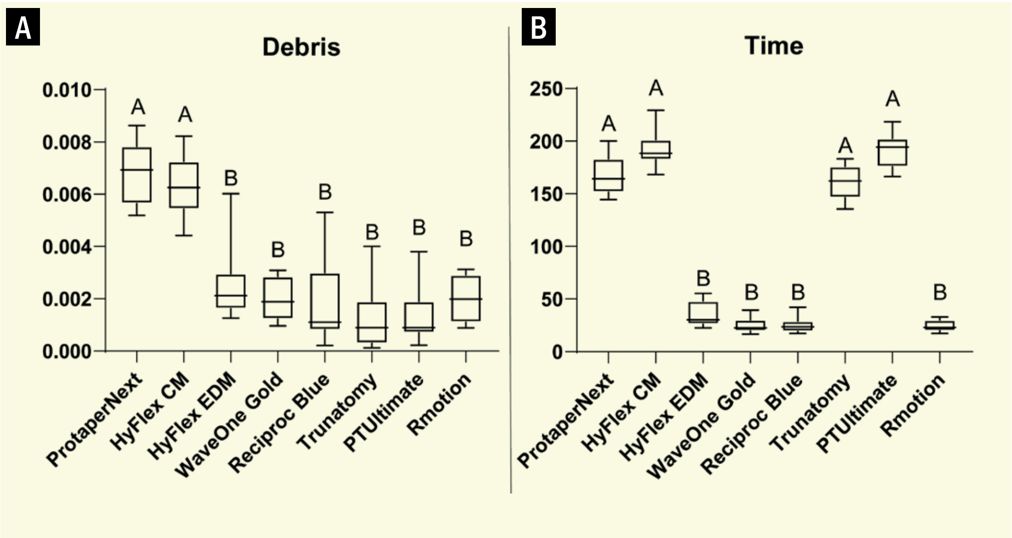

Figure 2
A) A box plot displaying the results related to debris extrusion across different endodontic systems, with varying letters indicating statistically significant differences among the groups; **B)** a box plot depicting the results concerning the time of instrumentation across different endodontic systems, with distinct letters indicating statistically significant differences among the groups.

Table 1

Differences between instrumentation systems regarding apical debris extrusion and time required for root canal instrumentation

Group	Debris		Time	
	Median±IQD	Mean±SD	Median±IQD	Mean±SD
ProtaperNext	0.0069±0.0019^{A}	0.0068±0.0012	164.330±28.870^{A}	168.905±17.392
HyFlex CM	0.0063±0.0016^{A}	0.0064±0.0012	188.350±17.025^{A}	191.660±17.372
HyFlex EDM	0.0021±0.0012^{B}	0.0025±0.0012	30.280±20.255 ^{B}	35.327±11.307
WaveOne Gold	0.0019±0.0014^{B}	0.0020±0.0008	22.560±8.015^{B}	24.923±7.014
Reciproc Blue	0.0011±0.0020^{B}	0.0019±0.0015	23.570±9.470^{B}	25.157±7.000
Trunatomy	0.0009±0.0012^{B}	0.0012±0.0011	162.230±26.740^{A}	161.615±5.675
PTUltimate	0.0009±0.0011^{B}	0.0013±0.0010	194.230±25.095^{A}	190.937±16.391
Rmotion	0.0020±0.0017^{B}	0.0020±0.0009	23.010±9.515^{B}	24.937±5.413
P-value*	<0,0001		<0,0001	

*Same superscript letters indicate no statistical difference between the groups, whereas different superscript letters indicate statistical difference. *Kruskal-Wallis test.*

Discussion

In summary, our study provides a evaluation of various endodontic instrumentation systems, with a specific focus on debris extrusion and instrumentation time. Consistent with existing literature (14-19), it is important to emphasize that all endodontic systems assessed in our study exhibited some degree of debris extrusion. Statistical analysis revealed that Protaper Next and HyFlex CM had the highest mean debris extrusion, and they were statistically similar in this respect. Conversely, the remaining systems, including Protaper Ultimate, HyFlex EDM, WaveOne Gold, Reciproc Blue, Trunatomy, and R-Motion, demonstrated lower mean debris extrusion, with no significant differences among them. Regarding instrumentation time, HyFlex CM proved to be the most time-consuming, while WaveOne Gold, R-Motion, and Reciproc Blue were among the quickest. These findings underscore the importance of considering multiple factors when choosing an endodontic system. The selection should not hinge solely on debris extrusion or time but should be an informed decision based on data. Our study's results led us to reject the null hypothesis.

In our study, the curvature angles of all the teeth used were standardized to be between 15-20º (10). This standardization is a crucial consideration, as existing literature has established that canal curvature can influence both debris extrusion and instrumentation time (5,20-23). By maintaining a consistent curvature within this range (24), we aimed to minimize the influence of this variable, enabling a more focused evaluation of the instrumentation systems themselves. When interpreting the results, it is essential to bear in mind that variations in canal curvature in a clinical setting could potentially alter both the quantity of debris extruded and the time required for canal preparation.

To ensure consistency in instrumentation, we employed the same motor and strictly adhered to the manufacturer's guidelines for each system. Additionally, we used the last instrument with a similar taper and tip across all systems to standardize the process as closely as possible. It is important to recognize, however, that achieving complete standardization is nearly impossible due to the diverse metallurgies, designs, tip, and taper variations in instruments used across different systems (25). This could be considered a limitation of our study, as these variations could potentially influence both debris extrusion and instrumentation time.

Specimens were irrigated with 3 mL of double-distilled water, utilizing a side-vented needle after every three in-and-out movements or when one-third of the root was instrumented (5). It is crucial to highlight this irrigation protocol, as inadequate irrigation can significantly influence debris extrusion (26). Moreover, the deliberate choice of double-distilled water as the irrigant was made to minimize methodological biases. In contrast to other commonly used irrigants such as sodium hypochlorite or chlorhexidine, double-distilled water evaporates without leaving any residues (26), thereby eliminating potential variables that could affect the study outcomes.

It is important to note that different irrigant activation techniques, such as passive ultrasonic irrigation, sonic irrigation, and manual dynamic agitation, have been shown to influence debris extrusion. A recent study by Ada et al. (2023) (27) demonstrated that passive ultrasonic irrigation caused significantly less debris extrusion compared to sonic irrigation and manual dynamic agitation, which aligns with our efforts to reduce extraneous variables in our study. These techniques, especially passive ultrasonic irrigation, have also been shown to improve bacterial elimination, which could further mitigate the risk of postoperative complications caused by apical debris extrusion. Future studies should consider comparing different irrigants and activation methods to more comprehensively evaluate their effects on extrusion and clinical outcomes.

The unintentional extrusion of debris and bacteria from root canals during root canal therapy has been the focus of extensive research in recent years (2, 6, 8, 28). Nevertheless, a consensus regarding the most reliable methodologies for measuring and quantifying extrusion remains elusive. Many studies explore factors contributing to extrusion, such as the type of instrumentation, root canal size and shape, and operator skill level (5, 29, 30). Our study rigorously adhered to established methodologies, drawing from existing literature (31), and even engaged a single operator to minimize variability. Despite these inherent challenges, in vitro studies of this nature provide invaluable insights. While it is impractical to conduct such experiments in a clinical setting, the findings furnish a scientific foundation that informs clinical practices and contributes to enhanced patient outcomes.

The kinematic factor's influence on debris extrusion is inconclusive in our study, as both rotary and reciprocating systems yielded similar results. This inconclusive influence aligns with some existing studies (3, 32), while contrasting with others that suggest a more definitive impact (33). This observation can potentially be justified by the balanced performance of low-taper files with reduced metallic mass, such as Trunatomy and Protaper Ultimate, when compared to reciprocating systems. The likely explanation for this balanced outcome could be the more conservative preparation approach employed by these files, which results in reduced debris production and, consequently, less extrusion. This suggests that the design features of the endodontic files, such as taper and metallic mass, may play a more significant role in debris extrusion than the kinematics of the system, a conclusion that aligns with existing research (2, 21, 34).

Recent studies have continued to explore the relationship between endodontic systems and apical debris extrusion. A systematic review (35) provides an updated perspective on this topic, investigating the risk of debris extrusion associated with both rotating and reciprocating instruments. This review emphasized the need for further exploration into the connection between extrusion and post-operative flare-ups, suggesting that while debris extrusion occurs in both systems, the flare-up risk might not solely be attributed to the instrumentation method but also to the instrument design and clinical. The review supports our findings that instrument design, such as lower taper and reduced metallic mass, may play a more significant role in mitigating debris extrusion than kinematics alone.

Furthermore, recent advancements in endodontic motors, which offer enhanced control through functions such as apical reverse, apical stop, and adaptive torque control, could also influence debris extrusion. A study by Kılıç et al. (2023) (36) explored the effects of these functions, finding that while different kinematic modes, such as apical reverse and apical slow down, did not show statistically significant differences in debris extrusion compared to continuous rotation, these advanced features provide greater apical control, which could reduce the risk of excessive debris extrusion and postoperative complications. Although our study did not utilize motors with these advanced features, future research should consider their potential to further refine debris management during instrumentation.

It's important to note that when a sequence of instruments is employed, those with lower taper and reduced metallic mass tend to yield less extrusion (34). This is in contrast to other rotary systems like Protaper Next and HyFlex CM, which may feature more aggressive cutting blades, higher tapers, and greater metallic mass, consequently contributing to increased debris extrusion.

The clinical relevance of our findings is highlighted by the impact of debris extrusion on postoperative outcomes, particularly the risk of pain and flare-ups (35). Studies indicate that debris extrusion is strongly associated with postoperative pain (37) due to the extrusion of infected material into periapical tissues, leading to irritation and inflammation. Our data show that Protaper Next and HyFlex CM extruded significantly more debris compared to other systems, aligning with findings that rotary systems, particularly those with more aggressive cutting edges and greater taper, can increase the risk of postoperative discomfort. Conversely, the other systems in our study - Protaper Ultimate, HyFlex EDM, Trunatomy, Reciproc Blue, WaveOne Gold, and R-Motion - demonstrated lower debris extrusion. This reduction in debris extrusion may contribute to a decreased risk of postoperative pain, as supported by literature suggesting that less extrusion is associated with fewer inflammatory responses in the periapical tissues (37). By choosing these systems, clinicians can reduce the risk of postoperative complications, especially in cases involving necrotic or inflamed tissues, where managing debris extrusion is crucial to avoid exacerbating symptoms.

It is worth noting the remarkable performance of the HyFlex EDM system, categorized as a 'single-file' rotary system, which yielded results comparable to those of reciprocating systems. This achievement can be attributed to its distinctive thermal treatment and the fact that it operates as a single-file system within a rotary framework. The thermal treatment likely enhances the file's flexibility and cutting efficiency (38) while the single-file design may minimize debris generation during the procedure. These features suggest that the HyFlex EDM system presents a balanced approach, incorporating the advantages of both rotary and reciprocating systems in terms of debris extrusion and instrumentation time. These findings align with the literature regarding instrumentation time but contrast with respect to the amount of extruded debris (39). While our in vitro study sheds light on the potential for debris extrusion, it's important to acknowledge that clinical conditions may mitigate some of these effects. In many instances, patients may not even present symptoms associated with debris extrusion (2). Nevertheless, clinicians should exercise caution, especially when dealing with contaminated canals or cases linked to lesions, as such scenarios may heighten the risk of postoperative complications (1). Therefore, the choice of the system should be tailored not only to the clinical context but also to the operator's proficiency with the system.

The time factor in our study was evidently and understandably linked to the number of instruments in the system (40). However, it's crucial to emphasize that time should not be the sole determinant in selecting an endodontic system. For example, Protaper Ultimate, despite having the longest mean instrumentation time among all systems, was also among the least likely to extrude debris. This implies that investing a few extra seconds or minutes in instrumentation can lead to a cleaner and potentially more successful outcome. Moreover, the longest time in our study (194 seconds) is clinically negligible, equating to slightly over 3 minutes of instrumentation. In alignment with current guidelines advocating for a "slow endo" approach, there's no need to rush the instrumentation process. While our study examined the time factor, we did so primarily to gather additional data. When applied to clinical practice, it's of paramount importance to remember that quality should take precedence over speed. Additionally, we acknowledge that our decision to investigate the time factor stemmed from our understanding that it might reveal potential challenges for operators when working with a system and guide clinicians regarding this aspect.

While this study provides valuable insights into the performance of various endodontic file systems, several limitations should be acknowledged. First, all procedures were carried out by a single experienced operator. Although this approach ensured consistency, it may introduce bias due to personal preferences or subtle variations in technique, which could affect the generalizability of the results. Additionally, the study was conducted in a laboratory setting on extracted teeth, which may not fully replicate the complexities encountered in clinical practice, such as patient-related factors and varying anatomical challenges. Finally, only the mesiobuccal canals of mandibular molars were instrumented, potentially limiting the applicability of the findings to other tooth types and canal configurations. These limitations should be considered when interpreting the results and applying them to clinical practice.

Conclusion

The current study provides a detailed comparison of debris extrusion and instrumentation time across a range of endodontic file systems. These finds underline the importance of careful system selection based on specific procedural requirements and desired clinical outcomes. The study offers evidence-based guidance that can assist clinicians in selecting endodontic file systems that balance efficiency with procedural cleanliness. This tailored approach is critical for optimizing patient outcomes, as it takes into consideration the specific advantages and potential drawbacks of each system in relation to the clinical context.

Clinical Relevance

The extrusion of debris may result in postoperative pain, flare-ups, and the necessity for retreatment, thereby affecting the patient's experience and the prognosis of endodontic treatment. Research in this field facilitates the development of more effective clinical protocols, ensuring patient safety and improved outcomes.

Conflict of Interest

The authors declare that they have no competing interests.

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Ethics Approval

After obtaining approval from the local Research Ethics Committee (opinion no. 5.731.282).

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