

Apical Debris Extrusion of ProTaper Next Versus iRaCe Rotary Files in Curved Root Canals: An in vitro Study.

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Abstract

Background: This study quantitatively compared the apical extrusion of debris during the shaping of moderately to severely curved mandibular molar mesio-buccal canals using two rotary systems: ProTaper Next and iRace.

Methods: Forty mesial roots from selected human mandibular molars, with inclusion criteria requiring a mesiobuccal canal curvature ranging from 25 to 35 degrees were selected. Then, teeth were mounted and scanned via CBCT to confirm anatomy. The roots were sectioned, and the mesiobuccal canals were instrumented to an apical size 30 using either ProTaper Next (PTN) or iRace (iR) systems (n=20/group) in a torque-controlled motor. Apically extruded debris were collected into pre-weighed Eppendorf tubes using a Myers-Montgomery apparatus, desiccated, and re-weighed to determine the net debris mass. A one-way ANOVA was employed for statistical analysis, with post hoc comparisons conducted using Tukey's HSD test. A p-value of less than 0.05 was considered statistically significant.

Results: While both instrumentation techniques resulted in apical debris extrusion, quantitative analysis demonstrated a statistically significant difference between the groups. A significantly higher mean volume of extruded debris was produced by the iR system in comparison to the ProTaper Next system ($p < 0.001$).

Conclusion: The ProTaper Next system decreases the incidence of postoperative pain or flare up after shaping of curved canals than the iRace system.

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1 Introduction

Root canal treatment (RCT) is a fundamental dental procedure with high success rates comparable to dental implants.¹ Despite its predictability, complications such as perforation, canal transportation, or instrument fracture can compromise the primary objectives of disinfection and infection control.² Among these, apical debris extrusion is a well-documented and seemingly unavoidable occurrence, first described by Myers and Montgomery in 1991.³ This extrusion of dentinal debris, irrigants, bacterial byproducts, and necrotic tissues apically into periodontal area is a significant clinical concern, as it can provoke postoperative inflammatory reactions and flare-ups.⁴ Apical extrusion of intracanal debris is a consistent and unavoidable sequela of root canal shaping and cleaning procedures, even with the adoption of modern instrumentation techniques designed to minimize it.⁵

The initial approach to root canal instrumentation relied on manual techniques with stainless-steel files. Many studies have proved that using stainless steel instruments for preparation of curved root canals usually yield to undesirable outcomes as pushing a great amount of extruded debris beyond the apex.^{6,7} Later on, flexible nickel-titanium (NiTi) rotary tools were introduced, and they have shown to reduce procedural mistakes, decrease chair time and safer than typical stainless steel.^{8,9} Comparative analyses have been performed to measure the amount of debris extruded apically when root canals are shaped with different file systems and techniques. However, there is no file system that could prepare root canals without debris extrusion was invented.¹⁰⁻¹²

The apical extrusion of debris is a multifactorial phenomenon, significantly influenced by endodontic instrument design features such as taper, cross-section, cutting angle, and flute depth as well as operational parameters like motion, torque, rotational speed, and the number of instruments in a sequence. However, evidence regarding the predominant contributing factor remains controversial and inconclusive. It is uncertain whether a single parameter is primarily responsible or if the outcome results from the complex interaction of several design and technical characteristics.¹³

The evolution of rotary Nickel-Titanium files, through numerous technological advancements, has revolutionized root canal treatment by enabling faster and simpler shaping procedures.¹⁴ The ProTaper Next (PTN) system, which was introduced in 2013, is characterized by its variable taper, off-center rectangular cross-section, and composition of M-wire alloy. Together, these special qualities improve the system's adaptability and effectiveness in creating deeply curved root canals.¹⁵

As a derivative of the RaCe system, the iRaCe (iR) utilizes an austenitic nickel-titanium composition. Its design incorporates several key features for clinical performance: a homogenous triangular cross-sectional shape, a sequence of alternating cutting edges, and a non-cutting tip. Additionally, the file's resistance to cyclic fatigue was significantly increased by the electrochemical surface treatment it underwent. Because of its effectiveness and minimal risk of iatrogenic mistakes, the file is frequently used and included in dentistry education.¹⁶

The assessment of apical debris extrusion provides valuable insight into the clinical performance of endodontic files. As a result, multiple studies have assessed debris extrusion with various clinically used NiTi rotary file systems.¹⁷⁻¹⁹ Thus, the objective of this research was to evaluate and compare the amount of debris extruded periapically during root canal preparation using two continuous rotation nickel-titanium instrument systems. The null hypothesis stated that no statistically significant difference in apical debris extrusion would be observed between the PTN and iRace file systems during canal preparation.

2 Materials and Methods

2.1 Ethical Approval:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on:

28/10/2015, approval number: 15104

2.2 Sample size calculation:

Based on the findings of Nevares et al., (2015)²⁰, which reported mean apical debris extrusion values of 0.108 g and 0.097 g (difference = 0.011 g) with an average variability of 0.015 g, a sample size calculation was performed using the PS software. A power analysis, conducted to detect the anticipated effect size with 80% power at a 5% alpha level, indicated that a minimum sample of 40 molar teeth was required.

2.3 Samples selection:

A sample of 40 human mandibular molars (first and second molars) was obtained for this investigation. All teeth were extracted due to severe periodontal disease or to facilitate orthodontic treatment plans. Following extraction, all specimens were disinfected by immersion in 5.25% sodium hypochlorite for ten minutes, and residual soft tissue and calcified debris were meticulously removed via manual scaling.

Included teeth were mandibular first or second molars with two separate mesial canals and apical foramina, featuring mesio-buccal canals with a distal curvature of 25°–35° according to Schneider's method, where a size 15 K-file fit tightly at the apical third. Furthermore, all teeth exhibited complete root formation with a mature apex and a crown-to-root length between 20–22 mm. Specimens were excluded if they presented with thin or calcified mesio-buccal canals, root caries, internal or external resorption, previous endodontic treatment, cracks, anatomic abnormalities such as fusion or C-shaped canals, a prosthetic crown or post, or mesial roots with a double curvature.

For standardized imaging, eligible teeth were mounted in U-shaped plastic models (ten per model) using an impression compound to ensure stability during cone-beam computed tomography (CBCT) scanning. The apices of the mesial roots were sealed with wax (Wilson, Sao Paulo, Brazil) to obviate the risk of impression material intrusion into the apical foramina. CBCT scans of the 20 plastic U-shaped models with mounted teeth were obtained to verify eligibility based on the study's inclusion criteria. Image acquisition was carried out with a Next Generation i-CAT® scanner (Imaging Sciences International, Hatfield, PA, USA). The scans were performed with the following technical parameters: 120 kVp, 37.07 mAs, and a 26.9-second exposure time. The scanner captured volumetric data through a flat-panel detector composed of amorphous silicon and a cesium iodide (CsI) scintillator, coupled with a 0.5 mm focal spot. The acquired field of view (FOV) was cylindrical, measuring 16 cm in diameter and 4 cm in axial height. The acquired data had a voxel size of 0.125 mm³ and a 14-bit grayscale resolution. The Digital Imaging and Communications in Medicine (DICOM) formatted dataset derived from the volumetric scan was exported and physically transferred using a compact disc to a personal computer, where all analytical procedures were performed.

Root curvature angles and lengths of the mesial roots were analyzed using Invivo Dental software (Version 5.4; Anatomage, San Jose, CA, USA). The angle of curvature was determined based on the method described by Schneider (1971)²¹. Briefly, a reference line was drawn parallel to the long axis of the root canal. A second line was then drawn from the apical foramen to the point of the first discernible deviation from the long axis. The acute angle formed at the intersection of these two lines was measured and recorded as the angle of curvature.

The mesial root length was also measured for each specimen using the software's calibrated measurement tools.

2.4 Samples preparation:

After selection of the samples, they were prepared by creating conventional access cavities using a tapered, round-ended stone (TR13; Mani Inc., Tochigi-Kan, Japan). The mesiobuccal canals were then verified for apical patency with a size 10 K-file (Mani Inc., Tochigi-Kan, Japan). To standardize the working length, the occlusal surfaces of all teeth were reduced with a diamond stone (Mani Inc., Tochigi-Kan, Japan), allowing the length of the mesiobuccal canal to be adjusted to precisely 19 mm. The working length was determined visually by inserting a size 10 K-file into the canal and reducing the occlusal reference point until the file tip was flush with the apex at 19 mm from the flattened mesiobuccal cusp, thereby establishing a final working length of 18 mm. Subsequently, the distal roots along with their corresponding coronal portions were sectioned at the furcation level using a low-speed diamond saw (Isomet® 4000 Unear Precision Saw; Buehler Ltd, Lake Bluff, IL, England) under continuous coolant irrigation, with the blade operating at a speed of 2050 rpm and a feed rate of 8.8 mm/min; the separated distal segments were then discarded.

2.5 Classification of samples:

A total of forty mesial roots were numbered and then randomly allocated into two experimental groups of twenty specimens each. Group A underwent instrumentation of the mesio-buccal canal with ProTaper Next (PTN) files, and Group B with iRace (iR) files, using random allocation software (Microsoft Corporation, WA, USA) for the assignment process.

2.6 Preparation of the test apparatus:

Forty Eppendorf tubes (Safe-Lock microcentrifuge tubes- Sigma-Aldrich, LLC) were sequentially labeled from 1 to 40 and their tare weights were individually established using a digital electronic balance (Sartorius weighing technology, Gottingen, Germany) with a sensitivity of 0.00001 g; each empty tube was weighed in triplicate, and the mean weight was calculated and recorded. A customized assembly was then fabricated, incorporating modifications to the protocol outlined by Myers and Montgomery.³ A hole was created in the lid of each tube to accommodate a mounted tooth, which was secured at the cemento-enamel junction using sticky wax to ensure a hermetic seal. This configuration suspended the mesial root within the tube, allowing it to function as a collection container for apically extruded debris. Finally, a needle was inserted through the wax seal into each vial to serve as a pressure-equalization port (Fig. 1)



Figure (1). The setup of the experimental device used to test extrusion of debris

2.7 Root canal preparation

A standardized glide path to the working length (WL) of 18 mm was established in the mesio-buccal canal of each specimen using a size 15 K-file. Following this initial preparation, the canals were instrumented according to their assigned group. In Group A, shaping was performed using the ProTaper Next (PTN) (Dentsply Maillefer, Ballaigues, Switzerland) sequence: PTN X1 (17/.04), followed by PTN X2 (25/.06), and finally PTN X3 (30/.07), with all instruments advanced to the full WL. Conversely, Group B was prepared using the manufacturer-recommended sequence for iRaCe (FKG, La Chaux-de-Fonds, Switzerland) rotary instruments. This involved a crown-down technique employing iRaCe R1 (15/.06), R2 (25/.04), and R3 (30/.04) files, which were used with 3 to 4 gentle, brushing, back-and-forth strokes under light pressure until the full working length was reached.

All mesio-buccal root canals were instrumented using a 20:1 reduction handpiece powered by a torque-controlled motor (NSK Nakanishi, Inc., Tochigi, Japan), with the individual torque limit and rotational speed for both the PTN and iRace instruments set according to the manufacturer's recommendations **Table 1**. Each canal was prepared to the working length using a crown-down sequence, with instruments operated in continuous clockwise rotation using an in-and-out motion and no intentional brushing against the canal walls. Each instrument was advanced using three gentle, rotating strokes in an apical direction. Following this, the instrument was removed from the canal, its flutes were meticulously cleaned of all adherent dentinal debris, and the procedure was repeated with the same instrument until the predetermined working length was attained. Upon reaching this length, the instrument was immediately retrieved. All rotary files were new and used for the first time, with no instrument fractures occurring during the study. Throughout instrumentation, the pulp chamber was filled with distilled water, and canals were irrigated with 2 mL of distilled water for one minute between each instrument using a 30-G Max-i-Probe needle (Dentsply-Rinn, Elgin, IL) placed 1 mm short of the working length. To ensure continuous patency, a size #10 K-file was passively introduced into the canal after each

irrigation cycle. The definitive apical preparation was completed to a uniform diameter of ISO size 30 for every mesio-buccal canal in the study.

Table 1: The individual torque limit and rotational speed for PTN and iR rotary instruments. ^{22,23}

Instruments	The Selected Torque and Rotational Speed	
	Torque (N.cm)	Rotational Speed (RPM)
PTN files	2.5	300
iR files	1.5	600

2.8 Debris collection:

Prior to root canal instrumentation, the initial weight of each collection tube was determined by performing and recording three separate measurements, establishing a mean pre-instrumentation weight. The instrumentation phase was directly followed by the immediate extraction of the roots. All apically extruded debris was collected directly within the tubes, while any debris adhering to the root surfaces was recovered by irrigating the apical portion with 2 ml of distilled water, which was also collected in the respective tubes. Subsequently, the tubes were incubated at 37°C for a period of 7 days to ensure full evaporation of any residual liquid. The mean post-instrumentation mass of the apically extruded debris was calculated for each sample based on three separate weight measurements taken after the desiccation phase (Fig. 2). The calculation of debris mass involved subtracting the mean tare weight of the tubes, measured prior to instrumentation, from their mean weight recorded following the instrumentation procedure.



Figure 2. The Eppendorf with the extruded debris inside after evaporating the fluids

2.9 Statistical analysis:

A one-way ANOVA was utilized to analyze the data within each experimental group, applying a significance threshold of $p < 0.05$. Following a significant omnibus F-test, post-hoc pairwise analyses were carried out using Tukey's

HSD procedure to mitigate the risk of Type I errors across multiple comparisons.

3 Results

Both instrumentation techniques under investigation resulted in the apical extrusion of debris. Quantitative analysis revealed that Group B (iR) produced a significantly higher mean volume of extruded debris (0.00801 ± 0.0008) compared to Group A (PTN) (0.00241 ± 0.0006). This difference was statistically significant ($p < 0.001$) Table 2 and (Fig. 3).

Table 2: Mean, standard deviation (SD) & results of ANOVA test for comparison of amount of apical extrusion of debris in (gm) between the two groups

	Protaper Next		iRace		<i>p-value</i>
	Mean	SD	Mean	SD	
Apical extrusion of debris	0.00241	0.0006	0.00801	0.0008	* <0.001

*=Statistically significant at $p \leq 0.05$

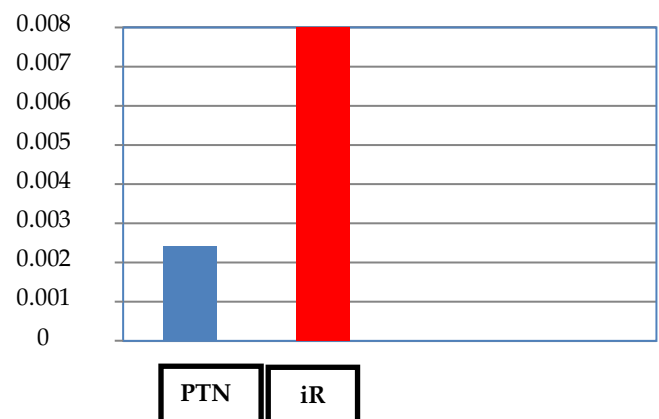


Figure 3. Bar chart showing the mean of apical extruded debris for different tested groups.

4 Discussion

During root canal preparation, the occurrence of a flare-up may result from apical debris extrusion. However, this risk can be minimized through the use of preparation techniques, working lengths, and instrument designs that are known to reduce such extrusion.²⁴ In our study, the ProTaper Next and iRace instrumentation systems were compared for this purpose. The ProTaper Next (PTN) file system represents a 5th-generation nickel-titanium (NiTi) system that operates in continuous rotation and is a successor to the ProTaper Universal system. Its cleaning efficacy is attributed to several key design features. Primarily, the system is featured by an off-center, asymmetrical rectangular cross-section.¹⁵ This offset design generates an uneven, snake-like ("swaggering") movement in the cutting segment, which reduces binding between the file and the root canal walls, thereby decreasing the risk of an unfavorable taper

lock.^{25,26} This specific design also aids in preventing unwanted dentin removal. Furthermore, the file is manufactured from M-wire alloy, which is reported to offer superior performance compared to conventional 55-nitinol. This alloy provides enhanced flexibility, increased resistance to cyclic fatigue, and improved cutting efficiency.^{27,28} These mechanical advantages can be explained by the M-wire's finer and more homogeneous alloy structure compared to austenite NiTi.²⁹ Thus the ProTaper Next was selected in the present study. Additionally, the iRace system was selected for this study due to its design philosophy, which aims to enhance procedural efficiency and safety.³⁰ The system utilizes a simplified sequence of only three to five instruments, thereby reducing both instrumentation time and the number of instruments required for root canal preparation.³¹ Furthermore, its design incorporates a triangular cross-section with alternating cutting edges, which serves to minimize the screwing-in effect.³² The instruments are electrochemically polished to eliminate surface flaws and reduce microcracks, and they feature a non-cutting, rounded safety tip to improve guidance within the canal and preserve the natural canal anatomy.³³ This study employed extracted human mandibular molars with complete root formation and closed apical foramina to better mimic a standard clinical presentation. Natural teeth provide a substrate of appropriate dentinal microhardness, three-dimensional root canal curvature, and anatomical variations, which are essential for evaluating endodontic instrument performance.³⁴ To standardize the apical diameters, apical patency was maintained using a 10 K-file. This standardization is a relevant consideration, as research indicates a relationship between apical preparation size and debris extrusion. *Tinaz et al. (2005)*³⁵ demonstrated that debris extrusion increases with larger apical diameters. Conversely, *Lambrianidis et al. (2001)*³⁶ observed, paradoxically, that significant extrusion still occurred despite the apical constriction being preserved. The apically extruded debris was quantitatively evaluated using a method adapted from *Myers and Montgomery (1991)*³. In this approach, debris extruded from the roots was collected into sterile, pre-weighed Eppendorf tubes. To ensure a hermetic seal, the detachable lids of the glass vials were fixed to the cemento-enamel junction (CEJ) using sticky wax.¹² Internal and external pressure was equalized using a rubber stopper and a 25-gauge needle. This methodology was selected over that described by *Brown et al. (1995)*³⁷, as their apparatus was found to produce an excessive amount of extruded irrigant, thereby potentially compromising the accuracy of debris measurement. The assessment of periapical debris extrusion has been conducted using various irrigants, as documented in endodontic research. Sodium hypochlorite (NaOCl) is commonly selected for this purpose across multiple studies.^{12,38} The use of distilled water as the irrigant was mandated by the need to prevent the crystallization of sodium hypochlorite (NaOCl). Such crystallization could introduce a confounding variable by adding mass to the debris, thereby compromising the accuracy of the extrusion measurements.^{39,40} Subsequent to instrumentation, the root surface was rinsed with 2 ml of distilled water, which was collected to account for any debris adherent to the apical surface.⁴¹ The samples were incubated at 37°C for 10 days to ensure total evaporative removal of the irrigant before obtaining a dry weight measurement of the

residual debris.^{12,42} The weight of the tubes was determined using a high-precision electronic balance (accuracy ± 0.00001 g) both prior to and following the instrumentation and incubation phases. This methodology permitted the highly sensitive detection of mass variation, with measurements accurate to 10^{-5} g.^{12,43} To ensure the validity of these measurements, it was crucial to standardize the cutting efficiency of all tested rotary files, as repeated use of NiTi instruments can compromise their surface sharpness and cutting efficiency factors known to influence the quantity of extruded debris.^{44,45} Consequently, all files employed in this study were new and had not been used in the preparation of any canals prior to testing. The present study descriptively demonstrated that both tested file systems, regardless of their design or kinematic motion, resulted in measurable apical debris extrusion. This outcome is consistent with the established consensus in the literature, which asserts that the extrusion of debris is an unavoidable consequence of all root canal instrumentation techniques.^{46,47} This finding supports the consensus that a certain degree of apical extrusion is an inherent outcome of chemo-mechanical debridement during root canal preparation. Subsequent research within the endodontic literature has further demonstrated that while extrusion occurs universally, all engine-driven instruments tend to extrude less intracanal bacteria than manual instruments.^{35,48,49} As suggested by *Reddy and Hicks (1998)*⁴⁸, the rotational action of engine-driven instruments can lead to the accumulation of dentinal debris within their flutes. This mechanism facilitates the coronal movement of debris toward the canal orifice, which in turn minimizes its apical extrusion. Regarding the intracanal debris apical extrusion findings, PTN observed a statistically lower extrusion than iRace. This can be explained by the PTN design's asymmetrical cross section, which allows the files to move like a snake.⁵⁰ By employing this movement, a pathway is created that allows debris to be effectively cleared and dentin shavings to be transported coronally. This process reduces the points of binding contact between the endodontic instrument and the canal wall.⁵¹ These results also were concurred with *Ruddle et al. (2013)*⁵² and *Elnaghy (2014)*⁵³. In contrast, the iRace file design features a symmetrical cross section that allows for concentrated file positioning inside the canals, perhaps improving the flow of intracanal debris apically, while having a lower taper than PTN, this was agreed by *Pedrinha et al. (2018)*⁵⁴. Furthermore, the combination of its alternating fluted and straight parts and rapid rotating speed, which removes more dentin in less time, increase the danger of pushing more debris in the apical direction. This was in agreement with *Tanlap et al. (2006)*⁵⁵, who stated that faster rotary systems extrude more debris. Our findings, which demonstrated that the ProTaper Next (PTN) system resulted in significantly less apical extrusion than the iRace system, stand in contrast with *Sobh et al. (2024)*⁵⁶. This discrepancy may be attributable to key differences in instrument design and methodology between the investigations. While the *Sobh et al. (2024)*⁵⁶ suggested that a smaller taper and a triangular cross-section with alternating cutting edges (as found in iRace) may reduce the "screwing effect" and facilitate debris removal, our results indicate that the metallurgy and design of the PTN system (M-Wire, off-centered rectangular cross-section) were more effective in minimizing extrusion. The higher percentage taper of the PTN instrument, previously hypothesized to potentially increase extrusion, did not prove to be a contributing factor in

our experimental model. Instead, the enhanced flexibility of M-Wire may have allowed for more efficient debris management within the canal space, ultimately leading to less apical extrusion. The findings of this study may have been affected by the inability to establish an apical barrier, which represents a key methodological constraint.⁵⁷ To replicate the periapical tissue surroundings, several researchers have recently employed floral foam.⁵⁸ However, the foam has the ability to absorb irrigants and particles, which might compromise the precision of the experimental results.⁵⁹ Thus, in our investigation, we did not attempt to replicate the periapical tissue environment. Given the constraints of this study, periapical resistance was not intentionally generated since prior research had shown that the used foam may be sucked up into the canal and that there was insufficient data to determine apical resistance.⁵⁶ Further investigations are needed to recreate the periapical resistance.

5 Conclusion

Under the in vitro conditions of this study, the ProTaper Next (PTN) instrumentation system produced a statistically significant decrease in extruded apical debris when compared to the iRace system, specifically in the curved mesial canals of mandibular molars. Consequently, the PTN system may offer a clinical advantage by minimizing the inadvertent forcing of debris into the periapical tissues, potentially reducing the risk of postoperative inflammation..

Authors' Contributions

Ahmed Ezz: Conceptualization, writing, original draft preparation, methodology and design .

Shaimaa Ismail Gawdat: Supervision, reviewing and editing

Alaa Hassan Diab: Supervision, Final reviewing, editing and data curation.

Conflict of interest

The authors declare that they hold no competing interests.

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