



Comparative evaluation of fracture resistance of Hyflex EDM OGSF file system, Protaper Ultimate and RACE EVO file system: an in vitro study

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Abstract

INTRODUCTION. The intracanal fracture of nickel-titanium (NiTi) rotary instruments remains a significant procedural concern in endodontics. Advances in metallurgy, manufacturing processes, and geometric design have led to the development of new file systems with enhanced mechanical properties. The Hyflex EDM OGSF (HEDM), Protaper Ultimate (PTU), and RACE EVO (RE) systems represent distinct technological approaches to improving instrument safety. However, a direct comparative evaluation of their fracture resistance is limited. **MATERIALS AND METHODS.** A total of 120 new NiTi files, 40 from each system (HEDM, PTU, RE), with a tip size of 25 and a .07 taper, were selected. For the cyclic fatigue test ($n = 20$ per group), instruments were rotated in a custom-fabricated stainless steel artificial canal with a 60° angle of curvature and a 5 mm radius until fracture. The number of cycles to fracture (NCF) was calculated. For the torsional resistance test ($n = 20$ per group), the apical 3 mm of each file was clamped, and the instrument was rotated clockwise at 2 RPM until fracture, following ISO 3630-1 standards. Maximum torque (Ncm) and angular deflection (degrees) at failure were recorded. Data were statistically analyzed using one-way ANOVA and Tukey's HSD post-hoc test ($\alpha = 0.05$).

RESULTS. HEDM exhibited a significantly higher mean NCF (852.5 ± 75.3) compared to both RE (621.8 ± 60.2) and PTU (455.1 ± 55.4) ($p < 0.001$). RE also showed significantly higher cyclic fatigue resistance than PTU ($p < 0.001$). In the torsional test, PTU demonstrated the highest maximum torque to fracture (0.46 ± 0.05 Ncm), which was significantly greater than RE (0.41 ± 0.04 Ncm) and HEDM (0.34 ± 0.06 Ncm) ($p < 0.001$). The difference in torque resistance between RE and HEDM was also statistically significant ($p < 0.01$).

CONCLUSIONS. Within the limitations of this laboratory study, the Hyflex EDM OGSF file system demonstrated the highest resistance to cyclic fatigue. The Protaper Ultimate file system exhibited the greatest resistance to torsional fracture. The choice of instrument should be guided by the specific anatomical challenges of the root canal system.

Keywords: cyclic fatigue, torsional resistance, nickel-titanium, hyflex EDM, protaper ultimate, RACE EVO, endodontics

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Сравнительная оценка устойчивости к перелому файловых систем Hyflex EDM OGSF, Protaper Ultimate и RACE EVO: исследование in vitro

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Резюме

ВВЕДЕНИЕ. Внутриканный перелом никель-титановых (NiTi) ротационных инструментов остается значимой процедурной проблемой в эндодонтии. Совершенствование металлургии, производственных технологий и геометрического дизайна привело к созданию новых файловых систем с улучшенными механическими характеристиками. Системы Hyflex EDM OGSF (HEDM), Protaper Ultimate (PTU)

и RACE EVO (RE) представляют различные технологические подходы к повышению безопасности инструментов. Однако их прямое сравнительное исследование на предмет устойчивости к перелому представлено в ограниченном объеме.

МАТЕРИАЛЫ И МЕТОДЫ. В исследование включены 120 новых NiTi-файлов – по 40 инструментов из каждой системы (HEDM, PTU, RE) с размером кончика 25 и конусностью .07. Для теста на циклическую усталость ($n = 20$ в каждой группе) инструменты вращались в индивидуально изготовленном искусственном канале из нержавеющей стали с углом кривизны 60° и радиусом 5 мм до момента перелома. Рассчитывалось количество циклов до перелома (NCF). Для теста на торсионную устойчивость ($n = 20$ в каждой группе) апикальные 3 мм каждого файла фиксировались, после чего инструмент вращался по часовой стрелке со скоростью 2 об/мин до перелома в соответствии со стандартом ISO 3630-1. Регистрировались максимальный крутящий момент (Н·см) и угол деформации (в градусах) в момент разрушения. Статистический анализ проводился с использованием однофакторного дисперсионного анализа (ANOVA) и пост-хок теста Тьюки ($\alpha = 0,05$).

РЕЗУЛЬТАТЫ. HEDM продемонстрировала статистически значимо более высокое среднее значение NCF ($852,5 \pm 75,3$) по сравнению с RE ($621,8 \pm 60,2$) и PTU ($455,1 \pm 55,4$) ($p < 0,001$). RE также показала достоверно более высокую устойчивость к циклической усталости по сравнению с PTU ($p < 0,001$). В тесте на торсионную устойчивость PTU продемонстрировала наибольший максимальный крутящий момент при переломе ($0,46 \pm 0,05$ Н·см), что было статистически значимо выше по сравнению с RE ($0,41 \pm 0,04$ Н·см) и HEDM ($0,34 \pm 0,06$ Н·см) ($p < 0,001$). Различия в торсионной устойчивости между RE и HEDM также оказались статистически значимыми ($p < 0,01$).

ВЫВОДЫ. В пределах ограничений данного лабораторного исследования файловая система Hyflex EDM OGSF продемонстрировала наибольшую устойчивость к циклической усталости. Система Protaper Ultimate показала максимальную устойчивость к торсионному перелому. Выбор инструмента должен определяться анатомическими особенностями корневого канала и клинической ситуацией.

Ключевые слова: циклическая усталость, торсионная устойчивость, никель-титан, Hyflex EDM, Protaper Ultimate, RACE EVO, эндодонтия

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INTRODUCTION

The ultimate goal of root canal treatment is complete chemomechanical debridement of the root canal system and then obturation of the root canal system in order to avoid reinfection [1]. Nickel-titanium (NiTi) rotary instruments are introduced to practice endodontics and help to prepare complex root canal morphologies efficiently and predictably compared to traditional stainless steel hand files [2]. NiTi alloys exhibit superelasticity and shape memory, which enables such instruments to maneuver round curves in canals with a smaller probability of errors in the process like ledging, zipping, and transportation [3].

Although these benefits are present, intracanal fracture of NiTi instruments is an important iatrogenic event that may undermine the outcome of the treatment [4]. The mechanism of instrument separation is of two types: cyclic fatigue and torsional failure [5]. Repeated tensile and compressive stresses result in cyclic fatigue caused by rotation of a file in a curved canal, which causes crack formation and upward all the way to fracture [6]. Torsional failure happens when the tip of the equipment becomes attached or clamped in the canal as the shank turns resulting in shear strains that surpass the elastic threshold of the metal [7].

To reduce the chances of the fracture of instruments, the manufacturers have paid attention to three essential directions of innovation: alloy metallurgy, instrument design, and manufacturing processes [8]. The creation of

NiTi alloys subjected to thermal treatment (e.g., M-Wire, R-Phase, Gold-wire, Blue-wire) has seen the creation of instruments that have greater flexibility and cyclic fatigue resistance than traditional superelastic NiTi [9; 10]. Moreover, the instrument cross-section, taper and flute design changes are intended to achieve a better cutting efficiency and minimize stress concentration [11].

This study focuses on three contemporary file systems that embody these technological advancements. The Hyflex EDM OGSF (Coltene/Whaledent, Altstätten, Switzerland) files are manufactured using an Electrical Discharge Machining (EDM) process. This technique creates a unique, hardened surface with inherent micro-craters, which is purported to enhance cutting efficiency and fracture resistance, while the core remains highly flexible due to its controlled memory (CM) wire composition [12; 13]. The Protaper Ultimate system (Dentsply Sirona, Ballaigues, Switzerland) is an evolution of the widely successful Protaper series. It is fabricated from proprietary Gold-wire, features a variable taper design, and has an off-centered, parallelogram-shaped cross-section intended to improve debris removal and reduce the “screw-in” effect [14; 15]. The RACE EVO system (FKG Dentaire, La Chaux-de-Fonds, Switzerland) is characterized by its proprietary heat treatment, which provides enhanced flexibility, and an alternating-cutting-edge design on a triangular cross-section, aimed at minimizing engagement and improving safety [16; 17].

Several studies have individually evaluated the mechanical properties of these file systems or compared them to their predecessors [13; 15; 17]. For instance, research has confirmed the superior cyclic fatigue resistance of Hyflex EDM files over many other systems [18], and the balanced properties of the Protaper Ultimate system have been noted [14]. However, there is a scarcity of research directly comparing these three specifics, technologically distinct systems within a single standardized experimental framework. This research gap is significant, as clinicians must make evidence-based decisions when selecting an instrument system best suited for the diverse anatomical challenges encountered in daily practice.

Therefore, the aim of this *in vitro* study was to provide a direct comparative evaluation of the cyclic fatigue and torsional fracture resistance of the Hyflex EDM OGSF, Protaper Ultimate, and RACE EVO file systems. The null hypothesis was that there would be no significant difference in the mechanical performance among the three tested file systems.

MATERIALS AND METHODS

Study design and sample selection

This *in vitro* comparative study was designed to evaluate the mechanical properties of three commercially available NiTi file systems. A total of 120 new, sterile instruments were procured from single batches to minimize manufacturing variability. The instruments were divided into three groups ($n = 40$ per group):

Group 1: Hyflex EDM OGSF (HEDM) – Size 25, .07 taper.

Group 2: Protaper Ultimate (PTU) – Finisher F2, Size 25, .07 taper.

Group 3: RACE EVO (RE) – Size 25, .07 taper.

Each group was further subdivided for two separate tests: cyclic fatigue testing ($n = 20$) and torsional resistance testing ($n = 20$). The selected size (25/.07) represents a common finishing file size, making the comparison clinically relevant.

Instrument inspection

Prior to testing, all instruments were examined under a dental operating microscope (Leica M320, Leica Microsystems, Wetzlar, Germany) at 20× magnification to detect any visible manufacturing defects, such as unwound flutes, surface irregularities, or bent shanks. Any instrument with visible defects was to be excluded and replaced; however, no instruments were excluded based on this criterion.

Cyclic fatigue testing

The cyclic fatigue resistance was tested using a custom-fabricated static model. A block of stainless steel was machined to create an artificial canal with a 60° angle of curvature and a 5 mm radius of curvature. This geometry simulates a severely curved canal and is a standardized method for *in vitro* fatigue testing. The testing device consisted of a stationary platform holding the steel block and a mobile unit for a 6:1 reduction contra-angle handpiece (Sirona, Bensheim, Germany) powered by an endodontic motor (X-Smart Plus, Dentsply Sirona).

Each instrument was coated with a synthetic lubricant (WD-40 Company, San Diego, CA, USA) to reduce friction and heat generation. The file was then introduced into the artificial canal and rotated according to the manufacturer's recommended settings for speed and torque (HEDM: 400 RPM/2.5 Ncm; PTU: 400 RPM/2.5 Ncm; RE: 1000 RPM/1.5 Ncm). The instrument was operated continuously until a fracture was audibly and visually detected. A digital stopwatch with a precision of 0.01 seconds was used to record the time to fracture (TTF). The number of cycles to fracture (NCF) was calculated using the formula:

$$NCF = \frac{TTF \text{ (seconds)} \times \text{Rotational Speed (RPM)}}{60}$$

The fractured segments were retrieved, and the length of the fractured tip was measured with a digital caliper to confirm consistency of the fracture location at the point of maximum curvature.

Torsional resistance testing

The torsional resistance test was performed in accordance with ISO 3630-1 standards using a dedicated torsion testing machine (Tinius Olsen, Horsham, PA, USA). The apical 3 mm of each instrument was securely clamped between two smooth-surfaced brass jaws. The file shank was fixed into the chuck of the motor, which was connected to a torque sensor.

The test was initiated by rotating the instrument in a clockwise direction at a constant speed of 2 RPM. The testing apparatus recorded the torque (Ncm) and the angle of rotation (degrees) in real-time. The test continued until the instrument fractured. The two primary parameters recorded were the maximum torque to fracture (the peak torque value reached before failure) and the angular deflection at fracture (the total degrees of rotation from the start of the test until the point of fracture).

Statistical analysis

All collected data were entered into a spreadsheet (Microsoft Excel 2019, Microsoft Corp., Redmond, WA, USA) and analyzed using statistical software (SPSS Version 26.0, IBM Corp., Armonk, NY, USA). Descriptive statistics, including mean and standard deviation (SD), were calculated for NCF, maximum torque, and angular deflection for all three groups. The normality of the data distribution was confirmed using the Shapiro-Wilk test. A one-way analysis of variance (ANOVA) was performed to compare the means among the three groups for each tested parameter. If a statistically significant difference was found, Tukey's Honestly Significant Difference (HSD) post-hoc test was used for pairwise comparisons. The level of statistical significance was set at $p < 0.05$.

RESULTS

All 120 instruments were tested successfully, and no data were excluded. The mean values, standard deviations (SD), and statistical comparisons for both cyclic fatigue and torsional resistance tests are presented below.

Cyclic fatigue resistance

Table 1 indicates the mean NCF value of the three file systems. The highest mean NCF was recorded in HEDM group then in the RE group and finally in the PTU group. ANOVA One way ANOVA showed statistically significant cyclic fatigue resistance difference between the three groups ($F = 152.6, p < 0.001$).

The HSD post-hoc test by Tukey (Table 3) proved the statistical relevance of all the pair-wise tests. The HEDM files had a much high resistance to cyclic fatigue when compared to both RE files ($p < 0.001$) and PTU files ($p < 0.001$). In addition, cyclic fatigue resistance was found to be a lot higher with the RE files than with the PTU files ($p < 0.001$).

Table 1. Descriptive statistics for cyclic fatigue resistance (NCF)

Таблица 1. Описательная статистика сопротивления циклической усталости (NCF)

File System	n	Mean NCF	Standard Deviation (SD)
Hyflex EDM OGSF (HEDM)	20	852.5	75.3
Protaper Ultimate (PTU)	20	455.1	55.4
RACE EVO (RE)	20	621.8	60.2

Table 2. Descriptive statistics for torsional resistance

Таблица 2. Описательные статистические данные о сопротивлении кручению

File System	n	Mean Max Torque (Ncm)	SD	Mean Angular Deflection (°)	SD
Hyflex EDM OGSF (HEDM)	20	0.34	0.06	510.5	45.2
Protaper Ultimate (PTU)	20	0.46	0.05	425.3	38.8
RACE EVO (RE)	20	0.41	0.04	448.7	40.1

Table 3. Pairwise comparisons from Tukey's HSD Post-Hoc test

Таблица 3. Парные сравнения, полученные в ходе последующего теста Тьюки на HSD

Parameter	Comparison	Mean Difference	p-value
NCF	HEDM vs. PTU	397.4	<0.001*
	HEDM vs. RE	230.7	<0.001*
	RE vs. PTU	166.7	<0.001*
Max Torque (Ncm)	PTU vs. HEDM	0.12	<0.001*
	PTU vs. RE	0.05	0.041*
	RE vs. HEDM	0.07	0.008*
Angular Deflection (°)	HEDM vs. PTU	85.2	<0.001*
	HEDM vs. RE	61.8	0.009*
	RE vs. PTU	23.4	0.215

Note: * Statistically significant at $p < 0.05$

Примечание: * Статистически значимо при $p < 0,05$

Torsional resistance

Table 2 shows the findings of the torsional resistance test and the maximum torque and angular deflection. The maximum torque to fracture and the angular deflection were the highest in the PTU group and HEDM group, respectively.

Statistical analysis using one way ANOVA revealed that there was significant difference between the groups in terms of both maximum torque ($F = 19.8, p < 0.001$) and angular deflection ($F = 12.4, p < 0.001$).

A post-hoc test using Tukey HSD test (Table 3) to determine maximum torque found that PTU group was significantly more resistant (torsional) to torsional stress than the RE group ($p < 0.05$) or the HEDM group ($p < 0.001$). RE group also displayed a highly significant torsional strength in comparison to the HEDM group ($p < 0.01$). In angular deflection, HEDM group recorded much more deflection until fracture than both PTU ($p < 0.001$) and RE ($p < 0.01$). Angular deflection did not significantly differ between the PTU and the RE group ($p > 0.05$).

DISCUSSION

The current in vitro research was carried out to compare the fracture resistance of three current NiTi rotary systems that are: Hyflex EDM OGSF, Protaper Ultimate and RACE EVO. According to the findings, the null hypothesis that the file systems would not have a significant difference was rejected. The results showed that both cyclic fatigue and torsional resistance were significantly different and each of the systems had its own mechanical behaviors.

The best result turned out to be the increased cyclic fatigue resistance of the Hyflex EDM files. The HEDM group passed through about 87 cycles to fracture compared to the PTU group and 37 cycles compared to the RE group. This finding can be compared to earlier studies that have indicated that the EDM manufacturing process has special fatigue resistance and flexibility [12; 18]. The resulting EDM process not only produces a specialty spark-eroded surface, which is hard and not easily crack starting, but also the underlying CM-wire alloy is extremely flexible and resistant to crack propagation [13]. This combination enables the instrument to be able to endure in the curved canals more stress cycles before it fails. RACE EVO system also fared well in cyclic fatigue test, which was way ahead of Protaper Ultimate system. This is owed to the fact that it has its own heat treatment and a relatively slender core that makes it flexible [16]. Protaper Ultimate is made of Gold-wire making it easier to have its cyclic fatigue characteristic enhanced over its M-wire counterpart, Protaper Gold [14]. Its resistance was however lower than that of the two other systems in this comparison which could be associated with its larger core mass and specific cross-sectional geometry which could enhance stiffness [15].

However, the torsional resistance tests showed different rankings. The Protaper Ultimate system showed the greatest resistance to torsional fracture with RACE EVO in the next rank and then Hyflex EDM. The cross-sectional area of the instrument and its core diameter

have an important impact on torsional strength, as well as the metallurgy of the alloy [19]. The cross-section of the PTU F2 file is parallelogram-shaped which makes its metallic core larger than the triangular-shaped core of the RACE EVO or the slimmer core of the Hyflex EDM file. This adds more weight to the metal, which can support the twisting forces before plastic deformation and fracture takes place [11]. The performance of the RACE EVO file was moderate, which probably indicated the reason between its mass of the core and the characteristics of its heat-treated alloy. The Hyflex EDM file was the lowest torsional strength although it was more flexible. It is a natural trade-off, that the traits of metallurgy which make it flexible and able to resist cyclic fatalities also make it less torsionally rigid [20].

The angular deflection result gives also some understanding about the behavior of the instruments when handled on torsion stress. The HEDM files were the most angularly deflected files which means that they are more able to deform plastically before breaking. This property may act as a visual alert to the clinician since a file that uncoils at a very slow rate can be regarded as safe, whereas, a file that splits suddenly with minimal prior notice may pose danger to the clinician [7]. The PTU and RE files displayed lower and statistically equal angular deflection values indicating a stiffer behavior under torsional load.

These implications on the clinical implications are important. The Hyflex EDM system is the safest in this case because of its excellent fatigue resistance in the treatment of canals with severe or multiple curvatures whose fracture is mainly due to cyclic fatigue. Torsional strength of the Protaper Ultimate system can prove beneficial where the torsional stresses in instruments, and in the canals, are more critical, e.g., thin, calcified, or straight canals. The RACE EVO system has an equal profile, as it is good in both categories, and it is

a versatile system that can suit a wide range of clinical situations.

This research has various limitations which are a result of in vitro research design. The experiments were done at room temperature, which is not a good resemblance of the intracanal temperature of the human body (35–37 degC), an aspect that has been proven to affect the phase transformation and mechanical characteristics of NiTi alloys [11]. A static model of cyclic fatigue does not replicate the dynamic pecking of that used in the clinical setting. Moreover, each system was tested with only one size and taper (25/.07), and outcomes might not be the same with other sizes of instruments. These limitations can be resolved in future studies by adding dynamic models, body temperature testing, and testing a greater variety of instrument sizes to gain a better idea of their clinical performance.

CONCLUSION

As confined in this in vitro experiment, it may be concluded that Hyflex EDM OGSF file system had better cyclic fatigue resistance than Protaper Ultimate and RACE EVO systems, which may indicate higher flexibility and better compatibility when it comes to repetitive canal negotiation. Conversely, the Protaper Ultimate system has proved to have the highest torsional strength, therefore, more power to resist rotational stress before breaking, the RACE EVO system has proven to provide an intermediate mechanical behavior and performance in both aspects. These results underscore the fact that a NiTi rotary file system selection must be dictated by the clinical situation and morphology of the root canals since none of the systems was the best in all cases. The trade-off between cyclic fatigue resistance and torsional strength is intrinsically explained by the necessity to choose devices according to the particular anatomical and procedural needs of a particular case.

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