



Article

Flexural Fatigue of Unicone, Navigator Evo and Protaper Next Files in Reciprocate and Continuous Rotary Systems in Simulated Curved Canals—An In Vitro Study

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Received: 29 October 2019; Accepted: 19 December 2019; Published: 22 December 2019



Abstract: This study investigated the cyclic fatigue resistance of three brands of nickel-titanium rotary files—Unicone (size 25 0.06; Medin), Navigator Evo (W-4; size 25 0.06; Medin) and Protaper Next (X2; size 25 0.06 Dentsply Tulsa Dental)—in reciprocating and continuous motion, during artificial canal instrumentation. Seventy-two samples—Unicone ($n = 24$), Navigator Evo ($n = 24$), and Protaper Next ($n = 24$)—each measuring 25 mm in length, were allocated to reciprocating ($n = 36$) and continuous motion ($n = 36$) experimental subgroups, and rotated in a simulated steel curved canal until fracture occurred. Fracture times and fragment lengths of samples in the experimental subgroups were recorded. One of the Unicone, Navigator Evo and Protaper Next fractured samples was randomly selected and analyzed for topographic characteristics by using scanning electron microscopy. Times to fracture and fragment lengths of samples were evaluated by analysis of variance and Tukey's tests. Independent sample t test was used to compare mean values between the different groups. Protaper Next samples displayed significantly higher resistance to cyclic fatigue in reciprocating motion than Unicone and Navigator Evo samples ($p < 0.001$). Unicone samples exhibited the least fracture-resistant in continuous and reciprocating motion.

Keywords: cyclic flexural fatigue; navigator evo; protaper next; simulated curved canals; unicone

1. Introduction

Root canal instrumentation is one of the most important steps in endodontic treatment. Appropriate and safe instrumentation of root canals depend on the mechanical actions of the instruments used in endodontic treatment [1]. Insufficient knowledge of the features of endodontic instruments may cause practical failures like ledge formation or the transportation and breakage of tools within root canals [1]. Nickel–titanium (NiTi) rotary instruments may fail unpredictably inside root canals during instrumentation, because instruments can break within their elastic limit [2]. Nickel-titanium root canal files were first introduced in order to beat the inflexibility of stainless-steel files for progressive instrumentation of curved canals [3]. Compared to stainless steel, the elastic limit of nickel-titanium is far greater, and its superelasticity decreases the re-establishing force [4], resulting in enhanced canal shaping and lesser transportation [5].

Two different separation mechanisms (i.e., torsional and flexural fatigue fracture) have been reported for rotary files [6]. In the first mechanism, torsional fracture takes place once "the tip or any part of the instrument locks in a canal while the shaft continues to rotate" but flexural failure happens as a result of "work hardening and metal fatigue" [6]. In the second, torsional fracture occurs more frequently than flexural fracture [6].

Cyclic fatigue arises after a metal is exposed to frequent cycles of tension and pressure and this initiates the breakdown of its structure, leading to fracture [7]. Cyclic fatigue occurs more often in a canal with an acute curve and a small radius of curvature [8], and it is the main reason for separation of NiTi instruments [9]. The cyclic fatigue resistance of NiTi rotary files has been examined using fixed models because they provide standardized situations for each tested instrument [10].

New ideas and designs of NiTi alloys coupled with thermomechanical developments have enhanced the cyclic fatigue resistance of NiTi-based files [11], but newer heat-treated NiTi systems such as Unicone and Navigator Evo) and M-wire type files such as ProTaper Next, need further evaluation to compare their relative cyclic fatigue.

This study aimed to evaluate the cyclic fatigue resistance of Unicone, Navigator Evo and ProTaper Next files used in reciprocating and continuous motions. The first null hypothesis is that the various file groups have no difference in the cyclic fatigue resistance. The second null hypothesis is that the reciprocating and continuous motions files have no significant difference in their cyclic fatigue resistance.

2. Materials and Methods

A priori sample size estimation was performed by using G* power statistical power analysis program 3.1.1. A sample size of 72 NiTi rotary files (Unicone, $n = 24$; Navigator Evo, $n = 24$; Protaper Next, $n = 24$) was chosen based on an alpha error probability of 0.05, a power of 0.90 and effect size (ρ) of 0.50 for the F tests. Samples were allotted to two experimental groups (A and B) as follows: Reciprocating motion (Group 1A: Unicone, $n = 12$; Group 2A: Navigator Evo, $n = 12$; Group 3A: Protaper Next, $n = 12$); Continuous motion (Group 1B: Unicone, $n = 12$; Group 2B: Navigator Evo, $n = 12$; Group 3B: Protaper Next, $n = 12$), as shown in Figure 1. The dimensions of the Unicone and N-Evo samples were alike (length: 25 mm, instrument tip size: 0.25 mm and taper: 6%), but Protaper Next samples had a multi-tapered design (Figure 2).

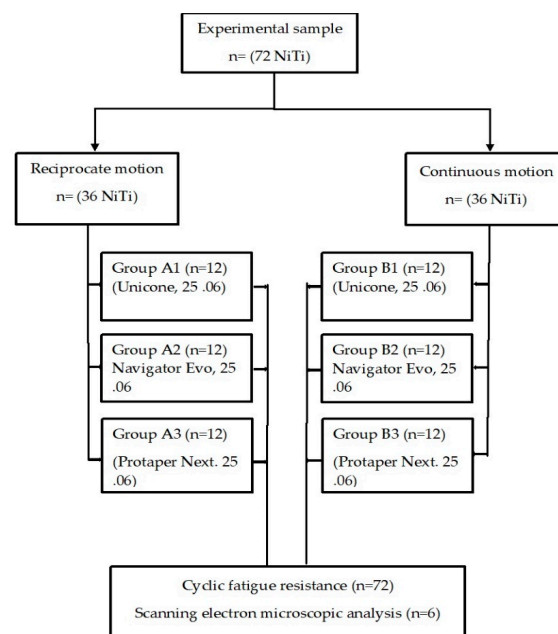


Figure 1. Flow chart of the distribution and treatment of experimental samples.



Figure 2. Study samples (A) Unicore, (B) Navigator Evo, (C) Protaper Next.

A purpose-built fatigue-testing device made up of a sloped block of stainless steel fixed to a frame was set up for the experiment. The steel block measured $85.8 \times 25.4 \times 9.5$ mm and was machined according to previous recommendations [10,12]. A simulated root canal (length: 19 mm, curvature: 60° , radius: 5 mm and depth: 1.5 mm) was prepared in the steel block. The steel block was shielded with a glass plate for clear visibility of the file motion, to protect the file and to help in easy removal of wrecked fragments after fracture. An electric rotary hand-piece fixed to a file was connected to the main frame and accurately positioned to the artificial canal with reproducible connection in the steel block (Figure 3).

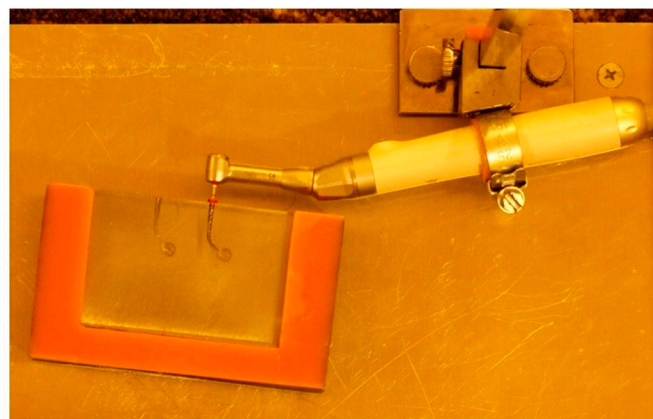


Figure 3. Purpose-built fatigue-testing device. Figure shows the block of stainless steel ($85.8 \times 25.4 \times 9.5$ mm) machined to create a simulated root canal of length 19 mm, curvature 60° , radius 5 mm and depth 1.5 mm, and shielded with a glass plate for clear visibility of file motion. Samples were rotated with the electric rotary handpiece fixed to the main frame and aligned to the artificial canal.

The continuous motion test samples were subjected to continuous clockwise rotation, until fracture occurred. Each sample was inserted up to 19 mm into the artificial canal, perpendicular to the orifice, while ensuring that the glass cover did not make contact with the file sample. Lubrication oil (WD-40 Company, Milton Keynes, UK) was injected into the artificial canal to reduce frictional heat.

An electric motor (X-Smart; Dentsply Maillefer) with a 16:1 gear reduction handpiece was used to rotate the samples at a speed recommended by the manufacturer (Unicone and Navigator Evo at 160 rpm, and PTN at 300 rpm). The reciprocate motion test samples were set in motion in a similar way.

To maintain accuracy, a single operator conducted all the tests. A digital chronometer (1/100 s) was used to record the time till fracture of each sample. The total number of cycles to failure for each sample was calculated by using the formula (time to fracture \times the number of rotations/60 s). A digital caliper (Mitutoyo, Tokyo, Japan) was used to measure the length of the broken segments. The primary outcome variable of the study was the cyclic fatigue resistance of reciprocating and continuous motion NiTi instruments in the simulated root canal. Surface topography of fractured fragments of samples was assessed under scanning electron microscope.

The experiments were conducted at the Biomechanical Laboratory of the Engineer Abdullah Bugshan Research Chair for Dental and Oral Rehabilitation (DOR), College of Dentistry, King Saud University, Riyadh, Saudi Arabia.

2.1. Scanning Electron Microscopy (SEM) Analysis

Images of the surface of broken samples were captured using a scanning electron microscope (JEOL JSM-6360LV, JEOL Ltd., Tokyo, Japan) and used to describe the topography of the fracture surfaces. All the broken samples (base part) were cleaned by ultrasonic bath (SONICER—YOSHIDA) using absolute ethanol for 10 min, dried at room temperature and mounted vertically on 15-mm SEM specimen metal mount stubs using double-sided carbon tape. Images at various magnifications were then taken to assess the broken area of each sample.

2.2. Statistical Analysis

The mean and standard deviation values of fragment length (mm), time to fracture (seconds) and number of cycles for failure (NCF) were calculated and compared between groups. One-way ANOVA was performed to investigate the effect of motion, and of file type, on fracture length of instruments. Post-hoc Tukey's test was used to calculate (Mean \pm Standard Deviation) of the data and to analyze the results obtained from the various groups. Two-way ANOVA was used to examine the combined effect of motion type (continuous versus reciprocating) and file type (Unicone, N-Evo and PTN) on length of fractured files, and the effect of motion type (continuous versus reciprocating) and file type (Unicone, N-Evo and PTN) on time taken to fracture the samples. Independent sample t test was used to compare mean values between two different groups. Level of significance of the statistical tests was set at $p < 0.05$.

Probabilistic modeling of fatigue failure and reliability evaluation is commonly performed in engineering components undergoing different loadings. Weibull reliability analysis was performed as previously described [13] to evaluate the chances of failure of the tested samples.

3. Results

Table 1 shows the Mean \pm SD of fragment length and the fracture time for various reciprocating and continuous file systems. Reciprocating files showed statistically significant difference in fragment length ($p = 0.001$). Unicone files exhibited significantly higher fragment length compared to the PTN files ($p = 0.001$). Similarly, reciprocating files showed statistically significant difference in time required to fracture the file ($p = 0.001$). The PTN took a significantly longer time to break the files as compared to N-Evo ($p = 0.01$) and Unicone ($p = 0.001$) files. The continuous file systems also showed statistically significant difference in time required to fracture the sample ($p = 0.000$). This difference was significant between Unicone group and PTN group ($p = 0.000$), and between N-Evo group and PTN group ($p < 0.000$). Furthermore, continuous group files showed significant difference in NCF ($p = 0.001$). Number of cycles to failure were significantly higher with PTN files as compared to Unicone files ($p = 0.001$).

Table 1. Comparison of Fragment length, time and Number of cycles to failure among different file systems.

Type of Motion.	Files (Test Groups)			Statistics	
Reciprocating	Unicone (A)	N-Evo (B)	PTN (C)	p §	Mean Difference between groups ¶
Fragment Length (mm)	4.03 ± 0.2	3.79 ± 0.2	3.63 ± 0.33	0.001	[A–C]
Time (sec)	109.5 ± 25.05	118.17 ± 19.45	144.5 ± 16.91	0.001	[A–C, B–C]
Continuous motion	Unicone (D)	N-Evo (E)	PTN (F)	p §	Mean Difference between groups ¶
Fragment Length (mm)	3.87 ± 0.21	3.75 ± 0.29	3.74 ± 0.26	0.417	-
Time (sec)	162.75 ± 36.35	182.08 ± 18.77	112.5 ± 16.69	<0.001	[D–F, E–F]
NCF	434 ± 96.95	485.56 ± 50.06	562.5 ± 83.46	0.001	[D–F]

Key: § = ANOVA; Mean. Diff. gr = Mean difference between groups; ¶ = Tukey's test; NCF = Number of Cycles to Failure.

Reciprocating motion Unicone samples showed significantly higher fragment length (4.034 ± 0.20 mm) compared to the continuous motion N-Evo samples (3.75 ± 0.29 mm) ($t = 2.770$, $p = 0.011$) and continuous motion PTN samples (3.742 ± 0.259 mm), ($t = 3.084$, $p = 0.005$). Similarly, continuous motion Unicone samples showed significantly higher fragment length (3.867 ± 0.205 mm), compared to the reciprocating PTN samples (3.867 ± 0.205 mm), ($t = -2.133$, $p = 0.047$).

Continuous motion Unicone samples took significantly longer time to break (162.75 ± 36.35 s), compared to the reciprocating Unicone samples (109.50 ± 25.05 s), ($t = -4.178$, $p = 0.000$). Compared to the reciprocating N-Evo samples (118.17 ± 19.45), continuous motion N-Evo samples (182.08 ± 18.77) took significantly more time to break ($t = -8.191$, $p = 0.000$). However, reciprocating PTN samples worked significantly longer before breaking (144.5 ± 16.90 s) as compared to the continuous PTN samples (112.5 ± 16.69 s), ($t = 4.665$, $p = 0.000$).

Continuous motion N-Evo samples exhibited significantly longer time to break (182.08 ± 18.77 s) as compared to the reciprocating Unicone samples (109.50 ± 25.05 s), ($t = -0.345$, $p = 0.000$). Continuous motion Unicone samples took significantly longer time to break (162.750 ± 36.355 s) as compared to the reciprocating motion N-Evo samples (118.167 ± 19.451 s), ($t = -3.746$, $p = 0.001$). Similarly, in continuous motion, the N-Evo files took a significantly longer time to break (182.083 ± 18.774) compared to PTN files (144.5 ± 16.909), ($t = 0.437$, $p = 0.000$), as shown in Table 2.

Table 2. Comparison of fragment length and times between individual reciprocating and continuous files.

Variables	Motion	Files	Mean	Standard Error of Mean	t	p †
Fragment length (mm)	Reciprocating	Unicone	4.03 ± 0.20	0.06	2.017	0.056
	Continuous	Unicone	3.87 ± 0.21	0.06	-	-
	Reciprocating	N-Evo	3.79 ± 0.20	0.06	0.400	0.693
	Continuous	N-Evo	3.75 ± 0.29	0.08	-	-
	Reciprocating	PTN	3.62 ± 0.32	0.09	-0.934	0.360
	Continuous	PTN	3.74 ± 0.25	0.07	-	-
Time (seconds)	Reciprocating	Unicone	109.50 ± 25.05	7.23	-4.178	0.000
	Continuous	Unicone	162.75 ± 36.35	10.49	-	-
	Reciprocating	N-Evo	118.17 ± 19.45	5.61	-8.191	0.000
	Continuous	N-Evo	182.08 ± 18.77	5.42	-	-
	Reciprocating	PTN	144.5 ± 16.90	4.88	4.665	0.000
	Continuous	PTN	112.5 ± 16.69	4.81	-	-

In general, continuous motion samples (152.44 ± 38.7) system took significantly higher time to break compared to the reciprocating motion samples (124.05 ± 25.17) ($t = 3.68$, $p = 0.000$), as shown in (Figure 4). Regarding the effect of motion type (continuous versus reciprocating) and file type (Unicone, N-Evo and PTN) on length of fractured files, results of the two-way ANOVA showed no

statistically significant interactions ($F(2, 66) = 1.854, p = 0.165$). Similarly, the effect of motion type (continuous versus reciprocating) and file type (Unicone, N-Evo and PTN) was investigated on time taken to fracture the files, and the results showed a statistically significant interaction ($F(2, 66) = 30.663, p = 0.000$).



Figure 4. Comparison of mean time to fracture files with different motion files.

Probabilistic modeling of fatigue failure and reliability evaluation was calculated using Weibull reliability analysis. The results, i.e., chances of failure, of the samples are displayed in the Table 3 and Figure 5. The continuous Navigator Evo samples showed higher reliability score compared to the other groups. Navigator Evo samples also showed the highest predicted time of 183.88 s for 50% failure rate.

Table 3. Sample group, sample size, time to fracture in seconds (mean; standard deviation), and Weibull calculations.

Groups	N	Mean	Standard Deviation	Weibull Modulus	R-Squared	Predicted Time for 50% Failure Rate
Reciprocating Unicone	12	109.50	25.05	4.9044	0.9117	110.24
Reciprocating Navigator Evo	12	118.17	19.45	7.3543	1.00	119.96
Reciprocating Protaper Next	12	144.50	16.91	9.3402	0.9011	145.63
Continuous Unicone	12	162.75	36.35	4.6349	0.9328	165.58
Continuous Navigator Evo	12	182.08	18.77	10.646	0.9133	183.88
Continuous Protaper next	12	112.50	16.69	7.1813	0.8562	114.02

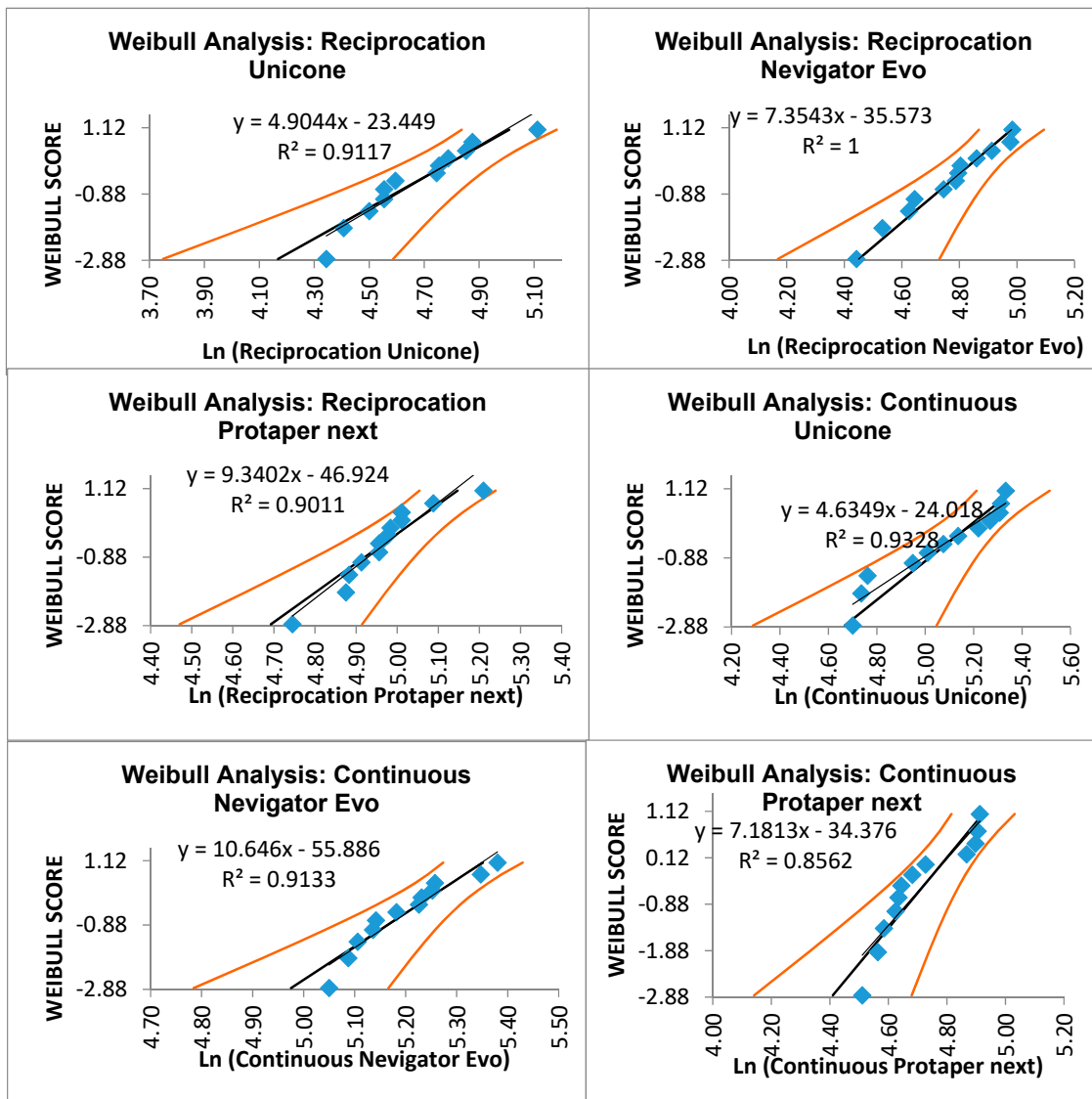


Figure 5. Weibull analysis of the time required to fracture the samples in different groups.

SEM Evaluation

The SEM analysis of the broken cross-sections demonstrated comparable fractographic features, such as crack initiation, fatigue striation, concentric abrasion mark and crack ending point (Figures 6 and 7). The specimens showed crack initiation at the cutting edges of the fracture cross-section with microscopic depressions on fracture surfaces.

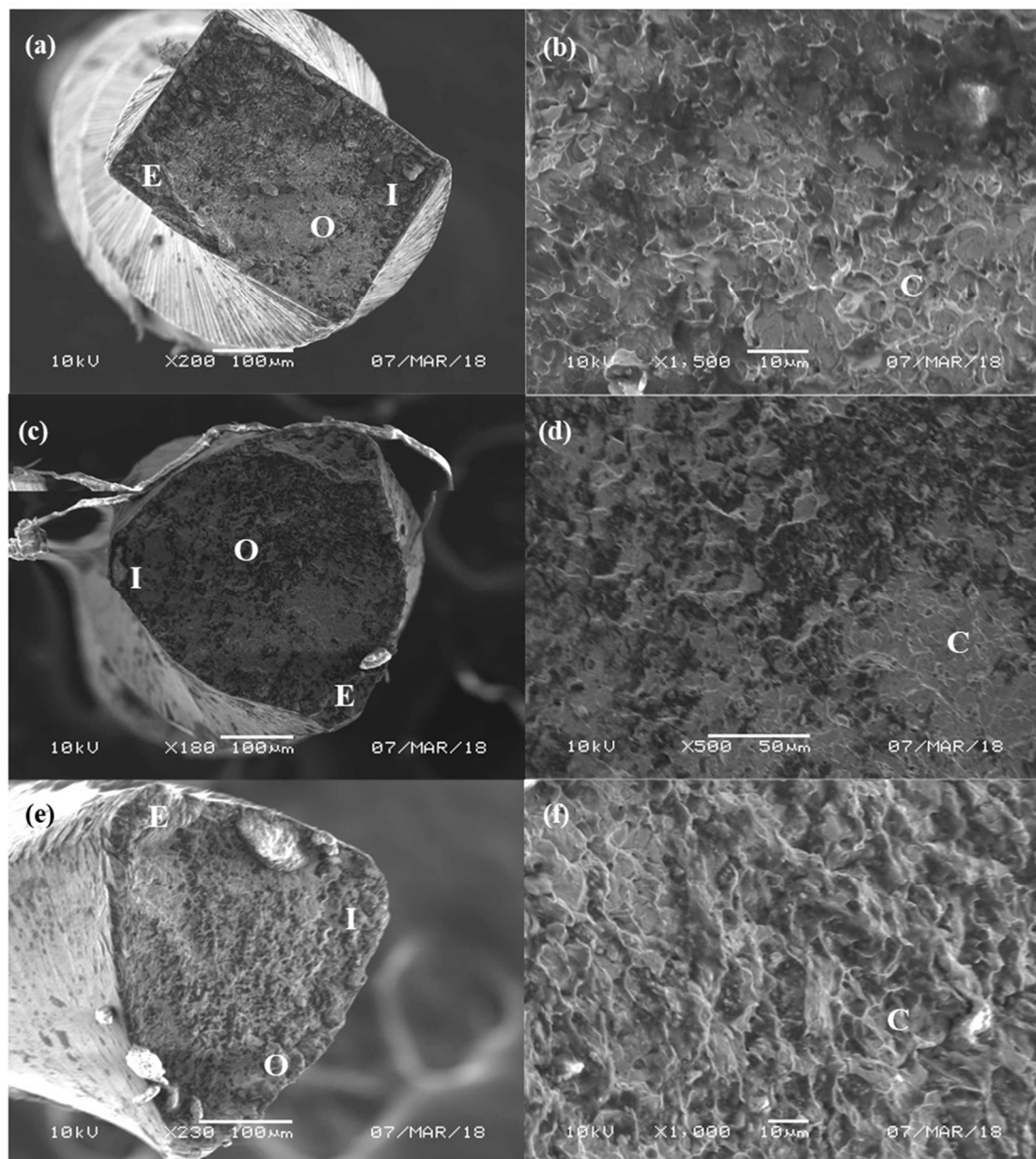


Figure 6. SEM micrographs of the fracture surface of separated fragment after cyclic fatigue test in continuous motion. Notice the crack initiation (I), fatigue striations (O), concentric abrasion mark (C) and crack ending point (E), as mentioned. (a,b) Protaper Next (magnification 200×, 1500×); (c,d) Navigator Evo (magnification 180×, 500×) and (e,f) Unicorn (magnification 230×, 1000×).

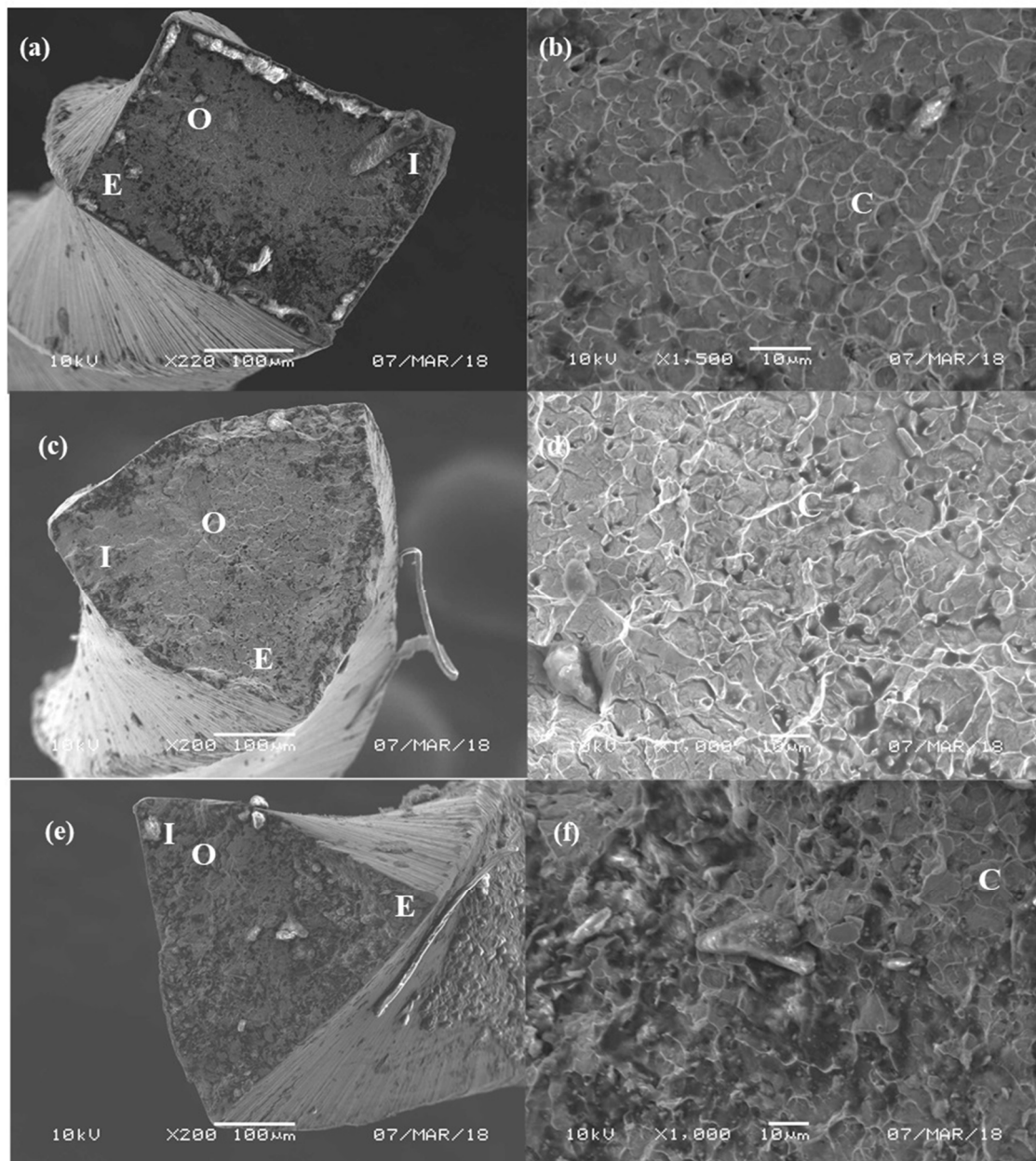


Figure 7. SEM micrographs of the fracture surface of separated fragment after cyclic fatigue test in reciprocating motion. Notice the crack initiation (I), fatigue striations (O), concentric abrasion mark (C) and crack ending point (E), as mentioned. (a,b) Protaper Next (magnification 220 \times , 1500 \times); (c,d) Navigator Evo (magnification 200 \times , 1000 \times) and (e,f) Unicorn (magnification 200 \times , 1000 \times).

4. Discussion

During root canal instrumentation, file fatigue is a matter of high concern and is considered as one of the main causes of file separation [14]. The new generation NiTi files have more flexibility and greater cyclic fatigue resistance. However, new generation rotary files should be tested against appropriate benchmarks to assist dental clinicians in choosing appropriate rotary file systems [10].

The aim of new NiTi rotary instrument design and manufacturing is to minimize file fracture during root canal instrumentation [15]. Cyclic fatigue resistance and shaping ability are of special importance when assessing the performance of NiTi files. Hence, the technology guiding the manufacture of the NiTi instruments is continually being improved. The primary objective of manufacturers is to

create instruments with superior flexibility and better resistance to cyclic fatigue [10]. In addition to the improvement of manufacturing methods, the use of new alloys is also encouraged to increase effectiveness and safety of new NiTi instruments [16].

This in-vitro study presents a comparison of the resistance to cyclic fatigue between the new Navigator Evo and Unicone rotary files with Protaper Next files, using a static metal block. Most of the previous reported investigations on cyclic fatigue resistance have involved the use of cylindrical metal tubes with a minimum of 1 mm diameter, different radii and various curvature angles [8,17,18]. Some other reports described the use of sloped metal blocks to simulate various angles [19]. It has been inferred that the results of these various test are highly influenced by size, shape and angle of curvature placed on the instrument [20]. Therefore, in this research, the simulated root canal was evaluated in a standard working parameters for each instrument, supported by the fact that all the instruments in this study fractured between D3 and D5. Although the in vivo situation cannot be matched in a simulated canal, it presents a comparative analysis of different instruments, using standard working parameters [10].

During the course of cyclic fatigue, heat generation could occur due to the friction between the instrument and the walls of the simulated metal canals, the internal friction of the materials [21] and increases of the local temperature, which may influence the test results [22,23]. Hence, to control the temperature, it is recommended to use a lubricant or coolant throughout the course of testing [22]. Nguyen et al. [24] described that rise in temperature rise was not more than 3 °C, when the testing was performed at 300 and 500 rpm in the presence of oil lubrication. Therefore, in the current study, a synthetic oil (WD-40 Company, Milton Keynes, UK) was used to minimize the rise in temperature.

The results revealed that the time to fracture for Protaper Next samples was considerably greater than that of the Unicone and Navigator Evo samples in reciprocating motion. However, the time to fracture for the Protaper Next samples was significantly lower than that of the Unicone and Navigator Evo samples in continuous motion. Therefore, the first null hypothesis was rejected.

The results of the present study also inferred that Protaper Next samples are more resistant to cyclic fatigue than Unicone samples under reciprocating and continuous motions. This may be attributed to factors such as differences in geometric design, surface condition, raw materials and microstructure between the two brands.

Protaper Next has rectangular cross section with two cutting edges, and Unicone has a convex triangular cross section. However, the study reported by Gambarini et al. [25] did not find any significant differences between M-wire technology and conventional Nitinol alloy in terms of resistance to cyclic fatigue. In fact, some studies claimed that the fatigue life of numerous files is not influenced by the file design, suggesting that the dimensions or shape of the instrument is not the key factor of the fatigue [26]. However, other researchers have claimed that cyclic fatigue resistance of different files are mainly influenced by cross-sectional design [8,12,14].

This study showed that the fragment length of the Unicone samples was considerably higher than that of the Protaper Next samples, but there was no significant difference with Navigator Evo samples in reciprocating motion. In addition, there was no significant difference in fragment length for the three types of files under continuous motion. These results are in line with previous studies [8,27].

Under continuous motion, the Numbers of Cycles to Failure (NCF) of the Protaper Next samples was significantly higher than that of the Unicone samples but there was no significant difference with the Navigator Evo samples. It was observed that under continuous motion, the Unicone and Navigator Evo files showed significantly higher mean times to fracture than did the reciprocating Unicone and Navigator Evo files. Rotation speeds per minute for Navigator Evo and Unicone files is lower in continuous motion than in reciprocating motion. Notwithstanding, the reciprocating motion Protaper Next samples showed significantly higher mean time to fracture than the continuous motion Protaper Next samples. Hence, the second null hypothesis was rejected.

To the best of our knowledge, only few studies have previously evaluated the mechanical properties of Unicone files [28,29]. The reciprocating Unicone samples showed lower cyclic fatigue

resistance than Protaper Next and Navigator Evo files. In line with current study's results, Silva et al. [28] inferred that Unicone had the lowest cyclic fatigue resistance as compare to Reciproc and WaveOne (Dentsply Maillefer, Ballaigues, Switzerland).

Similarly, Alcalde et al. [29] found lowest cyclic fatigue for Unicone as compare with ProDesign R 25.06 (Easy Equipamentos Odontologicos, Belo Horizonte, MG, Brazil) and Reciproc R25 (VDW GmbH, Munich, Germany). The authors described that the cross-sectional design and the NiTi alloy (proprietary treatment not reported by the manufacturer) of the Unicone instruments could explain these results.

On the other hand, the mean fragment length of Protaper Next in continuous motion, as reported by Uygun et al. and de Almeida-Gomes et al. [11,28], agrees with this study. However, the results disagree with that of de Almeida-Gomes et al. [28], which showed no significant difference in the cyclic fatigue resistance of Protaper Next files in comparison to Unicone files. It is noteworthy that de Almeida-Gomes et al. [28] used a smaller sample size and different motions between two files compared to current study in which reciprocating and continuous motions for both files was used.

Several studies have shown that the Protaper Next files have the highest cyclic fatigue resistance when compared with ProTaper Universal files [27], which is in line with the findings in this report. Same researchers identified that the higher cyclic fatigue resistance of Protaper Next files may be due to its non-uniform design and the decreased number of contact points between the file and the root canal walls. Nevertheless, to the best of the knowledge of the authors, this is the second attempt to evaluate the cyclic fatigue of Navigator Evo instruments.

The newer continuous file Navigator Evo showed no significant difference in Number of Cycles to Failure (NCF) when compared with Protaper Next and Unicone files. However, when compared with time it showed highly significant difference with ProTaper Next, due to the rotation speed per minute for Navigator Evo file, which is lower than that of Protaper Next file in continuous motion. Duarte et al. [30] evaluated the cyclic fatigue of Navigator EVO system with TF adaptive (25.06 and 35.04) instruments under continuous rotary motion, given higher resistance to cyclic fatigue than in adaptive motion, which is in line with the obtained results in this study. In the current study, continuous motion samples took significantly higher time to fracture compared to the reciprocating motion samples. Hence, the second null hypothesis was rejected.

In general, Protaper Next (PTN) instruments have a rectangular cross-sectional design and incorporate M-Wire to increase their cyclic fatigue resistance and flexibility. The enhanced fracture resistance may be due to the non-uniform design and the decrease in the contact points between the file and the root canal wall [28].

In this study, Protaper Next files were demonstrated to be stronger than the Unicone and Navigator Evo files in cyclic fatigue resistance during reciprocate motion.

5. Conclusions

Unicone files showed lower cyclic fatigue resistance than Protaper Next files in both reciprocating and continuous motion. Therefore, it should be used with caution, when preparing severely curved canals. The new continuous motion instrument, Navigator Evo, resulted in no significant difference in Numbers of Cycles to Failure (NCF) when compared with Protaper Next and Unicone files. Protaper Next gave high cyclic fatigue resistance when compared with Unicone and Navigator Evo in reciprocating motion.

Author Contributions: Conceptualization, S.A., M.A.-O. and A.A.; methodology, S.A., M.A.-O. and A.A.; software, M.A.-O. and A.A.; validation, S.A., M.A.-O., A.O.O. and A.A.; formal analysis, S.A., M.A.-O. and A.A.; investigation, S.A.; resources, M.A.-O. and A.A.; data curation, S.A., M.A.-O., A.O.O. and A.A.; writing—original draft preparation, S.A.; writing—review and editing, M.A.-O., A.O.O. and A.A.; visualization, S.A., M.A.-O., A.O.O. and A.A.; supervision, M.A.-O. and A.A.; project administration, A.A.; funding acquisition, A.A. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by the Deanship of Scientific Research, King Saud University, Riyadh, Kingdom of Saudi Arabia, through the Vice Deanship of Scientific Research Chairs, and the Engineer Abdullah Bugshan Research Chair for Dental and Oral Rehabilitation (DOR).

Conflicts of Interest: The authors declare no conflict of interest. The funder had no role in the design of the study; in the collection, analyses or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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