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A Critical Appraisal of Studies on the Cyclic Fatigue Resistance of HyFlex EDM Nickel-titanium Instrument

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Systematic Review Article

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ABSTRACT

Aims: To summarize the currently available evidence to point out the different outcomes of static versus dynamic tests and to assess whether cyclic fatigue tests provide useful data and information for clinical practice.
Study Design: Systematic review.
Place and Duration of Study: From May 2015 to July 2021, a total of 21 studies on HyFlex EDM cyclic fatigue have been published in the Journal of Endodontics and the International Endodontic Jour- nal and Odontology, and the Nigerian Journal of Clinical Practice and Journal of Den- tal Sciences restorative dentistry and endodontic and MDPI.
Methodology: Different studies comparing between Hyflex EDM and other rotary files as in: wave one gold, reciproc blue.

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Results: REC showed that HYFLEX EDM has the highest cyclic fa- tigue resistance and conforming that sterilization has no influence in cyclic fatigue resistance.
Conclusion: Non-invasive independent predictors for screening esophageal varices may decrease medical as well as financial burden, hence improving the management of cirrhotic patients. These predictors, however, need further work to validate reliability.

Keywords: Cyclic fatigue; HyFlex EDM; nickel-titanium instrument; rotary file.

1. INTRODUCTION

Nickel-titanium (NiTi) rotary files became more widely used in endodontics for preparing root canals and with the use of NiTi rotary files, the complications that can be observed when using stainless steel files such as ledges, zips, perforations, and straightened root canals started to be seen less frequently.

“In recent years, numerous engine-driven nickel-titanium (NiTi) systems have been introduced to the market” (Haapasalo & Shen 2013). “Topics of major interest in these instruments include bending properties and flexibility, cutting efficacy and safety of use, and fracture resistance” [1].

“Despite the advantages related to the superplasticity, fracture of NiTi files” (Serene et al. 1995) “due to torsional overloading or flexural fatigue remains a concern in clinical practice” (Iqbal et al. 2006). “There are Possible strategies to increase the efficiency and safety of NiTi rotary files including an improvement in the manufacturing process, or the use of new alloys that provide superior mechanical proper- ties” (Gambarini et al. 2011, Shen et al. 2013a) [2].

“Cyclic fatigue resistance of Ni-Ti instruments improved by using different technologies, including heat treatment, electrolytic polishing, and electro-discharge machining” [3] “of electrical discharge machining (EDM) with controlled-memory feature and have greater resistance to cyclic fatigue fracture, micro-hardness, maximum torque, and distortion angle. When compared to HyFlex CM (Coltene/Whaledent Inc.)” [4-6].

“HyFlex EDM files are known as a new-generation single-file system made of a controlled memory alloy using electro-discharge machining technology. It was re- ported that the mechanical properties of HEDM files were significantly improved using this technology Thus, it’s designed and marketed to shape root canals using a single-file technique in continuous rotation” [7].

“HyFlex EDM files have a constant 8% taper in the apical 4 mm; the taper de- creases to 4% toward the coronal region. Throughout the entire working part of the file, there are 3 different horizontal cross-sections: a quadratic cross-section in the apical region, a trapezoidal cross-section in the middle region, and an almost triangular cross-section in the coronal region” [8].

“The HyFlex EDM is the first file system to feature the use of electrical discharging machining (EDM) technology in contrast to the grinding method, which is conventionally used to produce NiTi files, using electric discharges, the file is shaped by melting and vaporization on the material using a ‘non-contact production method”.

(Pirani et al. 2015). “According to a previous study, the use of EDM technology creates a crater-like appearance and increased its cyclic fatigue resistance” (Pedulla et al. 2016) [9]. “It has been tested that Autoclave sterilization generally did not significantly increase the cyclic fatigue and torsional fracture resistance of HyFlex EDM” [10].

“Cyclic fatigue is caused by the alternating tension-compression cycles to which they are subjected when flexed in the maximum curvature of the canal during rotation” [11,12]. “Tension and compression cycles at the point of highest flexure during instrument rotation in a curve result in cyclic fatigue fracture” [13].

To evaluate the cyclic fatigue resistance of the file, a static cyclic fatigue resistance test is performed without axial motion, where the instrument rotates at a designated length in the simulated canal until the instrument fractures [14]. The dynamic test incorporates axial movement and simulates the clinical situation [14-17].

2. MATERIALS AND METHODS

Literature research strategy: There are a wide range between the cyclic fatigue results of the same instruments. The current review selected the Hyflex EDM instruments as a model and try

to figure out the reliability of the static and dynamic cyclic fatigue test as a tool for instruments survival.

Number of studies on cyclic fatigue: From May 2015 to July 2021, a total of 21 studies on HyFlex EDM cyclic fatigue have been published in the Journal of Endodontics and the International Endodontic Journal and Odontology, and the Nigerian Journal of Clinical Practice and Journal of Dental Sciences restorative dentistry and endodontic and MDPI. The number of such papers increased lately since 2017 only 8 of 21 (38.095%) used dynamic study tests while the majority of them (85.714%) used static methods (M. Hulsmann et al 2019).

Variables in study designs [18-27]:

Table 1. Study design variability

No.	Study Title	Authors	Journal Name	Year of Publication	Files used in comparison	Type of test (Static or dynamic)	Temperature during the test (Room temperature or simulated body temp.)	Results of the Hyflex EDM (Cyclic fatigue)
1	Cyclic fatigue resis- tance of HyFlex EDM, Reciproc Blue, WaveOne Gold, and Twisted File Adap- tive rotary files under diff erent temperatures and ambient conditions	Mustafa Gündoğar1, Taha Özyürek, 2 ,* Koray Yılmaz, 3 and Gülşah Uslu4	Odontol- ogy	2018	HyFlex EDM, Reciproc Blue, WaveOne Gold, and Twisted File	Stati c	35°C	The HyFlex EDM file (3456.33 ± 633.37) file had the statistically highest fatigue resistance.
2	Eff ect of autoclave sterilization on cyclic fatigue and torsional fracture resistance of NiTi rotary in- struments	Wooyoung Kim 1 , So- ram Oh 2 , Gil- Joo Ryu 3 , Tae-Hwan Kim 1 , Sung- Jae Kim 1 ,	Odontol- ogy	2019	ProTaper Uni- versal (PTU), K3XF, HyFlex EDM (EDM), and TF adap- tive (TFA).	Stati c		EDM CGr1 11,645.3 (1768.0)A ,CGr2 11,935.9 (1634.9)A, CGr3 12,577.6 (2525.0)A
3	Torsional and Cyclic Fatigue Resistance of a New Nickel- Titanium Instrument Manufactured by Electrical Discharge Machining	Eugenio Pedullà 1 , Fabio Lo Savio 2 , Simona Boninelli 3 , Gianluca Plotino 4	Journal of Endodon- tics, jendodon	2015	Hyflex EDM OneFile (Coltene/ Whaledent AG, Altstatten, Switzerland), Reciproc R25 (VDW, Munich, Germany), and WaveOne Primary (Dentsply Maillefer, Ballaigues, Switzerland)	Stati c		Hyflex EDM one file (NCF) mean: 973a, SD: 152, min:792, max:1186
4	Correlation between Temperature- de- pendent Fatigue Resistance and Diff erential Scanning Calorimetry Analysis for 2 Contemporary Rotary Instruments	Ana Arias ,Jose C. Macorra,San- jay Govindjee ,Ove A. Pe- ters	Journal of Endodon- tics	2017	Forty Hyflex EDM (H-EDM) files, 40 TRUShape (TS) files		Both	H-EDM behavior (room tem- perature mean life = 725.4 seconds; 95% CI, 658.8–798.8 and body temperature mean life = 717.9 seconds; 95% CI, 636.8–809.3).
5	Cyclic fatigue resis- tance of several nickel- titanium glide path rotary and	K Yılmaz , G Uslu , M Gündoğar , T Özyürek , N M Grande , G Plotino	Journal of Endodon- tics	2018	One G, Pro- Glider, HyFlex EDM, and R- Pilot glide path NiTi files	Dyna mic	Body tem- pera- ture.	There was no diff erence be- tween the HyFlex EDM and the ProGlider, HyFLex 388.21 ± 46.62b HY

No.	Study Title	Authors	Journal Name	Year of Publication	Files used in comparison	Type of test (Static or dynamic)	Temperature during the test (Room temperature or simulated body temp.)	Results of the Hyflex EDM (Cyclic fatigue)
	reciprocating in- struments at body temperature							
6	Cyclic Fatigue Resis- tance of OneShape, HyFlex EDM, Wave- One Gold, and Reci- proc Blue Nickel-titanium Instru-ments	Mustafa Gündoğar Ta ha Özyürek	Journal of Endodon-tics	2017	Reciproc Blue, HyFlex EDM, WaveOne Gold, One-Shape		Room tem-pera- ture	The HyFlex EDM file (3456.33 ± 633.37) file had the statistically highest fatigue resistance
7	HyFlex EDM: super- ficial features, met-allurgical analysis, and fatigue resis-tance of innovative electro-discharge machined NiTi ro- tary instrument	John Wiley & Sons Ltd	In- terna-tional Endodon-tic Jour- nal	2015	HyFlex EDM prototypes		50 °C	HyFlex EDM 25.08 EDM (981±329) ,40.04 EDM (2013 ±425) , 50.03 EDM (1682 ± 241)
8	Comparison of the Cyclic Fatigue Resis-tance of HyFlex EDM, Vortex Blue, ProTaper Gold, and OneCurve Nickel-Titanium Instru- ments	AD Uygun, M Ünal, S Falakaloğlu, Y Güven	Nigerian Journal of clinical practice	2020	HyFlex EDM, Vortex Blue, ProTaper Gold, and OneCurve Nickel-Titani-um Instru-ments	Dyna mic	35°C (±2)	HyFlex EDM number of cycles to fracture = (1710.42114.89), Fragment length = (6.7±049)
9	Cyclic Fatigue Resis- tance of Rotary and Reciprocating Nick- el-Titanium Instru- ments Subjected to Static and Dynamic Tests	Myint thu ,Arata ebihara ,kei-ichiro maki ,nishijo miki ,Takashi okiji	Journal Of En-dodontics	2020	Rotary and Reciprocating Nickel-Titani-um Instru-ments	Both	be- tween 20C and 40C	Static and dynamic cyclic fa- tigue resistance, median and interquartile range (IQR) of EDM, SCFR: median (723), IQR (621.08-792.33), DCFR: median : (2692.71), IQR : (1336.79-2949.06)
10	Cyclic fatigue resis- tance of R-Pilot, HyFlex EDM, and PathFile nickel-tita-nium glide path files in artificial canals with double (S-shaped) curvature	G. Uslu1, T. O€zyu€rek1 , K. Yılmaz2 & M. Gu€ndog! ar3	EN-DODON-TIC JOURNAL	2017	R-Pilot, HyFlex EDM, and PathFile NiTi glide path files	static		PathFile (1675.41 ± 201.55ax) (1062.03 ± 127.44ay) HyFlex EDM (2262.43 ± 271.44bx)(1706.72 ± 209.72by) R-Pilot (4894.82 ± 743.11cx) (3607.57 ± 519.06cy) R-Pilot had the greatest cyclic fatigue resistance, followed by the HyFlex EDM and PathFile in both the apical and coronal curvatures
11	Evaluation of the Cyclic Fatigue and Torsional Resistance of Novel Nickel-Titanium Rotary Files with Various Alloy	Mehmet Emin Kaval, DDS, PhD,* Ismail Davut Capar, DDS, PhD,† and Hu€seyin Ertas, DDS, PhD†	Journal of Endodon-tics	2016	Hyflex EDM, ProTaper Gold (PTG), and ProTaper Uni-versal (PTU)		23C	HyFlex EDM (3689a ± 1577) ProTaper Universal (350b ± 30) ProTaper Gold (5.9a ± 0.9) HyFlex EDM instruments ex- hibited the highest cyclic fa- tigue resistance and were followed by PTG and PTU

No.	Study Title	Authors	Journal Name	Year of Publication	Files used in comparison	Type of test (Static or dynamic)	Temperature during the test (Room temperature or simulated body temp.)	Results of the Hyflex EDM (Cyclic fatigue)
	Properties							groups
12	Evaluation of Cyclic Fatigue of Hyflex EDM, Twisted Files, and ProTaper Gold Manufactured with Diff erent Processes: An In Vitro Study	Pooja D. Khandagale,1 Prashant P. Shetty,2 Saleem D. Makandar,3 Pradeep A. Bapna,2 Mohmed Isaqali Karo- bari,3,4 Anand Marya,5 Pietro Messi- na, and Giuseppe Alessandro Scardina 6	Journal of Endodon- tics	2021	Hyflex EDM, Twisted files, and ProTaper Gold	static and dyna mic		Hyflex EDM (774.29) Twisted files (654.875) ProTaper Gold (375.575). A statistically significant diff er- ence was observed between the tested groups
13	Eff ect of Torsional and Fatigue Preload- ing on HyFlex EDM Files	Ya Shen, Charles Tra,, Ahmed Hieawy, Zhejun Wang,* and Markus Haa- pasalo,	j endod journal	2018	EDM and CM files were used		EDM files (51C– 54C) than for CM files (32C– 37C)	EDM instruments subjected to fatigue testing had a higher Nf compared to CM instruments. EDM (2490 306) results showed that EDM files had fatigue resistance superior to CM files, and the fatigue life of EDM instruments is longer than CM instruments. Even though a low amount of tor- sional preloading reduced the fatigue resistance of EDM instru- ments, the fatigue resistance of EDM is still higher than that of CM files without any pre- loading
14	Bending resistance and cyclic fatigue resistance of Wave- One Gold, Reciproc Blue, and HyFlex EDM instruments	Soram Oh ay , Kee-Yeon Kum by , Hyun-Jung Kim, Su-Young Moon c , Hyeon- Cheol Kim d , Antonis Chaniotis e, Hiran Perin- panayagam f , Eugenio Pedulla´g, Seok Woo Chang	journal of Dental Sciences	2019	WaveOne Gold, Reciproc Blue, and HyFlex EDM instru- ments	static	22C	The Af of HyFlex EDM was found to be far above BT, which results in instruments that are in the martensitic state in clinical temperature. HyFlex EDM: RT >596.4 (102.7) BT > 599.6 (108.5) compared to WOG, RPB, and HDM systems. HyFlex EDM will exert superior flexi- bility and fatigue fracture resistance and might be better for the treatment of curved canals. The cyclic fatigue resis- tance of WOG and RPB de- creased with the temperature increase. In contrast, the resis- tance of HDM didn't change.

3. RESULTS AND DISCUSSION

“The introduction of rotary NiTi files in the field of endodontics has significantly changed the outcome of endodontic therapy. Rotary file systems have greatly enhanced the level of precision and speed of the endodontic treatment. Apart from advantages, the rotary files also possess a few disadvantages. The file separation may take place inadvertently, which

compromises the outcome of the endodontic rehabilitation and healing of the periradicular tissues" [28].

"Several factors contribute to the fracture of the rotary instrument. These include handling by the operator, usage, anatomy of the root canal, and design of NiTi rotary instruments. Because of these, various studies have been performed to investigate the reasons and physics of the instrument fracture" [29]. "The mechanism of rotary instrument separation was reported as a torsional failure and cyclic fatigue fracture" [30]. " Cyclic flexural fatigue occurs when an instrument rotates in a curved canal by repetitive compressive and tensile stresses, and torsional failure occurs when the instrument's tip is locked or jammed in the canal, but the shank of the file keeps rotating" [31].

Although the resistance of files to CF has been improved with the development of new alloys [32-35], it is important to patients and still a concern for endodontists and general practitioners. Manufacturers in the field of endodontics continue to introduce new strategies to enhance the properties of rotary instruments.

"The endodontic literature contains a plethora of studies on static and dynamic cyclic fatigue resistance tests performed on a large array of rotary or reciprocating nickel-titanium endodontic instruments. This review aimed to summarize the currently available evidence to point out the different outcomes of static versus dynamic tests and to assess whether cyclic fatigue tests provide useful data and information for clinical practice" [36].

This focused review aimed to provide evidence-based answers to two main questions:

1. Are there a different outcomes from static versus dynamic tests?
2. Do cyclic fatigue tests provide useful data and information for clinical practice?

These results suggest that both static and dynamic tests are currently poorly standardized. Numerous parameters have been shown to exert a marked impact on the results [37], with the environmental temperature representing the most relevant parameter [38-44]. Environmental temperature has a 500% impact on the lifetime of an instrument [42]. It can therefore be deduced that studies con- ducted under room temperature or under temperatures that do not correspond to the clinical situation any longer appear acceptable from a scientific point of view.

"Furthermore, the available data strongly suggest that there is an urgent need to agree on either static or dynamic experimental set-ups. Evidence suggests that dy- namic tests might have some advantages compared to static approaches, although maximal differences between highest and lowest published values for one instru- ment were considerably higher in dynamic than in static tests. Thus, it might be speculated that dynamic tests are more prone to procedural errors and are more technique-sensitive than static tests as it is difficult to keep the instruments in a pre- cise trajectory" [45,46,47].

"Once a consensus has been reached on the favored method, the next step should be to clearly define all relevant experimental parameters to limit the diversity of experimental designs and, as a result, distortion of the results. A clearly defined test design, preferably similar to an ISO specification, is a prerequisite for a reliable assessment of the corresponding studies" [37]. On the other behave this review to answer if the cyclic fatigue provides information for clinical practice?

This question has no value since there is the vast majority of responses of the same instrument in different studies. All the studies that have been reviewed have limited information to be useful in clinician selection of instrument with no convincing evidence due to different study designs and results. Moreover, the majority of these studies have limitations in vitro, several variables such as taper, cross-sectional, size, and manufacturing techniques affect the performance of files [48].

4. CONCLUSION

Different studies comparing between Hyflex EDM and other rotary files as in: wave one gold, reciproc blue and REC showed that HYFLEX EDM has the highest cyclic fatigue resistance and conforming that sterilization has no influence in cyclic fatigue resistance. The clinician must use the data from the published study regarding the cyclic fatigue with a great caution.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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