Original Article

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Evaluation of Cyclic Fatigue of HyFlex CM and M3-Pro Gold NiTi Rotary Endodontic Instruments in Artificial Curved Canals

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Abstract:

Purpose: This study evaluated cyclic fatigue resistance of HyFlex CM and M3-Pro Gold NiTi rotary files.

Materials and methods: Two groups of endodontic rotary NiTi files were chosen (n = 20) based on file type (HyFlex CM and M3-Pro Gold). Files with tip size 25 and 4% taper were used in a customized model with a curvature angle of 60° and a 5 mm radius of curvature. Instruments failure were discovered by inspection via a clear glass and aided by a computer program. Total number of cycles to failure (NCF) has been calculated and the length of the fractured part (FL) was measured. The fracture surfaces of the split segments have been examined using SEM.

Results: Shapiro-Wilk test and Kolmogorov-Smirnov test were used to determine normality, and they indicated that the data came from normal data that was distributed in both groups. As a result, a comparison was made between different groups by independent-t-test and significance level was set at $p \leq 0.05$. Comparison between HyFlex CM and M3-Pro Gold regarding fractured segment length (FL) revealed that, there was insignificant difference between HyFlex CM (4.02 ± 0.63) and M3-Pro Gold (3.98 ± 0.68) with (0.04) difference between them as P=0.84. Regarding NCF, HyFlex CM (2932.82±646.35) was significantly higher than M3-Pro Gold (1422.1 ± 510.67) with (1511) difference between them as P=0.0001

Conclusion: HyFlex CM files showed higher cyclic fatigue resistance when compared to M3-Pro Gold.

Keywords: HyFlex CM, M3-Pro Gold, cyclic fatigue resistance

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Introduction:

Because of their efficiency, flexibility, and cutting capacity, nickel-titanium (NiTi) rotary files have become more and more popular for preparing the root canal system. [1]With NiTi rotary files, Complications including zip perforation, straightened root canals and ledges are less prevalent[2] .

Despite their many benefits, NiTi files have the potential to fail inseverly curved or S-shaped canals, which have a negative impact on treatment outcome[3]. However, torsional and cyclic fatigue are the most important variables contributing to NiTi file failures[4].Speed, metallurgical characteristic s and motion are all key factors that might induce cyclic fatigue of rotary files.[5].

Various cross-section forms and alloys have been proposed to improve the flexibility of rotary files and minimize fatigue failure[1]. Several thermally treated NiTi alloys, such as CM-Wire, M-Wire, T-Wire, and R-phase, were designed for better transitional behavior of NiTi alloy and microscopic structure, that influence the mechanical structure.[6].Instruments made with controlled memory (CM) wires are more resistant to cyclic fatigue (CF)than conventional Ni-Ti alloys.

HyFlex CM (HCM) has been introduced as first CM wire rotary file and it was considered a conventional CM wire file system. It has a shape memory known as 'controlled memory.' Along with austenite, CM instruments included R-phase and martensite. This system of files has been constructed with a minimal amount of nickel than most commercially available NiTi, and that was according to manufacturer[7]. In contrast to traditional NiTi rotary files, HCMdoes not return to its original shapedue to its content and proprietarymanufacturing method.

Their increased flexibility may decrease failure percentage that could result due to formation of ledge, canal transportation, or perforation[8].

M3-ProGoldNiTi-filesmade for usage in a continuous rotation mode has an inactive tip and convex triangular cross-section#25 and 4% taper. The manufacturer claimed that these files provide fast and safe preparation in curved canals due to the high flexibility.M3-ProGoldfilesaremanufacturedwithaCMwireh as an innovative triple coating surface that shows greater flexibility and cyclic fatigue resistance (CFR) to the files [9].

There is currently insufficient information on the mechanical characteristics of Chinese

rotating NiTi files manufactured of CM alloy. Thus, this study's objective was to examine M3-Pro Gold's cycle fatigue resistance and contrast it with that of the HyFlex CM rotary file.

The null hypothesis stated that there was no significant difference between HyFlex CM and M3 Pro Gold rotary endodontic file regarding resistance to cyclic fatigue and length of separated part of rotary file.

Material and Methods:

Ethical Approval

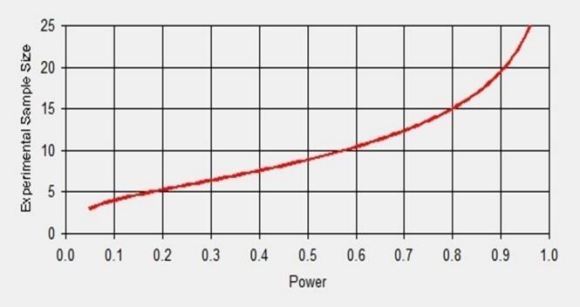
The study had been approved by the Research Ethics Committee, faculty of Dentistry, Ahram Canadian University; Research number: IRB0001289#106

Sample size calculation:

Sample size was calculated depending on a previous study (Abdelrahman T 2022***)*** as reference. According to this study, when mean ± standard deviation of NCF regarding group1is17220.82±2577.1.If the estimated mean difference with group 2 is 2000, when the (power) is 0.8 and for this test, the Type I error probability is 0.05. So, 15/group is the minimum sample size required.

To make up for the 25% dropout rate, the total sample size was raised to 20 in each group. For the independent t test, P.S. power 3.1.6 was used.

Calculated sample size=20 in group



Line chart representing power curve

Sample classification:

Forty endodontic rotary NiTi files were utilized, files classified into two groups (n = 20) based on the type of rotary file used. Rotary files have been used, namely Hyflex CM (HCM, Coltene/ Whaledent, Inc, Cuyahoga Falls, OH, USA) and M3-Pro Gold (United Dental Group, Changzhou, China). Tip #25 and 4%taper files were chosen and operated in a customized model that has curvature of 60° angle with 5 mm radius of curvature. Using a stereomicroscope, every file was examined for manufacturing flaws, and none were rejected.

Cyclic fatigue evaluation:

Custom-made simulated canal model fabrication

Customized canal model was created from stainless steel to resist friction wear, with a

curvature angle 60° , 5mmradius of curvature, 16 mm length (consisting of an 11 mm straight section and a 5 mm curved section), and 2 mm depth. Fabricated model was based on guidelines of **Pruett et al 1997[10]**, and canal's dimensions designed by the aid of AUTOCAD software (Autodesk, San Rafael, California, USA). Illustration was based on the size and taper of the tested files. To allow free movement of the file and elimination of friction, the canal was 0.2 mm wider along its length.

A cover which is made of transparent glass was attached to the model for monitoring the file until failure and to avoid slipping while rotating within the model. A circular reservoir collected the instrument's fragmented parts apically (figure 1).

Figure (1) cyclic fatigue testing block

Cyclic fatigue testing:

Cyclic fatigue testing was carried out using a testing machine which is computerized (Model LRX-plus, Lloyd Instruments Ltd., Fareham, UK), which have upper rotating part and an opposite fixed lower part. A customized jig was used to secure the contra-angled hand piece of an endodontic motor (NSK Endo-Mate Dt, Nakanishi Inc.) within a reproducible place. The jig was connected to an adapter that attached into the upper rotating part, and the customized model was tightly attached to the testing machine's lower fixed part by tightening the screws (figure 2).

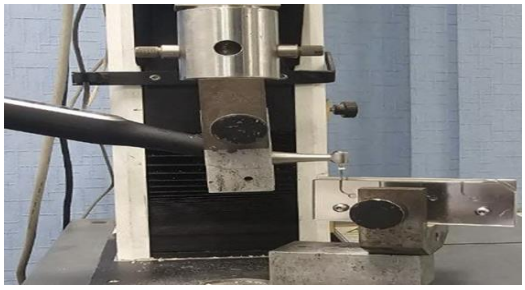


Figure (2) cyclic fatigue testing apparatus

Before each test, the artificial canal was completely inundated with synthetic lubricating oil (Pana spray plus from NSK, Japan). The files tested were coated with an engine oil before usage to allow for minimal friction between model and the files tested and minimize heat generation.

Each tested file was fastened to the endo motor's hand piece (Wismy Endo Motor, Bomdent, China) and inserted into the center of the artificial canal at the proper depth until file is inserted inside the straight part of

artificial model and perpendicular to the orifice guided by the rubber stopper. All files were rotated within artificial canal at room temperature till fracture occurred at 500 rpm speed and 2.5 N• cm torque as claimed by manufacturer. The instrument fracture was recognized visually via the transparent glass as well as automatically using computer, and the time from the start of rotation to the point of fracture was recorded in seconds.

The time to fracture in minutes multiplied by the number of rotations per minute (500 rpm) yields the total number of cycles to failure (NCF).A **Bhatt and Rajkumar 2019[11]**.

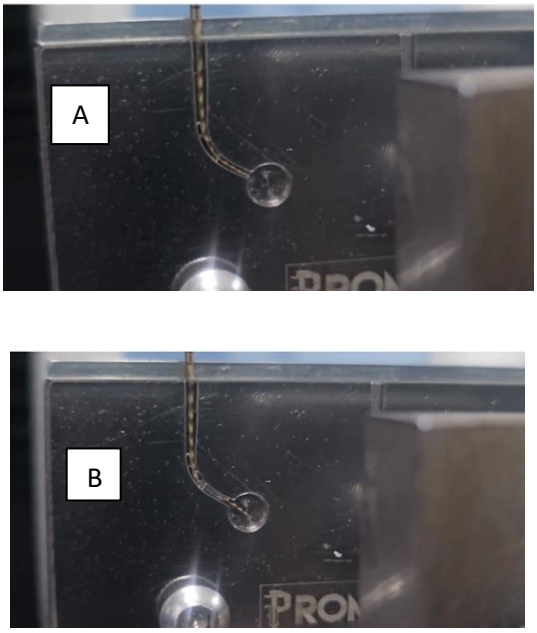


Figure (3) rotary file before fracture (a), rotary file after fracture with fractured part inside the model ring (b)

3-Measurement of the separated segment

The length of every separated file (FL) was determined by the aid of adigital caliper (Pinrui, Digital LCD Caliper, Shanghai, China) using0.01mm resolution.

4. Scanning electron microscopy (SEM) analysis of the separated files

Before being analyzed under a SEM, the fragmented files were cleaned ultrasonically and suspended in 70% ethyl alcohol for 15 minutes(SEM Model Quanta 250 FEG [Field Emission Gun], FEI Company, Eindhoven, Netherlands) for removal of oil or debris trapped between the flutes or in the fractured surface during test, and then dried. From each file system, two representative samples will be chosen at random and photographed using SEMat magnification of 600× for cross-sectional and lateral views to validate fracture modes.

Statistical analysis:

SPSS 16 ® (Statistical Package for Scientific Studies), Graph Pad Prism, and Windows Excel were used to conduct the statistical analysis, which was then displayed in two tables and two graphs.The Shapiro-Wilk and Kolmogorov-Smirnov tests for normality were used to examine the provided data, and the results showed that both groups' data came from a normal distribution. As a result, the Independent t test was used to compare various groups. A significance criterion of ($p \leq 0.05$) was established.

Results:

The mean and standard deviation of (FL) and (NCF) were summarized as follows.

Table (1) and figure (1) presents descriptive statistics for fractured segment (FL) and NCF in HyFlex CM and M3-Pro Gold. The table displays the minimum, maximum, mean, and standard deviation values.

Table(1): Descriptive result of Fractured segment length FL(mm) and NCF in HyFlex CM and M3-Pro Gold:

		Count	Minimum	Maximum	Mean	Standard Deviation
FL(mm)	HyFlex CM	20	3.31	4.87	4.02	0.63
	M3Pro Gold	20	3.32	4.8	3.98	0.68
NCF	HyFlex CM	20	1870.50	3571.35	2932.82	676.35
	M3 ProGold	20	846.23	2339.85	1422.10	510.67

Table(2): Comparison between NCF in HyFlex CM and M3-ProGold regarding FL, and NCF:

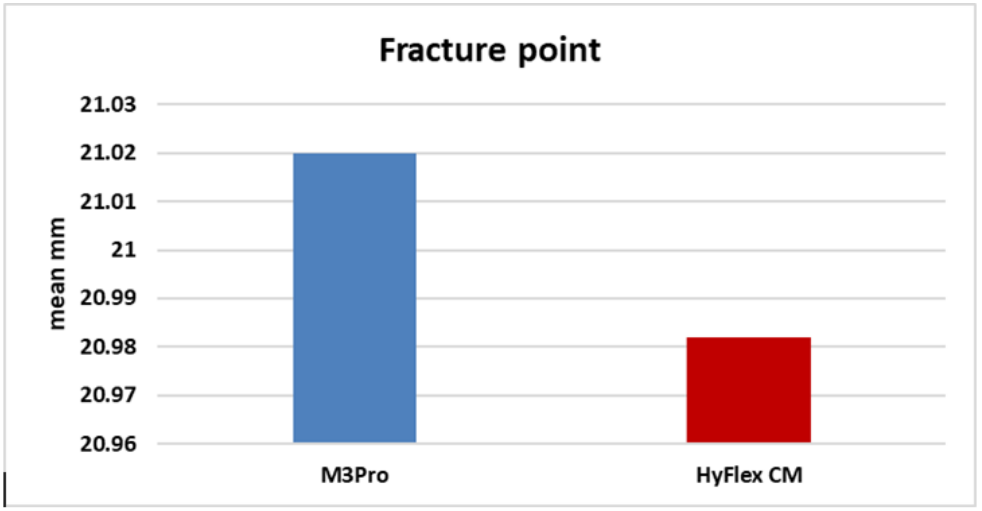
	HyFlex CM		**M3Pro Gold**		**Difference**				
					Mean difference	Standard Error of mean	95% Confidence interval		P value
	Mean	Standard Deviation	Mean	Standard Deviation			lower arm	upper arm	
FL (mm)	4.02	0.63	3.98	0.68	0.04	0.21	-0.37	0.45	0.84
NCF	2932.82	676.35	1422.10	510.67	1511.00	189.50	1127.00	1894.00	0.0001*

*Significant differenceas P<0.05

HyFlex CM versus M3-Pro Gold comparison regarding fractured segment length (FL) revealed that, there was insignificant difference between HyFlex CM (4.02 ± 0.63) and M3-Pro Gold (3.98 ± 0.68) with (0.04) difference between them as P=0.84.

Regarding NCF, HyFlex CM (2932.82±646.35) was significantly higher than M3-Pro Gold (1422.1 ± 510.67) with (1511) difference between them as (P=0.0001).

Figure (4): Bar chart showing FL (mm) in M3 Pro Gold and HyFlex CM group



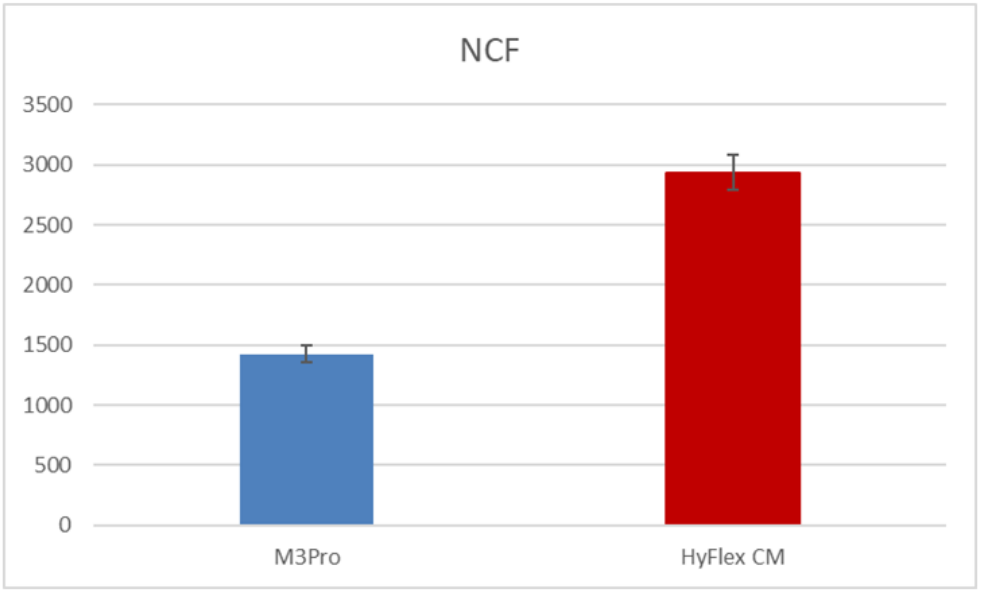


Figure (5): Bar chart representing NCF in M3 Pro Gold and HyfFex CM group

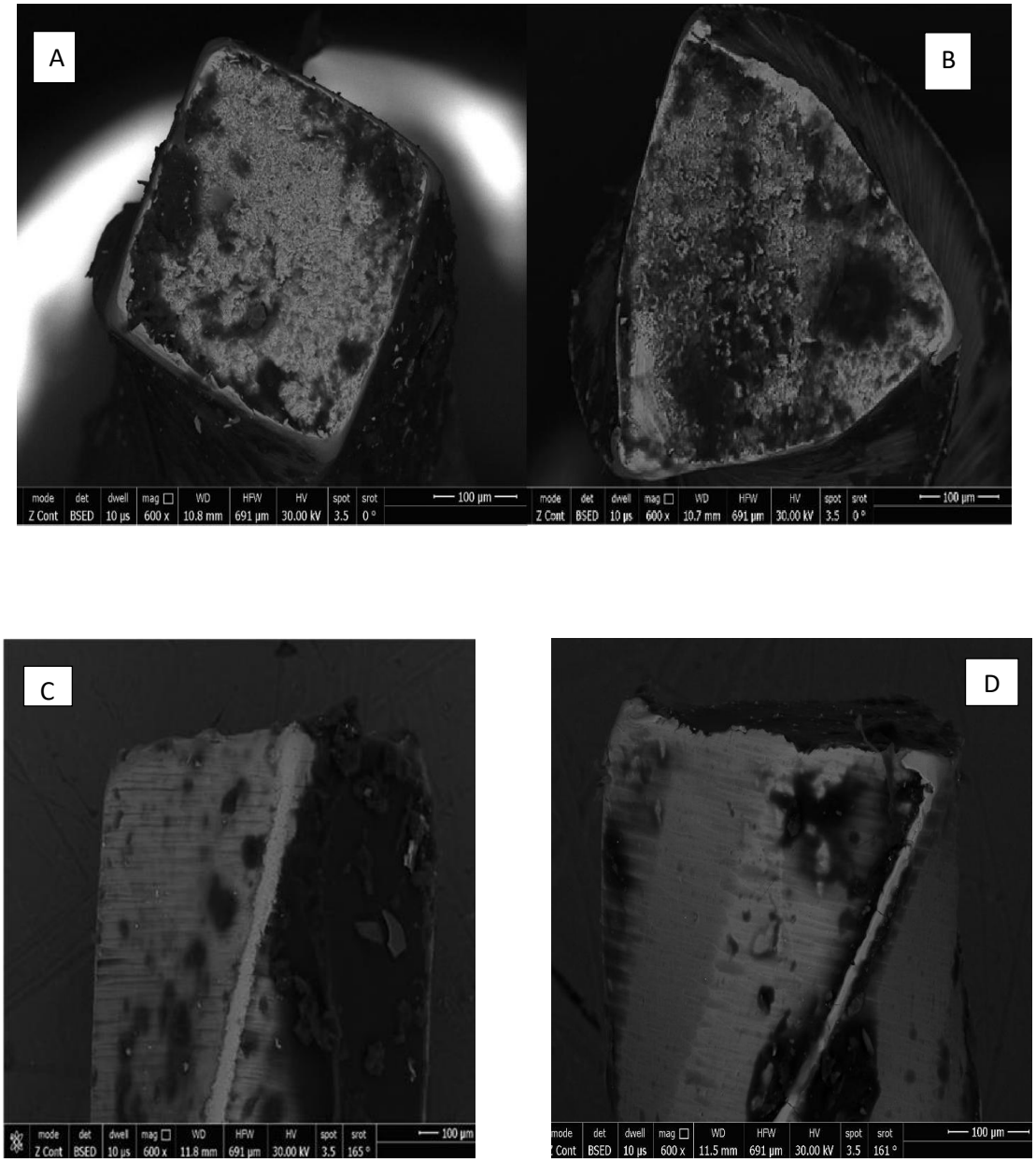


Figure (6): SEM photos for cross-section view of fractured files HyFlex CM (A) and M3-Pro Gold (B), and for longitudinal section Hyflex CM (C) and M3-Pro Gold (D)

Scanning electron microscope:

Photos of fractured files for cross section view of HyFlex CM after cyclic fatigue test with (600×) magnification revealed, the cutting edge was subjected to overload zone representing fast fracture, while area in the bulk showed multiple micro porosities indicating extreme rough dimpled surface. For longitudinal section, fatigue striations accompanied with micro-voids near to the cutting edge. Cross section view of M3-Pro Gold revealed multiple overload areas which is concentrated in peripheries, with dimpled rough surface in the bulk. In longitudinal section, fracture striations were observed, followed by extensive micro voids (overload zones) near to cutting edge. Extensive multiple cracks were shown in cutting edge, indicating brittle fracture.

The new generation of rotary files is made of thermo-mechanically treated alloys, which enhance flexibility and resistance to cyclic fatigue. Moreover, surface treatment improves the files' hardness with reduction of file failure. File design, cross-sectional geometry and core diameters, tip size, and measured file taper are all factors that influence fatigue resistance. Furthermore, radii and degree of curvature, rotation speed, torque, and movement kinematics (continuous, reciprocal, or adaptive) all have a major impact in the cycle fatigue resistance of file[12].

Separation of endodontic files during preparation of root canal is very critical because they can complicate root canal treatment. The static test was employed because it involves inserting the instrument to a specific depth into a simulated canal on the model and rotating it until a fracture occurs. The point of highest stress in this type of testing is typically found in the the middle of the curve. This type of test provides more information on the influence of various designs of instruments' blade or the NiTi-alloy finishing on cyclic fatigue, that is critical for the development and optimization and of other instruments[13].Another benefit is that the findings are reproducible and reliable in practicing. The dynamic test is challenging as it is sensitive to procedural errors since it is challenging to precisely identify axial motion's amplitude, as well as the precise direction and angle of the instrument's entry into the artificial canal.[14]

Natural teeth were used and it was considered the best method for evaluating the resistance to flexural cyclic fatigue of rotary files, as they are able to precisely replicate the conditions clinically. However, oneofthe test's drawback is that a tooth can only be used once due to the dimensional and morphological changes during root canal preparation, making it very difficult to be standard and replicated for the experiments.

[15]. As a result, in the current study, a customized model with an artificial canal that is made of stainless steel was employed to assure anangle of curvature, constant radius of curvature, and center of maximum curvature. Artificial canal utilized in the current study was designed according to the method provided by **Pruett et al**[10]**.**

The ability of rotary files to withstand cyclic fatigue reduced as the radius of curvature reduced and the angle of curvature increased and; thus, a 5mm radius was chosen. The artificial canal had a 60° curvature and 5mm curvature of radius, and maximum curvature was 5 mm away from the apical part of the canal as it simulates the curvature at the apical part that will be present clinically, where most of stresses on the instrument are accentuated , as was carried out in earlier investigations.[16-17]

Findings within this study were confirmed by **Pruett et al**[10], who found that curvature less than 30° and a radius of 5mm minimizing stress. In agreement with **Plotino et al**[18], the 0.2 mm added space was along the length of the canal. This permit files to move freely inside the artificial canal, to preclude torsional stresses that could arise from locking during movement. The two files that were evaluated had similar characteristics and were manufactured from CM wire to exclude any differences that could affect the CFR results.

According to **Haïkel et al**.[19], apical diameter and taper can greatly influence files' operating time. To ensure consistency, the apical diameter and taper of all files utilized in the current study were kept consistent. To reduce the influence of variables, standardized artificial canals (60° angle of curvature and radius of 5mm) were used with the same torque, rotation speed (500 rpm), and rotation type (continuous). At room temperature, the resistance to cyclic fatigue was investigated.[18]

Regarding the results, HyFlex CM exhibited higher cyclic fatigue resistance than M3-Pro Gold. This might be attributed to different NiTi alloys treatment temperature and the differences in surface coating and treatment, as it was treated through post machining heat treatment as well as grinding of CM alloy[20-21].

It has been found that HyFlex CM is more resistant to cycle fatigue since the file system's flexibility has been increased, and without a property of shape memory. It was manufactured in a phase between martensite and austenite phases, which may be linked to the higher fatigue resistance[22].

Compared to other manufactured CM wire instruments, HyFlex CM rotary files, which are largely constructed of martensite and R phase, displayed unique structural properties, such as higher phase change temperatures and increased hardness. It is believed that the increased flexibility of thermally treated files results from an increase in the proportions of R-phase and martensite. Out of the three phases R-phase showed the lowest shear modulus.[23]

Another explanation that M3-Pro Gold files exhibited a martensite and austenite combination at normal temperature. That was due to that it possess the austenite finishing temperature (A_f) 36.9° C which is near body temprature[9], while A_f of HyFlex CM is 47° C, which is higher than body and room temprature[24]. That lead to stable martensite phase at body temperature which is less rigid than austenite and more liable to deformation than austenite as it possesses a twinning process, defined as an interior lattices' movement avoiding destroying atomic connections by absorbing stress[25].

On contrary, **Reddy et al**[26] reported that M3-Pro Gold had higher cyclic fatigue resistance versus HyFlex CM, which could resulted from gold thermal treatment applied to M3Pro Gold. The energy absorption of twinned phase structure during heat treatment causes internal lattice movement that preserves atomic bonding, leading to the creation of complex array of secondary cracks leading to many interfaces, dissipating energy necessary for propagation of cracks. An additional explanation might be related to the significantly tougher surface layer in Gold heat-treated instruments, which can resist initiation of cracks and compensate for the reduced micro hardness[27]. That was consistent with **Pedullaet al**[9].

In the current study, the FL revealed that, there was insignificant difference between HyFlex CM (4.02 ± 0.63) and M3-Pro Gold (3.98 ± 0.68) with (0.04) difference between the mas P=0.84. This could be due to flexibility, which leads files to take a distinct path along the canal curve. The rigidity of each file, depending on the design causes it to travel a special path within same curvature, as files show various bending properties.[21]

The manufacturing process can act as a nucleating site for crack progression at grain boundaries and surfaces and micro voids, resulting in instrument fractures during clinical usage **Alapati et al**[28].

SEM analysis of all instruments displayed a multiple peripheral overloaded areas with dimples rough surface in the bulk, noting more extensive cracks and micro voids in M3 Pro Gold rather than HyFlex CM, which reflects the results of cyclic fatigue resistance.

The null hypothesis was partially rejected because the length of the broken section did not significantly differ between HyFlex and M3 Pro Gold endodontic rotary files, but there was a statistically significant difference between the two files in terms of cyclic fatigue resistance.

Conclusions:

1- All new thermo-mechanical treatment technique - controlled memory CM-Wire rotary systems represented great performance and remarkable enhancement in cyclic fatigue resistance

2- HyFlex CM rotary files showed the high cyclic fatigue resistance than the M3-Pro

Gold.

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