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Comparison of surface defects in Protaper Next and Hyflex EDM files after single clinical use: A stereoscopic evaluation

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RESEARCH ARTICLE

Comparison of surface defects in Protaper Next and Hyflex EDM files after single clinical use: A stereoscopic evaluation

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Abstract

Objective: To compare the surface defects created on the ProTaper Next files versus HyFlex Electrical Discharge Machining files after single clinical use in molars.

Methods: The cross-sectional study was conducted in the dental department of the Aga Khan University Hospital, Karachi, from December 2018 to June 2019, and comprised Nickel-Titanium files belonging to HyFlex Electrical Discharge Machining and ProTaper Next to perform complete root canal treatment of molar teeth. The files were first visually examined and then analysed under 25.6x magnification using a stereomicroscope for the evaluation of surface defects. A photographic record was maintained and studied. Data was analysed using SPSS 23.0.

Results: Of the 114 files, 38(33.3%) each were ProTaper Next X1, ProTaper Next X2 and HyFlex Electrical Discharge Machining. The number of files showing defects under microscopic evaluation were 17(14.9%). Deformation of the cutting edge was the most frequently seen defect type, found in 9(7.9%) files. The frequency of fractured files was 4(3.5%). The odds of microscopic defects in HyFlex Electrical Discharge Machining files was 2.64 times that of ProTaper Next files.

Conclusion: Even after single clinical use, HyFlex Electrical Discharge Machining files were more likely to get microscopic defects on their surface compared to ProTaper files.

Keywords: Dental materials, Endodontics, Operative dentistry. (JPMA 72: 37; 2022)

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Introduction

Nickel-Titanium (NiTi) files are predominantly used in endodontics for debridement and shaping of the root canal system. These endodontic files have the ability to recover their original shape even after undergoing large deformations.[1] This is important because it imparts greater flexibility and super elasticity compared to the conventional stainless steel files.[2] Various factors, such as taper, cross-sectional design and pitch length, affect flexibility of NiTi files.[3] Despite considerable advances in endodontic file design, methods of root canal preparation and manufacturing process, fracture of NiTi endodontic instrument remains a problem in clinical practice.[4,5] Alapati et al.[6] reported that 23% of ProTaper (PT) files were fractured at the time of disposal.

The main loading conditions to which the instruments are subjected during use are bending and torsion.[7] Therefore, flexibility and torsional stiffness are the two most desirable properties for these instruments in order to prevent instrument fractures. Inadvertent file fractures, especially in teeth with preoperative periapical radiolucency, adversely affect endodontic outcome.[8,9] Sattapan et al.[2] stated that files exhibit signs of deterioration before fracture, and proposed that all files should be analysed before each use to reduce the risk of separation in root canal systems. The risk of file separation increases if these instruments are re-used.[10,11] Nagi et al.[12] demonstrated that the odds of a file deforming were 5.56 folds when used three or more times.

In recent years, there have been advances in the thermo-mechanical treatment of NiTi that have resulted in the advent of the M-wire. The M-wire NiTi shows greater flexibility and resistance to fatigue compared to conventional super-elastic NiTi.1 Johnson et al.[13] found a 400% increase in cyclic fatigue resistance in M-wire files compared to traditional austenitic NiTi files. Another contemporary variation in manufacturing is the Electrical Discharge Machining (EDM) where sparks are generated to melt and evaporate the surface of the material. This creates a new and unique surface of NiTi files and leaves them stronger and more fracture-resistant.[3] Pirani et al.[14] reported Hyflex EDM files to be 700% more cyclic fatigue-resistant than traditional NiTi files.

ProTaper Next (PTN) and Hyflex EDM files are part of the contemporary generation of endodontic files. Goo et al.[15] concluded that HyFlex EDM showed greater cyclic fatigue resistance, toughness and ultimate strength when compared with PTN files. Contrary to this, Pedulla et al.[16] showed that PTN M-wire files had a higher maximum torque load compared to HyFlex EDM files.

To the best of our knowledge, no clinical study comparing PTN and HyFlex EDM files is currently available even

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though there is a lack of consensus among researchers with regards to the clinical performance of these file systems. The current study was planned to compare visual and microscopic defects on PTN and HyFlex EDM files after single clinical use, and to explore any association between the file type and type of defects.

Materials and Methods

The analytical cross-sectional study was conducted in the dental clinics of the Aga Khan University Hospital (AKUH), Karachi, from December 2018 to June 2019. After approval from the institutional ethics review board, sample size was calculated with OpenEpi version 3.01[17] (open source statistics for public health, www.openepi.com) using the module for comparing two means. The mean length of fractured file segment following cyclic failure for HyFlex EDM OneFile and ProTaper Next was kept at 2.64±0.6 mm and 3.02±0.31mm, respectively, in the light of literature.[15] Using these values at 95% confidence interval (CI) with 90% power, the required sample size was then inflated by 10%.

Ni-Ti HyFlex EDM and PTN files were included that had been new at the time they were used to perform complete root canal treatment therapy in a single mature permanent molar tooth. Files excluded related to endodontic retreatment cases; root curvature >30 degree; teeth with calcified canals; teeth showing internal root resorption; teeth with immature apices; deciduous teeth; and files with visible defects prior to use.

On the basis of this criteria, new HyFlex EDM OneFile (Coltene/Whaledent, Langenau, Germany), PTN X1 and PTN X2 (Dentsply Maillefer, Ballaigues, Switzerland) were selected for further analysis.

Pre-treatment periapical radiographs were exposed using a digital sensor (Xios XG Select, Dentsply Sirona, Bensheim, Deutschland) as part of routine examination. The image was post-processed using radiograph software (Sidexis XG 2.63, Dentsply Sirona, Bensheim, Deutschland) for enhanced delineation of the tooth anatomy. The angle of the root exhibiting the maximum curvature was measured using Schneider's method.[18] Teeth exhibiting maximum root curvature <30 were recruited. After obtaining a conventional straight-line access, the canals were filed sequentially with K-files from size #8 to #15 to establish a glide path. Copious syringe irrigation by 3% sodium hypochlorite (Antiseptic Liquid #2, Technodent, Belograd, Russia) with 30-gauge side-vented needles (Irrigating Needle Tips, Henry Schien, NY, United States) was performed between each step. Gates-gliden drills #1 and #2 (Schenzhen Perfect Medical Instruments Co., Schenzhen, China) were used sequentially to widen the orifice. Working length was established using #10 or #15 K or H file as per the operator's judgment. A decision to use either PTN or HyFlex EDM was made at this point. All files were used as per the manufacturers' instructions under continuous rotation. PTN sported a speed of 300 rpm with 2Ncm torque, whereas HyFlex EDM were used at a speed of 400 rpm with 2Ncm torque.

Following molar endodontic treatment, the files were ultrasonically cleaned and then placed in marked sterilisation pouches for easy identification. These then underwent an autoclave cycle at 121^{O}C at 15psi for 15 minutes. The files were periodically collected by the principal investigator from the sterilisation department.

All files were initially screened visually under illumination by the unaided eye for defects. This was followed by microscopic evaluation under 25.6x magnification using a stereomicroscope (AM-4000, ALLTION, Guangxi, China). A photographic record was maintained and evaluated for surface defects by two examiners. A proforma was designed to record the data regarding surface defects which included data about instrument bending, tip deformation, stretching/straightening of twist contour, cutting edge deformity, and fracture of instrument.

Data was analysed using SPSS 23. Descriptive statistics were computed for frequency of defects. Chi-square test was used to evaluate the association between file and type of defect. Odds ratio (OR) was applied to assess the strength of association between file type and microscopic presence of defects. Inter-class correlation coefficient was used to evaluate inter-examiner reliability. Level of significance was kept at $p \leq 0.05$.

Results

Of the 114 files, 38(33.3%) each PTN X1, PTN X2 and HyFlex EDM OneFile, the number of files showing defects under microscopic evaluation were 17(14.9%). The most commonly observed defect was deformation of the cutting edge (Figure 1A), seen in 9(7.9%) files. The number of file fractures (Figure 1B) was noted in 4(3.5%) files. The incidence of bending, straightening, tip deformation and combination defect was seen in 1(0.88%) file each (Table 1).

Of the PTN X1 files, 5(13.2%) showed defects; 3(60%) showing deformation of the cutting edge, and 2(40%) were fractured. Of the PTN X2 files, defects were found in 3(7.9%) files; 2(66.6%) showing deformation of the cutting edge, and 1(33.3%) file had fracture. Of the EDM files, 9(23.7%) exhibited defects (Table 2). The type of defect did not show a statistically significant association with the type of file ($p=0.64$).

The odds of developing microscopic defects in HyFlex EDM files was 2.64 times that of PTN files, but the association was only marginally significant (*p*=0.06) (Table 3).

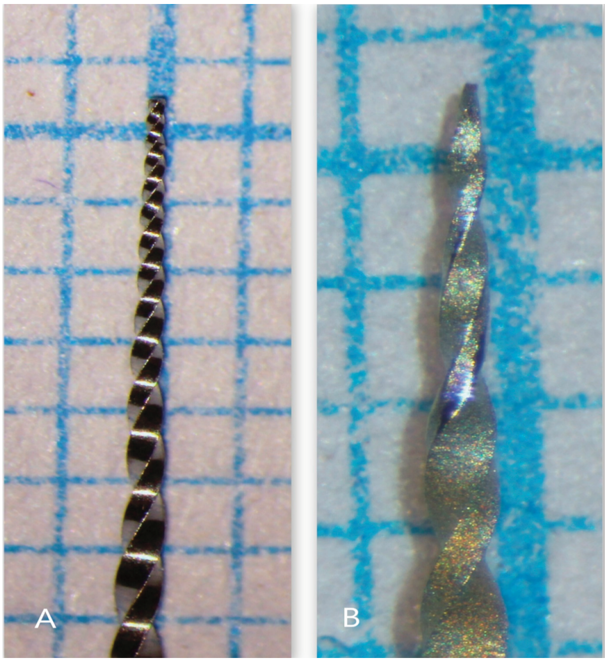

Figure: (A) Deformation of cutting edge in HyFlex Electrical Discharge Machining (EDM) OneFile at 25.6x magnification (B) Fracture of ProTaper Next (PTN) X1 at 25.6x magnification.

Table-1: Frequency of defects as seen under a stereomicroscope.

Type of Defect	n (%)
Bending	1 (0.88)
Straightening	1 (0.88)
Tip Deformation	1 (0.88)
Combination Defect	1 (0.88)
Fractured Instrument	4 (3.5)
Cutting Edge Deformed	9 (7.9)
Defects	17 (14.9)
No Defects	97 (85.1)
Total	114 (100)

Table-2: Distribution of type of defects encountered against the type of file.

	PTN X1 n (%)	PTN X2 n (%)	EDM n (%)	Total n = 114	*p*-value
Bending	0(0)	0(0)	1(2.6)	1(0.9)	0.64
Straightening	0(0)	0(0)	1(2.6)	1(0.9)	
Tip Deformation	0(0)	0(0)	1(2.6)	1(0.9)	
Cutting Edge Deformation	3(7.9)	2(5.3)	4(10.5)	9(7.9)	
Fractured Instrument	2(5.3)	1(2.6)	1(2.6)	4(3.5)	
Combination Defect	0(0)	0(0)	1(2.6)	1(0.9)	
No Defect	33(86.8)	35(92.1)	28(76.3)	97(85.1)	
Defect	5(15.2)	3(7.9)	9(23.7)	17(14.9)	

Chi-Square/ Fisher's Exact Test; Significant p value ≤ 0.05; PTN X1: ProTaper Next X1; PTN X2: ProTaper Next X2; EDM: HyFlex Electrical Discharge Machining OneFile.

Table-3: Strength of association between the presence of microscopic defects and file type.

	Microscopic Defect Present (n)	Microscopic Defect Absent (n)	Total	O.R. (95% C.I.)	*p*- value
EDM	9	29	38	2.64 (0.92 – 7.51)	0.06
PTN	8	68	76		
Total	17	97	114		

EDM: HyFlex Electrical Discharge Machining OneFile; PTN: ProTaper Next; OR: Odds ratio; CI: Confidence interval.

In order to gauge inter-examiner reliability, 10% data was re-assessed by the co-investigator. Inter-class correlation (ICC) coefficient was evaluated between the two examiners for the presence and type of defect, and there was found substantial agreement between the two examiners (ICC: 0.75).

Discussion

The present study evaluated the formation of microscopic defects created on the external surface of PTN and HyFlex EDM files after single clinical use in molars. Most of the previous studies assessing file systems have been done ex-vivo,[14-16,19] which would only show the relative risk of file deformation under a specific set of conditions that cannot be considered to be a true replication of how these files behave in the clinical setting.[20] The current study is similar to that of Pazos et al.[21] in which PTN files were assessed for defects after being used to endodontically treat a molar tooth. To our knowledge, no such study has previously been done for HyFlex EDM files.

The present study found microscopic defects on 10.5% of PTN files, and 3.9% of PTN files were fractured. In contrast, Pazos et al.[21] reported prevalence of surface defects to be 13.83% whereas 7.53% files were fractured. The higher incidence of file fracture can be attributed to their files being used to shape up to two molar teeth.

Studies with multiple use of files have reported up to 50% of files showing defects and up to 21% files ending up with fractures.[2] In comparison, Shen et al.[22] found 2.9% fractured files when the files were used only once in a clinical setting, which is in agreement with the current study.

Over the past decade, Ni-Ti files have undergone a multitude of changes; be it in terms of design characteristics, manufacturing processes or working motion. As a result, the number of file fractures has decreased. This can be seen in the current study and in those conducted over the last 10 years.[21-24] However, conflicting results can be seen in terms of frequency of defects, with Aziz et al.[24] reporting 68.2% defects under microscopic evaluation.

An in-vitro study by Goo et al.[15] demonstrated greater cyclic fatigue resistance, toughness and ultimate strength in EDM files compared to PTN files. The current study reported more microscopic defects in Hyflex EDM files (23.7%) compared to PTN (10.5%). The difference in defect formation between the two files can be attributed to the fact that in order to complete root canal preparation, a minimum of two files, X1 (#17/0.04) and X2 (#25/0.06), are required from PTN to achieve the same level of cleaning and shaping as would a single HyFlex EDM OneFile (#25/~). However, the increased number of defects does not directly translate into a proportional increase in the number of fractures, with both the files showing <4% fractures.

An increased number of defects was seen in files when they were viewed microscopically as opposed to direct visual examination. Therefore, it is recommended that some form of magnification be employed during procedures to analyse files before, during and after root canal therapy. This finding is concurrent with recommendations made by Sattapan et al.[2] and Aziz et al.[24] While greater magnifications may yield even more characteristic information about the type of defects, such high magnifications are rarely used for routine endodontic procedures. For fractographic analysis, scanning electron microscope remains the standard mode of assessment.

Currently, there is no consensus on the number of times a file can be reused. PTN files are marketed as single-use files by the manufacturers.[25] However, resource constraints in various practices force some clinicians to reuse files after autoclaving them. This is different from HyFlex EDM files which are marketed for multiple usage,[26] with a regenerative ability that allows the shape of the used files to be restored following the application of heat, such as through autoclaving or glass bead sterilisation. If the deformation remains after heat application, the files are to be assumed permanently deformed and should be discarded. Our findings recommend that wherever possible, even HyFlex EDM should be considered single-use, with each successive use increasing the potential for subsequent failure.

The limitation of the current study is not including endodontic retreatment cases and teeth with sclerotic or calcified canals. These cases present frequently in clinical practice and the incidence of surface defects on files may actually be greater since a higher amount of torsional stresses are generated in such cases. Another limitation is that the cases were not stratified according to the level of training of the clinicians. Also, the results are reflective of stresses generated clinically at a specialist practice, and may differ among different centres. Multi-centre randomised controlled trials (RCTs) using scanning electron microscope for data acquisition, with stratified analysis for tooth and operator-related variables are recommended.

Due to the relatively high incidence of surface defects, PTN and HyFlex EDM files should be limited to single clinical use. Since visual inspection alone may be inadequate, dental operating microscopes or magnification loupes should be routinely used to assess files before, during and after the shaping process.

Conclusion

Even after single clinical use, HyFlex EDM files were found to be more likely to acquire microscopic defects on their surface compared to PTN files.

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Conflict of interest: None.

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