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Scanning Electron Microscopic Analysis of Surface Alterations in Third-Generation NiTi Rotary Instruments Following Clinical Simulation

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ABSTRACT

Introduction: Third-generation nickel–titanium (NiTi) rotary files undergo proprietary thermomechanical processing intended to enhance flexibility and fatigue resistance.

Objectives: This study evaluated the qualitative and quantitative wear and fatigue behavior of four third-generation NiTi rotary systems following repeated use in extracted posterior human teeth using a simulated clinical model.

Materials and Methods: One hundred files (n=25 per group across four brands: ProFile Vortex™, Vortex Blue™, ProTaper Gold™, and Coltene HyFlex® CM™) were examined using Scanning Electron Microscopy (SEM) at 200x magnification at the same four positions along their length. Files were used to prepare root canals in extracted human posterior teeth (premolars and molars) in a simulated clinical model for up to three uses. Two blinded evaluators analyzed the SEM micrographs to score wear and deformation, categorizing files as usable, microscopically unacceptable, or visually unacceptable.

Results: Twelve files (12.0%) exhibited visual failure, most commonly during the first use. Canal curvature distribution differed significantly among brands; ProTaper Gold™ files were exposed to fewer severely curved canals, introducing confounding when interpreting comparative failure rates. Third-generation instruments predominantly failed by plastic deformation rather than separation. Regression analysis revealed no significant differences in wear between brands. Although microscopic wear increased significantly after initial use, it did not progress significantly with subsequent uses. Baseline manufacturing defects, present in 8% of files, did not significantly predict catastrophic failure.

Conclusions: Third-generation controlled-memory NiTi instruments tend to deform plastically rather than undergo abrupt separation, which may provide a visual warning of impending failure. While microscopic manufacturing defects were relatively common, they did not reliably predict fracture; however, absence of visible defects does not preclude internal fatigue accumulation.

Keywords: *Nickel-titanium endodontic files; Root canal preparation; Scanning electron microscopy; Instrument failure; Controlled memory.*

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1. INTRODUCTION

The shape and degree of root canal curvature are significant obstacles that impose limitations on successful endodontic cleaning and shaping of root canals. The ability of a clinician to adequately negotiate the canal system is coincident with their ability to adequately clean the canal system [(1)]. The introduction of nickel-titanium (NiTi) endodontic files has offered unseen flexibility when instrumenting curved canals while reducing the potential for file separation and canal transportation compared to their stainless steel predecessors [(2)].

The near-equiatomic nickel-titanium alloy (NiTi) was first invented at the Naval Ordnance Laboratory in Silver Spring, Maryland. The material proved effective as a missile nose cone, showing an improved ability to resist fatigue, heat, and impact [(3)]. From its discovery and use in missile manufacturing, the advantages of NiTi for orthodontics were described initially in detail by Andreasen and Morrow [(4)]. Unlike stainless steel files, which are normally manufactured by twisting a pre-milled wire to its desired design, Walia et al. employed a unique manufacturing process of milling the desired file fluting from round 0.02-inch diameter orthodontic NiTi archwire blanks. Walia et al. showed Nitinol files to have two to three times the elastic flexibility and superior torsional fracture resistance compared to stainless steel files [(5)].

The first generation of the nickel-titanium alloy used in dentistry was composed of approximately 52% nickel, 45% titanium, and 3% cobalt. The atoms of this alloy are arranged in two principal crystalline structures, either martensite or austenite, dependent upon temperature and the mechanical stress the material is subjected to [(6)]. The austenitic crystalline structure is complex body-centered cubic and exists at high temperatures (generally temperatures similar to those experienced intraorally,approximately 37°C-or higher) and low stress. At low temperature and high stress, the monoclinic martensitic crystalline form predominates. Since its early use in orthodontics, NiTi wire has been categorized as superelastic or non-superelastic, with the non-superelastic type having a much lower springback than the superelastic type. Upon stress activation, such as flexure or torsion, superelastic NiTi will undergo a phase transformation from austenite to martensite. This phase transformation is reversed as the wire is deactivated, returning to its austenitic arrangement and original shape [(7)].

Material characteristics, as well as manufacturing methods, have been implicated in the failure of endodontic instruments. Two fracture mechanisms have been found to be associated with NiTi file fracture: cyclic (flexural) fatigue and torsional overload. Cyclic fatigue occurs with the rotation of the endodontic file within a curved root canal. Cyclic failure is due to work hardening and metal fatigue associated with repeated loading and unloading of the NiTi file [(8)]. Torsional load occurs as the file encounters frictional resistance as it rotates in the root canal. When the torque exceeds the torsional strength of the NiTi file, this leads to either plastic deformation or fracture [(9)].

Recent changes in NiTi metallurgy (2007) have resulted in a NiTi alloy which is now more resistant to cyclic fatigue: M-wire™ [(4)]. Using the most commercially pure form of Nitinol, the raw wire is drawn under tension and heat-treated at various temperatures, resulting in a phase shift in the metal with emphasis on the martensitic and pre-martensitic (R) phases while still maintaining its pseudoelasticity. Advancements in metallurgy have brought about the third, and most recent, generation of NiTi-based rotary instruments. Using a proprietary thermomechanical process, Controlled Memory NiTi Technology™ (CM Wire) shows even greater improvements in cyclic fatigue and flexibility, as well as increased martensitic composition at intraoral temperature compared to conventional nickel-titanium [(10)].

Heat treatment of the alloy imparts the ability to raise the austenite finish temperature (Af) and maintain more of the desired martensitic form and characteristics at oral temperatures. Previous research on NiTi orthodontic wires had shown martensite to be less hard than austenite, so an endodontic file in its martensitic state could have decreased cutting efficiency. However, heat treatment in a nitrogen atmosphere can result in surface nitrides that actually increase hardness and cutting efficiency [(11)]. Most notably, these files can be bent similarly to stainless steel and maintain a desired shape rather than returning to their original form, allowing better adaptation to the natural curvature of the root canal and potentially less canal straightening [10].

Specific file systems utilize these technologies. Coltene HyFlex® CM™ files are machined from CM Wire. Vortex Blue™ is another controlled memory file made from 508 Nitinol that is machined and then undergoes a heating and cooling treatment to gain shape memory characteristics. The blue hue of the metal results from an oxide layer (titanium oxide – TiO_2) manufactured onto the file. It is speculated that the hardness of the TiO_2 layer may compensate for the loss of hardness of the underlying martensitic structure [12]. Most recently, ProTaper Gold™ has been introduced, boasting improved metallurgy and flexibility over its predecessor due to a proprietary thermal treatment [13].

Clinically, the lifespan of an endodontic file typically begins with sterilization, followed by at least one clinical use, with ultrasonic cleaning and sterilization in between treatments. Some file systems are marketed as single use, while others permit multiple uses following careful inspection for deformations after sterilization [14]. The improvements in cyclic fatigue of the third-generation systems present the question of multiple uses. Can these NiTi instruments be safely used more than once? Although some studies have looked at the wear of NiTi rotary files after multiple uses [15], none have looked at the actual degradation of the file after each use in an in-vitro situation using teeth. Therefore, this study offers a novel contribution by tracking the progressive wear of specific third-generation instruments through a realistic anatomical challenge.

2. OBJECTIVES

The purpose of this study is to evaluate the qualitative and quantitative wear/fatigue of four third-generation rotary endodontic file systems following use in extracted posterior human teeth in a simulated clinical model. The null hypothesis tested was that there would be no significant difference in the quantitative wear, visible deformation, or failure rates among the four tested rotary NiTi file systems, nor would the number of clinical uses (up to three) significantly affect their usability. The primary endpoint defined for this study was the proportion of files deemed microscopically or visually unacceptable (Scores 4 and 5). Secondary endpoints included the incidence of file separation and the specific mode of failure (plastic deformation vs. fracture).

3. MATERIALS AND METHODS

Study Design and Specimen Preparation

Data was aggregated across file sizes to evaluate the performance of the file system as a whole, though specific sizes were tracked to identify trends in failure. Five sets of files from four different endodontic rotary file systems were evaluated in this study. This sample size was selected based on similar previous ex vivo studies [1617] to detect significant differences in visible wear and deformation. To ensure a comprehensive assessment of the systems, a sequence of five sizes was tested for each brand, excluding orifice openers which were used but not imaged **(Table 1)**.

Table 1: Specifications and Sample Distribution of Tested Endodontic Files

File System	File Sizes Tested (Tip Size / Taper)	N per Size	Total N
ProFile Vortex™	20.04, 25.04, 30.04, 35.04, 40.04	5	25
Vortex Blue™	20.04, 25.04, 30.04, 35.04, 40.04	5	25
Coltene HyFlex® CM™	20.04, 20.06, 25.04, 30.04, 40.04	5	25
ProTaper Gold™	S1 (18.02*), S2 (20.04*), F1 (20.07), F2 (25.08), F3 (30.09)	5	25
TOTAL			**100**

To establish a baseline and ensure the elimination of manufacturing byproducts, instruments underwent a specific sequence of preparation prior to use [18]. First, instruments were removed from the manufacturer packaging and immersed in an ultrasonic bath containing 95% ethyl alcohol for 15 minutes. This solvent-based ultrasonic cleaning was selected to facilitate the removal of non-biological factory residues, including milling oils and metallic micro-debris (edge rollover), that enzymatic cleaners may fail to dissolve [19]. Following the ultrasonic cycle, instruments were rinsed with distilled water and air-dried.

Immediately following this preparatory cleaning and prior to sterilization, instruments were analyzed with a scanning electron microscope (SEM) (Quanta 200, FEI, Hillsboro, Oregon). The same surface and cutting edges were repeatedly examined following each procedure. Specimens were imaged using an Everhart-Thornley Detector (ETD) and an accelerating voltage of 20 kV. Images were captured in high-vacuum mode with a working distance of 10-12 mm and a spot size of 3.5 to ensure depth of field. A magnification of 200x was standardized for all captures to allow for the assessment of gross surface deformations, flute distortion, and wear across the full diameter of the active cutting edges at the specified locations (D0, D1, D3, D5). Care was taken to keep the image working distance slightly greater than 10 mm to avoid damaging the unit, with slight variance allowed for proper image focus.

Photomicrographs (secondary electron images) were taken of the leading edge of the cutting blades at the tip of the file (D0), 1 mm from the tip (D1), 3 mm from the tip (D3), and 5 mm from the tip (D5). The images were recorded digitally and labeled according to the file pack, file brand, stage of examination, file size, and position on the file. After initial imaging, the files were packaged and sterilized in a steam autoclave at 134˚C for 15 minutes prior to the first clinical simulation [20]. They were then ready to be used on selected, de-identified, extracted posterior teeth.

Tooth Selection and Preparation

Sixty extracted, de-identified posterior teeth (mandibular and maxillary molars and premolars) were collected and sorted from a collection of over 1000 teeth. Selected teeth were rinsed in a 3% NaOCl solution (Clorox®, Oakland, CA), and exterior tissue was removed from the roots with a periodontal scaler. Teeth were stored in 3% NaOCl for a period of 2 to 6 months prior to use. Before instrumentation, teeth were rinsed thoroughly with distilled water to remove residual hypochlorite. Inclusion criteria for the test teeth were: intact roots with closed apices, patent canals (as determined with a #8 K-file after access opening), individual canals (established radiographically–no Type 2 or 4 canals), and no signs of internal or external root resorption or root fractures (evaluated under 2.5x magnification using loupes).

Radiographs were taken of all teeth to calculate root canal curvature. Canals were divided into classifications of; <30˚, 30˚–45˚, 45˚–60˚, and >60˚ curvature [21]. Teeth were categorized as premolar, mandibular molar, and maxillary molar, and stored in sealed, opaque jars. To assign teeth to experimental groups, a stratified random sampling method was utilized. Teeth were drawn blindly from the opaque storage jars to ensure each file set treated exactly one of each tooth type (one premolar, one maxillary molar, one mandibular molar). While tooth type was balanced across groups, specific canal curvatures were not stratified prior to assignment, resulting in a random distribution of curvatures. The number of canals, curvature of each canal, and whether the file was used in the clinical simulation were recorded.

Clinical Simulation Procedure

The crown of each tooth was removed at the cemento-enamel junction (CEJ) using a diamond-impregnated blade (Vari/Cut VC-50, Leco, St. Joseph, MI). Access opening was further enlarged with a #4 round bur (Komet USA, Rock Hill, SC) in a high-speed handpiece. Canals were located and patency was determined with a #8 K-file. The working length of each canal was determined by working a #10 K-File (Kerr, Gilbert, AZ) out the apex of the canal until it could just be visualized, and then the file was retracted 1 mm. Working lengths were measured using Endoring® II (Jordco Inc., Beaverton, OR).

All instrumentation was done by a single operator. Initial canal path was prepared using a #15 K-File. Orifice shapers (ProFile Vortex™ 25/0.12 and 40/0.10) were utilized to achieve straight line access to the canals for the ProFile Vortex™ and Vortex Blue™ file groups. Orifice modification and shaping for the HyFlex® CM™ and the ProTaper Gold™ groups were achieved using the Hyflex® CM™ sizes 25/.08 (19 mm) and the Protaper Gold™ Sx (19 mm), respectively. EDTA gel (Glyde, Dentsply Maillefer, Tulsa, OK) was placed on each rotary file tip before use. Root canals were irrigated with approximately 1 mL 3% NaOCl solution per canal with a 27-gauge needle (BD PrecisionGlide™, Becton Dickinson and Co., Franklin Lakes, NJ), placed passively into each canal, after every two instruments used.

Between the uses of each rotary instrument, a #10 K-File was placed in the root canal to working length to maintain patency of the canal. Files were cleaned with a 4x4 cotton sponge soaked in 70% isopropyl alcohol after each use and were stored in EndoFoam™ (Jordco Inc., Beaverton, OR) during instrumentation of the tooth. The same set of files was used to instrument all of the canals for that tooth. Files that separated or showed catastrophic distortion were replaced with a similar file of the same brand and size to allow complete instrumentation of the canals. The old file was removed, labeled, and examined with the SEM. The replacement file was noted in the treatment history of that particular set of files, along with information regarding whether the new file was used during that particular clinical simulation and in which canal the separation occurred.

Rotary instrumentation followed the directions of each manufacturer in terms of rotational speed and torque settings. An 8:1 reduction handpiece (TUL-8M, Dentsply Tulsa Dental Specialties, Tulsa, OK) was utilized on a torque-control motor

(Aseptico® DTC®, Dentsply Tulsa Dental Specialties, Tulsa, OK). Instrumentation of canals continued to a minimal apical size of 25 or maximum size of 40 (with taper corresponding to the file system used), depending on the anatomy of the individual canal. This was meant to mimic most random clinical situations.

Following preparation of all the canals in the tooth, the rotary files were cleaned in an ultrasonic bath (as previously described) and autoclaved (as previously described). The instruments were then re-examined under the SEM at 200x (at the same locations previously described, using the custom jig to confirm proper orientation of the files) and digital images were prepared, labeled and stored for evaluation. The SX file of ProTaper Gold™ and the 25/.08 file of Coltene HyFlex® CM™ were used but not examined under SEM in this study because they are meant for orifice modification and are rarely used in the apical third of the canal. This process was repeated two more times, resulting in the set of files being utilized for three different teeth. A final SEM evaluation was conducted on the cleaned and sterilized files after the third clinical simulation.

Classification and Evaluation of Instruments

Two examiners analyzed the randomized digital images on a computer screen and scored the files for the presence of irregular cutting edges, grooves, microcracks/cavities, burrs and distortions of the flutes [22]. The evaluators then rescored a newly randomized set of the same images four weeks later to confirm intra-rater reliability. Inter-rater reliability was calculated using Cohen's Kappa. Any discrepancies in scoring between the two examiners were resolved through a joint review of the images to reach a consensus score [23]. This final consensus score was utilized for all subsequent statistical analyses to mitigate the impact of moderate inter-rater agreement. The rating process was conducted after the conclusion of all experiments and included the complete dataset of images from baseline (Use 0) through the third clinical use.

Each evaluator was calibrated to the grading criteria prior to both grading periods, using sample images that most accurately represent each category. Evaluators analyzed the randomized images of the files from each stage of this study, collectively, with no knowledge to which stage the image they were evaluating belonged. To ensure blinding, all file brand identifiers were removed from the images, and the evaluators were blinded to the specific stage of use (0, 1, 2, or 3) corresponding to each image. The following criteria were utilized to evaluate the NiTi files [24]:

Score 1: Long axis of file was undistorted – no stretching or compression of flutes and no wear on file edges.
Score 2: 1-3 defective/worn areas on cutting edges.
Score 3: Long axis of the file was mildly distorted – there was stretching/compression of the flutes and/or 4-5 worn areas on cutting edges.
Score 4: Long axis was moderately distorted – severe wear on flutes with more than 5 wear areas on cutting edges.
Score 5: Breakage of the file or visible deformation after sterilization.
Any files that showed breakage or visible deformation after use and sterilization received a score of 5 for all images to be taken on that file for that clinical simulation and were discontinued for future use/evaluation.

For each series (use 0 through 3) of the study, evaluators assigned a score to four positions on a file (D0, D1, D3, D5). The file was then assigned the maximum score from all four positions for that series and placed into one of three categories:
(1) Usable: Files that scored 1-3 having wear/defects/deformation that would not deter the examiner from continuing to use that instrument.
(2) Microscopically Unacceptable: Files that scored 4 having wear/defects/deformation that would deter the examiner from continuing to use that instrument but could not be observed without the aid of scanning electron microscopy.
(3) Visually Unacceptable: Files that scored 5 were deformed or separated after sterilization and could be identified as such by visual human inspection.

When interobserver disagreement existed between what one observer thought was usable and the other thought was microscopically unacceptable, the two observers discussed their evaluation and came to a consensus. Any file added to the study to replace one that had failed was not included in the final statistical analysis of wear and deformation. This was done to ensure that each file examined had an equal chance at being used through three clinical simulations.

4. STATISTICAL ANALYSIS

Data were analyzed using SPSS software (Version 25.0, IBM Corp., Armonk, NY). Kappa statistics for intra-rater and inter-rater reliability were calculated. Fisher's exact test was used to evaluate the distribution of canal curvatures experienced by each file brand. To account for the correlated nature of the data (repeated measures on the same files over three uses), a Generalized Linear Mixed Model (GLMM) was employed. The model included "File ID" as a random effect to account for within-subject correlation, with "Brand" and "Number of Uses" as fixed effects. Baseline microscopic status (Use 0) was included in the analysis to adjust for manufacturing defects. Odds ratios between brands and uses were calculated with a 95% confidence interval. Statistical significance was set at $\alpha=0.05$.

5. RESULTS

Reliability of Evaluation
Prior to grouping files into the three categories (Usable, Microscopically Unacceptable, Visually Unacceptable), weighted Kappa statistics were calculated based upon the original grading scale (1-5). Intra-rater reliability values for each evaluator were 0.6809 and 0.7608. Inter-rater reliability values for the first and second round of grading were 0.5176 and 0.4613, respectively. Due to these values, the consensus scores were used for final analysis.

Visual File Failures
Table 2 shows the overall file failures by brand. Vortex Blue™ files and Coltene HyFlex® CM™ files had the most overall failures with four each. The overall failure rate was 12.0%. Qualitative SEM analysis revealed characteristic surface pitting on Vortex Blue™ instruments that appeared to expand with repeated use, distinct from the wear patterns of other brands. Only three of the twelve failures were actual file separations; the remaining failures involved plastic deformation that remained after sterilization. All separations occurred approximately at the D1 level (1 mm from the tip of the file). The overall separation rate was 3.0%. Notably, most visual malfunctions happened when the files were initially used. For ProTaper Gold™, visual and microscopic failures were confined to sizes S1 and S2, while all size F1, F2, and F3 instruments remained usable throughout the study. Qualitative assessment of usable files revealed that minor unwinding or torsional distortion was most frequently observed after the first clinical simulation.

Table 2: Overall File Failures by Brand and Type

File Brand	N	File Failures	Separations	Plastic Deformations	Failure Rate (%)
ProFile Vortex™	25	2	2	0	8.0
Vortex Blue™	25	4	1	3	16.0
ProTaper Gold™	25	2	0	2	8.0
Coltene HyFlex® CM™	25	4	0	4	16.0
TOTAL	100	12	3	9	12.0

Microscopic Evaluation and Baseline Defects
Table 3 details the acceptability status of each brand. ProFile Vortex™ had the most files graded as microscopically unacceptable (Score 4). Although 8% of files were graded as microscopically unacceptable at baseline due to manufacturing defects (e.g., edge rollover), longitudinal tracking revealed that these specific baseline defects did not significantly predict visual failure (Score 5) in subsequent uses. Between 8.0% in the unused group and 11.0% in tooth 3 (usage), the overall percentage of files classified as microscopically unsatisfactory was largely constant.

Canal Curvature Distribution
Table 4 details the number of each type of root curvatures experienced by file sets of each brand. A significant relationship exists between file brand and the number of canal curvature types experienced ($p=0.0426$, Fisher's Exact Test). ProTaper Gold™ files experienced the most <30° canals and no canal curvatures greater than 45°. Consequently, the lower failure rate observed in the ProTaper Gold™ group must be interpreted with caution, as these instruments were subjected to significantly less anatomical challenge than the other groups.

Regression Analysis
Repeated-measures logistic regression indicated that there were no discernible impacts on brand, usage frequency, or their combination in terms of visual grade (Table 5). For microscopic acceptability (scores 1-3), no significance between brands was found. However, the number of uses did have a significant role ($p=0.0127$). Uses 0 versus 1, 0 versus 2, and 0 versus 3 indicated significant differences. However, contrasts of uses 1, 2, and 3 showed no significance, indicating that microscopic wear did not progress significantly after the initial use.

Table 3: File Acceptability Status by Brand and Use

Brand	Unused (%)	Tooth 1 (%)	Tooth 2 (%)	Tooth 3 (%)	Overall (%)
Visually Unacceptable (Score of 5)					
Vortex Blue™	0	12.0	0	4.0	4.0
ProTaper Gold™	0	8.0	0	0	2.7
Coltene HyFlex® CM™	0	8.0	0	8.0	5.3
ProFile Vortex™	0	4.0	4.0	0	2.7
Microscopically Unacceptable (Score of 4)					
Vortex Blue™	4.0	12.0	4.0	8.0	7.0
ProTaper Gold™	4.0	8.0	4.0	8.0	6.0
Coltene HyFlex® CM™	12.0	4.0	12.0	12.0	10.0
ProFile Vortex™	12.0	12.0	8.0	12.0	11.0
Clinically Usable (Scores 1-3)					
Vortex Blue™	96.0	76.0	84.0	76.0	83.0
ProTaper Gold™	96.0	84.0	88.0	84.0	88.0
Coltene HyFlex® CM™	88.0	88.0	80.0	72.0	82.0
ProFile Vortex™	88.0	84.0	84.0	80.0	84.0

Table 4: File Brand by Canal Curvatures Experienced (p=0.0426)*

File Brand	<30°	30-45°	45-60°	>60°	Total
Vortex Blue™	27 (73%)	5 (14%)	5 (14%)	0 (0%)	37
ProTaper Gold™	34 (94%)	2 (6%)	0 (0%)	0 (0%)	36
Coltene HyFlex® CM™	25 (66%)	7 (18%)	4 (11%)	2 (5%)	38
ProFile Vortex™	29 (71%)	9 (22%)	3 (7%)	0 (0%)	41
TOTAL	115 (76%)	23 (15%)	12 (8%)	2 (1%)	152

**P-value derived using Fisher's Exact Test*

Table 5: Repeated-Measures Logistic Regression Results

Effect / Comparison	P-value
Visual Acceptability (Scores 1-4)	
Brand	0.4589
Use Number	0.5971
Brand × Use Number (Interaction)	0.9888
Microscopic Acceptability (Scores 1-3)	
Brand	0.4510
Use Number	**0.0127***
Brand × Use Number (Interaction)	0.9875
Microscopic Contrast Analysis (Unused vs. Used)	
Use 0 versus 1	**0.0277***
Use 0 versus 2	**0.0061***
Use 0 versus 3	**0.0014***
Use 1 versus 2	0.4900
Use 1 versus 3	0.1976
Use 2 versus 3	0.5422

** Significant at $p < 0.05$*

Odds Ratios

Analysis showed that at use 0 (unused), a file of any brand was 3.287 times more likely to be microscopically acceptable than at use 1, 4.309 times at use 2, and 5.403 times at use 3 (Table 6). No brand was significantly more likely to be microscopically acceptable than any other brand.

Table 6: Odds Ratios for Microscopic Acceptability (Scores 1-3)

Comparison	Odds Ratio	95% Confidence Interval
File Brands (all comparisons non-significant)		
Vortex Blue™ vs ProTaper Gold™	0.722	0.264 - 1.976
Vortex Blue™ vs Coltene HyFlex® CM™	1.501	0.620 - 3.638
Vortex Blue™ vs ProFile Vortex™	1.049	0.424 - 2.599
ProTaper Gold™ vs Coltene HyFlex® CM™	2.079	0.837 - 5.167
ProTaper Gold™ vs ProFile Vortex™	1.453	0.572 - 3.687

Comparison	Odds Ratio	95% Confidence Interval
Coltene HyFlex® CM™ vs ProFile Vortex™	0.699	0.314 - 1.554
Number of Uses		
Use 0 vs 1	3.287	1.140 - 9.479
Use 0 vs 2	4.309	1.522 - 12.202
Use 0 vs 3	5.403	1.925 - 15.164
Use 1 vs 2	1.311	0.607 - 2.832
Use 1 vs 3	1.644	0.771 - 3.504
Use 2 vs 3	1.254	0.605 - 2.600

6. DISCUSSION

Because of their special flexibility and time-saving qualities, NiTi rotary devices significantly increase the technical standard of root canal treatment [(25)]. Additionally, because of the variety of their shapes and cross-sectional designs, researchers have conducted several experimental investigations to assess their clinical performance, primarily by examining the instruments' capacity for cleaning, shaping, and security [(26)]. Dental researchers continue to have serious concerns about the shaping capacity of endodontic nickel-titanium rotary devices. It shows that the endodontic files have the ability to form root canals, particularly curved canals, without producing any abnormalities. This is accomplished by determining if the file is straightening the canal's curvature, whether it is capable of staying centered, and whether it can keep the canal centered with little movement [(27)].

Extracted teeth offer a more realistic simulation of clinical root canal procedures compared to resin blocks due to differences in material properties and anatomical complexity [(28)]. The specific teeth chosen (one premolar, one maxillary molar, and one mandibular molar) exhibit distinct and variable root canal morphologies, presenting different levels of endodontic challenge [(29)]. This study aimed to approximate as accurate a clinical model as possible in vitro to examine the clinical lifespan of four brands of endodontic rotary files.

Our results indicated that Vortex Blue™ and Coltene HyFlex® CM™ had the highest number of visual file failures (four each). However, the mode of failure differed significantly between generations; both failures of ProFile Vortex™ (second-generation) were actual separations, whereas all but one of the visual failures in the third-generation brands (ProTaper Gold™ and HyFlex® CM™) involved plastic deformation, files appearing permanently unwound after use and sterilization [(4)].

This tendency for third-generation files to plastically deform rather than separate is a critical safety feature attributed to the Controlled Memory (CM) heat treatment [(30)]. It allows the clinician to identify a file no longer fit for use before potential separation and canal blockage occurs. The only separation among third-generation files occurred in a Vortex Blue™ instrument during its first use. The overall rate of file separation (3.0%) in this study was consistent with previous literature regarding fatigue failure [(3132)].

ProFile Vortex™ and Vortex Blue™ share identical geometry but differ in metallurgy (M-wire™ vs. heat-treated NiTi with titanium oxide coating). This metallurgical difference likely accounts for the divergent failure modes (separation vs. deformation) observed. A unique finding in the results was the extensive surface pitting observed on multiple Vortex Blue™ instruments [(12)]. This condition appeared to worsen with continued use, appearing as voids where the titanium oxide surface layer, intended to compensate for hardness lost during heat treatment, was chipping off. While examiners frequently scored this as severe wear (Score 4), no Vortex Blue™ files fractured or visibly deformed as a direct result of this defect. However, this degradation could reduce cutting efficiency, potentially supporting the manufacturer's single-use recommendation.

Regarding ProTaper Gold™, results showed that visual and microscopic failures were confined strictly to sizes S1 and S2, while all size F1, F2, and F3 instruments remained usable throughout the study. This suggests that the shaping files (S1/S2) experience the highest torsional and cyclic stress during canal preparation. Unlike previous studies on ProTaper® Universal where the F3 file was most prone to failure, all F3 ProTaper Gold™ files remained usable, likely due to the increased flexibility imparted by the new heat treatment process [(1333)].

A significant number (8%) of files were graded as microscopically unacceptable before any use, exhibiting defects such as edge rollover (metal flashing), rounded edges, and chips. Despite the rigorous pre-cleaning protocol utilizing ultrasonic alcohol to remove loose debris, structural edge rollover from the milling process persisted on these unused files, indicating these were attached metal fins rather than removable residue. This suggests a need for improved machining processes. Interestingly, repeated use often "improved" the microscopic score of these files by wearing away the edge rollover, making the surface appear smoother. This finding must be interpreted cautiously; while the edges appeared less irregular, surface abrasion likely reduces cutting efficiency, requiring more rotations and potentially increasing cyclic fatigue [(34)].

The current results demonstrated that the majority of visual file failures occurred during the first clinical simulation. In all but one case, files that failed had been rated as "usable" in the previous evaluation. This confirms previous findings that file fracture and plastic deformation occur with little-to-no observable warning [(35)].

Based on the results of the repeated-measures logistic regression, the null hypothesis regarding file brand was accepted. No specific file system demonstrated significantly superior resistance to wear, or failure compared to the others under the conditions of this study ($p > 0.05$). However, the null hypothesis regarding the number of clinical uses was partially rejected. While there was no significant difference in visual acceptability between uses, there was a statistically significant difference in microscopic acceptability between unused files and those used clinically ($p=0.0127$). Notably, this significance did not persist between the first, second, and third uses, suggesting that the most significant surface changes occur immediately upon first use.

This study had several limitations inherent to an ex vivo model. Although extracted teeth provide a more realistic challenge than resin blocks, the storage of teeth in NaOCl may have altered dentin microhardness. Additionally, the reliance on SEM imaging provides only topographical data; it cannot account for internal microstructural changes or invisible fatigue accumulation. Future research should incorporate metallurgic analyses, such as Differential Scanning Calorimetry (DSC), to track phase transformations through multiple uses.

Furthermore, this study utilized SEM at 200x magnification to assess general wear and deformation. While sufficient for identifying gross plastic deformation and edge deterioration, this magnification may be insufficient for detecting initial nano-scale crack nucleation or characterizing the specific depth of the pitting observed on Vortex Blue™ files. Future research utilizing high-magnification SEM (>1000x) or Energy Dispersive X-ray Spectroscopy (EDS) is recommended to further characterize these surface micro-features and definitively determine if the surface pitting correlates with a reduction in cutting efficiency.

7. CONCLUSIONS

Within the limitations of this study, third-generation controlled memory instruments demonstrated a specific tendency to deform plastically rather than separate, offering a visual warning of failure. Although microscopic manufacturing defects were common, they did not reliably predict instrument fracture; however, the absence of visible defects does not guarantee immunity from internal fatigue accumulation.

Clinical Implication: Limited reuse of third-generation files is supported by this study only if instruments are rigorously inspected and discarded immediately upon observing plastic deformation. Despite this, adherence to manufacturer single-use recommendations remains the superior standard of care to prevent instrument separation and cross-contamination.

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