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Understanding Cyclic Fatigue in Three Nickel-Titanium Pediatric Files: An In Vitro Study for Enhanced Patient Care

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Understanding Cyclic Fatigue in Three Nickel-Titanium Pediatric Files: An In Vitro Study for Enhanced Patient Care

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Abstract: *Background and Objectives:* Nickel-titanium (Niti) instruments have enhanced root canal cleaning in primary teeth, but file fractures are still common. This study evaluated the cyclic fatigue resistance of 120 Niti files from four different systems, A: Kedo SG (n=30); B: Neoendo Pedoflex (n=30); C: Pedoflex Waldent files (n=30) and D: Vortex Blue files (n=30). *Materials and Methods:* All the files had similar tip diameters (0.25 mm) and tapers (0.4%) and underwent heat treatment during manufacturing. Cyclic fatigue tests showed notable variations in cycles to fracture (NCF) across groups. All fracture surfaces of the files were assessed through scanning electron microscopy. *Results:* The mean values achieved in the experimental groups (A, B, C) were less than those in the control group D (976.90 ± 1085.19). Files in Group A demonstrated the highest NCF (697.01 ± 420.09), while Pedoflex files in Group C showed the lowest values (203.88 ± 155.46). Statistical analysis using the Mann-Whitney test revealed significant differences between groups A, B, and D compared to Group C. Still, no differences among groups A, B, and D. *Conclusion:* These findings suggest that Kedo SG and Neoendo Pedoflex files offer comparable cyclic fatigue resistance to Vortex Blue files. In contrast, Pedoflex Waldent files exhibit lower resistance to fracture.

Keywords: cyclic fatigue resistance; nikel titanium files; pediatric rotary systems

1. Introduction

Pulpectomy should be considered a treatment option to maintain primary teeth until physiological exfoliation to attain esthetics and functions like phonetics and mastication [1]. Using engine-driven nickel-titanium (Niti), instruments has dramatically facilitated the cleaning and shaping of canals [2]. Its use has also reduced iatrogenic errors like canal transportation and ledges [3]. Obturating the canals, which seemed tedious in canals prepared with conventional hand instruments, has also been eased due to the greater taper in most of these files, resulting in better-quality root canal fillings [4]. Studies among pediatric patients have revealed that it positively impacts treatment outcomes, increasing patient acceptance by considerably reducing the treatment time [5–7]. Despite the noted benefits and wide acceptance of mechanized Niti files among dentists, its influence in treating canals of primary teeth is relatively new [8,9].

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Despite the perceived advantages, fatigue-related file separations remain a problem with these files, especially when rotated in curved canals [10]. The reported incidence of fracture of instruments varies from 0.7% to 6% [11]. Most Niti file systems fracture abruptly without any previous warnings, unlike the stainless-steel files, whose flutes unfold, which can be recognized as shiny surfaces on the file [12,13]. Single-time use of files, as recommended by manufacturers, especially while treating constricted canals, has reduced the incidence of fracture but has not eliminated it [14,15]. Various methods are used to combat the issue, like incorporating novel cross-sectional geometrical designs, surface treatments, and heat treating to obtain Niti alloys that are more flexible and have better cyclic fatigue resistance due to achieving martensite or R-phase [16–18].

Studies have shown that heat treatment of files has improved the resistance to cyclic fatigue [19]. Additionally, factors like tip size, file diameters, and cross-sectional designs that could influence the cyclic failure of files have also been established [20–22]. However, limited details have been available comparing fatigue resistance in heat-treated Niti files with the same tip size [23]. More recently, several companies have started manufacturing rotary files for pediatric use. These files are generally prepared at reduced lengths in lieu of short root lengths and limited mouth openings in pediatric patients [24]. They are safe to use, resulting in better quality canal preparations and reduced iatrogenic errors comparable to files designed for permanent teeth [9].

One such file is the Kedo SG gold files (Reeganz Dental Care; Pvt. Ltd. India) manufactured exclusively for primary teeth. These are heat-treated controlled memory files with a triangular cross-section coated with titanium oxide [24]. Previous studies have shown it to be efficient with a low incidence of file separations [25]. Other files evaluated for cyclic fatigue in this study include those available in pediatric lengths with similar cross-sectional diameter, heat treatment, and tip diameter compared to Kedo SG files. These include the Neoendo pedoflex files (Orikam Healthcare, Gurugram, Haryana, India) and Pedoflex files (Waldent Innovations, 'Pvt. Ltd.' New Delhi, India). The sheer magnitude of such files imploding in the market, questionable standardization, and lack of adequate studies necessitate evaluating the mechanical properties of the most commonly used ones [26,27]. The Vortex Blue (VB) files (Dentsply Sirona, Ballaigues, Switzerland) are manufactured using a method to control the shape memory of Niti files. The propriety blue color is due to the titanium oxide coating on the surface of these instruments. The authors in this study used VB as a control as it was previously shown to be better suited for curved canals, being more flexible and fatigue-resistant than their counterparts [28]. The authors of this study aimed to assess the cyclic fatigue in pediatric files compared with the VB file, which had the same tip diameter. The null hypothesis was that the VB files would have superior resistance to cyclic fatigue.

2. Materials and Methods

2.1. Ethical Approval

Before commencing the study, ethical approval of the same was obtained from the Standing Committee of Bioethics Research (SCBR), Prince Sattam bin Abdulaziz University (PSAU), with the approval number (SCBR-046-2023).

2.2. Study Samples

Three systems of Niti rotary files, which are being promoted for pedodontic use with similar characteristics: heat treatment, 16mm length, 0.25 mm - tip diameter, were subjected to cyclic fatigue testing. Vortex Blue files with an identical 0.25 mm tip diameter and 4% taper were used as a control group. Sample size calculation was done using G power analysis with an effect size of 0.1 and power of 0.95. All files were visually inspected at 30X magnification for any deformities using the dental operating microscope (Zumax OMS2380, Suzhou, Jiangsu Province People's Republic of China), and those with noticeable deformities were excluded. A total of 120 standard files were selected and grouped according to the manufacturers: Group A: Kedo SG files (n=30); Group B: Neoendo pedoflex files (n=30); Group C: Pedoflex files Waldent (n=30) and Control Group D: Vortex Blue files (n=30).

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2.3. Cyclic Fatigue Resistance Test

A specially designed fatigue tester (Denbotix, Bucheon, Korea) was used to evaluate the files' resistance to cyclic fatigue. The component had two parts: an artificial metal canal of 17 mm length, 5mm radius, and 1.5mm intracanal diameter with 60 degrees curvature as described by Pruett et al. [29] and an arm part that helps firmly hold the handpiece for file rotation, as seen in Figure 1.

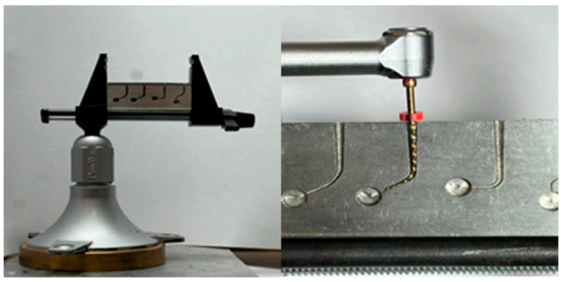

Figure 1. Cyclic fatigue testing apparatus with the test sample.

The artificial canal was sealed with a clear acrylic plate secured by screws. This setup allowed for the observation of instrument rotation until fracture and prevented any slippage. The Endo motor handpiece was mounted on a tester that allowed the unhindered placement of each instrument inside the artificial canal. Rotary files were rotated in an endo motor (X-Smart, Dentsply Sirona, Charlotte, NC, USA) using a conventional rotary motion; the speed and torque recommended by the manufacturer were used. Before each use of the file for testing, lubricant oil (Millet Franklin, BA, Argentina) was used to reduce the friction between the files and metal canal walls. During each test, the instrument was monitored and visualized through the clear plate until fracture occurred, and the time to fracture was registered in seconds using the digital timer (Timex, Middlebury, CT). The number of cycles to fracture (NCF) was calculated using the equation:

NCF = Number of rotations per minute *X* Time to fracture/60 seconds.

2.4. SEM Analysis

The fractured segments were examined using an FEI Quanta 250 FEG scanning electron microscope (Field Electron Ion Company, Hillsboro, Oregon, USA). Two broken files from each system were analyzed using SEM, and photomicrographs of the fractured regions were captured at various magnifications.

The length of the fractured segment was established using a millimeter ruler (Endo-Eze Ruler, Ultradent Products, Inc., South Jordan, UT, USA).

2.5. Statistical Analysis

The data was recorded and analyzed using SPSS version 20. Kruskal-Wallis test was performed for group comparisons, and Mann Whitney U test was used for inter-group comparisons with statistical significance set at $p \leq 0.05$.

3. Results

The NCF values for samples of all groups are represented as a graph in Figure 3.

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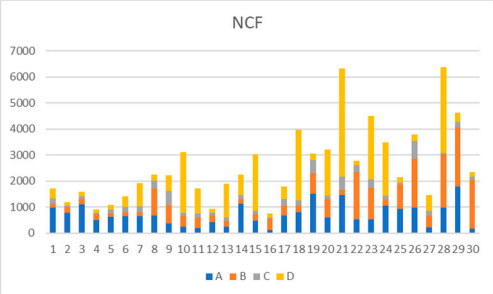

Figure 3. Graphical representation of NCF values of all samples.

As Table 1 shows, the Kolmogorov-Smirnov and Shapiro-Wilk normality tests were performed to measure the central tendency and methods for analysis.

Table 1. Test of Normality.

		Kolmogorov-Smirnov			Shapiro-Wilk		
	Group	**Statistic**	**df**	**Sig**	**Statistic**	**df**	**Sig**
NCF	A	.122	30	.200*	.939	30	.077
	B	.264	30	.000	.757	30	.000
	C	.207	30	.002	.808	30	.000
	D	.246	30	.000	.775	30	.000

Test results showing non-parametric distribution.

Since the data in Table 1 does not follow a normal distribution, a nonparametric Kruskal-Wallis test was performed to compare different groups. The mean values measured in all groups (A, B, C) were less than those in control group D (976.90). The highest mean NCF values were seen in control Group A (697.0191), while the lowest values were in Group C (203.88), as represented in Table 2.

Table 2. Non-parametric test based on mean NCF Values.

Group	n	Mean with Std. Dev	Median	Inter quartile range
A	30	697.01 ± 420.09	645.33	600.15
B	30	661.76 ± 655.09	386.47	721.28
C	30	203.88 ± 155.46	161.33	116.38
D	30	976.90 ± 1085.19	414.19	576.25

When intergroup comparisons were made using the Mann-Whitney test, Groups A and B significantly differed from Group C, with p-values < 0.001. However, no such difference was observed between the control Group D and Groups A and B, as seen in Table 3.

Table 3. Intergroup comparison.

Group	Groups	Mean difference	Z	P
A	B	35.25	1.373	0.17
	C	493.13	5.392	<0.001 ***
	D	-279.88	0.592	0.554
B	C	457.87	4.210	<0.001 ***
	D	-315.14	0.627	0.531
C	D	-773.02	4.259	<0.001 ***

Z = Mann-Whitney U test for inter-comparison; *** very highly significant.

The fractured segment was visualized, and SEM analysis was performed. The photomicrographs showed the formation of striation patterns and fracture regions, typical signs of cyclic fatigue failure in the images of the files' fracture planes. Representative SEM photomicrographs at 50 x

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magnification of the tested instruments and fractured segments are shown in Figure 4. The fragment's fractured surface was micrographed at 1500X magnification, revealing the striations, overload areas, and fracture initiation zones.

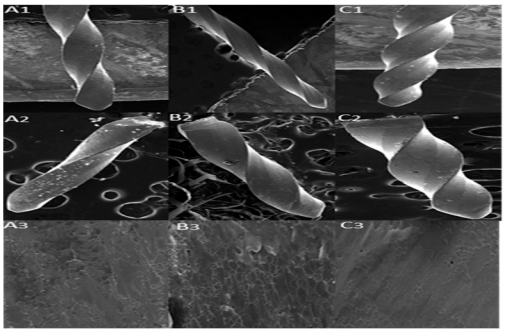

Figure 4. SEM Photomicrographs. A1 25 04% tapered Kedo SG file, A2 Fractured segment of the Kedo SG file, A3 Fracture zone at 1500 X magnification; B1 25 04% tapered Neoendo pedoflex file, B2 Fractured segment of the Neoendo pedoflex file, B3 Fracture zone at 1500 X magnification; C1 25 04% tapered Waldent Pedoflex file, C2 Fractured segment of the Waldent Pedoflex file, C3 Fracture zone at 1500 X magnification.

The mean lengths of fractured segments measured in mm are displayed in Figure 5.

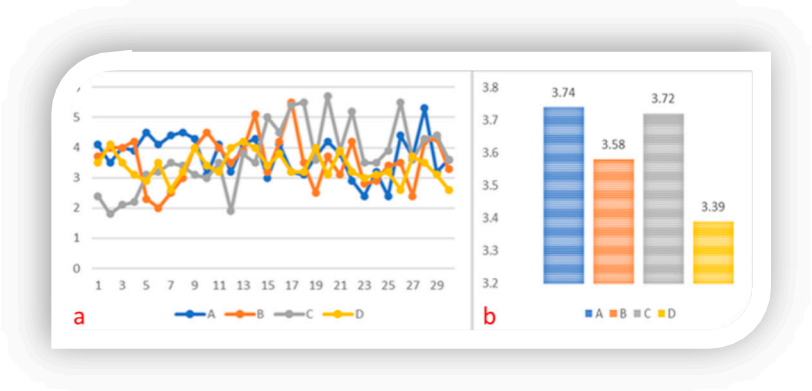

Figure 5. a. Graphical representation of the length of fractured segments of files; b. Mean values of fractured segments.

4. Discussion

While Niti files are continuously being manufactured and supplied due to the growing demands of dentists, there is an increasing need to select reliable file systems [30]. Moreover, Niti instruments do not have any standard guidelines for manufacturers to comply with [31]. The practitioners now have a plethora of instruments to choose from. This choice of files is often governed by the trust of the clinicians in the manufacturers based on their clinical experience and peer influence. The financial aspect of procuring these files can often influence the practitioner's choice [32].

As the use of Niti files in pediatric patients was first reported not too long ago, studies on their use, properties, and clinical performance are limited [8]. Many practitioners continue to use the Niti file systems similar to those used in adult patients [25,33]. However, a need for files of shorter length arose in pediatric patients due to limited mouth opening and comparatively shorter lengths of roots in these teeth [34]. More recently, dentists have reported an increase in the acceptance and use of rotary instrumentation in primary teeth, owing to the facilitation of homogenous fill, reduced debris extrusion, and shortened working time [35,36]. Its use could benefit pediatric patients, especially when performing quadrant dentistry and in patients under general anesthesia. Results from India suggest that around 50% of pediatric dentists prefer using rotary instrumentation to shape canals in primary teeth [4]. However, a cross-sectional study in Saudi Arabia showed that only 21.5% of the

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practitioners used rotary instruments [32]. In both these studies mentioned above, files from pro-taper systems were most commonly used, followed by dedicated pedodontic files like Kedo S and Prime pedo files in Saudi Arabia [4,32].

Nevertheless, file separation while using Niti files continues to be an impediment and can negatively impact the prognosis [37]. While either torsional or cyclic fatigue can lead to file separations, cyclic fatigue is more commonly the culprit, which can directly influence the prognosis of treatment [38]. Repeated bending of files in curved canals could lead to cyclic fatigue. The more the taper and size of the file, the lower its resistance to cyclic fatigue [39]. Although most of these could be operator-dependent, technological advances and the incorporation of heat and surface treatment have increased the file's resistance to fatigue [40]. As previously recognized, the file's tip size, diameter, and cross-sectional design could also influence these results [22,38]. To standardize the study, the authors used files with similar surface treatment, cross-sectional design, taper, and tip size: the Kedo SG, Neoendo Pedoflex, and the Pedoflex files from Waldent, and compared them against a commonly used heat-treated NiTi system, the Vortex Blue.

This study tested the rotary files in artificial metal canals designed on a stainless-steel block with known diameters, depths, and curvatures, as seen in previous studies investigating cyclic fatigue [41]. In comparison, others have utilized different methodologies, including bending instruments against 3 points and using inclined planes [42]. The authors in this study used an oil lubricant to reduce friction and heat generation during movement in a metal canal [43]. Cyclic fatigue is usually evaluated in either static or dynamic motion. Dynamic back-and-forth movement has been touted to replicate the clinically employed pecking motion. It could improve the cyclic fatigue of Niti files due to a broader distribution of stresses [44,45]. Nevertheless, studies have also shown that it may not accurately replicate clinical situations as the number of oscillations is far less than in the dynamic fatigue testing models [46]. On the other hand, during static motion, there are higher chances of stress concentration at the point of maximum curvature due to the lack of axial movement of files within the canals [47]. In this study, the cyclic fatigue test was carried out in static motion due to easier standardization and consideration of the difficulties in accurately setting up the dynamic model.

The NCF values attained in the three groups in this study were comparatively lower than those seen with VB (control). However, only the values from pedo flex files had statistically significant differences compared to others. Thus, the null hypothesis was partly rejected as the cyclic fatigue resistance difference was insignificant in two of the three experimental files. This superior cyclic fatigue of VB files compared to other files is attributed to the controlled memory and blue heat treatment [28,48,49]. The NCF values in some of the research on VB files varied due to the use of different tapers and tip sizes compared to this study [48,50]. Differences could also be due to stress concentration in the static model used in our research and the variation of canal curvatures [23]. Time to fracture and NCF value variations between studies could also be because guidelines for the production and testing are still lacking, and none of the previous work in the field seems to suggest it [51].

Sufficient studies regarding cyclic fatigue in pediatric Niti files are lacking. Nevertheless, a study conducted in Turkey compared two groups of heat-treated pediatric Niti files. The T-endo Must files (TEM; Dentac, Istanbul, Türkiye) manufactured to be used in reciprocation motion had better cyclic fatigue compared to the AF baby file (ABF; Fanta Dental Materials Co., Shanghai, China), which was used in rotation. Although both these file systems were heat treated, the difference in that study, as pointed out by the authors, could be due to the type of instrument motion [52]. In contrast, in a study on two 0.4 tapered pediatric file systems, the AF baby rotary files showed better resistance to cyclic fatigue than the i3 Gold deciduous teeth rotary files, with a mean NCF value (1516±204.05) higher than those seen in this study [41]. Recently, there were significantly higher mean NCF values when four pediatric rotary files were used, with mean values ranging from 453.65-2668.10. Variations in metallurgy, file geometry, and study design could also play a role in these variations [53]. Another clinical prospective study in India inspecting the incidence of fracture in Kedo S pediatric Niti files suggests these files had a low incidence of separation when used according to the manufacturer's

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guidelines. When file separations occurred, it was usually in the apical third [25]. As is commonly seen, most instruments fracture in the apical third of the root canals, usually the area of maximum curvature [54]. Terauchi et al. suggest retrieval is adversely affected if the length of the fractured instrument exceeds 4.5mm [55]. In this study, the fractured segments from all the files were below 4mm, with no significant difference. The data indicated that the VB file system exhibited the lowest mean values. Consistent with our findings, recent reports indicated that the lengths of fractured segments ranged between 3.43 mm and 3.65 mm [53]. In contrast, a recent study identified mean fracture lengths ranging from 7.25 mm to 9.12 mm [41]. Variations in performance may stem from using different file systems and the taper and wire technologies employed in the manufacturing process.

The methodology used in this study to test for cyclic fatigue was similar to those in many other previous studies where artificial metal canals of known curvatures were manufactured [41]. More importantly, using the passive movement of files in the canals was a drawback in this study and, as previously mentioned, could have resulted in stress concentrations and early fatigue. However, as passive motion was generalized between all groups, the results would be a fair analysis. Future studies should be aimed at evaluating the actual number of rotations needed to prepare canals in natural teeth based on their size, number, and degree of curvature, which can be used to correlate with the NCF values achieved with Niti files to determine the approximate number of uses of these files before their disposal.

5. Conclusions

Under the limitations of this study, Kedo SG and Neoendo pedo flex files performed amicably, similar to the VB files. These two files had more extended fatigue lives than the pedo flex files from Waldent. Although the NCF values for this file were lower, its use in a clinical environment cannot be questioned, mainly if used for a limited time, as none of the studies highlight the actual number of rotations needed to prepare a curved canal. So, the authors suggest limiting their use to minimum numbers based on the case's complexity.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Standing Committee of Bioethics Research (SCBR), Prince Sattam bin Abdulaziz University (PSAU), with the approval number (SCBR-046-2023).

Informed Consent Statement: Not applicable

Data Availability Statement: Available upon suitable request.

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Conflicts of Interest: The authors declare no conflict of interest.

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