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Novel Electronic Device to Quantify the Cyclic Fatigue Resistance of Endodontic Reciprocating Files after Using and Sterilization

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Abstract: Background: The aim of this study was to analyze the effects of the time of use (TU) and sterilization cycles (SC) of endodontic reciprocating files on cyclic fatigue resistance. Methods: One-hundred-and-twenty (120) Procodile NiTi endodontic reciprocating instruments were selected at random and distributed into the following study groups: A: 0 sterilization cycles/0s time of use (n = 10); B: 0/60 (n = 10); C: 0/120 (n = 10); D: 1/0 (n = 10); E: 1/60 (n = 10); F: 1/120 (n = 10); G: 5/0 (n = 10); H: 5/60 (n = 10); I: 5/120 (n = 10); J: 10/0 (n = 10); K: 10/60 (n = 10); and L: 10/120 (n = 10). A dynamic cyclic fatigue device was designed using computer-aided design/computer-aided engineering (CAD/CAE) technology and created with a 3D printer to simulate the pecking motion performed by the clinician. Failure of the endodontic rotary instrument was detected by a light-emitting diode-light-dependent resistor (LED-LDR) system controlled by an Arduino driver complex and management software. The results were analyzed using the ANOVA test. Results: All pairwise comparisons presented statistically significant differences between the time to failure, number of cycles to failure and number of cycles of in-and-out movement for the time of use study groups ($p < 0.001$), but not in the number of sterilization cycles ($p > 0.05$). Conclusions: The time of use of NiTi endodontic reciprocating files negatively affects dynamic cyclic fatigue resistance. Dynamic cyclic resistance is not affected by the number of sterilization cycles.

Keywords: endodontics; cyclic fatigue; time of use; sterilization cycles; reciprocating movement

1. Introduction

Nickel–titanium (NiTi) endodontic rotary instruments and the subsequent development of mechanical preparation has improved the prognosis of root canal treatment, as their increased taper and automated motion enable more effective cleaning and shaping of the root canal system [1]. Many advances have been made in the last few years, including innovations in instrument design, new NiTi alloys, thermal treating of NiTi alloys, and the addition of new movements to instrumentation systems. The changes produced in the martensitic phase of the NiTi alloy, led with little or no memory, and the decrease in the tendency of the file to straighten during use, results in a more flexible file [2] with greater resistance to both cyclic fatigue as a torsional fracture [3].

However, the possible separation of instruments remains a major concern during clinical use of NiTi files. Failure due to cyclic fatigue or torsional fracture occurs unexpectedly, without any sign of previous permanent plastic deformation. It is caused by alternating tension-compression cycles, which are generated in the instrument when it is turned in a curved channel. Many variables that can influence resistance to fracture due to cyclic fatigue and torsional stress of NiTi rotary files have been investigated, including operating speed, instrument design, metal surface treatments, effect of irrigation solutions, and the sterilization cycles to which rotary files are subjected [4].

NiTi rotary files are often reused in clinical practice for cost-saving reasons. The sterilization procedure follows the steps of disinfection, cleaning, washing, drying, packaging, and heat sterilization [5]. The disinfection and cleaning steps reduce the bacterial load and remove debris from the blades of the instrument, and the sterilization step kills any form of microorganism, including spores [6]. The most widely used method for sterilization in the dental field described in the scientific literature is heat sterilization [7].

Repeated autoclave sterilization is necessary to prevent cross-contamination between patients [8]. The heat used during sterilization procedures may affect the mechanical and physical properties of these files [9]. Previous research has found that autoclave sterilization resulted in an increase in the surface roughness of NiTi rotary files, which affects the mechanical properties [10,11]. These changes can affect the external surfaces in the form of micropitting and/or corrosion [12], reduction in cutting capacity, and/or by impairing resistance to cyclic fatigue or torsional fatigue [4]. Other studies hypothesize that after repeated clinical uses and sterilizations, there is a change in the austenite finishing temperature closest to the clinical operating temperatures. This would alter the proportions of austenite and microstructural phases of NiTi of martensite, ultimately affecting the mechanical properties of the files [2,3,13].

On the other hand, other studies suggest that autoclaving could improve the mechanical properties of instruments manufactured using a type of heat treatment, although this does not necessarily apply to other heat treatment methods. NiTi as an alloy is very "sensitive" to both thermal and mechanical (machining) tension that may occur during the raw material manufacturing processes and subsequent use of endodontic instruments. Adequate control of transition temperatures is essential to ensure optimum super-elastic properties. In addition, any other machining process will affect transition temperatures. This may explain why the performance of NiTi rotary instruments is affected by manufacturing quality processes and different thermal treatments [4,14].

Therefore, the most recent scientific literature does not always agree on the effects of sterilization. These differences may be due to the heterogeneity of the instruments researched. The endodontic instruments manufactured by various brands differ not only in diameter and the cone at the tip, but also in shape of the sections and the characteristics of alloys [15,16]. The scientific literature provides conflicting findings regarding the effects of heat sterilization on the properties of NiTi and steel instruments used in endodontics.

However, there have been no published studies analyzing the influence of clinical use and autoclaving cycles on the cyclic fatigue resistance of NiTi reciprocating files.

The aim of this study was to analyze and compare the effect of time of use and number of sterilization cycles on the dynamic cyclic fatigue resistance of NiTi endodontic reciprocating files, with a null hypothesis (H0) stating that the time of use and number of sterilization cycles would not affect the resistance of NiTi endodontic reciprocating files to dynamic cyclic fatigue.

2. Materials and Methods

2.1. Study Design

One-hundred-and-twenty (120) sterile 250 µm apical diameter and 6% taper (25.06) austenite NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo, Germany) with a variable tapered core, one-file system, 25 mm in length, counter-clockwise (CCW) reciprocating motion, and double-S cross-section were utilized in this in vitro study. All NiTi endodontic reciprocating files were first inspected under magnification (SZR-10, Optika, Bergamo, Italy), and all samples were included. A randomized controlled experimental trial was performed at the Department of Endodontics of the Faculty of Health Sciences at Alfonso X El Sabio University (Madrid, Spain), between September and November 2019. The NiTi endodontic reciprocating files were randomized (Epidat 4.1, Galicia, Spain) and categorized into the following study groups: A: 0 sterilization cycles and 0 seconds of dynamic cyclic fatigue ($n = 10$); B: 0 sterilization cycles and 60 s of dynamic cyclic fatigue ($n = 10$); C: 0 sterilization cycles and 120 s of dynamic cyclic fatigue ($n = 10$); D: 1 sterilization cycles and 0 s of dynamic cyclic fatigue ($n = 10$); E: 1 sterilization cycles and 60 s of dynamic cyclic fatigue ($n = 10$); F: 1 sterilization cycles and 120 s of dynamic cyclic fatigue ($n = 10$); G: 5 sterilization cycles and 0 s of dynamic cyclic fatigue ($n = 10$); H: 5 sterilization cycles and 60 s of dynamic cyclic fatigue ($n = 10$); I: 5 sterilization cycles and 120 s of dynamic cyclic fatigue ($n = 10$); J: 10 sterilization cycles and 0 s of dynamic cyclic fatigue ($n = 10$); K: 10 sterilization cycles and 60 s of dynamic cyclic fatigue ($n = 10$); and L: 10 sterilization cycles and 120 s of dynamic cyclic fatigue ($n = 10$).

2.2. Experimental Cycling Fatigue Procedure

Dynamic fatigue procedures were performed regarding the previously described cyclic fatigue device (utility model patent number ES1219520) [17]. The structure of the dynamic cyclic fatigue test device was planned by computer aided design/computer aided engineering (CAD/CAE) 2D/3D software (Midas FX+®, Brunleys, Milton Keynes, UK) and created using 3D printing (ProJet® 6000 3D Systems©, Rock Hill, SC, USA) (Figure 1A–F).

The Procodile 25.06 NiTi endodontic reciprocating file (Komet Medical, Lemgo) was assessed using a microcomputed tomography scan (Skyscan 1176, Bruker-MicroCT, Kontich, Belgium) to design an accurate standard tessellation language (STL) digital file. The STL file was used to generate a replica of an artificial root canal of 60° angle and 3 mm radius of curvature using the CAD/CAE 2D/3D software for inverse engineering technology (Figure 2A) [18]. The artificial root canal was created by means of a highly accurate subtractive technique from a stainless steel piece (Cocchiola S.A., Buenos Aires, Argentina). This process ensured intimate contact between the NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) and the artificial root canal walls (Figure 1H). The artificial root canal was positioned on its own support (Figure 2B) and failure of the endodontic reciprocating files was detected by analyzing the amount of light using emitted from a Light-Emitting Diode (LED) (20000 mcd) (Ref.: 12.675/5/b/c/20k, Batuled, Coslada, Spain) (Figure 1G) by a Light-Dependent Resistor (LDR) sensor (Ref.: C000025, Arduino LLC®, Ivrea, Italy) located opposite at 3 mm of the working length, with a frequency of 50 ms to accurately detect the time of failure. The axial pecking movement of the NiTi endodontic reciprocating files affects the measurement of the light signal received by the LDR sensor, which were shown in real time on a Liquid Crystal Display (LCD) (Ref.: LCD-09568, Spark Fun Electronics, Niwot, CO, USA). Therefore, the absence of variation in light values during three cycles of light analysis was interpreted as the NiTi endodontic reciprocating file's failure. The sensor data was conditioned by a processor (Arduino UNO Rev. 3, Arduino LLC®, Ivrea, Italy), and the hardware was managed by software that receives input signals from the Arduino board.

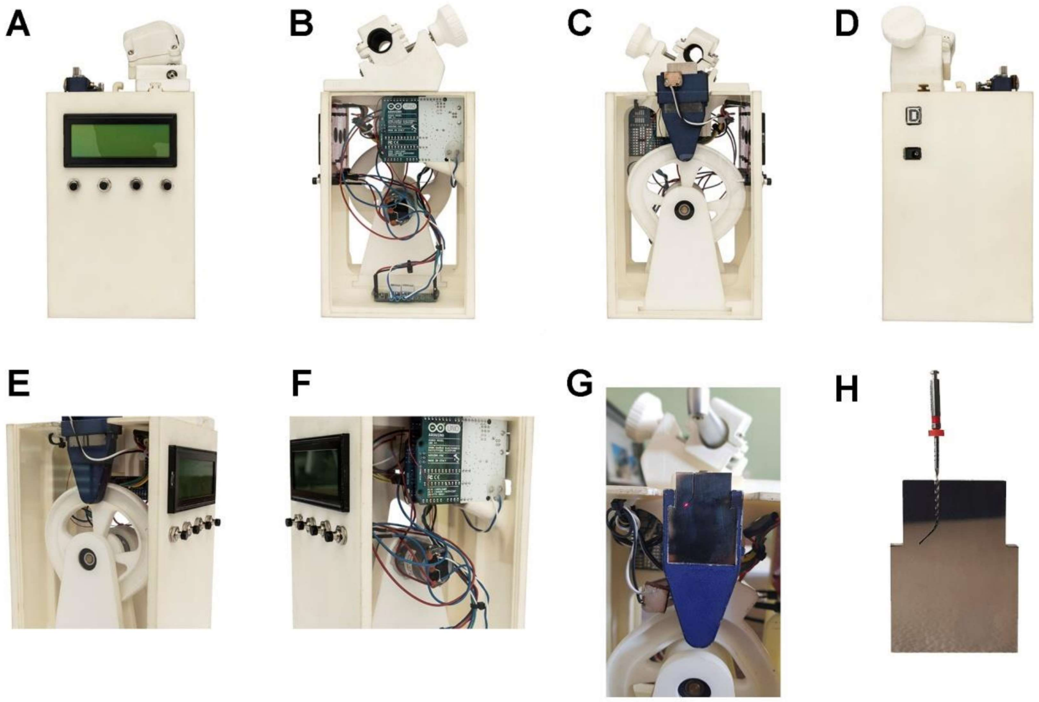

Figure 1. (**A–D**) Different views of the dynamic cyclic fatigue hardware device, (**E**) detail of the artificial root canal inside the artificial root canal support with the LDR sensor placed at working lenght, (**F**) detail of the Arduino board, gear motor, (**G**) detail of the artificial root canal and LED at 3 mm from working length, and (**H**) detail of the intimate contact between the artificial root canal and the NiTi endodontic reciprocating file.

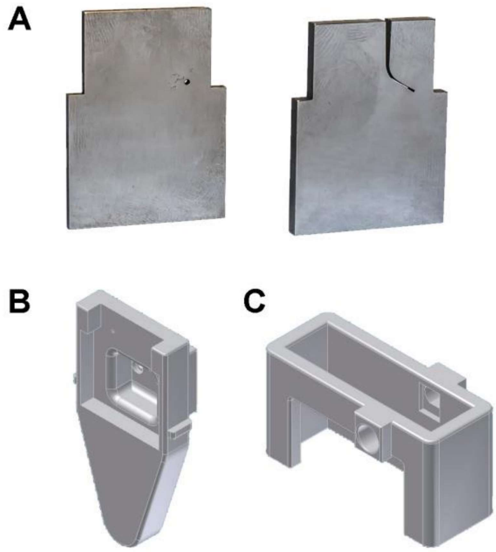

Figure 2. (**A**) Stainless steel artificial root canal plates, (**B**) CAD/CAE 2D/3D design of the artificial root canal support, and (**C**) CAD/CAE 2D/3D design of the LED-LDR detection complex.

The lineal displacement of the artificial root canal support on the lineal guide (Ref.: HGH35C 10249-1 001 MA, HIWIN Technologies Corp. Taichung, Taiwan) was generated by the gear motor (Ref.: 1589, Pololu® Corporation, Las Vegas, NV, USA) and controlled by the driver (Ref.: DRV8835, Pololu® Corporation, Las Vegas, NV, USA) through a roller bearing system (Ref.: MR104ZZ, FAG, Schaeffler Herzogenaurach, Germany). The NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) were used with a 6:1 reduction handpiece (EndoPilot, Komet Medical, Lemgo) and reciprocating motion, according to the manufacturer's instructions [19]. The endodontic handpiece (EndoPilot, Komet Medical, Lemgo) was digitalized (3D Geomagic Capture Wrap, 3D Systems©, Rock Hill, SC, USA) to enable accurate adjustment to the endodontic handpiece supports during the dynamic cyclic fatigue tests. Initially, the NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) were randomly (Epidat 4.1, Galicia, Spain) unsterilized or pre-sterilized 1, 5 or 10 times using the following parameters: 3 bar, 134 °C and 45 min. Next, the NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) were randomly (Epidat 4.1, Galicia, Spain) subjected to no fatigue, fatigued for 60 s or fatigued for 120 s in the dynamic cycle fatigue device. The NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) were used until fracture occurred in order to analyze the effect of sterilization cycles and the time of use on the resistance of NiTi endodontic reciprocating files to cyclic fatigue.

All NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) were used in the dynamic cyclic fatigue device at a frequency of 60 pecking movements/min according to a previous study [17]. To reduce the friction between the reciprocating files and the artificial canal walls, a special high-flow synthetic oil designed for the lubrication of mechanical parts (Singer All-Purpose Oil; Singer Corp., Barcelona, Spain) was applied.

All NiTi endodontic reciprocating files (Procodile®, Komet Medical, Lemgo) were used until fracture occurred. The time to failure, the number of cycles to failure, the number of cycles of in and out movements, and the length of the fractured file tip were measured and recorded.

2.3. Statistical Tests

Statistical analysis was performed by means of SAS 9.4 (SAS Institute Inc., Cary, NC, USA). Descriptive analysis is described as mean and standard deviation (SD) for quantitative data. Comparative statistics was carried out by comparing the time to failure (in seconds), the number of cycles to failure, the number of pecking movements (cycles of in-and-out movements), and the length of the fractured file tip (mm) using the ANOVA test. Furthermore, Weibull statistical analysis was also calculated. Statistical significance level was established at $p < 0.05$.

3. Results

The mean and SD values for time to failure (in seconds) and the mean length of the fractured file tip (mm) for each of the study groups are displayed in Table 1 and Figure 3.

Table 1. Descriptive analysis of the time to failure in relation to time of use and number of sterilization cycles.

Time of Use	Sterilization Cycles	*n*	Mean	SD	Minimum	Maximum	Fracture Length
0 s	0 [a]	10	235.29	45.07	153.20	282.83	3.06
	1 [a]	10	239.55	35.54	176.75	276.66	3.10
	5 [a]	10	225.26	32.04	164.10	265.31	3.17
	10 [a]	10	235.30	32.83	182.28	276.91	3.04
60 s	0 [b]	10	195.59	45.56	112.84	242.92	3.13
	1 [b]	10	191.45	31.82	136.77	234.89	3.06
	5 [b]	10	182.64	28.97	132.47	216.00	3.01
	10 [b]	10	191.18	29.71	145.94	234.33	3.04
120	0 [c]	10	88.58	12.39	61.82	102.35	3.11
	1 [c]	10	80.85	9.70	61.91	92.87	3.08
	5 [c]	10	86.90	9.56	72.16	102.01	2.99
	10 [c]	10	97.62	10.40	82.09	121.11	3.02

[a,b,c] Statistically significant differences between groups ($p < 0.05$).

The ANOVA analysis showed statistically significant differences between time to failure and the time of use of NiTi endodontic reciprocating files ($p < 0.001$) (Figure 3). However, no statistically significant differences were observed between time to failure and the number of sterilization cycles applied to NiTi endodontic reciprocating files ($p = 0.848$) (Figure 3). The mean length of the fractured file tip did not show statistically significant differences between time to failure of the time of use ($p > 0.05$) and the sterilization cycles ($p > 0.05$) of the NiTi endodontic reciprocating files (Figure 3).

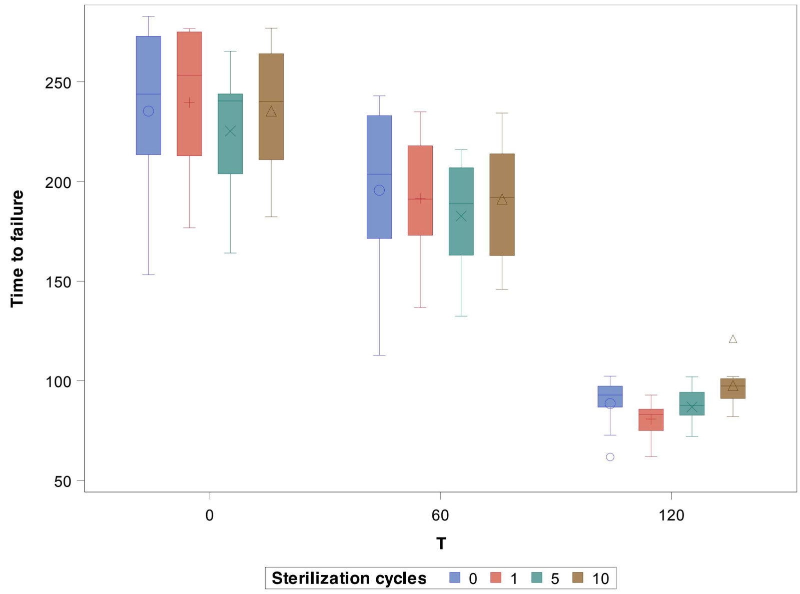

Figure 3. Box plot of the time to failure for the time of use and the sterilization cycles study groups. The horizontal line in each box represents the respective median value.

The scale distribution parameter (η) of Weibull statistics found statistically significant differences between time to failure and the time of use of NiTi endodontic reciprocating files ($p > 0.001$) (Table 2, Figure 4A); however, there were no statistically significant differences in time to failure between the number of sterilization cycles applied to NiTi endodontic reciprocating files ($p > 0.05$) (Table 2, Figure 4B). The shape distribution parameter (β) of Weibull statistics found no statistically significant differences between time to failure in relation to time of use ($p > 0.05$) (Table 2, Figure 4A), and the sterilization cycles applied to NiTi endodontic reciprocating files ($p > 0.05$) (Table 2, Figure 4B).

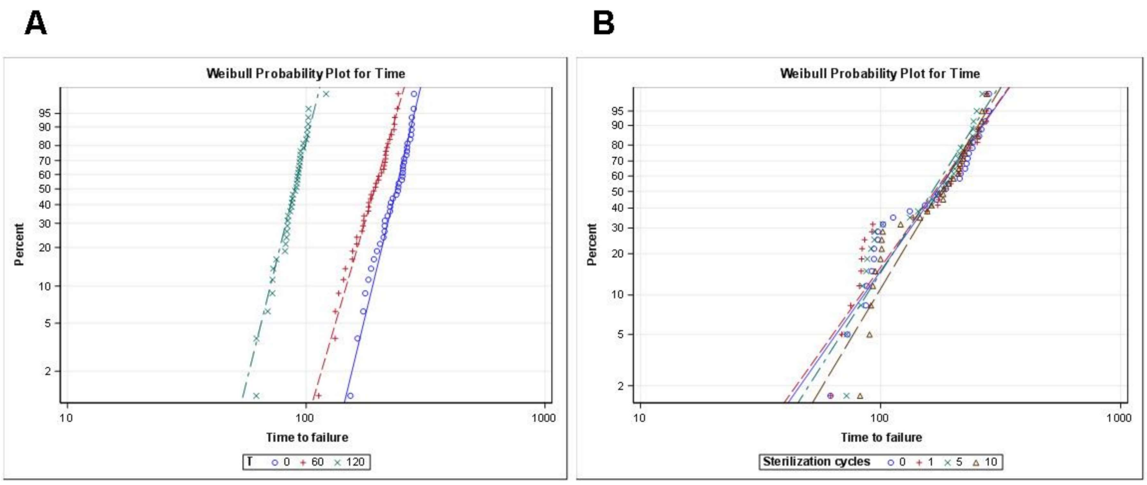

Figure 4. (**A**) Weibull probability plot of time to failure for the time of use and (**B**) sterilization cycles study groups.

Table 2. Weibull statistics of time to failure for the time of use and the sterilization cycles study groups.

Study Group	Weibull Shape (β)				Weibull Scale (η)			
	Estimate	St Error	Lower	Upper	Estimate	St Error	Lower	Upper
0 s	8.3142	1.0833	6.4404	10.7332	248.5615	4.9655	239.0173	258.4868
60 s	6.8989	0.8808	5.3716	8.8603	203.9091	4.9179	194.4944	213.7794
120 s	8.0777	0.9119	6.4743	10.0782	93.5190	1.9349	89.8025	97.3892
0 cycles	2.7040	0.4074	2.0127	3.6328	195.6014	13.9108	170.1516	224.8576
1cycle	2.6640	0.4060	1.9761	3.5913	192.7207	13.8859	167.3392	221.9521
5 cycles	2.9873	0.4529	2.2195	4.0208	185.5872	11.9333	163.6121	210.5138
10 cycles	3.1770	0.4761	2.3685	4.2617	195.9868	11.8612	174.0652	220.6693

The mean and SD values for number of cycles to failure and the length of the fractured file tip (mm) of the study groups are displayed in Table 3 and Figure 5.

Table 3. Descriptive statistics of the number of cycles to failure of the time of use and the sterilization cycles study groups.

Time of Use	Sterilization Cycles	*n*	Mean	SD	Minimum	Maximum	Fracture Length
0 s	0 [a]	10	1176.35	225.32	766.00	1414.00	3.06
	1 [a]	10	1259.40	162.90	989.50	1500.00	3.10
	5 [a]	10	1120.85	156.52	820.50	1316.50	3.17
	10 [a]	10	1176.44	164.09	911.35	1384.50	3.04
60 s	0 [b]	10	977.90	227.76	564.00	1214.50	3.13
	1 [b]	10	954.80	157.00	684.00	1174.50	3.06
	5 [b]	10	913.30	144.78	662.50	1080.00	3.01
	10 [b]	10	955.80	148.54	729.50	1171.50	3.04
120	0 [c]	10	442.96	61.98	309.10	512.00	3.11
	1 [c]	10	404.26	48.51	309.55	464.35	3.08
	5 [c]	10	431.98	48.33	360.80	510.00	2.99
	10 [c]	10	488.12	51.96	410.45	605.50	3.02

[a,b,c] Statistically significant differences between groups ($p < 0.05$).

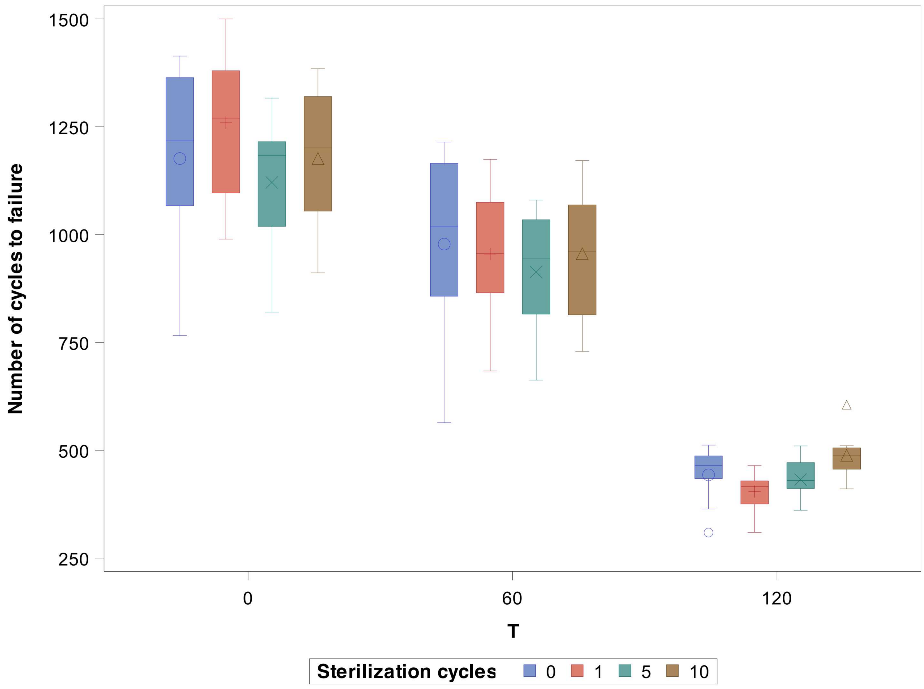

Figure 5. Box plot of the number of cycles to failure for the time of use and the sterilization cycles study groups. The horizontal line in each box represents the median value.

The ANOVA test revealed statistically significant differences between the number of cycles to failure and the time of use of NiTi endodontic reciprocating files ($p < 0.001$) (Figure 5). However, no statistically significant differences were observed between the number of cycles to failure and the number of sterilization cycles applied to NiTi endodontic reciprocating files ($p = 0.848$) (Figure 5). The mean length of the fractured file tip did not show statistically significant differences between the number of cycles to failure and the time of use ($p > 0.05$) and number of sterilization cycles ($p > 0.05$) applied to the NiTi endodontic reciprocating files (Figure 5).

The scale distribution parameter (η) of Weibull statistics showed statistically significant differences between the number of cycles to failure and the time of use of NiTi endodontic reciprocating files ($p < 0.001$) (Table 4, Figure 6A); however, there were no statistically significant differences between the number of cycles to failure and the number of sterilization cycles applied to NiTi endodontic reciprocating files ($p > 0.05$) (Table 4, Figure 6B). The shape distribution parameter (β) of Weibull statistics did not show statistically significant differences between the number of cycles to failure and the time of use ($p > 0.05$) (Table 4, Figure 6A), nor the number of sterilization cycles applied to NiTi endodontic reciprocating files ($p > 0.05$) (Table 4, Figure 6B).

Table 4. Weibull statistics of the number of cycles to failure for the time of use and sterilization cycles study groups.

Study Group	Weibull Shape (β)				Weibull Scale (η)			
	Estimate	St Error	Lower	Upper	Estimate	St Error	Lower	Upper
0 s	8.1790	1.0424	6.3712	10.4999	1257.379	25.5617	1208.264	1308.4906
60 s	6.9078	0.8808	5.3803	8.8690	1018.7335	24.5392	971.7553	1067.9829
120 s	8.0244	0.9069	6.4301	10.0141	467.0982	9.7300	448.4118	486.5633
0 cycles	2.7040	0.4074	2.0127	3.6328	195.6014	13.9108	170.1516	224.8576
1cycle	2.6640	0.4060	1.9761	3.5913	192.7207	13.8859	167.3392	221.9521
5 cycles	2.9873	0.4529	2.2195	4.0208	185.5872	11.9333	163.6121	210.5138
10 cycles	3.1770	0.4761	2.3685	4.2617	195.9868	11.8612	174.0652	220.6693

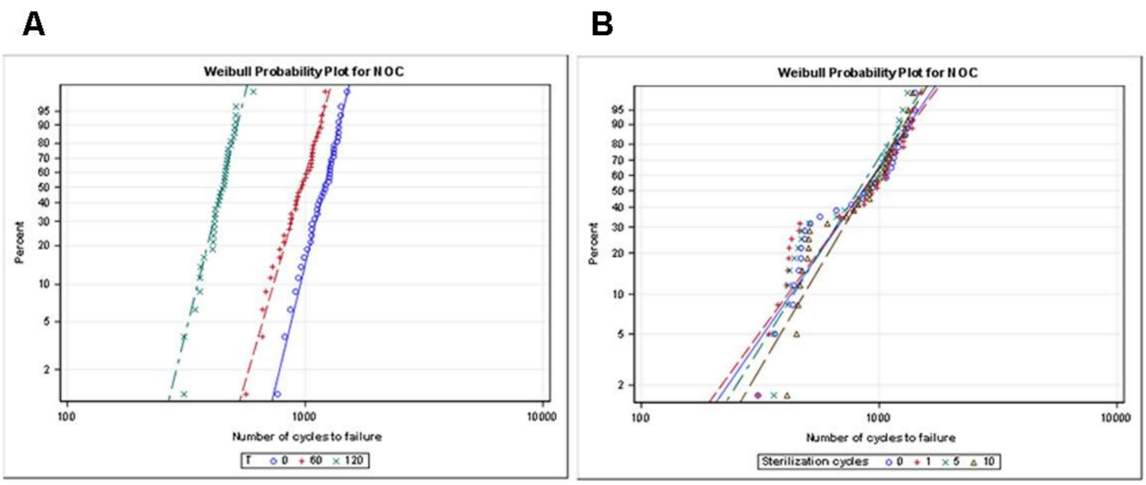

Figure 6. (**A**) Weibull probability plot of the number of cycles to failure for the time of use and (**B**) sterilization cycles study groups.

The mean and SD values for the number of cycles of in-and-out movement and the length of the fractured file tip (mm) of the study groups are displayed in Table 5 and Figure 7.

Table 5. Descriptive statistics of the number of cycles of in-and-out movement for the time of use and sterilization cycles study groups.

Time of Use	Sterilization Cycles	*n*	Mean	SD	Minimum	Maximum	Fracture Length
0s	0 [a]	10	235.29	45.07	153.20	282.83	3.06
	1 [a]	10	239.55	35.54	176.75	276.66	3.10
	5 [a]	10	225.26	32.04	164.10	265.31	3.17
	10 [a]	10	229.30	46.31	122.28	276.91	3.04
60s	0 [b]	10	214.69	30.30	162.27	251.10	3.13
	1 [b]	10	205.45	38.46	136.77	265.01	3.06
	5 [b]	10	186.64	38.88	132.47	246.87	3.01
	10 [b]	10	183.18	48.23	113.82	264.33	3.04
120	0 [c]	10	88.58	12.39	61.82	102.35	3.11
	1 [c]	10	80.85	9.70	61.91	92.87	3.08
	5 [c]	10	86.90	9.56	72.16	102.01	2.99
	10 [c]	10	97.62	10.40	82.09	121.11	3.02

[a,b,c] Statistically significant differences between groups ($p < 0.05$).

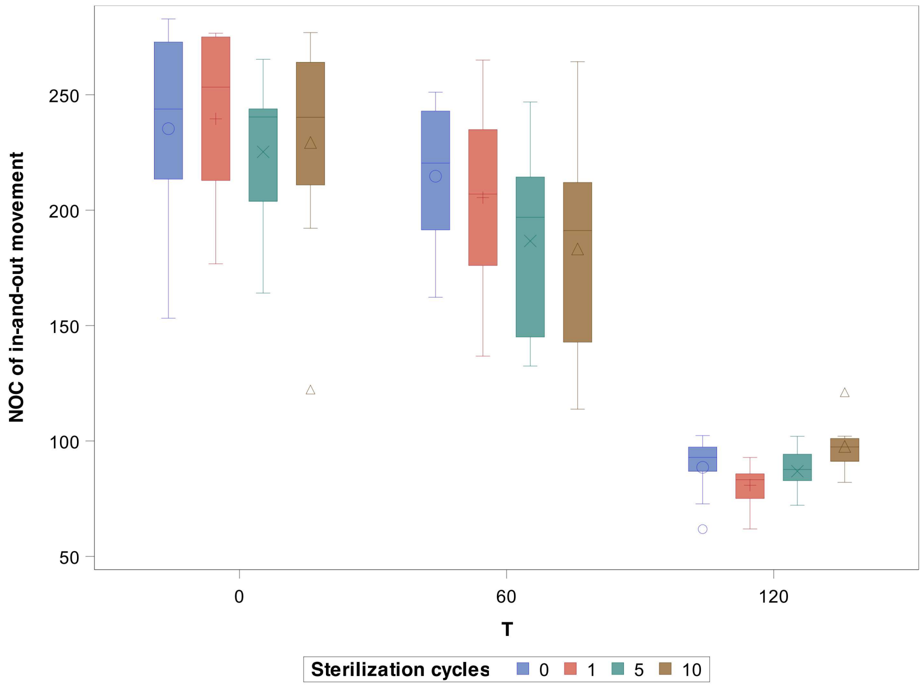

Figure 7. Box plot of the number of cycles of in-and-out movement for the time of use and sterilization cycles study groups. The horizontal line in each box represents the median value.

The ANOVA test revealed statistically significant differences between the number of cycles of in and out movement and the time of use of NiTi endodontic reciprocating files ($p < 0.001$) (Figure 7). However, no statistically significant differences were observed between the number of cycles of in and out movement and the number of sterilization cycles applied to NiTi endodontic reciprocating files ($p = 0.848$) (Figure 7). The mean length of the fractured file tip did not show statistically significant differences between the number of cycles of in-and-out movement and the time of use ($p > 0.05$) or the number of sterilization cycles ($p > 0.05$) applied to the NiTi endodontic reciprocating files (Figure 7).

The scale distribution parameter (η) of Weibull statistics showed statistically significant differences between the number of cycles of in-and-out movement and the time of use of NiTi endodontic reciprocating files ($p < 0.001$) (Table 6, Figure 8A); however, no statistically significant differences were found between the number of cycles of in-and-out movement and the number of sterilization cycles applied to the NiTi endodontic reciprocating files ($p > 0.05$) (Table 6, Figure 8B). The shape distribution parameter (β) of Weibull statistics did not show statistically significant differences between the number of cycles of in-and-out movement and the time of use ($p > 0.05$) (Table 6, Figure 8A) or the number of sterilization cycles applied to the NiTi endodontic reciprocating files ($p > 0.05$) (Table 6, Figure 8B).

Table 6. Weibull statistics of the number of cycles of in-and-out movements for the time of use and sterilization cycles study groups.

Study Group	Weibull Shape (β)				Weibull Scale (η)			
	Estimate	St Error	Lower	Upper	Estimate	St Error	Lower	Upper
0 s	7.8371	1.0332	6.0526	10.1478	247.8093	5.2331	237.7620	258.2813
60 s	5.9056	0.7502	4.6039	7.5752	213.5034	6.0177	202.0287	225.6298
120 s	8.0777	0.9119	6.4743	10.0782	93.5190	1.9349	89.8025	97.3892
0 cycles	2.8397	0.4369	2.1004	3.8391	202.3470	13.6633	177.2639	230.9795
1cycle	2.6486	0.4087	1.9573	3.5841	198.0170	14.3348	171.8235	228.2036
5 cycles	2.9091	0.4413	2.1610	3.9163	187.3384	12.3756	164.5872	213.2345
10 cycles	2.8747	0.4233	2.1540	3.8366	191.7153	12.8646	168.0889	218.6626

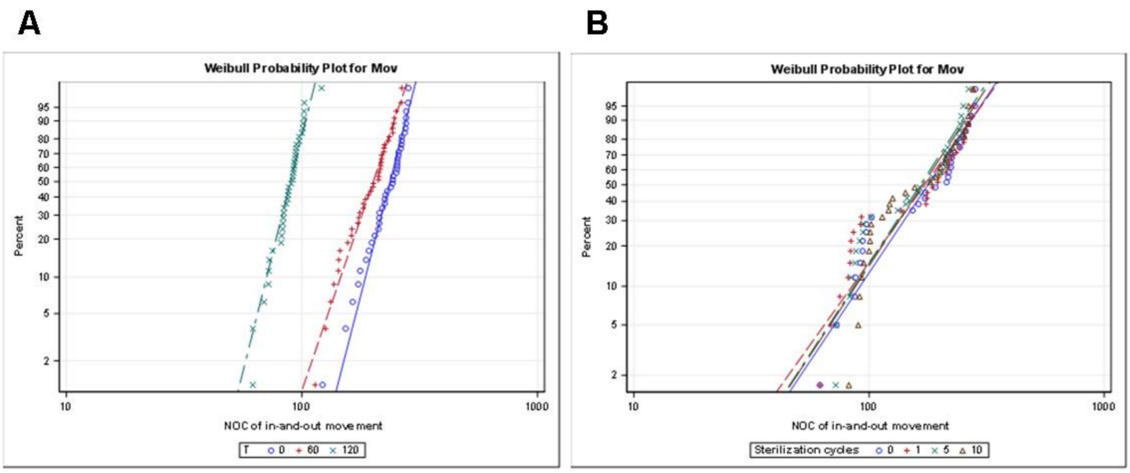

Figure 8. (**A**) Weibull probability plot of the number of cycles of in-and-out movements for the time of use and (**B**) sterilization cycles study groups.

4. Discussion

The results obtained in the present study reject the null hypothesis (H0) that states that time of use would have no effect on the dynamic cyclic fatigue resistance of NiTi endodontic reciprocating files. However, it also accepts the null hypothesis (H0) that states that the number of sterilization cycles applied to NiTi endodontic reciprocating files would have no effect on their resistance to dynamic cyclic fatigue.

The cyclic fatigue resistance of NiTi endodontic rotary and reciprocating instruments has been widely compared with regard to the NiTi alloy used, cross-section design, curvature angle, radius, pecking motion frequency, etc., with both static and dynamic custom-made cyclic fatigue devices having been used [20,21]. However, dynamic custom-made cyclic fatigue devices are the only ones that faithfully simulate the pecking movement performed by the clinician, more accurately representing the amount of time during which the NiTi endodontic rotary instrument remains in the artificial root canal. In addition, the artificial root canal should be custom-designed for the specific NiTi endodontic rotary instrument being tested in order to ensure immediate contact with the artificial root canal (as happens in a clinical setting). This also ensures that compression and tensile stress cycles are localized at the maximum flexure point [22], distributes the shear resistance homogeneously along the NiTi endodontic rotary instrument surface, and leads to the formation of microcracks on the instruments' microstructure [23] without any signs of plastic deformation in the static model; the area of these stresses spreads through the instrument shaft in the dynamic model [21]. Most of the static and dynamic custom-made cyclic fatigue devices provided a non-instrument-based artificial root canal [24,25], so the results extracted from these studies should be carefully considered and not applied to clinical practice. Di Nardo et al. reported statistically significant differences ($p < 0.05$) between the time to failure of Wave One Gold NiTi endodontic reciprocating files (50.75 ± 20.06 s) and Reziflow (30.13 ± 9.40) conventional NiTi endodontic rotary instruments [26]. Although this was a static cyclic fatigue test with an artificial root canal of parallel walls and 90° and 5 mm curvature radius, Reziflow has a similar design and manufacturing process as Procodile. In this study, a curvature angle of 60° was designed, because Topçuoğlu et al. reported that artificial root canals with a 45° angle of curvature did not show statistically significant differences ($p > 0.05$) between the time to failure of WaveOne Gold (412.4 ± 55.2 s) and R-Pilot (394.5 ± 45.3 s) glider files; however, artificial root canals with a curvature angle of 60° showed statistically significant differences ($p < 0.05$) between the time to failure of WaveOne Gold (368.3 ± 44.1 s) and R-Pilot (247.2 ± 36.2 s) endodontic instruments [27].

Kim et al. state that the endodontic reciprocating instruments must be disposed of after the first use because the mechanical properties, metallurgical features and risk of failure of the endodontic reciprocating instruments result from repeated usage [28]. Furthermore, Generali et al. reported that the continued usage of Reciproc and Reciproc Blue endodontic reciprocating instruments reduced resistance to cyclic fatigue, also reducing the martensite and R-phase in Reciproc Blue endodontic reciprocating instruments and causing microcracks near the tip of both endodontic reciprocating instruments after usage. In addition, there were statistically significant differences ($p < 0.05$) between the cyclic fatigue resistance of new and used Reciproc Blue endodontic reciprocating instruments, in keeping with the findings of the present study. However, no statistically significant differences ($p > 0.05$) were observed between the cyclic fatigue resistance of new and used Reciproc endodontic reciprocating instruments. Regardless of the NiTi alloy of the endodontic reciprocating system, the double-S cross-section design of Reciproc and Reciproc Blue endodontic reciprocating instruments and the reciprocating movement are similar to the Procodile NiTi endodontic reciprocating instruments; even the DSC curves confirm that the Reciproc Blue endodontic reciprocating instruments are made up of a mix of austenite and R-phase, as observed in XRD patterns [29]. However, this was a static cyclic fatigue test with an artificial root canal machined on a quenched martensitic carbon steel plate. The endodontic instruments are designed to cut dentin, but not materials with different cutting resistance values, so the results of the present study can hardly be accurately extrapolated to a clinical setting. However, in the present study, the NiTi endodontic reciprocating instruments were selected in the austenite phase due to their physical and metallurgical properties in terms of hardness and cutting capability in order to ensure the advance of the NiTi endodontic reciprocating instrument inside the stainless steel artificial root canal. In addition, the automatic, objective detection of the NiTi endodontic reciprocating instruments failure process using a LED-LDR system provided an accurate and standardizable measurement procedure, regardless of the subjective measurement protocol used in most studies to detect the precise moment of failure of the endodontic instrument tip. No statistically significant difference was found between the mean lengths of fractured file tips, whose maximum area of stress corresponded to the mid-point arc of the apical curvature, in keeping with the findings of Pruett et al. [22]. This result confirms the correct and repeated positioning of the tested NiTi endodontic reciprocating instruments within the artificial root canal.

Some researchers have postulated that the gamma-ray and autoclave sterilization processes used for fully sterile packaged Hyflex EDM and TRUShape endodontic rotary instruments might impact on the life span of NiTi martensitic endodontic rotary instruments in terms of their resistance to fatigue [30]. Furthermore, the heat sterilization method can also cause changes in the physical and mechanical properties of NiTi endodontic rotary instruments and even impact the torsional properties of NiTi endodontic rotary instruments [31]. Yang et al. reported that the surface roughness of K3XF R-phase NiTi endodontic rotary instruments increased after autoclaving, but this did not affect the cyclic fatigue resistance after 30 sterilization cycles [32]. Pedullà et al. found that repeated sterilization cycles did not impact resistance of NiTi endodontic rotary instruments to fatigue except for Twisted Files R-phase NiTi endodontic rotary instruments, which showed a significant decrease in flexural resistance after three sterilization cycles ($p < 0.05$) [33]. Champa et al. showed that multiple sterilization cycles significantly increased the cyclic fatigue resistance of Reciproc M-Wire NiTi endodontic reciprocating instruments, but decreased the cyclic fatigue resistance of Wave One M Wire NiTi endodontic reciprocating instruments in an artificial root canal (not anatomically modeled) with 60° of curvature in a static cyclic fatigue device [34]. Özyürek et al. also reported that the sterilization cycles significantly increased the cyclic fatigue resistance of Protaper Next M-Wire NiTi endodontic rotary instruments ($p < 0.05$) and Protaper Gold alloy NiTi endodontic rotary instruments ($p < 0.05$) [35]. Zhao et al. showed that the cyclic fatigue resistance of pre-sterilized HyFlex CM CM Wire NiTi endodontic rotary instruments and K3XF R-phase NiTi endodontic rotary instruments increased significantly ($p < 0.05$) after 10 sterilization cycles in an artificial root canal (not anatomically modeled) with a curvature of 60° and a radius of 3 mm in a static cyclic fatigue device [36]. Most of the martensitic endodontic rotary instruments (M-Wire alloys) have demonstrated an increase in cyclic fatigue resistance after heat sterilization procedures. However, in the present study, the cyclic fatigue resistance of austenite NiTi endodontic reciprocating files was not affected after 10 autoclave sterilization cycles ($p > 0.05$). The thermal treating of M-Wire endodontic rotary instruments makes the martensitic phase of NiTi alloy less subject to breakage during clinical use and stabilizes the NiTi alloy. The thermal heating induced by heat sterilization procedures make it even more stable, increasing cyclic fatigue resistance [31].

5. Conclusions

The conclusion derived from the present study is that the time of use of austenite NiTi endodontic reciprocating files negatively affects their dynamic cyclic fatigue resistance; however, resistance to dynamic cyclic fatigue is not affected by the number of sterilization cycles.

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