Dentistry 3000
Vol 13 No 1 (2025) DOI 10.5195/d3000.2025.782

The Impact of Autoclave Sterilization on Cyclic Fatigue of Nickel-Titanium Rotary Endodontic Instruments

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Abstract

Objective: The present study aimed to evaluate the impact of repeating sterilization in an autoclave on the cyclic fatigue resistance for three varieties of nickel-titanium (NiTi) rotary endodontic systems in double curved simulated canal.

Materials and Methods: During this research, three distinct varieties of nickel-titanium rotary endodontic files with a tip diameter of 0.25 millimeters and a taper of 0.06 millimeters were utilized: ProDesign Logic system, E-Flex Edge, and Endostar E3 Azure. Each type of rotary endodontic instruments (n=24) was then randomly divided into three sub-groups: non-sterilized instruments, sterilized instruments after 3 autoclave cycles, and sterilized instruments after 5 autoclave cycles. All the files from the various subgroups were examined to determine their ability to resist cyclic fatigue. Additionally, the period for fractures, the total number of cycles until failure (NCF), and the resulting fracture fragment length for every instrument were determined. SPSS software 29 was utilized for statistical comparisons (P<0.05).

Results: There were no differences among sterilized as well as non-sterilized files (P>0.05). There were no statistically significant differences in fractured length between tested groups.

Conclusions: The resistance to cyclic fatigue of NiTi rotary instruments was not considerably impacted by the repeated autoclave sterilization cycles.

Keywords: NiTi instruments, Cyclic fatigue, Autoclave.

Citation: Khudhur SY, et al (2025) The Impact of Autoclave Sterilization on Cyclic Fatigue of Nickel-Titanium Rotary Endodontic Instruments. Dentistry 3000.1:a001 doi:10.5195/d3000.2025.782
Received: November 26, 2024
Accepted: January 11, 2025
Published: February 12, 2025

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Introduction

A most important step in endodontic therapy consists of chemo-mechanical cleansing and reshaping for the root canal systems [1]. That important step; however, might be enhanced by the utilization of NiTi rotating endodontic tools, which would make the process both more expedient and more comfortable [2,3]. Despite the excellent characteristics of recent NiTi endodontic files, the risk of their separation throughout the clinical use still a major concern due to cyclic (flexural) fatigue [4,5].

Both torsional and flexural cyclical fatigue are the two mechanisms that are responsible for the separation of the endodontic files that are employed in rotating motion [6]. It has been established that cyclical fatigues occurs when the instruments are repeatedly bended in curved root canals that result in distortion and stress accumulation within the instruments and end with breakage because of alternating tension/compression cycles [7,8]. Cyclic fatigue failure can occur spontaneously without any indication of prior persistent plastic deformation. Numerous variables may influence the resistance to cyclical fatigue of NiTi rotating tools to fracture, including operating speed, treatment for metallic surfaces, instrument design, as well as the efficacy of irrigation solution [9].

By enhancing the micro-structuring of NiTi alloy to reduce the likelihood of cyclical fatigue tool fracture inside the canal, the manufacturers developed

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thermomechanical processing of Nickle-titanium alloys by adjusting the transformation temperatures [10,11]. The characteristics of NiTi, which include its super elasticity and shaping memory manufactured product were reported to be greatly affected by the history of thermomechanical processing [12]. The extra heat treatments that occurs during the autoclave sterilization process has been reported to have the potential to enhance the elasticity of NiTi devices [13].

Recently, a wide range of thermally processed NiTi endodontic instruments were introduced in the market with various metallurgical properties. The ProDesign Logic system was developed to act more conservatively by reducing the wear applied on the peri-cervical dentin. During the manufacturing process of this file system, conventional NiTi alloy is utilized. After that, the material undergoes thermal treatments, also known as controlled memory, to improve its flexibility as well as resistance to both torsional and cyclical fatigue. The cross section of this device is formed like a modified S, and it includes two or three cutting blades in addition to an inactivating tip [14,15]. On the other hand, E-Flex Edge endodontic instruments are machined from heat treated control memory NiTi wire which improve their flexibility and cyclic fatigue resistance. It has variable pitch to prevent intracanal instruments suction and locking; in addition to safety non-cutting tip that reduce apical extrusion, ledge formation, and canal transportation [16]. The_Endostar E3 Azure is a modern set of rotating files utilized for preparation the root canal effectively and more efficiently. They are manufactured from a highest quality NiTi alloy and then submitted to a special heat treatment (AZURE HT Technology by Poldent), which improves their flexibility and durability. The files can be easily fit even in very curved canals, this way minimizing the risk of canal perforation [17].

The single use of rotary endodontic instruments is recommended but it is rarely practiced clinically [18]. The vast majority of suppliers suggest to sterilize the endodontic instruments prior to use; besides, the unused new NiTi rotary instruments may undergo to many cycles of sterilization autoclave if the clinician does not use all the prearranged sets of files during a single appointment [7]. Furthermore, NiTi rotating files are typically reutilized several times in medical using for economic purposes and to prevent cross-contamination which leads to their repeated autoclave sterilization [7,19]. Sterilization using an autoclave is the most efficacious method for sterilizing dental equipment [20].

Numerous research had been conducted to investigate the effects of autoclave sterilization on the mechanical and physical characteristics of NiTi endodontic tools, and the findings of these investigations demonstrated a wide range of outcomes. According to the findings of a number of studies, repeating cycles of sterilizing have the potential to cause fractures and adverse effects on the files [20-23]. Furthermore, a study by Khabiri demonstrated that multiple autoclave sterilization__did not produce failures in NiTi files [24]. A recent review [20] demonstrated that the mechanically and physically features for majority NiTi rotary endodontic tools did not charge when being heat sterilized by autoclave. Repetition of rounds of autoclave sterilization substantially enhance the total number of cycles to fracture (NCF) and the resistance to cyclic fatigue of one tested set of files (K3XF) [9]. Zhao's study further indicated that Twisted Files, K3, and Race files had a lower cycle fatigue lifespan compared to K3XF and HyFlex CM subjected to autoclave sterilization [7]. Resistance for cyclical fatigue of the evaluated endodontic files diminishes with repeated autoclave sterilization; thus, the exclusive use of endodontic instruments is advised for reducing the possibility of breakage [25].

There are no studies that we are aware of that have been published in the scientific literature that have examined the resistance to cyclical fatigue of the ProDesign Logic system, E-Flex Edge, and Endostar E3 Azure equipment after they have been subjected to

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several cycles of autoclave sterilization. As a result, the purpose of this research was to investigate the impact that repeating autoclave sterilization cycles had on the cyclic fatigue resistance of three distinct Nickle titanium rotary endodontic tools when they were used in a double-curved simulated canal. According to the null hypothesis, there's isn't any difference in cycle fatigues resistant that could be achieved among the various NiTi rotary tools that were evaluated after being subjected to repeated autoclave sterilization.

Materials and Methods

To this randomization control *in vitro* research, NiTi endodontic rotary files (25/0.06) were utilized, and the sample size was 72. Group A consisted of the ProDesign Logic system, group B consisted of the E-Flex Edge, and group C consisted of the Endostar E3 Azure. The total number of these groups was twenty-four (n=24). There were three subgroups (n=8) within all the groups: instruments that had not been sterilized, instruments that had been sterilized after three autoclave cycles, and sterilized instruments after 5 autoclave sterilization cycles.

All file systems were sterilized in an autoclave (Clinclave 45.M, Germany). Every sterilization was performed at 134° C during 20 mins, followed by 5 mins of drying.

Cyclic fatigue testing

A special artificial canal was milled in stainless steel based on previously published design [26-28].

There are curves at both the apical and coronal levels in the artificial canal that is double-curved. In the first coronal curve, the curvature angle is 60 degrees, and the radius of curvature is 5 mm. 8 mm from the canal's terminus marked the beginning of this curve, which measured 5.25 mm in length. There is a curvature angle of 70 degrees on the second apical curve, and the radius of curvature is 2 mm. The length of the curve was 2.4 mm, and it began at 2 mm from the canal's terminus. Additionally, the interior diameter of this artificial canal was 1.5 mm, and its working length was 19 mm [28].

Stereomicroscopy (CARLCOLB, Germany) was used to detect any distortion in all instruments for the purpose of exclusion. The torque and speed of electric motor (X-Smart Plus, Dentsply Maillefer, Switzerland) was adjusted accordance to the instructions provided by the manufacturer for each rotary file system. The electric motor's handpiece was hold and fixed securely to a surveyor, as shown in Figure 1. A special tool was developed and built with taper to match and keep the dental handpiece within the surveyor [28] which give accurate positioning for every endodontic files for artificial canals and ensuring an optimal alignment of the files to similar working length [29].

After using each file, the canal had been lubrication with glycerin (Guangzhou Sanan Chemical Co., Ltd. China). The files were subjected to rotation until the separation of file happened. The time spent from the beginning of file rotation till its separation was documented in seconds. At the same time, a video recording was conducted for cross checking the time of file separation to erase any human mistakes and for standardization of this test [30]. The time multiplied by each file advocated speeding (rpm) utilized for calculating the total number of cycles for fracture (NCF) of every tool according to the equation [31]:

NCF = rpm × Time to fracture (seconds) / 60

Measuring the fractured fragment

To measure the length of the fractured fragment of every tool, we first use a digital Vernier to measure the length of fractured instrument, and then subtracted it from the original length of each instrument (25mm) [32] as in this equation:

Fractured fragment = Original length – Length of instrument after fracture.

Results

It was evident from the data presented in Table 1 that the E-Flex Edge system group had the highest values of NCF found. The results of the study indicated that there were no distinctions among the sterilizing and non-sterilizing files

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(P>0.05). In general, the E-Flex Edge system group had the highest cycle fatigue resistance, independent of whether it had been sterilized. This was followed by the Endostar E3 Azure group, and finally the ProDesign Logic group.

There were no significance variations in the number of fracture cycles, according to the results of the ANOVA test (Table 2), which was conducted on various comparison among cycles, fracture time and fracture length were found between different cycles (P>0.05).

According to the results of the analysis of variance (ANOVA) test presented in Table 3, that indicates a significant difference in NCF and fracture duration across various firms (P<0.05), however, no statistically significance variation was seen in fracture length among the companies (P>0.05).

An analysis of variance (ANOVA) test was performed (Table 4) to determine the statistical relationship between the number of cycles and the various firms. The results of the test indicated that there was no significant distinction in the NCF between the cycles and the brands (P>0.05).

Discussion

In the event that an instrument fractures due to cyclic fatigue, the production of micro cracks on the instrument surface is the cause of its repetitive loading, notably in the canal where the curvature is contrary to the instrument's maximum tension/compression point in the height of curvature [33]. The manufacturers support a single use of NiTi endodontic instrument in order for reducing the possibility of breakage; however, we decide to fulfill this work after 5 and 10 autoclave cycles like other previous studies [7,34,35] to evaluate the consequence of multiple sterilization trying to simulate the clinical usage.

The extracted tooth model represents the most preferred model to evaluate the cyclical fatigue resistant and its more precisely resembled the clinical situation, however; such tests might destroy the sample (the tooth model). Moreover, no teeth had entirely identical root canals, and because of curvature variations among the extracted teeth canal, it is not feasible to adjust the point and amount of stress applied on the instrument during its rotation. Furthermore, the experimental conditions is impossible to be standardized [36].

In most clinical scenarios, two curves may occur at the same canal. Additionally, radiographic studies (the presence of frequently and degree of canals curvature) indicated that all canals exhibited secondary curvatures [37].

Regarding the cycle fatigue resistant of Endostar E3 Azure, there are no documented studies that we are aware of that have been conducted and published in the scientific literature, ProDesign Logic, and Flex Edge instruments following many autoclave sterilizations cycles. Despite certain restrictions, lab testing can yield useful data [38].

One of the most intriguing findings from this research is that the cycle fatigue resistant of the among evaluated groups (sterilized and non-sterilized NiTi instrument) were equal. It has been found that the mechanical quality of Nickle-titanium alloy is affected by the phase composition (whether it is martensite or austenite), and its transformation temperature [39].

Regardless of the kind of NiTi file, sterilization using autoclave had no impact on the NCF of the testing files in our investigation. Our findings aligned with previous data that did not note any differences in the cyclic fatigue fractures resistant after five consecutive rotational cycles and autoclave sterilization [40].

It is believed that the 132°C autoclave sterilizing temperature was insufficient to allow for atomic structural rearrangement. Prior research indicated that when the austenite finish temperature of the tested NiTi file was below the temperature of the body, a disparity in cyclic fatigue resistance was seen between ambient temperature and the temperature of the body [41,42].

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Next to autoclave sterilization, the NiTi rotary instruments is allowed to cool down at room temperature, thus; the cycle fatigue fracture tests of this study was conducted at temperature of room to mimic the clinical conditions. Additional studies are required to evaluate the cyclical fatigues fracture tests of NiTi files at temperature of body to recreate the intraoral environment and get more trustworthy results, which is a primary limitation of our work.

This cyclic fatigue resistance test for E-Flex Edge, ProDesign Logic and Endostar E3 Azure was assessed before and after autoclave sterilization. For non-sterilized and sterilized rotary files, the E-Flex Edge exhibited the highest value of NCF in comparison to the other tested files. This may be ascribed to its enhanced processing methodology through investment in a targeted portfolio of "Industry 4.0 technologies," encompassing simulation, automation, robotics, digitalization, and additive manufacturing. It seems that the raw material is NiTi alloy, and the content of Ni is around 54.9-55.7%, the first heat treatment process of raw materials before grinding processing, to increase the Af temperature, to have good super elasticity, and facilitate grinding processing. Therefore, the low temperature austenitic crystal phase is present when the raw materials are received. Thread grinding after secondary heat treatment (300-650℃) in the high temperature stage or high temperature austenite, cooling process internal crystal rearrangement, below 40℃ is martensite (private communication). Through the utilization of this data, it is possible to infer the temperatures of transformation for the nickel-titanium alloy. The martensite phase does not undergo any crystallographic modifications when the temperature is lower than forty degrees Celsius. Increasing the temperature from 40°C to 650° C will result in an increase in the proportion of the crystal lattice that rearranges into the austenite phase. The Austenite phase is believed to have been entered by the complete crystals if the temperature is more than 650 C°. Because of this, it is highly improbable that the thermal treatment that results from autoclave sterilization would have a major impact on the reordering of the crystalline phases of NiTi filed materials.

Endostar E3 Azure system have an S-shaped cross-section. It seems that the Azure HT technology confers interesting metallurgical features to the Endostar E3 Azure system by combining the advantages of both austenitic and martensitic phases via transformation that warrant further study. The near-equiatomic Nickle-titanium alloys, which contain approximately 55% by weight Ni is used to fabricate most rotary NiTi files. The manufacturer of the instruments conveyed the tools composition to be 55% Ni and 45% Ti (Tulsa Dental Products, Quality Dental, personal communication).

Metallurgical qualities are reportedly possessed by the ProDesign Logic System (Easy Equipamentos Odontológicos, Belo Horizonte, MG, Brazil), as stated by the manufacturer. This system is characterized by a cross-section that is formed like a modified S, a changeable helix angle, and an inactive tip that contains two cutting blades. Since it may be employed in continuous rotating motion, it is meant to be compatible with any motor that is currently on the market. It can be found in two variable sizes of tips and tapers, which are 25/0.06 and 35/0.05. The point of greatest curvature at the midpoint of the arc is defined by the angle of curvature and the radius of curvature. The separated fragment of all rotary files that were used in this study has a mean length that is close to four to five millimeters [43]. The tension on the tool was probably higher at this juncture [31].

According to the findings of the current research, the null hypothesis is supported since there is no statistically significance variance in NCF between endodontic instruments that have been sterilized and those that have not been sterilized.

Conclusion

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The resistance to cyclical fatigue of NiTi rotary files was not considerably impacted by the repeating autoclave sterilization cycles.

Declaration

There are no potential conflicts of interest to declare.

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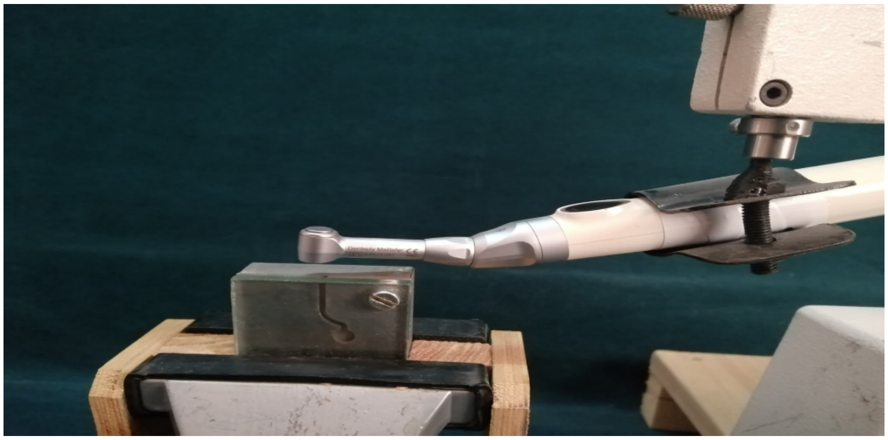

Figure 1. Electric motor's handpiece with surveyor.

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Table 1. **Descriptive statistical analysis for the (NCF) for each instrument group**.

Report NCF

		0 cycle	3 cycle	5 cycle	mean
E0	Mean	1527.0000	1375.5000	1638.0000	1513.5000 a
	N	8	8	8	24
	Std. Deviation	733.91553	544.12367	857.28342	699.85321
L0	Mean	841.0000	1138.0000	1163.5000	1047.5000 b
	N	8	8	8	24
	Std. Deviation	456.70497	357.53441	327.89850	396.82446
Azure	Mean	1110.5000	1020.5000	1137.0000	1089.3333 b
	N	8	8	8	24
	Std. Deviation	344.13909	303.79269	450.99382	358.64996
Total	Mean	1159.5000	1178.0000	1312.8333	
	N	24	24	24	
	Std. Deviation	588.68675	424.09187	611.21914	

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Table 2. ANOVA test for the fracture time, number of cycles to fracture and fracture length among cycles.

ANOVA

		Sum of Squares	Df	Mean Square	F	Sig.
Fracture_time	Between Groups	2.102	2	1.051	0.560	0.574
	Within Groups	129.374	69	1.875		
	Total	131.476	71			
NCF	Between Groups	336267.111	2	168133.556	0.560	0.574
	Within Groups	2.070E7	69	299998.280		
	Total	2.104E7	71			
Fracture_len	Between Groups	2.069	2	1.034	0.159	0.853
	Within Groups	447.599	69	6.487		
	Total	449.667	71			

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Table 3. ANOVA test for the NCF for two shape instruments among groups.

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Fracture_time	Between Groups	19.941	2	9.971	6.168	0.003
	Within Groups	111.535	69	1.616		
	Total	131.476	71			
NCF	Between Groups	3190587.111	2	1595293.556	6.168	0.003
	Within Groups	1.785E7	69	258631.324		
	Total	2.104E7	71			
Fracture_len	Between Groups	29.717	2	14.858	2.441	0.095
	Within Groups	419.951	69	6.086		
	Total	449.667	71			

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Table 4. ANOVA test among the different cycles and different brands.

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
VAR00002	Between Groups	11.945	2	5.972	3.312	0.056
	Within Groups	37.872	21	1.803		
	Total	49.817	23			
VAR00003	Between Groups	1911196.000	2	955598.000	3.312	0.056
	Within Groups	6059502.000	21	288547.714		
	Total	7970698.000	23			
VAR00004	Between Groups	29.276	2	14.638	1.949	0.167
	Within Groups	157.717	21	7.510		
	Total	186.993	23			
VAR00005	Between Groups	3.271	2	1.635	1.521	0.242
	Within Groups	22.583	21	1.075		
	Total	25.854	23			
VAR00006	Between Groups	523300.000	2	261650.000	1.521	0.242
	Within Groups	3613340.000	21	172063.810		
	Total	4136640.000	23			
VAR00007	Between Groups	0.890	2	0.445	0.075	0.928
	Within Groups	124.853	21	5.945		
	Total	125.743	23			
VAR00008	Between Groups	7.948	2	3.974	1.824	0.186
	Within Groups	45.756	21	2.179		
	Total	53.703	23			
VAR00009	Between Groups	1271609.333	2	635804.667	1.824	0.186
	Within Groups	7320934.000	21	348615.905		
	Total	8592543.333	23			
VAR00010	Between Groups	11.386	2	5.693	0.968	0.396
	Within Groups	123.477	21	5.880		
	Total	134.863	23			