Original Article

Effect of Sterilization on Cyclic Fatigue Resistance of Proflexendo Endodontic Rotary Files

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Abstract

Background: Proflexendo file (Nexen, Houston, TX, USA) is a recently developed, novel nickel-titanium rotary file. However, several physical properties of the Proflexendo system remain to be investigated.

Objectives: The aim of this study was to determine the effect of sterilization on cyclic resistance of Proflexendo files.

Material and Methods: A total of 120 unused Proflexendo rotary files (40 each of file sizes 40/0.04, 30/0.04 and 20/0.06) were used in this study. Each set of files was subdivided into four groups of ten files. Group 1 did not undergo any sterilization (control), Group 2 underwent two rounds (2×) of sterilization, Group 3 five rounds (5×) and Group 4 ten rounds (10×). Cyclic fatigue resistance was tested using an artificial canal with a 5-mm radius curve.

Results: The nonsterilized size 30/0.04 files had the highest cycles to failure, followed by the nonsterilized size 40/0.04 and 20/0.06 files ($P < 0.001$). With increasing rounds of sterilization, cycles to failure reduced for sizes 40 (2×, 5× and 10×) and 30 (2×) files compared with nonsterilized sizes 40 ($P < 0.05$) and 30 files ($P < 0.001$), respectively.

Conclusion: Under the conditions of the current study, the results provide preliminary evidence that autoclave sterilization of Proflexendo rotary files reduced their cyclic fatigue resistance, except for size 20 (2× and 5×) and 30 (10×) files, in which resistance increased. Single use of this file is recommended to reduce the risk of separation.

Keywords: Cyclic fatigue, endodontic rotary file, nickel-titanium, Proflexendo, sterilization

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INTRODUCTION

Since the introduction of the first nickel-titanium rotary files (NTRF) to overcome the rigidity of stainless steel files,[1] several types of NTRFs have become commercially available. The flexibility of NTRF allows these instruments to produce more centered preparations.[2-5] An adequate understanding of the physical properties and limitations of endodontic files can reduce undesirable procedural accidents, such as separation of the file in the canal, transportation and strip perforation. Previous reports have shown that cyclic fatigue resistance plays a major role in the separation of rotary files in canals with curvatures.[6,7] This is due to cycles of tension and compression that occur when a file is freely rotating in curved canals. At a certain point, the file reaches its flexural limit and fractures.[8,9]

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Infection control and cross-infections are major concerns for both patients and health-care providers, and thus endodontic instruments and files should always be sterilized to prevent the transmission of contagious diseases.[10] Several studies have investigated the effects of sterilization on the physical properties of NTRF, with contrasting results. Some investigators concluded that sterilization negatively affects the physical properties of NTRF and causes files to prematurely fail.[11-15] Other investigators have reported that up to ten cycles of heat sterilization do not increase the chance of NTRF failure.[16,17]

Recently, a novel nickel-titanium rotary file, the Proflexendo file (Nexen, Houston, TX, USA), was developed. This file is manufactured with controlled memory nickel-titanium technology and a triangular cross-section. Several recent studies have shown that files made from controlled memory technology have superior physical properties compared with rotary file made using other manufacturing techniques.[7,18-20] According to the manufacturer's instructions, to achieve a working length, the Proflexendo system should be used in a crown-down movement, starting with size 40/0.04 file, followed by size 30/0.04 and then size 20/0.06 files. Compared with the Profile Vortex size 30/0.04 file, the Proflexendo size 30/0.04 file has been found to have a significantly higher number of cycles to failure (CTF).[21] However, several physical properties of the Proflexendo system remain to be investigated. Therefore, the aim of this study was to evaluate the cyclic fatigue properties of three sizes of Proflexendo file with and without sterilization. The null hypothesis is that there is no difference between the cyclic fatigue resistance of different sizes of Proflexendo files, and that sterilization has no effect on their fatigue resistance.

MATERIALS AND METHODS

Files and sterilization

A total of 120 unused Proflexendo files (Nexden, Houston, TX, USA) of the following sizes were used for comparison: 40/0.04 ($n = 40$), 30/0.04 ($n = 40$) and 20/0.06 ($n = 40$) files (all 25 mm). Each set of files was subdivided into four groups of 10 files. The control group (Group 1) did not undergo any sterilization, whereas the other files were subjected to two rounds (2×) (Group 2), five rounds (5×) (Group 3) or ten rounds (10×) (Group 4) of sterilization. For each round of sterilization, the instruments were subjected to an autoclave cycle at a temperature of 134°C for 25 min, followed by 15 min of drying.

Cyclic fatigue testing

After completion of the respective number of autoclave cycles, all files (including those in Group 1) were subjected to fatigue testing, as previously described.[21] Briefly, a stationary stainless steel frame covered with a mobile transparent acrylic piece was fixed with screws to a steel block [Figure 1]. An artificial canal was machined within the steel block to achieve a 5-mm radius curve, a curvature of 60° and a groove of 1 mm, according to the recommendations of Pruett *et al*.[8] To ensure a reproducible three-dimensional relationship to the artificial canal in the steel block, an electric rotary hand-piece was fixed to the main frame. Each rotatory file was mounted in the hand-piece and precisely positioned to the same point in the testing block. Lubrication oil (WD-40 Company, San Diego, CA, USA) was used to reduce frictional heat.

All files were rotated at a fixed speed of 500 rpm (according to the manufacturer's instructions) in a 6:1 reduction hand-piece (Sirona, Bensheim, Germany) powered by a torque-controlled endodontic motor (Silver; VDW, Munich, Germany). To maintain consistency, the same operator performed the entire cyclic fatigue testing. Time to separation for each instrument was recorded using a digital 1/100 s chronometer. The total number of CTF for each instrument was calculated by multiplying the time to fracture by the number of rotations/min. Each separated segment of each file was measured with a digital caliper (Mitutoyo, Tokyo, Japan).

Statistical analysis

Data were analyzed using SPSS (v20.0; IBM, Chicago, IL, USA). Total CTF is presented as mean ± standard deviation (SD) values. Analysis of variance was applied to compare the mean cyclic failure and length of separated fragment among the three file sizes tested and the four sterilization conditions by splitting the datasheet with respect to sterilization techniques and file sizes, respectively. *Post hoc* Tukey's test was used to compare the means. $P \leq 0.05$ was considered statistically significant.

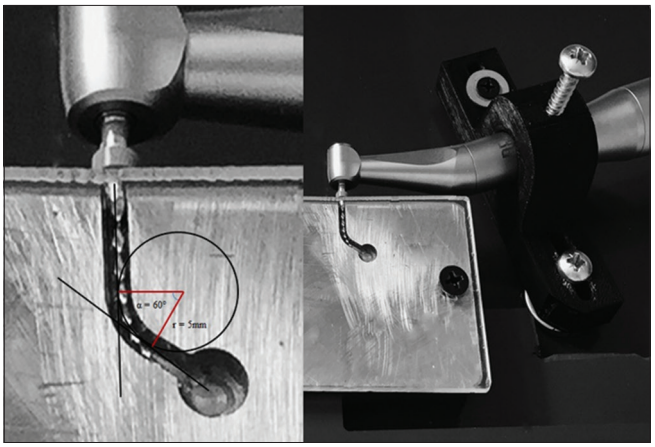

Figure 1: Cyclic fatigue testing machine and enlargement of the file within the groove (α – Angle of curvature; *r* – radius of curvature)

RESULTS

Nonsterilized Proflexendo files size 30/0.04 had the highest CTF followed by file sizes 40/0.04 and 20/0.06 ($P < 0.001$) [Table 1]. After sterilization, size 40/0.04 files (2×, 5× and 10×) had significantly lower CTF compared with nonsterilized size 40/0.04 files ($P < 0.05$). While 2× and 5× sterilized size 30/0.04 files had lower CTF compared with control ($P < 0.001$ and $P > 0.05$; respectively), the CTF of 10× sterilized size 30/0.04 files increased compared with control ($P < 0.05$). In contrast, the CTF of 2× and 5× sterilized size 20/0.06 file was higher than that of the control ($P < 0.001$), while the CTF of 10× sterilized size 20/0.06 file was lower than that of the control ($P > 0.001$). There were no significant differences in the mean fragment length of the three file sizes ($P > 0.05$) [Table 2].

DISCUSSION

Prolonged and repeated clinical usage of endodontic files has been found to negatively affect the physical properties of some rotary files, which in turn can lead to file failure.[22] Fear that a rotary instrument will undergo separation is one of the most common reasons clinicians avoid using NTRFs.[6,23,24] Previously, some reports attributed the majority of rotary file failures to cyclic fatigue.[25,26] Because files are often reused multiple times, they undergo repeated rounds of sterilization. Although the single use of files is advocated, it is rarely practiced. For example, in a survey of dentists in Germany, only 5% of the respondents reported using endodontic files as single-use files.[27] Some studies have concluded that single use of endodontic files is not justified, while other studies have described the use of a modified cleaning protocol for endodontic files to accommodate their reuse.[28]

To the best of the author's knowledge, this is the first study to test and compare the cyclic fatigue resistance of all three Proflexendo file sizes with and without increasing rounds of sterilization. Rotary file systems usually comprise different files with varying tapers and tip sizes, which may affect their resistance to fracture. Proflexendo files are manufactured using a controlled memory nickel–titanium technology, which involves a novel thermomechanical process that controls the memory of the file; this innovation allows the file to exhibit superior flexible properties.[7,18-21] The current study found that the cyclic fatigue resistance of nonsterilized size 30/0.04 Proflexendo files was approximately 296% and 220% greater than that of sizes 20/0.06 and 40/0.04 files, respectively. Because size 40 file has a larger tip size and 20 has a larger taper than size 30 file, there is an increased tendency to revert to its original shape. This, in turn, could create higher stresses when rotating in the inner side of the curve and lead to an earlier cyclic failure, thereby explaining the difference observed in this study. Further, the larger size and taper of these files can result in more heat being generated during the cyclic fatigue test and friction of the metal with walls of the artificial canal, leading to some changes in the metallurgic structure of the files.[29]

An earlier study demonstrated that Proflexendo size 30/0.04 file has almost 500% higher resistance to cyclic fatigue than Profile Vortex 30/0.04 file. When taken together with the results of the current study, this indicates that Proflexendo size 30/0.04 file is not only most appropriate for use compared with other brands but also among other sizes of Proflexendo files.

Using the autoclaving cycles described in previous studies,[30-32] this study found a significant reduction in the CTF of almost all sterilized files (2×, 5× and 10× cycles) compared with nonsterilized files. However, 10× size 30/0.04 and 2×, 5× size 20/0.06 sterilized files had a higher resistance to cyclic fatigue compared with the controls – there is no plausible explanation for this increase in CTF. The higher SD in these groups compared with other groups may be indicative of manufacturing differences between files from the same group; however, further studies are required to test this hypothesis.

The results of this study are in agreement with the findings of Casper *et al.*,[31] who evaluated the effect of autoclave sterilization on torsional resistance of three different manufacturing techniques of rotary files, including controlled memory files, and found significant discrepancies in the files' behavior. The current study results are also in

Table 1: Mean (±SD) number of cycles to failure for each file size according to sterilization condition

File size	Sterilization conditions				*P*
	No sterilization	2×	5×	10×	
40/0.04	1623 (274)[a,b]	1339 (170)[a]	1374 (228)[a]	1356 (297)[a]	<0.05
30/0.04	3568 (386)[a,b]	2542 (240)[a]	2555 (288)	3655 (619)[a]	<0.001
20/0.06	1206 (134)[a,b]	1786 (422)[a]	1426 (282)[a]	853 (109)	<0.001
P	<0.001	-	-	-	-

[a]Significant effect of sterilization according to file type at 5% level of significance (horizontal comparison), [b]Significant differences among the file types according to sterilization conditions at 5% level of significance (vertical comparison). SD – Standard deviation

Table 2: Mean (±SD) fragment length

File size	Sterilization conditions				*P*
	No sterilization	2×	5×	10×	
40/0.04	5.82 (0.32)	5.42 (0.18)	5.49 (0.26)	5.36 (0.13)	0.582
30/0.04	5.17 (0.14)	4.97 (0.29)	5.06 (0.27)	5.28 (0.70)	0.370
20/0.06	4.37 (0.19)	4.24 (0.21)	4.26 (0.18)	4.29 (0.26)	0.553

SD – Standard deviation

agreement with that of Zhao *et al.*,[33] who evaluated the effect of sterilization on Hyflex size 30/0.06 file made from controlled memory alloy and found that 10 cycles of sterilization increased its cyclic fatigue resistance compared with nonsterilized Hyflex size 30/0.06 file.

In contrast to the findings of the current study, a previous study found that repeated autoclaving cycles did not have a notable effect on the CTF of size 40 rotary files, except in K3 XF files, which had a higher CTF after sterilization compared with the control.[34] The results of the current study are also in disagreement with that of Canalda-Sahli *et al.*,[35] who indicated that sterilization did not significantly affect the flexibility, cutting efficiency or resistance to cyclic and torsional fatigue in the K-files of all sizes ranging from 25 to 40, and with that of Hilfer *et al.*,[36] who indicated that sterilization did not significantly affect the GT series X size 20/0.06 files. Similarly, the fracture of ProFile rotary files (Dentsply Maillefer, Ballaigues, Switzerland) did not increase after 10 cycles of heat sterilization,[16] whereas exposure of ProFile rotary files to dry heat and autoclave sterilization did increase their resistance to cyclic fatigue.[37]

Based on the results of the present study, which indicated differences in the cyclic fatigue resistance between the three files tested and a significant effect of sterilization, we reject the proposed null hypothesis.

CONCLUSION

Under the conditions of the current study, the results provide preliminary evidence that autoclave sterilization reduced the cyclic fatigue resistance of Proflexendo files, except in 2× and 5× 20 and 10× 30 files, where the resistance increased. Single use of this file may be recommended to reduce the risk of separation, especially with sizes 40 and 20. Further studies should evaluate the observed differences in the cyclic behavior between different sizes of Proflexendo file and its effect in clinical usage and compare them with other commercially available rotary files.

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Conflicts of interest

There are no conflicts of interest.

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