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Research Article

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The effects of autoclave sterilization on the cyclic fatigue resistance of ProTaper Universal, ProTaper Next, and ProTaper Gold nickel-titanium instruments

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No potential conflict of interest relevant to this article was reported.

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ABSTRACT

Objectives: It was aimed to compare the cyclic fatigue resistances of ProTaper Universal (PTU), ProTaper Next (PTN), and ProTaper Gold (PTG) and the effects of sterilization by autoclave on the cyclic fatigue life of nickel-titanium (NiTi) instruments.
Materials and Methods: Eighty PTU, 80 PTN, and 80 PTG were included to the present study. Files were tested in a simulated canal. Each brand of the NiTi files were divided into 4 subgroups: group 1, as received condition; group 2, pre-sterilized instruments exposed to 10 times sterilization by autoclave; group 3, instruments tested were sterilized after being exposed to 25%, 50%, and 75% of the mean cycles to failure, then cycled fatigue test was performed; group 4, instruments exposed to the same experiment with group 3 without sterilization. The number of cycles to failure (NCF) was calculated. The data was statistically analyzed by using one-way analysis of variance and *post hoc* Tukey tests.
Results: PTG showed significantly higher NCF than PTU and PTN in group 1 ($p < 0.05$). Sterilization significantly increased the NCF of PTN and PTG ($p < 0.05$) in group 2. PTN in group 3 had significantly higher cyclic fatigue resistance than PTN group 4 ($p < 0.05$). Also, significantly higher NCF was observed for PTG in group 2 than in groups 3 and 4 ($p < 0.05$).
Conclusions: PTG instrument made of new gold alloy was more resistant to fatigue failure than PTN and PTU. Autoclaving increased the cyclic fatigue resistances of PTN and PTG.

Keywords: Endodontics; Gold-wire; M-wire; Nickel-titanium; Sterilization

INTRODUCTION

Nickel-titanium (NiTi) alloys offer the files with flexibility and better adaption to the curved root canals [1]. In spite of all advantages of NiTi files, file failure during clinical use is a major complication of NiTi files. Fracture of NiTi files occur due to either torsional or cyclic fatigue [2]. The fracture due to cyclic fatigue occurs when files are exposed to repetitive compression and tension forces within the curved canals.

In order to decrease the cyclic fatigue fracture of files, the manufacturers carried out researches on the new file designs and production methods. ProTaper Next (PTN; Dentsply Maillefer,

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Ballaigues, Switzerland) is manufactured by applying heat treatment before the production in order to increase the cyclic fatigue resistance and flexibility of file [3,4]. PTN has variable regressive taper design and rectangular cross-section. The manufacturer claims that the design of the PTN aims to decrease the points of contact between the file and canal wall and to improve the fatigue resistance by minimizing the stresses that might accumulate on the file [5].

ProTaper Universal (PTU; Dentsply Maillefer) and ProTaper Gold (PTG; Dentsply Maillefer) files have similar designs, variable progressive taper, and triangular cross-section. The registered alloy, which the PTG files are made of, is claimed to increase the flexibility and fracture resistance of the files [6]. Generally, the thermo-mechanic treatments applied on the NiTi files are believed to provide the high level of shape memory and super-elasticity properties [7].

Sterilization of NiTi files must be ensured before clinical use, except for the pre-sterilized ones. Repetitive use of files under clinic conditions requires the autoclave sterilization after every use. Also, pre-arranged sets of selected files may not be used during in the same appointment. As a result, the unused rotary files are also subjected to multiple autoclave cycles. Researchers reported that the additional heat treatment during autoclave sterilization might improve the flexibility of files, and the sterilization of files by using dry-hot air and autoclave would have positive effect on the cyclic fatigue resistance [8,9].

In literature review, no study examining the effect of autoclave sterilization on cyclic fatigue of PTN, PTG, and PTU files was found. The aim of the present study was to evaluate the effect of autoclave sterilization on the cyclic fatigue resistances of PTN, PTU, and PTG files. The null hypothesis of the present study was that the cyclic fatigue resistances of files would not be affected from the autoclave sterilization.

MATERIALS AND METHODS

Eighty PTN X2 (25/0.06), 80 PTG F2 (25/0.08), and 80 PTU F2 (25/0.06) NiTi files were involved in this study. The effect of autoclave sterilization on the number of cycles to failure (NCF) was compared by performing autoclave sterilization both before and after cycling the files. All of the files involved in the present study were randomly divided into 4 groups. The files in group 1 (n = 20) were exposed to cyclic fatigue test without sterilization in order to find the baseline mean cycles determined for the fracture. The files in group 2 (n = 20) were exposed to cyclic fatigue test after applying 10 times of autoclave sterilization (Autohouse AD7, Apoza, New Taipei City, Taiwan). Each autoclave sterilization process was performed for 18 minutes under 30 psi of pressure at 134°C and then dried for 30 minutes [10]. The files in group 3 (n = 20) were cycled to the cycles of 25%, 50%, and 75% of baseline mean cycles determined in group 1, and after each cycling procedure (25%, 50%, and 75%) the files were sterilized using the same autoclaving procedure. Then, the files were exposed to cyclic fatigue test [11]. Each sterilization process was performed for 4 minutes under 30 psi of pressure at 134°C and then drying for 15 minutes [12]. After each sterilization cycle, the autoclave package of the files was replaced with a new one. The same cycling procedure (25%, 50%, and 75%) with group 3 was applied to group 4 (n = 20). However, in group 4, the files were not exposed to any autoclave sterilization procedures.

Groups 1, 2, 3, and 4 were tested inside an artificial curved canal with a single curvature of 60° angle and 5 mm radii in curvature, with the center of the curve located 5 mm from the tip of the artificial canal (**Figure 1**). The files were cycled using VDW Silver Reciproc endodontic

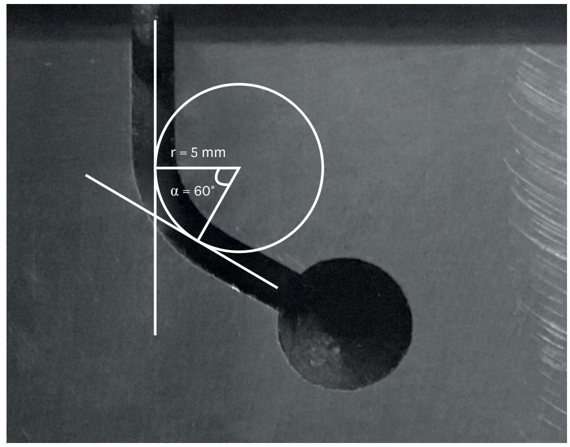

Figure 1. The artificial canal that used in the present study (the radii and the angle of the curvature).

motor (VDW, Munich, Germany) and static cyclic fatigue test device at 300 revolutions per minute (rpm) for PTN, PTG, and PTU until the files fractured. In order to minimize the friction between the files and artificial canals, a synthetic lubricant (WD Company, Milton Keynes, UK) was utilized. The NCF for each file was calculated with formula:

$$\text{NFC} = \text{rpm} \times \text{Time to fracture (sec)}/60$$

After the cyclic fatigue tests, the fractured surfaces of the instruments were observed under scanning electron microscopy (SEM; JSM-7001F, JEOL, Tokyo, Japan).

Statistical analysis

The NCF data was statistically analyzed by using one-way analysis of variance and *post hoc* Tukey tests. All of the analyzes were performed using SPSS 21 (IBM-SPSS Inc., Chicago, IL, USA) software, and the statistical significance level was set at 5%.

RESULTS

The numbers of NiTi files sterilized after being cycled to the cycles of 25%, 50%, and 75% of the mean baseline cycles to failure determined in group 1 are shown in **Table 1**. Some of the files fractured during the test procedures, and the number of fractured files and those exposed to cyclic fatigue test are presented in **Table 1**. The mean NCF and standard deviation values for PTU, PTN, and PTG files in all groups are shown in **Table 2**. When compared with PTU and

Table 1. Baseline scores of number of cycles to failure (NCF) for all nickel-titanium (NiTi) instruments (no sterilization)

Sterilization condition	ProTaper Gold			ProTaper Next			ProTaper Universal		
	NCF	G3	G4	NCF	G3	G4	NCF	G3	G4
No sterilization	1,045.21 ± 198.24			525.44 ± 94.67			248.12 ± 32.52		
After cycling to									
25% of NCF	262	20	20	132	20	20	62	20	20
50% of NCF	523	20	19	263	18	17	124	15	14
75% of NCF	784	19	18	394	16	16	186	13	12

Values are presented as number of instruments. The number of instruments that survived after being cycled to the cycles of 25%, 50%, and 75% of the mean baseline NCF values (ProTaper Gold, Dentsply Maillefer, Ballaigues, Switzerland; ProTaper Next, Dentsply Maillefer; ProTaper Universal, Dentsply Maillefer).
G3, group 3 (instruments tested were sterilized after being exposed to 25%, 50%, and 75% of the NCF); G4, group 4 (instruments exposed at 25%, 50%, and 75% of the NCF without any sterilization).

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Table 2. The number of cycles to failure (NCF) for instruments that were not sterilized as received from the package (group 1), instruments sterilized 10 times before any use (group 2), instruments tested were sterilized after being exposed to 25%, 50%, and 75% of the NCF (group 3), and instruments exposed at 25%, 50%, and 75% of the NCF without any sterilization (group 4)

Group	ProTaper Gold	ProTaper Next	ProTaper Universal	*p* value
As received without sterilization (group 1)	1,045.21 ± 198.24^{Aa}	525.44 ± 94.67^{Ba}	248.12 ± 32.52^{Ca}	< 0.05
Sterilization 10 times before cyclic stress (group 2)	1,306.34 ± 248.22^{Ab}	624.26 ± 112.72^{Bb}	252.09 ± 33.59^{Ca}	< 0.05
Sterilized after each cyclic stress (group 3)	1,107.55 ± 210.04^{Aa}	713.32 ± 128.92^{Bb}	223.52 ± 28.43^{Ca}	< 0.05
No sterilization, but tested after cyclic stresses (group 4)	1,003.67 ± 190.26^{Aa}	504.67 ± 90.23^{Ba}	231.87 ± 30.62^{Ca}	< 0.05
p value	< 0.05	< 0.05	> 0.05	-

Values are presented as mean ± standard deviation (ProTaper Gold, Dentsply Maillefer, Ballaigues, Switzerland; ProTaper Next, Dentsply Maillefer; ProTaper Universal, Dentsply Maillefer).
Different superscript letters indicate statistically significant differences between groups (^{A,B,C}for rows, ^{a,b}for columns) ($p < 0.05$).

PTN files, PTG files were significantly resistant to cyclic fatigue ($p < 0.05$). In addition, PTN files were significantly more resistant to cyclic fatigue than PTU files ($p < 0.05$).

When comparing the files unsterilized (group 1) and sterilized prior to the procedure (group 2), the NCF values of PTG and PTN files after sterilization (group 2) were significantly higher than the files without sterilization (group 1; $p < 0.05$) except for PTU. A significantly higher NCF value was observed for PTN files in group 3 than PTN files in group 4 ($p < 0.05$). A significantly higher NCF was also ascertained for PTG in group 2 than in groups 3 and 4 ($p < 0.05$).

The SEM images of the fracture surface revealed the mechanical features of the cyclic fatigue failure in all the groups (**Figure 2**).

DISCUSSION

The cyclic fatigue resistance of NiTi files is one of the most frequently studied subjects in the literature of endodontics. It was shown in previous studies that the main reason of file fractures during the clinic use is the cyclic fatigue [13-15]. In previous studies, generally the design properties of files and the composition of alloy, which have been used in manufacturing those files, were discussed [16-18]. Like the present study, there also are studies discussing the effects of autoclave sterilization on the cyclic fatigue resistance of files [9,12,19]. Many studies examining the NiTi files' cyclic fatigue resistance were carried out in artificial canals [7,8]. The aim of using artificial canals is to minimize the anatomic variation that might arise from the natural teeth and to ensure certain level of standardization.

During the clinic procedures, clinicians are exposed to various microorganisms, which exist in both blood and saliva and cause many infectious diseases. The sterilization comes to the forefront as an important factor in order to prevent the cross contamination and to ensure the aseptic conditions. The methods, which are preferred for sterilizing the instruments in endodontic practice, are the hot dry air and the autoclave sterilization [9].

Yared *et al.* [20] reported that the rotary files can be safely used in up to 10 curved canals. For this reason, it is very important to determine how the flexibility, cutting efficiency, and cyclic and torsional fatigue resistance of the NiTi instruments are affected by the repetitive sterilization procedures. In the literature, there are studies examining the effect of sterilization procedures on the non-used files [12,21]. Besides that, Zhao *et al.* [22] studied the effects of autoclave sterilization on the cyclic fatigue resistances of non-used and used files. It was reported that the highest temperatures during the autoclave sterilization

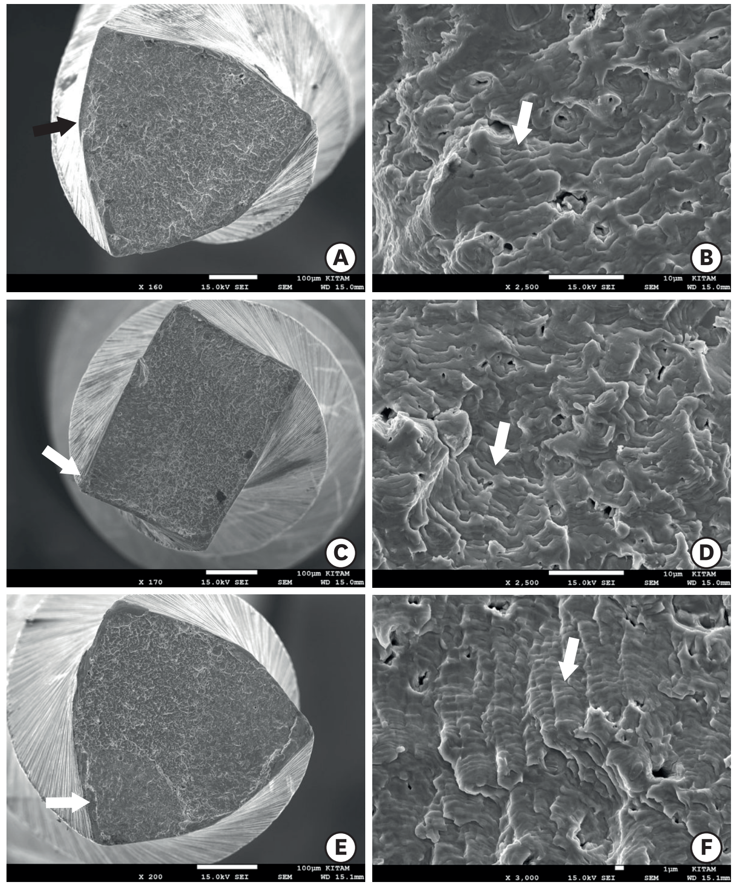

Figure 2. Scanning electron microscopic appearances of the ProTaper Universal (PTU), ProTaper Next (PTN), and ProTaper Gold (PTG) files after cyclic fatigue testing. View of the fractured surface (A) PTU, (C) PTN, and (E) PTG and high-magnification view of (B) PTU, (D) PTN, and (F) PTG instruments showing fatigue striations typical of cyclic fatigue (arrows).
ProTaper Gold, Dentsply Maillefer, Ballaigues, Switzerland; ProTaper Next, Dentsply Maillefer; ProTaper Universal, Dentsply Maillefer.

procedure do not cause any permanent damage that might increase the hardness of files, thus the sterilization procedures do not negatively affect the mechanical properties of files [9]. On the other hand, Canalda-Sahli *et al.* [23] reported that autoclave sterilization decreased the flexibility of the NiTi files but it didn't have any effect on clinical use of the files.

According to the results of the present study, among the unsterilized files (group 1), PTG files showed the highest cyclic fatigue resistance. Similarly, Uygun *et al.* [24] reported that, among PTU, PTN, and PTG files, the highest cyclic fatigue resistance was shown by PTG files. Authors attributed the result to the flexibility that the PTG files gained during the thermomechanical manufacturing process. Hieawy *et al.* [25] compared the cyclic fatigue resistances of PTG and PTU files, and reported that, similarly to the previous study, PTG group showed the higher cyclic fatigue resistance. Authors attributed the result to the exposure to a different heat treatment during the manufacturing of PTG files. According to the results of the present study, cyclic fatigue resistance of PTN files was found to be higher than the cyclic fatigue resistance of PTU files. Similarly, in the literature, there are studies indicating that the cyclic fatigue resistance of PTN files was higher when compared to PTU files. Researchers attributed the results to the difference of alloy, which is used in manufacturing PTN files, and the horizontal cross-sectional design of PTN file [26,27]. In the present study, the cyclic fatigue resistance of PTG was found to be higher than PTN. The different manufacturing process of the files (Gold alloy *vs.* M-Wire alloy) might play a role.

It was also determined that the exposure to autoclave sterilization for 10 times prior to the cyclic fatigue test increased the cyclic fatigue resistance of the files, and the increase was statistically significant for PTG and PTN files. For this reason, the null hypothesis of present study was rejected. However, the increase in cyclic fatigue resistance of PTU file after the sterilization procedure was not found to be statistically significant.

In the literature, there is limited number of studies examining the effects of autoclave sterilization on the cyclic fatigue resistance of files. Viana *et al.* [9] reported that the cyclic fatigue resistance of ProFile (Dentsply Maillefer) files increased after 5 times of autoclaving procedure. The other researchers also reported that the autoclave sterilization procedure at 170°C was not sufficient for altering the mechanical properties of the files [7]. Plotino *et al.* [10] applied 10 times of autoclaving procedure to K3 (SybronEndo, Orange, CA, USA), Mtwo (VDW), and Vortex (Dentsply Maillefer) files, and determined that the autoclaving for 10 times didn't alter the cyclic fatigue resistances of files, while the procedure increased the cyclic file resistance only in K3XF (SybronEndo) file. The authors attributed this result to R-phase of K3XF production. The heat treatment increases the transformation temperature of the files. The transformation temperature plays an important role in the NiTi file's mechanical behaviors. According to the data obtained in the present study, the reason for the increase in the cyclic fatigue resistances of PTN and PTG files after the autoclave sterilization is believed to be that the PTN and PTG files are subjected to heat treatment during the manufacturing process.

In present study, when the files were exposed to autoclave sterilization after cyclic fatigue stress (group 3), only PTN files showed statistically significant increase in the cyclic fatigue resistance among the files. However, no statistically significant change was observed in cyclic fatigue resistance values of PTU and PTG files. Hilfer *et al.* [11] examined the effects of autoclave sterilization procedure on cyclic fatigue resistances of Twisted File (TF) (25/0.06) and TF (25/0.04) files (SybronEndo). Researchers reported that the cyclic fatigue resistance of TF (25/0.06) files decreased after the autoclave sterilization but the cyclic fatigue resistance of TF (25/0.04) was not affected by the autoclave sterilization procedure. Zhao *et al.* [22] examined the effects of autoclave sterilization procedure on the cyclic fatigue resistance of files in artificial curved canals. Researchers reported that the sterilization after cyclic stress improved the cyclic fatigue behavior of HyFlex CM and K3XF files, while TF, K3 and Race were not affected. Moreover, it was reported that there was no statistically significant change in cyclic fatigue resistances of TFs (SybronEndo), K3, and Race (FKG Dentaire, La Chaux-de-Fonds, Switzerland) files. The authors also reported that the reason for this result might be the size of files, the sterilization application conditions, and the differences in curvature angles and diameters of settings, where the files were tested.

In the literature, no study examining the effects of autoclave sterilization procedure on the cyclic fatigue resistances of PTU, PTN, and PTG files could be found. For this reason, the results of present study cannot be directly compared to those of other studies.
Besides that, the files are exposed to cyclic and torsional stresses under clinical conditions synchronously. For this reason, even though the results obtained in present study provide the clinicians about the cyclic resistance of tested files, it is believed that different results might be obtained under clinical conditions.

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CONCLUSIONS

Within the limitations of the present *in vitro* study, PTG instrument made of new Gold alloy was more resistant to fatigue failure than PTN and PTU. Autoclave sterilization increased the cyclic fatigue resistance of PTN and PTG.

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