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EFFECT OF STERILIZATION ON CYCLIC FATIGUE RESISTANCE AND CUTTING EFFICIENCY OF NEWLY INTRODUCED HEAT TREATED ROTARY FILES

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ABSTRACT

The aim of this study was to evaluate the effect of sterilization on cyclic fatigue resistance and cutting efficiency of Protaper Next (PTN), Pepsi Gold (PG) and Plex V (PV) rotary files.

Methods: For cyclic fatigue resistance testing, 20 files of each type were divided into: nonsterile, underwent one, two and three sterilization cycles. The test was done on a static apparatus in an artificial canal. The number of cycles to failure was calculated for evaluation. For cutting efficiency testing, 10 files of each type were tested nonsterile and after every cycle for three cycles. The test was done on an apparatus that guided the file to cut along a plexiglass sheet. The cut area was measured on a special computer software after one minute of operation.

Results: Cyclic fatigue results showed no significant difference between the sterilized subgroups and the non-sterilized subgroups. PG demonstrated the highest cyclic fatigue resistance among the tested groups followed by PV then PTN. Cutting efficiency results showed a significant difference in PG and PV after one sterilization cycle and use while they showed a significant difference in PTN after the second sterilization cycle and use. PG demonstrated the highest cutting efficiency followed by PTN then PV.

Conclusions: Sterilization has no effect on cyclic fatigue resistance of the tested files. PG has the highest cyclic fatigue resistance followed by PV then PTN. Sterilization and use have a negative effect on the tested files. PG has the highest cutting efficiency followed by PTN then PV.

KEYWORDS: Cyclic Fatigue, Cutting Efficiency, Protaper Next, Pepsi Gold, Plex v

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INTRODUCTION

Nickel Titanium rotary files are an essential part of the modern-day endodontic armamentarium. They offer unique properties such as shape memory and superelasticity allowing them to prepare smooth tapered walls in curved root canals. These properties come at a great cost however, instrument separation without warning[1]. This is usually due to cyclic fatigue of the rotating file [2]. In this type of fracture, failure occurs due to repeated compressive and tensile stresses at the point of maximum flexure without the file locking in the root canal.

Another downside to the Nickel Titanium alloy is its pseudoelastic properties which limits its manufacturing to machining only rather than twisting as well. This machining process my lead to surface defects within the cutting surfaces leading to lower cutting efficiency[3]. Multiple other factors affect the cutting efficiency of Nickel Titanium rotary files such as: cross-sectional design, rake angle, helical angle, hardness of the alloy, heat treatment during manufacturing and manner of file motion.

To address these difficulties, new alloys, thermomechanical processing techniques and manufacturing technologies have been introduced. For instance, the mechanical properties of Protaper Next (Dentsply Sirona, Ballaigues, Switzerland) have been improved thanks to its M-wire alloy which is claimed to offer higher cyclic fatigue resistance than traditional Nickel Titanium alloys[4]. Two rotary file systems have been introduced recently; Plex V (Ordeka, Jining, China) and Pepsi Gold (Fanta Dental Material Co., Shanghai, China). Both systems are of the Controlled Memory alloy, and both have undergone “special heat treatment” to improve their mechanical properties as claimed by their manufacturers[5].

A common clinical scenario is one in which the clinician needs to sterilize rotary files before use. The heat produced during the autoclaving process is feared to alter the mechanical properties of Nickel Titanium files. Therefore, sterilization of Nickel Titanium rotary files before use raises concerns over their resistance to fracture and cutting efficiency.

To the present date, studies in literature have shown conflicting results regarding the effect of sterilization on cyclic fatigue resistance and cutting efficiency of rotary files[6,7,8,9,10]. The stance of literature on the effect of sterilization on cyclic fatigue resistance and cutting efficiency on our rotary files of interest remains to be a blurred area which sparked our interest to investigate the matter.

To the best of our knowledge, the two above mentioned newly introduced systems haven’t been examined previously regarding their resistance to cyclic fatigue nor to their cutting efficiency after multiple sterilization cycles. Thus, it was thought that it would be of value to investigate the effect of multiple sterilization cycles on the cyclic fatigue resistance and cutting efficiency of Plex V, Pepsi Gold and Protaper Next rotary files.

MATERIALS AND METHODS

Cyclic Fatigue

A total of 60 Size #25 .06 taper of the following file types were used in this study: Protaper Next (Dentsply Sirona, Ballaigues, Switzerland), Plex V (Ordeka, Jining, China) and Pepsi Gold (Fanta Dental Material Co., Shanghai, China). They were divided into three groups according to file type into:

- PTN group (20 files): Protaper Next
- PV group (20 files): Plex V
- PG group (20 files): Pepsi Gold

Each group was subdivided into 4 subgroups according to the number of sterilization cycles:

- Subgroup 1 (5 files): Non-sterilized
- Subgroup 2 (5 files): Underwent 1 cycle of sterilization
- Subgroup 3 (5 files): Underwent 2 cycles of sterilization

- Subgroup 4 (5 files): Underwent 3 cycles of sterilization

The autoclave used for sterilization was DAC Professional (Dentsply Sirona, Ballaigues, Switzerland). The Universal Program was used in all sterilization cycles. This program operated at the following parameters: 134 degrees Celsius, 2 bars/ 29 psi, 30 minutes operating time and 20 minutes drying time.

The cyclic fatigue testing device design was adapted from the work of **Plotino et al** with some modifications (figure 1). A holder for the endodontic motor was specifically designed to fit the dimensions of E-Connect Pro (Eighteeth, Jiangsu Province, China) endodontic motor. The artificial canal is 19 mm long and has a curvature of 60 degrees with a five mm radius of curvature. Before each test the artificial canal was flooded with WD40 (WD-40 Company, San Diago, USA) multi-use oil. The files were rotated following their respective manufacturers' instructions to failure. A video of each test was recorded using a D3200 Nikon digital camera (Nikon Corporation, Tokyo, Japan) with the video capture settings set to 720 P at 60 Frames Per Second. The videos were exported to INAA (Georgia Tech, Atlanta, GA) application (Version 1.1.2) to determine the time taken to fracture in milliseconds. The artificial canal was cleaned between tests and was reflooded again with the oil before the succeeding test.

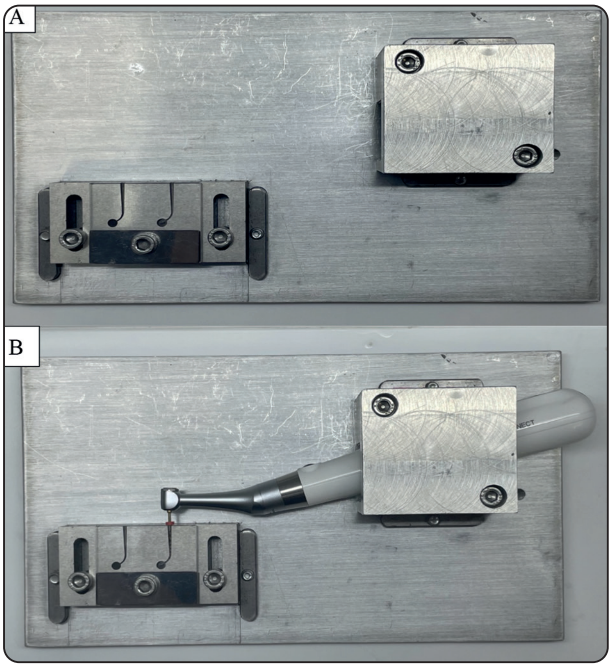

Fig. (1): (A) Cyclic fatigue testing apparatus. (B) Cyclic fatigue testing apparatus with E-connect Pro endodontic motor in the holder.

Cutting Efficiency

A total of 30 files were divided equally into three groups according to file type into: PTN group, PV group and PG group. Each of these groups underwent three sterilization cycles. Cutting efficiency was tested on the non-sterile files and was repeated after every cycle of sterilization. The method for cutting efficiency testing was adapted from the work of **Plotino et al** with modifications in the testing apparatus (figure 2). The substrate for evaluating cutting efficiency in this study was a one mm thick acrylic plexiglass plate (Spiroplastic, Cairo, Egypt). A holder was custom made to carry an E-Connect Pro endomotor along with 170 grams of weights on a ball bearing runner. Right in front of the runner was a plexiglass holder positioned such that the tested rotary file encounters the glass at position D14. The plexiglass plate had a laser cut one mm notch to prevent the tested file from slipping out during operation. An air/water tip of the dental unit was positioned on top of the testing area to remove the generated debris.

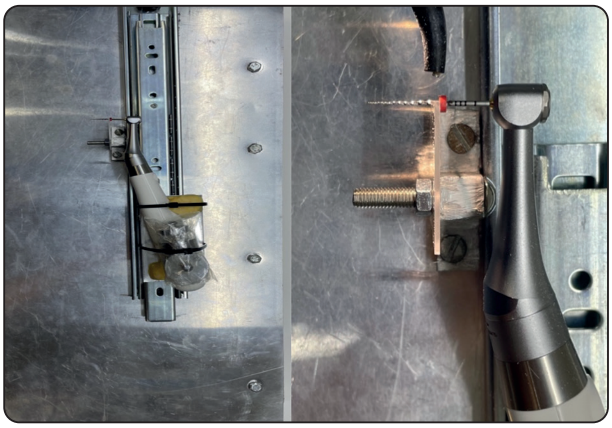

Fig. (2): Cutting efficiency testing apparatus

The tested files were operated at their respective manufacturers' instructions for one minute. All files underwent sterilization and were brought back for retesting for cutting efficiency. This process was repeated for 3 times. The files were wiped with a sponge soaked in 70% Isopropyl Alcohol after each cutting efficiency test to remove debris. The cut plexiglass plates were then each photographed using a Nikon D3200 digital camera. The images were then exported to Photoshop 2021 Version 22.5.1 (Adobe, California, USA) to calculate the area of penetration.

Statistical analysis

Numerical data were presented as mean and standard deviation (SD) values. They were explored for normality by checking the data distribution and by using Shapiro-Wilk tests. Data showed parametric distribution and were analyzed using one-way ANOVA followed by Tukey's post hoc test for intergroup comparisons and repeated measures ANOVA followed by Bonferroni post hoc test for intragroup comparisons. The significance level was set at $p \leq 0.05$. Statistical analysis was performed with R statistical analysis software version 4.1.3 for Windows(R Foundation for Statistical Computing, Computing, Vienna, Austria).

RESULTS

Cyclic fatigue

A) Effect of file type:

Cyclic fatigue resistance data among the different file types is presented in table (1). There was a significant difference among the different file types. PG exhibited the highest resistance followed by PV then PTN.

B) Effect of sterilization:

Data for sterilized and non-sterilized samples is presented in table (2). There was no significant

TABLE (1): Mean, Standard deviation (SD) values of number of cycles to failure for different files.

Sterilization	Number of cycles to failure (mean±SD)			p-value
	PG	PV	PTN	
Non-sterilized	2954.00±431.90^{A}	1560.13±63.58^{B}	351.00±55.83^{C}	**<0.001***
After one cycle	2748±60.96^{A}	1584.80±45.60^{B}	320.00±43.73^{C}	**<0.001***
After two cycles	2799.53±25.91^{A}	1591.33±81.98^{B}	342.00±37.52^{C}	**<0.001***
After three cycles	2912.00±236.03^{A}	1537.26±79.57^{B}	348.00±45.36^{C}	**<0.001***

Same letters indicate no statistical significance.

TABLE (2): Mean, Standard deviation (SD) values of number of cycles to failure for sterilized and non-sterilized samples.

File	Number of cycles to failure (mean±SD)				p-value
	Non-sterilized	After one cycle	After two cycles	After three cycles	
PG	2954.00±431.90^{A}	2748±60.96^{A}	2799.53±25.91^{A}	2912.00±236.03^{A}	**0.543ns**
PV	1560.13±63.58^{A}	1584.80±45.60^{A}	1591.33±81.98^{A}	1537.26±79.57^{A}	**0.295ns**
PTN	351.00±55.83^{A}	320.00±43.73^{A}	342.00±37.52^{A}	348.00±45.36^{A}	**0.713ns**

Same letters indicate no statistical significance.

difference between subgroups of the same file type after multiple sterilization cycles.

Cutting efficiency

A) Effect of file type:

Cutting efficiency data for the different file types is presented in table (3). There was a significant difference among the different file types. PG exhibited the highest cutting efficiency followed by PTN then PV.

B) Effect of sterilization:

Cutting efficiency data after multiple sterilization cycles and use are presented in table (4). There was a significant reduction in cutting efficiency of PG and PV after 1 cycle of sterilization and use. While there was a significant reduction in cutting efficiency of PTN after 2 cycles of sterilization and use. There was an insignificant reduction in cutting efficiency between the second and third cycles of sterilization and use.

TABLE (3): Mean, Standard deviation (SD) values of area cut (mm2) for different files.

Sterilization	Area cut (mm2) (mean±SD)			p-value
	PG	PV	PTN	
Non-sterilized	4.59±0.14^{A}	1.75±0.23^{C}	2.38±0.15^{B}	**<0.001***
After one cycle	4.25±0.18^{A}	1.30±0.15^{C}	2.25±0.12^{B}	**<0.001***
After two cycles	3.68±0.08^{A}	0.96±0.10^{C}	2.09±0.13^{B}	**<0.001***
After three cycles	3.52±0.13^{A}	0.88±0.10^{C}	1.95±0.11^{B}	**<0.001***

Same letters indicate no statistical significance.

TABLE (4): Mean, Standard deviation (SD) values of area cut (mm^2) for sterilized and non-sterilized samples.

File	Area cut (mm2) (mean±SD)				p-value
	Non-sterilized	After one cycle	After two cycles	After three cycles	
PG	4.59±0.14^{A}	4.25±0.18^{B}	3.68±0.08^{C}	3.52±0.13^{C}	**<0.001***
PV	1.75±0.23^{A}	1.30±0.15^{B}	0.96±0.10^{C}	0.88±0.10^{C}	**<0.001***
PTN	2.38±0.15^{A}	2.25±0.12^{AB}	2.09±0.13^{BC}	1.95±0.11^{C}	**<0.001***

Same letters indicate no statistical significance.

DISCUSSION

Cyclic fatigue and cutting efficiency are important properties of rotary file systems to shape canals in a safe and timely manner. It is therefore prudent to assess newly released files in the market for cyclic fatigue resistance and cutting efficiency under everyday use conditions. In the present study we investigated the effect of sterilization on cyclic fatigue resistance and cutting efficiency of the new released CM-wire rotary file systems: Pepsi Gold and Plex V, along with the M-wire Protaper Next rotary file system.

The cyclic fatigue testing device used was specifically designed to hold the endodontic motor in a fixed position after changing the tested files. It also allowed placing the rotary files in a reproducible position inside the artificial canal. We opted for an artificial "canal" in our test to standardize the experimental conditions. The artificial "canal" had a definite geometry and curvature hence controlling confounding factors related to any variation in canal geometry. WD40 multi-use oil was applied inside the cyclic fatigue testing groove to act as a lubricant to reduce stresses on the tested files as well as to act as a heat sink to dissipate the heat produced from friction[13-16].

In our study Pepsi Gold rotary files demonstrated the highest resistance to cyclic fatigue among the tested files. To our knowledge, no previous published data is available on PV and PG files. However, these files are made of CM wire alloy which can be compared to results by other CM wire rotary files. For instance, the results of our study are in accordance with the results of **Pedulla et al**[13] which showed that cyclic fatigue resistance of Protaper Next X2 was less than that of the CM wire Hyflex CM (Coltene, Cuyahoga Falls, OH, USA) after torsional preloading. In their study, it was hypothesized that Protaper Next performed worse because of its progressive taper design making it of larger diameter at the maximum stress point; Instruments with a larger diameter exhibit lower cyclic fatigue resistance[14,15]. **Plotino et als'**[16] results also supported that CM wire rotary files exhibit higher cyclic fatigue resistance than M-wire rotary files. They suggested that the difference was likely due to differences in the manufacturing process, particularly heat treatment. This heat treatment leads to improved flexibility and strength of the file which was reflected in their results. PV and PG rotary files tested in our study are claimed to have undergone a "special heat treatment" by their manufactures. Since details of these proprietary heat treatments are not disclosed by the manufacturers, we cannot tell if these heat treatments are similar to the one done by Coltene on Hyflex CM. Other studies further support that CM alloy rotary files exhibited higher resistance to cyclic fatigue than M-wire alloy rotary files such as Protaper Next [17-21].

As for the effect of sterilization on cyclic fatigue, results of the present study showed no statistically significant effect. Our studie's results are in accordance with the results of **SC Kamali et al**[22] which had the CM wire Hyflex CM and Protaper Next in their test groups and showed no effect on cyclic fatigue as well. Many other studies support the hypothesis that sterilization has no effect on cyclic fatigue resistance of Ni-Ti files[23-28] We believe that the temperature used in autoclave sterilization may not be high enough to cause significant changes in the alloy microstructure to influence its cyclic fatigue resistance.

The cutting efficiency apparatus used in this study was adapted from the work of **Plotino et al**[29]. It allowed for precise positioning of the endodontic motor as well as easy and reliable replacement of the files tested. Our test was performed on plexiglass blocks for standardization purposes since natural teeth had variable hardness and water content which would have affected the cutting efficiency. This of course doesn't mimic the clinical situation, but it allows for comparisons of the cutting ability of different files on the same substrate.

Cutting efficiency results of the present study showed that PG had the highest cutting efficiency followed by PTN and PV came last. To our knowledge, there are no previous data on the files tested in our study using this testing method. Nevertheless, we analyzed the data from other studies on cutting efficiency using different methods on M wire rotary files in comparison with CM wire rotary files to try to interpret our data. It is not unusual for CM wire rotary files to outperform M wire rotary files regarding cutting efficiency as demonstrated by **Takhellambam Premata Devi et al**[31]. Results of the present study may be due to differences in cross-sectional design at D14, the point at which the test was performed on the file. It is important to note that PTN has a larger cross-sectional diameter at D14 than the other files, so the downward force applied is spread over a larger area of the file which may result in lower cutting performance. If we are to compare PG's and PV's performance, the differences may be the result of other cross sectional design features as well as differences in heat treatment the files had undergone during the manufacturing process.

It was interesting to note the variable effect of autoclaving with simulated file use on cutting efficiency of the tested files. PG and PV started to deteriorate significantly after the first autoclaving cycle and use while PTN's cutting efficiency started deteriorating significantly after the second autoclaving cycle and use. The reduction in cutting efficiency could be attributed to flaking, pitting and crack formation on the surface of the rotary files after repeated use. The manner of reduction in cutting efficiency after the second simulated use exhibited by PTN is not unusual as witnessed on other files of different alloys in studies by **Seago et al**[33] and **Salih et al**[34]. In our study, we believe that the reason behind this may be due to PTN's larger cross-sectional area at D14 than the other tested files, hence the deterioration is "diluted" over a larger surface of the file at that point. All tested files demonstrated an insignificant decrease in cutting efficiency between the second and third cycles which is also not unusual as shown by results of different alloy files tested by **Salih et al**[38]. We speculate that the flaking and pitting on the files' surface form at a slower rate after a certain amount of use. We believe that the variability in the results of our study could be explained by differences in the files' heat treatments and cross-sectional design at D14 resulting in different manners of deterioration after multiple use.

CONCLUSIONS

PG demonstrated the highest cyclic fatigue resistance followed by PV then PTN. Sterilization had no significant effect on cyclic fatigue resistance after 3 cycles. As for cutting efficiency, PG demonstrated the highest cutting efficiency followed by PTN then PV. Sterilization with file use had a significant effect on cutting efficiency of both PG and PV after a single use and sterilization cycle while they had a significant effect on PTN after the second use and sterilization cycle.

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