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Effect of Multiple Sterilization Cycles on Time to Separation for VTaper Rotary NiTi Files

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Introduction

While nickel titanium rotary files have greatly aided endodontic procedures (Short et al 1997), they are not without their risks. [1] The risk of file separation is influenced by canal anatomy and file characteristics including design and manufacturing methods. [2] Nickel titanium rotary files have two modes of failure, torsional fatigue and cyclic fatigue. [3, 4] Torsional fatigue is failure which occurs when the tip of the instrument binds and the coronal portion continues to rotate causing separation. Cyclic fatigue occurs when a file continuously rotates in a curved canal causing alternating tensile and compressive forces which ultimately lead to file fracture. [5]

One of the recent methods to reduce this risk of file separation is heat treatment of files. Nickel titanium has two predominant phases which are separated by a transformation temperature. [6] The austenitic phase is seen above the transformation temperature and is characterized by a shape memory (also known as elastic deformation) meaning that when the alloy is bent, it tends to return to its original shape. The martensitic phase is seen at temperatures below the transformation temperature and is characterized by the ability to be plastically deformed meaning that when the alloy is bent, it tends to remain bent. Essentially, the austenitic phase is comparably more stiff and the martensitic phase is more flexible. Heat treatment of nickel titanium rotary files allows the transformation temperature to be altered to take advantage of the martensitic phase of the alloy. [2, 7-9] Elevation of the transformation temperature provides at least two benefits. First is the ability to "prebend" the files which can help with placement of the files in instances of limited space. Secondly, an improved resistance cyclic fatigue due to the material operating closer to the transformation temperature compared to a purely austenitic file. [10]

Many files are pre-sterilized from the manufacturer but it is possible that they could remain unused after being opened, requiring re-sterilization. Sterilization is an essential process for dental instruments (Chan) and generally does not negatively affect file properties. [11-13] Stainless steel hand files appear to be minimally affected by sterilization procedures [14] but other instruments, such as dead soft stainless steel heat tips show reduced performance after repeated sterilization cycles [15]. While some authors have found no detrimental effects on file properties after heat sterilization, the majority of these studies did not examine heat-treated nickel titanium files. [12, 13]

In the studies that have examined sterilization effects on heat treated files, several have actually shown improvements in cyclic fatigue resistance with additional cycles of heat sterilization (Viana, Zhao, Yahata, Ozyurek) but no studies have examined this effect on the VTaper2H rotary files. [16-19]

The VTaper2H rotary NiTi files are a heat treated file with a variable taper and a limited maximum file diameter. This allows a more conservative preparation of the coronal and middle thirds of the root which preserves the pericervical dentin. [20] The aim of the study is to evaluate the effect of multiple heat sterilization cycles on the Time to Separation (TTS) of VTaper2H nickel titanium rotary files.

Materials and Methods

One hundred and eighty VTaper2H rotary files (SS White) size 25/v06 and 25mm length were randomly divided into four groups (n=45 each) and exposed to varying cycles of heat sterilization to assess the effect of sterilization on TTS. The groups included a pre-sterilized control group and three experimental groups each of which were exposed to one, three, or five cycles of heat sterilization. The experimental groups were placed in file boxes and heat sterilized for 18 minutes at a pressure of 30 psi and temperature of 134 degrees Celsius. After the designated number of sterilization cycles, all files were tested individually in a specially designed jig. The jig allowed the files to be rotated at 500 RPMs around three preset pins to simulate a 60-degree curve with a radius of 6mm. Observed TTS was recorded with a digital stop watch.

Statistical Analysis

An a priori power analysis was conducted for a one-way analysis of variance (ANOVA). Given the four groups, a total sample size of 180 (45 per group) was required to detect differences in TTS assuming a type I error of 0.05, power of 0.80, and an effect size f = 0.25. Normality of the TTS distributions among the groups was assessed using the Shapiro-Wilk test. An ANOVA was used to evaluate the primary hypothesis that the number of sterilization cycles would affect the observed TTS. Significant results were analyzed using the Tukey post hoc test. Data are summarized as means and associated standard deviations. Significance was declared at $P < 0.05$ for all tests. All data were analyzed by using SPSS version 25.0 (SPSS, Chicago, IL).

Results

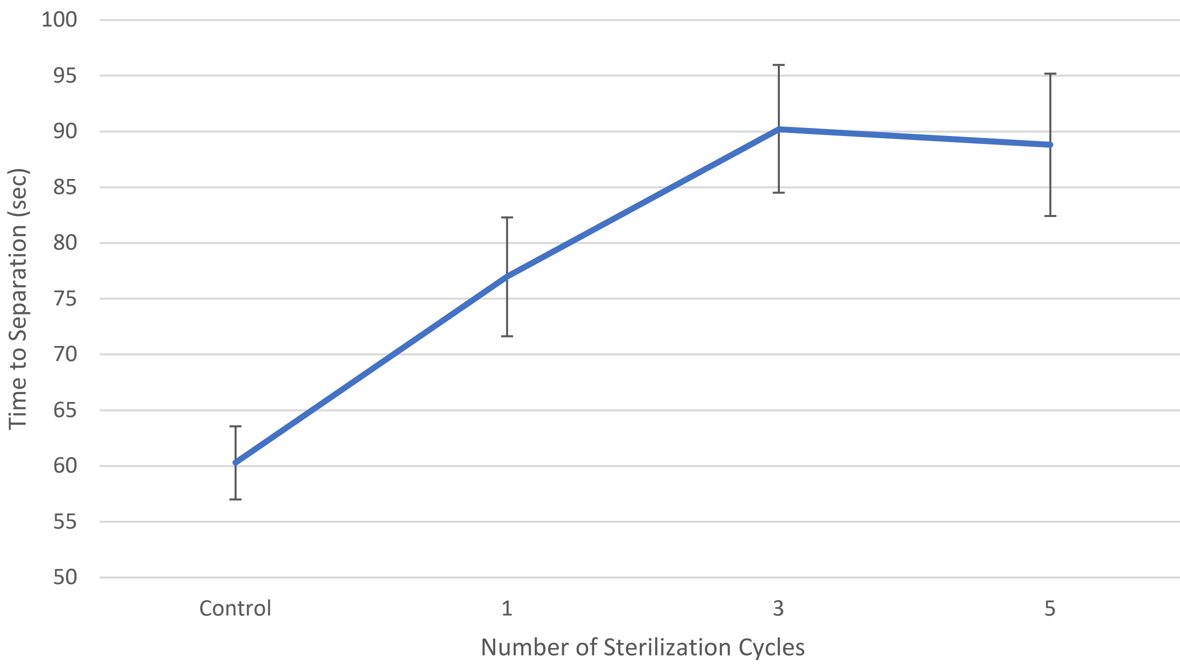
One hundred eighty VTaper2H files were tested to failure following varying cycles of heated sterilization. No outliers were identified in any of the groups. The overall mean TTS was 79.1 sec (SD=21.3). Table 1 details the mean TTS for all groups.

An ANOVA test indicated that the TTS was significantly affected by the number of times a file had undergone sterilization, $P<0.001$, $\eta^2= 0.32$. The effect size (η^2) indicates that 32% of the variance in TTS can be attributed to the number of sterilization cycles. This suggests a medium to large effect size. Post hoc comparisons using the Tukey HSD test revealed three distinct subsets in TTS. The pre-sterilized control group had the shortest TTS (60.3 sec, SD=10.9). The longest TTS was seen among the 3-cycle group (90.2 sec, SD=19.1). Statistically significant differences were seen between all groups except for the 3 cycle and 5 cycle groups, P=0.98. Figure 1 shows the mean TTS for all groups.

Table 1. Mean Time to Separation by Number of Sterilization Cycles

No. of cycles	n	Time to Separation, sec	SD
0 (control)	45	60.3	10.9
1	45	77.0	17.7
3	45	90.2	19.1
5	45	88.8	21.3
Total	180	79.1	21.3

Figure 1. Mean Time to Separation by Number of Sterilization Cycles



Error bars represent 95% Confidence Intervals.

Discussion

Separated instruments are a frustrating and at times detrimental complication of endodontic treatment. A meta-analysis in 2010 by Panitvisai et al concluded that presence of a separated instrument alone did not affect prognosis, but the presence of a periapical radiolucency combined with a separated instrument reduced the healing rate from 92% to 81%. [21] Parashos and Messer found that cyclic fatigue is one of the main reasons for instrument separation. [5] Spili found that the incidence of separated rotary instruments was around 3%. [22]

Heat treatment of nickel titanium rotary files is known to improve flexibility and cyclic fatigue resistance. These benefits have greatly aided conservative endodontic treatment and reduced the risk of file separation. The present study demonstrated that additional heat sterilization cycles can infer the benefit of improvement of cyclic fatigue resistance. While it is unknown what proprietary heat treatments the files are subjected to at the manufacturer, the results of this study suggest that the properties can be further enhanced with exposure to additional heat sterilization.

This study is not without limitations. The use of a stopwatch introduces the possibility for human error due to a delay in reaction time. The use of an artificial curved canal space also poses several limitations. Most obviously, it can be noted that each canal in vivo is unique and there are a wide variety of clinical scenarios which can influence the performance of nickel titanium rotary files. The benefit of the approach of this study is that the conditions were standardized to limit the effect of confounders. That being said, it is unknown how variable these results would be in clinical situations with canal spaces of more or less curvature and varying diameters.

Another notable limitation to the use of an artificial canal is the issue of operating temperature of the files. Klymus et al found that cyclic fatigue resistance was decreased up to 85% for Hyflex CM and Vortex Blue files when comparing use at room temperature (20 degrees Celsius) versus use at body temperature (37 degrees Celsius). [23] Plotino et al (2018) found the same effect for Reciproc Blue files. [10] Since the VTaper2H files have a transformation temperature of approximately 33 degrees Celsius, it is likely that testing of the files at room temperature limits the clinical applicability of this study. [24] The possibility exists that since this study was done at room temperature, the files may have stayed in the lower temperature martensitic phase for a longer period of time than may occur clinically at body temperature. Currently, however, it is unknown at what operating temperature rotary files actually reach in vivo. Many factors can influence the operating temperatures including body temperature, heat capacity (of the files, dentin and irrigants) along with the friction generated between the file and the canal wall. [25]

Rotational speed of the instruments has also been shown to affect cyclic fatigue. Lopes et al found a 30% reduction in the number of cycles to fracture for ProTaper files rotated at 600 rpms compared with 300 rpms. [26] The files examined in their study were not heat treated however so it is unclear to what degree this concept applies to our study.

The design of the VTaper2H files is geared towards dentin conservation. With this in mind, the size 25/v06 file was selected because of its range of possible uses, as an intermediate or final file size during shaping procedures. Larger or smaller file sizes may have shown different results.

The results of our study are in line with the findings of Ozyurek, who examined the effect of heat sterilization on ProTaper Gold and Universal (both of which are heat treated files). Their findings indicated that heat sterilization improved cyclic fatigue resistance for these files compared with controls. [19] Findings from Plotino et al also support the hypothesis that heat sterilization can improve the properties of heat treated files. [27] Their study examined the effect of heat sterilization on K3, Vortex and K3XF files and found improved cyclic fatigue only for the K3XF files which were the only heat treated files in the study. Heat sterilization of the K3 and Vortex files (both non-heat treated) did not seem to have an influence on the cyclic fatigue resistance.

Cyclic fatigue is a complex topic linked to many known and unknown variables. Within the limitations of this study, it appears that exposure of VTaper2H files to additional sterilization cycles can provide an improvement in cyclic fatigue resistance compared to controls.

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