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A Thesis submitted in partial fulfillment of the requirements for the degree of Master of
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Abstract

K3 ENDO, PRO TAPER, AND PRO FILE SYSTEMS: BREAKAGE AND DISTORTION IN SEVERELY CURVED ROOTS OF MOLARS.

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A Thesis submitted in partial fulfillment of the requirements for the degree of Master of
Science at Virginia Commonwealth University.

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It was the aim of this study to investigate the incidence of file breakage and distortion when the Pro Taper, K3 Endo and ProFile systems were used to instrument canals in the severely curved roots of extracted molars.

Forty-five roots of extracted mandibular and maxillary molars with curvatures between 40 and 75 degrees were chosen for use in this study. The roots in Group One were instrumented with the Pro File (PF) system and served as the control group. Roots in Group Two were instrumented with the Pro Taper (PT) system and those in Group Three

were instrumented with the K3 Endo (K3) system. The three systems were used according to the manufacturers' instructions.

The proportion of files distorted was 15.3% for the PF group, 2.4% for the PT group, and 8.3% for the K3 group. There was a statistically significant difference between the PF and PT groups ($p = .0079$). The percentage of broken files was 1.7% for the PF group, 6.0% for the PT group and 2.1% for the K3 group. No statistically significant differences were found between these three groups ($p = .4243$).

The results of this study showed that these three rotary tapered systems were not significantly different with regard to breakage. There were significantly more distorted files in the PF group when compared to the PT group, with regard to distortion there was no significant difference between the PT and K3 and the PF and K3 groups.

Introduction

One of the objectives of root canal therapy is to clean and shape the root canal system. (1) Breakage of files may prevent this objective from being achieved. It is desirable to remove or bypass a separated instrument but if neither of these corrective procedures can be achieved, periradicular surgery may be the only other endodontic option. (2) Depending on the pulpal status and degree of contamination of the root canal system, the broken file may result in a compromised prognosis for the case. (3)

A broken file is generally the result of excessive stresses being placed on the instrument while it is being worked in the canal. Nickel titanium (NiTi) endodontic instruments have been shown to be more flexible than stainless steel instruments. These files exhibit 'memory', which is the ability of the instrument to revert to its original shape after flexure. However, there is a limit to the amount of flexure an instrument can withstand. When this limit is reached or exceeded the instrument will distort or fracture. The elastic limit for NiTi files has been shown to be two to three times that of stainless steel. (4)

Proper cleaning and shaping of severely curved root canals may be difficult to achieve and file distortion or breakage is more likely to occur in these canals. Clinically, the chance of removing a file from a severely curved canal is very low and in some cases may be impossible without compromising the tooth itself. (5)

Manufacturers are attempting to design new endodontic files that will make root canal therapy easier and faster. In attempting to increase the efficiency of these new instruments, the issue of file distortion and breakage must be addressed. The NiTi Pro Taper file (PT) system (Tulsa Dental Products, Tulsa, OK) is a relatively new endodontic rotary canal preparation technique. The manufacturer claims that these files are specially designed to instrument difficult, highly calcified and severely curved root canals. (6) The basic system is comprised of three shaping and three finishing instruments. The PT files feature a convex triangular cross section which reduces the contact area between the file and dentin and has, what is described as, a “minimally aggressive” cutting tip. At this time there are no reports available to verify the manufacture’s claims with regard to these files. In the past, hand instruments which had an end cutting tip were found to produce ledges and perforations in the walls of curved canals. These hand files were also more liable to distortion and fracture. (7)

The K3 Endo (K3) NiTi rotary file system (Sybron Endo, Orange, CA) was introduced in 2002. These files are designed with a wide radial land which is meant to make the instrument more resistant to torsional and rotary stresses. It also features “radial land relief” which aids in protecting the file from “over engagement” in the canal, thus less instrument separation and/or distortion should occur. This file features a variable core diameter which was designed to increase flexibility and it has a safe ended tip to decrease the incidence of ledging, perforations and zipping. (8)

The Pro File (PF) system (Tulsa Dental Products, Tulsa OK) has been available for several years and is currently a popular technique used by many practitioners in the

preparation of severely curved canals. These instruments have a safe, non-cutting tip and feature a minimal transition angle to prevent ledging and transportation of the canal. Radial-landed U shaped flutes lift debris coronally. It has been reported that neither separation nor deformation occurs during instrumentation of simulated root canals when these files are used. (9,10) One study (11) found some distortion but no breakage when using these files in extracted teeth.

Rotary instrumentation has become a mainstay for preparation of the root canal system. When rotary systems were initially introduced there was an increase in file breakage but as practitioners have become more familiar with the techniques this problem has decreased. Most of the breakage occurred because there was a decrease in the tactile sensation which would warn the operator that a file was being stressed. One problem with the NiTi file systems is that there are no established standards with regard to the manufacture and testing of these instruments. Any new rotary NiTi file system can be manufactured and engineered into any shape or taper and can be marketed without critical evaluation. To date there is no information with regard to the incidence of file breakage or distortion when PT and K3 rotary file systems are used in severely curved canals.

It was the aim of this study to investigate the incidence of file breakage and distortion when the Pro Taper, K3 Endo and ProFile file systems were used to instrument the severely curved root canals of extracted molars.

Material and Methods

Forty-five mesial roots of extracted mandibular first and second molars and buccal roots of maxillary first and second molars were chosen for use in this study. All roots had mature apices and minimal caries. Prior to use the teeth were decontaminated by immersion in 5.25% sodium hypochlorite for 30 minutes. Teeth were then stored in sterile saline at room temperature. Root curvatures were determined using the method described by Schneider (12). Only those roots with curvatures between 40 degrees and 75 degrees were selected. Any roots with canals that curved in more than one plane were excluded. The forty-five roots were randomly assigned to one of three groups by a computer program (Microsoft Excel, Microsoft) which took into account the curvature of the samples. This was done so each test group of fifteen roots would contain roots with similar degrees of curvature.

The root canals in Group 1 roots were instrumented with the PF system and served as the control group since the frequency of separation and distortion of these files had previously been established (8-10). The root canals in Group 2 were instrumented with the PT system and those in Group 3 canals were instrumented with K3 file system.

The crown of each tooth was accessed with a #557 bur (SS White, Lakewood, NJ). Patency and working length of each canal was determined by passing the #10 flex-o-file (Maillefer, Johnson City, TN) to the anatomic foramen. The tip of the file was then

visualized using 16X magnification. This length was recorded and the final working length was established 1mm short of this recorded length. If patency could not be established the root was replaced with one with a similar degree of curvature where patency could be established. The crown of each tooth was removed at the cemento-enamel junction using a separating disc (Sintec, Wakefield, NH) so the working length could be standardized at 16mm. The coronal portion of the root was prepared with Gates Glidden burs #4, #3, #2 (Dentsply, Tulsa, OK) at 4mm, 6,mm and 8mm respectively. The apical portion of the canal was then enlarged to a size #15 flex-o-file prior to introduction of any of files in the rotary systems. All files were visually inspected at 16X magnification prior to insertion into the canal to be sure that none of the files were distorted prior to use. If any distortions were found, that file was eliminated. Irrigation with 2ml of .9% saline (Baxter, Deerfield, IL) was used between each file and RC Prep (Premier, King of Prussia, PA) was used to lubricate each file. Patency was maintained between each file with a #10 flex-o-file. Preparation was considered complete when a size #30 file reached the working length. Each file was used only once per tooth and if a file separated in a canal, instrumentation for that canal was considered to be complete.

All instrumentation was carried out according to each manufacturer's instructions. A 16:1 ratio gear reduction handpiece was used along with an electric motor (Air Technika, Pistoia, Italy) set at 250 r.p.m. and 40 Ncm for all three groups. This was within the range suggested by both manufacturers.

The rotary instrumentation technique used in Group 1 for the PF files was as follows: All files were advanced in a pecking motion until they bound in the canal or reached working

length. Size #30/.04 was used first, followed in sequence by the #25/.04, #20/.04 and finally the #15/.04. Once working length was achieved, the apical portion of the canal was prepared to the desired size (#30/.04).

In Group 2, PT files, (shaping and finishing files) were used in a pecking motion as follows: The Size S1 (#17/variable taper) was advanced to resistance but no more than two-thirds of the canal depth. The SX file was then advanced to resistance followed by the S1 file now advanced to working length. The other files were then used in the following sequence and all were advanced to working length: Size S2 (#20/variable); size F1 (#20/.07); F2 (#25/.08) and finally F3 (#30/.09) to achieve the size #30 for the apical preparation. It should be noted that the manufacturer (6) does not define the apical size and taper for the SX file and it lists the taper of the S1 and S2 file as variable.

The K3 files in Group 3 were used and removed after two cutting strokes to either resistance or working length in the following sequence: Size #30/.04 was used first followed by size #25/.04, size #20/.04, and finally size #15/.04.

After use, debris was removed from each file with a 2"x 2" cotton gauze moistened with isopropyl alcohol and it was then inspected for distortion and/or breakage under 16X magnification. One file of each type and size was activated while the apical 3mm of the file was held in place by a vise grip. The resultant distorted files from this procedure served as the positive control group (n=14). Negative controls (n=14) consisted of one of each of the new files which had not been used and which did not display any distortion. The results for the groups were expressed as a percentage of the total number of files used and were compared using chi-square statistical methods. Additional analysis used the

Fischer's test to determine if any significant difference existed between individual file sizes of the K3 and ProFile systems.

Results

The proportion of maxillary and mandibular molar roots was comparable in the three groups ($p = 0.4477$), as was the proportion of the canal types ($p = 0.1149$). In addition, the average curvature (mean = 56.8 degrees, SD = 8.22 degrees, range = 42-68 degrees) was comparable in the three groups ($p > .9$). The primary response variables were expressed as the percentage of files which were broken and the percentage of files which were distorted in each of the three groups.

The percentage of files which were distorted was 15.3% (9 of 59 files) for the PF group, 2.4% (2 of 84 files) for the PT group and 8.3% (4 of 48 files) for the K3 group (fig. 1). There was no statistically significant difference between the K3 and PT group ($p = .1895$), or between the K3 and PF group ($p = .3761$). There was a statistically significant difference between the PT and PF groups ($p = .0079$). The percentage of broken files was 1.7% (1 of 59 files) for the PF group, 6.0% (5 of 84 files) for the PT group and 2.1% (1 of 48 files) for the K3 group (fig. 2). There were also no statistically significant difference between any of these three groups ($p = .4243$). When the individual files sizes (#30, #25, #20 and #15) of the K3 group were compared with similar sizes the PF group, no significant differences were found with regard to either file distortion and/or file breakage (Fischer's exact p -value=1.0).

Additionally, the relationship between the probability of any failure (either breakage or

distorted) and degree of curvature was tested using logistic regression. Differences between the three instrumentation groups was accounted for and no significant relationship was found between the probability for failure in any group and the degree of curvature (chi-square = 0.4, $p = 0.5291$).

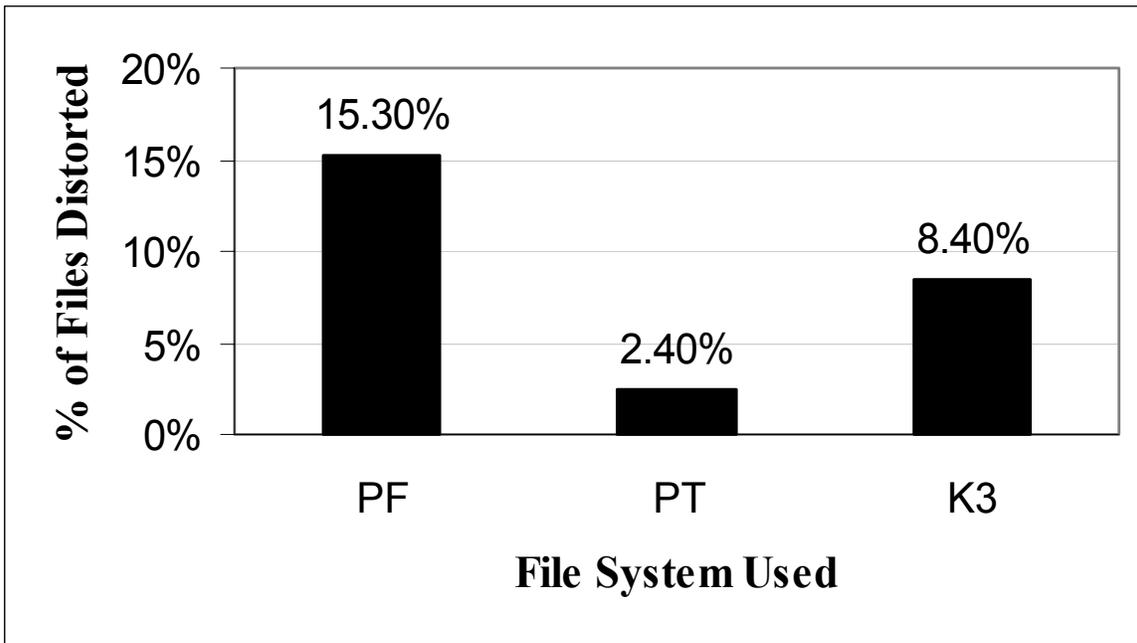


FIG 1. Percent of Files Distorted by File System.

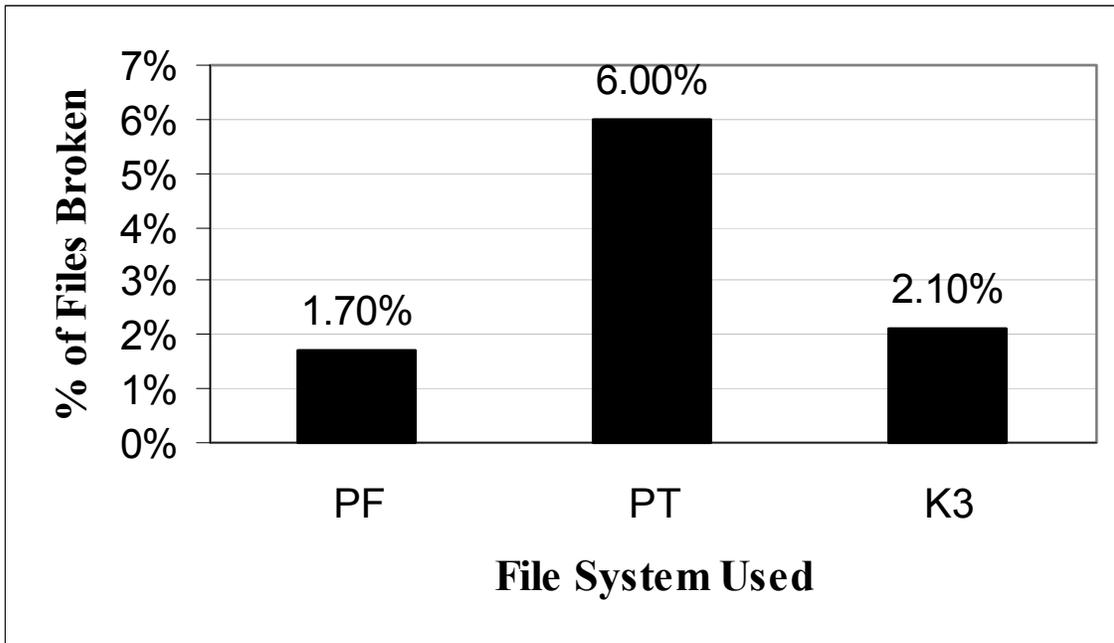


FIG 2. Percent of Files Broken by File System.

Discussion

The purpose of this research was to investigate distortion and/or breakage that might occur when new K3 and PT files were used to instrument severely curved root canals in extracted molars. Given the results, all three of these rotary systems should be used with caution in severely curved canals since all three rotary systems produced some breakage and distortion.

With regard to instrument breakage the PT group had more files break, 6% (n = 5) compared to the K3 group, 2.1% (n = 1) and the PF group, 1.7% (n = 1). One possible explanation for the different results noted with the PT system might be related to the different taper of the finishing instruments used in this system. The taper for finishing files used to clean the apical portion of the canals in the PT system were .07, .08 and .09 respectively. The taper of the files used to clean the apical portion of the root canals in the other two systems (K3 and PF) was .04. According to a study by Haikel,(13) taper was found to be a significant factor in determining fracture probability for files. The results of this study seem to suggest that these previous findings may well be true. Even though more files were broken in the PT group, the percentage was not found to be statistically significant when compared to the other two file groups.

When the percentage of distorted files in the three groups of this study were compared, PF files was shown to be more likely to distort than PT files ($p = .0079$). No other groups

showed statistically significant differences. The distortion of the PF files could be viewed clinically as a warning to the operator that the file is stressed and should be discarded. The PT group had the least number of files which distorted ($n = 2$) but, had the greatest number of files which broke ($n = 5$). The PT files tended to break without warning.

The typical distortion pattern of the different rotary systems was consistent within each system. The distortion with the PF system was typically seen as an unwinding of the file flutes. The K3 and the PT systems showed distortion as a bending of the file along its axis. The bending distortion in the latter two groups was more difficult to visualize than the unwinding.

A size #30 apical file diameter was selected because this was considered to be a typical final file size for instrumenting the small, curved canals of maxillary and mandibular molars. It can be argued that using a smaller final apical file size might be safer in the canals of severely curved molar roots. Haikel et al. (13) found this to be true. However, in the present study a size #20/.04 K3 file, a size #25/.04 PF file and a PT S2 file all broke in a canal. All files, regardless of size, should be used with caution when being introduced into the small, severely curved canals of molars.

The number of files needed to clean the 15 canals in each group to an apical size of #30 varied with each system. The least number of files used was for the K3 system ($N=48$) followed by the PF system ($N=59$) and finally the PT system ($N=84$). Sizes #30 and #25 of the K3 files tended to reach the working length without the need to instrument with the size #20 file or size #15 file. The protocol for the PT instrumentation requires that all files be used to create an apical file size of #30 because this system uses a crown down

approach with its shaping files and then uses a step-back approach for its finishing files. The K3 and ProFile system use only a crown down approach.

Severely curved roots of molars were used in this study to simulate the clinical conditions under which the manufacturer (6) of the PT files claim their files are designed to work. The advantage of this model is that the files would cut dentin rather than acrylic. The disadvantages are that the diameter of the canals and angle of root curvature would not be the same for every sample. Whether the results would be the same in straight or moderately curved canals needs to be determined.

The rpm settings used for the electric motor was that recommended by the manufacturers. While it is true that one study (14) showed that a lower setting of 150 r.p.m. was desirable to decrease file distortion and separation, another (15) has shown that a higher rpm of 350 r.p.m. increased efficiency without file separation or distortion.

The torque controlled electric motor was used at a setting of 40 Ncm. This Air Technika motor has a preprogrammed rpm and torque setting for the PT system. This was the determining factor in setting the torque at 40 Ncm for all systems. Even with a torque control motor, breakage and distortion occurred with all three instrument systems.

The amount of breakage in this study was higher than that reported by others (9-11) and was most likely due to differences in the methodology. This study used curvatures much larger than that of the other studies, (10,11) thus higher breakage would be expected due to increased stresses placed on the files. This project was just one of several critical evaluations which needs to be done with these two new file systems. Additional research needs to be done to evaluate the degree of canal transportation, apical extrusion of

materials, shape of the canal after instrumentation, number of times these files can be safely used, if manufacturer specifications are actually produced, cutting efficiency and torsional/fatigue testing.

The results of this study revealed that the PF group had statistically significant more distortion than the PT group and that all three systems demonstrated some file distortion. All three systems had at least one file break during instrumentation of these severely curved canals but there were no significant differences when the three groups were compared statistically. It can be concluded from this study that great care should be taken when instrumenting severely curved canals with any of these three rotary systems.

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