Comparison Between ProTaper Gold and EdgeTaper Platinum NiTi Rotary Files After

Simulated Clinical Use

BY

SUNDEEP DHAWAN

B.A. University of Illinois at Chicago, 2006B.S. University of Illinois at Chicago, 2008D.D.S. University of Illinois at Chicago, 2010

THESIS

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Thesis Committee

Satish Alapati, BDS, MS, PhD, Chair, Advisor Bradford R. Johnson, DDS, MHPE James K. Bahcall, DDS, MS

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
A _f	Austenite Finish Temperature
A _s	Austenite Start Temperature
CBCT	Cone Beam Computed Tomography
ETP	EdgeTaper Platinum
F1	Finisher 1 File
F2	Finisher 2 File
M _f	Martensite Finish Temperature
MR	Martensite Reorientation
Ms	Martensite Start Temperature
NaOCl	Sodium Hypochlorite
NiTi	Nickel-Titanium
PTG	ProTaper Gold
SD	Standard Deviation
SE	Superelasticity
SIM	Stress-Induced Martensite
SS	Stainless Steel
Sx	Shaper X File
S1	Shaper 1 File
S2	Shaper 2 File

- F1 Finishing 1 File
- F2 Finishing 2 File
- TFF Torsional Force to Fracture

1 INTRODUCTION

1.1 Background

Mechanical preparation of the root canal space is an important part in obtaining successful root canal therapy. Mechanical preparation via manual and rotary instrumentation is intended to remove tissue, infected tooth structure, debris, and bacterial contents of the root canal. The subsequent goal of root canal therapy is to obturate the cleaned and disinfected root canals. Initially, to complete the mechanical preparation phase of root canal therapy, stainless steel hand instruments were introduced into the root canals and were used to ream out canals. Stainless steel files are rigid and are known to create potential complications in root canal therapies. Larger stainless steel files often used in the later portion of the mechanical debridement phase could create apical ledges, zips, and elbows (Weine). These iatrogenic errors would often compromise the apical anatomy in root canals, which could lead to difficulty in obturation, a decreased ability to remove tissue from the critical apical portion of the root canal, and potentially decreased outcomes. Many techniques were employed to avoid these early mishaps, including Abou-Rass' anti-curvature filing method, which advocated curving stainless steel files and putting pressure against the outer portion of the roots curvature. This subsequently would avoid strip perforations and elbow formation. Weine described a method in which the outer flutes of a stainless steel hand file could be removed so the outer portion would be non cutting avoiding elbow formation in the apical anatomy. Unfortunately, this method did not effectively clean and shape root canals.

In 1988 Walia et al. developed a novel instrument for the shaping of root canals. The material was made of 508 Nitinol and possessed characteristics that were beneficial for endodontics. This novel nickel titanium alloy (NiTi) possessed unique characteristics such as superelasticity (SE), which is the ability of NiTi to be reversibly deformed up to 8% and return to its original characteristics. The high flexibility of NiTi endodontic instruments comes from the combination of its inherent low elastic modulus and superelasticity (Zhou). NiTi also develops other interesting characteristics upon heat treatment. In certain cases, when NiTi is subject thermomechanical changes it can develop a quality known as shape memory. This is defined as the ability of NiTi to be deformed when it undergoes a strain and then return back to its original for after heating again (Zhou). In clinical practice, if a file is deformed and it possesses the shape memory ability, it should return to its normal state after sterilization.

One all too common phenomenon that happens with both stainless steel and NiTi instruments is file separation. File separation occurs when an endodontic file breaks off in the canal due to increased stresses placed on the file. File separation occurs mainly by two methods: torsional stress and cyclic fatigue (Sattapan). Torsional stress on a file can occur when the tip of the instrument binds in the canal, as the motor continues to spin causing file separation. Cyclic fatigue can occur when a file is freely rotating in a curved canal and separates around the curve. This happens around the point of maximum

flexure (Bahcall). Spili et al. found that file separation during root canal therapy decreases prognosis up to 5-7%. For this main reason, it is imperative to avoid iatrogenic file separation.

1.2 Significance of study

Mechanical debridement of the root canal system is possibly the most important phase of root canal treatment (Schilder). If the appropriate amount of tissue, debris, and bacterial remnants are not removed from the root canal system, there is a higher incidence of decreased outcomes (Schilder). Irrigant placement in order to remove this tissue and debris is dependent on instrumentation. Irrigant delivery to the critical apical portion of the root canal is directly dependent on the size of the mechanical preparation (Haapasalo). Canal obturation is also largely dependent on debridement of the root canal, without thorough mechanical and chemical debridement the root canal obturation will be negatively affected (Schilder). latrogenic file separation occurs in approximately 5.1% of cases (Alapati). It has been postulated that file separation can lead to decreased outcomes. If a file is removed outcomes could be restored, however excessive dentin removal in order to remove the file could negate any positive benefit. Spili et al. found that a retained instrument in a completed root canal treatment could increase the failure rate up to 7%. The endodontic literature has many papers on file separation occurring due to cyclic fatigue, and the literature is lacking quality papers on file separation due to torsional stress (Bahcall). The importance of the subsequent study is to review the effect of thermomechanical changes to endodontic files and see how these changes effect file separation due to torsional stress.

1.3 Specific Aims

The objective of this study is to compare Torsional Force to Fracture (TFF) and Angle of Rotation to Fracture of EdgeTaper Platinum (ETP) and ProTaper Gold (PTG) Nickel-Titanium (NiTi) rotary instruments in as received condition, and after 1 and 3 simulated clinical uses.

1.4 Hypothesis

H(o): The null hypothesis is that there is no significant difference in the Torsional Force to Fracture (TFF) and Angle of Rotation to Fracture between Edge Taper Platinum (ETP) and Protaper Gold (PTG) endodontic rotary files in an as-received condition and after 1 and 3 clinically simulated usages.

2 REVIEW OF LITERATURE

2.1 Historical Overview of Endodontic files

For a long portion of time hand instrumentation was the gold standard for the mechanical preparation of root canals, this is due to multiple reasons, but most importantly a tactile feel is imperative when traversing complicated apical anatomy. In some instances, stainless steel instruments are considered superior to other available instruments due to the fact that stainless steel instruments blend strength with flexibility, especially in smaller diameter sizes. For instance, a root canal with a severe 90-degree curvature is more prudently instrumented with stainless steel hand files when compared to engine driven rotary files, as the clinician can decrease iatrogenic complications when using stainless steel hand files in this situation. If NiTi engine drive files are used too quickly around a severe curve instrument separation is likely to occur via cyclic fatigue.

Currently, there are numerous stainless steel type instruments clinicians employ when completing root canal therapy. Depending on the function required clinicians can choose from multiple hand instruments in their armamentarium. Although clinicians use stainless steel reamers, Hedstrom and k files, this discussion will be limited to K files which are intended for mechanical debridement of root canal systems. Typically, root canals are hand instrumented in most all situations to at least a size 10 or 15 hand file initially. This process is to create a guide path for subsequent rotary engine driven mechanical preparation. Stainless steel hand files come in many different variations. They were originally developed by Kerr manufacturing. Over the years K files have been made with square, triangular, and rhomboid cross sections. The most commonly used original K type files are triangular in cross-section which adds to its flexibility (Roane). Original stainless steel K type triangular cross-sectioned files are the most flexible stainless steel hand instrument. These files range in size 6 to 15 and sizes correspond to dip diameter, per ISO guidelines.

C type stainless steel files are the next stiffer version of the triangular cross-sectioned stainless steel hand files. C files are more stiff than traditional K files because C files possess a stiffer core metal than K files. C files only come in size 6 through 15 because after size 15 the difference in flexibility and strength is negligible between the stainless steel metal variations. These C files are more often used for negotiation of more difficult cases, and are the hand files most often employed by endodontists. Finally, the third type of stainless steel hand files are the Ready Steel[™] hand files by Dentsply. These files are the stiffest stainless steel hand file produced today. They are triangular in cross section as well and formed from a core steel that is more rigid than C files. As these files are often used to negotiate calcified canals and create guide path in difficult retreatment cases. The Ready Steel hand files come in sizes up to 15 as well. More often than not, the clinician will choose the C type stainless steel hand file, as this file is a good blend of rigidity and flexibility.

The blend of rigidity and flexibility is an important characteristic to keep in mind when choosing hand files. Hand files should be used when tactile sensation is necessary. This is often the case when negotiating calcified and tortuous canals, or when bypassing iatrogenic errors such as ledges. Due to the increased stiffness with increasing sizes, hand instrumentation with larger

stainless steel files would often lead to increased ledge formation, apical elbow formation, and apical transportation. These iatrogenic errors lead to decreased outcomes (Weine). Hence why they are often used only to create a glide path in current clinical situations. Unfortunately, there is no way to avoid these iatrogenic errors with stainless steel hand files as their inherent rigidity causes them to straighten in all curved canals. Since most root canals are curved, this error was seen quite often. When the instrument straightened under force in the curved canal, the tendency was for the instrument to cut dentin that did not follow the pulp remnants, thus leading to remaining tissue, which then could lead to decreased outcomes.

Many clinicians attempted to solve these errors, some of the more prominent examples included the Anti-Curvature Filing Technique, as employed by Abou-Rass. This technique promoted the idea of filing with hand pressure away from the curvature, which theoretically would stop the file from straightening, however thoughtful in theory, this technique did not solve the iatrogenic problems created by large stainless steel files, and itself added to increased dentin removal along the lateral mid-root area. The other technique employed by many clinicians was developed by Roane, and was coined The Balanced-Force Technique. This technique employed the use of small counterclockwise and clockwise rotations in concert to ream a file down the canal. The technique advocated using pressure in conjunction with the file size, where a small file should receive much less pressure than a big file. This is the type of technique many endodontists still employ today in order to negotiate tough canals. Unfortunately, this technique did not solve the iatrogenic complications described by Weine when larger stainless steel hand files were used, but it did help clinicians navigate small canals with small instruments, thus it is still a popular technique amongst clinicians today.

Overall, stainless steel hand files and the techniques used with them are pivotal in mechanical debridement of root canals. It is standard practice, to this day, to use small stainless steel hand files to create a guide path when initially negotiating canals. Unfortunately, larger size stainless steel hand files often create iatrogenic errors, and because of this, the development of newer materials and instrumentation methods were required. Engine driven rotary Nickel Titanium (NiTi) files are the gold standard in endodontics now to mechanically prepare and debride root canals after initial guide path management

2.2 Nickel Titanium Rotary Instruments

2.2.1 Properties and phases

Nickel-Titanium is an alloy that has been used in dentistry for over 30 years. Initially, it was used in orthodontics to wire brackets together until Walia introduced NiTi to endodontics in 1988. NiTi is an alloy containing 56% nickel and 44 % titanium. This leads to an equiatomic ratio of each metal in the alloy (Shen). The equiatomic ratio of nickel and titanium in NiTi alloy gives the structure of NiTi many unique characteristics. These characteristics are only found in those variants of the alloy that are forged with the 1:1 ratio of nickel and titanium (Zhou). One unique characteristic Niti alloy possesses is superelasticity. This is defined as the ability of NiTi alloy to elastically deform up to 8% and then return to its normal state (Zhou). If NiTi is subject to strain over 8%, it will plastically deform. This is in contrast to traditional stainless steel, which can only deform up to 1% before undergoing plastic deformation (Shen). Walia found that, Nitinol, when shaped to the same size and dimensions of a size 15 stainless steel file Nitinol possessed two to three times more bending and torsional flexibility. This is ideal for mechanical debridement, as the rigidity of stainless steel files was found to create iatrogenic complications. He also found that Nitinol files of the same size tended to separate less than their stainless steel counterparts. One possibly negative outcome of Walia's investigations into NiTi was that files made from NiTi tended not to hold a pre curve, however this is negligible as the NiTi files are more flexible and tend to stay centered in the root canal more so than stainless steel.

NiTi can be present in three different microstructural phases. These phases are: austenite, martensite, and the R-phase (Shen). Niti's ability to elastically deform up to 8% is a characteristic of its unique microstructural crystalline phase. The alloy's ability to transform phases based on stress, heat, and strain are the primary reason for its superior performance as an endodontic instrument (Zhou). Changing the alloys temperature will result in phase transformation, and at higher temperatures more austentite is present in the alloy. Once heated to a more austenitic phase, NiTi will take on its superelastic tendency. Figure 1 shows that superelasticity takes place at the austenite finish temperature (A_f) which is roughly at body temperature. As NiTi Cools, it loses its austenite microcrystalline structure and converts to martensite. Martensitic nickel titanium does not possess the ability of being superelastic, and tends to plastically deform easier under stress (Hargreaves). Martensitic NiTi possesses the ability of shape memory, though. Which is the alloy's ability to be plastically deformed and return to its normal state and recover from being deformed after heating (Zhou). Figure 2 is a

schematic explaining the phase changes of NiTi in response to heating, cooling, and strain. Once austenitic NiTi is cooled, the alloy takes on a phase called twinned martensite. This phase possesses the shape memory effect and is dramatically more flexible than austenitic NiTi. When stress is applied to this phase of the alloy, it deforms much easier. Once deformed it must be heated again and upon heating to approximately 37 degrees Celsius it will return to a non deformed austenitic structure.

The stress strain curve of NiTi (Figure 3) possesses eight stages. These stages progress from the least amount of strain on the alloy to the most strain on alloy. The first stage is the elastic deformation stage of austenite. This stage is characterized by a low strain on the alloy and once the strain is removed, the alloy will return to its normal state. Second, is the stress plateau related to the transformation from austenite to the R-phase. The third stage is the elastic deformation of the R-phase. The fourth stage is the SIM (stress induced martensite) stage, where the alloy is changing from the R-phase to the martensitic phase. Stage five is the elastic deformation stage of martensite, this stage is the progression of more stress and strain being applied to the alloy. In this stage martensite is elastically deformed and will return to its normal martensitic orientation if the stress is removed. Stage six is the martensitic reorientation (MR) phase. Stage seven is the uniform non-linear deformation stage of reoriented martensite and stage eight is the plastic deformation stage of reoriented martensite. Stages six, seven, and eight are the phases in which the stress and strain applied to NiTi alloy are increasing in an almost directly proportional ratio. Progression from stage six to eight will eventually lead to alloy failure (Zhou). Obviously, as stress increases on the alloy its tendency

to go towards plastic deformation will increase. Stage four, or the SIM phase is particularly interesting. When austenitic NiTi is put under stress the alloy converts to its martensitic phase. This phase change allows NiTi to undergo more stress and be more elastic than its austenite phase. This is advantageous in endodontics as files are constantly undergoing increased stress when mechanically debriding root canals, and when the NiTi alloy is in a more martensitic composition, file separation tendencies decrease (Zhou). It is of note to remember that superelasticity is associated with the SIM stage, while shape memory is associated with the MR stage (Zhou).

The R phase of nickel titanium is also interesting as it possesses characteristics of both the austenitic and martensitic phases. The R-phases can exhibit both superelasticity and shape memory. The R-phases is present in the second stage of the stress strain curve, which is known as the transformation of austenite to R-phase. The R-phase microstructure is in the form of a rhombohedral design and due to its unique ability to possess both shape memory and superelasticity it has garnered interest for future endodontic file designs. The R-phase of NiTi can be induced by temperature or strain, and at this time, design is focusing on the heat treatment of austenite NiTi in order to produce files that are present in the R-phase.



FIGURE 1. Superelastic Behavior of Nickel-Titanium. Temperature (Hargreaves et al. 2016, Chapter 6 pg. 222)



FIGURE 2. Superelastic Behavior of Nickel-Titanium. Strain (Hargreaves et al. 2016, Chapter 6 pg. 222)



FIGURE 3. Stress-Strain Curve of Nickel-Titanium. SIM: Stress-Induced Martensite MR: Martensite Re-Orientation (Zhou et al. 2013)

2.2.2 Alterations of Nickel-Titanium

In recent instrument advances the primary goal was to increase elasticity and decrease the separation, apical ledging and zipping tendencies of rotary NiTi instruments, all while maintaining cutting efficiency and NiTi's inherent ability of staying centered in the root canal system. Although NiTi has been proven to be more efficient and has a decreased tendency to ledge or zip the apical portions of root canals when compared to stainless steel, the risk is still present and these iatrogenic events will subsequently decrease prognosis (Panitvisai). The focus of research and development with NiTi in the recent past has been eliciting these wanted changes in NiTi via thermomechanical processing. As reported by Zhou, the differences in

mechanical properties between NiTi endodontic files lie in the properties of the phase that exist in the alloy, which are determined by the phase transformation temperatures. This is especially interesting, as manufacturers can develop proprietary heat treatment protocols to develop files that possess unique characteristics, which could potentially decrease iatrogenic events thus increasing outcomes. Alapati et al found, in 2009, that the superelasticity of austenitic NiTi was maintained when the alloy was subjected to heat treatments of NiTi up to 850 °C, over this temperature, however the alloy lost its superelastic behavior. An interesting outcome of this study also showed that when the alloy was heat treated at higher temperatures ranging from 400 °C to 600°C the A_f increased to 45-50°C, well above human normal body temperature. This subsequently allows for the alloy to maintain its austenitic phase longer than perhaps warranted, and showed that for future development, heat treatments at lower temperatures are necessary to increase the martensitic phase of NiTi, which subsequently can provide increased elasticity.

Another interesting alteration of NiTi is the process of electropolishing NiTi in order to remove surface defects inherent in the alloys composition. The thought is that removing these surface defects and polishing the files will result in a smooth more efficient alloy. Brasselar's EndoSequence file is such a file. The EndoSequence file is primarily austenitic in composition and is not heat treated, however it is electropolished. Electropolishing is a process in which file is attached to an anode and cathode while being submerged in a bath of electrolytes. As an electrical current is passed through the anode and cathode, the instrument in coated with a protective film which reduces surface defects. The process is thought to increase corrosion resistance and surface characteristics (Gutmann, Gao). Electropolishing has been seen to increase cyclic and torsional stress to fracture in NiTi instruments (Gutmann, Gao).

2.3 ProTaper[®] Gold and EdgeTaper Platinum[™]

Tusla Dentsply has created a proprietary thermomechanical heat treatment that has been implemented on their ProTaper® series files. The original ProTaper® series files produced by Tulsa Dentsply are files with ISO tip sizes and a progressive taper. These original files are made from austenitic NiTi and have a convex triangular cross section, which is thought to stay well centered in the root canal system while increasing cutting efficiency when compared to other engine driven files. In the recent past, Tulsa has developed a proprietary heat treatment process which is purported to increase the flexibility of these files while maintaining the cutting efficiency. The proprietary heat treatment gives rise to a gold color and increased flexibility when compared to the original ProTaper® series files. ProTaper® Gold (PTG) files have the same dimensions and cross sections as their original series counterpart and were introduced as a new system to replace the ProTaper® original series. Due to the heat treatment, the files come out of the package with a slight curve, indicating they are more martensitic in composition.

EdgeEndo has created a file system that mimics ProTaper® Gold NiTi instruments in size and cross sectional design. The premise of their EdgeTaper Platinum[™] (ETP) designed file system is to provide clinicians with the exact same file size and design while claiming even more flexibility and resistance to fatigue than ProTaper® Gold. EdgeEndo's premise is to provide

clinicians with a system of NiTi files that costs one half the amount as ProTaper® Gold, while optimizing performance. EdgeEndo claims that their proprietary heat treatment on their EdgeTaper PlatinumTM files can further withstand cyclic and torsional stress to fracture when compared to ProTaper® Gold. The thermomechanical processing completed on EdgeTaper PlatinumTM files leads to an uneven gold-purple-green color. When received out of the package EdgeTaper PlatinumTM files present with a curve as well, indicating a more martensitic composition. To date there has been no published data comparing these two systems.

2.4 Instrument Failure process

A phenomenon that can occur with both stainless steel and NiTi instruments is file separation. File separation occurs when an endodontic file breaks in the canal due to increased stresses placed on the file. This process occurs by two methods: torsional stress and cyclic fatigue (Sattapan). Torsional stress is described as when the tip of a rotating instrument binds into the canal wall and as the motor continues to spin, the bound instrument separates. Cyclic fatigue is when a file is continuously rotating in a curved canal and separates around the curve. This happens around the point of maximum flexure (Sattapan, Bahcall). Spili et al. found that file separation during root canal therapy decreases prognosis up to 5-7%. Alapati found that overall, NiTi instrument separation occurred around 5.1% of the time. These statistics create a definite concern for endodontic practitioners. Stainless steel files have a tendency to unwind when they have undergone increased stress. This plastic deformation of stainless steel files is important to the clinician as it is an indicator for the clinician to discard the file. Austenitic NiTi files possess the capability of superelasticity, which is the ability to deform up to 8% and then return to its original shape when the stress is removed (Zhou). This tendency for NiTi files is an exceptional for the strength of NiTi, however removes the warning sign that a file is going to separate, which causes concern for clinicians. Fortunately, with the progression of thermomechanical processing of NiTi, when in the martensitic phase, the NiTi alloy tends to unwind. This process of unwinding is present in both ProTaper® Gold and EdgeTaper Platinum^{™.} Since files tend to separate from a combination of torsional and cyclic fatigue, it is imperative that clinicians have external cues to know their instruments are overworked and require discarding.

2.5 Torsional Stress Testing and the Torsiometer Machine

Torsional stress resistance to fracture is an important mechanism in understanding how NiTi files separate, and overall has not been described in the endodontic literature as much as cyclic fatigue resistance to fracture (Bahcall). In order to test torsional stress to fracture, a custom made Torsiometer Machine was developed (Sabri Dental Enterprises, Inc., Downers Grove, IL) (Figure 4). The machine is made up of two individual pieces, one testing apparatus and a mechanical value readout machine. Files at the shank end are locked into the testing apparatus with a custom jig at one end of the testing device. At the other end the device, the file tip is locked in at a measured length of 3 mm from the file tip. The device rotates at the file tip end at 2 revolutions per minute in a clockwise manner while stationary at the shank end. This allows the file to be twisted under a torsional load. Upon separation of the file, the free end disengages, stops rotating, and the torque value (g-cm) and angle of rotation (°) to fracture are computed and displayed on the readout machine.



FIGURE 4. Torsiometer Instrument. Testing apparatus appears in foreground while readout machine is present in the background.

3 MATERIALS AND METHODS

3.1 Overview

This *in vitro* study was conducted in the labs of Drs. Satish Alapati at the University of Illinois at Chicago College of Dentistry (801 S. Paulina St, Rooms 536 Chicago IL, 60612) by the primary investigator.

3.2 Study Design

Torsional stress resistance to fracture of ETP and PTG NiTi files was performed on 25-mm length files. Sizes SX, S1, S2, F1 and F2 files were used. ISO tip sizes for the files are as follows: Sx-.19 mm, S1-.185 mm, S2-.2 mm, F1-.2 mm, F2-.25 mm. All instruments have a variable progressive taper of which dimensions have not been made publically known. Taper ranges from 2- 8% and each file is in a continuous funnel shaped design with the more apical portion being smaller than its adjacent coronal portion. Files were subjected to the Torsiometer instrument in as-received condition, and after 1 and 3 simulated clinical uses. Each experimental group had 10 files, totaling 100 files per group, thus a total of 300 files were tested.

3.3 Endo-Bloc Instrumentation

PTG and ETP files were subjected to applicable simulated clinical use via clear resin endoblocs (Endo-training block A0177, DENTSPLY Maillefer, Ballaigues, Switzerland). Files were randomly selected to be in the as-received, 1 use, or 3 use group. Files in the as-received group were subjected to the Torsiometer instrument without any clinical simulation. And for the files allotted to the 3 use group, were made to reach working length 3 separate times in 3 separate endo-blocs (simulating three separate root canals). The endo-blocs presented with a canal 16 mm in length with a 30-degree apical curvature. The blocks were standardized initially to a size #15 SS K file at their working length of 16mm. This was done to simulate hand filing a canal before beginning rotary instrumentation and create a guide path for subsequent rotary instruments. The sequence of filing was: SX was set to ½ the working length and was used to open the orifice of the Endo-training block. Next S1, S2, F1, F2 were taken to working length via rotary instrumentation (Tulsa Dentsply Torque Control Motor model E3). The files were used in 3 passes with light apical pressure (4 grams), removed and cleaned with gauze soaked in alcohol, the blocks were recapitulated with irrigant between passes (1 mL 5.25% NaOCI) and a size 10/02 SS K file in between instruments. The canals were instrumented with the manufacturer's suggested torque and RPM setting for each individual file. The set of files in each experimental group were randomly allocated either to prepare one or three endo-blocs. Each file was coated with RC Prep[™] (Premier Hannover, Germany) prior to usage and 5.25% NaOCI (1mL) was used for irrigation after each rotary file was used.

After files were subjected to their clinical use capacity, they were further tested on the Torsiometer instrument. The torque value (g-cm) and angle of rotation (°) to fracture were recorded for all 300 instruments.



FIGURE 5. Schematic of testing methodology. Files were taken to WL as described either 1 or 3 times in separate endo-blocs, and then subjected to the torsiometer machine.

3.4 Statistical Analysis

GraphPad Prism software (GraphPad Software, La Jolla California USA) was used to analyze the collected data. Statistical significance was determined using ANOVA and Tukey-Kramer Post Hoc tests. Significance was set to p < 0.05. Data is presented as means \pm SE and considered significant for *P* < 0.05.

4 RESULTS

This *in vitro* study 300 total files were subjected to the Torsiometer instrument. 100 asreceived, 100 after 1 simulated clinical use, and 100 after 3 simulated clinical uses. 50 ETP and 50 PTG files were present in each experimental group. Mean values for TFF and angle of rotation to fracture are listed in tables 1-6 for each experimental group.

As Received PTG				
File Size	TFF +/- SD (g-cm)	Angle of Rotation +/-SD (°)		
<u>Sx</u>	30.7 +/- 13.29	320 +/- 67.8		
S1	26.5 +/- 6.72	519.6 +/- 137.3		
S2	65.5 +/- 18.73	368.8 +/- 53.27		
F1	121.9 +/- 31.15	329 +/- 43.98		
F2	197.7 +/- 49.11	373.8 +/- 90.73		

Table 1: Mean values for TFF and angle of rotation to fracture for PTG files in the asreceived group

As Received ETP			
File Size	TFF +/- SD (g-cm)	Angle of Rotation +/-SD (°)	
Sx	57.4 +/- 11.22	399.6+/-92.09	
S1	25.3 +/- 10.84	444.5 +/- 104.1	
S2	59.9 +/- 11.5	361.7 +/- 67.94	
F1	68.9 +/- 14.9	456.9 +/- 101.2	
F2	115.0 +/- 30.3	476 +/- 74.42	

Table 2: Mean values for TFF and angle of rotation to fracture for ETP files in the as

 received group

Single Use PTG			
File Size	TFF +/- SD (g-cm)	Angle of Rotation +/-SD (°)	
<u>Sx</u>	44.4 +/- 14.27	376.2 +/- 142.4	
S1	47.1 +/- 13.36	367.9 +/- 63.86	
S2	55.5 +/- 16.86	350.9 +/- 47.85	
F1	126.7 +/- 32.18	374.2 +/- 20.3	
F2	143.5 +/- 34.68	365.5 +/- 98.46	

Table 3: Mean values for TFF and angle of rotation to fracture for PTG files in the after single use group

Single Use ETP			
File Size	TFF +/- SD (g-cm)	Angle of Rotation +/-SD (°)	
Sx	32.0 +/- 17.06	251.9 +/- 99.48	
S1	29.6 +/- 9.22	330.5 +/- 96.16	
S2	44.0 +/- 19.35	322.4 +/- 66.13	
F1	107.4 +/- 31.95	390.8 +/- 54.14	
F2	144.1 +/- 47.55	383.4 +/- 52.68	

Table 4: Mean values for TFF and angle of rotation to fracture for ETP files in the after single use group

Three Use PTG			
File Size	TFF +/- SD (g-cm)	Angle of Rotation +/-SD (°)	
Sx	24.5 +/- 9.20	309.1 +/- 100.6	
S1	20.8 +/- 6.86	311.8 +/- 117.2	
S2	26.4 +/- 5.481	308.2 +/- 118.3	
F1	40.4 +/- 14.1	279.6 +/- 68.28	
F2	79.7 +/- 25.53	316.1 +/- 82.16	

Table 5: Mean values for TFF and angle of rotation to fracture for PTG files in the afterthree use group

Three Use ETP			
File Size	TFF +/- SD (g-cm)	Angle of Rotation +/-SD (°)	
Sx	35.3 +/- 8.138	416.6 +/- 119	
S1	22 +/- 7.846	276.4 +/- 84.44	
S2	40.5 +/- 12.55	400.1 +/- 120.7	
F1	54.5 +/- 21.06	513.1 +/- 176.9	
F2	66 +/- 29.62	493.6 +/- 210.7	

Table 6: Mean values for TFF and angle of rotation to fracture for ETP files in the afterthree use group

4.1 As-Received Condition Between Groups

When comparing between groups in the as received category there was a statistically

significant difference (p<0.05) in TFF, with PTG files F1 and F2 requiring more torque to fracture

than their ETP counterpart F1 and F2 files. There was no significant difference in TFF amongst

other files tested. (Figure 6)



Instrument Type [As-Recieved]

Figure 6. Graph comparing TFF in as-received condition.

When comparing angle of rotation to fracture between groups in the as received category there was a statistically significant difference (p<0.05) in angle to fracture with ETP Sx, F1, and F2 files gaining a larger angle of rotation to fracture when compared to their PTG counterparts. There was no significant difference in angle of rotation to fracture amongst other files tested. (Figure 7)



Figure 7. Graph comparing angle of rotation in as-received condition.

4.2 One Simulated Clinical Use Between Groups

There was no statistical significance (p>0.05) found when comparing TFF between groups

after 1 simulated clinical use for all files tested. (Figure 8)



Instrument Type [1-Use]

Figure 8. Graph comparing TFF after one simulated clinical use

When comparing angle of rotation to fracture between groups in the after single use category there was a statistically significant difference (p<0.05) in angle to fracture with the PTG Sx file gaining a larger angle of rotation to fracture when compared to its ETP counterpart. There was no significant difference in angle of rotation to fracture amongst other files tested. (Figure







4.3 Three Simulated Clinical Use Between Groups

There was no statistical significance (p>0.05) found when comparing TFF between groups

after 3 simulated clinical uses for all files tested. (Figure 10)



Figure 10. Graph comparing TFF after three simulated clinical uses

When comparing angle of rotation to fracture between groups in the after three clinical use category there was a statistically significant difference (p<0.05) in angle to fracture with the ETP SX, S2, F1, and F2 files file gaining a larger angle of rotation to fracture when compared to their PTG counterparts. (Figure 11). There was no significant difference in angle of rotation to fracture amongst the other files tested in this category.



Figure 11. Graph comparing angle of rotation to fracture after three simulated clinical uses

4.4 Torsional Force to Fracture Within Groups - ProTaper® Gold

A. As-Received/1 Use

There was no significant difference in TFF values when testing PTG files in the as-

received and after 1 single clinical use (p>.05).

B. 1 use/3 use

When comparing TFF values of PTG files after 1 and 3 simulated clinical uses, it was

found that TFF values were lower in all files tested in the after 3 clinical use groups. This

difference was significant (p<.05).

4.5 Torsional Force to Fracture Within Groups - EdgeTaper Platinum[™]

A. As-Received/1 Use

There was no significant difference in TFF values when testing ETP files in the asreceived and after 1 single clinical use (p>.05).

B. 1 use/3 use

When comparing TFF values of ETP files after 1 and 3 simulated clinical uses, it was found that TFF values were lower in all files tested in the after 3 clinical use groups. This difference was significant (p<.05).

4.6 Angle of Rotation to Fracture Within Groups - ProTaper® Gold

A. As-Received/1 Use

There was no significant difference in angle of rotation to fracture values when testing PTG files in the as-received and after 1 single clinical use (p>.05).

B. 1 use/3 use

When comparing angle of rotation values of PTG files after 1 and 3 simulated clinical uses, it was found that angle of rotation values was lower in Sx, F1, and F2 file types tested in the after 3 clinical use groups. This difference was significant (p<.05). There was no significant difference in angle of rotation to fracture amongst the other files tested in this category.

4.7 Angle of Rotation to Fracture Within Groups – EdgeTaper Platinum[™]

A. As-Received/1 Use

There was a significantly decreased angle of rotation to fracture found in the Sx file after 1 clinical use when compared to the as-received condition (p<.05).

B. 1 use/3 use

When comparing angle of rotation values of ETP files after 1 and 3 simulated clinical uses, it was found that angle of rotation values was lower in the F1 file type tested in the after 3 clinical use group. This difference was significant (p<.05). There was no significant difference in angle of rotation to fracture amongst the other files tested in this category.

5 **DISCUSSION**

In this *In Vitro* study, ProTaper[®] Gold and EdgeTaper PlatinumTM were compared in their torsional force to fracture and angle of rotation to fracture in as-received, and after 1 and 3 simulated use conditions.

This study focused on torsional stress resistance to fracture because it has not been widely studied in endodontic literature and is clinically relevant. Instrument separation has been known to be an iatrogenic cause of decreased outcomes in clinical practice (Panitvisai). Endodontic literature focuses primarily on cyclic fatigue, a phenomenon when an instrument will separate at the point of maximum flexure, usually around a curve or as the instrument navigates a complex root canal system (Bahcall). Bahcall states that instrument separation is a phenomenon that is caused by both cyclic fatigue and torsional stress, thus the interest of this study focusing on torsional stress. Torsional stress is when an instrument binds at the tip and the chuck of the instrument continues to rotate, allowing for the bound apical segment of the instrument to fracture from the freely rotation chuck end.

Another concerning aspect that clinicians must account for is the anatomy of the root canal system. Ordinarily, canal anatomy is assessed via two-dimensional radiography, as this modality was the only available one. In a standard two-dimensional radiograph, it is impossible to assess curvatures in the bucco-lingual direction. These types of curvatures are often very common and often very torturous with high radius of curves. It is likely that instruments can separate in these severe bucco-lingual oriented curvatures unbeknownst to clinicians, effectively reducing outcomes. As the radius of curve increases less revolutions of the instrument are required to produce instrument separation (Parashos). With the advent of cone beam computed tomography (CBCT), clinicians can now be aware of severe curvatures via a full 3-dimensional rendering of the tooth that is undergoing root canal therapy. When these curvatures are visualized in the sagittal or coronal sections of a 3-D scan, clinicians can be prudent with engine driven NiTi file usage in order to avoid catastrophic instrument failure.

In this study, files were tested for torsional mechanical properties per ISO 3630-1 guidelines by using a Torsiometer (Sabri Dental Enterprises, Inc, Downers Grove, IL). The results of this study generally conclude that there is no difference between groups in regard to torsional resistance to fracture, thus negating any claims made by either manufacturer. Empirically, however, during the study it was seen by the primary investigator that ETP files were heat treated to have more martensitic characteristics while PTG files did not have such an extensive heat treatment. In regards to angle of rotation to fracture, ETP files generally displayed an increase in angle of rotation to fracture. This is likely due to its more martensitic composition and more malleable characteristics. Gao et al found that a higher angle of rotation to fracture was associated with a more ductile alloy. When completing this study, it was noted that ETP files tended to unwind more often when compared to PTG files during bench top use. The unwinding of files was also correlated with increased angle of rotation to fracture. This is especially important because when unwound files were subjected to the torsiometer, the force required for separation was markedly lower when compared to a non plastically deformed instrument. The unwinding can be considered a "warning sign" for operators and indicate to operators to discard these unwound instruments to avoid any iatrogenic separation. Unfortunately, PTG files

did not unwind as often, thus no "warning sign" was seen. It was also seen that files with larger dimensions tended to have higher values of torque resistance and angle of rotation to fracture. This trend is clinically obvious as a larger file will tend to have more alloy in its core, thus making it stronger. This finding is clinically relevant as smaller files could tend to separate easier and thus more caution should be exercised with smaller tip diameter and lesser tapered files (Xu).

While performing this study, more iatrogenic complications were noted as files were used more often. In the 3 simulated clinical use category, apical ledges, transportation, and zipping were seen in the endo-blocs. More separation of files occurred in the apical curved portion of the simulated canal as well. This is thought to be due to the files being overworked and losing their cutting ability. In the 3 use category files were made to enlarge 3 separate canals, which is translated clinically to using the same file in a molar with 3 canals. Empirically, it was seen that when the file was used more than two times more effort was needed to get the file to working length, and this was seen for all files in both groups. This increased workload and increased effort led to iatrogenic complications as seen in figures 12 and 13.

Overall, what could be the most important finding of this study is the fact that in both groups ETP and PTG, significantly less torque was required to fracture files that were used 3 times. This result shows that multiple use of files is cautioned and could lead to increased iatrogenic separation and complications, leading to decreased outcomes. The outcomes of this study indicate to the operator to make good judgment calls regarding file usage. If the file has been cutting aggressively and working to get down tortuous calcified and curved canals, it may be prudent to discard files after a single use and use new files for each canal to avoid iatrogenic complications. Since there is no way to quantify how much stress or torque has been placed on a file used in a clinical setting, one must use good judgment and discard files when they are in doubt to avoid catastrophic instrument failure.



Figure 12. latrogenic complications of multiple file use. Left: Instrument separation in the apical portion of canal. Right: Severe apical transportation of simulated canal.





Figure 13. latrogenic complication of multiple file use. Top: unwound instrument, Bottom: separated instrument.

6 CLINICAL RELEVANCE AND LIMITATIONS

Although this study was performed on the bench top, every effort was made to simulate clinical conditions, from using endo-blocs made of acrylic which possesses a similar hardness to that of natural dentin, to using full strength sodium hypochlorite for irrigation between file preparations and using RC Prep[™] as a lubricating medium. A study involving separated instruments would never be clinically tested, and thus bench top research in this area is the only method to test files and gain insight on how different heat treatment and alloy composition effects NiTi instruments.

Overall, the main outcome of this study that correlates clinically is that after a single use torsional resistance to fracture decreases significantly. This should caution operators to limit file use to single use. Since in clinical situations the amount of torque a file is undertaking cannot be quantified, it is up to the clinician to use better judgment and discard files that have had an increased workload and use new files when deemed appropriate to avoid instrument separation. Additionally, a pecking motion as suggested by Dederich should be employed when traversing down a canal to avoid progressive binding of the instrument. An outcome that can be transferred clinically with a good degree of certainty is the discarding of unwound files. Throughout this study, files that were used more than once had a tendency to unwind, especially ETP files, and once subjected to the torsiometer, these files had distinctly decreased torque to fracture levels. The unwinding of files can be a "warning sign" to clinicians, indicating that these files should be discarded immediately. Additionally, over used files tended to apically ledge and transport the simulated root canals, which if happens clinically can create adverse outcomes (Weine)

7 FUTURE RESEARCH DIRECTIONS

Future research should focus on sterilizing files in between uses and testing files after sterilizing to see if the sterilization process has any negative effects on torsional resistance to fracture. This would be particularly interesting in those files that possess NiTi's unique shape memory effect, such as ETP files. Overall, the endodontic literature is lacking on well designed studies comparing torsional or cyclic fatigue resistance to fracture of NiTi file usage after sterilization.

Another interesting research idea would be to take scanning electron micrograph photos of the files after they have been fractured and to measure the fractured segments of each file to determine if file fracture consistently happens in any one given area of a file or if file fracture happens at random areas propagated by possible surface defects in the alloy.

8 CONCLUSIONS

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In conclusion, this study found that generally, between groups there was no significant difference (p>0.05) in TFF when comparing ETP and PTG files. Meaning that both file systems possessed similar torque to fracture values. In regards to angle of rotation to failure, it was as a generalized trend that between groups, ETP files tended to have an increased angle of rotation to fracture value when compared to PTG.

Moreover, the most relevant conclusion of this study was that within both groups, it was seen that TFF decreased significantly after 1 simulated clinical use (p<0.05). The implication of this finding is that once a file has been used once, its torsional strength decreases significantly, and overusing files will may lead to catastrophic instrument failure.

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