Comparison between a Novel Nickel-Titanium Alloy and 508 Nitinol on the Cyclic Fatigue Life of ProFile 25/.04 Rotary Instruments

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Abstract

ProFile® 25/.04 instruments manufactured from three variants of Nitinol (1A, 1B & 2AS) were compared with stock production ProFile 25/.04 instruments and fatigue tested to failure. Cyclic fatigue testing was performed by rotating instruments at 300 RPM in a simulated steel root canal with 5 mm radius and 90° curve until instrument separation. Time to failure was recorded. Torsion testing was undertaken by clamping 3 mm of each instrument tip between brass plates and rotating it at 2 RPM until failure. Data were recorded for torque and angle at fracture. Statistical differences were found with nickel-titanium variant 1B (M-Wire™ NiTi) nearly 400% more resistant to cyclic fatigue than stock ProFile 25/.04 ($P < .001$). Torsion testing found differences between all 508 Nitinol groups and M-Wire™ NiTi ($P < .001$). ProFile 25/.04 files manufactured from M-Wire™ NiTi have significantly greater resistance to cyclic fatigue while maintaining comparable torsional properties. *(J Endod 2008;34:1406–1409)*

Key Words

Canal preparation, cyclic fatigue, M-Wire NiTi, nickel titanium, rotary endodontics

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Rotary endodontic instruments manufactured from the pseudoelastic alloy nickel-titanium (Nitinol 55) have revolutionized the biomechanical preparation of root canal systems. Civjan et al. (1) envisioned the use of nickel-titanium alloys in dentistry, but Walia et al. (2) are credited with the creation of a K-bladed file from nickel-titanium orthodontic arch wires machined to produce a fluted instrument. The hand files manufactured from nickel-titanium exhibited significantly greater elasticity and superior resistance to torsional fracture compared with stainless steel files, along with the memory effect that returned a Nitinol file from a bending moment of 90° to its original shape (2). Clinicians rapidly adopted rotary nickel-titanium instruments, with their increased flexibility and strength, when files with tapers greater than the ISO standard .02 taper were introduced (ProFile Series 29; Dentsply Tulsa Dental Specialties, Tulsa, OK) (3). Crown-down preparation techniques, in combination with nickel-titanium rotary files of greater taper, enabled predictable and expeditious tapered canal preparations while minimizing transportation and iatrogenic errors (4–8). The commercial success of the U-blade design of the ProFile rotary instruments led to the introduction of other nickel-titanium files of different designs and tapers.

Nickel-titanium instruments are considerably more flexible and resistant to cyclic fatigue than stainless steel, but they possess only comparable torque strength. The perception of high torque strength comes from the greater mass of metal found in the larger nickel-titanium tapers, whereas, in contrast, a larger metal volume results in earlier cyclic fatigue failure (9, 10). For instance, ProFile 25/.02 has the lowest torque strength, decreased metal mass, and the highest resistance to cyclic fatigue, whereas a ProFile 25/.06 has highest torque strength, greatest metal mass, and the least resistance to cyclic fatigue. ProFile 25/.04 instruments are found in a range between these two tapers (11). Although the advantages over stainless steel instruments are many, separation of nickel-titanium instruments still occurs, especially after extended use (12). Separation of rotary nickel-titanium instruments takes place by static torsional, dynamic torsional, or cyclic fatigue. Fractographic analysis of discarded instruments shows the mechanism of instrument fracture (12); cyclic fatigue occurs unexpectedly and without any visible signs of permanent deformation across transgranular boundaries, and torsional failure results in unwinding of the instrument before separation, seen as a dimpled rupture fracture surface, which is a characteristic of ductile fracture (13).

An instrument rotating freely in a curved canal is subjected to compression and elongation simultaneously, resulting in work hardening and metal fatigue and, ultimately, instrument separation. This will occur at the midpoint of the greatest curvature of the canal and is a function of the number of rotations the file undergoes (14). The factors determining cyclic fatigue including radius of curve, degree of canal curvature, instrument diameter, taper of instrument, number of times used, operator experience, and instrument mass have been well researched (11, 14–20). Torsional fracture occurs when the tip of the rotating instrument binds in the canal while the motor continues to rotate. The elastic limit of the file is exceeded in the absence of torque control settings on the motor, causing plastic deformation and, subsequently, fracture. Thus, an instrument needs to be resistant to cyclic fatigue to have sufficient flexibility to permit the preparation of curved systems but also has to have sufficient torque strength so instrument separation does not occur should the file bind at its tip. ProTaper (Dentsply Maillefer, Ballaigues, Switzerland) possesses exceptional torque strength, which as a result has diminished resistance to cyclic fatigue and a marked decrease in flexibility. A recent investigation found that ProTaper instruments altered the canal shape and recommended that more flexible instruments be used to prepare the apical portion in curved canals (21). To increase the flexibility and the resistance to cyclic fatigue and overcome the incidence of separation, a variant of the existing nickel-titanium alloy could be used in the ProTaper system and for rotary instruments in general.

A recent study using atomic force microscopy graphically showed a significant difference in surface irregularities as a consequence of machining differences between various nickel-titanium instrument manufacturers (22). The samples tested indicated that the files with the lowest to highest vertical depth profile were NitiFlex (Dentsply Maillefer), GT hand files and GT rotary files (Dentsply Tulsa Dental Specialties), and Quantec rotary files (SybronEndo, Orange, CA), respectively. The base of these surface irregularities acts as a stress inducer because an applied load will be concentrated at one point or area, instead of being spread over a smooth surface. A scanning electron microscopic study of discarded nickel-titanium instruments found widened machining groove cracks containing dentinal debris, postulating that dentin chips wedged into the surface defect resulted in instrument fracture (13). The investigators recommended that manufacturers use processes that minimize the production of surface cracks in addition to nickel-titanium alloys that improve fracture toughness (23).

The ProFile series of instruments are manufactured from the most commercially pure form of Nitinol (Nitinol SE508) by Nitinol Devices and Components Inc (Fremont, CA) for instruments produced in the United States and EuroFlex GmbH (Pforzheim, Germany) for those produced in Europe. The raw wire undergoes a series of cold annealing to draw the wire to the correct cross-sectional diameter followed by thermocycling while under strain (24). Once these treatments are complete, the wire blanks are manufactured into rotary endodontic instruments through a grinding process. The nickel component of 508 Nitinol is 55.8 wt%, with titanium accounting for the balance. Instruments and hardware manufactured from 508 Nitinol are used in many branches of medicine, including orthopedics for joint replacement and reconstruction and as cardiovascular stents that alter their size on introduction into the higher temperatures of the human body.

Recently, a replacement for the current nickel-titanium alloy used in endodontic instruments has been developed (25). The novel variant nickel-titanium alloy is composed of 508 Nitinol, which has undergone a proprietary method of treatment, comprised of drawing the raw wire under specific tension and heat treatments at various temperatures resulting in a material that includes some portion in both the martensitic and the premartensitic R phase while maintaining a pseudoelastic state.

The goal of this study was to assess the resistance to cyclic and torsional fatigue of ProFile 25/.04 rotary endodontic instruments made from 508 Nitinol alloy or an experimental alloy (M-Wire NiTi, Dentsply Tulsa Dental Specialties). The null hypothesis is that both cyclic and torsional fatigue will occur equally in rotary instruments manufactured from any alloy.

Materials and Methods

Wire blanks were created from three different lots of variant nickel-titanium that had been subjected to different thermocycling programs and strain, representing three different experimental groups (1B, 1A, and 2AS). Stock production wire that had not undergone proprietary processing was used as the control because this is currently used to manufacture commercially available ProFile rotary instruments. The wire blanks were machined to produce ProFile 25/.04 rotary instruments. The identical file design was machined at the Dentsply Maillefer facility by using a different source of raw Nitinol alloy (EuroFlex GmbH). The European samples were divided into two groups, with one group having undergone an additional surface electropolishing treatment. A total of 360 ProFile 25/.04 rotary endodontic instruments were used for testing resistance to cyclic fatigue (n = 180), and torsional fatigue (n = 180).

Experiment A (Cyclic Fatigue, n = 30/Group)

The cyclic fatigue testing protocol has been described previously and was reproduced throughout the experimental period (26). The file rotated freely in a grooved tempered steel assembly that replicated a 90° curve of a 5-mm radius. Two flutes at the tip of the instrument were visualized as it rotated just beyond the curve and was monitored on a magnified display. The handle of each instrument was inserted into an 8:1 gear reduction handpiece (TUL-8M, Dentsply Tulsa Dental Specialties) and attached to the assembly mounted on a laboratory bench. The handpiece was calibrated with the electric motor and oiled before each group. The tempered steel jig was lubricated with a silicone spray between groups. The torque control was set to maximum and 300 RPM (Aseptico Endo DTC; Aseptico, Woodinville, WA) before it was activated, and time to instrument separation was recorded to an accuracy of 0.1 seconds. Data were interpreted by using a Welch analysis of variance, with a Dunnet T3 post hoc test applied to all pair-wise comparisons between instrument alloys.

Experiment B (Torsional Fatigue, n = 30/Group)

Reproduction of the testing for torsional fatigue of instruments to ANSI/ADA specification no. 28 was performed similarly to previous investigators (27), providing data for torque at fracture (inch ounces) and angle of rotation at fracture. The handle of each instrument was removed and the shaft end fastened into a chuck controlled by a digital display showing degrees rotation preprogrammed to rotate at 2 RPM (Twist Test Unit; Mountain View Specialties, Mountain View, CA). The apical 3 mm of the file was clamped between two 3-mm thick soft brass inserts that permitted a connection through a conductive plate connected to a digital torque meter memocouple (MGT50Z; Mark-10 Corp, Long Island, NY) forming a break detection circuit. Only the apical 3 mm of each file was clamped consistently because this has been shown to be a source of variability (27), and the brass inserts were replaced between each experimental group. Each instrument was rotated until fracture occurred, recording torque and rotations to failure. Data were analyzed by using an analysis of covariance in which the degree of rotation was used as the covariate. All pair-wise comparisons were conducted by using a Tukey HSD test.

The examiner was blind to the type of alloy being tested in all experimental procedures, and data were recorded on a coded score sheet, with the code being broken at the end of testing all samples. Data were entered into a spreadsheet (Excel 2004; Microsoft, Redmond, WA) and analyzed by using StatView (SAS Institute Inc, Cary, NC).

Results

The mean and standard deviations for cyclic fatigue are shown in Table 1 and illustrated as a box plot (Figure 1). Differences between the groups were statistically significant ($p < 0.001$) except for the Dentsply Maillefer–produced samples, where there were no differences between the lifespan of electropolished and nonelectropolished instruments under cyclic fatigue testing.

Adjusting for the effect of rotation, the mean torque at fracture (Table 2) was found to be statistically significant between Dentsply Tulsa Dental, Maillefer, and variant nickel-titanium samples ($p < 0.001$). Variants 2AS and 1A and 2AS and 1B (M-Wire NiTi) groups were not significantly different.

TABLE 1. Cyclic Fatigue (in Seconds) Mean, SD, and Minimum and Maximum Values

Instrument	Mean	SD	Minimum	Maximum					
Variant NiTi 1B (lot 100416-1B, M-Wire)	670.43	117.27	449.02	903.77	A				
Variant NiTi 1A (lot 97670-1A)	578.38	109.76	364.86	783.66		B			
Maillefer electropolished	304.42	67.92	279.06	329.79			C		
Maillefer brushed	299.92	126.81	252.56	347.27			C		
Variant NiTi 2AS (lot 104010-2AS)	228.84	34.99	137.26	297.34				D	
Dentsply Tulsa Dental 25/.04	135.91	24.68	95.64	180.55					E

Levels not connected by same letter are significantly different.

Discussion

The aim of this study was to eliminate file design as a variable and assess the cyclic and torsional fatigue of a new nickel-titanium alloy, by using raw sources of wire blanks that were machined to a standard 25/.04 instrument design (ProFile 25/.04, Dentsply Tulsa Dental Specialties). This is the first study to compare rotary nickel-titanium instruments manufactured to the same file design but produced from three different sources of Nitinol (Nitinol Devices and Components Inc, Dentsply Tulsa Dental Specialties, and EuroFlex GmbH) permitting direct study of the differences between alloys and eliminating file design as a variable. To determine benchmarks for competing file designs and performance evaluations of altered nickel-titanium alloys, various investigators have reported reproducible mechanisms that can be used to compare the modes of instrument separation, cyclic, and torsional fatigue (19, 26). The protocol for this study followed the testing parameters of these prior authors.

Instrument separation has been recognized as a disadvantage of nickel-titanium files. Analyses of the modes of fracture from discarded instruments have been reported for cyclic and torsional fatigue occurring 44.3% and 55.7%, respectively (28). The incidence of separation has been reported as high as 14% of the instruments discarded, with ProTaper being discarded twice as frequently as ProFile instruments and exhibiting ductile fracture with no instrument distortion rather than cyclic fatigue failure with significant unwinding, which is characteristic of ProFile (13, 29).

Data from an earlier study clearly show that significant improvements have been made over time when older alloys are compared with the most recent derivatives of nickel-titanium alloy used to produce rotary instruments (26). The authors found cyclic fatigue mean values of 105 seconds ± 10 using ProFile 25/.04 in a 5-mm radius curve. Absolute values for cyclic fatigue reported here are improved compared with static cyclic fatigue values previously examined where the mean time to failure for ProFile 15/.04 was 139 seconds ± 18 (19). The present findings show ProFile 25/.04 instrument failure at 670 seconds ± 117 (M-Wire NiTi 100416-1B), 136 seconds ± 25 (Dentsply stock 25/.04), and 304 seconds ± 68 (Maillefer electropolished, br1a).

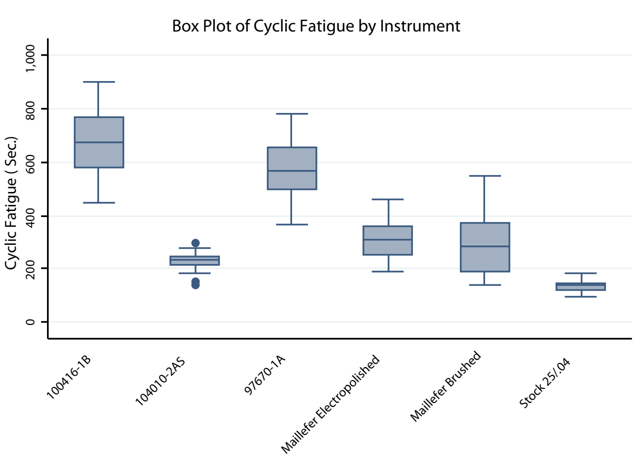

Figure 1. Box plot showing cyclic fatigue by instrument group.

Given that the samples obtained from Dentsply Maillefer are machined robotically and were supplied as new, one would not expect such a large standard deviation (SD) for the nonelectropolished group resistance to cyclic fatigue when compared with the labor-intensive Dentsply Tulsa Dental Specialties samples, where files are introduced by hand at the various stages of production. The large differences in the SDs of the experimental alloys are not unexpected because they are roughly proportional to the increase in resistance to cyclic fatigue of the control (stock Dentsply Tulsa Dental Specialties 25/.04).

Differences between endodontic rotary files produced at the different production plants may be caused by differences in the grinding process required to taper and place flutes into the nickel-titanium alloy blanks or the amount of cold work the suppliers perform while drawing the nickel-titanium wire. The study performed by Valois et al. (22) essentially is an investigation into the quality of the machining process of the manufacturer. Nickel-titanium instruments are typically ground by ceramic- or diamond-impregnated cutting wheels, the type of which is proprietary and undisclosed by the manufacturer, leading to different surface textures. The vertical depth profile of instruments manufactured by Dentsply Maillefer was found to be less than files manufactured by Dentsply Tulsa Dental Specialties and statistically different from Tycom (Irvine, CA)-produced instruments that reflected the "roughest grind." The authors did not investigate the source of the Nitinol, which may play a role in the creation of microfractures during instrument production. Investigators have shown that surface defects, created during the grinding process, can result in crack propagation (30) and have hypothesized that ductile fracture occurs when dentin chips become embedded in machining defects (23). The authors suggest surface defects introduced during the machining process and greater resistance to fracture could be achieved by electropolishing or ion implantation (13). A comparison of electropolished (EndoSequence; Brasseler USA, Savannah, GA) and nonelectropolished (ProFile, Dentsply Tulsa Dental Specialties) instruments with a 6% taper and multiple tip sizes in an *in vitro* model using extracted maxillary and mandibular molars found the electropolished samples exhibit crack formation significantly more often than nonelectropolished instruments (31). All the EndoSequence 35/.06 instruments showed microfractures after use in 7 canals, and cumulative results found that fractures occurred 15% of the time and deformed at 17%. ProFile instruments showed no microfractures and prepared canals without a single instrument separating. Investigation of Dentsply Maillefer produced electropolished and nonelectropolished ProFile 25/.04 files actually reduced resistance to cyclic fatigue and did not provide any benefit for torsional resistance (31). Our findings are in agreement showing that electropolishing does not increase fracture resistance in performing cyclic fatigue and torsional testing.

The degree of rotation at fracture was not significant during torsional fatigue testing and is in agreement with Yared and Kulkarni (27). Significant differences were found between the groups of variant nickel-

TABLE 2. Torsional Fatigue (in Degrees of Rotation to Failure and Peak Torque in Inch Ounces) Mean and SD

Instrument	Mean Torque at Failure	SD Torque	Mean Degrees Rotation to Failure	SD Rotation				
Dentsply Tulsa Dental 25/.04	1.44	0.14	485.55	65.35	A			
Variant NiTi 1A (lot 97670-1A)	1.28	0.10	492.30	56.82		B		
Variant NiTi 2AS (lot 104010-2AS)	1.20	0.14	456.70	73.33		B	C	
Variant NiTi 1B (lot 100416-1B, M-Wire)	1.13	0.11	597.90	59.29			C	
Maillefer brushed	0.90	0.08	680.23	52.96				D
Maillefer electropolished	0.80	0.09	662.13	78.63				D

Levels not connected by same letter are significantly different.

titanium, stock alloy, and Maillefer alloy with the range of mean torque values between 0.80 and 1.44 inch ounces.

Conclusion

The results of this study show that ProFile 25/.04 rotary instruments manufactured from variant 1B (M-Wire NiTi) has superior resistance to cyclic fatigue, representing an increase of up to 390% compared with the same instrument design produced from stock 508 Nitinol ($p < 0.001$). The torque at fracture of M-Wire NiTi ProFile 25/.04 instruments was comparable to existing Dentsply Tulsa Dental Specialties production and greater than Dentsply Maillefer–sourced alloy.

The proprietary-treated M-Wire NiTi has desirable properties superior to current 508 Nitinol–produced instruments and could be adopted by other file designs to provide significant advances in rotary endodontic instruments.

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