Effect of Clinical Use on the Cyclic Fatigue Resistance of ProTaper Nickel-Titanium Rotary Instruments

Hani F. Ounsi, DCD, DESE, MSc, FICD,* Ziad Salameh, DCD, DESP, MSc,† Thakib Al-Shalan, DDS, MSc, Ph.D.,‡ Marco Ferrari, MD, DDS, Ph.D.,‡ Simone Grandini, DDS, Ph.D.,‡ David H. Pasley, DMD, Ph.D.,‡ and Franklin R. Tay, BSc (Hons), Ph.D.§

Abstract
The resistance of ProTaper (Dentsply Maillefer, Ballaigues, Switzerland) nickel-titanium rotary instruments to cyclic fatigue was examined after their initial use in straight or curved canals in vivo. These instruments were rotated freely inside a steel phantom until separation. The number of rotations before failure and the lengths of the separated fragments were compared with data derived from new instruments under the same experimental setup (n = 20). With the exception of F1 and F3, instruments previously used in curved canals were more susceptible to cyclic fatigue than those previously used in straight canals (p < 0.05). Separation occurred predominantly at the D10 to D12 level. For the F series, a negative correlation (p < 0.05) was observed between the number of rotations before failure and the file diameters at their separation levels. ProTaper F3 instruments are highly susceptible to cyclic fatigue failure and should be reused with caution irrespective of whether they are initially used for shaping straight or curved canals. (J Endod 2007;33:737–741)

Key Words
Cyclic fatigue, fatigue zone, fractographic analysis, instrument separation, nickel-titanium, overload zone, rotational bending

Nickel-titanium rotary instruments have been developed to simplify and improve the efficacy of endodontic shaping procedures. However, instrument separation may occur insidiously during root canal shaping (1–4). Retrieval or bypassing of the separated fragments is unpredictable (5–7). The prognosis of leaving separated rotary instruments inside incompletely cleaned root canals remains a concern for the profession (8–13). Surgical endodontics may be subsequently required as an alternative treatment strategy.

Separation of endodontic rotary instruments may be caused by torsional or flexural (fatigue) fracture (4). Torsional fracture occurs when the elastic limit of the nickel-titanium alloy is exceeded during binding of the rotary instrument to root canal walls. This is usually accompanied by visibly discernible evidence of plastic deformation of the instrument. Conversely, cyclic fatigue failure is caused by the continuous rotation of an instrument in a curved canal space in the absence of binding, wherein the opposing sides of the instrument are subjected to alternating cycles of tensile and compressive stresses. Fatigue fracture occurs via the initiation and propagation of cracks at stress levels that are below the ultimate strength of the material under a static load (4, 5).

Clinically, instruments are subjected to composite stresses created by torsion and flexure (6–8). The risk of rotary nickel-titanium instruments to torsional fracture has been substantially reduced with the introduction of low-speed/low-torque motors that operate below the elastic limit of the nickel-titanium alloy (9) and the creation of glide paths manually with hand instruments before taking the rotary instruments to working length (10). Conversely, the susceptibility of these instruments to cyclic fatigue is affected by the angle and radius of canal curvature and the size and taper of the instrument (11, 12). Previous uses of an instrument also affect its resistance to fatigue fracture (8, 13, 14). Although torsional stresses may cause plastic deformation of the nickel-titanium rotary instruments (15, 16), instrument separation often occurs clinically without plastic deformation (17, 18) when they are subjected to prolonged cyclic fatigue stresses (19–22).

The aim of this study was to compare the resistance of ProTaper (Dentsply Maillefer, Ballaigues, Switzerland) nickel-titanium rotary instruments to cyclic fatigue after they have been used in two different clinical situations that differ in the susceptibility of the instruments to cyclic fatigue and torsional stresses. The null hypothesis tested was that there are no differences in the separation characteristics of new instruments and those that have been prestressed clinically in straight or curved canals.

Materials and Methods
The protocol used for the study was approved by the ethical board and research committee of Saint-Joseph University, Lebanon. Sixty sets of new ProTaper nickel-titanium rotary instruments (25 mm) were used and divided into three groups. Twenty sets were each used two times for shaping straight canals in either maxillary central incisors or canines. Another 20 sets were each used twice for shaping curved canals in the mesiobuccal canal of maxillary first or second molars. Because this initial clinical phase was performed in vivo, assessment of canal curvatures was achieved by using an X-ray angulator (XCP; Dentsply-Rinn, Elgin, IL) and a radiographic template (FKG Dentaire, La Chaux de Fonds, Switzerland). Teeth in the same group were checked for similar radii (5–7 mm) and angles of curvature (±5°). The canal curvature in the
straight canal group was 3.3° ± 1.7° and that in the curved canal group was 23.6° ± 2.6°. The remaining 20 sets were not used for clinical root canal shaping and served as the control.

**Clinical Prestressing**

For the clinical phase, negotiation of the designated root canal was performed with #10 K-Flexofiles (Dentsply Maillefer) by using RC Prep (Premier Dental Products, Philadelphia, PA) as a lubricant. Working length was determined with an apex locator (Root ZX; J Morita Corp, Kyoto, Japan). Canal instrumentation was initially performed with #10 and #15 K-Flexofiles (Dentsply Maillefer) to the working length. By using a crown-down technique, the ProTaper rotary instruments were then used with light pressure at 240 RPM generated by a TCM Endo III motor (Nouvag AG, Goldach, Switzerland) with a torque setting of “3.” These instruments were used in the sequence recommended by the manufacturer. Preshaping was performed with SX for straight canals and S1-SX for curved canals. Care was taken to ensure that the rotary instruments were not forced apically. To standardize the degree of prestressing in the in vivo phase of the experiment, each instrument was rotated in the canal for no more than 2 seconds, according to the manufacturer’s instructions. Size #20 K-Flexofiles were used to create manual glide paths before the introduction of the ProTaper instruments to the working length. Canal irrigation was achieved by using 5.25% sodium hypochlorite (Clorox; The Clorox Co, Oakland, CA). Canal patency was reconfirmed after the use of each ProTaper instrument. All canals were instrumented to size F3 apically. The instruments were checked under a surgical microscope for signs of plastic deformation. Instruments that exhibited visibly discernible deformation were excluded from the study. After the first use, the rotary instruments were cleaned for 15 seconds in an ultrasonic disinfecting bath (All Pro1400; Atomes, Thimens Ville Saint Laurent, Canada) and subsequently autoclaved (Statim; SciCan, Toronto, Canada) before their second clinical use in the same type of canals designated for that particular group. After the second clinical use, the instruments were further ultrasonically cleaned and autoclaved before in vitro testing.

**In Vitro Cyclic Fatigue Evaluation**

The experimental setup consisted of a custom-designed stainless steel phantom mimicking a 2 mm wide artificial canal space with an angle of curvature of 80° and a radius of curvature of 5 mm. The phantom was composed of two parts that were held together by bolts, forming a cavity that simulated a curved canal. The use of the steel phantom ensured reproducibility of the testing conditions in which each instrument could rotate freely without binding. Because the SX instrument differed in length and was designed to be used in a manner that was different from the other five rotary instruments, it was excluded from cyclic fatigue evaluation.

The new ProTaper instruments were used as received. Both the clinically used and new ProTaper instruments were placed in a contra-angle hand piece equipped with a 20:1 reduction head (WH 975AE; DentalWorks, Burmoos, Austria). They were inserted into the artificial canal to a length of 22 mm. Water was used as a universal lubricant and coolant without the use of additional chemical lubricants. Each instrument was allowed to rotate freely without binding in the water-filled artificial canal at 240 RPM by using the TCM Endo III motor until instrument separation occurred. The contra-angle hand piece and the steel phantom were attached to devices that held them in position. Rotation was performed with a torque setting of “3” and under constant air cooling to prevent the nickel-titanium instruments from overheating. Because the tip of the instrument was visible, separation was assessed by direct observation with the use of surgical loupes (Keeler Ltd, Windsor, Berkshire, UK) at 2.5× magnification.

The time required for fracture to occur was recorded for every instrument and used to calculate the number of rotations to fracture (RTF = 240 × time required for fracture/60). The level at which the separation occurred (L) was measured from the tip of the instrument.

**Statistical Analysis**

Because the normality (Kolmogorov-Smirnoff test) and homoscedasticity assumptions (Levene test) of the data were violated, nonparametric statistical methods were used for data analyses. For each file type, Kruskal-Wallis analysis of variance on ranks and Dunn’s multiple comparison test were used to examine if differences were present among the three subgroups (new files, files prestressed in straight canals, and files prestressed in curved canals), with α = 0.05.

**Fractographic Analysis**

Two separated coronal portions of each file type derived from the three subgroups were mounted on aluminum stubs. The characteristics of the fractured surfaces were examined by using a scanning electron microscope (JSM-6360LV; JEOL, Tokyo, Japan) at 15 KeV.

**Results**

No instrument experienced intracanal failure during clinical use. However, two S1 and one S2 instruments exhibited plastic deformation due to torsional fatigue during prestressing in the curved canals. They were replaced with three new sets of instruments that were re-subjected to the entire prestressing cycle. The RTFs (means ± standard deviations) of the new S1, S2, F1, F2, and F3 ProTaper instruments were 183.5 ± 25.3, 123.8 ± 13.8, 287.7 ± 31.1, 313.6 ± 23.9, and 71.2 ± 6.7, respectively. The RTFs of the S1, S2, F1, F2, and F3 instruments that had been prestressed in curved canals were 97.3 ± 18.7, 71.6 ± 13.7, 179.6 ± 20.9, 127.6 ± 16.2, and 49.7 ± 5.9, respectively. The RTFs of the S1, S2, F1, F2, and F3 instruments that had been prestressed in straight canals were 115.2 ± 29.5, 94.1 ± 25.2, 190.0 ± 39.7, 158.8 ± 38.9, and 50.3 ± 11.3, respectively. These results are graphically represented in Figure 1. For all file types, the RTFs of new instruments were significantly higher than the used instruments (p < 0.05). The S1, S2,
and F2 instruments that were prestressed in straight canals exhibited higher RTFs than those that were prestressed in curved canals (Fig. 1). There were no differences between instruments that were prestressed in straight or curved canals in the F1 and F3 instruments \( (p > 0.05) \). For the length of the separated fragment, there was no difference between the two prestressing modes for each type of instrument \( (p > 0.05) \). Separations occurred predominantly at the D10 to D12 level. By using file diameter data supplied by the manufacturer, a negative correlation \( (p < 0.05) \) was observed in the F series between the RTFs and the corresponding file diameters at their separation levels (Fig. 2).

Fractographic analysis revealed features that are characteristic of fatigue failure \( (23) \). These features are schematically represented in Figure 3A. They included a relatively flat and smooth “fatigue zone” where fatigue crack propagation occurred in response to cyclic stresses and a rougher “overload or instantaneous zone” representing the site of the final catastrophic failure. Progression marks were evident at low magnification along the “fatigue zone” that depicted load variations during the advancement of the crack front as well as the direction of crack propagation. New instruments that have not been used clinically exhibited smaller “overload zones” that were either close to or affiliated with one edge of the triangle (Fig. 3B). Instruments that have been prestressed clinically in curved canals exhibited large, centrally located “overload zones” (Fig. 3C). A high magnification of the “overzone zone” revealed evidence of dimpled rupture and the presence of multiple microvoids within the fractured alloy (Fig. 3D).

Discussion

The clinical use of nickel-titanium rotary instruments is advantageous because large reversible strains may be achieved via stress-induced austenite-martensite phase transformation of the alloy. However, these instruments suffer from the limitation of having relatively short working lives. The use of these instruments in severely curved canals is particularly taxing because the prevailing conditions predispose them to low-cycle, high-amplitude fatigue \( (3) \). A recent cohort clinical study indicated that the incidence of file separation for the ProTaper rotary instruments is 2.4% and that these instruments may be safely reused clinically for at least four times \( (24) \). This provides the rationale for examining the fatigue resistance of ProTaper instruments that have been used only twice clinically. This is because there is a tendency for clinicians to reuse these instruments even after they have been subjected to a combination of torsional and flexural stresses of unknown magnitude \( (6–8) \) and with the possible introduction of additional corrosion stresses by the use of sodium hypochlorite \( (25) \) and autoclaving \( (26) \).

In the present study, we had to compare clinically used instruments with new as-received instruments as the control because we did not have in-house data on the S-N curves \( (i.e., \text{plots of stress loads vs. logarithmic stress cycles}) \) or fatigue half-lives of the new instruments. For a more pragmatic appraisal of cyclic fatigue resistance of used instruments in the future, they should be compared with new instruments that have been prestressed to their fatigue half-lives in the absence of torsional stresses. Although it has been shown that work hardening \( (27) \) or heat treatment \( (28) \) has negligible influence on the fatigue resistance of these instruments, it would be more realistic if the new instruments are also subjected to simulated episodes of corrosion stresses as anticipated for the used instruments.

It has been shown that prolonged clinical use of the ProTaper rotary instruments \( (12–16 \text{ canals}) \) significantly reduced their cyclic fatigue resistance \( (29) \). The results of the present study indicate that the fatigue resistances of new instruments \( (i.e., \text{among the five file types S1, S2, F1, F2, and F3)} \) are not uniform \( (\text{statistics not shown}) \) and that their fatigue resistance significantly declined after two episodes of clinical application in either straight or curved canals. It is logical to assume that the fatigue resistance of instruments that have been used in straight canal is higher than those that were previously used in curved canals. Indeed, the S1, S2, and F2 instruments exhibited higher fatigue resistance in straight canals compared with curved canals, which corresponded well with what has been reported in the literature \( (11, 12) \). However, similar fatigue resistance were found in the F1 and F3 instruments irrespective of whether they were previously used in straight or curved root canals (Fig. 1). For the F3 instrument, this may be attributed to its wider diameter at the site of fracture \( (6, 22) \) or a difference in cross-sectional design from the other instruments. For the F1 instrument, we speculate that such a tendency may be caused by abrupt changes in taper between the S2 and F1 instruments. It would be interesting, thus, to examine the fatigue resistance of the recently introduced ProTaper Universal series in which the modified S2 instrument is claimed to provide a smoother transition between shaping and finishing of the root canal walls. Because the current F3 instrument showed the lowest resistance to cyclic fatigue, it is prudent also to examine the fatigue resistance of the F3-F5 instruments in the new ProTaper Universal series. Although these instruments are designed for use in canals with wider apices and are unlikely to be used in severely curved canals, their cross-sectional design have been substantially modified by introducing deeper grooves along the flute perimeter to improve flexibility.

Fractographic analysis is an integral part of cyclic fatigue testing because it reveals the history of the fractured interfaces that enables one to distinguish cyclic fatigue failures from those precipitated by quasi-static loads. Although all the in vitro separated instruments exhibited evidence of cyclic fatigue fracture \( (3A) \), differences in how the instruments were handled before separation could be conjured from the fracture histories of new and used instruments. For the new instruments, the smaller overload zones that were usually affiliated with one edge of the separated instrument \( (3B) \) are indicative of a localized origin of crack initiation, a longer period of comparatively slower crack propagation, and a lower stress magnitude during the instant of rupture \( (23) \). Crack initiation could have been initiated by a surface flaw produced during the machining of these instruments. Conversely, the larger, more centrally located overload zones seen particularly in instruments used previously in curved canals \( (3C) \) are indicative of...
multiple origins of crack initiation, and these instruments were heavily stressed at the time of final fracture. The multiple stress concentration sites could have been precipitated by a defect along the machined instrument surface (open arrow). Progression marks along the surface of the fatigue zone represent variations in the component stresses as the crack propagated in the direction indicated by the solid arrow. The eccentricity between the direction of slow crack growth (solid arrow) and the bisector (dotted arrow) of the overload zone (O) is indicative of a clockwise rotational bending failure. (C) A scanning electron micrograph of the fractured surface obtained from a clinically used instrument (F1 ProTaper) that was further subjected to in vitro cyclic fatigue failure. Debris was found along the machined instrument surface (pointers) after clinical root canal shaping. The relatively small fatigue zone (F) and a large overload zone (O) suggests that most of the fatigue life of the instrument was spent in the original crack formation, creating a heavy stress concentration that quickly led to instrument failure. The centrally located overload zone indicated that the failure was initiated at multiple locations (open arrows) around the perimeter of the shaft and then grew inward. (D) A high-magnification view of a typical overload zone revealed evidence of dimpled rupture that is characteristic of the ductile nature of the ultimate catastrophic failure. A large population of microvoids (open arrowheads) could be seen within the nickel-titanium material.

Figure 3. (A) A schematic representation of predominant surface features found in fatigue failure. (B) A scanning electron micrograph of the fractured surface obtained from a new instrument (S2 ProTaper) that has been subjected solely to in vitro cyclic fatigue stresses. The large, relatively smooth fatigue zone (F) was probably initiated by a defect along the machined instrument surface (open arrow). Progression marks along the surface of the fatigue zone represent variations in the component stresses as the crack propagated in the direction indicated by the solid arrow. The eccentricity between the direction of slow crack growth (solid arrow) and the bisector (dotted arrow) of the overload zone (O) is indicative of a clockwise rotational bending failure. (C) A scanning electron micrograph of the fractured surface obtained from a clinically used instrument (F1 ProTaper) that was further subjected to in vitro cyclic fatigue failure. Debris was found along the machined instrument surface (pointers) after clinical root canal shaping. The relatively small fatigue zone (F) and a large overload zone (O) suggests that most of the fatigue life of the instrument was spent in the original crack formation, creating a heavy stress concentration that quickly led to instrument failure. The centrally located overload zone indicated that the failure was initiated at multiple locations (open arrows) around the perimeter of the shaft and then grew inward. (D) A high-magnification view of a typical overload zone revealed evidence of dimpled rupture that is characteristic of the ductile nature of the ultimate catastrophic failure. A large population of microvoids (open arrowheads) could be seen within the nickel-titanium material.
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