# Instrument Separation Analysis of Multi-used ProTaper Universal Rotary System during Root Canal Therapy

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## Abstract

**Introduction:** The purpose of this study was to identify the influential factors responsible for clinical instrument separation of reused ProTaper Universal rotary instruments (Dentsply Maillefer, Ballaigues, Switzerland). **Methods:** Six thousand one hundred fifty-four root canals in 2,654 teeth were prepared using ProTaper Universal files in endodontic clinics. Separation incidence was determined based on the number of treated teeth or canals. Data were collected including the size of fractured instrument, the length and location of a broken segment within the root canal, and the curvature of canal. The chi-square test and independent samples *t* test were used to determine the statistical significance. **Results:** The overall instrument separation incidences were 2.6% according to the number of teeth and 1.1% according to the canal number, respectively. Separation incidences according to the number of teeth or canals were significantly higher ($P < .05$) in molars than those in premolars or anterior teeth. Because of its largest diameter, F3 file presented the highest separation incidence according to the number of teeth (1.0%) or canals (0.4%); 47.5% instrument separation of mandibular molars and 61.5% instrument separation of maxillary molars happened in the mesiobuccal canals. Moreover, 91.4% fragments were located in the apical third of root canals, and 54.2% instrument separation occurred in severely curved canals. There was a significant difference ($P < .05$) in the mean fracture length between shaping (2.42 $\pm$ 0.73 mm) and finishing files (3.32 $\pm$ 0.73 mm). **Conclusions:** Separation incidence according to the canal number is more reliable than that according to the number of teeth because of the variable canal number in different teeth. The tooth type, rotary file size, canal location, and anatomy were correlated with the instrument separation of reused ProTaper Universal files. *(J Endod 2011;37:758–763)*

## Key Words

Instrument separation, NiTi rotary system, ProTaper Universal, root canal, scanning electron microscopy

Nickel-titanium (NiTi) instruments have become very popular in endodontic practice. NiTi instruments are more flexible than stainless steel instruments and have the ability to revert to their original shape after flexure. It is generally accepted that a thorough debridement of curved root canals is much more difficult using the stainless steel instruments. However, with the advent of superelastic NiTi instruments, the efficiency of endodontic cleaning and shaping procedures has been greatly improved, especially in the curved canals (1–3). These instruments can minimize the procedural errors, such as ledge and transportation, and create more rounded/centered canal preparations (2, 4, 5). Despite these advantages, rotary NiTi instruments are prone to fracture especially when they are unknowingly bypassed or forced into a canal isthmus. Although separated files in root canals do not always result in an unfavorable prognosis, instrument fractures definitely impede the microbial control beyond the obstruction and complicate the process of endodontic treatment. Moreover, retrieving an instrument fragment in a canal may cause the excessive removal of dentin structure, decreased root strength, and even root perforation (6–9). The defect rate of NiTi instruments is affected by such factors as the operator, preparation technique, manufacturing process, instrument design, and root canal anatomy (10–15). On the other hand, the success rate of removing the separated instruments in root canals mainly depends on the location of fractured segments and the degree of canal curvature (6, 7).

ProTaper endodontic files (Dentsply Maillefer, Ballaigues, Switzerland) are designed with increasing percentage tapers over the length of their cutting blades, allowing each instrument to prepare a specific area of the canal (ie, each file engages a smaller zone of dentin). This design is supposed to reduce the torsional loads, instrument fatigue, and potential breakage (16, 17). The ProTaper Universal System consists of three shaping files (ie, SX, S1, and S2) and three finishing files (ie, F1, F2, and F3). It is a variable-taper rotary file system derived from the conventional ProTaper system in an effort to increase the flexibility and reduce the cross-section. As compared with the conventional ProTaper System, ProTaper Universal instruments have several modifications including (1) they have a new rounded tip in which the transition angle was removed in an effort to reduce the canal transportation and improve the operational safety, (2) the S2 file has been improved in order to better smooth the transition from shaping files to finishing files during the instrumentation, (3) grooves have been added to F2/F3 files in an attempt to make them more flexible, (4) the cross-section of F3 blades changes from U-shaped flutes to a triangular concave shape with a shallow U-shaped groove, and (5) the coronal taper of the ProTaper Universal finishing file has been further reduced to improve the tactile sense to feel the apical constriction and restrict the contact area of the instrument to the apical zone inside the canal (18–20).

To date, instrument separation of engine-driven NiTi rotary systems has been extensively investigated (21–24). Wolcott et al (23) have shown that the file size will

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determine the times that a ProTaper rotary file should be reused (23). Shen et al (25) have indicated that ProTaper files are likely to separate without warning, and flexural fatigue is involved in most ProTaper file fractures. However, little knowledge is available about the separation incidence and its influential factors of ProTaper Universal files after multiple clinical applications in root canals by a large-scale clinical investigation. Therefore, this study was designed to evaluate the separation incidence of reused ProTaper Universal rotary instruments and identify the relevant factors that may influence the instrument fracture generated during clinical applications.

## Materials and Methods

### ProTaper Universal File Instrumentation

Canal preparation was performed by the ProTaper Universal Series Rotary System according to the manufacturer's recommendations using a crown-down technique. First, a gliding path was created using a #10 hand file to the working length. Second, an SX file was fed into the canal with a brushing outstroke motion for two thirds of its blade length. Third, a #15 hand file was passively used to reach the working length. Then, S1/S2 files were used with a brushing outstroke action until the working length was reached. Finally, finishing files (ie, F1, F2, and F3) were used in sequence with pecking motions until reaching the working length. All files were inserted into root canals in a continuous in-and-out movement with a suitable force. Each file was coated with 19% EDTA during the mechanical instrumentation, and copious irrigation with 5% sodium hypochlorite was performed after the use of each file. A sponge was regularly used to wipe out the dentin debris on each file.

In some cases, the root canal orifice was enlarged by Gates-Glidden drills instead of SX instruments. Occasionally, some root canals were instrumented with an F3 file according to the canal curvature and cross-sectional diameter. Engine-driven files were used in an electric motor (X-SMART, Dentsply Maillefer) with a 16:1 reduction handpiece using recommended torques (1.5 Ncm for S2; 2.0 Ncm for F1; 3.0 Ncm for SX, S1, F2, and F3; respectively) and rotation speed (250 rpm). Instruments were discarded when they were worn, fractured, or with any other discernible defects. Each instrument was limited to the maximum operation number of treated teeth (3 molars, 10 premolars, or 30 anterior teeth) (10, 26). Instruments that had been used in very complex or severely curved canals were discarded at once.

### Reused ProTaper Universal File Collection and Examination

ProTaper Universal instruments after under such clinical conditions were collected and analyzed at Endodontics Department of Stomatology School of Nanjing Medical University over a 24-month period from August 2008 to July 2010. All fractured instruments were placed against a transparent plastic millimeter ruler and examined under a stereomicroscope (Micro-dissection; Zeiss, Bernried, Germany) at 30× magnification. The distance between fracture end and handle was measured, and the length of the broken segment was calculated according to this remaining length.

Information regarding the tooth and canal in which instrument separation took place were documented. Periapical radiographs of each tooth were taken to evaluate the anatomic variation, the curvature angle, and the fragment location in the canal (eg, apical, middle, or coronal). The canal curvature degrees (mild, <10°; moderate, 10°–25°; or severe, >25°) was determined and classified according to the previous reports by Schneider et al (27). Some typical changes of reused/fractured files including visible defects (eg, unwinding and reverse winding with or without the tightening of the spirals) and indiscernible microcracks were examined under the scanning electron microscope (Sirion-FEG; Phillips, Eindhoven, The Netherlands).

### Statistical Analysis

Statistical analyses were performed with SPSS version 13 software (SPSS Inc, Chicago, IL). The Pearson chi-square test was used to check the differences in separation incidence of various tooth types. To determine the statistical difference in fragment lengths between shaping and finishing files, data were subjected to independent samples $t$ test. $P$ values less than .05 were considered to be statistically significant.

## Results

### Instrument Separation in Different ProTaper Universal Files

Overall, there were a total of 70 ProTaper Universal instrument separations (2 for SX, 16 for S1, 10 for S2, 11 for F1, 20 for F2, and 11 for F3, respectively) after 6,154 root canal treatments of 2,654 teeth. The overall prevalence of file separation was 2.6% according to the number of teeth and 1.1% according to the canal number, respectively. The F3 file showed the highest incidence of instrument separation (1.0% according to the number of teeth and 0.4% according to canal number), whereas SX showed the lowest separation incidence (0.2% according to the number of teeth and 0.1% according to canal number, Table 1).

### Instrument Separation in Different Teeth

As shown in Table 2, 51.3% (1362/2654) of treated teeth were molars, 27.4% (726/2654) were premolars, and 21.3% (566/2654) were anterior teeth. The percentages of instrument fracture according to tooth types were also listed in Table 2, in which 94.3% (66/70) occurred in molars, 4.3% (3/70) in premolars, and 1.4% (1/70) in anterior teeth. There were 26 shaping files fractured in molars, of which 16 occurred in mandibular molars and 10 in maxillary molars. Moreover, 40 finishing files were separated in molars, of which 24 separations took place in mandibular molars and 16 in maxillary molars (Table 2). The separation incidences in anterior teeth, premolars, and molars were 0.2% (1/566), 0.4% (3/726), and 4.9% (66/1362), respectively, according to the number of teeth. However, according to the canal number, the separation incidences in anterior teeth, premolars, and molars became 0.2% (1/582), 0.3% (3/1008), and 1.5% (66/4564), respectively (Table 2). The separation incidences according to the number of teeth or canals were significantly increased in molars as compared with those in premolars ($P < .01$) or anterior teeth ($P < .01$). Nevertheless, there was no significant difference ($P > .05$) between premolars and anterior teeth in the separation incidences according to the number of teeth/canals. The separation incidences of total files, shaping files, and finishing files, respectively, presented no significant difference ($P > .05$) between mandibular and maxillary molars (Table 2).

**TABLE 1.** Incidence of Instrument Separation According to Instrument Size

| File size | Separation number | Number of teeth (%) | Number of canals (%) |
|---|---|---|---|
| SX | 2 | 873 (0.2) | 2070 (0.1) |
| S1 | 16 | 2654 (0.6) | 6154 (0.3) |
| S2 | 10 | 2654 (0.4) | 6154 (0.2) |
| F1 | 11 | 2654 (0.4) | 6154 (0.2) |
| F2 | 20 | 2654 (0.8) | 6154 (0.3) |
| F3 | 11 | 1257 (1.0) | 2856 (0.4) |
| Total | 70 | 2654 (2.6) | 6154 (1.1) |

**TABLE 2.** Incidence of Instrument Separation According to Tooth Type

| Tooth type | Number of teeth (canals) | Shaping files | | Finishing files | | Total files | |
|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % |
| Maxillary molars | 626 (2058) | 10 | 1.6 (0.5) | 16 | 2.6 (0.8) | 26 | 4.2 (1.3) |
| Mandibular molars | 736 (2506) | 16 | 2.2 (0.6) | 24 | 3.3 (1.0) | 40 | 5.4 (1.6) |
| Total molars | 1362 (4564) | 26 | 1.9 (0.6) | 40 | 2.9 (0.9) | 66 | 4.9 (1.5) |
| Maxillary premolars | 396 (672) | 0 | 0 (0) | 1 | 0.3 (0.2) | 1 | 0.3 (0.2) |
| Mandibular premolars | 330 (336) | 1 | 0.3 (0.3) | 1 | 0.3 (0.3) | 2 | 0.6 (0.6) |
| Total premolars | 726 (1008) | 1 | 0.1 (0.1) | 2 | 0.3 (0.2) | 3 | 0.4 (0.3) |
| Anterior teeth | 566 (582) | 1 | 0.2 (0.2) | 0 | 0 (0) | 1 | 0.2 (0.2) |
| Total teeth | 2654 (6154) | 28 | 1.1 (0.5) | 42 | 1.6 (0.7) | 70 | 2.6 (1.1) |

The percentages of separated instruments in mesiobuccal canals were higher than those in other canals of mandibular and maxillary molars. Briefly, for the mandibular molars, 47.5% (19/40) separations occurred in the mesiobuccal canals, 35.0% (14/40) in the mesiolingual canals and 17.5% (7/40) in the distal canals. For the maxillary molars, 61.5% (16/26) instrument fractures took place in mesiobuccal canals, 30.8% (8/26) in distobuccal canals, and 7.7% (2/26) in palatal canals.

## Instrument Separation in Canals with Different Curvatures

Over half of the instrument fracture (54.3%) occurred in the severely curved canals, 28.6% in the moderately curved canals, and 17.1% in the mildly curved canals. For the finishing file separation, the fracture incidences in the mildly, moderately, and severely curved canals were 11.9%, 26.2%, and 61.9%, respectively. The fracture incidence of shaping files was also increasing as the canal curvatures increased in severity (Table 3).

## Fragment Location and Length of Separated Files in Root Canals

Table 4 showed the instrument separation number according to the fragment location in the canal. All fractures happened in the middle or apical third of the canal, in which 91.4% separations appeared in the apical third. In addition, the mean length of all fractured segments was 2.96 ± 0.85 mm (Table 5). There was a significant difference ($P < .05$) in the mean fracture length between shaping and finishing files after multiple uses (2.42 ± 0.73 mm and 3.32 ± 0.73 mm, respectively).

## Morphology of Reused ProTaper Universal Files under SEM

Some reused or fractured instruments were examined by SEM, and these files presented the abrasion marks on the blade surface. Most reused shaping files exhibited the surface defects including the flute unwinding (Fig. 1*A*), pitting (Fig. 1*B*), and dimple (Fig. 1*C*) signs, implying the complex loading situations on S files during the canal instrumentation. Almost all separated F files presented the obvious deformation (Fig. 2*A*) and ductile cracks (Fig. 2*B* and *C*) adjacent to the fracture site.

# Discussion

The evaluation methods and results for the separation incidences of ProTaper rotary files are diverse in previous clinical studies. Wolcott et al (23) have shown that the overall rate of instrument separation was 2.4%. Another study has used 15 severely curved molars to assess the separation incidence of the ProTaper system with a 6.0% failure rate (24). Variations among these results may be attributed to the different clinical assessment approaches. For instance, all tooth types are involved in the study of Wolcott et al, whereas in the article of Ankrum et al, only molars with severely curved roots are chosen. Moreover, some researchers evaluate the separation incidences according to the number of teeth, whereas other authors use the number of canals, instead of the number of teeth, to investigate the file fracture incidences (23, 24, 28). Here, this study revealed a 2.6% overall incidence of ProTaper Universal rotary file separation according to the number of teeth. However, the incidence will jump to 4.9% if only molars are involved and 5.5% when only mandibular molars are analyzed. The separation incidence in total molars or mandibular molars was significantly higher than the overall incidence. More interestingly, the separation incidences of all teeth, total molars, and mandibular molars were 1.1%, 1.5%, and 1.6%, respectively, according to the canal number. No statistical difference was detected among these three data. Variations between the two different calculation methods are obvious. It is well known that there are usually three or four canals in molars and one or two canals in anterior teeth/premolars. When two instruments fracture in a molar with four canals, the separation incidence according to the number of teeth and canals will be 200% (2/1) and 50% (2/4), respectively. The former incidence is definitely unconvincing. Therefore, the separation in-cidence derived from the canal number is more accurate than that from the number of teeth because of the variable canal number in different teeth.

In this study, F3 files presented the highest separation incidence among all ProTaper Universal instruments, indicating that F3 files were susceptible to the cyclic fatigue failure (29, 30) and should be carefully reused in shaping canals. As the tip size of finishing instruments increased, the separation incidences were also progressively increased, suggesting that these larger and stiffer files may experience greater stresses during the canal instrumentation. Ounsi et al (29) have revealed a negative correlation between the initial rotation speeds and the diameters of finishing files at the separation sites.

**TABLE 3.** Percentage Distribution of Instrument Separation According to Degree of Canal Curvature

| Separated file type | Curvature < 10° | | Curvature = 10°–25° | | Curvature > 25° | | Total |
|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | |
| Shaping files | 7 | 25.0 | 9 | 32.1 | 12 | 42.9 | 28 |
| Finishing files | 5 | 11.9 | 11 | 26.2 | 26 | 61.9 | 42 |
| Total | 12 | 17.1 | 20 | 28.6 | 38 | 54.3 | 70 |

**TABLE 4.** Number of Instrument Separation According to Fragment Location in Root Canal

| | Fragment location in root canal | | |
|---|---|---|---|
| File size | Apical third | Middle third | Coronal third |
| SX | 0 | 2 | 0 |
| S1 | 13 | 3 | 0 |
| S2 | 9 | 1 | 0 |
| F1 | 10 | 0 | 0 |
| F2 | 20 | 0 | 0 |
| F3 | 12 | 0 | 0 |
| Total (%) | 64 (91.4) | 6 (8.6) | 0 (0) |

Another study has shown that instrument failures often happen at the fifth time when ProTaper Universal F3 file is reused (23). Together with the increase of instrument diameter, the resistance of rotary instrument to cyclic fatigue will decrease, which makes these files much more susceptible to fracture (29). Given this, larger and stiffer ProTaper Universal instruments (eg, F3 file) should be reused with caution in the endodontic practice (23, 29, 30).

ProTaper Universal S1 is initially used to shape the coronal third of root canal and subsequently taken to the working length to enlarge the middle third of the canal. Thus, S1 file is used twice for each canal, instead of once as for other instruments, indicating that S1 is more likely to suffer from the flexural fatigue or torsional loading (21, 31). In a torsional failure mode, the file tip is locked in the root canal while the remaining part of the file continues to rotate, which may bring about the unwinding of instrument flutes (26). Peng et al (32) have proved that the multiple use of S1 predisposes the instrument to the microcrack formation and wear of cutting edges, which may cause S1 fracture without any discernible sign of flute unwinding. In this study, some deformations or unwinding defects in S1/S2 files could be detected macroscopically or microscopically. Under scanning electron microscopic examination, the reused S1 instruments presented several surface defects including the distorted machine grooves, pitting, and dimples. These files should be discarded at once regardless of the operation number because these surface defects may increase the risk of instrument separation (21, 26). ProTaper Universal instrument is designed to cut dentin using its larger and stronger parts, and, thus, the rotation torque in different parts of a working file is usually mutative. It may require a higher torque to rotate the coronal portion of a ProTaper Universal file inside a narrow canal as compared with its apical portion, which is likely to induce a greater stress on the apical tip of this file especially in a curved canal. This factor may cause the plastic deformation or even microfracture at the smallest portion of S1 file. These microfractures may exacerbate and coalesce after the repeated use and, ultimately, cause an overt file fracture. Previous studies have shown that file fracture can happen without any visible sign of permanent deformations because early microfractures cannot be detected even with the help of a surgical operating microscope (10, 23). Therefore, visible inspection is not a reliable method to evaluate the reused NiTi instruments and stereomicroscope is recommended clinically to detect the early defects of these rotary instruments.

**TABLE 5.** Mean Fragment Length of Instrument Separation

| Separated file type | Fragment number | Mean fragment length (mm) |
|---|---|---|
| Shaping files | 28 | 2.42 ± 0.73* |
| Finishing files | 42 | 3.32 ± 0.73 |
| Total | 70 | 2.96 ± 0.85 |

*$P < .05$.

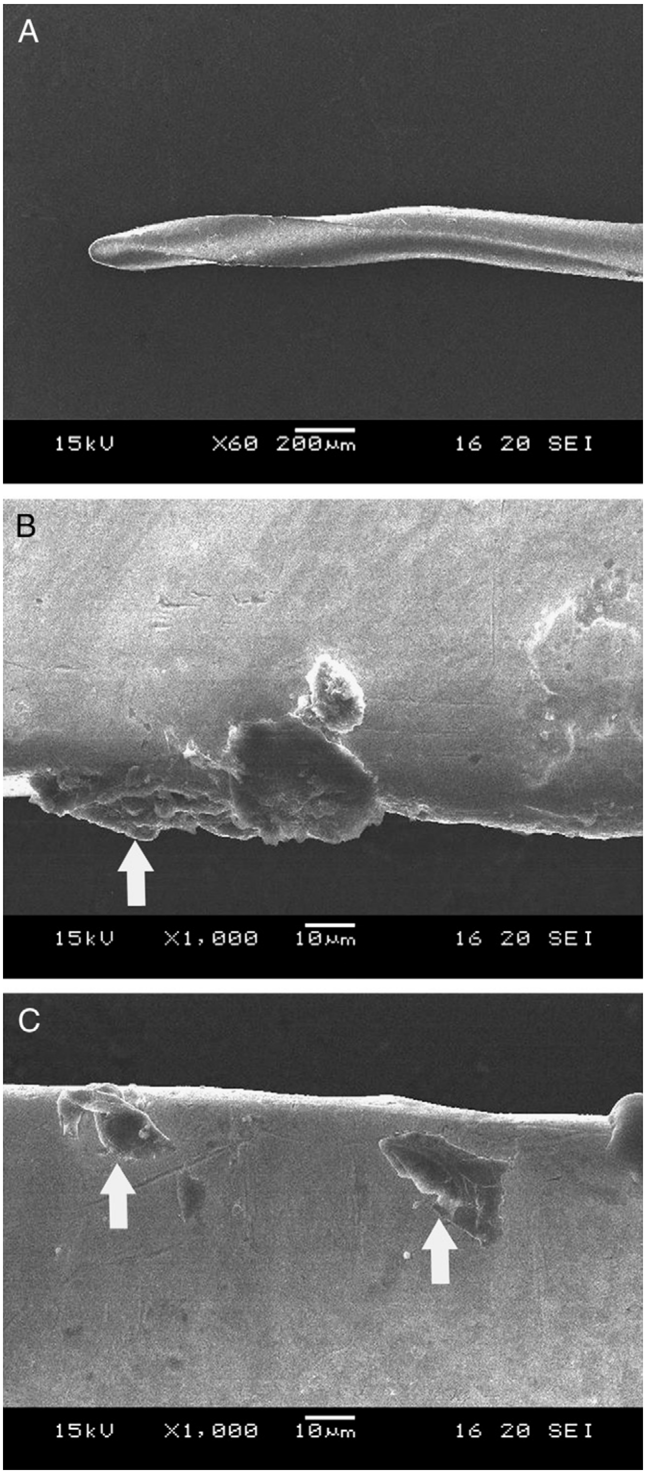


**Figure 1.** Longitudinal views of a distorted ProTaper Universal instrument S1 by scanning electron microscopy. (*A*) Deformation around the spiral sector of an intact ProTaper Universal Instrument S1 (original magnification 60×). (*B*) Pitting (*arrow*) on the surface of S1 file (original magnification 1,000×). (*C*) Dimples (*arrow*) on the surface of S1 file (original magnification 1,000×).

Moreover, 54.3% instrument fracture took place in the canals with a curvature greater than 25°, indicating that canal curvature was another important factor affecting the instrument separation. More severe root canal bends exert greater stresses on the rotary instruments

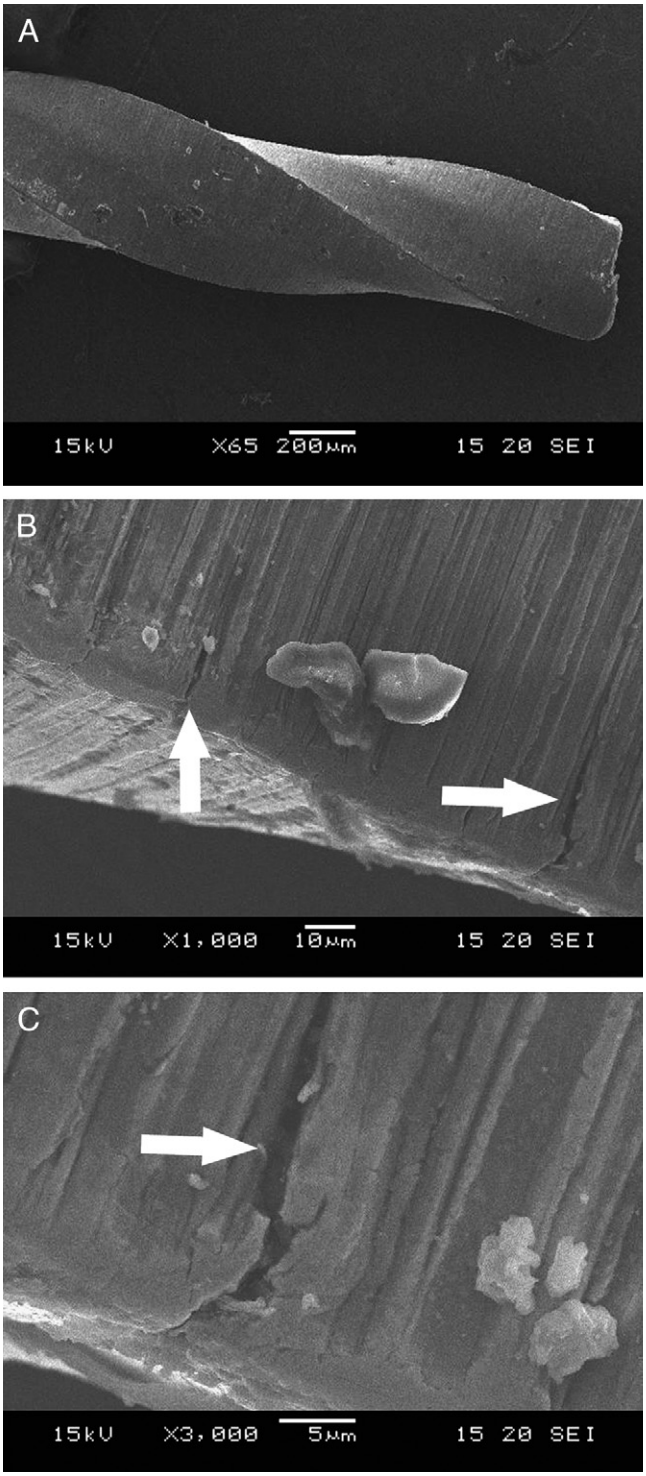


**Figure 2.** Longitudinal views of a separated ProTaper Universal instrument F2 by scanning electron microscopy. (*A*) A lower-magnification view of a fractured ProTaper Universal Instrument F2 (original magnification 65×). (*B*) Longitudinal cracks perpendicular to the axis (*arrow*) of F2 instrument (original magnification 1,000 ×). (*C*) A higher-magnification view of *B* (original magnification 3,000×).

when they are confined to the curved canals (33). Flexural fatigue accumulated during the curved-root canal preparation may reduce the torsional resistance of endodontic instruments (34) and make them more prone to fracture. Thus, the increased severity of the angle and curve radius, around which the instrument rotates, will definitely shorten the instrument lifespan.

ProTaper Universal instruments are designed with deep cutting flutes, progressive tapers, and rapidly changing cross-sectional diameters along the shafts, which usually develop a high level of torque and make them more prone to metal fatigue (35). As the file moves axially in the canal, different parts of the file are exposed to the flexure and cyclic fatigue (20). Given the same torque, smaller instruments would be more susceptible to torsional failure than larger instruments (36). In this study, the mean broken fragment lengths of shaping files were significant shorter than finishing files (Table 5), suggesting that shaping file separation may be related to the torsional failure. In contrast, most finishing files fractured at almost the same level of the instrument shaft, corresponding to the midpoint of the radius of canal curvature, indicating that finishing file separation is more likely because of the cyclic fatigue in which these files usually separated at the maximum flexure point of the shaft (20).

So far, there is no agreement on the reuse number of rotary NiTi instruments. Martin et al (37) have shown that the variables of operator and canal anatomy are more influential on the fracture rate than the instruments per se. Canal geometry (eg, cross-sectional diameter, angle, and radius of the curvature) can affect the stress magnitude on the instruments (38). Molars, often with fine and curved root canals, are a challenge for the instrumentation. Except for the SX instrument, which was never used at the working length, 78.6% (22/28) shaping and 100% finishing instruments in this study (Table 4) broke in the apical third of the canal. The apical third of the root canal usually exhibits a high incidence of curvature, small diameter, and complex canal divisions (39). When an instrument is engaged toward the apical part inside the canal, a great torsional force will be generated because of the increasing contact area between instrument blades and dentin walls (16, 40). The instruments that work in the apical third of mesiobuccal canals in mandibular and maxillary molars were more predisposed to the breakage. The probability of separating an instrument in the mesiobuccal canal of a maxillary molar was twofold greater than that in the distobuccal canal in this study. For mandibular molars, 47.5% instrument separations happened in the mesiobuccal canals. Because the canal anatomy is much more complicated in the apical third, it is important to establish a glide path as the manufacturer has suggested (23). Patiño et al (40) have recommended that stainless steel hand files should be used to prepare the apical third of curved canals before the use of rotary instruments. When a size 15 K-file at the working length is loose inside the root canal and a smooth glide path is confirmed, larger tapered rotary files will passively follow the canal contour to perform subsequent instrumentations. ProTaper Universal shaping files are best used with lateral forces to reduce the coronal screwing effect, whereas finishing files should be applied with slow penetration and introduced only into canals with a smooth glide path (16). Furthermore, the practitioner should always bear in mind that mechanized preparations are not the optimal approach to all root canals. Some canals should be instrumented by manual but not rotary methods in order to safely fulfill the root canal preparation.

In conclusion, the fracture incidence of reused ProTaper Universal rotary instruments remains at a low level in endodontic practice, in which the separation incidence according to the canal number is more reliable than that according to the number of teeth. Most instruments fractured in the apical third or curved site of root canal. Larger-diameter instruments such as the F3 file should be reused with caution especially in shaping curved canals, and all multiused instruments should be checked under the stereomicroscope regularly to detect the potential defects. Generally, ProTaper Universal rotary instrument separation is multifactorial, which is more likely relevant to the size of rotary files, tooth type, location and morphology of root canals, practitioner's experience, and preparation techniques. Some procedural mishaps can be effectively minimized if all basic principles regarding root canal mechanical instrumentation are well applied.

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