Defects in Nickel-Titanium Instruments after Clinical Use. Part 1: Relationship between Observed Imperfections and Factors Leading to Such Defects in a Cohort Study

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Abstract

The purpose of this study was to examine three different types of nickel-titanium (NiTi) systems (ProTaper [Dentsply Maillefer, Ballaigues, Switzerland], ProTaper for Hand Use [Dentsply Maillefer], and K3 [SybronEndo, Orange, CA]) that were discarded by 3 endodontic clinics. The instruments were evaluated for defects and factors leading to instrument deformation or fracture. A total of 1682 instruments were collected over 16 months and were examined. The location of the defect, if any, was recorded. The overall prevalence of unwinding defects was 3% and fracture 5%; the rates differed significantly between clinics. For one brand (ProTaper) used at two different clinics, a defect rate (fracture and distortion combined) of 7% (clinic A) vs. 13% (clinic B) for Shaping files ($P < 0.05$), and about 4% vs. 10% for Finishing files ($P < 0.05$) was observed. Fragments of broken Shaping file were significantly longer in clinic A than for clinic B ($P < 0.05$). The lowest defect rate was found for K3 instruments: unwinding 1%, and fracture 3%. It was concluded that the defect rates of NiTi instruments were influenced by such factors as the operator, preparation technique and instrument design. *(J Endod 2009;35:129–132)*

Key Words

Breakage, defect, fracture, nickel-titanium, rotary instrument

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Over the past 2 decades, nickel-titanium (NiTi) instruments have become part of the armamentarium for root canal therapy. They are increasingly used by generalists and specialists to facilitate the cleaning and shaping of root canals. With the increased adoption of these instruments in contemporary practice, instrument fracture seems to have become more prevalent (1–4).

Instrument fracture is a potentially serious mishap, which can complicate and compromise the endodontic treatment outcome, especially if the fragment has prevented access to the apical part of an initially infected canal (5, 6). NiTi rotary files are available in a variety of designs, each with features that affect the manner in which they engage and cut dentin (7) and the stress that may generate within them (8, 9). The safety of NiTi instruments in use requires an understanding of the basic mechanism for the development of defect and the factors involved (10, 11). Therefore, the purpose of this study was to analyze the type and location of defects from a large collection of discarded, clinically used NiTi instruments and to examine the factors involved.

Materials and Methods

Three NiTi rotary systems: ProTaper rotary (PT) (Dentsply Maillefer, Ballaigues, Switzerland), ProTaper for Hand Use (PHU) (Dentsply Maillefer), and K3 (SybronEndo, Orange, CA) have been adopted at three endodontic clinics, each in a stomatologic school in China (Beijing, Guangdong, and Wuhan). Two clinics (A and B, identity not revealed) used only the PT instruments, and the other (clinic C) used both PHU and K3 instruments (by different endodontists who consistently used either one or the other brand). There were different guiding principles in these clinics for the number of uses and replacement schedule (Table 1). Regardless of this schedule, instruments that had been used in very complex, severely curved, or calcified canals would be discarded at once. Canal preparation was performed according to the manufacturer's recommendations in a crown-down approach, except for one minor variation in clinic B (whereby the root canal orifice was enlarged by a Gates-Glidden drill instead of an Sx instrument of the ProTaper system). Engine files were used in an electric motor (ATR Tecnika, Milan, Italy) with a 16:1 reduction handpiece (W&H, Burmoos, Austria) at a setting and speed recommended by the manufacturer (at 300 rpm). Instruments were discarded when they had reached the designated number of uses or when they were worn, fractured, or with any other discernible defects.

A total of 1,682 NiTi instruments were collected after such normal clinical use from the three clinics over a 16-month period from January 2006 to April 2007. The collected instruments were ultrasonically cleaned, autoclaved, and then examined blindly by one investigator (YS) under a travelling stereomicroscope (Microdissection, Zeiss, Bernried, Germany) at 30× magnification with a precision of 0.1 mm. Any defect or distortion (plastic deformation) was noted and classified into one of the following categories: (1) intact with no discernible distortion or unwinding, (2) intact but with unwinding defects, and (3) fractured. For all intact but distorted instruments, the location was determined by measuring the length between the instrument tip and the beginning of the unwound region. For those fractured instruments, the distance between the fracture end and the handle was measured by using the same traveling microscope and the length of the broken segment estimated from this remaining length.

TABLE 1. Summary of Instrument Defects from Three Endodontic Clinics (% of Total Number for Each Instrument)

	File Usage Schedule	*N*	No Defect*	Distorted†	No. of Uses§	Fracture‡	No. of Use§
ProTaper-A	30 canals	621	583 (94)	13 (2)	17.38 ± 9.18C	25 (4)	16.88 ± 1.19 C
ProTaper-B	16 canals (for molars) to 30 canals (other teeth)	487	430 (88)	23 (5)	2.03 ± 1.00 M, 10.17 ± 2.67 P	34 (7)	2.83 ± 1.03 M, 10.1 ± 3.08 P
ProTaper Hand	16 canals (for molars) to 25 canals (other teeth)	280	261 (93)	8 (3)	3.00 ± 0.71 M	11 (4)	3.67 ± 0.47 M, 13.00 ± 1.09 P
K3	16 canals (for molars) to 325 canals (other teeth)	294	282 (96)	3 (1)	2, 3 M, 7 P	9 (3)	3.29 ± 0.69 M, 14 P, 14 P
Total		1682	1556 (92)	47 (3)		79 (5)	

*There was significant different among groups on defect ($p < 0.01$).

†There was significant different among groups on distorted ($p < 0.05$).

‡There was significant different among groups on fracture ($p < 0.05$).

§Numbers of uses were the mean recorded for the tooth type (M = molar, P = premolar) or as the number of canal instrumented (c). The actual number was provided for each instrument when $n \leq 3$.

Data were analyzed by using a chi-square, Fisher exact, or Student *t* test, where appropriate, at $\alpha = 0.05$.

Results

Of the 1,682 NiTi instruments collected, 126 (8%) were found to have failed: 47 (3%) were distorted, and 79 (5%) were fractured (Table 1). Large differences in the defect rate were found among the four instrument–clinic/operator combinations (PT-A, PT-B, PHU, and K3), which rate varied between 4% and 12% (chi-square, $p < 0.01$). Instruments from various clinics showed a significantly different amount of fractures (chi-square, $p < 0.05$) and unwinding defects (chi-square, $p < 0.05$). The distortion and fracture rates were highest with PT instruments in clinic B (5% and 7%, respectively) and lowest with K3 (1% and 3%, respectively).

For PT instruments, there were significant differences in the overall amount of defects between the two clinics, A and B (Table 2); both the Shaping and Finishing files showed more defects for clinic B than for clinic A (chi-square, $p < 0.05$). The beginning of the unwinding defect was situated farther from the tip for the Shaping than Finishing files (combined result from both clinics). The fragment length was significantly greater for Shaping files from clinic A than that for clinic B (*t* test, $p < 0.05$); that for Finishing files was comparable between the two clinics.

Of all fractured ProTaper instruments ($n = 70$, both PT and PHU inclusive), S2 separated most often ($n = 24$) followed by S1 ($n = 19$), F1 ($n = 16$), and Sx ($n = 11$) (Fig. 1). The incidence of fracture for K3 instruments ($n = 9$) was size #30 ($n = 3$, 0.06 taper), #25 (1 each for 0.02, 0.06, 0.08, and 0.10 taper), #20 ($n = 1$, 0.06 taper), and #15 ($n = 1$, 0.06 taper) (Fig. 1). The amount of unwound ProTaper instruments (n = 44) was Sx ($n = 1$), S1 ($n = 21$), S2 ($n = 6$), F1 ($n = 4$), F2 ($n = 6$), and F3 ($n = 6$). For the K3 instrument, the size was #25 ($n = 2$) and #20 ($n = 1$) (Fig. 1).

Nearly all breakage and unwinding defects occurred after multiple use (Table 1), except for 3 PT engine files (S1, S2, and F1) that broke and another 6 (two S1, one F2, and three F3) that were distorted during the first-time use (totally 0.8% for PT rotary); no other brand of instrument was distorted or fractured in first use. Collectively, about 0.5% of a brand-new instrument failed when it was first used in a canal. When the tooth type was concerned, the defect rate was about twice as frequent in molars as in premolar teeth for all brands.

Discussion

In a large-scale clinical study, many clinical factors, such as the type of teeth, morphology of the root canal (curvature, length and width), and interoperator variability, are rather difficult to control. However, it may be a truer reflection of what might happen in the

TABLE 2. Summary of Detects for Various NiTi Files from the Three Different Clinics (% of Total Number for Each Instrument)

File	N	Defect-Free*	Distorted†	Location of Unwinding /mm (from tip)	Fracture‡	Fragment Length/ mm
ProTaper (clinic A)						
Shaping file	433	402 (93)§	10 (2)	2.8 ± 0.8	21 (5)¶	3.7 ± 1.1[h]
Finishing file	188	181 (96)¶	3 (2)#	1.7 ± 0.9	4 (2)	3.1 ± 1.4
Subtotal	621	583 (94)	13 (2)	2.5 ± 0.9	25 (4)	3.6 ± 1.2
ProTaper (clinic B)						
Shaping file	293	256 (87)§	11 (4)	2.4 ± 0.7	26 (9)‖	2.9 ± 1.0**
Finishing file	194	174 (90)¶	12 (6)#	1.7 ± 0.5	8 (4)	2.9 ± 0.9
Subtotal	487	430 (88)	23 (5)	2.0 ± 0.7	34 (7)	2.9 ± 1.0
ProTaper Hand (clinic C)						
Shaping file	159	148 (93)	7 (4)	2.8 ± 0.9	4 (3)	4.0 ± 1.3
Finishing file	121	113 (93)	1 (1)	1.5	7 (6)	2.8 ± 0.8
Subtotal	280	261 (93)	8 (3)	2.6 ± 1.0	11 (4)	3.5 ± 1.3
K3 (clinic C)						
Subtotal	294	282 (96)	3 (1)	2.3 ± 0.5	9 (3)	3.0 ± 1.5

*Significant difference between clinics A and B in the number of defect-free instruments ($p < 0.01$).

†Significant difference between clinics A and B in the amount of distortion ($p < 0.05$).

‡Significant difference between clinics A and B in the amount of fracture ($p < 0.05$).

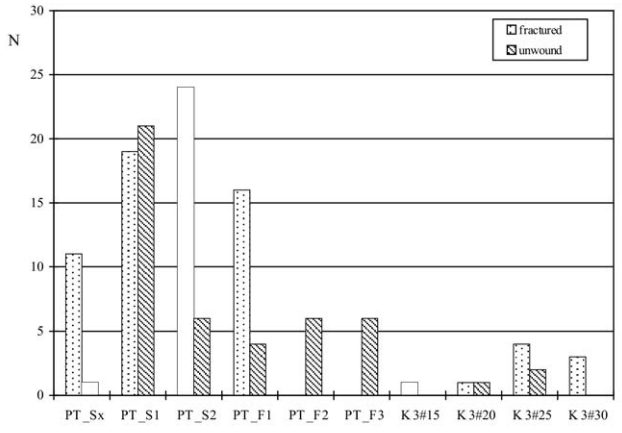
§Significant difference between shaping files of clinics A and B in defect-free instruments ($p < 0.05$).

‖Significant difference between shaping files of clinics A and B in the amount of fracture ($p < 0.05$).

¶Significant difference between finishing files of clinics A and B in defect-free instruments ($p < 0.05$).

#Significant difference between finishing files of clinics A and B in the amount of distortion ($p < 0.05$).

**Significant difference between shaping files of clinics A and B in the fragment length ($p < 0.05$).



*Note: PT = ProTaper instruments, rotary and hand-used inclusive (N = 70 fractured; 44 unwound)

K3 = K3 instruments (N = 9 fractured; 3 unwound), all were 0.06 taper except for fractured size #25 (of which one file each of 0.02, 0.06, 0.08 and 0.10 taper was affected)

Figure 1. The amount of defects observed for all instruments in this study.

general practice than for a well-controlled but artificial environment. This study should give an indication of the incidence of distortion and of fracture for NiTi instruments that are subjected to reuse (after proper cleaning and sterilization procedure) in a multitude of clinical cases, comprising a wide range of tooth types and canal configurations, by three groups of experienced endodontic practitioners in one country. Operator proficiency is an important consideration when evaluating the propensity of instrument failure (10, 12, 13). The operator's ability to sense and resist the binding or "locking" tendency is a skill that can be obtained only with experience. As different endodontists in clinic C used either the PHU or K3 instruments, not both, the two instruments might be considered as two separate groups. Although there has been a set of (slightly different) schedule for use of the various instruments at these clinics, it remained a clinical acumen for the operator to declare an end of the usage life for an instrument that might show dubious defect, or had been used in a canal of dubious level of difficulty. That is, judgment error or inadvertent misuse by the operator may be more important than the number of uses in causing breakage of the instrument in the canal. This collaborated with the findings of Parashos et al. (2) who reported a fracture rate for NiTi instruments ranging from 0.3% to 39%, which rate varied significantly among different endodontists worldwide. Reasons for fracture of NiTi instruments may be complex and multifactorial; some important ones may be operator-related, such as skill and experience (10, 12–14). Thus, proficiency with the use of a system and the decision/adherence to the schedule of use may partly explain the variation in the reported amount of instrument fracture by various studies.

It is widely accepted that NiTi instruments may fail because of incorrect or excessive use (1, 12, 15–17), reiterating the importance of proper training in the use of NiTi technology. However, many factors have been linked to the propensity for defects of NiTi engine files. A clinical study has suggested that the instrument design could influence the defect rate (3). Both the cross-sectional area and file design (influencing stress distribution during load) may affect an instrument's resistance to fracture (7–9, 18). An increase in instrument diameter and in its cross-sectional area could contribute to an increased resistance to torsional failure (19, 20) but also to a decrease in resistance to flexural (fatigue) failure (21). Compared with other brands of NiTi instruments (eg, FlexMaster, Hero 642, ProFile, and RaCe) of similar nominal size, K3 possesses the largest cross-sectional area and, hence, was the stiffest (22). It has been shown that K3 instrument appeared to remain relatively unaltered after the fifth use in simulated canals compared with RaCe instruments (FKG Dentaire, La Chaux-de-Fonds, Switzerland) when the amount of distorted spirals and wear was concerned (23). Another study has reported a lower deformation and fracture rate for K3 instrument used in human teeth, as opposed to simulated artificial canals (24). The lowest defect rate was also recorded for this brand by Ankrum et al. (25) who examined ProFile, ProTaper, and K3 instruments after use in extracted human teeth.

During canal preparation using a NiTi engine file, an alarming clicking noise may sometimes be produced by the repeated binding and release of the instrument (26). It follows that a fluctuating torsional load would be generated and, hence, the possibility of torsional fatigue (27). Varying the instrumentation sequence through incorporating files of different tapers seemed to provide some protection against torsional and fatigue breakage (28). It has been argued that greater operator experience and extensive preclinical training would result in a lower chance of "taper locking" of a regularly tapered instrument (29). Most manufacturers nowadays recommend a crown-down approach of instrumentation, in which the use of larger files precede the smaller ones, gradually progressing further apically with the latter. This approach is mandatory to reduce frictional stresses for the smaller instruments (28) and may improve shaping characteristics of hand files that may be used afterwards (30). Preflaring of the root canal was accomplished by Gates-Glidden burs, instead of a PT-Sx instrument, in clinic B. The defect rate of the Shaping files in this clinic was higher, with the fragment length being shorter (which suggested torsional failure) than for clinic A (where PT-Sx instrument had been used). Further study is required to determine whether such observations can be correlated to ex vivo experiment of the effect of binding and location of distortion and fracture.

There is no agreement in the literature with respect to the number of uses and the likelihood of an instrument to fracture. Many authors have accepted that the failure of NiTi files is influenced by how they are used more so than how many times they are used. Deterioration and microcrack formation at the surface may be found under the scanning electron microscope on clinically used instruments (16, 31, 32), but such deterioration may not be readily discernible in the clinical situation. The present results indicated that about 0.5% of a brand-new instrument might fail at first use; most breakages and deformations occurred after multiple uses. Canal geometry (eg, the radius of curvature and canal diameter) can affect the magnitude of stress on instruments (26). Molars, often with fine and curved root canals, are a challenge to prepare (33). Almost three quarters of the NiTi instrument deformations here occurred after use(s) in molar teeth, emphasizing the importance of a frequent and timely disposal of the instrument to avoid breakages.

In conclusion, although it may be difficult to predict when a NiTi file may fracture in the clinic, the magnitude of the problem is low (about 5% of all instruments broke); the number would be much lower if an engine file was to be treated as a disposable instrument. The amount of distortion is also low (3%), suggesting that a forewarning sign (in the form of unwinding of flutes) could hardly be noticed before fracture would occur. The defect rate of NiTi rotary instruments appears to be influenced by the operator, method of use, and the preparation technique and may also be related to instrument design.

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