Variability of the Diameter and Taper of Size #30, 0.04 Nickel-Titanium Rotary Files

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Abstract

This investigation examined the variability of tip diameter (D_0) and taper measurements among four different brands of #30, 0.04 nickel-titanium (NiTi) rotary files ($n = 15$/brand). With all brands, the mean percent D_0 difference from the manufacturer's reported (nominal) diameter (Profile GT, 1.73 ± 2.03%; Endo Sequence, 3.38 ± 3.91%; K^3, 4.56 ± 2.36%; Profile, 6.13 ± 4.07%) indicated that files tended to be larger than the nominal diameter. A 1-factor ANOVA and Tukey's post hoc test revealed a statistically significant difference ($p \leq 0.05$) between Profile GT (smallest difference from nominal) and Profile (largest difference). The ANOVA also indicated no significant effect ($p > 0.05$) of brand on the mean percent difference of the measured taper compared to the nominal taper with the majority of measurements at either 0.039 or 0.040 taper. *(J Endod 2006;32:1171–1173)*

Key Words

NiTi rotary files, taper, tip diameter, variability

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The first real call for standardization of endodontic instruments was proposed by Ingle (1) in 1955. In his proposal, Ingle suggested establishing a logical sequence between instruments, a standardized taper and length of cutting flutes, and a meaningful nomenclature. Several years later in 1958, Ingle and LeVine (2) proposed standardization of endodontic instruments, equipment, and filling material to help improve the quality of endodontic treatment. They recommended a simplified numbering system, consistent diameter and taper, and a consistent formula for size progression from one size to the next.

Width uniformity of the cutting portion of instruments, a uniform graduation of increase in size, and uniform tapering from one size number to the next were some of the proposed requirements related to root canal instruments Green suggested in 1957 (3). This proposal and another by Ingle in 1961 (4) were the impetus for the International Organization for Standardization (ISO) 3630-1 (5) and American National Standards Institute/American Dental Association (ANSI/ADA) specification 28 (6). The requirement for 0.02 taper was added to specification 28 in 1981 (7). With the advent and increased use of files of taper greater than 0.02, there was the associated need for additional standardization requirements. Thus, ANSI/ADA specification 101 covers dimensional requirements and designations that are inclusive of any taper or shape (8).

When the root canal system (RCS) is cleaned and shaped to a specific size, the goal is to achieve an adequate seal particularly at the apex and coronal aspect to prevent leakage and jeopardizing healing. This is best accomplished if files and the matching gutta-percha (GP) points are manufactured to the same exacting specifications. When using files to clean and shape canals, it is assumed the tip and taper reported by the manufacturer are accurate. However, even if the manufacturers are producing their products within the specified standards, there is a ±0.02 mm diameter tolerance for files up to size #60 and ±0.04 mm diameter tolerance for files larger than size #60 (5). For taper, the tolerance is ±0.05 for any size file (8).

According to Weine (9), the differences in instrument tip diameter and/or taper can vary even within the manufacturers. Several studies have been conducted on the dimensional variability of files and reamers with a taper of 0.02 (10–13) with one study including (14) some rotary nickel-titanium (NiTi) rotary files with larger taper (0.04 and 0.06). However, to date, there have been no published investigations comparing the percent difference from the manufacturer's reported (nominal) tip diameter and taper of various brands of greater taper rotary NiTi files. The purpose of this investigation was to compare variability in manufacturing (percent difference from nominal diameter and taper) among four different brands of size #30, 0.04 taper NiTi rotary files.

Materials and Methods

Size #30 NiTi rotary files with a 0.04 taper from four different brands were used: ProFile (Dentsply, Tulsa Dental, Tulsa, OK); K^3 (Sybron Endo, Orange, CA); Endo Sequence (Brasseler, Savannah, GA); and ProFile GT (Dentsply, Tulsa Dental, Tulsa, OK).

The diameter and taper of each file was determined according to the protocol outlined in ANSI/ADA specification 101 and ISO 3630-1 using a measuring microscope (Model W122, Gaertner Scientific Corp. Skokie, IL) with 0.001 mm accuracy and ±0.003 mm tolerance. Based on pilot data and a power analysis, it was determined that 15 files from each brand would meet the constraints of $\alpha = 0.05$ and power = 0.80. As per the specification, the files were conditioned at 20 ± 5°C for 10 hours before measurements.

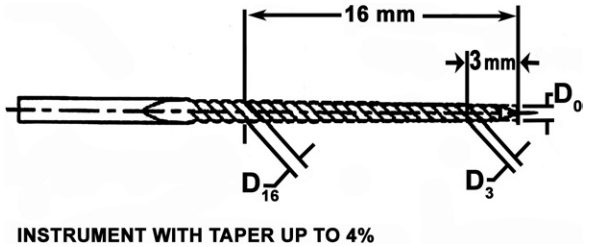

Figure 1. Diagrammatic representation of tapered file and measurement sites for diameter (D_0) and taper (D_3 and D_{16}). (Adapted from ANSI/ADA Specification No. 101-2001.)

According to the specification, the instrument nominal diameter is measured at D_0 (Fig. 1). Based on the diameter measurements, the percent difference from the nominal diameter was determined for each file.

Taper was determined from the diameter at D_3 and D_{16} (Fig. 1) using the equation: Taper = D_{16} diameter − D_3 diameter (mm)/Distance between D_{16} and D_3 (mm). The only exception was Endo Sequence files that required taper measurements to be made at D_{13} and D_3 with this difference divided by the distance between the diameters; this protocol modification was because of measuring difficulties related to the distance between flutes. Based on the taper measurements, the percent difference from the nominal taper value was calculated for each file.

Using the mean percent difference values, a one-way analysis of variance (ANOVA, $\alpha = 0.05$) was used to detect if there was a significant difference in the variability of diameter and taper of the files as a function of file brand. If any differences were detected, a Tukey's post hoc test ($\alpha = 0.05$) was used to identify where the differences existed.

In addition, the frequency percentages of the D_0 and taper measurement values were determined. The frequency distributions were included to more easily see the actual range of data.

Results

The tip diameter D_0 value frequency percentages are presented in Table 1. Across brands, from 13 to 40% of the files were at the nominal, 0.30 mm diameter. However, the majority of the files from each brand had diameters larger than the 0.30 mm nominal diameter with the exception of Profile GT and Endo Sequence, which had a small percentage of files below the nominal diameter.

The taper frequency percentages are presented in Table 2. With three of the four brands, the taper measurements were at or within 0.001 of the stated file taper; only Endo Sequence had some files with taper measurements 0.002 larger or smaller than the nominal taper.

The tip diameter and taper mean percent differences from nominal values are presented in Table 3. The one-factor ANOVA indicated there was a statistically significant effect ($p \leq 0.05$) of brand on the mean percent difference of the file D_0 as compared with the nominal diameter. The Tukey's post hoc test indicated that only ProFile GT and ProFile were significantly ($p \leq 0.05$) different from each other with all other comparisons nonsignificant ($p > 0.05$); subsets indicated in Table 3. ProFile GT, with 40% of the files with D_0 equal to 0.30 mm, exhibited the smallest percent difference from the nominal diameter (1.73 ± 2.03%). ProFile with 40% of the files >0.32 mm, exhibited the largest percent difference from the nominal diameter (6.13 ± 4.07%).

The majority of taper measurements were at or smaller than the nominal taper with only ProFile GT and Endo Sequence having files with larger than nominal taper, respectively 13 and 27%. Although the mean taper percent differences of K^3 or ProFile were larger than the taper differences of ProFile GT or Endo Sequence, it is important to note that both ProFile GT and Endo Sequence had larger SD values. The range of taper values (Table 2) for K^3 and ProFile was 0.039 to 0.040, whereas ProFile GT and Endo Sequence had taper measurements ranging from 0.039 to 0.041 and 0.038 to 0.042, respectively. However, because the differences were small overall, the ANOVA indicated there was no significant difference ($p > 0.05$) between the mean percent difference of the measured taper as compared with the nominal taper as a function of brand.

TABLE 1. Percent of D_0 diameter measurements based on data range categories

File Brand	0.28–0.29 mm (%)	0.30 mm (%)	0.31–0.32 mm (%)	>0.32 mm (%)
ProFile GT	7	40	53	0
Endo sequence	13	20	47	20
K^3	0	13	74	13
ProFile	0	13	47	40

TABLE 2. Percent of taper measurements based on taper categories

File Brand	0.038 (%)	0.039 (%)	0.040 (%)	0.041 (%)	0.042 (%)
ProFile GT	0	40	47	13	0
Endo sequence	20	27	27	20	7
K^3	0	47	53	0	0
ProFile	0	60	40	0	0

Discussion

Even with the call for standardization of endodontic instruments and establishment of ISO and ANSI/ADA standards, there are still variations in instrument taper and nominal diameter. In the current investigation, size #30, 0.04 taper files from four different brands were evaluated to determine the variability from the nominal diameter and taper.

The results indicate that all the brands studied exhibited tip diameters that were generally larger than nominal with the largest difference displayed by ProFiles that were 6.13 ± 4.07% larger than the nominal diameter. However, when examining the actual diameter mean measurements rather than mean percent difference from the nominal diameter, ProFile mean diameter was 0.318 ± 0.012 mm, only 0.018 mm larger than the stated 0.30 mm. Thus, although there was a statistically significant difference between brands related to the percent difference from the nominal diameter, this difference would probably not be clinically significant.

A comparison of the tapers demonstrated that across all file brands 27 to 53% of the files were at nominal taper, whereas 40 to 60% of the files across brands exhibited less than nominal taper. Only ProFile GT and Endo Sequence had files with larger than nominal taper. However, these differences between brands were not significant. K^3 and ProFiles all were at either 0.039 or 0.40 taper and ProFileGT files ranged from 0.039 to 0.041 taper. Endo Sequence exhibited the most taper variation; however, the minimum and maximum values were only plus or minus 0.002 from the nominal 0.04 taper.

TABLE 3. Mean percent difference and standard deviation from manufacturer's stated nominal diameter and taper

File Brand (N = 15)	Diameter (D_0)*	Taper**
ProFile GT	1.73 ± 2.03 a,b	−0.83 ± 2.04
Endo sequence	3.38 ± 3.91 b,c	−0.83 ± 3.09
K^3	4.56 ± 2.36 b,c	−1.17 ± 1.29
ProFile	6.13 ± 4.07 c,d	−1.50 ± 1.27

*Significant effect ($p \leq 0.05$) of brand on mean percent difference of file diameter (D_0) as compared to the manufacturer's stated diameter. Subsets are indicated by letters a–d.

**No significant effect of brand on mean percent difference of file taper.

Previous studies of 0.02 taper stainless steel and NiTi instruments showed variation in nominal size. Stenman and Spangberg (11) reported files of the same size varied by as much as 43% above and 12% below tolerance limits. Serene and Loadholt (12) reported similar results in their study. Kerekes (13) reported variation in the diameter of H-files from multiple manufacturers with Micro Mega exhibiting correct diameters and Maillefer H- demonstrating the least favorable results with 43% above the standard. That study also reported that on the whole, all root canal instruments exhibited correct taper. Zinelis et al. (14) reported that none of the files studied complied with nominal size but most were within the ISO limits of tolerance. There were two exceptions and both came from NiTi files of greater taper where the nominal size was below accepted tolerances. In contrast, the results of the current study of #30, 0.04 taper NiTi instruments indicate that the investigated files exhibited presumably clinically insignificant differences from the nominal diameter and taper.

Although the reported accuracy of the investigated size #30, 0.04 taper endodontic instruments is favorable, future studies should include measurements of 0.04 taper files with diameters other than size #30. In addition to accurately manufactured instruments, accurately manufactured GP cones are also important to match the diameter and taper of the last instrument used. Thus, future studies could also include the correlation of endodontic instrument diameter/taper measurements with the associated measurements of same size GP cones.

Acknowledgments

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