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Nominal Size and Taper Analysis of Novel Metallurgy NiTi Files

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ABSTRACT

Objective: The aim of this investigation was to assess the nominal tip diameter, taper and true pilot tip length of three nickel-titanium (NiTi) rotary files before and after use.

Methods: Three brands of NiTi files of size 25.08 were evaluated: ProTaper Uni-versal (Dentsply Tulsa Specialties, Tulsa, USA), Channels PT (Insight Endo for Henry Schein, Melville, NY) and ProTaper Gold (Dentsply Tulsa Specialties), with ten files from each brand (total n=30). Scanning electron microscope (SEM) images of the files at 50x magnification were acquired before and after the files were used on endodontic training blocks, and the images were analysed by two independent investigators using ImageJ software. The nominal tip diameter (D0), taper and true pilot tip length (measured as the distance from the advertised diameter size of the file to the tip of the file) were recorded for each file and were analysed for statistical differences using repeated measures of analysis of variance (r-ANOVA) and Tukey's post-hoc test ($P<0.05$).

Results: The marginal means of the nominal size showed statistically significant differences between brands of the same size; statistically significant differences were also observed between the advertised sizes and the actual sizes ($P<0.001$). The mean taper values showed statistically significant differences from the advertised ($p<0.001$) sizes, except for the ProTaper Gold ($P=0.023$) group. The changes in the true pilot tip length before and after use were not statistically significant ($P>0.05$). The pilot tip lengths varied between brands.

Conclusion: All nominal tip diameters and most taper sizes of the analysed brands show statistically significant differences from the nominal sizes advertised by the manufacturers. The differences in true pilot tip lengths between brands indicate a current lack of standardization.

Keywords: Accuracy, NiTi Rotary Files, Nominal size, Pilot tip, Taper

INTRODUCTION

Endodontic files are manufactured based on specifications set by the International Standards Organization (ISO 3630-1) (1) and the American National Standards Institute/American Dental Association (ANSI/ADA Spec 101) (2) to ensure that the dimensions of the files fall within the allowable tolerances for their advertised sizes. These guidelines exist due to pioneering efforts in the mid-1950s by Green (3), Ingle (4, 5) and others, who called for standardisation of stainless steel 0.02 taper endodontic instruments and obturation materials. Current guidelines for nickel-titanium (NiTi) rotary files set the tolerance for the diameter of the files to be within 50% of the difference between the next smallest and/or next largest instrument size (2), while the allowable tolerance for the taper is set to be within 0.05 of the advertised taper size (2). For example, if the difference in the stated diameters between one file and the next largest or smallest file is 0.05 mm, then the allowable tolerance would be $\pm$0.025 mm from the advertised size. For the taper, the generous allowance of $\pm$0.05 means that if the file is advertised as having a 0.06 taper, the actual file taper can be anywhere from 0.01 to 0.11 (2,6).

In 2002, Zinelis *et al.* (7) reported on the clinical relevance of the standardization rules of ISO 3630-1 specifications; they concluded that although the sizes of the tested files did not match the advertised sizes, they still fell within the acceptable tolerance range due to the large amount of

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allowable tolerance. Numerous studies have examined the diameters and tapers of continuous taper NiTi rotary files (6-11). To our knowledge, no publication has compared the dimensional values of conventional NiTi rotary files (ProTaper Universal) to those of the newly available duplicates of conventional NiTi systems (Channels PT) and the newer, heat-treated reproduction NiTi files (ProTaper Gold). When a file is heat treated, the flexibility of the file increases, which may lead to greater affinity for distortion during use (12).

The ISO and ANSI/ADA publications do not set a guideline for the pilot tip length of files; this specification is determined by the manufacturer. The pilot tip is the area of a file from its very tip to the first cutting edge. The purpose of the pilot tip is to enlarge the canal and to guide the file forward (13). The distance from the tip of the file to the point on the file where the advertised size of the file is actually measured is termed as the true pilot tip length. To our knowledge, no reports exist that evaluate the true pilot tip length of files.

In this study, we aimed to evaluate the nominal tip diameter, taper and true pilot tip length of NiTi rotary files before and after use; we also aimed to evaluate the manufacturers' compliance with ANSI/ADA guidelines.

MATERIALS AND METHODS

Three different brands of size 25.08 files were kindly provided for use in this research: ProTaper Universal (Dentsply, Tulsa Dental, Tulsa, OK), Channels PT (Insight Endo for Henry Schein, Melville, NY) and ProTaper Gold (Dentsply, Tulsa Dental, Tulsa, OK). Ten files were used from each brand (total n=30). Prior to the measurements, the files were steam sterilized and imaged by scanning electron microscope (SEM, FEI Quanta 200F Environmental Scanning Electron Microscope (ESEM), FEI Inc. Hillsboro, OR) at 50x magnification and at a resolution of 0.1 micron. The SEM imaging was performed by an electron microscopist in the University Microscopy Laboratories. To standardize the setup between the groups, all samples were imaged during the same session. An exempt status was approved by the Institutional Review Board Office of Human Research Ethics at the University of North Carolina at Chapel Hill.

All images were evaluated and measured by two independent and equilibrated examiners using ImageJ software (National Institute of Health, Bethesda, MD). The agreement was set at 0.001 mm.

The nominal diameter (D0) was measured at the first cutting edge of the file (Figure 1). If the obtained value did not correspond to the advertised size of the file, a measurement was made down the length of the file until the measurement of the advertised size was reached. This was termed the 'true D0'. This value was used to determine the true pilot tip length (from the tip of the file to the true D0).

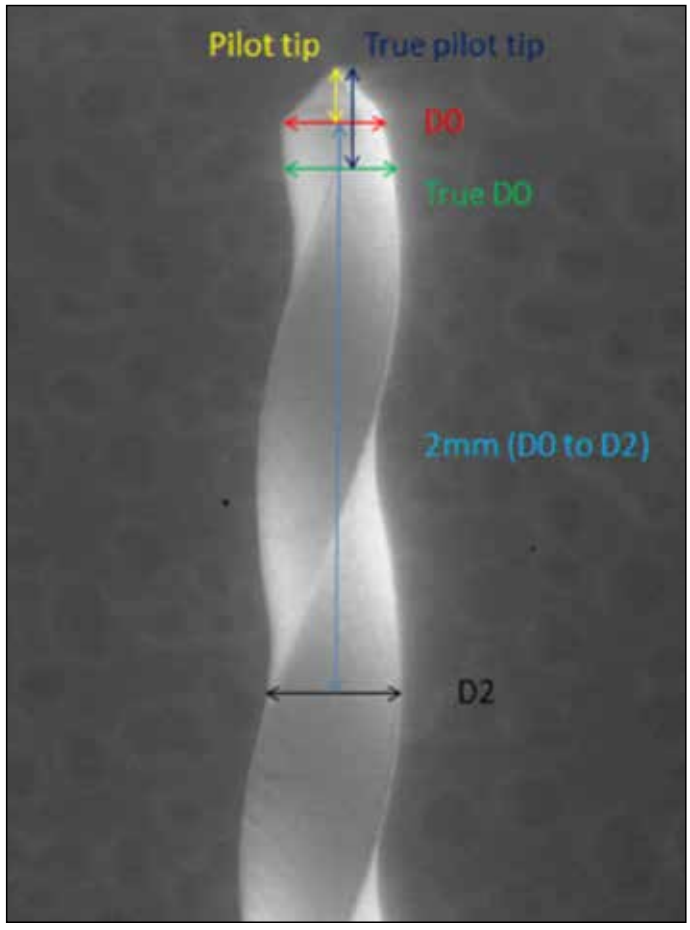

Figure 1. D0: Diameter measured at the first cutting edge of the file.
True D0: diameter of the advertised file size.
D2: diameter measured 2 mm from the tip of the file.
Pilot tip: length from the tip of the file to D0.
True pilot tip (TPT): length from the tip of the file to where the advertised diameter size was recorded (true D0).

The taper of the file was measured using the formula set by ANSI/ADA Spec 101: Taper = Distance of diameters/Distance between diameters. The guideline states that the diameters included in the above equation are D0 and D16 (or, alternatively, D3 and D16) (2). A protocol adjustment was performed here because the tapers of the tested files varied beyond the initial 4 mm of the file length. Therefore, the diameters included in our analysis were D0 and D2. The differences between the measured taper and the advertised taper were determined.

The pilot tip length was measured from the tip of the file to D0. The true pilot tip length was measured from the tip of the file to where the advertised size of the file was recorded (true D0).

After initial measurements, instrumentation was performed by a standardized methodology using plastic endodontic training blocks (Dentsply Maillefer, Ballaigues, Switzerland). The training blocks had the following specifications: ISO 015 (apical), 0.02 taper, 40° curvature and Knoop hardness of 22

TABLE 1. Diameter values (mm) before and after use compared to the advertised nominal size

		Tip Size D0 (diameter) Measurement			
		Before		After	
File Brand	Advertised Tip Size	Mean	p-value	Mean	p-value
ProTaper Universal F2	0.250	0.231±0.007	<0.001	0.225±0.006	<0.001
Channels C2		0.276±0.016	<0.001	0.272±0.008	<0.001
ProTaper Gold F2		0.219±0.016	<0.001	0.211±0.011	<0.001

*D0: Diameter measured at the first cutting edge of the file.

TABLE 2. Taper values (before and after use) compared to the advertised nominal taper sizes

		Taper Value Measurements			
		Before		After	
File Brand	Advertised Tip Size	Mean	p-value	Mean	p-value
ProTaper Universal F2	0.080	0.073 ± 0.003	<0.001	0.073±0.002	<0.001
Channels C2		0.0566 ± 0.007	<0.001	0.058±0.007	<0.001
ProTaper Gold F2		0.085 ± 0.008	0.105	0.088±0.009	0.023

TABLE 3. True pilot tip (TPT) lengths (mm) before and after use

	True Pilot Tip Measurements			
			Before vs.	
	Before	After	After	
File Brand	Mean TPT	Mean TPT	Mean	p-value
ProTaper Universal F2	0.41±0.10	0.40±0.06	+0.01±0.09	0.829
Channels C2	0.22±0.01	0.21±0.01	0.00±0.020	0.954
ProTaper Gold F2	0.40±0.07	0.41±0.05	-0.01±0.080	0.616

*True pilot tip (TPT): length from the tip of the file to where the advertised diameter size was recorded (true D0).

kg/mm^2. All files were operated at 300 RPM and 3 N torque. A total of 5 mL of saline per block was used for irrigation. After instrumentation, the files were imaged again by SEM (Figure 2). The measurements performed on the files during the initial setup were repeated.

Statistical Analysis

Data analyses were conducted using repeated measures of analysis of variance (r-ANOVA) and Tukey's test to evaluate the differences between the diameters, tapers and true pilot tip lengths before and after use; these values were then compared to the advertised sizes. The p-value was set at 0.05. The percentages of files that satisfied the ANSI/ADA tolerance level were determined ($\pm$0.025 mm for the diameter and $\pm$0.05 for the taper). All statistical analyses were performed using SAS version 9.3 (SAS Institute Inc, Cary, NC).

RESULTS

The mean and standard deviations of the diameter values are recorded in Table 1. None of the file sizes matched the advertised nominal diameter sizes. The mean measure of D0 in each group was significantly different from the advertised size (P<0.001); the mean D0 measure was less than the advertised size for all brands, except for the Channels PT files. Of the three brands, only ProTaper Universal fell within the ANSI/ADA specification range.

The taper values (Table 2) indicated that the mean measure of the taper in each group was significantly different (P<0.001) from the advertised taper both before and after use, except for the ProTaper Gold group (P=0.105). In the ProTaper Universal and Channels PT groups, the mean taper measures (before and after) were less than the advertised sizes; however, in the ProTaper Gold group, the mean taper measures (before and after use) were greater than the advertised size. However, given the generous tolerance range of +/–0.05, all of the tapers fell within specification limits.

The mean true pilot tip lengths varied between different rotary systems (Table 3) from 0.21 mm to 0.41 mm. There was no significant mean change in the true pilot tip length before and after use (P>0.05).

DISCUSSION

ProTaper Universal rotary files have been on the market for over a decade and are one of the top-selling rotary file systems in the world. Thus, these files were included in this study. The patent on ProTaper Universal files recently expired; several other companies now offer their own versions of ProTaper files, including Channels PT tapered files. Due to advances in metallurgy and in the heat treatment of nickel-titanium files, the newer ProTaper Gold files are more flexible and resistant to fracture (14). These newer files were included in the study for comparison with the original files.

The latest revisions and reaffirmations to the ISO 3630-1 and ANSI/ADA Spec 101 standards were made in 2008 and 2010, respectively (1,2). Although these guidelines are available,

variations in dimensional standards are still being reported (6-10). These guidelines were used in the present evaluation of the nominal diameter and taper analysis of three brands of size 25.08, as well as the lengths of the pilot tips of all the files.

An evaluation of stainless steel H- and K-files, as well as rotary NiTi files, by Zinelis *et al.* (7) showed that none of the files had the advertised nominal diameters. Lask *et al.* (10) evaluated the diameter and taper of four different brands of size 30.04 NiTi rotary files. They found that the files tended to be larger than the nominal sizes; however, they concluded that the difference was minimal and probably not clinically relevant. Kim *et al.* (9) evaluated the dimensional standards of several NiTi rotary files; they found that most of the diameter values were not in compliance with the advertised values. In the present study, only the ProTaper Universal files fell within the specification limits of between 0.225 mm and 0.275 mm. The ProTaper Universal and ProTaper Gold files tended to be smaller than the advertised nominal size, and the Channels PT files tended to be larger than the advertised nominal size.

The percentages of files in this study that were within the ANSI/ADA tolerance limit were 80% for ProTaper Universal, 50% for Channels PT, and 20% for ProTaper Gold. The files tended to be smaller for all of the groups except for the Channels PT group, where sizes consistently larger than the highest ANSI/ADA limit were observed. It is interesting to observe that more of the austenite phase files (ProTaper Universal and Channels PT) were within the ANSI/ADA tolerance limit than the newer, metallurgy heat-treated files (ProTaper Gold). It is also of interest that although the files may be advertised as exact replicas of one another (ProTaper Universal and Channels PT), practitioners should be aware of potential size differences, especially if employing a hybrid technique with rotary instrumentation. The mean nominal size of the ProTaper Universal files was 0.23 mm, and that of the Channels PT files was 0.28 mm. Zinelis *et al.* (7) pointed out the issue of file size overlap, where the next biggest size of one brand may be the same as the next smallest size of a different brand. To date, the clinical outcomes of larger preparations are still controversial, and the ideal master apical preparation is unknown (15). However, the clinician should have access to instruments with the best possible size to achieve a chosen preparation size.

Evaluation of the taper indicated that only ProTaper Gold had a mean taper that matched the advertised taper. However, all the files satisfied the ANSI/ADA tolerance range. This is in agreement with previous reports (6,8). The mean taper for the ProTaper Universal files was 0.07, and that for the Channels PT files was 0.06.

Similar to the measured diameters, the austenite phase files (ProTaper Universal and Channels PT) tended to undershoot the advertised taper sizes, while the heat-treated files (ProTaper Gold) tended to overshoot the advertised taper sizes. It should also be noted that the current ANSI/ADA Spec 101 taper tolerance guidelines of +0.05 are rather generous; a stricter updated guideline may be warranted.

The evaluation of the true pilot tip length indicated the complete lack of standardization between different files and manufacturers. The true pilot tip length ranged from 0.21 mm for the Channels PT group to 0.41 mm for the ProTaper Gold group. The ProTaper Universal and ProTaper Gold files displayed almost identical true pilot tip lengths of 0.41 mm and 0.40 mm, respectively.

CONCLUSION

In summary, the present study showed that the nominal diameter sizes of the tested files and most of their taper values are not in agreement with their advertised sizes and, often, are even outside specification limits. The clinical relevance of this finding is arguable; however, tighter manufacturing tolerances may be warranted to minimize the potential for sizing overlap, practitioner frustration and possible iatrogenic complications. Future studies should examine other sizes and brands of files and further evaluate these for differences in new metallurgies; also, the benefit of standardizing the length of the pilot tip should be determined.

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