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A comparison of dimensional standard of several nickel-titanium rotary files

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Objectives: The aim of this study was to compare the dimensional standard of several nickel-titanium (Ni-Ti) rotary files and verify the size conformity. ***Materials and Methods:*** ProFile (Dentsply Maillefer), RaCe (FKG Dentaire), and TF file (SybronEndo) #25 with a 0.04 and 0.06 taper were investigated, with 10 in each group for a total of 60 files. Digital images of Ni-Ti files were captured under light microscope (SZX16, Olympus) at 32×. Taper and diameter at D_1 to D_{16} of each files were calculated digitally with AnalySIS TS Materials (OLYMPUS Soft Imaging Solutions). Differences in taper, the diameter of each level (D_1 to D_{16}) at 1 mm interval from (ANSI/ADA) specification No. 101 were statistically analyzed using one-way ANOVA and Scheffe's *post–hoc* test at 95% confidence level. ***Results:*** TF was the only group not conform to the nominal taper in both tapers ($p < 0.05$). All groups except 0.06 taper ProFile showed significant difference from the nominal diameter ($p < 0.05$). ***Conclusions:*** Actual size of Ni-Ti file, especially TF, was different from the manufacturer's statements. (*Restor Dent Endod* 2014;39(1):7-11)

Key words: Diameter; Ni-Ti rotary files; Size verification; Taper; TF

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Introduction

In recent years, nickel-titanium (Ni-Ti) rotary files have taken place of stainless steel hand files and are being used widely in the area of endodontic treatment.[1] Ni-Ti rotary file systems have advanced to let clinicians clean and shape root canals more efficiently and effectively.[2] For effective and predictable cleaning and shaping of root canal system, the size of endodontic instruments should be accurate and precise. Taking this into consideration, Ingle had proposed standardization of endodontic treatment instruments.[3] The standard has been modified and revised since, and is still being used to this day.[4-10] In 2001, American National Standards Institute/American Dental Association (ANSI/ADA) specification No.101 which provides standards to the endodontic treatment instrument was proposed.[11]

Despite the development of manufacturing methods and the standardization of endodontic files, there still remains wide variation in the dimensions of endodontic files of the same nominal size within or between different manufacturers.[12-16] Taper and size differences were mostly within the tolerance limit, but there were still some variations in the group.[12,17,18] If taper or size is different from what the manufacturer claims, appropriate preparation of the root canal may not be achieved. Appropriate canal filling could be achieved when files and the matching gutta-percha (GP) points are manufactured to the same exacting specifications.[17] Due to this reason, incorrect file and GP cone size would affect the quality of canal filling and longevity of the teeth.[18]

The twisted file (TF) system, introduced in 2008, is made by twisting instead of machining so it does not show microfracture. TF file also demonstrated excellent flexibility and fatigue resistance due to R-phase heat treatment.[19] In several studies, TF has shown excellent centering ability in the canal, flexibility, and fatigue resistance, and also caused less transportation.[20-24] Oh *et al.* stated that when the cross sectional areas (CSA) of TF at 3 mm from the tip are compared to RaCe and ProFile, TF was the smallest.[22] This fact tells that, besides the physical characteristics of TF, the small CSA might have contributed to the excellent working characteristics of the TF file. However there was no additional explain whether small CSA came from small cross sectional shape or small diameters.

The aim of this study was to compare the dimensional standard of several Ni-Ti rotary files and verify the size conformity. In this study, under the assumption that the diameter and taper of the TF is smaller than that of other files, RaCe and ProFile was investigated and compared with TF to see whether they fulfill the standard.

Materials and methods

Ni-Ti rotary files of ProFile (Dentsply Maillefer, Ballaigues, Switzerland), RaCe (FKG Dentaire, LaChaux-de-Fonds, Switzerland), and TF (SybronEndo, Glendora, CA, USA) of identical Size (ISO #25) with 0.04 and 0.06 taper were used in this study. Rotary Ni-Ti files were divided into groups by the brands and tapers containing 10 files in each, and digital image of file was taken under the view of an optical microscope (SZX16, Olympus, Tokyo, Japan) at 32× magnification. AnalySIS TS Materials (OLYMPUS Soft Imaging Solutions, Münster, Germany) program was used to edit digital images and measure the file's diameter. Each file's images were taken in 8 parts and then reconstructed later to make a whole image of the file. The images were edited and analyzed by 0.001 mm accuracy (Figure 1).

The taper was calculated from D_3 and D_{16} according to ANSI/ADA specification No. 101 (Taper = D_{16} - D_3 diameter / Distance between D_{16} and D_3).[11] Each file's diameter was measured perpendicular to the axis by 1 mm interval starting at D_1, the point where the working edge starts, and ending at D_{16}. Imaginary lines were drawn between the working edges for measurement. Differences in taper and the diameter of each level (D_1 to D_{16}) were statistically analyzed and compared in the SPSS version 19.0 program (SPSS Inc., Chicago, IL, USA) by the one way ANOVA and Scheffe's *post-hoc* test at 95% confidence level.

Results

From D_1 to D_{16}, on each level, the average of the discrepancy with the standard diameter and the calculated taper is shown in Table 1. Difference of taper as compared with the nominal taper was different among the group. ProFile and RaCe showed similar tapers with the nominal taper, but TF showed significantly smaller taper ($p < 0.05$).

When comparing the diameter with the standard, there was significant discrepancy in all groups except 0.06 taper ProFile. The diameter of RaCe was bigger than the standard, and the diameters of 0.04 taper ProFile and 0.04, and 0.06 taper TF were smaller than the standard ($p < 0.05$). The diameters of the files are shown in graphs in Figures 2 and 3. With 0.06 taper files, the diameter and taper of TF was significantly smaller than others (Figure 2). With 0.04 taper files, the diameter of RaCe was bigger, and the diameter of ProFile and TF was smaller than the standard (Figure 3).

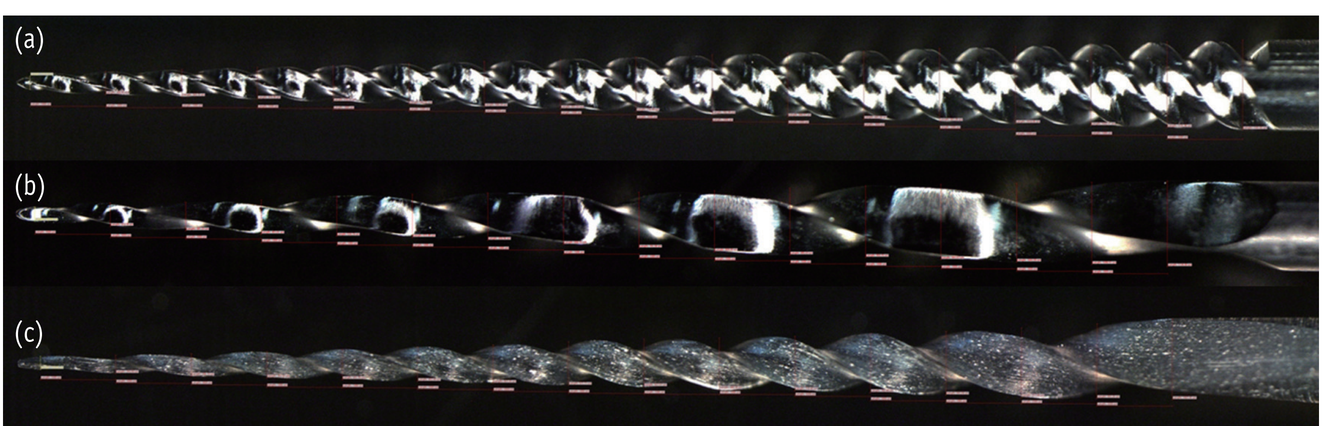

Figure 1. Representing digital image of Ni-Ti files. (a) ProFile; (b) RaCe; (c) TF.

Table 1. Taper and differences in the diameter from standard (n = 10)

File	Calculated taper		Differences of diameter from standard (μm) (D1 - D16)	
	0.06	0.04	0.06	0.04
ProFile	0.058 ± 0.0016[†]	0.040 ± 0.0006	4.75 ± 17.08	-22.35 ± 12.81
RaCe	0.059 ± 0.0007	0.040 ± 0.0010	9.13 ± 24.14	15.89 ± 21.06
TF	0.053 ± 0.0018	0.036 ± 0.0017	-74.61 ± 31.12	-39.24 ± 17.93

[†] Indicate statistically significant difference with standard taper and diameter ($p < 0.05$).

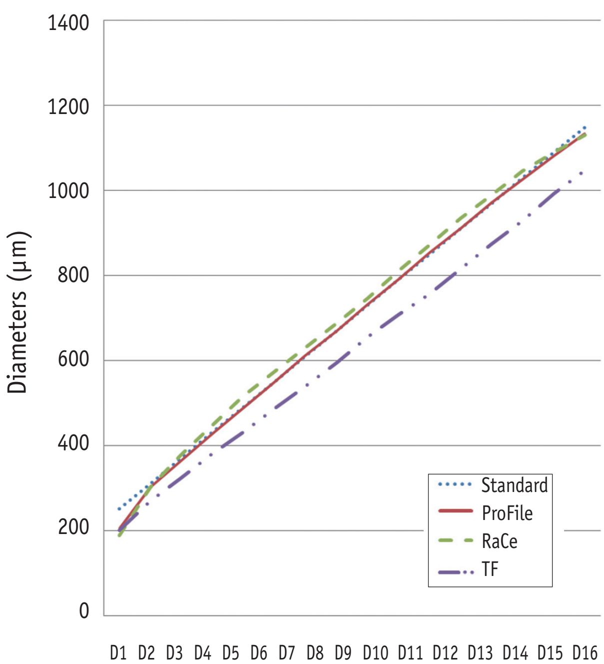

Figure 2. Mean value of diameter of 0.06 taper Ni-Ti rotary files at each level.

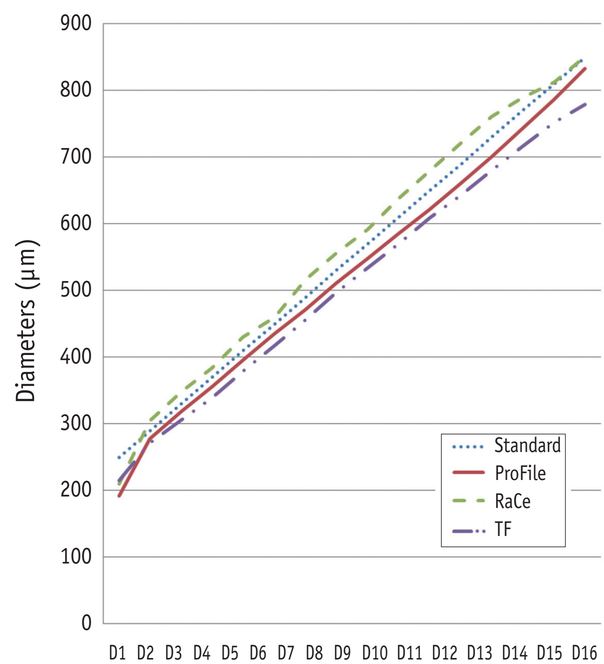

Figure 3. Mean value of diameter of 0.04 taper Ni-Ti rotary files at each level.

Discussion

When the endodontic file does not follow the standard and exceeds the tolerance limit, the file could get as big or as small as the following or preceding file size.[12] If the size difference between the successive files increases, it may get more difficult to reach the apex at the next step. In addition, the increased difference between sequential files causes an increase in rigidity and therefore leads to higher possibilities of transportation during canal preparation.[12] When the actual size of the master apical file (MAF) file is same as the file one step smaller, the clinician can't sufficiently clean the canal, and as a result, the prognosis of the treated tooth may not be optimum. Therefore, it is important to standardize endodontic files and follow the standards agreed upon.

Zinelis *et al.* studied diameters of some H-files, K-files and Ni-Ti rotary files and found out that although there were none which satisfied the standards perfectly, most were within the tolerance limit.[12] Lask *et al.* studied the diameter of file tip and taper of four kinds of 0.04 taper #30 Ni-Ti file and found out that normally the diameter is bigger and the taper was smaller than that of the standard.[17] Also Hatch *et al.* reported that the taper of Ni-Ti files satisfied the standards of ANSI/ADA specification No. 101 but that there were variables within the groups.[18]

Diameters at D_1 in all groups were significantly smaller than that of the standard, but limit of manufacturing at file tip part could be the reason for this size discrepancy.

According to ANSI/ADA specification no. 101, tolerance limit of instrument taper is ± 0.05%, and the diameter is to be within 50% of the difference between the next smaller and/or the next larger instrument of the available brand sizes.[11] In this study, the taper and diameter of 0.06 taper ProFile and RaCe showed some differences, but were within the tolerance limit. Therefore it could be speculated that the difference would not have much clinical importance in the actual practice. The taper of 0.04 ProFile and RaCe was within the tolerance limit and satisfied standard value, but the diameter exceeded the tolerance limit. Both diameter and taper of the TF did not satisfy the standard value and exceeded the allowable tolerance limit. Compared with other files, TF had significantly smaller taper and diameter. According to the ANSI/ADA specification no. 101, endodontic instrument size is to be measured using a microscope or show graph, with the accuracy of ± 0.002 mm.[11] In this study, an optical microscope was used to make measurements by 0.001 mm and a preliminary study was done to confirm the accuracy of the measuring method.

Cross sectional area is known to affect stiffness and fatigue resistance of file.[16,22,25-28] Cross sectional area changes with the cross section design, but small cross sectional area of the file does not necessarily mean small diameter of the file. For example, if cross section of one file is convex triangle and the other file is equiangular triangle, diameter of both file is same but CSA is different. Cross sectional shapes of RaCe and TF have the same equiangular triangle cross sectional design, the CSA of RaCe (89,175 μm^2) turned out to be 1.8 times larger than that of the TF (50,275 μm^2) at 3 mm from the tip.[22] From this we could assume that small taper and/or diameter was one of causes of the small cross sectional area. The TF's excellent characteristics seem to come from its manufacturing process, small taper and small diameter. According to the manufacturer, TF is made by transforming of a raw Ni-Ti wire in the austenite to R-phase through a heat treatment and then made by repeated heat treatment and twisting in the R-phase.

However, this processing procedure could be the reason for the size discrepancy of TF. When twisting the wire during heat treatment the wire could be elongated, causing small cross sectional area and size of the file. In this study, TF showed smaller diameter and taper compared with the other files made by machining. It could also be thought that this may have affected the result of past studies that showed better flexibility and high fatigue resistance of TF.[23,24] Therefore it is impossible to exclude the effects of small CSA on flexibility and fatigue resistance of the TF entirely.

Additional study on TF's physical characteristics using files with same cross sectional area, precisely measured, is needed. Also, when comparing rotary Ni-Ti files, aside from physical characteristics and cross sectional area, exact measurement of taper and diameter must be done. Recently, various rotary Ni-Ti files which vary in cross sectional design, taper, rake angle, helical angle, pitch and radical land are being introduced, and constant development of files with various manufacturing process and size is expected.[29] However, size standards specified for rotary Ni-Ti files are yet to be made and it is required that new standards be made.

Conclusions

The actual size of Ni-Ti file, especially TF, turned out to be different from what the manufacturer claims. In conclusion it is important that the clinicians consider possibility of incorrect file size when shaping canals or doing experiments using these files.

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Conflict of Interest: No potential conflict of interest relevant to this article was reported.

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