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Measurement of nickel-titanium rotary files against ISO standards using Light Microscopy

David J. Sabovich, DMD, Matthew B. Phillips, DMD, Joseph M. Dutner, DMD

Abstract

Introduction: Nickel-titanium rotary endodontic files are labeled according to their tip diameter and the taper along the length of the instrument. The purpose of this study was to evaluate whether the true tip diameter of the endodontic files matches the nominal size. **Methods:** Files were organized into 4 groups based on their brand and type. Edge Sapphire (n = 100) (EdgeEndo, Albuquerque, New Mexico), Edge X7 (n = 100), Vortex Blue (Dentsply Sirona, York, Pennsylvania) (n = 100), and Endosequence Scout (Brasseler USA, Savannah, Georgia) (n = 80) rotary files were examined and measured using an EVOS FL Auto light microscope (Thermo Fisher Scientific, Waltham, Massachusetts) with an accuracy of 1 nm to establish the actual diameter at the file tip. A one-way ANOVA was performed for comparisons between the file types. **Results:** The average tip diameters of all four types of files were significantly smaller than the manufacturer-claimed sizes. ANOVA demonstrated significant differences between file types; $F(3,376) = 25.38$, $p < .001$. **Conclusion:** The four file systems tested had mean tip diameters that were all smaller than their claimed diameters, and measurements varied considerably within the groups. There is considerable variability both within file systems and between file systems.

INTRODUCTION

The goal of endodontic therapy is the complete chemo-mechanical disinfection of the root canal system, and obturation of that system with a sealed material. Complete disinfection of the canal space requires instrumentation to both the correct width, and the correct length of the canal. There is disagreement about precisely how wide to instrument (2,3), or how close to the apex to instrument(4), but there is no disagreement about whether or not the operator should know how long his file is, or how wide it is. The length is checked both radiographically and with the aid of electronic apex locators, and these methods are quite accurate to within 0.5mm(5). The width, however, is simply printed on the packaging of the file and operator trusts that the manufacturer is within some specification for the true size. The true width of the file then, unlike the length, is not known to the operator. Since it is desirable to know both the length and the width of the endodontic file, this presents a problem.

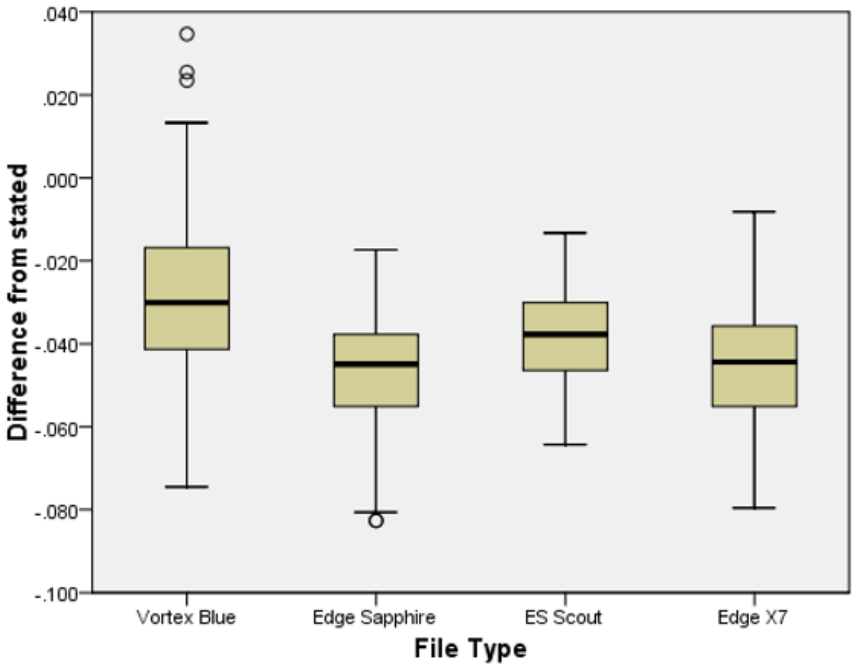
The International Standards Organization (ISO) provides guidance on the acceptable tolerance of endodontic files. ISO standard 3630-1 gives specific tolerances. For a tapered endodontic file the standard is +/- 0.02mm in diameter(1). Considering that endodontic files start at 0.06mm, this standard is quite generous. In other words, when an operator selects a size 10 file, the file tip diameter could in reality be as small as a size 08 or as large as a size 12, assuming the file is within specifications.

An endodontic file with a tip diameter that is either larger or smaller than labeled can result in less than ideal endodontic therapy. Endodontic procedures are performed with tolerances of thousandths of a millimeter, and departure from the expected file tip diameter can have major effects on two main areas of the endodontic procedure: irrigation, and obturation.

Irrigation of the root canal system involves placing an irrigant, under pressure, to within 1.0mm of the apical constriction. The most commonly used irrigant is sodium hypochlorite. Sodium hypochlorite is a commonly used irrigant in endodontic procedures because it is good at killing bacteria commonly found in the root canal system, it dissolves tissue, and it provides lubrication to the files(6). These same qualities mean that it is also quite harmful to the tissues if expressed past the root canal system. A standard needle size for endodontic irrigation is 30, which is 0.32mm. For this reason, it is common to instrument the canals to at least a size 30 endodontic file, which measures 0.30mm. This ensures that the irrigant is able to get to within 1mm of the apical constriction, which is required for effective disinfection of the canal system (7). If the endodontic file were undersized, then the irrigation may not reach the desired level, and if it were oversized then it may go too far. This can either affect the prognosis of the tooth, or can be patient safety issue if sodium hypochlorite is expressed out the apex of the tooth.

Obturation is the second area of the endodontic procedure where the outcome is largely dependent on the accuracy of the length and width at which the operator instruments the canal space. An operator may select a size 35 file as their finishing size, which may be up to a size 37 and still be within standards. If a size 35 gutta percha cone is then placed into the canal, which has its own tolerances then the cone may extend longer than expected. This can be circumvented by the standard practice of taking a master cone radiograph to confirm the length of the gutta percha cone, but these are then subject to interpretation, and the gutta percha may be longer or shorter than it appears on the radiograph (8). Taken together, it is clear that it would be helpful to the clinician

Only the Edge Sapphire and Edge X7 demonstrated no significant differences with each other.



and the patient if measured tip diameter of endodontic files were as close to their size stated size as possible.

The literature in this arena is sparse. A great deal of research has been done on the fatigue resistance, flexibility, and metallurgy of nickel-titanium (NiTi) rotary files (9, 10), but little research has been done on the actual measurements of the files. One group looked at the variability of the taper in /.06 tapered NiTi rotary files and found that most files tested tend to be under-tapered (11). Another group looked at 30/.04 files between four different brands and noted that most files tended to be larger than their nominal diameters, while having an accurate taper (12). Further studies have looked at rotary instruments and their matched gutta percha cones, and have found variability especially in the coronal portion (13,14), with the matched gutta percha cones tending to be significantly larger than the files (15).

METHODS

The files were divided into four groups: Vortex Blue, Edge Sapphire, Edge X7, and Endosequence Scout. 20 of each of 20/.04, 25/.04, 30/.04, 35/.04, 40/.04 files were measured. We could not get Endosequence Scout size 40.04 files in time, so they were not included in this study.

The files were placed on a microscope slide in groups of 5, and were then examined with a light microscope (EVOS FL Auto). After confirming calibration of the microscope, a

Difference from stated

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Vortex Blue	100	-.02886	.019646	.001965	-.03276	-.02496	-.074	.035
Edge Sapphire	100	-.04688	.013509	.001351	-.04956	-.04420	-.083	-.017
ES Scout	80	-.03763	.011921	.001333	-.04028	-.03497	-.064	-.013
Edge X7	100	-.04466	.014673	.001467	-.04757	-.04175	-.080	-.008
Total	380	-.03961	.016922	.000868	-.04131	-.03790	-.083	.035

screen capture was taken and EVOS software was used to measure the files. The EVOS FL Auto is capable of measurements to the thousandth of a micron, for our purposes data was only recorded to the micron level. Since endodontic files are not completely uniform at the tip where the cutting flutes interface with the tip, there is inherent uncertainty present in the measurements. Efforts were taken to minimize this by consistently measuring the same point on each file (figure 1)

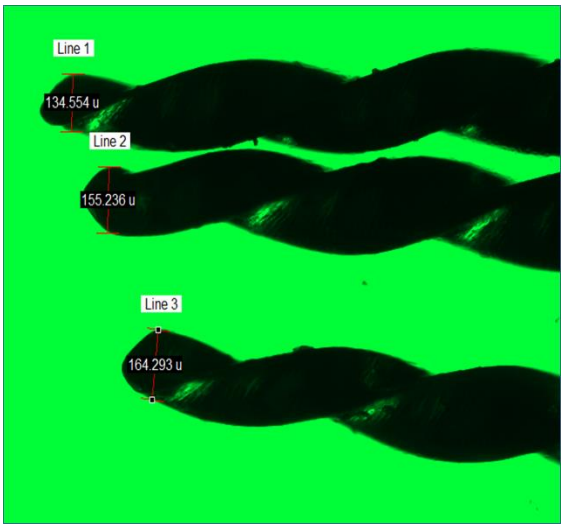


Figure 1: Endosequence Scout size 20

RESULTS

Means and standard deviations were calculated for each file. A statistical analysis was conducted by using an Analysis of Variance (one-way ANOVA). The level of significance was set at $P \leq 0.05$. Of the 380 files measured, the average tip size was .0396mm smaller than the labeled file size. Vortex Blue files had the smallest mean size discrepancy of -.0288mm, but also the largest standard deviation at .0196mm. Endosequence Scout files had a mean size discrepancy of -.0376mm, but the smallest standard deviation at .0119mm. These data are summarized in table 1 and graph 1. On average, none of the files conformed to ISO standards of plus or minus .02mm, though individual files from each manufacturer were in tolerance.

DISCUSSION

A common mystery among many practitioners is how a canal instrumented to a specific size can have the gutta percha stop short when it is in theory the same size and taper as the file. Multiple explanations exist for this phenomenon. Gutta percha has its own tolerances, so one explanation is that the gutta percha is incorrectly sized. Unpublished research from the author disputes that, as gutta percha sized in a Gutta Gauge is within 0.001mm of its nominal size. Two options remain: either the operators working length is slightly off, or the file is not the size that it is supposed to be. Being self-critical, many endodontists would assume that the former is correct, but this research says that it is the latter. The files are not the size that they are supposed to be.

Rounding up for easy numbers, the file systems tested were on average .040mm too small. That is almost one complete size too small. Some of the files were .075mm too small, roughly an entire size and a half. A select few files were too large. These findings are very clinically relevant.

One thing that was surprising to the researchers is that the gutta percha when used with the systems tested is not short more often. According to this research, when these file systems are used, a correctly sized gutta percha should be roughly 0.8mm too short. Sometimes significantly more, and sometimes less. This could take an obturation that would have been to the desired length, and turn it into something that is clinically unacceptable.

The apical constriction is typically 0.9mm from the radiographic apex and is usually a size 20-30 (16). An additional 0.8mm from an incorrectly size file would take the total distance from the radiographic apex to 1.7mm, dangerously close to the critical 2.0mm from the apex that is critical for good clinical outcomes (17). There are numerous ways to avoid this of course, namely master cone and void-check radiographs. Still, the inaccurate sizing of the tested endodontic files add a further element of uncertainly to the procedure.

CONCLUSION

Based on the results of this study, we conclude that rotary endodontic files are frequently one half to one full size too small, and that there is considerable variability both within and between file manufacturers.

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