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THESIS APPROVAL PAGE FOR MASTER OF SCIENCE IN ORAL BIOLOGY

Title of Thesis: Standardization of variable taper files and corresponding gutta-percha cones amongst manufacturers

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Master of Science Degree
April 14, 2023

THESIS/MANUSCRIPT APPROVED: DATE:

HINMAN.SUSAN.ELIZABETH.1261278240 Digitally signed by HINMAN.SUSAN.ELIZABETH.1261278240 Date: 2023.06.09 08:14:18 -04'00' 6/9/23

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OSBORNE.NANCY.1167256305 Digitally signed by OSBORNE.NANCY.1167256305 Date: 2023.06.09 08:17:08 -04'00' 6/9/23

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STANDARDIZATION OF VARIABLE TAPER FILES AND CORRESPONDING GUTTA-PERCHA CONES AMONGST MANUFACTURERS

by
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A thesis submitted to the Faculty of the
Endodontics Graduate Program
Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
In partial fulfillment of the requirements for the degree of
Master of Science
in Oral Biology
June 2023

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ABSTRACT

Standardization of Variable Taper Files and Corresponding Gutta-percha Cones Amongst Manufacturers

Aaron M. Keith, D.D.S., 2023

Thesis directed by: Susan E. Hinman, D.D.S., M.S., Director, Advanced Specialty Program in Endodontics, Naval Postgraduate Dental School

Introduction: Currently there is no standardization of variable taper endodontic files and corresponding gutta-percha (GP) cones. The aim of this study was to evaluate intra- and inter-manufacturer variability in the apical third diameter and taper of GP master cones and finishing files from three commercially available variable taper endodontic systems.

Methods: Diameter measurements were recorded using digital microscopy at 1mm increments (D1-D4) for F2 files and corresponding GP cones (n = 20 per system) from ProTaper Gold® (Dentsply Tulsa Dental Specialties, Johnson City, TN), EdgeTaper Platinum™ (EdgeEndo, Albuquerque, NM), and ExactTaper H™ (SS White, Lakewood, NJ). Taper was defined as the rate of change in diameter per 1mm increment. Mean differences in diameter were assessed using repeated measures of analysis of variance for D1 to D4 and the Wilks test for differences in taper.

Results: In the apical third, ProTaper and EdgeEndo mean file diameters were significantly smaller than corresponding GP cone diameters ($p<0.01$, $p<0.01$, respectively). Contrastingly, SS

White file diameters were significantly larger than their corresponding GP cones ($p=0.02$). Files from all manufacturers had significantly smaller diameters than nominal values ($p<0.01$). ProTaper GP cones had similar diameters than nominal values ($p=0.30$), while EdgeEndo and SS White GP cones were significantly smaller ($p<0.01$). Taper amongst files and corresponding GP cones from all systems was non-standardized.

Conclusions: Size discrepancies between finishing files and corresponding GP cones can be expected amongst variable taper endodontic systems.

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LIST OF ABBREVIATONS

GP	Gutta-percha
F1, F2, F3…	Finishing size 1, finishing size 2, finishing size 3…
D1, D2, D3…	1mm from tip, 2mm from tip, 3mm from tip…
ISO	International Organization for Standardization
ANSI	American National Standards Institute
ADA	American Dental Association
BRCS	Bioceramic root canal sealers

CHAPTER 1: Introduction

Quality of root filling directly affects the outcome of endodontic treatment (1). Obturation evaluated as having an adequate seal and radiographic absence of voids resulted in significantly higher success rates (1). The apical fit of the gutta-percha and its lateral adaption to the walls of the root canal are required to form an adequate apical seal (2). Understanding this, standardization of both endodontic files and endodontic gutta-percha becomes paramount to clinical success, even more so in endodontic systems that advertise gutta-percha cones that match the last file used.

Multiple studies identified shortcomings associated with a lack of standardization amongst endodontic instruments and gutta-percha cones (3-12). These discrepancies translate clinically to provider frustration (3, 13), increased case time (3, 13), and a potential negative impact on clinical outcomes (1, 3, 11).

Diameter and taper tolerances of endodontic files and gutta-percha cones are regulated by the International Standard ISO 3630-1 and ISO 6877, respectively (14, 15). Additionally, the American National Standards Institute/American Dental Association (ANSI/ADA) standards exist, which are identical adoptions of the aforementioned ISO standards (16). No new standards have been identified with the introduction of variable taper endodontic systems. Regarding non-uniform taper instruments, ISO 3630-1 states that, “The diameter and the tolerances shall be left at the discretion of the manufacturer. (15)” Tolerance of gutta-percha cones has remained unchanged and requires a diameter tolerance of +/- 0.05mm for sizes 10 to 25 and +/- 0.07mm for sizes 30 to 140 regardless of stated taper uniformity (14).

Currently several file systems are advertised as having the same shape, sizes, lengths, tapers, manufacturing process, and preparation technique as ProTaper Gold, a commonly utilized

variable taper endodontic system. These systems are marketed as costing less than ProTaper Gold while maintaining, and even exceeding, some of the mechanical properties (17, 18). No study has compared the diameter and taper variabilities of the files and corresponding gutta-percha cones of these endodontic systems compared to ProTaper Gold. Therefore, the aim of this study was to evaluate intra- and inter-manufacturer diameter and taper variability in the apical third of GP master cones and finishing files from three commercially available variable taper endodontic systems.

CHAPTER 2: Materials and Methods

F2 size files and corresponding gutta-percha cones from three manufacturers were included in this comparative study (N = 120, 3 manufacturers, 2 groups [file or gutta-percha], 20 per group): ProTaper Gold (Dentsply Tulsa Dental Specialties, Johnson City, TN); EdgeTaper Platinum (EdgeEndo, Albuquerque, NM); and SS White ExactTaper H (SS White, Lakewood, NJ). Gutta-percha cone samples were randomly selected from different packaging/lot numbers to account for batch/lot manufacturing discrepancies or dimensional instability during shipping and storage.

All testing was performed in accordance with ISO 3630-1:2019 section 7.2 “Test conditions” and ISO 6877:2006 section 6.1 Files and gutta-percha cones were acclimated to “test conditions” of 23 +/- 2 °C and 50 +/- 5 % relative humidity 24 hours prior to testing. File diameters were measured in accordance with section 7.3 “Measurement of dimensions” of ISO 3630-1:2019 using a calibrated Hirox KH-7700 digital microscope and MXG-2500REZ lens at 150x magnification (Hirox USA INC, Hackensack, NJ). (**Figure 1**)

File and gutta-percha cone diameters (DX; X = mm increment from tip, noted as DX) were measured at 1 mm increments (from D1 to D16). (**Figure 2**) Taper was calculated in accordance with section 6.4.3 “Taper calculation" of ISO 6877:2006 by subtracting the diameter DX from the diameter DX+1 and dividing by the distance between DX and DX+1 (1mm). As a modification to section 7.3.4 of ISO 3630-1:2019 “Taper calculation” of standard instruments, taper calculations were made for each 1mm increment from D1-D16 as opposed to calculating the overall taper between D3 and D16.

Intra- and inter-manufacturer variability in the apical third diameter and taper of GP master cones and finishing files were assessed by utilizing a repeated measures analysis of variance

(ANOVA) of the diameters of files and GP cones and the Wilks test for differences in taper from D1 to D4. The mean of the cumulative differences in file and GP cone apical third (D1 to D4) diameters and tapers from the advertised (nominal) values of ProTaper Gold were compared via ANOVA followed by pairwise comparisons using Tukey's method. Statistical analysis was conducted using R v4.0.5.

CHAPTER 3: Results

INTRA-MANUFACTURER:

From D1 to D4 ProTaper and EdgeEndo mean file diameters were significantly smaller than corresponding gutta-percha cone diameters ($p<0.01$, $p<0.01$, respectively) and SS White file diameters were significantly larger than their corresponding gutta-percha cones ($p=0.02$). (**Figure 3a**) ProTaper files had significantly less taper than the corresponding gutta-percha cones from D1 to D4 ($p<0.01$). (**Figure 3b**) EdgeEndo files had significantly greater taper than the corresponding gutta-percha cones from D1 to D2 ($p<0.01$), similar tapers from D2 to D3 ($p=1.00$), and significantly less taper from D3 to D4 ($p=0.04$). SS White files had significantly greater taper than the corresponding gutta-percha cones from D1 to D2 ($p<0.01$), similar tapers from D2 to D3 and D3 to D4 ($p=0.66$, $p=1.00$, respectively).

INTER-MANUFACTURER:

ProTaper file diameters were smaller than EdgeEndo and SS White file diameters, though not significantly different ($p=0.60$, $p=0.13$, respectively). **(Figure 3c**) EdgeEndo and SS White file diameters between D1 and D4 were not significantly different ($p=0.28$). Both ProTaper and EdgeEndo gutta-percha cone diameters were significantly larger than SS White gutta-percha cone diameters ($p<0.01$, $p<0.01$, respectively). ProTaper gutta-percha cones were significantly larger than EdgeEndo gutta-percha cones ($p=0.05$).

ProTaper files had a similar taper to EdgeEndo files from D1 to D2 and D2 to D3 ($p=0.26$, $p=0.08$), and a significantly greater taper from D3 to D4 ($p=0.02$). ProTaper files had significantly less taper than SS White files from D1 to D2 ($p=0.01$) and a similar taper from D2 to D3 and D3 and D4 ($p=0.52$, $p=0.41$, respectively). EdgeEndo files had a similar taper to SS White files from D1 to D2 ($p=0.10$) and significantly less taper from D2 to D3 and D3 to D4

($p=0.03$, $p<0.01$, respectively). ProTaper gutta-percha cones had a significantly greater taper than EdgeEndo gutta-percha cones between all increments from D1 to D4 ($p<0.01$). ProTaper gutta-percha cones had significantly greater taper than SS White gutta-percha cones from D1 to D2 ($p<0.01$), similar taper from D2 to D3 and D3 to D4 ($p=0.12$, $p=0.75$). EdgeEndo gutta-percha cones had significantly less taper than SS White gutta-percha cones between all increments from D1-D4 ($p<0.01$).

COMPARISON TO NOMINAL VALUES:

Files from all manufacturers had significantly smaller diameters than the reference or advertised (nominal) values ($p<0.01$). (**Figure 4**) ProTaper gutta-percha cones had similar diameters to nominal values ($p=0.30$), while EdgeEndo and SS White gutta-percha cones were significantly smaller ($p<0.01$).

CHAPTER 4: Discussion

Results from this current study demonstrated differences in intra- and inter-manufacturer F2 finishing file and corresponding gutta-percha cone diameters and tapers in the apical third. Intra-manufacturer comparison revealed that files from both ProTaper and EdgeEndo systems were significantly smaller than their corresponding gutta-percha cones; the opposite was true within the SS White system. In comparing between manufacturers, no significant difference was found amongst files from ProTaper, EdgeEndo and SS White; however, gutta-percha cones from SS White were significantly smaller than those from ProTaper and EdgeEndo. When compared to the advertised ProTaper values, this study found that files from all three manufacturers, and gutta-percha cones from EdgeEndo and SS White were significantly smaller than the advertised values in the apical third. ProTaper Gold gutta-percha cones matched the advertised values in the apical third.

Study findings that demonstrated significant variability between instruments and corresponding gutta-percha cones aligns with other well cited literaure. Chesler, et. al. evaluated EndoSequence, K3, and ProTaper, and found that all intra-manufacturer diameters and tapers were significantly different from each other (4). Salles, et. al. concluded that gutta-percha cones from MTwo were significantly larger than the corresponding files (11). Bajaj, et. al. found that diameters of both ProTaper Next and WaveOne gutta-percha cones were greater than their corresponding files (3). And Haupt, et. al. evaluated F360 files and corresponding gutta-percha cones and found the gutta-percha cones to be significantly smaller than the matching files (8).

Human measurements are subject to potential errors, regardless of the methodology used to obtain them. Similar to the present study, Haupt, et. al. utilized a single operator and a digital optical microscope, whereas Chesler, et. al. used a scanning electron microscope(4, 8). As

indicated by limitations observed in our study and others (4, 8), measuring D0 reliably was not feasible due to difficulties in determining the diameter at the sample tip. (**Figure 5**) Future endodontic research could explore the integration of artificial intelligence and other software advancements to eliminate the potential for human error.

Variability in size and taper of files and corresponding gutta-percha cones in the apical third demonstrated by this study can introduce clinical challenges such as over extension of gutta-percha or premature binding short of the working length. (**Figure 6**) In the present study, gutta-percha cones from SS White were significantly smaller than corresponding files from all three brands. Similarly, Haupt et. al. noted that extrusion of the gutta-percha in the periapical tissues may occur with smaller and less tapered cones, which could significantly reduce the success rate (8). Presenting another clinical challenge, the present study found that files were significantly smaller (ProTaper and EdgeEndo) and had significantly less taper (ProTaper) than their corresponding gutta-percha cones. Contrary to the concern of gutta-percha cone over extension, the use of corresponding gutta-percha cones following instrumentation with F2 files from ProTaper and EdgeEndo exhibit the potential to bind short of working length secondary to taper-lock in addition to allowing no space for sealer. This clinical challenge could result in obturation terminating well short of the desired working length and compromise of the apical seal secondary to lack of sealer (19). Experienced clinicians are able to recognize premature binding of the master gutta-percha cone and compensate by either trial fitting another cone of the same advertised size or going down a cone size (F2→F1). Though this should be the proper course of action if faced with these challenges, it is still a frustrating and time-consuming process (13).

A potential remedy to premature binding of corresponding gutta-percha cones are “Slim Fit” gutta-percha cones from EdgeEndo. These gutta-percha cones are advertised as compliments to

the F1, F2, F3, F4 and F5 files. Given the recent preference of providers for use of the "single-cone technique" in combination with bioceramic root canal sealers (BRCS) (20), it is likely these "Slim Fit" gutta-percha cones are manufactured for this purpose. Beyond the word "slim" in the name, information about the diameter and taper of these gutta-percha cones is lacking. However, it is logical to presume that these cones have smaller diameters, less taper, or both when compared to their corresponding files. Future studies could evaluate how the diameter and taper of these "Slim Fit" gutta-percha cones compare to the corresponding finishing files. Additionally, considering that the ideal thickness of sealer when using a single-cone technique in combination with BRCS is not known, future research could be aimed at answering this important question. With this knowledge, file and gutta-percha cone manufacturers could set their file and corresponding gutta-percha cone tolerances in a manner that would idealize the amount of space for sealer within the prepared canal space while ensuring adequate length control. Lastly, the influence of the shaping files from the three included endodontic systems (SX, S1, and S2) on the preparation of the coronal and middle thirds of the canal system was not within the scope of the present study; therefore, this should be an area of future research.

CHAPTER 5: Conclusions

Intra- and inter-manufacturer diameter and taper differences were identified between EdgeEndo, ProTaper, and SS White F2 sized files and corresponding gutta-percha cones. Further research is required to investigate the potential clinical impact of discrepancies in middle and coronal third file and gutta-percha size and taper, the size and taper correlation between "Slim Fit" gutta-percha cones and their corresponding files, and the optimal thickness of bioceramic sealer in single-cone obturation techniques. This collective knowledge has the potential to mitigate clinician frustration, improve the predictability of endodontic treatment, and, most importantly, enhance clinical outcomes.

FIGURES

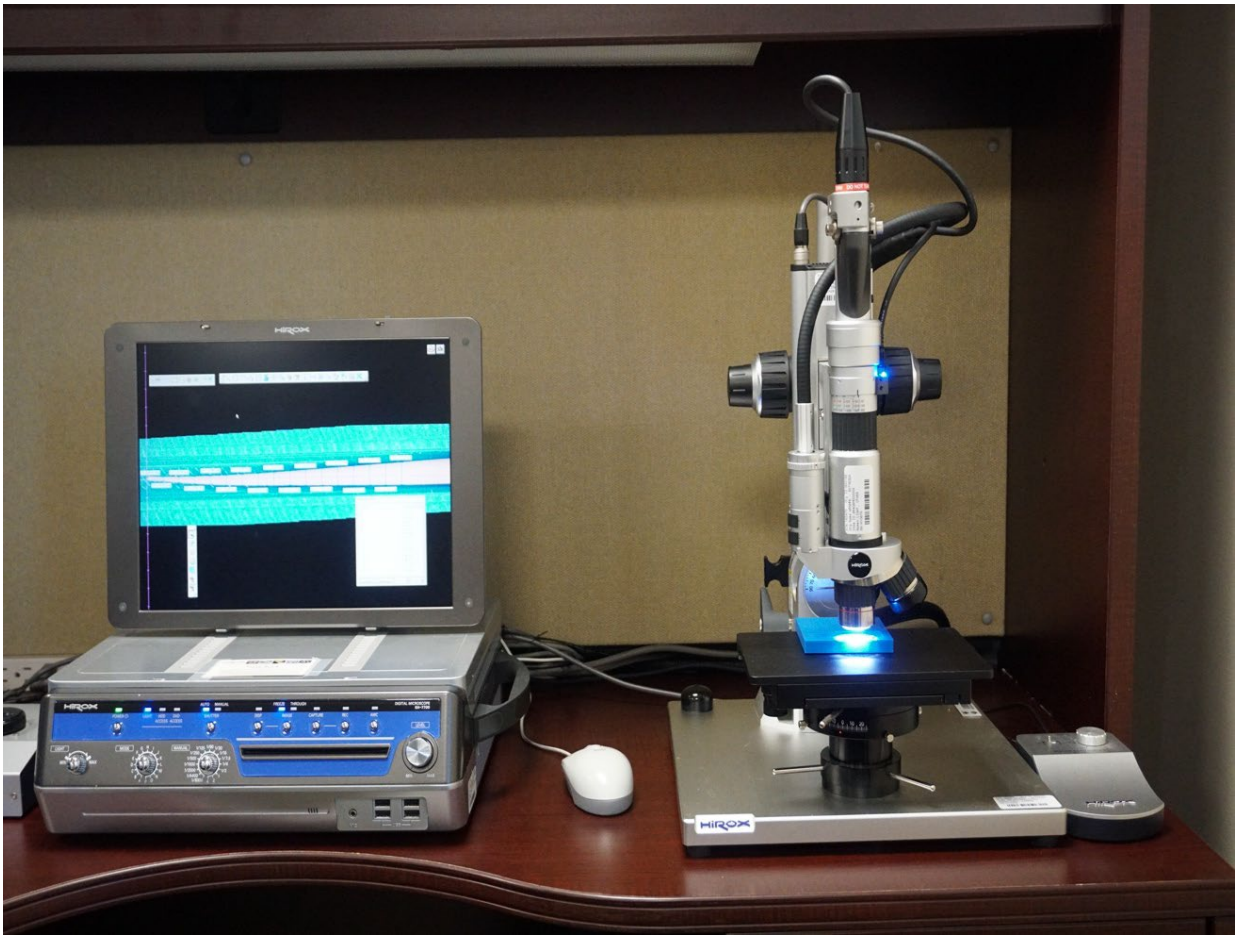


Figure 1. Hirox KH-7700 digital optical microscope set-up.
Pictured above is the Hirox KH-7700 digital optical microscope used to acquire the measurements within this study. On the right of the image is the microscope, microscope stand, and custom 3D printed jig used to position the file and GP samples. On the left is the computer unit of the digital optical microscope. This was used to acquire still images of the samples from the tip to the shank and make diameter measurements using the calibrated measuring tool within the Hirox software.

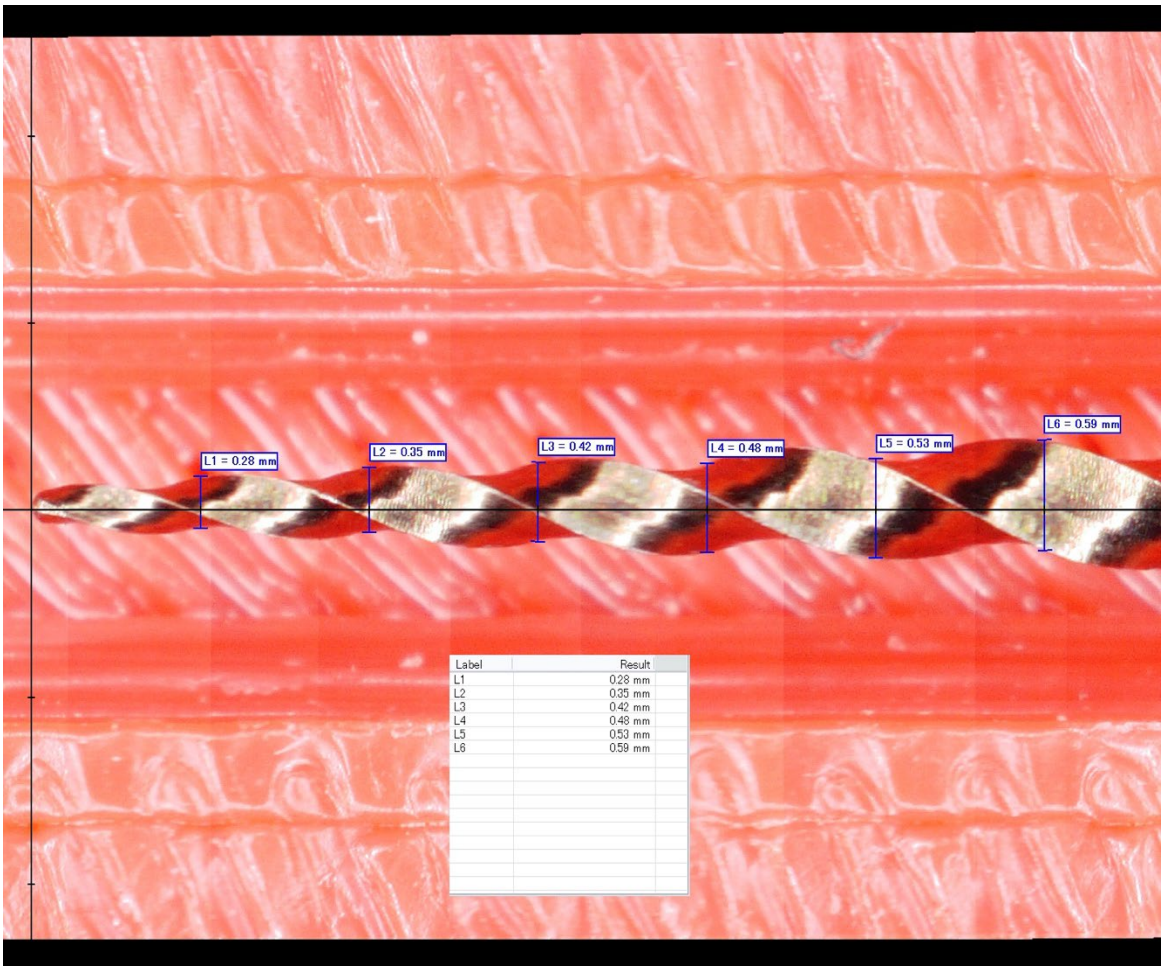
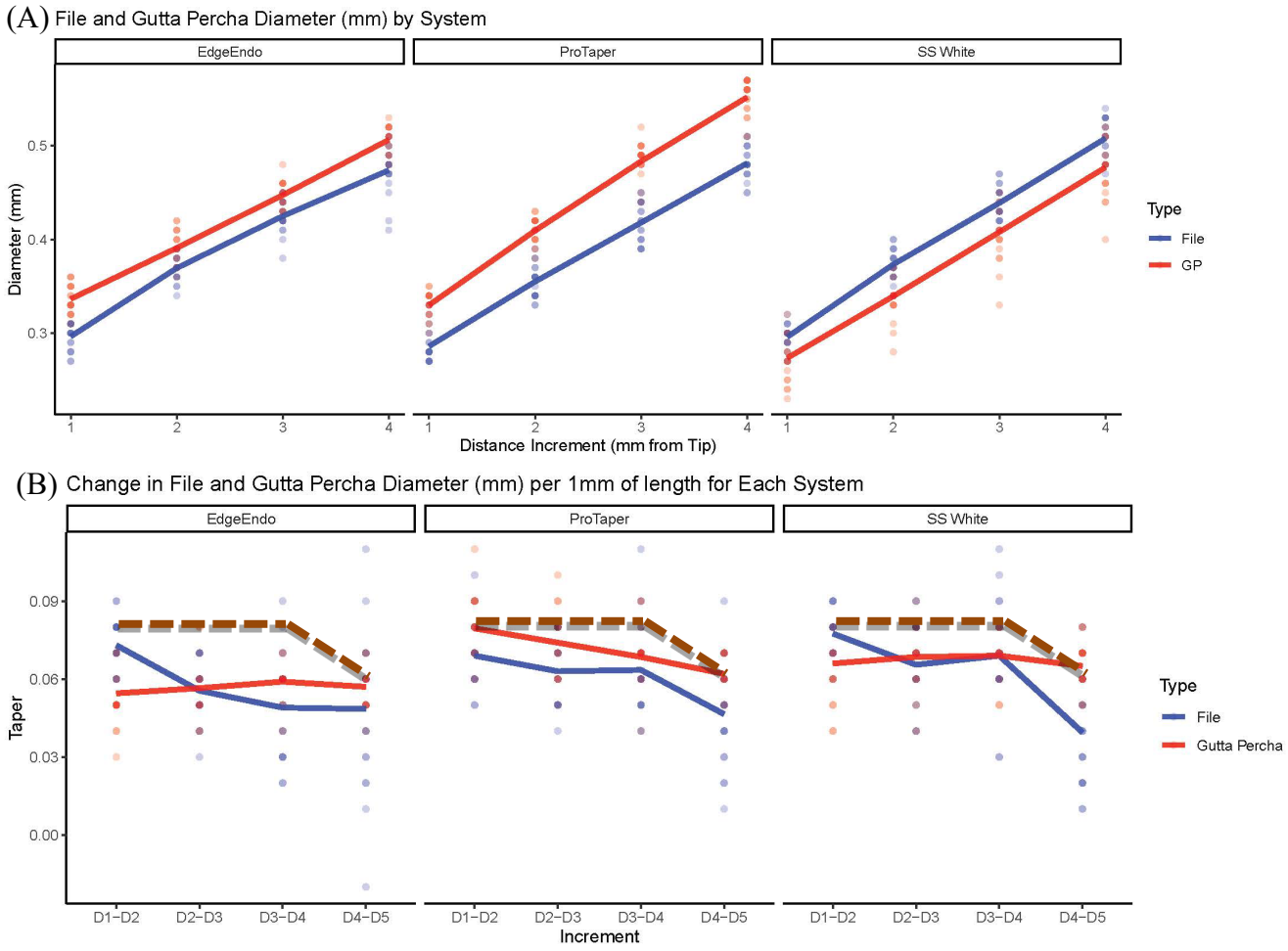


Figure 2: File diameter measurement and magnification.
(A) Example of a ProTaper Gold file sample overview. (B) D1-D6 of same ProTaper Gold file sample at 150x.



(C)	EdgeEndo		ProTaper		SS White		Nominal
	File	GP	File	GP	File	GP	
Diameter							
D1	0.297 (0.01)	0.336 (0.02)	0.286 (0.02)	0.330 (0.01)	0.296 (0.01)	0.274 (0.02)	0.33
D2	0.370 (0.01)	0.391 (0.02)	0.355 (0.02)	0.410 (0.01)	0.374 (0.02)	0.340 (0.02)	0.41
D3	0.425 (0.02)	0.448 (0.01)	0.418 (0.02)	0.484 (0.02)	0.439 (0.02)	0.408 (0.03)	0.49
D4	0.474 (0.02)	0.506 (0.01)	0.482 (0.02)	0.552 (0.02)	0.508 (0.02)	0.477 (0.03)	0.555
Taper							
D1-D2	7.3% (0.98)	5.4% (1.15)	6.9% (1.21)	8.0% (1.19)	7.8% (0.91)	6.6% (1.31)	8%
D2-D3	5.6 %(1.19)	5.7% (1.09)	6.3% (1.30)	7.4% (1.23)	6.6% (1.61)	6.8% (1.18)	8%
D3-D4	4.9% (1.97)	5.9% (0.64)	6.3% (1.81)	6.8% (1.09)	6.9% (2.00)	6.9% (0.91)	6.5%

Figure 3. Diameter and taper measurements by distance from file and gutta-percha tip. (A) Mean diameter measurements at D1, D2, D3, and D4 for file and GP cones from EdgeEndo, ProTaper and SS White. ProTaper and EdgeEndo mean file diameters were significantly smaller than corresponding gutta-percha cone diameters and SS White file diameters were significantly larger than their corresponding gutta-percha cones. (B) Mean taper measurements between D1-D2, D2-D3, and D3-D4 for file and GP cones from EdgeEndo, ProTaper and SS White. The dotted maroon line represents the nominal taper values. EdgeEndo files had significantly greater taper than the corresponding gutta-percha cones from D1 to D2, similar tapers from D2 to D3, and significantly less taper from D3 to

D4. SS White files had significantly greater taper than the corresponding gutta-percha cones from D1 to D2, similar tapers from D2 to D3 and D3 to D4. (C) Tabular form of mean (standard deviation) measurements.

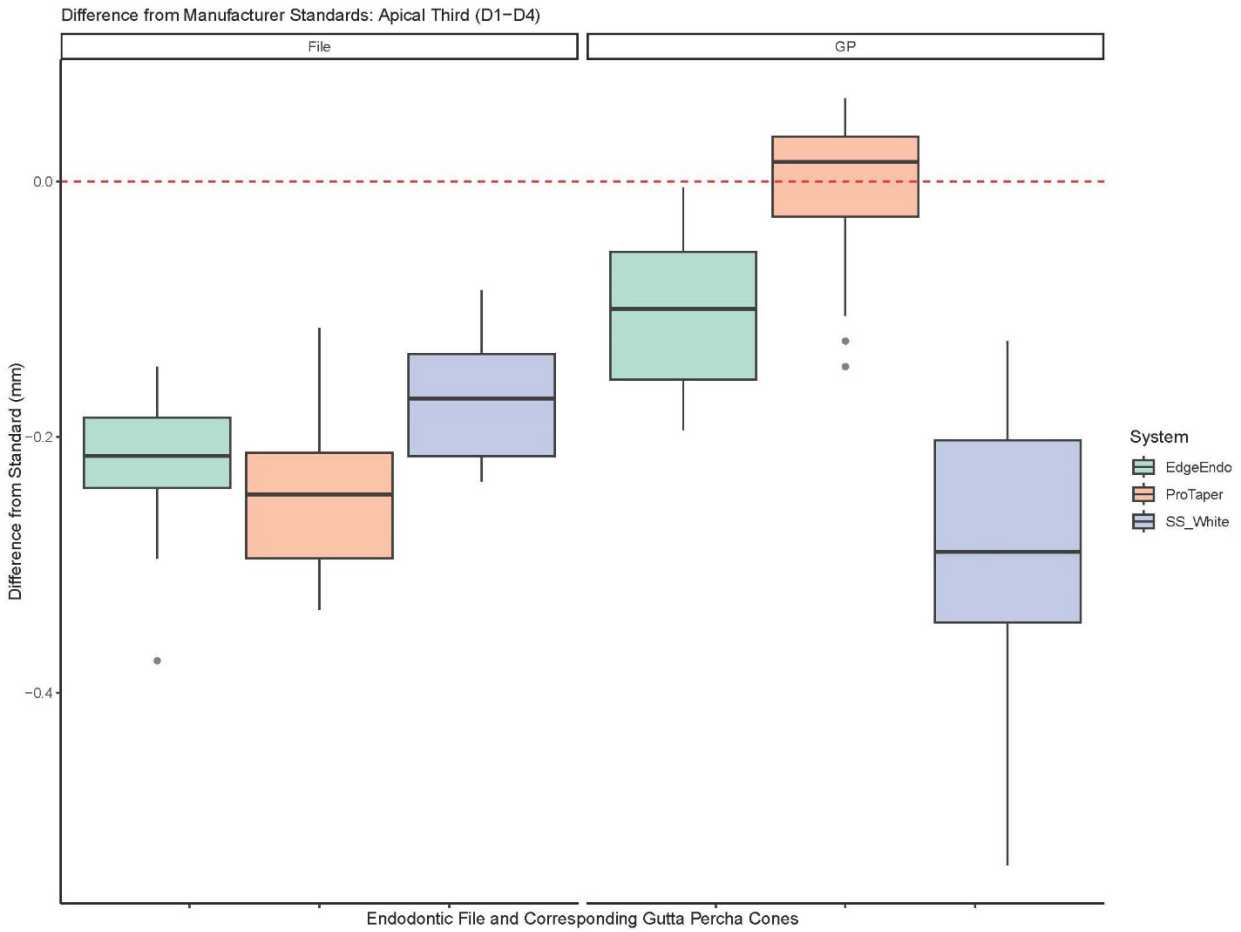


Figure 4. Comparison of diameters to nominal (ProTaper) values.
The dotted red line represents the nominal (advertised) sum of diameters from D1 to D4 of the included variable taper file systems. On the left half of the plot, the mean of the sum of diameters between D1 and D4 of the files from EdgeEndo (green), ProTaper (orange) and SS White (blue) are depicted. Similarly, on the right side of the plot, the mean of the sum of diameters between D1 and D4 of the GP cones from EdgeEndo (green), ProTaper (orange) and SS White (blue) are depicted. ProTaper and EdgeEndo GP cones are larger than their corresponding files. The opposite is true for SS White. GP cones from ProTaper are the only samples that matched the nominal values.

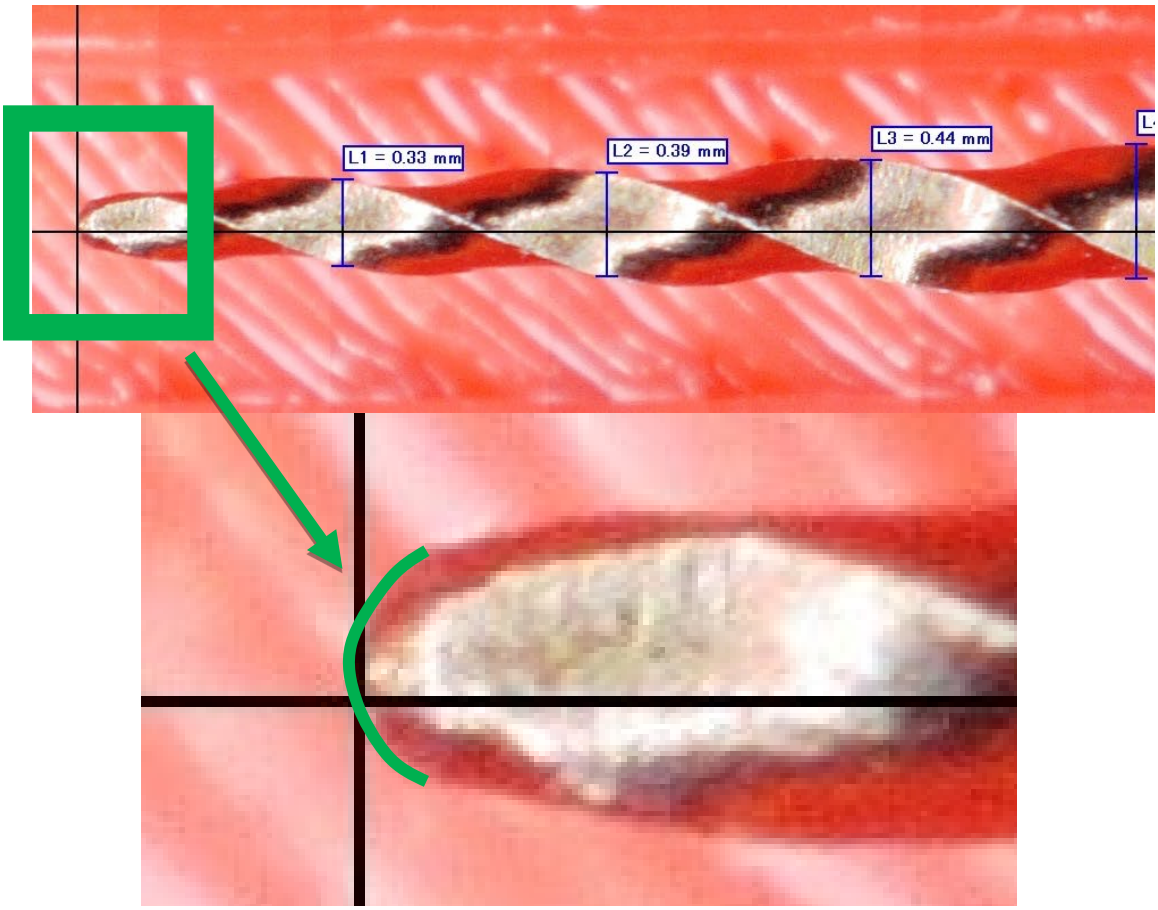


Figure 5. Example of difficulty in measuring D0.
Due to the rounded, non-cutting tip design of the file samples D0 was not able to be reliably measured.

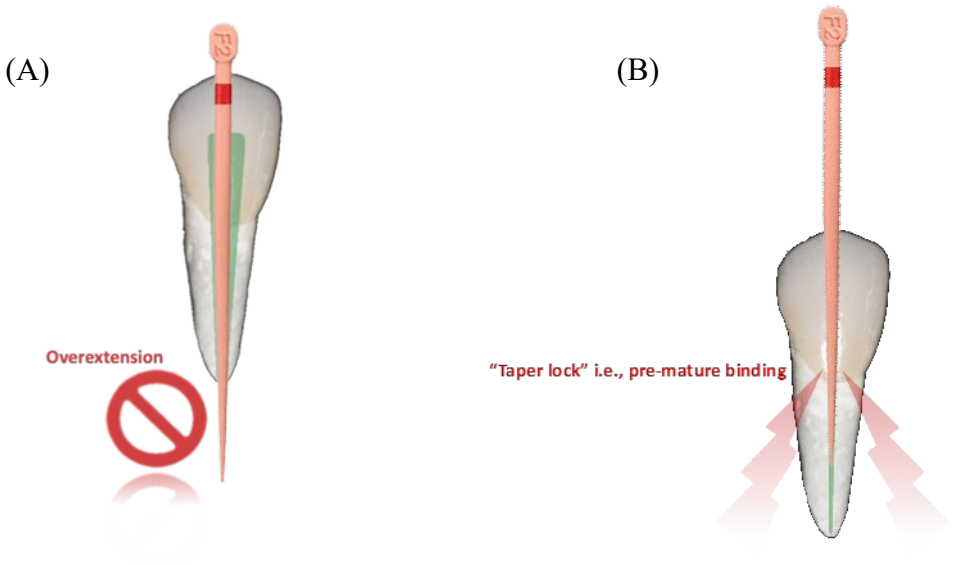


Figure 6. Adverse clinical results associated with size and taper discrepancies.
(A) Example of GP cone overextension. (B) Example of premature binding of a GP cone, also known as "taper lock."

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