Variability of the Diameter and Taper of Size #30, 0.04 Gutta-Percha Cones

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Abstract

The purpose of this investigation was to examine variability of gutta-percha (GP) cone tip diameter (D₀) and taper among five different brands of #30, 0.04 GP cones (n = 15/brand). Mean percent D_o difference from the manufacturer's reported (nominal) diameter of Maillefer (-15.42 \pm 7.16%) and Lexicon (-12.76 \pm 4.98%) were significantly different (p \leq 0.05) from Maxima (3.18 \pm 7.06%), Diadent (3.62 \pm 11.37%), and K^3 (7.27 \pm 7.84%), which were not significantly different from each other but exhibited diameters larger than the nominal diameter as indicated by positive values. Mean taper percent difference of Maxima $(-3.00 \pm 3.80\%)$ was significantly different (p ≤ 0.05) from Lexicon (3.67 \pm 3.64%) and Maillefer (6.67 \pm 3.49%), with comparisons to Diadent (-0.17 \pm 6.37%) and K³ (1.50 \pm 6.93%) not significantly different (p > 0.05) from each other or any other brand. Based on the evidence, there is significant variability between GP cone brands for both diameter and taper, with Maxima and Diadent, respectively, exhibiting the smallest mean difference from manufacturer's nominal tip diameter and taper. However, the high standard deviation values associated with most of the diameter and taper differences from nominal values also suggest high variability within individual brands. (J Endod 2006; 32:1081-1084)

Key Words

Cone tip diameter, dental obturating cones, gutta-percha, taper, variability

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G utta-percha (GP) has been used in dentistry for over 150 years. In 1847, Hill introduced the first GP root filling material, known as "Hills Stopping" (1). Despite its increasing popularity as a root canal filling material, it lacked universal manufacturing standardization. The standardization of instruments and dental obturating cones was first recommended by Ingle in 1955 (2). In 1958, Ingle and LeVine made the first attempt at standardization of endodontic instruments, equipment, and GP cones (3). They recommended a simplified numbering system, a consistent diameter and taper, and a consistent formula for size progression from one size to the next for instruments and obturating materials.

However, numerous previous investigations reported a continuing lack of standardization of both root canal instruments and GP cones (4-12). In 1979, Kerekes (13) compared the dimensions of root canal instruments to GP cones based on the 1975 version of the root canal instrument specification from the International Organization for Standardization (ISO) 3630 (14). The two current standards for dental GP obturating cones are the American National Standard Institute/American Dental Association (ANSI/ADA) Specification No. 78 published in 2000 (15) and ISO 6877, published in 1995 (16).

Obturating the root canal system (RCS) with GP and sealer is the most frequently used method to fill the prepared canal space. Ideally, GP cones should closely match the diameter and taper of the last hand or rotary instrument at the working length. This close adaptation of the GP to the prepared RCS then allows a minimal amount of sealer and provides an efficient way to fit a master GP cone before obturating the RCS. Variations in cone tip diameter can lead to frustration and time-consuming delays especially when fitting GP cones that do not have the same tip diameter and taper as the last instrument used. This can lead to premature binding, extrusion, or poor adaptability of GP to the canal walls.

Clinicians ideally expect that the manufacturers reported diameter and taper of GP cones will be accurate. However, even if the manufacturers are following the current standards, the accepted diameter tolerance levels vary from 0.05 to 0.07 mm, depending on the cone size. Such tolerance means that cones of one size can theoretically span more than one size above and/or below the stated size. For example, a size #30 cone has an allowable tip diameter of 0.23 to 0.37 mm. Therefore, the nominal diameter and taper values as listed by the manufacturer may vary greatly and still be in accordance with the "standards" (15). Previous studies of the dimensional variability of GP cones have primarily focused on 0.02 taper standardized cones (6, 10, 13, 17-19). To date, there are no published studies on the tip diameter and taper measurements of GP cones with larger tapers, e.g. 0.04 or larger.

The purpose of this investigation was to measure the variability from the listed cone tip diameter and taper of size #30, 0.04 taper GP cones from five different brands. A size #30 could be considered as a medium-sized GP cone commonly used to obturate RCSs.

Materials and Methods

Size #30 GP cones with an 0.04 taper from five different brands were used: Diadent (Diadent Group International Inc., Vancouver, BC, Canada); Lexicon (Dentsply Tulsa Dental, Tulsa, OK); Maillifer (Dentsply International, York, PA); K³ (SybronEndo, Orange, CA); and Maxima (Henry Schein, Melville, NY).

The diameters and tapers were measured according to the protocol outlined in ANSI/ADA Specification No. 78 using a measuring microscope with an accuracy of 0.001

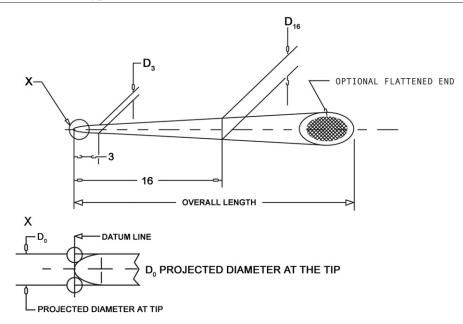


Figure 1. Diagrammatic representation of tapered sized cones and measurement sites for diameter (D_0) and taper $(D_3 \text{ and } D_{16})$. (Adapted from ANSI/ADA Specification No. 78.)

mm (Model W122, Gaertner Scientific Corp. Skokie, IL). Based on pilot data and a power analysis, it was determined that 15 cones from each brand would meet the constraints of $\alpha = 0.05$ and power = 0.80. As per the specification, the cones were conditioned at $23 \pm 2^{\circ}$ C at $50 \pm 5\%$ relative humidity for 24 hours before measurements.

According to Specification No. 78, the cone diameter was measured at the projected tip diameter D_0 (Fig. 1). Because the stated tolerance for $D_0 = 0.30$ is ± 0.07 mm, the overall acceptable range for D_0 measurements is 0.23 to 0.37 mm. Using this range, the frequency percentages of the D_0 measurement values were determined according to following categories: 0.23 to 0.25 mm, 0.26 to 0.29 mm, 0.30 mm (nominal value), 0.31 to 0.34 mm, and 0.35 to 0.37 mm. Based on the D_0 diameter measurement, the percent difference from the manufacturer's stated (nominal) diameter was also determined for each cone.

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). Based on the taper measurements, the percent difference from the manufacturer's stated (nominal) taper value was calculated for each cone.

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

Results

The tip diameter D_0 value frequency percentages are presented in Table 1. Maxima, Diadent, and K^3 were the only brands that had some percent of the cones at the nominal, 0.30-mm diameter, respectively,

20, 13, and 13%. The majority of the cones from those three brands were larger than 0.30 mm. In contrast, none of the Lexicon or Maillefer cones were at the nominal diameter, with all of the cones measuring less than 0.30 mm.

The tip diameter and taper mean percent differences from nominal values are presented in Table 2. Based on the one-factor ANOVA of tip diameter variability, there was a statistically significant effect ($p \le 0.05$) of brand on the mean percent difference of cone diameter (D_0) as compared to the manufacturer's nominal diameter. The Tukey's post hoc test indicated that the mean percent D_0 differences of Maillefer and Lexicon cones were significantly different ($p \le 0.05$) from the D_0 mean percent differences of Maxima, Diadent, and K^3 , which were not significantly different from each other. Both Maillefer and Lexicon cones were smaller than the manufacturer's reported diameter based on the negative values, -15.42% and -12.76%, respectively.

The remaining brands were larger than the reported cone diameter, with Maxima and Diadent exhibiting the smallest percent difference from the nominal diameter, 3.18 and 3.62%, respectively. Despite these lower mean differences, it is important to note the high SD values (Table 2), which indicate high variability between the individual D_0 cone measurements.

The one-factor ANOVA of taper variability also indicated there was a significant effect ($p \le 0.05$) on the mean percent difference of the measured taper as compared to the manufacturer's nominal taper. Based on the post hoc test, the mean percent taper difference of Maxima was significantly different ($p \le 0.05$) from taper percent differences of Lexicon and Maillefer, which was also significantly different ($p \le 0.05$) from Diadent. All other brand comparisons were not significantly different (p > 0.05) from each other (subsets indicated in Table 2).

TABLE 1. Percent of D_o diameter measurements within the defined range categories

GP Cone Brand ($N = 15$)	0.23–0.25 mm (%)	0.26–0.29 mm (%)	0.30 mm (%)	0.31–0.34 mm (%)	0.35–0.37 mm (%)
Diadent	13	7	13	53	13
K ³	0	13	13	53	20
Lexicon	27	73	0	0	0
Maillefer	60	40	0	0	0
Maxima	0	20	20	53	7

TABLE 2. Diameter and taper variability of size #30, 0.04 taper GP cones

GP Cone Brand (N = 15)	Mean percent difference & SD from nominal cone diameter (D ₀) ^a	Mean percent difference & SD from nominal taper ^a
Diadent	3.62 ± 11.37a	$-$ 0.17 \pm 6.37c,d
K ³	7.27 ± 7.84a	1.50 \pm 6.93c,d,e
Lexicon	−12.76 ± 4.98b	3.67 ± 3.64d,e
Maillefer	$-15.42 \pm 7.16b$	6.67 ± 3.49e
Maxima	3.18 ± 7.06a	-3.00 ± 3.80c

a Significant effect ($p \le 0.05$) of brand on the mean percent difference of cone diameters (D_0) and taper as compared to the manufacturer's stated (nominal) diameter and taper. Subsets are indicated by letters a-e.

However, it is valuable to examine the data more closely. Maxima exhibited the largest negative difference from nominal taper, -3.00% taper difference; Diadent and K³ had the smallest taper differences, -0.17 and 1.50%, respectively; and Maillefer exhibited the largest positive difference, 6.67%. As indicated in Table 1, the taper percent difference SD values were fairly high suggesting the same type of individual cone taper variability as noted with the cone tip diameter percent difference measurements.

Discussion

Because studies of dimensional variability of GP cones have primarily focused on 0.02 standardized cones (6, 10, 13, 17–19), this is the first investigation to study tip diameter and taper variability of larger taper cones, specifically, five brands of 0.04 taper GP cones.

The results of the current study indicate significant variability between GP cone brands for both diameter and taper, with Maxima and Diadent, respectively, exhibiting the smallest mean difference from manufacturer's nominal tip diameter and taper. However, the high standard deviation values associated with most of the diameter and taper differences from manufacturer's nominal values also suggests high variability within individual brands. The actual diameter values across brands varied from 0.226 to 0.365 mm, while the taper measurements across brands ranged from 0.035 to 0.047 mm. These results substantiate the clinical observation that there is great GP cone variability between and within GP brands for both diameter and taper.

However, despite the variability, all the diameter and taper measurements met the GP cone ANSI/ADA specification because of high diameter tolerance or lack of taper tolerance values within the specification guidelines. For example, the specification diameter tolerance is stated as $D_0 = 0.30$ is ± 0.07 mm, and taper tolerance is not addressed in the specification for 0.04 taper cones (15). Thus, even when manufacturers follow the recommended guidelines, it should be expected that there will be variability within and between different manufacturers. Besides the lack of narrow specification tolerance values, the diameter and taper variability may also be explained by GP's high plasticity (20, 21), which makes it susceptible to deformation during the manufacturing and packaging process or shrinkage and expansion related to temperature extremes during shipping and storage.

Although diameter and taper variability might not be a significant problem for the skilled endodontic practitioner, who anticipates this common occurrence when choosing a master GP cone, the inexperienced clinician may find the cone diameter and taper variability a source of frustrating, time-consuming delays. This could be especially true when fitting GP cones with a larger tip or taper than the last instrument used resulting in premature binding or poor adaptability of GP to the canal walls. The effectiveness of the seal produced by these cones could thus be compromised. A possible solution in those situations would be to use a smaller size tip diameter and use a GP gauge to cut the tip to the appropriate diameter. However, there is concern that the GP gauge might not accurately cut larger taper (0.04) GP cones to the correct tip size because the instrument was designed for use with 0.02 taper cones. Further research needs to be conducted in this area.

To be efficient and productive, the clinician must depend on the manufacturer's reported diameter and taper of GP cones to be as accurate as possible. However, based on the results of this study, the following conclusions were drawn:

- 1. There was significant diameter and taper variability of size #30, 0.04 taper GP cones both within and between GP brands.
- 2. Despite the reported variability, all diameter and taper measurements met the ANSI/ADA No. 78 specification guidelines, because of high diameter tolerance values and the lack of taper tolerance values within the specification.
- 3. The clinician should anticipate variability from the manufacturer's stated GP cone diameter and taper.

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