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Evaluation of the dimensional compatibility of bioceramic-impregnated gutta-percha cones with ISO standards

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Abstract

Aim: This study aimed to comprehensively evaluate the dimensional compatibility of bioceramic-impregnated gutta-percha cones across four ISO sizes (#20, #25, #35, and #45) by measuring their tip diameters (D0) with ISO 6877 size standards using a quantitative, in vitro approach.

Methodology: Bioceramic-impregnated gutta-percha cones with four different sizes were selected, and tip diameters (D0) were measured using an endodontic gauge ruler. Groups were #20 (primary), #25 (small), #35 (medium), and #45 (large), each containing 20 gutta-percha samples. All testing was performed in accordance with ISO 6877. Cones were categorized as compliant, undersized, or oversized. A chi-square test ($p = 0.74$) was conducted to assess intergroup differences.

Results: 72.5% of cones met ISO standards, while 27.5% were undersized. No cones were oversized. The rates of compliance across groups varied slightly but not statistically significantly.

Conclusion: While most cones comply with ISO 6877 standards, a notable proportion did not, indicating the need for enhanced manufacturing precision. The gutta-percha used during the cone fit trial may be used for the final obturation without being replaced with a new one from the package until manufacturers ensure comprehensive standardization.

Keywords: Bioceramic impregnated, gutta-percha, ISO 6877, standardization, dimensional accuracy, root canal obturation

Introduction

Endodontic success is highly dependent on effective irrigation, shaping, and three-dimensional obturation of the root canal system (1, 2). Obturation plays a pivotal role in preventing reinfection and sealing the apical region, which is often the most challenging to treat due to its anatomical complexity (3). Ingle recommended the use of standardized root-filling materials, such as gutta-percha, with the same-size master file used in preparation (4, 5).

Gutta-percha has long served as the primary obturating core material in endodontics and is typically used in conjunction with root canal sealers to achieve a tight apical and coronal seal (6, 7). The widespread use of gutta-percha stems from its thermoplastic nature, biocompatibility, and relatively inert behavior in periapical tissues (8). Numerous investigations have highlighted deficiencies in the lack of standardization across endodontic instruments and gutta-percha cones. These variations result in provider frustration, prolonged case time, and possible adverse effects on clinical outcomes (9). However, the physical dimensions of gutta-percha cones have been a recurring concern. Clinicians frequently encounter discrepancies between the dimensions of gutta-percha cones and those of the corresponding ISO-labeled endodontic files, potentially compromising the apical seal and overall obturation quality (10-12). To address this, the International Organization for Standardization (ISO) released ISO 6877, which standardizes the dimensional requirements for root canal obturating points. According to ISO 6877:2015, the tip diameter (D0) of a cone must lie within ±0.02 mm of its labeled ISO size (13). Despite these regulations, numerous studies have highlighted manufacturing inconsistencies across brands (9, 13-17). Moule et al. reported that, across 8 brands, both the diameter and the taper of the commercial 25, 30, and 35 cones did not meet the ISO standards (13).

In addition, Bielawiec et al. reported that approximately 28.8% of the tip diameters (D0) of 30, 35, and 40 gutta-percha cones (2% taper) did not meet the ISO standards (17). Similarly, independent from ISO standards, Gokduman et al. found that 0.04- and 0.06-taper gutta-percha cones of the same manufacturer exhibited significant dimensional variability between them (18). The dimensional problems of gutta-percha have been well understood based on these studies.

Such precision is particularly vital when using single-cone obturation techniques or when performing conservative canal preparations. Studies investigating the cones used for the single-cone obturation technique and proper files later corroborated this, noting that many cones labeled with the same ISO size displayed tip diameters significantly outside the acceptable tolerance range (9, 11, 14-16). Although such deviations are often small in magnitude, they can significantly affect the quality of the apical seal, particularly when the sealer thickness is excessive or unevenly distributed (19).

In parallel with these dimensional concerns, the field of endodontics has witnessed rapid evolution in obturation technologies. A key innovation is the introduction of bioceramic root filling materials, designed to be used alongside bioceramic sealers, such as calcium silicate-based formulations (20). Bioceramic cones incorporate mineral components such as tricalcium silicate and calcium phosphate into the gutta-percha matrix, potentially altering the mechanical and physical properties of the cones (8). These bioceramic sealers with cones are engineered to chemically bond to dentin and sealers, theoretically creating a monoblock that enhances sealing ability and minimizes microleakage (8, 20). The use of bioceramics, such as bioceramic-impregnated cone-sealers, is also recommended owing to their expected sealing ability (21, 22). While their bioactivity and interaction with sealers are well documented, there remains a lack of comprehensive data on whether the addition of bioceramics affects the dimensional consistency of these cones relative to ISO standards.

Despite its potential clinical implications, no published study has systematically evaluated the ISO dimensional conformity of bioceramic-impregnated gutta-percha cones. This knowledge gap is particularly notable given the widespread clinical adoption of bioceramic sealers and the shift toward single-cone techniques.

Therefore, the objective of this study was to evaluate the dimensional accuracy of bioceramic-impregnated gutta-percha cones across four ISO sizes (#20, #25, #35, and #45) by measuring their tip diameters (D0) and assessing their compliance with ISO 6877 standards. This study also aimed to identify the frequency of undersized or oversized cones and evaluate whether these deviations varied significantly between size groups. By clarifying the dimensional behavior of these materials, this study aimed to inform both clinicians and manufacturers about the reliability of bioceramic cones in daily practice, ultimately improving obturation outcomes and long-term treatment success.

The null hypothesis of this study was that there is no need to check the tip diameter (D0) of the master gutta-percha cone with an endodontic ruler before the obturation of the root canals.

Materials and Methods

Bioceramic-impregnated gutta-percha cones (Sure Endo, Sure Dent Corp., Seongnam, South Korea) were selected for this study. GP cone samples were randomly selected from various packaging and lot numbers to address manufacturing errors or dimensional alterations during transportation and storage. All testing was conducted in compliance with ISO 6877. Gutta-percha cones were conditioned to “test conditions” of 20 ± 5°C and 50 ± 5% relative humidity for 24 hours prior to evaluation.

The tip diameters (D0) of 80 cones from four groups (n=20) designated as #20 (primary), #25 (small), #35 (medium), and #45 (large) were measured three times by a calibrated endodontist with > 10 years of experience using an endodontic gutta-percha gauge ruler (DiaDent Group International, Cheongju, South Korea) (Fig. 1).

The cones were assessed according to ISO standards to determine whether they were fully compliant. Cones with tip diameters (D0) that were not fully compliant with the ISO standards were re-evaluated to determine whether they were oversized or undersized.

Figure 1. Bio GP gutta-percha cones and endodontic gauge ruler.

Statistical analysis

The statistical analysis was performed using the IBM SPSS Statistics for Windows software (Version 21.0; IBM Corp., Armonk, NY, USA).

Visually damaged and bent cones were excluded from the study. Statistical analysis was performed using the chi-square test (p = 0.74).

Chi-square testing revealed no statistically significant differences among the four groups regarding ISO compliance status (p = 0.74). This suggests that although dimensional deviations exist, they are distributed relatively evenly across cone sizes and are not confined to a specific group.

Results

Of the 80 bioceramic-impregnated gutta-percha cones, 58 (72.5%) were found to be fully compliant with the ISO 6877:2015 dimensional standards. Conversely, 22 (27.5%) cones were categorized as undersized, and none exceeded the maximum allowed tip diameter, confirming the absence of oversized specimens.

Group-wise analysis yielded the following compliance rates:

- **Group #20 (n=20):** 16 cones (80%) compliant, 4 cones (20%) undersized
- **Group #25 (n=20):** 13 cones (65%) compliant, 7 cones (35%) undersized
- **Group #35 (n=20):** 15 cones (75%) compliant, 5 cones (25%) undersized
- **Group #45 (n=20):** 14 cones (70%) compliant, 6 cones (30%) undersized

The schematic representation of the study is graphically illustrated in Figure 2. Table 1 presents the frequency and percentage of cones classified as compliant or undersized per ISO group. A bar chart (Fig. 3) illustrates comparative compliance levels, while a pie chart (Fig. 4) depicts the overall proportions of compliant versus undersized cones.

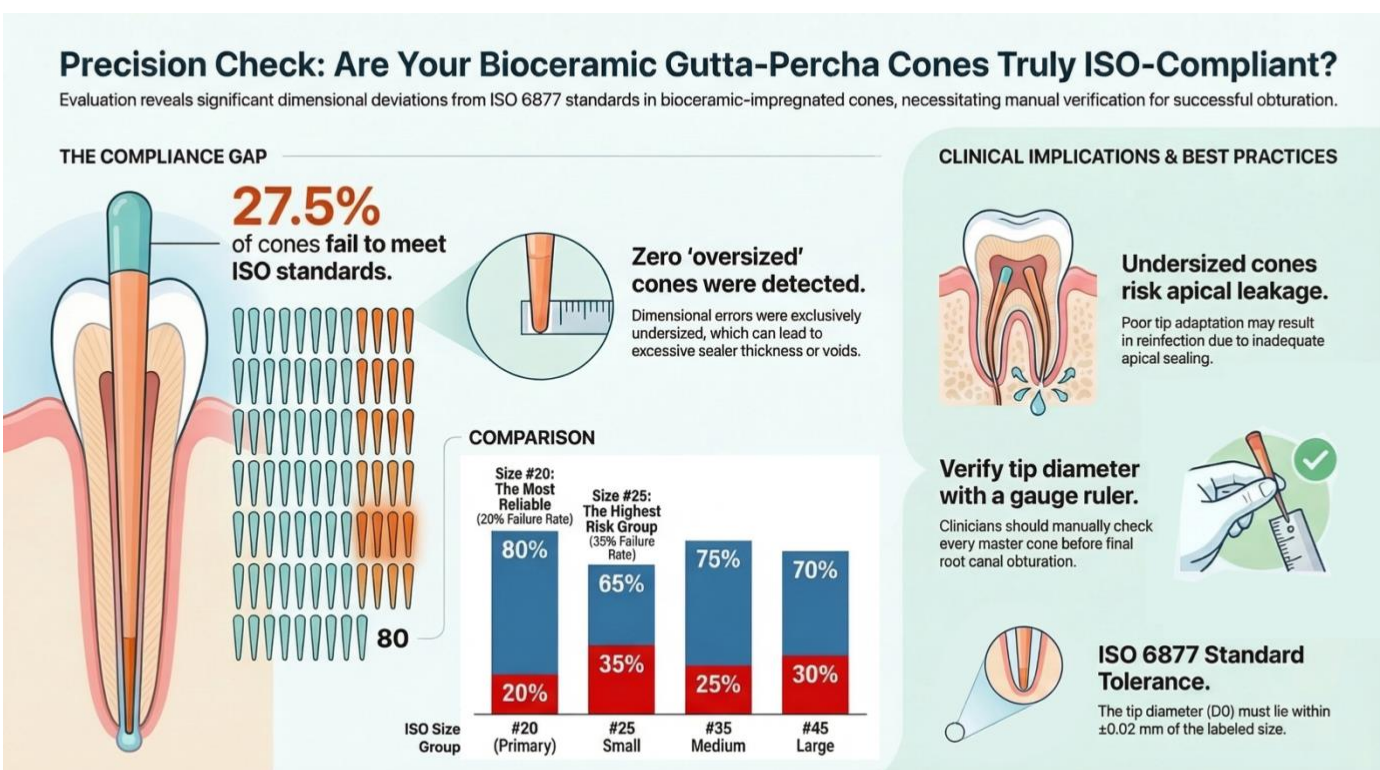

Figure 2. Schematic representation of the study.

Table 1. ISO compliance rates by group.

Group	Compliant (n)	Compliant (%)	Undersized (n)	Undersized (%)	Oversized (n)
#20	16	80%	4	20%	0
#25	13	65%	7	35%	0
#35	15	75%	5	25%	0
#45	14	70%	6	30%	0

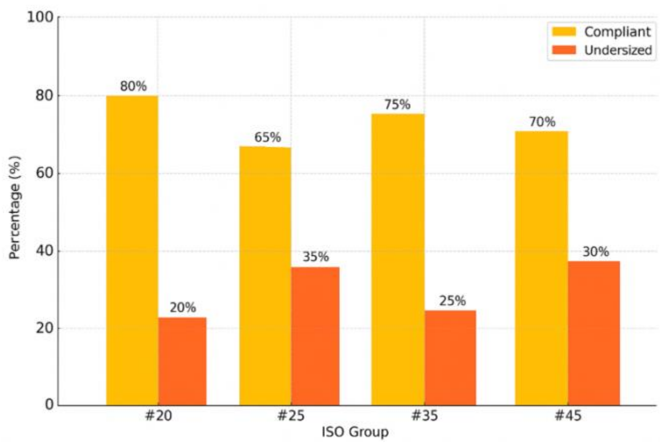

Figure 3. Bar chart – ISO compliance per group.

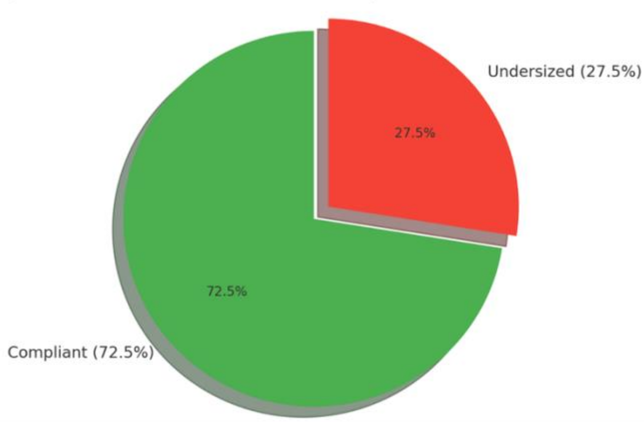

Figure 4. Pie chart – Overall distribution of compliant vs undersized cones

Discussion

The present study evaluated the dimensional compatibility of bioceramic-impregnated gutta-percha cones with ISO 6877 standards, focusing on the D0 tip diameter across four commonly used ISO sizes. The findings are consistent with previous literature reporting that gutta-percha cones, even those labeled according to ISO, may deviate from the standards to a clinically significant extent. In the literature, the diameter of gutta-percha cones was assessed at different points using various methods, such as an endodontic gauge/ruler, micrometer, profilometer, and dental operating microscope (9, 12-18). In this study, we determined the tip (D0) diameters visually using an endodontic gauge/ruler, similar to Bielawiec et al. (17).

The lack of oversized cones could reflect conservative manufacturing protocols or measurement bias toward underestimation. However, the relatively high rate of undersized cones in Group #25 (35%) highlights potential variability in mid-range manufacturing precision. In addition, the results indicated a 72.5% compliance rate, with 27.5% of cones categorized as undersized. Notably, no cones were found to be oversized. Although the observed deviations were not statistically significant across groups ($p = 0.74$), the presence of undersized cones remains clinically relevant. Undersized gutta-percha cones present several risks. Inadequate apical adaptation may lead to void formation, decreased sealing ability, and increased susceptibility to apical leakage and reinfection.

Studies have shown that inadequate obturation is one of the leading causes of endodontic treatment failure, and tip diameter plays a significant role in achieving a three-dimensional seal (2, 3, 6). The observed compliance rate aligns with the findings of Moule et al., who reported wide variability in cones from all brands and across all sizes in D1 and D5 of 2% taper gutta-percha cones that failed to meet ISO standards (4). Similarly, Bielawiec et al. found a 28.8% discrepancy even within the same product lines at D0, as well as variability across brands (17). These results are similar to those of our study, which found a 27.5% discrepancy. Similar to the results of these studies on gutta-percha evaluation, our results in bioceramic-impregnated gutta-perchas indicate that dimensional inconsistency is a systemic issue across manufacturers (4, 6, 17).

Thus, the standardization of gutta-percha and file/gutta-percha match research has been consistently emphasized and has become popular. In contrast, studies evaluating rotary file systems and compatible gutta-perchas, which different manufacturers claim to be compatible, have shown that rotary instruments and gutta-perchas from the same system are not compatible (9-12, 14).

Bioceramic-impregnated gutta-percha cones are designed to improve biological interaction, promote mineralization, and enhance compatibility with calcium silicate-based sealers (8). However, the addition of bioceramic particles may influence the physical behavior of the cones during manufacturing, leading to slight deviations in tip uniformity that have not been reported in the literature. The degree of filler dispersion, polymerization shrinkage, and extrusion properties may all contribute to tip inconsistencies. While ISO 6877 provides a universal benchmark, it permits a ±0.02 mm tolerance range, which may be too wide for advanced obturation strategies, especially in minimally invasive or conservative endodontic preparations (13). Recent critiques of ISO standards (13) have suggested the need for tighter tolerances or revised classifications that account for novel materials, such as bioceramic-impregnated cones.

Bioceramic-based obturation techniques aim to achieve a monoblock configuration, where the gutta-percha cone, sealer, and canal walls integrate into a single cohesive unit. This seal is sensitive to dimensional mismatch (21, 22). The presence of undersized cones may prevent uniform sealer distribution, leading to weak interfacial zones and potential leakage under functional conditions.

With the increasing popularity of conservative shaping, clinicians are relying more heavily on the precise match between canal preparations and cone dimensions. When working with narrower apical sizes and restricted flaring, even a small deviation can compromise sealing efficacy or necessitate cone trimming, which introduces subjectivity and risks of overextension (23). Inconsistent cone dimensions may result from thermal deformation, extrusion variability, or mechanical imprecision in cutting tips. Manufacturers must adopt advanced metrology and in-process quality checks to ensure conformity (24). The integration of digital image correlation and laser micrometry may improve production fidelity. Given the prevalence of dimensional deviations, clinicians should be encouraged to routinely verify cone sizes using calibrated gutta-percha rulers. Despite manufacturer labeling, chairside validation ensures a better fit and reduces reliance on subjective cone adjustment, particularly for inexperienced practitioners. The in vitro nature of the study does not account for clinical variables such as operator technique, anatomical variability, and thermoplastic behavior during obturation (25-28).

A limitation of this study is the lack of diameter evaluation at other points. Higher-resolution instruments, such as micrometers, profilometers, and dental operating microscopes, were not preferred instead of (or alongside) the ruler, which is a limitation. Using an endodontic gauge or ruler, only the correct DO evaluation was possible. Another limitation of this study is that the evaluations were made by more than one operator, and kappa analysis was not performed between operators.

The presence of undersized cones, even within ISO-labeled systems, has tangible clinical implications. Although bioceramic gutta-percha cones offer clear biological advantages, their dimensional fidelity remains a concern. Ongoing collaboration between researchers, clinicians, and manufacturers is essential to ensure that innovations in obturation material design are not undermined by basic physical inconsistencies. Although no significant differences were found, it is important to note that subtle variations in cone diameter could still impact clinical adaptation and sealing ability, especially in cases with minimal apical preparation or conservative shaping approaches. Additionally, factors such as operator technique, canal morphology, and thermal expansion of gutta-percha during warm techniques were not considered in this in vitro analysis. The use of an endodontic ruler for the selection of master cones may be beneficial in all cases.

Conclusion

In conclusion, to ensure a hermetic seal, it is recommended that the master cones be checked with an endodontic ruler, especially at D0 and at other points, if necessary, to control this lack of standardization in production. Furthermore, clinicians should be cognizant of the variations in size within the same boxes of gutta-percha cones and ensure conformity with periapical radiographs.

During root canal obturation, the appropriate gutta-percha should be meticulously disinfected and utilized without replacement to ensure its consistent size from the gutta-percha box. Variations in cone size may affect apical fit, particularly with conservative preparations; verification with a gauge is advisable.

Disclosures

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