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Clinical relevance of standardization of endodontic irrigation needle dimensions according to the ISO 9626:1991 and 9626:1991/Amd 1:2001 specification

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Abstract

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Aim To examine the current status of standardization of endodontic irrigation needles produced by different manufacturers.

Methodology Measurements of needle internal and external diameter were conducted under scanning electron microscopy and stereoscopic microscopy to determine the incidence and degree of deviation from ISO 9626:1991 and ISO 9626:1991/Amd 1:2001 specification.

Results None of the needles examined complied with the ISO nominal size. All SS needles were within the ISO tolerance limits. A Ni-Ti needle, which is not included in the specification, was found to exceed ISO external diameter limits.

Conclusions Exact knowledge of the tip's external diameter is crucial for the selection of the appropriate size irrigation probe during endodontic treatment. Units of the widely used 'gauge' system cannot be directly extrapolated to clinical practice. Adoption of millimetre as the standard metric unit, already recommended by ISO, should be accelerated. A colour-coding of needles corresponding to endodontic instruments would also be beneficial.

Keywords: irrigation, needle, probe.

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Introduction

Irrigation of the root canal with antibacterial solutions is considered an essential part of chemo-mechanical preparation (Haapasalo *et al.* 2005). The ability of the antibacterial agent to contact the bacteria is of great importance (Seal *et al.* 2002), whilst proximity of the irrigation needle to the end-point of canal preparation plays an important role in removing intra-canal debris (Abou-Rass & Piccinino 1982, Moser & Heuer 1982, Chow 1983). Thus, depth of needle placement is an important factor in the reduction of bacterial counts during root canal irrigation (Sedgley *et al.* 2005).

The overall effectiveness of irrigation is largely determined by the relative diameters of the irrigating needle and the canal (Ram 1977). Moreover, the needle should never bind against the canal wall during irrigation, as this would increase the risk of irrigant extrusion into the periapical tissue (Lambrianidis 2001, Ingle *et al.* 2002). Therefore, exact knowledge of the external diameter of the tip is crucial for selection of needles of appropriate size during root canal treatment. Such information is mostly unavailable and confusing, as the units of the widely used 'gauge' system are not directly comparable to the size of the instruments used for intracanal procedures (Zinelis *et al.* 2002).

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Table 1 Medical stainless steel needle specifications according to ISO 9626:1991/Amd.1:2001 (ISO 9626 2001)

Gauge size	Designated metric size (mm)	Range of external diameters (mm)		Internal diameter (mm)
		Min	Max	Min
21	0.8	0.800	0.830	0.490
23	0.6	0.600	0.673	0.317
25	0.5	0.500	0.530	0.232
27	0.4	0.400	0.420	0.184
30	0.3	0.298	0.320	0.133

Universally accepted medical stainless steel needle tubing dimensions are defined by the ISO 9626:1991/Amd 1:2001 specification (ISO 9626 2001) (Table 1) which revised the earlier ISO 9626:1991 (ISO 9626 1991). Although the ISO standards refer to medical needles in general, endodontic irrigation needles should also comply with the universal specifications. However, there is no available information concerning the compliance of commercially available irrigation needles with these specifications.

The aim of this study was to examine the current status of standardization of endodontic irrigation needles produced by different manufacturers by investigating whether commercially available stainless steel endodontic irrigation needles comply with ISO 9626:1991 and 9626:1991/Amd 1:2001 specification and to explore whether a Ni-Ti flexible needle lies within ISO limits.

Materials and methods

Measurements were conducted on selected needles (Table 2) under stereoscopic microscopy and scanning electron microscopy.

Preliminary study

Two needles of each size and selected manufacturer were examined at a horizontal position with the outlet oriented towards the magnifying lens (Fig. 1a) and then again with the outlet at right angle to the lens (Fig. 1b), under stereoscopic microscope (Stemi DV4; Carl Zeiss, Göttingen, Germany) with an attached digital still camera (DSC-S85; SONY, Tokyo, Japan). The higher magnification that permitted visualization of an approximately 10 mm length starting from the tip of the needle was selected for each specimen. Images of all specimens were recorded in a Tagged Image File (TIF) format and were imported in AutoCAD 2006 software (AutoDesk, San Rafael, CA, USA). The external perimeter of each needle along the axis was delineated with two straight lines. The relative external diameter for each needle orientation was determined in 15 equally spaced points along the needle as the minimum distance between the two lines (Fig. 1 – dashed lines).

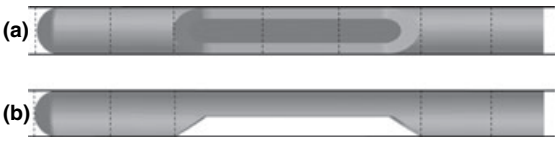

Figure 1 Verification of the cylindrical shape of the specimens during the preliminary study. (a) Needle outlet orientated towards the magnifying lens. (b) Needle outlet at right angle to the lens. Specimen external diameter was determined as the length of the dashed lines in 15 equally spaced points. Only a part of the specimen was included in the figure for illustration purposes.

Table 2 Materials used

Manufacturer	Type	Material	Gauge	Lot. no.
KerrHawe SA, Bioggio, Switzerland	KerrHawe Irrigation Probe	SS	21	70403645
KerrHawe SA, Bioggio, Switzerland	KerrHawe Irrigation Probe	SS	23	70403645
KerrHawe SA, Bioggio, Switzerland	KerrHawe Irrigation Probe	SS	25	70403645
KerrHawe SA, Bioggio, Switzerland	KerrHawe Irrigation Probe	SS	30	70403645
Dentsply, Surrey, UK	Max-i-probe	SS	25	204943
Dentsply, Surrey, UK	Max-i-probe	SS	30	194088
Ultradent Products Inc., South Jordan, UT, USA	Endo-Eze	SS	27	2075Q1Q
Hager & Werken GmbH & Co. KG, Duisburg, Germany	Miraject Endotec	SS	21	Not listed
Hager & Werken GmbH & Co. KG, Duisburg, Germany	Miraject Endotec	SS	23	Not listed
Hager & Werken GmbH & Co. KG, Duisburg, Germany	Miraject Endotec	SS	25	Not listed
Vista Dental Products, Racine, WI, USA	Stropko Flexi-Tip	Ni-Ti	30	PN201575

Main study

Needles were sectioned with a slow-speed diamond disk under constant water flow approximately 3 mm from the tip and again at 8 mm from the original tip. The resulting 5 mm lengths were embedded vertically in Epofix resin (Struers, A/S, Ballerup, Denmark), within plastic containers having a 25 mm diameter. Containers were maintained under a vacuum during resin setting to avoid bubble formation. Subsequently, the specimens were polished with silicon carbide powder and water on a glass plate. Polishing was continued using diamond powders (Struers) gradually down to 1 μm in a polishing device (Struers). Finally, specimens were immersed in a super-sonic water bath for 15 min to remove debris.

Specimens were examined under scanning electron microscope (JSM 840A; JEOL, Tokyo, Japan). The electron beam was adjusted to be perpendicular to the plane of each specimen and the working distance was constant for all measurements. The highest magnification permitting full view of the needle's external perimeter was selected for each specimen. Images of all specimens were recorded in a TIF format (resolution 1024×768 pixels).

Images were imported with AutoCAD 2006 software (AutoDesk, San Rafael, CA, USA). The external perimeter of each needle was delineated with an ellipse (Fig. 2). The length of the minor axis of the ellipse ($2R_{\min}$) was recorded as a measure of the external diameter ($\mathrm{Ext_D}$):

$$\mathrm{Ext_D} = 2R = 2R_{\min}$$

Straight lines were drawn along the minor and major axis overlying the wall of the needle. The wall thickness (W_{Th}) was determined as the weighted average of four measurements along the above mentioned lines (two measurements on the opposite sides of each axis).

$$W_{\mathrm{Th}} = [A + C + (B + D) \times \text{radius ratio}]/4,$$
$$\text{radius ratio} = R_{\min}/R_{\max}$$

All measurements were converted to millimetres using the length of the reference bar included in all images. Internal diameter ($\mathrm{Int_D}$) was calculated by subtracting wall thickness from the external diameter:

$$\mathrm{Int_D} = \mathrm{Ext_D} - 2W_{\mathrm{Th}}.$$

All measurements were repeated on sets of 10 needles for each size and manufacturer. The diameter values recorded for each needle were compared with the upper and lower ISO tolerance limits. Mean values and standard deviations were calculated for each size and manufacturer with SPSS 14.0 for Windows (SPSS Inc, Chicago, IL, USA).

Results

Preliminary study

High repeatability of the external diameter size was verified for all specimens. No variation of relative external diameter could be detected in any of the specimens.

Main study

Small differences between the major and minor axis of the ellipse were recorded in all specimens. Therefore, the perimeter of the polished free surface concerning all specimens was slightly elliptic in shape.

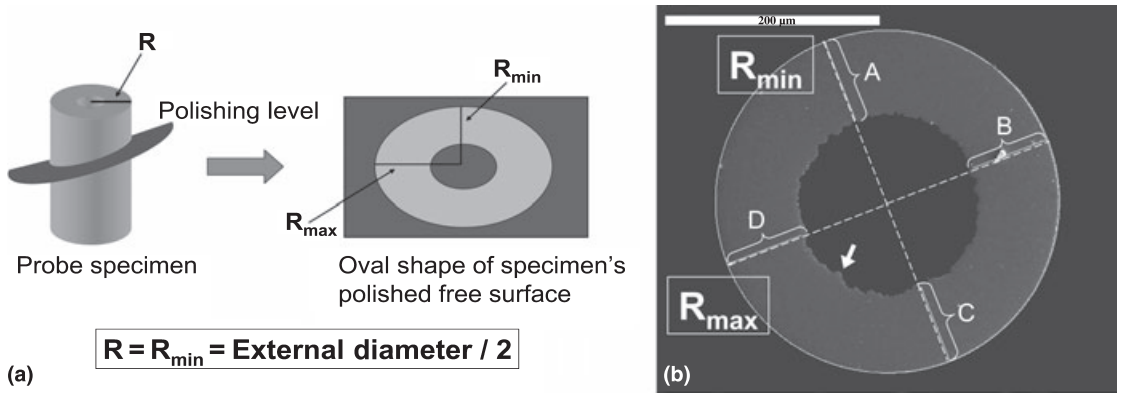

Figure 2 (a) Geometrical method of diameter calculation. (b) Application of the method to a specimen. Note the irregularities along the internal perimeter (arrow).

All SS needles complied with ISO tolerance limits, concerning both their external (Fig. 3) and internal (Fig. 4) diameter. The Ni-Ti flexible needle tested was found to exceed ISO external diameter limits. There was small inter-manufacturer deviation regarding each needle size (Table 3).

A common finding regardless of needle type and manufacturer was the presence of numerous irregular-

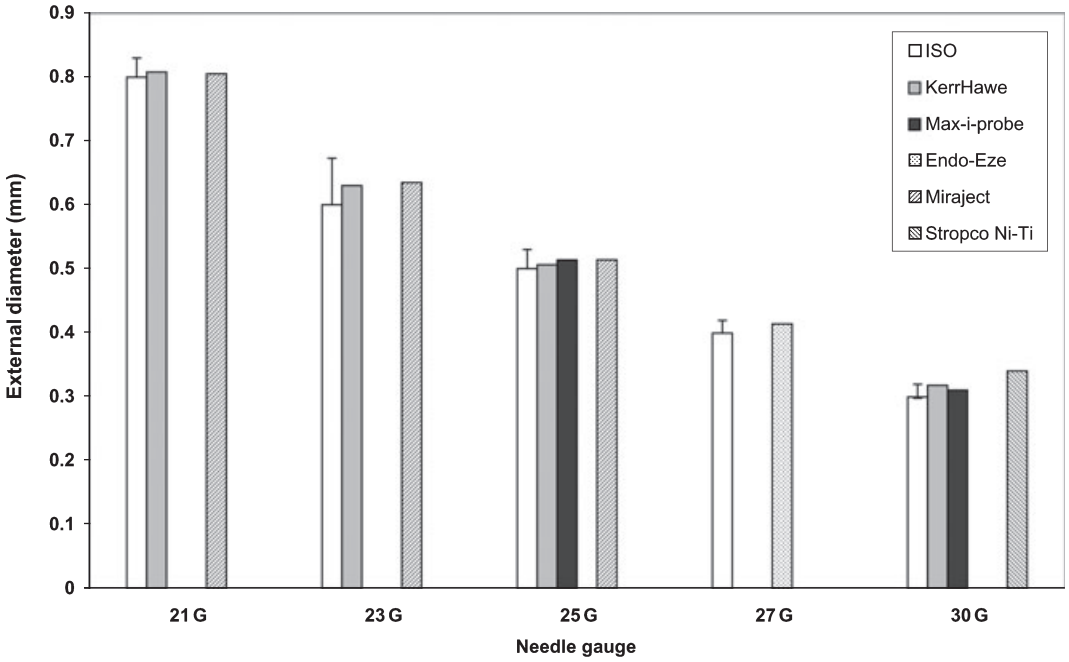

Figure 3 Mean external diameter of the selected needles compared with ISO tolerance limits.

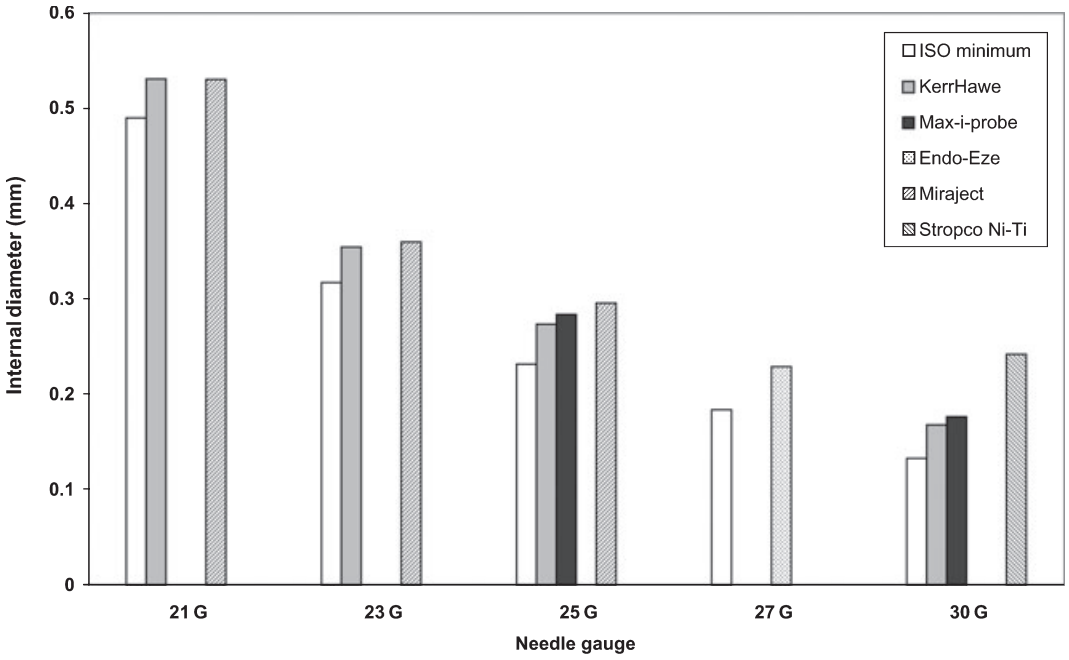

Figure 4 Mean internal diameter of the selected needles compared with ISO minimum limits.

Table 3 Descriptive statistics of the external diameter of the needles

Needle type	Gauge	ISO		Mean (SD)
		Nominal size	Limits	
KerrHawe	21	0.8	0.800–0.830	0.8082 (0.0024)
KerrHawe	23	0.6	0.600–0.673	0.6301 (0.0019)
KerrHawe	25	0.5	0.500–0.530	0.5060 (0.0016)
KerrHawe	30	0.3	0.298–0.320	0.3184 (0.0008)
Max-i-probe	25	0.5	0.500–0.530	0.5136 (0.0016)
Max-i-probe	30	0.3	0.298–0.320	0.3108 (0.0012)
Endo-Eze	27	0.4	0.400–0.420	0.4145 (0.0021)
Miraject Endotec	21	0.8	0.800–0.830	0.8054 (0.0020)
Miraject Endotec	23	0.6	0.600–0.673	0.6349 (0.0018)
Miraject Endotec	25	0.5	0.500–0.530	0.5137 (0.0016)
Stropko Flexi-Tip[a]	30	0.3	0.298–0.320	0.3408 (0.0017)

All diameters are expressed in millimetre.
[a]Not included in the ISO specification.

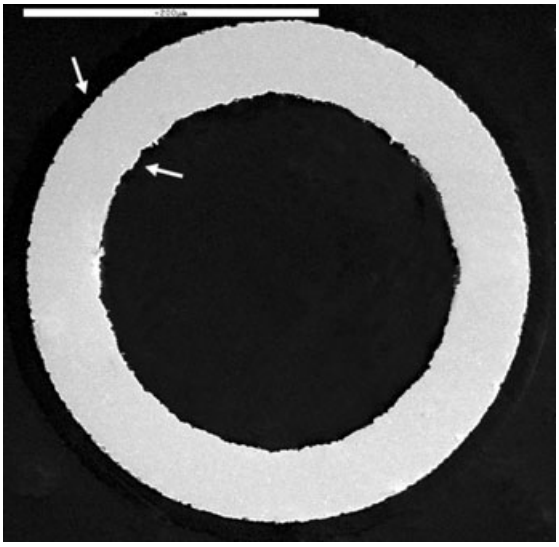

Figure 5 Irregularities along the external and internal perimeter (arrows) of the Ni-Ti needle examined (Stropko Flexi-Tip, Vista Dental Products, Racine, WI, USA).

ities on the internal surface (Fig. 2b), and in the case of the Ni-Ti needle on the external perimeter also (Fig. 5).

Discussion

Comparison of endodontic files and reamers to universally accepted ISO standards and suggestion of revisions have been topics of considerable interest for decades (Kerekes 1979, Cormier *et al.* 1988, Zinelis *et al.* 2002). Despite the development of standard specifications regarding medical needle tubing, there is no available information concerning the compliance of commercially available dental needles, either for irrigation or anaesthesia, with these specifications.

No exact point where measurements should be performed is specified in the ISO standards (ISO 9626 1991, 2001). The starting measurement point, 3 mm from the tip of the needle, was selected to standardize the procedure. Although, a point closer to the tip would represent more realistically the external diameter of the area with the greater interest, such a position could not be selected in all needles due to differences in tip morphology. Moreover, results of the preliminary study revealed high repeatability of the external diameter size within the first 10 mm of the needle, implying no detectable divergence of the cylindrical shape towards a conical outline. Such a shape could be expected when considering the manufacturing process through gradual narrowing of a large diameter tube (Pöll 1999). Thus, the present findings justify the absence of a specific site for measurements in the ISO standards.

The calculation scheme used for the determination of the dimensions of the needles (Fig. 2a) is derived from the fact that the intersection of a cylinder (needle) and a surface (polishing level) is generally an ellipse. On the occasion that the surface intersects the cylinder at a right angle, the resulting geometrical shape is a circle. Amongst the various diameters that can be determined from an ellipse, only the minor axis represents accurately the true diameter of the original cylinder (Finlayson *et al.* 1999). This applies to all measurements, i.e. external diameter, internal diameter and wall thickness.

Although every possible effort was made to place the specimens vertically in the resin, so that the resulting shape of the polished surface would be a circle, the final position had to be tested. Therefore, all specimens were considered to have an elliptic external and internal perimeter. Results of the study confirmed that small deviations from the exact vertical position were not avoided in all specimens.

Computational calculation of dimensions with the use of appropriate software has been previously reported and extensively validated (Sharp *et al.* 2003, Mazinis 2005). Due to the semi-automatic determination of the external perimeter and the wall thickness of the needles used in this study, the method had to be standardized to ensure high repeatability. All measurements were carried out by the same operator, who was accustomed to image processing. Moreover, a pilot study was conducted during which, the external diameter and wall thickness of five randomly selected specimens were determined repeatedly (10 times each). Results showed that sequential calculations differed from each other by <0.0005 mm, a deviation that was considered acceptable, as it was less than the sensitivity of the method. During the main study, a single measurement was made for each specimen.

The minimum length that can be measured using the selected method is limited by the true dimensions that correspond to the dimensions of a pixel. SEM images were obtained at a resolution of 1024×728 pixels. Assuming that the perimeter of the needle occupied the full range of the image's height, minimum spatial resolution varied between 0.00039 mm for the narrowest needle (30 G) and 0.00104 mm for the widest needle (21 G). This resolution equals approximately 0.13% sensitivity, regardless of needle size and provides accuracy comparable to that of previous dimensional studies of endodontic instruments (Zinelis *et al.* 2002) and materials (Cunningham *et al.* 2006). Although images of higher resolution would allow enhanced sensitivity, such images could not be obtained with the scanning electron microscope available.

According to the ISO standard, the designated size for the external diameter of needle sizes used in endodontics generally coincides with the minimum accepted external diameter (Table 1). The range of tolerance does not seem to follow a certain pattern. In the current study each value was directly compared to the ISO tolerance limits (ISO 9626 2001). No SS needle was found to exceed these limits. Tolerance limits should be re-evaluated to be equally different from the designated metric size, i.e. designated size ± tolerance. Calculation of standard deviation from measurements conducted on needles of the same size and manufacturer revealed high reproducibility of the needle tubing dimensions during manufacturing procedures.

A common finding amongst all needles was the irregular shape of the internal surface, which hindered the accurate determination of the wall thickness and internal diameter. The weighted average of four measurements on opposite sides of the surface was used, although equal distribution of the irregularities along the internal perimeter cannot be assumed. These irregularities occupy a small but important part of the needle lumen and may alter the irrigant flow. They probably result from the manufacturing process. Although the ISO standard refers to the external surface finish (ISO 9626 1991,2001), there is no reference concerning the internal surface morphology. Irregularities were also observed along the external perimeter of a Ni-Ti needle (Stropko Flexi-Tip, Vista Dental Products, Racine, WI, USA) that was tested.

Regarding the internal diameter of the needles, the ISO 1991/Amd 1:2001 specification replaced the earlier upper and lower limits with lower limits (ISO 9626 1991,2001). Such a limit assures proper space for the irrigant flow, as it is the internal diameter that determines the amount of flow through the needle (Ahn *et al.* 2002). No needle was found to violate the minimum internal diameter specified. No reference to the wall size of the needles is included in the ISO specifications (ISO 9626 1991,2001).

The ISO specification refers to stainless steel rigid needle tubing, but manufacturers of flexible tubing are encouraged to comply (ISO 9626 2001). The Ni-Ti flexible needle tested (Stropko Flexi-Tip, Vista Dental Products) was found to exceed the ISO maximum external diameter, but complied with the internal diameter specification.

Most manufacturers still use the 'gauge' system to categorize the size of the needles. This system has been widely accepted for some time and it possesses significant advantages concerning the manufacturing process (Pöll 1999), but its units cannot be directly extrapolated to clinical practice. Therefore, in cases when the exact dimension of the needles' external diameter is required, such as in endodontics or anaesthesiology, reference must be sought from the manufacturer's catalogue (Ahn *et al.* 2002). ISO recommendation for use of the millimetre as the standard metric unit for needle dimensions (ISO 9626 2001) has not been fully accepted by manufacturers. Thus, a plea can be made to the manufacturers to comply with ISO recommendation.

Correspondence of available needle sizing to the endodontic instrument sizing is presented in Table 4. Tolerance of the external diameter of both needles and files was taken into consideration to minimize the risk of binding in the root canal (ISO 9626 2001, Zinelis *et al.* 2002). Such correlation may aid the selection of the appropriate size needle, due to familiarity with the standardization of endodontic instruments. However,

Table 4 Correspondence of available needle sizing to the intracanal instruments' sizes

Gauge size	Corresponding instrument size
21	90
23	70
25	55
27	45
30	35

even if the clinician is aware of the needle size appropriate for a root canal, there remains a difficulty in distinguishing the different sizes under clinical conditions. There is no universally accepted colour-coding system for the needles. A coding resembling the colour-coding of corresponding instruments would be advantageous. Moreover, a numerical reference of the size of the needle should be imprinted both on the package and on the plastic base of the needle to further enhance size recognition.

Conclusions

Stainless steel irrigation needles comply with ISO specifications, whilst a Ni-Ti needle, which is not included in the specifications, was found to exceed ISO external diameter limits. Units of the widely used 'gauge' system cannot be directly extrapolated to clinical practice and, so, adoption of the millimetre size categorization as the standard metric unit, already recommended by ISO, should be accelerated. A colour-coding of needles corresponding to endodontic instruments would also be beneficial as part of a specific standard for endodontic needles that could be developed by a dental standards committee.

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