Correlation between the major apical foramen and readings from display's numbers

of two electronic apex locators: An ex vivo study

Correlação entre o forame apical maior e leituras dos números nos displays de dois localizadores

apicais eletrônicos: Um estudo ex vivo

Correlación entre el foramen apical mayor y las lecturas de los números de las pantallas de dos localizadores de ápices electrónicos: Un estudio *ex vivo*

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Abstract

Objective: The aim of this study was to determine the correlation between the distance from the file tip to the apical foramen and the readings on displays of two Electronic Apex Locators. Methodology: 46 human teeth were accessed, and electronic measurements were obtained at the display levels: 2.0; 1.5; 1.0; 0.5 and "apex", these electronic measurements were repeated. Results: At the 0.0 and 0.5 display numbers, there was an accurate detection of the apical foramen: 93.5% for the Root ZX II and 93.5% for the RomiApex A-15 (\pm 0.5 mm). Analysis of variance (ANOVA) revealed that the accuracies of the two devices did not differ (p > 0.05). At 2.0, 1.5 and 1.0, the accuracy was low and there was a significant difference in the accuracy of booth devices (p=0.000). When evaluating repetition of measurements, there was a high level of reproducibility (the ICCs ranged between 1.000 and 0.992 for the Root ZX II and between 1.000 and 0.989 for the RomiApex A-15) in all evaluated display's levels. Conclusions: Both devices displayed high accuracy and reproducibility at the 0.0 and 0.5 display numbers.

Keywords Endodontics; Root canal treatment; Dimensional measurement accuracies; Odontometry.

Resumo

Objetivo: O objetivo deste estudo foi determinar a correlação entre a distância da ponta da lima ao forame apical e as leituras nos visores de dois localizadores apicais eletrônicos. Metodologia: 46 dentes humanos foram acessados e medidas eletrônicas foram obtidas nos níveis de exibição: 2.0; 1,5; 1,0; 0,5 e "apex", essas medidas eletrônicas foram repetidas. Resultados: Nas marcas de exibição de 0,0 e 0,5, houve uma detecção precisa do forame apical: 93,5% para o Root ZX II e 93,5% para o RomiApex A-15 (\pm 0,5 mm). A análise de variância (ANOVA) revelou que as acurácias dos dois aparelhos não diferiram (p > 0,05). Em 2,0, 1,5 e 1,0, a acurácia foi baixa e houve diferença significativa na precisão dos dispositivos (p=0,000). Ao avaliar a repetição das medidas, observou-se um alto nível de reprodutibilidade em todos os níveis avaliados (os ICCs variaram entre 1.000 e 0.992 para o Root ZX II e entre 1.000

e 0.989 para o RomiApex A-15). Conclusões: Ambos os dispositivos apresentaram alta precisão e reprodutibilidade nas marcas de exibição de 0,0 e 0,5.

Palavras-chave: Endodontia; Tratamento do canal radicular; Precisão da medição dimensional; Odontometria.

Resumen

Objetivo: El objetivo de este trabajo fué determinar la correlación entre la distancia desde la punta de la lima hasta el foramen apical y las lecturas en las pantallas de dos localizadores electrónicos de ápice. Métodos: 46 dientes humanos fueron accesados y se obtuvieron medidas electrónicas en los niveles de visualización: 2,0; 1,5; 1,0; 0,5 y "apex", estas mediciones electrónicas fueron repetidas. Resultados: En las marcas de visualización de 0,0 y 0,5, hubo una detección precisa del foramen apical: 93,5 % para Root ZX II y 93,5 % para RomiApex A-15 (± 0,5 mm). El análisis de varianza (ANOVA) reveló que las precisiones de los dos dispositivos no diferían (p>0,05). En 2,0, 1,5 y 1,0, la precisión era baja y hubo una diferencia significativa en la precisión de los dispositivos (p=0,000). Al evaluar la repetición de las mediciones, hubo un alto nivel de reproductibilidad en todas las pantallas evaluadas (los ICC oscilaron entre 1.000 y 0.992 para Root ZX II y entre 1.000 y 0.989 para RomiApex A-15). Conclusiones: Ambos dispositivos mostraron una alta precisión y reproducibilidad en las marcas de visualización de 0.0 y 0.5.

Palabras clave: Endodoncia; Tratamento de conducto; Precisión de la medición dimensional; Odontometría.

1. Introduction

The working length is the distance from a coronal reference point to the point at which canal preparation and obturation should terminate (AAE, 2020). Over-preparation and over-filling have been reported to result in the failure of root canal treatment (Ricucci & Langeland, 1998). A conventional working length usually ranges between 0 and 1 mm from the radiographic apical foramen or apical end (Williams et al. 2006).

The location of the apical foramen, and consequent working length, can be obtained by conventional radiographic methods, cone-beam computed tomography (CBCT), or by the aid of electronic apex locators (Tsesis et al. 2015). Radiographic method can produce some distortions and does not locate the apical foramen precisely (Ratnakar et al. 2017; Tamperini et al. 2017; Serna-Peña et al. 2020). Cone-beam computed tomography is an accurate method that should be used for odontometry, only if the dentist already has this exam indicated for other treatments, avoiding unnecessary radiation to the patient (Connert et al. 2018; Paterson et. al 2020; Mahmoud et al. 2021) Therefore, the simplest and most used method to obtain the location of the apical foramen is the use of electronic apex locators (Melo et al, 2020; Pham 2021).

Electronic Apex locators are widely studied, however, a recent systematic review concluded that more in vivo or in vitro studies should be performed to obtain more precise and valid data on the accuracy of different generations of EALs (Nasiri et al. 2022).

The Root ZX (J. Morita Mfg Corp, Kyoto, Japan) is considered as a gold standard for electronic apex locators (Vasconcelos et al. 2014; Serna-Peña et al. 2020), that measures the impedance of 2 frequencies (0.4 and 8 kHz) simultaneously to calculate the ratio of the impedances. This calculated ratio is expressed as the position of the file inside the canal (Kobayashi & Suda, 1994). The Root ZX II (J. Morita Mfg Corp, Kyoto, Japan), works on the same electronic principles as the Root ZX. Operations manual explains that the readings on the meter gauge do not represent length in millimeters. However, the same manual claims that the meter's 0.5 reading indicates that the tip of the file is in the apical constriction. Additionally, if the file tip passes the point indicated by the apical line, the alarm sound changes from beeping to a solid tone. If the file tip reaches the major foramen, the word "APEX" and a small triangle next to the apical line will begin to flash (Root ZX II Operations manual, 2016).

RomiApex A-15 (Romidan Ltd, Kiryat Ono, Israel) is a device based on the comparison of mean square root levels of two signals at 8 and 0.5 kHz. According to the manufacturer, the mean square root levels represent the energy of the measured signal, which is more resistant to electromagnetic noise than the signal amplitude, which is often applied in other EALs. The file tip position relative to the apical constriction is calculated using reference values stored in the memory of the device (Miletic et al. 2011). The position of the file in the middle zone is visually indicated by coloring inside the representative

image of the root canal with a numerical reading between the 2.0 mm and 0.0 mm (Apex) segments. According to the manufacturer of the RomiApex A-15, at the apex point, the file is located at the major apical foramen (RomiApex-A15 User manual, 2014).

Several studies have evaluated the accuracy of different apex locators by calculating the distance between the file tip to the 0.0 or 0.5 number, the apical foramen, or the apical constriction (Piasecki *et al.* 2018; Bernardes *et al.* 2021; Cury *et al.* 2021). However, the use of EALs to determine the major foramen can led to overestimation of the working length (Connert et al. 2018). Moreover, few studies have considered correlation between the distance from the file tip to the anatomical point and electronic apex locators display readings and it is unclear how precise the numbers on the display correlate with file position inside the root canal (Higa *et al.* 2009; Vasconcelos *et al.* 2014; Haupt & Hulsmann *et al.* 2018).

The type of display, electronic components and the measuring frequencies used by individual EALs influences the determination of working length and that electronic apex locators displays should be calibrated on extracted teeth *ex vivo* prior to clinical use (Hör *et al.* 2005; Aguiar *et al.* 2017).

The aim of this laboratory study was to evaluate the correlation between the distance from the file tip to the major apical foramen and the readings from 2.0 to 0.0 ("apex") on the displays of the Root ZX II and RomiApex A-15. The null hypothesis is that there is no difference between the numbers on the displays of the Electronic Apex Locators and the actual distance from the file tip to the apical foramen.

2. Methodology

This study was performed in accordance with the guidelines issued by the Department of Health of the state of Paraiba, Brazil and after approval by its Ethics in Research Committee of Federal University of Paraíba.

Forty-six single-rooted human teeth with straight roots, a single canal and fully formed apices were evaluated using a magnifying lens at 10x magnification and radiographed mesiodistally and buccolingually. Canals with open apices, root fractures, obstructed foramen, root perforations and accessory canals were excluded from the sample. The samples were subjected to 2,5% sodium hypochlorite (NaOCl) for disinfection and then store in saline solution (0.9% NaCl) until used.

The crown of each tooth was removed using a diamond disk to standardize the mean specimen length at 13 mm. The contents of each canal were removed using a conventional k-type file with a diameter compatible with the canal, and a k-type file # 10 (Dentsply-Maillefer, Baillaigues, Switzerland) was used to confirm apical patency by introducing it into the root canal and pulling it back to a 1 mm distance from the apical foramen. The middle and cervical thirds were prepared using Gates-Glidden burs # 2, and 3 (Dentsply-Maillefer, Baillaigues, Switzerland) according to the diameter of the root canals (up to 5 mm short of the total root length).

A model similar to the Mounting Model designed by Elayouti and Löst was used for the measurement of electronic length obtained by the two electronic apex locators (Elayouti & Löst 2006).

The Root ZX II (J. Morita Mfg Corp, Kyoto, Japan) was used for electronic measurements. The teeth were connected to the mounting model and placed in contact with a 0.9% saline solution to simulate the periodontium. The lip clip of the electronic apex locator was attached to the 0.9% saline solution container, and the electrode was connected to the measuring file. The electronic and actual lengths were measured by using a # 15 K-File (Dentsply- Maillefer, Ballaigues, Switzerland).

The root canal was irrigated with 2.5% sodium hypochlorite, and the position of the file inside the apical third was determined: the file was slowly introduced into the root canal, and the micrometer connected to the file was moved apically up until the electronic apex locator displayed 2.0; 1.5; 1.0; 0.5 and "apex" on the screen. The measurements from 2.0 to 0.0 ("apex") were recorded, and the instrument was pulled back to the cervical end {R = 0.0 cervical}. The electronic measurements at 2.0; 1.5; 1.0; 0.5 and "apex" were repeated to confirm their reproducibility. After recording the electronic

measurements, all procedures performed with the Root ZX II were repeated for each specimen with the RomiApex A-15. Both devices are used in accordance with the instructions of the two manufacturers (RomiApex-A15 User manual, 2014; Root ZX II Operations manual, 2016).

After the last electronic measurement was recorded, the file at the 0.0 ("apex") position was cemented in place using the flow resin Natural Flow (DFL, Taquara, Rio de Janeiro, Brazil). Subsequently, the electronic length was confirmed to ensure that the file was in the same position. The teeth were removed from the mounting model, and a 3195F bur (K.G. Sorensen, São Paulo, Brazil) was used to expose the apical 4 mm of each root along the long axis of the tooth in a plane that produced the best representation of the apical foramen in relation to the file. This procedure was similar to that described by Saxena *et al.* (2017). The last layer of dentin was then carefully removed using a # 15 scalpel blade. Each root was photographed with a digital camera (Nikon D80, Nikon, Tokyo, Japan) under a stereomicroscope (Coleman XTB 1-B, Santo André, São Paulo, Brazil) at 20x magnification. The images were projected onto an LCD screen and analyzed using Image J 1.47 software (National Institutes of Health, Bethesda, MA, USA). Three investigators who were blinded to groups and procedures marked and recorded the distance from the file tip to the apical foramen for each specimen.

The most incisal limit of the apical foramen represented the apical foramen, while the smallest distance between the tip of the file and this limit was taken as the reference for the actual length. An exact correlation between the file tip and the apical foramen indicated that the electronic length was the same as the actual length into 0.0 ("apex") position A negative value indicated that the distance from the file tip to the apical foramen was shorter than the actual length, while a positive value indicated that it was longer. When a disagreement occurred between evaluators, the distances were reexamined until the evaluators reached a consensus.

Then the electronic measurements recorded in the positions in 2.0; 1.5; 1.0; 0.5 and "apex" of the display of the two locators were also compared with the actual position of the endodontic instrument at 2.0mm distances; 1.5mm; 1.0mm; 0.5mm of apical foramen for both Root ZX II and RomiApex A-15.

To determine the accuracies of the 3 EALs at 2.0, 1.5, 1.0, 0.5 and 0.0 ("apex"), the data were statistically analyzed using analysis of variance (ANOVA). The correlation coefficient was used to compare reliability. The intraclass correlation coefficient (ICC) was calculated to demonstrate the strength of agreement between the actual length and electronic length at both measuring points.

3. Results and Discussion

Accuracy

Statistical Package for Social Sciences software (SPSS 13.0; SPSS Inc., Chicago, IL, USA) was used for statistical analyses. Table 1 shows that the apical foramen was coincident with the 0.0 ("apex") display's number in 43 times (93.5%) by the Root ZX II and 43 times (93.5%) by the RomiApex A-15 with a clinical tolerance of \pm 0.5 mm, demonstrating the accuracy of the two devices.

Correlation between actual length and number on the EAL display		Root ZX II		RomiApex A15		
		(n = 46)	%	(n = 46)	%	
2.0 mm X 2.0	Correct	7	(15.2%)	2	(4.3%)	
	Incorrect	39	(84.8%)	44	(95.7%)	
1.5 mm X 1.5	Correct	14	(30.4%)	3	(6.5%)	
	Incorrect	32	(69.6%)	43	(93.5%)	
1.0 mm X 1.0	Correct	27	(58.7%)	13	(28.3%)	
	Incorrect	19	(41.3%)	33	(71.7%)	
0.5 mm X 0.5	Correct	34	(73.9%)	33	(71.7%)	
	Incorrect	12	(26.1%)	13	(28.3%)	
0.0 mm X 0.0	Correct	43	(93.5%)	43	(93.5%)	
	Incorrect	3	(6.5%)	3	(6.5%)	
	Total	46	(100.0%)	46	(100.0%)	

Table 1. The correlation between measurements taken by two electronic apex locators (± 0.5 mm).

Source: Authors.

Descriptive values

Table 2 shows the results of the Kolmogorov-Smirnov normality test and descriptive values (mean and standard error) for the differences between actual length and electronic measurements made with the two EALs.

When comparing the display points at the "apex" and the apical foramen as well as the display 0.5 and 0.5 mm away from the apical foramen, analysis of variance (ANOVA) did not reveal any significant differences in the accuracy of the Root ZX II (p>0.05) and RomiApex A-15 (p>0.05) at a 1% confidence level.

Comparing the display points 2.0, 1.5 and 1.0 with the respective distances 2.0 mm, 1.5 mm, and 1.0 mm from the apical foramen by analysis of variance (ANOVA) revealed a significant difference in the accuracy of the Root ZX II (p=0.000) and RomiApex A-15 (p=0.000) at a 1% confidence level.

Table 2 – Descriptive statistics for the statistics of the st	e differences between a	actual length and electronic	measurements at 2.0, 1.5, 1, 0.	5 and
0.0 ("apex").				

	Root ZX II				RomiApex A15			
Mean difference from AF	Display number	Ν	Mean	SE	Ν	Mean	SE	
Statistics	2.0	46	2.742	0.1420	46	3.894	0.1843	
Normality test (p value)			0.0	006		0.166		
Statistics	1.5	46	2.030	0.1362	46	2.590	0.1539	
Normality test (p value)			0.000			0.017		
Statistics	1.0	46	1.361	0.1320	46	1.579	0.1407	
Normality test (p value)			0.000			0.000		
Statistics	0.5	46	0.691	0.1312	46	0.748	0.1330	
Normality test (p value)			0.000			0.000		
Statistics	0.0	46	-0.133	0.1320	46	-0.044	0.1327	
Normality test (p value)		0.000 0.000				00		

* intra-observer * Negative values indicate the file position coronal to the measurement point. Source: Authors.

Repeatability

For the display points 2.0, 1.5, 1.0, 0.5 and 0.0 ("apex"), the intraclass correlation values ranged between 1.000 and 0.992 for the Root ZX II, and between 1.000 and 0.989 for the RomiApex A-15. For the two devices studied, there was no association between differences and mean repeated measurements. The repeatability coefficient ranged between $r_{clx} = 0.001$ and 0.016 for the Root ZX II and $r_{clx} = 0.001$ and 0.033 for the RomiApex A-15. The tested devices thus exhibited excellent reproducibility (Table 3).

Table 3. Results of intraobserver repeatability of electronic measurements obtained by two electronic apex locators in each measurement point.

		Root ZX II				RomiApex A15			
	(N)	Measurements	Intra-CC (I.C 95%)	Coeff(r) #	(N)	Measurements	Intra-CC(I.C 95%)	Coeff(r) #	
Display 2.0	46	92	0.992 (0.985 - 0.995)	0.016	46	92	0.989 (0.981 - 0.994)	0.033	
Display 1.5	46	92	0.999 (0.998 - 0.999)	0.002	46	92	0.993 (0.988 - 0.996)	0.015	
Display 1.0	46	92	0.998 (0.997 - 0.999)	0.003	46	92	0.998 (0.996 - 0.999)	0.004	
Display 0.5	46	92	0.999 (0.999 - 1.000)	0.001	46	92	0.997 (0.997 - 0.999)	0.003	
Display 0.0	46	92	1.000 (0.999 - 1.000)	0.001	46	92	1.000 (0.999 - 1.000)	0.001	

*ANOVA one-way # Coefficient of repeatability r = $1.96 \times \sqrt{2s_w^2}$. Source: Authors.

Discussion

Several researchers have shown the accuracy of different apex locators to determine CRT, ranging from 89% to 97.8% for Root ZX II (Aguiar et al. 2017; Saraf et al. 2017; Cury et al. 2021; Melo et al. 2020) and from 92,5% a 95,6% for Romiapex A-15 (Saraf et al. 2017; Melo et al. 2020), both devices used in the present study. In the present study, the Root ZX II and RomiApex A-15 were accurate in locating the apical foramen and the distance of 0.5 mm close from the apical foramen in 93.5% of the times. Similar accuracies were found in other studies, which reported an accuracy of 97.5% for the Root ZX, 95% for the Precision Apex Locator and 90% for the Elements Apex Locator in locating the apical foramen (Guise et al. 2010).

The accuracy of apex locator measurements increases as the file approaches the apical foramen. As in the present study, measurements at the 0.5 and 0.0 display numbers were considered accurate by other authors (Higa *et al.* 2009; Piasecki *et al.* 2018; Serna-Peña *et al.* 2020; Cury *et al.* 2021; Bernardes *et al.* 2022). Other studies found more accurate results when EAL's measurements were obtained at 0.0 in the apical foramen, and worse results at 1mm short of the apical foramen (Saxena *et al.* 2017; Adorno *et al.* 2021).

Melo *et al.* (2020) evaluated the ability of EALs to locate a point 1 mm away from the apical foramen, revealing accuracies ranging from 92.5% for the RomiApex A-15, and 97.5% for the Root ZX II. Another study evaluated different display's protocols of Electronic Apex Locators and observed only 50% of accuracy, when using 1.0 number in Root ZX's display, significantly lower, than 95% observed in the determinations performed at the 0.0 number (Oliveira et al. 2019).

Piasecki *et al.* 2018 evaluated the accuracy of three EALs in locating 0.5 number and 0.0 at the apical foramen. The authors concluded that Root ZX, that operates with the same characteristics of Root ZX II, and and Canal Pro device (Coltene-Endo, Cuyahoga Falls, OH) were accurate in locating both root canal marks. However, Apex ID was inaccurate, using the 0.0 landmark, producing longer measurements.

Many reports have evaluated the accuracy of EALs in apical constriction at 0.5 mm coronal from anatomic apex and the apical foramen 0.0 mm (Akisue *et al.*2014; Khandewal et al. 2015; Aguiar *et al.* 2017; Saxena *et al.* 2018; Golvankar *et al.* 2019; Mahmoud *et al.* 2021), but few studies have considered correlation between the distance from the file tip to the anatomical point and electronic apex locators display readings before the number 0.5 or 0.0, and it is unclear how precise the numbers on the display correlate with file position inside the root canal (Haupt et al. 2018; Oliveira et al. 2019). No study has assessed the RomiApex A-15 measurements between 2.0 and 0.0 number.

Numerals on the display do not represent millimeters, since the point called APEX on the display represents the major foramen (Root ZX II Operations manual, 2016). Likewise, for the RomiAoex-A15, the 0.0 point represents the foramen (RomiApex-A15 User manual, 2014). On the other hand, the Instruction Manual of the same devices recommends that a K file reach the apical foramen first, so that the readings are reliable (RomiApex-A15 User manual, 2014; Root ZX II Operations manual, 2016), a fact that is related to the clinical conditions of each dental element and the skill of the operator. Clinically, the measurement of root canal length for inexperienced dental clinicians, could be facilitated if the numeric meter reading values of EALs are known in relation to the actual distance in mm from the apical forame, in case operator cannot reach the apical foramen again.

In the present study, most accurate results occurred in display's readings 0.0 and 0.5 for the two tested devices, nonetheless, different results were found in the research by Aguiar *et al.* (2017). In the display position 0.0, when compared to the apical foramen position, results demonstrated 68.8% and 65.7% of accuracy, when using the Root ZX Mini and the Root ZX II. The authors attributed this low accuracy to the device's mechanism, however, to achieve these results, the mounting model platform was not used, nor the repeatability of the measurements was obtained, and these methodological differences may have influenced the results.

The low accuracy of electronic apex locators in measurements above 0.5 in EALs' displays can be explained. According to Vasconcelos *et al.* (2015), the numbers on the electronic apex locator displays do not correspond to the distance from the apical foramen. This can be explained because the working principle of electronic apex locators depends on impedance in the apical region. Close to the apical constriction, the impedance increases, and immediately decreases, when the tip of the file attached to the device reaches the apical foramen. It is based on this principle that electronic measurements closer to the crown, such as those shown on displays between 1.0 and 2.0, will not be accurate. That is why obstructions, apical patency, preflaring, resorptions, perforations and anatomical variations can interfere with the functioning of apex locators (Vasconcelos *et al.* 2015; Abdelsalam *et al.* 2020; Schacam *et al.* 2020; Léon Lópes *et al.* 2021; Saritha *et al.* 2021).

The clinically acceptable margin of ± 0.5 mm has been utilized in many studies (Connert *et al.* 2018; Piasecki *et al.* 2018; Melo *et al.* 2020; Adorno *et al.* 2021). To increase the methodological rigor of this research, the repeatability of measurements and the mounting model were used, has been shown to be efficient in studies of reproducibility, allowing greater control of variables compared to other methods (D'Assunção *et al.* 2014; Cornnet *et al.* 2017).

Few studies in the literature assess the reproducibility of the measurements by evaluating electronic apex locators. (Hör *et al.* 2005; Elayouti & Löst 2006; D'Assunção *et al.* 2010; D'Assunção *et al.* 2014; Connert *et al.* 2018).

A study concluded that Root ZX II presented better repeatability than RomiApex (Adorno *et al.* 2019). In the present research, the reproducibility of the two tested devices at "apex" and 0.5 ranged from 0.001 to 0.003. The high accuracy and reproducibility of the measurements obtained at the references 0.0 and 0.5 relative to the apical foramen locator suggest that these two apical points are useful as endpoints in endodontic treatment. However, the low accuracy and high repeatability at the display numbers 2.0, 1.5 and 1.0 demonstrate that there is indeed a discrepancy between the device readings and actual length, proving that as the file moves away from the apical foramen, the measurements obtained by electronic apex locators become less accurate. For inexperienced dental clinicians, EAL display's readings could represent a useful guide for indicating file tip position within the root canal whilst developing tactile sensitivity skills. A disagreement between numbers ranging from 2.0 to 1.0 on the display of the electronic apex locators compared with the distance to the major apical foramen can lead less experienced operators to use these numbers as parameters, in turn leading them to believe that the numbers on the display represent the actual distance to the major apical foramen.

In the present study, it was found that for measurements at 2.0, 1.5, and 1.0, neither device was accurate, suggesting that these display points should be disregarded by the operators or adjusted on the RomiApex A-15 and Root ZX II displays. Therefore, it is important that a professional using these devices is aware of this limitation to define protocols that make it possible to obtain more satisfactory results

4. Conclusion

In conclusion, within the limitations of the present ex vivo study, the Root ZX II and RomiApex A-15 exhibit high accuracy, correlation and reproducibility at the 0.0 and 0.5 EAL's display's numbers compared with the actual distance from the apical foramen. Display's numbers of 1.0, 1.5 and 2.0 should not be used as a clinical reference for decision making as reference end points.

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