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Clinical reproducibility of three electronic apex locators

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Abstract

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Aim To compare the reproducibility of three electronic apex locators (EALs), Dentaport ZX, RomiApex A-15 and Raypex 5, under clinical conditions.

Methodology Forty-eight root canals of incisors, canines and premolars with or without radiographically confirmed periapical lesions required root canal treatment in 42 patients. In each root canal, all three EALs were used to determine the working length (WL) that was defined as the zero reading and indicated by 'Apex', '0.0' or 'red square' markings on the EAL display. A new K-file of the same size was used for each measurement. The file length was fixed with a rubber stop and measured to an accuracy of 0.01 mm. Measurements were undertaken by two calibrated operators. Differences in zero readings between the three EALs in the same root canal were statistically analysed using paired *t*-tests with the Bonferroni correction, Bland–Altman plot and Linn's concordance correlation coefficients at $\alpha = 0.05$.

Results Mean and standard deviation values measured by the three EALs showed no statistically significant differences. Identical readings by all three EALs were found in 10.4% of root canals. Forty-three per cent of readings differed by less than ±0.5 mm and 31.3% exceeded a difference of ±1 mm.

Conclusions The clinical reproducibility of Dentaport ZX, RomiApex A-15 and Raypex 5 was confirmed with the majority of readings within the ±1.0 mm range. However, the small number of identical zero readings suggests that EALs are not reliable as the sole means of WL determination under clinical conditions.

Keywords: anatomical foramen, apical constriction, clinical, electronic apex locators, reproducibility, working length determination.

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Introduction

Determining and maintaining working length (WL) during root canal shaping is one of the crucial steps for successful root canal treatment. However, it remains controversial whether to complete instrumentation within the canal to the cemento-dentinal junction (CDJ), i.e. physiological or minor foramen, which is often identified as the apical constriction (AC), or to extend instrumentation into the cemental cone close to the major, i.e. anatomical foramen (AF) (Ricucci & Langeland 1998, Wu *et al.* 2000, Pommer *et al.* 2002, Gordon & Chandler 2004).

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Electronic apex locators (EALs) distinctively display the end-point of the root canal either as 'Apex', '0.0' or 'red coloured' markings, usually accompanied by an audible signal. However, most EALs have no exact marking for the AC, and practitioners may choose to reduce the zero reading by 0.5–1 mm or arbitrarily select a value between 0.5 and 1.0 on the display (Grimberg *et al.* 2002, Pommer *et al.* 2002, Versiani *et al.* 2009).

It is common knowledge that the numbers on the display of EALs do not correspond to the actual distance in millimetres to the AC or AF, although it has been reported that some EALs reveal significant correlations between the numeric meter reading and the distance of the file tip from the AF (Higa *et al.* 2009). It has also been reported that the accuracy of EAL measurements and numeric readings increase as the file tip approaches the major foramen (Kobayashi & Suda 1994, Venturi & Breschi 2005, 2007, Higa *et al.* 2009).

Many studies have evaluated the accuracy of EALs in laboratory studies or *in vivo* with respect to the AC and/or AF and indicated that the AF could be determined more precisely and consistently than the AC by more recent generations of EALs (Ounsi & Naaman 1999, Hoer & Attin 2004, Nekoofar *et al.* 2006, Wrbas *et al.* 2007, Jan & Krizaj 2009, Adorno *et al.* 2010). They generally concluded that it would be more objective to evaluate the accuracy of EALs in relation to the major foramen or AF, which seems to be a more reliable and reproducible landmark than the minor foramen or AC. This may be due to the fact that capacitance and resistance-based EALs require contact between the file tip and the periodontal ligament (De Vasconcelos *et al.* 2010). When the AF is located, the AC can be estimated according to the European Society of Endodontology Quality Guidelines (ESE 2006), which state that the WL enables the preparation of the root canal as close to the AC as possible.

Dentaport ZX (J. Morita Corporation, Tokyo, Japan) is the latest version of the Root ZX, one of the most evaluated EALs that is often used as the 'gold standard' to which other EALs are compared (Vajrabhaya & Tepmongkol 1997, Dunlap *et al.* 1998, Welk *et al.* 2003, Venturi & Breschi 2005, Plotino *et al.* 2006, Wrbas *et al.* 2007, Higa *et al.* 2009, De Vasconcelos *et al.* 2010). Similar to the Root ZX, the Dentaport ZX maintains the impedance ratio method with two different frequencies, 0.4 and 8 kHz (Kobayashi & Suda 1994), and may also serve as an electronic endo-motor.

Raypex 5 (VDW GmbH, Munich, Germany) operates at the same frequencies as the Dentaport ZX, but the measurement is based on the mean square root values of the electrical signals, and the results are presented on a display with a different metre scale. These two EALs were evaluated in clinical and laboratory conditions with no significant differences between them in determining the AF and/or AC (Wrbas *et al.* 2007, Pascon *et al.* 2009, Ding *et al.* 2010, Stoll *et al.* 2010). Furthermore, the Raypex 5 showed comparable results in determining the WL with different canal instruments (Sadeghi & Abolghasemi 2010).

RomiApex A-15 (Romidan Ltd, Kiryat Ono, Israel) is a new device based on the comparison of mean square root levels of two signals at 8 and 0.5 kHz, similar to Raypex 5. 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, often applied in other EALs. The file tip position relative to the AC is calculated using reference values stored in the memory of the device.

Although a number of studies have compared the accuracy of EALs in determining the AF or some point within the root canal shorter than the AF, there is little evidence on the reproducibility of EALs in clinical conditions (ElAyouti *et al.* 2005, D'Assuncao *et al.* 2010). Reproducibility indicates whether or not two or more techniques used to measure a particular variable, in otherwise identical circumstances, produce the same result (Petrie & Sabin 2009). Most previous studies show acceptable to high accuracy of EALs, so it is reasonable to expect that the WL measured by one EAL should be reproducible by similar EALs in the same root canal under the same clinical conditions.

The aim of this study was to assess the reproducibility of Dentaport ZX, RomiApex A-15 and Raypex 5 under clinical conditions. The null hypotheses were (1) there are no significant differences in clinical reproducibility between the three EALs and (2) the reproducibility of the three EALs lies within the range of ±0.5 mm.

Materials and methods

Ethical approval for this clinical study was granted by the Ethics Committee of the University of Belgrade, School of Dentistry. Forty-two patients, 19 men and 23 women, aged between 20 and 65 years, were selected. Informed consent was obtained from all patients, and the study was conducted in compliance with the ethical principles of the Helsinki Declaration and Good Clinical Practice.

Inclusion criteria were pulpal pathosis with or without radiographically confirmed periapical (PA) lesions in incisors, canines and premolars; all teeth scheduled for root canal treatment.

Exclusion criteria were previous endodontic treatment, marginal periodontitis, non-restorable teeth, internal or external root resorption, intracanal calcification, active systemic disease and physical or mental disability.

In total, 48 root canals were included. In each case, the diagnosis was based on the patient's history, clinical examination and radiographs taken by the bisecting angle technique (Trophy RVG, Trophy Radiologie, Paris, France). Local anaesthesia was applied in cases with vital pulps (Scandonest; Septodont, Maur-des-Foses, France). Access cavities were prepared with a round diamond bur (F 0001, 016; Dentsply Maillefer, Ballaigues, Switzerland), lateral walls refined with a conical carbide bur (Endo Z; Dentsply Maillefer), and coronal pulp or necrotic tissue was removed with a long-neck round carbide bur, either size 010 or 014 (E 0123; Dentsply Maillefer) using a high-speed handpiece. Where necessary, all remaining parts of metal restorations and carious tooth tissue were removed, and occlusal cusps were flattened using a high-speed conical diamond bur (F 0199, 016; Dentsply Maillefer) to achieve a flat reference plane. After verifying the initial patency of the root canal with size 08 or 15 K-files (MicroMega, Besançon, France), radicular pulp or necrotic tissue was removed with a hand K-file of appropriate size, without widening the canal space, using 0.5% sodium hypochlorite as an irrigant. The WL of each root canal was determined using the three EALs in the following sequence: Dentaport ZX, RomiApex A-15 and Raypex 5. In total, 144 measurements in 48 root canals were undertaken by two calibrated operators, 90 measurements in 30 root canals by operator KB and 54 measurements in 18 root canals by operator VM.

The WL was defined as the most apical point of the root canal and was registered when 'Apex', '0.0' or 'red square' appeared on the display of Dentaport ZX, RomiApex A-15 and Raypex 5, respectively, associated with an audible signal. The WL was determined by inserting a K-file into the root canal until any of the aforementioned marks were reached and remained stable for at least 5 s. The file was then disconnected from the EAL but left in place in the root canal at the determined WL. After 30 s, the file holder was re-attached to the file, and the reading repeated by the same operator using the same EAL. When initial and repeated readings were completed by one EAL, the next EAL was used to determine the WL in the same root canal as described previously. A new K-file of the same size was used for each EAL. Only root canals with stable and identical initial and repeated readings by all three EALs ('Apex', '0.0' or 'red square') were included in the study.

The WL was marked with a rubber stop, and the file was placed in a custom-made fixing device so that the measured length was preserved. Each file was photographed under standardized conditions: the digital camera (Olympus E-330, 8 megapixels; Olympus Corporation, Tokyo, Japan) was mounted on a copy stand with lens-to-object distance of 20 mm, at constant ambient light, and with the same camera parameters. In the image obtained, the tip-to-rubber stop distance on the file was measured with the accuracy of 0.01 mm using imaging software (Adobe Photoshop CS2; Adobe Systems Incorporated, San Jose, CA, USA). A millimetre scale was photographed under the same conditions as the files and was used as a length reference.

Data were analysed statistically using paired *t*-tests with the Bonferroni correction for multiple comparisons in order to control the overall Type I error rate at $\alpha = 0.05$. The Bland–Altman plot and Linn's concordance correlation coefficients were used to determine inter-EAL reproducibility. The differences in inter-operator measurements were compared using the *t*-test at $\alpha = 0.05$. Statistical analysis was performed in Minitab 15 (Minitab Inc., State College, PA, USA).

Results

Table 1 shows mean and standard deviation (SD) values of absolute differences between pairs of the tested EALs. There were no significant differences between the three EALs ($P > 0.05$; paired *t*-tests with the Bonferroni correction).

Figure 1 shows Bland–Altman plots of differences in WL measurements in all patients, irrespective of the PA status, with mean values and limits of agreement. Limits of agreement indicated the range that contained 95% of the differences between pairs of EALs and were between −1.7 and 2.4 mm for the three pairs of EALs. Bland–Altman plots with differences randomly scattered around a mean value close to zero confirmed the reproducibility of the three EALs. Random scatter of points along the *X*-axis on all the three plots indicated that the inter-EAL reproducibility was independent of the length of root canals. Random scatter of points along the *Y*-axis on all the three plots indicated that none of the three EALs showed predominantly longer or shorter WL measurements compared with the other EALs.

Table 1 Mean and standard deviation (SD) values of absolute differences between the three electronic apex locators (EALs)

Pairs of EALs	Mean absolute difference (mm)	SD of absolute difference (mm)
Dentaport ZX vs. RomiApex A-15	0.73	0.72
Dentaport ZX vs. Raypex 5	0.84	0.68
RomiApex A-15 vs. Raypex 5	0.86	0.71

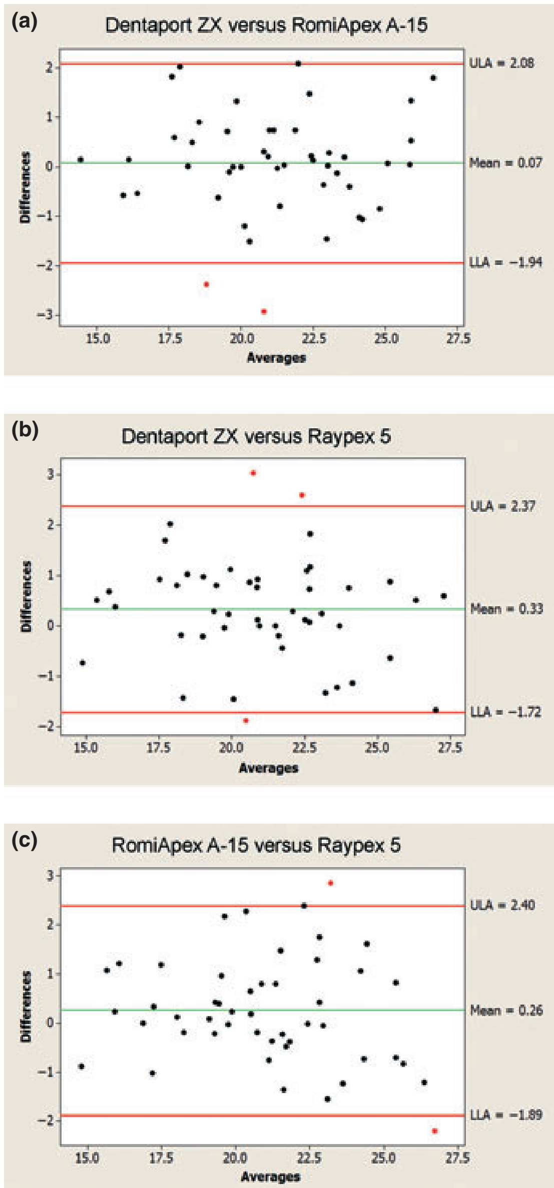

Figure 1 Bland–Altman plots of differences in WL measurements in all teeth, irrespective of the PA status. (a) Dentaport ZX versus RomiApex A-15. (b) Dentaport ZX versus Raypex 5. (c) RomiApex A-15 versus Raypex 5. ULA – upper limit of agreement, LLA – lower limit of agreement; *X*-axis shows the mean length (mm) of a certain root canal measured by each pair of electronic apex locators.

Bland–Altman plots of differences in WL measurements in teeth with and without PA lesions showed that the PA status had no effect on the reproducibility of the three EALs.

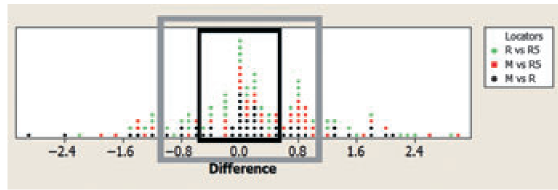

Figure 2 Distribution of differences in WL measurements by pairs of electronic apex locators. The black rectangle indicates differences of up to ±0.5 mm. The grey rectangle indicates differences of up to ±1 mm. M-Dentaport ZX, R-RomiApex A-15, R5-Raypex 5.

Linn's concordance correlation indicated good clinical reproducibility of the three EALs with coefficient values of $\rho = 0.9369$ for Dentaport ZX: RomiApex A-15, $\rho = 0.9334$ for Dentaport ZX: Raypex 5 and $\rho = 0.9291$ for RomiApex A-15: Raypex 5.

Figure 2 illustrates the distribution of differences in WL measurements by the three EALs. Sixty-two of 144 measurements or 43% of differences were in the range of ±0.5 mm. Ninety-nine or 68.7% of differences were in the range of ±1 mm, and the other 31.3% of differences were greater than ±1 mm.

Mean and SD values obtained by the two operators were 21.2 ± 2.8 mm (operator KB) and 20.4 ± 3.0 mm (operator VM). There were no significant differences in measurements by the two operators ($P > 0.05$; *t*-test) with mean absolute differences between zero readings by pairs of EALs being 0.82 ± 0.71 mm (operator KB) and 0.80 ± 0.68 mm (operator VM).

Discussion

The first null hypothesis was upheld because no significant differences were found in clinical reproducibility between RomiApex A-15, Raypex 5 and Dentaport ZX. The second null hypothesis was rejected because clinical reproducibility of the three EALs in determining the WL was outside the limit of ±0.5 mm.

The number of root canals to be treated in this study was determined using the sample size calculation, which showed that 48 root canal treatments were required for the paired *t*-test with Bonferroni correction to have an 80% chance of detecting a difference in means of 0.5 mm with SD = 1.05 mm at the $\alpha = 0.05$.

Several *in vivo* studies have investigated the accuracy of EALs in determining the AC as the reference point, defined as 0.5 or 1.0 mm short of the AF (Dunlap *et al.* 1998, Hoer & Attin 2004, Wrbas *et al.* 2007, Pascon *et al.* 2009, Versiani *et al.* 2009, D'Assuncao *et al.* 2010). This is a common approach because the accepted endodontic teaching advocates root canal instrumentation and filling to the CDJ or the AC, the narrowest point of the canal where the pulp ends and the periodontal ligament begins (Ricucci & Langeland 1998, ESE 2006). However, the CDJ and AC seldom coincide, with the AC being always coronal to the CDJ (Stein *et al.* 1990), and the exact positions of these two landmarks vary from the AF as well as from the anatomical root apex (Ponce & Vilar Fernandez 2003, Hoer & Attin 2004, Olson *et al.* 2008). Furthermore, the CDJ is often difficult to detect clinically and microscopically (Lee *et al.* 2002), and the AC is not often present in its classic form (Dummer *et al.* 1984, Leonardo *et al.* 2007). Pre-setting the WL on an EAL display to a certain distance short of the zero reading with the expectation to detect the AC/CDJ is methodologically erroneous because the distance between the AF and the AC/CDJ is never known clinically. Therefore, the zero reading was used in this study as the reference point to determine inter-EAL reproducibility. The authors do not advocate the AF as the apical limit of root canal preparation and filling and adhere to the ESE Quality Guidelines (ESE 2006) in routine clinical practice.

Root canals with unstable readings or different initial and repeated readings were excluded from this study. Only three root canals were excluded indicating certain consistency of the tested EALs.

Standardization of the WL measurements involved the same file type and size, irrigant concentration, reference point and teeth serving as their own controls. This approach is similar to other studies in the field and allows certain variables to be controlled in the clinical setting.

The present results showed no influence of the PA status on the reproducibility of EALs, which is in accord with other studies using EALs irrespective of their operating principles (Dunlap *et al.* 1998, Venturi & Breschi 2005, Smadi 2006, Akisue *et al.* 2007). However, some studies have reported that the accuracy of EALs was lower in the presence of necrotic canal content compared with the vital pulp tissue (Arora & Gulabivala 1995, Pommer *et al.* 2002).

Bland–Altman plots showed quite large limits of agreement, exceeding ±1 mm for all pairs of EALs. Overall, approximately two-thirds of the measurements were within ±1 mm. Similar reproducibility was found by Venturi & Breschi (2005) who examined electrical characteristics of different root canal environments and compared the Apex Finder and Root ZX clinically. Inconsistent reproducibility of EALs in clinical conditions, as shown in the present study, questions the reliability of these devices to determine the WL, particularly when targeting the AC.

In 15 of 144 measurements (10.4%), the Dentaport ZX, RomiApex A-15 and Raypex 5 measured exactly the same length with 100% reproducibility. When the range of tolerance was extended to ±0.5 mm, the reproducibility increased to 43% and when extended to ±1 mm, the reproducibility further increased to nearly 70%. One reason for accepting this wider limit is the variability of the apical zone in shape, diameter and local internal anatomy as previously mentioned. This indicates that the WL is more likely to end in an apical constriction zone rather than at an apical point or plane (Olson *et al.* 2008).

In the present study, no EAL showed predominantly long or short measurements compared with the other two EALs, suggesting that clinical factors may be more important than the working principle of a particular device in locating the AF. Previous articles identified several clinical factors that may affect *in vivo* accuracy of EALs, such as conductivity of the medium in the root canal (Venturi & Breschi 2005), variations in the anatomical characteristics of the apical region (Ding *et al.* 2010) and procedural variability of clinical measurements (ElAyouti & Löst 2006). In the present study, clinical reproducibility of EALs was independent of the pulpal and periapical status of the tooth, the length of the root canal or the size of endodontic instruments.

There is no study in the literature comparing the reproducibility of Dentaport ZX, RomiApex A-15 and Raypex 5 either *in vitro* or *in vivo*, whilst a few compared the accuracy of Raypex 5 and Dentaport ZX (Pascon *et al.* 2009, Stoll *et al.* 2010). It is impossible to compare the reproducibility with the accuracy results as the former may be perfect even when the EALs are inaccurate. Furthermore, comparison of an accurate to inaccurate EAL(s) results in unacceptable reproducibility. The accuracy of each EAL needs to be determined in order to differentiate which device is responsible for wide limits of agreement. The present study investigated the reproducibility and not the accuracy of EALs and so it cannot be concluded which EAL(s) resulted in wide limits of agreement. The aim of study was not to determine which device was more or less accurate than others but to examine the reliability of various EALs in reproducing zero readings under the same clinical conditions. Wide limits of agreement suggest that clinicians cannot rely solely on EALs in WL determination as different devices produce variable readings of what manufacturer suggests as the position of the AF. Lower reproducibility may be expected when detecting the AC even by latest generation EALs because of the aforementioned anatomical variations (Ponce & Vilar Fernandez 2003, Hoer & Attin 2004, Olson *et al.* 2008).

No study was found in the literature on the RomiApex A-15, although a few *ex vivo* studies compared the accuracy of RomiApex D-30, a model similar to the one used in the present study, with Root ZX, Ipex and Elements Diagnostic Unit and Apex Locator in determining the WL 1 mm short of the AF (Bernardes *et al.* 2007, De Vasconcelos *et al.* 2010). They found that all tested EALs could determine accurately the root canal length at the AF and 1 mm from the AF.

When determining the WL in clinical conditions, one should bear in mind that variations in measurements are expected because of factors that cannot always be controlled, such as adjustment of the silicon/rubber stopper and reading of the file length (ElAyouti & Löst 2006). The coefficients of repeatability between various EALs were below 0.1 mm for the mounting method (ElAyouti & Löst 2006, D'Assuncao *et al.* 2010), which was significantly lower than 0.9 mm for the conventional visual method (ElAyouti & Löst 2006). Although procedural errors may be reduced using the mounting method, the repeatability results should be extrapolated cautiously to the clinical situation because of the limitations of such laboratory models, which do not take into account the complexity of vital tissues in the periapical region. In addition, variations in the present results could be influenced by the differences in working principles and/or display characteristics of the three tested EALs. Dentaport ZX, RomiApex A-15 and Raypex 5 have different marking features on their displays, which might affect readings for the same landmark. To avoid ambiguity, manufacturers should define clearly which landmark their device is meant to locate in order to increase safety and accuracy.

The present study confirmed that inter-operator variability may not be the deciding factor in variations of WL measurements by different EALs. Training and strict adherence to the clinical protocol are vital for reducing the operator effect and maintaining the clinical reproducibility of EALs.

Several *in vivo* and *ex vivo* studies reported that EALs could overestimate the WL with the file tip protruding beyond the set landmark, either the AF or AC (Dunlap *et al.* 1998, Welk *et al.* 2003, Kim & Lee 2004, Wrbas *et al.* 2007, Higa *et al.* 2009, Pascon *et al.* 2009). On the contrary, there are clinical studies where no WL measurements were 1 mm through the AC, suggesting that EALs reduce the risk of over-instrumentation and over-filling of the root canal (Uzun *et al.* 2008, Adorno *et al.* 2010). Ravanshad *et al.* (2010) reported comparable success of root canal treatments based on either Raypex 5 or X-ray WL determination in a randomized clinical trial. Slightly lower overestimation of root canal length was reported for the Raypex 5 (Ravanshad *et al.* 2010).

Conclusion

The clinical reproducibility of Dentaport ZX, RomiApex A-15 and Raypex 5 was confirmed with the majority of readings within the ±1.0 mm range. However, a small number of identical zero readings suggested that EALs are not reliable as the sole mean of WL determination under clinical conditions.

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Disclaimer

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