

**CLINICAL SUCCESS OF TWO WORKING LENGTH DETERMINATION  
TECHNIQUES - A RANDOMIZED CONTROLLED TRIAL**

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**THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY**

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*in partial fulfilment for the degree of*

**MASTER OF DENTAL SURGERY**



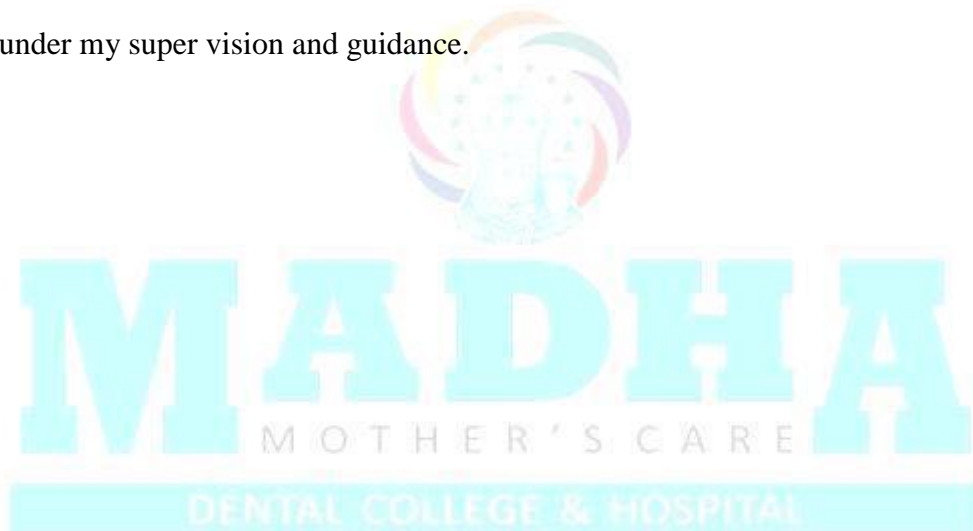
**BRANCH – IV**

**DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS**

**2016 – 2019**

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This is to certify that the Dissertation entitled “**CLINICAL SUCCESS OF TWO WORKING LENGTH DETERMINATION TECHNIQUES - A RANDOMIZED CONTROLLED TRIAL**” by **Dr. MINU JOSEPH**, Post Graduate student, **MDS Conservative Dentistry and Endodontics**, Madha Dental College & Hospital -Chennai – 69 Submitted to Tamilnadu Dr. M. G.R. Medical University for the MDS Degree Examination May 2019 is a bonafide research work carried out by her under my super vision and guidance.



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Title of the work: Clinical success of two different working length determination methods- A Randomized Controlled Trial

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The request for approval from the Institutional Ethical Committee ( IEC ) considered at the Institutional Ethics Committee meeting held on the 26-04-2017 at Madha Dental College and the documents related to the study referred above were discussed and reported to us through your letter have been reviewed. The decision of the members of the committee, the secretary and the Chairperson IEC of Madha Dental College is here under:

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## **ABSTRACT**

### **TOPIC OF THE STUDY: CLINICAL SUCCESS OF TWO WORKING LENGTH DETERMINATION TECHNIQUES - A RANDOMIZED CONTROLLED TRIAL**

**Objective:** To determine the clinical success of two working length determination techniques using Electronic apex locator (Root ZX mini) and Radiographic method.

**Materials and methods:** In this study, 83 teeth from 64 patients were randomly divided into groups; Group A: Electronic apex locator and Group B: Radiographic technique. A pre-operative radiograph was taken using customized tube positioners. After standard isolation and access cavity preparation, WL determination was carried out using Electronic apex locator in group A where as in group B pre-operative radiograph was used. After standardized cleaning and shaping technique, master cone verification radiograph was taken as the primary outcome and adjustments were accordingly made. After obturation, post-operative radiograph was taken. Differences in the end point of obturation and calculated working length were taken as the secondary outcome. Patients were recalled after 3 months. Clinical and radiographic evaluation of success was assessed as tertiary outcome.

**Results:** Accuracy of fit of master cone as verified by the radiograph (0.5mm short of radiographic apex) was the primary outcome. The frequency of under extension was not statistically significantly different between the 2 groups. Frequency of over extension and accurate fit was significantly different between the 2 groups. When absolute values of under extension was analysed, there was a statistically significant difference among the 2 groups. However, there was no significant difference between the 2 groups for absolute values of over extension.

The accuracy of obturation (0.5mm short of radiographic apex) as verified by the post obturation radiograph was the secondary outcome assessed. It was not significantly different between the 2 groups. The tertiary outcome of success rate of endodontic treatment after 3 months of obturation was assessed by presence or absence by clinical symptoms of disease and radiographic evidence of reduction or increase in peri-apical lesion. There was no significant difference in the clinical outcome of endodontic treatment. There was no significant difference in the lesion reduction between the 2 groups. However, 1 tooth in Group A (Electronic apex locator) developed a lesion.

**Conclusion:** The new radiographic technique showed greater frequency of over estimation than Electronic apex locator. It was similar to Electronic apex locator in the under estimation. However, there was no statistical difference in the long term success or the absolute values of over estimation. Hence, the new single radiographic technique for working length determination can be used as an alternative to Electronic apex locators.

**Keywords:** Working length, radiographic technique, Root ZX mini, Electronic apex locator, tube positioner, follow up, success, long term.

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## **LIST OF ABBREVIATIONS**

<b>WL</b>	: Working length
<b>RCT</b>	: Root canal treatment
<b>EAL</b>	: Electronic apex locator
<b>CBCT</b>	: Cone beam computed tomography
<b>2-D</b>	: Two dimensional
<b>3-D</b>	: Three dimensional
<b>AF</b>	: Apical foramen
<b>mm</b>	: millimeter
<b>cm</b>	: centimeter
<b>CDJ</b>	: cemento-dentinal junction
<b>ALT</b>	: Actual length of tooth
<b>ALI</b>	: Actual length of the instrument
<b>RLI</b>	: Radiographic length of instrument
<b>RLT</b>	: Radiographic length of tooth
<b>AC</b>	: Alternating current
<b>ANN</b>	: Artificial neural network
<b>RVG</b>	: Radiovisiography
<b>SNOSE</b>	: Sequentially numbered opaque sealed envelopes
<b>MATLAB</b>	: MATrix LABoratory
<b>n</b>	: number
<b>ml</b>	: milli litre

<b>ISO</b>	: International Organization for Standardization
<b>NaOCl</b>	: Sodium hypochlorite
<b>EDTA</b>	: Ethylene di- amine tetra acetic acid
<b>GP</b>	: Gutta percha
<b>PDL</b>	: Periodontal ligament
<b>NiTi</b>	: Nickel-Titanium
<b><i>p</i>- value</b>	: Probability value
<b>i.e</b>	: that is
<b>+</b>	: plus
<b>–</b>	: minus
<b>-</b>	: hyphen
<b>%</b>	: percentage
<b>kΩ</b>	: kilo ohms
<b>&amp;</b>	: and
<b>/</b>	: or
<b>θ</b>	: theta
<b>&gt;</b>	: more than
<b>&lt;</b>	: less than
<b>=</b>	: equal to

# ***INTRODUCTION***

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## **INTRODUCTION**

The main goal in root canal treatment is to reduce intra radicular microorganisms to a level below that is necessary to induce apical periodontitis (1). An essential prerequisite is establishment of correct working length during root canal preparation and failure to do so can result in accidental extrusion of irrigant, dressing or filling and persistent periapical inflammation and postoperative pain (2).

The working length (WL) can be defined as the distance between a coronal reference point and the point at which canal preparation and obturation should terminate (3). Maintaining a correct WL during RCT can positively influence the outcome of RCT and it prevents postoperative pain. Therefore, working length should be measured as precisely as possible (4). The apical constriction is accepted as the physiological apical limit for ending endodontic instrumentation and obturation. The apical constriction is defined as a minor diameter, represents the histologic point of transition between the pulpal and the periodontal tissue at the cemento-dentinal junction (5).

The significance of the working length are (6):

- The working length determines how far the instruments can be placed into the canal and worked.
- It affects the degree of pain and discomfort which patient will experience following over or under instrumentation.
- If placed within correct limits, it plays an important role in determining the success of treatment.
- When working length is short, it leads to apical leakage and continued existence of viable bacteria which contributes to periradicular lesion and thus poor success rate.



Traditional methods for determining working length are the knowledge of anatomy, tactile sensation, moisture on a paper point, and radiography. The most popular and common method has been the use of radiographs. The accuracy of radiographic methods of WL determination depends on the type of radiographic technique used. Sheaffer et al (7) revealed that higher density radiographs were better desirable for measuring working length. Tooth length determined by the bisecting angle technique correctly or incorrectly angulated was found to be less accurate than the paralleling technique.

One of the innovations in root canal treatment has been the development and production of electronic devices for detecting the canal terminus for WL determination. Main advantages of electronic apex locators (EALs) are that these measure the root canal length to apical foramen and not the radiographic apex. However, their clinical accuracy can be ascertained only with the verification radiograph for the fit of master cone. Nevertheless, they are easy to use, fast to operate, and have a good accuracy (8).

New imaging modalities have been also included in clinical practice. Cone-beam computed tomography (CBCT) represents an important technology recently introduced to dentistry. CBCT can be used to allow more accurate WL measurements, offering the advantage of this preexisting information (9).

In a stereomicroscopic study done by Kqikuand Stadtler, the electronically determined WL did not significantly differ from the radiographic working length determination. They concluded that the WL measured with EALs was within  $\pm 0.5$  mm of the apical foramen in 74.8% of cases and within  $\pm 0.5$  mm of the radiological control length in 90% of all the cases (10). The electronic apex locator and the cone-beam computed tomography found to be more accurate techniques to determine root canals working length than the normal and the 2D digital radiographs. According to de Morais,

working length determination using CBCT images was precise when compared to radiographic method and EAL (9).

## ***AIMS & OBJECTIVES***

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## **AIM AND OBJECTIVES**

The aim and objective of this study is to determine the clinical success of two working length determination techniques using Electronic apex locator (Root ZX mini) and Radiographic method.

# ***REVIEW OF LITERATURE***

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## REVIEW OF LITERATURE

Manual working length determination – **tactile method** (11) is an age-old method. The experienced clinician develops a keen tactile sense from passing an instrument through the canal. Accuracy in tactile working length determination requires a learning curve and may vary depending on operator tactile perception as well as the morphology of the root canal system.

**Audiometric Method** (12): It is based on the principle of electrical resistance of comparative tissue using a low frequency oscillation sound to indicate when similarity to electrical resistance has occurred by a similar sound response. By placing an instrument in the gingival sulcus and including an electric current until sound is produced and then repeating this by placing an instrument through the root canal until the same sound is heard, one can determine the length of the tooth.

**Paper Point Evaluation Method** (13): The paper point may be used to detect bleeding or apical moisture. A bloody or moist tip suggests an over extended preparation. Further assessment of the apical preparation and working length should be made. The point of wetness often given an approximate location to the actual canal end point. A wet or bloody point may also indicate that the foramen has been zipped or the apex perforated during preparation. These conditions would require additional canal shaping in addition to adjustment of working length. This method was found to be suitable for estimating the location of AF in relatively straight patent canals, because its performance was similar to current clinically acceptable standards of estimating AF location.

In 1896, Dr. Charles Edmund Kells introduced the **application of X-rays in dentistry**. During 19th century, WL was calculated by keeping an instrument in the canal and the point where the patient felt pain was recorded. **Radiographs came about in 1899** in dentistry.

In 1901, Dr. Weston A Price called attention to incomplete root canal fillings as evidenced in radiographs and suggested that radiographs should be used to check the accuracy of root canal fillings.

In 1900's the opinion was that dental pulp extended through the tooth and end at the apical foramen and that the narrowest diameter of the apical portion of the root was precisely at the site where the canal exits the tooth at the apex.

In the 1920's study of the apex of the tooth led Grove, Hatton, Blayney and Coolidge contradicted this position and offered information that filling slightly short of the root tip gave the best results (14).

A radiograph is a two dimensional image of a 3-dimensional object (15).

This method has many advantages: direct observation of the anatomy of the root canal system, the number and curvature of roots, the presence/absence of disease, as an initial guide for WL estimation. There are a number of limitations associated with it lack of 3-D dimensional representation, image distortion and subjectivity, the danger of ionizing radiation, and errors of superimposition. Tooth length determined by the bisecting angle technique, correctly or incorrectly angulated, was less accurate than the paralleling technique. Even when a paralleling technique is used, elongation of images has been found to be approximately 5%. Although it is accepted that the minor apical foramen and apical constriction is on an average located 0.5-1.0 mm short of the radiographic apex (16) there are wide variations in the relationship of these landmarks that would

result in under or over preparation of canals with an impact on the position of the root filling. Thus, a WL 1 mm short of the radiographic apex may result in over or under instrumentation and this 'rule' is not predictable or reliable (8).

**Bregman's Method** in 1950: In this method, 25 mm length flat probes are prepared and has a steel blade fixed with acrylic resin acting like a stop leaving a free end of 10 mm for its placement into the root canal. This probe is place in the tooth until the metallic end touches the incisal edge/cusp tip of the tooth. Then a radiograph is taken. In the radiographic image the following is measured (14).

ALT-Apparent length of the tooth (as seen in the radiograph)

RLI-Real length of the instrument

ALI-Apparent length of the instrument

Now RLT (Real length of the tooth) is calculated from the formula:

$$RLT = ALI \times ALT / RLI$$

In 1955 **Kuttler** studied on the microscopic anatomy of the root tip. According to Kuttler, the narrowest diameter is definitely not at the site of exit of the canal from the tooth but occurs within the dentin, just prior to the initial layers of cementum. He referred to this position as the 'minor diameter' of the canal (apical constriction) (14). He studied several thousand teeth. Not everyone embraced his ideas initially but over the past 40 years his ideas are still practiced. In individuals between the age group of 18- 25 years, the average distance between the minor and major diameters was 0.524 mm. In older individuals the average distance was 0.659 mm. Therefore



Kuttler felt that it was not necessary to fill to the radiographic apex as it caused postoperative pain thereby lowering the success rate. Many studies have supported Kuttler's findings (6).

In 1957, **Ingle** used the pre-operative radiograph in a mathematical procedure for determining working length (14).

Step by step procedure for Ingles method(6) :

- i. Measure the tooth length on the pre-operative radiograph
- ii. Subtract 1 mm "safety allowance" for possible image distortion or magnification.
- iii. Set the instrument at this tentative working length
- iv. Place the instrument in the canal until the stop and in case the instrument is left at that level and the rubber stop re-adjusted to this new point of reference.
- v. From the radiograph, measure the difference between the end of the instrument and the end of the root and add this to original measured length; if the instrument has extended beyond the apex subtract the difference.
- vi. From this adjusted length, subtract t 1 mm "Safety factor" to conform the instrument within the apical termination -CDJ.
- vii. Set the endodontic ruler at corrected length and readjust the stop on the exploring instrument.
- viii. A confirmatory radiograph of the adjusted WL is desirable because of any possible radiographic distortion, curved roots and operator measuring errors.

In 1960 **BEST** described a technique for determining the working length. In this, a steel pin measuring 10 mm is fixed to the labial surface of the root with utility wax. Keeping the pin parallel to the long axis of the tooth, a radiograph is obtained. The radiograph is then carried to a gauge, which would indicate the tooth length (14).

Everett & Fixott in 1963 (6) designed a diagnostic X-ray grid system for determining tooth length. The **diagnostic X-ray grid** designed consists of lines 1 mm apart running lengthwise and cross-wise. A heavier line to make the reading easier on the radiograph accentuates every fifth millimeter. Enameled copper wires are placed in plexi-glass fixed to a regular periapical film. The grid is taped to film between the tooth and film during exposure so that the pattern becomes incorporated in the finished film. The incorporated grid is used for accurate measurement of working length. According to a recent study (17), preoperative metrics with radiographic grid along with apex locator is a better WL measuring tool compared to the conventional radiographic WL in single-rooted teeth, thus preventing a confirmation radiograph at final WL and can be useful in patients who need not to be exposed to repeated radiation because of mental, medical, or oral conditions

In 1970, **Grossman's Method** (18) - The diagnostic radiograph is used to estimate the working length of the tooth from occlusal to the root apex. This length is then verified by placing instruments to the estimated working length and taking an instrumentation radiograph. The exact working length is determined by adjusting the length of insertion so that the tip of the instrument ends 0.5mm from the root apex.

Initially the diagnostic file (usually no. 10-20 K file) that fits into the root canal is inserted through canal with a slight wiggling motion to bypass any obstruction and then along the estimated working

length of the canal. A radiograph is taken to compare the exact position of the instrument with the measure depth of insertion. If needed, the measured length is adjusted so that the instrument tip is inserted up to 0.5 mm from the apical end to the reference point. If the K-file is 1 mm longer or shorter of the radiographic foramen, one should add or subtract the necessary length but if the differences are greater than 1 mm, one should make necessary adjustments on the file and take another radiograph. By measuring the length of radiographic images of both the tooth and the measuring instruments as well as the actual length of the instrument, the clinician can now determine the actual length of the tooth by a formula.

$$\text{Actual length of tooth} = \text{ALI} \times \text{RLT} / \text{RLI}$$

ALT -Actual length of tooth

ALI -Actual length of instrument

RLT -Radiographic length of tooth

RLI -Radiographic length of instrument

**Bramante's method** in 1974: He employed stainless steel probes of various calibers& lengths. These were bent at one end at right angle and is inserted partially in acrylic resin in such a manner that its internal surface is in flush with the resin surface contacting the tooth surface. The probe is introduced into the root canal so that the resin touches the incisal edge or cusp tip. The bent segment of the probe would be parallel to the mesio-distal diameters of the crown and thus making it possible to visualize it on the radiograph. Then the tooth is radiographed(14). A formula similar to Bregman's and Grossman's methods is followed to calculate the length.

**Xeroradiography (6)** was first used to produce dental images by Poyorzelska-Stonezak in 1963, The technique involves the exposure of a charged selenium alloy plate contained in a light-proof cassette. The incident X-rays discharge the electrostatic charge on the plate to produce a latent image composed of residual charged areas. This image is processed by the introduction of charged, pigmented particles over the surface of the plate, A concentration of particles is found at the interface of areas of highly differing charge. This phenomenon, known as edge enhancement, is responsible for the improvement of the imaging of fine detail and line structures. A permanent image is produced on opaque paper which can be viewed with reflected or transmitted light,

It has been stated that although there is no diagnostic difference between Xero-radiography and conventional radiography in determining the actual length of root canals, Xero-radiographic images of the file for determining length are sharper and can be measured faster. These might be useful in detecting carious lesions, especially proximal surface caries of adult and primary teeth.

According to Macro in 1984, Xeroradiography gave closer to accurate results in measurement compared to conventional radiographs (19).

**Apex Finder (6):** M.M.Negm in 1982 introduced a novel method of determining the length of root canal without the use of radiographs. The new instrument apex finder is used to locate the apex as well as measuring the root length. The application of this method is based on insertion of a fine plastic tapered bared shaft through a beveled tube into the root canal. When resistance to withdrawal is felt which indicates that some barbs have engaged the apical margin, the shaft is marked at the level of the cusp tip. The distance between the mark and the barbs, which caused the resistance, is measured.

**Radiovisiography** is a new imaging system invented by Mouyen et al. 1989 (20), Transmitted X-ray photons are received by a fluorescent screen in an intra-oral sensor. The light emitted from the screen is received via a fibre-optic connector, by a Charged Coupled Device (equivalent to a video camera). The resulting electrical signal is transmitted to the image-processing unit. An analogue-to-digital converter and computer convert the signal to a digitized image which is stored and may be displayed on a television monitor almost instantaneously. The image is displayed on a high resolution screen (625 lines, 500 dots) with a grey scale range of 256, This screen image is magnified to give a 70 x 90 mm display on the screen. There is also facility for viewing a small region at X 8 magnification, although at present a farther exposure is required to achieve this. A hard copy of the image may be obtained in black-and-white photographic form as either a positive (radiodense areas appearing white) or a negative (radiolucent areas appearing black) image. Based on many studies, the accuracy of digital and conventional radiography techniques were similar in determination of WL. Digital radiography confers advantages for patients and dentist compared with conventional radiography, and it is proposed as a more effective method for the endodontic WL determination.

### **Electronic Apex Locators.**

The term “apex locator” is commonly used and has become accepted terminology, it is a misnomer. Some authors have used other terms to be more precise such as Electronic Root Canal Length Measuring Instruments or Electronic Canal Length Measuring Devices. Electronic apex locators have been used clinically for more than 40 years as an aid to determine the file position in the canal. The apex of the root has a specific resistance to electric current which is measured using a pair of electrodes i.e. endodontic file & lip clip. These devices, when connected to a file, are able to detect the point at which the file leaves the tooth and enters the periodontium.

An electronic method for root length determination was first investigated by Custer in 1918 (21). The idea was revisited by Suzuki in 1942 who studied the flow of direct current through the teeth of dogs. He registered consistent values in electrical resistance between an instrument in a root canal and an electrode on the oral mucous membrane and speculated that this would measure the canal length. . The principles of EAL can be explained by Ohm's law (9). Ohm's law is expressed as  $\text{voltage}/\text{current} = \text{resistance}$ . Ohm's law is changed to  $\text{voltage}/\text{current} = \text{impedance}$ , in AC.

Sunada in 1962 took these principles and constructed a simple device that used direct current to measure the canal length which work on the principle that the electrical resistance of the mucous membrane and the periodontium registered  $6.0 \text{ k}\Omega$  in any part of the periodontium regardless of the person's age or the shape and type of teeth.

In 1960 Gordon was the second to report the use of a clinical device for electrical measurement of root canal. Inoue made significant contribution to the evolution of apex locators in North America with his reports on the Sono Explorer in 1970.

Later, frequency measurements were taken through the feedback of an oscillator loop by calibration at periodontal pocket depth of each tooth. **A third generation EALs developed in late 1980s by Kobayashi;** he used multiple channel impedance ratio based technology to simultaneously measure the impedance of two different frequencies.

Mode of action of EALs: Mode of action: EALs functions by using the human body to complete an electrical circuit. One side of the apex locator's circuit subsequently connected to the oral mucosa through a lip clip and the other side to a file. When the file is placed into the root canal

and advanced apically until its tip touches periodontal tissue at the apex, the electrical circuit is completed. The electrical resistance of the EALs and the resistance between the file and oral mucosa are now equal, which results in the device indicating that the apex has been reached. When a circuit is complete (tissue is contacted by the tip of the file), resistance decreases markedly and current suddenly begins to flow. Depending upon the devices, this sudden current flow signaled by a beep, a buzzer, digital readout, flashing light or pointer on screen display. The electrical characteristic of the tooth structure are measured and exact position of the instrument in the tooth is determined (22).

First Generation Electronic Apex Locators - Resistance Type (23): These are also known as Resistance Based Apex Locator, measures opposition to the flow of direct current or resistance. These devices were found to be unreliable when compared with radiographs, with many of the readings being significantly longer or shorter than the accepted working length. The Root Canal Meter (Onuki medical Co. Japan) was developed in 1969. It used the resistance method and alternating current of 150 Hz sine wave. Pain was often felt due to high current in the Endodontic Meter and the Endodontic Meter S II (Onuki medical Co. Japan) which used a current of less than 5  $\mu$ m. Other devices in the first generation include the Dentometer (Dahin Electro medicine, Denmark) and the Endo Radar (Electronica Liarre, Italy). It was not as popular as it gave inaccurate readings in wet canals, obstructed canals, in carious/ defective restorations, in case of perforations and in patients with cardiac pacemakers. Also when the instruments came in contact with metallic restorations, false readings were observed.

Second Generation Electronic Apex Locators -Impedance Type (24): Second generation apex locators are impedance type operates on the principle that there is electrical impedance across the wall of the root canal due to the presence of transparent dentin. The tooth exhibits increase in

electrical impedance across the walls of the root canal, which is greater apically than coronally. At the cemento-dentinal junction the level of impedance drops dramatically.

The change in frequency method of measurement of root canal was developed by Inoue in 1971 as the Sono-Explorer (Hayashi Dental Supply, Japan) which calibrated at the periodontal pocket of each tooth and measure the feedback of the oscillator loop. A later method, the Sono-Explorer M-III uses a meter to indicate distance to apex. With an electrode connected to the dental chair and a sheath over the probe it was able to make measurements in canals. A major disadvantage of these devices was that of electro-conductive materials gives inaccurate readings. The root canal has to be free of electro-conductive materials to obtain accurate reading. Also they required calibration and complicated calculations, required coated probes instead of normal endodontic instrument, no digital readout was present and it was very difficult to operate (10). The sheath caused problems because it would not enter narrow canals, could be rubbed off and was affected by autoclaving.

Third Generation Electronic Apex Locators -Frequency dependent comparative impedance Type ( 22 ): Third generation EALs are similar to the 2nd generation EALs except that they use multiple frequencies to determine the distance from the end of the canal. These units have more powerful microprocessors and are able to process the mathematical quotient and algorithm calculation required to give accurate readings. Since the impedance of given circuit may be substantially influenced by the frequency and the current flow, these devices have been called “Frequency Dependent” In Europe and Asia, this device is available as the Apit or Endex/Apit –Endex (Osada, Japan) . The device operates most accurately when the canal is filled with electrolyte such as saline or sodium hypochlorite. The disadvantage of this device needs “reset” or “calibrated” for each canal. The Root ZX (J. Morita Japan) is a 3rd generation EAL that uses dual-frequency and



comparative impedance principle, was described by Kobayashi. The electronic method employed was the “ratio method.” It simultaneously measures two impedances at two frequencies (8 kHz and 0.4 kHz) inside the canal. The Root ZX mainly detects the change in electrical capacitance that occurs near the AC. The advantages of the Root ZX are that it requires no adjustment or calibration and can be used when the canal is filled with strong electrolyte or when the canal is “empty” and moist.

Fourth Generation Electronic Apex Locators -Ratio Type (25): The observation that the ratio between two electrical impedances (oral mucosa and periapical tissue) decreases, as the file tip approaches the apical foramen, led to the development of the ratio method for WL determination. Ratio Type apex locators which determine the impedance at five frequencies and have built in electronic pulp tester. These devices not process the impedance information as a mathematical algorithm, but instead take the resistance and capacitance measurement and compare them with a database to determine the distance to the apex of the root canal. They are marketed by Sybron Endo and include the AFA Apex Finder and Elements Diagnostic Unit; also ROOT ZX II and PROPEX II come under this category. It uses a composite wave form of two signals, 0.5 and 4 kHz, the signals go through a digital to analogue converter into an analogue signal, which then goes through amplification and then to the patient circuit model. A significant disadvantage of the fourth generation devices is that they need to perform in relatively dry or in partially dried canals. In some cases, this necessitates additional drying. Also in heavy exudates or blood it becomes inapplicable.

Fifth Generation Electronic Apex Locators - Dual Frequency Ratio Type (26): To cope with problems associated with previous generations of apex locators a new measuring method has been developed based on comparison of the data taken from the electrical characteristic of the canal and

additional mathematical processing. And so the fifth generation apex locators (Dual Frequency Ratio Type) are now being used. 5th generation apex locators was developed in 2003 as E-magic Finder series. It measures the capacitance and resistance of the circuit separately. It is supplied by diagnostic table that includes statistic of the file. They have best accuracy in any root canal condition (dry, wet, bleeding, saline, EDTA, NaOCl). Devices employing this method experience considerable difficulties while operating in dry canals. During clinical work it is noticed that the accuracy of electronic root canal length measurement varies with the pulp and periapical condition. The device provides with a digital read out, graphic illustration and an audible signal. The built in pulp tester can be used to access tooth vitality.

Sixth Generation Electronic Apex Locators -Adaptive Apex Locators (27): The efficacy of 6th generation EALs in long term use yet to be established. A major advantage of adaptive apex locator is eliminating necessity of drying and moistening of the canal. Adaptive apex locators continuously define humidity of the canal and immediately adapts to dry or wet canal. This way it is possible to be used in dry or wet canals, canals with blood or exudates. Clinical observations are yet to come that will help assess the device's ability to determine the working length of root canals under various clinical conditions and situations.

According to previous studies, conventional radiography yields an 82% precision, whereas in a study done by Olson et al, electronic measurement is closer to 95%. Comparison between the two techniques shows apex locators to be more accurate and more reliable than radiography for determining working length (28).

**CBCT:** Cone-beam computed tomographic (CBCT) imaging is an imaging system that is useful in providing reliable anatomic information in 3 dimensions for diagnosis and treatment planning

before endodontic therapy. A preexisting CBCT scan might be potentially used for preoperative estimation of the WL (29).

A prospective, controlled clinical study showed that limited CBCT imaging can be used for endodontic working length measurement with a precision similar to measurements done by EAL. The inter operator reliability for the CBCT measurements is high (28).

According to Elshinawy (30), EAL and the CBCT are more accurate techniques to determine root canal's working length than the normal and the 2D digital radiographs.

**ARTIFICIAL NEURAL NETWORK** (31): An artificial neural network (ANN) is a mathematical model inspired by the structure and/or functional aspects of biological neural networks in the brain. ANN is a decision-making system and helps the diagnostic procedure used for prediction of different elements from radiographs. ANNs are computer models with a massive parallel structure, which imitate the human brain. A digital radiograph was taken of the tooth, with an initial file placed at the estimated working length. The estimated working length was then rated visually. The radiographic image was then processed using the Otsu method (The Otsu method was used to automatically perform shape-based image thresholding histograms. This method can separate the teeth from the surrounding tissues based on differences in grey scales on radiographs) and K-means (K-means clustering separates the teeth and surrounding tissues by differences in their colour) to yield a high contrast image of the tooth, with surrounding structures deleted. This image processing removed any image of the working length file and gave an outline only of the tooth itself. The tooth length was then determined in MATLAB by counting pixels. Tooth length and approximate and detailed images were then fed into 'Perceptron' and the reliability of the working length measurement was then decided by this system. A simple three-layer neural network

can be trained to reliably identify the position of files in root canals with a noninvasive method. The subtracted pictures can help dentists categorize the location of the file tip in the root canal with minimum error. The subtracted data from additional radiographs are the best teacher for ANN in the training stage. The ANN diagnosis method can contribute to improving future diagnosis and leads to better outcomes in working length determination by radiography. In addition, ANN can act as a decision making system in various similar clinical situations.

***MATERIALS &  
METHODOLOGY***

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## MATERIALS AND METHODOLOGY

This Randomized Controlled Clinical Trial was approved by the Institutional Ethical Committee of Madha Dental College and Hospital. CONSORT guidelines were followed for the clinical study. Healthy adult patients from 18 - 75 age groups reporting to Department of Conservative Dentistry and Endodontics at Madha Dental College and Hospital for root canal treatment were recruited after patient information was given/readout and the informed consent was taken. Recruitment was started in the month of February 2018 and follow was completed in January 2019. Following Inclusion and Exclusion criteria were followed for recruiting such cases:

### **INCLUSION CRITERIA:**

- Permanent teeth
- Teeth requiring conventional root canal treatment

### **EXCLUSION CRITERIA:**

- Primary teeth
- Patients less than 18 and more than 75 years of age.
- Teeth not indicated for RCT
- Pregnant women
- Teeth with open apex
- Patients with medical history of any systemic conditions/allergies/recent history of any surgeries and under medications for the same.

**SAMPLE SIZE CALCULATION:**

Calculation of the sample size by setting the power of the study to 90%, standard deviation of the outcome to 1mm based on previous studies and minimum detectable difference to 0.5mm gave a minimum number of 172 canals for this two treatment parallel – design study. At the end of the study, a total of 83 teeth (from 64 patients) with 208 canals were included in the study to compensate for the dropout rate of 20% (32). The allocation ratio was to be maintained between 1:1 and 1:1.2.

**MATERIALS:**

- Root ZX mini EAL-4<sup>th</sup> generation ( J. Morita Co, Tustin, CA)
- X-ray unit (TECHNOMAC)
- EZDENT RVG unit and software
- Custom made tube positioner (for molars, premolars, anteriors)
- High speed hand piece and diamond abrasive points
- Hand ProTapers (DENTSPLY)
- Barbed broaches (MANI)
- ProTaper gutta percha points and 2% gutta percha points (DENTSPLY)
- Hand files- (DENTSPLY K-FILES)
- Sodium hypochlorite 2.5% (Prime Dental Products)
- 17% EDTA solution (DE SMEAR)
- R C Help (Prime Dental Products)
- Saline (eurolife)
- Temporary restorative material- zinc oxide eugenol powder and liquid

- UNOLOK single use syringe
- Absorptive paper points (DENTSPLY)
- DENTSPLY Endo Bloc

### **PILOT STUDY:**

A pilot study was performed to design the customized X-ray positioners. Natural teeth were mounted in wax and upper and lower wax models in arch form were obtained. Total length of each teeth were measured and noted separately. Then different radiographs were taken in combinations of various object-cone distance (0 cm, 10 cm, and 20 cm) and object- sensor distance (0 cm, 1 cm, 2.5 cm) for each type of teeth in their respective horizontal angulations. Then the accuracy of each radiograph was compared with the actual tooth length previously measured. The most accurate combination was chosen for the study and the customized positioners were fabricated using stainless steel wire and heat cure acrylic accordingly. For incisors and molars, suitable object cone distance was 20 cm whereas for premolars it was 10cm. The object sensor distance for all type of teeth was 0 or sensor should be kept as close to the object as possible.



Fig 1: Pilot study model



Schematic representation of tube-object distance using customized tube positioner are shown in

Figure 2-7.

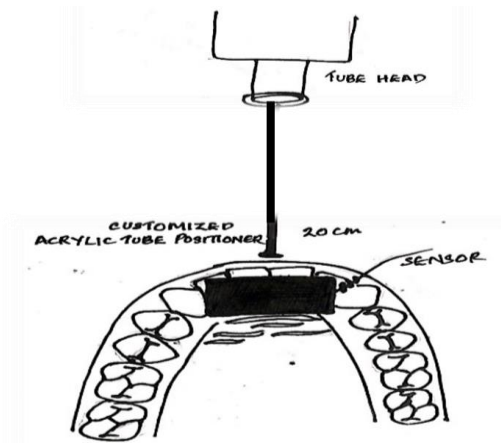


Fig 2: For upper anteriors

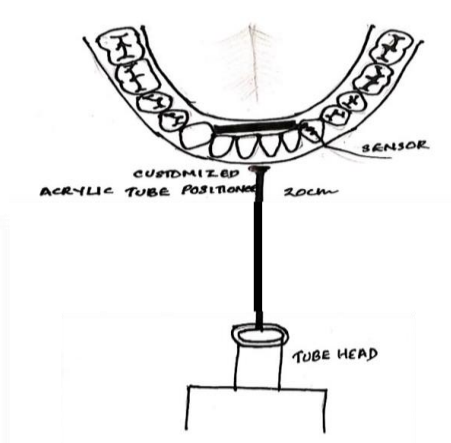


Fig 3: For lower anteriors

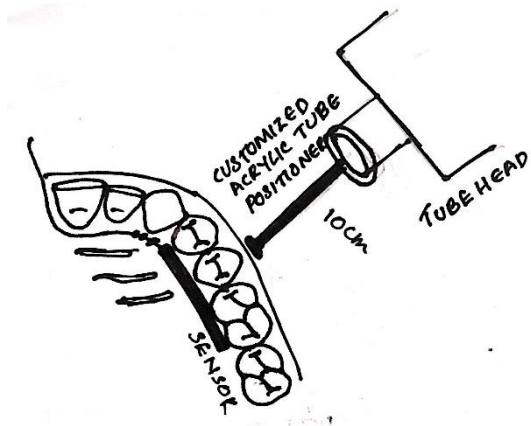


Fig 4: For upper premolars

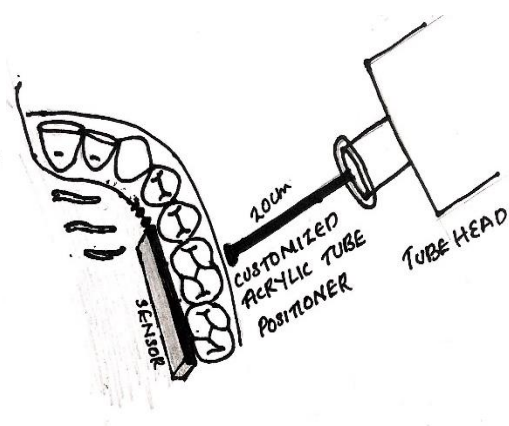


Fig 5: For upper molars

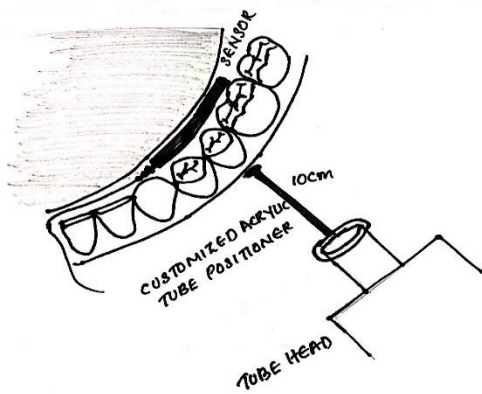


Fig 6: For lower premolars

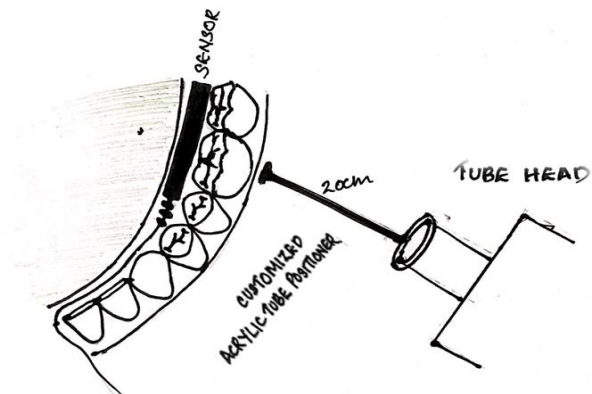


Fig 7: For lower molars

### RANDOMIZATION TECHNIQUE:

Block (anterior, premolar, upper molar and lower molar) randomization method using 'Table of Random Numbers' was followed for this study. Random numbers were generated by the research guide. Enrolling and assignment of the participants were done by the research student. Outcome assessment was done by the research guide.

**ALLOCATION CONCEALMENT:** Sequentially numbered opaque sealed envelopes (SNOSE) were used for allocation concealment for each block (category and ) - anterior, premolars, upper molars and lower molars and in each block, envelopes were numbered from 1-40.

**BLINDING:** Double blinded study (patient and outcome evaluator were blinded).

**METHODOLOGY:** 87 teeth were recruited of which 4 were excluded (Table 1). 83 teeth (from 64 patients) were then included in this study requiring conventional root canal treatment. These teeth were randomly divided into

Group A: n= 115 Electronic apex locator group (EAL) using ROOT ZX mini.

Group B: n=93 digital radiographic group (RVG)

A pre-operative periapical radiograph was taken using bisecting angle technique using customized tube positioners.

EXCLUDED TEETH	REASONS
16(Group A)	Instrument fracture
36(Group B)	Patient did not turn up for appointment
36(Group B)	Perforation
26(Group B)	Patient did not turn up for appointment

Table 1. Teeth excluded and reasons

## PROCEDURE:

### 1. LOCAL ANESTHESIA:

The patients received local anesthesia - 2% lidocaine with 1: 80,000 epinephrine

Maxillary anterior: supra periosteal infiltration (1 ml) and nasopalatine nerve block (0.5ml)

Maxillary posteriors: supra periosteal infiltration (1 ml) and greater palatine nerve block (0.4ml)

Mandibular anterior: Inferior alveolar nerve block (1.6ml)

Mandibular posteriors: Inferior alveolar nerve block (1.6ml) and long buccal nerve block (1ml)

Supplementary injections like Intra-ligamentary anesthesia (0.3ml) or Intra pulpal anesthesia (0.5 ml) were given if the above mentioned techniques failed to achieve the required anesthetic effect.

2. **ISOLATION:** All teeth were isolated with rubber dam.
3. **ACCESS CAVITY PREPARATIONS:** Caries removal and the initial access form were accomplished with Endo Access bur no: 2. The cavity access preparation was completed, pulp tissue was removed with the help of barbed broaches, and the canal orifices were localized. The canal patency was determined with a sterile stainless steel K-file (size #10 ISO). The coronal part of each canal was flared with an SX ProTaper file and then each canal was irrigated with 2.5% NaOCl solution using 26 gauge needle. Afterward, patients were randomly assigned to 1 of 2 groups according to the method used for working length determination, electronic apex locator group and the radiographic group.

4. **WORKING LENGTH:**

Working length determination was carried out using an apex locator -Root ZX mini (Fig 8) in the group A and measured as 0.5 mm from the apex locator 'zero' reading.



Fig 8: Root ZX mini EAL

In group B, pre-operative radiographs taken were used for measuring the working length. In radiographic method, we have followed the digital radiographic method. Only one preoperative radiograph was taken for both the groups. WL radiograph is not taken for the radiographic group separately.

Measurements are calculated using the pre-operative radiograph following the Laws of Symmetric triangles in trigonometry (Fig 9).

Actual length of the tooth =  $\cos \theta \times$  Hypotenuse (Radiographic length of the tooth)

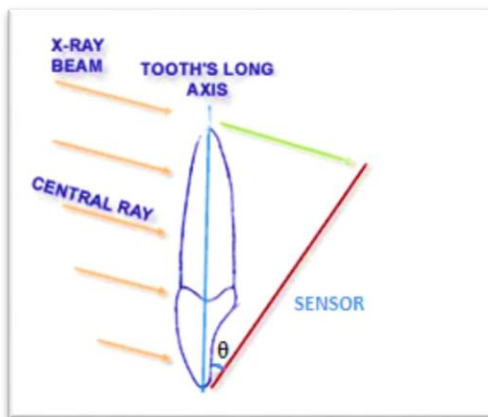


Fig 9: Measurement calculation using Laws of Symmetric triangles in trigonometry

## 5. CLEANING AND SHAPING:

- a. Chemo mechanical preparation was performed with Hand ProTapers/K files instruments for posteriors/anterior respectively. Instruments were used in a crown-down manner by using a gentle in-and-out motion. For posteriors, ProTaper S1 and S2 instruments were used to the working length; then F1 (for premolars, mesial canals of maxillary and mandibular molars), F2 (distal canals of maxillary and mandibular molars) and F3 (for palatal canal) were used to the full instrumentation

length. For anterior, depending on the initial apical file size, apical preparation was completed with 3 sizes up from the first file to bind at the apex. After each instrument change, 1 mL of 2.5% NaOCl and saline was used as irrigant. For final irrigation, 2 ml of 2.5% sodium hypochlorite, 2 ml of saline and 1 ml of 17% EDTA solutions were used.

- b. Number of visits: Barring 3 anterior which presented with vital pulp and no periodontal widening, all other teeth were treated in two visit procedure with 2-5 days interval between the visits.
- c. Closed dressing:
  - i. Inter appointment closed dressing material: Zinc oxide eugenol temporary restorative material. Teeth with any lesion or apical periodontitis were medicated with calcium hydroxide for 2-5 days.
  - ii. After 2-5 days, patients were recalled, dressing and medicament were removed. A master cone gutta percha was measured to the working length determined by each method and inserted into the root canal, and a 'master cone' radiograph was taken for all teeth in both groups. Differences were noted down and adjustments were done in all to ensure that the cone is 0.5mm short of apex.

## **6. OBTURATION:**

Obturation was completed by the cold lateral compaction technique for anterior and single cone obturation technique for posteriors using gutta percha and a zinc oxide-eugenol sealer.

This was followed by post-obturation radiographs for both groups.

**ASSESSMENT OF OUTCOMES:**

The distance between the master cone and the radiographic apex was measured in millimeters ( $\pm 0.05\text{mm}$ ) and recorded. The master cone GP was then adjusted accordingly and the quantum of adjustments were noted down for each canal (nil/0; addition/+; subtraction/-).

**OUTCOME MEASURES:**

The acceptability of the master cone GP, as defined above, was used as the primary outcome. Postoperative radiograph taken after obturation was used as the secondary outcome similar to the primary. Patients were recalled for 3 months follow up and clinical and radiographic healing were assessed. This was considered as the tertiary outcome.

Parameters for radiographic healing at three months follow up:

- PDL space widening as measured using the EZ DENT RVG software measuring tool was noted for each canal/root for all the teeth.
- Presence/absence of any radiolucency was noted
- The size of the radiolucency as measured using the RVG software was noted.

Parameters for clinical healing at three months follow up:

- Presence or absence of pain/discomfort
- Presence or absence of swelling in relation to the treated tooth
- Presence or absence of tenderness on palpation and percussion
- Presence or absence of sinus tract/discharge in relation to the treated tooth

# ***STATISTICAL ANALYSIS***

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## STATISTICAL ANALYSIS

To analyze the results, following tests were performed:

- Chi square test
- Mann-Whitney  $U$  test

The level of statistical significance was set at  $p < 0.05$ .

## ***RESULTS***

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## RESULTS

**Table 2: Demographic Data**

	<b>GROUP A</b>	<b>GROUP B</b>
<b>Age :</b>		
18-25	15	12
26-40	12	6
41-55	5	12
56-75	2	0
<b>Gender :</b>		
Male	24	18
Female	10	12
<b>Teeth type:</b>		
Anteriors	11	8
Premolars	10	9
Upper molars	13	12
Lower molars	12	8

**Table 3: Recruitment and Outcome Details**

<b>Total recruitment ( n=208 canals)</b>	<b>Primary outcome</b>	<b>Secondary outcome</b>	<b>Tertiary outcome</b>
<b>Group A (n=115)</b>	115	115	81
<b>Group B (n=93)</b>	93	93	70

## 1. PRIMARY OUTCOME:

**GROUP A:** ( n= 115 )Electronic apex locator group (EAL) using ROOT ZX mini.

- “+” ADJUSTMENTS (Under extension)
  - TOTAL = 38
  - AVERAGE= 1.1659mm
  - FREQUENCY= 33.04%

" + " ADJUSTMENT VALUES:
0.23
0.82
1
1.07
0.5
1
0.5
0.5
1
0.83
1
1
1.52
1.25
0.5
0.5
0.5
3
2
1
0.5
1.16
1.16
1.09
0.84
2.53
1.5
1.5
1.5
0.84
1.5
1.34
0.7
1.75
1.75
1.47
1.88
1.75

**MEAN = 1.1659**

- **“-” ADJUSTMENTS (Over Extension)**

- TOTAL = 6
- AVERAGE = -0.4983mm
- FREQUENCY = 5.21%

<b>" - " ADJUSTMENT VALUES:</b>
-0.09
-0.05
-0.05
-1.8
-0.5
-0.5
<b>MEAN = - 0.4983</b>

- **“0” ADJUSTMENTS (Accurate Extension)**

- TOTAL = 71
- FREQUENCY = 61.73%

**GROUP B:** (n=93) Digital radiographic group

- “+” ADJUSTMENTS (Under Extension)
  - TOTAL= 42
  - AVERAGE= 1.796
  - FREQUENCY= 45.16%

" + " ADJUSTMENT VALUES:
2.27
1
3.6
1.6
1.54
1.5
2.77
0.5
3.04
2.4
2.4
0.5
1.74
1
1
0.5
2.1
1.9
1.9
1.52
1.5
1.5
3.3
3.3
4
4
2.9
3.2
0.4
2
1.1
2.4
1
1.6
0.5
1.63
1.63
0.5
0.5
1.1
1.1
1.5
MEAN= 1.796

- **“-” ADJUSTMENTS (Over Extension)**

- TOTAL = 20
- AVERAGE = -0.749mm
- FREQUENCY = 21.5%

<b>" - " ADJUSTMENT VALUES:</b>
-0.23
-0.6
-0.5
-0.94
-0.5
-2.5
-1.63
-0.5
-0.21
-1.3
-0.5
-0.5
-1.75
-0.4
-1
-0.21
-0.21
-0.5
-0.5
-0.5
<b>MEAN = -0.749</b>

- **“0” ADJUSTMENTS (Accurate Extension)**

- TOTAL = 31
- FREQUENCY = 33.33%



**Table 4: Frequencies Of Adjustments Among The Two Groups**

GROUP A:

		adjustments <sup>a</sup>			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.0	49	52.7	52.7	52.7
	2.0	38	40.9	40.9	93.5
	3.0	6	6.5	6.5	100.0
Total		93	100.0	100.0	

a. groups = 1.0

GROUP B:

		adjustments <sup>a</sup>			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.0	29	31.2	31.2	31.2
	2.0	44	47.3	47.3	78.5
	3.0	20	21.5	21.5	100.0
Total		93	100.0	100.0	

a. groups = 2.0

**Table 5: Mean And Standard Deviation Of Adjustments Among The Two Groups**

GROUP A:

<b>Descriptive Statistics<sup>a</sup></b>					
	<b>N</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>Std. Deviation</b>
adujstments zero	49	.0	.0	.000	.0000
adjustments plus	38	.23	3.00	1.1705	.59222
adjustments minus	6	.05	1.80	.4983	.67277
Valid N (listwise)	0				

a. groups = 1.0

GROUP B:

<b>Descriptive Statistics<sup>a</sup></b>					
	<b>N</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>Std. Deviation</b>
adujstments zero	30	.0	.0	.000	.0000
adjustments plus	43	.00	4.00	1.7544	1.02872
adjustments minus	20	.21	2.50	.7490	.60820
Valid N (listwise)	0				

a. groups = 2.0

**Table 6: Comparison Between The Two Groups For The Adjustments:**

- Mann-Whitney U Test was run to compare the two groups for the three different types of adjustments.

Ranks				
	groups	N	Mean Rank	Sum of Ranks
adujstments zero	1.0	49	40.00	1960.00
	2.0	30	40.00	1200.00
	Total	79		
adjustments plus	1.0	38	33.32	1266.00
	2.0	43	47.79	2055.00
	Total	81		
adjustments minus	1.0	6	9.67	58.00
	2.0	20	14.65	293.00
	Total	26		

**Test Statistics<sup>a</sup>**

	adujstments zero	adjustments plus	adjustments minus
Mann-Whitney U	735.000	525.000	37.000
Wilcoxon W	1200.000	1266.000	58.000
Z	.000	-2.773	-1.442
Asymp. Sig. (2-tailed)	1.000	.006	.149
Exact Sig. [2*(1-tailed Sig.)]			.176 <sup>b</sup>

a. Grouping Variable: groups

b. Not corrected for ties.

- $p$  Value was found to be 0.006 for plus adjustment – indicating statistical significant difference among the groups at the plus adjustments

**Table 7: Comparison Between The Two Groups For The Adjustments:**

- Chi Squared Test - to compare the frequencies of the different adjustment among the two groups.

**Case Processing Summary**

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
groups * adjustments	186	100.0%	0	0.0%	186	100.0%

**groups \* adjustments Crosstabulation**

Count		Adjustments			Total
		1.0	2.0	3.0	
Groups	1.0	49	38	6	93
	2.0	29	44	20	93
Total		78	82	26	186

**Chi-Square Tests**

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	13.106 <sup>a</sup>	2	.001
Likelihood Ratio	13.578	2	.001
Linear-by-Linear Association	12.852	1	.000
N of Valid Cases	186		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 13.00.

Accuracy for fit of master cone as verified by the radiograph (0.5mm short of radiographic apex) was the primary outcome. The frequency of under extension was not statistically significantly different. Frequency of over extension and accurate fit was significantly different between 2 groups. When absolute values of under extension was analyzed, there was statistically significant difference among the 2 groups ( $p = 0.06$ ). However, there was no significant difference between the 2 groups for absolute values of over extension.

## 2. SECONDARY OUTCOME:

- Post obturation radiograph was taken for assessing secondary outcome. Adjusted WL was maintained.
- In 1 case from group A- EAL, tooth 12 showed root canal filling extending till the radiographic apex (Fig:10).



Fig 10. Radiograph of the tooth #12 post obturation

### 3. TERTIARY OUTCOME:

- All 64 patients were clinically asymptomatic.  
i.e No swelling/discomfort/discharge/pain/sinus tract
- Postoperative X rays after three months follow up were available for 45 patients i.e 59 teeth (151 canals).
- 13 teeth in Group A and 11 Teeth in Group B were not followed up radiographically as patients didn't want radiography to be done as their teeth were asymptomatic.

FOLLOW UP		
GROUPS	CANALS	TEETH
GROUP A	81	33
GROUP B	70	26

Table 8: Follow up

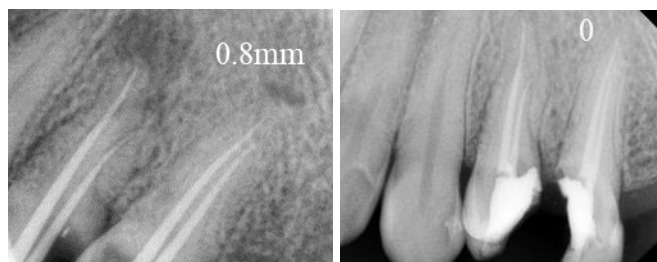
- 1tooth from EAL GROUP A – showed increased periapical radiolucency from <0.5mm to 1.6mm after 3 months follow up (Fig:11 a and b )



Fig 11 a: Post obturation radiograph of tooth#12    b: 3 months follow up

- Other 58 teeth showed periapical healing without any increase in PDL space widening/periapical radiolucency.
- Comparison of periapical lesion resolution in 12 teeth having pre-operative lesion at the time of obturation (a) and 3 months post-operatively (b) was done.

(Fig: 12 a and b Tooth #25)



(Fig: 13 a and b Tooth #25)



(Fig: 14 a and b Tooth #36)





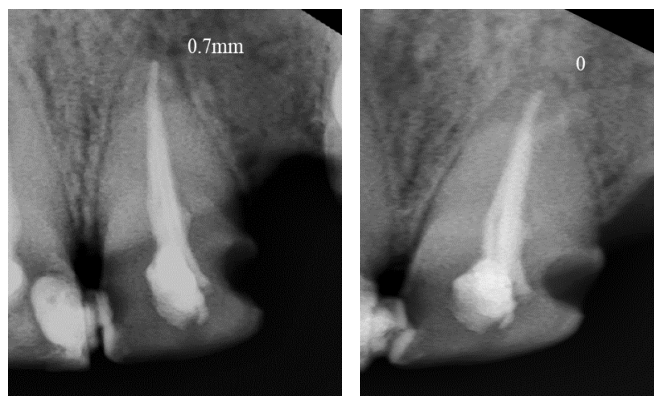
(Fig: 15 a and b Tooth #12)



(Fig: 16 a and b Tooth #47)



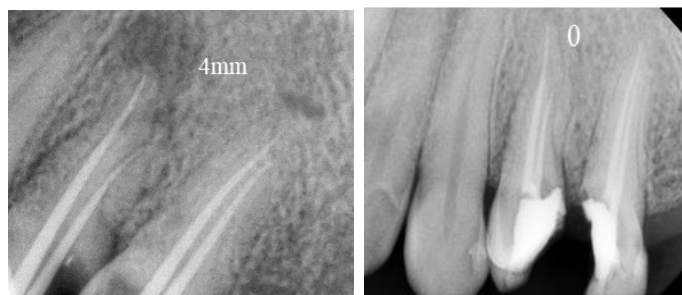
(Fig: 17 a and b Tooth #21)



(Fig: 18 a and b Tooth #11)



(Fig: 19 a and b Tooth #24)



(Fig: 20 a and b Tooth #14)



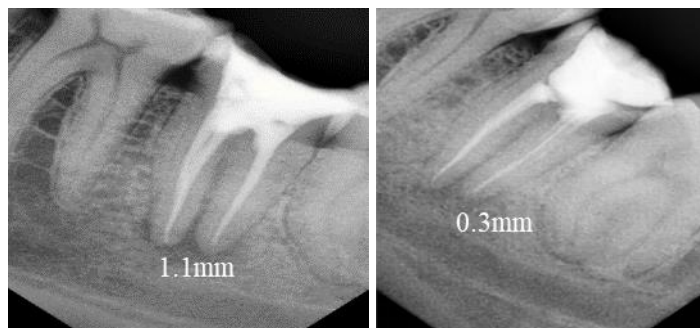
(Fig: 21 a and b Tooth #21)



(Fig: 22 a and b Tooth #37)



(Fig: 23 a and b Tooth #36)



<b>POST OPERATIVE RADIOGRAPHIC LESION RESOLUTION ANALYSIS</b>	
<b>GROUPS</b>	<b>CLINICAL PARAMETERS</b> <b>swelling/discomfort/discharge/pain/sinus tract</b>
<b>GROUP A</b>	7 teeth showed reduction in lesion when compared to pre-operative radiographs:
	1. 0.8mm reduced to 0 ( <b>Fig: 12a &amp; b</b> )
	2. >2mm reduced to 0.4mm ( <b>Fig: 13a &amp; b</b> )
	3. 1.2mm reduced to 0.3mm ( <b>Fig: 14a &amp; b</b> )
	4. 2.4mm reduced to 0.2mm ( <b>Fig:15a &amp; b</b> )
	5. 0.6mm reduced to 0 ( <b>Fig:16a &amp; b</b> )
	6. 0.7mm reduced to 0 ( <b>Fig:17a &amp; b</b> )
	7. 0.6mm to 0 ( <b>Fig: 18a &amp; b</b> )
<b>GROUP B</b>	5 teeth showed reduction in lesion when compared to pre-operative radiographs:
	1. 4mm reduced to 0 ( <b>Fig:19a &amp; b</b> )
	2. 0.6mm reduced to 0 ( <b>Fig:20a &amp; b</b> )
	3. 6.8mm reduced to 2.5mm ( <b>Fig:21a &amp; b</b> )
	4. 0.7mm reduced 0.2mm ( <b>Fig:22a &amp; b</b> )
	5. 1.1mm reduced to 0.3mm ( <b>Fig:23a &amp; b</b> )

Table 9: Post-operative radiographic lesion resolution analysis

There was no side effect or harm reported during the study.

## ***DISCUSSION***

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## DISCUSSION

Root ZX mini (J. Morita Corp., Tokyo, Japan), which is known to be one of the most reliable methods for determining WL, apex locator was employed to measure the electronic length of the root (33).

In a previous study done by Tuncer et al (34), effect of WL determination methods on post-operative pain was assessed between electronic apex locator (Root ZX) and digital radiography. Post-operative pain was assessed after 4, 6, 12, 24 and 48 hours using a 4-point pain intensity scale. Patients were also asked to record the number of days taken to achieve complete resolution of pain. This study concluded that no significant difference in post-operative pain was found between the 2 methods.

In another study by Jarad et al(35), ability of EAL( Ray-pex 5 ) as a tool in determining WL in comparison to traditional WL radiographs (taken using standardization holder EndoBite, Kerr US) was evaluated. The acceptability of master cone GP measured was used as the primary outcome. No significant difference was found in both the groups.

Similarly in a study done by Singh et al (36), effect of working length determination on the length adequacy of final WL using EAL (Raypex 5) and radiographic technique using a Rinn XCP holder. Length adequacy was assessed in each group for master cone and categorized into 'short' 'acceptable' and 'over' cases. Results showed that success of RayPex5 was comparable to the radiographic WL determination technique in terms of 'acceptable & short' cases. However there were significant lesser 'over' cases in EAL group showing that EAL can avoid the overestimation of WL.

In a study by Smadi et al (37), effect of WL determination using EAL alone or in combination with WL radiograph on the apical extent of root canal filling. Tri auto ZX – cordless hand piece with an integrated apex locator) is used for EAL group. Length of obturation was assessed and total number of radiographs were recorded. According to this study, no statistical difference of radiographic extent of root canal filling when using EAL alone or in combination with WL radiographs. It is suggested that correct use of EAL alone could prevent the need for further diagnostic radiographs for WL determination.

In a study by El Ayouti et al (38), consistency of EAL was determined by calculating the dysfunction frequency. 2 EAL used were: Root ZX and Raypex5. Different clinical parameters were recorded including tooth vitality, presence of obliteration and metallic restoration. Performance of EAL was considered ‘consistent’ when the scale bars were stable and moved only in correspondence with files in the root canal. A WL radiographs with files set to Electronic WL was performed. Acceptable: when file tip is 0-2 mm short of radiographic apex; long: beyond apex; short: >2mm short of radiographic apex. It was found that function of EAL was consistent in 85% of patients. All obliterated root canals with no exception resulted in inconsistent functioning of EAL. Statistically Root ZX was significantly higher than Raypex5 but clinically no significant difference was found. All other parameters had no correlation to the consistency of EAL. In the present study, accuracy was set as 0.5mm short of radiographic apex. Anything less or more was considered as under extended or over extended respectively. In the present study, accuracy was set as 0.5mm short of radiographic apex. Anything less or more was considered as under-extended/over-extended respectively. 33% of EAL cases, 45% of radiographic cases under-extended; 5.2% EAL and 21.5% of radiographic cases over extended. Magnitude of over extension on an average was 1.1mm of EAL, 1.7mm for radiographic method. The average magnitude of

under extension was 0.5mm of EAL and 0.7mm for radiographic method. Considering the accuracy limit set for study, these values are well within the acceptable range (0-2mm).

In an In vivo study (39), accuracy of Propex II and iPex II EAL was compared in determining the WL under clinical condition to that of radiographic working length using stainless steel and nickel titanium hand files. Results obtained with each EAL with stainless steel and NiTi files were compared with radiographic WL. No significant difference was found between EALs. No significant difference was found between Electronic WL & Radiographic WL and Stainless steel & Nickel Titanium files for WL determination. In the present study, there was significant difference between radiographic and EAL methods between mean values of positive adjustments (i.e under extension) ( $p = 0.006$ ). However, there was no significant difference between negative adjustments (i.e over extension) ( $p=0.14$ ). When the frequency for accuracy, under extension, over extension was considered there was significant difference between 2 groups in the accurate termination of obturation and over extension ( $p = 0.1$ ).

In a previous ex vivo study by Piaseki et al (40), accuracy of Root ZX II in locating the apical foramen in teeth with apical periodontitis was investigated. In this, after the endodontic access of 12 teeth with apical periodontitis and vital teeth, coronal portion of the canal was flared. A 15k file was placed in the canal until the EAL read 'apex' has reached. Keeping the file in place tooth was extracted. The distance from the file tip to the most coronal border of apical foramen was obtained. Apical foramen was accurately located with  $\pm 0.5$ mm in 83% teeth with apical periodontitis and in 100 % of vital teeth group. Therefore Root ZX was accurate in locating apical foramen regardless of the presence of apical periodontitis.



Similarly, an ex-vivo study by Wrbas et al (41) accuracy of 2 EAL : Root ZX and Raypex5 was checked in the same teeth. Minor foramen was located within the limits of  $\pm 0.5$ mm in 75% cases with Root ZX and in 80% of cases with Raypex 5. But statistically there was no significant difference. In the present study also, accuracy of master cone fit and obturation was set as 0.5mm short of radiographic apex.

In another ex-vivo study by Parekh et al (42), comparison between the measurement of apex locator and radiographic technique to determine the working length was done. After doing endodontic access and coronal flaring , radiographic length was determined with the help of K-file and electronic length with Root ZX apex locator. After extraction, stereomicroscope was used to confirm and compare radiographic and EAL length measurements. No significant difference was observed. In a study (10), WL measured with EALs was within  $\pm 0.5$  mm of the apical foramen in 74.8% of cases and within  $\pm 0.5$  mm of the radiological control length in 90% of all the cases. In the present clinical study, the accuracy of EAL (Root ZX mini) and radiographic technique was assessed using the master cone radiograph (0.5mm short of the apex). EAL showed 61% accuracy while radiographic technique showed 33%. However, when the tertiary outcome of clinical success of endodontic treatment at 3 months follow up was considered, there was no statistically significant difference (radiograph -100% success vs. EAL – 99.14% success). So far to the best of our knowledge, tertiary outcome of WL determination has not been reported in the literature.

In an ex-vivo study by Versiani et al (43), comparison of the accuracy of Root ZX II to locate the apical constriction with the display meter set at ‘0.5’ and ‘1’ reading was done. The accuracy was 90.5% and 83.78% for Root ZX II at ‘0.5’ and ‘1’ reading. It was concluded that meter reading by Root ZX II reduced the risk of working length over estimation. In the present

study also, frequency of over extension (>0.5mm short of the apex) was found to be less for Root ZX mini as compared to radiographic method.

In an ex-vivo study by Aguiar et al (44), precision of Root ZX, Root ZX II and Root ZX mini was evaluated. The percentage of precision of devices were 68.8% & 100% (Root ZX); 65.8% & 96.9% (Root ZX II) and 68.8% & 100% (Root ZX mini) considering  $\pm 0.5$ mm and  $\pm 1$ mm as the error range. But statistically there were no significant difference. Therefore, 3 models demonstrated similar and adequate precision when performing root canal length measurement at the apical foramen level. The results of the current study conform with the above study. The absolute values of over-extension was not statistically significantly different between Root ZX mini (EAL) and radiographic method.

In the long term success of endodontic treatment using one of the 2 methods of WL determination (EAL- Root ZX mini and radiographic–single radiographic method) was considered. Only 1 case (1 tooth) showed the obturation material extending till the radiographic apex which subsequently developed periapical lesion of 1.6mm in dimension at 3 month follow up ( +1.1 mm increase in lesion size). All other patients (all teeth) showed no evidence of continued post-operative pain, swelling, discomfort, sinus tract, discharge and change in the PDL space/ lesion development. So the long term success of WL determination using EAL can be considered as 99.14% and radiographic method as 100%. Therefore, there is no statistically significant difference between the 2 methods in the long term success of endodontic treatment.

The uniqueness of the current study is that the radiographic method relied on a single pre-operative radiograph taken with customized cone-positioners for optimizing the cone-object distance and the sensor-object distance. No further radiographs were taken for WL

determination/verification. Considering this uniqueness the resultant accuracy and the long term success assumes significance. Further, the present radiographic method, also tend to underestimate the length (>0.5mm short of radiographic apex) like apex locators. This is considered to be more safe than other methods that tend to over-estimate (other radiographic and non-radiographic methods) the working length. This is especially beneficial whenever there is systemic contraindication for multiple radiation exposure (for eg: Pregnancy). Also, in 31% of cases the new radiographic method gave more accurate determination. Hence, this new radiographic method may be considered as a non-invasive and simpler technique of accurate root canal working length determination and as a substitute for electronic apex locators.

## ***SUMMARY***

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## SUMMARY

Working length determination holds the key to success in Endodontics as the two crucial steps of cleaning & shaping and obturation rely on its accuracy. Different radiographic and non-radiographic techniques are available for measuring WL. The disadvantages of radiographic techniques are: radiation exposure and image distortion. Among the non-radiographic techniques, Electronic apex locators are more successful as they tend to objectively estimate the correct WL. The disadvantages of Electronic apex locators are: they are expensive and presence of fracture, accessory canals and other anatomic variations or moisture compromise their accuracy. In the present study, to circumvent the disadvantage of radiation exposure and image distortion of radiographic techniques, a single pre-operative radiograph with a customized tube positioner was designed. The accuracy of WL determination by this technique is compared with 4<sup>th</sup> generation EAL (Root ZX mini). The immediate (master cone and obturation) and long term success (3 months) were compared. The new radiographic technique showed greater frequency of over estimation than EAL. It was similar to EAL in the frequency of under estimation. However, there was no statistical difference in the long term success or absolute values of over estimation. Hence the new single radiographic technique for WL determination can be used as an alternative to Electronic apex locators.

## ***CONCLUSION***

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## CONCLUSION

The study was self-funded by the primary and secondary investigator. The accuracy of working length determination is an essential step in Endodontics. In this study, usefulness of a new radiographic technique was compared to 4<sup>th</sup> generation Electric apex locator at short and long term respectively. Since it is an *In-vivo* study radiographic accuracy could only be assessed in terms of fit of master cone and obturation adequacy at short term. With these limitations inherent to clinical study, it can be concluded the new radiographic technique tended to underestimate the working length similar to Electric apex locator. It was comparatively over estimating the working length more frequently than Electric apex locator. The accurate termination of working length was also less frequent compared to Electric apex locator. However, the absolute values of over estimation was not statistically significantly different between 2 groups. The long term success was higher for new technique compared to Electric apex locator though not statistically different.

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# ***ANNEXURES***

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## **PATIENT INFORMATION SHEET**

Information was explained to patient in their own native language in case they were not able to understand the printed language.

- Q1. Title of the study:**  
Clinical success of two different working length determination methods – A Randomized Controlled Trial
- Q2. Invitation:**  
You have been selected as a participant in the above study. Before finalizing your participation, you need to understand the nature of the study and responsibility as a participant. Hence kindly go through below given information and make a consensual decision. If you need any explanation, you may contact us. Take a decision to participate or not after patiently going through the information.  
Thank you for reading the information sheet.
- Q3. What is the goal of this research?**  
This research aims to determine an accurate technique for tooth length determination during root canal treatment.
- Q4. Why I have been selected for the study?**  
Based on clinical and radiographic evaluation, your tooth requires root canal treatment irrespective of you participating in the study. So by participating in the study, you are becoming an active member in helping the betterment of the population, in deriving an accurate method for tooth length determination.
- Q5. Should I participate in this study?**  
Your participation is purely voluntary. When you decide so, a consent form will be given to you to sign. However, if you have to withdraw due to any personal or professional commitments, you may do so. This study involves only 4-5 appointments, similar to normal endodontic treatment. Withdrawing during the course of study can adversely affect your tooth and the study outcome. So it is not advisable to withdraw during the study.
- Q6. Are there any risks involved?**  
In this study, no new chemicals/material/instruments are used. Regular endodontic treatment regimen will be used. So this study is safe with no risk involved. No unwanted outcomes are anticipated. In case of any adverse reactions, regular endodontic rehabilitation will be followed and you will be excluded from the study.
- Q7. What are the benefits if I participate?**  
Your tooth will be treated both aesthetically and functionally. Healing process will be closely monitored by 3 months follow up. Quality of treatment will be assessed. Being an active member in this study, you are contributing in knowledge gain to clinician in determining an accurate method for tooth length determination.
- Q8. Will my personal information be revealed during document preparation?**  
No
- Q9. What will happen to the results of the study?**  
The results of the study will not mention your personal information. However, if you would like to see the publication arising out of the study, you may contact the principal investigator.
- Q10. Who is conducting this study?**  
This study is being conducted by our own funding.
- Q11. Who reviewed this project proposal?**  
Madha Medical Ethical Committee.
- Q12. For more information whom should I contact?**  
Principal investigator- Dr Minu Joseph.

Thank you. If you wish, a copy of this information sheet will be provided to you.



**நோயாளியின்தகவல்தாள்**

1. ஆராய்ச்சியின்தலைப்பு:

இருவேறு பல் நீளம் அளக்கும் முறைகளின் சிகிச்சை வெற்றி -ஒரு பாகுபாடற்ற கட்டுபாடுடைய முயற்சி

2. அழைப்பு:

நீங்கள் இந்த ஆய்வில் பங்கெடுக்க அழைக்கப்படுகிறீர்கள்! பங்கெடுக்க முடிவு செய்யுமுன் இதன் தன்மையையும், பங்கெடுப்பின் கடமைகளையும் தெரிந்து கொள்ளுதல் அவசியம். தயவு செய்து பின்வரும் தகவல்களை கவனமாக படித்து, கலந்தாய்ந்தபின்னர் முடிவு செய்யுங்கள். விளக்கம் தேவைப்பட்டால் தயங்காமல் எங்களை அணுகுங்கள். பொறுமையாக சிந்தித்து பங்கெடுக்கலாமா வேண்டாமா என்று முடிவு செய்யுங்கள்.

இந்த தகவலை படித்ததற்கு நன்றி!

3. இந்த ஆராய்ச்சியின் நோக்கம் என்ன?

வேர் சிகிச்சை செய்யும் பல்லின் நீளத்தை துல்லியமாக அளப்பதற்கு இந்த ஆராய்ச்சி உதவும்

4. நான் ஏன் தேர்ந்தெடுக்கப்பட்டேன்?

தங்கள் பல்விற்கு வேர் சிகிச்சை தேவைப்படுவதால் தங்கள் தேர்ந்தெடுக்கப்பட்டீர்கள்.

5. நான் பங்கெடுக்க வேண்டுமா?

இதில் பங்கெடுப்பது உங்கள் விருப்பத்திற்குப்பட்டது. பங்கெடுக்க முடிவு செய்தால் இந்த தகவல் தாளும், ஒப்புதல் படிவமும் கையொப்பமிட வழங்கப்படும். பங்கெடுக்க முடிவு செய்தாலும், எந்தகாலக் கட்டத்திலும் காரணம் சொல்லாமல் விலகலாம். உங்கள் சிகிச்சை முறையில் இதனால் எந்த மாற்றமும் ஏற்படாது.

6. பங்கெடுப்பதால் எனக்கு என்ன ஆகும்?

இதில் பங்கெடுப்பதால் எந்த அபாயமும் இல்லை. வழக்கமான நோய் கண்டறியவும், சிகிச்சை வரையறுக்க பயன்படும் பரிசோதனை முறைகளே கையாளப்படும்.

7. பங்கெடுப்பதால் என்ன நன்மைகள் ஏற்படும்?

தங்களுடைய வேர் சிகிச்சை தேவைப்படும் பல்விற்கு பல் நீளம் கண்டு பிடிக்க உதவுவீர்கள்.

8. நான் பங்கெடுப்பது ரகசியமாக இருக்குமா?

ஆம். உங்களை பற்றிய விவரங்கள் அனைத்தும் மருத்துவமனையை விட்டு வெளியே செல்லு முன் உங்கள் பெயர் மற்றும் விலாசம் நீக்கப்பட்டுவிடும்.

9. இந்த ஆராய்ச்சியின் முடிவுகள் என்ன ஆகும்?

உங்கள் சுயவிவரம், ப்ரகரங்களில் வெளிவராது . ப்ரகரங்களை பார்க்க விரும்பினால், தலைமை ஆராய்ச்சியாளரை அணுகுங்கள்.

10. இந்த தஆராய்ச்சி யாரால் நடத்தப்படுகிறது?

எங்கள் சொந்த செலவில் நடத்தப்படுகிறது.

11. இந்த ஆராய்ச்சியை யார் பரிசீலனை செய்தார்?

மாதா மருத்துவ நெறிமுறை குழு

12. மேலும் விவரங்களுக்கு யாரை தொடர்பு கொள்ள வேண்டும்?

தலைமை ஆராய்ச்சியாளர் மினு ஜோசஃப

நன்றி! நீங்கள் விரும்பினால் இந்த தகவல் தாள் உங்களுக்கு வழங்கப்படும்

## INFORMED CONSENT

### Why this research is being undertaken?

This research has been undertaken to accurately measure the length of teeth indicated for root canal treatment.

### What is my role?

Since your tooth requires root canal treatment, you are helping in finding an accurate technique for tooth length determination.

### How long is the participation period?

You may have to visit 4-5 times with each visit extending maximum to 1 hour which is the normal protocol for root canal treatment and restorative rehabilitation.

As an informed consensual participant of the study, I have understood:

My participation is purely voluntary.

I understand the nature of my participation completely.

Explanations have been provided to all my questions.

I have completely understood the above given information and giving my consent to participate in this study.

Signature of the participant: J. SANTHOSH KUMAR

Date:

J. Santosh Kumar

I have explained all the questions of the recruited participant.

Signature of the principal investigator:

Date:

ஒப்புதல்படிவம்

இந்த ஆராய்ச்சி ஏன் மேற்கொள்ளப்படுகிறது?

வேர் சிகிச்சை செய்யும் பல்லின் நீளத்தை துல்லியமாக அளப்பதற்கு இந்த ஆராய்ச்சி உதவும்.

இதில் என்பங்கு என்ன?

தங்களுடைய வேர் சிகிச்சை தேவைப்படும் பல்லிற்கு பல் நீளம் கண்டு பிடிக்க உதவுவீர்கள்

பங்கெடுப்பின் கால நேரம் எவ்வளவு?

4/5 முறை வேர் சிகிச்சைக்கு வருவது போல் வர வேண்டும்

ஒவ்வொரு முறையும் சிகிச்சை சுமார் ஒரு மணி நேரம் நீடிக்கும்

இந்தசோதனையின் புரிந்துணர்ந்த பங்கெடுப்பாளராக நான் தெரிந்துக்கொண்டது:

என் பங்கெடுப்பு என் விருப்பத்திற்குட்பட்டது.

என் பங்கெடுப்பின் தன்மையை நான் முழுமையாக அறிவேன்.

என் வினாக்களுக்கு தக்க விளக்கங்கள் அளிக்கப்பட்டன.

நான் மேற் கூறியவற்றை புரிந்து கொண்டு பங்கெடுப்பிற்கு ஒப்புதல் அளிக்கிறேன்.

பங்கெடுப்பாளரின் கையொப்பம்:

நாள்:

*E. Vasanthi*

நான் பங்கெடுப்பாளரின் அனைத்து வினாக்களுக்கும் விளக்கம் அளித்தேன்;

ஆராய்ச்சியாளரின் கையொப்பம்:

நாள்:

**MADHA DENTAL COLLEGE AND HOSPITAL**  
**DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDOODNTICS**

**CASE SHEET**

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_  
 AGE/SEX: \_\_\_\_\_ ADDRESS: \_\_\_\_\_  
 OCCUPATION: \_\_\_\_\_ PHONE: \_\_\_\_\_

IN CASE OF EMERGENCY- TO CONTACT:

**SUBJECTIVE SYMPTOMS** CHIEF COMPLAINT: \_\_\_\_\_

ALERT	Completed Y/N	
CASE No.		
TREATMENT		
PHOTO		
PRE-OP	INTRA-OP	POST OP
RADIOGRAPH		
PRE-OP	INTRA-OP	POST OP
TREATED BY:		

HISTORY OF PRESENT ILLNESS:

LOCATION	CHRONOLOGY	QUALITY	STIMULATED BY	RELIEVED BY	ANY OTHER
Localized	Inception	Dull	Heat	Cold	
+ Diffuse	Constant	Sharp	Chewing	Heat	
	Momentary	Throbbing	Sweet	OTC- medication	
+ Referred	Intermittent	Constant	Spontaneous	Others	
	lingering		Palpation		
+ Radiation			Supination		
			Keeps awake at night		
			Cold		
			Biting		

PAST DENTAL HISTORY – First / RCT / Filling / Extraction / Prophylaxis / Others

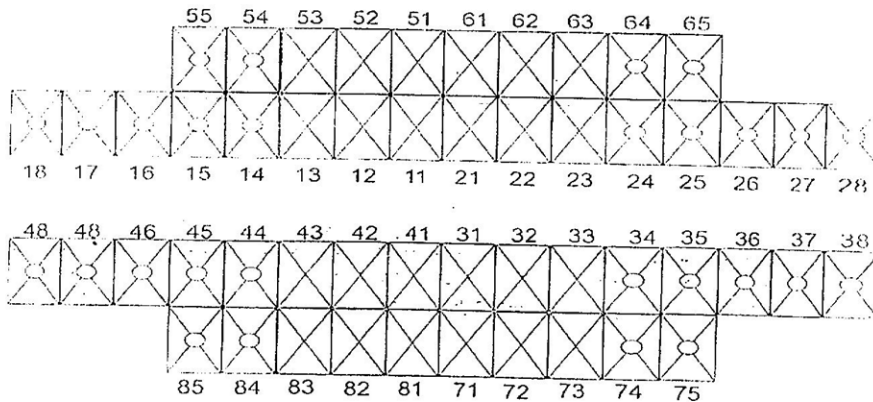
MEDICAL HISTROY – \_\_\_\_\_

HABITS/BRUXER / PERSONAL HABITS – \_\_\_\_\_

**OBJECTIVE SYMPTOMS**

EXTRA-ORAL – Facial swelling	INTRA-ORAL – Normal	Periodontium
Lymph nodes	Gingiva	Buccal mucosa
TMJ	- Swelling	Sulcus
	- Sinus tract – Yes / No / Closed	Frenal attachment

DMFS



Score :

Clinical crown – restoration / caries / fracture / crack / attrition / abrasion / discoloration /

Prior treatment / abutment / exposure of pulp

TOOTH	VITALITY TESTS							PERIODONTAL EXAMINATION								
	COLD	HEAT	EPT	percussion	palpation	mo bili ty	bite	MB	B	DB	DL	L	ML	recession	Furcal groove	Bleed on probing

CODE FOR VITALITY: N – normal response      DR – delayed response      NR – no response

SI – subside immediately after removal      L – lingering after removal

**RADIOGRAPHIC INTERPRETATION**

**TEETH SEEN -**

IOPA / Bitewing / Occlusal / Other

**CROWN**

**ROOT(S)**

Enamel

No. of roots

Dentin

Curvature

Resorption

Pulp Chamber

Dilaceration

Fracture

**ROOT CANALS**

**BONE (WNL)**

**L.D. (WNL)**

**PDL SPACE (WNL)**

No. of RC seen

Apical lucency

Obscure

Obscure

Type -

Lateral lucency

Broken

Widened

Curvature -

A/L opacity

Widened

Other Findings -

Crestal bone loss

SINUS TRACT traced to-

PROVISIONAL DIAGNOSIS:

DIFFERENTIAL DIAGNOSIS:

DIAGNOSIS:

PULPAL	PERI-APICAL	ETIOLOGY
Normal pulp	Normal apical tissue	Caries, Restoration
Reversible pulpitis	Symptomatic apical periodontitis	Attrition, Abrasion
Symptomatic irreversible pulpitis	Asymptomatic apical periodontitis	Trauma developmental
Asymptomatic irreversible pulpitis	Acute apical abscess	Periodontal orthodontics
Pulp necrosis	Chronic apical abscess	Intentional prior RCT
Previously treated therapy	Condensing osteitis	VRF
Previously initiated therapy	External resorption	Resorption
Internal resorption		Coronal leakage

**TREATMENT PLAN:**

<b>RESTORATIVE</b>	Caries control	GIC	LC	Veneers
	Inlay	Onlay	Bleaching	
<b>PERIODONTAL</b>	SRP	Crown lengthening		
	Splinting	Extraction		
<b>ENDODONTIC</b>	RCT	Apexification	Perf/Resorption repair	
	I & D	ReRCT	Surgical	Hemisection Radisection
<b>POST ENDODONTIC</b>	Core			
	Post			
	Crown			
<b>OTHERS -</b>				

**PROGNOSIS:**

ENDODONTIC			PERIODONTAL			RESTORATIVE		
GOOD	FAIR	POOR	GOOD	FAIR	POOR	GOOD	FAIR	POOR

P R E T R E A T M E N T	DATE			
	CARIES REMOVAL			
	PRE-ENDODONTIC TOOTH BUILD UP			
	OCCLUSAL REDUCTION			
	LOCAL ANESTHESIA			
	RUBBER DAM			
	ACCESS CAVITY			
	PULPECTOMY			
	CANALS	CANAL		
		REF		
WL				
TOOTH		Instrument size	I	
	F			
CLEANING & SHAPING	Irrigant			
	Dressing			
OBTURATION	Master cone			
	Sealer			
	Obturation technique			
	Dressing			
SURGICAL	I & D			
	Hemisection			
	Bicuspidation			
	Root resection			
	Retro filling			
MEDICATION				

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TREATMENT SHEET

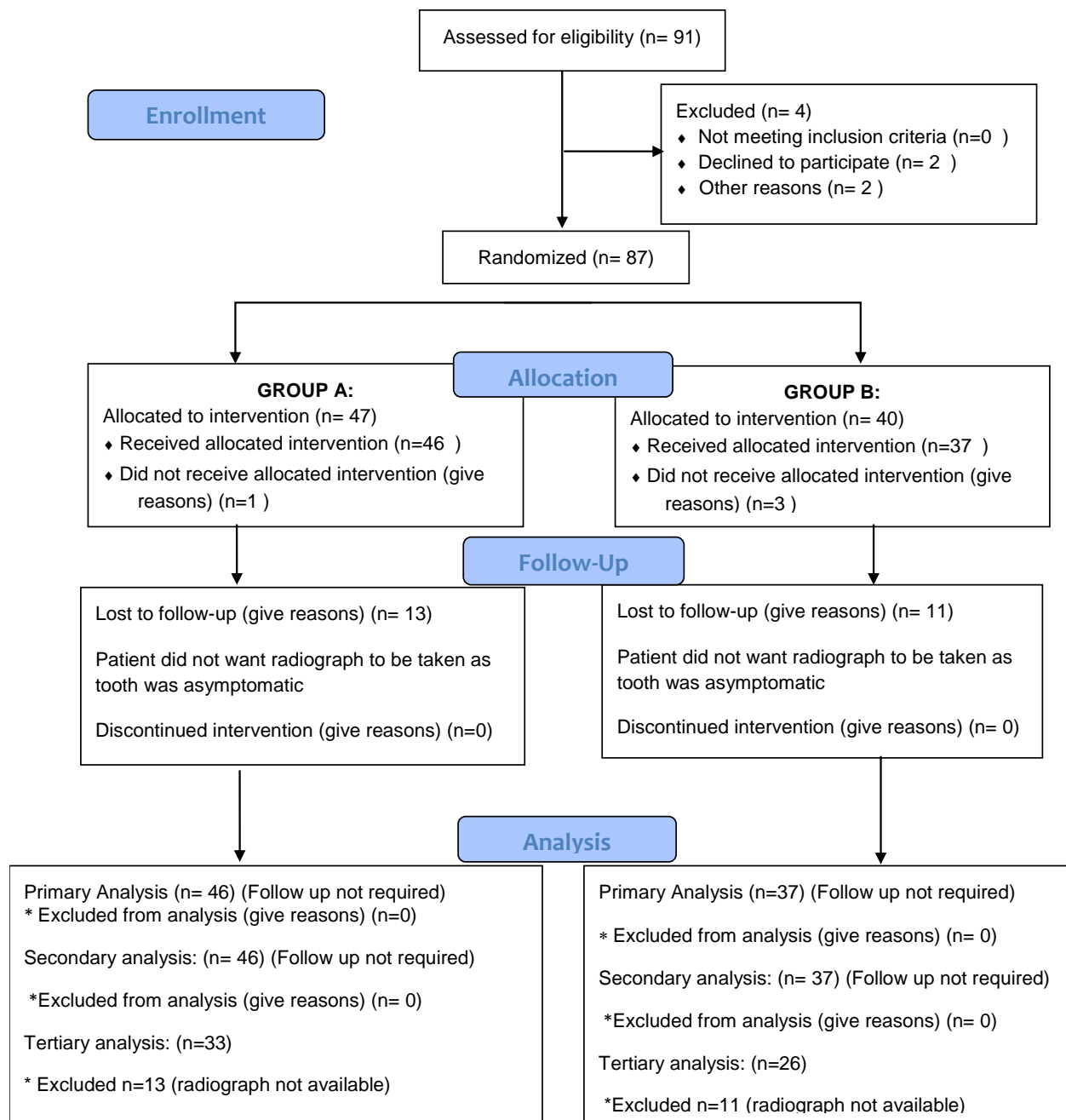
DATE	TREATMENT DONE	RECALL ON	SIGNATURE

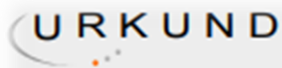
## CONSORT 2010 checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
<b>Introduction</b>			
Background and objectives			
	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	4
<b>Methods</b>			
Trial design			
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	21
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	20
Participants			
	4a	Eligibility criteria for participants	20
	4b	Settings and locations where the data were collected	20
Interventions			
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	24
Outcomes			
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	29
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size			
	7a	How sample size was determined	21
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation			
	8a	Method used to generate the random allocation sequence	24
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	24
Allocation concealment mechanism			
	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	24
Implementation			
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	24
Blinding			
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	24
	11b	If relevant, description of the similarity of interventions	-
Statistical methods			
	12a	Statistical methods used to compare groups for primary and secondary outcomes	30
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	30
<b>Results</b>			
Participant flow (a diagram is strongly recommended)			
	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	33
	13b	For each group, losses and exclusions after randomisation, together with reasons	25
Recruitment			
	14a	Dates defining the periods of recruitment and follow-up	20
	14b	Why the trial ended or was stopped	NA
Baseline data			
	15	A table showing baseline demographic and clinical characteristics for each group	31
Numbers analysed			
	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	32
Outcomes and estimation			
	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	33
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	38
Ancillary analyses			
	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	39
			40
Harms			
	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	48
<b>Discussion</b>			
Limitations			
	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	56
Generalisability			
	21	Generalisability (external validity, applicability) of the trial findings	56
Interpretation			
	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	49
<b>Other information</b>			
Registration			
	23	Registration number and name of trial registry	NA
Protocol			
	24	Where the full trial protocol can be accessed, if available	NA
Funding			
	25	Sources of funding and other support (such as supply of drugs), role of funders	56



### CONSORT 2010 Flow Diagram





## Urkund Analysis Result

**Analysed Document:** PLI.docx (D47174284)  
**Submitted:** 1/23/2019 10:16:00 PM  
**Submitted By:** mn29feb@gmail.com  
**Significance:** 7 %

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