EVALUATION OF POSTOPERATIVE PAIN AFTER WORKING LENGTH DETERMINATION USING ELECTRONIC APEX LOCATOR VERSUS DIGITAL RADIOGRAPHY IN MULTIROOTED TEETH. A RANDOMIZED CONTROLLED TRIAL.

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Abstract

The aim of this study was to assess the effect of working length determination using apex locator in comparison to digital radiography on post-operative pain and the number of analgesic tablets taken by the patient to relieve that pain. Subjects & Methods: Fifty four patients with multirooted asymptomatic teeth were randomly assigned to 2 groups according to the method of working length determination either apex locator or digital radiography. After that chemomechanical preparation was done using crown down technique. Master cone x-ray was taken for confirmation then obturation was done with gutta-percha and resin sealer using modified single cone technique. Postoperative pain was assessed at 4, 6, 12, 24 & 48 hours postoperatively using the numerical rating scale. Patients were also asked to report the number of days needed for complete disappearance of pain and the number of analgesic tablets taken by the patient to relieve pain if needed in a period of 7 days. Results: The total postoperative pain results between the apex locator group (0.96 ± 1.25) and the digital radiography group (0.73 ± 1.37) were statistically nonsignificant (0.29) (P > 0.05). Also the number of days needed for the complete disappearance of pain (1.50 ± 1.24 & 1.35 ± 1.23) of both groups respectively and the analgesic intake (0.96 ± 1.24 & 0.73 ± 1.37) of both groups respectively were statistically nonsignificant (P > 0.05). Conclusion: There is no difference in postoperative pain level or amount of analgesic intake when either apex locator or digital radiography is used for working length determination in multirooted teeth.

Introduction:

Fear of pain is one of the major reasons for dental apprehension & postoperative pain is one of the primary problems in endodontic treatment(1).
There are several factors associated with postoperative pain that may be overlooked by the dentist among which is the position of the apical foramen resulting in incorrect working length determination causing under or over instrumentation with possibility of apical tissue injury (2). Failure to accurately determine the working length of the tooth may lead to either incomplete cleaning and apical leakage or apical perforation and overfilling with increased incidence of postoperative pain (3).

Correct working length determination affects the degree of pain and discomfort that the patient would feel following the appointment. Thus it plays an important role in determining the success of the treatment (4).

The proper point to which root canals should be filled is the cementodentinal junction (CDJ) which is the anatomical and histological landmark where the periodontal ligament begins and the pulp ends and it is thought to be 0.5-1mm from the radiographic apex (5,6)

Radiographic determination of working length has been used for many years but when the apical foramen exits to the side of the root or in a buccal or lingual direction it becomes difficult to view on the radiograph. A radiograph provides a two-dimensional image of a three-dimensional structure and is technique sensitive in both its exposure and interpretation. Also dense bone and anatomical structures can obscure the apex of the tooth (7,8)

The development of electronic apex locators has been a major innovation in root canal treatment. Their advantages include equal or higher accuracy compared with the radiographic method, continuous monitoring of the working length in combination with rotary systems and reducing the total needed radiographs and radiographic exposure to the patient (9).

Subjects and Methods:-
Fifty Four participants (27 participants in the experimental group and 27 participants in the control group) were recruited from the outpatient clinic of the Endodontic Department, Faculty of Oral and Dental Medicine, Cairo University. The protocol of the trial was approved by the Ethics committee, Faculty of Oral and Dental Medicine, Cairo University. The treatment procedures, aim of the study, possible side effects, and treatment alternatives were thoroughly explained to all the participants. Participants were asked to follow the general instructions and to sign a printed informed consent. Sample size was calculated using G*Power program at the center of evidence based dentistry, Faculty of Oral and Dental Medicine, Cairo University.

Through diagnosis was made for the participants recording the patient data and taking full medical and dental history and the history of the chief complaint. Clinical visual examination, percussion and palpation evaluation were done. Electrical pulp tester was used to record the response of the affected tooth, the adjacent and the contralateral teeth, used as a control.

The patients were chosen based on inclusion criteria including being medically free, age range between 14 & 50 years old, having vital mandibular molars with Asymptomatic irreversible pulpitis caused by carious exposures or normal pulp treated for prosthetic reasons, normal periapical radiographic appearance & no history of taking analgesics 12 hours before root canal treatment.

The 54 participants were randomly divided into 2 groups ( apex locator group or digital radiography group) based on a sequence generated by a computer software at www.random.org at the center of evidence based dentistry, Cairo university and allocation concealment was done using four-folded numbered papers that were packed in opaque envelopes to be dragged by the patients. The written number on the paper assigned the patient to either the experimental (apex locator) or control (digital radiography) group according to the randomization table. The study was double-blinded where the patient and the assessor didn’t know the intervention done.

All patients (n= 54) were treated by a single endodontist in a single visit. Each patient was given a pain scale chart to record his /her pain level before any intervention. The tooth was anaesthetized using inferior alveolar nerve block injection & if needed infiltration technique was used as an adjunct, then an access cavity was performed using round bur and Endo-z bur. After that the tooth was properly isolated with rubber dam & the canal patency was determined with a stainless steel K-file size #10 ( Dentsply Maillefer, Ballaigues, Switzerland). The coronal part of each canal was flared with an SX Protaper file (Dentsply Maillefer, Ballaigues, Switzerland) & the patients were randomly assigned to 1 of the 2 groups according to the method used for working length determination.
Working length measurement:
In the apex locator group (DENTA PORT ZX J.Morita, Irvine, Japan), the clip was attached to the patient’s lip, and the electrode was connected to a K-file size #15. The file was advanced within the root canal to a point just beyond the major foramen, as indicated by the flashing ‘‘APEX’’ bar on the liquid crystal display. The file was then withdrawn until the liquid crystal display showed a flashing bar between ‘‘APEX’’ and ‘‘1’’. Measurements were considered correct if the instrument remained stable for at least 5 seconds. In the digital radiography group (SOREDEX, DIGORA optime, Tuusula, Finland), a file was inserted into the canal with an estimated working length. Then a radiograph was taken with the file inside the canal and working length was adjusted from the digital x-ray.

Root canal treatment:
The Chemomechanical preparation was performed with ProTaper Universal instruments (Dentsply Maillefer, Ballaigues, Switzerland) in a crown-down manner in the following sequence ProTaper S1 and S2, F1, F2, F3, F4, F5 were used as finishers to the full instrumentation length according to canal size using X-smart motor (Dentsply Maillefer, USA) and lubricating by MD-Chelcream EDTA cream (META BIOMED CO., LTD., Korea). After each instrument change, 1 mL 2.5% NaOCl was used as irrigant. A master cone radiograph was taken then canals were dried with paper points and were filled with ProTaper universal gutta-percha and ADSEAL sealer (META BIOMED CO., LTD., Korea) by using modified single cone technique and restored with temporary restorative material.

Postoperative questionnaire:
A questionnaire was given to the participants to record the intensity of pain & frequency of analgesic intake postoperatively at 4, 6, 12, 24 & 48 hours. Each patient was given a prescription for Brufen 200mg (Abbot, Egypt) (10), with instructions to take only if needed for pain. Patients were also instructed to record time and date of each tablet in a schedule on the pain scale paper. Also the patient was asked to record the number of days necessary to achieve complete pain resolution. One week after obturation, all the patients returned to the clinic with the filled forms.

Statistical analysis:
Data was decoded, tabulated and statistically analyzed. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows. The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Data showed non-parametric (not-normal) distribution. Friedman test was used to compare between more than two related samples. Mann Whitney test was used to compare between two non-related samples. Wilcoxon test was used to compare between two related samples. Independent sample t-test was used to compare between the two groups for numerical data. The significance level was set at P ≤ 0.05.

Results:
Apex locator showed group showed (23) 85.2% females and (4) 14.8% males, while Digital radiography group showed (17) 63 % females and (10) 37 % males. The participants’ age range was 14 – 47 years. The two groups had nearly equal distribution of the teeth that was treated either mandibular first or second molar. All the demographic data results were nonsignificant between both groups. There was no statistical significant difference between the apex locator group or the digital radiography group in pain scores at 4, 6, 12, 24 & 48 hours (P>0.05), However there was a statistical significant difference between all these time intervals within each group (P=0.03) where postoperative pain recorded its highest values at 4 & 6 hours in both groups then decreased by time. The mean, standard deviation (SD) values of pain scores are shown in (Table 1) and the pain scores in both groups are shown in (Figure 1). The total pain scores are shown in (Table 2, Figure 2).
Table (1): The mean, standard deviation (SD) values of pain scores.
ns=Nonsignificant, *= Significant

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pain</th>
<th>Digital radiography</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Apex locator</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>After 4 hours</td>
<td>0.31</td>
<td>0.47</td>
<td>0.19</td>
</tr>
<tr>
<td>After 6 hours</td>
<td>0.27</td>
<td>0.45</td>
<td>0.27</td>
</tr>
<tr>
<td>After 12 hours</td>
<td>0.23</td>
<td>0.43</td>
<td>0.08</td>
</tr>
<tr>
<td>After 24 hours</td>
<td>0.08</td>
<td>0.27</td>
<td>0.19</td>
</tr>
<tr>
<td>After 48 hours</td>
<td>0.08</td>
<td>0.27</td>
<td>0.00</td>
</tr>
<tr>
<td>After 7 days</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>P-value</td>
<td>0.003*</td>
<td></td>
<td>0.003*</td>
</tr>
</tbody>
</table>

Figure (1): Bar chart representing pain scores in both groups

Table (2): The mean, standard deviation (SD) values of total pain

<table>
<thead>
<tr>
<th>Variables</th>
<th>Total Pain</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Apex locator</td>
<td>0.96</td>
<td>1.25</td>
</tr>
<tr>
<td>Digital radiography</td>
<td>0.73</td>
<td>1.37</td>
</tr>
<tr>
<td>P-value</td>
<td>0.296 ns</td>
<td></td>
</tr>
</tbody>
</table>

ns=Nonsignificant
Regarding the number of days the pain persisted, there was no statistically significant difference between Apex locator group and the Digital radiography group (p=0.685). The highest mean value was found in the Apex locator group (1.50 ± 1.48) while the least mean value was found in the Digital radiography group (1.35 ± 1.23) shown in (Table 3, Figure 3).

Regarding the analgesic tablets intake, there was no statistically significant difference between the Apex locator group and the Digital radiography group (p=0.529). The highest mean value was found in the Apex locator group (0.96 ± 1.25) while the least mean value was found in the Digital radiography group (0.73 ± 1.37) shown in (Table 4, figure 4).

Table (3):- The mean, standard deviation (SD) values of number of days needed for the pain to disappear

<table>
<thead>
<tr>
<th>Variables</th>
<th>Number of days pain persisted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Apex locator</td>
<td>1.50</td>
</tr>
<tr>
<td>Digital radiography</td>
<td>1.35</td>
</tr>
</tbody>
</table>

P-value 0.685ns

ns=nonsignificant
Table (4):- The mean, standard deviation (SD) values of number of analgesic tablets.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Number of analgesic tablets</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td></td>
</tr>
<tr>
<td>Apex locator</td>
<td>0.96</td>
<td>1.24</td>
<td></td>
</tr>
<tr>
<td>Digital radiography</td>
<td>0.73</td>
<td>1.37</td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>0.529ns</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ns=nonsignificant

Figure (3):- Bar chart representing mean of number of days in both groups

Figure (4):- Bar chart representing mean of number of analgesic tablets in both groups
Discussion:-
Several attempts were made to correlate post treatment pain to many predictive factors including single versus multivisit treatment, different types of intracanal dressings, different treatment procedures, patient factors, analgesics, anesthetic solutions used, use of antibiotics, and pretreatment pain. However, relatively few articles have been directly focused on the patient experience \(^{(8,10,11,12,13,14,15,16)}\).

In this study the selected patients were Asymptomatic with carious exposures or normal pulp conditions to eliminate the confounder factor of preoperative pain thus allowing better correlation of the results to the experimental groups, as teeth with chronic apical periodontitis and necrotic teeth are at increased risk for postoperative pain \(^{(17,18)}\). Patients included in this study had no history of taking analgesics or other drugs in the 12 hours before the procedure, because pretreatment with analgesics and oral steroidal anti-inflammatory drugs was shown to affect post endodontic pain \(^{(19,20,21)}\). Baseline characteristics (age, gender and tooth type) were balanced between the two groups in this study as a result of randomization and allocation of participants that ensures similar distribution among both groups and exclude or control confounding variables \(^{(22,23)}\). Protaper universal rotary system was chosen for mechanical preparation in this study, owing to the fact that (NiTi) rotary instruments result in minimal debris extrusion compared to the stainless-steel hand K-files, which is attributed to their rotary action, Archimedes’ screw effect and copious irrigation associated with these instruments \(^{(24)}\). Nekoofar et al. \(^{(25)}\) compared the postoperative pain levels and analgesic consumption following root canal treatment using reciprocating M wire alloy Wave one and Rotary Protaper and he concluded that the postoperative pain was significantly lower in patients treated with ProTaper rotary instruments compared with the Wave One reciprocating single-file system and the analgesic intake was much more in the wave one group.

Coronal flaring of the root canal during endodontic treatment affects the incidence of postoperative pain \(^{(8)}\) and has many advantages, such as creating a reservoir for endodontic irrigation solution and facilitating direct access of the root canal file into the apical area, which allows for better accuracy with the electronic apex locator. In addition, coronal flaring is important in determining the correct initial apical size. Coronal flaring has been reported to result in a significantly larger hand file fitting to the apex \(^{(26,27)}\). Files inserted in pre-flared root canals had a significantly lower incidence of overextension than those placed in non-flared canals \(^{(28)}\). Obturation was done by the modified single cone technique and it was reported that more pain occurred after lateral compaction technique compared to single cone technique \(^{(29)}\) and that lateral condensation is time consuming and has the potential to place undue force on the root leading to root fracture \(^{(30)}\).

The Apex locator used in this study is DENTA PORT ZX (J.Morita, Irvine, Japan) was considered a gold standard in accuracy, which is supported by in vivo and in vitro studies that demonstrated accuracy of 75%–97.37% \(^{(31,32)}\). Tooth-related factors potentially influencing the precision of Root ZX included pre-operative pulp status, tooth type, position of the apical foramen, canal obliteration, and the size of apical diameter. Operative factors including coronal pre-flaring, presence or absence of irrigants, file size, file alloy, and mode of file operation could also influence the performance of Root ZX thus adopting the 0.5 mark of the digital meter of the Root ZX reduces chances of violating the apical foramen while factors influencing the precision of Root ZX must be considered while operating it \(^{(33)}\).

In previous studies, the accuracy of radiographic and electronic working length determination methods has been compared. Ravanshad et al. \(^{(9)}\) suggested that electronic root canal working length determination is not superior to radiographic methods. Brunton et al. \(^{(35)}\) and Hoer and Attin \(^{(36)}\) found that combined use of an electronic apex locator and radiography is more accurate in working length determination than radiography alone, so combination of electronic and radiographic methods is recommended for working length determination by the European Society of Endodontontology. Kim et al. \(^{(37)}\) reported that Root-ZX alone detected the apical constriction with a clinical accuracy rate of 84%, whereas the accuracy of Root-ZX combined with radiographs was 96%. However, the difference was not statistically significant. Saad and al-Nazhan \(^{(38)}\) showed that successful root canal treatment can be performed by determination of working length measurement with only an apex locator which will result also in reduction in radiation dose.

The results of this study showed no statistical significant difference between the two groups regarding the demographic data (age and sex) which is probably due to randomization. However, the gender difference in pain perception has been a controversy in literature as it is affected my many factors. Some studies showed that females have a higher risk for developing post-operative pain \(^{(39)}\), on the contrary other studies show that women has higher
pain thresholds than males, however, most studies doesn’t find a difference between the perception of pain between males and females. Gonadal hormones are known to modulate pain intensity and influence sensitivity to analgesics. Gender-related difference has been shown to disappear in elderly patients, this also favors the impact of gonadotrophic hormones on difference in pain \(^{40}\). The influence of patient age, gender or tooth/arch group on post-operative pain was reported to be of no significance \(^{13}\). In contrast, a retrospective study conducted by Torabinejad et al 1988\(^{13,41}\) showed a significant positive correlation of flare-ups with old age patients aged between 40 and 59 years, female patients and mandibular teeth. Also Sayed et al 2012\(^{14}\) found that prevalence of post-operative pain is significantly higher in old patients (41-65 years) as compared to young patients and stated that this may be because of less pain tolerance, less blood flow and delayed healing. He also found that the prevalence of post-operative pain is very high in women as compared to men which is attributed to differences in pelvic and reproductive organs that may provide an additional portal of entry of infection in females leading to possible local and distant hyperalgesia. He also found that in mandibular molars, post-operative pain is significantly higher as compared to maxillary molars which might be because mandible has a dense trabeculae pattern, thus there is reduced blood flow, accumulation of exudates and more localization of infection and inflammation, which might lead to delay healing.

Regarding postoperative pain results, there was a statistical significant difference among all the time intervals (4h,6h,12h,24h,48h & 7 days) within the apex locator group in relation to each other and also those of the digital radiography (4h,6h,12h,24h,48h & 7 days) in relation to each other. Postoperative pain decreased remarkably with time and nearly reached zero at 7 days. This is in agreement with a study by Pak and White\(^{11}\) showing that pain severity generally decreased during the course of a few days reaching its half at 1 day and less than 10% at 7 days. This may be attributed to the resolution of inflammation resulting from pulp extirpation and instrumentation with time and reduction of inflammatory mediators in the periapical area which created a clinical and statistical difference in pain values over time.

The results of this study showed that in the apex locator group, the highest mean score of pain was found after 4 hours and in the digital radiography group the highest mean score of pain was found after 6 hours where the inflammatory mediators are elevated to its peak level due to injury from the mechanical procedures & may also be attributed to the time required for complete disappearance of the anesthetic effect, after which the patients start experiencing the pain for the first time which may aggravate the pain perception. It has been reported that the onset of pain usually begins as the effects of the local anesthetic agent subside. Unless treated, moderate to severe pain usually occurs during the first 24 hours, with a peak intensity after about 6-8 hours. It was reported that very often the offset of the local anesthetic coincides with the peak release of important pain mediators such as histamine, prostaglandins and bradykinin \(^{34}\), this potentiates the feeling of pain.

There was no statistical significant difference between the two groups (apex locator group and digital radiography group) in the postoperative pain score results given at different time intervals (4h,6h,12h,24h,48h & 7 days) when compared to each other. These results coincide with the results of a study by Tuncer & Gerek\(^{8}\) that investigated the effect of working length determination by apex locator or digital radiography on postoperative pain in single rooted teeth, where there was no statistical significant difference between the two groups on different time intervals (4h,6h,12h,24h, 48h). The results also coincides with the results of Jarad et al\(^{42}\), Mohan et al.\(^{43}\) Nawab et al\(^{44}\) and Mousavi et al. 2017\(^{45}\) that showed no statistical significant difference between the accuracy of apex locators and radiography in determining the working length. However, most of these studies recommended using larger trials to investigate these methods in the future. Arslan et al\(^{46}\) agreed with these results, however, he concluded that simultaneous working length control during root canal treatment - where the instrument was automatically stopped on reaching the apex- using the Gold Reciproc motor (an electronic apex integrated endodontic motor that allows simultaneous working length control during instrumentation) reduced the postoperative pain significantly than separate working length determination.

It is known that statistical significance is not always coinciding with clinical significance, it is affected by several factors such as larger sample size & outliers. To decide whether a treatment is better than the other, statistical significance of its effectiveness over current treatment alone is insufficient. Measures of the size of the treatment effects (that is, clinical significance) are also necessary.\(^{47}\) The statistical significance associated with the P-value means that from the statistical point of view, the study result was not due to chance. On the other hand, the concept of clinical significance, also called clinical importance, can be summarized as a difference between two therapy results that is large enough to justify changing the standard of care. Some times in clinical studies a what is called “Type II error occurs (failure to reject a false null hypothesis). However, type II errors can be reduced by conducting
a power analysis prior to conducting the investigation and including an adequate large sample size \(^{(48)}\). So according to literature and in the clinical practice it was shown that the accuracy of apex locator was much more superior than that of digital radiography which may consecutively lead to less postoperative pain. This is in agreement with Ravanshad et al\(^{(50)}\) who stated that in addition to reducing the radiographic exposure, electronic apex locators are superior in reducing overestimation of the root canal length, also this is in agreement with Sharma and Arora\(^{(49)}\), Saroosh ehsan\(^{(50)}\), Mittal et al\(^{(51)}\), Elshinawy 2017\(^{(52)}\) and Jafarzadeh et al\(^{(53)}\). In the light of this evidence, it may be concluded that conducting this study on a larger sample size may have coincidence of both clinical and statistical significance.

Regarding the number of days that the pain persist (up to 7 days), there was no statistical significant difference between the two groups (the apex locator group and the digital radiography group). This is in agreement with Tuncer & Gerek\(^{(8)}\) who also found no difference in the persistence of pain in patients treated using apex locators or digital radiography for working length determination. There are several factors affecting the persistence of pain, one of the most important factors is the preoperative status of the pulp, which is eliminated in this study by the inclusion criteria of the candidates.

Regarding the number of analgesic tablets, there was no statistical significance difference between the two groups (the apex locator group and the digital radiography group) and it was realized that the number of analgesic tablets intake decreased with time. This may be also attributed to the resolution of inflammation resulting from pulp extirpation and instrumentation and reduction of the inflammatory mediators in the area with subsequent reduction in nociceptors stimulation and initiation of the repair process that decreased the need for analgesic intake with time. In conclusion, on the basis of the results of the present study, there is no difference in postoperative pain level or amount of analgesic intake when either apex locator or digital radiography is used for working length determination in multirooted teeth. However, the use of apex locator may provide the benefit of radiation dose reduction which is beneficial for the patients and follows the ALARA principle.

References: