Comparison of the effect on postoperative pain between instrumentation with and without connected electronic apex locator: a randomized clinical trial [version 1; peer review: awaiting peer review]

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Abstract

Background: The aim of the present study was to evaluate the postoperative pain between root canal instrumentation with unconnected electronic apex locator and instrumentation with connected electronic apex locator.

Methods: Forty-two patients were randomly divided into two groups (n=21). Group 1 was treated using the traditional endodontic motor with unconnected electronic apex locator (EAL) and group 2 was treated using the endodontic motor with connected EAL. All teeth were treated in single-visit endodontic therapy. Postoperative pain levels at 6, 24, 48, 72 h and 1 week were recorded by patients. The data were collected and analyzed using the $\chi^2$, and Mann-Whitney U tests with significance at 0.05.

Results: Postoperative pain levels were significantly reduced by half at 6 hours in both experimental groups; however, no significant differences were found in postoperative pain levels between the two groups at all considered times. The postoperative pain levels using a percussion test were reduced on day 7 in both groups, and there was no significant difference in this variable between two groups.

Conclusions: Both groups have a similar effect on reduction of the postoperative pain for endodontic patients undergoing root canal.

Keywords
nickel-titanium, electronic apex locator, single-visit endodontic, postoperative pain
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Introduction
One of the most important stages in endodontic therapy is root canal preparation, which required a working length (WL) determination. Therefore, the measurement of root canal WL is one of the most important factors in root canal instrumentation and can affect the success of the endodontic treatment. The complexity of the situation is that the WL is not constant, it changes during root canal preparation. Because the root canal space cannot be shaped and cleaned appropriately if the WL is not exactly determined, this value must be controlled, measured, and adjusted continuously during the preparation. This task is time consuming and can cause procedural errors as it can produce more stress for the operator. Although the electronic apex locator (EAL), a device for WL determination, has shown high accuracy and facilitation, such as ProPex PiXi (Dentsply Sirona, Ballaigues, Switzerland), it is still hard to satisfy the operator’s demand for continuous monitoring of the WL in root canal preparation. The E Connect S motor combined with E-Pex Pro EAL (Changzhou Eighteeth Medical Technology Co., China) is a solution for continuous control of WL. This motor offers very special function for the operator when the instrument reaches the WL, that is, the motor automatically decreases the speed of, stops and/or reverses the instrument. Using such strictly controlled WL, this is expected to reduce the postoperative pain caused by apical extrusion. Postoperative pain is one of the most sensitive consequence in root canal therapy and there are many efforts to reduce the postoperative pain to enhance the patient’s comfort, cooperation, and trust. The unremitting efforts of manufacturers and advancements in technology and materials have led to improved rotary nickel-titanium (NiTi) instruments. An offset cross-sectional design has become dominant in recent years because of its multi-advantages, such as larger envelope movement and good debris collection, facilitating its utilization. ProTaper Next (PTN, Dentsply Sirona, Maillefer, Ballaigues, Switzerland) possesses this offset design and is made of M-Wire.

The aim of the present study was to evaluate the postoperative pain after root canal treatment between utilization of a traditional endodontic motor with unconnected EAL and the motor with connected EAL. The null hypothesis was that there would be no differences in pain intensities between the two experimental groups.

Methods
This trial was registered at Thai Clinical Trials Registry with identification number of TCTR20200118001. The trial was registered retrospectively, as the study was started directly after receiving ethical approval; application for registration occurred after the enrollment of the first participant. The design of this study was a parallel group randomized, controlled trial with two arms, from May 2019 to March 2020.

Sample size
According to the data of a previous study, the sample size was calculated as 36. The sample size was calculated as the following formula for comparison of means from two independent samples:

$$n = \frac{(Z_{1-\beta} + Z_{1-\alpha})^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

With the power of 80%, significance of 0.05, the $Z_{1-\beta} = 1.96$, $Z_{1-\alpha} = 0.84$.

Considering the number of lost patients during follow-up, 42 patients were aimed to be included in the study with allocation ratio of 1:1.

Participants
Subjects of the study were enlisted from patients sent to the Department of Operative Dentistry and Endodontics of the University of Medicine and Pharmacy at Ho Chi Minh City for endodontic treatment from May 2019 to March 2020. Patients were asked prior to making an appointment for taking part in the study. Every patient was thoroughly informed about the study by the investigators, and each patient signed an informed consent form. The patients were blind to the modalities used for the endodontic treatment.

Patients were randomly distributed into two groups (n = 21 per group) using an online randomiser program (available at www.randomizer.org). Group 1 was treated using the traditional endodontic motor with unconnected EAL and group 2 was treated using the endodontic motor with connected EAL. In total, 26 women and 16 men with maxillary and mandibular molars indicated for endodontic therapy (as assessed with preoperative radiographs) were included in the present study. For each patient, one molar was treated for the study (a total of 42 molars for the study).
Eligibility criteria
Criteria for subjects included in the present study were healthy patients without systemic diseases with symptomatic pulpal or periapical pathology of the first or second molar. Criteria for subjects excluded from the study were those with systematic diseases and other conditions, and those aged less than 18 years. The inclusion and exclusion criteria of patients for the present study were displayed in the Table 1.

Data collection
Patient preoperative pain was recorded using the Heft Parker visual analogue scale (VAS) of Heft & Parker.6 The VAS was 170 mm in length and divided into four categories: 0 mm, no pain; 0-54 mm, mild pain (within this category: faint pain = 23 mm; weak pain = 36 mm); 55-113 mm, moderate pain; 114-170, severe pain (within this category: strong pain = 114 mm; intense pain = 144 mm).7 The patients had the VAS explained to them so that they knew how to record their pain on the line without any numerical markings, but with various descriptive words. The patients could place a mark anywhere on the line and use the verbal descriptors as a guide. Each patient’s mark was assigned a value between 0 and 170 mm on the scale by measuring the distance from the left end to the mark with a ruler.

The patients were required to record their own pain level at 6, 24, 48, 72 hours and one week after treatment was complete using the VAS. The patient was scheduled for an appointment at one week after treatment for recording the postoperative pain by percussion test and for collecting the VAS. The age, gender, number of teeth, diagnosis, preoperative and postoperative pain levels at 6, 24, 48, 72, one week, preoperative and postoperative pain levels at one week on percussion using the Heft & Parker VAS (HP-VAS), and the analgesic intake after procedure were recorded.

Interventions
All endodontic treatments were performed by one endodontist (C.M.H.). The indicated tooth was anesthetized using local anesthetic solution containing 2% lidocaine with 1:100,000 epinephrine (Lignospan Standard, Septodont, France). Inferior alveolar nerve block and buccal infiltration anesthesia technique were used for the mandibular molars and buccal and palatal infiltration anesthesia technique was used for the maxillary molars. After 10 minutes, the access cavity was prepared under the rubber dam and explored for all possible canal orifices. The canals were filled with 3% sodium hypochlorite (Canal Pro, Coltene Whaledent, Altstätten, Switzerland) and explored by the 10 ISO K-file (Dentsply Sirona, Maillefer, Ballaigues, Switzerland). The coronal third of the canals were pre-enlarged using the PTN X1 to the estimated lengths (determined by the preoperative digital X-ray images).

For subjects of the group 1, group of instrumentation with unconnected EAL, the root canal lengths were measured using ProPex Pixi EAL and teeth were treated using WaveOne endodontic motor with Proglider and PTN instruments (Dentsply Sirona, Maillefer, Ballaigues, Switzerland). After WL was determined and confirmed radiographically (short of the apex from 0.5—1 mm), rubber stop on the shaft of the Proglider was set at the WL, then the instrument was inserted into the handpiece of the WaveOne motor (velocity: 300 rpm; torque: 2 N.cm) and used in slow in-and-out pecking motions inside the canal until it reached the determined working length. The Proglider was replaced by the PTN X1 with the rubber stop on the shaft at working length. The PTN X1 was used in slow in-and-out pecking motion inside the canal until reaching the determined WL. This same procedure was used for the next PTN X2 (upper buccal or lower mesial canals) and PTN X3 (upper palatal and lower distal canals).

For subjects of the group 2, group of instrumentation with connected EAL, the teeth were treated using E Connect S endodontic motor combined with the E-Pex Pro EAL with Proglider and PTN instruments. The WL of each root canal was confirmed radiographically. The Proglider was inserted into the handpiece of the E Connect S motor (velocity: 300 rpm;
torque: 2 N.cm) connected with the E-Pex Pro EAL (set at the apex, 0.0). The hook wire of the motor was hung into the corner of the patient’s mouth, and the preparation was started. The instrument was inserted into the canal and used in slow in-and-out motion toward the apex until it was automatically stopped and reversed from the apex. This same procedure was used for the next PTN X2 (upper buccal or lower mesial canals) and PTN X3 (upper palatal and lower distal canals).

For the subjects of both groups, the 10 ISO K-file was used for patency file during the preparation after every instrument change. The file was inserted just past the apical foramen, with the amplitude of less than 0.5 mm.

The root canals were irrigated a final time using 5 mL 3% sodium hypochlorite following 5 mL 17% EDTA solution, then dried using matched paper cones and obturated with matched single gutta percha cones with AH Plus (Dentsply Sirona, Maillefer, Ballaigues, Switzerland). Digital radiograph was taken to check the quality of obturation. If the root canal treatment acquired all requirements of good obturation, without extrusion of material, the tooth was treated for the next step. The access cavities were restored using SDR flowable composite and Ceram X SphereTec composite resin (Dentsply Sirona, Konstanz, Germany).

A total of 400 mg ibuprofen (Stada, Vietnam) was prescribed for cases of unbearable pain.

Data analysis
Data were imported and stored in the Statistical Package for Social Sciences (SPSS) (IBM, Armonk, NY, USA) version 25.0. Data were first checked for normality of distribution using the Shapiro-Wilk test, however, almost all variables had not been distributed normally. Data transformation was performed using many arithmetical functions, however, there was not any successful transformation. Therefore, the Mann-Whitney U test was used for comparison between the two groups. Age, gender, tooth number, and analgesic intake data were analyzed using the $\chi^2$ test. All statistical analyses were performed at the significance of 0.05.

Ethical considerations
This study was approved by the Research Ethics Committee of the University of Medicine and Pharmacy at Ho Chi Minh City with the approval number of 306/DHYD-HDDD. Written informed consent was obtained from all subjects involved in the study. Written informed consent was been obtained from the patients to publish the article.

Results
There was not any loss of patients during follow-up (Figure 1). Demographic data, preoperative and post-operative pain levels, and pain levels on percussion are displayed in the Table 2.

Mean age of patients was 28.24 and 30.52 years for the group 1 and group 2, respectively. There were no significant differences in the age, gender, tooth number between the groups ($P > 0.05$). The preoperative pain levels and those on percussion were around the moderate level (85 mm) in both groups, and no significant differences were found in preoperative pain levels and these on percussion between two groups ($P > 0.05$). The postoperative pain levels were significantly reduced by half at 6 hours for both groups (greater than 50 mm); however, no significant differences were found in postoperative pain levels between two groups at all considered times ($P > 0.05$). The postoperative pain levels on percussion were reduced on day 7 in both groups, and there was no significant difference in this variable between two groups. There was only one patient who needed to use analgesics postoperatively in the instrumentation with unconnected EAL group (group 1). There was no patient who needed to use analgesics in the instrumentation with connected EAL group (group 2). There were not any signs of swelling, sinus tract, or palpation pain in the patients, and there were not any unscheduled appointments for the patients in the study.

Discussion
The result of the present study showed that postoperative pain levels of patients were lower than the “weak” level. Because the root canal length is changed during root canal preparation, therefore, it must be measured, controlled and maintained continuously. This makes the operator fatigued and exhausted. Using a common, separate EAL, the operator must use a reference from the remaining tooth structure on the occlusal surface, incisal edge or even the root surface in teeth missing structure. This reference can be lost during treatment, especially in multiple-appointment treatment. In addition, using the rubber stop on the shaft of the instrument is improper in certain circumstances. This rubber stop can be displaced or worse than that, the rubber stop can be overpassed because of its elastic property without notice from the operator if the instrument is sucked into the canal (screw-in tendency). Instrumentation with a connected EAL device will overcome these shortcomings of previous methods in WL determination, control, and maintenance. Although there are many in vitro studies on the WL determination of EALs, there are few studies on endodontic motors with built-in or connected EAL up to now and therefore, there is not much data on the effect of an endodontic motor on root canal
EAL connected to the endodontic motor in the present study has been investigated in a previous study, which shows that accuracy was at the highest level when compared with other EAL and cone beam computed tomography. In the present study, we showed that EAL’s accuracy is still at a high level when using with the endodontic motor.

The PTN is made of M-Wire with special offset design and unique dimensions in order to reduce operator’s fatigue and exhaustion, and procedure complexity and enhance effectiveness. In the two previous studies on causing apical extruded debris of PTN and other rotary NiTi instruments, the results showed that PTN caused significantly less apical debris extrusion than ProTaper Universal and PTN caused significantly more apical extruded debris than HyFlex CM. These studies of comparison between the continuous rotary NiTi and reciprocating instruments showed that...
there were not significant differences in apical extruded debris.\textsuperscript{13,15} Other authors reported that the continuous rotary NiTi instruments produced less apical extruded debris than the reciprocating instruments.\textsuperscript{16} These conflicting results may be due to differences in study design, setup, or type of teeth.

Root canal preparation techniques cause apical extrusion of dentine debris, pulp tissue, microorganisms, and irrigation solutions through apical foramen, leading to inflammation, resulting in postoperative pain.\textsuperscript{17} The instrument’s designs or modes of movement (continuous or reciprocating rotary) are considerable factors that influence the apical extrusion of debris and therefore, postoperative pain of the patient.\textsuperscript{18-21} Instruments with the reciprocating movement induce more debris through apical foramen when compared with instruments with continuous rotary movement.\textsuperscript{16,22} This affects the choice of instruments among a great array of nickel-titanium root canal instruments.

Sodium hypochlorite concentration of 3\% was used for the present study, that is similar to that of a previous study.\textsuperscript{11} A lower concentration of sodium hypochlorite has been considered to reduce the postoperative pain in one study,\textsuperscript{23} however, that result was different from another study.\textsuperscript{24} Although the standard concentration of 5.25\% was used in other studies,\textsuperscript{23,24} there was still one study that used a higher concentration of 8.25\% with no significant differences of postoperative pain among other lower concentration groups.\textsuperscript{25}

Because the first 48 hour after endodontic therapy is the most common period when postoperative pain is felt by patient, five time-points (right after treatment, after 6, 12, 24, 48 hours) were used for evaluation.\textsuperscript{23} Longer periods are also selected to further collect the data after 72 hours and 7 days.\textsuperscript{23}

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**Table 2. Demographic and pain data according to the two treatment groups.**

<table>
<thead>
<tr>
<th></th>
<th>Instrumentation with unconnected EAL (group 1)</th>
<th>Instrumentation with connected EAL (group 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>28.24 ± 10.40\textsuperscript{a}</td>
<td>30.52 ± 12.66\textsuperscript{a}</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td><strong>Tooth number</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>17</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>26</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>27</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>36</td>
<td>1</td>
<td>2</td>
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<tr>
<td>37</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>46</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>47</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative pain after treatment</td>
<td>96.95 ± 41.63\textsuperscript{a}</td>
<td>97.14 ± 45.08\textsuperscript{a}</td>
</tr>
<tr>
<td>Postoperative pain levels at 6 h</td>
<td>44.14 ± 41.51\textsuperscript{a}</td>
<td>43.86 ± 36.89\textsuperscript{a}</td>
</tr>
<tr>
<td>Postoperative pain levels at 24 h</td>
<td>29.43 ± 38.37\textsuperscript{a}</td>
<td>23.48 ± 26.67\textsuperscript{a}</td>
</tr>
<tr>
<td>Postoperative pain levels at 48 h</td>
<td>21.33 ± 34.38\textsuperscript{a}</td>
<td>13.62 ± 18.85\textsuperscript{a}</td>
</tr>
<tr>
<td>Postoperative pain levels at 72 h</td>
<td>14.67 ± 27.84\textsuperscript{a}</td>
<td>11.10 ± 18.36\textsuperscript{a}</td>
</tr>
<tr>
<td>Postoperative pain levels on day 7</td>
<td>08.00 ± 17.32\textsuperscript{a}</td>
<td>06.11 ± 15.62\textsuperscript{a}</td>
</tr>
<tr>
<td><strong>Pain on percussion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>84.95 ± 45.29\textsuperscript{a}</td>
<td>82.19 ± 41.30\textsuperscript{a}</td>
</tr>
<tr>
<td>Postoperative on day 7</td>
<td>20.48 ± 24.41\textsuperscript{a}</td>
<td>17.00 ± 31.60\textsuperscript{a}</td>
</tr>
</tbody>
</table>

Same superscript letters showed no significant differences on the same row ($P > .05$).
Postoperative pain related to rotary NiTi instruments was reported by many previous studies using the randomized clinical trial design.5,11,21,26 Two of these studies performed single appointment endodontic therapy with separate EAL, and the results revealed that there was no difference in postoperative pain between the reciprocating and continuous instruments.21,26 These studies enrolled the asymptomatic patients and evaluated only the postoperative pain levels with different VAS instruments. However, postoperative pain in the single-visit endodontic treatments with NiTi instruments was at low levels in these two studies.21,26 Another study also recruited asymptomatic patients with postoperative pain evaluation but used multiple-visit treatment and WL determination during the root canal preparation.11 There were no differences in postoperative pain among the experimental NiTi instruments with both modes of movement in the above studies. The remaining study used the same concept as the present study with the different modalities.5 The result of the previous study revealed that postoperative pain levels on only day 1 of the group using the traditional endodontic motor with separate WL determination were significantly higher than that of the other groups.7 On the other days of the study, the postoperative pain levels were not significantly different between two groups using different modalities.5 This result agreed with that of the present study.

There are many various scales used to record the pain levels for evaluation of the effectiveness of many endodontic treatments.5,6,27–29 Although the 4- and 5-point rating scales of pain are used commonly and successfully in a clinical setting because of easy instructions for use, these scales did not have enough sensitivity to record the pain experience of patients.6 The Numerical Rating Scale for pain evaluation has low sensitivity when compared with the VAS, and in some previous studies, the VAS proved the high sensitivity and positive correlation with treatment effectiveness. The most important advantage of the VAS among the other pain scales was the difference in pain intensity at the two different times showed the actual difference in pain level.30–32 The Heft-Parker VAS is a line with the dimension of 170 mm with different distances on the scales to describe the pain of the patient.6 The VAS is used commonly in oral-facial pain studies; however, this scale confuses patients in selection of right position on the scale because there are no guides for ratings other than the two extremities.6 Using category word designations on the line of a VAS, the graphic rating scale of Heft and Parker offers more sensitivity than a category scale and is easier to use than a VAS.6

The result of the present study revealed that although the postoperative pain of patients in the instrumentation with connected EAL group was lower than that of the instrumentation with unconnected EAL group, there was no significant difference in postoperative pain levels at all points in time between the two experimental groups. Therefore, the null hypothesis was accepted.

The limitations of the present study were the small sample size, that the operator was not blinded to the applications of the two different modalities.

Within the limitations of the present study, the result revealed that the preoperative pain levels of the subjects in both groups were above the “moderate” level and those reduced after single-visit endodontic treatment with the postoperative pain levels less than the “faint” level. There was just one patient that used anti-inflammation drugs after treatment. Along with many other advantages of single-visit endodontic treatment such as reduction of appointments, exclusion of leakage through temporary restorations and removal risk of additional missing of tooth structure in previously severe structure missing tooth, this mode of treatment is tolerated and preferred better by patients and becomes common practice in many situations.26 Within the limitations of the present study, the endodontic therapy with the single-visit treatment brings the benefit to the patients without increasing the pain.

Conclusions
Within the limitations of the present study, endodontic therapy with the single-visit treatment brings the benefit to the patients without increasing the pain. Both groups using the endodontic motors with unconnected or connected electronic apex locator have a similar effect on reduction of the postoperative pain for endodontic patients.

Data availability
Underlying data
Mendeley Data: Khoa Cuong PO Pain, https://doi.org/10.17632/48ytd79w39.1.33

Reporting guidelines
Mendeley Data: CONSORT checklist for ‘Comparison of the effect on postoperative pain between instrumentation with and without connected electronic apex locator: a randomized clinical trial’, https://doi.org/10.17632/48ytd79w39.1.33

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