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The influence of two instrumentation techniques with two sealers on postoperative pain after endodontic treatment "randomized clinical trial"

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ABSTRACT

Introduction: Postoperative pain is one of the primary problems in endodontic therapy and an unpleasant situation for both patient and clinician. According to patients, pain is a strong predictor for performance of Root Canal Treatment. When an unexpected pain is experienced, patient's confidence to dentist is undermined. However, etiology of pain is multifactorial and has not been determined precisely yet [1]. It is well known that a small, inadvertent extrusion of debris and irrigants into periapical tissues is a frequent complication during the cleaning and shaping procedures, both with manual stainless steel and nickel-titanium rotary instrumentation techniques. However, recent studies have shown that reciprocating instrumentation techniques seem to significantly increase the amount of debris extruded beyond the apex and, consequently, the risk of postoperative pain [2]. So, it was of prime importance to shed a light on assessment of post-operative pain after using two different instrumentation techniques with two different sealers.

Purpose: The aim of this Study was to assess degree of Post-Operative Pain after Endodontic Treatment done using two different instrumentation techniques with combination of two different sealers.

Materials and methods: 84 mandibular first and second molars were selected and randomly divided into four groups, Group 1 was prepared using Protaper Next and obturated using AH plus Sealer. Group 2, the molars were prepared using Protaper Next and obturated using Total Fill Sealer. Group 3, the molars were prepared using WaveOne Gold and obturated using AH Plus Sealer and Group 4, the molars were prepared using WaveOne Gold and obturated using Total Fill Sealer. Assessment of post-operative pain by using The Visual Analogue Scale Pain evaluation was done 3 times for each patient, Post-operatively after 12, 24 and 48 h respectively. Finally, the data was tabulated and statistically analyzed using Kolmogorov-Smirnov and Shapiro-Wilk tests. Results: Neither the type of file nor the type of sealer affected the post-operative pain, however time showed statistically significant difference between (12 h), (24 h) and (48 h) respectively. Conclusions: Protaper next versus WaveOne Gold was found to have no influence regarding post-operative pain, The pain intensity showed significant decrease by time in all groups especially after 24 h post-operatively.

1. Introduction

Postoperative pain is one of the primary problems in endodontic therapy and an unpleasant situation for both patient and clinician. According to patients, pain is a strong predictor for performance of Root Canal Treatment. When an unexpected pain is experienced, patient’s confidence to dentist is undermined. However, etiology of pain is multifactorial and has not been determined precisely yet [1]. It is well known that a small, inadvertent extrusion of debris and irrigants into periapical tissues is a frequent complication during the cleaning and shaping procedures, both with manual stainless steel and nickel-titanium rotary instrumentation techniques. However, recent studies have shown that reciprocating instrumentation techniques seem to significantly increase the amount of debris extruded beyond the apex and, consequently, the risk of postoperative pain [2]. So, it was of prime importance to shed a light on assessment of post-operative pain after using two different instrumentation techniques with two different sealers.

2. Materials and methods

A total of 84 patients were selected from the faculty of oral and dental medicine, Future University. Sixty patients were selected with Asymptomatic non-vital lower first and second molars with three separate canals and without periapical lesion and patients with medically compromised patients were excluded.

2.1. Clinical procedures

2.1.1. Pre-operative procedure

Preoperative instructions were given to the patient about type of the procedure, discomfort as well as benefits of this procedure and their informed consent was obtained prior to the procedure. The patients were randomized by pulling numbered slips out of a hat and divided into four groups according to techniques of instrumentation and type of sealer used.
In Group 1: fifteen teeth prepared by ProTaper Next and Obturated By AH Plus Sealer
- In Group 2: fifteen teeth prepared by Wave One Gold and Obturated by AH Plus Sealer
- In Group 3: fifteen Teeth prepared by ProTaper Next and obturated by Total Fill sealer
- In Group 4: fifteen teeth prepared by Wave One Gold and Obturated by Total Fill sealer

2.1.3. Post-clinical procedures
Tooth diagnosis has taken place through visualization, percussion, palpation, mobility and electric pulp tests. Inferior alveolar nerve block was administered immediately before access cavity opening and complete de-roofing, anatomically shaped size rubber dam was applied to isolate the tooth. Then the saliva ejector was introduced below the integrated frame and was positioned in the corner of the mouth. All superficial caries was removed to minimize bacterial contamination the access cavity was refined using a tapered diamond stone. The roof of the pulp chamber was removed by using Endo Z bur. Crown down technique was used in a gentle brushing motion according to the manufacturers’ instruction. Initial filing was done from 15 to 20 size k file. To make patency. The working length was taken using Root ZX mini® apex locator and was placed 0.5 mm from the apex then confirmed using periapical radiographic x-ray. The patients were divided into two main groups according to techniques of Instrumentation used that was done by X-smart plus endomotor:

- In Group 1: thirty teeth prepared by ProTaper Next according to manufacture instructions till the master apical file and irrigation is done between each file using plastic syringe with side perforated 27-G needle containing 2.5% sodium hypochlorite and another one containing 17% EDTA solution
- In Group 2: thirty teeth prepared by Wave One Gold according to manufacture instructions and irrigation is done using plastic syringe with side perforated 27-G needle containing 2.5% sodium hypochlorite and another one containing 17% EDTA solution.

Each group was subdivided into two subgroups. Each included fifteen teeth according to sealer used for obturation.

Master apical file was done by 35 size k file. After instrumentation each canal was flushed with saline and then dried by paper dry.

It was subdivided into two subgroups according to sealer used.

- In Sub-Group 1: Obturation was made by lateral condensation technique where AH plus sealer was introduced using Lentulo spiral and master cone was introduced and the accessory cones were added after it.
- In Sub-Group 2: Obturation was made by lateral condensation technique where Total Fill sealer was added using Lentulo spiral and master cone was introduced and the accessory canals were added after it.

2.1.3. Post-clinical procedures
Patients are asked to evaluate the pain level & although the patients are not prescribed an analgesics, they can take if needed.

2.2. Methods of evaluation
Assessment of post-operative pain by using The Visual Analogue Scale (VAS) described by Pinkham et al. The VAS consists of a list of adjectives describing different levels of pain intensity with scores assigned to each of the levels of pain intensity (Table 1). The (VDS) was translated in to Colloquial Arabic.

3. Statistical analysis
The data was tabulated and statistically analyzed using Kolmogorov-Smirnov and Shapiro-Wilk tests. Friedman test was used to test the difference between more than two groups in related samples and Wilcoxon test was used to compare the difference between two groups in related samples. While Mann-Whitney U test was used to compare the difference between two groups in non-related samples.

> Pain score results:
A) Effect of time on pain scores in each sealer with different types of files (Table 2, Fig. 1)
- For AH Plus groups:
  a) For AH Plus groups:
    i) Protaper next:
      The highest mean value of pain score was found in (12h) (5.93 ± 0.88) followed by (24h) (3.33 ± 0.89) while the least mean value of pain scores was found in (48h) (1.00 ± 0.92).
    ii) Wave One Gold:
      The highest mean value of pain score was found in (12h) (6.53 ± 1.06) followed by (24h) (3.66 ± 0.89) while the least mean value of pain scores was found in (48h) (1.00 ± 0.65).
  b) For Total Fill groups:
    i) Protaper next:
      The highest mean value of pain score was found in (12h) (6.06 ± 0.88) followed by (24h) (3.46 ± 0.99) while the least mean value of pain scores was found in (48h) (1.00 ± 0.92).
    ii) Wave One Gold:
      The highest mean value of pain score was found in (12h) (6.53 ± 1.06) followed by (24h) (3.80 ± 0.77) while the least mean value of pain scores was found in (48h) (1.06 ± 0.70).

B) Effect of File type on pain scores in each sealer with different time factor: (Table 3, Fig. 2)
- For AH Plus groups:
  i) 12h:
    There was no statistically significant difference between (Protaper next) and (Wave One Gold) where (p = 0.137). The highest mean value of pain score was found in (Wave One Gold) (6.53 ± 1.06) while the least mean value of pain scores was found in (Protaper next) (5.93 ± 0.88).
  ii) 24h:
    There was no statistically significant difference between (Protaper next) and (Wave One Gold) where (p = 0.325). The highest mean value of pain score was found in (Wave One Gold) (3.66 ± 0.89) while the least mean value of pain scores was found in (Protaper next) (3.33 ± 0.89).
  iii) 48h:
There was no statistically significant difference between (Protaper next) and (Wave One Gold) where ($p = 0.870$).

The mean value of pain score was (Protaper next) $(1.00 \pm 0.92)$ and (Wave One Gold) $(1.00 \pm 0.65)$.

b) For Total Fill groups:

i) $12 \text{h}$:

There was no statistically significant difference between (Protaper next) and (Wave One Gold) where ($p = 0.250$).

The highest mean value of pain score was found in (Wave One Gold) $(6.53 \pm 1.06)$ while the least mean value of pain scores was found in (Protaper next) $(6.06 \pm 0.88)$.

ii) $24 \text{h}$:

There was no statistically significant difference between (Protaper next) and (Wave One Gold) where ($p = 0.436$).

The highest mean value of pain score was found in (Wave One Gold) $(3.80 \pm 0.77)$ while the least mean value of pain scores was found in (Protaper next) $(3.46 \pm 0.99)$.

iii) $48 \text{h}$:

There was no statistically significant difference between (Protaper next) and (Wave One Gold) where ($p = 0.713$).

The highest mean value of pain score was found in (Wave One Gold) $(1.06 \pm 0.70)$ while the least mean value of pain scores was found in (Protaper next) $(1.00 \pm 0.92)$.

C) Effect of Sealer on pain scores in each file with different time factor: (Table 4, Fig. 3)

a) For Protaper groups:

Table 1

Description of levels of pain intensity.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No Pain: The involved tooth felt normal and corresponded to digit zero.</td>
</tr>
<tr>
<td>2</td>
<td>Slight Pain: The involved tooth was slightly painful for a time regardless of the duration, but there was no need to take analgesics and corresponded to digit 2.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate Pain: The involved tooth caused pain which was tolerable or was rendered to be tolerable with analgesics and corresponded to digit 4.</td>
</tr>
<tr>
<td>4</td>
<td>Strong Pain: The involved tooth caused pain which disturbed sleep and needed narcotic analgesic and corresponded to digit 6.</td>
</tr>
<tr>
<td>5</td>
<td>Severe Pain: The involved tooth caused pain which disturbed normal activity or sleep and analgesics had no effect and corresponded to digit 8.</td>
</tr>
<tr>
<td>6</td>
<td>Maximum Pain: Patient unable to sleep and unable to perform normal activity and corresponded to digit 10.</td>
</tr>
<tr>
<td>7</td>
<td>Odd Number: Represents intermediate pain levels between the main pain levels.</td>
</tr>
</tbody>
</table>

Table 2

The mean, standard deviation (SD) values of pain scores of time in each sealer with different types of files (Friedman test).

<table>
<thead>
<tr>
<th>Variables</th>
<th>AH Plus sealer</th>
<th>Total Fill sealer</th>
<th>Protaper next</th>
<th>Wave One Gold</th>
<th>Protaper next</th>
<th>Wave One Gold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
</tr>
<tr>
<td>12h</td>
<td>5.93</td>
<td>0.88</td>
<td>6.00</td>
<td>6.53</td>
<td>1.06</td>
<td>7.00</td>
</tr>
<tr>
<td>24h</td>
<td>3.33</td>
<td>0.89</td>
<td>3.00</td>
<td>3.66</td>
<td>0.89</td>
<td>4.00</td>
</tr>
<tr>
<td>48h</td>
<td>1.00</td>
<td>0.92</td>
<td>1.00</td>
<td>1.00</td>
<td>0.65</td>
<td>1.00</td>
</tr>
<tr>
<td>P-value</td>
<td>$\leq 0.001^*$</td>
<td>$\leq 0.001^*$</td>
<td>$\leq 0.001^*$</td>
<td>$\leq 0.001^*$</td>
<td>$\leq 0.001^*$</td>
<td>$\leq 0.001^*$</td>
</tr>
</tbody>
</table>

Mean with different letters in the same column indicate statistically significant difference *; significant ($p < 0.05$) ns; non-significant ($p > 0.05$).

![Fig. 1. Bar chart representing effect of time on pain scores in each sealer with different types of files.](image)

Table 3

The mean, standard deviation (SD) values of pain scores of file types in each sealer with different time factor (Mann–Whitney U test).

<table>
<thead>
<tr>
<th>Variables</th>
<th>AH Plus sealer</th>
<th>Total Fill sealer</th>
<th>Protaper next</th>
<th>Wave One Gold</th>
<th>Protaper next</th>
<th>Wave One Gold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
</tr>
<tr>
<td>12h</td>
<td>6.53</td>
<td>1.06</td>
<td>7.00</td>
<td>3.66</td>
<td>4.00</td>
<td>1.00</td>
</tr>
<tr>
<td>24h</td>
<td>5.93</td>
<td>0.88</td>
<td>6.00</td>
<td>3.33</td>
<td>3.00</td>
<td>1.00</td>
</tr>
<tr>
<td>48h</td>
<td>0.137ns</td>
<td>0.325ns</td>
<td>0.870ns</td>
<td>0.250ns</td>
<td>0.436ms</td>
<td>0.713ms</td>
</tr>
</tbody>
</table>

Mean with different letters in the same column indicate statistically significant difference *; significant ($p < 0.05$) ns; non-significant ($p > 0.05$).
i) 12h:
There was no statistically significant difference between (AH Plus) and (Total Fill) where ($p = 0.713$).
The highest mean value of pain score was found in (Total Fill) ($6.06 \pm 0.88$) while the least mean value of pain scores was found in (AH Plus) ($5.93 \pm 0.88$).

ii) 24h:
There was no statistically significant difference between (AH Plus) and (Total Fill) where ($p = 0.713$).
The highest mean value of pain score was found in (Total Fill) ($3.46 \pm 0.99$) while the least mean value of pain scores was found in (AH Plus) ($3.33 \pm 0.89$).

iii) 48h:
There was no statistically significant difference between (AH Plus) and (Total Fill) where ($p = 1$).
The mean value of pain score for both (AH Plus) and (Total Fill) was ($1.00 \pm 0.92$).

b) For Wave One Gold groups:

i) 12h:
There was no statistically significant difference between (AH Plus) and (Total Fill) where ($p = 1$).
The mean value of pain score for both (AH Plus) and (Total Fill) was ($6.53 \pm 1.06$).

ii) 24h:
There was no statistically significant difference between (AH Plus) and (Total Fill) where ($p = 0.870$).
The highest mean value of pain score was found in (Total Fill) ($3.80 \pm 0.77$) while the least mean value of pain scores was found in (AH Plus) ($3.66 \pm 0.89$).

iii) 48h:
There was no statistically significant difference between (AH Plus) and (Total Fill) where ($p = 0.806$).
The highest mean value of pain score was found in (Total Fill) ($1.06 \pm 0.70$) while the least mean value of pain scores was found in (AH Plus) ($1.00 \pm 0.65$).

5. Discussion
This study design was a randomized clinical trial (RCT) [4–7]. This design is regarded as the most reliable method of evaluating the effects of interventions in health care. A sample of 60 patients, which was nearly equal to the similar clinical trials [8–10], were included and randomly assigned into four equal groups each of 15 patients. Randomization keeps study groups as similar as possible from the outset to minimize bias. In this study, Single visit root canal treatment was done as Single visit root canal treatment fulfill patient's needs because of the inherited advantages. This technique has gained popularity, this can be credited to favourable reports which showed no difference in treatment complications or success rates when compared with teeth treated in multiple visits [11–13]. In the present study, Reciprocation versus linear motion were used to assess the difference in post-operative pain level as One of the important reasons of post-operative pain is the extrusion of debris that obtain virulent bacteria into the periradicular tissues. If the infected debris is extruded into periapical region during root canal instrumentation, it may cause or increase the various of periradicular inflammation [14,15]. In the result of the present study, There was no statistically significant difference between Protaper next and Wave One Gold. This came in the agreement of the work of Relvas et al. (2015) [16] and Kherlakian et al. (2016) [17] whom, they found that The Wave One Gold and ProTaper next groups extruded the least amount of debris in comparison to the other groups in their studies. This may be explained with the assessments of metallurgy, design features and kinematics of these systems. It has been shown that heat-treated alloys have less stiffness [18] and a lower ultimate tensile strength than conventional super-elastic wires [19]. Both of Gold systems are produced with using different alloys and a new proprietary thermal process named Gold wire in which the ground NiTi files are heat-treated and slowly cooled to obtain super-elastic NiTi files. It could be attributed to the 2-stage transformation behaviour and the high temperatures from which PTN and WOG is produced; as this material has greater flexibility [12,20] with an elastic modulus lower than that of the austenitic phase [21,22]. Consequently, it could be supposed that the martensitic NiTi wire may ensure a lower amount of apical extrusion at a similar torque.

Table 4
The mean, standard deviation (SD) values of pain scores of file types in each sealer with different time factor (Mann–Whitney U test).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Protaper next</th>
<th>Wave One Gold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12h</td>
<td>24h</td>
</tr>
<tr>
<td>AH Plus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>5.93</td>
<td>6.00</td>
</tr>
<tr>
<td>SD</td>
<td>0.88</td>
<td>6.00</td>
</tr>
<tr>
<td>Median</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>P-value</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Total Fill</td>
<td>6.06</td>
<td>4.00</td>
</tr>
<tr>
<td>Mean</td>
<td>0.88</td>
<td>0.92</td>
</tr>
<tr>
<td>SD</td>
<td>0.71</td>
<td>1.00</td>
</tr>
<tr>
<td>Median</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>P-value</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Mean with different letters in the same column indicate statistically significance difference *; significant ($p < 0.05$) ns; non-significant ($p > 0.05$).
than austenitic NiTi alloy [23]. These metallurgical superior properties that provide less stiffness and reduced restoring force to the instruments [24,25] may explain the least amount of apical extrusion after instrumentation performed by Gold systems.

The design of Gold systems also play a crucial role on apically bacterial extrusion. First of all, the roundly tapered, and semi-active features of Wave One Gold reduce the mass of the center of the tip and contribute to less debris extrusion compared with all other groups [25]. The ProTaper next system has a different geometry; smaller dimensions, an off-centered mass, and a regresive taper. The centering ability of ProTaper Next instruments may ensure that a greater percentage of dentin thickness is retained in the root canal and may facilitate greater bacteria elimination [26]. The convex triangular cross-section and progressive taper enhance the cutting efficacy of ProTaper Next, while decreasing rotational friction between the file blade and dentin. ProTaper Next had a significantly lower torsional resistance. The non-cutting tip design allows each instrument to safely follow the secured portion of the canal, while the small area at the tip enhances its ability to find its way through soft tissue and debris [27]. In the result of the present study, it was found that pain records after root canal treatment with two different sealers is statistically insignificant. This comes in accordance with the work of Kousalya Vuyyuru et al. [28], Tayfun Alacam et al. [29] and Fox J et al. [30] that stated there is no significant with the pain level with the sealer material used for obturation. In this study, Pain assessment was done by the patients. The time Intervals were recorded at 12, 24 & 48 h and compared as Genet and Wesselin (1986) [31]. Ercan and kaya who showed that most post-operative pain occurred on the first day after initiating endodontic treatment, post-obturation, as postoperative pain episodes are usually caused by the pressure inherent in the insertion of the root canal filling materials or by the chemical irritation from the ingredients of the root canal cements or pastes. Also the occurrence of periapical inflammation results in pain in the periodontal ligaments which usually is a short-lived effect and abate within a 24–48 h period. Seltzer and Naidorf, 2004 [32] and Yoldas et al., 2004 [33]. Furthermore, in the result A statistically significant difference was found between (12h) on one hand and each of (24h) and (48h) on the other hand. this comes in accordance with the work of M. Gotler [34] and Daniel Kherlakian [35] in where they found that there is statistically significant difference in pain level recorded at different intervals.

6. Conclusion

There was no difference in post-operative pain between the ProTaper Next and the WaveOne Gold. The pain intensity showed significant decrease by time in all groups especially after 24 h post-operatively. Total Fill sealers was found to be promising regarding post-operative pain.

References


Fig. 3. Bar chart representing effect of sealer types on pain scores in each file with different time factor.


