Clinical Research
Incidence and severity of pain following the usage of three different root canal instrumentation systems.

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Abstract
Introduction: Post-Operative pain is one of the most common issue that might happened during and after endodontic treatment, this prospective randomized clinical trial evaluated the incidence and severity of Post-Operative pain following root canal instrumentation using ProTaper Universal System, ProTaper Next system and WaveOne system. Methods: Ninety patients with asymptomatic irreversible pulpitis on their permanent molar teeth selected and distributed randomly into three different groups of 30 patients each, to have access opening and instrumentation at same visit, those patients were fitted with inclusive criteria that we put for this study. Group 1 instrumented with ProTaper system, Group 2 instrumented with ProTaper Next system and Group 3 instrumented with WaveOne system, all systems strictly followed manufacturing instruction. The assessment of Post-Operative pain carried out at day 1, 2, 3 and 7, using Verbal Rating Scale (4-point scale). Verbal Rating Scale pain score compared and analyzed using Chi-Square test. Result: total score for Verbal Rating scale (scores recorded for 4 days) showed significant difference among the groups ($P < 0.05$), there was a significant difference between ProTaper Next group and the other two group (ProTaper group and WaveOne group) ($P < 0.05$), while there was Non-significant difference between ProTaper System and WaveOne System ($P \geq 0.05$). Conclusion: ProTaper next system caused the lowest incidence and severity of Post-Operative pain, WaveOne system caused the highest incidence and severity of Post-Operative pain.

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Key words
Post-Operative pain, Root canal instrumentation, Endodontic Rotary instruments,Debris extrusion and Pain Scale.

Introduction:
Post-Operative pain (POP) during endodontic procedure is undesirable for both the patients and the clinicians (Torabinejad et al, 1994). Developing of POP not only affects on the confidents between the patients and the dentist but it would also affects on patients satisfaction toward the treatment (Mohammed et al, 2010). There are many reasons for developing of POP include mechanical, chemical and microbial injury to the pulpal and periradicular tissue that occur during endodontic procedure (Harikaran et al, 2012) but in fact, extrusion of infected debris to the periradicular area during root canal preparation is the main cause of developing of POP (Siqueira et al, 2002). Acute periradicular inflammation will form as a result of apical extrusion of debris, whose intensity directly proportional to the intensity of the tissue injury (Siqueira et al, 2002). Knowledge about the causes, mechanism, management and prevention of POP is integral part of endodontic procedure (Harikaran et al, 2012 and Gotler et al, 2012).
All instrumentation techniques are reported to cause apical extrusion of debris, even when the file action is maintained

short of the apical terminus (Siqueira et al., 2002), the difference is that some techniques extrude more debris than others do.

The main feature of ProTaper Next (PTN); it has offset design, which generates a traveling mechanical wave of motion along the active portion of a file, unique design of the apical portion of the file and off-centered rectangular cross-section. Studies show that the amount of debris extrusion was significantly lower in the ProTaper Next (PTN) group than the ProTaper Universal (PTU) group (Koçak et al., 2014). This could be related to the design of the apical portion of the PTN files and their off-centered rectangular cross-section, which provides the non-uniform and reduced contact points between the instrument and the root canal wall (Elnaghy, 2014). This in addition to the lower taper could lead to the removal of more debris in the coronal direction and result in less debris extrusion. Also ProTaper Next files have shorter Pitch design which extrudes less debris.

Moreover PTN files have an offset design, which generates a traveling mechanical wave of motion along the active portion of a file. This swaggering effect serves to minimize the engagement between the file and dentin. Reduced engagement limits undesirable taper lock, the screw effect, and the torque on any given file. File with an offset design affords more cross-sectional space for enhanced cutting, loading, and augering debris out of a canal compared to a file with a centered mass and axis of rotation. Importantly, an offset file design decreases the probability for laterally compacting debris and blocking root canal system anatomy. This swaggering motion means that at all times the file is only connecting with the canal in two places which allows a greater space for removal of debris beside PTN files are utilized with an outward brushing motion. Importantly, this method of use will enable any given PTN file to passively move inward, follow the glide path, and progress toward the working length. This brushing creates lateral space and allows the debris to move coronally rather than being pushed apically (Ruddle, 2013).

WaveOne and Reciproc techniques use a quite rigid, big single-file of increased taper (usually 08 taper, size 25), which directly reach the apex. In many cases, in order to reach the apical working length, reciprocating instruments are used with force directed apically, which makes an effective piston to propel debris from a patent apical foramen. Since instruments are used without any preliminary coronal enlargement. This result in a greater engagement of flutes and, consequently, more torque or pressures is needed. Moreover cutting ability of a reciprocating file is smaller when compared to a continuous rotation, and also debris removal is smaller, thus increasing the frictional stress and torque demand, due to entrapment of debris within the flutes this is in agreement with De-Deus et al., (2010); Gambarini G. et al., (2012) and Gambarini et al., (2013)

The purpose of this prospective study is to evaluate incidence and severity of Post-operative pain following root canal instrumentation using three different instrumentation systems.

Methods: Ninety patients (57 male and 33 female) out of initial 120 participates, were eligible to participate in this prospective randomized single blind study, those patients required endodontic treatment on their permanent molar with asymptomatic irreversible pulpitis caused by carious exposure. The treatment carried out in 2 appointments; access opening and instrumentation was conducted at the same visit (Fig.1).

Fig 1
Radiograph showing carious exposure without any periapical changes.

The patients assigned into three groups of 30 patients each. To randomize the patients, each candidate asked to withdraw a paper from a jar; this paper has a number and contain the name of the system applied. The groups were close similar concerning the gender because gender differs in pain reports. Treatment took place in Al-Mustansiriya dental faculty/ Conservative department/ Post-Graduate clinic/ Baghdad/Iraq, for eight-month period. Those patients ranged in age from 19 to 50 years old and all were in good health. Patients who had previously used antibiotic prior 30 days before treatment were excluded from the study (Table: 1).

Table 1: Inclusion and Exclusion criteria for participants patient in this study

Inclusion criteria	Exclusion criteria
1. The aims and requirements of the study were freely accepted. 2. Treatment was limited to patients that have no sign or symptom for any systemic disease. 3. All molar teeth, either maxillary or mandibular with asymptomatic irreversible pulpitis and without any radiographical changes. 4. Teeth with mild to moderate root curvature (5° to 20°). 5. No antibiotics before clinical procedures were used. 6. Treatment of only one tooth, completion of access opening and instrumentation in one session. 7. Absence of preoperative pain. 8. #10 K-file confirmed loose at length and #15 K-file was the initial file and snuggly fit at working length. 9. Teeth treated by one endodontic practitioner only (Researcher). 10. Treatment was limited to patients ranged in age from 19 to 50 years.	1. Presence of teeth with symptomatic irreversible pulpitis, preoperative pain, or necrotic pulp associated with clinical symptoms such as swelling or purulence. 2. Teeth with radiographical changes or tenderness to percussion. 3. Teeth with sever curved canals (degree of curvature above 20°). 4. Patients who treated with antibiotics (30 days prior Endodontic procedure). 5. Present of any systemic disease. 6. Teeth with sclerotic obliterated canals. 7. The canals of the teeth were too wide, initial file larger than #15 file. 8. Teeth had been fractured between the appointments. 9. Missing opposite teeth. 10. Pregnant and breast feeding female

Table (1)

Age, gender, medical history, dental history, tooth location and tooth vitality were recorded; the diagnosis was confirmed by obtaining dental history, periradicular radiographs, periodontal evaluation, percussion and pulp vitality confirmed by presence of pulpal hemorrhage.

Periapical status was determined by a periapical radiographic evaluation using wireless digital radiograph system MyRay X-Pod (WDS, Italy), Teeth with radiographic examination demonstrated no any visible periapical lesion were included in this study.

A single clinician (the researcher) evaluated all patients, using radiographic and clinical findings, and the same clinician assigned for treatment of all cases. This procedure performed to eliminate interpersonal variability in the treatment between clinicians.

Before initiating the treatment, informed consent obtained from the participants after adequate explanation about the nature of the procedure and possible discomfort following the treatment. Postgraduate committee approved both the scientific and ethical aspect of this study and the informed consent form was signed by all the patients; all the subjects treated in conformity with the Helsinki Declaration (www.cirp.org/library/ethics/helsinki).

Each patient anesthetized with local anesthesia solution (2% lidocaine 1:100,000 epinephrine, (Septodent, France), the volume of anesthetic and type of injection was being at the discretion of the operator.

The burs and all intra-canal instruments discarded following each patient to eliminate any possibility of contamination. After placement of Rubber dam (Dentsply, Maillefer, UK), Elimination of all carious lesions, then conventional straight-line access obtained. Working length for root canals considered to be 0.5-1 mm from radiographic apex (Fig. 2)

Fig 2: Radiograph showing the working length determination, K-file #15 was the initial file for all canals.

using Root ZX Apex locator and digital radiograph with X-Pod Myray wireless digital system (WDS, Italy), The teeth in group 1 (n = 30) instrumented with a crown down technique using Universal ProTaper system (Dentsply, Maillefer, Switzerland), whilst those in group 2 (n = 30) were instrumented using a ProTaper Next system. The teeth in-group 3 (n = 30) were instrumented with a single-file technique, using WaveOne 08/25 (Dentsply, Maillefer, Switzerland), torque and speed were predetermined using X-Smart™ Plus motor (Dentsply, Maillefer, Switzerland).
All canals reached the same MAF 25, to eliminate group disparity.
Apical patency was confirmed using small file (# 10 k-file) throughout the procedure.
All the three instrumentation systems strictly followed manufacturer›s instructions.
1% NaOCL and EDTA 17% used as irrigants using side vented needle, the needle was placed 2mm short from the working length. Endosepton (PD, Switzerland), used as intra-canal medicaments (strictly followed manufacturing instructions), after completion of cleaning and shaping of canals, the cavities were sealed by Riva self-cure, resin reinforced glass ionomer (SDI, Australia), to eliminate any possibility of coronal leakage between the appointments.
Proper occlusal contact confirmed by articulating paper. Pain assessment carried out at Day 1, 2, 3, and 7 using verbal rating scale (VRS) (4 – point scale).

0. No pain: the treated tooth felt normal. Patients do not have any pain.
1. Mild pain: recognizable, but not discomforting pain, which required no analgesics.
2. Moderate pain: discomforting, but bearable pain (analgesics, if used, were effective in relieving the pain).
3. Severe pain: difficult to bear (analgesics had little or no effect in relieving the pain).

Patients been called to obtain their reports for the first three days, at day 7 the patients› reports back to the clinic, their reports were reviewed and percussion test performed, then the teeth obturated by thermafil obturation technique. VRS pain score compared using Chi-square test; a value of ($P < 0.05$) was required for statically significances.

Result:
Results shown in (Table. 2).

Table 2: Incidence and severity of Post-Operative Pain following root canal instrumentation using ProTaper Universal, ProTaper Next and WaveOne Systems At day 1, 2, 3 and 7

	No Pain				Mild Pain				Moderate Pain				Sever Pain			
group/days	Day 1	Day 2	Day 3	Day 7	Day 1	Day 2	Day 3	Day 7	Day 1	Day 2	Day 3	Day 7	Day 1	Day 2	Day 3	Day 7
Group 1	9	27	29	30	14	2	1	0	6	1	0	0	1	0	0	0
Group 2	23	30	30	30	7	0	0	0	0	0	0	0	0	0	0	0
Group 3	11	18	25	29	7	8	2	0	10	2	3	1	2	2	0	0

(Table. 2)

for Verbal Rating Scale (VRS) pain scores a statistically significant difference was found between ProTaper Next group and other two groups at day 1 ($P < 0.001$), while there was non-significant difference between WaveOne group and ProTaper Universal Group at day 1 ($P = 0.269$). At day 2: there was significant difference between Wave One group and ProTaper Universal group ($P = 0.032$), also there was significant difference between WaveOne group and ProTaper Next group as well ($P < 0.001$), while there was non-significant difference between ProTaper Next group and ProTaper Universal group ($P = 0.116$). At day 3: there was significant difference between WaveOne group and ProTaper Next group ($P = 0.025$), Also there was non-significant difference between ProTaper Next group and ProTaper Universal group ($P = 1$) and non-significant difference was found between ProTaper Universal and WaveOne groups as well ($P = 0.091$). At day 7: there was non-significant differences among three tested groups ($P \geq 0.05$). When comparing patients who developed no pain, ProTaper Next and ProTaper Universal technique showed significantly better results. When evaluating patients experiencing moderate and sever pain, the incidence of symptoms was significantly higher with the WaveOne single-file technique

Result shown in (Table 3)

Table 3: Incidence of tenderness seven days after root canal instrumentation

Treatment group	No pain to Percussion	Pain to Percussion	Total
Group 1 ProTaper universal	25	5	30
Group 2 ProTaper Next	28	2	30
Group 3 WaveOne	15	15	30

(Table.3)

or tenderness, statistically non-significant difference was found between ProTaper Next group and ProTaper Universal group (P = 0.421), while there was significant difference between WaveOne group and ProTaper Next group (P < 0.001) and significant difference was found between WaveOne group and ProTaper Universal group (P = 0.006).

Discussion

Root canal preparation procedure not easy to performed, so many difficulties we might encounter due to anatomical variety and complexity of root canal system (Gambarini et al, 2013). During root canal instrumentation, a worm of debris includes bacteria, dentin chips, irrigants and other irritants may extrude through the apex to the periradicular area, forcing of these irritants leading to elicit inflammation whose intensity depend on the quantity and the quality of the extruded debris, The greater the amount of extruded debris, the greater severity of reaction will be (Gambarini et al, 2013 and Elham et al, 2009). In other words the intensity of the inflammation directly proportion to the intensity of tissue injury (Siqueira et al, 2002). Therefore, this inflammation that formed as a result of apical extrusion of debris, is the main cause of Post-Operative pain because following injury, chemical substances will released or activated which will mediate the inflammation process such as vasodilation and increase in vascular permeability etc. Therefore, the main inflammatory events that lead to developing of periradicular pain appears to be the increase in vascular permeability leading to exudation and edema formation. These phenomena induce hydrostatic pressure that lead to compression of nerve endings and pain generation, although some mediators can generate pain by direct action on sensory nerve fibers. (Siqueira et al, 2002).

In a previous study by (Gambarini et al. 2012), reciprocating single file techniques found to produce higher inflammatory response and pain when compared to rotary techniques, this is due to the facts that reciprocating motion extrude higher amount of debris than rotary motion, because reciprocation movement is formed by a wider cutting angle and a smaller releasing angle, while rotating in the releasing angle, the flutes will not remove debris but force them apically. Moreover, both WaveOne and Reciproc techniques use a quite rigid, big single-file of increased taper (usually 08 taper, size 25), which directly reach the apex. In many cases, in order to reach the apical working length, reciprocating instruments are used with force directed apically, which makes an effective piston to propel debris from a patent apical foramen. Since instruments are used without any preliminary coronal enlargement. This result in a greater engagement of flutes and, consequently, more torque or pressures is needed (Jayaprada et al 2014, Gambarini et al. 2013, Gambarini et al. 2012, De-Deus et al 2010, Bürklein and Schäfer 2010). Moreover, WaveOne Primary file has longer pitch design when compared to ProTaper Next and Universal ProTaper files, longer pitch design extrudes more debris than shorter pitch design (Elham et al, 2009).

De-Deus et al. 2010. In their study have reported no difference in debris extrusion between ProTaper Universal system and single-file ProTaper F2 used in reciprocating motion (De-Deus et al 2010). However, the results of this present study are in accordance with previous studies by Bürklein and Schafer (Bürklein and Schäfer 2010) which showed reciprocating single-file systems extruded more debris when compared with the full-sequence rotary motion. These findings could explain the higher incidence and severity POP in WaveOne group more than the other two groups (ProTaper Next and Universal ProTaper groups). ProTaper Next group showed the lowest inflammatory response and pain, this might contribute to the unique design of ProTaper Next files (PTN). PTN files have an offset design that produce a traveling mechanical wave of motion along the active portion of a file. This swaggering effect reduce the engagement between the file and dentin wall, also a file with an offset design along with lateral brushing motion give more central preparation and more cross-sectional space for the debris to accumulate and auguring out of the canal rather push them apically (Ruddle 2013). In Vitro study by Kocak et al. 2014, PTN system found to extrude a significantly less amount of debris than Universal ProTaper system (PTU) (13). Also study by Bürklein et al. (Bürklein and Schäfer 2010, Bürklein et al. 2014) found that there was more debris in the apical part of the canals after canal preparation with WaveOne and ProTaper systems as they are both characterized by three cutting edges with radial lands to support the blades and a relatively small chip space (Bürklein et al. 2014). ProTaper Universal and WaveOne are characterized by a triangular or modified triangular cross-section resulting in a lower cutting efficiency and smaller chip space (Bürklein et al. 2014). This design may intensify debris transportation toward the apex when used in combination with a reciprocal movement, while continuous rotation may improve coronal transportation of dentin chips and debris by acting like a screw conveyor (Bürklein and Schäfer 2010).

So based on previous studies (Jonathan et al, 2005, Bürklein and Schäfer 2010, Jayaprada et al 2014, Bürklein et al. 2014 and Nekoofar et al. (2015)) which showed PTU system extrudes less amount of debris than WaveOne system and the latest study by Kocak et al, 2014, Which showed PTN extrude significantly less amount of debris than PTU, so in

turn PTN system extrudes a significantly less amount of debris than WaveOne system. This explain the lowest incidence and severity of pain in ProTaper Next group than other two groups.
Tooth may become tender after the treatment; over instrumentation or forcing debris into the periapical tissues might causing tenderness, this tenderness occur because of increase in blood flow during healing process of the periodontal tissues (Neeta, 2005).
In the present study pain assessment carried out using Verbal Rating Scale (VRS) instead of other type of scales for pain assessment like Visual Analogue Scale (VAS) or Numerical Rating Scale (NRS) because, the VRS is easily assessed, takes less time than the VAS, and can be performed without the need of paper and pen, VRS preferred by the less educated and the elderly. It is relatively simple to understand. As line length in VAS is the response continuum, many patients find it difficult to judge distance accurately. Therefore, the VAS has some practical limitations in a clinic setting (Cork et al, 2003, Marianne et al, 2010). Further studies are warranted to investigate the influence of analgesic records, pain duration and root canal preparation time.

Conclusion:
Since there was no preoperative pain in all cases. The type of tooth, the pulp and periodontal condition were similar among the three tested groups, and the other variables like (operator, irrigation method, and intra-canal medicaments) were similar, the difference in postoperative pain might be related to the different instrumentation systems. Under the condition of this study, ProTaper Next system found to produce the lowest incidence and severity of Post-Operative Pain, while WaveOne System found to produce the highest incidence and severity of Post-Operative Pain.

Limitation of the study
Larger sample size would provide rigorous finding. Pain duration and root canal preparation time had not been considered as a variables in this study, it is suggested that future studies consider with larger sample along with registration of the pain experienced by the patients.

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