Comparison of the Effect of Root Canal Preparation by Using WaveOne and ProTaper on Postoperative Pain: A Randomized Clinical Trial

Mohammad H. Nekoofar, DDS, MSc, DoIBoE, PhD,[*†] *Mohammad S. Sheykhrezae, DDS, MSc, DoIBoE,*[*] *Naghmeh Meraji, DDS, MSc, DoIBoE,*[‡] *Azad Jamee, DDS,*[*] *Armin Shirvani, MD,*[§] *Javid Jamee, PhD,*[||] *and Paul M.H. Dummer, BDS, MScD, PhD, DDSc, FDSRCS(Ed), FHEA*[†]

Abstract

Introduction: WaveOne is a single-file reciprocating instrumentation system with the benefits of M-Wire alloy that has increased flexibility and improved resistance to cyclic fatigue over the conventional alloy. Root canal preparation techniques may cause postoperative pain. The goal of the present study was to compare the intensity and duration of postoperative pain when using WaveOne or ProTaper Universal systems for instrumentation of root canals. **Methods:** Forty-two patients who fulfilled specific inclusion criteria were assigned to 2 groups according to the root canal instrumentation technique used, WaveOne or ProTaper Universal. Root canal treatment was carried out in 2 appointments, and the severity of postoperative pain was assessed by numerical rating scale (NRS) score after each session until complete pain relief was achieved. Analgesic consumption, duration of pain, and root canal preparation time were also recorded. **Results:** The mean NRS score and duration of pain after both appointments were significantly higher in the WaveOne group ($P < .05$); however, the mean analgesic consumption was only significantly higher in the WaveOne group after the first appointment ($P < .05$). In all groups the highest mean NRS score was seen 6 hours after each therapeutic appointment. Canal preparation time was significantly shorter in the WaveOne group ($P < .001$). **Conclusions:** Postoperative pain was significantly lower in patients undergoing canal instrumentation with ProTaper Universal rotary instruments compared with the WaveOne reciprocating single-file technique. *(J Endod 2015;41:575–578)*

Key Words

Postoperative pain, ProTaper, WaveOne

The common factors influencing the occurrence of pain after root canal treatment include insufficient instrumentation, irrigant extrusion, intracanal interappointment dressing extrusion, hyperocclusion, missed canals, presence of preoperative pain, presence of periapical pathosis, apical debris extrusion, and apical patency during root canal preparation (1).

Most nickel-titanium engine-driven instrument systems extrude less debris than stainless steel K-files manipulated by hand because of their rotary action that, when combined with abundant irrigation, has the potential to reduce the risk of postoperative discomfort (2, 3). In 2008 the use of reciprocal motion during root canal preparation was revisited (4). WaveOne (Dentsply Maillefer, Ballaigues, Switzerland) is a single-file M-Wire reciprocating instrumentation system with potential advantages that include a reduced number of instruments, lower cost, reduced instrument fatigue (5, 6), better canal centering ability, reduction of taper lock (7), and the elimination of cross-contamination associated with single-use instruments.

Burklein and Schafer (8) reported that full-sequence rotary instrumentation was associated with less debris extrusion compared with the use of reciprocating single-file systems and suggested that this factor could be associated with less postoperative pain. Because there is no evidence that shows the correlation between debris extrusion and postoperative pain and no clinical evidence has been published regarding the comparison of postoperative pain between these 2 movement systems, the purpose of this study was to compare the incidence and intensity of postoperative pain after use of the WaveOne system and the ProTaper Universal (Dentsply Maillefer) rotary system to prepare root canals in permanent human teeth.

The null hypothesis is that preparation with WaveOne causes the same postoperative pain as ProTaper.

Materials and Methods

This randomized clinical trial was approved by the Ethics Committee of Tehran University of Medical Sciences (Reg. No. 92/s/1421/130) and registered in www.irct.ir (IRCT2013071313970N1).

The sample size calculation, which was based on an error of alpha = 0.05 and a power of 0.8, indicated that ideally a sample size of 21 in each group would be required.

Forty-two consented patients between the ages of 15 and 55 years who were referred to the Endodontic Department of Tehran University of Medical Sciences and

From the *Department of Endodontics, School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran; †Endodontology Research Group, School of Dentistry, College of Biomedical and Life Sciences, Cardiff University, Cardiff, United Kingdom; ‡Department of Endodontics, School of Dentistry, Shahrekord University of Medical Sciences, Shahrekord, Iran; §Faculty of Medical Education, Shahid Beheshty University of Medical Sciences, Tehran, Iran; and ||Payam-Noor University, Tabriz, Iran.

Address requests for reprints to Dr Mohammad S. Sheykhrezae, PO Box 14395-433, North Karegar Avenue, Department of Endodontics, School of Dentistry, Tehran University of Medical Sciences, Tehran 1439955991, Iran. E-mail address: sheykh_r@yahoo.com

0099-2399/$ - see front matter

http://dx.doi.org/10.1016/j.joen.2014.12.026

TABLE 1. Baseline Demographic and Clinical Characteristic of Patients in Each Group

Baseline demographic and clinical characteristic	WaveOne (n = 21)	ProTaper (n = 21)
Male	11	11
Female	11	11
Mean age (y)	38	40
Systemic disease	None	None
Vitality of the pulp	9	10
Molar	11	11
Premolar	11	11
Asymptomatic cases	21	21
Symptomatic cases	0	0

diagnosed with irreversible pulpitis participated in this study. The patients had no symptoms before treatment initiation, and all root canals had a curvature up to 25° when measured according to the method of Schneider (9).

The exclusion criteria were consumption of any type of medication before treatment, presence of internal or external resorption, apical pathosis, sinus tracts, trismus, internal ankylosis, periodontal scoring index less than 3, systemic disease, severe tooth malposition, history of trauma, pregnancy, severe malocclusion associated with a traumatic occlusion, anterior teeth, lack of patient compliance, history of intolerance of nonsteroidal anti-inflammatory drugs, and requiring endodontic retreatment (Table 1).

The patients were randomly stratified into 2 groups of 21 according to the type of tooth and their number of root canals (Table 2). Allocation was done by a person other than the person performing the root canal procedure. After evaluating the patient and tooth that required treatment, the information about each patient and the instrumentation technique assigned to the patient was written and sealed in an envelope, and then the envelope was given to the operator. After working length determination, the operator would open the envelope and use the instrumentation technique assigned to that patient.

All teeth were treated in 2 appointments by the same operator.

Two percent Persocaine-E (lidocaine) with 1/80,000 epinephrine (Daroupakhsh, Tehran, Iran) was applied to achieve profound local anesthesia. Afterwards, the access cavity was prepared, and the tooth was isolated by using rubber dam. The initial working length was then determined with an electronic root canal measurement device (Root ZX; J. Morita, Tokyo, Japan).

Preflaring was not done before working length determination.

Then the working length was established at 0.5 mm up to the radiographic apex and confirmed by 2 blinded operators by taking a periapical radiographic image. Subsequently, root canal preparation was accomplished by 1 of the following 2 instrumentation systems according to the manufacturer's instructions, ProTaper Universal rotary files or WaveOne.

The protocol used for ProTaper Universal rotary files was as follows. An S1 file was introduced with a brushing movement into the canal, 3 mm short of the estimated working length. Afterwards, an SX file was introduced into the canal with a brushing movement two thirds

TABLE 2. Details of Random Stratification of Patients in Each Trial Group According to the Type of Tooth

	Maxillary molars	Maxillary premolars	Mandibular molars	Mandibular premolars
WaveOne group	6	6	5	4
ProTaper group	5	6	6	4

of its blade length, and then S1, S2, and F1 files were used to the working length, respectively. The canal was then assessed with an ISO #20 file. If it would fit snugly at the apex, the preparation would be considered complete, but if the ISO #20 file did not fit properly at the apex, instrumentation would be continued with the F2 file, and the canal would be assessed with ISO #25 file. Once again, if the file would fit snugly at the apex, instrumentation would be considered completed; otherwise, it would be continued with an F3 file.

The protocol used for selecting the initial file in the WaveOne group was as follows. If #010 K-file was very resistant to movement in the root canal, the small file was used. If #020 K-file would easily go to the working length, the large file was used, and in other cases the primary file would be used.

During instrumentation, irrigation was achieved by using 2% chlorhexidine and a side-port closed-end needle (Max-I-Probe; Dentsply International, York, PA), and the access cavity was temporarily sealed by using a reinforced zinc oxide–eugenol cement (Zoliran; Golchai, Tehran, Iran), and the occlusion was checked. No intracanal dressing was applied. The time interval after working length determination until the end of instrumentation and irrigation was recorded. At the end of the first appointment a single dose of 400 mg ibuprofen (Gelofen; Jabberebne Hayyan, Tehran, Iran) was taken by the patient. Nine capsules of 400 mg ibuprofen (Jabberebne Hayyan) were also provided to them. A numerical rating scale (NRS) was used for recording pain levels. For the first 24 hours after treatment, patients were contacted by phone every 6 hours, and the NRS score was recorded. If necessary, depending on the intensity of pain, the patient was allowed to take a dose of analgesic. Afterwards, further NRS scores were recorded every 24 hours until complete pain relief was achieved. The number of analgesics taken by each patient was recorded.

In cases associated with severe pain, after recording the amount of pain, the patient was advised to use the alternative method of pain control including the use of 400 mg ibuprofen and 325 mg paracetamol alternatively every 2 hours.

If patients had side effects when using nonsteroidal anti-inflammatory drugs, they were excluded from the study.

At the second appointment 1 week after the first appointment, after removing the temporary coronal filling, the root canal(s) were irrigated by using 1 mL 17% EDTA (Ariadent, Tehran, Iran) to remove the smear layer, and the root canals were filled with gutta-percha (Meta Biomed, Cheongju, Korea) and AH26 (Dentsply DeTrey, Konstanz, Germany) sealer by using a lateral compaction technique. Afterwards, Zonalin

TABLE 3. Mean Numerical Rating Scale Scores of the WaveOne and ProTaper Groups in Various Time Intervals after Both Appointments

	After treatment before medication consumption	After 6 h	After 12 h	After 18 h	After 24 h	After 48 h	After 72 h
WaveOne							
First visit	0.13 ± 0.6	2.86 ± 2.2	2.18 ± 2.3	1.95 ± 2.6	1.00 ± 2.3	0.86 ± 2.5	0.36 ± 1.3
Second visit	0.23 ± 0.7	1.23 ± 1.4	0.86 ± 1.4	0.41 ± 0.9	0.05 ± 0.2	0.05 ± 0.2	0.00 ± 0.0
ProTaper							
First visit	0.55 ± 1.4	1.27 ± 2.3	0.86 ± 1.7	0.59 ± 1.6	0.55 ± 1.6	0.00 ± 0.0	0.00 ± 0.0
Second visit	0.00 ± 0.0	0.09 ± 0.4	0.09 ± 0.4	0.00 ± 0.0	0.00 ± 0.0	0.00 ± 0.0	0.00 ± 0.0

TABLE 4. Mean Time of Pain Relief in Each Experimental Group

	WaveOne (h)	ProTaper (h)
First visit	17.45 ± 20.7	5.45 ± 9.0
Second visit	7.36 ± 11.0	0.55 ± 2.5

TABLE 5. Mean Analgesic Consumption by Patients in Each Group

	WaveOne	ProTaper
First visit	2.36 ± 2.2	1.23 ± 0.06
Second visit	1.23 ± 0.9	1.0 ± 0.0

(Golchai, Iran) was used as temporary coronal filling material, and the patient's pain was recorded immediately at the end of the procedure. The data were then analyzed statistically by multivariate analysis of variance and the *t* test. Differences were considered statistically significant at $P < .05$. A 95% confidence interval was obtained.

Results

The mean NRS scores at the various time intervals associated with each canal preparation technique are shown in Table 3. The intensity and duration of pain experienced after both appointments by patients in the WaveOne group were significantly higher than in the ProTaper group ($P < .05$) (Tables 3 and 4). In both groups the highest NRS scores were recorded 6 hours after each appointment, after which the NRS scores decreased; however, 12 hours after the second session in the ProTaper group, the mean NRS score was similar to that at 6 hours and then decreased (Fig. 1). A significant difference occurred between the intensity and duration of pain experienced by patients in the WaveOne group at the various time intervals after both appointments ($P < .001$). On the contrary, in the ProTaper group no significant difference was seen between the NRS scores at the various time intervals after each treatment session. None of the patients encountered severe pain resulting in the use of the alternative pain control protocol.

The mean analgesic consumption by patients in each group is shown in Table 5. The consumption was significantly higher in the WaveOne group after the first appointment ($P < .05$), but no difference was seen between the 2 groups after the second session.

The canal preparation time was significantly shorter in the WaveOne group in comparison with the ProTaper group (3.17 ± 2.18 hours versus 5.32 ± 1.24 hours, $P < .01$).

Discussion

The primary aim of this study was to investigate the influence of root canal instrumentation with WaveOne versus ProTaper Universal rotary files on the incidence and intensity of postoperative pain. Therefore, all other variables such as the type of irrigation were consistently kept similar in both groups without any preference regarding the use of 2% chlorhexidine over other irrigants. However, it has been shown that 2% chlorhexidine has similar antimicrobial effects as 5.25% sodium hypochlorite (10, 11); the latter remains the most extensively chosen intracanal irrigant (12) because the former cannot dissolve pulp tissue and needs more time to accomplish the same antimicrobial effects (12). In addition, to increase the antibacterial effects of chemomechanical procedures and eradicate residual bacteria from root canal system, the use of an interappointment medication has been recommended (13). In our study to avoid the possible confounding effect of intracanal medication on postoperative pain (14, 15) and to reduce the number of variables, no intracanal dressing was used between the appointments. For future study the effects of various irrigants and intracanal medications on postoperative pain and long-term outcome of root canal treatment are suggested. Furthermore, considering the fact that the active time of canal preparation required when using an instrumentation system is an important factor considered by most clinicians, not least because of its impact on patient overall comfort and time available for irrigation, the preparation time of each of the evaluated instrumentation systems was also calculated. The WaveOne system required a significantly shorter time for instrumentation because only 1 file was used, whereas when using the ProTaper system, 6 files were used. Moreover, it has been shown that the application of reciprocating movement instead of full rotation decreases the preparation time (16).

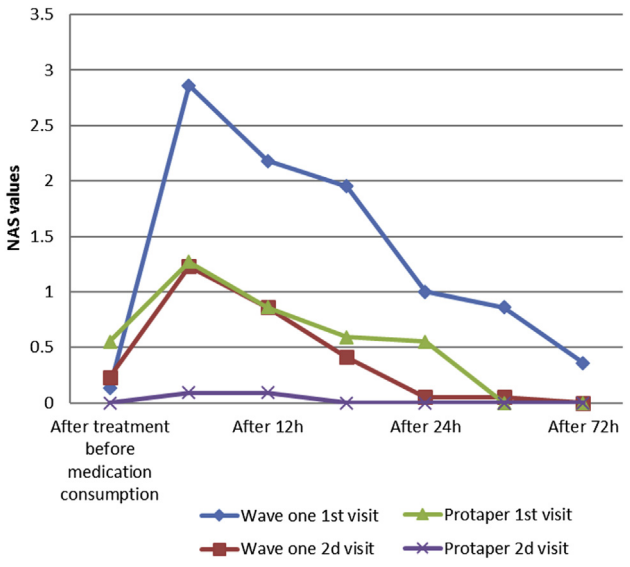

Figure 1. Mean NRS scores of the WaveOne and ProTaper groups in various time intervals after both appointments.

The intensity and duration of postoperative pain after both appointments were significantly higher in patients in the WaveOne group. However, Farrar et al (17) reported that in the case of mild pain (0–3.4 NRS values), a 2-point change in the NRS scores represented a clinically significant difference in the pain experienced by patients. Therefore, it is likely that the statistically significant difference seen in the intensity of pain between the 2 groups in this study is not likely to be clinically significant (Fig. 1). In addition, the differences seen in the intensity of pain did not affect the choice of analgesic. It should be noted that the results of only 1 clinical study cannot be generalized to all clinical cases, and more studies regarding this matter are required.

The results of laboratory studies demonstrate that all canal preparation techniques are associated with dentin debris extrusion from the root canal system even if the preparation ends shorter than the apical terminus (18–20). It has been reported that extrusion of microorganisms (21, 22), materials, or dentin debris into the periradicular area causes inflammation (15) and may be related to postoperative pain and flare-ups (15). The amount of debris extrusion (8, 19, 23) and neuropeptides released from C-type nerve fibers present in the periodontal ligament (24) differ between instrumentation techniques, and this difference has been suggested as a reason why there are differences in postoperative pain experienced by patients.

Burklein and Schafer (8) demonstrated that full-sequence rotary instrumentation was associated with less debris extrusion when compared with the use of reciprocating single-file systems. Continuous rotation may improve coronal transportation of dentin chips and debris by acting like a screw conveyor, therefore resulting in less apical debris

extrusion. This may explain the higher pain intensity, analgesic consumption, and longer pain duration in the WaveOne group. Furthermore, in the WaveOne single-file instrumentation technique, a relatively rigid, large single file with a greater taper is moved apically until it reaches the working length. This method may create a piston effect and push debris through a patent apical foramen (25).

Caviedes-Bucheli et al (24) evaluated the expression of substance P and calcitonin gene-related peptide in the periodontal ligament of humans after the use of single-file reciprocating systems and concluded that the amount of neuropeptide expression was higher in teeth where the root canals were prepared with the WaveOne system. They suggested that the concave triangular cross section at the tip end of the files, the convex triangular cross section at the coronal end, and reduced depth of flutes limited the coronal transportation of dentin debris and increased apical debris extrusion, resulting in a higher neuropeptide concentration. It should be noted that substance P and calcitonin gene-related peptide activate G protein coupled receptors on nociceptors, leading to the sensitization or activation of neurons (26), and these neuropeptides can cause peripheral sensitization characterized as hyperalgesia, allodynia, and spontaneous pain (27). Furthermore, central sensitization is initiated by a barrage in C-fiber inputs with sufficient intensity and duration; therefore, both peripheral and central sensitization may have a role in the pain experienced by patients in the WaveOne group. Further studies regarding the possible role of central pain mechanisms on postoperative pain experienced by patients are required.

WaveOne instruments are used without coronal enlargement; however, in the ProTaper group, the Sx file used initially was primarily included for the purpose of coronal flaring. It has been shown that the crown-down technique is associated with less debris extrusion compared with other instrumentation techniques (28). Therefore, it is possible that early preflaring is associated with less debris extrusion and postoperative pain.

In the current study a trend was seen regarding the intensity of pain experienced by patients after each therapeutic session. The greatest intensity of pain was recorded 6 hours after each appointment, and afterwards it decreased. Other studies also revealed a similar pattern (29, 30).

Future research comparing the postoperative pain experienced by symptomatic patients after root canal preparation with reciprocating and full rotational instruments is suggested.

Conclusion

Postoperative pain lasted longer and was more intense in patients treated with the WaveOne system compared with the ProTaper Universal system. However, the differences seen in the intensity of pain may not be clinically significant and did not affect the analgesic regime chosen by patients.

Acknowledgments

This study was supported by a grant from Tehran University of Medical Sciences (no. 92-03-69-22904).

The authors deny any conflicts of interest related to this study.

References

1. Alves Vd O. Endodontic flare-ups: a prospective study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2010;110:e68–72.
2. Vaudt J, Bitter K, Neumann K, Kielbassa AM. *Ex vivo* study on root canal instrumentation of two rotary nickel-titanium systems in comparison to stainless steel hand instruments. Int Endod J 2009;42:22–33.
3. Madhusudhana K, Mathew VB, Reddy NM. Apical extrusion of debris and irrigants using hand and three rotary instrumentation systems: an *in vitro* study. Contemp Clin Dent 2010;1:234–6.
4. Yared G. Canal preparation using only one Ni-Ti rotary instrument: preliminary observations. Int Endod J 2008;41:339–44.
5. Pedulla E, Grande NM, Plotino G, et al. Influence of continuous or reciprocating motion on cyclic fatigue resistance of 4 different nickel-titanium rotary instruments. J Endod 2013;39:258–61.
6. Gavini G, Caldeira CL, Akisue E, et al. Resistance to flexural fatigue of Reciproc R25 files under continuous rotation and reciprocating movement. J Endod 2012;38:684–7.
7. Roane JB, Sabala C. Clockwise or counterclockwise. J Endod 1984;10:349–53.
8. Burklein S, Schafer E. Apically extruded debris with reciprocating single-file and full-sequence rotary instrumentation systems. J Endod 2012;38:850–2.
9. Schneider SW. A comparison of canal preparations in straight and curved root canals. Oral Surg Oral Med Oral Pathol 1971;32:271–5.
10. Gomes BP, Ferraz CC, Vianna ME, et al. *In vitro* antimicrobial activity of several concentrations of sodium hypochlorite and chlorhexidine gluconate in the elimination of *Enterococcus faecalis*. Int Endod J 2001;34:424–8.
11. Vianna ME, Gomes BP, Berber VB, et al. *In vitro* evaluation of the antimicrobial activity of chlorhexidine and sodium hypochlorite. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2004;97:79–84.
12. Siqueira JF Jr, Rocas IN. Clinical implications and microbiology of bacterial persistence after treatment procedures. J Endod 2008;34:1291–301.
13. Anjaneyulu K, Nivedhitha MS. Influence of calcium hydroxide on the post-treatment pain in endodontics: a systematic review. J Conserv Dent 2014;17:200–7.
14. Ehrmann EH, Messer HH, Adams GG. The relationship of intracanal medicaments to postoperative pain in endodontics. Int Endod J 2003;36:868–75.
15. Seltzer S, Naidorf IJ. Flare-ups in endodontics: I—etiological factors. J Endod 1985;11:472–8.
16. Jin SY, Lee W, Kang MK, et al. Single file reciprocating technique using conventional nickel–titanium rotary endodontic files. Scanning 2013;35:349–54.
17. Farrar JT, Young JP Jr, LaMoreaux L, et al. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94:149–58.
18. Logani A, Shah N. Apically extruded debris with three contemporary Ni-Ti instrumentation systems: an *ex vivo* comparative study. Indian J Dent Res 2008;19:182–5.
19. Ferraz CC, Gomes NV, Gomes BP, et al. Apical extrusion of debris and irrigants using two hand and three engine-driven instrumentation techniques. Int Endod J 2001;34:354–8.
20. Kustarci A, Akpinar KE, Er K. Apical extrusion of intracanal debris and irrigant following use of various instrumentation techniques. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2008;105:257–62.
21. Siqueira JF Jr. Microbial causes of endodontic flare-ups. Int Endod J 2003;36:453–63.
22. Siqueira JF Jr, Rocas IN, Favieri A, et al. Incidence of postoperative pain after intracanal procedures based on an antimicrobial strategy. J Endod 2002;28:457–60.
23. Nair PN, Henry S, Cano V, Vera J. Microbial status of apical root canal system of human mandibular first molars with primary apical periodontitis after "one-visit" endodontic treatment. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2005;99:231–52.
24. Caviedes-Bucheli J, Moreno JO, Carreno CP, et al. The effect of single-file reciprocating systems on substance P and calcitonin gene-related peptide expression in human periodontal ligament. Int Endod J 2013;46:419–26.
25. Gambarini G, Testarelli L, De Luca M, et al. The influence of three different instrumentation techniques on the incidence of postoperative pain after endodontic treatment. Ann Stomatol (Roma) 2013;4:152–5.
26. Henry MA, Hargreaves KM. Peripheral mechanisms of odontogenic pain. Dent Clin North Am 2007;51:19–44. v.
27. Nakamura-Craig M, Smith TW. Substance P and peripheral inflammatory hyperalgesia. Pain 1989;38:91–8.
28. al-Omari MA, Dummer PM. Canal blockage and debris extrusion with eight preparation techniques. J Endod 1995;21:154–8.
29. Pak JG, White SN. Pain prevalence and severity before, during, and after root canal treatment: a systematic review. J Endod 2011;37:429–38.
30. DiRenzo A, Gresla T, Johnson BR, et al. Postoperative pain after 1- and 2-visit root canal therapy. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2002;93:605–10.