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Incidence and severity of postoperative pain after canal instrumentation with reciprocating system, continuous rotary single file system, versus SAF system

Key words *Nickel-Titanium instruments, One Shape, Self Adjusting File, WaveOne*

Objective: To evaluate the incidence and severity of postoperative pain and analgesics intake after root canal treatment of molars using single file systems: WaveOne (WO; Dentsply Maillefer, Ballaigues, Switzerland) and One Shape (OS; Micro Méga, Besançon, France) versus the Self Adjusting File (SAF; ReDentNova, Ra'anana, Israel).

Methods: One hundred and forty-one patients with vital molars indicating for conventional single-visit root canal treatment were randomly assigned to one of three groups (n = 47) according to the instrumentation system used: WaveOne, One Shape and SAF. Participants were asked to rate the intensity of postoperative pain on a Functional Pain Scale and to record the quantity of prescribed analgesic medication taken after 24 h, 48 h, 72 h and 7 days.

Data were statistically analysed using SPSS software (version 20; Chicago, Illinois, USA). Intergroup analysis was performed using the Kruskal-Wallis, followed by Mann-Whitney U tests for intragroup comparison. The Friedman test was applied for comparison between different time intervals. The level of significance was set at $P < 0.05$.

Results: Patients treated with the SAF system were associated with significantly less postoperative pain and lower analgesic intake compared to the other two groups at the four timepoints assessed.

Conclusion: The SAF system caused less postoperative pain and lower intake of analgesic medication at the timepoints assessed.

Introduction

A major complication of root canal treatment is the frequent pain[1]. Postoperative pain, defined as a sensation of discomfort after endodontic intervention, is reported in 25% to 40% of patients, irrespective of pulp or periradicular status[2,3]. According to Pak and White, the prevalence of pain in the first 24 h is 40%, falling to 11% after 7 days[4]. Although root canal treatment reduces the prevalence and severity of pain, the immediate post-treatment pain severity levels may sometimes slightly exceed the pre-treatment severity levels. The cause of this maybe the extrusion of dentinal debris, pulp tissue, microorganisms and irrigants into the periradicular tissues during root canal preparation, leading to inflammation of the tissues, which is especially exacerbated by pre-existing periradicular inflammation[4]. The extruded debris can lead to postoperative complications, such as flare-ups[5]. Therefore adequate control of working length may reduce the extrusion of material through the apical foramen but cannot prevent this completely[6]. All root canal preparation techniques and instruments available to date are still associated with some degree of apical extrusion of debris[7-9].

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Recently, the concept of single file root canal preparation was introduced, which requires a shorter period of time to prepare curved canals[10]. The WaveOne (WO) Nickel-Titanium (Ni-Ti) file system (Dentsply Maillefer, Ballaigues, Switzerland) is a single file system working in a reciprocating motion that involves initial rotation of the instrument in a counterclockwise direction, in which the instrument penetrates and cuts the dentin; followed by rotation in the opposite direction, during which the instrument is released. The One Shape (OS) Rotary Ni-Ti files (Micro Méga, Besançon, France) work in a continuous clockwise rotation. These files are designed with a variable cross-section along the blade of the instrument in order to increase their flexibility and reduce the instrument screwing effects.

The Self-Adjusting File (SAF; ReDentNova, Ra'anana, Israel) is also a single file system with a hollow compressible design. The SAF, accompanied by continuous irrigation with any desired solution, is used in a vibrating movement.

The purpose of the present study was to clinically compare the incidence of postoperative pain after root canal instrumentation of posterior teeth using single file systems: the Reciprocating System (WaveOne), Continuous Rotary System (One Shape) and Self Adjusting Files. Analgesic medication intake by patients was also studied.

Materials and methods

Patient selection and study protocol

The clinical study protocol was reviewed and approved by the University Research Ethical Committee. The subjects were treated in accordance with the Declaration of Helsinki and received thorough explanations concerning the experimental rationale, clinical procedures and possible complications of the procedures. Every selected patient signed an informed consent form. On receiving their informed consent, a total of 141 patients (aged 30 to 55 years) were included in the study. The sample size calculation was done using Cochran's method (1986). Based on a type I error of 5%, a confidence interval of 95% and 80% power, the sample size was calculated as 47 subjects per group. Two experienced operators, who were specialists in endodontics with over 4 years of practice, performed the clinical portion of this study.

All 141 patients were consecutively and independently selected between January and December 2015 from the specialists' private practice, which characterises the multicenter profile of the current setup. All participants had maxillary and mandibular molar teeth exhibiting normal root canal anatomy (maxillary: one of each root canal - mesiobuccal, distobuccal and palatal; mandibular: one of each root canal - mesiobuccal, mesiolingual and distal), diagnosed with symptomatic irreversible pulpitis (teeth containing vital pulps, that were exposed due to trauma, caries or mechanical reasons) or teeth indicating for intentional pulpectomy due to prosthetic reasons. The diagnosis of the tooth being treated was established by an experienced endodontist (more than 20 years into specialty practice), and confirmed by a radiologist. Patients were excluded from the study if they had non-vital teeth or third molars, apical periodontitis, endodontic retreatment, root resorption, immature/open root apex or a root canal in which patency of the apical foramen could not be established.

Patients refusing to participate in the study included those whose teeth had issues precluding single-visit treatment; those who had used any type of medication preoperatively, such as nonsteroidal or steroidal anti-inflammatory drugs or analgesics; and patients with any uncontrolled systemic disease.

Appropriate history (medical and dental), examination, investigation (intraoral periapical digital radiograph and cold test using 1,1,1,2-tetrafluoroethane), diagnosis and treatment planning preceded treatment in all patients. Occlusal adjustment was carried out and carious teeth were appropriately restored. Diagnostic findings were checked by comparing the tooth's response with that of an adjacent tooth with a vital pulp.

Treatment Protocol

In the current study, three clinicians, who were well trained in using the three different file systems (WO, OS and SAF), who had been using these instruments for a minimum of 3 years, performed the root canal treatment. After administering local anaesthesia

using 2% Lidocaine and 1:100,000 Epinephrine (Xylocaine; Dentsply Pharmaceutical, Pennsylvania), a rubber dam was applied and an access cavity was established, utilising a dental operating microscope (Opmi Pico, Carl Zeiss, Oberkochen, Germany). Disinfection of the tooth and the rubber dam was carried out by scrubbing a cotton roll, moistened with 5.25% of NaOCl, in a circular movement, starting from the tooth and going outwards to the rubber dam. The pulp chamber was rinsed with 3% sodium hypochlorite irrigant solution and using a watch-winding motion, the canals were explored with sizes 06, 08, 10 and 15 K-type hand files (Dentsply Maillefer) according to the initial diameter of the foramen and the canal curvature. The working length (WL) was established by introducing a size 10 K-file to the apical foramen as determined by an apex locator (i-Root, Micro Méga), and radiographically confirmed. All instruments were driven by a torque controlled endodontic motor (WaveOne Endomotor, Dentsply Maillefer). WO instruments were applied in a reciprocating mode, OS was used in a continuous rotary motion and SAF was operated in transline in-and-out vibration. Torque limits and rotation speeds were pre-set individually for each file system used. On reaching the WL after each file insertion, irrigation with 2 ml of 2.5% sodium hypochlorite was performed with a 24 G needle (Max-I-Probe; Dentsply Tulsa Dental, Pennsylvania, USA) during access and canal exploration and with a 31 G Navi Tip needle (Ultradent Products, Utah, USA). The teeth were randomly allocated to the three different instrumentation systems:

Group One (Wave-One; WO): Using Glyde (Dentsply Maillefer) as the lubricating agent, the glide path was created with PathFiles sizes 1, 2 and 3 (Dentsply Maillefer) until the full WL. The WO primary file (25.08) was used to prepare narrow and curved canals, and the WO large file (40.08) was used for large canals. Three in-and-out motions were applied in the cervical, middle and apical thirds, with an amplitude not exceeding 3 mm, until the established WL was attained.

Group Two (One Shape; OS): The glide path was created with G-Files (Micro Méga) until the full WL. Shaping was finished with OS files (size 25 and 6% taper) in a continuous mode of rotation. In-out strokes, dependent upon the complexity of the root canal anatomy were given in three steps without applying any pressure: up to one third of the WL; up to 3 mm short of the WL; and up to the WL.

Group Three (Self Adjusting File; SAF): The glide path was established up to a size 20 K-file in order to facilitate effective placement of the SAF until the apex, as described by Solomonov[11]. The root canal orifices were then enlarged using the Gates Glidden drill (Mani, Tochigi, Japan) size 2, followed by placement of the SAF up to the WL, which was confirmed radiographically. SAF 1.5 mm was used to prepare narrow and curved canals, and SAF 2.0 mm was used for large canals. The files were operated using a RDT3 handpiece head (ReDentNova) with a torque-control motor (WaveOne Endomotor, Dentsply Maillefer) at a frequency of 83.3 Hz (5000 movements per min) with an amplitude of 0.4 mm. In accordance with the manufacturers' instructions, it was used in a pecking motion for 4 min. The SAF was connected to a Vatea system irrigator (ReDent Nova) that pumped 2.5% sodium hypochlorite at a rate of 5 ml/min in a continuous flow.

Glyde File Prep (Dentsply Maillefer) was used as a canal lubricant before utilising each instrument. All instruments were used in only one tooth (single use) and then discarded. During all root canal preparations, apical patency was maintained by introducing a size 10 or size 15 K-file (Dentsply Maillefer) about 1 mm beyond the WL at each instrument change. In concluding the instrumentation, a size 25 hand K-file (with the SAF group: usually a size 30 K-type file) was checked for the previously agreed length and for apical gauging. The access cavity was flushed using 1 ml of 2.5% NaOCl and the solution was ultrasonically agitated for 1 min per root canal with a size 20/25 Irrisafe tip (Satelec Acteon Group, Merignac, France) placed inside the root canal up to 2 mm short of the WL. To remove the smear layer, 5 ml of a 17% EDTA solution was used and ultrasonic agitation was performed for 1 min. Irrigation was repeated with 5 ml of 2.5% NaOCl, and finally with 5 ml of 0.9% saline solution. The final aspiration was performed, using a capillary tip (Ultradent). An average of 40 ml of irrigant was used for root canal preparation of each tooth. All root canals were then dried, using absorbent paper points. Using the continuous wave of condensation technique, the canals were subsequently obturated with the gutta-percha cones of the

Table 1 Baseline demographic and clinical features of patients in the study groups.

Baseline demographic data and clinical features	WO Group N (%) (n = 47)	OS Group N (%) (n = 47)	SAF Group N (%) (n = 47)	Total (n = 141)
Male	28 (36.4)	27 (35.0)	22 (28.6)	77
Female	19 (29.7)	20 (31.2)	25 (39.1)	64
Maxillary teeth	26 (35.6)	23 (31.5)	24 (32.9)	73
Mandibular teeth	21 (30.9)	24 (35.3)	23 (33.9)	68

respective systems (for WO:25/0.08, OS:25/0.06 and SAF: usually 30.04 master cones were used. For SAF, as there is no taper or no definite size of apical preparation, the master cones were selected following apical gauging [which master cone felt a tug-back] and AH-Plus sealer [Dentsply Maillefer]).

The treatment phase was concluded by sealing the coronal access cavity with a dentine adhesive and composite resin (Filtek Bulk Fill, Posterior Restorative 3M Dental Products, Minnesota, USA).

A post-obturation radiograph was taken to confirm the quality of obturation. On completion of the root canal treatment procedure, each patient was instructed in the event of pain, to take analgesics (400 mg Ibuprofen) at a dosage of 1 tablet every 6 h.

Postoperative pain assessment

On completion of treatment, each patient was given a questionnaire based on the Functional Pain Scale to record the assessment of pain and analgesic intake (frequency and quantity) after 24 h, 48 h, 72 h and 7 days. After the defined time intervals the patients were asked by the clinical assistant to provide the following information over the telephone. This included their perceived pain rating, whether they had taken the analgesic medication prescribed and, if so, the quantity of tablets and the number of days that were required to control the pain. Each patient was instructed, in the event of severe pain or any other type of emergency, to contact the clinician in charge of the treatment.

Statistical analysis

The recorded data was compiled, entered in a spreadsheet computer program (Microsoft Excel 2007), and then exported to SPSS version 20.0 (SPSS, Illinois, USA). Nonparametric tests were applied since the data was non-normal and categorical. For intergroup comparison (between groups) the Kruskal-Wallis test was applied, followed by the Mann-Whitney U test for intragroup comparison (within the group) based on gender and dosage. The Friedman test was applied for comparison between different time intervals.

Results

The baseline demographic data and clinical features of the patients are summarised in Table 1.The mean age of the 141 patients was 36 ± 14 years. The recorded postoperative pain values in the SAF group were significantly lower when compared with the pain values of the WO and OS groups, while no significant differences were observed between the WO and OS groups (Table 2) at any of the four time intervals assessed. The highest postoperative pain scores in all the instrumentation groups were recorded after 24 h, with a decline thereafter (Table 3).

When compared with the other two groups, the analgesic intake was significantly lower in the SAF instrumentation group. However, no significant difference in the analgesics intake was observed between the WO and OS groups (Table 4). None of the 141 patients reported severe pain or any flare-ups during the study.

Discussion

One problem encountered when studying pain is the difficulty in evaluation, both for patients and professionals, because of the threshold range. This issue is

Table 2 Descriptive statistics and Kruskal-Wallis test applied to the postoperative pain results for the groups instrumented with WO, OS and SAF file systems.

	Score	Group 1 (WO)	Group 2 (OS)	Group 3 (SAF)	*P* Value	Intragroup comparison
Time 1 (after 24 h)	0	0	0	14	0.001	Group 3 significant to Group 1 and 2 No significance between Group 1 and 2
	1	1	7	23		
	2	29	24	8		
	3	17	16	2		
Time 2 (after 48 h)	0	0	2	29	0.001	Group 3 significant to Group 1 and 2 No significance between Group 1 and 2
	1	15	16	17		
	2	31	25	1		
	3	1	4	0		
Time 3 (after 72 h)	0	2	8	43	0.001	Group 3 significant to Group 1 and 2 No significance between Group 1 and 2
	1	37	31	4		
	2	8	8	0		
	3	0	0	0		
Time 4 (after 1 week)	0	27	35	47	0.001	Group 3 significant to Group 1 and 2 No significance between Group 1 and 2
	1	20	12	0		
	2	0	0	0		
	3	0	0	0		
Test applied: Kruskal-Wallis test (intergroup comparison) followed by Mann-Whitney U test (intragroup comparison) $P \leq 0.001$ (highly significant)						

Table 3 Mean postoperative pain scores after instrumentation with WO, OS and SAF file systems at the four timepoints assessed (24 h, 48 h, 72 h and 7 days).

	Time 1 (after 24 h)	Time 2 (after 48 h)	Time 3 (after 72 h)	Time 4 (after 1 week)	*P* Value
Group 1 (SAF)	3.78	2.93	2.09	1.21	0.001
Group 2 (WO)	3.68	2.98	2.09	1.26	0.001
Group 3 (OS)	3.41	2.62	2.05	1.91	0.001
Test applied: Friedman Test, $P \leq 0.001$ (highly significant)					

Table 4 Descriptive statistics of analgesic dose (frequency x dosage of 1 tablet, 400 mg) to control postoperative pain after instrumentation at different time intervals.

Time interval	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	Group 3 (Mean ± SD)	*P* Value	Intragroup comparison
Time 1 (after 24 h)	680.85 ± 262.62	672.34 ± 277.96	374.46 ± 357.81	0.001	Significant between 1 and 3 Significant between 2 and 3
Time 2 (after 48 h)	502.13 ± 317.25	570.21 ± 309.21	195.74 ± 342.59	0.001	Significant between 1 and 3 Significant between 2 and 3
Time 3 (after 72 h)	187.23 ± 233.70	297.87 ± 306.09	0	0.001	Significant between 1 and 3 Significant between 2 and 3
Time 4 (after 1 week)	59.57 ± 143.94	51.06 ± 134.92	0	0.027	
Test applied: Kruskal-Wallis test (intergroup comparison) followed by Mann-Whitney U test (intragroup comparison)					

confused by single and variable experience; and pain modulation by various physical and psychological factors. Many techniques have been used to assess pain intensity in human beings as described in the literature such as verbal, functional, numerical, visual analogue, coloured analogue and finger-reach rating scales; calibrated questionnaires; and cortical evoked potentials. The Functional Pain Scale used in the present study is an effective way to assess pain, which has proven to be helpful in identifying changes in pain. A study by Gloth et al compared the Functional Pain Scale, the Present Pain Intensity scale, the Visual Analogue Scale, the McGill Short-form questionnaire and the Numeric Pain Scale. The highest responsiveness was found in the Functional Pain Scale[12].

Preoperative pain is one of the strongest predictors of postoperative pain[13]. In an effort to isolate potential factors of postoperative pain from those strictly related to the instrumentation technique, non-vital teeth, symptomatic/asymptomatic apical periodontitis and endodontic retreatment were all excluded. Studies reported significantly lower postobturation pain in single-visit treatment when compared with a multiple-visit approach[14-16]. This may be attributed to immediate obturation, thereby avoiding complications of intracanal medications, repeated instrumentation and irrigation[17,18]. Nonetheless, a few studies also showed no significant difference in effectiveness (healing rates) and postoperative pain between these two treatment regimens[19,20]. Considering these factors, the single-visit root canal treatment procedure was chosen.

Although interappointment flare-up is uncommon, postoperative pain is relatively frequent; it is related to several factors, including infection, retreatment, preoperative pain, intracanal medication and physical and chemical damage to periapical tissues[5,21]. Possible causes of sustained postobturation pain include inadvertently missed strands of pulp tissue; possible extrusion of irrigant beyond the apex; failure to adequately seal the access cavity; and even non-cooperation of the patient with respect to postoperative instructions[22,23].The extrusion of infected debris into the periradicular tissues during chemomechanical preparation is considered to be one of the principal causes of postoperative pain[5]. Any injury to the periapical tissue during root canal treatment promotes more intensive secretion of inflammatory mediators, such as prostaglandins, serotonin, leukotrienes, histamine and bradykinin (all of which are also pain mediators)[24]. Root canal preparation techniques significantly diverge in terms of the amount of extruded debris, with some techniques extruding less than others. In the present study, the low pain rates observed in the SAF group could be related to a lower apical extrusion of bacteria, irrigants, dentin chips and inflamed pulp tissue, which could elicit postoperative pain. SAF is a single-file system which is devoid of a central metal core or any cutting edge or flutes; instead, it has an abrasive surface and is associated with continuous simultaneous irrigation. This continuous flow of the irrigant does not build up any pressure in the root canal, as the metal meshwork allows free escape of the irrigant. The SAF is effective in the narrowest apical part of a canal prepared up to a size 20 K-file, leaving more than 38% of the canal cross-section free for the backflow of fluid and dentinal debris[25]. De Melo Ribeiro et al stated that, in the apical third, the SAF system created cleaner inner canal walls when compared to a rotary system[26]. The results of this study demonstrated similar pain values in both the reciprocating and rotary instrumentation groups. This is supported by studies carried out regarding debris extrusion by De-Deus et al[27] and Kocaket al[28], who reported no differences between rotary and reciprocating movements. In contrast, previous studies have concluded that reciprocating systems can lead to a greater amount of extruded debris or debris remnants in the root canal than in rotary systems[8,29]. The WO files exhibit a larger taper of 0.08 at the apical 3 mm, which can be attributed to excessive debris formation apically and extrusion periapically.

Nonsteroidal anti-inflammatory drugs have been recommended as the medication of choice for postoperative pain management after root canal treatment and Ibuprofen has been included in several studies on pain relief that investigated the effects of different techniques and medications after root canal treatment procedures[30]. It is possible due to less periapical inflammation caused by reduced debris extrusion using the SAF system, the results of the present study demonstrated a lower intake of Ibuprofen by patients who underwent instrumentation by the SAF system when compared to the other two file systems.

The results obtained from the current study may be explained by differences in the instrument design and movement kinematics between the WO, SAF and OS file systems. In the present study, variations in the manipulation method were minimised by using protocols based on the manufacturers' recommendations. Instrumentation on root thirds, using three in-and-out motions with an amplitude not exceeding 3 mm was carried out with the reciprocating system, and for cases where the rotary system was used, a brushing action was employed. The Self-Adjusting File was operated with a trans-line in-and-out vibration accompanied by continuous irrigation with sodium hypochlorite solution.

In analysing the time course of reported pain, the overall intensity of postoperative pain was found to be greater after 24 h of root canal treatment but declined thereafter. These findings are in agreement with those of several authors[31-33].

The psychosocial factors of the participants in this study were not comprehensively assessed. Their absence could be a limiting factor in the study findings since, in other types of procedures, research exploring postoperative pain repeatedly demonstrates their significance as predictors[34].

Conclusion

In comparison with the other two types of Ni-Ti instruments assessed in the study, the Self Adjusting File system produced minimal postoperative pain after single-visit root canal treatment.

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