



Post-Endodontic Pain after Root Canal Treatment of Symptomatic Teeth with Mtwo and Safe Sider Multiple File Systems: A Randomized Clinical Trial

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Abstract

Background: Considering the increasing popularity of rotary files among dental clinicians and the emergence of several types of rotary systems, clinical trials are necessary to compare these systems from various aspects.

Objectives: This study compared post-endodontic pain following the use of Mtwo and Safe Sider multiple file system.

Methods: A total of 150 maxillary and mandibular molars with symptomatic irreversible pulpitis were selected. Their root canals were randomly instrumented with hand files, Mtwo and Safe Sider instruments. The severity of postoperative pain was assessed using a Visual Analog Scale (VAS) at 6, 12, 24, 48 and 72 hours. The data were analyzed using repeated measures ANOVA. $P < 0.05$ was considered statistically significant.

Results: The mean postoperative pain score significantly decreased in all three groups over time. The mean pain score at 12 and 24 hours post-treatment was significantly higher in the

Safe Sider group compared to the other two groups. At 6, 48 and 72 hours, no significant difference was noted in the severity of pain among the three groups.

Conclusions: Postoperative pain is significantly higher at 12 and 24 hours following endodontic treatment with Safe Sider compared to the conventional hand instruments and Mtwo system.

Keywords

Instrumentation; Post-Operative Pain; Root Canal Preparation

Introduction

Postoperative pain is among the major complaints of patients who have undergone endodontic treatment [1]. The prevalence of post-endodontic pain has reported to be 10.6% to 82.9% [2,3]. Many factors such as age and sex of patients, type of treated tooth, size of apical foramen preparation, extrusion of debris, expertise and skills of the clinician, presence of occlusal contact and interferences, severity of preoperative pain, presence of periapical radiolucency, use of analgesics and number of treatment sessions can affect the intensity of post-endodontic pain [2-8]. Apical extrusion of debris into the periradicular tissues is among the main causes of pain after endodontic treatment [9]. Evidence shows that dentin, necrotic tissue, pulp residues, microorganisms and irrigating solutions may extrude through the apex into the periapical tissues during root canal preparation [10,11]. This often occurs despite carefully limiting the root canal preparation to the root canal space [1].

Rotary systems are becoming increasingly popular among dental clinicians and evidence shows that up to 90% of dentists use rotary systems in their private practice [12]. Safe Sider system (Essential Dental Systems, South Hackensack, NJ, USA) has a flat-sided design and reciprocal motion, which according to the manufacturer's instructions, decreases the stress and risk of broken instrument inside the root canals. Each file has 16 flutes to decrease involvement of the file with the root canal walls [13]. Mtwo (VDW, Munich, Germany) files have full rotation motion and are available in different tapers for cleaning and shaping of the root canal system. The cross-section of Mtwo files is S-shaped, and by an increase in size, the cross-section of the file decreases. Mtwo files have two cutting edges [14].

In a study by Nekoofar, et al., root canal preparation was performed using full-rotation and reciprocal files. They reported significantly higher pain score following endodontic treatment with Wave-One, which has a reciprocal motion [15]. Gambarini, et al., showed that post-endodontic pain in the reciprocal group was significantly higher than that in the other two

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groups (rotary crown-down motion and a combination of full rotation and reciprocal motion) [16]. Wan, et al., indicated that SafeSider system created significantly higher amounts of debris compared to K-files and K-reamers [13].

Considering the increasing popularity of rotary files among dental clinicians and the emergence of several types of rotary systems, clinical trials are necessary to compare these systems from various aspects. Thus, this study sought to assess and compare postoperative pain in maxillary and mandibular first and second molar teeth with symptomatic irreversible pulpitis following endodontic treatment with Safe Sider reciprocating and Mtwo rotary multiple file systems.

Methods

The study protocol was approved in the ethics committee of Zahedan University of Medical Sciences (code 7203) and registered in www.clinicaltrials.gov (NCT02644031).

Of patients presenting to Zahedan University of Medical Sciences, School of Dentistry, 150 subjects who met the eligibility criteria were selected and enrolled. We hypothesized that pain after endodontic treatment in the prepared canals of the first and second maxillary and mandibular molars with multi-file reciprocating and full rotation systems was not statistically significant.

The primary outcome of treatment was that canal preparation with any of the above systems reduced post-treatment pain. Secondary outcomes were to assess probable associations between the type of canal preparation system and pain relief in cariously exposed mature teeth. The inclusion criteria were: age range of 20 to 50 years, systemic health and having a symptomatic mandibular and maxillary first or second molar with irreversible pulpitis requiring endodontic treatment (without periapical involvement) with $<25^\circ$ canal curvature according to the Schneider's technique. The exclusion criteria were pregnancy, history of allergy, history of medication intake (antibiotics, non-steroidal anti-inflammatory drugs, opioids and corticosteroids) within 12 hours prior to treatment, previous endodontic treatment, complex anatomy, obstructed (calcified) canals on radiographs, internal or external root resorption, open apex teeth, periodontal disease, swelling, abscess, presence of sinus tract, presence of periapical lesion on radiographs, tenderness to percussion and absence of occlusal contact. All patients were treated by the same clinician within a single session. Patients were briefed about the study and signed written informed consent forms. A demographic questionnaire was then filled out including age, sex, type of tooth, pulp status, presence of periapical lesion on radiographs, history of analgesic use and the intensity of preoperative pain using a Visual Analog Scale (VAS). The patients were calibrated for filling out the VAS form.

The pulp status was assessed using an electric pulp tester (Parkell pulp vitality tester Farmingdale, NY, USA) and cold test (Roeko Endo-Frost; Roeko, Langenau, Germany). The status of the pulp in terms of vitality was determined by observing bleeding during access cavity preparation. The mandibular teeth were anaesthetized by an inferior alveolar nerve block using 2% lidocaine with 1:80,000 epinephrine (Persicaine; Daroupakhsh, Tehran, Iran). The maxillary teeth were anesthetized by buccal infiltration of 2% lidocaine with 1:80,000 epinephrine (Persicaine; Daroupakhsh, Tehran, Iran) using a 27-gauge needle. After ensuring adequate anesthesia by electric pulp tester and cold test, rubber dam isolation was done and access cavity was prepared by a round bur and high-speed hand piece under copious water irrigation. Following access cavity preparation, working length of the root canals was determined using a #15 K-file (Mani Inc., Tochigi, Japan) and apex locator (Root ZX, J. Morita Mfg Corp., Kyoto, Japan). The working length was then radiographically confirmed. Patients were allocated in the three study arms with simple randomization using a computer-generated system and under the supervision of administrative staff, were automatically randomised into different study arms including Mtwo, Safe Sider, and hand K-files (control group). All the allocated patients received a unique patient identification code before starting the treatment. In the event of withdrawal from the study, the randomisation code was not reused. Patient and assessor were blinded.

In Mtwo group, patency was obtained using a #10 K-file and the root canals were prepared using files #10 with 4% taper, #15 with 5% taper, #20 with 6% taper and #25 with 6% taper. The instruments were activated by using a 6:1 reduction handpiece (Sirona Dental Systems GmbH, Bensheim, Germany) powered by a torque-controlled motor (Silver Reciproc; VDW, Munich, Germany).

In the Safe Sider group, a glide path was created by use of #8, 10, 15 and 20 files with 2% taper, and then orifice shaper (Pleezer) was used to widen the root canal orifices. Next, files #25 and 30 with 2% taper and then #30 with 4% taper, #35 with 2% taper and #40 with 2% taper were used one millimeter short of the working length. Finally, file #25 with 6% taper was used. All instruments were used in Endo-Express reciprocating handpiece (Essential Dental Systems, South Hackensack, NJ, USA), described as “¼-turn, ¼-speed reduction, ISO E type coupling, push-button endodontic handpiece for hand instrument” with reciprocating motion at 2500 rpm and in-and-out tip motion. In the control group, root canals were prepared using hand K-files (Dentsply Maillefer) with step-back technique. The apical region was prepared up to K-file #25 in mesiobuccal and mesiolingual canals of mandibular molars and mesiobuccal and distobuccal canals of maxillary molars. The apical region was prepared up to K-file #35 in distal canals of mandibular molars and palatal canals of maxillary molars. Each instrument was used for the instrumentation of only four canals and then discarded. Coronal flaring was performed using Gates Glidden drills #1, 2 and 3. During root canal preparation, irrigation was performed with 2.5% sodium hypochlorite and saline. Finally, 17% EDTA (Ariadent, Tehran,

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Iran) was used for smear layer removal, followed by a final rinse with 2.5% sodium hypochlorite and saline. After drying the root canals with paper points, a proper-size master cone was chosen and radiographically confirmed. The root canals were filled with gutta-percha (Gapadent Co., Ltd., China) and AH Plus sealer (Dentsply, Tulsa Dental, Tulsa, OK, USA) using lateral compaction technique in the same session. Optimal quality of obturation was ensured by taking a final radiograph. Access cavity was temporarily restored with Cavit (Ariadent, Coltosol, Tehran, Iran). The occlusion of patients was checked and they were referred for permanent restoration of their teeth. The mean duration of treatment was two hours in all patients. After completion of treatment, the patients were provided with a VAS form and they were requested to express the severity of pain experienced at 6, 12, 24, 48 and 72 hours, postoperatively by marking a VAS score corresponding to their level of pain.

The severity of pain on the VAS form ranged from 0-10; based on the selected score, the patients were categorized into no pain, mild pain, moderate pain and severe pain groups.

No pain: Patient had no pain at all and the sensation of the treated tooth was similar to that of sound teeth (score zero).

Mild pain: Slight pain, which was not irritating and did not require analgesics (scores 1-4).

Moderate pain: Irritating but tolerable pain manageable by use of non-steroidal anti-inflammatory drugs (scores 5-7).

Severe pain: Unbearable pain slightly relieved or not relieved by analgesics (scores 8-10).

At the end of treatment, all patients were provided with five 400 mg ibuprofen tablets to use in case of occurrence of severe pain. The patients were asked to write down the time and number of analgesics taken in the respective form. The VAS forms were assessed by an independent observer blinded to the group allocation of patients.

The data were analyzed using chi square test, repeated measures ANOVA and LSD post hoc test. Level of significance was set at $P < 0.05$.

Results

Of 187 patients treated in this study, 17 did not return the VAS forms; 11 patients had over-filled root canals on radiographs and nine were excluded from the study due to the use of more than two 400 mg ibuprofen tablets in the first 24 hours following treatment. Eventually, data of 150 patients in three groups of control, Mtwo and Safe Sider were analyzed (Fig. 1).

Patients had equal distribution in terms of age, sex, severity of preoperative pain and type of tooth .in the three groups and were not significantly different in this respect ($P>0.05$) (Table 1). Post-endodontic pain significantly decreased over time in all groups. In the conventional hand-file group, the trend of pain reduction was gradual and continuous.

Comparison of the mean pain score after treatment among the study groups at different time points revealed no significant difference among the three groups in the severity of pain at 6, 48 and 72 hours post-treatment but the mean pain score at 12 and 24 hours was significantly higher in the Safe Sider group compared to the conventional hand-file and Mtwo groups ($P=0.001$ and $P=0.001$, respectively (Fig. 2 and Table 2).

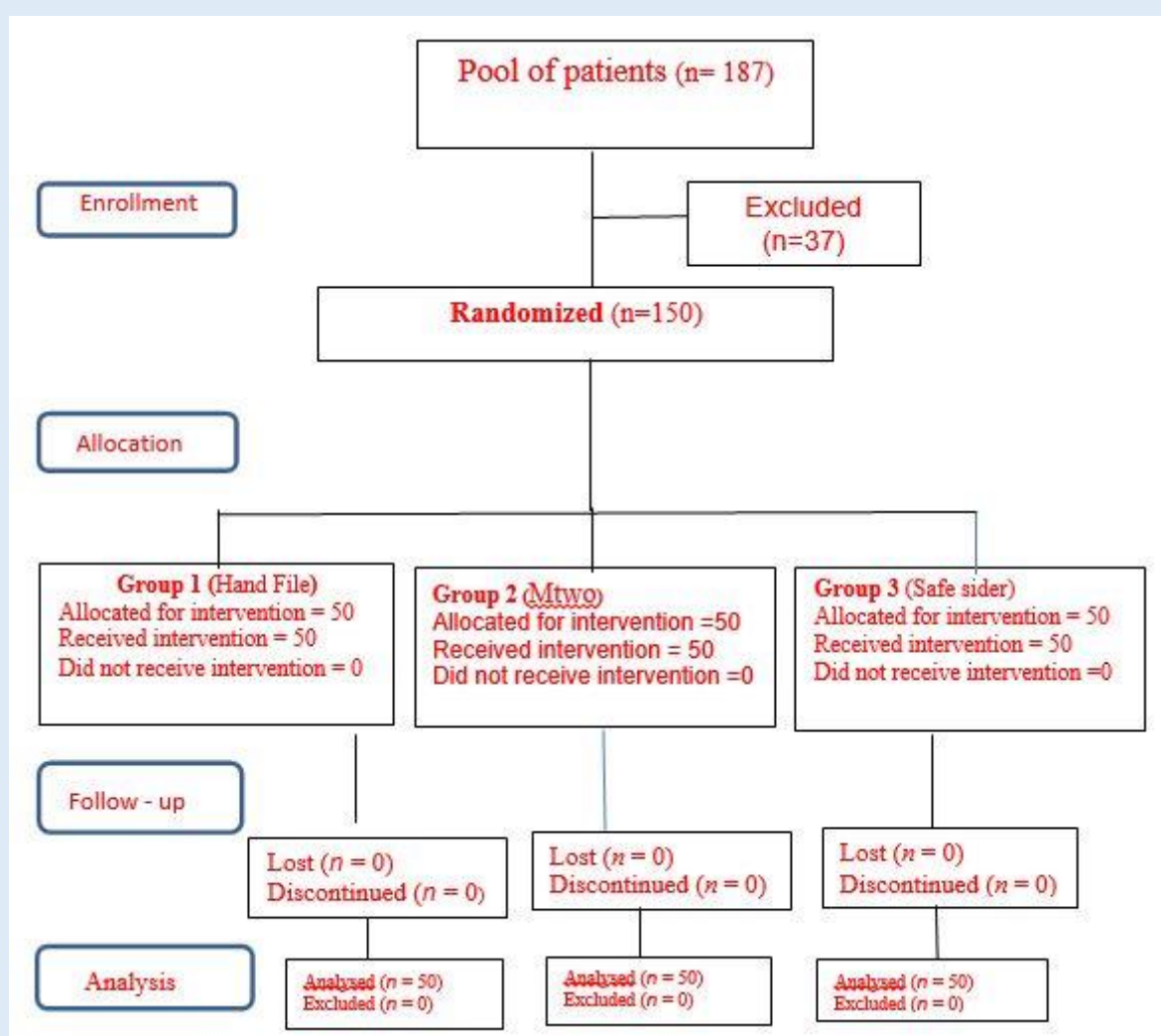


Figure 1: CONSORT flow diagram of participants through each stage of randomized clinical trial.

Baseline Demographic and Clinical Characteristic	Safe Sider N=50	Mtwo N=50	Control N=50	P value N=50
Female	25	23	25	
Mean age (y)	8.95±30.54	8.84±32.1	10.05±31.58	0.695
Systemic disease	None	None	None	
Vitality of the Pulp	25	25	25	
Maxillary Molars	29	26	25	
Mandibular Molars	21	24	25	
Preoperative Pain	2.79±6.08	2.75±6.16	3.06±6.36	0.882

Table 1: Baseline demographic and clinical characteristic of patients in each group.

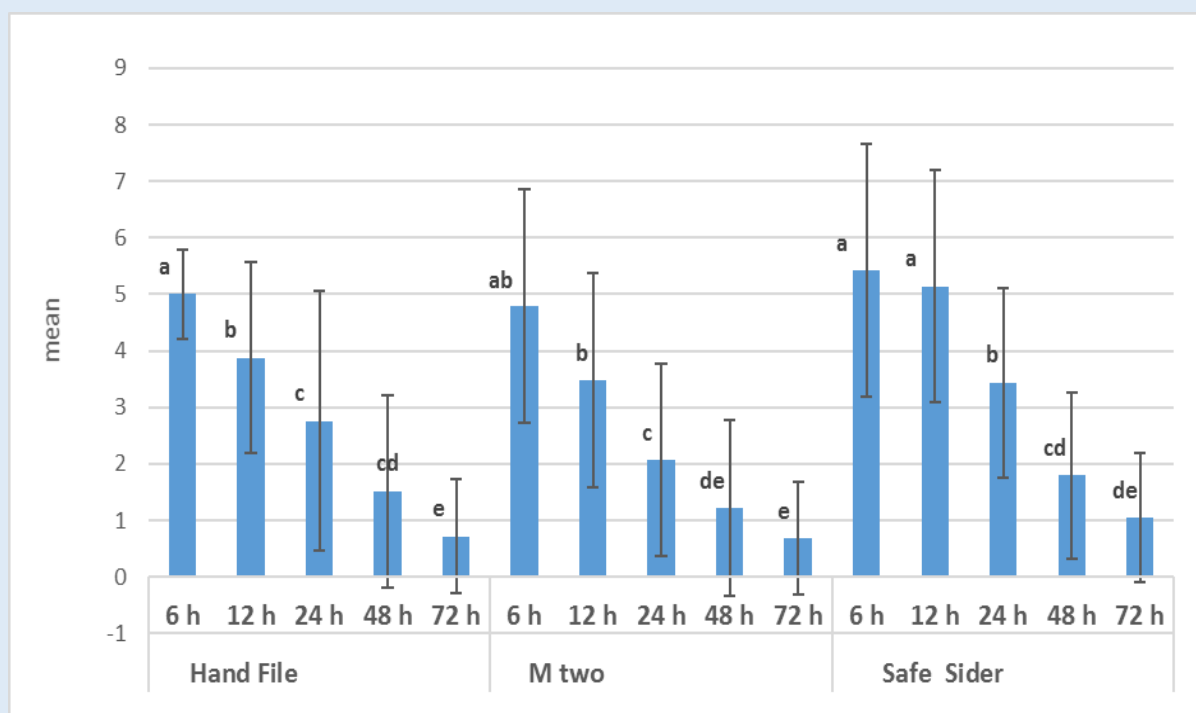


Figure 2: Comparison of pain intensity in groups resulting from the interaction effects of instruments and time.

Groups	After 6 h	After 12 h	After 24 h	After 48 h	After 72 h
Hand File	5 ±0/78	3.88 ± 1.68	2.76±2.29	1.52±1.98	0.72±1.40
M two	4.8 ±2.07	3.48±1.90	2.06 ±1.71	1.22±1.56	0.68±1.16
Safe Sider	5.42 ±2.23	5.14±2.05	3.44±1.68	1.8 ±1.47	1.04±1.14
P value	0/416	0.286	0.232	0.002	0.001

Table 2: Mean numerical rating scale scores of the Hand file, Mtwo and safe sider Groups in various time interval after one visit endodontic treatment.

Discussion

The current results revealed that irrespective of the root canal preparation technique, the severity of pain significantly decreased after endodontic treatment due to the elimination of local stimuli causing pain. However, a mild pain is usually expected after endodontic treatment, which is due to mechanical, chemical and microbial trauma to periapical tissues [17,18]. But, the severity of preoperative pain is also a strong predictor of postoperative pain [19]. Thus, only teeth with irreversible pulpitis and without periapical involvement were used in this study and symptomatic/asymptomatic non-vital teeth with apical periodontitis were excluded from the study in order to eliminate the potentially effective factors on postoperative pain. By doing so, we ensured to assess the intensity of pain in relation to the technique of root canal instrumentation. On the other hand, treatment was performed within one single session for all patients in order to eliminate the effect of intracanal medicaments and other possible factors on the intensity of postoperative pain. The current results revealed that the mean severity of pain in the first 24 hours following endodontic treatment rapidly decreased and reached its minimum score within 72 hours. Pak and White in a systematic review showed that the incidence of pain within the first 24 hours after treatment, and particularly in the first 2 days, decreased by 40% and reached 11% on day 7 [20]. Ng, et al., used a VAS and showed that 40.2% of patients had pain within the first 48 hours after treatment and less than 12% of them had severe pain (21). Postoperative pain and edema are commonly related to the technique of preparation and immune response to irrigants, extrusion of debris, over-instrumentation or foreign body reaction to filling materials [22].

Several medications are used to alleviate postoperative pain. Non-steroidal anti-inflammatory drugs are the first choice for post-endodontic pain control; among which, ibuprofen has been commonly prescribed for post-endodontic pain control in many studies [22,23]. Thus, five ibuprofen tablets were prescribed for our patients for pain control.

Evidence shows that factors such as the irrigation protocol, final apical size, duration of canal instrumentation, technique of preparation and instrument design affect the extrusion of debris and postoperative pain [24-28]. In the present study, the final apical size in study groups was file #25 with 6% taper. In the control group, narrow canals were prepared to file #25 and large canals were prepared to file #35 with 2% taper. The current results showed that the mean severity of pain at 6 hours post-treatment was not significantly different among the study groups, the null hypothesis was accepted. This finding was in contrast to the results of Nekoofar, et al., [29]. They found that postoperative pain was significantly lower in patients treated with ProTaper Universal rotary system compared to those treated with WaveOne reciprocating system [29]. This difference can be due to the differences in sample size (42 patients versus 150 patients), mean age of patients (38 and 40 years versus 31, 32 and 33 years),

type of treated teeth (maxillary and mandibular premolars and molars versus maxillary and mandibular molars), treatable symptoms (asymptomatic versus symptomatic irreversible pulpitis), number of treatment sessions (two sessions versus one single session), final apical size of the prepared canal (F2 and F3 corresponding to 25/8% and 30/9% versus 25/6% and 35/2%), type of irrigating solution (chlorhexidine versus sodium hypochlorite) and type of sealer used for obturation (AH 26 versus AH Plus).

The study results also demonstrated that the mean severity of pain in SafeSider group was significantly higher at 12 and 24 hours, post-treatment ($P=0.001$), the null hypothesis was not accepted. Which may be due to the higher extrusion of debris. Debris extrusion is related to the kinematics of the file, number of files used for canal preparation compared to Mtwo (11 files versus 4 files), rotational speed of the file (1000 versus 250-350 rpm) and file design. Although no previous study has compared this file with other files in terms of postoperative pain, evidence shows that all canal preparation techniques have some degrees of debris extrusion, and the amount of extruded debris depends on the technique of canal preparation and instrument design [25].

Burklein and Schafer evaluated debris extrusion caused by Mtwo and ProTaper Universal rotary systems and two reciprocating systems namely Reciproc and WaveOne *in-vitro*. The results revealed that full-sequence rotary instrumentation caused less debris extrusion [30]. In contrast, an *ex-vivo* study evaluated apical extrusion of bacteria and showed that reciprocating single files (WaveOne and Reciproc) caused less bacterial extrusion than BioRace rotary files [31]. However, another study reported that Mtwo caused less bacterial and debris extrusion than Safe Sider, which may be due to the different design and kinematics of the file as well as the number of files used [32,33]. Future studies are required to evaluate postoperative pain following the use of Safe Sider with fewer number of files (files #15, 20 and 25 with 2% taper followed by Pleezer and finally file #25 with 6% taper).

Conclusion

Post-endodontic pain in Safe Sider group was significantly higher than that in Mtwo and hand-instrument groups at 12 and 24 hours post-treatment.

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The authors wish to acknowledge all participants involved in this study.

Conflict of Interest

There are no conflicts of interest.

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