



## Evaluation of the Effect of Root Canal Preparation by TF and M-Pro on Postoperative Pain after Single Visit Endodontic Treatment: A Blinded Randomized Clinical Trial Therapeutic Study

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### Abstract

**Aim:** The aim of the present study was to clinically compare the incidence and intensity of postoperative pain after mechanically preparing the root canal using the Twisted file (TF) with an adaptive motion and M-Pro system in a continuous rotary motion in mandibular premolar teeth with symptomatic irreversible pulpitis.

**Methodology:** Forty-eight patients suffering from symptomatic irreversible pulpitis in mandibular premolars were treated in a single visit root canal treatment using TF and M-Pro for the preparation of the root canals, according to each patient group. The patients were classified into 2 groups according to the used rotary system: group A (TF Adaptive) and group B (M-Pro). The patients were informed to record the pain intensity at 6, 12, 24 and 48 hours postoperatively. Data were analyzed using chi-squared and Mann-Whitney U tests.

**Results:** There was no statistical difference between the two groups regarding the patient gender, age, type of tooth and preoperative pain except for the prevalence of postoperative pain. A statistically significant difference at 24 hours- time period was noted in the postoperative pain reduction between the two groups as it was higher in the M-Pro group than in the adaptive TF group.

**Conclusions:** Within the limitation of this study it was concluded that both files are considered reliable instruments for root canal preparation inducing a normal range of postoperative pain.

**Keywords:** Kinematics; M-Pro; Postoperative Pain; Single- visit; Twisted File

### Introduction

Postoperative pain can be defined as the discomfort sensation that comes after root canal treatment and it was reported to be 25 to 40% in patients' having endodontic disease [1,2]. The pain prevalence in the first 24 hours was reported to be 40% that fall to 11% according to a systematic review published by Pak and White [3].

There are several etiological factors that affects the occurrence of postoperative pain as: preoperative pain history accompanied with periapical pathosis, insufficient instrumentation, hyper occlusion, missed canals and extrusion of infected dentin debris apically [4]. Infected debris extrusion has been assumed to be the

main source of pain after endodontic treatment [5,6]. Whereas, the extrusion of infected debris in terms of Dentinal debris, pulp tissue and microorganisms during instrumentation of the root canal exacerbates the inflammatory response and causes inflammation of the peri-radicular tissues. The amount of extruded debris depends on: Instrument design as well as instrumentation technique [7].

Modern techniques used in preparation of root canal exploit using of the engine-driven nickel-titanium files which work built on two motion; rotation or reciprocation. The Fourth generation file system (TF Adaptive) (SybronEndo, Orange, CA) was introduced in 2008 and is marketed as having the ability to complete the root ca-

nal system shaping by using three files, utilizing the R- phase heat treatment technology which significantly increase the file flexibility [8].

While (M-Pro®) (IMD, China) was introduced to market in 2015 which has been fabricated by special heat treatment which produces more flexible file, with continuous rotation motion can complete the canal shaping with high cutting efficiency. M-Pro rotary systems present the recent metallurgy technology presented as the CM wire which has a martensitic property at room temperature [9]. M-Pro system was newly introduced to the market and has limited studies in literature evaluating its influence and its action on postoperative pain.

It is well acknowledged that apical debris extrusion may lead to inflammation of the peri- radicular tissues leading to postoperative pain and flare ups. Some studies proved that the continuous rotary files cause more postoperative pain than the reciprocating one [10-12] and others proved that the reciprocating files cause more postoperative pain than the continuous rotary files [13,14]. This remarked discrepancy might be related to the differences in the type of alloy, cross-section, design of cutting-edge, taper, flexibility, number of used files and kinematics.

From the previous studies, there is controversy on the effect of different movement kinematics when using rotation or reciprocation endodontic files on postoperative pain in cases having acute irreversible pulpitis.

Thus, this clinical trial was to assess and compare the postoperative pain after using different kinematics in treating symptomatic irreversible pulpitis in single-visit root canal treatment.

**Subjects and Methods**

**Ethics**

This randomized clinical trial was approved by the institutional review board and ethical committees (IRBs/ECs) of the Faculty of Dentistry and was documented in the www.clinicaltrials.gov (Code: NCT03412318).

**Selection of subjects**

After explaining the procedures and the possible risks, all patients signed an informed consent. The patients were enrolled from the endodontic clinic of the Endodontic Department from December 2018 to January 2020. Interventions were carried out by a master’s degree student in the Endodontic Department.

**Sample size**

With power 80% and 5% significant level, a total sample size of 42 patients (21 per group) was stated to be sufficient. That number increased to 48 patients (24 per group) to adjust for using a nonparametric test. Sample size calculation was performed by PS: Power and Sample size Calculation software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA). Each patient had equal chance to enter either the intervention groups A or B group as each patient took a number in excel sheet divided into two groups A and B chosen by assistant supervisor who determine which system would be used with this patient (Figure 1).

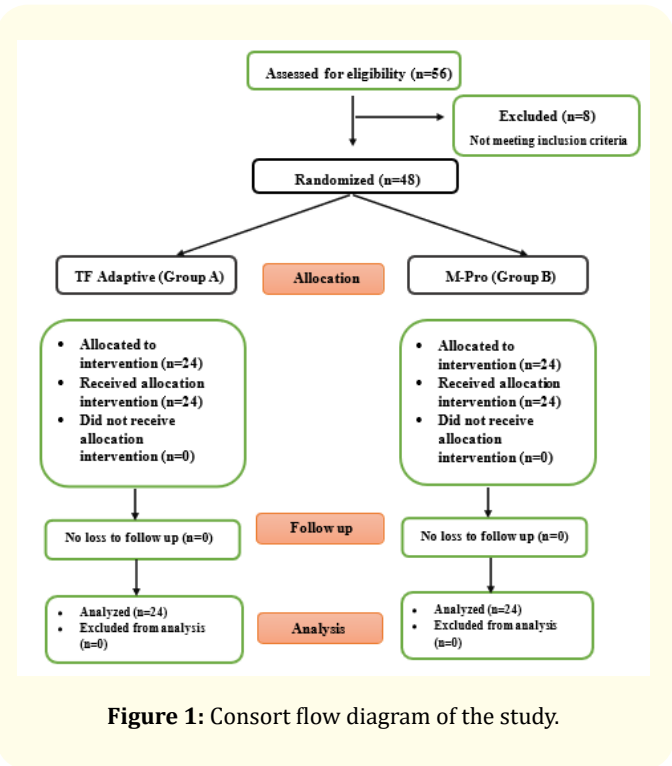


Figure 1: Consort flow diagram of the study.

**Inclusion and exclusion criteria**

Forty-eight adult patients diagnosed with irreversible pulpitis in mandibular premolar teeth were included in the study. Patients in a good health, were males and females aged from 20 to 60 years old and complaining of preoperative sharp, moderate/severe pain. Periapical radiographic findings were normal or showing minor widening in the lamina dura. Patients were able to communicate the use of pain scales. Patient having history of necrosis, either with/without apical pathosis. Teeth having extra oral or intraoral sinus tract or fistula. Patients whose teeth reacted positively to percussion test. Teeth having grade 2 or 3 mobility and dilacerated

roots were excluded from the trial. In addition to patients having severe ache in more than one premolar on the same side. Patients who had reserved analgesics in the 12 hrs prior treatment, pregnant females and mentally retarded patients were also omitted. A chief complaint of spontaneous pain was considered in diagnosing of symptomatic irreversible pulpitis. After that by using Numerical rating scale, patient marked his pain level on the NRS scale. For additional objective evidence, cold testing using ethyl chloride spray (Ethyl chloride spray; Walter Ritter GmbH, Germany), exhibited persistent moderate/severe painful response (> 10s).

### Randomization, allocation concealment and blinding

Random numbers from 1 to 48 were distributed in a table of two groups created using a computer program (www.random.org). The table was saved by the secondary supervisor to randomize the participants. The patients were blinded.

### Clinical procedures

Each patient was requested to mark the preoperative pain level on the Numerical rating scale (NRS). Then each patient received inferior alveolar nerve block injections of 2% mepivacaine hydrochloride with 1:100,000 epinephrine (Carpule Mepecaïne -L, Alexandria Company for pharmaceuticals and chemical industries). After that access cavity was achieved with endo Z bur/round bur (Dentsply Maillefer. Ballaigues. Switzerland). Isolation of tooth was done by rubber dam (Blossom, Mexpo International Inc, San Francisco, California) to inhibit entry of bacteria/saliva from the oral cavity. Patency of the canal was done by 10 K- file (Mani Inc., Tochigikan. Japan) and pulp extirpation was performed by 15H-file (Mani Inc., Tochigikan. Japan).

An electronic apex locator (Root ZX. Morita Corporation. Kyoto. Japan) was used for working length determination of the canal which was approved by radiograph to be 1 mm shorter than the apex of the root. The patients were categorized into two groups:

1. Group A: Mechanical preparation of the canal was completed with 3 (Adaptive) Twisted Files. The first file used was SM1 file (size 20 taper 4%) with a slow in and out brushing motion, followed by the SM2 file (size 25 taper 6%) and finally the SM3 file (size 35 taper 4%). All the files were used to full working length with 600-0° up to 370-50° by using TF Adaptive motor.
2. Group B: Mechanical preparation was done by 4 full rotary M-Pro files. The orifice opener (size 18 taper 9%) was used for flaring the coronal of 2/3 of the canal length, followed by second file (size 20 taper 4%) to the full working length, followed by third file (size 25 taper 6%) to the full working

length with in and out slow pecking motion, finally the last file size (35 taper 4%) to the full working length with in and out slow pecking motion. All files were used to full working length with preprogrammed motor with adjusted speed (300 - 500 rpm) and torque (1.5 N. cm.) (X-Smart). The two instruments were used according to the manufacturing instructions, each instrument used one time. Cleaning of the flutes of the file were done after three pecks and irrigation was completed by 3 ml of (2.5% sodium hypochlorite) by a 27-G side-vented needle (C-K side-vented needle. C-K Dental IND.Co. Korea).

Final irrigation was performed with 5 ml (2.5% sodium hypochlorite), then sterile saline and 3 ml of 17% EDTA solution (Calix E; Dharma Research, Florida, USA) for 1 minute to remove the smear layer. After that the final wash was performed by saline. Master cone-fit radiograph was taken with the corresponding size cones. Paper points were used for canal dryness. Modified single-cone technique was used to obturate the canals in matched-size gutta-percha points (Meta Biomed Co., Ltd. Chungbuk. Korea) and resin-based sealer (ADSEAL. Meta Biomed Co., Ltd. Chungbuk. Korea). Then, cotton pellet was positioned inside the pulp chamber, then the access cavity sealed with KETAC Silver Glass Ionomer Aplicap temporary restoration (3M ESPS, Germany).

When the visit was finished, patients were requested to mark their pain intensity by using Numerical Rating Scale after 6, 12, 24 and 48 hours and to return pain scale chart back to the investigator.

### Pain assessment

Pain was evaluated using an 11-point NRS, where the endpoints are the extremes of no pain and worst pain. The severity of pain was assigned into one of four pain categories: none (0)/mild pain (1-3)/moderate pain (4 - 6) and severe pain (7 - 10). The time points are 6/ 12/ 24 and 48 hours postoperatively.

### Statistical analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS), version 21 (IL SPSS, Inc, IBM Corporation, Chicago, USA). Numerical data were described as mean and standard deviation or median and range. Categorical data were described as numbers and percentages. Data were explored for normality using Kolmogorov-Smirnov test and Shapiro-Wilk test. Comparisons between two groups for normally distributed numeric variables were done using the Student's t-test, while for non-normally distributed numeric variables by Mann-Whitney test. Comparisons between categorical variables were performed using the Chi square test. A p-value less than 0.05 was considered statistically significant.

**Results**

Regarding patient’s age, gender, tooth type and preoperative pain, which demonstrated the fairness of the study. The results between the both groups displayed that there was no statistical difference ( $p > 0.05$ ) (Table 1 and 2).

Age	Group A		Group B		P- Value
Median	32.5		35.5		0.129
Minimum	19		20		
Maximum	49		30		
Tooth type	No.	Percentage	No.	Percentage	P- Value
1 <sup>st</sup> Premolar	14	58.3%	12	50.0%	0.562
2 <sup>nd</sup> Premolar	10	41.7%	12	50.0%	

**Table 1:** Median, minimum, maximum values and results of Mann Whitney U test for comparison of age and tooth type between the two groups (Group A: TF file, Group B: M-Pro file).

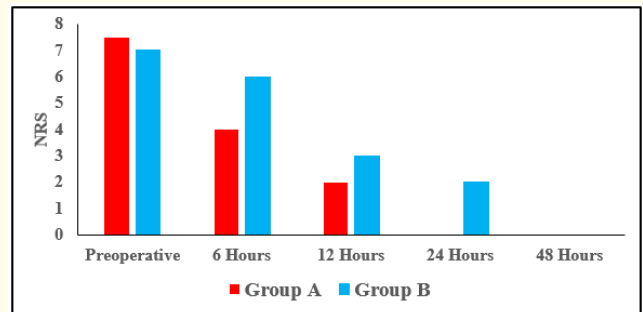
Gender	Group A		Group B		P-Value
	No.	Percentage	No.	Percentage	
Males	5	20.8%	6	25.0%	0.731
Females	19	79.2%	18	75.0%	

**Table 2:** Frequencies, percentages (%) and results of Chi square test for comparison of gender distribution between the two groups (Group A: TF file, Group B: M-Pro file).

There was a statistically significant rise in the incidence of postoperative pain in the M-Pro group compared to the TF Adaptive group at 24 hours postoperative, and a statistically non-significant difference between the two groups at the remaining periods 6, 12 and 48 hours (Table 3).

Group		Group A	Group B	P- Value
Pain intensity				
Preoperative	Median	7.5	7	0.755
	Range	4 - 10	4 - 10	
6h	Median	4	6	0.117
	Range	0 - 8	0 - 8	
12h	Median	2	3	0.089
	Range	0 - 6	0 - 7	
24h	Median	0	2	0.026*
	Range	0 - 3	0 - 7	
48h	Median	0	0	0.374
	Range	0 - 2	0 - 4	

**Table 3:** Median and range values of preoperative pain postoperative pain intensity at different time intervals, and calculated p-value in the two groups. (Group A: TF file, Group B: M-Pro file).



**Figure 2:** Bar chart representing the median preoperative NRS scores and the median NRS scores at 6, 12, 24 and 48 hours post-operatively in the two groups.

**Discussion**

The success of endodontic therapy not only on efficiency and proper execution but also depends on minimal patient discomfort. Postoperative pain is considered to be related to several factors, the most significant of which is debris extrusion which may cause flare ups and postoperative pain leading to short/long term failure [15].

The aim of this study was designed to assess the occurrence and severity of postoperative pain after single visit endodontic treatment by M-Pro (continuous rotation) and Twisted Files (Adaptive) NiTi Systems in patients with symptomatic pulpitis in mandibular premolar teeth.

The present study was designed as a prospective double blinded parallel randomized controlled trial (RCT) where the participant and the statistician were not informed of the intervention used, only the operator who knew the intervention after patient selection. This method is the most reliable type of experimental study considering it the gold standard, as it inherently corrects for unknown confounders and minimizes investigator bias [16]. The CONSORT 2010 guidelines for clinical trials were followed in this study.

Root canal instrumentation was carried out using rotary instruments. Since, Nickel Titanium files provide more flexibility, super elasticity, and more cutting ability. Root canal preparation more centered and nearly eliminated the iatrogenic instrumentation complications [17].

In the present study, root canal instrumentation was performed by Twisted File (TF) Adaptive system, based on its ability of maximizing the benefits of reciprocation, while decreasing its drawbacks, by using an exclusive motion. Also, the 3 files are characterized by a triangular cross section with no radial lands, giving high cutting efficiency and flexibility. It utilizes a combined motion of reciprocation and continuous rotation. When there is minimal pressure on the file, the instrument uses continuous rotation and uses reciprocation motion upon dentin engagement. After recipro-

cal motion is active, the cutting angles (CW) of TF Adaptive motion is greater than that of WaveOne/reciproc movements. These angles change depending on the intracanal stress applied on the file and the anatomical complications [18].

While other group was performed by M-Pro using full rotational system (IMD- China) which was newly introduced system to the market having limited studies in literature evaluating its influence and its action on postoperative pain. It has been fabricated by special heat treatment which produces more flexible file, increase fracture resistance and high adaptability to root canal curvatures [19].

In this study, the instrumentation technique followed the manufacturer's instructions. A crown-down technique was employed so that each instrument gradually reached the working length by a brushing movement and without pressure, this strategy reduces the debris extrusion since cleaning the wider portion of the canal have been addressed before the narrower portion. Moreover, the insertion of the instrument is slow and passive [8].

To assess the pain with minimal changing factors and to standardize the number of the canal preparation, mandibular permanent premolars with single root and single root canal were selected. Many studies showed a statistically significant difference between mandibular molars and premolars in postoperative pain [20]. Patients who had taken preoperative drugs within 12 hours before treatment such as steroidal or non-steroidal anti-inflammatory drugs and analgesics, were excluded from the study to avoid any misinterpretation of the diagnosis or the postoperative pain scores [21-24].

During the study, intensity of the pain was documented preoperatively as base line data and postoperatively at different time intervals. 6 hours was selected as it was the time that the influence of anesthetic solution will begin to diminish. 12, 24 and 48 hours were selected as it was verified that the greatest of postoperative pain happen among these time intervals [25].

After access cavity preparation, isolation by rubber dam was conducted since using the rubber dam throughout endodontic treatment is considered the standard of care as it improves the patient's care, a pivotal aspect of healthcare, and improves the odds of a successful treatment [26].

In the present study, working length (WL) determination was done by Root ZX mini electronic apex locator was used in this study

to determine the working length (WL) because of its high precision which had been asserted *in vivo* and *in vitro*, after that the working length was further confirmed by the radiograph. This greatly confines the instrumentation within the root canal system [27-29]. It is crucial to combine radiological data with the results of an electronic apex locator [30], because it is impossible to localize the junction area of cementum and dentine according to radiological working length evaluation technique, also there might be a distortion of radiological views in addition to the possibility that roots and adjacent structures might cover one another hindering proper working length determination.

In the current study, a standardized irrigation protocol was done using 3 ml of 2.5% NaOCl solution between every subsequent instrument as it was proved that it has lesser cytotoxicity than 5.25% sodium hypochlorite. Furthermore, the reduction of intracanal microbiota is not any greater when 5.25% NaOCl is used as an irrigant as compared to 2.5% NaOCl [31].

NaOCl has been broadly used in endodontics as an irrigant as it provides most of the requirements for an endodontic irrigant. It shows a broad-spectrum antimicrobial activity. Moreover, it facilitates cleaning and shaping while neutralizing necrotic content which benefits root canal enlargement for subsequent filling [32,33]. A side-vented 30-gauge needle was introduced into the canal without binding, to decrease the influence of irrigant extrusion into the periapical area, as regular needle irrigation proved to cause the highest fluid extrusion [34,35].

Obturation in this study was done using the modified single cone technique, by using a spreader that offers a room to put the auxiliary cones in the canals which are coronally broader than the gutta-percha cone [36]. The master cone used in both systems size (35/.04) for standardization. ADSEAL resin-based root canal sealer was utilized because it is insoluble in tissue fluid, has acceptable physical properties and provides good hermetic sealing, high adhesion to dentin, antimicrobial activity and good radiopacity [37].

Obturation using a technique of single cone has been proven to be a fewer successful technique in obturating the root canal because of the larger volume occupied by the cement in the absence of condensation and of the anatomic variations of the root canal, that cannot be filled with larger master cones particularly in the coronal part of the root canal space [36].

Regarding patient's age, gender, tooth type and preoperative pain, which demonstrated the fairness of the study. The results between the both groups displayed that there was no statistical difference.

The findings of this study documented a statistically significant rise in the incidence of postoperative pain with the M-Pro group compared to the TF Adaptive group at 24 hours postoperative. But at the remaining time intervals 6/ 12 and 48 hours there was no significant difference between both groups.

The significant difference could be attributed to the debris extrusion, the Adaptive motion extrudes lesser amount of debris than rotary motion, because the Adaptive motion alterations into a reciprocal motion, with a specifically designed (CW/CCW) angles that vary from (600-0°) when the load is minimal up to (370-50°) when the load is applied. Thereby, the TF Adaptive file is operating more time with a CW cutting angle, which allows for enhanced cutting efficiency, removal of debris and less tendencies to push debris in an apical or lateral direction, because the flutes of TF files are intended to eliminate debris in a CW rotation [38].

On the other hand, reciprocal movement contains a cutting motion (CCW) plus a releasing motion (CW). Since, the fact that the (CCW angle) is larger than that of (CW angle), it is recommended that the file continuously moves toward the apex, with more debris extrusion as the file acts as screw conveyer pushing debris more apically [39,40].

M-Pro rotary system is manufactured from the CM wire which contains a reduced percentage of nickel than other rotary systems [9]. The decrease in the nickel content exhibits lower hardness and is less likely to perforate the canal due to its control memory behavior [41]. This technology developed to provide superior flexibility except the shape memory property of other conventional Nickel Titanium files, enabling the files to preserve the original canal anatomy as well as enhancing the safety with efficiency during root canal preparation, with continuous rotation motion can complete the canal shaping with high cutting efficiency and adequate debris removal but less debris extrusion with anti-screwing effect, together with possibility pre-curved the file in difficult canal access [42].

In the present study, the M-Pro files showed higher postoperative pain incidence. This might be contributed by the rotational motion of the excessive taper of its orifice opener that applies high

force during preparation of the canal that may allow it to reach the full working length, which permits the debris to be pushed apically, and also the M-Pro has a convex triangular cross-section that have more metal mass with smaller clearance space which have no enough space for removal of debris through the orifice and allow pushing the debris beyond the apex [43]. This may explain the higher pain incidence in the M-Pro group.

Conversely, the Twisted file has a triangular cross section with no radial lands that have less metal mass with larger clearance space that allow better removal of debris toward the orifice, because the cutting flutes are created by twisting the file, not by grinding as M-Pro file and also the cutting flutes of the Twisted files are intended to eliminate debris in a CW rotation. This may explain the lower pain incidence in the TF group.

Although there were little studies in literature concerning the influence of M-Pro file on postoperative pain and debris extrusion. The outcome of the current study is in accordance with the results of recent study by Roshdy, and El Khodary [19] whom evaluated the amount of apically extruded debris using HyFlex CM files and M-Pro files versus ProTaper Next files and the result showed ProTaper Next group had the least mean weight of debris followed by the HyFlex group, while the highest mean was attributed to M-Pro group.

Bürklein and Schäfer [37] mentioned that the rotation movement of the files causes more apical transportation and push the debris more apically leading to more postoperative pain. On the other hand, Gambarini, *et al.* [42] stated that the reciprocating file acts as a piston that pushes debris beyond the apical foramen which leading to postoperative pain. While other researcher supposed that there was no significant difference between continuous rotation and reciprocation instruments concerning extrusion of debris [44-46] and postoperative pain [47-49].

In the current study there was a significant reduction in pain at all of the postoperative intervals compared to preoperative pain scores. This was agreement to several studies [12,50,51] displaying successfully treated cases. This was due to the high standard of care followed throughout cases included in this study.

Higher pain scores were recorded at 6 and 12 hrs postoperatively with significant difference among the 2 intervals. This was in accordance with numerous studies [48,49]. A higher pain scores at

6 and 12 hrs postoperatively were recorded by patients. This could be clarified due to the beginning of inflammatory response of the tissue resulting from debris extrusion and motivation of nociceptors of c-fibers that found in the periodontal ligaments that was supposed to extent its extreme level at 12 hrs postoperatively [52].

As stated by the systematic review of Pak and White, 3 occurrence of the pain in the first 24 hrs postoperatively is 40% that falls gradually near 11% after a week. There was a continuous significant decrease in the level of the pain at 24 and 48 hrs compared to each other and to all other tested intervals. This might be clarified due to dropping of the inflammatory reaction and the continuing progression of normal healing [25].

### Conclusion

Within the limitation of this study it was concluded that both files are considered reliable instruments for root canal preparation including a normal range of postoperative pain.

### Conflict of Interest

The authors deny any conflicts of interest in this study.

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