

## POST-INSTRUMENTATION PAIN AFTER THE USE OF FANTA AND M3 PRO GOLD SYSTEMS: A RANDOMIZED CLINICAL TRIAL

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### **ABSTRACT**

**Purpose:** The current trial sought to assess the intensity of post-operative pain following endodontic instrumentation of first mandibular molar teeth with Fanta (Pepsi gold) (FPG) and M3-pro+ Gold (assorted) (MPG) rotary files.

**Methods:** In a randomized; single-blind clinical trial, 40 asymptomatic first mandibular molars with irreversible pulpitis, normal periapical radiography, and a need for conventional endodontic treatment were offered treatment. It was registered under NCT06382545. The participants were randomly distributed into two groups (n=20) based on the file system utilized. The chemo-mechanical preparation was done in one session. Patients were requested to rate their post-instrumentation pain on a visual analogue scale (VAS) at 12, 24, and 48 hours, (no discomfort, mild pain, moderate pain, and severe pain).

**Results:** Following three time periods, the FPG group scored a higher VAS rating than the MPG group. The highest VAS value in both groups was achieved at 12 hours, although it decreased significantly after 24 and 48 hours. Conclusion: Post-instrumentation pain is common following the preparation of the root canal system using the FPG and MPG rotary systems tested, however it only lasts a short time. Although more common after utilising the Pepsi gold system, the majority of cases reported minimal discomfort at all time points.

**KEYWORDS:** Discomfort; nickel-titanium; rotary systems, visual analogue scale

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## INTRODUCTION

Post-instrumentation discomfort is one of foremost common challenges in endodontic treatment and considered as one of the unpleasant situations for the dentist and the patient. Patients report that pain is a strong predictor of root canal therapy performance. The prevalence of postoperative discomfort following endodontic therapy ranges between 1.4 and 16%<sup>(1)</sup>. It is widely acknowledged that a patient's trust in their dentist is damaged when they feel an unexpected pain.

However, the exact etiology of pain is still unknown and complicated. Postoperative pain and discomfort are frequently caused by insufficient instrumentation, extruded irrigants, extruded intracanal medicaments, traumatic occlusion, missing canals, earlier discomfort, periapical lesions, and ejection of apical debris<sup>(2)</sup>. Also, changes in periapical tissue pressure, environmental factors and inaccurate determination of working length are common expected causes<sup>(3,4)</sup>. Periapical tissue irritation usually causes inflammation with production of a variety of chemical compounds that initiate inflammatory reactions with subsequent pain sensation<sup>(5)</sup>. According to the evidence, apically extruded contaminated debris during chemo mechanical preparation is considered the primary cause of apical irritation and post-instrumentation discomfort<sup>(6)</sup>. Depending on the instrumentation approach employed, the quantity of extruded debris and neuropeptides produced from C-fibers in the surrounding periodontal tissues varies. This explains why patients' postoperative pain is different<sup>(7)</sup>.

The extrusion of debris is influenced by several variables; the irrigation routine<sup>(8)</sup>, master file size<sup>(9)</sup>, the period utilized in instrumenting the canals<sup>(10)</sup>, the technique used to do so<sup>(11)</sup>, and the instrument design<sup>(12)</sup>. Regardless of the amount of effort is made to maintain the preparation to the apical endpoint,

all instrumentation approaches result in some apical extrusion of debris. However, some instrumentation systems are claimed to reduce debris extrusion more than others<sup>(6)</sup>.

In contrast to hand K-files made of stainless steel, most of the recently developed nickel-titanium (NiTi) rotary files result in low debris ejection, which is due to their rotational motion, screwing action and excessive irrigation associated with these instruments<sup>(13)</sup>. Fanta (Pepsi gold) (FPG) rotary files and M3-pro+ Gold (assorted) (MPG) rotary files are two of the most frequently utilized systems in Egypt.

The FPG rotary file (Fanta Dental Material Co., Shanghai, China) are a recently launched NiTi file in the market that has a convex triangular cross-section, and all files have fixed taper. Because of its excellent flexibility and cutting efficacy, the manufacturer states that this device enables for speedy and safe preparation, particularly in curved root canals<sup>(14)</sup>.

The MPG rotary file (United Dental, Shanghai, China) is also a NiTi file that is designed for usage in continuous rotation motion with a convex triangular cross-section and an inactive tip, with two files having variable tapered angle and the rest of files with fixed tapered angle. According to the manufacturer, the instrument's exceptional flexibility enables speedy and safe preparation, particularly in curved canals. The MPG Rotary file is made from CM wire and an innovative triple surface coating, which gives the file better flexibility and cyclic fatigue resistance<sup>(15)</sup>.

To clarify the impact of each system on post-instrumentation discomfort, the purpose of our clinical investigation was to assess and compare the level of post-instrumentation discomfort following endodontic instrumentation of first mandibular molar teeth using the FPG and MPG rotary file systems.

## MATERIALS AND METHODS

Our randomized clinical study was granted approval by the research ethical committee of Faculty of Oral and Dental Medicine, Cairo University, Egypt (Approval number 36.3.22). It was registered on Clinicaltrials.gov under (NCT06382545). This study included individuals who came to or were referred to the Faculty of Oral and Dental Medicine Clinic (Ahran Canadian University, Giza, Egypt) for routine endodontic therapy,

### Patient Selection

This trial included 40 participants with ages between 20 and 50 years. According to Mollashabi et al (2017) <sup>(16)</sup> and using G power statistical power Analysis program (version 3.1.9.4) for sample size determination <sup>(17)</sup>, a sample size of 40 (equally divided to 20 in each group) was sufficient to identify a major effect size ( $d$ ) =0.9, with an actual power ( $1-\beta$  error) of 0.8 (80%) and a significance level ( $\alpha$  error) of 0.05 (5%) for the two-sided hypothesis test.

The patients were referred for treatment over a period of 7 months from November 2021–May 2022. Summary of inclusion and exclusion standards in Table 1. The medical and dental histories were collected. All patients had an asymptomatic first mandibular molar, irreversible pulpitis, and a normal periapical radiograph. The pulpal and peri radicular status was examined using thermal sensibility test, palpation, and percussion, and periapical radiography was then done. Radiographic and periodontal examinations, as well as the percussion and palpation tests, were all within normal limits. The normal pulp diagnosis was based on a positive cold test (Endo Ice; Coltene/ Whaledent Inc, Cuyahoga Falls, OH).

The results of the pulp sensibility test were compared to the reaction of the tooth on the opposite side, which was also found to have a normal pulp. Asymptomatic irreversible pulpitis was indicated by

an increased or prolonged reactivity to cold testing, as well as the presence of deep caries that extended into the pulp chambre on radiographic imaging, despite the lack of symptoms. The pulp diagnosis was verified after accessing the coronal cavity and observing pulp hemorrhage. The procedure protocol and regimen were explained to the participants who were unfamiliar with the system used in their situation. An informed consent form was signed by all the chosen patients.

### Pre-treatment Instructions

Before beginning therapy, the participants were taught how to use a visual analogue scale (VAS) <sup>(18)</sup> to assess the preoperative and postoperative discomfort levels. The VAS is a 10-cm-long horizontal straight line with numerical values arranged in visual sections. Participants were asked to assign a VAS score to their reported pain. The existence or absence of pain was classified into four groups: no pain (0), mild pain (1-3), moderate pain (4-6), and severe pain (7-10). <sup>(18)</sup> Throughout the preoperative period, all patients scored 0.

TABLE (1) Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• 20-50 years old</li> <li>• Absence of systemic diseases</li> <li>• Mandibular first molar</li> <li>• Asymptomatic tooth</li> <li>• Normal periapical area</li> <li>• Restorable tooth</li> <li>• Periodontal scoring index &lt;2</li> </ul>	<ul style="list-style-type: none"> <li>• Age &lt;20 and &gt;50</li> <li>• Any Systemic disorders</li> <li>• Articaine Allergy</li> <li>• Inability to take paracetamol.</li> <li>• Pregnancy or Nursing</li> <li>• Symptomatic pulpitis.</li> <li>• Pulp necrosis</li> <li>• Widening of PDL.</li> <li>• Periapical radiolucency</li> <li>• Existence of sinus tract</li> <li>• Periapical abscesses.</li> <li>• Existence of resorption</li> <li>• Tooth malposition.</li> <li>• Fixed partial dentures.</li> <li>• Analgesics intake in the last 12 hours.</li> </ul>



Using gauze soaked in alcohol, debris was removed from the device. Irrigation was carried out with a 25-G side vented needle (Disposable Syringe, Changzhou West Tai Lake Medical Industrial Park, China) and 3 mL of 2.5% sodium hypochlorite. By the end of instrumentation, every root canal received a total of 40 millilitres. To prevent debris compaction, the apical foramen was repeatedly repaired within all procedures by inserting a #10 or #15 K-type file (Dentsply Sirona) to a position 1 mm beyond the WL with using each file change. The needle was placed as far into each root canal as possible without binding it. A size 30/.04 taper gutta-percha cone (DentPlus, South Korea) correlated to the WL was used to confirm apical preparation size and length of the root canal enlargement. When the gutta-percha master cone did not extend to the WL, the preparation method was reaffirmed as previously described.

After apical enlargement confirmation, a plain cotton placed over orifices after that the cavity restored with MD-Temp (METABIOMED CO., LTD Chungcheong Buk-do, Korea) temporary restoration was placed. Even though no systemic drugs were recommended, the patients were told to take Paracetamol if they felt discomfort. If the analgesic drug did not offer pain relief or if there was another form of emergency, all patients were asked to notify the dental office or dental practitioner by whom was assigned for their dental care.

### Assessment of Postoperative Pain

A blinded researcher contacted the patients over the phone after 12, 24, and 48 hours. The researcher was in charge of data gathering and questioned the participants how they assessed the level of the pain on the VAS and whether they needed medication or not.

### Statistical analysis

The organization of data and statistical evaluation were carried out with the Statistical Package for

Social Sciences (SPSS) version 18. Numerical data were summarised using the mean, standard deviation, median, and range. Data were checked for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The Kruskal-Wallis test was used to compare groups based on non-parametric (not regularly distributed) numerical variables. The Friedman test and Wilcoxon signed rank test were used to compare results within the same group (impact of time). The Chi square test was used to compare categorical qualitative data, which were reported as numbers and percentages. Each p-value is two-sided. P-values < 0.05 were regarded as significant.

## RESULTS

### I- Comparison between groups

Comparison between groups regarding qualitative VAS is presented in Fig. (2)

At 12 hours, FPG recorded a higher VAS value (mean= 4.3±3.5), in comparison to MPG (mean= 2.85±2.91)

At 24 hours, FPG recorded a higher VAS value (mean= 2±2.2), in comparison to MPG (mean= 0.95±1.5)

At 48 hours, FPG recorded a higher VAS value (mean= 0.3±0.57), in comparison to MPG (mean= 0.1±0.31)

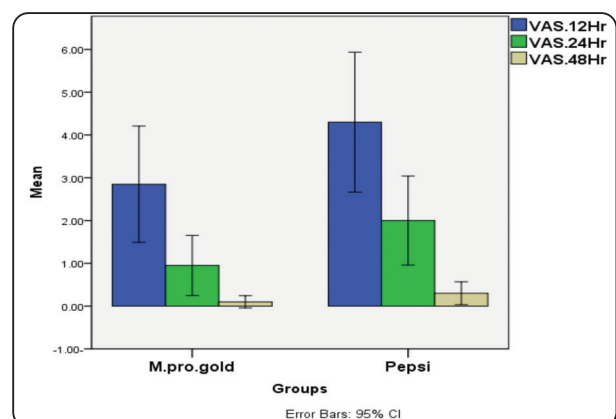


Fig. (2) Bar chart illustrating mean VAS in both groups.



### II- Comparison within the same group (Effect of time)

Comparison between various observation times throughout the same group regarding qualitative VAS is presented in Fig. (3).

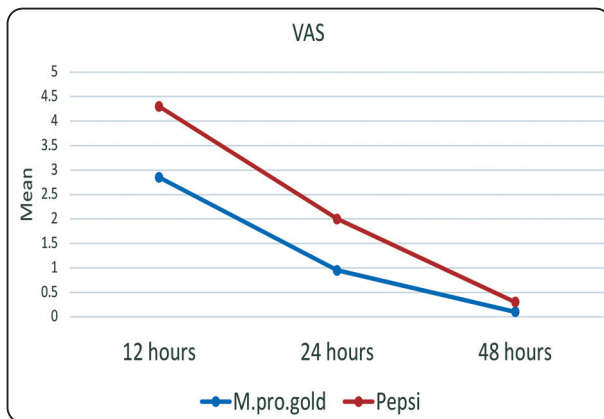


Fig. (3) Line chart illustrating mean VAS in both groups at different observation times.

**MPG:** A higher VAS value was recorded at 12 hours (mean= 2.85±2.91), this value significantly decreased at 24 hours (mean= 0.95±1.5), then showed further significant decrease at 48 hours (mean= 0.1±0.31). The Friedman test revealed that the effect of time was statistically significant (p=0.00). Wilcoxon signed Rank test revealed a significant difference between 24 hours versus 48 hours (p=0.001), between 48 hours versus 12 hours (p=0.001) and between 48 hours versus 24 hours (p=0.014).

**FPG:** A higher VAS value was recorded at 12 hours (mean= 4.3±3.5), this value significantly decreased at 24 hours (mean= 2±2.2), then showed further significant decrease at 48 hours (mean= 0.3±0.57). The Friedman test revealed that the effect of time was statistically significant (p=0.00). Wilcoxon signed Rank test revealed a significant difference between 24 hours versus 48 hours (p=0.00), between 48 hours versus 12 hours (p=0.00) and between 48 hours versus 24 hours (p=0.002).

### III-Comparison of frequency of VAS scores as qualitative data

Comparison of frequency of VAS scores as qualitative data is presented in Fig. (4-6).

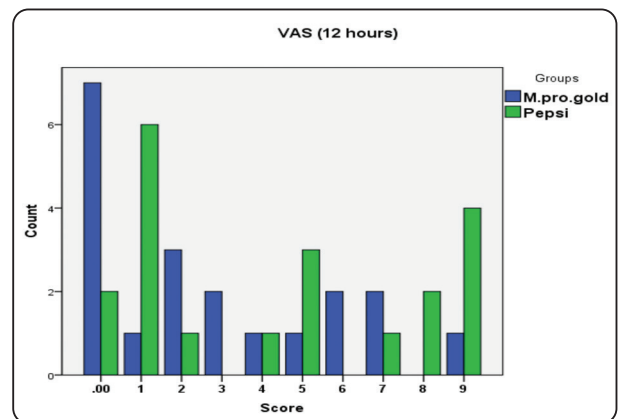


Fig. (4) Bar chart illustrating frequency of different VAS scores in both groups at 12 hours.

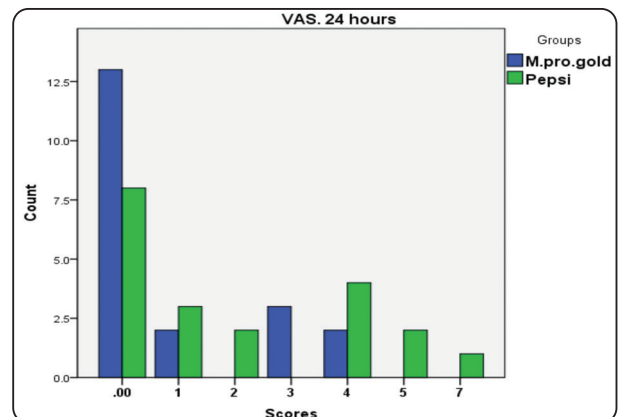


Fig. (5) Bar chart illustrating frequency of different VAS scores in both groups at 24 hours.

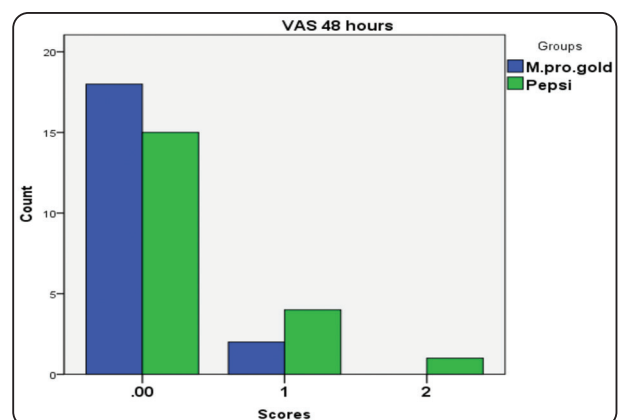


Fig. (6) Bar chart illustrating frequency of different VAS scores in both groups at 48 hours.

### *III-a- Comparison between groups*

At 12, 24,48 hours, the difference between groups didn't achieve statistical significance. (p=0.057, 0.122, 0.379)

### *III-b- Comparison within the same group*

In MPG group, 35% of cases recorded score 0 at 12 hours, in comparison to 65% at 24 hours and 90% at 48 hours. The difference over time was considered statistically relevant (p=0.00)

In FPG group, 10% of cases recorded score 0 at 12 hours, in comparison to 40% at 24 hours and 75% at 48 hours. The difference over time was considered statistically relevant. (p=0.00)

## **DISCUSSION**

During endodontic treatment procedure, the operator has control over only technical components of post-operative discomfort, such as instrumentation, irrigation, and obturation regimens. Apical ejection of contaminated material during chemo-mechanical preparation is thought to be the primary cause of periapical inflammation and postoperative pain <sup>(6,21)</sup>.

The purpose of the current research is to determine the level of postoperative discomfort following root canal instrumentation with FPG versus MPG rotary files. A sample of 40 patients were randomly allocated into two equal categories of 20. Randomization maintains study groups as similar as feasible from the start, reducing bias. The current investigation was designed as a single blinded parallel randomized controlled study in which the participant was unaware of the intervention used, but the operator and statistician were aware of the intervention following patient selection. This strategy is the most trustworthy sort of experimental investigation based on the gold standard because it automatically corrects for unknown confounders and reduces investigator bias <sup>(22)</sup>. The CONSORT 2010 guidelines for clinical trials were used in this investigation.

In this investigation, single-visit root canal instrumentation was performed. As previously stated, hand and engine-driven instrumentation which uses rotation motion appears to significantly diminish the debris ejected apically in relation to in and out (filing) approach <sup>(23)</sup>. Root canal preparation was performed with rotating instruments. Nickel Titanium files provide greater flexibility, elasticity, and cutting ability. The root canal preparation outcomes are more centred and practically get rid of iatrogenic instrumentation <sup>(24)</sup>.

In the current investigation, root canal instrumentation was carried out using FPG rotary files, which are NiTi devices designed for continuous rotation motion. Due to their high flexibility and cutting efficacy, these devices enable for speedy and safe preparation, particularly in curved root canals <sup>(14)</sup>.

The other group was performed by the MPG Rotary file, which is also a NiTi instrument designed for usage in continuous rotating motion with an passive tip and a convex triangular cross sectional area, with two files #12 and #16 having a variable tapered angle and the rest having a fixed tapered angle. During manufacture, it was subjected to a special heat treatment that increased the file's flexibility, fracture resistance, and adaptability to root canal curvatures.

According to the manufacturer, the instrument's outstanding flexibility allows for quick and secure preparation, particularly in curvy root canals. The MPG Rotary file is constructed using a CM wire associated with a sophisticated triple surface coating, which provides for increased flexibility and cyclic fatigue resistance of the file <sup>(15)</sup>.

The instrumentation approach utilised in this study was consistent with the manufacturer's guidelines. The use of a crown-down method allows each instrument to gradually attain the working length using a brushing motion with no pressure. This procedure lowers debris extrusion because the broader segment of the canal was cleaned first,

then the narrower section. Furthermore, the tool is introduced gradually and gently <sup>(25)</sup>.

Mandibular permanent molars were chosen to assess pain with the lowest factors change. It was reported that there is a statistically significant difference between mandibular molars and premolars in postoperative pain <sup>(26)</sup>. To avoid any misinterpretation of the postoperative pain scores, the study excluded individuals who had taken preoperative medications within 12 hours of intervention, such as steroidal or non-steroidal anti-inflammatory drugs and analgesics. <sup>(27,28)</sup>.

The severity of pain was measured using preoperative baseline data and postoperative data collected at various time points throughout the study. Twelve, twenty-four, and forty-eight hours were chosen because research has shown that these are the times when postoperative pain gets most severe <sup>(29)</sup>.

Root ZX, the small electronic apex locator was employed in the current study to assess working length due to its great accuracy, which has been established in vivo and in vitro <sup>(30,31)</sup>. The working length was then verified by a radiograph. To calculate working length, radiological data must be combined with results from an electronic apex locator <sup>(32)</sup>.

NaOCl is extensively used in endodontics since it meets almost all the parameters for an ideal irrigant. It has a wide spectrum of antimicrobial properties. Furthermore, it facilitates cleaning and shaping while neutralizing necrotic substance, hence expanding root canals for subsequent filling <sup>(33)</sup>. To limit the impact of irrigant extrusion into the periapical area, a side-vented 25-gauge needle was introduced into the canal without binding, as normal needle irrigation was found to cause the most fluid extrusion <sup>(34)</sup>.

As it was established that 2.5% NaOCl solution has less cytotoxicity than 5.25% sodium hypochlorite, 3 ml of it was used in our study's standardized irrigation technique between each instrument. Additionally, using 5.25% NaOCl as an

irrigation solution instead of 2.5% NaOCl does not result in a larger reduction of intracanal bacteria <sup>(33)</sup>.

Based on the findings of this research, a comparison of the two groups' mean pain severity at various postoperative intervals showed that the patients treated by using FPG files suffer more postoperative pain than patients treated by MPG files.

As previously mentioned, pushing root canal debris beyond the apex during instrumentation is the main cause of periapical tissue irritation <sup>(6)</sup>. Therefore, the number of residues ejected from the apical foramen into the tissues at the periapical end should be limited to minimum <sup>(35)</sup>. Decreased apical debris pressing has a great effect on the incidence of post-operative pain as well as inflammation. <sup>(23)</sup>. The design, cross section, and application techniques used for NiTi rotary instruments differed <sup>(36)</sup>, ending in varying volumes of debris ejected into the apical surrounding tissues <sup>(10)</sup>.

In our present study, the difference in postoperative pain might be caused by differences in taper between the two groups; as the orifice opener used in MPG rotary files kit has variable (progressive) taper #12, it is expected that it could enhance both cleaning and coronal extrusion of debris which may be the cause of the reduced post operative discomfort in the group treated with MPG files. This comes in accordance with what was reported by Buchanan <sup>(37)</sup>. In contrast, although ProTaper and Profile have greater taper than K-Flexofile; Azar et al. concluded that all the three systems result in comparable number of debris and irrigants being extruded <sup>(38)</sup>.

Another expected reason that might be the cause of post operative pain decrease in MPG group, is the variable design along its length that preserves tooth structure and minimizes the debris produced during canal preparation <sup>(37)</sup>. On contrast, all FPG rotary files have fixed tapered angle along its length.



## CONCLUSION

Within the restrictions of this study, it is possible to assume that postoperative discomfort is common after utilizing FPG and MPG rotary files, but it lasts only a short time. Although more common after using the Pepsi gold system, the discomfort was rated as low in the majority of subjects at all time points. Both files are regarded as reliable products for root canal preparation, with a normal level of postoperative pain.

## Conflict of Interest

The author disclaims any possible conflicts of interest in this study.

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