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RESEARCH ARTICLE

Comparison of two different file systems on postoperative pain after root canal instrumentation: A randomized controlled trial

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Introduction: In this study post instrumentation pain is evaluated between rotary hyflex CM files and conventional k-files at different time intervals. **Methodology**: fifty patients were equally assigned into two groups and instrumented using hyflex cm or conventional files. VAS for pain was noted before the start of a root canal and after the procedure at 12, 24, and 48 hours. **Results**: There was no significant difference at 12, 24, and 48 hours with P values being 0.127, 0.867, and 0.846 respectively. **Conclusion**: There is no significant difference in causing post-instrumentation pain between hyflex CM and conventional files at different time intervals. However, when accessing preop pain of the conventional file group, it had more pain mean score compared to hyflex group. According to this study, Conventional files may be able to slightly decrease the chances of post-instrumentation pain more than hyflex CM instrumentation.

Keywords: hyflex CM, post instrumentation, conventional files, VAS

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Introduction

The success of endodontic treatment depends upon proper root canal instrumentation, debridement, disinfection, and three-dimensional apical seal to coronal seal [1]. However certain canal morphologies, preparation techniques, and armamentarium may pose a challenge in achieving these goals. Due to the vast complexity of endodontic factors, there has been a huge advancement in the instrumentation system. The introduction of the Nickel-titanium rotary systems has brought a paradigm shift in endodontics due to its ability to respect the canal curvature and morphology [2, 3].

The initially introduced rotary file systems brought the challenge of file breakage, ledge formation, and perforations. Further advancement in these systems lead to the development of a 'controlled memory file' (Hyflex CM coltene) [4]. This file was made by CM wire which had the property to attain the shape of the curved canal even when out of the canal [5]. This six-file system had the advantage of having high fatigue resistance and drastically reducing the chances of ledge formation, transportation, and perforations, especially in curved canals.

Post-operative pain is the most frequent complication that is encountered during root canal treatment which can be due to insufficient root canal preparation, debris or intracanal medicaments, presence of preoperative pain, periapical pathosis, canal apical patency and apical extrusion of debris, irrigant or filling material [6, 7]. One of the integral part of endodontic treatment is prevention and management of this post endodontic pain. According to studies reported, frequency of post endodontic pain may range from 16% to 50% in endodontic cases [8].

Pain may occur after root canal preparation due to remaining endodontic microbiota within the canal system and the extrusion of dentinal debris beyond the apex [9]. Root canal treatment can be done in single or multiple visits. It has been shown that patients prefer single-visit treatment due to decreased number of operative visits, less time-consuming, and more economical [1, 10, 11].

Post-instrumentation pain presents as a common finding, the dentist should not get worried and not immediately initiate retreatment or extraction [12]. Also patients should be made aware of post-instrumentation pain and analgesic medication prescribed accordingly. This not only encourages an anxious patient for treatment but provides the dentist with the patient's compliance, cooperation, confidence and increases the dentist's rapport [13]. The shift from hand instrumentation to rotary systems has led to better cleaning and shaping of canal anatomy in less time duration, which has made rotary instrumentation a desired preference among patients and dentists [14-16]. This study therefore aims to clinically compare single visit post instrumentation pain between rotary file system Hyflex CM and conventional hand K-file system and their possible impact on pain.

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Materials and Method

This randomized control trial research was conducted in the accordance with the Declaration of Helsinki and by the regulations of the ethics committee of the Operative and Endodontic Department of Islamic International Dental hospital (Ref # 2021/007/007). The duration of study took approximately 12 months and was conducted by a single operator. A total of 50 sample size patients were taken and divided into two groups giving 25 participants in each group. The sample size was decided using the OpenEpi sample size calculator keeping a confidence level of 95%, with sample size (n) being 50.

The study was conducted between two different systems that are the conventional hand K-file vs the Rotary file system Hyflex CM. The patients' inclusion criteria were as follows:

- Permanent mature teeth having single roots.
- The age limit of the patient should ideally be between 20-60 years of age.
- Initially, before treatment, the patient should fall in the Visual Analogue Scale (VAS) "5" or more preoperatively.
- The tooth should be tender to percussion.
- Patients should have been diagnosed with Apical Periodontitis and pulpal diagnosis should be irreversible pulpitis or necrotic pulp.
- Patient with a necrotic tooth.

The exclusion criteria were as follows:

- Unrestorable grossly carious teeth, Perforated teeth with poor prognosis, or broken-down roots.
- Patient self-medicating or taking prescribed antibiotics or analgesics.
- Teeth with any sort of complexity like dilaceration, or internal or external root resorption.
- Teeth with previously endodontic treatment.
- Teeth with multiple roots.
- Teeth associated with draining abscess or sinus tract.
- Patients who had uncontrolled systemic diseases.

Patients were referred to the Operative and Endodontic Department. The pulpal and the apical diagnosis were confirmed by the operator with the help of periapical digital radiographic evaluation, periodontal evaluation, percussion, and use of the pulp tester. The treatment protocol was explained to the patient and an informed written consent form was signed for ethical consideration. VAS was presented as a numerical rating scale to the patient numbered from 0-10. The patient was explained pain intensity from "0" to be none and gradually increasing towards severe pain at a score of "10". While score of "5" being as moderate pain [17, 18].

VAS was noted before the treatment. Patients were randomly assigned into two groups. Local anesthesia (Medicaine, Korea) was administered and consisted of 2% lidocaine with epinephrine 1:100,000, and a rubber dam was applied. Access opening and single visit canal preparation were done.

Group 1 was assigned preparation with the rotary file system Hyflex CM (Coltene, Switzerland) while group 2 was prepared using conventional stainless-steel files (Mani, Japan). Each group consists of 25 participants.

For group 1, the glide path was made using a conventional hand file up to size 20 k-file. Followed by sequential canal preparation was initiated using Hyflex CM files as per the color coding red 0.08 taper (08/25), yellow 0.04 taper (04/20), red 0.04 taper (04/25), yellow 0.06 taper (06/20) and lastly 0.30 tip diameter blue color-coded file with 0.04 taper (04/30).

Copious irrigation between each file was done using 5.25% NaOCl (Sodium Hypochlorite) with an irrigation needle (27gauge pulpdent double-sided vent) as deep within the canal as possible but within a range of less than 2mm from the working length. Final irrigation with 5ml 5.25% NaOCl, 5 ml 17% EDTA, and 5ml 2% Chlorhexidine was done. 5ml distilled water was used following each irrigation to avoid interaction of irrigants with each other forming insoluble precipitates like para-chloroaniline [19]. The tooth was sealed by a temporary restorative material cavit (3M) till the next visit.

For group 2, sequential stainless steel hand K-files up to size 30 were used, respecting the working length of the canal, with the same irrigation protocol and temporary restoration placed as mentioned above.

Preoperative Pain and Pain after 12, 24, and 48 hours were assessed by VAS for both groups. The patient was contacted by the clinical assistant via telephone after 12, 24, and 48 hours to provide relevant information regarding pain rating. In the case of VAS being recorded above 9, analgesics were prescribed.

After 48 hours of data collection, patients were called back for obturation with Gutta Percha cones of the respective system and AH plus sealer (Dentsply, Sirona, USA) using the cold lateral condensation technique. Treatment was concluded by sealing the coronal access cavity with dental adhesive and composite resin (3M Filtek Universal composite, USA) [5].

Statistical analysis

Data analysis was done using Statistical Package for Social Sciences (IBM® SPSS® Statistics developed by Norman H. Nie, Dale H. Bent, C. Hadlai Hull, version 25, Chicago, USA). Descriptive statistics were expressed as mean and standard deviation. Frequencies and mean VAS were calculated for each group and tested for significance with Mann Whitney U test. The effect of age and gender on VAS between the two groups is also calculated using Mann Whitney U test.

Results

Patients enrolled in the clinical trial are shown in the following flow diagram in Figure 1.

Demographic data are shown in Table 1, Table 2, and Figure 2. Among the total participants of study 64% were

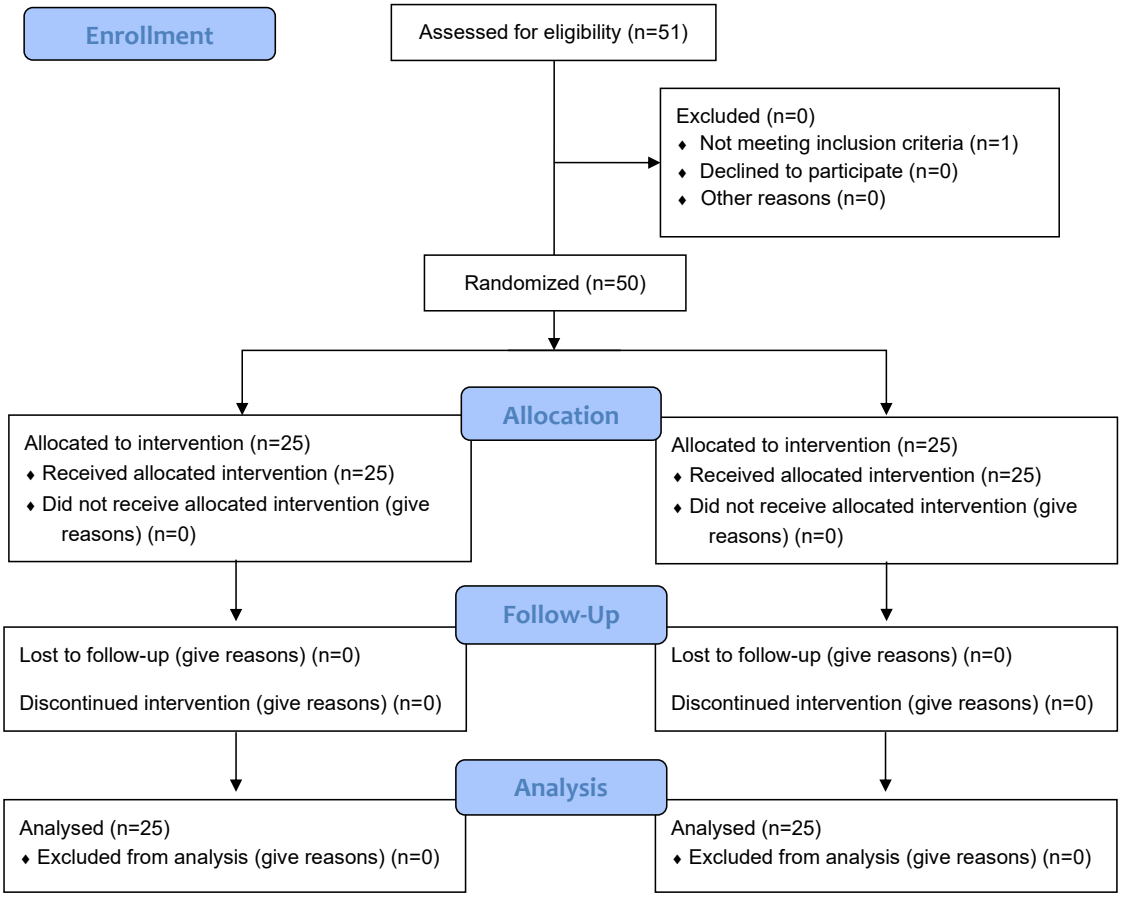

Fig. 1. Consort flow diagram

Table1. Gender distribution in both groups

		gender		Total
		male	female	
group	Control hand K-files	12	13	25
	Hyflex CM	6	19	25
Total		18	32	50

Table 2. Jaw frequency in both groups

		maxilla	mandible	Total
group	Control hand K-files	14	11	25
	Hyflex CM	14	11	25
Total		28	22	50

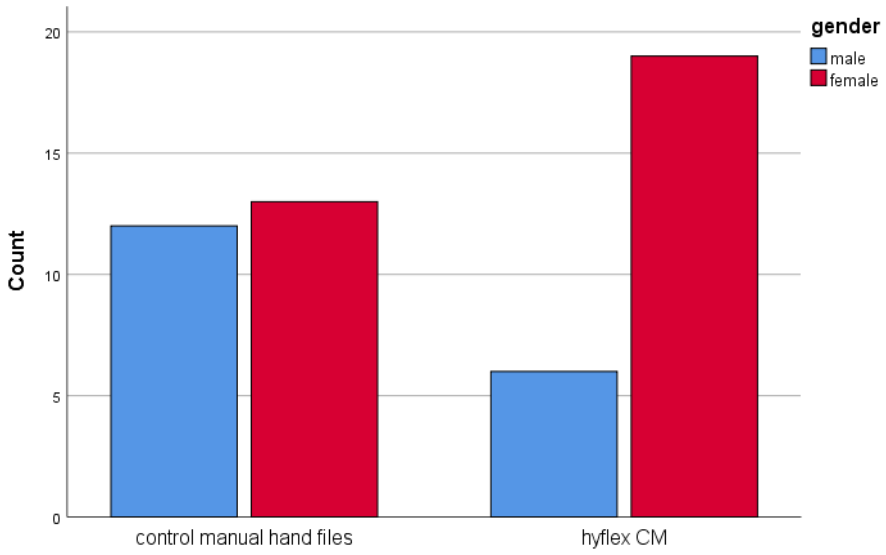

Fig. 2. Gender frequency in both groups

female and 36% were male. Also a total of 56% maxillary teeth were included in study and remaining 44% mandibular teeth. No significant difference was observed in causing post instrumentation pain between conventional K-file and Hyflex CM file system at 12, 24, and 48 hours (P value 0.127,0.867,0.846 respectively) Table 3. Although a significant difference was observed in preop pain VAS in the conventional file group compared to Hyflex CM group (P=0.004). (Table 3)

When gender groups were analyzed no significant difference was observed between the two groups at 12, 24, and 48 hours (P value 0.705, 0.172, 0.344 respectively) as shown in Table 4.

On jaw analyses also no significant difference was observed between the two groups at 12, 24, and 48 hours (P value 0.579. 0.266, 0.696 respectively) as shown in Table 5.

Among all the mean statistical values between the control group and Hyflex CM group, genders group and jaws group, the similarity of decreasing pain is visible when viewed on bar graph through 12,24 and 48 hour time period. This can be seen in figure 3, 4 and 5 respectively.

Discussion

In our study no significant difference was observed in post-instrumentation pain among genders and jaws. Although the bar graph shows slightly more pain prevalence among female patients but this could be due to more number of female participants (64%) compared to males (34%) as shown in Figure D in this study. Other studies have shown pain to be more prevalent among females compared to males [20-22].These results could be due to higher number of sample size taken by these studies which our study lacked. While some studies show no relevant difference

Table 3. Correlation between the two groups

	preo op pain VAS	12 hour VAS	24 hour VAS	48 hour VAS
Mann-Whitney U	164.500	235.000	304.000	303.000
Wilcoxon W	489.500	560.000	629.000	628.000
Z	-2.915	-1.525	-.168	-.194
Asymp. Sig. (2-tailed)	.004	.127	.867	.846

Table 4. Correlation between the two genders

	preo op pain VAS	12 hour VAS	24 hour VAS	48 hour VAS
Mann-Whitney U	207.000	269.500	221.500	243.500
Wilcoxon W	735.000	797.500	392.500	414.500
Z	-1.662	-.379	-1.365	-.947
Asymp. Sig. (2-tailed)	.096	.705	.172	.344

Table 5. Correlation between jaws

	preo op pain VAS	12 hour VAS	24 hour VAS	48 hour VAS
Mann-Whitney U	306.500	280.000	252.000	289.000
Wilcoxon W	559.500	533.000	505.000	542.000
Z	-.030	-.555	-1.112	-.391
Asymp. Sig. (2-tailed)	.976	.579	.266	.696

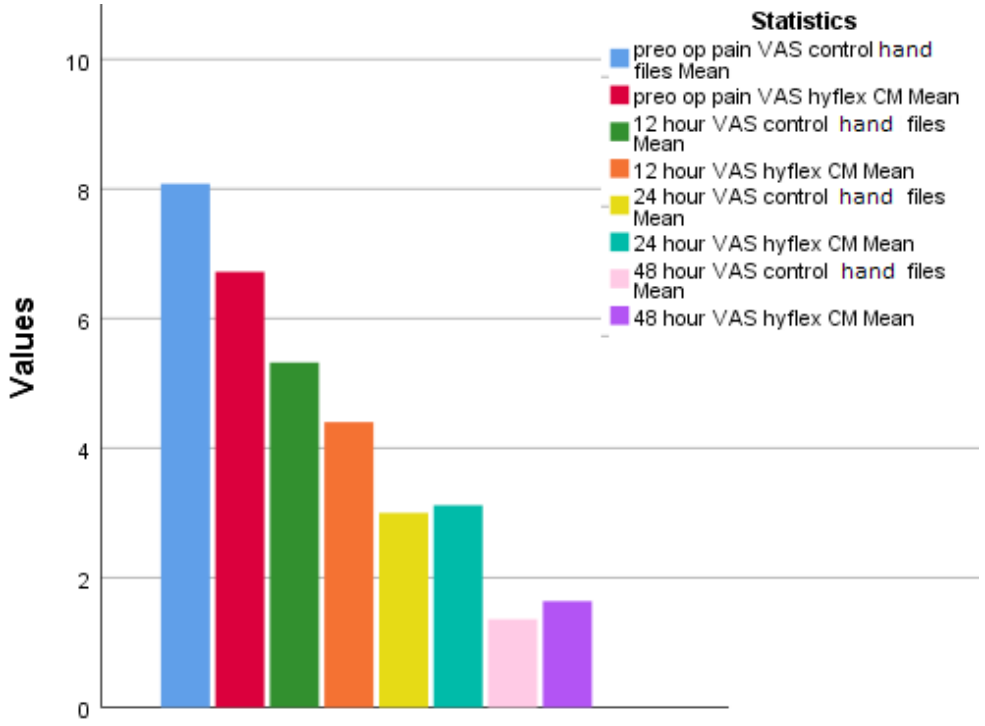

Fig. 3. Bar graph for mean statistics of manual group and Hyflex CM group

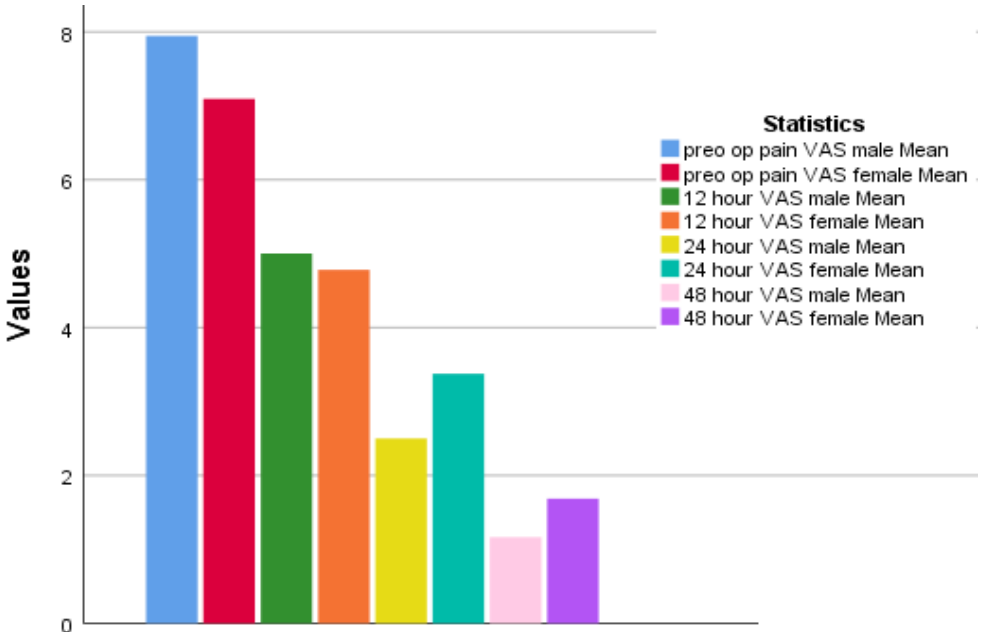

Fig. 4. Bar graph for mean statistics of gender group

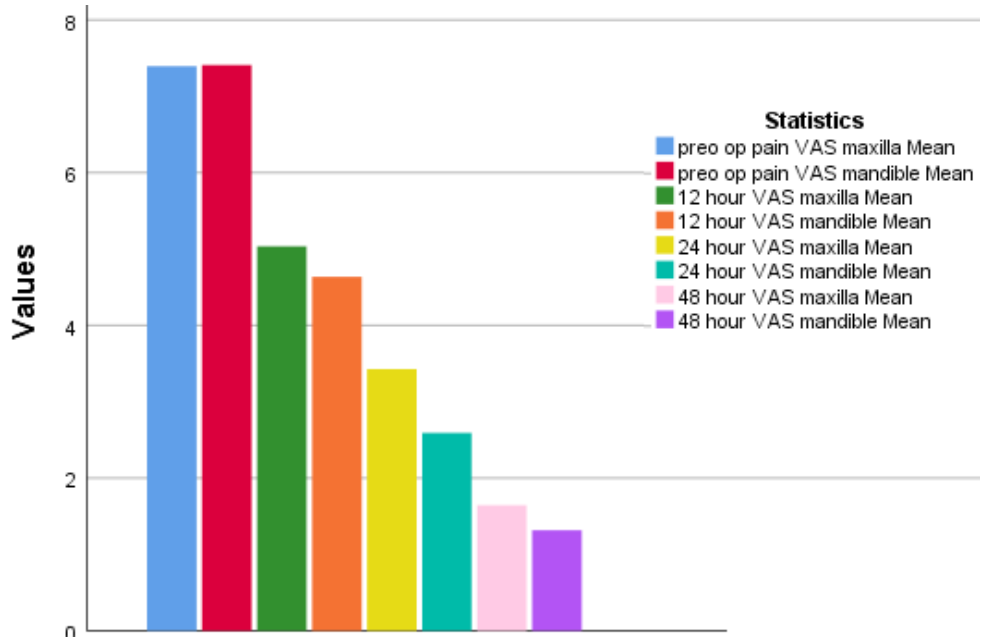

Fig. 5. Bar graph for mean statistics of jaws group

among male and females in experiencing pain and suggest large prospective studies with registry data including confounders to be done in the future [23, 24].

One of the major hurdles that a clinical study of this nature faces is that pain is very subjective when coming to its evaluation and calculating pain is rather vague. In this regard designing of the questionnaire needs to be investigated very carefully. It should be relatively straightforward and easy for the patient to interpret [25]. Hence the reason for choosing VAS in this study was its reliability for pain assessment [26].

Pain is multifactorial and numerous sensations contribute towards postoperative pain making it extremely challenging to associate all the possible causes of pain. The highest level of post-endodontic pain reporting was observed 48-72 hours postoperatively [27].

A strong correlation was found between pre- and postoperative pain. Patients experiencing higher pre-operative pain were more likely to experience long-term postoperative pain. Numerous causes for postoperative pain were identified such as periapical pathosis, missed canals, inadequate cleaning, and shaping, inability to maintain apical patency during instrumentation, apical extrusion of debris, irrigant, and intracanal medicament extrusion, overbite restoration, and even the type of tooth [28]. The most common errors that are generally reported are missed canals, perforation, improper cleaning and shaping of complicated root canal anatomy, and ledge formation.

Mild discomfort is a common complaint after endodontic procedures but literature reports postoperative pain and flare-up ranging from 3% - 58% [7]. Microbial, chemical, and mechanical injuries are the leading cause of acute peri-

apical inflammation. Mechanical reasons can be attributed to over-instrumentation, while chemical injuries include extrusion of medicines, filling materials, or irrigants [7].

Regardless of how much care was taken to keep everything standardized, it is not possible to eliminate all factors of pain and label it solely based on a single factor. In multiple rooted teeth, tissue debris along with bacteria can persist due to the complex canal anatomy hence good illumination and magnification with help of loupes or dental microscope are advised. Post-appointment soft tissue trauma causes a high level of discomfort at times due to local anesthesia administration or rubber dam placement.

The patients in our study did not report any complications like swelling or paraesthesia and utmost care was given to provide an atraumatic treatment protocol [27].

No intracanal medication was used in our study although it can reduce postoperative pain. Chlorhexidine alone and Chlorhexidine and CaOH reduce post-operative pain compared to no intracanal dressings between appointments [28].

A possible cause of flare-up is apical extrusion of dentinal mud.

It has been reported that the chances of apical extrusion increase with the increase in the diameter of the apical foramen [29] [30]. Which depends upon the selection of the final apical size of the instrument [31], instrumentation techniques, designs of instruments, the rotation speed of the file, and movements of the hand of the operator during preparation [32].

Other factors that could affect the extrusion of debris include root dentin hardness [33], quantity and momentum of flow of the irrigation in the root canal [34, 35], and the position of the tooth whether in the upper or lower jaw, which may be affected by the gravity.

Studies demonstrate rotary NiTi systems with continuous rotation method, compared to reciproc file system, to be associated with less apical extrusion. The reason is due to the pitch design of the file, forward kinematics which forces debris in a coronal direction instead of apical extrusion [36].

Numerous studies have been published comparing different file systems for apical debris extrusion. In a research reciprocating file system like Wave One Gold and continuous rotating ProTaper universal rotary instruments produced significantly more debris compared to Hyflex CM rotary instruments [37].

In another in vitro study ProTaper Universal and Hyflex systems extruded more debris apically compared to ProTaper Next and Twisted File Adaptive system [38].

Elmsallati et al. compared rotary instruments with different short, medium, and large pitch designs for apical extrusion of the debris. It was concluded that short pitch design extruded less debris compared to medium and large. The reason noted with Hyflex files for increased debris extrusion was the unwinding feature of the instrument. The spirals of the Hyflex system are well known to unwind during root canal preparation and were deformed around 80% as reported in the study [30].

Another study on Hyflex CM files showed a significant decrease in cutting efficiency and flexibility after six sterilization cycles [39] [40].

Each Hyflex CM file can be used once in each canal as it unwinds and needs heat treatment to return to normalcy. In our study since only single canal teeth were chosen hence each set of Hyflex CM files was used once per sample up to six different times with each time being sterilized.

No file separation occurred throughout the testing of our study. All Hyflex CM NiTi rotary files continued to prepare the canal without exceeding the torque control limiter value, and all files returned to their original shape after each sterilization cycle. This is similar to research by Thompson et al. [41], which showed no significant difference in Hyflex CM NiTi files' ability to maintain original canal curvature through 3 uses in resin blocks. It is, therefore, necessary for the clinician to be aware of different variables present during clinical use when determining the ability of an instrument that can be reused for subsequent instrumentation after sterilization, as statistical significance may or may not directly correlate to clinical significance.

Extrusion of irrigants can also be a leading cause of post-instrumentation pain. A study was conducted that analyzed that side vented needles extruded less irrigant compared to the regular needles. Pressure applied during irrigation can be standardized by the use of a device that provides a constant flow rate as the operator handling irrigation procedure can even differ [42]. Different methods of irrigation delivery can be used which include manual positive pressure irrigation, Endovac negative pressure irrigation, ultrasonic activation (Endoactivator), photon-induced photo-acoustic streaming (PIPS), and Rinsendo.

Among these all, Endovac and Endoactivator did the least amount of irrigant extrusion [43-45]. Different NaOCl concentrations have been reported to affect the biological properties. The higher the concentration of NaOCl (1.3% and 5.25%) the most long-lasting, adverse reactions were noted in comparison to the ones with lower concentration. Periapical extrusion was noted with higher concentration causing more clinical manifestations [46].

In the current study, the effect of two different types of instrumentation techniques on post-operative pain was evaluated at 3 different time intervals. From scoring to treatment protocol everything was kept as standardized as possible with a single clinician preparing for both groups. This study shows no significant pain difference using hand K-file system or rotary Hyflex CM file system. Therefore it can be safe to say that Hyflex CM file system can be used without the fear of eliciting any post instrumentation pain to the patient. This system will not only help clear more debris, adequately clean canal anatomy by maintaining original canal curvature but also save chair-side time with decrease in patient's visits to the dentist [47-52].

Conclusion

In conclusion, the incidence of postoperative pain in 2 different types of instrumentation systems assessed in this study had no significant difference at 12, 24, and 48 hours (0.127, 0.867, and 0.846 respectively). No significant difference was found between the different genders or between the maxillary or mandibular jaw. However, a significant difference was observed in initial preoperative pain VAS in conventional files compared to Hyflex CM group (P=0.004).

Therefore, the null hypothesis was accepted according to the conditions established for this study, there was no statistically significant difference among the different instrumentation systems in causing post-instrumentation pain.

Authors' contribution

SaS (Conceptualization; Data curation; Resources; Project administration; Formal analysis; Supervision; Writing – original draft & Writing – review & editing)
NS (Formal analysis; Data curation; Investigation; Methodology; Resources)
MA (Data curation; Methodology)
ShS (Data curation; Methodology)
MP (Supervision; Writing– original draft; Validation; Visualization)
AS (Validation; Visualization; software)

Conflict of interest

None to declare.

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