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ORIGINAL ARTICLE

Incidence of Postoperative Pain after Single Visit Root Canal Treatment using XP-endo Shaper, 2Shape and ProTaper Gold Rotary Systems: A Prospective Randomized Clinical Trial

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ABSTRACT

Objective: To evaluate the incidence of postoperative pain, treatment time and analgesic intake after single visit endodontic treatment of mandibular molars using XP-endo Shaper, 2Shape and ProTaper Gold rotary systems.

Methods: 150 patients with irreversible pulpitis were scheduled for single visit root canal treatment. Teeth were randomly assigned to one of the three groups: ProTaper Gold (PTG; Dentsply Tulsa Dental Specialties, Johnson City, TN), 2Shape (2S; Micro-Mega, Besancon, Cedex, France) and XP-endo Shaper (XPES; FKG Dentaire, La Chaux-de-Fonds, Switzerland). Preoperative and postoperative pain was rated by the patients at the beginning of treatment and after 24, 48, 72 hours and 7 days on Heft Parker's visual analog scale (HP-VAS).

Results: Highest mean postoperative pain score was recorded in PTG ($P<0.05$), followed by 2S and XPES respectively at all time intervals. XPES exhibited maximum reduction from preoperative pain at 24 (48.67%) and 48 hours (96.90 %) with no pain at 72 hours. Treatment time was significantly least in XPES ($P<0.05$) followed by 2S and PTG; but no significant difference in analgesic intake was noted.

Conclusion: XPES exhibited least postoperative pain at all time intervals and treatment time, followed by 2S and PTG rotary systems respectively.

Keywords: 2Shape, debris, postoperative pain, ProTaper Gold, XP-endo Shaper

HIGHLIGHTS

- Debris extrusion during chemo mechanical preparation is allegedly one of the principal causes of postoperative pain.
- Maximum mean pain in all groups occurred in first 24 hours showing a gradual reduction. After 7 days, no pain was noted in any of the groups.
- The instrument design and multiple files may have resulted in higher debris production and extrusion resulting in more postoperative pain of PTG group.
- There is a direct correlation between incidence of postoperative pain, instrument design and number of instruments used for preparation of the pulp space.

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INTRODUCTION

Endodontic intervention can result in postoperative pain varying from mild to severe. According to a review by Pak and White (2011), prevalence of postendodontic pain is 40% after 24 hours which falls to 11% after 7 days (1). Postendodontic pain results from mechanical, chemical or microbial injury in the pulpal or periarticular tissues (2, 3). Following endodontic treatment an antigen antibody complex

forms when antigens originating from pulp space are pushed beyond apical foramen leading to severe inflammatory reaction and pain (3, 4). All instruments and instrumentation techniques result in debris extrusion (5, 6). However, extent of extrusion may vary according to the preparation technique, irrigation, recapitulation, instrument design, and the number of instruments used (7-10).

Over the years a number of rotary instruments have been introduced into the market. Most of these file systems use multiple files for shaping of the pulp space. The current trend is to reduce the number of files for shaping procedures so as to reduce the shaping time and improve patient comfort. This has been made possible by the introduction of improved NiTi metallurgy and innovative instrument design, thereby simplifying the shaping procedures and consequently resulting in reduction of number of instruments and instrumentation time. Literature has reported numerous studies comparing single and multiple files, rotary and reciprocating systems (11, 12).

The purpose of this prospective randomized clinical trial was to compare the incidence of postoperative pain and analgesic intake after root canal preparation of posterior teeth using ProTaper Gold (PTG), 2Shape (2S) and XP endo Shaper (XPES) rotary systems. The null hypothesis tested was that there is no difference in the incidence of postoperative pain after using any of the three instrumentation systems.

MATERIALS AND METHODS

The protocol of this randomized clinical trial was approved by institutional review board and ethical committee of the Faculty of Dental Sciences. The clinical trial was registered in clinical trial registry (CTRI/2018/02/011652) and reported according to the consolidated standards of reporting trials CONSORT guidelines (13) and the study was conducted in accordance with the Declaration of Helsinki. One hundred and fifty patients were recruited from Faculty of Dental sciences. To ensure standardization, all patients were treated by single operator familiar with instrumentation systems, over a period of 8 months from February to September 2018. Age, sex, tooth type of all patients included in this study were not significantly different between groups; hence, effect of these variables on results was expected to be minimal. Inclusion criteria were restorable mandibular molars of both male and female patients in good health aged between 20 to 45 years, having diagnosis of irreversible pulpitis. Exclusion criteria included presence of root curvatures, periapical radiolucency, sinus tracts, internal or external resorption, tenderness on percussion, traumatic bite, intolerance to NSAID's, grade 2 or 3 mobility, open apex, nonvital teeth, history of medication prior to treatment, retreatments, pregnant patients, and anatomic variations All teeth selected for the study had #10 or #15 file snugly fitting at apex of root canals; to avoid variations in debris extrusion canals with apical diameter larger than 20 and smaller than 10 were excluded in the study.

For sample size estimation, a power analysis was established by G*power, version 3.0.1 (Franz Faul universitat, Kiel, Germany). A sample size of 46 per group would yield 80% power to detect significant differences, with effect size of 0.27 and significance level at 0.05. To compensate for the losses in follow up this number was increased to 50 per group.

The total number of patients assigned to three groups were 150 out of which, 6 patients did not report for follow up; therefore, total number of 144 patients were assessed (Fig. 1). Patients were asked to rate their preoperative pain on a HP VAS scale. An explanation of procedure and possible risks were explained after which informed consent was taken.

Diagnosis of symptomatic irreversible pulpitis was made by chief complaint of spontaneous pain, clinical examination and radiographic evaluation. A cold test (Endo frost – Roecko Langenau, Germany) was performed to confirm diagnosis of irreversible pulpitis. After rubber dam isolation, a cotton pellet saturated with Endo frost was applied for 5 seconds to the mid-third of the buccal surface of tooth's crown. Sensibility of contralateral/ adjacent tooth with vital pulp was also examined. If the response to the cold test of the affected tooth was severe and pain persisted after removal of the cold cotton pellet, then the diagnosis was confirmed as symptomatic irreversible pulpitis.

Randomization was done by SNOSE (sequentially numbered, opaque, sealed envelopes) method for allocation concealment which conceals the sequence until interventions were assigned. A piece of paper containing randomized group number was sealed in dark colored envelope with respective serial number by a clinical assistant. Patients were assigned numbers as they sequentially entered the study. The envelope was opened once the intervention was assigned. Based on group assigned, treatment was carried out by a single operating dentist for all the three groups. Patients were not aware of the file systems used. After the data was collected a second investigator who was blinded to the groups performed statistical analysis along with statistician.

Treatment Protocol

Administration of Inferior Alveolar Nerve Block, buccal infiltration was done using 1.8 mL 2% lidocaine with 1:80,000 epinephrine (Septodont, Saint-Maur-des- Fosses Cedex, France) at the rate of 1 ml/min. Patients were assessed for lip numbness every 5 min for 15 mins. Five minutes after full lip numbness was recorded buccal infiltration was administered. After confirmation of adequate anesthesia, under rubber dam isolation access cavity preparation was done. After confirming adequate anesthesia, under rubber dam isolation access cavity preparation was done and canals were explored in watch winding motion with a #10, #15 K type hand files (Dentsply Maillefer, Ballaigues, Switzerland) 0.5 mm beyond the apex to confirm apical patency, initial diameter of foramen and canal curvature. Working length was established using Root ZX apex locator (J Morita Corp, Kyoto, Japan). The file was withdrawn and 0.5 mm subtracted to establish final working length which was confirmed radiographically. Glide path was prepared till working length using #15 K- file in watch winding motion.

The sequence of instrumentation used for treatment in each group was according to the manufacture's recommendations:

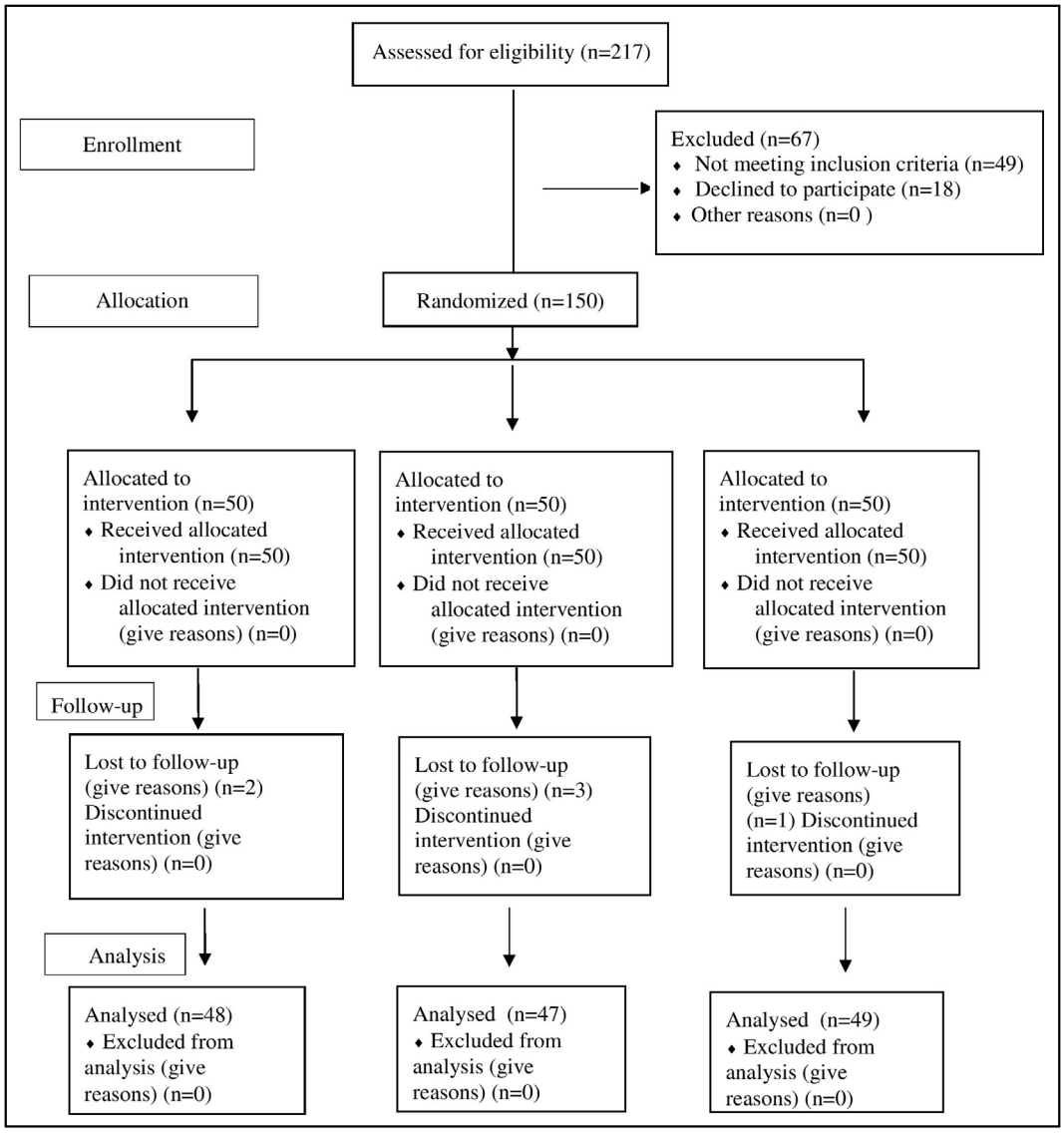

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing the progress of subjects at each stage of the clinical trial

Group 1: Protaper Gold (Ptg) (Dentsply Maillefer, Ballaigus, Switzerland) (n=48).

For PTG group, shaping files (S1, S2) were used with a brushing action on the withdrawal stroke in order to create a straight-line radicular access. Finishing files (F1, F2) were used passively till working length. For file size S1 speed was 300 rpm and torque used was 5.1 N-cm. For PTG file S2 and F1, speed was 300 rpm and torque used was 1.50 N- cm. For files F2 speed was 300 rpm and torque were 3.10 N-cm.

Group 2: 2Shape (2S) (Micro-Mega, Besancon, Cedex, France) (n=47).

It has two shaping instruments TS1(#25 .04) and TS2 (#25 .06) which were used at speed of 300 rpm and torque 1.2 Ncm with progressive upward circumferential filing movement. TS1 was inserted into the root canal until a resistance was felt, then two to three circumferential brushing strokes were performed to eliminate primary constraints. This was then followed by TS2 used with brushing motion till the working length.

Group 3: Xp- Endoshaper (XPES) (FKG Dentaire, La Chaux-de-Fonds, Switzerland) (n=49).

XPES is a one file shaper with initial taper of 1%. used at speed of 800 rpm and torque was 1 N-cm. In phase one, working length was achieved with a #15 K file. This was followed by irrigation and recapitulation after every three strokes and especially after reaching working length. In phase two use 5-10 long strokes were used to create taper of 4%.

During instrumentation, irrigation was done thoroughly and recapitulation done with #10 K file in all groups. A total of 2 ml 4% NaOCl was used for irrigation between each instrument change. Irrigation was performed with #30-gauge side venting needle (Maxi-i-probe, Dentsply, Rinn, Elgin, IL). After concluding instrumentation, canals were flushed with 2 ml 4% NaOCl, solution and agitated with sonic activation using Endoactivator (Dentsply Tulsa Dental Specialties, Tulsa, OK, USA) placed in canal 2 mm short of WL for 1 minute per canal followed by irrigation with 5 ml 17% EDTA solution and

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

Baseline demographic and clinical feature	PTG (n=48)		2S (n=47)		XPES (n=49)		Total (n=144)
	n	%	n	%	n	%	
Male	24	32.87	24	34.87	25	34.24	73
Female	24	33.80	23	32.39	24	33.80	71
Mandibular first molar	25	33.78	24	32.43	25	33.78	74
Mandibular second molar	23	32.85	23	32.85	24	34.28	70

PTG: Protaper Gold, 2S: 2Shape, XPES: XP-endo Shaper, n: Number of patients in a group

TABLE 2. Comparison of the Pre- and Post- operative pain scores among the three groups assessed using Kruskal-Wallis Test

Time interval	Instrumentation system	n	Min	Max	Mean	Standard deviation	Median	Kruskal-wallis	P
Preoperative pain	PTG	48	0	137	44.19	38.63	45.5		
	2S	47	0	142	49.04	44.87	52.00	0.55	0.75
	XPES	49	0	129	40.45	37.41	46.00		
Pain after 24 hours	PTG	48	0	125	40.69	35.30	43.0		
	2S	47	0	116	27.96	39.93	0.00	19.59	0.00*
	XPES	49	0	89	13.14	27.72	0.00		
Pain after 48 hours	PTG	48	0	120	32.77	36.38	40.50		
	2S	47	0	101	22.02	31.70	0.00	25.50	0.00*
	XPES	49	0	34	2.45	8.369	0.00		
Pain after 72 hours	PTG	48	0	45	4.52	10.94	0.00		
	2S	47	0	38	3.17	9.579	0.00	8.25	0.016*
	XPES	49	0	0	0.00	0.00	0.00		
Pain after 7 days	PTG	48	0	0	0.00	0.00	0.00		
	2S	47	0	0	0.00	0.00	0.00	0.00	1.00
	XPES	49	0	0	0.00	0.00	0.00		

*: P value significant at 0.05, indicates significant difference. n: Number of patients in a group, Min: Minimum, Max: Maximum, PTG: Protaper Gold, 2S: 2Shape, XPES: XP-endo Shaper

sonic agitation with Endoactivator for 1 minute to remove the smear layer. Final flush of the canals was done with 2 ml of 4% NaOCl.

Obturation was done with continuous wave of compaction technique using AH-plus sealer (Dentsply Maillefer, Ballaigus, Switzerland) followed by composite resin restoration (Coltene/Whaledent). Time taken to complete the treatment of every patient was recorded. In the event of moderate or severe pain, patients were advised to take analgesics (400 mg Ibuprofen) as a rescue medication at a dosage of 1 tablet SOS and repeated every 6 hours if required. They were also asked to record the number of tablets taken and mark the level of pain on the HP- VAS scale chart given. They were recalled after 7 days for follow up.

Assessment of Pain

Patients were asked to rate their pre- and postoperative pain on Heft parker visual analog scale (HP VAS). HP VAS is a 170-mm line marked with various terms describing levels of pain. The millimeter marks were removed from scale. Scale was divided into 4 categories: "no pain" corresponded to 0 mm; "faint, weak or mild" pain corresponded to 0–54 mm; "moderate" pain corresponded to 55–114 mm; and "strong, intense, and maximum possible" pain corresponded to greater than 114 mm. Patients received a questionnaire (pain assessment HP VAS chart and medication record chart) for postoperative pain.

Patients were asked to mark severity of their postoperative pain on HP VAS after 24, 48, 72 hours and 7 days; and record the number of analgesic tablets taken, if any on the provided chart. They were telephonically contacted after 24, 48, 72 hours and 7 days and reminded for the same. After 7 days charts were collected from the patients for analysis.

Statistical Analysis

SPSS (Statistical Package for Social Sciences) version 20. [IBM SPASS statistics (IBM corp. Armonk, NY, USA released 2011)] was used for statistical analysis. Data was checked for normalcy by Shapiro Wilk test. Data showed non–normal distribution hence, Kruskal-Wallis, non-parametric test was applied to check statistical difference of pain scores, number of analgesics taken, time taken among the groups and Post-hoc Mann-Whitney test was used for pair-wise comparison. The difference was considered statistically significant at 0.05 ($P<0.05$). A confidence interval of 95% was obtained.

RESULTS

The baseline demographic data used in study groups is shown in Table 1. The mean age of 144 patients assessed in this study

TABLE 3. Non parametric Post Hoc Mann Whitney test to compare the pain score at all time intervals

Time interval	PTG v/s 2S difference		PTG v/s XPES difference		2S v/s XPES difference	
	Mean	P	Mean	P	Mean	P
Preoperative	-4.85	0.96	3.73	0.80	8.50	0.33
After 24 hours	12.73	0.029	27.54	0.00*	14.81	0.021
After 48 hours	10.75	0.08	30.32	0.00*	19.57	<0.001*
After 72 hours	1.35	0.42	4.52	0.003*	3.17	0.02
After 7 days	0.00	1.00	0.00	1.00	0.00	1.00

*: P value significant at 0.05/3=0.016, indicates significant difference, PTG: Protaper Gold, 2S: 2Shape, XPES: XP-endo Shaper

TABLE 4. Comparison of percentage change in pain scores using Kruskal-Wallis test

Time Interval	Instrumentation system	n	Min	Max	Mean	Standard deviation	Median	Kruskal-wallis	P
Change from preoperative	PTG	48	-21	0	-5.13	4.967	-5.0		
Pain to 24 hours	2S	47	-100	0	-30.85	43.73	-1.96	9.13	0.010*
	XPES	49	-100	0	-48.67	46.19	-30.16		
Change from preoperative	PTG	48	-100	-4.65	-33.26	38.57	-13.33		
Pain to 48 hours	2S	47	-100	-1.96	-56.15	43.24	-59.84	28.77	<0.001*
	XPES	49	-100	-71.66	-96.90	8.27	-100.0		
Change from preoperative	PTG	48	-100	-44.3	-93.15	14.07	-100.0		
Pain to 72 hours	2S	47	-100	-41.8	-95.38	12.48	-100.0	8.97	0.018*
	XPES	49	-100	-100	-100	0.00	-100.0		
Change from preoperative	PTG	48	-100	-100	-100	0.00	-100.0		
Pain to 7 days	2S	47	-100	-100	-100	0.00	-100.0	0.00	1.00
	XPES	49	-100	-100	-100	0.00	-100.0		

*: P value significant at 0.05, indicates significant difference. n: Number of patients in a group, Min: Minimum, Max: Maximum, PTG: Protaper Gold, 2S: 2Shape, XPES: XP-endo Shaper

was 32 years. 144 patients responded to the questionnaire on postoperative pain score and analgesic intake at different time intervals (24, 48, 72 hours and 7 days). Maximum mean postoperative pain recorded was in PTG group followed by 2S and XPES groups respectively at all time intervals. The mean pain scores were found to be lower at all time intervals for all instrument systems used with statistically significant difference at 24, 48 and 72 hours (Table 2). Intergroup comparison of pain scores reveals statistically significant difference between XPES and PTG at 24, 48 and 72 hours (P<0.001) and between 2S and XPES at 48 hours (P<0.001) (Table 3). When comparing percentage change in preoperative and postoperative pain scores there was a significant (P<0.05) reduction in pain at 24, 48 and 72 hours (Table 4). There was a significant difference (P<0.05) among the groups with respect to time taken (Table 5). PTG group recorded highest mean time followed by 2S group and the lowest mean time was recorded in XPES group. There was no statistically significant difference in the analgesic intake between groups although XPES group consumed the least analgesic intake.

DISCUSSION

Postoperative discomfort after endodontic intervention is an undesirable effect. There is a wide range in incidence of postoperative pain and flareup reported in literature ranging from 3-58% (14). Postoperative inflammation following endodontic intervention may be due to mechanical, chemical or microbial injuries of periapical tissues (2). Debris extrusion during chemo mechanical preparation is allegedly one of the principal cause of postoperative pain (8).

Maximum mean postoperative pain recorded was in PTG group followed by 2S and XPES groups respectively at all time intervals. Maximum mean pain in all groups occurred in first 24 hours. This is in accordance to the previous studies, all of which have reported maximum postoperative pain at the end of 24 hours (1, 12). The results demonstrated gradual reduction of postoperative pain at all time intervals in all groups. The mean pain score was found to be lower at all time intervals with statistically significant difference at 24, 48 and 72 hours (P<0.001) (Table 2). At 24-hour time interval XPES exhibited least pain as compared to other groups with statistically significant difference (P<0.016) between XPES and PTG (Table 3). After 48 hours XPES resulted in significantly (P<0.016) less pain as compared to PTG and 2S (Table 3). At 72 hours, there was further reduction in postoperative pain scores, with statistically significant difference (P<0.016)

TABLE 5. Kruskal Wallis Test to compare the time taken for treatment among the three groups

Instrumentation system	n	Min	Max	Mean	Standard deviation	Kruskal-Wallis	P
PTG	48	120	130	123.02	3.219		
2S	47	110	115	112.02	2.480	130.58	<0.001*
XPES	49	95	100	97.55	2.525		

*: P value significant at 0.05, indicates significant difference. n: Number of patients in a group, Min: Minimum, Max: Maximum, PTG: Protaper Gold, 2S: 2Shape, XPES: XP-endo Shaper

between XPES and PTG (Table 3). After 7 days, there was no pain in any of the three groups.

All instrumentation techniques result in debris extrusion (5, 6). Extrusion of contaminated/noncontaminated debris into the periapical area during instrumentation can result in an inflammatory and/or immunological reaction leading to postoperative pain (3, 4).

There is also a significant correlation between preoperative and postoperative pain. Severe preoperative pain increases the possibility of more severe postoperative pain (15-17). In 1986, Genet et al. (16) reported that in cases without preoperative pain, only 23% experienced postoperative pain, whereas if there had been preoperative pain on the day of treatment 65% had postoperative pain. Torabinejad et al. (18) demonstrated that patients with pain or swelling before treatment were highly susceptible to flareups whereas patients without preoperative complaints were the least susceptible group. It has also been demonstrated that mandibular molars have significantly more postoperative pain than other teeth (19, 20). For these reasons, patient's preoperative pain was recorded prior to treatment and mandibular molars were selected for the present study. Furthermore, as single visit root canal results in lower post treatment pain as compared to multiple visit treatment, and to avoid the possible confounding effect of intracanal medicament on postoperative pain the root canals in this study were completed in one sitting (21).

Pain is modulated by a multitude of physical and psychological factors, thus making assessment difficult. Assessment of pain poses a significant challenge to researchers because of its highly subjective and variable nature. We have selected HP VAS as it is considered valid and reliable measurement scale for pain (22-24). In the present study preoperative and postoperative HP VAS pain scales were recorded to eliminate potential bias in subjective nature of pain assessment.

The different rotary instrumentation systems used in this study were in close match to each other in terms of tip size and taper for standardization of final preparation of root canals (PTG 0.25/.08v, 2S 0.25/.06, XPES 0.30/.04). The larger tip size of XPES was compensated by lesser taper. During instrumentation, irrigation protocol was similar for all three groups. Irrigation was done using sodium hypochlorite and apical patency was maintained using #10 K file for elimination. Moreover, occlusal reduction has been suggested as a means of managing endodontic pain but in the present study this was not done as it would have affected the postoperative pain perception (25).

PTG exhibited more pain as compared to other groups. ProTaper instruments have sharp cutting edges, progressively increasing taper along the shaft of instrument and stiffer tip for ProTaper finishing files. This results in significantly higher amounts of debris production and debris extrusion compared to other files (26). ProTaper have a series of six instruments all of which are used for preparation of canals. In the present study PTG was used because it resulted in less debris production than PTU (27). The instrument design and multiple files may have resulted in higher debris production and extrusion resulting in more postoperative pain of PTG (10, 28).

Two file system (2S) utilizes two files to complete cleaning and shaping procedure. They have an asymmetrical cross section design which results in non uniform, reduced contact between the canal wall and instrument. Smaller tip size of 2S along with asymmetrical design creates better space for coronal displacement of debris. 2S resulted in less postoperative pain as compared to PTG which can be attributed to reduced extrusion of debris apically (29, 30).

XPES produced least postoperative pain amongst all three groups. XPES is single file system, extremely flexible, having slender design with narrow taper and booster tip. The debris produced is reportedly removed more efficiently than other large core diameter instruments due to extra space available. XPES utilizes crown down technique for preparation in which early flaring of coronal root results in reduced microorganism load and apical debris extrusion (31, 32), as greatest number of microorganisms are present in coronal third of the canal. It has also been speculated fewer instruments may contribute to lesser extrusion of bacteria/debris apically (10, 33).

Instrumentation with multiple file systems require a number of passes by each instrument to reach the apex and to prepare the apex to the desired size, which causes greater debris extrusion (10, 33-35). In single/two file systems the same work is done by one or two files with constant irrigation and recapitulation in true crown down fashion resulting in early elimination of debris. The file tip and taper in study match closely. It is well documented that there is no difference in the debris extrusion between different taper preparations therefore the effect of the slight mismatch in tip and taper should not have an effect on results of study (36-38). Caviedes-Bucheli (39) attributed a greater expression of neuropeptides (substance P and CGRP) to increase instrumentation time generating increased mechanical stresses and debris extrusion into the periapical area.

Percentage change in pain was maximum for XPES followed by 2S and PTG. On comparing preoperative pain scores to the postoperative pain there was significant reduction in pain at 24 and 48 hours. XPES exhibited maximum reduction from preoperative pain at 24 (48.67%) and 48 hours (96.90 %) with no pain at 72 hours. Reduction in pain was also observed with 2S at 24 (30.85%) and at 48 (56.15%) hours when compared to preoperative pain. PTG exhibited reduction in pain at 24 (5.13 %) and 48 hours (33.26%) although the results were not as dramatic as the other two groups (Table 4).

The results obtained from the current study may be explained by differences in the instrument design and kinematics. Based on these observations it could be inferred that there is a direct correlation between incidence of postoperative pain, instrument design and number of instruments used for preparation of the pulp space.

The other criteria compared were the time taken and analgesic intake. It has been reported that longer instrumentation time may contribute to a higher degree of postoperative pain (35, 40). In the present study PTG instruments took significantly more time for preparation followed by 2S and XPES respectively (Table 5). There was no significant difference among the groups in analgesic intake but the mean analgesic intake was lower in XPES at all time intervals.

There was statistically significant difference in incidence of postoperative pain amongst the instrumentation systems assessed, therefore the null hypothesis was rejected.

CONCLUSION

In the present study, XPES exhibited the least amount of postoperative pain, time taken and the maximum decrease in pre and postoperative pain percentage. 2S performed better than PTG in postoperative pain, time taken and decrease in pre and postoperative pain percentage. PTG exhibited maximum pain and treatment time among the three groups.

Disclosures

Conflict of interest: The authors deny any conflict of interest.

Ethics Committee Approval: This study was approved by The Institutional Review Board and Ethical Committee of the Faculty of Dental Sciences. Shree Guru Gobind Singh Tricentenary University, Gurugram, Haryana, India (Date: 21/12/2017, Number: SGTU/FDS/MDS/24/1/672).

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