



A Prospective Randomized Clinical Trial Examining the Occurrence of Postoperative Pain Following Single-Visit Root Canal Treatment Utilizing XP-Endo Shaper, 2Shape, and Protaper Gold Rotary Systems

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ABSTRACT

Introduction: The aim of this study was to assess the frequency of postoperative pain, treatment duration, and use of pain medication after root canal treatment of mandibular molars during a single visit, using three different rotary systems: XP-endo Shaper, 2Shape, and ProTaper Gold.

Methodology: One hundred and fifty patients who had irreversible pulpitis were included in the study and were randomly allocated to one of the three groups. Patients rated their pain using the Heft Parker visual analog scale before and after treatment at 24, 48, 72 hours, and 7 days.

Results: Highest mean postoperative pain score was recorded in ProTaper Gold ($P < 0.05$), followed by 2Shape and XP-endo Shaper respectively at all time-intervals. At the 24 and 48 hour time interval, the XPES group exhibited the least pain compared to the other groups, with a statistically significant difference ($P < 0.016$). After 7 days, none of the three groups reported any pain.

Conclusion: XP-endo Shaper was found to be the most effective rotary system for single visit root canal treatment of mandibular molars in terms of reducing postoperative pain and treatment time.

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

INTRODUCTION

Postendodontic pain, which is defined as the feeling of discomfort following endodontic treatment, has been found to affect 25% to 40%¹ of patients, regardless of the condition of the pulp and periradicular tissues, and to affect 1.5% to more than 50%² of patients. There are numerous potential causes of postendodontic discomfort.³ During chemomechanical preparation, the extrusion of pulp tissue, microbes, and irrigants to the periapical tissues may result in inflammation.⁴ In recent years, numerous systems with novel designs have been introduced as a result of significant advancements in rotating instrumentation and metallurgy. Despite this, all preparation methods and tools currently in use are still connected to some degree of extrusion of debris, which can result in postendodontic discomfort.⁵

The majority of nickel-titanium engine-driven instrument systems extrude less debris than manually operated stainless steel K-files, which may lessen the possibility of postoperative pain.⁶ One of the traditional clockwise rotation multi-file rotary devices, ProTaper Universal (Dentsply) has been in use since 2001. It uses six files to prepare the root canals: three for shaping and three for finishing. The convex triangle cross-section and the various tapers along the instruments are distinctive design features.⁷ Launched in 2017, 2 Shape (2S, MicroMega) is a sequence with two shaping files rotating continuously. The files have been heat-treated using the T Wire technology to increase their flexibility and resistance to cyclic fatigue, according to the manufacturer. The newest cross sectional design (offset cross section) with triple helix produces the ideal balance between cutting effectiveness and debris clearance.⁸ The 2016-released XP-endo Shaper files (XPES;FKG Dentaire) are advertised for shaping root canals using a single tool rotated in a clockwise direction. It is 30 by 0.01 taper in dimension. MaxWire (Martensite-Austenite Electropolishing-Flex, FKG) metal is used to make XPES.⁹

Moreover, In contrast to patients who underwent numerous visits for endodontic treatment, Su et al. discovered that patients who underwent single visit endodontic treatment experienced significantly less pain on average.¹⁰ Clinical studies have shown that patients tolerate and prefer single-visit root canal therapy¹¹ due to a number of benefits, including fewer surgical procedures, no inter-appointment leakage, being quicker and less expensive, and being less time demanding.¹⁰ Thus, the aim of conducting a prospective randomized clinical trial was to assess and compare the frequency of postoperative pain and analgesic consumption following root canal preparation of posterior teeth utilizing three different rotary systems - ProTaper Gold (PTG), 2Shape (2S) and XP endo Shaper (XPES). The study's null hypothesis was that there is no disparity in the incidence of postoperative pain among the three instrumentation systems.

MATERIALS AND METHODS

The institutional review board and ethical committee of [INSTITUTION NAME] approved the protocol of this randomized clinical trial. The study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines¹² and the Declaration of Helsinki. One hundred and fifty patients were enrolled from the Out Patient Department of [INSTITUTION NAME]. A single operator, proficient in all the instrumentation systems, treated all patients over a 10-month period from March to December 2022 to ensure standardization. There were no significant differences in age, sex, or tooth type among the study groups, so their impact on the results was expected to be negligible. The study included restorable mandibular molars of male and female patients aged between 18 to 50 years, diagnosed with irreversible pulpitis, and in good health. The exclusion criteria comprised the presence of root curvatures, periapical radiolucency, sinus tracts, internal or external resorption, tenderness on percussion, traumatic bite, NSAID intolerance, grade 2 or 3 mobility, open apex, non-vital teeth, medication history before treatment, retreatments, pregnant patients, and anatomic variations. All teeth selected for the study had #10 or #15 file fitting snugly at the root canal apex. To avoid variations in debris extrusion, canals with apical diameters larger than 20 or smaller than 10 were not included in the study.

The required sample size was estimated using G*power 3.1.9.4 (Franz Faul Universitat, Kiel, Germany) to conduct a power analysis. To detect significant differences with an effect size of 0.3 and a significance level of 0.05, a sample size of 50 per group was determined to provide 80% power. To account for potential losses during follow-up, the sample size was increased to 60 per group. Out of the 180 patients assigned to the three groups, twelve patients did not show up for follow-up, leaving a total of 168 patients evaluated (Fig. 1). Patients were

instructed to rate their preoperative pain on an HP VAS scale and provided with an explanation of the procedure and potential risks before obtaining their informed consent. Symptomatic irreversible pulpitis was diagnosed based on the patient's chief complaint of spontaneous pain, clinical examination, and radiographic evaluation. A cold test (Endo frost – Roecko Langenau, Germany) was conducted to confirm the diagnosis of irreversible pulpitis. After isolating the tooth with a rubber dam, a cotton pellet soaked with Endo frost was placed on the mid-third of the buccal surface of the tooth's crown for five seconds. The sensitivity of the contralateral or adjacent tooth with a vital pulp was also examined. If the response to the cold test of the affected tooth was severe and pain persisted after the removal of the cold cotton pellet, the diagnosis of symptomatic irreversible pulpitis was confirmed. Treatment was performed by a single operating dentist for all three groups, based on the assigned group. Patients were unaware of the file systems used. After data collection, statistical analysis was carried out by a second investigator who was blinded to the groups, along with a statistician.

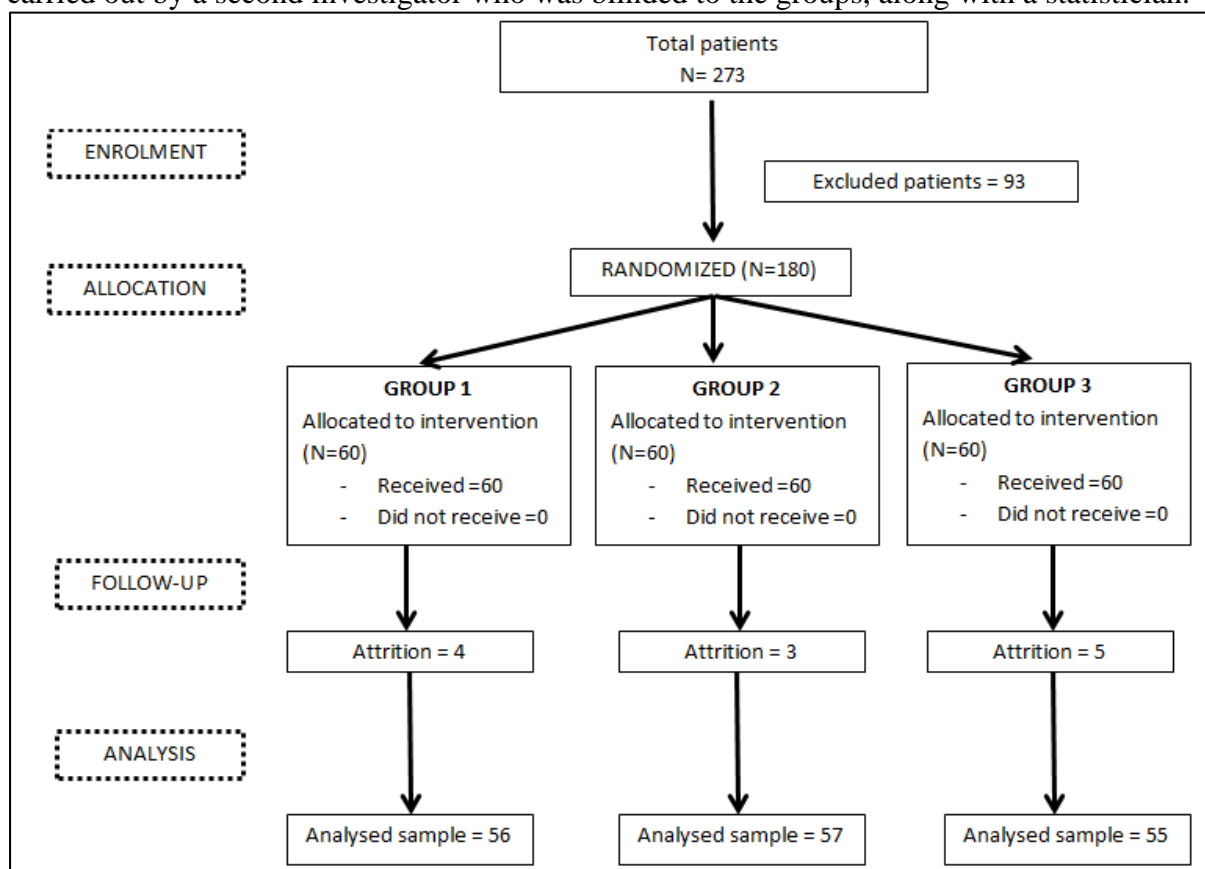


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram

Protocol: The treatment protocol involved the administration of Inferior Alveolar Nerve Block and buccal infiltration, which was performed using 1.8 mL 2% lidocaine with 1:80,000 epinephrine at a rate of 1 ml/min. The patients were monitored for lip numbness every 5 minutes for 15 minutes. After confirming full lip numbness, buccal infiltration was administered. Under rubber dam isolation, access cavity preparation was performed, and the canals were explored in a watch winding motion with a #10, #15 K type hand files, extending 0.5 mm beyond the apex to confirm apical patency, initial diameter of foramen, and canal curvature. Working length was established using the Coltene Canal pro® apex locator. The file was withdrawn, and 0.5 mm was subtracted to establish the final working length, which was confirmed radiographically. A glide path was prepared until the working length using a #15 K-file in a watch winding motion.

Each group received a different root canal instrumentation sequence as recommended by the manufacturer. Group 1 (n=56) received Protaper Gold (Ptg) (Dentsply), which involved using shaping files (S1, S2) with a brushing action on the withdrawal stroke to create a straight-line radicular access, followed by passive use of finishing files (F1, F2) till the working length. The speed used for file size S1 was 300 rpm and the torque was 5.1 N-cm, while for PTG file S2 and F1, the speed was 300 rpm and the torque was 1.50 N-cm. For files F2, the speed was 300 rpm and the torque was 3.10 N-cm.

Group 2 (n=57) received 2Shape (2S) (Micro-Mega), which included using two shaping instruments, TS1 (#25 .04) and TS2 (#25 .06), at a speed of 300 rpm and torque of 1.2 Ncm with progressive upward circumferential filing movement. TS1 was inserted into the root canal until resistance was felt, and then two to three circumferential brushing strokes were performed to eliminate primary constraints. This was followed by TS2, which was used with a brushing motion until the working length.

In each group, the treatment protocol followed the manufacturer's recommendations. Group 1 utilized Protaper Gold (PTG) (n=56), which involved using shaping files (S1, S2) with a brushing action on the withdrawal stroke to create a straight-line radicular access, followed by passive use of finishing files (F1, F2) until working length. Group 2 used 2Shape (2S) (n=57), which has two shaping instruments (TS1 and TS2) used at a speed of 300 rpm and torque of 1.2 Ncm with a progressive upward circumferential filing movement. Group 3 used Xp-Endoshaper (XPES) (FKG Dentaire) (n=55), which is a one-file shaper with an initial taper of 1% used at a speed of 800 rpm and torque of 1 N-cm.

In all groups, irrigation was done thoroughly, and recapitulation was done with a #10 K file. The canals were irrigated with 2 ml of 4% NaOCl between each instrument change, and final flushing was done with 2 ml of 4% NaOCl. Obturation was done with continuous wave of compaction technique using AH-plus sealer (Dentsply) followed by composite resin restoration (Ivoclar). The time taken to complete each treatment was recorded. Patients experiencing moderate or severe pain were advised to take analgesics (400 mg Ibuprofen) as a rescue medication and were recalled for follow-up after 7 days.

To evaluate the level of pain, patients were asked to rate their pre- and postoperative pain using the Heft Parker Visual Analog Scale (HP VAS). The HP VAS consists of a 170-mm line marked with various terms describing levels of pain, with millimeter marks removed from the scale. The scale was divided into four categories based on pain intensity: "no pain" corresponded to 0 mm, "faint, weak or mild" pain corresponded to 0-55 mm, "moderate" pain corresponded to 56-115 mm, and "strong, intense, and maximum possible" pain corresponded to greater than 115 mm. After the treatment, patients were given a questionnaire which included a pain assessment HP VAS chart and a medication record chart to monitor their postoperative pain. They were requested to indicate the severity of their pain using the HP VAS scale at 24, 48, 72 hours, and 7 days after the procedure and to record any analgesic tablets they took on the provided chart. To ensure compliance, they were contacted by phone at the specified intervals and reminded to complete the questionnaire. The completed charts were collected from the patients after 7 days for analysis.

STATISTICAL ANALYSIS

The statistical analysis was performed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Normality of the data was assessed using the Shapiro-Wilk test. As the data did not show a normal distribution, the Kruskal-Wallis non-parametric test was used to assess the statistical difference of pain scores, number of analgesics taken, and time taken among the groups. Post-hoc Mann-Whitney test was applied for pair-wise comparison. The level of significance was set at 0.05 ($P < 0.05$), and a 95% confidence interval was obtained.

RESULTS

Table 1 displays the baseline demographic data of the study groups. The study included 168 patients with a mean age of 33 years who completed the postoperative pain score and analgesic intake questionnaire at different time intervals (24, 48, 72 hours and 7 days). The PTG group reported the highest mean postoperative pain scores at all time-intervals, followed by the 2S and XPES groups. However, all instrument systems used demonstrated lower mean pain scores at all time-intervals, with a statistically significant difference at 24, 48, and 72 hours (Table 2). Intergroup comparison of pain scores showed a 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). Although there was no statistically significant difference in analgesic intake between groups, the XPES group consumed the least amount of analgesics.

Table 1: Baseline demographic and clinical features of participants in the respective study groups

Baseline demographic and clinical feature	PTG (N=56)	2S (N=57)	XPES (N=55)	Total (N=168)
Male	29	28	28	85
Female	27	29	27	83
Mandibular 1st Molar	28	29	28	85
Mandibular 2nd Molar	28	28	27	83

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	Instrument used	N	Mean	SD	Kruskal - Wallis	P
Preoperative pain	PTG	56	43.17	38.38	0.25	0.55
	2S	57	49.02	44.72		
	XPES	55	40.67	37.63		
Pain after 24 hours	PTG	56	40.96	35.93	18.92	0.00*
	2S	57	28.02	40.02		
	XPES	55	14.19	27.68		
Pain after 48 hours	PTG	56	32.69	36.70	25.25	0.00*
	2S	57	22.12	31.38		
	XPES	55	2.52	8.37		
Pain after 72 hours	PTG	56	4.45	11.03	8.05	0.01*
	2S	57	3.19	9.62		
	XPES	55	0.00	0.00		
Pain after 7 days	PTG	56	0.00	0.00	0.00	1.00
	2S	57	0.00	0.00		
	XPES	55	0.00	0.00		

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

*-P significant at <0.05

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

Time Interval	PTG Vs. 2S	PTG Vs. XPES	2S Vs. XPES
Preoperative pain	0.67	0.76	0.35
Pain after 24 hours	0.03	0.00*	0.05
Pain after 48 hours	0.09	0.00*	0.00*
Pain after 72 hours	0.52	0.00*	0.04
Pain after 7 days	1.00	1.00	1.00

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

*-P significant at <(0.05/3=0.016)

DISCUSSION

Postoperative discomfort following endodontic treatment is an unwanted outcome. The literature reports a broad range of incidence rates for postoperative pain and flare-up, varying from 3% to 58%.¹³ Endodontic postoperative inflammation may result from periapical tissue damage caused by mechanical, pharmacological, or microbial factors.¹⁴ One of the main causes of postoperative pain is reportedly debris extrusion during chemo mechanical preparation.¹⁵

The PTG group had the highest mean postoperative pain scores, followed by the 2S and XPES groups at all the time intervals. Maximum mean pain was reported in all groups within the first 24 hours, which is consistent with previous studies that have also reported maximum pain at 24 hours.^{3,16} Pain scores gradually decreased in all groups at all time-intervals. The mean pain scores were found to be significantly lower at 24, 48, and 72 hours ($P < 0.001$) in all groups (Table 2). At the 24-hour time interval, the XPES group exhibited the least pain compared to the other groups, with a statistically significant difference ($P < 0.016$) between XPES and PTG (Table 3). After 48 hours, XPES resulted in significantly less pain compared to PTG and 2S ($P < 0.016$) (Table 3). At 72 hours, there was a further reduction in postoperative pain scores, with a statistically significant difference ($P < 0.016$) between XPES and PTG (Table 3). After 7 days, none of the three groups reported any pain.

Every measurement method leads to debris extrusion.⁵ During instrumentation, the extrusion of contaminated or uncontaminated debris into the periapical region may cause an inflammatory and/or immunological response that causes postoperative pain.^{4,17}

Additionally, there is a strong link between preoperative and postoperative discomfort. The likelihood of more severe postoperative pain rises with severe preoperative pain.^{18,19} Genet et al.¹⁸ reported in 1986 that only 23% of patients without preoperative pain encountered postoperative pain, whereas 65% of patients whose preoperative pain was present on the day of treatment experienced postoperative pain. According to research by Torabinejad et al.²⁰, patients who experienced discomfort or swelling prior to treatment were more likely to experience flare-ups than those who had no preoperative complaints. Additionally, it has been shown that mandibular molars experience considerably more postoperative discomfort than other teeth.^{21,22} For these reasons, mandibular molars were chosen for the current research and the patient's preoperative pain was noted before the procedure. Additionally, the root canals in this study were completed in one sitting to avoid the potential confounding impact of intracanal medication on postoperative pain and because single visit root canals result in less post-treatment pain than multiple visit treatments.¹⁰

Assessment is challenging because a wide variety of physical and psychological variables influence how pain is modulated. Researchers face a lot of difficulty assessing pain because it

is such a highly subjective and changeable phenomenon. We chose the HP VAS because it is regarded as a reliable and valid pain measurement instrument.^{23,24} To remove any possible bias in the subjective nature of pain assessment, preoperative and postoperative HP VAS pain scales were recorded in the current research.

To standardize the final preparation of root canals, the rotary instrumentation systems used in this study were closely matched to each other in terms of tip size and taper (PTG 0.25/.08v, 2S 0.25/.06, XPES 0.30/.04). Despite the larger tip size of XPES, its lesser taper compensated for it. During instrumentation, all three groups followed a similar irrigation protocol using sodium hypochlorite, and apical patency was maintained using a #10 K file for elimination. Although occlusal reduction has been suggested to manage endodontic pain, it was not done in the present study as it could have affected the perception of postoperative pain.²⁵

PTG displayed more pain than the other categories. Sharp cutting edges, a growing taper along the instrument shaft, and a stiffer tip are all characteristics of ProTaper instruments. In comparison to other files, this causes noticeably more debris generation and debris extrusion.²⁶ Six different tools from ProTaper are all used for canal preparation. PTG was utilised in this research because it produced less debris than PTU.²⁷ There may have been more debris produced and extruded due to the instrument design and numerous files, which would have increased PTG postoperative pain.²⁸

Two folders are used in the two file system (2S) to finish the cleaning and shaping process. Because of their asymmetrical cross section construction, there is less consistent contact between the instrument and the canal wall. Better room for coronal debris displacement is created by the 2S's smaller tip size and asymmetrical design. Because there was less debris extrusion apically with 2S than with PTG, there was less postoperative discomfort.^{29,30}

Of the three groups, XPES caused the least postoperative discomfort. The XPES single file system has a thin construction with a narrow taper and booster tip. It is also very flexible. Due to the additional space, the produced debris is purportedly removed more effectively than with other big core diameter instruments. As the majority of microorganisms are found in the coronal third of the canal, XPES uses a crown down method for preparation. Early flaring of the coronal root reduces the microorganism load and apical debris extrusion.^{31,32} Additionally, it has been hypothesised that using fewer tools may result in less bacteria and debris coming out of the apex.^{28,33}

The use of multiple file systems for instrumentation necessitates several passes with each instrument to achieve the desired size at the apex, resulting in increased extrusion of debris.^{28,33} The same task is carried out by one or two files in single- or dual-file systems, with continuous irrigation and recapitulation in true crown-down fashion, leading to the early removal of debris. The file tip and taper in the research are very similar. Since it is well known that there is no difference in debris extrusion between various taper preparations, the findings of the study shouldn't be affected by a slight mismatch between the tip and taper.³⁴⁻³⁶ According to Caviedes-Bucheli³⁷ increased instrumentation duration led to increased mechanical stresses and debris extrusion into the periapical region, which in turn led to greater production of neuropeptides (substance P and CGRP).

Differences in instrument design and kinematics may explain the results obtained from the current study. It can be inferred that the number of instruments used for preparation of the pulp space and the instrument design have a direct correlation with the incidence of postoperative pain. Additionally, longer instrumentation time may contribute to a higher degree of postoperative pain.³⁸ In the current study, PTG instruments took significantly more time for preparation than 2S and XPES, respectively. There was no significant difference in analgesic intake among the groups, but the mean analgesic intake was lower in XPES at all time-intervals. The incidence of postoperative pain was statistically significantly different among the instrumentation systems assessed, and therefore, the null hypothesis was rejected.

CONCLUSION

The study findings indicate that XPES had the lowest level of postoperative pain, required the least amount of time for the procedure, and showed the highest decrease in pain percentage from preoperative to postoperative. 2S also performed better than PTG in terms of postoperative pain, time taken, and pain reduction. On the other hand, PTG resulted in the highest level of pain and required the longest treatment time among the three instrumentation systems evaluated.

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