

## Use of 2Shape® File in Adaptive Kinematics Influences Post-operative Pain After Single Visit Endodontics in Symptomatic Irreversible Pulpitis: A Double-blinded, Randomized Clinical Trial

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### ABSTRACT

**Objective:** This double-blinded randomized clinical trial aimed to compare postoperative pain using 2Shape® (TS) in rotary (TS<sub>Rot</sub>) and adaptive (TS<sub>AK</sub>) kinematics in the maxillary and mandibular molars in patients with symptomatic irreversible pulpitis and symptomatic apical periodontitis following single-visit endodontic treatment.

**Methods:** Seventy patients were randomly assigned to two groups (TS<sub>Rot</sub>/TS<sub>AK</sub>), (n=35 each). The preoperative and postoperative pain intensities at various time intervals up to 72h using a Visual-Analogue Scale was noted. Mann-Whitney U test (p<0.05\*) was used to compare pain intensity, and the chi-square test was used to compare the incidence of pain. Dunns test (p<0.05\*) was used for intragroup comparisons. Binary logistic regression was performed at consecutive time intervals.

**Results:** A total of 67 patients were included in the final analysis, and three were excluded due to medication intake. Both groups showed a gradual reduction in the mean incidence and intensity of postoperative pain from 6 to 72 hours. However, TS<sub>AK</sub> had a significantly lower intensity and incidence of pain than TS<sub>Rot</sub> at 24h (p=0.02\*). There was no statistically significant difference observed in the duration of instrumentation when the TS file was used in either adaptive or rotary kinematics (p=0.41).

**Conclusion:** Adaptive kinematics (TS<sub>AK</sub>) resulted in less pain incidence compared with rotary kinematics (TS<sub>Rot</sub>). A statistically significant difference in incidence was observed at 24 h but may not be clinically significant. The duration of instrumentation was similar between the TS<sub>Rot</sub> and TS<sub>AK</sub> groups. Thus, the 2Shape® (TS) file, which is a rotary file, can be used in adaptive kinematics to reduce the postoperative pain.

**Keywords:** Motion kinematics, postoperative pain, root canal treatment, single-visit endodontics, twisted adaptive motion

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### HIGHLIGHTS

- 2Shape files can be used for both rotary and Adaptive Kinematics.
- The incidence and intensity of postoperative pain were lower with adaptive kinematics than with rotary kinematics, even though both groups were clinically insignificant.
- Motion kinematics can influence the incidence and intensity of postoperative pain.

### INTRODUCTION

Postoperative pain (PoP) is an unpleasant experience for patients and a pressing challenge for clinicians. The incidence of PoP is approximately 40% within the initial 22.4 hours and gradually decreases to 11% after a week (1). It is a multi-

factorial phenomenon involving factors such as preoperative pain, insufficient disinfection, hyperocclusion, presence of periapical diseases, presence or absence of pulp vitality, extrusion of debris and microorganisms into periapical tissues, resulting in flare up (2, 3).

The canal instrumentation technique influences PoP because of the extrusion of bacteria and debris, which exacerbates the inflammatory response (2, 4, 5). However, the results are controversial regarding the influence of kinematics on PoP (6, 7). Adaptive Kinematics(AK) combine rotary and reciprocating kinematics, which automatically adapt to the instrumentation stress. When the instrument is under minimal/no stress, it rotates in the clockwise direction for 600°, stops, and then starts rotating in the clockwise direction (600°/0°). When the torque in the instrument is exceeded, the kinematics reverses to a counterclockwise direction (370°/50°) (8). The incidence of PoP was observed to be 10% lower in adaptive kinematics than in reciprocating kinematics, which is attributed to less apical debris extrusion and the metallurgical features of the file (9).

Recent advancements in metallurgy and heat treatment have improved the predictability and efficiency of root canal treatment and reduced torsional stress, and increased fracture resistance (10). The 2Shape® (TS)- manufactured using a newer T-Wire technology (post-grinding heat treatment) is a system comprising two shaping files [TS1(25/.04) and TS2(25/.06)] and two optional files [F35(35/.06) and F40(40/.04)] and is claimed to have increased cyclic fatigue resistance. The cross-section is a modified triple helix with two primary cutting edges for efficient cutting and a secondary cutting edge to improve debris removal (11, 12).

Till date, studies have compared the rotary, reciprocating, and twisted file adaptive kinematics in their respective kinematics to assess PoP (9, 13–15). The incidence or intensity of PoP is observed to be higher with reciprocation kinematics than with rotary kinematics in the initial 24 hours after treatment (16, 17). This study is the first to compare a rotary file system in adaptive kinematics. Therefore, in this study, we used a TS file with a similar cross-section to that of a Twisted File Adaptive (TFA) in two different kinematics, i.e., conventional rotary and novel adaptive kinematics.

The aim of this trial was to evaluate the role of motion kinematics on PoP after a single-visit endodontic treatment in teeth diagnosed with symptomatic irreversible pulpitis and symptomatic apical periodontitis (SIP & SAP). The null hypothesis was that kinematics would not affect PoP after a single-visit endodontic treatment.

## MATERIALS AND METHODS

### Study Design

The study was designed as a double-arm parallel, double-blinded, randomized clinical trial (allocation ratio of 1:1). The study approval was obtained by the Institutional Ethics Committee (MADC/IEC-I/033/2021) on 30<sup>th</sup> March 2021 Meenakshi Academy of Higher Education and Research, Chennai, India.

The study was conducted in accordance with the Declaration of Helsinki. According to the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines, the protocol was reported and registered at the Clinical Trial Registry of India ([www.ctri.nic.in/CTRI/2022/01/039767](http://www.ctri.nic.in/CTRI/2022/01/039767)) (18).

### Participants

The inclusion criteria were as follows: healthy patients classified under ASA Class 1 with an age range of 18–60 years who had mature maxillary or mandibular molars diagnosed with SIP & SAP, teeth with moderate to severe pain (Baseline VAS score:  $\geq 4$ ), pain due to cold stimulation with a lingering response, teeth with tenderness on percussion, and no periapical changes on radiographs (Periapical Index  $\leq 2$ ).

Teeth with fractures, open apices, periapical abscesses, resorption, pulp canal obliteration, compromised periodontium, pulp necrosis, or absence of bleeding at the access opening were excluded. Patients with compromised systemic health, pregnant and lactating women, any history of allergy to local anesthetic solutions or drugs, long-term history of medication intake, and higher anesthesia volume that influences pain threshold. Patients with a history of recent intake (past 24h) of steroids, antibiotics, and/or analgesics were also excluded. Endodontic mishaps such as sealer extrusion, overextended obturation, instrument separation etc. were excluded from the present study.

### Sample Size Determination

An alpha ( $\alpha$ ) error of 5% with a statistical power of 80% was used to calculate the sample size. Based on the previous literature, the mean (standard deviation) of the intensity of PoP score at 24h for Twisted file adaptive (0.26 (0.51) and Reciproc (0.93 (0.96) was considered (9). A total of 28 patients per group (56 patients) was estimated ( $d=0.67$ ) using OpenEpi ([www.openepi.org](http://www.openepi.org)) (19) and considering a potential dropout of 15%, the number was increased to 35 per group, resulting in a total sample size of 70 patients.

### Randomization and Allocation Concealment

A total of eighty-five patients were screened, and seventy patients who satisfied the inclusion criteria and wanted to participate were selected for the study. Randomization software ([www.sealedenvelope.com](http://www.sealedenvelope.com)) was used to create 7 permuted blocks with 10 patients in each block by a person who was not a part of the study (20). Sequentially numbered sealed opaque envelopes (SNOSE) were used for allocation concealment. After the patients were allocated to the groups, the number was recorded on the case sheet and decoded after the study was concluded. The study was double-blinded, thus, the participants and the outcome assessor for evaluating postoperative pain were blinded in this trial.

### Standardized Treatment Protocol

The treatment was carried out by a single operator who was trained in performing single-visit endodontic treatment. Local anesthesia was administered through a inferior alveolar nerve block (IANB) using a 27G needle containing 1.8 mL of 2% lidocaine with 1:80,000 epinephrine (Lignospan® Special, Septodont St Maur des Fosses, France) to anesthetize the mandibular molars and buccal infiltration to anesthetize the maxillary molars. Under rubber dam isolation, a 014 round carbide bur and Endo Z bur (Dentsply Sirona International, York, PA, USA) were used for access cavity preparation, and the canals were explored using a 10-size K-file (Mani, Utsunomiya, Tochigi, Japan).

In cases of pain after access opening, the patients were managed with supplemental anesthesia. The following groups were randomly assigned to the participants who were recruited:

- Group A ( $TS_{Rot}$ ) (n=35): The canals were cleaned and shaped with TS files in rotary kinematics using an Elements TM adaptive motor (Handpiece ratio of 8:1) (SybronEndo, Orange, CA) set in a custom mode with 400 revolutions per minute (rpm) and a torque of 200 g-cm.
- Group B ( $TS_{AK}$ ) (n=35): The canals were cleaned and shaped with TS files in Adaptive Kinematics (AK) using an Elements TM adaptive motor (Handpiece ratio of 8:1) (SybronEndo, Orange, CA) set in TFA mode.

An electronic apex locator (J Morita, Europe GVBH, Frankfurt, Germany) was used to determine the working length, which was confirmed using an intraoral periapical radiograph. The apical patency was ensured using a 10 size K-file (Mani, Utsunomiya, Tochigi, Japan), and the canals were pre-enlarged up to size 20/25(2% taper). The canals were prepared using TS files (Micro-Mega, Besancon, France) to a minimum size of 25 (6% taper) (21) or 35 (6% taper) using rotary and adaptive kinematics using an Elements TM Adaptive Motor (SybronEndo, Orange, CA).

The TS files were used in sequence progressively in three up-and-down strokes along with circumferential filing in the upward direction while maintaining apical patency with a 20 size K-file between the instruments. A 30G side-vented needle (Maxi-I-probe; Dentsply Sirona Tulsa Dental, York, PA, USA) was used for irrigation with 3 mL of 3% sodium hypochlorite (NaOCl) (Parcan; Septodont, Delhi, India) between successive instrumentation. Alternative usage of 3% NaOCl and 17% ethylenediaminetetraacetic acid (EDTA) (Dent Wash; Prime Dental Products Pvt. Ltd., Thane, India) followed by agitation using passive ultrasonic activation (PUI) with Irrisafe tips (size 20) (Satelac, Merignac, France) for 60 seconds (3 cycles/ canal) (22) and final rinse with 0.9% physiological saline. The absorbent points were used for drying the canals prior to the use of resin sealer (AH Plus, Dentsply Sirona) using a lentulo spiral and were obturated with a matched taper single cone and cold lateral condensation technique for the large palatal and distal canals (Dentsply Sirona). A dental resin composite (Te-Econom Plus universal restorative by Ivoclar Vivadent, India) was used to restore the access cavity, and the occlusal contact points were verified using articulating paper.

### Outcome Measures

The VAS system (0–10) of measuring pain, with a score of "0" at one end denoting no pain and a score of "10" denoting the worst pain imaginable at the other, was used (23). The preoperative baseline VAS was recorded prior to the treatment and at 6h, 12h, 24h, 48h, and 72h after the treatment. Following treatment, the primary goals were to assess the incidence, intensity, and duration of instrumentation, whereas secondary outcomes, such as gender, age, and tooth type on PoP were assessed.

### Data Collection

The data were tabulated in an Excel sheet (Microsoft). The blinded outcome assessor evaluated the VAS using two meth-

ods: first, by giving patients a diary to track their pain scores; and second, by utilizing an electronic method through phone text to patients at intervals of 6 h, 12 h, 24 h, 48 h, and 72 h. At 72 h, patients were asked to report for a review and to return the pain score diary. The approach that provided pain scores at all consecutive time intervals (i.e., electronic method assessment) was considered for further data analysis. In cases of excruciating pain, ibuprofen 400 mg was prescribed as a rescue medication (one tablet every six hours), and these participants were not included for the further analysis. Patients were asked to contact the principal investigator in case of any emergency. The incidence (percentage) and intensity (mean pain score) of PoP at 6h, 12h, 24h, 48h, and 72h were calculated based on the presence or absence of pain. The duration of instrumentation was recorded by a person not involved in the study using a stopwatch during active instrumentation of all root canals and was noted, tabulated, and compared between the intervention groups.

### Blinding

The participants and outcome assessor were blinded to the current trial. Thus, it is a double-blind trial.

### Statistical Analysis

The statistical analysis was performed using STATA version 17 (Stata Corp., College Station, Texas). Descriptive analysis was performed for all variables that have an impact on PoP. Mann–Whitney U test was performed to assess pain intensity at consecutive time intervals (intergroup comparison). The incidence of pain following a single visit endodontic treatment was assessed using the Chi-Square test. An  $\alpha$  value of 0.05 is considered statistically significant. The intensity of PoP at various time frames (6h, 12h, 24h, 48h, and 72h) for both groups was compared using Friedman's test. For pairwise comparisons, the post hoc analysis was conducted using Dunn's test.

Binary logistic regression analysis was performed, keeping the independent variables as the intervention groups ( $TS_{Rot}/TS_{AK}$ ), gender (Male/Female), age (18–60 years), type of tooth (Maxillary/Mandibular molars), and dependent variables as the PoP incidence at 6h, 12h, 24h, 48h, and 72h.

### RESULTS

The Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines were used to report the study (Fig. 1). A total of 85 patients were screened, and 70 patients based on the inclusion criteria were included in this study. Three patients were excluded after 6h ( $TS_{Rot}$ :2; $TS_{AK}$ :1) due to medication intake. Consequently, 67 patients were included in the final analysis.

The baseline demographic and clinical characteristics of the patients are presented in Table 1. There were no statistically significant differences observed in terms of age ( $p=0.67$ ), gender ( $p=0.33$ ), and tooth type ( $p=1.00$ ) (Table 1).

There was a gradual reduction in the mean incidence and intensity of PoP from 6h to 72h between the two intervention groups.  $TS_{AK}$  had significantly lower intensity ( $p=0.02^*$ ) and incidence of pain ( $p=0.01^*$ ) than  $TS_{Rot}$  at 24h (Table 2, 3).

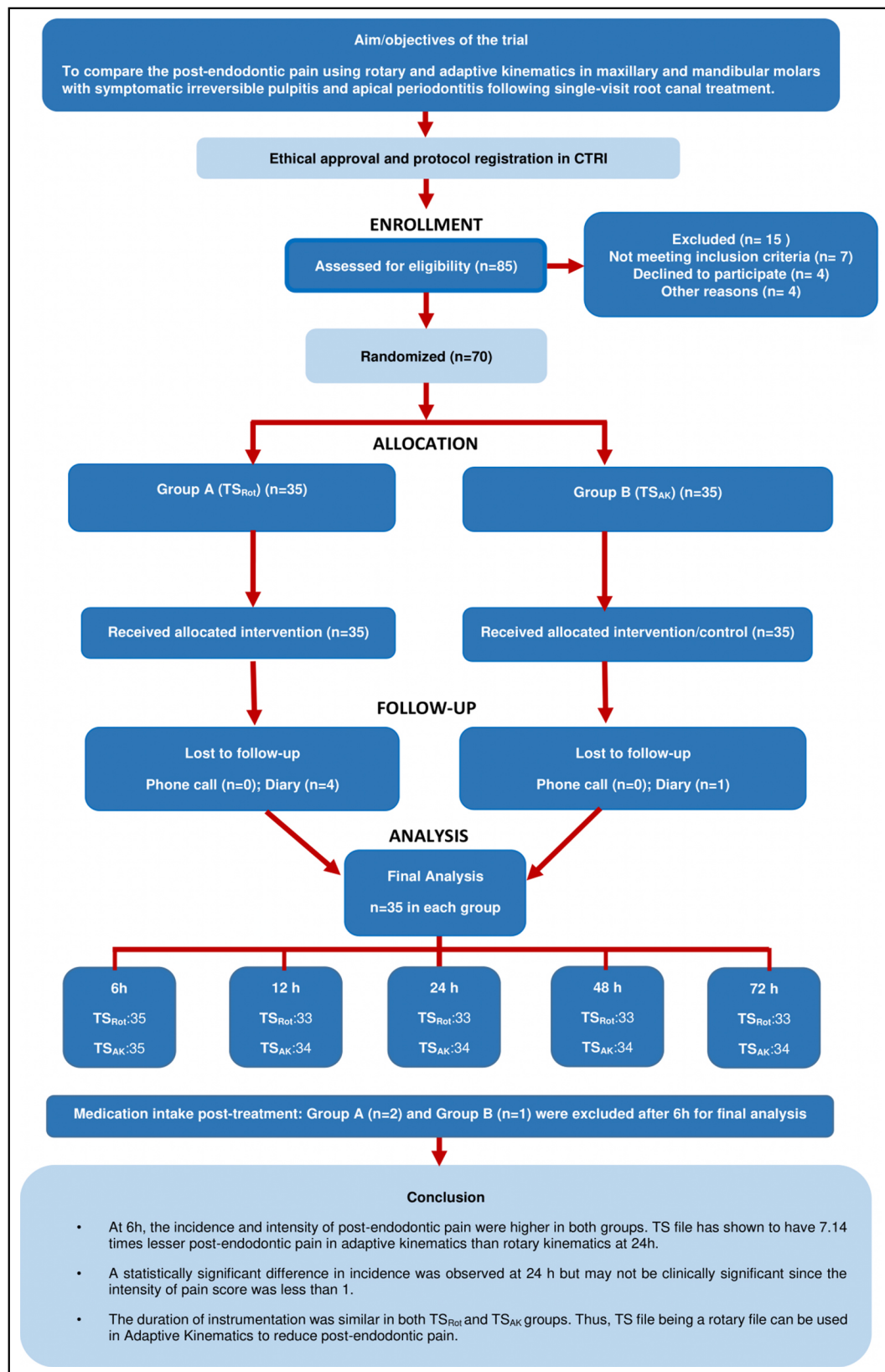


Figure 1. CONSORT flowchart

CTRI: Clinical Trials Registry India, TS<sub>Rot</sub>: 2Shape file in rotary kinematics, TS<sub>AK</sub>: 2Shape file in adaptive kinematics

The percentage (%) distribution of PoP intensity was categorized into no pain [0], mild [1–3], moderate [4–7], and severe [8–10] based on the Visual Analog Scale (VAS) score at 6h, 12h, 24h, 48h and 72h time intervals (Fig. 2).

The intragroup analysis showed that the mean intensity of pain scores was significantly reduced at 6h, 12h, 24h, 48h, and 72h compared with preoperative baseline VAS. The data are summarized in Appendix.



**TABLE 1.** Baseline demographics of distribution of patients among the groups

Variables	Group A (TS <sub>Rot</sub> )		Group B (TS <sub>AK</sub> )		p
	n	%	n	%	
Age (mean, SD)	32.97 (11.44)		31.2 (8.29)		0.672
Gender					
Male	14	40	18	51.4	0.337
Female	21	60	17	48.5	
Tooth type					
Maxillary	9	25.7	9	25.7	1.000
Mandibular	26	74.2	26	74.2	
Preop VAS score (median, IQR)	7 (1)		7 (1)		0.579

TS<sub>Rot</sub>: 2Shape file in rotary kinematics, TS<sub>AK</sub>: 2Shape file in adaptive kinematics, SD: Standard deviation, VAS: Visual analog scale, preop- preoperative, IQR: Interquartile range

**TABLE 2.** Incidence of postoperative pain among the two intervention groups at 6h, 12h, 24h, 48h, and 72h

	VAS at 6h		VAS at 12h		VAS at 24h		VAS at 48h		VAS at 72h	
	n	%	n	%	n	%	n	%	n	%
Group A (TS <sub>Rot</sub> )	34	97.1	25	75.8	17	51.5	3	9.1	1	3.0
Group B (TS <sub>AK</sub> )	34	97.1	22	64.7	8	23.5	2	5.9	1	2.9
p	1.00		0.32		0.01*		0.61		0.98	

\*: p<0.05-significant. VAS: Visual analog scale, TS<sub>Rot</sub>: 2Shape file in rotary kinematics, TS<sub>AK</sub>: 2Shape file in adaptive kinematics

The mean duration of instrumentation (Mean±SD in seconds) in TS<sub>Rot</sub> was 170 (32.81) and in TS<sub>AK</sub> was 167.2 (28.32). There was no statistically significant difference observed in the duration of instrumentation when the TS file was used in adaptive kinematics or rotary kinematics (p=0.41) (Fig. 3). The number of extra canals like second mesiobuccal, middle mesial, and distolingual in TS<sub>Rot</sub> (Mean duration ±SD:189.85±23.45) were 6, 1 & 7, and in TS<sub>AK</sub> were 7, 2 & 9 (Mean duration ±SD:180.11±26.34) respectively. The teeth with the presence of three canals were 21 in TS<sub>Rot</sub> (Mean duration ±SD:169.28±24.83) and 17 in TS<sub>AK</sub> (Mean duration±SD: 163.23±23.44). However, in the presence of extra canals, there was an increase in the duration of instrumentation approximately by 15–20 secs.

The logistic regression analysis results are presented in Table 4. The binary logistic regression (BLR) model showed that the incidence of PoP following a single-visit endodontic treatment was significantly influenced by the preoperative baseline VAS. Age, gender, and tooth type did not have any significant influence on the incidence of PoP at any consecutive time intervals. However, the preoperative baseline VAS showed a significant influence at 12h (p=0.01), 24h (p=0.00), and 48h (p=0.01). The block chi-square test of the model was not significant at 6h (0.367) and 12h (0.110), but was significant at 24h (0.0002) and 48h (0.001). This suggests a good-fit model of the analysis. The variability percentages at 6h, 12h, 24h, and 48h were 31.6%, 11%, 27.9%, and 56.4%, respectively.

The odds of a pain perception of PoP with TSAK is significantly less at 24h when compared to that of TS<sub>Rot</sub> (0.14).

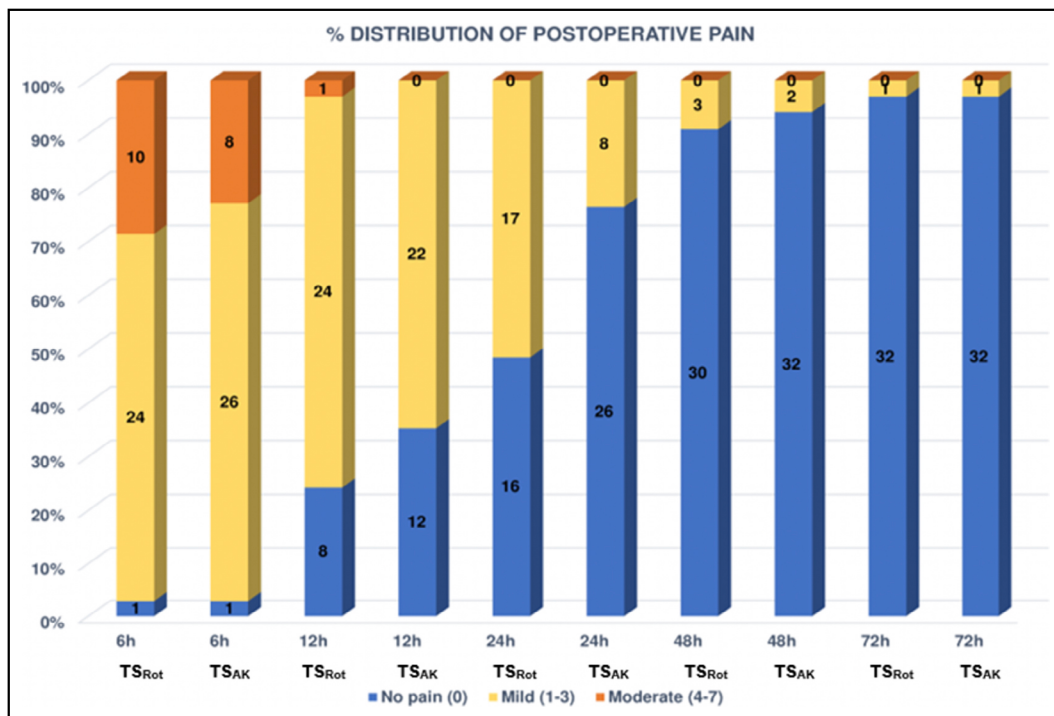
Supplemental intraligamentary/intrapulpal anesthesia was administered in 3/35 [8.57%] in TS<sub>AK</sub>. The rescue medicine

**TABLE 3.** Intensity of postoperative pain among the two groups at 6h, 12h, 24h, 48h, and 72h

	Group A (TS <sub>Rot</sub> )	Group B (TS <sub>AK</sub> )	p
6h			
Mean (SD)	2.97 (1.52)	2.66 (1.25)	0.336
Median	3	2	
IQR	2	1	
12h			
Mean (SD)	1.36 (1.11)	0.94 (0.88)	0.100
Median	1	1	
IQR	1	1	
24h			
Mean (SD)	0.70 (0.84)	0.29 (0.57)	0.020*
Median	1	0	
IQR	1	0	
48h			
Mean (SD)	0.09 (0.29)	0.06 (0.23)	0.620
Median	0	0	
IQR	0	0	
72h			
Mean (SD)	0.04 (0.20)	0.03 (0.17)	0.983
Median	0	0	
IQR	0	0	

\*: p<0.05-significant. TS<sub>Rot</sub>: 2Shape file in rotary kinematics, TS<sub>AK</sub>: 2Shape file in Adaptive Kinematics, SD: Standard deviation, IQR: Interquartile range

was consumed by 5.71% (2/35) and 2.85% (1/35) in TS<sub>Rot</sub> and TS<sub>AK</sub> respectively. No adverse effects were observed after medication intake. The participants who could not report for review at 72h were 11.42% (4/35) in TS<sub>Rot</sub> and 2.85% (1/35) in TS<sub>AK</sub>.



**Figure 2.** Mean % distribution of patients with postoperative pain in both groups at consecutive time intervals

TS<sub>Rot</sub>: 2Shape file in rotary kinematics, TS<sub>AK</sub>: 2Shape file in adaptive kinematics

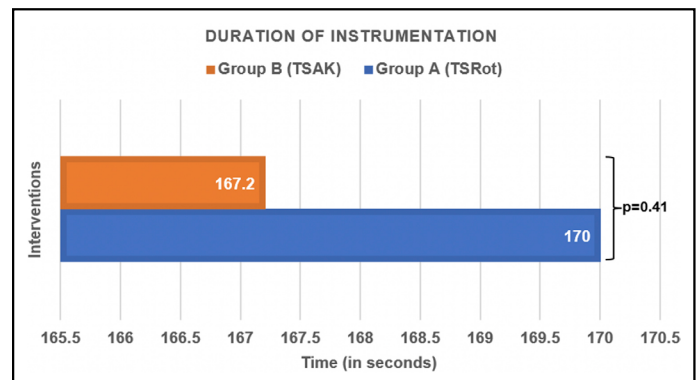
## DISCUSSION

This is the first clinical trial to assess the influence of motion kinematics using a 2Shape® (TS) rotary file in adaptive kinematics on PoP in teeth with SIP & SAP after single-visit endodontic therapy.

Adaptive kinematics enhance the resistance to cyclic fatigue and torsional failure (24, 25). In previous studies, it was reported that the TFA in adaptive kinematics is associated with less PoP when compared to other file systems in reciprocating and rotary kinematics (10, 26). This can be attributed to the enhanced flexibility, less apical debris extrusion, minimal shaping stress, and screw-in effect due to its file design and metallurgical properties (10, 26–28). Hence, the objective was to assess PoP with a file designed for rotary kinematics to be used in Adaptive Kinematics (AK).

TS is a rotary file with a cross-section very similar to that of a TFA, i.e., an asymmetric triangular cross-section with a triple helix providing two-point contact, thus reducing the torsional force (12, 13). A previous study by Bazuhair et al. (29) concluded that TS files were associated with lower pain scores in the mandibular first molars diagnosed with SIP than Reciproc Blue. Contrary to this, another study showed that TS files used in rotary kinematics were associated with higher pain levels 1 week following endodontic treatment in asymptomatic necrotic single-rooted teeth, compared to that of XP-endo Shaper (30). These controversial results could be attributed to local irritation of the periapical tissues.

In this study, the highest mean incidence of PoP was observed at 6h following the treatment, which gradually reduced at all consecutive time intervals in both groups from that of the baseline preoperative VAS. In both intervention groups, 97% of patients experienced pain at 6h, which gradually reduced



**Figure 3.** Bar graph depicting the duration of instrumentation in both the intervention groups

TS<sub>Rot</sub>: 2Shape file in rotary kinematics, TS<sub>AK</sub>: 2Shape file in adaptive kinematics

to 3% at 72h. The incidence of experiencing PoP at 6h and 12h is not significant between the TSAK and TS<sub>Rot</sub> following single-visit endodontics. However, the odds of pain perception at 24h was less than 1 for TSAK compared with TS<sub>Rot</sub>. Thus, the null hypothesis is partially rejected.

At 6h, only 2.9% of the patients were pain-free in both TS<sub>Rot</sub> and TS<sub>AK</sub> based on the baseline preoperative VAS. This observation of a higher incidence of pain at 6h was similar to that of previous studies and could be attributed to the cessation of the anesthetic effect after 2–3 hours (14, 31, 32).

The results of the present study are in agreement with the previous study by Al Omari et al. (9) where they reported that the incidence of PoP at 6h, 24h, 48h, 72h, and 1 week was lower in adaptive kinematics than in reciprocating kinematics, which might be attributed to less debris extrusion

**TABLE 4.** Logistic regression analysis with variables like age, gender, tooth type, and pain score at 6h, 12h, 24h, and 48h

Variables	OR	p	95% CI	
			Lower bound	Upper bound
At 6h				
Group B (TS <sub>AK</sub> )	5.34	0.54	0.024	1175.9
Preop VAS	4.01	0.41	0.142	112.83
Age	1.25	0.21	0.879	1.790
Gender (female)	1	–	–	–
Tooth type (mandible)	1	–	–	–
Constant	5.10	0.32		
At 12h				
Group B (TS <sub>AK</sub> )	0.48	0.21	0.151	1.523
Preop VAS	2.92	0.01	1.192	7.192
Age	0.99	0.80	0.930	1.057
Gender (female)	0.55	0.34	0.161	1.901
Tooth type (mandible)	1.46	0.55	0.415	5.153
Constant	0.00	0.06		
At 24h				
Group B (TS <sub>AK</sub> )	0.14	0.005	0.367	0.559
Preop VAS	4.66	0.00	1.988	10.96
Age	1.00	0.83	0.941	1.077
Gender (female)	1.00	0.99	0.266	3.778
Tooth type (mandible)	1.91	0.39	0.430	8.495
Constant	0.00	0.001		
At 48h				
Group B (TS <sub>AK</sub> )	0.24	0.40	0.008	6.700
Preop VAS	17.05	0.01	1.756	165.57
Age	0.84	0.16	0.667	1.068
Gender (female)	2.41	0.61	0.079	73.26
Tooth type (mandible)	1	–	–	–
Constant	9.52	0.01		

\*: p<0.05-significant. OR: Odds ratio, CI: Confidence interval, TS<sub>AK</sub>: 2Shape in adaptive kinematics, VAS: Visual analog scale, preop- preoperative

(the only confounding factor) and shaping stress due to the asymmetric triple helix cross-section of the file (12). However, in an *in vitro* study by Karatas et al. (33) the debris extrusion was similar in both adaptive and rotary/reciprocating kinematics when used for single-rooted teeth. In our study, the file system, irrigation protocol, and obturation technique were standardized. Thus, the motion kinematics may have contributed to the PoP.

Despite a statistical significance of the mean pain score at 24h in both groups, the values may not be clinically significant. Since pain intensity was higher at 6h and gradually declined from 12h, the analgesic intake was lower in this trial. It was observed that the percentage (%) distribution of patients with pain was highest at 6h and 12h in both groups, which was due to the release of various neuropeptides, thereby activating the neurons and resulting in PoP (34).

In this study, there was no significant difference in the mean duration of instrumentation between the groups. The mean duration of instrumentation of TSAK was observed to be 167.2 seconds in our study, whereas it was reported to be 552 seconds in a previous study (35). This could be attributed to the fact that only active instrumentation time inside the root canal

was accounted for in our study, whereas the entire sequence of inter-instrumentation procedure consisting of file exchange, irrigation between instruments, and cleaning of flutes was cumulated in the previous study. Previous studies comparing rotary, reciprocation, and adaptive kinematics in various clinical scenarios like retreatment, single visit endodontics has shown that instrumentation kinetics does not significantly influence instrumentation duration (28, 35, 36). The presence of extra canals did not significantly increase the mean duration of instrumentation compared with the three canaled molars.

The binary logistic regression (BLR) model revealed that pre-operative baseline VAS was the major confounding factor influencing the PoP, which is in agreement with a previous study (37, 38). The use of lentulo spiral can cause sealer extrusion, which can also be a major cause of PoP (39). However, we were not able to assess this because we did not encounter any sealer extrusions in this study.

Electronic pain assessment has been shown to be an effective alternative method to prevent loss of follow-up data (40). Thus, pain score assessment via an electronic method through a phone call was performed in our study, as it aids in reducing the loss of follow-up data.

The strengths of the present study include the following: A) this is the first study to assess the PoP after using a file indicated for rotary motion in adaptive kinematics; B) the study was properly randomized with allocation concealment; C) a standardized method of irrigation and obturation techniques; D) a double-blinded trial; and E) whole treatment was performed by a single operator.

The limitations of the current study are that the results can be translated to only patients diagnosed with SIP & SAP, and the PoP assessment scores by VAS were based on subjective responses of the patients.

In the future, studies should assess various rotary files in adaptive kinematics after single-visit endodontics in non-vital teeth.

## CONCLUSION

Within the limitations of the study, it can be concluded that both rotary and adaptive kinematics were associated with a significant reduction in the incidence and intensity of PoP compared with baseline VAS. At 6h, the incidence and intensity of PoP were higher in both groups. The TS file was shown to have 7.14 times less PoP in adaptive kinematics than in rotary kinematics at 24h.

A statistically significant difference in incidence was observed at 24h, but this may not be clinically significant since the intensity of the pain score was less than 1. The duration of instrumentation was similar between the TSRot and TSAK groups. Thus, the TS file is a rotary file and can be used in adaptive kinematics to reduce PoP.

## Disclosures

**Appendix File:** [https://jag.journalagent.com/eurendodj/abs\\_files/EEJ-38980/EEJ-38980\\_\(0\)\\_Appendix.pdf](https://jag.journalagent.com/eurendodj/abs_files/EEJ-38980/EEJ-38980_(0)_Appendix.pdf)

**Ethics Committee Approval:** The study was approved by the Meenakshi Academy of Higher Education and Research Ethics Committee (no: MADC/IEC-I/033/2021, date: 30/03/2021).

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