

An Observational Study To Evaluate The Impact Of Different Single-File Systems Used In Single-Visit Endodontics On The Incidence And Severity Of Postoperative Pain

Dr. Sadaf Ahmed¹, Dr. Danish Qureshi², Dr. Anshu Vij³, Dr. Richa Sharma⁴

¹Postgraduation Student, Department of Conservative Dentistry and Endodontics, Himachal Dental College and Hospital, Sundernagar, Himachal Pradesh, India

²Private Practitioner, Jammu and Kashmir, India

³Medical Officer (Dental), Department of Health and Family Welfare, Himachal Pradesh, India

⁴Medical Officer (Dental), District Hospital Bageshwar, Uttarakhand, India

*Corresponding Author:

Dr. Anshu Vij,

Medical Officer (Dental), Department of Health and Family Welfare, Himachal Pradesh, India

Email ID: anshusoni79@gmail.com

Cite this paper as: Dr. Sadaf Ahmed, Dr. Danish Qureshi, Dr. Anshu Vij, Dr. Richa Sharma, (2025) An Observational Study To Evaluate The Impact Of Different Single-File Systems Used In Single-Visit Endodontics On The Incidence And Severity Of Postoperative Pain. *Journal of Neonatal Surgery*, 14 (13s), 993-999.

ABSTRACT

Context: Pain, although of short duration, is a thwarting experience and a matter of concern after single-visit endodontics.

Aim: This study aims to evaluate the impact of different single-file systems used in single-visit endodontics on postoperative pain.

Design: This is an observational study involving one hundred fifty patients out of which thirty failed to participate. Therefore, one hundred twenty patients were selected as subjects for the study.

Materials and Methods: Patients aged between 18-55 years with symptomatic irreversible pulpitis with/without apical periodontitis and fully matured mandibular premolar teeth were selected and categorized into three groups based on instrumentation system used: Group I with WaveOne Gold, Group II with One Curve and Group III with TruNatomy. The root canal preparation procedures were performed according to the manufacturer's instructions. Presence of pain was accessed by modified Heft-Parker visual analogue scale (HP-VAS) scale.

Statistical analysis: Data were collected after obtaining the HP-VAS forms and one-way ANOVA and one-way repeated measure ANOVA were used for analysis. The level of statistical significance was set at $P < 0.05$.

Results: The intensity of pain was measured on 24, 48 and 72 hours. All the three groups showed less postoperative pain at 72 hours where the difference is statistically significant. After 24 hours, pain was seen least with TruNatomy, followed by One Curve and WaveOne Gold, but here the results were statistically insignificant.

Conclusion: Postoperative pain is mainly related to the instrumentation technique although there may be other contributory factors too.

Keywords: Single-File System, Postoperative Pain, Instrumentation, Visual Analog Scale.

1. INTRODUCTION

Postoperative pain after endodontic therapy has been a subject of concern. Incorrect instrument choice and extrusion of debris beyond the apical foramen during instrumentation may induce mechanical trauma to periapical tissues, resulting in postoperative pain.¹ Instrumentation has been an important contributing factor since it results in debris extrusion. According to the literature, both rotary and reciprocating instruments have an effect on postoperative pain.² A plethora of file systems and sequences for root canal preparation have been introduced. The modern concept of root canal preparation includes the use of "single-use, single-file system" to shape the canal completely from start to finish.³

2. MATERIALS AND METHODS

This *in vivo* study was conducted between 2021 and 2022 after obtaining approval from the Institutional Ethical Committee (HDC/Ethical/Conservative/2020/04). Patients were enlisted from the regular patient pool for endodontic treatment and were selected in accordance with the guidelines enclosed within the Declaration of Helsinki. The inclusion and exclusion criteria for sample selection are mentioned in Table 1.

Only one tooth for each patient was selected. The pulpal vitality was determined by an electric pulp tester (Analytic Technology Corp., Redmond, WA, USA) and clinical observation of haemorrhage during access cavity preparation. The root canal morphology was assessed using a radiovisiography imaging system.

Sample size and distribution

The sample size was estimated using the formula, $(Z\alpha + Z\beta)^2 \frac{\sigma^2}{x^2}$. To obtain a safe sample,

∴

$n =$

150 patients aged 18-55 years were included. However, 22 cases failed to fulfil the established criteria while 8 patients declined to participate, and hence 120 cases were selected (Figure 1).

After obtaining informed consent, the patients were randomly stratified using a computer-generated simple randomization procedure (www.random.org) into three groups of 40 patients, further equally assigned to three clinicians. The randomized order of instrument interventions and standard operating protocol were concealed in opaque discrete envelopes which was later opened by the operators. Baseline parameters such as age, gender, medical and dental history and pre-instrumentation pain score was recorded by the operators in the case history sheets using the modified heft-parker visual analog scale (HP-VAS).

Before initiating the endodontic therapy, all participants received a questionnaire (including HP-VAS sheet) to record their assessment of pain 24, 48 and 72 days after the treatment. The occurrence of pain was categorized as described by the patient conferring to the four levels (on the HP-VAS) (Figure 2).

Procedure

The treatment protocol was once again explained to the patients. The inferior alveolar nerve block (using 2% lidocaine with 1:80,000 epinephrine) was administered to anaesthetize the tooth. The tooth was isolated using a rubber dam (Dentsply Sirona, Ballaigues, Switzerland) and the access cavity was prepared with sterile round bur #2 and enlarged with Endo Z bur (Dentsply Maillefer, Ballaigues, Switzerland). The canal patency was established using K-file #10 (Mani, Inc., Japan). The working length was determined using an apex locator (Propex Pixi, Dentsply Sirona, Ballaigues, Switzerland) and verified using a digital radiograph (Satellac, Sopix, USA). The root canal was cleaned and shaped using WaveOne Gold (Dentsply Sirona, Ballaigues, Switzerland), One Curve (Micro Mega, Besancon Cedex, France), and TruNatomy (Dentsply Sirona, Ballaigues, Switzerland) in Group I, Group II and Group III respectively according to the manufacturer's instructions by applying the crown-down technique with the help of an X-Smart Plus Endomotor (Dentsply Maillefer, Ballaigues, Switzerland). The instrumentation of all canals was done up to the determined working length.

Group I (WOG): WaveOne Gold Glider file (15/.02 variable taper) was used for glide path preparation. The canals were prepared with the WOG primary instrument (25/.07). It was used with a slow, in-and-out pecking motion at 350 rpm speed.

Group II (OC): Preflaring was done with One Flare (25/.09) and glide path was prepared with One G file (14/.03). One Curve file (25/.06) was introduced into the canal at speed 300 rpm and 2.5 Ncm torque in three waves. The file was then withdrawn, flutes cleaned, and the canal irrigated.

Group III (TRN): TruNatomy orifice modifier (20/.08) was used in the coronal-third part of root canal, followed by TruNatomy glider (17/.02) for preparation of the glide path. The TruNatomy prime (26/.04) was used at 500 rpm speed and 1.5 Ncm torque according to the manufacturer's instructions. All the instruments were used with two to three gentle 2-5 mm movements into the root canal and then the file was withdrawn, its flutes were cleaned, and the canal was irrigated.

During instrumentation, the intermittent irrigation was done with 10 ml of 3% sodium hypochlorite (NaOCl) (Prime Dental Products Private Limited, Pune, India) using a 30-gauge side-vented needle at 1 mm short of working length. Glyde File Prep (Dentsply Maillefer, Ballaigues, Switzerland) containing EDTA and carbamide peroxide was used as a lubricant and for smear layer removal. Finally, a flush with 3% NaOCl followed by 0.9% saline solution was performed.

The canals were dried with paper points. The master cone radiographs were taken, and root canals were obturated at the same visit with gutta-percha cones and AH Plus Sealer (Dentsply Maillefer, Ballaigues, Switzerland) utilizing the lateral compaction technique. The teeth were restored temporarily with a provisional restoration (Prime TMP-RS eugenol free). A post-obturation radiograph was taken and the patient was recalled after 1 week for final restoration by composite (Herculite

precis, Kerr, Asia).

Ibuprofen (400 mg, 6 hourly till the pain decreased or disappeared) was prescribed and the patients were instructed to take it only if they continued to experience excruciating pain following treatment. They were asked to record the maximum pain level before they took the analgesics. If a patient in either group took medication within 48 hours after the start of therapy, he/she was debarrred from the study. Any patient with intolerable pain even after the intake of analgesics, was asked to report for emergency treatment.

Pain assessment

The patients were schooled to place a mark on the horizontal scale to signify the intensity of their pain experience. A telephonic reminder was given to them at regular intervals of 24-, 36-, and 72-hours pain levels to record their response on the HP-VAS sheet. Data were collected after patients returned to the department after 1 week with the HP-VAS forms.

Statistical Analysis

Data was found normally distributed as tested using the Shaperio-Wilk test ($P > 0.05$). Therefore, analysis was performed using the one-way ANOVA and one-way repeated measure ANOVA ($P < 0.05$).

3. RESULTS

All the file systems showed less postoperative pain at 72 hours when compared with 24 hours and 48 hours and the result is statistically significant (Table 2). After 24 hours, the postoperative pain was seen least with TruNatomy, followed by One Curve and WaveOne Gold, but the results were statistically insignificant (Table 3).

Table 1: Inclusion and exclusion criteria for sample selection

Inclusion criteria:	Exclusion criteria:
<ul style="list-style-type: none"> Patients aged between 18 and 55 years. Presence of symptomatic irreversible pulpitis with or without apical periodontitis, with no periapical lesion. Fully matured roots in mandibular premolar teeth. Patient who agreed to the planned single-visit treatment. 	<ul style="list-style-type: none"> Patients aged below 18 years of age. Curved root canals with curvature $> 25^\circ$. Tooth exhibiting complex root canal morphology, extra-root or procedural error during treatment. Tooth with periodontal disease or periapical radiolucency of more than 0.5 cm. Retreatment cases. Uncooperative or medically compromised patients or patients under premedication with non-steroidal anti-inflammatory drugs or opioid analgesics.

Table 2: Mean of post operative pain at different time interval by different file system

File System	Time period (hours)	Mean	Minimum	Maximum	Standard Deviation	P-value
Group I	24	4.32	2.12	5.76	0.12	0.001
	48	3.01	1.23	4.56	0.24	
	72	0.32	0.10	2.34	0.11	
Group II	24	4.22	1.45	4.68	0.56	0.001
	48	2.92	1.15	4.12	0.23	
	72	0.10	0.05	1.56	0.71	
	24	4.02	2.08	5.65	0.45	0.002

Group III	48	3.52	1.67	4.98	0.65	
	72	0.42	0.15	1.98	0.32	

Table 3: Comparison of post operative pain at different time interval of the different file system:

Time Period (hours)	File System	Mean	P-value
24	Group I	4.32	0.55
	Group II	4.22	
	Group III	4.02	
48	Group I	3.01	0.23
	Group II	2.92	
	Group III	3.52	
72	Group I	0.32	0.10
	Group II	0.10	
	Group III	0.42	

HPVAS SCORE	SEVERITY OF PAIN	REMARKS
0 mm	No pain	
> 0 mm but ≤ 54 mm	Mild pain (included the descriptors of faint, weak and mild pain)	Any discomfort, no matter how brief in duration that neither requires medication nor impairs masticatory function like difficulty in chewing in any way.
> 54 mm but ≤ 114 mm	Moderate pain	Necessitating medication or other palliative treatment or impairing masticatory function.
≥ 114 mm	Severe pain (included the descriptors of strong, intense and maximum pain)	Either patients reports of pain which is not relieved by medication or of increased swelling.

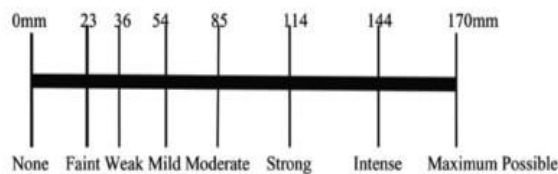


Figure 1: Modified Heft-Parker Visual Analogue scale and its scoring

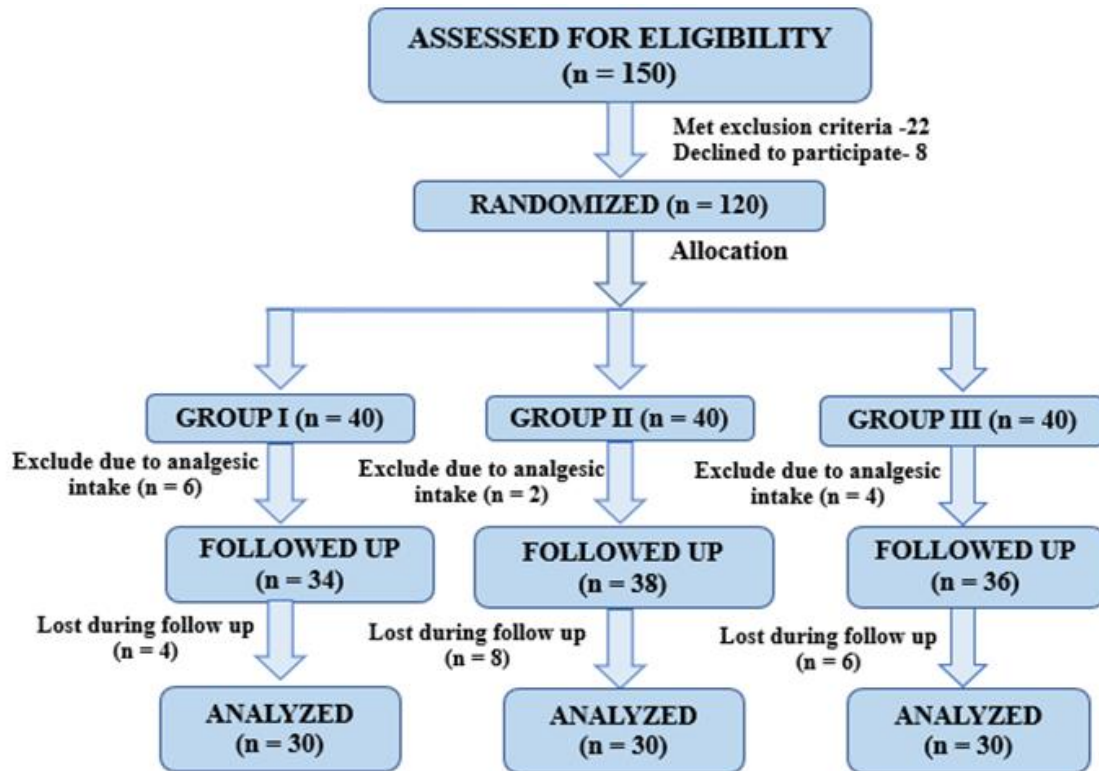


Figure 2: Diagram for sample segregation

4. DISCUSSION

The success of endodontic therapy is persevered by efficient cleaning and shaping, effectual seal achieved after obturation and intensity of postoperative discomfort or pain experienced by the patient. Postoperative pain is a frequently endured dilemma of endodontic therapy. The prevalence of postoperative pain has been reported to range from 3-58%, with < 12% of patients experiencing severe pain.⁴

The etiology of postoperative pain is related to a complex multifactorial process involving an interplay of various factors such as age and gender of the patient; medical history; previous endodontic treatment experience’ tooth type and arch; pulp condition; presence of a preoperative pain, swelling, periapical lesion; shaping techniques; irrigation, intracanal medicament; obturation technique, material, extent; presence of occlusal contacts; apical debris extrusion, and number of treatment visits.⁵ Among these aspects, the clinician has control over selecting an appropriate preparation method and shaping the canal. As a result, severe postoperative pain might be prevented by minimizing the extrusion of the canal contents into periradicular tissues during the preparation procedure.

The occurrence of postoperative pain is attributed to peripheral and central sensitization. A bacterial endotoxin, LPS may stimulate the release of substance P and calcitonin gene-related peptide, activating G-protein-coupled receptors on pulp nociceptors during peripheral sensitization.⁶ The upregulation of transient receptor potential vanilloid type-1 channel expression due to nociceptor excitation results in hyperalgesia, allodynia, and spontaneous pain. The persistent discharge of nociceptive impulses from peripheral C-fibers induces the excitation of central neurons. Once it has been well-established, it becomes independent. As a result, even if endodontic therapy has eliminated all peripheral inputs contributing to hyperalgesia, the central mechanism may persist for some time.

The single-visit endodontic treatment has been a hot topic in recent years and is more admissible by both patients and clinicians. Reduced number of visits and less risk of inter- appointment leakage are some of its merits resulting in less postoperative discomfort. Su et al reported that the incidence of pain after the single-visit endodontic treatment was less.⁷

One of the cardinal problems in studying pain is the patient’ s subjective evaluation. Accordingly, the methodology used in determining the intensity of pain is crucial. Modified Heft-Parker visual analogue scale was employed in this study because of its extensive use in research and credibility.⁸ In this scale, word descriptions of various pain levels are explained in ascending order along the axis. Values ranging from 0-170 can be marked by the patients on the scale according to the intensity of pain experienced by them (Figure 2).⁸

This study focuses solely on teeth diagnosed with irreversible pulpitis to avoid any probable interference of intracanal drugs or other variables causing discomfort. All of the teeth were treated in a single visit to eliminate bias. The entire procedure of endodontic therapy used a standardized amount, concentration, and kind of irrigating solution.

Recent ameliorations in metallurgy and kinematics have brought innovatory changes in the designs of instruments. WaveOne Gold, based on gold technology is programmed to be used in a reciprocating motion. It has a parallelogram cross-section with two 85° cutting edges that contact the canal walls. The tip is ogival, roundly tapered and semi-active to improve its penetration into the canal with smooth glide path. There are four tip sizes available: small (20/.07, yellow), primary (25/.07, red), medium (35/.06, green) and large (45/.05, white).⁹ They incorporate a reverse cutting helix that cuts dentin in a 150° counterclockwise direction and then, disengages 30° in a clockwise direction. The patented heat treatment used in the file system improves the flexibility, cutting efficiency, and cyclic fatigue resistance of the instrument.⁹

One Curve is a single file system having a variable cross-section all along the blade, being triangular in the apical-third and almost S-shape in the coronal-third (25/.06) designed to be used in continuous rotation. This system integrates C-wire technology which is heat-treated NiTi alloy having controlled memory and reduces the threading, and binding of the instrument to the curved canal walls, favouring effortless canal preparation.¹⁰

TruNatomy files are manufactured from heat-treated 0.8 mm NiTi wire. And consists of an orifice modifier (20/.08, purple), glider (17/.02, white), prime shaping file (26/.04 taper, red), medium shaping file (36/.03, green), and small shaping file (20/.04, yellow) employed in continuous rotation.¹¹ The geometry, regressive tapers, and heat treatment of the alloy aim at conserving the integrity of the tooth with the maximum preservation of pericervical dentin. The file's parabolic cross-section offers great flexibility and fracture resistance in curved canals.¹¹

The results of this study depict that the severity of postoperative pain was observed to decrease gradually with time in all three groups after the endodontic treatment with different file systems. WaveOne Gold, One Curve, and TruNatomy showed significantly less postoperative pain at 72 hours when compared to 24 hours and 48 hours. This is in accordance with Pak and White who concluded that the highest level of postoperative pain was observed in the early phase following endodontic therapy. The postoperative pain incidence was reported to be 40% in the first 24 hours, and 11% or less on the 7th day.¹²

After 24 hours, maximum pain was noted with WaveOne Gold followed by One Curve and minimum with TruNatomy. The reciprocating motion has been found to produce a more significant postoperative pain as it involves larger cutting angle and smaller releasing angle and the file travels apically during releasing angle. Thus, instead of removing debris, it gets pushed apically. For this reason, the WaveOne Gold acts as a piston to propel debris beyond the apical foramen.¹³ Apart from this, the WaveOne Gold is a single-file system of higher taper (usually 25/.08), used without preliminary coronal enlargement. As a result, the entire length of the file contacts the canal wall, increasing the amount of debris formed. Moreover, cutting ability of a reciprocating file is smaller when compared to continuous rotation, and also debris removal is smaller, thus increasing the frictional stress and torque, due to debris entrapment within the flutes.¹³

On the other hand, continuous rotary instrumentation provides a passageway for debris removal from the canal, thus reducing apical extrusion of debris, and severity of post-operative pain.¹⁴ That's why One Curve and TruNatomy both employing rotational movement resulted in less postoperative pain. But contrary results have been projected by certain clinical research.¹⁵

Pain, subjective experience is difficult to quantify. Pain is influenced by many factors.⁵ In addition, the Hawthorne effect (the change in the behavior of a subject because of the special attention received from participation in an investigation) can provoke the patients and overestimate their pain levels.¹⁶

In addition, Pasqualini et al evaluated some indicators of postoperative quality of life such as difficulty eating, performing daily activities, and sleeping and showed that the activities were more significantly affected by reciprocating instrumentation than rotary instrumentation. They concluded that reciprocating motion had an impact on immediate postoperative discomfort when preexisting periradicular inflammation was present and treatment was performed in a single visit, thereby negatively influencing patients' quality of life.¹⁷

Limitation of the study

The limitation of the study is pain may sometime result in bias depending on the varied patient's pain threshold. According to the criteria set forth in this study, there was a statistically insignificant difference in postoperative discomfort between the preparation systems tested at 24 hours, 48 and 72 hours.

5. CONCLUSION

The study suggested that after using the evaluated systems, short-term postoperative pain (lasting from 24 to 72 hours) can be anticipated. Debris extrusion could be related to a higher incidence of postoperative pain. The differences in instrument design and preparation of the single-file systems used in this clinical study seem to have some influence although statistically there was no significant difference between the file system on the incidence of postoperative pain at various time intervals.

The standardized and controlled kinematics used in this study may have contributed to minimizing debris extrusion.

Financial support and sponsorship: This study was self-funded and hence no financial support was taken.

Conflicts of interest: The authors declare no conflicts of interest.

REFERENCES

- [1] Harrison JW, Baumgartner JC, Svec TA. Incidence of pain associated with clinical factors during and after root canal therapy; Part 2-Postobturation pain. *J Endod* 1983; 9:434-8.
- [2] Burklein S, Schafer E. Apically extruded debris with reciprocating single-file and full- sequence rotary instrumentation systems. *J Endod* 2012; 38(6):850-2.
- [3] Liang Y, Yue L. Evolution and development: Engine-driven endodontic rotary nickel- titanium instruments. *Int J Oral Sci* 2022; 14:12.
- [4] Sathorn C, Parashos P, Messer H. The prevalence of postoperative pain and flare-up in single- and multiple-visit endodontic treatment: A systematic review. *Int Endod J* 2008; 41:91-9.
- [5] Seltzer S. Pain in endodontics. *J Endod* 2004; 30:501-3.
- [6] Henry MA, Hargreaves KM. Peripheral mechanisms of odontogenic pain. *Dent Clin North Am* 2007; 51:19-44.
- [7] Su Y, Wang C, Ye L. Healing rate and post-obturation pain of single- versus multiple- visit endodontic treatment for infected root canals: A systematic review. *J Endod* 2011; 37(2):125-32.
- [8] Heft MW, Parker SR. An experimental basis for revising the graphic rating scale for pain. *J Pain* 1984; 19:153-161.
- [9] Webber J, Machtou P, Pertot W, Kuttler S et al. The wave one single-file reciprocating system. *Roots* 2011; 1:28-33.
- [10] Topçuoğlu HS, Topçuoğlu G, Kafdag O, Balkaya H: Effect of two different temperatures on resistance to cyclic fatigue of One Curve, EdgeFile, HyFlex CM and ProTaper next files. *Aust Endod J* 2020; 46:68-72.
- [11] Van der Vyver PJ, Vorster M, Peters OA. Minimally invasive endodontics using a new single-file rotary system. *Int Dent Afr Ed* 2019; 9:6-20.
- [12] Pak JG, White SN. Pain prevalence and severity before, during, and after root canal treatment: a systematic review. *J Endod* 2011; 37(4):429-38.
- [13] Shivanna V, Nilegaonkar R. The effect of two continuous rotary and one reciprocating file systems on the incidence of postoperative pain after single-visit endodontic treatment. *Int J Oral Health Sci* 2015; 5:4-8.
- [14] Gambarini G, Testarelli L, De Luca M, Milana V, Plotino G, Grande NM, Rubini AG, Al Sudani D, Sannino G. The influence of three different instrumentation techniques on the incidence of postoperative pain after endodontic treatment. *Ann Stomatol (Roma)* 2013; 4(1):152-5.
- [15] Martins CM, De Souza Batista VE, Andolfatto Souza AC, Andrada AC, Mori GG, Gomes Filho JE. Reciprocating kinematics leads to lower incidences of postoperative pain than rotary kinematics after endodontic treatment: A systematic review and meta- analysis of randomized controlled trial. *J Conserv Dent* 2019; 22(4):320-331.
- [16] Wolfe F, Michaud K. The Hawthorne effect, sponsored trials, and the overestimation of treatment effectiveness. *J Rheumatol* 2010; 37(11):2216-20.
- [17] Pasqualini D, Corbella S, Alovise M, Taschieri S, Del Fabbro M, Migliaretti G, Carpegna GC, Scotti N, Berutti E. Postoperative quality of life following single-visit root canal treatment performed by rotary or reciprocating instrumentation: a randomized clinical trial. *Int Endod J* 2016; 49(11):1030-1039.