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Assessing Post Endodontic Pain with two different file system using dynamic irrigation technique: A randomised clinical trial

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A B S T R A C T

Introduction: Immediate condition just after root canal therapy takes a first impression of treatment as well as clinician's ability. In this pretext, evaluation of reduction of PEP using two different file system with Endoactivator is done.
Aim: Evaluation of post endodontic pain after using Endoactivator with ProTaper Gold and ProTaper Next file system in single visit root canal treatment.
Material method: A total of 100 patients were assigned who required endodontic treatment. They were divided into two **groups:** Group 1 (PTG-EA) and Group 2 (PTN-EA). Single visit root canal was performed under local anesthesia. Endoactivator was used for final irrigation protocol in all groups. The intensity of post endodontic pain (PEP) was evaluated by Visual Analogue Scale VAS score after 6,12,24 and 48 hours. Final data was combined and statically analyzed with the help of SPSS 20.0 software at a level of being significance being 0.05.
Results: As compared to ProTaper Gold, ProTaper Next showed the least score at 6 and 12 hours of PEP, there was a statistically significant difference noted. At 24 and 48 hours no statistically significance difference was noted among two groups.
Conclusion: The intensity of PEP was minimum when treated with ProTaper Next file system along with Endoactivator.

Keywords: Endoactivator, Post Endodontic Pain, ProTaper Gold, ProTaper Next.

INTRODUCTION

Success of endodontic treatment is acquired through cleaning, shaping and obturation. However, post endodontic pain (PEP) is a very usual but unfortunate complication of endodontic treatment. Occurrence rate of PEP varies from 3 to 58%[1]. Due to extrusion of microorganisms along with dentinal and necrotic debris during biomechanical preparation, PEP is developed.[2,3]

In order to prevent the PEP many researchers have suggested to maintain the septic environment during the endodontic treatment and choosing correct instruments for biomechanical preparation.[4] Various Nickle- Titanium rotary system have variation in cross sectional geometry, tip and taper, design of cutting blade, depth of flute, kinematics might produce debris extrusion which difference in PEP.[5]

The possibility of the irrigant as well as debris pushed beyond the apex are more, especially in the complex anatomy of the tooth were extrusion is difficult. To avoid the complication irrigation protocol with sonic device (1-6 kHz), EndoActivator (EA), which provide oscillation and vibration at the tip producing cavitation and acoustic steaming, which enhances the disruption of smear layer, unplugging dentinal tubules and biofilm disruption.[6]

Different number of file insertion could also influence the extrusion of debris which could be a difference in PEP.[7]ProTaper Gold (PTG) (Dentsply-Maillefer, Ballaigues, Switzerland) has a convex triangular cross section with variable progressive taper. ProTaper Next(PTN) (Dentsply-Maillefer, Ballaigues, Switzerland) has an off-center rectangular design with progressive and regressive taper.[8]

Single visit endodontics (SVE) are more popular as compared to multiple visit endodontics as it saves time, reduces cost and is comfortable in anxious patient.[9,10]Gupta NK et al also evaluated that the short term postoperative pain was higher in multiple-visit than single visit of mandibular molar.[11]Hence SVE is beneficial for both patient and doctors.

Ramamoorthi S et al evaluated post-operative pain using endodontic needle and Endoactivator during root canal treatment and concluded that endodontic needle showed more pain than Endoactivator.[1]Therefore, the purpose of the study was to evaluate PEP with different file design like PTG and PTN associated with Endoactivator as there is limited study available with the two file system.

The aim of the study was to compare and evaluate the impact of PEP using Endoactivator with two different file system i.e PTG and PTN in respect to single visit endodontics. The null hypothesis stated that there is no difference in PEP after using the three different file system.

MATERIAL AND METHOD

This is a factorial, randomized clinical trial which has been approved by the Research and Ethical committee of Narsinhbhai Patel Dental College and Hospital, Sankalchand Patel University, Visnagar, Gujarat (ref.no. NPDCH/2021/55). The CTRI registration Number allotted is as follow: CTRI/2022/04/041662. The present study was designed as per the CONSORT statement and conducted in obedience to the declaration of Helsinki. Before starting the treatment, all the protocol was explained to the patient, and the consent form was filled and signed. The sample size was decided according to $\alpha = 0.05$ and the power of study 0.8 which is 35 per group.

Patient Selection:

On clinical examination, the vitality of the pulp was checked with the cold test and electric pulp test. Followed by palpation, percussion and periodontal status. Radiographic evaluation was done to check periapical radiolucency. Therefore, confirming the diagnosis for asymptomatic irreversible pulpitis.

A total of 128 patients were allocated for the study, among which 28 patients were excluded, as they were not matched the inclusion criteria which makes a 50 patient in both groups. (Flowchart 1)

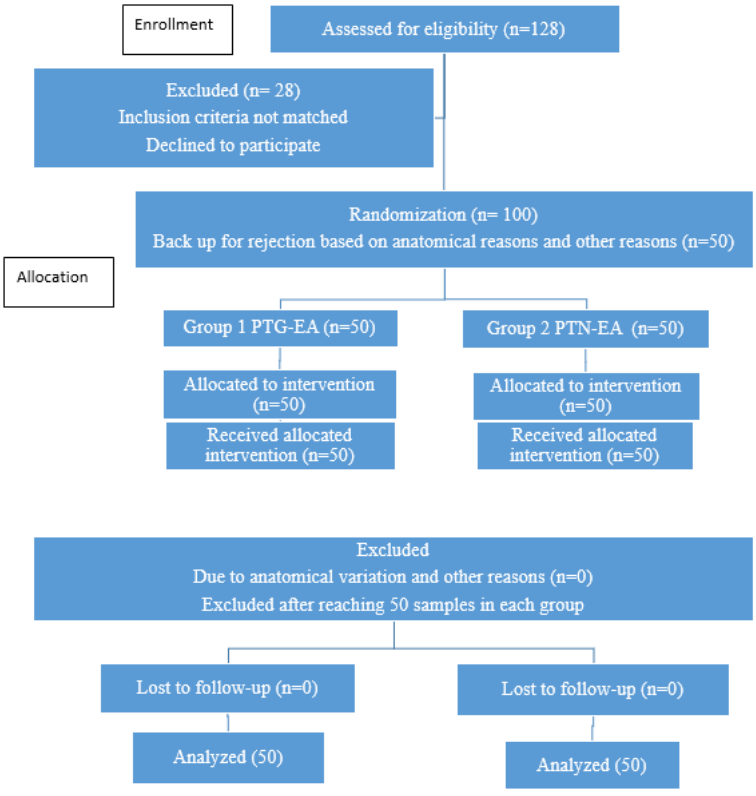


Fig. 1 Flow chart of CONSERT

Inclusion Criteria:In the age group of 20-60 years old the tooth with asymptomatic irreversible pulpitis in permanent maxillary and mandibular molars were included in the study.

Exclusive criteria:Calcified canals, root canal-treated teeth, cracked teeth, resorption and immature tooth, pregnant, lactating mothers who had a history of any medical condition, who had taken analgesic within the last 24 hours were excluded from the study.

Randomization protocol:

A total of 100 patients were selected and allocated to two different group (n=50) through double blinded randomization to minimize the bias. A total of 100 opaque envelopes were prepared and picked up by the dental assistant before the treatment.

Treatment protocol:

All the patient was treated by the single operator. 2% lignocaine was administrated followed by rubber dam isolation. Caries Excavation was done and the standard access cavity was prepared. Working length was measured using #10k file and PropexPixi Apex Locator (Dentsply-Maillefer, Ballaigues, Switzerland) and then confirmed radiographically. Canals were prepared using Group 1 PTG-EAand Group 2 PTN-EA with crown down technique according to manufacturer's instruction with X Smart Endomotor (Dentsply-Maillefer, Ballaigues, Switzerland). The final apical diameter was prepared till #25 file.

Irrigation Protocol:

During biomechanical preparation, canals were irrigated with 10mL of 3% NaOCl with conventional endodontic syringe. Then, the canals were flushed with 2mL of 17% EDTA solution for 1 minute.

Endoactivator tip (size 20/0.02) was placed loosely at 2mm from working length which was flooded with 3% sodium hypochlorite and activated at 10,000 cycle/minute which was used in pumping action to move the tip, 2-3 mm vertical strokes for 1 min.

Final irrigation was done with sterile normal saline. All the canals were dried using corresponding paper points. Obturation was done using AH PLUS resin based sealer along with gutta-percha points with lateral condensation technique. Post-operative radiograph was recorded to confirm accuracy.

Post-operative instructions:

In case of severe pain, the patients were advised to take an analgesic (Brufen 400mg). Patient were asked a questionnaire based on VAS for recording their pain after 6 hours, 12 hours, 24 hours and 48 hours.

Follow up Evaluation:

The pain assessment sheet given to the patients were collected after 48 hours during follow up appointment. A telephonic reminder was given to all the patient to write into the form.

Statistical Analysis:

The obtained data were analyzed statically using SPSS 20.0 (statistical package for the social sciences) software. VAS score for painwere summarized as mean and standard deviation (SD) and Mann Whitney U test. Number of Analgesic tablets took by patient for pain also examined. The degree of statistical significance was set at 0.05

RESULT

It was observed that for every time period, the PTN-EA group was seen less pain as compare to PTG-EA group. There was statistically significant difference was observed at the 6 hours and 12 hours in PTG and PTN. But at 24 hours and 48 hours, no statistical significant difference was seen.

Among 100 patients, the mean value of the age of the patient is 43.01 and 39.61 for PTG-EA and PTN-EA respectively. To avoid the bias, the gender distribution was done in equal number 25males and 25 females.

Mean pain score were recorded for both group. According to Mann Whitney U test, PEP at 6 and 12 hours' time intervals was statistically significant in PTN-EA group but after that time interval there was no statistical significant difference was found. (Table 1)

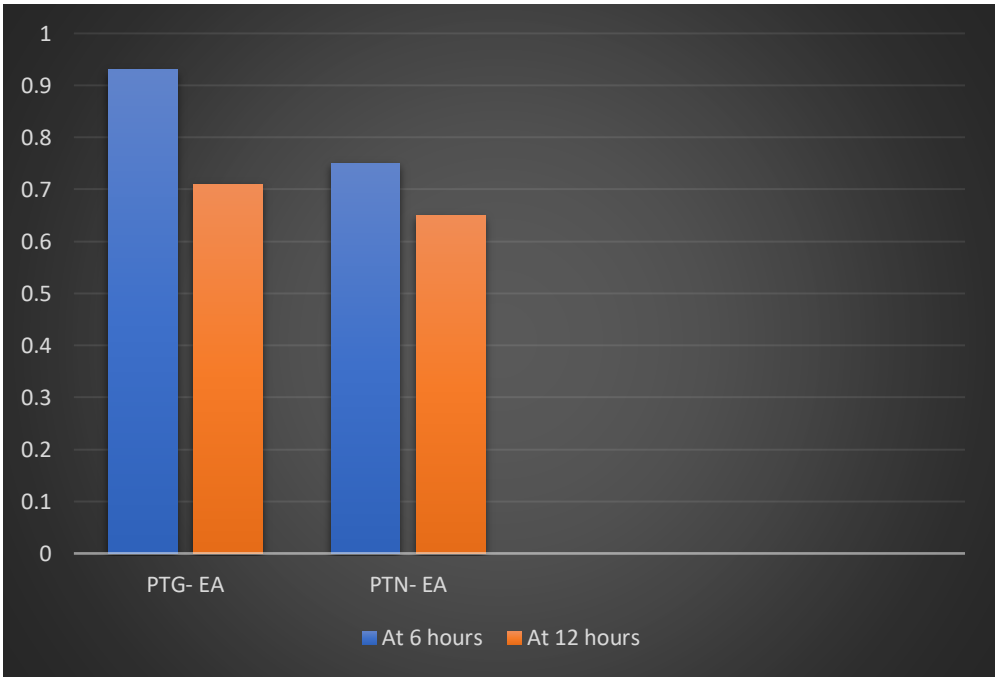
TABLE 1 Comparison of mean of vas score

Time	PTG-EA		PTN-EA	
	MEAN	SD	MEAN	SD
6 HRS	2.77	1.43	2.48	1.14
12 HRS	1.14	1.00	0.97	1.01
24 HRS	0.22	0.42	0.14	0.35
48 HRS	0.05	0.23	0.00	0.00
P VALUE	0.000*		0.000*	

*p< .05 statistically significant (Mann Whitney U Test)

The maximum intake of analgesics in the number of tablets was more in PTG-EA group at 6 hours. 9 patients took 1 tablet at 6 hours and 4 patients took 2 tablets in PTG-EA group. Where as in PTN-EA group, 8 patients took 1 tablet and 2 patients took 2 tablets. The correlation of mean pain intensity with the mean number of tablets was measured with Pearson correlation coefficient test. (Graph 1)

Graph 1 The correlation of mean VAS score with the Mean number of analgesics taken



The primary outcome of this study showed statistically significant difference in PEP at 6 and 12hours only. The secondary outcome of the study was noted in terms of the patient satisfaction. There was a positive response noted among the patient during the telephonic follow up.

DISCUSSION

There was a statistically significant difference was observed at 6 hours between PTG and PTN. Therefore, the null hypothesis is discarded.

There are many reasons for PEP and hence depends on various factors. Some of the reason are like mechanical and chemical causes that occurs due to over instrumentation and extrusion of irrigants or filling materials.[11] Due to extrusion of debris from the periradicular area, periradicular inflammation occurs immediately after Endodontic treatment, suggestive of higher score in PEP to occur.

The mechanism of pain is the substance p and calcitonin gene related peptide activates G protein coupled receptors on nociceptor which works to sensitise the neurons which happens to occur due to periradicular debris extrusion.[12]

Apical periodontists or necrotic pulp or periradicular lesion or sinus tract stomas were excluded from the study in order to avoid the microbial infection as in such cases chances of irrigating solution to go beyond the apex and cause infection are higher.[13] Hence the teeth affected with asymptomatic irreversible pulpitis only were included.

Literature shows that single visit endodontics treatment is less painful than multi visit. It also reduces the possibility of inter visit leakage and loss of temporary seal. Various researchers have found with SVE there is less PEP.[10]Although inter appointment flare ups are not very common, PEP is frequent even when the appropriate treatment is done.[11,13]

The main reason for using ProTaperGold and ProTaper Next is because of the results obtained by various authors in respect to PEP. Capar et al[14] and Ozsu et al[15] have opinionated that there is more PEP as apical debris extruded with PTU as compared to PTN. Cakici et al[16] concluded that the amount of debris forced out apically during root canal preparation with PTG, PTN and Reciproc system was significantly less than PTU. Arora and Joshi[18] stated that more the number of insertion of file, more extrusion of debris so the PEP was more. This might be the reason for more pain with PTG-EA.

The another reason for less PEP with PTG and PTN is the design of the file. PTG has a convex triangular cross section with variable progressive taper and advanced metallurgy in its structure. The shape is continuously taper with increased elasticity, flexibility and impedance to cyclic fatigue.[16] While PTN is made up of M-Wire Ni-Ti alloy for better flexibility and cyclic fatigue. It has off-center rectangular design with progressive and regressive tapers that reduce the connection between the file and root dentin, thus minimizing the screw-in effect and unwanted taper lock.[17]This was the reason for minimum pain with PTN-EA.

3% NaOCl is used as irrigation solution because of its efficacy to bacteria and great ability to dissolve in organic material. but for the inorganic material 17% EDTA was used for better results, followed by a saline irrigation inorder to avoid the prolonged chelating effect and good bonding with the resin cement[19]

Sonic irrigation protocol is used in the study as Kathiria NV et al in a study compared the irrigation protocol and concluded that the Endoactivator and Ultra X are causing less PEP when compared to Side Vented needle.[20] In present study only Endoactivator is taken as Ultra X might produce heating effect during irrigation. EndoActivator has the vibrating tip in up and down motion, the strokes are small and in vertical direction synergistically produces a powerful hydrodynamic phenomenon. The irrigation solution is changed at apex with stokes which prevents the extrusion of irrigant apically.[21]This explains the reduction of PEP due of debris excavation.

The result of the present study has shown that PTN has less PEP than PTG, and the reason would be due to the design of the file and number of insertion as the PTN bitterly flexible and the number of insertion are less as compared to PTG.

LIMITATIONS

The present study is limited to two file system and a single irrigation protocol, and only asymptomatic irreversible pulpitis is taken. Furthermore, characteristic of pulpal disease can be discussed with different file system and different irrigation protocol.

CONCLUSION

Within the limitation of the study, it can be concluded that the newer advancement in file system can reduce the PEP. With the sonic agitation technique, the levels of PEP can be brought down. The pain levels have gradually decreased after first 6 hours with the use of PTN.

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