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Influence of Instrument design on Post endodontic pain in Single visit Root canal treatment using PTN and MTWO Rotary systems in Asymptomatic irreversible pulpitis of Multirooted teeth- A Randomized Clinical Trial

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ABSTRACT

Aim: The aim and objective of the present randomized clinical trial is to evaluate the incidence of post operative pain after single-visit root canal treatment using two different rotary systems namely Protaper Next and M two in multi rooted teeth**.**

Materials and Methods: 40 adult subjects with multi rooted teeth diagnosed as asymptomatic irreversible pulpitis were randomly assigned into two groups. The teeth were instrumented using Protaper Next and M two rotary systems. Post operative pain was evaluated using Modified Verbal Descriptor Pain Scale at 8hr, 24hr, 48hr and 72hr.

Results: Data analysis was carried out using the Statistical Package for Social Sciences (SPSS version21)**.** Pair wise comparisons at different intervals was made using Mann-Whitney test. There is lower incidence of post operative pain in both the groups and the difference was not statistically significant ($p>0.05$).

Conclusion: Both Protaper Next and M two do not cause post operative pain while treating asymptomatic irreversible pulpitis in multirooted teeth. Both the files can be used for single visit endodontic procedures effectively..

Keywords; *Protaper Next, M two, post operative pain, single visit root canal treatment, modified verbal descriptor pain scale*

1. INTRODUCTION

Post-endodontic pain (PP) remains to be a major challenge for root canal treatment.[1,2] Many studies reported that the prevalence of PP is highly variable that ranges from 82.9[3] to 10.6%.[4] PP in root canal treatment is generally attributed to a complex multi factorial process[5] and is influenced by factors inherent to patients (age, gender), the tooth to be treated, the skills and intervention of the dentist.[6,7] Some other factors such as the number of appointments before the completion of the treatment, inter-appointment medication type, presence of pre-operative pain, pulpal and periradicular diagnosis, apical debris extrusion, preservation of apical patency during root canal preparation are known to be responsible for the occurrence

of PP.[8] It has been reported that peri apical extrusion of infected debris during chemo mechanical instrumentation of root canals may worsen the inflammatory response and cause periradicular inflammation.[9] It has been cited that, with the evolution of nickel–titanium (NiTi) rotary shaping systems, there is significant reduction in the extrusion of infected debris.[10] It also has been markedly reported that NiTi systems extrude significantly less amount of debris periapically than stainless steel hand files.[11,12] Recent advances in rotary nickel-titanium systems, irrigation dynamics, delivery systems, better patient tolerance, reduction of inter appointment infection risks has familiarized the single visit RCT.[13]

Mtwo (VDW, Munich, Germany) NiTi instruments have an S-shaped cross section. It has a non-cutting tip and the two cutting edges with positive rake angle for efficient dentine cutting. The pitch length increases from the tip to the shaft. This allows elimination of threading and binding in continuous rotation, and reduces apical transportation of debris.[14] The ProTaper Next which was used in the present study is the successor of the Pro Taper Universal system (Dentsply Maillefer) and has unique off-centered rectangular cross section. These instruments are manufactured from M-wire alloy that increases the file flexibility and resistance to cyclic fatigue while retaining cutting efficiency and shape memory.[15,16] However to date no study has been done to evaluate post operative pain after instrumentation with Protaper Next and M two systems. The present study is thus the first of its kind to evaluate post operative pain with M two and Protaper next system

2. MATERIALS AND METHODS

This study is a randomized, controlled, single-blinded clinical trial. This study was intended and realized according to the revised consolidated standards of reporting trials (CONSORT) updated in 2010 (CONSORT 2010). This study was approved by the Ethics Committee of Narayana dental college and hospital, Nellore, India (Ref.no: NDC/PG-2014-2015/IEC/2015) and the study protocol was registered in the http://ctri.nic.in/Clinicaltrials/login.php database with identifier number (CTRI/2017/02/007774).
All participants received written information about the trial and provided written informed consent for study participation.

PARTICIPANTS

Subjects who reported to the outpatient unit of Department of Conservative Dentistry & Endodontics, Narayana Dental College were screened. Subjects between the age group of 18- 55 years, who presented with asymptomatic irreversible pulpitis of multi rooted teeth were recruited in the study. Their health was determined by a health history and oral questioning. Multi rooted teeth with irreversible pulpitis, periapical radiolucency less than 2mm in radiographic appearance, and who had the ability to understand the use of pain scales were included in the study. Subjects with Sinus tract, periapical abscess more than 2mm radiolucency or facial cellulitis, presence of Allergies, or any contraindication to analgesics including aspirin or NSAIDs, local anaesthetics, chlorhexidine, and sodium hypochlorite, presence of systemic diseases, bleeding disorders, use of oral anticoagulants within last month, under medication for any other illness, pregnant and lactating mothers were excluded from the study. A total of 40 multi rooted teeth were selected and randomly divided into two groups with 20 subjects each. Single visit root canal treatment was performed for both the groups either with Protaper Next or with M Two. The level of pre- and postoperative pain was recorded as a continuous data using Modified verbal descriptor scale. The modified verbal descriptor scale consisted of a line of 10 cm length anchored by two extremes with 0 cm signifying no pain and 10 cm representing the worst pain imaginable.

RANDOMIZATION

Sequentially numbered opaque sealed envelopes (SNOSE) randomization a method of simple randomization, was used for assigning the patients to the two study groups. The participants were randomized into Protaper next group and M Two group. Because of the nature of the interventions, the operator was not blinded to the interventions. However, the patients were blinded and not informed of the allocation. Before the treatment, the operator opened the sealed envelopes in which, the type of intervention method was noted.

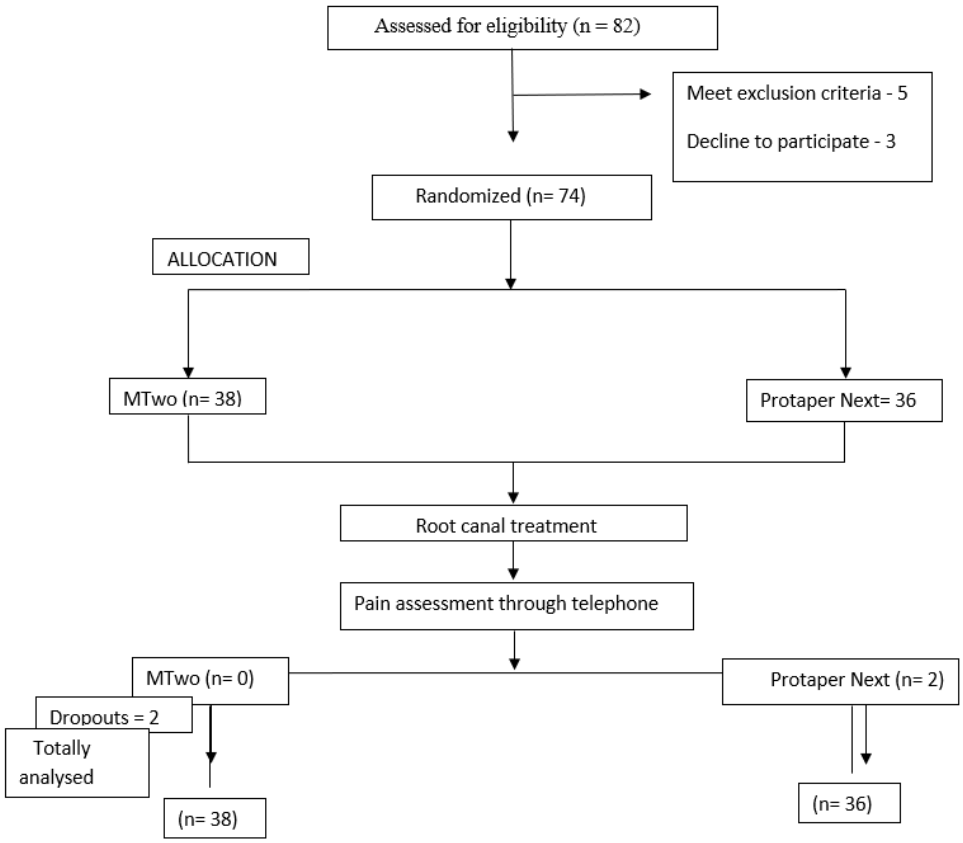


Figure 1: A consolidated Standards of Reporting Trial diagram showing the flow of participants through each stage of trial.

ROOT CANAL TREATMENT PROCEDURE

All the patients were treated by single operator using a standardized treatment protocol. Pulp vitality tests performed by hot and cold tests. Following administered local anesthesia (2% lidocaine hydrochloride with 1: 1,00,000 epinephrine), rubberdam isolation was maintained for all the subjects. Both the study groups underwent same protocol.

PROTAPER NEXT GROUP: The access cavity was prepared using endo access bur. A glide file was established with a size 10 hand k-file. Confirmatory radiographs were taken after determination of working length with apex locators (Root zx). All root canals were instrumented using the ProTaper Next files (Dentsply Maillefer) followed by X1 (size 17, 0.04 taper) and X2 (size 25, 0.06 taper) files. These files were used to sequentially enlarge the root canals using a continuous rotary movement at a speed of 300 rpm and a torque of 2 Ncm powered by the VDW Silver motor (VDW, Munich, Germany). Between each instrument, the canals were irrigated with 3% sodium hypochlorite using a 27-G irrigation needle (Ammdent, India). Instrumentation was performed in Crown down technique with gentle in- and out-motion. Copious irrigation was done with 5.2% sodium hypochlorite, 17% EDTA and saline by a 27-G irrigation needle canal clean needle during and after instrumentation.

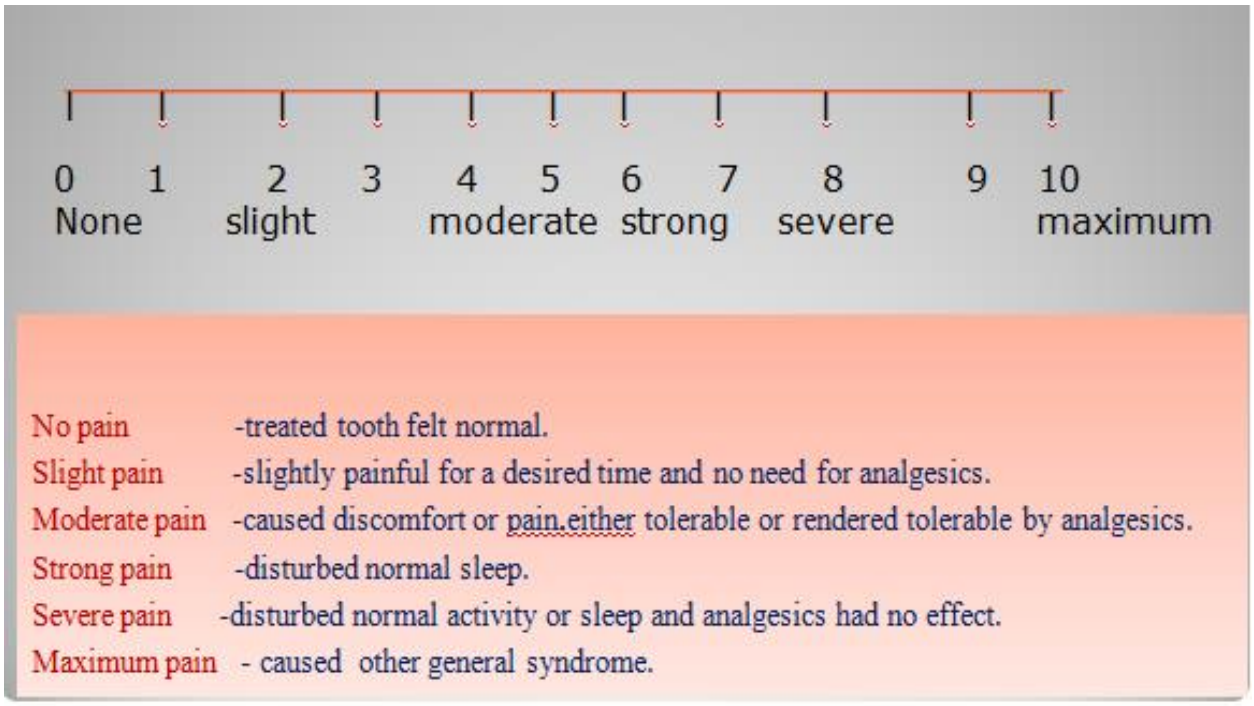
MTWO GROUP: All root canals were instrumented using M Two files. The instrumentation sequence employed four files as follows: 0.04 taper ISO 10, 0.05 taper ISO 15, 0.06 taper ISO 20, 0.06 taper ISO 25. All four instruments were used to full working length of canals, employing a cyclical in-out motion. Irrigation was performed after use of each instrument before proceeding to next size, with 2ml of 2.5% NaOCl and finally at the end of instrumentation with 5ml of saline.

After the canal preparation, all the root canals were dried with absorbent points. Then the root canals were coated with AH plus sealer with master cones (having same size as that of master apical file) and obturate the root canals and sealed with permanent restoration. Occlusal reduction was done in both the groups.

After completion of the treatment, all the subjects were given **MODIFIED VERBAL DESCRIPTOR PAIN SCALE** forms for evaluation of postoperative pain at certain time intervals (8hr, 24hr, 48hr and 72hr). Subjects were instructed to mark on the horizontal scale to represent the intensity of pain experience at 8hrs, 24hrs, 48hrs and 72hrs. The patients were contacted through phone calls by investigators. No systemic medications were given to patient after treatment. They were advised to take medications if pain occurs at 8hrs, 24hrs, 48hrs and 72 hrs. Subjects were asked to provide following information

regarding pain severity, number of days required to control pain, quantity of tablets taken, Furthermore, they were asked to use the verbal descriptors as a guide. The level of discomfort was rated as follows (Fig. 1).

Each mark was assigned a value between 0 and 10 on the VDS.



The pain scores were tabulated and subjected to statistical analysis.

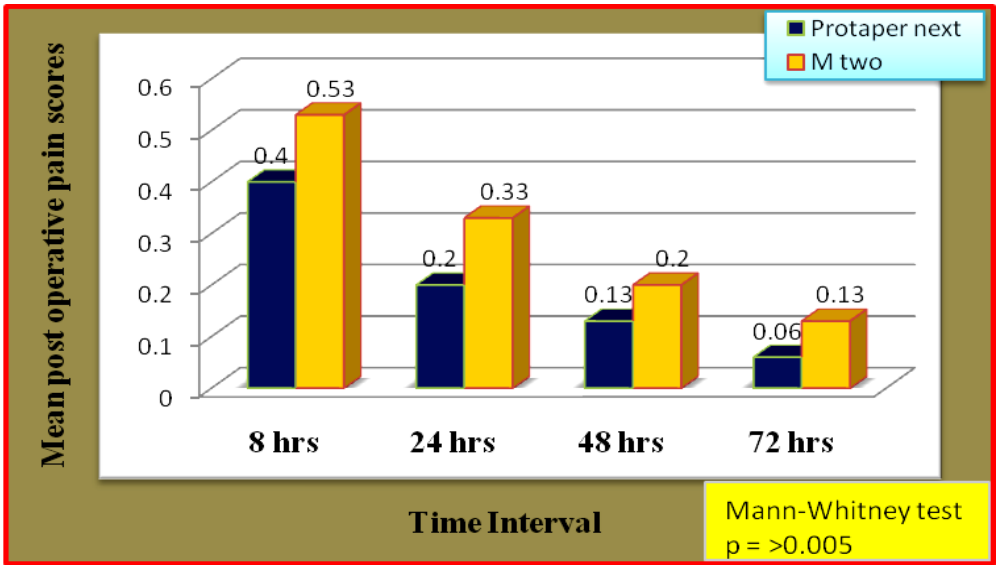
3. RESULTS

Data analysis was carried out using the Statistical Package for Social Sciences (SPSS version 21). Pair wise comparisons at different intervals was made using Mann-Whitney test. Basic descriptions were presented in the form of mean, standard deviation, minimum and maximum. The level of significance was set at $p < 0.05$ for the above test. As shown in table-1 the pain scores after 8 hours in Protaper Next was 0.40 with standard deviation of 0.50 and in M two group was 0.53 with standard deviation of 0.51. There was no statistically significant difference between the groups (p value – 0.472). The pain scores after 24 hours in Protaper Next was 0.20 with standard deviation of 0.41 and in M two group was 0.33 with standard deviation of 0.48. The differences were not statistically significant (p value – 0.417). The pain scores after 48 hours in Protaper Next was 0.13 with standard deviation of 0.35 and in M two group was 0.20 with standard deviation of 0.41. No statistically significant difference existed between the two groups (p value – 0.630). The pain scores after 72 hours in Protaper Next was 0.06 with standard deviation of 0.25 and in M two group was 0.13 with standard deviation of 0.35. The differences were not statistically significant (p value – 0.550). The mean pain scores after different intervals are represented in table-1 and graph-1.

Groups	Frequency	Mean	Standard Deviation	Minimum	Maximum	P value
8 hours						
Protaper next	20	0.40	0.50	0.00	1.00	0.472
M two	20	0.53	0.51	0.00	1.00	
24 hours						
Protaper next	20	0.20	0.41	0.00	1.00	0.417
M two	20	0.33	0.48	0.00	1.00	
48 hours						

Protaper next	20	0.13	0.35	0.00	1.00	0.630
M two	20	0.20	0.41	0.00	1.00	
72 hours						
Protaper next	20	0.06	0.25	0.00	1.00	0.550
M two	20	0.13	0.35	0.00	1.00	

Mann-Whitney test, *P < 0.05 (**Significant**),p > 0.05 (**No significant**)



4. DISCUSSION

Peri apical extruded debris that is also referred to as "worm" of necrotic debris,[17] is one of the main causative factor of Periapical inflammation, postoperative flare-ups and postoperative pain, which is associated with pain, swelling or both arises within few hours or days after starting the root canal treatment.[18] Hargreaves et al. studied the importance of pain in endodontic therapy and considered that both the terms root canal and pain are considered synonymous even in the 21st century.[19] Periapical extrusion of debris interferes with host Immunological response leads to the formation of an antigen antibody complex resulting in severe inflammation and postoperative flare-ups.[20] Push-pull filing motion technique usually tends to create a greater mass of apical debris than those of rotational action.[21,22] The most common factors that could cause postoperative pain and discomfort after root canal treatment include incomplete instrumentation, extrusion of irrigation solutions, extrusion of intracanal dressing, traumatic occlusion, missed canals, preoperative pain, periapical pathosis.[23] Many other factors like Instrument size, type, canal preparation technique and endpoint, irrigation solution could effects the amount of debris and irrigant extrusion.[24,25]

To isolate the effect of the shaping technique in PP, all the confounding factors like age, gender and the presence of radiolucencies were controlled by the random selection of cases in the control group. Many other previous studies compared the incidence of pp when instrumented with k-files and rotary files. Till now no study assessed the incidence of postoperative pain with M Two and Protaper Next. Hence the present study was designed to evaluate post operative pain when instrumented with M Two and Protaper Next rotary files. The same irrigation protocol was followed for both the groups in order to minimize confounding factors.

The results of Eleazer and Eleazer et al is consistent with the present study, who compared one visit and two visit endodontic treatment and reported that single visit has an advantage in terms of flare-ups.[26] Results of the present study showed that there is lower incidence of postoperative pain in both the groups which is in accordance with the Singla M et al, who reported that the incidence of post operative pain was less when teeth were shaped with NiTi rotary instrumentation than with stainless steel hand files.[12] This outcome can be possibly attributed to the reduction in the apical extrusion of infected debris that have been observed with NiTi rotary shaping techniques.

The results of the present study can be comparable with Mohamad Kashefinejad et al, who stated that the use of Mtwo (NiTi)

rotary instruments in root canal preparation contributed to lower incidence of postoperative pain than that of hand K-files.[27] Jogikalmat Krithikadatta et al reported that WaveOne reciprocating files cause more post instrumentation pain followed by ProTaper and Mtwo. Group Mtwo had the lowest post instrumentation pain.[28] Oubaid et al compared ProTaper Universal, ProTaper Next and WaveOne and reported that ProTaper next caused the lowest incidence and severity of Post-Operative pain, WaveOne system caused the highest incidence and severity of Post-Operative pain.[29] Frough Reyhani *et al.* showed that there is significantly less extrusion of debris with the use of RaCe instruments when compared to Mtwo system.[30] Tasdemir *et al*. (2010) showed that RaCe Rotary Ni-Ti instruments extruded less debris than Protaper and Mtwo Rotary instruments which is in line with Frough Reyhani *et al*. [31] A Ghobashy et al compared the shaping ability of single and multi-file rotary systems during the preparation of curved root canals and concluded that ProTaper Next, Protaper Universal and One Shape instruments respected original canal curvature and were safe to use. He also reported that Protaper Next was the fastest among them. [32]

E. Schafer et al compared the shaping ability of M two instruments with K3 and RaCe instruments and reported that M two instruments prepared curved canals rapidly, respected original canal curvature well and were safe to use.[33] In contrast to the present study Carlos Menezes Aguiar et al reported that Mtwo™ rotary system produced a larger number of deviations.[34] The results of the present study disagree with the study conducted by Hin et al. who observed that instrumentation with M two could cause damage to root canal dentin.[35] Pratik Mavani et al studied the Instrumentation of root canals with ProTaper, Mtwo, K3XF, WaveOne and ProTaper Next and concluded that they could cause damage to root canal dentin.[36]

s.no	TITLE OF THE STUDY	AUTHOR	ASSESSMENT METHOD	OUTCOME OF THE STUDY
1.	The influence of three different instrumentation techniques on the incidence of postoperative pain after endodontic treatment.	Gianluca Gambarin etal (2013)	visual analogue scale	The difference in postoperative pain mainly due to different instrument techniques.
2.	Postoperative Pain after Endodontic Treatment of Asymptomatic Teeth Using Rotary Instruments: A Randomized Clinical Trial	Shahriar Shahi etal (2015)	visual analogue scale	There were no significant differences in the postoperative pain reported between the two groups
3.	Comparison of the Incidence of Postoperative Pain after Using 2 Reciprocating Systems and a Continuous Rotary System: A Prospective Randomized Clinical Trial	Daniel Kherlakian etal (2016)	visual analogue scale	The reciprocating systems and the continuous rotary system were found to be equivalent in regard to the incidence of postoperative pain and intake of analgesic medication at the time points assessed
4.	Postoperative quality of life following single-visit root canal treatment performed by rotary or reciprocating instrumentation: a randomized clinical trial	D. Pasqualini etal (2015)	visual analogue scale	Reciprocating instrumentation affected POQoL to a greater extent than rotary instrumentation.
5.	Assessment of postoperative pain after reciprocating or rotary NiTi instrumentation of root canals: a randomized, controlled clinical trial	João Bosko Formigas Relvas etal (2016)	verbal rating scale (VRS) and verbal description	No significant difference ($p > 0.05$) in postoperative pain was found between the ProTaper® and Reciproc® instrumentation technique during endodontic treatment in this study.

5. CONCLUSION

With in the limitations of this study, there is no statistically significant difference in Protaper next and Mtwo rotary files system in evaluation of postoperative pain in single visit root canal treatment while treating asymptomatic irreversible pulpitis in multi rooted teeth

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