

The Effect of Speed and Rotation for Protaper File Systems on Post-obturation Pain in a Single Visit and Multiple (Two) Visits in Root Canal Therapy: An *In Vivo* Study

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ABSTRACT

Introduction: The basic idea of a root canal treatment is to alleviate the pain and heal the infection within the infected tooth, which can be resolved in a single visit or multiple visits in root canal therapy. Therefore, in this article, an *in vivo* comparison of single visits and multiple visits using different rotation and speed for two Protaper universal design file systems is done on the basis of time taken and incidence of pain. **Materials and Methods:** One hundred single-rooted premolars with irreversible symptomatic pulpitis were assigned to two groups of 50 patients each using the odd-even method, GA to be treated endodontically in a single visit and GB to be treated endodontically in multiple visits. Each group was further divided into two subgroups of 25 patients each on the basis of two different variations of speed and rotation for two Protaper file systems of the same design, GA1 (Hand Protapers) and GA2 (Rotary Protapers), GB1 (Hand Protapers) and GB2 (Rotary Protapers), respectively. After proper biomechanical shaping and cleaning, obturation was done with Gutta-percha cones and Ah plus sealer using Fast Pack obturation pen for warm vertical compaction. The pain was measured by a 100mm modified visual analogue scale, and time was measured using a stopwatch. **Results:** At 6-h intervals, post-obturation pain was more in single-visit root canal therapy than multiple-visit root canal therapy ($P < 0.01$). Single-visit rotary Protaper (GA2) had less incidence of post-obturation pain as compared with single-visit hand protapers (GA1) ($P < 0.05$). There was no significant difference in post-obturation pain in the multiple-visit hand protaper subgroup (GB1) and multiple-visit rotary protaper subgroup (GB2) ($P > 0.05$). Preoperative pain significantly influences the post-obturation pain. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) version 17.0 statistical Analysis Software. **Conclusions:** The presence of preoperative pain can significantly influence the presence of postoperative pain. Most of the pain in both single-visit and multiple-visits root canal therapy occurred in the first 48 h after obturation, which decreases thereafter. Single-visit rotary protaper (GA2) had less incidence of post-obturation pain as compared with single-visit hand protapers (GA1). There was no significant difference in post-obturation pain in the multiple-visit hand protaper subgroup (GB1) and multiple-visit rotary protaper subgroup (GB2). Presence of sealer puff influences the duration of pain.

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INTRODUCTION

Traditional root canal therapy was done in multiple visits.^[1] The methods advocated to achieve these objectives included aseptic procedures, mechanical debridement, enlargement and shaping of root canal system, irrigation with disinfecting and calcium chelating agents, intracanal medications with antimicrobial agents, temporization to seal access cavity, and obturation to completely seal the canal system.^[1,2] With multiple visits a success rate of 90% was obtained.^[3,4]

The completion of endodontic treatment in a single visit is also an old concept that can be traced through the literature for more than a hundred years.^[1] Due to its many pros over multiple visits, dental practitioners prefer single-visit endodontics.^[5] The advantages of single visits include time-saving and faster treatment in a single^[2] or reduced number of appointments,^[1] as there are low chances of microbial regrowth and contamination of root canals^[5] as compared with extended or prolonged treatment, reduction in inter-appointment flare-up resulting from temporary seal loss or leakage, and immediate restorations for anterior teeth.^[1,4] It also saves the expenses and time spent in the reestablishment of working length and canal anatomy,^[6] pain and anxiety resulting from repeated injections, and rubber dam placements.^[3,4,6] Also, immediate obturation of the prepared canal reduces the space available for microbial colony proliferation, thereby eliminating the need for antimicrobial therapy.^[4,7] It is always a controversial decision for a clinician, to perform endodontic treatment in either single or multiple visits.^[3,6]

Protaper (Universal) files are shaped as convex, triangular, and cross-sectional, with a guiding tip, and a factually variable helical angle and slope.^[8,9] Initially, hand-used files with Universal design were a revolutionary advancement in endodontics but mechanical preparations became faster with rotary instruments,^[4,10] and it is easier to maintain original anatomy, centered position, and taper of the root canals.^[11] Thus, improved and better forms of biomechanical preparation are being developed, which include the coronal to apical approach techniques, having advantages such as less debris extrusion and elimination of coronal interferences.^[12,13] Protaper rotary system was started with Protaper Universal, then improved to Protaper Gold and one of the recent refinements is Protaper Next files with M-wire technology, imparting

improved flexibility and less cyclic fatigue.^[9] Both Protaper Universal and Protaper Gold have the same convex triangular cross-sections,^[14] but Protaper Next have off-centered, rectangular cross-sections.^[9,15]

Pain is one of the reasons for dental apprehensions, and postoperative pain is an unpleasant experience for both patient and clinician.^[4,16] Many clinical studies have reported postoperative pain that commences a few hours and days after treatment.^[2,3] Post-endodontic pain after instrumentation is of great concern to the dentist, as due to the chances of over-instrumentation, extrusion of root cleaning, and filling materials, improper pulp debridement increases the chances of post-treatment pain.^[17]

The clinical significance of this study lies in the fact that experienced clinicians and also beginner endodontists find Hand Protapers (Universal design) more economical and comfortable as compared with Rotary Protaper systems.^[18] Many studies have been conducted to compare hand and rotary instrumentations, but *in vivo* studies comparing (more than 20 years old) Basic Hand Protapers^[17,19] with recent refinement of the same design such as Protaper Gold^[8] operating at higher speeds and rotations are few or rare. Hence, this study was undertaken to compare the incidence of post-obturation pain during single-visit root canal therapy versus multiple-visit root canal therapy using hand and rotary protaper files of the same design operating at different speeds and rotations.

MATERIALS AND METHODS

Patient selection

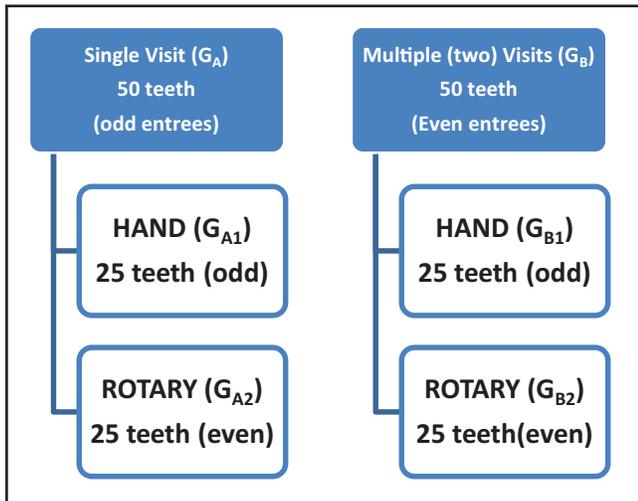
The present study was conducted in the Department of Conservative Dentistry and Endodontics, Daswani Dental College and Research Centre, Kota, Rajasthan. Ethical clearance was given by the Ethical committee of the institute for thesis approval. This study was conducted over two years with proper oral and written informed consent (Form 1) from the patients. All the patients were treated in the postgraduate unit by a single operator. After initial screening of the patients from regular OPD of the postgraduate unit and approval by staff, 142 patients with single-rooted premolars were diagnosed with symptomatic irreversible pulpitis,^[5,12,13] which required root canal therapy as a treatment modality; patients aged between 18 years and 60 years were selected for the study after the inclusion and exclusion criteria mentioned in Table 1. Out of these patients, 20 did not come for treatment and the

other 22 were not included in the study due to various reasons such as lost visual analogue scale (VAS) forms, fracture of the teeth, RVG software malware, etc. The sample size was estimated with a 95% confidence level. After consultation with a statics mentor, a total of 100 teeth from 92 patients were included in this study.

The receptionist had done the allocation of the patients with odd–even methods, on the basis of their arrival at the OPD desk; a list of the name of the patient who fulfilled the criteria for both single and multiple visits was prepared, and numbering was done daily from 1 to 10. All odd entrees (1, 3, 5, 7, and 9) were allocated to the single-visit group, and even entrees (2, 4, 6, 8, and 10) were allocated to two-visit groups [Table 2].^[20] Then, the same process was repeated for subgroups, after the allocation of patients to the single- and multiple-visit groups (GA and GB) list; all odd entrees were prepared with hand protapers and even entrees were prepared with rotary protapers (Protaper Gold).

PROCEDURE OF ROOT CANAL THERAPY

The standard procedure for root canal treatment in both groups was as follows:



- Proper oral and written consent obtained from the patient (Annexure 1-Form 1) and commencement of root canal therapy was done.
- Topical anesthesia (Lidayn, Global Dent Aids Pvt. Ltd., India) was used prior to the insertion of the needle for local anesthesia solution at the insertion site.
- The tooth/teeth selected for the study were isolated using a rubber dam (Hygienic, Coltene/Whaledent Inc., Germany)
- All the caries were removed from the tooth surface, and a standard access cavity was prepared using the air rotor and the diamond burs to obtain straight-line access to the root canal.
- Following the dentinal map canal orifices were located and pulp extirpation was done.
- The initial negotiation of canals with size #10 or #15 K-files up to about two-thirds of the estimated working length was done.
- The working length of each canal was determined by an electronic apex locator or two or more angled radiographs.

BIOMECHANICAL PREPARATION

- Canal preparation was done in the following way:
 - (a) Canals in group GA1 and GB1 were prepared by using hand protapers SX, S1, S2 (shaping files), F1–F5 (finishing files).
 - (b) Group GA2 and GB2 was prepared by using a combination of rotary protapers (Protaper Gold) SX, S1, S2, F1–F5 with Endo mate DT with gear reduction handpiece 20:1 at a speed

Table 2: Grouping stage: Two groups were divided randomly

Groups	Number of teeth (total = 100)	Visits
Group A	50 (odd entrées)	Single visit
Group B	50 (even entrees)	Multiple (two) visits

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ol style="list-style-type: none"> Teeth with symptomatic irreversible pulpitis premolars with uncomplicated single root canal Teeth with a fully formed apex Teeth with no or less than 0–1 mm periapical radiolucency Teeth fulfilling indications for both single and multiple visits 	Patients excluded from the study are those: <ol style="list-style-type: none"> Medically compromised patients TMJ problems/restricted mouth openings Younger than 18 years of age Using antibiotics or corticosteroids Non-restorable and periodontal compromised teeth Calcifications of teeth, internal and external resorption cases Mentally disabled patients Pregnant patients

of 250 rpm. For SX, torque 4; S1, torque 3; S2, torque 1.5; F1, torque 1.5; F2–F5, torque 2 was selected. All instruments were rotating when inserted in the root canal.

All instrumentation was done in the wet canals. All instruments were liberally coated with Glyde (EDTA). Irrigation was done with 2 mL of 2.5% NaOCl after each instrument. After each use, an inspection of the instrument was done and instrument flutes were cleaned of debris.

- After completion of canal instrumentation, all canals were irrigated with 2.0 mL of 17% ethylene diamine tetraacetic acid for 1 min followed by final irrigation with 2.0 mL of 2.5% sodium hypochlorite.

OBTURATION TECHNIQUE

After instrumentation and final irrigation, canals were dried with paper points. Obturation was done using a Gutta-perch cone of F1, F2, F3, F4 size according to the size of the canal. Ah plus sealer was used to coat the canal walls and also the GP cones. An obturation pen (Fast Pack) was used for warm vertical compaction of the GP cones in the canals. The temperature was maintained at 140°C. First, the Gutta-percha was softened at the canal orifice and then compacted using light pressure.

In the single-visit group (GA), obturation was done on the same day, but in multiple visit groups (GB), the canal was packed with sterile cotton and temporary restoration in the first visit and then obturation was done during the second appointment. Time taken for the procedures was measured using a stopwatch since the commencement of the access opening till the obturation was done. No intracanal medicament was used.

MEDICATION

All patients were prescribed mild painkillers (Ibuprofen), to be taken 8 hourly only if they experienced moderate pain. Any of the patients with intolerable pain was instructed to visit the clinician for emergency treatment.

CLINICAL EVALUATION OF POSTOPERATIVE PAIN

The clinical evaluation of post-obturation pain was done with the 100 mm Modified Heft–Parker VAS (Annexure 1-Form 2). The postoperative evaluation was recorded as:

- 0 = no pain
- 1 = slight pain/discomfort
- 2 = moderate pain relieved by analgesics
- 3 = moderate to severe pain not completely relieved by analgesics
- 4 = severe pain/swelling not relieved by analgesics and required an unscheduled visit

Clinicians in the postgraduate unit and patients were trained to use the modified Heft–Parker scale. The patient kept the VAS form along with them. The pain was recorded by the patient on the scale after the postoperative period of 6h, 24h, 48h, and 7 days. Telephonic reminders were given to the patients to note their pain readings. After 1 week of obturation, the final clinical evaluation for pain was done with the vertical percussion method by postgraduate students. At the same time, all patients were asked to report any other reactions they felt till that day. Modified VAS and record of medications taken were collected from the patients on this day.

STATISTICAL ANALYSIS

Data were collected, and results were statistically analyzed using Kruskal-Wallis ANOVA test. Differences were considered significant when the probabilities were equal to or less than 0.05. The statistical analysis was done using SPSS version 17.0 statistical Analysis Software.

RESULTS

At 6-h intervals, post-obturation pain was more in single-visit root canal therapy than multiple-visit root canal therapy ($P < 0.01$). Single-visit rotary protapers (GA2) had less incidence of post-obturation pain as compared with single-visit hand protapers (GA1) ($P < 0.05$). There was no significant difference in post-obturation pain in the multiple-visit hand protaper subgroup (GB1) and multiple-visit rotary protaper subgroup (GB2) ($P > 0.05$). Preoperative pain significantly influences the post-obturation pain. The statistical analysis was done using SPSS Version 17.0 statistical Analysis Software.

DISCUSSION

In root canal therapy, the patients always appreciate and desire faster and painless treatment.^[4] The motive of the study was to compare hand protapers (Universal)^[14] and rotary protapers (Protaper Gold)^[9] having the same design^[8] and operating at different speeds and rotations, in single and two visits. In single visits, the rotary protaper group was significantly faster and painless as compared with the single-visit hand group. In multiple visits, the rotary group was faster than the hand group, but the pain difference remained insignificant. The pain was influenced by the presence of preoperative pain or postoperative sealer puff^[21] and most of the pain was an experience in the first 24h, which was relieved thereafter.

A bounded scale, modified 100 mm Heft–Parker VAS, having absolute values at each end and descriptors of pain levels in words, placed along the horizontal axis,

in ascending order was used. The patient was asked to point a finger over the mark on the scale, which represents the current level of pain and to compare it with its previous report as a visual reminder.^[6]

While comparing the results for group GA with group GB, a statistically significant difference was found in preoperative pain ($P = 0.008$). It was found that postoperative pain was more in patients with a history of preoperative pain, which is same as a prospective clinical study (Ali *et al.* 2016),^[22] and that the most influencing variable for the prevalence of pain after obturation is the presence of pain before treatment.^[22] Table 3 shows a statistical evaluation of change in the intensity of preoperative pain after various postoperative time intervals. A considerable reduction in pain score and intensity was experienced at various time intervals of 6 h, 24 h, and 48 h in both groups. In a recent study, Jang *et al.* (2021)^[23] concluded that the presence of pulpal pain or mechanical allodynia (periapical infection) or both may cause postoperative pain; initially irritated tissue may become secondarily irritated during treatment.^[23] Psychologically, patients who arrive to the dental clinic feeling pain may be conditioned to expect pain both during and after treatment; patients presenting with pain usually have an inflamed periapical region.^[22,23]

Over the past few years, many studies have been conducted to compare single visits and multiple visits in root canal therapy for the assessment of post-endodontic pain. Wong *et al.* (2015),^[4] Manfredi *et al.* (2016),^[24] and a systematic review by Schwendicke *et al.* (2017)^[3] found an obviously insignificant difference in post-obturation pain between single visits and multiple visits of endodontic therapy.^[3,4,24] Al-Manei (2018)^[1] radio-graphically compared the quality of root canal therapy in single visits and multiple visits performed by dental students and proved that there is no difference

in the quality of treatment in both strategies.^[1-7] In our study, less post-obturation pain was experienced in the single-visit group. Alomaym *et al.* (2019)^[6] have found multiple-visit root canals to be significantly less painful than single-visit root canals.^[6] On the contrary, Singh *et al.* (2020)^[25] concluded that single-visit root canal therapy has comparatively lesser post-obturation pain than multiple-visit RCT.^[25] A new meta-analysis by Izadpanah *et al.* (2021)^[26] posits that postoperative pain in single visits is higher than multiple visits.^[26]

After a 6-h interval, 70% of teeth treated in group GB had pain in comparison to 42% of teeth in group GA [Table 3]. It was a statistically significant difference ($P = 0.008\%$). Hence, in the hand group, intensity, as well as the incidence of pain after 6 h, was significantly more, which is in agreement with Sun *et al.* (2018),^[17] who in a recent systemic review have concluded that single-visit root canal therapy with rotary instruments contributed to less intensity and incidence of postoperative pain than hand files. Also, in their study, Aggarwal and Dewan^[10] and found significantly less pain in protaper rotary (universal design) as compared to Hand Protapers. Also, in their study, Aggarwal and Dewan^[10] and found significantly less pain in protaper rotary (universal design) as compared to Hand Protapers. The reason for this, as per Bataiosu *et al.* (2012),^[27] is that although hand protaper instruments represent a revolutionary advance in endodontic treatment, deviation from the principles of mechanical treatment may have a negative effect on the prognosis and success rate of treatment.^[27] No pain was observed after a week in both groups. More pain was experienced in the hand group than the single-visit rotary. Also, this result is in agreement with Ghivari *et al.* (2011).^[28] Biomechanical preparation using two kinds of protaper (hand and rotary) differs in the time of actual contact between the instrument and the dentine of the root canal;

Table 3: Statistical evaluation of pain scores in groups (GA and GB) and subgroups (GA1, GA2, GB1, and GB2) at different time intervals by Kruskal-Wallis Test

Time	A. Single-visit hand (GA1)		B. Single-visit rotary (GA2)		C. Multi-visit hand (GB1)		D. Multi-visit rotary (GB2)		P value#
	Mean ± SD	Mean rank	Mean ± SD	Mean rank	Mean ± SD	Mean rank	Mean ± SD	Mean rank	
Pre-op	1.48 ± 1.00	41.68	1.52 ± 1.12	44.84	2.08 ± 0.70	58.74	2.00 ± 0.76	56.74	0.066
At 6 h	0.72 ± 0.79	49.02	0.40 ± 0.65	37.70	1.20 ± 0.96	63.06	0.80 ± 0.76	52.22	0.010*
At 24 h	0.76 ± 1.01	54.44	0.48 ± 0.82	46.36	0.44 ± 0.71	47.16	0.64 ± 0.76	54.04	0.531
At 48 h	0.52 ± 0.77	58.96	0.12 ± 0.33	45.76	0.08 ± 0.28	43.84	0.28 ± 0.46	53.44	0.034*
At 7 days	0.00 ± 0.00	49.50	0.00 ± 0.00	49.50	0.04 ± 0.20	51.50	0.04 ± 0.20	51.50	0.568

#Kruskal-Wallis test

* $P < 0.05$, significant

This table shows comparative evaluation of incidence of pain in teeth treated in single visit (subgroup GA1, subgroup GA2) and teeth treated in two visits (subgroup GB1, subgroup GB2) at different time intervals. The results were statistically significant at 6-h and 48-h time intervals in various subgroup combinations ($P < 0.05$)

hand protapers contact the apical area for more time than rotary protapers. Both Protaper Gold and Hand Protapers have a similar design and they also have similar preparation qualities in terms of centric ability (Arslan *et al.* 2017).^[18] However, also, as per Cakici (2016),^[19] Rotary Protaper Gold extrudes less debris than Hand Protaper Universal, as rotary files have a fixed torque and speed; however, in the case of hand protapers, it is variable depending on the operator.^[19] It can also be explained in agreement with Gambarini *et al.* (2013)^[29] and Kalra (2017),^[11] that during biomechanical preparation of root canals, the periradicular issues may interact with the extrusion of a worm of debris consisting of dentine shavings, irrigating solutions, and other irritants, which may elicit the inflammation of apical tissues.^[30] Intensity and severity of inflammation will depend on the quantity and quality of extruded debris.^[30] Therefore, this inflammation that formed as a result of apical extrusion of debris is the main cause of postoperative pain because after injury, chemical substances will be released or activated, which will mediate the inflammation process, such as vasodilation and increase in vascular permeability etc.^[11]

After 24h, a reduction in pain as compared with preoperative pain was more in group GA as compared with group GB but the results were statistically insignificant [Table 3]. There was no statistically significant difference in the incidence of pain after various time intervals of 24h, 48h, and 7 days. The reason may be that the biomechanical debridement and irrigation can significantly reduce the number of bacteria but bacteria remaining in the root canal system and dentinal tubules can rapidly multiply to an original number within 2 days.^[31] However, when immediate obturation of the prepared canal is done, the remaining bacteria are eliminated or rendered harmless by entombing them by complete and three-dimensional obturation to deprive the microorganisms of nutrition and the space required to survive and multiply.^[10,32] Immediate obturation also prevents further communication to the apex via the canal. This, in turn, prevents the occurrence of painful episodes resulting from re-infection of the canals as a consequence of leakage past the temporary seal.^[1,5]

Postoperative pain in all cases subsided with the use of mild analgesics (ibuprofen) only. In none of the teeth treated in single visits, more than two tablets of analgesic were required in any case. A stronger analgesic was not required.^[12] This is in agreement with Germack *et al.* (2017),^[33] who found that endodontic

pain is best managed by eliminating the source of infection or inflammation as completely as possible and whenever drugs are required, judicious use of nonopioid analgesics can be beneficial and provide the first course of action.^[33] The AAE statement (2016)^[34] also found that postoperative pain after instrumentation or obturation is usually associated with periradicular inflammation, not periradicular infection. As per Bansal *et al.* (2019),^[32] prescribing antibiotics for pain due to the inflammatory process is inappropriate and ineffective.^[32]

Time taken to complete the procedure was more for the teeth in which biomechanical preparation was done using hand protapers than for the teeth in which biomechanical preparation was done using endomotor and rotary protapers. This is in agreement with Pasqualini *et al.* (2008),^[35] who found that significantly fewer rotations are used in the hand protapers, which increase the effective working time to fully clean and shape the canals in hand protapers than rotary protapers.^[35,36] When comparing both groups GA and GB, time was more in multiple visits as compared with single visits. According to Wong *et al.* (2015),^[16] the reason may be the additional time required for chair preparation, patient education, reorientation, isolation, and re-entry into the canal.^[16] Single-visit RCT is better in terms of time and convenience for both patient and dentist (Manfredi *et al.* 2016).^[24]

In all the cases, the sealer used was Ah plus. Sealer puff was seen in 19 cases (15 in GA and 4 in GB), and pain remained for 6–24h in those cases and subsided with the use of medication. The extrusion of Ah plus sealer causes pain but due to its low solubility and antibacterial effect, it helps in healing (Shashirekha *et al.* 2018).^[21]

Thus, PROTAPER files clean and shape the canals effectively along with irrigants such as NaOCl; with the crown down technique, post-obturation pain is less while using rotary protapers (Protaper Gold) than hand protapers (Universal), which minimizes the extrusion of the debris beyond the apex. The presence of preoperative pain may influence the post-obturation pain significantly; after a 6-h interval, the postoperative pain difference is significant. However, pain perception is a highly subjective and variable experience that is modulated by multiple physical and psychological factors.^[36]

Clinical significance of this study is that beginner endodontists and experienced clinicians (more than 20 years old) still find hand Protapers more economical and comfortable than Rotary Protapers. From the

patient's side, faster and painless root canals are always appreciated. In spite of patient and clinician choices, the basic idea of endodontic treatment is to alleviate pain,^[4] as well as to heal the infection through the complete elimination of the bacteria count and necrotic tissues.

The strengths of the study were: The variations in inclusion criteria and methodology were avoided, and single-rooted uncomplicated canals with irreversible symptomatic pulpitis were selected. Post-obturation pain due to the presence of sealer puff is also evaluated.

The limitations of our study were: a short sample size due to lost VAS forms or RVG software malware.

KEY FINDINGS

In single-visit root canal therapy, the use of high speed and rotations for protaper universal design can significantly shorten the time and lessen post-obturation pain, which is influenced by preoperative pain and post-obturation sealer puff.

CONCLUSION

Within the limitations of this study, it is concluded that:

- The presence of preoperative pain can significantly influence the presence of the postoperative pain.
- Most of the pain in both single-visit and multiple-visits root canal therapy occurred in the first 48h after obturation, which decreased thereafter.
- Single-visit rotary protaper (GA2) had less incidence of post-obturation pain as compared with single-visit hand protapers (GA1).
- There was no significant difference in post-obturation pain in the multiple-visit hand protaper subgroup (GB1) and the multiple-visit rotary protaper subgroup (GB2).
- Presence of sealer puff influences the duration of pain.

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Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest.

AUTHORS' CONTRIBUTIONS

Dr. Navdeep Jethi was involved in the idea conception, study design, acquisition, interpretation, and article writing and editing. Dr. Jyoti Beniwal, Dr. Ruby Yadav, and Dr. Charvi Gupta were involved the patient data management. Dr. Sharanjit Kaur and Dr. Vikram J.

Nain contributed in article editing. All the authors read and approved the final manuscript.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

Ethical clearance was given by the ethical committee of the institute for thesis approval and according to declaration of Helsinki. Ethical letter number is DDC/ACAD/2014/623 on 11/12/2014.

PATIENT DECLARATION OF CONSENT

Informed consent (written and oral) was obtained from all the parents and participants.

DATA AVAILABILITY STATEMENT

Data is not available.

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ANNEXURE 1

FORM 1: CONSENT FORM (सहमति प्रपत्र)

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS, DASWANI DENTAL
COLLEGE AND RESEARCH CENTRE, KOTA
(कंजर्वेटिव दंत चिकित्सा और एण्डोडॉन्टीकस विभाग, दासवानी डेंटल कॉलेज एंड रिसर्च सेंटर, कोटा)

AN IN VIVO COMPARISON OF SINGLE VISIT VERSUS MULTIPLE VISIT ROOT CANAL THERAPY.
(विवो में एकल यात्रा बनाम एकाधिक यात्रा रूट कैनाल उपचार के लिए तुलना।)

I, _____ aged _____ have been informed about my involvement in the study to be conducted by Dr. NAVDEEP JETHI (मैं आयु मुझे अध्ययन में मेरी भागीदारी के बारे में सूचित किया गया है, जो कि डॉ. नवदीप जेठी द्वारा ही किया जा सकता है।)

•I agree to give my personal details like Name, Age, Sex, Address, Previous dental history and the details required for the study to the best of my knowledge. (मैं अध्ययन के लिए आवश्यक, मेरी निजी जानकारी जैसे कि नाम, आयु, लिंग, पता, पिछला चिकित्सकीय इतिहास और विवरण मेरे के सर्वोत्तम ज्ञान अनुसार देने के लिए सहमत हूँ।)

•I will allow him to take my X-ray and use for research purpose. (मैं उसे अपने एक्स रे लेने और अनुसंधान के उद्देश्य के लिए उपयोग करने की अनुमति देता हूँ।)

•I will cooperate with the dentist for my intra oral and extra oral examination. (मैं अपने इंद्रा मौखिक और अतिरिक्त मौखिक परीक्षा के लिए दंत चिकित्सक के साथ सहयोग करूंगा।)

•I will follow the instructions given by the dentist during the study. (मैं अध्ययन के दौरान दंत चिकित्सक द्वारा दिए गए निर्देशों का पालन करूंगा।)

•I permit the dentist to utilize the information given by me and results obtained from this study for presentation and publication. (मैं दंत चिकित्सक को मेरे द्वारा दी गई जानकारी और इस अध्ययन से प्राप्त परिणामों को प्रस्तुति और प्रकाशन के लिए उपयोग करने की अनुमति देता हूँ।)

•I will not claim any returns for my co-operation in the study, even if it is being sponsored by any agency. I am participating with my own will and wish. (मैं अध्ययन में मेरे सहयोग के लिए किसी भी रिटर्न का दावा नहीं करूंगा, भले ही यह किसी भी एजेंसी द्वारा प्रायोजित किया जा रहा हो। मैं अपनी स्व-इच्छा के साथ भाग ले रहा हूँ।)

•If for any reason I am unable to participate in the study, for reasons unknown, I can withdraw from the study. (किसी भी कारण से मैं, अगर मैं अध्ययन में भाग लेने में असमर्थ हूँ, चाहे अज्ञात कारण से, तो मैं अध्ययन से निष्काशित किया जा सकता हूँ।)

I have read, gone through and understood the above information given by the doctor about the study. (मैंने अध्ययन के बारे में डॉक्टर द्वारा दी गई उपरोक्त जानकारी को पढ़ा और अच्छी तरह समझा है।)

I have entered and signed this application. (मैं अध्ययन में प्रवेश किया और इस आवेदन पर हस्ताक्षर किए हैं।)

Date (दिनांक): _____

Serial no (सीरियल): _____

Address (पता): _____

Dentist's signature (डेंटिस्ट के हस्ताक्षर): _____

Subject's Signature (विषय के हस्ताक्षर): _____

FORM 2:

Modified 100mm Visual Analogue Scale Form
(सशोधित 100mm दृश्य एनालॉग पैमाना प्रपत्र)

(to be carried and filled by patient according to severity of pain experienced after RCT)
(ले जाने के लिए और आर.सी.टी. के बाद दर्द की गंभीरता के अनुसार रोगी द्वारा भरा जाए।)

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS, DASWANI DENTAL COLLEGE AND RESEARCH CENTRE.

(कंजर्वेटिव दंत चिकित्सा और एण्डोडॉन्टीकस विभाग, दासवानी डेंटल कॉलेज एंड रिसर्च सेंटर)

OPD NO. NAME. Age/gender Dæ

1. Preoperative pain (ईलाज से पहले का दर्द)



2. Pain after 6 hours of treatment (दर्द 6 घण्टे बाद)



3. Pain after 24 hours of treatment (दर्द 24 घण्टे बाद)



4. Pain after 48 hours of treatment (दर्द 48 घण्टे बाद)



5. Pain after 7 days of treatment (दर्द 7 दिन बाद)



The post-operative pain evaluation (ऑपरेशन के बाद दर्द मूल्यांकन)

0 – No pain (कोई दर्द नहीं)

1 - Slight pain/discomfort (मामूली दर्द / परेशानी)

2 - Moderate pain relieved by analgesics (मध्यम दर्द दर्दनाशक दवाओं से राहत मिली)

3 - Moderate to severe pain not completely relieved by analgesics (मध्यम से गंभीर दर्द दर्दनाशक दवाओं से राहत नहीं मिली)

4 Severe pain/swelling not relieved by analgesics and required unscheduled visit (गंभीर दर्द / सूजन दर्दनाशक दवाओं से भी राहत नहीं मिली है और आवश्यक अनिर्धारित समय अस्पताल आना पड़ा।)