

# Comparative evaluation of post-operative endodontic pain using various intracanal medicaments after instrumentation with rotary single-file system.

Abhilasha Bhawalkar\*, Sanjyot Mulay, Himali Desai, Rajesh Shetty

Department of Conservative Dentistry and Endodontics, University of Dr. D. Y. Patil Vidyapeeth, Pimpri, Pune, India

## Abstract

**Background:** To compare the action of intracanal medicaments: Calcium hydroxide and 2% Chlorhexidine, 10% Metronidazole gel, Septilin and 2% Chitosan as intracanal medicaments after instrumentation with One curve® (Micromega) Rotary Single-file System at 6 hrs, 12 hrs, 24 hrs, 48 hrs, 72 hrs and one week.

**Method:** Total of 50 mandibular molars were included (n=50) with occlusal caries and mild to moderate pre-operative pain with minimal periapical radiolucency. After completing access cavity preparation under local anaesthesia and isolation with rubber dam, instrumentation with One curve single file was completed and patients divided into groups of medicaments with a group of no medicaments or only normal saline. The data was statistically analysed using Friedman's two way analysis, Kruskal Wallis ANOVA and Post hoc pairwise comparison.

**Results:** In all the study groups, there was significant decrease in post-operative pain at 6 hrs. Calcium hydroxide with 2% Chlorhexidine showed significant decrease in post-operative pain and its efficacy was evident from 24 hrs upto 7 days. Metronidazole 10% intracanal medicament at 6 hrs and 12 hrs showed maximum pain reduction post-operatively, which had sustained effect upto 7 days.

**Conclusion:** In accordance to the results, it could be concluded that 10% Metronidazole and Calcium hydroxide plus 2% Chlorhexidine proved to be beneficial for reducing post-operative pain followed by Septilin; Septilin and 2% Chitosan showed shorter duration of efficacy as compared to other medicaments.

**Keywords:** Intracanal medicaments, Calcium hydroxide, Septilin, Metronidazole, Single file system, Post-operative endodontic pain.

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## Introduction

Pain is an unwanted and unpleasant sensation which interferes with the normal day-to-day activities of an individual. It is this pain in the teeth which brings an individual to dental facility with a hope of relief after the treatment. But experience of inter-appointment pain is something which is unexpected at the same time quite common which may be associated with several host related and operator related factors. The pain observed after endodontic treatment showed the incidence of 1.7% -70%. The inter-appointment discomforts were around 50% out of 2000 patients with necrotic teeth treated endodontically [1]. There are various causes of pain including micro-organisms, alterations in the pressure at the periapical region, chemical changes, various physiological factors, etc. Persistent micro-organisms post disinfection failure result in symptoms and here the action of intracanal medicaments comes into picture. Along with the elimination of inflammatory products, these medicaments also eliminate the micro-organisms from the canals. Calcium-hydroxide, Ledermix paste, Triple Antibiotic paste, Double Antibiotic paste, Chlorhexidine gel, PBSC paste, different Antibiotic preparations, etc have been used as intracanal medicaments in different clinical conditions [2]. Calcium hydroxide is the traditionally used medicament inside the root canals. Its antibacterial effect is attributed to the alkaline pH achieved after the dissociation of hydroxyl ions.

Chlorhexidine being an extended spectrum agent showing antibacterial activity is being used in endodontics very efficiently [3]. It has an advantage of being able to retain in root canal dentin and also has less toxicity. Certain studies have proved that chlorhexidine could be used along with calcium hydroxide against the resistant strains. More recently, inflammations have been treated with the help of natural agents [4]. One such being Septilin® (Himalaya Drug CompanyTM), which has shown modulations in immune systems in animal studies. Also a newer natural polymer named Chitosan is being studied. The antibacterial and antifungal properties of Chitosan make it appropriate for use in various medical applications [5]. Metronidazole 10% has shown to inhibit the growth of majority of obligate anaerobes. One curve® is a single file system introduced recently in endodontics. The advantages are that it reduces the working time and lowers cross contamination between patients, a common problem associated with the use of multiple files and less debris extrusion due to the continuous rotation motion of the One curve® file system [6]. Use of a single file will save both time and cost [7]. The novelty of the study is use of Septilin® and Chitosan as intracanal medicaments along with Calcium-hydroxide and Chlorhexidine in combination and Metronidazole after intracanal instrumentation with One curve® Rotary Single-File System in evaluating and comparing Post-Operative Endodontic Pain [8].

## Materials and Methods

This study was approved by ethics Committee on 15/10/2018 with ref no. DYPDCH/77/37/2018. CTRI/2021/03/032269 is the clinical trial registration number. Patients reporting to the Department of Conservative Dentistry and Endodontics within the age group of 15-45 yrs were screened for moderate pain with Mandibular first and second molars and presence of occlusal caries. These teeth showed Apical Periodontitis with widening of the Periodontal Ligament Space, Periapical lesion less than 2 mm and fully formed root apices. Patients were systemically healthy with no Diabetes, Hypertension, Hyperthyroidism, Hypothyroidism etc, influencing the outcome of root canal treatment. Patients on any oral medication or having consumed any medication (i.e. anti-inflammatory-analgesic, antibiotic) within 48 hrs of treatment were excluded from the study. Thorough case history was taken and intraoral examination was done. Pulp vitality test was done to ascertain the pulpal status using Electronic Pulp Tester (ParkellTM). A total of Fifty patients were selected and included in this study. Written informed consent was taken. The oral prophylaxis was done using ultrasonic scaler (EMS). Local anesthesia given using Lignocaine Hydrochloride with Adrenaline 1:200000 (Lignocad Adr, Cadila PharmaceuticlasTM). Rubber dam was applied (Hygenic® Coltene) and the concerned tooth was relieved from occlusion. Access cavity preparation was made using round diamond abrasive point # ISO BR 41 (Mani® , Tochigi, Japan) and non end cutting tapered fissure bur #EX24 (Mani® , Tochigi, Japan). Canals were irrigated with 3% NaOCl (Prime dentalTM), Normal saline (Prime dentalTM, 17% EDTA (Prime dentalTM) [9]. The root canal shaping procedures were performed using One curve® (Micromega) Rotary Endodontic Single-File System according to the manufacturer's instructions. After Access Cavity Preparation use of One Flare; rotation speed of 250-400 rpm; torque of 3 N.cm. was done. Establishing patency of the root canal with #10 K-File was done. Glide Path established with One G; rotation speed of 250-400 rpm; torque of 1.2N cm. Working Length was established with #15 K-File with the help of electronic apex locator and affirmation using digital radiograph was done. Shaping the Root Canal with One curve; rotation speed of 300-450rpm; torque: 2.5 N.cm. was carried out. Canals were irrigated with 3% NaOCl (2 ml) after each instrumentation, a total of 10 ml was used [10]. Final flush with 17% EDTA followed by normal saline was done. Paper points (DentsplyTM) were used to dry the canals. Selected patients being segregated into 5 Groups using SNOSE method: Group I: No intracanal medicament (n=10)(Control group) ,Group II: Combination of Calcium-Hydroxide and 2% Chlorhexidine gel (n=10), Group III: 10% Metronidazole gel (n=10), Group IV: Septilin (n=10), Group V: 2%Chitosan (n=10) Respective Intracanal medicaments were placed in the root canal using Lentulospiral. Temporary restoration using Cavit was placed in the access cavity. Post operative instructions were given to the patients.

Method of preparation of 10% metronidazole GEL- Metronidazole has solubility in water of 10 mg/mL and 2 mg/ml respectively at 20°C. The specific quantity of drug Metronidazole was mixed in specific quantity of water. The gelling agent was dispersed in drug Metronidazole containing water under moderate speed with mechanical stirrer. Gel was made neutral in pH by using triethanolamine.

### Preparation of other materials

Calcium Hydroxide powder (Prime dentalTM) was mixed with 2% Chlorhexidine gel (GLUCO-CHeX, CerkamedTM) in 1:1 proportion. Septilin® (Himalaya Drug CompanyTM ) was provided by the manufacturer as an aqueous extract of the drugs. 2% Chitosan (NanoshellTM) was provided by the manufacturer in powdered form. It was dissolved in Normal Saline to get a paste consistency.

### Statistical analysis

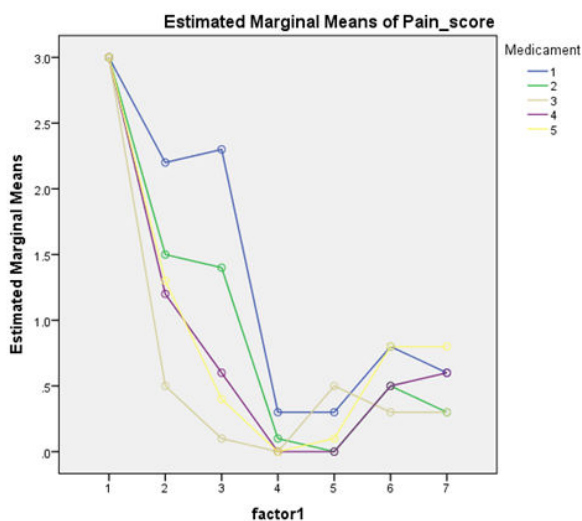
Data was entered in Excel sheet and analyzed using IBM SPSS 26 software. Since the pain scale was considered to be non parametric the data was summarized in form of median in addition to mean and SD. Statistical test for intra-group comparison was Friedman's test. Inter-group comparison was carried out using Kruskal Wallis test. When these tests were statistically significant, post hoc pairwise comparisons were performed.

## Results

All the study groups showed significant reduction in post-operative pain at all time intervals. For Group I (no medicament), it was observed that at 6 hrs postoperative pain reduced significantly from 6 hrs to 7 days (p=0.033), least seen at 24-48 hrs postoperatively (p=0.007). In Group II (calcium hydroxide plus chlorhexidine), postoperative pain reduced significantly as compared to pre-operative pain throughout the observation period, with almost no pain in 24-48 hrs postoperatively(p=0.004). Group III (10% Metronidazole) showed more reduction in postoperative pain from 6 hrs through 7 days after root canal instrumentation, as compared to other study groups. At 24 hrs after procedure and placement of intracanal medication no pain was observed (p=0.004). This result was statistically significant. In Group IV (Septilin), pain reduced significantly as compared to preoperative pain over the 7 days of study period. At 24 hrs and 48 hrs there was no pain (p=0.004). At 72 hrs, there was recurrence of minimal pain. For Group V (Chitosan), there was pain reduction postoperatively at 6 hrs and 12 hrs; at 24 hrs (p=0.003) and 48 hrs (p=0.006) there was statistically significant reduction in pain when compared to preoperative pain. Overall comparison of pain scores for study groups at different time intervals (Table 1 and Figure 1).

**Table 1.** Overall comparison of pain scores for study groups at different time intervals.

Groups	Pre-op	6 hrs	12 hrs	24 hrs	48 hrs	72 hrs	7 days
	Mean	Mean	Mean	Mean	Mean	Mean	Mean
	(SD)	(SD)	(SD)	(SD)	(SD)	(SD)	(SD)
Group I	3.00 (0.0)	2.20 (1.398)	2.30 (1.160)	0.30 (.949)	0.30 (.949)	0.80 (1.751)	0.60 (.966)
Group II	3.00 (0.0)	1.50 (1.650)	1.40 (1.897)	0.10 (.316)	0.00(0)	0.50 (1.581)	0.30 (.949)
Group III	3.00 (0.0)	0.50 (.972)	0.1 (0.316)	0.00 (.00)	0.50 (1.581)	0.30 (.949)	0.30 (.949)
Group IV	3.00 (0.0)	1.2 (1.549)	0.6 (0.966)	0	0	0.5 (1.581)	0.6 (1.265)
Group V	3.00 (0.0)	1.30 (1.494)	0.40 (.516)	0.00 (.000)	0.10 (.316)	0.80 (1.751)	0.80 (1.751)



**Figure 1.** I- No medicament, II-Calcium hydroxide + 2%Chlorhexidine, III-10% Metronidazole gel, IV-Septilin, V-2% Chitosan.

**Discussion**

Post-Endodontic pain is an extremely unpleasant and unwanted incidence. It is multifactorial and can occur not only prior but also during and after the commencement of the root canal treatment. It is a combined phenomenon due to microbial, mechanical and chemical injury before and during the treatment [11]. Mediators of pain such as prostaglandins, serotonin, leukotrienes, histamine and bradykinin are extensively secreted post injury to the periapical tissue at any instance during the treatment [12]. Patient factors like pre-operative pain, pulpal status, amount of peri-radicular inflammation present and host response also play an important role. The procedures carried out inside the root canals which cause maximum eradication of the irritant like placing an antimicrobial intra-canal medicament are significant in controlling endodontic infections. This prevents the chances of postoperative pain [13]. Calcium hydroxide, most standard amongst medicaments is traditionally placed inside the canals [14]. It is a strong alkaline substance with pH of upto 12.5. It is

beneficial in root canal treatment due to its antimicrobial activity. The limited action of calcium hydroxide is due to the buffering effect exerted [15]. Moreover, some bacterial species become resistant to its high pH. 34 Chlorhexidine being a cationic biguanide with antimicrobial activity and a pH 5.5 to 7.0 as stated a broad spectrum antimicrobial drug that can retain in dentin [16]. There are few studies stating that chlorhexidine plus Calcium hydroxide act better against these resistant bacteria [17]. 2% Chlorhexidine with Calcium hydroxide was shown to be more effective than Calcium hydroxide in aqueous environment. Metronidazole is a nitroimidazole compound and has been widely used for its expanded spectrum against Anaerobic cocci, as well as Gram negative, Gram positive bacilli [18]. Penetrating the bacterial cell membranes, it reaches the nuclei and binds with the DNA. This disrupts DNA's helical structure and cell death occurs [19]. Metronidazole being inhibitory to all strict organisms living in anaerobic environment, was better against Porphyromonas endodontalis and Fusobacterium nucleatum than Calcium hydroxide plus CPMC. Septilin® (Himalaya Drug Company, Bangalore, India), is a natural agent with high potency to modulate immune functions in animals. Mechanism of Septilin® on immune system have shown to regulate the production of pro-inflammatory mediators like TNF α, IL-6, IL-8, NO, cyclooxygenase 2 and phosphor diesterase 4. Its extract contains Maharasnadiquath 65 mg, Tinosporacordifolia 49 mg, Rubiacordifolia 32 mg, Emblicaofficinalis 16 mg, Moringapterygosperma 16 mg, Glycyrrhizaglabra 6 mg. There is a study which showed less anti-microbial activity compared to calcium hydroxide and chlorhexidine against E. faecalis and Streptococcus mutans. On the contrary, a study stated that 2 % chlorhexidine and Septilin showed efficient reduction of E. faecalis than Aloe vera, Propolis and Calcium Hydroxide. Chitosan, an aminopolysaccharide biopolymer is biodegradable and biocompatible. It is derived from the outer surface of crustaceans shell [20]. Chitosan being an antiviral, antibacterial, and antifungal agent, is being extensively researched in dentistry. Gram-positive bacteria have been found to be more susceptible than Gram-negative [21]. It is thought to exhibit immune stimulatory action on innate immune cells and induce them to release pro and anti-inflammatory cytokines. A study proved that when Chitosan

was used with 2% Chlorhexidine, the combination did reduce the colonies of *E. faecalis* but not substantially. One curve® (Micromega) is a single use endodontic file working on continuous rotation movement [22]. It undergoes C. wire heat treatment on the Nickel Titanium alloy during its manufacturing. This feature gives it the property of controlled memory [23]. The 4-millimeter part of the file at apical third has triple helix cross section, the remaining being S shaped. It can be used at a speed of 300-450 rpm with a maximum torque upto 2.5 N.cm. A study stated that single- file rotary instrument showed less apical extrusion of debris as compared to the reciprocating ones [24]. Chances of cross-infection and fatigue during use of multiple file system for root canal instrumentation may cause mishaps or complications, thus indirectly affecting the disinfection of the canal. The One curve system exhibited lower amounts of debris and irrigant in comparison with the 2Shape system.

On comparison of all the five study groups at each time interval, the following observations were noted. At 6 hrs and 12 hrs, 10% Metronidazole intracanal medicament group showed maximum reduction in pain compared to other groups [25]. At 6 hrs postoperatively, although all the study groups presented reduction in pain, the least pain was observed in 10% Metronidazole gel, followed by Septilin, then Chitosan, Calcium hydroxide plus Chlorhexidine groups [26]. So it can be inferred that the reduction in pain at 6 hrs postoperatively may not necessarily be due to the therapeutic action of the respective intracanal medication [27]. At 12 hrs postoperatively, least pain was observed in 10% Metronidazole followed by 2% Chitosan, then Septilin and Calcium hydroxide plus Chlorhexidine [28]. At 24 hrs, 10% Metronidazole gel, Septilin and 2%Chitosan intracanal medicament showed no pain postoperatively [29]. Calcium hydroxide plus 2% Chlorhexidine also proved very efficient at this time interval. At 48 hrs Calcium hydroxide plus 2% Chlorhexidine and Septilin groups showed similar efficacy with no pain. This was followed by 2% Chitosan, no medication and metronidazole groups [30]. This suggests that drug combination proved more effective and Septilin has sustained effect. At 72 hrs, 10% Metronidazole intracanal medicament showed maximum pain reduction [31]. At 7 days, Calcium hydroxide plus Chlorhexidine and 10% Metronidazole intracanal medication showed maximum pain reduction and minimal recurrence of pain postoperatively [32]. This was followed by Septilin group and no medicament alike [33]. Chitosan showed least efficacy in pain reduction at 7 days. This suggests limited duration of action of Septilin and 2% Chitosan and sustained bio-availability of the therapeutic drugs 10% metronidazole and Calcium hydroxide plus Chlorhexidine, during the 7 days of observation period.

## Conclusion

Under the limitations of the study, it could be concluded that in all the study groups, there was significant decrease in post-operative pain at 6 hrs. Calcium hydroxide with 2% Chlorhexidine showed significant decrease in postoperative pain and its efficacy was evident from 24 hrs upto 7 days.

Metronidazole 10% intracanal medicament at 6 hrs and 12 hrs showed maximum pain reduction post-operatively, which had sustained effect upto 7 days. This result was statistically significant. Septilin and 2% Chitosan intracanal medicaments showed maximum decrease in post-operative pain at 24-48 hrs, with shorter duration of efficacy.

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#### \*Correspondence to

Dr. Abhilasha Bhawalkar

Department of Conservative Dentistry and Endodontics

University of Dr. D. Y. Patil Vidyapeeth, Pimpri

Pune

India

E-mail: researchassist2000@gmail.com