Four years of clinical experience with the efficacy of Pulpotec® as a root canal dressing for the management and control of odontogenic pain: A prospective randomized clinical trial

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Abstract:

Background: The choice of methods and materials for the relief of preoperative symptom and control of inter-appointment flare-up remains an important consideration in endodontic therapy. Aim: The objectives of this study was to discover clinically the influence of pulpotec (Produits Dentaires S.A., Switzerland) on the incidence of inter-appointment flare-up, with a view to advance the resolution of pain and/or swelling in patients presenting for emergency root canal treatment. Materials and Methods: Pulpotec paste was used as an intracanal medicament in multi-appointment root canal treatment in 860 teeth (510 symptomatic and 350 asymptomatic) belonging to 860 patients from February 2008 to March 2012. The follow-up visit was scheduled, and the incidence and severity of inter-appointment pain was recorded at different time periods (8, 24, and 48 h, 3 days, and 1 week after the treatment) on simple descriptive pain intensity scale. Results: The incidence of intense pain was 10 (1.16%) and 6 (0.69%) of the treatment cases at 24 and 48 h, respectively. Moderate pain was described only by 137 patients within the 24 h–3 days time interval after treatment. Conclusion: Pulpotec intracanal dressing is beneficial in rapid resolution of pain and/or swelling in emergency root canal treatment and in controlling postoperative pain in multi-appointment root canal treatment.

Keywords*:* Odontogenic pain, pulpotec, root canal dressing

Introduction:

Correct and exact knowledge of pain prevalence and severity associated with pulpal or periradicular disease and its diminution by root canal treatment has the potential to change the attitudes of the public, dentists, and other health care professionals, thus allowing more natural teeth to be retained [1,2] .

It has been reported that nearly 90% of patients seeking emergency dental treatment have symptoms of pulpal or periapical disease [3, 4].Treatment of the endodontic emergency has a great influence on postoperative pain. Studies showed that complete pulpectomy is the most effective method of preventing postoperative sequels in those patients presenting preoperative pain with vital pulpitis. The next effective method is pulpotomy and the least effective is partial pulpectomy [5].

Essentially, endodontic infections are treated by chemomechanical preparation. Although a substantial reduction in intracanal microbial communities is usually reached after chemomechanical procedures with antimicrobial irrigants such as sodium hypochlorite (NaOCl), it has been shown that predictable disinfection and reduction of interappoinment or postoperative pain in

most cases can only be achieved after an interappointment intracanal medication [6]. Single-visit treatment has been shown to result in higher frequency of post endodontic pain and, consequently higher consumption of analgesics [7].

In general, the term flare-up is used to describe moderate to severe pain and/or swelling that usually begins 12–48 h after treatment, lasts at least 48 h, and requires unscheduled emergency interappointment and active treatment [8]. The incidence of endodontic postoperative pain and/or swelling widely varies from one study to another. The rates reported in the literature range from 1.4 to 5.5%, and in particular conditions, it goes up to 16%; this could be attributed to the fact that each study follows a particular protocol, thus using different samples and criteria to evaluate the stage of pain and/or swelling [9].

Intracanal medicaments were used for various purposes, including relief of preoperative pain and/or prevention of post-treatment symptoms. Many medicaments have been used in an attempt to achieve these aims, such as formocresol, phenolics (camphorated monochlorophenol, cresatin, eugenol, beechwood, creosote), iodine–potassium iodide, or calcium hydroxide, but no single preparation has been found to be completely predictable in its efficacy [10]. Hence, further research is required.

Pulpotec (Produits Dentaires S.A, - Vevey, Switzerland) is a radiopaque, non-resorbable filling paste, composed of powder (polyoxymethylene, iodoform, and zinc) and liquid (dexamethasone acetate, formaldehyde, phenol, guaiacol, and subsidiary substances), and is used for rapid and long-term treatment of pulpitis by pulpotomy in vital molars, both permanent and deciduous [11].

The purpose of this prospective study was to assess the influence of pulpotec as an intracanal dressing on interappointment flare-up, with a view to advance the resolution of pain and/or swelling in patients presenting for emergency root canal treatment.

Methods:

The outline of this clinical trial has received approval from the Ethical committee of the University of Sulaimani (Sulaimani, Iraq). Eight hundred and sixty patients were included in this clinical trial at a private dental clinic in Sulaimani from February 2008 until the end of March 2012. Before commencing treatment, the test material was explained to the patients who signed a form agreeing to treatment. Conditions diagnosed were asymptomatic pulp/periapical pathosis, or teeth with moderate to severe pain with or without swelling at the time of treatment**.**

All patient-related procedures applied in this clinical study conformed to well-known standardized protocols of root canal preparation. An aseptic technique was used throughout the endodontic treatment. Chemomechanical preparation was performed in all the teeth using a step-back or a modified crown-down enlargement technique, but with variations as necessary for each case. Also, 5% NaOCl was used as the main irrigant in all the teeth. Reduction of occlusal contact was individually adapted for each tooth with moderate to severe pain and swelling, accompanied by prescription of analgesics and antibiotics. Pulpotec paste was inserted into a dried root canal by means of a file that was smaller than the master apical file to approximately 5 mm from the apex. A dry, sterile, cotton pellet was placed in the chamber, followed by an Intermediate Restorative Material (IRM) or Cavit. The

follow-up visit was scheduled after 7 days, and most treatments were completed at this time.

The entire patients were instructed to mark a self-reporting questionnaire which was prepared in the form of a simple descriptive pain intensity color-coded scale, in order to determine the rating of his/her postoperative pain according to their perception, at 8, 24, and 48 h, 3 days, and 1 week after the treatment. The scale was divided into four equal dimensions with different colors, and corresponded to the four pain categories, no, mild, moderate, and intense (*Figure 1*).

White color: No pain

Yellow color: Mild pain; discomfort that required no analgesic

Green color: Moderate pain; discomfort that was controlled by analgesics

Red color: Intense pain; required analgesics, but uncontrolled by them

Immediately, each patient with pain or patients who presented for emergency relief of pain received instruction about the assessment of preoperative pain based on a verbal scale (none, mild, moderate, and intense). If the patient had intense postoperative pain and/or swelling, unscheduled emergency active treatment was performed at that time, and antibiotics and analgesic were prescribed as indicated.

The overall incidence of postoperative discomfort was recorded and expressed as a percentage of the total number of teeth evaluated. The level of discomfort was also calculated for each emergency root canal treatment case at different time periods. Effectiveness of treatment was evaluated on the basis of clinical methods of investigation. This comprised subjective data: collection of patient complaints, questionnaire, and objective clinical finding. The incidence and severity of pain that was experienced by the study participants is described in (*Table 1*) and (*Table 2*). The statistical analysis of the patients' pain levels was done by using Chi-square test. Differences were considered significant when probabilities were less than 0.05.

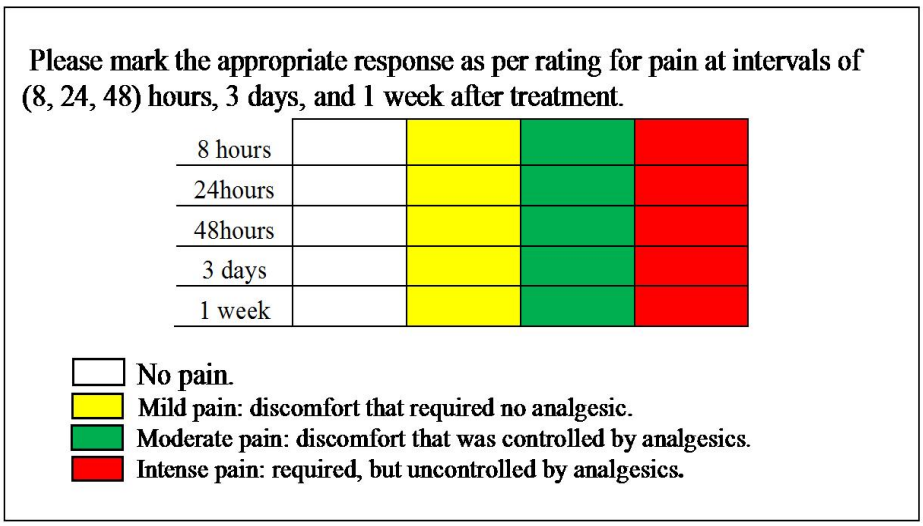

Fig. 1 A colour- coded horizontal representation of the descriptive pain intensity scale.

Results:

During the study period, 860 teeth belonging to 470 men and 390 women, of age ranging from 15 to 67 years, received root canal treatment. Diagnostically, of the 860 patients, 350 had asymptomatic teeth and 510 had symptomatic teeth of which 176 presented for emergency relief of pain. All patients responded to the questionnaire. The distribution of the study participants according to the presence or absence of preoperative symptoms and statistical analysis of the obtained data are presented in (*Tables 1 and 2*) and (*Figures 2-4*).

No pain was reported by the majority of patients at 8 h [582 (67.67%)] up to 1 week [831 (96.63%)] after treatment. Mild pain at some moment was experienced by 278 (32.33%), 190 (22.09%), 147 (17.09%), 94 (10.93%), and 29 (3.37%) of the treatment cases at 8, 24, 48 h, 3 days, and 1 week, respectively (*Figure 2*). There was absence of moderate or intense pain in all the cases treated during the first 8 h after the first treatment session. Moderate pain was described by 68 (7.90%) patients at 24 h, and the number reduced to 50 (5.81%) at 3 days and 19 (2.21%) at 7 days after treatment. Most of them were taking analgesic drug (*Figure 3*).

The overall incidence of intense pain was relatively low [10 (1.16%) and 6 (0.69%) of the treatment cases at 24 and 48 h, respectively]. Out of 16 cases with intense pain during the study period, only 4 cases presented with swelling and required unscheduled emergency treatment visit. After these periods, until the end of the treatment session and completion of the treatment, no case with intense pain was recorded. At 7 days, all patients experienced no pain or only weak pain levels, and treatment in most of the cases was completed, except for 29 cases that required a second treatment session. (Figure 4).

Table 1: Descriptive and inferential statistics for rating of pain experienced at 8, 24, and 48 h after the treatment for 860 study participants.

Rating for pain	**8 h**		**24 h**		**48 h**	
	Symptomatic	**Asymptomatic**	**Symptomatic**	**Asymptomatic**	**Symptomatic**	**Asymptomatic**
No pain	311 (61.0%)	271 (77.4%)	291 (57.1%)	301 (86.0%)	337 (66.1%)	320 (91.4%)
Mild pain	199 (39.0%)	79 (22.6%)	152 (29.8%)	38 (10.9%)	123 (24.1%)	24 (6.9%)
Moderate pain	0 (0%)	0 (0%)	60 (11.8%)	8 (2.3%)	46 (9.0%)	4 (1.1%)
Intense pain	0 (0%)	0 (0%)	7 (1.4%)	3 (0.9%)	4 (0.8%)	2 (0.6%)
Total	510 (100.0%)	350 (100.0%)	510 (100.0%)	350 (100.0%)	510 (100.0%)	350 (100.0%)

P value = 0.000, highly significant (i.e. symptomatic teeth experienced higher rate of pain after 8, 24, and 48 h of treatment)

Table 2: Descriptive and inferential statistics for rating of pain experienced after 3 days and 1 week from the treatment for 860 study participants.

Rating for pain	Three days		One week	
	Symptomatic	Asymptomatic	Symptomatic	Asymptomatic
No pain	405 (79.4%)	342 (97.7%)	494 (96.9%)	337 (96.3%)
Mild pain	90 (17.6%)	4 (1.1%)	16 (3.1%)	13 (3.7%)
Moderate pain	15 (2.9%)	4 (1.1%)	0 (0%)	0 (0%)
Intense pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total	510 (100.0%)	350 (100.0%)	510 (100.0%)	350 (100.0%)

P value = 0.000, highly significant.

P value=0.65, not significant.

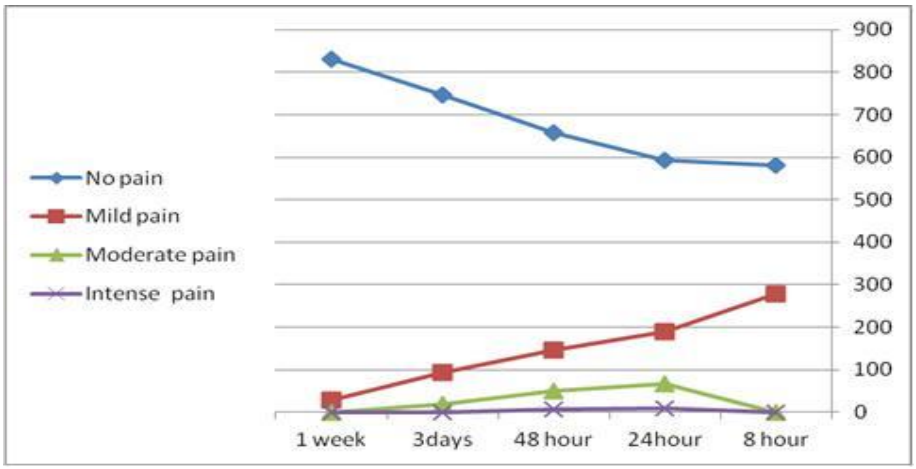

Fig. 2 The rating of pain experienced at different post-operative time period for 860 study participants.

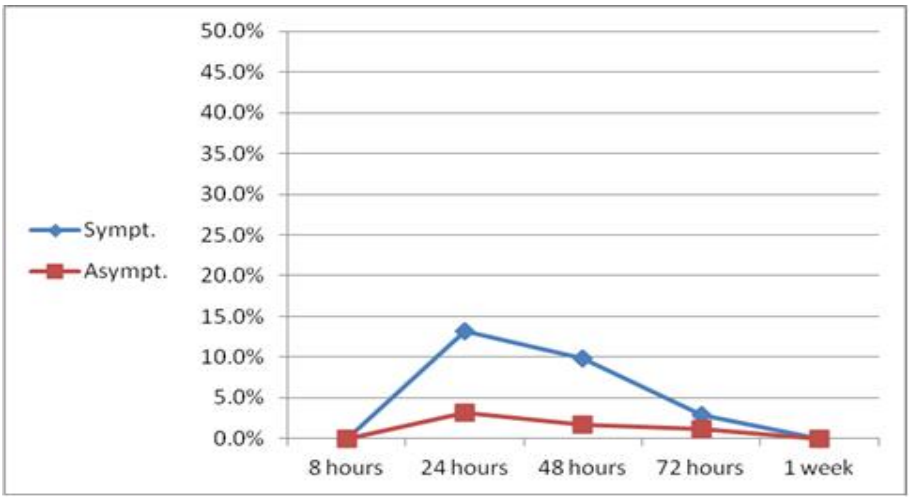

Fig.3 Moderate and severe pain experienced at different post-operative time period for 860 study participants.

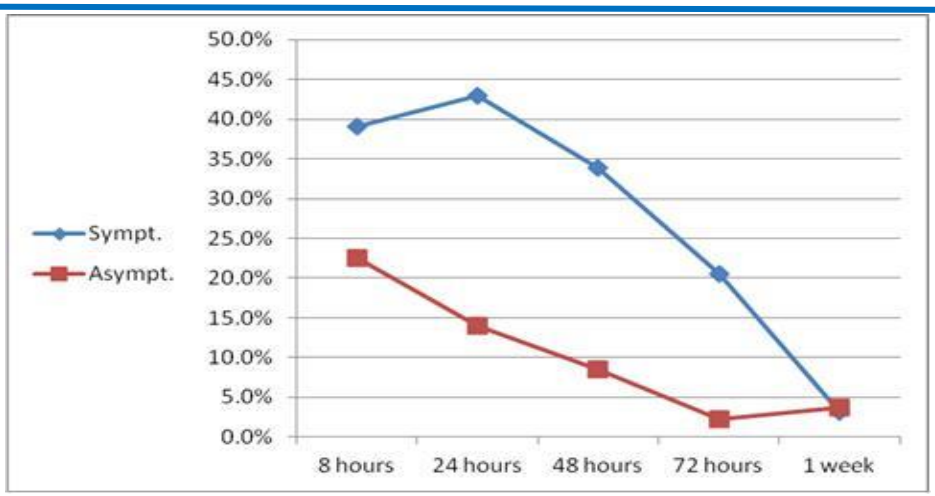

Fig. 4 Occurrence of pain according to preoperative clinical condition during one week for 860 study participants.

Discussion:

The use of an antimicrobial strategy during the endodontic therapy can significantly remove microorganisms from the root canal and theoretically prevent postoperative pain. Sodium hypochlorite irrigation accompanied by antimicrobial intracanal medication could prevent postoperative pain [12].

The main purpose of this clinical trial was to study the feasibility of pulpotec as a root canal medicament, through the measurement of the incidence and severity of interappointment pain, subsequent to multiple visit orthograde root canal treatment in symptomatic and asymptomatic teeth and after emergency root canal therapy with different pulp and/or periapical conditions. Pulpotec possesses many of the requirements of a material to be used as an intracanal medicament following chemomechanical root canal preparation. In this way, a protocol based on an antimicrobial strategy was designed to conduct this clinical study. This study was not designed to investigate, for example, outcome differences of pulp or periradicular pathology. This would have required nearly equal subject sampling for different pulp and periradicular status and this was not the aim of this study. On the other hand, evidence in the literature of the effect of pulp status (vital or necrotic) on the incidence and severity of interappointment pain is nearly not giving a decision.

In the present study, irrigation was always performed using 5% NaOCl solution because sodium hypochlorite at different concentrations has been the most commonly used intracanal irrigant till now due to its tissue dissolution ability, lubricating action for instrumentation, and antimicrobial action [13].

A good feature of this clinical study is that a large number of follow-up data were collected from a large number of dental patients receiving initial orthograde root canal therapy. Root canal preparations were performed by a single operator to avoid interoperator variation. Effectiveness of treatment was evaluated on the basis of subjective data collection, like on pain and/or swelling, and objective clinical findings of periradicular area of treated teeth, such as percussion and palpation.

One of the main problems in studying pain is the patient's subjective evaluation and its measurement, which depend on personal feelings [14].For this reason, the greatest importance should be directed toward the design of the pain measuring scale, in order to be understood by the study participants to

the largest degree possible and to be easily interpreted by researchers. In the present study, a simple descriptive pain intensity scale was designed to be easily understood by the patients. The color-coded categories were defined by the presence or absence of the need for analgesic treatment and by the relief of the pain if produced.

In the present study, although we did not compare different irrigants and intracanal medications, the low incidence of postoperative swelling and a rapid onset of pain reduction in emergency root canal treatment can perhaps be explained by the antimicrobial therapy used. The chemical composition of pulpotec involves steroid and formaldehyde. Steroids have been shown to eliminate acute apical symptoms during endodontic treatment [15]. The antimicrobial efficiency of pulpotec may be due to the strong antibacterial action of formaldehyde vapor, as reported by Simon *et al.* [16]. As well, the treatment was effective in completely eliminating pain in most of the previously symptomatic teeth, which can also be explained by the fact that maximum removal of irritants was performed in the emergency visit. The expected role of drugs like analgesic and/or antibiotic in the event of systemic complications (fever, lymphadenopathy, cellulitis) or of a supplemental treatment measure like drainage of the tooth, which was often required, should be considered.

The overall incidence of postoperative intense pain was low [16 (1.85%)]. This incidence was compatible with most data from the literature. However, it is difficult to compare the flare-up incident rates across studies as flare-up diagnosis varies across studies because both sample populations and case definitions differ [17].

According to the subjective and objective data from the findings of this study, root canal treatment in symptomatic teeth with different pulp and/or periapical conditions was more painful than in asymptomatic teeth; this in agreement with the findings of Walton and Fouad [11], Imura and Zuolo [13] and Segura-Egea *et al.* [18]. Maximum post-treatment pain occurs within the first 24 h after treatment and this finding is consistent with the previous research findings [19].

A limitation of this study was lack of microbial culture to assess the efficacy of the treatment procedure, and to confirm whether the test material has been successful in reducing or eliminating the bacterial load. For this reason, the future work in the area should also include a bacteriological investigation. Further chemical and pharmacological investigations in animal models using different consistencies of prepared pulpotec paste material are underway, in an attempt to better identify their effectiveness and clinical applicability as a root canal medicament.

Conclusions:

According to the obtained data and applied antimicrobial strategy, intracanal irrigation with 5% sodium hypochlorite, accompanied by pulpotec intracanal dressing is beneficial in rapid resolution of pain and/or swelling in emergency root canal treatment. The results also support the intracanal use of pulpotec for controlling postoperative pain in multi-appointment root canal treatment.

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