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ORIGINAL RESEARCH

# Flare-ups in endodontics and their relationship to various medicaments

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## Abstract

The purpose of this research is to investigate the frequency of endodontic flare-ups using a visual analogue scale. Definitions of flare-ups vary widely as does their reported frequency. A flare-up was defined as an increase of 20 or more points on the visual analogue scale for a given tooth, within the periods of 4 h and 24 h after the initial treatment appointment. The data from a previous study were used to determine the incidence of flare-ups after using three modalities (Ledermix, calcium hydroxide and no medication) to manage patients presenting for relief of pain of endodontic origin. A statistical analysis showed that there were no significant differences in flare-up rates at both the 4-h and 24-h periods between the three modalities. Further research is required using the above definition of a flare-up and standardising treatment protocols.

## Introduction

In the mind of the layperson, there is an association between undergoing root canal treatment and the occurrence of pain. It is obvious that this does occur because there is a voluminous literature on the subject of flare-ups during endodontic treatment (Table 1). What seems unusual is that there is no agreement among different investigators as to the incidence of such flare-ups. These are said to vary between 1.58% (17) and 90% (16). Henry *et al.* (15) stated unequivocally 'The majority of patients with symptomatic necrotic teeth had significant postoperative pain, and required analgesic medication to manage this pain.' On the other hand, Trope (44) reported a flare-up rate of only 2.53%. A careful analysis of Trope's data discloses that he included both vital and necrotic pulps in his investigation. It is generally accepted that the flare-up rate after the extirpation of a vital pulp is either non-existent or very low, even if the pulps were painful before instrumentation. In view of this, a flare-up rate of 48.5% after extirpation of a vital pulp as reported by Negm (31) seems rather unusual. Another factor in which Trope's study differs from those of other authors is that it did not include patients who had taken antibiotics or even anti-inflammatory medication during the week prior to the endodontic consultation. This would result in the exclusion of many severe cases from his study.

Thirty years ago, O'Keefe (35) reported that there was a relationship between preoperative and postoperative pain levels. This has been confirmed by Genet *et al.* (13) who found that 65% of patients reporting with preoperative pain had postoperative pain, while only 23% of those with no preoperative pain had postoperative pain. Genet's findings are corroborated by many other investigators (Claffey *et al.* (5), Houk *et al.* (16), Moos *et al.* (28), Marshall and Walton (24), Nist *et al.* (32), Nusstein *et al.* (33)). It can therefore be observed that the single most important determinant of severe postoperative pain is the presence of a preoperative painful condition.

There is no objective method for measuring pain, as the pain experience is very subjective and is dependent on so many factors. In the past, there have been numerous methods of pain measurement. These have included telephone interviews on certain days after the endodontic procedure and asking patients to describe whether their pain has been mild, moderate or severe (4,9,10,11,26) Several investigators have considered the situation as painful only if the patient telephones the office with a

**Table 1** A summary of articles on flare-ups

| Authors, year of publication | Pre-op state of pulp | No. of teeth in trial | Flare-up percentage | Canal medication | Systemic medication | Method of measuring pain | Remarks |
|---|---|---|---|---|---|---|---|
| Abbott *et al.* 1988 (1) | Asymptomatic<br>Pulpal necrosis and periapical pathosis | 195 | 2.6% | Nil | Penicillin and erythromycin | Visual Analogue Scale 1–5.<br>Flare-up recorded when unscheduled emergency visit occurred | Recommends prophylactic pre-op penicillin |
| Alaçam and Tnaz 2002 (2) | Both vital and necrotic pulps | 474 [170 nonvital, 304 vital] | 7.17% overall, [9.14% symptomatic cases] | $Ca(OH)_2$ | Diffusinal (Orally) | Rimmer flare up index 1–10 | Complications may occur in cases of pulp necrosis |
| Albashaireh and Alnegrish 1998 (3) | Both vital and necrotic<br>Proportion not stated. | 291 | Post-obturation pain 38% in multiple visit cases<br>27% single visit group | None | Paracetamol tablets prn | 4 categories from no pain to severe pain | Pain significantly associated with treatment of nonvital pulp |
| Chance *et al.* 1987 (4) | Not stated. Both vital and nonvital teeth treated | 300 total, 147 experimental 133 controls, 20 not evaluated | 37% corticosteroid, 52% saline in vital pulps | Meticortelone (2.5% Predni-solone solution)<br>Saline controls | Narcotic medication for pain relief | Phone or personal interview. 4 categories from no pain to severe pain | Pail relief only in vital cases. No pain relief in necrotic cases |
| Claffey *et al.* [Abstract] 2001 (5) | Symptomatic necrotic teeth also periapical radiolucency. No clinical swelling | 34 in all<br>17 each prednisolone or placebo group | Day 1 – 47% placebo group,<br>18% prednisolone group. | Not stated | Ibuprofen and Tylenol #3. | Diary to record pain. No further details given | Systemic corticosteroid superior to placebo<br>In achieving pain control |
| Creech *et al.* 1984 (6) | Not stated | 49 | At 24 h, 17% occlusal relief group) 11% mock equili-bration group | None | None | Numbers 0–9 to measure spontaneous pain | Prophylactic removal of occlusal contacts may not prevent pain |
| Doroschak *et al.* 1999 (7) | Both vital and nonvital | 49 | Pain reduction greatest for combination of therapy with both drugs | None | 1. Placebo<br>2. Fluorbiprofen<br>3. Tramadol<br>4. Combination of 2 & 3 | 1–100 (visual analogue scale VAS) | Combination of Fluorbiprofen and Tramadol together with endotherapy may be useful in managing endodontic pain |
| Eleazer and Eleazer 1998 (8) | Pulpally necrotic first and second molars | 402 teeth<br>201 in 2 visits<br>201 in 1 visit | Pain recorded<br>8% in 2 visit group<br>3% in 1 visit group | Metacresyl acetate | None | Patient reports with pain if not controlled by over-the-counter medicine, or reports with increased swelling. | One-visit technique is superior to two-visit schedule |
| Elliott and Holcomb 1988 (9) | Asymptomatic teeth, necrotic and with periradicular area | 40, half trephined, half not trephined | 25% of nontrephined moderate to severe pain<br>All trephined no pain | Nil | Aspirin or paracetamol prn for pain. | Telephone contact for 3 consecutive days. If pain not controlled by drugs prescribed, or if pain kept patient awake – classified as moderate to severe pain. | A minimally traumatic trephination appears to be justified |
| Fava 1992 (10) | Vital maxillary central incisor teeth | 60 | 6.6% moderate pain | 1. Hydro-cortisone and antibiotic solution<br>2. $Ca(OH)_2$ | Analgesics prn | Phone interviews with patient at 2 and 7 days | No difference between hydrocortisone and $Ca(OH)_2$ in controlling pain |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Fava 1998 (11) | Nonvital maxillary central incisors with apical periodontitis | 60 | At 48 h, 2 of group 1 moderate pain, 1 of group 2 moderate pain.<br>At 7 days no pain at all | 1. Hydrocortisone and antibiotic solution<br>2. $Ca(OH)_2$ | Analgesics prn | Phone interviews with patients at 2 and 7 days | No difference between hydrocortisone and $Ca(OH)_2$ in controlling pain |
| Fouad *et al.* 1996 (12) | Pulp necrosis, pain and/or swelling | 32 | No significant difference between 3 groups | $Ca(OH)_2$ | 1. Penicillin V<br>2. Placebo<br>3. No medication<br>All were given Ibuprofen 600 mg q i d | Visual analogue scale 0–100 | Systemic penicillin does not appreciably reduce symptoms<br>Local measures suffice |
| Genet *et al.* 1987 (13) | Various | 443 teeth in 443 patients | 27% (5% severe and 22% moderate) | None | Not reported | 3 categories: no pain, moderate pain, severe pain; recorded by patient. | Post–op pain related to<br>1. Pre-op pain in a nonvital pulp<br>2. Radiolucency > 5 mm<br>3. No.of roots<br>4. Women more than men |
| Glassman *et al.* 1989 (14) | Asymptomatic vital, inflamed pulps | 37 | At 24 h post-op<br>Pain ratings:<br>Dexamethasone – 1.1%.<br>Placebo – 14.3% | None | 1. Oral Dexamethasone 3 tablets of 4 mg<br>2. Placebo | Visual Analogue Scale 1–100 | Oral Dexamethasone is more effective than a placebo in reducing interappointment pain |
| Henry *et al.* 2001 (15) | Symptomatic necrotic teeth with periapical radiolucency | 41<br>Group 1<br>19 patientsts, Penicillin<br>Group 2<br>22 patients, placebo | 'Majority had pain'<br>Day 1<br>Group 1 – 53%<br>Group 2 – 68% | None | All patients had ibuprofen + paracetamol + codeine<br>Half were given either penicillin V or a placebo | Pain rated 1–3 by patient | No difference in pain between penicillin and placebo groups |
| Houck *et al.* 2000 (16) | Symptomatic necrotic teeth with periapical translucency | 50 | Significant pain (90%) | None | 400 mg Ibuprofen or Paracetamol + 30 mg Codeine prn + 28 tablets penicillin V of 500 mg | Pain rated 1–3 by patient for 7 days in 7-day diary | No difference in pain between trephined and nontrephined groups |
| Imura and Zuolo 1995 (17) | Various | 1012 | 1.58% | None | Analgesics | Verbal Instructions 'If you have pain or swelling, call the office' | Flare-up defined as problem requiring unscheduled visit and treatment |
| Jostes and Holland 1984 (18) | Various | 58 | No significant difference between groups (teeth ground out of occlusion and those that were not) | Not stated | Not stated | Analogue scale graph 0–20 Patient to bite on cotton tipped applicator. Very complex system of scoring | Reducing the occlusion at the instrumentation visit does not affect the pain experienced by the patient |

**Table 1** (Continued)

| Authors, year of publication | Pre-op state of pulp | No. of teeth in trial | Flare-up percentage | Canal medication | Systemic medication | Method of measuring pain | Remarks |
|---|---|---|---|---|---|---|---|
| Kaufman *et al.* 1994 (19) | 22% vital, 78% necrotic, | 47 | 63%<br>group 1, 22%<br>group 2, 76%<br>group 3, 50% | None | 3 groups had intraligamentary injections<br>(a) Methylprednisolone<br>(b) Mepivacaine<br>(c) no drug | Phone interview after 24 h pain graded 1–10 | Less pain for group 1 – (slow release methylprednisolone) |
| Krasner and Jackson 1986 (20) | Not stated | 50 | Placebo 39% at 8 h, 28% at 24 h. Dexamethasone 16% at 8 h and 6% at 24 h. | None | 25 patients on oral Dexamethasone 0.75 mg<br>25 patients on placebo | Telephone interview. Patients to rate pain on 0–100 scale at 8 h and 24 h | Oral Corticosteroid is superior to placebo |
| Liesinger *et al.* 1993 (21) | Irreversible pulpitis and/or apical periodentitis | 106 | At 8 h, placebo 80%, Dexamethasone 65% | None | Intramuscular Dexamethasone varying concentrations. Also placebo | Recorded by patient on scale 1–10, i.e. pre-op and 4, 8, 24, 48 and 72 h | Differences between Dexamethasone and placebo not statistically significant |
| Maddox *et al.* 1977 (22) | Pulpitis and periodontitis equal groups | 252 | 21–44% | One of: Cresatin, formocresol iodine +KI, CMCP, Eugenol, or no dressing | None | Patient questionnaire, no scoring by numbers | No difference between drugs including no drug<br>Less posttreatment pain after obturation |
| Marroquin *et al.* 2004 (23) | Irreversible pulpitis | 79 | No flare-ups only continuing reduction of pain | Nil | Ledermix | VAS (1–100) | No flare-ups when vital teeth treated |
| Marshall and Walton 1984 (24) | Not stated | 50 | Less pain Dexamethasone: 4 h 9%, 2 h 10%<br>Placebo: 4 h 29%, 24 h 24% | None | Dexamethasone by intramuscular injection | Patient questionnaire. no scoring by numbers | Intramuscular Dexamethasone reduces pain |
| Mata *et al.* 1985 (25) | Necrotic pulps together with asymptomatic periapical radiolucencies | 100 | Flare-ups 24%, in placebo group, 6% in penicillin group | None | 50 patients on systemic penicillin tablets, 50 on placebo. All after first endodontic visit | Flare-up recorded when unscheduled emergency visit occurred. Pain scored 1–5 | Prophylactic penicillin prevents flare-ups |
| Matthews *et al.* 1994 (26) | Sundry | 172 | Nine different conditions from acute pulpitis to sinusitis and soft tissue lesions<br>Pain relief related to de-compression of inflamed tissue | Variable | Variable | Phone call to patient at 24 h after treatment. Patient's pain graded on a 1–5 scale | Conditions investigated: acute apical periodontitis, acute pulpitis, acute pericoronitis, TMJ pain, sinusitis, necrotising ulcerative gingivitis |
| Menke *et al.* 2000 (27) | Various periapical conditions | 36 | At 12 h Ibuprofen better than placebo or Etodolac | None | | VAS 1–100 | 600 mg Ibuprofen is more effective than 400 mg Etodolac or a placebo |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Moos *et al.* 1996 (28) | Pre-op pain | 17 | Not stated | $Ca(OH)_2$ | Analgesics prn | VAS 1–100 | Pulpectomy to working length did better than pulpectomy + trephination |
| Mor *et al.* 1992 (29) | Vital and nonvital | 334 | 4.2% | Formocresol | Analgesics and antibiotics, prn | Only interappointment emergencies measured | There was no quantitative assessment of the pain |
| Morse *et al.* 1990 (30) | Asymptomatic pulp necrosis and a pa radiolucent lesion | 200 | Cefadroxil 1% Erythromycin stearate 2% Base 2% | Not stated | Erythromycin or Cefadroxil | 10 point analogue scale | All antibiotics reduce flare-ups |
| Negm 2001 (31) | Vital exposed or pulpitic pulps | 475 | 93% for Kenacomb 20% for placebo | 1. Kenacomb cream, (steroid+ antibiotics) 2. Placebo | Analgesics prn | Pain scale 1–4 | Kenacomb cream is superior to a placebo |
| Nist *et al.* 2001 (32) | Symptomatic necrotic pulps with pa radiolucency | 50 | Day 1: post-op trephination 80%, mock trephination 96%. Day 2: trephination 64%, mock trephination 84% | None | Analgesics | Patients rated pain from 1 to 3: mild, moderate or severe | Trephination does not significantly reduce pain |
| Nusstein *et al.* 2002 (33) | Symptomatic necrotic with pa areas all testing NV to vitality tests | 124 | Day 1: drainage group 97%, non-drainage group 89% | None | Ibuprofen and paracetamol + codeine 30 mg | Patients rated pain 0–3 | Short-term drainage upon access did not significantly reduce pain |
| Oguntebi *et al.* 1992 (34) | Irreversible pulpitis with or without apical periodontitis, all vital pulps | 956 | Pulpotomy 8%, partial pulpectomy 13%, complete pulpectomy 6% (All molar teeth) | Cresatin on cotton wool pellet | 1. 600 mg aspirin 2. 400 mg Ibuprofen 3. 650 mg paracetamol All above every 4 h | Patients reporting to emergency room after increase of post-op pain and failure to control pain with analgesics supplied | Partial pulpectomy had the highest incidence of pain |
| O'Keefe 1976 (35) | Group 1: emergency treatment previous visit then obturation Group 2: one visit endo (vitality not stated) | 147 patients | Pain after first visit: none to mild 134, moderate tosevere 13 patients (9%) | Group 1: formocresol Group 2: Cortisporin Group 3: Neosporin Group 4: Neosporin + Dexamethasone | Not stated | Patient grade pain as none, mild, moderate or severe | Operative and post-op pain proportional to pre-op pain |
| Peters 1980 (36) | Necrotic pulp and pa rarefaction | 100 + 125 controls | One-appointment cases 16% Two-appointment cases 9.6% | Not stated | Aspirin or paracetamol | Patients reporting with severe pain and inability to sleep | Patients relieved by trephination. More pain when filling material is overextended |
| Pickenpaugh 2001 (37) | Asymptomatic necrotic teeth with a pa radiolucency | 70 | 10% 4 in amoxicillin group and 3 in control group | None | Ibuprofen, paracetamol + 30 mg Codeine | Flare-up is moderate to severe pain as measured on a 0–3 scale (2 or 3 were denoting pain) | Prophylactic dose of amoxicillin has no effect on flare-ups in treating asymptomatic necrotic teeth |
| Rosenberg *et al.* 1998 (38) | Vital and nonvital | 117 posterior teeth | Severe pain: 4% after total reduction, 10% after simulated reduction, 11% control | None | Analgesics | 3 categories recorded by patient: 1. no pain; 2. moderate pain; 3. severe pain. All at 48 h | Occlusal reduction is indicated in a limited number of situations |

**Table 1** (Continued)

| Authors, year of publication | Pre-op state of pulp | No. of teeth in trial | Flare-up percentage | Canal medication | Systemic medication | Method of measuring pain | Remarks |
|---|---|---|---|---|---|---|---|
| Schneider 1968 (39) | Pulpitic (vital) 62 Necrotic 90 | 152 (only 16 with pre-op pain were treated and reported) | 63% in CMCP group. In 6% of patients treated with Ledermix pain did not subside in 1–2 days | 96 Ledermix. 56 CMCP (controls) | Not stated | Patients reporting hypersensitivity or discomfort | Ledermix is effective in the relief of pain; often quite rapidly |
| Siqueira *et al.* 2002 (40) | Necrotic pulp or retreatment | 627 teeth from 602 patients | 1.9%- severe pain, 3.3% moderate pain 10% mild pain | $Ca(OH)_2$ + CPMC + glycerine paste | Analgesics prn | Questions to patients: no pain? mild pain? moderate pain? severe pain? | Flare-ups related to previously symptomatic teeth |
| Torabinejad *et al.* 1988 (41) | Necrotic pulps | 2000 | 36% males 64% females | 1. CMCP 2. Formo-cresol, both on a small pledget of cotton wool 3. No medication. | None | Pain or swelling resulting in an interappointment (nonscheduled) emergency visit | Significant relationship between presence of preop complaint and higher incidence of interappointment emergency |
| Torabinejad *et al.* 1994 (42) | Necrotic pulps | 588 | Nil | Medication (not stated) 53%, no medication 43% | Analgesics and antibiotics | VAS 1–10 | Association between pre- and postoperative pain |
| Trope 1990 (43) | Vital and necrotic pulps | 474 (equal numbers for 3 medicaments | 2.53% | 1. Formocresol 2. Ledermix 3. $Ca(OH)_2$ | 600 mg Ibuprofen prn | Patient complained of severe pain or swelling | Ledermix placed in canal with paper points. Patients who had been on systemic antibiotics prior to treatment were excluded |
| Trope 1991 (44) | Vital and necrotic pulps | 226 | 135 no apical periodontitis. 91 with apical periodontitis. Flare up: 4.4% | Nil | Nil | Patient felt that pain was intolerable or pain was not improving | |
| Van Cura and Remeikis 1970 (45) | Secondary apical periodontitis | 94 | No relief in 13/94, 13.8% | Mycolog cream (triamcinolone + nystatin, neomycin, gramicidin) | Not stated | Patient reporting 'severe pain' | Relief of symptoms 81/94 (86%), mostly during first hour |
| Villanueve 2002 (46) | Necrotic pulps and pa lesion | 28 | Deals only with patients who had a flare-up-10/28 | CMCP | None | 2 categories only nonsevere and severe pain<br>VAS 1–10 | Fusobacterium nucleatum is associated with most severe forms of flare-ups |
| Walton and Fouad 1992 (47) | Pulpitic and necrotic pulps | 946 | 3.17% | None | Not stated | Patient calling with problem and being treated | Flare-ups occur with painful presenting symptoms |
| Walton and Chiappinelli 1993 (48) | Pulp necrosis and apical periodontitis | 80 | 1.25% | None | Penicillin 26, placebo 24, nothing 30 | VAS 1–100 to measure pain. Unscheduled appointments to measure a flare-up | No difference in pain between three groups. Penicillin not recommended |

prn, pro re nata; TMJ, temporo-mandibular joint pain syndrome; pa, periapical.

**Table 2** Analysis of variance: preoperative 4 h post-operative

| Source of variation | Degrees of freedom | Sum of squares | Mean square | F-statistic | *P*-value |
|---|---|---|---|---|---|
| Modality | 2 | 4524 | 2262 | 3.57 | 0.030 |
| Error | 192 | 121685 | 634 | | |
| Total | 194 | 126208 | | | |

complaint or requests an emergency appointment (17,43,41). Other investigators issued a 'pain diary' to the patient (5,13,21,32,38) and suggested that the patient should record pain as being mild, moderate or severe.

In order to minimise the various factors and to be able to compare how different procedures can affect the pain experience it is desirable to use a standard method. With this in mind, Rimmer (49) suggested a 'Flare-up Index' This extends from 0 to 45 and encompasses no fewer than nine variables. These include not only different degrees of pain but also swelling and trismus. This index has not found acceptance as it is altogether too complicated.

In an effort to quantify and measure pain, the visual analogue scale (VAS) has been proposed by Seymour *et al.* (50). This is a mathematical progression from 0 to 100, 0 being no pain and 100 being the most severe pain imaginable. Others have used numbers from 1 to 5 e.g. Abbott *et al.* (50), Matthews *et al.* (26), Negm(31); numbers from 0 to 9 (Creech *et al.* 6), or numbers from 1 to 3 Houk (16). The VAS from 0 to 100 seems the easiest to use because it does away with decimal points. The introduction of the Visual Analogue Scale has introduced some consistency into the results. Nevertheless, it is realized that the VAS is only suitable for use in an academic or research environment and not in routine clinical practice.

Table 1 summarises the studies into flare-ups. It will be seen that there are many variables that have not been standardised and that there is a great variation in the actual flare-up rates. Above all there is no satisfactory definition of a flare-up. Some investigators (Mata *et al.* (25), Peters (36), Torabinejad (41), Walton and Fouad (47), Mor *et al.* (29), Oguntebi *et al.* (34)) suggest that a flare-up occurs when the patient requests a nonscheduled emergency appointment. Any definition of flare-up must be arbitrary to some extent. If a flare-up is defined as a relatively small increase in pain, there will be many such cases. Conversely, if a flare-up is defined as a relatively large increase in pain, there will necessarily be very few such cases. As a practical solution to this problem, for the purposes of this study a flare-up was defined as a rise of 20 or more points on the VAS. This corresponds to approximately one residual standard deviation as given in the Analysis of Variance table (see Table 2). This definition was then used in the subsequent statistical analyses applied to data that is available in Ehrmann *et al.* (51). The VAS at least attempts to be quantitative. Just as there is no absolute measurement for pleasure, there is no absolute measurement for pain. Pain still remains a subjective response on the patient's part to a stimulus. An approximation of this scale to more subjective categories of pin severity is given below.

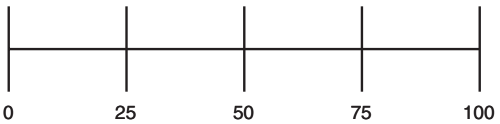


**Figure 1** The VAS pain scale.

## The pain (or visual) analogue scale – VAS

0–24 No pain to mild pain, requires no pain killer.
25–49 Moderate pain requires Aspirin, Paracetamol, Ibuprofen, or similar medication for relief.
50–74 Severe pain not relieved by above medicaments necessitating use of narcotic analgesics such as Codeine-containing preparations, e.g. Panadeine
75–100 Extreme pain, pain not relieved by any measures taken.

Figure 1 is a horizontal representation of the pain scale.

## Materials and methods

### Ethics approval and informed consent

The outline of this clinical trial was approved by the Ethics in Clinical Research Committee of the Royal Dental Hospital of Melbourne. The trial was explained to patients who signed a form agreeing to treatment.

This investigation was confined to teeth that were nonvital and painful. All patients presenting for treatment were included in the trial provided the tooth was functional and the patient was willing to undergo endodontic treatment. Teeth with a fluctuant facial swelling were not accepted because it was felt that relief is often obtained simply by incision and drainage. Full details of the 221 patients have been reported previously (Ehrmann *et al.* 51).

At the initial visit the following conditions were recorded: presence or absence of mild swelling, sensitivity to percussion, presence of a periapical lesion, previous

treatment, presence or absence of a coronal restoration/seal, administration of a preoperative analgesic or antibiotic. Before commencing treatment, the aims of the study were explained to the patient and their consent was obtained. When the patient so requested, a local anaesthetic was administered. All caries and all suspicious restorations were removed and were replaced with intermediate restorative material (IRM). Most posterior teeth were banded with stainless steel bands particularly where caries had extended subgingivally. The tooth was isolated under rubber dam, access was obtained and the canals were measured and instrumented using the step back technique. Throughout the treatment teeth were irrigated with Milton's solution (1% sodium hypochlorite) alternating with 15% EDTAC. At the conclusion of treatment the canals were dried and were medicated with one of the following medicaments randomly selected using a random numbers table.

**1.** Group 1 – Ledermix paste (Riemser Arzneimittel Wolfsratshausen, Germany).
**2.** Group 2 – Calcium hydroxide paste.
**3.** Group 3 – No dressing; the canals were left empty.

Ledermix and calcium hydroxide were inserted into the dried root canal by means of a file that was at least two sizes smaller than the file last used to approximately two millimetres of the apex. Cavities were sealed with either IRM or Cavit. At the conclusion of each appointment, each patient was handed an evaluation sheet and the VAS was explained to the patient. In consultation with the patient, the pain score for the previous night was recorded. The patient was then requested to record the pain score 4 h after the completion of treatment and then daily for a further four days.

No antibiotics were prescribed and where patients had been taking antibiotics this was recorded. Patients were then requested to stop taking the antibiotics. They were also requested to stop taking analgesics, with the proviso that if pain were to persist or recur analgesics could again be taken. Prior to the trial, nine vital painful teeth (irreversible pulpitis) were treated according to the above criteria. It was found that all pain either disappeared within 24–48 h regardless of the dressing used or if any pain remained it was of negligible proportions. As a result it was decided to exclude vital painful teeth from the trial.

Originally there were 223 teeth belonging to 221 patients in the trial. However the data from only 195 teeth were analysed. The reasons for the exclusion of 28 teeth were given in the previous paper (Ehrmann *et al.* 51).

## Results

### Changes in pain levels 4 h and 24 h after treatment

Figures 2 and 3 show histograms for each treatment modality, of the *changes* in pain level from preoperative to 4 h and 24 h after treatment. Change was defined so that negative values correspond to an improvement (reduction) in pain level and positive values correspond to an increase in pain level. At both postoperative time periods

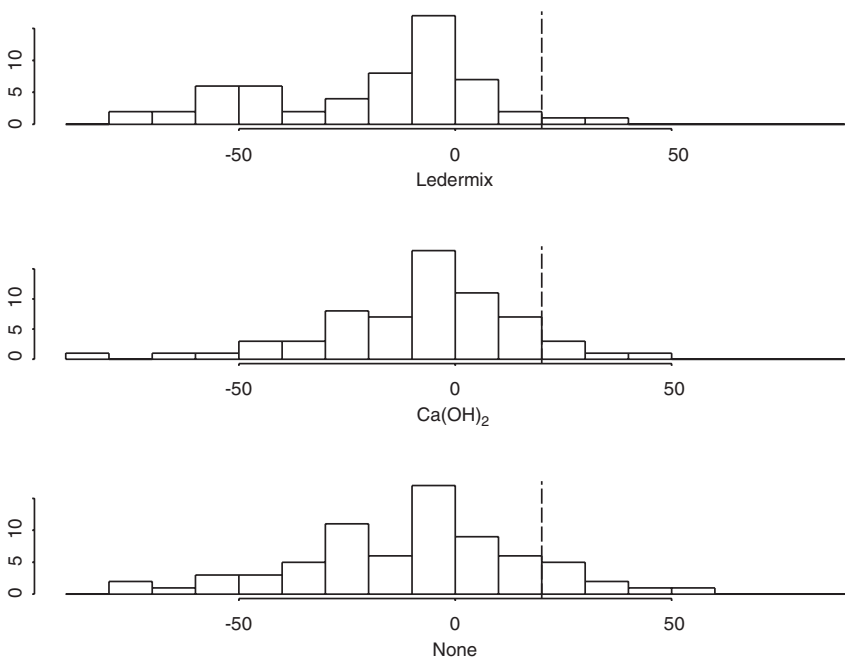


**Figure 2** Change in pain level from preoperative to 4-h postoperative. Vertical dashed line corresponds to the definition of 'flare-up'.

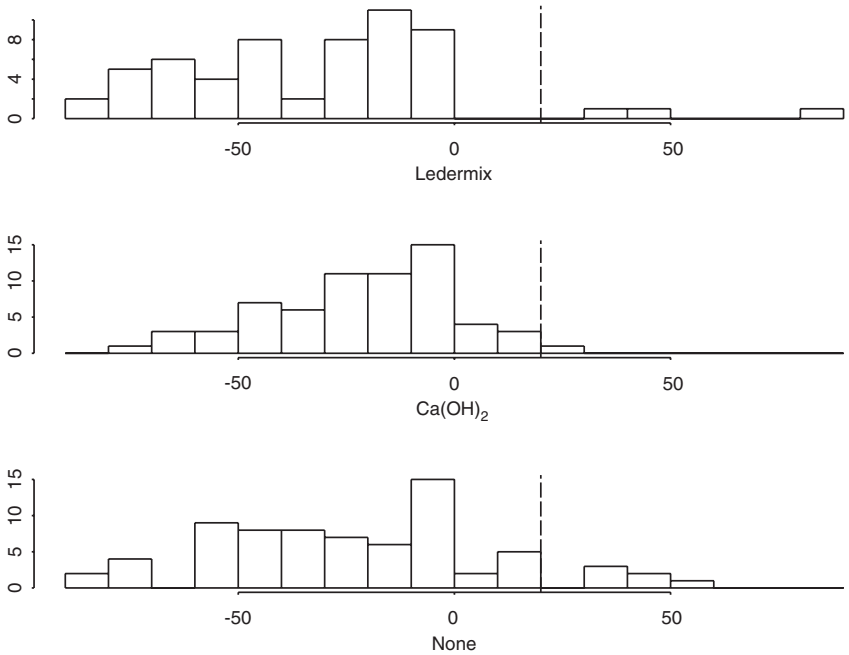


**Figure 3** Change in pain level from preoperative to 24-h postoperative. Vertical dashed line corresponds to the definition of 'flare-up'.

and for all treatment modalities, a wide range in the extent of change was evident (from a reduction of −90 to an increase of +60). The majority of patients recorded a reduction in pain level in all treatment groups. A one-way Analysis of Variance (Table 2) suggested that there were possible differences in the mean change in pain level from preoperative to 4 h ($P = 0.03$). A similar analysis indicated no significant differences from preoperative to 24 h ($P = 0.104$). These significance levels must be treated with caution, since the data are clearly not normally distributed. Accordingly, the nonparametric Kruskal Wallis test was used to compare the median change in pain level in response to the three treatments. A marginally significant ($P = 0.04$) difference in median levels was noted 4 h postoperatively, with the Ledermix group significantly lower by approximately 10 units on the VAS than either the calcium hydroxide group ($P = 0.03$) or the unmedicated group ($P = 0.007$) (Mann–Whitney *post hoc* tests). No differences were observed at 24 h.

The sensitivity of this statistical analysis is measured by the power, which in this case is the probability of correctly detecting a difference in the flare-up rates between the three treatments. This probability depends on the actual (true) flare-up rates. With the large samples available here, the power is relatively high. For example, if the difference in flare-up rates is 15% (5% to 20%, close to the estimated rates) then the power is approximately 0.66.

**Table 3** Incidence of flare-up, 4 h post-operative

| | Treatment | | | |
|---|---|---|---|---|
| | Ledermix | $Ca(OH)_2$ | None | Total |
| No flare-up | 54 | 57 | 60 | 171 |
| Flare-up | 4 | 8 | 12 | 24 |
| Total | 58 | 65 | 72 | 195 |

The corresponding $\chi^2$-statistic was 2.841, with a *P*-value of 0.252.

## Incidence of flare-ups

As noted above a flare-up was defined as an increase in pain level of 20 or more on the VAS, since any smaller increase could be explained by random variability (based on the standard deviations of the residuals in both Analyses of Variance). The incidence of flare-ups at 4 h and 24 h is summarised in Tables 3 and 4. The proposed definition of flare-up is indicated by the dashed vertical line in Figures 2 and 3. The overall incidence was 12.3% at 4 h (24/195) and 6.7% at 24 h (13/195). No significant differences among treatment groups were found at either time period (Chi square test, $P = 0.252$ and 0.161 at 4 h and 24 h respectively).

Flare-up rates and confidence intervals (C.I.) expressed in percentages are to be found in Table 5. All confidence intervals overlap one another, confirming that there are no statistically significant differences in the incidence of flare-up. It will be noted that at 4 h the flare-up rate for

**Table 4** Incidence of flare-up, 24 h post-operative

| | Treatment | | | |
|---|---|---|---|---|
| | Ledermix | $Ca(OH)_2$ | None | Total |
| No flare-up | 55 | 63 | 64 | 182 |
| Flare-up | 3 | 2 | 8 | 13 |
| Total | 58 | 65 | 72 | 195 |

The corresponding $\chi^2$-statistic was 3.840, with a *P*-value of 0.161.

**Table 5** Flare-up rates and 95% confidence intervals (C.I.) expressed in percentages

| | Ledermix | $Ca(OH)_2$ | Nothing |
|---|---|---|---|
| 4 h | 6.9% | 12.3% | 16.7% |
| C.I. | 1.9–16.7% | 5.5–22.2% | 8.9–27.3% |
| 24 h | 5.2% | 3.1% | 11.1% |
| C.I. | 1.1–14.4% | 0.4–10.7% | 4.9–20.7% |

Ledermix was 6.9%, which was less than that for calcium hydroxide or for no dressing, but not significantly different. This is in accordance with the work of Abbott *et al.* (52) who found that the rate of release of triamcinolone into the tissues from the tooth was highest during the first 3–8 h and declined exponentially thereafter and Ehrmann *et al.* (51) who found that the efficacy of Ledermix was most marked at 4 h postoperatively.

## Discussion

It has been observed that when the pain is either nonexistent or mild an increase of 20 points in the VAS scale of pain would still only be in the category of no or mild pain. Out of 24 cases of flare-ups at 4 h, there were three cases in this category. Their initial pain scores were 0 or 5 and their pain reading at 4 h was 25. A score of 25 is the highest entry for a patient with no or mild pain. However it is also the lowest entry for a case where the pain is moderate and an analgesic is required. Out of 13 flare-up cases at 24 h there was one case with an initial score of 5 and a final score of 25. The same remarks as above would apply in this case.

For many years, it was common practice to provide emergency relief in the case of an acute abscess by leaving the canal open (Sommer *et al.* 53, Siskin 54). As late as 1988 this was still being advocated by some authors (Grossman *et al.* 55). None of the studies cited in this paper have advocated this course of action. Leaving a canal open introduces more organisms into an infected tooth thus negating all principles of modern endodontics which strive to eliminate bacteria from the root canal system. Any benefit in terms of relief of pain achieved by this procedure is out-weighed by the problem of further contamination of the canal space.

Another unusual finding was that by Peters (36) who reported that postoperative pain frequency for patients treated in one appointment was higher (16%) than patients treated in two appointments (9.6%). Most other studies (Albashaireh and Alnehrish (3), Eleazer and Eleazer (8), Fox *et al.* (56)) found that one-visit treatments resulted in less pain than those taking two visits. Again, use of standardised scoring systems would allow a better comparison among studies.

While it is not the focus of this study, the management of flare-ups or their prevention also merits brief mention. In order to reduce pain and swelling after an endodontic intervention many practitioners prescribe antibiotics. This is somewhat controversial. One study by Mata *et al.* (25) found that the administration of penicillin V at the first visit and continued for one week thereafter resulted in less pain than a placebo. A case was designated as a flare-up when the patient had pain and/or swelling that necessitated an unscheduled emergency visit. In another very similar study, Abbott *et al.* (52) compared the efficacy of penicillin V with that of erythromycin and found no difference. They both were said to lower the incidence of flare-ups. In a third study, Morse *et al.* (30) compared cefadroxil with erythromycin and a low (2%) flare up rate was claimed. Controls were only used in the first paper cited. They were not used in the later papers.

The opposite view was held by Walton and Fouad (47) who found no statistical difference in pain experience when antibiotics had been used. However their definition of a flare-up differed from those reported by Morse and his group. Patients who called their practitioner with a problem were asked to report to the clinic immediately. A decision was then made whether active treatment was necessary. Simply talking to the patient and prescribing or dispensing medication did not constitute a flare-up. A flare-up was recorded only when treatment was carried out. As their definition of a flare-up is different from that of Morse, their results are not strictly comparable. In another study Walton and Chiappinelli (48) were able to confirm their earlier findings that systemic penicillin does not alter the pain experience. What is of great interest is that they used the occurrence of an unscheduled appointment as a measurement of a flare-up and the visual analogue scale to measure pain. The two are clearly related and it would be simpler if the VAS were to have been used to record both pain and a flare-up.

With regard to the VAS it must also be realised that when no preoperative pain is present, an increase of 20 points in the VAS is not very significant as such pain is still only mild and does not require an analgesic.

## Conclusion

A reasonable definition of a flare-up would be an increase of 20 or more points on the Visual Analogue Scale. A statistical analysis of pain data from 195 cases showed that the use or type of intracanal medicament did not alter the frequency of flare-ups. Hence there was no difference in the flare-up rates at 4 h or 24 h between Ledermix, calcium hydroxide or no dressing. Further research is required using the above definition of a flare-up and standardising treatment protocols.

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