An investigation of the relative efficacy of Buckley's Formocresol and calcium hydroxide in primary molar vital pulp therapy

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Objective To compare the clinical and radiological outcomes following two different, single visit vital pulp therapy techniques, in cariously exposed primary molar teeth.
Setting A paediatric dental clinic within the Dental Hospital, Newcastle upon Tyne, UK.
Subjects Fifty two child patients were sequentially enrolled in the clinical investigation, 26 males and 26 females with an age range of 3.3–12.5 years. Primary molar teeth requiring vital pulp therapy were randomly allocated to either the formocresol group (F) or the calcium hydroxide group (C). The total number of teeth treated was 84.
Design Recruitment was on the basis of strict inclusion criteria. Coronal pulp amputation was prescribed only in teeth with vital, cariously-exposed pulp tissue. Treatment was undertaken between October 1994 and December 1996. All cases were reviewed using predefined clinical and radiological criteria. The statistical tests used were logistic regression of a triple nested data structure, chi-squared analysis of equality of treatment and probability of success with relation to subject age.
Results Eighty four cariously-exposed primary molars required vital pulp therapy. Forty six (55%) teeth were included in the F group and 38 (45%) allocated to the C group. Five teeth were lost to follow-up, leaving 79 teeth: forty four (56%) in group F and 35 (44%) in group C. Eighty four percent (37/44) of teeth treated with formocresol and 77 percent (27/35) treated with calcium hydroxide were classed as clinically and radiographically successful at the cut-off date, December 1997, after a mean clinical review of 22.5 months (range 6.1–38.5 months) and a mean radiographic review of 18.9 months (range 1.3–36.9 months).
Conclusion This investigation confirms the clinical efficacy of a one-fifth dilution of Buckley's Formocresol as an agent in pulp treatment of cariously exposed, vital primary molar teeth. However, calcium hydroxide in its pure, powder form is a clinically acceptable alternative when combined with strict selection criteria for this method of restorative care. There was a statistically insignificant difference in successful clinical and radiological outcome between the two treatment groups. Success was unrelated to the duration of time taken to achieve haemostasis and the presence or absence of bleeding after placement of the medicament.

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Restoration of primary molar teeth damaged by dental caries is an important part of paediatric dentistry. From data derived from the UK survey of child dental health[1] 40% of five-year-olds and 50% of eight-year-olds had dental caries in primary molar teeth. In the case of pre-school children, the National Diet and Nutrition Survey[2] showed 17% of children aged between 1.5 and 4.5 years had experienced some dental caries. Of those children with dental caries, decay involving the pulp occurred in 0.7 teeth per child. Of these children the mean number of teeth with pulpal involvement was 2.9.

If a carious primary molar tooth remains untreated or inadequately treated, bacterial invasion of the coronal pulp will occur, producing an inflammatory response in the coronal pulp. At this stage pulp inflammation is often confined to the coronal pulp and if the affected tissue is removed and the radicular pulp stumps dressed with an appropriate agent, the remaining tissue has the capacity to recover. This facility to recover is used when cariously-exposed vital primary teeth are treated by vital pulp therapy. In a recent review,[3] the outcomes following vital pulp therapy were broadly classed as devitalisation, preservation and regeneration of the remaining pulp tissue. The outcome obtained was said to be dependent upon the agent or pulp medicament used to treat the radicular pulp stumps. There appears to be no consensus as to the best method of optimizing pulp tissue recovery.

If the infected coronal pulp remains, micro-organisms invade the radicular pulp resulting in irreversible pulpitis and necrosis. At this stage the radicular pulp is unable to recover. Complete removal of the infected, inflamed pulp (pulpectomy), or tooth extraction are indicated.

The aim of pulp therapy for carious primary molar teeth is to conserve the damaged tooth in order to maintain it. Successful treatment of pulp tissue will reduce the potential for unwanted sequelae from the unplanned extraction of primary molar teeth.

Buckley's Formocresol

A recent review of Buckley's Formocresol[4] used as a primary molar pulpotomy medicament, showed the agent to have a long history of clinical success in vital primary pulp therapy, ranging from 55–98% over time periods ranging from 1 to 87 months. The use of a one-fifth dilution of this formulation appeared to be equally effective.[5]

Formocresol contains formaldehyde, a toxic, potentially carcinogenic/mutagenic compound, and concern has arisen over its use in dentistry.[6,7] Evidence of local and systemic distribution exists to support these concerns.[8–10] As a consequence, other medicaments have been evaluated. Alternative techniques and pulp therapy agents include glutaraldehyde,[11] calcium hydroxide,[12,13] electrosurgery,[14] lasers,[15] ferric sulphate,[16] collagen solutions and bone morphogenic proteins.[17]

Calcium hydroxide

The results from published data on the degree of clinical success using calcium hydroxide for vital pulpotomies are equivocal.[14]

Schröder[12,18] emphasized the importance of avoiding a blood clot between the amputation site and the calcium hydroxide for clinical success. With calcium hydroxide, the problem seems not of systemic or local toxicity but of adequately controlling pulpal haemorrhage, to permit good contact between medicament and pulpal tissue. This seems, from the evidence available, to be important in the prevention of internal resorption, post-pulpotomy.[13,19]

The aim of this study was to compare clinical and radiographic outcomes in cariously-exposed primary molar teeth assigned to either formocresol or calcium hydroxide single-visit pulpotomy technique.

Materials and Methods

Sample

Ethical approval was granted by the Combined Ethics Committee for Newcastle and North Tyneside Health Authorities and the University of Newcastle. Child patients attending for routine care were recruited from the Department of Child Dental Health, Newcastle Dental Hospital.

Patient Assessment

Children with at least one carious primary molar tooth were assessed for inclusion into the study. Initial assessment included a review of medical and dental histories, details of any presenting complaint, followed by clinical and radiographic examination.

If there was radiographic evidence of caries close to the pulp or involving pulp horns, the treatment and aim of the study were explained to the parent and child. An information sheet and a consent form were issued. The child was enrolled into the trial after receipt of a signed consent form from the parent/guardian.

Inclusion Criteria

For a child to be included in the study, the following criteria had to be met:

- Patient co-operation
- Parental co-operation (indicated by the signed consent form)
- Absence of a medical condition which would contraindicate pulp therapy
- Absence of clinical signs or symptoms suggesting a non-vital tooth such as a suppurating sinus, soft tissue swelling, mobility or tenderness to percussion
- Absence of symptoms indicative of advanced pulpal inflammation and poor prognosis for vital pulpotomy, such as spontaneous pain
- Absence of radiographic signs of pulp necrosis i.e. apical or furcal radiolucency or advanced physiological root resorption.

The Clinical Technique

Forty six carious primary molars were included in group F (formocresol). The teeth were treated by coronal pulp amputation followed by a five minute application of a 20% Buckley's Formocresol solution to radicular pulp stumps (19% formaldehyde, 35% tricresol, 15% glycerin, 31% water, supplied by the Pharmacy Department, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne, UK) .

Thirty eight carious primary molars were included in group C (calcium hydroxide). The teeth were treated by coronal pulp amputation followed by placement of AnalaR Calcium Hydroxide powder, containing 99% calcium hydroxide, (Sigma-Aldrich Chemical Company Ltd, Poole Dorset, UK) to the radicular pulp stumps.

Procedure

Allocation to the F or C group, was randomised by the toss of a coin. In the case of any subsequent vital pulp therapy, for example of the antimere, the alternative medicament was used to allow direct comparison of each medicament within the same mouth, providing the tooth in the F group with a positive control. If the antimere was present and did not require vital pulp therapy it was recorded as the negative control.

Wherever possible, radiographs were standardized with the use of paralleling views by a staff radiographer. Alternatively, if the radiographer was unable to use this technique, bite-wing or panoramic views were used.

Topical anaesthesia was achieved with 20% benzocaine gel (Xylonor gel, Septodont Incorporate, Newcastle, Delaware, USA) before 2% lignocaine with 1:80 000 adrenaline local anaesthetic solution was administered (Astra Pharmaceuticals Ltd, Kings Langley, UK).

Isolation was achieved with rubber dam or cotton wool rolls and saliva ejection. The method of isolation depended upon patient compliance. Cavity outline was established at high speed with a water-cooled air rotor and round and fissure diamond burs. Caries was removed with slow-speed air turbine and round steel burs. Pulpal exposure was deemed present if pulpal haemorrhage could be seen, access to the pulp chamber could be detected with a probe, or if the roof of the pulp chamber was sufficiently thin to see pulpal tissue, indicative of probable bacterial contamination.

If pulpal exposure was confirmed, the pulp chamber was entered and the roof removed with a sterile, non-end cutting slow-speed bur (Batt cone bur ISO 016, Mailleffer Instruments SA, 1338 Ballaigues, Switzerland). Sterile, physiological saline was delivered by syringe and needle to wash away dentine debris.

Coronal pulp amputation was achieved with small and medium slow-speed sterile round burs, taking care to avoid cutting the pulp chamber floor. The remaining pulp tissue was excavated with sterile excavators and the chamber irrigated with sterile, physiological saline. Haemorrhage was controlled using sterile pledgets of dry cotton wool and pressure. The time taken from removal of the roof of the pulp chamber to cessation of bleeding was recorded as the bleeding time.

Group F

A sterile pledget of cotton wool was placed in 20% solution of Buckley's Formocresol and immediately blotted dry on sterile gauze. The pledget was placed directly over the radicular pulp stumps and covered with dry cotton wool, to avoid seepage of the agent from the cavity. The cotton wool was removed after 5 minutes. If pulpal haemorrhage occurred after placement of the medicament ('post-placement' haemorrhage), this was gently blotted with a sterile cotton wool pledget and its occurrence recorded.

Group C

Calcium hydroxide powder was delivered to the pulp chamber using a small, sterile endodontic amalgam carrier ('PD' Messing root canal gun, Produites Dentaires SA., Vevey, Switzerland). The powder was gently packed over the pulp stumps with an amalgam condenser and small pledgets of cotton wool. Excess agent was removed with an excavator. If post-placement pulpal haemorrhage occurred through, or around the sides of the packed powder, this was gently blotted with a sterile cotton wool pledget and its occurrence recorded.

Groups F and C

A 3–4 mm thick lining of zinc oxide-eugenol cement (Kalzinol DeTrey, Konstanz, Germany) was placed, to seal the coronal pulp chamber, and allowed to set. The tooth was restored with amalgam (Dispersalloy Dentsply International Incorporate, Milford, D.E. USA), glass-ionomer cement (Ketac-Fil Aplicap ESPE, Dental-Medezin GmbH and Company K.G., Seefeld, Germany) or compomer (Dyract DeTrey, Konstanz, Germany). A pre-formed

stainless steel primary molar crown (Ion 3M Dental Products, Loughborough, Leicestershire, UK) was placed, if indicated. Occlusal contacts were checked and adjusted where necessary.

Details of each pulpotomy were entered in code onto a data form. A separate sheet was completed for each tooth treated and the sheets were stored separately from the clinical records. The same data form was used to record coded details of findings at subsequent clinical and radiographic reviews.

Review

Patients were reviewed where possible, at six-monthly intervals until two years. At two years post-pulpotomy the patients were assessed annually until exfoliation of test, positive or negative control teeth occurred. Review radiographs were obtained for both the test and control teeth after six, twelve and twenty four months and annually thereafter. Teeth were terminated from the study because of either exfoliation, extraction and finally when the clinical and radiographic reviews ended in December 1997.

Assessment

Control and test teeth were reviewed by one operator (PJW) for the presence or absence of the following findings. Objectivity was maximised during both clinical and radiographic assessment, by not having direct access to records detailing which pulp therapy agent was used.

Clinical

- Symptoms from the treated tooth reported by the child or parent; spontaneous pain, or pain initiated by stimuli
- Signs of a defective restoration or recurrent caries
- Signs of mobility, sinus formation, tenderness to percussion, soft tissue swelling
- Signs of exfoliation; mobility or signs/symptoms of the successor tooth erupting.

Radiographic

- Defective restoration or recurrent caries
- Periradicular pathology such as periapical, or furcal radiolucency
- Pathological internal resorption, replacement resorption, intracanal calcifications, physiological resorption
- Position and eruption pathway of the permanent successor tooth.

If treatment failed, clinical and radiographic reasons were documented on the data form. Treatment failure was said to have occurred if the test tooth showed either clinical signs or symptoms of infection with or without radiographic signs of infection. If the tooth was extracted, the time lapsed since pulpotomy was recorded and the tooth immediately preserved in 10% formal-saline, for later histological examination (reported elsewhere). If a tooth exfoliated during the review period, the parent was asked to place the tooth immediately into a pre-dispensed formal saline solution and deliver the specimen at the following review.

Results

Fifty two patients were involved in the investigation (26 female and 26 male). Eighty four teeth were treated by vital pulp therapy, with a total of 53 controls. Fifty first primary molar teeth were treated compared with 34 second primary molar teeth. Forty-six teeth were treated with formocresol and 38 teeth with calcium hydroxide. However, 5 treated teeth from 3 patients were lost to follow-up, leaving 44 in group F and 35 in group C. Forty four test teeth in total had untreated controls, (ie teeth treated by pulp therapy). In group F, 24 teeth had untreated (negative) controls and 12 teeth in group F had positive controls, which underwent treatment with calcium hydroxide. Eight teeth from group C had no control; 20 had untreated (negative) controls, 12 had positive controls and 3 teeth did not have controls present.

Four control teeth were extracted before the child was enrolled into the study and 2 control teeth were extracted less than 30 days after pulp treatment of the antimere. Therefore, including these teeth in the overall number of teeth lost to the investigation, 9 untreated teeth and 5 treated teeth were lost from 9 patients.

Pre-operative radiographs

Pre-operative radiographs were taken for 78 teeth. One child refused radiographic examination. From radiographs in group F, 96% of teeth were diagnosed carious and 11% of teeth also showed radiographic evidence of early physiological resorption. Radiographs in group C showed 97% of these teeth to be carious, with one tooth showing evidence of physiological resorption.

Clinical and radiographic reviews

The mean review periods for both clinical and radiographic outcomes were 22.5 and 18.9 months respectively (range 6.1–38.5 months and 1.3–36.9 months respectively). The combined outcomes at the last review for each tooth, are detailed in Table 1. Eighty four per cent of teeth treated with formocresol and 77 percent of teeth treated with calcium hydroxide were clinically and radiographically successful. Data from the 6 month and 12 month clinical review are shown in Table 2. At 6 months, the clinical success for formocresol-treated teeth and teeth treated with calcium hydroxide were 71% and 69% , respectively. Both cohorts had records missing for this review; 16% and 26% respectively. At 12 months clinical success rates were seen of 68% and 80% respectively, 14% of teeth treated with formocresol were not seen at this time.

The diagnoses made at the 12 month radiographic assessment are shown in Table 3.

Table 1 Clinical and radiological outcomes at last review for teeth treated with 20% Buckley's Formocresol Solution and AnalaR calcium hydroxide powder.

Treatment Group	Clinical Success	Radiographic Success	Percentage of teeth (n)
Group F	✓	✓	81.8 (36)
	✓	×	9.1 (4)
	✓	×	9.1 (4)
	×	×	6.8 (3)
	×	✓	2.3 (1)
Group C	✓	✓	77.1 (27)
	✓	×	11.4 (4)
	×	×	11.4 (4)

Key: Group F, Buckley's Formocresol solution; Group C, AnalaR calcium hydroxide powder.

A comparison was made between those teeth treated with formocresol which had antimeres treated with calcium hydroxide as positive controls. Of the 12 teeth included in this group, 100% of those treated with formocresol were clinically and radiographically successful. Ten of the 12 teeth treated with calcium hydroxide were successful (83%). Two teeth from this latter positive control group were classed as failures, one tooth requiring extraction because of tenderness to percussion and furcal pathosis. Statistical analysis showed no significant difference in the proportion of successful outcomes of teeth from Group F or Group C. The chi-square test for independence of group and outcome gives a value of 0.61 on 1 degree of freedom, with a P-value of 0.42. There was no difference in the success rates between the two treatment groups when assessed within their broad groups.

Termination

Teeth were terminated from the study because of extraction or exfoliation. In both groups, more teeth exfoliated than were extracted

Table 2 Clinical outcomes at six and twelve months after treatment.

	Percentage of teeth (n) Diagnosis								
Treatment	NAD	Mobility	Sinus	Swelling	Leaking restoration	Caries	Tooth absent	Diagnosis unrecorded	Total Healthy (%)
F6	70.5 (31)	4.5 (2)	2.3 (1)	—	2.3 (1)	6.8 (3)	6.8 (3)	15.9 (7)	75.0 (33)
F12	54.5 (24)	13.6 (6)	—	—	—	—	18.2 (8)	13.6 (6)	68.1 (30)
C6	68.6 (24)	5.7 (2)	—	—	—	—	—	25.7 (9)	74.3 (26)
C12	71.4 (25)	8.6 (3)	—	2.9 (1)	2.9 (1)	—	8.6 (3)	8.6 (3)	80 (28)

Key: F6 and F12 = Group F at 6 and 12 months resp. C6 and C12 = Group C at 6 and 12 months resp. NAD = nothing abnormal detected. Healthy = absence of signs or symptoms of infection or failure of coronal restoration. A tooth may have more than one clinical outcome.

Table 3 Radiographic outcomes at twelve months after treatment.

	Percentage of teeth (n) Diagnosis							
Treatment	NAD	Caries	Physiological resorption	Periradicular radiolucency	Internal resorption	Intrapulpal calcification	Film not taken	Tooth absent
F12	15.9 (7)	—	20.5 (9)	4.6 (2)	2.3 (1)	—	40.9 (18)	18.2 (8)
C12	17.1 (6)	2.9 (1)	8.6 (3)	5.7 (2)	5.7 (2)	17.1 (6)	42.9 (15)	8.6 (3)

NB: A tooth may have more than one radiographic outcome.
Key: F12 and C12 = Group F and C at 12 months respectively. NAD = nothing abnormal detected.

(n=20 and n=7 respectively). Seven per cent (n=3) of teeth in the F group and 11% (n=4) in the C group were terminated due to clinical and radiographic failure. One tooth from the F group 'exfoliated' because of internal resorption. For the 3 teeth extracted in Group F, 2 were diagnosed with a sinus and furcation radiolucency and 1 tooth was very near to exfoliating and extraction was requested. In Group C, 2 teeth were tender to percussion and had furcation radiolucency, 1 had gingival swelling and periapical radiolucency and 1 was tender to percussion and carious. The treatments do not differ significantly in the proportion of exfoliated teeth. The chi-square test for independence of group and outcome gives a value of 0.31 on 1 degree of freedom with a P-value of 0.58. Overall, significantly more teeth exfoliated than were extracted, chi-square = 6.26 on 1 degree of freedom, P = 0.012.

Haemostasis

The mean bleeding time and (s.d.) for the 64 'successful' teeth was 6.4 minutes (3.19), compared with 6.9 minutes (3.22) for those teeth classed as failures (15 teeth). Analysis of the effect of bleeding time upon outcome by logistic regression showed strongly skewed data. The skew was reduced by converting to log (variable +1), showing that bleeding time was statistically insignificant with respect to outcome, (P = 0.57).

Thirty one teeth in group F, and six in group C, bled post-placement of the medicament. A total of 37 teeth showed evidence of post-placement bleeding with a mean bleeding time of 6.6 minutes (range 2–15), prior to placement. Forty two teeth did not bleed after placement of the medicament and had a mean bleeding time of 6.4 minutes (range 1–15) prior to placement of the medicament. Statistical analysis of post-placement bleeding showed its presence or absence to be statistically insignificant upon treatment outcome. The chi-square test for independence of treatment and post-placement bleeding gives a value of 2.34 on 1 degree of freedom with a P-value of 0.126.

Discussion

Pre-operative assessment of both patient and oral status is important before embarking upon restorative treatment. This involves consideration of the inclusion criteria listed earlier and pre-operative radiographic assessment. Pre-operative radiographs were prescribed for all children before enrolment. One child refused to cooperate for radiographic examination, but accepted pulp therapy. However, it is important to assess carious teeth radiographically as caries may be more advanced than the 'clinical picture' suggests. Furcation involvement, for example, would be a contraindication to treatment.

A greater number of teeth were treated with a one-fifth dilution of Buckley's Formocresol (N = 46) than AnalaR Calcium Hydroxide powder (N = 38) because of the random allocation. Five teeth, 2 from Group F and 3 from Group C, were lost to follow-up and therefore not included in post-treatment data.

In this study, there appears little difference between the clinical outcomes for both medicaments. When the number of successful outcomes in group F are compared with group C, 37 of 44 teeth from group F (84%) and 27 of 35 teeth from group C (77%) were classed as both clinically and radiographically successful. This decision was taken at the last review each tooth received and corresponds to the review periods detailed earlier. The minimum review at the end of the study was one year.

Successful outcome from treatment of a tooth was ascertained by both clinical and radiographic analysis. At the 6 and 12 month review periods not all patients were examined (Table 2). This resulted in data being 'unrecorded'. However, these teeth were seen at least at a time after 6 or 12 months. If a tooth was not reviewed clinically up to at least 6 months then it was classed as lost to follow-up.

From the literature, formocresol appears clinically and radiographically more successful compared with calcium hydroxide. The success rate of 84% for Group F in our study, compares favourably with previous studies using formocresol,[4] however, results obtained using calcium hydroxide in the present study show greater success than previous work.[12,13,19] This may be because of the strict selection criteria employed, the nature of the calcium hydroxide in its pure powder form providing close apposition of powder and pulp tissue, compared with relatively hydrophobic proprietary preparations. It is, however, difficult to compare previous studies of calcium hydroxide, both against each other and against this study because of the wide range of preparations used.[4] Care must also be taken in the comparison of previous work involving Buckley's Formocresol, because it too is subject to variation.[20]

Teeth involved in the investigation were terminated either due to extraction following failure or loss due to exfoliation. A greater number of teeth failed in group C compared with group F, although numbers were small and the difference statistically insignificant (Table 1). The reasons for failure, ascertained by both clinical and

radiographic criteria, were due to signs and symptoms of infection. Not all teeth classed as failures required extraction. For example; a tooth could be classed as clinically successful, with absence of clinical symptoms but showing radiographic evidence of a widened periodontal membrane space, and thus be classed as a radiographic failure.

It is generally thought that the longer an amputated pulp takes to cease bleeding, the more inflamed the radicular pulp tissue. To investigate this, the time taken for each amputated pulp to stop bleeding was recorded. The teeth classed as either clinically and/or radiographically unsuccessful bled for a mean time of 6.9 minutes, whereas 'successful' teeth bled for 6.4 minutes. This difference is statistically insignificant. The time recorded for each tooth pulp to stop bleeding was probably affected by the ability of the operator to achieve thorough coronal amputation. If coronal remnants remain, bleeding may persist longer. Teeth showing post-placement bleeding did not display a statistically significant increase in bleeding time.

Relatively little post-placement bleeding was seen with calcium hydroxide (6 teeth) compared with 30 teeth treated with formocresol. A one-fifth dilution of Buckley's Formocresol may have a lower styptic ability than full-strength solution, furthermore, the calcium hydroxide powder may serve to 'soak-up' unclotted blood. Thirty teeth treated with formocresol bled after removal of the medicament-moist cotton wool and one would expect therefore, a lower success rate than that of 84%, because the inability to stop bleeding is thought an empirical marker of irreversible pulpal inflammation.

Internal resorption has been cited as an unwanted outcome from vital pulp treatment using calcium hydroxide, from studies involving review periods from 1–60 months.[4] This was not substantiated in this study, but the longest radiographic review was 37 months. Two teeth in group C and 1 tooth in group F were diagnosed as having internal resorption.

The assessment of radiographs in this study were undertaken by one operator in the clinical setting, because of this the radiographic interpretation may be subjective. To validate the radiographic results, a parallel study was undertaken by two examiners in order to assess both intra-examiner (in two film viewing conditions) and inter-examiner variability. Predefined diagnostic codes were used whilst viewing 121 unidentified long-cone periapical films derived from the main study. Results showed that there was no significant difference in the two lighting conditions used to view the films. Furthermore, inter-examiner agreement for the use of the predefined codes was good (77 %).

Conclusion

This investigation confirms the clinical efficacy of a one-fifth dilution of Buckley's Formocresol as an agent in pulp treatment of cariously exposed, vital primary molar teeth. However, calcium hydroxide in its pure, powder form is a clinically acceptable alternative when combined with strict selection criteria for this method of restorative care.

Successful outcome in vital pulp therapy procedures may be more dependent upon correct diagnosis of the inflammatory state of the remaining radicular pulp. Once coronal pulp amputation has been achieved, the absence of irreversible inflammation in the radicular pulp may dictate the long term clinical outcome. Formocresol is perhaps more obtundent of an inflamed pulp, even as a 1:5 dilution, as its action upon pulp tissue serves to devitalise and fix it, therefore pulpal status is not crucial. However, the status of radicular pulp tissue may have more bearing upon the clinical outcome following calcium hydroxide pulp therapy, since this agent relies on the tissue itself being able to recover sufficiently to heal, with or without the formation of a calcific barrier. Therefore, calcium hydroxide may be more technique sensitive than formocresol.

In addition to the inflammatory status of radicular pulp tissue at the time of treatment, the subsequent provision of an adequate coronal restoration, providing effective coronal seal, is thought to be important to a successful outcome. The impact of coronal restoration was not considered in this report as the number of leaking restorations detected was small (Table 2).

On the basis of the favourable clinical outcome of the calcium hydroxide vital pulp therapy technique described here, it appears that the agent, in its pure powder form, may be used as an alternative to a one-fifth dilution of Buckley's Formocresol Solution. However, it is recommended that future comparative studies involving calcium hydroxide powder are undertaken to consolidate our data before calcium hydroxide powder is unequivocally advocated.

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