
Endodontic complications after plastic restorations in general practice

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Abstract

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Aim To test the hypothesis that dentine and pulp protection by conditioning-and-sealing is no less effective than using a conventional calcium hydroxide lining.

Methodology A cohort of healthy adults requiring a new or replacement restoration in a posterior tooth was recruited in six general practices. All procedures received local Ethics Committee approval. Exclusion criteria included signs and symptoms of pulp necrosis or inflammation, and patients unable to commit to a long-term trial. Cavity preparations were randomized to receive a calcium hydroxide lining or conditioning-and-sealing with a smear-removing bonding system. Choice of bulk restorative material (composite resin or amalgam) was at the discretion of the dentist. The key outcome measure was evidence of pulpal breakdown identified at unscheduled (emergency) or scheduled recall examinations. Postoperative sensitivity was recorded on 100 mm VAS at 24 h, 4 days and 7 days. Pulp status was assessed at 6, 12, 24 and 36 month recall, and at any emergency recall appointment. The relationship between pre-treatment and treatment variables and pulp breakdown was assessed by logistic regression ($P = 0.05$).

Results A total of 602 teeth were recruited, with comparable numbers of cavities lined (288, 47.8%) or conditioned and sealed (314, 52.2%). The majority (492, 81.7%) were replacement restorations, and amalgam was the most common bulk restorative material

(377, 62.6%). A total of 390 (64.8%) restored teeth were reviewed at 6 months, 307 (51%) at 12 months, 363 (60.3%) at 24 months, and 279 (46.3%) at 36 months post-restoration. Sixteen cases of pulp breakdown were identified within 36 months of restoration placement, 11 presenting as emergencies and five detected at routine recall examination. Logistic regression showed that preoperative pain, cavity treatment by lining or conditioning-and-sealing and the use of rubber dam isolation had no association with pulp breakdown. Pulp breakdown was associated with deep or pulpally exposed cavities ($P < 0.001$, odds ratio 7.8) and with composite rather than amalgam restorations ($P = 0.001$, odds ratio 2.13). Re-coding to identify teeth with pulp exposures revealed that pulpal exposure was the key determinant of adverse pulp outcomes ($P < 0.0001$, odds ratio 28.4) and that composite resin restorations were again more likely to be associated with pulp breakdown than amalgam ($P = 0.017$, odds ratio 3.92).

Conclusions Considered within the context of routine primary dental care,

- Dentists can be confident that pulps will be equally well protected from post-restorative breakdown up to 36 months by calcium hydroxide lining and conditioning-and-sealing with adhesive resins.
- Residual dentine thickness appears to be a key determinant of pulp responses after restorative dental treatment.
- In deep and pulpally exposed cavities in posterior teeth, composites were associated with more pulpal breakdown than amalgams.

Keywords: conditioning dentine, general practice, plastic restorations, pulp breakdown.

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Introduction

Inflammation develops in the pulps of teeth following dental caries, cavity preparation and restoration (Mjör

2001, Mjör & Ferrari 2002). Traditionally, clinicians have concluded that after the insults of cariogenic microorganisms and mechanical caries removal, pulps were vulnerable to chemical irritation from restorative materials themselves, or from acidic etching and conditioning agents applied to dentine (Browne & Tobias 1986). Postoperative sensitivity which followed the insertion of a plastic restoration was attributed largely to material irritancy or thermal conduction through the bulk restorative material. In an effort to limit thermal and chemical injury, dentists have customarily 'protected' pulps with cement linings or bases (Pickard 1976, Cox *et al.* 1999). Calcium hydroxide-based cements have been particularly popular in this role, and were believed to actively promote the deposition of reactive or reparative tertiary dentine within the pulp (Schröder 1985).

Classical studies by Kakehashi *et al.* (1965) laid the essential groundwork for current concepts of microbial infection and pulp pathosis (Bergenholtz 2000). These have gone hand-in-hand with an understanding of microleakage at tooth/restoration interfaces and the importance of interfacial exchange in dental sensitivity, recurrent caries and pulp irritation (Trowbridge *et al.* 1980, Cox *et al.* 1999, Hilton 2002).

Experimental studies in humans and animals conducted during the last 15 years have shown strong association between pulpal lesions and marginal leakage of bacteria, while acidic etching and conditioning agents and dental restorative materials *per se* have been suggested to cause little or no clinically relevant pulp irritation (Cox & Hafez 2001, Murray *et al.* 2002, 2003).

During the last decade, materials have become available which allow restorative materials to be reliably bonded to dentine (Swift *et al.* 1995). Most contemporary systems seal by hybridizing surface dentine (Nakabayashi *et al.* 1992), and pulp healing has been demonstrated following the use of dentine bonding systems in deep cavities (Cox 1992) and even as direct pulp caps (Heitmann & Unterbrink 1995, Cox *et al.* 1998, Costa *et al.* 2003).

Against this background, many dentists have abandoned the use of traditional lining procedures in favour of cavity conditioning and hybridization to create a resin-sealed surface of 'artificial enamel' (Nakabayashi 2004) prior to restoration placement. However, many remain cautious in extrapolating the evidence of tightly controlled, often non-human studies involving non-carious teeth, to the realities of general dental practice. Further investigations are therefore required to exam-

ine the issues in clinically realistic settings which may test materials and outcomes more harshly than is customary or capable of being modelled in the laboratory.

This report forms part of a single-blind randomized controlled trial conducted in mainstream general dental practice to test the hypothesis that dentine and pulp protection by conditioning-and-sealing is no less effective than using a conventional calcium hydroxide lining. The key outcome measure for this investigation was evidence of pulpal breakdown identified at unscheduled (emergency) or scheduled recall examinations after the placement of plastic restorations in posterior teeth.

Materials and methods

Patient recruitment

The study was conducted by six dentists based in six established general dental practices in the north of England.

All healthy adult patients requiring a new or replacement occlusal or multi-surface restoration in a posterior tooth with a vital pulp were eligible for recruitment.

Only one trial tooth was admissible for each patient.

All documentation and procedures received written approval from the local Ethics Committee responsible for each participating practice, and written informed consent was provided by all participants. All data were collected on standard proformas, designed with the input of health service researchers, a statistician and data entry professionals, and piloted before the trial. Each participating dentist had more than 10 years experience of general practice, and extensive pre-recruitment training was conducted to ensure full conversance with trial procedures and scoring criteria. Pre-trial training included review, piloting and development of trial protocols, information and scoring sheets; practical sessions to ensure commonality of approach in scoring and data entry, and updating from University staff on the optimal handling of restorative materials.

Active patient recruitment extended from 1 August 1999 to 31 July 2001.

Preoperative assessment and exclusion criteria

Preoperative assessment included a review of the medical history; record of patient age and gender; tooth and

cavity to be restored, whether the proposed restoration was new or replacement, reason for restoration placement; clinical and radiographic evaluation of pulp and periapical condition, relationship of existing restoration/caries with the pulp, presence of apical or marginal periodontitis. Pulp vitality assessments at all stages of the trial included stimulation of the tooth with an electronic pulp tester (Gentle Pulse Analogue Pulp Tester; Parkell Inc., Farmingdale, NY, USA), in accordance with the manufacturer's instructions (<http://www.parkell.com>).

Patients with significant medical history which may have placed them at risk from adverse pulp outcomes, evidence of irreversible pulpitis, cervical dentine hypersensitivity, pulp necrosis, apical periodontitis or advanced marginal periodontal disease, in addition to irregular dental attenders and those unable to commit to recalls up to 5 years were excluded from the study.

Restoration placement

After routine cavity preparation according to normal practice procedures and evaluation of cavity class, depth and width, cavities were allocated for lining with a setting calcium hydroxide cement or etching, priming and sealing with a commercial resin bonding system. Allocation for lining or conditioning-and-sealing was randomized, with each dentist adopting the treatment dictated by a sequential list supplied to them by University researchers, which was generated from a random number list in Microsoft Excel (odd number = line, even number = condition and seal). Trial regulations dictated that dentists should use dentine bonding systems which removed the dentine smear layer, and that calcium hydroxide preparations should be setting cements (assessed by submission of product data-sheets to the University-based research directors). Specific materials were not dictated in an effort to enhance the transferability of results.

All materials were applied in accordance with the manufacturer's instructions, and in a manner reflecting routine activity in the participating practices. There was, for example, no specific requirement for dentists to isolate trial teeth with rubber dam unless their routine practice activity and clinical judgement dictated this. Choice of bulk restorative material (amalgam of composite resin) and the particular brand employed was at the discretion of the dentist.

In the case of composite resin restorations, where the cavity was allocated for lining, the walls, but not the floor of the cavity were etched, primed and bonded as part of the composite placement protocol.

Patients were not advised of the cavity treatment they had received.

Postoperative follow-up

Postoperative pain scores were self-recorded by patients on standard 100 mm visual analogue scales (VAS), tagged with descriptors 'no pain' (0 mm) and 'unbearable pain' (100 mm) at 24 h, 4 days and 7 days. Routine recalls for assessment of the restored tooth and its pulpal status were undertaken at 6, 12, 24 and 36 months. Periapical radiographs were exposed at 12, 24 and 36 months post-operatively. Clinical and radiographic findings were entered into standard review proformas. Details of any emergency attendances occurring between scheduled review appointments were recorded on standard proformas. Each trial patient carried a card with details of the study, the tooth involved, and guidance notes for attending dentists in the event of an emergency away from home.

Reports detailing adverse pulpal outcomes (emergency attendances, pulp breakdown identified at recall appointments) were monitored throughout the recruitment period to highlight concerns which might necessitate closure of the trial.

Data processing and analysis

After manual checking of patient-specific proformas and clarification of missing/unclear entries with practitioners, data were professionally entered in duplicate (validated data entry) to a flat ASCII file. After further manual checking and cleaning, analysis was conducted in SPSS version 10 for Windows (SPSS, Chicago, IL, USA).

The representation of individual patient, tooth and treatment variables in pulp breakdown and no pulp breakdown populations were first compared by pairwise chi-squared analysis ($P = 0.05$). Factors associated with pulp breakdown were further investigated by stepwise logistic regression ($P = 0.05$).

Results

Recruitment

A total of 602 teeth were recruited to the trial. Table 1 shows that randomization produced similar numbers of lined and conditioned-and-sealed cavities, while amalgam was the commonest bulk restorative material chosen by the participating general dentists. A total of 109 (18.1%) of the sample restorations were new; the

Table 1 Cavity treatment and bulk restorative material ($n = 602$)

Cavity treatment	Bulk restorative material		Total
	Amalgam	Composite	
Calcium hydroxide lining	193	95	288
Conditioned-and-sealed	184	130	314
Total	377	225	602

overwhelming majority (492, 81.7%) being replacements. A total of 390 (64.8%) restored teeth were reviewed at 6 months, 307 (51%) at 12 months, 363 (60.3%) at 24 months, and 279 (46.3%) at 36 months post-restoration.

Cases of pulp breakdown

Adverse events occurred infrequently during the recruitment period and posed no ethical questions on continued recruitment.

Thirty-nine emergency recalls involving trial teeth were recorded in the 36 months after restoration placement (Table 2). Eleven (28.2%) of these were associated with pulp breakdown (irreversible pulpitis or pulp necrosis requiring pulpectomy or extraction), four occurring within 6 months, four between 7 and 12 months, and three between 13 and 24 months of restoration placement. A further five cases were detected at routine 6 month and two at routine 12 month recall. Details of all 16 cases in which pulp breakdown was identified are shown in Table 3.

VAS records of short-term post-restoration sensitivity showed no relationship with the need for emergency care or pulp breakdown detected at routine review (Table 3). The other pre- and intra-operative variables shown in Table 3 were compared in the two defined populations: those in which pulp breakdown had

been identified, and those in whom it had not. Single variables shown by chi-squared analysis to be more strongly represented in the cohort of pulp breakdown cases, including preoperative pain, deep or exposed cavities, and the placement of a composite resin restoration, in addition to factors with no apparent association such as rubber dam use and cavity lining or conditioning-and-sealing, were employed as covariates in a stepwise logistic regression with pulp breakdown as the dependent variable ($P = 0.05$).

The presence of preoperative pain, cavity treatment by lining or conditioning-and-sealing, and the use of rubber dam isolation had no association with pulp breakdown. Pulp breakdown was more common in teeth with deep or pulpally exposed than moderately deep or shallow cavities ($P < 0.001$, odds ratio 7.8), and in those restored with composite resin than amalgam ($P = 0.001$, odds ratio 2.13).

Re-coding of cavities in which pulp exposure was identified (11 in the whole sample) showed that pulp breakdown was more common in teeth with pulp exposure than in teeth with no visible pulp exposure ($P < 0.0001$, odds ratio 28.4). There was again no association between pulp breakdown and the cavity/exposure treatment (lining or conditioning-and-sealing with adhesive resin), or the use of rubber dam isolation. Composite resin restorations were more commonly associated with pulp breakdown than amalgam restorations in pulpally exposed teeth ($P = 0.017$, odds ratio 3.92).

Discussion

Dental materials and procedures may not always behave identically in the research laboratory, the University clinic and the busy general practice. General dentists may therefore be cautious in extrapolating the outcomes of 'idealized' research and may base many of their clinical decisions on anecdotal impressions of what works for them and their peers until the evidence is sufficient, and sufficiently well communicated to bring about change. Barriers to the implementation of research evidence are recognized in many areas of clinical practice (Barnett 2002, Dean-Baar & Pakieser-Reed 2004). While it is responsible to exercise caution in technology transfer, important developments may diffuse slowly from academia to general practice and patient benefits may be delayed.

One example is the decision to use conventional cement linings or conditioning-and-sealing agents for pulp protection in premolar and molar cavity prepara-

Table 2 Profile of all emergency recalls ($n = 39$)

Presenting pain	Diagnosis
None (10)	Reversible pulpitis (5)
Mild (7)	Irreversible pulpitis (6)
Moderate (9)	Pulp necrosis/acute apical periodontitis (6)
Severe (13)	Lost restoration/part restoration (4)
	Fractured tooth (5)
	Fractured restoration (2)
	High restoration (6)
	Inadequate contact (2)
	Exposed dentine (1)
	Restoration to be modified (1)
	Ill fitting denture (1)

Table 3 Teeth with pulpal breakdown requiring root canal treatment or extraction within 36 months of restoration placement

Presenting pain	Presenting problem	Treatment	Filling material	Cavity treatment	VAS 24	VAS 4	VAS 7	Time (m)	New or replacement	Reason	Pre-op pain	Cav occ	Cav prox	Cav depth	R. Dam	Moisture control
1	1	1	2	2	49	49	13	6*	2	2	2	3	2	2	2	2
3	3	1	1	2	67	53	11	1	1	1	2	1	2	3	2	1
4	2	1	1	1	0	0	0	6*	2	2	1	3	2	2	1	1
4	2	1	1	2	3	3	0	12*	2	2	1	3	2	3	2	1
4	1	1	1	2	MD	MD	MD	9	2	1	2	3	2	4	2	1
4	2	1	1	1	19	27	18	4	2	2	2	2	2	4	2	1
4	2	2	1	1	2	3	1	14	1	1	1	1	2	4	2	1
4	2	1	1	2	8	0	0	12*	2	1	2	2	2	3	2	1
4	2	1	1	2	37	23	4	12	2	1	1	2	2	3	2	1
4	2	1	2	2	20	12	5	6	1	1	2	2	3	3	2	2
4	2	1	1	1	11	51	19	10	2	1	2	2	2	4	2	1
4	1	2	2	1	91	92	94	19	2	2	1	2	2	2	2	3
4	1	1	1	2	31	11	7	3	2	MD	2	3	3	3	2	2
4	1	1	1	2	MD	MD	MD	1	1	1	2	1	2	3	1	1
4	2	1	2	1	0	0	0	22	2	3	2	3	3	3	2	2
4	1	2	2	2	35	12	0	8	1	1	2	3	3	3	2	2

Presenting pain: 1 = none, 2 = mild, 3 = moderate, 4 = severe. Presenting problem: 1 = irreversible pulpitis, 2 = pulp necrosis/acute apical periodontitis, 3 = reversible pulpitis. Treatment: 1 = root canal treatment, 2 = extraction. Filling material: trial restoration 1 = composite resin, 2 = amalgam. Cavity treatment: trial cavity treatment: 1 = calcium hydroxide lining, 2 = conditioned and sealed. VAS 24: trial VAS score at 24 h post-op (mm). VAS 4: trial VAS score at 4 days post-op (mm). VAS 7: trial VAS score at 7 days post-op (mm). Time (m): time of pulpal diagnosis following restoration placement (months). *Scheduled recall. New or replacement: was trial restoration 1 = new, 2 = replacement. Reason: reason why trial restoration placed 1 = caries, 2 = # or worn filling, 3 = lost proximal contact. Pre-op pain: was there pain before the trial restoration 1 = no, 2 = yes. Cav occ: size of trial cavity occlusally 1 = small, 2 = moderate, 3 = large. Cav prox: size of trial cavity proximally 1 = small, 2 = moderate, 3 = large. Cav depth: depth of trial cavity 1 = shallow (Just into dentine), 2 = moderate (well into dentine, but 0.2 mm from pulp), 3 = deep (into secondary dentine or near exposure), 4 = exposure. R Dam: was rubber dam used 1 = yes, 2 = no. Moisture control: 1 = excellent, 2 = some leakage, 3 = poor. MD = missing data.

tions. This report describes a major study of pulp protection in the international context which is strengthened by its primary care setting, its large sample size, its randomization of cavity treatments and the non-prescription of material brands to enhance transferability.

The sample represented the stable patient populations of established general dental practices in the north of England. Patient demographics have been presented elsewhere and reflect the nature of practice in the UK National Health Service (Smith *et al.* 2003). The predominance of replacement restorations also reflects everyday clinical practice in the UK, Scandinavia and the USA (Deligeorgi *et al.* 2001).

Exclusion criteria were applied in an effort to control for overt signs and symptoms of irreversible pulp damage or related conditions such as dentine hypersensitivity which may have compromised the assessment of responses to restorative treatment.

Having eliminated such teeth, the recorded incidence of pulp breakdown within 3 years of restorative treatment (16/602 teeth, 2.7%) was low. There are, however, few data from general practice to put this into clear context.

It is recognized that many pulps die quietly (Michaelson & Holland 2002) and our report included both those presenting with symptoms and those identified without symptoms during routine recall examinations to 36 months. Acknowledgement should also be made that clinical methods of pulp diagnosis are relatively crude. Despite careful examination by experienced dentists with radiographs and pulp testing, some pulps could have been falsely diagnosed as healthy at recruitment and at recall. This is one of the constraints of primary care-based research, but the methods employed did represent reality in everyday clinical practice.

The emergency recall data was considered to present a full picture of symptomatic pulp breakdown within the initial sample. However, the fall in recall attendances with time presents questions on the number of undetected asymptomatic cases. It is likely that our findings under-represent the prevalence of silent pulp death and chronic apical periodontitis in an established adult general practice population (Eriksen *et al.* 2002, Michaelson & Holland 2002). Such problems are common in longitudinal clinical trials (Hogan *et al.* 2004), and cannot be fully controlled by working with stable patient groups or recruiting only subjects who have committed to long-term recall.

VAS scores are widely employed for assessing pain and discomfort (Parente *et al.* 1998, Seymour *et al.*

1998, Ide *et al.* 2001). There is no defined VAS score regarded as 'significant' following restorative treatment. Most patients probably regard some postoperative discomfort as normal after an invasive dental procedure, but it is not possible to indicate scores above which patients would be concerned. Pragmatically, this might be a level above which patients would usually return to the dentist for emergency care. Within the constraints of this study, it was not possible to demonstrate any simple relationship or critical threshold. More work is needed to explore the pain experience and behaviour of patients after restorative dental treatment.

Logistic regression proved to be useful in exploring the relationship of a broad range of pre- and intra-operative co-variables with pulpal breakdown. Material toxicity was for many years considered central to adverse pulpal events following restorative dental treatments. Current consensus holds that even a very thin layer of intact primary dentine may give enough protection for the pulp to survive irritation from dental materials and their associated bonding systems (Bergenholtz 2000, Murray *et al.* 2002). The data from the present study support this view, with a greater incidence of adverse events in deep and pulpally exposed than moderately deep or shallow cavities (odds ratio 7.8). Frank pulp exposure appeared to be most strongly associated with an unfavourable pulp outcome (odds ratio 28.4). These observations raise important questions about the avoidance of pulp exposure during caries and cavity management, and methods to control this risk, for example, by serial caries excavation (Bjørndal 2002).

The findings on the pulpal outcome in deep and pulpally exposed cavities may reflect the challenges faced by clinicians in diagnosing the condition of symptom-free pulps (Michaelson & Holland 2002) and in judging when caries removal is sufficient. The outcome of this study would suggest that in the event of a pulp exposure during deep caries excavation, a pulpotomy or pulpectomy may be preferred options to pulp capping with calcium hydroxide cement or adhesive resin.

The application of a calcium hydroxide lining or resin bonding system was not a critical determinant of pulp outcome to 36 months post-restoration. This finding was true even for the small number of teeth with frank pulpal exposures, and suggests that the messages of laboratory-based studies may, at least in the medium-term, translate to the realities of general practice (Cox *et al.* 1998, Bergenholtz 2000, Murray *et al.* 2002). The occurrence of only two pulpal

emergencies within 1 month of restoration placement also provides a strong message about the absence of acute toxic effects from restorative materials in a typical population of general practice patients with no pre-existing features of pulpal compromise.

More critical than the cavity treatment may be the bulk restorative material and its long-term marginal integrity. Amalgam restorations are free from polymerization shrinkage events which may compromise the integrity of the tooth/restorative interface. In addition, even contemporary high copper amalgams improve marginal seal with time (Hilton 2002). Composite resins, on the other hand, are technique sensitive, requiring incremental buildup to prevent excessive dimensional change during application. Polymerization stresses are believed to be particularly marked in materials with high filler loading which are typically used for posterior, load-bearing restorations (Braem *et al.* 1986). While they may be able, with careful technique, to develop tight interfaces with dental tissues in the short-term, this may not reflect in their long-term clinical performance, particularly in the wet environment of the mouth under conditions of thermal and mechanical cycling (Huang *et al.* 2004, Nakabayashi 2004).

It is likely that these issues dominate the relatively poorer performance of composite resin restorations in our study, particularly when applied to deep and pulpally exposed cavity preparations. Perhaps surprisingly, we were unable to demonstrate a relationship between the absence of rubber dam use and adverse consequences. The majority of reports were, however, of excellent moisture control by other means.

This work supports the null hypothesis that dentine and pulp protection by conditioning-and-sealing is no less effective than using a conventional calcium hydroxide lining.

Conclusions

Considered within the context of routine primary dental care,

- Dentists can be confident that pulps will be equally well protected from post-restorative breakdown up to 36 months by calcium hydroxide lining and conditioning-and-sealing with adhesive resins.
- Residual dentine thickness appears to be a key determinant of pulp responses after restorative dental treatment.
- In deep and pulpally exposed cavities in posterior teeth, composites were associated with more pulpal breakdown than amalgams.

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