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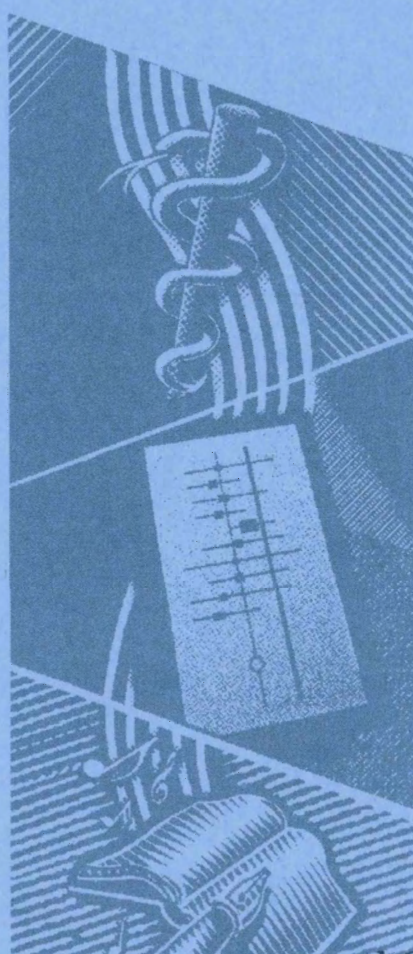
The Longevity of Dental Restorations
A Systematic Review



THE UNIVERSITY of York

REPORT 19

The Longevity of Dental Restorations
A Systematic Review

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ISBN 1 900640 17 1

This report can be ordered from: Publications Office, NHS Centre for Reviews and Dissemination, University of York, York YO10 5DD. Telephone 01904 433648; Facsimile: 01904 433661: email: crdpub@york.ac.uk
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The NHS Centre for Reviews and Dissemination is funded by the NHS Executive and the Health Departments of Wales and Northern Ireland. The views expressed in this publication are those of the authors and not necessarily those of the NHS Executive or the Health Departments of Wales or Northern Ireland.

Printed by York Publishing Services Ltd.

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GLOSSARY

Bitewing Radiograph – a form of radiograph which enables diagnosis and treatment planning in conservative dentistry, especially effective for observing the crowns of posterior teeth.

Buccal – term denoting the tooth surface adjacent to the cheeks.

Carious – describes a tooth affected by caries (decay)

Cavity – carious lesion or area of destruction in a tooth.

Class I Cavity – cavities involving pits and fissures.

Class II Cavity – cavities involving mesial and distal surfaces of molar and premolar teeth.

Class III Cavity – cavities involving mesial and distal surfaces of incisors and canines but not involving the incisal edge.

Class IV Cavity – cavities involving mesial and distal surfaces of incisors and canines **and** involving the incisal edge.

Class V Cavity – cavities involving the cervical third of the buccal and lingual surfaces of all teeth.

Demineralisation – reduction of the mineral content of a tissue.

Dental caries (tooth decay) – disease resulting in the demineralisation, cavitation and breakdown of calcified dental tissue by microbial activity.

Direct inlay – method of construction of an inlay using a wax pattern taken directly from a tooth preparation and not from a model.

Direct intra-coronal restoration – involves a direct insertion of a pliable material (such as dental amalgam, composite, and glass ionomer cement) into the preparation, which subsequently becomes rigid and is retained by the surrounding walls.

Dispersed phase – a specific formulation of amalgam alloy powder.

Distal surface – the surfaces of the tooth most distant from the midline.

Effect modifier – a factor which modifies the effect of an intervention.

Enamel bevel – a sloping surface, at a cavity margin.

Etching – partial demineralisation of a selected area of tooth substance following application of an acid.

Erosion – irreversible loss of tooth-substance by a chemical process that does not involve bacterial action.

Extra-coronal restoration – a crown.

Fissure – a small groove or trough in the enamel of the tooth.

Hypocalcification – a deficiency in the normal content of enamel due to a disturbance during the maturation period of the tooth.

Hypoplasia – defective formation of dentine due to illness such as measles or due to starvation.

Indirect Inlay – method of construction of an inlay by using an impression of the tooth taken from a model of a tooth. Indirect technique is more suitable for complex cavities, preparations with veneers and full crowns.

Labial – adjacent to the lip.

Lingual – adjacent to the tongue.

Lining – covering for the pulpal surface such of a cavity preparation. Applied to seal the dentinal tubules and to protect the dental pulp as well as to promote the growth of reparative dentine.

Lute – a cement used in a placement of an inlay.

Marginal Degradation/Ditching – the breakdown of the periphery of a filling which can lead to recurrent decay, sensitivity and discolouration.

Mesial Surface – the surfaces of the tooth in the dental arch that face towards the midline.

MOD – mesio-occlusal-distal - describes the surfaces of the teeth involved in the cavity.

Occlusal – refers to the surfaces of the teeth that make contact with those of the opposing jaw.

Occlusal Load – the load on a tooth or filling due to the forces of biting or clenching.

Parafunction – abnormal occlusal loads placed on teeth because of habits or function of a patient.

Periodontal Disease – disease of the supporting tissues of the teeth.

Pit – a small depression in the enamel of a tooth.

Recurrent Caries – dental caries that extends either beneath or beyond the margins of a restoration.

Resin – a low viscosity liquid monomer that is applied to the cavity usually to improve adaptation of the material.

Root Canal (or endodontic) Treatment – the treatment of a diseased or damaged necrotic pulp in a tooth to allow the tooth to remain functional in the dental arch.

Rubber Dam – thin sheet of rubber perforated by a punch and clamped over a tooth or teeth to isolate them from the rest of the mouth. A frame keeps the rubber stretched away from the teeth. It keeps the tooth in question **dry** and prevents foreign bodies, debris and strong medicaments escaping into the mouth and hence the possibility of inhaling or swallowing them. Also prevents the contamination of the field of operation by saliva or micro-organisms.

Secondary Caries – see recurrent caries.

Smear Layer – loosely attached mineral and organic debris left on a surface, particularly dentine, after it has been mechanically instrumented.

Xerostomia – dryness of the mouth due to a lack of saliva.

ACKNOWLEDGEMENTS

This review was commissioned and funded by the Scottish Office. The contents are the responsibility of the authors. We are grateful to the large panel who advised us in the preparation of the systematic review and to the following people who commented on various drafts: Professor Nigel Pitts, Unit Director & Head of Department of Dental Health, University of Dundee; Professor Edwina Kidd, Guy's Dental School, London; Professor John Murray, The Dental School, University of Newcastle; Professor Martin Tyas, Faculty of Medicine, Dentistry & Health Sciences, University of Melbourne; Professor Ivar Mjor, Academy 100 Eminent Scholar, University of Florida College of Dentistry; Professor Hideo Ogura, Dept of Dental Materials Science, School of Dentistry at Niigata; Linda Davies, Centre for Health Economics, University of York; Olwen Jones, Andy Clegg and Alison Eastwood of the NHS Centre for Reviews and Dissemination, University of York. We acknowledge with thanks the support and advice of Trevor Sheldon and staff of the NHS Centre for Reviews and Dissemination.

FOREWORD

Before reading this review it is essential to appreciate the nature of a formal systematic review and how it differs from other less structured literature reviews. In particular, it is important to understand the effect such differences have on the articles accepted for inclusion and on the conclusions that can be derived.

In contrast to other types of review, systematic reviews adhere to a strict scientific design; this ensures they are comprehensive, unbiased, and reliable. Rather than reflecting the views of individual authors or being based on only a selection of the published literature, they provide a comprehensive summary of all the available evidence in all languages. The inclusion criteria for papers is defined at the outset and, in broad terms, they are based on the study design and outcome measures used in a given report. For systematic reviews to be reliable, they must be carried out rigorously and adhere fully to the predefined methodology. Clearly, the results of any review rely totally on the volume and quality of the available literature.

In general, well-designed randomised controlled trials (RCTs) give the most reliable estimates of effect and are preferred. There are a number of RCTs in the current review but the bulk of the dental literature in this area used alternative study designs, some of which this review has included. The lack of clinical trials probably reflects the difficulties inherent in setting up such studies in the primary care setting. There is no doubt that this is where such work should be undertaken, but there are considerable problems in achieving this. The authors of this report appreciate that in excluding some study designs large numbers of well-known articles were omitted. However, in the context of a systematic review it is important that only robust study designs are included since limitations in the way the data are collected in other studies severely limit and bias the findings.

In the present review substantial thought was given to how true restoration failure could be determined. This is problematic since there is no universally applied standard for dentists to determine the success or failure of a restoration. In general, two possible approaches were considered; the first was to accept that if a restoration was actually replaced it had failed. The second was to accept that a restoration had failed when the decision was based on clearly defined criteria (guidelines).

These two options may at first appear to be identical. However, they are different! The literature informs us that individual clinicians often find the decision to replace a restoration difficult. They disagree with themselves when they view the same filling on another occasion (intra-examiner variability) and they also disagree with other clinicians (inter-examiner variability). This subjective decision making when replacing restorations occurs in the "real world", and is understandable. However, this implies that a group of clinicians viewing the same restorations over a period would determine failure at different points in time. In other words, this subjective method of making decisions reflects how long a clinician allows a restoration to last rather than determining true restoration failure.

The second outcome measure requires that the clinicians examining restorations have guidelines around which they base their decision to replace. This is similar to the approach used in epidemiological trials where standardising the diagnostic criteria and calibrating examiners has been shown to decrease inter-examiner variability (Backer-Dirks et al, 1951; Shaw and Murray, 1975; Poulsen et al, 1980). It has been suggested that standardising such criteria may improve diagnosis in both a teaching environment (Mileman et al, 1982) and clinical practice (Pitts, 1983). Thus, where criteria are used it is far more likely that clinicians are determining failure of a restoration more consistently (at the same point in time) with the result that the decisions are more objective and comparable.

This review used criteria-based decision making only and excluded studies that did not state clearly how failure was determined. It is likely that there will be disagreement with these inclusion criteria. The decision to only include studies that defined failure clearly has limited the generalisability of this report, since much work carried out in primary care has been excluded; the studies included are largely university or hospital based. What this systematic review tells us, therefore, is how long a given restoration of a particular material is likely to last if an attempt is made to standardise the way in which failure is determined. The authors are fully aware that the conditions under which much of the work in this review was carried out are different to those under which the majority of restorations are placed. But to have included work that did not rely on criteria to determine failure would have answered a different question, namely how long are restorations lasting, not how long could (should) a restoration last.

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1. BACKGROUND

1.1 Epidemiology

Dental caries (tooth decay) is one of the most common diseases affecting humanity with approximately 80% of the population in developed countries having had experience of the condition. Dental caries, together with chronic destructive periodontal disease, represents the predominant cause of tooth loss throughout the world. In England and Wales, dental caries and its sequelae account for almost half of all tooth extractions (Agerholm and Sidi, 1988).

There are many measures of dental health, but dmft and DMFT (ie decayed, missing and filled teeth - deciduous and PERMANENT) for five, 12, and 14 year olds are the most widely used. Other measures include the percentage of children with no decayed, missing or filled teeth, the percentage of non-dentate adults, and the average number of teeth retained by dentate adults. Table 1 shows some measures of recent dental status in the UK.

Table 1. Measures of caries status in UK

	1968 [Todd, 1991]*	1973 [Todd, 1975]*	1978 [Todd, 1991]	1983 [Todd, 1985]	1988 [Todd, 1991]	1993 [O'Brien, 1994]	1995 [Nugent, 1997]	1996 [Pitts, 1998]
Mean dmft for 5 year olds		3.5		1.8		1.7	1.8	
Mean DMFT for 12 year olds		4.8		3.1		1.4		1.1
Number of adults retaining some natural teeth	63%		70%		79%			
Mean number of teeth retained by dentate/ partially dentate adults	21.9		23.2*		24.4*			

*England and Wales figures only.

The prevalence of dental decay in the population using the decayed, missing and filled teeth (DMFT) notation is on average 1.9 dmft at five years (deciduous teeth) and 1.6 DMFT at 12 years (permanent teeth) (Akehurst and Sanderson, 1993). The most recent Adult Dental Health Survey found that the average number of sound teeth per adult was 14.8, the number of decayed/unsound teeth was 1.0 and the number of restored teeth 14.8 (Todd and Lader, 1991).

Over the last 30 years, a variety of factors including the widespread use of fluoride in toothpaste has resulted in reductions in caries rates of between 40 and 50%. The decline in the UK has been most clearly seen amongst children. The national surveys of child dental health 1973 (Todd, 1975), 1983 (Todd and Dodd, 1985) and 1993 (O'Brien, 1994) showed that the average number of 5-year-old children with caries experience fell from approximately 70% to below 50%. They also revealed wide regional variations in disease levels. However, the most recent studies have shown that not only have the previously reported improvements come to a halt, but the trends now appear to be in reverse in some areas, with levels of disease reverting to those of 10 years ago (Pitts and Palmer, 1994). It must be noted that these surveys report caries diagnosed at a gross level (without radiographic diagnosis) and thus the level of caries is an underestimate.

As the dental health of the population has improved the number of teeth present has increased and so has the number of fillings. In England and Wales, from 1968 to 1988, the population increased from 36.4 million adults to 40.3 million, an increase of 11%; the estimated number of filled but sound teeth increased from 156 million to 268 million, an increase of 72%. Many thousands of restorations are inserted and replaced each year in both deciduous and permanent teeth, placing an enormous burden on NHS resources. The treatment of carious teeth within the National Health Service by the placement of simple restorations alone, costs £173 million per year, with the provision of crowns costing an additional £156 million (Dental Practice Board, 1995-96). Restorations are also provided in the private sector, where reliable data is unavailable.

Failure to restore carious teeth may result in considerable pain and suffering, and their eventual loss. Progression of caries into the pulp allows the micro-organisms within lesions to initiate an acute inflammatory response and cause severe toothache. Progression of this process may create an abscess, sometimes accompanied by facial swelling. Removal of diseased teeth may create substantial aesthetic and functional problems for the individual, while their prosthetic replacement would place a considerable burden on the National Health Service.

1.2 Preventing and treating caries

The aim of prevention and restorative treatment is to maintain an aesthetic and functioning set of teeth. Preventive measures can halt and even reverse the development of caries and its progression through enamel by reducing the frequency of exposure to sugar, and by exposure to fluoride either topically (eg in toothpaste) or systemically (eg in the water supply).

Through preventive care at an individual level, caries can be managed by the use of topical and/or systemic fluoride, and the use of fissure sealants on the pits and fissures of posterior teeth to prevent them acting as stagnation areas for plaque (Kay and Locker, 1997; Simonsen, 1996; Sprod et al., 1996; ADA Council on Access Prevention and Interprofessional Relations, 1997; Riordan, 1996).

If decay has not been prevented or arrested, cavities develop and progression of caries into the dentine and eventually the dental pulp ('the nerve') will occur. Thus, in order to prevent considerable pain and tooth loss it may be necessary to remove the diseased tissues and restore the cavities (a filling). The decision to restore will depend on the likely rate of progression of caries and the age of the child or adult. Restorations are also undertaken for other reasons such as trauma, wear and erosion.

Restoration failure: Evidence suggests that restorations have a limited life span and that once a tooth is restored the filling is likely to be replaced many times in the patient's lifetime - the 'restorative cycle' (Elderton and Nuttall, 1983).

Studies in the UK suggest that much of restorative dentistry is replacement of existing restorations accounting for 60% of all restorative work carried out (Nuttall, 1984). Similar figures have been found in other parts of Europe (Qvist et al., 1986; Qvist et al., 1986) and the USA (Maryniuck and Caplan, 1986; Klausner and Charbeneau, 1985).

The longevity of a restoration has been associated with factors such as the age of the patient, the properties of the filling and the initiation and rate of progression of caries in the filled tooth (Hunter, 1985; Walls et al., 1985; Mjor and Medina, 1993). Successive restorations of the sort that are placed inside the tooth (intra coronal) tend to increase in size, leading to an increased risk of subsequent tooth fracture. Replacement restorations tend to be more complex and sometimes more expensive than the initial restorations. They may have a shorter life span and can have a detrimental effect on the pulp, occasionally leading to the need for root canal treatment involving further expense.

It has been demonstrated that the treatment planning decisions made by clinicians are subject to a great deal of variation (Elderton and Nuttall, 1983). In clinical dental practice, decisions are often made subjectively with a lack of standardisation, as there are no valid criteria used to decide when a restoration requires replacement. It is difficult to distinguish between subjective and objective factors in the decision making process and it is possible that this influence will have a greater impact on longevity than the physical properties and biocompatibility of a material.

The critieria used for the evaluation of restoration failure vary widely between dentists and may not be explicit. It is therefore often difficult to determine whether a restoration was replaced because the restoration actually failed, or a clinician subjectively deemed it to have failed. For example, one clinician may decide to replace an old, corroded amalgam while another may polish it. For these reasons the criteria used to include studies in this review are based on objective decision-making based on clearly stated criteria.

1.3 Classification of lesions and restorations

Carious lesions have been classified traditionally into five categories based on the location of the lesion (Table 2). Some commentators include a sixth category that is not used in this review. It is also important to note that there are reasons other than caries for restoring a tooth, notably traumatic loss of tooth tissue and other non-carious tooth tissue loss (abrasion, attrition and erosion). The design of cavity preparations is determined by the specific surface and the physical properties of the restoring material; some materials are relatively weak and cannot be used in load bearing areas, whilst others with greater strength can be used in a variety of teeth and surfaces. Aesthetic as well as functional considerations need to be taken into account.

Table 2. Lesion and Restoration Classification

Lesion / Restoration type	Description
I	Affecting pits and fissures of all teeth
II	Affecting the interproximal areas of posterior teeth
III	Affecting the interproximal areas of anterior teeth
IV	Affecting the interproximal and incisal edges of anterior teeth
V	Affecting the smooth buccal/lingual surfaces of any tooth

Restorative materials: Tooth restorations may be classified as intra-coronal or extra-coronal. Intra-coronal restorations are most commonly direct restorations where a 'plastic' (adaptable, pliable, mouldable) material is inserted into the preparation. The material subsequently becomes rigid and is retained by the surrounding walls of the remaining tooth tissue. The materials most commonly used are dental amalgam, composites and glass ionomer cements. A second type of intra-coronal restoration uses an indirect technique. Here an impression of the cavity is taken and a laboratory formed inlay is constructed. Subsequently, this is cemented into the prepared cavity. Inlays may be made of composite, gold or porcelain. In contrast, extra-coronal restorations 'wrap around' the tooth and cover (protect) the remaining tooth tissue, for example, crowns or onlays.

The ideal filling material should have the same aesthetic and physical properties as tooth tissue, and be biocompatible. Although most materials fulfil some of the ideal requirements, no material has yet been developed that satisfies all the criteria.

New restorative materials are tested using one of three experimental models. *Ex vivo* (laboratory based) that give results of chemical, physical and biological properties, but do not necessarily translate to the patient model. *In vivo* (animal) experiments provide a transition from the physical based laboratory studies to the human model; they provide elements of the biological aspects of tooth tissue replacement but do not mimic exactly the environment of the human mouth. Experiments involving human volunteers may be undertaken in institutions or in the primary care environment and can evaluate clinical performance. The former provides a strict experimental design while the latter is more pragmatic as it allows for real-life interaction between tooth, filling material, operator and patient factors.

As a part of their marketing strategy, the dental industry is constantly searching for new materials. Not all these materials have undergone stringent testing in the human situation, controlling for all patient and clinical factors, and this has led to uncertainty and lack of comparison between materials. Manufacturers may dictate who undertakes the trials and may place restriction upon the release of data, with a tendency to publish favourable findings only.

Manufacturers invest large sums of money carrying out pre-clinical and clinical studies and usually market a material capable of coping with the oral environment when placed under 'clinical trial' conditions. Consequently, it is unlikely that any restoration failures are due to a catastrophic deficiency of the material.

1.4 Conclusions

There is a large choice of materials that can be used for fillings. Many are introduced into the market place with very limited evidence that they are more efficient or effective than existing materials. Key questions are:

- All other things being equal, what type of filling is best?
- What lessons can be learnt from idealised settings and transferred to every day clinical practice?

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2. ISSUES OF EVALUATION

2.1 Aims and objectives

The call to tender for this systematic review set out the following review questions:

A systematic review is needed to:

1. *Assess whether there are variations in the longevity and the cost of the different routine dental restorations;*
2. *Establish the factors that influence the longevity of routine dental restorations focusing on:*
   - i *The patient and the problem - the type of dentition, site of restoration, size of restoration, reasons for placement, type of caries, or age, sex and socio-economic, characteristics of patient;*
   - ii *the intervention - the type or brand of restorative material, method of placement or bonding agent*
   - iii *the practitioner and environment - knowledge and practices of dental practitioner, type of dental practice, or country of operation; and,*
   - iv *the outcomes - rate of failure, level of occlusal/marginal wear, or other clinical characteristics*

Taking the call for tender as a basis, the aim of this study was to undertake a systematic review of the literature on the longevity and cost effectiveness of intracoronal restorations including plastic materials (amalgam, composite and glass ionomer cements) and inlays. The study question fell neatly into three main categories:

- factors affecting the longevity of each material type (the intra-material factors)
- factors affecting the longevity between material types (the inter-material factors)
- cost-effectiveness; dealt with by exploring the current costs of materials and treatment

The factors indicated in the call to tender (2 (i) to 2 (iv)) above were included as effect modifiers, described in full below, and were recorded on the data extraction sheet. It was recognised at the outset that a number of patient factors which principally influence disease risk could differentially affect materials, eg diet, salivary quality; where possible these have been reported.

The data derived from this review will permit research-based recommendations on:

- the use of previous and current restorative materials
- the future introduction of new materials
- areas requiring further research
- the design and reporting strategy of clinical trials

2.2 Study designs

A preliminary literature search revealed over 14,000 scientific articles relating to direct placement, intra-coronal, plastic restorations. The design of studies reported varied enormously and included cross-sectional observational studies, retrospective and prospective observational studies with or without controls, and a wide variety of clinical trials.

The cross-sectional data, particularly that collected by self-reported questionnaires, usually considered restorations at one point in time, that is, the point at which they were replaced. These surveys report what dentists do and why they think they do it. However, there is no information about the standardisation of this approach, the outcome variables used by multiple respondents or the restorations that are not replaced. It is therefore not possible to calculate objectively the longevity of all restorations from this design. Such studies have therefore been excluded from this review.

Case series studies often consist of reports of only one practitioner's work. Case series can be retrospective or prospective with or without comparisons; the most useful being prospective with comparisons. The results of prospective case series are going to be strongly influenced by both the dentist's practice and the population served. This problem can also be turned to advantage as the effect modifiers related to the dentist are largely removed, and their follow-up may be considerably longer than most clinical trials. Reservations must exist where selective reporting of subjects occurs, such reports have only been included where objective criteria have been cited, and where over 90% of subjects were available at first follow-up or where the fall out was clearly accounted for. Retrospective case series were excluded as they are based on record searches and cannot therefore use objective criteria.

Relatively few prospective observational studies involving multiple operators were identified in the preliminary search. If the evaluation criteria were objective and consistently applied these studies were included.

The controlled clinical trial has been referred to as the gold standard for clinical research. These prospective, randomised and when possible blinded trials may offer the greatest understanding of an experimental treatment when properly executed (Duke, 1992). The most common study design is a clinical trial in an institution such as a dental hospital or university. This is a good environment for ensuring standardisation but does place limitations on the generalisability of the results to non-institutional settings.

Some clinical studies used a paired design where two restorations were placed in the same subject, one of the test material and the other of the control material. This design has many advantages as the confounding variables are standardised, however, problems may still exist, eg the randomisation of the test and control material may have been undertaken improperly or not at all. In some paired studies a subject may have more than one pair placed in a mouth; while this does not weaken the comparison of the material it does influence the generalisability of the results to the whole population.

2.3 Outcome measures

To be acceptable outcome measurement had to be reproducible, ideally between individuals, and identify the point when an individual restoration failed. A number of widely used systems do not use objective outcome measurements and were excluded. One notable example of this is the Ridit Analysis system. Many reports combine data and report on groups of restorations making it impossible to determine the longevity of individual restorations.

Ridit analysis was initially introduced by Bross (Bross, 1958) for both the description of differences between groups on an ordered categorical scale and the testing of the significance of these differences. The term 'ridit' is derived from the term 'relative to an identifiable distribution'. The method, first used in dentistry by Mahler and co-workers (Mahler and et al, 1970), ranks restorations from best to worst but does not indicate at what point a restoration fails. This scoring system was subsequently revised by Mahler and co-workers (Mahler et al., 1973) and a sixth group was added for restorations that required replacement.

However, there are a number of problems with 'ridit' analysis. Firstly, the technique is highly subjective and secondly there is little clinical evidence to suggest that marginal deterioration *per se* results in recurrent caries; this is more likely to be a reflection of diet. Studies using 'ridit' analysis have only been included if the sixth category of 'restoration needing replacement' was identified.

There are two possible outcome measures for longevity of restorations - time until failure or time until replacement. In this study a distinction is made between these outcomes because of the subjective nature of many decisions made in clinical practice. The fact that a restoration is replaced may not mean that it has failed, but that in the opinion of that examiner it had failed. In assessing the longevity of restorations in 'the real world' subjective opinion may be valid, but in seeking to improve standards subjective opinion does not allow comparison. Complete failure is a better validated outcome but can only be used as the endpoint if no intervention is permitted; it is most usually reported in studies investigating the adhesive properties of materials where complete failure is reported as 'loss'. However, many studies reach their endpoint before the restorations fail and other studies allow intervention before the restoration (or tooth) has been lost; it would be unethical to do otherwise. It has therefore been necessary to devise parameters that indicate that a restoration is on its way to failure.

The United States Public Health Services (USPHS) or Ryge criteria (Ryge, 1973) are widely used in clinical studies to assess the performance of restorative materials. These criteria require the use of two independent examiners. The system uses a grading system based on subjective observations of such parameters as restoration colour, marginal adaptation, recurrent caries, anatomical form, to 'quantify' clinical performance. For each parameter there is a range of scores from Alpha (perfect) to Delta (failure). Charlie is a grade that indicates the restoration should be replaced. However, these parameters are being used in many studies as a continuum to judge longevity or failure, a strategy that may be inappropriate. No study has attempted to correlate continuum of the USPHS criteria with the ultimate failure of a restoration. In addition, a number of studies have used a modified version of the criteria. This review concentrated on the final two gradings (Charlie and Delta) for each parameter where the fault was so great that replacement was required. For the scores concerning caries there are only two grades, alpha and beta. Beta indicates the presence of caries, hence a failure of the restoration, and was therefore accepted as such.

Although USPHS is widely used it is not consistently applied and some of the variations incorporated may seriously weaken the study and are likely to introduce bias eg the use of the criteria by one examiner-operator as opposed to the two independent non-operators that are recommended.

Many studies compare times until replacement. This reflects clinical practice, but reasons for replacing a restoration are often not validated; it is common for different practitioners to exercise their judgement in line with certain written criteria without any efforts to check on inter-observer (or even intra-observer) variation. These studies were not ignored, as they represented a considerable proportion of the comparative work reported but were considered to have a weaker outcome measure than those using USPHS as designed which, in turn, was considered to be a weaker outcome measure than those studies that allowed comparisons between times to total failure. However, studies where the decision was made on a subjective opinion without stated criteria were excluded, except where the comparison was between payments systems.

Outcome measures divided into those relating to the restoration, which are discussed above, and those relating to the tooth. For example, a restoration may be mechanically sound but the pulp tissue may have been damaged. This is a valid outcome but is particularly difficult to measure. The sensitivity of the pulp can be assessed through thermal or electrical stimulation. A single test is notoriously unreliable but the results of a series of tests taken together represents a valid outcome. Finally, reported 'pain' indicates that the restoration is not functioning satisfactorily for the patient. Taken in isolation it is not possible to determine the source of the pain and there are no regularly used pain scales in this area. Nevertheless patient pain was recorded. In this context radiographic evidence cannot be used reliably.

It is necessary to accept that some of the criteria used in isolation as outcome measures may be flawed, however, when they are taken together it is likely that conclusions can be drawn about the characteristics of a material with more confidence. A hierarchy of outcomes was developed, but all reported outcome studies were recorded except for subjective decisions without stated criteria.

2.3.1 Examples of excluded and included papers

In order to clarify some of the reasons for the choice of study designs and outcome measures and the decision to include or exclude particular studies some papers are described briefly along with the reasons for their exclusion or inclusion.

Paper	(Davies et al., 1998)
Study design	Prospective study with concurrent controls (6)
Outcome measures	None
Short description of paper	A cohort of Scottish subjects examined in the 1988 UK Adult Dental Health Survey were followed to investigate patient attendance and tooth specific data
Reasons for exclusion	Data concerning the longevity of individual restorations were not presented
Questions the paper raises	Is there further data to be presented?

Paper	(Davies, 1984)
Study design	Prospective study with concurrent controls (6)
Outcome measures	number of fillings placed
Short description of paper	A cohort of Scottish subjects examined in the 1978 UK Adult Dental Health Survey were followed for five years and the number of fillings placed at subsequent courses of treatment recorded together with a note of any change of dentist. Patients who changed dentist received many more restorations than those who did not.
Reasons for exclusion	There are no data on the longevity of individual restorations.
Questions the paper raises	What are the reasons for these findings? Might it be that patients are dissatisfied with their dentists treatment and are therefore more likely to change dentists? Alternatively, is it the subjective opinion of dentists as to the standard of their colleagues' treatment that leads to the large number of restorations.

Paper	(Mjör et al., 1990)
Study design	Case study (1)
Outcome measures	Restoration replacement (subjective criteria) (1)
Short description of paper	A large number of dentists were requested to report the age of restorations they replaced, the material and the reason for replacement.
Reasons for exclusion	This study gives a good picture of what is happening in clinical dental practice. However, the subjective criteria limit the usefulness of the paper because it is impossible to be confident that fillings are being replaced appropriately or that different clinicians viewing the same restoration would reach the same conclusion. It is also impossible to identify which effect modifiers are influencing the results. Furthermore the study only looks at the longevity of restorations that were replaced. It is impossible to calculate the longevity of restorations because no data are presented for restorations that did not failed.
Questions the paper raises	Is the relative longevity of restorations reported?

Paper	(Robinson, 1971)
Study design	Retrospective study with concurrent controls (4)
Outcome measures	Restoration replacement (use of criteria but no training) (2)
Short description of paper	One dental practitioner reviewed his own restorations placed in 1948 or 1949 over a 20 year period. He stated his own criteria for replacement and compared the longevity of restorations of different materials.
Reasons for exclusion	The study design overcomes the problem of multiple examiners and many of the effect modifiers related to the practitioner are considerably reduced by using one operator. Unfortunately, patients who had not attended for two years at any point over the study are excluded. This means that the follow-up of this cohort may be biased, and the paper was excluded.
Questions the paper raises	How does the longevity of the restorations reported compare to those in clinical trials?

Paper	(Elderton, 1983)
Study design	Prospective study with concurrent controls (6)
Outcome measures	Restoration replacement (subjective opinion) (1)
Short description of paper	A cohort of Scottish subjects examined in the 1978 UK Adult Dental Health Survey were followed for five years. The study reported the survival time of restorations placed during that period.
Reasons for exclusion	The strength of this study is that it has been carried out prospectively but its weakness is that the criteria were subjective. The study shows how long restorations lasted but it does not relate this to the failure of the restoration because of the subjective nature of the examination and the use of multiple operators.
Questions the paper raises	How do the failure rates reported in this study related to survival times in clinical trials?

Paper	(Walls et al., 1985)
Study design	Retrospective study with concurrent controls (4)
Outcome measures	Restoration replacement (subjective opinion) (1)
Short description of paper	This paper reviewed all record cards belonging to new patients attending a dental hospital. All patients, under 16 years, with occlusal amalgam restorations in first permanent molar were included and their records reviewed for up to 12 years. Note was made of the patient's age, sex, the number of times the restoration had been replaced, the use of local anaesthetic and the tooth designation.
Reasons for exclusion	This study was stronger than others because it used a whole population as its baseline. There were two major reasons for its exclusion. First, the use of subjective criteria by multiple examiners and multiple operators mean that it is not possible to say that all restorations that were replaced had reached the same point of failure or had indeed failed. Because the data were collected retrospectively from clinical records the subjective nature of the criteria was inherent to the study. Secondly, it is impossible to compare the characteristics of those who returned for treatment with those who did not. It may be, for example, that those with problems or higher caries rates were more likely to return to the dental school thus reducing the longevity of the restorations. They concluded that restorations placed in younger children or without local anaesthetic were more likely to fail. This paper thus gives an excellent description of what happens in the dental school environment but the subjective criteria mean that it is not possible to compare like with like.
Questions the paper raises	Does the age of the patient at placement of a restoration affect the longevity of the restoration? Does the use of local anaesthetic at time of placement affect the longevity of the restoration? Do these factors influence the longevity of other types of restorations?

Paper	(Welbury et al., 1991)
Study design	Well designed randomised controlled trial (8)
Outcome measures	Restoration replacement (use of any criteria, training and / or calibration, including USPHS) (3)
Short description of paper	This paper describes a well-designed clinical trial to compare the longevity of glass ionomer cement with amalgam over a five year period.
Reasons for inclusion	This is an extremely well designed trial and the outcome measures used (USPHS) fall within the criteria of this study. However, USPHS ideally uses two independent, calibrated examiners (Code 4) this study used two examiners with training and calibration but because examiner-operators were used the outcome code is lowered (Code 3).
Questions the paper raises	What is the generalisability of these results? (How do these results relate to what dentists do in everyday practice?)

2.4 Effect modifiers

In considering the longevity of dental restorations, the properties of the material are only one factor. Many other factors are likely to affect the longevity of a restoration and these are known as 'effect modifiers'. One of the major problems of interpretation is that it is often impossible to separate out the effect modifiers and thus it is not possible to identify which are involved in the failure of a given restoration. Table 3 shows the effect modifiers that have been reported. Where possible, data on all of these factors were collected from each study.

2.5 Population studied

The subjects included in studies reported in the literature reflect the whole spectrum of the population. Some workers evaluated longevity in adults; others used adolescents or young children. Some have restricted their study to permanent teeth; others have looked exclusively at deciduous teeth, or a mixture of both. Some studies used rigid criteria when accepting volunteers; others simply used regular patients who presented for restorations. Others used dental students. Few mentioned socio-economic status.

Table 3

a) Possible objective influences

General patient factors: replace with table 1 bulletin

- Exposure to fluoride
- Caries status
- General health
- Parafunction
- Age (particularly child / adult)
- Xerostomia
- Socio-economic status
- Diet

Tooth factors

- Tooth location / type / size
- Cavity design / type
- Dentition
- Occlusal load
- Tooth quality e.g. hypoplasia

Operation and restoration process factors

- Material type
- Physical properties
- Quality of finish
- Moisture control
- Anaesthetic during restoration
- Expertise
- Training

b) Subjective factors

- Incentive (payment structure: salaried, government funded, private, or insurance)
- Clinical setting (university, private practice, general dental practice, specialist practice, field trial,)
- Country (local treatment fashions)
- Clinician's diagnostic, treatment and maintenance philosophy (influenced by training)
- Patient preferences

Overall, the actual type of the population may influence the generalisability of the results. Clearly, it is essential to derive information on the type of patients included in studies, although this is not always provided in sufficient detail. Details of the populations studied were included.

2.6 Length of follow-up

Length of follow-up varied and reporting studies have results at specific (but varying) intervals, and often repeated analysis of the same cohort after a number of follow-up periods. It was important that these repeated follow-up reports were married to the original report in order to reduce confusion and maximise data extraction. For some comparisons, eg evaluation of adhesive systems, a study length as short as six months can provide important results. For this reason no minimum length of follow-up was set as a criterion.

2.7 Economic evaluation

Cost effectiveness analysis is one of the techniques of economic evaluation designed to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing. As with all economic evaluation techniques, the aim of cost effectiveness analysis is to maximise the level of health effects relative to the resources available. In this study the intention was to assess the costs of dental restorations using different materials and their relative effectiveness measured in terms of survival and longevity.

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3. METHODS OF THE SYSTEMATIC REVIEW

3.1 Search strategy

A systematic review (a comprehensive synthesis of the literature) was carried out using rigorous scientific methodology. The search strategies were cross-disciplinary and included international published research literature. Review articles, published bibliographies and relevant citations in articles were included. All languages were included and individual databases were searched back to their inception. A printout of each search strategy for the major databases is included as part of the report. A scoping search was carried out in the first instance.

3.1.1 Subject searches

Initial searches were carried out on Medline, Embase, DARE, CDBR, the Cochrane Library and the CRD Database of Ongoing Reviews in order to establish the existence of any systematic reviews, meta-analyses or literature reviews. This was achieved by running subject searches against appropriate search filters (see Appendix 1).

Further searches were then carried out on Medline and Embase using additional filters to identify RCTs, CTs and different types of study. The subject search strategies involved looking under textwords, commercial names etc as well as under recognised subject headings.

Specialist databases were also searched and the approach was modified accordingly, eg when looking at a non-medical database such as Econlit, terms to be input were more general.

3.1.2 Sources searched:

Electronic databases

Database	Years	Method of access
Medline	1966-date	Networked version of Ovid
Embase	1980-date	On-line via BIDS/ISI service
SciSearch	1981-date	On-line via BIDS/ISI service
Index of Scient.and Tech. Proc.	1981-date	On-line via BIDS/ISI service
ASSIA	1980-date	CD ROM
Cochrane Library (CDSR, DARE, CCTR/CENTRAL)		CD Rom
CRD Database of Ongoing Reviews		CD Rom
DHSS Data	1983-date	On-line via Datastar
Healthstar	1986-date	CD ROM
National Research Register		CD ROM
Health ReferenceCentre	1994-date	CD ROM
Current Research in Britain (CRIB)		CD ROM
NHS Economic Evaluation database	WWW	
ECONLIT	1987-date	CD ROM
SIGLE		BritishLibrary (via Blaiseline)
ECRI (Health technology)		via CRD at York

The following publications were hand searched on a regular basis
ACP Journal Club
Bandolier
Evidence-Based Medicine
Evidence-Based Purchasing
Evidence

Other printed sources
Aslib Index to Theses
Directory of Registries of Clinical Trials. (Contact: Dr Easterbrook, St Stephen's Hosp)

WWW Sources
DerWeb
Dentistry on Line

UMDS Dental Materials Science
Centre for Evidence-Based Medicine
CORDIS (EU Research)
HSTAT
AHCPR Agency Health Care Policy and Research)
OMNI - Giving access to a range of databases eg UK Clearing House on Health Outcomes - NIH
On-Line library catalogues eg COPAC (Major Univ. catalogues) and British Library catalogue.
CRSP (US Research)
Scharr-Lock's Guide to the Evidence

Hand searches
Following the electronic literature search, a hand search to identify recent publications not yet cited or indexed in the databases, was undertaken. The following journals were searched once:

Acta Odontologica Scandinavica
American Journal of Dentistry
Australian Dental Journal
Biomaterials
British Dental Journal
Bulletin of the Tokyo Med Dent Univ.
Bulletin of Kanagawa Dental College
Caries Research
Clinical Materials
Clinical Research Assoc. Newsletter
Community Dental Health
Community Dentistry and Oral Epidemiology
Dental Materials
Dentistry Japan
Dental Materials Journal
European Journal of Oral Science
European J. Prosthodontics & Restorative Dentistry
Hellenic Dental Journal
Internat. J. Perio. and Restorative Dentistry
International J. Prosthodontics
J. of the American Dental Association
Journal of the Canadian Dental Association
Journal of Dentistry
Journal of Dental Research
Journal of Dentistry for Children
Japanese Journal of Conservative Dentistry
J. of the Osaka Univ. Dental School
J. of the Nihon Univ. Dental School
J. of Pedodontics
J. of Prosthetic Dentistry
New Zealand Dental Journal
Nihon Univ. J. Oral Scince
Operative Dentistry
Quintessence International
Scandinavian J. of Dental Research
Swedish Dental Journal

In addition, the abstracts of articles published in the proceedings of the International, British, Australian and New Zealand, Continental European, Japanese, Scandinavian and South American divisions of the Societies for Dental Research were hand searched.

3.2 Inclusion/exclusion criteria

3.2.1 Population groups to be included

No studies were excluded on the basis of the population that was studied. Likewise studies were not excluded because of the setting where the study took place. Differences between studies taking place in different institutions and also with different types of population were noted.

3.2.2 Exclusion criteria

From the titles and abstracts derived from the searches, papers were excluded on the basis of:

- Non-human
- Laboratory based
- Toxicity studies only
- Non-relevant – materials tested in apical surgery, not intra-coronally

Study design

A flow chart was used to determine the study design (Figure 1). Descriptive studies, case studies and retrospective case series (Study designs 1 and 2) were excluded. f the study was observational, ie study designs three to six, it was excluded if the percentage of subjects at first follow-up was less than 90% unless a random sample of subjects had been taken or the reasons for the subject loss were explained.

3.3 Outcome measures

The following criteria were used to assess the outcome measure(s) reported.

Restoration degradation (not replacement) Code 0
Studies were coded as 0 if restorations had been evaluated using criteria that exclude a replacement, eg wear. Studies that reported wear but also reported restoration failure were not coded as 0. Studies coded as 0 were excluded from the dental data extraction but were screened for economic data.

Restoration replacement (subjective) Code 1
Studies were coded as 1 if replacement was based on the subjective opinion of the person making the decision rather than predetermined criteria. Studies coded as 1 were excluded from the dental data extraction but were screened for economic data.

Studies using these criteria alone were included if they compared longevity of restorations within different payment systems.

Restoration replacement (use of criteria but no training or calibration) Code 2
Studies were coded as 2 if the criteria for making the decision to replace had been stated but there had been no training or calibration of the evaluators making the decision. USPHS or equivalent systems were included in this code if the examiner had not been trained or calibrated.

Restoration replacement (use of criteria, training and / or calibration) Code 3
Studies were coded as 3 if the criteria for making the decision to replace had been stated and there had been training and/or calibration. USPHS criteria or equivalent systems were included if, only one examiner had been used or the examiner was also the operator.

Restoration replacement (valid outcome, criteria training and calibration) Code 4
Studies were coded as 4 if a valid outcome had been recorded. The two systems accepted as valid were Californian Dental Association (Ryge, 1989) and the USPHS system (Cvar and Ryge, 1971) where they measured failure, or systems based on them. Training, calibration and independence of the two (minimum) examiners were necessary for the correct use of USPHS.

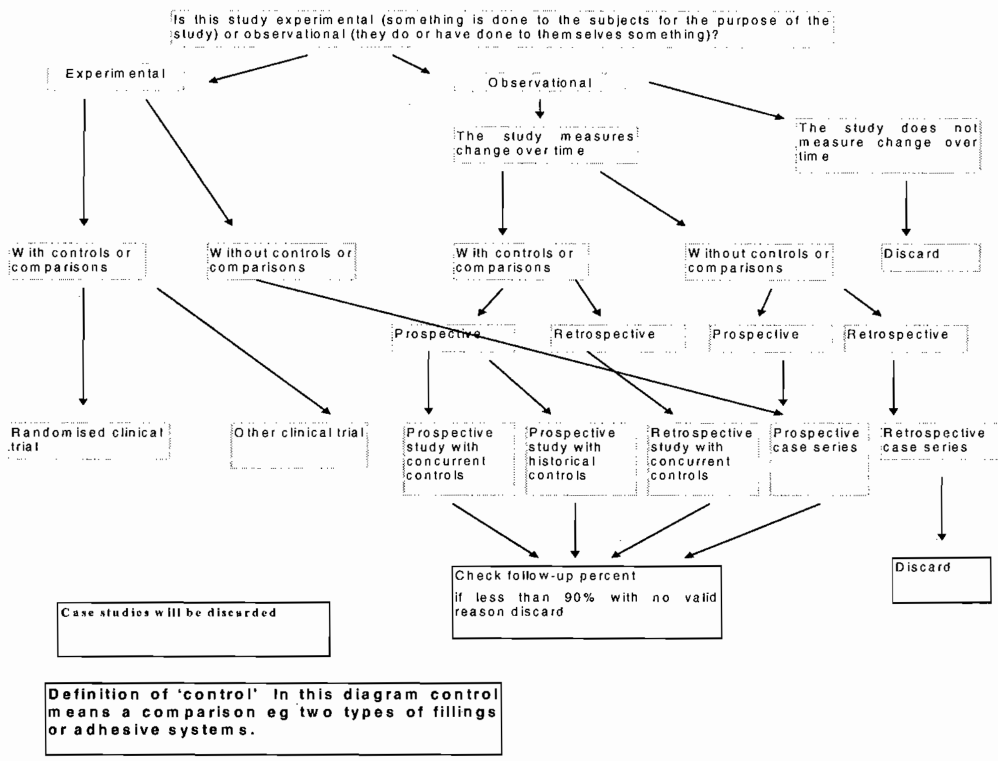

Figure 1: Flow chart for allocating study design

Restoration failure (without previous intervention) Code 5

Studies were coded as 5 if restorations had failed without previous intervention (the restoration was observed from placement to failure with no repair or re-treatment). Most failures with previous intervention were recorded under one of the other categories. Failure was defined as: the total mechanical failure of the restoration (eg loss), or the death of the pulp. Criteria that assessed failure were therefore: recording that the restoration had been lost, or a series (not one) of pulp sensitivity tests.

Recording of pain

The reporting of pain by a subject was recorded. Intractable sensitivity leading to replacement was recorded.

3.4 Decision processes

3.4.1 Pilot testing the inclusion criteria

A sample of articles were pilot tested by all reviewers. The pilot test was used to refine and clarify the inclusion/exclusion criteria, train those who were applying them, and ensure that the criteria were applied consistently by more than one person.

3.4.2 Study selection

Following identification, each paper was considered against the predetermined criteria. This followed a three-stage process.

The reviewers were present when the searches were undertaken to determine what material was retained. Reproducibility studies were completed on 10% of the searches to ensure that the selection was consistent. Two people checked the material on two occasions. This process was undertaken for each stage of the literature retrieval and selection.

3.4.3 Stage 1 Assess titles and abstracts to determine whether each article might meet predetermined eligibility criteria

All titles and abstracts were reviewed to determine whether each article might meet the predetermined eligibility criteria. If, given the information available, it was determined that an article definitely did not meet inclusion criteria, it was excluded. If there was doubt in the reviewer's mind then the full article was retrieved.

3.4.4 Stage 2 Read retrieved articles to determine whether each article might meet predetermined eligibility criteria

All papers that passed stage 1 were allocated a unique identifier that was written on the paper, the Endnote (Reference Management Software) file and entered on the data extraction sheet together with the screener's identification. The paper was then examined to see if it met the predetermined eligibility criteria. The eligibility criteria were based on the assessment of study design and outcomes. **The paper was first assessed for study design.** The code number for the study type was then entered on the form. A note was made of any flaws in the study design; including details on randomisation.

The next stage was to assess the outcome measures used in the study according to the criteria listed above. The outcome criteria code number was entered on the data sheet together with a description of the outcomes used. The reason for allocation to a specific criteria was noted, eg USPHS criteria used but with one examiner who had been trained and calibrated only resulted in the study being allocated a Code 3, not a Code 4.

Figure 2 was then used to determine which cell the study fell into. This grid had two codes; 'X' the study was excluded and 'I' the study was included. This was entered on the data sheet and, if the study was coded 'I' then data extraction continued.

All studies were assessed to see if mention was made of time or costs. Studies with any economic data were retained for further evaluation even if excluded on other grounds.

The aim of each study was entered on the sheet. This was copied from the paper.

All studies to be included were entered on the master grid. This grid listed the distribution of studies by material type and differentiated between studies where a comparison had been made (both inter- and intra-material) and those studies where no comparison occurred. This demonstrated the volume of literature meeting the predetermined criteria for each material type. The grid square was noted on the data extraction sheet and a code number applied.

3.4.5 Stage 3 Abstract data from all articles passing first two stages

All papers passing the first two stages, and coded as 'I' (include), were read and the data extraction sheet completed (Appendix 2). This sheet was completed with a brief written description under the appropriate headings. All papers were read and the data extracted. 10% of all reviewers' papers were checked for accuracy. If problems were identified in one data extractor, all that individual's papers were re-extracted.

3.4.6 Identification of issues related to generalisability

Most of the accepted studies were undertaken in academic and controlled institutional situations. The generalisability of the results of these trials would appear to be limited because of the different nature of routine general dental practice. The study situation was included as an effect modifier. Such differences may also be applicable between countries due to the very different nature of their payment systems. It is well recognised that replacement of restorations is influenced by the payment system - a factor not relevant in the majority of clinical trials. Patients used in clinical trials are usually different from the general population; they tend to be recruited for specific age characteristics, and defined levels of oral and general health. It may be difficult to generalise results from these groups to, for example, people with poor oral health. For each study a note was made of any issues of generalisability.

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Weaker outcome measures →→ → Stronger outcome measures

Weaker study design ↓ **Stronger study design**

Outcome measure / Study design	Study design code number	Restoration replacement (subjective opinion)	Restoration replacement (use of criteria but no training)	Restoration replacement (use of any criteria, training and / or calibration, include USPHS where not two examiners etc)	Restoration replacement (valid outcome, criteria, training and calibration, include USPHS where properly used)	Restoration Failure (without previous intervention)
Outcome measure code nos.		**1**	**2**	**3**	**4**	**5**
Descriptive studies / Reports of expert studies / Reports of expert committees	**1**	**X**	**X**	**X**	**X**	**X**
Case studies	**1**	**X**	**X**	**X**	**X**	**X**
Retrospective case series	**2**	**X**	**X**	**X**	**X**	**X**
Prospective case series	**3**	**X**	**I**	**I**	**I**	**I**
Retrospective study with concurrent controls	**4**	**X**	**I**	**I**	**I**	**I**
Prospective study with historical controls	**5**	**X**	**I**	**I**	**I**	**I**
Prospective study with concurrent controls	**6**	**X**	**I**	**I**	**I**	**I**
Other controlled trial	**7**	**X**	**I**	**I**	**I**	**I**
Well designed randomised controlled trial	**8**	**X**	**I**	**I**	**I**	**I**

Figure 2 - Groups to which studies will be allocated

4. ECONOMIC EVALUATION

The first phase of the study was a review of the literature relating to the costs and effectiveness of dental restorations; the second phase was a small-scale survey of dentists to identify 'real-world' estimates of the time to place a restoration and subsequent replacements; and the third phase consisted of an economic model, constructed on the basis of cost data generated from the literature and the survey, plus the data relating to survival and longevity from the systematic review.

The intention of the first phase was to review studies which considered the survival, longevity, costs, benefits, effects, problems, cost-effectiveness and cost benefits associated with different interventions in restorative dentistry. The number of studies which examined more than one of these areas was limited and were based on the results of modelling or from retrospective analyses of case notes rather than data from prospective investigations.

Studies were included if they dealt with:

- A consideration of the time involved in restorations and the factors which influenced the processes.
- An estimate of cost of procedures relative to a scale based on complexity of procedures.
- A prediction of the long-term costs of restorations.
- An indication of the effectiveness of restorations, expressed in terms of longevity, durability, survival, life-span, etc.
- A view on the relative cost effectiveness of different materials and interventions

Studies were not included in the analysis if they were methodologically based, ie if they provided an indication of how to determine costs, effectiveness and cost effectiveness rather than generating any data, but noted separately.

The second phase involved a small-scale survey of local dentists to ascertain some 'real-world' times of restorations with which to 'validate' the timings provided by the studies included in the literature review. Twelve questionnaires were sent and nine were returned.

The third phase involved the construction of a cost profile of each restoration type, based on the findings from the survey of dentists and studies included in the review. The costs of each type of restoration were based on the time taken to place an initial restoration, material costs, follow-up visits and subsequent replacements. In order to arrive at an indicator of cost effectiveness the costs were compared with the number of tooth life years. These were based on the findings on survival and longevity from the systematic review and translated into the probability of material survival at various points of time.

A decision analysis framework was adopted to assess the impact of using different materials for dental restorations. The identification and measurement of the costs and effectiveness of each of the approaches were considered and emerging issues highlighted at each stage.

The costs of each treatment scenario were based on the costs of materials used and the time of staff in the placement and replacement of the restorations. Patient costs in terms of the number of visits for treatment were also noted. Estimates of the time taken to complete a restoration and replacement were those obtained from the literature and the survey of dentists. The multiplicity of factors which affect both the time of restoration and restoration survival were allowed for in the sensitivity analysis. Survival rates were generated from the findings of a systematic review on the longevity of dental restorations and used to produce estimates of the number of tooth life years generated by each approach to treatment.

The cost per tooth life year was used as the indicator of cost effectiveness for each treatment scenario. Future costs were discounted to present values, while tooth life years were presented in discounted and non-discounted formats.

The model

The model was based on the direct costs of providing restorations. In the baseline analysis differences between dental settings were not taken into consideration but were discussed in the sensitivity analysis. Data relating to the cost of materials were provided from relevant price lists obtained from current dental catalogues, the procedure times from the literature and survey of dentists, and the staff cost from data obtained from the British Dental Association.

The direct cost for each restoration was based on the time of procedure multiplied by the pay rate for that period of time plus the material cost weighted for complexity and size. The cost per restoration type for each approach was computed for different restorations and a range of costs per amalgam, per composite and per inlay arrived at by adjusting the relative proportion of each restoration type undertaken.

The cost profile also embraced the number of replacements required over time, based on the inverse of the probability of survival for each material type, generated from a meta analysis of studies included in the systematic review. The costs of extractions and crowns were not included, as the inclusion of these costs only served to add to the cost-effectiveness differential between materials.

The databases searched to access relevant economic studies included MEDLINE, EMBASE, ECONLIT, ECRI, INAHTA and NEED and search terms consisted of costs, effectiveness, cost effectiveness, economics, dental, dentist, teeth, tooth, cavity, etc.

5. STATISTICAL METHODS

One aim in this systematic review is to combine the data from a variety of papers in order to obtain pooled estimates of key parameters reflecting the longevity of the various materials. Such parameters include, for example, the survival rates after particular time periods since the restoration was placed, say the two or three year survival rates. Another possibility is to attempt to estimate the overall survival function for each material, possibly separately for different subgroups. So we might try to estimate an overall survival function for amalgam restorations or we might restrict them to a particular subgroup of, say, high copper amalgams for Class I cavities in permanent teeth.

A particular difficulty about survival analysis is that data are almost invariably incomplete. Not only is there loss to follow-up in most studies, but data are 'censored' in that at the end of a study many restorations will usually be in place and not have failed. Thus while the life-time of a restoration which failed is known, that of one which has not failed is not known; if it is still intact after five years, we know only that its lifelength is at least five years.

When individual lifelengths are known, the usual method of analysis uses the Kaplan-Meier method of estimation of the survival function (Collett, 1994), that is the probability that a restoration survives intact for at least a given period of time. In most of these studies the exact lifetime is not known, since restorations are reviewed at intervals. A more appropriate method of estimation for such data is the life table method (Parmar and Machin, 1995). Both methods allow the computation of an estimate of the standard error of the estimated survival function at each time point

It is possible to compare survival functions for different levels of certain factors, such as different materials, different cavity types and different study types. These tests use Gehan's statistic, (Collett, 1994; Parmar and Machin, 1995), a variant of the Wilcoxon test statistic which makes allowance for the presence of censored data. If several different levels are compared simultaneously, then allowance must be made for the familiar multiple comparison problem analogous to that in one way analysis of variance, for example.

Studies of a particular material are compared by showing graphs of 95% confidence intervals for the survival rates at specified times. For amalgam, composites and inlays these are at one, two, three and five years, with amalgam also being shown for 10 years. For some other materials, one year rates are also shown. These confidence intervals can be computed from estimated standard errors calculated routinely by the life table analyses. When the failure rate is very low, however, it is well known that this simple procedure can be inaccurate and can lead to inappropriate results. For example, if the failure rate is 0, then the usual simple methods for calculating confidence intervals lead to an interval of (100%, 100%) - clearly incorrect. For this reason, Wilson's method (Newcombe, 1998) was used to compute the intervals. This gives appropriate intervals, always in the range (0,100).

It was hoped initially that it would be possible to incorporate information on effect modifiers into the synthesis of the data but these are usually described in very little detail, if at all, and so this has not been attempted.

No formal meta-analysis has been performed. This could be carried out on the survival rates at, say two years. However the heterogeneity displayed by the studies means that estimation of an overall survival rate is inappropriate; the differences between the studies are greater than can be explained by random variation and other explanatory factors would be needed to account for this variation.

Few of the studies had sufficient failures to enable the estimation of a median survival time unless a parametric model for the lifetime was used. These few studies were not typical of the main body of studies and hence no attempts were made to combine these into an overall estimate of the median survival time.

The dropout rate varied greatly between studies, even those of the same overall duration. The analysis assumes that dropout is at random, that is dropout is not related to outcome. We have no way of testing this but all the analysis in the literature examined would be invalid if this were not the case.

References

Collett D. Modelling survival data in medical research. 1994; London, Chapman and Hall.

Newcombe RG. Two-sided confidence intervals for the single proportion: a comparison of seven methods. *Statistics in Medicine 1998*; 17: 857-72.

Parmar M, Machin D. *Survival analysis: a practical approach*. 1995, Wiley.

6. SUMMARY OF RESULTS

The number and distribution of studies identified during the systematic review is outlined in Figure 3. Searches of the various databases revealed 5675 studies, with a further 113 being identified following hand searches. Of the 5788 studies, 652 were reviewed at stage 2 with 399 of these being excluded subsequently. Of the remaining 253 studies, a number were found to be linked in some way, often because reports were published of the same study at increasing time from baseline; this left a total of 195 studies that were retained for further evaluation.

Database Searches = 5675 Studies

+

Hand Search = 113 studies

Number of Studies Reviewed at Stage 2 = 652 Studies

Excluded Studies

399

Total No of Papers Included in the Review

253

Number of Studies Included in the Review Exclusive of Link Papers

195

Figure 3 - Flow Diagram Representing the Number and Distribution of Studies Identified by the Review

Table 4 provides a detailed breakdown of the numbers and types of studies, including details of the restorative material and inter-material comparisons. In each square the numbers in parenthesis give the study design.

The results of the survival analysis are divided into the various materials. Some of the studies that were identified and included do not appear in the results section because they formed small unique groups. For example, study 404 (Navarro et al., 1996) investigated a gallium based alloy ;- the material performed poorly with only 50% survival at 1 year. Studies investigating composite used with dentine bonding agents in Class I, II or III lesions have also been excluded (398, 450, 412, 802, 445, 348, 317, 818, 269/223/274, 830, 208, 477, 466, 471) (Oldenburg et al., 1987; van Dijken and Horstedt, 1987; Berry and Osborne, 1989; Satou et al., 1989; Shintani et al., 1989; Morikawa et al., 1990; Krejci et al., 1991; Wendt and Leinfelder, 1992; Ferrari et al., 1993; Ianzano and Gwinnett, 1993; Qvist and Strom, 1993; Willems et al., 1993; de Freitas et al., 1994; Krejci et al., 1994; Wendt and Leinfelder, 1994; Abdalla and Alhadainy, 1996; Rasmusson et al., 1998). This group of 13 studies were not included with the Class V studies as they all had supplementary mechanical retention as well as the DBA; as a result it would have been inappropriate to include them with the Class V or the composites without DBA.

References

Abdalla AI, Alhadainy HA. 2-year clinical evaluation of Class I posterior composites. American *Journal of Dentistry 1996*; 9: 150-2.

Berry TG, Osborne JW. Dentin bonding vs. enamel bonding of composite restorations: a clinical evaluation. *Dental Materials 1989*; 5: 90-2.

de Freitas AR, de Andrada MA, Baratieri LN, Monteiro Junior S, de Sousa CN. Clinical evaluation of composite resin tunnel restorations on primary molars. *Quintessence International 1994*; 25: 419-24.

Ferrari M, Bertelli E, Finger W. A 5-year report on a enamel-dentinal bonding agent and microfilled resin system. *Quintessence International 1993*; 24: 735-41.

Ianzano JA, Gwinnett AJ. Clinical evaluation of Class V restorations using a total etch technique: 1-year results. *American Journal of Dentistry 1993*; 6: 207-10.

Krejci I, Besek M, Lutz F. Clinical and SEM study of Tetric resin composite in posterior teeth: 12-month results. *American Journal of Dentistry 1994*; 7: 27-30.

Krejci I, Lutz F, Loher CE. Quantitative in vivo evaluation of four restorative concepts for mixed Class V restorations. *Quintessence International 1991*; 22: 455-65.

Morikawa A, et al. [Long-term clinical observations on two posterior restorative composite resins]. Hiroshima Daigaku Shigaku Zasshi - *Journal of Hiroshima University Dental Society 1990*; 22: 332-41.

Navarro MF, Franco EB, Bastos PA, Teixeira LC, Carvalho RM. Clinical evaluation of gallium alloy as a posterior restorative material. *Quintessence International 1996*; 27: 315-20.

Oldenburg TR, Vann WF, Jr., Dilley DC. Composite restorations for primary molars: results after four years. *Pediatric Dentistry 1987*; 9: 136-43.

Qvist V, Strom C. 11-year assessment of Class-III resin restorations completed with two restorative procedures. *Acta Odontologica Scandinavica 1993*; 51: 253-62.

Rasmusson CG, Kholer B, Odman P. A 3-year clinical evaluation of two composite resins in classII cavities. *Acta Odontologica Scandinavica 1998*; 56.

Satou N, et al. [Clinical evaluation of a posterior composite resins]. Hiroshima Daigaku Shigaku Zasshi - *Journal of Hiroshima University Dental Society 1989*; 21: 180-9.

Shintani H, Satou N, Satou J. Clinical evaluation of two posterior composite resins retained with bonding agents. *Journal of Prosthetic Dentistry 1989*; 62: 627-32.

van Dijken JW, Horstedt P. Effect of the use of rubber dam versus cotton rolls on marginal adaptation of composite resin fillings to acid-etched enamel. *Acta Odontologica Scandinavica 1987*; 45: 303-8.

Wendt SL, Jr., Leinfelder KF. Clinical evaluation of Clearfil photoposterior: 3-year results. *American Journal of Dentistry 1992*; 5: 121-5.

Wendt SL, Jr., Leinfelder KF. Clinical evaluation of a posterior resin composite: 3-year results. *American Journal of Dentistry 1994*; 7: 207-11.

Willems G, Lambrechts P, Braem M, Vanherle G. Three-year follow-up of five posterior composites: in vivo wear. *Journal of Dentistry 1993*; 21: 74-8.

Table 4 - Number and type of studies included in the review **TOTAL = 195 *(not including link papers)***

	AMALGAM	COMPOSITE	COMPOSITE & BONDING AGENTS	GIC	COMPOMER	INLAYS CERAMIC	INLAYS COMPOSITE	INLAYS GOLD	CERMET	SILICATE CEMENT	GALLIUM	TOTAL
AMALGAM	(3)= 2 (6)= 4 (4)= 0 (7)= 18 (5)= 0 (8)= 1 Total = 25	(3)= 1 (6)= 7 (4)= 0 (7)= 20 (5)= 0 (8)= 0 Total = 28		(3)= 0 (6)= 1 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total = 2					(3)= 0 (6)= 1 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total =2			57
COMPOSITE		(3)= 13 (6)= 7 (4)= 0 (7)= 14 (5)= 1 (8)= 3 Total = 38			(3)= 0 (6)= 1 (4)= 0 (7)= 0 (5)= 0 (8)= 1 Total =2					(3)= 0 (6)= 1 (4)= 0 (7)= 0 (5)= 0 (8)= 1 Total = 2		42
COMPOSITE & BONDING AGENTS			(3)= 11 (6)= 4 (4)= 0 (7)=14 (5)= 1 (8)= 4 Total =34									34
GIC		(3)= 0 (6)= 2 (4)= 0 (7)= 6 (5)= 0 (8)= 2 Total = 10		(3)= 5 (6)= 2 (4)= 0 (7)= 1 (5)= 0 (8)= 1 Total = 9	(3)= 0 (6)= 1 (4)= 0 (7)= 0 (5)= 0 (8)= 0 Total = 1				(3)= 1 (6)= 0 (4)= 0 (7)= 0 (5)= 0 (8)= 1 Total = 2			22
COMPOMER					(3)= 3 (6)= 0 (4)= 0 (7)= 0 (5)= 0 (8)= 0 Total = 3							3
INLAYS CERAMIC	(3)= 0 (6)= 0 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total =1					(3)=11 (6)= 2 (4)= 0 (7)= 3 (5)= 0 (8)= 0 Total = 16	(3)= 0 (6)= 0 (4)= 0 (7)= 2 (5)= 0 (8)= 0 Total =2					19
INLAYS COMPOSITE		(3)= 0 (6)= 0 (4)= 0 (7)= 2 (5)= 0 (8)= 0 Total =2					(3)= 3 (6)= 0 (4)= 0 (7)= 2 (5)= 0 (8)= 0 Total =5					7
INLAYS GOLD								(3)= 1 (6)= 0 (4)= 0 (7)= 0 (5)= 0 (8)= 0 Total =1				1
CERMET									(3)= 2 (6)= 0 (4)= 0 (7)= 0 (5)= 0 (8)= 0 Total =2			2
SILICATE CEMENT										(3)= 1 (6)= 0 (4)= 0 (7)= 0 (5)= 0 (8)= 0 Total = 1		1
GALLIUM											(3)= 0 (6)= 0 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total = 1	1
TOTAL	26	78	34	11	6	16	7	1	6	3	1	189

THREE OR MORE MATERIAL COMPARATIVE STUDIES

	GIC	COMPOSITE/ GIC SANDWICH	COMPOMER	SILICATE CEMENT	CERMET	GOLD	TOTAL
AMALGAM V COMPOSITE	(3)= 0 (6)= 0 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total = 1				(3)= 0 (6)= 0 (4)= 1 (7)= 2 (5)= 0 (8)= 0 Total = 3		4
COMPOSITE V GIC		(3)= 0 (6)= 0 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total = 1	(3)= 0 (6)= 0 (4)= 0 (7)= 1 (5)= 0 (8)= 0 Total = 1				2

KEY

(3)= PROSPECTIVE CASE SERIES
(4)= RETROSPECTIVE STUDY + CONCURRENT CONTROLS
(5)= PROSPECTIVE STUDY + HISTORICAL CONTROLS
(6)= PROSPECTIVE STUDY + CONCURRENT CONTROLS
(7)= OTHER CLINICAL TRIAL
(8)= RANDOMISED CONTROL TRIAL

6.1 Amalgam restorations

Summary of Amalgam studies

There were a total of 62 studies involving Amalgam restorations:

25 studies evaluated various amalgam restorations
28 studies compared amalgam with composite restorations
Two studies compared amalgam with glass ionomer cement restorations

Two studies compared amalgam with cermet restorations
One study compared amalgam with ceramic inlay restorations
One study compared amalgam with composite and with glass ionomer cement restorations
Three studies compared amalgam with composite and with cermet restorations

Of the 62 studies:

One study was a Randomised Control Trial (8)
44 studies were Other Clinical trials (7)
13 studies were Prospective Studies with Concurrent Controls (6)
One study was a Retrospective Study with Concurrent Controls (4)
Three studies were Prospective Case Series (3)

Survival of amalgam restorations - Permanent teeth

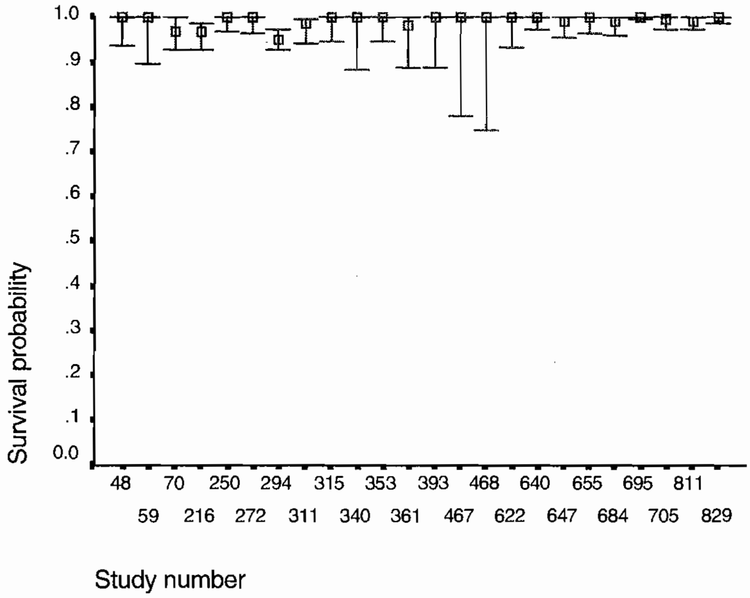

Figure 4 - Amalgam restorations in secondary teeth at 1 year

1 year

At 1 year all the studies reported good survival rates.

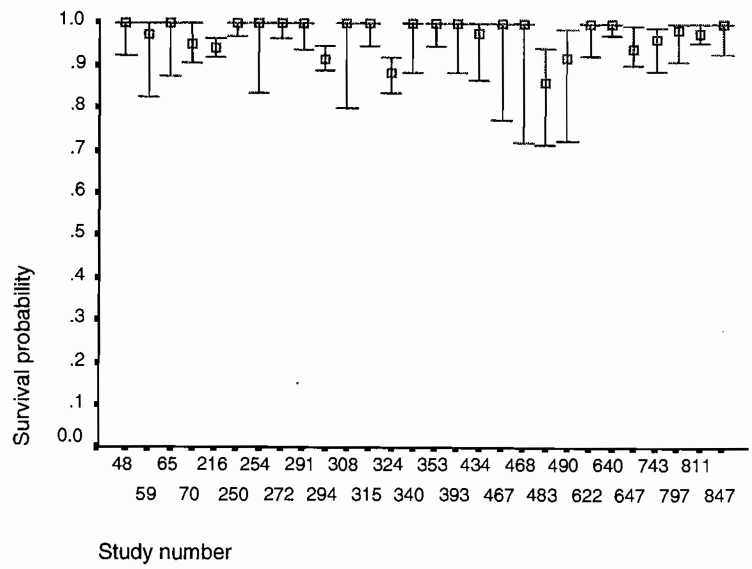

Figure 5 - Amalgam restorations in secondary teeth at 2 years

2 years

Most of the amalgams studied at two years had good survival with 16 out of 28 studies indicating no failure of the restorations. However, some of the studies showed lower survival rates. For example, the survival of amalgam in study 324 (Letzel et al., 1987) was obviously less than in the other studies. The failure rate in this study may be explained by the greater failure of amalgam due to a combination of one particular clinician (Operator 1; 8 out of 124 failed; Operator 2; 20 out of 114 failed) and also a particular amalgam (Luxalloy). In addition, oral health behaviour had a small but statistically significant effect on replacement (ie Poorer oral hygiene was associated with increased replacement rates). Study 483 (Wood et al., 1993) also shows a low survival rate, but this study was carried out in patients that had a marked xerostomia as a result of radiotherapy given for the treatment of malignancy.

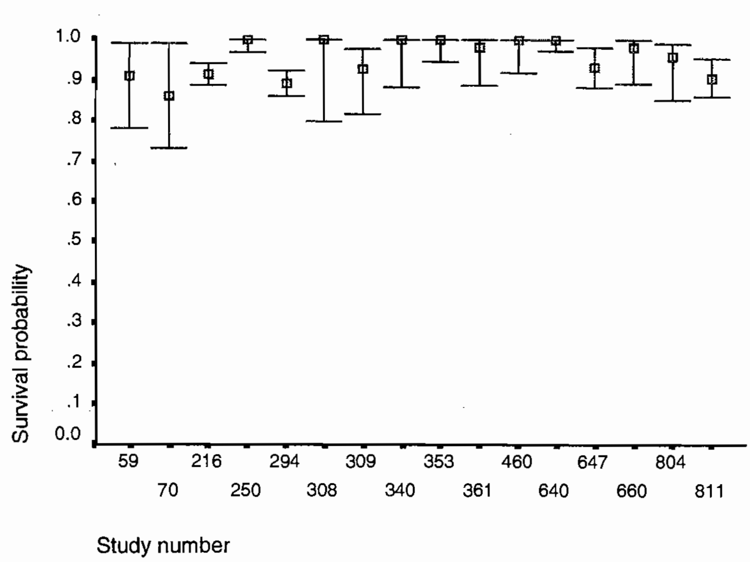

Figure 6 - Amalgam restorations in secondary teeth at 3 years

3 years
At three years, six out of 16 studies indicated no failures. In the studies indicating poorer survival, study 294 (Kusner et al., 1988) did not define the amalgam used and there was little detail about the design and size of preparations. Interestingly, the study indicated poorer survival with non-extended restorations (22 out of 175 non-extended cavities failed compared to 18 out of 175 extended restorations). Study 811 (Hamilton et al., 1983) compared two amalgams (Spheralloy and Dispersalloy); Spheralloy showed greater failure (10 out of 77) compared with Dispersalloy (four out of 67). However, there were no statistically significant differences. Study 216 (Jokstad and Mjor, 1991) compared replacement restorations with five different amalgams and found that survival depended on the patient's age and caries activity. Study 70 (Phillips et al., 1973) also showed a low survival rate, but the reasons for this are not immediately obvious. However, the study gave little detail about the participants or the balance between premolars and molars.

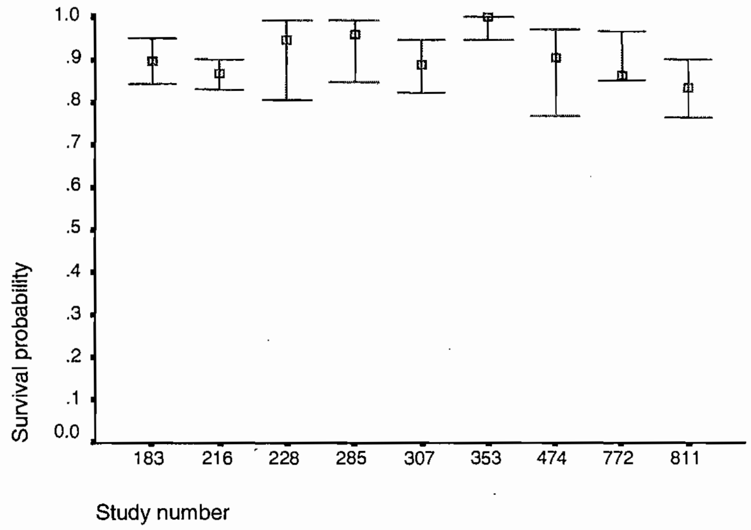

Figure 7 - Amalgam restorations in secondary teeth at 5 years

5 years
One out of the nine studies found no loss of amalgam at five years (353) (Johnson et al., 1992). This study compared two high copper alloys with and without indium. The remaining studies showed a survival probability of around 85% or better. Study 216 (Jokstad and Mjor, 1991) was a relatively large multi-centre study using five different amalgam alloys; 68 out of 468 amalgams were replaced. Indiloy showed the greatest survival (38 out of 44 survived after five years).

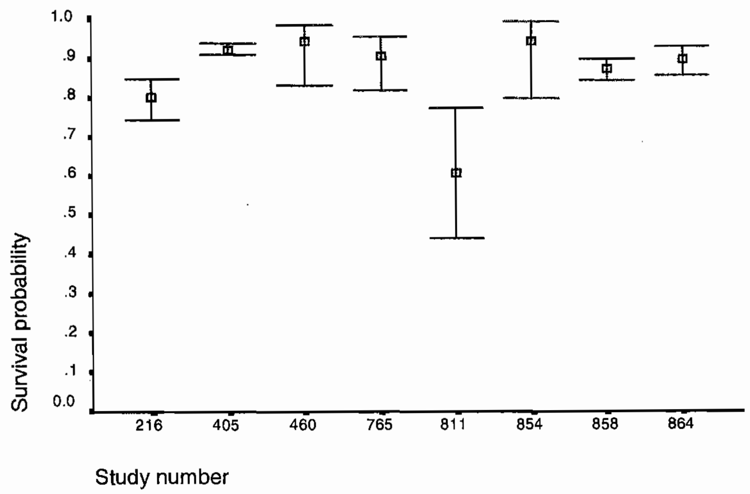

Figure 8 - Amalgam restorations in secondary teeth at 10 years

10 years
Seven out of eight studies at 10 years reported survival probabilities of 80% or better. Study 811 (Hamilton, Moffa et al., 1983) showed the greatest variation and poorest survival over this period. In that study there were no statistically significant differences in survival rates between Dispersalloy and Spheralloy but 79% of restorations were lost to follow-up. Study 858 (Roberts and Sheriff, 1990) included both primary and permanent teeth with apparently greater failure in Class I and II amalgams in the primary dentition compared to the permanent dentition.

Primary teeth

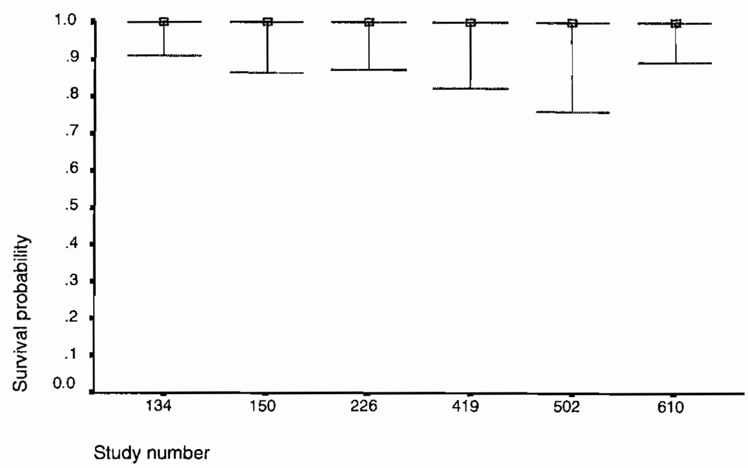

Figure 9 - Amalgam restorations in primary teeth at 1 year

1 year
At one year all six studies undertaken in primary teeth had no failures.

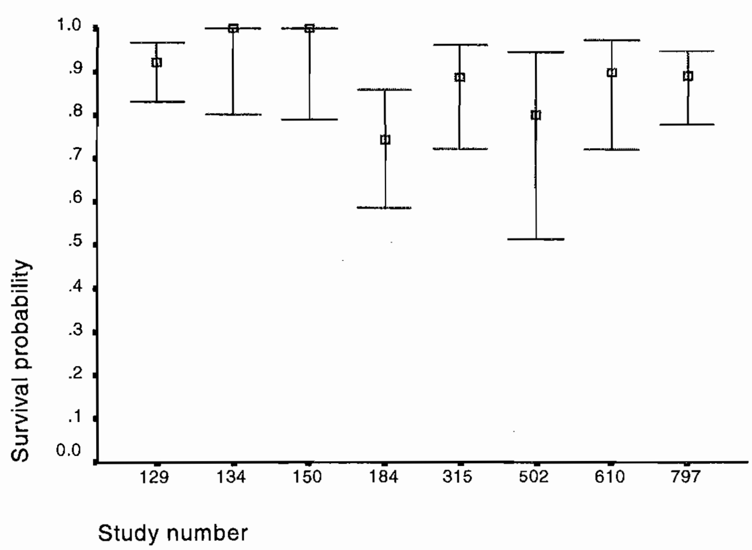

Figure 10 - Amalgam restorations in primary teeth at 2 years

2 years
At two years two out of eight studies reported no failures (studies 134 and 150) (Nelson et al., 1980; Morris et al., 1979). Of the remaining studies four reported survival probabilities of greater than 85%. Studies 184 and 502 (Barr-Agholme et al., 1991; Chu et al., 1996) showed lower survival probabilities than this, although the reasons for this are not clear. However, these studies involved small numbers of teeth and had relatively large subject dropout

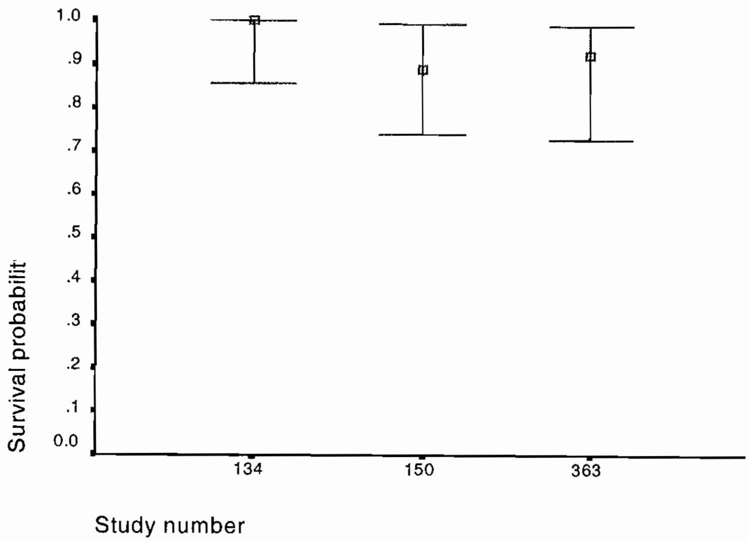

Figure 11 - Amalgam restorations in primary teeth at 3 years

3 years
At three years one study (134) (Nelson, Osborne et al., 1980) had no failures and the remaining two studies (150 and 363) (Morris, Barkin et al., 1979; Ostlund et al., 1992) had survival probabilities of 90% or greater.

Survival analysis

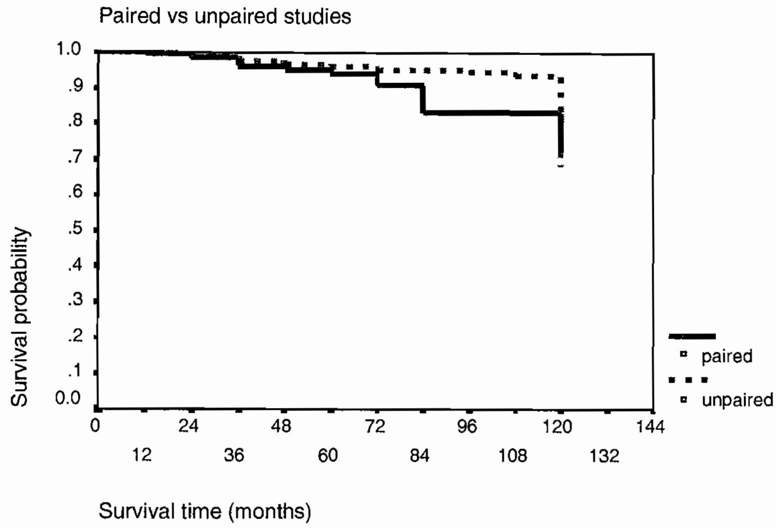

Figure 12 - Comparison of survival functions in amalgam restorations

Overall the survival rates for amalgam were good with an average failure rate of less than 10% for individuals examined at 10 years. The relatively high survival rate has to be viewed in the context that 52% of restorations were lost to follow up.

A further interesting finding was that when the type of clinical study was compared, the survival of amalgam restorations was greater in unpaired studies compared to paired studies. The reason for this is not immediately obvious.

Problems with study design
Most of the studies dealt with comparisons of amalgam alloys or various placement techniques. The study designs were not sufficiently rigorous to provide confidence in making firm conclusions on the

factors influencing the longevity of restorations. Although some examiners were calibrated in outcome measures there were no 'gold standards' whereby the examiners could be judged.

Conclusions

There was only one multi-centre multi-operator study (216) (Jokstad and Mjor, 1991). This study analysed the survival of five different amalgam alloys in three service settings in four countries with seven dentists.

In summary:

1. Most of the studies were undertaken in a hospital or institutional environment.
2. Most studies had pre-selection criteria before patients entered the study. Arguably the findings may represent the best survival scenario.
3. Many studies at 3 years showed no failure of amalgam restorations. However, this finding must be viewed with a certain amount of caution since it is difficult to determine if this is an accurate reflection of survival or that failure was not recorded or the patient failed to return.
4. After 10 years less than 20% of amalgams were replaced.
5. A series of effect modifiers also seemed to influence survival. Poor oral health appeared to be associated with reduced survival (216, 324, 705/788, 483) (Jokstad and Mjor, 1991; Letzel, van 't Hof et al., 1987; Rydinge et al., 1981; Goldberg et al., 1980; Wood, Maxymiw et al., 1993).
6. Operators had an influence in two areas; skill in placing the restoration and level of agreement on whether to replace a restoration (216,324,829) (Jokstad and Mjor, 1991; Letzel, van 't Hof et al., 1987; Letzel and Vrijoef, 1980, 1982).
7. There appeared to be no greater reduction in survival of more extensive amalgam restorations (# 294,393,864) (Kusner, Markitziu et al., 1988; Belcher and Stewart, 1997; Plasmans et al., 1998).
8. There appeared to be inconclusive evidence that MO/DO restorations survived longer than MOD restorations (216, 405/496) (Jokstad and Mjor, 1991; Gruythuysen et al., 1996; Akerboom et al., 1993).
9. There were no differences in survival over 36 months between polished and unpolished amalgam restorations, which strongly questions the need for this procedure. (640/641, 718/719) (Corpron et al., 1982; Corpron et al., 1983; Straffon et al., 1983; Straffon et al., 1984).
10. The use of amalgam to restore primary teeth seems justified as failure rates of 10% or less were reported at 3 years (134,150,363) (Nelson, Osborne et al., 1980; Morris, Barkin et al., 1979; Ostlund, Moller et al., 1992).
11. Detecting differences in survival rates of restorations in primary and permanent teeth is difficult over long periods, as primary teeth will exfoliate. The studies suggest that there is greater replacement of restorations in primary teeth, although there is also a great number of teeth lost to follow-up (797,858) (Matsson et al., 1982; Roberts and Sheriff, 1990).
12. Certain types of amalgam were associated with greater survival (216,272,324,405/496, 684, 811) (Jokstad and Mjor, 1991; Capel Cardoso et al., 1989; Letzel, van 't Hof et al., 1987; Gruythuysen, Kreulen et al., 1996; Akerboom, Advokaat et al., 1993; Morris et al., 1981; Hamilton, Moffa et al., 1983).

Future research

- To assess the effects of tooth type, cavity type and amalgam type on survival using rigorous study design and more empiric measures of the effect modifiers.

- To develop multi-centre, multi-operator studies with stratification of tooth type, cavity type and other effect modifiers for assessment periods of greater than 10 years.

6.2 Composite restorations

Summary of composite studies

There were a total of 122 studies involving composite restorations:
38 studies evaluated various composite materials
34 studies evaluated various composite materials used with dentine bonding agents
28 studies compared composite with amalgam restorations
10 studies compared composite with glass ionomer cement restorations
Two studies compared composite with compomer restorations
Two studies compared composite with silicate restorations
Two studies compared composite with composite inlay restorations

One study compared amalgam with composite and with glass ionomer cement restorations
One study compared composite with glass ionomer cement and with compomer restorations
Three studies compared amalgam with composite and with cermet restorations
One study compared composite composite with glass ionomer and with composite/glass ionomer cement sandwich restorations
Of the 122 studies:
11 were Randomised Control Trials (8)
58 were Other Clinical Trials (7)
22 were Prospective Studies with Concurrent Controls (6)
Two were Prospective Studies with Historical Controls (5)
One was a Retrospective Study with Concurrent Controls (4)
28 were Prospective Case Series (3)

Survival of composite restorations without dentine bonding agents
The analysis of the direct placement composite resins has been divided into permanent and deciduous teeth

Permanent teeth
The following survival graphs contain all the data for Class I, II, III, IV and V restorations.

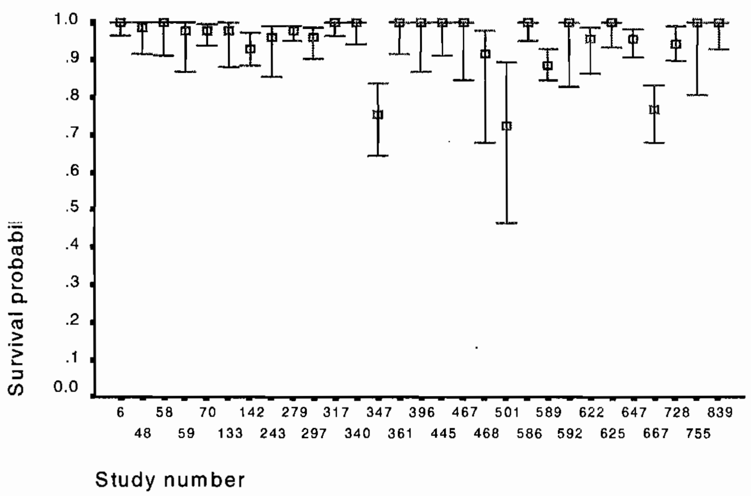

Figure 13 - Composite restorations in secondary teeth at 1 year

<u>1 year</u>
Overall, at one year 14 studies out of 29 reported no failure (studies 6, 58, 317, 340, 361, 396,586, 592, 625, 755, 839) (Scheer, 1975; Eriksen, 1974; van Dijken and Horstedt, 1987; Johnson et al., 1992; Knibbs and Smart, 1992; Millar et al., 1997; Osborne and Gale, 1980; Osborne and Berry, 1986; Davis et al., 1982; de Araujo et al., 1998; Richardson and Derkson, 1987). Of the remaining studies, the reported survival rates for composite restorations was 90% or better, except for three studies (347, 501, 667) (Saleh et al., 1992; Matis et al., 1996; Kullmann, 1985) that reported higher failure rates.

Study 347 (Saleh, Peretz et al., 1992) examined Class III and IV cavities, but it is difficult to draw any conclusions from this study due to a lack of detail and a composite of unknown formulation.

Study 501 (Matis, Cochran et al., 1996)was designed to assess the retention of glass ionomer cements and used composites as a control. The cavities were all Class V.

Study 667 (Kullmann, 1985) investigated a mix of Class III, IV and V preparations restored with two autopolymerising composites. Since most of the preparations had mechanical retention and an etchant and resin were used, the high failure rate is difficult to explain.

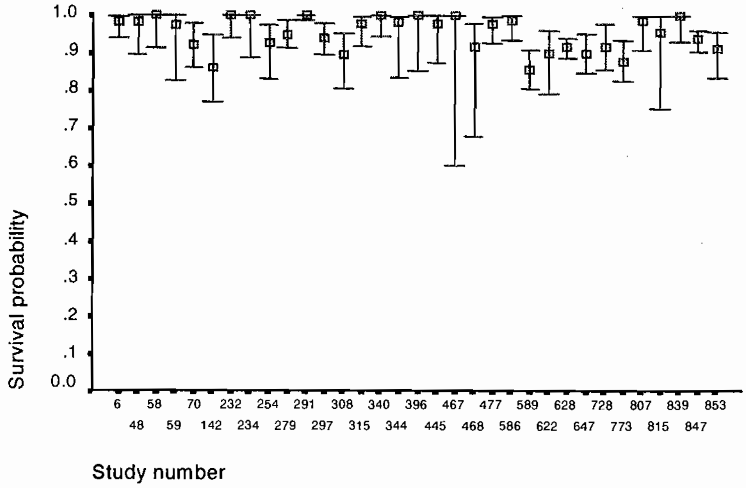

Figure 14 - Composite restorations in secondary teeth at 2 years

2 years

At two years, six out of 33 trials reported no failures (58,232,234,291,467,839) (Eriksen, 1974; Dietschi and Holz, 1990; Grogono et al., 1990; Fukushima et al., 1988; Lidums et al., 1993; Richardson and Derkson, 1987), while the remaining studies reported survival probabilities of 90% or better. The only exceptions to this were studies 142 and 589 and 773 (Smith and Wilson, 1979; Raadal, 1978; Heymann et al., 1986).

Study 142 (Smith and Wilson, 1979) compared an early light-cured composite with an autopolymerising resin; the restorations were largely Class III with some Class IV and V. Etchant was used only with Class IV restorations and no enamel bonding resin was used.

Study 589 (Raadal, 1978) was restricted to Class I restorations in first molars. Critically, the preparations were confined to enamel and the material was an autopolymerising, macrofilled composite with occasional dilution with bonding resin

Study 773 (Heymann, Wilder et al., 1986) was confined to Class I and II restorations in posterior teeth. Most of the failures occurred because of bulk fractures within the material.

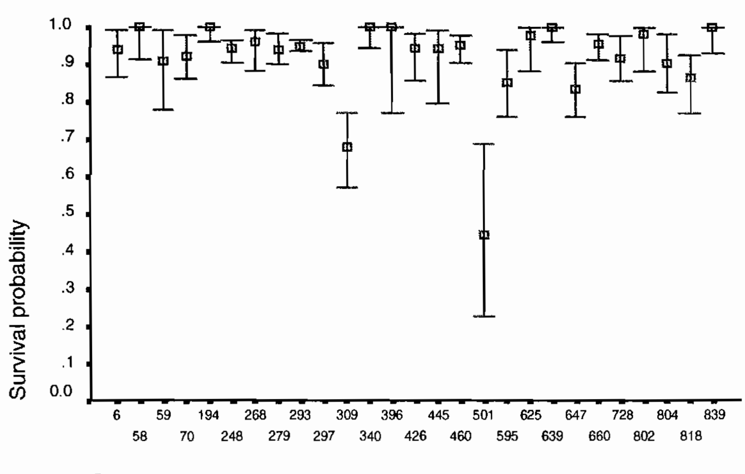

Figure 15 - Composite restorations in secondary teeth at 3 years

3 years

At three years, six studies out of 27 reported no failures (studies 58, 194, 340,396, 639, 839) (Eriksen, 1974; Wilder et al., 1991; Johnson, Bales et al., 1992; Millar, Robinson et al., 1997; Christensen and Christensen, 1982; Richardson and Derkson, 1987). Of the remaining studies, only three had survival rates below 90% (309, 501, 647) (Prati and Montanari, 1988; Matis, Cochran et al., 1996; Derkson et al., 1982). Study 309 (Prati and Montanari, 1988) used an early autopolymerising microfine composite (Silar) in Class I and II cavities. Study 501 (Matis, Cochran et al., 1996) involved a very small sample of 30 patients. Study 647 (Derkson, Richardson et al., 1982) included both primary and secondary teeth and was confined to Class I & II restorations.

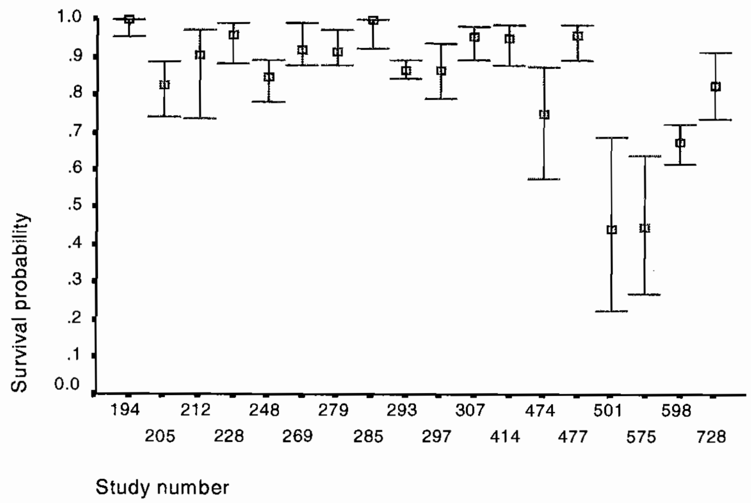

Figure 16 - Composite restorations in secondary teeth at 5 years

5 years

At five years only two studies reported no failures (194 and 285) (Wilder, Bayne et al., 1991; Hoyer et al., 1988). The majority of studies reported survival rates of around 80% or better; four studies reported much lower survival rates (474, 501, 575 and 598) (Mjor and Jokstad, 1993; Matis, Cochran et al., 1996; Matis et al., 1991; van Dijken, 1986).

Study 474 (Mjor and Jokstad, 1993) had marked differences in follow up and failure rates between three different operators.

Study 501 (Matis, Cochran et al., 1996) was carried out using a small sample size of 30 patients and in Class V cavities.

Study 575 (Matis, Carlson et al., 1991) was carried out in non-carious Class V cavities, unfortunately the age of the patients was not stated. It is likely that the average age of these patients was quite high so that bonding to sclerotic dentine may well account for the high failure rate recorded.

Study 598 (van Dijken, 1986) investigated Class III, IV and V restorations and a variety of materials placed by a single operator; no resin enamel bond was used.

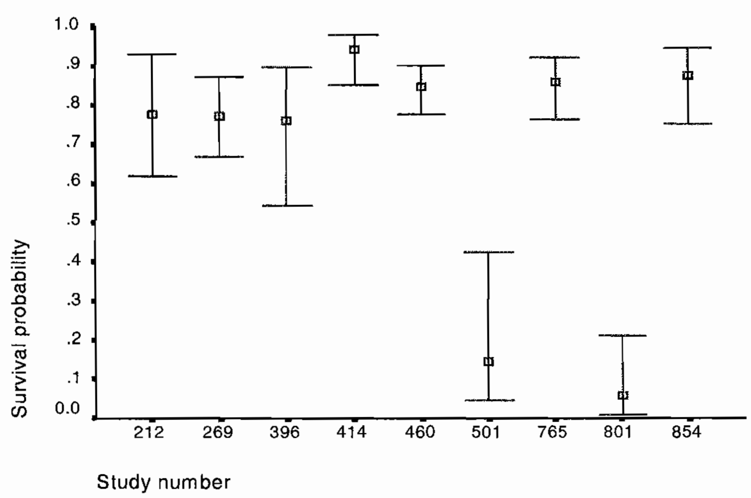

Figure 17 - Composite restorations in secondary teeth at 10 years

10 years
Only nine studies report results at 10 years. Of these studies, seven report survival rates of 75% or better. The remaining two studies (501 and 801) (Matis, Cochran et al., 1996; Beere et al., 1984) reported survival rates of less than 20%.

Study 501 (Matis, Cochran et al., 1996) was carried out using a small sample with only 18 of the patients reviewed at 10 years.

Study 801 (Beere, Cautley et al., 1984) examined only Class IV composite restorations used to restore fractured incisors in children following trauma. All the teeth included in the trial, except one, were maxillary anterior teeth.

Primary teeth

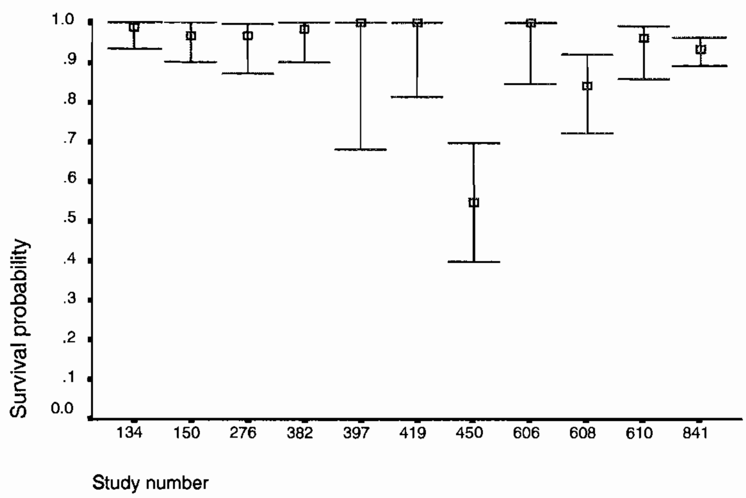

Figure 18 - Composite restorations in primary teeth at 1 year

1 year
At one year, four out of 11 studies had no failures. Of the remaining studies, five had survival rates in excess of 90%, while one study (608) (Varpio, 1985) showed rates below this value.

Study 608 examined composite resin in Class II cavities in deciduous molars. The age range of the patients was low (5-11 yrs), so it is possible that this contributed to the poor success rate; younger children are more difficult to manage and hence operating conditions may have been compromised.

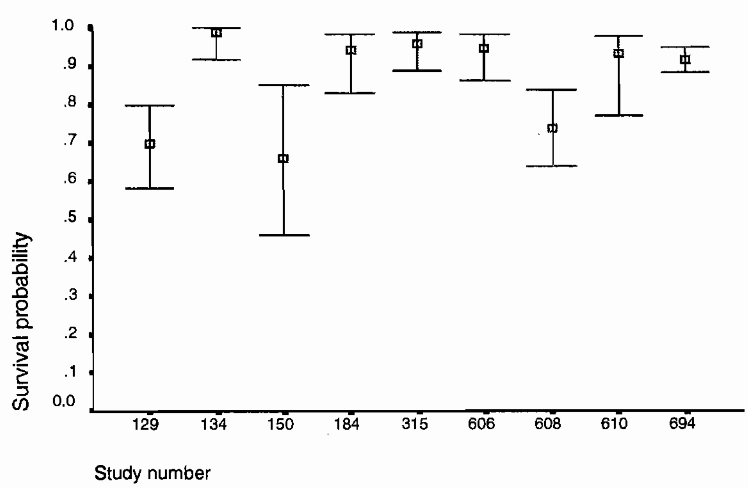

Figure 19 - Composite restorations in primary teeth at 2 years

2 years
At two years only one study (134) (Nelson et al., 1980) reported no failures with five reporting survival probabilities greater than 90%. Three studies (129, 150 and 608) (Tonn et al., 1980; Morris et al., 1979; Varpio, 1985) reported survival rates of between 60% and 75%.

Study 129 (Tonn, Ryge et al., 1980) involved Class II restorations in primary molars. The composite used was on autopolymerising macrofilled resin. No etchant or enamel resin bond was used.

Study 150 (Morris, Barkin et al., 1979) included Class II restorations in primary molars; the composite could not be categorised. The use of etch and bonding resin was not described and very few restorations were reviewed at the end of the study (nine at 42 months).

The problems with study 608 (Varpio, 1985) have been discussed above.

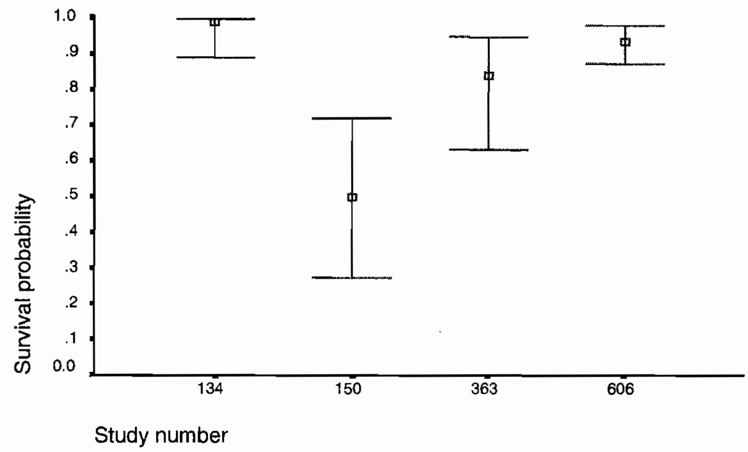

Figure 20 - Composite restorations in primary teeth at 3 years

3 years
At three years, only four trials were included. Of these studies, three report survival probabilities in excess of 80%. The other trial (150) (Morris, Barkin et al., 1979) reports a survival probability of only 50%; this study has been discussed above.

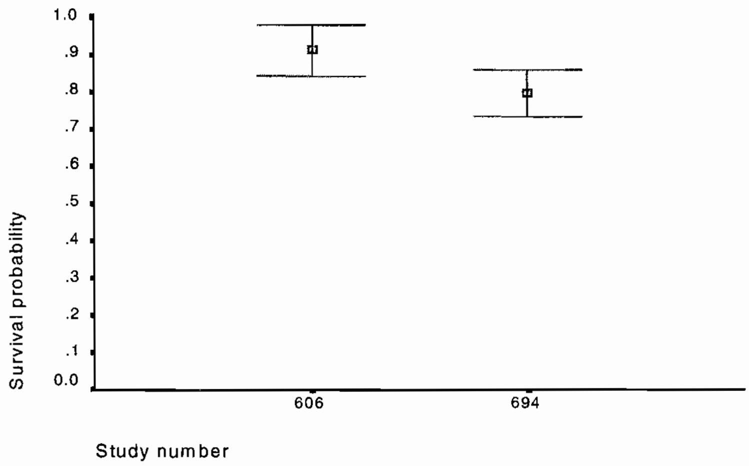

Figure 21 - Composite restorations in primary teeth at 5 years

5 years
At five years only two studies were included; they reported survival probabilities of between 80 and 90%.

Problems with study design
Most of the studies dealt with comparisons of composite resins or operating techniques. The study designs were not sufficiently rigorous to provide confidence in making firm conclusions on the factors

influencing the longevity of restorations. Although some examiners were calibrated in outcome measures, there were no 'gold standards' whereby the examiners could be judged.

Conclusions

1. Most of the studies were undertaken in the hospital or institutional environment.
2. Most studies had pre-selection criteria before patients entered the study. Arguably the findings may represent the best survival scenario.
3. Many studies used small sample sizes.
4. Many studies at three years had no failures. However, this finding must be viewed with a certain amount of caution, since it is difficult to determine if this is an accurate reflection of survival or that failure was not recorded or the patient failed to return.
5. Many of the studies that reported particularly poor survival rates were carried out in an older age group in non-undercut Class V cavities (eg study 263) (Levy et al., 1989).
6. Class IV composite restorations in permanent teeth seemed to have a particularly poor survival rate (Study 801) (Beere, Cautley et al., 1984) although the data was based on one study only.
7. The survival rate of composite in deciduous teeth formed a rather heterogeneous group. As placement of composite resin is technique sensitive, it is likely that the age of the patient will be a major effect modifier for survival

Future research

- To assess the effects of tooth type, cavity type and composite resin type on survival in deciduous and permanent teeth using rigorous study design and more empiric measures of the effect modifiers.
- To develop multi-centre, multi-operator studies with stratification of tooth type, cavity type and other effect modifiers for assessment periods of 5-10 years or more.
- More research to be carried out in a general practice setting.

6.3 Dentine bonding agents and class V restorations

Summary of dentine bonded studies

There were a total of 40 studies involving DBA's:

34 studies evaluated composite restorations with DBA's
Four studies evaluated GIC with Composite resin restorations
One study evaluated GIC with Composite resin & DBA and with a Composite resin/GIC sandwich restoration
One study evaluated Compomer with Composite restorations & DBA

Overview

The following information relates exclusively to the study of Class V restorations. Studies that used DBA but were not Class V have not been included in the survival graphs. Not all studies are illustrated in the one year survival graph as they do not report data for this period. However these studies are represented in later graphs.

27 studies investigated non-retentive Class V cavities which used completely or partly a composite and dentine bonding agent as the restoration. The restorations therefore relied almost entirely on the retention of the bonding mechanism to resist total loss. The outcome measure most commonly used was absolute, namely complete loss of restoration.

Dentine bonding agents are a relatively new method of retaining restorations (usually composite) and have been changing and evolving rapidly. Initially the adhesive mechanism was thought to be entirely chemical but more recently, laboratory experiments have indicated that superior bonds are achieved when hydrophilic resins impregnate the surface of the dentine. To achieve this the surface smear layer needs to be removed and the superficial dentine softened by partial demineralisation using an acid primer. A number of different acid primers have been used although the trend at present is to employ phosphoric acid (which is also used for etching enamel) for this process. Early dentine bonding agents did not use acid primers.

To ease analysis of the results the studies reviewed have been divided where possible into the following groups (Van Meerbeek et al. 1993):-

- *Group 1:-* Dentine bonding agents that remove completely the smear layer and impregnate the dentine surface. Group 1a uses phosphoric acid to prime the dentine whilst group 1b uses other acids such as EDTA, Maleic and Nitric acids. In some studies a material normally in group 1b has been put into group 1a because phosphoric acid was used as the primer.
- *Group 2:-* Dentine bonding agents that impregnate and alter the smear layer only.
- *Group 3:-* Dentine bonding agents that only impregnate the smear layer.

Survival of Restorations

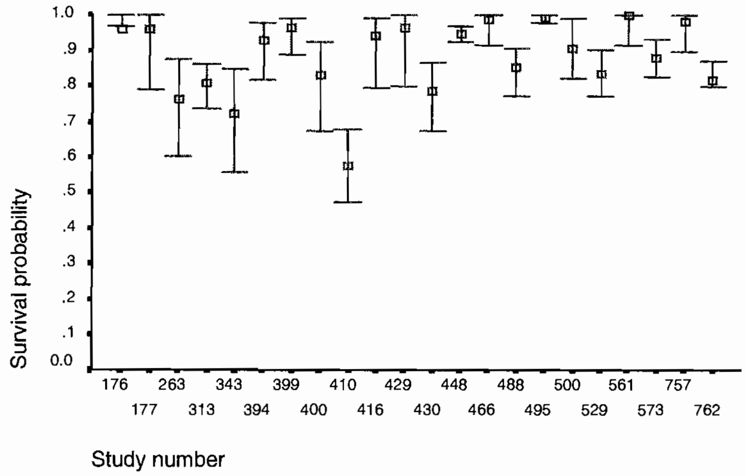

Figure 22 - Dentine bonding agents in Class V restorations at 1 year

1 Year

Most of the studies indicated good survival rates (90% or above) at one year, although within a number of studies there were large variations. The majority of studies with the poorest survival rates (263, 313, 410, 430, 488, 529,762) (Levy et al., 1989; Ziemiecki et al., 1987; Tyas, 1996; Wilson and Wilson, 1995; Van Meerbeek et al., 1993; Horsted-Bindslev et al., 1988; Heymann et al., 1988) used older dentine bonding agents (groups 2/3) in part or completely. However, study 343, (Tyas, 1992) which used a modern system (1b), demonstrated particularly poor results; the dentine bonding agents (Mirage, 1b) had a 50% failure rate whilst the other one (Tenure, 1b) had only one out of 20 failures. However, the number of restorations was low. These results are surprising, given the similarity of the materials.

Where studies used a number of dentine bonding agents ranging from older group three materials through to group one materials, the results generally indicated improved success where the more modern materials were employed. Study 529 (Horsted-Bindslev, Knudsen et al., 1988) for example investigated six experimental groups with failure rates ranging from 0 to 56%. In this and other studies (395, 448, 488) (Boghosian, 1996; Van Meerbeek et al., 1994; Van Meerbeek, Braem et al., 1993) the use of acid etching of enamel in addition to otherwise poor dentine bonding systems, improved retention rates significantly.

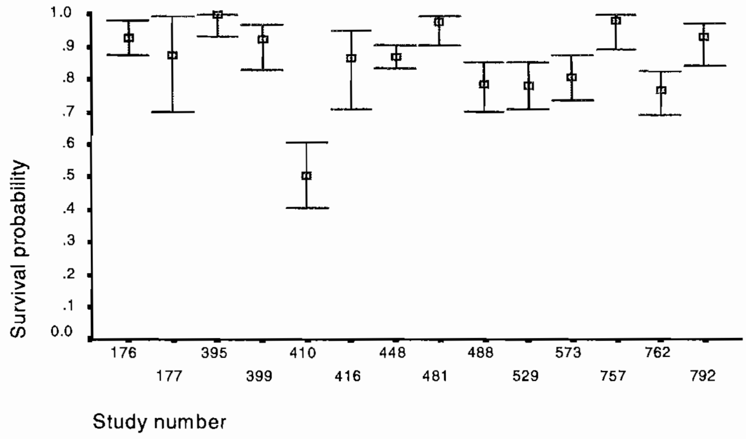

Figure – 23 - Dentine bonding agents in Class V restorations at 2 years

2 Years
The majority of studies reported a success rate of 85% or better, with only five studies falling below this. Study 410 (Tyas, 1996) demonstrated poor success at year one and this continued into year two. In this study the majority of failures were limited to three out of the five groups, indicating particular problems with these products. The dentine bonding systems used were classified as either 1b or 3 and the reason for the high failure may relate to the bonding mechanism and/or the technique sensitivity of the materials. However, the numbers in each group (20) make it difficult to draw firm conclusions.

Study 488 (Van Meerbeek, Braem et al., 1993) is interesting as it investigated two dentine bonding agents with and without etching of the surrounding enamel. Significant improvements were seen in the etched groups. Study 529, (Horsted-Bindslev, Knudsen et al., 1988) however, reported that the two group 3 dentine bonding agents used with etched enamel had poor success, whereas the success of a 1b dentine bonding agent was improved following etching.

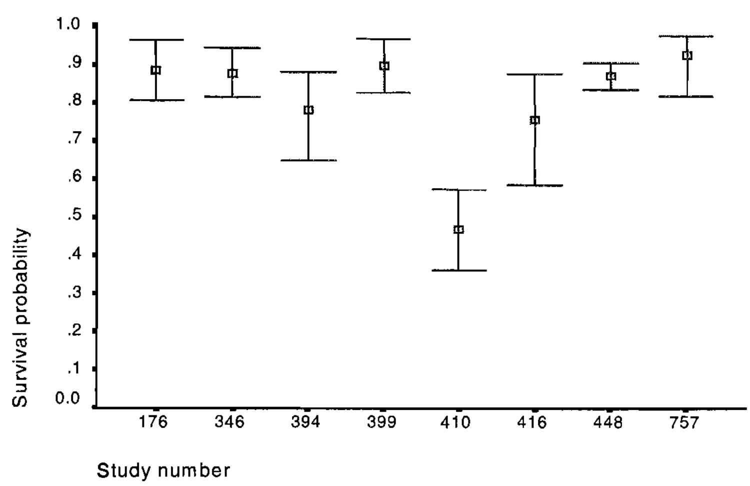

Figure 24 - Dentine bonding agents in Class V restorations at 3 years

3 Years
At three years, the majority of the studies had success rates in excess of 80%. Study 410 (Tyas, 1996) again had the poorest success.

Study 416 (Powell et al., 1995) had a success rate just below 80%. This study compared a glass ionomer restoration (GIC), a dentine bonded composite restoration and a composite restoration lined with a resin modified liner (RMGIC). At three years, there had been no failures in the RMGIC lined composite group, only one failure in the GIC group but almost 25% of failures in the dentine bonded composite group. In both composite groups the surrounding enamel had been bevelled and etched and from other studies this could be expected to improve the retention rate. It is possible that the technique employed in this study (etch enamel then dentine prime) may have had a deleterious effect. In the RMGIC lined group the liner was placed prior to etching the enamel.

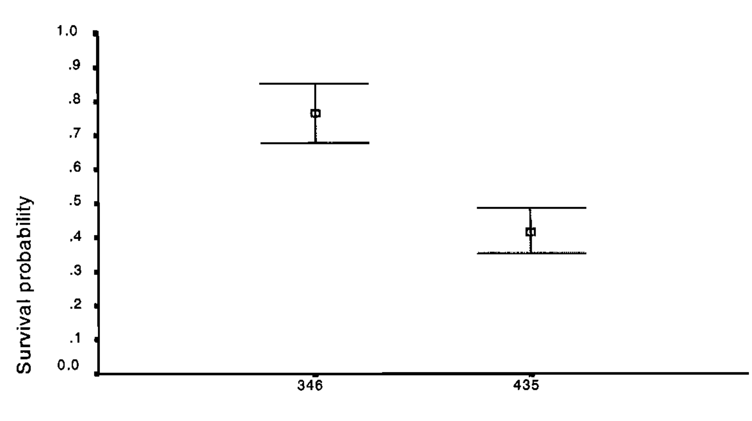

Figure 25 - Dentine bonding agents in Class V restorations at 5 years

5 Years

Only three studies are reported in this graph, one of which (435) (van Dijken, 1994) reported on four year data. The four year results in study 435 reported that two out of the four materials had high failure rates (75% and 83% failure) whilst the remaining two DBA systems recorded 22% and 50% failure rates. All but one of the materials tested (the material with the highest failure rate) were classified as group 1b. The remaining material was classified as group 2.

Study 346 (Hansen, 1992) investigated a group 3 material (Scotchbond) with a survival rate of 47% whist the other material, Gluma (group 1b) had a 90% survival rate.

Problems with study design?

- The use of Class V cavities to test dentine bonding agents has a number of advantages which include the ability to compare different agents within the same mouth. However, not all studies took advantage of this, so weakening the power of the study.
- Study design could have been improved by better randomisation and separation of the operator and assessor.
- Control of variables
- Not generalisable because mainly hospital/university environment

Problems with interpretation

The 27 studies included the following effect modifiers

- Many different dentine bonding agents. As discussed above the mechanism of operation of the different agents has evolved
- Use of acidic primers which, in addition to priming the dentine may etch the surrounding enamel
- Many different combinations of dentine bonding agent and composite restorative material. The success of the bonding agent may relate to the use of a particular composite type
- Use of etched enamel/bevelled enamel/rubber dam.
- Lack of detail in studies relating to occlusal stresses, patient age, dental arch in which restorations placed.
- Generalisability of the majority of the studies was limited because they were carried out within University institutions, often with only a few operators.
- The use of composite failure outcome measure reduced the subjectivity of assessment seen in other studies within this review.
- Studies often had small numbers which became even less as patients were lost to recall.
- Few studies went beyond three years.
- The aim of the studies was to test the effectiveness of the DBA, but the use of acidic primers which may etch the enamel cloud this aim.
- Comparison between studies is difficult because over a large number of variables, rapidly changing materials and lack of standardisation of sample.

Summary

Significant problems of interpretation have been encountered because of :-

- Poorly designed studies
- Lack of detail in papers, especially relating to losses to recall or technique used
- Use of materials which are no longer available
- Total etch systems look promising
- Use of all systems reduced sensitivity

The results of these studies suggest

- Enamel etching (with or without enamel bevel) is clinically effective for long term retention
- Mechanical retention is also effective for the retention of restorations
- Newer materials (group 1) appear to perform better than older materials (groups 2/3)
- Total etch systems look promising
- Use of all systems reduced sensitivity
- Retention rate for class V composite restorations was higher in the maxillary than mandibular teeth

Future research

- Large scale Primary care based (or multi-centre) clinical study investigating the effectiveness of GIC, RMGIC, Compomer and Composite/Dentine Bonding Agent restorations in Class V cavities.

6.4 Glass Ionomer Cement restorations

Summary of GIC studies

There were a total of 28 studies involving Glass Ionomer Cement restorations:

Nine studies evaluated glass ionomer cement materials
Nine studies compared composite with glass ionomer cement restorations
Two studies compared amalgam with glass ionomer cement restorations
Two studies compared cermet with glass ionomer cement restorations
Three studies compared glass ionomer cement restorations with compomer restorations
One study compared amalgam with composite with glass ionomer cement restorations
One study compared composite with glass ionomer cement with composite/GIC sandwich restorations
One study compared composite with glass ionomer cement with compomer restorations

Of the 28 studies:

Three were Randomised Control Trials (8)
13 were Other Clinical Trials (7)
Six were Prospective Studies with Concurrent Controls (6)
Six were Prospective Case Series (3)

Survival of GIC restorations

The analysis of the glass ionomer cements has been divided into permanent and deciduous teeth.

Permanent teeth

The following survival graphs contain all the data for Class I, III, III and V restorations.

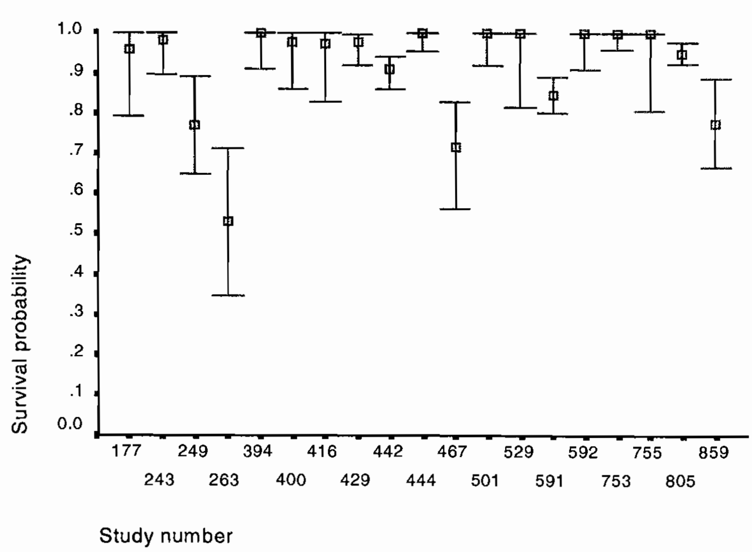

Figure 26 - GIC restorations in secondary teeth at 1 year

<u>1 year</u>

Of the 19 studies that provided data at one year seven reported no failures (394,444, 501, 529, 592, 753, 755) (Neo and Chew, 1996; Gray and Paterson, 1994; Matis et al., 1996; Horsted-Bindslev et al., 1988; Osborne and Berry, 1986; Abdalla et al., 1997; de Araujo et al., 1998). Of the remaining studies, many reported survival of greater than 90%. However, five studies report survival of between 50% and 80% (249, 263, 467, 591, 859) (Welbury and Murray, 1990; Levy et al., 1989; Lidums et al., 1993; McLean and Wilson, 1977; Mallow et al., 1998).

Study 249 (Welbury and Murray, 1990) investigated glass ionomer/composite sandwich restorations in permanent teeth; this reported high failure at the gingival margin of approximal boxes.

Study 263 (Levy, Jenson et al., 1989) was carried out in Class V cavities so that it is likely that there were problems bonding to dentine.

Study 467 (Lidums, Wilkie et al., 1993) involved sandwich restorations in posterior teeth.

Study 591 (McLean and Wilson, 1977) was a early study carried out using the original glass ionomer material ASPA.

Study 859 (Mallow, Durward et al., 1998) reports the use of glass ionomer in a rural setting using the Atraumatic Restorative Technique.

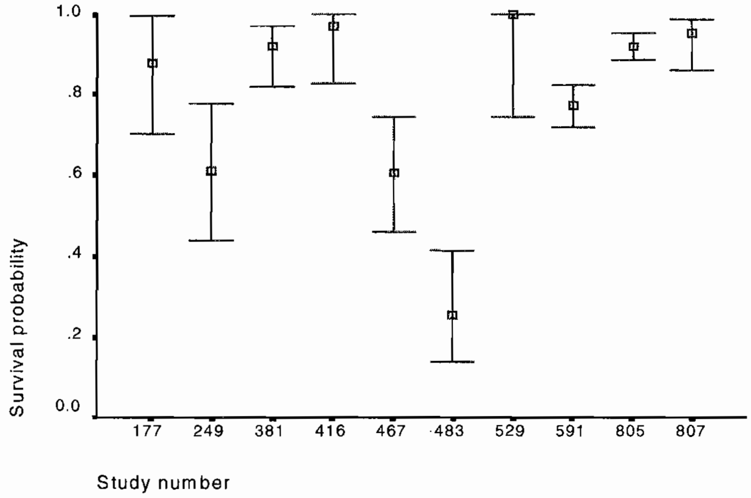

Figure 27 - GIC restorations in secondary teeth at 2 years

2 years
One set of studies (77, 381, 416, 529, 591, 805, 807) (Kaurich et al., 1991; Knibbs, 1992; Powell et al., 1995; Horsted-Bindslev, Knudsen et al., 1988; McLean and Wilson, 1977; Frencken et al., 1998; Kilpatrick et al., 1996) had survival probabilities of above 80%, while a second group had survival probabilities of between 25% and 60% (249, 467, 483) (Welbury and Murray, 1990; Lidums, Wilkie et al., 1993; Wood et al., 1993).

Studies 249, 467 (Welbury and Murray, 1990; Lidums, Wilkie et al., 1993) all involved glass ionomer/composite sandwich restorations that continued to display the high failure rates reported at one year.

Study 483 (Wood, Maxymiw et al., 1993) was carried out in patients who had a xerostomia following radiotherapy; it study used a very small sample size.

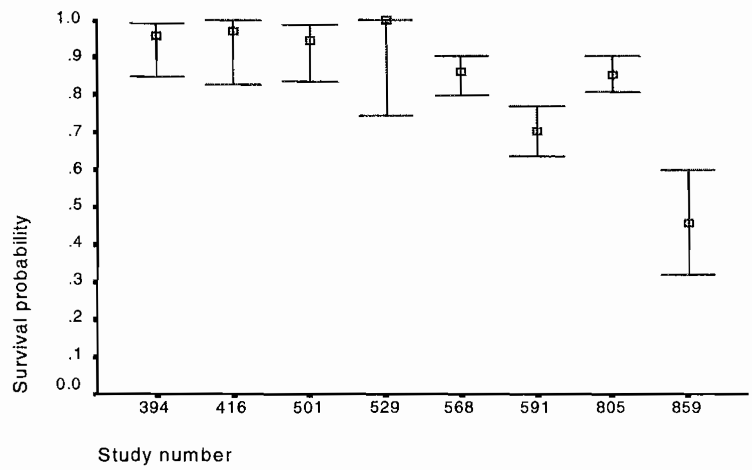

Figure 28 - GIC restorations in secondary teeth at 3 years

3 years
At three years, eight studies were reported. Of these, six showed survival probabilities of 85% or better (394, 416, 501, 529, 568, 805) (Neo and Chew, 1996; Powell, Johnson et al., 1995; Matis, Cochran et al., 1996; Horsted-Bindslev, Knudsen et al., 1988; van Dijken, 1992; Frencken, Makoni et al., 1998). The remaining studies had a survival probability of 70% (591) (McLean and Wilson, 1977) and 45% (859) (Mallow, Durward et al., 1998).

Study 591 (McLean and Wilson, 1977) was an early study carried out using the original glass ionomer material ASPA.

Study 859 (Mallow, Durward et al., 1998) reported the use of glass ionomer in a rural setting using the Atraumatic Restorative Technique.

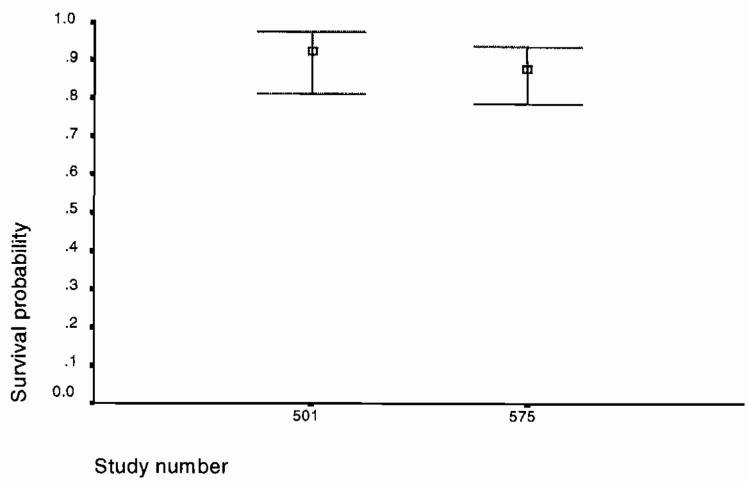

Figure 29 - GIC restorations in secondary teeth at 5 years

5 years
At five years, only two studies were available and these (501 and 575) (Matis, Cochran et al., 1996; Matis et al., 1991) reported survival rates of between 85% and 95%.

Primary teeth

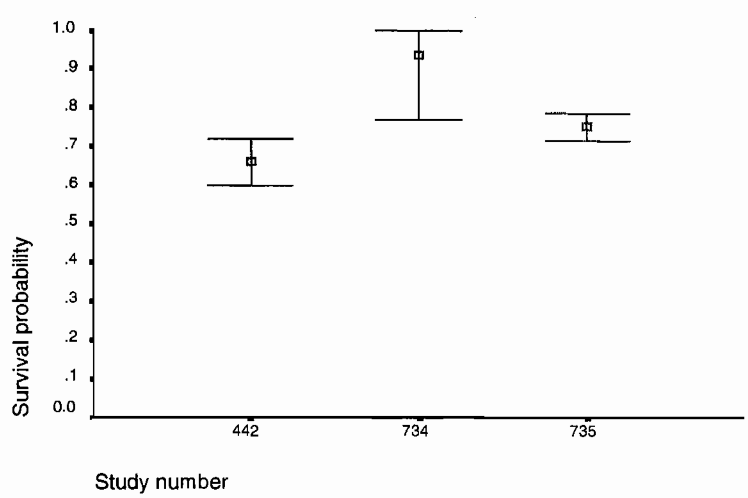

Figure 30 - GIC restorations in primary teeth at 1 year

1 year
At one year there were only three studies available. The first study (734) (Andersson-Wenckert et al., 1995) reported a survival rate of around 95%, while the other 2 studies (442 and 735) (Frencken et al., 1994; Attwood et al., 1994) had much poorer survival rates of between 65% and 75%

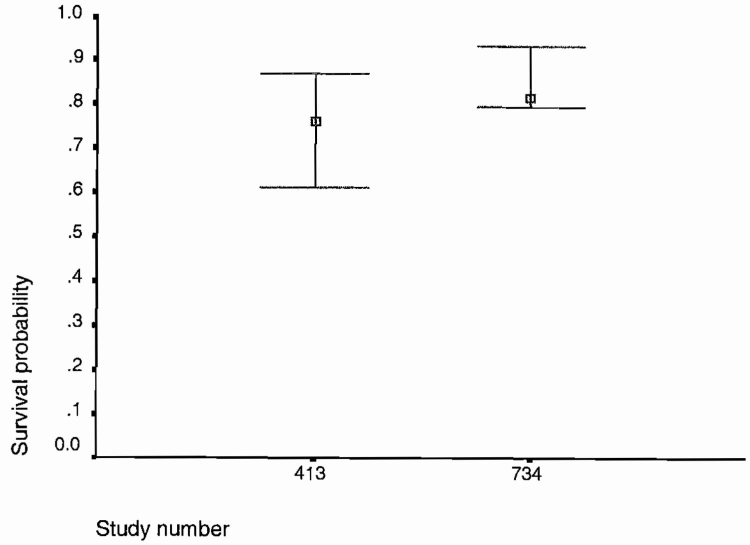

Figure 31 - GIC restorations in primary teeth at 2 years

2 years
At two years only two studies were available (413 and 734) (Kilpatrick et al., 1995; Andersson-Wenckert, van Dijken et al., 1995) had poor survival rates of approximately 75% to 80%.

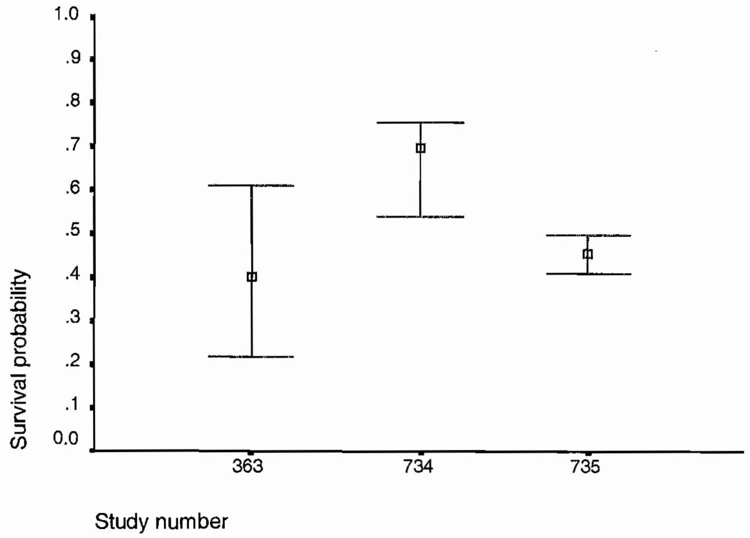

Figure 32 - GIC restorations in primary teeth at 3 years

3 years
Study 734 (Andersson-Wenckert, van Dijken et al., 1995) reported further failures since year 2, the survival rate at year 3 being 70%. The other two studies (363 and 735) (Ostlund et al., 1992; Attwood, Reid et al., 1994) reported even lower survival rates of 40% and 45%, respectively.

These studies have shown that glass ionomer is a poor long-term restorative material in deciduous teeth. This could well be related to the problems of placing a technique sensitive adhesive material in a young patient who is not particularly co-operative.

Conclusions

1. Avoid glass ionomer/composite sandwich due to high failure rate at the gingival margin of the approximal box (249, 467) (Welbury and Murray, 1990; Lidums, Wilkie et al., 1993).
2. Use of glass ionomer in a rural setting using the Atraumatic Restorative Technique (859) (Mallow, Durward et al., 1998) resulted in high failure rate. This is not surprising given the compromised environment in which the restorations were placed.

3. High failure rate for glass ionomer reported in patients who had a xerostomia following radiotherapy (483) (Wood, Maxymiw et al., 1993). This questions the usefulness of the fluoride leach of these materials. However, this result must be interpreted with a degree of caution as this is based on the findings of one study that used a very small sample size.
4. GIC have relatively high failure rates in deciduous molar teeth.
5. Conditioning of dentine prior to the placement of GIC does not affect longevity. However, this must be interpreted with caution, as this finding is based on one small study.

Future research

- More long term studies (only two studies available at five years 501 and 575) (Matis, Cochran et al., 1996; Matis, Carlson et al., 1991)
- More studies in deciduous teeth
- More studies in general practice setting
- Further studies to substantiate the finding that conditioning dentine does not influence longevity

6.5 Inlays

Summary of inlay studies

There were a total of 27 studies involving inlay restorations:

One study evaluated gold inlay restorations
16 studies evaluated ceramic inlay restorations
Five studies evaluated composite inlay restorations
Two studies compared composite inlays with ceramic inlay restorations
Two studies compared composite inlays with direct composite restorations
One study compared ceramic inlays with amalgam restorations

Of the 27 studies:

10 were Other Clinical Studies (7)
16 were Prospective Case Studies (3)
One was a Prospective Study with Concurrent Controls (6)

Survival of restorations

The analysis of inlays has been divided into composite inlays and ceramic inlays.

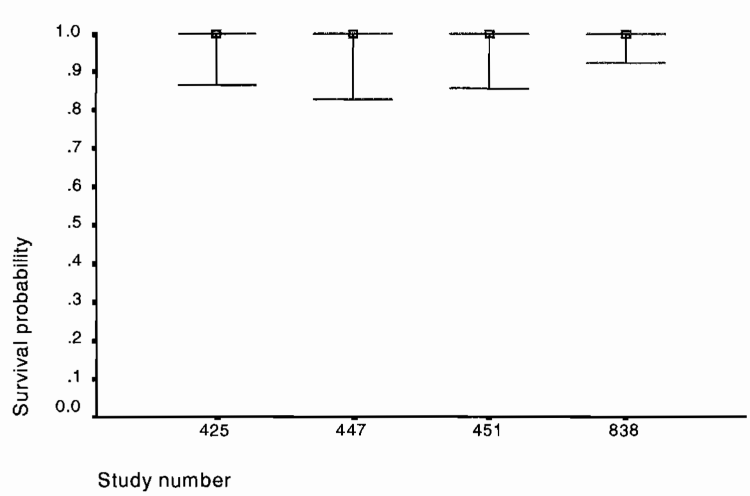

Figure 33 - Composite inlays at 1 year

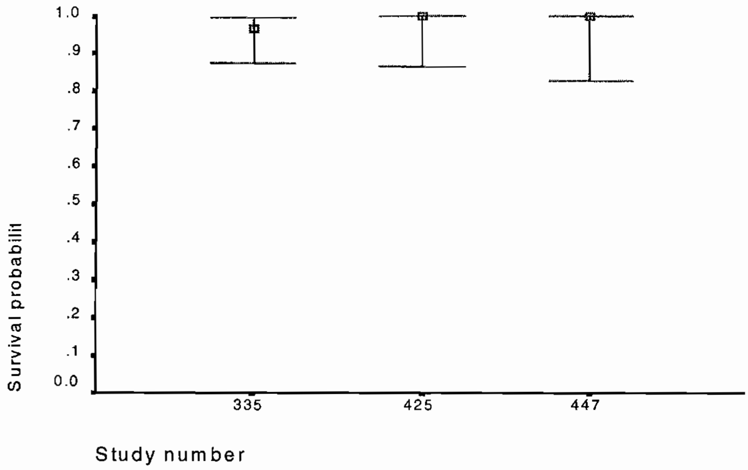

Figure 34 - Composite inlays at 2 years

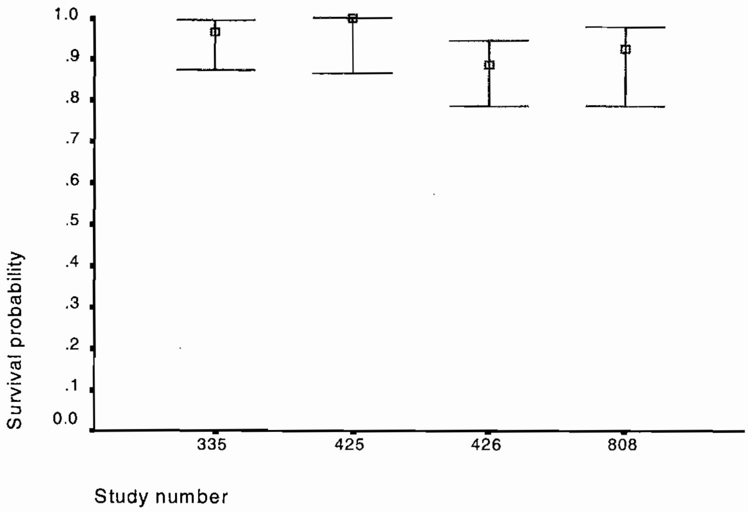

Figure 35 - Composite inlays at 3 years

1, 2 & 3 years

At one and two years the survival of composite inlays was generally excellent. At three years there was a slightly worse survival rate for study 426 (Wassell et al., 1995) although the confidence intervals are not significantly different.

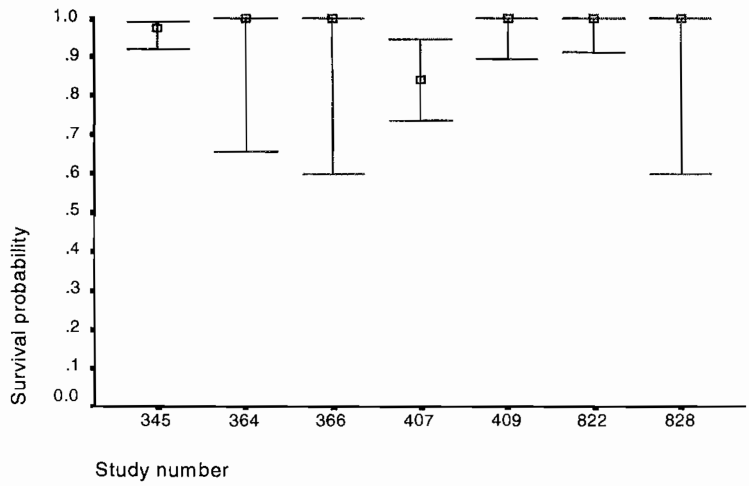

Figure 36 - Ceramic Inlays at 1 year

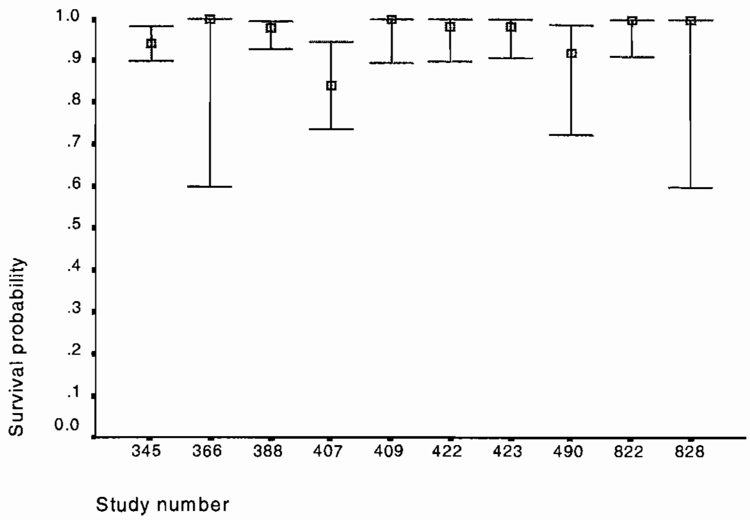

Figure 37 - Ceramic inlays at 2 years

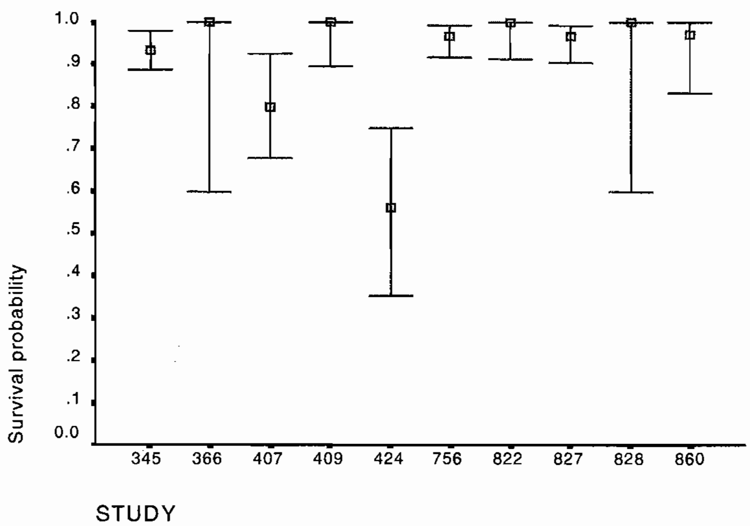

Figure 38 - Ceramic inlays at 3 years

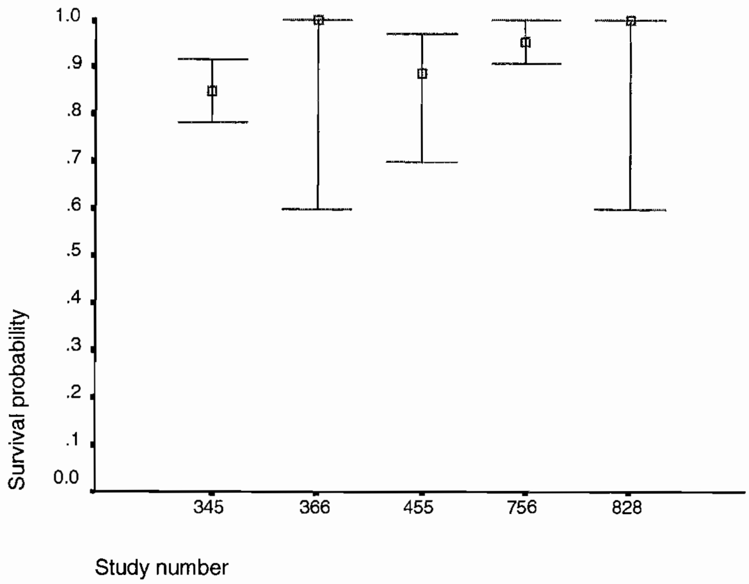

Figure 39 - Ceramic inlays at 5 years

<u>1, 2 , 3 & 5 years</u>

For ceramic inlays at one year, study 407 (Qualtrough and Wilson, 1996) had a higher failure rate, although the confidence intervals are not markedly different from other studies. In that study, all but one of the nine failures occurred within the first six months, but the reasons for this higher failure rate are not clear. At three years there are no substantial differences between the studies; study 407 had no additional failures.

At five years only three studies (Mormann and Krejci, 1991; Mormann and Krejci, 1992; Thordrup et al., 1994) were available for follow up; survival remained above 80%.

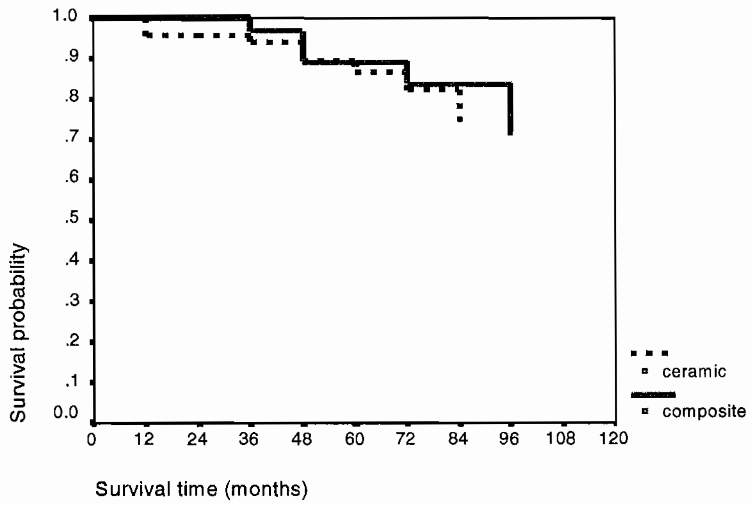

Figure 40 - Comparison of survival functions of different inlay types

<u>Survival Function</u>

Very little difference was seen between the different types of inlays when composite was compared with ceramic. However, these results must be treated with caution due to the small numbers involved, especially beyond 36 months.

Problems with study design

The studies included in this section often had few subjects and were of weaker design. Very few of the studies undertook any form of comparison and only one compares inlays to amalgam.

Problems with interpretation
The majority of the studies were case series, which makes it difficult to draw comparisons unless they can be combined statistically.

The following effect modifiers were included:
Types of cement
Methods of curing inlays
Permanent and primary dentition
Class of restorations

Conclusions
The results of these studies suggest that:
1. Survival in primary teeth (Motokawa et al., 1990) has a markedly worse survival rate than permanent teeth.
2. There is limited evidence to support the use of a resin compared with a GIC lute (Hoglund Aberg et al., 1992; Wendt and Leinfelder, 1992; Hoglund Aberg et al., 1994; van Dijken et al., 1998). Another study reported no difference between cements (Mormann and Krejci, 1991).
3. There is limited evidence to support the use of heat cure in addition to light cure in composite inlays (Wendt and Leinfelder, 1990).
4. There are some reports of post-operative sensitivity with inlays (Sjogren et al., 1995; Tidehag and Gunne, 1995; Wassell, Walls et al., 1995; Qualtrough and Wilson, 1996) and this needs further investigation

Future research
Further research is needed in order to compare composite and ceramic inlays with other materials, particularly gold and amalgam. Research is also required to clarify which sort of luting material is most beneficial. The problems associated with post-operative sensitivity need further study.

6.6 Cermet restorations

There were a total of nine studies involving cermet restorations:
Two studies evaluated cermet restorations
Two studies compared GIC and Cermet restorations
Two studies compared Amalgam and Cermet restorations
Three studies compared Amalgam with Composite and with Cermet restorations

Of these studies:
Three were Prospective Case Series (3)
One was a Retrospective study with Concurrent Controls (4)
One was a Prospective study with Concurrent Controls (6)
Three were Other clinical Trials (7)
One was a Randomised Controlled Trial (8)

Survival analysis

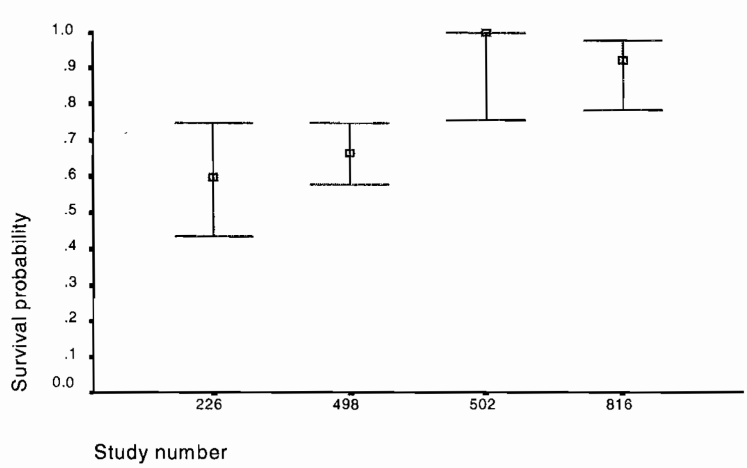

Figure 41 - Cermet restorations in primary teeth at 1 year

1 year
Of the four studies reported at one year, two (502, 816) (Chu et al., 1996; Stratmann et al., 1989) had good survival rates. Both were small studies using both Class I and Class II restorations. However, the other studies (498, 226) (Holst, 1996; Hung and Richardson, 1990) both had high failure rates. In study 498 (Holst, 1996), 40 of 172 Class I and II restorations failed, with high abrasion rates being the major problem. Study 226 (Hung and Richardson, 1990) had a high failure rate for Class II cermet restorations (16 of 40 compared with 0 of 40 failures for paired amalgams).

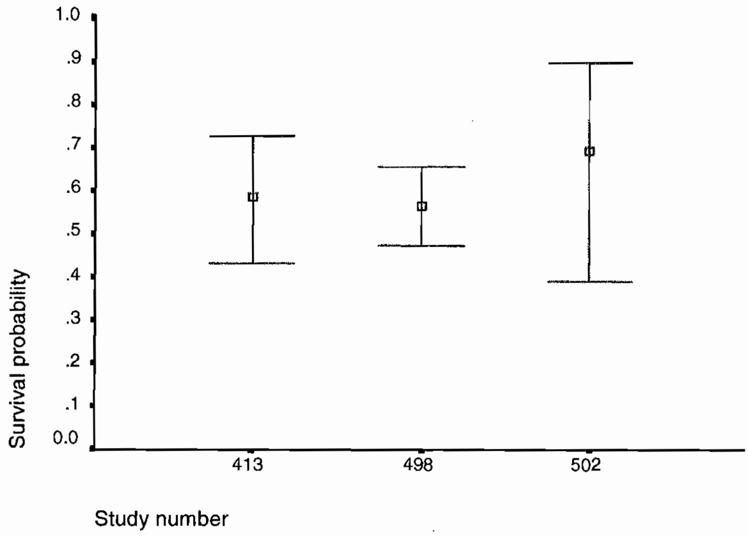

Figure 42 - Cermet restorations in primary teeth at 2 years

2 years
At two years all three studies had poor survival. Study 498 (Holst, 1996) continued the trend seen at one year, with continuing failures due to wear. Study 413 (Kilpatrick et al., 1995), an RCT with a glass ionomer cement, included Class II cavities only and reported a 23% failure for the glass ionomer compared with a 41% failure for the cermet. In both trials the same cermet (Ketac-Silver) was used. It should be noted that the results for study 413 are actually for 18 months and not one year. Study 502 (Chu, King et al., 1996) had a small sample size (10 Ketac-Silver, 10 Chelon-Siver, 20 Amalgam) and a high drop out rate, however, the survival probability for Ketac-Silver fell between one year and 18 months.

Conclusions
Despite the low number of studies reported it is concluded that Ketac-Silver cannot be recommended for use in the primary dentition because of its poor wear characteristics.

6.7 Compomer restorations

There were a total of seven studies involving compomer restorations:

Three studies evaluated compomer restorations
One study compared GIC with Compomer restorations
Two studies compared composite with compomer
One study compared Composite with GIC and with Compomer

Of these studies:

Two were Prospective Case Series (3)
Two were Prospective Studies with Concurrent controls (6)
One was an Other Clinical Trial (7)
One was a Clinical Trial (8)

Overview
Compomers are relatively new materials and this is reflected by the low number of studies, all of them of short duration.

Survival of compomer restorations

Permanent teeth

Permanent teeth at 2 years (no figure appears)

<u>2 years</u>

The single study had no failures for class V restorations after 24 months. It is worth noting that the glass ionomer restorations placed in this prospective study were also all successful.

Primary teeth

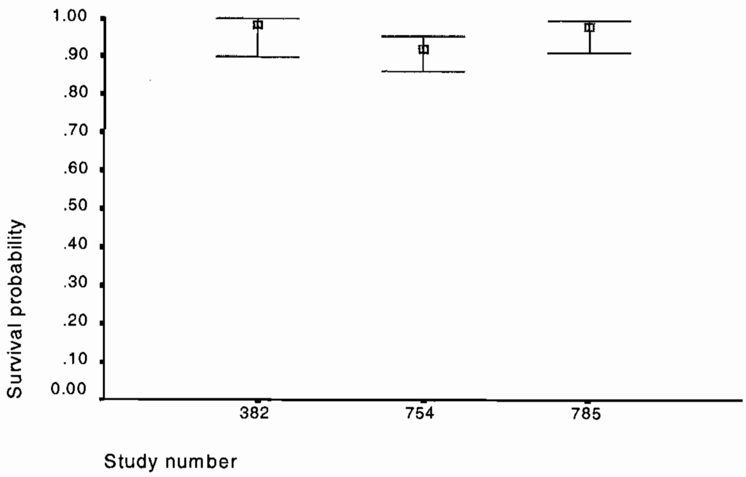

Figure 43 - Compomer restorations in primary teeth at 1 year

<u>1 year</u>

All three studies had good survival rates in the first year. Study 754 (Andersson-Wenckert et al., 1997), included only Class II restorations, had a slightly lower survival rate at this period; the other studies included both Class I and Class II restorations.

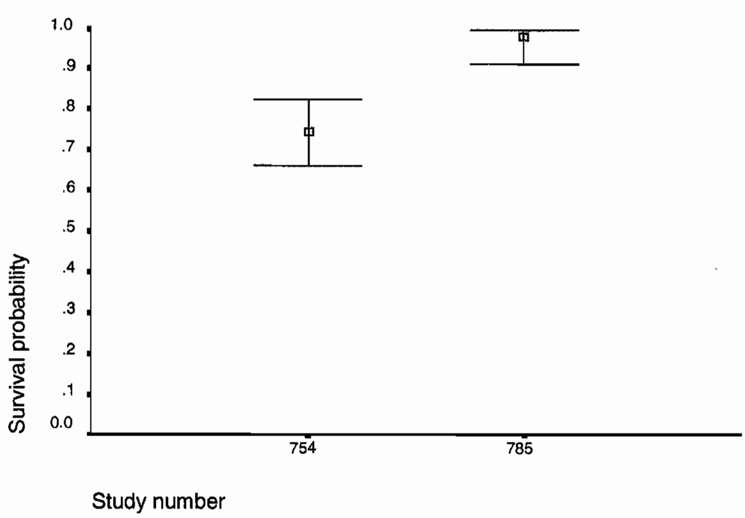

Figure 44 - Compomer restorations in primary teeth at 2 years

<u>2 years</u>

The survival rate in study 785 (Peters et al., 1996) was good. However, the survival in study 754 (Andersson-Wenckert, Folkesson et al., 1997) continued to fall. This study used six operators and the failure rate may be explained by the wide variation in failure rates between operators (range 12% to 35%).

Problems with interpretation

The main difficulty with the compomer group of studies is the small number of trials and their short duration. It is too early to predict how this material will survive over extended time periods.

Future research
Long-term data over extended periods are required to supplement the good survival reported at two-years in primary molars.

Randomised controlled trials comparing compomer with established materials in primary teeth with multiple operators.

6.8 Economic results

Results of search
Thirty studies were identified and are summarised in Table 5. The findings from the papers included are discussed in relation to the time required to undertake a restoration, the complexity of procedures, and the effectiveness and cost effectiveness of dental restorations.

Time involved in the process of providing restorations
Estimates of the time taken to provide dental restorations are based on studies identified from the literature search and summarised in Table 6 below. Some studies used a stopwatch to record time, while in one study (Dilley et al., 1990), the procedures were videotaped and operators, using a stopwatch, measured the time. Other studies did not indicate the method employed to record time. In virtually all studies, operator effect was identified as a significant factor affecting time of procedure, while the existence and type of previous restoration and tooth type were also identified in the studies as significant contributory factors.

With regard to operator effect, one study (Plasmans and Van't Hof, 1987) demonstrated a 26% difference in total treatment time between operators, while for a number of studies highlighted the effect of different types of existing restorations on preparation time. One study (Krejci et al., 1995) showed that there was nearly a 10 minute difference in the time required to completely remove restorations from lower molars - amalgam was timed at 15.2± 9.3 and composite 24.9± 11.4 minutes. The type of tooth was also identified as a significant factor in determining the time required, with most studies providing different time estimates for different tooth types.

The range of mean times for amalgam was between 7.5 and 46.7 minutes, while for composites the range was between 10.1 and 24.9 minutes. Using median times the ranges were between 22 and 50 minutes for amalgam and 39 and 63 minutes for composites.

Other studies offered comment without actually identifying the actual time involved. These were used to verify, to some extent at least, the times generated by the other studies. For example, in a study of Class I/Class II restorations (Hendriks et al., 1985), it was suggested that the total treatment time for amalgam was the same as composite and, while there were differences in time between composite and amalgams for preparation, less time was needed for composites in applications and finishing. The study also found that operator factor, tooth type and the number of approximal surfaces were significant factors. However, on the basis that the productivity of composites was 4-10 times less than best amalgam, two times better than worst amalgams and equal to common amalgams, the study concluded that conventional composite materials should not be used as restorative material in posterior restorations because of their low effectiveness and productivity. Another study of Class I/Class II restorations in posterior primary teeth (Bevan and Braham, 1989) argued that 'with the detailed attention that must be paid to fitting, wedging and burnishing the matrix band and the highly exacting technique for condensing, carving and finishing, it can safely be stated that a posterior composite resin restoration will require much more time than an equivalent amalgam restoration,' but concluded that 'aesthetic results achieved by composite more than justify the time required'.

TABLE 5. Studies included in economic section

Reference ID Number	Cost component	Teeth	Restoration type	Other 1	Number of dentists	Results 1	Results 2
#2	Removal time	Lower molars	Amalgam; GIC; Composite; Glass Ceramic	Dental tissue lost during removal	Six	Mean time (sd) A: 15.2 (9.3) GIC: 11.9 (4.7) C: 24.9 (11.4) GC: 30.4 (11.5) (groups st sig except for AvGIC and CvGC)	
#10	Treatment time: preparation (1), preliminaries (2), filling (3), finishing (4) and polishing (5) (separate visit)	included as separate analysis	Class II composite resin restorations	Type of tooth; type of restoration; existing amalgam; skill & experience of dentist	Three	Mean (sd) 1: 9.1(4.5) 2:15.1(3.6) 3: 7.6 (2.8) 4: 9.2 (2.7) 5: 4.4 (1.7) Total: 45.4 (11.9) Gem Mean (90% ci) 1: 8.1 (3.8-17.5) 2: 14.7 (10.1-21.5) 3: 7.2 (4.2-12.4) 4: 8.8 (5.5-14.1) 5: 4.0 (2.1-7.8) Total: 44.0 (29.5-65.6) Type of tooth, type of restoration and existing amalgam have significant impact on times	After learning effect: Mean (sd) 1: 7.8(3.2) 2:14.2(2.6) 3: 7.2 (2.8) 4: 8.7 (2.5) 5: 3.9 (1.5) Total: 41.8 (8.8) Gem Mean (90%ci) 1: 7.2 (3.8-13.8) 2: 13.9(10.2-19.1) 3: 6.9 (4.1-11.6) 4: 8.3 (5.4-13.0) 5: 3.7 (2.0-6.7) Total: 41.0 (29.8-56.3)
#22	Fabrication time: Clinical 1 cavity prep (1), pulp protection (2) impression (3) Laboratory model making (4) modelling (5) Clinical 2 fitting (6) cementation (7) finishing (8)	Inclusion criteria: at least one upper premolar or first permanent molar for which a tooth-coloured restoration was desired; teeth in occlusal function following restoration; teeth vital with no disease etc	ICS: P-50 resin bonded ceramic	operator, extent of restoration, number of restorations	Four	Median times for 1/2 1 2 rests 1: 10.1 7.5 12.5 2: 9.0 7.4 10.3 3: 6.5 5.8 7.2 4: 22.0 20.7 22.9 5: 18.4 15.0 21.2 6: 11.4 9.3 13.3 7: 8.4 6.9 9.7 8: 16.9 14.5 18.8 Total : 1/2 - 110.3 1 - 92.8 2 - 124.8 operator and number of restorations sig variables	patient acceptability dubious
#11	Cost of placement and restoration: first placement first replacement	Primary molars	amalgams and crowns	based on relative cost of restoration: Type rel cost 1 surf a 1.0	dental students between 1970 and	adopts a relative cost unit perspective based on cost of one-surface amalgam = 1.0.	does not detail actual components of cost

	second replacement third replacement • Cost to restore a molar • Cost to restore a molar with 1st pl or repl • Cost units for amalgams + crowns • time scales: exfoliation, end of study, extraction, 1yr of good service			2 surf a 1.6 3 surf a 2.0 st steel c 2.4 pulp +ssc 4.0	1982	Cost to maintain molars to tooth exfoliation mean (sd) amalgam only 2.1 (1.2) amalgam- crown 4.9 (1.1) crown 2.9 (0.7) to extraction amalgam only 2.2 (0.8) amalgam - crown 5.6 (0) crown 3.7 (1.1) Also computed cost of amalgam restorations and cost of crowns conclusions that amalgam the most economical to restoring a molar; amalgam and crowns provide similar periods of good service .	
#12	Restoration time: procedures dependent on method	Children with four permanent first molars to retain rubber dam clamp, to have at least two first permanent molars with Class I decay of pits and fissures, to have at least 1 Class II (and/or Class I) carious lesion in primary molar	Composite v amalgam with sealant as necessary	number of restorations, operator	four	Single Mean time (Class I): composite 10.13 amalgam 7.48 sealant 2.65 Small samples for combinations so see paper	Additional steps required for composite accounted for 86% of mean time difference No operator effect
#13	Treatment time: preparation of cavity, preparation of restoration, restoration	Class I/Class II restorations	strontium glass filled system microfilled composite system conventional composite high copper amalgam	operator, tooth type, number of surfaces	three	total treatment time for amalgam same as composite differences in time between composite & amalgams in preparation time needed but time shorter for composites in applications & finishing productivity of composite 4-10 times less than best amalgam but 2 times better than worst amalgams & equal to common amalgams.	operator factor, tooth type, number of approximal surfaces significant factors conventional composite materials should not be used as restorative material in posterior restorations because of their low effectiveness and productivity
#5	Handling properties of materials: packing consistency, adhesion to instruments, ease of insertion, working time, ease of finishing	Class I/Class II restorations in posterior primary teeth.	composite resin system - herculite Condensable with Bondlite compared with high copper mixed-			'with the detailed attention that must be paid to fitting, wedging & burnishing the matrix band & the highly exacting technique for condensing, carving & finishing it can safely be stated that a	'aesthetic results achieved by composite more than justify the time required'

			phase spherical/regular grind silver alloy			posterior composite resin restoration will require much more time than an equivalent amalgam restoration.'	
#6	long-term cost: initial costs longevity - material properties, handling characteristics, oral hygiene, bruxism	permanent teeth (60yr perspective) primary teeth (10 yr perspective)	amalgam composite gold	relative cost based on weightings - see paper		graphs showing that amalgam cheaper than composite and gold in large posterior restorations and small restorations AND amalgam cheaper than composite in primary teeth.	'data on longevity of restorations is the weakest link in predicting long term cost of restorative treatment' 'amalgam restorations presently clearly represent the most cost-effective dental restorative material.'
#3	relative value of eight dental procedures compared with two-surface amalgam filling	depending on procedures	includes non-restorative work		142 respondents - general practitioners, clinical specialists & private practitioners	relative values higher than prices recommended by Finnish dental Assoc	
#7	treatment times - preparation, retention, matrix, condensation, carving, polishing	molars in patients with almost complete dental arches and the potential to reconstruct the occlusal surface in contact with the opposing teeth.	extensive amalgam restorations (EAR) with both approximal surfaces restored with amalgam	operator, retention design, extension of the EAR, tooth type, side and jaw location	three	mean median 1: 10.0 9.6 2: 4.6 3.5 3: 4.3 6.2 4: 6.2 5.9 5: 21.6 19.8 6: 10.2 9.8	tooth type not significant operator, side, retention, extension significant on overall time see paper for specifics
#8	life-long costs: treatment time expenses Involved	permanent teeth	amalgam, glass ionomer, composite	relative cost based on UK fees and weightings		graphs show that long term cost of small composite and gold restorations was similar and four times that of amalgam restorations, glass ionomer was 3.5 times that of amalgam	see paper
#9	relationship between prices and quality	range of six dental procedures - adult prophylaxis, amalgam (two surfaces, permanent), crown (porcelain fused to gold), complete denture, root canal (molar), extraction (single tooth)		impact of process factors on price and quality	4,923 (represented 92% of dentists in Michigan)	dentists who provided services which were ranked in top 15% of technical quality would be expected to charge $3 more than the average dentist for a two-surface amalgam.	significant positive relationship between prices charged and level of provider training and index of technical quality.
#18	not specifically stated - judged to be cost effective on basis of acceptability to patients and dentists because of simplicity of procedures involved	primary teeth with multisurface destruction	stainless steel crowns v amalgam restorations		not reported	survival rates of at least 83% for crowns at 8 years, amalgams survival rate at 1 year just under 80%. replacement rate of 4/66 for crowns and 38/66 amalgams	nothing documented on actual costs of interventions

#19	report on other papers- use of costs	N/A				reports that 'amalgam fillings are the most economical and a failed amalgam replaced by a stainless steel crown the most costly the average time needed to restore a primary molar by ION crown treatment was the same but amalgam fillings require more recall visits...stainless steel crowns should be used especially in high caries group while in others GPA cements in modified cavities could serve well.'	Levering et al 1988 Pediatric Dentistry 1988; 10: 86-93
#21	estimate the time required to perform a good restoration. Phases of treatment - preparation, preliminaries to filling, packing and carving, polishing	Class II two or three surfaces restorations		influencing factors: tooth type, premolar or molar, - restoration extension, two surfaces (MO, DO) or three surfaces (MOD), - preparation size, standard or large, regardless of the extension, - operator.	seven	Mean 2 3 Median 2 3 1: 9.2 12.1 8.3 11.1 2: 5.0 5.8 3.7 4.5 3: 9.7 11.7 9.2 11.1 4: 24.3 30.0 22.6 28.2	highly significant operator effect and differences between standard and large restorations and premolars and molars.
#20	cost of tooth restoration dependent on expected lifetime of tooth	review study on posterior restorations				50% of amalgams exceed 8-10 years, cast gold restorations may last longer and multisurfaced composite restorations have a shorter life-span. Glass ionomer cements lack the physical properties needed.	
#17	extent of usage of sealants compared with one surface amalgam restorations	insurance claims data				22/48 states had a mean charge for one surface amalgams over $40 and eight states were below $35.	
#16	review study with comment on economics					cast gold and bonded ceramic restorations are expensive silver amalgam remains very cost-effective modality as long as amount of tooth structure lost to caries or trauma is minimal. With larger restorations cast gold is extremely cost effective.	
#14	Survival and cost-effectiveness of restorative materials	permanent teeth	cusp-covered amalgams, cast gold crowns and ceramometal crowns	use of relative cost based on a one-surface amalgam =1.0	twenty	cusp-covered amalgams 3.8 times more cost effective than cast gold or ceramometal crowns; resin composites were	

			in posterior teeth; Class III glass-ionomer cements & resin composites placed in anterior teeth; Class IV resin composites and cast gold inlays placed in anterior teeth; Class V glass-ionomer cements and resin composites placed in anterior teeth; Class V glass-ionomer cements & amalgams placed in posterior teeth	use of case notes		3.7 times more cost effective than cast gold inlays for Class IV restorations; no difference in materials for Class III or Class V preparations.	
#15	long-term cost and side effects of restorative materials	reference to another study looking at side effects	direct and indirect restorations		137	incidence rate of subjective and objective symptoms was 1:700 relative costs based on amalgam = 1.0 material no. s median l amalgam 1 10 amalgam 3 8 composite 1 7 composite 3 4 compacted gold 1 22 gold inlay 3 14	
#23	cost effectiveness of replacement of amalgams with crowns	posterior teeth	lifetime restorative needs of a posterior tooth	decision analysis modelling based on 42 year utility		costs based on dental fees for crowns, amalgams and root canals estimates of longevity derived from literature potential lifetime cost savings are between 11 and 24% if first replacement was an amalgam - the longer a crown is postponed the greater the lifetime savings	
#1	cost effectiveness of dental sealants	first molars		determines cost savings and cost effectiveness ratios	costs included dental sealants and restorative treatments over time	identifying children with restorations and sealing remaining molars produces cost savings within 4-6 years.	
#24	long-term survival in randomised controlled trial of amalgam restorations	molars	extensive amalgam restorations	to test the hypothesis that type of retention & operator effect have influence on	three	survival rate of extensive amalgam restorations as independent restoration was 88±2% and 92±2% as independent restoration or	Age only significant variable in influencing survival.

				survival & clinical functioning of restorations		substructure.	
#26	service time in relation to cavity design	class II restorations	amalgam	28 variables relating to cavity design	seven	several factors of the cavity design have a significant impact on service time and reason for replacement	
#27	survey of restorations during working days	silver amalgam restorations	amalgam		fifty	average number of 6.6 amalgam surfaces replaced each working day - equivalent to 1518 per year	estimate that each surface costs $6 - thus $9108 worth of amalgam restorations removed per year
#28	treatment times for two cavity groups - time from beginning of preparation to final application of protecting varnish	class II restorations in primary teeth	glass ionomer		two	mean treatment time in microcavity group - 20 minutes mean treatment time in modified Black Class II cavity group - 23 minutes	
#29	comparison of standard alloy with disperse phase alloy including discussion of cost-effectiveness.	first molar teeth	standard alloy and disperse phase alloy		four community dental officers	costs of conventional alloy (Solila) is 8p while copper alloys vary between 34 and 60p	Extra cost of non alloy γ_2 would require restoration to last for additional 12 months.
#31	Working time of polymeric restorative materials			validity of using rheologic methods in determining working times		use of correct handling techniques necessary ton ensure that composite materials provide durable restorations.	
#30	Results from two-year study of box-resin composite restorations	teeth with proximal carious lesions but free of occlusal caries	box resin composite restorations		Four	Treatment times: preparation 6.3 (2.3) preliminaries 12.1 (3.3) application 4.7 (1.5) finishing 6.5 (2.3) polishing 2.6 (1.2) TOTAL 32.3 (7.5)	
#25	Cost effectiveness of amalgam v composite	class II posterior restorations	composite amalgam	rct with 5 year follow up 53 composite 20 amalgam		median time for premolars composite 39 mo/do * 42 mod amalgam 22 mo/do 26 mod median time for molars composite 52 mo/do * 63 mod amalgam 25 mo/do 50 mod *(Mann-Whitney p< 0.00) all restorations were in place at end of 5 years, two composites were repaired. Composite performed slightly better in terms of marginal adaptation for mo/do in premolars	Need for longer follow -up

Table 6 Time taken to provide restorations

Reference	*Tooth type*	*Material Type*	*Time (minutes)* Mean	sd	Median	*Number of dentists*
(Tobi et al., 1998)	Pre-molars	Amalgam			22-26[1]	2
		Composite			39-42[1]	
	Molars	Amalgam			25-50[1]	
		Composite			52-63[1]	
(Plasmans and Van't Hof, 1987)	Molars	Amalgam - extensive	46.7[2]		42.5	3
(Advokaat et al., 1992)	Molars	Amalgam -				7
		two-surface	24.3[3]		22.6	
		three- surface	30.0[3]		28.2	
(Dilley, Vann et al., 1990)	Permanent molars - single	Amalgam	7.48	1.85		4
		Composite	10.13	1.82		
	Two-tooth combination in permanent and primary molars	Amalgam	7.93-13.07[4]			
		Composite	14.28-18.37[4]			
	Three-tooth combination in permanent and primary molars	Amalgam	14.71-20.20[5]			
		Composite	16.15-22.34[5]			
(Kreulen et al., 1991)	Molars and pre-molars	Composite	31.8[6]			3
(Plasmans et al., 1992)	Molars and premolars	Indirect composite resin -				4
		one restoration	90.0		92.8	
		one/two restorations	120.0		124.8	
(Kreulen et al., 1995)	Molars and pre-molars	Box-only resin composite	23.1[7]			4

Notes
1 Range based on both MO/DO and MOD restorations
2 Excluding finishing and polishing time of 10.2 minutes
3 Excluding finishing and polishing time of 6.3 minutes
4 Range based on comparisons of all Class I, all Class II and combination of both
5 Range based on one-third Class I/two-third Class II and two third Class I/one-third Class II
6 Excluding finishing and polishing time of 13.6 minutes; with significant differences in times between premolars and molars at each stage
7 Excluding finishing and polishing time of 9.1 minutes

Complexity of procedures

Some studies based the relative cost of procedures on complexity weights. The mean cost of placement and restoration of primary molars to tooth exfoliation using amalgam only was 2.1 (1.2), for crowns was 2.9 (0.7) and for amalgam followed by crown was 4.9 (1.1) (Levering and Messer, 1988). Similar findings emerged when the cost to extraction was computed, with the mean cost using amalgam only was 2.2 (0.8), for crowns was 3.7 (1.1) and for amalgam followed by crown was 5.6 (0). The conclusion of this study was that, while amalgams and crowns provided similar periods of good service, amalgam was the most economical material in the restoration of a primary molar. The findings of this study were also 'confirmed' in a review (Varpio, 1993) and in a study (Maryniuk et al., 1988), which used decision analysis to estimate the lifetime restorative needs of a posterior tooth and concluded, on the basis of longevity estimates from the literature, that the longer a crown was postponed the greater the lifetime savings.

Other studies (Crall and Beazoglou, 1989; Tuominen and Tuominen, 1994), which examined the value of restorative work undertaken in relation to the prices charged, using a two surface amalgam filling as a base, concluded that the relative value of each type of restoration was dependent on the level of complexity.

Long-term costs

A study based on UK fees and weightings (Mjor and Wilson, 1997) showed that the long term cost of small composite and gold restorations was similar but four times that of amalgam restorations, while glass ionomer restorations were 3.5 times that of amalgam. Using the same approach, another study argued that amalgam was cheaper than composite and gold in large posterior restorations and small restorations and also cheaper than composite in restorations in primary teeth. Another study emphasised that data on longevity was the weakest link in the prediction of long-term cost of restorative treatment (Mjor, 1992).

Studies which considered effectiveness of restorations

In addition to the studies identified as part of the broader search, measures of survival and longevity were used to construct the long-term cost profile of different restorations. One study (Einwag and Dunninger, 1996) reported survival rates of at least 83% for crowns at eight years, while for amalgams the survival rate at one year was under 80%, while another review (Mjor et al., 1990) concluded that 50% of amalgams exceeded 8-10 years.

In a 100 month follow-up of a randomised controlled trial of extensive amalgam restorations (Plasmans et al., 1998), 300 restorations were placed by three operators in molar teeth in which one or more cusps were reconstructed. The survival rate of extensive amalgam restorations as an independent restoration was 88±2% and 92±2% as an independent restoration or as a substructure. The influence of retention method, operator effect, tooth type, extension of extensive amalgam restorations were not statistically significant and the age of the patient was the only significant variable in influencing survival time.

Studies which considered the cost effectiveness of restorations

The quality of the cost effectiveness papers identified was generally limited when assessed against established criteria (Drummond et al., 1997). Methodological papers (Creugers and Käyser, 1992; Doherty and Crakes, 1985; Forbes and Donaldson, 1987; Jacobson et al., 1990) were eliminated, while others used the term cost-effective without any indication as to how that view was arrived at. For example, in one paper (Einwag and Dunninger, 1996) cost effectiveness was judged on the basis of acceptability to patients and dentists because of the simplicity of procedures involved. Another (Donovan and Chee, 1993) concluded that 'cast gold and bonded ceramic restorations are expensive. Silver amalgam remains a very cost-effective modality as long as amount of tooth structure lost to caries or trauma is minimal. With larger restorations cast gold is extremely cost effective.' Another paper (Smales and Hawthorne, 1996), using survival analysis and the relative values of procedures suggested that cusp-covered amalgams were 3.8 times more cost effective than cast gold or ceramometal crowns; resin composites were 3.7 times more cost effective than cast gold inlays for Class IV restorations; while no difference existed in materials for Class III or Class V preparations.

One study which went some way to assessing cost-effectiveness compared different alloys in first molar teeth (Bates and Douglas, 1980) and concluded that the extra cost associated with higher cost materials would require the restoration to last for an additional 12 months.

One study which did conform to quality standards in cost effectiveness analysis examined the cost effectiveness of dental sealants (Weintraub et al., 1993) and concluded that "by identifying children with restorations and sealing remaining molars produced cost savings within 4-6 years."

Discussion

The extent of variation in the times reported in the studies to place restorations and the effect of other factors in determining the times made it difficult to arrive at a reliable estimate. Similarly, the issue of complexity was not covered in either adequate detail or rigour to enable any substantive information to be utilised. Thus, while data relating to the survival and longevity of the materials was available from other sections of the systematic review, in order to estimate the time required to place a restoration and estimate the costs of each restoration additional primary research was undertaken.

Findings - Phase II

The aim of this small-scale survey was to generate additional data relating to the time procedures for the initial placement and subsequent replacement of restorations. Dentists were asked to provide indications of time taken and asked to identify factors which would result in time differences emerging. The number of dentists included in the survey was small but exceeds the number of dentists in any one of the studies from the review.

Results of survey

Nine responses were received - five from NHS general practice, one from private practice, one from hospital-university practice, one who indicated NHS general practice, private practice and hospital-university practice and one who did not indicate. Interestingly, one of the responses was prefaced by the comment that the questions had been answered in relation to the 60% of NHS practice and that if answered for the 40% of private practice "you may be surprised at the difference."

The times taken to place initial and replacement restorations for amalgam, composite and inlays are shown in Table 7 below:

Table 7 Time taken to place initial and replacement restorations

	Class III	**Class IV**	**Class I**	**Class II**	**MOD**	**Cusp-replacement with pins**
	Mean (sd) [Median]	*Mean (sd) [Median]*	*Mean (sd) [Median]*	*Mean (sd) [Median]*	*Mean (sd) [Median]*	*Mean (sd) [Median]*
Amalgam						
Initial			(3.99) [12]	14.67 (3.81) [15]	19.22 (5.85) [20]	(10.51) [20]
Replacement			(3.74) [10]	(3.67) [15]	(5.70) [20]	(10.90) [30]
Composite						
Initial	(3.91) [15]	(4.66) [20]	(2.67) [15]	(3.78) [25]	(8.38) [25]	(11.36) [30]
Replacement	(3.20) [15]	(6.37) [20]	(3.00) [15]	(5.35) [20]	(8.96) [25]	(13.28) [30]
Inlay						
Initial			(11.09) [40]	(8.54) [45]	(8.16) [45]	(10.84) [45]
Replacement			(11.09) [40]	(7.07) [45]	(8.16) [45]	(10.84) [45]

The wide variation in the times were accounted for by a range of factors, highlighted in the box below. There was a consistency across the three restorative approaches and it was not apparent that any one method was likely to be subject to greater variation than the others.

Tooth factors	*Patient factors*	*Practice and organisational factors*
Size	Age	Local anaesthetic problems
Site	Extent of compliability	Use of bonding agent
Extent of caries		use of rubber dam
Extent of occlusal adjustment		Moisture control
Visibility of residual		Material used
Area of cavity		use of lines
Bleeding gingiva		Nursing staff

The average timings were similar to those reported in some of the studies (Krejci, Lieber et al., 1995; Dilley, Vann et al., 1990; Tobi, Kreulen et al., 1998) and similar to the time, excluding polishing, reported in others (Krejci, Lieber et al., 1995; Dilley, Vann et al., 1990; Tobi, Kreulen et al., 1998). They were therefore used as a baseline in developing the cost profile of each restorative approach.

Findings - Phase III

The model

The cost profile for each material type was computed as:

$C_0 + \Sigma C_i$ with $i = 1.....n$

where:

C_0 was the cost of initial placement and C_i the additional costs incurred each year. The additional cost incurred each year were derived as follows:

At the end of year I the probability of survival of material = P_I

Thus, $C_i = (1-P_i)*CR_i*d_I$

where:

CR_i was the cost of replacement in Year 1.......n
d_i is the discount factor to apply in Year 1....n

The number of tooth life years for each material type was computed as:

$\Sigma P_i T_i$

where:

P_i was the probability of survival of material in Year$i$ and T_i was the number of years since the initial placement. These were also expressed as discounted tooth life years, computed as:

$\Sigma P_i T_i d_i$

where

d_i was the discount factor to apply in Year 1....n

The costs of dental restorations
The procedure times resulting from the survey were used as the basis of the costs associated with initial placement and replacement of the restorations. The gross cost per dentist hour of £62.54 was used. Obviously this is an average across dental settings and therefore variations between NHS and private practice were not considered. The material unit costs were calculated from catalogue prices and weighted to reflect the quantity of material used in each type of restoration. In order to arrive at a proxy cost for each material type the cost of each type of restoration was weighted to reflect their relative proportion of the total number of amalgam, composite and inlay restorations respectively.

The resulting costs are shown in Table 8 below:

Table 8 Cost per restoration

	TIME	UNIT COST	STAFF £	UNIT COST	MATERIAL WEIGHT	£	TOTAL £	AV COST
AMALGAM								
Initial								
Class I	11.22	62.54	11.70	0.50	1.50	0.74	12.44	
Class II	14.67	62.54	15.29	0.50	2.50	1.24	16.53	
MOD	19.22	62.54	20.04	0.50	3.00	1.49	21.53	
CRwP	25.33	62.54	26.41	0.50	3.00	1.49	27.89	
								19.60
Replacement								
Class I	10.67	62.54	11.12	0.50	1.50	0.74	11.86	
Class II	13.33	62.54	13.90	0.50	2.50	1.24	15.14	
MOD	19.00	62.54	19.80	0.50	3.00	1.49	21.29	
CRwP	26.38	62.54	27.49	0.50	3.00	1.49	28.98	
								19.32
COMPOSITE								
Initial								
Class III	14.00	62.54	14.59	0.85	1.00	0.85	15.44	
Class IV	17.67	62.54	18.41	0.85	2.00	1.69	20.10	
Class I	15.00	62.54	15.64	0.85	1.50	1.27	16.90	
Class II	23.57	62.54	24.57	0.85	2.50	2.11	26.68	
MOD	29.29	62.54	30.53	0.85	3.00	2.54	33.06	
CRwP	33.43	62.54	34.84	0.85	3.00	2.54	37.38	
								22.44

Replacement								
Class III	15.63	62.54	16.29	0.85	1.00	0.85	17.13	
Class IV	18.44	62.54	19.23	0.85	2.00	1.69	20.92	
Class I	15.56	62.54	16.21	0.85	1.50	1.27	17.48	
Class II	24.29	62.54	25.31	0.85	2.50	2.11	27.43	
MOD	31.00	62.54	32.31	0.85	3.00	2.54	34.85	
CRwP	34.43	62.54	35.89	0.85	3.00	2.54	38.42	
								26.04
INLAYS								
Initial								
Class I	33.75	62.54	35.18	50.25	1.00	50.25	85.43	
Class II	41.25	62.54	43.00	50.25	1.00	50.25	93.25	
MOD	45.00	62.54	46.91	50.25	1.00	50.25	97.16	
Onlay	44.00	62.54	45.86	50.25	1.00	50.25	96.11	
								92.99
Replacement								
Class I	33.75	62.54	35.18	50.25	1.00	50.25	85.43	
Class II	40.00	62.54	41.69	50.25	1.00	50.25	91.94	
MOD	45.00	62.54	46.91	50.25	1.00	50.25	97.16	
Onlay	44.00	62.54	45.86	50.25	1.00	50.25	96.11	
								92.66

These costs can then be used to determine the cost of restorations over different time periods. The data on likelihood of failure was based on the analysis undertaken as part of the review. The total expected costs of each approach are shown in Table 9 below (with discounted figures @ 5% in brackets):

Table 9 Expected costs of different restorative materials

	EXPECTED COST (£)			
	Median survival time[1]	**5 years**	**10 years**	**15 years**
APPROACH				
Amalgam	62.03 (42.99)	21.56 (21.22)	32.93 (28.41)	62.03 (42.99)
Composite	107.33 (78.05)	33.01 (31.17)	91.66 (69.32)	-
Inlay	202.74 (175.00)	130.00 (123.78)	-	-

[1] Median survival time for amalgam was 180+ months, for composite was 133.5 months, for inlay was 84+ months.

The expected cost of composite was 1.5 times that of amalgam over a five year period and nearly three times that of amalgam over a 10 year period, which was slightly less than the estimate produced in a previous study (Mjor and Wilson, 1997). If the expected costs were based on median procedure times, the differentials between the approaches are very similar. These findings confirm the magnitude of the difference between the approaches in restorative dentistry.

The cost effectiveness of dental restorations

The economic evaluation was undertaken from the perspective of the NHS. If a partial-societal perspective was introduced to reflect the costs to patients in terms of time and number of consultations, this would only serve to compound the differential between the materials reflected in the cost profile above, since the patient costs would be positively correlated with the probability of failure of a material type.

The cost effectiveness analysis uses *tooth life years* as the outcome measure for each material type and the cost per tooth life year as the cost effectiveness ratio. The results are shown in Table 10 below:

Table 10 Cost effectiveness ratios

	5-year time period			10-year time period		
	Tooth years	**£**	**Cost per tooth year**	**Tooth years**	**£**	**Cost per tooth year**
Amalgam	4.89 (4.24)	21.56 (21.22)	4.41 (5.01)	9.56 (7.41)	32.93 (28.41)	3.45 (3.84)
Composite	4.61 (4.01)	33.01 (31.17)	7.16 (7.78)	7.90 (6.26)	91.66 (69.32)	11.60 (11.08)
Inlay	4.64 (4.03)	130.00 (123.78)	28.01 (30.71)	-	-	-

Composite is between 1.5 and 3.5 times more expensive than amalgam to generate one tooth-year, which is less than previous estimates (Mjor and Wilson, 1997).

The results in Table 6 are based on average cost effectiveness ratios. The recognised approach for economic evaluations is to use incremental cost effectiveness ratios. These indicate the additional costs which are incurred to generate additional units of output or outcome. Incremental cost effectiveness ratios are computed by dividing the difference in costs between two approaches by the difference in tooth-years generated and are shown in Table 11 below:

Table 11 Incremental cost effectiveness ratios

	5-year time period			10-year time period		
	Tooth-years	**£**	**Cost per additional tooth year**	**Tooth-years**	**£**	**Cost per additional tooth year**
Composite	4.61 (4.01)	33.01 (31.17)	7.16 (7.78)	7.90 (6.26)	91.66 (69.32)	11.60 (11.08)
Inlay	4.64 (4.03)	130.00 (123.78)	3233.00 (4630.50)			
Amalgam	4.89 (4.24)	21.56 (21.22)	-433.76 (-488.38)	9.56 (7.41)	32.93 (28.41)	-35.38 (-35.57)

The negative ratios for amalgam indicate that it dominates composite and inlays across all time periods considered. The analysis to date has been based on NHS costs and fees paid, whereas the proportion of dental restorations carried out under the NHS has declined considerably over the last five years or so. It is also the case that a number of composite and inlay restorations are not available on the NHS. In order to adjust for this potential skew in favour of amalgams, and to include an adjustment factor for dental settings, given that the baseline costs associated with composite and inlay may include additional costs as a result of private practice, a threshold analysis has been undertaken to identify the extent to which variables would have to change to affect the baseline findings.

In order for composite to be more cost effective than amalgam, the costs associated with providing amalgam restorations would have to increase by 62% over a five year period and by 237% over a 10 year period.

If amalgams are not considered appropriate on aesthetic grounds, the number of tooth-life years resulting from the use of amalgam would have to fall by 38% over a five year period and 70% over a 10-year period.

When the analyses were undertaken based on the longevity of restorations in secondary teeth only, virtually no differences emerged in the baseline findings reported above.

The differential in cost effectiveness ratios between amalgam and composite is reduced slightly when the longevity is based on studies which directly compared amalgam versus composite materials. In this case the threshold points are a reduction in cost for amalgam of 55% and 189% for five and 10 year periods respectively, or a reduction in the number of tooth life years of 36% and 66% for five and ten year periods respectively.

Conclusions

The aim of the economic evaluation has been to assess the relative cost effectiveness of dental restorations. It is clearly evident that amalgam represents the most cost effective restorative material and dominates composites and inlays, both in terms of costs and in the number of tooth-years produced. Adjusting for potential skew in favour of amalgams and excess costs resulting from private practice in order for composite to be more cost effective than amalgam would require the costs of amalgam to fall by 62% over a 5-year period and 237% over a 10-year period, or because of aesthetic factors and the acceptability of amalgams, the number of tooth life-years from amalgam falling by 38% over a five year period and by 70% over a 10-year period. In addition, the costs associated with extractions, crowns and other interventions have not been included in the analysis. If they had been, the cost-effective differential between amalgam and other materials would have been even greater.

Further work

The quality of any economic evaluation is predicated by the quality of the cost data and evidence relating to the effectiveness of the intervention. In this report an attempt has been made to estimate the direct costs of restorations, without the actual overheads associated with different settings included. What would be of interest is to undertake a prospective cohort study across different dental settings and to accurately document the inputs and costs associated with dental restorations over a relatively long period of time. The cost profile for each material type for different types of restorations could be constructed and used in conjunction with the evidence relating to the longevity of each restorative material.

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7. DISCUSSION

7.1 Opening remarks

The results of any systematic review are limited by the range (quantity and quality) of the available literature. During this review, exhaustive electronic and hand searches of the literature were carried out in all languages; papers not written in English were translated when required. In addition, relevant work that had not been published, the so-called grey literature, was also reviewed when available. Thus, the scientific and comprehensive nature of the search strategy provided the maximum volume of relevant literature.

A limitation of systematic reviews is the fact that studies that provide unfavourable findings may not be written up for publication with the result that the information does not reach the public domain. For example, unpublished data that describes the outcome of clinical trials may be held in confidence by dental manufacturing companies. Although we did contact dental companies, no additional information was supplied.

Another concern with systematic reviews is publication bias. That is, bias arising from submission or acceptance for publication of studies being based on the magnitude of any effects discovered, rather than on the quality of the study. In other words, reports that find no differences between control and experimental groups are less likely to be accepted for publication. To investigate this issue further, funnel plots were constructed for studies involving amalgam and composite; Figure 45 presents this data for the materials at two years. The plot has a somewhat unusual shape but does not display any obvious asymmetry that would suggest publication bias.

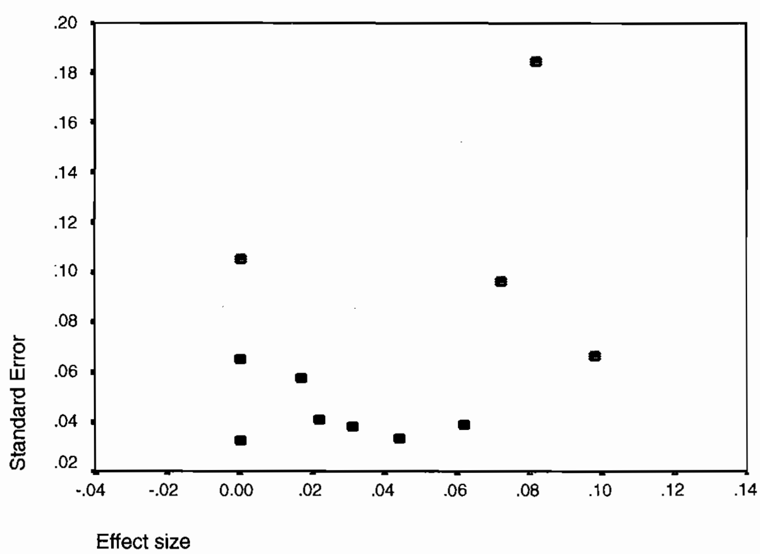

Figure 45

7.2 The search

Developing the electronic search strategy in the various databases was not problematical. However, it was clear that the categorisation of papers within MedLine and other indices was not entirely accurate. For example, many *in vitro* studies were identified following the search, despite clear instructions for the search to be confined to human clinical studies only. The converse was also true in that many studies that should have been identified were not found through MedLine, but were only found after meticulous hand searches. This problem highlights a major difficulty for future systematic reviews of the dental literature.

7.3 Inclusion criteria

Study design
The criteria for inclusion ensured that the review identified papers in an objective manner, from which reliable information on the longevity of restorations could be derived. In particular, the design of each

study was evaluated carefully and then categorised; as described earlier in the report some designs were considered more robust than others. The controlled clinical trial has been referred to as the "gold standard" for clinical research. These prospective, randomised and, when possible, blinded trials offer the greatest understanding of an experimental treatment when properly executed (Duke, 1992). However, the literature search revealed relatively few such trials; indeed, the total number included in the review was only 14. Clearly, it is not always possible to use a blind approach with restorative materials as experienced clinicians and/or evaluators can identify particular materials from their appearance. Furthermore, true randomisation is difficult, if not impossible, to achieve if 'conventional' patients are included, because some may prefer or opt for a particular type of restoration on the basis of aesthetics, safety, etc.

Other types of prospective trials or studies on the longevity of restorations are less rigorous but were included in this review because they made-up the vast majority of the papers identified in the search. As long as they reported the core information, such papers were included. Cross-sectional and retrospective studies of dental records, on the other hand, were excluded as they are hampered by the lack of uniform criteria defining when to place and replace restorations and by variations in decision making between clinicians (Mjör et al., 1990).

Training/calibration of clinicians/evaluators
A wide disparity in treatment planning decisions made by dentists has been reported in terms of both inter and intra-practitioner variation. This is obviously an important confounding influence when trying to identify the point at which a restoration fails (Elderton and Nuttall, 1983; Bader and Shugars, 1995; Tveit and Espelid, 1992). This problem was outside the scope of this review, however, the coding of the study design did take examiner training and calibration into account; those studies that reported using two or more calibrated examiners acting independently were deemed more valid.

Criteria for determining 'failure' – outcome measures
The impact of subjective criteria to assess restorations has been noted previously (Mjör, Jokstad et al., 1990). Practitioner knowledge and practice have a major influence on when the decision is made to replace a restoration, and the authors accept that this is what happens on a day to day basis when treatment is planned. However, there is a difference between identifying how long a restoration **could** last if objective outcome measures were used and how long it is **allowed** to last when individual practitioners use their own subjective and possibly changing criteria. The present review aimed to identify the former.

It is often difficult to determine the point at which a restoration fails, but that does not mean that it cannot be done. It was deemed appropriate to exclude studies that used subjective assessments; to accept such work would have resulted in data being included that was unreliable, both within and between studies. Furthermore, such an approach would have perpetuated the use of subjective diagnostic criteria. Rather we attempted to use objective and appropriate outcome measures that could and should be used in clinical practice.

To accept the validity of subjective criteria is similar to saying that we accept without reservation the decision a car mechanic makes when he/she replaces a tyre on a car. We do not accept that it be replaced when a mechanic bases his/her decision on subjective factors such as how much profit is to be made, how much time is available to replace it, whether the tyre is in stock or because they look a little muddy. Clearly, a tyre should be replaced only when the tread has reached a level that has been identified as illegal in vehicle legislation, that is, using an objective measure.

Only studies that used objective outcome measures to identify restoration failure or replacement were included in this review. Studies that used USPHS or Ryge criteria were accepted, but a note was also made of any variations in their application, for example, the number and independence of examiners. Where the text did not include relevant details of how the system was used, eg no details on the number of examiners, it was assumed that only one examiner was used and the study was then assigned a lower outcome grade. The grade was altered where authors provided additional information at a later date. However, other systems were accepted provided the criteria were clearly stated, for example, the criterion "failure due to secondary caries" was not accepted unless the paper clearly stated how secondary caries was diagnosed.

Unlike the criteria for restoration failure and replacement, which are notoriously difficult to validate, wear can be measured objectively. A number of studies reported wear (Stanford et al., 1985; Freilich et al., 1992; Fullemann et al., 1992; Berry et al., 1995) however, the ability to measure wear does not indicate necessarily that it is a valid way to identify restoration failure. Many studies reported variations between wear rates of different materials; in some cases the differences in wear could only be detected using SEM evaluation of study casts with the restorations all remaining in function. Furthermore, it is not clear whether wear *per se* leads inevitably to restoration failure. In the present review wear was only accepted as a valid outcome measure when it was related to the USPHS 'anatomical form' score of 'Charley' (C). That is, where sufficient restoration was lost to expose underlying dentine.

7.4 Data extraction

All studies with appropriate inclusion criteria were retained for data extraction. It soon became obvious, however, that not all studies reported fully the data that was required for meaningful conclusions to be drawn. Thus, even after their initial inclusion, in order for meaningful comparisons to be made between studies, a minimum core of data had to be present for a study to be analysed. For example, each restoration placed at the start of a study had to be accounted for until the censure date of the study, until it failed or until the patient, and hence restoration, was lost to follow up. Thus, the number of restorations placed at baseline and seen at each review visit had to be recorded. At follow up visits the number of failed restorations and restorations lost to follow up had to be provided. Where comparison groups were present these numbers had to be deduced for all groups. Where these figures could not be identified from the papers or by contacting the authors, the paper was excluded.

The tender to specification posed a wide range of questions that this review has attempted to answer. Many of them, for example, the effect on longevity of the type of dentition (Hunter, 1985; Holland et al., 1986; Qvist et al., 1986; Qvist et al., 1986), site of restoration (Mjor, 1985), size of restoration (Qvist, Thylstrup et al., 1986 a; Qvist, Thylstrup et al., 1986 b; Maryniuck and Caplan, 1986) reasons for placement, type of caries, or age, sex and socio-economic, characteristics of patient (Dolan, 1992 ; Maryniuck, 1990), oral cleanliness (Eriksen, 1986), age of practitioner, type of salary structure (Atchisonn and Schoen, 1990; Grytten, 1991) are quoted in the dental literature to affect longevity. In the present review these were identified as effect modifiers and details were sought in all papers and recorded where present. Provided that the minimum data set was present, no paper was excluded if these variables were not recorded.

7.5 Included studies

Few studies in this area will be sufficiently large and under carefully controlled conditions to be definitive. Relatively low failure rates and the difficulty of maintaining a long follow up period mean that the number of failures in any study will not be large. With the growth in evidence-based dentistry it must be anticipated, therefore, that studies will contribute towards systematic reviews and meta-analyses and data should be presented in such a way that it is possible for readers to extract the necessary information. Some papers displayed a masterly ability to hide the useful information and so could not be included in this review and in many others the information was very hard to extract.

The literature searched identified over 5,600 papers for potential inclusion in the review, after the application of inclusion criteria 652 remained. Of the 652 papers, only 253 had the minimum core of data required for inclusion. Because some investigations were reported on more than one occasion, this represented 195 separate studies. In each case a letter was written to the author in order to identify the missing information, and we are grateful to those who took the time to reply, even when they could not provide the appropriate information. In many cases the authors had retired or had not retained the original data and some excellent studies were excluded at this stage of the process.

A number of recurrent problems in the presentation of results were identified, some of which are listed below, with points that we hope authors will bear in mind when presenting results in future studies:

- *Dropout rates* should be stated clearly

- *Reporting of actual number or percentages.* The actual number of patients and restorations at baseline were invariably reported but results at follow-up were presented as percentages, rather than as absolute values. In those studies it was impossible to identify how many restorations were reviewed, so the number of restorations that failed at each follow-up period and the number lost to follow up at each stage could not be determined.

- *It should be clearly stated whether failures are cumulative.* For example, data are often presented in the following way (the example is fictitious)

  Initial number of restorations 100
  At 12 months there were three failures out of 80
  At 24 months there were four failures out of 70
  At 36 months there were four failures out of 60

  It is quite unclear if there are four or 11 failures in total. It is possible to deduce the style of presentation on occasions, since the number of failures appears to decrease with time! It is also not clear whether, in the event that these are new failures, the previous failures are included in the denominator. Ideally the data should be presented in such a way that it is possible to deduce exactly how many restorations were lost to follow-up and how many new failures occurred for each material group and at each time point.

- *Description of USPHS results.* Confusion occurred when USPHS data were presented in all its component parts. Although this was very useful in appreciating whether or not a restoration was failing because of one or more particular fault, it was often impossible to determine how many restorations failed overall if a particular restoration failed in more than one USPHS category. For example, a table within a paper may have recorded one failure for marginal adaptation, one for anatomical form and one failure for recurrent caries. This may be a single failed restoration with three different faults, three failed restorations each with a single fault or even two failed restorations! Thus, while it is useful to present data on the separate USPHS categories, authors must also be aware that it is essential that the actual number of failed restorations are also recorded.

- *Baseline information.* Some papers provided information only after 12 months and thus only reported failures from that time onwards. In these cases, it was not possible to calculate failure rates because the number of restorations at the beginning of the study was unknown, and any failures occurring before 12 months were omitted.

- *Methods of randomisation*, where used, should be clearly described and any breaches of a random allocation explained, for example in a within-mouth comparison when two cavities must be filled. Some studies comparing amalgam with composite appear to place the amalgam in the larger cavity and the composite in the smaller. Such practice will tend to bias the results against amalgam.

- *Inappropriate analyses* must be avoided. For example it is not possible to quote a median survival time in a study in which fewer than 10% of the restorations failed, unless a parametric modelling process is used. In spite of this, some authors quote a median in such circumstances, presumably using the last follow-up time as the lifetime of a restoration which is still intact. This procedure is hopelessly biased and should be avoided.

- *Non-significant results* should be properly interpreted. A small comparative study which does not lead to a statistically significant result does not prove that there is no difference between the materials under test. In such a case there is insufficient evidence to reject the null hypothesis and so the study does not demonstrate a difference.

7.6 Effect modifiers

The data extraction form used in the present study had several extraction fields, many of these were included to answer specific questions posed in the original tender and were referred to as effect modifiers. Unfortunately, very few papers included these details, and it was impossible to analyse them effectively. Thus, there was no robust and reliable evidence to describe the effect of many of these variables on the longevity of routine restorations. A number of key areas were poorly documented in the majority of papers:

- *Clinical procedures.* Clinical procedures were in general discussed in great, occasionally irrelevant, detail. However, some information was commonly omitted. Moisture control is said to affect the quality and longevity of restorations (Grytten, 1991; Curzon et al., 1996; Curzon et al., 1996), however, a large number of studies did not report how moisture control was achieved. Others reported that a variety of moisture control procedures were used but did not examine their effect on the results. Similarly, the use of local anaesthesia was often not reported, perhaps because the authors assumed that its use is universal.

- *Population characteristics.* In contrast to the excessive technical detail that accompanied cavity preparation/restoration, the method of allocating subjects and teeth to test and control groups was often handled superficially. How subjects were selected for the study as well as specific inclusion and exclusion criteria were not stated explicitly. How individual teeth were assigned to test or control groups was also frequently omitted.

  In many cases the population characteristics were poorly described. Gender and age of patients were often omitted. This was unfortunate, as some studies excluded from the present review have suggested that the age at which a restoration is placed, particularly in a child, may influence durability (Hunter, 1985; Holland, Walls et al., 1986; Qvist, Thylstrup et al., 1986 a; Qvist, Thylstrup et al., 1986 b). Few studies in this review provided equivalent data to test this assumption.

  Few studies give details of socio-economic status, general health, oral hygiene or ethnicity, although these factors are important in determining caries risk and possibly restoration failure. The majority of studies did not record caries status or the patients DMFTS/dmfts status at entry to the study, although there is some evidence to suggest that restorations are replaced sooner in patients with high caries rates (Elderton and Davies, 1988). This may suggest that patients with a high caries risk (as judged by past DMF scores) are more likely to have restorations that fail or that practitioners apply different criteria when treatment planning patients with different DMF levels. It would be interesting to know if the same difference is observed when objective replacement criteria are applied, however, it was not possible to test this hypothesis in the present review.

- *Control groups.* The restorations included in control and comparison groups should be described fully for meaningful results to be obtained. Often the control group was derived from the same population as the test group but, as described above, the population characteristics were often omitted. Where historical controls are used, details of the population and the year of the study are essential as, in addition to any potential differences between individuals, changes over time may be significant. For example, an historical control group may have had different fluoride exposure or a different risk from dental caries. Data such as DMFTS/dmfts would be helpful in this context but was seldom reported.

- *Study environment.* The environment in which a study took place was often omitted from reports. However, the majority of studies in this review took place in academic institutions, using dental students or patients as subjects. Such subjects are likely to have different characteristics than the general population, perhaps in some important ways, eg age, caries status. Unfortunately, in most instances there was no way that any relevant differences could be identified. Clearly, it is desirable for any clinical trial to use a representative population, not one that is likely to be biased for various characteristics.

- The type of cavity. The type of lesion/cavity included in the study was often not described in detail. The majority of studies identify cavity type using the traditional five category system. However, this classification provides only a crude estimate of cavity size. For example, a Class I cavity may be minimal, only just involve dentine, and never come under stress during function. Alternatively, it may involve almost the entire occlusal surface of the tooth, be deep enough to expose the pulp and be in routine function. Thus, the stresses placed on the restoration and tooth may be quite different but cannot be identified. A few studies reported cavity size (Welbury et al., 1990) and suggested that preservation of tooth tissue was important. No studies used the size of cavity as an integral component of the analysis, even though cavity size is a factor that is often reported to affect longevity in cross sectional and retrospective work (Hunter, 1985; Maryniuck and Caplan, 1986; Qvist, Thylstrup et al., 1986 a; Qvist, Thylstrup et al., 1986 b).

Some studies listed the number of restorations placed at baseline by cavity type, for example, x Class I and y Class II, but did not give similar information when reporting the results at follow up, so that any differentiation between cavity types was impossible. A similar problem was seen with the reporting of tooth type and arch; the type of tooth was commonly stated as premolar or molar but it was often not possible to determine the proportion of each. Furthermore, the results were rarely related to those important data. The Class II cavity is said to be the best test of a restorative material as it is stressed in function, indeed, retrospective (subjective studies) have reported that Class II cavities fail more quickly than Class I cavities (Hunter, 1985; Holland, Walls et al., 1986). Clearly, it is not possible to test this assumption when the results are reported in a combined fashion.

- *Objective criteria to identify failure.* The importance of objective **evaluation** has been debated at length, but remains an important consideration. If possible, a recognised and validated evaluation system should be used and be described clearly. When alterations are made to an established system they should too, be described fully. It is of particular importance to state how many evaluators examined the restorations, what training, calibration and reproducibility were undertaken, and if the examiners were also the operators. All of these factors affect bias and the validity of the results. It should also be stated if the examinations were carried out blind.

- *Operator characteristics.* Operator characteristics were reported rarely. The age, training, gender and time since qualification may be significant. For example, several studies noted that different operators achieved different results when working under the same conditions, however, it is not possible to determine what specific factors may have been involved (Letzel et al., 1987).

- *Payment system.* Just as information on the environment of the studies was often omitted, the reporting of the payment system (for the dentist and patient) under which the study was carried out was also poorly described. It is important for studies to report details of the payment systems as these have been described as having a strong influence on how dentists behave (Atchisonn and Schoen, 1990; Grytten, 1991).

- *Sponsorship.* Clinical trials are organised either directly by dental companies, by dentists/consultants who receive a fee for the work completed on behalf of a company or independently by dentists who have no links with the manufacturers or retailers. The relationship of the authors and the product manufacturer should be stated clearly as there is the possibility that paid consultants may not be entirely independent.

8. GENERAL APPLICABILITY OF RESULTS

The majority of papers included in the current review were undertaken in hospital or dental school clinics, whereas the majority of patients, certainly in the United Kingdom, are treated in a primary dental care environment. The lack of practice-based studies may reflect the difficulty of organising prospective studies in general practice (Mackie, 1998), or the fact that such studies rarely used objective outcome measures and so they were not included. This is an important issue and must affect the extent to which the results of this review can be generalised to the primary care setting.

The advantage of the academic setting is that it is easier to manage and control the study, as well as train and calibrate the operators and examiners. In addition, many of the financial and time factors that beset practitioners do not apply. The data are likely therefore to be more reliable. The main disadvantage of studies from an academic environment is the fact that the setting is quite different to those under which most patients are treated. This, in turn, may influence the type of patients seen, the time taken to complete the treatment, the expertise of the operator, the payment system etc. Any or all of these factors may affect longevity to greater or lesser extents. Large multi-centre trials are of great value as they allow effect modifiers to be investigated more easily, however, relatively few such trials were included.

The other major criticism that could be levelled at many of the studies included in the present review is that results were often reported after a relatively short follow-up period. A clinical study is expensive to set-up and requires several years to draw meaningful conclusions (Duke, 1992). Companies understandably want to market materials as soon as possible and see the results reported at an early opportunity. There is also pressure on academics to publish; this must also contribute to premature reporting. Finally, there is no agreement on what is an acceptable period of time for reporting clinical trials.

Unless catastrophic problems are obvious at an early stage and should therefore be made known (Wilson and Wilson, 1995) the value of publishing results after a short period is questionable. When discussing adhesive restorative materials Duke (1992) reported that "all too often in the past we have seen materials perform well in the laboratory, only to fail prematurely under clinical conditions. Unfortunately, clinical validation emerges years later, and the unsuspecting public has often been the victim of our premature endorsement of adhesive materials."

Where results are published at an early stage, it is important that subsequent follow-up data is also published, as the failure of restorations is normally seen only after a considerable period. For example, Welbury et al (1991)) reported a significant difference in Median Survival Time in favour of amalgam over glass ionomer cements in deciduous teeth after five years, whereas the earlier report after two years had found no difference between the performance of the two materials (Walls et al., 1988).

Although the long-term review of materials is crucial for a complete understanding of their performance, the extension of studies over many years creates potential problems. For example, it is difficult to follow a cohort of patients over a long period of time; many otherwise excellent studies suffered from large dropout rates that severely limited their relevance (Hamilton et al., 1983; Roberts and Sheriff, 1990). Such studies are also time consuming and expensive to set-up and manage, and funding may only be available in the short term.

Applying objective outcome measures in routine practice could provide the potential for the entire caseload of practitioners to be assessed (Roberts and Sheriff, 1990). Wilson (1990) suggested that "pragmatic clinical studies" using a representative group of practitioners on a large sample of their patients may be one way to bridge the gap between the strict control of a RCT and the purely observational clinical studies which this review has largely eliminated. With appropriate evaluation, such studies would allow an overview of a material's spectrum of performance in different clinical environments.

Despite their limitations, prospective trials indicate what can be achieved when using a given material under a standardised set of conditions. The question that arises from this approach is why do the reports derived from cross sectional and retrospective data produce different results?

8.1 Manufacturers

The pressures on manufacturers to take a new material from the laboratory stage to clinical practice have been discussed already. But there are a number of other difficulties that result from the rapid improvements in materials that have occurred over the last decade. Manufacturers are constantly striving to enhance their products; in many cases before the preliminary clinical trial data is published a product is in widespread use. On occasions it is obvious that constituents of materials have changed as a result of the data from early clinical evaluation, with the result that when a study is reported in the literature, the product in question may no longer be available, or if available, has changed substantially.

An inability to obtain details on the exact constituents of various formulations of amalgam also created problems. It has been suggested that high copper amalgams are resistant to creep and that this may lead to improvements in longevity. Attempting to classify the copper content of all the amalgams in the current review proved impossible. Manufacturers were able to guarantee the proportion of, for example, copper in a product to within x%, but reported that different batches had varying proportions. Unfortunately in the classification of high copper amalgam, the cut off point for low and high copper is 6% and in some cases the variation quoted by manufacturers was sufficient that the product could have been classified as low copper on some occasions and high copper on others. This restricted the statistical analysis and the way in which amalgams could be usefully classified.

8.2 Survival of restorations reported in cross-sectional and retrospective studies

This review used specific inclusion criteria to ensure that the most objective information on longevity of routine restorations was obtained. Of necessity, these criteria excluded a large body of work comprising cross-sectional and longitudinal studies undertaken in a variety of settings that provide an overview of what is potentially happening in clinical practice. Comparison of the results from excluded studies and those in the present review lead to a number of important questions:

- What are the differences in reported longevity between included and excluded studies?
- What factors may account for any differences?
- How can clinical practice be changed so that restoration longevity in all settings approaches the best that can be achieved?

Placement of simple intra-coronal restorations costs the NHS £173 million per year (Dental Practice Board, 1995-96). Studies in the UK suggest that between 60% (Wilson et al., 1997) and 71% (Nuttall, 1984) of restorations placed are replacement of existing restorations. Similar figures have been found in Europe (Mjor, 1979; Qvist, Thylstrup et al., 1986) and the U.S. (Klausner and Charbeneau, 1985). It has been estimated that replacement of a restoration costs at least as much as the one initially inserted and probably more because of its increased size (Elderton, 1983).

- **Amalgams.** Cross sectional retrospective studies have revealed wide variation in the median failure rate of amalgam restorations. In adult patients Robinson (1971) reported failure of 5.5 years; a longitudinal survey of patients from the 1978 UK survey of adult dental health in Scotland found a survival time of less than five years (Elderton, 1983). In contrast, in the USA it has been reported that 50% of amalgams lasted 10 years and that 5% of restorations lasted between 25 to 50 years (Klausner et al., 1987). Cross sectional surveys in general dental practice from Sweden and Denmark reported a median age of failed amalgam restorations between 8-10 years. Interestingly, the Swedish data from 1981 and 1997 shows no change in longevity of amalgams (Mjor, 1997; Qvist et al., 1990).

  In child patients amalgam has been reported as having median survival time of 30.9 months for deciduous molars with 46% surviving three years (Holland, Walls et al., 1986). However, Qvist et al (1986 a) reported 50% of deciduous amalgams failed within 2 years.

  Despite the variations alluded to above, it is clear that overall, the longevity of amalgams as determined from cross sectional studies is considerably less than that reported in the prospective studies included in this review.

- **Composite.** Elderton 1983 reported a 50% survival time of less than five years for synthetic restorations (composites and silicates). A cross sectional survey of 62 Italian private practitioners reported a median survival time of 3.3 years for composite restorations (Mjor, 1992); when using the same questionnaire format a survey of 177 Swedish practitioners reported a median survival time of six years (Mjor, 1997). While the survival rates had not markedly changed from earlier Swedish surveys (Mjor, 1981) the latter authors reported that there were fewer problems with wear of composites in the later study. Danish practice data based on questionnaires from 341 clinicians reported that 80% of composites were replaced within 10 years. For adult patients, Class III and V composites were most durable with median survival over six years, in contrast Class I and II median survival was less than four years (Qvist, Qvist et al., 1990).

  As with amalgam restorations, the survival in child patients was worse. For example, the Danish study (Qvist, Qvist et al., 1990) reported a median survival time of less than two years for composites in permanent teeth, and less than one year for deciduous teeth.

- **Glass ionomer cements.** These materials have not been in use as long as other materials and there are fewer cross sectional studies available. Mjor et al (Mjor, 1996) reported on 790 glass ionomer cement restorations placed in a private practice setting with a median survival time of five years. In contrast, a practice survey from Swedish found a median survival time of three years (Mjor, 1997); half of the restorations in this study had failed because of recurrent caries.

- **Gold.** Bentley and Drake (1986) reported that 90% of gold inlays lasted 10 years, despite being placed by inexperienced clinicians. A survey of selected practitioners reported a mean age at failure of 18.5 years for 745 cast gold restorations (Mjor and Medina, 1993).

The brief review of cross sectional data above suggests that restorations in these studies were not, in general, lasting as well as those placed in clinical trials. The following section uses amalgam to illustrate some of those differences.

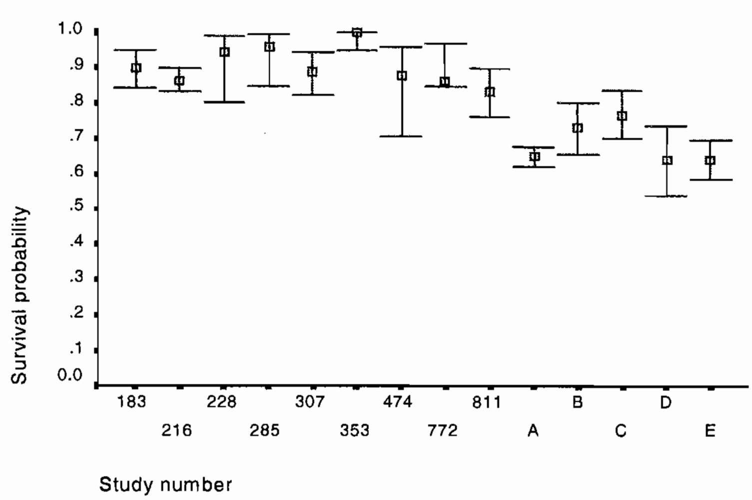

Figure 46 Comparison of selected and rejected studies
Amalgam restorations in secondary teeth at 5 years

Key

A Crabb HSM. The survival of dental restorations in a teaching hospital. British Dental Journal 1981; 150: 315-318.

B Robinson AD. The life of a filling. British Dental Journal 1971; 130: 206-208.

C Allan DN. A Longtitudinal Study of Dental Restorations. British Dental Journal 1977; 143: 87-89.(20-year period)

D Allan DN. A Longtitudinal Study of Dental Restorations. British Dental Journal 1977; 143: 87-89. (15 year period)

E Wilson NHF, Burke FJT, Mjor IA. Reasons for the placement and replacement of restorations of direct restorative materials by a selected group of dental practitioners in the United Kingdom. Quintessence International 1997; 28: 245-248.

Figure 46 gives the five year survival probabilities for five studies included in the present report. In addition, the graph shows five excluded UK based studies. In general, amalgam restorations from the excluded surveys, arguably carried out under "real world" conditions, display a lower survival probability than those placed in clinical trials. Unlike clinical trials the excluded studies did not control the restorations that were included, and to some extent may reflect more accurately what occurs in General Dental Practice.

It would appear from the cross sectional studies that cavity type, patient age, use of local anaesthetic and practice setting may all influence the longevity of dental amalgam. The data presented from clinical trials suggests that if one is able to standardise placement and assessment methods, then the longevity of such restorations can be increased.

8.3 Limitations of pooled data

The present report has pooled data from many different studies to give an overall survival rate along with 95% confidence intervals for a restorative material at a given point in time following placement. Tables 12 to 19 present this data for the major material types in permanent and, where possible, primary teeth. However, when the data is pooled there are a number of factors that must be borne in mind when interpreting the results.

Number of studies included. Many studies were of short duration and the vast majority reported on the longevity of restorations over 12 or 24 months. In contrast, there were few reports in excess of 84 months. Thus, when considering amalgam restorations at 24 months, Table 12 includes a large number of different brands of amalgam placed by many operators in different countries and environments over the last 30 years or so. Clearly, for this 24 month period almost all survived. In contrast, the data for amalgams at 120 months relates to a single study, and so far less reliance can be placed on the survival estimate.

Types of studies. The pooled data includes RCTs and other studies with comparators as well as prospective studies with no control groups. Any differences between study designs are lost when the data are pooled.

Study environment. Using the pooled data it is not possible to make comparisons between practice based studies and studies carried out in academic institutions. In the present survey most studies were carried out in the latter and it is likely that the data reflects longevity of restorations in hospitals, rather than in the primary dental care setting. Thus, the results tell us how long restorations could last when placed under strictly controlled conditions, not how long they actually last when placed in routine general practice conditions.

8.3.1 Survival functions in various settings

Tooth and cavity types. For amalgam the data was pooled for all restorations in all cavity types, thus Class I, II and V restorations were represented; furthermore the restorations were placed in both molars and premolars. The proportion of tooth types will vary and so the pooled data can only give an estimate of the survival of amalgam restorations in a posterior tooth. Because Class II restorations are not, in general, as durable as Class I and V restorations, the results may overestimate the survival of Class II restorations and underestimate the survival of Class I and V restorations.

When considering composites, the effect of cavity type and tooth type is more complex. Composites are used in both anterior teeth and posterior teeth and they may be used to restore Class I, II, III, IV and V cavities. Thus, while composites appear to fail sooner than amalgams, the tables are not really comparing like with like. To determine if a Class II amalgam will last longer than a Class II composite, paired studies would give a more accurate determination than the pooled data which includes many other confounding variables.

Effects of time. Restorative materials are constantly evolving and changing. The composite placed in a 20 year old study would have been an autopolymerising material, while more recent reports will have used light cured materials. Pooling data has also masked the effects of dentine bonding agents on composites.

8.3.2 Survival functions of materials

The pooled data (Tables 12 to 19) gives an overview of the reported survival of the main classes of materials. The best results occurred with amalgam where in permanent teeth the survival function at nine years was in excess of 90%, with a reduction to approximately 80% at ten years. In primary teeth a survival function over 90% up to five years was found.

With composite restoration in permanent teeth, a survival function of 90% was found for the first three years, but this declined thereafter to 59% at eight years. A similar trend was seen for composites in primary teeth, but the reduction in survival function was more rapid; 90% survival occurred for the first 18 months, but by four years this had fallen to 67%.

Both ceramic and composite Inlays had a survival function of over 90% for the first four years, but declined after that point to yield a survival function of 68% at seven years.

Glass ionomers in permanent teeth had a survival function above 90% for the first 18 months, declining steadily to 64% by five years. In primary teeth a 90% survival was seen only during the first six months.

Table 19 gives the survival function for Class V composite restorations using dentine bonding agents. For this specific restoration, a survival function in excess of 90% was found at 18 months, however, by five years only 41% of restorations had survived.

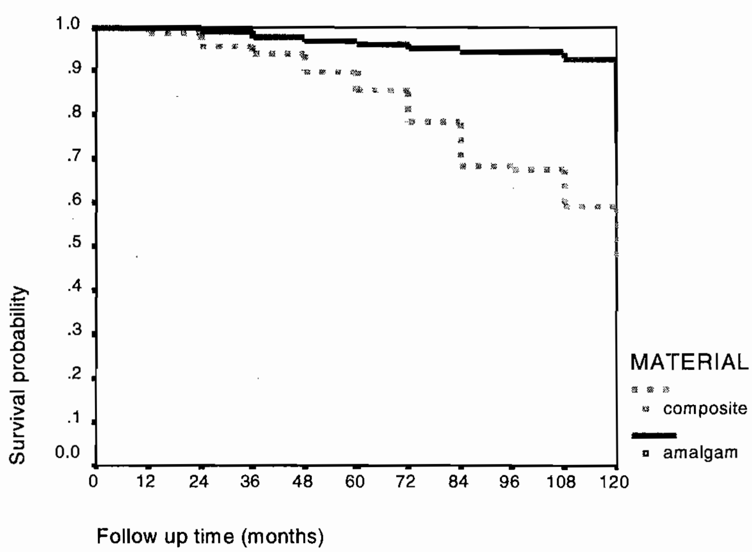

Figure 47 - Amalgam vs composite in secondary teeth

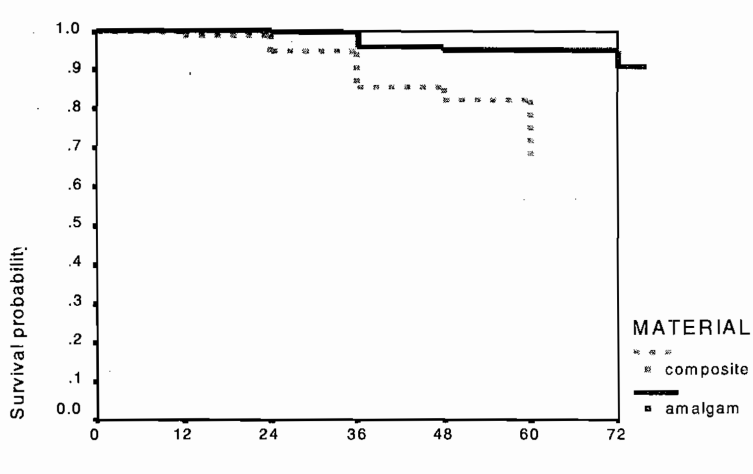

Figure 48 - Amalgam vs composite in primary teeth

Figures 47 and 48 show the combined survival probabilities for all amalgam and composite restorations in all studies for permanent and primary teeth respectively. The trends are similar for both dentitions, with amalgam restorations lasting significantly longer than composite restorations (p=0.0001). In both dentitions the survival probabilities for each material are similar for the first 24 months; beyond this period the survival probability for composites begins to decrease.

It is important to emphasise that these graphs ignore all effect modifiers with the exception of material and dentition type. Therefore, results for amalgam restorations will include only Class I and II cavities, while composite studies will also include Class III, IV and V cavities. Figure 49 compares the two materials in all subjects with permanent teeth but includes only clinical trials of Class I and II cavities. The difference in survival is less marked but still favours amalgam (p=0.0001).

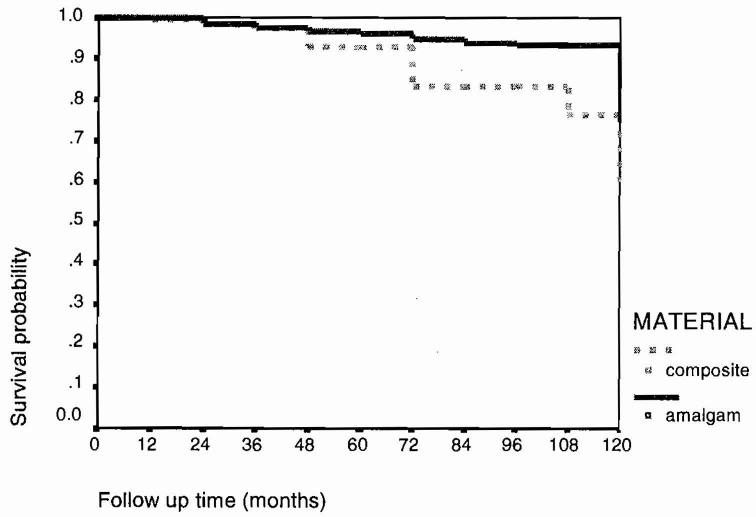

Figure 49 - Amalgam vs composites in clinical trials, secondary teeth Cavities I and II

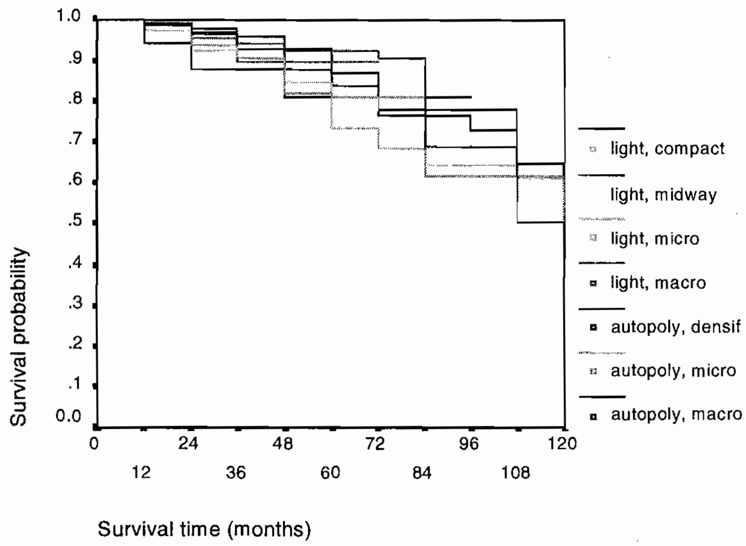

Figure 50 - Comparison of composite types

Figure 50 shows the survival probability for different formulations of composite material ignoring all other effect modifiers. When all cavity types and dentitions are considered together autopolymerising macrofilled and light cured compact filled composites performed best. However, when specific cavity types were considered, the ranking of the materials changed. For example, Figure 51 shows the survival probability for Class I and II cavities only; for these cavities light cured microfilled composites were significantly better than other composites.

The results for composite restorations with dentine bonding agents (DBA) were restricted to Class V cavities only. Figure 52 shows the survival probability by type of DBA. Class 1a and 1b DBA performed significantly better than classes 2 and 3 (p = 0.026). When the bonding agents are pooled into two categories, 1a and 1b versus 2 and 3, the difference is highly significant (P<0.0001). Thus, the more modern DBA that use an acid to remove the smear layer and modify the dentine surface were superior.

Overall in permanent teeth amalgam is the most durable material followed by inlays, composites and glass ionomer cements. The order in primary teeth is the same with the exception of inlays which are rarely prescribed.

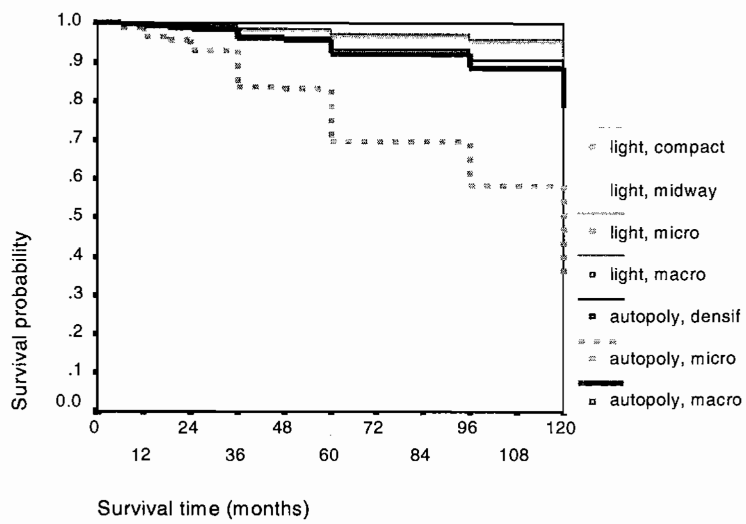

Figure 51 - Comparison of composites in type I and II cavities

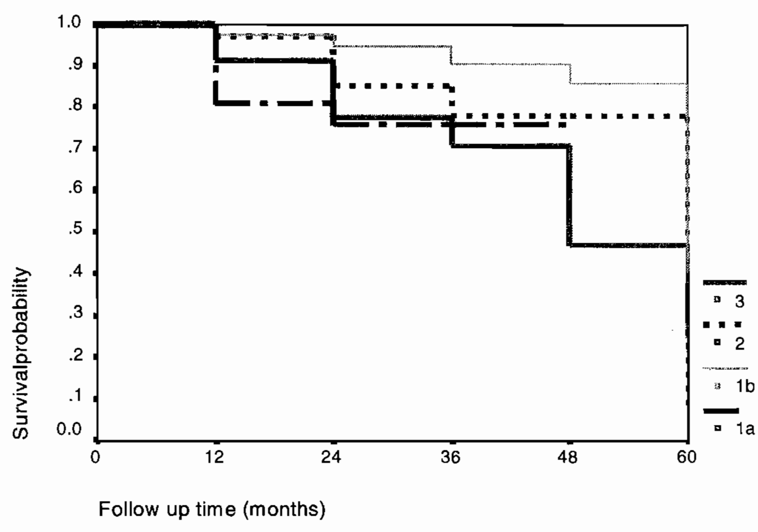

Figure 52 - Comparison of dentine bonding agents

8.4 Implications for policy and practice

The dental manufacturing industry is constantly promoting new materials; some are modifications to existing products whilst others are introduced as new and innovative products. Typically they are marketed and introduced into practice before reliable and comprehensive clinical trials have reported. This makes it difficult, perhaps even impossible, to determine the relative merits of materials and allow the clinician to make an informed choice based on sound evidence. Mechanisms should be sought to ensure that the introduction of dental materials into clinical practice is incorporated into any new NHS regulatory structures designed to promote quality of health care (Department of Health, 1998).

There are clear differences in the longevity of restorations reported in optimally designed studies compared to those carried out in routine clinical practice. This raises the issue of how clinical practice can be improved to allow restoration longevity in all settings to approach the best, and what resource implications this may have. There is insufficient information available from this review to assess the likely impact of better clinical training, changes in restorative techniques, enhanced protocols to ensure the optimal process of restoration, the effect of the time spent, and remuneration systems.

Appropriate incentives (including the fee structure) that reward cost-effective practice need to be explored; this is an area that might be worth considering for inclusion in the National Performance Framework.

Variations exist between dentists in the way they diagnose caries and identify failed restorations. This in turn will influence the decision to replace restorations when patients change dentists. To reduce unjustified variation in the diagnostic level at which restorations are replaced, there is a need for appropriate criteria for replacement of restorations to be developed. The systems utilised in clinical trials to standardise diagnosis of restoration failure (eg USPHS) should be examined in routine practice to identify whether they may assist dentists in decision making. Dental Schools should train dentists in using standardised definitions of what constitutes a failed restoration and to adopt appropriate maintenance policies. This should improve the quality of professional decision-making and prevent the possibility of unnecessary treatment.

Dental amalgam is the direct restorative material with the longest duration and, from the perspective of the NHS, is of lower cost. Unless there is a contra-indication (eg aesthetics, pregnancy) it is recommended for routine use, wherever possible.

8.5 Implications for research

Co-ordinated research is needed in the primary dental care setting to assess the effects of clinicians' skill, tooth type, cavity type and material type on restoration survival, taking into account the evolving disease patterns. This requires the establishment of multi-centre, multi-operator studies with stratification of tooth type, cavity type and other effect modifiers (such as fluoride availability and oral hygiene), for assessment periods of greater than 10 years. It has been suggested that "pragmatic clinical studies" using a representative group of practitioners, on a large sample of their patients, may be one way to obtain the internal validity of a randomised trial, and the generalisability of purely observational studies excluded in the current review (Wilson, 1990). With appropriate clinical and economic evaluation, such studies would allow an overview of a material's spectrum of performance in different clinical environments.

To obtain a more reliable cost and relevant outcome estimates, a long-term prospective cohort study is needed across different dental settings. The cost profile for each material type for different types of restorations could be constructed and used in conjunction with the evidence relating to the longevity of each restorative material.

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Table 12

	Amalgam in secondary		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.999	0.998	0.999
12	0.995	0.993	0.997
18	0.993	0.991	0.995
24	0.987	0.984	0.990
30	0.979	0.975	0.983
36	0.972	0.967	0.977
42	0.970	0.965	0.975
48	0.966	0.961	0.971
54	0.964	0.959	0.969
60	0.954	0.948	0.960
66	0.953	0.946	0.960
72	0.947	0.940	0.954
78	0.946	0.939	0.953
84	0.945	0.938	0.952
90	0.944	0.937	0.951
96	0.931	0.922	0.940
102	0.930	0.921	0.939
108	0.930	0.921	0.939
114	0.930	0.921	0.939
120	0.797	0.779	0.815

Table 13

	Amalgam in primary		
Time (months)	Estimate	CI lower limit	CI upper limit
6	1.000	0.995	1.000
12	1.000	0.995	1.000
18	0.990	0.988	0.992
24	0.959	0.945	0.973
30	0.959	0.945	0.973
36	0.953	0.938	0.968
42	0.951	0.936	0.966
48	0.951	0.936	0.966
54	0.951	0.936	0.966
60	0.908	0.885	0.931

Table 14

	Composite in secondary		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.985	0.983	0.987
12	0.960	0.956	0.964
18	0.958	0.954	0.962
24	0.938	0.935	0.943
30	0.938	0.935	0.943
36	0.900	0.893	0.907
42	0.900	0.893	0.907
48	0.856	0.846	0.866
54	0.856	0.846	0.866
60	0.782	0.768	0.796
66	0.782	0.768	0.796
72	0.684	0.662	0.706
78	0.684	0.662	0.706
84	0.674	0.651	0.697
90	0.674	0.651	0.697
96	0.590	0.561	0.619

Table 15

	Composite in primary		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.991	0.986	0.996
12	0.950	0.938	0.962
18	0.945	0.932	0.958
24	0.854	0.828	0.880
30	0.854	0.828	0.880
36	0.824	0.792	0.856
42	0.824	0.792	0.856
48	0.672	0.600	0.744

Table 16

	Inlays		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.992	0.987	0.997
12	0.991	0.986	0.996
18	0.991	0.986	0.996
24	0.977	0.967	0.986
30	0.977	0.967	0.986
36	0.933	0.914	0.952
42	0.923	0.902	0.944
48	0.901	0.874	0.928
54	0.901	0.874	0.928
60	0.853	0.813	0.893
66	0.853	0.823	0.893
72	0.804	0.747	0.861
78	0.804	0.747	0.861
84	0.683	0.546	0.820

Table 17

	GIC in secondary		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.985	0.980	0.990
12	0.906	0.892	0.920
18	0.903	0.889	0.917
24	0.833	0.813	0.853
30	0.833	0.813	0.853
36	0.738	0.708	0.768
42	0.738	0.708	0.768
48	0.738	0.708	0.768
54	0.738	0.708	0.768
60	0.649	0.597	0.701

Table 18

	GIC in primary		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.998	0.995	0.999
12	0.778	0.753	0.803
18	0.763	0.737	0.789
24	0.755	0.728	0.782
30	0.755	0.728	0.782
36	0.515	0.479	0.551
42	0.515	0.479	0.551
48	0.515	0.479	0.551
54	0.515	0.479	0.551
60	0.312	0.257	0.367

Table 19

	DBA in class 5		
Time (months)	Estimate	CI lower limit	CI upper limit
6	0.965	0.958	0.972
12	0.913	0.903	0.923
18	0.912	0.902	0.922
24	0.872	0.859	0.885
30	0.872	0.859	0.885
36	0.837	0.821	0.853
42	0.837	0.821	0.853
48	0.477	0.428	0.526
54	0.477	0.428	0.526
60	0.415	0.359	0.471

APPENDIX 1
SEARCH STRATEGIES

STRATEGY FOR SYSTEMATIC REVIEWS (INCLUDING META-ANALYSES) IN MEDLINE (OVID) (from CRD - York))

01 (meta-analysis or review literature).sh.
02 meta-analy$.tw.or (meta adj anal$).tw.
03 metaanal$.tw.
04 meta-analysis.pt.
05 review, academic.pt.
06 review literature.pt.
07 case report.sh.
08 letter.pt.
09 historical article.pt.
10 review of reported cases.pt.
11 review, multicase.pt.
12 or/1-6
13 or/7-11
14 12 not 13
15 animal.sh.
16 human.sh.
17 15 not (15 and 16)
18 14 not 17

STRATEGY FOR RCTs, CTS AND STUDIES IN MEDLINE (OVID) (based on Cochrane strategy)

01 randomized controlled trial.pt.
02 randomized controlled trials/
03 random allocation/
04 double-blind method/
05 single-blind method/
06 clinical trial.pt.
07 exp clinical trials/
08 (clinical$ adj5 trial$).tw.
09 ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).tw.
10 placebos/
11 (placebo$ or random$).tw.
12 research design/
13 comparative study/
14 exp evaluation studies/
15 follow-up studies/
16 prospective studies/
17 (control$ or prospectiv$ or volunteer$).tw.
18 or/1-6
19 or/7-12
20 or/13-17
21 or/18-20
22 cohort stud$.tw.
23 exp case-control studies/
24 multicenter studies.sh.
25 or/22-24
26 21 or 25
27 ..l/26 hu=y

DENTAL AMALGAM, COMPOSITE RESINS AND INLAYS
SEARCH STRATEGY - MEDLINE (OVID)

01 Inlays.sh.
02 (Inlay$ or onlay$).tw.
03 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.
04 2 and 3
05 cast restoration$.tw.
06 exp crowns.sh.
07 crown$.tw.
08 6 or 7
09 5 not 8
10 1 or 4 or 9
11 exp composite resins.sh.
12 composite resin$.tw.
13 (bisphenol A-glycidyl methacrylate$ or bisphenol A glycidyl methacrylate or bisphenol-A).tw.
14 BIS GMA.tw.
15 1565-94-2.rn.
16 preventive resin restoration$.tw.
17 resin cements.sh.
18 or/11-17
19 dental amalgam.sh.
20 dental amalgam/ae,to
21 19 not 20
22 amalgam.tw.
23 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$ or silver).tw.
24 22 and 23
25 8049-85-2.rn.
26 21 or 24 or 25
27 10 or 18 or 26
28 ..l/27 hu=y
29 in vitro/
30 28 not 29

DENTAL CEMENTS SEARCH STRATEGY - MEDLINE (OVID)

01 Exp dental cements.sh.
02 (Dentin-bonding or dentin bonding).tw.
03 (Dentine-bonding or dentine bonding).tw.
04 2 or 3
05 Glass ionomer$.tw.
06 GIC.tw.
07 5 or 6
08 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.
09 7 and 8
10 Polyalkenoates.tw.
11 9 or 10
12 Cermet cement$.tw.
13 Polycarboxylate$.tw.
14 zinc phosphate cement$.tw,sh.
15 7779-90-0.rn.
16 zinc cement$.tw.
17 zinc oxide eugenol cement$.tw.
18 zinc oxide eugenol adj4 cement$.tw.
19 zinc oxide-eugenol cement$.tw,sh.
20 ZOE$.tw.
21 or/12-20

22 Resin$.tw.

23 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.

24 22 and 23

25 1327-39-5.rn.

26 Silicate$.tw.

27 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.

28 26 and 27

29 25 or 28

30 1 or 4 or 11 or 21 or 24 or 29

31 ..l/30 hu=y

32 in vitro/

33 31 not 32

STRATEGY FOR META ANALYSES AND REVIEWS IN EMBASE (OVID)

01 meta anaysis/ or meta analysis.ti,ab,hw,tn,mf.

02 literature review.ti,ab,hw,tn,mf.

03 review/ or review@.ti,ab.hw,tn,mf.

04 overview.ti,ab,hw,tn,mf.

05 3 or 4

06 systematic@.ti,ab,hw,tn,mf.

07 critical@.ti,ab,hw,tn,mf.

08 academic@.ti,ab,hw,tn,mf.

09 6 or 7 or 8

10 5 and 9

11 1 or 2 or 10

STRATEGY FOR RCT'S, CCT'S AND STUDIES IN EMBASE (OVID)

01 exp randomized controlled trial/

02 randomi#ed controlled trial.ti,ab,hw,tn,mf.

03 (random$ or placebo$ or double-blind$) .ti,ab,hw,tn,mf.

04 Controlled clinical trial.ti,ab,hw,tn,mf.

05 1 or 2 or 3 or 4

06 case control study/

07 prospective study/

08 multicenter study/

09 follow-up stud$.tw.

10 cohort stud$.tw.

11 evaluation stud$.tw.

12 or/6-11

13 in vitro stud$.tw,sh.

14 12 not 13

15 5 or 14

DENTAL CEMENTS SEARCH STRATEGY - EMBASE (OVID)

01 cements.tw.

(dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.

03 1 and 2

04 (dentin-bonding or dentin bonding).tw.

05 (dentine-bonding or dentine bonding).tw.

06 4 or 5

07 glass ionomer$.tw.

08 GIC.tw.

09 7 or 8

10 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.

11 9 and 10
12 polyalkenoates.tw.
13 11 or 12
14 cermet cement$.tw.
15 zinc phosphate$.tw,sh.
16 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.
17 15 and 16
18 7779-90-0.rn.
19 zinc oxide eugenol.tw,sh.
20 zinc oxide-eugenol.tw.
21 ZOE.tw.
22 14 or 17 or 18 or 19 or 20 or 21
23 3 or 6 or 13 or 22
24 tooth cement$.sh,tw.
25 acrylic cement$.sh,tw.
26 zinc cement$.tw.
27 polycarboxylate cement$,sh,tw.
28 or/25-27
29 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.
30 28 and 29
31 resin$.tw.
32 silicate$.tw.
33 31 or 32
34 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or cement$).tw.
35 33 and 34
36 1327-39-5.rn.
37 23 or 24 or 30 or 35 or 36
38 ..l/37 hu=y
39 in vitro study/
40 38 not 39

DENTAL AMALGAM, COMPOSITE RESINS AND INLAYS SEARCH STRATEGY - EMBASE (OVID)

01 Inlays.tw.
02 composite resin$.tw.
03 (bisphenol A-glycidyl methacrylate$ or bisphenol A glycidyl methacrylate or bisphenol-A)
04 "bisphenol a bis (2 hydroxypropyl) ether dimethacrylate"/
05 bis gma.tw.
06 1565-94-2.rn.
07 or/1-6
08 (dental or dentist or mouth or tooth or teeth or dentin$ or enamel or oral or caries or cavit$ or ement$).tw.
09 7 and 8
10 amalgam.sh.
11 amalgam/ae,an,cb,cm,dt,to,ec,pr,pd,si
12 10 not 11
13 mercury.sh,tw.
14 12 not 13
15 9 or 14
16 ..l/15 hu=y
17 vitro.ti,ab,hw,tn,mf. not (vitro and vivo).tw.
18 16 not 17

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E = unable to extract, NR = not relevant, O = did not meet outcome criteria, S = less than 90% followed up with no valid reason or follow -up numbers unclear, D = design

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Table A1 Studies involving amalgam restorations only

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Osborne and Gale 1974) 65 **Year:** 1974 **Country:** USA **Aim:** A clinical evaluation that is designed to compare some of the clinical performance characteristics of a lathe-cut alloy when it is triturated according to the manufacturers instructions and when it is under-triturated. **Follow-up:** 48 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** Correctional facility **Clinicians:** 1 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 16 **Restoration Type(s) and Baseline Nos:** 25 Class I and Class II cavities, normal and under triturated, within mouth comparison. **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Twentieth century Fine cut. **Participant final Nos:** Not stated **Restoration final Nos:** 8 normal-triturated and 8 under-triturated **Tooth type final Nos:** Not stated **Materials final Nos:** Normal trituration Months (n) 24 17 36 9 48 8 Under triturated (n) 24 17 36 9 48 8 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Lining:*** *Dycal/Copal varnish* ***Mechanical:*** *Converging walls* ***Other:*** *Not stated*	No failures in triturated and non-triturated groups. **Normal trituration** Months (n) 24 0/17 36 0/9 48 0/8 **Under triturated** Months (n) 24 0/17 36 0/9 48 0/8	Generalisability limited by small numbers and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (van Dijken 1991) 183 **Year:** 1991 **Country:** Sweden **Aim:** To compare the longevity of three dental alloy restorations with different copper contents. **Follow-up:** 72 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** Not stated **Clinicians:** 1 **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Adults – 44 aged 25-65 **Restoration Type(s) and Baseline Nos:** 132 - Class II **Tooth types and Baseline Nos:** Not stated Premolar/molar (ratio 1:4) **Materials and Baseline Nos:** Epoque 80 44 Dispersalloy 44 Standalloy 68 44 **Participant final Nos:** Not stated **Restoration final Nos:** Epoque 80 42 Dispersalloy 42 Standalloy 68 42 **Tooth type final Nos:** Not stated **Materials final Nos:** Epoque 80 42 Dispersalloy 42 Standalloy 68 42 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Cotton wool suction* ***Lining:*** *Dycal* ***Mechanical:*** *Not stated* ***Other:*** *cleanser Tubulicid-blue*	Failures at 72 months Epoque 80 2/42 Dispersalloy 3/42 Standalloy 68 8/42 ANOVA No differences between Dispersalloy and Epoque 80. However, Standalloy was statistically worse than the other two alloys.	Within mouth comparison with only one operator. Generalisability is affected by single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Jokstad and Mjör 1991) 216 **Year:** 1991 **Country:** Norway, Finland, Denmark, Sweden **Aim:** To evaluate the influence of clinical variables in the replacement of Class II amalgams **Follow-up:** 120 months **Design:** (7) Other clinical trial **Criteria** (2) Modified USPHS **Environment:** 2 public health service 2 School dental service 3 private practice **Clinicians:** 7 **Evaluators:** 7 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 210 aged 8-71 years **Restoration Type(s) and Baseline Nos:** 468 Class II **Tooth types and Baseline Nos:** Secondary dentition **Materials and Baseline Nos:** 1 conventional and 5 non-gamma 2 amalgams Amalcap 85 Dispersalloy 81 Indiloy 78 Revalloy 143 Tytin 81 **Participant final Nos:** 88 **Restoration final Nos:** 188 **Tooth type final Nos:** Not stated **Materials final Nos:** Amalcap 46 Dispersalloy 48 Indiloy 44 Revalloy 83 Tytin 35 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Not stated* ***Lining:*** *Not stated* ***Mechanical*** *Not stated* ***Other:*** *Not stated*	8-120 months Replacements Amalcap 18 out of 46 Dispersalloy 13 out of 48 Indiloy 6 out of 44 Revalloy 17 out of 83 Tytin 14 out of 35 68 out of 468 replaced 30 secondary caries 24 bulk fractures 8 tooth fractures 3 marginal fractures 3 included in larger restorations 86 patients with 212 restorations dropped -out of the study ANOVA, MCA analyses Age range 8-71 years. Different operators treating different age groups. No differences between MO/DO and MOD restorations Restorations placed in lower premolars showed longer survival than restorations placed in upper and lower molar Cox regression model - Survival dependent on patients age and caries activity Operator, patient's caries activity, patients age, alloy, restoration location, restoration type and patient gender accounted for 46% of the variance. No difference between 4 gamma and 1 non-gamma alloys over 9 years. Months Res Rep laced Rest Withdrawn	Authors report that the number of replacements and the criteria for replacement varied between operators e.g. secondary caries was diagnosed frequently by two operators and seldom by the other five. In addition, two operators had made 17 of the 24 restorations that fractured as well as the four restorations replaced owing to poor marginal integrity. It is not possible to deduce whether the variation was due to differences in applying the criteria, in the study population or in the operator technique. This is a relatively large multi-operator/ multi-centre study. The generalisability is limited by the drop-out rate. Nevertheless, the study covers a considerable time period and undertakes a multi-variate analysis.

Amalgam restorations

0-6	468	3	7
6-12	458	3	6
12-18	449	8	5
18-24	436	2	7
24-30	427	10	14
30-36	403	3	3
36-42	397	8	30
42-48	359	3	16
48-54	340	6	28
54-60	306	3	7
60-66	296	4	32
66-72	260	4	14
72-78	242	2	17
78-84	223	3	4
84-90	216	2	33
90-96	181	2	15
96-102	164	2	26
102-108	136	0	21
108-114	115	0	54
114-120	61	0	61

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mahler, Engle et al. 1990) 250 **Year:** 1990 **Country:** USA **Aim:** To compare the performance of 2 high copper amalgams with and without palladium **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (3) Photographic scale (Mahler and Marantz, 1979) **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** USPHS Research Grant	**Participants and Baseline Nos:** 8th grade students – 59 **Restoration Type(s) and Baseline Nos:** 193 - Class I and Class II cavities **Tooth types and Baseline Nos:** Secondary dentition Premolars molars (ratio 3:10) **Materials and Baseline Nos:** Valiant without palladium 101 Valiant with 0.5% palladium 92 **Participant final Nos:** Not stated **Restoration final Nos:** 147 **Tooth type final Nos:** Not stated **Materials final Nos:** Valiant without palladium 72 Valiant with 0.5% palladium 75 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Not stated* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	Failures not stated. Presumably there were none. No differences in marginal fracture (Kruskal Wallis and Dunn's Multiple comparison test). Surface Lustre was better with the inclusion of Palladium.	Requires long-term follow-up. Generalisability limited by no clear statement on restoration loss.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Capel, Gomes et al. 1989) 272 **Year:** 1989 **Country:** Brazil **Aim:** To assess amalgam with low silver and high copper content over a 2 year period **Follow-up:** 24 month **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** Not stated **Clinicians:** 5 **Evaluators:** 3 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 125 – Class I and Class II cavities **Tooth types and Baseline Nos:** Secondary dentition Premolar/molar (ratio 0.4:1) **Materials and Baseline Nos:** Veralloy 26 Novaloy 37 Aristaloy21 37 Ventura III 25 **Participant final Nos:** Not stated **Restoration final Nos:** Veralloy 26 Novaloy 37 Aristaloy 21 37 Ventura III 25 **Tooth type final Nos:** Not stated **Materials final Nos:** Not stated **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Rubber dam* ***Lining:*** *Ca(OH)s (LIFE)* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	Failures not stated. Could be presumed that there were no failures. Wear was examined (Chi square tests) Aristaloy 21 was superior to Veraloy and Ventura III, which were then superior to Novaloy.	Novaloy did not demonstrate satisfactory marginal integrity. No within mouth comparisons. Requires longer follow-up. Generalisability limited no clear statement on loss.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kusner, Markitziu et al. 1988) 294 **Year:** 1988 **Country:** Israel **Aim:** To compare the longitudinal behaviour of occlusal amalgam fillings in molars and premolars of 16-28 year olds with and without an extended cavity outline. **Follow-up:** 48 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** High school and university **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 123 16-28 year olds **Restoration Type(s) and Baseline Nos:** 201 extended and 201 not extended Class I **Tooth types and Baseline Nos:** Premolars and molars **Materials and Baseline Nos:** Amalgam Not stated **Participant final Nos:** Not stated **Restoration final Nos:** Non-extended 159 Extended 159 **Tooth type final Nos:** Not stated **Materials final Nos:** Not stated **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Lining:*** *Not stated* ***Mechanical:*** *Converging walls* ***Other:*** *Not stated*	Failure due to marginal deterioration Time Non-extended Extended 6 1/199 4/199 12 11/198 3/198 24 6/182 6/182 36 4/175 5/175 48 9/159 2/159	Generalisability limited by lack of definition of amalgam and description of cavities and size of preparations.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Knibbs, Plant et al. 1987) 311 **Year:** 1987 **Country:** UK **Aim:** i) To determine the physical properties of a new single composition lathe-cut high copper alloy and to compare these with an established conventional lathe-cut alloy. ii) To evaluate the general handling properties of the high copper amalgam. iii) To investigate the clinical performance of the two alloys by means of a blind controlled clinical trial. **Follow-up:** 21 months **Design:** (7) Other clinical trial **Criteria:** (2) Restoration replacement **Environment:** Not stated **Clinicians:** 2 **Evaluators:** 1 **Sponsorship:** DeTrey	**Participants and Baseline Nos:** 66 **Restoration Type(s) and Baseline Nos:** 62/4 Class II/Class I Solila Nova 60/6 ClassII/Class I Dentalloy **Tooth types and Baseline Nos:** Premolars and Molars **Materials and Baseline Nos:** Solila Nova 66 New True Dentalloy 66 **Participant final Nos:** 66 62/4 Class II/Class I Solila Nova 60/6 ClassII/Class I Dentalloy **Restoration final Nos:** 62/4 Class II/Class I Solila Nova 60/6 ClassII/Class I Dentalloy **Tooth type final Nos:** Premolars and molars **Materials final Nos:** Solilia Nova 66 Dentalloy 66 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Lining:*** *ZnO and Eugenol/copal varnish* ***Mechanical:*** *Converging walls* ***Other:*** *Not stated*	Failure 6-21 months Solila 1/66 New True Dentalloy 1/66	Randomised blind matched paired trial. Generalisability limited by small numbers and limited number of clinicians.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Letzel, van't Hof et al. 1987) 324 **Year:** 1987 **Country:** Netherlands **Aim:** To assess the influence of the condensation instruments on the clinical performance of amalgam restorations. **Follow-up:** 30 months **Design:** (6) Prospective study with concurrent controls. **Criteria:** (3) Photographic scale (Letzel and Vrijhoef, 1984) **Environment:** Practice **Clinicians:** 2 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 49 **Restoration Type(s) and Baseline Nos:** 250 - Class I and Class II **Tooth types and Baseline Nos:** Permanent teeth **Materials and Baseline Nos:** Luxalloy operator 1 125 Luxalloy operator 2 125 **Participant final Nos:** 49 **Restoration final Nos:** 238 Luxalloy operator 1 125 Luxalloy operator 2 125 **Tooth type final Nos:** Not stated **Materials final Nos:** Not stated **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Rubber dam* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	28 out of 210 restorations had fractures at 30 months. Failure Operator 1 8 out of 124 Operator 2 20 out of 114 ANOVA: there was no difference in the packing techniques. Oral Health behaviour and dentist had an influence on the loss of restorations. One operator was consistently better in terms of marginal integrity.	Small study assessing condensation techniques. The influence of oral hygiene and operator factors was reported. Condensation technique was randomised within the mouth. Generalisability is limited by the use of only two operators.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Johnson, Bales et al. 1992; Johnson, Bales et al. 1992) 353/341 **Year:** 1992 **Country:** USA **Aim:** To evaluate two high copper amalgams with and without Indium **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (3) Photographic scale, (Bryant, et al., 1985) **Environment:** Not stated **Clinicians:** 2 **Evaluators:** 2 calibrated examiners **Sponsorship:** Not stated	**Participants and Baseline Nos:** 25 **Restoration Type(s) and Baseline Nos:** 175 Class I and Class II cavities **Tooth types and Baseline Nos:** Premolar/molar - equal distribution **Materials and Baseline Nos:** Dispersalloy 60 Indisperse 5 54 Indisperse 10 61 **Participant final Nos:** Not stated **Restoration final Nos:** 88 **Tooth type final Nos:** Not stated **Materials final Nos:** 88 Dispersalloy 30 Indisperse 5 28 Indisperse 10 30 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Not stated* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	Replacements at 60 months Dispersalloy 0/30 Indisperse 5 0/28 Indisperse 10 0/30 ANOVA: Amalgam with Indium had less marginal breakdown.	Within mouth comparison. Generalisability limited by drop-out rate and use of only two operators.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Belcher and Stewart 1997) 393 **Year:** 1997 **Country:** USA **Aim:** Evaluation of an amalgam adhesive in complex amalgam restorations **Follow-up:** 2 yrs **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 3rd/4th year dental students (number not stated) **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 45 (15 in each group; assumed 1 restoration placed per patient) **Restoration Type(s) and Baseline Nos:** Complex amalgam restorations **Tooth types and Baseline Nos:** Premolars and molars (no further details) **Materials and baseline Nos:** 15 Pinned amalgam (Dispersalloy + Link plus pins) 15 Amalgam + amalgam adhesive (without additional powder)(Dispersalloy + amalgambond) 15 Amalgam + amalgam adhesive (with additional powder)(Dispersalloy + amalgambond) **Participant final Nos:** Not stated **Restoration final Nos:** Pinned amalgam:13 Amalgam + amalgam adhesive:14 Amalgam + amalgam adhesive:11 **Tooth type final Nos:** Not stated **Materials final Nos:** As stated in restoration final nos. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *When required* ***Lining:*** *Not stated* ***Mechanical:*** *pins when required and amalgambond* ***Other:*** *Not stated*	All teeth in all groups rated alpha for retention, sensitivity, marginal adaptation and recurrent caries There were no failures in the 3 groups at 24 months.	Generalisability limited by small sample, university environment and use of different materials in different mouths. 8.5.1.1.1.1.1

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Akerboom, Advokaat et al. 1993; Gruythuysen, Kreulen et al. 1996) 405/496 **Year:** 1993/1996 **Country:** Netherlands **Aim:** To assess replacement rates over a 10-15 year period. **Follow-up:** 120-180 months **Design:** (7) Other clinical trial **Criteria:** (3) Own criteria **Environment:** Hospital **Clinicians:** 3 **Evaluators:** 3 Calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 183 aged 15-40 years **Restoration Type(s) and Baseline Nos:** 1544 Class II amalgams **Tooth types and Baseline Nos:** **Premolars** MO/DO 376 320 MOD 447 401 **Molars** MO/DO 303 245 MOD 367 315 **Materials and Baseline Nos:** New True Dentalloy 960 Cavex non-gamma 344 Tytin 240 **Participant final Nos:** Not stated **Restoration final Nos:** Time 120 180 **Premolars** MO/DO 345 283 MOD 410 370 **Molars** MO/DO 303 245 MOD 367 315 **Tooth type final Nos:** Not stated **Materials final Nos:** **At 10 yrs** New True Dentalloy 874 Cavex non-gamma 307 Tytin 234 **At 15 years** Not stated. **Techniques:** ***LA:*** *Most* ***Moisture control:*** *Rubber dam* ***Lining:*** *Dycal* ***Mechanical:*** *Not stated*	120 months 105 out of 1415 restorations replaced. Failures at 120 and 180 months Time 120 180 New True Dentalloy 73/801 22/198 Cavex non-gamma 18/307 10/92 Tytin 14/234 17/104 Total 105/1415 49/394 Treatment times 2 surface 24 minutes, 3 surface 30 minutes. More females than males attended follow-up. No statistical differences in replacements in 4 quadrants or upper and lower jaws. True failures twice as often in MOD than MO/DO in molars only. Replacement by cavity type at 10 years MO/DO MOD Premolar 17/345 29/410 Molar 15/303 44/367 Replacement by cavity type at 15 years MO/DO MOD Premolar 38/283 69/370 Molar 38/245 69/315	More detailed statistical analysis, (including multi-variate) would have provided more information. Generalisability limited by drop out rate and hospital environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Cipriano and Santos 1995) 434 **Year:** 1995 **Country:** Brazil **Aim:** To evaluate repaired amalgam restorations **Follow-up:** 24 months **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** Hospital **Clinicians:** Not stated **Evaluators:** 3 calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 45 amalgam repairs Class I, II, V (most class II) 29 recurrent caries, 10 fractures amalgam/enamel, 6 damaged margins at placement **Tooth types and Baseline Nos:** Permanent **Materials and Baseline Nos:** 45 Dispersalloy or New True Dentalloy **Participant final Nos:** Not stated **Restoration final Nos:** At 24 months 45 restorations Class I, II, V **Tooth type final Nos:** Not stated **Materials final Nos:** 45 Dispersalloy or New True Dentalloy **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	1 out of 45 failed due to fracture 3 out of 45 were ranked Charlie for lustre after 24 months.	This paper suggested that repairs may be considered acceptable procedures for small areas or recurrent caries or fractures at margins. There was some lack of agreement over restorations ranked Charlie. No statement of reliability was made.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Corpron, Straffon et al. 1982; Corpron, Straffon et al. 1983) 640/641 **Year:** 1983 **Country:** USA **Aim:** To compare polishing immediately and 24hours after placing amalgam **Follow-up:** 36 **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** 3 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 33 7-13 years old **Restoration Type(s) and Baseline Nos:** 66 contra-lateral pairs and 30 pairs involving buccal or lingual pits. **Tooth types and Baseline Nos:** Permanent **Materials and Baseline Nos:** Tytin immediate polishing 96 Tytin 24hour polishing 96 **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Permanent dentition **Materials final Nos:** Tytin immediate polishing 82 Tytin 24 hour polishing 82 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Lining:*** *Varnish* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	There was no loss of amalgam in either group.	This study suggests that there is no difference at 36 months between amalgams polished at 8 minutes or 24 hours. Generalisability limited by small numbers and little information about the dentists placing the amalgam and sample population.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Fenton and Smales 1984) 655 **Year:** 1984 **Country:** Australia **Aim:** To assess effects of Tytin Class II amalgams carved and polished. **Follow-up:** 12 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Photographs and dental casts **Environment:** Not stated **Clinicians:** 1 **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27 volunteers aged 20-50 years **Restoration Type(s) and Baseline Nos:** 126 Class II **Tooth types and Baseline Nos:** Premolar and molars **Materials and Baseline Nos:** Tytin 63 polished 63 unpolished **Participant final Nos:** 27 **Restoration final Nos:** 63 polished 63 unpolished **Tooth type final Nos:** Not stated **Materials final Nos:** 126 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Rubber dam* ***Lining:*** *Not stated* ***Mechanical:*** *Converging walls* ***Other:*** *Not stated*	No restoration failures. No evidence of recurrent caries.	Paired within mouth comparisons. Requires longer-term follow-up. Generalisability would have been improved if more operators were included.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Morris, Braham et al. 1981) 684 **Year:** 1981 **Country:** USA **Aim:** To compare 3 copper rich random particle alloys and one conventional alloy **Follow-up:** 12 months **Design:** (7) Other clinical trial **Criteria:** (3) Own criteria **Environment:** Not stated **Clinicians:** 3 dentists and 3 residents **Evaluators:** 2 calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 325 grammar school Apache Indians **Restoration Type(s) and Baseline Nos:** 262 Class I and complex cavities **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Aristalloy 63 Tytin 50 Dispersalloy 35 Sybraloy 114 **Participant final Nos:** 61 **Restoration final Nos:** Aristalloy 49 Tytin 36 Dispersalloy 28 Sybraloy 83 **Tooth type final Nos:** Not stated **Materials final Nos:** Aristalloy 49 Tytin 36 Dispersalloy 28 Sybraloy 83 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Lining:*** *Dycal* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	Time (months) 6 12 Aristalloy 0/59 0/49 Tytin 0/43 0/36 Dispersalloy 0/35 0/28 Sybraloy 2/103 2/83 No statistical analyses. Failures for Sybraloy were not explained.	This study was a within mouth matched pair comparison using multi-operators. Failures not explained. Generalisability limited by study population and short study period.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Osborne and Friedman 1986) 695 **Year:** 1986 **Country:** USA **Aim:** To compare marginal fracture and creep of 18 amalgams over 1 year. **Follow-up:** 12 months **Design:** (7) Other clinical trial **Criteria:** (3) Ridit and Photographic technique (Mahler, 1980) **Environment:** Not stated **Clinicians:** 1 **Evaluators:** 2 **Sponsorship:** Suppliers of the amalgams	**Participants and Baseline Nos:** 134 **Restoration Type(s) and Baseline Nos:** 82 % Class II and 18% Class I **Tooth types and Baseline Nos:** 835 **Materials and Baseline Nos:** Cluster 57 Contour 43 Cupralloy 43 Cupralloy ESP 45 Cupralloy ESP2 46 Dispersalloy 49 Disperalloy 2 45 Indiloy 48 Orosphere II 41 Premalloy 46 Summalloy 43 Sybraloy 47 Tytin 48 Tytin 2 50 Unison 46 Unison 2 47 Velvalloy 43 High copper blend 48 **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** Cluster 57 Contour 43 Cupralloy 43 Cupralloy ESP 45 Cupralloy ESP2 46 Dispersalloy 49 Disperalloy 2 45 Indiloy 48 Orosphere II 41	No failures. Ranked amalgams according to percentage creep. No data on individual amalgams.	Generalisability is limited by single operator and short study period.

	Premalloy 46 Summalloy 43 Sybraloy 47 Tytin 48 Tytin 2 50 Unison 46 Unison 2 47 Velvalloy 43 High copper blend 48 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Rubber dam* ***Lining:*** *Ca(OH)2/Copalite* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*		

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Goldberg, Munster et al. 1980; Rydinge, Goldberg et al. 1981) 705/788 **Year:** 1980/1981 **Country:** USA **Aim:** To evaluate the marginal integrity of 5 high copper amalgam alloys and to compare 2 types of evaluation scheme. **Follow-up:** 18 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** Hospital **Clinicians:** 4 **Evaluators:** 2 **Sponsorship:** Johnson and Johnson	**Participants and Baseline Nos:** 77 **Restoration Type(s) and Baseline Nos:** Class I and Class II **Tooth types and Baseline Nos:** Molars and bicuspids **Materials and Baseline Nos:** Aristalloy CR 71 Dispersalloy 76 Indiloy 75 Experimental amalgam 72 Tytin 71 New True Dentalloy 70 **Participant final Nos:** Not stated **Restoration final Nos:** 252 **Tooth type final Nos:** Not stated **Materials final Nos:** Aristalloy CR 42 Dispersalloy 42 Indiloy 46 Experimental amalgam 42 Tytin 42 New True Dentalloy 38 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Lining:*** *Ca(OH)2/Copal resin* ***Mechanical:*** *Not stated:* ***Other:*** *Not stated*	Failures Months 6 12 18 Aristalloy CR 1/60 1/61 1/42 Dispersalloy 0/68 0/62 0/42 Indiloy 0/63 0/60 1/46 Experimental amalgam 0/61 0/61 0/42 Tytin 0/61 0/61 0/42 New True Dentalloy 0/58 0/59 0/38 Occlusal surface deterioration was independent of the number of restored surfaces. There were no 2-way interactions between class of restoration type, operator and alloy. When patients received all 6 restorations the patient was the statistically significant factor. Restorations in molars experienced greater marginal deterioration than those in premolars.	Generalisability limited by dropout rate and hospital environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Straffon, Corpron et al. 1983; Straffon, Corpron et al. 1984) 718/719 **Year:** 1983 **Country:** USA **Aim:** To compare high copper amalgam restorations which were allowed to remain as carved with similar restorations that were finished and polished after post-insertion period of at least 24 hours **Follow-up:** 36 months **Design:** (8) Randomised controlled trial **Criteria:** (4) USPHS **Environment:** Not stated **Clinicians:** 2 dentists **Evaluators:** 3 consensus **Sponsorship:** Not stated	**Participants and Baseline Nos:** 26 5-13 year olds **Restoration Type(s) and Baseline Nos:** 67 Class I amalgams unpolished 67 Class I amalgams polished **Tooth types and Baseline Nos:** Primary/secondary molars **Materials and Baseline Nos:** Tytin **Participant final Nos:** 20 **Restoration final Nos:** 40 Class I amalgams unpolished 40 Class I amalgams polished **Tooth type final Nos:** Not stated **Materials final Nos:** Not stated **Techniques:** ***LA:*** *Yes* ***Moisture control:*** *Rubber dam* ***Lining:*** *Dycal/Copalite* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	No losses or replacements after 36 months	No difference between unpolished and polished amalgams. Generalisability limited by 17 pairs being lost to follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Bates and Douglas 1980) 743 **Year:** 1980 **Country:** UK **Aim:** To compare a standard alloy with a disperse phase alloy **Follow-up:** 24 **Design:** (7) Other clinical trial **Criteria:** (3) Own criteria with training **Environment:** Community **Clinicians:** 4 **Evaluators:** 2 **Sponsorship:** Johnson and Johnson	**Participants and Baseline Nos:** 100 **Restoration Type(s) and Baseline Nos:** Class I **Tooth types and Baseline Nos:** Permanent teeth **Materials and Baseline Nos:** Amalcap 50 Dispersalloy 50 **Participant final Nos:** 41 **Restoration final Nos:** 82 **Tooth type final Nos:** Molars **Materials final Nos:** Amalcap 41 Dispersalloy 41 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Lining:*** *Tubulitec* ***Mechanical:*** *Converging walls* ***Other:*** *Not stated*	Replacement at 24 months Amalcap 2 /41 Dispersalloy 1/ 41	The blind nature of this randomised controlled trial was lost at 24 months when the two amalgams presented with different surface characteristics. Generalisability limited by small numbers. In addition' two restorations were replaced by other dentists and were excluded from the study.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Doglia, Herr et al. 1986) 772 **Year:** 1986 **Country:** Switzerland **Aim:** To compare 3 high copper amalgams and 1 conventional amalgam **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (2) Photographic, dental casts and scanning electron microscope **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 13 **Restoration Type(s) and Baseline Nos:** 110 Class II **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Premix 29 Dispersalloy 27 Sybraloy 26 Tytin 28 **Participant final Nos:** 12 **Restoration final Nos:** 96 **Tooth type final Nos:** Not stated **Materials final Nos:** Premix 24 Dispersalloy 24 Sybraloy 24 Tytin 24 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *Rubber dam* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	Cumulative replacements at 24, 36 and 60 months Months 24 36 60 Premix 1/29 1/29 3/24 Dispersalloy 1/24 Tytin 1/24 Sybralloy 2/24 No multi-variate analyses.	This study suggests that high copper alloy may be better than conventional (Premix). Only 2 patients with all four amalgams placed in the same mouth and thus design may affect generalisability.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Matsson, Ryge et al. 1982) 797 **Year:** 1982 **Country:** Sweden **Aim:** To compare margin adaptation in silver amalgam restoration of a dispersed types and traditional alloy from which mercury was and was not compressed prior to insertion into the cavity **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** Hospital **Clinicians:** 1 **Evaluators:** Calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 36 Children **Restoration Type(s) and Baseline Nos:** 180 Class II amalgams **Tooth types and Baseline Nos:** Primary/secondary teeth Not stated **Materials and Baseline Nos:** 180 Equal allocation to groups, paired design, 45 in each group **Participant final Nos:** Not stated **Restoration final Nos:** 132 Royal Dental Alloy Not pre-condensed Primary 15 Secondary 18 Pre-condensed Primary 17 Secondary 16 Dispersalloy Not pre-condensed Primary 15 Secondary 18 Pre-condensed Primary 17 Secondary 16 **Tooth type final Nos:** Primary 64 Secondary 68 **Materials final Nos:** Royal Dental Alloy 66 Disperalloy 66 **Techniques:** ***LA:*** *Not stated* ***Moisture control:*** *No* ***Lining:*** *Not stated* ***Mechanical*** *Not stated* ***Other:*** *Not stated*	24 months 11 restorations were lost to the study due to shedding of teeth or uncontrolled operative interference by other dentists. Another 37 restorations were unaccounted for. Failure assessed at 24 months **Royal Dental Alloy** Not pre-condensed Primary 3/15 Secondary 0/18 **Pre-condensed** Primary 3/17 Secondary 1/16 **Dispersalloy** **Not pre-condensed** Primary 1/15 Secondary 0/18 **Pre-condensed** Primary 0/17 Secondary 0/16	Assessment of restoration/ fracture between the test groups was not evaluated. Failure in the primary dentition was greater than in the secondary dentition and was more frequent with Royal Dental Alloy (Royal Dental Alloy: Dispersalloy 7:1). Generalisability is affected by single operator and hospital environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hamilton, Moffa et al. 1983) 811 **Year:** 1983 **Country:** USA **Aim:** Comparison of 2 different amalgams to resist marginal failure. **Follow-up:** 120 months **Design:** (6) Prospective study with concurrent controls. **Criteria:** (4) USPHS **Environment:** Clinical Research Facility **Clinicians:** 1 **Evaluators:** 2 blind **Sponsorship:** NIH	**Participants and Baseline Nos:** 77 in fluoridated area **Restoration Type(s) and Baseline Nos:** Not stated **Tooth types and Baseline Nos:** Molars and premolars. **Materials and Baseline Nos:** 112 Spheralloy 97 Dispersalloy **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 25 Spheralloy 19 Dispersalloy **Techniques:** ***LA:*** *Not stated* ***Rubber dam*** *Yes* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	There were no statistical significant differences in the number of restorations surviving between the Spheralloy and Dispersalloy at 120 months. Dispersalloy had significantly less deterioration than Spheralloy at recall periods. **Failed restorations** Months Spheralloy Dispersalloy 12 1/99 1/88 24 1/88 3/79 36 10/77 4/67 48 12/65 7/56 60 13/52 9/47 120 17/25 11/19 Chi square tests with Yates correction factor. Data not modelled.	Little detail is provided on the type of cavites that were evaluated. Provides a long-term assessment of 2 amalgams. Clearly separates marginal deterioration from failure in the statistical analysis. Generalisability is affected by single operator and environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mormann and Krejci 1991) 829 **Year:** 1980 **Country:** Holland **Aim:** To assess the influence of patient and operator on marginal fracture. **Follow-up:** 12 months **Design:** (7) Other clinical trial **Criteria:** (3) Photographic technique **Environment:** Practice **Clinicians:** 3 **Evaluators:** 1 independent **Sponsorship:** Not stated	**Participants and Baseline Nos:** 77 aged 15-44 years old **Restoration Type(s) and Baseline Nos:** 180 Class I and Class II **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Indiloy 90 Sybralloy 90 Dispersalloy 90 Tytin 90 Luxalloy 90 Amalcap non gamma 2 90 **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** Indiloy 90 Sybralloy 90 Dispersalloy 90 Tytin 90 Luxalloy 90 Amalcap non gamma 2 90 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Lining:*** *Not stated* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	1 failure not attributed to any material type. Patient, alloy and operator have an influence on marginal integrity.	One failure not stated. Generalisability limited by small number of operators.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Roberts and Sheriff 1990) 858 **Year:** 1990 **Country:** UK **Aim:** To compare the survival of amalgam and preformed crown molar restorations **Follow-up:** 120 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** specialist private practice **Clinicians:** 1 **Evaluators:** one (examiner-operator) **Sponsorship:** not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** Class I Class II Primary 318 706 Permanent 489 163 **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** All restorations were Tytin, a non-gamma 2 phase alloy **Participant final Nos:** Not stated **Restoration final Nos:** Primary teeth 273 Class I restorations 197 Class II restorations Permanent teeth 425 Class I restorations 140 Class II restorations **Tooth type final Nos:** Not stated **Materials final Nos:** As restoration details **Techniques:** ***LA:*** *most* ***Rubber dam:*** *over 90% yes* ***Lining:*** *calcium hydroxide and copalite* ***Mechanical:*** *Not stated* ***Other:*** *Not stated*	The following restorations were replaced, others were satisfactory or exfoliated Primary teeth 53 Class I restorations 104 Class II restorations Permanent teeth 56 Class I restorations 16 Class II restorations Class I Age 5-9 23 out of 145 10-14 28 out of 264 15 - 20 5 out of 80 Class II Age 5-10 0 out of 26 10-15 13 out of 103 15 - 20 3 out of 34	Results are presented only for the amalgam restorations in this study as preformed crowns are extra-coronal restorations and outside the scope of this study. The generalisability is limited because it was undertaken in a private practice by a single operator. Restorations were added to this study over a ten-year period making an estimate of mean survival time difficult. 8.5.1.1.1.1.2

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Plasmans, Creugers et al. 1998) 864 **Year:** 1998 **Country:** Netherlands **Aim:** To assess the type of retention on survival of extensive amalgam restorations; to assess the effect of operator on survival. **Follow-up:** 100 months **Design:** (6) Prospective study with concurrent controls. **Criteria:** (2) Criteria **Environment:** Hospital **Clinicians:** 3 **Evaluators:** Not stated **Sponsorship:** University of Nijmegen	**Participants and Baseline Nos:** 130 17-54 year olds. **Restoration Type(s) and Baseline Nos:** 300 Extensive amalgams **8.5.2 Vital teeth** a) pins b) slot c) slot/grooves d) self-threading pins ***8.5.2.1 Non-vital teeth*** a) cemented dowel **Tooth types and Baseline Nos:** Molars only. **Materials and Baseline Nos:** 300 Cavex non-gamma –2 **Participant final Nos:** 126 **Restoration final Nos:** 291 **Tooth type final Nos:** Molars only **Materials final Nos:** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Lining:*** *Not stated* ***Mechanical:*** *Pins/grooves/dowel* ***Other:*** *Not stated*	9 restorations were lost to follow-up. 100 months 30 out of 291 restorations failed 14 amalgams were lost (mechanical failure) 9 teeth were extracted 7 had cast crowns placed over the amalgam. 100 months 44 amalgams were "repaired" out of these 44 repaired amalgams 4 were crowned. The statistical analysis was not fully explained (type of retention, operator and age of the patient). A log rank analysis was undertaken . Anova revealed no significant inetractions between the age of patient and other variables. There were no statistical differences for type of retention on survival rates. Age of patient influenced the survival, in that, amalgams were more prone to failure in the older patient.	Long-term study of large amalgams. Undertaken in a hospital environment which may limit generalisability. 22% of the baseline restorations had 4 cusps reconstructed.

Table A2 Summary of studies involving composite restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Osborne, Norman et al. 1978; Osborne and Gale 1980) 586/162 **Year:** 1980 **Country:** USA **Aim:** Clinical evaluation of a radio-opaque and conventional composite resin in anterior teeth **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27 patients. No details provided **Restoration Type(s) and Baseline Nos:** Class III; 50 pairs, Random allocation of materials. Adjacent/contralateral pairs of restorations **Tooth types and Baseline Nos:** Not stated; all permanent; mostly maxillary anteriors with some mandibular anteriors **Materials and Baseline Nos:** 50 Adaptic composite (macrofilled, autopolymerising); 50 Adaptic (radio-opaque, macrofilled, autopolymerising) **Participant final Nos:** 25 **Restoration final Nos:** Class III; 46 pairs **Tooth type final Nos:** Not stated **Materials final Nos:** 46 Adaptic; 47 Adaptic (radiopaque) **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	0 failures (Grade C) for either material at 12 and 36 months At 36 months 1 tooth presented with a fractured incisal edge and restoration was replaced Restorations discoloured with time and displayed marginal staining	Materials not currently available Generalisability is limited by university environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wilder, Bayne et al. 1991) 194/621 **Year:** 1991 **Country:** USA **Aim:** Clinical evaluation of 4 composites in posterior teeth **Follow-up:** 60 months **Design:** (8) Randomised control trial **Criteria:** (4) Modified USPHS **Environment:** University (assumed) **Clinicians:** 2 **Evaluators:** 2 **Sponsorship:** NIDR grant	**Participants and Baseline Nos:** Patient details not stated. Number of patients with each material: 18 Estilux, 16 Nuvafil, 14 Nuvafil PA, 13 Uvio-Fil **Restoration Type(s) and Baseline Nos:** 96 Class I; 34 Class II, Random allocation of materials, operator, tooth, arch, restoration type **Tooth types and Baseline Nos:** Permanent; 50 Premolar; 80 molar **Materials and Baseline Nos:** 29 Estilux composite (macrofilled, light cured), 41 Nuvafil (macrofilled, light cured), 26 Nuvafil PA (macrofilled, light cured), 34 Uvio-Fil (macrofilled, light cured) **Participant final Nos:** At 60 months: 14 Estilux, 9 Nuvafil, 10 Nuvafil PA, 10 Uvio-Fil **Restoration final Nos:** At 60 months: 82 Class I; 26 Class II **Tooth type final Nos:** At 60 months: Permanent; 48 Premolar; 60 molar **Materials final Nos:** At 36 months: 119 restorations but no details. At 60 months: 24 Estilux, 33 Nuvafil, 21 Nuvafil PA, 30 Uvio-Fil **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Incremental placement*	0 failures at 36 and 60 months Wear (not failure) was significantly worse in molar teeth	Materials not currently available Generalisability is limited because of University setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Christensen and Christensen 1982) 639 **Year:** 1982 **Country:** USA **Aim:** Clinical evaluation of a microfilled composite resin with a conventional composite resin in anterior teeth **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** Private practice **Clinicians:** 10 (trained) **Evaluators:** 10 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 71 patients; No other details **Restoration Type(s) and Baseline Nos:** 142 Class III, Matched pairs in same mouth; no mention of randomization **Tooth types and Baseline Nos:** Not stated; all permanent anterior teeth **Materials and Baseline Nos:** 71 Adaptic composite (macrofilled, autopolymerising); 71 Isocap composite (microfilled, autopolymerising) **Participant final Nos:** 61 **Restoration final Nos:** 122 Class III **Tooth type final Nos:** Not stated **Materials final Nos:** 61 Adaptic; 61 Isocap **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	0 failures for either material after 36 months Ridit and Arcsine transformations were employed during analysis of clinical data – not relevant as no loss of restorations occurred, only degradation. However, Isocap was always better than Adaptic	Materials not currently available Results generalisable to private practice setting because 10 evaluators and operators were used.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Oldenburg, Vann et al. 1985; Oldenburg, Vann et al. 1987) 694/318 **Year:** 1985 **Country:** USA **Aim:** Clinical evaluation of 2 composite resins and 3 cavity designs during the restoration of primary molar teeth in young children **Follow-up:** 48 months **Design:** (8) Randomised controlled trial **Criteria:** (3) Modified USPHS **Environment:** University (assumed) **Clinicians:** 3 **Evaluators:** 3 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 50 children between 4 and 8 years **Restoration Type(s) and Baseline Nos:** 357: 137 Class I, 188 Class II, 32 Class V, Randomization of cavity type/material with 6 possibilities –110 conventional, 119 conventional with bevel, 128 modified (minimal) with bevel **Tooth types and Baseline Nos:** 357 Primary molars **Materials and Baseline Nos:** 184 Ful-Fil composite (light cured, densified midway-filled), 173 X-55 composite (light cured, densified midway-filled) **Participant final Nos:** 48 at 24 months, 48 at 48 months **Restoration final Nos:** 297, no details at 24 months; 123, no details at 48 months At 24 months: 91 conventional,90 conventional with bevel, 93 modified (minimal) with bevel. At 48 months: 42 conventional preparations,37 conventional preparations with bevel, 44 modified (minimal) preparations with bevel **Tooth type final Nos:** 297, no details at 24 months, 123 , no details at 48 months **Materials final Nos:** At 24 months: 148 Ful-Fil, 126 X-55, at 48 months: 62 Ful-Fil, 61 X-55 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Varied – see above* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**At 24 months** 39 teeth lost through exfoliation 21 restorations not available for recall 23/297 failures **At 48 months** 169 teeth lost through exfoliation 26 restorations not available for recall a further 16 failures occurred 10 failures before 6 months; 4 between 6 and 12 months; 9 between 12 and 24 months, 9 failures between 24 and 36 months, 7 failures between 36 and 48 months At 24 months: 5 conventional preparation failed; 3 conventional preparations with bevel; 15 modified (minimal) preparations with bevel At 48 months additional failures included: 4 conventional preparation; 5 conventional preparations with bevel; 7 modified (minimal) preparations with bevel At 24 months: 8 Ful-Fil failed; 15 X-55 failed At 48 months additional failures: 9 Ful-Fil, 7 X-55 At 24 months: 5 Class I failed; 18 Class II, 0 Class V At 48 months additional failures inc: 0 Class I, 16 Class II, 0 Class V There were no significant differences in terms of successful restorations	Although not statistically significant the following trends were seen. More modified (minimal) preparations failed More X-55 restorations failed More Class II restorations failed Using these materials the modified preparation resulted in most failures and the conventional with bevel the least. Generalisability is limited because of university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Beere, Cautley et al. 1984) 801 **Year:** 1984 **Country:** New Zealand **Aim:** Clinical evaluation of Class IV incisal edge composite restorations **Follow-up:** 8-9 years **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 48 school children and young adults **Restoration Type(s) and Baseline Nos:** 55 Class IV following trauma **Tooth types and Baseline Nos:** Permanent: 54 maxillary incisors; 1 mandibular incisor **Materials and Baseline Nos:** 55 Concise composite (autopolymerising, macro-filled) **Participant final Nos:** 29 **Restoration final Nos:** 16 (34 – see opposite) **Tooth type final Nos:** Not stated **Materials final Nos:** 34 Concise **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	21 of the original 55 were not reviewed (no details) 18 of the 34 restorations recalled had been replaced prior to review 2 of the 16 remaining restorations were judged to be successful	Long-term survival of Class IV autopolymerising macrofilled composite restorations in anterior teeth is extremely poor in this study. Most failures were reported to be related to chemical and physical changes in the material Generalisability limited because of the university setting and the lack of follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Brunson, Bayne et al. 1989) 268 **Year:** 1989 **Country:** USA **Aim:** Clinical evaluation of a self-cured posterior composite resin **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** 6 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27; details not stated **Restoration Type(s) and Baseline Nos:** 40 Class I; 50 Class II **Tooth types and Baseline Nos:** Permanent: 42 premolar; 48 molar; 47 maxillary, 43 mandibular **Materials and Baseline Nos:** 90 P-10 composite (autopolymerising, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** At 36 months: 36 Class I; 41 Class II **Tooth type final Nos:** At 36 months: 36 premolar; 41 molar; 39 maxillary, 40 mandibular **Materials final Nos:** 77 P-10 composite resin **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Mechanical retention*	1 failure at 6 months, 1 further failure at 24 months 1 further failure at 36 months 1 failed because of sensitivity, 2 through secondary caries (latter cases in same patient) Minor colour changes and moderate wear, worse in molars	Generalisability compromised because of University setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Leifler and Varpio 1981; Varpio 1985) 608/752 **Year:** 1985 **Country:** Sweden **Aim:** Clinical evaluation of a composite resin in Class II cavities on primary molar teeth **Follow-up:** 72 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 61 children between 5 and 11 years **Restoration Type(s) and Baseline Nos:** 91 Class II **Tooth types and Baseline Nos:** Primary molars; 38 maxillary; 53 mandibular **Materials and Baseline Nos:** 91 Concise Cap-C-Rynge composite (autopolymerising, macrofilled) **Participant final Nos:** Not stated **Restoration final Nos:** 82 at 12 months, 61 at 24 months, impossible to work out at 72 months **Tooth type final Nos:** At 12 months: Primary molars; 34 maxillary; 48 mandibular At 24 months: Primary molars; 29 maxillary; 32 mandibular **Materials final Nos:** Concise Cap-C-Rynge: 82 at 12 months, 61 at 24 months, impossible to work out at 72 months **Techniques:** ***LA:*** *Rarely* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes – except floor of box* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Occlusal lock in enamel only – no undercut*	**At 12 months** 13 restorations were judged as failures and 10 of these restorations were replaced because of defects **At 24 months** a further 7 restorations were judged as failures, previous 10 replacements not included in tables **At 72 months** All but one of the teeth were exfoliated. Many were examined *ex vivo* to determine which were successful at exfoliation. While it is impossible to derive exact figures the following cumulative survival rates were estimated: All teeth – 12 months 85% 24 months 70% 36 months 60% 48 months 40% 60 months 40% 72 months 40%	It is difficult to derive some of the results, particularly at 72 months. The restorative material is currently unavailable. Generalisability is limited because of the university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Millar, Robinson et al. 1997) 396 **Year:** 1997 **Country:** UK **Aim:** Clinical evaluation of an anterior composite resin **Follow-up:** 96 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** University **Clinicians:** 3 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 24: 12 male, 12 female; 16-70 years **Restoration Type(s) and Baseline Nos:** 25 Class III, 3 Class IV, 16 Class V **Tooth types and Baseline Nos:** Not stated, but clearly permanent anterior teeth **Materials and Baseline Nos:** 44 Opalux (light cured, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** 33 at 12 months, 28 at 24 months, 17 at 36 months, 25 at 96 months **Tooth type final Nos:** Not stated **Materials final Nos:** 25 Opalux at 96 months **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Mechanical preparation except for Class IV*	No failures up to 36 months. 6 restorations failures between 36 and 96 months (no time given) The failures were: 3 Class III, 1 Class IV, 2 Class V	Generalisability is limited by university setting and operators' experience.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Saleh, Peretz et al. 1992) 347 **Year:** 1992 **Country:** Israel **Aim:** Clinical evaluation of a composite resin in anterior teeth **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** University (assumed) **Clinicians:** 2 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 12-50 years, no numbers quoted **Restoration Type(s) and Baseline Nos:** 81 Class III, 12 Class IV **Tooth types and Baseline Nos:** Not stated, clearly permanent anterior teeth **Materials and Baseline Nos:** 93 Blendax (formulation unknown) **Participant final Nos:** Not stated **Restoration final Nos:** 81, no details **Tooth type final Nos:** Not stated **Materials final Nos:** 81 Blendax **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Incremental packing*	5 failures at 6 months, 20 at 12 months (6 month failures may be included in 12 month data as the restorations were not lost/replaced) 5 of the 20 failed restorations had defective margins and secondary caries at 12 months – replaced Failures occurred in patients under 14 years	Failures were reported to be associated with clinical problems in younger patients. **Generalisability is limited because of university setting.**

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	**Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques**	**Results (to include failures and summary of statistical analysis)**	**Commentary**
Author & No: (Davis, Mayhew et al. 1982; Davis and Mayhew 1986) 625/643 **Year:** 1982 **Country:** USA **Aim:** Clinical evaluation of 3 composite resins in Class III restorations **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 18, 25-62 years. 1 set of 3 in 12 patients; 2 sets of 3 in 8 patients **Restoration Type(s) and Baseline Nos:** 28 sets of 3 Class III Within mouth comparison of each (3) material. Dice thrown to determine placement of material **Tooth types and Baseline Nos:** Permanent anteriors, no details **Materials and Baseline Nos:** 28 Concise (autopolymerising, macrofilled), 28 Silar (autopolymerising, microfilled), 28 Prisma-Fil (light-cured, densified midway-filled) **Participant final Nos:** Not stated **Restoration final Nos:** At 12 months:23 sets of 3 Class III At 36 months: 17 sets of 3 Class III **Tooth type final Nos:** Not stated **Materials final Nos:** At 12 months: 23 Concise, 23 Silar, 23 Prisma-Fil At 36 months: 17 Concise, 17 Silar , 17 Prisma-Fil **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Concise/Silar - chemical; Prisma-Fil-light* ***Other:*** *Mechanical retention*	0 failures at 12 months 1 Prisma-Fil failure out of 17 at 36 months	Generalisability is limited by the military setting and the single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Barnes, Blank et al. 1991) 212 **Year:** 1991 **Country:** USA **Aim:** Clinical evaluation of a composite resin in Class I and II restorations **Follow-up:** 96 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** LD Caulk (manufacturer)	**Participants and Baseline Nos:** 12, no details **Restoration Type(s) and Baseline Nos:** 33 in total; 25 Class I, 8 Class II **Tooth types and Baseline Nos:** Permanent: 23 molars, 10 premolars **Materials and Baseline Nos:** 33 Ful Fil composite (light cured, densified midway-filled) **Participant final Nos:** Not stated **Restoration final Nos:** At 60 months: 24 Class I, 8 Class II At 96 months: 23 Class I, 7 Class II **Tooth type final Nos:** Not stated **Materials final Nos:** At 60 months: 32 Ful-Fil At 96 months: 30 Ful-Fil **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Mechanical retention.*	1 (Class II) failed at 36 months 1 (Class I) failed at 48 months 1 (Class I) failed at 60 months 1 (Class I) failed at 72 months 1 (Class I) failed at 84 months 2 (Class I) failed at 96 months Failures in molar teeth only.	Generalisability is limited by the university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Lundin, Andersson et al. 1990; Rasmusson and Lundin 1995) 248/420 **Year:** 1990 **Country:** Sweden **Aim:** Clinical evaluation of 6 posterior composite resins in Class II restorations **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** Public Health Dental Clinics (7 in all) **Clinicians:** 24 **Evaluators:** 24 **Sponsorship:** Local county council research committee	**Participants and Baseline Nos:** 213, 14 - 75 years **Restoration Type(s) and Baseline Nos:** 242 Class II **Tooth types and Baseline Nos:** 236 in premolars, 6 in molars **Materials and Baseline Nos:** 47 Occlusin composite (light cured, densified compact filled), 49 P-30 composite (light cured, densified compact filled), 62 Ful-Fil composite (light cured, densified midway-filled), 32 Profile (light cured, unknown filler), 30 Heliomolar (light cured, microfilled), 27 Distalite (light cured, microfilled) **Participant final Nos:** 153 **Restoration final Nos:** At 36 months: not stated, At 60 months: not stated **Tooth type final Nos:** At 36 months: not stated, At 60 months: not stated **Materials final Nos:** At 36 months: 39 Occlusin, 46 P-3, 53 Ful-Fil , 24 Profile , 25 Heliomolar , 27 Distalite At 60 months: 23 Occlusin, 32 P-30, 46 Ful-Fil , 23 Profile, 27 Heliomolar, 25 Distalite **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Rarely* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Incremental packing, mechanical retention*	**At 36 months** 14 failures out of 242: 3 Occlusin, 1 P-30, 7 Ful-Fil, 1 Profile, 1 Heliomolar, 1 Distalite **At 60 months** 27 failures out of 176: 3 Occlusin, 2 P-30, 13 Ful-Fil, 3 Profile, 4 Heliomolar, 2 Distalite Ful-Fil failed significantly more than other composites	Vast majority of teeth in study (93%) were premolars. Carried out by many clinicians in routine (but salaried) clinical environment in several clinics. Generalisable and relevant There is a discrepancy between data presented for Heliomolar between the two papers. We have assumed the latter publication has the correct baseline figures.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Sturdevant, Lundeen et al. 1986; Sturdevant, Lundeen et al. 1988) 297/770 **Year:** 1988 **Country:** USA **Aim:** Clinical evaluation of 2 posterior composite resins in Class I and II restorations **Follow-up:** 60 months **Design:** (8) Randomised controlled trial **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** 4 **Evaluators:** 2 **Sponsorship:** LD Caulk (manufacturer) & NIDR	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 136 in all, 59 Class I, 77 Class II -Material, tooth sites and clinician randomised **Tooth types and Baseline Nos:** 56 premolars, 40 molars **Materials and Baseline Nos:** 65 Ful-Fil (light cured, densified midway-filled), 71 X-55 (light cured, densified midway-filled) **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** At 36 months: 47 Fil-Fil, 49 X-55 At 60 months: 44 Ful-Fil, 53 X-55 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Mechanical retention*	**For Ful-Fil** 2 out of 60 replaced at 12 months, 0 failures out of 47 at 24 months, 2 out of 47 failed at 36 months, 2 failures out of 44 at 60 months. **For X-55** 3 failures out of 62 at 6 months, 2 out of 68 replaced at 12 months, 1 failure out of 62 at 24 months, 2 out of 49 failed at 36 months, 0 failures out of 53 at 60 months Failures eliminated from study with time	No data on tooth type/restoration type Generalisability is limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Granath, Schroder et al. 1992) 344 **Year:** 1992 **Country:** Sweden **Aim:** Clinical evaluation of preventive and Class I posterior composite resin restorations **Follow-up:** 24 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (4) USPHS **Environment:** University **Clinicians:** Many – dental students **Evaluators:** More than 1 **Sponsorship:** ICI (manufacturer)	**Participants and Baseline Nos:** 111 children, 5-14 years **Restoration Type(s) and Baseline Nos:** 135 Class I **Tooth types and Baseline Nos:** 87 permanent molars and 13 premolars; 35 primary molars **Materials and Baseline Nos:** 135 Occlusin (light cured, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** 134 Class I at 6 months, 117 at 12 months, 95 at 24 months **Tooth type final Nos:** At 12 months: 76 permanent molars and 11 premolars; 30 primary molars At 24 months: 68 permanent molars and 9 premolars; 18 primary molars **Materials final Nos:** 134 Occlusin at 6 months, 119 at 12 months, 95 at 24 months **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Minimal Class I in permanent teeth, no undercuts*	**For Class I in permanent molars:** 3 failures out of 87 at 24 months **For Class I in permanent premolars:** 0 failures out of 13 at 24 months **For primary molars:** 0 failures out of 30 at 24 months Proportion of successful treatments described under each fault parameter but overall failures as above	Instructors acted as evaluators Generalisability limited by university setting and possibly experience of operators..

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Eidelman, Fuks et al. 1989; Fuks, Chosack et al. 1990) 276/227 **Year:** 1989 **Country:** Israel **Aim:** Clinical evaluation of Class II composite resin restorations in primary molar teeth using either a bulk or incremental placement technique **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** School Dental Clinic **Clinicians:** 3 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 22, 8-12 years **Restoration Type(s) and Baseline Nos:** 60 Class II: number of bulk: incremental packing not stated- Toss of coin to determine technique **Tooth types and Baseline Nos:** 60 Primary molars **Materials and Baseline Nos:** 60 Herculite composite (light cured, microfilled) **Participant final Nos:** At 12 months: not stated, At 24 months: not stated **Restoration final Nos:** At 12 months:27 packed incrementally, 31 packed in bulk At 24 months: not stated **Tooth type final Nos:** At 12 months: 58 primary molars At 24 months: 19 primary molars **Materials final Nos:** At 12 months: 58 Herculite At 24 months: 19 Herculite **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Incremental and bulk packing*	2 failures out of 58 at 12 months, no details of experimental groups Clinical data not presented for 24 months	Generalisable within a salaried setting but limited because of short study period.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Ameye, Lambrechts et al. 1981; Lambrechts, Ameye et al. 1982; Lambrechts and Vanherle 1984) 628/817/831 **Year:** 1981/82/84 **Country:** Belgium **Aim:** Clinical evaluation of conventional and microfilled composite resins **Follow-up:** 18 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** 4 **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 455 (not really clear): Class III, IV and V. No details **Tooth types and Baseline Nos:** Permanent: details not stated **Materials and Baseline Nos:** 100 Adaptic (autopolymerising, macrofilled), 120 Concise (autopolymerising, macrofilled), 57 Estic (autopolymerising, microfilled), 66 Isopast (autopolymerising, microfilled), 112 Silar (autopolymerising, microfilled) **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 455 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *Not stated* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Mechanical retention*	37 restorations 'failed' because of partial or total loss; 11 macrofilled resins, 26 microfilled	The emphasis of this paper was on reporting changes in colour over time. It is unclear whether etch and enamel bonding resin was used. Generalisability limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Lundin and Koch 1989) 279 **Year:** 1989 **Country:** Sweden **Aim:** Clinical evaluation of two posterior composite resins in Class I and II restorations **Follow-up:** 48 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 2 **Evaluators:** 2 **Sponsorship:** County Council Research Committee	**Participants and Baseline Nos:** 65 patients, mainly dental students, 14-45 years old. 38 female, 27 male **Restoration Type(s) and Baseline Nos:** 45 Class I, 92 Class II- Randomization of material **Tooth types and Baseline Nos:** 59 permanent premolars, 78 molars **Materials and Baseline Nos:** 65 Occlusin composite (light cured, densified compact filled), 72 PC 4502 composite (light cured, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** 44 Class I, 77 Class II **Tooth type final Nos:** 51 premolars, 70 molars **Materials final Nos:** Occlusin: 63 at 6 months, 60 at 12, 59 at 24, 61 at 36, 58 at 48 months Composite Resin PC 4502: 70 at 6 months, 67 at 12, 68 at 24, 67 at 36, 63 at 48 months **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Mechanical retention*	10/121 failed by 48 months **Occlusin** 1 failed at 6 months, 1 at 12 months, 2 at 24 months, 0 at 36 months, 2 at 48 months 1 Class I failed, 5 Class II **PC 4502** 0 at 6 months, 1 at 12 months, 2 at 24 months, 1 at 36 months, 0 at 48 months 0 Class I, 4 Class II There were no significant differences between the two materials.	Generalisabilty is limited by university setting and possibly by operators' experience.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kiremitci, Bolay et al. 1998) 815 **Year:** 1998 **Country:** Turkey **Aim:** Clinical evaluation of beta-quartz ceramic inserts in composite resin restorations **Follow-up:** 24 months **Design:** (3) Prospective case series **Criteria:** (3) USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 3 **Sponsorship:** Not Stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** Not stated **Tooth types and Baseline Nos:** 12 permanent premolars, 6 molars, 4 incisors **Materials and Baseline Nos:** 22 Charisma (composite resin, light cured, densified midway-filled) with Beta-quartz ceramic inserts **Participant final Nos:** Not Stated **Restoration final Nos:** 22 **Tooth type final Nos:** 12 permanent premolars, 6 molars, 4 incisors **Materials final Nos:** 22 Charisma (composite resin) with Beta-quartz ceramic inserts **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Mechanical retention*	1 out of 22 restorations failed and required replacement due to loss of proximal contact and poor anatomic form	This study reports, unusually, the use of ceramic inserts in combination with composite restorations. The generalisability is limited because of the university setting, small sample size and limited period of study.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Dietschi, Ciucchi et al. 1989; Dietschi and Holz 1990) 232/813 **Year:** 1989/1990 **Country:** Switzerland **Aim:** Clinical evaluation of four light curing composite resins in Class I and II cavities **Follow-up:** 9 & 24 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Own criteria **Environment:** Not stated **Clinicians:** 1 **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 13 patients **Restoration Type(s) and Baseline Nos:** 13 Class I, 67 Class II. One group had conventional preparations with bevel, other had adhesive (minimal) preparations with bevel **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** 19 P30 composite (light cured, densified compact filled), 20 Ful-Fil composite (light cured, densified midway-filled), 20 Heliomolar composite (light cured, microfilled), 21 Estilux-Posterior (light cured, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** 77 **Tooth type final Nos:** 26 premolars, 51 molars **Materials final Nos:** 17 P30, 20 Ful-Fil, 20 Heliomolar, 20 Estilux-Posterior **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Mechanical retention*	0 failures after 24 months	Generalisability compromised by probable university setting and the limited period of the study.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kullmann 1985) 667 (German) **Year:** 1985 **Country:** Germany **Aim:** Clinical evaluation of a microfilled and hybrid composite resin restorations **Follow-up:** 12 months **Design:** (7) Other clinical trial **Criteria:** (2) USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 74: no details **Restoration Type(s) and Baseline Nos:** 150 Class III, IV or V in a paired cavity design, mainly Class III **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** 75 Brilliant composite (autopolymerising, densified midway- filled); 75 Estic composite (autopolymerising, microfilled) **Participant final Nos:** 69 at 6 months, 64 at 12 months **Restoration final Nos:** 6 months: 136 restorations; 12 months: 129 restorations **Tooth type final Nos:** Not stated **Materials final Nos:** 69 of each material at 6 months, 64 of each material at 12 months **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *cleaned with chlorhexidine* *Mechanical retention*	**Overall** **At 6 months:** 9 / 69 failed Brilliant, 5 / 69 failed Estic **At 12 months:** a further 8 / 64 failures for Brilliant, a further 8 / 64 failures for Estic **At 6 months** 4 Brilliant and 3 Estic restorations had been lost **At 12 months** a further 1 Brilliant and 2 Estic lost 4 teeth excluded because of prosthetic reasons or trauma **At 6 months:** Brilliant 2 C for colour, 1 C for anatomic form, 1 C for occlusal roughness and 1 C for marginal seal; a total of 5 failures Estic 1 C for colour, 1 D for marginal seal; a total of 2 failures **At 12 months:** Brilliant 1 C for colour, and 1 C and 5 D for marginal seal; a total of 7 failures Estic 1 C and 5 D for marginal seal; a total of 6 failures	Mechanical retention within preparations except for Class IV. Generalisability is limited because of university setting and short follow-up period.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Dondi dall'Orologio, Piana et al. 1980) 133 (Italian) **Year:** 1980 **Country:** Italy **Aim:** Clinical evaluation of a composite resin and enamel preparation **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (2) USPHS **Environment:** University **Clinicians:** 3 **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated; 15 to 25 years **Restoration Type(s) and Baseline Nos:** 40: 22 Class III, 8 Class IV, 10 Class V. Prepared with retentive form and all enamel margins were bevelled for 2 mm. 10 with coronal fracture (probably Class IV): 9 Class 1 (Ellis) and one Class 2 (Ellis) As much of the surface of the enamel was prepared as was to be restored. **Tooth types and Baseline Nos:** 50 anterior teeth, no details **Materials and Baseline Nos:** 50 Super- C composite (no details) **Participant final Nos:** Not stated **Restoration final Nos:** At baseline **Tooth type final Nos:** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *see above* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical (assumed)* ***Other:*** *Not stated*	0 / 40 failures for Class III, IV and V restorations with bevels in anterior teeth using chemically cured composite after 12 months 1 / 10 failure for coronal fracture group after 12 months	Generalisability is limited by university setting and lack of detail on composite.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Tonn and Ryge 1985; Tonn and Ryge 1988) 606/304 **Year:** 1985/1988 **Country:** USA **Aim:** Clinical evaluation of a light cured composite in primary molars **Follow-up:** 48 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** Private practice **Clinicians:** 1 **Evaluators:** 2 **Sponsorship:** L.D.Caulk (Dentsply)	**Participants and Baseline Nos:** 44: (25 female, 19 male). Mean age 5 yrs 8 mths (range 3 to 8 yrs). All mentally/physically healthy **Restoration Type(s) and Baseline Nos:** 96: 22 Class I, 74 Class II with bevels **Tooth types and Baseline Nos:** 96 primary molars **Materials and Baseline Nos:** 96 Ful-Fil (light cured, densified midway-filled) **Participant final Nos:** At 48 months: 26 (18 female, 8 male) **Restoration final Nos:** 44: 12 Class I, 32 Class II **Tooth type final Nos:** 44 primary molars (15 exfoliated) **Materials final Nos:** 44 Ful-Fil **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured in increments* ***Other:*** *Class II pre-contoured wedge, polished at placement, mechanical preparation*	0 out of 94 failures at 6 months, 0 out of 87 at 12 months, 4 out of 76 at 24 months (recurrent caries), a further 1 out of 62 at 36 months (recurrent caries), a further 1 out of 44 at 48 months (recurrent caries).	Results generalisable to restorations in primary molars placed under dam but limited by single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Scheer 1975) 6 **Year:** 1975 **Country:** UK **Aim:** Clinical evaluation of fractured incisors treated with acid-etch technique **Follow-up:** 36 months **Design:** (5) Prospective study with historical controls **Criteria:** (2) Own identified criteria **Environment:** University **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** None (assumed)	**Participants and Baseline Nos:** 92 children (36 female, 56 male) aged 8 to 13 **Restoration Type(s) and Baseline Nos:** 126 Class IV incisal repairs (84 uncomplicated, 42 complicated) with production of shoulder at margins **Tooth types and Baseline Nos:** 126 permanent incisors **Materials and Baseline Nos:** 126 Adaptic or Concise composite, no details given (autopolymerising, macrofilled) **Participant final Nos:** Not stated **Restoration final Nos:** 126 12-24 months; 94 for 24-36 months; 57 observed for 36+ months Class IV **Tooth type final Nos:** 126 12-24 months; 94 for 24-36 months; 57 observed for 36+ months Class IV **Materials final Nos:** 57 Adaptic or Concise composite, no details given **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No – shoulder* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Celluloid crown form, polished immediately*	2/126 failed between 12-24 months (98.4% success) 2/94 failed at 24-36 months (96.8% success) 1/57 failed at 36+ months (91.2% success)	Generalisability limited by university setting and limited detail on operators and examiners.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Raadal 1978) 589 **Year:** 1978 **Country:** Norway **Aim:** Clinical evaluation of composite resins in Class I occlusal lesions in first permanent molar teeth **Follow-up:** 30 months **Design:** (7) Other clinical trial **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** Staff and students **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated, children aged 5-7 years **Restoration Type(s) and Baseline Nos:** 249 Class I, minimal preparation confined to enamel only **Tooth types and Baseline Nos:** 249 first permanent molars **Materials and Baseline Nos:** 249 Concise (autopolymerising, macrofilled) with occasional dilution with bonding resin **Participant final Nos:** Not stated **Restoration final Nos:** 190 at 6 months, 134 at 12 months, 74 at 18 months, 37 at 24 months **Tooth type final Nos:** 37 first permanent molars **Materials final Nos:** 37 Concise **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *No* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *No mechanical retention in enamel only cavities.*	17 failures out of 249 at 6 months; 9 failures out of 190 at 12 months; 3 failures out of 134 at 18 months; 1 failure out of 74 at 24 months; 0 failures out of 37 at 30 months	The study reported a higher failure rate in the first 12 months. Generalisability is limited by university environment and possibly operator experience.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Shimizu, Kitano et al. 1995) 414 **Year:** 1995 **Country:** Japan **Aim:** Clinical evaluation of composite resin restorations **Follow-up:** 144 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 20 patients between 10 and 40 years **Restoration Type(s) and Baseline Nos:** 91: 49 Class I; 14 Class II; 9 Class III; 19 Class V **Tooth types and Baseline Nos:** 16 maxillary anterior; 1 mandibular anterior; 17 maxillary premolars; 12 mandibular premolars; 28 maxillary molars; 17 mandibular molars **Materials and Baseline Nos:** 91 LFP composite resin (Light cured, microfilled) **Participant final Nos:** Not stated **Restoration final Nos:** At 120 months: 34 Class I; 9 Class II; 7 Class III; 18 Class V At 144 months: 27 Class I; 8 Class II; 7 Class III; 18 Class V **Tooth type final Nos:** At 120 months: 14 maxillary anterior; 1 mandibular anterior; 14 maxillary premolars; 11 mandibular premolars; 14 maxillary molars; 13 mandibular molars At 144 months: 14 maxillary anterior; 1 mandibular anterior; 13 maxillary premolars; 11 mandibular premolars; 10 maxillary molars; 11 mandibular molars **Materials final Nos:** 72 LFP at 120 months; 60 at 144 months **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Mechanical retention*	4 failures out of 90 at 48 months, 4 failures out of 72 at 120 months because of caries (total of 8 failures) 4 failures in Class I, 2 in Class II, 1 in Class III, 1 in Class V 0 failures in premolars, 6 failures in molars, 2 in anterior teeth	Generalisability is limited by university setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Qvist, Strom et al. 1985) 853 **Year:** 1985 **Country:** Denmark **Aim:** Clinical evaluation of anterior composite resin restorations in cavities with and without enamel bevels **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** 1 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 37 adults, no details given **Restoration Type(s) and Baseline Nos:** 104 Class III; 52 with enamel bevel, 52 without matched pairs of restorations **Tooth types and Baseline Nos:** 94 in maxillary incisors and canines, 10 in mandibular incisors **Materials and Baseline Nos:** 104 Silar (autopolymerising, microfilled), 52 with comonomer treatment (those without bevels) **Participant final Nos:** 36 adults **Restoration final Nos:** 102, 51 with bevel 51 without bevel **Tooth type final Nos:** Not stated **Materials final Nos:** 102 Silar, 51 with comonomer **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *Yes – in 52* ***Lining:*** *Yes* ***Etch:*** *Yes plus co-monomer in 52* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Mechanical retention*	5 initial failures resulting in immediate replacement; 3 with bevel, 2 without (no details given) 4 further failures out of 102 after 24 months; all associated with fractures of adjacent tooth tissue, 2 with bevel, 2 without	The initial failures were ignored in their analysis. Generalisability is limited by university setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (van Dijken 1986) 598 **Year:** 1986 **Country:** Sweden **Aim:** Clinical evaluation of anterior conventional, microfilled and hybrid composite resin restorations **Follow-up:** 72 months **Design:** (7) Other clinical trial **Criteria:** (3) USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 1 with calibration **Sponsorship:** JC Kempes Memorial Foundation	**Participants and Baseline Nos:** 27; high caries experience, 22-65 years **Restoration Type(s) and Baseline Nos:** 183 Class III, 39 Class IV, 80 Class V **Tooth types and Baseline Nos:** Anterior teeth, details not provided **Materials and Baseline Nos:** 302 in total: 42 Adaptic (autopolymerising, macrofilled), 25 Profile (autopolymerising, macrofilled), 55 Silar (autopolymerising, microfilled), 29 Isopast (autopolymerising, microfilled), 46 Durafil (light cured microfilled), 33 Miradapt (autopolymerising, macrofilled), 72 DRS (autopolymerising, macrofilled) **Participant final Nos:** 27 **Restoration final Nos:** 183 Class III, 39 Class IV, 80 Class V **Tooth type final Nos:** Anterior teeth, no details provided **Materials final Nos:** 302 in total: 42 Adaptic, 25 Profile, 55 Silar, 29 Isopast, 46 Durafil, 33 Miradapt, 72 DRS **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *Yes* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Durafil-light, others chemical* ***Mechanical retention*** *except Class IV*	**72 months** 8 out of 42 Adaptic failed 5 out of 25 Profile, 18 out of 55 Silar, 17 out of 29 Isopast, 9 out of 46 Durafil, 5 out of 33 Miradapt, 37 out of 72 DRS Data for 6 monthly cumulative relative frequencies of replaced restorations is provided 2 Class III restorations were lost, 10 Class IV were lost, i.e. fell out	Generalisability is limited by university setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Heymann, Wilder et al. 1986) 773 **Year:** 1986 **Country:** USA **Aim:** Clinical evaluation of composite resin restorations in posterior teeth **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** University **Clinicians:** 3 **Evaluators:** 2 **Sponsorship:** ESPE; NIDR	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 182: 79 Class 1, 103 Class II **Tooth types and Baseline Nos:** Permanent posterior teeth, no details provided **Materials and Baseline Nos:** 29 Visio-Fil (light cured, macrofilled), 39 Nimetic (autopolymerising, macrofilled), 38 Visio-Radiopak (light cured, macrofilled), 33 Visio-Dispers (light cured, macrofilled), 43 Nimetic-Dispers (autopolymerising, macrofilled) **Participant final Nos:** Not stated **Restoration final Nos:** 142: no details provided **Tooth type final Nos:** No details provided **Materials final Nos:** 142: 25 Visio-Fil, 29 Nimetic, 33 Visio-Radiopak, 27 Visio-Dispers, 28 Nimetic-Dispers **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Mixture – see above* ***Other:*** *Mechanical retention*	17 out of 142 failures after 24 months (12 fractures/breakdown, 5 recurrent caries) 6 Visio-Dispers, 6 Nimetic-Dispers fractured 2 Nimetic, 2 Visio-Dispers, 1 Nimetic-Dispers had recurrent caries	Generalisability limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Richardson and Derkson 1987) 839 **Year:** 1987 **Country:** Canada **Aim:** Clinical evaluation of chemically cured and light cured composite resin restorations in posterior teeth **Follow-up:** 48 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** Unknown number of senior dental students **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 102 children, no details **Restoration Type(s) and Baseline Nos:** 176 Class 1, 61 Class II minimal preparations **Tooth types and Baseline Nos:** Posterior teeth details not stated **Materials and Baseline Nos:** 116 FulFil (light cured, densified midway-filled), 121 P-10 (autopolymerising, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** 52 Class I, 9 Class II, 5 Class I and II in primary molars **Tooth type final Nos:** Not stated **Materials final Nos:** 27 FulFil, 39 P-10 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *see above* ***Other:*** *Not stated*	0 failures out of 66 restorations at 48 months No differences between light and chemically cured materials	Generalisability is limited by university setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Paquette, Vann et al. 1983) 841 **Year:** 1983 **Country:** USA **Aim:** Clinical evaluation of modified cavity preparations for composite resins in primary molars **Follow-up:** 12 months **Design:** (3) Prospective case series, **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 3 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 32 children between 4 and 8 years with at least 2 Class II lesions in primary molars **Restoration Type(s) and Baseline Nos:** 240 Class I and II. Conventional preparations with bevels or minimal preparations with bevels random allocation of material **Tooth types and Baseline Nos:** 240 Primary molars, details not provided **Materials and Baseline Nos:** Profile (autopolymerising, macrofilled), Visio-Fil (light cured, macrofilled). Numbers not provided **Participant final Nos:** 30 **Restoration final Nos:** 229 Class I and II; 11 lost through exfoliation **Tooth type final Nos:** 229 primary molars **Materials final Nos:** 130 Profile, 99 Visio-Fil **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *see above* ***Other:*** *Not stated*	15 failures out of 229 after 12 months **For conventional preparations:** 1 failure out of 50 with Profile, 1 out of 46 with Visio-Fil **For modified preparations**: 8 failures out of 80 for Profile, 5 out of 53 for Visio-Fil 1 failure for Class I, 14 for Class II	Greater failure rate with minimal preparation, particularly Class II Generalisability is limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wilson, Wilson et al. 1985; Wilson, Wilson et al. 1986; Wilson, Smith et al. 1986; Wilson, Wilson et al. 1988; Wilson, Wilson et al. 1988) 728/730/731/289/290 **Year:** 1988 **Country:** UK **Aim:** Clinical evaluation of light cured composite resin restorations in posterior teeth **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 2 or 3 **Evaluators:** 2 or 3 **Sponsorship:** ICI	**Participants and Baseline Nos:** 41: 23 female, 18 male. Age range 16-66 **Restoration Type(s) and Baseline Nos:** 40 Class I, 37 Class II **Tooth types and Baseline Nos:** 18 maxillary premolars, 21 maxillary molars, 10 mandibular premolars, 28 mandibular molars **Materials and Baseline Nos:** 77 Occlusin (light cured densified compact filled) **Participant final Nos:** Not stated at any review period. **Restoration final Nos:** At 12 months: 35 Class I, 24 Class II; At 24 months: 30 Class I, 22 Class II; At 36 months: 33 Class I, 22 Class II; At 48 months: 29 Class I, 19 Class II; At 60 months: 39 Class I, 28 Class II **Tooth type final Nos:** At 12 months: maxillary 15 premolars and 12 molars, mandibular 9 premolars and 22 molars At 24 months: maxillary 15 premolars and 12 molars, mandibular 8 premolars and 17 molars At 36 months: maxillary 15 premolars and 12 molars, mandibular 8 premolars and 20 molars At 48 months: maxillary 14 premolars and 12 molars, mandibular 4 premolars and 18 molars At 60 months: maxillary 13 premolars and 24 molars, mandibular 7 premolars and 23 molars **Materials final Nos:** At 12 months: 59 Occlusin; At 24 months: 52 Occlusin; At 36 months: 55 Occlusin; At 48 months: 48 Occlusin; At 60 months: 67 Occlusin **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *On occasions* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light*	1 initial failure at 1 week due to discomfort; 4 further restorations replaced by 12 months 2 further failures by 24 months due to fracture and poor marginal adaptation 0 failures between 24 and 36 months 2 failures between 36 and 48 months because of bulk fracture 13 failures over the 60 month period in total – presumably 4 failed between 48 and 60 months 9 failures were of Class II restorations	Note that the number of cases at recall increases at 60 months. Not every case was reviewed at every recall. Material not currently available. Generalisability is limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Smith and Wilson 1979; Wilson and Smith 1984) 142/727 **Year:** 1984 **Country:** UK **Aim:** Clinical evaluation of a light cured and chemically cured composite resin restorations in anterior teeth **Follow-up:** 24 months **Design:** (7) Other clinical trial, **Criteria:** (3) Unique criteria **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** ICI	**Participants and Baseline Nos:** 41: 27 male, 24 female. Aged 9-56 **Restoration Type(s) and Baseline Nos:** 101 Class III, 36 Class IV, 36 Class V split mouth design **Tooth types and Baseline Nos:** Permanent anterior teeth, no details provided **Materials and Baseline Nos:** 88 Fotofil (light cured macrofilled), 85 Adaptic (autopolymerising, macrofilled) **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** At 6 months: 78 Fotofil, 73 Adaptic; At 12 months: 70 Fotofil, 72 Adaptic; At 24 months: 39 Fotofil, 45 Adaptic **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *For Class IV only* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *see above* ***Other:*** *Mechanical retention except in Class IV*	**6 months** 3 failures out of 73 for Adaptic 2 out of 78 for Fotofil **12 months** 0 further failures out of 72 for Adaptic 4 further failures out of 70 for Fotofil **24 months** 1 further failure out of 45 for Adaptic 2 further failures out of 39 for Fotofil No data for restoration type	Materials not currently available Generalisability is limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Norman and Wilson 1988; Letzel 1989; Rowe 1989; Wilson and Norman 1991; Wilson, Wilson et al. 1991; Wilson, Wastell et al. 1996) 293/411/271/202/205/270 **Year:** 1988/91 **Country:** Multi-centre – 12 units **Aim:** International multi-centre clinical evaluation of a posterior composite resin **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University **Clinicians:** Numerous **Evaluators:** Numerous **Sponsorship:** ICI	**Participants and Baseline Nos:** Baseline not given; some dental students included **Restoration Type(s) and Baseline Nos:** 281 Class I, 729 Class II **Tooth types and Baseline Nos:** Baseline not given **Materials and Baseline Nos:** 1010 Occlusin (light cured, densified compact filled) **Participant final Nos:** At 36 months: 363 adults, aged 15-66 **Restoration final Nos:** At 36 months: 193 Class I, 513 Class II **Tooth type final Nos:** At 36 months: 351 premolars, 355 molars **Materials final Nos:** 706 Occlusin **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	Results at 36 months, 11 centres: 34 failures out of 706 after 36 months 10 failures within 6 months, 11 further failures before 12 months, 9 further failed between 12 and 24 months and a further 4 between 24 and 36 months 27 failures were large restorations 11 failures with sensitivity, 10 fractures, 8 poor margins (more than one reason possible)S **Results at 48 months, 10 centres:** 92 failures out of 715 after 48 months 54 failures attributed to material, 30 failures attributed to the restorative process, 8 failures attributed to external factors Results at 60 months, 11 centres: 88 failures out of 649 after 60 months 46 failures attributed to material, 34 failures attributed to the restorative process, 8 failures attributed to external factors	The study categorises the failures into material, external factors and restorative process. The division between these categories is unclear. Material not currently available Generalisability is limited by university setting but strengthened by the large number of clinicians and centres involved.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wilson, Wilson et al. 1991) 205 **Year:** 1991 **Country:** UK **Aim:** Clinical evaluation of composite resin restorations in butt joint and bevel-edged preparations. NB Butt-joint results reported as part of a multi-centre trial 293 **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** ICI	**Participants and Baseline Nos:** 55, 29 female, 26 males. Age 16-66 years **Restoration Type(s) and Baseline Nos:** 119: 59 Class I and 60 Class II; 84 with butt-joint, 35 with bevel-joint **Tooth types and Baseline Nos:** 45 premolars, 74 molars **Materials and Baseline Nos:** 119 Occlusin (light cured, densified compact filled) **Participant final Nos:** Not stated **Restoration final Nos:** 94: 52 Class I, 42 Class II. 67 butt-joint, 27 bevel-joint **Tooth type final Nos:** 32 premolars, 62 molars **Materials final Nos:** 94 Occlusin **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *No* ***Bevelled enamel:*** *See above* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	20 failures out of 119 before 60 months 14 failures out of 84 in butt-joint group, 6 out of 35 in bevel-joint group 6 failed within 6 months, 6 failed between 22 months and 48 months, 8 failed between 48 and 60 months 4 out of 59 failures in Class I, 16 out of 60 in Class II 10 failures out of 45 in premolars, 10 out of 74 in molars 0 failures out of 94 at the 60 month review	More failures in Class II restorations 15 failures related to material, 3 for restorative process, 2 from external influences Data for butt-joints presented with paper 293 (previous page) Generalisability limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Knibbs 1992) 381 **Year:** 1992 **Country:** UK **Aim:** Clinical evaluation of glass ionomer cement as an 'open' and 'closed' sandwich beneath composite resin in Class II cavities **Follow-up:** 30 months **Design:** (6) Prospective with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 1 **Sponsorship:** DeTrey Dentsply	**Participants and Baseline Nos:** 22 (7 male, 15 female; mean age 31 range:20-55) **Restoration Type(s) and Baseline Nos:** 64 Class II **Tooth types and Baseline Nos:** 20 maxillary molar, 12 maxillary premolar, 20 mandibular molar, 12 mandibular premolar **Materials and baseline Nos:** 32 Fulfil composite (light cured, densified midway-filled) with glass ionomer cement as an 'open' sandwich 32 Fulfil composite (light cured, densified midway-filled) with glass ionomer cement as a 'closed' sandwich **Participant final Nos:** 22 **Restoration final Nos:** As baseline **Tooth type final Nos** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Glass ionomer* ***Etch*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Mechanical retention*	4 out of 32 failures for 'Open sandwich': (All failures in exposed cervical glass ionomer; 1 deficiency detected clinically at 4 months, the other 3 detected radiographically) 1 out of 32 failures for' Closed sandwich': (cervical deficiency detected radiographically)	Variable review period (4-29 months) This study suggests a higher failure rate for the 'open' sandwich technique Generalisability is limited by university setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Grogono, McInnes et al. 1990) 234 **Year:** 1990 **Country:** USA **Aim:** Clinical evaluation of two posterior composite resins in Class II cavities. A subsidiary aim was to evaluate the use of the glass ionomer laminate technique. **Follow-up:** 24 months **Design:** (6) Prospective with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 3 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Numbers not stated **Restoration Type(s) and Baseline Nos:** 40 Class II **Tooth types and Baseline Nos:** 33 premolar, 7 molars **Materials and Baseline Nos:** 20 Status composite (light cured, densified midway-filled), 20 Ful-Fil composite (light cured, densified midway-filled) 20 teeth were randomly allocated to be restored with a glass ionomer (Ketacbond) base in an 'open' sandwich laminate technique **Participant final Nos:** Not stated **Restoration final Nos:** 38 **Tooth type final Nos:** Not stated **Materials final Nos:** 18 Status, 20 Ful-Fil **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Glass ionomer (Ketacbond)* ***Etch:*** *Yes (all restorations)* ***Enamel bond:*** *Yes (all restorations)* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Mechanical retention*	0 failures at 24 months Scores for anatomic form of Fulfil better at 2 years than Status	The interpretation is complicated by the attempt to carry out two investigations in one study. **Generalisability is limited by university setting and small sample size.**

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Welbury and Murray 1990) 249 **Year:** 1990 **Country:** UK **Aim:** Clinical evaluation of a glass-ionomer cement-composite resin sandwich technique in posterior teeth **Follow-up:** up to 24 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 1 (operator/evaluator) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 23 aged 9-18 years (Entered over 16 month period) **Restoration Type(s) and Baseline Nos:** 49 Class II (43 MO/DO, 6 MOD) **Tooth types and Baseline Nos:** 29 permanent molars, 20 premolars **Materials and Baseline Nos:** 49 class II Ketac-Bond/Occlusin, glass ionomer-composite 'open' sandwich (composite – light cured, densified compact filled) **Participant final Nos:** 21 reported at 24 months (in place 6-24 months) **Restoration final Nos:** 49 restorations at 6 months, 38 at 12 months, 31 at 18 months, 11 at 24 months (failures excluded) **Tooth type final Nos:** 46 reported at 24 months (in place 6-24 months) **Materials final Nos:** 46 class II sandwich (in place 6-24 months) **Techniques:** ***LA:*** *Yes (assumed)* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide/GIC* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	At 6 mths 8/49 failed At 12 mths 3/38 failed At 18 mths 4/31 failed At 24 mths 1/11 failed 17 failed in total. 10 failed due to loss of GIC from box cervical gap formation (7 molars, 3 premolars; 4 at 6 mths, 1 at 12 mths, 4 at 18 mths, 1 at 24 mths) 5 failed fracture or loss composite (4 molar 1 premolar; 3 at 6 mths, 2 at 12 mths) 1 molar restoration fractured composite and lost GIC (6 mths) 1 restoration replaced at 24 months caries elsewhere on tooth No statistical analysis	Authors note a high failure rate of glass ionomer at the base of box. Generalisability is limited by university setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Boksman, Jordan et al. 1986) 595 **Year:** 1986 **Country:** Canada **Aim:** Clinical evaluation of a posterior composite resin **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** LD Caulk Co	**Participants and Baseline Nos:** 39: 19 female, 20 male **Restoration Type(s) and Baseline Nos:** 98: 55 Class II, 43 class I **Tooth types and Baseline Nos:** 49 molars, 49 premolars **Materials and Baseline Nos:** 98 F-70 (Ful-Fil) (light cured, densified midway-filled) **Participant final Nos:** 79 **Restoration final Nos:** 79: 40 Class I, 39 Class II (Premolars: 4 Class I, 27 Class II; Molars: 36 Class I, 12 Class II) **Tooth type final Nos:** 31 premolars, 48 molars **Materials final Nos:** 79 F-70 (Ful-Fil) **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Pre wedged, conventional amalgam cavity, Tofflemire matrix, incremental pack, polished immediately, mechanical retention*	5/79 failures at 36 months; all 5 failures related to lack of interproximal contact All failures in Class II 21/79 cases reported postoperative sensitivity initially, most disappeared by 12 months. 2 teeth received endodontic therapy within 12 months of placement .	Generalisability is limited by the university setting.

Table A3 Summary of studies involving composite restorations using bonding agents

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Duke, Robbins et al. 1991) 176 **Year:** 1991 **Country:** USA **Aim:** Clinical evaluation of a dentine bonding system for restoring Class V abrasion/erosion root caries **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 38, aged 44-70, no medical complications, normal oral hygiene, no bruxing or periodontitis **Restoration Type(s) and Baseline Nos:** 100 Class V, paired cavities 2-4 per patient **Tooth types and Baseline Nos:** Permanent, not stated **Materials and Baseline Nos:** 34 Silux composite (light cured, microfilled) plus Scotchbond 2 dentine adhesive, mixed margins with no enamel etch 34 Silux/Scotchbond 2 dentine adhesive, mixed margins with enamel etch 32 Silux/Scotchbond 2 dentine adhesive, dentine (root) cavity no etch **Participant final Nos:** 35 **Restoration final Nos:** 90 Class V (30 per group) **Tooth type final Nos:** Not stated **Materials final Nos:** 30 Silux/ Scotchbond 2 no enamel etch 30 Silux/Scotchbond 2 with enamel etch 30 Silux/Scotchbond 2 dentine cavity no etch **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Deep dentine cavities only* ***Etch:*** *see above* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *No mechanical retention*	**Mixed margins with no enamel etch** 3 out of 34 failures at 6 months, 1 further at 12 months, 1 further at 24 months 1 further at 36 months. Retention rate of 91%, 88%, 86% and 80% at 6, 12, 24 and 36 months **Mixed margins with enamel etch** 0 failures out of 34 at 6 and 12 months, 2 failures out of 30 at 24 months, No further failures at 36 months. Retention rate of 100%, 100%, 94% and 93% at 6, 12, 24 and 36 months **Root cavity without etch** 0 out of 32 failures at 6, 12 and 24 months, 1 failure out of 30 at 36 months. Retention rate of 100%, 100%, 100 & 97% at 6, 12, 24 and 36 months	This study reports that enamel etching improves retention for Class V cavities in enamel and dentine when a dentine bonding agent used Generalisability is limited by university setting. **Our Classification for analysis** Silux / Scotchbond2 - Group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Abdalla and Alhadainy 1996) 398 **Year:** 1996 **Country:** Egypt **Aim:** Clinical evaluation of composite resin restorations in Class 1 cavities **Follow-up:** 24 months **Design:** (7) Clinical trial **Criteria:** (4) USPHS **Environment:** University **Clinicians:** not stated **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 45: age range 22-38 years **Restoration Type(s) and Baseline Nos:** 120 Class 1 cavities, no description of randomization, each patient had at least two materials **Tooth types and Baseline Nos:** 120 molars **Materials and Baseline Nos:** 30 Clearfil photo posterior (light cured, densified compact filled), plus dentine adhesive and enamel bond 30 Z100 (light cured, densified compact filled), plus dentine adhesive and enamel bond 30 Herculite XR (light cured, densified midway-filled), plus dentine adhesive and enamel bond 30 Heliomolar RO (light cured, microfilled), plus dentine adhesive and enamel bond **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 26 Clearfil photo, 26 Z100, 25 Herculite XR, 27 Heliomolar RO **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *as material details* ***Dentine adhesive:*** *as material details* ***Light/Chemical cure:*** *as material details* ***Other:*** *Mechanical retention*	0 failures for any material after 24 months	Generalisability is limited by university setting. **Our Classification for analysis** Clearfil dentine adhesive – 1b Z100 dentine adhesive – 1b Herculite dentine adhesive – 1a Heliomolar dentine adhesive – 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (de Freitas, de Andrada et al. 1994) 450 **Year:** 1994 **Country:** Brazil **Aim:** Clinical evaluation of composite resin in tunnel preparations in primary molars **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** Not stated **Evaluators:** 3 **Sponsorship:** No (assumed)	**Participants and Baseline Nos:** 20 children **Restoration Type(s) and Baseline Nos:** 66 Class II tunnel preparations **Tooth types and Baseline Nos:** 60 primary molars **Materials and Baseline Nos:** 66 P-50 composite (light cured, densified compact filled) with dentine adhesive Scotchbond II **Participant final Nos:** Not stated (3 patients with 6 restorations did not return, 28 restorations extracted after 6 months evaluation) **Restoration final Nos:** 30 tunnel preparation **Tooth type final Nos:** Not stated **Materials final Nos:** 30 P50 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *No* *Etch:* *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light, incremental set* ***Other:*** *Caries dye used, composite syringed, light reflecting wedges*	**Clinical failure** 0/60 failures at 6 months 0/30 at 12 months **Associated with tooth fracture** 2/60 at 6 months, 0/30 at 12 months **Radiographic failure** 11/60 at 6 months, 9/30 at 12 months show caries **Total failure** 13/60 at 6 months 9/30 at 12 months Performance of occlusal portion of restoration was good with no caries or loss of restoration. 2 marginal crests fractured at 6 months Poor agreement between radiographic and direct examination of proximal caries	Tunnel preparations with P50 composite cannot be recommended because of possible secondary or residual caries at the proximal surface Generalisability is limited by the short follow-up period and university setting. **Our Classification for analysis** Dentine adhesive – 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Krejci, Besek et al. 1994) 412 **Year:** 1994 **Country:** Switzerland **Aim:** Clinical evaluation of a posterior composite and dentine bonding agent in conventional posterior restorations **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (3) Kreijci et al (1992) **Environment:** University (assumed) **Clinicians:** 2 **Evaluators:** 2 (trained) **Sponsorship:** Vivadent	**Participants and Baseline Nos:** 35 adults with sound periodontium **Restoration Type(s) and Baseline Nos:** 39: Class II or complex Class I **Tooth types and Baseline Nos:** Permanent 15 premolars, 24 molars **Materials and Baseline Nos:** 39 Tetric (light cured, hybrid filled) plus Syntac dentine adhesive **Participant final Nos:** Not stated **Restoration final Nos:** At 6 months 37, at 12 months 33 **Tooth type final Nos:** Not stated **Materials final Nos:** 33 Tetric plus dentine adhesive **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light, incremental set* ***Other:*** *Rounded internal line angles, contoured plastic matrix strips, light transmitting wedges, composite syringed, polished after set Mechanical preparation*	0/37 failures at 6 months, 0/33 failures at 12 months	Generalisability limited by university setting and short follow-up period. **Our Classification for analysis** Syntac group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Willems, Lambrechts et al. 1993) 802 **Year:** 1993 **Country:** Belgium **Aim:** Clinical evaluation of 5 posterior composites in Class II cavities **Follow-up:** 36 months **Design:** (7) Clinical trial **Criteria:** (2) Vanherle et al 1986 **Environment:** University (assumed) **Clinicians:** 4 **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 20-25 year old dental students with normal occlusions **Restoration Type(s) and Baseline Nos:** 52 Class II (20 MO, 18 DO, 14 MOD) **Tooth types and Baseline Nos:** 52 permanent mandibular/maxillary 1st & 2nd molars **Materials and Baseline Nos:** 10 Exp.LF composite (light cured, densified midway-filled) with Gluma dentine adhesive; 13 Marathon composite (light cured, densified compact filled) Creation bond & Visar Seal dentine adhesive; 13 P-30 composite (light cured, densified compact filled) with Scotchbond dentine adhesive; 8 P-30 APC composite (light cured, densified compact filled) with Scotchbond dentine adhesive; 8 P-50 APC composite (light cured, densified compact filled comp) with Scotchbond dentine adhesive **Participant final Nos:** Not stated **Restoration final Nos:** 52 **Tooth type final Nos:** 52 Permanent 1st and 2nd molars **Materials final Nos:** As above **Techniques:** ***LA:*** *Yes (assumed)* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes(various see above)* ***Dentine adhesive:*** *Yes(various see above)* ***Light/Chemical cure:*** *Light incremental cure* ***Other:*** *Elastic separation 3 days before treatment, polish, centric stops marked, teeth pre-wedged, transparent matrix, finish, final polish 1 month, mechanical preparation*	1/10 Exp LF failed at 6 months (recurrent caries). Tooth was subsequently root treated All other groups 0 failures at 36 months	Results suggest that with meticulous technique these posterior composites perform well at 36 months. Generalisability is limited by the small sample size and use of dental students and (assumed) university setting. **Our Classification for analysis** Exp LF dentine adhesive – 1b Marathon dentine adhesive – 1b P-30/P-50 dentine adhesives – 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wendt and Leinfelder 1994) 445 **Year:** 1994 **Country:** USA **Aim:** Clinical evaluation of a resin composite and bonding restorative system **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** 1 (assumed) **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27 adults **Restoration Type(s) and Baseline Nos:** 15 Class I and 45 Class II **Tooth types and Baseline Nos:** 60 permanent molars and premolars **Materials and Baseline Nos:** 60 Prisma APH composite (now Prisma TPH) (light cured, densified midway-filled) with Prisma Universal Bond **Participant final Nos:** Not stated **Restoration final Nos:** 35 Class I and II **Tooth type final Nos:** 35 molars and premolars **Materials final Nos:** 35 Prisma AP.H **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Class II gingival margin only* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Pre wedging prior to class II, Tofflemire matrix, incremental packing, polished immediately, mechanical retention*	0/50 failures at 6 months, 0/52 failures at 12 months, 1/47 failures at 24 months, 2/35 failures at 36 months at 24 months 1 failed because of recurrent caries; at 36 months 2 failed because of marginal integrity/wear	Generalisability is limited by university setting, small sample size, drop-out rate and single operator (assumed). **Our Classification for analysis** Dentine adhesive - 2

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wendt and Leinfelder 1992) 348 **Year:** 1992 **Country:** USA **Aim:** Clinical evaluation of a new composite and bonding system **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 20 Class I and 40 Class II **Tooth types and Baseline Nos:** 30 molars and 30 premolars **Materials and Baseline Nos:** 60 Clearfil Photo Posterior (light cured, densified compact filled) with Clearfil Photo Bond adhesive **Participant final Nos:** Not stated **Restoration final Nos:** 39 at 36 months **Tooth type final Nos:** 39 molars and premolars **Materials final Nos:** 39 Clearfil Photo Posterior **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Class II gingival margin only* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Pre wedging prior to class II, Tofflemire matrix, incremental packing, polished immediately, mechanical retention*	0/60 failures 6 months; 0/60 failures at 12 months; 0/52 failures at 24 months; 1/39 failures at 36 months (recurrent caries)	**Generalisability is limited by university setting** **Our Classification for analysis** Dentine adhesive – 1a

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (van Dijken and Horstedt 1987) 317 **Year:** 1987 **Country:** Sweden **Aim:** Clinical evaluation of moisture control using rubber dam or cotton wool rolls on adaptation of composite resin fillings **Follow-up:** 12 months **Design:** (7) Other clinical trial **Criteria:** (2) Unique criteria for marginal adaptation **Environment:** Not stated, probably University **Clinicians:** 1 **Evaluators:** Not stated **Sponsorship:** Faculty of Odontology funds; MC Kempes Memorial Foundation	**Participants and Baseline Nos:** 35 adults; no details provided **Restoration Type(s) and Baseline Nos:** 140 Class III, within mouth comparisons of four materials **Tooth types and Baseline Nos:** Number not stated; maxillary and mandibular incisors and canines **Materials and Baseline Nos:** 35 Miradapt composite plus Scotchbond (autopolymerising, macrofilled) with rubber dam; 35 Miradapt plus Scotchbond (autopolymerising, macrofilled) with cotton rolls; 35 Silar (autopolymerising, microfilled) plus Scotchbond with rubber dam; 35 Silar (autopolymerising, microfilled) plus Scotchbond with cotton rolls **Participant final Nos:** 35 **Restoration final Nos:** 140 **Tooth type final Nos:** Not stated **Materials final Nos:** 35 Miradapt with rubber dam; 35 Miradapt with cotton rolls; 35 Silar with rubber dam; 35 Silar with cotton rolls **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *in 50% of cases* ***Bevelled enamel:*** *Yes – where possible* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Scotchbond with Silar group* ***Light/Chemical cure:*** *Light* ***Other:*** *all restorations polished after 1 week, mechanical retention*	No failures with either material or technique out of 140 restorations	Generalisability is limited by university setting, single operator and short follow-up period **Our Classification for analysis** Dentine adhesive - 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Rasmusson, Kholer et al. 1998) 818 **Year:** 1998 **Country:** Sweden **Aim:** Clinical evaluation of composite resin restorations in posterior teeth **Follow-up:** 36 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (3) USPHS **Environment:** Dental Public Health Clinics, 3 in all **Clinicians:** 12 **Evaluators:** 2 **Sponsorship:** Bohus County Council	**Participants and Baseline Nos:** 95, 52 female, 43 male. Age range 11 to 69 **Restoration Type(s) and Baseline Nos:** 104 Class II **Tooth types and Baseline Nos:** 59 premolars, 45 molars **Materials and Baseline Nos:** 46 Superlux Molar (light cured, densified midway-filled) with Superlux Universal Bond, 49 P-50 APC (light cured, densified compact filled) with Scotchbond 2 **Participant final Nos:** 68 details not given **Restoration final Nos:** 82 Class II **Tooth type final Nos:** 47 premolars, 35 molars **Materials final Nos:** 42 Superlux, 40 P-50 APC **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes – Superlux or Scotchbond II* ***Light/Chemical cure:*** *Light* ***Other:*** *Compomer base in Superlux group*	11 failures out of 82 restorations after 36 months; 7 P-50, 4 Superlux. Not a statistically significant difference 6 secondary caries, 3 fractures of material, 1 cusp fracture, 1 sensitivity 16 subjects moved, 7 could not be contacted, 4 refused	**Generalisability good within a salaried environment.** **Our Classification for analysis** Superlux dentine adhesive – 1b Scotchbond 2 dentine adhesive – 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wilson and Wilson 1995) 430 **Year:** 1995 **Country:** UK **Aim:** Clinical evaluation of a dentine bonding agent **Follow-up:** 12 months **Design:** (8) Randomised control trial; **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 (no details) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 40: 24 female, 16 male. Aged 17-78 **Restoration Type(s) and Baseline Nos:** 102 Class V crown/root lesions with bevelled enamel, split mouth, single blind (to patient), randomized (within patient) **Tooth types and Baseline Nos:** 102 permanent canines and premolars **Materials and Baseline Nos:** 51 Opalux (light cured, densified compact filled), 51 experimental light cured composite M221984 (light cured, densified compact filled) **Participant final Nos:** 40 **Restoration final Nos:** At 6 months: 96 Class V crown/root lesions; at 12 months: 79 **Tooth type final Nos:** 96 at 6 months 79 at 12 months: permanent canines and premolars **Materials final Nos:** 79 Opalux and experimental light cured composite M221984. No details given **Techniques:** ***LA:*** *When required* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes, on crown* ***Lining:*** *No* ***Etch:*** *On enamel* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes – Trypton* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	1 failure at 6 months, 16 further failures by 12 months A total of 17/79 at 12 months 8 failures in patients over 65 years 6 failures in teeth with abnormal occlusal loads Study aborted after 12 months	The authors reported that the failures were related to the co-variables of age and function. The study was halted because of the high failure rate. They felt that exclusion criteria for trials of Class V restorations should be reviewed. Generalisability limited by university setting. **Our Classification for analysis** Dentine adhesive – 2

<table>
<tr><th>Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship</th><th>Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques</th><th>Results (to include failures and summary of statistical analysis)</th><th>Commentary</th></tr>
<tr><td>Author & No: (Satou, Fukunaga et al. 1989; Shintani, Satou et al. 1989; Morikawa, Ohmoto et al. 1990) 269/223/274
Year: 1989/1990
Country: Japan
Aim: To compare 2 posterior composite resins inserted using a similar placement technique
Follow-up: 84 months
Design: (7) Other clinical trial
Criteria: (3) Restoration replacement USPHS 1 evaluator, training not stated)
Environment: Factory Dental Clinic
Clinicians: Dentist 5 years post qualified
Evaluators: 1 (training not stated)
Sponsorship: Not stated</td>
<td>Participants and Baseline Nos:
82 Factory workers (a:- 41; b:- 41)
Restoration Type(s) and Baseline Nos:
surface a b
occlusal 36 21
ling/buccocclusal 36 47
buccolinguo-occlusal 33 32
mesio/distocclusal 1 7
Tooth types and Baseline Nos:
Permanent a b
1st premolar 11 9
2nd premolar 12 5
1st molar 39 35
2nd molar 37 51
3rd molar 7 7
Materials and Baseline Nos:
a)-Clearfil posterior (light cured, densified, compact filled) (total etch, clearfil bond) - 106
b) P10 posterior (light cured, densified, compact filled) (total etch, Scotchbond)- 107
Participant final Nos:
a): 41; b):- 41. No dropouts at 48 months
a) 25; b) 24 at 84 months
Restoration final Nos:
a b
Months 48 84 48 84
O 36 20 21 10
L/BO 36 21 47 29
BL-O 33 18 32 14
M/DO 1 1 7 6
Tooth type final Nos:
a b
Months 48 84 48 84
1st premolar 11 1 9 8
2nd premolar 12 7 5 2
1st molar 39 25 35 19
2nd molar 37 22 51 26
3rd molar 7 5 7 4

Materials final Nos:</td>
<td>Restorations failed
(Replaced after examination at recall)
At 48 months
Clearfil 10/106
P-10 7/107
At 84 months
Clearfil 4/60
P-10 4/59
No sensitivity at 48 or 84 months
Replacement more prevalent in more complex cavities.
No statistical analysis carried out</td>
<td>Material formulations have changed since study.
Enamel and dentine “etched” for both dentine bonding materials
Generalisability is limited by single operator.

Our classification for analysis
Clearfil bond group 1a
Scotchbond group 1a</td></tr>
</table>

	Months 48 84 a) 106 60 b) 107 59 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Minimal* ***Etch:*** *60 seconds* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*		

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Tyas 1992; Tyas 1994) 343/741 **Year:** 1992/1994 **Country:** Australia **Aim:** To compare the 1 year clinical performance in non-undercut Class V abrasion lesions of resin restorations bonded by Mirage and Tenure and the 3 year results of Tenure **Follow-up:** 36 months **Design:** (6) Prospective design and concurrent controls **Criteria:** (5) Restoration failure (loss) **Environment:** Not stated **Clinicians:** 1 (experienced) **Evaluators:** Operator/assessor/author **Sponsorship:** Not stated	**Participants and Baseline Nos:** Tenure – 5 Mirage bond – 6 **Restoration Type(s) and Baseline Nos:** Non retentive Class V – 40 **Tooth types and Baseline Nos:** Permanent teeth - Posterior Upper / lower; Anterior upper / lower Tenure 7 4 8 1 Mirage 4 2 7 7 **Materials and Baseline Nos:** Tenure 20; Mirage 20 Same composite used for both (Silux, light cured, microfine) **Participant final Nos:** As above **Restoration final Nos:** 12 months as above 38 Tenure at 36 months 40 Mirage at 36 months **Tooth type final Nos:** As above at 12 months No further data given **Materials final Nos:** As above at 12 months As above at 36 months **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Cotton wool* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *Not intentionally (although bonding agents have potential to etch enamel)* ***Enamel bond:*** *Probably* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**At 12 months** Tenure 1/20 failed Mirage failed 10/20 **At 36 months** 2/18 failed Life table analysis given up to 12 months 36 months results only for Tenure	Materials now not available Generalisability is limited by single operator who acted as evaluator, the short period of the study and the small numbers. **Our classification for analysis** Tenure group 1b Mirage group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hansen 1989; Hansen 1992) 346/265 **Year:** 1992 **Country:** Denmark **Aim:** To compare retention rate light cured composite in non-retentive Class V cavities using 2 dentine bonding agent (initial version of Scotchbond and Gluma) and enamel etching. Both using Silux **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (5) Restoration failure (loss) **Environment:** Hospital/University **Clinicians:** 1 **Evaluators:** 2 calibrated examiners **Sponsorship:** Danish Dental Association	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** Non retentive Class V cavities 105 **Tooth types and Baseline Nos:** permanent Incisor/canine premolar Scotchbond 22 8 Gluma 58 17 **Materials and Baseline Nos:** Scotchbond 30 Gluma 75 Both with the same composite (Silux, light cured, microfine) **Participant final Nos:** Not stated **Restoration final Nos:** Months 36 60 Scotchbond 30 26 Gluma 75 64 **Tooth type final Nos:** 60 months incisor/canine premolar Scotchbond 18 8 Gluma 51 13 **Materials final Nos:** Months 36 60 Scotchbond 30 26 Gluma 75 64 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *Yes* ***Lining:*** *Deep cavities only* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restorations failed (loss)** Months ScotchBond Gluma 36 10/30 3/75 60 15/26 8/64 Survival analysis (Log rank test) **60 month survival** Gluma 90% (95% CI =83-98%) Scotchbond 47% (95% CI=27-67%) There was a highly significant trend for failure ($p<0.005$) in different regions of the mouth (lowest in the maxillary incisor/canine region). **Retention rates** %Gluma %Scotchbond Upper incisor /canine 100 75 Upper premolar 91 40 Lower incisors 86 27 Lower premolars 56 0	There were uneven numbers in the Gluma and Scotchbond groups. Materials are not currently available. Generalisability is limited by single operator and university environment. **Our classification for analysis** Gluma group 1b Scotchbond group 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (van Dijken 1994) 435 **Year:** 1994 **Country:** Sweden **Aim:** To compare the retention rates of 4 dentine bonding agents in non retentive Class V cavities (Mirage bond, Tenure, Tripton, & Scotchbond 2) **Follow-up:** 48 months **Design:** (7) Other Clinical Trial **Criteria:** (5) Restoration failure (loss) **Environment:** Not stated **Clinicians:** 1 **Evaluators:** Not stated **Sponsorship:** Swedish MRC	**Participants and Baseline Nos:** 81 patients **Restoration Type(s) and Baseline Nos:** All Class V – 216 **Tooth types and Baseline Nos:** Not stated (assumed permanent) **Materials and Baseline Nos:** Mirage 63 Tenure 47 Tripton 53 Scotchbond 2 53 Mirage and Scotchbond 2 used Silux composite (light cured, microfilled) Tenure and Tripton used Opalux composite (light cured, densified, compact filled) **Participant final Nos:** 77 **Restoration final Nos:** 8 restorations in 4 patients lost. **Tooth type final Nos:** Not stated **Materials final Nos:** 8 restorations in 4 patients lost. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No (cotton wool)* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**At 48 months** Restorations failed (lost) Mirage 47/63 Tenure 23/47 Tripton 44/53 Scotchbond 2 12/53 Not including the 8 restorations lost to the study – no details given No significant difference between Tripton and Mirage. Scotchbond 2 demonstrated significantly lower failure rates than the other materials ($p< 0.001$) No significant differences were found in the failure rates when tested against patient age.	Materials are not currently available Generalisability is limited by single operator. **Our classification for analysis** Mirage group 1b Tenure group 1b Tripton group 2 Scotchbond 2 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kanca 1990) 561 **Year:** 1990 **Country:** USA **Aim:** To assess a modified dentine bonding technique in Class V cavities **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (5) Restoration failure (loss) **Environment:** Practice **Clinicians:** 1 **Evaluators:** 1 operator/assessor/author **Sponsorship:** Author's product	**Participants and Baseline Nos:** 28 patients. No other details **Restoration Type(s) and Baseline Nos:** Class V - 52 **Tooth types and Baseline Nos:** Not stated (assumed permanent) **Materials and Baseline Nos:** A combined dentine bonding technique (total etch (phosphoric acid), Tenure primer, Scotchbond 2 unfilled resin) using Silux composite (light cured, microfilled) **Participant final Nos:** 28 **Restoration final Nos:** As above **Tooth type final Nos:** Not stated **Materials final Nos:** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *No* ***Etch:*** *Yes (of enamel and dentine)* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Possible mechanical retention*	**At 12 months** 0/52 loss of restorations No post operative pain No statistical testing	Generalisability is limited by the single operator who is the assessor and the short duration of the study. **Our classification for analysis** Scotchbond 2 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Tyas 1996) 500 **Year:** 1996 **Country:** Australia **Aim:** To evaluate the clinical performance of 2 dentine bonding systems in non retentive Class V cavities **Follow-up:** 24 months **Design:** (3) Prospective case series **Criteria:** (5) Restoration failure (loss) **Environment:** University/Hospital (assumed) **Clinicians:** Not stated **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Scotchbond Multipurpose– 5 ART Bond (Coltene) – 4 **Restoration Type(s) and Baseline Nos:** Non retentive Cl V – 43 **Tooth types and Baseline Nos:** Permanent / Scotchbond MP / ART Bond Upper anterior 6 0 Lower anterior 4 13 Upper posterior 4 2 Lower posterior 8 6 **Materials and Baseline Nos:** a) Scotchbond MP, Silux composite (light cured, microfilled) 22 b) ART Bond, Brilliant composite (light cured, densified, midway filled) 21 **Participant final Nos:** As above **Restoration final Nos:** As above **Tooth type final Nos:** As above **Materials final Nos:** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Not specifically* ***Enamel bond:*** *Not specifically* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Cumulative failure (loss)** **At 6 months** Scotchbond MP 2/22 ART 0/21 **At 12 months** Scotchbond MP 3/22 ART 1/21 **At 24 months** Scotchbond MP 6/22 ART 1/21 No statistical analysis of the results	Generalisability is limited by university environment and the small number of restorations. **Our classification for analysis** Scotchbond multipurpose group 1b ART bond group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Horsted-Bindslev, Knudsen et al. 1988) 529 **Year:** 1988 **Country:** Denmark **Aim:** To evaluate 6 different adhesive restorative systems (1 glass ionomer, 1 dentine bonded composite and 4 enamel/dentine bonded composites) in non retentive Class V cavities **Follow-up:** 36 months **Design:** (8) Randomised controlled trial **Criteria:** (5) restoration failure (loss) and modified USPHS **Environment:** Not stated **Clinicians:** 1 (training not stated) **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Groups (see below) a) and b) – 10 patients in total c) and d) – 6 patients in total e) and f) – 10 patients in total Total – 26 patients **Restoration Type(s) and Baseline Nos:** All non retentive Class V – 146 restorations a) and b) – 22 pairs c) and d) – 25 pairs e) and f) – 26 pairs **Tooth types and Baseline Nos:** Not stated (assumed permanent) **Materials and Baseline Nos:** a) Encapsulated GIC (Fuji cap2) – 22 b) Gluma, Pekalux (light cured, densified, midway filled) – 22 c) Gluma & etched enamel, Pekalux – 25 d) J&J dentine bonding agent & etched enamel + Certain composite(light cured, microfine) – 25 e) Gluma & etched enamel, Lumifor composite (light cured, densified, midway filled) – 26 f) Scotchbond light cured dentine bonding agent & etched enamel, P30 composite(light cured, densified, compact filled) – 26 **Participant final Nos:** Not stated **Restoration final Nos:** See below **Tooth type final Nos:** Not stated **Materials final Nos:** Months 0 6 12 18 24 36 a) 22 22 22 20 15 15 b) 22 22 22 21 17 17 c) 25 25 25 25 25 25 d) 25 25 25 25 25 25 e) 26 26 26 26 25 f) 26 26 26 26 26 No recall for e) & f) at 36 months **Techniques:**	**Restorations failed (lost)** Months6 12 18 24 36 a) 0/22 0/22 0/20 0/15 0/15 b) 4/22 5/22 5/21 5/17 5/17 c) 0/25 0/25 0/25 0/25 0/25 d) 6/25 10/25 11/25 14/25 16/25 e) 0/26 0/26 0/26 0/25 NS f) 6/26 7/26 9/26 10/26 NS (NS not stated) a and c had no observed loss up to 36 months e had no observed loss up to 24 months d and f had continuous loss of the restorations over the observation period The restorations using the phosphate ester dentine adhesives (d and f) had a significantly higher failure rate than those restorations retained with acid etch and Gluma (c and e) (p<0.01) Glass ionomer restorations (a) were well retained. Life table analysis carried out.	Generalisability is limited by single operator. **Our classification for analysis** Gluma group 1b Scotchbond group 3 J & J Dentine bond group 3

Composite restorations using bonding agents

	LA: *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Deep cavities only* ***Etch:*** *As required* ***Enamel bond:*** *As required* ***Dentine adhesive:*** *As required* ***Light/Chemical cure:*** *All light cured except GIC* ***Other:*** *Not stated*		

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Van Meerbeek, Braem et al. 1993) 488 **Year:** 1993 **Country:** Belgium **Aim:** Clinical performance of 2 dentine bonding agents in etched and non-etched Class V cavities (non-retentive) **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (5) Restoration failure (loss) **Environment:** Not stated **Clinicians:** 2 trained dentists (no further details) **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 35 patients **Restoration Type(s) and Baseline Nos:** 132 non retentive Class V **Tooth types and Baseline Nos:** All permanent teeth Incisor canine premolar molar a) Upper 3 1 1 1 Lower 3 7 13 2 b) Upper 5 2 6 1 Lower 7 5 6 0 c) Upper 3 1 1 0 Lower 4 2 16 2 d) Upper 7 2 5 2 Lower 7 5 10 2 **Materials and Baseline Nos:** Four groups using combinations two dentine bonding agents, two composites , with or without bevelling and enamel etching a) Herculite (light cured, densified, midway filled), Tenure 31 b) Herculite,Tenure, etch 32 c) Opalux (light cured, densified, compact filled), Tripton 29 d) Opalux, Tripton, etch 40 **Participant final Nos:** Not stated **Restoration final Nos:** 126 **Tooth type final Nos:** Not stated **Materials final Nos:** Months 6 12 24 a) 29/30 30/30 30/30 b) 30/32 28/32 32/32 c) 29/29 29/29 29/29 d) 40/40 35/40 35/40 **Techniques:** ***LA:*** *When required* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *For etched cavities only* ***Lining:*** *Not stated* ***Etch:*** *For etched cavities only* ***Enamel bond:*** *For etched cavities only* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light*	**Restoration failure (loss)** Months 6 12 24 a) 4/29 (13%) 4/30 (13%) 9/30 (30%) b) 0/30 (0%) 1/28 (4%) 1/32 (3%) c) 11/29 (38%) 12/29 (41%) 16/29 (55%) d) 1/40 (3%) 1/35 (3%) 1/35 (3%) No specific statistical analysis	The results were given as percentages and we have calculated the figures. The authors suggest that bevelling and etching the available enamel improves retention rate in non retentive Class V cavities. Generalisability is limited by the use of rubber dam, which is unusual for Class V cavities. **Our classification for analysis** Tenure group 1b Tripton group 2

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mandras, Thurmond et al. 1997) 757 **Year:** 1997 **Country:** USA **Aim:** To evaluate the clinical performance of one adhesive system (Clearfil Photo anterior composite + Clearfil Liner Bond dentine bonding agent) placed in non retentive Class V **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (5) loss but also modified USPHS and post-operative sensitivity **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** 2 (training and calibration Not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 25 patients **Restoration Type(s) and Baseline Nos:** Non retentive Class V – 62 **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Clearfil Photo anterior composite (light cured, densified, compact filled), Clearfil Liner Bond dentine bonding agent – 62 **Participant final Nos:** Not stated **Restoration final Nos:** 6 months 60 12 months 59 24 months 58 36 months 55 **Tooth type final Nos:** Not stated **Materials final Nos:** 6 months 60 12 months 59 24 months 58 36 months 55 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Not specifically* ***Enamel bond:*** *Not specifically* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Cumulative restoration failure (loss)** 6 months 1/60 12 months 1/59 24 months 1/58 36 months 4/55 No replacements for any other reason No specific statistical analysis	It is not possible to comment on the generalisability because of the lack of detail given. **Our classification for analysis** Clearfil liner bond group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Jordan, Suzuki et al. 1993) 481 **Year:** 1993 **Country:** Canada **Aim:** To evaluate the clinical performance of one adhesive system (Pekafil composite and Gluma 2000 dentine bonding agent) placed in non retentive Class V **Follow-up:** 24 months **Design:** (3) Prospective case series **Criteria:** (5) restoration failure (loss) **Environment:** University/Hospital **Clinicians:** 1 **Evaluators:** 2 (training and calibration Not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 42 patients **Restoration Type(s) and Baseline Nos:** Non retentive Class V – 95 **Tooth types and Baseline Nos:** Not stated assumed permanent **Materials and Baseline Nos:** 95 Pekafil composite (light cured, densified, midway filled) and Gluma 2000 dentine bonding agent **Participant final Nos:** Not stated **Restoration final Nos:** 83 **Tooth type final Nos:** Not stated **Materials final Nos:** 83 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Not stated* ***Etch:*** *No (effect of primer may etch enamel)* ***Enamel bond:*** *Not specifically* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restoration failure (loss/partial loss)** 2/83 at 24 months No replacements for any other reason No specific statistical analysis	The authors reported good retention at 24 months without specific enamel etch. Generalisability is limited by the university environment, use of single operator and of rubber dam, which is unusual in Class V cavities. **Our classification for analysis** Gluma 2000 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Ferrari, Bertelli et al. 1993) 471 **Year:** 1993 **Country:** Italy/Germany **Aim:** To evaluate the clinical performance of Pekalux and Gluma 2000 dentine bonding agent in various types of cavity over a 5 year period **Follow-up:** 60 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** Not stated **Clinicians:** 3 **Evaluators:** Operator/Assessor (training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 51 patients **Restoration Type(s) and Baseline Nos:** Class III 21 Class IV 19 Class V 20 **Tooth types and Baseline Nos:** 60 Permanent teeth Upper anterior teeth 31 Lower anterior teeth 15 Posterior teeth 14 **Materials and Baseline Nos:** Pekalux composite (light cured, densified, midway filled) and Gluma 2000 dentine bonding agent – 60 **Participant final Nos:** Not stated **Restoration final Nos:** Class III 14 Class IV 12 Class V 14 **Tooth type final Nos:** Upper anterior teeth 22 Lower anterior teeth 9 Posterior teeth 9 **Materials final Nos:** 40 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Glass ionomer lining in deepest parts of class III and IV* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Mechanical retention in some cases*	**Replaced restorations** 6 months 1/60 12 months 2/60 24 months 2/60 60 months 4/40 No specific statistical analysis.	It is difficult to comment on generalisability due to insufficient detail in paper. Three operators were used who were also the assessors. **Our classification for analysis** Gluma 2000 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Berry and Osborne 1989) 830 **Year:** 1989 **Country:** USA **Aim:** To compare the clinical performance of 2 enamel only bonded composites with the same composites dentine bonded in class III cavities **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (3) modified USPHS **Environment:** University/Hospital **Clinicians:** 2 **Evaluators:** 2 (training and calibration not stated) **Sponsorship:** Johnson & Johnson	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** Class III – 192, paired design **Tooth types and Baseline Nos:** Permanent. **Materials and Baseline Nos:** a) Aurafil (unknown) and etch 46 b) Certain (light cured, microfilled) and etch 45 c) Aurafil and dentine bonding system 53 d) Certain and dentine bonding system 48 Dentine bonding system not marketed – based on a Bis-GMA autopolymerising phosphorus ester based system **Participant final Nos:** Not stated **Restoration final Nos:** Class III – 176 **Tooth type final Nos:** Not stated **Materials final Nos:** months 12 24 a) 45 42 b) 42 42 c) 51 50 d) 42 42 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Where required* ***Etch:*** *Yes in a) & b)* ***Enamel bond:*** *Yes in a) & b)* ***Dentine adhesive:*** *Yes in c) & d)* ***Light/Chemical cure:*** *Light* ***Other:*** *Mechanical retention*	**Replacement of restorations** Months 12 24 a) 0/45 0/42 b) 0/42 0/42 c) 0/51 0/50 d) 0/42 0/42 Some suggestion that marginal discoloration and marginal adaptation worse with dentine bonded restorations. Statistical tests only on degradation of restoration.	This study is not a test of dentine bonding agents alone as mechanical retention was also used. Generalisability is limited by the university environment. **Our classification for analysis** Dentine bonding system not marketed – based on a Bis-GMA autopolymerising phosphorus ester based system group 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Horsted-Bindslev, Knudsen et al. 1996) 399 **Year:** 1996 **Country:** Denmark **Aim:** To evaluate the clinical performance of 2 experimental formulation modifications of the original Gluma system (one now marketed as Gluma 2000) and a hybrid composite (Pekafill) in non retentive Class V cavities **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (5) restoration failure (loss) also modified USPHS **Environment:** University/Hospital **Clinicians:** 1 **Evaluators:** Not stated **Sponsorship:** Bayer AG, Germany	**Participants and Baseline Nos:** 40 patients **Restoration Type(s) and Baseline Nos:** Paired, non retentive Class V – 40 pairs (80 restorations) **Tooth types and Baseline Nos:** Permanent Incisor 11 Canines 11 Premolar 49 Molar 9 **Materials and Baseline Nos:** Both a & b were primed using Gluma 2000 -1 primer then bonded and restored with one of the following a) HEMA, Bis-GMA, glutaraldehyde, acetic acid & tetrahydrofuran dentine bonding agent (Bayer 667/1)+Pekafill (light cured, densified, midway filled) b) Gluma 2000-2 adhesive (Bayer 667/2)+ Pekafill **Participant final Nos:** Not stated **Restoration final Nos:** 70 at 36 months **Tooth type final Nos:** Not stated **Materials final Nos:** months 12 24 36 a) 40 39 36 b) 40 38 34 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Not specifically* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restoration failure (loss)** Months 12 24 36 a) 2/40 3/39 4/36 b) 1/40 3/38 4/34 A number of USPHS C ratings given for marginal adaptation and discoloration no further discussion regarding replacement **Marginal Adaptation** Months 12 24 36 a) 0/40 0/39 1/36 b) 0/40 0/38 1/34 **Marginal Discoloration** Months 12 24 36 a) 0/40 0/39 0/36 b) 1/40 1/38 2/34 No relationship between loss and upper or lower jaw position. No specific statistical analysis carried out for replacement/loss of restoration.	The authors did not discuss the outcome of the 'C' rated restorations. Generalisability is limited by university environment and single operator. **Our classification for analysis** glutaraldehyde, acetic acid & tetrahydrofuran dentine bonding agent group 1b Gluma 2000 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Krejci, Lutz et al. 1991) 208 **Year:** 1991 **Country:** Switzerland **Aim:** To assess the clinical effectiveness of cavity design and dentine adhesive on the success of Class V restorations. **Follow-up:** 6 months **Design:** (7) Other clinical trial **Criteria:** (2) modified USPHS **Environment:** Private practice **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 15 patients **Restoration Type(s) and Baseline Nos:** 28 Class V cavities **Tooth types and Baseline Nos:** 14 anterior; 14 posterior teeth **Materials and Baseline Nos:** a) box cavity, Durafil bond, Durafil (light cured, microfine) - 7 b) box cavity, glass ionomer/Durafil bond, Durafil - 7 c) saucer cavity, Gluma/, Clearfil New Bond, Clearfil F2 (light cured, densified, compact filled), - 7 d) V shaped cavity, Gluma/, Clearfil NB, Clearfil F2 - 7 **Participant final Nos:** 15 **Restoration final Nos:** 28 **Tooth type final Nos:** As above **Materials final Nos:** 100 % recall. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes (all CaOH except (b))* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restoration failure (loss)** **6 months** 0/7 0/7 0/7 0/7 No specific statistical analysis	The generalisability is limited by the length of study, small numbers of restorations, the groups were not comparable and the single operator. **Our classification for analysis** Durafil bond group 3 Gluma / Clearfil New Bond group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Ziemiecki, Dennison et al. 1987) 313 **Year:** 1987 **Country:** USA **Aim:** To evaluate the retention of non retentive Class V restorations using enamel etching and/or dentine bonding **Follow-up:** 12 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (5) failure **Environment:** Not stated **Clinicians:** 2 trained dentists **Evaluators:** 2 independent **Sponsorship:** Not stated	**Participants and Baseline Nos:** 37 patients **Restoration Type(s) and Baseline Nos:** Non retentive Class V – 171 **Tooth types and Baseline Nos:** Assumed permanent Maxillary arch 117 (68.4%) Mandibular arch 54 (31.6%) Maxillary premolar & canines 85 (49.7%) **Materials and Baseline Nos:** a) Scotchbond, Silar (autopolymerizing, microfine) composite 54 b) Scotchbond, Silux (light cured, microfine) composite 66 c) Bevel/etch enamel, Scotchbond + Silux 51 **Total 171** **Participant final Nos:** 37 at 6 and 12 months **Restoration final Nos:** 171 at 6 and 12 months **Tooth type final Nos:** None lost – as above **Materials final Nos:** None lost – as above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Only group c* ***Lining:*** *Not stated* ***Etch:*** *Only group c* ***Enamel bond:*** *Only group c* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Group a chemical, other groups light cured* ***Other:*** *Not stated*	**Failure due to total loss restoration** Months 6 12 a) 7/54 (13%) 15/54 (28%) b) 9/66 (13.6%) 13/66 (20%) c) 0/51 (0%) 5/51 (10%) **Sensitivity** Preoperatively 29% Immediately after treatment 14.6% 6 months 8.2% 12 months 3% Retention rate higher in maxilla than mandible (6% higher at 6 months and 14.9% higher at 12 months) No specific statistical analysis At each time period the retention was less in the mandibular.	Authors report results in percentages which we have been converted. The authors report that beveling and etching adjacent enamel (group c) increased the retention of the restorations. Generalisability is limited by the short follow-up. **Our classification for analysis** Scotchbond group 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Qvist and Strom 1993) 477 **Year:** 1993 **Country:** Denmark **Aim:** To compare the clinical quality and durability of Class III composite restorations completed with 2 modifications of the conventional acid etch technique **Follow-up:** 132 months **Design:** (8) Randomised controlled trial **Criteria:** (2) Own criteria **Environment:** University/Hospital **Clinicians:** 1 **Evaluators:** 2 (one being operator/assessor) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 35 patients **Restoration Type(s) and Baseline Nos:** Class III - 52 pairs (104) **Tooth types and Baseline Nos:** 52 pairs – of incisors and canines **Materials and Baseline Nos:** a) bevel/etch enamel margins only, Silar (autopolymerizing, microfine) b) Butt margin/etch enamel/NPG-GMA & ethanol solution (dentine bonding solution) sprayed into cavity/ re-etch enamel, Silar 52 paired cavities **Participant final Nos:** 132 months, 30 patients **Restoration final Nos:** 45 paired Class III cavities **Tooth type final Nos:** 45 paired anterior teeth **Materials final Nos:** Months (a) (b) baseline 52 52 24 51 51 48 50 50 72 48 48 132 45 45 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Group a only* ***Lining:*** *Yes (CaOH)* ***Etch:*** *Group a only* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Group b only* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Mechanical retention*	**Replaced restorations** Months (a) (b) 24 1/51 1/51 48 2/50 2/50 72 2/48 2/48 132 8/45 7/45 Survival rates similar for both groups Estimated 120 months survival = 89% (95 CI 83-96%) Estimated 132 months survival = 84% (95 CI 76-91%)	Because of etched enamel and mechanical retention this study is not a true test of the dentine bonding agent. Generalisability is limited by university environment and single operator. **Our classification for analysis** NPG-GMA & ethanol group 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Heymann, Sturdevant et al. 1988; Bayne, Heymann et al. 1991; Heymann, Sturdevant et al. 1991) 762/174 (571 – not directly relevant) **Year:** 1988/1991 **Country:** USA **Aim:** To evaluate the clinical performance of 2 dentine adhesives in conjunction with 3 composite materials and several technique variations in Class V cavities **Follow-up:** 24 months **Design:** (8) Randomised controlled trial **Criteria:** (5) restoration failure, also modified USPHS and post operative sensitivity **Environment:** University/Hospital **Clinicians:** Not stated **Evaluators:** 2 (training and calibration Not stated) **Sponsorship:** Dentsply/NIH-NIDR grant	**Participants and Baseline Nos:** Not stated adults 21-80 years **Restoration Type(s) and Baseline Nos:** 178 Class V **Tooth types and Baseline Nos:** 64 – anterior; 93 – premolar; 21 – molar teeth **Materials and Baseline Nos:** Prisma-fil (light cured, densified midway filled), Prisma Universal Bond Prisma Micro-Fine (light cured, microfine), Prisma Universal Bond Silux (light cured, microfine), Scotchbond Application techniques:- 1. Acid etch enamel followed by 1 coat dentine adhesive to enamel and dentine 2. Acid etch enamel followed by 2 coats dentine adhesive to enamel and dentine 3. Application of dentine adhesive to dentine, then acid etch enamel and finally application of dentine bonding to both enamel and dentine Composite / Application / n a) Prisma-fil 1 25 b) Prisma Micro-Fine 1 25 c) Silux 1 25 d) Prisma-Fil 2 26 e) Prisma Micro-Fine 2 25 f) Prisma-Fil 3 26 g) Prisma Micro-Fine 3 26 **Participant final Nos:** Not stated **Restoration final Nos:** 12 months 168 24 months 167 (sites seen) **Tooth type final Nos:** Not stated **Materials final Nos:** Months 12 24 a) 25 17 b) 25 21 c) 25 21	**Restoration failures (loss)** Failures are cumulative Months 12 24 a) 6/25 8/25 b) 4/25 4/25 c) 4/25 4/25 d) 5/23 7/23 e) 2/23 2/23 f) 6/24 10/24 g) 4/23 4/23 Of the 39 restorations lost 22 occurred before the 6 month recall. No statistical difference between using one or two coats of bond (application 1) **At 12 months** Prisma-fil 17 failures Prisma Micro-fine 10 No statistical difference. **At 24 months** Prisma-fil had statistically more failures than Prisma Microfine ($p<0.01$) **Occlusal stress** 31 failures in 13 patients. 12 patients with positive rating for occlusal stress. Positive association to failure $p<0.05$ At 24 months 12 of 16 patients with failures had positive occlusal stress ($p<0.01$) **Age** Logistic regression failures increased in older patients ($p<0.01$) at both 12 and 24 months. **Sensitivity** Pre-operative sensitivity improved and was gone in most groups at	In this study results suggest that the bonding systems used had little effect on retention. However, failure may be related to occlusion, patients' age, dental arch and restorative material. Generalisability is limited by the university environment. Please note that there is a difference between the final number of sites examined (167) and the final number of restorations seen (139). **Our classification for analysis** Prisma universal bond group 2 Scotchbond group 3

	d) 23 19 e) 23 23 f) 24 16 g) 23 22 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes (usually)* ***Bevelled enamel:*** *Yes* ***Lining:*** *Deep cavities only (CaOH)* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Occlusal load assessed*	12 months. The exception was group (f) where still 10% of sample continued to suffer sensitivity.	

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Alhadainy and Abdalla 1996) 792 **Year:** 1996 **Country:** Egypt **Aim:** To clinically evaluate the performance of 4 adhesive systems in non retentive Class V composite restorations **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (5) restoration failure (loss) **Environment:** University/hospital **Clinicians:** Not stated **Evaluators:** 2 independent assessors **Sponsorship:** Not stated	**Participants and Baseline Nos:** 38 patients **Restoration Type(s) and Baseline Nos:** 80 non retentive Class V cavities **Tooth types and Baseline Nos:** Not stated (assumed permanent) **Materials and Baseline Nos:** a) Clearfil Photobond, Clearfil Photoanterior (light cured, densified, compact filled) 20 b) Scotchbond Multipurpose, Silux plus (light cured, microfine) 20 c) Syntac, Heliomolar (light cured, microfine) 20 d) Gluma 2000, Pekalux (light cured, densified, midway filled) 20 **Participant final Nos:** Not stated **Restoration final Nos:** 75 Class V **Tooth type final Nos:** Not stated **Materials final Nos:** After 24 months a) Clearfil Photobond/Clearfil Photoanterior 20 b) Scochbond Multipurpose/Silux plus 20 c) Syntac/Heliomolar 18 d) Gluma 2000/Pekalux 17 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes(CaOH)* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restoration failure (loss)** Months 24 a) 0/20 b) 0/20 c) 2/18 d) 3/17 Differences between groups are not significant.	Generalisability is limited by the university environment and the small numbers. **Our classification for analysis** Clearfil Photobond group 1b Scotchbond Multipurpose group 1b Syntac group 1b Gluma 2000 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Van Meerbeek, Peumans et al. 1994; Van Meerbeek, Peumans et al. 1996) 448/389 **Year:** 1994/1996 **Country:** Belgium **Aim:** Evaluate older and modern dentine bonding systems (total 10) using 2 cavity designs in non retentive class V cavities **Follow-up:** 36 months **Design:** (5) Prospective study with historical controls **Criteria:** (5) Restoration failure (loss) **Environment:** Hospital/University **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Bayer Dental, 3M and Cavex Kuraray	**Participants and Baseline Nos:** 346 patients of Dental School **Restoration Type(s) and Baseline Nos:** Non retentive Class V – 1177 **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Dentine bond, Composite / No bevel/etch / Bevel/etch a) Scotchbond, Silux (light cured microfine) 66 90 b) Gluma, Lumifor (light cured, densified, midway filled) 59 115 c) Clearfil NewBond, Clearfil Ray (light cured, densified, compact filled) 41 141 d) Scotchbond2,Silux plus (light cured, microfine) 47 66 e) Tenure, Herculite XR (light cured, densified, midway filled) 31 32 f) Tripton, Opalux (light cured, densified, compact filled) 29 40 g) Bayer Exerimental 1, Pekafil (light cured, densified, midway filled) 49 51 h) Bayer Exerimental 2, Pekafil (light cured, densified, midway filled) 51 52 i) Clearfil Liner Bond, Clearfil Photo anterior (light cured, densified, compact filled) 55 55 j) Scotchbond Multipurpose, Silux plus (light cured, microfine) 54 53 **Total 482 695** **Participant final Nos:** Not stated **Restoration final Nos:** Not stated for groups 1-6 Groups 7-10 –361 Class V (initially 420) **Tooth type final Nos:** Not stated	**Restoration failure (loss)** **No bevel/ no intentional etch group** Months 6 12 24 36 g) 3/44 3/38 9/40 10/39 h) 6/48 13/49 17/48 15/40 i) 0/49 0/49 0/41 0/48 j) 0/51 0/49 1/48 2/49 ***Bevel/etch group*** Months 6 12 24 36 g) 2/49 2/31 3/46 4/39 h) 1/45 3/41 15/46 15/45 i) 0/52 0/52 0/47 1/52 j) 1/50 1/49 1/45 1/49 No details of actual numbers given for groups a to f so results are given in percentages for these groups. **Restoration failure (% loss)** **No bevel/no intentional etch group** Months 6 12 24 36 a) 15 33 42 NS b) 44 52 67 NS c) 16 7 2 NS d) 5 14 13 23 e) 13 13 30 28 f) 38 41 55 54 g) 7 8 23 26 h) 13 27 35 38 i) 0 0 0 0 j) 0 0 2 4 **Bevel/etch group** Months 6 12 24 36 a) 2 8 15 NS b) 0 2 7 NS c) 2 2 1 NS d) 0 0 0 0	Results from the whole study are tabulated but, because no details of recall numbers for groups a to f are given, analysis is only done on groups g to j. This study suggests that bevel/etch procedure improved performance of "poorest" systems. The nobevel, no intentional etch groups may have etched enamel during priming phase. The authors suggest that newer systems showed improvements over older systems (oldest systems a, b and c; newer systems i and j). Systems which removed smear layer and demineralised the dentine surface appeared clinically more effective. However further work is needed because of the problems with analysis. Generalisability is limited by the university setting and use of rubber dam. **Our classification for analysis** Scotchbond group 3 Gluma group 1b Clearfil NewBond group 3 Scotchbond 2 group 1b Tenure group 1b

	Materials final Nos: Not stated for groups 1-6 No bevel/etch Bevel/etch g) Bayer Exerimental 1 39 39 h) Bayer Exerimental 2 40 45 i) Clearfil 48 52 j) Scotchbond Multipurpose 49 49 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes some –see above* ***Lining:*** *Not stated* ***Etch:*** *Yes some – see above* ***Enamel bond:*** *Some* ***Dentine adhesive:*** *Yes All* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	e) 0 0 3 3 f) 3 3 3 5 g) 4 6 7 10 h) 4 7 34 33 i) 0 0 0 2 j) 2 2 2 2 Some survival analysis carried out	Tripton group 2 Bayer Exerimental 1 group 1b Bayer Exerimental 2 group 1b Clearfil Liner Bond group 1b Scotchbond Multipurpose group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Boghosian 1996) 395 **Year:** 1996 **Country:** USA **Aim:** To evaluate the 2 year performance of Optibond dentine bonding system in Class V non retentive cavities **Follow-up:** 24 months **Design:** (3) Prospective Case Series **Criteria:** (3) Modified USPHS **Environment:** Hospital/University **Clinicians:** 1 (previously standardised) **Evaluators:** 2 calibrated **Sponsorship:** Sybron Dental Specialities	**Participants and Baseline Nos:** 35 patients **Restoration Type(s) and Baseline Nos:** 80 non retentive Class V **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Enamel etch (30 secs), Optibond, and Herculite XRV (light cured, densified, midway filled), 48 Enamel etch (30secs), dentine “etch” (15 secs), Optibond, Herculite XRV, 32 **Participant final Nos:** 29 patients at 24 months **Restoration final Nos:** 69 Class V restorations **Tooth type final Nos:** Not stated **Materials final Nos:** 69 restorations in total **Techniques:** ***LA:*** *No* ***Rubber dam:*** *No (cotton wool/retraction cord)* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *In one group* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**24 months** No retention failure No replacement from any other cause **Sensitivity** At baseline 14 patients with 24/80 After restoration, 12 patients with 23 restorations reported no sensitivity No significant differences between groups.	All cavities used etched enamel therefore limiting the test on the dentine bond. Generalisability is limited by single operator and university setting. **Our classification for analysis** Optibond group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Jordan and Suzuki 1993) 495 **Year:** 1993 **Country:** Canada **Aim:** Evaluate the clinical effectiveness of Tenure, Allbond 2, Gluma 2000 and Prisma Universal bond 3 when used with their respective composites in non retentive Class V cavities **Follow-up:** 12 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (5) restoration failure (loss) **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** None stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 411 Non retentive Class V **Tooth types and Baseline Nos:** Not stated – (assumed permanent) **Materials and Baseline Nos:** Dentine bond / Composite / n a) Prisma Universal Bond. / Prisma / 100 (light cured, densified, midway filled) b) Gluma 2000 / Pekafil / 95 (light cured, densified, midway filled) c) Tenure / Marathon / 115 (light cured, densified, compact filled) d) Allbond2 / BisfilM / 101 (unknown) **Participant final Nos:** Not stated **Restoration final Nos:** See below **Tooth type final Nos:** Not stated **Materials final Nos** Months / 6 / 12 a) Not stated / 98 b) Not stated / 91 c) 110 / Not stated d) 100 / Not stated **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *No* ***Etch:*** *Not specifically* ***Enamel bond:*** *Not specifically* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failure by restoration loss** Months / 6 / 12 a) Not stated / 1/98 b) Not stated / 0/91 c) 2/110 / Not stated d) 0/100 / Not stated No replacements for any other reason No specific statistical analysis	Insufficient information to assess generalisability but it is a short study. **Our classification for analysis** Prisma Universal Bond group 2 Gluma 2000 group 1b Tenure group 1b Allbond 2 group 1a

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Tyas 1994; Tyas 1996) 410, 456 **Year:** 1996 **Country:** Australia **Aim:** To compare the clinical performance of five dentine bonding agents **Follow-up:** 36 months **Design:** (7) Other clincial trial **Criteria:** (5) Restoration failure (loss) **Environment:** Dental institution **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 15 patients aged 36 - 79 years mean age 63 years **Restoration Type(s) and Baseline Nos:** 100 restorations in cervical abrasion erosion lesions **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Materials allocated clockwise around the mouth a) Silux (light cured, microfine), All Bond 20 b) Clearfil Photo Anterior (light cured, densified, compact filled), Photobond 20 c) Silux, Denthesive 20 d) Silux, Pertac 20 e) Silux, Geristore 20 **Participant final Nos:** Not stated **Restoration final Nos:** See materials **Tooth type final Nos:** Not stated **Materials final Nos:** a) 20 b) 20 c) 20 d) 20 e) 20 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *No intentional enamel bond, for All-Bond their dentine etch was used (phosphoric acid)* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Yes, manufacturer's instructions followed* ***Light/Chemical cure:*** *According to group* ***Other:*** *No*	**Restoration failure (loss)** Months 3 6 12 24 36 a) 1/20 4/20 5/18 5/20 5/20 b) 3/20 4/20 4/19 5/20 5/20 c) 8/20 10/20 10/18 10/20 11/20 d) 13/20 16/20 17/20 18/19 18/20 e) 3/20 5/20 7/18 12/19 13/20	This study reports major differences in the survival rates of these dentine bonding agents. All Bond and Photobond have better retention rates than the other materials. It is difficult to comment on generalisability because of the lack of detail reported. **Our classification for analysis** All Bond group 1a Photobond group 1b Denthesive group 1b Pertac group 3 Geristore group 1b The name 'Geristore' is now used to market a different material which is a resin modified glass ionomer. Pertac is classified as a 3 because it leaves the smear layer intact.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Bohm, Schutze et al. 1991) 573 (German) **Year:** 1991 **Country:** Germany **Aim:** To compare 5 dentine adhesive composite systems in cervical lesions **Follow-up:** 12 or 24 months **Design:** (7) Other clinical trial **Criteria:** (5) restoration failure (loss) **Environment:** Dental institution (assumed) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 15 patients, each had a maximum of 2 fillings in a system **Restoration Type(s) and Baseline Nos:** 143 cervical lesions in shallow to medium non carious with a smooth shiny surface. Optically and mechanically dull surfaces were excluded. **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Silux (light cured, microfine), Scotchbond 36 Silux, Dentin adhesive 36 Valux (light cured, densified, compact filled), Scotchbond LC 23 P 30 (light cured, densified, compact filled), Scotchbond 28 Cavex Clearfil F2 (autopolymerising, macrofilled), Clearfil New Bond 20 **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos:** Not stated **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *10% rubber dam* ***Bevelled enamel:*** *Yes* ***Lining:*** *Calcium hydroxide* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *As materials details* ***Light/Chemical cure:*** *All light cure except Cavix Clearfil F2* ***Other:*** *Not stated*	**Restoration failure (loss)** Months 12-15 24-30 a) 2/36 4/36 b) 8/36 10/36 c) 3/23 NS d) 1/28 2/28 e) 3/20 7/20	It is difficult to comment on generalisability because of the lack of detail reported. **Our classification for analysis** Scotchbond group 3 Scotchbond LC group 3 Clearfil New Bond group 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Ianzano and Gwinnett 1993) 466 **Year:** 1993 **Country:** USA **Aim:** To evaluate the long term clinical performance of All Bond 2 dentine bonding system (total etch, wet bonding system) in non retentive Class V cavities **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (5) Restoration failure (loss) and post-op sensitivity **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** 2 (training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 36 patients **Restoration Type(s) and Baseline Nos:** 78 - Non retentive Class V **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** 78 All Bond 2, (total etch, wet bonding system), Bis-fil M (unknown) **Participant final Nos:** 6 months – 34 12 months – 34 **Restoration final Nos:** 6 months – 73 12 months – 71 **Tooth type final Nos:** Not stated **Materials final Nos:** 6 months – 73 12 months – 71 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No (cotton wool rolls)* ***Bevelled enamel:*** *Yes* ***Lining:*** *Not stated* ***Etch:*** *Yes (etch enamel and dentine)* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restoration failure (loss)** 6 months 1/73 12 months 1/71 No replacement restorations for any other reason **Sensitivity** Baseline 15/78 teeth 6 months 0/73 teeth 12 months 0/71 teeth No specific statistical analysis	The study shows that restoration of these cavities eliminated sensitivity. It is difficult to comment on generalisability because of the lack of detail reported but this is a short study. **Our classification for analysis** All Bond 2 group 1a

Table A4 Studies comparing amalgam with composite restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hendriks, Letzel et al. 1986) 660 **Year:** 1986 **Country:** The Netherlands **Aim:** To compare amalgam with 3 brands of composite in Class I and Class II cavities in premolars and molars **Follow-up:** 36 months **Design:** (7) Clinical trial **Criteria:** (3) Modified USPHS **Environment:** University (assumed) **Clinicians:** 3 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 49 (no further details) **Restoration Type(s) and Baseline Nos:** Class I & Class II (no data on numbers) Composite (Profile, light cured microfine): 56 restorations Composite (Estic microfill, light cured microfine): 58 restorations Composite (Adaptic R, autopolymerising macrofilled): 60 restorations Amalgam (Dispersalloy): 58 restorations **Tooth types and Baseline Nos:** Premolar and molars Composite (Profile):61% Premolars; 39% Molars Composite (Estic microfill): 53%Premolars; 47%; Molars Composite (Adaptic R): 62%Premolars; 38%Molars Amalgam (Dispersalloy): 35%Premolars; 62%Molars **Participant final Nos:** 47 **Restoration final Nos:** Composite (Profile): 54 Composite (Estic microfill): 56 Composite (Adaptic R): 58 Amalgam (Dispersalloy): 56 **Tooth type final Nos:** Not stated **Materials final Nos.** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Yes, for composites* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures after 36 months** Composite (Profile): 2/54 (both due to bulk fracture) Composite (Estic microfill):2/56 (1 due to recurrent caries, 1 due to pulpal injury) Composite (Adaptic R): 3/58 (2 due to bulk fracture, 1 due to pulpal injury) Amalgam (Dispersalloy): 1/56 (due to recurrent caries) After 36 months the results for anatomic form for the composite Estic microfilled was the only one acceptable of the 3 composite resins studied	The authors reported that the main reason for failure of composites was bulk fracture and the failure rate was similar between amalgam and composite restorations. Generalisability is limited due to probable University setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Knibbs and Smart 1992) 361 **Year:** 1992 **Country:** UK **Aim:** To compare amalgam and composite in Class I and Class II cavities in premolars and molars **Follow-up:** 36 months **Design:** (7) Clinical Trial **Criteria:** (3) Modified USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 2 (1 evaluator was also operator) **Sponsorship:** Ivoclar	**Participants and Baseline Nos:** 30 dental students (14 male, 16 female; age range 17-23 years) **Restoration Type(s) and Baseline Nos:** Amalgam: Class I:18; Class II:34 Composite: Class I:18; Class II:34 **Tooth types and Baseline Nos:** Amalgam:40 Premolars; 7 Molars Composite:33 Premolars; 14 Molars **Materials and baseline Nos:** Amalgam (Dispersalloy, low Cu):54 Composite (Heliomolar RO, light cured microfine):54 **Participant final Nos:** 30 **Restoration final Nos:** 54 pairs **Tooth type final Nos:** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *26 placed with dam (breakdown not given)* ***Bevelled enamel:*** *No* ***Lining:*** *Amalgam:ZincOxide/Eugenol; Composite:Calcium hydroxide* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures at 12 months** Amalgam:1/54 Composite:0/54 **Failures at 36 months** Amalgam: 1/54 Composite:4/54 (3 due to recurrent caries) No reports of postoperative sensitivity No Significant difference between results at 12 months and at 36 months Possibly a reflection of small sample size	Length of follow up variable (24- 41 months) Generalisability is limited due to sample type (all dental students), University setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Collins, Bryant et al. 1998) 460/863 **Year:** 1994-1998 **Country:** Australia **Aim:** To compare amalgam with 3 brands of composite in Class I and Class II cavities **Follow-up:** 96 months **Design:** (7) Clinical Trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 3 evaluators; (2 evaluators from pool of 3 assessed restorations; calibration or training not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 72 (age range of <u>most</u> patients 13-18 years) **Restoration Type(s) and Baseline Nos:** Mixture of CI & CII restorations with systematic allocation of materials, breakdown not stated Composite (Heliomolar): 83 Composite (Herculite): 82 Composite (P30APC): 83 Amalgam (Dispersalloy): 82 **Tooth types and Baseline Nos:** Mixture of premolars and molars **Materials and baseline Nos:** Composite (Heliomolar; light cured microfine): 83 Composite (Herculite; light cured, densified, midway filled): 82 Composite (P30APC; ; light cured, densified, compact filled): 83 Amalgam (Dispersalloy; high Cu): 82 **Participant final Nos:** 36 months:48; 96 months:46 **Restoration final Nos:** <u>Months 36 98</u> Composite (Heliomolar): 56 47 Composite (Herculite): 54 46 Composite (P30APC): 57 50 Amalgam (Dispersalloy): 56 50 **Tooth type final Nos:** 36 months: Not stated 96 months: Molars 90.6%; Premolars 9.4% **Materials final Nos:** As stated in restoration final nos. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *For 95% of restorations* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *For composites* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light*	**Failures/replacements at 36 months** Composite (Heliomolar): 4/56 2 replacements due to deep pit in central fossa; 2 due to bulk fracture Composite (Herculite): 4/54 1 replacement due to deep pit in central fossa, 1 bulk fracture, 1 void at margin, 1 recurrent caries Composite (P30APC): 0 Amalgam (Dispersalloy): 0 **Failures/replacements at 8 years** Composite (Heliomolar): 9/55 4 bulk fracture, 2 recurrent caries, 1 caries not associated with restoration,1 non-margin defect, 1 extracted for orthodontic reasons Composite (Herculite): 8/52 1 bulk fracture, 4 recurrent caries, 1 non-margin defect, 2 unknown Composite (P30APC):5/54 1 bulk fracture, 1 recurrent caries, 1 pulpitis, 2 unknown Amalgam (Dispersalloy):3/52 2 bulk fracture and 1 recurrent caries	This 8 year study, in a fluoridated area, concluded that failure rate of composite restorations in posterior teeth was two to three times higher than amalgam Generalisability is limited due to likely University setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Norman, Wright et al. 1990) 228 **Year:** 1990 **Country:** USA **Aim:** To compare amalgam and composite in Class I and Class II cavities in premolars and molars **Follow-up:** 60 months **Design:** (6) Prospective with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** ICI	**Participants and Baseline Nos:** 62 **Restoration Type(s) and Baseline Nos:** Mixture of Class I & Class II with random allocation of materials Composite: 107 Amalgam: 53 **Tooth types and Baseline Nos:** Composite: 55 Premolars; 45 Molars Amalgam: 40 Premolars; 60 Molars Materials and baseline Nos: Composite (Occlusin; light cured, densified, compact filled): 107 Amalgam (Dispersalloy): 53 **Participant final Nos:** Not stated **Restoration final Nos:** Composite: 79 Amalgam: 37 **Tooth type final Nos:** Not stated **Materials final Nos:** As stated above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide when required* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures at 60 months** Amalgam (Dispersalloy):2/37 (1 failure due to recurrent caries and 1 due to tooth fracture) Composite (Occlusin):3/79 (all failures due to recurrent caries) The only statistically significant result was a poorer marginal integrity for Amalgam and greater wear rate for Composite	There is a large difference in sample size between groups at baseline. This is one of the longest studies published and the authors conclude that there is little difference between the failure rates of amalgam and composite in Class I and II cavities Limited generalisability due to likely University setting and the high drop-out rate of subjects with composites (approximately 25%).

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Gibson, Richardson et al. 1982) 622 **Year:** 1982 **Country:** USA **Aim:** To compare amalgam and composite in Class I cavities in permanent molars **Follow-up:** 24 months **Design:** (7) Clinical Trial **Criteria:** (3) Own criteria **Environment:** Hospital/Private practice (assumed) **Clinicians:** 1 dentist + 1 student **Evaluators:** 2 dentists **Sponsorship:** Not stated	**Participants and Baseline Nos:** Participant Nos. not stated Age:9-16 years **Restoration Type(s) and Baseline Nos:** Class I restorations, no randomisation reported Amalgam (Dispersalloy): 84 Composite (Adaptic; autopolymerising macrofilled): 84 **Tooth types and Baseline Nos:** 84 pairs in permanent molars **Participant final Nos:** Not stated **Restoration final Nos:** 12 months: 66 pairs 24 months: 61 pairs **Tooth type final Nos:** Molars **Materials final Nos:** As stated above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes, but type not stated* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	**Failures** **12 months** Amalgam: 0 Composite: 3 **24 months** Amalgam: 0 Composite: 3	Authors report replacement and failure only failures used in this review. This study suggests that amalgam has lower failure rate than composite. Generalisability is limited due to University setting and small number of operators.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Nelson, Osborne et al. 1980) 134 **Year:** 1980 **Country:** USA **Aim:** To compare amalgam with 2 brands of composite in primary molars **Follow-up:** 36 months **Design:** (7) Clinical Trial **Criteria:** (2) Modified USPHS **Environment:** Hospital **Clinicians:** 1 **Evaluators:** 2 (no mention of training or calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 50 children (3 materials placed in each subject) **Restoration Type(s) and Baseline Nos:** Not stated, randomisation of materials used **Tooth types and Baseline Nos:** Primary molars, 50 sets **Materials and baseline Nos:** Composite (Adaptic; autopolymerising macrofilled):50 Composite (Adaptic RO; autopolymerising macrofilled):50 Amalgam (Dispersalloy):50 **Participant final Nos:** Not stated **Restoration final Nos:** Composite (Adaptic):28 Composite (Adaptic RO:27 Amalgam (Dispersalloy):29 **Tooth type final Nos:** Not stated **Materials final Nos:** As stated above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *For composites* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures** **12 months** Composite (Adaptic):0/49 Composite (Adaptic RO):1/47 (failure due to recurrent caries) Amalgam (Dispersalloy):0/49 **24 months** Composite (Adaptic):0/38 Composite (Adaptic RO):1/37 Amalgam (Dispersalloy):0/36 **36 months** Composite (Adaptic):0/28 Composite (Adaptic RO):1/27 Amalgam (Dispersalloy):0/29 No significant difference in caries rate between groups	This study reported little difference in failure rate between amalgam and composite Generalisability is limited due to hospital setting, single operator and high drop out rate (approaching 50% at 36 months).

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Oldenburg, Vann et al. 1987) 315 **Year:** 1987 **Country:** USA **Aim:** To compare amalgam and two types of composite resin in primary and permanent molars **Follow-up:** 24 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** 4 **Evaluators:** 2 calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 41 children (no further details) **Restoration Type(s) and Baseline Nos:** Class I & Class II in primary/ permanent teeth **Tooth types and Baseline Nos:** Primarymolars Class I: 87, Primary molars Class II: 115, Permanent molars Class I: 183 **Materials and Baseline Nos:** Composite (H120 – experimental): Primary Class I: 40, Primary Class II: 51, Permanent Class I: 94 Amalgam (Sybralloy): Primary Class I: 27, Primary Class II: 34, Permanent Class I: 89 Composite (Ful-Fil; light cured, densified, midway filled): Primary Class I: 20, Primary Class II: 30, Permanent Class I: 0 **Participant final Nos:** Not stated **Restoration final Nos:** Composite (H120):142/185 (77%) Amalgam (Sybralloy): 120/150 (80%) Composite (Ful-Fil): 43/50 **Tooth type final Nos:** Not stated **Materials final Nos:** As above **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Composite only* ***Dentine adhesive:*** *No* ***Light/Chemical cure*** *Light cured*	**Failures at 24 month** Composite (H120):4/185 (2/50 primary, 2/92 permanent) Amalgam (Sybralloy):4/150 (4/35 primary, 0/85 permanent) Composite (Ful-Fil):2/50 (2/43 primary) 64 primary molars lost due to exfoliation	The allocation of materials to teeth cannot be deduced. There are differences in the number of restorations placed at baseline and it is not possible to separate results into primary and permanent teeth. The authors reported extensive wear in permanent teeth restored with H120. Generalisability limited due to University setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Johnson, Bales et al. 1992) 340 **Year:** 1992 **Country:** USA **Aim:** To compare amalgam in Class I and Class II cavities in premolars and molars with two different hybrid composite materials **Follow-up:** 36 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 2 **Evaluators:** 2 (calibrated, no details given) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27 subjects (no further information) **Restoration Type(s) and Baseline Nos:** Class I & Class II Composite (P-30): Class I:23; Class II:17 Composite (Bis-Fil):Class I:26; Class II:22 Amalgam (Dispersalloy) Class I: 30, Class II:10 **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Composite (P-30; light cured, densified, compact filled):Premolar: 11; Molar: 29 Composite (Bis-Fil; light cured, densified, compact filled):Premolar: 10; Molar: 38 Amalgam: Premolar: 8; Molar: 32 **Participant final Nos:** 12 months: 23 subjects 24 months: 18 subjects 36 months: 23 subjects **Restoration final Nos:** Composite (P-30):37 Composite (Bis-Fil):41 Amalgam 37 **Tooth type final Nos:** Not stated **Materials final Nos** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide or glass ionomer* ***Enamel bond:*** *Composites only* ***Dentine adhesive:*** *Bis-Fil (Scotchbond)* ***Light/Chemical cure:*** *Composite light cured*	**No failures** reported at 36 months Significantly less wear for amalgam ($p<0.05$) Wear less in premolars compared to molars Wear less in Class I compared to Class II restorations	This study found that both amalgam and composite restorations were clinically acceptable after 3 years. Generalisability is limited due to University setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Prati and Montanari 1988) 309 **Year:** 1988 **Country:** Italy **Aim:** To compare amalgam in Class I and II cavities in molars and premolars with a microfilled composite and a hybrid composite **Follow-up:** 36 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 2 **Evaluators:** 2 (evaluators also operators; calibration during study not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 38 patients (21 females, 17 males; average age 30.5 ± 10.5 years) **Restoration Type(s) and Baseline Nos:** Mixed Class I and Class II, randomisation not reported Microfine composite: (Silar):27 Class I;18 ClassII Hybrid composite: (P-10):30 Class I;18 Class II Amalgam (Dispersalloy):30 Class I;25 Class II **Tooth types and Baseline Nos:** Microfine composite:27 Premolars; 18 Molars Hybrid composite:25 Premolars; 23 Molars Amalgam 29Premolars; 26 Molars **Materials and Baseline Nos:** Composite (Silar; autopolymerising, microfilled) 45 Composite (P-10; autopolymerised, densified, compact filled) 48 Amalgam (Dispersalloy) 55 **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos::** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Enamel bond:*** *Composites only* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	**Failures at 36 months** Microfine composite: 56% Hybrid composite 17% Amalgam: 9% Microfine composite (Silar) had significantly higher 'unsatisfactory' restorations at 36 months ($p < 0.001$) No statistically significant difference between the hybrid composite and amalgam Main reason for replacing restorations appears to be recurrent caries Microfine composite: 20% Hybrid composite 6.2% Amalgam:5.5%	Interesting early study which compares chemically cured composite resins with amalgam Study suggests that Amalgam had fewer numbers of unsatisfactory restorations at 3 years, but this was not statistically significant from microfine composite Unable to determine number of restorations assessed at 3 years No mention of randomisation method No mention of calibration of assessors Weak study design Limited generalisability due to University setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Phillips, Avery et al. 1971; Phillips, Avery et al. 1972; Phillips, Avery et al. 1973) 70/87/102 **Year:** 1971 - 1973 **Country:** USA **Aim:** To compare amalgam and composite in Class II cavities in posterior teeth **Follow-up:** 36 months **Design:** (7) Clinical Trial **Criteria:** (2) Modified USPHS **Environment:** Not stated **Clinicians:** 2 (no further details) **Evaluators:** 2 (no further details) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 73 (no further details) **Restoration Type(s) and Baseline Nos:** Class II, 124 restorations in each group with random allocation of materials, paired design **Tooth types and Baseline Nos:** Premolars and molars; balance not stated **Materials and baseline Nos:** Composite (Adaptic; autopolymerising, macrofilled): 124 Amalgam (Velvalloy): 124 **Participant final Nos:** Not stated **Restoration final Nos:** 12 months: Composite: 92; Amalgam: 92 24 months: Composite: 92; Amalgam: 92 36 months: Composite: 44; Amalgam: 44 **Tooth type final Nos:** Not stated **Materials final Nos:** As stated above in restoration final nos. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Composite chemically cured* ***Other:*** *Not stated*	**Failures** **Composite** (Adaptic) 12 months 2 replacements (reasons unknown) 24 months 4 replacements (colour match grade C) 36 months No further replacements **Amalgam** (Velvalloy) 12 months 3 replacements (marginal adaptation grade C) 24 months 1 replacement (due to suspected hairline crack) 36 months 2 replacements (marginal adaptation grade C)	The study reported similar rates of replacement restorations between composite and amalgams. Generalisability is compromised by the high drop out rate at 24 and 36 months.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Osborne, Gale et al. 1973) 48 **Year:** 1973 **Country:** USA **Aim:** To compare amalgam and composite in Class II cavities in premolar and molar teeth **Follow-up:** 24 months **Design:** (7) Clinical Trial **Criteria:** (2) Modified USPHS **Environment:** Prison **Clinicians:** 2 **Evaluators:** 2 with training (no mention of calibration throughout study) **Sponsorship:** No	**Participants and Baseline Nos:** 65 paired restorations (up to 3 pairs per patient) **Restoration Type(s) and Baseline Nos:** All Class II, randomisation method not reported Composite (Concise, autopolymerising, macro-filled):103 Amalgam (Velvalloy):103 **Tooth types and Baseline Nos:** Premolars and molars (but balance not stated) **Participant final Nos:** Not stated **Restoration final Nos:** 12 months :73 of each 24 months 59 of each **Tooth type final Nos:** Not stated **Materials final numbers** Composite: 59 Amalgam: 59 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Composite only* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical cure composite* ***Other:*** *Not stated*	**Failures** No failures in Amalgam group Failures in Composite group Baseline 1/103 12 months 1/73 24 months 1/59 Failure due to marginal adaptation (grade C)	Generalisablity is limited by high drop out rate, small sample size and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Robinson, Rowe et al. 1988) 308 **Year:** 1988 **Country:** UK **Aim:** To compare amalgam and composite in Class I and II cavities in premolars and molars **Follow-up:** 36 months **Design:** (7) Clinical Trial **Criteria:** (3) Modified USPHS **Environment:** Hospital **Clinicians:** 1 **Evaluators:** 2 used from pool of 3 (1 evaluator was also clinician) **Sponsorship:** ICI	**Participants and Baseline Nos:** 58 patients (30 females; 28 males) Average age 28 years (range:19-66 years) **Restoration Type(s) and Baseline Nos:** Mixed Class I & Class II, random allocation of material in ratio 3 composites to 1 amalgam Composite (Occlusin; light cured, densified, compact filled):98 Amalgam (Aristalloy):27 **Tooth types and Baseline Nos:** Composite: Class I 11% Class II 89% Amalgam: Class II 100% **Participant final Nos:** Not stated **Restoration final Nos:** Composite: 78 Amalgam: 20 **Tooth type final Nos:** Not stated **Materials final numbers** Composite: 78 Amalgam: 20 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *82% of cases (no further details)* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide and Zinc phosphate if required* ***Enamel bond:*** *Composite only* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Not stated*	**Failures** No amalgam restorations replaced Composite replacements 8/78 (10%) 3 due to bulk fracture 2 due to marginal leakage 2 due to sensitivity 1 due to discolouration No direct link found between size of restoration and failure.	The randomisation method resulted in a large difference in sample size between groups, additionally no Class 1 amalgams were placed. The study reported a higher failure rate in composite restorations. Generalisability is limited due to University setting and the single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Holan, Chosack et al. 1996) 397 **Year:** 1996 **Country:** USA **Aim:** To compare composite in Class II restorations in primary molars with combined amalgam-composite restorations **Follow-up:** 6 to 30 months **Design:** (3) Prospective case series **Criteria:** (4) Modified USPHS **Environment:** Hospital (assumed) **Clinicians:** Not stated **Evaluators:** 2 or 3 assessors **Sponsorship:** Not stated	**Participants and Baseline Nos:** 12 boys, 6 girls(mean:8 years; range:6.5 – 12 years) **Restoration Type(s) and Baseline Nos:** Class II in primary molars with random allocation of materials Amalgam (Silmet) and Composite (Estilux posterior; autopolymerising, macrofilled) **with** Amalgambond: 14 Amalgam (Silmet) and Composite (Estilux posterior) **without** Amalgambond: 17 Composite (Estliux posterior): 11 **Tooth types and Baseline Nos:** All deciduous molars (22 maxillary/17 mandibular) **Participant final Nos:** Not Stated **Restoration final Nos:** Amalgam and Composite **with** Amalgambond: 12 Amalgam and Composite **without** Amalgambond: 16 Composite (Estliux posterior): 11 **Tooth type final Nos:** Not stated **Materials final Nos** As above **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *Amalgambond in 1st group* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures** No failures or postoperative pain recorded No replacements due to recurrent caries	This is an unusual study examining combined amalgam/composite restorations in primary molars. Generalisability is limited by the small sample size and assumed hospital environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Derkson, Richardson et al. 1982; Derkson, Richardson et al. 1983; Derkson, Richardson et al. 1984; Holan, Chosack et al. 1996) 647/648/649 **Year:** 1982/83/84 **Country:** Canada **Aim:** To compare amalgam and composite in Class I, Class II and MOD cavities in primary and permanent teeth **Follow-up:** 36 months **Design:** (7) Clinical Trial **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** Dental students **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 101 children (no further details) **Restoration Type(s) and Baseline Nos:** Mixed Class I, Class II, MOD, randomisation of materials is not described. **Tooth types and Baseline Nos:** Mixed primary and permanent molars (no further details) **Materials and baseline Nos:** Amalgam (Dispersalloy): 135 Composite (Profile; light cured microfine): 143 **Participant final Nos:** Not stated **Restoration final Nos:** 12 months :Amalgam:135 Composite:143 rests. 24 months:Amalgam:104 Composite:121 rests. 36 months Amalgam:90 Composite:94 **Tooth type final Nos:** Not stated **Materials final Nos:** As stated in restoration final nos. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Composite chemically cured* ***Other:*** *Not stated*	**Failures** **Amalgam** (Dispersalloy) 12 months:1/135 24 months:4/104 36 months:2/90 **Composite** (Profile) 12 months:6/143 24 months:7/121 36 months:6/94	It is not possible to deduce the proportion of permanent to primary teeth. The study found that more composite restorations were replaced than amalgam restorations Generalisability is limited due to University setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Roberts, Folio et al. 1992) 804 **Year:** 1992 **Country:** USA **Aim:** To compare amalgam and composite in Class II and MOD cavities in posterior teeth **Follow-up:** 36 months **Design:** (7) Clinical Trial **Criteria:** (3) USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2; calibrated at baseline and annually after this **Sponsorship:** Not stated	**Participants and Baseline Nos:** 34 patients **Cavity Type(s) and Baseline Nos:** Class II randomisation not described Amalgam group:30 Composite group:31 MOD Amalgam group:25 Composite group:21 **Tooth types and Baseline Nos:** Permanent. Amalgam group:27 premolars, 28 molars Composite group:35 premolars, 18 molars **Materials and baseline Nos:** Amalgam (Dispersalloy):55 restorations Composite (Herculite; light cured, densified, midway filled):53 restorations **Participant final Nos:** Not stated **Cavity final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos** Amalgam: 51 restorations Composite:53 restorations **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Ca(OH)2* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures** 2 amalgam restorations replaced; 1 due to recurrent caries, 1 due to fracture 5 composite restorations replaced; 2 due to recurrent caries, 2 due to fracture and 1 due to pulpal hyperaemia No significant difference ($p>0.05$)	Examiners may also have been operators. The study reported no difference in performance between amalgam and composite. Generalisability is limited by the likely university setting, the possibility that dental students formed the sample and the small sample size.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Barr-Agholme, Oden et al. 1991) 184 **Year:** 1991 **Country:** Sweden **Aim:** To compare light cured composite and amalgam in primary molars **Follow-up:** 24 months **Design:** (7) Clinical Trial **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 2 (trained) **Evaluators:** 2 (calibration not stated; operators were also examiners) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 43 children (mean age 6.4 years) **Restoration Type(s) and Baseline Nos:** All Class II restorations, no mention of randomisation **Tooth types and Baseline Nos:** All primary molars **Materials and baseline Nos:** Amalgam:55 Composite:64 **Participants final Nos:** Not stated **Restorations final Nos:** 43 Amalgam (Dispersalloy) 52 Composite (P30, light cured densified compact filled) **Tooth type final Nos** 95 **Materials final Nos** 43 amalgam, 52 composite **Techniques:** ***LA:*** *When required* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *calcium hydroxide* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures** 2 years Amalgam: 11 (3 due to recurrent caries, 8 due to marginal degradation) Composite: 3 (2 due to marginal discolouration, 1 recurrent caries) Difference in replacement rates between amalgam and composite significant ($p<0.005$)	Generalisability is limited by the university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Morris, Barkin et al. 1979) 150 **Year:** 1979 **Country:** USA **Aim:** To compare Class II amalgam and composite in primary molars **Follow-up:** 42 months **Design:** (7) Clinical Trial **Criteria:** (2) Own criteria **Environment:** Not stated **Clinicians:** 3 (training not stated) **Evaluators:** 3 (calibration not stated; at least 2 operators were also evaluators) **Sponsorship:** Califomia Dental Association	**Participants and Baseline Nos:** 34 children (age 4-7 years) **Restoration Type(s) and Baseline Nos:** Amalgam (Aristalloy) 47 Class II Composite (Prestige) (composition unknown) 48 **Tooth types and Baseline Nos:** 95. All primary molars, random allocation of materials **Materials and baseline Nos:** Amalgam:47 Composite:48 **Participant final Nos:** 25 primary molars **Restoration final Nos:** Amalgam:16 Composite:9 **Tooth type final Nos** 25 **Materials final Nos:** 16 amalgam, 9 composite **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light and chemical* ***Other:*** *Not stated*	**Failures** **Amalgam** 6 months:0/35 9 months:0/31 18 months:0/25 24 months:0/19 30 months:0/18 36 months:2/18 42 months:1/16 **Composite** 6 months:0/34 9 months:1/30 18 months:5/24 24 months:2/15 30 months:3/12 36 months:0/9 42 months:0/9	Insufficient detail to comment on generalisability in this study of primary teeth.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Walls, Murray et al. 1988; Welbury, Walls et al. 1990) 307/239 **Year:** 1988/1990 **Country:** UK **Aim:** To compare minimal occlusal amalgam and composite restorations in permanent molars **Follow-up:** 60 months **Design:** (7) Clinical Trial **Criteria:** (3) Modified USPHS **Environment:** University **Clinicians:** 2 (initial cavity preparation carried out by student) **Evaluators:** 1 (trained and calibrated, but assessor changed after 2 years) **Sponsorship:** Medical Research Council	**Participants and Baseline Nos:** 126 (age range 6-17 years) **Restoration Type(s) and Baseline Nos:** 174 pairs of Class I restorations, materials not randomised, amalgam placed first. **Tooth types and Baseline Nos:** All permanent molars **Materials and baseline Nos:** Amalgam (Amalcap; lathe cut conventional) 174 Composite (Prisma-fil; light cured, densified, midway filled) 174 **Participant final Nos:** Not stated **Restoration final Nos:** Amalgam: 109 Composite: 109 **Tooth type final Nos** As baseline. **Materials final Nos:** Amalgam:109 Composite:109 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *No (cotton wool)* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures at 60 months** Amalgam: 11/109 (all due to recurrent caries) Composite: 5/109 (5 due to recurrent caries, 3 due to loss of restorative materials, some failed on one than more category) Mean survival times quoted (months) Amalgam:61.5 months (SE 1.6) Composite:63.3 months (SE 1.4) No significant difference between these mean survival times	Although there was no significant difference between restoration types the composite restorations occupied 5% of the occlusal surface compared with 25% for the amalgams. Generalisability is limited by the university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mertz-Fairhurst, Call-Smith et al. 1987; Mertz-Fairhurst, Williams et al. 1991; Mertz-Fairhust, Williams et al. 1991; Mertz-Fairhurst, Richards et al. 1992; Mertz-Fairhurst, Smith et al. 1992; Mertz-Fairhurst, Adair et al. 1995; Mertz-Fairhurst, Curtis et al. 1998) 765/201/763/351/330/432/806 **Year:** 1988-1998 **Country:** USA **Aim:** To compare composite sealant restorations with Class I amalgam restoration and sealed Class I amalgam restorations in premolars and molars **Follow-up:** 120 months **Design:** (7) Clinical Trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** NIH/NIDR	**Participants and Baseline Nos:** 123 patients (43 male; 80 female; age 8-52 years(median 23 years)) **Restoration Type(s) and Baseline Nos:** Randomisation of material reported. Class I amalgam, unsealed: 79 Class I amalgam sealed: 77 Composite sealant: 156 **Tooth types and Baseline Nos:** Premolar and molar (numbers not stated) **Materials and baseline Nos:** Amalgam (Dispersalloy):79 Amalgam (Dispersalloy) sealed with Delton (assumed) :77 Composite (Miradapt; autopolymerising, macrofilled) sealed with Delton: 156 **Participant final Nos:** 85 **Restoration final Nos:** Class I amalgam, unsealed: 41 Class I amalgam sealed: 44 Composite sealant: 85 **Tooth type final Nos** Not stated **Materials final Nos:** As above **Techniques:** ***LA:*** *When required* ***Rubber dam:*** *No* ***Bevelled enamel:*** *For composite* ***Lining:*** *Not stated* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures** 25 clinical failures overall, 5 unrelated to study **Failures at 120 months** Class I amalgam, unsealed: 7/41 (14%) Class I amalgam sealed: 1/44 (2%) Composite sealant: 12/85 (14%) Survival analysis using Wilcoxon's test showed that there was no difference in the longevity in the unsealed amalgam and the composite sealant restoration. The sealed amalgam restoration had significantly better longevity ($p= 0.0242$)	This unique 120 month study reported that sealed amalgam restorations perform better than unsealed amalgam or composite sealant restorations in Class I cavities. Generalisability is limited due to probable university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Eames, Strain et al. 1974) 59 **Year:** 1974 **Country:** USA **Aim:** To compare amalgam and composite in posterior teeth **Follow-up:** 48 months **Design:** (6) Prospective with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 31 (no further details) **Restoration Type(s) and Baseline Nos:** Class II, 43 pairs **Tooth types and Baseline Nos:** Not stated **Materials and baseline Nos:** Composite (Adaptic; autopolymerising, macrofilled): 48 Amalgam (Velvalloy): 48 **Participant final Nos:** Not stated **Restoration final Nos:** 12 months: 43 pairs 24 months: 33 pairs 36 months: 30 pairs **Tooth type final Nos** Not stated **Materials final Nos:** 12 months: Composite: 43; Amalgam: 43 24 months: Composite: 33; Amalgam: 33 36 months: Composite: 30; Amalgam: 30 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Dam used if possible* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not stated* ***Other:*** *Not stated*	**Failures** **Composite** 12 months: 1/43 (recurrent caries) 24 months: 0/33 36 months: 1/30 (anatomic form grade C) **Amalgam** 12 months: 0/43 24 months: 1/33 (anatomic form grade C) 36 months: 1/30 (anatomic form grade C)	Generalisability is limited by small sample size and likely university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Tonn, Ryge et al. 1980) 129 **Year:** 1980 **Country:** USA **Aim:** To evaluate the clinical performance of a new, carvable composite restorative material in class II restorations in primary molars **Follow-up:** 24 months **Design:** (7) Clinical trial **Criteria:** (4) USPHS **Environment:** Private practice **Clinicians:** 1 **Evaluators:** 2 independently with concensus **Sponsorship:** Lee Pharmaceuticals	**Participants and Baseline Nos:** Age 3 years 2 mths to 8 years 9 mths (mean 5 years 9 mths) No baseline nos **Restoration Type(s) and Baseline Nos:** 105 paired Class II **Tooth types and Baseline Nos:** Primary molars 67 contralateral, 38 adjacent pairs **Materials and Baseline Nos:** 105 Epoxydent (autopolymerised, macrofilled composite) , 105 Optaloy (amalgam) **Participant final Nos:** 7 patients lost to follow up, 5 teeth exfoliate **Restoration final Nos:** 76 paired class II **Tooth type final Nos:** Primary molars 76 pairs **Materials final Nos:** 76 Epoxydent (composite) , 76 Optaloy (amalgam) **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes (Handi-Liner)* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light (2 step cure)* ***Other:*** *All cavities, custom matrix, 30 sec cleansing with 50% citric acid.. Composites contoured after set. Amalgams polished 24 hrs to 7 days.*	**Failures at 24 months** Composite: 13/76 Amalgam: 6/76 Amalgam restoration anatomical form statistically better at 6, 12, 24 months ($p < 0.01$) No other statistically significant findings	Authors report that composite should not be recommended due to excessive wear compared to amalgam although no statistical difference in failure rates were shown. Generalisable to restorations in primary molars placed under dam but is limited by the single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Fukushima, Setcos et al. 1988) 291 **Year:** 1988 **Country:** USA **Aim:** To assess cavosurface marginal breakdown between 7 posterior composites and 1 amalgam **Follow-up:** 24 months **Design:** (7) clinical trial **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 505 (203 Class I, 195 MO/DO, 107 MOD) **Tooth types and Baseline Nos:** Permanent (215 premolars, 290 molars, 257 maxillary, 248 mandibular) **Materials and Baseline Nos:** Occlusin (light cured, densified, compact filled) 110 (36 class I, 52 MO/DO, 22 MOD) ICI exp (composition unknown) 57 (18 class I, 34 MO/DO, 5 MOD) Herculite Syringeable (light cured, densified, midway filled) 50 (28 class I, 14 MO/DO, 8 MOD) Herculite Condensible (light cured, densified, midway filled) 42 (19 class I, 16 MO/DO, 7 MOD) Heliomolar Radiopaque (light cured, densified, midway filled) 48 (26 class I, 17 MO/DO, 5 MOD) Kerr 1 exp (composition unknown) 66 (32 class I, 24 MO/DO, 10 MOD) Kerr 2 exp (composition unknown) 59 (24 class I, 19 MO/DO, 16 MOD) Dispersalloy 73 (20 class I, 19 MO/DO, 34 MOD) **Participant final Nos:** Not Stated **Restoration final Nos:** 472 **Tooth type final Nos:** Not Stated **Materials final Nos:** Occlusin 104 ICI exp 54 Herculite Syringeable 49 Herculite Condensible 38 Heliomolar Radiopaque 48 Kerr 1 exp 57 Kerr 2 exp 51 Dispersalloy 71 **Techniques:** No details reported	**Failures** No failures for any material at 24 months	Limited detail makes it difficult to comment but generalisability is limited due to university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Roberts, Broring et al. 1985) 610 **Year:** 1985 **Country:** USA **Aim:** To compare a strontium glass filled composite with amalgam in primary molars **Follow-up:** 24 months **Design:** (7) Clinical trial **Criteria:** (3) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not Stated **Evaluators:** 2 independent but not trained **Sponsorship:** SS White Co (partial)	**Participants and Baseline Nos:** 37 children **Restoration Type(s) and Baseline Nos:** 111 (Class I and II) **Tooth types and Baseline Nos:** 111 Primary molars **Materials and Baseline Nos:** 61 Composite (Profile; light cured microfine) 50 Amalgam (Ease) **Participant final Nos:** Not stated **Restoration final Nos:** 67 at 24 months **Tooth type final Nos:** 67 primary molars **Materials final Nos:** 37 Profile 30 Ease **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide (all composite, when indicated amalgam)* ***Etch:*** *Yes 60 sec (composite)* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Standard class I and II preparations, copal varnish with amalgam. Amalgams polished within 48 hours. Composite syringed*	**Failures at 12 months** 2/52 Profile fail (1 caries, 1 marginal adaption) 0/41 Ease fail **Failure at 24 months** 1/37 Composite(Profile) (1 caries & 1 marginal adaption) 3/30 Amalgam (Ease) (1 each caries, marginal adaption, anatomical form) No significant differences between the two materials (chi square) for any of the failure criteria Loss of teeth between 12 and 24 mths due to exfoliation	This study reported no significant difference between the performance of Profile (composite) and Ease (amalgam) in primary molars over a 2 year period. Generalisability is limited due to likely University setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mair 1995; Mair 1998) 854/865 **Year:** 1995-1998 **Country:** UK **Aim:** To compare two types of amalgam and three types of composite in posterior teeth **Follow-up:** 120 months **Design:** (6) Prospective case series with concurrent controls **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** 1 **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Routine patients/1st year dental students **Restoration Type(s) and Baseline Nos:** Class II/ MOD restorations: 103, random allocation of materials. **Tooth types and Baseline Nos:** Premolars and molars **Materials and baseline Nos:** Amalgam (New True Dentalloy): 30 Amalgam (Solila Nova):30 Composite (Clearfil Posterior; light cured, densified, compact): 30 Composite (Occlusin; ; light cured, densified, compact): 30 Composite (P-30; ; light cured, densified, compact): 30 **Participant final Nos:** Not stated **Restoration final Nos:** Amalgam (New True Dentalloy): 15 Amalgam (Solila Nova):20 Composite (Clearfil Posterior): 18 Composite (Occlusin): 20 Composite (P-30): 18 **Tooth type final Nos** Not stated **Materials final Nos:** As stated above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Clearfil: Clearfil bonding agent Occlusin: Occlusin bond P-30: Scotchbond* ***Light/Chemical cure:*** *Composites ;light cured* ***Other:*** *Not stated*	**Failures** **0-36 months** Occlusin: 3 (1 bulk fracture, 1 due to poor contact and food packing and 1 due to periodontal pain) P-30: 1 (recurrent caries) New True Dentalloy: 1 (bulk fracture) Solila Nova: 1 (tooth fracture) **36-60 months** Occlusin: 2 (due to pulpal irritation) **60-120 months** Clearfil posterior: 1 (tooth fracture) P-30: 1 (recurrent caries)	This long term study reported low failure rates for amalgam and composite Generalisability is limited due to University setting, single operator and study population (some dental students).

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hoyer, Gangler et al. 1988) 285 (Gerrman) **Year:** 1988 **Country:** East Germany **Aim:** To compare the clinical performance of a hybrid composite (P10) with amalgam (Dentargam) **Follow-up:** 48 months **Design:** (7) Clinical trial **Criteria:** (2) Modified USPHS **Environment:** Dental institution (polyclinic) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 24 patients aged 18 -25 years **Restoration Type(s) and Baseline Nos:** 131 Class 1 restorations **Tooth types and Baseline Nos:** Premolars and molars **Materials and Baseline Nos:** Composite P10 (; light cured, densified, compact): 76 Amalgam Dentargam: 55 **Participant final Nos:** Not stated **Restoration final Nos:** 101 **Tooth type final Nos:** Not stated **Materials final Nos:** P10: 61 Dentargam: 40 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes for both groups* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes, Adhesor* ***Etch:*** *Composite etched* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Scotchbond* ***Light/Chemical cure:*** *Not stated* ***Other:*** *Not stated*	**Failures** At 48 months no composites had failed and 2 amalgams had fractured.	Generalisability is limited by the small sample size, the university setting, and the possible use of dental students as subjects.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	**Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques**	**Results (to include failures and summary of statistical analysis)**	**Commentary**
Author & No: (Stangel and Barolet 1990) 254 **Year:** 1990 **Country:** Canada **Aim:** Clinical evaluation of 2 posterior composites in Class I and II preparations compared to a dispersed phase amalgam alloy **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2 (with consensus) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 32, no further details **Restoration Type(s) and Baseline Nos:** Almost equal number of Class I and II, randomisation of materials **Tooth types and Baseline Nos:** Not stated; clearly permanent posterior **Materials and Baseline Nos:** 42 Heliomolar composite (light cured, microfine); 38 Fulfil composite (light cured, densified midway filled); 31 Dispersalloy **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 37 Heliomolar; 32 Fulfil; 25 Dispersalloy **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes - for composites* ***Enamel bond:*** *Yes – for composites* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Mechanical preparation:*** *Yes*	**Failures** 5 Class I and II composites restorations in permanent posterior teeth failed and 0 amalgams after 24 months 2 Heliomolar restorations replaced within 10 weeks because of intractable sensitivity At 24 months 1 further Heliomolar had failed, 2 Fulfil, 0 Dispersalloy 3 Heliomolar failures (light cured, microfilled) and 2 Fulfil failures (light cured, densified midway-filled)	Generlisability is limited due to university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Leinfelder, Sluder et al. 1975; Leinfelder, Sluder et al. 1980) 847/837 **Year:** 1975/80 **Country:** USA **Aim:** Clinical evaluation of 5 types of composite resin and one amalgam alloy in Class I, II, III and V cavities **Follow-up:** 24 & 60 months **Design:** (6) Prospective study with concurrent controls. **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 4 **Evaluators:** 4 (clinicians, trained) **Sponsorship:** NIH Research Grant	**Participants and Baseline Nos:** Dental students, numbers not stated **Restoration Type(s) and Baseline Nos:** 899: 308 Class I, 155 Class II, 374 Class III, 62 Class V Randomisation of clinician, material and restoration **Tooth types and Baseline Nos:** Permanent: details not stated **Materials and Baseline Nos:** 174 Adaptic (autopolymerising, macrofilled) 61 Class I, 18 Class II, 83 Class III, 12 Class V 178 Blendant (autopolymerising, macrofilled): 64 Class I, 26 Class II, 77 Class III, 11 Class V 170 Concise (autopolymerising, macrofilled): 63 Class I, 25 Class II, 70 Class III, 12 Class V 146 DFR (autopolymerising, macrofilled): 52 Class I, 13 Class II, 67 Class III, 14 Class V 88 Sevriton (acrylic): 77 Class III, 11 Class V 143 Velvalloy (amalgam): 68 Class I, 73 Class II, 2 Class V **Participant final Nos:** Not stated **Restoration final Nos:** At 60 months: 418: 91 Class 1, 56 Class II, 218 Class III, 53 Class V **Tooth type final Nos:** Not stated **Materials final Nos:** 60 months — Class I / Class II / Class III / Class V 74 Adaptic: 16 / 3 / 46 / 9 81 Blendan: 17 / 8 / 45 / 11 73 Concise: 24 / 4 / 34 / 11 72 DFR: 15 / 8 / 41 / 8 53 Sevriton (acrylic): - / - / 46 / 7 65 Velvalloy (amalgam): 19 / 33 / 6 / 7 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Mechanical retention:*** *Yes*	**Failures** No failures at 24 months 3 failures at 60 months; 1 composite (not detailed), 2 Sevriton through recurrent caries 19 failures for marginal staining at 60 months: 3 Adaptic, 2 Blendant, 3 Concise, 0 DFR, 11 Sevriton 0 failures for amalgam but the figures for amalgam do not add up between papers and are excluded from the analysis	Generalisability is limited by university setting with dental student subjects.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Olmez and Ulusu 1995) 419 **Year:** 1995 **Country:** Turkey **Aim:** To compare the clinical effectiveness of Amalgambond Plus when used to bond amalgam (Alloxy) or composite (Superlux Molar Resin) to deep cavities in primary teeth **Follow-up:** 15 months **Design:** (7) Other clinical trial **Criteria:** (2) Restoration replacement using USPHS (training and criteria not stated) **Environment:** University/Hospital **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 25 children (6-9 years) **Restoration Type(s) and Baseline Nos:** Large Class II (mesio-occlusodistal) – 50 **Tooth types and Baseline Nos:** All Primary molars – no other details given **Materials and Baseline Nos:** Amalgambond Plus to bond both:- Amalgam Alloxy : 23 Composite Superlux Molar Resin (light cured, microfine : 22 **Participant final Nos:** 22 children **Restoration final Nos:** 50 **Tooth type final Nos:** 50 **Materials final Nos:** Amalgam Alloxy: 23 Composite Superlux : 22 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *If pulp visible* ***Etch:*** *Not stated* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *mechanical retention*	**Failures** 0/23 amalgam & 0/22 composite lost/replaced **Pain** Amalgam Composite baseline 5/23 3/22 3months 0/23 0/22 No subsequent hypersensitivity Patient excluded from study at 2nd visit (6m) because of acute "symptoms". Not included in data given No specific statistical analysis	Generalisability limited by University environment.

Table A5 Studies comparing amalgam with glass ionomer cement restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wood, Maxymiw et al. 1993) 483 **Year:** 1993 **Country:** Canada **Aim:** To compare a Glass Ionomer Cement with Amalgam in patients with xerostomia following radiotherapy for head and neck cancer. A further aim was to examine the effect of daily fluoride gel use on longevity of these materials. **Follow-up:** 2 years **Design:** (7) Other Clinical Trial **Criteria:** (2) Use of Criteria **Environment:** Hospital **Clinicians:** 2 **Evaluators:** 2 (Calibration & Training Not Stated) **Sponsorship:** Not Stated	**Participants and Baseline Nos:** Patients = 36 (no further details) **Restoration Type(s) and Baseline Nos:** 108 Restorations All Class II box only restorations Half of patients used daily application of NaF gel (pH=5.8) **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Glass Ionomer –(Material not stated) 54 Silver Amalgam (Sybralloy) 54 **Participant final Nos:** Patients =34 **Restoration final Nos:** 86 restorations **Tooth type final Nos:** Not stated **Materials final Nos:** 35 GIC with topical fluoride 8 GIC without topical fluoride 35 amalgam with topical fluoride 8 amalgam without topical fluoride **Techniques:** ***LA:*** *Yes (all restorations)* ***Rubber dam:*** *Yes –where possible* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not stated* ***Other:*** *Not stated*	**Failures at 24 months** GIC Mean failure time = 8.52 months Amalgam mean failure time = 8.4 months No significant difference between the failure times of the 2 materials In the group of patients whose fluoride use was >50% compliance 32/35 GIC failed 0/35 Amalgam failed In the group of patients whose fluoride use was <50% compliance 0/8 GIC failed 6/8 Amalgam failed In patients who used NaF gel, glass ionomer restorations failed and amalgam restoration did not (P<0.0001) In patients who did not use NaF gel, glass ionomer restorations did not fail but amalgam restoration did (P<0.001)	This study recommended that amalgam in conjunction with fluoride gel should be used in patients with xerostomia to prolong the longevity of amalgam restorations Generalisablity limited to patients who had received radiotherapy

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	**Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques**	**Results (to include failures and summary of statistical analysis)**	**Commentary**
Author & No: (Walls, Murray et al. 1988; Welbury, Walls et al. 1991) 217/306 **Year:** 1989 - 1991 **Country:** UK **Aim:** To compare an amalgam and glass ionomer cement in deciduous molars **Follow-up:** 5 yrs **Design:** (6) Prospective with concurrent controls **Criteria:** (3) Modified USPHS **Environment:** Hospital **Clinicians:** 2 **Evaluators:** 2(trained and calibrated) **Sponsorship:** MRC	**Participants and Baseline Nos:** 76 patients (age 5-11yrs) **Restoration Type(s) and Baseline Nos:** Mixed Class I & Class II, randomisation of materials but amalgam always placed first **Tooth types and Baseline Nos:** All primary molars **Materials and baseline Nos:** Glass ionomer (Ketacfil):119 Amalgam (Amalcap):119 **Participant final Nos:** Not stated **Restoration final Nos:** 99 in each group **Tooth type final Nos:** All primary molars **Materials final Nos:** 99 in each group **Techniques:** ***LA:*** *As required* ***Rubber dam:*** *No (Cotton wool rolls)* ***Bevelled enamel:*** *No* ***Lining:*** *Glass ionomer:Calcium hydroxide; Amalgam: Zinc oxide/eugenol* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Glass ionomer:chemical* ***Other:*** *Not stated*	**Failures** Amalgam:24 failures Glass iononer:39 failures Reasons for failure GIC Am Total loss 17 4 Partial loss 6 3 Fractured restoration 6 5 Fractured tooth 3 1 Recurrent caries 7 11 15 restorations in teeth that were exfoliated – 9 Glass ionomer/6 Amalgam **Median Survival Times as quoted by authors** Amalgam: 41.4 months (SE2.24) Glass Ionomer: 33.4 months (SE2.26) Difference between mean survival times statistically significant (P<0.01 Mantel-Cox)	These studies reported a greater longevity for amalgam in deciduous molars compared to glass ionomer over the whole length of the study although in the initial phases the longevity of the two materials was similar. Generalisability is limited due to University setting.

Table A6 studies comparing amalgam with cermet restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Chu, King et al. 1996) 502 **Year:** 1996 **Country:** Hong Kong **Aim:** To compare two types of cermet cement with amalgam in deciduous molars **Follow-up:** 24 months **Design:** (6) Prospective with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** Not stated **Sponsorship:** Partially supported by ESPE	**Participants and Baseline Nos:** 20 children (7-9 years) **Restoration Type(s) and Baseline Nos:** Class I and Class II, paired amalgam with one other **Tooth types and Baseline Nos:** Primary molars: 20 in each group **Materials and baseline Nos:** Cermet (Ketac-Silver; capsulated):10 Cermet (Chelon-Silver; hand mix):10 Amalgam (Dispersalloy; high Cu):20 **Participant final Nos:** Not stated **Restoration final Nos:** 12 months Cermet (Ketac-Silver):7 Cermet (Chelon-Silver):9 Amalgam (Dispersalloy):16 24 months Cermet (Ketac-Silver):7 Cermet (Chelon-Silver):6 Amalgam (Dispersalloy):15 **Tooth type final Nos** Primary molars **Materials final Nos:** As stated above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *In majority of cases* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *No* ***Other:*** *Not stated*	**Failure** **12 months** Cermet (Ketac-Silver):0/7 Cermet (Chelon-Silver):0/9 Amalgam (Dispersalloy):0/16 **18 months** Cermet (Ketac-Silver):3/7 Cermet (Chelon-Silver):0/9 Amalgam (Dispersalloy):1/16 **24 months** Cermet (Ketac-Silver):4/7 Cermet (Chelon-Silver):0/6 Amalgam (Dispersalloy):3/15	Generalisability is limited due to presumed university setting, single operator and variable drop out rates.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hung and Richardson 1990) 226 **Year:** 1990 **Country:** Canada **Aim:** To compare amalgam and silver cermet cement in Class I & Class II cavities in primary molars **Follow-up:** 1 year **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 1 (assumed) **Evaluators:** 1 **Sponsorship:** Not Stated	**Participants and Baseline Nos:** 22 children (age 5-7 years) **Restoration Type(s) and Baseline Nos:** Class I:3, Class II:70, randomisation used to allocate materials **Tooth types and Baseline Nos:** All primary molars **Materials and baseline Nos:** Amalgam (Dispersalloy):33 Silver cermet (Ketac Silver):40 **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Cermet; chemically cured* ***Other:***	**Failures** At 12 Amalgam: None Cermet:16/40 All 16 restorations were Class II cavities and fractured 1/16 also had recurrent caries	This short term study reported the high failure rate of silver cermet cement in Class II cavities in primary molars Generalisability is limited due to likely University setting and the single operator.

Table A7 Summary of studies comparing composite with glass ionomer cement restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Osborne and Berry 1986) 592 **Year:** 1986 **Country:** USA **Aim:** To compare 2 different glass ionomer cements and a composite resin in Class III cavities **Follow-up:** 12 months **Design:** (6) Prospective with concurrent controls **Criteria:** (5) Restoration failure **Environment:** University **Clinicians:** 1 **Evaluators:** 2 (no mention of training or calibration) **Sponsorship:** ESPE	**Participants and Baseline Nos:** 24 (assuming each patient only received one set of restorations) **Restoration Type(s) and Baseline Nos:** All Class III restorations: 24 per group **Tooth types and Baseline Nos:** All incisors/canines (assumed) **Materials and baseline Nos:** Capsulated glass ionomer (Ketac Fil): 24 Hand mixed glass ionomer (Chelon): 24 Composite (Adaptic, autopolymerising macrofilled): 24 **Participant final Nos:** Capsulated glass ionomer (Ketac Fil): 24 Hand mixed glass ionomer (Chelon): 24 Composite (Adaptic): 24 **Restoration final Nos:** 24 restorations in each group **Tooth type final Nos** Not stated **Materials final Nos:** As stated in restoration final nos. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** Yes ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Composite chemically cured* ***Other:*** *Not stated*	No failures reported in any group at 12 months	Generalisability is limited by the university environment, the single operator, small sample size and short duration of the study.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (de Araujo, Araujo et al. 1998) 755 **Year:** 1998 **Country:** Brazil **Aim:** To compare a composite resin with a glass ionomer cement in Class III cavities in permanent teeth **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (4) Modified USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 2 – Trained & calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 21 **Restoration Type(s) and Baseline Nos:** 42 Class III, randomisation used to allocate materials, but method not stated **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Composite (Herculite XRV, light cured, densified, midway filled) = 21 Glass ionomer (Chelon-fil) = 21 **Participant final Nos:** 21 **Restoration final Nos:** 42 Class III **Tooth type final Nos:** Not stated **Materials final Nos:** Composite Resin (Herculite-XRV) = 21 Glass ionomer (Chelon-fil) = 21 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes (all restorations)* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes (all restorations)* ***Enamel bond:*** *Yes (all restorations)* ***Dentine adhesive:*** *Primer XR bond with composite* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *Not stated*	No failures in either group at 24 months	Generalisability is limited by the university setting (assumed), single operator and small sample size.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Matis, Cochran et al. 1996) 501 **Year:** 1996 **Country:** USA **Aim:** To compare 2 types of glass ionomer cement with composite in Class V cavities (further subsidiary aim was to investigate effect of immediate or delayed finishing of glass ionomer on retention) **Follow-up:** 120 months **Design:** (8) Randomised controlled trial **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 2 (with training and calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 30 (18 male, 12 female; mean age 58 years, range 29-76 years) **Restoration Type(s) and Baseline Nos:** Class V **Tooth types and Baseline Nos:** Glass ionomer (with immediate finish) Incisors:5, Canines:5, Premolars:18, Molars:2 Glass ionomer (with delayed finish) Incisors:3, Canines:7, Premolars:20, Molars:0 Glass ionomer (hand mixed) Incisors:3, Canines:2, Premolars:15, Molars:0 Composite Incisors:3, Canines:8, Premolars:15, Molars:3 **Materials and baseline Nos**: Glass ionomer (Ketac-Fil (capsulated)) with immediate finish:30 Glass ionomer (Ketac-Fil (capsulated)) with delayed finish:30 Glass ionomer (Chelon-Fil (hand mixed):30 Composite (Cervident, light cured,cannot categorize):29 **Participant final Nos:** Not stated **Restoration final Nos:** 18 in each group **Tooth type final Nos** Not stated **Materials final Nos:** 18 in each group **Techniques:** ***LA:*** *Topical for applying rubber dam clamp* ***Rubber dam:*** Yes ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *Not stated*	**Failure** **Glass ionomer (Ketac-Fil with immediate finish** 12 months:0/18 36 months:2/18 60 months:2/18 120 months:3/18 **Glass ionomer (Ketac-Fil with delayed finish** 12 months:0/18 36 months:0/18 60 months:1/18 120 months:3/18 **Glass ionomer (Chelon-Fil (hand mixed** 12 months:0/18 36 months:1/18 60 months:1/18 120 month:2/18 **Composite (Cervident)** 12 months:5/18 36 months:10/18 60 months:10/18 120 month:15/18 All glass ionomers showed statistically significantly greater retention than composite resin ($P<0.002$)	The authors suggest that the immediate or delayed finishing of glass ionomer restorations had no effect on failure rate. Generalisability is limited by likely university setting, high drop out rate in the first 12 months and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Matis, Carlson et al. 1991) 575 **Year:** 1991 **Country:** USA **Aim:** To evaluate the performance of two Glass Ionomers and a Composite Resin in non-carious cervical cavities. A subsidiary aim was to investigate the effect of delayed finishing of glass ionomers on longevity. **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 30 adults **Restoration Type(s) and Baseline Nos:** 119 Class V non-carious cervical lesions, materials allocated randomly to teeth using computer generated random numbers, paired study. **Tooth types and Baseline Nos:** Permanent (assumed) **Materials and Baseline Nos:** Glass ionomer (Ketac-Fil plus immediate finish) 30 Glass ionomer (Ketac-Fil plus delayed finish) 30 Glass ionomer (Chelon-Fil) 30 Composite (Cervident, light cured cannot categorize) 29 **Participant final Nos:** 30 adults **Restoration final Nos:** 96 Class V **Tooth type final Nos:** Not stated **Materials final Nos:** Glass ionomer (Ketac-Fil plus immediate finish) 30 Glass ionomer (Ketac-Fil plus delayed finish) 30 Glass ionomer (Chelon-Fil) 30 Composite Resin (Cervident) 29 **Techniques:** ***LA:*** *Topical –when necessary* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *Yes (composite only)* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *All GIC restorations were varnished, no mechanical retention*	**Restoration failures (loss)** **At 60 months** Glass ionomer (Ketac-Fil plus immediate finish) 3/30 Glass ionomer (Ketac-Fil plus delayed finish) 3/30 Glass ionomer (Chelon-Fil) 4/30 Composite resin (Cervident) 16/29	Authors report that delayed or immediate finishing of glass ionomer had no effect on longevity. The failure rate of composite resin in Class V non-carious lesions was much higher than glass ionomer. Generalisability is limited by the university environment. Although there is a small sample size the study lasted for 60 months.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Powell, Gordon et al. 1991; Powell, Gordon et al. 1992; Powell, Johnson et al. 1995) 416 & 336 & 179 **Year:** 1992-1995 **Country:** USA **Aim:** To compare a glass ionomer cement with a composite resin and a glass ionomer/composite sandwich restoration in Class V cavities **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (4) Modified USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** Not	**Participants and Baseline Nos:** 25 patients (mean age 70 years) **Restoration Type(s) and Baseline Nos:** 116 Class V abrasion/erosion lesions **Tooth types and Baseline Nos:** Glass ionomer cement Incisors/Canines 13 Premolars/molars 26 Composite resin/dentinal bonding agent Incisors/Canines 20 Premolars/molars 19 Composite resin/glass ionomer cement sandwich Incisors/Canines 18 Premolars/molars 20 **Materials and Baseline Nos:** Glass ionomer cement (ketac fil) 39 Composite resin/dentine bonding agent (Silux, light cured, microfilled with Scotchbond 2) 39 Composite resin/glass ionomer cement (Vitrebond) sandwich 38 **Participant final Nos:** 24 Patients **Restoration final Nos:** 110 Class V **Tooth type final Nos:** Not stated **Materials final Nos:** Glass ionomer cement 37 Composite resin/dentine bonding agent 37 Composite resin/dentine bonding agent/glass ionomer cement 36 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No – cotton rolls* ***Bevelled enamel:*** *Yes, both composite groups* ***Lining:*** *Yes, composite/GIC liner* ***Etch:*** *Yes, composite/dentine bonding agent* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Yes = Composite/dentine bonding agent* ***Light/Chemical cure:*** *Light, composite /dentine bonding agent* ***Other:*** *Not stated*	**Failure rates** Glass ionomer cement (Ketac fil) 12 months 1/34 24 months 1/39 36 months 1/38 Composite resin (Silux)/ dentine bonding agent (Scotchbond 2) 12 months 2/35 24 months 5/38 36 months 9/37 Composite resin (Silux)/glass ionomer cement (Vitrebond) sandwich 12 months 0/34 failed 24 months 0/38 failed 36 months 0/36 failed Failure rate of composite resin significantly higher than the other materials (Cochran Q test P=0.012) Two teeth were crowned and eliminated from the study. One subject moved	No mention of randomisation method for allocation of materials and no mention of the maximum number of restorations placed in a single patient (116 restorations placed in 25 patients). This study showed a higher failure rate of composite resin compared with glass ionomer when used to restore Class V cervical abrasion/ erosion lesions Generalisability is limited by university environment and the number of restorations placed per patient. **Classification for our analysis** Scotchbond 2 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Neo, Chew et al. 1996) 400 **Year:** 1996 **Country:** Singapore **Aim:** To compare two types of glass iononer and two types of composite resin in Class V cavities **Follow-up:** 18 months **Design:** (7) Clinical trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2 (training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 10 (4 males, 6 females; mean age 47 years) **Restoration Type(s) and Baseline Nos:** 83 Class V **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Glass ionomer cement (auto cured)-Fuji II Cap 21 Glass ionomer cement (light cured)-Fuji II LC 21 Composite resin (light cured)- APH and dentine bonding agent 21 Composite resin (light cured) Lite Fil II APH and dentine bonding agent 20 **Participant final Nos:** 10 **Restoration final Nos:** 83 **Tooth type final Nos:** Not stated **Materials final Nos:** Glass ionomer cement (auto cured)-Fuji II Cap 21 Glass ionomer cement (light cured)-Fuji II LC 21 Composite resin (light-cured hybrid)- APH 21 Composite resin (light-cured) Lite Fil II 20 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No (Cotton rolls & saliva ejector)* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *Yes (Composite only')* ***Enamel bond:*** *Yes (all restorations)* ***Dentine adhesive:*** *APH – Prisma UB3 Fil II – Imperva Bond* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Restoration failure (loss)** **At 18 months** Glass ionomer cement (Fuji II Cap): 0/21 Glass ionomer cement (Fuji II LC): 1/21 Composite resin (Prisma APH): 0/21 Composite resin (Lite Fil II): 7/20 Loss of retention was significantly greater for the composite Lite Fil II compared to the other materials using Kruskal-Wallis analysis (P=0.0001) and Wilcoxon matched pairs signed-ranks test (P=0.018)	Generalisability is limited by university environment, the small sample size and the number of restorations placed per patient. **Our classification for analysis** Prisma UB3 group 2 Imperva bond group 2

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kaurich, Kawakami et al. 1991) 177 **Year:** 1991 **Country:** USA **Aim:** To compare a glass ionomer cement with a composite resin in Class V cavities **Follow-up:** 24 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 4 **Evaluators:** 1 (one of the clinicians, training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 9 (8 male, 1 female; mean age 40.3 years, range 27-63 years) **Restoration Type(s) and Baseline Nos:** Class V.restorations: 54 (27 pairs), randomisation used for allocation of materials (method not stated). **Tooth types and Baseline Nos:** Anterior/canine 9 pairs Premolar 13 pairs Molar 5 pairs **Materials and Baseline Nos:** Composite resin (Silux, light cured, macrofilled) and Scotchbond 27 Capsulated glass ionomer cement(Ketac -Fil) 27 **Participant final Nos:** 8 **Restoration final Nos:** 23 pairs **Tooth type final Nos:** Not stated **Materials final Nos:** Composite resin(Silux) 23 Glass ionomer cement (Ketac-Fil) 23 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *No, cotton rolls* ***Bevelled enamel:*** *Yes, composite only* ***Lining:*** *Calcium hydroxide used in 33 restorations* ***Etch:*** *Yes, composite only* ***Enamel bond:*** *Yes, composite only* ***Dentine adhesive:*** *Scotchbond used with composite* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *Not stated*	**Restoration failures/replacements (Cumulative failures)** **12 months** Glass ionomer cement (Ketac-Fil): 1/27 (due to partial loss of restoration) Composite (Silux): 1/27 (due to recurrent caries) **24 months** Glass ionomer cement (Ketac-Fil): 2/23 (2nd restoration replaced due to recurrent caries) Composite (Silux): 2/23 (2nd restoration replaced due to recurrent caries) The only statistically significant difference between groups was found in anatomic form.	Generalisability is limited by university environment and the small sample. **Our classification for analysis** Scotchbond 2 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kilpatrick, Murray et al. 1996) 807 **Year:** 1996 **Country:** UK **Aim:** To assess the durability of a glass ionomer sealant restoration compared with a minimal composite restoration in occlusal caries of permanent teeth **Follow-up:** up to 27 months **Design:** (8) Randomised controlled trial **Criteria:** (5) Restoration failure **Environment:** Hospital **Clinicians:** 1 **Evaluators:** 1 operator evaluator **Sponsorship:** MRC grant	**Participants and Baseline Nos:** 67 patients recruited over 23 months. Minimum of 2 small occlusal cavities in different quadrants. Clinical and/or radiographic diagnosis, no radioluceny beyond half dentine **Restoration Type(s) and Baseline Nos:** 80 paired class I **Tooth types and Baseline Nos:** Permanent molars and premolars **Materials and Baseline Nos:** Group a 80 glass ionomer sealant restoration Vitrebond (Triared GIC/hybrid resin) Group b 80 minimal composite restoration P-50 (light cured, densified, compact filled) Concise sealant **Participant final Nos:** 58 patients aged 8 years 8 months to 28 years, mean age 15 years 1 months. 25 female, 33 male. (patients with 14 pairs failed to attend). **Restoration final Nos:** 66 pairs **Tooth type final Nos:** Group a 66 - 2 premolars, 40 1st, 24 2nd molars, 40 Maxillary, 26 mandibular Group b 66 - 2 premolars 36 1st, 28 2nd molars, 40 Maxillary, 26 mandibular **Materials final Nos:** Group a 66, Group b 66 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *For 27 of 66 pairs at censor* ***Bevelled enamel:*** *No* ***Lining:*** *Yes group a calcium (Dycal hydroxide)* ***Etch:*** *Yes group b 30 secs prior to filling, group a enamel surface only after filling 30 secs* ***Enamel bond:*** *group b Scotchbond* ***Dentine adhesive:*** *group b Scotchbond* ***Light/Chemical cure:*** *Both light cured* ***Other:*** *Fissure sealant (Concise) placed over both restoration types and light cured*	At censor date mean follow up 17 months (range 6-27 months) a) 3/66 (4.5%) restorations failed at censor b) 1/66 (1.5%) restorations failed at censor Of sealants over restorations: a) 7/66 (10.6%) required additional sealant b) 3/66 (4.5%) %) required additional sealant Only 14 restoration required additional treatment during study. a) 27/66 (40.9%) lost third sealant or more b) 14 (21.5%) lost third sealant or more Statistically significant ($p<0.05$) Median survival time (MST) a) 20.7 months, b) 24.7 months MST both materials less in 1st molars than 2nd molars ($p<0.05$) MST patients under 12 years 16 months, over 12 years 20.0 - 25.0 months ($p<0.05$)	Under the conditions of this trial no difference in the durability of the two restorations (glass ionomer sealant restoration and minimal composite restoration). Significantly better sealant retention over minimal composite restoration may have significance to caries prevention in the longer term Neither the use of rubber dam or dental arch affected restoration durability. Restorations in 1st permanent molars were less durable than those in 2nd permanent molars, as were restorations placed in patients less than 12 years of age. However patient numbers (n=12 under 12 years) were small. Generalisability is limited by hospital environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Reich, Schmalz et al. 1990) 243 (German) **Year:** 1990 **Country:** Germany **Aim:** To compare the clinical performance of composite, sandwich technique and GIC in cervical lesions **Follow-up:** 12 months **Design:** (7) Clinical trial **Criteria:** (2) Modified USPHS **Environment:** Dental institution (assumed) **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 42 aged 20 to 75 years **Restoration Type(s) and Baseline Nos:** 187 carious and non-carious cervical lesions of similar size for each group, no randomisation used to allocate materials. **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** a) 57 composites Heliosit (light cured, microfilled) with Heliobond, bevelled, etched and retention groove apically b) 64 sandwich Ketac Bond and Heliosit, no retention grooves, polyacrylic acid, bevelled c) 66 GIC Ketac Fill, polyacrylic acid, Heliobond applied to surface of restoration **Participant final Nos:** 38 patients **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** a) 52 b) 58 c) 59 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Yes, groups a and b* ***Lining:*** *Yes, calcium hydroxide (Life)* ***Etch:*** *Yes, group a* ***Enamel bond:*** *Yes, group a* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light groups a and b* ***Other:*** *Mechanical retention group a*	**Restoration failure (loss)** **At 12 months** a) 2/52 b) 1/58 c) 1/59	Generalisability is limited by university environment and short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Levy, Jenson et al. 1989) 263 **Year:** 1989 **Country:** USA **Aim:** To compare glass iononer cement and microfilled composite in Class V cavities **Follow-up:** 12 months **Design:** (7) Other clinical trial **Criteria**: (2) USPHS **Environment:** University (assumed) **Clinicians:** 2 dentists **Evaluators:** 1 (no training mentioned) **Sponsorship:** NIDR	**Participants and Baseline Nos:** 50 (mean age:52 range25-76 years) **Restoration Type(s) and Baseline Nos:** 104 Class V carious cavities **Tooth types and Baseline Nos:** Not stated **Materials and baseline Nos:** Composite (Silux, light cured, microfilled) with bonding agent (Scotchbond): 59 Glass ionomer cement (Ketac-fil): 45 **Participant final Nos:** Not stated **Restoration final Nos:** 72 (Numbers in each group not available) **Tooth type final Nos** Not stated **Materials final Nos:** Not stated **Techniques:** ***LA:*** *As required* ***Rubber dam:*** *No, cotton wool rolls* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Calcium hydroxide in deep cavities* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Scotchbond with composite* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *Not stated*	**Failures** (partial and total loss of restorations combined) **Composite** 6 months: 9/44 12 months: 10/42 **Glass ionomer** 6 months: 18/34 12 months: 14/30 Differences between materials not statistically significant.	Generalisability is limited by university environment and the short follow-up. **Our classification for analysis** Scotchbond group 3

Table A8 Summary of studies comparing composite with silicate restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Eriksen 1974) 58 **Year:** 1974 **Country:** Norway **Aim:** Clinical evaluation of two composite resins and two silicate materials in anterior teeth **Follow-up:** 36 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 2 (training not stated) **Evaluators:** 1 (one of the clinicians; training/ calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** Dental students, number not stated **Cavity Type(s) and Baseline Nos:** Class III with some Class V. Number not stated, no details on allocation of materials **Tooth Types and Baseline Nos:** Permanent. Types and numbers not stated **Materials and Baseline Nos:** 31 Silicap (Silicate), 45 Bio Trey (Silicate), 24 Addent composite (macrofilled, autopolymerising), 26 Adaptic composite (macrofilled, autopolymerising) **Participant final Nos:** Not stated **Cavity final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** No dropout. As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Mechanical retention*	**At 36 months** 12 failures for combined Silicates 7 for Silicap and 5 for Bio Trey 0 failures for combined composites Failures defined as C grades for marginal adaptation and anatomical form; no loss of restorations Silicates significantly worse (Chi Squared P<0.005) than Composites for anatomical form, marginal adaptation and colour match	Autopolymerising, macrofilled composite resins had significantly better survival rate than Silicates up to 36 months in Class III and V preparations in anterior teeth. Materials no longer available Generalisability is limited by university setting and the use of dental students.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Jokstad, Mjor et al. 1994) 463 **Year:** 1994 **Country:** Norway **Aim:** Clinical evaluation of 3 anterior restorative materials **Follow-up:** 120 months including annual reviews **Design:** (8) Randomised controlled trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 2 (trained up to 6 years - later years only failures/replacements recorded **Sponsorship:** Not stated	**Participants and Baseline Nos:** 57, 9-72 years **Restoration Type(s) and Baseline Nos:** 112 Class III, 6 Class IV, 13 Class V **Tooth types and Baseline Nos:** Permanent maxillary and mandibular anteriors **Materials and Baseline Nos:** 28 Concise composite (autopolymerising, macrofilled), 66 Silar composite (autopolymerising, microfilled), 37 Silicap (silicate) **Participant final Nos:** 22, no details **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** At 72 months, 20 Concise, 24 Silar, 13 Silicap At 120 months, 65 restorations reviewed, 35 patients dropped out/ 26 restorations were replaced (by other clinicians), 5 teeth were extracted or crowned **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Yes* ***Lining:*** *Yes* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	Impossible to derive failure at 120 months; survival analysis provided diagrammatically – estimated from figure as: **Concise** 1 up to 24 months, .96 from 36 to 120 months **Silar** .98 at 12 months, .96 at 24 months, .94 at 36 months, .9 at 48 and 60 months, .84 at 72 months, .82 at 84 months, .8 at 96, 108 and 120 months **Silicap** .9 at 12 months, .84 at 24 months, .8 at 36 months, .74 at 48 months, .6 at 60 months, .58 at 72 months, .5 at 84 months, .48 at 96 months, .44 at 108 and 120 months **Up to 72 months, failures** were Concise – 0 Silar – 24 recordings (6 replaced); 1 (out of 57) at 6 months, 5 (41) at 12 months, 2 (41) at 24 months, 3 (41) at 36 months, 3 (31) at 48 months, 4 (30) at 60 months, 6 (24) at 72 months Silicap – 20 recordings (13 replaced); 7 (out of 30) at 6 months, 1 (27) at 12 months, 1 (26) at 24 months, 7 (25) at 36 months, 2 (17) at 48 months, 1 (14) at 60 months, 1 (13) at 72 months *Possibility of more than 1 recording per restoration*	Difficult to derive accurate data at 10 years C grade ‘failures’ up to 6 years may have been recorded more than once per restoration Criteria for replacement Not stated 26 restorations replaced by other clinicians during study Composites had superior performance than Silicate, but higher secondary caries incidence Macrofilled superior to microfilled Materials not currently available Mechanical retention within preparation With etch but enamel bonding resin Not stated, no dentine bonding agent Generalisability compromised because of University setting, materials not available

Table A 9 Studies comparing composite with compomer restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hse and Wei 1997) 382 **Year:** 1997 **Country:** Hong Kong **Aim:** To compare the clinical performance of a compomer (Dyract) and a composite resin in primary teeth (Prisma). **Follow-up:** 12 months **Design:** (8) Randomised clinical trial **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 2 (with training and calibration) **Sponsorship:** Dentsply (Asia) provided material	**Participants and Baseline Nos:** Patients 36 (4 - 7 years) **Restoration Type(s) and Baseline Nos:** Class I, 38 pairs Class II, 21 pairs Class V, 1 pair Materials randomly allocated **Tooth types and Baseline Nos:** Primary **Materials and Baseline Nos:** Compomer (Dyract) 60 Composite (Prisma, light cured, microfilled) 60 **Participant final Nos:** 36 patients **Restoration final Nos:** 120 **Tooth type final Nos:** Not stated **Materials final Nos:** Compomer (Dyract) 60 Composite (Prisma) 60 **Techniques:** ***LA:*** *Dyract yes* ***Rubber dam:*** *Dyract yes* ***Bevelled enamel:*** *Prisma yes* ***Lining:*** *Not stated* ***Etch:*** *Prisma yes* ***Enamel bond:*** *Prisma yes* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Both light* ***Other:*** *Not stated*	**Failure at 12 months** Compomer (Dyract): 1/60 Composite (Prisma) and 1/60 Both failures occurred in proximal slice class II restorations.(ie no isthmus) No failures due to recurrent caries.	This study was in a fluoridated area. Generalisability is limited by university setting, single operator and short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Barnes, Blank et al. 1995)429 **Year:** 1995 **Country:** USA **Aim:** To compare resin modified glass ionomer with composite resin in Class V cavities (The study also examined resin modified glass ionomer as a lining material) **Follow-up:** 12 months **Design:** (6) Prospective with concurrent controls **Criteria:** (5) Restoration failure **Environment:** University **Clinicians:** 2 **Evaluators:** 2 (with training and calibration) **Sponsorship:** LD Caulk/Dentsply	**Participants and Baseline Nos:** 63 patients, severe bruxists were excluded **Restoration Type(s) and Baseline Nos:** Class V restorations **Tooth types and Baseline Nos:** Resin modified glass ionomer without mechanical retention; Anterior:25; Premolar:45; Molar:5 Composite resin; Anterior:13; Premolar:15; Molar:3 Resin modified glass ionomer plus mechanical retention; Anterior:13; Premolar:15; Molar:3 **Materials and baseline Nos:** Resin modified glass ionomer (Variglass) without mechanical retention (used to restore cervical abrasion/erosion/abfraction lesions) 75 Composite resin (Prisma APH, light cured, densified, midway filled) with dentine bonding agents (used to restore cervical abrasion/erosion/abfraction lesions) 32 Resin modified glass ionomer with mechanical retention (used to restore cervical carious lesions) 31 **Participant final Nos:** Not stated **Restoration final Nos:** Resin modified glass ionomer without mechanical retention:68 Composite resin:28 Resin modified glass ionomer with mechanical retention:26 **Tooth type final Nos** Not stated **Materials final Nos:** As stated for restoration final numbers. **Techniques:** ***LA:*** *When required* ***Rubber dam:*** *Rubber dam or cotton wool rolls (proportions not stated)* ***Bevelled enamel:*** *Composite only* ***Lining:*** *Calcium hydroxide in deep cavities* ***Enamel bond:*** *Composite only* ***Dentine adhesive:*** *Composite only* ***Light/Chemical cure:*** *Composite and resin modified glass ionomer light cured* ***Other:*** *Not stated*	**Restoration failure (loss)** **At 12 months** Resin modified glass ionomer without mechanical retention:2/68 Composite resin:1/28 Resin modified glass ionomer with mechanical retention:0/26 Chi squared analysis showed no difference in the failure rates between the different groups	There is a large difference in the number of restorations placed in the resin modified glass ionomer without mechanical retention group Generalisability is limited by university setting and short follow-up. **Our classification for analysis** Primsa universal bond 3 group 2

Table A 10 Studies involving glass ionomer restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (McLean and Wilson 1977) 591 **Year:** 1977 **Country:** UK **Aim:** To establish durability of glass ionomer cement in erosion lesions **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (5) Restoration failure **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 86 patients **Restoration Type(s) and Baseline Nos:** 276 Class V erosion cavities **Tooth types and Baseline Nos:** Permanent **Materials and Baseline Nos:** 276 ASPA IV **Participant final Nos:** 29 at 36 months **Restoration final Nos:** 90 Class V **Tooth type final Nos:** Permanent **Materials final Nos:** 90 ASPA IV **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *prophylaxis, dentine conditioner (citric acid), mixed manufacturer's instructions, cervical matrix 5 minutes, finish*	**6 months** 86/276 lost **12 months** 19/237 lost **24 months** 16/182 **36 months** 8/90	Follow-up rate acceptable at first follow up but high by 36 months. The authors concluded that restorations lasted better in V-shaped deep cavities than shallow saucer shaped cavities but no figures reported. Failure was highest in first 6 months It is difficult to comment about generalisability because of insufficient detail.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Charbeneau and Bozell 1979) 587 **Year:** 1979 **Country:** USA **Aim:** To assess clinical charcteristics of a new glass ionomer cement in cervical cavities **Follow-up:** 6 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** Not stated **Clinicians:** Hospital (assumed) **Evaluators:** 2 independant and trained **Sponsorship:** Not stated	**Participants and Baseline Nos:** 31 patients with at least 1 cervical erosion deeper than 1mm **Restoration Type(s) and Baseline Nos:** 113 Class V **Tooth types and Baseline Nos:** Permanent **Materials and Baseline Nos:** 113 ASPA **Participant final Nos:** 31 **Restoration final Nos:** 113 **Tooth type final Nos:** Permanent **Materials final Nos:** 113 **Techniques:** ***LA:*** *No* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Prophylaxis, dentine condition citric acid, capsules mixed in amalgamator, packed and compressed with matrix*	**6 months** 6/113 (5.3%) failed at 6 months (all or part of material lost) 2 failed at 1 month, 1 at 3 month, 3 between 3-6 month Patient sensitivity to temperature and tactile sensation diminished or eliminated after placement	Suggests that capsular ASPA had a low failure rate in the first 6 months Generalisability is limited by likely hospital setting and short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (van Dijken 1992) 568 **Year:** 1991 **Country:** Sweden **Aim:** To evaluate 3 dentine pretreatments on the durability of the bond formed between dentine and anhydrous GIC (Chemfil II) **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (5) Total loss of restoration and partial loss **Environment:** Not stated **Clinicians:** 1 (author) **Evaluators:** 1 (author) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 74 patients **Restoration Type(s) and Baseline Nos:** 212 non-retentive Class V **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** All cavities restored with a glass ionomer (Chemfil II). Pretreatments consisted of:- a) mechanical cleaning with prophylaxis paste, 72 b) scrubbing with a surface active cleanser for 60 seconds tubulicid blue, 71 c) 10-15 seconds application 40% polyacrylic acid, 69 **Participant final Nos:** 70 **Restoration final Nos:** 193 Class V **Tooth type final Nos:** Not stated **Materials final Nos:** a) 69 b) 57 c) 67 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No (Cotton wool rolls)* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *No* ***Enamel bond:*** *Yes (Glass ionomer)* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	**Failure (loss or partial loss).** a) 8/69 (11.6%) b) 7/57 (12.3%) c) 12/67 (17.9%) No statistical difference reported between treatment groups	Generalisability is limited by the single operator who was also the examiner. Other factors are difficult to assess due to insufficient detail.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Andersson-Wenckert, van Dijken et al. 1995) 734 **Year:** 1995 **Country:** Sweden **Aim:** To evaluate durability of GIC in 2 designs of Class II cavities in primary molars **Follow-up:** 36 months **Design:** (8) Randomised controlled trial **Criteria:** (2) Modified USPHS **Environment:** Public Health Clinic **Clinicians:** 2 **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 25 children, age 6-10 years (mean 8 years) **Restoration Type(s) and Baseline Nos:** 28 paired Class II (28 microcavity - caries removal only rounded angles, 28 modified Class II - rounded angles, broad isthmus) **Tooth types and Baseline Nos:** 56 primary molars **Materials and Baseline Nos:** 56 Chemfil II (small number Chemfil junior) 28 microcavity - caries removal only rounded angles 28 modified Class II - rounded angles, broad isthmus **Participant final Nos:** Not stated **Restoration final Nos:** 21 Class II at 36 months **Tooth type final Nos:** 21 molars at 36 months **Materials final Nos:** At 36 months - 9 microcavity , 12 modified Class II **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide (Dycal)* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical set* ***Other:*** *Steel matrix and wedge, dentine condition 40 seconds polyacrylic acid, mixed and syringed, 5 minute set under preformed foil, varnish, polish 1 week*	**Microcavity** 1/21 failures at 6 months (restoration lost, 1 tooth exfoliated, 6 lost to follow up) 1/24 failures at 12 months (caries, 2 teeth exfoliated, 1 lost to follow-up) 2/18 failures at 24 months (anatomical form, 7 exfoliated, 1 lost to follow up) 1/9 failures at 36 months (lost restoration, 14 exfoliated, 1 lost to follow up) Cumulative percentage failure rate 6 - 36 months + 0, 5, 8, 16, 25 **Class II cavity** 1/21 failures at 6 months (isthmus fracture, 1 tooth exfoliated, 6 lost to follow up) 0/24 failures at 12 months (caries, 2 teeth exfoliated, 1 lost to follow-up) 3/20 failures at 24 months (isthmus fracture, caries, anatomical form, 6 exfoliated, 1 lost to follow up) 2/12 failures at 36 months (lost restoration, isthmus fracture, 9 exfoliated, 3 lost to follow up) Cumulative percentage failure rate 6 - 36 months + 0, 5, 4, 16, 32 Mean treatment time micro cavity 20 minutes, Class II cavity 23 minutes. Mean cavity sizes microcavity smaller than Class II cavity bucco-lingual, mesio-distal and inciso-cervical.	This study suggests that extension of cavity form to increase bulk is not of major importance in the durability of glass ionomer cement in primary molars, provided internal angles are rounded. The microcavity is slightly quicker to prepare and restore, and destroys less tooth tissue. Results generalisable to public health clinic setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Attwood, Reid et al. 1994) 735 **Year:** 1994 **Country:** Scotland **Aim:** To report the use of glass ionomer cements in Class I and II cavities in primary molars placed in community dental practice **Follow-up:** 36 months **Design:** (6) Prospective study with concurrent control **Criteria:** (3) Own criteria **Environment:** Community clinics **Clinicians:** 9 trained at 'hands-on' course **Evaluators:** 2 calibrated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 635 (193 Class I, 360 Class II, 82 others) 416 (65%) restorations placed in nervous patients **Tooth types and Baseline Nos:** Vital symptomless primary molars 1st primary molar 39 Class I, 177 Class II, 27 other; 2nd primary molar 154 Class I, 183 Class II, 55 other **Materials and Baseline Nos:** 635 glass ionomer cement **Participant final Nos:** Not stated **Restoration final Nos:** 606 at 12 months 359 at 36 months **Tooth type final Nos:** Not stated **Materials final Nos:** As above **Techniques:** ***LA:*** *301 (47.4%)* ***Rubber dam:*** *123 (19.4%)* ***Bevelled enamel:*** *No* ***Lining:*** *Deep cavities, calcium hydroxide 562 (88.5%)* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Cavity caries free, unsupported enamel removed, dentine conditioner, varnish 585 (92.1%)*	**At 12 months** 149/606 failed (26 class I, 102 class II, 17 others) **At 36 months** 142/359 failed (65 class I, 64 class II, 13 others) Total of 291 failures over 36 months: 91 class I (68 lost restoration, 15 fracture restoration, 8 recurrent caries) 170 class II (136 lost restoration, 25 fracture restoration, 9 recurrent caries) 30 others (27 lost restoration, 1 fracture restoration, 2 recurrent caries) At 12 months failure rate of Class II greater than Class I cavities for GIC placed in community ($p<0.05$), no statistical difference at 3 years. No statistically significant differences noted between using or not using: LA, Rubber dam, matrices.	The authors suggests that these materials are suitable short-term restorative materials in primary molars and that the material performs best in Class I cavities. Results generalisable to community setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Frencken, Makoni et al. 1996; Frencken, Makoni et al. 1998) 805/824 **Year:** 1996/1998 **Country:** Zimbabwe **Aim:** To present the 3-year survival rates for 1-surface glass ionomer cement ART restorations placed in a school oral health programme **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (2) Own criteria **Environment:** Field trial **Clinicians:** 2 dentists 2 dental therapists **Evaluators:** 2 independently with concensus **Sponsorship:** Lever Brothers Zimbabwe WHO Centre for Oral Health Services research Gronigen DENTSPLY/DeTrey (materials)	**Participants and Baseline Nos:** 144 schoolchildren mean age 13.9 years **Restoration Type(s) and Baseline Nos:** 307 one-surface ART restorations (Class I, V) **Tooth types and Baseline Nos:** Permanent 49.3% patients one restoration, 23.6% two restorations, 9% three restorations, 10.4% four restorations, 7.6% five or more restorations **Materials and Baseline Nos:** 307 one-surface chemfil superior **Participant final Nos:** Not stated **Restoration final Nos:** At 36 months 197 **Tooth type final Nos:** Not stated **Materials final Nos:** At 36 months 197 chemfil superior **Techniques:** ***LA:*** *No* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Dentine conditioner* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Hand excavation carious dentine, material mixed after manufacturer's details, petroleum jelly applied. single operator no assistant*	**At 12 months** 12/213 (6 marginal defects, 4 lost, 2 wear to dentine) **At 24 months** 7/228 **At 36 months** 14/197 Overall 33 restorations in 24 school children failed, average failure rate of 5% per year (9 lost, 7 caries, 17 material failure) Operator success rate varied from 100% to 88% at 12 months and 96.1% to 69.3% at 36 months. Statistically significant in survival percentage for 1 operator ($p=0.001$) Average time to complete ART restoration 22.1 minutes	Operator variables influence the success of restorations This technique is currently recommended in populations with limited access to care This study is generalisable within this population.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Frencken, Songpaisan et al. 1994) 442 **Year:** 1994 **Country:** Thailand **Aim:** To evaluate the use of glass ionomer cement in the atraumatic restorative treatment (ART) technique in primary and permanent teeth **Follow-up:** 12 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Own criteria **Environment:** 3 rural villages **Clinicians:** 1 dentist/2 dental nurses **Evaluators:** 2 **Sponsorship:** Netherlands Minister of Development Co-operation Materials supplied by De Trey Dentsply	**Participants and Baseline Nos:** 227 patients **Restoration Type(s) and Baseline Nos:** 529 ART fillings (Primary teeth:120 Class I restorations, 148 Class II/ MOD restorations Permanent teeth:239 Class I restorations, 22 Class II/ MOD restorations) 148 Fissure sealants **Tooth types and Baseline Nos:** ART fillings: 268 primary teeth 261 permanent teeth Fissure sealants: 27 primary teeth 121 permanent teeth **Materials and baseline Nos:** ART fillings and fissure sealants used glass ionomer cement (Chemfil) **Participant final Nos:** Not stated **Restoration final Nos:** ART fillings: 254 primary teeth 230 permanent teeth Fissure sealants: 26 primary teeth 107 permanent teeth **Tooth type final Nos:** **Not stated** **Materials final Nos:** As stated for restoration final numbers. **Techniques:** ***LA:*** *No* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Dentine conditioner used with ART* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Hand excavation carious dentine, material mixed after manufacturer's details, petroleum jelly applied.*	**Failure/required replacement ART restorations** Primary Class I: 24/116 (21%) Primary Class II/MOD: 62/138 (45%) Permanent Class I: 15/212 (7%) Permanent Class II/MOD 6/18 (33%)	No data presented about the tooth types or age range of the patients in each of the 3 villages chosen The authors suggest that 1 surface restorations last longer than multisurface restorations in both deciduous and permanent teeth Generalisablility is limited by the short follow-up..

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Gray and Paterson 1994) 444 **Year:** 1994 **Country:** UK **Aim:** To assess effectiveness of glass ionomer sealant restoration in permanent teeth **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (5) Sealant retention/ Restoration retention **Environment:** Community clinics **Clinicians:** 14 **Evaluators:** 2 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Mean age 10.6 years **Restoration Type(s) and Baseline Nos:** Class I sealant restorations **Tooth types and Baseline Nos:** Premolars and molars **Materials and baseline Nos:** Glass ionomer (Chemfil) restoration with Delton sealant **Participant final Nos:** 12 months: 86 **Restoration final Nos:** 12 months: 98 **Tooth type final Nos** 12 months: 96 molars; 2 premolars **Materials final Nos:** As stated for restoration final numbers. **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Glass ionomer chemically cured, sealant light cured* ***Other:*** *Not stated*	**At 12 months** No restorations lost (4/98 (4%) of sealants totally lost)	This short term field trial in the Community Dental Service shows that the glass ionomer sealant restoration had good retention rates over 12 months using 14 clinicians. This study is generalisable to community setting but has a short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mallow, Durward et al. 1998) 859 **Year:** 1998 **Country:** Cambodia **Aim:** To assess the use of a glass ionomer cement in the atraumatic restorative technique (ART) in permanent teeth **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (2) Own criteria **Environment:** Rural Cambodian High School **Clinicians:** 17 student dental nurses **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 53 (age 12 - 17 years), individuals randomly assigned to operator **Restoration Type(s) and Baseline Nos:** 50 Class I: (56.2%); 6 Class III: (6.7%); 33 Class V (37%) **Tooth types and Baseline Nos:** Upper incisors:7 (7.9%) Upper 1st molars 2 (2.2%) Upper 2nd molars 4 (4.5%) Lower 1st molars 31 (34.8%) Lower 2nd molars 45 (50.6%) **Materials and baseline Nos:** All glass ionomer cement (Fuji II) **Participant final Nos:** 12 months:31 36 months:26 **Restoration final Nos:** 12 months:59/89 (66%) 36 months:39/89 (44%) **Tooth type final Nos** Not stated **Materials final Nos:** As stated for restoration final numbers **Techniques:** ***LA:*** *No* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *No cavity conditioner used*	**Failures** **12 months** Class I: 4/32 (12.5%) Class III: 3/5 (6%) Class V: 6/21 (29%) **36 months** Class I: 9/23 (39%) Class III: 3/4 (75%) Class V: 4/12 (33%)	This ART field study demonstrates a relatively high failure rate of glass ionomer cement. Generalisability is limited due to low follow-up rate and operator experience.

Table A11 Studies comparing glass ionomer cement with cermet restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Kilpatrick, Murray et al. 1995) 413 **Year:** 1995 **Country:** UK **Aim:** To compare a glass ionomer cement and a silver cermet cement in Class II cavities in primary molars **Follow-up:** 30 months **Design:** (8) Randomised controlled trial **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 1 (trained and calibrated, examiner-operator) **Sponsorship:** MRC	**Participants and Baseline Nos:** 37 children mean age 7 years 8 months (range 4 years 10 months - 10 years 10 months) 21 males, 16 females **Restoration Type(s) and Baseline Nos:** Class II restorations: 92 (59 in 1st molars and 33 in 2nd molars) **Tooth types and Baseline Nos:** Primary molars: 92 **Materials and baseline Nos:** Glass ionomer cement (Ketac-fil):46 Silver cermet cement (Ketac-Silver):46 **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Cavity cleaned with polyacrylic acid*	**Failure at 18 months** Glass ionomer cement (Ketac-fil): 11/46 (23%) Silver cermet cement (Ketac-Silver): 19/46 (41%) **Mean Survival times** Glass ionomer cement (Ketac-fil) 25.3 months Silver cermet cement (Ketac-Silver) 20.3 months Difference significant ($P<0.05$)	This study used variable follow-up times which ranged from 4-31 months (mean 18 months) The authors reported poor survival rate of silver cermet cement in Class II cavities in primary molars and do not recommend its use in this situation. Generalisability is limited by university setting, single operator who acted as an examiner.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hasselrot 1993; Hasselrot 1998) 473/846 **Year:** 1993-1998 **Country:** Sweden **Aim:** To assess the longevity of tunnel preparations in permanent and deciduous posterior teeth **Follow-up:** 84 months **Design:** (3) Prospective case series **Criteria:** (5) Restoration failure **Environment:** Community clinic (assumed) **Clinicians:** 1 **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** 224 (Age range 10 - 30 years) 193 with permanent restorations **Restoration Type(s) and Baseline Nos:** Permanent teeth tunnel preparations classified as: 229 Class I tunnel: approximal enamel unbroken 53 Class II tunnel: approximal enamel perforated) **Tooth types and Baseline Nos:** 282 permanent teeth (premolars/molars) 36 primary teeth **Materials and baseline Nos:** Cermet cement (Ketac Silver): Glass ionomer cement (BaseLine): (NB PrismaFil composite resin, light cured, densified, midway filled, used to restore occlusal portion of tunnel preparations in permanent teeth and Ketac silver used to restore occlusal portion in primary teeth) **Participant final Nos:** Not stated **Restoration final Nos:** Primary teeth 31-56 months 21 teeth Permanent teeth 79 - 90 months 49 teeth **Tooth type final Nos** As restoration numbers **Materials final Nos:** As restoration numbers **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Enamel bond:*** *For composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *Not stated*	**Permanent teeth** Months n failures 8-18 267 17 19-30 227 22 31-42 176 11 43-45 148 7 55-66 109 8 67-78 84 7 79-90 49 3 75 failed in total 31 fracture marginal ridge 30 recurrent caries 14 enamel cavitation and / or degraded glass ionomer restoration (NB some teeth fail on more than one criteria) Class 1 tunnel 60/245 Class 2 tunnel 15/37 The failure rate per year was 5-10% (mean 7%). The 50% survival time was approximately 6 years. **Primary teeth** Months n cumulativefailures 5-20 31 6 14-30 27 17 31-56 21 19 16 fracture marginal ridge 2 cavitation in approximal enamel 4 recurrent caries (NB some teeth fail on more than one criteria)	Very few primary teeth in sample (36) and none left at 84 months. The authors report that while there was a high marginal ridge fracture in primary teeth the underlying glass ionomer restorations were mostly intact with minor grinding the restoration remained functional. No comparison made between the two different materials used to restore tunnel preparations. Generalisability is limited by the single operator who is also the examiner and the high drop out rate.

Table A12 Studies comparing glass ionomer cement with compomer

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Abdalla, Alhadainy et al. 1997) 753 **Year:** 1997 **Country:** USA **Aim:** To compare two different polyacid-resin modified glass ionomers in Class V carious lesions **Follow-up:** 24 months **Design:** (6) Prospective study with concurrent controls **Criteria:** (4) USPHS **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** 2 (calibrated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 32 (range 21-48 years) **Restoration Type(s) and Baseline Nos:** Class V carious cavities 120 **Tooth types and Baseline Nos:** Maxillary anterior 51, posterior 32 Mandibular anterior 5, posterior 32 **Materials and Baseline Nos:** Compomer - Dyract 30 Compomer - Compoglass 30 Glass ionomer - Fuji II LC 30 Glass ionomer - Vitremer 30 **Participant final Nos:** Not stated **Restoration final Nos:** 114 **Tooth type final Nos:** Not stated **Materials final Nos:** Compomer - Dyract 29 Compomer - Compoglass 28 Glass ionomer - Fuji II LC 28 Glass ionomer - Vitremer 29 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes (all restorations)* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Calcium hydroxide if cavity deep* ***Etch:*** *No* ***Enamel bond:*** *Yes (Fuji II restorations)'* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured (all restorations)* ***Other:*** *Not stated*	No failures reported at 24 months (95% recall rate)	Generalisability is limited by university setting and the small sample size.

Table A 13 Studies involving cermet restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Holst 1996) 498 **Year:** 1996 **Country:** Sweden **Aim:** To evaluate Ketac-Silver in primary molars **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** Specialist practice **Clinicians:** 1 **Evaluators:** 2 out of a pool of 36 operator evaluators in community clinics **Sponsorship:** No	**Participants and Baseline Nos:** 48 children aged 4-7 years (referred to specialist practice with behaviour problems and caries, then returned to home clinics) **Restoration Type(s) and Baseline Nos:** 172 Ketac-silver (Class I and II) placed **Tooth types and Baseline Nos:** 172 Primary molars **Materials and Baseline Nos:** 172 Ketac-silver **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** 94 Primary molars **Materials final Nos:** 119 Ketac at 36 months **Techniques:** ***LA:*** *Yes with nitrous oxide sedation* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Deep cavities Calcium hydroxide (Dycal)* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Round line angles, syringed into cavity*	**At 12 months** 40 failed (21 wear to dentine, 9 fracture/margin adaption, 7 marginal discolouration, 3 caries) **At 24 months** A further 12 failed (6 wear to dentine, 2 fracture/margin adaption, 1 marginal discolouration, 3 caries) **At 36 months** A further 12 failed (5 wear to dentine, 1 fracture/margin adaption, 2 marginal discolouration, 4 caries) Success rate at 12 months 66%, 24 months 56%, 36 months 46% Failure rate by surface single surface: M/D 47%, occlusal 50%; 2 surface: DO/MO 54%; 3 surface: 65% **NB** this excludes 8 extracted for infection during first 24 months 27% failure abrasion to dentine, 10% marginal adaption/fracture, 8% marginal discolouration, 8% secondary caries Of 172 restorations: 15 lost as patient moved, 11 failed to attend (3 patients), 6 lost as dentist moved, 13 exfoliated during trial, 8 extracted because of infection within 2 years which left 119 for evaluation.	The authors report a high failure rate for Ketac-Silver used in primary molars, the major reason for failure being high abrasion. Ketac-Silver is not recommended for use in primary molars The results are generalisable to community setting but limited by the single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Stratmann, Berg et al. 1989) 816 **Year:** 1989 **Country:** USA **Aim:** To assess silver cermet cement in Class II cavities in primary molars **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (3) Modified United States Public Health Service **Environment:** University (assumed) **Clinicians:** Not stated **Evaluators:** 2 (with calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** Class II restorations: 40 **Tooth types and Baseline Nos:** Primary molars **Materials and baseline Nos:** Silver cermet (Ketac Silver) **Participant final Nos:** Not stated **Restoration final Nos:** 39 **Tooth type final Nos** 39 Primary molars **Materials final Nos:** 39 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes (assumed)* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Chemical* ***Other:*** *Not stated*	**12 months** USPHS Grade 'C' 3/40 2 replaced due to defects at marginal ridge 1 replaced due to bulk fracture	Generalisability is limited by likely university setting and short follow-up period.

Table A14 Studies involving compomer restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Krejci, Gebauer et al. 1994) 458 (German) **Year:** 1994 **Country:** Switzerland **Aim:** To evaluate a compomer as a restorative material instead of amalgam **Follow-up:** 6 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** School clinic **Clinicians:** Not stated **Evaluators:** 2 (trained and calibrated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 17 children, 6 girls 11and boys selected randomly aged 7 to 11 years **Restoration Type(s) and Baseline Nos:** 29 Class II cavities, 5 with pulpotomies **Tooth types and Baseline Nos:** Primary dentition **Materials and Baseline Nos:** Compomer Dyract placed as a single increment **Participant final Nos:** 17 children **Restoration final Nos:** 29 restorations **Tooth type final Nos:** as for baseline **Materials final Nos:** as baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Calcium hydroxide* ***Etch:*** *Not stated* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Primer PSA* ***Light/Chemical cure:*** *Yes* ***Other:*** *Not stated*	**6 months** There were no failures for any restoration.	Generalisable to community setting although it is limited by short follow-up there is insufficient detail for further comment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Peters, Roeters et al. 1996; Roeters, Frankenmolen et al. 1998) 785/844 **Year:** 1998 **Country:** The Netherlands **Aim:** A clinical evaluation of a compomer (Dyract) in Class I and II cavities in primary molars **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (3) Modified USPHS **Environment:** Paediatric Clinic in University Hospital **Clinicians:** 3 **Evaluators:** 2 (trained and calibrated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 55 children (3.6-9.3 years) **Restoration Type(s) and Baseline Nos:** 11 Class I 80 Class II **Tooth types and Baseline Nos:** 91 primary teeth **Materials and Baseline Nos:** 91 Dyract restorations **Participant final Nos:** 12 months Not stated 24 months 49 33 months 28 **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 12 months 86 24 months 76 36 months 37 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *cotton wool rolls* ***Bevelled enamel:*** *short bevel* ***Lining:*** *No* ***Etch:*** *Primer used not phosphoric acid* ***Enamel bond:*** *Yes* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	Restorations: Exfoliated / Replaced 6months 0 / 1/89 12 months 1 / 1/86 24 months 6 / 0/76 36 months33 / 2/37 **Total 40 / 4** 2 restorations fractured (6 months 7 & 1-year) 2 were completely lost (2-3 years) No sensitivity was reported over the course of the study.	Generalisability is limited by university environment and the short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Andersson-Wenckert, Folkesson et al. 1997) 754 **Year:** 1997 **Country:** Sweden **Aim:** To assess compomer in Class II cavities in primary molars **Follow-up:** 24 months **Design:** (3) Prospective case series **Criteria**: (3) Modified United States Public Health Service **Environment:** Dental Public Health Clinics (6 in total) **Clinicians:** 6 **Evaluators:** 2 (out of a pool of 6 possible evaluators) **Sponsorship:** Swedish Medical Research Foundation, Swedish Dental Society	**Participants and Baseline Nos:** 79 children (Mean age 8 years; range 5-12 years) **Restoration Type(s) and Baseline Nos:** Class II restorations: 159 (144 microcavities, 15 conventional Class II) **Tooth types and Baseline Nos:** Primary molars **Materials and baseline Nos:** Compomer (Dyract):159 **Participant final Nos:** Not stated **Restoration final Nos:** 12 months:151 24 months:104 **Tooth type final Nos** Primary molars **Materials final Nos:** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No (cotton wool)* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide in deep cavities* ***Enamel bond:*** *No* ***Dentine adhesive:*** *Dyract primer* ***Light/Chemical cure:*** *Light* ***Other:*** *Not stated*	**Failures** **12 months:** 12/159 (2 due to caries, 5 due to loss of retention, 3 due to caries and loss of retention, 2 due to bulk fracture) **24 months:** 20/159 (5 due to caries, 7 due to loss of retention, 3 due to caries and loss of retention, 1 due to bulk fracture and caries, 3 due to marginal adaptation grade C and 1 unknown) Failure rates for different operators ranged from 12 % to 35%.	This short term study demonstrates that placement of compomer material in Class II cavities is technique sensitive and success rates vary between different operators. This study is generalisable to a community setting.

Table A15 Studies involving silicate restorations

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Jodkowska 1985) 607 **Year:** 1985 **Country:** Poland **Aim:** To compare the longevity of two different silicate cements in Class I, II, III, IV & V cavities **Follow-up:** 24 months **Design:** (3) Prospective study with **Criteria:** (2) Own criteria **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 1 **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated (age 14-60 years) **Restoration Type(s) and Baseline Nos:** Class I, II, III, IV & V **Tooth types and Baseline Nos:** Permanent teeth (numbers not stated) **Materials and baseline Nos:** Silicate cement (Biotrey):50 (8 Class I; 12 Class II, 20 Class III; 5 ClassIV; 14 Class V) Silicate cement (Silicap):55 (8 Class I, 12 Class II; 20 Class III; 5 ClassIV:; 14 Class V) **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos** Not stated **Materials final Nos:** 12 months: Biotrey:48; Silicap:50 24 months: Biotrey:45; Silicap:40 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Not stated* ***Other:*** *Not stated*	**Replacements/failures at 24 months** Biotrey: 8/45 (3 Class II, 3 Class IV, 2 Class III) Silicap: 6/40 (4 Class IV, 2 Class II) All replacements or failures due to loss of the restoration or recurrent caries (no further details available)	Generalisability is limited by the single operator who was also the evaluator and the assumed university environment.

Table A16 Studies involving gallium

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants & baseline numbers, Cavity Type(s) & baseline numbers, Tooth types, Participant & Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Navarro, Franco et al. 1996) 404 **Year:** 1996 **Country:** Brazil **Aim:** To compare a gallium alloy GF with a high copper amalgam in Class I and Class II cavities **Follow-up:** 8 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** Not stated **Clinicians:** 2 **Evaluators:** 2 independent calibrated examiners **Sponsorship:** Not stated	**Participants and Baseline Nos:** Military police academy - 28 **Restoration Type(s) and Baseline Nos:** Amalgam Class I and Class II (ratio 1:2) - 61 Molar and premolar teeth (ratio 1:1) **Tooth types and Baseline Nos:** Permanent dentition **Materials and Baseline Nos:** Gallium Alloy GF 30 Dispersalloy 31 **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** Gallium Alloy GF 26 Dispersalloy 28 **Techniques:** ***LA:*** *Yes* ***Moisture control:*** *Rubber dam* ***Lining:*** *Not stated* ***Mechanical:*** *Converging walls and grooves* ***Other:*** *Not stated*	**Failures up to 8 months** Time Gallium GF Disperalloy 1 week 1/30 0/31 8 months26/26 1/28 3 of the 26 Gallium GF restorations were associated with tooth fracture. All Gallium Alloy GF restorations were replaced at 8 months. All were rated Charlie for surface texture. 20 teeth restored with Gallium GF and 9 teeth restored with Dispersalloy were reported sensitive at baseline.	There is insufficient detail to comment on the generalisability but the results are dramatic.

Table A17 Studies comparing three or more materials

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Ostlund, Moller et al. 1992) 363 **Year:** 1992 **Country:** Sweden **Aim:** To compare amalgam, composite resin and glass ionomer cement in Class II cavities in primary teeth **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** Public Dental Service Clinic **Clinicians:** 2 **Evaluators:** 2 (no mention of training or calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 50 (age 4-6 years) **Restoration Type(s) and Baseline Nos:** 75 Class II **Tooth types and Baseline Nos:** 75 primary molars **Materials and Baseline Nos:** 25 Amalgam(ANA 2000) 25 Composite resin (Occlusin) 25 Glass ionomer cement (ChemFil) **Participant final Nos:** 50 patients **Restoration final Nos:** 75 Class II **Tooth type final Nos:** Not stated **Materials final Nos:** 23 Amalgam(ANA 2000) 23 Composite resin(Occlusin) 25 Glass ionomer cement (ChemFil) 2 amalgam and 2 composites exfoliated, all teeth accounted for. **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes for Composite and glass ionomer cement* ***Bevelled enamel:*** *No* ***Lining:*** *Yes for all material types* ***Etch:*** *Yes for composite* ***Enamel bond:*** *Yes for composite* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Occlusin light cured* ***Other:*** *Not stated*	**Cumulative failures at 36 months** Amalgam(ANA 2000) = 2 (1 due to bulk fracture and 1 due to recurrent caries) Composite resin (Occlusin) = 4 (1 due to bulk fracture and 3 due to recurrent caries) Glass ionomer cement (ChemFil) = 15 (all due to bulk fracture, usually across the isthmus area)	Generalisable to community clinic setting

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Lidums, Wilkie et al. 1993) 467 **Year:** 1993 **Country:** Australia **Aim:** To compare a silver cermet cement, a posterior composite resin and a high copper amalgam in Class I cavities in permanent teeth **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (2) Own criteria **Environment:** Hospital **Clinicians:** 2 **Evaluators:** 2 direct operator - evaluators. Training or calibration not stated 1 indirect evaluator **Sponsorship:** Not stated	**Participants and Baseline Nos:** 35 adults **Restoration Type(s) and Baseline Nos:** 116 Class I Occlusal **Tooth types and Baseline Nos:** 7 Permanent Premolar 109 Permanent Molar **Materials and Baseline Nos:** 57 Glass Ionomer Cermet - Ketac-Silver 38 Composite - Visio-Molar 21 High Copper Amalgam - Dispersalloy **Participant final Nos:** Not stated **Restoration final Nos:** 55 Class I Occlusal Restorations **Tooth type final Nos:** Not stated **Materials final Nos:** 30 Glass Ionomer Cermet - Ketac-Silver 8 Composite - Visio-Molar 17 High Copper Amalgam - Dispersalloy **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Glass ionomer* ***Etch:*** *Yes, with composite* ***Enamel bond:*** *Yes, with composite* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light, with composite* ***Other:*** *Not stated*	**High Copper Amalgam – Dispersalloy** Months Intact Failed Withdrawn 0-6 21 0 3 6-12 18 0 1 12-18 17 0 0 18-24 17 0 17 **Composite - Visio-Molar** Months Intact Failed Withdrawn 0-6 38 0 11 6-12 27 0 4 12-18 23 0 15 18-24 8 0 8 **Glass Ionomer Cermet – Ketac-Silver** Months Intact Failed Withdrawn 0-6 57 3 7 6-12 47 11 1 12-18 35 1 4 18-24 30 4 26 All failures of silver cermet due to surface crazing and cracking, usually within the first 6 months of service	Generalisability is limited by the University setting, operator evaluator and the unexplained drop out rate in the composite group

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wilkie, Lidums et al. 1993) 468 **Year:** 1993 **Country:** Australia **Aim:** To compare the survival of a cermet, a composite and an amalgam used in tunnel preparations and class II preparations **Follow-up:** 24 months **Design:** (4) Prospective study concurrent controls **Criteria:** (2) Own criteria **Environment:** University **Clinicians:** 2 **Evaluators:** 2 operator/ evaluators. Training or calibration not stated **Sponsorship:** ESPE	**Participants and Baseline Nos:** 26 adults **Restoration Type(s) and Baseline Nos:** 86 (44 class II, 42 tunnel preps) **Tooth types and Baseline Nos:** Permanent 35 premolars, 51 molars **Materials and Baseline Nos:** 16 Dispersalloy (high copper) class II 42 Ketac-Silver tunnel preps 28 Visio-Molar RO (microfilled) closed sandwich **Participant final Nos:** Not stated **Restoration final Nos:** 47 (31 Class II, 16 tunnel prep) **Tooth type final Nos:** 47 **Materials final Nos:** 13 Dispersalloy 16 Ketac-Silver 18 Visio-Molar RO **Techniques:** ***LA:*** *Yes (assumed)* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Ketac-Bond (Dispersalloy and Visio-Molar)* ***Etch:*** *15 seconds (Visio-Molar)* ***Enamel bond:*** *Visio-Bond (Visio-Molar* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Visio-Molar light* ***Other:*** *Dispersalloy and Visio-Molar minimal perps. Visio-Molar incremental pack/set. Dispersalloy polished at 2nd appointment. Ketac-Silver dentine condition 10 seconds*	**Dispersalloy** 0/16 failures at 6 months 0/15 at 12 and 18 months 0/13 at 24 months. Cumulative survival 100% at 24 months **Ketac-Silver** 3/42 failures at 6 months 14/37 failures at 12 months 2/22 at 18 months 1/16 at 24 months (surface crazing and cracking) Cumulative survival 45 % at 24 months **Visio-Molar** 1/28 at 6 months 1/21 at 12 months 0/18 at 18 and 24 months (1 fractured, 1 lost) Cumulative survival 91 % at 24 months Although 20 Ketac-silver reported as failed, only 2 replaced the remainder under observation.	Ketac-silver cannot be recommended as a longterm restoration for permanent teeth Generalisability is limited due to University setting and evaluator/operator.

Three or more materials

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mjör and Jokstad 1993) 474 **Year:** 1993 **Country:** Norway **Aim:** To compare a silver cermet, an amalgam and a composite resin in Class II cavities in permanent teeth **Follow-up:** Up to 60 months (minimum 36 months) **Design:** (7) Other Clinical Trial **Criteria:** (2) USPHS **Environment:** Public Dental Service **Clinicians:** 3 **Evaluators:** 3 Training or calibration not stated **Sponsorship:** Not Stated	**Participants and Baseline Nos:** 142 adolescents (mean age 13 years) **Restoration Type(s) and Baseline Nos:** 274 Class II, no mention of randomisation method used to allocate materials **Tooth types and Baseline Nos:** 107 Premolars 167 Molars **Materials and Baseline Nos:** 88 Amalgam - Dispersalloy 95 Glass Ionomer Cermet - Ketac-Silver 91 Composite Resin - P-10 **Participant final Nos:** Not stated **Restoration final Nos:** 172 Class II at 36 months 113 Class II at 60 months **Tooth type final Nos:** 34 Premolars 79 Molars **Materials final Nos:** <u>60 months</u> 33 Amalgam - Dispersalloy 44 Glass Ionomer Cermet - Ketac-Silver 36 Composite Resin - P-10 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes (all restorations)* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes (composite resin')* ***Enamel bond:*** *Yes (composite resin)* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Light (composite resin)* ***Other:*** *Not stated*	**Amalgam** 36 months 4 failed 60 months no further failures **Glass Ionomer Cermet** = 22 failures 36 months 19 failed 60 months 22/44 failed **Composite Resin_= 9 failures** 36 months 9 No further failures The glass ionomer cermet and amalgam restorations failed primarily due to bulk fractures, while the resin composite restorations failed due to secondary caries and bulk fracture	There is variations in the drop-out rate of subjects between 3 clinicians placing materials. This study does not report number of different types of restorations reviewed at 36 months but does at 60 months. Generalisable to community clinic setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Neo and Chew 1996) 394 **Year:** 1996 **Country:** Singapore **Aim:** Clinical evaluation of a glass ionomer cement, a composite resin with a dentine bonding agent and a composite resin/glass ionomer sandwich restoration to restore Class V cavities **Follow-up:** 36 months **Design:** (7) Other Clinical trial **Criteria:** (3) Modified USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 2 (with training and calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 18 (13 male, 5 female; mean age 52, range:22-73) Patients with history of clenching/bruxing excluded **Restoration Type(s) and Baseline Nos:** 159 Class V (non carious cervical lesions), No mention of randomisation for allocation of materials **Tooth types and Baseline Nos:** Glass ionomer: Incisor 14, Canine 12, Premolar 19, Molar 5 Composite resin: Incisor, 19, Canine 8, Premolar 24, Molar 4 Composite/glass ionomer sandwich: Incisor 14, Canine 12, Premolar 23, Molar 5 **Materials and Baseline Nos:** 50 Glass ionomer cement (Ketac-Fil) 55 Silux composite (light cured, microfilled) with Scotchbond Dual Cure dentine adhesive 54 Glass ionomer (Ketac-Fil)/ Composite (Silux) Sandwich with Scotchbond Dual Cure on enamel **Participant final Nos:** 18 **Restoration final Nos:** As baseline **Tooth type final Nos:** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *Yes, composite resin and sandwich* ***Lining:*** *Yes with Sandwish* ***Etch:*** *Yes with composite* ***Enamel bond:*** *Yes for GIC and sandwich* ***Dentine adhesive:*** *Yes, composite and sandwich* ***Light/Chemical cure:*** *Light*	**12 months** 0/50 failures for Glass ionomer cement (Ketac-Fil) 4/55 failures for Composite resin (Silux) with dentine adhesiver 0/54 failures Glass ionomer (Ketac-Fil)/ Composite (Silux)Sandwich **36 months** 2/50 failures for Glass ionomer cement (Ketac-Fil) 12/55 failures for Composite resin (Silux) and dentine adhesive 2/54 failures for Glass ionomer (Ketac-Fil)/ Composite Sandwich) Failure rate of composite resin at 36 months significantly greater than the other materials (Kruskal-Wallis test $P<0.05$)	Generalisability is limited due to University setting and single operator. **Our classification for analyis** Scotchbond group 3

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (van Dijken 1996) 835 **Year:** 1996 **Country:** Sweden **Aim:** To compare a compomer, resin modified glass ionomer and composite resin in Class II cavities in posterior teeth **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** University (assumed) **Clinicians:** 1 **Evaluators:** 1Training or calibration not mentioned **Sponsorship:** Swedish Medical Research Council, De Trey/Dentsply	**Participants and Baseline Nos:** 50 (mean age = 51 yrs range:33-72) 26 female, 24 male **Restoration Type(s) and Baseline Nos:** 154 Class III **Tooth types and Baseline Nos:** Anterior teeth **Materials and baseline Nos:** Compomer (Dyract):Numbers not stated Resin modified glass ionomer (Fuji II): Numbers not stated Composite (Pekafil): Numbers not stated **Participant final Nos:** 48 **Restoration final Nos:** 148 **Tooth type final Nos** As baseline **Materials final Nos:** Not stated **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Gluma with composite* ***Light/Chemical cure:*** *Composite light cured* ***Other:*** *Not stated*	**Failures** Compomer (Dyract) 1 replaced at 24 months and a 2nd replaced at 36 months due to recurrent caries Resin modified glass ionomer (Fuji II) 1 replaced at 6 months (reason unknown) Composite (Pekafil) No restorations replaced	Generalisability is limited by the university setting and single operator who is also the evaluator. **Our classification for analyis** Gluma group 1b

Table A18 Studies involving all types of inlays

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wendt and Leinfelder 1992) 335 **Year:** 1992 **Country:** USA **Aim:** Clinical evaluation of the performance of an indirect heat treated resin composite inlay compared to a indirect bulk placement inlay in permanent teeth **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (4) USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 (trained and calibrated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** 30 Class I, 30 Class II, within mouth comparison, random allocation of materials **Tooth types and Baseline Nos:** 30 permanent premolars, 30 permanent molars **Materials and Baseline Nos:** 30 Occlusin (light cured, densified, compact filled) direct bulk placement and light cured intra-orally before cementation 30 Occlusin bulk placement and light cured intra-orally and dry heat cured extra-orally before cementation **Participant final Nos:** Not stated **Restoration final Nos:** 60 **Tooth type final Nos:** Not stated **Materials final Nos:** 30 of each **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Gingival only* ***Lining:*** *Yes* ***Etch:*** *Only during cementation* ***Enamel bond:*** *Only during cementation* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light; Light and Heat* ***Other:*** *Light cured composite resin cement*	**At 24 months** 2 failures out of 30 light cured composite inlays 0 failures out of 30 for light/heat cured composite inlays **At 36 months** No further failures (1 Light cured failure out of 30 due to bulk fracture - replaced 1 Light cured failure out of 30 due to defective margin - replaced) 0 Heat cured reported post-operative sensitivity 3 Light cured post-operative sensitivity – transient and not classified as failure Marginal integrity worse with light cured only group	Generalisability limited by university setting and small sample size.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Krejci, Krejci et al. 1992) 364 **Year:** 1992 **Country:** Switzerland **Aim:** Clinical evaluation of glass ceramic Class II inlays in permanent teeth **Follow-up:** 18 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 10 **Restoration Type(s) and Baseline Nos:** 10 Class II **Tooth types and Baseline Nos:** 10 permanent premolars **Materials and Baseline Nos:** 10 IPS/Empress (pressed glass ceramic) **Participant final Nos:** 10 **Restoration final Nos:** 10 Class II **Tooth type final Nos:** 10 premolars **Materials final Nos:** 10 IPS/Empress glass ceramic **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes; during cementation* ***Enamel bond:*** *Yes: during cementation* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Box shaped cavities* *Cavit/or GP temporaries* *Inlays silane treated* *Dual cure cement (Dual Cement, Ivoclar)*	**At 18 months** 0 failures	Generalisability limited by university setting, short follow-up and small sample size.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mormann and Krejci 1992) 366 **Year:** 1992 **Country:** Switzerland **Aim:** Clinical evaluation of the performance of computer designed/machined Class II inlays in permanent teeth **Follow-up:** 60 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 8 **Restoration Type(s) and Baseline Nos:** 8 Class II MOD **Tooth types and Baseline Nos:** 8 permanent mandibular molars **Materials and Baseline Nos:** 8 Cerec CAD/CAM (Computer-aided design/computer-aided machining) **Participant final Nos:** 8 **Restoration final Nos:** 8 MOD **Tooth type final Nos:** 8 permanent molars **Materials final Nos:** 8 Cerec CAD/CAM (Computer-aided design/computer-aided machining **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *Yes; during cementation* ***Enamel bond:*** *Yes, during cementation* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *4 inlays cemented with light cured composite resin 4 inlays cemented with Dual Cure cement* *Inlays etched with hydrofluoric acid*	**At 60 months** 0 failures	Generalisability limited by university setting and small sample size.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Studer, Lehner et al. 1996) 388 **Year:** 1996 **Country:** Switzerland **Aim:** Short term clinical evaluation of glass ceramic inlays and onlays in permanent teeth **Follow-up:** Range: 11 to 40-months **Design:** (3) Prospective Case Series **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 18 (trained) **Evaluators:** 2 (trained and calibrated, poorest rating accepted when disagreement) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 37 (22 female, 15 male); good oral hygiene, low gingivitis scores, low caries activity **Restoration Type(s) and Baseline Nos:** Not stated **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** Porcelain IPS-Empress- Numbers not stated, see results **Participant final Nos:** 36 **Restoration final Nos:** 130: 27 single surface including Class I/II (slot), 78 Class II, 25 Onlays **Tooth type final Nos:** 50 premolars, 80 molars **Materials final Nos:** 130 IPS-Empress ceramic **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes; during cementation* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *No* ***Dentine adhesive:*** *During cementation with 1 material* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Inlays sandblasted* *Etched (hydrfluoric acid)* *Silane coupling agent* *4 cements; 1 Panavia TC, 3 dual cure composite*	**Failed between 12 to 17-months** 3 out of 130 Estimated survival time of 97.5% after 2 years Failures in different patients One patient dropped-out- number of restorations not stated	A variety of cavity types and cements confound the outcome; no details of these parameters for the failures are included. Generalisability limited by university setting but benefits from the large number of clinicians. **NB** 36/37 patients were reviewed. The initial number of inlays placed is not known.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Qualtrough and Wilson 1996) 407 **Year:** 1996 **Country:** U.K **Aim:** Clinical evaluation of Class I and II porcelain inlays in permanent teeth **Follow-up:** 36 months **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 2 (trained and calibrated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27, over 16 years. Regular attenders at University **Restoration Type(s) and Baseline Nos:** 21 Class I, 29 Class II; occlusal keyways not routine **Tooth types and Baseline Nos:** 25 permanent molars; 25 premolars **Materials and Baseline Nos:** 50 Mirage porcelain **Participant final Nos:** 27 **Restoration final Nos:** 21 Class I, 29 Class II **Tooth type final Nos:** 25 permanent molars; 25 premolars **Materials final Nos:** 50 Mirage porcelain **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes; during cementation* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes; during cementation* ***Enamel bond:*** *Yes; during cementation* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Non eugenol temp cement* *Inlay etched with hydrofluoric acid* *Silane coupling agent* *Dual cure cement*	**At 36 months** 9 failures out of 50 5 failed within 1 month; 3 failed by 6 months (1 due to post-operative sensitivity); 1 failed at 18 months. 4 failures were Class I, 5 Class II 6 molar restorations failed, 3 premolars 7 maxillary restorations failed, 2 mandibular 5 bulk fractures occurred, 3 marginal fractures and 1 pain	Generalisability limited by university setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Heymann, Bayne et al. 1996) 409 **Year:** 1996 **Country:** USA **Aim:** Clinical evaluation of the performance of computer designed/machined Class I and II inlays in permanent teeth **Follow-up:** 48 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 4 (trained) **Evaluators:** 2 (calibration and training not stated) **Sponsorship:** Siemens	**Participants and Baseline Nos:** 28 **Restoration Type(s) and Baseline Nos:** 50: 19 Class I, 31 Class II **Tooth types and Baseline Nos:** 21 premolars, 29 molars **Materials and Baseline Nos:** 50 CAD/CAM made from Dicor MGC **Participant final Nos:** Not stated **Restoration final Nos:** 42 **Tooth type final Nos:** 42 **Materials final Nos:** 42 CAD/CAM made from Dicor MGC **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes: during preparation* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *Yes: during cementation* ***Dentine adhesive:*** *Yes: Gluma* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *inlays etched with ammonium bifluoride* *Silane coupling agent* *Dual cure cement*	**At 48 months** 0 failures out of 42 inlays	Generalisability limited by university setting. **Our classification for analysis** Gluma group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Motokawa, Braham et al. 1990) 235 **Year:** 1990 **Country:** Japan **Aim:** Clinical evaluation of light cured composite resin inlays in primary teeth **Follow-up:** 24 months **Design:** (3) Prospective study with concurrent controls **Criteria:** (2) Modified USPHS **Environment:** University **Clinicians:** 1 **Evaluators:** 2 (training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 40: 3-11 years. 27 female, 19 male **Restoration Type(s) and Baseline Nos:** 2 Class I (complex), 32 Class II, 12 MOD and 4 onlay **Tooth types and Baseline Nos:** 50 primary molars **Materials and Baseline Nos:** 50 composite resin inlay - P-30 (light cured, densified, compact filled). Incremental pack, Light cured in laboratory **Participant final Nos:** Not stated **Restoration final Nos:** 46 at 6 months, 34 at 12 months, 11 at 24 months. All restorations examined at different times **Tooth type final Nos:** Not stated **Materials final Nos:** 46 at 6 months, 34 at 12 months, 11 at 24 months - composite resin inlay - P-30 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes, during cementation* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Panavia EX cement*	Restorations examined at different periods were never the same, ie. restorations examined only once 1 failure out of 4 at 3 months 3 failures out of 12 at 6 months 0 failures out of 23 at 12 months 1 failure out of 11 at 24 months 0 failures out of 2 for Class I 1 failure out of 32 for Class II 3 failures out of 12 for MOD	Generalisability limited by university setting and single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Sjogren, Molin et al. 1995) 423 **Year:** 1995 **Country:** Sweden **Aim:** Clinical evaluation of CAD/CAM Class II inlays in permanent teeth cemented with chemically cured or dual cured cement **Follow-up:** 24 months **Design:** (3) Prospective case series **Criteria:** (4) USPHS **Environment:** Public Dental Health Clinics and University **Clinicians:** 3 (training not stated) **Evaluators:** 4 (working in pairs, calibrated, consensus) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 27, 15-65 years, 17 female, 10 male **Restoration Type(s) and Baseline Nos:** 66 Class II, within mouth comparisons **Tooth types and Baseline Nos:** 13 permanent molars, 53 premolars **Materials and Baseline Nos:** 33 porcelain Vita Cerec Mark II cemented with dual cured resin 33 porcelain Vita Cerec Mark II cemented with chemically cured resin **Participant final Nos:** 27 **Restoration final Nos:** 66 Class II **Tooth type final Nos:** 13 permanent molars, 53 premolars **Materials final Nos:** 33 porcelain Vita Cerec Mark II cemented with dual cured resin 33 porcelain Vita Cerec Mark II cemented with chemically cured resin **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *Yes: during cementation* ***Dentine adhesive:*** *Yes: Gluma* ***Light/Chemical cure:*** *Chemically cured and Dual cured* ***Other:*** *Inlays etched with hydrofluoric acid* *Silane agent used* *Chemically cured and Dual cured cements*	**At 24 months** 1 failure out of 66 1 fractured adjacent tooth tissue Transient sensitivity reported	Results generalisable to public dental service. **Our classification for analysis** Gluma group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Tidehag and Gunne 1995) 422 **Year:** 1995 **Country:** Sweden **Aim:** Clinical evaluation of Class II porcelain inlays in permanent teeth **Follow-up:** 26 months (mean), range 12-31 months **Design:** (3) Prospective Case Series **Criteria:** (4) USPHS **Environment:** Public Dental Health Clinic **Clinicians:** 1(training not stated) **Evaluators:** 2 (training and calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 18: 10 female, 8 male. 35-67 years **Restoration Type(s) and Baseline Nos:** 62 Class II **Tooth types and Baseline Nos:** 40 permanent premolars, 22 molar **Materials and Baseline Nos:** 62 heat pressed ceramic IPS Empress inlays **Participant final Nos:** 16 **Restoration final Nos:** 60 **Tooth type final Nos:** Not stated **Materials final Nos:** 60 heat pressed ceramic IPS Empress inlays **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *Yes: during cementation* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Eugenol free cement for temporary* *Inlays etched with hydrofluoric acid* *Silane agent on inlays* *Light cured composite resin cement*	**At recall (range 12-31 months)** 1 failure out of 60 examined Transient sensitivity	Generalisability limited by university setting, single operator and some inlays having a short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Stenberg and Matsson 1993) 490 **Year:** 1993 **Country:** Sweden **Aim:** Clinical evaluation of ceramic Class II inlays compared with amalgam in Class II restorations in permanent teeth **Follow-up:** 24 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** Not stated **Clinicians:** 1 **Evaluators:** 2 (1 was clinician; training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 39: 15-19 years. No parafunctional habits **Restoration Type(s) and Baseline Nos:** 50 Class II **Tooth types and Baseline Nos:** 26 permanent premolars, 24 molars 39 maxillary teeth, 21 mandibular **Materials and Baseline Nos:** 26 Amalgam (ANA 2000), 25 Porcelain (Dicor) inlays **Participant final Nos:** 39 **Restoration final Nos:** 50 Class II **Tooth type final Nos:** 26 permanent premolars, 24 molars 39 maxillary teeth, 21 mandibular **Materials final Nos:** 25 amalgam, 25 inlays **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Inlays etched* *Glass ionomer cement lute*	**At 24 months** 2 inlay failures out of 25 (bulk fractures) 2 amalgams failed out of 25 (caries)	Generalisability limited by single operator. There are insufficient details to comment further.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Fradeani, Aquilano et al. 1997) 756 **Year:** 1997 **Country:** Not stated **Aim:** Clinical evaluation of ceramic Class I and II inlays in permanent teeth **Follow-up:** 40.4 months (mean), range 7 - 56 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** Private practice **Clinicians:** Not stated **Evaluators:** 3 (training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 29: 23 female, 6 male. Mean age 28.4 years. No parafunctional habits **Restoration Type(s) and Baseline Nos:** 125: 15 Class I, 57 Class II (two-surface), 35 (three-surface), 18 onlays **Tooth types and Baseline Nos:** 50 permanent premolars, 75 molars **Materials and Baseline Nos:** 125 porcelain IPS Empress ceramic inlays **Participant final Nos:** 29 **Restoration final Nos:** 125: 15 Class I, 57 Class II (two-surface), 35 (three-surface), 18 onlays **Tooth type final Nos:** 50 permanent premolars, 75 molars **Materials final Nos:** 125 porcelain IPS Empress ceramic inlays **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes: during cementation* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *Yes: during cementation* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured* ***Other:*** *Eugenol free cement for temporary* *Inlays etched with hydrofluoric acid* *Silane agent applied* *Dual cure cement*	**Variable follow-up** 4 failures out of 125 1 failure due to tooth fracture (on the only non-vital tooth); 3 failed due to ceramic fracture Kaplan and Meier survival rates at almost 5 years was 95.6% (95% CI, 90.77%-99.95%) No differences between premolars and molars 3 failures out of 60 maxillary teeth; 1 failure out of 65 mandibular teeth	Generalisable to dental practice but some of the inlays had a short follow up period.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Krejci, Guntert et al. 1994) 451 **Year:** 1994 **Country:** Switzerland **Aim:** Clinical evaluation of a fine particle hybrid composite resin inlay/onlay system in Class I and II restorations in permanent teeth **Follow-up:** 12 months **Design:** (3) Prospective case series **Criteria:** (2) USPHS **Environment:** University **Clinicians:** Not stated **Evaluators:** 2 (training and calibration not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 24: 13 female, 11 male. Mean age 28.2 years **Restoration Type(s) and Baseline Nos:** 30: 10 Class I, 7 Class II, 4 MOD, 9 onlays **Tooth types and Baseline Nos:** 3 premolars, 27 molars 28 mandibular, 2 maxillary **Materials and Baseline Nos:** 30 APH composite resin laboratory made inlays (composite not categorised) **Participant final Nos:** 23 **Restoration final Nos:** 29 **Tooth type final Nos:** Not stated **Materials final Nos:** 29 APH composite resin laboratory made inlays **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes: during preparation* ***Bevelled enamel:*** *No* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light cured inlay system* ***Other:*** *Fitting surface roughened* *Adhesive on fitting surface* *Dual cure*	**At 12-months** 0 failures out of 30 Transient sensitivity in 10%	Generalisability limited by university setting, small sample size and short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Isidor and Brondum 1995) 424 **Year:** 1995 **Country:** Denmark **Aim:** Clinical evaluation of porcelain inlays cemented with light or dual cured composite resin **Follow-up:** 40 months (mean) – range 20 - 57-months **Design:** (6) Prospective study with concurrent controls **Criteria:** (2) Own criteria **Environment:** Private Clinic **Clinicians:** 2 **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** Not stated. No parafunctional habits, poor oral hygiene, high caries rate **Restoration Type(s) and Baseline Nos:** 25 MOD (small number of onlays). Supragingival margins **Tooth types and Baseline Nos:** 12 permanent molars, 13 premolars **Materials and Baseline Nos:** 25 porcelain (Mirage) inlays **Participant final Nos:** Not stated **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 25 porcelain (Mirage) inlays **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Yes* ***Etch:*** *Yes: during cementation* ***Enamel bond:*** *Yes: during cementation* ***Dentine adhesive:*** *Yes: during cementation* ***Light/Chemical cure:*** *Not relevant* ***Other:*** *Non eugenol temporsry cement* *Inlays etched with hydrofluoric acid* *10 inlays with light cured cement/ 11 dual cure cement/ 4 unknown cement*	**Variable follow-up** 12 failures out of 25 over follow-up period 10 due to isthmus fracture, 1 caries, 1 marginal gap 8 out of 10 light cured cements failed 2 out of 11 dual cured cements failed 8 out of 12 molars failed, 4 out of 13 premolars failed Average intra-oral service before failure was 15.7 months (range 1-42 months) Overall survival analysis demonstrated: 10 months - 88% 20 months - 60% 30 months - 55% 40 months - 55% 45 months - 37%	Techniques modified during progress of study – (cement, clinical techniques) The authors suggested that the results be treated with caution Not generalisable. Classification for our analysis Scotchbond 2 group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mormann and Krejci 1991) 828 **Year:** 1991 **Country:** Switzerland **Aim:** To clinically evaluate posterior CAD/CAM inlays **Follow-up:** 60 months **Design:** (7) Other clinical trial **Criteria:** (2) Modified USPHS **Environment:** Hospital-Dental Institute **Clinicians:** Not stated **Evaluators:** Not stated, -training and calibration not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 8 **Restoration Type(s) and Baseline Nos:** MOD ceramic inlay 8 **Tooth types and Baseline Nos:** 8 molars **Materials and Baseline Nos:** Porcelain Vita CEREC 8 **Participant final Nos:** 8 **Restoration final Nos:** 8 **Tooth type final Nos:** 8 molars **Materials final Nos:** Porcelain-Vita CEREC 8 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Not applicable* ***Other:*** *4 restorations cemented with light cured posterior composite 4 with dual cured composite*	**At 60 months** No failures. No difference between the two types of cement used	Generalisability is limited by the hospital environment and the very small sample size. It is not possible to comment further because of insufficient detail.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Mormann, Gotsch et al. 1991) 827 **Year:** 1991 **Country:** Switzerland **Aim:** To evaluate the clinical status of CERC ceramic Inlays and onlays after 3-years in situ **Follow-up:** 36-months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** Hospital/University **Clinicians:** 2 **Evaluators:** 1 independent (training not stated) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 30 **Restoration Type(s) and Baseline Nos:** 23 one surface 28 two surface 57 three surface **Tooth types and Baseline Nos:** 35 premolars 59 molars **Materials and Baseline Nos:** 94 Porcelain-CEREC **Participant final Nos:** 30 **Restoration final Nos:** 94 **Tooth type final Nos:** Premolars 35 Molars 59 **Materials final Nos:** 94 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Not applicable* ***Other:*** *'Almost equal numbers cemented with a light cure or a dual cure cement'*	**At 36 months** 3/94 failed Of which two had fractured Sensitivity to cold was reported by 7 patients in 7 teeth but all were symptom free at 36 months. No results presented concerning differences between types of luting material.	The generalisability is limited by the hospital environment.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Friedl, Schmalz et al. 1996; Friedl, Hiller et al. 1997) 822 and 823 **Year:** 1997 **Country:** Germany **Aim:** To evaluate and compare clinical long term results of feldspathic ceramic inlays in posterior teeth **Follow-up:** 48 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** Hospital **Clinicians:** 1 **Evaluators:** 2 evaluators (1 for clinical evaluation and 1 for SEM evauation). No training or calibration **Sponsorship:** Not stated	**Participants and Baseline Nos:** 20 with good oral hygiene and periodontal pockets less than 3mm, 13 females and 7 males **Restoration Type(s) and Baseline Nos:** 50 Class II **Tooth types and Baseline Nos:** Maxillary Premolar 20 Mandibular Premolar 9 Maxillary Molar13 Mandibula Molar 8 **Materials and Baseline Nos:** 50 Porcelain feldspathic **Participant final Nos:** 20 **Restoration final Nos:** 50 Class II **Tooth type final Nos:** Maxillary Premolar 20 Mandibular Premolar 9 Maxillary Molar13 Mandibular Molar 8 **Materials final Nos:** Porcelain feldspathic all silanated- 50 **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Yes* ***Light/Chemical cure:*** *Not applicable* ***Other:*** *Some cemented with dual cure and some with light cure, Optec universal bond Type 2*	**48 months** No failures / replacements	Generalisability limited by university setting and single operator. **Our classification for analysis** Optec Universal bond Type 2 group 2

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Thordrup, Isidor et al. 1994; Thordrup, Isidor et al. 1998) 455 and 848 **Year:** 1998 **Country:** Denmark **Aim:** To compare the performance of four types of tooth coloured inlay systems **Follow-up:** 60 months **Design:** (7) Clinical trial **Criteria:** (4) CDA system **Environment:** Dental institution **Clinicians:** Not stated **Evaluators:** 3 independent **Sponsorship:** Not stated	**Participants and Baseline Nos:** 37 patients **Restoration Type(s) and Baseline Nos:** Not stated, randomisation not described **Tooth types and Baseline Nos:** Not stated **Materials and Baseline Nos:** 15 direct ceramic (Cerec Vita) 15 direct composite (Coltene Brilliant, light cured, densified, midway filled) 14 indirect ceramic (Vita Dur) 14 indirect composite (Estilux, , light cured, densified, compact filled) **Participant final Nos:** 37 patients at 12 months, 31 patients at 60 months **Restoration final Nos:** Not stated **Tooth type final Nos:** Not stated **Materials final Nos:** 14 direct ceramic (Cerec Vita) 12 direct composite (Coltene Brilliant) 13 indirect ceramic (Vita Dur) 11 indirect composite (Estilux) **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Calcium hydroxide* ***Etch:*** *Yes* ***Enamel bond:*** *Yes, Durafill bond* ***Dentine adhesive:*** *Yes, Gluma 2 and 3* ***Light/Chemical cure:*** *Light* ***Other:*** *Luted with CEREC Dual Cement*	1 Cerec inlay fractured at 54 months 2 Brilliant replaced due to secondary caries at 12 months and 60 months 2 Vita Dur fractured at 12 and 48 months 1 Estilux replaced due to sensitivity (time not stated)	Generalisability limited by university setting. It is not possible to comment further due to insufficient detail. Our classification for analysis Gluma 2 – group 1b Gluma 3 – group 1b

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	**Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques**	**Results (to include failures and summary of statistical analysis)**	**Commentary**
Author & No: (Gladys, Van Meerbeek et al. 1995) 425 **Year:** 1995 **Country:** Belgium **Aim:** Comparison of four resin composite luted inlay systems **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (2) Own criteria **Environment:** Dental institution **Clinicians:** 2 dentists **Evaluators:** 2 independent evaluators **Sponsorship:** National Fund for Scientific Research of Belgium funded one of the investigators	**Participants and Baseline Nos:** 20 dental students **Restoration Type(s) and Baseline Nos:** 32 Class II restorations, cavities randomly allocated to material **Tooth types and Baseline Nos:** Molars and premolars **Materials and Baseline Nos:** 8 Cerec Dicor MGC with Dicor MGC lute, Prisma universal bond and Dicor etching gel 8 Cerec Vita Porcelain Mark with Microfill Ponitc C, Estiseal and Vita Cerec Etch 8 Cerec Porcelain Mark with experimental Cerec-Coltene Duo cement, Duo Bond, Vita Cerec Etch 8 P50 indirect inlay system, experiment 3M luting composite, Scotchbond 2 **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos:** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide and GIC* ***Etch:*** *Yes* ***Enamel bond:*** *Yes,varied for each group* ***Dentine adhesive:*** *Scotchbond 2* ***Light/Chemical cure:*** *Dual cure* ***Other:*** *Inlays etched and silanised,*	No restorations failed No symptoms reported by patients.	Generalisability limited by university setting. **Our classification for analysis** *Scotchbond 2 – group 1b*

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wendt and Leinfelder 1990) 838 **Year:** 1990 **Country:** USA **Aim:** To compare the clinical performance of a light cured bulk placed posterior composite with one which was light cured and then subjected to dry heat as a secondary curing method **Follow-up:** 12 months **Design:** (7) Other clinical trial, **Criteria:** (4) USPHS **Environment:** Dental institution **Clinicians:** Not stated **Evaluators:** 2 **Sponsorship:** No commercial interest in any product	**Participants and Baseline Nos:** Not stated **Restoration Type(s) and Baseline Nos:** Equal number of Class I and Class II cavities 60 restorations, randomly allocated, at least one restoration of each type in each subject **Tooth types and Baseline Nos:** Equal numbers of molar and premolars **Materials and Baseline Nos:** 30 bulk placement of posterior composite (Occlusin, light cured densified compact filled) light cured, removed and cemented 30 bulk placement of posterior composite (Occlusin) light cured, removed, heat treated and cemented **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos:** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *GIC* ***Etch:*** *Yes* ***Enamel bond:*** *Yes (Coe)* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *As baseline data* ***Other:*** *Not stated*	**At 12 months** No failures 3 of the light-cured inlays exhibited postoperative sensitivity, 2 resolved after 3 weeks and 1 required the marginal edge rebonding.	Generalisability limited by university setting and short follow-up.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Krejci, Fullemann et al. 1994) 447 **Year:** 1990 **Country:** Switzerland **Aim:** To evaluate clinically the performance of composite inlays **Follow-up:** Mean follow-up of 13.3 and 30.5 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** Dental institution **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 6 patients who wanted tooth coloured restorations **Restoration Type(s) and Baseline Nos:** 12 two-surface restorations 12 three-surfaces restorations **Tooth types and Baseline Nos:** 13 molars 11 premolars **Materials and Baseline Nos:** Brilliant (light cured, densified, midway filled composite **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos:** As baseline **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Glass ionomer cement* ***Etch:*** *Not stated* ***Enamel bond:*** *Vitrebond* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Dual cured cement* ***Other:*** *Duo Cement*	Various follow-up times but no failures during the course of this study.	Generalisability limited by university setting. It is not possible to comment further due to insufficient detail.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Wassell, Walls et al. 1995) 426 **Year:** 1995 **Country:** UK **Aim:** To compare the 3-year clinical performance of direct inlays versus conventional restorations made of the same compostie (Coltene Brilliant Dentin) **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** Dental institution **Clinicians:** 2 **Evaluators:** 2 who were also the clinicians evaluators worked independently and then agreed results **Sponsorship:** Coltene	**Participants and Baseline Nos:** 73 patients mean age 29.6 ± 10.3 years (54 female, 19 male) entered trial over 30 months, patients with poor oral hygiene, spontaneous gingival bleeding excluded **Restoration Type(s) and Baseline Nos:** Excluded if two cusps involved or margin of restoration more than 3mm subgingivally, 9 teeth root filled at study start, 66% inlays Class II, 61% conventional composites Class II, paired design at least one pair per subject random allocation of operator to patient, material to tooth and restoration order **Tooth types and Baseline Nos:** 76% in molars and 24% in premolars in both groups **Materials and Baseline Nos:** 100 pairs of restorations (Brilliant, light cured. Densified, midway filled) 100 Direct inlays, after curing treated with dry heat, luted with Duo Cure 100 Conventional composite placed with Duo cure bond **Participant final Nos:** As baseline **Restoration final Nos:** As baseline **Tooth type final Nos:** Not stated **Materials final Nos:** As baseline **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Calcium hydroxide and cermet (Ketac silver)* ***Etch:*** *Yes* ***Enamel bond:*** *Both* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Light* ***Other:*** *Duo Cure Cement*	**Variable follow up** 12 restorations have failed (10 completely and 2 requiring repair) - 8 inlays and 4 conventional composites 71 pairs of restorations have been followed for 36 months. Reasons for failure: pressure sensitivity, four inlays, one composite periapical abscess, one inlay, two composites fractured restoration, two inlays fractured tooth, one inlay one composite Twice as many inlays failed as composites and inlays were more likely to be associated with sensitivity. It is not possible to calculate the longevity from this study or when the restorations failed. 10 inlays were remade before insertion because they were difficult to remove during fitting.	The difference in failure rate might be due to the possibility that more inlay restorations were class II. This is unclear from the study. This trial suggests that in these operators' hands inlays were more likely to fail. Generalisability limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hoglund-Aberg, van Dijken et al. 1992; Hoglund-Aberg, van Dijken et al. 1994; van Dijken, Hoglund-Aberg et al. 1998) 345/453/833 **Year:** 1998 **Country:** Sweden **Aim:** to evaluate a fired feldspathic porcelain as an inlay material in combination with two adhesive luting cements **Follow-up:** 72 months **Design:** (7) Other clinical trial **Criteria:** (3) Modified USPHS **Environment:** Dental institution, and public dental service **Clinicians:** Not stated **Evaluators:** 2 independent observers trained and calibrated **Sponsorship:** Swedish Medical Research Council, County of Västerbotten and Swedish Dental Society	**Participants and Baseline Nos:** 50 patients,17 men and 33 women, age range 19 - 70 **Restoration Type(s) and Baseline Nos:** 118 Class II using paired design matched for tooth type. Each received 2 or 4 inlays (except one patient only had one inlay) **Tooth types and Baseline Nos:** 77 in premolars, 41 in molars 46 in mandibular teeth, 72 in maxillary teeth **Materials and Baseline Nos:** Group 1: 59 Ceramic inlays (Mirage, Chameleon) cemented with dual cured composite resin (Mirage) Group 2: 59 Ceramic inlays (Mirage Chameleon) cemented with glass ionomer luting cement (Fuji I) **Participant final Nos:** 50 patients examined at recalls up to 36 months, 48 at 48 and 60 months and 49 at 72 months **Restoration final Nos:** At 72 months 115 inlays were reviewed. **Tooth type final Nos:** See patient final numbers **Materials final Nos:** See patient final numbers **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *No* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide or glass ionomer cement* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Not applicable* ***Other:*** *Cemented with* dual cured composite resin (Mirage) or glass ionomer cement (Fuji I)	**Cumulative failures at time** Months Group 1 Group 2 0 0 0 6 1 1 12 1 2 24 1 6 36 2 6 48 3 11 60 4 13 72 7 15 Over 72 months 7 (12.1%) inlays cemented with resin failed compared with 15 (26.3%) inlays cemented with glass ionomer cement One patient with two inlays dropped out after 36 months, one patient with 2 inlays and 2 onlays was not seen at 48 or 60 months. One tooth was extracted for periodontal reasons. Friedman's two-way analysis of variance difference between cements significant p<0.001	This study is undertaken in a dental school and a salaried service which improves its generalisability.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Zuellig-Singer and Bryant 1999) 860 **Year:** 1998 **Country:** Switzerland **Aim:** To report on the marginal adaptation of Cerec Vita Mark II inlays with different luting agents **Follow-up:** 36 months **Design:** (7) Other clinical trial **Criteria:** (2) Own criteria **Environment:** Dental institution **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 21 randomly selected from dental hospital patients **Restoration Type(s) and Baseline Nos:** 42 Class II, 'systematic allocation' of lute **Tooth types and Baseline Nos:** Group a 5 premolars, 3 molars; Group b 7 premolars, 4 molars; Group c 8 premolars, 5 molars; Group d 5 premolars, 5 molars **Materials and Baseline Nos:** Group a Dual cement, Heliobond, silane coupling agent, enamel etched Group b Duo cement and Duo bond, silane coupling agent and etched enamel Group c Clearfil CR inlay cement, Clearfil porcelain bond and enamel etched Group d GIC (Ketac Cem) and Silux bonding agent 3M **Participant final Nos:** Not stated **Restoration final Nos:** 35 at 36 months **Tooth type final Nos:** Months 12 24 36 Group a premolars 4 4 4 Group a molars 3 2 2 Group b premolars 6 5 6 Group b molars 4 3 4 Group c premolars 8 6 6 Group c molars 5 4 4 Group d premolars 5 4 4 Group d molars 4 5 5 **Materials final Nos:** As tooth type final numbers **Techniques:** ***LA:*** *Yes* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Calcium hydroxide, glass ionomer (Ketac Bond)* ***Etch:*** *Yes, except group d* ***Enamel bond:*** *Yes, group a* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not applicable* ***Other:*** *As for materials*	**At 36 months** One inlay in Group c (a molar) failed. While this study was reporting SEM findings relating to different cements failure was also noted.	There is insufficient detail to comment on generalisability.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Hanning 1996) 808 (German) **Year:** 1996 **Country:** Germany **Aim:** To investigate the marginal seal of composite inlays after 7 years **Follow-up:** 84 months **Design:** (7) Other clinical trial **Criteria:** (2) Own criteria **Environment:** Dental institution **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 10 patients with good occlusion and anterior guidance **Restoration Type(s) and Baseline Nos:** 20 Class II and 20 Class I restorations **Tooth types and Baseline Nos:** Premolar and molar teeth **Materials and Baseline Nos:** Composite inlay, SR Isosit **Participant final Nos:** 10 patients **Restoration final Nos:** 20 Class II and 20 Class I **Tooth type final Nos:** As above **Materials final Nos:** As above **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Zinc oxide and dentine protector* ***Etch:*** *Enamel* ***Enamel bond:*** *Yes, heliobond* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Yes* ***Other:*** *Inlays were sandblasted*	**Cumulative failures** **At 36 months** 3/40 failed **At 84 months** 6/40 failed 3 Class I restorations fractured 3 Class II restorations fractured Not able to distinguish which cavity type failed when. (An additional 3 Class II were replaced because of marginal imperfection but these are not classified as failures for this review)	Generalisability is limited by university setting.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Reiss and Walther 1991) 207 (German) **Year:** 1991 **Country:** Germany **Aim:** To evaluate the performance of CEREC inlays **Follow-up:** Variable maximum of 36.2 months **Design:** (3) Prospective case series **Criteria:** (2) Modified USPHS **Environment:** Dental practice **Clinicians:** One **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 142 patients mean age 33.5 years, 58 men and 84 women **Restoration Type(s) and Baseline Nos:** Not stated **Tooth types and Baseline Nos:** 228 molars, 198 premolars **Materials and Baseline Nos:** CEREC inlays placed between June 1987 and March 1989 **Participant final Nos:** See materials below **Restoration final Nos:** See materials below **Tooth type final Nos:** Not stated **Materials final Nos:** 6 months 43 7 -12 months 29 13-18 months 97 19 - 24 months 111 25 - 30 months 98 31 - 36 months 39 more than 36 months 9 **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *Not stated* ***Lining:*** *Not stated* ***Etch:*** *Not stated* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Not stated* ***Light/Chemical cure:*** *Not stated* ***Other:*** *Not stated*	12 restorations failed but the time at which they failed cannot be deduced. 4 fractured, 2 marginal fractures, 4 sensitivity on biting, 1 pulpitis, 1 secondary caries. The mean time for failure was between 19 and 23 months. 10 molars and 2 premolars failed but the difference betweeen tooth type just failed to reach statistical significance.	Generalisability is limited by the use of a single operator.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Goto, Taguchi et al. 1969) 106 **Year:** 1969 **Country:** Japan **Aim:** A clinical evaluation of gold inlays in first molar teeth in children **Follow-up:** Variable **Design:** (3) Prospective case series **Criteria:** (2) Own criteria **Environment:** Not stated **Clinicians:** Not stated **Evaluators:** Not stated **Sponsorship:** Not stated	**Participants and Baseline Nos:** 51 children 5-12 years **Restoration Type(s) and Baseline Nos:** 1surface 50 (44 O, 6 B) 2 surfaces 42 (27 OB, 11 OL, 4 MO) 3 surfaces 6 (4 MOB, 1 MOL, 1 BOL) 4 surfaces 2 (1 MODL, 1 MOBL) (O – occlusal, M – mesial, D – distal, B – buccal, L – lingual) **Tooth types and Baseline Nos:** 100 Permanent 1st molars **Materials and Baseline Nos:** 100 gold restorations **Participant final Nos:** Not stated **Restoration final Nos:** Variable, restorations placed over a period of time and reviewed at a later date Months in situ at review n 30-180 29 181-365 28 366-730 22 731-1095 9 1096-1770 12 **Tooth type final Nos:** Not stated **Materials final Nos:** Not stated **Techniques:** ***LA:*** *Not stated* ***Rubber dam:*** *Not stated* ***Bevelled enamel:*** *No* ***Lining:*** *No* ***Etch:*** *No* ***Enamel bond:*** *No* ***Dentine adhesive:*** *No* ***Light/Chemical cure:*** *Not stated* ***Other:*** *Not stated*	6/100 restorations failed (1 restoration loss, 5 secondary caries) 0 post operative sensitivity	Variable follow-up time makes analysis difficult. There is insufficient detail to comment on generalisability.

Author(s), Year, Country, Aim, Follow-up, Design, Criteria, Environment, Clinicians, Evaluators, Sponsorship	Participants and baseline numbers, Cavity Type(s) and baseline numbers, Tooth types, Participant and Restoration final numbers, Materials, Clinical techniques	Results (to include failures and summary of statistical analysis)	Commentary
Author & No: (Cavel, Kelsey et al. 1988) 288 **Year:** 1988 **Country:** USA **Aim:** To evaluate the clinical acceptability of intracoronal Dicor restorations cemented with Dicor light activated cement and also evaluate manipulative variables affecting this restorative system **Follow-up:** 6 months **Design:** (3) Prospective case Series **Criteria:** (4) USPHS **Environment:** Hospital **Clinicians:** Not stated **Evaluators:** 2 (with calibration) **Sponsorship:** Not stated	**Participants and Baseline Nos:** 31 **Restoration Type(s) and Baseline Nos:** 19 Class I 12 Class II **Tooth types and Baseline Nos:** Premolars and molars **Materials and Baseline Nos:** Ceramic –Dicor and Dicor dual cured cement with bonding agent 16 Ceramic –Dicor and Dicor dual cured cement without bonding agent 15 **Participant final Nos:** 31 **Restoration final Nos:** 19 Class I 12 Class II **Tooth type final Nos:** Premolars and molars **Materials final Nos:** 16 Ceramic –Dicor and Dicor dual cured cement with bonding agent 15 Ceramic –Dicor and Dicor dual cured cement without bonding agent **Techniques:** ***LA:*** *Yes –when necessary* ***Rubber dam:*** *Yes* ***Bevelled enamel:*** *No* ***Lining:*** *Not stated* ***Etch:*** *Yes* ***Enamel bond:*** *Not stated* ***Dentine adhesive:*** *Yes (16 restorations)* ***Light/Chemical cure:*** *Not applicable* ***Other:*** *Rounded internal line angles, dual cured cement*	No failures after 6 months No post operative sensitivity 2 of the first 3 inlays fractured when occlusal evaluation was performed prior to cementation	Generalisability limited by university setting and short follow-up.

APPENDIX 2
DATA EXTRACTION SHEETS

Reference ID		Screeners ID	

STUDY DESIGN (follow flow chart)

Case study	**1**	Prospective study + historical controls	**5**
Retrospective case series	**2**	Prospective study + concurrent controls	**6**
Prospective case series	**3**	Other clinical trial	**7**
Retrospective study with concurrent controls	**4**	Randomised controlled trial	**8**

For observational studies only (i.e. categories 3 - 6)			
No. of subjects at start	No. at first follow up	% at first follow up	If less than 90% state reason for less

Comment on flaws in study design and if sufficient follow up to include observational study

Outcomes

0	Restoration degradation (not replacement)	X	**complete economic section**
1	Restoration replacement (subjective)	X	**complete economic section**
2	Restoration replacement (use of criteria)		
3	Restoration replacement (criteria, training and calibration)		
4	Restoration replacement (valid outcome eg USPHS)		
5	Restoration Failure (no intervention)		
	Pain in subjects recorded enter yes if recorded		

List all outcome measures used and note any weaknesses in their use

1.

2.

3.

4.

Outcome Score (a)		
Study design Score (b)		
Sufficient follow-up? (categories 3-6 only) enter yes or no		**if no exclude**
Include or exclude (a on grid against b)		

Does this paper include economic data?

	Yes	**No**
Time		
Costs		

Enter grid description ______________________ Enter grid number ________

Enter the aims of this study

Is this paper part of a series of papers? **Yes** ☐ **No** ☐

Description of papers required to be combined ______________

Reference ID ______ Reviewer No. ______

STUDY DETAILS (describe)

Country of study ______ Commercially sponsored ______

Length of study ______ Recruitment method ______

Subject inclusion criteria ______

Basis of comparison:-

Same mouth different teeth		Different mouth similar teeth	
Same mouth similar teeth		Different mouth different teeth	

Age range	Child		Adult 18+		Mixed		Not stated	
Gender	Male		Female		Both		Not stated	

No. of Examiners assessing restorations ______

	Yes	**No**	**Not possible**	**Not stated**
Operator training				
Treatment protocol followed				

	Rest code	**Trade name**	**Physical type** **Describe eg low Cu**	**Adhesive / base describe**	**Codes**	
Group 1					Amalgam = Am	Compomer = Cmp
Group 2					Composite direct = Co	Cermet = Cer
Group 3					Composite inlay = Coi	Gold = Au
Group 4					GIC = GIC	Porcelain = P
Group 5					S = sealant	
Group 6						

Describe sample:- **Insert number of patients and restorations for each group and give totals**

	Time	**No. Patients**							**No. Restorations**						
	Mths	**Gr 1**	**Gr 2**	**Gr 3**	**Gr4**	**Gr 5**	**Gr 6**	**Total**	**Gr 1**	**Gr 2**	**Gr 3**	**Gr4**	**Gr 5**	**Gr 6**	**Total**
Baseline	0														
Assess 1															
Assess 2															
Assess 3															
Assess 4															
Assess 5															

Insert details of cavities

	GR 1	**Gr 2**	**Gr 3**	**Gr 4**	**Gr 5**	**Gr 6**	**Codes**
Cavity type							Insert Class(es)state mixed or NA
Cavity modifications							Describe eg grooves
Tooth type							describe ant, pre, mol
Dentition							1 = dec 2 = perm

Insert % of restorations in each tooth type

	G1	**G2**	**G3**	**G4**	**G5**	**G6**
Incisors						
canines						
Premolar						
Molars						

Comment on comparability of experimental groups

______

If same for all groups enter for group one and draw arrow across other groups
In all categories NS = not stated

Effect modifier	**Gr 1**	**Gr 2**	**Gr 3**	**Gr 4**	**Gr 5**	**Gr6**	**Codes**
Social class:-							Describe or not stated NS
Ethnicity							Describe or not stated
Moisture Control							D = dam, C = cotton wool, NS = not stated
Local Anaesthetic							Y = always, N = never, WR when required, NS
Exposure to Water Fluoride							Y = yes, N = no, NS
No. of Dentists placing rests.							Enter number
Number of Clinics							Enter number
Parafunctional occlusal load							Y = Wear facets recorded, X = pts excluded,
Operators clinical expertise:							D = dentist A = auxiliary S = Student
Age (or range) of operators							Enter number or NS
Years since qualification							Enter number or NS
Environment							P = practice, H = hosp/uni, S = spec prac, F = field trial, C = comm, M = army, NS
Payment:							G = gov, I = ins, P = priv, O = other, NS
	M1/M2	M1/M2	M1/M2	M1/M2	M1/M2	M1/M2	
DMFS							Enter number, state mean (M1) or median (m2)above
	M1/M2	M1/M2	M1/M2	M1/M2	M1/M2	M1/M2	
DMFT							as above
Systemic disease:							Describe or not stated NS
Oral cleanliness							Describe or not stated NS
Dietary sugar:							Describe or not stated NS

Insert details of results

Time (months)	**GR 1**	**Gr 2**	**Gr 3**	**Gr 4**	**Gr 5**	**Gr 6**	**What measure? eg fail / replace**

ECONOMIC ANALYSIS	**Yes**	**No**
Cost mentioned		
Treatment time		

STATISTICAL DETAILS	**Yes**	**No**
Statl analysis undertaken (describe)		
Comparison of failure rates		
Length of follow up (time)		
Mean/median survival times		

Evaluation Stage 3

	Yes	**No**	**Comments**
Objectives achieved			
Results generalisable			

Main findings and summary. Comment on bias, generalisabilty, internal/external validity, randomisation

Decision stage 3

Accept paper ☐ More information required ☐

Letter to author asking what?