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Quality of dental restorations

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A major undertaking for general practitioners is the provision and assessment of dental restorations. High quality restorative therapy encompasses several key elements that fulfil specific criteria. Enhanced knowledge of these elements is a significant step toward improvement of the quality of restorative dental care[1].

Several studies have demonstrated that a major component of a dentist's work is re-restoration of previously restored teeth. Collectively this represents a worldwide billion-dollar industry[2]. Estimates of annual expenditures for 'replacement dentistry' are US$5000m (USA, 1984)[3], NLG600m (Netherlands, 1988)[4], and GB£100m in the public sector alone in UK in 1991[5].

Quality of dental restorations encompasses wide-ranging clinical considerations, which are reflected by many strategies used to explore the issue. Such strategies include appraisals of criteria for quality or causes of failures of restorations[6,7], health gains through improvement of clinical practice[8], standards of dental care and practice[9–11], and methods for evaluating restoration performance[12].

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Longevity of restorations has frequently been reviewed. Recent reports address longevity of restorations of glass-ionomer cements[13], inlays[14] and CEREC ceramic inlays[15]. A systematic review of 652 relevant papers on directly placed materials commissioned by UK National Health Services has also been published[5,16]. In addition, another group of investigators has reported a detailed appraisal of the scientific validity of clinical studies[17]. The reviews highlight that clinical studies have generally been carried out under optimal conditions, and suggest that reported longevity is unlikely to be achieved in routine general dental practice. It is more likely that in routine practice subjective factors have a greater impact on longevity than objective factors such as the physical properties and biocompatibility of the restorative material.

The aim of the present report is to thoroughly review all factors that may affect the quality of a dental restoration and to review studies that have investigated those issues. This analysis will consider:

- Specific definitions of quality
- Variations among clinicians
- Analysis of longevity
- Material, operator, and patient-factors affecting initial technical excellence
- Material, operator, and patient factors contributing to clinical failure
- Treatment decisions.

What is quality?

Definition of quality

The literature abounds with papers focused on quality aspects in restorative dentistry. It becomes apparent when reading these papers that there is little consistency in the use of the term 'quality'. This is probably because the term has multiple interpretations, as the originally Latin term 'qualitas' has varied in different languages throughout history. Furthermore, it is reasonable to assume that individuals' use and interpretation of the term 'quality' depend on socio-economic and cultural backgrounds. Moreover, the term invokes different interpretations depending on the context in which it is used, for example, in English. In the dental literature it seems that restoration 'quality' is regarded as synonymous to 'technical excellence'. However, technical excellence is but one factor among others that constitute quality.

In industrial production systems quality is described as: 'The quality of a product is measured against some objective standard, which includes appearance, performance characteristics, durability, serviceability, and other physical characteristics; timeliness of delivery; cost; appropriateness of documentation and supporting materials; and so on'[18].

It is not complicated to assess a single restoration relative to timeliness of delivery and cost. Nor is it difficult to grade appearance and physical characteristics of a restoration versus a natural tooth. Data on durability and serviceability of restorations can be aggregated for the operator, clinic or even for national levels to give some indication of the 'standard' of quality. However, measuring quality of a dental restoration in this manner is untenable for several reasons. The most fundamental reason is that the primary aim in restorative therapy is not 'production' of restorations. Dental restorations must be evaluated in terms of pre-set aims such as preserving remaining tooth tissues or improving appearance. Of course, this should not deter dentists from striving to consistently place restorations of the highest technical excellence.

Dental restorations and quality

The term, dental restoration, is used to describe three-dimensional inserts and additions to teeth, custom-made in a wide range of clinical situations and using different restorative materials. It is used for any alloplast put in or on a tooth, regardless of size, location or reasons for placement. The validity of this practice can be questioned. Consider, as examples, bonding thin ceramic laminates on worn cuspids in a 60 year old patient, applying 'preventive resin restoration' in the fissures of the first permanent molar in a 7 year old, and placing a large MODBL amalgam filling in a lower second molar caused by gross caries in an 18-year old patient. What do these different variants of 'restoration' have in common besides a name? They are all being made to improve or restore morphology and/or function with a technical solution designed to last indefinitely. When the question of quality is of concern, restoration characteristics should not be of primary interest. Rather, focus should be on the extent to which the objectives for placement have been achieved and maintained.

It follows that there are fundamental differences between laboratory and clinical research outcomes regarding assessment of restoration quality. Laboratory research can, at best, only provide indications of probable or possible technical excellence. Clinical studies can, under controlled conditions, provide indications of potential restoration quality. Clinical performance needs to be appraised in general practice settings.

Most restorative therapy is associated with managing damage caused by dental caries. Other reasons include managing effects of trauma, wear or erosion with a common goal being prevention or avoidance of further damage. Alternative indications are aesthetic and functional considerations. Although the outcome, that is a restoration, is similar, it would seem illogical to prescribe different quality criteria for restorations placed following caries versus placement

Figure 1. Risk considerations of three restorations. 1. Is the remaining tooth integrity intact on both laterals? 2. Are the periodontal tissues damaged? 3. Are remaining tooth tissues jeopardised by the discrepancies in the restorations? 4. Will any of the restorations wear or degrade to an unacceptable level before the next appointment?

due to other reasons. With these points in mind, quality of a dental restoration can be described in terms of:

- Risk to the integrity of dental and oral tissues
- Extent of imitation of natural form, function and properties of the tooth
- Patient satisfaction, over time.

Several comments are pertinent to this definition. A prime concern of any therapeutic intervention is to cause no harm. Thus, any other criteria for assessment of quality must be secondary to this aspect. The risk of adverse biological effects is always possible when a foreign material is introduced into the oral cavity (*Figure 1*). Restoration quality and technical excellence are related, but not synonymous. The operational consequences of lack of technical excellence must be considered in the context of the oral environment. The consequences of a particular defect in a restoration may be completely different between individuals. In some patients, less than ideal restorations may be considered acceptable, yet in need of replacement in other patients. By way of an example, loss of approximal surface integrity in a patient with rampant caries may have greater effects than in a patient with no caries incidence during the previous ten years.

Quality assessment is influenced by tooth prognosis and not by level of technical excellence. Consequently, evaluations of restoration quality are only valid when done clinically by a trained clinician with knowledge of the patient's past and present oral disease history. The patient's opinion of a restoration, which includes satisfaction with aesthetics, tooth sensitivity, surface texture and contour is an important determinant of quality. However, the possibility of inducing an increased risk of adverse biological effects following an operative intervention (or lack of it) versus a patient demand must always be considered.

Restorations should not be presumed to be 'permanent'. Certain restorations, for example tooth-coloured restorations in non-carious cervical lesions, may be placed in the knowledge that longevity may be limited. However they may still be considered to have excellent qualities because of reduced future risk of adverse biological effects as a result of iatrogenic tooth substance loss. Finally, there are cost implications of differences in dentists' restorative treatment decisions that need to be considered when discussing restoration quality versus replacements[19].

Clinical evaluation systems

Direct and indirect methods for assessing technical excellence of dental restorations[12] focus on specific restoration features rather than general state of the restoration. Criteria have been developed to assess occlusal margins[20–24], approximal margins[25], surface wear[26,27], and surface roughness[28]. Indirect evaluation methods further obscure any global assessment of restoration quality. Clinical assessment should be preferred, whether or not it is subjective or objective according to precisely specified criteria[29].

Evaluation systems differ in number of criteria used, extent of rating options, and completeness of descriptive criteria. Quite often, training of the evaluators varies or the procedures for evaluation are not detailed. Moreover, evaluation procedures and use of supplemental aids (for example radiographs and colour photographs) varies. All such factors significantly affect the validity of clinical findings. Two clinical systems for evaluating restorations are widely used. The original system was developed by Cvar and Ryge in 1971 and introduced as 'Criteria for the clinical evaluation of dental restorative materials' for use by United States Public Health Service[30]. These criteria are also often termed 'Ryge' or 'USPHS' criteria. The second system is a variation of the USPHS system and titled 'Standards of quality of dental care' used by the California Dental Association (CDA)[31]. Both systems evaluate colour, anatomic form and marginal characteristics (adaptation, discolouration, and caries); both are based on an ordinal scale and on 'an operationally defined threshold', that is acceptable or not acceptable. Several authors have described 'modified criteria' to complement the basic USPHS and CDA systems for scoring different types of characteristics of direct and indirect restorations[32,33]. The argument against using the USPHS and CDA systems as a basis for restoration replacement is that they describe only degrees of deviation from an 'ideal' state. As such, only degree of technical excellence is addressed, with operational consequences that cannot be applied with validity in different patients, with for example, high versus no caries activity. An attempt to apply the CDA criteria as a component in a treatment decision process is presented in the last section of this report.

An entirely different concept for addressing quality of restorative care was proposed by Lutz *et al.*[34]. The authors describe three standards, whereby various goals are pursued: preservation as the lowest aim, through function, to the highest level of 'imperceptible restitution of teeth'. The authors advanced suggestions for applying specific USPHS criteria to satisfy the three standards. In order to classify technical quality of restorations in children, Carpay *et al.*[35] reported a combined quality assessment-dental treatment index with six criteria. Quality was analysed in relation to the child's age and region of residence, type of dental professional regularly visited, size of the restoration, and whether or not the restoration was polished. Unfortunately, the index has not been validated in any longitudinal clinical studies.

Variations amongst clinicians

Several studies have explored variations in clinical, perceptual and judgmental abilities of dentists and related this to education, clinical training, practice experience and commitment to continuing dental education.

Clinical variation

Variations in material handling among practitioners and auxiliary personnel have been reported. Usually, this will compromise the physical properties of the material. However, most of these studies have been carried out as process studies without any assessment of the clinical consequences of the variations. It is therefore uncertain to what extent such variations influence the long-term clinical performance of restorations.

In a cross-sectional study of 6,761 restorations replaced in permanent teeth, some interesting links were observed between replacement and characteristics of the 243 operators who participated. The result revealed that the median age of amalgam and composite resin restorations replaced by male clinicians was higher than that for female clinicians irrespective of clinical setting. Moreover, the median age of restorations replaced by salaried dentists was significantly lower than that by private practitioners. Finally, the age of the restorations was shortest for the group of clinicians with least clinical experience, and highest for those that graduated more than thirty years earlier[36].

In a study comparing students and dentists' abilities to handle adhesives, Sano *et al.*[37] concluded that clinical experience is not necessarily predictive of satisfactory material handling. Ciucchi *et al.*[38] evaluated adhesive bonds produced by 92 dentists attending clinical courses using nine different adhesive systems. After an introductory hands-on course, a total of 2,508 composite cylinders were bonded to prepared bovine dentine. The measurement of bond strengths demonstrated a large variation in results and a significant effect in respect of the handling. The variation in results among the practitioners was larger than that among nine tested adhesive systems.

The condensation pressure used during the placement of amalgam varies greatly. In a study among 44 practitioners it was reported that lower condensation pressure was used than that recommended in the manufacturers' directions for use[39]. Wasson and Nicholson[40] reported that, in general, the ability to evaluate correct material consistency among inexperienced operators was poor. Thus, lower values for physical properties for glass-ionomer cements were obtained, compared to semi-skilled or skilled operators.

A report on handling of glass-ionomer cements by general practitioners suggested that these were often mixed in a much lower powder:liquid ratio than recommended[41]. Gjerdet and Hegdahl[42] reported substantial variations in strength properties of amalgam restorations placed by 59 dentists although the study was carried out in the laboratory, so it is difficult to interpret its clinical significance. However, the findings suggest that there is a potential that restorations may be made from a material with less-than-optimal physical properties if improperly handled by the operator.

Interestingly, variability in material handling is also a major problem in institutions where standards testing is carried out. Dermann[43] reported variations in amalgam specimen strengths, and attributed this to variable condensation pressure when preparing the specimens. McCabe *et al.*[44] reported variability among three test centres, and speculated that this could be explained by subtle differences in material handling, or in the surface finish of the specimen moulds. Ferracane and Mitchem[45] commented in a study of composite resin testing among seven centres, that the production of specimens occurred in a non-uniform manner, despite a similar protocol being used by all participants. They suggested that the reason was difference in experience of the personnel, which significantly influenced the results. It seems difficult to avoid such inter-individual variations in dental clinics, when similar problems are experienced even amongst highly trained investigators working in laboratory environments.

Perceptual variation

The clinical examination of restorations requires a clean, dry and well-lit field. For approximal restorations, additional prerequisites are dental floss and high quality radiographs[46]. The lack of adherence to these requirements partly explains reports of large variations in clinical treatment decisions among clinicians. The importance of conducting a comprehensive clinical evaluation to appraise the true condition of restorations has been highlighted by Poorterman *et al.*[47]. The authors reported on the basis of a clinical epidemiological study of 621 participants that the prevalence of approximal caries and defective restorations was highly underestimated. Of the total number of recorded decayed or defective restoration surfaces, only 10–15 per cent were found clinically. Added to this are problems of inter- and intra-examiner variations of interpretation and different diagnostic abilities.

Tobi *et al.*[48] examined observer variation in assessing marginal adaptation of composite inlays and amalgam restorations. The authors concluded that the observers' agreement depended on the clinical performance of the material. Consequently, they advocated a log-linear modelling approach for evaluating materials that simultaneously takes into account observer agreement and material performance.

Finishing and polishing may influence the decision to replace amalgam restorations. In a study including 60 practitioners and students 'appearance' or anatomic shape was the most frequently cited reason for replacement before finishing and polishing, followed by marginal defects and secondary caries. Subsequent finishing and polishing significantly reduced the number of replacement decisions for all practitioners[49].

Dental students have large variations in visual ability to accurately judge size, depth and angle[50]. Interestingly, ability to improve visual perception by training seems to be limited. The author advocated use of standardised objects to allow size or angle judgement by direct comparison. A logical deduction of this finding is that it is probable that many dentists daily make inaccurate and variable judgements caused by poor visual perception.

Dunninger *et al.*[51] observed that agreement between investigators assessing restorations ranged from 56 per cent to 88 per cent, depending on the criteria used. The more positive the results of the assessment and the more objective the criteria, the higher the level of agreement.

The reports on variations in dentists' assessment of dental restorations are perhaps not surprising. Substantial variations have also been documented in dentists' abilities to diagnose, for example, occlusal caries clinically[52], dentine caries on radiographs[53], approximal caries and deficient restorations on radiographs[47] and perception of tooth colour[54]. Much can be summed up by the statement 'operators detect what they are trained to see'. Research is needed to assess the effectiveness of different strategies to improve clinical diagnostic abilities.

Figure 2. Reasons for replacement of restorations (Table copied from: NHS Centre for Reviews and Dissemination, 1999[5]; with permission).

Judgmental variation

Factors associated with operator's treatment decisions and recommendations are not well documented. This is unfortunate, since it is important to determine normative treatment needs, to evaluate interventions designed to reduce the frequency of inappropriate treatment, and for developing valid practice parameters. In a systematic review of 652 reports on clinical studies of dental restorations, several factors influencing clinicians' decisions to replace restorations were identified[5] (*Figure 2*).

Kay and Blinkhorn[55] have suggested, following in-depth interviews with 20 randomly selected general dentists, that an understanding of disease processes and of available treatment options may be an insufficient basis for treatment decision-making. The authors uncovered many considerations outside straightforward concepts of oral health that influenced the choice of clinical treatment decisions.

Hawthorne and Smales[56] investigated the amount of treatment provided for 100 adult patients treated by 20 male dentists over approximately 25 years in three selected private practices. Particular types of restorative treatments were significantly related to patient age, gender and frequency of attendance, to practice location, change of dentist and number of changes of dentist, and to the experience or time since graduation of the dentist. These factors were of special significance for the number of crowns provided, of which the majority were placed in older patients by the most-experienced dentists. However, there was no evidence of increased numbers of direct placement restorations being received by patients who attended frequently or who changed their dentists often.

Paterson *et al.*[57] attempted to develop policy statements on maintenance and replacement of amalgam restorations. A Delphi technique commonly used in social sciences was used to produce a consensus view on 17 statements. Agreement was rapidly reached that 'ditching' of amalgam restoration margins did not justify their replacement, and that repair was preferable to total replacement. However, some difficulty was experienced in arriving at a consensus view on the correct management of 'white spot' lesions at restoration margins and dentinal staining adjacent to amalgam restorations.

In a study of restorative decision making among dentists, significant relationships were noted between replacement rates and several dentists' practice and demographic characteristics. These included dentists' gender, year of graduation and type of practice[58]. Bader and Shugars[59] reported agreement of treatment recommendations made by 51 dentists on 1,187 teeth in 43 patients. The reliability of inter-examiner agreement for restorative treatment was lowest for recommendations concerning previously restored teeth. It was concluded that much of the variation in dentists' practice profiles was explained by basic differences in decisions to recommend treatment for individual teeth with specific conditions. The presence of previous restorations seemed to magnify these differences. The same authors had in an earlier paper also suggested that a lack of knowledge about relative effectiveness of treatment options might be an important cause of dentists' variations in treatment planning[60].

Drake *et al.*[61] compared three dentists who replaced restorations using various failure criteria. The authors attributed differences to individual practice philosophies, demonstrating that clinical information was not the sole determining factor as to the type of replacement restorations that patients received.

Risk evaluation

Probably the most important factor explaining variation in treatment decisions is the difference of estimation of risk as well as attitude towards risk among dentists. Worthington *et al.*[62] surveyed 24 general dental practitioners with respect to general treatment or treatment related to caries on 2,553 patients. The authors concluded that common assumptions used by practitioners to estimate their patient's risk for future treatment varied, as well as the practitioners' attitudes towards risk. Dentists should have a basic understanding of the terms association, risk and causality. These terms are fundamental in causal theory. In epidemiology, the terms are applied to understand diseases, but they are also applicable to the clinical performance of dental restorations. By example, the risk of occurrence of a specified outcome or incident of interest, such as secondary caries, bulk fracture or degradation.

An association exists if two variables appear to be related by a mathematical relationship. Thus, a change of one appears to be related to the change in the other. Association is necessary for a causal relationship to exist, but association alone does not prove that a causal relationship exists. By example, surface discolouration and wear are often associated, but there is no causal relationship. A risk is the likelihood that a specified outcome will develop in a defined time period. By example, risk of bulk fracture within five or ten years of a ceramic inlay. A risk factor (sometimes also termed 'condition determinant' or 'predisposing factor') is an attribute (intrinsic characteristic) or exposure (external environment) that is positively or negatively associated with the occurrence of a specified outcome. By example, inadequate thickness of inlay (intrinsic characteristic) placed in the second molar of a patient showing marked signs of heavy bruxing (external environment) are risk factors related to inlay bulk fracture. Cause is a combination of necessary and sufficient factors, the presence of which, alone or in combination, at some time inevitably result in an incidence of interest. A necessary factor/cause is a risk factor that must be, or have been, present for a specified outcome to occur. By example, plaque remaining close to a restoration margin can lead to secondary caries, but although plaque is required it is not inevitable that caries develops. A sufficient factor/cause is the minimal or combination of risk factors that inevitably results in a specified outcome. By example, plaque remaining close to a restoration margin combined with frequent intake of carbohydrate-rich foods that continues over time in an individual avoiding fluoride result in secondary caries. However, from clinical experience we know that an incident of interest, such as the example here using secondary caries, can often be caused by more than one set of sufficient causes. Thus, different causal pathways may exist in different situations. Causal pathways (alternatively termed causal web or cause-and-effect relationships) involve the actions of risk factors acting individually, in sequence, or together that result in an incidence of interest. These pathways may vary with different sets of risk factors. Understanding these pathways is necessary to devise preventive countermeasures or interventions to avoid a specified outcome, and the countermeasure may be unique to the pathway.

Causal relationship can be determined using various levels of evidence. In theory, all information regarding a hypothetical causal relationship can be labelled evidence and must therefore be appraised. However, formal requirements are needed to address validity of evidence, and this is applied on scientific data. Inferences of causal relationship are directly associated with study design. For many clinical questions, randomised controlled trials (RCTs) are regarded as the strongest evidence for causal relationship. However, many determinants of aetiology, diagnosis and prognosis can for various reasons only be estimated indirectly using cross-sectional, cohort or case-control study designs. In these situations, inference must be assumed on the basis of how findings satisfy different criteria of causation.

Statistical issues

Clinical studies may be classified as experimental or observational. Only studies with experimental designs can be considered inductive, that is, can give an indication of a cause-effect relationship between different factors or variables with a certain degree of uncertainty. All other methods involve limitations through bias or confounding. However, data from observational studies should not be regarded as unimportant or incorrect. Hypotheses are often generated first on the basis of observational studies, and are then tested for validity under more rigorous experimentally designed conditions.

Certain requirements must be fulfilled to qualify as an experimental study. These are the presence of control groups, predefined allocation of variables, and standardised evaluation procedures and criteria for the evaluation of outcomes. The allocation of variables is randomised if possible, in order to make even stronger statistical inferences, i.e. a randomised controlled trial. The specific aim of the study and the formulation of a hypothesis should be documented. When these criteria are not met, or when observations are made of phenomena that are not manipulated by the investigator, a clinical study is classified as observational.

Relatively few clinical studies in restorative dentistry fulfil the criteria of an experimental design[5,16,17,63]. The majority of clinical studies where an association has been reported between clinical variables and restoration performance have been observational studies. This is because although the studies were experimentally designed to obtain information on differences between, for example materials or commercial products, the observations and descriptions of the influence of other factors were not obtained by the manipulation of these factors.

Many clinical studies are carried out according to recommendations outlined by various national or international acceptances programme guidelines, for example FDI[64], NIH[65] and ADA[66–68]. These guidelines are designed to address ‘safety’ and ‘efficacy’, that is attempts to score performance as passing or failing and not to rank clinical performance. This is why many of the criteria are based on a passing level of, for example 85–90 per cent alpha scores according to the USPUS criteria after one to three years, and only distinguish between unacceptable and acceptable performance. For different reasons these guidelines do not require controls, do not test for placebo effects and do not have statistical powers great enough to answer anything other than simple experimental questions. The most commonly tested hypothesis is whether a new material or product has been comparable to a specific traditional material.

Many of these trials are carried out in research environments, as opposed to general practitioners’ practices. The operators are often selected and trained to ensure optimal handling. Furthermore, the patients are often dental students, dental school staff or dentists with above average oral hygiene[12,13,16,17,69]. Controlling operators and their working environment, patients, and size and intra-oral location of the restorations reduces confounding, when comparing different materials or products. However, data from such studies do not reflect the situation in ‘real-world’ dental practice[70]. This is especially apparent when technique-sensitive materials are involved[1]. In general practice, treatment times are constrained, the diagnostic thresholds for replacement may vary with the patient load, and there are no economic incentives to produce higher clinical standards above acceptable[61]. In general, there is public concern that there is lack of data on clinical performance of restorative materials and on the quality of service provided by dentists in general practice, and especially on the interaction between clinical performance of restorations and quality of service[71].

It is evident from the literature that there are disagreements concerning the material, operator and patient effects on restoration quality. One of the major issues appears to be the statistical treatment of data. It is difficult to conduct clinical studies, with the aim of establishing a numerical relationship between one specific risk factor and the technical excellence, restoration service period or replacement reasons. The main reason is that the clinical performance of a restoration is dependent on many known and unknown clinical variables that are difficult to control or record. It is also difficult, if not impossible, to assure independence among many clinical variables that affect restoration clinical performance. Currently, there do not appear to be any generally acceptable, valid statistical techniques for isolating the influence of a single variable; indeed, many of the variables may not be independent. In full knowledge of this situation, clinical researchers employ various strategies when designing trials aiming to clarify parameters of restoration quality (*Figure 3*).

Figure 3. Parameters of the quality of dental restorations. The horizontal axis represents time, while the vertical axis is the proportion of restorations remaining over time. The bold line represents the proportion of restorations remaining in situ (that is 'survival'), and these are in the category 'excellent' (for example 'alpha'), 'acceptable' ('beta') or 'defective' ('charlie'). Replacements may be 'true' reasons, that is bulk fractures, secondary caries, marginal deficiencies, discolouration, etc, or because of faulty diagnosis, inclusion into larger restorations, primary caries on other surfaces, etc. Arbitrarily lines depict the proportion of restorations/replacements that fall into the carious categories. The horizontal line at 50% marks the median survival time. The intersections between this line and the other lines represent from left to right when 50% of the remaining restorations are: excellent, acceptable and remaining *in situ*.

Restoration quality has been addressed in both prospective and retrospective longitudinal studies as well as in cross-sectional studies. Data from prospective and retrospective longitudinal studies can be used for constructing survival curves, proportions of restorations with varying technical excellence as a function of time and reasons for replacement.

Current restorative materials have excellent physical and mechanical properties. Prospective clinical studies therefore need to be extended for many years and/or include large numbers of restorations before any strong statistical inferences can be made. Long observation periods are associated with problems such as patient dropouts, patient representativity and changes in the clinician's diagnostic abilities or understanding of replacement criteria. Finally, also ethical reasons may occasionally restrict the possibility of conducting prospective clinical studies.

Retrospective studies are based on analysing patient records or a combination of patient records and quality evaluation of restorations. A frequent problem with many retrospective studies is that little or no information is available on possible reasons for replacement. Several studies have revealed that replacements are not always explained by restoration failure[1], and even if they are, retrospective data give no indication regarding whether the failures are related directly to the restoration, to the restorative process or to external factors[72].

Cross-sectional clinical studies have either been presented as replacement studies or recordings of data from patients' records. Other data have been derived from assessment of technical excellence of restorations *in situ* or in extracted teeth, or from detailed studies of failed restorations. Cross-sectional studies that focus on mean age of failed restorations identify the 'geometric centre' of the area above the survival curve in *Figure 3*, while studies that focus on the age of remaining restorations identify the centre below this curve.

In replacement studies, the previous history and age of the restorations is often unknown. Although the type of material usually is recognised, specific trade names or batch numbers are seldom recorded. A characteristic of the study method is that the evaluation criteria are not explicit, which leaves the diagnoses to the operators involved in the study. The results do not indicate any causal relationships, and they are probably influenced by factors such as socioeconomy, patient demography and the dentist:patient ratio. The same arguments are applicable when interpreting results from cross sectional studies. Although the evaluation criteria may often be accurately described, the history and clinical parameters at the time of restoration placement remains unknown.

Most clinical studies have been conducted with the aim of enhancing the performance of restorative materials. In this context, rigorous adherence to the study protocol is required to minimise any confounding factors. However, this is quite different from 'real-life' dentistry. Although there is much literature on clinical performance of restorative materials, the strict protocol and controlled environment of these studies does not permit generalisations to the environment of general practice. Only rarely have pragmatic studies been conducted that are aimed at assessing how materials behave in the hands of general practitioners. There are various reasons for this situation. Medical research funding is very competitive, and the performance of dental restorations in the general population does not have high priority. The industry is not responsible for assessing how restorative materials behave when used by the 'average' dentist, since quality assurance of dental care in society is the responsibility of local health authorities. Thus, the industry sponsor mandatory clinical studies to satisfy criteria set by various acceptance programmes[64–68] while pragmatic studies are limited to field testing of various handling properties for subsequent marketing purposes.

Technical excellence

The ultimate aim when restoring or improving the integrity of teeth is to simulate tooth tissues both initially and over time. A restorative material should ideally possess similar mechanical and optical properties to tooth tissues, which at present no material fulfils. Furthermore, the outcome regarding the restoration adaptation, form and function depends very much on the operator's clinical skills. Besides the material and operator factors, patient factors have a significant influence on the deterioration of the restoration's technical excellence.

Laboratory screening tests

The present body of knowledge on clinical performance of materials indicates that there is a poor correlation between laboratory and clinical findings[70,73]. There is also the factor of 'clinical time'. One might say that on average, low-copper dental amalgam restorations fail by penetrating corrosion, which is reflected by continually worsening occlusal margins. The actual failure is secondary caries, not the poor margins, but the observation does correlate with the problem. Furthermore, one would say that typically, high-copper dental amalgam restorations fail by secondary caries and then later by bulk fracture if they survive a long time. This is clearly a different set of processes than for low-copper dental amalgam, and the processes are dependent on intra-oral conditions of the patient and linked to age, caries risk and restoration survival time. What laboratory test should be used to screen high-copper amalgams? Creep predicts corrosion level but does not predict approximal caries or bulk fracture, and static mechanical tests predict bulk fracture. Information on fatigue is sparse or not available or done only on simple geometries that do not mimic actual clinical restoration shapes. Tests are run with stand-alone samples and not with those that are interfaced to tooth structure, wet at 37°C, and after long periods of time. Some investigators use, for example, 500 cycles while others use 5,000 cycles, and some even include other parameters of questionable value in laboratory tests, for example thermocycling. Others argue that no significant heat transfer occurs during short-term thermal cycling and so this is a worthless exercise. In a similar vein, some solubility tests of dental cements have been determined to be of little scientific value, even though they are still used as screening tests for materials.

Clinical studies

The following sections present data from studies that have reported an association between technical excellence and material, operator and patient factors. The references are limited to clinical studies including adult or adolescent patients and which have been published since 1980, although it is possible that the authors have failed to mention the work of some investigators. Such omissions do not necessarily reflect the importance of such studies, but the inability in identifying or gaining access to this material

A vast number of controlled clinical studies have compared the performance of an array of different dental materials. Obviously, there are large differences in clinical performance among the many dental restorative materials, both in general as well as relative to intraoral location and cavity class. Because of the sheer number of publications, little emphasis is given to these differences. Rather, data reported under 'material factors' are limited to variations in composition and physical characteristics within one specific type of material that may seem to have a potential effect on the clinical performance of restorations.

Several publications have examined the influence of the operator and/or patient on the performance of restorations. Those factors that collectively describe the operator factors are the dentist's clinical experience, cavity design and size variables, material handling and procedures, isolation of the working field and finishing. In clinical trials, good operators are often selected to participate, and the operator influence is usually examined secondarily. Therefore, only small differences between good operators are usually distinguished. There is also a tendency to try to distinguish differences without analysing the reasons for differences, such as perceptual differences, treatment philosophies, decision-making and technical skill. The patient factors include gender, age, frequency of attendance and oral environment factors such as bite force, caries activity and microflora.

Dentists should be aware of the concept of power in relation to hypothesis testing, that is the probability that a study of a given size will detect as statistically significant a real difference of a given magnitude. Terms in this context are type 1 and type 2, or alpha and beta, errors[74]. Many of the papers being cited in this review conclude that there are no or minor differences between variables. The real truth is, however, that the great majority of clinical studies do not have sufficient sample sizes to have enough statistical power to distinguish such differences. Thus, very few studies supply good evidence of making strong statistical inferences of relationship between quality and clinical variables[74].

Form (contours, texture and wear)

Surface wear is a complex phenomenon that depends on several known and unknown factors, both extrinsic and intrinsic. Thus, the multifactorial aspects of the wear process explain the wide variations in observed wear, and are exemplified by large standard deviations in clinical wear measurements. For the same reasons, laboratory-testing protocols that predict clinical wear remain to be developed. Consequently, it is inappropriate to generalise laboratory findings to the clinical situation. The terminology used to describe wear in dentistry is also variable, but there is gradual understanding in the dental profession that the most appropriate terms should be those used by tribologists, that is scientists who study lubrication, friction, and wear[75].

Surface wear results from a combination of several mechanisms. Abrasive wear occurs when a hard body ploughs grooves, which is often the case in two-body contacts. Erosive wear occurs if hard particles are present in a medium between two moving objects, in particular in acidic environments. Fatigue wear occurs when the surface is overloaded beyond its elastic limit. Adhesive wear happens when two opposing surfaces touch each other resulting in extremely high pressure at isolated points, causing parts of the weaker material to adhere to the other if relative movement occurs. This is most likely to occur for metals. Finally, corrosive wear takes place when the surface is attacked chemically. A major problem with the early composite resins (and with silicate cements and old style copper amalgams) was poor resistance towards chemical degradation, that is, corrosive wear.

Any of the five wear mechanisms can occur in isolation, or interact with each other. Dental restorative materials vary in resistance to the various wear mechanisms. Restorative materials may therefore show extensive wear in some patients with a particular oral environment, while they can be completely absent in other patients.

Material factors

Comprehensive reviews of dental material performance and wear have been published[14,76]. In general, the wear resistance is in the order gold > ceramics > amalgam > composite resins > glass-ionomer cements. However, large variations in wear resistance have been observed within ceramics and composite resins. This is presumably related to differences in physical properties as well as variations in material handling.

Should restorative materials wear at the same level and in a similar manner to natural tooth tissues? If the answer is yes, then restorative materials such as gold fail in this regard and, as a consequence, should have limited applications to situations where the clinician wishes, for example, to manage abnormal wear.

It has been suggested that the overall wear of a composite resin restoration is more dependent on the material properties than on other clinical variables such as cavity class and tooth type[77]. However, data to support this statement are weak.

Operator factors

Cavity design

Wilson *et al.*[78] reported on a longitudinal study of a posterior composite material over five years. The greatest amount of generalised occlusal wear tended to be seen in large-sized Class II restorations in molar teeth, the main factor influencing wear being the type of restoration (Class I or Class II). The occlusal wear after five years did not differ between occlusal butt joint and bevel-edged preparations.

Wear in the occlusal contact area was higher in two MOD cavity types by a factor of 1.5 and 2.5 for amalgam, and 2.5 and 4.5 for composite resins in a clinical study over one year[79]. The wear of composite resin restorations was approximately 2.5 to 9 times higher in contact areas compared to contact-free areas. The authors stated that for composite resins, wear data from Class I restorations could not be extrapolated to MOD restorations[79].

Finishing

In a longitudinal study of 600 posterior composite resin restorations over three years, extensive wear developed in the restorations placed by one of three clinicians[80]. It was suggested that the cause was variations in the surface contouring process. Neither was use of a rubber dam identified as a significant factor for wear.

Surface finishing with carbide finishing burs compared to white stones was associated with a higher amount of occlusal wear in posterior composite resin restorations observed over one year[81].

Patient factors

Bite forces are probably a significant aetiological factor with respect to changes in surface texture and wear. Several papers conclude that the highest bite force occurs in the first molar region, and it is therefore to be expected that the greatest changes in form will occur in this region. An additional confounding element when appraising the relationship between form changes and effects of different patient factors is that males have on average higher bite forces than females, and that large variations occur in bite forces in both genders.

Intraoral location

Restorations in permanent molar teeth show more wear than in premolars. One estimate is that if restorations in the first mandibular premolar wear at 1x, the wear in the first maxillary premolar is 3x, in the second maxillary and mandibular premolars 4x, in the maxillary molars 5x and in the mandibular molars 6x[26]. Lambrechts *et al.*[82] and Johnson *et al.*[83] have in part supported these ratios. In contrast, Freilich *et al.*[77] report that cavity class and tooth type had no association with the occlusal wear of restorations in an investigation of three composite resins.

Approximal wear was observed by using indexed transfer copings on 70 direct and indirect composite resin restorations over two years. No differences in wear, as a function of tooth position in the arch, were detected[84].

Gender and age

Wendell and Vann[85] compared the wear of 190 composite resin restorations in primary versus permanent molar teeth after two years. They concluded that there were no significant differences between the wear level of restorations in primary teeth and permanent teeth at any recall. They claimed also that this finding was in contrast to previous findings of less wear in primary molars.

Oral environment

In a multicentre study on Class II composite resin restorations a significantly higher wear level was recorded after three years in patients with a high level of salivary lactobacilli (> 10^5 colony-forming units/ml at base line) compared with those with lower levels. The authors suggested that an acid environment might enhance the wear level of composite resin restorations[86]. However, the association between wear level and high levels of salivary lactobacilli at baseline compared with those with low levels observed after three years did not reach significance at the five-year recall[87].

Significant correlations were found between patients' consumption of alcoholic beverages and surface wear in an investigation of 52 pairs of Class III microfilled composite resin restorations after eleven years[88].

Optical properties

Optical characteristics include both the match of colour and translucency with the remaining tooth tissues, and lack of discolouration along the restoration-tooth interface. Surface tarnish of metallic restorations was previously considered by many as an important 'aesthetic parameter' when different metallic products were compared. Today, the promotion of restorative materials focuses on how closely the material imitates the optical properties of tooth tissues.

Material factors

Microfilled composite resins are considered to have the best optical properties among the tooth-coloured materials. In general, composite resins have superior optical properties to resin-modified glass-ionomer cements, which are superior to the glass-ionomer cements[89,90].

Marginal, or perhaps more correctly interfacial, discolouration is the result of percolation of chromatic substances along the restoration-tooth interface. Both this phenomenon and 'microleakage' have received much attention in the literature, since it is assumed they may lead to secondary caries and pulpal complications. However, the alleged relationship has not been adequately verified in long term clinical studies. In a recent review it was concluded that 'microleakage' was unrelated to the development of secondary caries[91].

Operator factors

Composite resins shrink during polymerisation, and numerous papers have detailed often elaborate clinical procedures to minimise shrinkage. Special cavity preparations have been employed[92,93], together with techniques for the use of light-reflecting wedges[94], incremental placement of materials[95], various devices and procedures for light curing[96], and different procedures for polishing[97]. On the other hand, it has been suggested that current adhesives appear to be less sensitive to substrate and other clinical variables than earlier products[98]. It has also been suggested that marginal gaps resulting from polymerisation shrinkage eventually disappear following water sorption and expansion that re-establishes the composite resin volume. However, the initial adhesion is not restored and remains damaged[99].

In a study of 88 composite resin restorations over three years it was observed that the marginal discolouration was significantly lower in the two-surface cavities compared to the three-surface cavity restoration[100]. This was not apparent at the two-year observation[101].

Elimination or minimising possible microleakage is the aim of the use of material laminate combinations in approximal and cervical restorations, for example, composite resin/glass-ionomer cement, composite resin/resin-modified glass-ionomer cement and resin-modified glass-ionomer cement/glass-ionomer cement. Several studies have reported comparisons between 'sandwich' versus homogeneous restorations, but the conclusions are conflicting.

Patient factors

Empirical observations indicate that not only surface, but also bulk and marginal discolouration vary among patients. However, very few studies have identified specific patient factors that may influence the optical characteristics of restorations.

Marginal discolouration along veneers made from composite resin on 87 maxillary anterior teeth in 23 young patients was more common among smokers compared to non-smokers in a longitudinal study over five years[102].

In a study of 52 pairs of Class III microfilled composite resin restorations after eleven years, surface discolouration was most often recorded among smokers, and significant correlations were found between the patients' consumption of alcoholic beverages and body and surface discolouration[88].

Adaptation

Traditionally, the terms used to describe adaptation have varied with the examination method, the type of restoration and the nature of the restorative material. Horizontal discrepancies on smooth and approximal surfaces have often been termed 'overhangs', while the term 'marginal ditching' has been used to describe defects along margins on the occlusal surfaces of teeth containing mainly amalgam restorations. The terms over- and under-extension, with additional descriptors of the cement margin morphology, for example 'marginal wear' and 'cement excess', have usually described the adaptation of indirect restorations. Finally, the term 'gap' has also been used for many years to infer a lack of adaptation between the materials and tooth tissues. However, this term is rather ill defined and non-specific.

Discrepancies measured along a horizontal or a vertical axis tangential to the interface have occasionally been interpreted as synonymous to marginal adaptation. Such discrepancies can be assessed clinically, but will necessarily only express the adaptation along the margin on the tooth surfaces. Several methods have been used to assess adaptation of the entire restoration-tooth interface, but all these methods are destructive[103].

The clinical evaluation of marginal discrepancies is questionable, explained by a lack of reliable diagnostic skills of clinicians. It has therefore been argued that the scientific community must accept that dental restorative materials will be misjudged during the process of evaluating the marginal qualities of restorations[104].

Material factors

The dental literature contains numerous papers in which marginal degradation has been evaluated as a function of material composition. The prevailing material in these studies has been amalgam, and there is consensus that high-copper alloys are clinically superior to low-copper alloys[105].

Inter-group differences in respect of the marginal degradation of amalgam restorations often appear after a short time, and remain constant[29,69,106–109]. This signifies that at least one process that results in marginal fractures occurs during the first year after placement of the restoration. This hypothesis, however, does not identify or exclude other aetiological factors that may be associated with marginal fractures, including creep, mercuroscopic expansion, biomechanical relationships, bulk and crevice corrosion or fatigue rupture.

There may also be differences between composite resins, Bryant *et al.*[110] having reported that particular types of marginal defects are commonly associated with specific types of composite resins. In general, restorations of microfilled composite resins show more marginal degradation compared to restorations of other types of composite resins.

Operator factors

Jokstad[29] reported an influence of the operator on the performance of 468 amalgam restorations of five alloys placed in 210 patients after five years. The five dentists were all able to obtain superior marginal adaptation with the best alloys, and contrary to the findings of Mahler and Marantz[21], all five alloys performed equally well for the five operators. Further, it was evident that one operator also obtained satisfactory marginal adaptation with a low-copper alloy. It was concluded that the main operator variables influencing the marginal adaptation were the final condensation of the amalgam and the treatment of the surface and margins.

Mahler and Marantz[21] reported on restorations of four amalgam alloys placed by four operators. The amalgams were chosen on the basis of their marginal fracture behaviour as found in an earlier study, ranging from little to extensive fracture. Following placement of the restorations, three-year evaluation of marginal fracture was undertaken using a linear rating scale. It was found that the operator influenced the marginal fracture index, but in different ways depending on the alloy. For the alloys with the most and least marginal fracture, there was no operator difference. However, for the two intermediate alloys, there were large differences among the operators. Overall, the association with alloy was stronger than with operator, and it was therefore recommended that non-gamma-2 amalgams should be used.

Cavity design

Stratis and Bryant[111] carried out a two-year study of 111 Class I and II amalgam restorations placed by one operator, and reported that a combination of modification of the occlusal cavo-surface angle and finishing of the restoration had an influence on the marginal fracture at two years.

Kreulen *et al.*[112] reported a photographic evaluation of the margins of 245 Class II amalgam restorations placed by three dentists. The principle variable influencing marginal adaptation was the dentist. In addition, improvement of the marginal adaptation by an occlusal bevel was discussed compared with non-bevelled margins.

Investigations published before 1992 on the possible relationship between marginal fracture and Class I and Class II cavity preparations for amalgam has been reported in a previous paper, and will not be discussed further[113].

Fukushima *et al.*[114] reported a study on the early marginal breakdown of 432 posterior composite resin restorations. It was determined that smaller cavities, greater bulk of material at the margin (especially in functional cusp areas), and well-finished margins without overfilling seem to reduce the occurrence of marginal fracture.

Material handling and procedures

Successful bonding is associated with several technique-related factors. The use of adhesives is technique sensitive because of complex multi-step application techniques[38,115]. Careful management of the status of the collagen meshwork is important to prevent it from disintegration or collapse and thereby ensuring optimal resin penetration[116].

A clinical technique, commonly referred to as 'wet bonding', has been recommended especially for adhesive systems that utilise water-free, acetone-containing primers. However, recent research has revealed that bonding systems that utilise water-based primers appear to bond with equal effectiveness to dry and wet dentine[117]. Adhesive systems using acetone-based primers revealed a higher technique sensitivity[118], whereas adhesive systems containing water-based primers appear to be less technique-sensitive, as far as the remaining wetness of the acid-etched dentine surface is concerned[119].

Clinically, the exact timing of the different stages of bonding as recommended by the manufacturer is often very difficult. For example, parts of the dentine may be etched for the same amount of time as the enamel because the precise differentiation between the two substrates is not always possible. Excessive etching may result in demineralisation depths that are greater than monomers can effectively penetrate[115,119], and cause severe collapse of the collagen meshwork[119]. The depth of demineralisation is dependent on etching time and phosphoric acid concentration[120], while the thickness of the monomer penetration, or 'hybrid', layer is a function of conditioning time[121]. However, the implications of these variables on long-term clinical outcomes remain uncertain.

Isolation

Desiccation of the demineralised dentine causes collapse of the collagen meshwork, which impedes the proper infiltration of the primer[121]. Therefore, a wet bonding technique is recommended[122,123]. However, there is a wide range of interpretations of 'wet'[124,125], with no clear guidelines in manufacturers' directions for use. While the negative consequences of excessive air-drying are well documented for acetone-based systems[122,123], the results for water-based systems are variable[125].

Contamination of the etched enamel surface with saliva prior to the placement of a resin-based material significantly reduces the bond strength to enamel. Studies on the influence of saliva contamination on dentine bonding are variable. Although the tolerance of modern adhesives to saliva contamination has improved, reductions in bond strengths may be anticipated after saliva contamination. It is therefore important to prevent saliva contamination after application of the primer[126].

The effect of using rubber dam remains uncertain. In an experimental study comparing shear bond strength of 36 composite resin restorations placed either with cotton rolls or under rubber dam, no significant differences were noted between the two groups[127]. In another study using the same protocol, microleakage was assessed. This study concluded that the use of rubber dam isolation resulted in less microleakage at the enamel-resin interface[128].

Patient factors

Intraoral location

As for wear, bite force is probably a significant aetiological factor regarding the extent of material deterioration. As a result of relatively high bite forces in the first molar region, it can be assumed that more marginal fractures will occur in this location.

In a study of 88 composite resin restorations placed by nine dental students, it was observed after two and three years that marginal integrity was significantly better in premolars compared to that in molars[100,101].

Berg and Derand[129] reported data on 51 out of originally 115 porcelain inlays made with the Cerec technique after five years in 46 patients. No significant differences in marginal ditching were detected between molars and premolars.

Jokstad[29] did not find any strong relationship between marginal degradation and intraoral location after five years observation of Class II amalgam restorations. Only the lower premolars showed less marginal degradation compared to the other tooth groups. Osborne and Gale[130] reported that the marginal fracture of high-copper amalgam restorations could not be related to the intraoral location after fourteen years service. Interactions between tooth position and width indicated that lower premolars with conservative restorations exhibited the least fracture at the margins, and upper premolars with a wide preparation exhibited the most. Osborne and Gale[131] reported that the marginal degradation of 429 Class II amalgams after two years was less in lower premolars than in the other posterior teeth.

Goldberg *et al.*[132] studied 475 restorations over 1.5 years. Using ANOVA analyses, these investigators compared marginal fracture scores among different subgroups, categorised by intraoral location and found more fractures in molars than in premolars.

Oral environment

Derand[133] assessed restorations of four amalgam alloys in 163 teeth after 2.5 years. The patients were divided into three levels of biting force. It was found that marginal fractures increased with increasing bite force for the conventional alloys, but that the relationship was not significant for the three non-gamma-2 alloys.

Restoration failure and clinical factors

Technical excellence of restorations deteriorates in clinical service and may or may not be linked to restoration failure. Certain investigators, including those of Harris[134] and Owens[135], reflect a common opinion that materials themselves are often the least of the problems and that most restoration failures can be attributed to poor attention to detail in cavity preparation and material handling. However, this view can at best be regarded as expert opinion, and is linked to the failure criteria. In a survey of 571 dentists, perceived causes of restoration failure were ranked by patient-related factors (45 per cent), dentist-related (35 per cent) and material choices (20 per cent)[136]. An amusing secondary finding was that these estimates were for restorations in general, while the percentages were 48, 26 and 26 per cent respectively when dentists addressed the causes of failure of the restorations they had made themselves.

The following sections present the effects of the numerous dependent and independent variables influencing the quality of restorations, notably the operator; the operative techniques and instrument used; the material; the location; type; size; initial and short-term technical excellence of the restoration and patient factors.

General performance

Material factors

Differences in composition and physical properties

Subtle differences in physical properties within specific material groups may be considered to have a small effect on clinical performance in general practice settings. A particular exception is perhaps composite resin cements for indirect restorations, where the microfilled cements seem to be superior to cements with larger fillers[14,136], although conflicting results have been reported[138]. Two longitudinal multicentre studies involving 24 dentists in seven clinics revealed only minor differences amongst six composite resins after three and five years[139,140]. Dunne and Millar[141] reported the evaluation of 315 porcelain labial veneers in 96 patients, fitted up to five years previously in two teaching hospitals. Increased problems and failure rates were associated with veneers where inappropriate luting agents were employed, that is, luting cements not dedicated to veneer cementation. In studying over 1,544 amalgam restorations, 1,213 restorations remained after 15 fifteen years. The conclusions from this study was that the type of amalgam alloy used had no association with restoration survival[108,109]. Van Noort and Davis[142] observed in a five-year prospective study the survival of 2,399 Class III and 1,093 Class V chemically-activated anterior composite resin restorations in 26 general dental practices, that the differences in clinical performances between six materials was small. In a cross-sectional study, 75 private practitioners evaluated 1,147 two-to-four years old anterior restorations of 25 different materials according to the CDA system. With the exception of one composite resin, no obvious differences in the quality of dental restorations were observed[33].

Operator factors

Among various clinical factors affecting restoration performance, an operator association is frequently detected in multicentre and cross-sectional studies (*Table 1*). Controlled clinical studies are usually designed to avoid such operator effects, and different research groups have employed various strategies (see section on statistical issues) to control these effects.

Most of the relevant papers offer no explanation of the observed variation in operator effect, although some authors stress the necessity of specific training for dental personnel using new materials. It is also possible that an indirect patient association may have influenced an apparent operator association. Whether the experience of the operator can be associated with technical excellence is uncertain. For example, Hawthorne and Smales[150] reported that the survival for composite resin restorations was best for the most recent graduates. By contrast, Shaini *et al.*[151] commented that the poorest results were seen in relation to the inexperienced operators. Of course, appropriate clinical training and experience are necessary prerequisites for favourable clinical outcomes.

Table 1 Clinical studies that have investigated a possible association between restoration performance and operator

Reference	Centres/dentists[1]	Restorations[2] (application)	Operator variation observed after years[3]
Longitudinal studies			
Pilebro *et al.* (1999)[143]	12d	374 glass cermets (tunnel)	3 yrs: yes
Köhler *et al.* (2000)[87]	3c/12d	104 composites (Class II)	5 yrs: not reported
Rasmusson *et al.* (1998)[86]			3 yrs: yes
Kreulen *et al.* (1998)[109]	3d	1544 amalgams – Class II	15 yrs: yes
Gruythuysen *et al.* (1996)[108]			15 yrs: yes
Akerboom *et al.* (1993)[107]			10 yrs: yes
Meijering *et al.* (1998)[144]	7d	180 ceramic (veneers)	2.5yrs: no
Plasmans *et al.* (1998)[145]	3d	300 amalgams (complex)	9 yrs: no
Wilson *et al.* (1996)[146]	5c	172 amalgams (Class II)	5 yrs: no
Wilson and Norman (1991)[147]	12c	958 composites (Class II)	5 yrs: yes
Letzel (1989)[72]	12c	232 amal. +932 compos. (Class I and II)	4 yrs: yes
Phantumvanit *et al.* (1996)[148]	3d	446 glass ionomer cement (ART)	3 yrs: no
Rasmussen and Lundin (1995)[140]	7c/24d	247 light cured composites (Class II)	5 yrs: yes
Lundin *et al.*, 1990[139]			3 yrs: yes
Retrospective studies			
Wendt *et al.* (1998)[149]	11c	6012 amalgams and composites	5–13 yrs: yes
Smales and Hawthorne (1996)[150]	3c/20d	404 restorations, 100 patients,	25 yrs: yes and no
Hawthorne and Smales (1997)[56]		regular attenders for 25 years	
Shaini *et al.* (1997)[151]	'Several'	372 ceramic veneers	6.5 yrs: yes
Mahmood and Smales (1994)[152]	4c	1588 amalgams, composites, inlays	25 yrs: yes
Smales (1991)[153]	'Many'	950 composites	18 yrs: no
Smales (1991)[154]	'Many'	1476 amalgams	18 yrs: yes

[1]d= number of dentists in study, c= number of centres in study
[2]ART = Atraumatic Restorative Treatment, tunnel = tunnel preparation with glass-ionomer
[3]yrs = observation years, yes/no= operator associated/not associated with restoration performance

Cavity design

The relationship between cavity morphology and restoration quality is uncertain because of opposing or controversial results. A systematic review of restoration longevity concludes that large amalgam restorations would appear to survive as long as small amalgam restorations. Moreover, the investigators suggested that the evidence that two-surface restorations survive longer than three-surface restorations is inconclusive[5]. This conclusion is supported by most studies, while other studies suggest differences in longevity and clinical quality depending on morphology.

For Class II composite resin restorations, special cavity preparations have been appraised clinically, but they seem to have a limited influence on the long-term failure rates[92,93].

Lundin and Koch[155] reported the outcomes after ten years of 117 Class I and II restorations made from two different composite posterior materials. Only minor differences in the failure rate between moderate and large restorations were observed.

Köhler *et al.* reported in a five-year study of 63 Class II composite resin restorations similar failure levels in teeth with conservative and with larger conventional study designs[87].

Burke *et al.*[156] examined the reasons for replacement and median age of 4,608 restorations reported by 73 vocational dental practitioners and their trainers. The median age of the amalgam restorations ranked from Class I>V>II (7.4 to 6.6 yrs), for composite resin restorations Class III>II and V>IV>I (5 to 3.3 yrs), and for glass-ionomer cement restorations Class III>IV>V (4.8 to 3.2 yrs).

Raskin *et al.*[157] reported on a ten-year longitudinal study of 100 light-cured posterior composite resin restorations. Class and size of restoration were not found to significantly influence the survival.

Tunnel restorations gained in popularity in the early 1990s. In a longitudinal study of 242 tunnel restorations in 142 individuals, the cumulative survival was 81 per cent after two years and 64 per cent after 3.5 years. Secondary caries caused replacement of 50 per cent of the restorations, while marginal ridge fractures constituted 26 per cent of the failures. The statistical analyses revealed that success was related neither to the radiographic stage of initial approximal caries nor to type of preparation technique[158]. Several studies have revealed that technique sensitivity is high concerning tunnel preparations. Strand *et al.*[159] showed that the complexity of the preparation and operator experience were the principal determinants of survival in a three-year study of 161 glass-ionomer cermet cement tunnel restorations.

Stoll *et al.*[160] reviewed the clinical performance of 3,518 cast restorations placed in 890 patients between 1963 to 1993 in a dental school in Germany. They found that the ten-year survival for Class

I inlays was lower than that for the other types of inlays, that is two-, three- and four-surface inlays.

In study of over 1,544 amalgam restorations, 1,213 restorations remained after fifteen years. It appeared as if the three-surface restorations had less favourable clinical outcomes compared to two-surface restorations after 15 years. Also, the provision of a 90° cavosurface angle combined with a cavity wall finish reduced the risk of failure of amalgam restorations, compared to larger cavosurface angles[108,109].

Prati *et al.*[161] reported three-year data on 116 Class III and V polyacid-modified composite resin ('compomer') restorations. They found no statistical differences with respect to the USPHS criteria between the Class III and V restorations.

In a cross-sectional appraisal of 520 cast restorations in 56 patients made between one to 40 years previously, the restorations including more than two surfaces were associated with less favourable outcomes of quality and survival[162].

The outcome after three years of 446 restorations placed by one dentist and two dental nurses in 282 patients using the ART technique was reported by Phantumvanit *et al.*[148]. The survival was lower for occlusal surface restorations compared to those in other surfaces.

Friedl *et al.*[163,164] carried out a cross-sectional study in which 102 dentists provided information about 3,375 composite resin and 5,240 amalgam restorations. The failed restorations with four surfaces had a lower median age compared to the other types of restorations.

Jokstad *et al.*[165] reported on a cross-sectional study of 8,310 restorations a marked association between the age of the restorations and both the types and the size of the restorations.

Data from a five-year prospective study of the of 2,399 Class III and 1,093 Class V chemically-activated anterior composite resin restorations assembled from 26 general dental practices indicated that the overall probability of survival at five years was 10 per cent higher for Class V restorations than for Class III restorations[142].

Smales and Gerke[166] evaluated 700 anterior composite resin restorations over four years. Significantly more failures occurred in Class IV and V preparations. Of all failures, 81 per cent were from Class V preparations, which may reflect undue reliance on dentine-bonding systems for restoration retention in premolar non-carious cervical lesions.

Fritz *et al.*[167] reported the long-term outcome of 2,717 cast restorations provided for 548 patients during 1960–1989. Relatively minor differences in the 15 year survival were noted for four sizes of casts: single surface (65 per cent), two-surface (60 per cent), three-surface (68 per cent) and inlays and onlays (70 per cent).

Investigations published before 1992 on the association between Class I and Class II cavity preparations for amalgam and restoration survival has been reported in a previous paper and will not be discussed further[113].

Wilson and Norman[147] reported five-year findings of an 11-centre trial of a posterior composite resin. The findings were based on data collected from 649 (68 per cent) of the 958 restorations originally placed. Chi-square analyses indicated that of the independent variables investigated, size of restoration had the greatest association with clinical performance.

In a study of 950 anterior composite resin restorations over sixteen years there were significantly more failures with the Class IV compared to the Class III restorations[153].

Bentley and Drake[168] reported a study of 1,207 restorations placed by students in 70 patients. Single-surface restorations lasted longer than multi-surface restorations. Moreover, multisurface restorations including the occlusal surface survived significantly longer than did those including the facial or lingual surface.

Material handling and procedures

Factors associated with material handling and procedures that may affect the incidence of margin failures of amalgam restorations include trituration time[106], use of rubber dam[169,170], condensation techniques[171], and the carving, burnishing and polishing techniques[172]. The effect of burnishing amalgam restoration margins is difficult to estimate, and nearly impossible to quantify since the 'surface treatment' is influenced by factors such as burnishing load, direction of the strokes, number of strokes, beginning time after trituration and the size of the burnisher[172].

To what extent cavity varnishes and their thicknesses promote marginal failures is unknown. It is conceivable that some varnishes may be incorporated into the amalgam along the margin, and thereby reduce the strength in these areas. Thus, there is a theoretical possibility that the type or amount of varnish may be related to margin fracture. However, clinical data on such a relationship is sparse, and existing data are not conclusive. In one longitudinal study it was revealed that application of a varnish or silver suspension did not influence the risk of long-term restoration failure[107–109].

Letzel *et al.*[171] assessed the type of condensation instrument, together with patient and operator on the performance of a single amalgam alloy over 2.5 years. The authors reported an association between failure and the patient and the operator, but there were too few failures to establish an association with condensation instrument. However, the authors did not indicate how 'failure' was assessed.

Isolation

The debate about the necessity of using rubber dam in operative dentistry has been ongoing with variable intensity for many decades. In this context it should perhaps be emphasised that working without rubber dam does not necessarily allow saliva contamination during operative procedures.

Raskin *et al.*[157] reported a ten-year longitudinal study of 100 Class I and II composite resin restorations in a group of selected, predominantly young patients under highly controlled conditions. The method of isolation was not found to significantly influence clinical performance and survival.

Dunne and Millar[141] reported the evaluation of 315 porcelain labial veneers in 96 patients, fitted up to 63 months previously in two teaching hospitals. The use of rubber dam could not be associated with survival.

The consequence of using either rubber dam or cotton roll isolation on clinical deterioration was reported by Smales[169,170]. In one study, 546 polished amalgam and 148 anterior enamel-bonded composite resin restorations were evaluated over periods of up to 15 years. He concluded that although a statistically significant difference was found between the two isolation methods for marginal fracture of the composite resins, the clinical relevance of this difference was questionable. In the second paper the survival of the restorations was related to the possible influence of six other clinical parameters. There were no clinically significant differences present in the initial high quality of the restorations, or in their later survivals, which could be directly related to the use of rubber dam.

In a survey where the clinical handling properties of glass-ionomer cements were addressed, Knibbs and Plant[173] attributed the main cause of unsatisfactory restorations in deciduous teeth made by 17 general dental practitioners to poor handling of the material, principally by moisture contamination.

Van Dijken and Horstedt[174] assessed 35 patients who received one hybrid and one microfilled composite resin restoration placed in anterior teeth with and without rubber dam. After one year the marginal adaptation was investi-

Table 2 Clinical studies reporting a relationship between restoration performance and intraoral location

Reference	Restorations/ patients	Restoration types	Obs. period (years)	General performance
Longitudinal				
Köhler *et al.*, 2000[87]	63/45	Posterior composite	5	No statistically significant difference between premolars and molars, and between maxillary and mandibular teeth
Lundin and Koch 2000[155]	117/65	Posterior composite	10	Restorations in premolars had a higher failure rate than in molars
Pyk and Mejare, 1999[158]	242/142	Glass cermets – tunnel	3.5	Failure occurred about five times as often in molars as in premolars
Raskin *et al.*, 1999[157]	100/	Posterior composite	10	Location not found to influence survival
Donly *et al.*, 1999[176]	72/18	Gold cast and composite inlay	7	The acceptable restorations were located mainly in the premolars
Prati *et al.*, 1998[161]	116/	Class III and V polyacid-mod. composite	3	No association with respect to the USPHS criteria and intra-oral location
Geurtsen and Schoeler, 1997[177]	1209/	Class I and II composite	1–4.5	More restorations with rating Alpha in premolar teeth compared to molar teeth
Gruythuysen *et al.*, 1996[108]	1213/	Class I and II amalgam	15	The type of tooth had no association with survival
Smales and Gerke, 1992[166]	700/	Class III and V composite	4	More failures occurred in premolar teeth compared to other locations
Jokstad, 1992[29]	468/	Class II amalgam	10	No effects of intraoral location detected
Retrospective				
Pelka *et al.*, 1996[162]	520/56	Cast	1–40	Molars had less favourable outcomes of quality and survival compared to premolars
Drake *et al.*, 1990[61] Bentley and Drake, 1986[168]	1207/70	All types	1–20	No statistically significant differences were observed. Mandibular incisive restorations lasted longer than maxillary
Cross-sectional				
McDaniel *et al.*, 2000[178]	706/	Class I and II amalgam	ns	Mandibular first (36%) and second (20%) molars accounted for most fractures among cuspal-coverage restorations
Jokstad *et al.*, 1994[165]	10091/575	All types	>10	The restoration age is possibly influenced by intra-oral location
Kerschbaum *et al.*, 1991[179]	/1841	Fixed prostheses	1–15	An anterior placement and the lower jaw associated with a lower survival

Table 3 Clinical studies reporting a relationship between restoration performance and gender and age.

Reference	Restorations/ patients	Restoration types (application)	Obs. period (years)	General performance
Longitudinal				
Pyk and Mejare, 1999[158]	242/142	Glass cermet (tunnel)	3.5	Success rate was not related to patient age
Plasmans *et al.*, 1998[145]	300/	Amalgam (complex)	8.5	Restorations more prone to failure in patients >30 yrs old than in younger ones
Prati *et al.*, 1998[161]	116/	Class III/V polyacid – modified composite	3	No association between USPHS criteria and patient age and gender
Phantumvanit *et al.*, 1996[148]	446/282	Glass-ionomer (ART)	3	No differences between ART restorations in children and adults
Gruythuysen *et al.*, 1996[108]	1213/	Class I and II amalgam	15	20% of the study restorations were replaced in males, 16% in females
Jokstad, 1992[29]	468/	Class II amalgam	10	Survival associated with patient age, but sample included caries-susceptible children
Smales and Gerke, 1992[166]	700/	Class III and V composite	4	Significantly more failures occurred among the elderly patients
Retrospective				
Hawthorne and Smales, 1997[150]	/100	Amalgam and composite	1–40	Lowest survival rates in the 0–20 and 61+ year age groups
Pelka *et al.*, 1996[162]	520/56	Cast	1–40	No association between patient age and outcomes of quality and survival
Mahmood and Smales, 1994[152]	/1588	All types	1–15	Restoration survival was superior in female patients
Dunne and Millar, 1993[141]	315/	Porcelain (veneer)	5	Patient age and gender could not be associated with failure
Bentley and Drake, 1986[168]	1207/70	All types	1–20	Survival less favourable for patients >60 yrs old compared to the younger patients. No differences between males and females
Cross-sectional				
Mjör *et al.*, 2000[36]	6761/	Amalgam and composite	1–30	Minor differences noted in longevity between male and female patients
Glantz *et al.*, 1993[180]	/77	Fixed prosthesis	1–15	No differences regarding fracture, loss of retention and/or dental caries between age subgroups
Dawson and Smales, 1992[181]	1918/100	Amalgam and composite	1–16	Survival lower in the oldest of three age groups. A small gender difference also noted
Smales, 1991[153]	950/	Anterior composite	1–16	Median survival 7 yrs in age group <20 yrs and >60 yrs, 12 yrs in group 21–60 yrs. More failures seen in the oldest group
Smales, 1991[154]	1476/	Amalgam	10	Patient age had a significant association for one of five alloys
Kerschbaum *et al.*, 1991[179]	/1841	Fixed prosthesis	1–15	A lower survival of fixed prostheses was associated with higher age group (especially if the patient was older than 70 yrs)
Kroeze *et al.*, 1990[182]	/600	All types	ns	The prevalence of unsatisfactory restorations tended to be higher with increasing age

gated and no differences were observed.

Patient factors

Collins *et al.*[175] concluded, after an eight-year longitudinal study of posterior composite resin restorations, that there was evidence to confirm the importance of the influence of the patient, since many of the observed failures occurred among few patients. However, no details were reported that characterised these patients.

The findings related to an association between restoration performance and patient factors are summarised in *Tables 2* and *3*.

The majority of the studies describe a minor difference. However, as for many of the other alleged associations to clinical factors one must be aware of publication bias. Moreover, most clinical studies were designed to address specific clinical problems. Issues such as influence of operator, patient factors and intraoral location were usually carried out as secondary analyses. It is impossible to know if no such relationships are reported because no secondary analyses have been carried out, or if the relationships were negative and thus omitted in the text (*Figures 4*).

Oral environment

Reduced salivation and xerostomia are associated with older patients, side effects of drug therapy and cancer treatment. Consequently, a

b

c

d

e

Figure 4 (a–e). Old composite resin restorations remaining *in situ* due to patient satisfaction. Other patients, as well as clinicians, might well consider the restorations 'unacceptable'.

caries risk increases significantly. Wood *et al.*[183] studied 54 pairs of Class V amalgam and glass-ionomer cement restorations over two years in 36 xerostomic cancer patients. Survival times were very short (8.5 months) for all restorations. Among the individuals using fluoride, 8 per cent of the glass-ionomer cement and 100 per cent of the amalgam restorations survived after six months. For the subgroup of eight non-fluoride users survivals were approximately 100 per cent and 24 per cent. Thus, the degree of fluoride use was associated with the rate of restoration failure.

Caries activity might be expected to affect the performance of restorations; however, there are few data on this aspect. In a longitudinal study of 242 tunnel restorations in 142 individuals, the cumulative proportion of successful restorations was 81 per cent after two years and 64 per cent after 3.5 years.

Secondary caries caused replacement of 50 per cent of the restorations, but statistical analyses revealed no association between caries activity and replacement[158].

Strand *et al.*[159] observed in a three-year study of 161 glass-ionomer cermet cement tunnel restorations that there were significantly more failures among patients with a high caries activity.

Restoration survival was strongly influenced by caries activity in a ten-year longitudinal study of Class II amalgam restorations[29]. The 210 patients in the study were divided into high, medium and low caries activity, depending on the incidence of primary and secondary caries lesions during the first eight years of a 10 year study of amalgam restorations. However, some caution was expressed in interpreting these data, as the study sample included a group of caries-susceptible children.

Bentley and Drake[168] reported on a study of 1,207 restorations placed by students in 70 patients. A subset of the population (19 per cent) with a disproportionately higher failure rate accounted for 56 per cent of all failed restorations. The authors speculated that it may have been a reflection of higher caries activity, but the precise nature of this group remained uncertain. A subsequent analysis of the study material identified only minor differences of salivary risk markers for caries between patients in the high- and low-failure groups[184].

Patient attendance

Hawthorne and Smales[150] related survival for amalgam and composite resin restorations with patient attendance in a retrospective study of five types of restorations placed by 20 male dentists in 100 adult patients. There were no significant effects on restoration survival from change of dentist, and generally only one or two types of restorations had their survivals influenced significantly by frequency of patient attendance or experience of dentist. Restoration survival was not influenced significantly by whether, or not, any replacements were made by the dentist who placed the initial restorations.

Regularly attending patients are probably more dental health conscious than irregular attenders. Furthermore, at recalls, dentists correct minor discrepancies that are believed to put the prognosis of a restoration at risk. Therefore, improved restoration longevity is more likely in regular attenders. However, Jokstad *et al.*[165] did not detect this difference in a cross-sectional study of 8,310 restorations, where similar restoration ages were recorded for the regular and irregular attenders.

Mahmood and Smales[152] compared longevity of dental restorations in selected patients from different practice environments in two countries, private practices in Pakistan and a dental hospital in Australia. In both countries, restoration survival was significantly improved when patients attended infrequently for treatment, and when the patient routinely changed dentist.

In an examination of the survival of 1,918 restorations in an Australian military population, no differences in survival as a function of frequency of attendance or frequency of change of dentists were reported[181].

Kroeze *et al.*[182] examined, in a national epidemiological survey, the restoration quality of 600 dentate adults. The authors reported that the restoration quality could be related to the frequency of visits to a dentist.

A re-examination of 720 dentate Scottish residents who had taken part in a dental health survey five years previously suggested superior restoration longevity among the patients who had not changed dentist frequently[185].

Does technical excellence predict failure?

In several longitudinal studies in general practice settings, it has been observed that dentists do not necessarily replace restorations even when one or more features have been graded as unacceptable according to the USPHS/CDA criteria[140,186–190]. Thus many dentists practice a treatment philosophy where the discrepancy is observed rather than effecting an immediate operative intervention. Interestingly, the same longitudinal studies also reveal that restorations will perform satisfactorily for many years in spite of 'unacceptable' USPHS/CDA scorings.

One main conclusion from a fifteen-year longitudinal study of 1,213 Class II amalgam restorations was that the short-term marginal performance was not an indication of long-term survival, and that there was a lack of a valid predictive parameter[107–109].

In a longitudinal study of Class V composite resins, the authors reported that it was apparent that the results after two years of observation could not be used to predict the three-year results[191].

Smales and Webster[188] attempted to determine the relationship between the deterioration and the later failure of a very large number of amalgam and anterior composite resin restorations examined over periods of up to sixteen years. Assessments were made of the deterioration in various characteristics of restorations that were thought to predict later failure. For amalgam, there was a significant association found between surface tarnishing and failure. Marginal fracture and marginal staining were not significantly associated with any of the three failure modes. For the composite resins there were significant associations between the surface roughness, marginal fracture and colour mismatch. However, surface and marginal staining were not associated with any of the three failure modes. Many restorations assessed as being unsatisfactory continued to function on average for a further two to three years before being replaced, often for unrelated reasons.

The median function period of restorations can possibly be predicted by a Weibull distribution function. However, Smales *et al.*[192] reported, after applying such a theoretical model on three restorative materials, that this is problematic if the model includes slowly deteriorating restoration features.

Specific replacement reasons

Allergy

Given the enormous number of dental restorations placed world wide, the incidence of adverse reactions seems exceedingly small. Researchers have tried to estimate the population risk of adverse reactions to materials used in dentistry[193], but the accurateness of such estimates of risk remains uncertain. However, there are in all populations a minority of individuals that responds negatively to various extrinsic and intrinsic substances, including biomaterials found to be of acceptable biocompatibility according to International Organisation for Standardisation (ISO) standards. All dental restoratives have the potential to cause adverse effects, even when used correctly. Higher risks of adverse reactions are present if the material is not properly stored or handled, for example, incorrect proportioning, contamination, inadequate polymerisation, date expiration, incorrect storage temperature and/or humidity. Several comprehensive review articles[194,195] proceedings and consensus statements on the subject of biocompatibility of materials can be found in the dental literature.

Endodontic complications

Postoperative sensitivity is an outcome that is a complex combination of the effect of the extent and depth of the initial caries lesion, cavity preparation depth, period of dentine exposure to saliva and caries, material-to-cavity adaptation, quality and quantity of exogenous bacterial products, restoration sealing and variable patient pain thresholds[196,197].

Post-operative sensitivity after cementation may be associated with a deformation of the abutment following high pressure or misalignment of the casting during cementation. The hypersensitivity results from fluid movement within the dentinal tubules[198].

Material factors

The previous belief that pulp complications following restorative treatment were either the consequence of insufficient removal of bacteria in the dentine or to toxic effects from the material was challenged approximately 10 years ago. In a consensus report from 1992, it was stated that much of the previous work on pulpal reactions to restorative procedures and materials had up to then been flawed because of leakage of bacteria and their products around filling materials[199]. The general view today is that most restorative materials do not *per se* cause pulp damage as long as they are properly handled, but problems will develop if the handling procedures are not followed to ensure optimal adaptation to the cavity walls[200]. An exception is perhaps glass-ionomer cements when applied in a very close proximity with the pulp[195].

Poor adaptation between a restoration and remaining tooth tissues increases the risk for endodontic complications given the potential leakage of detrimental substances. A number of highly sophisticated laboratory techniques has been developed to measure adaptation, but the association with clinical significance remains uncertain. Thus, quantitative data from laboratory leakage studies do not give sufficient information to predict clinical performance. The environmental conditions in the microspace between restoration and cavity walls remains unknown, as well as the interaction mechanism between the potentially detrimental substances in the space and the tooth tissues. Even the characteristics of the bacteria in, or adjacent to, the gap have not been firmly established. It is clear that the surface chemistry of the material significantly influences the microecological environment[201]. However, it is unclear if this is due to a local toxic effect of possible components released from the restorative material, or if it is indirectly due to an effect on the initial biofilm composition that is formed on the restoration surface.

Anecdotal sources have reported that in some practices, alarming numbers of endodontic procedures have become necessary because of pulp damage after prosthesis cementation[202]. Third-party payment companies report that many teeth receiving crowns require endodontic therapy within five years. It is uncertain if this can be related to a gradual shift of use from conventional zinc phosphate cements to alternative cements and/or cementation techniques.

Operator factors

Cavity design

The remaining dentine thickness is a critical factor in the development of pulp damage given the large surface area of open dentine tubules close to the pulp. Dentine tubules may provide diffusion channels for noxious substances, which diffuse toward the pulp where they can activate the immune system, provide chemotactic stimuli, cytokine production, and elicit pulpal inflammation[116]. Post-operative hypersensitivity, on the other hand, seems to occur in some individuals regardless of the depth of the prepared cavity[203].

The incidence of pulpal complications following crown and bridge work was discussed by Valderhaug *et al.*[190] in a report describing the results of a longitudinal clinical study of initially 158 fixed prostheses made by senior dental students 25 years previously. The results indicated that the frequency of pulp deterioration in association with bridges tends to be related to the size of the prosthesis. It can be speculated that this can be the effect of biomechanical complexity, including factors such as a complex alignment of preparations with possible iatrogenic tissue removal and overtapered abutments; lack of acceptable fit in parts of the casting; tendency to accept small discrepancies in large, fixed prostheses compared to single crowns, and the complications of oral hygiene procedures.

Periapical complications and vertical root fractures following the placement of restorations or crowns with pulpal or parapulpal posts may be considered as iatrogenic. Cross-sectional studies indicate that this is perhaps more common than is acceptable. Grieve and McAndrew[204] examined radiographically 327 post-retained crowns for length of post, length of remaining root filling, periapical condition, fit and angulation of the post and quality of root filling. Most root fillings were judged to be unsatisfactory, and there was no radiographic evidence of any root filling in nearly 10 per cent of cases.

Investigations published before 1992 on the possible relationship between Class I and Class II cavity preparations for amalgam and adverse effects on the pulp has been reported in a previous paper, and will not be discussed further[113].

Material handling and procedures

The principles for prevention of pulpal damage during preparation with rotating instruments were outlined many years ago, and are still valid today. Key factors are frictional heat and adequate cooling, excessive dehydration and air blast, and vibration and high speed[46].

Concerns over possible microleakage and postoperative sensitivity with amalgam restorations have led many practitioners to use various varnishes and resin-containing lining, or 'adhesive' materials. However, others have questioned the merit of amalgam bonding, and the results are conflicting[205].

Cases of persistent post-operative sensitivity with composite resin restorations following total etching and application of some dentine adhesives have been reported. This clinical phenomenon can occur despite careful isolation prior to direct restorative procedures and the use of an incremental build up technique, as well as after cementation of indirect restorations in conjunction with using a composite resin cement. Problems regarding post-operative sensitivity are hypothesised to be related to a deficient light-curing source, or incomplete evaporation of the primer solvents prior to application of the bonding agent. Alternative suggestions are gaps, cracks in enamel related to polymerisation stresses, fracture of tooth substance at the restoration cavity interface and polymerisation shrinkage followed by hydraulic forces induced during mastication on the dentinal tubule fluid following flexure of the restoration[195,206].

Patient factors

Intraoral location

In a study of 88 composite resin restorations over two years it was observed that the postoperative symptoms were significantly lower in premolars compared to molars[101].

Borgmeijer *et al.*[196] reported postoperative sensitivity after placing 244 Class II restorations of composite resin and amalgam. Postoperative sensitivity occurred more often in the molars than in the premolars although the difference was not statistically significant. The research group reported that this finding had also been observed in another study of 240 indirect Class II composite resin inlays and amalgam restorations[207].

Age and gender

During function, secondary and reparative dentine is deposited in the pulp. At age 55 years, the volume of the pulp is about 20 per cent of that at age 25, and contains only 20 per cent of the blood supply[208]. This suggests that the pulp's capacity of recovery decreases with age. However, there are no data in the literature reporting the incidence of endodontic complications as a function of patient age following restorative therapy.

Oral environment

Anecdotal observations suggest that bruxism may be associated with an increased risk of pulpal complications following flexing of the restorations and gap formation. The clinical evidence for this is poor. In one early *in vitro* study it was demonstrated that composite resin restorations placed in third molars exhibited increased microleakage when an antagonist was present compared to none[209]. The author concluded that bacterial leakage around restorations in cavities surrounded by enamel would most often be the result of stress in the restored tooth during occlusion and articulation. The study has not been duplicated using modern dentine bonding systems, so it is uncertain to what extent the conclusion is applicable to newer composite resin materials.

Does technical excellence predict failure?

A clear relationship between endodontic complications and criteria for technical excellence of dental restorations has not been demonstrated. Several review papers have suggested that such a relationship exists, but this is substantiated mostly with laboratory and microleakage studies[210]. In one clinical study the radiographic quality of the root filling and the appearance of the apical one-third of

1,010 endodontically treated teeth was scored[211]. This was related to the presence of open margins, recurrent decay or overhangs detected in radiographs. By calculating the odds ratios of periapical inflammation as a function of the root-filling and restoration qualities, the authors concluded that restoration qualities are more important than root-filling quality. Although this finding may give rise to concerns there are many methodological issues that can be raised, and scientifically sound research designs are needed to substantiate the hypothesis. Indeed, a recent identical study resulted in contradictory results[212].

Periodontal problems

The research focused on dental restorations and periodontal disease is a good example of how the criteria for causation as established by Hill have been applied successively to clarify the relationship between the two factors[213]. There is consistent association for several epidemiological studies between restorations with and without discrepancies and indicators of periodontal disease[214,215]. Strength of association and degree of exposure has also been demonstrated. For example, Lang *et al.*[215] observed a close relationship between an inflammatory response to poor margins and increasing sizes of overhangs. Hill's criteria of temporality has been verified in numerous studies, showing that the periodontal tissues around restored teeth have more gingival inflammation than the periodontal tissues around intact teeth in intra- and inter-patient comparisons. The criteria for intervention effect was demonstrated in a study by Coxhead[216], who reported that following removal of restoration overhangs on 50 patients, the conditions of the periodontal tissues improved significantly. A biological plausibility and coherence of results has been established in experimental studies where significant changes in the microbial ecosystem following introduction of unfavourable characteristics of the restorations were observed[217]. Finally, experimental evidence of a causal relationship has been confirmed in numerous animal studies.

Material factors

Multiple studies have compared the periodontal response to different dental materials, but only small differences have been detected provided that the restoration surface is smooth[218,219]. No studies have been located in the literature linking periodontal problems to specific physical properties of materials. A speculative suggestion is that restorations made from materials with high creep values will extrude out of the cavity as a result of occlusal stress, and thus cause plaque retention with periodontal disease as a consequence. However, no clinical data substantiate this concept.

Operator factors

Cavity design

In general, the proportion of restorations with poor margins gingivally, correlates with the gingivoaxial location, and thus contributes more to periodontal disease than restorations placed away from the gingival sulcus[215,216]. In one clinical study, no improvement in gingival status was noted following the removal of overhangs. It was hypothesised that this was due to a correlation between, on one side, the axial location of the restoration margin, and, on the other side, the dimensions of the overhangs and gaps[220].

Investigations published before 1992 on the possible relationship between Class I and Class II cavity preparations for amalgam and adverse effects on the periodontium have been reported in a previous paper, and will not be discussed further[113].

Material handling and procedures

Indirect restorations may be overcontoured or overextended if the impression of the preparation is deficient. One paper reported that there was little evidence that established guidelines for the preparation of teeth for porcelain laminate veneers were being applied in full in general dental practices[221]. Other papers conclude that the general quality of impressions for crowns received at commercial dental laboratories may be a cause for concern[222,223]. Johnson *et al.*[224] reported a wide variation of quality between three-unit bridges made from different commercial dental laboratories. Lack of a satisfactory prescription, representative of which may be used by clinicians, was singled out as an important explanatory factor.

Patient factors

The most important aetiological factor in periodontal disease is the presence of microbial plaque. Unless the patient can establish plaque control the risk of developing periodontal disease is high, regardless of the technical excellence of a restoration. The fact that oral health maintenance is a major significant factor in avoiding periodontitis and caries has been established repeatedly since the mid-1970s[225]. Grasso *et al.*[214] concluded after a cross-sectional study including 291 patients that plaque control measures were probably more important in reducing periodontal disease than improving the technical excellence of the restorations.

No studies have been identified in the literature linking periodontal problems to restoration properties as indirectly influenced by specific patient factors.

Does technical excellence predict failure?

It is difficult to separate the effects

of various local aetiological factors, when assessing the association between periodontal disease and restorations. Reported restoration parameters include the axiogingival location of the restoration margin, the location of the contact area and the axial contour of the restoration. Other factors are the plaque retentive ability, chemical state and roughness of the restorative material, the occurrence and size of overhangs and crevices, and the possible contributing effects of a restoration on an adjacent tooth.

Adverse effects on the soft tissues have been attributed either to improper contact areas with food impaction[226] or to details such as surface roughness, contour gaps and overhangs. Within limits, it appears that surface roughness does not lead to gingival changes[218,219,227].

There is general consensus that all factors that enhance the accumulation of plaque promote periodontal disease. Therefore, cavity designs that increase the prevalence of restoration discrepancies indirectly cause supportive tissue breakdown. The prevalence of gingival restoration margin discrepancies varies among different reports. One major reason is the lack of common assessment techniques and a common terminology.

Aesthetics

The topic of aesthetics includes both the qualities of shape and appearance[228]. Shape depends on the operator's ability to contour and finish the surface, as well as the material's wear resistance. Appearance depends primarily on material optical properties of colour and translucency. Metamerism, (a difference in colour appearance that varies with the light source) is also a common concern in aesthetic dentistry. The same concern exists for fluorescence of materials and teeth.

Many would argue that a highly polished, anatomically correct casting or amalgam restoration is aesthetically pleasing. When patients are asked their opinion of aesthetics, it comes as little surprise, that tooth-coloured restorations are preferred. Numerous clinical studies have confirmed strong patient acceptance of tooth-coloured inlays. Rimmer and Mellor[229] evaluated patients' perceptions of different types of fixed anterior restorations. Respondents thought that crowns and fixed prostheses with normal margins were of a higher technical standard, and those restorations were preferable to crowns with metal margins. The shade and colour of the restorations were the most important factors in the participants' assessments.

Abrams *et al.*[230] compared the assessment of quality by 117 patients after two dentists had assessed their restorations. The authors observed that when the patients and dentists' perceptions of the quality of the dental restorations were compared, no relationship existed. It was concluded that patients and dentists employ different criteria and priorities when judging quality of dental care. The logical view of aesthetics of dental restorations is related to the patient perspective, notably to what extent do dental restorations deviate from the appearance of sound teeth? (*Figure 5*)

Material factors

Several tests have been devised to screen materials at risk for bulk discolouration. These tests employ high intensity light sources and/or liquids with high chromaticity to evaluate colour stability. No tests exist that correlate laboratory findings with clinical observations of discolouration. The complex events producing restoration discolouration in the oral environment are poorly understood. Bulk and marginal discolouration varies considerably among different types of dental materials, and within dental material groups such as composite resins[189,231,232] and glass-ionomer cements[233].

In general, there is consensus that amongst the direct restorative materials, the composite resins have the best long term clinical performance regarding aesthetics[234–236]. Some differences among the composite resins have also been reported:

- Among conventional chemically cured composite resins, restorations with macrofillers discolour more over time compared to the same composite resin containing microfillers[189].
- Chemically cured composite resins discolour more than light-cured over time, probably because of different polymerisation initiators[232].
- Most restorative materials increase opacity and lightness after a period intraorally following water absorption, but this varies considerably between various products[237].

Operator factors

Material handling and procedures

The aesthetic limits of restorations in anterior teeth are determined mainly by :

- The size and nature of the lesion
- The characteristics of the filling materials
- The technique of application
- The age of the filling
- The oral environment[231].

It is self-evident that an optimal material handling and restoration process should be followed to ensure a satisfactorily aesthetic result. Numerous papers have detailed techniques necessary to create aesthetically satisfactorily restorations focusing on variables such as long bevels, polishing, anatomic and surface sharpening, multi-layering techniques, sufficient veneering and application of subsurface tints. No clinical studies, however, have tested the relative importance of these various procedures on the aesthetic outcomes in a long-term perspective.

Patient factors

Oral environment

In a clinical study over 18 months

a

b

c

d

e

Figure 5 (a–e). ‘Quality’ has a different meaning for different individuals, patients and dentists alike.

of composite veneers and artificial resin teeth the effects of consumption behaviour, such as coffee, tea and smoking, and cleaning habits on discolouration was evaluated. No significant influence on discolouration could be detected[238].

Qvist and Strom[88] observed 52 pairs of Class III composite resins over 11 years. Surface discolouration was most often recorded among smokers. Significant correlations were also found between the patients’ consumption of alcoholic beverages and bulk and surface discolouration of the restorations.

On the basis of a clinical study it has been suggested that local oral hygiene may play a role in the extent of surface staining[239].

Does technical excellence predict failure?

Although the initial aesthetics of restorations of tooth-coloured materials can be outstanding, a lasting outcome requires a material that has a high proportion of polymerised matrix. Restorations with an insufficiently polymerised matrix will discolour faster than those with a well-polymerised matrix, and for light-cured materials this depends, among other things, on an acceptable light intensity. There are a large number of variables (instrumentation, manipulative, restorative) that also influence the degree of conversion of monomer to polymer. Rarely are restorations well cured, which is partly because many dentists use light-curing units with low light intensities[240]. The intensity output from a lamp in a light-curing unit deteriorates over time, and the minimum acceptable light intensity level is 300mW/cm^2. Unfortunately, there seems to be a low awareness among dentists of the need for maintenance and regular checking of light intensity as part of a quality management programme[241].

Material deterioration

Material deterioration includes bulk and marginal fracture, as well as excessive wear or dissolution of the material. Excessive dissolution is seldom seen when materials which comply with ADA or ISO standards are correctly used. In particular, the presence of saliva during material placement may have a strong negative effect on the resistance to deterioration, for example glass-ionomer cement[242]. Excessive wear of luting cements may occur if the cement margin is wide. Modern composite resin cements seem to resist wear better than conventional cements[243]. Cements may also begin to disintegrate under luted restorations during deformation of the restoration, initiating and propagating cracks leading to cement fracture.

Bulk fracture is a common reason for restoration replacement, and it is often associated with caries. Caries may either have preceded the fracture, or have developed rapidly after fracture if a remnant of a broken restoration remains in the cavity[244]. No reference in the literature has been found as to estimates of the incidence of the two occurrences.

Material factors

Mjör[245] compared reasons for replacement of restorations with those from another study recorded 16 years previously. The proportion of replacements of amalgam restorations due to bulk fracture had remained much the same over the period, which suggest little effect of the improvements in amalgam alloy compositions. On the other hand, a significant relationship between the zinc and copper contents of amalgam alloys and bulk fractures was reported by Letzel *et al.*[69] on the basis of a longitudinal study over 15 years. The authors attributed this to the superior corrosion resistance of the non-gamma-2 (high-copper) amalgams compared to conventional alloy compositions.

For composite resin restorations there has been a notable decrease in the relative frequency of replacements as a result of degradation and wear, and an increase in the replacements following bulk and marginal fractures, which is attributed to changes of material composition[245].

Tyas[246] reported three-year observations of 102 Class IV restorations of four composite resins. Significant correlations ($P < 0.01$) were found between surface chipping/bulk fracture and fracture toughness, elastic modulus and tensile strength. Moreover, there was a trend towards an association between incisal wear and both elastic modulus and inherent flaw size.

Operator factors

It is difficult to assess the influence of important operator factors such as poor cavity adaptation, extent of porosities and extent of contamination of the material during handling on the restoration. It can be assumed this occurs at least occasionally with a possible detrimental effect on restoration strength. To what extent this accelerates material deterioration remains unknown.

Of the 15 studies inclu-ded in a systematic review of CEREC restorations, comparable results in terms of fracture rates were seen in studies undertaken in general practice and university environments[15].

Malament and Socransky[247] observed 1,444 restorations made from Dicor glass-ceramic over 14 years, and found no significant difference between the bulk fracture of inlay and onlay restorations. The fracture incidence improved significantly when restorations were acid-etched before luting. There was no significant difference between acid-etched Dicor restorations that were placed on shoulder or chamfer preparations, nor did the thickness of the restoration measured at the mid-axial point of each surface relate to fracture incidence.

Letzel *et al.*[69] reported a significant association between amalgam alloys and bulk fractures over an observation period of five to 15 years. Although not much was commented on in their report, a table showed a marked association between operator and incidence of bulk fracture.

Lemmens *et al.*[248] reported an analysis of 176 fractured amalgam restorations and concluded that there was a statistically significant influence of the dentist on the incidence of bulk fracture.

Cavity design

Wilson *et al.*[146] reported on a five-centre study for the five-year outcome of 232 restorations. Large restorations consistently deteriorated more than moderate-sized ones, with respect to class of restoration or type of tooth restored. In a cross-sectional study of approximately 2,500 amalgam restorations bulk fractures were most prevalent in fillings with three or four surfaces[163].

In a three-year study of 438 Class I restorations of glass-ionomer cement, composite resin and amalgam, loss of material and surface cracking or crazing appeared to a greater extent in large conventional preparations, and especially among glass-ionomer cement restorations[249].

The possible relationship between bulk fracture risk and Class I and Class II cavity preparations for amalgam has been reported in a previous paper, and will not be discussed further[113].

Patient factors

Intraoral location

Malament and Socransky[245] found fewer fractures of Dicor restorations in female than in male patients. The highest fracture level was observed in second molars.

Mjör and Jokstad[187] examined the clinical performance of 274 amalgam, glass-ionomer cermet cement and composite resin restorations over five years in small Class II cavities. The majority of the bulk fractures, which were mostly in glass-ionomer cermet cement restorations, were located in the upper molars.

In a 10 year longitudinal study of 468 amalgam restorations, Jokstad[29] reported findings that contrasted with the results by Lemmens *et al.*[243]. Only one of 27 fractured restorations was located in lower premolars. No effect of the intra-oral location on bulk fracture was observed.

On the basis of longitudinal studies over seven years, including 176 fractured amalgam restorations, it was suggested that restorations in the mandibular teeth and especially in the premolars were very susceptible to bulk fracture[248].

Oral environment

Wilson *et al.*[146] reported that the presence of occlusal contacts had a significant effect on deterioration of occlusal marginal adaptation over five years. This appeared greatest in the large Class I and both small and large Class II amalgam restorations in molars. This finding led the authors to suggest that future longitudinal studies should include assessment of occlusal function, diet and chewing patterns.

In a longitudinal clinical study of ceramic inlays over three years Åberg *et al.*[251] reported that of the fractured inlays, two-thirds occurred in patients with signs of bruxism.

In a retrospective study after 10–15 years on the quality of 793 restorations, bulk fractures in amalgam restorations were recorded primarily in patients with severe bruxism[170]. The levels of oral health and smoking were also included in the analyses, but no influence of either was found.

Klausner *et al.*[252] recorded the reasons for replacements of restorations. For bulk fracture, 43 per cent of restorations were 10 years of age or older, while 80 per cent were older than four years. The authors commented that if faulty occlusion or thin pulpal-occlusal sections of amalgam were the principal reasons for isthmus fracture, then these fractures should have become evident at an earlier time.

Does technical excellence predict failure?

Few clinical studies have addressed the correlation between material deterioration and duration of clinical service. Early occlusal marginal fractures, may[69,106,248] or may not[188,253,254] correlate with further material deterioration. Jokstad[29] observed 468 amalgam restorations of five alloys placed in 210 patients for 10 years. Marginal fractures after relatively short clinical service were associated with later bulk fracture.

Wear is not linear over time. It has therefore been suggested that it is misleading to calculate and describe wear levels in terms of micrometre/year[255]. It is probable that wear decreases over time, because the more wear-resistant adjacent enamel surface protects the remaining material surface to an increasing extent[256].

Caries

There is no reason to consider secondary caries as any different from primary caries[257]. It is a localised disease caused by a local accumulation of mechanically undisturbed bacterial biomass. Several facts should be examined in this regard. First, even when there is a very close adaptation between a restoration and tooth, there is still more than enough space for bacterial ingrowth. Second, there is little evidence of 'undetectable microleakage' causing secondary caries. Third, most papers have reported only weak evidence of a relationship between marginal discrepancies and secondary caries. Fourth, in spite of hundreds of laboratory microleakage studies, no correlation with secondary caries has been established. Fifth, ground sections of restored teeth with secondary caries often reveal subsurface lesions unrelated to the cavity wall. Finally, some clinical data suggest that the occurrence of secondary caries is a localised phenomenon related to the conditions for evolution of cariogenic plaque, rather than a universal attack along the entire interface between tooth and restoration[257].

Thus, secondary caries may develop in the presence of cariogenic plaque, but will never develop if cariogenic plaque is absent regardless of the technical excellence of the restoration. A discussion of which restoration detail constitutes a major or a minor 'focus' of plaque retention appears from this aspect to be an academic discussion. It is the patient's oral hygiene habits that will determine if caries develops, not whether the restoration can be considered as 'excellent', 'adequate' or 'deteriorated'.

Material factors

The increased popularity of restorative materials that release fluoride is in part explained by the belief that secondary caries can somehow be prevented by incorporating this component. The anticariogenic properties of glass-ionomer cement restorations are not strongly substantiated by clinical investigations[13]. On the other hand, the lack of strong evidence of an anticariogenic potential may stem from clinical studies conducted in academic environments on selected patients with minimal caries risk instead of in 'real-life' general practices.

In a longitudinal study of 274 large Class II open-sandwich resin-modified glass-ionomer cement restorations over three years, no secondary caries was noted, despite a large number of participating patients with high caries risk[258]. In these patients, a far higher caries frequency around the other restoratives was recorded, leading the authors to suggest a possible anticariogenic effect of this material.

Operator factors

Several textbooks advise that because of polymerisation shrinkage, the location of the gingival margin for posterior composite resin restorations should be placed at least one millimetre, when possible, from the enamel-cement margin. Several cross-sectional studies imply that this rule is not followed by general practitioners. However, it has not been possible to identify in the literature any clinical studies that have associated this characteristic of the cavity design with the development of secondary caries.

The possible relationship between secondary caries risk and Class I and Class II cavity preparations for amalgam has been reported in a previous paper, and will not be discussed further[113].

Patient factors

In a clinical evaluation of 63 Class II composite resin restorations over five years, 8 of the 11 patients with restorations that failed because of caries and marginal defects had higher counts of mutans streptococci at baseline compared to the remaining patients. This led the authors to suggest that the caries activity should be managed to avoid future secondary caries[87].

In a study of 4,294 children observed over three years, the incidence of secondary caries be associated with some oral hygiene parameters[259]. Water rinsing after brushing and the use of a beaker for rinsing was associated with secondary caries. Also, subjects who brushed less often than twice a day developed more secondary caries than the others did.

Clarkson and Worthington[260] reported that in a group of 270 adults an association was seen between caries, most commonly secondary caries, and attendance. The irregular attenders experienced more caries than did the regular attenders.

van Dijken[261] has carried out several longitudinal clinical studies where part of the study design has been to classify the patient according to few or many caries risk factors, based on the net effect of microbial counts, oral hygiene, salivary flow levels, buffer values, and fermentable carbohydrate intake[32]. However, the difference between these two groups has only been reported in two studies. In a six year longitudinal study of 150 tooth-coloured restorations, all restorations which subsequently developed secondary caries (n=7), except for one, were from the high-caries-risk group[261]. In another six year study of seven anterior composite resins, a markedly higher increment of caries was recorded among the patients with many caries risk factors[32].

In a 10 year longitudinal study of 468 amalgam restorations, the most important factor that could be associated with the development of secondary caries was the patient's yearly DFT increment[29].

Does technical excellence predict failure?

Roulet[104] stated categorically that marginal integrity is an important parameter for restoration longevity, since recurrent caries and pulpal disease is associated with marginal gaps. However, the gap size *per se* may not play any role in secondary caries initiation. What is of importance is whether it promotes formation of cariogenic plaque, which encompasses additional variables besides just gap size. It is theoretically possible that the quantity and quality of the plaque formation around restorations may be a better prognostic marker of restoration longevity than various criteria of technical excellence[201].

The alleged correlation between marginal fractures and recurrent caries is controversial. Two factors should be considered in this context. What is the association between the location of the defect and location of secondary caries? What is the relationship between the size of the defects and secondary caries? No reports have been identified that demonstrate a correlation between occlusal discrepancies and marginal adaptation on the approximal surfaces, which are the areas where secondary caries lesions prevail. Therefore, it is difficult to understand how marginal fractures on the occlusal surface can be related to a higher risk of secondary caries.

While some authors report associations between marginal fracture and secondary caries[262], others do not[263,264]. Other laboratory experiments suggest that a correlation does not seem to exist between the size of the crevice and secondary caries[265], or describe only a correlation in extremely cariogenic environments[266].

Staining around both amalgam[267] and tooth-coloured restorations[268] is considered unreliable in the diagnosis of active recurrent caries. Hewlett *et al.*[269] reported that 86 per cent of 822 restorations with marginal defects revealed no secondary caries on radiographs. This led the author to suggest that the replacement of all restorations with defects related to a perceived risk of secondary caries would constitute overtreatment.

After observing 468 amalgam restorations of five alloys placed in 210 patients for ten years, Jokstad[29] reported that those restorations with early marginal fractures could not be correlated with later development of secondary caries.

In an observational longitudinal study, an increased prevalence of secondary caries was recorded in the restorations with the poorest margin fracture scores[270].

A longitudinal clinical study over 10 years demonstrated no differences in secondary caries levels between a spherical amalgam alloy and a non-gamma-2 alloy, despite differences in marginal deterioration during the first years[271].

Goldberg *et al.*[272] examined 1,556 restorations in 87 patients in a cross-sectional study. The prevalence of secondary caries was correlated with the marginal fracture scores and indices of the patients' oral health. Using log-linear analyses, the investigators suggested that there was a significant relationship between these three factors.

Tooth fracture

Tooth fractures include cusp fractures, dentine cracks, incomplete dentine fractures, crack lines, and cracked tooth syndrome. Some use the term 'infraction' when the crack line is limited only to the enamel. There is general consensus that a restored tooth is stronger than a non-restored tooth with caries, but that a tooth with an intracoronal restoration is weaker than an intact tooth regardless of material. The processes involved regarding the way in which tooth strength is associated with choice of restorative material, adaptation and the microstructural relationship at the tooth-material interface are controversial. This can be explained by the fact that the incidence of tooth fractures is relatively low, which impedes the execution of clinical studies. Our understanding of the relationship between clinical factors and tooth fractures is therefore to a large extent based on extrapolation of case descriptions and laboratory findings[273–275].

Material factors

Thermal dimensional stability, hygroscopic expansion and setting/polymerisation shrinkage of restorative materials, as well as excessive loading, have been related to stress build-up in tooth tissues[1,65,73]. The stress will be best tolerated by dentine due to its elasticity, while infractions may develop in the enamel. The material-caused stress applies to restorative materials that do not exceed the limits according to the existing material test standards. An *in vitro* investigation has demonstrated fractures of ceramic crowns with cores made from resin-modified glass-ionomer cement materials. It was hypothesised that the fractures were caused by hygroscopic expansion[276]. Several manufacturers do not recommend this class of material for core builds or as a luting cement for full-ceramic restorations.

Several papers postulate that infractions in enamel and cusp fractures in teeth restored with amalgam are caused by an expansion associated with heat or with chemical reactions in the alloy, or corrosion of the amalgam. However, there is no clinical documentation of such relationship. Furthermore, no standardisation tests have been devised to screen materials for this alleged expansion.

Operator factors

Cast restorations, especially inlays or dowels with improper fit, cause stress that increases the risk of tooth fracture. Strain can also be introduced if high pressure is used or misalignment of the casting occurs during cementation. Also, it has been suggested that tooth preparation using eccentric or worn burs increase the risk of crack propagation in the tooth.

The possible relationships between tooth fracture risk and Class I and Class II cavity preparations for amalgam have been reported in a previous paper, and will not be discussed further[113].

Patient factors

Most tooth fractures originate in the 30–50 year age group and in teeth with large intracoronal restorations or caries. Fractures of contralateral teeth are common[275]. All factors that cause high strain on tooth tissue increase the risk of crack-line development and cusp fractures. Examples are bruxism, lack of occlusal support following loss of teeth, malocclusion, supra-contacts or frequent intake of coarse foods. Cusp fractures and crack lines in the posterior teeth are most frequently observed on balancing cusps, which are subjected to lateral chewing forces (that is, the lingual cusps in the mandible and buccal cusps in the maxilla).

Ellis *et al.*[274] reported a meta-analysis of the influence of patient age on tooth fracture and concluded that incomplete tooth fractures are uncommon in students attending an emergency clinic. It was noted that complete fractures might occur at any age, while it appears that incomplete fractures are associated with older age groups.

Does technical excellence predict failure?

No papers were found that report any association between clinical observations of technical excellence of restorations versus the incidence of later tooth fractures.

Loss of restoration

Loss of entire restoration is limited mostly to Class V restorations, especially when placed without cavity preparation. Loss of other types of restorations would only occur due to inappropriate selection of material, improper preparation of the tooth before restoration, violation of biomechanical principles for designing the restoration, mishandling the material, or a combination of these factors.

Material factors

Deviations from the manufacturer's direction for use may lead to decreased clinical performance. This has been reported in a three-year study of resin-modified glass-ionomer cements placed in cervical cavities, where retention was associated with surface wetting following variations in the powder/ liquid ratio at the time of placement[277].

Much discussion has taken place on the importance of the modulus of elasticity of polymeric materials[278]. There are diverging views on its relevance, and this confusion typifies our poor understanding of tooth biomechanics. There is also an ongoing discussion about which material is most appropriate for non-carious cervical lesions. Is composite resin, glass-ionomer cement, polyacid-modified composite or resin-modified glass-ionomer cement the optimal material of choice[279,280]?

Operator factors

Although presented as anecdotal evidence, Friedman[281] recounts his clinical experiences after placing a substantial number of porcelain veneers (n=3,500) over 15 years. The author attributes the three main failure reasons (debonding, marginal discolouration and adhesive fractures) to poor bonding, which is an indirect indication of improper tooth preparation or material handling. It has been suggested that the effectiveness of dentine bonding, and thus the retention of restorations, is influenced by operator factors such as cavity preparation relative to the active caries process, technique for material application, and procedures for polishing[282].

Cavity design

Vital dentine is continuously remodelling its microstructure to respond to physiological and pathological changes. Therefore, bonding may encounter differences such as sclerotic dentine, hypersensitive dentine (with open tubules), caries-affected areas, superficial dentine with few tubules, or deep dentine layers close to the pulp[283].

Isolation

Cervical composite resin restorations placed with isolation either with rubber dam or with cotton rolls suggested no statistically significant differences in retention after two years of service. Thus, loss of retention was not different when a careful cotton roll technique was used as a moisture control method, as long as saliva contamination was avoided[174].

Patient factors

Gender and age

It has been suggested that bonding to sclerotic dentine is less reliable than to young dentine, at least with older restorative materials[284]. Two recent clinical studies have refuted the hypothesis[285,286]. In these studies, lower failure frequencies were seen in the oldest age groups and the restorations placed in sclerotic dentine had an almost equal failure rate compared to the ones placed in non-sclerotic lesions.

McCoy *et al.*[191] suggested, after a three-year longitudinal study of Class V composite resin restorations, that a high proportion of old patients in the study contributed to relatively high proportion of loss, as a result of changes in the character of the dentinal surface.

Heymann *et al.*[287] reported on the determinants of failure of bonded composite resin restorations in non-carious cervical lesions. A strong association between patient age and restoration loss was identified, which was attributed to the greater tooth flexure in older patients, and the smooth, sclerotic nature of 'old' dentine.

Oral environment

In a recount of a clinical experience after placing 3,500 porcelain veneers over 15 years, Friedman[281] distinguishes between three fracture types, and suggests the aetiological mechanism for each type. The author ascribed static fracture lines and cohesive fractures to excessive loading.

McCoy *et al.*[191] noted in a three-year longitudinal study of Class V composite resin restorations that some restorations were lost from teeth with marked signs of occlusal wear, supporting earlier reports of higher loss of restorations among bruxers compared to non-bruxers[288].

Does technical excellence predict failure?

There are no known papers that have reported any association between clinical observations of technical excellence of restorations versus later loss of restorations.

Orthodontic changes and temporomandibular joint problems

Composite resins placed during 1970–1980 had relatively poor resistance to wear when used in the posterior occlusal segments. In spite of this, products were sold in large quantities and used for this purpose by many general practitioners. Annual wear of 30–60mm was reported, raising concerns for possible hypereruption of opposing teeth and mesial migration of teeth distal to those undergoing loss of approximal contact[289]. Despite concerns that composite resins were unsuitable for surfaces exposed to heavy masticatory forces, there were no reports that extensive use led to tooth misalignments or temporomandibular joint problems caused by occlusal changes.

The resistance to wear of correctly handled modern materials has now been markedly improved. Thus, the risk of large generalised wear and potential pathological joint changes and temporomandibular problems are minor. However, the potential exists if materials are handled incorrectly, following eating disorders or harmful occupational environments, or if new restorative materials are applied that have not been adequately tested for clinical wear.

Treatment decisions and technical excellence

The planning of restorative treatment consists of a series of interactive exchanges of information between the dentist and the patient. Lack of awareness of a patient's complaints and expectations can lead to unnecessary conflicts, a situation cherished by sensational news media. A common principle in marketing is 'do/say the right thing to the right people at the right time'. This quotation can be improved for our purposes by refining the words into the dental strategy. Optimal dental treatment of patients consists of: (1) At the right time, (2) offer the right treatment, (3) to the right patient, (4) in the right way, (5) with the right results.

The interpretation into dental terms is (1) make the correct diagnosis at the outset, (2) explain to the patient the options and suggest the best alternative, (3) take into consideration the patient's priorities and preferences, (4) carry out the restorative intervention according to correct procedures and material handling to ensure the highest possible technical excellence, and (5) aim to accomplish the pre-set objectives that you as a dentist and patient have agreed on. The most relevant issue is the evaluation of the technical excellence of dental restorations as part of the first step: making a correct diagnosis. Main objectives are to recognise a pathological condition, understand the patient's problem and identify risk markers of progressive oral disease. The technical excellence of restorations is, at this stage, of secondary importance.

Patient dissatisfaction

Patient dissatisfaction with a particular restoration is easy to detect. It includes complaints about pain, aesthetics, surface roughness, contour, detectable margins, supraocclusion or food retention. As long as the contributing factor is identified and corrected, there is no problem. However, if the patient's dissatisfaction is with a restoration that meets all criteria for technical excellence the situation is more complicated. Then patient information and ethical considerations must prevail, tempered by existing local or national legislative precedents or regulations. The patient must always be advised of the potentially iatrogenic damage associated with restoration replacement, such as risk of pulp deterioration and increased cavity dimensions, as well as the possibility of no improvement in spite of restoration replacement.

Some studies have attempted to categorise or distinguish patient characteristics versus expectations of dental treatment. Several taxonomies have been presented. Håkestam *et al.*[290] suggests there are three groups: the aesthetic, the cost conscious and the longevity-focussed. Lutz and Krejci[291] categorised the patients as in orally 'functional', 'presentable', 'healthy', 'beautiful' and 'metal-free' groups. Other studies have applied further patient classifications. Although such systems tend to appear simplistic, they highlight the fact that patients' personalities, values and priorities differ considerably. Modern health care places great emphasis on patient satisfaction as a criterion for quality. However, the theoretical principles of patient satisfaction are complex and correlate poorly with criteria for technical excellence commonly used by dentists[292].

Estimating risk for oral disease

Assessment of risk markers of oral disease is detailed in at least one excellent textbook on risk and oral diseases[293], and within textbooks on cariology[46,267,294,295] and periodontology[296,297]. Briefly, risk assessment associated with susceptibility to oral disease consists of determining factors related to the patient's social and medical history, plaque control, saliva and clinical signs of disease. Estimating the risk for oral disease progression can be assessed at the patient, tooth and site levels.

At the patient level, the key oral disease risk markers are the presence of a systemic disease, irregular dental attendance, prior caries history, periodontal problems, plaque and/or bleeding scores, medication side effects and saliva quantity and quality. Other risk markers may refine decisions about interventions. For example, information on social deprivation, active oral disease in siblings or low dental IQ and history of repeated interventions may be relevant factors.

For periodontal disease, presence of residual pockets and cigarette smoking are additional factors to be considered when assessing risk while additional factors for addressing risk for future caries are dietary habits, frequency of sugar intake, availability of snacks and use of fluorides.

At the tooth and site levels, risk factors include residual periodontal support, inflammatory parameters

Table 4 Intervention strategies based on combining a risk assessment for oral disease and the technical excellence of the patient's restorations. The codes used in the CDA evaluation system criteria[31] are included to enhance the interpretation of the table (see Table 5 for abbreviations)

1. Consider consequences of monitoring, correcting, removing or replacing restoration in case of:	
Caries	
Caries along restoration margin (VCAR)	
Radiographic evidence of caries/voids	
Margin	
Retained excess cement (TCEM)	
Restoration overhang/surplus (TOV)	
Other	
Tooth structure is fractured (VTF)	
Mobile restoration (VMO)	
Superficial or penetrating fracture line (VFR)	
Restoration is partially or in toto missing (VMIS)	
Evoked pain during clinical examination	
2a. If markers of high-risk caries present:	***2b. If markers of high-risk periodontitis present:***
1. Assess if these criteria possibly are associated with or can contribute to disease	1. assess if these criteria possibly are associated with or can contribute to disease
2. Consider consequences of monitoring, correcting or replacing restoration	2. Consider consequences of monitoring, correcting or replacing restoration
Surface	*Surface*
Fractured, rough or pitted or irregular, flaking or has gross porosities (SRO)(TGI)(TPIT)(VSF)(VFK)(VGP)	Fractured, rough or pitted or irregular, flaking or has gross porosities (SRO)(TGI)(TPIT)(VSF)(VFK)(VGP)
Contour	*Contour*
Exposed dentine or base (TDE)(TBA)	Contact slightly open or faulty (SCO)(TCO)
Undercontoured cervical area approximally (SPX)(TPX)	Undercontoured cervical area approximally (SPX)(TPX)
Margin	*Margin*
Ditch or gap along the margin (SCR)(TMD)	Ditch or gap along the margin (SCR)(TMD)
Discoloured margin (SDIS)(TPEN)	*Other*
	Traumatic occlusion (VTO)
3. Limit intervention to monitoring – unless the patient is dissatisfied.	
Contour	
Undercontoured or overcontoured restoration (SUCO)(TUCO)(SOCO)(SOC)(TOCO)(VUO)	
The occlusion is affected (SOH)(TET)(TOC)	
Under-contoured marginal ridges (SMR)	
Flattening present facially or lingually (SFA)(SLG)	

and their persistence, presence of ecological niches with difficult to access sites such as furcations, and the presence of iatrogenic factors such as restoration discrepancies. Information gathered by clinical monitoring and continued multi-level risk assessment produces an estimate of the oral health status of an individual, and risk of oral disease progression at a particular tooth or site. It is not until this stage that concern about the technical excellence of one or more particular restorations should be addressed. Thus, the risk level for oral diseases must in a systematic way first be recognised, and then coupled with treatment options that are consistent with the potential future caries increment or periodontal disease. It has been suggested that a decision-tree approach and/or treatment-index concept should be applied to specific clinical conditions and preventive-restorative options to estimate the probable outcomes[298].

In the introduction, a definition of the quality of restorations emphasised the risk of jeopardising the integrity of remaining dental-related tissues. Patients with indications of severe caries or periodontal disease require more attention to possible detrimental characteristics of restorations compared to patients with no signs of disease. The concept of such an approach is consistent with the treatment decision philosophy practised by many clinicians. The clinician always has three options in deciding on a strategy for intervention. Either to ignore the current status, to adjust or repair, or restoration replacement.

Table 4 suggests how the technical excellence of restorations should be appraised clinically in light of risks of oral disease. The wording of the criteria parallels descriptions used in the CDA evaluation system[31] and textbooks cited at the start of this section. *Table 5* shows the CDA quality evaluation rating system and USPHS criteria for evaluation.

It must be emphasised that the considerations of the consequences of monitoring, correcting, removing or replacing an existing restoration must be but one component of the management of oral disease. Further requirements to justify operative intervention should include patient understanding of risks and prognosis, assessment of aetiology and the instruction of preventive proce-

Table 5 Relationship between the CDA and the USPHS criteria for evaluation of dental restoration systems[30,31].

Surface and color		Anatomic form		Margin Integrity	
R: Range of excellence Restoration is of satisfactory quality and is expected to protect tooth and surrounding tissue					
CDA	USPHS	CDA	USPHS	CDA	USPHS
Surface of restoration is smooth No irritation of adjacent tissue is occurring There is no mismatch in color or translucency between restorations and adjacent teeth*	The restoration appears to match the shade and translucency of adjacent tooth tissues (The restoration must be examined without using a mouth mirror)	Restoration contour is in functional harmony with adjacent teeth and soft tissues with good individual anatomic form	The restoration is a continuation of existing anatomic form or is slightly flattened. It may be over-contoured. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavosurface line angles at the same time	No visible evidence of crevice on margin into which explorer will penetrate. Satisfies principles of margin placement wherever possible. No discoloration on margin between restoration and tooth structure*	There is no visual evidence of dark, deep discoloration adjacent to the restoration The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does catch there is no visible crevice along the periphery of the restoration There is no visual evidence of marginal discoloration difference from the color of the restorative material and from the color of the adjacent tooth structure
S: Range of acceptability Restoration is of acceptable quality but exhibits one or more features that deviate from ideal					
CDA	USPHS	CDA	USPHS	CDA	USPHS
SRO Surface of restoration is slightly rough or pitted; can be polished SMM Slight mismatch between shade of restoration(s) and adjacent tooth or teeth* *(... and tooth structure within the normal range of tooth color, shade and/or translucency)*	The restoration does not match the shade and translucency of adjacent tooth tissues, but the mismatch is within the normal range of tooth shades	SOCO Restoration over-contoured slightly *(but excess material can be removed)* SUCO Restoration slightly undercontoured SOH Occlusion is not totally functional *(or height reduced locally(not in toto))* SMR Marginal ridges slightly undercontoured SCO Contact slightly open SFA Facial flattening present SLG Lingual flattening present SAF Anatomic form of pontic may cause food retention; no irritation of soft tissue *SOC Occlusal contour not continous with that of cusps and planes* *SPX Interproximal cervical area slightly undercontoured*	A surface concavity is evident. When the side of an explorer is placed tangentially across the restoration, the explorer touches two opposing cavosurface line angles at the save time, but the dentin or base is not exposed	SCR Visible evidence of slight marginal discrepancy with no evidence of decay; repair can be made or is unnecessary *(visible ditching along the margin not extending to the DE junction)* SDIS Discoloration on margin between restoration and tooth structure*	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction The explorer catches and there is visible evidence of a crevice, into which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The dentin and/or the base is not exposed, and the restoration is not mobile

T: Replace or correct for prevention
Restoration is not of acceptable quality. Future damage to tooth or surrounding tissue is likely to occur

CDA	USPHS	CDA	USPHS	CDA	USPHS
TGI Surface grossly irregular, not related to anatomy and not subject to correction TMM Mismatch between restoration(s) and adjacent tooth or teeth outside normal range of color, shade, or translucency* *TPIT Surface deeply pitted, irregular grooves (not related to anatomy) cannot be refinished*	The restoration does not match the shade and translucency of the adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency	TUC0 Restorations grossly undercontoured TOCO Restorations grossly overcontoured TET Occlusion affected TCO Contact is faulty TOV There is marginal overhang TAF Anatomic form of pontic likely to result in food retention, causing irritation to soft tissue or caries in abutments *TDE Dention is exposed* *TBA base is exposed* *TOC A occlusion is affected* *TPX contact is faulty – self-correction unlikely*	There is a loss of restorative substance so that a surface concavity is evident and the base and/or dentin is exposed	TFAM Faulty margins that cannot be properly repaired TPEN Penetrating discoloration along margin of restoration in pulpal direction* TCEM Retained excess cement *TMD visible ditching along the margin extending to the DE junction* *TMB ditching along the margin extending to the center base*	There is visual evidence of dark, deep discoloration adjacent to the restoration (but not directly associated with cavosurface margins) The explorer penetrates a crevice defect that extends to the dentoenamel junction There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction

V: Replace statim
Restoration is not of acceptable quality. Damage to tooth or its surrounding tissues is now occurring

CDA	USPHS	CDA	USPHS	CDA	USPHS
VSF Surface is fractured VGP There are gross porosities in crown material VSD Shade in gross disharmony with adjacent teeth* *VFK surface is flaking* *VUN Esthetically displeasing color, shade and/or translucency*		VTO Traumatic occlusion VUO Gross underocclusion or restoration VPN Restoration causes unremitting pain in tooth or adjacent tissue VDM Damage is now occurring to tooth, soft tissue, or supporting bone *VMIS restoration is missing*		VMO Mobile restoration VFR Fractured restoration VCAR Caries continuous with margin of restoration VTF Tooth structure is fractured	

*Criteria apply only to anterior teeth

dures, including dietary advice, counselling and plaque control instruction.

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