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Review Article

Prediction and diagnosis of clinical outcomes affecting restoration margins

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SUMMARY **The longevity of dental restorations is largely dependent on the continuity at the interface between the restorative material and adjacent tooth structure (the restoration margin). Clinical decisions on restoration repair or replacement are usually based upon the weakest point along that margin interface. Physical properties of a restorative material, such as polymerisation shrinkage, water sorption, solubility, elastic modulus and shear strength, all have an effect on stress distribution and can significantly affect margin integrity. This review will focus on two aspects of margin deterioration in the oral environment: the *in vitro* testing of margin seal using emersion techniques to simulate the oral environment and to predict clinical margin failure and the relationship between clinically observable microleakage and secondary caries. The many variables associated with *in vitro* testing of marginal leakage and the interpretation of the data are presented in detail. The most recent studies of marginal leakage mirror earlier methodology and lack validity and reliability. The lack of standardised testing procedures makes it impossible to compare studies or to predict the clinical performance of adhesive materials. Continual repeated *in vitro* studies contribute little to the science in this area. Clinical evidence is cited to refute earlier conclusions that clinical microleakage (penetrating margin discoloration) leads to caries development and is an indication for restoration replacement. Margin defects, without visible evidence of soft dentin on the wall or base of the defect, should be monitored, repaired or resealed, in lieu of total restoration replacement.**

KEYWORDS: **microleakage, margin discoloration, margin gap, secondary caries, Caries Adjacent to Restorations and Sealants, clinical testing**

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Introduction

As clinicians, we are constantly faced with making decisions related to the conditions of existing dental restorations. Some decisions are rather easy when clear signs or symptoms are present, and in these cases, we expect to find acceptable agreement among practitioners that some intervention is needed. Total loss or mobility of a restoration, frank caries with dentinal exposure and periodontal damage because of lack of proximal contact or gingival margin overhangs are clinical findings that require restorative intervention, either restoration replacement or repair. Fracture of a restored tooth may also require replacement or repair of an existing restoration. These clinical signs are easily detected and will likely evoke a recommendation for treatment by a majority of dentists. However, the form of treatment is likely to vary considerably. One other, often perplexing, situation is the presence of chronic or severe pulpal pain in restored teeth that is not otherwise explained. This can be caused by dentinal fractures, caries not visible clinically or on radiographs, or pulpal necrosis without periapical pathology. When the patient reaches the point of demanding treatment, removal of the restoration as an exploratory procedure would be indicated. Likely, the most difficult restorative

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decision is the assessment of restoration margins and determination of the appropriate treatment.

The advent of bonding resin to tooth structure has created many opportunities in the past decade for the advancement of aesthetic dentistry. The bond to pretreated enamel has proven to be particularly strong in the oral environment, and a more conservative cavity design has been the result. Current textbooks in operative dentistry (1, 2) provide evidence of the reliability of the resin to enamel bond as part of the retentive aspects of cavity design. Aesthetic restorative procedures have been developed to modify both the colour and the contour of healthy unrestored teeth with procedures such as direct resin veneers, diastema closures and porcelain laminates. Preventive treatments have been developed by bonding resin sealants to enamel and functional posterior restorations are being placed routinely with composite resins, in lieu of amalgam. The bond to enamel is largely biomechanical and relies on the preparation of a high energy, etched surface that can be wetted easily by low-viscosity bonding resins, producing micromechanical resin tags (3).

Similar procedures have also been developed to bond resin to dentin, although the substrate varies greatly from enamel in organic composition and water content (4). As in enamel, the role of surface preparation in dentin bonding is critical in creating a 'hybrid zone' of demineralised dentin, into which hydrophilic polymers can penetrate and interlock with exposed collagen to provide another form of micromechanical retention (5). Commercial products available as dentin bonding agents have been improved over the years to provide a clinically acceptable adhesive bond at the restorative material–dentin interface, depending to some extent on the resin material and the dentin surface preparation (6).

In clinical service, both the bond to enamel and the bond to dentin can fail and result in penetration of oral fluids into the interface. This phenomenon was first documented by Nelsen *et al.* (7), in 1952, as 'marginal percolation', when unfilled methacrylate resins were first introduced as anterior tooth-coloured restorative materials. For many years, it has been taught that the penetration of oral fluids into the restoration interface would lead to the development of secondary caries (1, 2). This was no doubt true in earlier years when the interface gap was large, the bond to tooth was either weak or non-existent, the restorative resins were flexible and saliva was high in cariogenic substrate and bacteria. However, with the advent of fluoride therapy in both systemic and topical forms, there is a reduced susceptibility to secondary caries, especially in the younger segment of the population. Fluoridated enamel is more resistant to acid demineralisation, and early caries is either prevented or its development is slowed down significantly (8). In this case, it is possible for localised areas of debonding to develop at a restoration interface, fluid penetration to occur and yet not lead to the development of active caries. The challenge for the dentist is to assess the condition of the margin and to determine whether treatment, if any, is needed. Certainly, predictive tools that can tell the clinician what the likelihood is of present or future secondary caries associated with marginal gaps would be highly beneficial.

In vitro microleakage testing as a predictor of clinical outcomes

The assessment and/or prediction of margin microleakage in dental restorations has attracted a long and continued interest from the dental research community. Cox (9) reported 344 juried publications on the subject between the years 1966 and 1992. Most of these studies have been performed *in vitro* for convenience and because the *in vivo* model is so difficult to simulate. Research on margin leakage has largely been performed using restored extracted teeth, either bovine or human. Such tests are inexpensive to perform, use elementary technology, require minimal scientific training and provide a research experience for clinical dental faculty. This review will attempt to answer two questions:

Question #1: Are *in vitro* microleakage tests reliable and valid to predict the clinical outcome of margin discoloration in adhesive restorations?

Question #2: Is margin discoloration and the presence of margin gaps in adhesive restorations a reliable and valid predictor of secondary caries?

To address Question #1, the review will describe the variety of *in vitro* tests documented in recent dental literature, compare *in vitro* findings to published *in vivo* clinical studies and assess the reliability and validity of *in vitro* modelling as it is currently being performed.

Clinical causes of bond failure and microleakage

The clinical evidence of margin debonding and the occurrence of microleakage can have several forms. The

initial appearance is visual during routine hard tissue examination, when areas of discoloration appear along a margin interface. Colour can be orange, tan, dark brown or black. It can be a collection of surface stain at the margin area or it can penetrate into the interface, demonstrating more of a shadow or undermining effect. Penetrating stain may be the first sign of incubating debris that contain cariogenic bacteria with the potential to initiate an active carious wall lesion at the interface.

In most cases, this stain accumulation is associated with a margin defect, creating a gap between the cut tooth and the restorative material. It was shown in 1968 with amalgam (10) that a margin crevice >0·5 mm wide was most likely to result in secondary caries. There are a number of factors that can contribute to margin debonding. Once an adhesive bond is established, internal shrinkage stress will produce tensile forces that may be sufficient to break the bond and produce a margin gap (11). Thermal cycling from coffee (55 °C) to ice drinks (5 °C) can also introduce pump-like forces because of expansion followed by contraction that will eventually fatigue the bond to failure (12). Water sorption in a resin material can also draw fluids into the interface through the material and hydrolyse the bond. Inadequate surface preparation (insufficient etching, over-extended etching and salivary contamination), inadequate surface wetting and penetration of the bonding agent are operator and material factors also associated with bonding failures. There are also mechanical reasons for margin discrepancies to occur. Excessive occlusal biting forces or hard food particles at the margin can concentrate the stress and result in small fractures of either weakened tooth structure or restorative material, producing a crevice. The finishing process can exert heat within the resin margin and cause microscopic cracks that propagate later into fractures. With all of these external and internal forces working against an adhesive bond, it is amazing that any resin restoration can endure clinically. It is these clinical and material variables that laboratory studies attempt to simulate in experimental designs.

In vitro testing

The literature cited in this section was taken largely from a PubMed search using 'microleakage' and 'composite' as search terms (1005 articles) and limited to 2009 publications (38 articles), as representative of past research history in this area of *in vitro* testing.

Clinical simulation

Tooth substrates. The ideal substrate for testing microleakage is tooth structure. Earlier studies were performed on bovine incisors, because the teeth are larger, the surfaces are flatter and they are more accessible for research. However, the majority of studies have been performed on extracted human teeth (incisors, premolars or third molars) without caries or restoration. Studies have been performed to compare results between bovine and human teeth, but with mixed results. Reeves *et al.* (13), in 1995, and Almeida *et al.* (14), in 2009, both reported no difference in results using both substrates; while Lopes *et al.* (15), in a recent study, showed bovine teeth to have greater microleakage penetration than human premolars under the same conditions. The most reliable approach is to use human teeth, if at all possible.

Test cavities. Study designs for microleakage usually use standardised class 5 preparations to evaluate adhesives or class 2 mesial-occlusal-distal (MOD) preparations to evaluate restorative systems on the cervical areas of extracted teeth. In typical class 5 preparations, the occlusal margin is in enamel to analyse dye penetration associated with an enamel bond, and the cervical margin is placed on dentin or cementum to provide comparative data on the dentin bond using the same tooth (16). In typical class 2 mesial-occlusal-distal (MOD) preparations, one box is placed with the cervical floor in enamel and the other box with the cervical floor on cementum or dentin (17). The age of the tooth, the occlusal forces under which the tooth functioned, the eating habits of the patient and the forces applied during the extraction are uncontrollable confounding variables that have an effect on the condition of the tooth surface at a margin interface and could cause variation in the microleakage patterns.

Storage conditions. Storage conditions before and after testing are important factors that standardise study conditions and allow data to be compared. Freshly extracted teeth are obviously better than teeth that have been in storage for an unknown period of time, but they take time and effort to obtain in sufficient numbers. The important variables to consider in attempting to simulate the oral environment are the time and storage media

from the time of extraction until the study begins, the environment in which the restorative materials were placed and the time and storage medium from restoration placement until immersion into the test medium. Most investigators use distilled water or solutions of saline, thymol, formal, chloramine or azide for post-extraction storage. The time between extraction and preparation for the study varies from 1 to 6 months for those studies in which the period is reported. In some studies, a gluteraldehyde (18) or formaldehyde (19) soak is used immediately prior to starting the study as an antibacterial treatment. The effect of storage or treatment solutions on the tooth structure or as a latent contaminant during bonding is not known. Besnault and Attal, in 2002 (20), showed that inserting the restorative material at 37 °C created significantly greater leakage than inserting at 20 °C. Storage after cavity restoration and before testing is either in water or 100% humidity at 37 °C, and storage time can range from 24 h to 7 days for standard testing. Prolonged storage for up to 4 years before testing increased the effect of water storage and material ageing on microleakage around fissure sealants (21). Most investigators give no rationale or clinical time estimation for the storage solutions that they used or the time selected for testing.

External stimuli. External stimuli have also been applied to test specimens to simulate the function of the oral environment and to accelerate the clinical effect (microleakage). Most studies use some form of thermal cycling to simulate the thermal extremes of ingested food or fluids. A range from 5 to 55 °C is the exposure usually used, but dwell times (full immersion) in each bath vary from 15 s (22) to 60 s (14). Holding periods (between immersions) also vary among studies and often are not reported. There is not a reliable estimate as to how well this cycling simulates what takes place in the mouth. A material must come to thermal equilibrium to expand and contract in the full range, but the time a restoration is actually exposed to a stimulus in the mouth or in the simulated water bath probably does not allow equilibrium to be reached. Mechanical loading has also been used to simulate functional stresses. Koyuturk *et al.* (23) demonstrated, on fissure-sealed occlusal surfaces, that cyclic loading (50 N, 0·5 Hz, 50 000 times) in conjunction with thermocycling (10 000 times) increased microleakage significantly over either method of ageing alone. Arisu *et al.* (24) also have shown that cyclic occlusal loading at 250 N increased microleakage at the margins of class V restorations. The problem with simulation experiments is that there is not good evidence how closely, if at all, simulated conditions duplicate a functioning clinical environment.

Salivary substitutes (tracers). A great number of media have been used over the years to duplicate the oral fluids that penetrate into a restoration interface. The most frequently selected media are dyes, which can readily be seen on magnified images of cross-sections of teeth after controlled exposure by submersion into a dye solution. The most popular dyes used are 0·6–2% rhodamine B or T (15, 25), 1–5% methylene blue (26, 27) and 0·5% basic fuchsin (17). Another medium that is frequently selected is a 50% solution of silver nitrate. This involves a little more extensive technique, and the protocols used vary significantly. The teeth are soaked in the silver nitrate solution for 2–24 h (14, 18) for penetration and then in radiographic developing solution with exposure to a light from 6–8 h (16, 18) to turn the silver particles black for identification. Other media that have been used over the years include fluorescent dyes, radioisotopes, neutron activation analysis, bacterial cultures, fluid filtration, air pressure and *in situ* lesions for caries. Of the 36 publications listed in the PubMed search for 2009 that assessed microleakage *in vitro*, seven used methylene blue, 14 used basic fuchsin, three used rhodamine, seven used silver nitrate solutions, one used fluid filtration, one used an *in situ* clinical approach and three did not report their tracer. None of the studies published in 2009 gave any rationale for the tracer solution or concentration selected for use.

Heintze *et al.* (28) conducted a study on class 5 restorations in extracted molars to compare results among the three most frequently used tracer solutions. They used 2% methylene blue for 24 h, 0·5% basic fuchsin for 24 h and 50% silver nitrate for 4 h, followed by 8 h in developing solution under fluorescent light. All teeth were mechanically cycled for 1 200 000 times at 49 N/1·7 Hz plus 3000 thermocycles. The depth of microleakage was measured using a stereomicroscope, and the values were compared with SEM measurements of continuous margins on both enamel and dentin. Results showed that on enamel, there was no correlation between the leakage values and the SEM evaluations. For dentin margins, there was a significant correlation between SEM and leakage data for basic fuchsin and silver nitrate, but not for methylene blue.

All three tracers had similar penetration on either enamel or dentin. This is evidence that tracer penetration can occur at a margin that appears in SEM analysis to be completely bonded.

Using generally similar methodology in class 2 restorations, de Almeida *et al.* (29) found that rhodamine B produced more leakage than radioactive 45Ca or methylene blue and that 45Ca showed greater leakage than methylene blue. The same research group, in 2004 (30), used standardised class 5 restorations to evaluate the penetration of four tracers: 0·5% basic fuchsin for 24 h, 2% fluorescent dye for 24 h, 1·5% reactive orange #14 for 2 h and radioisotope 45Ca for 2 h. Measurements were performed on a rating scale from 1 to 5 based primarily on penetration beyond 50% of the wall length. Results showed that the tracer penetration was least with fluorescent dye and 45Ca; Rhodamine was significantly higher; and basic fuchsin was significantly higher than the other three. It is obvious that different tracer systems can lead to varying microleakage scores. Some of this variation may be due to the particle size of the tracer particles, the concentration of the tracer solution, the sensitivity of the detection system, the inconsistency in sample preparation and the operator variation in conducting the test procedure. Therefore, tracer selection alone is a critical factor in designing an *in vitro* microleakage study and results should be interpreted in that light. The studies cited earlier are only a small sample of recently published articles, but they represent the lack of standardisation in tracer selection up to the present time.

Measurement systems

Tooth sectioning. After soaking in the selected tracer solution, teeth are dried and sectioned for visual or microscopic evaluation. Another variable that affects the penetration values measured is the number of tooth sections evaluated. It is convenient to section the tooth in half and look only at the two exposed sides, which really are closely related and were randomly selected as the cut was made. Raskin *et al.* (31) studied the reliability of data obtained from three independent sites measuring the microleakage from up to five sections (10 surfaces evaluated). They used an established adhesive restorative system (Scotchbond MP, Z100*) and standardised protocols. Two sites used silver nitrate and one site used methylene blue; all teeth were thermocycled 3000 times, and sections were scored with a scale of 0 to 3. Correlation between the reference (deepest reading of five sections) and the data from a number of sections increased from 0·47 for one section to 1·0 for three sections. There was no difference in the data from the three centres. There is still an uncertainty whether sectioning through a dye-stained tooth will smear the tracer and make the smear appear as penetration. This could be a potential confounder in data interpretation.

Rating scales. After tooth sectioning, penetration along the interface from the cavosurface into the tooth is then measured using a number of protocols. For facility, rating scales have been developed and used over the years in most studies. The scales attempt to measure the depth of tracer penetration into the margin interface in a semi-quantitative way to produce data that can be analysed statistically, usually with non-parametric tests. Figure 1 illustrates typical tooth sections with tracer penetration using two different bonding agents.

On the seven scales used in published articles in 2009 and shown in Table 1 (14–17, 26, 32–37), there is no correlation between the numbers on one scale and the numbers on another scale, except that the higher the rating, the greater the tracer penetration. Scales #1, 3, 5 and 6 draw their main reference from penetration along

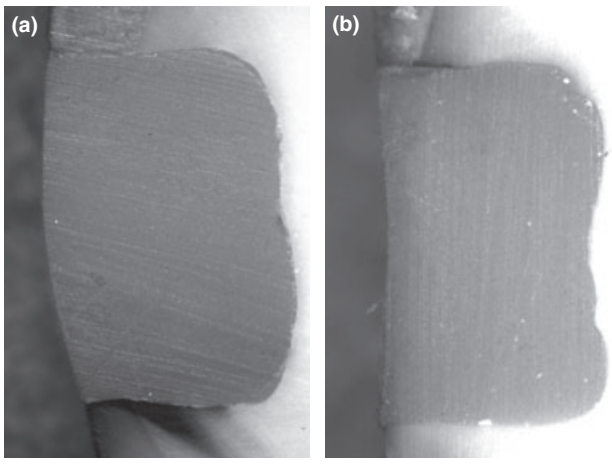

Fig. 1. Tooth sections with silver nitrate dye penetration into restoration margins. (a) Penetration along the dentin cervical wall after placement of a total-etch DBA and no penetration at the occlusal enamel margin; (b) Penetration along the enamel occlusal wall after placement of a self-etch DBA and no penetration at the cervical dentin margin.

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Table 1. Various rating scales used for measuring microleakage *in vitro*

Score	Scale #1	Scale #2	Scale #3	Scale #4	Scale #5	Scale #6	Scale #7
0	No tracer penetration	No tracer penetration	No tracer penetration	No tracer penetration	No tracer penetration	No tracer penetration	No tracer penetration
1	Penetration < half the wall length	Penetration in enamel to DEJ	Penetration up to 1/3 wall length	Penetration in enamel to DEJ	Penetration < half the wall length	Penetration < half the enamel wall length	Penetration in enamel to DEJ
2	Penetration > half the wall length	Penetration into dentin – up to axial wall	Penetration > 1/3 but < 2/3 wall length	Penetration < half the wall length	Penetration > half the wall length	Penetration > half the enamel wall length	Penetration into dentin – up to pulpal/axial wall
3	Penetration to axial wall/pulpal floor	Penetration along axial wall/pulpal floor	Penetration > 2/3 wall length, including axial and pulpal	Penetration > half the wall length	Penetration up to 1/2 the axial wall length	–	Penetration into pulpal/axial wall
4	–	–	–	Penetration to axial wall/pulpal floor	Penetration along full axial wall	–	Penetration beneath pulpal/axial wall
Ref. nos.	(17, 32–34)	(26)	(14, 35)	(36)	(37)	(16)	(15)

the wall length, but the specific reference points vary. Scales #2, 4 and 7 use the dentinal-enamel-junction (DEJ) as the first reference point, but differ as the penetration depth increases. Also, scale #6 has three divisions; scales #1, 2 and 3 have four divisions; and scales #4, 5 and 7 have five divisions. Although inter-rater agreement is often calibrated between two independent examiners for a specific scale, it is still impossible to make reliable interstudy comparisons.

Continuous measurements. Some studies have used image analysis tools to measure the depth of tracer penetration in mm (18, 22, 25). This makes the measurement a continuous variable and allows for parametric statistical analysis. Using magnified images, with measurement software, should also provide a more accurate measurement of the amount of microleakage. Quantified measurements have also been attempted using fluid filtration (Endo) (38), air pressure (39), neutron activation analysis (40), confocal microscopy (41) and *in situ* histological analysis for demineralisation (42).

Two newer techniques have been proposed in recent years, electrochemical assessment and Micro CT scanning. The electrochemical method was proposed by Jacobson and von Fraunhofer (43) in 1976, specifically for the evaluation of apical seal in endodontic procedures. A steel rod was placed in the coronal end of a treated canal and the corrosion rate was measured electrically as the tracer solution penetrated through the apical seal and reached the steel surface. Application of this technique is limited to endodontics and is time consuming. Moosavi *et al.* (44) used this method to evaluate the effect of two antioxidants on leakage during a bleaching procedure. They also compared the results obtained with the electrochemical method with similar results obtained on the same teeth using 0·5% basic fuchsin dye penetration over 24 h and the evaluation of sections at 16× magnification. Results were similar with both the electrochemical and staining techniques, and there was a strong correlation at $P = 0{\cdot}006$. The application of micro CT scans to analyse leakage quantitatively and non-destructively was proposed by Sun *et al.* (45), in 2009. They evaluated volume changes during polymerisation, estimated gap formation after shrinkage and related gap size to microleakage. They also compared their spatial analysis with data obtained using a 1% solution of rhodamine dye as a tracer and found good agreement. These techniques are more complicated and expensive to

implement, and therefore have more limited application than estimating dye penetration with rating scales.

Independent variables studied

There is a myriad of independent variables that have been studied over many years. As microleakage is an interface phenomenon, it is used mainly as an assessment of the completeness of a bond between a restorative material and tooth structure. The quality of an adhesive bond can also be evaluated with *in vitro* bond strength testing and by analysing the gap formation at the clinically exposed margin. An assumption is also made that polymerisation shrinkage and/or shrinkage stress influence the integrity of an adhesive bond. These measurements are often linked together in laboratory studies, but there is little evidence of a strong correlation among them. Fleming *et al.* (46) evaluated the effect of incremental placement of posterior composite in extracted premolars on cuspal deflection during light curing. They found that materials with lower volumetric shrinkage had less cuspal deflection, but neither factor affected the degree of microleakage at the proximal cervical margins of the restorations, using 0·2% basic fuchsin as the tracer. Amaral *et al.* (47) compared curing methodologies for both microleakage and gap formation in bovine teeth. They used 2% methylene blue dye to evaluate microleakage and SEM analysis of epoxy replications at 500× magnification to evaluate gap width. There was no correlation between gap formation and microleakage results with any of the curing techniques.

The independent variables that have been studied, just in 2009 alone, include the following:

Surface preparation
- Bovine substrate versus extracted human teeth
- Total-etch versus self-etch
- One-component self-etch versus two-component self-etch
- Effects on enamel versus dentin margins
- Laser treatments versus standard etch
- Antibacterial pre-treatment of dentin versus mechanical cleaning
- Post-bleaching of enamel-bonded restorations
- Effect of site contamination with saliva
- Effect of immediate dentin sealing

Material comparisons
- Layering techniques
- Effect of flowable composites as liners
- Low shrinkage versus nano-filled composites
- Clear matrix and wedge versus metal matrix and wood wedge
- Effect of embedded fibre networks

External factors
- Light curing intensities and curing modes
- Operator variation
- Orthodontic brackets and cements
- Endodontic sealers or filling materials
- Mechanical versus thermal cycling

As the range of variables differs so much, there is little in common among studies to make comparisons or to determine whether *in vitro* microleakage testing has validity to estimate clinical outcomes or reliability to discriminate among materials/techniques based on maintaining a cavity margin seal. Table 2 illustrates the variation in results for four standard dentin bonding agents used in different studies as controls, but with similar technique (14–16, 22, 32–34, 36, 48, 49). The variation is explained by many of the factors discussed earlier (cavity location on the tooth, tooth structure variation in the mouth and after extraction, storage media, mechanical and thermal stimuli applied, tracer technique selected and the measurement system used to generate the data). It is this variation in methodologies that creates difficulty in making interstudy comparisons for reliability.

Prevalence of studies

There has been extensive use of *in vitro* microleakage testing to assess the quality of an adhesive bond over the past three decades. Figure 2 illustrates the number of studies carried out in each 5-year period since 1975. From 1975 to 1985, adhesive materials were in the early marketing stage and *in vitro* microleakge tests were being developed to test the effectiveness of the bond. For each 5-year period from 1985 to 2000, 143 to 197 articles were published using *in vitro* tests. From 2001 to 2005, a peak number of 247 articles were published using *in vitro* testing. From 2006 to 2009 is only 4 years and yet there were 212 publications, all with the same variations in methodologies. This continued repetition of non-validated *in vitro* testing does not speak well for the science being published in this area.

In 2001, Raskin *et al.* (50) published a review article evaluating the reliability of *in vitro* microleakage tests. They chose 144 studies published between 1992 and 1998, in which 917 microleakage experiments were conducted. A database was prepared and analysed for

Table 2. Comparison of microleakage values for standard bonding agents

Study	Clearfil SE	Single Bond	Scotchbond MP	Prime & Bond NT
Lopes, et,al. (15) *RC: Wave™, SDI* (% of total interface)	36·01%	47·35%	–	–
Khosravi, *et al.* (16) *RC: Filtek Z100™, 3M Espe* (mean scores; 0–2)	0·5	–	0·0	–
Fakhri, *et al.* (48) *RC: Clearfil AP-X™, Kuraray* (AV mm from cavosurface)	*E* = 0·093 ± 0·043 *D* = 0·125 ± 0·113	–	–	–
Froes-Salgado, *et al.* (34) *RC: Esthet-X™, Dentsply Caulk* (mean scores; 0–3)	–	–	–	2·0 ± 1
Moldes, *et al.* (32) *RC: Filtek Z250™, 3M ESPE* (Av rank score)	–	*E* = 0 *D* = 33·55	–	–
Duarte, *et al.* (33) *RC: Rely X Arc™, 3M ESPE* (% score to axial wall)	–	60%	–	–
Siso, *et al.* (36) *RC: TE-Econom™, Ivoclar* (% score > DEJ; 0–4)	*E* = 0% *D* = 26·7%	–	–	–
Calabrez-Filho, *et al.* (22) *RC: Filtek Flow™, 3M ESPE* (Av mm from cavosurface)	–	*E* = 0·06 ± 0·07 *D* = 0·24 ± 0·04	–	–
Bulucu, *et al.* (49) *RC: Filtek Z250™, 3M ESPE* (Av Rank Score)	*E* = 0 *D* = 40·02	–	–	*E* = 0 *D* = 50·41
Almeida, *et al.* (14) *RC: Fill Magic™, Vigodent SA* (mean scores; 0–3)	–	–	–	*H* = 0·44 ± 0·63 *B* = 0·31 ± 0·48

*All values were taken from human teeth using standard technique for that bonding agent and the measurement system used.
E, Enamel; D, Dentin; H, Human; B, Bovine.

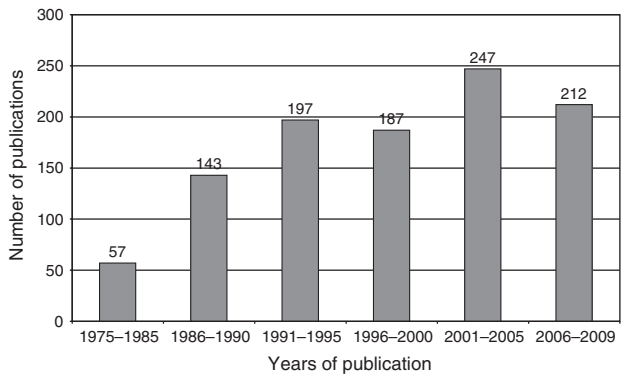

Fig. 2. A graphic display of the number of microleakage publications from 1975 to 2009 in 5-year increments.

selected criteria; such as substrate, cavity class, restorative materials, operating procedures, thermal cycling, mechanical cycling, tracer medium and evaluation method. He concluded that the great variability in the methods used prevented any comparison of the results, reducing the value of this type of testing. The literature search for this review does not indicate that any effort has been made to standardise methodology or to improve the reliability of data generated in this manner over the past 10 years.

Clinical evaluation of microleakage

The clinical evaluation of microleakage is obviously the 'gold standard' in measuring the effectiveness and durability of an adhesive margin in a dental restoration. Prospective randomised clinical trials provide the most reliable data on the incidence of margin leakage, as it relates to specific independent variables in the study design. Such trials are expensive to conduct and require

long time periods to gain sufficient data. To meet specific objectives of a study, the independent variables must be very limited and the hypotheses very well defined. Samples of representative populations are difficult to recruit and retain in a study unless monetary incentives are provided for recalls, thus adding additional costs to already expensive studies. To account for the many patient variables that influence clinical data (food types, drinking liquids, saliva, xerostomia, functional and non-functional forces, smoking, patient habits, medical history, etc.), larger sample sizes are required and multiple restorations on the same patient should be restricted unless the study involves a paired design. All of these factors affect the quality of the data obtained from a clinical study and the generalisations that can be made from the results. Although long-term studies are more ideal, costs are prohibitive, subject loss is significant and the materials become obsolete before a good longitudinal study can be published.

Microleakage associated with an adhesive restoration is manifested visually as a discoloration along a margin defect. The discoloration can range from straw coloured to black; it can be localised or generalised; it can be a surface discoloration or penetrate into the interface. As clinical evaluations must be non-destructive, visual rating scales are used most frequently. Dr. Gunnar Ryge in the early 1970s (51), in conjunction with the US Public Health Service, developed a set of criteria for clinical evaluation of dental restorations that have become standard and are used in most clinical studies, with only slight modifications. The purpose in developing these criteria was to make the evaluation more objective than subjective and to improve reliability. Clinical evaluators in controlled studies are trained to use these criteria and are usually calibrated to produce interexaminer, as well as intra-examiner reliability of 85% or greater. The specific criteria for margin discoloration are as follows:

Rating	Criteria
Alfa	No margin discoloration evident.
Bravo	Discoloration at margin, not penetrating in pulpal direction
Charlie	Discoloration at margin, penetrating in pulpal direction

There is a normal progression anticipated for areas of microleakage. A localised stain can become more extensive along a margin as more adhesive bonds break or a localised stain can progress to a penetrating discoloration, which creates a more serious problem. Figure 3 illustrates the degree of discoloration that is typical for both Bravo and Charlie ratings. The discrimination between these ratings is based upon the assumption that once the fluid has penetrated into the interface, the potential for secondary caries to develop is significantly greater and indicates a need for intervention. The ratings do not take into account the extent of colour (light brown to black) or the width of the colour band along the margin, although penetration can be identified by broader colour dispersion into the restorative material.

At the beginning of a 5-year clinical trial, Dennison *et al.* (52) created magnified images of 360 composite restorations exhibiting various levels of margin discoloration. They used a surgical microscope to capture *in vivo* digital images at 40× and characterised the primary location of the discoloration within the interface of each lesion. Results showed that visually, 22% were surface stains (rated Bravo) and 78% were penetrating stains (rated Charlie). Microscopically, 12% showed discoloration that was within the tooth structure, 52% showed stain accumulated in the interface and 36% showed stain within the composite material. There did not appear to be a relationship between the morphology of the margin defect and the location of the stain.

Table 3 documents 11 typical recently published clinical studies that follow margin discrepancies of adhesive restorations over time. In posterior restorations after 3 years (53–56), the incidence of discoloration ranged from 4% to 47%, with no restorations showing

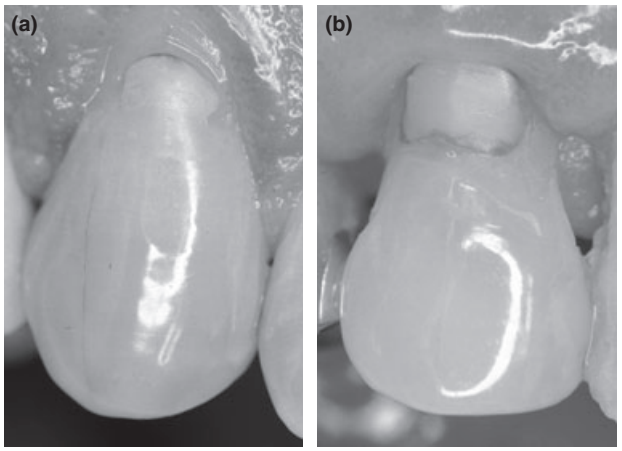

Fig. 3. Class 5 restorations exhibiting margin discoloration. (a) Surface discoloration along the margin that does not penetrate pulpally into the interface (Bravo rating); (b) A similar restoration with discoloration that does penetrate in a pulpal direction (Charlie rating).

Table 3. Clinical evaluation of microleakage (margin discoloration) in longitudinal studies of composite restorations

Clinical study	*n*	Years	Bonding agent	Restorative material	Incidence of margin discoloration
Palaniappan, *et al.* (53) (class 1 & 2)	20	3	Single bond, TE	Z100	*A* = 13; *B* = 6; *C* = 0
				Filtek Supreme	*A* = 9; *B* = 8; *C* = 0
Swift E, *et al.* (54) (class 1)	25	3	Xeno Iii, SE	Esthet-X	*A* = 73%; *B* = 27%
			Solobond Plus, TE	Point 4	*A* = 84%; *B* = 16%
Aw, *et al.* (56) (class 5)	38–46	3	Scothbond MP, TE	Silux Plus	*A* = 23; *B* = 17; *C* = 6
			Single Bond, TE	Silux Plus	*A* = 27; *B* = 9; *C* = 2
			One Coat Bnd, TE	Synergy	*A* = 26; *B* = 11; *C* = 6
Poon, *et al.* (55) (class 1 & 2)	24–27	3·5	P & B NT, TE	Sureful Pack	*A* = 24; *B* = 3; *C* = 0
				TPH Hybrid	*A* = 23; *B* = 1; *C* = 0
Franco, *et al.* (57) (class 5)	27	5	Excite SE	Tetric Ceram	*A* + *B* = 100%
Fagundes, *et al.* (58) (class 1 & 2)	30	5	P & B NT, TE	SureFil	*A* = 23; *B* = 7; *C* = 0
			Bond 1, TE	Alert	*A* = 19; *B* = 10; *C* = 0
Peumans, *et al.* (59) (class 2)	84	5	Clearfil SE	Clearfil AP-X	*A* = 68%; *B* = 32%
			Clearfil SE + Etch		*A* = 83%; *B* = 17%
Kiremitci, *et al.* (60) (class 2)	44	6	Single Bond, TE	P60 Packable	*A* = 40; *B* = 4; *C* = 0
Wilder, *et al.* (61) (class 5)	16, 25	12	Optibond, TE-E only	HercuIltie XRV	*A* = 17; *B* = 8; *C* = 0
			Optibond, TE	Herculite XRV	*A* = 13; *B* = 3; *C* = 0
Wilder, *et al.* (62) (class 1 & 2)	85	17	UV Light cured (data pooled)	UV Light cured	*A* = 94% at 10 years *A* = 100% at 17 years
da Rosa, *et al.* (63) (class 1 & 2)	72–112	17	Scotchbond 2, TE	P-50	*A* = 48; *B* = 24; *C* = 0
			XR Prime/Bond, TE	Herculite XR	*A* = 67; *B* = 43; *C* = 2

TE, Total etch; SE, Self-etch.
USPHS Criteria: A, Alfa; B, Bravo; C, Charlie.

penetration. In one class 5 study (57), the range was from 29% to 50%, but with 5–14% showing penetration. This is usually more evident in class 5 cervical studies on abrasion lesions, because there is less bulk to the material and no retention in the preparation to resist deflection under the forces of occlusion. In studies that followed posterior restorations for 5–6 years (58–60), the range was from 10% to 34%, with no restorations showing penetration. In a class 5 study after 12 years (61), the incidence was 18–32%, with no restorations showing penetration, and in two posterior studies after 17 years (62, 63), the rate was between 33% and 40%, with one group showing 2% with penetration. It is possible in such long-term studies that the restorations showing penetrating stains could have totally debonded and been lost to follow-up at later recalls. Based upon these 11 clinical studies chosen for longevity, the incidence of penetrating margin discoloration does not appear to be significant or progressive over time. With these low rates of discoloration, it is difficult to make a direct correlation to the results of *in vitro* studies. There were, however, two trends in Table 3 results: (i) that self-etch adhesive systems showed somewhat greater leakage than total-etch systems both *in vitro* and *in vivo* and (ii) that class 5 restorations placed over non-carious lesions demonstrate margin discoloration to a greater extent than posterior restorations with retentive cavity preparations.

Correlation between *in vitro* and *in vivo* testing for microleakage

There are a few studies that have been conducted to assess the correlation, if any, between *in vitro* and *in vivo* testing for microleakage. Heintze, in 2007 (64), conducted systematic reviews to compare margin integrity of adhesive restorations with margin discoloration. These reviews document an annual increase in margin discoloration of 5–6%, with a wide range from 0–15% depending on the study parameters. He documented three main *in vitro* methods that are used to evaluate marginal seal of a restoration; bond strength tests, microleakage tests and margin gap analysis. In 30 studies that compared bond strength with microleakage

tests, 77% (23 studies) showed no correlation and only 13% (three studies) showed a moderate correlation. In 18 studies that compared bond strength to gap analysis, 78% (14 studies) showed no correlation and 11% (two studies) showed a correlation. The evaluation of microleakage and gap formation was complicated by the multiplicity of methodologies used. There was some indication of correlation with enamel margins, but not with dentin margins in class 5 cavities. When Heintze compared marginal leakage results with clinical outcomes in class 5 restorations, there was some correlation between margin discoloration and restoration retention, but not with gap analysis or margin integrity.

In a similar study comparing *in vitro* testing to clinical performance, Frankenberger *et al.* (65), in 2007, conducted a study to compare five different adhesives: 4-step etch/rinse, 3-step etch/rinse, 2-step etch/rinse, 2-step self-etch and 1-step self-etch. The *in vitro* tests were performed using standardised class 1 preparations in extracted third molars. All teeth were thermo-mechanically loaded (TML) in a chewing simulator for 100 000 cycles at 50 N force plus 2500 thermal cycles from 5 to 55 °C. Replicated models were made for each tooth before TML and after. In the matching clinical study, class 1 preparations were made as indicated in molar teeth. After 2 weeks and again after 2 years, replicated models were made for each tooth. An SEM evaluation of the margins was performed for each model at 200× magnification. Margins were rated as 'gap' or 'gap-free' and recorded as a percentage of continuous margin length. There was a close correlation between the two groups, and the conclusion was that *in vitro* margin integrity after TML is a good predictor of *in vitro* clinical performance. Etch/rinse adhesives resulted in better margin adaptation than self-etch adhesives, and this difference was accentuated *in vivo*. There was no attempt to evaluate microleakage or margin discoloration in this study.

In the most recent attempt to establish correlation, Heintze *et al.* (66), in 2009, evaluated the quantitative margin analysis of two established *in vitro* test methods and the clinical outcome in class 5 restorations. They chose 34 clinical studies, for which *in vitro* data on margin integrity was also available. The *in vitro* method developed at the University of Zurich involved wedge-shaped class 5 cavities in extracted premolars, occlusal margin in enamel and cervical margin in dentin. The teeth were connected to a device that simulated the hydrostatic pressure of dentinal fluid during the restoration placement and thermo-mechanical loading (3000 thermal cycles and 1 200 000 load cycles at 49 N and 1·7 Hz). Replicated models were made of each restoration before and after testing and evaluated for gaps under SEM at 200× magnification, using software to determine the percentage of continuous margin. The second *in vitro* method, developed at the University of Berlin, used class 5 restorations placed on the labial surface of extracted maxillary central incisors, with the enamel wall bevelled. The teeth were thermocycled for 2000 - cycles, and the margins were evaluated directly before and after cycling using a four-point rating scale for gap analysis with 2 μm width as the critical dimension. Comparable clinical studies were selected, and the percentage of retention loss, margin discoloration and detectable margins was used as data to calculate an *in vivo* index to make comparisons. The Berlin *in vitro* Index was calculated based upon the percentage of total margins receiving each of the four ordinal ratings, with an index of 1 being 100% gap-free. In the Zurich *in vitro* Index, a ΔD or $\Delta D/E$ was calculated based upon the difference in percentage of gap-free margins before and after thermal cycling. The Spearman correlation coefficient for the Berlin Index *in vitro* versus Margin Discoloration in the clinical studies was 0·29, 0·12 and 0·08 at 12, 24 and 36 months, respectively. The correlation for the Zurich Index was 0·14, 0·23 and 0·21 at similar periods. When the data were analysed using only studies with the same composite restorative, the correlation improved, but was still very weak. When the entire calculated clinical index was used with only studies of the same composite for the comparison, the Berlin Index appeared to have a better correlation (0·37, 0·6 and 0·69 versus 0·0, 0·54 and 0·46). When the two *in vitro* indices were compared with each other, there was no correlation (0·12 for all composites and 0·36 for the same composite). The variation in outcome of similar clinical studies also contributes to the problem, because of variations in study design, evaluation criteria and calibration of operators and examiners.

Summary and answers to question #1

The general consensus among those researchers who have tried to correlate *in vivo* and *in vitro* testing of adhesive margins is that microleakage tests are not consistent among present studies and fail to correlate with margin discoloration after durable periods in the clinical environment.

Answers

1 *In vitro* microleakage tests are not reliable laboratory tests as presently conducted in the published literature.
2 *In vitro* microleakage tests are not valid predictors of the clinical outcome of margin discoloration as documented in published clinical studies.
3 If a standardised microleakage methodology could be established and universally accepted, then it could be a valuable means to compare adhesives on a relative scale and to make some controlled interstudy comparisons possible.

Secondary caries diagnosis

Diagnosing and determining appropriate treatment for teeth with secondary caries is one of the more challenging clinical tasks. It is well known that the diagnosis of caries is the primary reason dentists replace restorations, accounting for about 50% of replacements in adults (67). Mjör and Toffenetti (68) found differences in the rates of secondary caries reported in practice-based cross-sectional studies versus longitudinal studies, which indicate that the incidence of secondary caries is over-estimated by dentists deciding to replace restorations for this reason. Hickel *et al.* (69) reviewed longitudinal trials and found the failures because of secondary caries in composite restorations over 10 years to be only 4% to 8%.

It is also well accepted that this specific diagnosis is over-used. Often the decision to replace a restoration is made and then the diagnosis is appended to the decision (70). Several studies have pointed out the inconsistency in diagnosis of secondary caries (68, 70, 71). The visual, tactile and radiographic information used by dentists to make a diagnosis of secondary caries are not rigidly linked to diagnostic criteria that are universally accepted or taught in the profession. Thus, the sensitivity and specificity of these diagnostic indicators are low. Only in the situation of a clinically frank carious site adjacent to a restoration is the diagnosis of secondary caries likely to be correct (72, 73).

Yet, the profession seeks diagnostic methods and devices that offer the ability to discriminate the earlier stages of caries without subjecting patients to over-treatment. There is clear need for improved methods to reduce over-treatment. Elderton (70) reported inconsistencies between restorative treatment provided and what was predicted by epidemiological surveys. In addition, 1145 decisions to restore or re-restore a total of 326 surfaces made by 15 dentists showed only two surfaces where all 15 dentists agreed. The study by Bogacki *et al.* (74), that found significantly higher restoration replacement rates in patients who changed dentists, documents the inconsistency between practitioners in assessing the clinical acceptability of existing restorations.

Secondary caries is described as a combination of an outer lesion and a wall lesion (75, 76) with the outer lesion considered essentially new caries in the tooth structure adjacent to the restoration. The main mechanism for development of a secondary carious lesion is the outer lesion. This is supported by the findings that the bacteria found in primary and secondary carious lesions are not different (77). In a review, Mjör found studies which showed that secondary caries are found mostly on the gingival margins of restorations and less frequently at occlusal margins (67). These findings also indicate that the aetiology of secondary caries is likely similar to primary caries.

Marginal gaps and secondary caries

Studies that have attempted to relate the presence of marginal gaps between the restorative material and tooth structure have shown conflicting evidence of a relationship with the presence of secondary caries activity (78–83). Microleakage, long thought to be related to secondary caries, is now not considered a predisposing factor or a predictor of secondary caries, supporting (64, 65) the aetiology of secondary caries as being similar to primary caries and occurring in the tooth structure adjacent to a restoration. Thus, the presence of defects at the margins of restorations, without a clinically undisputable frank carious lesion, is not predictive of secondary caries. The presence of a marginal gap is often misdiagnosed as secondary caries because a probe may stick or discoloration is present (67). A relationship between restorative margin quality and the presence of secondary caries is not well supported by clinical evidence (84). However, two studies do indicate that marginal gaps of 250 and 400 μm are predictive of the presence of caries (73, 85). Kidd *et al.* (73) reported on the presence of cariogenic bacteria in marginal gaps around amalgam restorations. Their data indicated only gaps wider than 400 μm, contained significantly more bacteria compared with narrower gaps or intact margins. They also found that in the absence of a frank

carious lesion, the colour of the enamel adjacent to the restoration margin was not related to the underlying bacterial levels. Kidd and Beighton (72) reported that marginal colour change and gaps were not predictive of the underlying soft dentin following removal of tooth-coloured restorations and only the presence of a frankly carious margin is a reliable indicator of secondary caries. Based on the uncertainty of making a correct diagnosis of secondary caries, it is more prudent to resist operative intervention to treat secondary caries unless there is clear evidence of soft dentin in marginal gaps larger than 250 μm.

Restorative intervention

More recently, investigations into using treatment interventions other than total restoration replacement have been reported (86–90). As it is now generally accepted that current diagnostic methods for secondary caries lead to many incorrect diagnoses, it is timely to examine treatment approaches other than total restoration replacement. The minimally invasive technique for exploration of an enamel fissure to determine the caries status and extent of caries is now an accepted technique. Executing this procedure in lieu of preparing the entire fissure to the depth of dentin mitigates errors made in caries diagnoses. Likewise, using this same philosophy for diagnosing and treating marginal defects seems logical and prudent. Clinical studies that have reported on repairing, sealing and refurbishing restorations with finishing and polishing methods generally show improvements in restoration quality after 2 years compared with untreated controls. When a marginal defect is found, the defect should be noted and scheduled for follow-up evaluation. The caries risk of the patient should be taken into consideration when determining the time period before the next evaluation. Acceptable recall periods can range from 3 months to several years. At each follow-up evaluation, the condition should be noted and compared with valid reasons for restoration repair or replacement. Certainly, after 2–3 recall periods with no change in status, increasing the recommended time between evaluations would be reasonable.

Terminology associated with caries in restored teeth

Several terms exist to describe caries associated with restored teeth (68, 91) including secondary caries, recurrent caries, remaining caries and residual caries. According to Mjör (68), the term recurrent caries is used more in North America, while the term secondary caries is more commonly used in European languages. Users of the term secondary caries tend to be referring to caries adjacent to a restoration margin. The terms remaining and residual caries are more synonymous with caries that was not removed during placement of the restoration.

Assessment and documentation systems

There are also differences in systems for caries detection and documentation. The concept that caries is a yes/no diagnosis associated with the presence or absence of a cavity versus the concept of a disease with clinical stages that preceded the level of cavitation (91) leads to these differences. We see the dichotomous approach in the Ryge/USPHS system for assessing restoration performance (51, 92–94) as a determining factor for the most severe rating for marginal integrity. When using this system, the decision is either caries is present or absent. A point to make is that this diagnostic scoring system depends on an apparent association of marginal defects and caries, as the criteria to evaluate both conditions were created with the least severe defects being marginal quality issues and the most severe defect including caries. When initially developed by Ryge, the presence of marginal gaps or other defects was thought to promote the development of secondary caries.

Hickel *et al.* (69) have recommended new methods and criteria for conducting clinical studies of dental restorations (Table 4). In this system, three overarching categories are assessed: aesthetic properties, functional properties and biological properties. Marginal adaptation is considered under functional properties and pathology, including caries, is considered under biological properties. This is an important step forward in decoupling the assessment of these properties, as the establishment and maintenance of acceptable marginal adaptation is clearly more related to properties of the restorative material, while the development of secondary caries is more related to the oral environment and patient behaviours. It is also consistent with the fact that margin quality is not considered a predisposing factor for development of secondary caries.

The criteria published by Hickel *et al.* (69) have five scoring levels that take into account the progression of secondary caries from demineralisation to frank

Table 4. Comparison of the Ryge/USPHS, ICDAS and FDI clinical trials criteria for assessment of secondary caries

Ryge/USPHS criteria		FDI/Hickel *et al.* 2007 (69) criteria		ICDAS CARS criteria 2005	
Alfa (A)	No evidence of caries continuous with the margin of the restoration	12·1	No recurrence of initial pathology and no other pathology present	0	Sound tooth surface with restoration or sealant
Bravo (B) but later called Delta (D)	Evidence of caries continuous with the margin of the restoration	12·2	Small/localised area of demineralisation but no operative treatment required	1	First visual change in enamel
		12·3	Areas of demineralisation, erosion or abrasion/abfraction, no dentin exposed, preventive measures only needed	2	Distinct visual change in enamel/dentin adjacent to a restoration/sealant margin
		12·4	Recurrence of initial or other pathology, including cavitated caries, erosion or abrasion/abfraction in dentin, is more localised and accessible and can be restored/repaired by operative intervention	3	Carious defects of <0·5 mm with signs of Code 2
				4	Marginal caries in enamel/dentin adjacent to restoration/sealant with underlying dark shadow from dentin
		12·5	Severe recurrence of initial pathology or other pathology, generalised or localised such as deep caries or exposed dentine that is not accessible for repair and requires immediate restoration replacement	5	Distinct cavity adjacent to restoration/sealant with gap >0·5 mm
				6	Extensive distinct cavity with visible dentin on walls and base

CARS, Caries Adjacent to Restorations and Sealants.

cavitation between the restorative material and tooth. A distinguishing feature between the two most severe levels considers whether repair could be used to eliminate the pathology (code 12·4) or the tooth requires restoration replacement (code 12·5). Thus, to determine the correct scoring level would require operative intervention to some degree. This seems consistent with clinical practice, where the final decision to completely remove a restoration may not be made until some restorative material and defective tooth structure are removed to assess the extent of the pathology.

Publication of the International Caries Detection and Assessment System (ICDAS II) (91) in 2005 following a series of workshops held in the USA and Europe includes diagnostic criteria for Caries Adjacent to Restorations and Sealants (CARS). ICDAS considers the diagnostic process in three steps: detection of caries lesions, assessment of severity and, finally, assessment of current activity. The ICDAS system addresses detection and severity of carious lesions, but because of lack of clinical evidence, only draft criteria were proposed for lesion activity. A search of PubMed on 21 March 2009 using the search term 'ICDAS' located 13 publications, all of which related to dental caries; however, none appeared to be addressing CARS. Thus, at this point, the incorporation of this system for use in studies related to restorative materials must be very limited.

The ICDAS CARS criteria use seven levels of codes, zero to six (Table 4). One distinguishing feature of this system is the combination of a breakpoint in marginal gap at 0·5 mm and the presence or absence of a shadow of dentin discoloration. For example, a Code 3 and 4 would have a carious defect <0·5 mm with signs similar to Code 2, but displaying increasing enamel opacity or dentin discoloration. On the other hand, a Code 5 is distinguished by a marginal cavity >0·5 mm. It is recommended that a 0·5-mm-diameter ball-ended probe be used for assessment of the gap width. Using such a probe would be consistent with work described by Kidd *et al.* (73) and Kidd and Beighton (72), where a marginal gap of at least 400 μm is more likely to be associated with the presence of true secondary caries. The ICDAS does not relate the severity of CARS to the need for operative intervention or use the need for repair or replacement of a restoration to describe any level of the codes.

In conclusion, correctly diagnosing CARS or secondary caries would seem more useful for the purposes of monitoring in epidemiological studies or clinical trials of restorative materials that have either a cariogenic or anticariogenic potential. More importantly, dentists should assume that secondary caries is not present unless there are visible signs of soft dentin in the marginal defect. In the absence of these signs, the recommended actions would be monitoring or repair of the defect.

Summary and answers to question #2:

Several conclusions and recommendations for researchers and practitioners for assessment of restorations for secondary caries or CARS can be made:

1 The term, 'Caries Adjacent to Restorations and Sealants', is an inclusive term, which can account for all mechanisms for the development of caries in restored teeth. CARS should be used in lieu of the terms 'secondary caries, recurrent caries, residual caries and remaining caries'.

2 CARS is most likely to be present at the gingival margins of restorations that have a cavity width >400 μm.

3 Changes in opacity or colour of adjacent tooth structure are not predictive of CARS in the absence of a frankly carious gap.

4 Marginal defects without visible evidence of soft dentin on the wall or the base of the defect should be monitored for change or repaired or sealed and then monitored. Removal of existing restorative material to better visualise the walls and base of the defect is recommended prior to repair or sealing.

5 For clinical trials of restorative materials that are considered anticariogenic or would be considered to possibly promote caries, the assessment of CARS would be appropriate. For other materials, it may not be useful to measure CARS.

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