Assessing Restorative Dental Materials: 1. Test Methods and Assessment of Results

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Abstract: **Many methodologies are used during the testing of dental materials. Among these are compressive, tensile and flexural strengths, and fracture toughness. However, different tests are relevant to different materials and clinical situations. This paper describes different test methodologies and discusses the substantiation of research claims in publications and advertising.**

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Clinical Relevance: **The clinician practising evidence-based dentistry should be able to assess the relevance of test methods and the adequacy of evidence presented in papers and advertising.**

The worldwide market for dental materials is expanding, as a result of growing dental expectations of patients and the retention into advanced years of increasing numbers of teeth by larger proportions of the population of developed countries. There is also an expansion in the variety of dental materials available for the preservation or replacement of teeth.

Most dental manufacturers behave ethically, and many countries have regulations which prevent materials from being sold unless they are deemed 'fit for the purpose'. Although dental manufacturers are in the market to provide an ethical service to dentists and their patients, they are also in business to make a profit for their shareholders, owners and workers. Dentists demand from manufacturers cost containment allied to good performance, excellent aesthetics, ease of use and repair and acceptable failure mode, but manufacturers may also be under pressure from their marketing personnel to produce new claims for incorporation into advertising, or to reformulate a material in order to increase market share.

The clinician needs to decide whether to purchase a material that performs well both clinically and in the research literature and which has not changed for a number of years (i.e. the manufacturer 'got it right' at the outset) or one that is regularly altered minimally (i.e. the manufacturer did not 'get it right' at the outset, so what guarantee is there that they have done so subsequently?). However, we should be grateful for the introduction of new and better materials as well as the development of existing products. Market demands have been the driving force for much of what we use today – without that the toothbrush might still have a wooden handle and hog-hair bristles![1]

The practising dentist is a busy professional and, for the most part, has geared his or her practice to function efficiently and effectively. However, this may not leave much time for reading research publications or attending lectures or courses, and so much of the information a practitioner gleans may be from advertising or from sales representatives. It is therefore essential that dental professionals are in a position to assess and/or question the data with which they are presented and readily to assess the validity of advertising claims.

In this paper, we describe methods for assessing dental materials and discuss some of the factors that will help to validate claims made by the manufacturers of particular dental materials and/or the advertising and publications associated with them.

RELEVANCE OF TEST METHODS

The oral environment is a hostile one, with restorations being bathed by saliva, foodstuffs and fluids (of variable temperature), and being coated by plaque, the micro-organisms that it contains and the attendant release of organic acids. Furthermore, restorations are subjected to the physical forces of mastication, with their attendant compressive, tensile, shear and bending forces (Figure 1). Parafunctional activity, such as encountered during nocturnal bruxing, may greatly increase the

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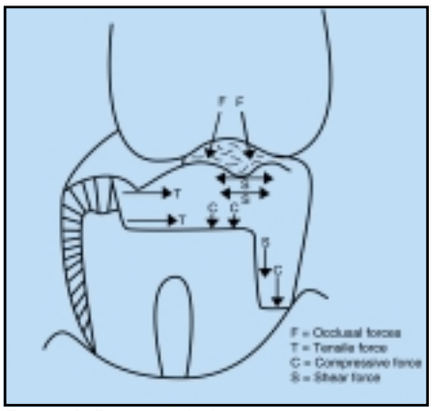

Figure 1. *Forces applied to restorations (reproduced with the kind permission of Quintessence Publishing Co., Chicago, USA).*

frequency and intensity of tooth-to-tooth loading contacts.

As properties of materials differ according to the direction of loading, it is important to determine the anticipated direction of loading of a restoration before assessing the mechanical properties of interest.

Load-bearing restorations need to withstand indentation by opposing cusps and wear both by opposing teeth and by foods (two-body and three-body wear, respectively). It therefore follows that the laboratory tests appropriate to restorative materials will depend on the situation of the material. For example, the forces applied to a glass-ionomer restoration placed in a Class V cavity are different from those applied in a Class II cavity:

- In the Class V cavity, the material will be principally subjected to tensile forces (which may pull the restoration from the cavity) and indirect compressive forces as the tooth flexes under masticatory loading. There will be less need for high wear resistance, other than from abrasive forces (such as are applied during toothbrushing).
- In the Class II cavity, wear resistance will be necessary at the occlusal contact area (OCA) and at the contact free area (CFA), wear in the latter situation being mostly due to abrasion from food particles rather than tooth-to-tooth contact. In the Class II situation, the restoration will also have to withstand mostly compressive and tensile masticatory forces without cracking or fracturing.

Since conventional glass ionomer materials are strong in compression but weak in flexural strength and fracture toughness, and have relatively poor wear resistance, these materials may be considered suitable for use in Class V cavities but unsuitable for Class II cavities, except in deciduous teeth – where lower loads are generally experienced and the need for longevity is less than in permanent teeth.

More recently introduced members of the glass ionomer family, such as the resin-modified glass ionomers and the viscous, more heavily filled glass ionomers, may have the physical properties to make them suitable for use in some load-bearing situations.[2]

TESTING MECHANICAL PROPERTIES

A wide variety of tests is available to the dental materials scientist (Figure 2), and it is normal practice to make a series of measurements on a number of nominally identical specimens.[3] Results from such tests may show considerable variation, typically being presented as a mean value and standard deviation. McCabe and Carrick[3] considered that low values are explained by assuming specimen flaws, but that extraordinarily high values are more difficult to explain, except by assuming that these are approaching the 'true' strength of the material. These workers also consider that Weibull analysis more accurately predicts the failure probability of a material at any given level of stress. However, this non-parametric statistical method requires a minimum of 15, and preferably more, specimens for valid application.

Compressive Testing

Compressive testing is normally applied to materials that are expected to be placed in situations of occlusal loading. However, this test has been considered imperfect, given that the material may 'barrel' under loading, with the sides of the specimen being placed under tension.[4]

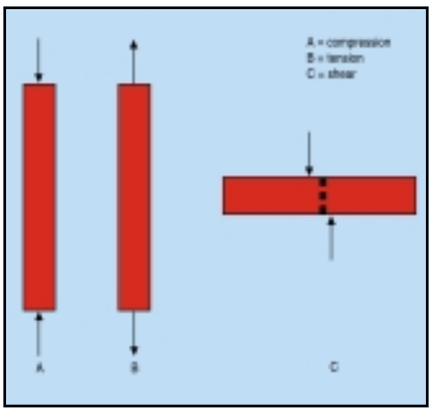

Figure 2. *Diagrammatic representation of compressive (A), tensile (B) and shear (C) tests.*

Tensile Testing

Tensile testing is normally applied to materials which are placed under loading that is generally applied in different directions, as the opposing cusps move over the restoration surface. Loads that stretch or elongate a material cause tensile stresses.

The diametral tensile strength (DTS) test is useful for materials that exhibit very limited plastic deformation and where information regarding stretching or elongation resistance is required. It represents the minimal stress that a body will withstand without rupture when tensile loads are applied. The DTS test is considered useful because masticatory forces are frequently applied obliquely and tend to create tensile stress.

Transverse or Flexural Strength

This is a measure of the strength of a beam of restorative material supported at each end and subjected to a static load (Figure 3). Stresses on the upper surface of the beam tend to be compressive, whilst those on the lower surface are tensile. This test may be considered to combine elements of tensile and compressive testing.

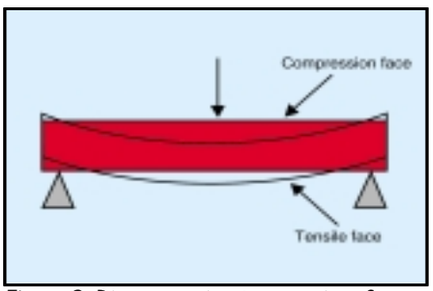

Figure 3. *Diagrammatic representation of transverse strength testing. The upper surface of the specimen is in compression, the lower surface is in tension.*

Fracture Toughness

A more recently introduced test is fracture toughness, which determines the resistance of a material to the propagation of a crack (Figure 4). This test has been considered to be efficient given that other parameters can be derived from it.[4] It should be kept in mind, however, that fracture toughness measures the failure of a material after one continuous period of loading, whereas fatigue strength experiments measure crack propagation after repeated applications of a small cyclic load.

Elastic Modulus

Clinical evidence would suggest that most of the fractures that occur in prosthodontic structures do so after many years and are generally the result of fatigue failure rather than one episode of acute overload.[5] The modulus of elasticity, or measure of a material's stiffness, is also important in relation to anticipated longevity of a restoration. An elastic material (one with a low elastic modulus) will deform when a load is placed on it but will return to its original shape once the load falls below the elastic limit of the material.

As a general rule, restorative materials need to be very stiff (high elastic modulus), so that under load the elastic deformation will be very small. An exception to this is in the Class V situation. Microfilled composite materials have a lower modulus of elasticity than hybrid composite materials: this may be why microfilled materials show higher retention rates in Class V cavities, given that they deform more readily as the tooth deforms at the cervical area under occlusal loading.[6,7]

It is therefore apparent that a wide variety of tests can be carried out on a given material, although only a small number may be relevant to its particular clinical use(s).

Bond Strength Testing

Adhesive systems are often tested under conditions of shear, although it may well be that no one laboratory test fully encompasses the full range of forces that are applied to a non-retentive, adhesive restoration. Laboratory tests for bonding systems are poorly standardized[8,9] owing to differences in the properties of the types of dentine that may be used and to differences in the methods of specimen preparation. As a result, test results from one laboratory may not readily be comparable with those from another.

Shear Testing

Shear testing is used frequently as a measure of the effectiveness of bonding systems. However, such testing has been criticized, given the complex distribution of forces in these tests,[10] and the results of laboratory tests should be interpreted with caution.

Microscopic analysis of failure mode should be undertaken in conjunction with shear or tensile bond strength testing. An assessment should be made of whether the bond has failed completely cohesively (fracture has occurred through restorative material or tooth tissue) or adhesively (interfacial failure between adhesive and substrate), or whether failure is of a mixed nature. It would seem reasonable to suggest that the material that performs well in the tests of different laboratories is most likely to be effective.

Glass ionomer materials yield relatively low shear bond strengths to dentine in comparison with dentine-bonded resin composite materials, yet they nearly always have better clinical retention rates in non-retentive Class V situations than composite materials. The failure mode of glass ionomers is usually cohesive through the test cylinder of material; thus the true bond strength to dentine is not being measured and the low bond strength values obtained are more a reflection of the relatively modest mechanical properties of these materials.

The Microtensile Test

Traditional bond strength tests tend to use specimens with large bonding surface areas (in the order of 7–12 mm^2) and the fracture of these specimens frequently occurs cohesively in dentine.[11] It may therefore be considered that this form of failure does not provide reliable information on the *actual* strength of the adhesive bond.

Additionally:

- most tests use non-carious human or bovine teeth and few studies are available which simulate the adhesion of resins to carious, cervical or sclerosed dentine because of the technical difficulties of using such dentine in traditional test methodologies; and
- the tensile bond strength is dependent on the bonded surface area.

In response to these problems, Sano and co-workers[12] developed their microtensile test method, which uses specimens of much smaller surface area (1.6–1.8 mm^2) than traditional specimens. These specimens tend to show adhesive, rather than cohesive, failure and minimum scatter of results. Other advantages include the ability to prepare specimens in a manner closely

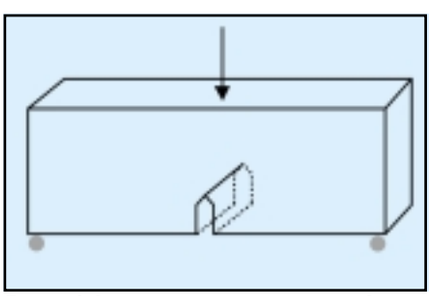

Figure 4. *Diagrammatic representation of a fracture toughness test. The test illustrated is for a single-edge notch (SEN) specimen.*

simulating the clinical situation[11] (by building up the restoration as in the clinic and sectioning to produce the small specimens[12]) and the possibility of assessing bond strengths to excavated carious or sclerotic dentine.[12] This test method is expected to be developed further and, because of its advantages, its use will probably become more widespread.

Microleakage Testing

The tests for shear bond strength are usually expressed as a mean value of the results of a group of specimens. This figure is readily understood, especially if one is aware that the bond strength measurement of a dentine-bonding system should be greater than the stresses set up by the polymerization contraction of a resin-based composite restorative material. This figure has been calculated to be about 18 Mpa.[13] However, such measurements are often quoted in isolation, without reference to microleakage, a parameter of equal importance.

Microleakage data is often expressed as the proportion of margins that were found to leak to, for example, 1 mm into the cavity–restoration interface (Figure 5). Such data may therefore be less readily understood, at least in comparison to one bond strength figure.

The measurement of maximum marginal gap width of specimens by an ocular screw micrometer may be more readily quantified and therefore more easily understood by 'lay' readers (as opposed to trained dental scientific workers).[14] The direct measurement of marginal gaps at dentine/restoration cavo-surface margins by optical microscopy (or indirect measurement via SEM examination of replicas) is also valuable. This is a measure of the 'effective' or 'wall to wall' polymerization contraction of a material.[15] Clinicians should be encouraged to request data on microleakage in addition to the more commonly presented data on shear bond strength for dentine-bonding systems.

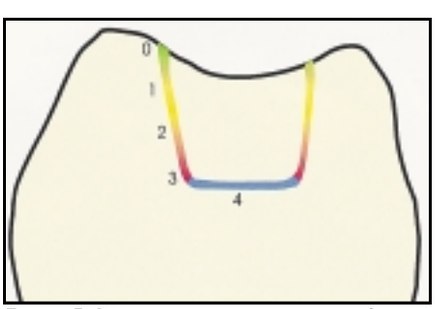

Figure 5. *Diagrammatic representation of a microleakage test. The numbers denote differing levels of microleakage.*

SUBSTANTIATION OF RESEARCH CLAIMS

This is the era of 'evidence-based' dentistry – the evidence of success of a particular technique or material should be available to provide evidence of the potential for success of treatment that is prescribed. At present such 'evidence' is principally found in journals and books, but results of research projects are increasingly being published on the Internet and the practice computer is becoming the tool by which 'evidence-based' dentistry is brought to the chairside. The practice computer could also be used to calculate success rates of the various treatments carried out in a particular practice or by one particular dentist – data that could be given to patients to help them decide on treatment options.

One deficiency of the 'evidence-based' concept is that new materials may have to be used initially with little evidence as to their success. Total adherence to the evidence-based philosophy would prevent the use of new materials and techniques, and potentially stop their adoption.

Research in dental materials science is often laboratory-based because of constraints of technology and control,[1] and may be considered to have a different 'personality' from clinically-based research. Indeed, laboratory research is usually carried out by the manufacturer 'in house' rather than by an independent organization. It is necessary to verify, by laboratory research, that a given material is capable of withstanding the forces applied to it and functions required from it in the intra-oral situation before it can be used on patients, either experimentally in the form of a trial or in the dental practice under normal situations of payment. The principal advantages of laboratory research are:

- the ability to control variables;
- production of comparative data between 'competing' and/or similar products;
- comparison of old with new.

The difficulty comes in deciding whether any of the laboratory research may be applied appropriately to the clinical situation.

For some materials, and in some situations, non-human animals are used to test toxicological properties or clinical effectiveness. The results of such experiments can be extrapolated to the human clinical situation, but concerns over animal welfare have limited their use.

Publication of Research

Following in-house testing of materials, independent research is usually carried out in specialist university laboratories, although much of this work is still funded by the manufacturer. Claims made following such research should be presented in a properly structured research paper in a peer-reviewed journal detailing the methods used, the results, discussion and the conclusion(s). It will then be in the public domain for further discussion.

Abstracts of research papers presented at scientific meetings are another form of publication. These may be valuable, but the text generally contains only a brief description of the methods, results and conclusions. Furthermore, abstracts are generally less rigorously refereed than full papers; authors of abstracts should be encouraged to aim for a full publication as only a limited number of people will have had the opportunity to hear or see the 'live' presentation of the abstract and to criticize and question the methodology, results and conclusions.

Levels of Information

Emling[1] considers there to be three levels of information. It is for the reader to decide into which category the claims made in advertising or in meetings with sales representatives falls.

Level I Information

Level I information is that which is distilled into everyday language ('It cleans better'; 'It lasts longer', etc. – language that most patients see and use in their everyday lives). The dental practitioner must be able to assess the scientific validity of such claims by keeping up to date with the scientific literature.

Level II Information

Level II information may have a scientific basis, but the methodology and the full results are not in the public domain. According to Emling[1] this level of information often appears in promotional material to back up a product, sometimes with a reference being given or the statement 'data on file'. However, practitioners should question whether this information is simply an opinion by a researcher, employee of the manufacturing company or a paid endorsement.

Level III Information

Level III information is the source itself – a research paper published in a peer-reviewed journal, with the standard sections of introduction/literature review, methods, results, discussion and conclusion. In a research paper, the results section should be devoid of opinions, presenting only the data and suitable statistical analysis.

The all ceramic crown of choice!
- Strongest all ceramic crown
- Unsurpassed aesthetics
- Easy preparation
- Biocompatible (metal free)

The 'smart' restorative that's a real alternative to amalgam
- Intelligent pH control releases active ions on demand, preventing or significantly hampering the formation of secondary caries
- Simple ultra-fast technique – up to 40% quicker to place than similar-sized amalgam restorations

**** is a hybrid composite containing barium glass and fumed silica with a submicron particle size, contains fluoride, is available in 8 Vita shades, can be used for small restorations with difficult access, repairing margins ... This is a truly brilliant product.**

One bond for all
- Truly universal adhesive
- Fluoride in the formulation provides fluoride to the tooth structure
- Postoperative sensitivity is a problem of the past – a comprehensive study of 350 patients showed that when posterior composite restorations were placed using this adhesive, no symptoms of sensitivity occurred. (Abstract reference given)
- Bond strength at its peak
- Elastomeric resins act as shock absorbers and help absorb setting shrinkage

Brilliant aesthetics and easy placement
- Polishes to a natural brilliance
- Extremely low water absorption to promote long-term stability
- Superior handling

Strength and aesthetics combined:
- Direct and indirect restorations
- Unique filler for maximum wear resistance and fracture toughness
- Answers patient demands for a white filling - excellent polishability and blends to tooth colour
- Ease of use – non-sticky and non-slumping

No etch simplicity
- Greater strength and more clinical indications
- More fluoride release

Table 1. *Statements made in a selection of advertisements.*

The Meaning of Statistical Values

Ideally, it should be possible to analyse results statistically, with measures of confidence that the results are true and not the result of an accident, expressed as a '*p*' value (*p* = probability). The lower the *p* value the higher the confidence in the results; scientific opinion generally considers a *p* value of less than 5% ($p < 0.05$) as an acceptable probability that the results are correct. A *p* value below 0.001 ($p < 0.001$) indicates that the risk of an incorrect, or chance, finding is less than 0.1%; in other words there is a 99.9% chance of the result being correct.

Key Elements in a Study

Key elements to look for in a study are:

- whether the sample sizes are adequate (justified by so-called 'power calculations', which try to ensure that enough subjects are studied to allow a sensible conclusion);
- whether any treatment/material allocation has been randomized;
- whether all patients/test results are accounted for in the results section so that side effects and drop-out rates can be clearly identified.

The 'ideal' study is also one that is carried out in a similar fashion in a number of hospitals or general dental practices (i.e. it is a multi-centre study). This is essential if the conclusions of the study are to be widely applicable in practical contexts. Incorporating a number of operators or centres reduces the chance that the results will be influenced by the use of only one operator.

In the results section of a good study, the analysis must first ascertain whether any comparison across treatments or materials is 'fair', in the sense that there are no 'significant' differences between the samples being allocated to different treatments/materials (otherwise any reported differences at the end of the study may be compromised). Appropriate statistical analyses must be clearly presented with summary statistics of the raw data and good informative plots that draw the reader's

attention to the important aspects of the study. In terms of facilitating the reader's appreciation of the clinical (as opposed to the statistical) significance of the study, the results should be presented using confidence intervals rather than *p* values, which are wholly uninformative of the magnitude of any differences across treatments or materials. For some studies, a 'complicated' statistical analysis may be essential, but the casual reader should not be disturbed by this, provided that the analysis is justified in the text and the results are clearly and simply presented. Helpful checklists for judging the suitability of the statistical content of a study are presented by Gardner and Altman.[16]

Assessing Advertising Claims

A number of claims taken from advertising material are presented in Table 1. Readers may like to place these claims into Emling's[1] levels of information. Claims often appear to be made without any reference to the source of the data, even if this is valid and available – few of the statements in Table 1 could be considered to be at Emling's optimum level (level III).

Assessment of Clinical Research

The above considerations may principally be applied to laboratory-based research, but clinical research into the effectiveness of a particular treatment should also be capable of critical appraisal. The methods of measuring the effect of a clinical intervention have the following hierarchy:[17]

- meta-analysis;
- large randomized controlled trial (multi-centre trial);
- small randomized controlled trial (single hospital/general practice);
- case-control study;
- non-randomized trial with contemporaneous controls;
- non-randomized trial with historical controls;
- cross-sectional study;
- series of consecutive cases;
- single case report.

The best evidence as to the effectiveness of a particular type of treatment is provided by a meta-analysis of a series of controlled clinical trials. The single case report may be useful as a means of stimulating others to carry out a rigorous appraisal of the technique described but is without value in robust scientific terms. To tell a patient simply 'It works for me' leaves too many unpredictable factors in the equation – in lectures as well as in written reports.[18] The case has been described by Grace[19] of the persuasive lecturer who shows his/her audience a series of clinical slides illustrating the effectiveness of a technique, with the audience asking themselves whether they dare question the validity of the lecturer's findings. Lecturers should always state whether their findings are purely anecdotal or whether they have carried out a properly constructed study in a scientific manner to be able to draw robust conclusions from their findings. They should also state whether the success of their technique demands a level of skill and/or experience that would not be available to the average practitioner.

CONCLUSION

The ability to find and correctly interpret the information presented by advertisers and manufacturers is an integral aspect of 'evidence-based' clinical practice, given that blind acceptance of advertising claims can lead to the disappointment of poor clinical performance. Researchers must therefore present their data in a manner that can be readily understood by the clinician. It is also essential that the researcher has used the correct methodology and that, where possible, the publisher of research has ensured the validity of the publication.

However, in the final analysis it is important that the clinician has the ability to appraise the data that is presented scientifically; an ability that will become more important as patients increasingly request evidence as to the potential success and cost-effectiveness of their treatment options.

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Editorial decisions for this series of two papers organized by Professor Chris Stephens, University of Bristol Dental School.