

Evidence-based decision making: Guide to reading the dental materials literature

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Although potential links between materials data and clinical behavior are often implied, the status of such linkage is often left obscure. This paper provides clinicians a context within which to view materials information as evidence for clinical indications and to broaden readers' appreciation for the subject. Hierarchies of both clinical and nonclinical data are presented and discussed from the point of view of their predictive potential regarding clinical performance. Excellent sources of information are identified for the clinician making treatment decisions, and perspectives are offered on the value of other published materials data. (J Prosthet Dent 2006;95:152-60.)

OVERVIEW OF CONCEPTS

Materials information in context

One of the 5 hallmarks distinguishing ethical practice from quackery and fraud is a "reasonable scientific base"; "practitioners should be able to give reasons for their actions that are acceptable to their peers."¹ Dentistry's long comfort with empirical science and personal experience² is ending, in part, because many ingrained concepts and treatments approaches are being revealed as unsubstantiated. This paper seeks to enhance clinicians' understanding of the origin and types of dental materials information and to provide a comprehensive context within which to view published literature as potential evidence. Such a context has not yet been well developed for clinicians.

All dentists are exposed to materials science during training and information about materials is among the most widely available and sought. Although potential links between in vitro measured properties and clinical behavior are frequently implied, the status of such linkage is often left obscure. In general, few single in vitro tests have been validated as being predictive of clinical behavior. Those writing international and national standards for dental materials have long relied on batteries of laboratory tests, but often only to assure quality, safety, and handling, with limited emphasis being placed on clinical efficacy. The Council on Scientific Affairs of the American Dental Association (ADA) voted in January of 2004 to discontinue the ADA Seal Program for professional products and to move towards more clinical "performance-based" criteria by 2007.

Another issue relevant to this paper is that both the patient and the dentist contribute variables influencing the performance of materials. As will be shown, factors such as technique sensitivity and patient diet have been

demonstrated to be as significant as the material chosen. Fortunately, clinical trial data is becoming increasingly available along with systematic analyses of multiple clinical trials that can provide much improved practice guidance. The previously described concepts and issues are part of the context developed in this guide.

"Observational data" - highly comfortable, inherently problematic

Opinions are formed in part by intuition which develops from both personal and professional observations. Such intuitive analyses can mislead and, unfortunately, easily become ingrained in the profession as dogma. Consider these 2 seemingly intuitive "facts"—(1) that marginal gaps encourage secondary caries, and (2) that fluoride-releasing restoratives and cements inhibit this process—both representing dogma. Both observational "facts" regarding secondary caries have fallen to careful analysis of clinical trial data and more sophisticated thinking.³⁻⁶ Hyperbole and marketing pressures add to the confusion, creating "... an atmosphere of minimal trust that fosters confusion when dentists attempt to make the proper selection for their patients."⁷

At its essence, science is nothing more than a method of discovery biased against getting fooled by either faulty intuition or situations involving conflicts of interest. As will be demonstrated, portions of the peer-reviewed literature are becoming increasingly approachable and meaningful for the practicing dentist. It is hoped that this contribution encourages the discovery and use of solid evidence by clinicians faced with treatment and purchase decisions.

INTRODUCTION TO HIERARCHIES AND SOURCES OF EVIDENCE

This paper first examines an accepted hierarchy of clinical evidence within which to place materials research. It is then necessary to evaluate information gathered from 2 types of laboratory studies, property measurements and simulations, as well as to illustrate

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where bridges do and do not exist between such surrogate data and the clinic. This second evaluation is not as well grounded, involving an additional novel hierarchy and classification scheme proposed here for this purpose. Clues to the appropriate weight to give various forms of information can come from understanding their position within one or the other hierarchy.

Evidence from clinical data

Five commonly referenced levels of evidence, relying primarily on clinical findings, are presented in Table I. These levels begin with the "gold standard" of a systematic analysis of 2 or more randomized controlled trials and end with consensus statements from expert groups.⁸ The authors of this hierarchy provided a value scale with 5 denoting the highest level of evidence and 1 the lowest level. Two brief explanations are in order to clarify some terminology presented in Table I.

First, a randomized controlled trial directly tests an experimental treatment against a control treatment, a simple step often not possible in other clinical trials. Further, such trials then randomly distribute both the experimental and control treatments across the study population to minimize biases that can influence purely observational studies.

Second, in systematic analyses, as many studies as possible are selected related to a specific clinical question. Then, using protocols designed to minimize bias, systematic analyses (1) evaluate the suitability of those studies and eliminate many, (2) extract pertinent information, and (3) collapse all data into a single analysis.⁹ This collapsed data can be in the form of a qualitative summary or a combined statistical analysis, for example, a meta-analysis. Systematic analyses of multiple randomized controlled trials are considered the highest level of evidence for basing treatment decisions.

Expert analyses of clinical data

It is apparent, however, that dentists are faced with many materials and technique questions for which there will never be answers from multiple randomized controlled trials, let alone systematic analyses of them. However, good systematic analyses that include randomized controlled trials, along with many other types of clinical studies, are increasingly available. The reader is directed to the following 3 sources: *Journal of Evidence-Based Dental Practice* (Elsevier Inc), *Evidence-Based Dentistry* (Nature Publishing Group), and the National Library of Medicine's searchable Internet database, PubMed.

The *Journal of Evidence-Based Dental Practice* examines systematic reviews of multiple trials, multicenter trials, and a variety of single site trials. These reviews with accompanying commentary and analysis are accomplished within 1 to 2 pages. *Evidence-Based Dentistry* provides concise abstracts of clinical trials and systematic

reviews, followed by an informed commentary limited to 1 page. This journal then provides a summary of specific clinical questions and answers organized by specialty, along with general guidelines provided in each volume in a section entitled, "Toolbox." Both make it possible to simply and inexpensively scan the clinical trials literature quickly on a quarterly basis and select areas in which to read more thoroughly if interested.

PubMed (<http://www.ncbi.nlm.nih.gov/PubMed/>) provides access to bibliographic information in MEDLINE, the premier repository of biomedical literature. A useful search tool within PubMed is the "Limits" option. With "Limits" selected, 2 search limits become available: "Publication Type" and "Subset." Under "Subset," a search can be limited to dental journals, and under "Publication Type," the search can be set to report back only in categories such as "Clinical Trial," "Meta-Analysis," "Practice Guideline," or "Randomized Controlled Trial."

Evidence from in vitro data

Much of that recognized as "materials research" does not derive from clinical trials. Many materials questions will never be addressed by clinical studies due to cost and ethical considerations, necessitating reliance on surrogate information from performance-based laboratory tests. Surrogate data indirectly measures what is of interest; for example, pocket depths are an indicator versus an end-point measure of periodontal disease. The best surrogate in vitro data would be capable of reproducing an important clinical behavior or correctly rank-ordering trends in clinical data. Examples of good and poor surrogate in vitro data will be presented later.

Common sources of such *potential* evidence based on nonclinical data are listed in Table II. Although there is some good guidance available from in vitro research, the majority has never been shown to validly simulate clinical behavior. In an effort to help bridge this gap, a classification scheme is offered at the end of this paper to assist the reader of materials literature in weighing in vitro data for potential value as evidence. In the final analysis, clinical data remain the best guide to materials use and are fortunately becoming more widely available and easier to access.

RANDOMIZED CONTROLLED TRIALS, NONCONTROLLED STUDIES, AND SYSTEMATIC ANALYSES OF CLINICAL STUDIES

Controlled trials

Under National Institutes of Health (NIH) definitions, the term clinical "trial" is reserved for tests of a specific intervention (drug or treatment) under a controlled design. Other clinical research such as retrospective examinations and case studies will be referred to as

Table I. Types and strength of evidence based on clinical trials⁸

Strength of evidence	Type of evidence
Strongest	
5	Systematic review of multiple, well-designed, randomized controlled trials
4	One published randomized controlled trial of an appropriate size in an appropriate clinical setting
3	Published, nonrandomized single group, prepost, time series, or matched case-controlled study
2	Evidence from well-designed studies from more than 1 center or research group
1	Opinions of respected authorities based on clinical evidence, or report of expert consensus committees
Less strong	

Although such data are available increasingly to dentists, not much materials literature falls within these categories. Sources of information from these categories appears in text.

“clinical studies.” The highest level of evidence (Table I) involves systematic analysis of more than one randomized controlled trial. Approximately 176 randomized controlled trials have been published in dental literature since 1991 (PubMed, National Library of Medicine database described in the text). Of these, 34% tested dental materials, with dentin bonding, restorative materials, prosthesis fit, and orthodontic bonding being of particular interest. Such studies have the potential of being level-4 evidence on the scale in Table I. Systematic analyses of a number of these (potential level-5 evidence) will be discussed later in more detail.

Noncontrolled studies

Noncontrolled studies are far more frequent than randomized controlled trials, whether materials-related or not. Many clinical trials cannot be truly controlled due to considerations involving ethics and cost. For example, a study of local anesthetics could never be conducted using a comparison to a nonfunctional negative control or placebo. New tooth-colored restorative materials are often compared against amalgam for both durability and recurrent caries by secondary comparisons against an extensive existing literature, rather than by product-to-product comparison in a controlled trial. In addition, many studies of new products are simply designed to screen for unexpected risks over a short term (2-3 years), rather than as true studies of efficacy. If a number of independent centers participate in such research, results can rise to level 2 on the evidence scale in Table I.

At least 2 important sources of bias should be recognized as decreasing the value of noncontrolled studies—bias that can lead to a false conclusion or obscure a correct one. One common type of bias involves patient selection and another relates to definitions of restoration

Table II. Common sources of *potential* evidence derived from materials data, continuing from far higher levels of evidence in Table I

Strength of evidence	Type of evidence
Less strong	Opinions of respected authorities or report of expert consensus committees, based on combinations of clinical and laboratory data
	Published peer-reviewed in vitro clinical simulations
	Published peer-reviewed physical property comparisons
	Abstract data
	Dental laboratory recommendations
	“Data on file”
	Advertising
Weak	

Value system from Table I is continued here for editorial purposes.

failure or condition. It is likely that the study material in a recent trial may not have been exposed to a clinical challenge comparable to the “historic control,” or that significant differences in placement technique make the 2 difficult to compare. Patient selection problems are highlighted by a recent trial of resin-based composites in which different wear rates were experienced by patients in Belgium versus patients in Florida, even though the same 2 dentists placed half the restorations at each site using the same restorative materials.¹⁰ Differences in access to alcohol-containing mouthwash, gum chewing habits, and use of ice in beverages were proposed as potentially distinguishing the 2 study populations. In addition, wear results differed for the 2 dentists placing these restorations, presumably due to finishing technique or the handpieces used.¹⁰

The second type of bias can arise from differing definitions of outcomes and calibration among examiners; for example, it can be difficult for dentists to agree on the diagnoses of secondary caries or margin quality even within 1 study at 1 site. It is unrealistic to expect that dentists in multiple unrelated studies will have judged outcomes in the same way. Consider that one of the most influential reasons for the replacement of resin-based composites or amalgam restorations was recently found to be that the patient changed dentists; those remaining with the same practitioner were significantly less likely to have a restoration deemed in need of replacement.¹¹ Two studies reported that female dentists replaced amalgam restorations significantly more frequently than male dentists,^{12,13} and another reported that female patients in Iceland received more resin-based composites and fewer amalgam restorations than their male counterparts.¹⁴ These last 3 points begin to illustrate that hidden biases may make seemingly similar studies incomparable.

Systematic analyses of clinical studies

Given that most materials studies are not controlled and that technique variables, outcomes measures, and statistical treatments can differ, how does the clinician evaluate the literature? Fortunately, expert systematic analyses often provide well-grounded advice and clarity by identifying and removing as much bias as possible. Such analyses involve (1) posing a specific clinical question, (2) identifying potential studies addressing the question, (3) independent evaluation of each study by at least 2 investigators using preset inclusion/exclusion criteria, (4) extraction of predetermined data, (5) analysis or tabulation of the data, and (6) discussion of both the results and the quality of the data. Discussions of the quality of the data include not only scientific methods but also usability—that is, whether study “...findings are consistent across populations, settings, and treatment variations, or whether findings vary significantly by particular subsets.”¹⁵ Systematic studies will either provide strong evidence for or against specific treatments or conclude that the literature does not yet yield evidence-based guidance. Both of the evidence-related journals mentioned previously examine the quality of the analysis as well as comment on the clinical findings.

Bader and Ismail⁹ recently searched for and evaluated systemic analysis of clinical studies from multiple sources. The authors reported that clinically relevant systematic reviews have been published with increasing frequency over the past 14 years. In their investigation of 595 reviews, 131 well-executed reviews were identified, 96 were deemed as being clinically relevant, and 12 addressed materials questions. It is important to note that only 39% of these reviews limited coverage to true randomized, controlled trials. Bader and Ismail found that 80 of the 96 clinically relevant reviews (83%) answered the key question or satisfied their purpose, 48 (60%) “hedged their answers,” indicating some reservation, and in 16 instances (17%), the authors concluded that insufficient evidence yet exists in the literature to form a conclusion.⁹ Such expert commentary is of particular value to the clinician and is a standard feature of reviews in the 2 evidence-based journals previously mentioned.

OPINIONS OF AUTHORITIES OR EXPERT CONSENSUS COMMITTEES (BASED PRIMARILY ON CLINICAL STUDIES)

Both the NIH and the ADA use the consensus development conference mechanism to examine materials issues, but only when they are controversial or highly topical. Three examples of such consensus evidence include the examination of the effects and side-effects of restorative materials¹⁶ and the diagnosis and management of caries throughout life,¹⁷ both by the NIH,

and a revised set of indications and contraindications for the posterior use of resin-based composites by the ADA.¹⁸ Consensus conference participants typically examine both clinical and laboratory data in their entirety, bringing to bear a wealth of knowledge regarding the measure and meaning of all materials data. In the case of NIH conferences, scientists from appropriate areas outside of dentistry are often included. This level of evidence is the highest that begins to consider non-clinical, published in vitro data. NIH consensus conferences related to dentistry and held in the past 5 years can be found on the National Institute of Dental and Craniofacial Research (NIDCR) Web site, and both NIDCR and ADA consensus findings are typically published in dental journals.

OPINIONS OF AUTHORITIES OR EXPERT CONSENSUS COMMITTEES (BASED PRIMARILY ON LABORATORY DATA AND CLINICAL EXPERIENCE)

Table II continues the hierarchy of potential evidence (begun in Table I) into the realm of information most commonly available to dentists regarding materials. Consensus committees are repeated here, since their reports often represent the highest use of materials data and expert knowledge not derived entirely from clinical trials. An example of such a committee is the ADA Council on Scientific Affairs (CSA). This group of 17 dentists and dental scientists works with the ADA Division of Science staff throughout the year, including 3 onsite meetings, to help develop and disseminate science policy. Recent guidance has been published by the CSA on lasers,¹⁹ direct and indirect restorative materials,²⁰ beryllium-containing alloys,²¹ managing silver and lead waste,²² and mercury hygiene recommendations.²³

It may be appropriate to include some fee-based services that publish recommendations based on combinations of laboratory findings and the personal experience of participating dentists. While not counting as expert *consensus* opinion, such fee-based services can offer valuable insights and augment the peer-reviewed literature. At worst, these services combine unpublished laboratory methods and limited statistical analysis with opinions from individuals whose respect derives from name recognition, and are not peer-reviewed for quality or objectivity. At best, they represent an honest attempt to use the lower categories of potential evidence (Table II) along with personal clinical observations to present their clients with opinions and purchase recommendations. Many of the laboratory evaluations by such services relate to handling, ease of use, features, packaging, and cost and, thus, represent information not found in the peer-reviewed literature. The nature and value of personal experience from service dentists has been well articulated in a recent review of evidence-based dentistry

by Healey and Lyons²⁴: “Personal experience is reliable when the treatment under consideration has a large effect, occurs quickly, and has a clear outcome – such as hitting one’s thumb with a hammer. The reliability of personal experience declines markedly in instances where the symptoms are variable, the time course is long, the effects of treatment complex, and the outcome measures ill defined.”

PHYSICAL PROPERTIES AND LABORATORY SIMULATIONS AS EVIDENCE

The remaining sources of information (Table II) are derived from *in vitro* studies and are more problematic in being considered as evidence. Perspective regarding such information comes from considering the expertise required of the observer, the complexity of the clinical problem being addressed, and the effort placed on validating the predictive nature of the laboratory finding(s).

Dental school materials courses provide a balanced overview, including distinguishing characteristics of various material categories, handling and processing information, descriptions of important physical properties, and concepts regarding biocompatibility. However, this level of knowledge is introductory compared to that achieved through masters and doctoral level training in materials science and engineering. Thus, there exists an awkward gap between the level of knowledge of clinicians and manufacturers, leaving the majority of practitioners at a distinct disadvantage when examining data provided by manufacturers. Dental laboratory personnel are even more reliant on industry sources for their information and perspectives. All of these factors may cloud the ability to interpret and apply materials information as evidence.

Performance certification: safety, handling, and quality control

Dentists have been conditioned to expect linkage between a material’s properties and its clinical behavior. Most product improvements are described and advertised based on purported changes in specific physical properties such as ceramic strength, or performance during *in vitro* simulations, as from dentin bonding, microleakage, and wear testing. However, thoughtful consideration regarding long-term clinical function reveals (1) that specific physical properties have only rarely proven to be predictive of clinical performance, and (2) that many *in vitro* simulations do not faithfully reproduce important aspects of the intraoral challenges that limit the lifespan of restorations and prostheses. Examples justifying these 2 statements are provided in the following sections.

The most sophisticated use of laboratory testing that is publicly available is likely derived from expert consensus committees, including both academic and industry scientists, that develop dental standards such as

Technical Committee 106 (Dentistry) of the International Organization for Standardization (ISO) (www.iso.org). Dental standards have traditionally relied on numerous basic property limits in certifying materials for clinical use. However, such certification is more related to safety, handling, and quality control than screening for clinical efficacy. Table III lists the battery of laboratory evaluations and physical property tests required for 3 selected American National Standards Institute (ANSI)/ADA Specifications, often equivalent to or the source of ISO standards.²⁵⁻²⁷ Two main messages can be derived from the standardized testing criteria in Table III: (1) all use a battery of tests, and (2) the more complex the clinical use, the more complex is the battery of tests. Note that there is no reliance on a single property or evaluation as may be seen in advertising. An additional key point is that none of these standards/specifications are intended for use in making comparative judgments regarding the superiority of one material versus another.

Manufacturers often use even more extensive combinations of tests, both *in vitro* and clinical, in their pre-market evaluation of new materials. This approach has given dentistry an ever-changing and generally improving set of materials. It is unlikely that any manufacturer would make a premarket decision based on only 1 physical property or simulation test, although many marketing efforts often give this appearance.

In vitro data: basic forms and links to clinical behavior

Two types of studies are performed in the research laboratory. First are physical property measurements, including the following: (1) properties inherent to single materials, such as fracture toughness, translucency, stiffness, or elastic modulus; (2) the performance of specimens under specific conditions, including fracture strength of a ceramic, impact strength of denture resins, and force delivery of an orthodontic wire; (3) the condition of materials as the result of processing, such as the dimensional accuracy of impression materials, porosity of castings, surface roughness, and degree of polymerization; and (4) the performance of 2 or more materials acting together, as in bond strength, thermal shock resistance, and color. Such research often compares 2 or more commercial products with the implied assumption that differences among products are predictive of differences in clinical behavior.

Second, another type of testing attempts to simulate clinical conditions, often involving definitive clinical specimens such as prostheses, restorations in extracted teeth, and post-and-core preparations. Clinical simulations can involve single or combined challenges such as mastication, microleakage, loading to failure, resistance to removal (cemented crowns, implant-supported retainers), thermal cycling, and accelerated

aging. In most instances, the simulation derives from assumptions regarding clinical behavior and not from validated clinical failure mechanisms identified through careful study. Therefore, many simulations derive from intuitive assumptions regarding the oral environment, and few have been validated as reproducing observed clinical behavior or damage.

Single physical properties and clinical behavior

There have been instances in which a single material property has proven to be predictive of clinical behavior. The classic example is “creep” or flow of low-copper amalgam under constant load being predictive of marginal fracture over a few years of clinical function.²⁸ Unfortunately, creep cannot be used to predict marginal fracture of high-copper amalgams. More recently, fracture toughness, a measure of the difficulty of driving a crack through a material, was found predictive of clinical wear, bulk chipping, and fracture of resin-based composites.^{29,30} No additional examples appear to exist tying a single property to long-term clinical performance.

For simple clinical uses of materials, certain properties are informative. For example, the elastic recovery of an impression material after being compressed against tooth convexities during removal is related to its clinical performance, as is overall dimensional stability in allowing delayed pouring by a distant laboratory.³¹ High-pH pulp-capping materials can induce the formation of reparative dentin.³² Force-delivery ranges for orthodontic wires provide clinically useful information.³³ However, this list of simple clinical uses for which a single property provides valuable information is rather limited for the following reasons.

Most dental uses of materials involve combined materials and, thus, may be considered as “materials systems” that are subjected to complex stresses and environmental challenges. Examples of material systems include resin-based composites bonded to dentin, metal-ceramic systems, bonded veneers, all-ceramic crowns (bonded or luted), and prostheses-abutment-implant systems. Material systems introduce material-material boundaries with unique stresses and interfacial flaws, distinct fabrication variables, and stress distributions dependent on thickness ratios and geometric factors. The longevity or performance of material systems often involves a combination of properties specific to that combination; therefore, their performance cannot be predicted based on information about only 1 material.

Environmental factors, which can be patient specific, also play a role in clinical behavior. Water is likely the most influential environmental factor and can alter the clinical performance of both resin-based materials and ceramics.^{34,35} Such factors further limit the value of specific material properties unless studied within a well-designed oral simulation. Influential clinical technique variables are also not addressed when product

Table III. Laboratory evaluations required for 3 selected material-related ANSI/ADA specifications

Simulation/characterization	Property
Pit and fissure sealants*	
Color, consistency, appearance	
Working time	
Setting time	
Curing time	
Depth of cure	
Uncured film thickness	
Dental elastomeric impression materials†	
Mixing time	Elastic recovery
Working time	Strain in compression
Compatibility with gypsum	Linear dimensional change
Consistency	
Detail reproduction	
Metal-ceramic dental restorative systems‡	
Solubility (ceramic)	Flexural strength (ceramic)
Uranium 238 concentration (ceramic)	Yield stress (metal)
	Coefficient of thermal expansion (ceramic and metal)
	Glass transition temperature (ceramic)
	Percent elongation at fracture (metal)

Note increasing level of evaluation with increasing complexity of clinical function.

*ANSI/ADA Specification No. 39.²⁵

†ANSI/ADA Specification No. 19.²⁶

‡ANSI/ADA Specification No. 38.²⁷

comparisons are based on simple physical properties. Recall the patient and dentist variables identified in the resin-based composite wear study mentioned previously (Noncontrolled studies section).¹⁰

Laboratory simulations

Laboratory simulations should accomplish more than recreating stresses and environmental factors *thought* to be operative. They should induce *known* mechanisms of damage or degradation, or correctly rank-order materials consistent with the ranking in clinical studies. One recently validated simulation serves as a good example. Results from dentin bonding tests involving microtensile specimens receiving appropriate accelerated aging in water appear to be consistent with clinical studies based on survival of nonretentive class V lesions.³⁶ Two well-known laboratory simulations fail in this regard: microleakage tests and traditional load-to-failure of ceramic crowns. Issues raised regarding these 2 tests may extend to others that appear as sensible on casual examination.

The first test, microleakage, typically involves restorations or cemented crowns (using extracted teeth) that

Table IV. Examples of materials (and material systems) categorized by duration and type of function

	Duration	Type of function	Examples
Class A	Short duration	Extraoral or predominantly extraoral Simple, specific function	Impression materials Occlusal registration materials Gypsum products
Class B	Moderate duration	Intraoral Simple function	Orthodontic brackets, wires and elastics Endodontic instruments Dental burs Restorative armamentarium
Class C	Long-term duration	Intraoral Simple function (esthetic and/or space obdurate only; limited or no structural function)	Basing materials Cements Endodontic sealers and canal filling materials Simple intracoronal restorations (amalgam or resin-based composite) Veneers – esthetic function only (ceramic or resin-based composite)
Class D	Long-term duration	Intraoral Complex function Single material	Stress-bearing intracoronal/ extracoronal restorations (amalgam or resin-based composite) Veneers – esthetic and structural function (ceramic or resin-based composite) Endodontic dowels Denture bases Denture teeth Maxillofacial prostheses Implants
Class E	Long-term duration	Intraoral Complex function Multiple materials (material systems)	Fixed partial dentures (metal ceramic, all-ceramic) Implant components Implant-supported prostheses

Classification proposed by author as aid in assessing likelihood that physical property and laboratory simulation data might correlate with clinical performance (higher for Class A, lower for Class E).

are thermally cycled in the presence of a water-soluble dye, marking where fluid has migrated between tooth and restorative material. One classic example would be the comparison of well-bonded resin-based composites versus amalgams, resulting in minimal leakage for the bonded restoration and extensive dye penetration around the amalgam. Presumably, this result predicts that amalgams will experience far more extensive secondary caries than well-bonded resin-based composites. Clinical data indicate the opposite, with amalgam restorations lasting longer, and equal percentages of both materials being removed due to secondary caries.³⁷⁻³⁹ Further, recent findings indicate that secondary caries do not develop due to bacterial migration along restoration margins, but rather begin as a reinfection of surface enamel adjacent to a restoration.⁴⁰ Additionally, clinical studies have shown that obvious gaps at restoration margins are not associated with increased risk for secondary caries.^{5,41-44} Thus, secondary caries involve primarily a biological process with all the usual host susceptibility factors, and microleakage tests simulate none of these with fidelity, nor do they rank-order materials by clinical longevity.

Load-to-failure of all-ceramic crowns is another example of a test that produces results without clinical meaning. In these tests, a small ball is loaded on the occlusal surface of molars or premolars, or a flat platen is loaded against the incisal edge of anterior crowns. Such testing creates damage at the loaded spot such as crushing or cracking and causes failure by fracture of the unit into numerous pieces from this damage. Clinical failures typically involve single cracks that form at the cementation surface beneath the crown and propagate up to the loaded surface, leaving the crown fractured in 2 pieces.⁴⁵⁻⁴⁷ Traditional load-to-failure tests create nonclinical damage, nonclinical stress states at excessively high loads and contact pressures, and do not replicate any known mode of clinical fracture.⁴⁸

Evaluating surrogate data within a hierarchy based on use and function

Dentists may be exposed to more research reports, evaluations, and advertising claims based on physical properties and laboratory simulations than to any other category of potential evidence. Therefore, it is of value to organize this type of information further, even

considering the doubts raised previously regarding such surrogate data. Two simplifying concepts are offered by the author regarding the likelihood that property data and laboratory simulations can serve as evidence: (1) the duration and type of intended function, and (2) whether multiple materials are functionally involved. These simplifying assumptions provide the rationale for the classification scheme offered in Table IV.

The first assumption involves consideration of 3 factors: (1) the period of use, (2) whether the material is manipulated and used primarily extraorally, and (3) whether it provides a simple function. It will be seen that certain physical properties can be emphasized appropriately in judging behavior for extraoral manipulations, such as gypsum products and casting alloys, as well as for those intraoral materials used for a limited time and to provide a simple function, such as impression materials and endodontic instruments. Similarly, materials designed to perform simple functions over a moderate length of time (1 to 3 years) may also often be judged by basic tests, as in the case of orthodontic wires, cements, and elastics. However, many materials are expected to perform complex functions over extended periods of time, for example, by simultaneously resisting loading stresses, wear, and chemical degradation, as do ceramics and resin-based composites.

Many materials function in concert with another material, such as metal-ceramics and dentin-bonded restorations. Therefore, the second concept involves recognizing when complex clinical failure processes are likely involved and when secondary materials, and interfaces between materials, play a role in clinical performance. Simple properties rarely correlate with clinical data for materials undergoing complex failure processes, such as wear, or where different and competing failure mechanisms operate, for example, in bulk fracture versus component failure of implants. Thus, many restorations and prostheses are essentially coupled systems of numerous materials, the overall clinical behavior of which involves the properties of each material and, often, the quality of the interfaces between them. For such coupled systems, it is likely that only clinical data or validated laboratory simulations and models can serve as evidence.

One final distinction can be useful for the clinician in making a purchase or treatment decision. Does this new material represent an incremental improvement over an existing product or a whole new category or clinical indication? For the former, physical property and simulation data may form good evidence; the latter likely requires evidence from clinical trials.

SUMMARY

Systematic reviews of clinical studies are becoming increasingly available and more user-friendly. Such analyses often provide excellent evidence regarding the use

and choice of materials, restorations, and prostheses. These reviews are the best resource available to clinicians interested in well-grounded and unbiased information. Two new journals, specializing in concisely abstracting both systematic reviews and major clinical studies in a user-friendly format, are an excellent source for the practicing dentist.

Consensus opinions of experts or authorities represent the highest level of materials evidence that begins to consider some *in vitro* data in concert with clinical studies. Both the NIDCR and the ADA periodically hold workshops and technology assessment conferences on topical or controversial issues and publish their consensus findings. The ADA CSA publishes guidance on specific clinical issues and sets the ADA research agenda, often involving dental materials matters.

In vitro data involving either physical property measurements or attempts to simulate intraoral function have rarely been validated in predicting clinical behavior. *In vitro* tests should be developed that either rank materials or predict lifetimes that are consistent with clinical findings, or mimic damage accumulation or failure mechanisms observed from clinical specimens. Dental standards typically rely on combinations of numerous physical properties and material assessments to assure safety, handling, and quality control—but rarely efficacy. For many reasons, the ADA has moved away from the sole reliance on traditional laboratory testing and is developing a new product evaluation program for professional products that will rely more heavily on clinical evaluation and laboratory tests validated as being clinically predictive.

Answers to serious questions should continue to be found in clinical trials. Certainly, clinical trials must investigate interventions that involve risk to patients, clearly novel restorative materials, and the radical extension of clinical indications for existing materials. Guidance on such issues is becoming increasingly available in dental literature.

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