CONTINUING EDUCATION

EBD AND DENTAL MATERIALS

Evidence-Based Dentistry
As It Relates to Dental Materials
Stephen C. Bayne, MS, PhD; and Mark Fitzgerald, DDS, MS

Abstract: Evidence-based dentistry (EBD) is reviewed in depth to underscore the limitations for evidence-based dental materials information that exist at this time. Anecdotal estimates of evidence for dental practice are in the range of 8% to 10%. While the process of evaluating the literature base for dental evidence began 20 years ago, it was not practical to implement it until high-speed wireless connections, open access to journals, and omnipresent connections via smartphones became a reality. EBD includes five stages of information collection and analysis, starting with a careful definition of a clinical question using the PICO(T) approach. Clinical evidence in randomized control trials is considered the best. Clinical trial perspectives (prospective, cross-sectional, retrospective) and outcome designs (RCTs, SCTs, CCTs, cohort studies, case-control studies) are quite varied. Aggregation techniques (including meta-analyses) allow meaningful combinations of clinical data from trials with similar designs but with fewer rigors. Appraisals attempt to assess the entire evidence base without bias and answer clinical questions. Varying intensities to these approaches—Cochrane Collaboration, ADA-EBD Library, UTHSCSA CATs Library—are used to answer questions. Dental materials evidence from clinical trials is infrequent, short-term, and often not compliant with current guidelines (registration, CONSORT, PRISMA). Reports in current evidence libraries indicate <5% of evidence is related to restorative dental materials.

Evidence-based care had its early political beginnings with the first appeals by Archibald Cochran1 in 1972 to require scientific justifications as part of the decision-making process. Cochran is often credited with being the "father" of modern evidence-based medicine. Until that time, most medical (and dental) practice was based on tradition or clinical preference rather than analysis of the information in the published literature and consideration of patient factors. Table 1 provides a list of useful resources.

Evidence-based medicine (EBM) or dentistry (EBD) is a combination of three key criteria that are the foundation for decision-making: 1) best evidence; 2) clinical expertise; and 3) patient values. This practice triad is logical but often misinterpreted. Clinical expertise includes consideration of an individual's clinical talents and personal experiences. Patient values take into account the cultural, socioeconomic, and other special patient values influencing choices. Best evidence for EBD is filtered from all the available evidence about the clinical question of interest. All three criteria are of equal importance. Several common misconceptions arise. First is that EBD is only about evidence, when, in fact, it involves all three parts of the triad. Second is the notion that identifying a publication or source of agreement for a given decision is sufficient evidence; however, evidence is based on examining all available information in an unbiased and systematic way. Third is that evidence is truth. It is not; evidence is the collection of scientific information that is available at a specific time, but it is typically incomplete and can be misleading.

While different definitions may be cited for EBM or EBD, the traditional one is "...the conscientious, explicit and judicious use of..."
current best evidence in making decisions about the care of individual patients..." Notice again that the focus tends to be on the evidence portion of the trial, yet all three components are equally important. Determining how much evidence actually exists has long been difficult. What is generally accepted is that very little evidence is known. An anecdotal estimate is that there is only about 8% to 10% evidence to support what occurs in general dental practice. This is partly because good evidence usually is associated with a well-conducted clinical trial that has been extensively peer-reviewed and published in a reputable journal. Clinical trials are expensive, not often done, and may only cover a few of the variables of interest for an issue. They also require several years to collect the answer, and even more years for that information to reach the public domain, thereby creating a significant time lag. Thus, it is estimated that under optimal circumstances, about 50% of the evidence may be available, while the rest is in some earlier stage of investigation and discovery. This means that only about 10% of complete evidence is available while 50% is needed, but it takes time to conduct the necessary clinical trials. Therefore, 10 to 15 years or more may pass before a practical evidence base is available.

This process has only been initiated in recent years partly because the necessary technologies are just now becoming widely available (Figure 1). Also, there are many tedious steps involved in collecting an answer that are not yet standardized. Collecting evidence is remarkably similar in stages (Figure 1) to all research operations of writing protocols for grants or writing scientific publications—it is "the scientific method." The path includes: 1) asking a clinical question; 2) collecting knowledge in the published literature; 3) assessing the quantity and quality of that information; 4) weighting and/or aggregating the information; and 5) creating a conclusion or answer. Once the answer is available, it can be published in one form or another and used to create new published literature. Often these answers are reported as critical reviews or critical appraisals and collected into evidence libraries. The answers, whether involving small questions or large ones, may not be satisfying if little published information exists. It is much more common for them to be included as part of a summary mentioning that more information or investigation should be done to provide a complete answer.

There are many challenges along the path to producing an answer, including writing a clear, well-defined clinical question. The PICO approach can ensure that this happens. It involves breaking apart the clinical question into four parts: P = patients, population, or problem of interest; I = intervention, treatment, or other option for care; C = control or comparison; O = outcome of interest. In many cases, there is also concern for the time period of measurement and a T may be added to the acronym (PICOT). Once the question is well formed, a search is conducted in available biomedical databases (eg, PUBMED, Web of Knowledge [Table 1]).

**Related Content:**

The Current State of Adhesive Dentistry:
A Guide for Clinical Practice
dentalaegis.com/go/cced521

---

<table>
<thead>
<tr>
<th>TABLE 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resources for Evidence-Based Dentistry for Dental Materials</td>
</tr>
</tbody>
</table>

**Publication Databases**
- EMBASE, http://embase.com/

**Clinical Trials Registries**
- EU Clinical Trials Registration System, https://www.clinicaltrialregister.eu/

**Clinical Trial Guidelines**
- PRISMA, Rules for preferred reporting items for systematic reviews and meta-analyses, http://prisma-statement.org/

**Evidence-Based Dentistry Libraries**
- Cochrane Collaboration, http://www.cochrane.org/
- American Dental Association EBD Library, http://ebd.ada.org/
- UTHSCSA CATs Library, https://cats.uthscsa.edu/

**Tutorials**
- Center for Evidence Based Medicine, http://www.cebm.net/

**Books**

**Journals**
- Evidence-Based Dentistry, http://www.nature.com/ebd/

**APPs**
to identify information. Quantity and quality considerations are essential. Defining the quality can be quite involved, and currently there is no widely accepted and standardized approach for this. If there were, EBD might become a fully automated process. Meta-analyses and other tools for combining information are helpful as well, but, again, they are not uniform. Locating information to be considered as evidence can now be done relatively quickly compared to two decades ago. Today, with high-speed networks, digital libraries, and open access, this process can occur in seconds. There are applications (APPs) that facilitate this (Table 1).

Evidence appears in many forms. EBM and EBD tend to focus on clinical trials. There is a great variety of evidence to consider, all of which is valuable depending on the particular stage of evidence collection. New procedures or products often precede the clinical trial evidence desired. Early information may have little peer review, even if it is of good quality. After 1 to 2 years, more information typically becomes available as early non-clinical reports are published and peer groups develop Delphi assessments. After 5 to 10 years, the clinical data of interest finally begins to emerge. Different clinical trial types or efforts may assess different patient variables, so the information may continue to accumulate for several years. Figure 2 is an evidence map meant to cover all of these situations. At the top right-hand corner is the best possible evidence—that is, evidence that is highly peer-reviewed, good quality, and includes critical appraisals and meta-analyses. Other similar explanations of quality or confidence in evidence use a linear scale or pyramid and deal only with the methods found in the top right-hand corner of the map. It should be noted, however, that all evidence on the map might have some value at some point.

Clinical Trial Types

Clinical information is collected in a variety of ways, and those differences impact the value of the information. Different biases may be included. Different types of calculations may not be possible. Three major parameters of clinical trial designs involve the "timing," the "sampling method" of the population, and the nature of the "outcomes" being assessed. A quick summary of all types is presented in Figure 3. A more expansive treatise on types is presented by Spilker. A trial may be designed as a longitudinal prospective one (to project into the future), a cross-sectional one, or a longitudinal retrospective one. Longitudinal prospective trials allow for careful planning of all the factors to be controlled and the information to be collected. Retrospective ones are limited to what might have been previously planned in a trial. A cross-sectional trial audits the status or current outcome of patients already treated and generally does not include much information about the variables associated with that treatment. Cross-sectional studies are often different from others, due to the limited qualification of the information being collected. In testing the longevity of dental materials, a cross-sectional trial will often report less than half the value of that of prospective longitudinal trials.

Longitudinal prospective trials may be carefully designed with controls and measures of many key factors, with randomization for patient selection and treatment—ie, randomized controlled trials (RCTs). Less-well-controlled trials may simply be referenced as controlled clinical trials, or CCTs. In dental materials testing, in lieu of controls, the assessment system relies on calibrated evaluators and published standards for assessment. They are distinguished as standards-based clinical trials, or SCTs. If patients are selected
Restorative dental materials present some distinctive challenges for clinical testing. A number of additional factors beyond the treatment or choice of materials affect outcomes. These are characterized as: 1) operator factors; 2) design or preparation factors; 3) materials factors; 4) intraoral location factors; and 5) patient factors. Experience strongly hints that operator factors dominate and may represent more than half the risk affecting the outcomes measured.

Two options exist for data collection. The first is to employ only highly trained and calibrated clinicians following specific rules. Historically, this has been the case for trials managed in clinical research units (CRUs) of universities or institutions. The alternative is to ignore those operator factors and let them affect the results in order to observe outcomes that reflect typical practices. Trials managed this way involve a large number of practices contributing information and are called Practice Based Research Networks (PBRNs). Both types have strengths, but information from PBRNs is more limited in interpretation because the variables are not as well controlled.

Results from CRUs and PBRNs can be quite different and often conflicting. For example, PBRNs allow for restoration replacement when clinically anticipated, not necessarily because of real failure, while CRUs measure performance to the point of failure. Therefore, longevity based on PBRN performance is typically calculated to be only half that of CRUs. Additionally, PBRNs report clinical assessments of secondary caries based on uncalibrated or unconfirmed clinical judgments, which are often skewed by misinterpretation of margin performance, and they report secondary caries as the major reason for restoration failure. In contrast, CRUs report secondary caries as almost non-existent, and they report restoration fracture as the major failure mode. It must be noted that CRUs usually actively manage caries risk, use inclusion criteria that exclude high-risk patients, and are much more discriminating about what changes in restoration margins connote.
Aggregation of Clinical Evidence

Rarely are clinical trials large and complete enough in design that they can stand alone in answering a question. A number of variables, such as patient age, gender, risk factors, pre-existing conditions, socioeconomic factors, and trial design biases, are confounders. These challenges can often be managed when there are several good trials in existence by combining the information from the trials. There are statistical approaches such as meta-analyses\(^2\) to weigh the quality of the trials, potentially combine the data, and forge a greater understanding of the true answer for a clinical question.

An early example of applying this process to posterior composite wear results was reported by Taylor et al.\(^2\) If the data cannot be combined, it is possible to systematically review\(^2\) and aggregate results in terms of relationships or risks (forest plots) to estimate the true answer. Therefore, critical appraisals or meta-analyses are often described as the "gold standard" of clinical evidence.

Examples of Types of Laboratory Tests Performed on Dental Materials

<table>
<thead>
<tr>
<th>Physical Properties</th>
<th>Chemical Properties</th>
<th>Mechanical Properties</th>
<th>Biological Properties</th>
<th>Clinical Manipulation</th>
<th>Clinical Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Thermal (diffusivity, conductivity, LCTE)</td>
<td>- Chemical corrosion</td>
<td>- Modulus</td>
<td>- Toxicity</td>
<td>- Minimal isolation</td>
<td>- Caries resistance</td>
</tr>
<tr>
<td>- Electrical</td>
<td>- Electrochemical corrosion</td>
<td>- Elastic limit, yield strength</td>
<td>- Mutagenicity</td>
<td>- Bulk placement</td>
<td>- Color</td>
</tr>
<tr>
<td>- Light (color, gloss, index of refraction, opacity, translucency, fluorescence, radiopacity)</td>
<td>- Absorption/adsorption</td>
<td>- Percent elongation</td>
<td>- Sensitivity</td>
<td>- Bulk cure</td>
<td>- Surface texture</td>
</tr>
<tr>
<td>- Mass (density)</td>
<td>- Solubility</td>
<td>- Ultimate strength</td>
<td>- No worrisome ingredients (eg, BPA) (measured at molecular, cellular, and tissue levels)</td>
<td>- Self cure</td>
<td>- Marginal adaption</td>
</tr>
<tr>
<td></td>
<td>- Diffusion (F recharge rates)</td>
<td>- Strain-rate sensitivity</td>
<td></td>
<td>- Bonding</td>
<td>- Marginal staining</td>
</tr>
<tr>
<td></td>
<td>- Shrinkage on setting</td>
<td>- Temperature dependence</td>
<td>- Finishing/polishing</td>
<td>- Finishing/polishing</td>
<td>- Surface texture</td>
</tr>
<tr>
<td></td>
<td>- Percent conversion</td>
<td>- Bond strengths (to dentin, enamel, casting alloys, porcelain, other dental ceramics)</td>
<td>- Good wetting</td>
<td>- Good wetting</td>
<td>- Wear resistance</td>
</tr>
<tr>
<td></td>
<td>- Degree of polymerization</td>
<td></td>
<td></td>
<td>- Low shrinkage</td>
<td>- Postoperative sensitivity</td>
</tr>
<tr>
<td></td>
<td>- Tm and/or Tg</td>
<td>- Wear (two-body, three-body), attrition, abrasion, erosion, food wear, polishing, dentifrice wear</td>
<td></td>
<td>- Minimal recycling, waste, and packaging</td>
<td>- Fracture resistance</td>
</tr>
<tr>
<td></td>
<td>- Copolymerization rates and Q/e</td>
<td>- Toughness</td>
<td>- Toxicity</td>
<td>- Caries resistance</td>
<td>- Retention</td>
</tr>
<tr>
<td></td>
<td>- Cross-link density</td>
<td>- Fracture resistance</td>
<td>- Mutagenicity</td>
<td>-色</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Heats of reaction</td>
<td>- Fatigue resistance (mechanical, thermal)</td>
<td>- Sensitivity</td>
<td>- Surface texture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Residual materials</td>
<td></td>
<td></td>
<td>- Low shrinkage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Degradation events (depolymerization, chemical degradation, silane hydrolysis)</td>
<td></td>
<td></td>
<td>- Minimal recycling, waste, and packaging</td>
<td></td>
</tr>
</tbody>
</table>

While it stands to reason that everyone would like to be able to combine their information with sufficient good clinical trials using these methods, this is rarely possible. It is also the underlying reason why evidence-based dentistry has been characterized as involving only 8% to 10% evidence.
Clinical trials require much more time and expense than laboratory investigations of properties or clinical simulations. Only a few laboratory investigations have shown correlations with actual clinical results.

Foundation for Dental Materials
For dental materials, the clinical research effort has been limited, representing only about 10% of all research for many years. Clinical trials require much more time and expense than laboratory investigations of properties or clinical simulations. Only a few laboratory investigations have shown correlations with actual clinical results. This occurs for a variety of reasons. Individual laboratory properties (such as flexural strength) do not line up well with the performance data measured clinically for restoration surfaces and margins. Simulations are attempts to bridge the gap, but they are generally too limited in design, not validated, use water to mimic saliva, and are not conducted long enough to represent reasonable clinical lifetimes. As indicated in Table 2, a large range of laboratory properties could be tested. However, researchers face significant challenges in detecting meaningful correlations (C) between laboratory tests and simulations (small circles in Figure 4) and clinical results or combinations of clinical data (small boxes in Figure 4). Relationships (R) may occur with laboratory or clinical results that do not produce correlations. Figure 4 also shows types of factors that typically confound data for the lab and clinic.

Table 2 provides examples of the wide range of laboratory tests performed on dental materials for physical, chemical, mechanical, and biological properties, as well as clinical manipulation and clinical performance properties. Typically, only a couple are tested, and the results do not correlate with clinical properties. Table 2 summarizes the limited range of clinical categories evaluated. The original categories were published by Cvar and Ryge while working for the United States Public Health System (USPHS). They are: color match, marginal discoloration, secondary caries, anatomic form, marginal adaptation, and surface texture. The original list has been expanded to include more information, such as: proximal contact, functional occlusion, axial contour, pre- and postoperative sensitivity, restoration retention, and resistance to fracture. Most of these categories concern clinical observations of restoration margins or surfaces, and a rating system (A - Alfa = clinically "ideal"; B - Bravo = clinically "acceptable"; C - Charlie = clinically "unacceptable") is used to determine clinical steps from idea to failure.

Almost all dental materials trials are short-term (1 to 5 years) and involve low-risk participants. Generally, about 20% of the population is considered at high risk for dental caries. Because of
pre-existing restorations, lost teeth, or existing dental caries, that high-risk group is primarily excluded from trials. As a result of these two practices combined, reports of dental restorative materials' clinical performance are generally very positive. Understanding potential differences or problems, however, requires that failures and their patterns be observed. These are missing from most dental materials clinical trials.

Finally, the prevalence of clinical research reports from the different EBD library databases must be considered. As shown in Table 3, which provides a summary of dental materials reports for three major evidence libraries for direct restorative biomaterials, many of these reports conclude that there was little or no sufficient or good evidence available at the time of the report.

**Related Content:**

Flowable Composite Resins: Do They Decrease Microleakage and Shrinkage Stress?

dentalaegis.com/go/ceds523

The number of reports involving dental materials that appeared in October 2013 in the Cochrane Collaboration, ADA EBD Library, and UTHSCSA CATS library were 12, 89, and 69, respectively. For the first two, fewer than 5% of the libraries discovered information. For the last one, the inclusion of laboratory research in the process elevates it to 32%. It is clear that very little information exists. Compiling the evidence needed to answer 50% of the important questions will still require 15 to 20 more years and much more concerted efforts.

**Summary**

Evidence for restorative dental materials performance is very limited due to the scarcity of clinical trials. A much greater effort to conduct clinical research over the next 15 to 20 years is required to build the needed evidence base. Fast access to the available known information is already possible.

**ABOUT THE AUTHORS**

Stephen C. Bayne, MS, PhD
Professor and Chair, Cariology, Restorative Sciences, and Endodontics, School of Dentistry, University of Michigan, Ann Arbor, Michigan

Mark Fitzgerald, DDS, MS
Associate Professor and Vice Chair, Cariology, Restorative Sciences, and Endodontics, School of Dentistry, University of Michigan, Ann Arbor, Michigan

Queries to the author regarding this course may be submitted to authorqueries@aegiscomm.com.

**REFERENCES**
