Tincture of Time: A Vital Ingredient for Dental Success

For many years now, from both editorial pages and the podium, clinicians have been encouraged to practice "evidence-based" dentistry. Scholars have described different versions of the hierarchy of evidence. Clearly systematic reviews of randomized controlled clinical trials (RCTs) are at the top of almost every version. The only problem with this approach is that in restorative dentistry there are relatively few properly conducted RCTs, hence few conclusive systematic reviews have been published. Published reviews and studies almost always conclude there are too few quality RCTs available, and those that are available have sample sizes that often are too small, are underpowered, and at a high risk for bias.

Consequently, all too often, conclusions regarding various dental materials and techniques are drawn from simple trends that seemingly are apparent in underpowered clinical trials, case reports, or from in vitro research. Many top speakers at symposia, national meetings, conventions, and continuing dental education courses synthesize such information and present this information to practitioners as if it were gospel. However, one factor that is often missing from available information is the factor of "time." Dr. Gerald Denehy once made the very perceptive comment, "The effectiveness of materials must be measured in time" (Dr. G. Denehy, Wonewok, MN, personal communication, 2005).

The potential life span of a restorative material must be considered in the context of the tooth/restoration complex. Many factors exist related to the patient, the restorative dentist, the material, and the remaining tooth structure that all must be considered when determining a prognosis.[1] It is clear that some materials, such as properly done cast gold, can provide a very long lifetime of service, primarily because of little susceptibility to fatigue failure.[2] However, in order to accurately establish the longevity of a material, studies must be conducted over a long enough time frame to have clinical value and credibility.[3] We will provide three such examples that will clearly illustrate why short-term studies frequently provide misleading data.

The first example is regarding the restoration of endodontically treated teeth. When restoring endodontically treated teeth that exhibit extensive loss of tooth structure, it is frequently necessary to use an endodontic dowel or post to help retain the core material upon which a crown subsequently will be fabricated. Traditionally, stiff metal dowels have been used that may be either prefabricated or custom fabricated as a cast post and core. In recent years, flexible dowels have been available. The primary rationale for using flexible dowels is that they will flex along with the tooth, and if fracture occurs, the mode of fracture will be less catastrophic than the mode of fracture with stiff dowels.

One of the first published clinical trials of flexible endodontic dowels was reported in 1998.[4] Two hundred and thirty-six teeth restored with a flexible post, composite resin core and crown were followed for a mean time of 30 months. The failure rate was only 2% over this time period, which was considered quite favorable by the authors. Indeed a success rate this high would be considered outstanding. However, it should be noted that no specific criteria were defined as to when a post was placed, so it may have been possible that the flexible posts were placed in some teeth that did not really require a dowel in the first place.

A follow-up examination of the same patient population in the previous study was published later in 2006 with a mean time of service at that point of 6.7 years.[5] The reported failure rate had risen from 2% at 30 months to 35% at 6.7 years! In other words, the study results regressed from spectacularly successful to woefully failing. Speculated failure mechanisms included hydrolytic breakdown of the post polymer, fatigue failure of the resin cement, and/or failure to achieve an adequate ferrule height of the subsequent crown. Whatever the cause(s) for failure, the study

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clearly illustrates the necessity for long-term evaluation of new concepts and materials. The authors should be congratulated for publishing the followed-up report, because it clearly showed a more complete and accurate assessment of this approach.

Another example of short-term success and long-term failure is provided in the evaluation of a self-etching adhesive (Prompt-L-Pop, 3M ESPE, St. Paul, MN, USA). The primary method of evaluation of dentin bonding agents is to record the retention of restorations in Class V non-carious cervical lesions (NCCLs) with no mechanical retention. One such clinical trial initiated at UNC School of Dentistry reported 96% retention at 6 months, but only 81% retention at 2 years (Dr. Al Wilder, personal communication). The study was discontinued at this point because of the high failure rate and the results were never published. Similarly, a study using the same adhesive recorded a retention rate for Class V resin composites of only 76% at 6 months and 65% at 1 year.[6] Regardless, 3M ESPE should be commended for conducting the clinical trials to begin with. Even negative results are of value and help redirect future research efforts. But again, the necessity of collecting such data over time is obvious. To put this failure rate in perspective, a 12 year clinical trial of fourth generation bonding agents performed at UNC School of Dentistry found an overall retention rate of 89% for Class V composite resin restorations.[7]

Another area where data from long-term clinical trials are essential is in the evaluation of new all-ceramic materials. In 1996, Dr. Peter Schärer proposed that before a clinician uses any new all-ceramic material, he/she should have data available from independent clinical trials of 5 years minimum duration, and the data should indicate a survival rate no lower than 95%.[8] The time period of 5 years is essential with all-ceramic crowns because of their well-documented mechanism of failure by progressive defect and crack propagation. Although these criteria are admittedly somewhat stringent, they do take into account the substantial financial and emotional costs of premature failure of a ceramic restorative material. Those costs have been well-documented in an outstanding 2009 editorial feature in this journal by Dr Frank Spear.[9] It should be noted that at the time of this writing, NO all-ceramic material has been able to completely meet Schärer's criteria for molar crowns or for three-unit fixed partial dentures. Yet speakers continue to make broad, largely unsubstantiated recommendations to their audiences for many new all-ceramic systems. It is clear that Dr. Spear's cautions are obviously not being heeded.

It is clear that new materials are being introduced to the profession at an unprecedented rate. Most of these materials come to market with in vitro testing of physical properties that have little or no predictive value related to long-term clinical performance. Few materials come to the market with adequate clinical testing. In fact, by default, the practicing dentistry community as a whole has become the unwitting grounds for clinical testing. If a new product elicits multiple practitioner complaints owing to mediocre performance, that material simply dies a quiet death, only to be supplanted by the next hopeful effort.

Please let us be clear. Companies that "do their homework" and conduct the requisite research should be heartily commended, even if the results are not favorable. Companies that are committed to generating high quality materials and fostering clinical excellence should be rewarded. In fact, dentists should be cognizant of these efforts and patronize ethical companies of this type accordingly. Companies that simply concentrate on selling, selling, selling with no regard for responsible research or quality deserve extinction.

Owing to this "trial and error" approach, the marketing of all too many of these new materials has become increasingly aggressive, and as a result, dentists often are left feeling that they have become "dinosaurs" who are "behind the times" since they are not using "the latest and greatest." Academicians often experience the same unfortunate characterization. It is our opinion that these "dinosaurs" are indeed practicing in an extremely responsible manner by using time-proven materials and techniques, and their conservative approach should be applauded. This approach is perfectly consistent with current cries that call for the practice of "evidence-based" dentistry. As for us in

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academics, we have a very weighty responsibility to teach what we know works, not what we think or hope works, or what some self-appointed "guru" has hyped as the "material du jour."

In conclusion, it is apparent that the deluge of new unproven restorative materials will continue unabated, and that the marketing efforts of many dental manufacturers will continue to take precedence over the views of scientists and researchers. This practice unfortunately is the nature of the dental materials business. Dentists must be very discriminating dental consumers when making purchasing decisions about new dental materials. Practicing dentists must realize that "tincture of time" is an essential ingredient in determining the long-term efficacy of any dental material. Our patients deserve it and our practices require it.

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