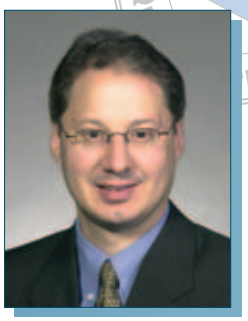
GUEST EDITORIAL

Implant Dentistry and Prenuptial Agreements



Have we become so enamored with the ability to replace teeth with titanium that we have let our guard down? As we all know, before the existence of well-documented endosseous implant systems, a small set of innovative clinicians sought to provide the benefits of tooth replacement therapy using a variety of implant designs (eg, blades, vents, subperiosteals, cages) and surgical procedures (eg, implant to tooth prosthesis, immediate loading, etc). In that era, the scientific literature and clinical practice suffered from a level of evidence that was simply opinion and case studies. Following the introduction of at least 2 systems with good documentation (Branemark System and Straumann ITI System), we entered an era of enhanced appreciation that implant therapy may work in a set of experienced hands with a clear set of systematic documented outcomes in well-controlled and preferably randomized, controlled trials. Today these criteria for clinical trial designs are accepted as an international standard and are summarized in what is called the CONSORT protocol (http://www.consort-statement.org). Following these initial outcomes on the *efficacy* of therapy, there would be an assessment of how implant therapy performs in a range of skill sets of general practice—a measure of the *effectiveness* of a therapy.

Dental practice has always involved a unique combination of professional opinion and artistry. Judgments are often made without strong evidence to support diagnostic and treatment decision-making. Over time, the level of science has increased in our profession along with expectations from the public that we are a science-based profession with a high degree of critical skepticism of manufacturers' claims. The experience with dental implant therapy is a good example of this principle. Before the long-term studies documenting a set of clinical handling procedures, implant device designs, surface technologies, etc, the predictability of outcomes was unknown. In the past decade, we have seen a surge in the market with a number of new products from existing and new manufacturers from around the world. Some of these products are highly innovative; others are direct copies of existing implant and abutment design features offered by manufacturers with an agenda to capture a portion of the implant market for less than altruistic reasons.

As a profession we need to stop and think about what we are doing. We place a portion of the device (the implant) in our patient with the intention that it will perform in an esthetic and functional manner for *the rest of our patient's life*. Think about it; we perform no other dental procedures intentionally for the rest of a patient's life. Here the morbidity to reverse the procedure is so high and, further, we rely on the ongoing support of an individual company to be there for the rest of that patient's life. We in effect create a prenuptial agreement between the company and our patient. Since we are responsible for this marital union of sorts, we must advocate with the dental implant industry—as a marriage counselor, if you will—to prevent divorce. Divorce occurs when a manufacturer fails to provide clinical performance outcomes prior to marketing a product and ongoing product support for the systems they currently and previously sold.

Innovations to medical devices are a logical result of research and clinical demands, but we must separate innovations that are simply attention-grabbing marketing innovations from those that are necessary to improve patient care. Even though a product may be cleared by a regulatory body such as the FDA (eg, under a 510k clearance), it is our due diligence to report complications and notify these agencies of emerging issues (http://www.fda.gov/medwatch).

Clinicians need to think twice before they purchase a dental implant system that has limited to no formal clinical documentation and limited or unknown manufacturer interest in remaining in the marketplace. Are the challenges of dealing with a company that has limited experience in the dental industry and a limited understanding of the regulatory environments worth the risk? Is the company still in business a year later? Can we locate parts versus going to a dental version of *eBay*? How, in the end, does this make the dental profession look in the eyes of our patients?

Where does this leave us? As a profession we must insist on innovative but clinically well-tested products. We must then use these products in clinical procedures that encompass a systematic assessment with an eye for optimal patient outcome, even if this takes a tincture of time. We must also insist that once a manufacturer decides to transition a product off the market that the support materials continue to be available and, if not, that the technical information be made available for an aftermarket CAD/CAM manufacturer to make these parts to the original or superior specifications. Implant therapy is for the duration of our patients' lives; this is our most important responsibility. In the end, we also must continue to learn and improve our knowledge of the science and clinical use of tooth replacement therapy. An *education* is what is left when our *knowledge* becomes obsolete; *intelligence* is knowing the difference.

Clark M. Stanford, DDS, PhD
Centennial Fund Professor for Clinical and Translational Research
University of Iowa
Iowa City, Iowa, USA