DENTAL IMPLANT RESEARCH: A PERSPECTIVE

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In recent years, the profession has witnessed the introduction and subsequent withdrawal from the market of numerous unsatisfactory implant products and techniques. The profession was forced to field test many of these unsatisfactory products for dental manufacturers and responded by discarding them. These unsatisfactory products should never have been made available to the profession. As long as there is little or no control over what dental manufacturers can place on the market for implant restorative and surgical purposes, it is up to the individual dentist to exercise utmost caution over the products he or she uses.

While doing research for his master's thesis, one of our graduate students observed that the HA implant coating of a major manufacturer had an extremely high contact angle, with the resulting poor wettability. When the company was notified, we were informed that they did not have the equipment for contact angle determination and therefore never checked the contact angles. Today, many years later, the HA implant coating remains available to the profession unchanged.

Research at Temple University School of Dentistry suggests that the high initial torque values recommended by some manufacturers for their implant screws are beyond the limitations of the screws provided and may result in stripping, breakage, and other problems.

A recent request to a major implant manufacturer for copies of all educational material distributed at their 1-day training sessions resulted in a telephone call and letter from their general counsel, with nothing provided.

These are just 3 examples from our experience. We can easily list many more, just as we are certain readers of this editorial can also do. Where American Dental Association specifications exist for specific product groups, dentists are urged to limit themselves to using certified materials. The specification and certification programs of the American Dental Association have been designed to enable the dentist to select the most suitable products for his or her dental health services, with the thought that concern for the patient's well-being is paramount. The dentist can obtain a listing of all certified materials from the American Dental Association on request.

Unfortunately, the American Dental Association certification program is voluntary. Manufacturers would not subject their products to American Dental Association testing if they are aware that the products could not meet the current specifications.

There are a number of independent research groups that conduct limited clinical research on dental products and publish newsletters, such as Gordon J. Christensen's *Clinicians Report*. These groups are of benefit to the profession but have financial and other limitations. Some of these groups do not have a sufficient number of qualified investigators and rely on volunteers, who in some cases participate only to receive free dental product samples.

Clinical research is an experiment designed to assess the efficacy of a new treatment, a device such as an implant, a new drug, or a new procedure by comparing its effect in humans. In evaluating the results of an implant clinical study, the dentist should consider whether it was an efficacy-type or an effectiveness-type investigation.

Efficacy-type clinical studies generally involve a small number of professional participants and patients. They tend to involve only the most highly skilled dentists and select patients who are ideal candidates. The studies exclude or control many variables (ie, potential risk factors) present in a clinical environment, which helps reduce study costs. In the case of dental implants, a major limitation of efficacy-type studies is that they tend to test the skill and experience of the dentist more than the influence of the implant. This explains why when the product is used by dentists with clinical skills and experience that are different from those of the investigators, the clinical results often vary considerably as compared with those originally reported.

An effectiveness-type clinical trial is a much larger and more expensive study, which generally involves a large number of patients, investigators with different backgrounds, and research centers in widely different geographic locations. Effectiveness studies are difficult to design, the variables are difficult to identify and control, and it is difficult to effectively gather data and complete a detailed scientific analysis of the large database that is collected.

Effectiveness-type clinical trials have a much greater external (global) validity when compared with efficacy-type studies. Efficacy-type studies, on the

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other hand, generally exhibit high internal validity (ie, the scientific quality of the data gathered). The results of effectiveness-type clinical trials can be translated to a much larger group of dentists and patients and show results that the average dentist in an average clinical setting could expect by using the same type of implants.

Commercial sponsors of clinical investigations must not have veto power over publication and/or presentation of experimental results. Dental manufacturers have been known to prevent dissemination of results that do not reflect favorably on their products.

The responsibility of decision in the selection of implant materials and techniques rests with the dentist, who must evaluate all factors in relation to the results he or she hopes to achieve. If dentists do not care enough to make the effort, who else can be expected to act on their behalf?

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