Biomaterials and Medical Implant Science

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I just returned from a conference at the National Institutes of Health (NIH) titled "Biomaterials and Medical Implant Science." This meeting's recommendations will undoubtedly influence much of what we do, or plan to do, ill biomaterials and biomechanics research in the rest of this decade and into the next century. Accordingly, the JOMI readership should be most interested in the meeting's results. A complete report will be forthcoming soon from NIH, but in the meantime, what follows can serve as one participant's informal report back to that segment of the biomaterials community interested in oral and maxillofacial implants.

Dr Harold Varmus, director of NIH, commissioned "Biomaterials and Medical Implant Science" and charged its participants "to explore the scientific opportunities and recommend areas of research that will improve the success of medical implants." While this was the officially stated purpose of the meeting—couched in global terms from the highest levels of NIH—there are those who might say, "Biomaterials have been used for many years; Why *this particular meeting at this particular time?"* The answer was clear at the meeting; it was impossible to miss a more pointed motivation for the conference, stated later in the program booklet: "Despite advances in biomaterials, permanent medical implant design and quality of life benefits for patients, *their failure in Some applications, and certain related legal issues, have recently bought considerable attention to the biomaterials field"* [italics mine]. For the italicized words, you may insert the recent litigation over silicone breast implants and TMJ implants. The NIH undoubtedly recognized that the time is right, both scientifically *and* politically, for this meeting on the past and future of biomaterials and medical implant science.

Some of the mailings to me before the meeting were particularly informative. For instance, a survey by Moss et al[1] noted that 11 million (M) Americans (4.6% of the population) have one or more implants. About 4.4 M have fixation devices; 2.6 M have lens implants; 1.3 M have artificial joints (half of which are hips); 0.9 have ear vent tubes; 0.46 M have pacemakers; 0.38 M have silicone implants (90% breast implants); and 0.25 M have artificial heart valves. Curiously, in the mass of statistics I could not find a direct figure for how many persons actually have dental implants! However, when it comes to numbers of implants in the United States in 1988, I did find that 0.275 M dental implants were used, which was only about 1.8% of the 15 M total implants. The rest of the implants included 4.9 M fixation devices; 3.7 M lenses; 1.6 M artificial joints; 1.4 M ear vent tubes; 0.62 M silicone implants (0.54 M breast implants); 0.32 M shunts/catheters; and 0.28 M artificial heart valves. Beforehand I probably would have guessed that dental implants represented a bigger share than 0.275 M. (An update of this 1988 study was urged at the conference.)

At the 2-day (October 16-17) workshop-style conference, the participants included prominent basic scientists, clinicians, bioengineers, NIH staff, consumer advocates, and chief executive officers from various key companies in the biomaterials field. There were eight plenary speakers, 50 invited participants for five breakout sessions, and another 50 or more observers and federal employees. The plenary speakers were asked to give overviews of key problem areas and to identify areas for future research. The NIH and the conference co-chairs (Diane Rekow, PhD, DDS, Chair of the Department of Orthodontics, University of Medicine and Dentistry of New Jersey, and Peter Eisenberger, PhD, Princeton Materials Institute, Princeton University) challenged the breakout session participants to come up with research goals for the future that went beyond being mere proposals of incremental advances in existing areas. Rather, the charge was to generate truly innovative research goals with potentially large impact into the next century, ie, "to propose a new research enterprise—its mission, priorities, and educational components." Using the plenary speakers' talks and background information supplied by the conference organizers, the participants in five breakout sessions tried to develop a research agenda related to each of the following biomaterials areas: commercial implant materials; basic design principles; biocompatibility; manufacturing; laboratory and clinical evaluation; and device monitoring, retrieval, and databases.

Looking over my notes from the plenary talks and breakout sessions, I can only give a taste of what went on. Here's a list of some key words and phrases in no particular order: $400 billion annual health costs related to tissue loss and organ failures; about $92 million of NIH-funded extramural research related to biomaterials in 1994, of which $13 million was from the National Institute of Dental Research (NIDR); tissue engineering of skin, liver, cartilage, bone and. . . ?; biomaterials for drug delivery systems; emulating nature's techniques for biomaterials synthesis and manufacturing; biomaterial-based microsensors; nonvital vector delivery systems for genetic engineering (biomaterial microspheres instead of retroviruses?); smart materials; computer aided design-computer aided manufacturing (CAD CAM); minimally invasive surgery; new imaging methods; a biomaterials "embargo"[2]; and biomaterials designed with cell receptors in mind. Some notable history also came into focus, such as the fact that hardly any of the biomaterials now in use were actually *designed* to be used as biomaterials. Titanium is a perfect example, having been developed originally for purposes other than oral implants! Dr Robert Langer of MIT added that polyurethane for artificial hearts was adapted from ladies' girdle material; dialysis membranes came from sausage casings in Germany; vascular grafts came from fabric for clothing; and breast implants derived from silicone lubricant materials!

Conferees also advocated initiatives to support additional education and training of clinicians so that they could understand and use new technologies more safely and effectively—likewise for engineers and materials scientists when it comes to

concepts of biology and medicine. In other words, before we go speeding off to find more biomaterials and applications, we should also make a concerted effort to do a better job for patients using what we already have. Two quick examples: (*1*) How about more clinical use of biomechanics in case planning with oral implants? (2) How about more interest from the orthopedics community in how and why osseointegrated implants have worked so well during the last three decades? Moreover, beyond hard science, legal issues and funding strategies arose. The need for tort reform was noted more than once, especially by the chief executive officer of Dow Corning, Mr Richard Hazelton.

On funding, this question arose: Must the only thing funded by NIH be hypothesis-driven research? What about an explicit support of *engineering design*, the act of creating a new device or system based on scientific principles? It was pointed out that some worthy achievements of scientists and engineers such as the Apollo moon missions of the past—and perhaps the design of new diagnostic techniques or biomaterials in the future—would not be fundable if subjected to a strict rubric of hypothesis-driven research as applied by many NIH Study Sections. Might future NIH Study Sections be more sensitive to the fact that the *engineering design process*, of which research may be a part, is also worthy of support, especially if medical device design is being proposed? As if to emphasize what I just wrote, the entire last page of the conference program was devoted to a description of "Medical Implant Design" prepared by Dr John T. Watson, Head of the Bioengineering Research Group of NIH's National Heart, Lung, and Blood Institute.

After the breakout sessions made their recommendations to NIH, I think the participants came away with a sense of having worked hard to address critical and timely issues. Certainly we should be grateful to Dr Varmus and NIH for having taken the initiative to hold such a conference. We should keep track of this story to see how it comes to closure within NIH. Certainly this conference will help set the agenda for biomaterials science and engineering design, a field where the United States has been, and would like to continue being, a world leader—scientifically and economically.

1. Moss AJ, Hamburger S, Moore RM, et al. Use of selected medical device implants in the United States. 1988. Advance Data From Vital Health Statistics, No. 191. Hyattsville, MD: National Center for Health Statistics, 1990.

2. Benson JS, Boretos JW. Biomaterials and the future of medical devices. Med Devices Diagn Industry 1995;17(4):32-37.