Journal of Cellular Biochemistry 56:143–144 (1994)

VIEWPOINTS

Biotechnology Applications in Biomaterials *

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A National Center for Health Statistics survey conducted in 1988 indicates that more than 11 million people in the United States have biomaterial implants [Moss et al., 1991]. A biomaterial is defined here as any material used in the body to achieve a therapeutic or diagnostic purpose. Biomaterial-containing implants range from artificial heart valves, arteries and veins to artificial joints, drug delivery systems, and silicone implants. The survey did not include dental restorative procedures and devices that may apply to nearly the entire U.S. population. The numbers and variety of these products speak to the importance of biomaterials and biomaterial-containing medical devices for our national health.

Although many functionally sufficient materials are in use, chronic problems have been recognized with different types of materials and their applications. Materials may be limited in their use for a number of reasons, including poor biocompatibility, infection susceptibility, immune responses, thrombus formation, limited biodurability, and elicitation of cellular degradatory responses. There is, therefore, a critical need for biomaterials that provide longer-term clinical benefit and fewer complications for patients requiring acute or chronic biomaterial-containing implants. A reduction in implant-related complications of 2% would enhance the quality of life and reduce costs for an estimated 100,000 to 200,000 new patients each year.

Received July 15, 1994.

The opinions and statements contained in this report are those of the authors and may not reflect the views of the Department of Health and Human Services (HHS) and/or the Food and Drug Administration (FDA).

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Substantial clinical experience and prolonged use of implanted medical devices indicate that biocompatibility is enhanced when biomaterials closely resemble tissues in the human host. Processed natural tissue and tissue constituents from different animal species have, to date, met this requirement to some extent. However, the use of biotechnology-derived biomaterials that achieve homology with the host and the structuring of hybrid artificial tissues and organs provide a strategy for improving the longevity and functionality of implants for medical use.

Several research groups have demonstrated the feasibility of using biotechnology approaches to develop biomaterials for clinical use over the past few years. We are now beginning to see breakthroughs that will revolutionize the field and provide approaches to problems that have been recalcitrant to practical solutions. A major goal is the discovery of new routes to produce structural and functional materials using biological organisms and principles derived from biology. The focus of much current research is to reveal principles underlying the production of a wide variety of biomaterials at the molecular level.

Bringing together the research and development efforts of biotechnology and materials science has led to a new field of scientific endeavor that can tailor biomaterials for desired purposes. These new types of biomaterials incorporate living cells, cellular components, cellular products, and synthetic components modeled on cellular biosynthesis. The different areas of this field include, generally, biomolecular materials, self-assembly systems, and tissue engineering.

Recognizing the increased applications of biotechnology methods and approaches in biomaterials development and the critical role of biotechnology in developing increasingly biocompatible materials, the Food and Drug Administration

(FDA) and the Society for Biomaterials[1] cohosted the first Workshop on Biotechnology Applications in Biomaterials on April 28, 1993, in Birmingham, Alabama [Hellman et al., 1993a,b]. The Workshop was organized by a committee drawn from academia, industry, and federal agencies.[2]

In order to develop initiatives toward common goals, the conference was also sponsored by the National Science Foundation, the National Institute of Standards and Technology, and the Industrial Biotechnology Association. The central goal of the workshop was to assess current and future prospects for application of biotechnology-derived biomaterials in clinical medicine and provide recommendations for regulatory strategies to assist evaluation of the ensuing products.

The Workshop had five broad objectives:

1. Review research and development advances in each topic area (e.g., biomolecular materials, self-assembly systems, and tissue engineering).
2. Gain a better perspective on the application of these technological advances in current and future medical devices and their impact on public health and clinical medicine.
3. Identify safety and effectiveness issues associated with these new products, to determine scientific and clinical criteria for product evaluation.
4. Examine the industrialization potential of the new products, to identify manufacturing problems and quality assurance issues.
5. Identify strategies to further research and development in the field and to develop appropriate regulatory guidance using cooperative approaches among government, industry, and academe.

Review of research and development advances were accomplished in a formal one day program featuring lectures and poster presentations. These are summarized in this issue in a Viewpoint by Eugene Bell entitled "Biotechnology Meets Biomaterials" and in selected articles. An analytical treatment of principal issues influencing the incorporation of biotechnology advances into biomaterials applications was based on formal presentations and discussions among panelists and the audience and developed in working sessions and discussions among the invited workshop participants.[3] Their conclusions and informal recommendations arising from these discussions are treated in a Viewpoint (Hellman et al., this issue) entitled "Prospects for Application of Biotechnology-Derived Biomaterials."

REFERENCES

Hellman KB, Mueller EP, Picciolo GL (1993a): Presidential initiatives and national policy foster biotech biomaterials applications. Genetic Engineering News, p 4.

Hellman KB, Picciolo GL, Mueller EP (1993b): "Biomaterials and Biotechnology." Bio/Technology Vol. 11, pp 1179–1180.

Moss AJ, Hamburger S, Moore RM Jr, Jeng LL, Howie LJ (1991): Use of Selected Medical Device Implants in the United States, 1988, Advance Data from Vital and Health Statistics, No. 191. Hyattsville, MD: National Center for Health Statistics, February 26, pp 2–24.

[1]The Society for Biomaterials promotes advances in biomedical materials research and development by encouraging cooperative research, educational programs, clinical applications and professional standards in the biomaterials field. Standing committees deal with educational and professional development, devices and materials, and liaison on a national and international level with other societies and agencies having similar or related research, teaching and clinical activities, and objectives.

[2]Lisa Christenson, Micro Gene Systems, Inc.; Arthur J. Coury, Focal, Inc.; Alan R. Goldhammer, Industrial Biotechnology Organization (BIO); Fred G. Heineken, National Science Foundation; Lura Powell, National Institute of Standards and Technology; Rosealee M. Lee, SOCIETY FOR BIOMATERIALS; and Kiki B. Hellman and Grace Picciolo; Center for Devices and Radiological Health, Food and Drug Administration.

[3]Robert E. Baier, State University of New York at Buffalo; Hagan Bayley, Worcester Foundation for Experimental Biology; Eugene Bell, Massachusetts Institute of Technology; Harvey Blanch, University of California at Berkeley; D. Bruce Burlington, Food and Drug Administration; Linda Griffith Cima, Massachusetts Institute of Technology; Arthur J. Coury, Focal, Inc.; C. Fred Fox, University of California at Los Angeles; Fred G. Heineken, National Science Foundation; Kiki B. Hellman, Food and Drug Administration; Ron B. Herberman, University of Pittsburgh Cancer Institute; Allan Hoffman, University of Washington; David S. Kaplan, Food and Drug Administration; Michael Lysaght, CytoTherapeutics, Inc.; Robert M. Nerem, Georgia Institute of Technology; Grace Lee Picciolo, Food and Drug Administration; Michael D. Pierschbacher, Telios Pharmaceuticals, Inc.; Lura J. Powell, National Institute of Standards and Technology; A.H. Reddi, The Johns Hopkins University; Alan S. Rudolph, Naval Research Laboratory; Uwe B. Sleytr, Der Universitat fur Bodenkultur; David A. Tirrell, University of Massachusetts at Amherst; and Ioannis V. Yannis, Massachusetts Institute of Technology.