Proceedings of a Special Symposium on Critical Emerging Issues in Biomedical Engineering

Proceedings of a Special Symposium on Critical Emerging Issues in Biomedical Engineering

(Held Concurrently with the Eighth Annual Conference of the IEEE Engineering in Medicine and Biology Society)

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86CH2369-7

Additional copies may be ordered from:

IEEE Service Center
445 Hoes Lane
Piscataway, NJ 08854

IEEE Catalog No. 86CH2369-7
Library of Congress Catalog Card No. 86-82679

PREFACE

When I was asked to be a Program Chair of this major IEEE Conference, I was flattered until I realized that I would need to come up with some way to at least equal and possibly surpass the outstanding programs put together by previous EMBS Program Chairs. Quite a tall order indeed!

Just before the September '85 EMBS Conference in Chicago, I wanted to put together some sort of special Symposium for the 1986 EMBS Conference much like the Biosensors workshop held at the Los Angeles EMBS Conference. This idea was nurtured during many invigorating discussions with a number of individuals, most notably this year's Conference Chair George Kondraske and International Chair Swami Laxminarayan, and Al Potvin of Eli Lilly and Co., Bill Friedman of NSF, and my Track Chairs. I wanted to insure that, whatever idea that we came up with, it would truly serve to entice potential attendees to come to the 1986 Conference. Also, as more of an engineering generalist than an engineering specialist, I wanted the Symposium to be broad enough to cover a number of areas, yet with sufficient content to interest almost all perspective attendees. Above all, the Symposium had to serve an educational role.

Many good suggestions were made as to the appropriate focus of such a Symposium. Some were along one or more subdicipline lines within biomedical engineering. Some suggested that it was time to review where we were in this or that field. A consensus slowly emerged during last year's meeting that maybe what we needed to do was look ahead, rather than backwards, and assess where biomedical engineering was going. Al Potvin had just previously recruited some of us to help him draft a position paper on research needs in biomedical engineering (see the Jan. '86 IEEE TRANS BME) for the National Research Council. It seemed natural that a Symposium organized along these lines might be well received.

One of the charges of the Biotechnology section of our National Science Foundation is to keep abreast of critical and emerging areas in biomedical engineering. Bill Freidman of NSF indicated that NSF might be willing to support partially a Symposium that addressed these critical and emerging issues, but that a conference grant would need to be submitted for peer review.

George Kondraske and I then met over the next three months to firm up the Symposium plans and to prepare appropriate conference grants to NSF and NIH. We decided that the Symposium would need to have some sort of tutorial for each subarea featured and that further more-in-depth reviews would also be carried out within the Symposium structure. We required that the Symposium and the Conference Technical Sessions complement each other. Finally, we decided to set aside a part of each Conference day just for the Symposium so that attendees need not miss any technical sessions nor miss the Symposium because of a technical session. This latter requirement necessitated changing the platform paper length from the customary 20 minutes to 15 minutes to accommodate the anticipated number of papers.

After much consultation, we chose to present 12 one-half hour tutorials covering 12 different areas of bioengineering. Three of the tutorials would be sequentially given each day of the Conference. Concurrent one hour MiniSymposia would immediately follow the tutorials to support each day's three topics. We would attempt to get the best authorities in the world in a given field to come and give tutorials or to participate in the MiniSymposia, whether or not they were IEEE or IEEE/EMBS members.

I must say that neither George nor I could have anticipated the immense interest that such a Symposium idea has had among the medical, scientific and bioengineering communities. Many people called with suggestions for speakers or helped recruit speakers. We have been honored that 40 or so of the world's top authorities have agreed to participate in the Symposium even though we can only offer a few of them full travel support.

Finally, it would be presumptuous of us to assume this Symposium will cover where the entire field of biomedical engineering is going. Many new areas are waiting on the horizon. But, maybe we can look over that horizon by discussing what is critical and emerging in the 12 areas we have chosen to highlight. Time will tell!

Charles J. Robinson, D.Sc., P.E.
Hines, IL USA
24-Sept-86

Symposium Schedule

Friday, Nov. 7

9:00AM **Conference Opening**

Prognostic Tutorials (Gulf Room)
- Surveying Critical and Emerging Issues in:

9:30AM **Biomedical Engineering**, Theo Pilkington, PhD, *Duke University, Durham, NC, USA*

10:00AM **Artificial Organs**, George Pantalos, PhD, *Univ. of Utah, Salt Lake City, UT, USA*

10:30AM **Neuromuscular Systems**, Carlo DeLuca, PhD, *Boston Univ., Boston, MA, USA*

Concurrent Mini-Symposia
-Discussions on Critical and Emerging Issues:

11:15AM **Biomedical Engineering** (Gulf Room)
(Moderator: T. Pilkington, PhD)

* **Biomedical Education**, Bernard Gordon, *Analogic Corporation, Peabody, MA, USA*
* **Biomedical Engineering Education**, Dennis Hill, PhD, *Thames Reg.Health Auth., London, England*

11:15AM **Artificial Organs** (Pacific Room)
(Moderators: G. Pantalos, PhD and Glenn Rahmoeller PhD)

* **New Artificial Devices: From the Laboratory to the Clinic - The Engineer's Role in the Ethics of Experimentation**, Dov Jaron, PhD, *Drexel Univ., Philadelphia, PA, USA*
* **What Data Do We Need in Developing New Artificial Devices?**, Panel Discussion

11:15AM **Neuromuscular Systems** (Great Lakes Rm)
(Moderator: M. Solomonow, PhD)

* **Muscle Receptors and the Regulation of Muscle Contraction**, W. Zev Rymer, MD, PhD, *Northwestern Univ., Chicago, IL, USA*
* **Control of Limb Movement in Amputees and Spinal Cord Patients**, Richard Stein, PhD, *Univ. of Alberta, Edmonton, Alberta, Canada*
* **Human Exercise and Heat Exchange in Thermal Environments**, Michael Sawka, PhD, *U.S. Army Res. Inst., Natick, MA, USA*

Technical Sessions:
1:15-2:45, 3:00-4:30, 4:45-6:15PM

6:30PM **Conference Reception**

Saturday, Nov. 8

7:45-9:15AM **Technical Sessions**

Prognostic Tutorials: (Gulf Room)
-Surveying Critical and Emerging Issues in:

9:30AM **Biosensors**, Michael Neuman, MD, PhD, *Case Western Reserve Univ., Cleveland, OH, USA*

10:00AM **Analysis of Bioelectric Potentials**, Robert Plonsey, PhD, *Duke University, Durham, NC, USA*

10:30AM **Medical Intelligence Consultation Systems**, Casimir Kulikowski, PhD, *Rutgers University, New Brunswick, NJ, USA*

Concurrent Mini-Symposia:
-Discussions on Critical & Emerging Issues:

11:15AM **Biosensors** (Gulf Room)
(Moderator, M. Neuman, MD, PhD)

* **Physical Sensors**, Willy Sansen, PhD, *Catholic Univ Leuven, Heverlee, Belgium*
* **Problems in Chemical Sensor Realization**, Richard Cobbold, PhD, *Univ. of Toronto, Toronto, Ontario, Canada*

11:15AM **Bioelectric Potentials** (Pacific Room)
(Moderator: R. Plonsey, PhD)

* **Analysis of Muscle Bioelectric Potentials**, Eric Stålberg, MD, *University Hospital, Uppsala, Sweden*
* **Quantification of the EEG**, Joseph Bronzino, PhD, *Trinity College, Hartford, CT, USA*
* **Electrocardiology**, Fernand Roberge, PhD, *Univ. of Montreal, Quebec, Canada*

11:15AM **Computers and Instrumentation**
(Great Lakes Room)
(Moderator: J. Bourne, PhD)

* **Medical Models**, Ewert Carson, PhD, *The City University, London, England*
* **Advances in Intelligent Instrumentation**, Janos Sztipanovits, PhD, *Vanderbuilt Univ., Nashville, TN, USA*

12:15-1:15PM **Poster Session**

Technical Sessions:
1:15-2:45, 3:00-4:30, 4:45-6:15 PM

Symposium Schedule

Sunday Nov. 9

7:45-9:15 **Technical Sessions**

Prognostic Tutorials: (Gulf Room)
-Surveying Critical and Emerging Issues In:

9:30AM **Biomaterials**, Robert Ward, *MERCOR, Berkeley, CA, USA*

10:00AM **Electromagnetic Field Interactions With Biological Tissues,** Alan Grodzinsky, PhD, *MIT, Cambridge, MA, USA*

10:30AM **Integrated Monitoring in the Operating Room**, Nick Gravenstein, MD, *Gainesville, FL, USA*

Concurrent Mini-Symposia:
-Discussions on Critical and Emerging Issues:

11:15AM **Biomaterials** (Gulf Room)
(Moderator: R. Eberhart, PhD)

* **Biocompatibility Testing of Materials and Devices for Cardiovascular Use**, Paul Didisheim, MD, *NIHLB Inst., NIH, Bethesda, MD, USA*
* **Conductive, High Charge Density Polymer Electrodes for Neural Stimulation**, Joseph Foos, PhD, *EIC Corp, Norwood, MA, USA*
* **Orthopaedic Biomaterials**, Harold Alexander, PhD, *UMDNJ-NJ Med. Sch., Newark, NJ, USA*

11:15AM **Electomagnetic Interactions**(Pacific Rm)
(Moderator: K. Foster, PhD)

* **Biological Effects of Transmission Line Fields**, Edwin L. Carstensen, PhD, *Univ of Rochester, Rochester, NY, USA*
* **Biological Effects of Radio Frequency Signals**, Om Gandhi, PhD, *Univ of Utah, Salt Lake City, Utah, USA*
* **Hyperthermia**, John Strohbehn, PhD, *Dartmouth Collage, Hanover, NH, USA*

11:15AM **Critical Monitoring** (Great Lakes Room)
(Moderators: S. Blanchard, PhD and K. Cummins, PhD)

* **Automated Record Keeping and Data Management in the Operating Room**, N. Ty Smith, MD, *VA Med Cntr, La Jolla, CA, USA*
* **Intraoperative Electroneurophysiology**, Betty Grundy,MD, *Univ. of Florida, Gainesville, FL, USA*
* **Perinatal Monitoring**, Peter Rolfe, PhD, *Oxford Univ., Oxford, England*

Technical Sessions:
1:15-2:45, 3:00-4:30, 4:45-6:15

6:30PM **IEEE/EMBS Business Meeting**

Monday Nov. 10

7:45-9:15AM **Technical Sessions**

Prognostic Tutorials: (Gulf Room)
-Surveying Critical and Emerging Issues in:

9:30AM **Cardiology**, Glenn Rahmoeller, PhD, *Biomedical Res Inst., Arlington, VA, USA*

10:00AM **Rehabilitation Engineering**, Morris Milner, PhD, *Hugh McMillan Cntr., Toronto, Canada*

10:30AM **Diagnostic Imaging**, Robert F.Wagner, PhD, *FDA, Rockville, MD, USA*

Concurrent Mini-Symposia:
-Discussions on Critical & Emerging Issues:

11:15AM **Cardiology** (Gulf Room)
(Moderator: G. Rahmoeller, PhD)

* **Heart Assist Devices**, David Geseiowitz, PhD, *Penn State U., University Park, PA, USA*
* **Devices Used in Cardiac Electrophysiology**, Philip Reid, MD, *Eli Lilly Inc., Indianapolis, IN, USA*

11:15AM **Rehabilitation Engineering** (Pacific Rm)
(Moderator: S. Levine, PhD)

* **The Manufacturer's Decision on New Products and the Resulting Process**, Barry Romich, PE, *Prentke-Romich Co., Wooster, OH, USA*
* **Clinical Interactions for Effective Technology Implementation**, Hunter Peckham, PhD, *Case Western Reserve Univ, Cleveland, OH, USA*

11:15AM **Imaging** (Great Lakes Room)
(Moderator: S. Orphanodaukis, PhD)

* **Developments in Medical Imaging**, Roland W. Redington, PhD, *GE Corp., Schenectady, N.Y., USA*
* **Picture Archiving and Communications Systems for the Medical Profession**, Samuel J. Dwyer III, PhD, *Univ. of Kansas, Kansas City, KS, USA*

Technical Sessions
1:15-2:45 PM

SYNOPSIS

The major disciplines within the field of Medical Engineering are in a state of flux today. To help define this flux, this special topic **Symposium on Critical and Emerging Issues in Biomedical Engineering** is being held during the Institute of Electrical and Electronic Engineers' Engineering in Medicine and Biology Society's (IEEE/EMBS) 8th Annual Conference in Fort Worth, TX, Nov. 7 -10, 1986.

Both the Symposium, and the Conference itself through its technical sessions, involves national and transnational academic, medical and industrial research leaders focusing on scientific and technical advances, applications, limitations, and problems to be solved in the interactions of the engineering and medical disciplines. Many of the recent advances in medicine have coincided with equally important advances in technology, and emerging areas of technology may well allow marked future improvements. All Symposium papers are published in this Special Proceedings.

The Symposium consists of a series of **12 prognostic** (i.e., forward- looking) **tutorials** and **12 related MiniSymposia**, that focus on the different engineering sciences and technologies that make up biomedical engineering. For each tutorial, a recognized expert forecasts future engineering technologies involved in different areas of biomedical engineering. **The tutorials are spread across 4 days** to provide attendees a good mix of tutorials and state-of-the-art presentations from the technical sessions. **The tutorials do not overlap in time** with any technical sessions, thus giving Conference attendees the opportunity to attend technical sessions in their own track, as well as this "diagonal" Symposium track encompassing the main theme of each technical track. Three 30 minute tutorials are sequentially given during each day's Symposium session, followed by 3 concurrent one hour MiniSymposia.

The Conference technical sessions build on the topics covered in the Symposium and MiniSymposia. Thus, attendees are exposed first to a tutorial overview of a particular field, then to a more detailed overview of 2 or 3 areas within that field, and finally to state-of-the-art detailed technical reviews and invited and submitted technical papers on narrowly defined areas within the field.

The selection of the Critical and Emerging Fields to highlight is of necessity limited by the time constraints brought about by having the Symposium as the central educational focus of the Annual Conference. From a broad list of possible topics, we have chosen to highlight the following areas: Artificial Organs; Neuromuscular Systems; Biosensors; Bioelectric Phenomena; Intelligent Devices, Systems and Models; Biomaterials; Tissue- Field Interactions and Electromagnetic Compatibility; Critical Care and Operating Room Monitoring; Cardiology; Rehabilitation Engineering; and Medical Imaging. In addition, the opening session presents an overview of the future state of Biomedical Engineering, with a MiniSymposium that takes a similar look at Biomedical Engineering Education.

In his or her own way, each Tutorial and MiniSymposium speaker has interpreted differently our charge to focus on critical and emerging issues. Some have taken a historical approach. Some are philosophical. Others have focused on very specific problems in a narrow area. But, all have contributed to the success of this special Symposium. We thank them!

Biomedical Engineering Overview and Education

Theo Pilkington opens the Symposium by presenting an overview and a rather personal viewpoint of where biomedical engineering might be heading. Dr. Pilkington has served for many years as an Associate Editor and as Editor of our Society's Transactions on Biomedical Engineering, so he has seen fields in biomedical engineering evolve from emerging areas to full-fledged subdisciplines. Rather than present hasty speculations, he proposes that a better test of an emerging technology lies in the use of techniques for critical assessment and appraisal. He applies these techniques to the areas covered by this Symposium to take a critical look at the future of biomedical engineering.

Bernard Gordon and Dennis Hill take a critical look at how biomedical engineering education fares in enabling today's bioengineer to cope with emerging issues. As President of a major electronics and medical equipment company, Mr. Gordon presents his challenging views on what industry considers as the critical issues in biomedical engineering education. He discusses why some industry leaders seem not to recognize entry-level Biomedical Engineers as either Engineers or Biologists, and offers his studied solution. Professor Hill's talk illustrates that each country's perception and need for what constitutes a biomedical engineering education is shaped by factors within that country as he relates his views on such education within the United Kingdom. Professor Hill serves as News Editor for the Journal of Biomedical Engineering and Computing and is professionally responsible for all biomedical engineering activities within the N.E. Thames Region.

Artificial Organs

George Pantalos, of the Division of Artificial Organs at the University of Utah draws first upon his association with Dr. Willem Kolff, a pioneer in artificial organs, to give some historical perspectives to the development of artificial organs. Dr. Pantalos then outlines what he feels to be the critical factors needed: a pioneering and persevering spirit; a vigorous commitment by government and industry to funding artificial organ research and development; a willingness to use technologies now in hand if feasible, rather than be sidetracked into developing esoteric new technologies that might yield only moderate improvements in a proposed device; and finally a discussion of the social risks of not employing artificial organs when indicated simply because some risk *per se* is involved.

Dov Jaron of Drexel University draws upon his experiences as an engineer involved in the development of artificial devices to discuss what role an engineer has in the ethics of artificial organ experimentation in the clinical setting. Dr. Jaron points out the detailed steps that must be followed before any medical device can be tried on humans and indicates that such a trial must have the potential to benefit the patient, even though the risks involved may make true "informed consent" difficult to achieve. Dr. Jaron further differentiates two areas where artificial organs are coming into increased clinical use: 1) as a matter of life or death and 2) as providing an incremental or marked improvement in the "quality of life". He notes that an inventor often is stymied in safeguarding the use of his new technology once it reaches the clinician. He suggests that innovators 1) responsibly communicate the new technology, 2) play a role in assessing whether such technology is ready for clinical use and 3) whether such use is appropriate, 4) determine the costs, benefits and risks of the technology, and 5) enlighten our political leaders as to technology's role in medical innovation. A 30 minute panel discussion follows Dr. Jaron's talk in this MiniSymposium.

SYNOPSIS

Neuromuscular Systems

Carlo DeLuca, of Boston University's NeuroMuscular Research Center, presents a very studied and balanced overview of the contributions that biomedical engineers have made toward an understanding of the neuromuscular system, especially in signal detection and processing, modeling and bioelectric control, and electrical stimulation for prosthetic applications. He laments that the field of neuromuscular engineering is still in its infancy, being barely 30 years old, and that confusion exists even today as to what encompasses this subfield of biomedical engineering and what to call it. Dr. DeLuca puts forth an exciting prospectus for the future, but one that requires immediate attention now to a number of basic issues, which he has enumerated, that are slowing future development.

Zev Rymer, Richard Stein and Michael Sawka respectively deal with the analysis, control and quantification of the neuromuscular system. Dr. Rymer, a physician researcher at Northwestern University, focuses on the muscle spindle, the feedback sensing element involved in muscle movement. He points out that these spindles display a complex pattern of linear and non-linear features that pose a challenge to future analysis. Dr. Stein, of the University of Alberta, first describes the muscle "engine" and the control schemes that the nervous system uses during movement in neurologically intact individuals. He next discusses how control can be reapplied to muscles that have been paralyzed by nerve injury, stroke or spinal cord injury and points out where future research is needed. Dr. Sawka, of the US Army Research Institute of Environmental Medicine, quantifies heat production, one of the end products of muscle work, and looks at the gaps where our knowledge of thermoregulatory mechanisms needs to be improved.

Biosensors

Michael Neuman, a physician and engineer from Case Western University, does an outstanding job reviewing the current status and recent advances in the field of biosensors, and then proceeds to address future biosensor needs. Better exploitation of microelectronic and micromachining technology would make possible multiple, redundant biosensors with integrated electronics (and/or optics) that would enhance reliability and reduce size and energy needs. Sensors that directly produce digital output would eliminate the need for costly A/D conversion. Dr. Neuman also forsees the use of biological elements themselves as biosensors. He suggests that as biosensors become more complex, they will need to account for their cross-reactivity to various parameters and to separate out only the significant information. Such an ability is crucial for the development of implantable closed-loop control systems.

Professor Willy Sansen of the Catholic University of Leuven and Dr. Richard Cobbold of the University of Toronto describe recent advances in physical and chemical biosensors, especially in the miniaturization of electronics. They point out that biocompatible packaging remains a critical problem.

Bioelectric Phenomena

Robert Plonsey of Duke University introduces the general topic of the quantification of bioelectric potentials with a detailed mathematical review of the fundamentals that underlie a non-invasive analysis of bioelectric signal sources. His ultimate goal is to be able to infer from these measurements what is taking place at the nerve, organ or tissue source itself. Dr. Plonsey stresses a reliance on these deterministic inverse models rather than on a purely empirical approach. The challenge comes in developing models that are based on sound electroneurophysiological principles.

Eric Stålberg, Joseph Bronzino and Fernand Roberge respectively support Dr. Plonsey's introduction by focusing on the analysis and quantification of electromyograhic (EMG), electroencephalographic (EEG), and electrocardiographic (EKG) potentials. Dr. Stålberg, a clinician from the Department of Clinical Neurophysiology in Uppsala, Sweden, discusses the electrical activity of a motor unit and the use of the EMG in the diagnosis of neuromuscular disorders and in other situations. He feels that collaboration between medical and technical experts in developing new recording, analysis and modeling techniques will result in a better understanding of physiology and pathophysiology, and that important research remains to be done to better understand the relationship between electrophysiological data (the EMG) and mechanical, biochemical, histochemical, and morphological parameters of muscle and nerve.

Dr. Bronzino, from Trinity College in Hartford, CT, highlights the most widely used approaches, and the opportunities presented by on-line microcomputer processing, to quantify the EEG and neuronal activity. He discusses why the automatic extraction of relevant information from a multi- lead EEG, and the ways that this extracted information can be displayed, present a challenge that has only partially been solved. Further, he points out the difficulties in inferring from the EEG where and how the underlying neuronal structures are activated. Finally, he describes techniques used to quantify individual and multi-unit nerve cell activity, and illustrates how such knowledge might ultimately enable one to direct the activity of electronic or mechanical devices which provide assistance to patients.

Dr. Roberge, of the University of Montreal, focuses on recent direct and inverse models that have been developed in cardiac electrophysiology, based on the structure and electrical properties of cardiac tissue, on the bulk conductivity and geometry of the heart-torso system and associated blood masses, and on metabolic and hormonal influences. He suggests that improvements in these models will require a better understanding of electrical events at the cellular level, of action potential propagation, and of extracellular, cardiac tissue and body surface potentials. Improved mathematical techniques are also needed to formulate well defined constraints on any inverse solution and to provide rapid and stable solutions.

Intelligent Devices, Systems and Models

Casimir Kulikowski of Rutgers University discusses why medical consultation systems based on artificial intelligence principles have generally not been commercially successful despite impressive performances. They are complex and not readily interconnected with instruments. Dr. Kulikowski uses as an example of a successful system one for serum protein analysis as he discusses issues in the possible regulation of medical software.

Ewart Carson from London's City University and Janos Sztipanovits of Vanderbilt University respectively discuss interrelated advances in medical modeling and in intelligent instrumentation. Dr. Carson highlights a number of emerging issues in the application of modeling to medicine. He analyzes the role of models in medical research, medical education, open-loop decision support systems, and on-line closed-loop control. He gives a strong argument for inclusion of dynamic models within knowledge-based decision support systems. Over the next few years, he predicts that the major impact of such models will be enhanced by the increasing availability of powerful but inexpensive microcomputers, by better biosensors, and by a better understanding of the human factors involved at the man - machine interface.

Dr. Sztipanovits presents the motives for applying artificial intelligence (AI) techniques in attempting to produce a new generation of bioinstruments and then outlines the basic problems of merging AI techniques with real-time instrumentation needs. He presents an expanded concept of "model" as an essential aspect of AI techniques. This "model" includes structure, constraints and qualitative and quantitative interrelations. He then enumerates some of the new possibilities and problems including 1) the relative incompatibility of AI languages like LISP with real time processing, 2) the need for tight coupling between knowledge- based software and the sensing and processing characteristics of the measurement system, and 3) the need for symbolic representation of system state to permit this coupling.

SYNOPSIS

Biomaterials

Robert Ward, President of MERCOR, Inc (a Thoratec Company headquartered in Berkeley, CA) restricts his tutorial to synthetic polymeric biomaterials, but his comments are germane to all biomaterials. Dr. Ward calls for a better understanding of surface chemistry (including surface dynamics and component segregation), more sensitive analytical testing methods and more realistic real-time in vivo testing, along with an appreciation of a material's "processability". He comments on the mysterious and poorly understood concept of "compatibility" and on the fact that any polymer will be of heterogeneous composition by its very nature and will contain auxilliary additives often unknown to the end user. He sets as needed goals the ability to 1) vary the surface chemistry, bulk composition, and physical and mechanical properties of a polymer to reduce (or enhance) in a predictable way its bioreactivity and longevity, and 2) measure exactly what is happening at the biological interface. Dr. Ward laments that the relatively small commercial market for biopolymers makes it hard to support the expensive research effort that a company must undertake to advance the state of the art. Finally , he states that any effort to improve biomaterials will remain rather empirical without a better knowledge of how blood and tissue components react to the materials they contact.

Paul Didisheim, Joseph Foos and Harold Alexander respectively discuss materials for cardiovascular, neural and orthopædic use. Dr. Didisheim of NIH echoes many of Dr. Ward's concerns. Dr. Didisheim discusses what we now know about the nature of interactions between materials and blood, and puts forth possible reasons: 1) why a standard test of a biomaterial has not yet been devised that adequately predicts problems or failures of a cardiovascular device that uses this material, and 2) to what extent laboratory or animal tests of implant materials might not adequately mimic in vivo responses in humans.

Dr. Foos of EIC Laboratories describes the use of one type of polymer for neural prosthetic applications and the rather stringent requirements for cortical stimulating electrodes. Dr. Alexander of New Jersey's School of Medicine and Dentistry surveys the history of the myriad of materials used in orthopædics. Musculoskeletal tissues are poorly approximated by currently available devices made from homogeneous materials, but engineered composite materials that are now under development promise enhanced biocompatibility. Alexander concludes that some rather unique orthopædic implants could be developed by combining absorbable and non- absorbable matrices with a reinforcing fiber, glass or ceramic material.

Tissue-Field Interactions and Electromagnetic Compatibility

Alan Grodzinsky of MIT presents a tutorial on the controversies involving the beneficial and harmful effects of electromagnetic fields on biological tissue.

Edwin Carstensen of the University of Rochester discusses the difficulties in attempting to determine whether high voltage power lines affect biological organisms and why there is a controversy. Have multiple independent investigators confirmed effects that are proportional to field strength? And, who judges whether the magnitude or nature of a biological effect is cause for concern? Dr. Carstensen puts forth a very reasoned and often philosophical treatment of these controversial questions.

What are safe limits? Om Gandhi of the University of Utah highlights current knowledge on radio frequency electromagnetic absorption and discusses why a frequency-dependent safety standard is being modified to reflect longitudinal absorption anisotropies that can result in excessive heating of the lower limbs.

Electromagnetic energy can also be used for healing. John Strohbehn of Dartmouth College describes the various electromagnetic and ultrasound devices for producing elevated temperatures (hyperthermia) in tumors and reviews current whole-body, regional, and interstitial hyperthermia systems. Computer simulations point out limitations and advantages of both invasive and non-invasive types of these devices. Dr. Strohbehn lists some unsolved problems that require more fundamental theoretical studies and better designs: 1) Can regional hyperthermic systems bring the entire tumor volume to therapeutic temperatures without overheating normal tissue? 2) Can better implantable microwave antennas be developed? 3) Can power distributions be better controlled?

Critical Care and Operating Room Monitoring

Joachim Gravenstein, an anesthesiologist at the University of Florida, begins his tutorial with a caveat: " the technologic developments in anesthesia are outpacing the human operators of anesthesia systems" and then proceeds to review the current practice of anesthesiology. Dr. Gravenstein asks "Where do we go from here?" He challenges designers to produce easily manageable and transparently logical anesthesia systems (rather than individual monitors) that contribute to the safety of patients undergoing anesthesia. These systems must intelligently integrate pharmacokinetic and physiological models, drug delivery systems and monitors into a cohesive unit that permits the anesthesiologist easy control of all components.

Ty Smith and Betty Grundy are also anesthesiologists. Dr. Smith, from the San Diego VA Medical Center and the University of California at San Diego, expands on Dr. Gravenstein's concerns as he discusses the complexities and politics of record keeping and data management in the operating room. He describes the development of an automated anesthetic record (AAR) system that must account for the type of surgery being performed, physiological variables, bolus or continuous infusions of drugs (and identify the drugs and their pharmacokinetics), settings on anesthesia machines and ventilators, and preanesthesia and medical history. He suggests that voice entry is an attractive feature and feasible.

Dr. Grundy, a coworker of Dr. Gravenstein, concentrates on neurological monitoring in the operating room and critical care unit. The extremely small potentials involved in electroencephalic and evoked potential (somatosensory, brainstem auditory, and visual) recordings make intraoperative monitoring difficult and their variability makes diagnosis and tracking difficult even under the most ideal of conditions. Equipment is fickle and cumbersome. Dr. Grundy compares the present state of neurophysiological monitoring with that obtained with cardiovascular monitoring of a few decades ago. She suggests that we need to know how much change in a recorded signal is acceptable.

Peter Rolfe of the University of Oxford discusses perinatal monitoring as another area of critical care monitoring. Dr. Rolfe points out the differences in the approaches taken by developed versus developing countries, where low-cost, appropriate technology could have a major impact in maternal and perinatal mortality and morbidity. He lists techniques for assessment of fetal growth and development and for detection of fetal distress during labor and points out that the high maternal post-partum mortality seen in some countries could probably be significantly reduced if a simple means of detecting maternal anemia during pregnancy were available. He describes impressive technological tools for management of the premature neonate, but again points out that developing countries often lack simple incubator facilities. Thus, Dr. Rolfe sees sharply contrasting challenges facing the bioengineer in perinatal monitoring. While technological advances are still needed and will continue to reduce mortality in developed countries, a more difficult challenge for bioengineers might well be to produce reliable, low-cost, socially acceptable aids for use in developing countries.

SYNOPSIS

Cardiology

Glenn Rahmoeller, from the Biometric Research Institute in Arlington, Virginia, surveys past and present developments in cardiovascular devices and looks at future directions where challenging engineering problems must be solved. Dr. Rahmoeller traces the miniaturization and increasing sophistication of pacing devices, noting that significant needs remain: 1) dual but interactive and physiologically correct atrial and ventricular pacers are needed that can respond to a wide variety of conditions including exercise, 2) algorithms for exhaustive testing of all programmable parameters are needed to insure that certain parameter sets do not produce unsafe conditions, 3) physician education is needed in differentiating device malfunction from uncommon physiological situations, and 4) the design and appropriate life testing of pacing leads are needed. Dr. Rahmoeller next applies a similar survey to heart valves and finds: 1) still no well tested procedures to define and correlate in-vitro wear, fatigue, and hydrodynamic accelerated testing with long-term clinical results, 2) no ideal artificial heart valve, free of thromboembolic or calcifying complications, and no way to predict whether changes in a design will reduce or promote these complications, and 3) no non-invasive way to diagnose incipient failure, especially that of catastrophic mechanical valve failure. Dr. Rahmoeller lastly discusses artificial total hearts and left ventricular assist devices and feels that the engineer will become more involved in making risk-benefit analyses for these devices.

David Geselowitz of Penn State University next concentrates on mechanical heart assist devices, while Philip Reid, executive director of Eli Lilly and Company, focuses on one of the newest innovations in electrical heart assist devices, an implanted device to treat ventricular tachyarrhythmias. The new electrical devices discussed by Dr. Reid represent a significantly more aggressive intervention, since the device must slow or convert rather than speed up the rhythm, and failure to do so properly could cause the arrhythmia to continue or worsen. Dr. Reid describes results suggesting that implantable defibrillators can significantly improve the survival of certain classes of patients who are at high risk for recurrent tachyarrhythmias.

Rehabilitation Engineering

Morris Milner, of Toronto's Hugh MacMillan Medical Centre, reviews the many facets of rehabilitation engineering and lists these critical issues: consert of services, education of engineers and other disciplines as to what is rehabilitation engineering and what can be accomplished, effective collaboration, economics and funding of rehabilitative engineering devices, documentation of clinical achievements and transfer of technology to the industrial sector. Dr. Milner discusses emerging issues in: 1) postural support, seating systems and personal transportation; 2) augmentive and alternative communication and sensory aids; 3) prosthetics and orthotics; 4) robotics; 5) service delivery including community, rural and third world concerns; and 6) quantitative assessment of the extent of disability.

Barry Romich, President of the Prentke Romich Company, and Hunter Peckham of Case Western Reserve University both deal with problems of technology implementation for the rehabilitation field. Mr. Romich describes the manufacturer's perspective of rehabilitation technology transfer from the laboratory to a commercial product as well as some of the problems inherent in this process. Hunter Peckham voices the need for strong clinical interactions (as a necessity) and for graduate student involvement (as an excellent learning opportunity) in the development of any new rehabilitation device or procedure.

Medical Imaging

Robert Wagner, from the Food and Drug Administration, attempts to find unifying questions that cut across all the modalities of diagnostic imaging. Dr. Wagner reviews the various measurement techniques (X-ray, MRI and Ultrasound) and the stochastic and deterministic errors in each. He suggests that one should consider the interdependence and variability of these measures to determine which technique(s) are optimum for a given diagnostic task, thereby potentially reducing the number of tests to which a patient might be subjected. He elegantly proposes that a statistical decision theory analysis of the vector feature space of each technique, alone or in combination, is an emerging area for future fruitful research.

Roland Redington from General Electric's Corporate R&D Center describes recent developments in Magnetic Resonance Imaging (MRI) and on *in vivo* NMR spectroscopy. Dr. Redington details magnetic resonance physics and signal-to-noise ratio considerations as he presents some of the technical problems that remain to be solved in the near term. As for long range developments, electronic radiography that yields chest-size images remains an elusive goal.

Samual Dwyer, of the University of Kansas, tackles another problem that has accompanied the marked utilization of medical imaging techniques -- how to archive the resultant images. Dr. Dwyer points out possible electronic solutions for archiving images that have as an added benefit the ability to transmit these images without hardcopy. He discusses potential problems with this approach.

REVIEW PAPERS WITHIN the TECHNICAL SESSIONS

The issues raised in this Symposium are further reinforced by a number of reviews that occur during Technical Sessions themselves. These reviews are listed below.

Artificial Organs and Cardiology

Cardiac Engineering has always been a strong component of the Annual EMBS Conferences and this year is no exception, thanks in large measure to the efforts of the Cardiology Track Chair, Dr. Glenn Rahmoeller. A number of session chairs have organized special sessions dealing with the latest advances in:

- **Cardiovascular Imaging.** (1.010, Friday at 1:15 PM, organized by N. Bom of The Netherlands)
- **Using Lasers in Cardiovascular Surgery.** Dr. James Livesay, a surgeon from the Texas Heart Institute in Houston, presents an "Overview of Lasers in Cardiovascular Surgery" and chairs a panel discussion on the same subject (papers1.021 & 1.024, Friday at 3:00 PM).
- **Pacing Leads.** (1.030, Friday at 4:45 PM, organized by Stan Saulson)
- **Left Ventricular Assist Devices and Artificial Hearts.** (1.070, Saturday at 3:00 PM, organized by Peer Portner).
- **Pacing and Pulse Generators.** (Session 1.080, Saturday at 4:45 PM, organized by Edwin Duffin).
- **Heart Valves.** (Session 1.100 & 1.110, Sunday at 1:15 & 3:00 PM). At 4:00 PM, Dr. Glenn Rahmoeller leads a 30 min round table discussion on the prediction of clinical performance of heart valves from in-vitro test results.
- **Innovative Cardiac Research by Small Businesses.** (1.120, Sunday at 4:45 PM, organized by John Watson).
- **Defibrillation.** (1.160, Monday at 1:15 PM, chaired by Philip Reid).

Other Tracks contain additional sessions of interest to those in Cardiology Research. On Friday afternoon from 1:15 to 6:15 PM, there are 3 sessions (2.010, 2.020 & 2.030) on the EKG; and on Sunday at 7:45 AM, a session (8.090) on Intraoperative Cardiac Mapping. Magneto-cardiographic techniques are reviewed in a 30 min paper (2.121) on Sunday at 3:00 PM.

Analyses of Bioelectric Potentials and of Neuromuscular Systems, including Biophysics

Another focus of the Annual Conferences has been the analysis and quantification of bioelectric phenomena and neuromuscular systems, including EKG, EEG, EMG, and underlying sources, system analyses of control strategies that are used, clinical diagnoses that can be made, and augmentative actions for coping with pathologies. Track Chairs Robert Plonsey, Joseph Bronzino, and Moshe Solomonow have overseen the development of sessions dealing with:

- **EKG.** Platform Sessions 2.010, 2.030, 2.040, 2.070 on Friday and Saturday afternoons deal with the EKG. Platform sessions 2.060, 2.120 and 2.130 on Saturday morning and Sunday afternoon contain many papers dealing with techniques for impedance mapping, a technique that helps set down a rational basis for solving calculations of actual cardiac source behavior from surface EKG measures.
- **EMG.** A special review session (2.080, Saturday at 3:00 PM) on the latest techniques and theories about needle EMG has been organized by S. D. Nandedkar of Duke University. Platform sessions on other aspects of the EMG are held on Friday afternoon (3.010, 3.020, 3.030). Sessions 3.070 on Saturday and 3.080 on Sunday integrate EMG's and biomechanics.
- **EEG.** Dr. Joseph Bronzino of Trinity College reviews spectral analysis approaches to EEG ontogeny (paper 2.091, Saturday at 4:45 PM). EEG's are also treated in sessions 2.100 and 2.140 on Sunday and Monday mornings.
- **Biomagnetism.** Dr. Gideon Kantor of the FDA has organized special reviews of biomagnetism, beginning with Professor Williamson's 30 min review (paper 2.111) at 1:15 PM on Sunday. Dr. Katila from Finland presents another, shorter review (2.115) in the same session. Dr. Gerhard Stroink of Dalhousie University reviews magneto- cardiographic techniques (30 min paper 2.121 on Sunday at 3:00 PM).
- **Systems Analysis of Neuromuscular Control.** Dr. Micheal Rosen of MIT has assembled a session (3.060) quantifying neuromuscular control; Dr. Roger Glaser of Wright State has done likewise for human performance (3.050). Session 5.150 on Monday afternoon treats neurological devices and models especially as they relate to the visual and oculomotor systems.
- **Neurophysiology and Neurology.** Dr. Roger Gaumond of Penn State has organized a session (2.020) dealing with the automation of data collection in the neurophysiology laboratory (Friday at 1:15 PM). Three sessions (8.100, 8.110, 8.120) in the Critical Care Track treat intraoperative neurological monitoring.
- **Biophysics.** Dr. J. J. McArdle has assembled an international set of speakers for his sessions (6.010, 6.020 & 6.030) on Biophysics and is presenting a review (paper 6.011) on Friday at 1:15 PM.
- **Postural Stability.** Dr. Gerald Harris presents a 30 min review (paper 11.011) of current models of postural stability at 3:00 PM on Friday . This session (11.010) and the next one (11.020) dealing with postural stability also feature an international list of invited experts.

Intelligent Devices, Systems and Models

The title of this category is somewhat of a misnomer; however it does sum up the fact that more and more decision-making capabilities are being built into the instruments that we design and use and the systems we develop, or are being inferred from the models we construct. Track CoChairs Janos Stzipanovits and Ewart Carson have combined their expertise to develop quite a strong group of sessions that encompass:

- **Models.** David Ingram from London reviews the use of physiological simulation models in medical education (paper 5.011, 1:15 PM Friday) and the rest of this session organized by Dr. Ingram deals with other models in medical education. Derek Linkens presents a session (5.020, Friday at 3:00) on models for on-line control and chairs a Sunday session (5.100) on models in cardiology and respiratory care. R.L. Flood discusses medical research models as educational tools (paper 5.111). Ewart Carson's sessions (5.110 & 5.120) on models in clinical research follow on Sunday at 1:15 PM and 3:00 PM.
- **Computer-Aided Decision Making Systems.** Torgny Groth from Sweden reviews decision support systems in the clinical laboratory setting (paper 5.061, Saturday at 1:15 PM), followed by sessions 5.060 & 5.070 at 1:15 and 3:00 PM. Lucien Duckstein's session (5.050) on knowledge-based image processing for aiding diagnosis is on Saturday at 7:45 AM.
- **Measuring Systems and Devices.** Ewart Carson of London opens the session (5.080) on intelligent measuring systems with a look towards intelligent measurement in critical care medicine (Paper 5.081, Saturday at 4:45 PM). Janos Sztipanovits has assembled 6 international speakers for his session on intelligent devices.

REVIEW PAPERS WITHIN the TECHNICAL SESSIONS

Imaging

The mix of papers submitted to this Conference in the field of medical imaging falls into two categories: those that deal with a specific device (X-Ray, CT scan, MRI, ultrasound, etc.) and those that deal with general image processing techniques. Ultrasound is covered in Saturday afternoon's sessions 7.030, 7.040 & 7.050. Image processing techniques are covered in Sunday sessions 7.060 through 7.090. MRI is discussed in two Monday sessions (7.100 & 7.110) and a late Saturday session (7.050).

Critical Care and OR Monitoring

Track CoChairs Susan Blanchard of Duke University and Ken Cummins of Nicolet have organized an outstanding series of papers dealing with intraoperative monitoring. Peter Rolfe of England has done likewise for the perinatal monitoring area. The Critical care area can be subdivided into:

- **OR Monitoring.** The rapid proliferation of monitoring devices in the operating room has the potential to confuse those involved in monitoring a patient's safety. Roy Wallen of Hewlett-Packard opens the series of sessions on critical care in the OR with a discussion of some integrated solutions for the operating room (Paper 8.051, Saturday morning). Bill Paulsen has included this paper in his session (8.050) on anesthesia monitoring in the OR. William Smith of Duke reviews intraoperative cardiac mapping techniques (paper 8.091) in Susan Blanchard's session (8.090) of the same title (Sunday AM). J.R. Boston, Art Sherwood and Joel Mykelbust have assembled an impressive list of speakers for their sessions (8.100, 8.110, 8.120) on EEG, evoked potential and neurological monitoring in the OR and ICU (Sunday afternoon).
- **Perinatal Monitoring.** Sessions 8.010 (Friday at 1:15 PM, organized by Peter Rolfe), 8.080 (Saturday at 4:45 PM), 8.130 and 8.140 (Monday) deal with perinatal monitoring. Michael Carter from London reviews the current state of electronic fetal monitoring on Monday afternoon (Paper 8.141).
- **Sleep.** Anne Cornwell's two sessions (8.020 & 8.030) on sleep research detail the current findings in this area (Friday afternoon).
- **Respiratory Care.** Three sessions on Saturday afternoon treat respiration (8.060, 8.070 and 8.080).
- **Space.** William Crosier chairs a session (8.150) dealing with the special topic of monitoring in space (Monday afternoon).

Electromagnetic Interactions with Biological Tissue

Ken Foster of the University of Pennsylvania has structured a strong 12 session track on biological effects of electromagnetic and acoustic fields. These sessions reflect two concerns. On the one hand, these fields are specifically used in a controlled fashion to destroy tissue (as in hyperthermia treatments for cancer). In other instances, it is still unknown just how safe low levels of electromagnetic energy are.

- **Biological Effects.** Charles Polk of the University of Rhode Island has organized two special review sessions (9.010 and 9.020) dealing with the effects of static and low frequency electric and magnetic fields at the cellular level, with a panel discussion scheduled for 4:00 PM on Friday. Support for these sessions is pending from the Office of Naval Research. Robert Lebovitz opens Om Gandhi's session (9.110) with a detailed review of the quantitative behavioral effects of microwaves (paper 9.111, Sunday at 3:00 PM).
- **Hyperthermia.** Hyperthermic techniques are discussed in a number of sessions on Saturday and Sunday. Gilbert Nussbaum has formed a special in-depth review session (9.080) on externally induced EM hyperthermia. Dr. Hynynen's session (9.060) deals with ultrasound hyperthermia while Dr. Trembly's session (9.070) treats interstitial hyperthermia. Tillman Saylor's (9.100) looks at thermal dosimetry.

Biosensors, Biomaterials and Biomechanics

Banu Onaral of Drexel and Robert Eberhart of the University of Texas, Arlington have respectively structured the biosensors and biomaterials tracks. Allen Tencer heads the biomechanics track. Two sessions (12.010 and 12.020) on Saturday present papers on biosensors. Sessions dealing with neurological (13.030), orthopaedic (13.040) and cardiovascular (13.050) biomaterials are scheduled for Sunday afternoon. Other aspects of biomaterials are featured in Saturday's two sessions (13.010 and 13.020). The biomechanics sessions (10.010 and 10.020) are on Monday.

Rehabilitation Engineering and Neuromuscular Rehabilitation

Simon Levine of the University of Michigan has organized a strong set of sessions in rehabilitation dealing with: quantification of performance (sessions 16.020 and 16.070 on Sunday and Monday mornings), prosthetics (Monday sessions16.060 and 16.080), computers and intelligent aids (Sunday sessions 16.030 and 16.040), and the biomechanics of seating and posture (Sunday session 16.050).

Bioengineering in Third World Countries

As Peter Rolfe points out in his MiniSymposium address on critical perinatal care, perceptions of what biomedical engineering is must be changed when looking from the aspect of a developing country. Our International Chair, Swami Laxminarayan of New Jersey has combined with T. G. Krishna Murthy of India to introduce a new area to the Conference that deals with health care delivery in third world countries. They begin their Saturday afternoon sessions (15.010 through 15.030) with a review (paper 15.011). Dr. Srinivasan has organized one of these sessions (15.030) to deal with alternate therapies. We are honored to have two officers of the World Health Organization review the problems and participate in a panel discussion on Sunday afternoon (15.040).

ACKNOWLEDGMENTS

This Symposium is partially supported by the National Science Foundation under Grant No. ECE-8608945. Pending NIH participation in the support of this meeting would be under grant # 1 R13 HL37253-01 from the National Heart, Lung, and Blood Institute.

Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the National Science Foundation, the National Institutes of Health, the IEEE, or the Engineering in Medicine and Biology Society.

We would be remiss if we did not also acknowledge the yeoman (and unpaid!!) effort put into this Symposium by our secretaries and proof readers Vickie Zweisler, Andrea Gonzales, Anita Hoffpauer and Rosemary Robinson. They really made it all come about.

A number of companies and institutions have helped underwrite the cost of this Symposium either through grants to the Conference or by picking up some of the travel and lodging costs of their employees who are participating in this Symposium. We thank the following (and apologize to any we have missed):

Nicolet
Trinity Computing
Hewlett-Packard Waltham Division
Neurosciences Inc.
General Electric Company
Analogic Corp.
Journal of Medical and Biological Engineering and Computing
Liberty Mutual Insurance Co.
Vanderbilt University
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EIC Laboratories, Inc.
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Hugh MacMillan Medical Center
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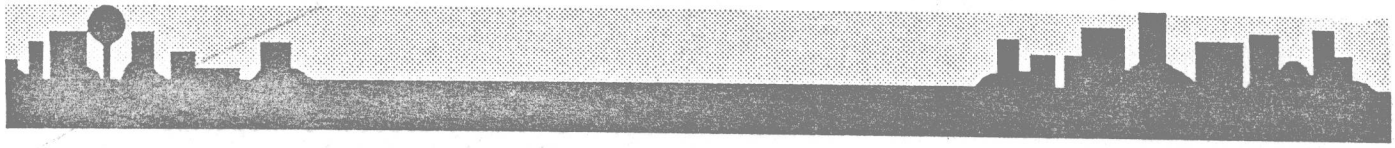

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CRITICAL AND EMERGING ISSUES IN BIOMEDICAL ENGINEERING

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ABSTRACT

This lecture will attempt to apply some methods of basic technology assessment to evaluate critically the potential of twelve emerging areas of biomedical engineering: artificial organs, neuromuscular systems, biosensors, analysis of bioelectric potentials, medical intelligence-data bases, biomaterials, electromagnetic field interactions with biological tissues, integrated monitoring in the operating room, cardiology, rehabilitation engineering, imaging, and biomedical engineering education.

INTRODUCTION

This 8th Annual Conference of the IEEE Engineering in Medicine and Biology Society will present a series of 11 prognostic tutorials surveying critical and emerging issues in artificial organs, neuromuscular systems, biosensors, analysis of bioelectric potentials, medical intelligence-data bases, biomaterials, electromagnetic field interactions with biological tissues, integrated monitoring in the operating room, cardiology, rehabilitation engineering, and imaging. The purpose of this lecture is to present an overview and a rather personal viewpoint of biomedical engineering with particular emphasis on the eleven areas listed above and on biomedical engineering education.

TECHNOLOGY ASSESSMENT

It is my belief, based on about a decade of active involvement with the IEEE Engineering in Medicine and Biology Society (EMBS), biomedical engineering accreditation activities, University biomedical administration, and my personal research, that most of us and the EMBS have been more interested in cheerleading than assessing critically where we are and allowing the results of this assessment to guide us forward with creative vision. This is understandable because the cheerleading is rather easy and fun if the team is "moving forward," and we have been moving forward, while critical assessment requires analytic and inventive thinking and can imply major changes in present activities.

It seems that a major function of a professional society is to provide a dynamic and continuing forum where answers to tough questions about where the profession is or should be going can be evolved. Thus, in this lecture I want to encourage moving actively into the arena of critical assessment and appraisal as opposed to hasty speculation. However, I would like to confess at the start that it can be very difficult to discern which of these two very different roads we are traveling.

As a start in this direction, I will ask each of the prognostic tutorial lecturers to answer three questions which have been suggested by Emerson Pugh [1] as a first order basis for technology assessment.

(1) What, primarily, will govern the rate of progress?

(2) What are the ultimate or practical limits to progress?

(3) Given that the rate of progress cannot be predicted precisely, can we predict the relative rate for two or more competing technologies?

In examining technology assessment as a technique for assessing the future importance of an area of biomedical engineering, we should be fully aware of suggested guidelines and limitations of utilizing such an approach. Pugh has suggested the following general rules.

"First, it is important to identify critical features determining the short-term and long-term success of each technology under consideration. These should be separated into features in common and those which are unique ... If few experimental data are available on the unique features, the study can only identify them as elements of risk. Future research should be directed to acquire the needed information...

"It should be stressed that a simplistic approach to technology assessment is only a starting point. All common features must be treated with care to assure the equivalence of their use, and proper assessment of the unique features requires detailed technical knowledge...

"The most critical factor in the practice of technology assessment is assuring that experts in all technologies under study are involved and committed to the success of the study...

"Finally, it should be noted that the decision process following a technology assessment is not as simple as the preceding narrative may imply. Many issues beyond those analyzed in the assessment are likely to influence the decision... A requirement of a good technology assessment is therefore that it identify what is analyzed, what is not, and why. It should clearly state the limits of knowledge and the uncertainty in judgments presented ... Few technologists are without views on related matters, but the credibility of an otherwise good assessment can be lost by delving into subjects beyond its appropriate bounds.

EVALUATIONS AND CONCLUSIONS

After presenting the answers provided by the prognostic tutorial lecturers to the three technology assessment questions and my interpretation of the implications of these answers, I shall attempt to use technology assessment to take a critical look at the future of biomedical engineering education.

References

1. E. W. Pugh "Technology Assessment," Proc. of the IEEE vol. 73, No. 12, pp. 1756-1763, 1985.

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