FROM BASIC CONCEPT TO CLINICAL USE

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Biomedical engineering, or the application of the principles of engineering and the physical sciences to the solutions of health problems, is now recognized as an important entity. Some aspects merge with overlapping fields with similar names such as bioengineering, medical engineering, biomechanics, and human factors. Committees of the National Academy of Engineering and other groups, divisions of existing societies, and special societies here and abroad have been formed to promote exchange of information and to carry out specific programs. Special journals are available, many conferences concerning one or more aspects of this broad subject are held each year, and biomedical engineering in various forms is receiving increasing attention not only in universities, as Dean Ragazzini and Mr. Contini discussed in the past issue, but in government and industry.

There is a great deal of concern about the effectiveness of effort in this rather new interdisciplinary field, with expressions of impatience with delays in acceptance of new developments, as exemplified in a recently published report of the United States Senate.[a]

Possibly encouragement may be found in a specific example, the "Artificial Limb Program," a pioneering effort in the field of biomedical engineering, initiated in 1945 by the National Research Council at the request of the Surgeon General of the Army. The Artificial Limb Program has unquestionably revolutionized its field, and, though constant self-examination emphasizes that much remains to be done, observations on history and on common factors may help efforts in other areas of biomedical engineering.

At the outset of the program, it seems to have been the consensus that the problems associated with artificial limbs were primarily engineering problems. All that seemed needed was for the surgeons and physicians to tell the engineers what kind of knee joint or artificial hand was required and for the

[a] Research in Service to Man, Hearings before the Subcommittee on Government Research of the Committee on Government Operations, United States Senate, Ninetieth Congress, First Session, on Biomedical Development, Evaluation of Existing Federal Institutions, Feb. 28, Mar. 1, 2, 3, and 16, 1967 (83–470).

engineers to design and build it. However, the fallacy of this concept was revealed in the very early stages when it was discovered that neither group could develop design criteria without assistance from the other. Clarification of talents each could contribute led to sound cooperation. With greater understanding, there was less risk of gadgeteering design with inadequate fundamental data. Conversely, closer touch with clinical practice reduced the danger of prolonged academic research on imagined problems before transition into trials on patients.

A comprehensive study of functions of the human lower extremities, for example, was undertaken by a team of surgeons and engineers in order to gain a better understanding of the functions lost as a result of amputation at various levels. Design of components was carried on simultaneously, results were compared with data accumulated in the fundamental studies, and refined design criteria were developed. Trials on increasing numbers of amputees led to frequent iteration through redesign and reevaluation until, with patience, useful items emerged.

Experience with above-knee suction sockets brought about the realization by both professions that the connection between man and his prosthesis is the foundation for any success that is to be achieved in prosthetics. The traditional skills of the limb maker were supported by increasing understanding of anatomical and biomechanical principles of fitting and alignment. At this point the "Artificial Limb Program" began to emerge as a true interdisciplinary team effort.

It was also recognized that the successful completion of a research and development project did not insure that the results would be applied to patients that needed them. In order to accelerate the introduction of new devices and techniques into application in the field, formal education programs for clinical teams were established in three leading universities. These programs have proven to be very successful and today there exists a truly coordinated program made possible by interdisciplinary teamwork.

As a result of the integrated research, development, evaluation, and education program, nearly every aspect and detail of the management of amputations and amputees has been changed. The practice of limb prosthetics is entirely different from the practice two decades ago. Prosthetists spend more time with patients and less time in lengthy manual tasks. Prefabricated parts, especially of the new designs, are very widely used.

Amputation techniques have been improved. Surgeons no longer discharge patients as soon as the wound is healed, but follow the course of the patient through fitting and training. More functional devices are available so that the patient has a much better chance of realizing his potential. Hospital time has been reduced as well as time for the total rehabilitation process. Indeed the general attitude of the medical profession toward ampu-

tation and rehabilitation of the amputee has taken on a much more positive character.

Today it is possible for the amputee to receive a temporary artificial leg in the operating room immediately after surgery and to begin ambulation the next day. It is not unusual for the patient to be discharged from the hospital before the end of the first week and receive a "permanent," or definitive, artificial leg three or four weeks after amputation. This concept in its very early experimental stages was introduced from Europe late in 1963. Teamwork on the part of surgeons, prosthetists, and engineers in the Artificial Limb Program in developing and perfecting methods of treating amputees at all levels made it possible to offer formal instruction in this technique in the spring of 1967. Now, one year later, some 150 teams of surgeons and prosthetists have been trained, and in many parts of the country fitting of prostheses immediately after surgery is routine.

For the first decade the Veterans Administration carried nearly all of the financial burden for the program. Now other government agencies, notably the Social and Rehabilitation Service and the Children's Bureau, the organizations which are responsible for rehabilitation of nonveterans, also have authority from Congress to support research, and it has been possible to expand the Artificial Limb Program to include orthotics—a closely allied field which also calls for a combined effort by the medical and engineering professions if progress is to be made. Already, a number of the principles developed in the study of limb prosthetics have been applied to orthopaedic bracing to advantage.

It is an almost universal rule that research uncovers more questions than it answers; that the more one learns about a subject, the more he realizes how little he actually knows. This generalization certainly applies to research in limb prosthetics and orthotics. With this attitude, however, it is expected that workers in these fields of biomedical engineering will gradually bring about further revolutionary improvements in the treatment of individuals with musculoskeletal deficiencies.