The Objectives of the Lower-Extremity Prosthetics Program

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Man depends upon his legs to support the body and to move it from place to place as occasion warrants. Since mobility is nearly indispensable to most human activities, the loss of part or all of a leg—through accident, war, or disease—imposes serious limitations and has always made a replacement of some sort more or less of a necessity. Accordingly, artificial legs of one kind or another have been made and used since the most ancient times. As a result of the long-continued effort, leg prostheses have undergone progressive, if slow, development through the centuries, so that many lower-extremity amputees have in the past been successfully restored to something resembling a normal life. With the advent of industrial development, and of improved tools and materials with which to work, the nineteenth century marked the appearance of many new lower-extremity devices and of new techniques in the medical treatment of amputations.

Impetus provided by World Wars I and II gave rise to rapid advancement in all branches of technology and thus made possible a concerted attack on the problem of supplying the best possible artificial limbs. The term "lower-extremity prosthetics" has now come to mean the practice of rehabilitation of the leg amputee by providing him with an artificial limb that will restore lost functions to the greatest possible degree. But more than just the artificial leg is involved. The amputee himself is a most important part of the end-product, and amputees, like other people, are individuals with widely differing characteristics and abilities. Of course surgical procedures should be designed to secure a painless stump and to retain maximum function, and it would seem that the artificial leg, when properly fitted, should duplicate as closely as possible the normal activity of the lost part. Moreover, physical conditioning and gait training are both important phases of the whole rehabilitation process.

This concept of lower-extremity prosthetics has developed during the years since the start in 1945 of the program of the Advisory Committee on Artificial Limbs, National Research Council. Initially, the primary objective was to develop improved devices, it being considered as obvious that, if a better prosthetic knee or ankle or foot could be devised, the amputee would benefit. Attempts to produce such items, however, made necessary the determination of functional requirements and thus immediately revealed the lack of necessary fundamental information. Basic research into the complicated phenomenon we call "locomotion" was therefore carried on simultaneously with the development of devices. These investigations indicated a need for the application of basic mechanical principles to fitting and alignment of artificial legs. A three-

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A more logical and systematic approach, had there been sufficient time, might have been to postpone device development until the results of the basic work became available. But the urgency of amputee demands at the end of World War II made such an approach less desirable than the one adopted.
pronged approach, all parts of which are complex and interrelated in various ways, has thus evolved. Basically, the three objectives are:

1. To extend knowledge of the amputee, of lost and remaining functions affecting locomotion, and to collect information on the best possible medical treatment.
2. To improve fitting techniques and practices, including training, so that existing devices might be used with greater comfort and function.
3. To develop improved lower-extremity devices.

Relative emphasis on these three phases is shown in Figure 1. Implied in such a program is the dissemination of information and techniques to those who serve the amputee. Many of the accomplishments to date are recorded, and fully documented with the report literature, in Klopfsteg and Wilson's *Human Limbs and Their Substitutes* (McGraw-Hill, in press). In addition, various seminars and short courses for surgeons and prosthetists have been conducted throughout the program.

**FUNDAMENTAL STUDIES**

Detailed and comprehensive study of normal human locomotion is the basic key to improvement in all phases of the lower-extremity problem. Walking is to all appearances so natural and simple a process that it is difficult to conceive of its complexity. A knowledge of the behavior and the contribution of each anatomical part in providing the many services required of legs in normal use is essential to determine the functions that have been lost through amputation and the functions that still remain. The surgeon needs such information in order to provide the best amputation stump with maximum remaining function. The prosthetist must understand the limitations and potentialities of the amputee-prosthesis combination for optimum fitting, alignment, and adjustment. The designer needs detailed information on angles, displacements, velocities, accelerations, forces, energy requirements, and functions in order to improve existing devices and to develop new ones. And finally, the amputee himself has problems that require a fundamental approach. Causes and treatment of phantom or other pain, circulatory difficulties resulting from amputation, skin tolerance to pressure in areas never intended for such use, as well as the better understanding of the psychological problems of the amputee are examples of important areas of investigation.

The objectives of the program of fundamental studies of the lower extremity may be summarized as:

1. To study the phenomenon of locomotion in a sample of normal individuals and to analyze the results for use by the surgeon, the designer, and the prosthetist.
2. To develop design criteria for new or improved devices and as a basis for evaluating existing devices.
3. To develop an understanding of the compensatory mechanism of the human body and its ability to adapt itself to overcome functional deficiencies of its parts.
4. To provide a frame of reference for evaluating the degree of success obtained in replacing lost functions by means of an artificial leg.
5. To obtain information on the cause and possible
treatment of phantom pain and other medical problems of the amputee.

DEVELOPMENT OF TECHNIQUES OF FITTING AND ALIGNMENT

It appears obvious that, no matter to what degree an artificial leg is perfected mechanically, its effectiveness will depend upon the comfort afforded the wearer. Comfort is a function of the fit and alignment of the prosthesis.

Although the artificial-limb industry has, through the years, developed reasonably successful techniques for fitting and aligning artificial legs, the results have been obtained mostly by trial-and-error methods; seldom have basic mechanical and anatomical principles been employed. It was found, for instance, that even among the most successful prosthetists there existed little agreement as to what constituted a satisfactory fit. For these reasons it appeared necessary to include in the lower-extremity program a project to develop fitting and alignment techniques based on sound scientific principles and to include, if necessary, the development of auxiliary tools and a study of materials and methods of suspension.

The study was launched with the following objectives in mind:

1. To learn from the artificial-limb industry the procedures used in fitting and alignment of artificial legs.
2. To work with the industry in applying fundamental principles to the problem of fit and alignment and to formulate the guiding principles involved.
3. To develop mechanical aids to improve fit and alignment and to serve as tools to simplify shop operations.
4. To investigate and evaluate types of suspension as well as materials and methods used in socket fabrication.
5. To develop simplified methods of evaluating the amputee-limb combination—to be used as a check by the prosthetist, the surgeon, and the physiotherapist.
6. To improve methods of training the lower-extremity amputee in order to get better functional and more effective use of his prosthesis.

Out of this study came such developments as the introduction of the above-knee suction socket (page 29) and the University of California adjustable legs and alignment duplication jig (page 23). The study of fitting and alignment continues at the University of California, Berkeley Campus.

DEVELOPMENT OF PROSTHETIC DEVICES

New and improved devices have always been a major objective of the ACAL program. Great effort has been expended in this direction, often without the necessary or valid criteria. Although engineering designs can be made to accomplish nearly any specified function, the end result of any given design may be unsatisfactory if the specifications were unrealistic. The device may be too complicated, too heavy, uneconomical for the improvements obtained—or it may actually interfere with some service functions though improving others. Since the beginning of the ACAL research program, a number of outstanding industrial firms have engaged in development of devices. As a result of these activities, a great deal has been learned about what is possible—and about what not to do. Together with the fundamental studies, a body of knowledge has been developed to provide a realistic approach to design criteria. A number of devices based on this information are now in the development stage; they show promise for the future.

Criteria for improved knee joints for above-knee amputees have undergone great changes as fundamental knowledge of locomotion has increased and as various knees, alleged to be improved ones, have been tested on amputees. Similarly, dependence of knee performance on ankle function, fit and alignment, training, and total coordination is becoming better understood. In the light of present knowledge, it seems clear that "super-devices" are not apt to be the solution to improved artificial legs and that considerations of natural appearance, minimum energy consumption, and simplicity of mechanism for maintenance and economy will in the end be the controlling factors. Of course no device should be made available for general distribution until it has been checked thoroughly for function, strength, maintenance requirements, life expectancy, and adaptability to different types of amputees. A complete testing program has there-
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fore been established under the direction of New York University to ensure the adequacy of each device approved under the program.

Present objectives for the development of prosthetic devices may be stated as:

1. To invent new mechanisms, improve and adapt existing mechanisms, and apply new materials so as to add functions, or to improve presently provided functions of prostheses, seeking in the end to provide better devices to meet the needs of every amputee type.

2. To perfect those functions involved in level walking, with the best possible solution for other services such as sitting down, walking on slopes and stairs, etc.

3. To adapt devices that take advantage of remaining functions in the amputee's stump.

4. To increase stability during the weight-bearing phase but to reduce the energy requirement during transition as well as during the entire cycle of walking.

CLINICAL STUDY

Throughout the program, amputees have been fitted with experimental prostheses in order to conduct studies, trials, and tests of the equipment. Techniques and practices involved in fitting amputees are so varied, however, that some orderly means of investigating these areas became necessary. Accordingly, in 1952 a program of clinical studies was established under the project at the University of California, Berkeley, in space at the Artificial Limb Shop of the U. S. Naval Hospital at Oakland, California. Here an orderly approach can be made to a review and formulation of best practice in lower-extremity prescription, fabrication, fitting and alignment, and training in the use of the prosthesis. Complete documentation of each step in the process, as applied to a variety of amputee types, under the supervision of an advisory panel and with the cooperation of members of the limb industry in the San Francisco Bay Area, will serve to close the gap between fundamental work in the laboratory and practice in the field. Besides this, it will serve to supply source material for the information of the various professions involved in physical rehabilitation of the amputee as well as to define areas where more information or new devices are required.

In addition to establishing what is the best prosthetic practice, the objective of the clinical study is to develop, for distribution to each member of the rehabilitation team, including the amputee, information such as:

1. Medical data for use by the surgeon in connection with amputee problems.


3. Principle* and practices of fabrication, fitting, and alignment of a prosthesis.

4. Suggested means of evaluating prosthesis and amputee. Including gait analysis, performance checks, and achievement tests for use by the prosthetist, the surgeon, and the physical therapist.

5. Suggested curriculum for training the amputee in the use of his prosthesis.

6. A comprehensive list of specific prosthetic appliances and devices, with descriptions of their individual characteristics and functions, for use in preparing prescriptions.

7. Suggested curriculum for training the prosthetist, the surgeon, and other members of the clinic team in lower-extremity prosthetics.

8. Data useful to the research and development laboratories in continuing their studies.

FUTURE PROGRAM

The investigation and development involved in a lower-extremity prosthetics program are complicated and time-consuming. And since it appears impossible to reach the ultimate goal of replacement of all functions that have been lost, the task must be considered as never-ending. For the immediate future it is contemplated that development of devices, the clinical study, fitting and alignment studies, and fundamental research will continue. The relative emphasis on each phase is projected on Figure 1 through 1956.

As progress is reflected in the results of the clinical study, some means must be developed for effectively transmitting this information to orthopedic clinic teams throughout the nation. Whether this is to be accomplished a priori at a central location, or whether through field teams on a continuing basis, will depend to a large extent upon the results obtained in the clinical study during the coming year. Whatever method evolves, every effort will be made to ensure that any useful information is disseminated to the field as quickly and efficiently as possible.