Economic Aspects of the Artificial Limb Industry*

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In discussing the economic aspects of the artificial limb industry, I would like to begin with a description of its general nature, then sketch briefly the historical development from the middle 19th century to date. This will enable us to visualize the progress being made and to make some observations as to the future.

An artificial limb or prosthesis is to a great extent a custom-made or individually fabricated device. The variations in size and contour of the anatomy of human beings are practically infinite. Because of the added variations in amputation conditions, such as site of amputation, size, shape and condition of stump, physical condition of the amputee himself, and the uses to which the prosthesis are to be put, the variations that are needed in the prosthesis to properly fit a given individual, are certainly no less and probably much greater than the variations in humans in general. The amputation stumps of new amputees are subject to gradual change in size and shape during the first few months, as they become accustomed to wearing a prosthesis, so that a limb which fits satisfactorily when it is first applied must be adjusted from time to time to maintain a correct fitting.

In prostheses for lower extremity, the principal functional characteristics desired are weight-bearing with reasonable comfort, and ambulation. If the prosthesis does not fit precisely the amputee may not be able to tolerate weight-bearing with any comfort, and the gait will be less than desirable. A small variation from the proper fit in the weight-bearing section of the prosthesis can cause intense discomfort.

In artificial arms or prostheses for upper extremity, the principal functional characteristics are the ability to grasp, to lift, and to put the prosthesis in the desired position. To obtain maximum efficiency in these functions a precise fitting of the prosthesis is necessary.

Therefore it is obvious that prostheses cannot be sold over the counter like an electric toaster, nor can they be sold by size like a pair of shoes. Each prosthesis must be made in accordance with careful anatomical measurements, frequently using plaster of paris moulds of the amputation stump, and must be fitted very precisely to the individual. As adjustments become necessary, these must be performed with a high degree of skill.

The better equipped shops or facilities in the prosthetic field have a considerable variety of tools and equipment. For example, one well equipped facility has 23 different types of power tools in use. One work bench will have 50 different hand tools. Examples of power tools in common use are band saws, disc, spindle and belt sanding machines, electric drills and grinders. Thus, they are more of the nature of time savers rather than substitutes for craftsmanship.

The necessity to handle each case individually, and the knowledge and skill required to perform the task satisfactorily, cause this industry to be much more of the nature of professional service than of mere manufacture and sale of a device.

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Limited Size

There are no accurate figures available on the number of amputations performed, or of the number of amputees in the population. Widely varying estimates have been made by people interested in the problem. After reviewing all available figures, the headquarters of our association, the Orthopedic Appliance and Limb Manufacturers Association, estimates the number of amputations of arms and legs to be 25,000 per year. The number of amputees among the population of the United States is estimated at 840,000.

There are approximately 31,000 prostheses sold per year. I estimate the average selling price at $250.00. This would indicate a total volume of $7,750,000 per year.

When allowance is made for the costs of repairs, and other articles directly related to the use of limbs, such as special stump stockings, the total sales volume of the industry appears to be about nine million dollars per year. Obviously, this is one of the country's very small industries.

In our own company, we find that about one-half of our prosthesis sales are to *new* amputees, and one-half are for replacement of worn-out limbs. If this proportion holds good throughout the country, then only about 15,500 limbs per year are sold to the 25,000 new emputees, leaving 9,500 or 38% who are not supplied limbs. And, the estimated sale of 15,500 prostheses for replacements among the existing amputee population of 840,000 indicates the purchase of a limb by only 1.8% of them per year. If every amputee had a prosthesis this would indicate an average useful life of over 55 years per prosthesis. This is obviously incorrect.

I have estimated above that perhaps 62% of the new amputees receive prostheses. Applying this percent to the amputee population would indicate that approximately 520,000 amputees have received an appliance. The replacement sales of 15,500 per year would indicate that 3% of the amputees replace their appliances each year—an average life of over 33 years. This figure still appears incorrect.

Allowance must be made for persons who for reasons of age, extreme handicap, economic status or location in a remote area, do not receive a prosthesis. Also, because of their ages at time of amputation, many persons only need one prosthesis. Others, unable to master the prosthesis, discard it and so do not need a replacement. It is difficult to believe that these factors explain the discrepancies in the figures, and it would be very worthwhile if a census could be made which would reveal the true situation.

Size and Distribution of Facilities

If we can accept the estimate of 31,000 prostheses furnished per year and given a total population in the United States of 165,000,000, then the number of limbs furnished each year is of the order of 1 prosthesis for each 5,300 persons. Obviously, limb wearers form a very small segment of the population. For various reasons, amputees are more heavily concentrated in some areas than in others, proportionate to the general population.

There are approximately 700 qualified and competent Prosthetists (fitters of artificial limbs) in the country. Again using the figure of 31,000 prostheses per year, we get an average of forty-four and a half (44½) limbs fitted by each Prosthetist. At an average cost of $250.00 per appliance, the annual volume per Prosthetist is an average of $11,125. Yet it requires an area of 236,000 population to support each Prosthetist.

It is therefore not surprising that the industry contains a large number of small shops consisting of one to

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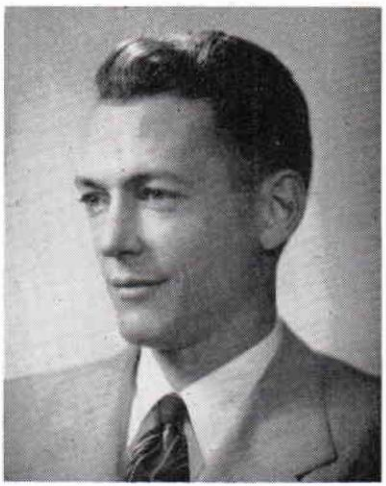
Mr. Hanger was elected one of the seven directors of the American Board for Certification in 1955. He is a past president of the Orthopedic Appliance and Limb Manufacturers Association. In 1954, he received the C. H. Davies Award for Outstanding Service to the Artificial Limb and Brace profession.



McCARTHY HANGER, JR.

four persons. Furthermore, many of these shops furnish not only prostheses, but orthopedic braces, surgical supports and other similar products. In large metropolitan centers, there are commonly shops staffed by from 5 to 15 persons and a few which are even larger.

Some Prosthetists are also qualified to fit orthopedic braces. There are other fitters who are qualified to fit orthopedic braces only. The latter are called "Orthotists." The combined total of qualified Prosthetists and Orthotists is about 1,100 persons.

There are approximately four hundred (400) qualified establishments where limbs or braces may be procured.

In view of the large amount of population required to sustain one Prosthetist, it is evident that very few are located in smaller towns or sparsely settled areas. Hence a considerable number of amputees living in such areas must travel long distances to have prostheses fitted and serviced. The industry at least partially offsets this inconvenience by the use of field representatives, or by shops operated part time.

In some such areas, there have been a few shops established by hospitals or similar institutions. Although figures are not available, I believe it could be demonstrated that the industry, which operates on a highly competitive cost basis, can furnish amputee service at a lower cost than a shop of this type. Where there are not enough amputees to support a commercial shop, a hospital shop is justified by the need for service, but when such a shop encroaches on the trade area of established shops, reducing their volume, it can make it difficult for the commercial shop to survive and provide adequate service to its other clients.

Historical Development

Man's attempt to find an adequate artificial substitute for the loss of an extremity begins with the earliest history of mankind. Throughout ancient writings we find many references to amputation stumps and artificial limbs. References to leg supports and to artificial hands are found as early as 500 BC.

Many ingenious devices, presenting evidence of skilled craftsmanship, and a gradually increasing knowledge of basic principles, were made

throughout history. I will omit details however and cover only developments in the United States since the middle of the 19th century.

In 1846 the "Palmer Leg" was invented in Philadelphia and was claimed to be a great improvement over the Anglesby Leg, a somewhat earlier English design. The Palmer leg had a foot made somewhat on the modern American pattern but with a catgut cord and an anterior spring instead of rubber bumpers in the foot. The "Bly leg," invented and patented in 1858 by Douglas Bly, M.D., of Rochester, New York had lateral or side motion at the ankle like that of the natural leg. Dr. Bly is said to have been the first to introduce the curved knee joint, which is now generally used on all below knee limbs.

The Civil War gave great impetus to artificial limb development in the United States.

A. A. Marks was the first to introduce the use of the rubber foot, eliminating ankle motion because the resiliency of the rubber foot was thought to make it unnecessary. J. E. Hanger, the first to perfect the cordless ankle, also introduced and made popular the wood socket.

Many of the limbmakers of this period wore artificial limbs themselves, and while many of them actually thought they had achieved the maximum improvement in artificial limbs, newcomers were constantly announcing something better. Many of the claims made for their products were extravagant; nevertheless a great development in artificial limbs in the United States was made during this period.

The beginning of the twentieth century saw many new names contributing to the development of artificial limbs: the Rowley Brothers of Chicago, Detroit, and Pittsburgh; Frees and Pomeroy of New York; Milligan of Los Angeles; Gaines-Erb of Denver; Hittenberger of San Francisco; Trautman, Winkley and Buchstein of Minneapolis. At the time the United States entered the First World War there were about 200 established artificial limb manufacturers in this country employing approximately 2,000 skilled workmen.

Until the time of World War I the limbmakers in this country, as in all others, were an unorganized group of rugged individualists, each going his own way, rarely speaking to his competitor, and much less consulting with him. There was little or no cooperation between the limbmakers and the surgeons; in fact the surgeon sometimes looked upon the limbmaker as some sort of shyster preying on the amputee, and avoided contact.

OALMA Founded: 1917

In October, 1917, the Surgeon General of the United States Army issued an invitation to the limbmakers of this country to come to Washington, D. C., to discuss the problem of supplying artificial limbs to war veterans. This meeting, no doubt, contributed more to the development of the science of prosthetics than any other occurrence in its history up to that time, for from this meeting originated the organization which is now known as the Orthopedic Appliance and Limb Manufacturers Association. Through the medium of this national organization, limbmakers and bracemakers meet on common ground and discuss their common problems. As a result, an entirely new conception of this industry has developed, as well as a great improvement in the ethical standards of the limbmakers and bracemakers, not only in their own business relationships but in their relationship with the medical profession as well. Through their national association, they have developed scientific and educational programs that are helpful

to the limbmaker, the surgeon, and the amputee alike.

Inventions

Some of the more outstanding of the mechanical devices invented by members of the industry in the last 50 years are:

Many different designs of artificial hooks, which are designed to fulfill particular needs such as those of the farmer, mechanic, or office worker, as well as the needs of daily living; ball bearing joints of several different designs for amputations below the knee or at the knee; the hip control or pelvic belt method of suspension of above the knee limbs; limbs made of aluminum alloy and of fiber; all-rubber functional ankle joints; mechanical hands of several different designs, which have contours resembling a human hand, and which provide grasp; non-functional hands with cosmetic plastic coverings which are quite life-like in appearance.

Government Research Program

Even though history records substantial progress, up to ten years ago there had never been an organized scientific program of research and development in the field of prosthetics.

Toward the close of World War II, the War Department undertook a program of research in limbs, in order to solve more adequately the problem of rehabilitation of the large number of veterans who had suffered amputations in active service. There was established, through the National Academy of Sciences—National Research Council, a Committee on Artificial Limbs, supported first by the office of the Surgeon General of the Army alone, and later by the Veterans Administration.

The research program can be classified broadly into four phases or types of activities:

First, fundamental studies of the nature of locomotion and related problems to form a basis for development of artificial legs, and fundamental studies of the normal and amputee biomechanics of the upper extremity, to form the basis for the solution of upper extremity problems.

Second, invention and development of devices.

Third is amputee case study and application of the first two phases to solution of specific amputee problems.

The fourth phase is the dissemination of the knowledge gained and the evaluation of its use in the field.

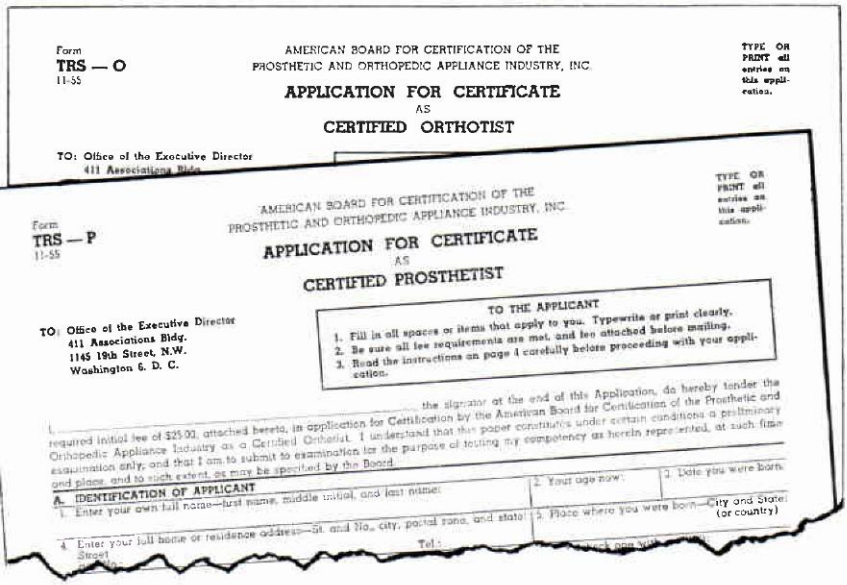
The outstanding development in lower extremity devices which has come into common use up to date is the suction socket method of suspension of the above the knee limb.

The Suction Socket limb represents a tremendous advance over any previous known type of prosthesis for this amputation. Greater control, greater freedom, reduction in the sensation of dead weight and greater neatness of fitting of the clothes, have made this prosthesis the preferred type wherever the conditions for its use are favorable.

Other devices which are gradually coming into use are the Navy type soft socket for below knee, variable cadence knee for above knee, and a new improved functional ankle which provides universal motion.

In upper extremity prostheses, there were developed the use of plastics for sockets and forearms, mechanical elbows and wrist units with greatly improved function, and new terminal devices. The principles of fitting and harnessing were studied and improved methods were developed.

While these new developments have greatly improved the function of prostheses, they also are generally more complicated. They require more time and skill to fabricate, to fit, and to maintain. Thus, they are more expensive.



Form TRS — O 11-55

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1. Fill in all spaces or items that apply to you. Typewrite or print clearly.
2. Be sure all fee requirements are met, and fee attached before mailing.
3. Read the instructions on page 4 carefully before proceeding with your application.

I, _____, the signator at the end of this Application, do hereby tender the required initial fee of $25.00, attached hereto, in application for Certification by the American Board for Certification of the Prosthetic and Orthopedic Appliance Industry as a Certified Orthotist. I understand that this paper constitutes under certain conditions a preliminary examination only; and that I am to submit to examination for the purpose of testing my competency as herein represented, at such time and place, and to such extent, as may be specified by the Board.

A. IDENTIFICATION OF APPLICANT

1. Enter your own full name—first name, middle initial, and last name:
2. Your age now:
3. Date you were born.
4. Enter your full home or residence address—St. and No., city, postal zone, and state:
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The Certification Forms. Filling out these applications is only one step in the process which includes careful checking, practical work and written examinations.

The artificial limb industry never has had the resources or personnel available to undertake a program comparable to the government research program. The progress being made represents a very substantial improvement in the quality of service available to amputees. Therefore the members of the industry acknowledge and appreciate the great debt which they and the amputees themselves owe to this program.

Progress Toward Professional Status

Although the leaders in the industry starting at the time of World War I recognized the need for improvement in competence and in ethics, progress in this direction was slow and gradual up to 1948. Then the industry set up a voluntary board to establish standards of competence, equipment and ethics, the American Board for Certification of the Prosthetic and Orthopedic Appliance Industry. This Board conducts examinations to determine the qualifications of fitters of artificial limbs and braces and gives qualified candidates the title of Certified Prosthetist or Certified Orthotist.

The Board examines shops or facilities where artificial limbs or braces are made and fitted to see that they are qualified to carry on this work. The progress since the advent of the Certification Board has been greatly accelerated. Certification by this Board is becoming recognized by the medical profession, by others concerned with rehabilitation of the handicapped, and by the general public as the emblem of recognition of qualified firms and fitters in this field.

There are now 345 Certified Facilities and over 1,000 Certified Prosthetists and Orthotists in the United States. They constitute almost 90% of the known qualified facilities and fitters.

The education program in this field consists of three types: Short courses in specialties, apprenticeship courses, and college courses. The Federal Government, the medical profession and the artifical limb industry have cooperated in holding short courses in the fabricating and fitting of the suction socket leg and the newly de-

signed artificial arms. Starting next spring, short courses are to be held to teach the latest developments in principles of fitting above knee limbs, the Navy type soft socket leg for below knee and other related subjects.

The generally accepted method for teaching skilled crafts has been apprenticeship. Through the joint efforts of the American Board for Certification and the Orthopedic Appliance and Limb Manufacturers Association, a national standard for apprenticeship programs was developed and is gradually being put into effect. This embodies the latest principles of apprentice education.

Considerable thought and discussion has been devoted to establishing college courses in prosthetics. The University of Buffalo has explored thoroughly the problems involved in such an undertaking and hopes to establish a school for this purpose in the near future.

Current Prosthetic Methods

This review of the nature of the industry, the history of its development and the latest changes occurring through research gives us the proper background for a discussion of Current Prosthetic Methods—a picture of the industry as it operates today.

The relatively small number of new amputations and of amputees in the population, scattered all over the United States, has required the artificial limb shops to be scattered throughout the country and has tended to cause them to be small. The extremely individual nature of each fitting of a prosthesis, together with the other factors just mentioned, explains why there have not been developed any machines capable of turning out prostheses in large numbers by essentially mechanical means.

Nevertheless, there are certain components of artificial limbs which can be produced mechanically in large job lots rather than individually by hand. For example, wooden or metal knees, shin pieces, ankle pieces, and feet are readily obtainable. Usually these prefabricated parts are capable of alterations so they can be fitted and aligned to the individual. There are also shops which specialize in the construction of complete limbs, made to individual measurements, on a wholesale basis. Through division of labor processes, the greatest possible mechanization, closer supervision, and large scale purchasing, such shops are able to realize increased efficiency and economy of production. There are a total of 12 such factories which made complete limbs, prefabricated parts, or sub assemblies.

Based on a sample survey of representative firms in the industry, it can safely be said that a very large majority of artificial limb companies use pre-fabricated parts to some extent. Probably one-half of the firms use pre-fabricated parts, rather than a hand-made corresponding part, for one-half of their construction requirements or better.

Almost all the metal joints used are produced by machine shops specializing in this work.

In upper extremity prosthetics the production of elbow units, wrist units, joints, and terminal devices, using machine tools and high precision manufacturing methods is prevalent. Mechanical and passive hands and cosmetic glove coverings are specialties which practically the entire industry purchases from one of ten establishments.

New tools are gradually coming into use in this country. There are now available adjustable walking legs, for providing a complete range of adjustment at the knee and ankle. In connection with the adjustable leg a transfer jig is used to transfer the alignment information to the permanent limb. The latest power tool is a high-speed low-powered cutter with automatic clutch, which greatly reduces the carving time required to prepare a wood socket for fitting, yet which eliminates the danger in using a cutter of high power.

Modern Rehabilitation

So much for the mechanical side; now let us cover the personal side, a new concept of amputee management which might be called "Modern Ideal Rehabilitation."

Since World War II, a great deal of thought and experimentation has been devoted to developing means of rehabilitating amputees, using some of the methods which were used in the Army hospitals during and after World War II. The procedures developed have proved to be a marked improvement. The more difficult the amputee's problem, the more valuable become these procedures of "Ideal Rehabilitation." The procedures followed will vary according to the particular needs of each patient, but will include part or all of the procedures described below.

The amputee is examined and his problem evaluated, by an experienced Prosthetics Clinic Team. This team usually consists of an Orthopedic Surgeon, or a Physiatrist, or both; a Physical Therapist, or an Occupational Therapist, and the Prosthetist. During the examination the patient is analyzed as an individual case. Then a course of rehabilitation is prescribed by the physician, including the therapy necessary, the type of prosthesis, and other special treatment or training required. The physician is in charge of the team and responsible for the entire program, but he calls on the knowledge and experience of each member of the team for consultation as well as to carry out their particular phases of the work.

The patient may receive pre-prosthetic therapy in which the stump is conditioned to provide the most efficient use of the prosthesis. When the patient actually begins to wear the prosthesis, the clinic team again works closely together in the rehabilitation program. The prosthesis itself has been fabricated according to the measurements and specifications taken by the Prosthetist. Careful attention is now given to fitting, adjustments, continued therapy, and training exercises, such as walking, sitting, steps, etc. Unusual problems may require a complete review and possible change of the prescription.

In the case of arm amputees, occupational therapy follows the fitting of the prosthesis. The amputee spends part of each day learning to use the prosthesis and to live an independent life. He is taught dexterity and manipulation through blocks, games, doorknobs, faucets, tools, etc.

On completion of training, the amputee must appear before the clinic team again for final Prosthetic Performance Check-out and official release by the physician.

By the use of the Prosthetics Clinic Team, the patient is brought closer to the goal of the physician and the prosthesis-maker—complete rehabilitation. Small problems, which might otherwise cause the patient to discard the limb, can be corrected and the problems which so often disturb the new limb wearer can be explained as they arise, with the result that a much larger percentage of amputees become satisfied limb wearers. Today, Prosthetics Clinic Teams are used throughout the United States, particularly in the large metropolitan centers.

Many clinic teams operate in a Rehabilitation Center, an establishment especially equipped for carrying out rehabilitation of persons having many different types of handicap.

While the procedures of Modern Ideal Rehabilitation are much more expensive, the amputee can return to useful life more quickly, and with a much higher degree of proficiency in the use of his prosthesis. In almost every case, the cost of these procedures is more than saved by the benefits obtained.

What of the Future

From the foregoing facts and trends, it is possible to predict certain possibilities and suggest alternate directions in which the industry may go. Probably the future developments will consist of a mixture of these rather than any one type of development.

With respect to the size and location of facilities, there are certain factors which lead toward centralization of artificial limb services and others which lead toward decentralization. As devices become more complicated, and as the standards of fitting reach higher, one would expect a greater specialization by prosthetists just as specialties developed in the medical profession. Thus, the artificial limb facility of the future would have several different technicians, each of whom specialized in a particular amputation. For example, one prosthetist specializing in arms, another prosthetist for below knee, ankle, and partial foot amputations, and a third prosthetist for above the knee, and hip and knee disarticulations. There might be, in addition, a manager who had a working knowledge of the appliances for all amputations, who could attend clinics, handle inquiries and outside calls, as well as the usual managerial functions.

There might be two or three additional employees capable of performing the tasks requiring less skill, such as repairing, painting and assembling. Such a facility could be quite efficient. It could give prompt service for rush orders and take care of amputees promptly when they come in for repairs and adjustments. However, a trade area of about seven hundred thousand population is needed to justify its existence.

The increasing ease of transportation would seem to foster greater centralization. On the other hand, amputee patients and their doctors in outlying areas seem more and more to demand nearby service. Amputees object to the time and expense involved in travelling great distances. In many instances they are willing to accept a lower quality of service or a less adequate prosthesis in order to avoid excessive travel. If the facilities are to be further decentralized, and the distances between them thereby reduced, then it is axiomatic that they will have to be smaller.

One of the leaders of the industry has visualized a practical method of operation for small but highly competent facilities as follows: All components of artificial legs and arms except the socket would be mass produced in a large variety of sizes by factories specializing in this work. The fitter would make and fit the socket of the prosthesis. Such a fitter might be a college graduate, who has been trained in one of the large mass production shops to be an expert fitter only. He spends the great majority of his time in fitting and adjusting limbs.

The typical facility might have one Prosthetist and one Orthotist in a medical center or rehabilitation center working closely with the doctor and the physical therapist. These fitters would be competent to handle the majority of amputees or amputee types, and brace cases. However, the unusually difficult case or rare type of condition would be referred to someone who specialized in that type of condition. There would be only a few, probably four to six, large facilities spread throughout the country where such specialists would work and which would also mass-produce components for limbs.

The use of Clinic Teams and of Rehabilitation Centers is well established, but it seems clear that there will be a steady increase of these in the years to come.

The Research Program is far from finished with its task. Much remains to be learned in this field. As new ideas and principles of fitting and amputee management are developed,

they will be disseminated and become a part of the practices of the industry. In the development of devices, there are many fields yet to be explored, many devices which are in various stages of development. For example, improved methods of control of artificial hands to more closely approach the function of a natural hand will require many years of study. The application of external power to the operation of artificial arms holds possibilities. Hydraulic knees are still under development and test. Methods of providing more natural foot action, such as the solid ankle cushion heel foot, will continue to be investigated.

Many of the devices which will be developed will be much more complicated, more difficult to manufacture and to maintain and inevitably more expensive than the devices in use today. The use of the practices of Modern Ideal Rehabilitation and the more expensive devices, will inevitably mean that a great deal more money will be spent on each patient. However, when one considers the tremendous improvement in the quality of rehabilitation received, this increased cost certainly will be money well spent.

As the industry faces the future, it is well aware that its most important task is to furnish the amputee the best possible service. This will require constantly improved training and education, resulting in ever increasing skill, an ever higher standard of ethics, and convenience of location of service.

A large proportion of prostheses, perhaps as much as 60% of the total, are purchased by welfare agencies such as the Veterans Administration, Divisions of Vocational Rehabilitation and others. These agencies, operating on limited appropriations, are vitally concerned in economical prosthetic service, so they can rehabilitate as many eligible handicapped as possible. Yet they, too, want amputees to be rehabilitated in accordance with the best methods attainable.

Thus the challenge of the future to the industry is clear: it must continually improve its service to the amputee, yet it must do so at the most economical cost consistent with such service.

WORDS AND THEIR USAGE—(Continued)

Exercise caution in using the word "joint." In the language of anatomy and limb prosthetics, it can get you into trouble. In one and the same manuscript, we find "joint study," "joint effort," "joint proposal," "joint torque," "joint lubricants," "joint motion," "joint forces," and so on.

In referring to a normal person, do not speak of a "nonamputee" or a "nonamputated person." If you do, you suggest that to be an amputee is a pleasure afforded only the privileged few. If you mean "normal," say "normal."

Do not speak of "forward flexion of the shoulder" to mean forward rotation of the arm upon the shoulder. "Forward flexion of the shoulder," or more simply "shoulder flexion," means forward rotation of the shoulder upon the chest, as in scapular abduction.

Do not refer to "shoulder abduction" to mean arm abduction. One abducts limbs, not parts of the torso. You may flex, extend, elevate, or depress your shoulder, but there is no such thing as "shoulder abduction."