External Power in Prosthetics and Orthotics, an Overview

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THE large number of persons who could be materially helped if highly developed orthotics and prosthetics systems were available is not generally appreciated. The conquest of infectious diseases has increased life expectancy to the point where disability caused by the failure of physiological systems is common in old age. The ever-increasing rate of injuries resulting from vehicle accidents adds to the numbers of paralyzed and maimed, and at the present time the Vietnam conflict is adding its toll.

Detailed statistics are difficult to obtain, but it has been estimated that there are 25,000 to 30,000 amputations per year in the United States from all causes. The Veterans Administration reported 25,000 lower-extremity and 6,000 upper-extremity service-connected cases treated during 1967 (incomplete figures), resulting from several wars. There are no immediately available statistics related to the Vietnam conflict.

Dr. Virginia Badger[4] has estimated the numbers of patients in the United States with various types of rheumatic, arthritic, and neurological disorders, including quadriplegia, as follows:

NATURE OF DISORDER	TOTAL NUMBER
Arthritic and Rheumatic	12,000,000
Neurological Disorders:	
Epilepsy	1,800,000
Cerebral Palsy	550,000
Multiple Sclerosis	500,000
Muscular Dystrophy	200,000
Parkinsonism	500,000
Stroke	2,000,000
Quadriplegia	500,000 (20,000 to 30,000 high level)

Of these patients, Dr. Badger estimates that *2* million could benefit markedly from orthotic devices, provided that the difficult problems of patient acceptance could be overcome.

Unfortunately, much remains to be done in defining the need more precisely. Many persons suffering from neurological disorders are not recorded in hospital statistics; and, if they are, the nature of their disability is not. The specific types and numbers of disabilities need to be codified in a way which could lead to the development of engineering specifications and decisions on priorities of effort and specific engineering designs.

THE MAN-MACHINE SYSTEM

The human being and his assistive device comprise a man-machine system. When the orthotics or prosthetics system uses external power and is operated by means of feedback

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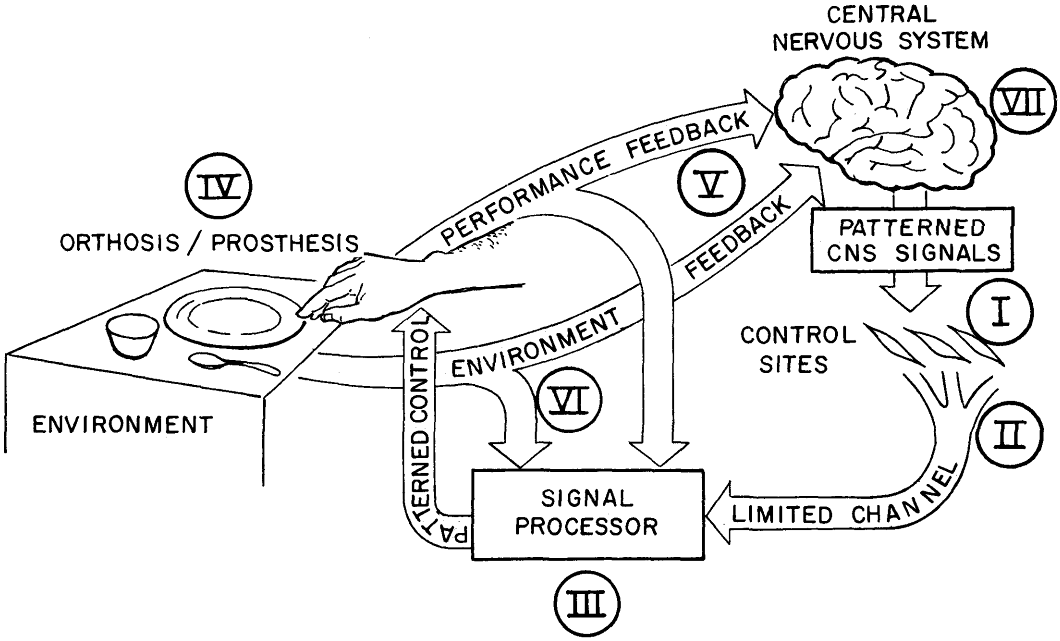

Fig. 1. Elements of a prosthetics or an orthotics system. *I.* Signal Sources: muscle motion, electromyographic, electroneurographic, electroencephalographic, eyeball motion, sound. *II.* Transducers: direct connections, switches, valves, proportional analog, proportional digital, electrodes, radio transmitters. *III.* Signal Processors: on-off, electromyographic, coupled function devices, proportional or velocity control systems, adaptive computer. *IV.* Output Systems: communication devices, environment and tools designed to work with the orthotics or prosthetics system, vehicles controlled by the orthotics or prosthetics system. *IV. A.* Prosthetic: terminal devices, upper-extremity components, lower-extremity components. *IV. B.* Orthotic: splints and casts, implant bone supports, body-powered splints, externally controlled splints, externally powered splints, functional electrical stimulation. *V.* Feedback Receptors: vision, hearing, proprioception, touch, "stereo" vibration, "stereo" electrical stimulation. *VI.* Local Feedback: Pressure sensors, slippage sensors, position, velocity, force. *VII.* Adaptive Learning.

control, the result is a cybernetic system in the true sense of the term. Figure 1 illustrates the possible information paths of an orthotics or a prosthetics system. The following important elements are depicted: I. Signal Sources; II. Transducers; III. Signal Processors; IV. Output Systems; V. Feedback Receptors; and VI. Local Feedback. In addition to these physically identifiable elements, an important element in the performance of the system is the capability of man to learn to use a complex assistive device (VII. Adaptive Learning). Here, age and motivation are important; for example, "thalidomide children" show tremendous learning capacity with complex prostheses, while many geriatric lower-extremity amputees are not able, or are not motivated, to use an artificial leg.

This article will discuss each of the elements of the prosthetics or orthotics system depicted in Figure 1, briefly indicating the present levels of research activity and future possibilities.

I. SIGNAL SOURCES

The human desire to initiate movement of an orthotics or a prosthetics system originates at some conscious level in the central nervous system, but it must take the form of some voluntary physical action if a result is to be achieved. This action may be, for example, a simple muscle movement resulting in the closing of a switch, the pressing of a key, or the very sophisticated use of the tongue (Fig. 2) to activate a keyboard of miniature switches.

Recently, electrical signals associated with muscle and neuron activity have been explored for use as control signals. Although electroneurographic (ENG) signals seem attractive because of their proximity to the central nervous system (3), the practical difficulty of

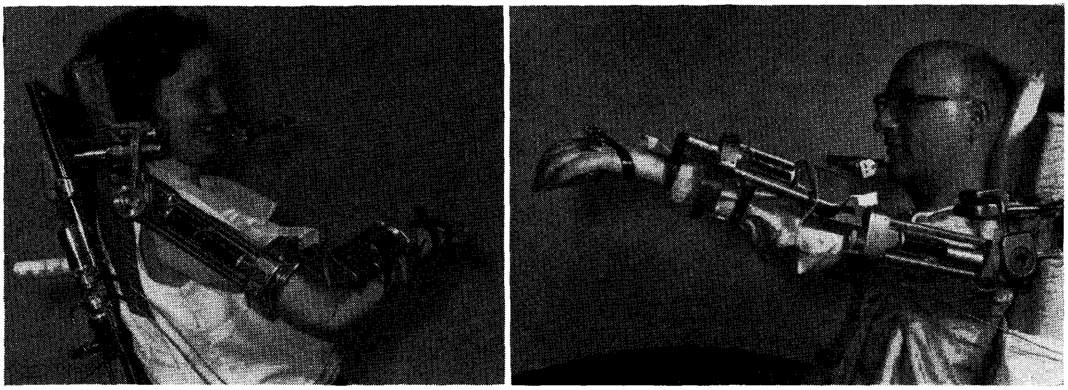

Fig. 2. The Rancho Los Amigos Hospital electric arm orthosis. The various degrees of freedom are actuated by a series of bidirectional microswitches placed in front of the patient's mouth and operated by his tongue. A number of these devices are in use.

maintaining electrodes proximal to nerves in human subjects over extended periods of time has not been overcome. Instead, the more accessible electromyographic (EMG) signals have been used as sources of control signals. Most practical to date has been the use of so-called surface EMG signals obtained by means of electrodes resting on the surface of the skin near a muscle whose electrical activity is to be detected.

A number of prosthetic hands and some hand orthoses have been developed to operate from EMG signals picked up through surface skin electrodes *(5,6,8,9,10,11,12,18,26,38,40,41, 66,76)*. More recently, interest has grown in obtaining EMG signals from within a muscle. Such intramuscular EMG signals exhibit a wider range (from single motor unit pulses to signals of many asynchronous pulse combinations) and are more free from "cross talk" resulting from the activity of neighboring muscles *(4,12,13,24,61,62,63,64)*. Practical use of intramuscular EMG signals requires either wire electrodes which penetrate the skin and which can exist for long periods of time without breaking or promoting infection (Fig. 3), or the development of implantable radio transmitters capable of long-term operation (Figs. 4 and 5) *(35,37.)* Future research will undoubtedly press in both of these directions.

Many other sources for voluntary signals from the human being have been suggested from time to time. The electroencephalogram (EEG) signal is often mentioned, but, to date,

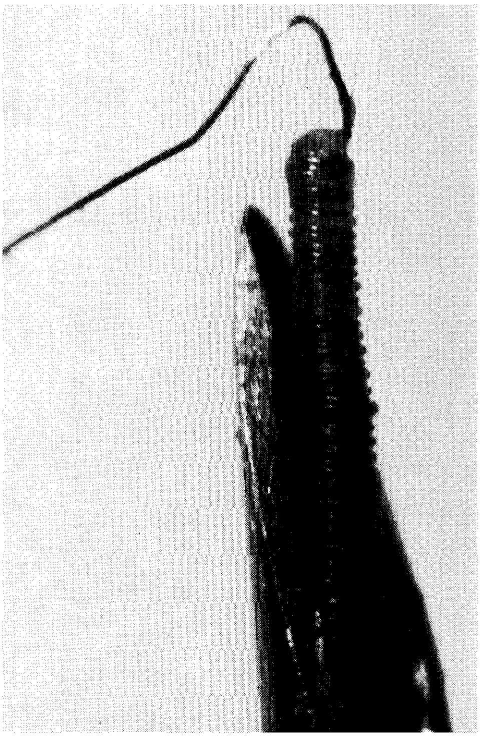

Fig. 3. A monopolar, helically wound, percutaneous electrode. It is used to detect electrical activity within a muscle. The electrode is inserted into the proper muscle by a hypodermic needle which, when withdrawn, leaves the electrode comfortably implanted. A surface connector protects the electrode-skin interface.

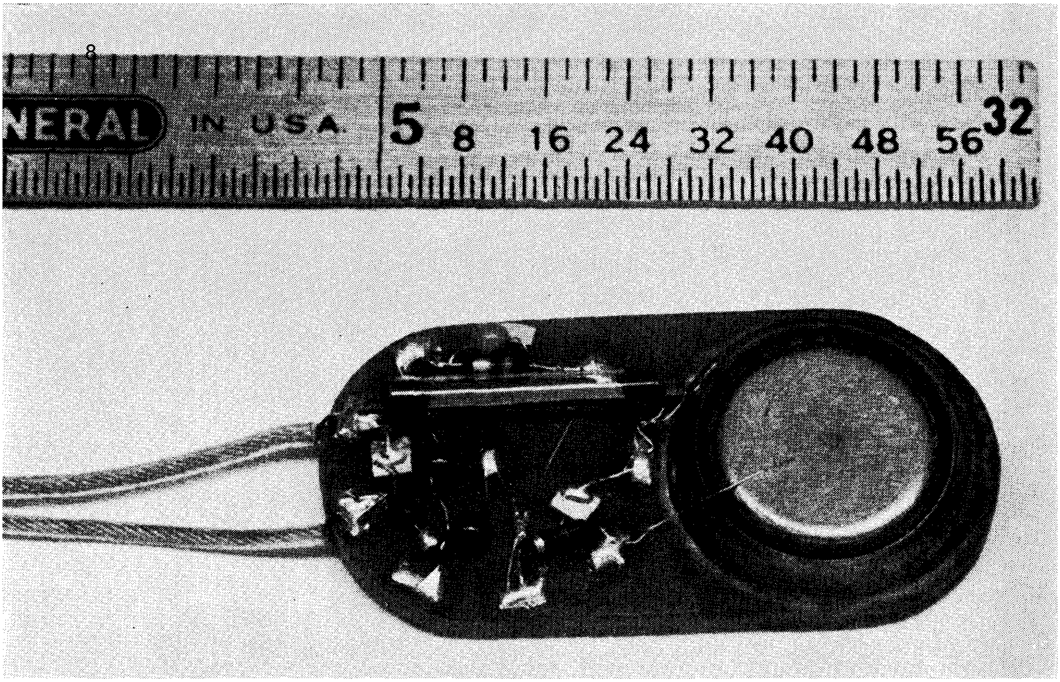

Fig. 4. Miniature FM radio transmitter used to obtain electromyographic signals by complete implantation. The signals are received externally and, after processing, can be used as control inputs in a control system. The transmitter shown will be encapsulated in epoxy and coated with medical grade silicone rubber.

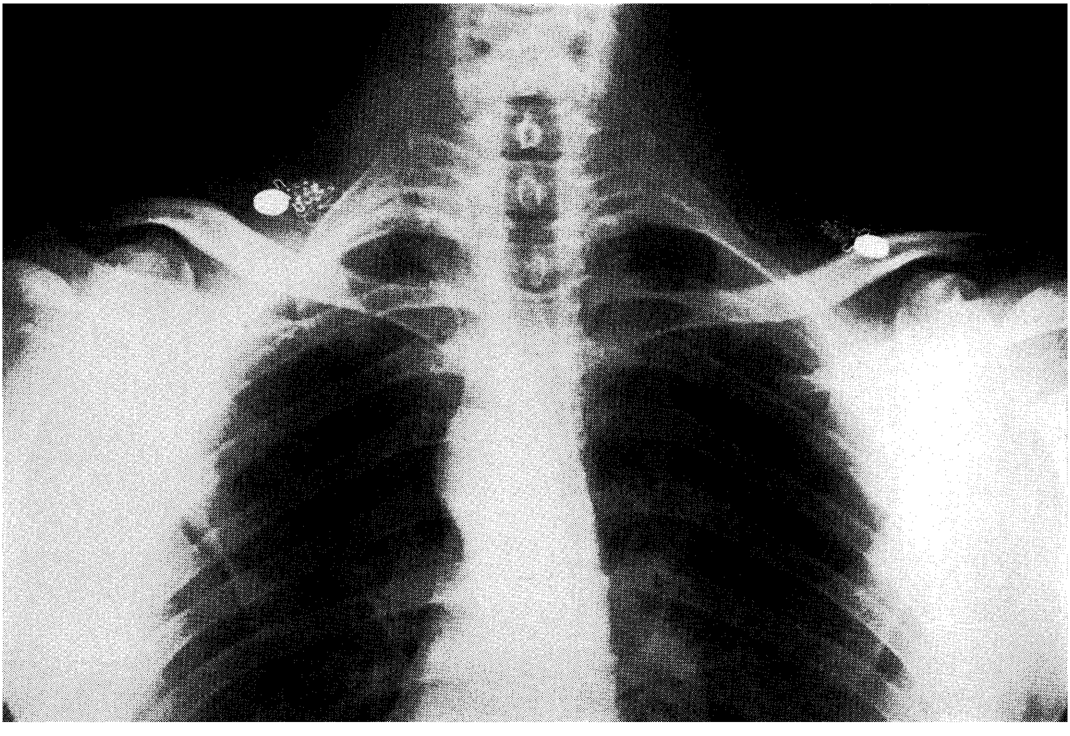

Fig. 5. Transmitters implanted in a human and attached to the trapezius muscles. The electromyographic signal obtained by lifting the shoulder (a motion possessed by many quadriplegics) was used to drive a variable-speed motor, a bidirectional prehensile hand splint, and a multilevel selector. The transmitter was turned on by changing the state of a magnetic switch influenced by an external magnetic field.

it has been used only as an on-off switch responding to the presence or absence of the alpha rhythm *(16).* Enticing as the idea may be, many years must pass before thoughts will will be transformed directly into meaningful electrical signals.

The human voice, including whistles and the like, has been proposed and used as a signal source. Much research at present is devoted to machine recognition of human speech for voice-operated typewriters and for speaking directly to a computer *(56).* These efforts show promise, but they are probably far too complicated at present to be considered for use in a prosthetics or an orthotics system. The human eye has also been used to switch devices by means of ultrasonic and infrared reflections *(67).* Unfortunately, many such promising sources of control signals are involved in the normal activities of living, such as eating, looking around, speaking, and the like. This could be a disadvantage when the patient desired to control his orthotics or prosthetics system with a signal such as sound while he was talking or eating *(14).*

II. TRANSDUCERS

Transducers are the devices used to change physiological phenomena into engineering signals that provide inputs to signal processors and output systems. A transducer may be as simple as an on-off switch or as complicated as an implantable FM radio transmitter. Some elements of orthotics and prosthetics systems are difficult to classify. Bowden cables used to transmit shoulder movements to an amputee's terminal device are an example. More recently, hydraulic systems which function as a wire cable have been demonstrated *(54).* Such systems combine the roles of transducer and actuator in a single unit.

Electric switches and pneumatic-hydraulic control valves which convert body movements into changes in electric current or fluid flow are highly developed. Many types of reliable, very small electric switches have been easily adapted to prosthetics and orthotics systems, but, in the case of hydraulic and pneumatic control valves, it has been necessary to develop a number of appropriate special valves.

Not so widely used in prosthetics and orthotics systems, but highly developed for general instrumentation purposes, is a wide range of proportional analog and digital transducers capable of converting pressure or movement into voltage or current changes. These devices range from analog potentiometers and capacitive and inductive devices which convert motion to smooth voltage changes, to linear transducers which produce pulse-coded signals proportional to incremental changes or absolute position. Also available are the very ingenious accelerometers and other motion transducers developed for space research and guidance control systems. Accelerometers have been used in at least one head-motion-activated control system *(65).*

Generally speaking, the mechanical-to-electric transducers have been highly developed, but only limited use has been made of their capabilities in prosthetics and orthotics systems. This does not imply, however, that a number of mechanical - to - electric transducers are immediately available for use in prosthetics and orthotics systems. An actual application often requires either a major redesign or a new design to take into account the unique problems inherent in physiological-data transduction. It is appropriate to mention here the National Aeronautics and Space Administration's Space Technology Utilization Program, in which NASA is actively searching for ways to apply transducers developed for space applications in orthotics and prosthetics systems.

The recent interest in electrophysiological signals for control of orthotics and prosthetics systems has focused attention on the development of electrodes. A large variety of surface electrodes used in electrocardiographic diagnosis and long-term monitoring systems is already available. From space technology come the "spray-on" electrodes and other surface electrodes used in telemetry and in obtaining physiological data from astronauts.

Two main approaches exist for obtaining EMG signals from within a muscle, namely: percutaneous wires inserted by means of hypodermic needles; and surgically implanted radio-transmitting devices. In the first method, wires leading through the surface of the skin from inside the muscle must be capable of flexing as the muscle moves and maintaining contact with motor units for many months. Present indications are that tissue-reaction and infection at the point of exit from the skin are minimal. Some newly developed silastic-impregnated spiral electrodes show promise of solving the problem of mechanical reliability *(75).* Similar problems exist for the electrodes of surgically implanted devices. In fact, the electrodes may well prove to be the weakest link in a biotransmitting system. It is well known that electrode failures in heart pacers continue to be a vexing problem. Research will continue to find ways to prevent metal fatigue and to discover contact materials which produce no body-tissue reaction, and which do not corrode and weaken.

In the foregoing paragraph, electrodes were discussed in the context of signal-sensing devices. Their importance is much more critical in transducers used for the electrical stimulation of muscle, as in the case of functional electrical stimulation to be described later on in this article, and in heart pacemakers and bladder stimulators, which have been excluded from this discussion of orthotics and prosthetics systems. The relatively higher currents associated with electrical stimulation, as compared with detection of electrophysiological signals, create problems. It is believed that the material, corrosion, and tissue-reaction problems associated with electrodes for picking up signals are not severe and can be easily overcome through present technology.

Electrical powering, long-term body acceptance, and sealing of the package are the issues around the active transmitters used for detecting electrophysiological signals from within the body and the passive and active implantable transducers for electrical stimulation of muscles. At present, all such experimental devices are powered by mercury cell batteries. Much effort is being devoted to minimize total electrical power requirements and to obtain electrical energy from within the body through mechanical and chemical transformers *(31,36, 51,52,59).* Battery-powered biotransmitters of a total size of 0.1 cu. in. have operated continuously for 200 hr. and, intermittently, over a three-month period in dogs. An EMG transmitter was first implanted in a human being in Sweden in 1966 *(25).* More recently, one was implanted in a subject in Cleveland, Ohio *(75).* Many problems remain to be overcome before such transmitters can be used routinely in the clinical situation, but progress with packaging techniques which produce no tissue-reaction in animals over long periods of time, and with electrode designs which can survive mechanical and electrolytic effects, indicates that prototype systems will be evaluated in human subjects within the year.

III. SIGNAL PROCESSORS

This discussion of signal processors is concerned primarily with the special electronic and computer-type systems used for converting low-level control signals containing noise and artifacts to useful, high-level input for orthotic or prosthetic devices.

Although not specifically designed for signal processing, the mechanical and hydraulic characteristics of many systems may be viewed as signal processors. For example, the speed of response of a gas-powered orthotics or prosthetics system is often limited by the size of the valve openings and tubing used in the system. In this way, the on-off characteristic of the valve is converted inherently into a velocity output and is so observed by the patient. In fact, subjects are often very much aware of the noises and speeds of response associated with their control devices, and improve their skills with practice and knowledge of how the system will perform for given input operations.

Signal processors designed specifically to alter electrical wave forms include a wide range of circuits used for processing EMG information. Most such circuits involve rectification, integration, and various nonlinear components used to reject noise and provide the smoothest possible electrical systems for operating the orthotic or prosthetic device. Since the EMG signal, especially when detected from within the muscle, consists of an asynchronous train of pulses, signal conditioners based upon digital - signal - handling theory are being developed. Some of these systems would "clean up" the pulse signals from within a muscle to the point where they might be used as direct signals into a digital computer.

Under another kind of theory for signal processing, combined or patterned functions are produced from one or more inputs. Among body-powered orthotic devices, the linkage feeders widely used by quadriplegics are an example *(6,29,30)*. These mechanical linkage systems support the forearm and allow the patient to convert shoulder and trunk movement into controlled movement of his hand. When given a controlled prehensile function, patients often learn to feed themselves and perform many other useful tasks. Externally powered arm prostheses have been designed for children, with coupled movements such that the programmed movement of an eating implement is obtained by the child through a single input action *(48,49)*. The conversion of a single input action to interrelated movements of each part of the prosthesis may be regarded as a type of signal processing, especially when one considers the possibility of using an electrical computer to do the same sort of thing. The sophisticated prosthetic hands built in France and, more recently, in Yugoslavia and Japan *(44,46,58,69,70)*, in which a simple set of input signals is mechanically converted to a smoothly closing movement of all fingers, constitute a type of signal processing.

Another type of signal processing is found in the automatic control systems used in some orthotic and prosthetic devices (Fig. 6). Recently, interest has developed in systems possessing automatic proportional and velocity control. Such systems differ from so-called "open-loop" systems in that feedback position or force signals are fed back to the control system itself rather than the patient. The patient provides command signals, such as a new position, to which the control system automatically responds. Such techniques have not been widely used in orthotics and prosthetics systems to date, but they have been

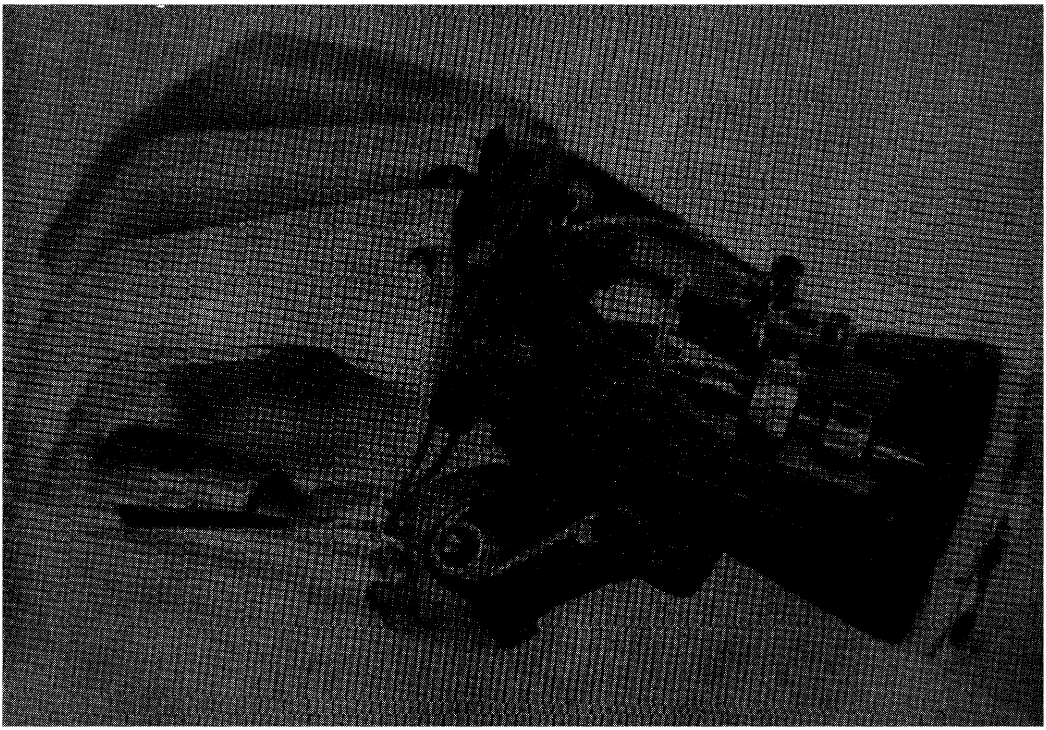

Fig. 6. A prototype automatic prehension system developed at the Army Medical Biomechanical Research Laboratory. It includes miniaturized electronics, a motor-driven No. 4 hand, and a thumb sensor. A cosmetic glove is worn over the assembly.

demonstrated in research prototypes and will probably find increasing application *(60).*

Most human motor activity is a combination of direct conscious control and patterned movements which are coordinated at levels below the conscious nervous system. Many research projects are now concerned with using computers or high-speed data processors to perform for an advanced prosthetics or orthotics system what the lower motor neuron system does for the human being. The problem is essentially one of information-channel capacity, wherein much information may be required to control a complex device but only limited channels are available for converting the desires of the patient into electrical command signals *(20,43).*

One approach to this problem was the Case Research Arm Aid, Mark I (Fig. 7) *(14),* which used a computer with pre-programmed tapes for a number of activities of daily living. The quadriplegic patient was required to select the portion of tape appropriate for the action he wished to accomplish, but he did not need to be actively involved once the action had started. More recently, proposals have been made for using computers adaptively to learn to provide patterned functions. The idea would be to store within the computer patterns or subroutines for elementary body movements which combine to produce walking or upper-extremity movement. The subject would then provide only "coarse" information about where he wanted his limb to go, and the computer would calculate according to some pre-programmed strategy how best to move his limb most efficiently from one place to another. The tremendous progress in machine computation has opened unlimited possibilities for research in such systems which can be reduced

Fig. 7. The Case Research Arm Aid, Mark I. The pneumatic system shown allowed five degrees of freedom through the shoulder, arm, and wrist. Modifications being made include conversion from a pre-programmed tape control to computer-calculated trajectories by means of myoelectric input control signals.

practically to patient needs. One can visualize, for example, a paralyzed leg being electrically stimulated according to a patterned program stored in a solid-state, micrologic computer worn on the belt. Although such a system can be imagined, it will be many years before it is technically and economically feasible *(47,71).*

IV. OUTPUT SYSTEMS

In the past, most of the research, development, and clinical application of orthotics and prosthetics systems has been concerned with the output systems, for these are the hardware devices which perform the functions required by the handicapped person. Through intuition, designers have shown awareness of control and feedback, but their attention has been primarily directed toward the powering and fitting of devices to improve the function of the handicapped.

Almost all the elements in the man-machine systems are applicable to both orthotics and prosthetics; but, when output systems are considered, it is necessary to discuss orthoses and prostheses independently, except for certain communication devices which apply to both. For example, much effort has been devoted to modifying telephone, recorder, typewriter, radio and television equipment for easier use by handicapped persons. Touch dialing, alone, is an important asset. Tape-recording and typewriters operated through coded signals from the tongue or voice make it possible for the paralyzed person to carry on a business and communicate with friends.

In addition to communication devices, attention has also been given to the development of special tools and machines so that the handicapped can perform useful work. Interestingly, much of the philosophy in the development of such tools is common with the development of special tools for astronauts to use in space. This occurs because the normal man in an alien environment is similar in many respects to the handicapped man in a normal environment. Vehicles for the transportation of handicapped persons, including powered wheelchairs (Fig. 8) and modified automobiles, must also be included in output systems for the handicapped.

Prosthetics

The term "prosthesis" brings to mind artificial hands, arms, and legs. The historical development of these artificial limbs is an extensive and fascinating study in itself. Although seemingly simple and perhaps crude, the cable-controlled, rubber-band hooks commonly used by below-elbow amputees are, in fact, quite sophisticated, and many amputees have developed remarkable dexterity with them. Probably many years will elapse before the users of EMG-controlled, electrically powered hands achieve the same level of reliability and dexterity now found in thousands of skilled hook-users around the world.

The problem is much more severe for the above - elbow and shoulder - disarticulation amputee, especially the bilateral case. It is a fact that when a patient has one good arm the margin of increase in function provided by a prosthetic second arm is often too small to make it worth his while to learn to use it. Much effort is now under way to provide improved functions for high-level amputees, especially bilateral cases. The most successful systems to date are powered by gas or electricity *(2,19,28,32,33,34,50).* Each clinical application represents a major engineering achievement, and each one is usually somewhat different from all others. This is the real limitation in the development of sophisticated upper-extremity systems, for the problem of fitting and the nature of disability are so different among the relatively limited numbers of amputee patients and congenitally deformed children that the sophisticated engineering required is often economically unjustified. However, the obvious challenge presented by the creation of an artificial human limb continues to fire the imagination of engineers throughout the world, and one may expect continued progress.

The case for the lower-extremity prostheses is somewhat different, because a man cannot walk with just one leg. Much effort has been devoted to developing lower-extremity prostheses for both above-knee and below-knee amputees. A successful prosthetic application requires close collaboration between the orthopaedic surgeon and the prosthetist. Thoughtful

Fig. 8. Ampersand Research, Highland View Hospital, three-level electromyographic control of wheelchair and flexorhinge splint.

planning concerning the nature of the stump to be produced can make a great difference in the effectiveness of the final prosthesis. Walking is one of the most sophisticated patterned functions in man. Many muscles are interrelated in producing a gait of minimum energy expenditure. One area of intensive research has been the study of human gait in order to improve the design of lower-extremity prosthetic and orthotic devices. Although considerable data have been gained through cinematography and EMG studies, there is still much to be learned, and one can expect continuing research in this area *(27,53).*

Lower-extremity prostheses are more complicated than one might imagine. The acceleration sequences required for normal human gait are not produced by a simple pendulum swing. Instead, one must build nonlinear damping devices into a lower-extremity prosthesis to control the swing phase so that it will approximate that of a normal human being. In the simplest versions, disks of leather are used to provide this friction. Recently, nonlinear and hydraulic devices have been built into artificial limbs. These hydraulic devices still suffer occasionally from seal and other failures, but they have been successfully used by amputees under a Veterans Administration evaluation program.

The problem of socket design and fitting is still under investigation, for one must transfer considerable forces to the limb, both in direct compression and in torsion. Sockets providing total-surface contact, air cushions, "breathing effect" and special types of support have been developed. For a number of years, researchers have attempted to measure the pressure distributions occurring under dynamic conditions within lower-extremity sockets. In general, these attempts have not been successful, and this remains a challenging area for future research. Such pressure-distribution data are urgently needed for the intelligent design of lower-extremity prostheses and, in some cases, for upper-extremity devices.

Orthotics

The first orthoses were the splints used to support a fractured limb and the canes and crutches used by early man. Bracing of weakened limbs due to neurological disorders and the therapeutic appliances used to overcome deformities have been widely applied by the orthopaedic surgeon and his collaborating orthotist. Through surgical reconstruction and tendon transplants, the orthopaedic surgeon can provide concepts for rehabilitation which complement improved engineering systems *(1,23).* The future possibilities of such combined surgical intervention and engineering systems development have been only hinted at and much research undoubtedly will be carried on between the engineer and the surgeon in this area.

A number of new, externally powered, and controlled splint systems are being made available to paralyzed patients. A kind of race is now occurring between the proponents of gas-powered orthotics systems and electrically powered systems. Actually, these systems are highly competitive when one considers the energy-storage capacity and weight of motors and batteries as compared to gas actuators and storage containers. The gas-powered systems still provide the best force-to-weight capability, but electric motors are being improved continuously and the overall simplicity of an all-electric system has many advantages *(22,57).*

A number of prehensile splints to provide grasp to paralyzed patients have been applied routinely, and many new multiaxis powered splints are being applied *(2,19,28).* As in the case of the complex prosthesis, the need for many different approaches to meet the many different types of disability in paralysis or neurological disorders has slowed down the broad development of externally powered orthotic systems. We believe, however, that engineering developments will soon reach the point where such systems will be widely applied to the very large number of patients who can benefit from increased functions, especially in old age. Expanded research and development in externally powered orthoses for both upper and lower extremities is certainly going to occur.

A promising new approach is being investigated throughout the world. This approach suggests the use of electrical stimulation of muscles for functional activity *(15,17,21,39,42,* *73,74).* While electrical stimulation of muscles has been used extensively for a number of years in diagnosis and in therapy, its use for functional action has only recently been studied. The increased sophistication of electronic systems and the possibility of passive and active implants suggest the realization of controlled muscle activity. Such systems would certainly operate in parallel with some sort of external functional bracing, for in the foreseeable future one can imagine only a limited number of agonist and antagonist muscles being functionally stimulated.

There is much to be learned about whether denervated muscles can be kept in an active stimulatable condition for long periods of time and whether intact lower motor systems will respond to controlled stimulation without inducing spasticity and other aberrations. The progress to date, however, is exciting and it is urged that serious consideration be given to programs of electrical stimulation of the muscles of recent victims of neuron lesions so that the atrophy of involved muscles can be retarded awaiting the day that functional stimulation can be made available.

Expanded research around the understanding of the process of functional stimulation and physiologic factors in muscle stimulation, both from a physiological and an engineering point of view, is to be expected.

V. AND VI. FEEDBACK RECEPTORS AND LOCAL FEEDBACK

A human being controlling either the most simple or the most complex assistive device must have feedback information. In normal human motor activity, feedback comes via sight, sound, touch (pressure), and proprioceptive senses. These normal feedback channels are always impaired to some degree in handicapped persons and may be altogether missing. The visual path is still the most important for control in most orthotics and prosthetics systems, but much research has been undertaken recently to relieve the patient of the need to keep his eyes consciously fastened on each part of an output task. The sounds of electric motors and gas-operated systems provide many cues for feedback control, some of which may not be consciously appreciated by the subject. Many amputees learn to interpret reflected forces and motions through Bowden cables and other body-powered components.

Much interest in sensory feedback research has been shown throughout the world, but only minimal progress has been made to date. Stereo effects are also being investigated, including transducers which produce vibration of varying phase and intensity at two points on the surface of the skin from which a sensation of spatial position proportional to an actual position can be produced *(68).* The possibility of producing a similar spatial position sense through "stereo" electrical stimulation at two different points on the surface of the skin is also being investigated.

Recently proposed orthotics and prosthetics systems, using data processes, may require local feedback which is not processed by the human. Figure 1 indicates some paths which are analogous to some afferent paths in lower motor neuron systems in the human. Systems to select the grasping pressure in terminal devices have been developed. A recent approach to the problem at the Army Medical Biomechanical Research Laboratory uses a sound pickup to detect incipient slip in lieu of pressure to modulate the force applied in an artificial hand *(60).*

To date, feedback control of orthotics and prosthetics systems has been severely limited by the inability to provide effective artificial sensory feedback, and will constitute a major barrier to overall system effectiveness for some years to come. It seems clear that a maximum research effort should be made to develop effective pseudosensory feedback signals, not only for orthotics and prosthetics systems, but also for sensory aids to the blind and deaf—areas which are, of course, closely related.

VII. ADAPTIVE LEARNING

The success of any orthotics or prosthetics system or device must depend on acceptance by a patient and his abilty to learn to use it effectively. If the device proves to be more trouble than it is worth, it will be rejected. Thousands of rejected devices now rest in closets and dark corners.

An important element of an orthotics or prosthetics system is the capability of a

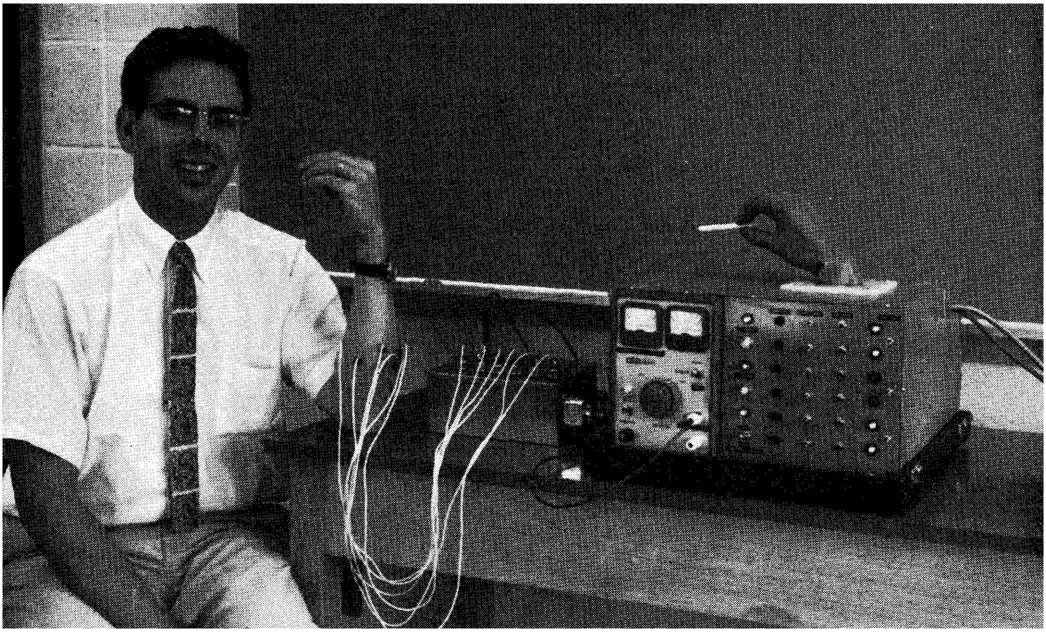

Fig. 9. A test of the feasibility of exercising three degrees of freedom by means of myoelectric control. Six muscle sites received percutaneous electrodes, all in the forearm. The six sites were then connected to a model hand trainer possessing three degrees of freedom. The motions of the trainer could be controlled to correspond with those of the control muscles.

patient, whether young or old, to learn to employ his device skillfully *(72).*

As new systems become ever more complex with many degrees of freedom (moving elements), the problem of control becomes more difficult *(45,46,78).* One may visualize a multiaxis orthosis controlled by EMG signals from six or more voluntarily excited muscles (Fig. 9). An unanswered question remains as to how well the patient can train the six or more muscles to perform the functions required, especially when the functions may be very different from those for which the muscle was naturally used. The authors have discussed this difference between so-called naturally conditioned communication channels (NCCC) and operant-conditioned communication channels (OCCC) (Fig. 10) *(75).* It appears intuitively correct to use the naturally conditioned channels wherever possible as signal sources for natural functions. The EMG-controlled artificial hands previously referred to use signals obtained from the prehensile extensors and flexors so that the amputee may open and close his artificial hand with the same muscles he would have used prior to the amputation. However, as degrees of freedom increase and the nature of the disability precludes naturally conditioned sources, one is forced to employ other muscles, such as the auriculares muscles behind the ears *(7)* or the trapezius muscles in the shoulders, as signal sources.

It is clear that much research on these issues remains to be done. Age is certainly an important factor, for it is known that young children adapt very much more easily to orthotic and prosthetic devices than do older persons. Learning capability is closely related to the amount of information being received by the patient through his feedback channels and to the amount of patterning and programming that can be done at the signal-processing level. No doubt the future will bring clarification of these matters.

EVALUATION

Before closing, a major problem which continues to face the American orthotics and pros-

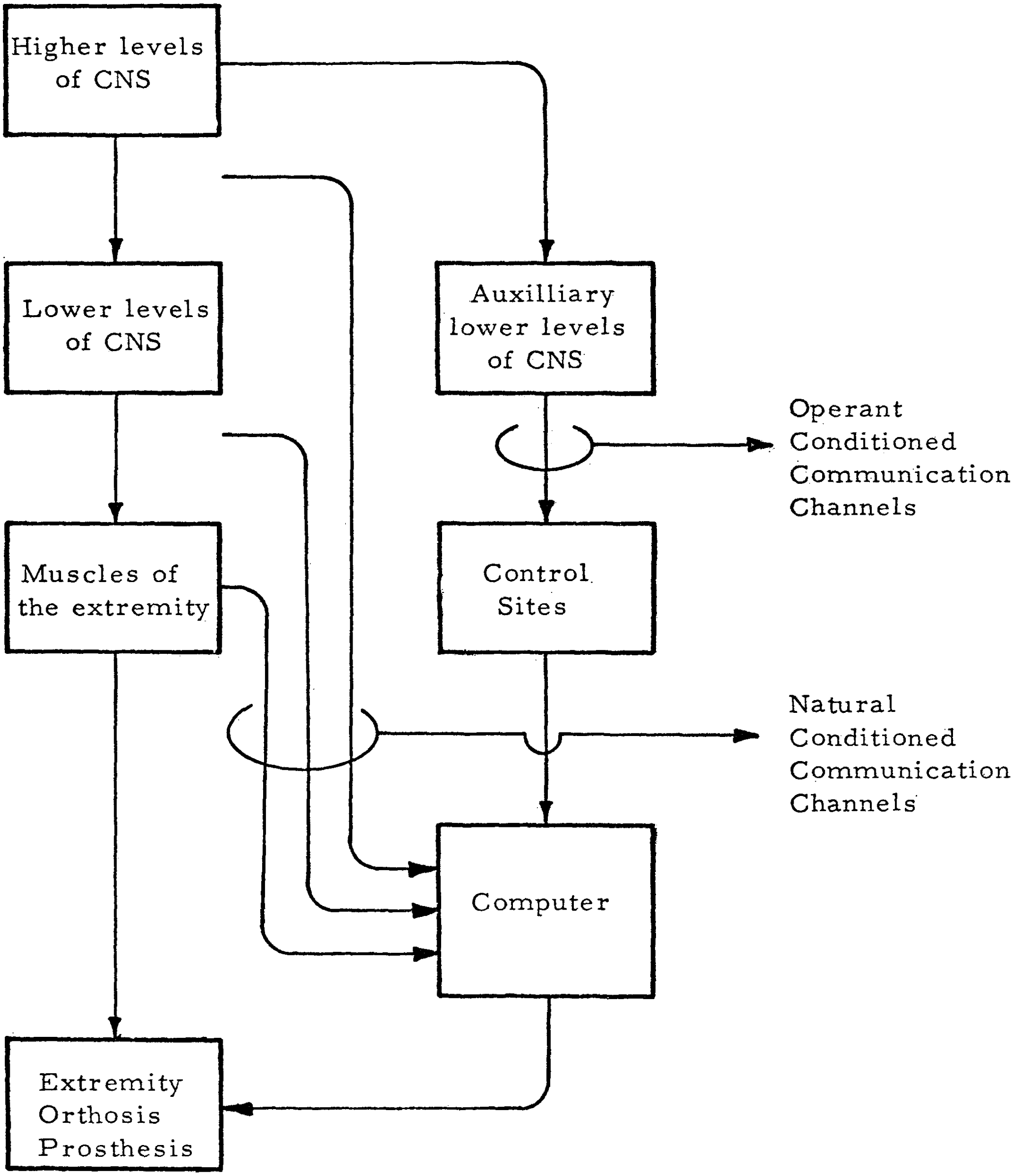

Fig. 10. Schematic representation of naturally conditioned communication channels (NCCC) and operant-conditioned communication channels (OCCC).

thetics research, development, and clinical application program should be mentioned. This is the important issue of effective *evaluation.* Evaluation does not stand alone as a specific activity. The theory that a prototype developed by one group can be taken over by a separate evaluation agency to determine if it "works," and if it works can then be taken over by a manufacturer for production, just does not often succeed in practice. Problems in the medical engineering field of prosthetics and orthotics development are immensely complicated, and often the true nature of the problem to be solved is not understood until one or two attempts have been made at solution. A constant interplay between the needs of the patient, the requirements of the physician, and the technical development by the engineer must be maintained. It is the rule, rather than the exception, that most new developments brought to the prototype stage require continued research and redesign. It seldom happens that a first-prototype development can be picked up and replicated in quantity for the field.

The implication of the foregoing remarks is that the evaluation process is a continuing and integral part of the overall design-development process and is perhaps the hardest and most expensive part. To date, inadequate funds have been allocated for its accomplishment in grant programs. The result has been that not nearly so many fruits have accrued from the research and development programs as might otherwise have been the case.

The specific need could be met by providing an overall systems-management function for the broad spectrum of activities throughout the nation. This systems-management function would be a cooperative effort authorized by federal government agencies and their advising groups. The lessons learned by the National Aeronautics and Space Administration in the management of the space effort seem applicable here, and it is the strong recommendation of these authors that the need for systems management in the broad field of orthotics and prosthetics research and development be recognized.

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