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I. Amputations and Limb Prostheses

A. General

Thermographic and Electromyographic Correlates of Stump and Phantom Limb Pain

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Sponsor: VA Rehabilitation Research and Development Service and D.D. Eisenhower Army Medical Center

Progress—Thirty amputees reporting stump and/or phantom limb pain were recorded using thermographic measures of near-surface body heat and surface electromyographic measures of muscle tension. Each subject was recorded between two and four times while reporting varied pain intensities. A consistent inverse relationship between intensity of pain and stump temperature relative to the intact limb occurred for only the burning, throbbing, and tingling descriptions of phantom limb pain and stump pain, but not for other descriptions. For subjects giving these descriptions of pain, increasing muscle tension resulted in a decrease in blood flow and an increase in pain.

Psychological Factors Influencing Chronic Phantom Limb Pain: Analysis of the Literature and a Survey of Locus of Control

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Progress—We have reanalyzed the behavioral literature concerning chronic phantom limb pain in order to determine the role of psychological factors in initiating and controlling the intensity of its episodes. We also surveyed a group of amputee veterans to determine the role which locus of control has in the report of phantom limb pain and its characteristics. Some of the behavioral literature presents an inaccurate picture of amputees who have phantom pain. This happened because much of the data were gathered from those amputees requesting treatment for phantom pain who were referred to mental health professionals.

Results—There was no relationship between locus of control and any aspect of phantom pain. We conclude that phantom pain is similar to other chronic pain syndromes in that episodes are greatly influenced by psychological factors such as stress and depression. Repeated requests for treatment are influenced by personality structure. There is no convincing evidence that major personality disorders are important in the etiology of chronic phantom pain. Nor is there evidence that such personality disorders are more prevalent among those amputees reporting phantom pain than among those who do not report it.
Fluorometric Quantification of Low-Dose Fluorescein Delivery to Predict Amputation Healing

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Purpose—This retrospective study measured the delivery of fluorescein to skin by fiberoptic fluorometry to determine the healing potential of an amputation site. Fluorometry employs a dual-channel fiberoptic light guide; one channel transmits blue light to excite the fluorescein in the skin under study, and the other transmits the emitted fluorescence from the skin to a photomultiplier tube where it is measured. Ten minutes after intravenous administration of sodium fluorescein (4-8 mg/kg), fluorometric readings were obtained at more than 100 skin sites.

Progress—In the 86 cases without preoperative cellulitis at the site of amputation, preoperative fluorometry clearly distinguished between healing and nonhealing sites. Healing sites average 76 percent of the fluorescence of a healthy reference area (Dye Fluorescence Index or DFI = 76), while failing sites averaged only 27 percent (p < 0.01 by analysis of variance). In all but one case where the DFI was greater than 42, the amputation healed. In all cases where the DFI was less than 38, the amputation failed. The technique maintained its high accuracy in diabetic patients and for distal amputations. However, in 12 cases it was not accurate at sites of active cellulitis. There were no significant adverse effects from the slow injection of the low dose of fluorescein employed for this technique. We conclude that fluorometry is an effective means of predicting healing in patients undergoing amputation.

Development of Materials for Percutaneous Passage

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Purpose—This study has the following objectives: 1) to examine whether percutaneous devices fabricated from porous vitreous carbon can function satisfactorily in vivo over extended periods of time; 2) to determine whether the interface formed between dermal tissue and porous carbon devices is capable of preventing the infiltration of bacteria present at the exit site; and 3) to evaluate the effects of cyclic loading upon wound healing, tissue ingrowth, and the long-term performance of the percutaneous implant.

Progress—During this report period, results of the work have been very promising. The overall goal of developing a material system that can be used for creating long-term percutaneous passageways seems feasible. A preoperative conditioning program has been developed for use with the pigs to reduce the need for drugs during handling and inspection of the implant sites. The protective vests have been fabricated and modified for pigs to provide an effective mechanism for preventing the animal from rolling on the implants and yet provide easy access to the implant for daily inspection and infection control.

Baseline information on the time required for wound healing in the miniature swine has been established and is available for the study that will be conducted during the third year as well as the bacteriological studies which are
currently being performed.

Histopathology exams have been accomplished on the implants which have been excised from the rabbits and pigs. Tissue ingrowth into the pores of the prostheses has occurred and there is a mild chronic inflammatory response to the prostheses. There is light to moderate fibrosis around the implants. There is no histological evidence of infection in the tissue surrounding the implants.

Bacteriology studies have been conducted on percutaneous devices implanted in miniature swine. The implants were permitted to heal for 4 weeks during which time daily visual inspections were made to detect sinus tract formation or marsupialization. During the 4th week after the devices were implanted, swab cultures were taken to describe the bacterial flora present at the implant site. The bacteria recovered represented typical flora that would be expected from skin cultures that might be taken from healthy animals.

During the 5th week after implantation two implants on each of the swine were given a very aggressive bacterial pathogenesis challenge. Saline containing 100,000 cells per ml each of S. aureus and Ps. aeruginosa were painted on the test devices and cultures were collected 24 and 72 hours later.

Results—These studies have shown that percutaneous devices can be implanted in both rabbits and miniature swine successfully and that the implant sites resist infection with normal flora bacteria for as long as 5 weeks. The pathogen challenge studies show that although superficial surface colonization and infection may occur after application of the pathogens, penetration of the challenge pathogens into the tissue under the implanted devices did not occur.

Myoelectric Controller for Orthotic/Prosthetic Systems

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Purpose—The aim of this project is to develop the techniques and instrumentation necessary for the high spinal cord injury and amputee population to obtain multiple command control signals, for use in activation of upper extremity orthotic and prosthetic appliances. Emphasis is placed on producing command signals that are proportional in nature and with sufficiently high signal-to-noise ratios for the execution of controlled movements. As a result of this research, we will develop a command control scheme which optimizes the performance and fidelity of the output device.

Progress—The focus of this project has been the development of the implanted circuitry of the telemetry device. The design has been completed and the central component, a semicustom CMOS integrated circuit has been fabricated. The device will process up to eight channels of information at a total rate of 11 KHz. Powering and transmitting of the device is via radio frequency energy. The transmitter design is nearing completion.

Future Plans—The telemetry circuitry layout and fabrication will be completed and packaged in already developed and tested titanium enclosures. We plan to evaluate the reliability and performance of the device in a dog animal model.
B. Lower Limb

1. General

**Computer-Aided Alignment of Lower Limb Prostheses and “Expert” Systems**

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**Purpose**—Alignment of a lower limb prosthesis when an amputee walks is largely a subjective exercise that is guided by certain principles or rules that have developed over the years. It is a procedure that requires knowledge, judgement, and experience. Our objective is to develop quantitative tools which we can use to understand the alignment process better in order to improve the alignment procedure and thereby improve prosthetic management of lower limb amputees.

The first part of our plan to gain understanding of the alignment process is to develop tools through which we can quantify and represent, in an objective domain, the subjective rules that characterize the alignment protocol of experienced prosthetists. This quantification will be carried out with a movement-analysis system, the CODA-3. Since alignment is now carried out by visual observation, the motion analysis equipment should be able to gather, in greater detail, the information now gathered visually and used by prosthetists for dynamic alignment procedures.

During the alignment process, the CODA-3 Movement Monitoring Instrument will be used in two modes. These modes may exist simultaneously. During one mode, the real-time, high accuracy feature of the CODA (300 Hz sampling of landmark 3D-Cartesian coordinate position, accuracies on the order of plus or minus 0.3 mm) will be used to assist the prosthetist in establishing a particular limb alignment state (the socket-foot relationship consisting of three position and three orientation degrees-of-freedom). In the second mode, the CODA-3 will be used in a more traditional “observational” mode to evaluate the gait characteristics at that particular alignment state. By making these quantitative tools accessible (both measuring state of alignment and facilitating the display of quantitative information pertinent to amputee performance) the prosthetist will be able to carry out the alignment process in a more objective and quantified domain.

To understand the alignment process and to establish a functional relationship between alignment variables and those gait variables which strongly influence alignment, the motion analysis tools will be used in a study involving ten below-knee amputees who are “good” walkers and two prosthetists who are considered to be “expert.” This study will proceed by comparing pertinent measured walking parameters established during walking within the “range” of good alignment for each amputee/prosthetist combination, with these same parameters measured while walking in an alignment state which has resulted in a prosthetist identifiable “gait deviation.” Since alignment is a highly individualized process these studies will be self-referential while the feasibility of using this approach is tested.

In the second part of our plan, we will organize and focus our thoughts by establishment of a so-called “expert” system for alignment. This is a knowledge-based computer system based upon expert prosthetist knowledge and experience with alignment. By coupling rules of thumb and heuristics with mathematical models based on physical principles in an expert system framework, our understanding is
not only formalized and can be recalled, but potentially, new knowledge can be compared with our present understanding of alignment and added to the expert system, if appropriate. For example, once we have established a reasonable understanding regarding alignment state, prosthetist observable gait variables, and the correlating types of amputee motor strategies during walking, additional parameters such as the floor reactions and joint moments can be studied from within the context of an identified amputee walking strategy.

**Progress**—Our present work relates to the development of quantitative measurement tools and information displays which make the full potential of these tools accessible to the prosthetist. A computer system integrating the CODA-3 and two biomechanics platforms (force-plates) has been developed. Our computer system has been designed with the potential for also acquiring and storing EMG data. While the present CODA-3 model we possess needs to be updated to realize its potential, we expect this to be done in the near future, not causing significant project delays.

Software allowing real-time interactive or post-processed displays of the socket-foot relationship has been partially completed. The facility for overlaying data (real-time or post-processed) on video images of amputee activity (floor-reaction, EMG, kinematic information, etc.) is also currently in progress. We will soon be mounting our biomechanics platforms permanently within a raised walkway to allow the walking-trials portions of this project to proceed on a continuing basis.

It is hoped that our understanding of objective alignment criteria will mature in the future to the point that the prosthetist, guided by the expert system, can utilize the objective measurement tools to quickly and accurately arrive at an acceptable alignment state.

### Automated Fabrication of Lower Extremity Prosthetic Sockets

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**Sponsor:** VA Rehabilitation Research and Development Service

**Purpose**—The goal of this project has been to demonstrate the technical and economic feasibility of using CAD/CAM techniques to fabricate sockets for above-knee amputees.

**Progress**—During this report period, a mechanical shape sensing system has been fully automated and is capable of collecting circumferential data that are at least as accurate as the data collected by prosthetists and the instrument is capable of providing both overall and segmental shape information that is not easily obtainable when using conventional casting procedures.

The interface pressure loading on the stump has been defined and characterized using a series of pneumatic pressure sensors. This activity has demonstrated that the most proximal 4-6 inches of the stump is where most of the differentiation occurs when the cast is rectified. The interface pressures in this region range between 90 and 120 mm Hg when the socket is comfortable. When the interface pressure exceeds 150 mm Hg the socket is perceived to be uncomfortable by the user. Below the top 6 inches of the socket the interface pressure remains relatively uniform over the surface of the stump and has an average magnitude of 60 mm Hg. An ultrasonic based tissue property measuring system has been finalized and is being used to collect modulus information to characterize the soft tissue which comprises an amputee's stump.

Tissue property data collected with the ultrasound based system have been compared with tissue properties collected using the more conventional measuring systems and the data are in good agreement. The ultrasound system is capable of detecting stiffness changes due to edema and muscle contraction.
Two sockets for above-knee prostheses have been fabricated using the algorithm developed in the project and have been fitted with no modification by the prosthetist. One of these legs has been worn for 6 months and is now not being worn because the user has lost 20 pounds and the socket is loose. The second leg has been used for approximately 1 month with no negative indications at this time.

The technology which has been developed in this project has proven the technical feasibility of using CAD/CAM techniques to emulate the socket casting process that is currently used by prosthetists. It remains to be demonstrated that the laboratory prototype instrumentation can be transferred into clinically reliable tools. Moreover, the patient population who can be best served by using this process must be defined empirically through clinical use.

Using the ANSYS finite element code, a model for the above-knee stump has been developed that is capable of calculating the shape of the stump that will provide the desired surface loading characteristics as a function of the material properties of the soft tissue comprising the stump. The model has been developed and refined so that it now runs on the Cyber 175 computer in less than 25 minutes.

Software has been developed that enables us to take the displacement solution from the ANSYS analysis and interpolates the data so that an input file can be created that is compatible with the requirements of any numerical control (NC) machine programmer. This software makes use of an interpretation scheme developed by Akima which can be used for both closed curves and open curves. This technique has been shown to be more accurate than the Spline functions that are customarily used to fit the data that generate the tool pattern for an NC machine. This software is modular in nature and can be used with a variety of mainframe computers or the larger personal computers, such as the AT&T 6300.

CAD/CAM of Lower Extremity Prostheses: The San Antonio System

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Sponsor: In-house funding

Progress—The Rehabilitation Engineering Lab (REL) at the University of Texas Health Science Center at San Antonio is currently working on a system for computer-aided design and computer-aided manufacture of prostheses. This system, when perfected, will offer the amputee an opportunity for optimal prosthetic socket fit. It will also provide computer analysis of current socket design for research purposes.

The project is divided into three sections:
1) The development of a shape sensing device. There are four subdivisions of this section: ultrasound, radiant image, digitized, and video images.
2) The development of a user-friendly software package capable of running on a microcomputer. This section has two subdivisions. One is a software packaged interfaced with the shape sensing device that will allow the operator to custom design a prosthetic socket. Two, a software package that will interface with the computer-aided designed package for computer-aided manufacture of the prosthetic socket from the computer-generated data.
3) The development of an automatic computer-operated alignment device that can be permanently mounted in the prostheses.

Results—The shape sensing devices are described in other progress reports. The computer program for prosthetic design is approximately 80 percent complete and the program for control of the computer-operated milling machine is 95 percent complete. The REL is actively seeking research funds to accelerate this project. Currently, the project is a part-time, in-house funded study.
Ultrasound as an Aid to Prosthetic Socket Design

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Progress—The ultrasound shape sensing device currently in use at the San Antonio Rehabilitation Engineering Lab (REL) is capable of producing an accurate computer-generated database topographical image of a residual limb. The system is composed of two subsystems: the ultrasound and analog electronics subsystem; and, the computer-based data acquisition and control subsystem.

An image of a patient's residual limb is automatically generated in five to ten minutes. The data representing the topological shape of the limb are stored on the computer's hard disk unit as a set of X, Y, and Z coordinates. This data may then be retrieved, viewed, and modified by a number of custom and commercially available application programs. One such program would allow a prosthetist to easily modify the data so as to reshape the topological surface according to normal prosthetic principles. The final version of the data may be sent via modem or floppy disk to a machine shop where a socket mold could be manufactured on a computer numerically controlled milling machine. One advantage of a computer-based system is that the original and modified data are permanently stored. Thus, if there is a problem with the fit of the first socket, or atrophy of the residual limb over time, then corrections may be made using the computer (rather than re-scanning the patient).

Results—We are currently using an AT&T 6300 (IBM compatible) microcomputer to acquire data and control the imaging system. However, any computer with a parallel data port, a GPIB interface, and graphics capabilities may be used (if appropriate software is available). The REL is actively seeking funding to improve the USSD so that it can detect and image bone, image residuals up to 20 inches in length, and then acquire the image in five seconds or less real-time.

Computerized Tomography as an Aid to Prosthetic Socket Design

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Progress—The Rehabilitation Engineering Lab (REL) at the University of Texas Health Science Center in San Antonio recently acquired a computer system developed by Contour Medical Systems, Inc., of Mountainview, CA. This machine, the CEMAX 1000, can reconstruct three-dimensional images of tissue and bone from an analysis of computed tomography data. This system is used as a shape sensing device to capture the exact topographical image of an amputee's residual limb. The CEMAX 1000 has software written for it which allows the research prosthetist to modify the CT scan in much the same way as he or she would modify a positive model.

This modified image is then transmitted to Contour Medical System's computer-controlled milling machine for positive model manufacture. The model is then returned to the REL where a transparent check socket is fabricated. CT data scans of an amputee's residual limb provide an excellent quantitative record. The CEMAX 1000 also provides a system that allows the operator to quickly and accurately reconfigure a three-dimensional computer image of the residual limb for prosthetic socket
design and manufacture.

Future Plans—The next step in this project proposes the milling of a below-knee prosthetic socket by Contour Medical Systems bypassing the positive model step.

The 3-D Digitizer as an Aid to Prosthetic Socket Design

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Purpose—The 3-D digitizer currently used by the San Antonio Rehabilitation Engineering Laboratory is the "Preceptor TM." It is a precision electromechanical unit that allows direct spatial digitization of solid three-dimensional objects.

In operation the stylus at the end of the Preceptor's arm is tracked over a solid object such as a negative cast of the amputee's residual limb. A precision potentiometer housed in the extension arm computes the X, Y, and Z coordinates based on the angle of rotation and known arm length that reaches to 17 inches.

Utilizing the "Advanced Space Graphics TM", a three-dimensional graphic software package which can be used for quickly creating and manipulating images in three dimensions, we can produce wire frame objects and line sketches that can be quickly and easily modified and stored for future use.

Progress—The REL has developed a companion software package that allows us to digitize a negative cast of the amputee's residual limb after we have split the cast in half. After digitization, the two halves are reunited and sent via telephone modem to a central fabrication unit. Here socket manufacture takes place utilizing computer-controlled milling machines.

Study of Alignment in Lower Limb Prostheses

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Purpose—The 1985 issue of Rehabilitation R&D Progress Reports gave an outline of the aims and methodology employed in this project. This work is still in progress. The investigation is a systematic study of the lower limb alignment parameters in order to gain an understanding of the biomechanical factors which make a limb configuration acceptable to the amputee.

Progress—In the experiments carried out, three prostheses were involved in the majority of 183 below-knee and 100 above-knee fittings. It was found that each patient was satisfied by a range of alignments and the range for each amputee was established. The study also showed that, on average, an amputee can tolerate a variation of ± 5 degrees in socket flexion, ± 25 mm in socket forward set, ± 4 degrees lateral tilt and ± 20 mm socket set-out. From the data acquired it was possible to arrive at recommendations for bench alignment and for the range of adjustment required to be incorporated into the design of alignment units for both below- and above-knee prostheses. The results of this part of the investigation have been published in the Journal of Rehabilitation Research and Development, Vol. 23, No. 2.

A study of the effect of various acceptable alignments on an amputee's gait patterns was made using kinetic and kinematic measurements. It was found that for an amputee walk-
ing on a certain prosthesis there exists a step-to-step variation in the various gait parameters. This variation must be quantified before any attempt is made to obtain comparisons of gait parameters resulting from various acceptable alignments.

Taking the step-to-step variations into account it was established that the alignment of a prosthesis has a direct effect on the amputee’s gait pattern. Although small differences in gait pattern can be detected, using an analysis of the kinetic parameters alone, for a complete understanding of amputee locomotion both kinetic and kinematic information is necessary.

Using biomechanical considerations, it was found that it was possible to select the most appropriate alignment from a number of acceptable alignments.

**Preliminary Results**—The work so far carried out has indicated that a considerable amount of work is still necessary before a proper understanding of the biomechanics of amputee locomotion and the effects of alignment changes on prosthetic gait can be obtained. Further investigations incorporating the study of the contralateral side and the movements of the trunk are planned.

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### The Effect on Gait Using Various Ankle-Foot Devices

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**Purpose**—The purpose of this study is to determine criteria for the prescription of prosthetic ankle-foot devices. The study examines relationships between physical characteristics of amputees and locomotion performances when using different ankle-foot devices on level and non-level smooth surfaces. Five different configurations under investigation are: 1) SACH, 2) SAFE, 3) articulated single axis, 4) multi-axial Greissinger, and 5) SEATTLE.

**Progress**—The design, construction, and testing of special equipment needed to conduct the study were completed: a) a ramp incline/decline apparatus to test locomotion while accommodating ascent/descent of a ramp and a lateral incline to one side and to the other, b) an accelerometer pack to attach to the prosthesis for measuring angular accelerations in two planes, and c) special foot switches. In addition, a manually actuated, spring loaded horizontal pendulum was constructed and used to calibrate the accelerometer pack. Equipment used in a concurrent grant titled “Analysis of Below-Knee Suspension Systems: Effect on Gait,” including knee electrogoniometers, a gimbal mounted biaxial accelerometer, and a tachometer are used in this study. A test protocol was developed and testing of amputees was started. Data treatment will be a comparative biomechanical analysis and will focus on identifying and interpreting anomalies in the locomotive performances of the amputees which are expected to relate to effects resulting, for example, from the different ankle-foot devices and the length of the stump. Computer programs and computing procedures developed for the suspension study have been modified and adapted for use in this study.

**Future Plans**—The five ankle-foot devices will be tested on 20 unilateral below-knee amputees, results will then be analyzed, and a report will be written on the findings.
Survey of Design Criteria for Prosthetic Knee and Ankle Joints

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Sponsor: Scottish Home and Health Department

Purpose—Although many knee mechanisms, some incorporating ingenious features, have been designed to provide stance phased stability and swing phased control for above-knee prostheses, apart from very few exceptions, most of these have been rejected by the amputee. The only mechanisms that have had some success have been the very simple types despite their limitations. A reason for this failure may be due to the lack of a complete specification of the design requirements or due to inability of the designer to satisfy all criteria. In order to investigate the situation, a preliminary study was undertaken and briefly described in the VA Rehabilitation R&D Progress Reports of 1985.

Progress—The survey has been extended to involve some 150 amputees. Basically the aim is to obtain the amputee's opinions towards his prosthesis taking into account function, comfort, and cosmetic restoration aspects. The survey, which takes the form of a structured conversation, attempts to obtain answers to questions relating to the following: comfort, integration, and acceptance of the prosthesis; determination of problem areas; phantom pains and conditions under which they exist; physical characteristics of the prosthesis (e.g., mass, alignment); performance during ambulation and other daily activities; performance of the artificial knee and ankle joints; and, determination of desirable features to be incorporated in future prostheses. The opinions of prosthetists and clinicians on the above topics also are being sought.

It is hoped that this investigation will provide useful data for the formulation of criteria for the design of enhanced prosthetic knee and ankle joints.

Fiberoptic Fluorometry as a Useful Adjunct in Determining Lower Extremity Amputation Level

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Purpose—Preoperative prediction of amputation healing in the ischemic lower extremity remains difficult. When attempting to maximize the patient's rehabilitative potential by performing the amputation as distally as possible, amputation failures have been frequent. Quantitative fluorometry is a method for evaluating cutaneous perfusion following intravenous administration of the dye sodium fluorescein. Using a well-perfused reference site on the upper extremity, a retrospective study predicted amputation failure when the fluorescein delivery at the amputation site was less than 38 percent of the reference site, and success when it was greater than 42 percent (see abstract: Silverman, et al., Fluorometric quantification of low dose fluorescein delivery to predict amputation healing).

Progress—In this prospective study, 48 patients underwent fiberoptic fluorometry before undergoing 65 amputations, and preoperative predictions of amputation healing were made. Four amputations were excluded because the extremities were either edematous, cellulitic, or had abnormally thickened skin. In our experience,
the presence of any of these factors reduces the predictive value of the test. Of the remaining 61 amputations, four had fluorescein ratios of less than 38 percent and these amputations failed. Fifty-two amputations had ratios greater than 42 percent, and 47 (90 percent) healed.

Preliminary Results—The test had a sensitivity of 100 percent, a specificity of 44 percent, and a predictive value of 91 percent. We conclude that fiberoptic fluorometry is a useful adjunct to the clinical judgement of the surgeon, when he is attempting to optimize his patient’s rehabilitative potential while avoiding amputation failures.

Determining the Need or Level of Amputation by Assessing Nutritive Skin Blood Flow

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Adequate nutritive skin blood flow is the prime requirement for the healing of amputation sites in patients with peripheral vascular disease. We developed a multidisciplinary approach to the measurement of skin blood flow and the clinical evaluation of these patients. The purpose of the studies was: 1) to develop an accurate-clinical test of skin blood flow which was predictive of skin wound healing in patients coming to amputation; 2) to develop a quantitative measurement of skin blood flow for comparison to existing methods; and 3) to compare and correlate several different skin blood flow methods including quantitative fluorometry, xenon washout, helium flux, and laser doppler velocimetry.

Progress—

1) Clinical Studies of Fluorometry. We have completed studies of quantitative fluorometry in a large group of patients coming to amputation. In a retrospective study of 62 patients we found that the mean level of fluorescein delivered to the amputation site was 79 ± 37 percent of a well perfused reference area in all patients whose amputations healed. The mean fluorescein delivery to non-healing sites was 27 ± 14 percent. Using criteria developed from this study, we found in a prospective investigation, that the fluorescein test had a sensitivity of 100 percent, a specificity of 44 percent, and a predictive value of 91 percent. We find fiberoptic fluorometry to be a useful adjunct to clinical judgement in patients requiring amputations.

2) Evaluation of Helium Flux for the Measurement of Skin Blood Flow. We set up the helium flux measurement of skin blood flow developed by Baumgardner, et al. (J Appl Physiol 58:1545, 1985). We measured the helium flux through the skin with a small heated probe at several temperatures in the range between 32 degrees C and 42 degrees C. The diffusional resistance of the skin to helium was minimized (assumed equal to zero) by skin stripping with adhesive tape. We found a linear relationship between helium flux determined blood flow and temperature of the skin probe in normal subjects. The average blood flow at 33 degrees C was 2.4 ± 1.1 and at 42 degrees C was 5.8 ± 1.6 mls/min cm^2.

3) Comparison of Skin Blood Flow Measurement Techniques. In preliminary studies of fiberoptic fluorometry versus laser doppler velocimetry, we find a close correlation between relative skin blood flow by fluorometry and the increase in laser doppler signal to an increase in laser probe temperature. The use of a temperature “challenge” with the laser doppler provides consistent data between subjects and skin sites. We found a linear relationship between blood flow determined by helium flux and Xe^{133} washout. We compared helium flux
blood flow measurements to the laser doppler at several skin temperatures and found the laser to give non-linear response to rising temperature (as described by others) while the helium flux determination yields a linear response over the same temperature range.

**Future Plans**—While the measurement of skin blood flow by helium flux is the most reliable quantitative method we have tested so far, it is slow and requires that the stratum corneum be removed prior to the study. We are developing a new method to measure stratum corneum diffusive resistance which hopefully will eliminate the need for skin stripping. Studies are planned to examine the transport of other gases across the skin including oxygen, carbon dioxide, argon, and xenon to further characterize the relationships among blood flow, diffusive resistance, solubility, and metabolic activity. In addition, we are developing new techniques for rapid comparison of laser doppler measurements which do not require a change in probe temperature.

**Aerobic Training Improves Cardiovascular Fitness and Increases Efficiency of Walking in Lower Limb Amputees**

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**Sponsor:** VA Rehabilitation Research and Development Service and The Special Team for Amputation and Mobility Prosthetics/Orthotics, Dallas VA Medical Center

**Progress**—Ten lower limb amputees were studied before and after a 15-week aerobic conditioning program to determine if regular exercise involving the upper limbs and the remaining lower limb(s) would improve their cardiovascular fitness and reduce the effort of walking. Each subject exercised on a Schwinn Air-Dyne ergometer (SAE) regularly during each week at 60-80 percent of their estimated maximal heart rate (HR). A maximum exercise test on the ergometer and a treadmill walking test were administered before and after training. After training there was a 27 percent increase in maximal exercise capacity on the SAE as well as significantly lower values in heart rate and oxygen consumption (ml/min/kg) during treadmill walking at various inclined grades, whereas there were no changes in control amputees. Aerobic conditioning of the lower limb amputee was shown to not only improve cardiovascular fitness but increase their walking efficiency as well.

**Relation Between Cardiac Condition of Leg Amputees and the Success of Their Prosthetic Rehabilitation**

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**Sponsor:** Dutch Heart Foundation

**Purpose**—Most leg amputations are performed because of peripheral vascular insufficiency. In patients who are over 50 years atherosclerosis may have caused changes in the brain and heart. When prescribing a prosthetic training program to the leg amputee it must be considered whether the patient is capable of undergoing the physical and emotional stress of the training involved.

The aim of this study was to investigate the influence of the cardiac status on the rehabilitation process and to assess cardiac loads provoked during prosthetic training exercises.

**Progress**—Cardiac loads were estimated from the results of automatic analysis of the ECG: heart rate responses (as a measure of cardiac load), morphological changes (ST-segment anal-
ysis), and arrhythmia detection (as possible indicators for overloading of the heart). An integral system for ECG-analysis during rehabilitative exercises was developed.

Of the 39 leg amputees taking part in the study two-thirds had a history of previous cardiac disease. All performed a graded exercise test (rowing ergometry) within one month after starting the rehabilitation to assess their cardiac response to exercise and to evaluate the cardiac status. In 87 percent of the patients the prosthetic training was completed successfully. The functional rehabilitation result showed relationships to age and peak workload in the initial exercise test. The level of amputation had no prognostic value for the functional rehabilitation result. It was noted that total rehabilitation time was strongly related to the progress of wound healing.

Heart rate response was obtained during one leg walking, walking with a preliminary prosthesis, and prosthetic walking. The averaged peak heart rate values were not different, whereas the steady-state heart rate level was lower during walking with a preliminary prosthesis and the definitive prosthesis than during one leg walking. The walking speed and walking distance increased with the stage of rehabilitation. Monthly repetition of the graded exercise test showed that during normal rehabilitation no overall improvement of a patient's cardiac condition is to be expected.

**Results**—No excessive cardiac loads are to be expected when the leg amputees with peripheral vascular disease are allowed to choose their own walking speed during training exercises. In patients with a low peak workload during the exercise test it is advised that ECG be monitored frequently, especially when the patients are exercised in one leg walking.

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**Limb Viability: Vascular Reconstruction and Amputation Surgery**

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**Sponsor:** VA Rehabilitation Research and Development Service

**Progress**—Work on the limb viability project is divided into three main components: 1) evaluation of new instruments and techniques for assessment of limb viability with vascular reconstruction and the assessment of objective preoperative amputation level selection; 2) evaluation of the role of education in the prevention of amputations in high risk diabetic patients; and 3) evaluation of regional hyperbaric oxygen as an adjunct to amputation stump and/or wound healing.

The limb viability studies have involved head-to-head comparison between intradermal Xenon$^{133}$ skin blood flow techniques, transcutaneous oxygen, transcutaneous carbon dioxide, laser doppler, and doppler derived ankle and segmental limb blood pressures. In a prospective evaluation which is currently under study, the preliminary results show that both transcutaneous oxygen and transcutaneous CO$_2$ provide statistically valid end points for the preoperative determination of amputation level selection. Neither the laser doppler, ankle/arm blood pressures, nor Xenon$^{133}$ had statistical reliability. In addition, intraoperative monitoring with transcutaneous oxygen and transcutaneous carbon dioxide are suggesting that those techniques have utility for intraoperative and postoperative monitoring with respect to the ability to predict both short-term and long-term graft patency. Material on both the amputation level selection data and the intraoperative monitoring have been submitted to meetings for consideration for presentation; however, at this time none of the data have been accepted for publication.

**Preliminary Results**—A prospective evaluation of the role of education in prevention of recurrent foot ulceration, foot infection, or amputation in high risk diabetic patients has just been completed. The data are currently undergoing
statistical analysis, but the preliminary evaluation suggests that patient education can produce a three-fold reduction in the incidence of limb amputation in diabetic patients with foot infection, foot ulceration, or contralateral limb amputation. When analysis of the data is completed, a formal manuscript will be submitted for publication. In addition, it would be anticipated that these preliminary data need verification by a larger study, possibly a VA-wide or S.T.A.M.P. evaluation.

The final area of research has involved an evaluation of the use of regional hyperbaric oxygen in an effort to obtain healing of non-reconstructable ischemic limbs. The project involved the assessment of transcutaneous oxygen values before and after treatment with regional hyperbaric therapy. Although there are individual patients in whom hyperbaric oxygen has been of help, it is impossible to predict beforehand which patients are likely to benefit from therapy.

**Future Plans**—During the upcoming year we plan to expand our prospective study of tests on limb viability, to expand our educational diabetic program, and complete and publish our findings with hyperbaric oxygen. In addition, we anticipate finalizing development of a new noninvasive tool for the determination of skin blood pressure and tissue oxygen saturation.

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**Use of Cutaneous Pressure Photoplethysmography in Managing Peripheral Vascular Occlusive Disease**

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**Sponsor:** VA Rehabilitation Research and Development Service

**Progress**—A technique for local measurement of cutaneous perfusion pressure (CPP) has been developed which utilizes photoplethysmographic measurement during local pressure application to the skin. A total of 225 limbs have been studied to evaluate the usefulness of the method in detecting peripheral arterial disease and in differentiating disease severity. In a further study of 11 prospective amputees, CPP measurements were taken to determine the usefulness in evaluating amputees. A significant decrease in CPP from the chest to the dorsum of the foot was seen in limbs with arterial disease, where the disease was evidenced by intermittent claudication, rest pain, and/or gangrene.

**Results**—The results indicate that the technique can successfully identify the presence of peripheral vascular disease, distinguish among different levels of severity, and aid in determining the optimal level of amputation consistent with wound healing, as well as assisting in following the patient’s course of recovery after reconstructive vascular surgery.

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**Clinical and Laboratory Study of Amputation Surgery and Rehabilitation**

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**Sponsor:** VA Rehabilitation Research and Development Service

**Purpose**—During the past year, the Seattle foot has become commercially available. Approximately 9,000 feet are now being worn by veterans and other amputees around the world. The design has been and has continued to be improved. The research and evaluation provided by the VA Rehabilitation Research and Development Service is responsible for the development and technology transfer that has stimulated extensive additional research into prosthetic design.
thetic feet by both the industry and by other prosthetic research sources. This activity translated through technology transfer is directly reflected in improved quality of life for lower limb amputees throughout the world.

**Progress**—The Prosthetic Research Service is continuing active related development of additional lower limb components. A monolithic, gravity energy storing ankle is now in the process of clinical, bench and gait laboratory evaluation. The ankle provides controlled and programmed rotation, inversion, eversion and modestly enhances flexion/extension for the Seattle foot when the two units are used together. Force/motion vectors are provided by design and materials and not through conventional mechanisms.

The shank assembly intrinsic incorporated alignment device and cosmetic foam and cover are being developed to complete the VA/Seattle Below-Knee Prosthesis. At the rate of present development and evaluation we plan to have the total prosthesis available for national field testing before the end of the current (1987) fiscal year.

**Socket Research.** Our facility is actively engaged in automated fabrication of below-knee prosthetic sockets. We have a working agreement with the University College London, Roehampton Bioengineering Unit. Below-knee plaster male residual limb molds are digitized magnetically. These numerical data are forwarded by satellite (Easylink) to our London collaborators where they are transferred to milling and socket forming equipment. Completed sockets are then returned to us. They can be fitted to the limb and aligned exactly as they were received from London. The fit is compliant, comfortable and the wearer can run an average of 5 miles per day 4 to 5 days per week.

We are continuing to investigate a variety of types of shape sensing including ultrasound under pressure which will allow some definition of durometer or stiffness of the tissues as well as the physical shape. The present magnetic shape sensing we use can be combined with a transducer to also measure firmness of the underlying structures, i.e. directly from the residual limb. CAD/CAM automated fabrication systems are being studied both in this country, Canada, and a number of other centers throughout the world. We are in communication with these various investigators.

Limb Viability studies continue through recent extension of funding of the micro-wound biological structure investigation and TCPO₂ evaluation of the circulatory status of residual limbs under pressure. This latter information should be useful to us in the CAD/CAM project. Forthcoming scientific publications and/or monographs will describe the progress made in this essentially basic evaluation of the healing capacity of the skin *in vivo* in the presence of ischemia and related pathological states necessitating limb ablation.
Amputations and Limb Prostheses

B. Lower Limb

2. Below-Knee

Sockets with Flexible Brims

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Sponsor: VA Rehabilitation Research and Development Service

Progress—A practical and simple design for the below-knee amputee that uses an inner lining that is vacuum-formed from a thin sheet of the ionomer, Surlyn, has been tried and proved quite satisfactory. The change in stiffness between the supporting structure of the socket and the proximal border of the socket in this design is a function of the distance between the trim lines of the liner and the supporting structure on one hand, as well as the thickness of the Surlyn.

Preliminary Results—Patient reaction to this design was very positive, and prostheses with sockets of this design are being used rather routinely even though until very recently we have not had the opportunity to collect objective data in a systematic way.

One patient completed the evaluation protocol, which consists of monitoring the subject's heart rate and walking and standing activity under controlled and uncontrolled conditions with the best-fitting conventional prosthesis and with the experimental prosthesis. Experience with this 78-year-old, rather inactive subject demonstrated that the physiological monitoring system is practical, but for other reasons—such as the patient's general weakness and lack of motivation to increase his activity level—the improvement in comfort above that provided by a well-fitting light prosthesis did not affect his activity level.

Adjustable Below-Knee Socket

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Purpose—The original purpose of this project was the development of custom-fitted sockets that have provisions for changing their volume as the stumps of new patients shrink. Such a feature has long been considered desirable, but was unattainable until the recent advent of new materials.

Progress—The original concept involved maintaining a constant cross section at the level of the patellar tendon and changing the volume progressively distally by making use of the properties of polypropylene and Surlyn. Results of this approach were positive and led to a design of a two-piece system that provides a means of donning and doffing the prosthesis without subjecting the stump to shear forces. Experiments with several versions of the two-piece design have been very positive. A manual covering a design thought to be practical is nearly ready for design evaluation and testing by other facilities. Although the original purpose of an adjustable below-knee socket was to eliminate the need for a succession of sockets
until the new stump became stable and ready
for a definitive artificial limb, it is felt that the
concept will probably be useful to a number of
amputees as a definitive prosthesis.

ISNY Below-Knee Flexible Socket

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Purpose—The chief project goal is the development and application of the Iceland-Sweden-New York University (ISNY) prosthetic socket system to the below-knee amputee. The ISNY socket has previously been applied very successfully to above-knee and below-elbow prostheses. The fundamental advantage of the ISNY approach is the comfort achieved by the separation of the two socket functions—tissue containment and weight-transmission—with a separate structure providing each function. This separation allows the thin ISNY socket to contain the residuum (stump) tissues and yet to retain the qualities of lightness, flexibility, coolness, and enhanced intimacy of fit and sensory feedback. The weight-transmitting frame covers only 25 to 60 percent of the residual anatomy depending on stump length, yet it is sufficiently sturdy and durable. The major purpose of the ISNY frame is to capture the important weightbearing areas of the residual limb and to transmit these forces through the prosthesis to the floor, with minimal tissue coverage. It is designed to load the pressure-tolerant patellar tendon, medial tibial flare and shaft, and the interosseous space, while relieving the sensitive tibial crest, distal anterior tibia (kick-point), and distal end of the fibula. The "three-strut" frame design, therefore, consists of: 1) a medial horizontal brim that is continuous with the patellar bar anteriorly and popliteal pad posteriorly; 2) a distal end-cup that joins the frame to the shank; and 3) three struts that arise from the end-cup to support the horizontal brim. The two anterior struts run vertically just medial and lateral to the tibial crest, whereas the third strut runs vertically or posterolaterally along a diagonal path.

Progress—Design modifications have been accomplished to permit accommodation of the three major types of suspension: 1) the conventional leather cuff suspension is placed in the usual location relative to the patient’s anatomy with the medial portion attached to the rigid frame and the lateral portion to the polyethylene socket. 2) In the supracondylar suspension, the areas below the proximal frame extensions have been left open and the usual wedge suspensions utilized. 3) In the corset suspension, the lateral aspect of the frame extends circumferentially to surround the entire residuum to provide an attachment point for the lateral upright and to enhance the structural stability at the points of side joint attachment, because these have only abbreviated distal extensions below mid-patella level.

The most important aspects of the tissue-containing polyethylene (PE) socket are thinness and flexibility, so that the socket-wall deflection reduces impact loading on the residual limb during stance phase. Studies indicate that the optimal thickness for the PE socket is approximately 0.030 to 0.060 inches. Comfortable juxtaposition of the weight-supporting rigid frame and the residuum is achieved by utilizing 5-mm Pelite cushion padding.

By the end of May 1986, a total of 27 patients had been fitted with BK ISNY prostheses. In this group, 16 prostheses utilized cuff suspension, 7 supracondylar suspension, and 4 corset suspension.

Patient reactions have been uniformly positive, with all but 3 of the 27 subjects preferring to wear the ISNY BK. Comments indicated that the socket is lighter and substantially more comfortable. Patients frequently said, “The prosthesis feels more like a part of me.”
Analysis of Below-Knee Suspension Systems: Effect on Gait

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Purpose—The purpose of this study was to determine criteria for the prescription of suspensions of below-knee prostheses. The study examines the relationships between physical characteristics of an amputee and locomotion performances when using different suspensions. Several different suspensions under investigation were: 1) supercondylar suprapatellar; 2) supracondylar; 3) PTB with cuff; 4) PTB with waistband; 5) PTB with figure-eight; 6) rubber sleeve; and 7) articulated supracondylar wedge.

Progress—The testing of 20 adult, unilateral, below-knee amputees was completed. A broad variety of analytical methods were developed to discriminate effects of different suspensions and to differentiate between subjects. Included in these methods were harmonic analyses of wave forms of the horizontal and vertical accelerations of the body and tachometer wave forms, and the calculation of mechanical work and efficiency. Numerous variables and combinations of variables were found to distinguish differences in locomotion performances between suspensions and among subjects. Variables that provided the stronger indications of quality of gait as relating to suspensions and to stump length and shape included: a) prosthetic side knee flexion-extension wave-form deviations; b) the amount of axial movement of the stump with respect to the socket; c) harmonic ratios of the horizontal and vertical acceleration and the tachometer wave forms; and d) a quotient derived from the 5th, 6th, 7th, and 8th harmonics of the horizontal acceleration of the body.

A paper entitled “Effect of Velocity and F/L Ratio on External Work and Gait Movement Wave Forms—Preliminary” was submitted for publication. This paper, delineating locomotor performance of normal adults, presents the results of a study done to provide a biomechanical basis for analytical procedures used in the suspension study.

Computer-Aided Analysis of Below-Knee Socket Pressure

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—This is an ongoing project to determine if finite element analysis can be used to predict pressures at the socket-limb interface of patellar-tendon-bearing (PTB) prostheses under static loading. Three-dimensional finite element models are being developed for each of three subjects, based on CT scans. To verify the models, normal pressures at seven locations along the socket-limb interface will be measured experimentally for each subject. The effects of socket-liner stiffness, prosthesis alignment, and socket-casting techniques on the interface pressures will be examined.

Progress—A linear, elastic finite-element model for the first subject has been completed. The bone and soft tissue of the residual limb are represented by 3-D brick elements; the socket liner is simulated by boundary elements, which behave like linear springs; and the socket is assumed to be rigid. The soft tissue was assigned a uniform stiffness. A force of half body weight was applied to the proximal femur in the distal direction, and the stresses normal to the surface of the limb were calculated. The normal stresses fell within the range expected from the experimental measurements of previous investigators. The areas of highest stress,
the patellar tendon bar and the distal end of the limb, were less than $1.0 \times 10^5$ Pa. A parametric study was conducted by varying the stiffnesses of the liner and soft tissue. Increasing the liner stiffness produced the same effect as decreasing the tissue stiffness. The normal stresses increased significantly at most bony areas, such as the anterior tibia and the tibial condyles, but decreased slightly at the patellar tendon bar. These results suggest that the relative stiffness between the liner and the soft tissue is important. The clinical significance is that the socket liner could be selected to complement the condition of an amputee’s soft tissue.

Preliminary Results—Much of the work for the experimental phase of the project was devoted to testing and selecting a pressure transducer. The testing consisted of applying known pressures through liner material to a transducer flush mounted in a flat plate. A strain gauge, metal diaphragm transducer was chosen for its high linearity and reproducibility, and low hysteresis. Some preliminary pressure measurements have been made with the transducer installed at the distal end of the first subject’s socket. The subject used a Pelite liner, and his prosthesis was aligned so that the pylon was vertical. The forces at the distal end of the prosthesis were measured by a force plate. During the testing session, the normal pressure indicated by the transducer increased from $1.0 \times 10^4$ Pa in the morning to $6.5 \times 10^4$ Pa in the afternoon. This trend agrees with the clinical observation that the residual limb shrinks over the course of a day, which would cause it to sink down into the socket. The final pressure measurement correlated well with prediction of the finite-element model.

Future Plans—Future efforts will be directed toward collecting additional experimental pressure data and toward enhancing the finite-element models. Nonlinear material properties and large displacement capability will be added to the models if necessary to obtain agreement with the experimental data. The soft tissue stiffness at various points on each subject’s residual limb will be measured in order to refine the material properties of the models.

Optimum Prosthetic Foot Characteristics for the Dysvascular Below-Knee Amputee

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Purpose—The characteristics of the prosthetic foot presently prescribed for the dysvascular below-knee amputee are based on parameters developed for the young traumatic amputee and, therefore, are not directed toward minimizing energy expenditure while maximizing ambulatory function. Current guidelines for component selection are based on patient weight only. Waters and Perry have shown that the elderly dysvascular amputee walks with a sufficiently different gait pattern to demand higher energy. The dysvascular population has a lower energy reserve than other amputee populations. Thus, they require a prosthesis that allows for the most efficient pattern of walking possible. Improving the gait pattern and decreasing physical demand will result in minimizing energy requirements while maximizing ambulatory function for the dysvascular amputee. The purpose of this study was to determine if below-knee amputee gait can be optimized by adjusting the heel firmness of the SACH prosthetic foot.

Progress—Ten dysvascular, and one elderly (67 yrs) traumatic, below-knee amputees were
tested in the Pathokinesiology Laboratory. Each subject was tested with a soft, medium, and firm-density cushion in the SACH foot. Intramuscular EMG of the lower gluteus maximus biceps femoris (long head), vastus intermedius, and vastus lateralis were recorded simultaneously with hip, knee, and ankle motion and stride analysis. Force measurements to calculate joint torques during gait were also recorded with each of the three density heels.

There were no statistically significant differences between the three heel types for EMG activity, joint motion, joint torques, or stride characteristics at the 95 percent confidence level. But, there were significant differences in these parameters compared to normal gait.

**Results**—The average velocity was 55.8 m/min (sd 9.4), which is 64 percent of normal. Stance comprised 64 percent of the gait cycle (sd 4.2) for the amputated limb and 67 percent (sd 4.4) for the sound limb. All three density heels resulted in prolonged heel-only contact and decreased single limb support time on the amputated side compared to normal. Although there were no significant differences between heel types, the firm-density heel cushion had a foot-floor contact pattern of slightly longer heel-only time than the medium or soft heel.

The torque measurements revealed loading response torques of slightly greater plantarflexion, and decreased knee and hip flexion torque compared to normal. Plantarflexion torque was prolonged until the end of loading response. The knee torque remained an extensor torque throughout stance phase with very minimal rate of change. The firm-density heel demonstrated a trend toward greater plantarflexion and knee flexion torque than the soft heel. The motion at the hip, knee, and ankle in loading response was much less than normally seen in gait. The compression of the heel cushion in loading created only 5 degrees of plantarflexion motion at the ankle; this was accompanied by a 3-degree increase in knee flexion and a hip posture of 20-degree flexion. From midstance to terminal swing, knee motion was similar to that seen in normals. However, the hip reached peak flexion in mid- to terminal swing and began extending in terminal swing, just prior to initial contact. The prosthetic foot dorsiflexed to 8 degrees following heel off (i.e., forefoot motion) and returned to neutral at toe off, as expected from the SACH foot. The firm-density heel resulted in less plantarflexion and greater knee flexion than the soft or medium heels.

The EMG record showed the same phasing for each heel type for each muscle tested. Activity of all four muscles was prolonged during stance. The lower gluteus maximus was active from 0 percent (initial contact) to 22 percent of the gait cycle (end of heel-only contact in midstance), and the vastus lateralis and vastus intermedius from 0 to 36 percent (terminal stance). The long head of the biceps femoris was active from 0 to 55 percent of the gait cycle (preswing). In swing, the vastus lateralis, vastus intermedius, and long head of the biceps femoris demonstrated appropriate timing; the lower gluteus maximus activity was premature. EMG intensity was the same for all heel types for the gluteus maximus, biceps femoris, and vastus intermedius. During loading, the vastus lateralis had slightly greater EMG activity response with the firm heel than with the medium or soft heel.

The soft, medium, and firm-density heel on the SACH prosthetic foot demonstrated no significant differences between heel types in stride characteristics, joint torque, joint motion, or EMG. There were significant differences in these parameters compared to normal gait. In addition, the firm-density heel tended to create a slightly greater physical demand compared to the soft or medium-density heel as indicated by joint torques and EMG measurements. The lack of differences in gait using the three density heels commercially available suggests that further developments in prosthetic design should concentrate on ankle function in response to loads created during walking.
B. Lower Limb

3. Above-Knee

Geriatric Prosthetics: Design and Development of an Improved Above-Knee Socket

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Purpose —The purpose of this project is to investigate prosthetic socket design to determine an optimum design with respect to comfort and performance for geriatric above-knee amputees. Anatomical, physiological, and biomechanical characteristics of geriatric above-knee amputees are being studied to develop a set of design criteria for geriatric above-knee sockets. Factors such as residual limb circulation; muscle strength, tone, and size; tissue compressibility and compliance; skin elasticity; limb spatial orientation; and sensation are being measured and a database compiled for use in determining the requisite socket design criteria.

Progress —During the past reporting period, physiological data have been collected on 13 amputees and 6 control subjects. A tissue compressibility and compliance measurement system has been developed utilizing a low-temperature, thermoforming plastic thigh band with apertures through which a probe is inserted. The thigh band is molded around the subject’s thigh at the perineal level and represents the relaxed shape of the residual limb. By applying a probe at a constant force through apertures evenly spaced around the circumference, a socket cross-sectional shape is generated from measurements of the depth of travel of the probe. This gives a measure of the compressibility and compliance of the underlying residual limb tissues.

From these data, a casting brim is fabricated, and a mold of the subject’s residual limb is made using standard prosthetic techniques. Within minimal to no modification of this mold, a socket is fabricated, and the resulting prosthetic fit is evaluated. A prosthesis incorporating this new socket is then fabricated. The static and dynamic performance of this experimental prosthesis is then evaluated and compared with the subject’s previous prosthesis. Three experimental sockets have been fabricated to date.

An alternative method of determining socket shape utilizing a pneumatic system has been tried on several subjects. This method applies a constant pressure around the perineal circumference. It results in a nearly circular cross-section and thus may not provide adequate rotational control. At the present time both socket designs are under evaluation.

Future Plans —Work on this project will continue with collection of anatomical and physiological data from 96 subjects. Twenty-four of the test subjects are to be geriatric above-knee amputees, 24 are to be nongeriatric above-knee amputees, and 48 control subjects are to be nonamputees with approximately the same chronological age distribution as the amputee test subjects. These data will be compiled and stored in a computerized database for statistical analysis. Sockets and prostheses for 12 subjects will be fabricated using the criteria developed from these studies. All prosthetic parameters other than the shape of the sockets will be kept identical to the subjects’ previous prostheses for purposes of comparison and evaluation. Prosthetic socket fit, comfort, and static and dynam-
ic performance will be evaluated and compared to the subjects’ previous prostheses by a prosthetist, a physical therapist, and the subjects themselves.

Rigid Knee Prosthesis

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Purpose—The use of a rigid-knee gait by an above-knee amputee provides exceptional safety, stability, and proprioceptive feedback. A prosthesis especially designed for this type of gait may prove to be effective for sporting activities and for geriatric amputees whose inadequate swing phase knee flexion actually inhibits ground clearance.

Progress—In order to restore the ground clearance function normally provided by sufficient knee flexion, a dorsiflexing ankle mechanism can be used, thereby reducing energy expenditure and gait deviations. A simple design was developed, having a single-axis joint centered through the usual ankle joint location, providing plantarflexion relative to the midstance position, and rotating to a dorsiflexed position during the swing phase. Two methods are being investigated for activating the dorsiflexion stop during the stance phase: the application of body weight and the presence of shank torsion. Rigid-knee prostheses of both designs are being prepared for testing over a variety of walking surfaces.

Preliminary Results—A geometric investigation of ground clearance has been completed. This study involved 2-D and 3-D models of conventional AK prostheses as well as dorsiflexion requirements for a rigid-knee prosthesis. In order to more closely examine ground clearance and the means by which it may be achieved, a three-dimensional model of clearance was developed. In this model, the shape of the rim of a shoe was described by a series of points, representing both the transverse and sagittal profiles of the shoe. This 3-D model allowed an examination of the effects of initial foot rotation (with respect to ankle axis), ankle axes that are skewed in the coronal and transverse planes, swing phase rotation about the long axis of the limb, and circumduction.

Although the major effects of ground clearance were evidenced by the 2-D models, it was discovered that the “roundedness” of the toe and heel sections in the transverse plane do contribute slightly to ground clearance when used with a skewed-single-axis dorsiflexing ankle. That this design feature does not inhibit ground clearance is important from the standpoint that it allows one the flexibility to choose ankle orientation that would achieve the best stance phase response.

The models indicate that a mechanism providing about 4 degrees of dorsiflexion relative to the unloaded midstance position of a normally aligned foot provides the most clearance in rigid-knee walking. Because the alignment of the VA SEATTLE Foot places the foot in relative plantarflexion in order to preload the energy-storing keel, the dorsiflexing device for such a foot should provide an additional 10 to 15 degrees of dorsiflexion relative to the unloaded foot. This combination of foot and dorsiflexion mechanism would provide energy storage without increasing the possibility of ground clearance problems.
Myoelectrically Controlled Above-Knee Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The need exists for active volitionally controlled above-knee (AK) prostheses that are more easily controlled by the amputee. Currently, control of lower limb prostheses has been largely limited to preprogrammed, passive devices that are awkward and difficult to control. The most popular means of passive control is the use of fluid damping mechanisms at the knee joint. Active volitional control of a prosthesis permits continuous adjustment to changing gait conditions, decreasing metabolic energy usage and enhancing the ability to respond to extraordinary events, such as stumbling.

A myoelectrically controlled AK prosthesis is under development at this laboratory that provides greater conscious and subconscious active control in gait and nongait activities. This prototype prosthesis has three principal operating subsystems: a myoelectric signal processor, a controller, and a hydraulic/pneumatic (H/P) actuator.

The myoelectric signal processing that we employ includes spatial pattern recognition and time-series methods. At present, it is believed that the patterns of EMG used for control are nonstationary and therefore may compromise controller performance and/or require more energy, effort, and concentration on the part of the user over time. The requirements for relevant specifications for adaptive spatial pattern recognition are being quantified.

Progress—Progress was made in the following areas:

a) Successful application of spatial pattern recognition methods in discrimination between intended knee and hip activity among normal and above-knee amputee subjects.

b) Development of a pneumatically powered AK test actuator with the following characteristics: 1) the ability to produce torques actively and in opposition to externally applied torques; 2) the ability to recover energy as opposed to conventional actuators, which act only as energy dissipators.

c) Successful integration of the actively powered test actuator with the spatial pattern recognition control algorithm.

d) Demonstration of an alternative control strategy based on time series features of the EMG signal.

e) Development of an optimal electrode placement technique for spatial pattern recognition that provides a quantitative means for locating electrodes.

Preliminary Results—Results thus far include the following:

a) Development and verification of a complete and robust multichannel time series myoprocessor that performs both limb function classification and muscle force estimation. The system consists of an optimal myoprocessor applied to the prewhitened residual sequences of each AR filter employed in the limb function classifier and offers the following advantages: 1) Modeling the EMG as an autoregressive process incorporates temporal information that reduces the number of electrodes required for the reliable detection of the direction of intended limb motion. 2) Incorporating spatially distributed information in the parallel filtering classifier by modeling multiple channels of EMG activity as a vector process with multidimensional AR filters increases the peak performance of the detection system, reduces classifier sensitivity to exertion level, and expands the operating range to include clinically useful levels of contraction. 3) Prewhitening the EMG with the AR filters extends and completes the optimal myoprocessor to include multiple channels of serially correlated data. It allows both muscle force estimation and limb function detection to be accomplished simultaneously by a single, hybrid system with great computational economy. The multichannel time-series myoprocessor (MTSM)
represents the first time-series-based system to provide both binary decisions and a proportion-
al control signal, and therefore specifies a com-
plete and self-consistent intent recognition
system. In both simulations and tests with real
EMG data from sites intermediate to the vastus
lateralis and biceps femoris, identifying the AR
models at lower levels of contraction was found
to improve total system performance. Classifier
performance and range of operation increased
with the number of channels included in the
processor. Contrary to the simulations and ex-
pectations based on the work of Hogan, neither
prewhitening nor multichannel processing was
observed to improve the fidelity of the force es-
timates obtained from electrodes located be-
tween muscle groups.

b) Development of Gaussian Bayesian refer-
ence models to EMG-based intent recognition
models to EMG-based intent recognition
and real time control of artificial lower limbs
was accomplished. SNR and percent CC were
obtained and proved superior to short-term
models. Minute and hour scale stationarity was
observed in parameters that were nonstation-
ary in short-term models.

c) Simulation, design, and fabrication of a
second actuator prototype has been completed.
This new actuator is a hybrid hydraulic/pneu-
matic that is currently being assembled.

**Future Plans**—Next year the following efforts
are planned:

a) Complete construction of pneumatic/hy-
draulic prototype.
b) Complete design of Robust Pattern Class-
ifier.
c) Begin development of time-series-based
prosthesis controller in real-time.

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**Transparent Flexible Sockets for Above-Knee Prostheses**

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**Sponsor:** Department of Veterans' Affairs

**Purpose**—This project compared the two major
types of transparent flexible AK sockets for in-
troduction on the D.V.A. Free Limb Scheme. The study concentrated on durability and
reliability.

**Progress**—Twenty-two patients were successful-
ly fitted with transparent flexible sockets. It
was found that a modified IPOS type is more
suitable for the Free Limb Scheme because: 1) The standard quadrilateral brim is prone to
breaking at the corners, especially the postero-
lateral one. 2) The rounded IPOS brim is more
resistant. 3) “Surlyn” is easily deformed by
“creeping” to the point of losing suction within
weeks of wearing. 4) Polyethylene sockets seem
to be much less affected by creeping. 5) The
semi-flexible IPOS frame seems more resilient
to axial rotating torque forces. 6) The IPOS
valve provides a simple and reliable device for
fixing the socket to the frame.

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**A Telemetric Data Acquisition and Processing System for Biofeedback Training and as a Diagnostic for Human Movement Training**

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**Sponsor:** National Institute of Handicapped Research

**Purpose**—This work is a continuation of a past
effort that began with the specific aim of im-
proving gait training of AK amputees. The
result of previous work was a self-contained
portable force and movement measurement
system that provided biofeedback of gait pa-
rameters. Two transducers, prosthesis shank axial load and hip angle, were developed and integrated into the MIT STRIDER system. The STRIDER has been used and evaluated by the physical therapy staff at the Massachusetts General Hospital (MGH), and their reactions were enthusiastic.

A second version of the system, the MIT TRAINER, has been designed and developed. Measurements from the same transducers are input to a computer via a telemetry data transmission system. The personal computer increases the flexibility of the system in many ways. The therapist can easily alter threshold values and choose among various forms of biofeedback both visual and audio. Also, data analysis can be accomplished with relative ease. Another benefit of this system is the reduction of the size and weight of the devices worn.

Progress—During the past year, a comprehensive software package was developed for this system. It allows the design of images that are used to display feedback for a person undergoing rehabilitation. After calibration, these images move on the CRT screen as a representation of the current sensor values. During a training session, the system simultaneously records the input data and displays the dynamic images. Graphs of the data are available when the session is complete. Packaging of the circuitry that interfaces the STRIDER transducers with the new system has been completed. This includes fabrication of printed circuit boards and cases to house them.

Currently, the system is complete, and plans for experiments are under way. Goals of these experiments are to establish the effectiveness of this system as a learning aid.

C. Upper Limb

1. General

Improvement of Body-Powered Upper Limb Prostheses

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Purpose—The overall goal is to improve the acceptance and use of standard body-powered upper limb prostheses by arm amputees in the United States. The specific objective of this project is to improve conventional arm prostheses by means of a hydraulic force transmission system.

Estimates of population in the U.S. place the number of upper limb amputees at 100,000, with 50 percent actually wearing prostheses. Of the 50,000 wearers, an estimated 90 percent use body-powered and 10 percent externally powered arm prostheses.

Standard, body-powered upper limb prostheses have not changed significantly since developments in the 1950s spurred by World War II. They still employ aircraft technology, using shoulder harnesses and steel cables for operation. Many arm amputees are now purchasing externally powered arm prostheses because they look more modern and "bionic," when, in fact, a body-powered type may be more appropriate functionally. Amputees may be going to the more expensive externally powered type to get comfort and appearance they should be getting from the body-powered type.

Progress—Progress to date has been made in
the following areas:

1) This project has confirmed strongly that current body-powered upper limb prostheses need improvement and that the force transmission system is critical in doing so.

2) The replacement of the cable control system by a hydraulic control system is feasible and offers possibilities for more efficient use of body power.

3) The use of a hydraulic control system unlocks potential benefits in function, comfort, and appearance not feasible with the cable control system.

4) There are problems with the use of hydraulics that must be solved to be acceptable. These problems are not easy ones, or changes would have been made over the past 35 years. Still, it appears that they are solvable and that this line of work should continue.

5) The benefits of bringing the potential of this project to successful implementation include: a) cost savings with appropriate prescription and purchase of body-powered arm prostheses for some amputees; b) psychosocial improvement to current users from better function, comfort, and appearance; and c) conversion of some nonwearers into wearers, with resultant increase in body image, bilateral function, and vocational achievement.

Future Plans—Effort will be directed toward below-elbow prostheses because they are the most common and fundamental. Hydraulic control systems will be designed, built, and tested in use with amputees and compared with conventional cable control prostheses.

In some ways, the below-elbow prosthesis is the most difficult level to implement hydraulics because amputees need improvement less than at higher levels and because there is not as much space in the forearm for packaging the components. However, if the hydraulic control system can be implemented successfully at the below-elbow level, the presumption is that benefits will be amplified at higher levels of amputation.

Myoelectric Prosthetic System

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Purpose—The objective of this project is to develop modular electronic components for the control of electric powered prostheses. These components are: 1) An active encapsulated electrode that contains the preamplifier and is to be used with any of the below-described processors for controlling electric powered prosthetics components. 2) A single-site signal processor with a single output for controlling a powered device such as the Michigan child’s hook or the Hosmer Dorrance Prehension Actuator. 3) A single-site signal processor to control any hand, hook, or elbow in two directions.

Progress—A manufacturer has begun the production of Items 1 and 2. The development phase of Item 3 has been completed, but it has not been clinically evaluated nor presented to a manufacturer.

Extended-Limb Prostheses

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Sponsor: National Institute of Handicapped Research

Purpose—The objective of this project is to determine if under some conditions, simple extensions of the limbs of persons with high level upper limb amputations can be more effective
functional tools than conventional types of prostheses. One concept is a prosthetic socket with a device attached to its immediate distal end that will enable a person with an above-elbow amputation to write more easily. This would utilize a writing device that is now commercially available but that is intended for a hand orthosis. It comes with three interchangeable tips that allow the user to choose a pencil, a pen, or an eraser.

Progress—The first subject for a clinical evaluation of this concept was a 30-year-old man with traumatic amputations above-elbow bilaterally and hip disarticulation on the right side. He was fitted bilaterally with above-elbow prostheses; a lower limb prosthesis allowed the subject to walk quite well. The left above-elbow prosthesis consists of a 5XA hook with a Hosmer Dorrance Prehension Actuator (PA) and standard body-powered elbow. The right side consists of a 555 (lyre-shaped) hook canted medially approximately 20 degrees, a PA (outer shell only) to provide passive wrist rotation, and a standard body-powered elbow. Both PAs have the rotational resistance set low to allow the subject to achieve wrist rotation by “rolling” on the table edge. Although the subject was able to accomplish many activities of daily living, he was unable to write legibly with these prostheses.

A prosthetic socket with a writing device attached to the distal end was fabricated for the subject’s right (dominant) side. This was intended to replace the standard prosthesis only when the subject wanted to write. The subject was able to write legibly. In fact, he stated that it resembled his handwriting prior to the accident that caused the amputations. He was readily able to change tips to choose between pen and pencil. He found the device useful and wanted to keep this prosthesis for use at home.

Future Plans—The next step in development is to incorporate this device into a standard prosthesis so that the user does not require someone to change the entire prosthesis whenever he wishes to write. This will require a simple disconnect mechanism that can be operated by the person wearing the prosthesis to permit easy removal of that part of the prosthesis distal to the writing device. It must also contain electrical contacts when electrical components are distal to this point and electrodes or switches and/or battery cables are proximal.

An Electric Artificial Limb for Children Without Limbs

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Sponsor: National Institute of Handicapped Research

Purpose—The objective is to develop an artificial arm that can be used by children born without arms. To provide effective control of the arm, we will be implementing a force-actuated position-servo controller based on Simpson’s concept of extended physiological proprioception (EPP).

Progress—A prototype EPP-controller has been developed and implemented on the NU/Michigan Arm. This arm is a child-size prosthesis (ages 3-6 yrs) developed by our laboratory for the Area Child Amputee Center in Grand Rapids, Michigan. Four of these arms have been constructed for the ACAC and are presently controlled with switches. We are refining the electronics of the EPP-controller in preparation for an initial clinical fitting. An upscaled version of the NU/Michigan Arm (Size 2) has recently been completed on contract the ACAC. This arm is sized for children ages 7-13 years. If warranted by our field evaluations with the EPP-controller on the Size 1 arm, we will evaluate the controller with the Size 2 arm.
Design of Prehension Systems for Upper Limb Amputees

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The overall objective is to increase the variety of powered prehensile devices available to persons with upper limb amputations. Specifically, we are proposing: 1) new utilitarian prehensile fingers that are not based on the traditional hook shape; 2) a cosmetic hand with high performance characteristics; and 3) a utility hand that would serve as a compromise between utilitarian and cosmetic designs but would have advantages of both.

Progress—We are presently completing refinement of a power-base mechanism that will serve as the actuator of the prehension devices outlined above. Details of this mechanism were given in the last progress report. We also have initiated contact with an industrial design group that will be consulting on the design of the utility hand.

Position-Servo Control of Upper Limb Powered Prostheses

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Purpose—Experience has shown that users of powered multijoint prostheses must give considerable attention to the control of these prostheses. The effective use (i.e., with low mental loading) of more than two-powered joints in coordinated movements does not appear possible using “velocity-control” approaches (e.g., switch and myoelectric controllers).

We are proposing to implement a force-actuated position-servo controller, coupling an anatomical joint(s) and a prosthetic joint(s), as a means of achieving improved control of multijoint powered prostheses. This type of controller is based on Simpson’s concept of extended physiological proprioception (EPP). Position and velocity of the prosthetic joint are controlled by the anatomical joint. And, because of the coupling between the joints, the user is constantly aware of the position and velocity of the prosthetic joint through the proprioception of the anatomic joint. The effectiveness of this control has been demonstrated empirically in Simpson’s applications to gas-powered prostheses and experimentally in comparisons with velocity control of electric-powered prostheses.

Progress—We intend to evaluate the EPP-controller through field testing. Consequently, it is necessary that the force transducer have low power consumption, be relatively inexpensive, and be mechanically rugged. After rejecting strain gauge, capacitive, and pressure transducers for failure to meet one or more of these criteria, we are presently experimenting with a relatively new, commercially available thick-film force-sensitive resistive material. Although our evaluation of the material for the EPP-controller is not complete, a prototype controller has been constructed and appears to be very promising. A Hosmer NYU elbow has been modified for the prototype controller. Initial results suggest that its mechanical response is sufficiently good to exploit the advantages of an EPP-controller. We are also beginning to develop the prosthesis’ support and harnessing system for the field evaluation. The initial fitting will have only the electric elbow controlled by the EPP-controller, with the terminal device under myoelectric control.
Cosmetic Covers for Upper Extremity Prostheses (Male/Female)

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—A project objective is to develop realistic and durable cosmetic covers for hand and arm prostheses for men and women. Advanced materials and procedures are being used to achieve this objective. A concept being investigated is to use, where possible, a subject's remaining hand for mirror-image replication to produce a matching cosmetic cover.

Preliminary Results—Activities and results to date include the following:

1) Studies were made of advanced materials for primary molding (e.g., two-component vinyl silicones with an inline mixer); for casting (wax compositions); for secondary molding (castable polyurethanes that do not inhibit the cure of silicones); and for the final cover (clear vinyl silicones).

2) Means were developed for making an essentially seamless split mold of flexible material. The developed device, termed a “zip strip,” is a preformed, flexible strip with hemispherical keys on a separator-treated face. The zip strip is fabricated in straight and curved configurations in silicone rubber for primary molding and in polyurethane rubber for secondary molding.

3) A 3-D reversing pantograph was fabricated and demonstrated with hands and forearms.

4) Techniques were developed for making skin-textured forms with fingers and wax-shell overlays cast in silicone-rubber primary molds.

5) A concept was made for a universal-sized internal skeleton for cosmetic covers. Active-hand prototypes were made using pivoted, square telescoping tubing with polyester film tendons for flexion and torsion springs at each joint for extension. The single-control prototypes (thumb plus two moving fingers) show excellent dexterity and conformability in grasping objects of various sizes and shapes.

6) A color triangle series is being designed for quantitative pigmentation for intrinsic coloration.

7) Experimental efforts have begun on development of flexible, split secondary (final) molds and on multilayer fabrication of cosmetic covers using intrinsic coloration.

Future Plans—Plans include fabrication of appliances for wearer studies and technology transfer to those in the field.

Prosthetic Terminal Device for Playing the Piano

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Sponsor: Rehabilitation Engineering Division, Department of Physical Medicine and Rehabilitation, University of Michigan

Purpose—This project involves the development of a device to enable a person fitted with a below-elbow prosthesis to play the piano. Our efforts have been geared for a particular client, but the design could have general application for other below-elbow amputees.

The client for whom the device has been developed is a 10-year-old girl who has both natural ability and a strong desire to play music. She has a congenital deficiency of the left arm, a disability equivalent to a short below-elbow amputation.

Progress—We continue to work closely with this client, her piano instructor, family, and Rehabilitation Engineering staff. Early in the project, a prototype was constructed with two fingers which could be adjusted and then fixed in position. The client was successful in using this device to develop a large repertoire and
even to perform recitals with her peers.

**Preliminary Results**—Recently, an interim device that enables finger spread via a foot control and cable has been developed. A design for a more sophisticated device with variable finger-spread and wrist rotation has also been developed, but it now seems unlikely that the more complex system will need to be implemented at this time.

**Quantification for the Functional Capability of Upper Extremity Amputees**

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**Sponsor:** National Institute of Handicapped Research

**Purpose**—This project will develop and apply a technique for quantification and measurement of the upper extremity functional capability of able-bodied and disabled persons. The technique being developed has a sound practical and theoretical basis. Performance is measured on specific tasks that represent the functional role an upper extremity prosthesis can realistically be expected to play. Competent mathematical models of normal human control strategies are then used to produce a single meaningful number derived from accessible measurements (such as myoelectric activity, speed, range of motion, etc.) and provide the essential link between measured performance and inferred functional capability. Previous progress reports and several publications have described the mathematical techniques used to model human upper extremity motor coordination. Efforts in the past year have focused on the refinement of the experimental tasks.

**Progress**—A unique approach to the assessment of the causes underlying the functional disability of an amputee using a prosthesis has been developed. The disability of an amputee using a prosthesis could be attributed to many causes: sensory loss, damage to the amputee’s nervous system, poor mechanical performance of the prosthesis, and poor interfacing between amputee and prosthesis are among the prominent candidates. In this project, we will attempt to determine how much of the observed functional deficiency can be attributed to the dynamic performance of the prosthesis itself. To do this we have developed an arm brace (similar to an orthosis) that allows us to add passive dynamic loading to the arm of an able-bodied subject. With this device we can approximate in the able-bodied subject the relation between muscular activity and arm motion that an amputee using a myoelectrically controlled prosthesis has to deal with. For example, the maximum speed of intact elbow motion can be restricted to that of the prosthesis.

To quantify performance precisely, we have investigated some simple but representative contact tasks an amputee may need to perform (e.g., opening a drawer or opening a door). These tasks can be difficult with current artificial limbs because the tasks require the artificial joint to accommodate a nontrivial kinematic constraint. In addition, the mechanical joint (the elbow) must be coordinated with the natural joints (e.g., the shoulder). An analysis of the mechanics of crank-turning showed that there are critical points along the crank trajectory where shoulder/elbow coordination is essential; at these points, due to the geometry of the arm/forearm/crank linkage, neither joint torque alone is sufficient to drive the crank—some combination of the two is required.

**Preliminary Results**—To date, our investigations of crank-turning have shown distinct performance differences between able-bodied and amputee subjects, but they also showed that the subject’s ability to recruit other joint motions, such as bending the knees and “floating” the scapula, could compensate surprisingly well for functional limitations of the elbow joint. We could have restricted body motions by seating the subjects and strapping the torso to the chair, but then the test would little resemble...
the conditions under which activities of daily living are performed.

We therefore modified the crank-turning task to better resemble a more difficult but reasonably common activity: wiping a curved surface, moving a hand along it in a controlled way while exerting a normal force. This task is especially interesting if the surface is convex, because unless the direction of the hand's force on the surface changes appropriately with its position, the hand will tend to "fall off" the convex surface. The problems posed by a convex surface are simulated (in two dimensions) by a crank whose handle is cradled in a V-shaped notch at the end of the crank arm, but not attached to it. If the notch is sufficiently shallow, this is a challenging task even for an intact subject. To vary the level of difficulty, the angle of the notch is adjustable from a broad V (70 to 80 degrees), through to full capture of the handle. In the limiting case (a fully captured handle) this task becomes kinematically equivalent to the original crank-turning task.

At present, project activities are focused on conducting experiments with amputee and able-bodied subjects.

A Microprocessor-Controlled Prosthesis with Extended Physiological Proprioception

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Sponsor: Royal Ottawa Hospital

Purpose—The objective of this project is to design a new upper extremity prosthesis with extended physiological proprioception (EPP), that will have improved performance characteristics compared with already existing devices. The prototype prosthesis is designed for an above-elbow amputee. It is equipped with powered actuators for elbow flexion/extension, wrist rotation, and hand prehension. Elbow and wrist functions are controlled by shoulder flexion/extension, which is measured by a specially designed shoulder goniometer. Hand prehension, which is not a position function, is controlled by EMG signals from biceps and triceps muscles.

Progress—Unique features of the prosthesis are as described below.

Instead of a single input/output relation, as is found in standard prostheses with EPP, up to eight different input/output relationships (or linkages) can be programmed into the microprocessor memory for selection by the user. This will significantly increase the usefulness of the prosthesis. However, the absence of a single input/output relationship may confuse some of the users. The extent of this limitation has yet to be determined experimentally.

Conventional EPP prostheses have what is termed an "unbeatable servo" feature that continuously prevents the input from exceeding the output capabilities of the system. Our prosthesis will not have such a facility. However, it will warn the user with a vibrotactile stimulus if the input is exceeding the output capabilities of the system. The user can then either backtrack or wait until the output catches up with the input signal.

System dynamics are controlled by the microprocessor system. This gives users more flexibility than they would have if the system dynamics were controlled by hard-wired electronic circuitry.

Future Plans—A bench prototype has been constructed and tested. Presently, a prototype to be worn by an amputee is being constructed, and tests will be performed on it in the near future.
Implementation of Extended Physiological Proprioception for Prosthesis Control

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Extended Physiological Proprioception (EPP) is a control concept that has demonstrated certain advantages for the position control of upper limb prostheses. The goal of this project is to control a Utah Arm with EPP, fit it to an above-elbow amputee and evaluate its performance.

Progress—Previous research by this investigator developed a small transducer and the necessary electronic circuitry to control a VA elbow by EPP. The initial phase of this project focused on getting the EPP system to control the Utah Arm under laboratory conditions. Following discussions with Motion Control, Inc., manufacturers of the Utah Arm, it was decided that the best method to control the arm would be to generate a simulated myoelectric signal and utilize the arm’s circuitry. Therefore, a circuit has been designed and tested which generates a synthetic EMG signal of the appropriate sign to cause the arm to move in the desired direction. The complete circuit has been packaged onto a circular circuit board which will enable it to be contained in a small space above the elbow.

Computer simulations of the four-bar linkage which provide the final drive of the elbow were undertaken in order to design the optimum attachment point for the mechanical feedback cable. The goal is to have as linear a relationship as possible between elbow angle and cable excursion. The variables that affect the relationship are the cable attachment points on the forearm housing. The computer simulation allowed these parameters to be varied until an acceptable combination of cable excursion and linearity were achieved.

Future Plans—Final integration of the mechanical and electrical systems is nearing completion. The next phase of research will be to instrument the prosthesis for monitoring of significant variables during amputee testing. These include input cable excursion, feedback cable position and elbow angle. Also under development is the data acquisition system for an IBM PC-AT which will allow the data to be recorded by the computer for analysis.

C. Upper Limb

2. Below-Elbow

Below-Elbow Prosthetic System

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The objective of this project is to develop a below-elbow prosthetic system with prehensor (hook/hand) interchangeability and easily removable modular components. The components consist of the prehensors: a NUVA Synergetic Prehensor and an electric hand; the signal processor circuit board; the active electrodes; a ground electrode; a battery pack; and
a wrist connector, which provides the mechanical and electrical connection between the prehensor and forearm.

**Progress**—A manufacturer has fabricated production prototypes of all the components except the battery pack. Commercial availability of this system to the consumer, through a prosthetics facility, is expected in the near future. This laboratory will continue to work with the manufacturer in an advisory capacity.

**Acceptability of the “Contour” Terminal Device for Below-Elbow Amputees**

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**Sponsor:** Department of Veterans’ Affairs

**Purpose**—A trial conducted last year on 10 below-elbow amputee patients concluded that the “Contour” terminal device (T.D.) is less functional than the standard Split Hook T.D., but seems socially much more acceptable to patients and their families because of its streamlined “robot hand” appearance.

**Progress**—One of our patients, a male congenital amputee, has volunteered to use exclusively the new “Contour” T.D. for a period of 6 months. He reported that despite its functional shortcomings, he prefers it by far to the old “hook” for his professional activities as a solicitor, as well as at home.

**The VIENNA ROTATION ARM—a Below-Elbow Prosthesis**

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**Sponsor:** Special fund

**Purpose**—The objectives of this project were to design and evaluate a comfortable, lightweight, and cosmetically acceptable prosthetic system for the requirements of unilateral below-elbow amputees. For these patients, their natural hand is dominant; the prosthesis is mainly utilized in a supporting role. Therefore, the advantage of using the remaining stump prosupination for operating and control of the terminal device outweighs the loss of active wrist rotation of the prosthesis. Besides, this kind of control offers a high degree of sensory feedback relative to force and position.

**Progress**—The terminal device has been designed to provide the “3-jaw chuck” type prehension. Rotation of the stump is transmitted into finger movement by means of a highly efficient spatial transmission. A simple gear-shifting mechanism increases by 70 percent the finger prehension force during holding phases.

In addition, this mechanism avoids reaction forces at the stump while carrying objects in the “hook or snap” type prehension.

The hand has been designed to fit into a standard cosmetic PVC glove, size 7-3/4. A small open above-elbow harness rests on the epicondyles of the humerus and is hinged at the elbow to two steel bars fixed to the hand. An inner socket fitting the stump end is connected to and operates the terminal device. The total weight of the VIENNA ROTATION ARM is about 600 g.

**Final Results**—In the past 3 years, 12 amputees were fitted with this arm prosthesis with very good results. Patients’ stump lengths varied from 15 cm to wrist exarticulation. Some of our patients primarily fitted with myoelectric hand prosthesis were pleased especially with respect to the light weight and comfort of the open socket.
The project has been finished. Because its design is simple, the VIENNA ROTATION ARM is suitable for mass production, and manufacturers are invited to contact the Institute. In the near future, a detailed paper on the VIENNA ROTATION ARM will be published.