I. Amputations and Limb Prostheses

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I. Amputations and Limb Prostheses

A. General

Comprehensive Management of Upper and Lower Extremity Amputation

**Purpose** — The goal of this project was four-fold: 1) to complete our work using intradermal Xenon-133 for amputation level selection; 2) to finalize techniques for building inexpensive, rapidly fabricated, temporary, or throwaway prostheses; 3) to study follow-up information regarding the role of immediate postsurgical fitting for upper extremity amputation; and, 4) to define the role of an elective amputation with early prosthetic fitting for patients with neurologic dysfunction.

**Progress** — Intradermal Xenon-133 amputation level selection was performed in the Nuclear Medicine Department using a Gamma camera interfaced with a microcomputer. Simultaneous two-point injection was performed in order to provide comparison for detection of injection error. All isotope wash out curves were computer analyzed for statistician validity. Besides accuracy of the measurements, an additional advantage of the Gamma camera technique was that multiple amputation levels could be checked simultaneously.

*Lower Extremity* — For all below-knee amputees, immediate postsurgical prosthetic fitting (IPSF) included touchdown weightbearing the morning after surgery. The patients then progressed during the next 7 to 14 days to full weightbearing and they were usually discharged from the hospital the third week after amputation. Partial foot and high level amputees had rigid dressings placed at the time of surgery; however, touchdown weightbearing and ambulation were postponed until wound healing had occurred (7 to 10 days). At the time of hospital discharge all lower extremity amputees were fitted with a lightweight, throwaway prosthesis that was changed as required to maintain prosthetic fit. No patient was referred for a permanent prosthesis earlier than six months after amputation in order to allow time for stump maturity.

*Upper Extremity* — All upper extremity amputee patients were fitted with IPSF standard conventional body-powered prosthetic devices. Upper extremity rehabilitation began the day after surgery, and included all Activities of Daily Living (ADL) skills. The prostheses were changed as required to maintain function (every 3 to 5 days). Harnessing was individually adapted in each patient to maximize prosthetic function. All patients were discharged with standard body-powered conventional prosthetic devices an average of 14 to 21 days after surgery. Only those patients who continued to use their body-powered prosthetic devices were evaluated for externally powered components (mean: 3 months).
Results — 1) Intradermal Xenon-133 skin blood flow had greater than 95 percent accuracy for the prediction of healing of major forefoot, below-knee, and above-knee amputations; however, intradermal Xenon-133 had less reliability for the prediction of healing of toe and distal forefoot amputations (80 percent).

2) We have previously reported that there is a 30-day grace period for early/rapid prosthetic fitting following upper extremity amputation, after which time the success rates of rehabilitation declined dramatically. Further analysis of patients treated in our program, as well as analysis of patients treated in our local community during the past year, reaffirm the 30-day rule. In addition, it would seem from a review of data from other centers that there are two breaks in the rehabilitation curve with respect to the success of prosthetic fitting after upper extremity amputation, one occurring at 30 days and one occurring at three months. The likelihood of long-term prosthetic success, if an upper extremity amputee is fitted more than three months after amputation, seems to be small.

3) We have concluded that there is a role for elective amputation, shoulder fusion, and prosthetic fitting for patients who have neurologic dysfunction due to brachial plexus injury. We also have concluded that this modality does not have value for patients with neurologic dysfunction due to stroke.

4) Our techniques for fabrication of temporary throwaway prostheses from inexpensive materials have been previously described. The techniques have been extremely effective in bridging the prosthetic/monetary gap between the last postsurgical fitting and the first definitive or permanent prosthesis.

Future Plans — Our present program has been divided into clinical and research counterparts. The research program will become a collaborative effort between the College of Engineering at the University of Arizona and the Tucson VA Medical Center. The direction of that program will involve comparison studies on amputation level selection and investigations into the value of educational programs in preventing amputation in high risk patients, especially those with diabetes mellitus. The clinical program will continue to be involved in early and rapid prosthetic fitting for both upper and lower extremity amputees.

A Bibliographic Database and Information Retrieval System to Prosthetics and Orthotics

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Purpose — A database of bibliographical references is being established in the subject area of prosthetics and orthotics. The database will be utilized to offer a variety of regular and selective information services to health care professionals. An information officer and clerical assistant concern themselves with the day-to-day running of the project including data entry, retrieval, and the handling of requests.

Progress — The database is under development on the university triple VAX 11/782 cluster utilizing the Famulus software process. Bibliographical references to English language journal articles, conference proceedings, technical reports, and
monographs concerning scientific material are being utilized. The subject area will be prosthetics and orthotics, including seating, wheelchairs, and other aids for the physically disabled. A thesaurus of terms is planned to facilitate flexible classification and retrieval of information.

The system has been conceived to meet the needs of rehabilitation professionals and established with a view to offering a broad service. Some 6000 records have been created in work so far. Funding has been secured for three years in which time the system will be promoted widely and its effectiveness assessed with a view to securing long-term funding.

Flexible Sockets for Prostheses

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Sponsor: Department of Veterans’ Affairs

Purpose — Silicone liners are investigated for both upper and lower limb prostheses. The major indication seems to be for upper limbs, especially for a better containment of the electrodes for myoelectric hands.

A comparative study is progressing between the ISNY and the ISPO above-knee transparent flexible sockets. High acceptance rate by the patients is being recorded. The study continues to assess durability and reactions of the stump in hot weather, with the view of introducing this type of socket on the D.V.A. Free Limb Scheme.

Determination of Causes of Phantom Limb Pain

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Purpose — We have surveyed over 6,300 amputee veterans and established that a minimum of 80 percent experience significant, frequently debilitating, episodes of phantom limb pain at least several times per year. Responses from this survey and from a survey of physicians treating phantom pain showed that treatment success is almost nonexistent except in rare cases where the specific referral mechanism is identified and the cause corrected. Our recent physiological studies have demonstrated relationships between burning phantom limb pain and stump blood flow as well as between sharp/shooting phantom pain and stump microspasms.

Progress — We are carrying out a three-part study to demonstrate the actual mechanisms underlying phantom pain that should provide the information necessary to develop effective treatments for it:

1) Survey of factors initiating and altering the intensity of phantom limb pain. We will send a survey to 6,000 veteran amputees in which we will elicit detailed information about these factors and their effects. This will provide a firm basis for determining which physiological mechanisms are related to phantom pain. We have sent out the trial survey (1,000 letters) and have already proven that there is no relationship between respondents’ need to control what happens (locus of control) and whether or not they are aware of what causes their phantom pain.
2) Objective log of factors changing with changes in intensity of phantom pain. We are requesting respondents who are able to identify factors clearly effecting their pain to make daily logs of changes in those factors and the intensity of their phantom pain for one year. Sixty respondents from the trial survey are participating in this phase of the research. It is already clear that changes in humidity have a very real effect on phantom pain intensity for some but not for others. We are still evaluating the data to determine whether there is a difference between humidity effects and description of phantom pain. When we carry out the main survey, 20 respondents for each of the major factors identified will be asked to participate in this part of the study. Experience indicates we can expect 50 percent compliance over one year of keeping a log. This will permit analysis of temporal and rhythmic alterations as well as complex interrelationships between several factors that would not be obtainable in other ways.

3) Physiological evaluation of subjects with phantom limb pain. Groups of 12 amputee subjects having each of the nine major descriptive types of phantom pain we have identified are being recruited for recording in our Psychophysiology Laboratory twice while pain free and twice while experiencing phantom limb pain. Near surface blood flow in the stump and paired extremity are being measured using a TV videothermography system. Muscle tension in the major stump, the paired intact limb, and the low back are being measured with standard noninvasive surface electromyographic techniques. Blood pressure is being measured in all four limbs using an automatic sphygmomanometer. To date, we have recruited 16 amputees for this portion of the study. All are showing a relationship between changes in phantom pain intensity and at least one of the above physiological parameters.

Morphological and Clinical Studies of Microwounds in Ischemic Human Tissue

**Purpose** — The purpose of this project is to study in a systematic fashion morphological and clinical features of small standardized wounds created on the lower extremities of patients with severe peripheral vascular disease (PVD) necessitating amputation.

**Progress** — The wounds are created with a Simplate II bleeding time device under sterile conditions at locations immediately distal to the planned site of amputation and at a variety of clinically and biologically relevant time periods for the study of wound healing. Wounds are examined clinically immediately prior to amputation and then excised from the amputation specimen and fixed for morphological studies. When normal control subjects are used, standard skin punch biopsies are used to remove the microwounds.

Standard techniques are used for tissue fixation, sectioning, and evaluation of all samples by light microscopy and of selected samples by transmission and scanning electron microscopy. Morphological events of healing are then compared with forearm wounds of young adults from previous studies and leg microwounds from age-matched controls. Transcutaneous oxygen tension ($TcPO_2$)
at the site of microwounds, the clinical appearance of the microwounds, the outcome of the amputation, and a variety of risk factors for PVD, such as smoking, diabetes, and hypertension also are correlated with microwound healing.

**Preliminary Results** — During the past year, seven additional patients have had microwounds created prior to amputation and ten normal elderly subjects have had microwounds created and biopsied to serve as age-matched controls for the amputation patients. In addition to the morphological studies of the normal and abnormal wound tissue, immunohistochemical studies also have been performed on all normal and selected abnormal wounds. The normal subjects have wound repair which is clearly more advanced than patients undergoing amputation but it is significantly more delayed than the normal young adult forearm microwounds. The observations of normal elderly leg wound healing are unique and will provide an important point of reference for both past and future investigators regarding wound healing in diabetic and ischemic patients.

### B. Lower Limb

1. **General**

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

**Purpose** — There are two specific objectives to this project: 1) obtain quantitative information concerning relationships between alignment variables and gait characteristics typically associated with these variables in the alignment protocol; and 2) develop an expert system for alignment of below-knee prosthesis that has as its knowledge base a formalization of the rules for prosthetic alignment which have been derived from expert prosthetists’ knowledge, judgment and experience. The development of the expert system is contingent upon transforming and formalizing the rules utilized in the alignment protocol into a quantitative, objective domain. Our efforts during the first year of our grant period have been focused on developing objective measurement tools that will be used initially during the alignment process to establish a pre-determined alignment state and evaluate the gait characteristics of several amputees at this particular alignment state.

**Progress** — Near the beginning of the grant period, we received a major component of our measurement system, the CODA-3 Movement Monitoring Instrument. We have successfully interfaced our LSI 11/23-based computer to the CODA-3 (requiring both hardware and software). In addition, we have fabricated
The Development of a Computer-Aided Measurement System for Prosthetic Applications

**Purpose** — A computer-aided measurement system is being developed to permit the identification and measurement of selected stump dimensions of lower limb amputees. The system aims to be compatible with processes of automated prosthesis design and manufacture under development by collaborators at the Bioengineering Centre, University College London (UCL), England and the Medical Engineering Resource Unit (MERU), University of British Columbia, Canada. The system is intended to function in a complementary manner to the computer-aided socket design (CASD) system devised by MERU. The measurement system functions as electronic calipers utilizing a video camera to view the stump, hardware to capture an image of the stump, and software to furnish the required measurements.

**Progress** — The measurement system does not contact the amputee; the stump is viewed by a monochrome video camera interfaced with a commercially available image processor and controlled by an IBM PC-AT computer system utilizing Pascal software. In its current state of development lighting of the stump is arranged to give a silhouette image which may be acquired under software control in 1/25th of a second, 768 × 576 pixel resolution and in 128 grey levels. Images are loaded into the 1MByte frame buffer for processing and then image processing...
principles are used to identify the stump.

The prototype measurement system is now operational and future work will be directed toward clinical trials of the system when used in conjunction with the CASD software package and methods of automated prosthesis manufacture being produced by UCL. The feasibility of extension of the system to total shape sensing is being investigated.

Biomechanical Evaluation of Prosthetic Feet

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Sponsor: University of Strathclyde

Purpose — The biomechanical evaluation of SACH and uniaxial feet outlined in the VA Rehabilitation R & D Progress Reports — 1983 has been published. During the investigations it became apparent that more information could be obtained if the local action of the foot could be examined in greater detail. It was therefore decided to continue the project by first considering the uniaxial type of foot.

The aim of this work is to obtain a better understanding of the function of prosthetic feet and to obtain data which would allow criteria for improved designs to be established.

Progress — The kinematics and kinetics of the foot/ankle complex are being investigated by strain gauging the ankle adaptor and recording the angular motion by means of a specially designed flexible goniometer. A series of membrane switches attached along the length of the plantar surface of the foot provide detailed information of its movements and temporal parameters.

Tests carried out so far show that the function of the foot is affected by the alignment configuration of the prosthesis and by the stiffness characteristics of the plantar flexion bumper. The foot function in above-knee amputees differed from that in below-knee amputees. The results also show that the action of the foot in a typical walking cycle can be broken down into distinct phases. The events taking place during these phases can be considered in detail and related to other parameters of amputee gait. This phasic activity should facilitate the formulation of a mathematical model of the function of the uniaxial foot which is being contemplated.

Prosthetic Loading Data for the Development of Standards for Lower Limb Prostheses

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Purpose — Several research programs have been undertaken at the University of Strathclyde in order to obtain prosthetic loading data during amputee activities. These data were essential in order to formulate appropriate criteria for the design and proof testing of lower limb prostheses. This work culminated in the "Philadelphia Standards" published by ISPO in 1978. These Standards, however, were based on tests performed within the confines of the laboratory, and the majority of amputees were healthy active adults who acquired amputation through
trauma. Although, since that time, data on lightweight limited activity and child amputees for level walking were obtained at the University of Strathclyde, there is a serious lack of prosthetic loading data in more realistic day-to-day encountered situations.

**Progress**—In the VA Rehabilitation R & D Progress Reports—1983, a portable tape recorder system capable of measuring prosthetic loading during ambulatory activities outwith the laboratory was reported. This system now has been used to acquire data from 20 below-knee and above-knee amputees of a wide range of activity levels during ambulatory activity on a variety of terrains.

It was found that the maximum axial load and anterior/posterior ankle bending moment, and the most critical loads on a prosthesis on flat surfaces were on average higher outdoors than in the laboratory by about 10 percent. Other parameters, viz. medio-lateral bending moment at the ankle and knee and anterior/posterior bending moment at the knee, were not greatly affected by the type of walking surface but rather by the alignment configuration of the prosthesis. Another significant finding of this study was that limited activity patients may at times develop loads in the prosthesis approaching those developed by active users. Statistical analysis of the large amount of data collected in order to establish the effect of various terrains on prosthetic loading is being planned. The possibility of using such data for amputee assessment also will be investigated.

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**Study of Alignment in Lower Limb Prostheses**

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**Sponsor:** University of Strathclyde

**Purpose**—This study has shown that for any amputee there is a range of alignments that are acceptable to himself and the prosthetist. This is contrary to the widespread belief that there is only a unique configuration, the so-called “optimum alignment” which can be achieved by the prosthetist during fitting.

**Progress**—Twenty above-knee and below-knee amputees were dynamically aligned on a number of occasions and the range of acceptable alignments for each amputee was established. It was found that an amputee’s gait is affected by the geometrical configuration of the limb (i.e., its alignment or the relative position and orientation of the various components to each other). By quantifying the kinematic and kinetic parameters of gait, it was found that it is possible for a given patient to select on the basis of biomechanical analysis the real optimum alignment from a range of acceptable alignments. From the data collected it is also possible to make recommendations on suitable bench alignment setting values. Additionally, design criteria for future alignment devices have been established.

On a long-term basis, it is planned to develop a procedure that would allow the optimum alignment configuration to be determined in the clinical situation. However, before this can be done, it is necessary to develop means for measuring alignment in the limb-fitting center. Implementation of the procedure already
developed at the University of Strathclyde for measurement of alignment was not possible as it is time consuming and requires specialist operator skills.

In order to overcome these drawbacks, a special device has been designed. It consists of a centralizing mechanism that accurately and repeatably locates the socket on a predefined axis. Two mechanisms each incorporating two bar linkages with potentiometers measure the position and orientation of the knee (for above-knee prostheses) and the foot relative to the socket axis in three dimensions. The output from the complete device is fed into a 16-channel 12-bit analogue to digital converter that acts as an interface to a microprocessor. Suitable software performs the geometrical calculations for the determination and listing of the alignment parameters, i.e., the shifts, tilts, and rotations of the various components relative to the socket axis system. A graphic display of the limb configuration also is provided as an option.

The device has been designed to be robust, relatively inexpensive, requiring minimum maintenance, and suitable for use by unskilled operators. The system presently is undergoing evaluation to determine its accuracy and repeatability.

Development of Improved Sockets for Lower Limb Amputees

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Purpose — This project has two objectives with respect to sockets: 1) to design and test sockets with flexible brims for lower limb prostheses; and 2) to design and test adjustable sockets for below-knee and above-knee prostheses for use in early fitting of amputees. Providing more comfortable sockets by the use of flexible brims is an application of results of previous theoretical work.

Progress — The adjustable sockets for use in early fitting procedures will use polypropylene sockets molded over positive models and will be constructed in such a way that the volume below the tibial condyles can be controlled easily by tightening and loosening a screw.

Prototype models of below-knee sockets with flexible brims have been fabricated and tried on test subjects. One design is essentially ready for extensive clinical trials to compare this supposedly more comfortable socket with those made using present practices.

The evaluation of results will attempt to determine how much the experimental prosthesis changes the activity level of the amputee by recording the number of heart beats and number of steps taken over an extended period. A 4-channel tape recorder worn by the amputee can record the heart beats and steps taken for a period as long as 24 hours. Heart beat and step data can be plotted against time to provide an energy consumption index and an activity level.

The sensitivity and usefulness of this technique currently is being determined. A healthy, active 37-year-old above-knee amputee has been fitted with an Otto Bock modular unit with a hydraulically controlled artificial knee. To test usefulness, the knee is aligned in what would seem to be the optimum condition to obtain heart beat and step data under both controlled and uncontrolled conditions.
The controlled condition consists of a specified course over which the subject walks. The uncontrolled condition occurs when the subject is asked to wear the recorder for his walking hours. To test sensitivity, the same kind of data is recorded as the prosthesis is deliberately misaligned.

If this system is as sensitive and reliable as it appears to be, it should make a significant contribution to evaluation programs for all lower limb prostheses, orthoses, and methods of treatment for locomotion problems.

As soon as the sensitivity of the physiological monitoring system has been determined, the part of the study concerning sockets with flexible brims will be continued full scale. Shortly afterwards, prototypes of the adjustable below-knee sockets will be fitted to patients who are being provided prostheses for the first time.

It is probable that the two socket techniques can be combined eventually, but initial trials will be made independently.

The Effect on Gait Using Various Ankle-Foot Devices

Purpose — The development of multiaxial feet has changed the focus of biomechanic interest from the proximal to the distal aspects of the prosthesis and to the effects on ambulatory performance with the currently available array of foot-ankle devices. Even with a well-fitting socket and an appropriate suspension, the nature of the substratum will effect the ambulatory function and comfort of the patient. There is a need to evaluate the commercially available ankle-foot devices in a precise scientific fashion to establish definitive criteria for their use.

The following key questions will be addressed:
1) What bearing does stump length have on the choice of foot-ankle assemblies?
2) Do factors such as speed of walking or walking on unlevel surfaces help distinguish choices in foot-ankle assemblies?
3) What factors need to be considered in prescribing a specific foot-ankle assembly?
4) Can selected objective gait measurements be used to facilitate reaching optimum settings in alignment and adjustment of the foot-ankle assemblies?

Progress — Twenty unilateral below-knee amputees in the age range from 35 to 75 years will be tested. Stump lengths from two to eight inches will be included. Each patient will be fitted with a lined PTB prosthesis with an endoskeletal system to allow for easy change of foot-ankle assemblies. Five different foot-ankle assemblies will be tested: SACH, articulated single axis, SAFE, multiaxial Greissinger, and SEATTLE. The subjects will be given one week to become accustomed to each assembly.

The subjects will be tested with each of the five different ankle-foot devices under three conditions of walking: 1) level at three speeds; 2) ramp ascent/descent at comfortable speed; 3) lateral incline/decline at comfortable speed. They will be
instrumented with bilateral heel and toe footswitches, bilateral knee electrogoniometers, and accelerometer pack attached to the prosthesis, accelerometer assembly at the sacro-lumbar area, and a tachometer cord attached to the sacro-lumbar area.

In addition to treating the collected data for commonly used gait variables, mechanical work of locomotion will be calculated together with an efficiency figure representing the effectiveness of transfer between potential and kinetic energies. Angular accelerations of the prosthesis in both AP and ML directions will be registered. Wave forms of the knee flexion-extension, vertical and longitudinal accelerations of the body, and the tachometer will be examined for deviations. Harmonic ratios for the latter three wave forms will be calculated. Effects of perturbations induced during the stance phase will be related to the physical characteristics of the amputees in an effort to derive prescription criteria.

THE ICEPOSS System

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**Sponsor:** Ossur hf., Prosthetics and Orthotics

**Progress**—A new concept for fitting TE, TK and TA (Syme) amputees is ICEPOSS (Icelandic Pull on Suction Socket). The system consists of an injection moulded silicone socket of 10-15 centimeters and an open, ISNY type, frame with a full-ring proximal brim. The silicone socket is secured to the distal cup of the frame by screws or by a specially designed coupling device. The silicone socket fabrication is quite similar to the ICEROSS-socket fabrication. The socket is a compressive suction socket and is donned by inserting the residual limb, forcing all the air out. When donning, the amputee inserts a finger down into the socket and lets air in to break the seal. Three TK, one TE and two TA amputees are using this type of socket in Iceland.

THE ICEROSS System

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**Progress**—A new method for fitting below-knee and above-knee amputees is ICEROSS (Icelandic Roll on Suction Socket). The system consists of: 1) an injection moulded silicone socket that is relatively unstretchable axially but highly elastic radially; 2) a coupling device for bottom-to-bottom connection; and 3) a rigid total contact socket or alternatively a flexible socket type ISNY.

The silicone socket is fabricated over a high density plaster of paris model that is somewhat smaller in circumference than the original model. A Pelite socket dummy is made over the model and a thin rigid socket is then laminated over the dummy. The dummy is removed and silicone injected into the 2-part mould thus created. The silicone socket is fitted over the original model and a rigid or a flexible socket made over it. When donning the socket the amputee turns it inside out and rolls it over the residual limb. The coupling device is connected to a nylon tape that goes through the bottom of the rigid or flexible socket to a buckle on the
posterior socket wall. The silicone socket adheres to the skin and acts like a second skin, transferring the action of interface friction from the skin-stump sock level to the interface level between the silicone and the supporting socket. The result is a total contact suction socket with excellent suspension and load distribution properties even for very short residual limbs.

ENDOLITE — The High Technology Prosthesis

Purpose — International opinion over the last two decades has highlighted the need for lighter weight prostheses for patients of all categories. Clinicians have in fact specified the desirable weight limit as being 1 kilogram for the below-knee and 2 kilograms for the above-knee prosthesis. These factors were foremost in our minds when the design specifications were drafted some eight years ago for a new second generation system to replace our aging modular assembly prosthesis. The design specifications can generally be divided as follows.

Progress —

1) The Weight Factor. This was the single most difficult problem to solve. In order to achieve the objectives set by the clinicians, we felt a need to depart from the materials generally used in the construction of prostheses. We chose to investigate the possibilities of using high technology materials generally associated with the aerospace industry, and of these carbon fiber reinforced plastics, with a high strength to weight ratio and good rigidity seem to promise most.

Fully endoskeletal limbs with the load bearing structure packaged within a soft cosmetic foam are an ideal application for material whose relative weakness could be damaged due to impact.

In order to use a somewhat expensive material in an efficient and cost-effective manner we would need to achieve an optimized fiber/resin ratio and effective control of voids on a production basis. We chose for consideration two main structural components, the shin and the rigid keel of the foot. With assistance from the Atomic Research Establishment at Harwell, England, we were able to establish a good design and identify a production route. In order to ensure the quality and structural integrity, we had to develop and have produced sophisticated and unique special purpose machinery able to control closely the temperature and pressure cycles during the moulding process. These main structural elements within the ENDOLITE System are now in full production.

2) Function at Knee and Ankle. For the knee, our design department produced a compact design for a mechanism with similar functions to our established and well proven stabilized knee intended for the more active patient. A complementary pneumatic swing phase control is provided. Also available within the system is a semi-automatic knee lock usually prescribed for the enfeebled geriatric amputee. These and other alternative knee controls were designed to be fully interchangeable within the system.

At the ankle level, a new design that gives a full range of movement allowing controlled inversion and eversion in addition to plantar and dorsiflexion was produced. The resistance to motion in each direction can be varied by careful
selection and fitting of rubber elements of different hardnesses within the module. Some rotation or torque absorption and general cushioning also are provided. The MULTIFLEX ankle mechanism gives a natural action to the foot and is beneficial over rough terrain.

3) Cosmetic Covering. In keeping with modern systems currently available, the system has a fully endoskeletal covering that is lightweight and has a choice of outer cover, either fabric or a nylon reinforced silicone skin to give the limb a lifelike appearance.

4) Sockets. It was considered necessary to provide the facility for accepting sockets of any type. However, we find the most popular socket is produced from thermoplastic material, usually polypropylene. This necessitated designing equipment to drape the thermoplastic sockets over a cast of the patient’s stump. Latterly, we have produced a number of ISNY sockets for ENDOLITE with soft inner sockets housed in a reinforced polypropylene outer frame.

Preliminary Results — A test program over a period of two years was undertaken in conjunction with a series of clinical trials. The Department of Health Scientific and Technical Branch at Roehampton, England, has tested and approved the system in the laboratory to standards based on the report of the meeting on Physical Test Standards in Philadelphia, PA in June 1977.

The first stage of the project is now complete with over 1000 above-knee and 1500 below-knee limbs currently in service in the United Kingdom, with a considerable number supplied throughout Europe. Our research now is directed to expand the system to other levels of amputation, notably the through hip and through knee disarticulation. Initial investigation suggests that this new technology will benefit patients with amputation at these levels.

Automated Fabrication of Lower Extremity Prosthetic Sockets

Purpose — This project is designed to evaluate the feasibility of using computer-aided design and computer-aided manufacturing (CAD/CAM) technology to fabricate sockets for lower extremity prostheses.

The project is based on the premise that by employing a finite element computer code which uses data that characterize the shape of the non-loaded residual limb and the mechanical stiffness of the issue, it is possible to generate the shape that the socket should have in order to effectively transfer the body weight through the soft tissue and thus minimize tissue trauma and user discomfort.

Progress — During the course of the work two new pieces of instrumentation have been developed and reduced to clinical prototypes. The first system is an automated shape sensor that can characterize the surface topography of the amputee’s residual limb to an accuracy of ± 0.01 inches. The second instrument is a pulsed doppler ultrasonic system that uses the sound to measure the motion of points in the tissue when it is subjected to a cyclic forcing function. The motion data are then used to calculate the elastic modulus of the tissue.
Amputations and Limb Prostheses

To date these instruments have been used to collect information on one above-knee amputee and a socket has been fabricated using the CAD/CAM system. The fit of the socket is currently being evaluated. If it is satisfactory, e.g., the amputee uses the socket regularly, sockets for an additional eight to ten amputees will be fabricated and evaluated.

Predictive Value of Transcutaneous PO2 in Peripheral Vascular Disease

Purpose — Patients requiring amputation or vascular reconstruction because of peripheral vascular insufficiency receive standard vascular evaluation and also segmental transcutaneous PO2 measurements using an 8-channel noninvasive transcutaneous oxygen tension monitor which was developed under this project in collaboration with the Department of Electrical Engineering at the University of Washington. The preoperative results of 250 patients were correlated with the subsequent healing of the amputation and ulcers. Postoperative vascular reconstruction results of 50 patients were correlated. The relationship between peripheral sensation, clinical condition, and skin perfusion of 400 patients also were done under this study.

Progress — Data from the legs of over 400 patients with peripheral vascular disease, a third of whom have diabetes, indicate that patients with segmental TcPO2 values of less than 20 mm Hg are more likely to have rest pain, ulcers, or to need an amputation within two months; furthermore, any amputation performed through an area where the TcPO2 is less than 20 mm Hg is much less likely to heal. The effect of chronic limb ischemia on peripheral sensation was relatively weak when compared to the effects of diabetes and alcoholism. Cutaneous ulcers were more common in those nondiabetic patients with poor sensation, whereas ulcers in diabetic patients were unrelated to the integrity of peripheral sensation. It was found that TcPO2 is a good predictor of the outcome of reconstructive surgery in patients without diabetes and is a better predictor of outcome in diabetics than is ankle blood pressure.

A Program for Evaluation of the Dysvascular Patient

Purpose — The objectives of this program are: 1) to determine the role of lumbar sympathectomy in the management of artherosclerotic disease; 2) to obtain and analyze hemodynamic data to evaluate the potential amputee with respect to lowest level of amputation consistent with wound healing; and, 3) to evaluate the patient requiring vascular reconstructive surgery.

Progress — The research plan includes the development of instrumentation that can quantitatively and qualitatively measure subcutaneous and cutaneous blood
flow pre- and post-sympathectomy or bypass graft. Techniques being explored include plethysmography, fluorescein, and H2 clearance. Currently the development and use of these three techniques to assess the hemodynamic effects of lumbar sympathectomy are being evaluated in the research lab using the canine and primate models. All clinical cases of vascular disease are being followed by standard noninvasive procedures (i.e., Doppler, EMF, TCPO2).

The technique of H2 clearance has been used to monitor blood flow in the gastrocnemius muscle following sympathectomy in animal models. The contralateral non-sympathectomized limb was used as control. Average blood flow for the sympathectomized limb was from 33 percent to 83 percent greater than contralateral non-sympathectomized limb and the difference also was statistically significant at $p > 0.005$.

Preliminary data analysis was conducted of lumbar sympathectomy for toe gangrene long-term follow-up: retrospective review of 45 patients (50 limbs) with toe gangrene was not amenable to direct arterial surgery and was managed by lumbar sympathectomy alone. Follow-up data regarding toe salvage, limb salvage, and limb loss were compiled. At five and eight years follow-up cumulative limb salvage was 71 percent and cumulative toe salvage was 51 percent. The presence of diabetes did not significantly influence limb or toe salvage. Mortality during the immediate postoperative period was 2 percent. In the majority of patients with digital gangrene who were not amenable to arterial surgery, lumbar sympathectomy was of benefit for salvaging the limb and toes.

Using Cutaneous Photoplethysmography (CPP) in normals, there was no gradient in cutaneous pressure from the chest to the dorsum of the foot; cutaneous pressure at each level of the leg was higher than that of the chest. In patients with vascular disease, marked gradients in cutaneous pressure occurred from the chest to the dorsum of the foot. CPP was much lower in the presence of ulceration, rest pain, and/or gangrene. A cutaneous pressure of about 50 mm Hg was the predictive criterion for wound healing.

The fluorescein technique presently is being applied to the canine model pre- and post-sympathectomy.

MACH Foot Study Development

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Sponsor: VA Rehabilitation Research and Development Service

Progress — The MACH (moveable ankle cushion heel) foot project has progressed to a point where four prototypes have been made and are currently being used by amputee research subjects. These test feet exhibit 10 to 15 degrees of initial plantar flexion (before heel compression), 5 to 7 degrees of inversion, eversion, and rotation. The weight of these have run 1/8 to 1/4 of a pound less than a similar sized SACH foot.

The response from the amputees has been overwhelmingly in favor of the foot. While we are very satisfied with the function of the present design, there are problems with the fabrication procedure. Some changes in the design of the ankle joint need to be incorporated with a new method of fabrication that will be less labor intensive than the current procedure.
SACH Foot Study

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The SACH foot (solid ankle cushion heel) is frequently prescribed for below-knee and above-knee prostheses. The objective of this portion of the study was to evaluate the static and dynamic characteristics of the SACH heel. Static measurements of the SACH heel have been performed.

Progress — This study has demonstrated that there is little difference between the static characteristics of soft, medium and regular heels on the SACH foot. The dynamic response of the SACH foot has been investigated in two amputees using data obtained on two below-knee amputees from the gait analysis laboratory in San Diego at Children’s Hospital. These data have been analyzed and have been used to help analyze a dynamic model of the SACH heel.

B. Lower Limb

2. Below-Knee

Computer-Aided Analysis of Below-Knee Socket Pressure

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Sponsor: VA Rehabilitation Research and Development Service

Progress — There were two areas of concentration during the first year of this project: 1) computer modeling of the socket and limb; and 2) development of a system for measuring socket-limb interface pressures. The major achievement in the first area was the construction of the initial finite element model. Extensive software revision was necessary to accomplish this task. The finite element programs were converted to run on a new CYBER 180/845 computer and enhanced to accommodate the features of the model. As a first order approximation, the model of the prosthesis and limb assumed linear material properties, homogeneous soft tissue properties, a rigid socket, and small strains and displacements. The geometry of the model was derived from a plaster cast of a subject’s limb and CT scans.

For the initial model studies, an approximate value of tissue stiffness was used, but in the future, soft tissue stiffness will be determined experimentally for each subject. An instrument that simultaneously measures force and displacement when gently pressed against the skin has been designed for this purpose. A series of computer runs were made to examine the effects of the socket liner and soft tissue stiffnesses on the stresses (pressures) calculated for the model. Preliminary results have been encouraging: the pressures at the socket-limb interface of the model were in the same range as those measured experimentally by previous investigators.
Work on the interface pressure measurement system focused on the development of a suitable pressure transducer. A commercially available diaphragm pressure transducer was modified. In the current design pressure is transmitted through a column of water to the silicon diaphragm. Several different fluids and fabrication methods were attempted before a stable device was produced. Special fixtures were designed for mounting the transducers on the socket, and a platform was built to facilitate loading the transducers during calibration. An LSI 11/23-based data acquisition system is being set up to monitor seven voltage inputs simultaneously. Using the calibration data for each transducer, the computer will calculate the pressure at each measurement site on the socket. The software for data collection and processing has been written and tested.

Comprehensive Alignment Procedure of Below-Knee Artificial Leg

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Purpose — Three major factors are involved in the successful delivery of a leg prosthesis: adequacy of the stump-prosthesis interface, properties of the main components, and mechanisms and alignment of the prosthesis. In this study we investigate all three factors and develop procedures for objective optimization of prosthetic fitting. We believe that it will be possible to clinically apply these procedures in the actual process of individual fitting of prostheses.

Progress — For both the socket geometry and the alignment studies, gait analysis is used for evaluation of performance. Gait is monitored on a 10 m walkway, including at halfway two Kistler piezoelectric force platforms, from which the foot-ground forces are recorded. A complete television system consisting of three TV cameras connected to a special effect generator and video tape recorder is used during the experiments for kinematics measurements and synchronization of this measured kinematics with the actual forces.

To study the effect of variation of socket geometry via the PT insertion, the sockets of the prostheses of the subjects who take part in the procedure are modified to enable variations in the geometry of the PT insertion and attachment of load cell.

The results are obtained, both numerically and graphically, in terms of the geometrical parameters of a torus for the condyles of the endoprostheses. These include values for both the shape and location of the torus. Geometry of the tibial component represents the tangents of the femoral surface in subsequent positions of motion. The optimal positioning of the endoprosthesis, for which the gliding index becomes minimal, is obtained at the margins of the anatomical constraints. It corresponds to the innermost possible location into the femur. Apart from determining the obtained new surfaces, the present model allows us to evaluate existing endoprostheses from the point of view of their gliding motion and to relate this to their clinical performance.

Study of adaptation and of compensatory mechanisms of amputees walking with prostheses is made on patients using modular prostheses. These are advantageous because the prosthesis alignment can be altered easily and the
resulting gait performance evaluated. The same applies to the deliberate introduction of variations of the prosthesis components. Optimization of alignment is studied through an elaborate monitoring technique enabling a systematic alignment of the prosthesis for the achievement of the best possible performance.

**Preliminary Results** — The results show a strong dependence between positioning of the PT insertion and the force transmitted there. Correct positioning of the PT insertion is established for each individual subject when gait performance is optimal. The parameters, for which optimization is performed, are selected for each patient from both subjective and objective information.

With respect to adaptation, our results clearly indicate that in amputees a symmetry function seems to be automatically reached in extremely different alignment conditions. Symmetry values are different from patient to patient, probably depending on the degree of severity of pathology and on the ability of the patient to generate compensatory mechanisms. Other functions, however, mainly those related to the detailed activity of the prosthesis as compared to the sound leg, clearly reflect the alignment variations introduced. Apart from parameters such as impulse ratio, these functions include minimization of observed disturbances which tend to appear on the force curves in position of incorrect alignment. This analysis, conveniently done on the computer, is characterized by determination of the time duration of the different phases of the disturbance on the anterior-posterior (AP) force.

Presently, the developed techniques are being refined to enable easy and convenient application for clinical procedures of prosthetic fitting, including socket geometry, dynamic alignment and component selections.

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**Lightweight Three Component Below-Knee Prosthesis**

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

**Purpose** — The objective of this study is the development and testing of a new design for below-knee prostheses that will combine the advantages of a lightweight design, prefabrication of shank and foot components, a more foolproof method of alignment, and improved foot function and gait performance.

**Progress** — The development state of this project is presently 75 percent complete. Nine of the 12 initial mastermolds for the shank portion of the prosthesis have been completed. Two others are in various stages of completion.

During this time, numerous test shanks have been laminated from the completed mastermolds. A laminate, consisting of polyester resin with fiberglass and carbon fiber reinforcing, is being used. The resultant weight of these shanks vary from 11 to 13 ounces, depending on the shank size.

Master positive models of the foot component have been completed for ten of the initial 12 feet. Eight of these have been converted into master molds. Three polyurethane foams of varying free foam density have been obtained and are currently being evaluated for patient use.
Patient testing and evaluation have begun for the Three-Component Prosthesis. Four amputee research subjects have been fitted with prototype prostheses. The weights of these finished prostheses are 1.75, 2.15, 2.25, 2.5 pounds (without shoe). Patient acceptance has been very high in terms of function, comfort, cosmesis, and weight. The prosthesis also has proven to be durable with no structural failures in up to two-and-a-half years of prosthesis use.

**Optimum Prosthetic Foot Characteristics for Dysvascular Below-Knee Amputees**

**Purpose** — The purpose of this study is to reduce skin breakdown in dysvascular patients, decrease compromise of cardiac, respiratory, and musculoskeletal systems by improving energy expenditure and reducing unwanted pressure over the anterior tibia inside below-knee prostheses.

**Progress** — Below-knee amputee gait can be optimized by adjusting the heel firmness and keel length of the SACH or SAFE prosthetic foot. This project is studying the effect of varying prosthetic foot heel compressibility and prosthetic foot keel length on velocity, stride length, single support time, cadence, heel dwell time, EMG, joint torques and dynamic heel compression.

**Volume Changes Occurring in Postoperative Below-Knee Stumps**

**Purpose** — A frequent problem occurring during the rehabilitation of postoperative amputees is how to determine precisely when the stump is ready to be fitted with the first permanent prosthesis. Inaccurate estimates often lead to ordering a prosthesis at a time when the stump volume is still changing. This results in stump-socket disparities, often the cause of pain and skin breakdown, necessitating a new prosthesis.

**Progress** — A study was completed that focused on stump maturation procedures, monitoring stump dimensions, determining when to fit the first permanent prosthesis, and the efficacy of the choices. Three stump volume reduction methods included: 1) elastic wrap, 2) plaster cast and pylon; and 3) lined plastic laminate socket and pylon.

A water displacement method was used to monitor stump volume. Stump circumferences were measured with a tension-tape at two and four inches from the distal aspect. Among patients demonstrating a definable decline in stump volume as a function of time, the first permanent prosthesis was fitted when the rate of change in volume reached 1.0 ml/day. Among those not showing a definable decline in stump volume, the prosthesis was fitted after 70 days on the program. Patients having been fitted with their prosthesis were followed for the duration of the project by collecting volume and circumference data bimonthly.
Amputations and Limb Prostheses

Preliminary Results — Nearly 80 patients were enrolled in the project. Over half of them discontinued for a variety of reasons including stump healing problems, further surgery, disinterest, moving away, and death. The final data treatment included 36 patients who were approximately equally distributed among the three methods of stump volume reduction. Approximately half of the sample demonstrated a definable decline in stump volume as a function of time. The other half did not; most of these, in retrospect, were presented with a compromised cardiovascular system indicating a tendency to venous pooling.

The lined laminate plastic socket and pylon showed the fastest decrease in volume and the elastic wrap showed the slowest. Two reasons for the results with the elastic wrap: 1) all patients were not candidates for the plaster cast or the plastic laminate socket for health reasons; and 2) patients did not ambulate weight bearing on the amputated side prior to being issued the first permanent prosthesis.

A high correlation existed between circumference measurements and stump volumes. In most cases, the correlation was significant to the $p = 0.01$ level.

Effects of health status resulted in an inability to satisfactorily characterize a stabilization point either by volume or circumference change. However, of the ten patients followed for the longer time, the results suggested potential cost savings and greater comfort to the patient. The performance included one for over three years, four for over two years, two for over one year, and three just short of one year. Three others were discontinued before end of the project: one requiring amputation on the contralateral side, and two for looseness of fit at about nine months each. The latter two were in the category not showing a definable decline in stump volume prior to being fitted with their first permanent prostheses.

Development of the ISNY Flexible Socket System for Below-Knee Amputees

Purpose — In approaching the problem of the ISNY Flexible Socket for the below-knee amputee, the following design specifications were formulated:

1) that the frame capture all of the desired weight supporting areas of the stump, viz. patellar tendon, medial tibial flare, tibial and fibular shafts, popliteal bulge and distal end; cover no more than 40 to 45 percent of the stump surface; and, be as lightweight as possible;

2) that the socket insert be of low density polyethylene and of approximately the same flexibility (approximately .055 throughout) as that utilized in the above knee design; and

3) that the wearer of the socket require only a nylon sheath or at most a one-ply cotton sock.

Progress — Two designs were developed to meet these criteria: one involving a helical frame and a second more rigid structure utilizing vertical struts.

After a substantial number of exploratory fittings, six ISNY below-knee prostheses have been delivered for full time wear — two of the spiral and four of the three strut design. Four of the above have been worn over a two-month period and the last two over a two-week period. All six wearers consistently report that
both ISNY designs are superior to conventional sockets by virtue of providing more intimate fit, being lighter, cooler, having better suspension, and necessitating fewer stump socks, thereby enhancing comfort and reducing the chances of integumentary lesions.

A number of additional patients are now in the process of being fitted with the two ISNY designs as well as conventional PTB sockets. Each socket is being fabricated over a single modified cast for wear in our laboratory to permit comparative reactions to all three devices under controlled conditions.

Analysis of Below-Knee Suspension Systems: Effect on Gait

Purpose — It is well known that the main purpose of a given suspension for a below-knee prosthesis is limb retention, but the specific effects on other areas of stump-socket biomechanics are not as obvious. Factors such as restrictions of knee range of motion either by suprapatellar-supracondylar socket enclosure not only imposes specific effects on life style but also on gait patterns and on locomotory work expenditure. In addition, certain suspension modifications designed to minimize axial stump-socket movement may alter the basic biomechanical principles of the prescribed prosthetic device. What emerges from clinical observations is the need for guidelines and specific prescription criteria for specific suspension systems.

The key questions expected to be answered through this study are:

1) What are the specific prescription criteria for a suspension system for a given patient?
2) How does patient activity level effect the choice of suspension system?
3) How do stump characteristics and physical capability effect the choice of suspension system?
4) What gait variables, measured or derived, are useful to differentiate effects on gait resulting from different suspension systems?
5) What gait variables, or combinations of variables, serve to discriminate relative effectiveness of a given suspension system?
6) What are the advantages and disadvantages of a given suspension system?

Progress — Twenty unilateral below-knee amputees in the age range of 40 to 65 years are tested. Each is tested with the following seven suspension systems:

1) supracondylar suprapatellar; 2) supracondylar; 3) PTB cuff; 4) PTB cuff with waist belt; 5) PTB cuff with figure-of-eight suprapatellar strap; 6) rubber sleeve; and 7) articulated suprapatellar wedge. The plan employs one PTB-type prosthesis, altered successively in the order listed. Each subject is expected to wear the test prosthesis at least two hours per day between weekly test appointments.

The subjects are instrumented with bilateral heel and toe switches, bilateral knee electrogoniometers, an axial stump-socket movement detector, a gimbal mounted triaxial accelerometer mounted at the sacrolumbar area, and a cord connected to a stationary tachometer. The subjects are instructed to walk at three
different speeds: 1) comfortable; 2) faster than comfortable; and 3) slower than comfortable. The purpose of the fast and slow speeds is to provide challenges to the systems.

In addition to treating the collected data to the commonly used gait variables, mechanical work of locomotion is calculated together with an efficiency figure representing the effectiveness of transfer between potential and kinetic energies. The axial movement of the stump in the socket is analyzed for amplitude and for when in the gait cycle the signal occurs. Wave forms of the accelerometer and tachometer are treated for harmonic ratios. Deviations in the knee, accelerometer, and tachometer wave forms are identified and correlated to the suspensions. This scheme of testing allows comparative biomechanical analyses within each subject and a basis for comparison among subjects to ascertain the effect on gait by the seven different suspension systems.

**Preliminary Results** — Ten amputee subjects have been tested to date. Classification methods operating on the biomechanic variables demonstrate distinction among subjects and discriminate among the suspensions. It is too early to attempt to determine why the subjects distribute as they do.

Ten normal adult subjects were tested at various combinations of stride length and stride frequency. The results were analyzed and deployed into the evaluation of amputee gait.

**Future Plans** — We plan to continue the test and data processing protocols and to determine the relation between physical characteristics of the amputee subjects and the manner in which they distribute in locomotor performance.

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**Biomechanical Evaluation of ISNY Flexible Socket**

**Progress** — Using linear motion transducers and strain-gauge pressure sensors, we are evaluating the ISNY flexible sockets to determine shape and inner pressure during walking. We find that the degree of socket movement is not remarkable and change in socket shape seems not to correspond to bulging of each muscle but mainly to the pressure of the stump acting as lever arm.

The comparisons of inner pressure between the ISNY sockets and conventional hard sockets indicate that the inner pressure is almost the same. At the present stage, we believe that, biomechanically, the ISNY socket is nearest to a suction socket with a soft liner.

We also are measuring thickness of the ISNY sockets on numerous spots.
Survey of Prosthetic Knee Joint Design Criteria

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Sponsor: University of Strathclyde

Progress — The survey included a review of present-day knee mechanisms and research developments in knee design and control. No device has yet fulfilled all known requirements of an artificial knee mechanism although many have solved some of the problems.

A questionnaire survey of 50 amputees was carried out in interview form. Questions were concerned with the amputees’ opinions about their present limbs, walking ability, knee joint problems and with suggestions for improvements to limbs as a whole and to knee joints in particular. It was found that 85 percent of the respondents would like a power-assisted limb to facilitate in activities such as stair climbing. However, only 36 percent of the patients would be willing to carry an external device.

A biomechanical evaluation of three conventional knee mechanisms (free, locked, and safety types) was performed in which four amputees of various activity levels were analyzed for uphill, downhill, and level walking. Forces and moments at the lower limb joints, distance-temporal parameters, and hip and knee angle data were collected for each situation. The function achieved from each knee depended on the ability of the amputee to control the limb. Interestingly, from a biomechanical point of view, it was found that in three out of the four patients tested, performance was better with a knee other than the one originally prescribed to them. An element of patient dependency regarding the achieved function of different knees indicates the need for a system of prosthetic prescription to cope with individual requirements.

Microcomputer-Controlled, Individualized, Multimode Prostheses for Lower Extremity Amputees

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Purpose — This research aims toward improving the above-knee amputee’s mobility through development of new computer-controlled knee mechanisms and new algorithms for their control.

Progress — The most fundamental assumption in the program is that a prosthesis should have characteristics which are custom tailored to the user and to the user’s current mobility task, (i.e., multimode; changing according to the disabled person’s need such as flat walking or stair climbing). This type of variable or versatile behavior is being sought through microcomputer control of new knee
mechanisms. The most conservative version of such a prosthesis uses a knee mechanism that can only absorb energy. The most advanced concepts include knee mechanisms that contain motors and can also operate as generators and energy storage elements. Such energy regenerative artificial legs will allow more symmetric gait by providing active stance-phase control. Such a mechanism would not, however, provide the large power and energy needed for tasks such as climbing a long staircase.

The project tasks include:
1) Developing and evaluating control algorithms for both stance and swing phase;
2) Developing new knee mechanisms that allow control by computers;
3) Developing control algorithms which optimize energy regenerative systems; and
4) Assessing the marginal value of active mechanisms for providing gait symmetry and stability.

The ultimate objective is the improvement of the above-knee amputee’s mobility and the furthering of his/her independence by meeting specific needs.

Sensory Feedback System for Above-Knee Prosthesis

Purpose — Our goal is to develop a sensory feedback system for the above-knee prosthesis which is useful in daily activities.

Progress — We have constructed a system in which auditory feedback of knee angle is transmitted to the amputee. Presently, we are testing this system with normal persons fitted with simulated prosthesis. We do not find any effective results of sensory feedback in the prosthetic training. However, we are planning to evaluate our system in many situations, e.g., walking on un-even ground, a slope, or a zigzag course.

Evaluation of Load-Actuated-Brake Knee for Above-Knee Prosthesis

Progress — Using pylon study, knee moment was measured on the above-knee prostheses equipped with load-actuated-brake knee during walking. We found that load-actuated-brake knee can not play any role at the moment of heel contact. It can prevent knee collapse after weight is borne but at the same time interference of knee flexion at the end of the stance phase resulted.

Therefore, we conclude that the load-actuated-brake knee is not appropriate for active or inactive above-knee amputees. We are presently recording EMG on these amputees.
Myoelectrically Controlled Above-Knee Prosthesis

Two configurations were developed. The first system (a) employs four hydraulic valves, one liquid-air reservoir, one actuator piston and one liquid sump. The second system (b) consists of an additional pneumatic valve and a split liquid-air reservoir.

a. Single Reservoir System. For this system, the energy is stored in a single liquid-air reservoir. The control is achieved by opening groups of valves and keeping the others closed. There are six distinct combinations, yielding six linear models. The control mechanism chooses one of these configurations. The choice is based on the pressure in the liquid-air reservoir, A and B sides of the piston, along with the direction of the desired actuator force and piston velocity. The mathematical model was developed and the simulation results were obtained. These results reveal that the system does not conserve enough of the available energy.

b. Split Reservoir System. The single reservoir system model was modified to overcome the energy conservation problem. A considerable amount of energy can be retrieved by splitting the liquid-air reservoir into two compartments. In many circumstances it is possible to discharge one part of the reservoir while charging the other. Therefore, the energy which was lost by discharging to the sump in the case above is now conserved in the system. Furthermore, a pneumatic valve between the two compartments of the reservoir adds an extra dimension to the control. Systems now can be switched among 14 linear models versus six in the single reservoir case. The simulation results for the split reservoir system demonstrated a substantial and acceptable improvement in the performance of the force actuator.

The next phase of the modelling and simulation will study cascading the split reservoir system. The cascade will further separate the reservoir system into high and low pressure compartments.

In the projects’ Time Series Studies spectral changes in the surface EMG have been characterized by autoregressive (AR) models and used to detect the direction of limb movement. Such time series models prewhiten the EMG signal generated during the activity for which they are matched. Assuming that the signal fits one of the time-series models preconstructed for each limb function, the probability of occurrence of each motion has been computed from the residual sequences from each filter and a multiple hypothesis test has been successfully implemented to select the most likely limb function. The prewhitened EMG sequence also is being used to estimate the magnitude as well as detect the direction of limb motion.

Multichannel myoprocessors are being investigated in order to increase the reliability of limb function classification and the fidelity of muscle force estimation by incorporating the spatially-distributed information contained in the surface EMG. In preliminary studies, multichannel processors have been shown to be less sensitive to the spatial shifts in myoelectric activity observed during different limb function. Initial testing also indicates that multichannel controllers operate more reliably over a wider range of input conditions than processors relying on more limited spatial information.
Recent progress has been made in estimating muscle force as well as limb function from a time-series system. Time-series processors have, in the past, yielded only binary decisions. This research is unique in its attempt to develop a signal from a time-series system which is proportional to force and simultaneously specify magnitude and direction of movement. The work in progress has attempted to estimate muscle force from multiple channels of serially dependent EMG data by first prewhitening the EMG with the AR filters used for function classification, obtaining a polled estimate of prewhitened signal variance, and fitting a power law relationship to the variance signal and force. Testing and evaluation of the complete myoprocessor is underway.

Software has been developed and experimental data collected to examine the effects of contraction level, electrode position and number, and AR model building on the performance of both the limb function classifier and force estimator.

The project also has included EMG Pattern Studies. Data qualification procedures have been applied to raw, processed, and patterns of processed EMG. In addition, linear discriminant function (LDF) coefficients from static spatial pattern recognition limb function classifiers, and estimated and actual joint moments also were analyzed. Static refers to classifiers that are obtained from a single initial training and are not modified as time goes on. A repeatable task of tracking a trapezoidal waveform with medial-lateral axis knee moment has been designed to allow examination of data from isometric-isotonic and isometric-anisotonic (linearly increasing force) muscle states. Stationarity of both the means and variances of the aforementioned variables was examined on the second, minute, and hour scales.

The ability of the static spatial pattern recognition system to recognize the intended limb function of the amputee in terms of force magnitude and direction has indicated adequacy of the fundamental model structure. Current studies in adaptive spatial pattern recognition methods have been aimed at transforming the minute and hour scale nonstationarity of the estimated joint moment mean to a stationary space, such as the observed joint moment mean.

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

**Purpose** — The overall objective is to develop an improved above-knee prosthesis for geriatric amputees. The primary concentration presently is on the stump socket interface where an increase in comfort is sought. The plan is to apply force in such a way as to obtain uniform pressure that would be expected to provide the most comfort.

Specific objectives are to examine the external elements of residual limbs as well as internal anatomical and physical characteristics, and to develop cross-sectional socket patterns for geriatric amputees. The subject population is planned to allow comparison of geriatrics versus non-geriatrics, amputees versus non-amputees, and males versus females. When sufficient data are collected, a socket
configuration will be designed and fabricated and geriatric amputees will be fit with it for evaluation.

**Progress** — The physical and physiological parameters that form the database for the related study of the residual limbs have been organized into a form adaptable for computer use to allow storage and future comparisons. The necessary equipment for performing the involved measurements has been obtained and the data collection system has been tried on several patients.

Various systems for measuring tissue compressibility have been tested. For example, brims for the perineal area have been made of thermoplastic to contain the area under study while tissue compressibility was measured with a force gauge adapted to give additional readout concerning the depth of displacement. Trials have been performed with the stump relaxed and with isometric contraction. Alternative systems, including an airtight drum made of ortholen and latex applied to the stump's brim area to allow pneumatic force to be applied equally throughout the area under consideration, are being evaluated.

Data from tissue compressibility studies will be reduced to cross-sectional diagrams that can be compared. These diagrams will contribute to the design of an alternative socket configuration for geriatric amputees.

C. Upper Limb

1. General

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

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**Purpose** — This project will develop 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 theoretical basis: dynamic optimization theory is used to produce a single meaningful number derived from accessible measurements (such as myoelectric activity, speed, range of motion, etc.) and provide an essential link between measured performance and inferred functional capability. It also has a sound practical basis: performance will be measured on specific tasks that represent the functional role an upper extremity prosthesis can realistically be expected to play.

**Progress** — In previous work, dynamic optimization theory successfully predicted patterns of muscle activation of an able-bodied person maintaining one posture of the forearm against changing gravitational loads. More recently, the approach has been used to describe all of the major kinematic features of voluntary upper extremity pointing motions of an able-bodied person. This work demonstrates the
feasibility of the approach. In this project, the mathematical technique has been refined to separate the analysis into two separate components, one dealing with the static constraints of the non-linear geometry of the musculoskeletal system, the other accounting for the dynamics of posture. The benefit of this separation is that realistic representations of the moving limb can be dealt with more simply. The analysis has been extended to provide a description of the maintenance of any posture of the forearm against changing loads.

A unique approach to the assessment of the causes underlying the functional disability of an amputee using a prosthesis is under development. The disability of an amputee using a prosthesis can be attributed to many causes: sensory loss, damage to the amputee’s nervous system, poor mechanical performance of the prosthesis, poor interfacing between amputee and prosthesis. 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 mimic in the able-bodied subject the relation between muscular activity and arm motion an amputee, using a myoelectrically-controlled prosthesis, has to deal with. For example, the maximum speed of elbow motion can be restricted to that of the prosthesis. Our immediate plans for this device are to use it to measure how much of an amputee’s dysfunction can be duplicated in an able-bodied subject (with no sensory loss, neural damage, etc.) simply by limiting the dynamic capabilities of the limb.

One important requirement for our experimental work is a clean, high-fidelity measurement of myoelectric activity. A new, improved method of processing myoelectric activity has been developed. The processing technique is based on a mathematical model of surface myoelectric activity, from which the optimal estimator of muscle force was derived. This optimal processor has now been implemented using microprocessor technology and yields about an order of magnitude improvement over conventional processing techniques. A major advantage of digital microprocessor implementation is that the tedious but essential calibration process is performed automatically without user intervention. This is an important step towards making this new technology accessible on a turn-key basis to a clinical user with no specialized knowledge of computer programming.

Feasibility for Innovation and Improvement of Body-Powered Upper Limb Prostheses

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Sponsor: National Institute of Handicapped Research

Purpose — Standard body-powered upper limb prostheses have not changed significantly since developments in the 1950’s spurred by World War II. They still employ aircraft technology using shoulder harnesses and steel cables for operation.

Estimates place the number of arm amputees in the U.S. at 100,000 with 50 percent actually wearing prostheses. Estimates further suggest there are 45,000
body-powered and 5,000 externally-powered arm prostheses in use. However, there is little research being conducted to improve body-powered systems.

The objective of this project is to assess the feasibility of effecting innovation in body-powered arm prostheses toward the ultimate goal of increasing their acceptance and use. The need is well documented.

**Progress** — The first step was to conduct a survey of amputees and professionals to assess what wearers like most and like least about their prostheses and to solicit ideas for change. (The results of the survey are described in the Winter 1985 issue of *Clinical Prosthetics and Orthotics*.) Fundamentally, arm amputees strongly desire improvement and rate: (1) function; (2) comfort; and (3) appearance of most importance to them. In analyzing the results of the above survey, the force transmission system is critical to effecting improvements in the function, comfort, and appearance of arm prostheses.

The second step was to evaluate ways to increase the efficiency of the force transmission system. Various combinations of plastic and steel cables and housings were tested along with a prototype hydraulic control system. (Results were presented at the 1985 annual conference of the Rehabilitation Engineering Society of North America.) The hydraulic system has good potential for increasing the efficiency and for allowing significant improvements in body-powered upper limb prostheses.

**Future Plans** — The next step will be to further pursue the use of hydraulics for transmission of body forces from the amputee to the prosthesis. The plan is to develop a clinical prototype system and evaluate it in use with arm amputees.

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**Myoelectric Prosthetic System**

*Purpose* — The purpose of this project is to develop modular electronic components for the control of electric-powered prostheses. The components consist of:

- **NU 126 Myo-Trode** — An active encapsulated electrode to be used with one of several different processors for controlling electric-powered terminal devices.
- **NU 110 Myo-Processor** — A single-site signal processor with a single output for controlling a powered hook such as the Michigan Child's Hook or the Hosmer/Dorrance Prehension Actuator.
- **NU 112 Myo-Processor** — A two-site signal processor to control a motor in two directions for use with the NU Synergetic Hook or any commercially available electric hand, hook, or elbow.
- **NU 114 Myo-Processor** — A single-site signal processor to control any hand, hook, or elbow in two directions.

**Progress** — All systems are designed with low power CMOS devices which permit the use of small batteries. Construction utilizes Surface Mounted Device
(SMD) techniques for extremely small, reliable circuit packaging.

A manufacturer working with the Northwestern University Rehabilitation Engineering Program has completed a prototype production run of the NU 126 Myo-Trode and the NU 110 & 112 Myo-Processors. Field evaluation utilizing the electronics is being conducted by the manufacturer.

Our laboratory has completed five fittings for evaluation: two below-elbow prostheses using interchangeable hand/hook, one above-elbow prosthesis using a myo-electric hand and manual elbow, one shoulder disarticulation prosthesis using the NU 114 single-site processor for hand control and one partial hand prosthesis. The partial hand was fitted on a five-year-old child. The miniature size and low power requirements of the system facilitated fabricating a slim, cosmetically pleasing prosthesis for a small child with a partial hand amputation.

Multifunctional Compliance Hand Prosthesis — The LSU Spider Hand

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Sponsor: United Cerebral Palsy of New Orleans

Purpose — The control aspects of hand prostheses have substantially improved in the last two decades. However, many patients find the mechanical structures and the associated functional performance still unacceptable. In particular, the following factors presented disadvantages and need additional attention:

- weight
- rigidity of grasp
- limitation of three jaw chuck or rigid digits grasp (i.e., inability to consistently grasp irregular objects with equal pressure at all five fingers)
- cost
- reliability
- sensory feedback from all fingers.

The hydraulic approach was selected as the actuator design concept and lightweight plastic as the structural and packaging material.

Progress — A prototype hydraulic activator unit was developed and is currently being tested. The prototype includes a pressure distribution chamber to which six cylinders are attached. The actuation cylinder develops pressure in the unit by means of its piston deflection, which could be accomplished by a lever attached to a Bowden cable or by an electric motor controlled with myoelectric signals. On increase in pressure in the chamber, each deflection of cylinder fluid produces movement in its piston that is coupled kinematically to the finger, inducing the grasping action. As a finger encounters resistance on contact with the object to be grasped, the contact pressure remains constant until all fingers touch the object, while the first-to-touch finger does not move or apply an additional pressure. Pressure is distributed evenly to all fingers, inducing equal pressure grasp. The hydraulic medium in the chamber is a "solid silicon" fluid that eliminates the risk of spillage. For sensory feedback purposes the equal pressure grasp principle requires only a single pressure transducer that may be incorporated in the distribution chamber, eliminating the need for multisensors in each finger.
Utilization of a viscoelastic medium allows a certain amount of compliance
during the grasping cycle, thus simulating to some extent a human grasp with its
soft-tissue deformation.

Current work focuses on testing the activator prototype and developing an
electrotactile-based sensory feedback system.

Considerations for New Design of Human Hand Prosthesis

**Purpose** — The MTM-1 system is employed for the development of ‘performance
profiles’ for impaired individuals. The study deals with hand amputees who
are involved in manual tasks and is aimed towards improving their occupational
potential. The informed procedure of performance profiles is based on micro-
motion analysis which uses MTM-1 for definition of motion patterns and on
biomechanical consideration for the locomotion of the amputated organ. The
procedure is useful as an objective evaluation of the amputee’s performance and is
directed to the assessment of his occupational abilities in the non-sheltered
situation.

The informed performance profiles serve as criteria for mechanical design of
manipulative aids for amputees to replace their lost hand. In this study, an
improvement of the standard hook that advances the manipulative abilities of the
amputee is suggested.

**Progress** —

*The Performance Profiles.* Characteristics and limitation of repeatable motion
elements of amputees who wear a standard ‘lyre-shaped’ hook was investigated
by using the MTM-1 procedure for manual operations in terms of their motion
elements. The five motion elements involved in this investigation were reach,
grasp, move, position, and release. A task layout was established for the
investigation using two task boards, 12 objects, and a standardized routine of task
handling. The 12 objects differ in shape (ball, cylinder, cube and triangle),
weight, and size (small, medium and large). The objects were picked up from
their stations on one task board, transferred and positioned in appropriate recesses
on the other task board.

*Analysis of Prosthetic Design.* The performance profiles obtained from micro-
motion analysis of the deviation in performance between amputee and non-
amputee individuals defined the motion element “grasp” to be the main cause of
manual time delays for all the four basic geometrical shapes. Two improved
versions of the tested hook were developed in the Work Study Laboratory at the
Industrial Engineering Department of Technion-Israel Institute of Technology.
The new configurations of hooks were based on the Dorrance Lyre-shaped hook
fingers and are easily fitted to any regular prosthesis. The improvements were
designed according to the criteria defined in the micro-motion study and ADL
(activity of daily living) considerations from objective evaluation of amputees
movements. Both versions have lyre-shaped hook fingers with smooth outer
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surfaces to allow easy access for entering pockets and sleeves. The hook fingers have rubber bonded to their inner sides to provide the necessary friction for holding smooth objects and for preventing possible vibrations if they occur. One of the versions has two fixed thumb fingers originating at the base of the main fingers which forms a double forceps finger device for the better maintenance of grasp ability of multiform and rounded shapes. These supporting fingers were designed curved and of appropriate size in order to embrace large spherical shapes. The added fingers have additional embossments which have a swivel ability to provide a tight grip potential for carrying handles attached to weight (attache cases, bags, etc.). A third version was designed with two additional fingers with swivel ability on ratchet type hinges. These provide a widely adaptable supportive ability to the basic lyre-shaped fingers. When closed, the two double fingers form a nearly closed curve which enables the clasp of objects with parallel surfaces and enables the support of rounded figures. Such designs of hook fingers may reduce the tendency of objects to eject asprehension forces are increased as well as making a better supportive contact when gripping objects with parallel surfaces and spherical contour lines.

Design Evaluation. Evaluation of the improved versions in relation to the standard Dorrance hook followed. The evaluation was based on a micro-motion comparison of motion element grasp for performance ability of the three hooks. The same task was performed by a small sample of individuals who performed the task three times, each time with another hook. The versions developed in this study provided an improvement in hook performance ability with small and large objects. For the triangle, cylinder, and ball, which are more problematic shapes, there was also relevant improvement.

Cosmetic Covers for Upper Extremity Prostheses (Male/Female)

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — A goal of this program, started in April 1985, is to develop realistic and durable cosmetic covers for hand and arm prostheses for men and women. A basic thesis is that the subject’s remaining hand is to be used as the master for fabricating the prosthetic cover (as opposed to using a stock glove). Advanced materials and techniques are to be applied in this program. These include: silicone rubber primary molds, use of a 3-D reversing pantograph, cast thin shells for texture transfer, castable polyurethane final molds, quantitative approaches to intrinsic coloration, and durable silicone rubber materials for the covers.

Steps in the projected overall procedure include: 1) making a precision mold of the hand and arm; 2) making a rigid cast from the primary mold; 3) using this cast as the master from which to make a mirror image with the reversing pantograph; 4) providing accurate skin texture to the mirror-image form by applying thin wax overlays cast from the silicone rubber primary mold and bridging and texturizing the gaps between these; 5) making a final mold (e.g., evertable or split polyurethane elastomer) from the mirror-image master; and 6) fabricating the prosthetic cover in layers, using intrinsic coloration for heterogeneities and mass tones.
Progress — Included in the efforts this year have been: 1) studies of materials for molding procedures and for fabrication of the covers; 2) investigation of methods for making a precision primary mold (one-piece evertable with split mother mold, two-piece using custom-molded alginate resting base to define the split line, and two-piece cast as one-piece with specially embedded alignment keys); and, 3) fabrication of the reversing pantograph.

Future Plans — Further work will include development studies on fabricating and texturizing the mirror-image form, on making the final mold, and on fabricating the prosthetic cover itself. Wearer studies and technology transfer to prosthetists also are planned.

Orthoses and Prostheses for Partial Hand Amputation/Evaluation of the Hosmer Contour Terminal Device

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Progress —

Orthoses and Prostheses for Partial Hand Amputation. Simple devices are made of light plastics in order to allow amputees bimanual activities.

Evaluation of the Hosmer Contour Terminal Device. Evaluation was performed on a series of ten patients with below- and above-elbow amputations. The Contour hook needs a cable approximately four centimeters longer than the classical hook. The activation lever arm is shorter so that more power is needed to open it for the same number of elastic bands.

Design of Prehension Systems for Upper Limb Amputees

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Progress — Our research work has centered on the refinement of the synergetic power base for the prehension systems that are to be developed. The power base contains the two-motor mechanism. The first step has been to design the base in a symmetrical manner so that its case may be used on the left side or on the right side. The case has been designed so that the palmar side has a form of thenar prominence that can be used for pushing on handles (e.g., lawn mowers). This prominence is covered with a soft pad that facilitates its use for pushing and also for pressing down (e.g., to hold paper) on objects. Likewise, the lateral side has a soft surface to be used for holding down objects. The power base has been given a neutral color. The base itself is gray and the rubber pads for the pressure surfaces are black. The color is designed to make the prehensor appear technical in nature and to be compatible with the prehensor finger and with the color of prostheses for black and white people.

Mechanically, a breakaway finger mechanism has been added so that the fingers may be forceably released with a force of approximately 225N. at the finger tips. The prehensor with lyre-shape adult hook fingers develops a pinch
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force of 110N., has a speed of 3.0 radians per second, and will make approximately 1200 full openings and closures (closure to 70N) using a nine-volt transistor battery (80 mah) as a power source. The power base is being readied for evaluation by the Veterans Administration. Packaging of the myoelectric control electronics and of the battery remains to be completed. Several other finger designs have been developed and will be evaluated when the design of the power base is complete.

Position-Servo Control of Upper Limb Powered Prostheses

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Progress — During the first phase of this development project, work has concentrated on the development of a low-power small force transducer. Several low-power (e.g., less than 1.0Ma) transducers have been developed. The first used a twin-T differential capacitor. This unit had low power and functioned well, but in tests it proved to be temperature sensitive. The second system consists of a capacitance bridge. It requires low power and appears to be suitable for practical applications. However, the supporting electronics required are more complex than desired. Pulsed (sampled) strain gauge systems have been examined but they too are complex. Other pressure transducer schemes are being investigated.

The force transducer is used as the input to the position-servo mechanism that is controlled from body joints acting upon cables connected to the powered joint and in series with the transducer. We have acquired the Hosmer Elbow, the Liberty Mutual Boston Elbow, and the Utah Elbow for clinical trials of the new controller, which is based upon the principle of extended physiological proprioception.

C. Upper Limb

2. Below-Elbow

Below-Elbow Prosthetic System

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Purpose — The objective of the project is to develop a below-elbow prosthetic system with hook/hand interchangeability and easily removable modular components. The components consist of the terminal devices, battery, electronics package, and wrist connector.

Progress — A manufacturer is now preparing this system for production. This laboratory has fabricated several prostheses using prototype components. Development work will continue with the Northwestern University Prosthetics Research Laboratory as advisor to the manufacturer. Presently a break-away device is being designed for the synergetic hook.