I. Amputations and Limb Prostheses

A. General

B. Upper Limb
   1. General
   2. Above-Elbow
   3. Below-Elbow

C. Lower Limb
   1. General
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I. Amputations and Limb Prostheses

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A. General

[I] Mechanism-Based Treatments for Phantom Limb Pain

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Sponsor: VA Rehabilitation Research and Development Service (Project #A314-2RA)

Purpose—The purpose of this study is to determine causes and mechanisms of phantom pain and to test treatments based on identified mechanisms.

Methodology—Amputees reporting stump and/or phantom limb pain were recorded using thermographic measures of near-surface body heat and surface electromyographic measures of muscle tension. Each subject was recorded between two and four times while reporting varied pain intensities. Each subject used a body map to identify areas with phantom, no, and normal sensations. When decreased blood flow in the stump is related to increased burning phantom limb pain, peripheral vasodilators and temperature biofeedback are used to decrease the phantom pain. When increased muscle tension and spasms in the stump are related to episodes of cramping phantom pain, muscle relaxants and muscle tension biofeedback are used to control the pain.

Results—Physiological Mechanisms. Among amputees, a consistent inverse relationship between intensity of pain and stump temperature relative to the intact limb occurred for burning, throbbing, and tingling descriptions of phantom limb pain and stump pain, but not for other descriptions. Surface electromyographic (EMG) recordings made while amputees are experiencing multiple, brief, discrete episodes of cramping phantom pain show a clear predictive relationship between the start of spasms in the residual limb and the onset of phantom pain. There is no convincing evidence that major personality disorders are important in the etiology of chronic phantom pain. Evaluation of logs indicates that phantom limb pain can be affected by the external environment.

Treatment. The treatments described above have been completed for most of the subjects, but follow-ups are not complete. Pending confirmation upon follow-up, it is clear that burning phantom pain responds to interventions which increase blood flow to the residual limb while cramping phantom pain responds to interventions which decrease tension and spasms in major muscles to the residual limb. Shocking/shooting phantom pain does not respond well or consistently to either type of intervention.

Future Plans—Limited local Army funds, as available, will be used to perform pilot studies which will record physiological factors and phantom pain in subjects’ normal environments to establish predictive relationships between variables.

Recent Publications Resulting from This Research


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Sponsor: VA Rehabilitation Research and Development Service (Project #A89-25PA)

Purpose—The purpose of this study is to examine optical skin reflectance at multiple light wavelengths in the presence of soft tissue ischemia. The study seeks to identify clinically useful parameters and a measurement protocol for comparing reflectance methods with fluorometry. The application is the assessment of soft tissue ischemia, which is encountered with pressure ulcers, tissue necrosis associated with vascular disease, and trauma. The ischemia, when unrecognized, can lead to further unexpected death of soft tissue following intervention to close open wounds.

Methodology—Fluorometry and a variety of other methods are available for perfusion measurements. However, there is a need to consider methods which might provide totally noninvasive and easy to use measurements. Recently reported studies by us on the optical properties of soft tissue have prompted us to investigate ways in which skin reflectance spectrophotometry might provide useful data for evaluating ischemia and flow obstructions. The spectrophotometric methods are an expansion upon principles employed in photoplethysmography and pulse oximetry.

Progress—Preliminary data has been obtained from both animal studies in a surgical flap model and from post-surgical studies. The data is being correlated with tissue survival outcomes and examined in the context of soft tissue perfusion models.

[3] Intraoperative Assessment of Amputation and Decubitus Flap Perfusion

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Sponsor: VA Rehabilitation Research and Development Service (Project #A463-RA)

Purpose—The surgical flap is a widely used and often effective closure following removal of necrotic and gangrenous tissue from a limb. This form of treatment permits salvage of limbs and tissues, thereby preserving more patient function and reducing requirements of extended rehabilitation. However, flaps to cover an amputation site in the presence of peripheral vascular disease are reported to show a failure rate of 20%. In the spinal cord injured patient, flaps to cover a pressure sore site are reported to show a 6 to 7% failure rate associated with suture separation and necrosis. Prediction of these failures before they occur would permit an alteration of surgical procedures with reduced morbidity and mortality. At the present time, the survival of the flap remains in question for extended periods after surgery.

Methodology—Our hypothesis is that quantitative measurements taken intraoperatively after the flap has been formed can be used to assess flap physiological function, and can be predictive of flap survival. We have conducted intraoperative testing to determine the presence or absence of perfusion based upon fluorescein flowmetry. Measurements were taken immediately postoperatively with tissue survival 7 days after the operation.

Since the testing is done intraoperatively after the flap is developed, and also after the flap has been moved into its anticipated location, the results should be of more use in prediction than testing done preoperatively.

Preliminary Results—In nine patients studied, two showed fluorometric readings consistent with poor perfu-
Amputations and Limb Prostheses

One subject, an overweight smoker, showed a mal-distribution of skin perfusion prior to surgery, including areas of hyperemia and ischemia in measurements at 24 sites. This data supported the conclusion that measurements at a single site can produce an inaccurate view of extremity perfusion status and that readings at multiple sites can elucidate pathologic changes and the return towards normal perfusion levels.

One subject studied had a service-connected spinal cord injury. A surgical flap was developed and utilized to repair a decubitus ulcer wound. Immediate post flap reconstruction, the fluorometry studies revealed a region of low perfusion at a flap corner. Upon further examination, there was visual evidence to suggest mechanical tension. Subsequently, the flap separated in this suspect region. From this data, we conclude that fluorometry can predict regions requiring further attention.

These clinical results to date, although limited in number, are consistent with the view that skin perfusion must be adequate if healing is to occur. Laboratory animal data in our recent work also support this view. A surgical flap model provided a gradation of perfusion levels from near normal perfusion at the base to severe ischemia and eventual tissue necrosis at the end of the flap. A study of 132 sites for 15 flaps was done. Study results following flap formation showed fluorometry sensitivity and specificity of 100% and 97%, respectively, in predicting flap survival, while initial visual appearance of the flap could not be used to predict survival.


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Sponsor: VA Rehabilitation Research and Development Service (Project #A086-4RA)

Purpose—This program consisted of two studies: 1) experimental-clinical examination in arteriosclerotic occlusive disease; and, 2) the role of blood perfusion and regional tissue mechanics measurements. The premise being that noninvasive assessment of blood perfusion and mechanical properties of a limb will provide needed information for prediction of optimal intervention (surgical and/or pharmacological) to achieve healing while minimizing the length of hospital stay and costs. The measurements applied in this study for blood perfusion are inert H2 clearance, fluorescein fluorometry, and tissue mechanics measured by pressure displacement relationships of limb tissues.

Methodology—The program was a continuation of a previous program which consisted of development of instrument systems followed by experimental and clinical studies and data analysis. The animal studies focused on the sensitivity of the instrument responses to conditions of poor perfusion, edematous changes, and postsurgical intervention. Clinical studies involved accumulation of serial testing in patients during and subsequent to treatment. For comparison, standard noninvasive vascular tests were performed.

Implications—Arteriosclerotic occlusive disease (ASOD) is a major cause of morbidity and mortality in the United States. Within the VA patient population, high incidence of ASOD in the lower extremities is reflected with the loss of function of the lower extremities, reduced mobility, increased morbidity, and interference with daily activities. Ischemic ulcers and gangrene become a chronic medical dilemma. When amputation is necessary, this leads to irreversible functional loss and lengthy rehabilitation. Given these conditions, the early assessment of limb tissue viability and the effects of different treatment modalities (i.e., surgical/pharmacological) is vital. Reduction of costs of care associated with rehabilitation requires improved noninvasive instrumentation for early assessment and treatment of ASOD.

Results/Future Plans—Significant progress has been made in both clinical and experimental studies. Instrumentation and testing techniques have been developed for the assessment of blood perfusion and mechanical properties in the limb. Both tissue compliance and fluorescein/tissue viability will be studied via individual programs.
Cosmetic Covers for Upper and Lower Extremity Prostheses

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Sponsor: VA Rehabilitation Research and Development Service (Project #A252-2RA)

Purpose—This program is directed toward the development and practical application of realistic cosmetic covers for upper and lower extremity prostheses for men and women. Objectives include: 1) continuing the development and demonstration efforts begun under the previous VA contract with Franklin Research Center (FRC), toward realistic and durable cosmetic covers for hand and arm prostheses, including studies on materials and procedures for molding, casting, and intrinsic coloration; 2) conducting technology transfer and training of VA-associated prosthetists in the specialized techniques of this program; 3) conducting research and development studies toward application of the cosmetic covers to active hand systems, including FRC’s conforming-grasp design; and, 4) developing cosmetic covers for lower extremity prostheses (feet and legs).

Progress—Efforts were continued on the technology of molding and casting, particularly toward eversible final molds derived from primary molds of donor hands. A promising new multistep procedure was developed: 1) a primary mold of the extremity is made with an alginate (alternatively, silicone) impression material; 2) a flexible cast is made with a flexible polyurethane (durometer 55A); 3) an eversible mold is formed from acetoxy-moisture-curing sealants, with a very thin fluorosilicone inner layer and thicker (e.g., 2 mm) dimethylsilicone outer layer; and, 4) a multilayer addition-cure silicone cover is formed using intrinsic coloration. A silicone cover was fabricated using this technology for the passive prosthetic hand of a veteran.

A 3-day training session on the techniques and materials for making cosmetic covers was held at FRC in March 1990, with certificates of completion awarded to six VA prosthetic personnel and providers. The areas covered included primary molding of the hand, casting a polyurethane master, making an eversible two-layer mold, and intrinsic coloration procedures.

Results—For the conformable grasp hand, a suitable understructure was identified. A knitted Kevlar sleeve which slides over the fingers and bunches to make a space-filling convoluted form prevents cut-through from the metal parts while not resisting joint flexion. The Kevlar sleeve is more satisfactory than liners of silicone gel or elastomeric foam.

Studies were conducted on materials suitable for covers for active hands. One promising high-tear material is a solution-based 5%-diphenyl siloxane copolymer.

Examples of several commercial prosthetic feet were obtained to investigate approaches to making realistic, durable covers. Ways of making covers with several high-tear-strength, solvent-based silicones were studied. Areas studied included mold materials, solvent removal, and silicone composites.

A flexible support was conceived for lower-extremity covers using a flexible thermoplastic foam thermoformed into the shape of the leg with convolutions incorporated to allow knee flexion with minimal resistance. Experiments showed that sheets of EVA foam (2.9 lb/ft^2) can be vacuum-formed effectively over a convoluted knee-area model.

Studies were made of the stretching of skin over the ankle joint. Silicone molds were made of a human ankle region in a neutral position (with raised markers at measured points), in full dorsiflexion, and in full extension. Measurements made on epoxy casts to determine the elongation and contraction of the skin in various locations and directions will be useful in designing soft covers.

Future Plans—Efforts will continue on high-tear-strength materials and on associated molds and release agents. Covers and supports for upper and lower prostheses will be demonstrated. Training activities will be continued.

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Sponsor: VA Rehabilitation Research and Development Service (Project #A335-2RA)

Purpose—To predict the viability of the skin in patients coming to amputation, we have compared Laser Doppler Velocimetry Temperature Stress Test (LDV.TST), Quantitative Perfusion Fluorometry (QPF), and Ankle-Brachial Indices (ABI) in 39 preoperative patients who underwent either a transmetatarsal or below-knee amputation.

Methodology—LDV.TST involves heating the skin to three different temperatures (34, 38, and 42 degrees Centigrade), then doing a regression analysis of the rise in LDV signal as a function of applied temperature. Previously, we had found a significant difference in the regression coefficients for ischemic, dysvascular, and normovascular skin. As reference, we assessed comparable areas (dorsum, medial, and lateral below the knee, above the knee, and upper arm and forearm) from 20 nondiabetic controls with normovascular blood flow. Ten of the subjects were black and 10 were white.

QPF involves taking background readings of the skin with a dermofluorometer, injecting fluorescein (4-6 mg/kg) diluted to 20 cc with normal saline, over a 2-minute interval, following with a 10-minute, postinjection reading (subtracting the background). The area in question is referenced to a comparable area of color with normovascular blood flow (i.e., forearm, upper arm). Since many of these patients do not have a comparable area of normovascular blood flow, we have found a high degree of inaccuracy (35%). In each of the 39 patients, the mean dye fluorescence index (DFI) at the amputation site is used for comparison with the other measurements.

Results—Ankle-brachial indices were done on every patient at the end of the LDV.TST. This test was probably the least sensitive with regard to healing of the amputation site due to the diabetic’s noncompressible arteries.

[7] Computerized Methods for Prosthetics and Orthotics

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This series of projects strives to apply the power of computers to the fields of prosthetics and orthotics. Applications we are examining include the modeling and processing of body structures.

Progress—Structural Modeling. Soft Tissue Modeling. An investigation into the static mechanics of muscular tissue was concluded. Results show that a Mooney material representation, combined with a Herrmann finite-element variational statement will accurately predict the mechanics of muscular soft tissue. In cases without significant areas of high deformation, linear, constant-dilatation elements were found to be sufficient. These are essentially the linear form of the Mooney/ Herrmann elements, yet result in models which are four times faster.

Additionally, modeling of problems involving incompressible solids was found to be sensitive to an accurate specification of the incompressibility. Historically, standard (fully-integrated, displacement-based) finite-elements with a Poisson’s ratio of 0.45 are used as an approximation for this case. Using generic models, however, we found this method leads to under-prediction of stresses by a factor of 5. Linear constant-dilatation elements do allow for the correct specification of incompressibility.

Above-Knee Socket Modeling. A finite element analysis (FEA) study of three clinical A/K socket designs (quadrilateral, NSNA, NURIC) was initiated. A 3-D finite-element model of an undeformed residual limb was developed consisting of 3,485 nodes and 2,673 elements. Limb and socket shape data were aligned to produce rectification maps which were input to the model as surface displacements. A loading of one-half body weight was distributed to the proximal hip.
The FEA pressures for the quadrilateral socket were highest at Scarpa's triangle, and in the broad ischial-gluteal region, averaging about 6.5 N/cm². For the NSNA socket, the pressures were more uniformly distributed with mid-limb pressure generally between 4.5 to 7.5 N/cm². For the NURIC socket (a total ischial-containment type), mid-limb pressure values were higher (5.0 to 12.0 N/cm²). The percent change in volume below ischial level was calculated for each socket and correlated fairly well with predicted mid-limb pressures.

An experiment was conducted to measure pressures at seven sites along the socket/limb interface for each socket. The highest pressures measured in the quadrilateral socket appear in Scarpa's bulge and in the ischial and gluteal areas. The NSNA socket also showed high pressures in the ischial and gluteal regions and somewhat higher pressure at mid-limb sites. The NURIC socket yielded peak pressures against the medial wall near the ischium and in Scarpa's compression, and showed the highest of the three mid-limb pressures. In general, the trends agreed with those predicted by the FEA, although the values measured are consistently lower than the values predicted.

**Determination of Centers of Rotation.** Work continues on examining methods to calculate the center of rotation between two rigid bodies. The methods examined in this study are: Least-Squares Estimator (LSE); Generalization of the Reuleaux Method (GRM); Maximum Likelihood Estimators (MLE). It has been found that for all methods, the accuracy and precision improve when the angle of rotation of the rigid body is larger, and/or when the measuring noise decreases. Additionally, the LSE and GRM have the same precision.

A two-step optimization procedure was developed to locate the femoral transverse axis (FTA) using knee kinematics. The first step is used to find the direction of the FTA relative to the femur. The second step is used to find a point on the FTA at the mid-width of the knee (femoral origin). To test the procedure, kinematic data for 18 knees was used, for which the position of the femoral origin and the orientation of the FTA had been previously determined geometrically and checked radiographically. The calculated FTA orientation was found to be in error by an average of 2.39 degrees (s.d. 3.73), and the origin was found to be in error by an average of 2.58 mm (s.d. 2.78).

**Structural Processing.** Software. Software which uses surface data information to automatically form a finite-element model of the structure has been written. Presently, only surface point data is used (i.e., internal bony shapes are not modeled).

**Manufacturing Demonstration.** A prototype B/K prosthetic socket was made using the stereolithography process. This was accomplished with the assistance of the Baxter Healthcare Corporation. Stereolithography relies on a laser-based instrument developed by 3D Systems that forms solid models by optically curing a photo-polymer. The production of the socket, which took 2 days, was the first known application of this technique to the field of prosthetics.

**Recent Publications Resulting from This Research**


**[8] Prosthetic/Orthotic Materials**

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Sponsor: National Institute on Disability and Rehabilitation Research

**Purpose**—Standardized testing modalities are being used to characterize the composition, structure, and performance of the current armamentarium of prosthetic and orthotic polymers prior to and after fabrication, and after weathering and quenching. Also, new thermoplastic elastomeric materials are being examined for their potential for providing improved prosthetic and orthotic devices.

**Progress**—Properties of tensile elongation, dynamic modulus, and infrared spectra were measured on three polymers, namely, Subortholen, polypropylene, and Surlyn, having undergone four different processing treatments (i.e., "as-received," weathering, quenching, weathering and liquid nitrogen quenching).
Results—

a. Polymer degradation as proposed from monitored infrared spectra. Weathering of the samples was performed according to ASTM standard G53-84. Specimens were placed in a weatherometer for 5 weeks in a cycle of 80 degrees C ultraviolet light for 8 hours, followed by 60 degrees C water vapor for 4 hours.

Degradation of these polymers during weathering was seen by the infrared spectra as originating in the propagation stage where:

\[R + O_2 \rightarrow ROO^-\]
\[ROO^- + RH \rightarrow ROOH + R^-\]

The decomposition of the hydroperoxide ROOH into various alcohols is suggested by the observation of primary alcohol (RCH\(_2\)OH, at 1050 and 3400 cm\(^{-1}\)), secondary alcohol (R\(_2\)CHOH, at 1100 and 3400 cm\(^{-1}\)), and tertiary alcohol (R\(_3\)COH, at 1150 and 3400 cm\(^{-1}\)).

b. Tensile testing. Tensile testing was carried out on an Instron Table Model 1101 testing machine, using ASTM standard method D638-87a. Three cross-head speeds were used: 0.05, 0.2, and 0.5 in/min. Quenching was performed by heating to the manufacturer's recommended "softening temperature," followed by immediate quenching into liquid nitrogen. The liquid nitrogen temperature (−196 degrees C) is far below the glass transition temperatures of either polypropylene (−10 degrees C), or Subortholen (−80 degrees C).

The surface morphology of the Subortholen weathered tensile test specimens revealed a thin, cracked layer of embrittled material on the surface, which did affect certain mechanical properties. For Subortholen at a cross-head speed of 0.05 in/min, a dramatic reduction of the tensile elongation, from more than 500% to about 100%, was found by weathering the as-received material. On the other hand, the liquid nitrogen quenched Subortholen increased its tensile elongation from 500% in the as-received condition to about 900%. It was interesting that if both the quenching and weathering treatments were applied to the same sample, the value of tensile elongation was three times as that of a sample which had only been weathered.

At all treatments, the specimens were negatively strain-rate sensitive (i.e., less percent elongation at higher test speeds).

c. Dynamic mechanical testing. Dynamic mechanical testing was carried out on a Rheovibron Model DV-II-B testing machine at 11 Hz, over a temperature range from −100 degrees C to 200 degrees C. The Rheovibron applies a sinusoidal strain on the specimen and measures the amplitude of the resultant stress, and the magnitude of the phase angle \(\delta\) between the stress and strain. The loss moduli definitely change as a function of temperature, and definitely decrease as a function of weathering time. The glass transition temperatures of these tested polymers appeared to remain the same during weathering.

Future Plans—Characterization activities are to be carried out on several series of thermoplastic elastomers to be compared with the conventional prosthetic and orthotic armamentarium.
self-help groups, nursing care, prosthetic/orthotic schools and service providers, prosthetic/orthotic publications, and manufacturers’ information. New information on prosthetic/orthotic products and services is reviewed by the Unit, added to the database, and made available to the public. Conversion to a hypertext database solution for information management is being implemented.

The help-line, available on (312)908-6524, disseminates information in the database to the many callers contacting it monthly. Additionally, by delving into alternative resources, the help-line directs callers to other information clearinghouses or professionals which may be better able to service their request. Follow-up occurs via telephone or correspondence where the caller receives written confirmation of their request and accompanying materials if available. No charge is made for any help-line service.

Consumer feedback to the Resource Unit is formally acquired through yearly meetings of the Consumer Advisory Panel of the Rehabilitation Engineering Program. Educators and clinicians have benefitted from their invited attendance at these meetings. The Panel, consisting of persons with disabilities managed by prosthetic/orthotic solutions, met in Phoenix this year for a state-of-the-art workshop and conference in connection with the annual AAOP meeting. Input from consumers contacting the help-line is also extremely valuable, as it represents the experience and real-life situations of prosthesis and orthosis users who do not have ready access to a body of research professionals or up-to-date information.

Programs, presentations, and publications disseminate information collected or generated by the Resource Unit. In addition to the Phoenix conference, the Unit assisted in the creation of a small part of the exhibit, “Bionics and Transplants: The World of Replacement Medicine,” now at the Museum of Science and Industry, Chicago, IL. We regard papers published and presented by the staff as one method of research information dissemination. Titles of such papers are under other project descriptions in this journal. The Project Director of the Resource Unit participated in the 13th Annual RESNA Conference in Washington, DC, in June, 1990. The Resource Unit is playing a major part in organizing and hosting the Seventh World Congress of ISPO in 1992.

Brochures describing work at the Rehabilitation Engineering Program were published early this summer, and previous to this, articles about the Resource Unit appeared in two major prosthetic/orthotic journals. A Resource Unit newsletter is being planned for 1991.

Recent Publications Resulting from This Research

[10] Extended Physiological Proprioception in the Control of Prosthetic and Robotic Systems for Physically Disabled Persons

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Sponsor: Natural Sciences and Engineering Research Council of Canada; Kinnear Foundation

Purpose—Extended physiological proprioception (EPP) involves controlling a prosthesis (or robotic system) by linking its position in space with the positions of intact joints of the user’s body. This control method can improve accuracy, speed of operation, and safety of the controlled system.

Progress—Work has been underway for a few years on the control of prosthetic systems. Work is starting now in the use of EPP in the control of robotic systems, along with some special modifications which we are implementing. To help quantify our results and to speed up the making of changes to our systems, we have opted for the use of 3-dimensional (3-D) simulations on a computer screen, rather than bench-top models. A 386 computer with a VGA monitor and appropriate 3-D software have been installed. Further work will be undertaken in this area during the next two years.

Recent Publications Resulting from This Research
B. Upper Limb

1. General

[II] Computer-Based Myoelectric Training

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Sponsor: Hospital for Sick Children Foundation

Purpose—Our purpose was to design, develop, and evaluate a computer-based system for training amputees to control the myoelectric signals which they will use later to operate artificial limbs.

Progress—One of the recognized limiting factors in training children to use myoelectric prostheses is their limited attention span. In 1987, the Institute proposed to investigate the possibility that computer games, with myoelectric rather than manual control, could be useful supplements to normal training protocols.

Between March 1989 and March 1990, 11 clients of the Prosthetics Research Centre used the game, and data was recorded. The youngest client was 4-and-a-half years old, and the oldest 13-and-a-half years old. These clients were segregated into three age groups, pre-school (4 to 6 years), elementary school (7 to 11 years), and early teens (12 years and above). Several clinical observations with regard to these age groupings were made during the period of the trials.

These trials have shown that the game has definitely provided a motivating, interesting alternative to myoelectric signal training. However, whether this system has a beneficial effect with regard to client performance with a prosthesis is, at present, impossible to say.

Clinical trials are being extended to allow rigorous statistical analysis of the data to be performed. It is hoped that we can collect sufficient data to determine if any real benefit is achieved using this technique.

Recent Publications Resulting from This Research


[12] Multifunctional Hand Prosthesis Based on a New Pattern of Prehension

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Sponsor: Institut de recherche en santé et en sécurité du travail du Quebec

Purpose—The objectives of this project are to: 1) develop a multifunctional hand prosthesis for which the prehension geometry and the architecture have been developed around the most essential opposition movements of the thumb, and within its preferred plane of flexion; 2) overcome the complexity of the design by using a three-dimensional (3-D) computer-aided program (CATIA) for both the design and modeling processes; and, 3) validate the new pattern of prehension by clinically comparing the prehension performances with a hand prosthesis featuring a traditional pincer type prehension pattern.

Progress/Methodology—Based upon the results of an ergonomic analysis of prehensile activities, a first laboratory prototype was completed in 1988. The prehension geometry was elaborated using a 3-D computer program. This has been followed by the production of a first series of six revised clinical versions which are now functionally evaluated by candidates previously fitted with an Otto-Bock myoelectric hand prosthesis.

The new hand prosthesis is constructed with a morphology resembling the natural hand and powered from a single motor. The prosthesis prehension calls upon four active fingers, each flexed at the level of the
two proximal joints. The opposing thumb is also flexed at the level of the carpometacarpal (CMP) and interphalangeal (IP) joints. It can also be rotated passively in order to perform the two complementary patterns of prehension: the tridigital and the lateral grips. The finger's metacarpophalangeal (MP) joints describe a dome curve in both the transversal and the longitudinal planes of the palm and are oriented to spread the fingers apart during extension. The fingers are made adaptive and they will flex when pushed by an external force.

Preliminary Results—The comparative prehension performance between the new hand and the Otto-Bock hand is not yet completed. However, the new prehension geometry, with the plane of flexion of the thumb (tridigital mode) intersecting the palmar plane with an angle of 45 degrees, has permitted the identification of the following functional advantages: 1) it reduces greatly the recourse to arm and trunk compensatory movements during both the approach and the utilization phases of most of the objects; 2) it allows a better orientation of many objects held for use; 3) it improves the working visibility, the cosmesis of the prehension, and the grasping stability, particularly for large objects; 4) because of the thumb trajectory in the tridigital mode, the new hand is also more suited than the pincer type for the prehension of cylindrical and spherical objects; and, 5) although it still requires to be affined, the lateral pinch has proved to be very useful in many activities.

To summarize our partial results, the new geometry seems functionally very promising. However, a certain number of design corrections would have to be implemented in the present version in order to meet the required level of reliability and all the original specifications, especially when the prosthesis is covered with a cosmetic glove.

Future Plans/Implications—Following an evaluation of the required design corrections, we are presently studying the possibility to implement them on prostheses already produced. This approach would offer the advantage of concluding the clinical evaluation more rapidly. In parallel with this study, we are also investigating the possibility of joint development, manufacturing, or commercialization of the new prosthetic hand.

Recent Publications Resulting from This Research

Patents


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Purpose—This project is a continuation of earlier work, which indicated that myoelectric signals from muscle remnants in the residual limbs of amputees differ significantly from signals from normal muscles. The primary objective is to obtain further information on myoelectric signals from amputees. A second objective is to study the effects of various algorithms for selecting decision thresholds in level-coded myoelectric control systems. The outcome of this research will be used in optimizing future myoelectric control systems.

Progress—The analysis of amputee myoelectric signals is a cooperative project with Dr. Evelyn Morin of Queen's University. Agreement has been reached on all aspects of data collection and analysis protocols, software has been written for use by both centers, and data collection has begun at the University of New Brunswick (data collected from 10 amputees thus far). While these data are insufficient for statistical analysis, the trend noted in the previous report seems to be persisting. That is, there may be two populations of amputees, with myoelectric spectra (from stump musculature) shifted respectively up and down in frequency relative to the normal limb, or to typical data for nonamputees.
Recent Publications Resulting from This Research


[14] Objective Assessment of User Interface Control Strategies for Proportionally Controlled Prostheses and Orthoses

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The research proposed here aims at: 1) developing a laboratory system which will facilitate the objective evaluation of an individual's performance in reaching and grasping tasks using any interface control strategy to control a wide range of assistive devices; and, 2) using this tool to compare the performance of several common interface strategies.

The research questions to be answered are: 1) Is the laboratory system a reliable tool for objectively assessing the performance of a prosthetic or orthotic device? 2) Of the commonly used interface control strategies, which are the best performers? How significant is the difference in performance between strategies? and, 3) To perform well, what features should an interface control strategy have?

Methodology—The user-device interface consists of three components: 1) the command sources and transducers; 2) the proportional control strategy; and, 3) user feedback strategy.

The choice of a user interface to a prosthetic or orthotic device involves choosing a combination of all facets of the above components. “Ease of use” is often the justification for a particular choice of interface, but objective evaluation of the interface is rarely done. The focus of this study will be the first two components of the user interface.

Progress—The system will be designed so the full range of command source transducers and prosthetic or orthotic devices can be tested with the system. At the heart of the system is a software program called the Interface Strategy Management System (ISMS). The ISMS selects the appropriate strategy modules required to implement a particular interface strategy. The ISMS uses these modules to process the command sources and feedback from the prosthesis or orthosis. The processed information is presented as a positional command to the assistive device. In the assessment phase of the project the laboratory system will be used in the evaluation of four common user interface control strategies. Initially, the command source will be a 2-axis joystick controlled by shoulder movement. The assistive device will be a powered prosthetic arm with an electric hand and electric elbow. The subject will be asked to reach for an object, grasp it, and place it on a target. The target and object will be placed automatically in different work planes under computer control. The tests aim at evaluating the user's ability to integrate prehension/release of the prosthetic hand, flexion/extension of the prosthetic elbow and movement of the intact shoulder. The performance of each of the interface strategies will be measured according to: 1) reaction time: the time from the placement of the target and object until the subject begins to move the prosthetic limb. We hypothesize that reaction time will indicate the amount of conscious planning required to use the strategy; and, 2) total time to complete the task. We hypothesize that this time will indicate the feasibility of integrating the strategy into a functional activity.

Twenty able-bodied subjects will participate in the study. Five subjects will be randomly assigned to each of the following strategies: 1) Velocity control. Elbow flexion and hand opening will be proportional to vertical shoulder velocity. Elbow extension and hand closing will be proportional to horizontal shoulder velocity. The subject will use a quick jerk of the shoulder to switch from hand to elbow control. 2) Positional control. The vertical joystick axis will be proportional to elbow position and the horizontal axis to hand position. The prosthesis will lock if the shoulder is motionless for 1 second, and
unlock if shoulder excursion passes the locked position. This is similar to the strategy used in the Utah Artificial Arm. 3) Impedance control. Joint stiffness will be proportional to the sum of signals from the two joystick axes. The velocity of the joint will be defined as in velocity control. 4) On-Off control. The user either moves the elbow or hand at full speed or keeps them stationary. No intermediate speeds (proportionality) are allowed.

The entire assessment procedure will be repeated using an EMG command source. The vertical joystick axis will be replaced by biceps EMG and the horizontal axis will be replaced by triceps EMG.

Results—This project is currently in the development phase and no results can be reported at the present time.

[15] Improved Actuation of Body-Powered Prostheses

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Approximately 90% of all upper-limb prosthesis-wearers still wear body-powered systems. The purpose of this project is to develop improvements to these systems ranging from new designs for voluntary-closing prehensors to more efficient cable systems.

Progress—Quantitative Evaluation of Body-Powered Prostheses. The goal of this phase is to develop methods to measure the force and excursion used in operating prostheses which can be used to determine the operating characteristics including range of force, excursion and mechanical energy required. A buckle transducer that can easily be slipped into any harness without modification was designed and tested to measure harness force. To measure excursion, 1 mm diameter mercury-filled Silastic strain elements were used. The output from both devices was analog voltage which can be read into a digital computer.

Alternative Cable Material. An ultra-high molecular weight polyethylene, Spectra, was evaluated as an alternative to stainless steel cable for actuating prostheses. Various tests including tensile, fatigue and friction, comparing steel and Spectra indicate that the latter would be an acceptable alternative.

Custom end fittings were designed which are compatible with conventional prosthetic devices. They utilize an internal taper which captures a simple knot tied in the Spectra cable. Clinical tests of Spectra systems at 16 clinics throughout the U.S. have been completed. Spectra compared favorably with conventional methodology.

New fittings have been designed which are easier to adjust for cable length than the tapered fittings. Preliminary fatigue and tensile tests indicated that these fittings offer adequate performance; production will begin soon.

Holding Assist. Voluntary-closing prehensors offer advantages over the more prevalent voluntary-opening devices, but suffer in occasional situations from requiring active cable tension to keep them closed. A holding assist is a mechanism which can keep the gripper closed, but still allow the prehensor to function normally. A prototype device based on the concept of an overrunning roller clutch was designed and tested. It was designed to maintain grip force as long as a small tension was maintained in the cable. The transition from the locked to open states was rough and unpredictable. Therefore, it was redesigned to function in an alternating mode so that it would remain locked without the need to apply cable tension.

Redesign and testing is continuing, including the preliminary investigation of using hydraulic mechanisms to provide the desired locking.

Synergetic Prehensor. All mechanical prehensors must obey the fundamental laws of mechanics, so that there is a trade-off between cable excursion required and grip force generated. The act of gripping, however, requires minimal mechanical energy in most cases. The goal of the synergetic prehensor is a device which can develop large grip force with minimal cable force and excursion requirements. This is accomplished with two moving fingers. The sizing finger is designed to adjust the prehensor aperture as desired. Once an object is encountered, the gripping finger applies a large gripping force with a high mechanical advantage linkage. Many mechanisms for locking the sizing finger and powering the gripping finger have been explored.

Results/Implications—A prototype prehensor has been built and is currently undergoing laboratory testing and refinement.
In the course of fatigue testing of cable systems, it became apparent that the lift tab of a conventional dual-control above-elbow prosthesis was a key failure point due to the sharp bend the cable undergoes at that point. A simple lift pulley was designed and tested which eliminates the sharp bend. Instead, the cable always passes tangent to the pulley. The system becomes more efficient and exhibits significantly increased fatigue life for both steel and Spectra cables. The device is being evaluated for commercial production.

Recent Publications Resulting from This Research
Spectron 12 Cable for Upper-Limb Prostheses. Carlson LE, Radocy B, J Prosthet Orthot (accepted for publication).


Dudley S. Childress, PhD; Craig W. Heckathorne; Edward C. Grahn; John S. Stryisk; Michael D. Brncick, CPO; Harold J. Krick, CP; Ilyas Khan; Erick Knox; Michael Redding; Pam Toth
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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The title represents a set of projects within a component of the NIDRR-funded Rehabilitation Engineering Center in Prosthetics and Orthotics. The projects are part of the effort to develop methods of characterizing upper- and lower-limb prosthetic and orthotic components and devices and to gain understanding of the relationship between design characteristics and functional performance. The upper-extremity prosthetics projects are divided under two areas of investigation: 1) increasing the security of grasp with a prosthetic prehensor; and, 2) improving approach trajectories and alignment of prehension devices.

Within the first area, two lines of work are being pursued. One is to characterize the types of materials currently used to cover prehension surfaces and identify those characteristics which contribute most effectively to prevention of slip. The second line of work is the development of a slip transducer to be used in an automatic gripping system adapted for commercial electrically-powered prehensors. This report will focus on these two lines of work.

Progress/Preliminary Findings—Characterization of prehensor surface materials. The first effort in this area has focused on a study of the frictional properties of elastomer surface materials currently used in commercial prosthetic prehensors. The study included neoprene (used to line Hosmer Dorrance split hooks), “rubber gripping pads” (used with the Otto Bock Greifer), polyvinyl chloride (PVC) glove material (Otto Bock), and silicone glove material (Centri). The primary testing apparatus allowed for direct measurement of the normal force applied to the sample, the frictional force, and the shear rate.

Preliminary analysis of the data indicates that the coefficient of friction (defined classically as the ratio of the frictional force to the normal force) decreases nonlinearly with increasing normal force. This finding is in agreement with published data on other soft materials with elastomeric properties.

Backing materials of various hardness were studied in conjunction with PVC glove material and included aluminum (high hardness), PVC samples from an Otto Bock System Inner Hand (medium), and Aliplast (low). Data from these experiments indicate that the choice of material over which the surface material is applied (the backing material) can significantly affect the frictional property of the assembly.

Results from experiments varying the shear rate and the surface area of contact are presently being analyzed.

Slip detection for automatic gripping. Progress during the past year has concentrated on refinement of the slip transducer and implementation of the slip detection and automatic grasping system with a commercially available electric-powered prehensor. The slip transducer is based on a piezoelectric polymer polyvinylidene fluoride (PVDF). The transducer’s common mode rejection (to extraneous mechanical vibrations) was significantly improved by producing two interdigitated transducers within the same polymer layer.

Realization of the system in operation with an electric prehensor required further development to eliminate sources of electrical and mechanical noise arising from attachment of the transducer to a motorized component.
This was achieved by a combination of electrical and mechanical shielding, and electronic processing of the signals coming from the composite slip transducer.

The system, in prototype form, has been demonstrated with the NUVA Synergetic Prehensor. This electric-powered prehensor (developed with funding from the Department of Veteran Affairs Rehabilitation Research and Development Service and commercially available through Hosmer Dorrance Corporation) responds immediately to a drive signal (as would be generated by the slip detector), and develops force at a sufficient rate to stop a slip event. An earlier attempt to utilize the Otto Bock Greifer was unsuccessful because this prehensor has a time delay before the force begins to increase in response to a drive signal.

**Recent Publications Resulting from This Research**


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**[17] Control Strategies for Artificial Limbs**

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**Sponsor:** Natural Sciences and Engineering Research Council of Canada; Liberty Mutual Research Center

**Purpose**—Our purpose is to develop a system for comparative evaluation of alternative control strategies for multifunction prostheses.

**Progress/Methodology**—Several elbow-hand control strategies are utilized by commercial myoelectric arm prostheses. More are proposed in prosthetics literature. In order to facilitate comparative evaluation and selection of the most suitable one, a computer-controlled model is being developed.

Myoelectric signals are fed into the computer via the analog-to-digital converter channels. One of several software-implemented control strategies is used to process the signals. Two digital-to-analog converter channels link the computer with a commercial elbow mechanism and an electric hand, thus allowing for a realistic visual feedback to the subject. The arm assembly is mounted against a semicircular board on which a random sequence of target positions is displayed. Throughout the duration of the arm movement, its position information is fed back into the computer, compared with the generated target, and stored. The positioning errors are collected in file for further analysis.

**Results/Future Plans**—The hardware for arm control and target decoding has been prototyped. The software interface to the arm and to the subject has been developed and tested. Further work will involve the building of the hardware control block in its final form, software coding of the strategies, and testing of the system with the subjects.

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**[18] VLSI Telemetry Implant for Myoelectric Control**

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**Sponsor:** Natural Sciences and Engineering Research Council of Canada

**Purpose**—The objective of this study is to design and develop a surgically implantable very large scale integrated (VLSI) telemetry system for the acquisition of site-specific myoelectric signals.

**Progress/Methodology**—Work has progressed in two distinct areas: differential amplifier design, and the power induction scheme. The current approach to amplifier design is to investigate the use of current feedback using active current mirrors to implement a differential amplifier.

Work has continued in the power induction field to improve power coupling efficiency. The effects of body tissue attenuation have been briefly studied. However, no attempt was made to model the inhomogeneity of the arm, in particular the effects of the bone.
Future Plans—Direction for further work in this area has been identified as implementing a high-efficiency power amplifier/oscillator for driving the induction system. To this extent, the Class E configuration looks very promising, with quoted efficiencies of the order of 90%.

B. Upper Limb

2. Above-Elbow

[19] Implementation of Extended Physiological Proprioception for Prosthesis Control

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Sponsor: VA Rehabilitation Research and Development Service (VA Contract #U55P-2069)

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

Progress—A new design for the transducer has been designed for a Boston Arm. Located on the lateral side of the elbow, the transducer fits within a 1 cm thick by 5 cm diameter housing. A small control cable passes through a miniature Bowden housing to transmit the control force to the transducer. A force-sensitive resistor (FSR) inside the housing senses cable tension and converts it to a DC electrical signal. Application of tension to the control cable causes the elbow to flex, while relaxation of tension drives the elbow in extension.

Results—Laboratory testing has been completed with the new transducer. This included random tracking and blind positioning, in which the subject flexes the elbow repeatedly to a predetermined location without visual cues. Results for the Boston Arm with EPP were comparable to the amputee’s body-powered prosthesis and to his normal limb.

Future Plans—The system will be sent to Liberty Mutual Insurance in Boston, who generously loaned us the Boston Arm, for evaluation as an addition to their commercial product line.


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Sponsor: VA Rehabilitation Research and Development Service (Project #A306-2DA)

Purpose—Based on experiences with prostheses for persons with high-level amputations, this laboratory believes that body-powered or manually-positioned positive-locking components, with their comparative mechanical simplicity, general ruggedness, and lower cost, have not been fully exploited. Mechanical arm prostheses can be configured for above-elbow and shoulder disarticulation fittings in which the body-actuated elbow/prehensor control cable can also be used to position positive-locking wrist components (for rotation and flexion). This configuration has many advantages. Perhaps most significant among these is that the cable control utilizes the person’s otherwise intact musculoskeletal and sensory systems. Consequently,
there is close coupling between the user and the prosthesis, presumably reducing the mental effort required in positioning the prosthesis. Once positioned, the joints are locked in place through some mechanical control.

We believe that the dependency on mechanical linkages to operate the locking mechanisms in these devices limits their effectiveness for the user and complicates the prosthetic fitting. To provide more efficient and versatile control of these components, a simple, modular electromechanical lock actuator is being developed which can be used in conjunction with existing cable-operated elbows and positive-locking wrist components. The principal advantage of the lock actuator is the replacement of the high forces needed to operate the mechanical controls used now with the considerably lower forces needed to operate an electrical switch controlling a motorized actuator. A second advantage is greater facility in placement and configuration of the switch control over that possible with a cable or lever mechanically linked to the locking pin.

**Progress/Preliminary Results** — *Modular electromechanical lock actuator.* A trial fitting of a prototype electromechanical actuator adapted to the locking mechanism of a USMC cable-actuated elbow has been carried out in conjunction with the Orthotic/Prosthetic Clinical Service Department of the Rehabilitation Institute of Chicago. The elbow was part of a preparatory body-powered shoulder disarticulation prosthesis used by a person with quadrimembral amputations over a period of 3 1/2 months. The controller for the lock was operated by a momentary push switch mounted to the socket and actuated by the chin. Switch closure occurred with approximately 4.5 N (1.0 lb-force). The mechanical chin-operated lock actuator generally used (the Sierra Nudge Control) would require approximately 36 N (8 lb-force) to cycle the lock.

Reliability problems with the electronic controller and with the actuator itself have been corrected by relatively minor design changes, and further field testing is planned.

As a spin-off of this project, we have adapted the electronic controller for use in sequential control of a switch-actuated Boston Elbow and switch-actuated electric prehensor. The arrangement enables one control action to operate either the elbow or the prehensor and a second (generally less capable) control action to cycle the control. The Orthotic/Prosthetic Clinical Service Department has fitted two prosthetic systems using this control arrangement.

**Positive-locking shoulder.** Toward the design of a locking shoulder joint appropriate to a shoulder disarticulation amputation, we are using a prototype computer-based prosthesis design system to investigate the hypothetical result of locking the shoulder at various flexion angles. The primary effects we are studying are changes in the work envelope in which the prehensor of the prosthesis can be positioned, and changes in the body contact map (the area on the body which can be touched with the prehensor). Our purpose is to determine if a shoulder joint having a small number of locking positions (possibly only two or three), could provide adequate functional advantage in comparison to a joint with a greater number of discrete positions or a joint having infinite locking positions. A joint having a small number of locking positions may be simpler mechanically, which in turn may permit a smaller, lighter design.

**Recent Publications Resulting from This Research**


**[21] Development of Advanced Body-Powered Prosthetic Arms**

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Sponsor: VA Rehabilitation Research and Development Service (Project #A421-DA)

**Purpose**—The primary objective of this work is to design an advanced, body-powered artificial arm. The design criteria include: an adjustable elbow cable excursion to simplify fitting; a cable recovery system which allows independent elbow and terminal device control each with full cable actuation; a lightweight and strong structure...
with a front hinge for high excursion capabilities; and, internal cabling using polymer cable materials for better cosmetics.

Methodology/Progress—Packaged in the humeral section of the arm is the actuation mechanism which consists of the state changer and elbow lock. The state changer sequentially changes the control of the actuation cable from the elbow to the terminal device when the elbow unlock/lock is changed. A prototype of the actuation mechanism has been built and has undergone evaluation. Modifications and redesign are currently being done to improve the manufacturability of the arm, and the adjustability of the arm to the amputee. The terminal device cable routing is such that it can be run inside the forearm to attach to a center pull hand or be run outside the forearm to attach to a standard hook-type terminal device.

The design of the structure involves the material selection and manufacturing techniques. We have focused on injection molding and resin transfer molding (RTM). Injection molding is estimated to be half the cost of RTM, but also less strong. We have designed and injection-molded a forearm structure. Strength tests will be performed to see if the structure meets our criteria. If it is determined that the injection-molded structure cannot meet the criteria, we will then pursue resin transfer molding. The forearm is a one-piece structure for strength and good cosmetics. The distal end of the forearm is constant diameter so it can be cut to the desired length for the amputee and still enable the wrist unit to be easily attached. The forearm length is adjustable from 5 inches to 12 inches.

Preliminary Results—We have investigated polyethylene (Spectra 1000) fiber cables for use as the control cables for the arm and terminal device. Of interest is the wear and fatigue of the cables when run around pulleys, through cable housings, and rubbing on dry surfaces. We have completed the wear tests.

One of the main difficulties with the use of polyethylene cables is the problem of attachment to terminations. Simple knots do not hold, and glue will not bond to polyethylene, so it is difficult to make a simple, small, neat termination. We have designed a termination system which can attach the cables to standard prosthetic devices. The cables and termination systems are undergoing tests on amputees. The steel cables of their prostheses are replaced without cable systems.


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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—Experience has shown that users of electric-powered multi-joint prostheses using “velocity-control” operation, such as with switch or myoelectric controllers, give considerable attention to the control of the prosthetic components, primarily through visual monitoring of the component’s response to the controlling action. Such systems having two or more powered components are generally arranged with the components operated sequentially so that the user need attend to only one component at a time. Efforts to provide coordinated control through multiple velocity-control sites have been, for the most part, clinically unsuccessful.

On the other hand, users of body-powered cable-actuated components generally appear to have better positioning control of their components and, in hybrid arrangements, are able to operate the body-powered components in a coordinated manner with velocity-controlled electric-powered components. The linkage of the body movement to the prosthetic component through the harness and control cable gives the user direct control over the position, velocity, and acceleration of the component and perception of that movement through the proprioception of the controlling physiological joints. D.C. Simpson (Edinburgh, Scotland) demonstrated empirically that linking body movements to externally-powered (pneumatic) components in a position-servo arrangement enabled children to control four degrees-of-freedom simultaneously in such coordinated activities as feeding. We have demonstrated quantitatively, through two-degree-of-freedom pursuit tracking experiments, the superior performance of cable-linked force-actuated position-servo control over velocity control.
Our recent goal has been the design and implementation of cable-actuated position controllers to improve the control of multi-joint electric-powered prostheses.

**Progress**—We have made progress in two areas. First, we have begun implementing electronic cable-actuated position controllers, or extended physiological proprioception (EPP) controllers, in clinical fittings. Our first fitting, in conjunction with the Orthotic/Prosthetic Clinical Service of the Rehabilitation Institute of Chicago, was of a person with a unilateral above-elbow amputation. The residual limb was too short to provide adequate excursion and force for operation of a body-powered elbow in conjunction with a myoelectrically-controlled hand-like prehensor. The body-powered elbow was replaced with a NYU-Hosmer electric elbow operated by one of our controllers.

With this controller, the electric elbow is actuated in the same way that the body-powered elbow would have been actuated (i.e., a cable and control strap attached between the prosthetic forearm and the suspension harness is pulled by glenohumeral flexion). However, the power to flex the elbow and lift the forearm is not provided by the body movement, but is provided by the elbow’s battery pack. The body movement is used only to direct the movement of the elbow with the cable linkage, insuring that the body’s joints and the prosthetic elbow move in concert during flexion, producing a one-to-one correspondence between the position of the shoulder joint and the position of the prosthetic elbow. Thus, the proprioception of the shoulder joint can inform the user of the action of the prosthesis. This prosthesis has been in use since mid-April 1990. We are presently involved in two preparatory shoulder disarticulation fittings incorporating the electronic EPP controller for the elbow.

The drive signal for the electric elbow is derived from tension in the control cable. The force transducer now used is based on a force-sensitive resistor (FSR). Our second area of progress has been in the development of an alternative transducer based on strain gauges. The relatively high power consumption of a strain-gauge bridge has been overcome with the development of a micropower sampling circuit which pulses the bridge. The sampling circuit and bridge together have an operating current of less than 50 μA. In comparison to the FSR-based transducer, the strain gauge transducer has a linear response to loading and considerably less day-to-day variance in output signal for a given load. A comparative study of user performance with the two types of transducers is planned.

**Recent Publications Resulting from This Research**


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**[23]** **Quantification of Tool Use by Amputees**

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**Sponsor:** National Institute on Disability and Rehabilitation Research; National Science Foundation; National Institutes of Health; Whitaker Foundation; Fairchild Foundation

**Purpose**—The goal of this project is to quantify the motor performance of upper-extremity amputees and identify those features of an amputation prosthesis which enable effective functional behavior such as the use of hand tools.

**Methodology**—A computer-controlled prosthesis emulator has been developed. This externally-powered prosthesis can be worn by an above-elbow amputee and operated through any of the usual command channels (e.g., switch control, myoelectric activity, cable pull, etc.). It can be
programmed to mimic the behavior of any prosthesis—whether an existing device or a proposed new design. It is fully instrumented to provide automatic measurements of all relevant variables (e.g., motions, forces, etc.).

Observations of intact and amputee subjects performing functional tasks (including tool use) showed that the upper extremity must frequently operate in the presence of a kinematic constraint—simple examples are opening a drawer, or sliding the hand along a tabletop. In general, these tasks cannot be performed without coordinated action of both the natural and artificial segments; therefore the ability to coordinate natural and artificial limb segments is of paramount importance. To assess this ability quantitatively, a simple but surprisingly informative test was devised: turning a crank in a vertical plane.

**Progress**—To provide a clinically meaningful interpretation of our crank-turning task, we performed a series of experiments to measure amputee subjects' performance on a selection of tasks representing activities of daily living (ADL), and compared the results with their performance on the crank-turning task. The ADL tasks were selected from a battery of common test tasks and were as follows: 1) donning socks (a self-care activity); 2) simulated eating (cutting play-dough with ordinary eating utensils); and, 3) rolling play-dough with an ordinary kitchen rolling pin.

One of the most important aspects of powered prostheses is the way in which the devices are controlled. We believe that to achieve satisfactory coordination of natural and artificial limb segments, it is necessary that the artificial limb respond to the amputee's muscles in much the same way that the natural limb does. A controller which mimics the natural limb's adaptable compliant behavior (technically: its *mechanical impedance*) has been developed.

To test the effectiveness of a “natural controller,” measurements were made of the performance of unilateral amputees using the prosthesis emulator, programmed to respond to the amputee in two different ways: 1) the emulator was programmed to mimic the behavior of the NYU elbow. Myoelectric signals from elbow flexor and extensor muscles were used to command the speed of movement of the elbow; and, 2) using the same myoelectric signals, the emulator was programmed to mimic the compliant behavior of the natural elbow. In particular, when the amputee co-activated the elbow flexors and extensors simultaneously, the elbow stiffened (as does the natural arm).

In the past year, we have worked to develop prior work on myoelectric signal processing into a usable product. The major hurdles we have overcome are related to the calibration of the processor. Accurate calibration is essential if a reliable estimate of muscle action is to be obtained. It is especially important to properly account for the possible co-contraction of antagonist muscle groups and the modulation of muscle force by muscle length (or joint angle). Our earlier work showed that a net joint torque *in the wrong direction* will be predicted from measured myoelectric activity, if antagonist activity and the compliant behavior of muscle is not accounted for. We believe that this has had a profound impact on the effectiveness of myoelectric activity (EMG), both as a clinical measurement and as a control signal for externally-powered prostheses.

**Recent Publications Resulting from This Research**

[24] Elbow Disarticulation Prosthesis

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Sponsor: War Amputees of Canada; E.N. Biden

Purpose—Elbow disarticulation amputees are difficult to fit because their stumps are the same length as their sound upper arm, making it difficult to attach a prosthetic elbow at the level of the normal joint. Thus, our aim is to develop and evaluate a prosthetic elbow for elbow disarticulation amputees which will allow for a naturally proportioned, functional, and cost-effective artificial arm.

Progress—Our system uses a multilink mechanism to overcome this problem. A prototype elbow has been built, fitted to a subject, and undergone a brief home trial. The elbow was fitted with support from the War Amps CHAMPS program. Funding is being sought to further this work.

B. Upper Limb

3. Below-Elbow

[25] Powered Prosthetic Fingers

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Sponsor: VA Rehabilitation Research and Development Service (Project #A306-2DA)

Purpose—The primary purpose of this project is to develop externally powered fingers (including thumb) that can be combined to create a functional, yet cosmetic, partial-hand prosthesis that will preserve the independent motion of the wrist. The secondary function is to see if powered fingers (or thumb) can be used with persons who have fingers remaining, and also to examine whether they can be of use in devices for wrist and below-elbow amputations. The fingers are to be the same size as those of an average adult. They are to have one articulation (metacarpophalangeal joint).

Progress/Methodology—As this project has evolved, the emphasis has shifted from the concept of each finger as an individual unit into the idea of a total partial-hand prosthesis. A design has been finalized and a prototype partial-hand device has been fabricated.

The feasibility of individually powered prosthetic fingers arose from the advent of motors only 10 mm in diameter that are small enough to be placed within a prosthetic finger. Initial tests revealed that the motor was capable of meeting either the speed or the force criterion, but was incapable of meeting both simultaneously. The principle of synergy was adopted to boost overall performance. In a synergetic system there are at least two motors, one delivering high speed at low force, and the other providing high force at low speed.

The resulting design uses three motors, all 10 mm in diameter with 256:1 gearheads, one each in the thumb, index finger, and middle finger. In order to achieve the maximum pinch force, the thumb motor provides the speed, and the index and middle fingers provide the force.

The drive system for the fingers uses the gearmotor mentioned previously along with a drive screw. The pinch force per finger is 8.5 lbf using a standard number 3-56 screw thread which gives the hand a total gripping force of 17 lbf.

The drive system for the thumb uses the same gearmotor in combination with a 3:1 bevel gear set attached to a reverse locking mechanism. This provides an angular velocity for the thumb in excess of 2 radians per second and an excursion of 3 inches at the tip.

The thumb pivot is inclined at an angle of 45 degrees to the palmar surface. This maintains a cosmetic
geometry for the thumb motion while providing a usable width of opening for the hand. The dynamic cosmesis and width of opening considerations for an inclined thumb are dictated by the synergetic design. This requires the thumb to provide all the width of opening while maintaining a dynamically cosmetic geometry.

The power source for the hand is a 9-volt transistor battery; the preferred suspension of the hand is a suction socket. Myoelectric or switch control can be used.

A redesign of the system is under way; a brief laboratory evaluation of the first prototype suggested several changes to improve performance and reduce size.

Results/Future Plans—The first prototype system that has been built exceeds the dynamic performance requirements of the original specification. However, its size and weight preclude clinical applications. A redesign of some of the components is underway to produce a smaller, lighter, more efficient version of this prototype for clinical evaluation.

[26] A Myoelectrically-Controlled, Pneumatically-Powered Hand Prosthesis for Children

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Sponsor: Delft University of Technology

Purpose—The objective of this project is to develop a myoelectrically-controlled, externally-powered hand prosthesis for children age 2 to 6. This prosthesis should be light in weight, fast, reliable and small enough to fit even children with a long forearm stump. Thus, the disadvantages of the presently available child-size myoelectrically-controlled, electrically-powered prostheses are eliminated.

Methodology—Theoretically, in externally-powered prostheses, pneumatic power is the better choice in terms of weight, speed, and reliability. To reduce gas consumption, the operating cycle of the hand was split into two parts: a prehension phase, and a pinching phase. In the prehension phase, the hand can be opened and closed. As soon as the thumb touches an object, the mechanism is automatically switched to the pinching phase. In the pinching phase, a force is exerted between fingers and thumb. To resist the reaction forces, a locking mechanism is provided.

Progress—A pneumatically-powered hand prosthesis was designed, built, and tested. It validated the concept of pneumatic power. A pneumatically-powered hand prosthesis can weigh as little as 100 grams, including the energy storage unit. Gas consumption is low; only 12 mg gas per cycle. The speed of operation is approximately 1 second per cycle.

Future Plans—A prototype for clinical evaluation is under construction. In order to obtain clinical results as soon as possible, several commercially available components are incorporated into the design, even though they are relatively heavy and bulky. Eventually, they will be replaced by components of our own design.

Recent Publications Resulting from This Research

[27] Below-Elbow Prosthetic System

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Sponsor: Nederlands Comité Kinderpostzegels; Innovatief Onderzoeksprogramma-Hulpmiddelen Gehandicapten; Stichting Nederlands Revalidatiefonds; Stichting Bingo Nederland; Lion’s Club, Utrecht

Purpose—The object of this project is to develop a body-powered hand prosthesis for children with a unilateral below-elbow defect. This prosthesis should combine appearance and comfort with ease of operation.
**Methodology**—In order to avoid the disadvantages of both the body-powered, harness-controlled, hand prostheses (i.e., harness, low-pinching force), and the myoelectric hand (i.e., weight, speed, reliability, outward appearance), elbow control was adopted: extension of the elbow opens the hand against a spring; flexing the elbow permits the spring to close the hand. As the triceps power is only one-third of that of the shoulder muscles, a special hand mechanism will be needed to combine elbow control and a high-pinching force. In this mechanism, the operating cycle is split into two parts: the prehension phase, and the pinching phase. In the prehension phase, the hand can be opened and closed. As soon as the thumb touches an object the mechanism is automatically switched to the pinching phase. In the pinching phase, a force is exerted between fingers and thumb. A locking mechanism is provided to resist the reaction forces.

**Progress**—Several technical prototypes and clinical trials have resulted in an elbow-controlled hand prosthesis. It is available in two sizes: 1) type 08-10 for 2- to 6-year-olds, with system weight of 110 g, pinching force 16-20 N, and energy demand per cycle of 0.25 Nm; and, 2) type 08-32 for 5- to 12-year-olds with system weight of 150 g, pinching force 20-25 N, and energy demand per cycle of 0.55 Nm. Presently, four children are using the 08-10: one child is using the 08-32.

**Future Plans**—A redesign of the 08-10 is intended to reduce system complexity and weight. Also, we would like to increase the number of children using the elbow-controlled hand prosthesis.

**Recent Publications Resulting from This Research**


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**Evaluation of Arm Prostheses for Children with Forearm Defect by Observations in Daily Life**

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**Sponsor:** Nederlands Comite Kinderpostzegels; Nationaal Revalidatiefonds; Stichting Phoenix; IOP-HG; Lion’s Club, Utrecht

**Purpose**—In support of the activities of the Design Group for Prostheses and Orthoses of the Delft University of Technology, a field study is being conducted. The goals are to: 1) gain insight into the function of a prosthesis for a child and his parents; 2) identify the benefits and burdens of available prosthesis types; 3) formulate design specifications; and, 4) conduct comparative studies with newly-designed prototypes.

**Methodology**—A child with a forearm defect is observed during a normal school day. All activities executed during that day and the way they are performed, with or without the prosthesis, are registered according to a predefined classification system. Some simple measurements are executed, and a number of items are discussed with the parents and child. The participating children come from two cooperating rehabilitation centers in The Netherlands. Both centers have a specialized team for the treatment of persons with missing or paralyzed upper extremities—De Hoogstraat at Utrecht, and the Sint Maartenskliniek at Nijmegen.

**Progress**—Approximately 40 visits have been paid to 24 children. The prosthesis types observed were myoelectric hands, body-powered hands and hooks, and cosmetic hands. On the average, about 100 different, or differently executed actions were observed during a day, which have been compiled in a database. Prostheses with a prehension function were used in about 17 actions. The investigation included a number of newly-designed experimental prototypes. In a number of cases, it was possible to compare two different types of prostheses worn by the same child.

**Results**—Two prehension control principles for body-powered prostheses were compared (shoulder control versus elbow control), as well as voluntary opening versus voluntary closing of the prosthesis. The idea of elbow control was based on the wish to omit the shoulder harness. A voluntary closing device was chosen because it seemed a more natural operating principle.

The main results for the case of elbow control were that the prehension function was used less than in the case of shoulder control. This can be explained by the
smaller workspace for the prehension function with the elbow-controlled hand. However, the children preferred the elbow-controlled hand because of its comfort and its cosmetic properties.

A comparison between the voluntary opening and the voluntary closing prosthesis showed no significant differences in the use of the prehension function. Some children preferred one type, some the other. However, some improvement in the present prototype might influence this choice.

Future Plans—The project is in its final stage. Present activities are focused on publication of the results.

Recent Publications Resulting from This Research


[29] Development of a Child-Size Powered Wrist

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Sponsor: Variety Club of Ontario, Tent 28

Purpose—Our purpose was to develop a child-size powered wrist unit to: 1) fit Variety Ability Systems (VASI) wrist lamination rings; 2) be compatible with VASI hand-body mounting arrangements; and, 3) allow the current wire harness to be routed through the mechanism to minimize the overall length.

Progress/Methodology—One prototype wrist unit has been created. The overall diameter of the wrist unit is sized to allow it to be fastened coaxially inside the current lamination rings using three equally-spaced screws. The overall length is 2 1/16 inches, making it less than 1 inch longer than our present large wrist unit.

The prototype utilizes the same motor and some of the gearing currently used on the VASI 0-3 hand. Two additional planetary gear sets are added to achieve the required output speed. To conserve space, no anti-rollback mechanisms are used. It is expected that the friction in the system due to the high ratio of the gear train will offer the required locking.

The output shaft is coaxial with the two planetary stages and is supported by two ball bearings. The end of the output shaft is configured to fit all current VASI hand-bodies, and a mechanical stop is incorporated to limit the rotation of the wrist to 90. The wire harness enters the wrist unit at the center of the hand-body, and exits at the distal side of the motor housing. Engineering tests and clinical trials will be conducted to investigate the performance of the prototype.
C. Lower Limb

1. General

[30] Development of a Model for Modified Transfusion Enhancement of Grafts:
A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A980-PA); Prosthetic Research Study; Pacific Northwest Research Foundation

Purpose—This project is part of an overall goal to develop a comprehensive research program on tissue and limb allograft transplantation. This pilot project was initiated to develop and adapt the dog model for assessing the ability of modified blood transfusions to induce immunologic unresponsiveness to subsequent transplantation of bone marrow from the donor of the blood product. This marrow transplantation model had previously been demonstrated to be a very sensitive model for detection of sensitization/tolerance induction. The rationale for these studies is that pretransplant transfusions in humans and rodents facilitate/enhance kidney transplants. In experimental models, modification of the white cells contained in the transfusion product appears to preferentially induce tolerance rather than sensitization when used for transfusion. Thus, we proposed to use the canine bone marrow transplant model to examine the effects of modified blood product transfusions on induction of tolerance in this preclinical model. Our initial hypothesis was that blood transfusion products modified to eliminate Class II lymphocyte stimulating determinants on the leukocytes contained in the transfusion product would result in lack of sensitization and possibly the induction of tolerance in this model.

Progress—We have established collaboration with the division of canine shared resources at the Fred Hutchinson Cancer Research Center and have initiated and completed preliminary experiments in this transplant model which demonstrate that modification of blood products alters their ability to sensitize/tolerize to foreign graft antigens.

Methodology—Transfusions of 50 ml of whole blood, or the platelet and leukocyte contents of such whole blood, are given on day-24, -17, and -10. On day 0, bone marrow is transplanted from the donor of the blood product into the recipient dog. The recipient animal is conditioned on day 0 for receiving the bone marrow transplant by 920 cGy gamma irradiation from a cobalt source. Animals are maintained in intensive care for approximately 5 to 7 days after transplant, and provided leukocyte support therapy and antibiotics. The engraftment is monitored by white blood cell and platelet counts and occurs in successful engraftment by days 10 to 14. After achievement of stable engraftment, the animals are either euthanized or transferred to other studies. Engraftment is also documented by bone marrow biopsy and autopsy when appropriate. Blood products are being modified by UV-B irradiation, and heat treatment at 45 degrees C for 45 minutes, gamma irradiation, or a combination of these.

Results/Implications—In the major transplant antigen-compatible (HLA-identical) recipient donor combination, the model tests for sensitization and subsequent bone marrow rejection across minor transplantation antigens. We have found that the modified blood transfusion products almost completely prevent rejection. Historical data show that three transfusions from the bone marrow bone donor to the recipient in this model will sensitizze and result in 27 out of 27 rejections. Four out of four dogs given three transfusions of UV-B irradiated platelet preparations successfully engrafted. Eight of ten dogs given three transfusions of whole blood which had been heated to 45 degrees C for 45 minutes followed by low dose (2,000 cGy) gamma irradiation also successfully engrafted. Unexpectedly, a control group of 10 dogs given three whole blood transfusions treated only with gamma irradiation resulted in nine engraftments out of 10 animals entered. This finding has not previously been reported in the literature. It suggests that low dose gamma
radiation interferes with processing and presentation of minor histocompatibility antigens on the transfusion product. The implications of this finding are that blood products might be low dose gamma radiated for use in humans in order to prevent sensitization to minor histocompatibility antigens which results in rejection of donor bone marrow, solid organs, and possibly composite tissue allografts.

**Future Plans**—The pilot project is completed and now this model has been incorporated into research project #A618-RA entitled, “Prevention of Immunologic Rejection of Tissue and Limb Allografts.”

**Recent Publications Resulting from This Research**

Treatment of Marrow Donor Blood Products with Gamma-Irradiation Prevents Transfusion-Induced Sensitization to DLA Identical Marrow Grafts. Storb R et al., in Transplantation Proceedings (in press).

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**Sponsor:** VA Rehabilitation Research and Development Service (Project #A981-PA); Prosthetics Research Study; Pacific Northwest Research Foundation

**Purpose**—As part of the development of a comprehensive program in tissue and limb allograft research, this pilot study was initiated to develop the rat hindlimb allograft model. This model is to be used to study the effects of immune manipulation on graft outcome, and eventually in the future to study the effects of cloned growth factors on nerve growth regeneration/reinnervation. The practical goals of this pilot project were to establish a rat colony consisting of Lewis (LEW, RT-1\(^1\)), LEW × Brown Norway F\(_1\) (LBN, RT-1\(^{10\text{th}}\)) and ACI (RT-1\(^3\)). In addition to setting up the rat colony, we proposed to establish the necessary surgical techniques to perform the whole limb transplants. This model was to be established to be initially used to study the effect of new immunosuppressants and modified blood transfusions on the induction of tolerance to composite tissue allografts in the rat.

**Progress**—We have established the necessary rat colony and a microsurgical laboratory. Dr. Kuroki, a fully trained microvascular surgeon, has established these microsurgical techniques and has additionally developed a technique of skin allografting. In addition, he has refined the mixed lymphocyte culture assay utilizing rat lymph node cells in order to monitor *in vitro* the immunologic outcome of the immunologic manipulations *in vivo.*

**Methodology**—Limb allografts are constructed using standard surgical techniques described by Hewitt, et al. Both donor and recipient limbs are amputated at mid-femur under general anesthetic. The donor femur is then joined to the recipient site with 4-0 stainless steel suture by placement through both femurs at perpendicular angles. Stay sutures are placed through a few dorsal and lateral muscle groups present in the thigh. The femoral artery and vein are anastomosed end-to-end with interrupted 10-0 monofilament nylon on a 70-micron needle. Both the sciatic and femoral nerves are repaired with four 10-0 interrupted sutures. The remaining muscle groups in the thigh are then approximated with interruptible 4-0 absorbable suture. Lastly, the skin is closed by running 3-0 absorbable sutures. Rejection of the allografted limb is evaluated by two methods: 1) limb allografts are observed daily for visual signs of rejection such as erythema, edema, eschar-necrosis; and, 2) by a temperature decline in the limb as measured daily with a needle thermistor. A 5-degree C decline is defined as rejection end point. Representative histology will also be examined where appropriate.

Two to three centimeter square full thickness skin grafts between histoincompatible strains are also used as an end point in order to produce a larger number of animals to measure rejection reactions.

**Results**—The rat colony and the microsurgical techniques have been established along with a reliable skin graft model and an *in vitro* mixed leukocyte culture assay for evaluation for immune responsiveness of animals. We
have established the mean survival time of allogenic skin grafts as an end point against which to evaluate immune modifications on graft outcome. Baseline mixed lymphocyte culture responsiveness of naive rats against allogenic lymphocytes and the conditions for performing the assays have also been defined.

**Future Plans**—The allograft model described in this pilot project has now been integrated into research program A618-RA entitled, “Prevention of Immunologic Rejection of Tissue and Limb Allografts.”

[32] Development of HLA Class I Transfectants as Suppressor Cell Inducers: A Pilot Study

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**Sponsor:** VA Rehabilitation Research and Development Service (Project #A982-PA); Prosthetics Research Study; Pacific Northwest Research Foundation

**Purpose**—As part of an overall comprehensive approach to developing a tissue and limb allograft research program, this pilot proposal was initiated to develop expertise with the technique of class I gene transfection of normal lymphoblastoid cell lines in order to make HLA-defined transfected cell lines for use in studies of immune regulation in humans in vitro. Construction of autologous lymphoblastoid cell lines from normal healthy blood that express defined class I HLA antigens provides the reagents to test whether or not different class I HLA antigens in humans are able to preferentially induce suppression of the immune response. It also enables us to determine whether or not there is variation in the population in terms of the ability of different individuals to mount suppressor cell responses to the same HLA class I antigen. The rationale for these studies is that alloantigen-specific-suppressor T-cells appear to be important in the establishment of tolerance to allografts and one of the mechanisms through which the beneficial effects of donor-specific transfusions on kidney graft survival in rodent and human models is mediated is hypothesized to be through the development of these allospecific suppressor T-cells. As yet, the exact mechanisms and the inducer and target antigens responsible for the development of these cells is not known. Developing these defined cell lines would greatly facilitate investigations of these questions.

**Progress**—We were successful in transfecting defined HLA class I genes and getting them expressed in EBV-transformed lymphoblastoid cell lines from normal individuals. We have now established a panel of cell lines, grown them up in quantity and cryopreserved them for use in assays.

**Methodology**—Previously cloned HLA-A2 and HLA-B27 were inserted into a plasmid which contains the EBV origin of replication sequence and a gene for drug resistance to hygromycin B. These vectors can then be inserted into EBV-transformed lymphoblastoid cell lines by the method of electroporation. The lymphoblastoid cells are then selected for resistance to hygromycin B by addition of that drug to the tissue culture medium. Growing cells are then cloned, grown up in hygromycin B and the expression of A2 or B27 confirmed by the use of antibodies to HLA-A2 or B27 with the appropriate fluorescein aminated second antibody conjugate using the fluorescence-activated cell sorter. When grown up in quantity, a portion of these cells are cryopreserved in liquid N2 and growing cultures are used as a source of cells to stimulate autologous peripheral blood mononuclear cells from individuals from which the cell line was derived. The prolonged (10-12 day) mixed lymphocyte culture is used to assess the development of suppressor responses.

**Results**—We have been able to successfully express both HLA-A2 and HLA-B27 in B lymphoblastoid cell lines. We have established/acquired 13 cell lines from people in the area who can be used as blood donors for further studies. Of these, eight have been successfully transfected with HLA-B27 and six with HLA-A2. Five of these cell lines are currently undergoing the transfection procedure and have not yet been fully analyzed.

**Future Plans**—Now that these transfected cell lines have been produced, these cell lines and the normal blood donors from which they were originally derived have been incorporated into research project A618-RA entitled, “Prevention of Immunologic Rejection of Tissue and Limb Allografts.”
Prevention of Immunologic Rejection of Tissue and Limb Allografts

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Sponsor: VA Rehabilitation Research and Development Service (Project #A618-RA); Prosthetics Research Study; Pacific Northwest Research Foundation

Purpose—The overall goal of this project is to develop means by which to overcome the immunologic rejection mechanism so that we might transplant highly immunogenic tissue such as skin, bone, nerve, and composite tissues such as vascularized whole joints and whole limbs. Our goal is to develop conditioning regimes that will suppress the immunologic rejection reaction without producing unacceptable morbidity to the recipient. Clinical application of tissue transplants such as nerve, bone, and vascularized whole joints will be used in situations where the disability being corrected is nonlife-threatening. Therefore, existing immunosuppressive drugs and protocols for induction of nonresponsiveness to transplants are unacceptable because of their significant morbidity/side effects which are only acceptable for reversing a life-threatening situation. The main thrust of our research is to study the effectiveness of modified immunization with transplantation antigens with or without the concurrent use of new immunosuppressant drugs in immunologic models of allograft rejection reactions in the rat, dog, and human.

Progress—As a result of pilot funding, we have now established three allograft reaction models in which to assess the effects of manipulation of the immunization procedures on tolerance induction. Experiments are now underway to test effects of manipulation of alloantigen presentation to the recipient immune system in each of these three models to clarify mechanisms by which sensitization or induction of nonresponsiveness/tolerance occurs.

Methodology—For studies in humans, we are using B-lymphoblastoid cell lines (BLCL) from normal readily available blood donors which have had HLA-A2 or HLA-B27 transfected and expressed in them. These reagents provide us with the ability to test the target antigens and the inducers of T suppressor cells generated in mixed leukocyte culture (MLC) in vitro with human lymphoid cells under conditions where the target antigen is precisely defined. In the rat model, we have three end points with which to assess the effects of immune manipulation. These are: 1) the in vitro lymph node MLC responses; 2) histoincompatible skin graft survival in vivo; and, 3) hindlimb allograft survival in the histoincompatible rats. In the dog, we have utilized the bone marrow transplant model to assess the effects of transfusion from donor animals into recipients followed by marrow grafting from the donor animal. This allows us to determine the effects of modifications of the transfusion product on graft outcome. We use either DLA-identical littermates to measure sensitization to minor histocompatibility antigens, or DLA-nonidentical dogs to examine the effects of major DLA transplantation antigen differences on graft outcome.

Results—Experiments using the HLA-A2 or B-27 transfected LCL as targets and inducers of MLC-generated T suppressor cells have been initiated, but as yet there are only preliminary results. That is, we can demonstrate that the transfected gene product is expressed on the cell surface of the LCL and that LCL act as efficient stimulators of normal donor blood mononuclear cells in MLC. In the rat model, we have found minor reductions in recipient antidonor MLC responses after one donor-specific transfusion. After three donor-specific transfusions, there appears to be enhanced cellular activity in vitro. We are still evaluating whether or not this MLC reaction will be precise enough to pick up minor alterations in immune responsiveness induced by the transfusion procedures. In addition, we have found minor prolongation of unrelated skin graft survival with donor-specific transfusion, as has been reported by others. But we have found that the transfusion given in conjunction with the new immunosuppressant, FK-506, results in significantly prolonged allogenic skin graft survivals. Naive rats have skin graft survivals in the range of 9 1/2 days; after one donor-specific transfusion, it is 12 days. If they receive FK-506 I.M. at 1 mg/kg/day for 7 days before, and 7 days after the skin graft, survival goes up to 33 days; if they receive the same schedule of FK-506 and one donor-specific transfusion 7 days prior to the graft, survival is significantly increased to greater than 48 days.
In the dog model, we have observed that UV-B treatment inactivates the blood lymphocytes contained in the platelet preparation to the point where they do not sensitize (4 out of 4 engrafted versus 0 out of 4 expected). In addition, heat treatment of the blood at 45 degrees C for 45 minutes with additional treatment with low dose (2,000 cGy) radiation allowed successful engraftment in 8 out of 10 DLA identical littermate transfusion recipients. This result also was a significant improvement over the 27 out of 27 graft failures previously observed after three untreated transfusions. Unexpectedly, a control group of 10 dogs that received blood treated only with gamma irradiation resulted in nine engraftments. This data is consistent with low dose gamma radiation abolishing minor histocompatibility antigen presentation/sensitization in this dog model.

Further studies are needed to clarify the exact mechanism of this effect which has not yet been studied because this phenomenon has never been reported. Studies are currently underway to evaluate the same treatment protocols described above in the DLA-identical dogs, but instead to use them in DLA-mismatched and unrelated dogs, where the stimulus will be the major transplantation antigen barrier.

Future Plans/Implications—The synergistic effects achieved with FK-506 (the new highly effective immuno-suppressant drug) are highly encouraging, and lead to additional study designs aimed at producing complete tolerance in this skin allograft model. The rationale is to optimize the suppressive regimes and condition for highly immunogenic skin grafts before applying them to the limb allograft model.

The finding that gamma radiation at low doses abolishes sensitization to minor histocompatibility antigens in this dog bone marrow transplant model is remarkable. This observation has not been made before. In addition, the fact that such low dose gamma radiation prevents transfusion-induced sensitization to minor histocompatibility antigens suggests that in humans, blood products should be gamma irradiated to prevent sensitization to these minor antigens. The magnitude of the effect of minor histocompatibility antigens/sensitization on solid organ and composite grafts is unknown, but would be estimated to be considerable, as skin allografts are known to strongly express these minor antigens, making it very difficult to induce tolerance to them.

Recent Publications Resulting from This Research

Treatment of Marrow Donor Blood Products with Gamma-Irradiation Prevents Transfusion-Induced Sensitization to DLA Identical Marrow Grafts. Storb R et al., in Transplantation Proceedings (in press).

[34] National Program for Automated Fabrication of Mobility Aids: Eastern Region

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Sponsor: VA Rehabilitation Research and Development Service (Project #A54-DA)

Purpose—The National Program for the Automated Fabrication of Mobility Aids (AFMA) is a research and development project being conducted at the VA Medical Center, New York, NY, in collaboration with the Prosthetics Research Study in Seattle, WA, and the Prosthetics Research Laboratory at Northwestern University in Chicago, IL. The purpose of this program was to conduct clinical developmental testing of computer-aided socket design and computer-aided manufacturing (CASD/CAM) systems for below-knee (BK) prosthetics. The software and equipment primarily being tested are those developed at: 1) the University College London (UCL) Bioengineering Centre (currently marketed by Nutem, Ltd.-ART, Inc., and by Applied Bioengineering Technology, Inc.); and, 2) the University of British Columbia—Medical Engineering Resource Unit (UBC-MERU) (currently being marketed by Shape Technologies, Inc.). Clinical tests are being performed with these systems to determine the feasibility and benefits of AFMA technology in prosthetics, to obtain quantitative data to determine the efficacy of present CASD/CAM systems, to obtain data for further CASD/CAM system development, and to provide a limited introduction of CASD/CAM technologies to practicing prosthetists and other rehabilitation and health care professionals.

Progress—Clinical testing of the UCL/Nutem CASD/CAM system continued during the present project
period. To date, test sockets and definitive prostheses have been designed, fabricated, and fitted on 42 BK amputees. Five major software and four major hardware upgrades were obtained for the UCL CASD/CAM system. These upgrades have remedied most of the problems encountered and previously reported.

Software for the UBC-MERU/Shape Technologies CASD system was obtained in February 1990 and clinical testing begun. The UBC-MERU Canfit software is being tested in conjunction with the UCL/Nutem CAM equipment. To date, clinical trials on 10 BK amputees have been conducted.

Results from the clinical trials of both the UCL/Nutem and UBC-MERU/Shape Technologies CASD/CAM systems, together with the prosthetics, biomechanical, and physiological data on the test subjects compiled during the clinical trials have been input into a computerized relational database management system and analyzed: 1) to identify those areas/components of these systems requiring design refinement; 2) to obtain quantitative data for use in further research and development of prosthetics CASD/CAM systems; and, 3) to identify categories and characteristics of patients that can be successfully fitted and those (if any) that cannot, using CASD/CAM techniques. A final report of the project results is being prepared.

In addition, preliminary tests were conducted using the Cyberware Laboratory optical digitizer for profilometric characterization of limb and stump spatial geometry and surface topography for CASD/CAM system input. Initial results are very encouraging.

Implications—The AFMA clinical trials demonstrate that CASD/CAM technologies can be effective, clinically viable tools that: 1) provide prosthetists with a means of quantitatively designing and fabricating sockets of consistently high quality; 2) enable prosthetists to expeditiously provide sockets accommodating amputee stump changes; 3) enable prosthetists to provide patients with exact duplicates, or precise, quantitatively modified variations of previous, well-fitting sockets; 4) provide prosthetists, physicians, and therapists with quantitative records and histories of the physiological, biomechanical, and prosthetics characteristics of patients; and, 5) provide a quantitative and efficacious aid for the education and training of prosthetists and other rehabilitative health care professionals.

[35] National Program for Automated Fabrication of Mobility Aids: Central Region

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Sponsor: VA Rehabilitation Research and Development Service (Project #A521-DA)

Purpose—The Prosthetics Research Laboratory of the Northwestern University/VA Lakeside Medical Center (NU/VALMC) in Chicago—in collaboration with the Prosthetics Research Study (PRS) in Seattle, and the New York University/VA Manhattan Medical Center in New York City—is involved in this cooperative clinical study of computer-aided design and computer-aided manufacturing (CAD/CAM) of sockets for below-knee prostheses. The purpose is to determine the efficacy of the present equipment and methods, and to uncover possibilities for refinement and improvement. The results should have a salutary influence on this newly emerging area of limb prosthetics.

Progress—As agreed by the participating centers, each center will fit approximately 40 amputees, for a total of 120 amputees through the computer-aided approach. We have invited several practicing prosthetists to participate in the program; prosthetic laboratories from Illinois, Wisconsin, Ohio, and Tennessee have responded positively.

Thirty-six qualified below-knee subjects from our center and from participating prosthetics laboratories have been part of our clinical study. Eight VA subjects have participated. The sockets were designed using the equipment and techniques developed at the Bioengineering Centre of the University College London (UCL). Of these subjects, 31 have accepted the CAD/CAM sockets. Ten subjects accepted the socket on the first socket fitting, 13 on the second fitting, 7 on the third fitting, and one on the fourth fitting. The fitting failed for one subject after four socket trials. One subject died during the study. Twenty-three subjects have been issued the definitive limbs and are walking on the CAD/CAM-designed prosthesis. Socket fittings for the other subjects are in progress.
Aside from the UCL System, we also have the ShapeMaker software from the Prosthetics Research Study, Seattle, WA, and the CANFIT software from Shape Technologies, Inc., Vancouver, BC. We are in the process of evaluating these software systems. In general, we find the CAD/CAM systems being tested to be serviceable and adaptable to many below-knee residual limb shapes. We also found several aspects of fitting persons with below-knee amputations by CAD/CAM techniques to be considerably easier than when using conventional prosthetic techniques.

A promising new method for direct fabrication of solid models from computer-generated data is called stereolithography. Stereolithography, as developed by 3D Systems, is a laser-based instrument that forms solid models by utilizing a computer-controlled laser beam to cure a liquid photopolymer. The photopolymer solidifies when exposed to ultraviolet (UV) light. With this system, a three-dimensional (3-D) object can be formed directly from computer-aided designed data. Our laboratory, in collaboration with the Advanced Engineering/Design Center of Baxter Healthcare Corporation, in Round Lake, IL, has formed a prototype socket using stereolithography. This was a feasibility demonstration project. It suggests that in the future, sockets may be formed directly, eliminating plaster carving and vacuum forming.

Results/Implications—We found several advantages in using the CAD/CAM system. The system provides what we term “controlled modification techniques.” Conventional prosthetic modifications make the measurement of build-ups and reductions very time-consuming. It is also difficult to return to the premodified shape. The CAD/CAM system enables the design of definitive sockets with respect to the number of plies of socks desired for fit. The software allows for the increase or decrease of size of the socket with reasonably accurate predictions of the resulting socket size. The CAD/CAM system not only makes accurately measured rectifications, it records them for future analysis. Both the socket shape and the history of socket modifications are recorded in the computer files. These records are useful for future reproduction of existing sockets, or for evaluation and analysis.

These are a few of the significant advantages we feel the CAD/CAM system provides to consumers and their prosthetists. Our experience with the system has been, in general, very positive. Further experience, coupled with continued modifications of the software, will further improve existing techniques.

[36] National Program for Automated Fabrication of Mobility Aids: Western Region

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Sponsor: VA Rehabilitation Research and Development Service (Project A504-DA)

Purpose—The purpose of this program was to assess, develop, and improve the computer-aided design and manufacturing technologies used in the fabrication of mobility aids.

Results—Use and testing of the University College of London (UCL) software has been phased out with the exception of finishing a few outreach subjects. Efforts have been focused on technology transfer to VA prosthetics clinics and the private sector.

Prosthetics Research Study (PRS) has a large body of information already collected in Automated Fabrication of Mobility Aids (AFMA) research trials. This information was gathered mostly from VA Medical Centers in the two years prior to finalizing data collection standards. As agreed at the March 1990 AFMA meeting, all previously completed questionnaire sets were recoded onto the newly adopted forms. This meant that questions that had been added since the original drafts had to be left blank. Every effort was made to fill in the new forms as completely as possible, including recalling subjects for measurement. Forms for 38 subjects have been sent to New York for inclusion in their database. Ten subjects have to complete only the final evaluation form.

Current copies of the ShapeMaker software as well as user support and training have been provided to the two VA prosthetics services which have requested it: Hines and Seattle. Hines purchased digitizing and fabrication equipment; it has been operational since May 1990. Seattle VA purchased a computer and has a digitizer on loan from PRS. Socket fabrication will be provided by PRS on a research basis.

Seattle ShapeMaker Software Development. Both the ShapeMaker software and templates have undergone
continual improvement. Additions to the software have made it compatible with the stand-alone parallel interface digitizers available commercially. PRS has refined the application of AFMA to above-knee (AK) prosthetics. Both the AK template and Seattle Limb fabrication techniques have been remarkably successful. Seven of nine AK prostheses have been completed, with two in progress. The last three AK sockets required no changes in the design to produce a definitive prosthesis.

AFMAP Software. At the request of the Chicago AFMA group, the AFMAP software developed at PRS was altered. The file format change simplifies use of the AFMAP data generated by analyzing relative tissue displacements occurring in sockets. The Chicago group has successfully used AFMAP to provide basic information required for the development of finite element models of limbs of sockets.

Documentation Report. For the cooperative AFMA study, 40 subjects were required per site. As of Fall 1990, PRS had submitted 38 subjects. Of those, 2 were rejected, 26 were finished, and 10 are still in process. These were divided by 11 in-house subjects, 6 outreach patients, and 18 veterans taken from several of the VA Medical Centers. One of the two subjects rejected was a duplicate from another site and the second was a bilateral amputee and would not fit the research criteria.

PRS has submitted the following questionnaires: 1) all the release forms; 2) 15 of the 36 measurement charts; 3) all the Subject Initial and Prosthetist Initial Questionnaires; 4) 25 of the 36 Subject Initial and Prosthetist Initial Questionnaires; and, 5) all the Prosthetist Information Questionnaires. The remaining Evaluation Questionnaires will be submitted when the subjects are completed.

In-house and Outreach Measurement Charts will be submitted when the subjects are completed.

VA Medical Center subjects were transcribed from the initial study in which VA prosthetists did not receive measurement charts and there has been some difficulty in obtaining them. This is due to the following: two of the subjects have passed away, seven of the subjects were unable to reach a facility in order to be measured, and nine of the subjects' prosthetists have not responded to requests for data.

In the three years since the study began, PRS has fitted 466 BK amputees (464 adults, 2 children), and 20 AK amputees (17 adults, 3 children).

Education. June 10-15, 1990. In collaboration with the Northwestern University Prosthetics and Education Program, private prosthetists were introduced to the ShapeMaker and AFMAP software.

June 20-28. PRS participated in the AFMA course given at the University of Texas, San Antonio.

August 7-9. PRS hosted two prosthetists from the Hines VAMC for advanced training in the use of the ShapeMaker software.

Fall 1990. PRS sponsored an AFMA course for VA personnel and others.

[37] CAD/CAM in Prosthetics: Direct Socket Carving

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Sponsor: London Department of Health

Purpose—The University College London's Computer-Aided Socket Design (UCL-CAD/CAM) system enables a patient's socket to be produced, first as a computer representation, and then as a positive model carved by a numerically-controlled machine. Thereafter, the production of a socket involves the same methods of liner production and socket forming as with conventional procedures.

The process would be considerably shortened if the socket could be carved directly. One way would be to carve the socket shape out of a thick layer of liner material fitted inside a standard container. This would also speed up subsequent fitting modifications, since only a new liner would be carved, retaining the existing socket and cosmetic cover. A feasibility study of this approach is being carried out, concentrating initially on the production of below-knee, patellar tendon bearing (PTB) sockets.

Areas requiring development are: 1) modifications to a standard carver to enable internal carving of the liner; 2) design of software to align the patient's socket and container, and to control the carving; 3) identification of a suitable material for the liner; and, 4) determination of the sizes and shapes of the standard containers.

Methodology—Carver Modifications. The carver's normal cutter, which is arranged perpendicular to the
axis of the carver, and carves the positive model from a solid block of material, was replaced by a high-speed cutter tipped with a two-bladed router bit, positioned on the axis of the carver so that the cutting head moves down inside the socket and cuts outward from the central axis. An extended shaft enables the cutter to reach to the distal end of a PTB socket about 12 inches in length.

**Software Development.** Parts of the program needed to be rewritten to align the socket to be carved with the standard container shape. Several approaches were considered, including aligning both with respect to their anterior tibial surfaces. However, the original method, which is to align them about a central axis, was found to have advantages, although it requires the container to be physically aligned in a jig on the carver. The proximal shape of the patient's socket is blended into that of the container to ensure an even liner thickness at the top.

Other changes enabled the socket to be carved from its proximal end, rather than distal as before, and modified the interference-checking algorithm which ensures that the cutter does not remove extra material when moving to a specific point on the socket.

**Liner Material.** Since parts of the liner will inevitably be thicker than in conventional sockets, ideally, the material used in this application should be lighter and stiffer than current liner materials. However, the only material found to date which satisfies other requirements, such as suitability for carving, resistance to compression over a period of use, and biocompatibility, is “PElite.” This is available in a maximum thickness of 1-inch, which imposes a limit on the allowable liner thickness at any point, and has implications for the number of standard containers that will be required.

**Standard Container.** The intention is to base the shape of the container on that of a normal leg, so that much of the cosmetic shape of the finished prosthesis will be automatically provided. A range of sizes would be used which were scaled versions of this shape. The optimum one would be selected for the patient, and the carved liner would then compensate for the differences in size and shape between socket and container. During the present experimental stage, 3 sizes of container have been used. It is envisaged that more, perhaps between 5 and 10, would eventually be used for a better cosmetic appearance.

**Progress/Results**—The modified software has been integrated into the existing UCL-CAD/CAM package, and a number of sockets carved. Three patients have been fitted to date, and the sockets were deemed to be comfortable. An alignment jig for the container socket which can be easily adjusted remains to be designed, and a more optimal alignment algorithm for aligning the computer socket model and container model needs to be devised. Problems remain with the thickness limitation of the PElite liners and with the liner-blank forming process. The technique has shown to be viable under laboratory conditions; whether it is feasible as a commercial product remains to be determined.

[38] **Functional Biomechanical Characterization and Functional Design Specification: Lower-Extremity Prosthetics**

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**Sponsor:** National Institute on Disability and Rehabilitation Research

**Purpose**—This project has two areas of emphasis. First, is the development of instrumentation and techniques for making biomechanical measurements and assembling visualization tools for the presentation of these data. Second, is the formulation and evaluation of models to test basic theories of human movement and prosthesis control in walking. The two areas are related in that accurate and reliable measurements are needed in order to test the validity of our models. In addition, the visualization tools also assist in the communication among engineers, clinicians, and users of prosthetic and orthotic devices.

**Progress**—**Instrumentation.** For motion measurement, what is wanted is a system for 3-dimensional (3-D) position measurement with high positional accuracy, fast sampling rate, real-time output, and the ability to distinguish and determine the position of a large number of markers. This laboratory has a machine that uses optoelectronic planar scanners to compute the positions of reflective markers. Unfortunately, the performance of the device does not meet our performance needs.

The first step was to characterize the machine by running some elementary tests, particularly related to the
scanner optics. The purpose of this was to examine the operation of the individual components in situ, so that idiosyncrasies could be accounted for at the time of measurement and later compensated for in any design modifications or enhancements. At this time, many of the characteristics of the individual scanners have been documented, and procedures have been developed to sufficiently determine the remaining characteristics.

In parallel with the hardware characterization, analytical techniques are being developed which will use redundant measurements to heighten the accuracy of the position estimates, while at the same time eliminating an existing problem with distinguishing multiple markers. The procedure uses statistical analysis to predict the maximum likelihood estimate of the position of any marker in 3-D space. The statistical nature of the technique results in data precision that exceeds the hardware/software precision of the individual scanners, and minimizes the variance of the data error. In addition to motion measurement, a system has been developed for monitoring the temporal characteristics of walking.

The final, necessary piece of instrumentation allows the measurement of reaction forces between the foot and the floor. For this purpose, two biomechanics platforms have been installed that give the 6-degree-of-freedom reaction at the floor (3 forces and 3 moments). Because the performance of these platforms will vary slightly depending on the particular installation, it was necessary to characterize and calibrate the platforms in situ. A loading apparatus was constructed to allow the application of purely vertical loads of known magnitude at any desired point on a platform. A matrix of loading locations was mapped out on each of the two platforms, and measurements were taken at three different load magnitudes at each site. The data from these spatial/load calibrations will be used to filter data taken using the biomechanics platforms.

In addition to instrumentation, visualization tools are being developed for the presentation of biomechanics data. With these tools, video data can be combined with quantitative measurements or analytical results. For example, video recordings can be produced which will combine a television image with stick figures, ground reaction force mappings, data graphs, etc.

**Modeling.** The modeling efforts approach the biomechanics of prosthetics from two directions. On one hand, the mechanics of normal human walking are studied to gain a basic understanding of that activity. On the other hand, amputee interaction with and control of prostheses are studied to gain knowledge of the differences resulting from prosthetic replacement and an awareness of the problems that exist and possible solutions for those problems.

**Recent Publications Resulting from This Research**


[39] Posturographic Assessment of Balance Reorganization in Patients with Peripheral Neuromuscular Lesions

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Sponsor: Nijmegen Institute of Cognition Research and Information Technology

**Purpose**—Our purpose is to develop a clinically valid posturographic procedure to assess the balance performance and reorganization of two different groups of patients with peripheral lesions: 1) lower limb amputees (acute disorder); and, 2) hereditary neuropathies (chronic disorder).

**Methodology**—Besides simple task conditions such as quiet upright standing, more complex conditions were implemented into the posturographic procedure to obtain a better picture of the overall balance disability. Using an information processing theory, perceptual, cognitive, and motor variables were manipulated by changing the visual input, using a dual task paradigm, or by requiring anticipatory activity. Equipment included a dual plate force platform and an electromyogram (EMG).

**Results**—In lower limb amputees, complex task conditions provide additional and indispensable information about balance restoration, degree of automaticity, and...
visual dependency in postural control. In patients with hereditary neuropathies, a dual task procedure revealed a temporary loss of balance automaticity when adapting to new rehabilitation footwear with ankle-stabilizing devices.

Implications—This research has shown that important information about sensory-motor reorganization may not be found when only relatively simple task conditions are applied in the assessment of gross motor skills, such as upright standing. This viewpoint has clear implications for rehabilitation methodology, particularly with respect to therapy evaluation studies. It is suggested that data obtained from gross motor assessment using complex conditions may reflect essential aspects of the motor skill at a disability level as defined by the World Health Organization (WHO) in 1980.

Recent Publications Resulting from This Research


From the Analysis of Movements to the Analysis of Skills: Bridging the Gap Between the Laboratory and the Clinic. Geurts ACH et al., J Rehabil Sci (in press).


[40] Ongoing Lower-Limb Amputee Database

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Sponsor: Tayside Health Board

Purpose—The aim of this project is to establish an ongoing database on lower-limb amputees admitted to the Dundee Limb Fitting Centre, providing statistical information on all lower-limb amputees, including medical, surgical, and social information, as well as information from the physiotherapy and occupational therapy departments.

Progress—A database has been established on amputees admitted to the Dundee Limb Fitting Centre since September 1965. The information initially collected was basic patient data, but has now expanded to include those elements described above. In addition, the date of death is obtained and included in the files.

Analysis of the information is ongoing, providing progress analysis of the amputee program and long-term amputee survival cases.

Methodology—A purpose-designed database has been developed using DBase 3+ software. The information is collected during the admission of the patient to the Unit, and entered into the computer upon discharge. Readmission may require updating the information on the patient’s file.

Results—Statistically-based figures are provided annually from the basic amputee medical/surgical information. These are used in lectures and publications, and also to monitor our rehabilitation program. Currently, 1,842 files are on record. Survival curves for amputees are currently being generated, demonstrating that the longevity of the amputee has increased significantly in the two decades 1970-79 and 1980-89.

Future Plans—It is intended to continue collecting information on amputees indefinitely, and modifying the database to include prosthetic information in the future.
C. Lower Limb

2. Above-Knee

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

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Sponsor: VA Rehabilitation Research and Development Service (Project #A308-2RA)

Purpose—The purpose of this project is to investigate the prosthetics requirements of geriatric above-knee (AK) amputees, and to develop quantitative design procedures for prosthetic sockets for these amputees.

Progress—Work on measuring the physiological, biomechanical, and prosthetics parameters of 99 geriatric AK amputees and control subjects was completed. Analysis of the data compiled shows the following trends. All of the geriatric subjects tested, both amputees and non-amputee control subjects alike, evidenced symptoms of circulatory impairment. No common localized regions of poor circulation were observed, however, in the geriatric amputees tested. The thigh tissue mechanical elasticity measurements were anisotropic for all subjects tested. In general, the tissue elasticities measured were lower (less elastic) on the stumps of the amputee test subjects than on the thighs of the non-amputee control subjects. The stump tissue elasticities measured on geriatric amputees were lower, in general, than the corresponding stump tissue elasticities measured on non-geriatric amputees. In addition, no common local regions or common directions exhibiting higher or lower elasticity were observed for any of the subjects tested. With respect to sensory input and proprioception, 12 geriatric amputees evidenced slight sensory diminution, in their stumps. But no major impairment was observed in these or any of the other amputee subjects tested, including those subjects amputated because of diabetes and peripheral vascular disease. Four of the geriatric amputees showed more localized stump tissue sensory diminution than any of the other amputees tested, but their sensory diminution was localized, and not of major consequence.

Work continued on AK socket design in conjunction with the above physiological and biomechanical testing. Investigations using tissue compliance measurements with uniform cross-sectional loading for quantitative derivation of socket shape, as previously described, continued. Compilation of data on prosthetic loading, load distribution, and load tolerance ranges as a function of stump tissue compliance continued. Investigations of socket design versus energy and agility required for prosthesis donning and doffing, and effectiveness of prosthesis suspension were conducted. Work on development of socket instrumentation also continued. Prototypes of miniature shear stress transducers developed in the project were fabricated and installed in test sockets. Clinical tests to measure the static and dynamic normal and shear stresses at the stump/socket interface were begun.

Implications—Data have been compiled in this project quantitatively documenting differences in the tissue mechanical properties, circulation, muscular strength and endurance, and other physiological and biomechanical properties, prosthesis alignment and functional requirements, and stump/socket interface forces and moments between geriatric AK amputees and other, younger, more active amputees. Since the way prosthetic forces and moments are transferred to and from, and are distributed in an amputee's tissues is a function of prosthetic socket design, it follows that different design considerations should be used for geriatric amputees than for younger, more active amputees. The uniform force/tissue displacement procedures developed in this project have been shown to provide a first step in quantitatively achieving a more comfortable geriatric socket design. These studies demonstrate that socket design methodologies based on tissue mechanical and circulation properties are feasible and can produce more comfortable sockets. This has been shown to be especially important in the prosthetics care of geriatric AK amputees.
[42] **Comparison of Four Types of Swing-Phase Knee Controls by Gait Analysis**

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**Sponsor:** Commonwealth Department of Veterans’ Affairs, Australia

**Purpose**—Gait analysis is part of our clinical evaluation of prosthetic componentry. Video recording of patients walking at known speeds on a treadmill, filmed against a 10-centimeters reference grid, provides the relevant coordinated spatial and temporal parameters.

**Progress/Methodology**—Three patients, unilateral above-knee amputees, participated in this study. All three were vigorous, active walkers, with long stumps. They were all fitted with AK prostheses with flexible sockets, universal Multiplex Mark V modular systems, Mauch S-N-S knee control units, and multiaxial feet. None of them spontaneously used the capability of the S-N-S for walking with a yielding knee after heelstrike.

The knee controls investigated were the Mauch S-N-S, the USMC Dyna-Plex, the Hosmer 55914 constant friction, and the Otto Bock 3R43. The first three are interchangeable within the Multiplex V frame. For the Otto Bock 3R43, the socket of the prosthesis was transferred to an Otto Bock modular system, with a multiaxial foot. The Mauch S-N-S controls were left for each patient at their usual levels of adjustment; other knee controls were adjusted to the patient’s preferred resistance.

The patients walked at speeds of approximately 40, 50, 70, and 80 m/min. Symmetry of gait, expressed by the duration of the swing-phase and its percentage of the gait cycle was used as a comparison criterion.

**Preliminary Results**—Preliminary results indicate that for the speeds of 40, 50 and 70 m/min the rhythm of gait remains almost constant for each given knee control (including the constant friction one). Swing-phase dysymmetry averaged 1.7% for the S-N-S, 2.6% for the Dyna-Plex, 6.5% for the Hosmer constant friction, and 11.6% for the Otto Bock 3R43. At 80 m/min, the Hosmer constant friction and Otto Bock 3R43 could not adjust to the speed. The Dyna-Plex swing dyssymmetry increased to 10.4%. Swing with the S-N-S control was symmetrical.

[43] **Swing-Phase Control Mechanisms for Above-Knee Amputees**

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**Sponsor:** Tayside Health Board

**Purpose**—A number of studies have compared the performance of different swing-phase control mechanisms in an attempt to understand their functional benefits for the above-knee amputee. However, in doing so, none of these studies have held constant all the other variables of the prosthetic system, calling into question the validity of some of the conclusions. What is required is an adapter which allows a number of different knee systems (that is, knee-plus-shank units) to be attached to the same socket with the same static alignment of the knee and the same prosthetic foot. Tests carried out under these circumstances would minimize the effect of gait deviations from sources other than the differing knee systems.

**Progress**—Such an adapter has been designed and gait tests have been carried out on four different knee systems for a single amputee. The four single-axis knee systems tests were: Blatchford internal coil spring, Blatchford pneumatic swing-phase control system, Otto Bock 3R15 constant friction system, and Otto Bock 3R44 hydraulic swing-phase control system, with a Blatchford Multiflex foot being used in each case.

Each knee system had its swing-phase characteristics set by a prosthetist to the subject’s preference. The gait tests included bilateral kinetic and kinematic data for a single stride using a VICON system with simultaneous multi-stride recording from foot switches placed under both feet, and a goniometer placed across the prosthetic knee.

**Results**—Two-tail Student’s t-tests with p<0.002 show significant differences between all the knee systems for
the most temporal parameters examined. Consistent moment data about the joints of the contralateral limb for all four knee systems support the view that the amputee adjusted his cadence to suit the swing characteristics of the different knee systems. The fluid control systems showed similar maximum knee-flexion angle, as did the two friction systems with the two fluid systems showing smaller and more normal values. The two Otto Bock knee systems exhibited similar swing periods, as did the two Blatchford systems. The flexion-extension cycle of the hip in late swing using friction knees, reported in previous literature, was confirmed. It was also seen, although to a lesser extent, with the fluid control knee systems.

C. Lower Limb

3. Below-Knee

[44] Efficiency of Dynamic Elastic Response Prosthetic Feet

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Sponsor: VA Rehabilitation Research and Development Service (Project #A517-RA)

Purpose—Following years of accepting the SACH foot as the optimum compromise between durability and functional effectiveness, as well as reasonable cost, several new feet with dynamic response (DR) qualities have been designed. However, apart from manufacturers' claims, the prosthetic team has no objective guidelines for prescribing DR feet. There are no criteria for selecting one design over the other. Nor is it known whether both the dysvascular and traumatic amputee will realize functional benefit from these new feet during normal community ambulation. The objectives of this study are: 1) to compare the efficiency of walking with the four DR foot designs to that of the SACH foot; 2) to define the influence of these designs on gait mechanics; and, 3) to evaluate the relative effectiveness of these prosthetic feet for the dysvascular and traumatic amputees.

Methodology—Tasks associated with community ambulation are being evaluated in the gait laboratory. Walking on ramps, stairs, and a level surface are being assessed under five different prosthetic conditions. The five designs being evaluated are the SACH, Flex-Foot, Carbon Copy II, Seattle-Lite, and Quantum. A total of 20 below-knee amputees (10 dysvascular and 10 traumatic) will undergo repeated testing resulting in 100 prosthetic fittings and gait analysis sessions by completion of the project. A new prosthetic socket is made for each subject and is used for the duration of their participation in the study. The subjects wear each of the five feet for approximately one month prior to gait analysis. Thus, testing takes place over a 5- to 6-month period for each subject. The participants are kept blind as to the type of foot being worn to prevent subjective bias.

Electromyographic activity of six hip and knee muscles, kinematic, kinetic, and temporal characteristics of gait are collected during free- and fast-walking on level ground, as well as ascending and descending ramps and stairs. Ground reaction forces during the stance phase of gait are also measured during level walking for both the amputated and sound limb. In addition, the energy expenditure of walking is determined from the oxygen consumption monitored during a 20-minute self-selected pace walk.

Progress—Design and construction of a portable ramp and portable stairs suitable for use in the gait laboratory were completed.

To date, nine subjects have been provided with new prosthetic sockets. Twenty-four gait analysis sessions have been completed on seven subjects. Three subjects have completed all five prosthetic conditions; the remaining subjects are in various stages of the testing process.
Data processing and analysis is in progress on all subjects tested. Preliminary data analysis has been completed on one subject (DT) who has been tested with all five feet. The following findings are based on this single subject.

Ground reaction force data gathered during stance of the sound limb have demonstrated greater differences between the five prosthetic conditions than did the force data recorded during stance of the amputated limb. The magnitude of the progressional force during loading and preswing was less with the Flex-Foot and Quantum than with the other prosthetic designs. The Flex-Foot also had the lowest vertical force in loading of the five conditions. These findings suggest a more controlled transfer of weight from the prosthetic limb to the sound limb with these two feet.

Analysis of the data gathered during ascending and descending a ramp indicated the trends between feet were similar to that of level walking. The Flex-Foot and the Quantum had the greatest amount of dorsiflexion in late stance of all the feet tested.

Ambulation on the stairs resulted in more variation between feet during descent than during ascent. While descending the stairs, use of the SACH foot resulted in a longer gait cycle duration and total double-limb support time than the DR feet. This suggests that there is less stability on the stairs with the SACH foot. Also, knee motion with the Flex-Foot and Seattle-Lite foot approached normal flexion in early stance (20 to 30 degrees), more so than the motion recorded with the other feet.

Final conclusions regarding the performance of these five prosthetic feet must be reserved until data from all subjects have been analyzed.

Recent Publications Resulting from This Research


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Sponsor: VA Rehabilitation Research and Development Service (Project #A613-RA)

Purpose—The objective of this research is to investigate the transient movement phenomena associated with gait initiation in below-knee (BK) amputees. This study will record how variation in prosthetic alignment, speed of movement, and choice of initial swing limb (intact or prosthetic) affect the safety and efficiency of gait initiation.

The neuromuscular coordination necessary for balance maintenance and postural control is compromised in the amputee. Feedback channels including calf muscle spindle activity and ankle joint proprioceptive signals are lost. Since functional (daily living) activities require frequent transitions from stance to ambulation, amputees need to develop skills to safely negotiate the involved weight transfer and postural imbalances. This study will investigate the strategies the BK amputee uses to compensate for musculoskeletal asymmetry and will provide insight into the potential for gait training or prosthetic mechanical design to improve patient function.

Methodology—The ground reaction forces, center of pressure location, and lower limb electromyographic activity will be monitored in three groups of subjects: 1) 20 age- and sex-matched normal controls; 2) 20 unilateral BK amputees with good ambulatory skills who will use an adjustable prosthesis for testing sessions; and, 3) 20 BK amputees wearing conventional prostheses. The subjects will stand on force platforms and begin walking at slow, normal, and fast speeds with their intact and prosthetic legs. Subjects with adjustable prostheses will have adjustments systematically made to their prosthetic limb (socket tilts and shifts, foot eversion/inversion and plantar/dorsiflexion, changes in prosthesis length) and will then repeat the gait initiation trials. Results of the normal and amputee populations will be compared and changes in gait initiation behavior with change in prosthesis alignment will be noted. Specifically, magnitude and direction of center of pressure excursion, magnitude and timing of peak vertical and shear ground reaction forces, and sequence of electromyographic activity including periods of antagonistic cocontraction will be recorded and used to evaluate the symmetry, safety, and efficiency of the movement preparation.
[46] CAD/CAM of Below-Knee Prosthetics: Program Studies

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Sponsor: VA Rehabilitation Research and Development Service (Project #A17-2RA)

Purpose—The first project uses finite-element analysis to predict pressures between a residual limb and prosthetic socket. Once a viable modeling technique is established, the procedure will provide a valuable tool for quantifying the nature of a good prosthetic fit as well as actually aiding in the design of prosthetic sockets. The second project evaluates spatial foot positioning (alignment) for below-knee prostheses within a coordinate reference frame established from skeletal geometry.

[46a] Computerized Analysis of Below-Knee Socket Limb Mechanics

Progress—As reported previously, the use of constant dilatational elements to model the incompressibility of tissue in a linear analysis, coupled with the iterative removal of constraints on surface elements which go into tension, greatly improved the accuracy of the finite-element (FE) prediction of pressure to the experimentally measured pressure. As a final step in the validation of the modeling approach, another subject, fitted with an unrectified socket, and thus assuring total tissue/socket contact, has been tested. Measured pressures around the surface ranged from 5 to 30 psi for various alignments. Analysis of the FE model is underway.

The use of a generic model as a predictor of residual limb/socket pressures is also being evaluated for both unrectified and patellar tendon-bearing (PTB) rectified sockets. Scaling of the model for an individual is based on residual limb length, distal tissue thickness, and mediolateral and anteroposterior measurements at the proximal, distal, and tibial plateau levels. Socket rectification was implemented similar to that used in the UCL Computer-Aided Socket Design system, that is, radial modifications at frequently rectified local patches (fibular head, medial tibial flare, popliteal depression, patellar tendon bar, etc.). Experimental verification of local interface pressures for multiple subjects is currently underway. Pressures are measured for multiple static loading conditions and for various alignments (5 degrees plantar flexion—5 degrees dorsiflexion), providing a sizeable database for comparison with FE predicted pressures.

Preliminary Results—We now believe that the careful use of the FE method can sufficiently describe the mechanics between the limb and socket. In addition to the proper representation of an incompressibility condition, the analyses seem sensitive to perturbations to the assigned stiffness of the tissue. This “stiffness” includes not only the modulus of elasticity of the tissue, but perhaps more importantly, the effects of the underlying tendinous and bony structures of the limb. Further work is being carried out in this area.

Implications—We have already begun work to integrate FE into the design of prosthetic sockets. Desired pressures will be input onto the surface of a model of a residual limb. The calculated shape will then become the rectified shape of the prosthetic socket.

[46b] Anatomically-Based A Priori Alignment Prescription Studies

Progress—In this analytical study, our goal is to first characterize what is acceptable prosthesis positioning in terms of loading patterns on the residual limb/prosthesis system during ambulation. Secondly, to use this information to position prosthetic components to allow a desired loading time course during an acceptable gait. Much of the effort has continued realizing and verifying hardware measurement and analytical techniques which allow us to obtain accurate results from which confident conclusions can be drawn. Maximum likelihood statistical techniques have been implemented so position estimates benefit from multiple redundant observations. Techniques for establishing anatomical coordinate systems are being realized.
The Diabetic Foot with Partial Amputation: A Biomechanical Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A573-RA)

Purpose—The purpose of this study is to conduct a retrospective biomechanical evaluation of diabetic veterans with successful partial amputations of the foot. Four groups will be formed according to the following levels of amputation: 1) hallux and first ray resection; 2) other digital and ray resections; 3) transmetatarsal amputations; and, 4) short transmetatarsal amputations, Lisfranc’s and Chopart’s procedures. Ten patients in each group will be studied. The shape of the partial foot will be measured. Traditional range of motion, strength, and deformity measurements will be taken, together with a battery of gait analysis parameters, including pressure distribution and kinematic measurement. Results will be compared with the “classical” opinions concerning the partial foot and a number of hypotheses with respect to deformity and function will be tested. The intact foot will also be examined to assess the presence of a number of putative risk factors.

Results of the study should lead to a better understanding of the partially amputated foot and a better definition of criteria that should be used for management during rehabilitation. Favorable results could be extremely important in convincing surgeons that a partial foot amputation is a viable procedure, thus resulting in the saving of many limbs that would otherwise have been amputated.

Methodology—A complete medical history, including a description of the surgical procedure(s), will be obtained for each subject prior to participation. Testing will be conducted during the course of one day and will be subdivided into four distinct stations: 1) collection of a detailed history of the subject’s diabetes, measurement of sensation of each foot, as well as a vascular assessment; 2) the foot is thoroughly examined, the range of motion of the lower extremities is measured, and the degree of strength is determined (photographs and a bivalve cast of the amputated foot are also taken); 3) weightbearing A-P and lateral X-rays; and, 4) footprints, pressure distribution, and kinematic analysis.

Risk factors (such as sensation, peak pressure under the forefoot, joint mobility, and ankle-brachial vascular index) on the nonamputated side in these subjects will be compared to age-matched diabetic individuals without ulcer or amputation. Data on healthy diabetic patients have been collected previously and are available in a database.

Sensory thresholds will be measured using monofilaments and vibration tests. Joint mobility measurements will include hallux dorsiflexion, subtalar total range of motion and ankle dorsiflexion. Independent t tests will be used to compare the two groups on each of seven different variables. In addition, a descriptive analysis of the contralateral and ipsilateral side in the patients with amputation will be made using the same variables. Pressure, kinematics, and radiographic measurements will be compared between the four levels of amputation. The group means for each criterion measure will be compared using a one factor analysis of variance.

Progress—The project team has had difficulty in identifying a sufficient subject pool at the VA hospital in Altoona, PA. Although at the onset of the study the search looked promising, the subject pool identified initially has been depleted due to subject expiration or to additional, more extensive surgery (such as BK amputation).

Future Plans/Implications—It will be necessary to go outside of the James E. Van Zandt VA Medical Center to other VA hospitals in the eastern United States to form a subject pool large enough to be statistically significant. An initial search has already begun at the VA hospital in Pittsburgh, PA, with others to follow at hospitals in West Virginia and Washington, D.C., among others.

Recent Publications Resulting from This Research


Progress/Results—Prosthetics Research Study: Research and development of the Seattle-DVA below-knee prosthetic system has been completed. The socket is designed and fabricated of structural thermoplastics using automated computer-controlled techniques. Generic design templates and individually directed shape manipulations are accomplished using software programming prepared by us: Seattle ShapeMaker. Distal components consist of an intrinsic alignment device, ankle shank, and foot. Appropriate cosmesis has been developed and is available.

This prosthetic system was conceived to provide physiological force-movement vectors factored into the endoskeletal materials. Energy input and response, gravity-initiated, are physiologically programmed to body weight and activity level of the wearer. The limb is designed to be light, comfortable, energy-conserving, responsive, and essentially monolithic in construction, thus sharply reducing costs.

The DVA/BK prosthesis has been tested in-house extensively over the past year. It is now under field evaluation on 25 subjects at Edward Hines Jr., VA Hospital in Hines, IL. It was made available for veteran use and commercialization began around the end of 1990.

Ongoing prosthetics research continues with the development of a compatible prosthetic knee and above-knee (AK) socket to complete the Seattle VA lower-limb system. AFMA/AK socket design using the ShapeMaker Program is under way. Ten AK amputee subjects are participating in the “in-house” development and evaluation of the AK prosthetic system. We plan to complete this project during the 1991 fiscal year.

Automated Fabrication of Mobility Aids. The three-center study of CAD/CAM lower-limb prosthetic sockets has now concluded. Technology transfer of these techniques has proceeded rapidly. In addition to the several hundred amputees fitted during the course of this project, commercialization has paralleled our research. Installation of various components of the Department of Veterans Affairs (DVA)-developed system is in place in DVA Medical Centers. Private and institutional facilities in this country and abroad are beginning use of the system. The AFMA project is being aptly described as a revolution in a profession. Considerable international interest in this research and development for application to the large unserved needs of Third World countries is being explored.

This research center participated in a number of training sessions and workshops on AFMA and VA Seattle Shapemaker during 1990. A national AFMA 4-day workshop took place in Seattle in October, 1990, sponsored by the DVA Rehabilitation Research and Development Service, Prosthetics Research Study, and the University of Washington.

Limb Viability and Amputation Surgery Techniques. Limb viability studies continue both for limbs at risk from peripheral vascular disease, diabetes, and other medical states, as well as limb salvage and/or amputation for primary trauma. The rapidly changing field of reconstructive limb salvage surgery following trauma has modified earlier thinking regarding limb salvage versus amputation. Guidelines are clouded. There is a need for clear-cut decision-making data and guidelines. Most of these individuals are young, and are seen initially in hospital emergency rooms and trauma centers. Vehicular and industrial accidents are primarily responsible. We have the opportunity at Prosthetics Research Study to statistically evaluate and carefully document a significant number of individuals being admitted to a major trauma center (Washington/Harborview) located a short distance from our research laboratories. Dr. Sigvard Hansen and Dr. Douglas Smith, together with Dr. Ernest Burgess, are conducting this clinical research. The information obtained is relevant to the military establishment.

We are continuing to study methods previously developed for tissue and limb liability evaluation through laboratory means. In addition to statistical information, the present basic research uses NMR spectrometry to study molecular activity of high energy phosphorus in skin. Dr. David Williams has developed a coil which isolates information received from the skin, which is the key tissue relevant to wound healing in the limb threatened by medical disease. The coil sufficiently eliminates “noise” from the deeper structures. As clinical information is obtained, this technique will be used as a laboratory tool to evaluate now-standard laboratory techniques such as TcPO₂ and PcO₂ measurements.
Biomechanical Power Analysis of Prosthetic Feet: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A992-PA)

Purpose—Below-knee (BK) amputation results in altered gait biomechanics and an increased metabolic energy expenditure during walking. Recently there has been a focus on the development of improved prosthetic components to reduce the metabolic energy expenditure of ambulation and enhance the functional outcome following amputation. Energy-storing (ES) prosthetic feet, although initially developed to improve running and sports performance, have achieved widespread acceptance as an effective component to improve the walking gait of amputees. There is, however, little objective information regarding the influence of these feet on the biomechanics of BK amputee walking. As a result, guidelines for the use and prescription of these feet are empirical and vary widely. The purpose of this study was to determine the biomechanical adaptations used by the BK amputee to walk while wearing a conventional prosthetic foot-ankle assembly, and to subsequently evaluate the effect of ES feet in restoring normal gait characteristics.

Progress—Combined sagittal plane, lower extremity joint kinematic and kinetic data have been analyzed for five young amputee subjects during walking. Using an inverse dynamics linked segment modeling technique, calculation of joint moment, muscular power, and energy output have been completed for walking trials using three prosthetic feet: the SACH, SEATTLE, and Flex. An additional six elderly unilateral BK amputees have been studied during walking at natural cadences with each subject using four different prosthetic feet.

Preliminary Results—Energy generation during the pushoff phase of walking was diminished with all three prosthetic feet when compared to normal. As expected, the nonenergy-storing SACH foot demonstrated the least energy generation, the SEATTLE intermediate, and the Flex the greatest.

Major differences were present in the knee power output characteristics of the amputee subjects. The normal eccentric knee extensor energy-absorbing phase which occurs after heel contact, and the subsequently following concentric knee extensor energy-generating phase were absent or markedly reduced in amplitude in the amputees. The loss of these power phases was the result of a reversal of the normal net knee extensor moment to a flexor moment.

With all three prosthetic feet, there was a marked increase in the magnitude and duration of the initial concentric hip extensor positive-power phase following heelstrike. This alteration represents one of the major biomechanical adaptations present in the BK amputee. Of particular note, there were no differences in the hip power outputs between prosthetic feet.

Future Plans/Implications—Of major importance is the finding that despite the improvements in the mechanical performance of ES prosthetic feet, no significant differences were found in the pattern or magnitude of knee and hip power outputs when compared to the SACH foot. Although a slight trend toward normalization may have been present with the Flex foot, it was anticipated that the increased energy generation of the Flex foot would have resulted in a reduction in some of the abnormalities noted while using the SACH foot.

Further analysis of the effects of prosthetic foot design on ambulation in the elderly amputee where walking speeds are slower is in progress. Studies are planned to assess the contribution of the intact limb and the swing-phase limb to the overall biomechanical adaptations that follow BK amputation.
[50] A Quantitative Method of Prosthetic Socket Construction for Below-Knee Amputees

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Sponsor: Clynch Prosthetic and Orthotic Laboratory; Western Economic Diversification; Variety Club of Southern Alberta—Tent 61; Alberta Children’s Hospital Foundation

Purpose—The purpose of this investigation was to develop a quantitative method of constructing prosthetic sockets.

Methodology—1) An optical/laser digitizer collects numerical data describing the surface of the residual limb. 2) The numerical information for the residual limb is altered using a custom computer-aided design (CAD) software system running on a workstation. 3) Using the altered numerical data, a program is created for a numerically controlled (NC) milling machine. This machine mills out a positive mold. 4) The socket is constructed by laminating over the positive mold.

Results—Utilizing this method, we have successfully fit 15 patients. All the patients believe that their “computer-designed” sockets fit better than their conventionally made sockets. This subjective belief appears reasonable since we can apply modifications with our custom CAD software that are virtually impossible utilizing conventional methods. Further confirmation of an adequate fit exists with the fact that these patients are wearing the sockets on a regular, full-time basis without complaint.

Future Plans—Additional clinical testing is necessary to further refine the procedures. In addition, an objective quantifiable method must be determined to evaluate the fit and comfort of the prosthetic socket.

Recent Publications Resulting from This Research

[51] Dynamic Alignment of Below-Knee Amputees

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Sponsor: Dundee Limb Fitting Centre

Purpose—Gait analysis has had some effect for a number of years on the dynamic alignment of below-knee amputees, but even with modern high-speed gait analysis systems it has proved inconvenient to wait for analysis between alignment changes, thus limiting its clinical role.

Progress/Methodology—By performing full kinematic and kinetic bilateral gait analysis on 32 established below-knee amputees while attending regular prosthetic clinics, it was possible to identify the fore-aft shear component of the ground reaction force as being a sensitive indicator of the quality of alignment. It was found that certain symmetrical criteria for this curve correlated closely with the amputees’ own preferred alignment. This quality not only proved sensitive to alignment changes, but appeared to produce consistently repeatable alterations in shape for various alignment changes.

This study is concentrating on establishing the nature of the relationship between the shape of the fore-aft shear ground reaction curve and changes in prosthetic alignment. The subjects are provided with prostheses incorporating Berkeley Jigs to allow precise alignment changes to be made, and recording the alterations in the shape of the fore-aft shear ground reaction force for a complete range of alignment changes.

Implications—These tests will lead to the establishment of a rule-set governing the relationship between alignment changes and the shape of the fore-aft shear curve. If an adequate set of relationships can be established between them, it will be possible to predict the required alignment changes from the fore-aft shear curve. A system operating on this basis could be incorporated into the prosthetic prescription process.
Biomechanical Evaluation of Energy-Storing Prosthetic Feet

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Sponsor: Dundee Limb Fitting Centre

Purpose—All lower-limb amputees require a prosthetic ankle-foot mechanism to be incorporated into their prostheses. Traditional designs of prosthetic feet have incorporated articulations which deflect the actions of the normal ankle/foot joints under load simulating. More recently, a range of nonarticulated ankle/feet have been developed which achieve their function by the deformation of their structural elements. This study evaluated the mechanical properties and the gait pattern of four energy-storing prosthetic feet (ESPF): the DYNAMIC foot, the CARBON COPY II foot, the SAFE foot, and the SEATTLE Light foot.

Methodology—Two test methods were followed: 1) mechanical tests involved the compression loading of the heel and forefoot parts of the prosthesis in order to analyze the load-deformation responses, and to calculate the input/output works and efficiencies; 2) clinical tests involved the gait analysis of an active unilateral below-knee amputee while wearing each of the four ESPF. The subject used each foot for one week prior to gait laboratory tests. These included force place analysis, motion analysis, and joint moment analysis during normal walking.

Results—The compression tests showed that the heel parts had similar load response characteristics. The CARBON COPY II foot and the SEATTLE foot showed stiffer forefoot parts than the DYNAMIC foot and SAFE foot. The work efficiencies of the heels and forefeet were higher for the DYNAMIC foot and the SEATTLE foot than for the CARBON COPY II and the SAFE foot.

It was evident from the clinical tests that the ankle moments for each prosthetic foot followed similar patterns to the normal joint moments. However, all the feet showed higher dorsiflexion and knee extension moments during push-off phase than the normal. The hip and knee moments produced by the prostheses were similar in pattern but different in magnitude to the normal moments during the stance phase. No significant differences were found in the joint moments during the heel strike.

It was concluded from the mechanical and clinical results that the prosthesis with the stiffest forefoot part (CARBON COPY II) produced the largest dorsiflexion and knee extension moments during the push-off phase, whereas the softest forefoot (SAFE) produced the smallest moments.

Future Plans/Implications—We hope to carry out a more detailed clinical study using several patients in order to derive a relationship between the mechanical and clinical tests. Eventually this information may be used to assist in prescription of the most appropriate prosthetic foot for an individual patient.

An investigation of the viscoelastic properties of the feet would also be required to produce a mathematical model of the prosthetic feet, so that their stiffness characteristics could be analyzed.

Gait of Children Having a Unilateral Below-Knee Amputation

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Sponsor: Hospital for Sick Children Foundation; Variety Club of Southern Alberta—Tent 61; Alberta Children's Hospital Foundation

Purpose—The long-term goals of our research are to improve and then maintain the gait of below-knee-amputee (BKA) children. In order to accomplish these goals we have divided our research into three phases (description of gait, factors influencing gait, procedures for improving gait). We have completed the data collection for Phase I and are in the process of analysis.

Progress—We performed a 3-D kinematic analysis of BKA children during both walking and running and
compared centers of mass (COM) and segment and joint angular orientations with those of typical children. In addition, we measured oxygen uptake and maximum vertical displacement of a marker representing the COM on three BKA (2 SACH foot and 1 Flex foot terminal device), and two typical children while walking on a treadmill.

**Results**—Results from the kinematic analysis indicated that the COM of BKA children was generally: 1) lower, relative to the ground; 2) farther forward relative to the midpoint of the hip joint centers; and, 3) positioned on the nonprosthetic side of the body during support when compared to that of typical children. This appeared to be due to: 1) greater hip and knee joint flexion; 2) more horizontal orientations of the trunk, thighs, and legs; and, 3) a trunk side flexion towards the nonprosthetic side of the body.

With respect to the treadmill study, the results for oxygen uptake and maximum vertical displacement of the COM seemed to separate the five subjects into two groups. The first group consisted of BKAs wearing a SACH foot terminal device and the second group consisted of the typical children and the child with the Flex foot terminal device. The first group generally displayed greater effort for three different walking speeds when compared to respective values in the second group.

**Future Plans**—The remaining data from Phase I will be analyzed and reported. We will then focus on Phase II, that is, to quantify the effects of six factors influencing the gait of BKA children: 1) socket shape; 2) prosthetic alignment; 3) prosthetic components; 4) BKA structure; 5) growth; and, 6) activity level.

**Recent Publications Resulting from This Research**


[54] Analysis of Metabolic Factors in the Gait of Congenital Below-Knee Amputees: A Comparison of the Seattle Foot and the SACH Foot

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**Sponsor:** National Health Research and Development Programme, Department of Health and Welfare, Canada

**Purpose**—The purpose of this study is to determine the extent to which the energy-conserving Seattle Foot permits more normal gait kinematics, dynamics, and energetics compared to the conventional SACH Foot for congenital, unilateral, below-knee amputees walking at their preferred cadence.

The specific goals are: 1) to quantify the effectiveness and efficiency of locomotion when wearing the Seattle Foot or SACH Foot; 2) to further the understanding of gait energetics when wearing a prosthetic foot; and, 3) to investigate the compensation strategies used by amputees to walk with prosthetic feet.

**Progress/Methodology**—In this 2-year project, assessments will be performed on 15 subjects who: 1) have congenital, unilateral below-knee amputations; 2) are between 10 and 19 years of age; 3) have a foot length greater than 22 cm; and, 4) are successfully fitted with a patellar tendon bearing (PTB)-type prosthetic socket.

Each subject requires a biomechanical and metabolic assessment for the Seattle Foot and for the SACH Foot. The biomechanical assessment consists of 10 walking trials, during which lower-limb kinematics are measured using the VICON motion tracking system. Footswitches are used to measure the timing of foot-floor contact.
Ground reaction forces are measured with a Kistler force platform. The three-dimensional kinematics, anthropometrics, and ground reaction force information are combined in an inverse dynamics analysis to determine joint reaction forces, net joint torques and powers for the hip, knee, and ankle joints, bilaterally.

The metabolic assessments are performed at Variety Village. Heart rate is monitored throughout testing with a standard three-lead electrocardiogram (ECG) configuration. Oxygen consumption, carbon dioxide production, and respiratory exchange ratio are being monitored using a Beckman Metabolic Measurement Cart (MM-I).

[55] Feedback at Heelstrike for the Primary Below-Knee Amputee

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Sponsor: Tayside Health Board

Purpose—Because of the absence of proprioception on the amputated side, some amputees are initially unable to perceive prosthetic heelstrike during walking. This means that initial contact tends to be further forward on the prosthetic foot, and for a below-knee amputee this leads to a rapid rollover with little weight being borne through the prosthesis.

Progress/Methodology—A study was carried out on a limited group of patients using a footswitch at the heel with audible feedback. Gait analysis was used to confirm clinical observations and some promising results were obtained.

A more detailed study is currently being undertaken with the use of a limb-load monitor. It is intended to monitor below-knee amputees at the primary fitting stage for load bearing through the prosthesis. These subjects will be compared with a control group not using the limb-load monitor, and using gait analysis in order to assess the clinical benefits of feedback.

[56] Mechanical Properties of Soft Tissue

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Sponsor: Whitaker Foundation; Prosthetics Research Study

Purpose—We have used our designed instrumented pylon successfully with our interface normal and shear stress measurement system to collect clinical data on below-knee amputees.

Progress/Results—Results from walking trials show that shank pylon bending waveforms are similar for different subjects. This is also the case for shank axial force curves. However, pylon shear force waveforms are distinctly unique. Both peak magnitudes and waveform shapes differ between subjects. In addition, peak axial force and peak shear force in a step do not necessarily occur at the same time. Thus ratios between different force directions change significantly over the course of stance phase.

Future Plans/Implications—These subject-dependent differences in shank loading patterns during walking may explain differences in anteromedial versus anterolateral interface stress patterns we have measured. To investigate this possibility we are developing analytical finite-element models of the residual limbs under clinical investigation and subjecting them to the shank loading conditions that we have measured clinically. A match between predicted and measured interface stress trends may provide us with an understanding of this “coupling” and better insight into interface stress tissue mechanics.

Recent Publications Resulting from This Research


Stresses at the Amputee Residual Limb/Prosthetic Socket Interface. Sanders JE, Daly CH, First World Congress of Biomechanics, La Jolla, CA, 1990.