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I. Amputations and Limb Prostheses

A. General

Comprehensive Management of Upper and Lower Extremity Amputation

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Plan—The purpose of the project is to continue to define the use of Xenon-133 for amputation level selection; to develop techniques for building inexpensive, rapidly fabricated, temporary prostheses; to evaluate the role of immediate postsurgical fitting for upper extremity amputation; and to investigate the role of elective amputation for patients with neurologic dysfunction.

Methods—Amputation level selection is performed using intradermal Xenon-133, the laser doppler, and doppler ankle systolic blood pressure measurements. Prostheses are provided at the time of surgery, and all patients are fitted with temporary lightweight prostheses which are modified as needed until the patient is eligible for a permanent prosthesis. Patients undergoing upper extremity amputation in the Tucson VA Medical Center, the University of Arizona HSC, the Atlanta VA Medical Center, and Emory University were pooled into one group to evaluate the role of immediate, early, and late prosthetic fitting after upper extremity amputation. Finally, elective amputation with subsequent prosthetic fitting was evaluated in a group of patients with neurologic dysfunction due to brachial plexus injuries.

Results—

1. Intradermal Xenon skin blood flow continues to have greater than 95 percent accuracy for prediction of healing at all levels of lower extremity amputation and continues to be superior to the laser doppler or doppler ankle systolic pressures. In addition, our Xenon work has been validated by the University of Cincinnati.

2. Our results on immediate postoperative fitting for upper limb amputation demonstrate that there is a 30-day grace period for early or rapid fitting after which the success rates of rehabilitation decline dramatically.

3. For patients with non-reconstructable brachial plexus injury, elective amputation with shoulder fusion, and early or rapid prosthetic fitting is an excellent rehabilitation tool.

4. Fiberglass casting tapes and PVC plastic pipe can be combined to build easily fabricated, lightweight, inexpensive, temporary prostheses, which allow evaluation of patients with marginal rehabilitation potential, continued rehabilitation of patients who are already ambulatory, or economic fabrication of permanent prostheses for patients with limited financial resources.

During the last year, this research program has resulted in 9 publications, 5 audio-video tapes, and 22 presentations at national meetings.

Future Direction and Efforts—The areas that our program is moving toward include biomedical research and closer ties with the College of Engineering at the University of Arizona; patient education; teaching, both at a regional level and to appropriate referral hospitals; evaluation of new prosthetic components; evaluation of limb sparing or salvaging techniques which might obviate the need for upper and lower extremity amputation; and continued comparison and evaluation of Xenon-133 with other methods of amputation level selection.
Successful Application of CAD Automation to the Production of Individual Prostheses

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**Background**—The first step along the path to computerized, automated socket and prosthesis production was taken several years ago, when the Rapidform technique for automatically fabricating thermoplastic sockets was developed and brought into service. Those sockets were the first thermoplastic sockets in clinical service in the United Kingdom and they have proved to be highly successful. They are accurate, hygienic, extremely tough, slightly resilient, and very reliable. In fact, there have been no mechanical failures of any socket—and some have been used regularly by patients for over 6 years. These sockets are fabricated very rapidly, and they are very inexpensive to produce. The Rapidform machines form consistent high-quality sockets without the need for a skilled operator. The United Kingdom Government’s Central Office of Information (COI) made a film of the process about 4 years ago. It is entitled “Fit A Limb” and was part of the Living Tomorrow series. The United Kingdom Department of Health and Social Security provisioned Rapidform machines for their Limb Centres, and private purchases were also made by certain major limb manufacturing firms. There are many thousands of patients now fitted with Rapidform sockets, including a number of patients of one Arab country. More recently, the Rapidform sockets became available in Canada through the University of British Columbia (UBC).

The successful development of the Rapidform socket fabrication system was followed by a semi-automated system for rapidly and cheaply fabricating a type of below-knee prostheses called Tapered Column Prostheses. This technique fabricates thermoplastic shin sections by rotationally casting the required section in a specially controlled machine. No operator skill is required. The tapered columns are extremely lightweight and strong. They interface via plastic alignment couplings at either end to the socket and the foot. These sections are fabricated quickly and very cheaply. A typical below-knee prosthetic system comprising a Rapidform socket, tapered column and alignment couplings, and a SACH foot weighs just under one kilogram. The system has an exceedingly good fatigue life. An above-knee system is being finalized.

The fabrication of the socket requires a model that represents the rectified shape of the stump. The usual techniques were considered inadequate, and a joint project was carried out with the Medical Engineering Resource Unit of UBC which evoked a computer-aided design system for defining the required stump shape. The rectification is carried out with reference to a video display and is stored in the computer memory. The result is a set of coordinates that define the required shape of the interior of the socket. The Bioengineering Centre designed and built a cheap, rapid, and accurate computer-numerical-controlled (CNC) machine that uses this coordinated data to cut and shape a wax blank. This carved wax blank is the model of the rectified stump shape over which the thermoplastic socket is then Rapidformed.

**In Less than 2 Hours at Low Cost**—The computer-aided design (CAD) shape definition system typically takes 10 minutes to define the required shape (using a few key measurements taken from the patient). The CNC machine then takes about 10 minutes to produce the model representing the stump shape. This is used in Rapidform to fabricate a socket in 20 minutes. In parallel with this socket preparation, the shin section (tapered column) is rotationally molded.

A patient can be measured and fitted with a prosthesis within a very short timescale—typically less than 2 hours even with trimming and adjusting. Because of the low cost and high speed of the process, it is considered preferable to manufacture and issue a new prosthesis than to undertake repairs.

Effectiveness of Prosthetic and Orthotic Devices Used in Pakistan

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This project’s objectives were to determine the effectiveness of prosthetic and orthotic devices presently in use in Pakistan, and to determine the kinds and frequency of disability in the geographic area of the research effort.

**Methodology**—The project has been spread over 4 years, with the fifth year being used to evaluate all the collected data.

Each year 20 handicapped persons were chosen...
from each disability category and evaluated individually from medical, psychological, and social or prosthetic/orthotic aspects. They were then fitted with either a standard or experimental device under supervision of a physician, prosthetist, social worker, and physiotherapist, and allowed to return to their normal environments.

The evaluation team examined the participating patients at least twice a year, and necessary modifications were made. Detailed records were kept. At the end of the study period it should be possible to determine the merits and deficiencies of the so-called modern prosthetic/orthotic devices as compared to more conventional devices.

Currently, final data collection is in progress and a critical review of all project activities is being carried out prior to preparation of a final report.

**Preliminary Findings** — Perhaps because of the peculiar climatic conditions, we find that above-knee sockets made of synthetic materials cause far greater problems than wooden ones. The modified Geisenger foot developed at the centre had to be further modified, with the deletion of the anterior rubber wedge, as it had an unacceptable incidence of breakdown.

The peg leg has still a place in the management of an above-knee amputee, as it gives complete freedom of movement in the manual worker.

Bonding agents are still a problem, with some solidifying in their containers even before delivery to the centre. Others show a marked tendency to bond with less strength and cause the parts to come apart, particularly during hot and humid temperatures which are characteristic of the summer months.

The below-knee amputee has been the most satisfied patient, as the modern PTB (patellar tendon bearing) prosthesis has revolutionized the patient’s life. It has found universal acceptability and patients manage to do their fairly demanding manual jobs without many problems. In contrast, there has been little progress in pleasing the upper limb amputee. The locally fabricated mechanical hand has had a very high failure rate, and we have no access to myoelectric devices.

On the orthotic side, the high incidence of poliomyelitis and its devastating effects have been highlighted in our previous report. A nationwide preventative program is in progress, effects of which may be evident in the next 4 years.

Light alloys for the construction of calipers and various assistive devices, which should be easy to work with, are very much needed. We find that the aluminum alloys currently available are highly susceptible to metal fatigue and breakage.

**Psychological Aspects** — It has been possible to help most of our patients to readjust themselves to their handicaps. Most have been rehabilitated to reasonable employment; a few have continued on their original jobs. The most maladjusted are the upper limb amputees, for reasons mentioned above.

The centre was pleased to receive Mr. G. A. Engstrom of the National Institute of Handicapped Research for a review of our project activities in the summer of 1983.

**Evaluation of the Effectiveness of Modern Prosthetic/Orthotic Techniques and/or Hardware in Pakistan at King Edward Medical College**

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The project was started with the aim of investigating regarding the frequency of various types of disabilities, to examine their causes, and to evaluate in a phased way the modern prostheses and orthotic techniques in rehabilitation of the patients with their own peculiar social and cultural customs. It was started in January, 1979, and the following phases were earmarked:

1. Rehabilitation of below-knee amputees;
2. Rehabilitation of above-knee amputees;
3. Rehabilitation of upper limb amputees;
4. Rehabilitation of patients requiring lower limb orthoses; and
5. Rehabilitation of amputees requiring upper limb orthoses.

The initial phase of the project was conducted in an improvised workshop in the old hospital building, but now the work is being done in the new, fairly well equipped and well staffed Orthopaedic Workshop Building.

At present, we are beginning phase 3, and this report covers our experiences in the first two phases.

Twenty patients with below-knee amputations were fitted with a-patellar tendon bearing (PTB) prostheses. The component parts were custom-made and plaster of Paris model of the amputation stump was used for initial fabrication of socket. Basically a leather socket with a rubber lining was used which was hardened on external surface by application of layer of araldite and...
hardener. An effort is made to give the surface of the socket a color matching the patient's skin color. The willow wood shin piece is mounted on a SACH foot that is made here.

The below-knee amputees included 12 adult male patients (one of them with a bilateral amputation), 5 adult female patients, and 3 children (one girl and two boys). Eight of these patients had amputation following road traffic accidents, two resulted from war injuries, and two others suffered blast injury from a minefield. Four patients had amputation following infection, and four were congenital amputations. The patients had a variety of occupations, both active and sedentary. The residual limb sizes among adult patients ranged from 3¼ inches to 10 inches. The youngest patient was 2-years-old and the oldest was 70 years.

An elaborate examination of the prostheses and the patients was made before final checkout and gratifying experiences have been recorded. However, congenital amputees and amputation among those young in age tend to show the best rehabilitative results in terms of routine activities, including active sports. The sockets prepared with araldite have proved quite satisfactory; they are light in weight and strong.

In phase 2 of the project, 40 patients with above-knee amputations were registered, including 1 bilateral. The youngest was a child of 6 and the oldest was 65. Thirty-three were adult males and seven were adult females. Their occupations ranged from school teacher, housewife, and blacksmith to cart or rickshaw driver, tailor, shopkeeper, student, and soldier. The reasons for amputation were as wide-ranging as had been the case with the below-knee amputation group: malignancy, infection, road accidents, war, industrial accidents, and homicidal attempts were recorded. Residual limb lengths among the adult patients ranged from 8 cm to 32.5 cm.

Typical of the above-knee prosthesis used was one with a wooden anatomically shaped socket with rubber lining, mounted on a wooden thigh piece and shin piece joined by a hinge at the knee. The knee joint is fitted with a manual lock. The foot-ankle assembly is the same as that used with the PTB prostheses.

At present, suspension for the above-knee prosthesis is supplied, through a hip hinge joint, by a pelvic belt. Arrangements are being made to develop suction sockets in the near future.

Initial results of the prostheses used have been quite satisfactory. Long-term results will be evaluated in the final phase of the project.

[See also VII. Wound and Fracture Healing, Morphological and Clinical Studies of Microwounds in Ischemic Human Tissues, and Transcutaneous Oxygen Tension as Predictor of Wound Healing]

**B. Lower Limb**

**1. General**

**Automated Fabrication of Lower Extremity Prosthetic Sockets**

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**Sponsor:** Veterans Administration Rehabilitation Research and Development Service

Our study is a demonstration of the feasibility of applying computer-aided-design (CAD) and computer-aided-manufacturing (CAM) technologies to the design and construction of prosthetic sockets. Briefly, the process involves quantifying the shape of the unloaded stump, defining the mechanical properties of the residual limb, e.g., modulus and density, and using these data as input for a finite element analysis of the limb to predict what the socket shape should be so that the loads are distributed over the surface of the stump in a manner that accounts for load sensitive areas. The output of the analysis is then used to drive a numerical control cutter that shapes the socket mold.

During this report period, January 1, 1984, through April 30, 1984, our efforts have been focused in four areas.

The first has been collecting data about the economic feasibility of using CAD/CAM technologies to produce sockets. Specifically, we have been collecting information to help answer the following questions. What are the economic dimensions of the existing system? Given the limits of production and product price limits, can the proposed system be profitable? What is the likely impact of the proposed system on those who presently provide prosthetic services?

The second activity area has been to develop an automated shape-sensing instrument that provides sufficient sensitivity and is simple and quick to use. The instrument has been designed to collect the necessary data in 5 minutes or less, depending on the size of the residual limb, and a prototype is nearing...
completion with clinical trials of the sensor scheduled for June, 1984.

Most of our effort has been spent on developing the instrumentation that is required to characterize the mechanical properties of the soft tissue composing the residual limb. An ultrasonic system has been designed to define the tissue properties and the internal structure, i.e., the location of the skeleton within the soft tissue mass. The device consists of three range-gated doppler transducers that are used to measure the internal displacements of the tissue that result from the application of an external cyclic mechanical perturbation of the tissue.

The fourth set of activities has focused on selecting a finite element code that can be used in an interactive manner. A version of ANSYS has been selected and we are currently working with Swanson Analysis System, Inc., and CDC to develop the software that we will need to make the program friendly and usable in a clinical setting.

Our preliminary findings indicate that the results of the project promise to enhance the feasibility of using central fabrication facilities within the VA service delivery system and thus increase the system's capacity and ability to continue high quality care to the growing population of amputees.

[See also XIV. Miscellaneous, A Program for Evaluation and Monitoring the Dysvascular Patient]

The VA SEATTLE Foot

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Research and evaluation continue at this facility on the VA SEATTLE foot, a prosthetic foot created to improve the storage and release of gravity generated energy. Conceptually, the foot is designed to improve energy storing throughout the weight-bearing phase of the gait cycle. This energy is then progressively released as the foot continues through toe-off to rebound and propel the body forward. The kinesiology data used to arrive at the materials and engineering design were obtained under a Veterans Administration contract to conduct a comprehensive study of the development and improvement of running skills in unilateral below-knee amputees. These studies extended over a three year period terminating in June of 1984. (Doris I. Miller, Ph.D., Michael W. Passer, M.D., and Ernest M. Burgess, M.D., were co-investigators.)

The studies were conducted at the Department of Kinesiology at the University of Washington in Seattle, the Prosthetics Research Study, and the VAMC, Seattle, Washington.

The resultant joint torque patterns determine the mathematical specifications for design and materials used in the keel of the VA SEATTLE foot. A wide variety of synthetic and composite materials were tested. Simplicity of design, durability, and cost effectiveness were considered together with the force/deflection patterns needed. The foaming of the keel was initially in the general shape of a foot and suitable for shoe fitting. This shape corresponded to the one generally used in commercially available prosthetic feet. As design progressed, anatomical models were prepared so the foot would actually resemble a natural foot for those people who preferred this type of cosmesis.

At this time, the keel design and the cosmetic cover have been standardized. Bench testing has included a thorough force/motion study of all parameters of performance together with breakage, fatigue, and endurance studies. In addition to these bench tests carried out at the Prosthetics Research Study and in contract facilities, the foot has been tested at the Army laboratories, NATICK, Massachusetts. Gait research continues also in our facilities and in other established gait laboratories.

The outstanding acceptance of this component by users encourages us to recommend its broad use in the large majority of adult lower limb amputees. The VA SEATTLE foot is ready for commercialization and general availability. Data gathered from the 550 amputees who have been wearing the foot for varying periods of time over the past 3 years are being compiled by the Evaluation Unit of the Rehabilitation Research and Development Service at the Veterans Administration Central Office in Washington, D.C. The Prosthetics Research Study will continue to improve and refine the concept that has resulted in the successful development of the VA SEATTLE foot.
2. Below-Knee

Volume Changes Occurring in Postoperative Below-Knee Amputees

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

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

Hypotheses—The hypotheses in this study are the following:

1. Factors can be determined that point to the most efficacious method, among a choice of three, for achieving early maturation of stumps in recent below-knee amputees.

2. A method can be found to determine and define the stabilization point in the maturation of a stump for the purpose of choosing the proper time to fit the first permanent prosthesis.

3. The service life of the first permanent prosthesis can be extended through more precision in stump management techniques and choice of time to fit the prosthesis.

Methodology

Sample Size—A target of 20 subjects in each of three categories of stump reduction methods:

a. elastic wrap;
b. plaster cast and pylon; and
c. plastic laminate and pylon.

Measurements—Measure volume of the stump using a water displacement method, measure stump circumferences at 2, 4, and 6 inches from the distal aspects, measure circumference of contralateral calf, and record weight. These measurements are made weekly (Phase I), until fitting of first permanent prosthesis, then bimonthly for duration of first permanent prosthesis (Phase II).

Criteria for Stabilization Point—Initially an arbitrary stump-volume change rate was chosen as the criterion—that is, when the rate of change reached 1.0 ml/day, the stump was declared stable. Based on the success of that criterion during the first 2 years of testing, correlates were determined and incorporated into the study as additional criteria are mentioned in the findings.

Preliminary Findings

Subject Performance—Forty of the target number of 60 patients have completed the pre-prosthesis phase (Phase I) of the study, and are distributed nearly equally among the three stump treatment methods. Only about two-thirds of the patients enrolled in the study completed Phase I. Further, a total of 14 subjects who completed Phase I did not enter Phase II. The drop outs occurred for a variety of reasons, such as moving away, stump healing problems, further surgery, disinterest, and death. A total of 10 subjects are currently being monitored during the use of their first permanent prosthesis (Phase II). Three subjects were discontinued from Phase II, two for looseness of fit at 8 and 9 months, respectively, and one when it was necessary to amputate the contralateral limb. One subject has worn the first permanent prosthesis for over 3 years; four have been monitored for over 2 years; two have been monitored for over 1 year; the three more recent entrants into Phase II have been monitored for less than a year.

Volume vs. Time—Approximately one-half of the subjects showed a clearly defined decline in stump volume as a function of time. The balance did not. Interestingly enough, the two subjects demonstrating looseness of fit in Phase II were among those not showing a decline in stump volume.

Correlation of Circumference with Volume—A high correlation exists between circumference measured at 2 and 4 inches from the distal aspect. In most cases the correlation is significant at the $p=0.01$ level or better.

Stabilization Criteria—When stump volume and circumference relate to time during maturation, the decrease is logarithmic with time. A line of regression or curve of best fit can be drawn through the data. At the onset of the study, stabilization was declared when the rate of change of volume reached 1.0 ml/day. Because of the relative success of this, other relations have been incorporated to supplement the original criterion. These include percent change in volume and circumference: 20 percent reduction in volume, and 15 percent and 9 percent reduction in circumference at 2 and 4 inches, respectively.

The average time to reach the stabilization point is about 65 days. Those patients not showing a decline
in volume were fitted with their prosthesis after 70 days.

**Stump Reduction Method**—To date, no clear distinction has been shown between the method stump reduction and performances in Phases I and II. However, the results may be somewhat skewed. Philosophically, the individuals were patients first and test subjects second. All patients were not considered equal candidates for each of the categories. Moreover, half of the subjects showed no definable decrease in stump volume as a function of time regardless of the category to which they were assigned. Currently, no trends are seen.

**Future Plans**—The foremost goal is to incorporate at least 20 more subjects into the study to increase the reliability of results.

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

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**Hypothesis**—Below-knee amputee gait can be optimized by adjusting the heel firmness and keel length of the SACH or SAFE prosthetic foot.

**Method**—To study the effect of varying prosthetic foot heel compressibility and prosthetic foot keel length on velocity, stride length, single support time, cadence, heel dwell time, EMG, joint torques, and dynamic heel compression.

**Goal**—To reduce skin breakdown in dysvascular patients, decrease compromise of cardiac, respiratory, and musculoskeletal systems by improving energy expenditure and reducing unwanted pressure over the anterior tibia inside below-knee prostheses.

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**Analysis of Below-Knee Suspension Systems: Effect on Gait**

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**Sponsor:** Veterans Administration Rehabilitation Research and Development Service

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

**Key Questions**—The key questions expected to be answered through this study are:

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

**Methodology**—Test 20 unilateral below-knee amputees in the age range of 40 to 65 years. Each will be tested with the following seven suspension systems: (i) suprapatellar suprapatellar, (ii) supracondylar, (iii) PTB cuff, (iv) PTB cuff with waist belt, (v) PTB cuff with figure-eight suprapatellar strap, (vi) rubber sleeve, and (vii) articulated supracondylar wedge. The plan employs one PTB-type prosthesis, altered successively in the order listed. Each subject is expected to wear the test prosthesis at least 2 hours per day between weekly test appointments.

The subjects are instrumented with bilateral heel and toe switches, bilateral knee electrogoniometers, an axial stump-socket movement detector, a gimbal mounted triaxial accelerometer mounted at the sacrolumbar area, and a cord connected to a stationary tachometer. The subjects are instructed to walk at three different speeds: (i) comfortable, (ii) faster than "comfortable," and (iii) slower than "comfortable." The purpose of the fast and slow speeds is to provide challenges to the systems.
In addition to treating the collected data to the commonly used gait variables, mechanical work of locomotion will be calculated together with an efficiency figure representing the effectiveness of transfer between potential and kinetic energies. The axial movement of the stump in the socket will be analyzed for amplitude and for when in the gait cycle the signal occurs. Wave forms of the accelerometer and tachometer will be treated for harmonic ratios. Deviations in the knee, accelerometer, and tachometer wave forms will be identified and correlated to the suspensions. This scheme of testing will allow comparative biomechanical analyses within each subject and a basis for comparison among subjects to ascertain the effect on gait by the seven suspension systems.

Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

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Functional capacity in below-knee amputees relate directly to the accuracy of the prosthetic fit. Prosthesis suspension is necessary to maintain this accuracy throughout the gait cycle. Ancillary mechanisms, suction, and physiologic mechanisms contribute to prosthesis suspension.

Hypotheses
1. Below-knee amputee function can be improved by effective utilization of physiologic capabilities specific to muscle stabilized residual limbs.
2. The degree of this capability is clinically assessable.
3. Specific socket guidelines are necessary to achieve physiologic suspension.
4. Training within the prosthesis socket is an effective method for improving physiologic suspension.

Project Objectives and Methodologies
1. Create apparatus, measurement techniques, and a data base for below-knee amputee physiologic suspension parameters and performance. Establish techniques for clinical prediction of physiologic suspension capability.
   A. We have built force/displacement, surface and subsurface contour and dimension, and stump and socket volume measurements apparatus.
   B. We evaluate physiologic suspension potential clinically by determining how much weight the amputee can lift with the prosthesis without using ancillary suspension.
2. We have measured suspension factors and suspension performance in 60 definitive and 30 research prostheses.
3. Establish guidelines for optimal prosthesis design. Our socket design guidelines include:
   A. Distal m-1 measurement of the residual limb at the apex of the muscle bulge with the stump musculature contracted. VAPC calipers are used to provide appropriate tissue compression.
   B. A measurement of axial skin looseness.
   C. Premodified casting using thixotropic water clay.
   D. A vacuum casting technique.
   E. Casting with the residual stump musculature contracted.
   F. Careful molding and replication of the flares of the tibia. A radical PTB bar with the associated high popliteal pressures and deep anterior tibial relief is replaced by anatomical configurations and a selective liner.
   G. Distal molding of the skin and soft tissue during casting and use of a pull in liner (for suction and nonsuction fits).
   H. 5-10 percent tissue compression by the prosthesis (approx. \( \frac{1}{4} \)" tension).
4. Develop a technique by which the amputee can train the stump musculature for physiologic suspension. We have established a protocol using ankle weights to train for physiologic suspension within the environment of the prosthetic socket.
5. Correlate differences in performance between trained and untrained groups of amputees by applying multiple regression analysis technique to suspension factors. This analysis indicated that we were not measuring all of the relevant factors for physiologic suspension or that the sample size was too small. Volume measurement was not included. Definitive correlations could not be established.

Accomplishments—We have made two prostheses as described above during this period and project more for high performance amputees. Our training protocol continues to be followed by two or three wearers.

Despite continued work, the volume device is still hung up at the Timex computer interface.

We have established a retention evaluation protocol using ankle weights and a flexed knee.

During this reporting period we have presented this research at a regional meeting of the AAOP. Three more presentations, including the AOPA and the UCLA advanced below-knee prosthetics course, are scheduled over the next year.
Our investigation has determined that 3-D CAD and digitization technology now offer microcomputer systems capable of providing complete display and analysis of prosthetic fit clinically. These systems would be upgradable for actual socket production.

Findings
1. Appropriate prosthesis design for physiologic suspension improves existing suspension; inappropriate treatment can allow these same muscles to eject the socket.
2. Research prostheses as described above are well accepted by the two amputees presently wearing them. Both can lift approximately five times the weight of the prosthesis by physiologic components alone. Subjects wearing limbs of our earlier configuration are able to lift approximately two times the prosthesis weight by physiologic components.
3. Amputees indicate that our training protocol improves and maintains the tone of their residual limb musculature. Evaluation of test and control groups showed statistically significant improvement in tensile retention force for the trained group.

Conclusions—Both potential for and function of physiologic suspension are easily evaluated in the clinic with our methods.

Physiologic suspension can improve the suspension of any below-knee prostheses where the residual limb offers some degree of purchasable contour and where the amputee is willing to train the musculature.

Our training protocol is an effective adjunct to physiologic suspension.

Maximum benefit from physiologic suspension is derived by suction suspension systems.

Real world application of these findings is limited by commercial constraints.

3. Above-Knee

Myoelectrically Controlled Above-Knee Prosthesis: A Pilot Study

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Problem Statement—The need exists for volitionally controlled above-knee (A/K) prostheses that are more easily controlled by the amputee. In the past, control of lower limb prostheses has been largely limited to preprogrammed, passive devices that are not easily controlled. Presently, the most popular means of passive control is the use of fluid damping mechanisms at the knee joint. Passive damping control can only be made appropriate over a limited range of gait and does not provide for active movement of the prosthesis. Active control of the prosthesis permits continuous adjustment to changing gait conditions, decreasing metabolic energy usage, and the ability to respond to extraordinary events, such as stumbling.

A myoelectrically controlled pneumatically operated above-knee prosthesis has been developed at this laboratory that provides greater conscious and subconscious active control in gait and nongait activities for the above-knee amputee. The specific questions being explored during the pilot study are:

1. Can the observed limitations of the current myoelectrically controlled pneumatically operated prototype actuator, which utilizes air as the only working fluid, be obviated by replacing air with an incompressible hydraulic fluid, and continue to employ pneumatic regenerated energy storage?
2. What is the nature of time-series methods and what are the advantages and disadvantages of multichannel processing for control of prostheses?
3. How long can an amputee maintain adequate control over the prosthesis with the static spatial pattern recognition system?

Methodology

Generate alternative controller-actuator hydraulic/pneumatic configurations.
Select promising controller-actuator hydraulic/pneumatic configurations.
Derive dynamic equations for the most promising hydraulic/pneumatic controller-actuator configurations.
Conduct simulations using new model.

2. Methods for Time-Series Studies—Define the most accurate time-series representation of the surface EMG, choosing from AR, MA, or ARMA filter structures of varying order.

Identify single and multichannel processor structures and algorithms.
Implement the processors in software to simulate their real-time operation and allow performances to be monitored.
Compare system performances.
Examine effects of electrode number and location on classifier behavior.
Development of an Above-Knee Prosthesis Adaptable to a Voluntary Walking Period

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Sponsor: Waseda University

Disabled persons using conventional above-knee prostheses have not been able to walk with their voluntary walking period on level ground. The most recent above-knee prosthesis, model WLP-6 (Waseda Legg Prosthesis-6) developed in our laboratory, has the following mechanisms for amputees to enable ambulation with any walking period according to intention:

1. A mechanism for automatically adjusting damping moment around a knee joint. A damper for depressing rotation of a knee joint consists of a pneumatic piston and cylinder and a needle valve which is adjusted by a DC motor.
2. A mechanism for generating a little driving moment for walking fast. Compressed air is accumulated by an air compressor which is activated by the rotation of an ankle joint during stance phase. In the subsequent swing phase, the compressed air is injected into the piston and cylinder of a knee joint to swing the prosthetic shank.

The weight of the below-knee prosthesis of WLP-6 is 2.3 Kg and the entire weight with socket is about 3.5 Kg. The plastic reinforced with carbon fiber is used in the structural part to lessen the weight.

EMG (Electromyogram) readings picked up from an amputated leg are used as signals that enable an amputee to voluntarily control WLP-6. EMG is picked up by a bipolar surface electrode, preamplified, treated with analog and digital filters, and summed its absolute values with real time for 0.1 second at the beginning of heel contact.

The prediction algorithm predicts the next step's walking period by using EMG data. Coefficients between EMG data and walking period in the prediction algorithm are always regulated by past EMG data and measured walking period data so that precise prediction is achieved and gain variation of EMG by tiredness and perspiration is neglected. The whole software treatment of EMG—digital filtering, summation, and prediction algorithm of the next step's walking period—was assembled into the tiny microcomputer unit (ZILOG z-8 one chip microprocessor).

The control sequence of WLP-6 by the microcomputer unit during one walking period is as follows:

1. EMG is analog to digital (A/D) converted, digital...
2. The predicted walking period of the next step is calculated with EMG data by the proposed prediction algorithm.

3. The rotational degree of the needle valve is adjusted by the DC motor according to the predicted walking period calculated. The procedures 1 through 3 are terminated within a stance phase (at least 0.6 second). In the same duration, compressed air is accumulated into the accumulator by rotation of the ankle joint.

4. At a timing of a transition from flexion to extension during a swing phase, accumulated compressed air is injected into the chamber of the piston cylinder of the knee joint by turning on the DC solenoid valve to generate a little extension moment around the knee joint.

The walking experiments by the amputees were performed using the developed WLP-6 system. The microcomputer unit and the battery were attached on the subject's back. The subject walked with his voluntary walking period. The results of those walking experiments were as follows:

1. The most suitable position of the electrode of EMG was M. adductor longus.

2. The proposed prediction algorithm of the next step’s walking period was predicted within 10 percent of prediction error.

3. Subjects could walk with voluntary walking period of between 1.1 to 1.6 seconds. This walking period is almost the same as the one with which a normal person walks in daily life.

4. Subjects did not feel any burden by the weight of WLP-6 (2.3 Kg below-knee prosthesis).

C. Upper Limb

1. General

Myoelectric Controls for Orthotic/Prosthetic Systems

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Sponsor: National Institute of General Medical Services

The investigator proposes to build a myoelectric controller consisting of an implantable electrode array, an implantable telemetric device, a receiver/decoder and a low-power myoprocessor. Its purpose will be to drive orthotic/prosthetic systems with the residual neuromuscular activity of the affected limbs. The telemetric device will be powered by radio frequency. All the electronic components of the system will be miniaturized. The implantable telemetric device will be hermetically sealed in a titanium capsule.

The electrode array already has been tested in animals. The prototype circuit for the four-channel telemetric device has been designed and is near completion. Miniaturization will involve use of CMOS and a number of semi-custom integrated circuit units. Commercially available implant packages will be used to house the electronics. The prototype receiver/decoder has been built and tested; the systems function as designed and are now being miniaturized.

Myoprocessor NU-110

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Sponsor: Northwestern University
Rehabilitation Engineering Program

The design work on the NU-110, a single-site signal processor with a single output, has been completed. In its final design, the same printed circuit board can be assembled as a controller for the Michigan Hook, the Hosmer Dorrance Prehension Actuator, or a Myo-switch by changing only a few components. The Myoprocessor with a NU-126 Myotrode has a total quiescent current of only 30 microamps at 6.25 volts. Because of the extremely low power requirements, an on-off switch is not necessary.

A manufacturer has contracted for an initial production run of 25 units.

Myoprocessor NU-112

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Rehabilitation Engineering Program

The objective of this project is to develop a two-site signal processor to control a motor in two directions. This controller could be used with the NU Synergetic Hook and any commercially available electric hand.
Surface-mounted device (SMD) techniques will be used to build an extremely small circuit. This will facilitate fitting long below-elbow prostheses and children's prostheses.

The low power requirements will permit the use of smaller batteries. Four prototype processors have been constructed for trial fittings.

**Myotrode NU-126**

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Rehabilitation Engineering Program

Work on the active electrode package has been completed. The final design is a small molded unit enclosing the preamplifier, and shaped so as to be easily removed from a prosthesis. The unit contains two threaded inserts to allow the use of electrode buttons of suitable height. The cable can be replaced if broken or damaged. Cost of the Myotrode should be low enough to make it a nonrepairable, throw-away item.

A manufacturer has started an initial production run of 100 units. These will be used with the Myoprocessor for myoelectric control of the Michigan Hook and the Hosmer Dorrance Prehension Actuator.

[See also VIII. Properties of Muscle, Surface Electrode for Detecting Myoelectric Signals]

**Long-Term Recording of Voluntarily Elicited Nerve Signals**

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**Sponsor:** Liberty Mutual Insurance Company

We are developing a recording electrode unit that can easily be implanted around a severed nerve and that will continuously detect neuroelectric signals associated with functionally distinct limb movements. Our specific goal is that the neuroelectric signals will be transmitted externally to control a multiple-degree-of-freedom version of the myoelectric prosthesis, the Boston Elbow.

A recording electrode unit with these capabilities will also have countless other useful applications.

When a neuroelectric signal associated with volitional intention can be made available outside the body, it may be employed to control any number of devices or appliances in the environment. Such a recording electrode has exciting prospects: it could revolutionize both our approach to rehabilitating physically handicapped individuals and the interactions of people in general with their environments.

In preliminary experiments with rabbits, several complications affected the time duration and the amplitude of the neuroelectric signal, but we have clearly demonstrated that long-term recording of such signals from the surface of severed peripheral nerves is feasible. We must now demonstrate that the signal is related to the animal's volition. Two experiments with trained subhuman primates had limited success. With a third primate, results were ambiguous and require further consideration. We will continue our investigations into this exciting area.

**2. Below-Elbow**

**Below-Elbow Prosthetic System**

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

Design work has been completed with the exception of a holder for the battery and electronics. Prosthetics lamination techniques have been developed to mount the removable electrodes into a below-elbow prosthesis.

A manufacturer is in the process of preparing this system for production. This laboratory will work with the manufacturer in an advisory capacity.

[See also V. Functional Assessment. Quantification of the Functional Capacity of Upper Limb Amputees]