PROSTHETIC DEVICES STUDY FINAL REPORT[a]

July 1, 1958–June 30, 1970

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INTRODUCTION

The history of the research program in prosthetics at New York University, School of Engineering and Science, dates back to February 1946. At that time, the Office of Naval Research had awarded a grant of $25,000 to the School (then known as the College of Engineering). The grant was made so that research would be conducted leading to the development of a better "biomechanical knee."

The awarding of the grant to New York University was due perhaps to the interest shown by the Biomechanics Committee of the American Society of Mechanical Engineers in the improvement of prosthetic devices. This Committee included Dr. Charles Murray Gratz, orthopedic surgeon and former Naval officer, Dr. George Stetson, Editor of Mechanical Engineering, and Professor Frederick Teichmann, then Chairman of the Department of Aeronautical Engineering. The College of Engineering was approached and prevailed upon to consider this research activity.

When this program was organized, there was a very limited background history of prosthetic research or of any related research to use as a point of departure. Works of a similar nature had been started at the Berkeley Campus of the University of California, and at various Government laboratories and hospitals, with a very limited amount of research at certain industrial concerns. These programs were independent of each other with minimal integration of efforts and as yet no published material.

The initial effort, as it also developed with other investigators, was to consider the device as an entity independent of the man who was to wear it. Contacts were made with various rehabilitation centers, with

[a] A report of activities performed under VA Contract V1005M–1917.

Dr. Mandell Shimberg, Chief of the Medical Rehabilitation Clinic, at the New York Regional Office of the Veterans Administration, Dr. Herbert Elftman, Professor of Anatomy at the College of Physicians and Surgeons, Columbia University, and others.

From these contacts, and from information trickling in from various other sources, it became quite evident that consideration of the device to the exclusion of the wearer was a faulty concept. With the granting of additional funds (Contract N60NR–279) from the Office of Naval Research, and with the active cooperation of the project officer, Lynn S. Beale, Jr., Commander, M.C., U.S.N., and Dr. Clifford Seitz, Head Research Section, Human Engineering Branch, Special Devices Center, the research program was given a new direction. For anyone who may be interested in a complete report of the work done during this first program, copies of a final report (1) are now available through the Clearinghouse for Scientific and Technical Information.

Although the design program, including measurement of locomotion patterns, was continued, a major emphasis was assigned to the study of amputee attitudes and needs. This was implemented by a series of questionnaires addressed to orthopedic surgeons, prosthetists, and amputees posing a number of questions to each. The replies to the questionnaires (2, 3, 4) were to provide new guidelines governing the design of a prosthetic leg.

In 1948, a major research program in upper- and lower-extremity prosthetics was initiated, administered by the Veterans Administration. In the organization of this program, there was recognition of the fact that the group at New York University had established an interdisciplinary activity capable of playing an active role in the program. Under Contract V1001M–184 New York University, through the Research Division of the College of Engineering, agreed to perform the role of evaluator of devices that issued from the laboratories of other participants, with the interdisciplinary efforts focused on the many problems involved.

New York University was to abstain from the design of devices, but could continue with such research necessary to improve evaluative procedures. During the life of this contract, July 1, 1948, to June 30, 1958, a significant number of prosthetic devices, and major or minor components, were studied and recommendations made for acceptance, improvement, or rejection. These included the Catranis leg, the Stewart-Vickers leg, the Henschke-Mauch Knee Control, a number of Navy knee devices, the Army Prosthetic Research Laboratory's hand, hook, and glove, the UC-BL Quadrilateral Socket and SACH foot. Many manufacturing techniques were also studied.

During this period, also, the group assisted in the establishment of numerous clinics in which to conduct field tests of devices which had passed laboratory evaluation procedures. The experience with the clinics

suggested the possibility of courses in prosthetics. In 1953 the Veterans Administration funded the establishment of a prosthetics education program at the University of California at Los Angeles. A similar program was funded by the Veterans Administration at New York University in 1956. With the support of the Vocational Rehabilitation Administration (now the Social and Rehabilitation Service), an educational program was established in 1959 at Northwestern University. At the termination of this first VA contract, therefore, the New York University Prosthetic Devices Studies were engaged in evaluation and education, the former supported with VA funds, the latter with V.R.A. funds.

THE PRESENT CONTRACT

In July 1958 the Veterans Administration and New York University entered into a new contract, number V1005M–1917. The task initially assigned to New York University in July 1948 was in effect extended. In 1962, however, the direction of the study was altered to meet changing conditions in the overall program for prosthetics and orthotics.

Program July 1958-June 1962

The subject work in the initial stage of this contract was so described:

"The Contractor shall, in accordance with the instructions of the Scientific Officer, supply the necessary personnel and facilities for and conduct evaluation studies in the field of artificial limbs and related appliances, primarily for disabled Veterans Administration beneficiaries; the development of methods and instruments for evaluation of such devices; the testing of devices and techniques by physical means and/or on pilot wearers; the correlation of experiences in application of such devices and techniques in clinics designated by the Scientific Officer; and the reporting of such results, evaluations of devices and techniques, and suggestions for improvements in strength, performance, and other factors leading to better acceptance."

At the end of fiscal year 1962, the Veterans Administration, satisfied that many of the clinics were now performing some of the activities which before had been conducted only at New York University, indicated a desire to modify the program there.

In their letter dated May 21, 1962, it was stated: "We desire to concentrate on bioengineering evaluation of *major* devices wherein essentially new functions are offered, supported by prosthetic evaluation of such new devices. We do not expect to support evaluation by N.Y.U. based upon psychological or medical disciplines. Any metabolic studies which appear needed will be subject to negotiation.

We consider that bioengineering involves:

a. Objective measurements and related analyses of the motions and forces involved when an individual wears a prosthetic device, and

b. Design critiques and analyses of prosthetic components and devices in terms of their intended functions.

The prosthetic approach involves the study of the prosthetic considerations and variables, including fit and alignment, in the wearing of prosthetic devices by amputees."

EVALUATION METHODOLOGY

The evaluation procedures had evolved during the first 10-year program. These procedures had finally come to fruition in the service test of the Vickers-Stewart hydraulic leg which was completed in 1952, and which was succeeded by field tests, and eventually approved in 1958. The Hydra-Cadence device is the production model finally evolved from these efforts.

The Evaluation Team

Four groups were essentially involved in the evaluation procedures: the psychological, the performance, the engineering, and the limbfitting group respectively.

The responsibility of each group is quoted verbatim from the report on the service tests of the Stewart-Vickers leg (5).

a. "Psychological studies were used in order to obtain a firm conception of the amputees' attitudes toward the conventional leg prosthesis and the Stewart-Vickers hydraulic leg. These studies attempted to evaluate the personal and psychological requirements of each participating subject and to determine how these were met by the experimental prosthesis.

b. Performance Evaluation Studies were made in order to compare the amputee's performance while wearing his conventional leg and the Stewart-Vickers hydraulic leg. This involved a determination by a committee of gait specialists of the amputee's degree of skill with each device. In addition this group gathered information from the amputee concerning the functional advantages and disadvantages of the experimental leg.

c. Engineering Studies were performed to obtain comparable kinematic, dynamic, and time data concerning the functions of the conventional and Stewart-Vickers legs. These involved the objective measurement and analysis of specific aspects of gait."

d. Although that group's responsibilities were not specifically described in the report, the Limbfitting group was the fourth group participating in the evaluative process for any new prosthesis.

Purposes

Again we quote from the same report. In quoting from the report, however, we have substituted the expression "experimental device" wherever the portion quoted states the Stewart-Vickers hydraulic leg.

Psychological Group

"Psychological procedures have both direct and indirect application to the test of an experimental device. Primarily it is the function of the psychologist to determine the total and true nature of each pilot wearer's acceptance or rejection of a device.

"In order to accomplish this objective, it is necessary to consider the emotional and attitudinal aspects of the individual personalities of the test subjects. Previous studies concerning the psychology of the amputee have shown increasing evidence that an amputee's acceptance or rejection of a prosthesis depends not only on the functional characteristics of the device, but also upon the personality makeup of the individual who uses this device. In other words, a prosthetic device is of value to the handicapped individual it serves only insofar as it enhances the individual's adjustment to his disability while assisting in the practical aspects of everyday life.

"The psychologist's role, therefore, is to interpret and evaluate such intangibles as attitudes and feelings and their affect on the acceptance or rejection of experimental devices."

Performance Evaluation Group

"Basically, performance evaluation procedures are designed to study and compare an amputee's use of his conventional prosthesis to his use of an experimental device. Evaluation of one's use of a prosthesis involves a definition of ideally efficient performance and a comparison of the subject's performance to the accepted standards. Such factors as naturalness of appearance . . . . . ease and technique of performance, as well as confidence and security with the prosthesis are included in the concept of an amputee's use of an artificial limb.

"Evaluation procedures, accomplished with the same amputees wearing first their conventional [device] and then the experimental device, yield comparative ratings of the prostheses in terms of the closeness of their approach to ideal standards of performance. For this process to be meaningful, the activities used during performance evaluation must be practical and important to the subject.

Engineering Group

"Although psychological and performance tests shed light on certain aspects of the experimental device under test, their data are by nature relatively subjective. . . . . In order to supplement these findings with purely objective data, engineering procedures and equipment are introduced to test the performance of the experimental device while it is being worn by the amputee.

"The methods used in the engineering evaluation of the experimental device aim at the controlled comparison of certain features of gait which

are adjudged to be significant and important to the quality of performance. Previous studies have indicated that the major differences between the performance of the prosthesis and the remaining normal limb..... are to be found in the temporal, kinematic and kinetic characteristics of movement."

Evaluation Techniques

Although the precise techniques to be used in any evaluation must vary with the particular nature of the device, the general nature of the technique used in the evaluation of devices may be described.

Psychological Testing

In the psychological testing of the amputee certain test instruments generally were used:

I. The California Test of Personality—Adult Form A
II. The Ascendance—Submission Reaction Study
III. The Clinical Interview
IV. Progressive Interviews.

Performance Testing

In the course of performance testing many of the instruments used were tailored to the particular device. For example, in the performance evaluation of an above-knee prosthesis, certain gait characteristics were checked. These included: swing phase rearward; heel rise on normal side; swing phase forward; timing of heel-contact; arm swing, prosthetic side; lumbar lordosis; lateral bending of trunk; lateral dipping of pelvis; abducted gait (side-sway); circumduction; general appearance of gait; off-guard appearance of gait.

The performance of certain general activities would also be evaluated. Activities in the case of above-knee prosthesis could include: ramp ascent and descent (14 deg.); metal stair descent, with railing; ascending earthy hill; ascending and descending rocky hill; descending grassy hill; descending stone stair without rails; ascending and descending steep grassy hill; and general performance.

Engineering Testing

Engineering evaluation tools and techniques were many. They are described in detail in other reports and chapters on biomechanics (6, 7). To enumerate a few, there are:

1. Force plates, to measure ground reaction forces in locomotion and other weight-bearing activities;
2. Interrupted light camera, to stop, at sequential intervals, "instantaneous" positions of a progressing movement;
3. Motion picture photography, to achieve similar results;
4. Tachography, to measure the instantaneous velocity of a point on the body in the performance of a movement;

5. Accelerometers, to measure forces at some location on the body;
6. Pressure sensors, to measure force per unit area on some part of the body.

THE DEVICES AND TECHNIQUES

A large number of devices and a limited number of techniques were studied and evaluations made during the period July 1, 1958, when the new contract started and December 31, 1962, when the support of the evaluation program was assumed by the Office of Vocational Rehabilitation. A listing of the major items considered is shown in Table I.

It must be noted that the starting and terminating dates are approximate, the data being taken from monthly and quarterly progress reports issued by New York University. The starting date is assumed to be when the device was first reported. The termination data is given as that indicated in some progress report or that period in which the last report of a device appeared. A further complication is that unless there is specific mention, the start or end of the study may have occurred at any time in the 3-month period. For purposes of preparing Table I, it has been assumed that a program began during the first month of the period in which it was first reported and ended in the last month of the period in which it was last reported.

It would be impractical to describe in great detail all the devices that were evaluated during this period and it is hoped that the comments in the right-hand column of Table I will be sufficient for most purposes. A few of the more important devices are reported and the material is based on that which has already been published.

Henschke-Mauch "Hydraulik" Swing Control System (Item 24) (8)

This unit "consists of a sealed hydraulic cylinder which is attached to a specially designed knee block of laminated plywood and is contained within a wood shin to which it is also attached. Attachment of the unit at the knee block is accomplished by two knee straps which are held in place by the knee bolt and by a pin passing through the piston rod and into a pair of Superoilite bearings. This point of attachment is superior and slightly posterior to the knee bolt.

"An adjustment screw which is accessible on the anterior aspect of the shin allows for changes in the flexion-extension attitude of the knee. A knurled ring at the top of the hydraulic cylinder, which is accessible from the rear of the shin, permits independent adjustment of flexion and extension resistance. Above the ring is a rubber boot which is designed to prevent the entrance of foreign particles into the system."

The device "is designed to enable above-knee amputees to walk at various walking speeds or 'cadences,' and to do this in a natural-appearing manner. This is achieved by controlling swing forces about

the knee joint of the prosthesis, closely approximating the muscle forces acting during the swing of a natural leg. The system, once properly adjusted to the 'normal' gait of an amputee, need not be reset if he desires to vary his speed, the unit being self-compensating in this regard. Furthermore, once adjusted, swing characteristics should remain stable with use and not require readjustment."

In order to verify the developer's claim a limited series of five production model units were fitted by the N.Y.U. study group. These units, over the duration of the test, were worn by more than one subject and for a minimum time of 77 days for one unit, to a maximum time of 133 days for another unit. Certain minor problems developed, but generally both the subjective responses of the wearers and the observations of the test group were favorable. Accordingly, the device was recommended for field tests.

The item made available for the field study presumably was a production model. The field study was designed to duplicate, insofar as possible, the conditions which would prevail in general clinical practice. All cases were processed either through Veterans Administration or civilian amputee clinics. All fittings were accomplished by prosthetists without prior experience in the installation of the experimental unit.

The alignment of the prosthesis normally being worn by the amputee was duplicated in the experimental setup by use of an alignment duplication jig. Initial reactions of all involved were solicited and recorded. The subject was given appropriate training and instructions. Clinic evaluation visits were made by the amputee subjects after periods of 1 month, 3 months, and 6 months. At each such visit mechanical checkups and subjective questioning were conducted. A final visit was scheduled at the end of 12 months of wear.

Seven clinical facilities and 12 limb shops participated in three areas—New York, Chicago, and Los Angeles. Eighteen amputees were fitted. A number of observations were made during the course of the study. Suggestions for modifications to both the mechanism itself and the knee block were recommended to the developer.

At the time of the report several of the units had been functioning for over 2 years and a statement in this report was made to the effect that:

"1. The original Mauch units were basically well made and durable, but with defects requiring correction present in some of the systems.

"2. These defects have essentially been corrected and their source eliminated in the current systems."

It is interesting to note in the report that although the reaction of the subjects was generally favorable, 16 of the 18 accepting the Mauch unit at the end of the study, the clinic teams were at that time much more wary in expressing their opinions.

Other devices, although not in all instances, were processed similarly when it was warranted.

Metabolic Measures (9)

Throughout the course of the contract, even as in the previous one, considerable thought was given to ways of improving evaluative procedures. The desire for objective measures was paramount, although subjective observations were seriously considered in each evalution.

From the past experience of some members of the staff, from observations during the course of previous studies, and from discussions with other similarly concerned research people, it was decided that metabolic measures would provide such objective data. In fiscal year 1960–61 the Prosthetic and Sensory Aids Service of the Veterans Administration decided to support studies at New York University to determine the feasibility of applying energy measurement techniques to the evaluation of prosthetic and orthotic devices.

In all human activity there is an expenditure of energy. Even when there is no movement, a certain amount of energy expenditure occurs merely to maintain the necessary body processes. This minimum energy is called the basal metabolic cost. When any activity is performed, there is added to this basic amount an additional energy expenditure that is required to overcome external and internal resistance to the movement.

By computation, given certain known characteristics of the segments involved in the movement, and the physical characteristics of that movement, the external work done can be obtained with a fair degree of accuracy. The internal work cannot be computed. It may be obtained with some relative accuracy by experimentation. For this purpose a particular program was devised.

General Procedures

Standard metabolic measurement practices were used. These included indirect calorimetry (the amount of oxygen consumed) and the open-circuit technique (analysis of respired air samples). Since blood pressure and pulse rate are related to oxygen consumption, these two were monitored at the same time.

The tests were conducted as rigorously as conditions allowed. The subject was given a rigid set of instructions to which he was to conform to maintain reasonable uniformity in successive test periods. The test procedures, too, were carefully organized to maintain reliable results.

Experimental Studies

Four studies were attempted:

1. The effect of anterior-posterior knee joint alignment on energy expenditure in walking with an above-knee prosthesis;
2. The effect of shank center-of-gravity location and mass moment of

inertia on energy expenditure in walking with an above-knee prosthesis;

3. Energy expenditure of walking on an above-knee prosthesis with conventional and hydraulically controlled knee, and
4. Energy cost of walking with a long leg brace with the knee joint locked and unlocked.

Results

1. The hypothesis for Study No. 1 was that a knee in "trigger" alignment would require less energy in extension and more than compensate for the energy required to maintain a stable knee. Based on the results, this hypothesis was refuted. It was found that the knee in stable position required less energy expenditure than the knee in an "optimal" position, and still less than the knee in "trigger" position.

The main question raised in this study is that the 12 test trials on one subject may have been inadequate for reliable statistical analysis.

2. The hypothesis for Study No. 2 was based on the physical principle that given two masses having identical external envelopes, both being swung from a center similarly located, that one with the greater mass will require more energy to swing it; and another physical principle that given a mass within a prescribed envelope, the disposition of the mass will affect the energy cost in swinging. That component with the center of mass further away from the center of rotation will require the greater energy expenditure.

The hypotheses were generally confirmed. Although the net oxygen consumption did not vary greatly from one test to another, the increase in oxygen consumption always occurred as anticipated.

3. The development of the hydraulic knee was predicated on two factors: the first, that by controlling terminal acceleration of the swing a more normal appearance of gait would be obtained; the second, that energy expenditure on the part of the amputee should be reduced by appropriate damping action in the prosthesis. This latter consideration was to be tested.

Unfortunately, the weight of the prosthesis incorporating the hydraulic unit was considerably heavier (about 25 percent) than that without. This factor would normally tend to increase the energy expenditure in locomotion. The results were not necessarily conclusive. The hydraulic leg required more oxygen per minute per pound of body weight, but not enough more as might be anticipated by the increased energy required by the weight differential. In fact, it would be reasonable to assume from the data developed that pound for pound, a prosthesis incorporating an hydraulic device would require less energy expenditure than a conventional device.

4. The study (No. 4) was to test on a normal subject a long leg brace with the knee locked and unlocked. It was hypothesized that a locked brace should require greater energy expenditure. The results tended to confirm the hypothesis.

In the conduct of this last test certain intriguing possibilities developed which, unfortunately, could not be carried to fruition.

In addition, to the specific information sought after in these four studies, correlation studies were made between pulse rate and blood pressure versus oxygen consumption. It was found that a fairly consistent relationship existed between energy cost (oxygen consumption) with both pulse rate and blood pressure, but that this relationship became less significant as the severity of exercise increased. It seemed evident, therefore, that for an objective measure of the relative energy cost of varying devices on an amputee, metabolic techniques were desirable.

The Henschke-Mauch "Hydraulik" Swing and Stance Control System

The successful result with the production model of the Henschke-Mauch Swing Phase unit was immediately followed by a careful evaluation of the Swing and Stance Control System. This latter system incorporated, besides the successful swing-phase control, a hydraulic valving system that provided support in the stance phase. This support which would become effective at any time during the return from maximum knee flexion was provided with a relief valve system, such that it would release at some predetermined load to prevent harm to the amputee in certain unusual situations. The model which was to be evaluated had evolved from a long series of tests in its preliminary stage.

This evaluation program, therefore, had to incorporate procedures which would assess these added characteristics and also judge the life of the unit under normal conditions, and its performance under a variety of extreme conditions.

Bench tests were devised to check the weight-bearing characteristics of the unit, the relief valve system, performance under possible extremes of hot and cold, and consistency between units.

Several pieces of test apparatus were developed. A "constant torque drop test device" and an environmental chamber for the unit were the major fixtures. The first test fixture was for the purpose of loading the model with a predetermined load and noting the deflection characteristics. The load could be varied as desired; consequently the relief valve characteristics could be measured, as well as the performance under hot and cold temperature extremes.

Two controlled environmental boxes, rather conventional in their design, were fabricated. The first maintained a temperature of 130 deg. ± 10 deg. F. for the warm extreme and the second a temperature of 30 deg. ± 10 deg. F. for the cold extreme.

The "Hydraulik" Swing and Stance Control unit essentially met the developer's claims for torque, overload relief, temperature effects, and consistency among units.

Biomechanics tests included all those normally administered and some innovative features such as tri-axial accelerometer at a point near the center of gravity of the subject and angular accelerometer locations on the prosthesis or normal limb. Complete biomechanics data were acquired in most instances, enough to make a decision in favor of the Henschke-Mauch device as compared to the conventional prosthesis similarly fitted. As a result of this series of tests a whole program based on accelerographic analysis of normal and pathological gait evolved. Results were reported in the A.S.M.E. paper 64–WA–HUF–8 (10).

Subjective evaluation procedures were followed as they had been for many previously tested devices. The reactions of the amputee subjects as to the performance of the unit under a variety of conditions, their problems with adjustment of control elements, the use in walking on ramps and stairs and on various types of terrain, malfunctions, and other factors which influenced their judgment, all were noted. The prosthetist too was questioned as to the problems presented by the unit and its general application to the problems involved in the training of the amputee.

As a result of this intensive battery of evaluation devices and techniques, the Henschke-Mauch Swing and Stance Control System was recommended for general application.

Subsequently the Veterans Administration conducted a clinical study upon the recommendation of the Committee on Prosthetics Research and Development. The device has received high acceptance among the amputee population.

BASIC STUDIES (Socket Pressure and Slip Studies)

At the conclusion of the evaluation of the Henschke-Mauch Swing and Stance Control system, the group, with the consent of the sponsor, abandoned evaluation in favor of more basic research into locomotion. Several programs were developed: accelerographic analysis of pathological gait, factors which may predispose some people to fall more than others, and pressure distribution within the socket. This last program was supported by the Veterans Administration and is reported upon at some length, although more complete material may be found in references 11, 12, 13, 14, 15.

Introduction

The pressures and motions developed at the socket-stump interface are significant with respect to the comfort, stability, and proprioceptive sense experienced by the amputee. While the basic mechanics of walking

dictate the loads necessarily transmitted through the socket-stump interface, it is clear that the pressures locally developed may depart considerably from mean pressures estimated from overall load considerations. Indeed it is this very departure, influenced by local fit and stump stiffness, that is of particular interest.

Little work had been done in this area prior to our entry; the only known dynamic pressure results (16) are based on pneumatic transducers sampling relatively large areas (25 sq. cm.). Such devices have large inherent phase lags and a low frequency response; the results obtained are thus subject to considerable "smoothing" or "slurring." To improve this effort, more sophisticated devices are necessary; devices able to sense local "squeeze pressure" or compressive pressure between the stump and socket. Devices capable of registering the tangential or shear pressure were also required, in addition to a means of registering relative motion between the stump and socket.

Instrumentation

The search for suitable instruments (circa 1965) uncovered a great number of potentially useful transducers, many of which were purchased and tested. It was learned that all of the tested, commercial devices (Filpip, Whitney Gage, various differential transformers, and piezoelectric transducers) were subject to serious drawbacks when applied to the stump-socket interface problem. Specifically, the Filpip proved unreliable in calibration, the Whitney difficult to seal, the differential transformers hypersensitive to mounting conditions, and the piezoelectric devices (which do not respond to a steady application of load) difficult to calibrate. A report (17) of a workshop sponsored by the Committee on Prosthetics Research and Development discussed many of the problems associated with this research.

Accordingly, a special series of transducers was developed to suit the particular needs and environment existent at the stump-socket interface. Pressure measurements were achieved with conventional wire-type strain gage elements arranged to signal deflections of a beam impinging on the stump through ports machined into the socket wall. By alternating separate units, the measurement of compressive and tangential pressures sequentially at a given locale was obtained. Both gage types were mounted flush with the socket wall and offered a stiffness roughly corresponding to that of the socket proper. In this manner, the stump flesh sensed the gage as a continuation of the socket-wall, not as a discrete lump.

To obtain relative motion, a pen-type marker was mounted in the port in such a way as to lightly scribe on the stump skin. Relative motion between the stump and skin produced a pen line on the skin. The length of the line so produced was simple measurement of the motion. In the

event that the relative motion possessed an uncertain or random quality, the line drawn would thicken and occasionally produce a filled-in circle as each successive step contributed a different chord line within an envelope representing maximal motion.

Pressure data were recorded on a suitable oscillograph and evaluated by hand. Peak pressures were sought as a form of output, in addition to the pressures developed at significant times within the stride period.

Test Program and Results

Volunteers were recruited from a list of amputee subjects. Test sockets were made, duplicates of their own sockets, with provision for the placement of the normal force and shear measuring transducers. The socket and adjustable leg were fitted to the amputee, and alignment was as close to the alignment of the amputee's own prosthesis as the techniques and experience of the fitter and therapist could provide.

Sampling sites were distributed about the socket in a reasonably uniform fashion, with the exception of the brim, which contained a higher site density. Typically, in evaluating the effect of a given variable some 30 sites were sampled within a test socket of two to four above-knee subjects.

Compressive Pressure Results and Comments

The results indicate that maximum instantaneous compressive pressures varied from a small negative value (at the distal end of the stump to +50 p.s.i. (on the brim, near the ischial seat). Typical maximum pressure values in the mid-shank section were in the +3 to +5 range. In general compressive pressures are lowest at the stump distal region and highest on the brim. Day-to-day variations in pressure can be large; i.e., a given site may experience a shift of compressive pressure equal to 3 p.s.i. Run-to-run variations can also be large (it is understood that the shifts described are remainders after allowing for variations attributable to experimental error); in one exceptional instance continued walking resulted in a reaction of some 20 p.s.i. of compressive pressure at a given site, apparently by shifting the local load center several inches along the socket. That is, a corresponding increase in load appeared at a sampling site several inches from the first.

It follows that compressive pressure cannot be viewed as fixed, even for a given subject-socket combination, but rather as a highly variable parameter, sensitive to the precise placement of the stump within the socket and those local changes in anatomical local configuration experienced even in the course of hours of leg usage.

Investigations of the effect of leg alignment modification upon local compressive pressures were conducted with a practical application in mind, the possibility of augmenting normal alignment procedures by means of a local pressure check. In this manner, one might hope to

"fine tune" the alignment of a given prosthesis to some objective standard such as the minimal impulse imparted to the socket in gait or perhaps some desired pressure distribution consistent with comfort requirements. In practice, we found that only large changes in alignment or prosthesis makeup could be discerned through a reasonable number of local pressure readings. The difficulty is partly derived from the variant nature of gait (no two steps are quite alike) and the known day-to-day variations in local pressure previously discussed. Determining the true pressure at a given site is a statistical undertaking in which the standard deviation is large (i.e., much data are required to arrive at an accurate mean). In general, the shift in the mean local pressure produced by an alignment change is small; indeed, the shift is usually within the scatter range to be expected of normal time dependency. Separating that change due to alignment alteration from that due to passage of time is not simple. Data accumulation and processing are burdensome.

A second difficulty is the disparate reactions of local pressure to a given leg modification. For example, in one subject medial-lateral pressures were found quite sensitive to the adduction-abduction setting; in another subject equal alteration of the same variable produced no change in response. It follows that the response to alignment change may be of a complex nature where the subject's reaction is not necessarily predictable. In our view, employing a knowledge of local pressure as an alignment tool currently is of doubtful practicality where small order modifications are involved.

Eventually, as more research is conducted and more data are gathered, it is anticipated that this may change. It may then be possible to offer some objective technique to implement the experienced fitter's judgment.

Tangential Pressure—Results and Comments

Tangential pressure, or some pressure developed in the plane of the stump skin, may be viewed as analogous to a friction loading on the skin. Experimental results support this view and indicate a coefficient of friction of approximately 0.3 to exist between the skin and socket. However, the local tangential pressure is not always directed along obvious force lines. Thus in the stance phase, when the basic load imparted by the stump to the socket is clearly defined in direction (downwards), a number of sampling sites will display an upwards load. Implicit is a discontinuous distribution of tangential pressure, in turn probably due to a discontinuous skin tension in the stump produced by skinfolds, local "hard" spots, etc.

Slip Measurements

Slip measurements, in above-knee suction sockets indicated the slip to be limited to small fractions of an inch. Never greater than ¼ in.

even in the case of a poorly fitted or improperly donned socket, most slip motions are $\frac{1}{16}$ in. or less. The precise nature of fit, even including the manner of donning the socket, is the key factor in establishing slip magnitude. In general, the larger values of slip motion occur in the distal portions of the socket. As the brim was approached, slip motion decreased, until at the anterior and lateral brim no instance of appreciable (i.e., $>\frac{1}{16}$ in.) slip was detected.

Comparisons between Sensors

Recently, small pressure gages have become commercially available leading to the possibility of routine clinical pressure testing. The aspirin-like form of these devices permits simple mounting to the inner wall of the socket, an impossibility when employing any of the N.Y.U. transducers previously described. It became of interest to test the new gages on a comparative basis to ascertain effectiveness. In particular, the effect of the protruding aspect of the newer gages was sought, since the N.Y.U. transducers were mounted flush within the socket, and the newer gages necessarily extended into the stump domain from the wall.

Sequential testing was performed on given subjects, equipped with a flush N.Y.U. small compressive pressure gage, a deliberately protruding ($\frac{1}{16}$ in.) N.Y.U. compressive pressure gage, and a Sensotec clinical gage. It was learned that the employment of a protruding gage generally increases the pressure value obtained, as compared to a flush type. The extent of the increase depends largely on the local stump stiffness. At the brim, in the vicinity of the ischial seat, loads recorded with the clinical gage averaged three times those recorded with the flush mounted gage. In the most severe cases this ratio increased to five. In a region of soft flesh remote from bones, there is little difference in results. It is clear that clinical application of the Sensotec gage requires careful assessment of the results. It also follows that minor contour changes at strategic locations within the socket may produce striking effects on local pressure values. In other words, the results to be expected in terms of local pressure from minor socket alterations or minor stump form changes may be of a larger order. Thus frequent reworking of the socket on the basis of complaints by the user may well have a real basis of need.

Efforts to learn the effect of distal inserts on overall socket pressure characteristics were not completed within the program period. It may be said only that fragmentary data, gathered on one subject equipped with two distal pads, showed no clear trend of results.

The Future

Concerning future steps the need now is to develop the physiological significance of the local pressures and motions, for it is from the integration of the engineering approach (given above) and the biological

approach that practical applications will result. For example, the practical problems of edema formation, tissue damage, ulceration, cyst formation, and stump pain are most probably related to "engineering" factors, physiological factors, and dermatological factors. While approaches to the listed problems have been made within each of the listed professions, there appears to be little or no interaction between professions. The next step may well consist of a combined, multi-professional approach to those problems given above.

CONCLUSIONS

The Research Division participated in a variety of programs in the area of prosthetics during the 22 years it enjoyed support from the Veterans Administration (Table 1). In that period it not only enjoyed financial support, but in most instances received help in other forms, either in facilities, or in experienced personnel. In turn, the Research Division personnel contributed to the training of Veterans Administration personnel, particularly those of the Bioengineering Laboratory, at 252 Seventh Avenue, New York, N.Y., now a part of the VA Prosthetics Center. At all times contacts with Dr. Eugene F. Murphy and Mr. Anthony Staros were cordial and helpful to the program.

Among the many techniques that were introduced or modified for use in the evaluation process, these seem worthy of attention:

1. The introduction of the use of statistics, especially the "t" test to determine the significance of differences between activities performed with the new and conventional prostheses.
2. The introduction of the ratio of step length on up-and-down ramps to the step length in level walking.
3. The introduction of displacement curves in interpreting walking studies.
4. The introduction of the gliding cyclogram as a technique especially where action takes place in a limited area.
5. The introduction of mass center oscillations (registered on force plates) as an evaluative procedure.
6. The introduction of accelerographic techniques in locomotion studies.
7. The application of harmonic analysis to acceleration patterns in locomotion studies.
8. The development of the tachograph for recording electrically instantaneous velocity changes.
9. The initiation of electrogoniometric techniques for studying elbow flexion-extension patterns.

10. The replacement of motion picture techniques in knee-joint resistance studies with direct kymograph records.
11. The suggestion to use motion picture photography in conjunction with the glass walkway contactograms.
12. The use of static and dynamic stability tests as evaluative techniques.
13. The use of a balancing platform as a measure of self confidence of the amputee on a prosthesis.
14. The use of X-ray pictures in the study of the SACH foot.
15. Heel elasticity tests in conjunction with the SACH foot.

There undoubtedly have been other contributions of lesser nature, and of course the major contribution at the very beginning of the initial contract was *the introduction of subjective criteria, and the correspondingly appropriate research personnel.*

There have been disappointments and frustrations, but essentially the program has been a rewarding one, both for those who participated in it and for the amputee population that was served by it. We regret its ending.

TABLE 1

Device tested	Period reported	Comments
1. Blevens B/K	Through December 1958	Difficulties experienced. Final report prepared April 1959.
2. Stewart-Vickers Hydraulic	Completed July 1958	Approved for production.
3. Henschke-Mauch Swing Phase Production Model	August 1958 through March 1961	The tests included a field study and reports were generally favorable.
4. Canadian Hip Disarticulation	July 1958 through January 1959	No progress was reported and apparently the program was never fully developed.
5. Canadian-Type Syme	Through November 1958 when Phase III tests were started continuing until November 1959	Several failures were experienced during the series and a final report was issued in November 1959.
6. Navy B/E Socket	Through December 1958	Study stopped to await revised construction manual. No mention of having been resumed.
7. Navy A/E Socket	Through December 1958	Complete study with positive results indicated.
8. APRL Arm Alignment jig	July to October 1958	Complete study with final report indicating approval.
9. APRL Ratio Change Velocity Lock Elbow	Through September 1958	Reduced to inactive status December 1958.

TABLE 1.—*(Continued)*

Device tested	Period reported	Comments
10. VAPC Hydraulic Leg Cycling Device	Through March 1959	This was a joint development program involving VAPC and NYU.
11. Navy B/K Socket Closed End, Semi-flexible	August through November 1958	No comments as to its outcome.
12. Hosmer FD-100 Wrist Unit	August through November 1958	Results were positive; a program model was being awaited in January 1959.
13. Sierra Model 280 Wrist Unit	September through November 1958	No comments as to outcome.
14. B/E Step-up Hinges	September, October, November 1958	Reduced to inactive status.
15. Hosmer E-400-2 Elbow Unit	October 1958	Reported on just this once with no comments.
16. Navy B/K Clevis Joint	Started November 1958; stopped January 1959, resumed January 1960, completed September 1960.	Tests started, returned to developer; resumed; final report approved device with reservations.
17. Navy Molded Foot	November 1958	Reduced quickly to inactive status.
18. UCB Polycentric Knee	December 1958; resumed July 1960 till December 1961	Although subjects were recruited in 1958, no units were received till July 1960 and these were returned to the developer in June 1961.
19. UC-BL Knee-Bearing Joints	December 1958 to February 1958	Subjects were recruited but difficulties were experienced. The devices were sent back to the developer and a memo report issued in April 1959.
20. UC-BL Rotation Ankle	December 1958; January 1961 through March 1962	Preparations for tests were made in December 1958. Delays were then encountered and a modified ankle with a SACH foot was received in the January 1961 period. A favorable report based on work with three subjects was published early in 1962. It recommended the consideration of the device for A/K subjects.
21. APRL Ethocel Biceps Tunnel Pin	February 1959	The study was conducted and completed in 1 month.
22. Hosmer PL-100 Positive Locking Wrist Unit	February 1959 through September 1959	Design changes were recommended in the report issued to the developer.

TABLE 1.—*(Continued)*

Device tested	Period reported	Comments
23. APRL Porous Laminate Sockets	February 1959 through December 1960	A report approving the technique, but with some reservations, was issued in late 1960.
24. Henschke-Mauch Swing and Stance Phase Hydraulik Leg Production Model	April 1959 through December 1964	This device went through a series of revisions during this period, being returned several times to the developer. It was field tested by N.Y.U., given extensive engineering tests, and finally released for VA field tests in December of 1964. (See detailed comments in text.)
25. UC-BL B/K Fabrication Technique	April 1959 through December 1960	The technique was evaluated and a preliminary report made in June 1960 favored it. A final report was issued December 1960 favoring it with reservations.
26. Nielson Glove, Production Model	April 1959 to December 1959	A report was issued to the developer indicating some problem areas.
27. Navy Molded Foot (Revised)	April 1959 to December 1960	A number of difficulties were experienced with this foot and reported to the developer. The device was finally approved with reservations in December 1960.
28. Regnell Hydraulic Knee	May 1959	No comments noted; apparently not much was done.
29. Sierra V.O. Hand Size #4	April 1960 to December 1960	A report to the developer was made in the period July to October 1959, and work was resumed in April 1960. No further comments appear after December 1960.
30. Hosmer E-400-2 Elbow	October to December 1959	No comments were made; no action reported.
31. APRL Epoxy Laminate Technique	April to September 1960	No comments made in the report.
32. APRL Milton Dilaminar Cosmetic Gloves	April 1960 to December 1962	Difficulties were experienced early; defects were reported January-March 1961, a letter report was issued January-March 1962, and a new series of tests initiated in July 1962; final results not indicated.

TABLE 1.—*(Continued)*

Device tested	Period reported	Comments
33. Robin Aids V.O. Hand Size #8	July 1960 through June 1961	A report of further investigation being necessary was made in the period October-December 1960. Difficulties continued and the program was terminated April-June 1961.
34. APRL Cosmetic Leg Cover	July to September 1960	Reported in quarterly reports without comments.
35. UC-BL Streamlined B/K Joints	October to December 1960	Reported in the January to March 1961 report that it was discontinued.
36. UC-BL A/K Quadrilateral Socket Brims	January 1961 through December 1961	Limited progress was reported.
37. APRL Acrylate Liner B/K	January 1961 to June 1961	No special comments reported.
38. NU Adjustable Hip Disarticulation Joint	April through December 1961	The device was favorably discussed in the report.
39. VAPC Adjustable Coupling	April through December 1961	Last comment noted was report of difficulties.
40. NU Single Control Elbow	April 1961 through December 1962	A favorable report was issued in the final quarter of 1962.
41. APRL Acrylate Gloves	April to June 1961	Mention of these appeared only in one report without comment.
42. Energy Studies	April through September 1961	Studies were discontinued in September probably due to the departure of the principal investigator. A report appeared in March 1962. The study is commented upon in greater detail in text.
43. Prosthetic Evaluation Scale	April through September 1962	Undoubtedly this work had been started before the date indicated since the first report indicates the scale was ready for evaluation. It was delayed in late 1962, and probably resumed under OVR auspices.
44. Biomechanics Program	April 1961 through December 1962	The engineering staff was augmented to work with the VA staff in the updating of VAPC laboratory equipment.
45. Henschke-Mauch Swing and Stance Control	October 1961 through December 1964	The study was initiated on the completion of the swing-phase model and concentrated on the mechanical and biomechanical

TABLE 1.—*(Continued)*

Device tested	Period reported	Comments
		characteristics of the device. A VA field study was undertaken upon the termination of the engineering evaluation. More comments are included in the text.
46. UC-BL Pneumatic Knee (Polycentric)	October 1961 through December 1962, December 1964	The study was reported on first in October 1961 and no further reports were made after December 1962. Undoubtedly this was continued under other auspices, although mention is made in the December 1964 report.
47. APRL Porous Laminate	April through December 1961	No comments appear in these reports as to the adequacy of the material.
48. UC-BL A/K Total Contact Technique	January 1962 through December 1962	This technique was tried and reported as satisfactory.
49. APRL VO Hand	January 1962 through September 1962	The short study reported the VO hand as generally acceptable.
50. UC-BL Pneumatic Swing Control	April 1962 through December 1962, December 1963	This study was conducted without comments in the various progress reports. It undoubtedly was interrupted in 1962 due to the transfer of evaluation responsibilities from VA to OVR auspices. It appears again without comment in the December 1963 report.

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