PRESSURE AND FORCE MEASUREMENT

A REPORT OF A WORKSHOP SPONSORED BY THE
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
OF THE DIVISION OF ENGINEERING
NATIONAL RESEARCH COUNCIL · NATIONAL ACADEMY OF SCIENCES

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held at the Bioengineering Laboratory
Veterans Administration Prosthetics Center
New York City May 27-28, 1968

NATIONAL ACADEMY OF SCIENCES
Washington, D. C.
1968

REPORT

WORKSHOP ON PRESSURE AND FORCE MEASUREMENT
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT

BIOENGINEERING LABORATORY

VETERANS ADMINISTRATION PROSTHETICS CENTER

New York City May 27-28, 1968

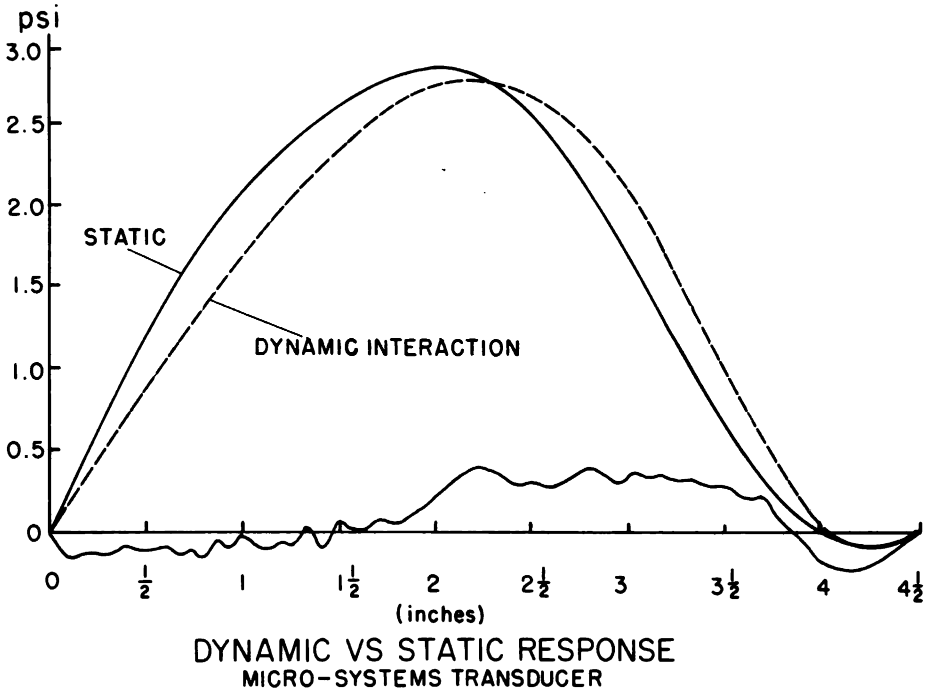
Mr. Anthony Staros, Director of the Veterans Administration Prosthetics Center, opened the meeting at 9:00 a.m., and welcomed the participants on behalf of the host agency. Noting the absence of Mr. A. Bennett Wilson, Jr., because of illness, Mr. Staros introduced Dr. Herbert Elftman, Chairman of the Committee on Prosthetics Research and Development, who extended greetings from that Committee. He expressed the hope that all problems of pressure would be solved during the forthcoming discussions, including problems of pressure on CPRD. Dr. Elftman then presented Mr. Colin A. McLaurin, the Chairman for the meeting, who told of the continuing concern of CPRD's Subcommittee on Design and Development with pressure effects and pressure measurements. A prime reason for holding the workshop meeting was to enable participants to learn what others were doing in pressure measurements. The meeting then followed the agenda (Attachment 1). A list of the participants is included in this report as Attachment 2.

I. REPORTS FROM PROJECTS

A. New York University (College of Engineering)

Mr. Francis A. Appoldt of the Special Projects Group, New York University, opened the technical aspect of the program with a talk-slide presentation and a live demonstration concerning the pressure measurement work being done by his group. Mr. Appoldt mentioned that the NYU group had earlier worked with transducers developed by Microsystems and then had decided to develop their own transducers as back-up. The characteristics of these transducers are presented in Chart I. (See also Figs. 1 and 2.)

According to Mr. Appoldt, the work pursued at NYU essentially involves provision for the insertion of flush-diaphragm transducers and the recording and analysis of pressure profiles at 25 points in the wall and brim of above-knee total-contact sockets.


psi
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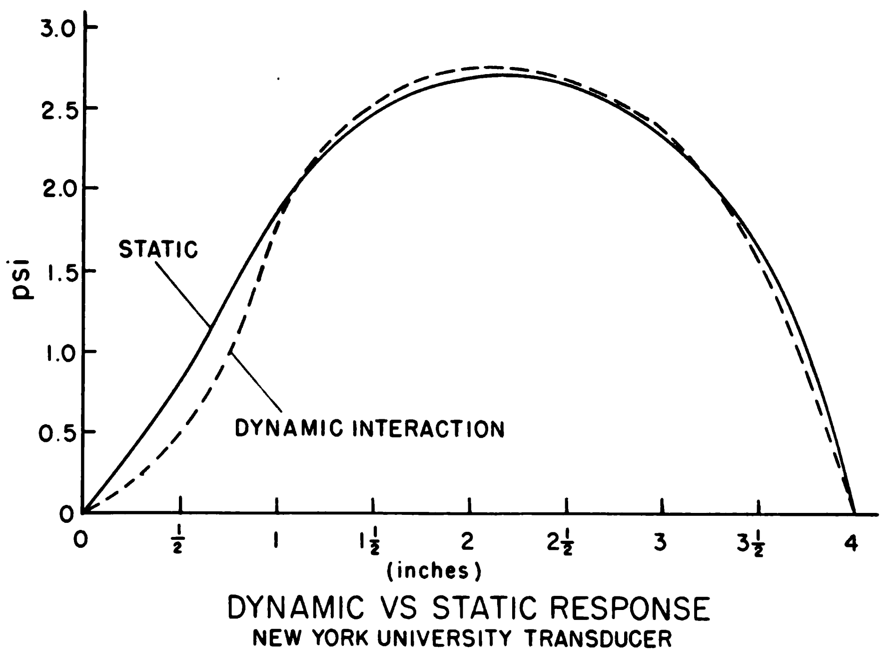
(inches)
DYNAMIC VS STATIC RESPONSE
MICRO-SYSTEMS TRANSDUCER

Fig. 1.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DYNAMIC VS STATIC RESPONSE
NEW YORK UNIVERSITY TRANSDUCER

Fig. 2.

In his presentation, Mr. Appoldt discussed and illustrated with projection slides: 1) the dynamic and static characteristics of the transducers used (Figs. 1 and 2); 2) calibration procedures (Fig. 3); 3) transducer response to loading (Fig. 4); and 4) loadings on transducers inserted in selected locations in the socket under both normal and experimentally manipulated conditions (see Attachment 3).

Mr. Appoldt concluded his presentation by demonstrating one of the subjects in the NYU study who ambulated with the experimental socket that had been prepared and instrumented for him (Fig. 5).

B. Veterans Administration Prosthetics Center

In opening the presentation on behalf of the Veterans Administration Prosthetics Center, Dr. Edward Peizer stated that although his laboratory had been interested in pressure measurements for the past five years, no single massive program of development had been mounted. Dr. Peizer remarked that he had never been convinced that there is a need for a complete map of pressures over all of the stump. He thought that there were four or five points of particular interest in the socket, such as the distal-lateral end of the femur, the ischial seat and the socket rim in the above-knee fitting. Perhaps also, the need was not for a single gauge but for several, depending on the required application. Dr. Peizer went on to say that the VA was interested in pressure measurements in many connections such as elastic hosiery, arch supports, shoe modifications, upper-extremity harnesses, etc. However, in general, they had waited for others to develop suitable pressure gauges and had then looked for applications for these devices. Dr. Peizer then spoke of a particular application of pressure-measuring devices being planned cooperatively with the Prosthetics Research Study in Seattle, Washington, which involved the measurement of pressures in the initial plaster wrap following the immediate postsurgical fitting of prostheses and determination of the homeostatic response over the first several days of postsurgical activity. Dr. Peizer then introduced Mr. Carl Mason, Staff Engineer of VAPC Bioengineering Research Service.

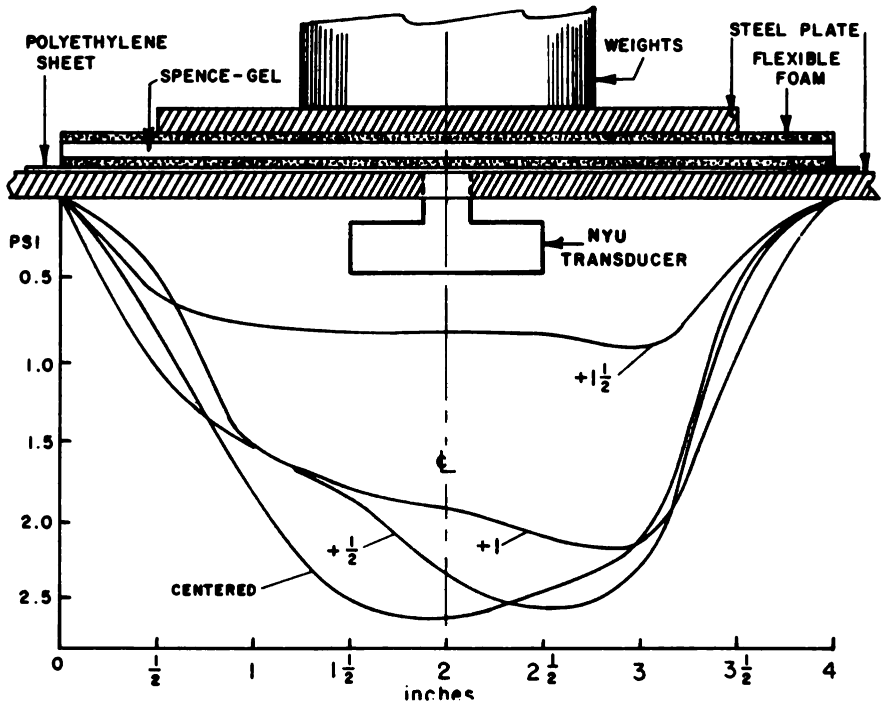

Fig. 3. Calibration of NYU transducer.

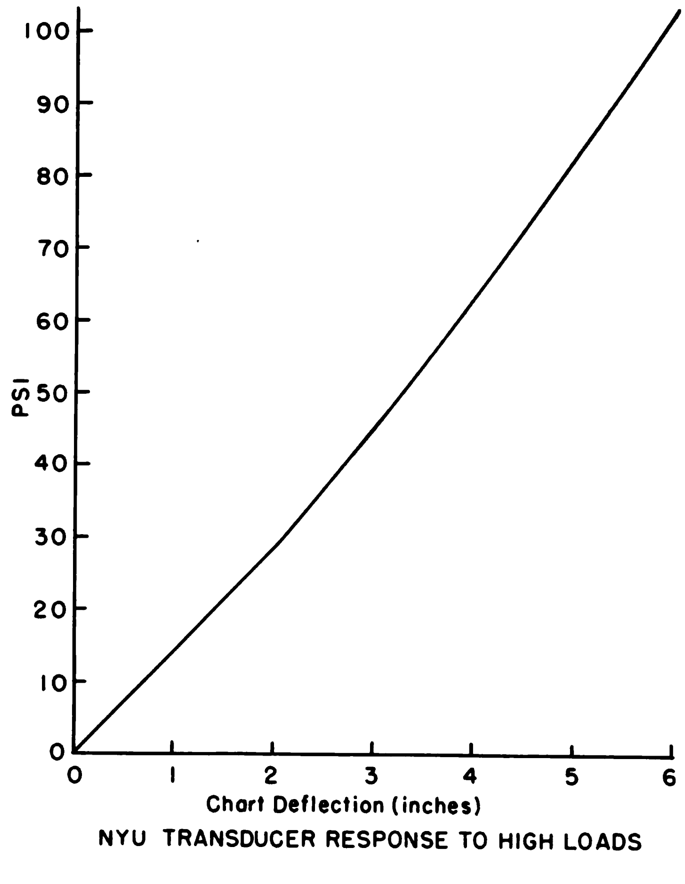

Fig. 4.

Fig. 5. **Patient walking with NYU instrumented AK socket.**

Mr. Mason briefly recounted VAPC's experience with a variety of pressure-measurement devices. In early studies Filpips had been found to be sensitive to temperature and the measurements obtained were not repeatable. A gauge consisting of iron particles embedded in Silastic inserted between copper sheets had been found to be better for the measurement of temperature than pressure. Mr. Mason also stated that VA had tried making their own diaphragm-type gauges which they found they could do but not in ultra-small sizes. Mr. Mason then went on to describe the transducers currently being used by VAPC in studies of AK socket pressures and the pressures between the stump and the rigid dressing used in immediate postsurgical fitting procedures. These gauges are made by Sensotec (Scientific Advances). The characteristics of these gauges were described (see Chart 1).

In continuance of the VAPC presentation, Mr. Thomas Pirrello, Jr., of VA Prosthetics Center, and Mr. Joseph H. Zettl, Director of the Prosthetics Research Study in Seattle, demonstrated the application of the Sensotec gauges to the stump of a below-knee amputee followed by the application of a plaster-of-Paris rigid dressing simulating the conditions of an immediate postsurgical fitting. The patient (Mr. Linwood Kai) then ambulated with the instrumentation in place (Fig. 6).

Dr. Peizer spoke of plans for an "instant lab," or portable instrumentation that he and Mr. Mason have developed that will be used by the Seattle project for study of pressures in immediate postsurgical fittings.

C. Rancho Los Amigos Hospital

Mr. Roy Snelson reported that he had noted the development of ulcers on the feet of diabetic patients and had become interested in measuring the pressure between the foot and the shoe. He had found in some instances these peak pressures were as high as 100 psi. When the pressure was reduced to below 40 psi the foot healed. Mr. Snelson went on to say that experience with a number of patients seemed to indicate that pressures below 40 psi seemed to be tolerated comfortably in intermittent walking, whereas pressures above this level tended to

Fig. 6. Patient walking with VAPC-instrumented rigid dressing. Sensotec gauges are used here.

create problems. Mr. Snelson also mentioned that the RLAH system had been used to measure pressures in below-knee sockets as a guide to reworking the socket for better distribution of loads.

Mr. Snelson then called upon Mr. Daniel J. Antonelli of RLAH staff to describe the equipment used. Mr. Antonelli stated the RLAH transducer had a single silicone strain gauge in the center. It was made by the Electro-Optical Company which was formerly Microsystems and now was said to be a subsidiary of Whittaker Company. This company also makes temperature-compensated gauges.

Also mentioned were semi-conductor strain gauges with stainless steel diaphragms made and sold by Kulite Semi-Conductor Products, 1030 Hoyt Ave., Ridgefield, N. J.

The portable meter used at Rancho Los Amigos Hospital was an inexpensive ($20), highly damped unit (Fig. 7).

D. Louisiana State University

In speaking of the work at LSU, Professor Eugene F. Tims spoke of the group's association with the Public Health Hospital at Carville, Louisiana, and their interest in developing a pressure-measuring device for patients with Hansen's disease. The lack of limb sensitivity of these patients frequently resulted in tissue damage because of excessive loadings. What was sought was a simple, cheap, pressure-measuring device that would give warning to patients when excessive loads are encountered.

Professor Tims indicated that the circuitry of such devices as Filpips, piezoelectric devices and similar equipment was too elaborate for use by patients. They also preferred not to use "hard" devices which were potentially hazardous to human tissue. Some Sensotec units, he said, showed directional sensitivity. He was, therefore, working on a semi-conductor sensor in his own laboratory which he hoped would eliminate the shear problem and the problem related to the direction of applied forces. Professor Tims also indicated that his group were trying some conducting rubbers. They were interested in units which would follow the contour of the body

Fig. 7. Application of technique used at Rancho Los Amigos Hospital. Note use of portable meter.

parts including the fingers and the toes. In this connection, he mentioned some of the work that was being done by Dr. Paul Brand at Carville. This work involved the use of 1/8 in. thick polyurethane foam, sprayed with an adhesive coat and micro-capsules filled with ink that burst upon application of a known pressure. Professor Tims passed around gloves being made for the hands and socks for the feet in which the broken capsules showed the pressure distribution.

Mr. Charles Voss of LSU then spoke and indicated that his group would like to develop an alarm device which would signal when excessive pressures were being applied, and they were also seeking a laboratory device which would measure pressures in all ranges. He told of an experience with rubber transducers obtained from the Polymer Rubber Corporation, Baton Rouge, La. (see Chart 1). Mr. Voss indicated that these transducers consisted of a combination of rubber, carbon black and oil and that these elements can be varied in numerous ways. There were, for example, 39 kinds of carbon black. He also mentioned that the static and dynamic characteristics of rubber differ. Additional problems mentioned were those of both time lag and hysteresis.

E. University of Virginia

Dr. David W. Lewis, speaking on behalf of the University of Virginia, stated that it seemed worthwhile to them to take a large number of pressure measurements and try to develop a "profile" of what constitutes a successful prosthesis.

Dr. Lewis described two types of transducers tried by the U. of Va. group: 1) The variable-capacitance-type--these devices are of emitter-follower design which cancels lead capacitance (Fig. 8). 2) Fiber optics pressure transducer--these transducers were non-linear in response but the results are very reproducible (Fig. 9).

F. University of Michigan

Mr. Edward B. Corell described the work being done at the University of Michigan, using the Scientific Advances (Sensotec) transducer. The work at the University of Michigan is described in some detail in the paper, "Single Channel Data Acquisitions System," which is appended as Attachment 4.

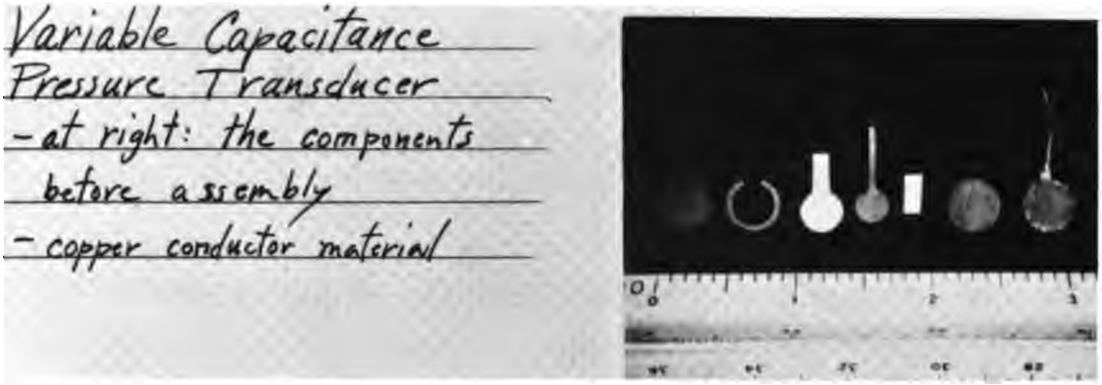

Fig. 8. Capacitance-type gauge under study at the University of Virginia.

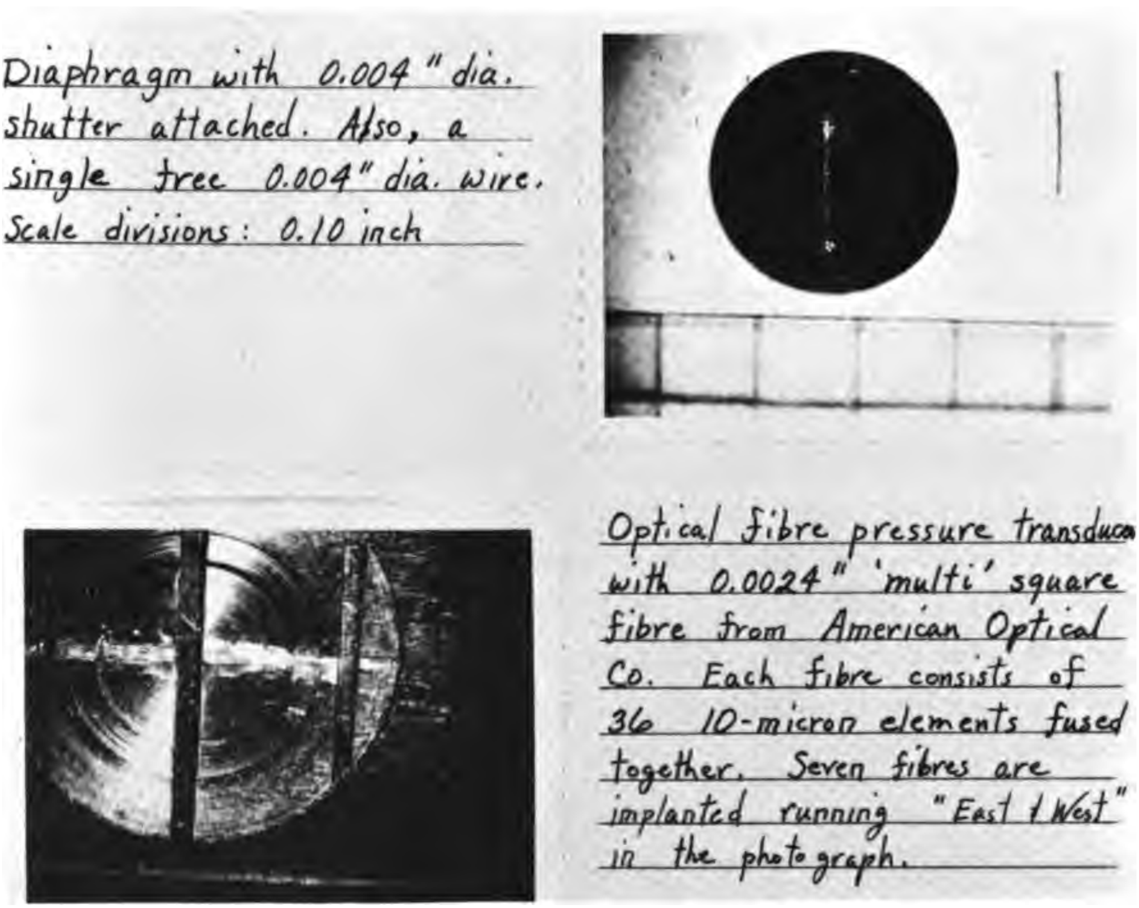

Fig. 9. Fibre-optic system under development at the University of Virginia.

G. University of Illinois

Dr. Jorge O. Galante reported that the focus of attention at the University of Illinois was on spinal orthotics with particular reference to idiopathic scoliosis. He indicated that if this condition is not treated, it progresses to severe deformities and complications.

Methods of treating idiopathic scoliosis had involved either the application of an external plastic cast or the use of metallic devices inserted in the spine (Harrington rods). Since 1958, the Milwaukee brace had been used increasingly in the treatment of scoliosis. At the University of Illinois clinic, 60 patients have now been fitted with Milwaukee braces. Some problems had been experienced, particularly with respect to mandibular and pelvic deformities. A knowledge of the magnitude of the forces acting between the body and the brace was urgently needed.

Dr. Albert B. Schultz discussed the preliminary steps that have been taken in the proposed research at the University of Illinois. The strain gauges being used were applied to the upright supports of the Milwaukee brace. Two of these gauges, which have the form of an octagonal ring, were being inserted at right angles to each other on each upright. Figure 10 shows an instrumented Milwaukee brace and the electronic gear for recording data.

H. Massachusetts Institute of Technology

Mr. Charles Carlson, a graduate student, whose advisor is Dr. Robert Mann, spoke on his thesis project at MIT. This work involved an attempt to measure the spatial and temporal distribution of forces on the cartilage in the hip joint. Mr. Carlson stated that no one seemed to have precise data on the forces acting within the hip. An estimate of 1000 psi by Rydell in Sweden and Paul in England seemed a fairly safe guess.

The instrumentation involved the use of a modified Moore hip prosthesis. This prosthesis is hollow and an attempt was being made to insert 20 pressure transducers into the outer spherical wall. Mr.

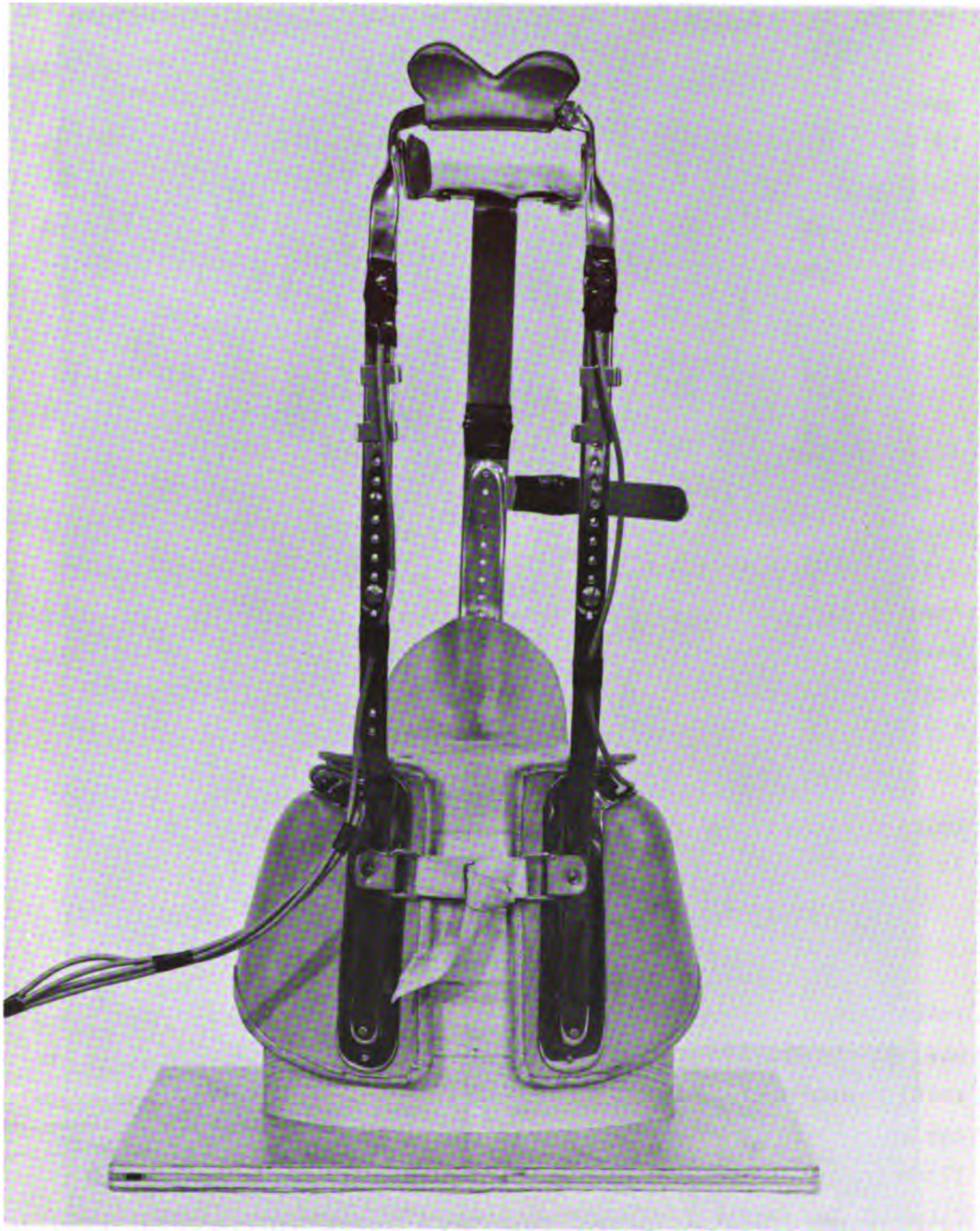

Fig. 10. Milwaukee Brace instrumented by University of Illinois.

Carlson emphasized the delicacy of this operation since the sphericity and the smoothness of the outer wall of the prosthesis must be maintained.

Continuing, Mr. Carlson described plans for installing strain gauges in the walls of the hip prosthesis, locally thinned to 0.010 in. by electrical discharge machining. The characteristics of the strain gauges were also discussed (see Chart 1). It was proposed that a 20-channel transmitter be placed inside the prosthesis, powered, and the strain-gauge data transmitted through leads terminating just beneath the skin.

I. Baylor University College of Medicine

Dr. Lewis A. Leavitt reported on the study at Baylor University which had just been funded following a year's feasibility study. Essentially, the study involved correlation between socket fit and numerous kinematic and pressure measurements (Fig. 11). Seventy-nine different measurements had been used originally. These had now been reduced to 38 and it was felt that the study might end with five or six measures that were of major significance. It was hoped that the study might yield procedures that could be applied in the clinics and that insights leading to changes in socket design might be gained.

Dr. Leavitt showed numerous slides illustrating the work being done at Baylor. The Sensotec pressure transducer is being used in this project also.

J. Case Western Reserve University

Dr. Victor H. Frankel and Mr. Albert H. Burstein reported on behalf of Case Western Reserve University. The first study reported was that of the instrumentation of a crutch to measure pressure in the axilla to determine the effect of pressures there on the vascular system (Fig. 12). The study attempted to measure forces applied at the floor and at the axilla. As it was expected, it has been found that force at the axilla depends on the type of crutch covering used. A padded crutch, for example, permitted higher forces in the axillary area because of greater distribution of pressures.

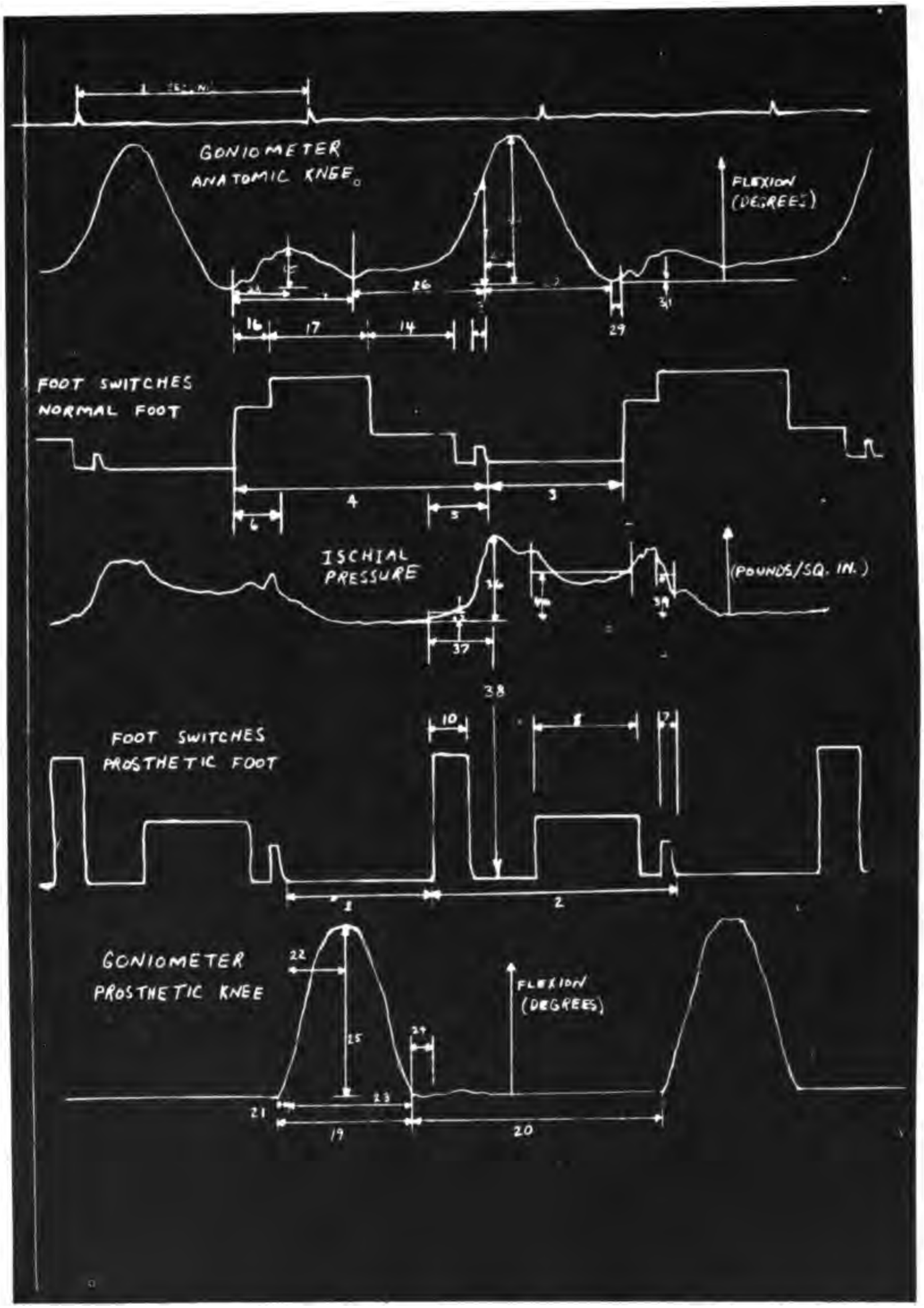

Fig. 11. Typical data recorded by Prosthetics Research Project at Baylor University.

Fig. 12. Instrumented crutch developed at Case Western Reserve University.

In discussing the instrumentation of the crutch, Mr. Burstein stated that axial load was measured near the axillary end of the crutch; while three orthogonal forces were measured near the floor-tip end. Strain gauges were of the 120 ohm SR-4-type. Dynamic response was high and there was little hysteresis.

An attempt had been made to correlate kinematic data with force measurements by stroboscopic photography. A three-dimensional system was now being developed using two TV cameras.

Dr. Frankel then spoke of efforts to build a force-plate system that could be used by other patients than amputees; e.g., those with arthritis of the hip, muscular dystrophy (before and after surgery); and to study the effects of knee surgery. This force plate had been started when Dr. Frankel was in New York and had now been moved to Case Western Reserve University. The center of the plate was transparent so that foot activity could be watched. The transparent section was 2 ft. x 3 ft. and overall dimensions 6 ft. x 6 ft. The cost was approximately $25,000.

Dr. Frankel then discussed a proposed project to measure the forces and moments on nail plates used to repair fractures in the neck of the femur. For this study an attempt would be made to develop nails which would be hollow (3/16 in. stainless steel construction) and instrumented with Dr. Ko's K-6 transmitters to send out data. Each nail would have two sets of four gauges inside. The nails would be given a Silastic first coat, an epoxy second coat and Silastic again for the third or outer coat.

Dr. Frankel also spoke of a study of stresses on cartilage and joints. By measuring and analyzing stresses between cartilage and bone it was hoped that a model of such interfaces could be developed. Animal experiments with a commercial gauge are anticipated.

K. Albert Einstein College of Medicine, Yeshiva University

In reporting on the research work being done at Albert Einstein College of Medicine, Dr. Heinz I. Lippmann discussed the dual role of the rigid dressing applied immediately following surgery.

These two purposes were: 1) edema control, and 2) early weight-bearing. According to Dr. Lippmann the mechanical principles involved in these two functions are quite different, and the same plaster shell should not be used for the two tasks. It was his intention to try to develop separate procedures for dealing with edema control and weight-bearing. (A paper prepared by Dr. Lippmann shortly after the conference is included in this report as Attachment 5.)

II. GENERAL DISCUSSION

A. Practical Application

In opening the meeting to general discussion, Dr. Elftman stated that it was hoped that participants would consider practical applications for the instrumentation currently available while dreaming of new theoretical concepts for future research.

Dr. Elftman reiterated that the present conference had been stimulated by the problems of intra-socket pressures and interfacial stresses, shearing stresses perhaps being particularly important. For the immediate future we should possibly concentrate on the socket-stump interface.

Mr. Muilenburg commented that at the present time prosthetists do not have any exact means for determining the effectiveness of the fittings they perform. Moreover, stumps do not remain constant and the prosthetist is confronted with the further problem of how to maintain "good" fit. Experience had shown that tissue reduction as a result of pressure was not uniform for the entire stump. It would be very useful if some form of "volume control" could be built into the socket to compensate for changes in stump volume.

Dr. Peizer remarked that we have been trying to measure pressures in sockets for many years and over that period may have lost sight of the original reasons for wanting to know what the socket pressures were. He suggested that we needed to redefine our purposes. He called attention to possible use of pressures as control signals.

Mr. Mauch attempted to draw a comparison between the scientific and the classical approach. According to his analysis the scientific approach involved the measurement of many variables, their correlation by computers, and the development of understanding on a broad basis. The classical approach, on the other hand, attempted to visualize what is happening in the socket, form a mental model, establish working hypotheses, carry out experiments, and then arrive at a practical application. This classical approach typically goes faster than the scientific.

Both Mr. Snelson and Mr. Muilenburg emphasized the use of existing transducers in achieving a better socket fit and in the training of the patient. Mr. Staros suggested that we needed to reconsider basic socket design in the light of new surgical techniques. We also needed a parallel study of how tissues reacted to pressures. Other speakers, including Mr. Larry Lamoreux and Dr. Peizer, suggested the use of force and pressure measurement data in the reevaluation of socket designs for both the below-knee and above-knee amputee.

Mr. Staros stated that it was evident from the discussion of the meeting that useful gauges were now available and that there seemed to be little need for further development of gauges. However, there was disagreement with this point of view, the consensus being that while presently available gauges could be used now in some applications, it would be advantageous to develop even better gauges. Mr. Traub emphasized the interests of SRS in research geared to practical applications rather than research for its own sake. The sense of the meeting seemed to be that some investigators should begin gathering data with currently available measuring instruments but that this should not preclude attempts to improve instrumentation.

B. Shears

The question was raised as to whether any work had been done on the measurement of shear forces within sockets.

Mr. Lamoreux stated that in dermatological studies at UCB pressures and shears had been implicated in the development of epidermoid cysts near the top of the socket.

Mr. Corell reported that he had made measurements of coefficients of friction of socket walls and obtained values of 0.25 to 0.50 depending on socket material, pressures, and perspiration.

Mr. Burstein mentioned that Kenedi had done quite a lot of work on the effect of shears on skin. His technique involved the painting of grid lines on the stump, then photographing the distortions of the grid lines through transparent sockets. Dr. Pearson stated that the grid approach was a good one if injuries to the skin occurred at places other than at high pressure points. Mr. Muilenburg suggested that the grid technique would help in determination of how the stump behaves in the socket.

C. Temperature Distribution

Mr. Staros reported that Duke University was trying to get a Barnes thermograph for temperature study. Dr. Leavitt mentioned that M. D. Anderson Hospital had a thermograph available to them and Prof. Tims mentioned that Dr. Brand had a Barnes unit.

D. Moisture-Sweating

It was mentioned that the skin was much more vulnerable when it was moist because of a greater tendency to stick to the inner surface of the socket.

E. Closing

In closing the meeting Mr. McLaurin thanked Mr. Staros, Dr. Peizer, and other members of the VAPC staff for the excellent conference arrangements. He urged participants to take advantage of the available instrumentation that had been presented during the discussions and to begin to put numbers to what, to date, had been only theoretical conceptions.

Lat	lexibility of Sensors	Suitable for Clinical Use	Calibration	REMARKS
Sensotec Scientifi 1400 Holi Columbus, VAPC	o	Yes, but very expensive	Linear to 30 psi	
Developed		No	Linear to 30 psi See note #1	Note #1. System calibrated by NYU Note #2. Calibrations supplied by manufacturer are linear to 100 psia Note #3. Baseline shift, room temperature to approximately 100 deg. F.
Micro Sys Whittaker NYU	b	No	Linear to 30 psi See notes #1 and #2	
Electro C Whittaker Rancho Lc	5	Yes	Linear	
KULITE, M LPS-125-2 (adv. spe Sensotec Rancho Lc				
Conductin under dev Departmer State Uni	s	Yes	Non-linear, reproducible	
Ink-fille Southwest Institute USPHS Hos Carville,	s	Yes	Qualitative	Shows patterns of pressure distribution with qualitative measure of magnitude in gloves, stump socks, and foot socks.
Fiber Opt developme Universit		Yes	Non-linear reproducible	No possibility of electrical shock.
Variable under dev Universit		Yes	Non-linear, reproducible	Multiplexing and short range telemetering built-in.
Under dev Universit		Yes	Linear, calibrate with known forces	Measures three components of corrective force.
Carlson E MIT		No		Not available commercially. Transducer diaphragm machined by "electric-discharge machining," which can be done only on metals.
Filpip USPHS Hos Carville,	ightly exible	Yes		
"IDEAL" C		Yes		

Attachment 1

A G E N D A

WORKSHOP ON PRESSURE AND FORCE MEASUREMENT

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DIVISION OF ENGINEERING - NATIONAL RESEARCH COUNCIL

BIOENGINEERING LABORATORY
VETERANS ADMINISTRATION PROSTHETICS CENTER

New York City — May 27-28, 1968

I. REPORTS FROM PROJECTS

A. New York University (College of Engineering)
B. Veterans Administration Prosthetics Center
C. Rancho Los Amigos Hospital
D. Louisiana State University
E. University of Virginia
F. University of Michigan
G. University of Illinois
H. Massachusetts Institute of Technology
I. Baylor University College of Medicine
J. Case Western Reserve University
K. Albert Einstein College of Medicine, Yeshiva University

II. GENERAL DISCUSSION

A. Practical Application
B. Shears
C. Temperature Distribution
D. Moisture-Sweating
E. Closing

Attachment 2

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Attachment 3

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A PRELIMINARY REPORT ON DYNAMIC SOCKET PRESSURES

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A PRELIMINARY REPORT ON DYNAMIC SOCKET PRESSURES [a]

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I. INTRODUCTION

The quadrilateral suction socket, in either of two forms, open-end or total contact, is currently the most advanced type of suspension with which above-knee amputees may be fitted. Several of the more important advantages of the open-end type are the elimination of the pelvic belt and hinge joint, improved control and position sense, and the development of the stump muscles which are used rather than allowed to atrophy (1). The total contact socket has several additional advantages (2). The slight pressure on the distal tissue helps to support and stabilize this portion of the stump. This additional contact area increases control and contributes in a small way to body support, but more importantly it allows for a looser fit in the critical proximal area where sealing is thought to take place.

There are little actual data concerning the static and dynamic pressures exerted by stumps on these sockets; the only known dynamic results, published by Müller, Hettinger, and Himmelmann, are based on pneumatic transducers sampling relatively large areas (25 sq. cm.) (3, 4).

Therefore, the Veterans Administration, as sponsor of this program, proposed that the project ". . . at New York University should work with the VAPC Bioengineering Laboratory in performing studies of above-knee and below-knee sockets, particularly total contact. The studies should try to discern the effects of total contact on socket pressure distribution and how the pressure distribution achieved by modern sockets affect: 1. the biomechanics of socket design, and 2. the physiology of the stump."

The initial results of a program to measure instantaneous stump socket pressure are described in this paper. The pressure profiles developed at 25

[a] Based on work performed under VA Contract V1005M–1917.

points in the wall and brim of the test socket of a single above-knee amputee were recorded and analyzed. The effects of parametric variations such as alignment and time (diurnal changes) are detailed (Fig. 1 and 2).

II. INSTRUMENTATION

A. Sockets

A well-fitted socket is a primary requirement in a study such as this, if meaningful data are to be collected. Since two of the criteria used in selecting subjects were the possession of a comfortable socket and a healthy stump, it was decided to duplicate the subjects' sockets rather than fabricate entirely new sockets for these tests. In this way, it was felt, the fitting problems often associated with a new socket would be avoided.

Coalginate and a tapered plaster plug were used to take a male impression of the socket; this impression was used to make a plaster-of-paris bandage

FIGURE 1.—A subject and the complete test setup.

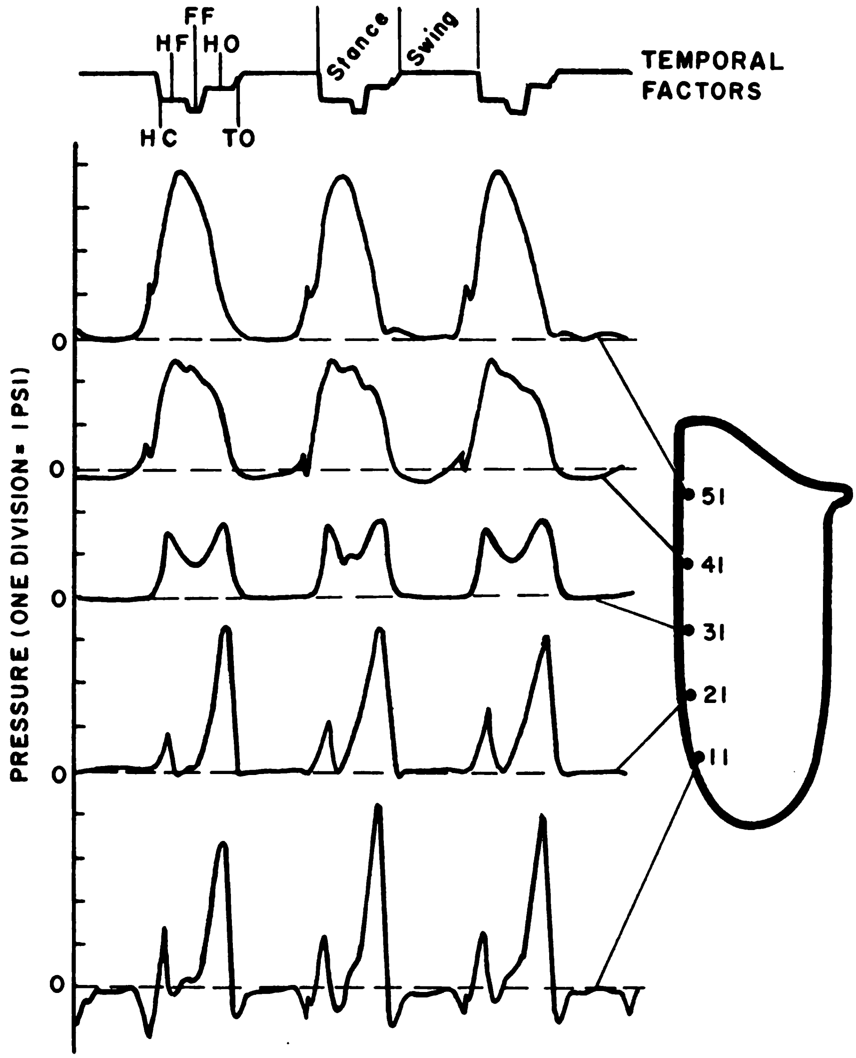

FIGURE 2.—Typical recordings of socket pressures—transducers inserted in anterior wall.

cast. The master model was produced in the usual fashion by pouring plaster into the female bandage cast.

Fabrication of the socket follows normal procedures excepting the placement of the transducer mount inserts. This modification is described in the next section. Upon completion, the socket is glued to a roughly shaped knee block. This assembly is mounted on a Hosmer adjustable above-knee pylon. Lastly, the prosthesis is fitted with the type of foot normally used by the amputee.

B. Transducer Mounts

The transducer mount currently being used required a certain amount of design and development because the special application and overall test program had to be considered. Since a large number of sampling locations were planned, the mount had to be simple to fabricate. Installation should be accomplished with relative ease and without the use of jigs and machine tools, if at all possible. Alignment of the transducer should be automatic and the sensing head of the transducer should always be flush with the inner surface of the socket. The design should allow access to the transducers while the prosthesis is being worn and should include a provision to seal the hole in the socket wall when a location is not being used. The inside face of the sealing device should match the inner surface of the socket.

At a very early stage in the program the transducer mounts were flanged and were attached to the outside of the socket wall with machine screws. This system was discarded owing to the complex jigging required for accurate alignment of the mount.

Another design avoided these problems by incorporating all of the alignment adjustments in the mount itself. However, this design was quite bulky and could not be used on the medial wall of the socket as it would have interfered with the subject's gait.

The system finally adopted integrates the transducer mounts and the test socket into one unit. Although it complicates the prosthetist's task, it is perhaps the easiest way to locate a large number of transducer mounts in a socket, and it is at the same time quite accurate.

The transducer mount consists of four pieces: 1. the insert, a flanged tube with a knurled outer face; 2. the mounting tube, slit for one quarter of its length; 3. the split clamp ring; and 4. a metal plug for sealing the mount when it is not being used (Fig. 3).

The prosthetist starts to fabricate the socket in the usual manner by drawing a polyvinyl alcohol (PVA) bag over the plaster model of the stump. The bores of the inserts are filled with wax (to prevent seepage of the polyester resin) and the inserts are cemented on the PVA bag at the proper locations. A stockinet is drawn over the model, followed by the outer PVA bag. The usual fabrication technique is then followed. After curing and removal of the plaster model, the laminate which covers the inserts is ground off and the wax plugs are removed.

The insert bores are enlarged slightly with a hand reamer and the mounting tubes are cemented in place. The assembly is completed by cementing the clamp rings on the mounting tubes. As a final step, the bore of each tube is tested with a "go, no-go" plug gage and enlarged if necessary. A complete assembly is shown in Figure 4.

On several occasions, when transducer mounts have been installed at new locations after the test socket has been in use, the following technique has

Figure 3.—Transducer mount parts.

Figure 4.—Cutaway of socket and transducer mount.

been employed. The socket is set on the drill press table and blocked or clamped with the socket wall approximately perpendicular to the drill. The hole which is drilled through the socket wall should provide a snug fit for the transducer mounting tube. (The knurled insert is not used.)

In all probability the transducer mounting tube, when inserted, will not be perpendicular to the inside surface of the socket. If the hole is enlarged by redrilling or reaming, holding the tube in proper alignment until the adhesive sets can become a problem, requiring a jig. A simpler and more workable solution has been devised—countersink the hole from outside the socket wall. The material which has been removed by the countersink allows the tube to be aligned properly while being held in place by what remains of the original snug hole. This is a trial-and-error solution, since it is not possible to specify the final diameter of countersinking due to variations in the thickness of socket wall. Unless jigs [b] are to be used this system should be limited to the number of mounts one wishes to locate on one wall.

When not being used as an active sampling location, a metal plug (Part No. 4, Fig. 1 and 2) seals the mount. Since the portion of the plug which is inserted is the same length as the mounting tube, the inner surface of the socket is smooth.

C. Pressure Sampling Locations

There are two basic plans which may be used to locate the sampling sites on a socket. The first would be based on anatomical considerations, sampling pressures at the various critical points or areas on the stump such as the ischium, the ramus, the distal end of the stump, and the belly of a muscle. The second would systematically divide the socket into equal areas or equally spaced sampling sites so that an isobaric chart may be drawn.

The latter plan was employed by Müller and Hettinger when they determined static socket pressures. However, they divided the socket walls into small areas of equal pressure rather than plot isobars.

A hybrid plan was adopted for this program. The pressure transducer mounts are arranged in four columns located on the anterior, lateral, posterior, and medial walls of the socket. The mounts are spaced vertically approximately 2 in. on center. In addition, four to seven mounts are located in the brim (the number being dependent on the length of the brim), and one is located in the region bounded by Scarpa's Triangle. If the subject's stump is not too long, an access hole is placed in the wall of the knee block and a transducer mount is provided at the distal end of the socket.

A two digit numbering system is used to code the locations of the transducer mounts: the first digit (in the tens column) is the row, starting at the distal

[b] It has been our practice to use an epoxy cement which cures in 8 hours at room temperature; thus a jig would be required to accurately position and hold the mounting tube for this period of time. Curing at elevated temperatures for shorter periods of time (1 hour at 200 deg. F.) will still require a jig since the uncured epoxy is not viscous enough to support the mounting tube.

end with #0; the second digit (in the units column) is the column: #1—anterior, #2—lateral, #3—posterior, and #4—medial; for example, location #22 is in the lateral wall in the mid-stump region. The exceptions are the mounts located in the brim which are numbered consecutively starting at the lateral side of the posterior brim. The number of the closest row is used as the first digit, and is fixed; the second digit is changed, starting with the next consecutive column number. This system gives the reader an indication of the approximate length of the subject's stump from the ischium to the distal end since, as mentioned earlier, the mounts are spaced approximately 2 in. apart. Two views of a completed socket are shown in Figure 5.

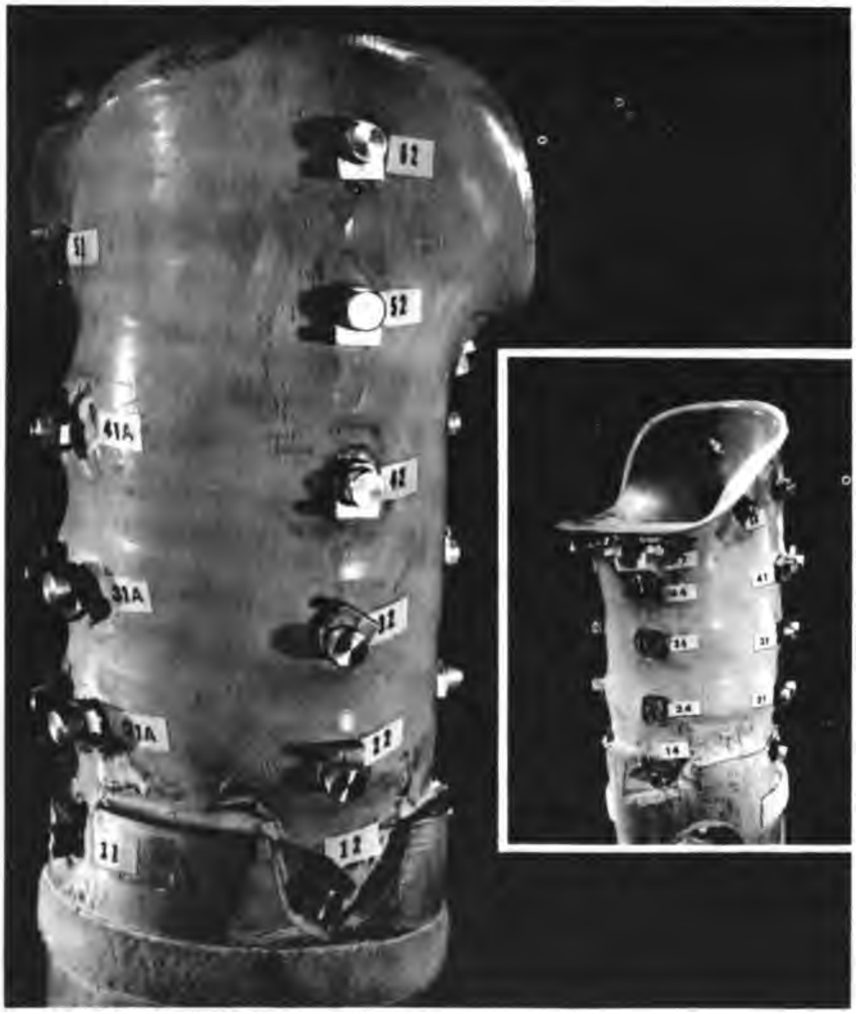

FIGURE 5.—Two views of the test socket.

D. Transducers

1. Background

When this program was initiated, the first task undertaken was a survey of commercially available pressure transducers. The following are the more important criteria which were used: sensitivity, size of the unit and of the sampling area, weight, compatibility with recording system, frequency response, accuracy, stability, and price.

It became clear early in the program that despite the number of pressure transducers manufactured, the majority are of the type designed to measure fluid pressures. This type of transducer is mounted in the system using pipe or tubing fittings, and the pressure sensing element is submerged in the transducer body. This program required that the transducer would, 1. have a configuration which allowed the sensing head or element to be mounted flush with the inner surface of the socket or 2. be small enough to permit mounting the unit in or on the inner surface of the socket.

The latter type of transducer, mounted on the inner surface, would be ideal for this project since the fabrication of the test sockets would be greatly simplified by obviating special transducer mounts. It would allow a large number of amputees to be tested using their regular prostheses, once the most critical or indicative pressure areas had been determined by prior and extensive tests of a select few.

This type of transducer could be used readily as a laboratory-clinical tool in many instances to determine quantitatively why certain and often used corrections are effective. Edema, for example, is caused by strangulation of the distal end of the stump and can be cured by reshaping the socket so as to reduce the pressure. The transducers could be used to map the pressure gradients before and after the socket is reshaped.

2. Principles of Operation

Generally speaking, one of the following principles is employed to detect pressure: piezoelectric effect, capacitance change, differential transformers, and resistance change.

The piezoelectric transducers are usually the least expensive and the smallest but were rejected because, as purchased, they were not compatible with the amplifying equipment on hand. The additional circuitry required to effect compatibility will increase the cost to that of a strain gage unit. In addition these units require dynamic calibration. Since the piezoelectric effect is dynamic, the units cannot read static pressure nor can they be calibrated statically.

The capacitance change transducers are typified by the Franklin Institute Laboratories Pressure Indicating Patch (FILPIP) developed by The Franklin Institute. Prior experience with these units led to their rejection.

They do not respond linearly to pressure change, hysteresis cannot be eliminated, and bending the units will change their characteristics.

Differential transformers, which are capable of measuring very small displacements, could be used to measure force or pressure when connected to a beam or diaphragm. As in the case of the FILPIP, prior experience with such units indicated that they are very sensitive to small alignment changes (they require very rigid mounts), require a complex calibration procedure, and do not respond linearly.

The last principle, resistance change, is the most commonly used for this application, and the most common forms are the wire or foil strain gage (SR–4) and the newer, high sensitivity, semiconductor strain gage. These gages are usually arranged in a Wheatstone Bridge configuration with four active arms for maximum sensitivity. Both of the transducers currently used in this program utilize this principle and configuration.

Two other devices which were tested and which operate on the resistance change principle are the solid state pressure cell and the mercury column strain gage.

The solid state pressure cell is a very attractive unit at first glance because of the very low cost, the simplicity of both the unit and of the recording equipment required, and the sensitivity claimed by the manufacturer. Unfortunately, the cells which have been tested have exhibited the following characteristics—nonlinearity, nonrepeatability and high hysteresis. The manufacturer of these cells also markets a pressure sensitive paint which was thoroughly tested by the VAPC Bioengineering Laboratory with the same disappointing results.

The last gage to be tested was the mercury strain gage (Whitney Gage). This unit was designed to be used with a plethysmograph designed and manufactured by Parks Electronics Laboratory. The gages are made of a synthetic elastic tube which is filled with mercury. The ends of the mercury column make electrical contact with solid lead wires which also seal the ends of the tubing. As normally configured the tubing is wrapped to form a ring which is slipped over a finger or a toe.

These units showed promise although they were not designed for this application. The units are tension gages and are not designed to be compressed in a direction perpendicular to their length. Since the leads were simply forced into the ends of the tube (not bonded) the compressive load often forced the mercury out of the end of the tube, separating the column end and destroying electrical continuity. Testing was discontinued because it was felt that this sealing problem could become a minor project in itself. In addition, the use of the elastic tube as a container would probably introduce hysteresis effects.

3. Description

Two different transducers are presently being used on this program. Both employ the same electrical principle, that is, four active strain gages arranged as a Wheatstone Bridge, but they differ markedly in physical detail and sensitivity.

The Micro-Systems Pressure Transducer—a flush-diaphragm unit designed to record fluid pressures. (In this application the flesh of the amputee's stump may be considered a highly viscous fluid.) The transducer is basically a hollow cylinder, 1/4 in. in diameter by 5/32 in. long, hermetically sealed at one end by an electrical feed-through terminal plug and at the other end by the pressure-sensing diaphragm. The terminal plug and diaphragm are separated, leaving a small chamber which acts as a pressure reference cavity. The stresses in the diaphragm, produced by externally applied pressures, are sensed by four semiconductor strain gages which are bonded to the inner surface of the diaphragm.

This transducer has a range of 0–85 p.s.i.g., but is routinely calibrated to 27 p.s.i.g. since the pressures encountered rarely exceed this value.

The NYU Pressure Transducer—a plunger or piston-type force gage. Since the area of the head of piston is known it can be used to detect pressure. The head of the piston normally used is 1/4 in. in diameter.

The piston is rigidly fixed to the center of a small steel beam. The ends of the beam are in turn rigidly clamped to the body of the transducer. Four SR–4 foil strain gages are bonded to the beam and detect the bending stresses produced in the beam when it is flexed by pressures applied to the face of the piston.

Extensive calibrations have confirmed that the transducer's response is linear to 30 p.s.i.g.

The sensitivity of this unit is approximately one-tenth that of the Micro-Systems transducer, because the SR–4 gages are much less sensitive than the semiconductor gages used in the latter unit. Sensitivity may be increased by substituting semiconductor gages or by reducing the thickness of the steel beam. The latter solution would decrease the linear range of the transducers. An advantage of this design is the ease with which the sampling area may be changed simply by changing the diameter of the piston head. As presently configured, the diameter may be increased to 7/16 in., without modifying either the transducer or the transducer mount.

The decision to employ two gage types reflected the desire to have a backup system available should one system prove ineffective. The results of extensive testing indicate both systems to be highly effective. The advantage of the Micro-Systems transducer is the greater range and sensitivity; that of the NYU unit is the readily altered pressure sensing area. In a system comparison, such advantages appear as second order factors; there are no first order differences with respect to the task.

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E. Calibration

The Micro-Systems pressure transducers are statically calibrated with a system which uses nitrogen to apply pressure and a differential manometer filled with mercury to determine the gas pressure. Basically, the calibration system (Fig. 6) consists of: 1. a baseplate in which, 2. the transducers are mounted, and 3. a small metal chamber resembling a bell jar which is

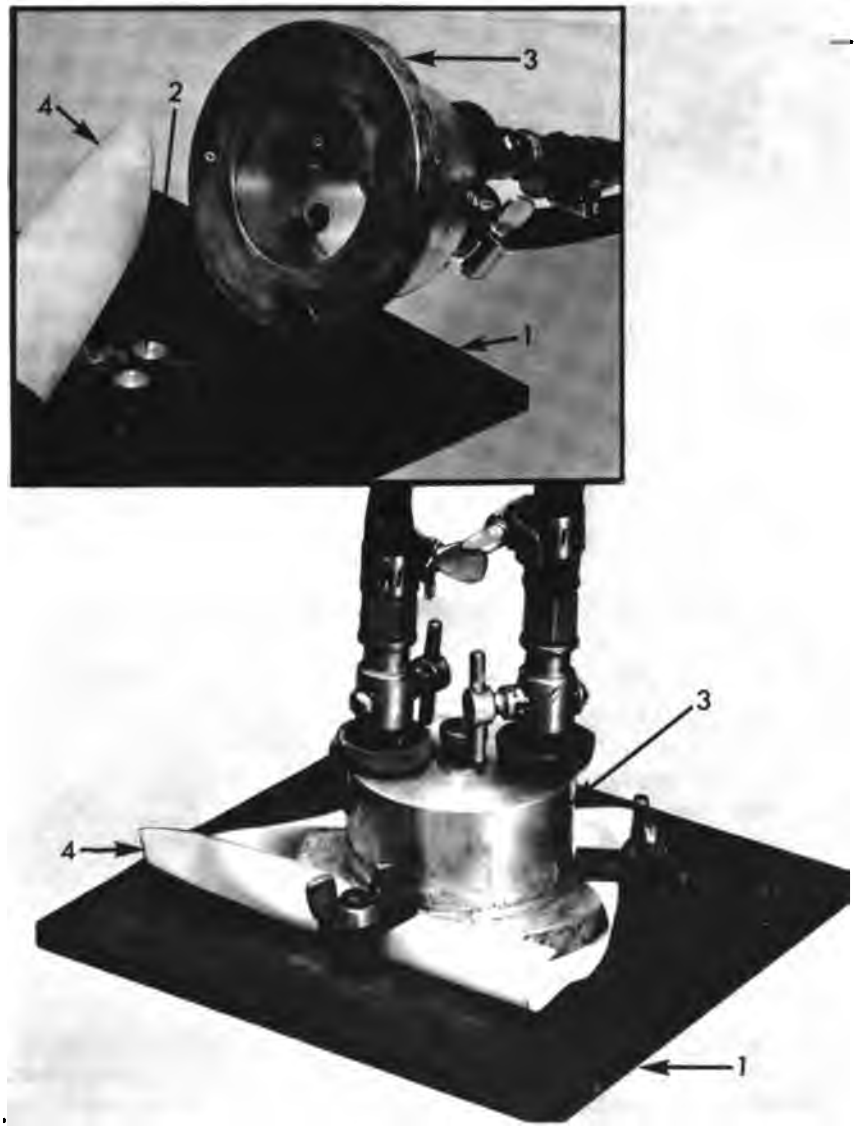

FIGURE 6.—Calibration device for the Micro-Systems pressure transducer.

mounted atop the base. The transducers are mounted so that their sensing heads are flush with the upper surface of the baseplate. A rubber diaphragm, 4., sandwiched between the chamber and the baseplate, both seals the system and applies pressure to the metal diaphragm of the transducer's sensing head.

The NYU transducers are calibrated by direct application of weight or by gas pressure. The equipment used to apply the weights (Fig. 7) consists of: 1. a rigid base in which, 2. the transducer is inserted, and 3. a small weight pan mounted on the plunger.

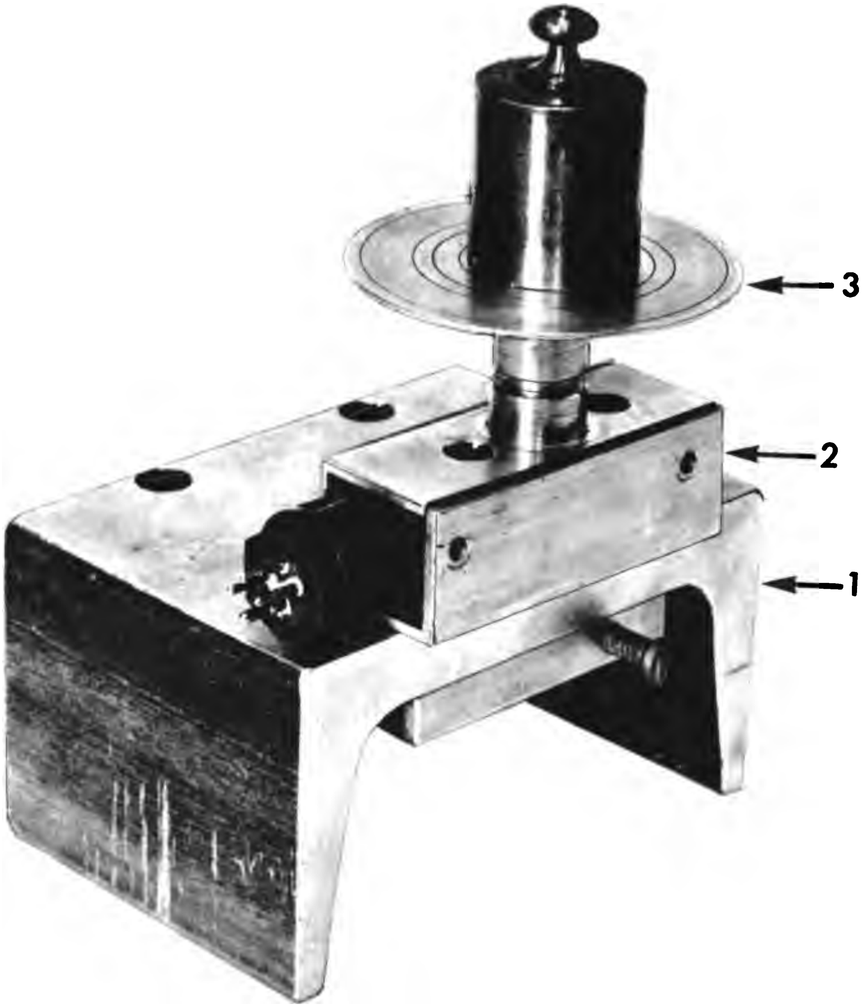

FIGURE 7.—Calibration device for the NYU pressure transducer.

F. Attenuator Settings

The amplifier attenuators are set so that maximum transducer outputs are recorded consistent with the galvanometer beam location on the recorder paper.

The normal procedure has been to determine the attenuator setting for a particular transducer and a particular location on the test socket. This setting is then used throughout all succeeding tests and would only be adjusted if the output signal is either too weak or too strong, e.g., due to a change in alignment.

In many instances this system obviates data reduction, allowing direct comparison of the pressures recorded during several runs at specific locations to determine whether a change in the subject's test prosthesis has produced a corresponding change in pressure. It does not allow comparison of the pressures recorded at several locations during one run since each transducer will respond differently, depending on the individual transducer's sensitivity and attenuator setting.

G. Sampling Technique

The ideal sampling technique would record all of the pressure sites simultaneously. This would produce the truest and most accurate picture of the various pressure patterns, would show the interactions which occur due to subtle changes in the subject's gait, and would reduce the time required for a test. Unfortunately, the system required for such a technique exceeds the capacity of the equipment on hand, both of New York University and the Veterans Administration. The true capacity of the oscillograph is the number of information channels which may be recorded simultaneously without overcrowding the recorder paper. The Consolidated Electrodynamics Corporation (CEC) oscillograph has an 18-channel capacity but only six to eight channels may be used to record the pressures encountered in this program with a reasonable degree of accuracy, i.e., permitting galvanometer deflections of at least 1 in. for peak pressures. Since the recorder paper is 7 in. wide, any additional channels of pressure data would require additional attenuation of the individual signals, otherwise the resulting crowding and intertwining would make data reduction and interpretation of the records extremely difficult.

A system which was tested but proved to be unworkable was sequential sampling. Using this system, all the sites could be sampled during the same run but not simultaneously. If, for example, 18 transducers were used and arranged electrically in six groups of three, only six amplifiers and six galvanometers would be required, this number being within the capacity of the CEC oscillograph. By means of a switch, the outputs of each group would be fed, in sequence, to one amplifier and then to a galvanometer. The sampling time increment could either be fixed by using a motor-driven rotary switch or synchronized with the subject's cadence by using a stepping switch activated by a switch mounted on the subject's shoe.

In order that this system functions properly, the transducers which are grouped should have identical electrical characteristics and almost identical response characteristics since the amplifier can only be balanced once—before the test. The sites at which the grouped transducers are located would have to be chosen with care since marked differences in the pressures at the sites would result in very poor oscillograph records. As an example, suppose that the peak pressures at sites A, B, and C are 25, 20, and 5 p.s.i. respectively, since only one attenuator setting on the amplifier is possible for the three transducers, the setting for site A would have to be used, at the expense of sensitivity at site C.

To compensate for this and for the differences in the electrical characteristics would require that supplementary circuitry be added—one circuit for each transducer. It was the opinion of the group that the added complexity and expense outweighed any advantages of the system.

Eight channels are currently being used, six for pressure data and two for temporal data. This is, of course, a compromise solution which has worked quite well. The oscillograph record is relatively uncluttered by locating the temporal data traces on either edge of the paper; therefore, almost the full paper width may be occupied by the six pressure data traces.

H. Temporal Factors

In a study such as this, identification of the swing and stance phases of walking is of importance; if the various parts of stance phase can be recognized the analysis of data can be refined.

This, of course, has been recognized by the earliest investigators, who used various methods to determine the locomotion cycle and its component parts. Until recently, the most commonly used systems were interrupted light photography, several types of walkways, and foot contact switches.

The interrupted light camera is usually used in conjunction with the force plates and produces stick pictures of the subject as he approaches, contacts, and departs from the force plates. During stance phase the shank and foot, in essence, rotate about one point, and as a result, the sticks representing the successive positions of the shank and the sole of the foot are crowded together. This makes it much more difficult to distinguish the segments of stance phase.

Because of this, the various temporal factors have been determined by other and usually more simple means. One very successful and simple method, used by NYU and the VA Prosthetics Center, is the metal walkway. The walkway consists of two parellel metal plates upon which the subject walks while wearing aluminum foil soled sandals or aluminum foil fastened to the soles of his shoes.

The plates, isolated from one another electrically, are connected in series with a power supply and an oscillograph. The subject, whose foil soles are connected electrically by a jumper wire, acts as a switch, closing the circuit during double support time and opening it during swing phase. The disadvantages of this system are its inability to detect the constituent parts of stance phase, the need for the metal walkway, and finally, the foil-soled shoes or sandals which could subtly alter the subject's gait as a result of reduced traction.

The system which is currently in use employs an array of switches which are arranged along the foot so that the stance phase can be divided into its constituent parts. This system is new in detail but not in concept—a number of previous investigators have used various types of switches to determine swing and stance phase and to identify the components of stance. What distinguishes this system is its simplicity, reliability, ruggedness, and freedom from fussy adjustments.

The heart of the system is a strip switch [c] which may be cut to any length. Five strips are cemented in the transversely grooved heels and soles of the subject's shoes; wired in two parallel circuits (Fig. 8), they divide stance phase into five discrete segments—heel-contact, heel-flat, foot-flat, heel-off, and toe-off.

III. TEST RESULTS

The experimentally measured stump socket pressures are presented for a single above-knee amputee, believed to be representative of those amputees

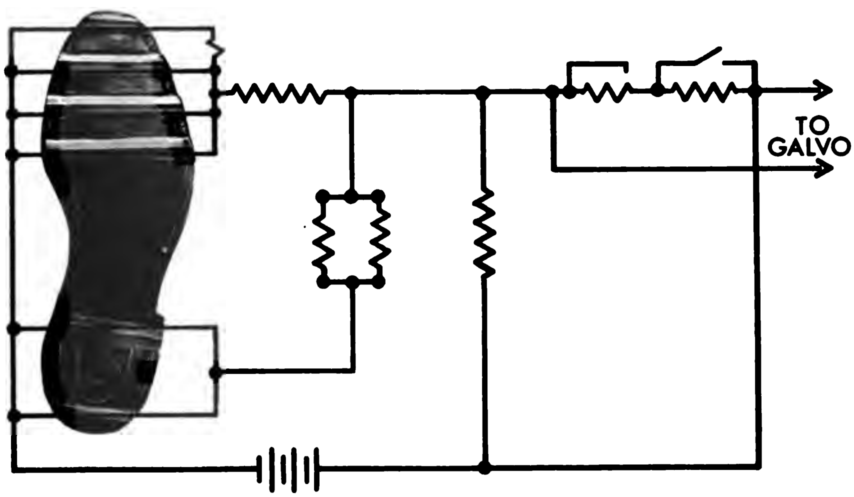

FIGURE 8.—Schematic of the temporal factors circuit.

[c] Controflex Ribbon Switch, manufactured by the Tapeswitch Corporation of America.

possessing a long stump and wearing properly fitted prostheses. Two alignments have been tested—normal and abducted shank.

Four discrete points of stance phase are analysed. They were chosen because peak pressures were recorded at these points at many of the sampling locations. The peaks were recorded at 100, 300, 470, and 540 milliseconds (msec.) after heel-contact. Figure 9 depicts the attitude of the socket at these instances.

The sign convention used in this analysis is one in which the stump is considerd to be acting on the socket.

It should be noted that two assumptions were made in this analysis. They are that:

1. The instantaneous pressures, represented by vectors, act perpendicular to the vertical axis of the socket. In actual practice the transducer is mounted in the socket with the pressure sensor flush with the inner wall at the point of insertion. Figure 10 illustrates the angular deviation of the longitudinal axis of each transducer mount from the transverse plane of the socket. Since large deviations occur only at four positions, the effects of angulation may be neglected.

2. A given pressure value represents the mean value experienced over

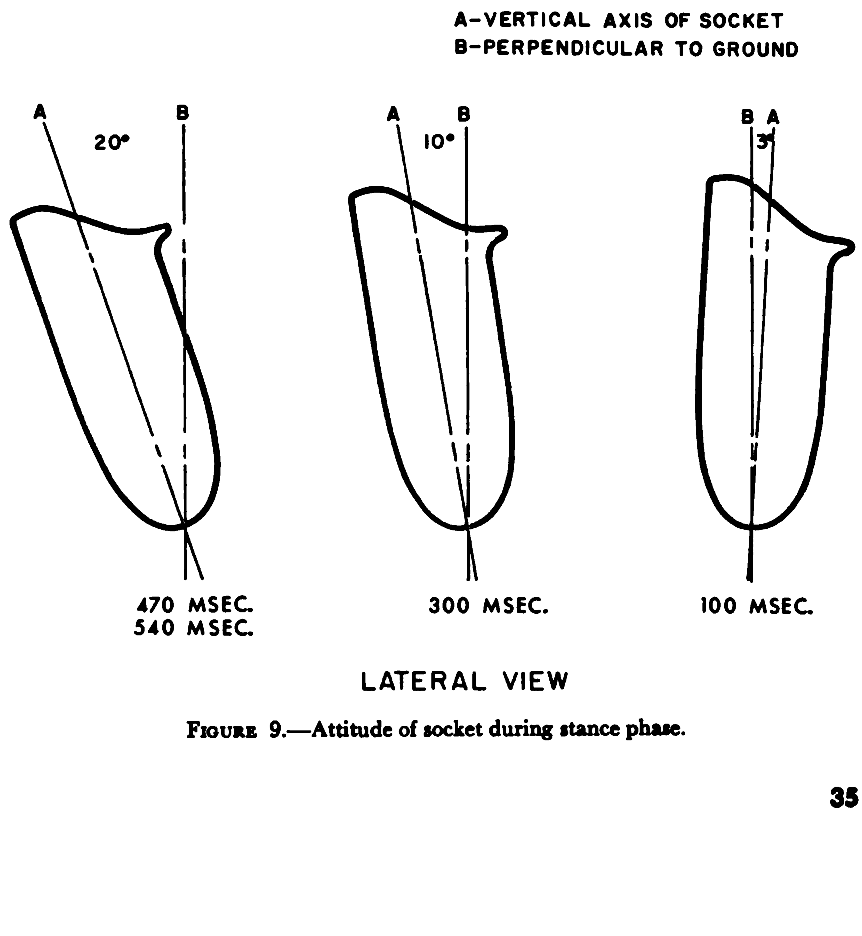

Figure 9.—Attitude of socket during stance phase.

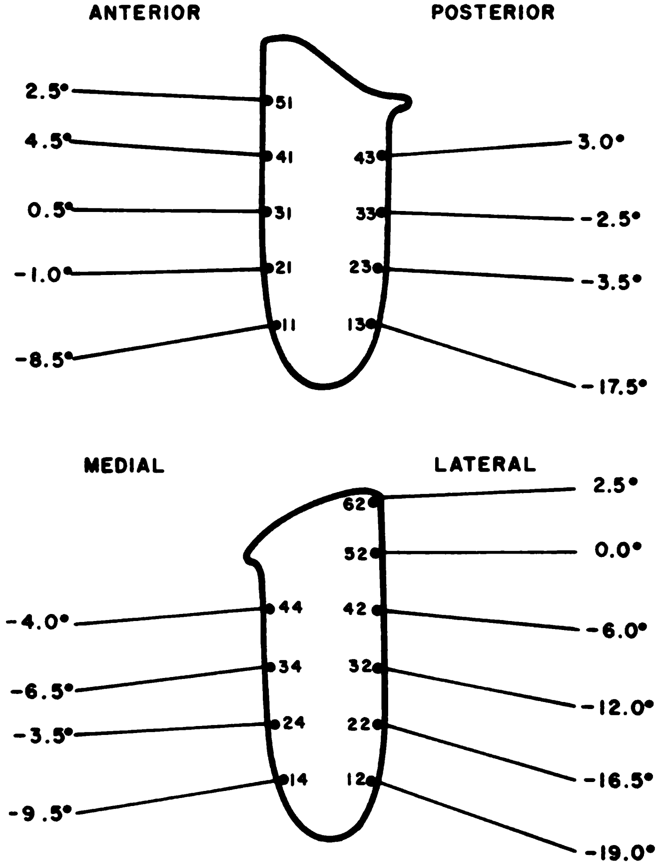

FIGURE 10.—Angular deviation of transducers from the transverse plane of the socket.

1 sq. in., and that the pressure distribution is smooth and continuous. In making this assumption it is possible to determine net loadings in the plane of interest by summing the resulting force vectors acting on opposite walls of the socket.

A. Normal Alignment

In what follows, the results of the tests with the subject's prosthesis normally aligned are detailed. Normal alignment is defined as that alignment which would produce the highest overall rating on a gait evaluation. It is the alignment the subject's test prosthesis had when he was originally fitted by the project prosthetist.

1. Anteroposterior Loading (*Fig. 11a and 11b*). Each pressure diagram represents a scaled construction of the anteroposterior pressures developed on the socket walls along the sagittal plane as time increases after heel-contact. The range of all pressure results falls between 0 and +8 p.s.i.

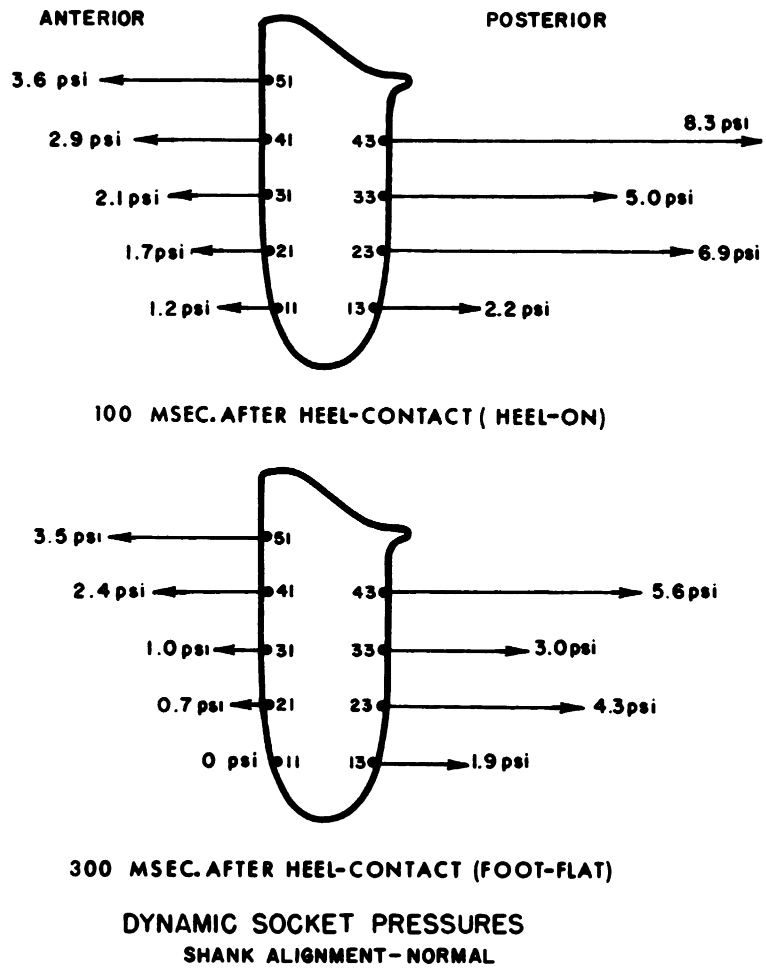

FIGURE 11a.—Anterior and posterior wall pressures: 100 and 300 msec.

Maximum values are experienced approximately 100 msec. after heel-contact.

Initially, the largest individual pressures are developed at posterior proximal locations. Further, there is a net overall loading in the posterior direction corresponding to the extension moment about the hip. The unbalanced resultant force is what is to be expected as the stump is accelerated into the socket.

By the time mid-stance is reached all of the pressures decrease in magnitude. In particular the distal end of the stump produces small anterior pressures. With the passage of still more time the net load has decreased and then reversed direction, corresponding to a flexion moment about the hip.

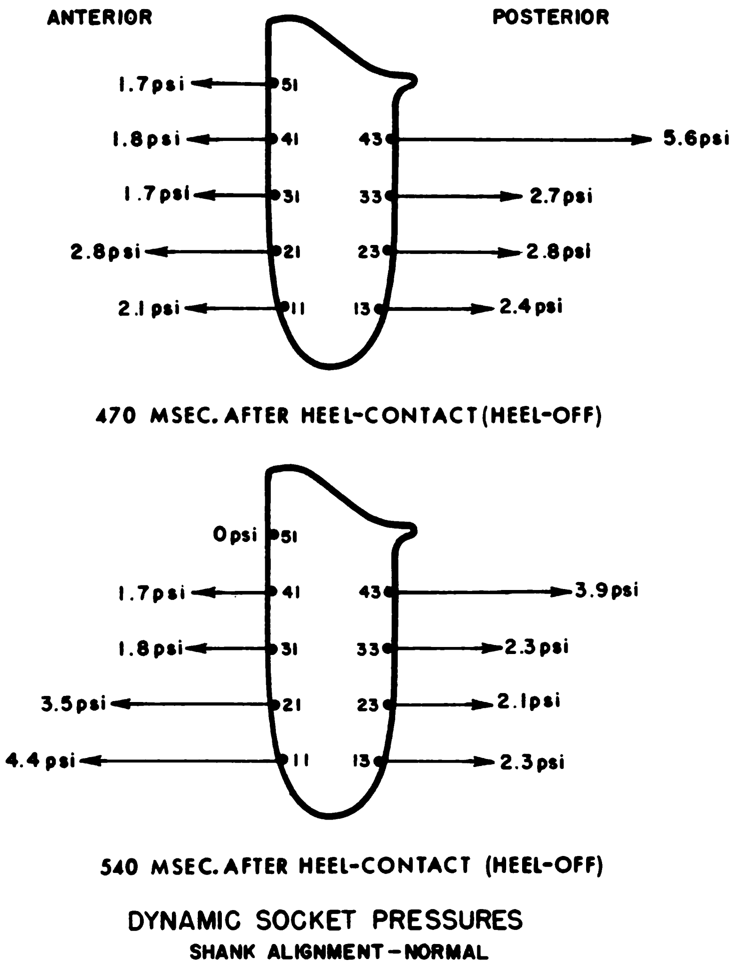

Figure 11b.—Anterior and posterior wall pressures: 470 and 540 msec.

Specifically, late in stance, anterior pressures increase with distance from the hip and posterior pressures decrease. The highest pressure region shifts to the distal end of the stump.

2. *Mediolateral Loading.* A corresponding set of pressures for the same subject is given in Figures 12a and 12b. Maximum pressures, developed soon after heel-contact (100 msec.) are experienced distally and are directed laterally with a peak pressure of 6 p.s.i. The net load is directed laterally, suggesting an acceleration of the stump relative to the socket.

As time increases and mid-stance is reached, the pressures are reduced in magnitude but the pattern of pressures is similar. Towards the end of the

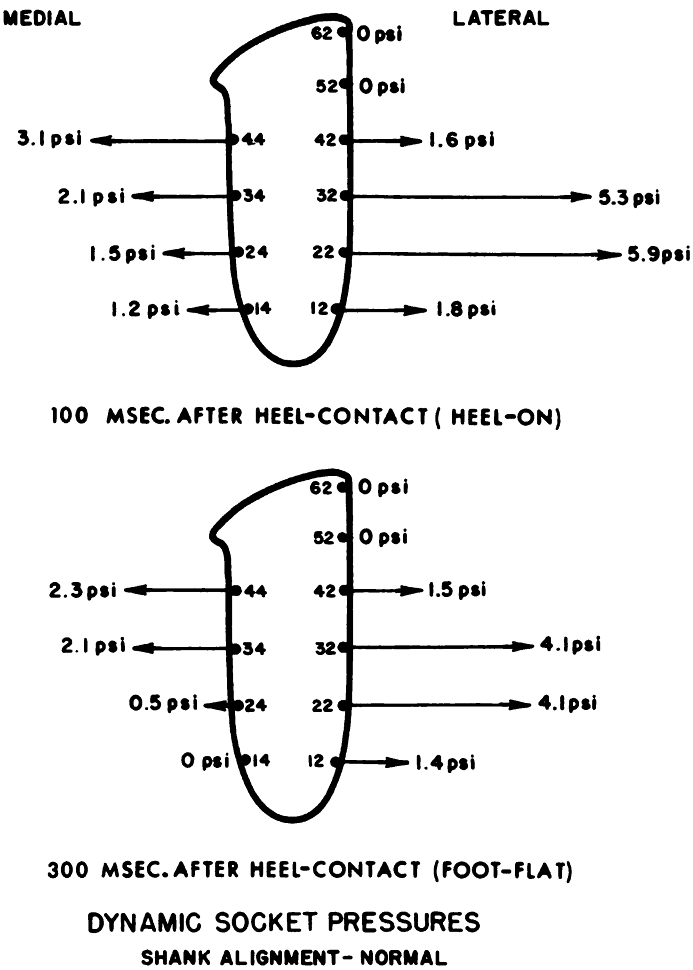

FIGURE 12a.—Medial and lateral wall pressures: 100 and 300 msec.

stance phase (Fig. 12b) all pressures tend to vanish; nonetheless, a small net lateral load remains.

3. Brim. Those pressures developed on the brim are given for the same subject (normal alignment) in Figure 13. Pressure values are a maximum immediately after heel-contact (100 msec.) and decrease everywhere on the brim as a function of increasing time. Local pressure values are in general large, exceeding maximum values developed elsewhere in the socket by a factor of 2 to 3. For example, position No. 53 realizes a maximum pressure of 24 p.s.i., 100 msec. after heel-contact, by far the largest value obtained at any test location within the socket. By contrast, those values developed in

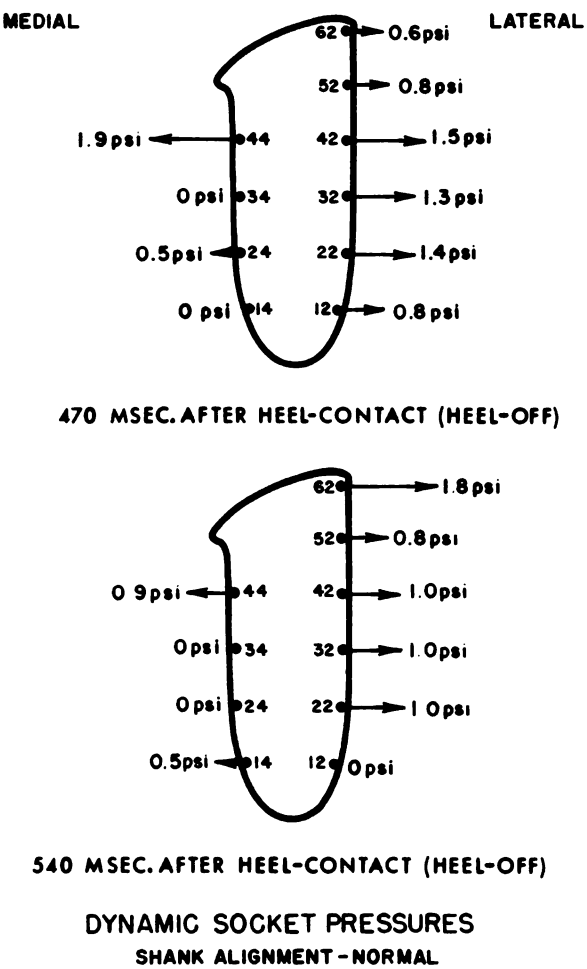

FIGURE 12b.—Medial and lateral wall pressures: 470 and 540 msec.

the anterior locations lower in the socket at the same point in time (same percent stance phase) are an order of magnitude lower in value.

While data at precisely the location of the ischial seat have not been obtained, and interpolation is at best an uncertain affair, the existent data do not suggest the ischial seat as possessing the greatest pressure value.

B. Scatter and Diurnal Variation

1. General. To examine the effects of alignment changes on stump socket pressure values, it is necessary first to examine confidence levels of the data. Should the subject produce large day-to-day variations in output, it is

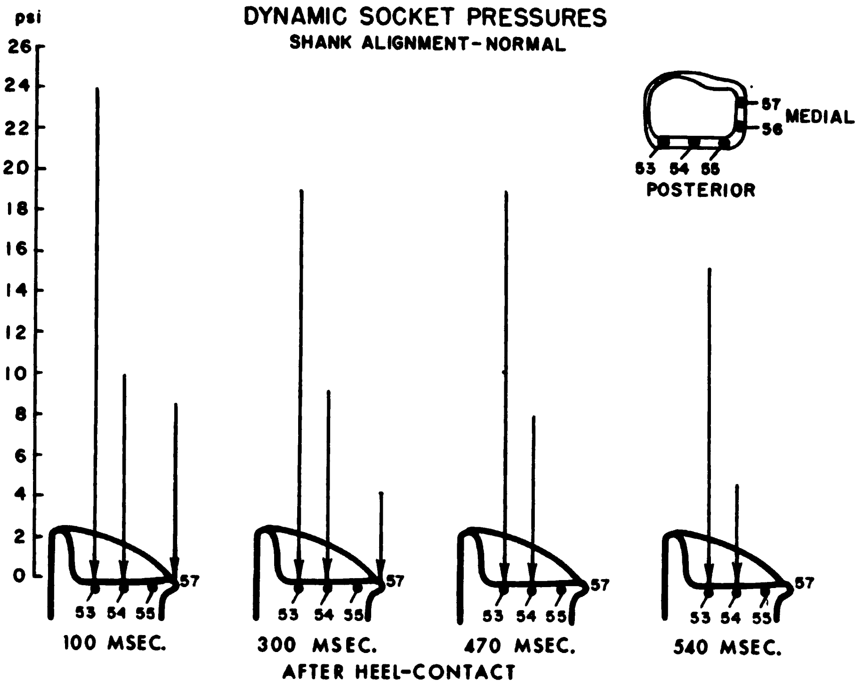

FIGURE 13.—Posterior and medial brim pressures.

conceivable that a small order change in trend due to an alignment change may be hidden in scatter.

Variability of results has many potential sources including instrumentation error, the inability of the test subject to repeat his gait precisely throughout a test sequence, the tendency of the subject to don the prosthesis in a slightly different manner at each fitting, the tendency of the test subject to tire when completing a lengthy series of runs, and week-to-week variations in stump size. Each of these conditions has been examined in a preliminary manner utilizing the subject under discussion. While the small sample precludes broad applicability, certain of the resulting trends are of interest. In this section, the maximum pressures developed between socket and stump of a nominally unchanged above-knee socket are examined in terms of variability.

2. *Transducer Error*. Combined nonlinearity and scatter results obtained in static pressure calibration tests indicate the maximum transducer error to be less than the larger of either ±0.5 p.s.i. or ±3 percent of the reading. Such values are small when compared to certain of the following sources of variability.

3. *Transducer Mounting Error*. Varied means of sealing the transducers in the socket were tested for repeatability by comparing the results obtained

from successive tests of the subject. No specific sealing error, as distinct from human variability, emerged from an analysis of the results.

4. *Step-to-Step Variation.* Generally, a run consists of approximately 20 steps. The data presented in this work are generally based on those values determined from a single step chosen as typical through visual inspection unless otherwise noted. To determine the degree of confidence to be placed in so small a sample, standard deviations have been computed for a number of runs in which all step data have been reduced. The results, which vary with the location in the socket, are shown in Table 1.

TABLE 1.—*Variation in Steps*

Transducer		Pressure (p.s.i.)		
Pos.	Location	Mean	Std. dev.	Largest scatter
51	High anterior	5.2	0.5	1.4
54	Brim	15.1	1.6	3.5
55	Brim	7.7	0.7	1.0
58	High anterior[a]	5.9	0.4	0.7
52	Upper lateral	1.6	0.1	0.2

[a]Scarpa's Triangle.

A value (last column) is also given for the largest single departure (worst scatter point) from the mean. If we assume a standard unimodal distribution, some two-thirds of the data will fall less than one standard deviation from the mean. This implies that even a relatively poor choice of a "typical" step on the part of the data reducer will alter the predicted mean value less than 10 percent (≈Std. Dev./Mean). In the unlikely event that the reducer chooses the most atypical step for reduction, an error of roughly 20 percent (≈Largest Scatter/Mean) in predicted values might result. While possible, this occurrence is regarded as improbable; the personnel involved are well trained. It is our opinion, therefore, that single step data presented in this work are representative of a series of steps and offer results within ±10 percent of the mean obtained from a series of steps.

For those interested in the concept of employing a pressure pickup point as a means of triggering apparatus, the statistical results may be summarized as follows. Over the short run, two-thirds of the steps taken yield values within roughly ±10 percent of those given; the remainder of the steps taken yield values within roughly ±20 percent of those given.

5. *Donning and Doffing Variation.* When the subject removed and then replaced his prosthesis between tests, no significant change in pressure

output was obtained as a specific function of the replacement process. This result applies to but small "leg off" time periods (minutes).

6. *Fatigue.* Towards the end of all day testing periods, with the test subject visibly demonstrating fatigue (subjective evaluation) significant changes occur in the pressure patterns. Step-to-step and run-to-run variability increases; the results become increasingly erratic with time. Further, normally high pressure regions, particularly those in the brim, decrease significantly, approaching a value 10 percent less than the mean value for the day. Regions other than the brim are less influenced; lateral loading appears unchanged by fatigue, anteroposterior loading is but slightly altered.

7. *Day-to-Day Variability.* When the subject is tested repeatedly over many days, weeks, and months under nominally identical conditions, the variations in maximum pressure developed can be large. The results, for different pressure regions, given in Table 2, are in the form of the departure of the mean (of maximum pressure values) either plus or minus obtained on a given day from that obtained not less than 10 days later and not more than one month later. Inspection of the results shows that the departure of the mean for positions remote from the brim is small. On or near the brim, a shift of some 2–3 p.s.i. in mean value does occur as a function of time (weeks).

TABLE 2.—*Short Term Pressure Variation*

Transducer pos.	Pressure level (p.s.i.)	Shift of mean (p.s.i.)
53	18	2.5
55	7	2.5
44	6	1.1
42	3	0.4
23	4	0.0
34	4	0.2

8. *Month-to-Month Variability.* See Section E, part 3.

C. Change in Alignment

The above-knee amputee, whose "normal alignment" stump socket pressures are given in the previous section, was tested on the same day with the shank of the test prosthesis abducted 2 deg. (Valgus). Since this change moves the foot only ½ in. laterally (outset), the SACH foot was not realigned. In all other respects the prosthesis was unchanged. To the observer, the alteration in gait attendant the modified alignment, appeared qualitatively evident; the gait style might be described as a form of inverse circumduction or "skating." The following paragraphs detail a comparison between "normal alignment" stump socket pressures and corresponding values obtained for the 2 deg. abducted alignment.

1. Anteroposterior Loading (*Fig. 14a and 14b*). The abducted alignment does not change the order of magnitude of pressure loading; the greatest alteration in values is +2.4 to −2.7 p.s.i. relative to normal alignment. However the net loading on the socket is considerably altered. Abduction produces a small posterior net load at the beginning of the stance phase and a large anterior net loading as stance time increases. With normal alignment, while the same basic trend exists, i.e., posterior net load changing to anterior, the time averaged net loading is posterior in direction; with abduction, the time averaged net load is anterior in direction.

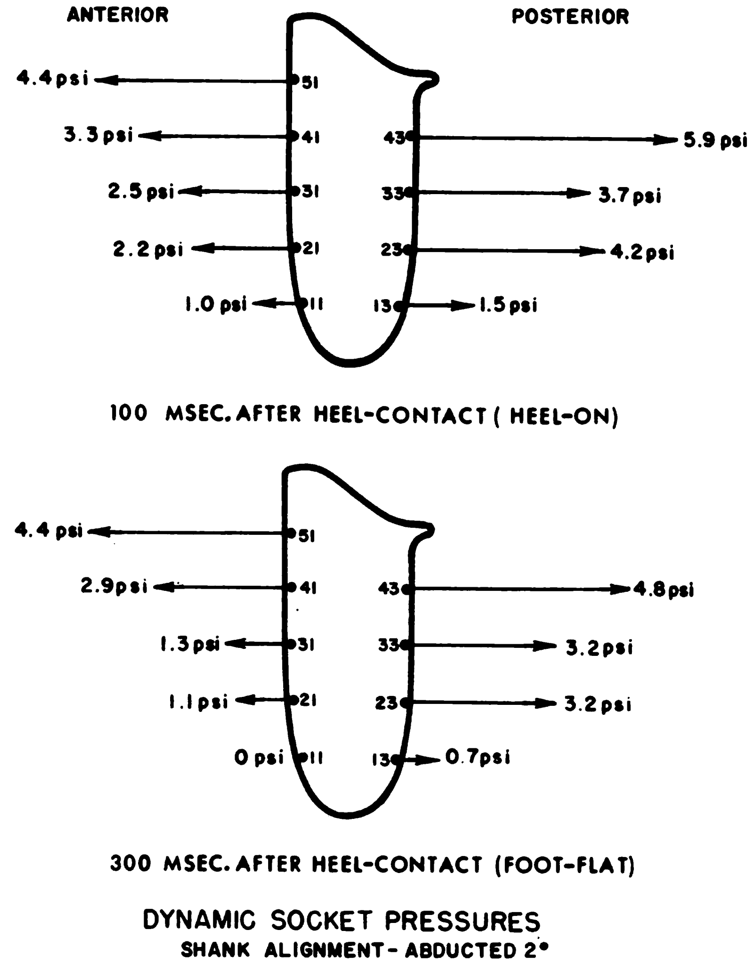

FIGURE 14a.—Anterior and posterior wall pressures: 100 and 300 msec.

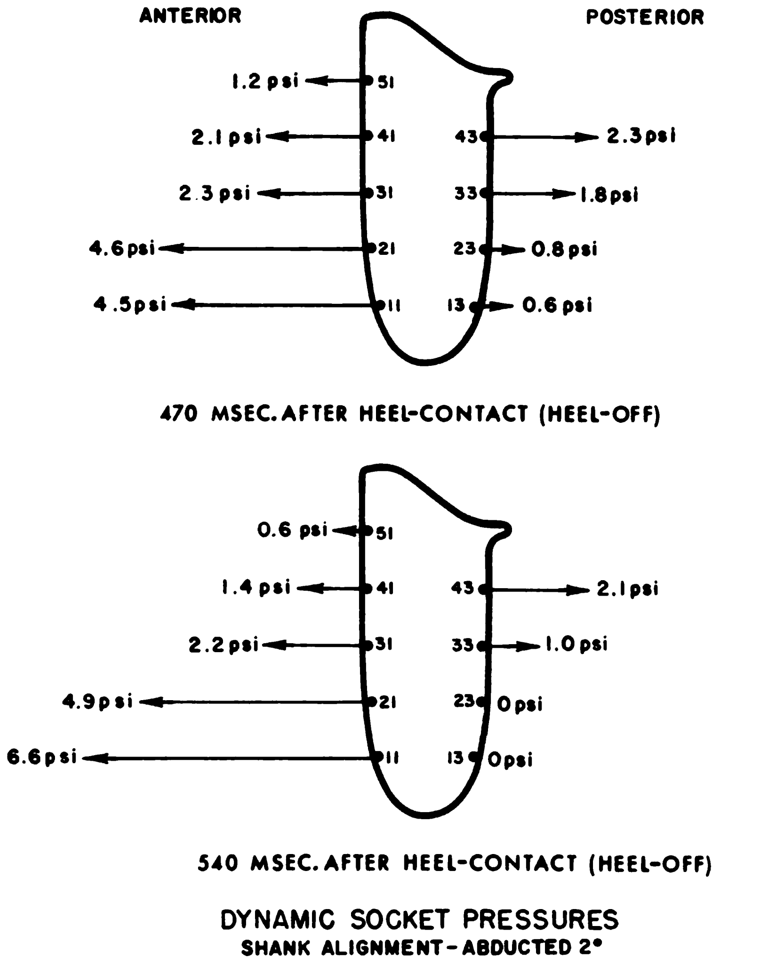

FIGURE 14b.—Anterior and posterior wall pressures: 470 and 540 msec.

2. *Mediolateral Loading* (*Fig. 15a and 15b*). The mean departure of all medio-lateral pressure data (either + or −) obtained in the abducted condition is 0.8 p.s.i. with respect to the normally aligned results. While significant statistically, the difference is small. No basic change in trend of loading with time is apparent.

3. *Brim* (*Fig. 16*). Brim pressures are sensitive to alignment. Abduction changes both the manner of loading, with respect to time and location, and the absolute loading values. The position of greatest pressure (No. 53, the most lateral transducer location on the posterior brim) experiences from 14 to 24 p.s.i. as a function of alignment and time (see Fig. 13). The effect of abduction is to decrease the absolute pressure at position No. 53 during

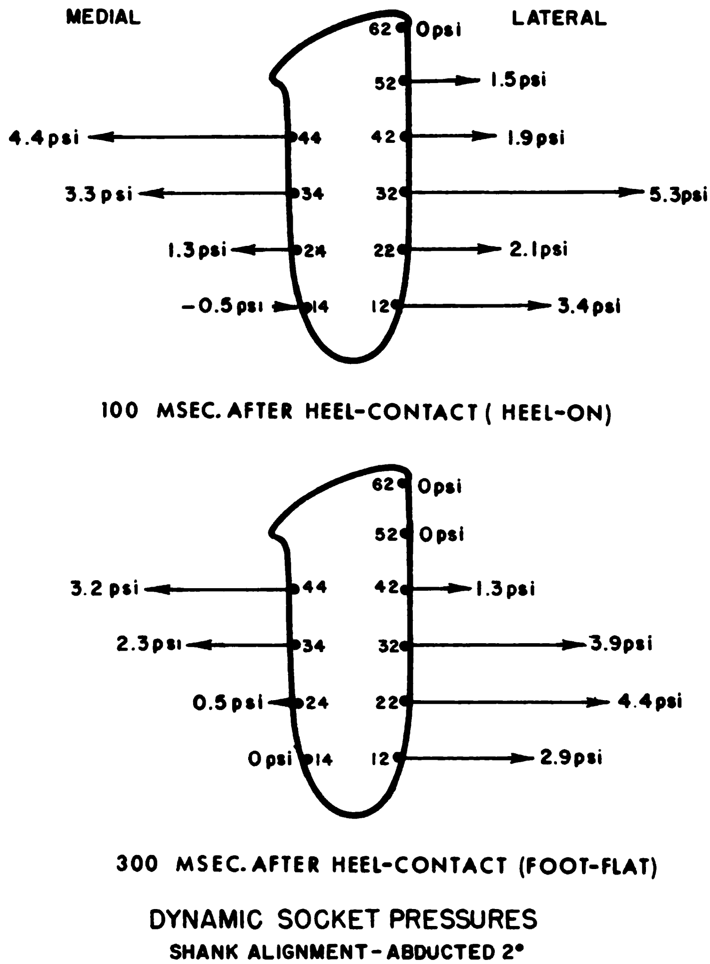

FIGURE 15a.—Medial and lateral wall pressures: 100 and 300 msec.

the initial 300 msec. of stance phase. The pressure at position No. 54 is correspondingly increased, throughout the stance phase, to maintain vertical equilibrium. It is of interest to note that the ischial seat location (roughly midway between No. 54 and No. 55), while not directly measured, would not appear to experience a large pressure with either the normal or abducted alignments.

D. Standing

The maximum pressures developed while standing are in every case smaller than those experienced while walking (Table 3). The subject was instructed to stand quietly, without favoring either leg, while the pressures were recorded.

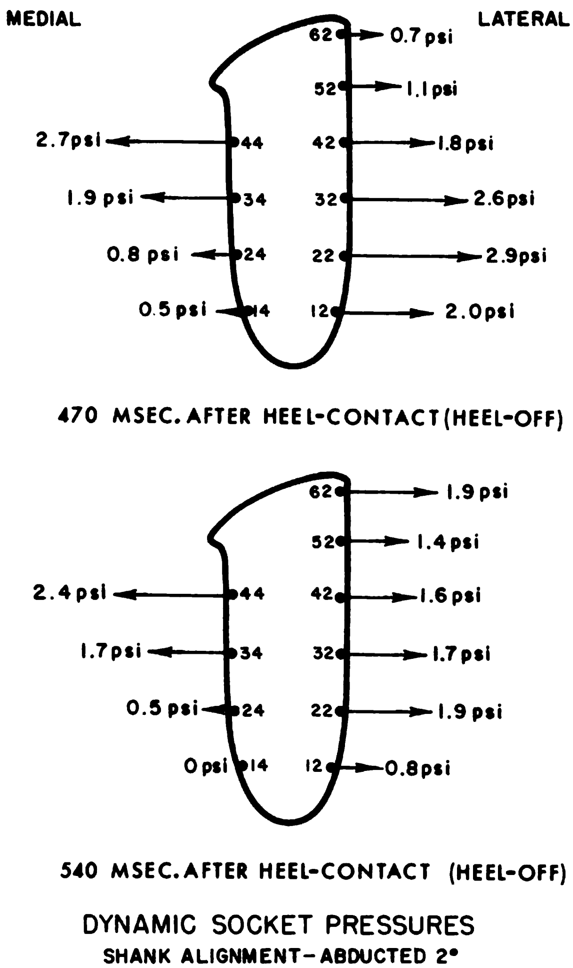

FIGURE 15b.—Medial and lateral wall pressures: 470 and 540 msec.

The mean brim load (proportional to the sum of the brim pressures) is roughly 40 percent of the maximum load developed in walking. Similar reductions occur at other pressure sampling sites.

E. Preliminary Results of Additional Testing

1. Background

Three months after the completion of the tests which have just been discussed, a duplicate set of tests was conducted. The duplication was planned to confirm the findings of the earlier tests, e.g., the pressures are changed when the alignment of the shank is altered. In addition, a new change in alignment was added—adduction of the shank.

TABLE 3.—*Comparison of Dynamic and Standing Pressures*

Transducer		Pressure (p.s.i.)	
Pos.	Location	Dynamic	Standing
53	Brim	15.3	5.9
54	"	13.3	4.2
55	"	3.7	2.1
56	"	3.1	2.5
57	"	4.1	1.1
12	Lateral wall	2.7	1.2
22	" "	2.4	1.1
32	" "	3.0	1.1
42	" "	1.2	0.9
44	Medial wall	4.3	1.7

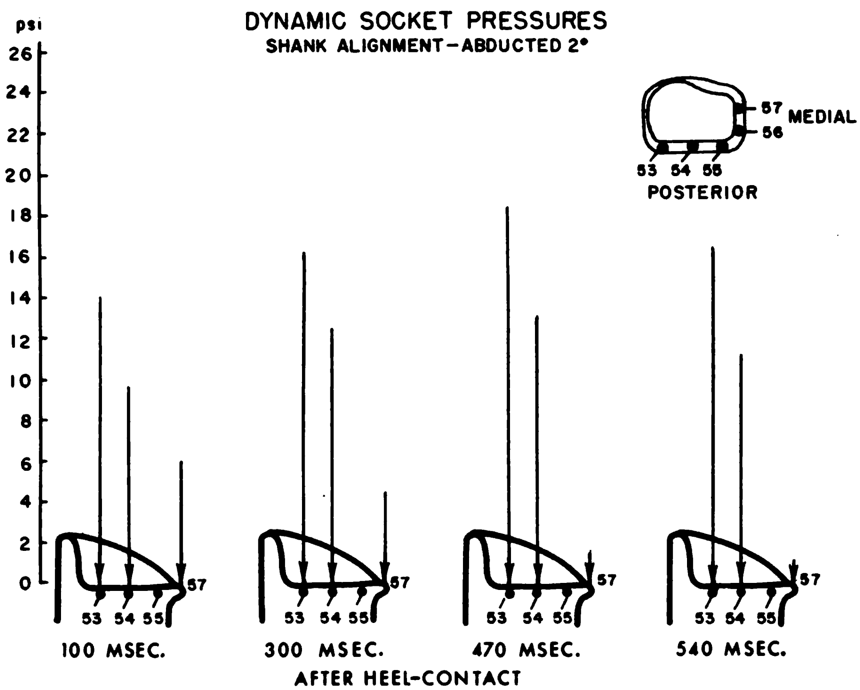

FIGURE 16.—Posterior and medial brim pressures.

Several factors had to be taken into consideration in planning these tests. First, the tests should be completed in one day to be sure that diurnal variations in pressure do not mask the changes in pressure due to altered alignment. Second, the "test day" should be no more than four hours and should include several rest periods to prevent fatigue. Third, a performance evaluation of the subject, by a qualified person, should be scheduled for the same day.

Because of the conflicting requirements it was decided to reduce the number of pressure sites sampled to shorten the testing time. In general, the sites chosen were those which were most affected by changes in alignment and were picked after a review of the earlier data.

2. Results

A preliminary analysis of the data partially confirmed the results of the earlier tests, i.e., the dynamic pressures were changed and the pressure gradients modified by changes in alignment. However, when both days' results for a given alignment were compared there were marked differences in the values of the pressures recorded.

For example, Figure 17 depicts the pressures on the anterior and posterior walls of the socket, recorded at 100 msec. after heel-contact. The shank alignment is normal in both cases. All of the locations were sampled during the earlier tests (top diagram) while five were sampled during the later tests (lower diagram).

Of the five locations sampled on both days, the only position at which equal pressures were recorded was on the anterior wall (position No. 31). The pressures sampled at the other locations were reduced considerably. The pressures at positions No. 11 and 21, which were 1.7 p.s.i. and 1.2 p.s.i. on the first day, dropped to zero. On the posterior wall the pressures at positions No. 23 and 43, 6.9 p.s.i. and 8.3 p.s.i. originally, decreased to 3.5 p.s.i. and 5.3 p.s.i. respectively, on the second day.

Large changes in the instantaneous pressures sampled on the medial and lateral walls also occurred as shown in Figure 18. Pressures of almost equal magnitude were recorded at only one location, position No. 12. The pressures recorded at the other sites which were sampled were affected.

3. Month-to-Month Variability

Since the paired pressures which were recorded on the two test dates were markedly different in many instances, the corresponding pressure data of three tests performed in the intervening period were also plotted.

These data, shown in Figures 19 and 20, indicate that the pressure values may change considerably over a period of months. While basic trend lines retain validity, inspection of the data shows that a given location, subject to a nominal pressure of 6 p.s.i., may experience a pressure shift as large as 3 p.s.i. Therefore, in evaluating a given variable, it is important to make comparisons over small elapsed time periods (days). The alteration in local pressure does not seem to follow a discernible pattern; simple inspection reveals only a random variation about the mean.

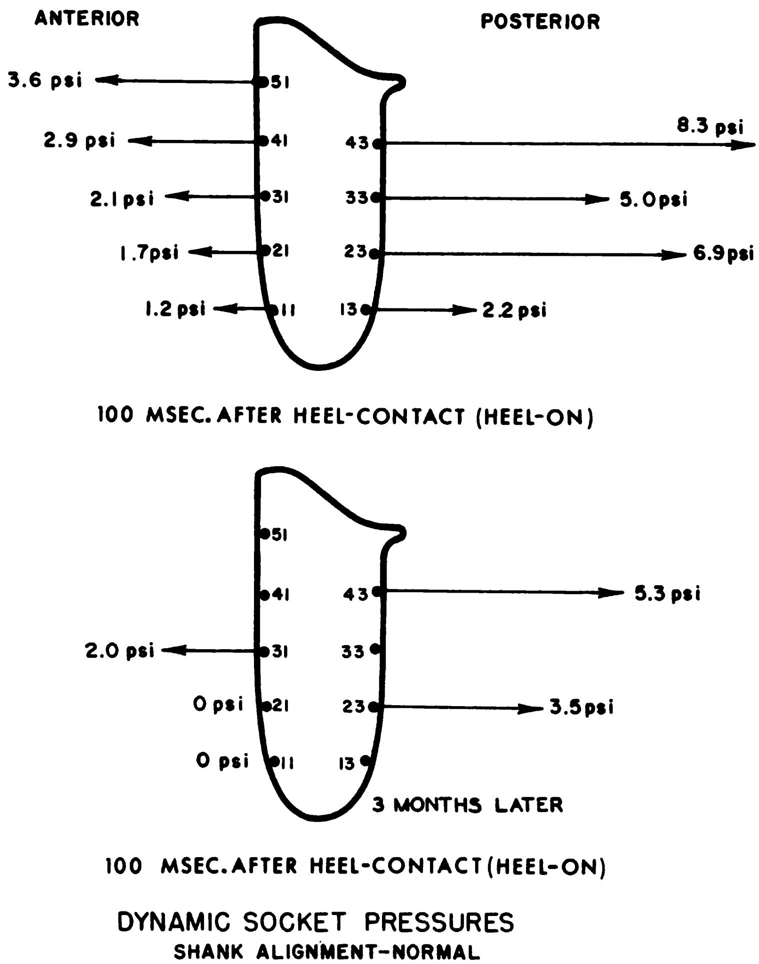

FIGURE 17.—Comparison of anterior and posterior wall pressures—three months apart.

4. Performance Evaluation

The evaluation was scheduled in order to determine whether:

a. The alignment changes affected the subject's gait in any noticeable way.

b. The noticed gait changes were consistent.

The evaluation was performed by a qualified member of the VAPC Bioengineering Research Service, who was aware that alignment changes would be made but was not informed as to the nature of the changes. The results are contained in Table 4.

TABLE 4.—*AK Performance Evaluation—Gait During Level Walking*

Rating: 1 = Greatest deviation from normal
10 = No Deviation from normal

Gait deviation	Rating (& comments)		
	Normal	2° Abd.	2° Add.
Lateral bending of trunk	[a]9	[a]9	10
Abducted gait	[b]8	[c]9	10
Medial whip of foot	10	10	10
Lateral whip of foot	10	10	9
Circumduction	10	10	10
Uneven toe-out	[d]9	[d]9	9
Lumbar lordosis	—	—	—
Uneven arm swing on prosthetic side	[e]8	[e]7	8
Swing phase, forward	[f]8	[f]8	8
Swing phase, rearward	[g]6	[g]7	8
Vaulting	[h]8	[i]7	7
Uneven step lengths	[j]9	[j]9	9
Uneven timing of heel contacts	7	7	[k]8
Others	—	—	—
General performance	8+	8−	8

[a] Slight bending to prosthetic side.
[b] Space of about 3 in. between medial sides of heels. Skates once in a while.
[c] Space of about 2 in. between medial sides of heels. Has a tendency to skate.
[d] Slight toe-out normal side. Prosthesis usually straight, but toes-out occasionally at heel-contact.
[e] Tends to walk with shoulders back. On prosthetic side, holds arm restricted at shoulder, but swings forearm.
[f] Terminal impact minimized by good timing.
[g] About 2 in. difference between prosthetic and normal sides.
[h] Tends to remain on toe of normal foot while waiting for prosthesis.
[i] On toe of normal foot waiting for prosthesis.
[j] Bilaterally long steps.
[k] Slightly shorter on prosthetic side.

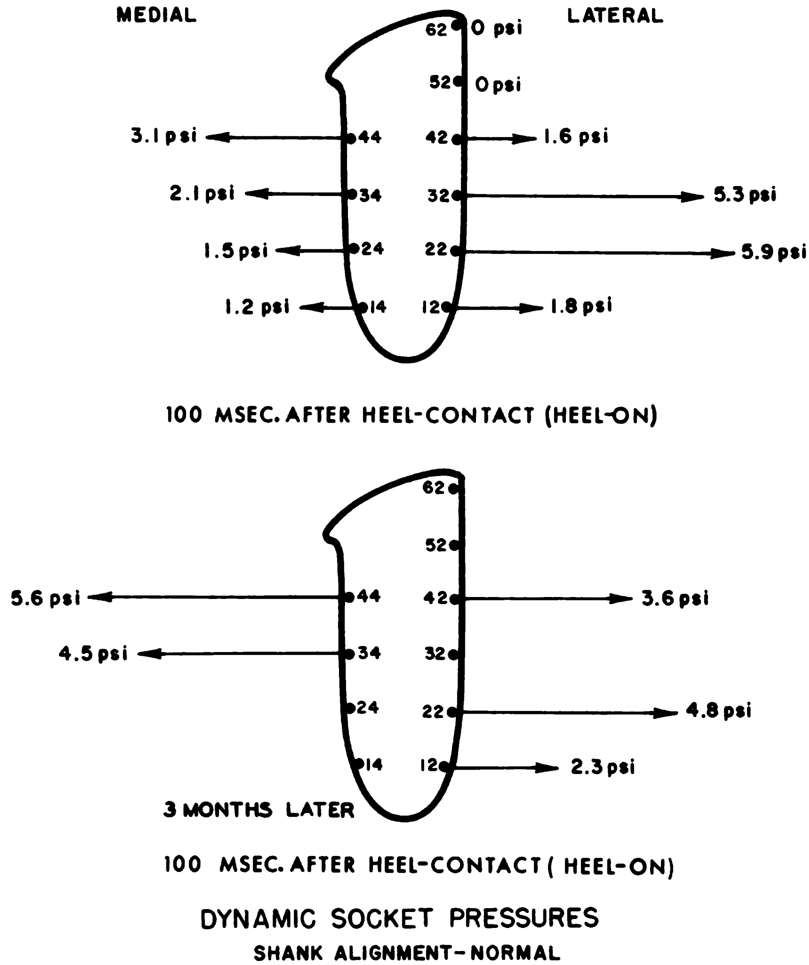

FIGURE 18.—Comparison of medial and lateral wall pressures—three months apart.

IV. SUMMARY AND CONCLUSIONS

1. Socket pressures, developed between stump flesh and socket, have been measured in normal walking, as a function of time.

2. Socket pressures range from −1 p.s.i. gage to 24 p.s.i. gage as a function of location within the socket and phase of walking. In general, maximum positive pressures are developed on the brim (typical range 10–25 p.s.i.); however, the ischial seat is not necessarily the location of maximum pressure. In general, lowest pressures are realized distally on the stump (typical range 0–3 p.s.i.). Mid-stump pressure values (typical range 4–10 p.s.i.) fall between those of the brim and the distal locations.

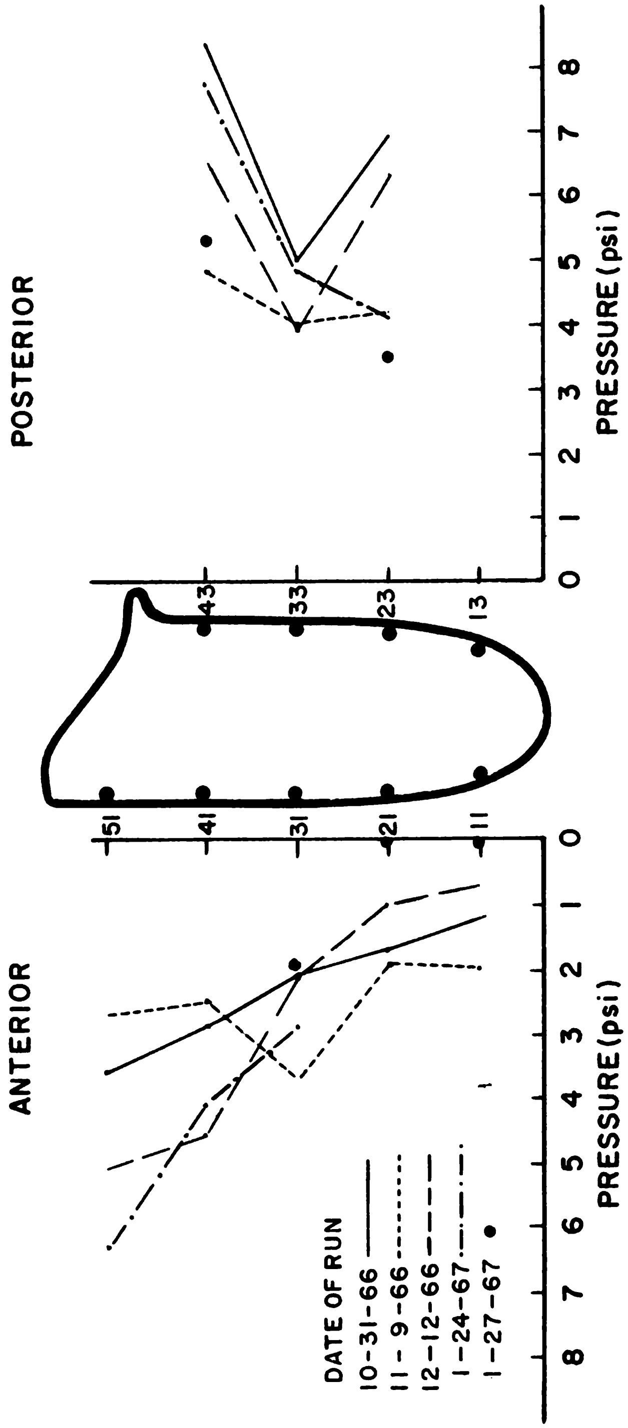

FIGURE 19.—Month-to-month variability of anterior and posterior wall pressures.

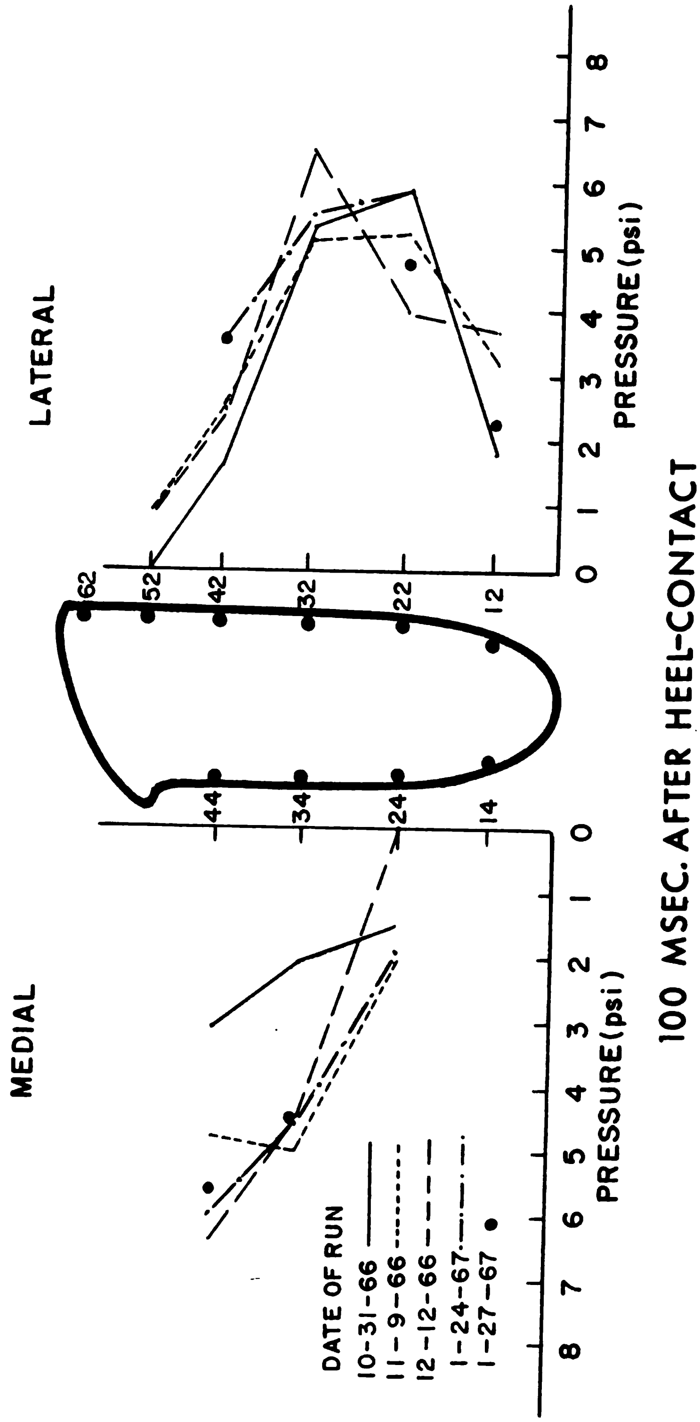

FIGURE 20.—Month-to-month variability of medial and lateral wall pressures.

3. Diurnal variations in socket pressure are large, particularly on the brim. A difference in pressure values of 2.5 p.s.i. has been recorded on the lateral part of the posterior brim on a day-to-day basis. On a month-to-month basis, local changes are sufficiently large to preclude simple comparison of old and new data. While basic trends are preserved, local variations can be high, e.g., in excess of 3 p.s.i. in a 6 p.s.i. environment.

4. Pressure alterations resultant from abduction and adduction of the shank through a 2 deg. angular change generally are small (typical range 0–2 p.s.i.) with the exception of the brim location, where a change as large as 10 p.s.i. has been noted. Such changes are larger than those to be expected on a day-to-day basis; therefore, while small, they are significant.

5. The pressures developed in walking are sharply higher than those experienced in standing.

ACKNOWLEDGMENTS

The authors wish to thank Messrs. Albert J. Yatkauskas and Saleem Sherados, of the New York University Biomechanics Group, for their contributions to the program. This report would not have been possible, but for their efforts.

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Attachment 4

SINGLE CHANNEL DATA ACQUISITION SYSTEM

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Ann Arbor, Michigan

May 27, 1968

SINGLE CHANNEL DATA ACQUISITION SYSTEM

As a prelude to a larger system, a single channel data acquisition scheme to acquire, store and calculate upon analogue signals has been established. At the University of Michigan, the main emphasis of the interface research resulting in multichannel analogue signals from the measurement of normal stress and/or shear stress, has been placed upon signal manipulation and treatment. It is believed that the entire problem can be segmented into three main problems.

1. The transducer to record the stress and appropriate amplification.
2. Recording of the multichannel signals emanating from the transducers.
3. Calculation upon the recorded data.

We established some very definite criteria regarding the type of system it was felt desirable to design. These criteria are as follows:

1. Maximum transducer mobility so that the experiment can have maximum flexibility. This would allow grouping of the transducers or small movements in critical areas depending upon the results that are being obtained.
2. An effective means to collect from one to one-hundred channels of information without creating a clumsy scheme that does not lend itself to change.
3. Provide means to calculate upon the data gathered. This should encompass means to correlate to other researcher's efforts as well as new treatment.

These criteria were the basis for system described in this paper.

With regard to the transducer, preliminary tests with the wafer transducer of Scientific Advances Corporation leads us to believe that it will satisfy our criteria. Certainly it has some limitations, but we believe we can work around them. This one quarter inch diameter, twenty-one thousandths inch thick transducer facilitates movement and provides the flexibility needed.

Anticipating that the Scientific Advances Transducer will be satisfactory and taking advantage of the possibility of acquiring a PDP-8 Linc Computing System, we have proceeded to prepare the necessary software to handle the data output of pressure measurements and thereby satisfy the second and third criteria. Hence, my contribution here will deal with methods of handling the data rather than producing it. It is my hope that this will serve as a counterpart to other talks dealing with the primary problem of the measurement itself.

The second and third criteria will be solved by the introduction of a small general purpose digital computer. The computer software handles two primary external devices, a multiplexed analogue to digital converter and digital magnetic tape units. Conceptually, the computer's function will be as follows:

1. The computer's software allows the experimenter to choose the time increment between Analog/Digital conversions.
2. The computer's software allows manual or asychronous gating to instigate computer data gathering.
3. The computer's software catalogues the gathered data under and experimenter's file name and handles all cataloging.
4. The computer's software allows execution of a user defined program on each individual test. Input/Output devices available for the user program include magnetic tapes, program controlled relays, five inch dual beam oscilloscope with Digital/Analogue units and teletype.

Externally the user names the file with the name of the patient or making up an appropriate name. The software must then accomplish many menial tasks.

1. Allow for introduction of experimenters comments with regard to the

test.

2. Assign appropriate magnetic tape as the test is in progress.
3. Allow the user to exit at his pleasure.
4. Keep records of where this particular data is located on one of many tape reels.
5. Allow for the creation of many files operating as above.
6. Allow for reentry at a later date to any existing file and amend the indexing.

We are presently writing an eight channel version of the single channel version already written. The single channel version is presently being verified and examined for design information for the eight channel version.

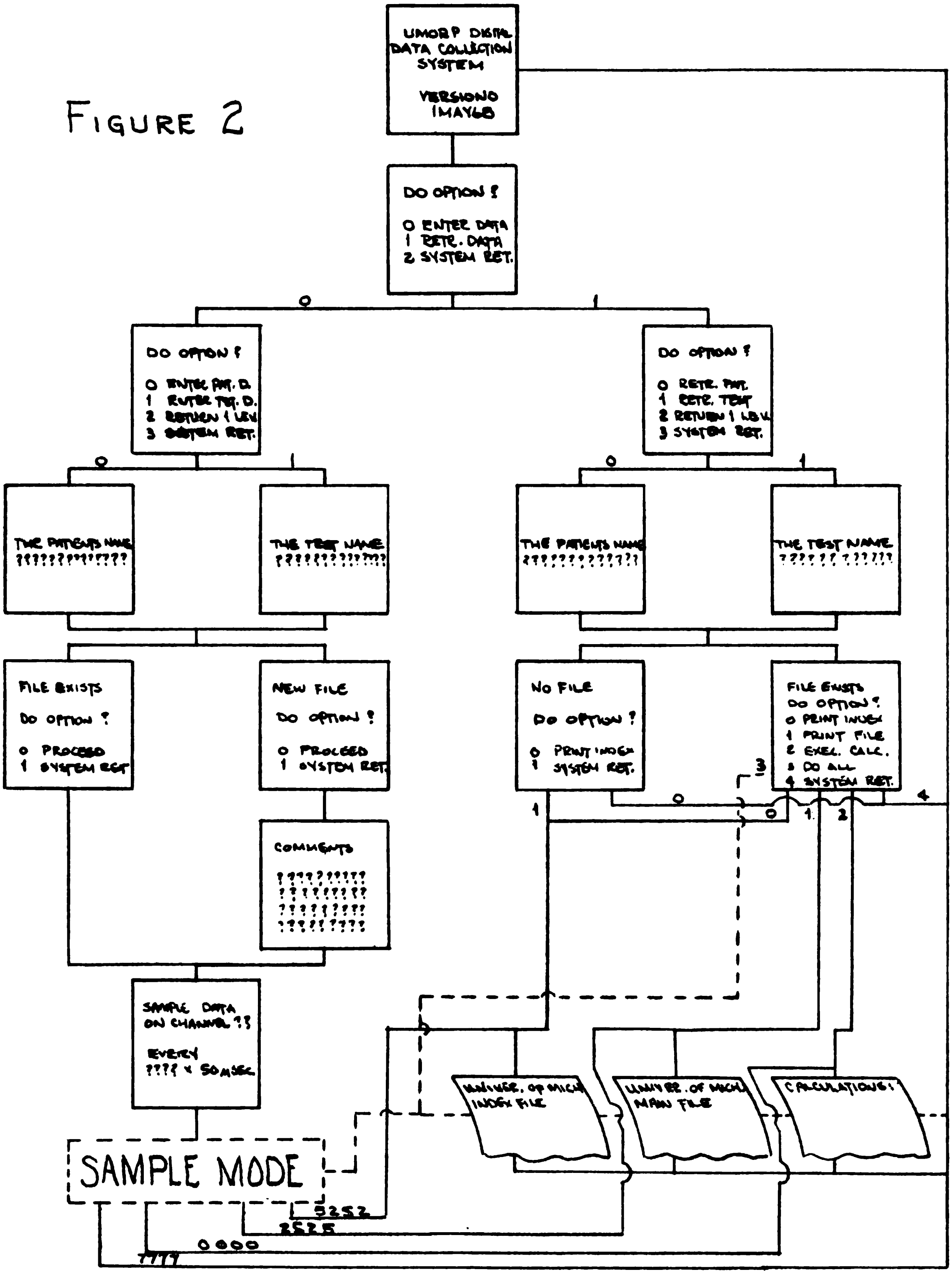
A write-up of the detailed use of this program follows. The writing of such software involves many intuitive requirements, with regard to creating a file. To facilitate comprehension, Figure 1 shows the panel of the computer which has the following organization. Two tape units are located immediately above the Linc console. The left tape unit is numbered Unit 0 and the right numbered Unit 1. For this recording system the executive routine tape is mounted on Unit 0 and 1 of the data tapes is located on Unit 1. The executive routines number and keep track of which tape should be on Unit 1 and notify the user.

The organization of the program can be visualized with the aid of Figure 2 which is a graphical representation of the ebb and flow of information. Reference to this as I proceed with a verbal explanation should be helpful in elucidating my remarks.

Figure 1

The left half of the lower panel is the console for the Linc side of the computer. The right half of the panel is the console for the PDP-8 computer. On the extreme left of the Linc console are several toggle levers which include the START 20 LEVER, LOAD LEVER and RESUME LEVER. Immediately underneath the Linc console are several switches. The six left-most switches are the Sense switches numbered 0 through 5. These switches may be raised or lowered and under program control read as binary 0 or 1 providing decision capability for the computer. Adjacent to them and continuing to the right are twelve switches called the Left switches. These switches may be set to a 12 bit binary number. The Up position sets the bit to 1 and the Down sets the bit to 0. These switches may also be read under program control. In the upper right hand side of the front panel of the machine are eight analogue input terminals numbered 10 through 17. Directly in the center of the machine is a 5 inch cathode ray tube.

FIGURE 2


UMORP DIGITAL DATA COLLECTION SYSTEM
VERSION0 1MAY68
DO OPTION ?
0 ENTER DATA
1 RETR. DATA
2 SYSTEM RET.
DO OPTION ?
0 ENTER PAT. D.
1 ENTER TES. D.
2 RETURN 1 LEV.
3 SYSTEM RET.
DO OPTION ?
0 RETR. PAT.
1 RETR. TEST
2 RETURN 1 LEV.
3 SYSTEM RET.
THE PATIENTS NAME
THE TEST NAME
FILE EXISTS
DO OPTION ?
0 PROCEED
1 SYSTEM RET.
NEW FILE
DO OPTION ?
0 PROCEED
1 SYSTEM RET.
NO FILE
DO OPTION ?
0 PRINT INDEX
1 SYSTEM RET.
FILE EXISTS
DO OPTION ?
0 PRINT INDEX
1 PRINT FILE
2 EXEC. CALC.
3 DO ALL
4 SYSTEM RET.
COMMENTS
SAMPLE DATA ON CHANNEL ??
EVERY ???? × 50 MSEC.
SAMPLE MODE
UNIVER. OF MICH. INDEX FILE
UNIVER. OF MICH. MAIN FILE
CALCULATIONS:
5252
2525
0000
7777

APPENDIX
to
Attachment 4

UMORP DIGITAL
DATA COLLECTION
SYSTEM

VERSION 0

9 MAY 68

Introduction:

UMORP Digital Data Collection System is a program to collect analogue signals and convert them to digital values for later off-line computation. The System is file oriented and accomplishes its task by creating user named files. Each file has a maximum storage of 100 tests, i.e. X sets of data, thus limiting the amount of data that can be stored in any one file. The System capacity is eight data tapes. The user can enter and exit a file any number of times until the file capacity is exceeded.

Usage:

The System resides on Unit 0 while data tapes reside on Unit 1. To initiate operation, mount the System tape on Unit 0 and data tape 0 on Unit 1. Raise LOAD LEVER. The following initial display will appear:

```
UMORP DIGITAL
DATA COLLECTION
SYSTEM

VERSION  0
9 MAY 68
```

It is terminated by striking the end of line (EOL) key. Then the following display will appear:

```
DO OPTION?

0  ENTER DATA
1  RETRIEVE DATA
2  SYSTEM RETURN
```

The SYSTEM RETURN option always returns the initial display to the user.

Option 0 (Enter Data):

This can be entered by typing 0 and then striking the EOL key. The user will then be presented with the following display:

```
DO OPTION ?

0  ENTER PATIENT DATA
1  ENTER TEST DATA
2  RETURN 1 LEVEL
3  SYSTEM RETURN
```

RETURN 1 LEVEL will merely take the user back to the previous display. By either typing 0 or 1 and then striking the EOL key, the following displays will appear:

```
THE PATIENTS NAME
??????????????
```

OPTION 0

```
THE TEST NAME
??????????????
```

OPTION 1

At this point one may assign a file name, by filling in the question marks and terminate it by striking the EOL key. All unfilled question marks will be filled automatically with blanks. Both frames will continue to the following sequences. The System at this point will check its files and determine if this name exists. If it does find the name the following display will appear:

```
FILE EXISTS

DO OPTION ?

0  PROCEED
1  SYSTEM RETURN
```

If it does not find the name, the following display will appear:

```
NEW FILE WILL BE
    CREATED

DO OPTION ?

0  PROCEED
1  SYSTEM RETURN
```

If it is a new file, the following display will appear:

```
COMMENTS:

????????????????????
????????????????????
????????????????????
????????????????????
```

The user can store any comment pertinent to his test he wishes one line at a time.

After terminating the above display, the System will request the following information:

```
SAMPLE DATA
ON CHANNEL ??

EVERY
???? X 50u SEC.
```

The System Program is written so that it will accept data information on channels from 00 to 17 in time increments and are from 1 to 1024 u seconds. Each set of question marks is filled in separately and terminated by striking the EOL key. At the conclusion of this display, all sense switches are operative as follows:

Sense Switch Number	Position	Function
0	UP	At the conclusion of taking data new information may be entered for channel number and increment size.
0	DOWN	System will retain last channel number and increment size until a change is requested.
1	UP	Diagnostics will be typed at the conclusion of data gathering on the following: a. maximum value

Sense Switch Number	Position	Function
		b. minimum value
		c. signal level threshold exceeded
		d. frequency threshold exceeded
		e. saturation threshold exceeded
1	DOWN	Interruption of data gathering will occur if:
		a. signal level is too low
		b. frequency is too high
		c. saturation is occurring
2	UP	Input data will be displayed as a moving window until sense switch is lowered.
2	DOWN	Termination of display.
3	UP	The System will declare through teletype when it is ready for next test.
3	DOWN	No operation; i.e. System will not declare through teletype.
4	UP	No tape will be written at the conclusion of data gathering.
4	DOWN	Tape of digitized analogue data will be written at the conclusion of data gathering.
5	UP	Test can be concluded and data gathering stopped.
5	DOWN	Computer will continue to take data.

Data gathering is initiated either by depressing the START 20 switch or by shorting sense line 0 which is a device to impose a threshold of acceptance on analogue input values. If sense line 0 is continuously closed, gathering will continue automatically until the file is full or until sense switch 5 is raised.

At the conclusion of data gathering, file updating will occur automatically. If the left switches are set to one of three different values, three different exits as described below will occur.

Left Switch Setting	Exit
7777	SYSTEM RETURN (return to initial frame) will occur.
5252	File index will be printed containing all file names followed by SYSTEM RETURN.
2525	Data allocation of the file just concluded will be brinted followed by a SYSTEM RETURN.
0000	User calculations will be executed test by test followed by a SYSTEM RETURN.
Anything Else	Standard exit will occur. This means the first file index is printed, then data allocation is printed, then user calculations will be executed test by test followed by a SYSTEM RETURN.

Option 1 (Retrieve Data):

This option is exercised by typing 1, then striking the EOL key. After doing so, the following display will appear:

```
DO OPTION ?

0  RETRIEVE PATIENT DATA
1  RETRIEVE TEST DATA
2  RETURN 1 LEVEL
3  SYSTEM RETURN
```

Option 2 and 3 are as previously explained. Striking 0 and 1 and then the EOL key will result in the following:

```
THE PATIENTS NAME
??????????????
```

OPTION 0

```
THE TEST NAME
??????????????
```

OPTION 1

At this time the file name may be entered. Both of the above frames will result in the following sequence. If the file is not present, the following display will appear:

```
NO FILE

DO OPTION ?

0   PRINT INDEX FILE
1   SYSTEM RETURN
```

Exercising Option 0 will print a list of the names and main file tape and block numbers. Obviously Option 1 will return to the original display. If the file is present in index, the following display will appear:

```
FILE EXISTS

DO OPTION ?

0  PRINT INDEX FILE
1  PRINT MAIN FILE
2  EXECUTE CALCULATIONS
3  DO ALL OF ABOVE
4  SYSTEM RETURN
```

All of the above options will end with a SYSTEM RETURN.

Marking Tapes and Removing Files:

When the user wishes to initiate the System, he must first mark the data tpaes. The marking that occurs is not the same as MARKL8 (Digital Equipment Corporation supplied tape marking program) but instead marks the tape so that the System can recognize them. Therefore, one starts with eight MARKL8 marked tapes and puts the System tape on Unit 0 and the tape to be marked on Unit 1. Then the LOAD LEVER is raised. At that time the following display will appear:

```
 UMORP DIGITAL
DATA COLLECTION
    SYSTEM

  VERSION  0
   9 MAY 68
```

Then strike the EOL key. At this time the following frame will appear:

```
DO OPTION ?

0  ENTER DATA
1  RETRIEVE DATA
2  SYSTEM RETURN
```

Although an Option 7 does not appear, strike 7 and then the EOL key. The following display will appear:

```
DO OPTION ?

0  DELETE 1 FILE
1  DELETE ALL FILES
2  MARK TAPES
3  SYSTEM RETURN
```

Exercising Option 0 allows the user to delete any file name. It will result in the following display:

```
  FILE NAME
??????????????
```

If it cannot find the file name, the following display will appear:

```
NO SUCH NAME
```

It is important to realize that deleting all file names individually is not the same as DELETE ALL FILES (Option 1).

In exercising Option 2, the System will start by asking the user to mount data tape 0 on Unit 1. It will continue until all eight tapes have been marked at which time it will return to the original display.

COMMENTS MADE AT THE TWO-DAY MEETING ON PRESSURE MEASUREMENTS AT THE PROSTHETICS CENTER OF THE VETERANS ADMINISTRATION

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Immediate postoperative fitting of the amputee, as developed in detail by the fine work of Weiss, et al., and Burgess and his group, represents a true advance in medical therapeutics. The three principles on which its success appears to be based are: 1) Postoperative edema control, 2) Early weight-bearing, and 3) Maintenance of muscle fiber tension by myodesis. I omitted the last-mentioned from today's comments since it is not immediately related to the present discussion.

I believe that the mechanical principle invoked for edema control differs from that for weight-bearing. The use of one and the same plaster shell for both seems to me an unwarranted simplification of essentially two tasks. The need for today's conference is an outgrowth of this questionable method employed to solve the desirable goal of "immediate fitting."

The fitting plaster shell applied as elastic bandage soon after the operation, will, as soon as hardened, no longer fit after the first attempt at weight-bearing. The volume reduction of a below-knee stump on comparable external compression, according to my measurements with the electromagnetic induction plethysmograph, may amount to 0.50 percent in a lean stump and to more than 5 percent in an edematous stump. The stump will hence move about in its plaster shell and will be separated from it by silk, gauze, and gauze fluff imbibed with variable amounts of serum, and it will contact parts of the hard shell depending on its own shape, on body weight, on gait characteristics, etc. To define the pressures exerted by the stump upon the plaster shell, at rest and during motion, as this conference is attempting to do for the purpose of standardizing procedures, seems to me a meaningless task, unless stump-volume reduction, the location, amount and composition of material inserted, gait characteristics and various other factors are precisely defined. To look for representative pressure points in the stump seems equally spurious.

I believe we should separate postoperative edema control from early weight-bearing. Edema control is accomplished by any nonstretchable mold applied upon the stump. The application of a gelatin-zinc bandage is standard procedure in edema control due to chronic venous insufficiency in peripheral vascular-disease clinics. The bandage consists of a simple roller bandage permeated with a mixture of zinc oxide, gelatin, water and glycerine in such proportions that the bandage is just moist when applied. The dried bandage forms a nonstretchable mold around the stump.

In contrast to the hard plaster shell it is pliable. Hence it permits alterations in cross-sectional areas without change in its circumferential expansion. Thus, it would permit any equicircumferential cross-section to change its shape (for instance, from round to oval and vice versa) and thus cause a cylindrical body enveloped by it to lose volume when deformed. In a below-knee stump the noncompressible fluid would then have the tendency to be drained off pre-formed channels due to an increase in internal pressure. Changes in cross-sectional areas of the stump will then be as effective in moving out edema as is the magnitude of such deforming forces. Admittedly, the application of this bandage is an art which must be practiced and which is quite different from that of applying a plaster bandage. If properly applied it forms a very accurate mold of the stump.

Recently my colleagues and I measured the segmental volume changes caused by such a mold in normal legs and the compressive forces developed during movements. The movement of the ankle up or down, passive or active, produced such deformation of the leg that compressive pressure gradients were set up in a proximal direction, resulting in a centripetal pump effect. Our data permit to differentiate between three mechanisms:

1 The anatomical spatial relationship between bones and muscle-tendon attachments which is stable at rest, and which continually changes during ankle movements.

2 The deforming forces produced by contracting muscle.

3 The shifts of blood caused by muscle contraction and muscle stretch.

Obviously, in a below-knee stump the first of these three mechanisms is not operative, but Dr. Perotta and I have found that below-knee stumps fashioned by traditional methods, even without the benefit of myodesis, can undergo segmental deformation and volume changes during volitional contraction of residual muscle fibers. The pressure gradients thus created do not have to be large to be effective in causing loss of edema. McMaster's work has shown clearly that pressure gradients as small as one cm. of water between interstitial tissue and lymphatics can force fluid from tissues.

Thus, we expect a gelatin boot applied soon after the amputation on the operating table directly on the approximately cylindrical stump, to keep the stump edema-free and to promote loss of edema, if present. We also expect this effect to be enhanced by systematic muscle setting exercises in the tightly fitting mold.

Advantageous by-products of this method are:

1) The bandage is porous and permits drainage from the operative wound.

2) Drains left in place during the operation can be removed through the bandage without change.

3) In case of incongruity between stump and mold due to loss of edema from the stump, new bandages can be applied to take up the slack. It takes but three minutes in experienced hands to do that.

4) This bandage has proved in many cases to promote healing delayed by edema. Wound edges are kept together and it seems reasonable to expect enhanced epithelization as occurs in venous ulcerations.

5) It appears not unreasonable to study modes of application which might make it possible to do away with skin sutures altogether.

The second principle inherent in immediate fitting, namely that of weight-bearing, could thus be separated from the first procedure leading to edema control. Plaster casts could be applied without any pressure on the stump itself which, as previously described, has now been protected against edema formation. When prosthetists are not available, preformed weight-bearing devices such as the ischial weight-bearing Cosmevo leg could be used. I would like to try first pursuing the use of a plaster cast according to the principles of conventional below-knee prosthetics, however, with a thigh corset, side bars and patellar-tendon-bearing or by some form of ischial weight-bearing; pull on the skin would be minimized if a gelatin cast had been applied. If some work is conducted considering feasibility, practicality and safety for the patient, this part of immediate fitting can be worked out.

In summary, I believe it is possible to separate the procedures leading to early weight-bearing and to edema control without compromising the effectiveness or the further development of either procedure; such has been the unfortunate by-product of using the hard plaster shell for two separate functions. It need not be said that the complications which prompted today's conference could hardly occur and that standardization of each of the two proposed procedures would be infinitely easier than standardization of one procedure to serve two functionally and physically different purposes.

In conclusion I propose the use of the gelatin-zinc mold to be applied directly on the freshly amputated stump as edema control and the use of a plaster shell to be applied without weight-bearing on the stump as means of early postoperative ambulation. I propose to test this out first on below-knee amputation stumps.

Thank you for inviting me to this interesting meeting and for giving me an opportunity to be heard.