T H E U N I V E R S I T Y O F M I C H I G A N

MEDICAL SCHOOL
Department of Physical Medicine and Rehabilitation

Final Report

BIOMEDICAL ENGINEERING IN PHYSICAL REHABILITATION

James W. Rae, M.D., Project Director
James L. Cockrell, Ph.D., Research Coordinator

July 1, 1967 - June 30, 1970

This investigation was supported, in part, by Research Grant No. RD-2604-M from the Division of Research and Demonstration Grants Social and Rehabilitation Services, Department of Health, Education, and Welfare, Washington, D.C., and by Kenny Michigan Rehabilitation Foundation.

administered through:

OFFICE OF RESEARCH ADMINISTRATION

ANN ARBOR, MICHIGAN

January, 1971

Findings for the Rehabilitation Worker:

From the study of the mechanical properties of connective tissue:

Animal tendon (cats) are characterized by visco-elasticity and plastic-like flow. The latter proceeds when a critical load is exceeded. Above 44°C (reached in some therapeutic modalities) this critical load (the load at which plastic-like flow begins) decreases sharply reaching a minimum at about 49°C, and then increasing again. Although this property has not been measured for human tissue, the suggestion is made that such tissues are altered most efficiently by long term application of moderate forces at tissue temperatures elevated to about 45°C.

From the study on the normal (perpendicular to the interface) forces between the stump and prosthesis in below-knee amputations:

Peak pressures during walking seldom exceed 40 psi at any location. The maximum observed was about 150 psi. Patient discomfort did not correlate well with the pressure magnitudes.

Significantly lower pressures were observed for instances where soft liners were used, and particularly for a new silicone gel liner assembly.

There are indications that shear forces (those parallel to the interface) are more decisive than normal forces alone in relation to comfort and function achieved with the prosthesis.

An instrumentation system using semiconductor strain-gage transducers and computer-assisted data acquisition and display has been assembled for general interface pressure measurements in research or clinical situations.

From the study on clinical application of external control:

For quadriplegic patients with high-level cord injuries, the platysma muscle was found to have superior properties as a myoelectric control site. It is generally easily trained, and accessible over a wide area for surface electrodes easily hidden under a collar. Other motions of head and shoulder cause minimal false control.

From the study on device design and development:

Using polyvinylchloride resins, a gel material has been developed and fabricated into a number of patient support devices such as wheelchair seat pads, hospital mattress insert pads, and leg-brace pads. This material offers excellent flotation characteristics at significant savings compared with pads using silicone materials. These devices are available now from the University of Michigan Medical Center and also a number of commercial houses.

TABLE OF CONTENTS

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

ABSTRACT

FINAL REPORT

"Biomedical Engineering in Physical Medicine"

This final report presents the results of five sub-projects carried out in the Department of Physical Medicine and Rehabilitation during the years July 1967 through June 1970. They are abstracted separately in the paragraphs which follow.

Mechanical Properties of Connective Tissue.

Elongation responses of cat extensor digitorum communis tendon to triangular wave loading and to constant loads achieved by ramp loading were studied over a temperature range from approximately 22° to 55°C.

The time-dependent portion of the elongation was found to be composed of two parts, a viscoelastic component and a component which at a constant load appeared plastic-like. This plastic-like elongation differed from classical plastic flow, however, since it represented a progressive decrease in stiffness with little or no apparent increase in unstressed length. Plastic-like elongation was observed only after specimens had been loaded to sufficiently large loads and, therefore, appeared to have a critical load similar to the yield stress for true plastic flow. This critical load decreased a plastic-like elongation proceeded, suggesting that the progressive decrease in stiffness might be the result of a gradual failure of the material. However, values for the critical load were relatively consistent from one experiment to another when determined from graphs of elongation rate as a function of load for tests performed shortly after plastic-like elongation had begun. Such 'early critical loads' were found to be nearly independent of temperature over the range from 22° to 44°C but decreased sharply with increasing temperature from 44° to 47°C. The 'early critical load' reached a minimum between 47° and 51°C and increased with further increases in temperature up to 55°C. It was noted that the temperature

range over which the 'early critical load' decreased sharply with increasing temperature corresponded closely to the 'glass-type' transition temperature which has been reported for collagen.

Dynamic stiffness and damping (hysteresis energy dissipation) measured under triangular wave loading with peak loads less than the early critical load, however, showed no marked changes at temperatures around the 'glass-type' transition temperature and appeared to be nearly independent of temperature over the entire range from 22° to 55°C. Possible trends toward a slight increase in damping and a slight decrease in dynamic stiffness with increasing temperature were noted, but these were not statistically significant in the results from this study.

Attempts to develop a mathematical model for the mechanical behavior of tendon were unsuccessful but did show that the damping displayed by cyclicly loaded tendon could not be adequately described by a linear differential equation in load and elongation or by simple Coulomb friction as the major dissipative process.

Interface Pressure & Stress Distribution in Prosthetic Fitting.

A prosthesis socket - amputated limb interface pressure measurement system was developed and used in preliminary research on the patellar-tendon total contact below-knee prosthesis. The system comprises:

1. A new miniature pressure transducer developed as a part of the research effort in conjunction with a commercial manufacturer.
2. A laboratory digital computer together with commerically available signal conditioning, amplification, and interface hardware.
3. A collection of computer programs designed for collection, storage, computation, and presentation of pressure information.

The pressure interface system is a research tool for the study of load transfer from a below-knee prosthesis to skin tissue in particular, and is concerned with the presentation of this basic information. Its use is extensible to many other problems of this nature.

A description of the amputated limb and the prosthesis in question is presented to establish the interface to be examined.

The investigation of pressure distribution is initiated with discreet measurements taken from sets of five transducers first arranged in linear array. Continuous curves of pressure as a function of location of the transducers are generated by interpolation procedures. Pressure distribution surfaces over areas are developed by interpolation after fitting continuous curves to five discreet values collected from the transducers set in a 1/2" x 1/2" square array with one transducer at the center. Regions of pressure distribution are displayed by successive positioning of these areas.

A mode of display of pressure distribution and variation on an oscilloscope screen was developed. It consists of a gray scale of eight levels that are generated by control of the density of illuminated raster points. This effectively represents the variation of pressure as function of location and time.

Repeatability and reproducibility of pressure patterns are discussed.

Representative data from several subjects are presented and studied for evaluation of the system and initiation of investigation of pressure distribution in critical areas.

The pressure interface system was designed to satisfy two distinct disciplines of study.

1. The hospital staff which services the amputees.
2. The engineering researcher who is concerned with basic redesign problems.

The importance of fundamental studies of the tissue-prosthesis interface to prosthetic research is discussed.

Clinical Applications in Myoelectric Control

Two problems illustrating clinical applications of myoelectric control for orthotic and prosthetic devices are presented. In one instance, criteria for the selection of myoelectric sites for surface electrodes were developed and tested using three representative muscles, - trapezius, frontalis, and platysma. A standard contraction as measured at fixed electrodes was elicited while measuring integrated voltages at coordinate points drawn on the skin over the muscle. From the data of this series the platysma provided the most reliable set of sites. Criteria for judgement were magnitudes, proportionality, and freedom from interference by accessory activities.

The other problem concerned development for myoelectric control of prosthetic or orthotic devices a quantitative testing procedure that utilizes an on-line digital computer. Variables are defined which separate operator proficiency from electronic and mechanical hardware performance. Programs were written to evaluate the time variables. Close interaction between subject and computer for task display and measurement of performance was design objective. Final implementation of the system and clinical use were not completed in the grant period.

Brace Design and Development

Clinical use of the Michigan Mobile Arm Support and Arthritic Knee Brace are described. Initial use of polyvinylchloride (PVC) gels in orthotic and prosthetic devices is presented. Substantial patient acceptance has been achieved for the use of this material and an initial series comparing prosthesis liner materials is documented. It appears, from these results, that lower peak pressures at the tissue-device interface during walking can result from careful use of the gel material. Further substantiation of this inference is urged.

Basic Study of Joint Mechanics.

This study was directed toward a detailed examination of the mechanical location of the tendons and stabalizing forces produced during various hand positions. The hypothesis, that indirect measurements of tendon moment arms could be effected by direct measurement of inter-axis distances of the finger phalanges proved to questionable. The experimental procedures are discussed in times of the errors encountered and some projections made for alternate methods to obtain the desired tendon locations.

1. Introduction

1.1 Nature of the Research

"Biomedical Engineering in Physical Rehabilitation" describes an approach taken to a group of rehabilitation problems in the Department of Physical Medicine and Rehabilitation at the University of Michigan Medical Center, Ann Arbor. These problems are noted in relation to patient disability, and under the guidance of a Research Advisory Committee consisting of a coordinated team of professionals, aspects of each problem needing serious engineering study are identified. In some instances the problem is very fundamental, for example, understanding the mechanical nature of collagen tissue as it affects problems involving contractures or extensive scar tissue. On the other hand the problem may be very specific, such as the design of a knee brace for a patient with valgus deformity resulting from rheumatoid arthritis. The research activity is carried out in a clinical-educational setting where most of the components for research are already present and committed to the medical/educational functions. The inclusion of the engineering function as a coordinating and facilitating force has made it possible to sustain and intensify the creative work of all of the members of the rehabilitation team.

1.2 Description of the Report

The main divisions of this report describe the studies undertaken during the three-year period July 1, 1967 to July 1, 1970.

Chapter 2 summarizes the sub project undertaken to examine the mechanical properties of connective tissue. The chapter includes tissue as seen in cat tendon, and specifically describes the influence of temperature on these properties. Since the design of mathematical and mechanical models of these properties was the original goal of the work, the experimental approach was to measure stress as well as strain. This necessitated a detailed sub-study of cross-sectional measurement techniques.

Chapter 3 describes the steps taken to effect the measurement and display of forces acting at the interface between a below-knee prosthesis and the stump tissue. This study produced a technique and system for measuring not only these prosthetic interface pressures, but also those encountered in other rehabilitation problems arising from interface forces in brace pads, wheelchair-seat pads, and orthopedic shoes.

Chapter 4 presents two problems illustrating clinical applications of myoelectric control for orthotic and prosthetic devices. In one instance, criteria for the selection of myoelectric sites were developed and tested in relation to three selected muscles. In the other instance, a method was developed for effecting measurements on myoelectrically controlled devices which would effectively separate parameters associated with the patient and his training from those associated with the electrical and mechanical performance of the device.

Chapter 5 summarizes brace design and development activities related to some final aspects of the Michigan Mobile Arm Support and the Arthritic Knee Brace, and some aspects of patient support using synthetic gel materials. Chapter 6 concerns a basic study of hand joint mechanics. This was work carried during the early period of the project and closed out after year 1 because of a number of difficulties associated with the experimental procedures and the necessity to concentrate the group's effort in the other areas.

1.3 Impact and Direction of Work at the Conclusion of this Project

The connective tissue study has revealed the rheologic properties of cat tendon in the normal state. Two directions for the work ahead are suggested: First is to investigate in human tissue the parameters herein reported for cats. The other is to begin an investigation of pathologic collagen tissues;for example scar tissue or tissue from arthritic joints.

The interface force measurement study has made available a system for measuring the normal forces (perpendicular to the interface surface) in many interface situations. It can be used in a research or clinical setting. It has also revealed the urgency to explore the shear components of the interface force; that is, the component of interface force parallel to the interface surface. There are many signs that this may indeed be the more critical direction in terms of patient comfort and tissue tolerance, particularly for prosthetic applications.

At this writing the evaluation of myoelectric control performance as described in paragraph 4.2 has not evolved to the point where it is immediately applicable to clinical use. The method chosen involves interaction between a patient wearing a myoelectrically controlled device and a laboratory computer operating on-line. Adequate programs have been written. However refinement of these and experience with associated hardware are required to make this an effective measurement technique. In the area of brace design and development, the Michigan Mobile Arm Support is being prescribed routinely, and although installation is generally accomplished by an orthotist, the adjustments are carried out completely by Occupational Therapists in the evaluation and training of the patients using these devices. The arthritic knee brace is being used where indicated and has been applied to over 40 patients during the past three years as indicated in Chapter 5 of this report. Synthetic gel materials increasingly are being used for patient support in orthotic situations and in liners for prosthetic limbs. Because patient acceptance has been substantial, efforts are being extended to continue prescription of these materials from a clinical viewpoint, and to understanding their performance from an engineering point of view.

1.4 Personnel

Professional participants during the three year period were;

Project Director: James W. Rae, M.D., M.S.

Physiatrists: L.F. Bender, M.D., M.S.
G.H. Koepke, M.D.
E.M. Smith, M.D.
M.C. McPhee, M.D.

Staff Engineers: D.P. Bauer, M.S. (BioEngineering)
J.L. Cockrell, Ph.D. (EE)
E.B. Corell, Ph.D. (M.E.)*
D.G. Ellis, Ph.D. (BioEngineering)*

Staff Engineers (cont.):

D.H. Harden, M.S.M.E.
R.C. Juvinall, M.S.M.E.
J.R. Pearson, M.S.M.E.

Therapists: L. Spelbring, M.S., O.T.R.

Orthotist-Prosthetists: R.D. Koch, C.O.
J.P. Giacinto, C.P.
H.J. Sturza

Medical Writer/Editor: R. Good

The staff was further augmented by W.J. Nelson, Electronic Technician, H. Sullivan, Machinist; and M. Marshall, L. Corell, B. Alway, and P. Blackford, Secretaries. Significant contributions were also made from time to time by Medical Students and Engineering graduate students who were attached to the project briefly.

*Received Ph.D. during the project period.

2. MECHANICAL PROPERTIES OF CONNECTIVE TISSUE

2.1 BACKGROUND INFORMATION

2.1.1 GENERAL

The mammalian organism normally regulates its body temperature within relatively narrow limits except during hibernation. Even in non-hibernaters such as man, however, significant shifts in body temperature do occur. DuBois (1948)[2] has noted that rectal temperatures in normal human individuals may range from near 36°C in the early morning or in cold weather up to between 38.5° and 40°C with strenuous exercise. Also, rises of 3°C or more are commonly associated with a variety of diseases. In clinically induced "moderate" hypothermia, with the regulatory mechanisms temporarily suppressed as in hibernation, the core temperature is lowered to 23°C or below (Smith and Stetson, 1965).[3] Relatively large changes also occur locally with external heating or cooling.

There is at least one instance in which the therapeutic application of heat is presumed to induce medically important changes in the mechanical properties of fibrous connective tissue. In the treatment of contractures resulting from fibrosis or scarring of tissues around joints, therapeutic heat (as applied by ultrasonic heating) has proved to be of value. It is presumed that the extensibility of the fibrous structures increases with increasing temperature, facilitating subsequent therapy through range-of-motion exercises (Lehmann, 1965).[4]

Some previous experimental work, most notably that of Rigby[5] et al (1959) on rat-tail tendon, has indeed suggested that marked changes in the mechanical properties of collagen tissue are associated with temperature changes within the usual range of tissue temperatures. Among the changes which have been reported to occur with increasing temperature are an increase in the amount of stress relaxation and a decrease in the elongation at rupture. Some data also suggest a possible decrease in stiffness with increasing temperature (cf. LaBan, 1962)[6]. Rigby[5] et al (1959) reported that some of these changes occurred in "an abrupt and irreversible manner" at about 40°C, and went so far as to speculate that fever-induced changes of this kind in human collagen might be severe enough to impair the function of the heart valves.

Another abrupt change in the properties of collagen, the hydrothermal shortening which typically occurs at around 60°C, has been studied extensively for some time. However, the changes occurring near body temperature have received only limited attention in the ten years since Rigby[5] et al published their study. Since such changes could be of medical significance, the study reported here was undertaken in the hope of gaining further information which might be useful in anticipating and analyzing the effects of connective-tissue changes associated with those shifts in tissue temperature which result from physiological and environmental factors. It was assumed that the changes in mechanical properties having the most physiological significance would be those changes in extensibility which would influence joint stiffness. Therefore, the study was designed to emphasize these characteristics -- dynamic stiffness, plastic-like elongation, and damping (hysteresis) -- while omitting traditional determinations of tensile strength. Failure of tendons following plastic-like elongation, however, was included in the study.

2.1.2 MECHANICAL PROPERTIES OF COLLAGEN TISSUES IN UNIAXIAL TENSION

STRESS-STRAIN RELATIONS

Investigators who have dealt with the mechanical behavior of collagen tissues have generally found the load-extension characteristics of these materials to be markedly nonlinear, their stiffness increasing with increasing load (or elongation) except at quite large loads where yield may be presumed to occur with a resultant decrease in stiffness with increasing load (cf. Rigby et al, 1959)[5]. This behavior is illustrated in Figures 2-1 and 2-2. Figure 2-1 shows stress-strain curves obtained by Wright and Rennels[7] (1964) from tests on several specimens of human plantar fascia. Figure 2-2 shows a stress-strain curve for human Achilles tendon as obtained by Abrahams (1967)[8] and illustrates yield behavior. Specimens retested after yield occured have been found to be less stiff and to yield again at smaller loads than in the initial test (Rigby, et al, 1959).[5]

Exceptions to the observation of increasing stiffness with increasing stress, however, are found in the works of Walker et al (1963,[9] 1964[10]) and Benedict et al (1966,[11] 1968[12]). These studies, all performed by the same group of investigators, yielded stress-strain curves of highly variable character for embalmed specimens (Benedict et al, 1966,[11] 1968[12]) of human tendon. In these studies, tests were performed in unsaturated air, and strains were determined with reference to gage lengths established with specimens under "impending tension" (Walker et al 1964)[10] or under some preload (Benedict et al, 1968).[12]

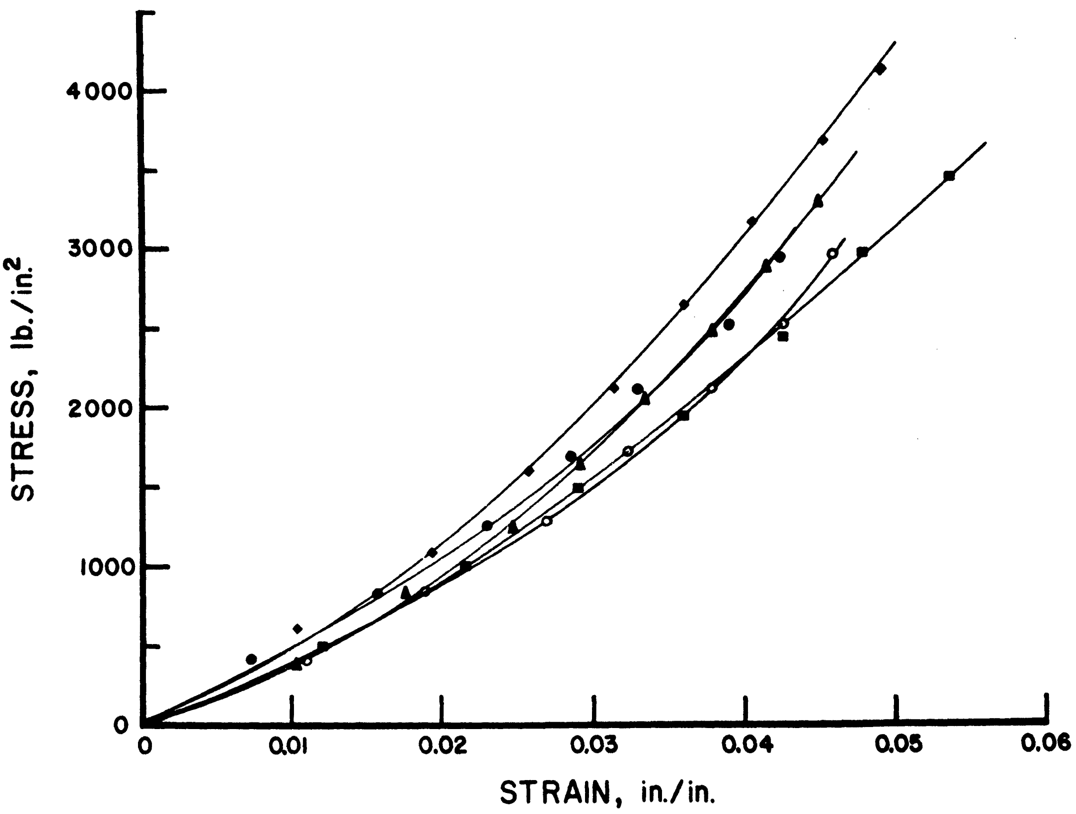


FIGURE 2-1 STRESS-STRAIN CURVES FROM TESTS ON HUMAN PLANTAR FASCIA. REDRAWN FROM WRIGHT AND RENNELS (1964).

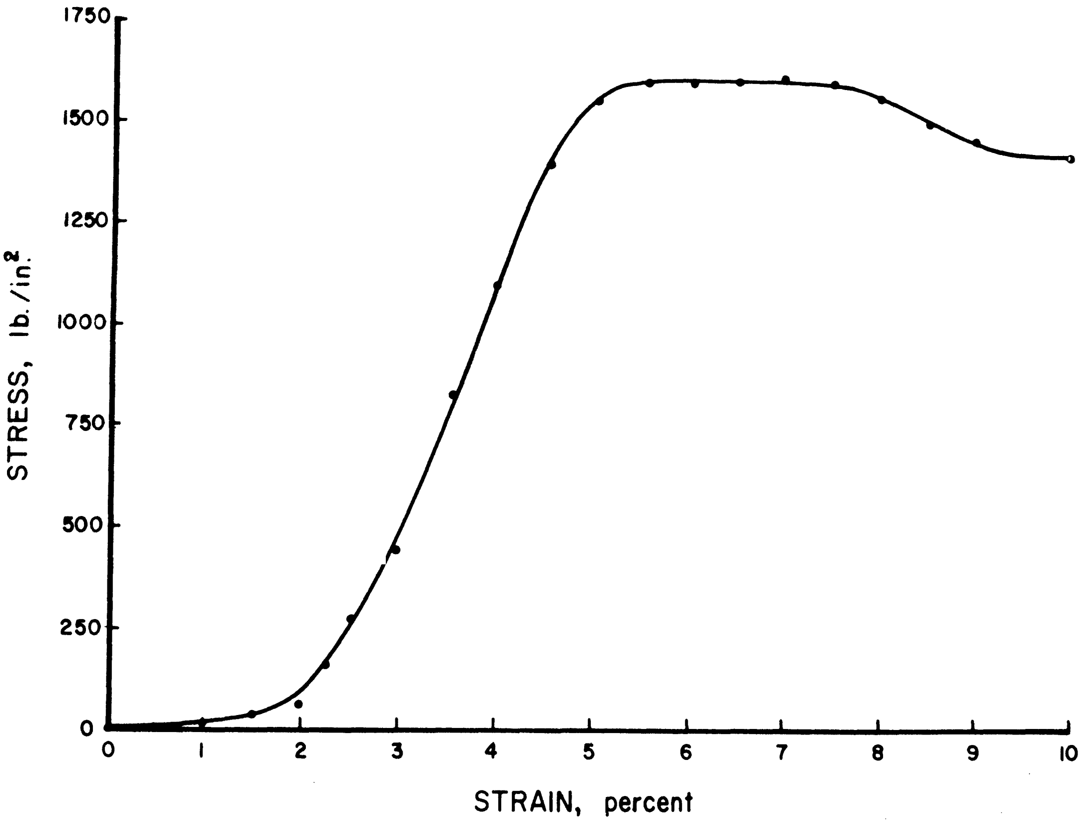


FIGURE 2-2 STRESS-STRAIN CURVE FOR HUMAN ACHILLES TENDON (NOTE YIELD BEHAVIOR). REDRAWN FROM ABRAHAMS (1967).

Werthein (1847)[13] noted the forms of stress-strain relations for several tissues including tendon and described them by a quadratic expression having two constants a and b:

$$(\text{strain})^2 = a(\text{stress})^2 + b(\text{stress})$$

In more recent reports, a variety of descriptions for the stress-strain relations of collagen tissues have been used.

Several authors including Reuterwall (1921),[14] Rigby et al (1959),[5] Partington (1963),[15] and Viidik(1966)[16] have described stress-strain curves for collagen tissues below the yield region as being composed of two parts, a "toe" portion at low stresses, in which stiffness increases markedly with increasing stress, and an approximately linear region in which the proportionality between changes in stress and changes in strain is nearly constant.

The two regions of the stress-strain curve for tendon below the yield region, i.e., the "toe" region in which the stiffness increases markedly with increasing stress and the region of intermediate stresses over which the stiffness increases only slightly with increasing stress, were suggested by Reuterwall (1921)[14] to correspond, respectively, to straightening of the initially wavy collagen fibers and to stretching of the straightened fibers. This has been demonstrated by Rigby et al (1959)[5] who photographed unstretched and stretched rat-tail tendons under a polarizing microscope and later by Abrahams (1967a,b)[8] who employed formalin fixation of unstretched and stretched specimens. Both Rigby el al[5] and Abrahams[8] found that the wave pattern was restored after the release of stretch in fresh specimens which were not stretched beyond a "safe limit" of approximately 4 percent strain.

Similar fiber-straightening and fiber-stretching phenomena in skin were noted by Daly (1966).[17] To describe the consequent mechanical behavior he developed a "semi-empirical" model which was composed of four elastic (or viscoelastic) elements connected as a parallelogram with a fifth element forming a diagonal of the parallelogram.

DAMPING AND TRANSIENT PHENOMENA

Transient phenomena, creep and stress relaxation, have been observed and studied in collagen tissues by a number of investigators.

Reuterwall (1921)[14] observed that specimens of human plantaris and extensor digitorum tendons subjected to a constant load showed time dependent extension (creep). His data tend to suggest that a limiting value of extension was approached after some time.

Stress relaxation in specimens of rat-tail tendon was investigated in some detail by Rigby et al (1959).[5] They found that the load in specimens held at a fixed extension decreased markedly with time but eventually approached a limiting value. In semilogarithmic plots of percent stress relaxation against the logarithm of time, they noted two approximately linear regions, the first extending for roughly 60 minutes. The amount of relaxation observed in their experiments was found to increase with increasing strain and with increasing rate of initial strain application. For initial strains of less than 4 percent (i.e., below the yield region) and stress relaxation times of "considerably less than 60 minutes" they found the stress relaxation behavior to be "entirely reproducible."

Haut and Little (1969)[18] investigated stress relaxation in canine anterior cruciate ligament over 10-minute relaxation periods and found the percentage relaxation to increase with increasing initial stress. They also found that at each strain, differences in stress which were associated with different rates of strain during the initial stretching persisted after 10 minutes of stress relaxation.

Coupled with transient behavior like that which has been described for collagen tissues, one would expect to find hysteresis or damping when specimens of these materials are subjected to cyclic loading.

In studies of the tensile properties of human fascia lata by Gratz (1931)[19] and of Achilles tendon by Stuke (1950),[20] the stress-strain curves for loading and unloading did not coincide, the curve for unloading showing slightly greater stiffness. Thus, in one stress cycle, energy was dissipated; and the material might be regarded as having displayed some form of damping (cf. Lazan, 1964).[21]

Rigby (1964)[22] studied rat-tail tendon subjected to cyclic extension for over 1000 cycles. He found that with repeated cycling the portion of the stress-strain curve above the "toe" region became steeper (increasing stiffness) but that the overall length of the specimen increased. He also noted that the hysteresis energy dissipation in each cycle decreased with repeated cycling. These changes continued to occur, although rather gradually, even after several hundred extension cycles. An improvement in the definition of x-ray diffraction patterns and an increase in shortening temperature (see subsequent section) with cycling in these experiments suggested that cycling increased the crystallinity of the fibers.

Other investigators have reported that behavior in the first cycle or first few cycles differed noticeably from that in subsequent cycles, but that after the first few cycles the stress-strain hysteresis loop became repeatable (VanBrocklin and Ellis, 1965[23]; Daly, 1966[17]; Viidik, 1968[24]). Such a phenomenon had apparently also been considered by Rigby et al (1959)[5] who applied a "conditioning stretch" to their specimens before initiating their testing procedures. Considering Rigby's findings (Rigby, 1964)[22] it seems probable that these latter observations do not represent the establishment of a true steady state response but rather a condition in which the change with continued cycling is slow enough not to be detected in a few cycles.

The effective stiffness, taken from stress-strain tracings obtained under cyclic loading or with a ramp loading or strain function, has been observed to increase with increases in some rate parameter (strain rate, cycle frequency, etc.) for human toe extensor tendon (Van Brocklin and Ellis, 1965),[23] human skin (Daly, 1966),[17] rabbit mesentery (Fung, 1967),[25] and canine anterior cruciate ligament (Haut and Little, 1969).[18] However, the energy dissipated in each cycle in a cyclicly loaded specimen has been reported to be nearly independent of rate parameters (Van Brocklin and Ellis, 1965[23]; Fung, 1967[25]).

There have been several attempts to develop mathematical analogs for the dynamic and transient behavior of collagen tissues in simple tension. Based on LaBan's creep experiments and on measurements of finger-joint torque-displacement characteristics, a rather simple rheological model consisting of a Kelvin body in series with an elastic element having a extension limit was suggested (Final Report, The University of Michigan Orthetics Research Project, 1964). This model is diagrammed in Figure 2-3. An analog "displaying the creep phenomenon with an element of plasticity" was mentioned by Viidik (1966).[16]

Other models have been developed to represent specific loadings or regions of response and are described by Ellis (1970).[1]

TENSILE STRENGTH

Numerous determinations of tensile strength have been made for collagen tissues. Since this report is not primarily concerned with strength characteristics, an extensive review of published work will not be presented here.

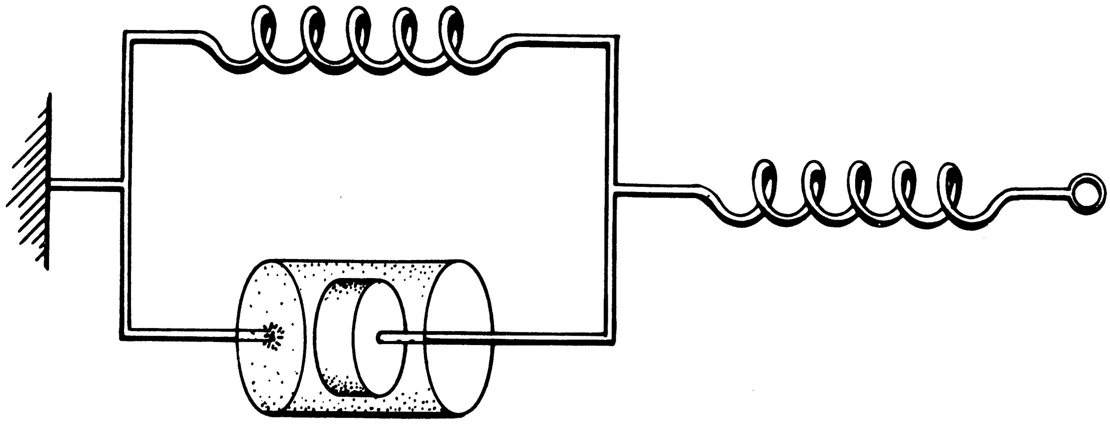


FIGURE 2-3 SIMPLE RHEOLOGICAL MODEL SUGGESTED AS AN ANALOG TO THE MECHANICAL BEHAVIOR OR COLLAGEN TISSUE.

Elliott (1965)[26] has reviewed published information on the tensile strength of tendon, noting that strengths reported for fresh material have typically been in the range 5 - 10 kg/mm^2, although much lower values have been reported, for example 63.1 x 10^6 dynes/cm^2 (0.62 kg/mm^2) by LaBan (1962).[6] The tendency of specimans to break where they are attached to the testing apparatus, as pointed out by Elliott, the occasional practice of disrupting the fiber array in order to obtain a test section of reduced cross-sectional area (see: Elliott, 1965),[26] and the large differences among cross-sectional area determinations (Eliss, 1969)[27] have probably all been major factors in the considerable variability in the published data.

Tensile failure of tendon is typically of a "slipping" type (cf. Takigawa, 1953).[28] In tests on muscle-tendon-bone preparations, though, failure has rarely been induced in the body of the tendon, but has typically occurred at the muscle-tendon junction or, more frequently, by a fracture of the bone around the insertion (McMaster, 1933[29]; Stuke, 1951[30]).

2.1.3 TEMPERATURE EFFECTS IN COLLAGEN TISSUES

HYDROTHERMAL SHORTENING

Certainly the most prominent effect of temperature on collagen tissues is the "hydrothermal" shortening observed at a temperature which is usually well above the range of physiological temperatures and above the range of temperatures considered in the study reported here. When an unloaded specimen of collagen tissue is heated to this temperature it is seen to shorten rather abruptly to roughly a quarter of its original length and to take on a slightly yellow, translucent appearance, in contrast to the reflective white appearance of the original material. Its consistency is similar to that of a rubber-like mass which can easily be stretched or compressed.

This profound change has probably been observed since the time man first began cooking meat, and has attracted significant attention from biophysical chemists during the past several decades. It has been interpreted as a rate-limited chemical reaction (Weir, 1949),[31] as the result of rupturing of interchain bonds (Thies and Steinhardt, 1950),[32] and as a phase change like crystal melting (Wöhlisch and deRochemont,[33] 1927; Garrett and Flory, 1956[34]; and others).

In x-ray diffraction studies, both the high-angle pattern, which shows prominent reflections corresponding to periodicities of 2.86 A in the axial direction and approximately 10 A in the transverse direction, and the low-angle pattern which shows reflections corresponding to an axial periodicity of around 640 A have been found to disappear upon shortening. The high-angle pattern (which is the same for collagen and gelatin) has been found to reappear with cooling, drying, or stretching, but for some time it was thought that the low-angle pattern was destroyed irreversibly (cf. Bear, 1944[35]; Wright and Wiederhorn, 1951[36]). Recovery of the low-angle pattern was demonstrated, however, by Frenkel et al (1965)[37] who restretched shortened specimens to their original lengths and then cooled these stretched specimens.

The absorption of heat, analogous to latent heat of fusion, has been found to accompany shortening (Wölisch and deRochemont, 1927[33]) as has a small increase in volume (Weir, 1949).[31] The volume increase has been used to identify the transition point in collagen-diluent systems; and a depression in the transition temperature with the addition of diluent, analogous to that generally found for crystal melting, has been observed (see: Garrett and Flory, 1956[34]; Flory and Garrett, 1958[38]).

It has been pointed out that the temperature at which shortening occurs, T_s, is typically not the equilibrium melting temperature unless the material has been partially premelted so that there is a fresh interface between crystal-line and amorphous phases (Oth et al, 1957).[39]

Tensile loads have been found to stabilize the native crystalline state and to retard the shortening transition, so that a specimen under load will attain a higher temperature before shortening than a unloaded specimen. This phenomenon has been described in terms of a one-dimensional analog to the Clausius-Clapeyron equation (Wölisch, 1940),[40] and a refinement of the description has been obtained using the equilibrium melting temperature rather than the shortening temperature (Oth et al, 1957).[39] predicted that there would be a critical stress above which the transition temperature would decrease with increasing load and were able to obtain experimental evidence for the existence of such a critical stress.

THE "GLASS TYPE" TRANSITION AND LOWER TEMPERATURE EFFECTS

In their investigations on the "melting" of collagen, Flory and Garrett (1958)[38] noted discontinuities in the slopes of volume-temperature curves for beef Achilles-tendon specimens. These discontinuities, which were found at 95° C for dried specimens but 40° C (only a few degrees above body temperature) for fully hydrated specimens, indicated a second order, "glass type," transition. The occurrence of such a transition in largely crystalline collagen was rather unexpected and was tentatively interpreted in terms of side-chain mobility.

Somewhat earlier, Weiderhorn and Reardon (1952)[41] had studied the properties of thermally contracted collagen and had obtained data indicating that the volume fraction of collagen in specimens which were swollen in a solvent (water, 1 molal LiCl in 1:1 water-ethanol, or formamine), and then blotted, decreased with increasing temperature over the range 21° to 65° C. Their data indicate, however, a possible inflection point in the volume fraction-temperature relation around 40° C. This is shown in Figure 2-4 in which Weiderhorn and Reardon's volume fraction data for thermally contracted collagen swollen in water have been plotted as a function of temperature.

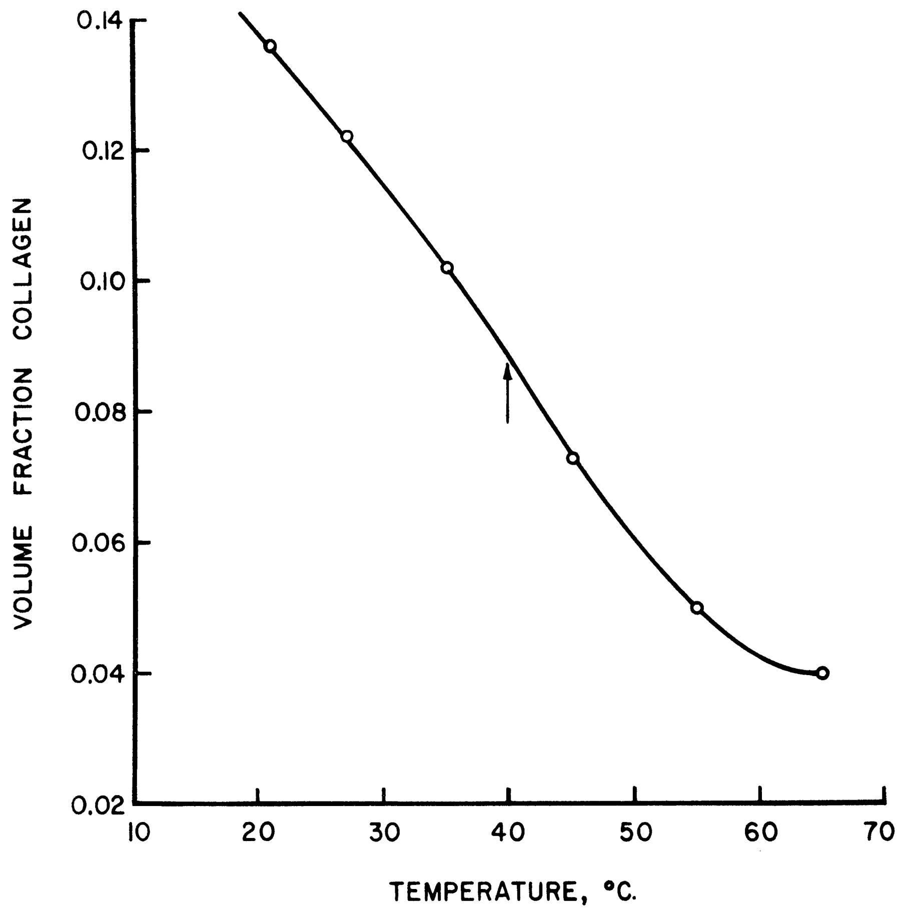


FIGURE 2-4 VOLUME FRACTION COLLAGEN AS A FUNCTION OF TEMPERATURE FOR THERMALLY CONTRACTED COLLAGEN SWOLLEN IN WATER. (ARROW INDICATES INFLECTION POINT) DATA FROM WEIDERHORN AND REARDON (1952).

Marked changes in the tensile mechanical properties of rat tail tendon which have been assumed to coincide with the "glass type" transition (see: Elden, 1968[42]) have been reported by Rigby et al (1959).[5] They found that above approximately 37° - 40° C specimens frequently ruptured at strains of only 3 to 4 percent, while below 37° C, specimens could be repeatedly strained to 4 percent and showed temperature independent load-strain behavior. In addition, they noted that stress relaxation behavior at strains below the "safe limit" of approximately 4 percent strain was nearly independent of temperature between 0° and 37° C but that as the temperature was increased above approximately 37° - 40° C the rate and amount of stress relaxation became substantially greater with increasing temperature. This effect is illustrated in Figure 2-5 which shows stress relaxation curves at 3 percent strain obtained at several temperatures by Rigby et al. These changes were described by Rigby et al as "abrupt and irreversible" and were interpreted as possibly reflecting the breakage of some hydrogen bonds in the collagen structure, a process analogous to that which occurs in melting.

Mason and Rigby (1963)[43] obtained both specific volume and isometric tension (in specimens stretched to a fixed extension) as functions of temperature for tendon specimens and found that the "glass transition" which Flory and Garrett (1958)[38] had identified as a discontinuity in the slope of the isometric tension-temperature curve. This is indicated in Figure 2-6, which shows the isometric tension-temperature curves obtained by Mason and Rigby,[43] one for native beef tendon and four for partially premelted beef tendon (see below). Similar changes in the slopes of isometric tension-temperature curves have also been reported more recently by Elden (1964a,[44] b,[45]; 1965[46]), who examined the effect of partial premelting and found that it decreased both the shortening temperature, T_S, (in accord with the work of Oth et al, 1957[39]) and the "glass transition" temperature, T_G. They reported the change in T_G to have been irreversible. Their data also show that partial premelting reverses the slope of the isometric tension-temperature curve below the shortening temperature, (see Figure 2-6). In the native material the isometric tension decreases with increasing temperature below the shortening temperature, but according to the data of Mason and Rigby,

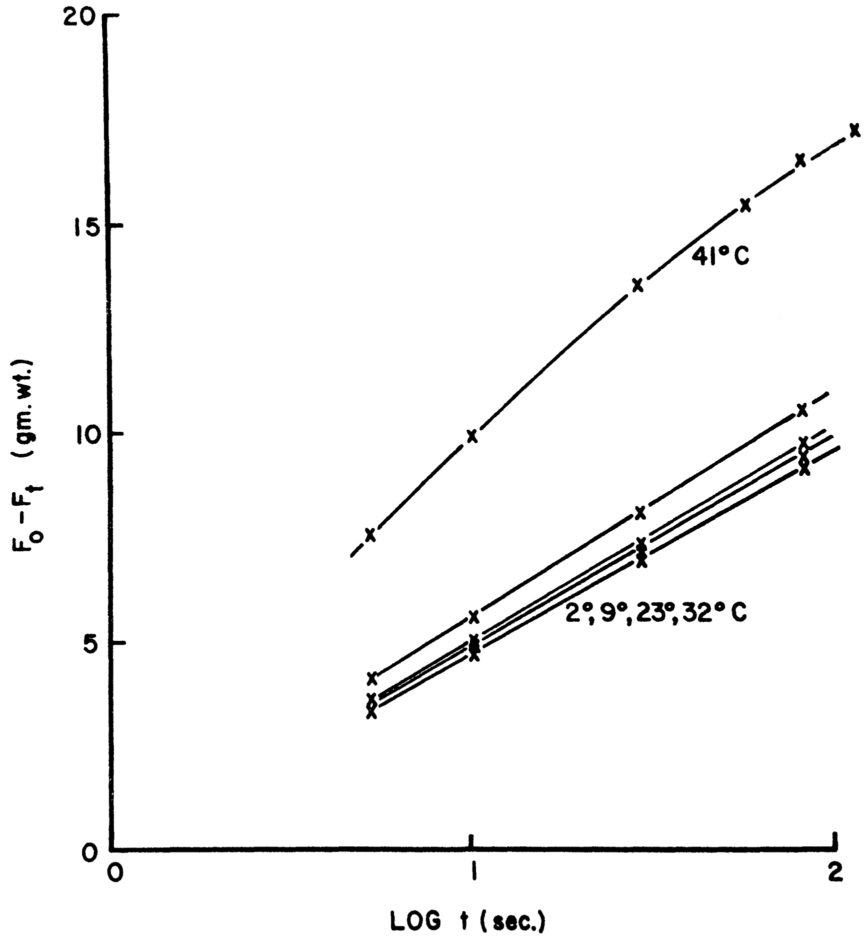


FIGURE 2-5 STRESS RELAXATION CURVES (DECREASE, F_o-F_t, IN LOAD PLOTTED AS A FUNCTION OF THE LOGARITHM OF TIME) FOR RAT TAIL TENDON AT 3 PERCENT STRAIN, AT SEVERAL TEMPERATURES. REDRAWN FROM RIGBY et al (1959).

isometric tension increases with increasing temperature in partially premelted specimens. If partial premelting was presumed to create amorphous regions displaying rubber-like thermoelasticity, this result would be anticipated in light of the discussion of partially melted proteins presented by Flory (1956).[47]

Rigby (1964)[48] determined transition temperatures from isometric tension-temperature curves in a series of experiments in which he examined the effect of strain history on the transition temperatures of rat-tail

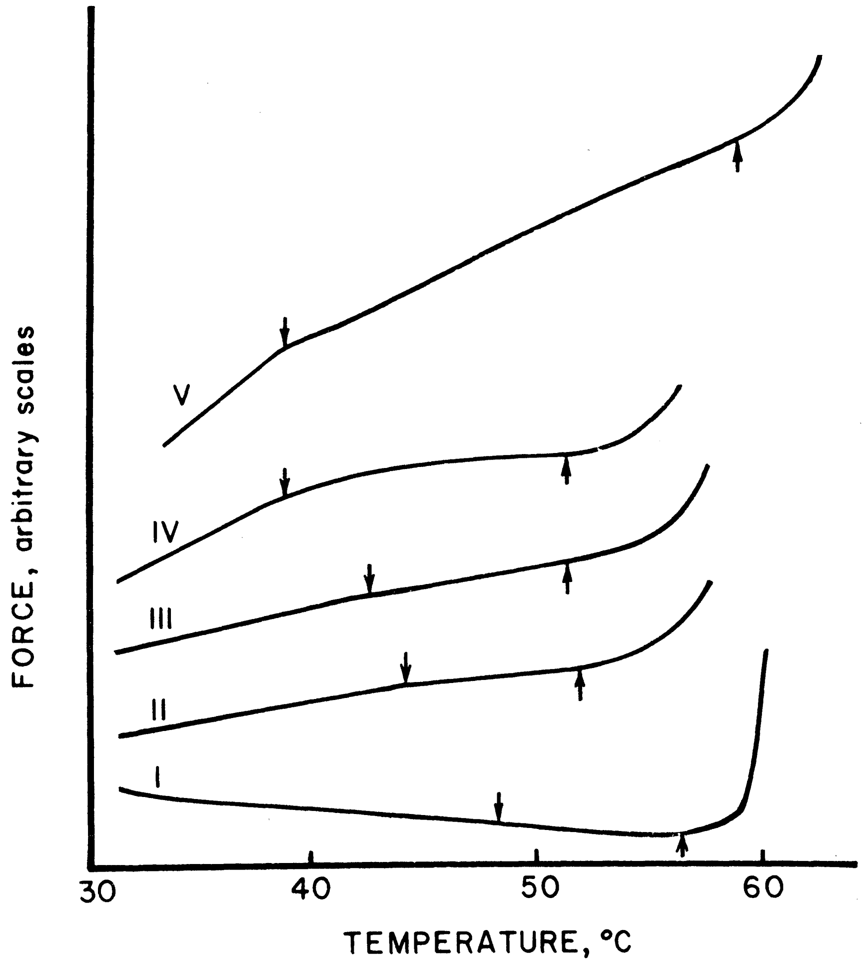


FIGURE 2-6 ISOMETRIC TENSION-TEMPERATURE CURVES FOR BEEF TENDON. (1) NATIVE, (II,III, IV) SUCCESSIVE TESTS, ALL PERFORMED THE SAME DAY ON A PARTIALLY PREMELTED SPECIMEN, (V) TEST ON THE SAME SPECIMEN AS IV, PERFORMED THE FOLLOWING DAY. ↓ T_G, ↑ T_S. (MASON AND RIGBY, 1963).

tendon in 0.9 percent saline. The curves which he obtained in these experiments (Figure 2-7) were significantly different from those obtained by Mason and Rigby (1963)[43] and differed from one another depending on the strain history. For native specimens, Rigby found only one transition "shortening" at 60° C (curve I). For specimens strained for long periods at moderate strains (curve II) or for short periods at large strains (curve III), he found an additional transition, a "partial shortening" at around 51° C. This effect was reported to have been reversible when small strains were employed, but not when large strains were used. After

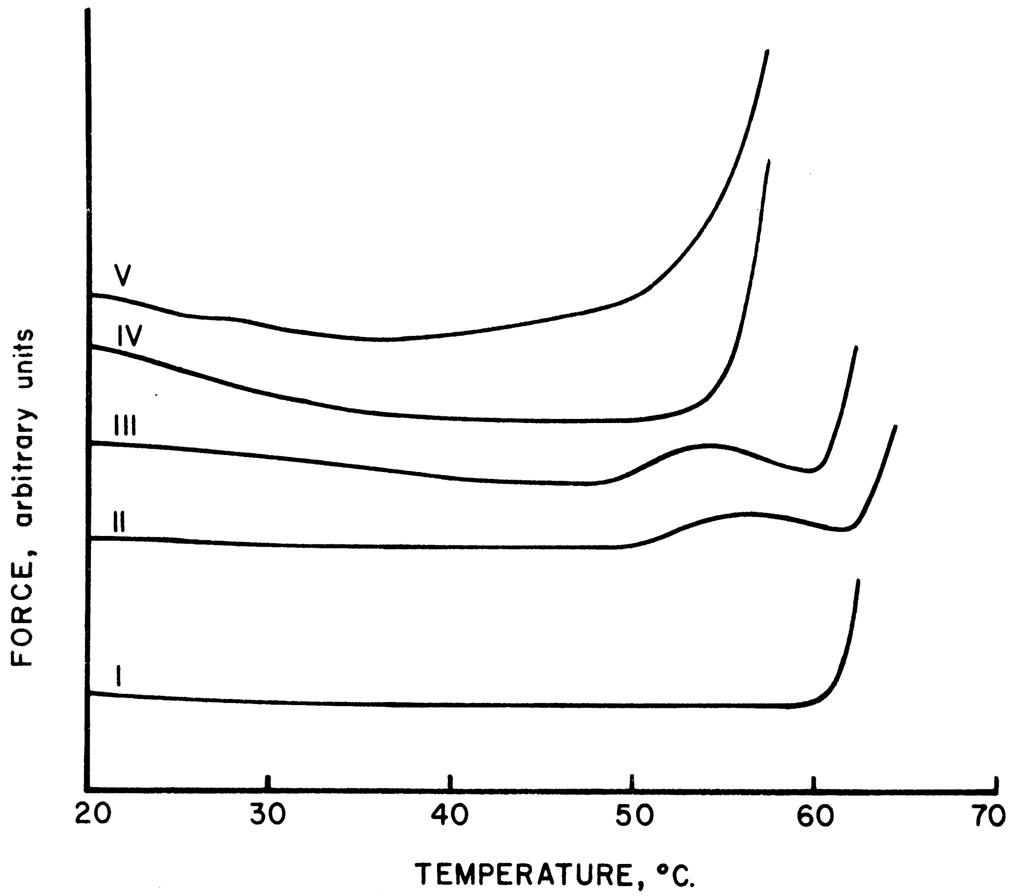


FIGURE 2-7 ISOMETRIC TENSION-TEMPERATURE CURVES FOR RAT TAIL TENDON IN 0.9 PERCENT SALINE, OBTAINED AFTER VARIOUS STRAIN HISTORIES. (I) UNSTRETCHED, (II) 1.0 PERCENT STRAIN FOR 22 HOURS, (III-V) 10 PERCENT STRAIN FOR 4, 17, AND 69 HOURS, RESPECTIVELY. (RIGBY, 1964b).

long periods at large strains he no longer observed this 51° transition but found, instead, a transition like that seen by Mason and Rigby (1963),[43] occurring at around 35° C (curves IV and V). "Shortening" in these specimens occurred at a lower temperature than in unstrained specimens, around 50° - 55° C.

2.1.4 OBJECTIVES AND SCOPE OF THE INVESTIGATION

Initially, the objective of this investigation was defined only in very general terms: to obtain a description of the way in which the tensile mechanical properties of tendon, exclusive of tensile strength, change with temperature. The description was viewed at first as a constitutive equation having coefficients which might be functions of temperature. The early work consisted of a loosely structured series of experiments, analyses, and computer simulations directed toward the development of such a constitutive equation but without temperature as a parameter (that is, with all experimental work performed at a single test temperature).

Since this work failed to yield a satisfactory mathematical analog to the mechanical behavior of tendon, this approach was abandoned, and the subsequent work was directed toward the determination of values for parameters associated with prominent features of the mechanical behavior of tendon at a sequence of temperatures. The features included were damping (hysteresis energy loss), dynamic stiffness, and plastic flow. These were investigated over a temperature range from approximately 20° to 55° C, which included the usual range of physiological temperatures and extended nearly to the shortening temperature.

2.2 MATERIALS AND METHODS

2.2.1 GENERAL CONSIDERATIONS:

Since the primary reason for undertaking this study of tendon mechanics was to obtain information which could be used in analyzing the effect of temperature on the functional characteristics of connective tissue structures in the living animal, it was desirable for the test situation to approximate the physiological condition of the tendons studied. The physiological environment of tendon fibrils is the ground substance. It might therefore have been desirable to test the specimens while they were surrounded by this substance, or by synovial fluid which has a similar composition. The large volume of bathing medium required in the test apparatus, however, made this impractical. The use of an artificial medium with similar ionic and specific mucopolysaccharide compositions would also have been impractical because of the difficulty of obtaining sufficiently large quantities of the mucopolysaccharides.

Therefore, the test environment was made to approximate the physiological environment only in inorganic ion composition (Ringer's solution at a neutral pH).

To assess the extent to which these and related changes were occurring in the experiments in this study, however, preserved specimens were used primarily in exploratory experiments such as those associated with attempts to develop mathematical models. In the temperature studies, results obtained from tests on preserved specimens were considered to be quantitatively valid only after they had been verified by subsequent tests on fresh material.

Earlier work has suggested that preservation by freezing may have some effect on the mechanical properties of connective tissue although the effect is probably small. Thomas and Gresham (1963)[49] found no significant differences in tensile strength among fresh, frozen, and freeze-dried specimens of human fascia lata. Viidik and Lewin (1966)[50] also failed to find a significant difference between the strengths of fresh rabbit anterior cruciate ligaments and those which had been preserved by freezing, but they did find that specimens preserved by freezing exhibited higher failure energy than fresh specimens, even though stiffness, gross shape of the stress-strain curve, and elongation at rupture were not found to be altered. Matthews and Ellis (1968),[51] however, did find a statistically significant decrease in stiffness (around 10%) associated with preservation by freezing in their experiments on extensor digitorum communis and extensor lateralis tendons from the cat.

2.2.2 EXPERIMENTAL PROTOCOL

Tendons used in this study were extensor digitorum communis tendons from adult cats (Felis catus, L). Each cat was sacrificed using an intraperitoneal injection containing 750 mg. sodium pentobarbital, and after dissection was completed the chest cavity was opened by an incision to ensure that the animal would not revive.

As soon as the cat became totally unresponsive to stimuli, the extensor digitorum communis tendons were dissected from its front paws, four from each paw, and were immediately placed in a tray of slightly chilled Ringer's solution. One of these eight tendons was cut to length and tested at once. The remaining seven were wrapped in paper towelling moistened with Ringer's solution and then in aluminum foil, and were stored in a freezer at approximately - 20° C for subsequent testing. Just before the time of testing these specimens were thawed in Ringer's solution at room temperature (approximately 20° C) and then cut to the test length.

Most specimens as they were dissected from the animal were over 5 cm. long. These were cut to a standard length of 5.0 cm. immediately before they were tested, using the cutting machine employed by Ellis (1969).[27] In this machine, which is illustrated in Figure 2-8 the specimen

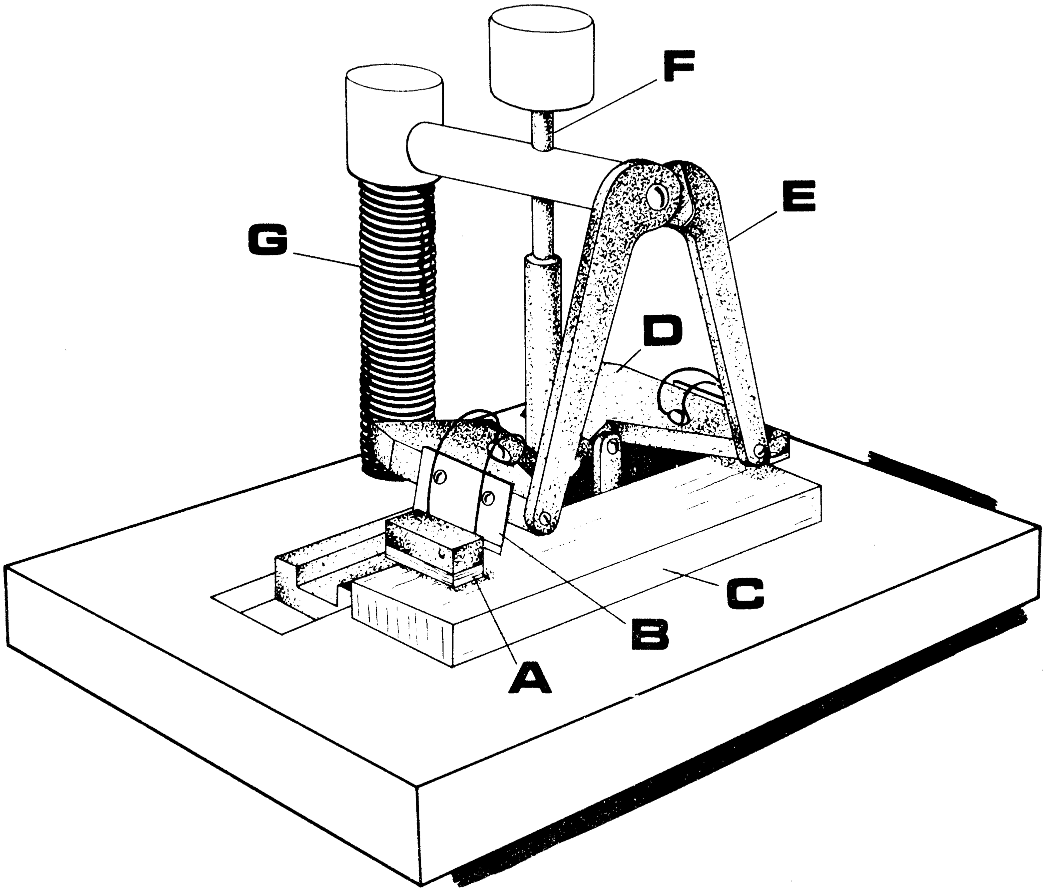


FIGURE 2-8 TENDON CUTTING MACHINE; (A) TENDON STRAIGHTENING PAD, (B) BLADE, (C) CHOPPING BLOCK, (D) ARM CARRYING PAD AND BLADE, (E) LINKAGE TO ARM, (F) GUIDE PIN, (G) SPRING-LOADED SLIDING POST. [DRAWING BY G.N.TAN, FROM ELLIS, 1969].

is straightened by a pair of rubber pads sliding along the "chopping block," and is then cut by a pair of blades which come down onto the chopping block simultaneously. Those few specimens less than 5 cm. long were trimmed with a scalpel so that their ends were cut straight across; their lengths were then measured with a rule having 0.05 cm. graduations, and the measurements were recorded on the test record.

After a specimen was cut to length, it was clamped in the testing machine; the strain-measuring vanes were clipped to it; and the Ringer's solution bath was raised so that the specimen was immersed. Then, a sequence of tests having the following general form was begun:

First, the specimen was subjected to a triangular wave loading function at roughly 2 cycles per minute until a steady-state response was approached. Then the specimen was held at a constant small load (either 0.1 or 0.05 megadyne) for approximately one hour. At the end of this time it was subjected to a triangular wave loading function of the same amplitude and frequency as the one used initially, again until a steady-state response was approached. Following this, it was subjected to a sequence of traingular wave loading functions comprising the first main test sequence. All tests up to this point were performed at a low temperature, in the range 22° - 25° C. At the end of the first main test sequence, the specimen was completely unloaded; the strain-measuring vanes were removed; and the bath temperature was raised to a second test temperature. Although the second test temperature was attained within one hour, two hours were allowed before the specimen was subjected to further tests. The strain sensor was then re-standardized, using the output obtained with the unobstructed light beam as a reference for adjusting the sensitivity; the vanes were clipped to the specimen; and a second main test sequence was begun. The second main test sequence consisted of a sequence of triangular wave loading functions the same as that in the first main test sequence. At the end of the second main test sequence, the specimen was removed from the testing machine and hung on a stainless steel hook to dry.

There were two deviations from this general form: (1) In a few experiments, three test temperatures were used. In these, the specimen was unloaded and the vanes removed at the end of the second main test sequence; then a two-hour interval was allowed during which the bath attained the third test temperature. At the end of this interval, the strain sensor was re-standardized; the vanes were reattached; and a third main test sequence, like the first and second sequences, was performed. (2) In experiments on plastic flow, the first main test sequence was omitted, and the second sequence consisted of a triangular wave loading function followed by a series of steady loads each held for several minutes and each attained from the preceding one by ramp loading.

After the tests in an experiment were completed, the specimen was dried in room air (temperature 20° - 25° C, relative humidity 50 - 80 percent) for at least 24 hours and was then weighed using a Mettler M5 microchemical balance having an accuracy better than $\pm$ 2μg. over the range of specimen weights.

2.2.3 PRESENTATION OF DATA (UNITS):

The usual practice in reporting results of tests such as those described here is to express the applied force in terms of force per unit of cross-sectional area of the test specimen, or stress, (lb_f/in^2, $Mdyne/cm^2$, etc.). Various methods which have been used to measure cross-section areas of tendon specimen, however, have been found to give widely differing results and to show relatively poor repeatability (Ellis, 1969).[27] Of the measurements examined by Ellis, those based on the initial, unstressed, length and the weight of dry material comprising the specimen were found to be the most repeatable.

For this reason, and because it is reasonable to assume that tensile properties of tendon would correlate well with the mass of solid material per unit length, dry weight per unit length is adopted here as a measure of cross-section area. This practice follows that used by Elden in most of his work. When the quantity *dry weight per unit length* is used in defining a stress, the resulting expression,

$$\frac{\text{Force}}{\text{dry weight/unit length}},$$

does not have the usual units of stress. To avoid confusion, a different name, specific load, is applied to the quantity defined by the expression. The unit of specific load in this report is Mdyne cm./gm. (i.e. $\frac{\text{Mydne}}{\text{gm/cm}}$).

Stiffness or elastic modulus is normally defined as the ratio of stress to strain. Since strain is dimensionless, the units are the same as the units for stress. In reporting results in this study, stiffness has been defined using specific load rather than stress and has the same units as specific load.

In analyzing data from experiments on damping, areas of hysteresis loops in the coordinates "specific load" and "strain" were used as members of the energy dissipated by the specimen in each load cycle. Since strain is dimensionless, these areas also have units of Mdyne cm/gm. In analogy to the term specific load, such areas are here referred to as specific damping.

2.2.4 APPARATUS

TESTING MACHINE:

The testing machine used for these studies was a modification of the low capacity dead weight testing machine described by VanBrocklin and Ellis (1965).[23] This machine, which is shown in Figure 2-9, operates as a balance in which load applied by filling a weight bucket (K) is balanced by tension in the test specimen.

Details of all aspects of the machine, specimen clamps, force transducer, strain sensor, controlled temperature bath, and the loading system are presented in ref. 2.5-1.

2.3 RESULTS AND THEIR DISCUSSION

2.3.1 MODELLING STUDIES

Since the mathematical analogs which have been suggested as models for the mechanical behavior of collagen tissues seemed to lack either sufficient detail or adequate experimental verification, a series of experimental and model studies was undertaken in the hope of establishing an analog whose parameters could be used for reasonably accurate quantification of the behavior of tendon in the temperature experiments. As neither the

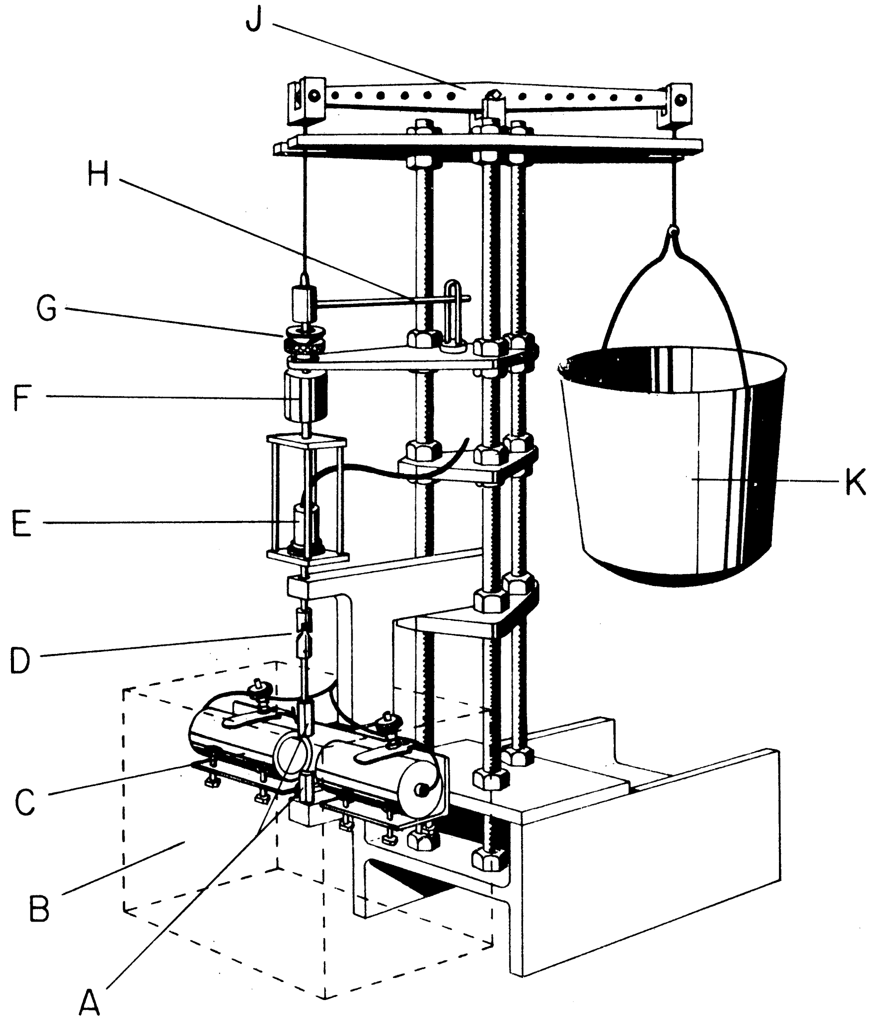


FIGURE 2-9 TESTING MACHINE; (A) SPECIMEN CLAMPS, (B) CONTROLLED TEMPERATURE BATH, (C) STRAIN SENSOR OPTICS, (D) UNIVERSAL JOINT [NOT USED], (E) LOAD CELL, (F) COUNTERWEIGHT, (G) ADJUSTABLE LIMIT STOP, (H) GUIDE AND PIN ASSEMBLY, (J) BALANCE BEAM, (K) WEIGHT BUCKET.

final form of the analog nor the steps leading to it were anticipated at the outset, there was no attempt to establish a preformed protocol for this series. Rather, each experiment was designed either to test or to obtain parameter values for the particular model being considered at the time; and, at various stages, the model was altered in an attempt to obtain better agreement with the experimental findings.

The description of this phase of the investigation will trace the evolution of the mathematical analog and will emphasize those experiments which were important in its development. (A complete list of the experiments performed in Reference 2.5-1.)

Two well-established features of the mechanical behavior of collagen tissue served as the starting point for development of the analog. These were: (1) the nonlinear character of the load-elongation relation, and (2) the existence of history dependent behavior, as seen in creep and stress relaxation phenomena and in the dissipation of energy under cyclic loading.

The form of the load-elongation relation for rat-tail tendon has been analyzed by Ridge and Wright (1966)[52] who found that this relation could be described by the same equations that they used for describing skin (see also Ridge and Wright, 1964).[53] These equations have the form:

$E = a + c \ln P$ .... at low loads

$E = (KP)^b$ .... at intermediate loads

where P and E represent load and elongation, respectively, and the other symbols represent constants.

Previous experience in dealing with the data obtained by VanBrocklin and Ellis (1965)[23] had also suggested that the stress-strain relation for tendon at low stress levels might be represented by a logarithmic function. This may be seen from Figure 2-10 which shows the "mean low rate elastic modulus" (tangent modulus) reported by VanBrocklin and Ellis, plotted as a function of stress in semilogarithmic coordinates. The applicability of the power function formulation at intermediate stresses for the material

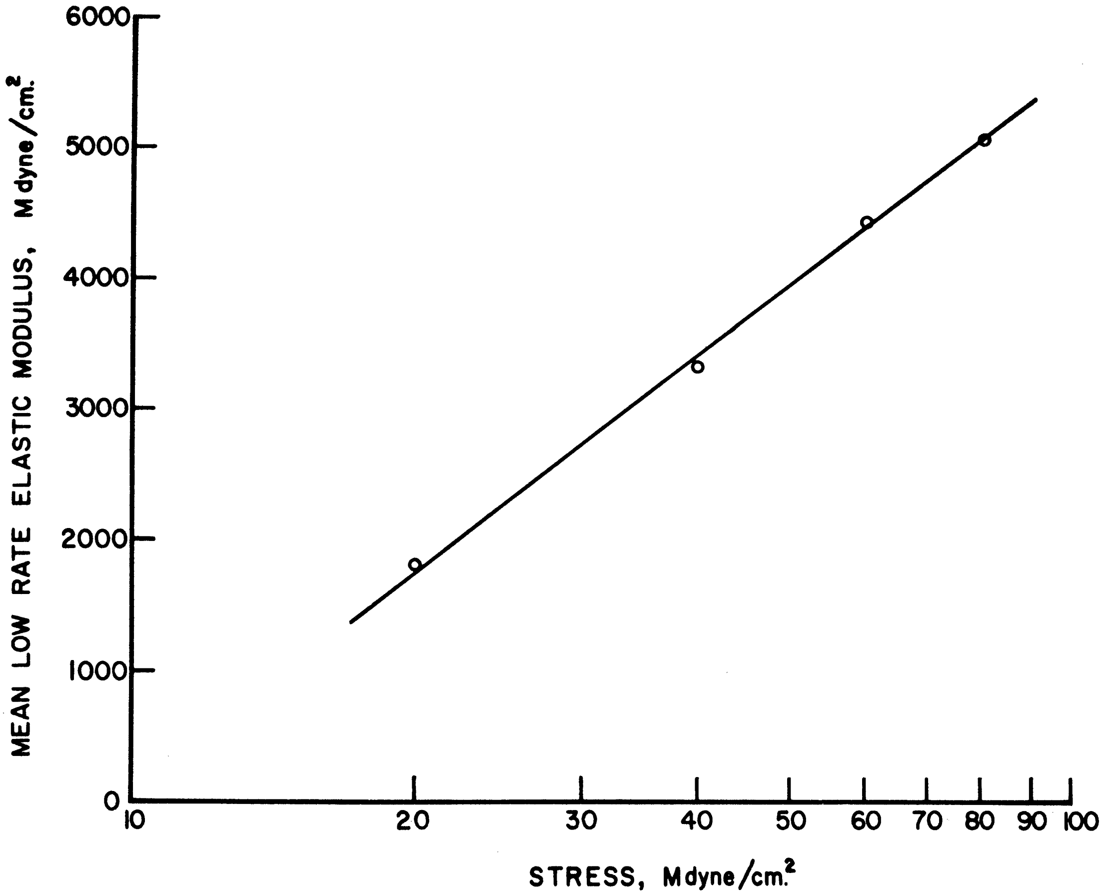


FIGURE 2-10 "MEAN LOW RATE ELASTIC MODULUS" AS A FUNCTION OF STRESS FOR HUMAN EXTENSOR DIGITORUM TENDONS, PLOTTED IN SEMI-LOGARITHMIC COORDINATES. DATA FROM VANBROCKLIN AND ELLIS (1965).

used in the present study is indicated in Figure 2-11, which shows a load-elongation hysteresis loop obtianed under triangular wave loading at 3.8 cycles per minute, replotted in logarithmic coordinates.

A simple mechanical analog which would display creep, relaxation, and energy dissipation properties somewhat like those which have been reported for collagen tissue is the model for the standard anelastic solid shown in Figure 2-12 (cf. Norwick, 1965).[54] This model consists os a Kelvin body in series with an elastic element. As noted elsewhere, models based on this arrangement of elements have been prominent in the literature. The load-elongation characteristics of this model might be brought into correspondence with those for tendon by the use of a non-

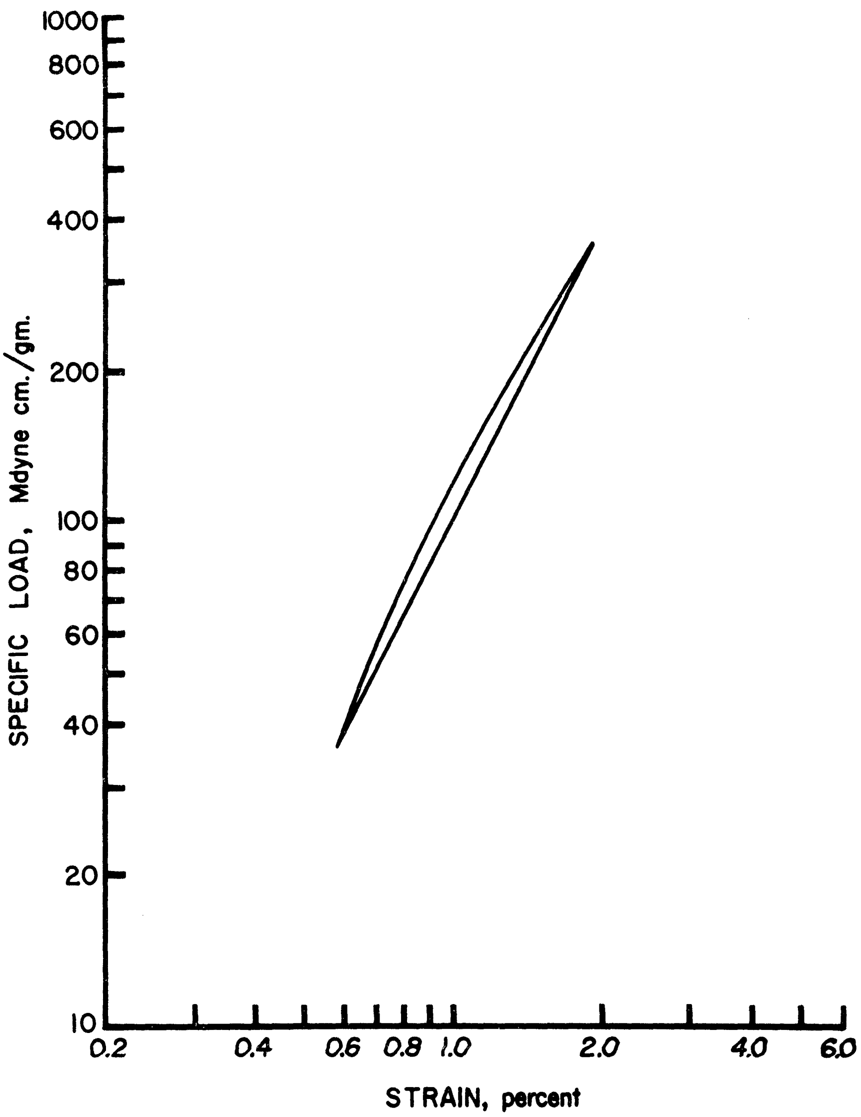


FIGURE 2-11 LOAD-ELONGATION HYSTERESIS LOOP FOR CAT EXTENSOR DIGITORUM COMMUNIS TENDON (SPECIMEN 30C5) CYCLED AT 3.8 CYCLES PER MINUTE, LOGARITHMIC COORDINATES. (SPECIMEN PRESERVED BY FREEZING).

linear elastic element.

Before doing this in the model studies, however, the damping characteristics of the linear model were compared with those measured for cat extensor digitorum communis tendon under triangular wave loading.

Since, in the model, energy would be dissipated only in the Kelvin body, only its behavior was considered.

An approximation obtained from the first five terms of the expression for the damping (energy dissipation per cycle) is plotted as a function of frequency, ω, in Figure 2-13 for a Kelvin body having unit parameters.

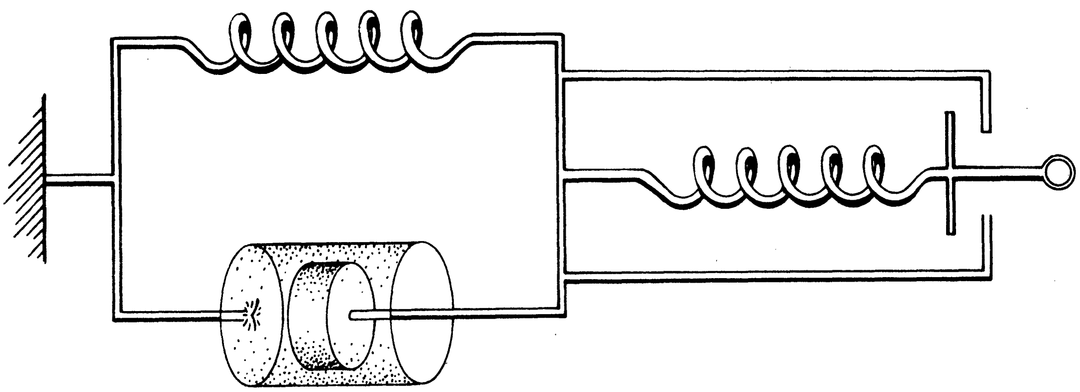


FIGURE 2-12 MECHANICAL ANALOG FOR THE STANDARD ANELASTIC SOLID.

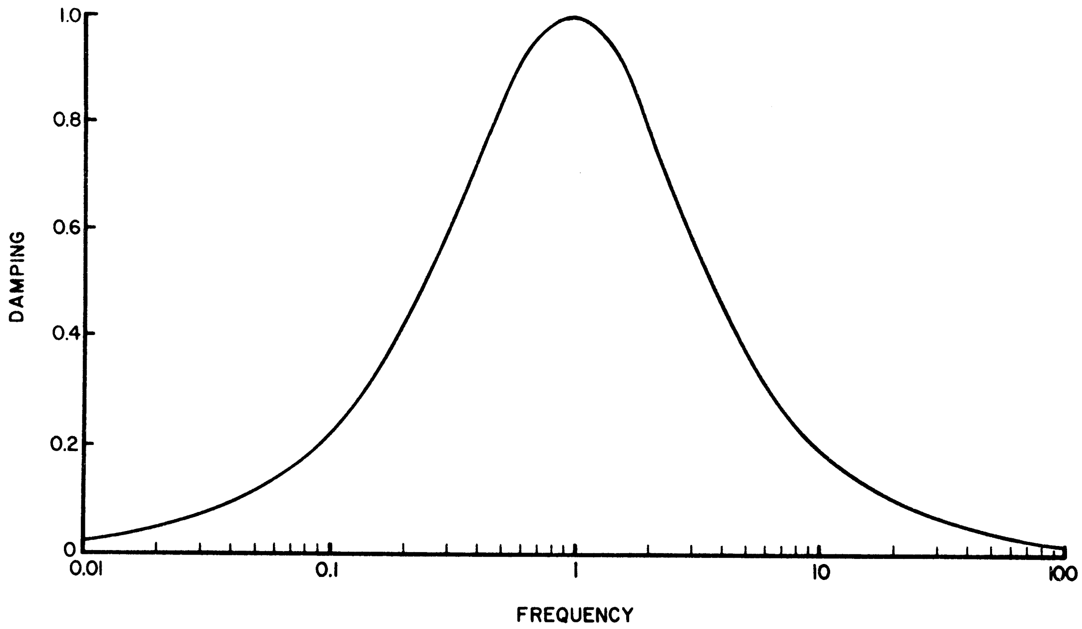


FIGURE 2-13 DAMPING SPECTRUM FOR A KELVIN BODY WITH UNIT SPRING CONSTANT AND DAMPING COEFFICIENT SUBJECTED TO A TRAINGULAR WAVE FORCE (5 TERM APPROXIMATION), NORMALIZED.

Figure 2-14 shows a corresponding plot of specific damping data obtained from a cat extensor digitorum communis tendon subjected to triangular wave laoding of constant amplitude at a number of frequencies. These data are in substantial agreement with observations by VanBrocklin and Ellis (1965)[23] for human toe extensor tendons and by Fung (1967,[25] 1968[55]) for rabbit mesentery that the energy dissipation per cycle is relatively insensitive to frequency. As pointed out by Fung (1967,[25] 1968[55]) this situation is not compatible with a simple linear visco-elastic model.

A number of approaches to modeling the behavior indicated in Figure 2-14 are possible. Among these are the use of several Kelvin

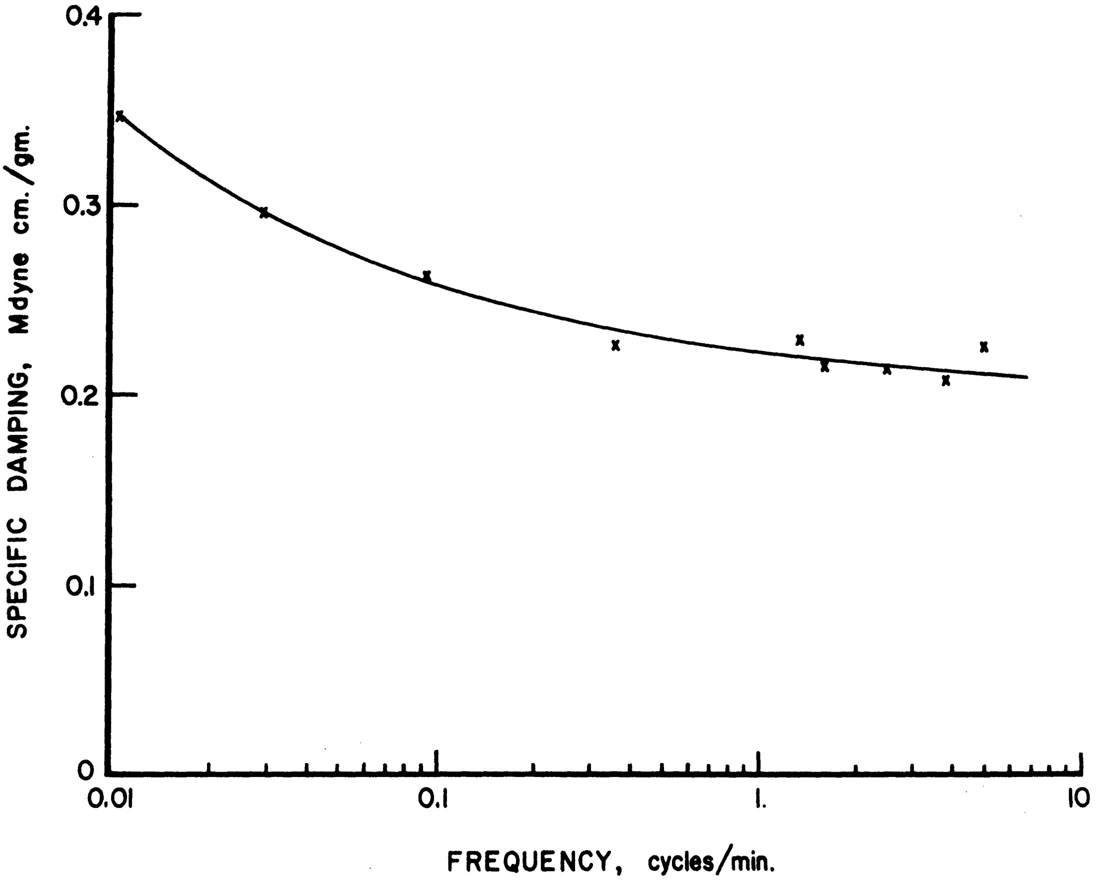


FIGURE 2-14 DAMPING SPECTRUM FOR CAT EXTENSOR DIGITORUM COMMUNIS TENDON (SPECIMEN NO. 30C5) CYCLED BETWEEN LIMITS OF 71 and 356 MEGADYNE CENTIMETERS/GRAM. (SPECIMEN PRESERVED BY FREEZING).

bodies with different time constants (corresponding to one of the approaches which was employed by Daly (1966)[17] to describe stress relaxation in skin), the use of a continuous relaxation spectrum as suggested by Fung (1967,[25] 1968[55]), and the use of Coulomb damping to account for a major portion of the energy dissipation.

Several rheological models are discussed in detail as they pertain both to the damping and to the linearity by Ellis (Ref. 2.5-1). Simulations reveal the difficulty of describing tendon by a small number of mechanical elements.

Although the work reported here did not fully explore the possibility of constructing either a conventional rheological model or a chemical kinetics model for the mechanical behavior of tendon, it has suggested some restrictions on the class of models which might be suitable. Most notably, it has indicated that the damping behavior cannot be adequately described by a linear differential equation in load and elongation or by taking simple Coulomb friction as the major dissipative process.

2.3.2 PLASTIC-LIKE ELONGATION

Relatively early in the experiments on temperature effects it was noted that some specimens, especially at temperatures high in the temperature range studied, failed to approach a steady-state response with cyclic loading. Instead, they demonstrated progressive elongation such that each loop in the load-elongation record was displaced toward somewhat greater strains than the previous loop (Figure 2-15). Typically, the displacement between successive loops was nearly constant for several loops and then increased progressively until the specimen broke. This behavior appeared similar to the constant rate creep which had previously been described (cf. Fry et al, 1964[56]).

To further investigate this phenomenon, a sequence of experiments was performed according to the protocol presented earlier. Each specimen was subjected to triangular wave loading, first at a low temperature and subsequently at the test temperature; then it was subjected to a sequence of steady loads, each obtained by ramp loading from the preceding load level and each held for several minutes. (The sequences of tests for these experiments are listed in Ref. 2.5-1).

At each load level, the elongation showed an initial (viscoelastic) transient response. At small loads, the elongation seemed to approach a constant value after 5 to 10 minutes (Figure 2-16, A). At large loads, however, the elongation did not appear to approach a limiting value, but proceeded to increase at a rate which became nearly constant (in most instances) after a period of 3 to 6 minutes during which the viscoelastic transient appeared to be significant (Figure 2-16, B). The distinction

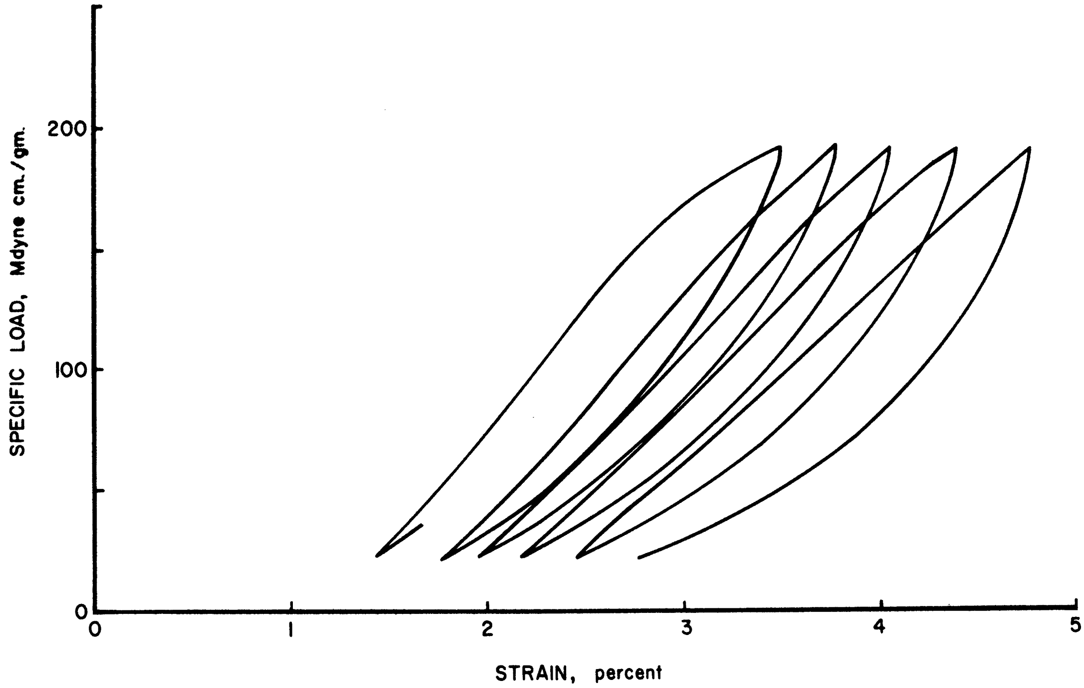


FIGURE 2-15 LOAD-ELONGATION RECORD FOR A TENDON SHOWING PROGRESSIVE ELONGATION UNDER CYCLIC LOADING (TEST AT 40°C, 0.072 CYCLES PER MINUTE: SPECIMEN 34C4, PRESERVED BY FREEZING).

between the viscoelastic transient and the constant rate (plastic-like) elongation was most clearly demonstrated when a specimen was unloaded from a large load to significantly smaller load which was still great enough for the plastic-like elongation to be seen. When this was done the viscoelastic transient was observed as an initial shortening of the specimen while the plastic-like elongation yeilded a subsequent lengthening (Figure 2-16, C). In those instances when a specimen was held for a sufficiently long time at a load at which it appeared to be elongating plastically, the elongation proceeded until the specimen

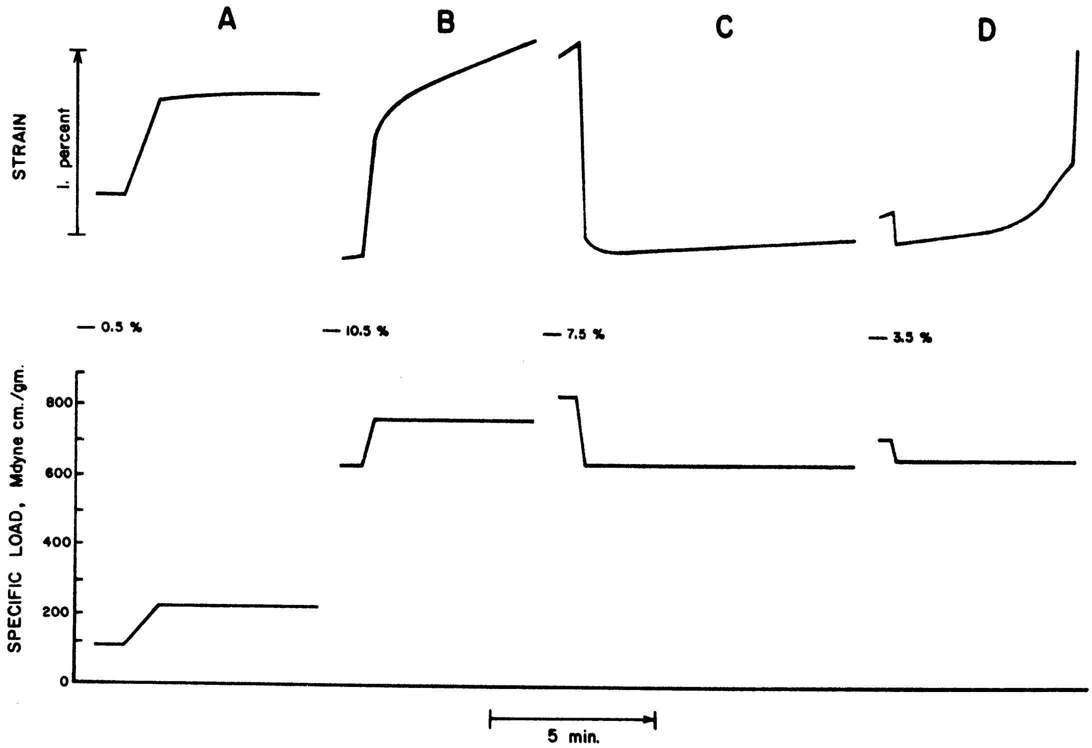


FIGURE 2-16 ELONGATION RESPONSES OF TENDONS HELD AT CONSTANT LOADS AFTER RAMP LOADING: (A) VISCOELASTIC EXTENSION. (TEST AT 46.6°C; SPECIMEN 36C6, PRESERVED BY FREEZING), (B) VISCOELASTIC AND PLASTIC-LIKE EXTENSION FOLLOWING AN INCREASE IN LOAD (TEST AT 25°C; SPECIMEN 43C1), (C) VISCOELASTIC SHORTENING AND PLASTIC-LIKE ELONGATION FOLLOWING A DECREASE IN LOAD (TEST AT 25°C; SPECIMEN 43C1), (D) PLASTIC-LIKE ELONGATION JUST PRIOR TO RUPTURE; NOTE INCREASING RATE OF ELONGATION (TEST AT 40.s°C; SPECIMEN 44C1).

broke. Shortly before the failure occurred, the rate of elongation began to increase rapidly (Figure 2-16, D).[1]

---

[1] Frequently, specimens failed at the testing machine clamps before the rate of elongation within the gage length began to increase dramatically. The pattern described was typical of those specimens which did not fail at the testing machine clamps.

To evaluate the plastic-like component of elongation, the rate of elongation (taken after the viscoelastic component appeared small) was plotted as a function of load for each specimen tested. The resulting graphs were either linear, as would have been expected for ideal plastic flow (Figure 2-17) or concave upward (Figure 2-18), but never concave downward. The intercept of each such curve with the load-axis indicates a critical load above which plastic-like elongation was observed but below which such elongation was not to be expected. Such a critical load might be considered similar to a yield point, the load at which plastic flow commences. However, it differs from a yield point because it was determined only by the behavior of the material after plastic-like elongation had been initiated. The critical load should therefore be regarded as the load at which plastic-like elongation might have been expected to stop as the material was unloaded, rather than the load at which it commenced as the material was loaded.

To summarize the observations presented thus far: (1) The time-dependent elongation in tendon appears to be composed of two components, a viscoelastic component and a component which appears plastic-like in creep experiments. (2) The plastic-like component is the result of a progressive decrease in stiffness rather than an increase in unstressed length as in classical plastic flow. (3) There appears to be a critical load at which plastic-like elongation would be expected to stop as a specimen undergoing plastic-like elongation was unloaded. (4) This critical load apparently decreases as plastic-like elongation progresses.

By using those elongation rates obtained early in each experiment (and in experiments in which plastic-like elongation did not proceed to great extent), it was possible to obtain early critical loads by plotting graphs such as those of Figures 2-17 and 2-18. Such early critical loads might be considered as approximations to a hypothetical initial critical load. Values of the early critical load obtianed in different experiments performed at temperatures below 44°C were remarkably consistent when compared, for example, with published values for tensile strength.

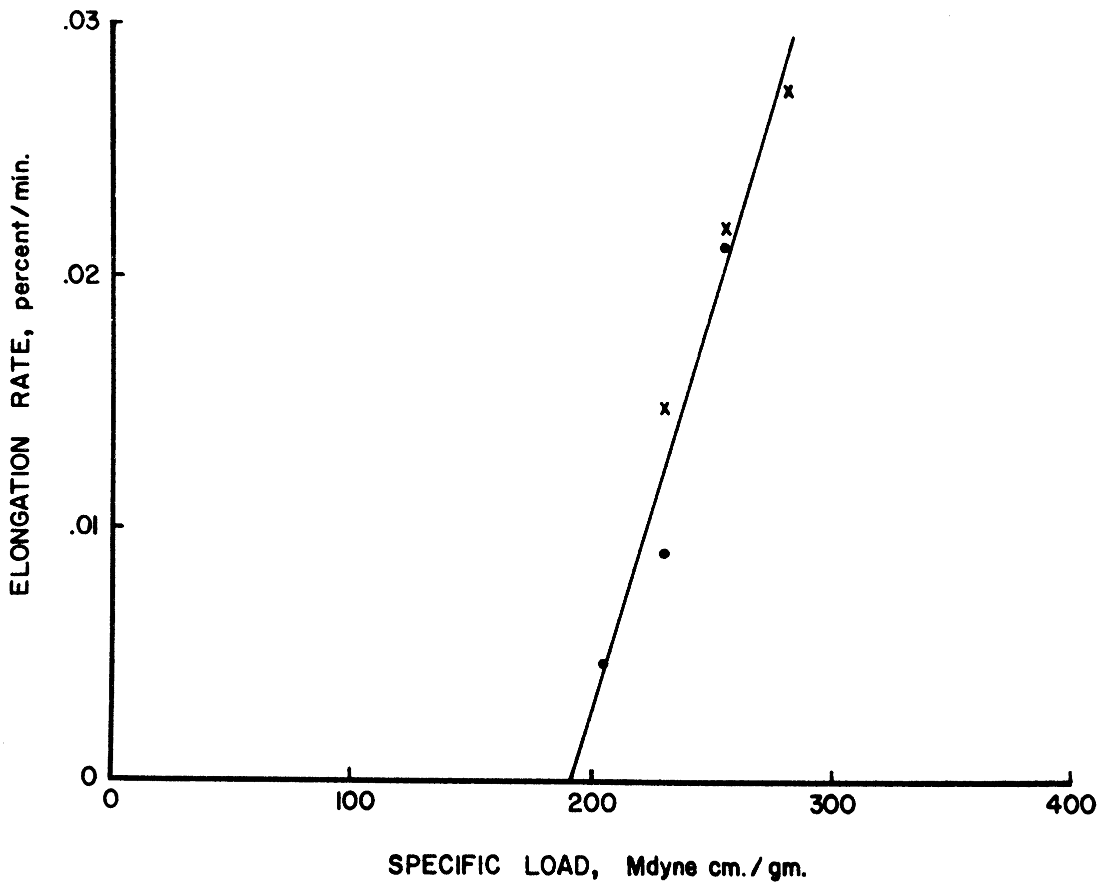


FIGURE 2-17 RATE OF PLASTIC-LIKE ELONGATION AS A FUNCTION OF SPECIFIC LOAD (TESTS AT 47.2°C; SPECIMEN 35C6, PRESERVED BY FREEZING).

X FOLLOWING AN INCREASE IN LOAD

● FOLLOWING A DECREASE IN LOAD

Thus, the initial critical load seems to be a relatively consistent property of the material.

Creep experiments were performed at various temperatures over the range 22° to 56°C, and the early critical load was determined from a plot of elongation rate as a function of load for each experiment that provided sufficient data. The values of early critical load from these experiments are plotted as a function of temperature in Figure 2-19. These data indicate that the early critical load remained nearly constant or decreased slightly with increasing temperature over the range 22° to 44°C. Over the range 44° to 47° the early critical load decreased sharply with increasing temperature, dropping from nearly

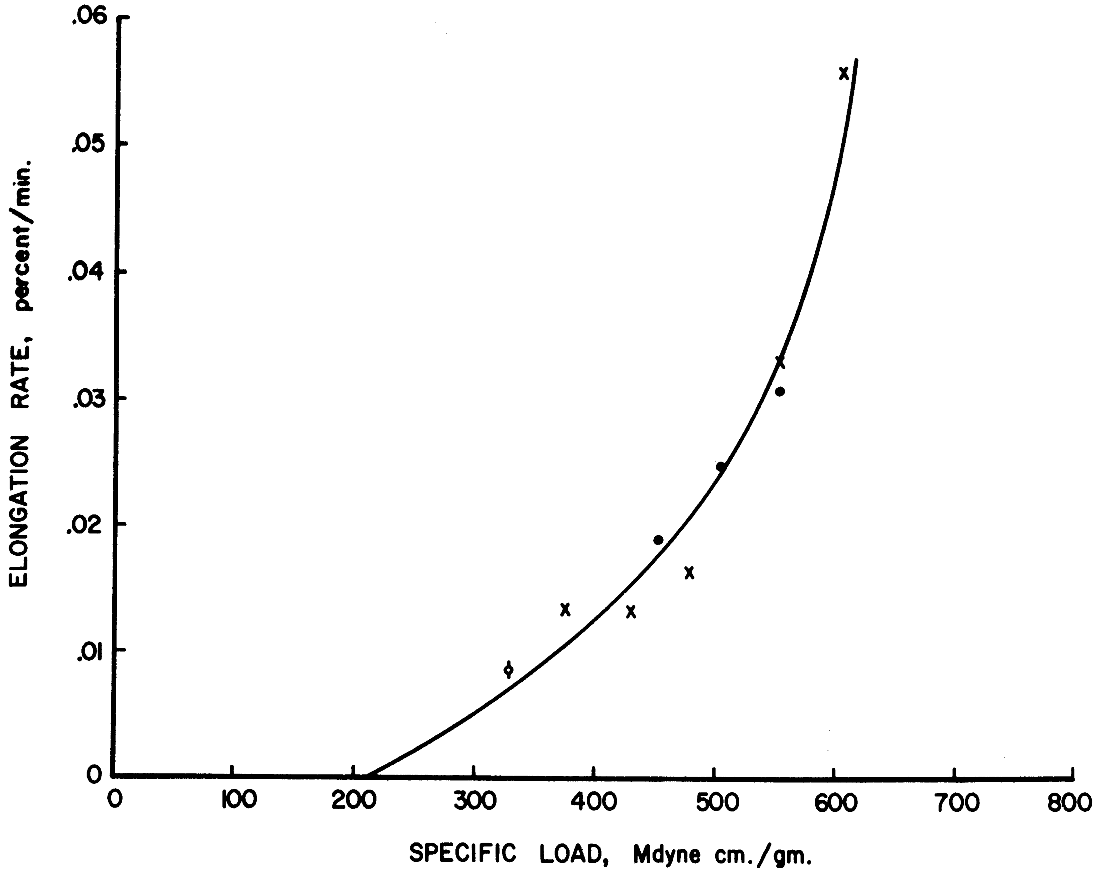


FIGURE 2-18 RATE OF PLASTIC-LIKE ELONGATION AS A FUNCTION OF SPECIFIC LOAD (TESTS AT 49.4°C; SPECIMEN 41C1).

X FOLLOWING AN INCREASE IN LOAD.

ϕ FOLLOWING AN INCREASE IN LOAD, WITH OVERSHOOT.

• FOLLOWING A DECREASE IN LOAD.

600 Mdyne cm./gm. to about 200 Mdyne cm./gm. Above approximately 50°C the early critical load increased with increasing temperature. There was little difference between early critical loads obtained from experiments on fresh tendons and those obtained from experiments on tendons which had been preserved by freezing; however, there appeared to be some tendency for values obtained from fresh material to be slightly higher (Figure 2-19).

To assess the reversibility of the transition responsible for the decrease in early critical load which was noted as the temperature increased above 44°C, several experiments were performed in which unloaded specimens were placed in 50°C Ringer's solution for 2 hours and were subsequently tested at temperatures around 24°C. In these experiments the specimens were permitted to remain in room temperature Ringers's solution (approximately 20°C) for various periods of time

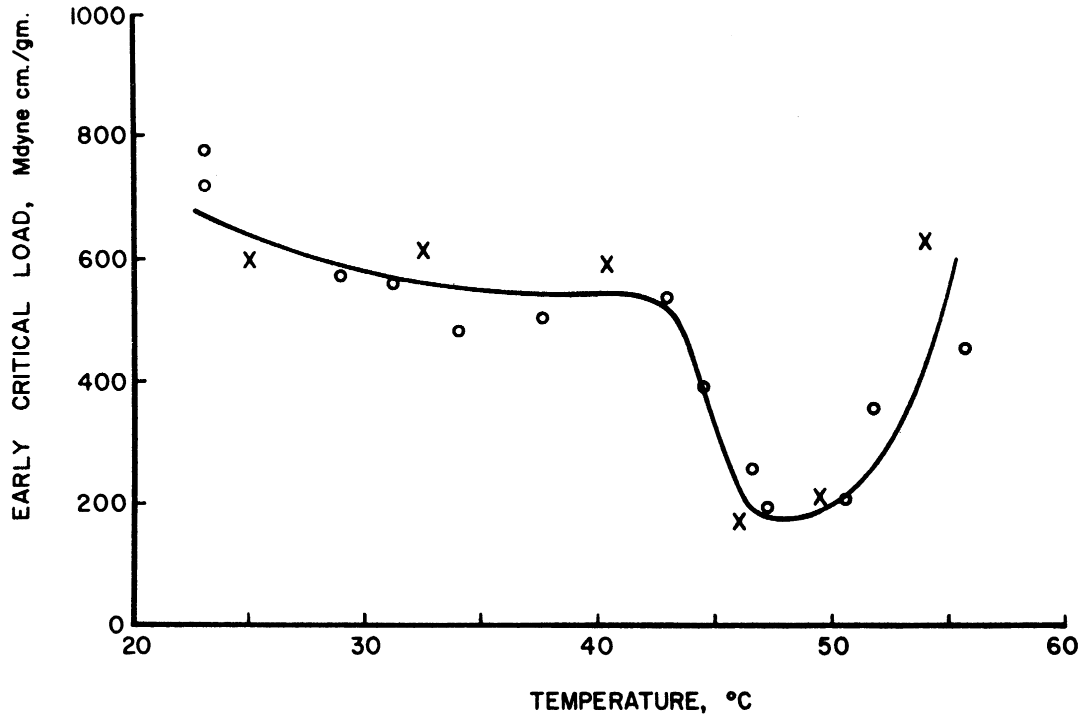


FIGURE 2-19 TEMPERATURE DEPENDENCE OF THE EARLY CRITICAL LOAD FOR PLASTIC-LIKE ELONGATION (SEE TEXT).

X EXPERIMENTS ON FRESH SPECIMENS

o EXPERIMENTS ON SPECIMENS PRESERVED BY FREEZING

between their exposure to 50°C Ringer's solution and the time they were tested. The creep tests in these experiments constituted the first main test sequence in the protocol given in Section 2.2.2. Data from these experiments are presented in Table 2.1. A comparison of these data with the data from low temperature (<44°C) tests on specimen which had not been preconditioned at 50°C (see: Figure 2-19) indicates that even after 10 or more hours at room temperature, specimens which had been immersed in 50°C Ringer's solution for 2 hours had early critical loads which were significantly lower than those of specimens which had never been subjected to a temperature above 44°C. Partial recovery, however, is indicated by the difference between values of early critical load obtained in these experiments and those obtained in experiments in which tests were performed at temperatures near 50°C. Also, a trend toward increasing early critical load with increasing time at room temperature suggests progressive recovery.

These data do not indicate whether the transition is fully reversible with respect to its effect on early critical load.

SPECIMEN NUMBER	57C1	54C7	57C3	53C2	51C3
SPECIMEN CONDITION	FRESH	FROZEN	FRESH	FROZEN	FROZEN
TIME AT ROOM TEMPERATURE, HOURS	1	1	4	10.5	17
EARLY CRITICAL LOAD, Mdyne cm./gm.	331	316	221	398	414

TABLE 2.1 RESULTS FROM EARLY CRITICAL LOAD DETERMINATIONS FOR SPECIMENS PRECONDITIONED IN 50°C RINGER'S SOLUTION FOR 2 HOURS, THEN IN ROOM TEMPERATURE RINGER'S SOLUTION FOR VARIOUS TIMES (TIMES REPORTED INCLUDE 1 HOUR IN THE TESTING MACHINE PRIOR TO THE CREEP TEST).

2.3.3 DYNAMIC STIFFNESS AND DAMPING

A series of exploratory experiments was performed in an attempt to identify the effects of temperature on dynamic stiffness and damping in tendon in the load range above the "toe" portion of the load-strain curve and below the region of plastic-like elongation.

When a tendon is subjected to cyclic loading with loads in this range, the strain response approaches a nearly steady state in which load-elongation records from successive load cycles coincide, and the load-elongation record for each cycle is a closed loop. The area within such a loop represents the energy dissipated in one load cycle (hysteresis energy loss, or damping). This energy dissipation increases roughly as the square of the amplitude, but decreases slightly as the mean load is increased. It also decreases slightly with increasing frequency, at least over the range of approximately 0.05 to 5 cycles/minute which has been investigated in this study. However, the frequency dependence of damping accounts for a change of only about 30 percent in the energy dissipation over this range, much less than would be found for a simple viscoelastic material.

Dynamic stiffnesses (or moduli) can be found from load-elongation loops in two ways, by taking the slopes of tangents to the loops at defined locations or by taking the ratios of stress (or specific load) amplitudes to strain amplitudes.

Effects of amplitude on dynamic stiffness were further demonstrated in a series of three experiments designed to assess the temperature dependence of the nonlinearity of the relation between (steady) load and dynamic stiffness. In these, each specimen was subjected to load cycles of various amplitudes centered at each of 5 steady loads. Two cycle frequencies, 2 and 0.25 cycles/minute, were used in each experiment; and the sequence of tests was performed twice for each specimen, once at a temperature between 22° and 25°C and once at a higher temperature.

To analyze the data from these experiments, it was assumed that the load-strain relation of a hypothetical elastic element approximating the tendon could be represented by a power function such as that proposed by Ridge and Wright (1964)[53]. This relation was taken to have the form

$$E = c + (KP)^b$$

with E and P representing strain and specific load, respectively, and the other symbols representing empirical constants. For load cycles with load limits P_1 and P_2, application of this equation gives extension limits E_1 and E_2 such that

$$E_2 - E_1 = K^b(P_2^b - P_1^b).$$

For each set consisting of all data from one specimen at a single frequency and temperature, values of K and b for this relation were obtained by a least squares fit of an equivalent form of this second equation to the set of data triplets $[P_1, P_2, (P_2 - P_1)/(E_2 - E_1)]$. Then the equation with these two coefficients was used to obtain the dynamic stiffness, $(P_2 - P_1)/(E_2 - E_1)$, of the hypothetical elastic component as a function of load amplitude for each of the steady loads used in the experiment. Figure 2-20 shows one family of dynamic stiffness curves calculated in this way, along with the experimentally determined points from the corresponding data set. At each steady load shown here, the measured dynamic stiffness increased more sharply with decreasing amplitude than did that calculated from the equation of the hypothetical elastic component. Such deviations were found in all of the 12 data sets at all steady load levels except the highest. However, the magnitude of these systematic deviations seemed to be quite variable.

Despite these deviations, the hypothetical elastic components seemed to provide moderately good descriptions of dynamic stiffness at a fixed frequency. For example, only 3 of the 181 measured stiffness values in the 12 data sets differed by more than 10 percent from the corresponding calculated values.

Exponent provides an indication of the degree of nonlinearity of the hypothetical elastic component and hence of the relationship between dynamic stiffness and load (most easily conceived of as steady load at zero amplitude). To assess the temperature dependence of this indicator of nonlinearity, results from analyses of the three experiments described above were taken together with results from similar analyses of two additional experiments in which tests were made at a frequency of 1 cycle/minute and in which the lower cycle limit was held constant.

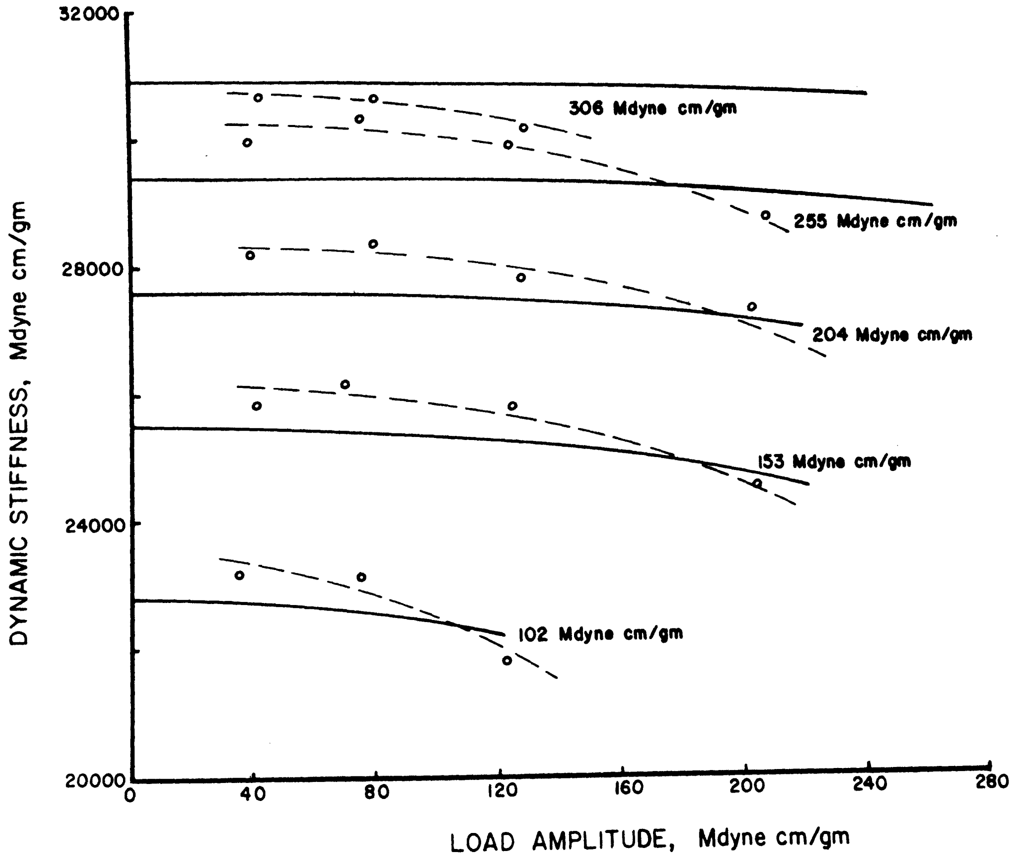


FIGURE 2-20 DYNAMIC STIFFNESS (AMPLITUDE RATIO) AS A FUNCTION OF CYCLE AMPLITUDE AT SEVERAL MEAN LOADS, AS INDICATED. (TESTS ON SPECIMEN 52C1 AT 2 CYCLE/MIN. AND 23.6°C) SOLID CURVES FROM THE EQUATION $(E_2 - E_1) = K^b(P_2^b - P_1^b)$ FITTED TO THE DATA; b = .723, $K = 8.66 \times 10^{-6}$ gm./Mdyne cm.

These results fail to demonstrate a significant change in nonlinearity either with temperature over the range 22° - 52°C or between the first and second main test sequences, although they do suggest the possibility that nonlinearity decreases slightly with increasing temperature.

To explore the effect of temperature on the magnitude of dynamic stiffness, another set of experiments was performed in which the load limits were the same for all tests in each experiment. For the sake of resolution in these experiments the load limits were chosen so that the load excursion covered a large part of the range between the "toe" region and the critical load.

For each main test sequence, which in these experiments consisted of tests at a series of frequencies, the dynamic stiffness (amplitude ratio) was plotted as a function of frequency as indicated in Figure 2-21. From such curves, values of stiffness were taken at three frequencies, 0.3, 1.0, and 3.0 cycles/minutes and the ratio *stiffness from the second test sequence/stiffness from the first test sequence* was found for each of the three frequencies for each specimen. Linear regression analyses for the relation of this stiffness ratio to second test temperature for each frequency yielded the results given in Table 2.2. While these may suggest possible trends toward decreasing stiffness between first and second main test sequences, they fail to demonstrate a statistically significant correlation between stiffness and second test temperature.

	0.3 cycle/min.	1 cycle/min.	3 cycle/min.
Temperature coefficient for the stiffness ratio	-.00303/°C	-.00298/°C	+.00163/°C
Correlation coefficient	-.153	-.318	+.314
Values of the stiffness ratio within the range of first test temperature (22° - 25°C), from the regression line	1.032 - 1.041	1.033 - 1.042	.993 - .998

TABLE 2.2 RESULTS FROM LINEAR REGRESSION ANALYSES FOR THE RELATION OF THE STIFFNESS RATIO *STIFFNESS FROM THE SECOND MAIN TEST SEQUENCE/STIFFNESS FROM THE FIRST MAIN TEST SEQUENCE* TO SECOND TEST TEMPERATURE.

The effect of temperature on damping was explored in substantially the same way as the effect of temperature on the magnitude of the dynamic stiffness. Areas from the load-elongation hysteresis loops obtained in the series of experiments just described were measured with a polar planimeter (K & E 620022) and were plotted as functions of frequency for each test sequence (Figure 2-22). From the curves obtained in this way, values

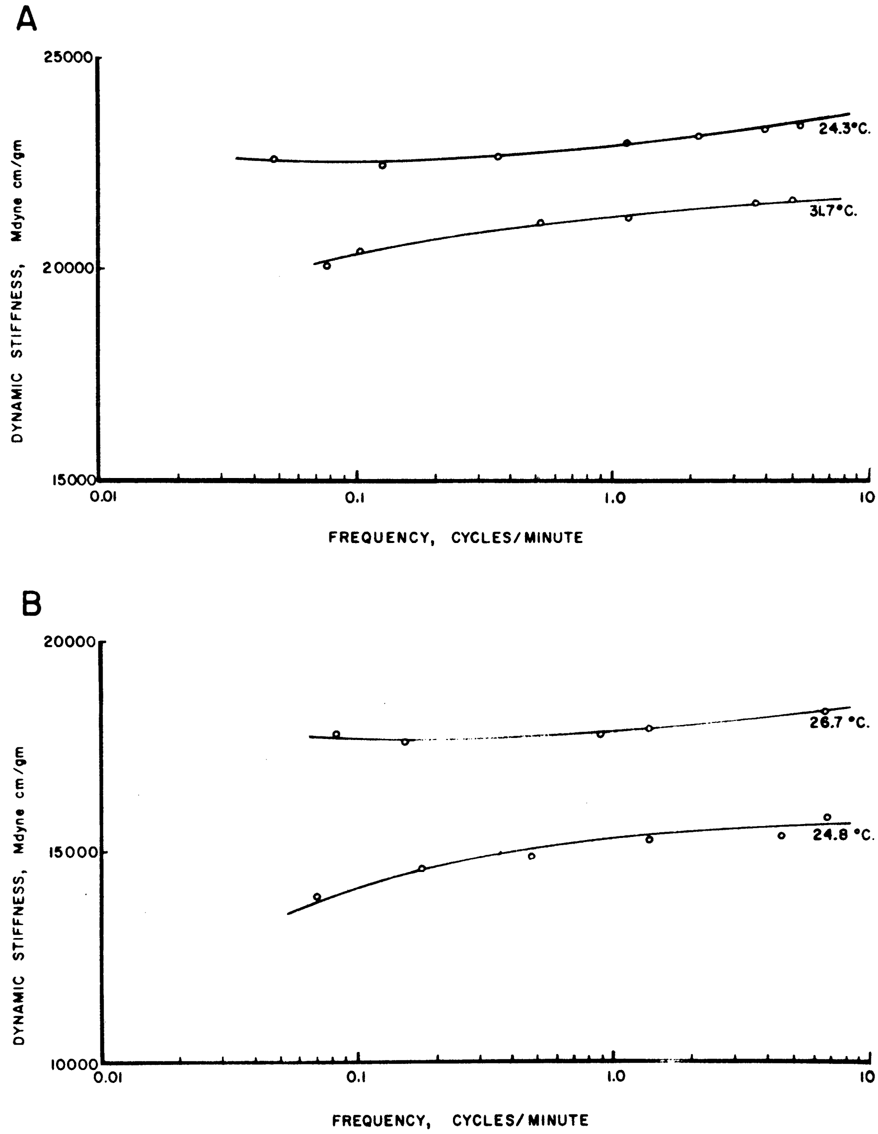


FIGURE 2-21 DYNAMIC STIFFNESS (AMPLITUDE RATIO) AS A FUNCTION OF FREQUENCY FOR EACH OF 2 SPECIMENS EACH TESTED AT 2 TEMPERATURES. (A) SPECIMEN 54C4 (PRESERVED BY FREEZING), CYCLE LIMITS 35 AND 353 MDYNE CM/GM. (B) SPECIMEN 61C1, CYCLE LIMITS 29 AND 232 MDYNE CM/GM.

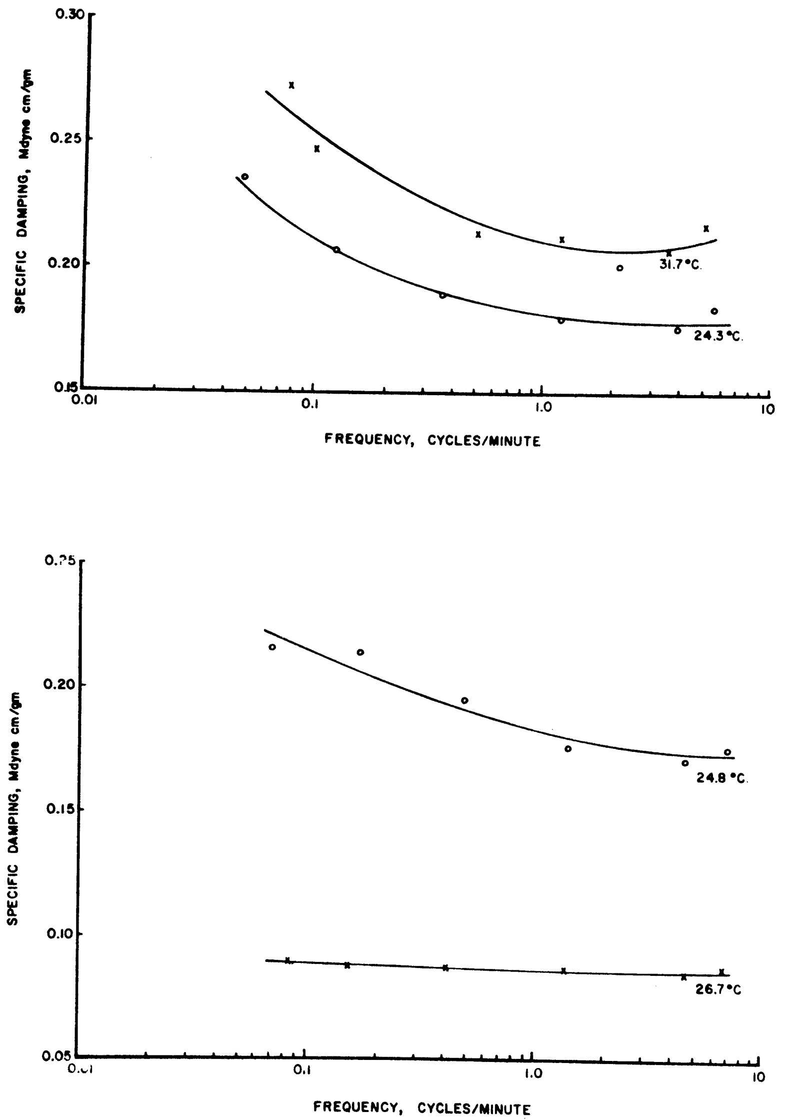


FIGURE 2-22 DAMPING AS A FUNCTION OF FREQUENCY FOR EACH OF 2 SPECIMENS EACH TESTED AT 2 TEMPERATURES. (A) SPECIMEN 54C4 (PRESERVED BY FREEZING), CYCLE LIMITS 35 AND 353 MDYNE CM/GM. (B) SPECIMEN 61C1, CYCLE LIMITS 29 AND 232 MDYNE CM/GM.

of damping at frequencies of 0.3, 1.0 and 3.0 cycles/minute were taken; and the ratios *damping from the second main test sequence/damping from the first main test sequence* were computed for each of the three frequencies for each specimen. Again the data provide little indication of a systematic change with temperature. Results from linear regression analyses for the relation of this ration to second test temperature for each of the three frequencies are given in Table 2.3. While these might

	0.3 cycle/min.	1 cycle/min.	3 cycle/min.
Temperature coefficient for the damping ratio	+.072/°C	+.00373/°C	+.000876/°C
Correlation coefficient	+.478	+.139	+.031
Values of the damping ratio within the range of first test temperatures (22° - 25°C), from the regression line	.888 - .939	.981 - .992	.982 - .984
Number of ratios	10	13	11

TABLE 2.3 RESULTS FROM LINEAR REGRESSION ANALYSES FOR THE RELATION OF THE DAMPING RATIO *DAMPING FROM THE SECOND MAIN TEST SEQUENCE/DAMPING FROM THE FIRST MAIN TEST SEQUENCE* TO SECOND TEST TEMPERATURE.

suggest possible trends toward increasing damping with increasing temperature and toward a decrease in damping between first and second main test sequences, they fail to demonstrate correlation between damping and temperature which is significant at any reasonable confidence level ($P < 0.8$).

There is some theoretical basis for expecting that damping would increase with increasing temperature. If the dissipative processes require activation energies, increasing the temperature is expected to influence damping in the same way as decreasing the frequency (Norwich, 1964).[54] Since damping in tendon specimens was found to increase slightly with decreasing frequency, it might also have been expected to increase with increasing temperature. However, since the increase in damping with increasing frequency which was found over the frequency range covered by these experiments was relatively small, the increase in damping with increasing temperature would also be expected to be small, unless the activation energies for the dissipative processes were exceedingly large. Thus, the failure to clearly demonstrate temperature dependence for damping is not suprising.

Comparing the results of these experiments with those in Section 2.3.1, it is interesting to note that, unlike the early critical load, the dynamic stiffness and damping characteristics did not show large changes in the region of the "glass type" transition do not contribute significantly to the viscoelastic dissipative processes or the overall compliance of the material at loads below the early critical load.

2.3.4 CHANGES DUE TO STORAGE AND HANDLING

Throughout this investigation, two rather consistent differences were noted between the initial test, immediately after a specimen was mounted in the testing machine, and the second test, 1 hour later. These reflected (1) an increase in dynamic stiffness and (2) a decrease in damping between the first and second tests. Figure 2-23 presents a histogram indicating the magnitude of the increase in stiffness for those specimens used in the temperature studies of Sections 2.3.1, and 2.3.3.[1] These data show that an increase in dynamic stiffness of roughly 3 percent (at approximately 2 cycles/minute) was typical for both fresh specimens and specimens which had been preserved by freezing. Figure 2-24 shows histograms for the ratio *damping from the second test/ damping from the first test* for the same specimens. From these it appears that the decrease in damping was less for fresh specimens than for those preserved by freezing. A t-test for significance in the difference between the means of the damping ratios for fresh specimens (0.939) and for specimens preserved by freezing (0.758) indicated

[1]Tests involving specimens preconditioned at 50°C have been excluded as have tests for which the load-strain record from the first test was not clear enough for both dynamic stiffness and damping to be evaluated.

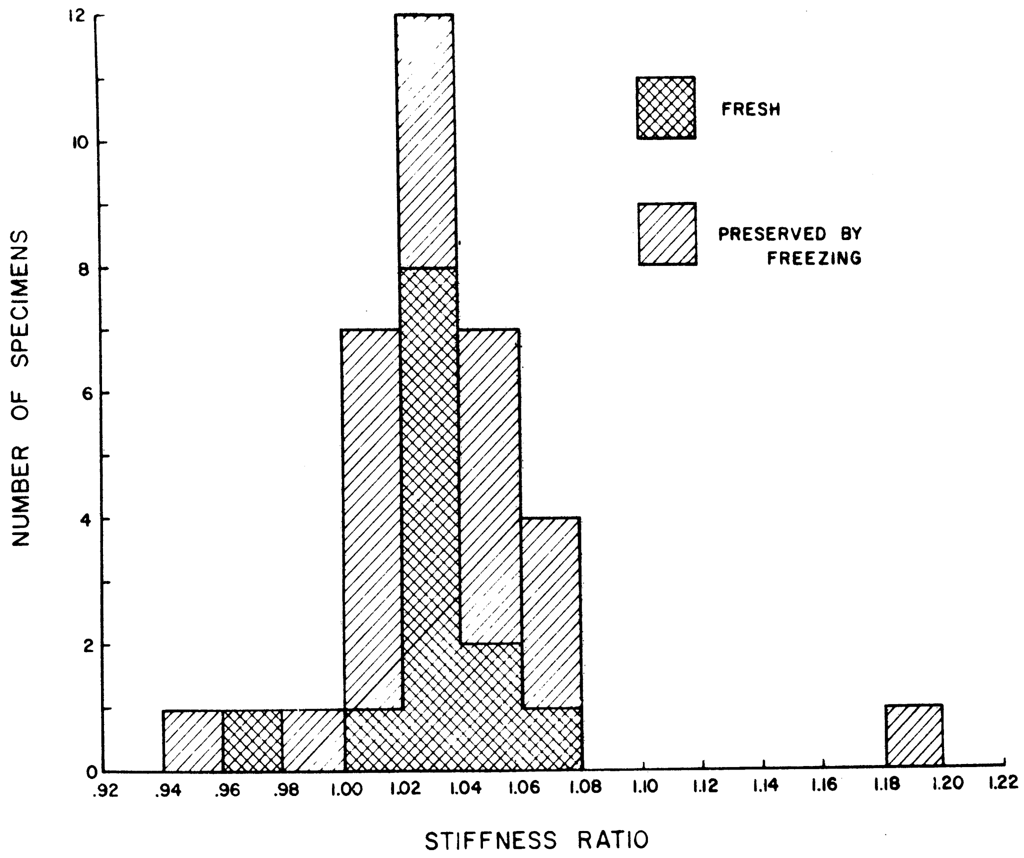


FIGURE 2-23 HISTOGRAM SHOWING THE DISTRIBUTION OF THE RATIO OF STIFFNESS AFTER 1 HOUR IN THE TESTING MACHINE TO INITIAL STIFFNESS FOR SPECIMENS USED IN THE TEMPERATURE STUDIES.

that this difference was significant at the 99 percent confidence level. Another possible difference between fresh and preserved specimens, a slightly lower early critical load for specimens preserved by freezing, was noted in Section 2.3.1.

The observed increase in stiffness and decrease in damping in this initial interval might be accounted for by the loss of polysaccharide plasticizers (Section 2.2.1) There is an indication from the analyses of these changes that they may have continued to occur after the first main test sequence also (i.e. during the second and third hours of the experiment). However, such changes during this interval were not positively identified.

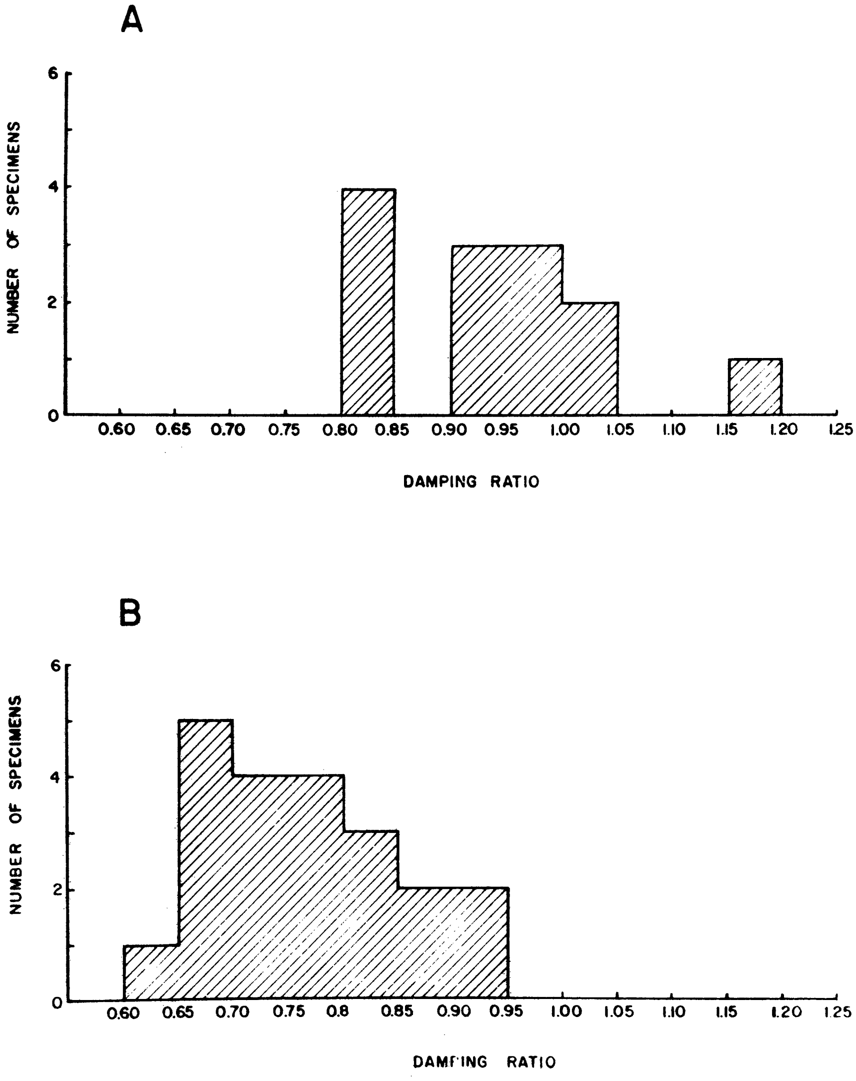


FIGURE 2-24 HISTOGRAMS SHOWING THE DISTRIBUTIONS OF THE RATIO OF DAMPING AFTER 1 HOUR IN THE TESTING MACHINE TO INITIAL DAMPING FOR SPECIMENS USED IN THE TEMPERATURE STUDIES (A) FRESH SPECIMENS, (B) SPECIMENS PRESERVED BY FREEZING.

REFERENCES

1. Ellis, D.G. (1970) Temperature Effects on the Dynamic and transient Mechanical Behavior of Tendon; Technical Report No. 11, University of Michigan Press.

2. DuBois, E. F. (1948) Fever and the Regulation of Body Temperature (Thomas, Srpingfield, Illinois).

3. Smith, J. W. (1954) "Mechanical properties" in: S. Rothman, ed. Physiology and Biochemistry of the Skin, (Chicago, The University of Chicago Press).

4. Lehmann, J. F. (1965) "Ultrasound therapy", in: S. Licht, ed. Therapeutic Heat and Cold, 2nd ed. (Licht, New Haven, Conn.)

5. Rigby, B. J., N. Hirai, J. D. Spikes, and H. Eyring (1959) "Mechanical properities of rat tail tendon" J. Gen. Physiol. 43:265-283.

6. LaBan, M. M. (1962) "Collagen tissue: Implication of its response to stre-s in vitro", Archs. Phys. Med., 43:461-466.

7. Wright, D. G. and D. C. Rennels (1964) "The mechanical properties of joints and skin" in: Structure and Function of Connective and Skeletal Tissue, S. F. Jackson, S.M. Partridge, R. D. Harkness, Scientific Committee, St. Andrews, Scotland.

8. Abrahams, M. (1967) "Mechanical behavior of tendon in vitro a preliminary report" Med. Biol. Engng. 5:433-443.

9. Walker, L. B., E. H. Harris, and J. V. Benedict (1963) "Stress-strain relationship in human cadaveric planaris tendon: 16th Ann. Conf. Engng. in Med. Biol.

10. Walker, L. B., E. H. Harris, and J. V. Benedict (1964) Stress-strain relationship in human cadaveric planaris tendon: A preliminary study" Med. Electron. and Biol. Engng. 2:31-38.

11. Benedict, J. V., E. H. Harris, and L. B. Walker (1966) "Stress-strain relationship of unembalmed human tendon" 19th. Ann. Conf. Engng. in Med. Biol.

12. Benedict, J. V., L. B. Walker, and E. H. Harris (1968) "Stress-strain characteristics and tensile strength of unembalmed human tendon: J. Biomechanics 1:53-63.

13. Wertheim, M. G. (1847) "Memoire sur l'elasticite et la cohésion der principaux tissus du corps humain" Ann. Chim. Phys. 21:385-414.

14. Reuterwall, O. P. (1921) "Uber die Elasticitat der Gefasswande und die Methoden ihrer nahren Prufung" Acta. Med. Scand., Suppl. II, 175 pp.

15. Partington, F. R. (1963) Studies on the Physical Properties of Tendon Fibres, Ph.D. Thesis, University of Manchester.

16. Viidik, A. (1966) "Biomechanics and functional adaption of tendons and joint ligaments" in: F. G. Evans, ed. Studies on the Anatomy and Function of Bone and Joints (Springer-Verlag, New York, Inc.)

17. Daly, C. H. (1966) The Biomechanical Characteristics of Human Skin, Ph.D. Thesis, University of Strathclyde, Glasgow.

18. Haut, R. C. and R. W. Little (1969) "Reological properties of canine anterior cruciate ligaments" A.S.M.E. Technical Paper 69-BHF-9.

19. Gratz, C. M. (1931) "Tensile strength and elasticity tests on human fascia lata" J. Bone & Joint Surg. 13:334-340.

20. Stuke, K. (1950) "Uber der elastische Verhalten der Achillessehne im Belastungsversuch", Langenbek's Archiv fur Klinische Chirurgie, 265:579-599.

21. Lazan, B. J. (1964) "Damping studies in materials science and materials engineering" in: Internal Friction, Damping, and Cyclic Plasticity, A.S.T.M. special technical publication No. 378 (A.S.T.M., Philadelphis).

22. Rigby, B. J. (1964a) "Effect of cyclic extension on the physical properties of tendon collagen and its possible relation to biological ageing of collagen" Nature 202:1072-1074.

23. VanBrocklin, J. D. and D. G. Ellis (1965) "A study of the mechanical behavior of toe extensor tendons under applied stress", Archs. Phys. Med. 46:369-373.

24. Viidik, A. (1968) "A rheological model for uncalcified parallel-fibred collagenous tissue" J. Biomechanics 1:3-11.

25. Fung, Y. C. B. (1967) "Elasticity of soft tissues in simple elongation" Am. J. Physiol. 213:1532-1544.

26. Elliott, D. H. (1965) "Structure and function of mammalian tendon" Biol. Rev. 40:392-421.

27. Ellis, D. G. (1969) "Cross-sectional area measurements for tendon specimens: A comparison of several methods: J. Biomechanics 2:175-186.

28. Takigawa, M. (1953) "Study upon strength of human and animal tendons" J. Kyoto Pref. Med. Univ. 53:915-933.

29. McMaster, P. E. (1933) "Tendon and muscle ruptures: clinical and experimental studies on causes and location of subcutaneous ruptures", J. Bone and Jt. Surg. 15:705-722.

30. Stuke, K. (1951) "Sehnenbelastung und - ruptur im Tierversuch" Der Chirug 22:16-18.

31. Weir, C. E. (1949) "Expansivity of leather and collagen" J. Am. Leather Chems. Assoc. 44:79-90.

32. Theis, E. R. and R. G. Steinhardt, Jr. (1950) "Protein axial movement studies II Data obtainted through use of dynamic and strain gage shrinkage meters" J. Am. Leather Chems. Assoc. 45:591-610.

33. Wölisch, E. (1940) "Muskelphysiologie vom Standpunkt der Kinetischen Theorie der Kollagens. Ein Beitrag zum Problem der thermischen Sehneverkurzüng" Zeitschrift fur Biologie 85:406-434.

34. Garrett, R. R. and P. J. Flory (1956) "Evidence for a reversible first-order phase transition in collagen-diluent mixtures: Nature 177:176-177.

35. Bear, R. S. (1944) "X-ray diffraction studies on protein fiber. 1. The large fiber-axis period of collagen" J. Am. Chem. Soc. 66:1297-1305.

36. Wright, B. A. and N. M. Wiederhorn (1951) "Studies concerning the structure of collagen 1. An X-ray investigation of the denaturation of collagen: J. Polymer Sci. 7:105-120.

37. Frenkel, S. J., Kuchareva, L. V., Ginsberg, B. M., Gasparyan, K. A., Vorobev, B. I."Effect of Tension on order-disorder Transformations of Native Collagen Fibers"; (1965) Biophysia, Vol. 10. p.735-742, in Russian.

38. Flory, P. J. and R. R. Garrett (1958) "Phase transitions in collagen and gelatin systems" J. Am. Chem. Soc. 80:4836-4845.

39. Oth, J. F. M., E. T. Dumitru, O. K. Spurr, Jr., and P. J. Flory (1957) "Phase equilibrium in the hydrothermal shrinkage of collagen" J. Am. Chem. Soc. 79:3288-3289.

40. Wölisch, E. (1940) "Muskelphysiologie vom Standpunkt der Kinetischen Theorie der Hochelastizität und der Entspannungshypothese der Kontraktionsmechanismus" Die Naturwissenschaften 28:305-312.

41. Wiederhorn, N. M. nad G. V. Reardon (1952) "Studies concerned with the structure of collagen II. Stress-strain behavior of thermally contracted collagen" J. Polymer Sci. 9:315-325.

42. Elden, H. R. (1965) "Biophysical aspects of aging in connective tissue" Advances in Biology of Skin 6:229-243.

43. Mason, P. and B. J. Rigby (1963) "Thermal transitions in collagen" Biochem. Biophys. Acta. 66:448-450.

44. Elden, H. R. (1964a) "Hydration of connective tissue and tendon elasticity" Biochim. Acta. 79:592-599.

45. Elden, H. R. (1964b) "Aging of rat tail tendons" J. Gerontology 19:173-178.

46. Elden, H. R. (1965) "Biophysical aspects of aging in connective tissue: Advances in Biology of Skin 6:229-243

47. Flory, P. J. (1956) "Role of crystallization of polymer and proteins" Science 124:53-60.

48. Rigby, B. J. (1964b) "The effect of mechanical extension upon the thermal stability of collagen" Biochim. Biophys. Acta. 79:634-636.

49. Thomas, E. D. and R. B. Gresham (1963) "Comparative tensile strength study of fresh, frozen and freeze-dried human fascia lata" Surg. Forum 14:442-442.

50. Viidik, A. and T. Lewin (1966) "Changes in tensile strength characteristics and histology of rabbit ligaments induced by different modes of postmortal storage" Acta. Orthop. Scand. 37:141-155.

51. Matthews, L. S. and D. Ellis (1968) "Viscoelastic properties of cat tendon: effects of time after death and preservation by freezing: J. Biomechanics 1:65-71.

52. Ridge, M. D. and V. Wright (1966) "Rheological analysis of connective tissue: A bio-engineering analysis of the skin" Ann. Rheum. Dis. 25:509-515.

53. Ridge, M. D. and V. Wright (1964) "The description of skin stiffness" Biorheology 2:67-74.

54. Norwick, A. S. (1964) "Anelastic phenomena in metals and nonmetallics" in: Internal Friction, Damping, and Cyclic Plasticity, A.S.T.M. Special Technical Publication No. 378 (A.S.T.M., Philadelphia).

55. Fung, Y. C. B. (1968) "Biomechanics, its scope, history and some problems of continuum mechanics in physiology" Appl. Mech. Rev. 21:1-29

56. Fry, R., M. L. Harkness, and R. D. Harkness (1964) "Mechanical properties of the collagenous framework of skin in rats of different ages" Am. J. Physiol. 206:1425-1429.

3.0 INTERFACE PRESSURE AND STRESS DISTRIBUTION IN PROSTHETIC FITTING

3.1 INTRODUCTION

The research described herein is intended to extend the level of understanding of lower extremity prosthetic aids which will eventually lead to improving the quality of application. Much time and effort have been spent on improving prosthetic fit and standardizing fabrication procedures[2,3] in an attempt to restore normal gait. This particular work studies the basic mechanism affecting fit, i.e. associated pressure patterns and their variation with respect to time.

3.1.1 NEW FITTING TECHNIQUES

The phrase "comfortable fit" as applied to prosthetic aids is more a concept than a definition. A suitable objective definition for "comfortable fit" has not evolved. The recognition of variables, their individual orders of magnitude, and the amount they contribute to this concept would greatly enhance the fitting and alignment of prostheses. In addition, they would provide a basis on which to improve existing technology as applied in clinical practice. Within the last ten years, and since the publication of "The Manual of Below-Knee Prosthetics",[3] the application and use of total-contact patellar-tendon-bearing below-knee prosthetics has undergone some dramatic changes. New techniques of load bearing and suspension[4] are in practice today and more and are under development. The soft liner socket, so widely accepted a few years back, is now being challenged by such new concepts as the hard-shell socket with soft distal end pad, the air cushion sockets, and the water filled socket. The supracondylar strap suspension is also being challenged by the supracondylar wedge and the extended shell suprapatellar support. In the weight-bearing mechanism, one notices a wide difference of opinion in the techniques employed to obtain desired results. Whether one should attempt to transfer load in particular regions of the stump or to uniformly distribute the load on the stump is highly dependent upon hypotheses rather than fact. The occasional failure to accommodate a patient with a patellar-tendon-bearing prosthesis may be a problem of poor execution rather than concept. This inability may result from a poor socket or a poor alignment. It is believed that the parameter causing physiological stump damage are normal stress (pressure) and shear stress at the interface between the prosthesis and the limb.

The measurement and display of this three-dimensional stress profile in time, presents an interesting engineering evaluation with definite physiological implications. Other instrumentation and data reduction schemes have shown a need to present the data in a meaningful manner to the physician. This research presents a new approach which emphasizes the visualization of the phenomena at the interface rather than individual numbers representing pressure values.

3.1.2 PREVIOUS AND CONCURRENT STUDIES

Various investigators have been interested in measuring and explaining normal stress between the body and a supporting surface. Most attempts have been more an exercise in explaining pressure at a point as a function of time, rather than display of pressure on a surface as a function of time. Muller, Hettinger and Himmellmann[(5)] measured dynamic pressures between an above-knee prosthesis and a stump. These results are based on pneumatic transducers which recorded pressures over relatively large areas, of the order of twenty-five square centimeters.

In 1962, G. Boni[(4)] published results of his attempts to record the pressure patterns between a stump and a socket. His work was not limited to lower extremity prosthetics, as he worked primarily with below-elbow amputees. The preliminary portion of his work was the determination of the type of transducer to be used. The choices involved a conventional strain gage bridge, capacitance bridge, a piezoelectric crystal, or a magnetic inductance transducer. His preliminary experiments led to the development of a new transducer which consisted essentially of two silver electrodes separated by a layer of conductive rubber containing numerous holes. The electrodes and the layer of rubber were bonded and the holes in the rubber filled with microphonic granules. This composite was covered with a layer of continuous rubber. The transducer was relatively large, 9/16 inch diameter and one inch thick. A second transducer was made with a conventional strain gage affixed to a thin steel blade. This thin steel blade acted as a diaphragm and was riveted to a second blade which acted as a support. The size of this transducer was 1/2 inch by 1-1/8 inches. The result of the experimental work showed both transducers were suitable for socket fit analysis, but the strain gage transducers were preferable.

At Case Western Reserve University, a pneumatic cell was developed to record static pressure profiles[7,8,9]. This multicellular pad was used to measure pressure distributions between a patient and a wheelchair. It was basically a binary procedure utilizing stepwise changes in pressure level. Although quite successful, it could not be used to measure time-varying distributions with ease. The technique does not lend itself to the complicated geometry of the leg.

Work has been conducted at New York University recording the interface pressure in above-knee prostheses.[10] The work involved permanently positioned transducers, flush mounted in the prosthesis wall. The time-continuous pressure transducers are capable of measuring dynamic changes. In this work, twenty-five transducers were mounted in the wall and brim of the test socket of a single above-knee amputee. These transducers were designed and developed at New York University and were built into the prosthesis at the time of its construction. The transducers could be removed from the porsthesis at any time by inserting a dummy plug after its removal. The results of the suction socket studies showed a pressure range from -1 psig to 24 psig during normal gait. It was also found that large diurnal variations in socket pressure occurred particularly in the brim. It was felt that this difference in pressure could amount to 10 percent from day to day. It was also observed that pressure variations resulting from abduction and adduction of the shank through two degrees angular change generally were small. They showed that the pressures developed during walking were higher than those experienced during stance.

Work is being conducted at Baylor University[4] measuring interface pressure on above and below-knee prostheses. The purpose of this work is to develop a method for the quantitative and kinesiological evaluation of prosthetic fit and gait analysis in the above-knee and/or below-knee amputee and to apply this method to a series of patients in clinical and vocational follow-up programs. They intended to quantify the characteristics of gait and prosthetic fit in successfully rehabilitated amputees, and compare these "normal" patterns with the unsuccessfully fitted amputees. The areas of interest are the pressure on the ischial seat, the lateral aspect of the socket, and the distal tissues. Combining this information with goniograms of the prosthetic and anatomical knees and with event markers attached to both shoes, they hope to obtain a quantitative evaluation of prosthetic fit and gait analysis in amputees. They also feel that a recording of skin temperature on both limbs would provide signficant information. Their present system includes a multichannel analog magnetic tape recorder and a small computer connected in parallel for controlled data acquisition and storage on IBM compatible digital tape. It is intended that this digital tape can be further processed on larger computer systems located within that university.

3.1.3 PROBLEM DEFINITION

In the work conducted thus far, the investigators have faced two serious problems. The first was the transducer itself. It was either too bulky or too fragile. The second problem was that all recordings were made in analog form which presented a tremendous data reduction problem. At the prosthesis interface, both pressure [normal stress] and shear stress are present. Thus far, no one has attempted to record shear stress. This problem presents a unique instrumentation dilemma since all the criteria of size, sensitivity, etc., for the pressure transducer are necessary for the shear stress transducer except that the shear stress transducer must also indicate direction. At the basic level suggested by the previous investigators and this author, a general problem statement might be,

> "Measure and display normal pressure and shear stress distributions as continuous functions in geometry and time at the interface between a below-knee prosthesis and skin tissue."

The general problem statement is a comprehensive evaluation of the prosthesis-tissue interface. From an economic viewpoint, insertion of transducers to totally cover the interface could easily become prohibitive. It was decided, for purposes of economy, to test only one section of the stump at a time rather than the entire surface. Although pressure transducers are commercially available, no shear-strain indicating instrument was available. It was this reasoning that led to the decision not to record shear stress now but to concentrate efforts on the pressure recording. The problem was then defined as follows:

> "Measure and display normal pressure distributions as continuous functions in geometry and time at a portion of the interface between a total contact below-knee prosthesis and skin tissue."

3.1.4 SIMILAR RESEARCH AT OTHER CENTERS

Since two other organizations, Baylor University and New York University, concurrently were conducting research on pressure studies in either above-knee or below-knee prosthetics, communication was maintained with these groups for the purpose of sharing techniques and eliminating overlap in experiments or methodology, while augmenting each other's work with as much common technology as possible.

3.2 ANATOMIC COORDINATE SYSTEMS

3.2.1 THE ANATOMIC PROBLEM

At the University of Michigan, with rare exceptions, below-knee prostheses are patellar-tendon-bearing. Most cases involve recent amputations, and the prostheses have soft liner inserts so that the socket can easily be modified to compensate for shrinkage of the stump. The amount of "end-bearing" depends on the reason for the amputation, condition of the stump, and patient comfort.

The solid ankle-cushion heel foot [Sach foot] is used with patellar-tendon-bearing prostheses, with few exceptions. Side bars and corset are applied to the initial prosthesis, and supracondylar suspension is usually prescribed for subsequent artificial limbs. Pressure-tolerant and pressure-sensitive areas have been defined (Figure 3-1), but pressure levels and distributions have not been defined. These pressure profiles are influenced by a combination of factors. The more important of these are:[2]

1. Socket geometry
2. Socket alignment
3. Geometrical relationship of the socket to the foot
4. External influences of the thigh corset and side joints

The biomechanics of the below-knee prosthesis describing the force distribution for below-knee prosthesis was presented in some detail in the patellar-tendon-bearing below-knee prosthesis manual[2] published in 1961. This simplified analysis shows the forces resulting from the interface pressure distributions. Although this study is conceptual, it exemplifies the complex form that the interface pressure distribution must display.

3.2.2 A PROPOSED COORDINATE SYSTEM FOR A BELOW-KNEE STUMP

The anatomic frame of reference previously defined was neither convenient nor precise enough for the purpose at hand. A frame of reference oriented to a specifically defined kick-point instead of an area in the general region of the distal end of the tibia appeared to be essential. Four transducers were arranged in a 1/2-inch-square matrix with a fifth transducer at the center. With a precise system of coordinates it was possible to discriminate between individual transducers for one layout or position of the matrix. By overlay of subsequent and adjacent layouts it was possible to relate pressure readings from one layout to the next as well. The necessity for a precisely located coordinate system as a frame of reference existed for the patellar region also.

A more precise coordinate system was defined utilizing existing terminology and reference points as much as possible. The philosophy was to define anatomical points and recognize perturbations from these points

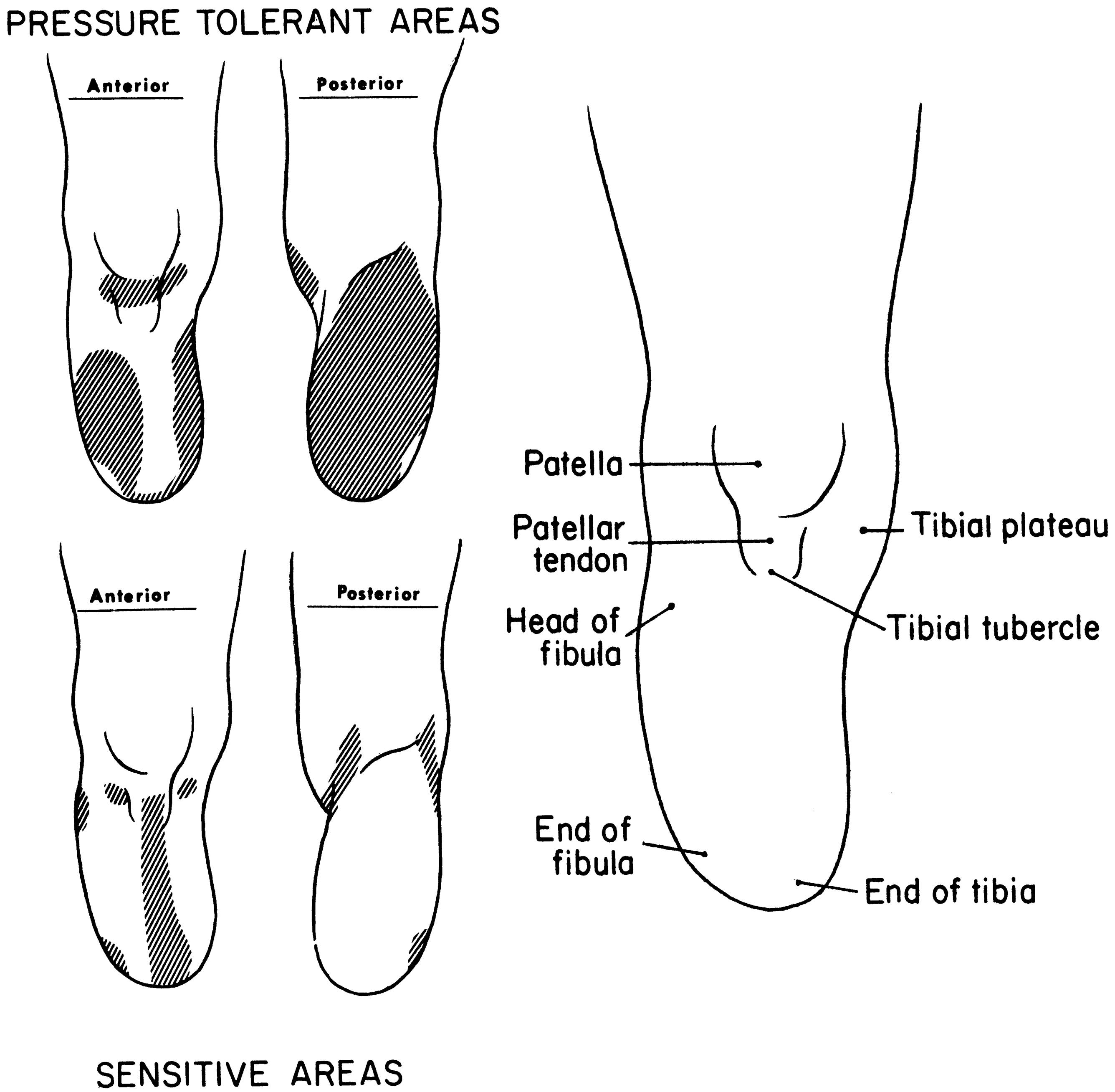


Figure 3-1

Pressure tolerant and sensitive areas
with anatomical reference points

rather than define an absolute coordinate system for the stump. This would compensate for variations in stump sizes and shapes and its accuracy would be in direct proportion to the magnitude of the perturbation from a point. Since one of the primary areas of interest in this research was the distal end of the stump, this required a precise definition of the kick point. Figure 3-2 is a lateral view of the anterior-posterior plane showing the relationship of the tibia, fibula and epidermal tissue.

The kick-point was defined as the point on the tibia where the bevel occurred on the anterior crest and was transferred to the skin tissue. This point was found by palpating the stump. The anterior crest of the tibia is easily traced to the point where the crest breaks into the bevel. The point was then marked on the skin and used as the origin for the coordinate system (Figure 3-3). It is certainly true that under loading this point may shift because of the relative movement of the skin in relation to the tibia, but we are unable to locate this point by direct measurement once the prosthesis has been applied. With the point located, there was now a need for orthogonal X and Y coordinates from which to measure grid locations. For the +Y coordinate, a line is traced up the anterior crest of the tibia from the kick-point. The +X coordinate is orthogonally perpendicular to the Y axis at the kick-point and runs circumferentially in the lateral direction around the distal end of the stump.

With the kick-point and coordinates defined in the unloaded condition, it was now possible to define a pattern of transducer grids referenced to the coordinate system. Zones with dimensions of 1/2 inch by 1/2 inch were located and named. The first such area was placed two zone widths in the +X direction from the origin as shown in Figure 3-3 and was called Kick-Point Zone A. Kick-Point B was located 1/2 inch laterally from Zone A. Kick-Point Zone C was placed 1/2 inch laterally beyond Zone B. Zone D followed Zone C to complete one row. Just above the row reading from A to D was a second row of four zones reading from E through H. Below the A to D row was a third row of four zones designated I through L.

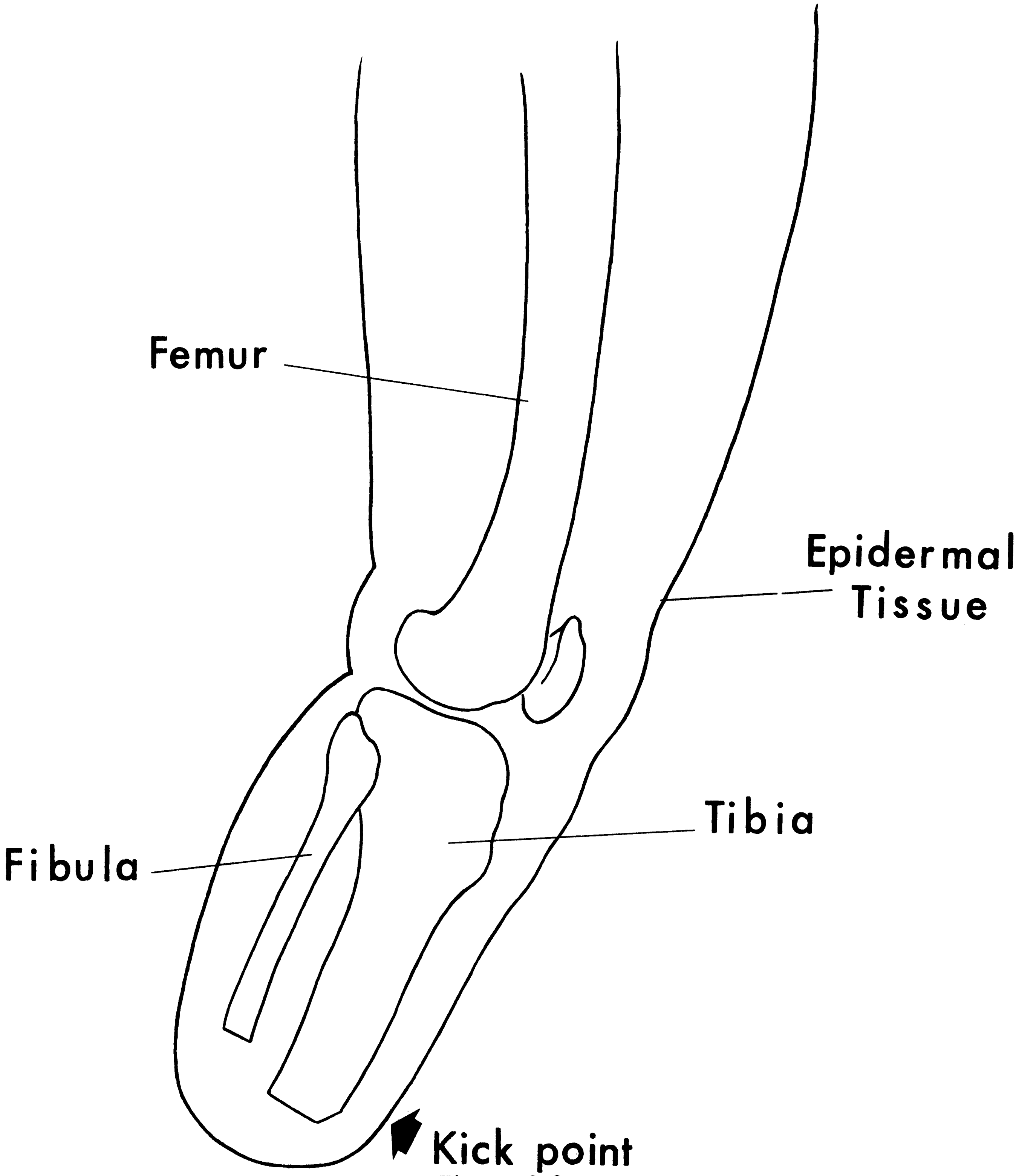


Figure 3-2

Lateral view of the A-P plane showing bone relationships after surgery

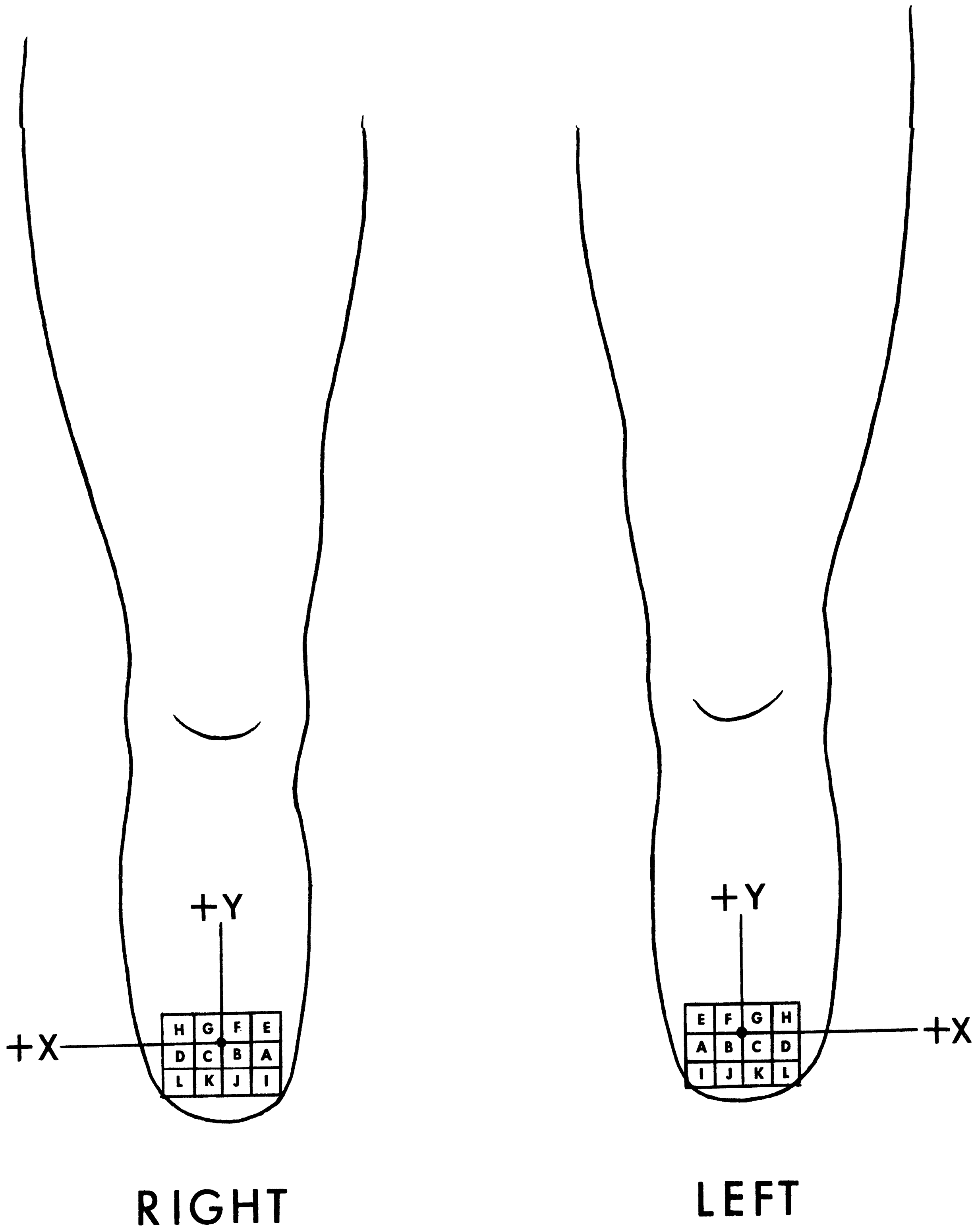


Figure 3-3

Kick point zone definitions for both right and left amputations (anterior view)

Thus the total pattern consisted of a matrix of three rows and four columns lettered from A through L and expandable in either or both directions.

This same nomenclature of zones could be applied to any area having an anatomic structure resolvable to a point. In the case of the patella, the same method of nomenclature was applied. The patella point was located at the intersection of the anterior crest of the tibia and the base of the patella. This is shown in Figure 3-4.

Since these geometric points can be transferred from one stump to another and the perturbations from these points do not represent large dimensions when compared to the nominal stump dimensions, it is anticipated that the results may be comparable from one patient to another in general form. If not, these geometrical areas should be reproducible from one experimenter to another on the same patient and the phenomena occurring within the area can be scrutinized for repeatability.

3.3 THE HARDWARE SYSTEM

The experimental work falls logically into two divisions: the selection of sensing elements that will measure the experimental quantities, and the treatment of the signal from the transducer so that effective use can be made of the information collected. On the basis of experience reported by previous investigators, the following represent the criteria for overall performance of the whole system.

1. A pressure transducer with minimal sensing area and volume
2. Flexibility in positioning the transducer on the body
3. Ability to measure the pressure in regions of small radius of curvature with a reasonable degree of accuracy
4. Ability to gather multichannel data with ease
5. Ability to calculate results from the information gathered with ease
6. Ability to present the data efficiently to either a medical or engineering audience.

The system finally selected utilizes a Linc-8 laboratory computer

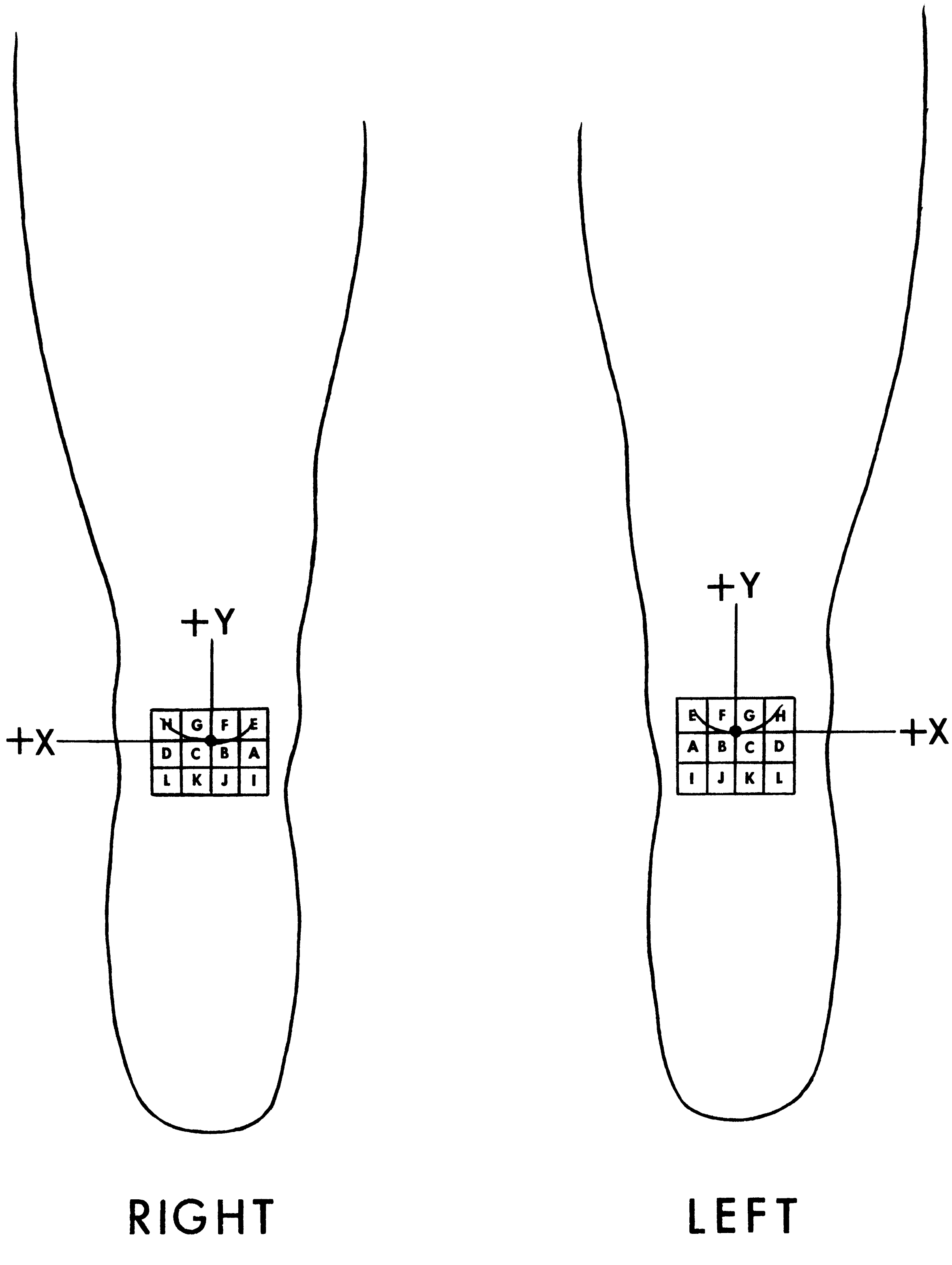


Figure 3-4

Location of the patellar point and
zone definition (anterior view)

(Digital Equipment Corporation) having 8 analog channels to receive the experimental data. This computer is a dual-processor, 12-bit machine having 4,096 words of core-memory. In addition it is equipped with an ASR-33 teletype, dual magnetic transports and a 5-inch Tektronix 561 oscilloscope. The 8 analog channels as well as 6 sense lines can be sampled under program control and represent the primary inputs to the system while taking pressure data. Control, remote from the machine using these features, was achieved to provide coordination with the experimental procedures.

The 8 available data channels were appointed as follows:

5 - analog pressure

2 - hip and knee positions

1 - foot - floor contacts

3.3.1 THE PRESSURE TRANSDUCER

Since it was not the intent of this investigation to completely develop a pressure transducer, commercial products were surveyed to find the smallest transducer available. At the outset the transducer manufactured by Scientific Advances, Inc., met the criterion of size. It is a strain-gage diaphragm-operated transducer originally intended to record dynamic pressure on helicopter blades. Figure 3-5.

Two of these transducers were purchased and installed in a below-knee prosthesis and some preliminary determinations made. Results indicated that the transducer responded reasonably well to the environment and that the sizing was approximately correct. Serious questions arose regarding the use of the transducer on or around bony prominences within the stump. The radii of curvature at the kick-point, condylar flares, and medial and lateral flats of the tibia led to questions of applicability of the transducer in these regions. Since no transducer was available that would provide complete adaptation to the curvature of the stump, the problems of complex geometry were solved by instrumentation techniques rather than by the development of any new transducer. With this provision the transducer was judged acceptable for the purpose of obtaining the

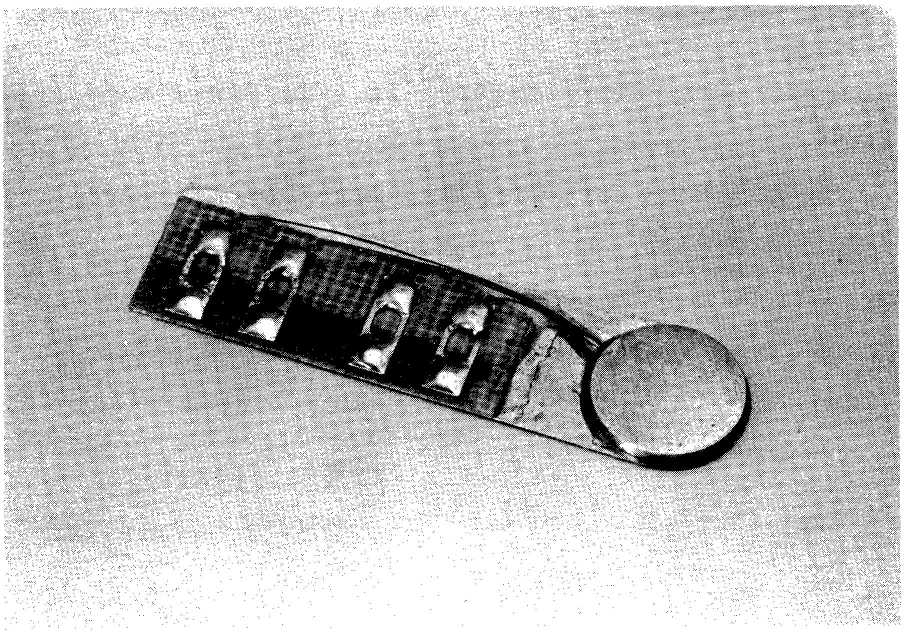


Figure 3-5

Scientific Advances, Inc., M-7F Series 100
psi pressure transducer

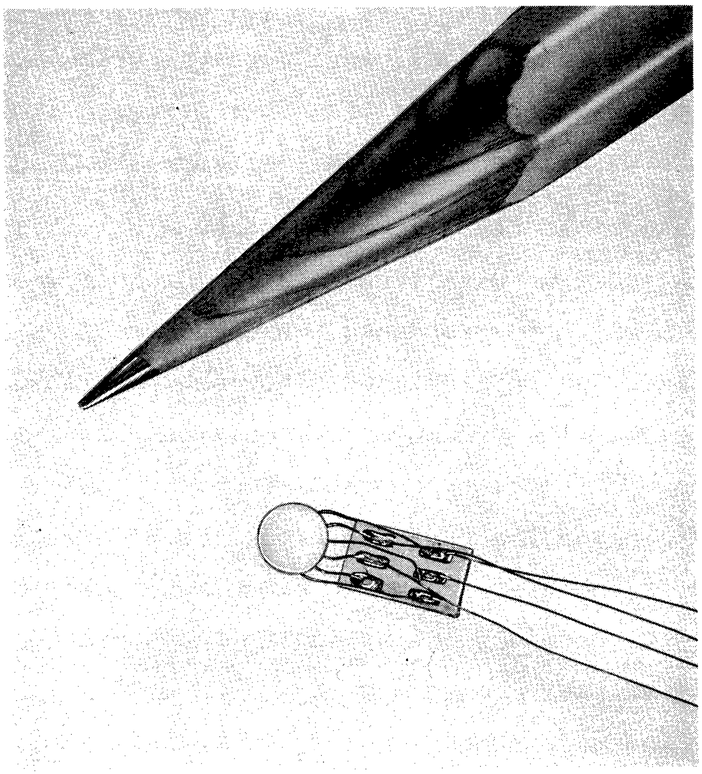


Figure 3-6

Kulite Semiconductor Products, Inc.,
LPS Series transducer

pressure information. An active search for a smaller and less expensive transducer was maintained. In particular, contact was made with Kulite Semiconductor Products, Inc., where the transducer shown in Figure 3-6 was produced. This transducer incorporates a monolithic integrated-circuit Wheatstone bridge formed directly on a silicon diaphragm. It was also developed for measurements of dynamic surface pressure on such structures as helicopter and turbine blades or air foils.

Table 1 gives the specifications for both of these transducers

Specification	Kulite LPS-125-500	Scientific Advances M-7F-100
Diameter	0.125 inch	0.250 inch
Thickness	0.030 inch max.	0.027 inch max.
Internal Pressure	- (sealed)	- (sealed)
Pressure Range	0 - 500 psia	0 - 100 psia
Natural Frequency	350 KHz	-
Overpressure	100% F.S.	25% F. S.
Excitation	5 VDC or ACRMS	3 VDC or ACRMS
Impedance (Nom.)	350 ohms	120 ohms
Zero Balance	$\pm$ 3% F.S. max.	-
Sensitivity (Nom.)	0.05 mv/v/psi	0.01 mv/v/psi
Temperature Effect on Zero	$\pm$ 0.02% F.S./°F	$\pm$ 0.2% F.S./°F
Temperature Effect on Sensitivity	$\pm$ 0.03% F.S./°F	$\pm$ 0.08% F.S./°F
Non-Linearity and Hysteresis	$\pm$ 1.0% F.S.	$\pm$ 0.5% F.S.
Repeatability	$\pm$ 0.2% F.S.	$\pm$ 0.25% F.S.

TABLE 1

Comparison of Kulite and Scientific Advances Transducers

The transducers in the forms shown in Figures 3-5 and 3-6 were unacceptable for one basic reason: the mechanical lead connection and

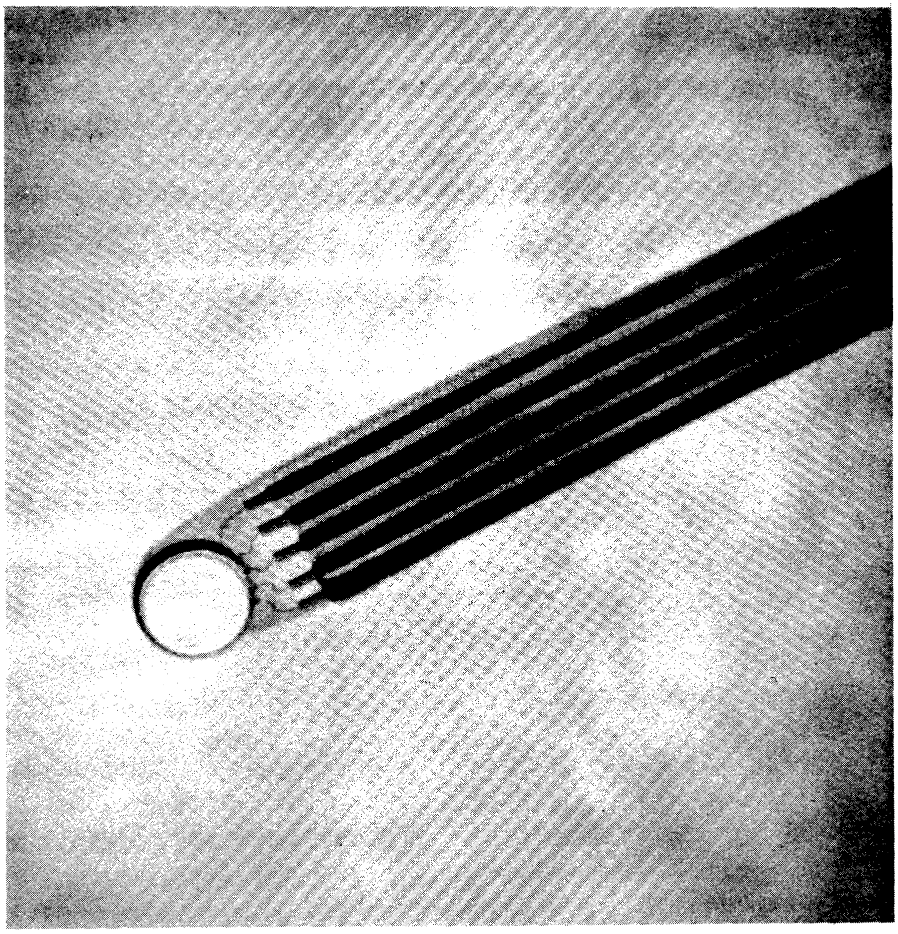


Figure 3-7

Altered Kulite pressure transducer

terminal strip lacked the strength required to operate durably in a prosthesis. The possibility of working with the Kulite Corporation to alter their transducer to meet the need was investigated. Since they were agreeable, this was done.

In order to use a ribbon-cable conductor as an integral part of the transducer and to strengthen the mechanical connection, alterations were made to develop the transducer as shown in Figure 3-7. This transducer retains all the attributes of the original transducer while providing increased mechanical strength at the terminal connection. As can be seen in the figure, the temperature compensation network has been removed from the terminal pad, and the ribbon-cable overlies the paddle. After soldering, the entire connection was fixed in epoxy resin and the temperature compensation network installed at the other end of the ribbon-cable.

Acceptance Tests

When it was decided that the modified transducer would serve for the experimental work, a 100 psi unit was ordered. Acceptance was based on a shock test and thermal drift of zero.

The following procedure was adopted: The transducer was inserted between the heel and sock of a 120-pound person, the shoe was replaced, and the transducer was then jumped on. Although this produces shock loadings, preliminary investigation had indicated that such pressures might well be produced with a below-knee prosthesis. In addition, the instrumentation for measuring temperature effect on zero was tested. Since this is a semiconductor device, assurance had to be provided that variation in skin temperature after insertion would not seriously impair the output of the transducer. In view of the type of calculation to be executed on the data, it was decided that the 3 per cent zero drift that resulted was acceptable. It should be noted that use of the transducer at less than the rated pressure range increases the transducer sensitivity to temperature changes proportionately. The 100 psi unit failed to pass the impact loading tests. With transducer costs as a major factor and zero drift not so critical, a 500 psi unit was ordered. This transducer met acceptance criteria and was inserted in a below-knee prosthesis. The subject chosen had a highly atrophied twenty-five year old stump which exhibited numerous bony prominences and little soft tissue. The transducer was found acceptable for use in all the precarious regions that were anticipated. At this point in the investigation the remaining transducers needed for the study were ordered.

After receiving the transducers, it was found that the manufacturer had used bare copper ribbon-cable for attachment to the transducer, as well as a corrosive flux that wicked by capillary action between the wire and insulation. The result was that the cable in turn corroded and oxidized the AWG-34 wire (consisting of forty strands of Number 50 wire) and broke electrical contact. The fault was identified after considerable study of the manufacturing processes for both the wire and the transducer. At this point the transducer manufacturer replaced the previous transducers with transducers constructed of silver-plated wire, which obviated all corrosion and oxidation problems and thus became the final form of the transducer used in all experimental work.

CALIBRATION

The pressure range involved in the studies was estimated to be 0-200 psig. The manufacturer was requested to supply calibration data for each transducer at 0, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 125, 150, 175, and 200 psig. Since each transducer shows some nonlinearity and a slightly different sensitivity, the calibration was checked with all signal conditioning attached, and the results actually represent a total-system calibration. The pressure vessel used for this testing was the valve body from an air regulator. The gas used was carbon dioxide, and the pressure indicator was a bourdon-tube dial indicator calibrated against a dead-weight testing unit.

PRESSURE TRANSDUCER FORMAT

Five pressure transducers were used simultaneously, the number of transducers being related directly to the recording equipment. The transducer information could be used in at least two distinct manners. First, if five transducers were placed in a square matrix, the discrete information at any fixed time could be expanded mathematically to a two-directional one-pressure dimension curve. In this manner a pressure surface could be reproduced by curve-fitting the data. The matrix used (Figure 3-8) was sandwiched in place by tape [Blenderm surgical tape, Number 1525, 1-1/2 inches wide]. In turn, this tape could be applied to a stump at a test area. This matrix is a half-inch square with the fifth transducer at the geometric center. The transducers are shown applied to a limb in Figure 3-9.

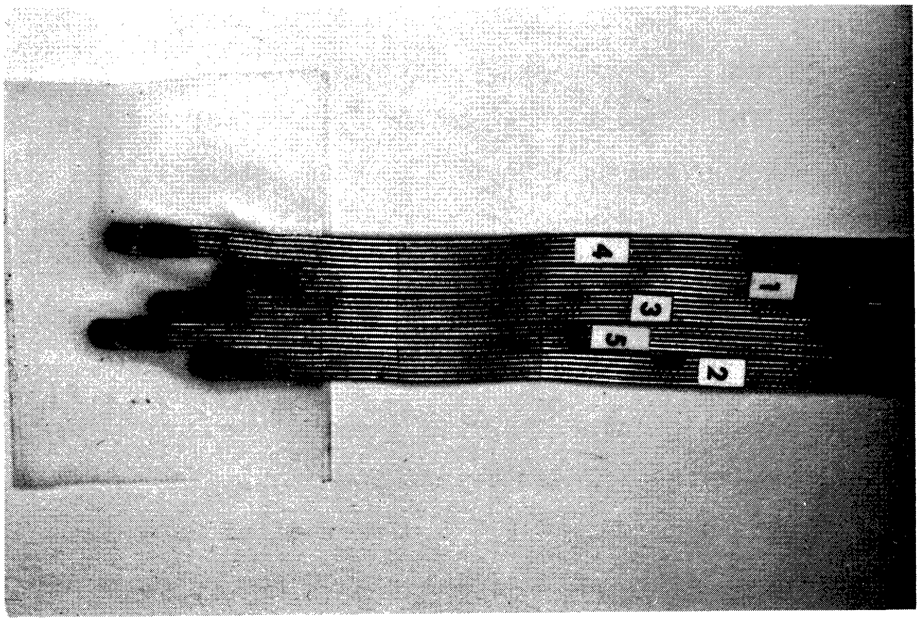


Figure 3-8

Pressure transducers in an area array

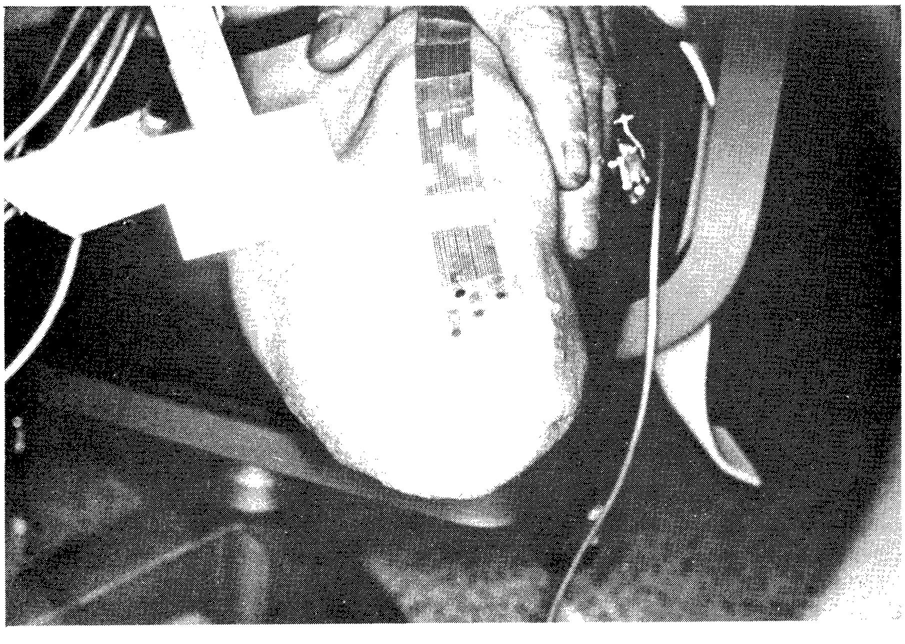


Figure 3-9

Pressure transducers in an area array
applied to a limb

The second experimental layout was a liner array with the transducers in a straight line one-half inch apart and the taping scheme the same as before. This layout is shown in Figure 3-10. Figure 3-11 shows this layout applied to a limb. In this instance, the discrete pressure information is interpolated in one spatial dimension to form a curve. Figure 3-12 shows the composite transducer array and cabling.

3.3.2 SIGNAL TREATMENT - PRESSURE CHANNELS

Low level signal conditioning was accomplished using Daytronic Model 601B units having isolated bridge power supplies and bridge balance circuits. Hewlett-Packard type 8875A differential data amplifiers having variable gain settings from 1 to 1,000 and upper band-limit filtering capability from 2 to 20 KHz, provided the analog signal multiplication needed for the pressure channels.

KNEE AND HIP GONIOMETERS

Goniometers were required in order to record the angular positions of the knee and hip during walking. These units and adapting hardware are shown in Figures 3-13 and 3-14. Matching 1,000 ohm potentiometers were mounted in the control panel, and output was read across the center taps of the two potentiometers. The control panel potentiometer provided zeroing capability.

The power supply for the potentiometers was a $\pm$ 15 volt common supply mounted in the control panel where the output signal was stepped down to provide a $\pm$ 1 volt signal.

FOOT SWITCHES

Foot switches are electrical contacts mounted in various positions directly on the heel and sole of the shoe to indicate where the foot was in relation to the floor. The research group at Baylor University had approached the same problem and had tried to use a commercially available ribbon switch. They eventually manufactured switches of their own, using shim stock separated by sponge rubber. In their work, they were

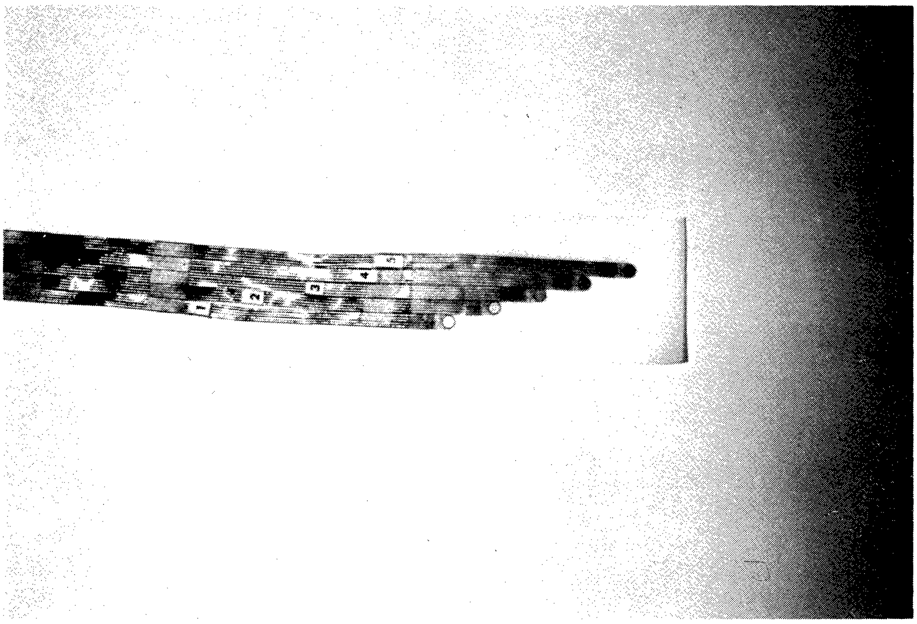


Figure 3-10

Pressure transducers in a linear array

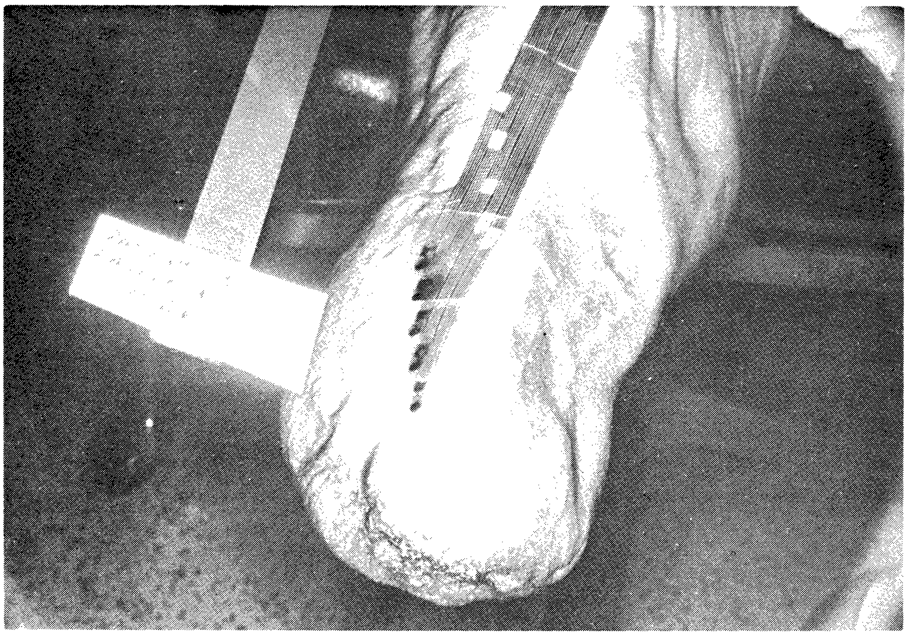


Figure 3-11

Pressure transducers in a linear array
applied to a limb

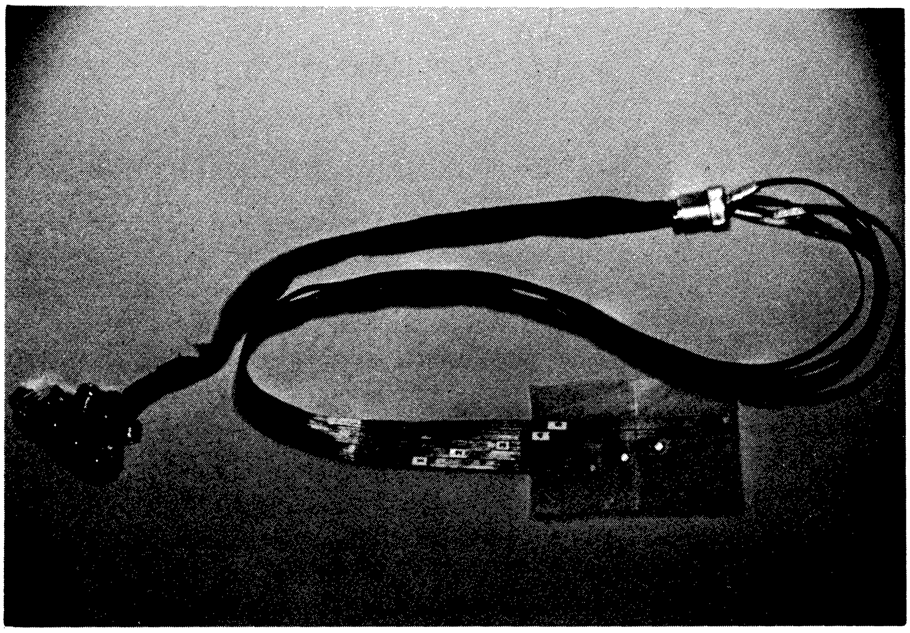


Figure 3-12

Pressure transducer array and cabling

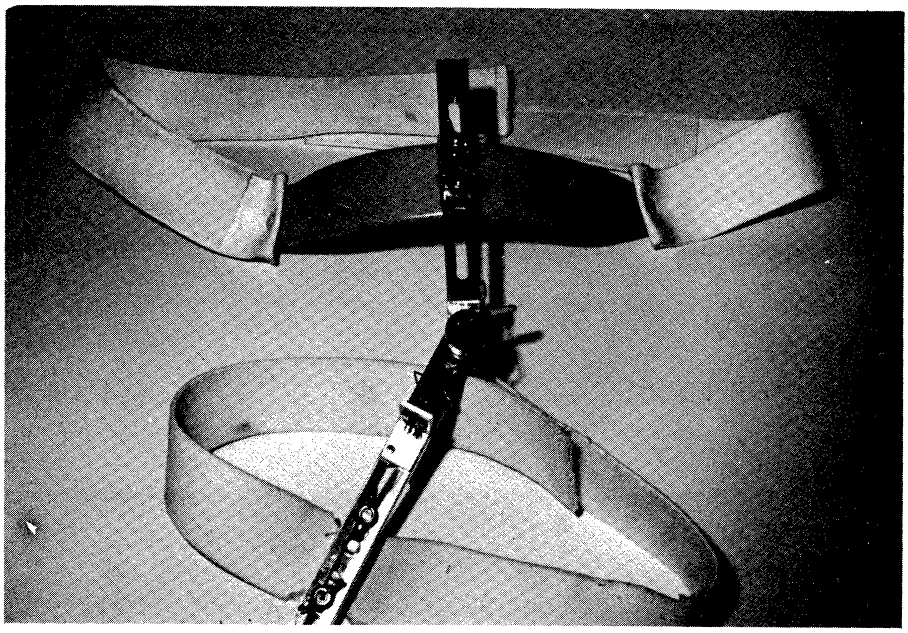


Figure 3-13
Hip goniometer and adapting hardware

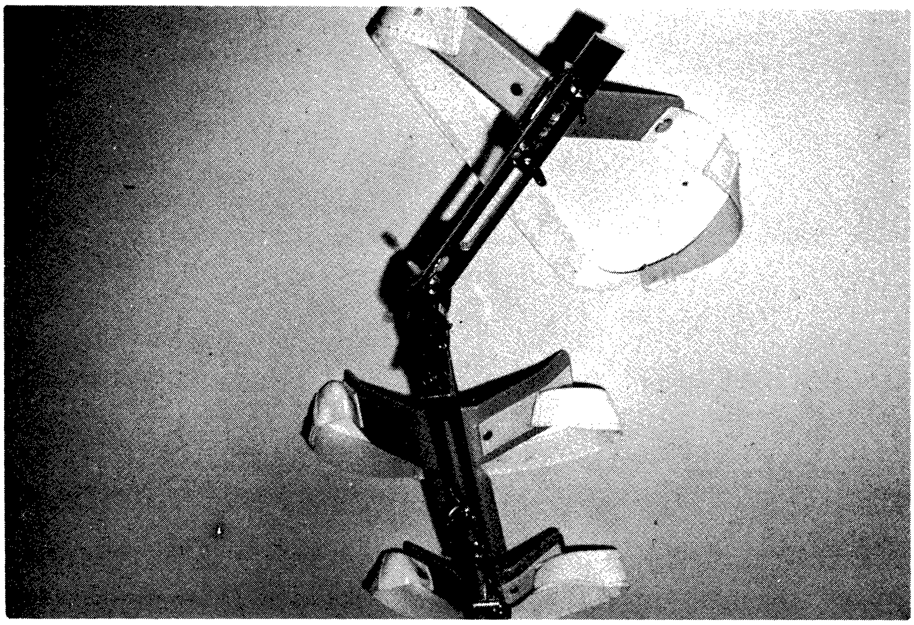


Figure 3-14
Knee goniometer and adapting hardware

attempting to provide timing marks for computation of interval sizes during gait. They initially used five switches on the bottom of the shoe, but eventually reduced this to three.

On the basis of their experience, switches were fabricated from .010 inch brass shim stock and wired in a resistive network to provide a single channel of information, the signal level indicating the switches closed. These switches are shown in place in Figure 3-15.

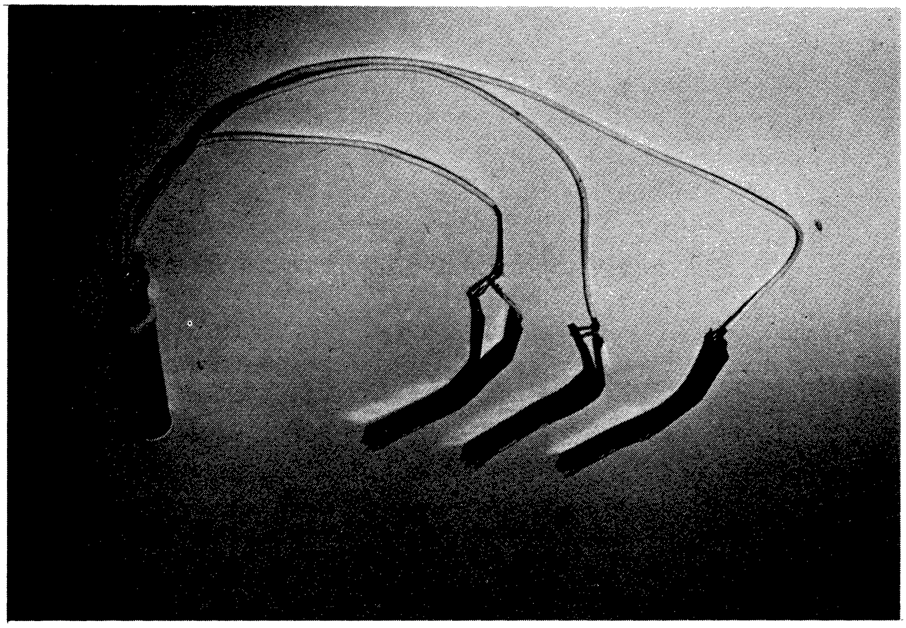


Figure 3-15

Fabricated foot switches and connector

3.3.3 CONTROL PANEL

With eight channels of information, it was necessary to assemble the active elements of signal control and output control in some manner. This was done by housing all the elements in a master control panel that provided the following conditions:

1. Central processing of all signal conditioning and amplification

2. Source of necessary power

3. A central place for the connection of all input and output cabling

4. A convenient means for the parallel output of resultant signals to as many recorders as necessary

5. A simple way to control all recording equipment as well as to monitor the status of the equipment.

For the basic rack we used an Ingersoll Products IEII assembly with casters. The slanted front panel was divided into three sections: The lower section housed the differential amplifiers; the center section housed the signal conditioners; the upper section contained hip and knee balance potentiometers and stepdown amplifiers, main power switch, recording indicator lights and switches, and two automatic ranging voltmeters which could read any individual channel. The control panel assembly is shown in Figure 3-16.

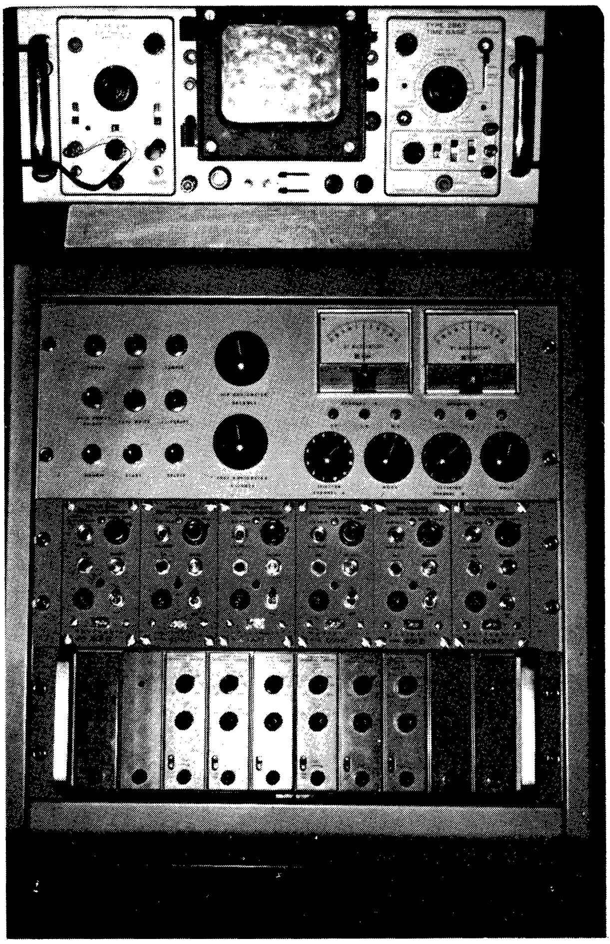


Figure 3-16

Control panel assembly

AUTOMATIC RANGING VOLTMETERS

Two automatic ranging voltmeters (Channels A&B) were constructed which can operate in either fixed or automatic range and which have three full-scale ranges-- 0.1, 1.0, and 10.0 volts. These meters made it possible to select a channel of interest and visually observe the signal behavior.

PARALLEL SIGNAL MONITORING EQUIPMENT

A Tektronix Model 564 memory oscilloscope was attached to channel A [the left-hand channel] to simultaneously display and record signals. A Sanborn dual channel dc strip chart recorder was attached to Channel A and Channel B to simultaneously record a permanent trace of any channel. A Hewlett-Packard Model 419A dc null voltmeter was attached to Channel A and used in calibration procedures for higher accuracy work.

INTERNAL CIRCUITRY

Each individual panel mounted in the rack is provided with a 32 pin connector. These connectors, as well as one from the experiment in process and one from the primary recording equipment, all connect to a master terminal strip inside the control panel. Thus any individual panel can be powered by disconnecting the 32-pin connector and pulling the module out of the panel. All wiring diagrams and details of the various panels are given in Ref. 1 of this section.

3.4 THE COMPUTER PROGRAMS (SOFTWARE)

3.4.1 SOFTWARE DEVELOPMENT

The development of software for handling multichannel information involves problems in both the collection and processing of data. In most instances the digital computer presents little complexity in the over-all problem solution, paritcularly when dealing with compiler languages such as FORTRAN, MAD, BASIC, etc. In these cases converting the mathematics to a machine algorithm takes little time compared to machine-language programming, and the mathematics can be highly complex. All large machine installations provide this computational capability but are not easily dedicated to the data-gathering aspects of a problem from the economic point of view.

Small machines such as a Linc-8 are easily dedicated to the experimental data-gathering, but usually limited in magnetic core storage within the machine. This means that programs are generally written in machine language rather than compiler language. In turn, it is a more time-consuming process to prepare an individual program. All programs used in this research were written in machine language.

The Linc-8 is equipped with a multiplexed analog/digital converter which provides a convenient method for converting data from analog to digital form convenient for processing by analysis programs. Since these machines have limited magnetic-core storage, full use is made of additional input/output equipment such as the magnetic tape decks. The 10 Hz teletype presented a problem due to its speed. Conversation with the machine was mostly handled via the Tektronix 561 oscilloscope except where a typed copy was absolutely necessary.

3.4.2 EXECUTIVE SYSTEM

The computer came equipped with a standard executive system from which individual programs may be called and executed; all executable programs are stored in its library. Unfortunately, the binary storage area for programs on tape was limited to a small percentage of the total tape length. Since requirements exceeded this limit, it was necessary to devise a means for enlarging the functional capacity of the executive system. This was accomplished by removing from magnetic tape the assembler and manuscript file-storage area present on the standard executive system, thus allowing the binary storage area to encompass the entire tape except for the small amount required for the executive system. By judicious placement of the executive system and the index format of the program library on the tape, compatibility was maintained with manufacturer's supplied programs and the St. Louis University machine-language assembling program--inherent attributes of our Linc-8 computer. A queue routine was added to allow execution of a list of programs rather than single programs. Because of the size of core memory available, the degree of supervision exerted during execution of any individual program is nil. Its inter-active function is to load a program in memory and provide means for return after completion.

The first step in executing computer programs related to a given research topic is to load the executive system into memory and selecting the desired program from its library. When the system is fully loaded, the display shown in Figure 3-17 will appear on the cathode-ray tube over Channel 0; this display merely inquires of the user which program he wishes to execute. As the program name is typed it appears on the oscilloscope as in Figure 3-18. But if instead of a single program the user calls for display of the index, the oscilloscope will show a list of titles, as in Figure 3-19, and the user may type the desired program name into this display (Figure 3-20). The queue feature can be signalled by typing "QUEUE" or some abbreviation of this term, followed by a list of programs which are to be executed in the order given.

While the executive system is running it renders inoperative all the Linc console switches except "LOAD" and "STOP." If necessary, however, this feature can be overridden at any given point. In addition, specific allowance is made for hidden programs--those not shown in the index--and for unloadable programs--those the executive system will not load. The first of these two features serves as a protection for novices, and the second offers the advantage of allocating additional tape to any program.

Operational details for this and other computer programs may be found in Appendix 1, Ref. 3.

3.4.3 PROGRAM LIBRARY

The library of titles compiled for this pressure study represent programs for collecting and analyzing data recorded from instruments inserted at the interface between a stump and a prosthesis. The programs can be

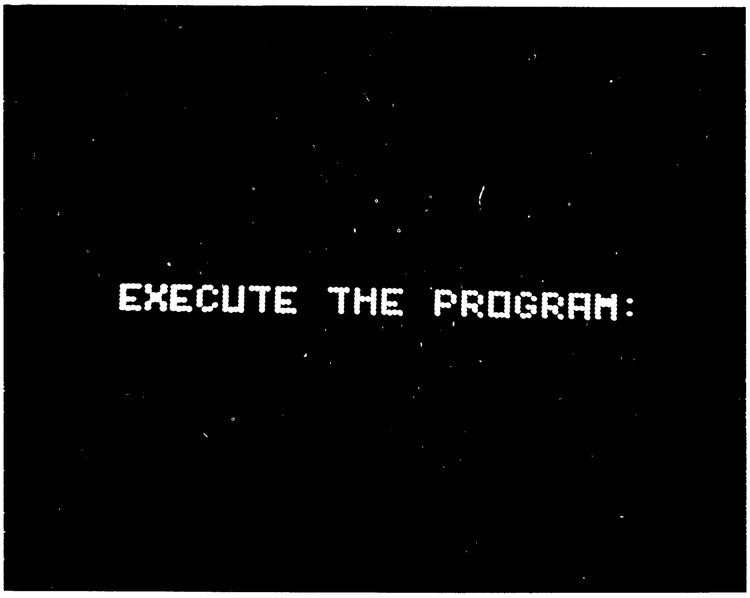


Figure 3-17

Executive system inquiry display

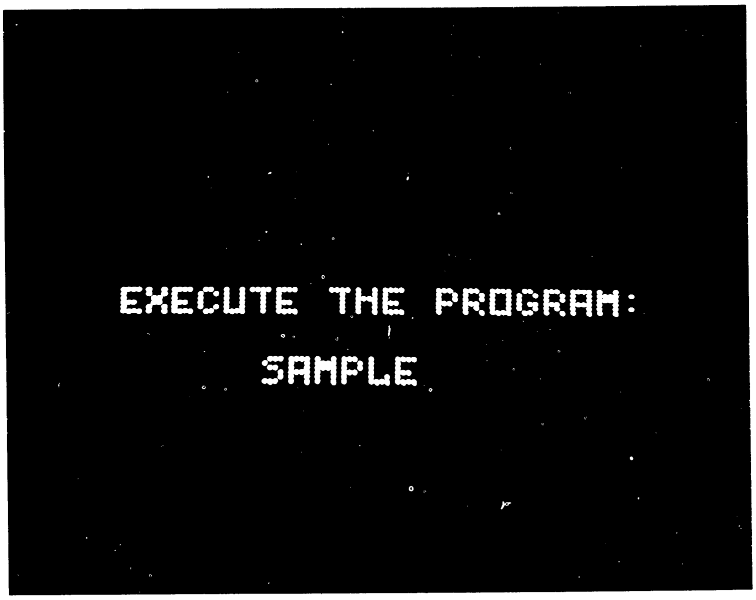


Figure 3-18

An example of input from teletype

Executive system index display

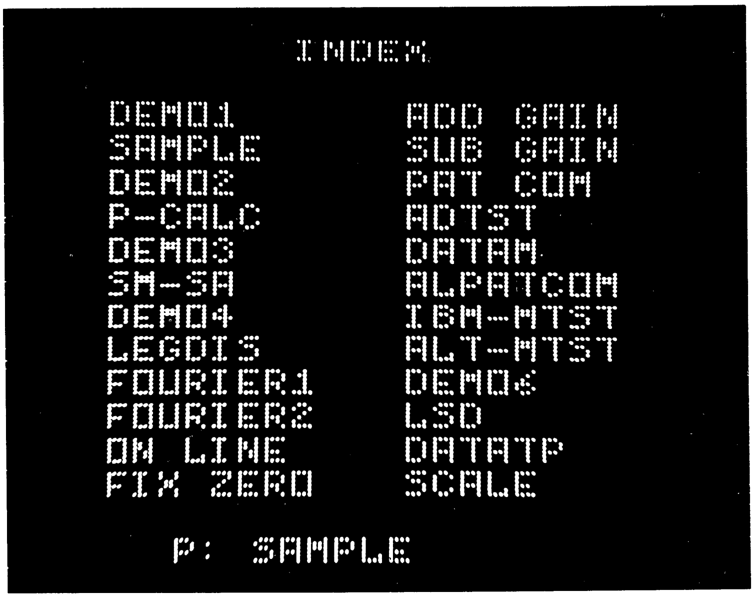


Figure 3-20

Program name with index display showing

executed by typing the library titles. For example, "P-CALC" designates a three-dimensional display program involving a computational curve-fitting routine. Following are brief descriptions of the programs written or altered for the pressure studies.

3.4.3.1 PROGRAM SAMPLE

This is a sampling program designed to obtain the analog data in digital form by using the analog/digital converter. Its function is to gather the data and write the results on magnetic tape in some predetermined format.

The data tape is always mounted on tape unit No. 1. The entire magnetic tape is used to store digitized experimental data, including the experimenter's comments regarding the testing and loading protection against inadvertent hardware program loads from the tape. The information layouts on tape were chosen to provide ease of programming as well as information retrieval. When the program is loaded, the display shown in Figure 3-21 will appear. The user then answers the question whether the required data tape is new or existing, and also specifies the sampling interval (Figure 3-22). The next frame asks for a 4-character alpha numeric patient identification number (Fig. 3-23). When typed in, this ID becomes part of the record upon any subsequent use of the data. The next step is to apply the zero-checking routine which was adapted from the program library supplied with the computer (Figure 3-24). This allows the user to set "zero" on all instruments in the static condition; it is not intended to be a dynamic digital voltmeter. The patient ID is displayed along with the next test number.

At this point in the operation, the machine will no longer respond to the teletype, but now senses three external lines which are triggered from the remote control panel. The sampling process begins when the "START" button on the remote control panel is pushed. After 256 points per channel have been sampled the machine will make some preliminary checks on the digitized data just gathered. If neither condition exists,

Figure 3-21
"SAMPLE" program first frame

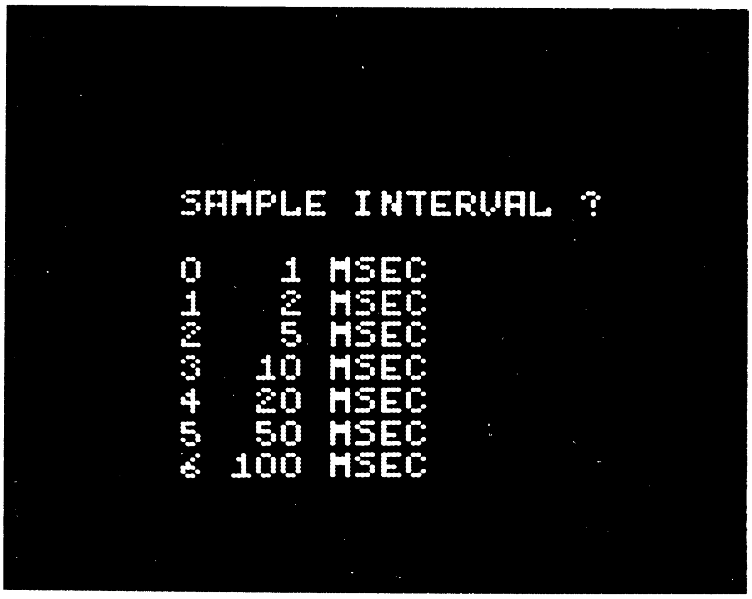


Figure 3-22
"SAMPLE" program second frame

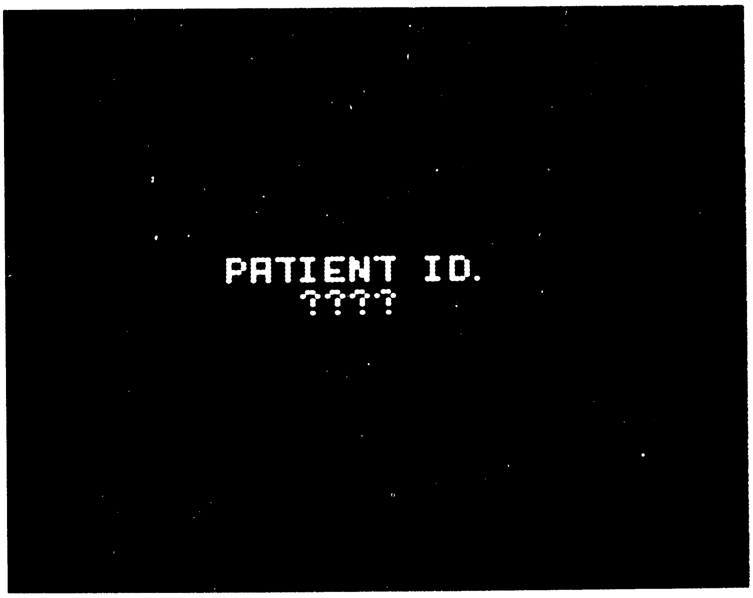


Figure 3-23

Patient I.D.

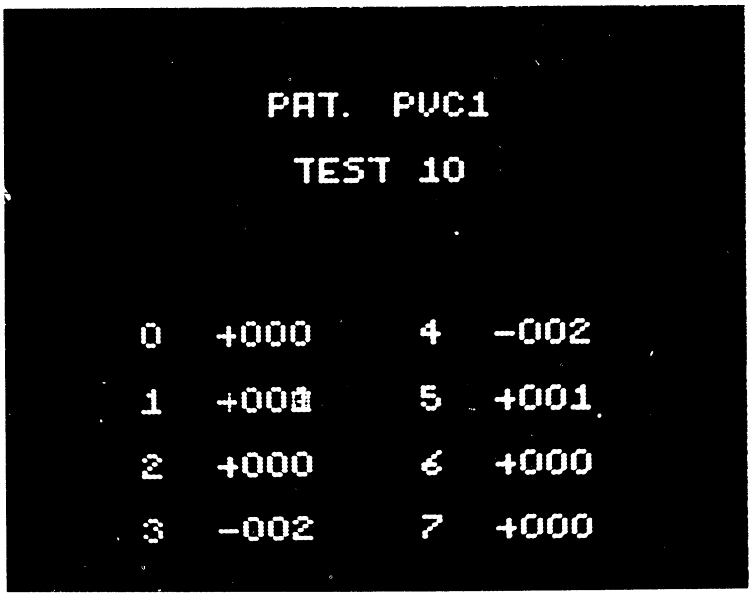


Figure 3-24

Zero Checking Routine

the machine proceeds with the writing of magnetic tape; if either or both exist, it will provide a program interrupt. The interrupt routine will define the type of error and also designate the channel number. A typical interrupt for negative data is shown in Figure 3-25.

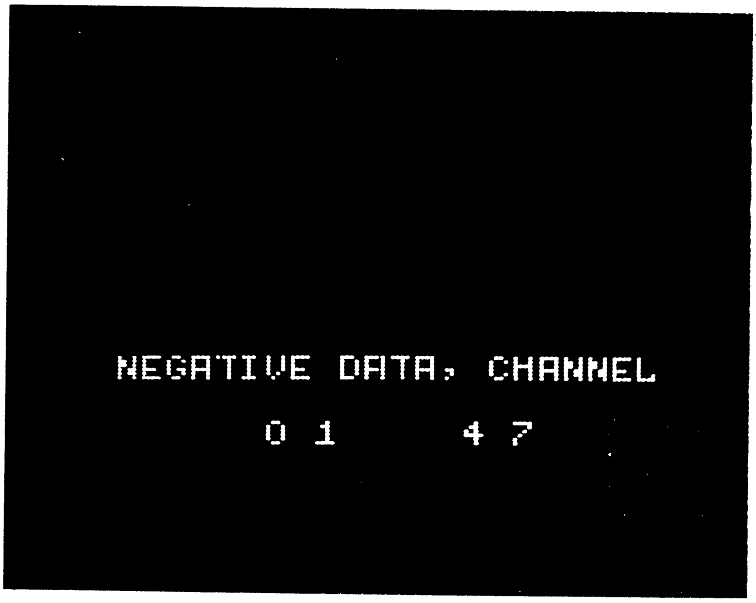


Figure 3-25
Typical interrupt for Negative Data

The program maintains a count of the last position in the data field on magnetic tape. It does this by two different methods in order to provide a double check on this information.

If during the dampling process there is a need to discontinue the sampling, the process can be halted by pushing in "DELETE" button. If the machine is waiting to start sampling and "DELETE" is pushed, the program will delete the data of the last test. "DELETE" may be pushed as many times as desired, thereby deleting data starting with that of the last test and proceeding to the second last test, etc.

If an interrupt occurs during the sampling process the data may be retained by pushing "START" and proceeding when a new test number appears as in Figure 3-24. Indicator lights on the remote control panel are

PAUSE, SAMPLE, TAPE WRITE and INTERRUPT indicator lights. After the sampling is completed, the SIGNOFF button is pushed, returning the program to the executive system. If SIGNOFF is not used, and this magnetic tape is later used to continue taking data, the program will provide an interrupt indicating improper previous exit.

3.4.3.2 PROGRAM P-CALC

"P-CALC" is a three-dimensional display program to display pressure applied to a surface. The program displays two dimensions in space co-ordinates and one dimension in pressure. It is a computational curve-fitting routine to expand the five pressure channels from discrete points to a spatial curve. The program calculates on data gathered by the program sample described in section 3.4.3.1. It operates with the machine's Tektronix 561 oscilloscope set to Channel 0 and a remote Tektronix 564 oscilloscope set to Channel 1.

The program retrieves five instantaneous pressure values and fits them to a mathematical relationship. The relationship chosen was a polynomial power series. A two-dimensional infinite series expansion in pressure would look as follows:

$$P(X,Y) = A_0+A_1X+A_2X^2+A_3X^3+\ldots B_0+B_1Y+B_2Y^2+B_3Y^3+\ldots$$

For this application the series was truncated and simplified as follows:

$$P(X,Y) = A_1X+A_2X^2+B_1Y+B_2Y^2+C$$

where A_1, A_2, B_1, B_2 and C are parametric functions of time. This approximation provides a second order polynomial expansion in two spatial co-ordinates. The selection of this relationship is a matter of choice. It was felt that arguments regarding other possibilities could and should be raised during the experimental portion of the work. At that time, experimental matching of adjacent areas would serve as a mode of evaluation.

During execution of the porgram one can specify the test number, interval size or print-out of the parameters used in the equation solution. The transducer matrix upon which the calculation is executed is a square.

The transducers were arranged in a 0.5 inch square with one transducer at the intersection of the diagonals.

The program normalizes this matrix which is inserted at the pressure area and places one transducer output value in each corner of the 564 oscilloscope screen and one transducer output value in the center. These pressures and their locations substituted into the power series equation establish five simultaneous equations with the parametric functions of time A_1, A_2, B_1, B_2, and C as unknowns. Simultaneous solution of the set of equations establishes values for the parametric functions. Thereafter, intermediate values of X and Y are fed back into the equations to yield the interpolated values of pressure corresponding to the positions lying between those of the experimental grid. The program then divides the X axis into 32 increments and the Y axis into 21 increments and calculates 672 interpolated values. It also defines, for display purposes, a gray scale from 0 through 7 and assigns each of the 672 points to a gray scale value. The calculated points have a 4 x 6 grid on the scope face and the gray scale range intensifies between 0 and 24 raster points in each grid. Attention was given to the order in which the raster points appeared so as to assure uniformity and continuity to the light scale representation of pressure changes. Figure 3-25 shows an example of the resulting pressure display with all 8 gray scale pressure levels indicated. The dot densities are proportional to the measured pressure.

3.4.3.3 SM-SA

This program is an attempt to treat skin tissue grossly in the same manner as a conventional engineering material. The intent is not to define tissue tolerance, but pressure tolerance. It is not suggested that tissue reacts atomically the same as metals, but perhaps that we will be able to present dynamic pressure conditions in a similar manner.

Metals often exhibit a phenomenon called fatigue, which is a result of repetitive loading. Although a metal initially can withstand the dynamic loads to which it is subjected, at a later time the metal fractures for no visually apparent reason. On a mocroscopic level, a basic understanding of the atomic movements occurring that result in fracture are well understood. Engineers are able to describe the stress conditions and predict when and if fracture will occur. This is done, basically, by constructing a mean stress-alternating stress diagram. The designer then calculates the expected loading conditions to which the material will be subjected and plots the point on the graph that describes the operating condition. Superimposed on the graph are curves characteristic of the material's properties. A comparison between the operating condition and material characteristics is then made to determine if fracture will occur.

With tissue as the material it would be difficult to construct a fatigue diagram if it exists with material characteristics that would accurately represent skin tissue for different individuals. Instead, this program will calculate the mean and alternating stress values [pressure] which have occurred on an individual, and plot the point. The only intent of the program is to determine whether an operating range exists and if not, to at least characterize the total data for an individual.

The program requires a data tape to be mounted on Unit 1. The software will immediately start searching tape Unit 1, gathering all pressure information from the tape and display as a result a mean stress-alternating stress diagram. The mean stress is defined as the arithmetic average of the minimum and maximum stress occurring on one test for one transducer. The display of the results is shown in Figure 3-26.

3.4.3.4 LEGDIS

The intent of this program is to reproduce the digitized data taken with program "SAMPLE," in almost an analog form. It is an observation program, performing no calculations on the existing data, but reconstructing the digitized data for concept.

The program constructs a stick figure to represent the patient's leg and draws the hip and knee angle to correspond to the test data. This construction is accomplished by affixing the coordinate system to the

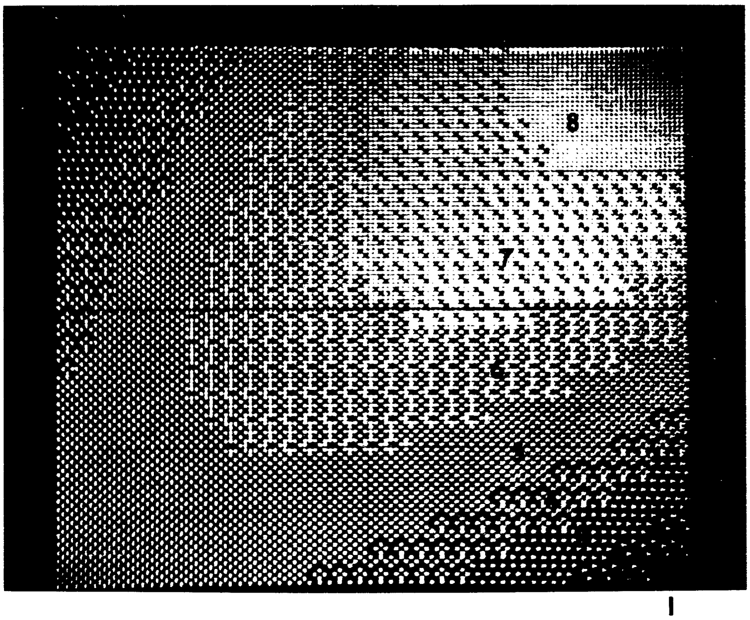


Figure 3-25

Example display showing all eight gray scale dot densities

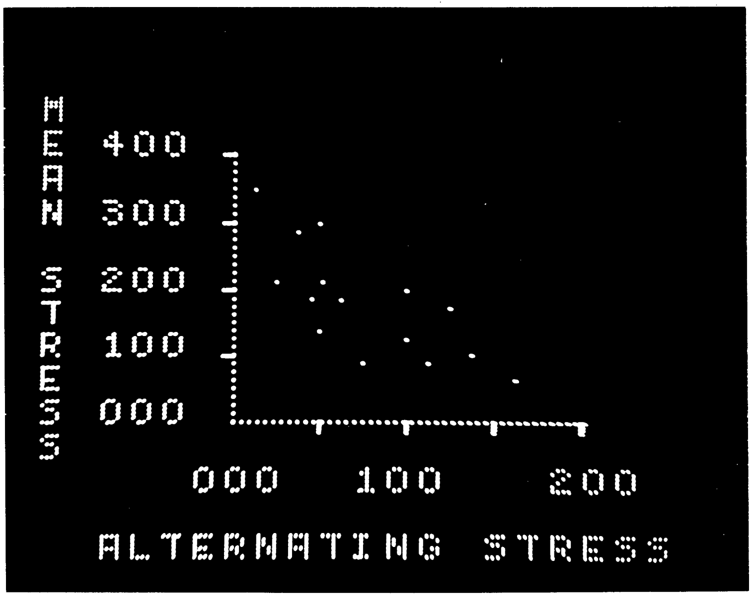


Figure 3-26

Example display of "SM-SA"

vertex of the hip angle. Reconstruction of the angles are displayed in approximately 6-degree increments. This was necessary as a result of display problems on the digital oscilloscope which displays raster points.

In addition to the stick figure construction, the program also displays five pressure manometers to represent each pressure transducer. These vertical manometers display a height representative of the pressure magnitude. Attached to each manometer are maximum pointers that indicate the maximum pressure attained during an individual test. Figure 3-27.

The program can be controlled to allow specification of any test number, instantaneous frame number or cycling speed.

3.4.3.5 FOURIERI

The purpose of this program is to determine the frequency content of all pressure, hip and knee signals gathered by program "SAMPLE." The

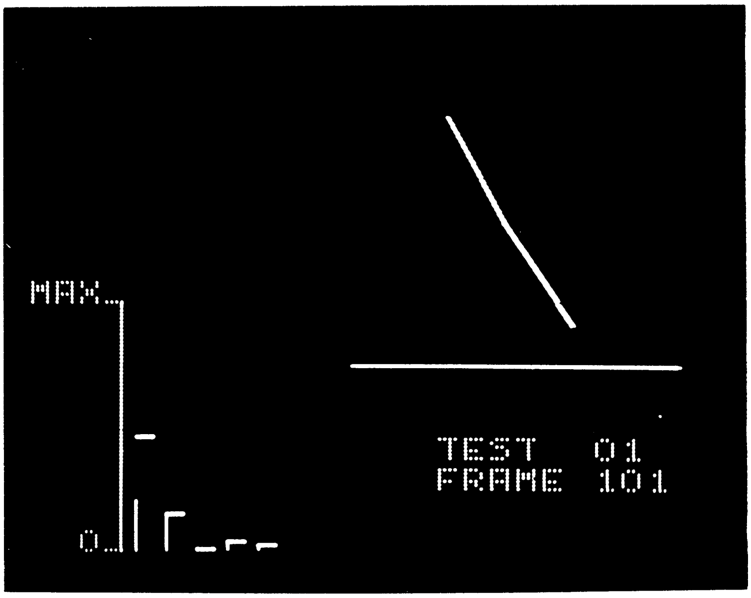


Figure 3-27

Instantaneous exposure of "LEGDIS" showing leg and prosthesis position, instantaneous pressure, maximum pressures attained thus far, test number and frame number equation solved is the Fourier infinite series;

$$f(t) = \frac{a_o}{2} + \sum_{n=1}^{oo} a_n \cos \frac{2n\pi t}{\tau} + b_n \sin \frac{2n\pi t}{\tau}$$

where

$$a_n = \frac{2}{2N+1} \sum_{p=1}^{2N} f_p(t) \sin \frac{2\pi pn}{2N+1}$$

$$b_n = \frac{2}{2N+1} \sum_{p=1}^{2N} f_p(t) \sin \frac{2\pi pn}{2N+1}$$

and $n = 1,2,\ldots, N$, $p = 0,1,\ldots, 2N$ and $f_p(t)$ are the values of a given function. This classical equation is solvable by many numerical techniques. One of the more popular solutions uses a recursive technique described by Goertzel.(11) The reader is referred to the literature for a complete development of the algorithm. The algorithm requires that one cycle of data be passed to the program for synthesis. The definition of a cycle is defined by the foot switch information. Figure 3-28 shows a typical trace of foot switch information. The foot switch shows a periodicity, one cycle of information lying between the leading edges of two consecutive cycles. This means that the program counts down the zero line and determines when the first switch was closed. It then counts the time from when this switching occurred, while pressure and other parameters are changing, until a zero line is re-established. When it then finds another switch closure, it stops the interval count. Multiplying the interval count by the interval time establishes the fundamental period or frequency. The program was written to perform the analysis on any of the sampling rates in the program "SAMPLE."

The program output is completely handled by the teletype. It titles the paper with block number and period size in data points to the base eight. Then it lists five columns of numbers. The left column is a counter "P". The second column is the frequency (Hertz); the third is

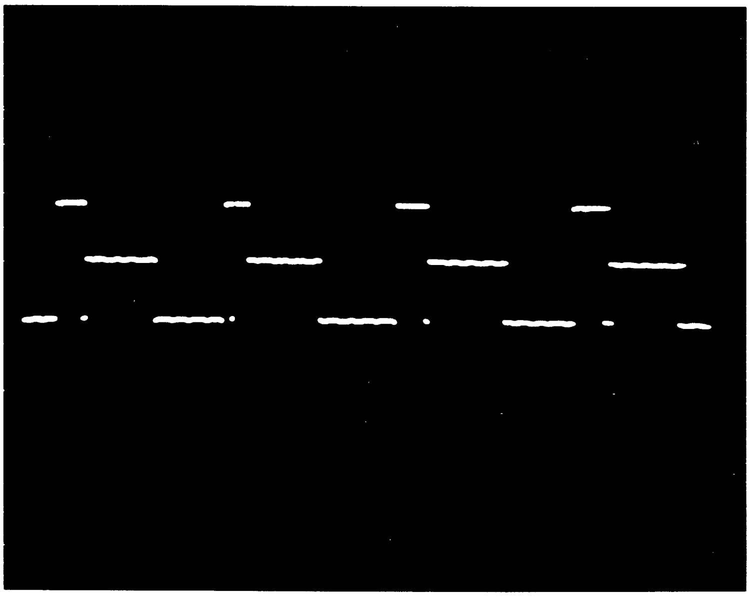


Figure 3-28

Foot switch trace obtained from program "DATAM" the "A" coefficient. The fourth column is the "B" coefficient and the fifth column is the normalized amplitude which is defined as follows:

$$\text{Normalized Amplitude} = \left[\frac{A(K)^2 + B(K)^2}{A(F)^2 + B(F)^2}\right]$$

where K equals the instantaneous value and F equals the fundamental value.

Although for this research no problems were anticipated regarding frequency response of the hardware, future research may benefit by requiring less expensive signal processing and recording equipment. This program was written to provide basic signal definition for this and other general purposes.

An example output is shown in Figure 3-29 for a 20,000 micro-second sampling interval. Note that the program determines the fundamental frequency, and in the right margin marks it with an "F". It computes this independent of position. It should always be in the first position as shown.

3.4.3.6 PROGRAM FIX ZERO

In some of the early investigations, it was found that the temperature sensitivity of the transducer had an appreciable effect on zero-offset. Two basic alternatives exist to correct this condition. The first and most straight-forward was to assure that the original data were taken only after the transducer had stabilized to a new zero. In this case, the transducers were zeroed immediately before taking data. The second alternative was to have a program correct for the zero offset condition after data were taken, by forcing the minimum value pressure to zero and translating the entire curve accordingly. After loading, the program scans the data tape by reading in each individual channel of pressure data, finds the minimum value, adds or substracts it to all data points and rewrites the magnetic tape.

BLOCK NO. 020 FOURIER1 PERIOD 103

P	FREQUENCY.C/S.	A.P.COS	B.P.SIN	N=NORM. AMPL.	
000	+0.000000E+000	+9.773132E+001			
001	+7.462691E-001	+7.005947E+000	+3.925976E+001	+1.000000E+000	F
002	+1.492537E+000	+2.321539E+001	+2.056045E+001	+7.776110E-001	
003	+2.238805E+000	+7.030235E-001	+1.422734E+001	+3.571895E-001	
004	+2.985075E+000	+6.398669E-003	+1.554550E+001	+3.898077E-001	
005	+3.731343E+000	+2.062622E+000	-9.126983E-001	+5.655806E-002	
006	+4.477611E+000	+2.512415E+000	-6.914996E-001	+6.534212E-002	
007	+5.223880E+000	+1.171954E+001	+3.447669E+000	+3.063228E-001	
008	+5.970149E+000	+6.053598E+000	+3.971033E+000	+1.815406E-001	
009	+6.716417E+000	-1.841258E-002	+6.834828E+000	+1.713856E-001	
010	+7.462686E+000	+1.154971E+000	-1.847719E+000	+5.463887E-002	
011	+8.208953E+000	+1.450445E+000	-4.813061E+000	+1.260497E-001	
012	+8.955224E+000	+7.778982E+000	-4.150466E-001	+1.953373E-001	
013	+9.701492E+000	+6.013542E+000	+9.418975E-001	+1.526295E-001	
014	+1.044776E+001	-6.873037E-001	+3.161689E+000	+8.113181E-002	
015	+1.119402E+001	-2.420089E-001	-1.716941E+000	+4.347829E-002	
016	+1.194029E+001	+7.170506E-001	-6.283661E+000	+1.585869E-001	
017	+1.268656E+001	+4.478830E+000	-2.120114E+000	+1.242548E-001	
018	+1.343283E+001	+4.665005E+000	-3.075885E-001	+1.172301E-001	
019	+1.417910E+001	-1.379102E+000	+9.550754E-001	+4.206435E-002	
020	+1.492537E+001	-1.654171E+000	-1.483026E+000	+5.570799E-002	
021	+1.567163E+001	-3.001363E-001	-5.784392E+000	+1.452401E-001	
022	+1.641790E+001	+1.513542E+000	-2.713197E+000	+7.790399E-002	
023	+1.716417E+001	+2.802378E+000	-4.352711E-001	+7.111292E-002	
024	+1.791044E+001	-1.880110E+000	-2.564454E-001	+4.758074E-002	
025	+1.865671E+001	-2.615665E+000	-5.936437E-001	+6.725647E-002	
026	+1.940298E+001	-1.053929E+000	-4.009460E+000	+1.039535E-001	
027	+2.014925E+001	-7.929094E-001	-2.299102E+000	+6.098276E-002	
028	+2.089552E+001	+9.443503E-001	-1.942458E-001	+2.417555E-002	
029	+2.164179E+001	-1.515900E+000	-6.579629E-001	+4.143770E-002	
030	+2.238805E+001	-2.966858E+000	+4.402773E-001	+7.520944E-002	
031	+2.313432E+001	-1.550366E+000	-1.446582E+000	+5.317039E-002	
032	+2.388059E+001	-2.331101E+000	-1.586531E+000	+7.070650E-002	
033	+2.462686E+001	-6.739224E-001	+2.730496E-001	+1.823311E-002	

Figure 3-29

Typical output from "FOURIER1", sample interval equal 20,000 microseconds

3.4.3.7 PROGRAM DATAM

This program was written to retrieve one channel of data from a single test and display it in a convenient format. After specifying a particular piece of data, the program finds the information from a data tape mounted on Unit 1. A trace from a pressure transducer is shown in Figure 3-30 with coordinate system.

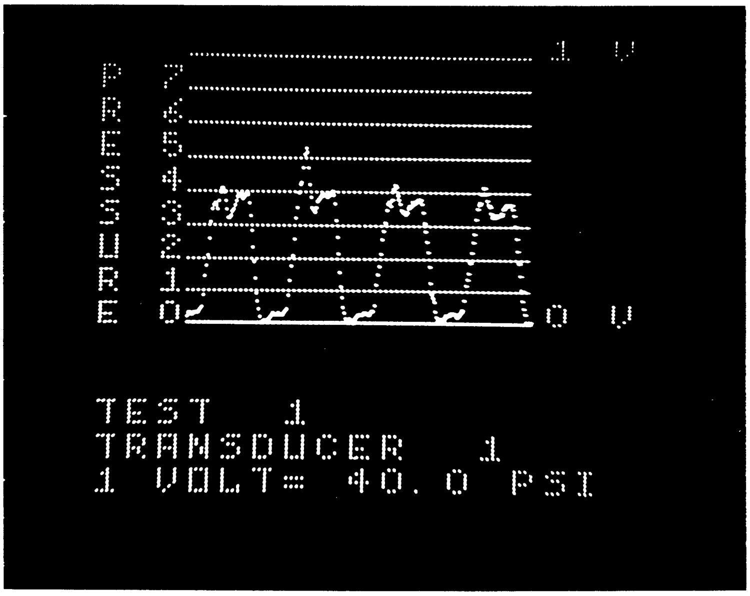


Figure 3-30

Typical pressure data recalled by program "DATAM"

The display can be shown as in the figure or without the vertical graduations and scale, test number, transducer number and scale factor. The vertical numbering of the pressure ordinate on the left side refers to the gray scale values represented in the program "P-CALC". The ordinate on the right side refers to voltage level, from 0 to 1 volt. The test number and transducer number are automatically calculated and displayed by the program. The test number refers to the sequential test referenced and the transducer number to the pressure transducer represented.

Since the full scale pressure value is dependent upon the hardware during acquisition, this number is typed in during the display.

3.4.3.8 LSD

"LSD" is a two-dimensional display program utilizing the Tektronix 564 memory oscilloscope. The program displays a set of pressure values in one spatial coordinate from a rectilinear array of pressure transducers. The curve fitting routine expands five pressure points from discrete values to a complex curve. The program computes on data gathered by the sample program described in section 3.4.3.1. The program retrieves five instantaneous pressure values and fits them to a mathematic relationship. The relationship chosen was a truncated polynomial power series:

$$P(X) = A_0+A_1X+A_2+X^2+A_3X^3+A_4X^4$$

where A_0, A_1, A_2, A_3, and A_4 are parametric functions of time.

The program solves the equation for the A_n parameters from the five discrete equally spaced transducers. It then divides the X axis into 100 equal increments and interpolates the value at each point and displays the resulting curve.

At any time the user can specify test number, frame number, or stop the display temporarily. Its control is very similar to "P-CALC". Program interrupts, indicating bad results or poorly formatted data, are the same as in "P-CALC".

3.4.3.9

Related programs were developed to aid in formulating the experimental protocol, and adding versatility to the displays. These are discussed in detail in Ref. 1.

3.5 EXPERIMENTAL WORK

3.5.1 APPLICATION OF THE INSTRUMENTATION

The application of the pressure transducers to the stump was done after palpating the anatomical reference point and drawing the zones on the limb. In general, it was found that after insertion and removal of the prosthesis, the transducers did not move perceptibly on the skin. In rare instances, it was necessary to reapply the instruments, taking the data a second time.

When the subject had a thigh corset attached to the prosthesis, it was necessary to cut a hole in the stump sock just above the brim of the prosthesis and feed the lead wires through this hole. It was done in this manner to avoid the problem of running the lead wires all the way up to the hip in order to mate with the harness connector.

The major pressure transducer application problem was encountered in the application of the transducer to a stump with redundant tissue. On such a stump, normally firm tissue degenerates to excess fat tissue which provides a considerable amount of relative movement between the tibia and the skin tissue. During the application of the array on this type of stump the transducers tend to pull loose from the taped position during insertion as a result of inelastic ribbon-cable. This condition was encountered on two subjects and testing had to be halted.

The hip and knee goniometers were applied in straightforward manner. The greatest concern was the alignment of goniometer axes with anatomical axes. With reference to anatomical landmarks the axis of rotation of the knee is located approximately 3/4 of an inch above the medial tibial plateau edge on an extension of the posterior edge of the tibia.[12] The hip axis was found anterior to the greater trochanter.[13] In both the above cases, having the subject flex the hip and knee joint and observing the alignment of goniometer axis relative to the anatomy, as well as checking the straps for tightening or loosening during flexion, revealed deviations and led to more precise axis alignment.

The three foot switches were attached to the heel and sole of the shoe with skin tape. The heel and toe switches were taped at the extreme ends of the shoe and the intermediate switch located approximately at the ball of the foot. Since all three of these switches provided only relative gait signals, positioning did not need to be exact.

3.5.2 DATA COLLECTION

In general, experimental work took between two and three hours for an individual patient. It was found that the method of application of the transducers to the stump consumed most of the time during data acquisition. When the method of encapsulating the transducers as a fixed array was developed, it reduced the application time sufficiently and allowed gathering of three to four times the amount of data previously taken in one experimental session. During the early work at least eight zones were measured so that an integrated pressure area could be assembled. The majority of data gathered was from the kick point zones and on one subject a complete mapping of the patellar tendon region was done. For the mapping work six subjects formed the basis final data, and six other subjects were used to establish experimental techniques. On a later study, pointed toward evaluation of liner materials[14] 26 subjects were measured at four critical stump areas.

3.5.3 PRESSURE MAPPING ON AN AREA

With the aid of program "P-CALC" and the program "LEGDIS", a reconstruction of a 1/2 inch by 1/2 inch area can be accomplished and correlated with gait information. This type of computer generated information is shown in Figure 3-31 and indicates the presence and form of the pressure profile occurring during a fraction of the walking cycle. The pressure display information is viewed from left to right, top to bottom, with the reconstruction of the stick figure and pressure manometers directly beneath each frame. For purposes of comparison, each gray-scale represents a range of 5 PSI.

The first frame indicates only a small pressure ridge [5-10 psig] extending from transducer P4 to P3, while the second frame indicates that a uniform pressure distribution has built up. The individual frames of the display indicate that a pressure wave entered from the bottom of the test area and traveled approximately halfway across the

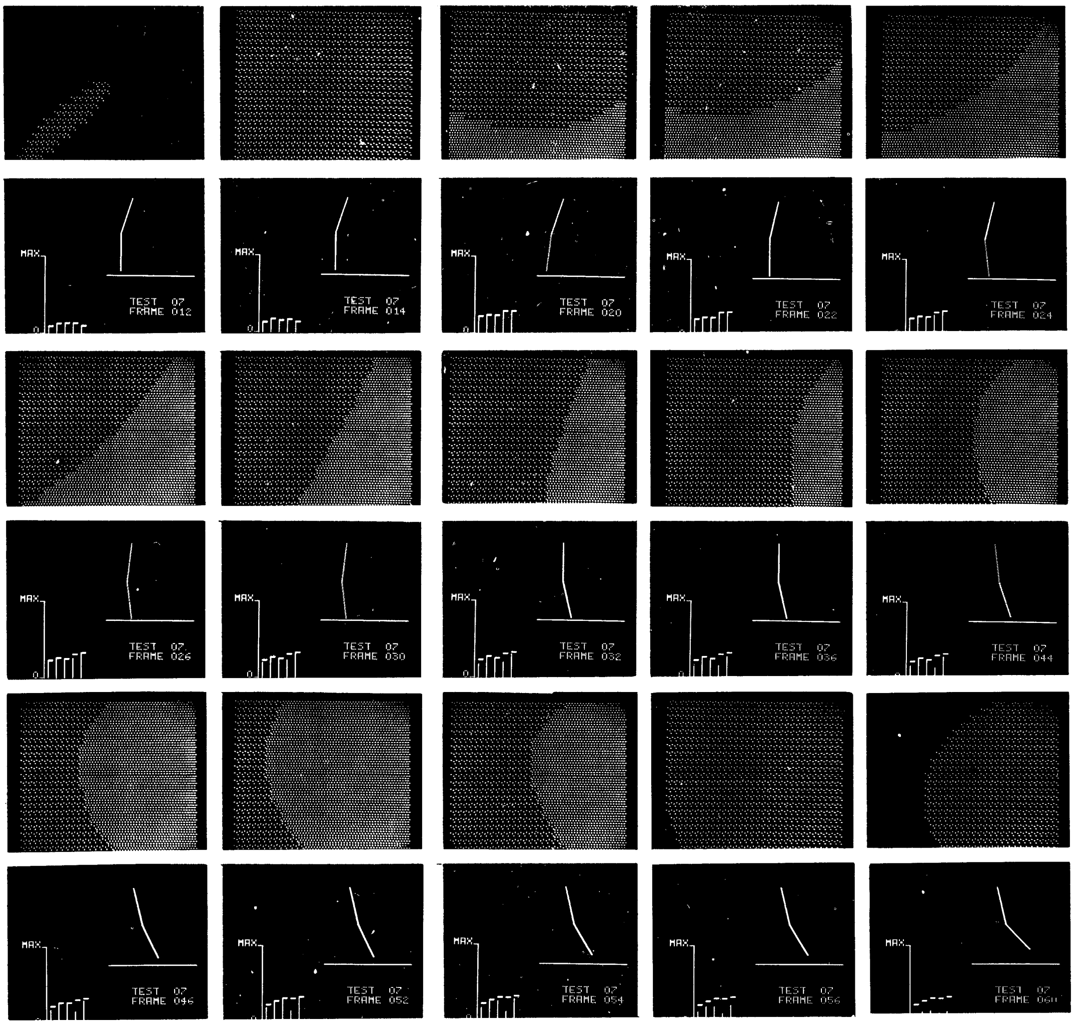


Figure 3-31

Composite showing the correlated output from program "P-CALC" and program "LEGDIS". Gray scale shows 5 psig per level, 40 psig full scale (Patient No. 10) test area and then altered directions and moved off to the right-hand side of the display until it eventually disappeared.

This test was run on kick-point Zone D on a left below-knee amputee and shows that the pressure started on the distal end of the stump building toward the kick-point and relieved by moving toward the lateral side of the socket. The highest pressure attained was 10-15 psig.

In viewing only the stick figure construction, the fixed amount of flexion built in the prosthesis appears quite vividly.

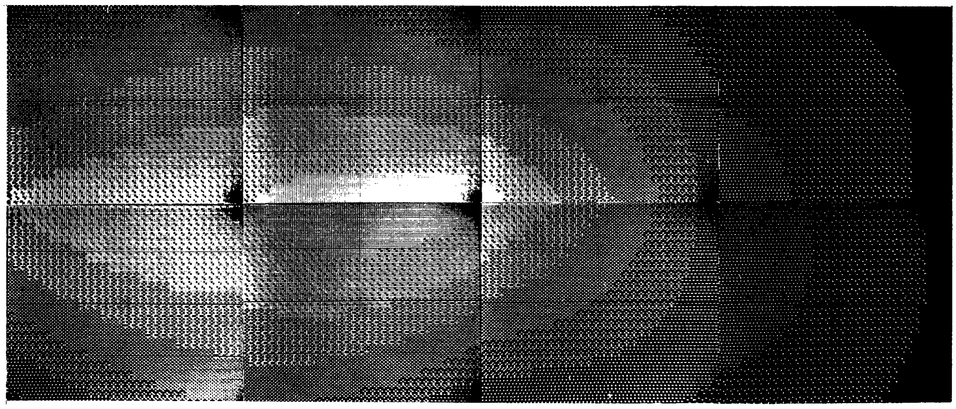
When data are acquired from adjacent areas on the anatomy, the results of individual transducer arrays can be placed side-by-side to reconstruct a larger area. In order to demonstrate this principle, a demonstration version of the program "P-CALC" was used to reconstruct a hypothetical pressure region. In Figure 3-32a the pressure specifications and resulting pressure are shown. In the upper portion, octal pressure specifications (400 octal=40 PSI) were entered for each individual area. In the upper left corner, the array consisted of five pressure values, P1 having a value of 100, P2 a value of 200, P3 a value of 250, P4 a value of 310, and P5 a value of 340. The resulting pressure display is shown in the upper left-hand corner of Figure 3-32b. When eight adjacent areas were calculated and placed side by side, the area reconstruction shown in Figure 3-32b was produced. The results show an adequate representation of the hypothetical profile. Note that concurrent points show identical pressure readings.

Reconstruction of Pressure Profiles Using Patient Data.

In using actual patient data several problems were encountered, all relative to mismatching of instantaneous pressure values at adjacent sites of the transducer array during the mapping process. Specifically:

1. Successive pressure zones were recorded during different steps (separated by as long as 15 minutes). Accordingly all the difficulties of matching non-identical studies

a



b

Figure 3-32

Hypothetical reconstruction of an area of pressure
(a) Octal values chosen for the individual arrays
(b) Resulting region mapping

were encountered. That is, data taken each 20 milliseconds on one stride do not match with consecutive 20 millisecond intervals on the next stride.

2. The exact location of the stump in the socket varies slightly each time the limb is put on.
3. Transducer arrays move slightly in use.
4. Individual transducer zero-pressure values drift slightly.
5. Individual transducer calibrations are not exact.
6. Other factors, yet unknown.

Typical difficulties are shown, using the DATAM display, in Figure 3-33, where each group of 4 displays shows data from a single point on the stump. Ideally the time history, even taken on separate steps, would be identical. The peaks however vary by as much as a factor of three. The relative importance of the 6 "mismatching" problems listed above have not been satisfactorily delineated at the time of this writing. The transducer calibration and zero drift problems are probably least important. Since the transducers are significantly sensitive to bending, and because the diaphragm does not receive a true pressure but rather discreet forces in contact with the irregular anatomy these may be primary factors and would fall into the "yet unknown" listing above.

These and other aspects of the matching problem are discussed in considerable detail in Chapter V ref. 3.8-1.

3.5.4 LINEAR PRESSURE MAPPING

This program computes on a linear array of transducers spaced one-half inch apart. Figure 3-34(a) shows the pressure traces obtained from program "DATAM" for a linear array of transducers. For the linear array, data was acquired from the anterior crest of the tibia. The array ran from a position 1/2 inch on the +X axis up and parallel to the +Y axis. Transducer P5 located at the X = 1/2, Y = 0 position. Figure 3-34(b) shows a parametric representation in time of the pressure curves. Nine curves are displayed on each photograph and the photographs continue from left to right, top to bottom, presenting the pressure wave measured

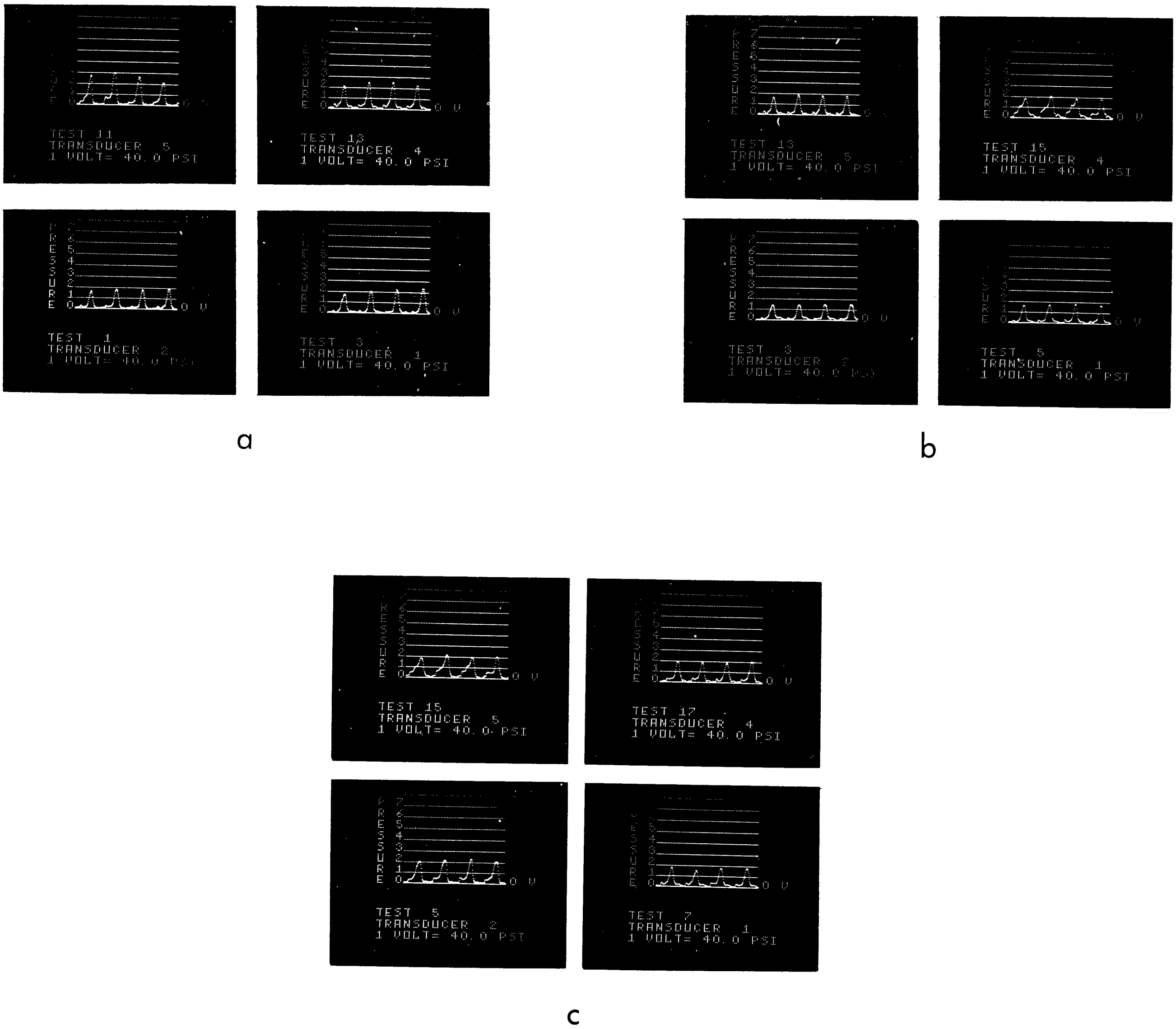
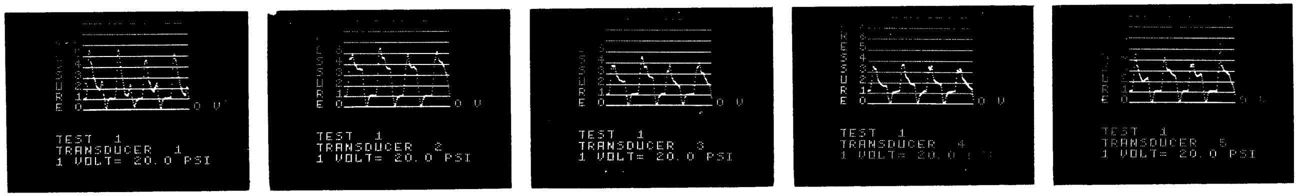
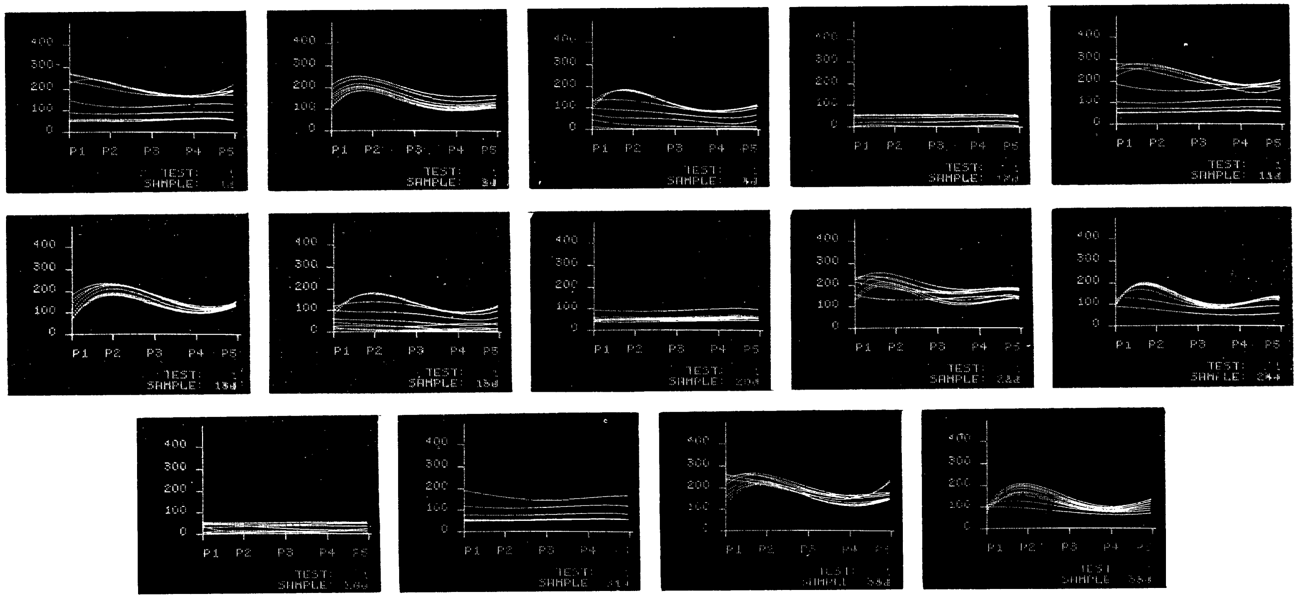


Figure 3-33

Pressure curves at the major intersection points (original data) reproduced by program "DATAM" (Patient No. 10)



a



b

Figure 3-34

(a) "Rezeroed pressure curves from the linear array

(b) Parametric representation of pressure distribution calculated by program "LSD", 20 psig full scale by transducers P1 through P5 as a continuous function of time from the first photograph to the last. In this instance, every other data point was used to construct the graphs. That is to say, 126 curves are shown in the fourteen pictures.

It might be noted that the maximum pressure values of 15 pounds per square inch occur 1/2 inch laterally and 2 inches proximally from the kick point for this setting of the linear array of gages. Since this region has not yet been scanned no conclusions can be drawn that this represents the optimal pressure value.

3.5.5 PRESSURE MAGNITUDES AT THE INTERFACE

In order to view the aggregate of data and disclose the range of pressures at the kick point and patelllar regions, the results were studied using program "SM-SA". (Figure 3-35). It might be anticipated that the pressure would have a nonzero value during swing phase in some regions. This did not occur. The tissue was subjected to zero or nearly zero pressure while the subject was seated, and the same was true during most of the swing phase. Since the pressure at a point is represented by a curve going from zero to some maximum value and returning, the data plotted on these graphs exhibit linear characteristics. In a plot of this type the maximum stress of pressure is the sum of the abscissa value plus the ordinate value.

In Figure 3-35 (a), (b), (c), (d), the data were acquired from the kick point region. The higher values were obtained on a prosthesis with a cuff suspension for a diabetic subject. This means that the subject had much less sensitivity at the distal end of the stump than a subject traumatically amputated. The lower value pressures shown in the (c) and (d) portions of this figure were obtained from subjects having very good skin sensitivity.

Figure 3-35 shows results of data acquired from the patellar region. These results show pressure values ranging to forty psig.

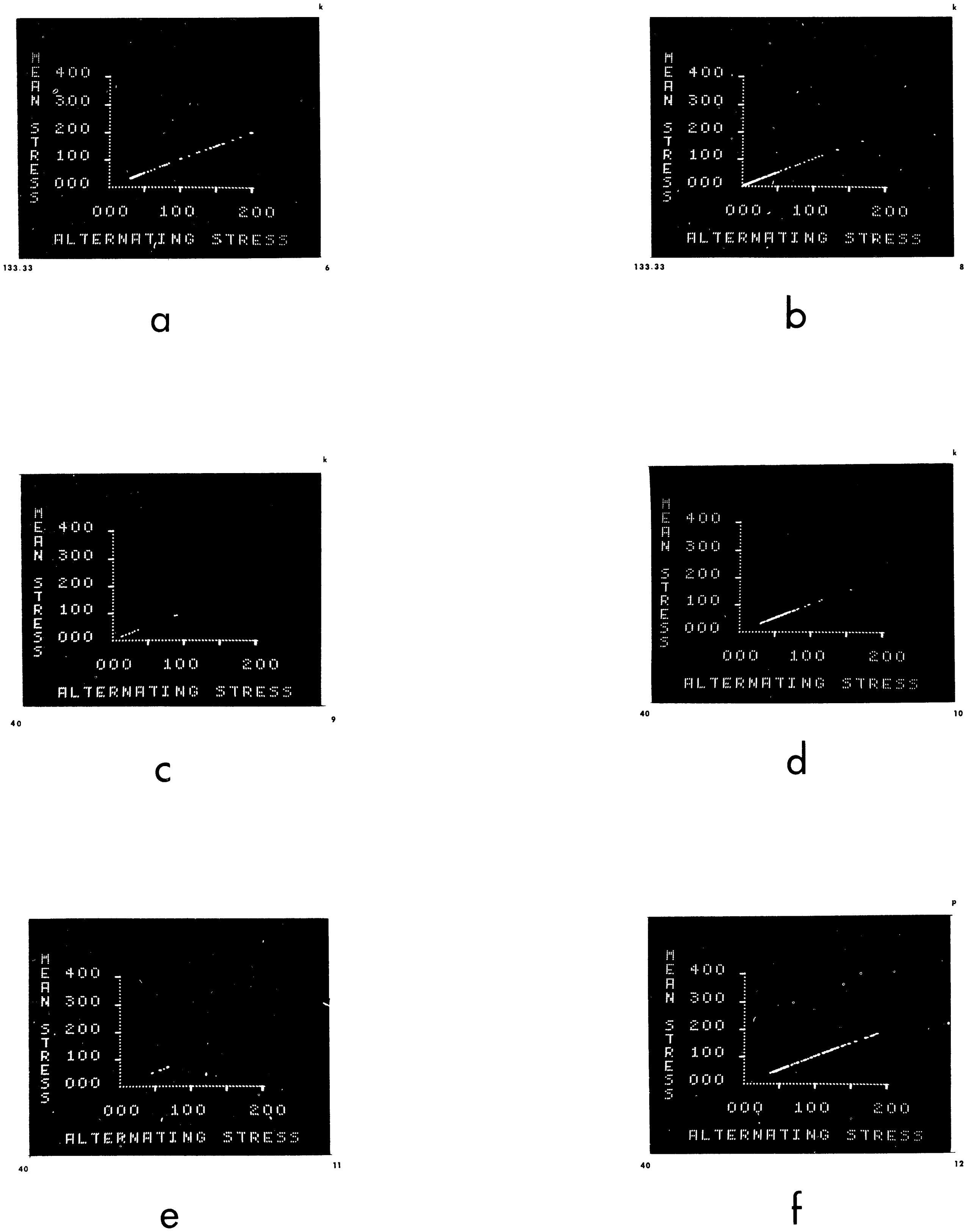


Figure 3-35

Mean stress-alternating stress representation
of all the data acquired

Full Scale Values: Abscissa 20 PSIG
Ordinate 40 PSIG

Although it is tempting to believe that the skin tissue in a below-knee prosthesis is subjected to relatively uniform pressures, it is obvious from these wide variety of pressures occur within a patellar-tendon-bearing prosthesis and that relatively sharp pressure gradients do occur. It is also indicated that the highest pressure is not always in the patellar region. Other areas are sometimes subjected to pressure magnitudes equal to or greater than these.

3.5.6 PRESSURE SIGNAL SPECTRUM (0 - 25 Hz)

An investigation of the signal frequency content was undertaken in order to better understand the dynamics to which the tissue was being subjected. In this portion of the work, a single cycle of the pressure curve was subjected to a discrete Fourier analysis. A typical print-out of the results of this computation is shown in Figure 3-36.

Referring to this figure, the column on the extreme left lists the harmonic number starting with the dc component. The number of coefficients which can be recovered is a function of the number of data points in one cycle. For the sampling frequency chosen, the program averaged approximately thirty Fourier coefficients.

The data curve and results are illustrated in Figure 3-37 which shows the data curve and Figure 3-38 which shows a graph of the amplitude spectrum. In the latter graph, a large decay in the spectrum occurs around the 5 to 6 cycle level, but the higher harmonics do not go to zero.

One of the initial requirements for performing the frequency analysis is that the wave form examined be periodic. This requires that the repeatability of the signal be complete and that the value of the signal and its derivatives be in agreement at the interval extremities. The application of these criteria to these experimental data, the interval for which was defined by gait dynamics, would make the calculation impossible. When discontinuities in the signal and its derivatives occur at the interval extremities, higher order harmonics are introduced from the mathematics in its attempt to curve-fit the data, forcing the

BLOCK NO. 010 FOURIER1 PERIOD 101

P	FREQUENCY.C/S.	A.P.COS	B.P.SIN	N=NORM. AMPL.
000	+0.000000E+000	+8.329229E+001		
001	+7.692313E-001	+9.091224E+000	+4.090770E+001	+1.000000E+000 F
002	+1.538461E+000	+1.585434E+001	+8.100387E+000	+4.248546E-001
003	+2.307691E+000	+1.506445E+000	+1.657591E+001	+3.971828E-001
004	+3.076922E+000	+7.185354E+000	+6.757405E+000	+2.353774E-001
005	+3.846154E+000	-2.171210E+000	+4.400255E+000	+1.170907E-001
006	+4.615383E+000	+5.447136E+000	+4.283753E-001	+1.303867E-001
007	+5.384615E+000	+2.137228E+000	-3.674140E+000	+1.014308E-001
008	+6.153844E+000	+8.861164E+000	-1.131461E+000	+2.131715E-001
009	+6.923077E+000	+7.495172E+000	-3.358637E+000	+1.959944E-001
010	+7.692307E+000	+8.971680E+000	+2.509580E+000	+2.223100E-001
011	+8.461536E+000	+7.658037E+000	-3.277392E-001	+1.829117E-001
012	+9.230766E+000	+5.145286E+000	+3.458269E+000	+1.479388E-001
013	+1.000000E+001	+5.138456E+000	+2.582305E-001	+1.227741E-001
014	+1.076923E+001	+2.201272E+000	+1.754299E+000	+6.717017E-002
015	+1.153846E+001	+4.364347E+000	+9.987283E-002	+1.041740E-001
016	+1.230768E+001	+1.318750E+000	+7.880244E-001	+3.665982E-002
017	+1.307691E+001	+3.022965E+000	+1.634795E+000	+8.201021E-002
018	+1.384615E+001	-7.210539E-001	+1.136145E+000	+3.211111E-002
019	+1.461538E+001	-6.619972E-001	+2.158286E+000	+5.387164E-002
020	+1.538461E+001	-3.571692E+000	-6.853668E-001	+8.678664E-002
021	+1.615384E+001	-4.048837E+000	-2.807292E-001	+9.684982E-002
022	+1.692307E+001	-4.080831E+000	-4.101646E+000	+1.380695E-001
023	+1.769230E+001	-3.868089E+000	-3.238664E+000	+1.203869E-001
024	+1.846153E+001	-2.075191E+000	-5.233238E+000	+1.343413E-001
025	+1.923076E+001	-2.726121E+000	-3.736252E+000	+1.103685E-001
026	+2.000000E+001	-7.069002E-001	-4.411924E+000	+1.066250E-001
027	+2.076922E+001	-2.462131E+000	-3.786575E+000	+1.077815E-001
028	+2.153846E+001	-4.837142E-001	-3.796794E+000	+9.133561E-002
029	+2.230768E+001	-1.252118E+000	-4.501240E+000	+1.114918E-001
030	+2.307691E+001	+1.088577E+000	-2.906575E+000	+7.406479E-002
031	+2.384615E+001	+1.282542E+000	-3.457605E+000	+8.800264E-002
032	+2.461537E+001	+2.422847E+000	-8.181379E-002	+5.784960E-002

Figure 3-36

Representative Fourier analysis of pressure data obtained from "FOURIER1"

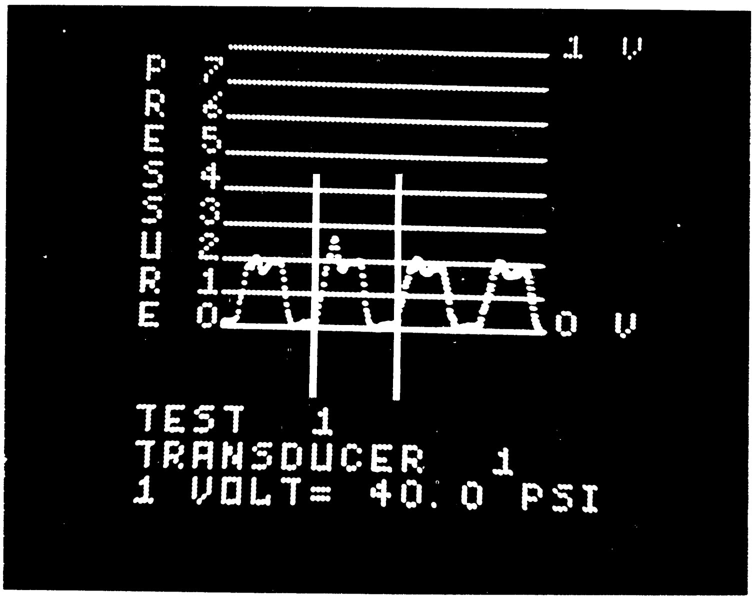


Figure 3-37

Pressure curve from which Fourier analysis

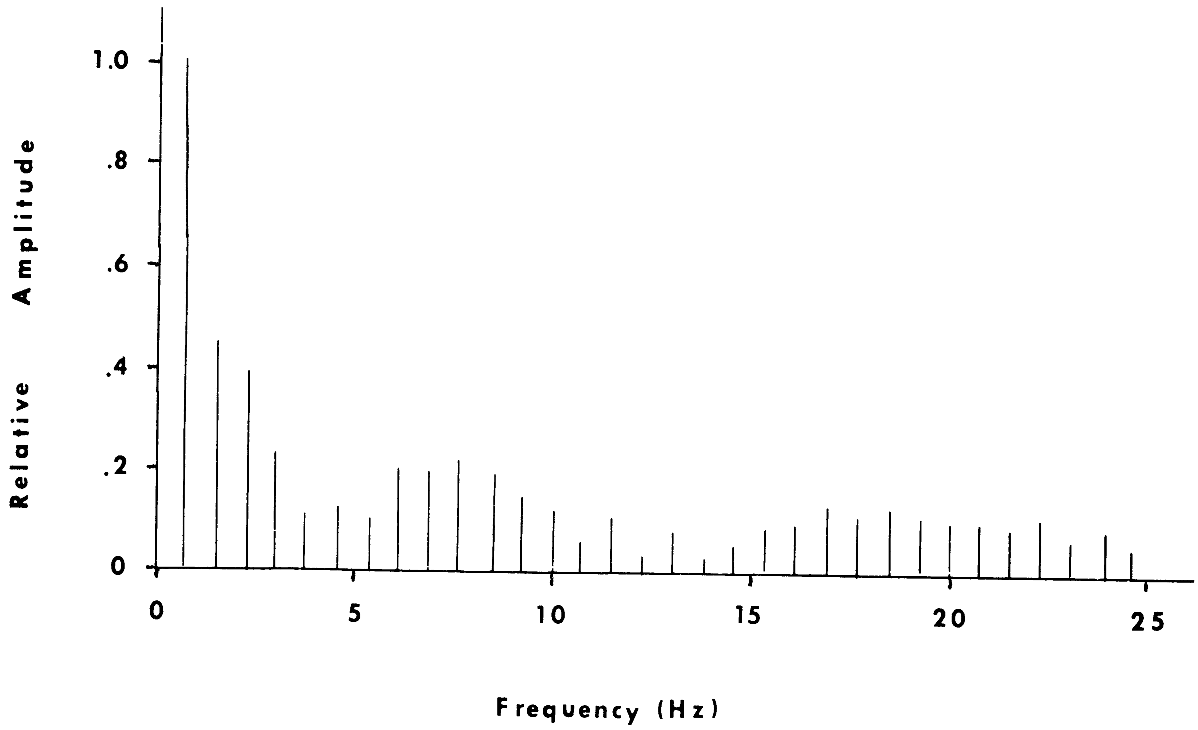


Figure 3-38

Amplitude spectrum of results obtained from
Figure 3-36

experimenter to correct for this in either the preparation or interpretation of the data.

A thorough study would include higher sampling rates and more samples per interval. It would also be assisted by a highly repeatable signal which may or may not be experimentally possible.

3.5.7 FOOT-SWITCH RESULTS

A study was undertaken to examine the pattern that the foot-switches produced during the experimentation period. The foot-switch patterns were compared within an individual test which constituted approximately four cycles, as well as between tests. Comparison of foot-switch traces within an individual test should evaluate the repeatability of foot contact with the floor during approximately five seconds of gait. The comparison of foot-switch traces between tests should evaluate foot contact with the floor after reapplication of the prosthesis.

It has been shown that the pressure traces at a point are repeatable within a test but not reproducible from one test to the next. It can also be stated that the foot-switch traces exhibit the same characteristics. Examinations of printed listings of the data showed that in some instances the subject did not close the foot-switches in the same manner more than half the time. In some instances it was found that the subject did repeat a foot-switch closure pattern a substantial part of the time. Primarily the difference was found to exist at the intermediate and toe foot-switches. Sometimes the subject would conclude a step with the intermediate foot-switch closed and sometimes with only the toe foot-switch closed.

At heel contact, distal pressure is generated and the resulting pressure wave moves up and around the kick-point area. Therefore transducer positioning must be specified before peak values of pressure at a point can be correlated with foot-switch closure.

In general, the foot-switch pattern consisted of two or three levels which resulted from individual closures of the heel, intermediate, and toe switches. Simultaneous closure of two foot-switches was rare.

The original intent of the foot-switches was to correlate pressure and time curves. Since the general form of the pressure curves exhibit fourth or fifth order power series behavior, a more sophisticated foot-switch timing device is needed.

Alterations in the mechanical construction of the foot-switches as well as electrical signal treatment of their output would improve them. They should be run through a summing transistor or an operational amplifier rather than the resistive network employed so that better voltage increments can be chosen.

In fact, placing one foot-switch on the opposite limb to provide a gaiting signal during swing phase of the leg being tested would facilitate the Fourier analysis. In a large percentage of cases the pressure generated during swing phase is very small and discontinuities in the pressure signal at the extremities of the cycle interval would be minimized. The Fourier analysis would improve by eliminating spurious frequency content.

3.5.8 SUMMARY

The University of Michigan pressure interface equipment has been developed as a research tool for studies on tissue-adaptive device interfaces. This project was conceived as an essential step in the basic understanding of below-knee prosthetics. The hardware was designed to obtain pressure information to two distinct groups of staff members:

1. The physicians who prescribe prostheses and the prosthetists who fabricate them.
2. The engineers who approach the problem from an analytic standpoint and desire quantitative information.

During research, two purposes were proposed and accomplished:

1. A hardware-software system was designed and developed as a research device for studying the basic interface.
2. Preliminary research was conducted with clinical subjects and information obtained on the below-knee prosthesis.

The University of Michigan interface pressure research equipment has been designed around three subsystems:

1. A miniature pressure transducer which was developed in cooperation with the Kulite Semiconductor Products, Inc. It is durable enough for insertion at the prosthesis limb interface and sensitive enough to obviate expensive electronics.

2. A commercially available signal amplification and data recording system. The introduction of the digital computer into the field of physical medicine and rehabilitation is not limited to this individual study. It represents a new dimension to the research activities within this area and offers a potential for daily clinical activity.

3. The specific software necessary to gather, store, and display meaningful results. This part of the research represents the most flexible component and is limited only by the ingenuity of the researcher.

It has been demonstrated that analog type displays of digitized computer data can be reconstructed to appear in more meaningful representations than conventional strip chart recordings provide. These graphic representations of pertinent experimental data provide an effective means of communication between the engineer and the medical staff.

It has also been demonstrated that a graphic representation of pressure in an area can be reconstructed to provide a conceptual as well as analytic representation of a pressure profile. This area reconstruction has a gray-scale representation adequate for good recognition. Furthermore, it has been shown that these individual areas can be placed side-by-side to reconstruct larger regions of pressure.

The results of the experimental work in the reconstruction of larger pressure regions raises questions about a reproducibility of pressure signals. In spite of the magnitude of the differences in pressure traces conceptual results were shown. Non-reproducibility is probably the result of four major factors:

1. Repetitive application of the prosthesis, resulting in different alignments of the prosthesis to the bone-tissue composite, or juxtaposition of the soft tissue in relation to the prosthesis shell.

2. The type of suspension system used, which may or may not be controlled by the patient himself. Although the patient apparently has little effect on pressure distribution with cuff suspension adjustment, he may have significant influence on pressure by the manner in which he puts on a thigh corset.

3. Stump sock positioning and composition can change with application or time.

4. Individual variations in gait.

It has also been shown that the computer provides indispensable aid in its ability to scale data. This removes a heavy burden from the hardware specifications and experimental procedure common to straight analog recordings. That mapping and curve-fitting of pressure traces is a feasible means for examining data was also demonstrated.

Pressure magnitudes are probably not sufficient to categorize pressure interface measurements. The fact that absolute numbers do not show a coherence between patients indicates that the individual's pressure tolerance varies significantly.

The frequency investigation indicates that the tissue is not subjected to low frequency pressure components only, but that high frequency content is also present in the average below-knee prosthesis.

3.6 LINER STUDY

Reference 3.8 covers a study to determine whether different prosthesis liner materials contribute significantly to different peak pressures during normal walking for a person wearing a PTB prosthesis. Differences were observed and are presented in Figure 3-39. The study concerned the socket using no liner (hard); the conventional sponge material (Kemblo) and a new silicone gel liner being fabricated and tested at the University of Michigan Medical Center (Gel). The specific areas tested were the two condylar flairs (MTC, LTC), the patellar tendon region (PT) and the anterior distal region commonly referred to as kick-point (KP). Pressure values shown are the range (lines) of peak values during each step and the average (bars) of peak values.

3.7 HAND-HELD PRESSURE DEVICE

In order to make interface pressure measurements readily available to the prosthetist or clinician, a completely portable device has been designed and built. The unit shown in Figure 3-40 contains power and indicating circuitry for a single Kulite transducer. Full scale pressure readings of 10, 50, or 100 PSI can be selected. Provision is made for an independent standardizing signal of 10 PSI, and zero correction is readily made at the front panel. Through an external socket the output (0-1 V F.S.; into 500 ohms or greater) can be connected to a recording or display device or a computer. The self-contained cells provide about 15 hours of continuous operation when fully charged. At current prices the cost of the device is broken down into these estimates of components:

LPS - 200 transducer	\$325.00
Hardware	\$ 50.00
Assembly	\$100.00
	\$475.00

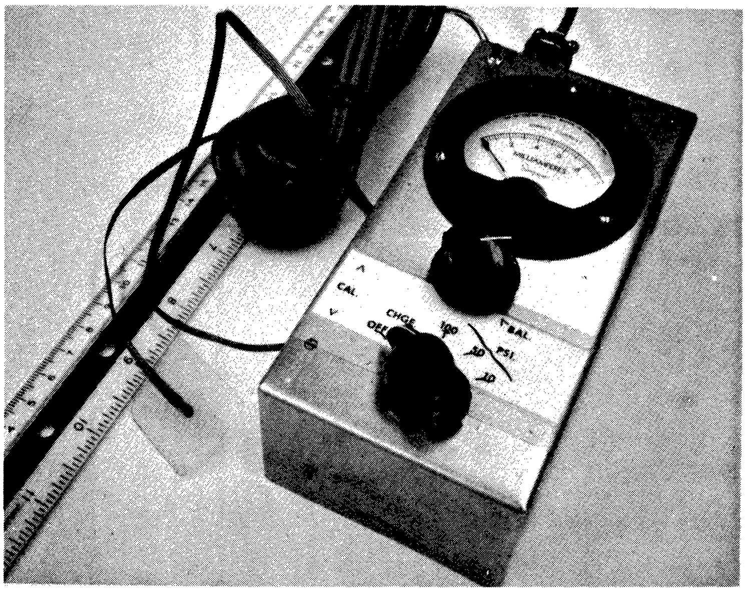


Figure 3-40

Hand Held Interface Pressure
Instrument

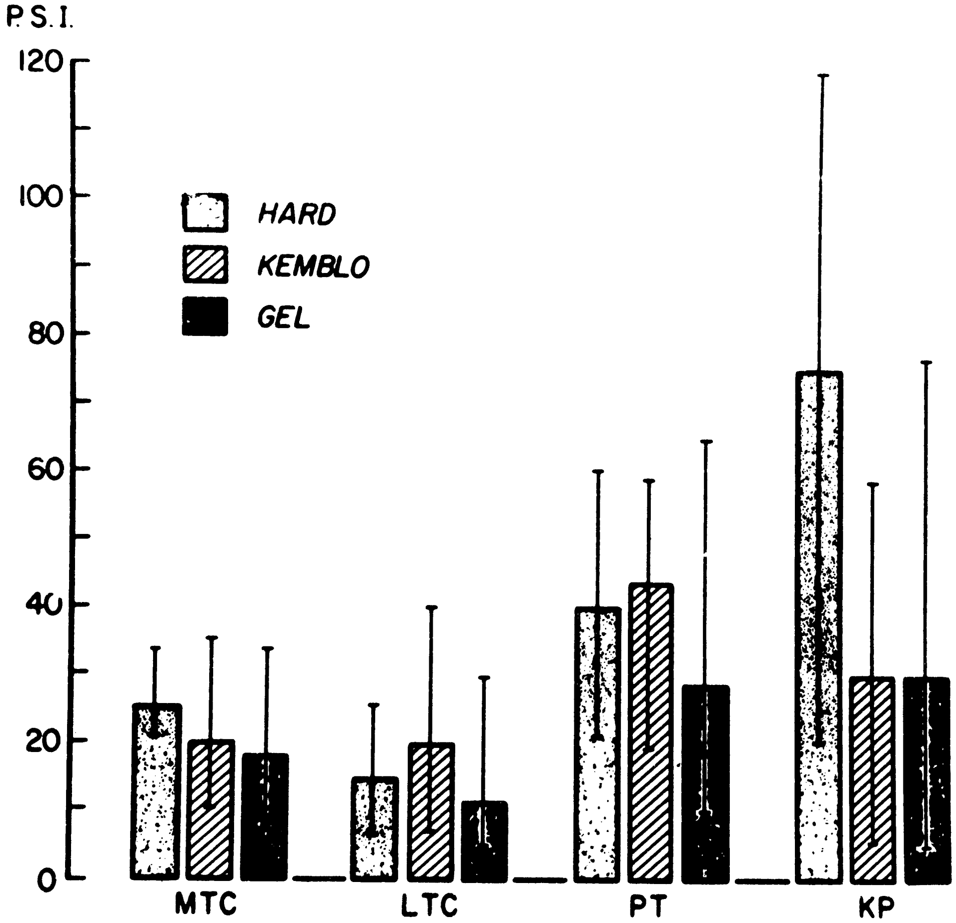


Figure 3-39
LINER COMPARISON FOR THE
AVERAGE OF PEAK PRESSURES
OBSERVED AT FOUR AREAS DURING WALKING

3.8 REFERENCES

1. Corell, E.B., "Normal Pressure Distributions Applied by Total Contact Below-Knee Prostheses," University of Michigan, Technical Report No. 9, Ann Arbor, May, 1969.

2. Radcliffe, C.W., Foort, J., "The Patellar-Tendon-Bearing Below-Knee Prosthesis," University of California, Berkeley; 1961.

3. Staff of Prosthetics Research Group, "Manual of Below Knee Prosthetics," University of California, Berkeley, November, 1959.

4. "Below-Knee Prosthetics," A Report of a Symposium Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering National Research Council, National Academy of Sciences, New York City, December, 1968.

5. Mueller, Hettinger, and Himmelman, "Pressure Distribution about the Brim and Surface of an Above Knee Socket in Walking," Orthopaedie-Tecknik, pp. 132-138: June, 1956.

6. Boni, G., "Socket Fit Studies: An Investigation of the Pressure Patterns Between Stump and Socket,: Biotechnology Laboratory Technical Note No. 25, University of California, Los Angeles; May, 1962.

7. Aronovitz, R., "An Instrument of Measure Contact Pressure on the Human Body," A Thesis Submitted to Case Institute of Technology in Partial Fulfillment of the Requirements for the Degree of Master of Science in Mechanical Engineering, 1962.

8. Aronovitz, R., Greenway, R., Lindan, O.L., Reswick, J., Scanlan, J., "A Pneumatic Cell Matrix to Measure the Distribution of Contact Pressure Over the Human Body," Proceedings, 16th Annual Conference on Engineering in Medicine and Biology, Baltimore; November, 1963.

9. Reswick, J.B., Lindan, O., Lippay, A., "A Device to Measure Pressure Distribution Between the Human Body and Various Supporting Surfaces," Case Institute of Technology and Highland View Hospital, Cleveland, Ohio; June, 1964.

10. Appoldt, F.A., Bennett, L., "Socket Pressure Studies", Preliminary Report, New York University, 1968.

11. Goertzel, G., "Fourier Analysis," From "Mathematical Methods for Digital Computers" Ralston, A., Wilf, H., John Wiley Anderson, New York, 1960.

12. New York University, Class Notes from Lower Extremity Orthotics for Orthotists, Course #749D, 1962.

13. Licht, S., "Orthotics," New Haven, Connecticut, 1966.

14. Sonck, W.A.; Cockrell, J.L.; and Koepke, G.H.; "Effect of Liner Materials on Interface Pressures in Below-Knee Prostheses", Archives of Physical Medicine & Rehabilitation; (to be published in December issue, 1970).

4.0 CLINICAL APPLICATIONS IN MYOELECTRIC CONTROL

4.1 SELECTION OF CONTROL SITES FOR MYOELECTRIC SWITCHES

4.1.1 BACKGROUND INFORMATION

Although research in myoelectric control appeared as a new field less than ten years ago,[Ref. 4-1] fundamental studies underlying the recent developments were under way in the early 1950's. Inman[Ref. 4-2] and his associates, for example, investigated the relationships between muscle tension and differences in surface electrical potential. They concluded that integrated electrical activity as demonstrated by electromyography does parallel tension in human muscle contracting isometrically. With respect to muscle length, their view was that no quantitative relationship existed between the electromyogram and tension when the muscle length was allowed to change. Later, however, Bigland and Lippold[Ref. 4-3] showed that when shortening or lengthening took place at a constant velocity, electrical activity remained directly proportional to tension. The problem of using these myoelectric currents in the control of externally powered devices was under investigation at about the same time, notably by Battye and his associates.[Ref. 4-4]

With the sudden acceleration in technologic developments after 1960, interest in this field became centered largely on the design of suitable mechanical devices and electrodes. In 1966 Scott[Ref. 4-5] reviewed the myoelectric systems then being tested around the world. One such control system, developed for below-elbow prostheses, incorporates control sites over forearm stump muscles which activate prehension of an artificial hand. Another system makes use of control sites over the trapezius muscle to activate an artificial hand or to initiate electrical stimulation of the extensor digitorum communis muscle to provide finger extension. The mode of control has also been considered; for example, a control site may provide on-off control of two functions-- a slight contraction of the muscle activating one function such as finger extension, and a stronger contraction activating finger flexion. A greater number of functions might be controlled by varying the combinations of muscles. If the concept of voluntary control of single motor units within a muscle can be expanded, then perhaps a coding system can be developed whereby each control function is represented by a distinct number of control motor units.[Ref. 4-6] Already accomplished is the implementation of proportional control, which enables the velocity and force of prehension to be controlled by the amount of contraction of the control muscle.

4.1.2 OBJECTIVES

The objective of this study is to provide measurements on which to base the choice of a control site for a myoelectric switch. By amplifying the potential differences produced at the control site, the myoelectric switch activates an orthotic or prosthetic device. This system is especially suitable for patients with severe quadriplegia who are unable to use manually operated devices but require something to facilitate prehension and hand positioning. A good control site must be an area where the patient can voluntarily generate sufficiently high potential differences by a simple muscle contraction and yet be able to keep the area relatively free from unwanted electrical activity generated during accessory movements of the body. In order to find such a site three problems must be investigated:

1. Which muscle provides the best sites?
2. Is there some predictable spatial pattern of electrical activity generated by the contraction of each muscle?
3. Is there some predictable spatial pattern of electrical activity generated during accessory movements of the body?

4.1.3 MATERIALS AND METHODS

Data recording - The Grass Polygraph is a writing oscillograph which can be used to record the EMG, EKG, and EEG. It is used in this problem to measure electrical potentials generated by muscel contraction. The simple EMG presents a recording of each individual electrical event, i.e. a change in potential for each firing of each motor unit. Since surface electrodes are used, the input consists of potentials from many motor units, i.e. many positive and negative deflections are all recorded, and the EMG has many sharp peaks and valleys. This waveform is difficult to analyze because it fluctuates so rapidly. The integrator circuit takes all negative deflections and makes them positive, and these are summed with the positive deflections or potentials. Thus the integrated EMG sums the positive and negative potentials and smooths the recording, making it useful for coupling with mechanical devices, because it is more precise and offers graded responses up to a maximum.

Electrodes - Ten Beckman biopotential electrodes were used to record the surface muscle potentials. The Grass Polygraph was equipped with six channels, each of which received input from any two of the ten electrodes, and which recorded the integrated EMG from the inputs of these two electrodes. A multiple channel selector attached to the Polygraph allowed the connection of any two of the ten electrode inputs to any of the integrator channels; hence, without changing the position of the electrodes the inputs to each channel could be altered, thus changing the site measured by a particular channel.

The integrated EMG is displayed as a deflection of the marking pen from the base line; the Polygraph is calibrated in such a manner that a 0.5 cm. deflection of the marking pen corresponded to an input potential of 100 μV.

Subjects - Subjects for this research were 13 men and 8 women from the staff personnel of the Physical Medicine Department. There was no preference in selection of subjects on the basis of sex, age, or any other criteria.

Mapping procedure - A grid showing x and y coordinates was drawn with a wax pencil on the skin overlying each muscle to be tested. Beckman biopotential surface electrodes were then taped at desired locations on the grid. A small amount of Beckman Offner Paste was applied to the electrodes in order to decrease skin resistance. The subject was asked to contract the test muscle and then to perform various motions and activities, such as turning the head or coughing. The potentials for several pairs of electrodes were simultaneously recorded. The electrodes were then moved to new locations, and more recordings were made.

Standard electrodes - When the potentials for several pairs of electrodes are recorded simultaneously it is clear that the values pertain to the same maximal contraction of the muscle. When a "maximal" contraction is repeated and recorded there is no guarantee that this maximal contraction is the same as the first. Therefore one pair of electrodes was kept in the same position and used as a reference in determining a maximal contraction. Thus the subject can adjust the force of contraction (either maximal or submaximal) to produce a given potential at the reference electrodes throughout all the trials, assuring a nearly constant degree of contraction for each individual test.

Proportional control - The newest myoelectric devices are designed to operate in such a manner that they reflect the degree of contraction of the muscle used as a trigger. They respond to a given amount of electrical activity produced by the muscle with a given degree of force of prehension. The device is adjusted to produce a maximal force when triggered by a maximal amount of electrical activity from the muscle trigger site, e.g. 600 μV. Therefore, if the muscle trigger produces only 300 μV, the hand will contract with only half the force. For any other submaximal electrical stimulus, the hand will move proportionally.

It was necessary to determine whether the subject could voluntarily produce various submaximal amounts of electrical activity by contracting his trigger muscle. He would need to produce these increments of electrical activity in order to control a proportionally responding myoelectric device. Included in the tests for each muscle was this test of proportional control. The subject was instructed to watch the recording pen as it registered the potential from the muscle he was contracting. He was to produce various amounts of electrical activity between the two reference electrodes; i.e., 100μV, 200 μV, 300 μV, 400 μV, etc., up to the maximum amount. The electrodes over the other areas of the muscle recorded the potential under these controlled conditions.

Most of the muscle sites could be controlled to produce increments of potential. At some of the sites the order of the 100 μV potential stimuli as recorded at the standard electrodes was reversed or altered, but this did not mean that this site could not be used to control a proportional switch. At some sites the recordings of these 100 μV increment stimuli were all compressed into a 50-100 μV range, and it would be difficult for the myoelectric device to discriminate between such fine gradations. Clearly this was a hard criterion to evaluate.

Grounding, Electrode Orientation, and Electrode Separation - Subjects were grounded with a 2-centimeter square plate on which EMG paste was applied to decrease skin resistance. The position for the ground varied for each muscle tested, but was constant for the series of tests with a particular muscle.

In preliminary tests, the exact electrode separation and orientation seemed to make little difference with regard to the amount of electrical activity recorded. These tests show that the largest (Fig.4-1) potentials were recorded for an 8 cm. separation, but the magnitudes when using a 4 cm. separation were also large, and the convenience of using a 4 cm. separation outweighed any slight gain in magnitude. For separations greater than 8 cm., there was an artifact in the recording that resulted from a superimposition of an EKG recording onto our EMG recording. Therefore, a horizontal orientation with a 4 cm. gap between electrodes was chosen.

4.1.4 MUSCLE MAPPING

The muscles chosen for the experimental work were trapezius, frontalis, and platysma. Each presented specific problems of coordinates and accessory movements. These are discussed serially below.

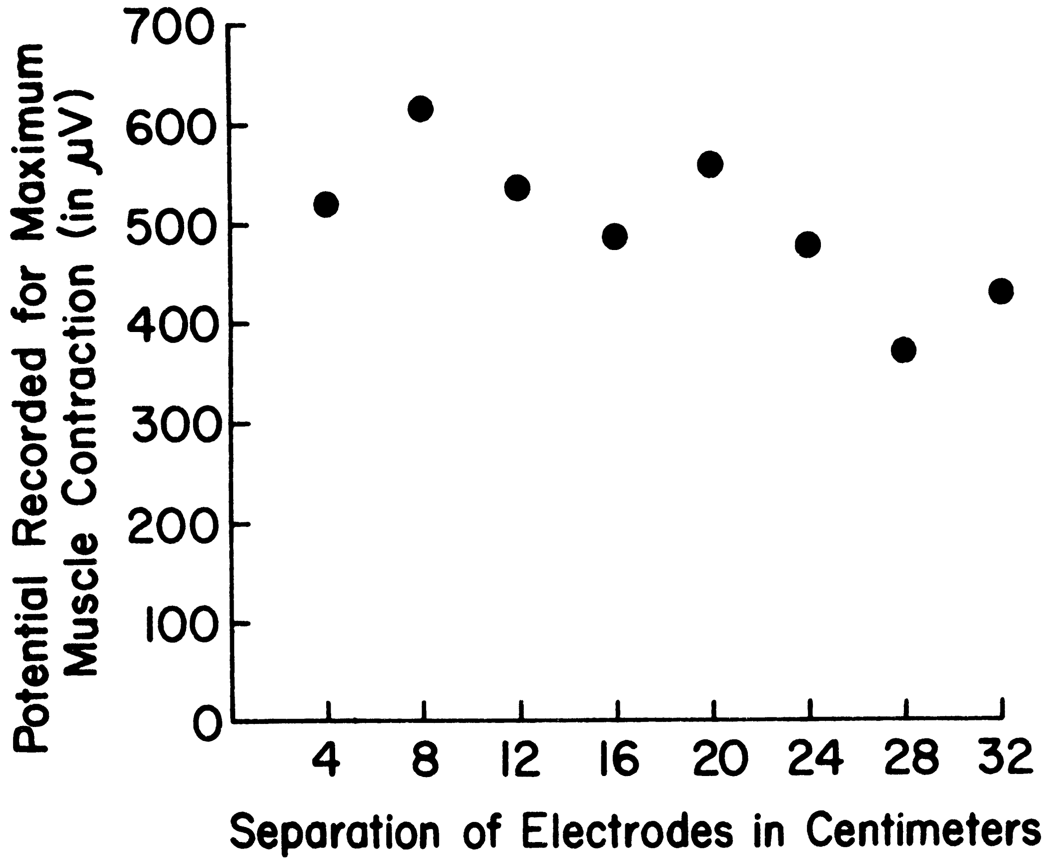

Potential Recorded for Maximum Muscle Contraction (in μV)
700
600
500
400
300
200
100
0
4
8
12
16
20
24
28
32
Separation of Electrodes in Centimeters

Figure 4-1

TRAPEZIUS PROCEDURE

The upper trapezius was selected for testing because a quadriplegic patient with a lesion below the 4th cervical vertebra would still retain trapezius function. Electrodes were placed on the skin over the upper trapezius (Figure 4-2) and a ground electrode was placed on the spine of the opposite scapula. The subject was seated in a wheelchair with his arm in an attached feeder device, which was

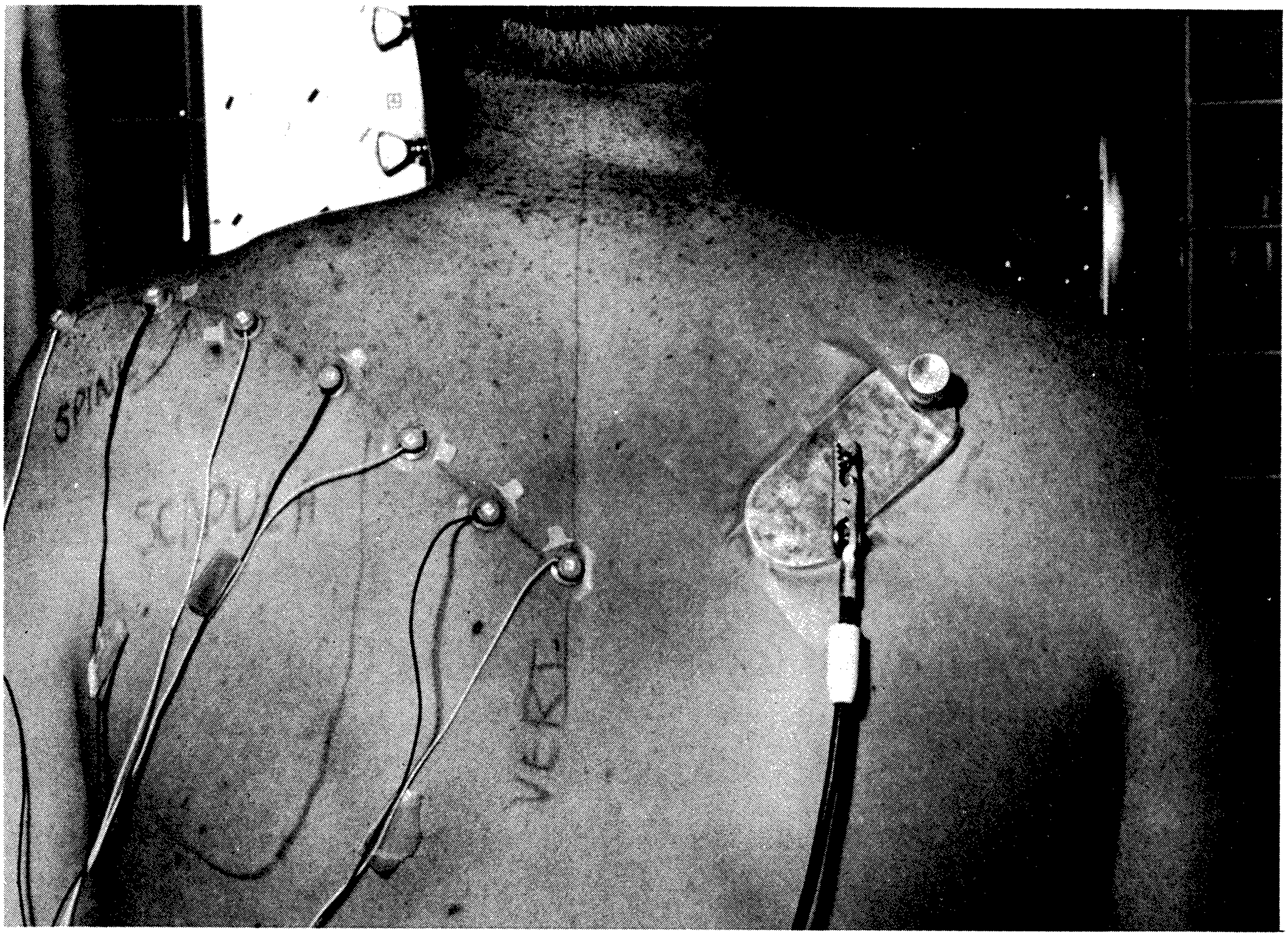


Figure 4-2

THE AXES FOR ORIENTATION OF THE ELECTRODES OVER THE TRAPEZIUS MUSCLE.

adjusted so as not to assist the required arm movements (see Figure 4-3). This experimental condition approximated the eventual clinical application, since the quadriplegic patient needing a myoelectric control for his hand orthosis is the type of patient who requires the assistance provided by a feeder device.

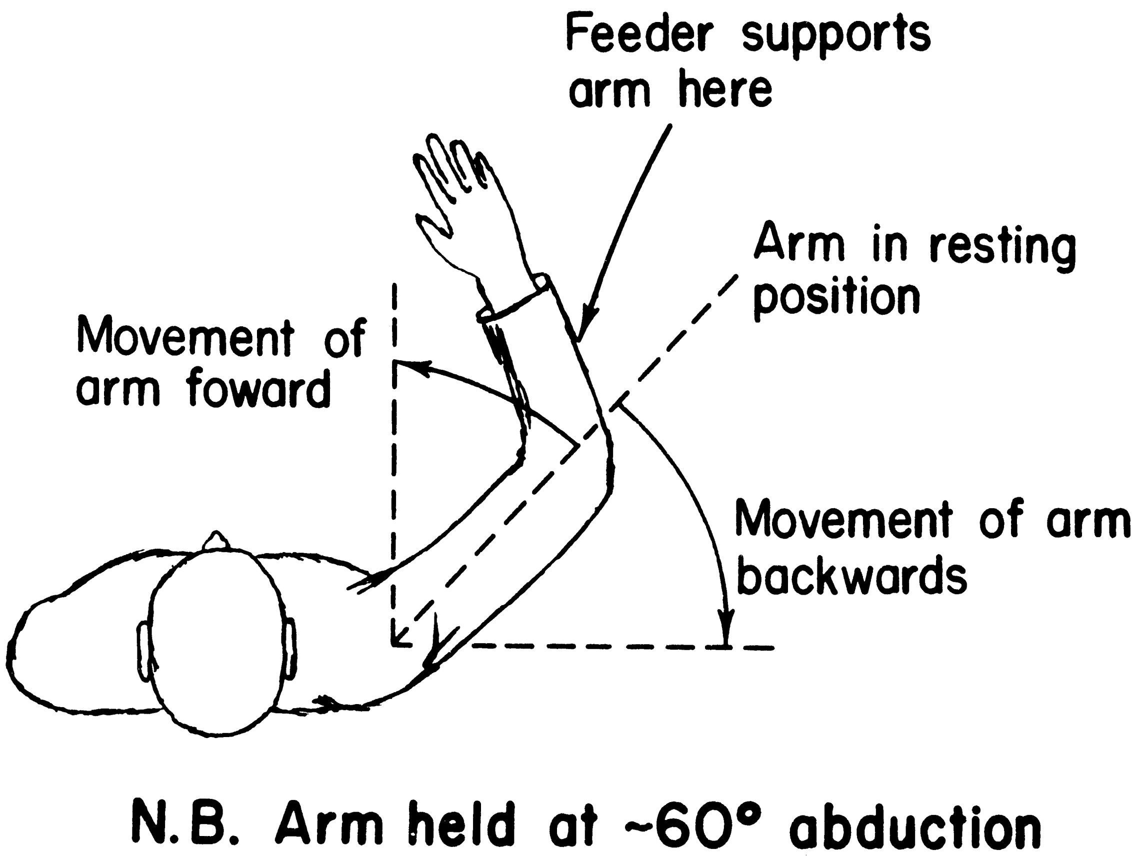


Figure 4-3

Since the upper trapezius acts to elevate and square the shoulders, these were the movements the subjects were instructed to perform - moving the shoulder up, moving it back, and a combination of the two. The accessory body movements investigated included arm, trunk, and head movements.

RESULTS (see Figure 4-4)

The recordings for the 5 subjects were widely divergent, making generalizations difficult. These variations were due to the great differences in muscle strength, size, and electrical activity, as well as to differences in the impedance between muscle and electrode because of changes in moisture, temperature and thickness of skin and connective tissue.

In general it was found that the least of potential was recorded for electrodes placed more than 8 cm. cephalad from the x axis.

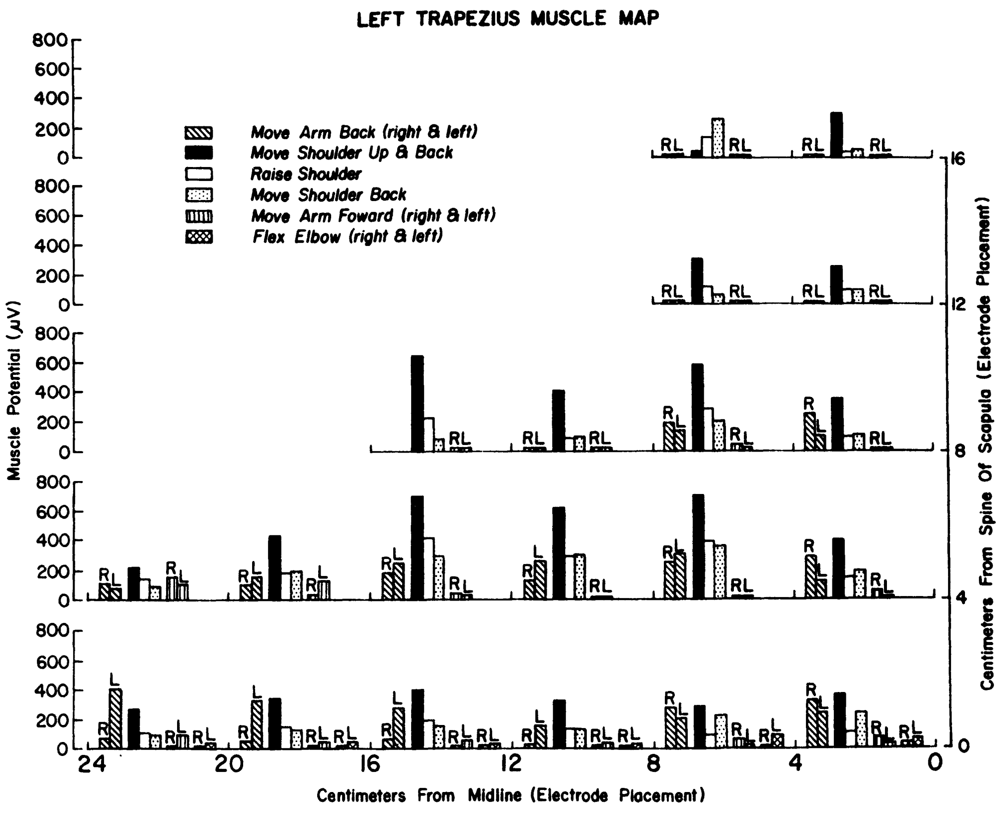


Figure 4-4

The movement of the shoulder up and back produced the largest and most adequate potentials for use in triggering a myoelectric device. These potentials recorded for the combined movement up and back were equal or greater than the sum of potentials for separate movements of the shoulder up or back. If necessary, either the movement up or the movement back could suffice.

Shoulder movements backward produced maximum potential at an area one third of the distance between the lateral and medial aspect of the muscle. The peak response for raising the shoulder occurred midway between the lateral and medial border.

Vigorous movements forward and back, as well as abduction of the arm, caused much undesired electrical activity, but a quadriplegic patient would not have the ability or the occasion to produce these movements, if his arm is supported by a splint.

Movements of the arm backward usually produced most activity near the lateral aspect of the ipsilateral trapezius. This could make this area unacceptable as far as unwanted electrical interference is concerned, if the orthetic device to be triggered by the trapezius is located on the same side as the myoelectric switch site. Hence, the overall number of good sites on the trapezius for a device worn on the same side of the body was 47% of those available, whereas 54% of the sites would be acceptable if the device were on the opposite side of the body from the motorized device. For many sites an inability to relax was demonstrated even though the subject was voluntarily relaxing. The head, trunk, and forward arm movements produced a maximum of less than 100 μV (the minimum needed to trigger the orthetic device), and would therefore not register or interfere with a myoelectric switch site.

Larger potentials were recorded for thin people, even larger than those measured on muscular people, probably because of the relative lack of adipose tissue which would impede electrical transmission from the muscle to the recording sites on the skin.

FRONTALIS PROCEDURE

The frontalis was mapped even though it was recognized that having electrodes taped to one's forehead would be cosmetically undesirable. These electrodes could perhaps be masked (for example by hair), or indwelling electrodes might some day be perfected.

The ground was placed on the back of the neck.

The frontalis acts to raise the brow, so the 9 subjects were instructed to do this. Closing the eyes tightly and clenching the jaw were actions producing electrical interference. See figure 4-5.

RESULTS (see Figure 4-6)

The magnitude of the potential produced by frontalis contraction increases toward the periphery of the muscle, as seen in the muscle map.

The rows nearest the eyebrow (y = 0 and y = 2) were eliminated from consideration, because the orbicularis oculi muscle used in eye-blinking produced too much electrical interference. The potential from closing the eye is greatest not only in the lower aspects of the frontalis (nearer to the orbicularis occuli) but at the periphery. Potential from clenching the jaw is greatest at the periphery because of proximity to the temporalis.

Although the central sites were more free of interference, they also produced the smallest desired potentials. Therefore, as a compromise the best sites were judged to be generally half way between the midline and the lateral edge of the muscle. Of all the sites tested, almost half (48%) were acceptable.

PLATYSMA PROCEDURE

The platysma muscle draws the corner of the mouth downward and widens the aperture. Activities performed by the 5 subjects included simple contraction of the muscle, smiling, clenching the teeth, chewing, swallowing, and head-turning. Activities such as talking, opening and closing the mouth, frowning, raising the eyebrows, and tilting the head

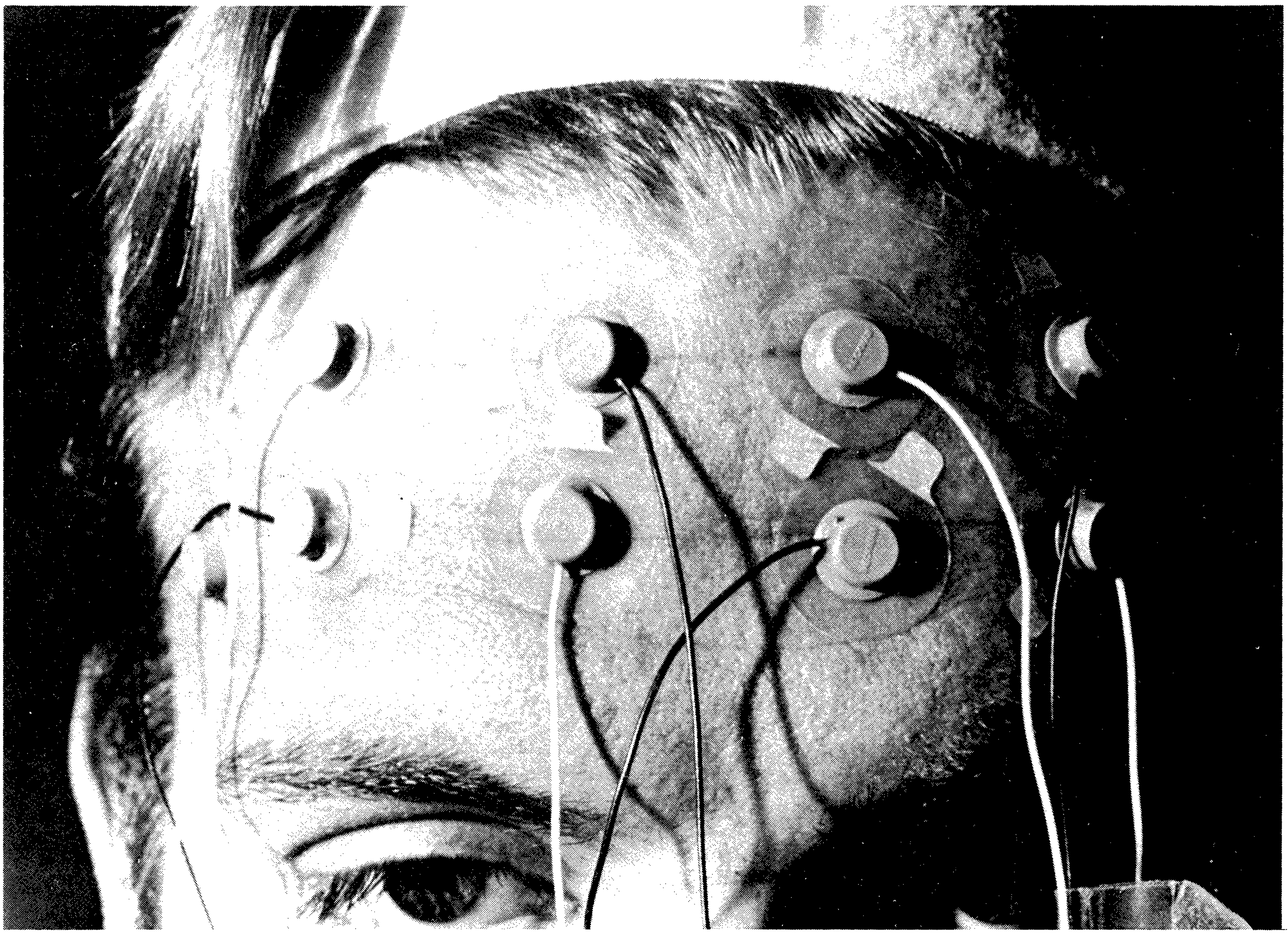


Figure 4-5

THE AXES FOR ORIENTATION OF THE ELECTRODES OVER THE FRONTALIS MUSCLE

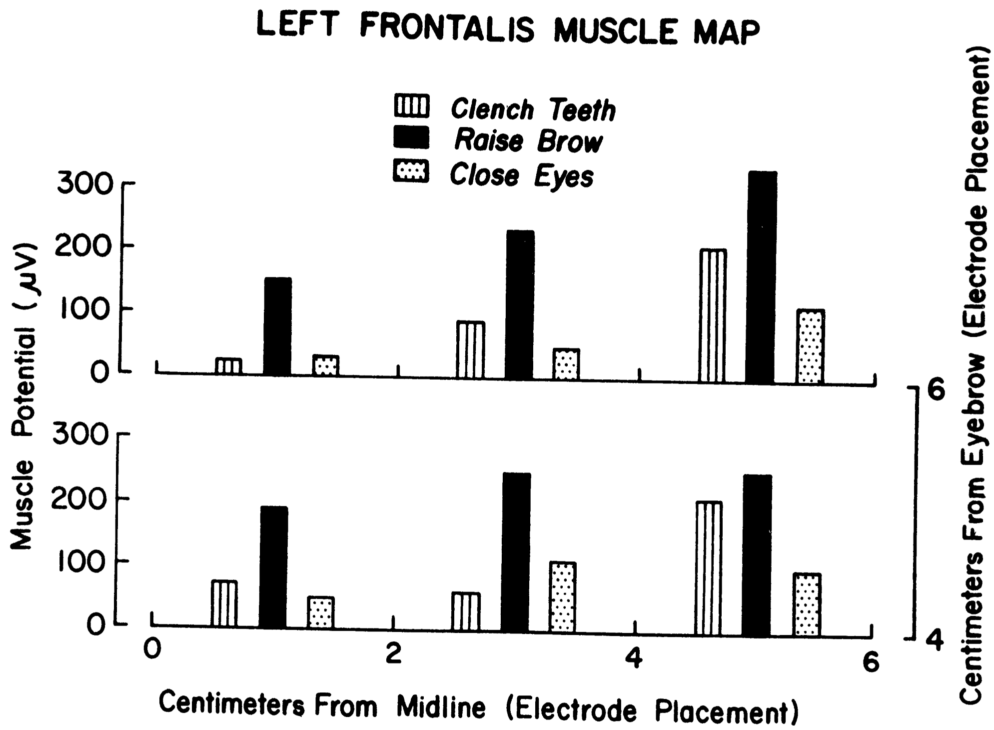

LEFT FRONTALIS MUSCLE MAP
Clench Teeth
Raise Brow
Close Eyes
300
200
100
0
300
200
100
0
Muscle Potential (μV)
0
2
4
6
Centimeters From Midline (Electrode Placement)
6
4
Centimeters From Eyebrow (Electrode Placement)

Figure 4-6

back induced such a small electrical response in initial studies that they were omitted from most of the tests.

Results (see Figures 4-7 and 4-8)

Results indicated that good control sites can be found all over the platysma muscle. Electrical interference from accessory activity is minimal. In all, 92 sites were tested, and 63 of the 92 (68%) were found to be satisfactory control sites according to the limits previously outlined.

No pattern relating the degree of electrical activity produced by simple contraction of the platysma with the y coordinate of the electrodes was observed in more than half the subjects tested. In 2 subjects the highest potentials were found in the bottom three rows ($y = 0$, $y = 4$, $y = 8$), and in one subject the highest potentials were found in the bottom two rows ($y = 0$, $y = 4$).

Simple contraction of the platysma produced in all six tests a pattern of potentials such that in the bottom row only ($y = 0$) the lowest values were found along the midline ($x = 0$) and along the lateral edge ($x = 16$). No relationship with the x coordinate was found in any of the other rows.

In five tests, head-turning was investigated. In three of the tests, turning the head in one direction caused greater electrical activity from the platysma on the opposite side from the direction of turn than from the same side, and this was more pronounced for sites over the cephalad aspect of the platysma. No such pattern was found with the other two subjects.

Smiling, clenching the teeth, chewing, and swallowing produced more interference in the top rows underneath the chin. No such pattern was found for coughing.

In four of the six tests the best control sites were in the bottom two rows.

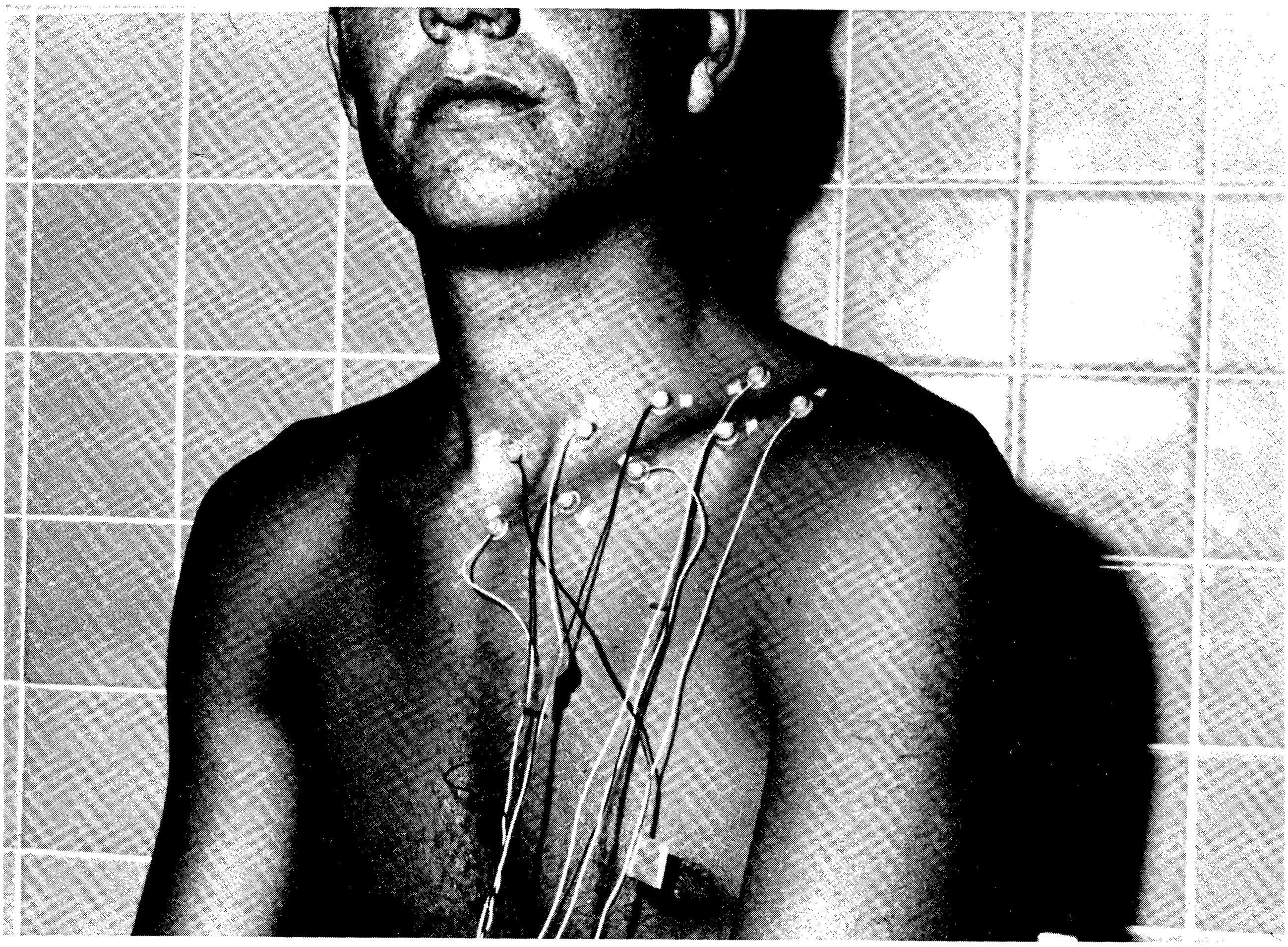


Figure 4-7

THE AXES FOR ORIENTATION OF THE ELECTRODES OVER PLATYSMA MUSCLE (SEE ALSO THE FOLLOWING DRAWING)

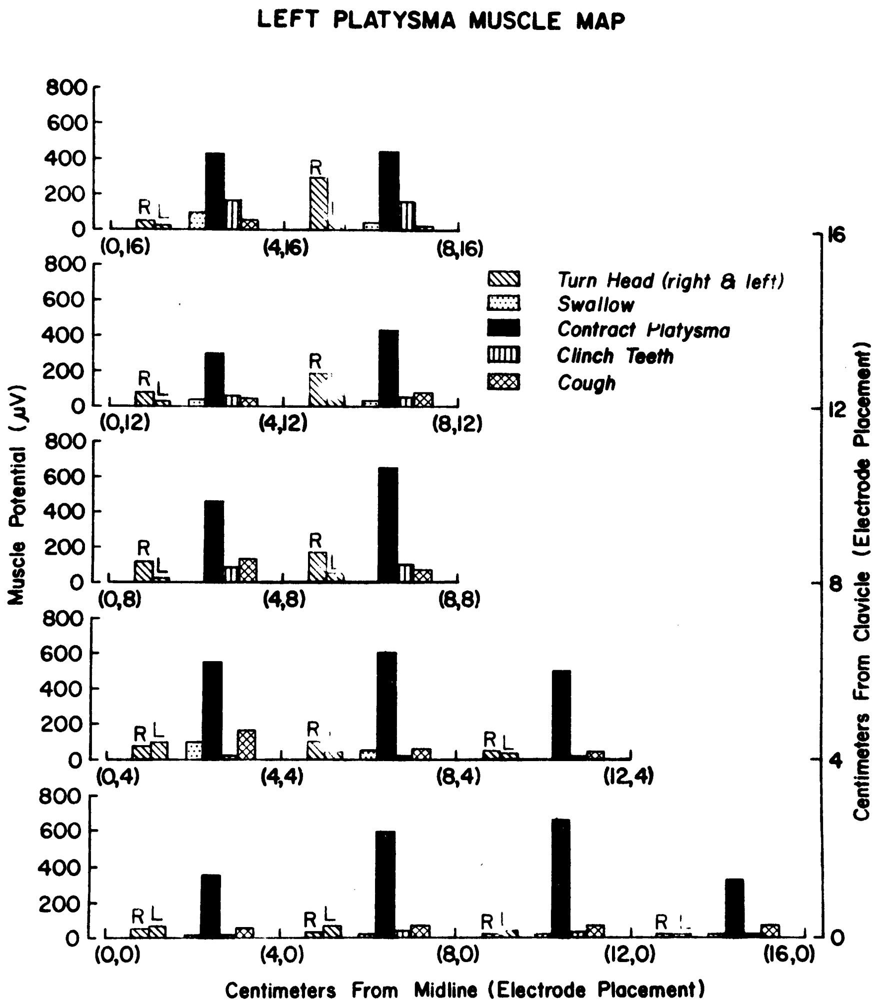

LEFT PLATYSMA MUSCLE MAP
Muscle Potential (μV)
800
600
400
200
0
(0,16)
(4,16)
(8,16)
(0,12)
(4,12)
(8,12)
(0,8)
(4,8)
(8,8)
(0,4)
(4,4)
(8,4)
(12,4)
(0,0)
(4,0)
(8,0)
(12,0)
(16,0)
R
L
Turn Head (right & left)
Swallow
Contract Platysma
Clinch Teeth
Cough
16
12
8
4
0
Centimeters From Clavicle (Electrode Placement)
Centimeters From Midline (Electrode Placement)

Figure 4-8

4.1.5 DISCUSSION AND SUMMARY

It is clear that even when a standard channel was used in all tests, the data were not exactly reproducible from one test to the next at any given site. The least difference between two recordings from the same site was 12%.

The Grass Polygraph was the first source of error. The integrator cannot be linearily calibrated, and once calibrated the adjustment of the machine "drifts" after a short time. For example, when calibrated to produce a 1-cm. deflection with a 200 µV input, it produces a 2.75 cm. deflection with a 500 µV signal rather than the 2.5-cm. deflection predicted by a direct correlation between input and pen deflection. The source of errors lies in the diode of the integrator circuit, which modifies amplification of the recorded potential in a non-linear fashion. To control for drift, repeated zero settings were necessary.

A second source of error lay in the assumption that identical contractions at one site, as indicated by equal potentials produced at the standard electrodes, implied identical contractions for all sites. Actually there was no guarantee that a muscle produced proportional potentials at every site at the same time. In fact, some studies have reported that with practice a person can cause the contraction of only the portion of a muscle lying under the recording electrodes and as the subject repeats a muscle contraction he may subconsciously be learning to contract several muscle bundles in a muscle without contracting other muscle bundles as much as in the initial trials. Nevertheless, for the purpose of standardizing the test movements and increasing reproducibility of data, it was expedient to make the assumption that contractions were identical.

The platysma is a better muscle for a myoelectric switch than the frontalis or trapezius. The frontalis or trapezius could be used but only with certain modifications. Placing electrodes on the forehead over the frontalis would be cosmetically undesirable, and these electrodes would need to be masked in some manner. Many of the potential sites in the trapezius muscle demonstrated an inability to relax, a period after each contraction during which there was a considerable amount of electrical activity recorded for 10-15 seconds, even though the subject was voluntarily relaxing his muscle.

In contrast, 68% of the sites tested on the platysma muscle were acceptable, and the best sites were located close to the clavicle, which would make hiding these sites under clothing very convenient. The platysma relaxes immediately, and with practice it can be triggered without much noticeable facial grimace. Some subjects were able to control each half of their platysma separately, suggesting that it might be possible to use two sites on the two halves of the platysma for triggering two modes of control of an orthetic device.

4.1.6 REFERENCES

1. Long, C., and Eboskov, B: Research Applications of Myoelectric Control. Arch Phys Med 47:190-198 (Mar.) 1966.
2. Inman, V. T., Ralston, H. J., Saunders, J. B., Feinstein, B., and Wright, E. Relation of Human Electromyogram to Muscular Tension. Electroenceph Clin Neruo-phys 4:187, 1952.
3. Bigland, B., and Lippold, O.C.J.: The Relation Between Force, Velocity, and Integrated Electrical Activity in Human Muscles. J. Physiol 123:214, 1954.
4. Battye, C. K.; Nightingale, A., and Whillis, J.: The Use of Myo-Electric Currents in the Operation of Prostheses. J. Bone Joint Surg. 37-B: 506-510 (Aug.) 1955.
5. Scott, R. N.: Myo-electric Control of Prostheses. Arch Phys Med 47:174-181 (Mar.) 1966.

4.2.1 OBJECTIVES

The specific aim of this research effort was to devise, for myoelectric control of prosthetic or orthotic devices, a quantative testing procedure that utilizes an "on-line" analogue-to-digital computer. The test system would serve two primary functions: First, where a patient's natural ability and his experience in the use of a particular device are the most significant independent variables, data obtained from the analysis would indicate the patient's operational proficiency at any given time during his training period. Normal levels of control skill could be established and compared with patient scores so that further advice regarding his progress and his difficulties could be given. Second, where the primary independent variables are the device design and the surface electrode placement strategy, data could be applied to a comparative evaluation of the efficiency with which various devices operate and to a criticism of current electrode positioning techniques. This latter study could be of value in suggesting improvements for existing designs and techniques, or elimination of those that are entirely obsolete. Furthermore, a consideration of the advantages and disadvantages of each device in each aspect of its operation could aid in assuring therapists of more reliable prescriptions.

4.2.2 FACILITIES

The major facility for recording data was the Linc-8 analogue-to-digital computer located in the Orthetics Research Laboratory of the Department of Physical Medicine and Rehabilitation. It is a 12-bit machine with a memory word storage of 4096; the assembly uses an ASR-33 teletype for most input and output processes and dual magnetic tape transports for transfer of program and data material. The computer is equipped with external lines that can be examined and evaluated under program control in order to make logical decisions about the status of experimental hardware. Further details concerning the operational capabilities of the machine may be found in manuals provided by the manufacturer, The Digital Equipment Corporation.

4.2.3 DEFINITION OF TIME VARIABLES - see Figure 4.2-1

In order to accomplish the proposed objectives, several relevant parameters were defined as well as a group of tasks suitable for studying the prehension operation. In each task or activity, the mode of operation was always restricted to a single degree of freedom, viz., a prehensile motion. Though the dimensions of movement were thus simplified, the tasks were adequately conceived to study on-off, proportionally controlled, and additional systems as well.

The first set of dependent variables for study consisted of operation times and operation velocities. Because an individual operating a myoelectric device must initiate his reaction with a muscle contration either indirectly or remotely related to his intended movement, and furthermore, since translation of the contraction into electrical energy utilizable by a mechanical effector is unnatural in contrast to normal limb function, the operator's reaction time (either functional reaction time, ie., duration from the time a stimulus is given until movement begins, or net reaction time, ie., duration from stimulus to device motor start) was thought to depend significantly upon factors entirely unique to myoelectric activity. For example, regardless of the particular device that the patient operated and the positioning of the electrodes, his reaction time was expected to decrease to a limit characteristic of that individual with continued practice. In addition, it was hypothesized that electrode placement would significantly influence reaction time since certain muscles, for instance, are less readily fatigued or more reflexive than others. Finally, it was proposed that the speed of response might vary in a peculiar way with the forward and reverse actuation threshold potentials of the device, fixed by its internal amplification circuitry. When these levels were high, it was presumed that reaction time in both on-off and proportional devices would approach values greater than those at lower levels because of the greater effort required to achieve the potentials and increased possibility that a reverse response could fall short, causing a forward motor run. On the

Events in Activation of Prehension (on-off mode)

1. stimulus
2. muscle contraction to required level NRT
3. myoelectric signal reaches threshold level FRT
4. motor start DLT TFT
5. motion start
6. prehensile surfaces touch (or final distance reached) NOT GOT
7. prehensile force achieved (motion stop) SLT
8. motor stop
9. rest time

-Notation-

FRT Functional reaction time

NRT Net reaction time

GOT Gross operation time

TFT Total function time

DLT Device lag time

NOT Net operation time

SLT Stopping lag time (assumed zero)

AGOV Average gross operation velocity D/GOT

ANOV Average net operation velocity D/NOT

AJV Average functional velocity D/TFT

D = Prehensile surface travel (separation of initial & final position)

Figure 4.2-1

other hand, if the levels were decreased sufficiently, reaction time would first decrease to a minimum and again increase as very low levels were attained. An increase here was considered the result of extra care taken so that a quick uncontrolled contraction would not cause a signal beyond the threshold limits. If the reverse threshold limit were exceeded during a forward response effort, a reverse motor run would also serve to increase the apparent reaction time.

4.2.4 HARDWARE - SOFTWARE

Initially, a simple stimulus-response system was built to examine the net reaction time parameter. The hardware consisted of a panel upon which were mounted three colored lights (white, red, and amber) for convenient display. They were used in different combinations as visual stimuli. The balance of the hardware included a detachable sense-line cable drawn from the device's motor terminals to the computer for the purpose of evaluating the motor's operation status. The software system for measuring the net reaction time contained five routines: DCLOCK, PRMODE, REDREP, REDSIM, AND DCLKCF.

It was hoped that the net reaction time would provide guidelines for determining the patient's training progress, for classifying devices by the ease with which they can be actuated, for further criticism of electrode placement techniques, and for the calibration of internal amplification circuitry to achieve a minimum response period.

Once the net reaction time was established, an additional parameter was required to compute the total duration of a stimulated prehensile function. This was the gross operation time, ie., duration from motor start to motor stop. FATCLK was designed to make this measurement. The total function time was then defined as the duration from stimulus administration to motor stop such that the prehensile surface separation distance is a given constant. It was obtained by summing the net reaction time and the gross operation time.

Next, it was acknowledged that the gross operation time of a device is itself dependent upon two time parameters so that poor engineering of the mechanics of one could easily be masked or compensated for by the other with a consequent efficient gross operation time. Specifically, when the motor of a device begins to operate, the prehensile surfaces remain static for a measurable moment until the internal mechanical resistance of the machine is overcome and motion begins. This was designated as the device's lag time, i.e., duration from motor start to motion start. Two programs were developed to calculate the lag time, VELCLK and VELMIL. Once this value was known, the net operation time, i.e., from motion start to motion stop (it was assumed that motor stop and motion stop were simultaneous), could be obtained by subtracting the lag period from the gross operation period.

4.2.5 VELOCITY VARIABLES

It was clear that a computation of the average gross operation velocity, the average net operation velocity, and the average function velocity could be ascertained provided that the prehensile surface separation distance was known.

In tests of limited duration, it was assumed that the results were independent of the fatigue level of the subject. This assumption was not entirely valid and was expected to become erroneous during longer examination periods. Therefore, the net reaction time established with DCLOCK, for example, could be used further as a fatigue indicator in sustained experiments. Since fatigue was thought to depend not only upon the duration of testing and upon individual stamina but also upon device design and electrode placement, a correlation between fatigue and these independent variables was expected to further the critical evaluation of devices and electrode placement techniques. An additional feature of FATCLK was employed to determine the patient's required rest time between sustained, but unstimulated forward and reverse operations. This parameter was conceived to be a better fatigue indicator than the tendencies in net reaction time data.

4.2.6 MYOELECTRIC SIGNAL ACCURACY

The next problem that was undertaken, after the time and velocity study, was the development of a procedure to measure myoelectric signal accuracy. This work was started with an arbitrary selection of several experimental parameters. It was apparent that measurement of signal uniformity and time variations were of the sort required and could be made by evaluating the function: Time X Signal amplitude. Three variables were ultimately identified: (1) the percentage of response time during which the signal remains within specified electric potential limits, (2) the percentage of response time during which the signal remains above, below, or at the midpoint of the potential limits, and (3) the average deviation from the midpoint.

Naturally, it was supposed that a visual feedback instrument like those used in myoelectric training would greatly enhance performance in the examination. SP5FB was expressly designed to evaluate a feedback performance. This feedback, however, was expected to be even more effective than that gained by actual device operation, since information regarding the exact magnitude of the signal was displayed and not merely an indication that the signal was enough or greater than enough to start the motor. Unfortunately, such elaborate feedback control has little practical significance, and in fact, because the efficient operation of a device requires an approximation to the entire elimination of visual feedback of any sort, a blindly controlled device operation was simulated with SAMP5 and SAMP10 (the latter was used in conjunction with SCOPE8) to examine the efficiency with which the mind and muscles can be trained to respond with accuracy.

Two additional software components, SAMP1 and SAMP6, were added to provide the necessary training for the patient. They were structured to be set at the same signal level requirements of SAMP5 and SAMP10, but provided visual feedback in preparation for the blind experiment. Another program, SAMP4, was generated for calibrating the potentiometers on the computer console to establish the desired signal limits. A final feature of SAMP5 and SAMP10 was used to find the maximum signal amplitude that the patient could attain under the given conditions. This datum was employed in achieving meaningful settings of the signal boundaries in the training and accuracy evaluation routines.

A serious problem was recognized during the development of the sampling routines: The execution time required to manipulate the sampled analogue signal severely limited the sampling frequency of SAMP5. The frequency was permanently set at 100/second. Although this frequency was relatively rapid, 512 samples were required by the program before processing began, making the response period at least 5.12 seconds, which would be too long a period for most types of controlled muscle activity. Therefore, another program, SCOPE8, was selected from the Linc-8 Program Library, appropriately modified to work in conjunction with a new modification of SAMP5, SAMP10. SCOPE8 had a capability of sampling at a variable rate up to 20,000/second, or 512 samples in 25.6 milliseconds. Information retrieved by SCOPE8 was stored on magnetic tape and subsequently transported to the processing area of SAMP10.

The results of the sampling tests could be utilized in a variety of ways. The feedback routines, originally for conditioning subjects for further sampling tests, could be saved and used only as myoelectric trainers. The accuracy data might be used to determine the patient's progress during his training period. It was hoped that the major benefit of the accuracy sub-system would be the construction of a linear potential band graph, or accuracy spectrum - that is, adjusting the limits of the required input so as to maintain a certain level of accuracy constituted a delineation of an accuracy band. Readjustment of the limits so that the upper limit of the first, for instance, equalled the lower limit of the second, followed by manipulation of the upper limit of the second until the same accuracy level was obtained, constituted the next highest accuracy band, etc. It was assumed that the number of accuracy bands in the spectrum was equal to the number of degrees of freedom of which the examined individual is capable (provided, of course, that the electric circuitry of a given device is engineered to distinguish between any two accuracy bands). The accuracy spectrum could serve as a guideline in the future construction and design of multi-mode devices and in setting upper limits upon human signal accuracy capabilities.

4.2.7 TRACKING MEASUREMENTS

A study of accuracy under dynamic conditions was undertaken to further evaluate the feasibility of various engineering designs featuring multi-mode and proportional control. For this purpose, the tracking series TRACK1 through TRACK8 was developed. Unlike sampling routines, the required input signal was now time-dependent and random in direction of change. The patient was supposed to follow a pre-set, but apparently random, visual pattern with a similar pattern created by his own signal. In later tests, the visual feedback provided by the operator's signal was eliminated to see how effective the training period had been. The measurements made in the tracking series were similar to those used in previous accuracy tests, except that they could be interpreted to provide more information about dynamic control.

Up to this point, the prehension study had remained quite removed from practical prehensile activity, but several ideas remained to be tested. One involved a problem most familiar to the operator of an on-off device, although it significantly influenced activity in the proportional mode as well. Unlike a normal individual who receives visual and proprioreceptive feedback upon which he can act after starting a grasping motion, the operator of an elementary artificial device obtains only visual feedback, and if he is restricted to on-off activity, he cannot act upon this feedback once motion has been initiated. As a means to identify the extent of this problem and to provide training to resolve it, the "catching series" was conceived. These routines simulated a falling projectile, for example a ball, and required the patient to catch it in simulation. This catching task was expected to require very precise judgment before activating the device, since no adjustment could be made after the initial response. If the ball began to fall and the patient initiated too quick a response, he would miss the ball even though there might have been sufficient time to adjust if his limb function were normal. This was because the device was set to go at constant velocity once the initial impulse was given, and to continue until the prehensile activity was complete. The proportional mode device has some capacity for adjustment, but it is awkward and the wearer still could not act upon proprioreceptive feedback.

It was believed that these programs would be instructive to patients in training and would also provide data for comparative study of different devices and electrode placements with respect to the problem of an unalterable initial judgment.

The final parameter examined in the study was the pressure generated at the initial contact point of the opposing prehensile surfaces. This was done to obtain an indication of a more practical variable, the lifting force. Since this force was extremely dependent upon the coefficient of static friction characterizing the opposing surfaces, pressure was a significant indicator for comparative study only when the surfaces of each of the measured devices were about the same. Experiments for measuring frictional forces were planned but not carried out.

Several programs written for other pressure studies by Edward Corell were applied in this evaluation. They required the mounting of a pressure transducer at one of the prehensile contact points. The transducer and surrounding mounting were of known area. A mounting of identical area was placed on the opposing point. The pressure over the mounting surfaces and transducer was then sampled during the total time that the surfaces remained together.

5.0 BRACE DESIGN AND DEVELOPMENT

5.1 MICHIGAN MOBILE ARM SUPPORT

The improved arm-support device described in the Final Report for SRS project #RD 1527-M(Ref.5.4-1) is now available from S.H. Camp Company, Jackson, Michigan. During the period covered by this report an instruction manual (Ref. 5.4-2) was prepared for use by physicians, therapists, or the patient's family.

The mobile arm support ("feeder") is a device for balancing gravity forces without restraining useful motion at the shoulder and elbow. In this way, meager muscle forces in the severely paralyzed upper extremity can be used for functional purposes rather than for trying to overcome the weight of the extremity. To accomplish this, the Michigan Mobile Arm Support employs 5 precision adjustments: "X", "Y", "pitch", "roll", and "height". With these, precise control can be exerted on all forces acting on the basic degrees of freedom of the system, so that the best use of remnant muscle forces can be made by the patient.

5.2 ARTHRITIC KNEE BRACE

During the report period a brace has been developed which in selected cases relieves pain in the unstable arthritic knee by counteracting valgus (or varus) and anterior displacement of the tibia during weight-bearing. Control is achieved by two force systems incorporating seven individual forces. Free flexion-extension of the knee is preserved. The brace is prescribed when pain with weight-bearing can be reduced by manual correction of mediolateral and/or anteroposterior instability; it is not indicated if the patient is a candidate for corrective knee surgery, or has flexion and/or valgus contractures of more than 15-20°, serious hip involvement, poor motivation, or inability to walk for other reasons. The degree of correction is often critical, so that precise alignment and repeated adjustment of the brace may be necessary for pain relief. Of 50 patients followed more than 6 months, 38 have worn the braces successfully for periods of 7 to 48 months;

some, however, have later discontinued them because of the progression of their disease. An expectation that the benefit will be only temporary is not regarded as a contraindication.

The details of the development and clinical use of this device are found in Ref. 5.4-3.

5.3 POLYVINYLCHLORIDE GEL IN ORTHOTICS AND PROSTHETICS

The gel pads used during the past several years have brought considerable improvement in prosthetic and orthotic devices and in patient care for the prevention of ischemic ulcers. Because of the high cost of this material, however, many patients have had to do without these much-needed pads. One reason for the cost is that the gel formula has been based on silastic material which is very expensive. Now, however, a polyvinylchloride (P.V.C.) gel has been developed without silicone or silastic ingredients, and consequently the cost has been significantly reduced. Moreover, this new material offers several advantages over the gel previously used.

P.V.C. gel has been in use at the University of Michigan Medical Center for about two years. It has been found very easy to work with, particularly since the "stickiness" inherent in such substances can readily be controlled by the application of talcum powder after the gel has been processed and cooled. This simple factor greatly facilitates the covering of pads.

The key to the gel's effectiveness is its ability to distribute pressures. One danger in being bedridden or confined to a wheelchair is that skin under constant pressure tends to break down, resulting in the sores called ischemic ulcers. At this Medical Center, P.V.C. gel has been used in wheelchair pads for more than 100 patients, as well as in specially designed breast prostheses and pads of all shapes for assistive devices and artificial limbs. In the rehabilitation ward, two gel mattresses, 36" x 24" x 1" are in constant use;

this size covers the spinal area completely, and with separate pads for heels, elbows, and head, all pressure sites are adequately protected.

Details about the preparation of the material and fabrication into various shapes are given in Ref. 5.4-4. Technical evidence regarding extended clinical uses for the gel is still meager; however, a thorough study is being proposed in which these concerns as well as all parameters of the materials and devices can be considered.

5.4 REFERENCES

1. Advanced Development of Upper Extremity Ortheses Final Report for a project supported in part by SRS Research Grant #1527-M. June 1968.
2. Instruction Manual; Michigan Mobile Arm Support, 1968 - available from S. H. Camp Co., Jackson, Michigan, or Dept. of Physical Medicine and Rehabilitation, University of Michigan Medical Center, Ann Arbor, Michigan 48104
3. Bracing the Unstable Knee; Edwin M. Smith, M.D.; Robert C. Juvinall, M.S.M.E.; Edward B. Corell, M.S.M.E.; and Victor J. Nyboer, M.D.; Archives of Physical Medicine & Rehabilitation, Vol. 51, January 1970.
4. Polyvinylchloride Gel in Orthotics and Prosthetics: Technical Report #10, Richard D. Koch, C.O. and H. V. Sturza; Department of Physical Medicine and Rehabilitation, University of Michigan Medical Center, Ann Arbor, Michigan. June 1969.

6.0 BASIC STUDY OF HAND JOINT MECHANICS

6.1 BACKGROUND

The joint deformities accompanying rheumatoid arthritis have been described in terms of normal articulating forces as affected by pathologic imbalance among the usual constraining forces of healthy connective tissue. The current study is directed toward a more detailed examination of the mechanical location of the tendons and stabilizing forces produced during various hand positions. The experimental procedure uses a cadaver hand with clamped metacarpals and with the phalanges pinned approximately at the rotation axes and connected to force transducers. Thus the various forces can be measured under conditions approximating those of actual function. For example, for the metacarpophalangeal joint, as shown in Figure 6-1, the dimension d_o in terms of the other quantities is:

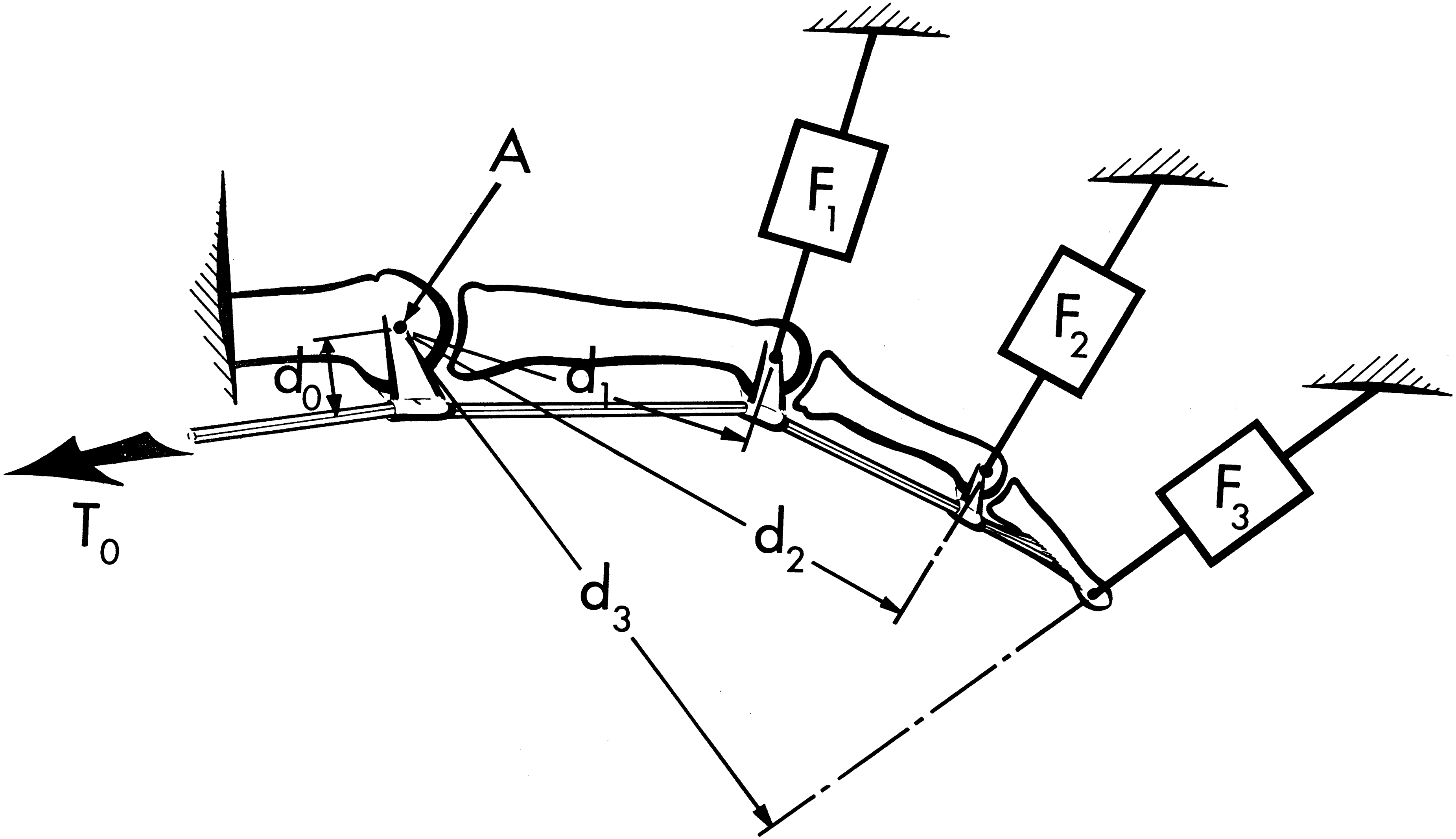
$$d_o = \frac{F_1 d_1 + F_2 d_2 + F_3 d_3}{T_o}$$

The errors involved in measuring these distances and forces are significantly less than those expected in attempting to measure d_o directly. This procedure carried out at the proximal interphalangeal and distal interphalangeal joints produces similar measures of the moment arms of the associated tendons crossing these joints.

The experimental apparatus is shown in Figure 6-2.

6.2 SUMMARY OF RESULTS

Details of the entire experimental procedure and results are given in an internal report by Mr. John M. Drlik, B.S.M.E. (Ref. 6.3-1). This report brings together the work of several earlier segments of the study and presents the data in full. Since the outcome of this work has been negative, in that a definitive description of the mechanical elements under investigation was not achieved, comments below, abstracted from the "Summary" of Ref. 6.3-1, relate chiefly to the difficulties encountered.



PLANAR FORCES IN FINGER MODEL

Figure 6-1

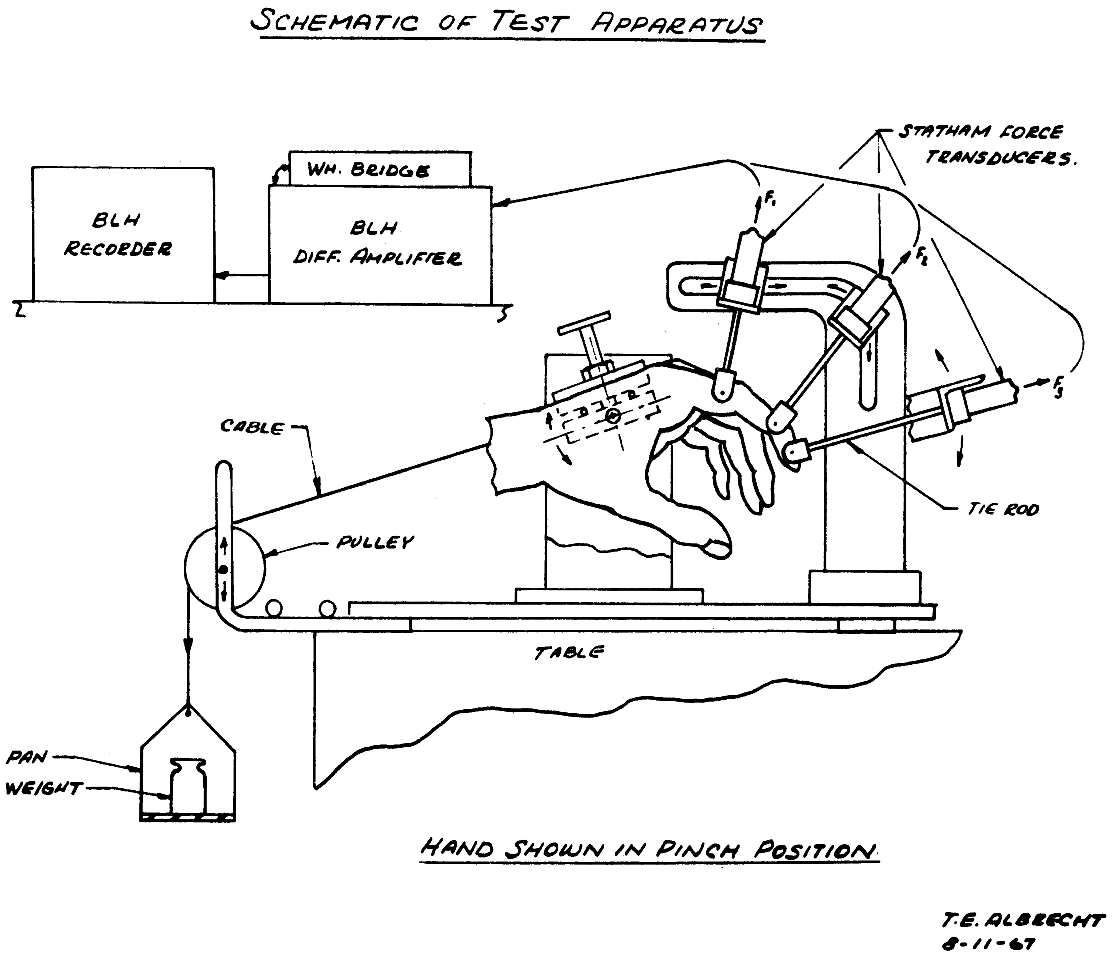

SCHEMATIC OF TEST APPARATUS
STATHAM FORCE TRANSDUCERS.
WH. BRIDGE
BLH RECORDER
BLH DIFF. AMPLIFIER
F_1
F_2
F_3
CABLE
PULLEY
TIE ROD
TABLE
PAN
WEIGHT
HAND SHOWN IN PINCH POSITION
T.E. ALBRECHT
8-11-67

Figure 6-2

The main result of the test series has been the inability to obtain repeatability of data. Although the averages calculated for the moment arms are reasonably close to those determined from previous studies, as shown in Table 6-1, the value of these averages is suspect. The calculated average moment arms from the current study are from data having such a wide spread that the range of values has exceeded 100% of the average. Considering this, it would be difficult to conclude that this study had measured the true tendon moment arms, nor is there assurance that the data cover nearly the whole spectrum of values which could be obtained by testing in the current manner.

MOMENT ARM CHANGE WITH TENDON LOAD

Analysis of the data raises several questions. The trend towards lower values of moment arms at higher tendon loads, particularly with the flexor tendons, is hard to explain. Although part of the change could be attributed to stretching of the collateral ligaments at the joints, it is hard to rationalize all of the change to this alone. (e.g., as much as 50% from .22 to 14 pounds at the MCP joint). This change in calculated moment arm took place without any measurable or observable physical change at the joints.

On the final series of tests a tendon load of 15.5 pounds was maintained on the flexor digitorium profundus for 8 minutes. During this time the calculated moment arm at the MCP joint changed from 00.38 in. to .450 in., i.e., a change of 15.6%. This finding can be attributed partially to stretching of the collateral ligaments at this joint, thus lending support to the theory that it is the tendon forces that cause the deformities of the diseased MCP joint. It must be noted that during this test the calculated DIP and PIP tendon moment arms were constant.

TRANSDUCER-MEASURED IRREGULARITIES

Upon occasion it was noticed that a force transducer would measure a force in one direction at a certain load on one day and on the next day measure a force in the opposite direction at the same load and joint, and then back to the original direction on a third run. If this

SUMMARIZED HISTORY OF RECORDED AVERAGE VALUES
FOR THE MOMENT ARMS OF THE FLEXOR TENDONS -
FINGER IN STRAIGHT POSITION

Source	Flexor Digitorum Profundus			Flexor Digitorum Superficialis		
	DIP In.	PIP In.	MCP In.	DIP In.	PIP In.	MCP In.
Smith and Juvinall[1] Measured Hand	.21	.32	.40	0	.26	.47
Ferguson[2] Hand No. 1 Calculated	.15	.24	.44	.016	.25	.42
Rau[3] Hand No. 4 Calculated	.18	.30	.37	-	.28	.42
Albrecht[4] Hand No. 4 Calculated	.21	.32	.39	-	.27	.40
Current Study Hand No. 9 Calculated	.20	.36	.46	.08	.35	.45
Avg. from the Five Sources	.19	.308	.41	.048	.28	.43

DIP Distal Interphalangeal joint
PIP Proximal Interphalangeal joint
MCP Metacarpophalangeal joint

TABLE 6-1

effect is due to positioning of the hand and digit the definite cause is undiscernible, since each day's position was slightly different. It must be reemphasized that from day to day an attempt was made to place the hand in the same position as in the previous test.

It was also observed that the forces generated, particularly at the PIP joint, in tests of the extensor tendons changed directions as the tendon loads changed. This might seem to suggest an explanation for swan neck and boutonniere deformities seen in rheumatoid arthritis, but the evidence cannot be regarded as conslusive.

POSSIBLE SOURCES OF DIFFICULTY

Some thought has been given to the possibility that freezing and thawing of the hand could change the physical properties of the tissue. However, research by others, including Dr. Donald G. Ellis of the Orthetics Research Project of Physical Medicine and Rehabilitation of the University of Michigan, indicates that the day-to-day effect of this treatment on tendons and ligaments is very slight. It is known that changes in physical properties of these tissues due to freezing occur only after a considerable time period, such as 8 to 12 months. However, it is unknown whether freezing and thawing could affect the joints.

If the inconsistencies and unexplained events that occurred are attributable to positional differences, then one must question the method of study and/or the assumptions. If a procedure could be devised to hold the hand and digits rigidly in exactly the same position for each test, of what value would be the results? If every position has different moment arms for each tendon, it is obvious that the model for the mechanics of the joints and tendons is either incorrect or incomplete.

Because of these problems and the need to devote more attention to the projects described above, the hand-mechanics study was discontinued in August, 1968.

6.3 REFERENCES

1. Drlik, John M.: "Experimental Determination of Tendon Locations with respect to Joint Axes in the Human Hand" Internal Progress Report; August 1968, Department of Physical Medicine and Rehabilitation, University of Michigan Medical Center, Ann Arbor, Michigan.