A Microcomputer-Controlled Above-Knee Prosthesis and Biofeedback/Gait Analysis System for Immediate Post-Operative Amputees

by

Michael P. Shepley

A.S. Aerospace and Astrospace Engineering
Wentworth Institute
(1975)

B.S. Mechanical Engineering
Northeastern University
(1978)

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Signature of Author ____________________
Department of Mechanical Engineering
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Certified by ____________________
Woodie C. Flowers, Thesis Advisor

Accepted by ____________________

A MICROCOMPUTER-CONTROLLED ABOVE-KNEE PROSTHESIS AND BIOFEEDPACK/GAIT ANALYSIS SYSTEM FOR IMMEDIATE POST-OPERATIVE AMPUTEES

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ABSTRACT

A microcomputer-controlled above-knee prosthesis and Biofeedback/Gait Analysis System have been used for early gait training of immediate post-operative amputees. This system has been used to demonstrate the viability of prosthesis weight bearing and knee torque feedback, costomized swing phase damping and gait analysis in a clinical environment. Preliminary results show that it may be possible to use quantitative gait analysis for describing the performance of patients and that versatile swing phase control, biofeedback training and gait analysis are effective in addressing the variety of problems encountered in early gait training of these amputees.

Thesis Supervisor: Dr. Woodie Flowers

Title: Associate Professor of Mechanical Engineering

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Michael Shepley

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1.0 Introduction

The above-knee amputee has faced a life, that has often been difficult due to a lack of versatile function of her/his prosthesis. The problems of socket fitting and oversimplified swing phase control are two of the major difficulties facing these amputees.

The MIT Knee Group has committed itself to addressing the problems of meeting the needs for increased function and cosmesis of A/K prostheses. This work began 12 years ago by W. C. Flowers (9). Flowers developed a laboratory based A/K prosthesis simulator. From his and subsequent studies, (3, 10, 11, 12, 13, 16) much has been learned about A/K prosthesis control. As a result of this laboratory based research, the feasibility of using microcomputers for portable simulators was considered. With the rapid advancements being made in microcomputer technology, the stage was set for the development of a protable simulator.

By June 1978 the first device was completed and tested. The Motorola 6800 based system, developed by Tanquary (19) is purse size and worn over the shoulder as shown in figure 1. The prosthesis, developed by Cone and Flowers (8) is also shown.

The system's function was to provide versatile swing phase damping control via easy programmability of the microcomputer controller. This is the feature that provided the potential for use as an early gait training aid for immediate post-operative above-knee amputees. The use of the MIT Knee

Front View

Side View

Figure 1. An Amputee Wearing the Prosthesis-Controller System.

Front View

Side View

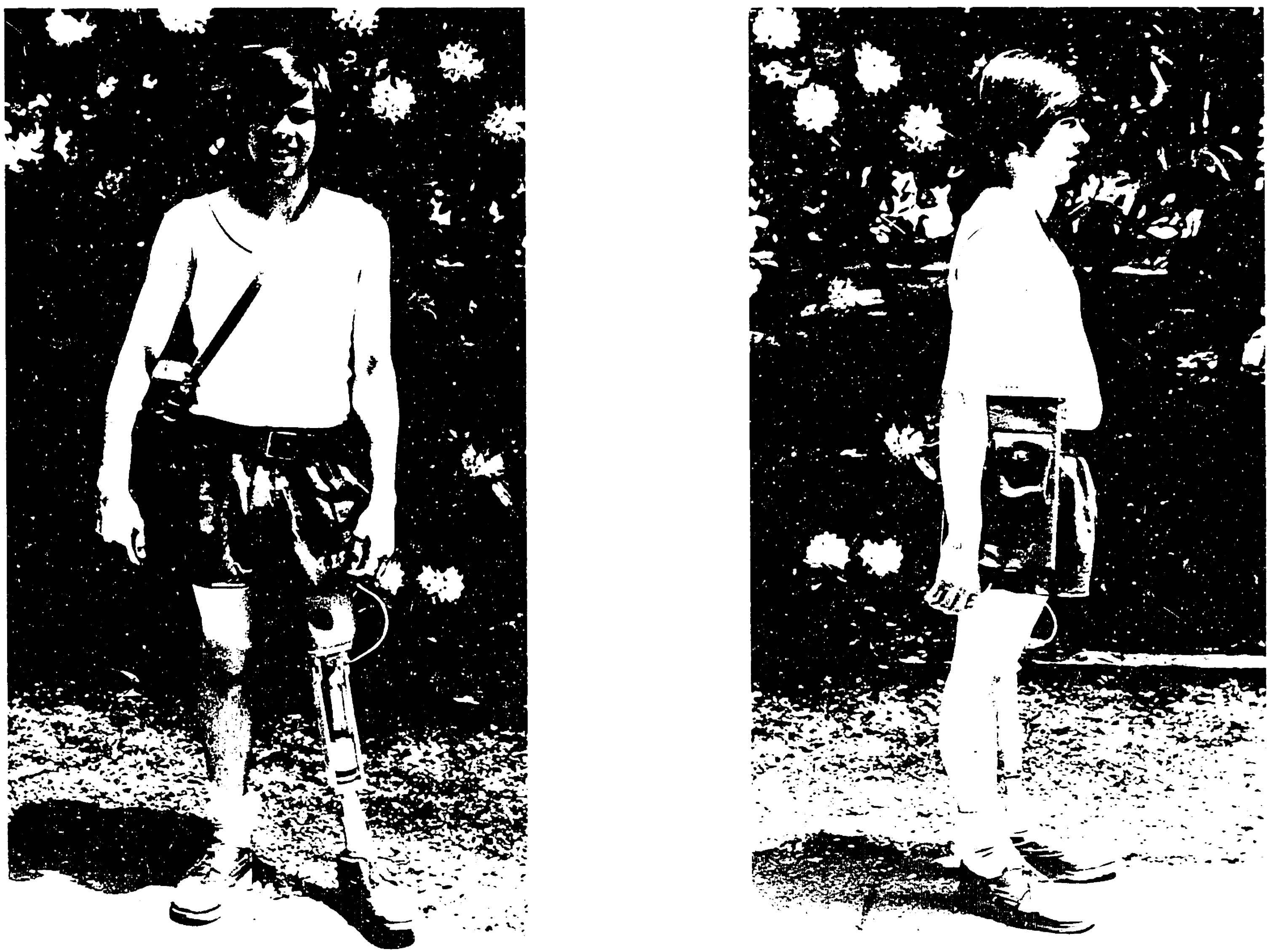


Figure 1. An Amputee Wearing the Prosthesis-Controller System.

in the clinic and the subsequent learning process that followed are the subjects of this thesis.

1.1 The Problem

The rehabilitation of immediate post-operative above-knee amputees is a multi-faceted problem (15) involving months of inpatient and outpatient care and gait training. Conventionally, the pylon shown in figure 2, is used for gait training. It is only capable of being locked or free swinging with no reasonable means for changing its swing phase dynamics. The immediate post-operative amputee in early training must first learn to bear weight on a locked pylon. Soon, however, the pylon is unlocked and learning to walk on an articulated prosthesis begins. This abrupt change from a stiff pylon to an undamped pendulum is often very difficult, especially for geriatric amputees. The MIT Knee with its programmable swing phase controller, was proposed as a more user-interactive training prosthesis capable of providing a more gradual transition from locked to articulating prosthesis.

Closer observation of the rehabilitation process, however, led to the discovery that immediate post-operative A/K amputees are often faced with a variety of other problems any one of which may become the greatest impedement to progress. Other major problems include prosthetic knee instability in stance, inadequate prosthesis weight bearing and a lack of quantitative descriptions of A/K gait.

1.2 The Approach

Six immediate post-operative, above-knee amputees were

Front View Side View

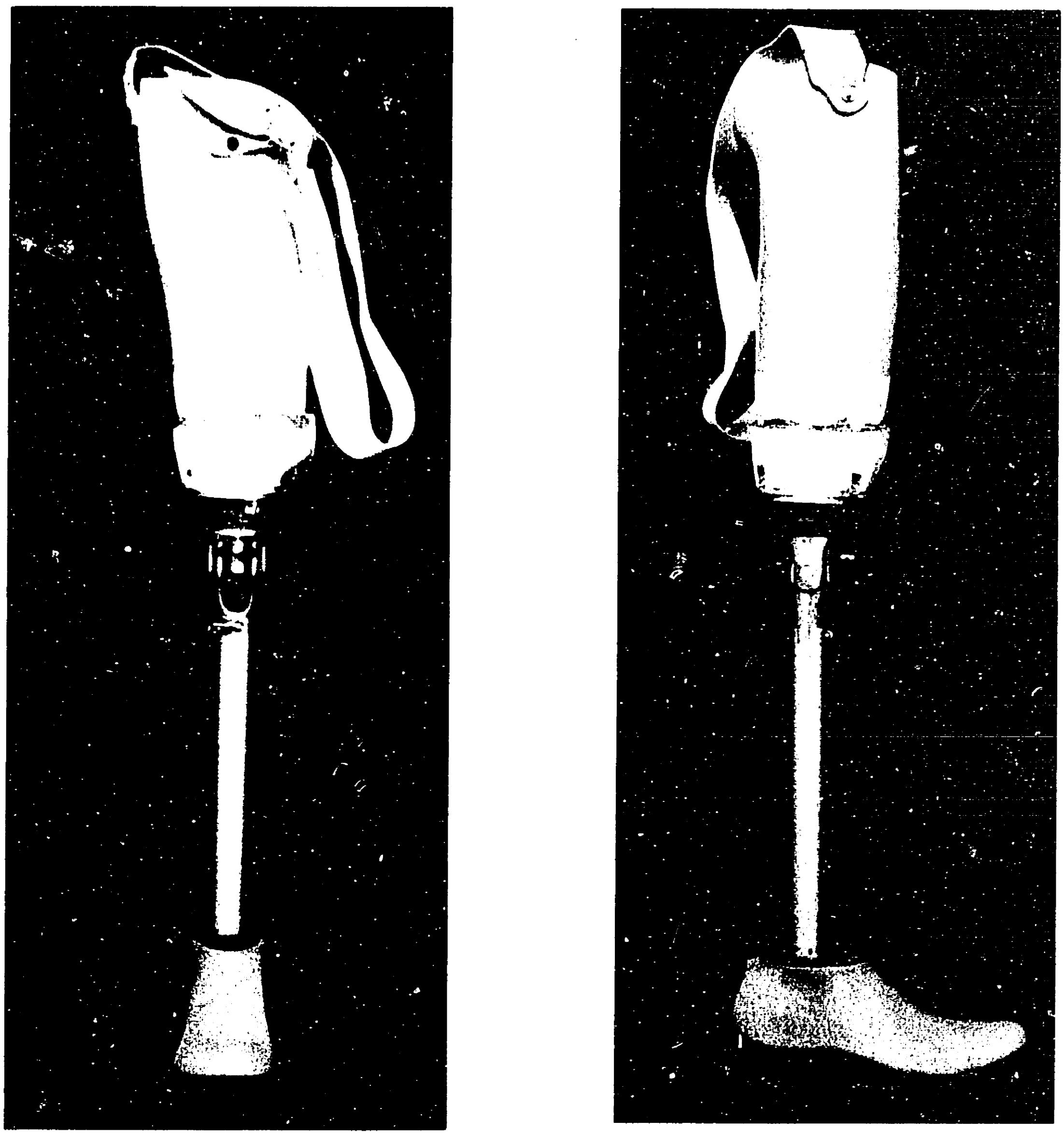


Figure 2. The Conventional Early Gait Training Pylon.

Front View Side View

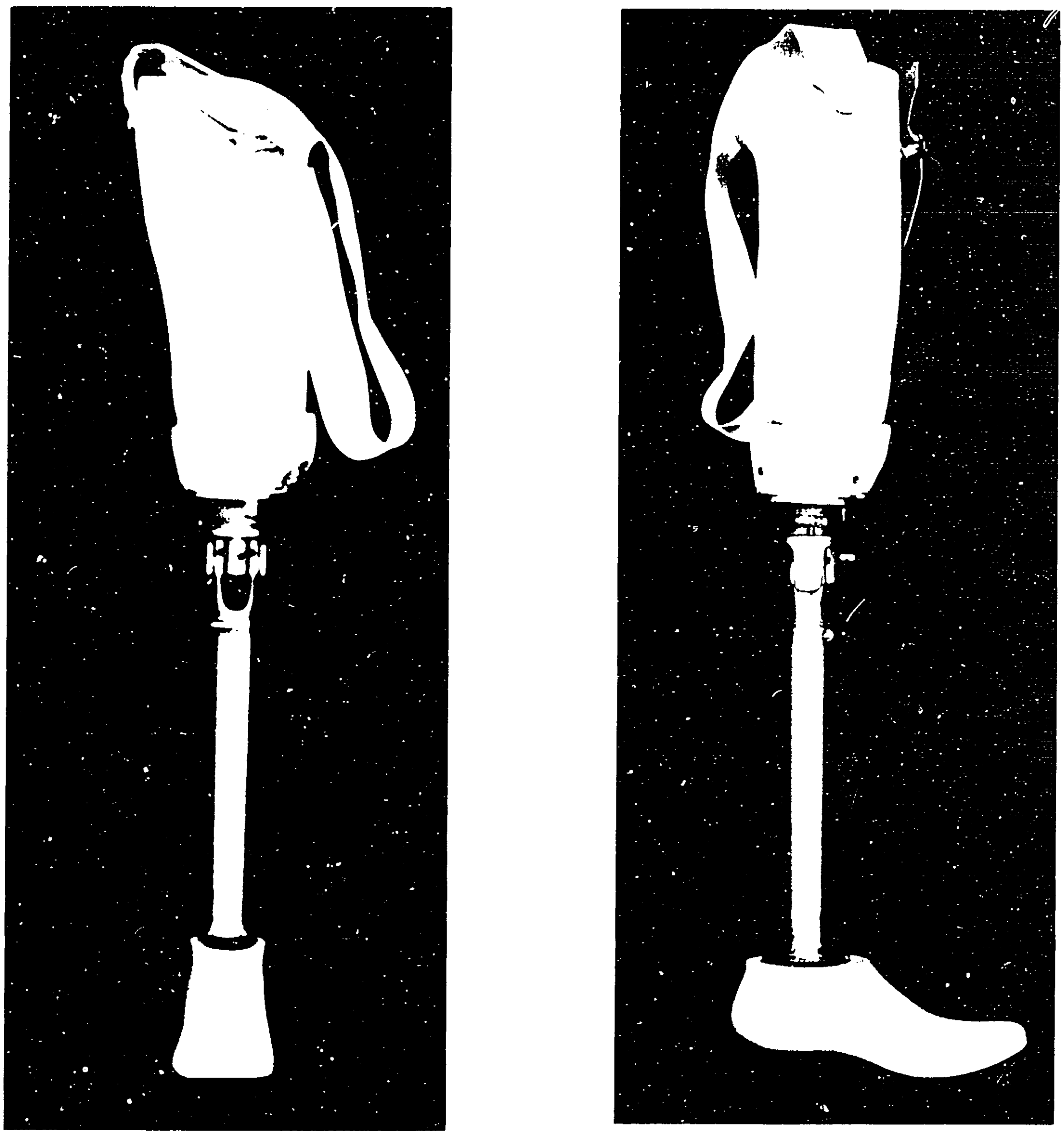


Figure 2. The Conventional Early Gait Training Pylon.

trained with the MIT Knee at the White 9 Physical Therapy Unit of the Massachusetts General Hospital. The research was carried out in two stages. The first phase focused on preliminary evaluation of the swing phase controller and on acquiring clinical insight into the problems associated with early gait training. The second phase, focused on the development and use of biofeedback techniques to promote stance phase stability and increased prosthesis weight bearing during early gait training. An attempt was also made to demonstrate the use of quantitative gait analysis in early training.

1.3 Other Applications of Biofeedback and Gait Analysis In Physical Medicine

Numerous forms of feedback have been used in physical medicine (5). Warren and Lehmann (20, 21) have studied weight bearing feedback using force plates, sensors under the feet and instrumented crutches. They found that proportional feedback of limb loading reduced the probability that the subject would overshoot the target load. Craik and Wannstedt (1, 2) have used a versatile pressure sensitive insole for limb loading feedback. Their evaluation of the device indicated that lower extremity amputees benefited from its use. Moore and Byer (16) have developed a load threshold sensing device for use in controlling prosthesis loading by A/K and B/K amputees. This device utilizes a preloaded, adjustable spring. When the preload is exceeded, the spring compresses, triggering an audible alarm. The device does not transmit a continuous signal proportional to load. Fernie (7) has used position feedback with A/K amputees to promote full extension before heal strike. Patient performance was monitored in the clinic by a specially constructed counter which determined the number of steps taken and the percent of steps in which errors occurred. Flexion of the knee immediately after full extension or during stance, was used as the criteria for errors. Fernie (6) is also developing a portable microprocessor based system to monitor outpatient performance.

Perry (18) had designed a gait analyzer for clinical use. It calculates the velocity of the subject and the swing stance ratio of both sides. Analysis of the end bearing characteristics of petellar-tendon-bearing prostheses for B/K amputees has been reported by Kalman and coworkers (14) by utilizing a load cell which transmits a continuous signal. Using a floor mounted force plate in conjunction with their load cell, they determined the percent of weight born on the end of the stump by their subjects.

Part of the work described in this thesis, was directed toward integrating gait analysis with biofeedback training for immediate post-operative A/K amputees. In addition to the prosthetic load cell designed, a torque transducer has been incorporated into the prosthetic knee. The transducers allow continuous monitoring of the knee torque and prosthesis weight bearing, simultaneously. Feedback of either signal can be presented to the patient in a variety of forms.

This versatile approach was also incorporated into the gait analysis techniques developed. Ten parameters of prosthetic gait were recorded simultaneously, in order to understand their relative significance in describing gait. Further, an attempt was made to develop gait parameters which indicate the relative task difficulties of swing and stance phase, as this information is useful in the diagnosis of gait deficiencies and prescription of the permanent prosthesis.

2.0 Equipment

2.1 The Original Microcomputer-Controlled Prosthesis

The prosthesis knee mechanism is shown in figure 3. The magnetic particle brake is connected to a ball screw which rotates in a preloaded pair of recirculating ball nuts. This unit transmits the linear motion of the ball screw shaft to rotary motion of the particle brake. The overall gear ratio of 40:1 allows the relatively low resistive torque of the brake to be a sizable 400 inch-pounds at the knee axis.

The brake is controlled by a Motorola 6800 microcomputer system which provides swing phase damping control by computing the equation:

$$T = b\ (\theta,\ \text{sign}\ \dot{\theta})\ \dot{\theta}^2$$

where θ is the knee angle, $\dot{\theta}$ is the knee angular velocity, and and b is a programmable damping constant. θ is defined as shown in figure 3. b is a function of θ and the sign of the angular velocity, thereby making it possible to provide damping in flexion and extension independently. Figure 4a shows the face of the microcomputer with the ten slide potentiometers (pots) used to program in the damping constants. Five are used for extension and five for flexion; each slide pot is associated with an angular position in the swing of the prosthesis. The pots are arranged so that the damping used in a cycle proceeds from left to right. One can "draw" in the damping profile desired.

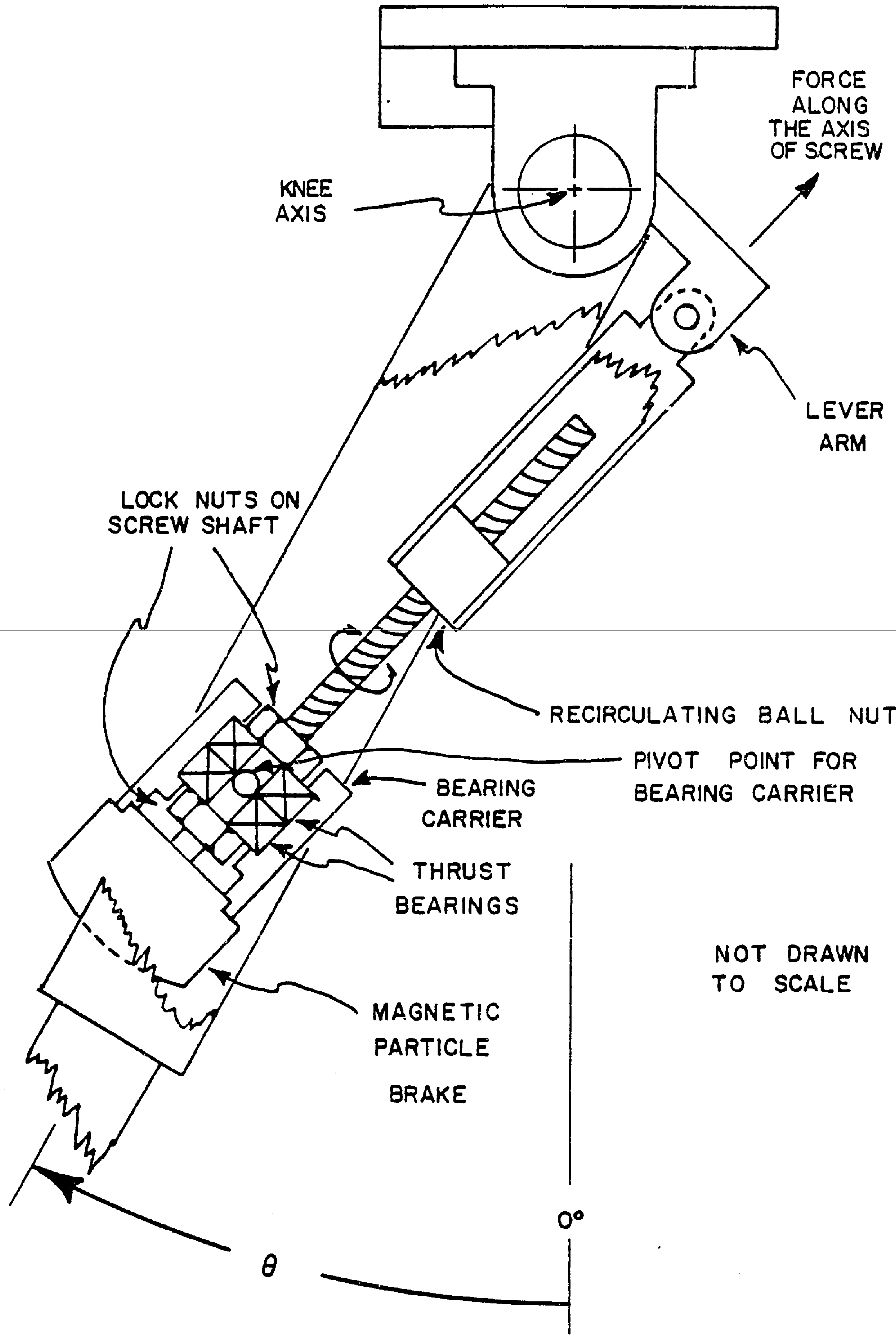


Figure 3. The Prosthesis

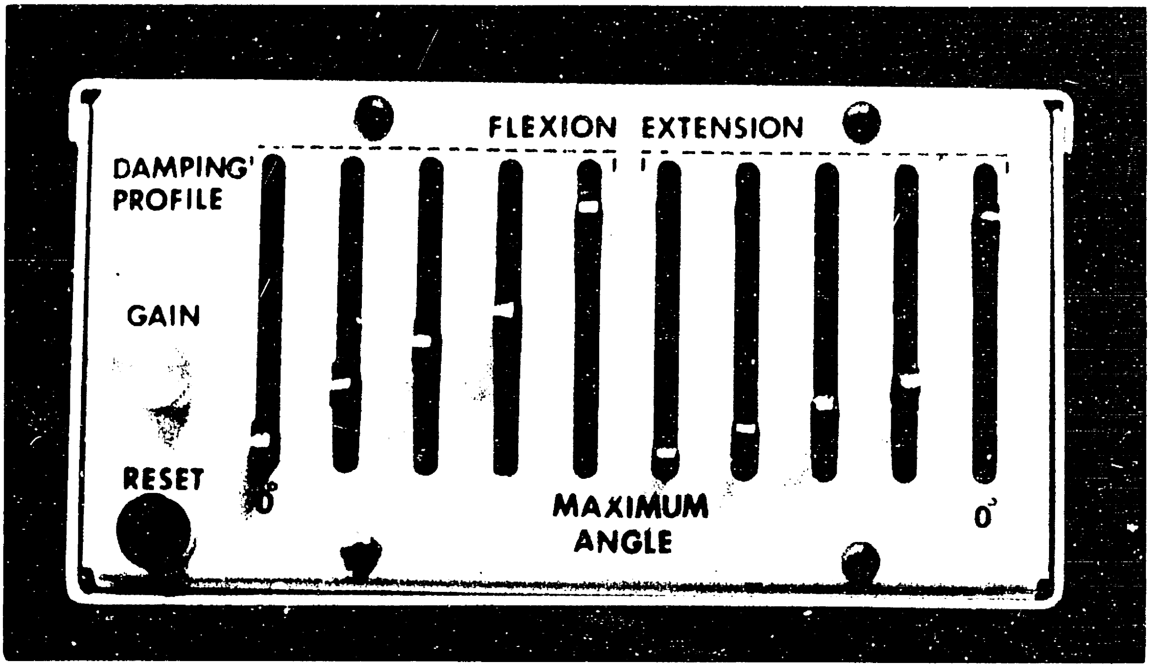


Figure 4a. Damping Profile Display

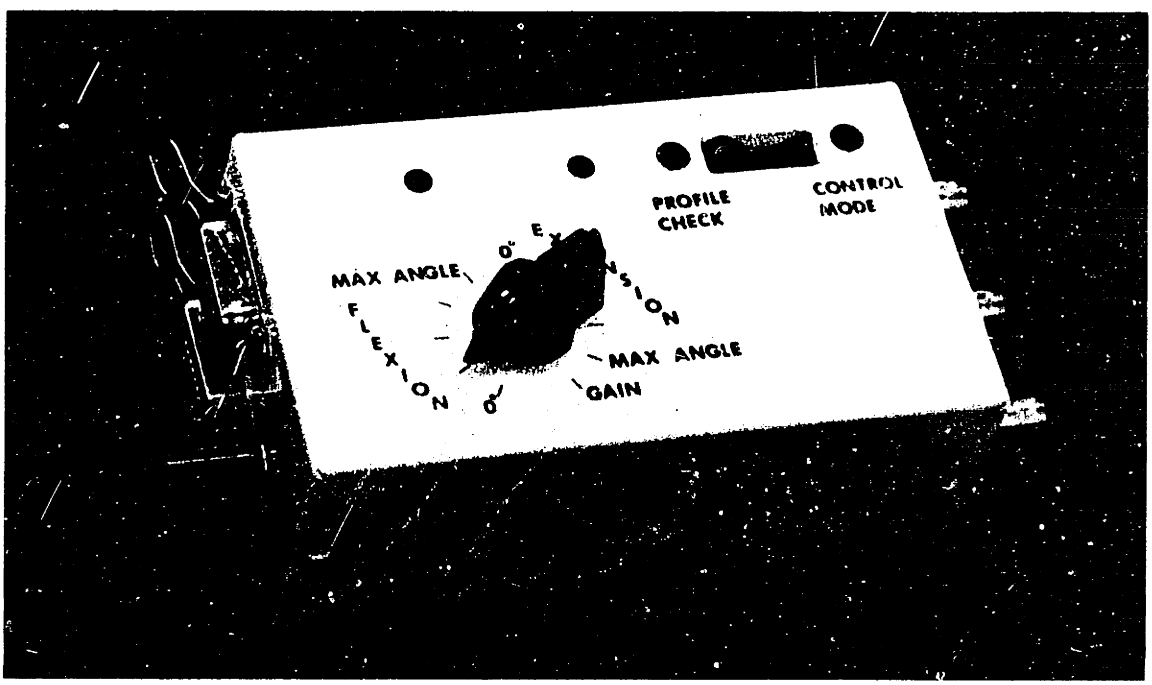


Figure 4b. Interface Box

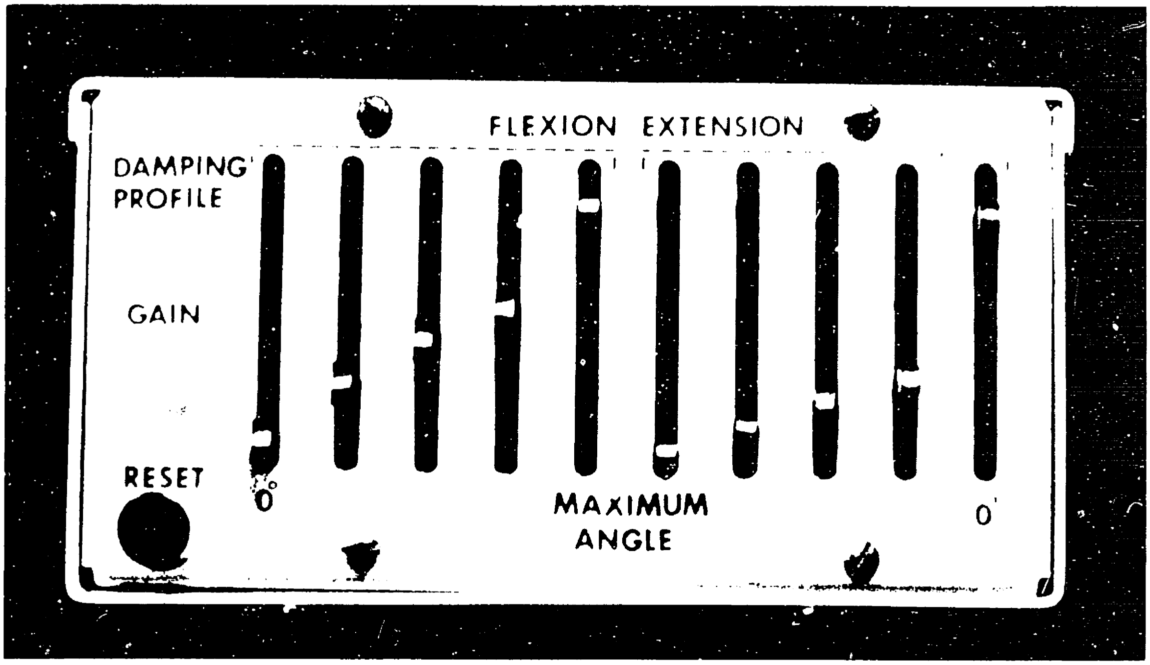


Figure 4a. Damping Profile Display

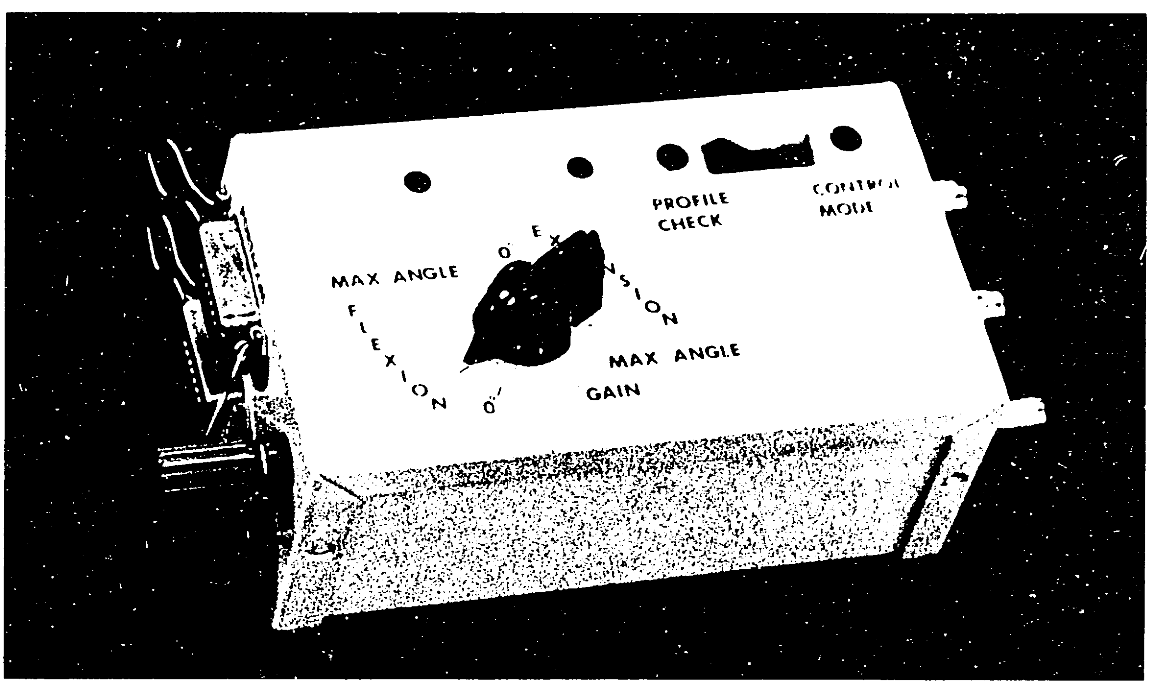


Figure 4b. Interface Box

The maximum angle referred to in the display is an internally set value which defines the angular position of the slide pots in the damping profile. For instance, if the maximum angle is set to 90 degrees, each pot is at intervals of 22.5 degrees.

When the reset button is pushed, the profile described by the pots is read into the system. The microcomputer creates two tables of damping constants, one for flexion and another for extension. Each has 32 points resulting from linear extrapolation between the positions of the pots.

A gain dial is provided so that the overall amplitude of the profiles can be changed without changing their shape. The amputee also may carry a push-button control which will lock the knee in case of stumbling.

Shown in figure 4b is an interface box, which is used to relay the profile and gain settings to a volt meter or a portacom. The latter is achieved by a subroutine in the microcomputer program, which allows serial transmission of the data to the portacom.

2.2 The Modified Microcomputer-Controlled Prosthesis

In response to the need for additional functions, the original prosthesis system was modified to provide knee torque, prosthesis weight bearing and knee power dissipation signals in addition to the already available knee angle and angular velocity signals. This enabled the use of more quantitative gait analysis and made biofeedback of prosthesis weight bearing and knee torque possible.

The prosthesis and microcomputer unit were not changed in appearance and only 9 ounces were added to the total weight. All of this weight was from the transducers and accompanying electronics.

2.2.1 The Weight Bearing Transducer

This transducer, shown in figure 5, is a fully contained system which provides a signal directly from the instrumentation amplified inside the unit. It attaches to the bottom of the prosthesis in place of the previously used shank adaptor. A schematic of its electronics is shown in Appendix A. A full strain gage bridge is used with a very low power instrumentation amplifier.

The mechanical design and placement of the strain gages are such that the transducer has a maximum response to axial loads, while having a minimal response to side loads or moments. This was achieved by consideration of the sign, magnitude, and symmetry of strains occurring in a number of possible transducer elements. The rectangular cross section was chosen for its strength and ease of construction. Also, since bending moments were measured, a temperature compensated full strain gage bridge could be used. The placement of the gages, shown in figure 6, can be compared with the schematic in Appendix A. These illustrations define the unique arrangement of gages used. The load cell was designed to have a factor of safety of two under the worst conditions with a 200 pound amputee, and had good linearity in the tested range of 200 pounds. The only mode of failure that would occur was

Figure 5. The Load Cell

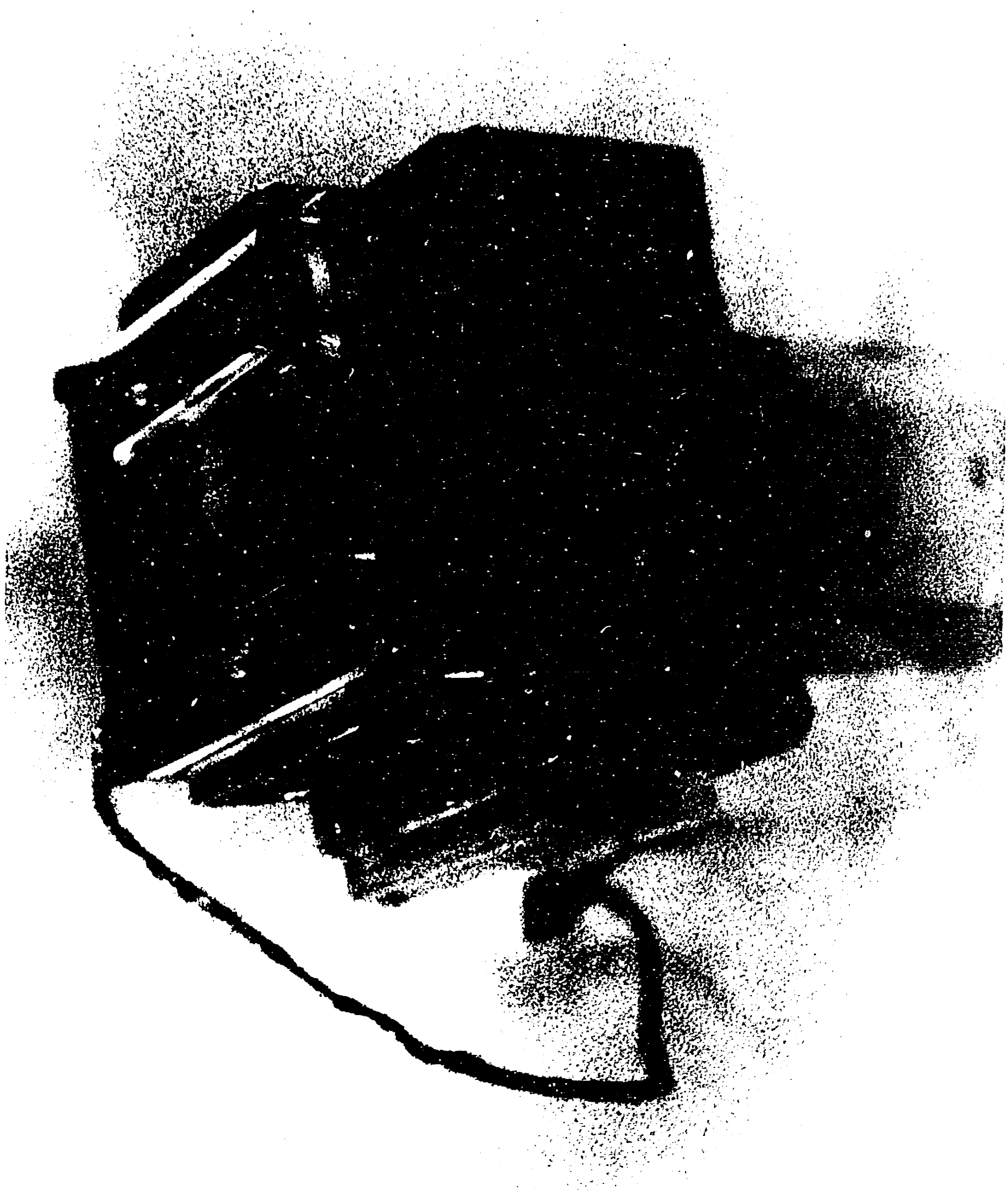


Figure 5. The Load Cell

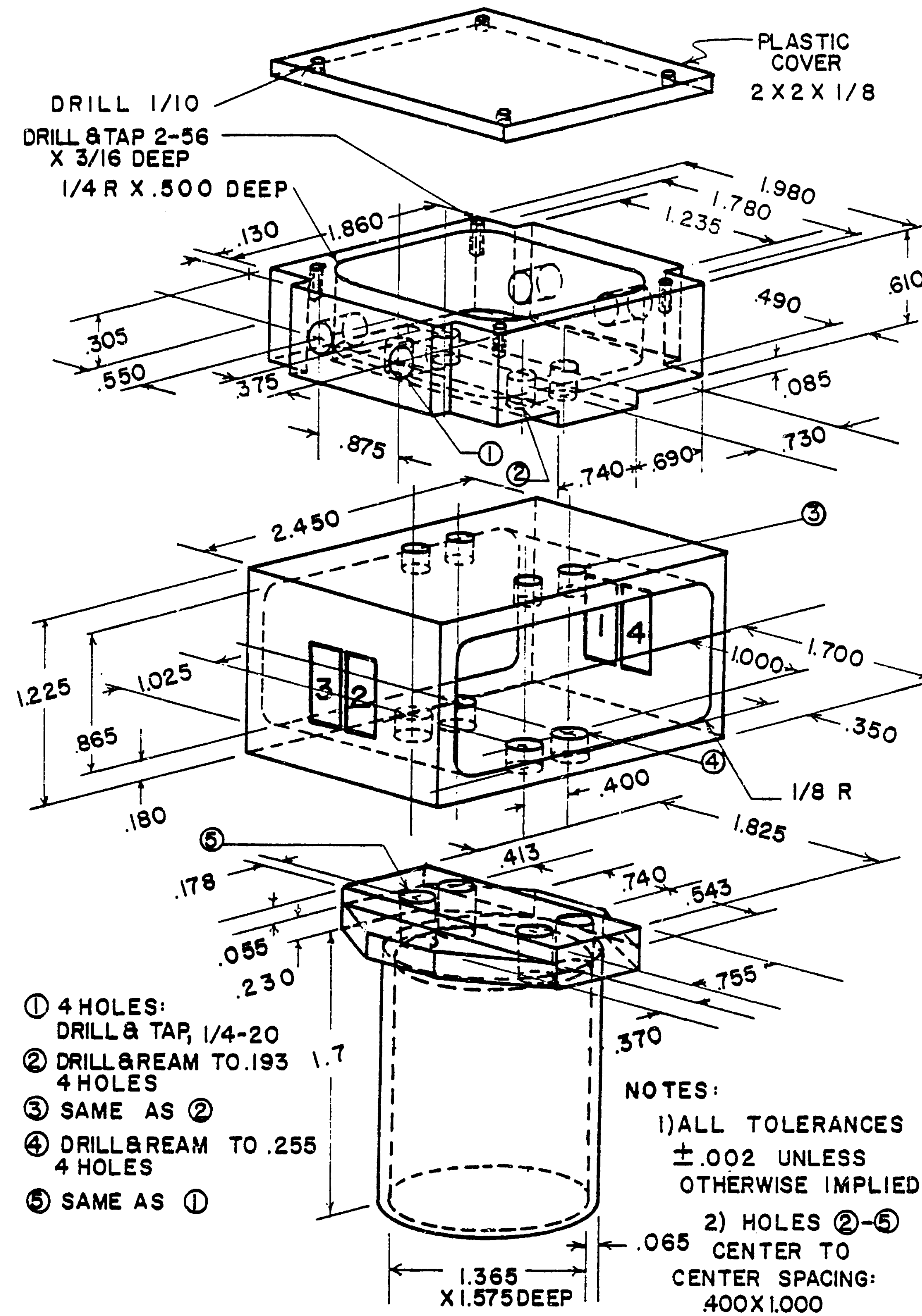
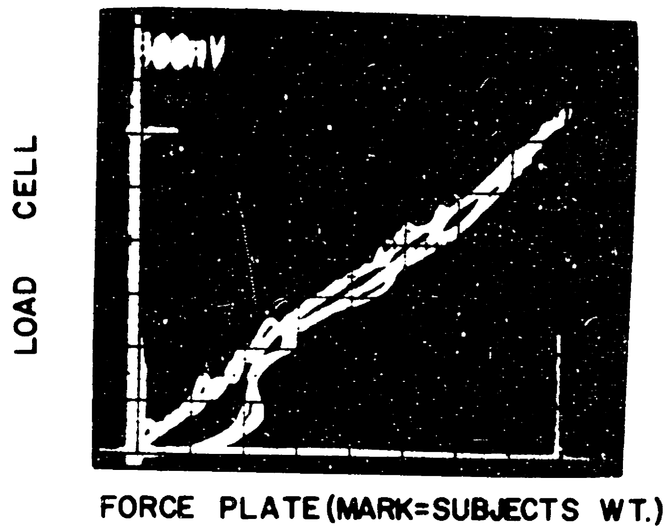


Figure 6. THE LOAD CELL: EXPLODED VIEW

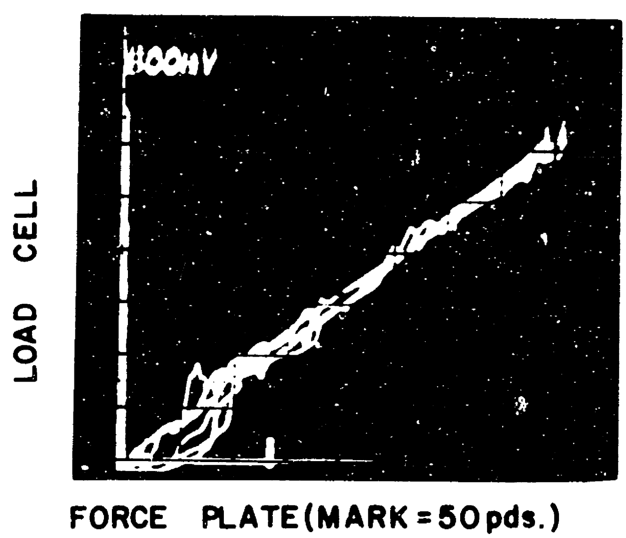
slow yield. The signal to noise ratio was 48 db at a load of 200 pounds.

Each of the three pieces shown in figure 6 were machined from 2024 T4 aluminum. The transducer element fits between the shank adaptor below and the prosthesis adaptor above, which contains the electronics.

The accuracy of this device was determined both statically and dynamically. The dynamic test was important because the prosthesis was not always vertical as the amputee vaulted over it. The deviation from the vertical caused errors since the weight vector did not always pass through the load cell axis. An X - Y plot of the prosthetic load cell output versus the output of a Kistler, type 9281A force plate was obtained while an experienced amputee walked on the force plate. The results of these tests are shown for fast and slow walking in figure 7. The error seen near the origin was due to a 50 Hz low pass filter which was initially used to remove high frequency noise. A 1000 Hz low pass was put in place of it. Note, also that there appears to be a moderate orientation error, which appears at faster walking speeds. Simultaneous strip chart recordings showed that the load cell, reliably and fairly accurately, reproduced the wave form seen from the force plate output. In the static test, the output of the transducer was again compared to that of the Kistler force plate. Two comparisons were made with the load vector passing through both the prosthetic heal and toe. The results of these static tests, shown in figure 8, indicate highly linear



FAST WALKING

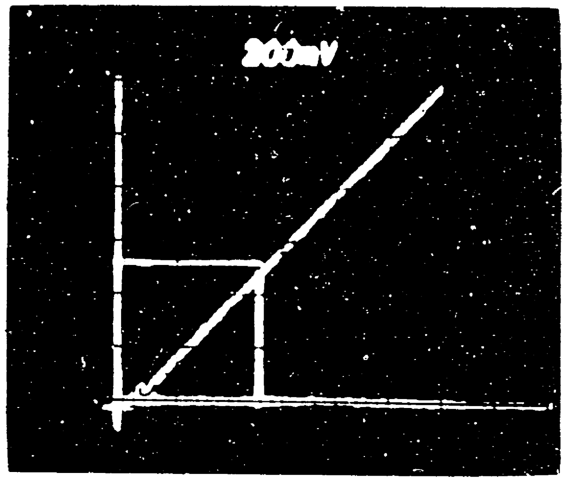


SLOW WALKING

DYNAMIC TESTS

Figure 7

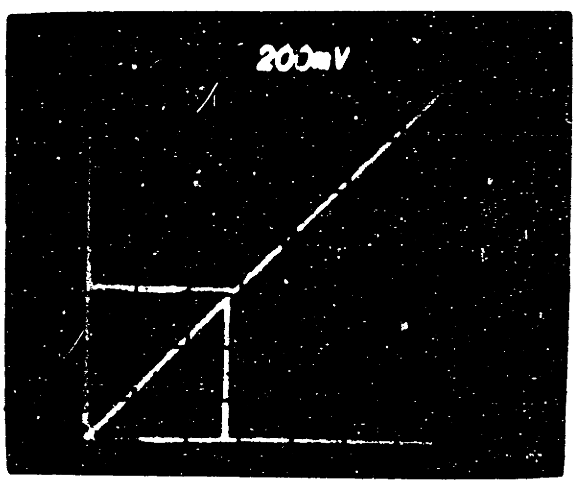
LOAD CELL



FORCE PLATE (CAL.LINE=26 pds.)

LOAD VECTOR PASSING THROUGH HEEL

LOAD CELL



FORCE PLATE(CAL.LINE=26 pds.)

LOAD VECTOR PASSING THROUGH TOE

STATIC LOAD TESTS

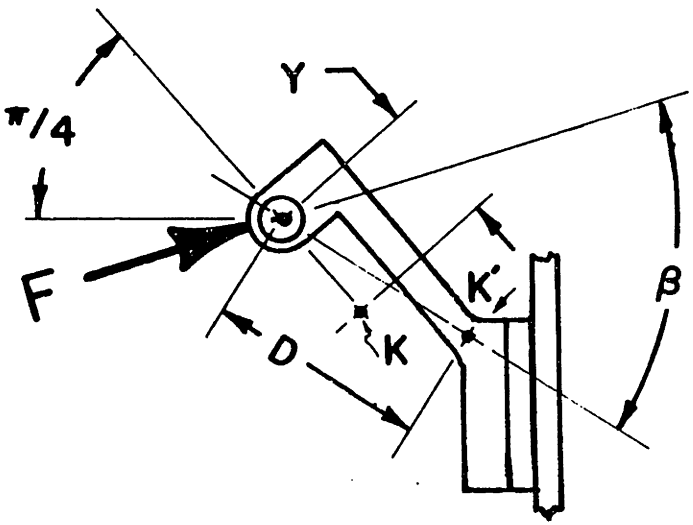
Figure 8

behavior. Thus this 6 ounce transducer performed well and used only 32 milliwatts of power.

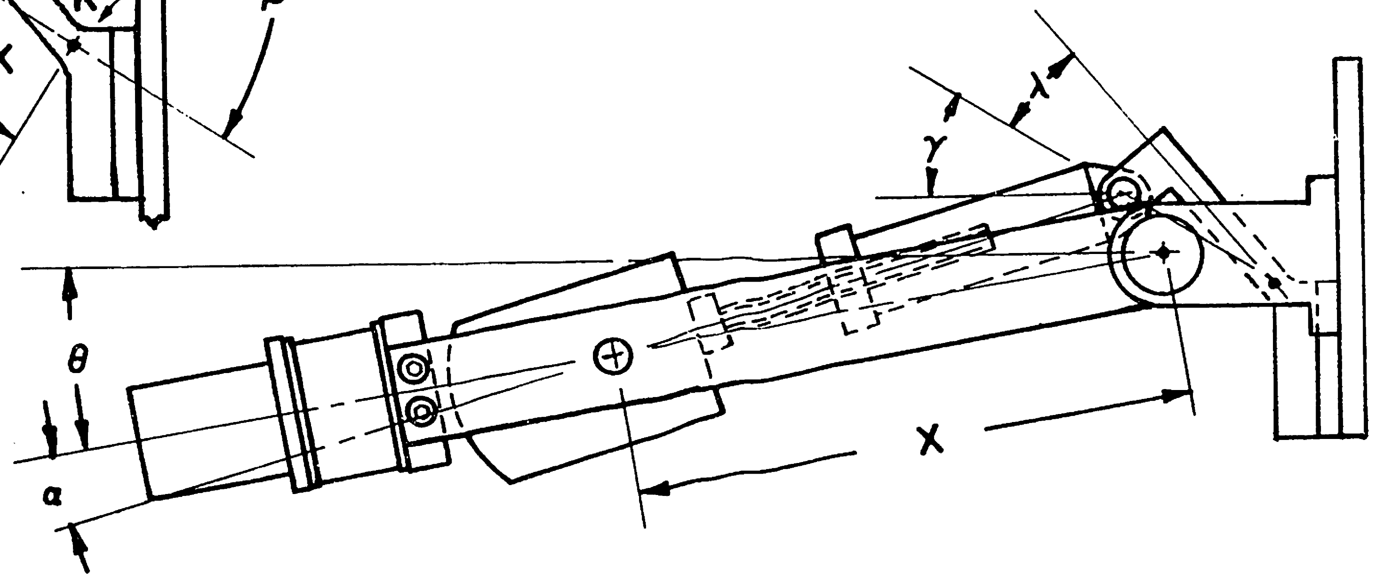
2.2.2 The Knee Torque Transducer

A lever arm, already designed into the knee mechanism for this purpose, was instrumented with a full strain gage bridge. However, the ratio of moments at the lever arm to those at the knee axis was found to be a complicated function of knee angle. The output of the transducer was compensated for this function. Figure 9 shows the knee mechanism with the appropriate variables used in the derivation of this function. The resulting equation is also shown and may be derived from the defined variables in figure 9.

All of the variables in the equation are known except for γ and D. For γ, this is because an accurate determination of the angle is difficult due to, (a) the geometry of the lever arm base, and (b) the compliance of the lever arm, which makes the angle a function of knee torque. This situation coupled with the high sensitivity of MK'/MK to γ, led to the decision to fit the equation to data determined experimentally. A least squares fit of data, found by successive loading of the knee at constant angles, was used to fit the equation, as shown in figure 10. As shown in figures 11 and 12, a simple approximation was made to the theoretical curve. This trade off of simplicity for accuracy was justified by the small amount of electronics needed to perform the correction (see Appendix B). The circuitry for making the correction was put into the microcomputer unit and provides a knee



$$\frac{MK'}{MK} = \frac{\sin(\sin^{-1}(\sin(\theta+\pi/4)Y/X)+\gamma+\theta)D}{\sin(\theta+\pi/4)Y/X}$$



ANALYSIS OF TORQUE TRANSDUCER SENSITIVITY

Figure 9

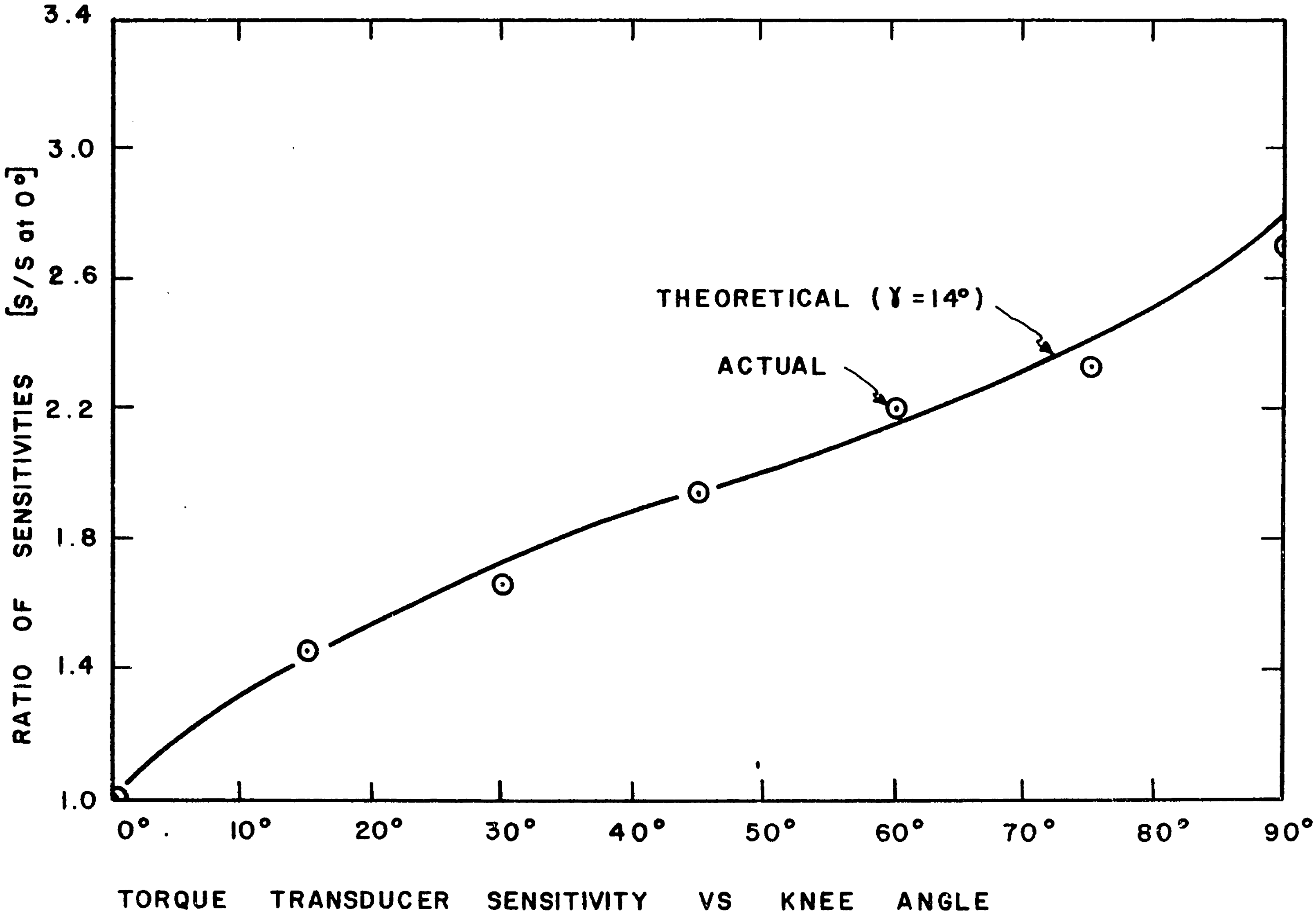
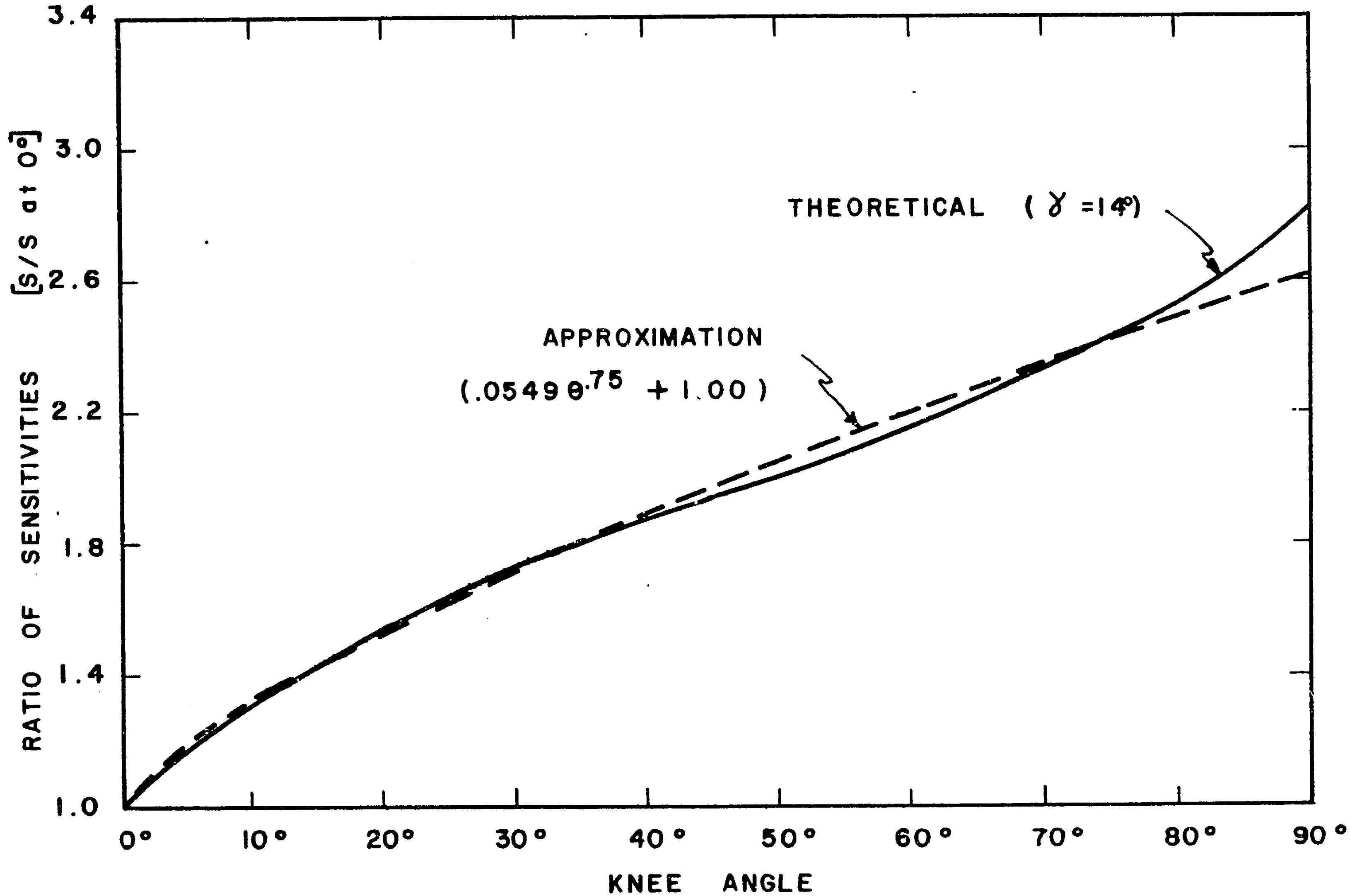

3.4
3.0
2.6
2.2
1.8
1.4
1.0
RATIO OF SENSITIVITIES [S/S at 0°]
THEORETICAL (γ = 14°)
ACTUAL
0°
10°
20°
30°
40°
50°
60°
70°
80°
90°
TORQUE TRANSDUCER SENSITIVITY VS KNEE ANGLE

Figure 10



THEORETICAL TRANSDUCER SENSITIVITY AND APPROXIMATION VS KNEE ANGLE

Figure 11

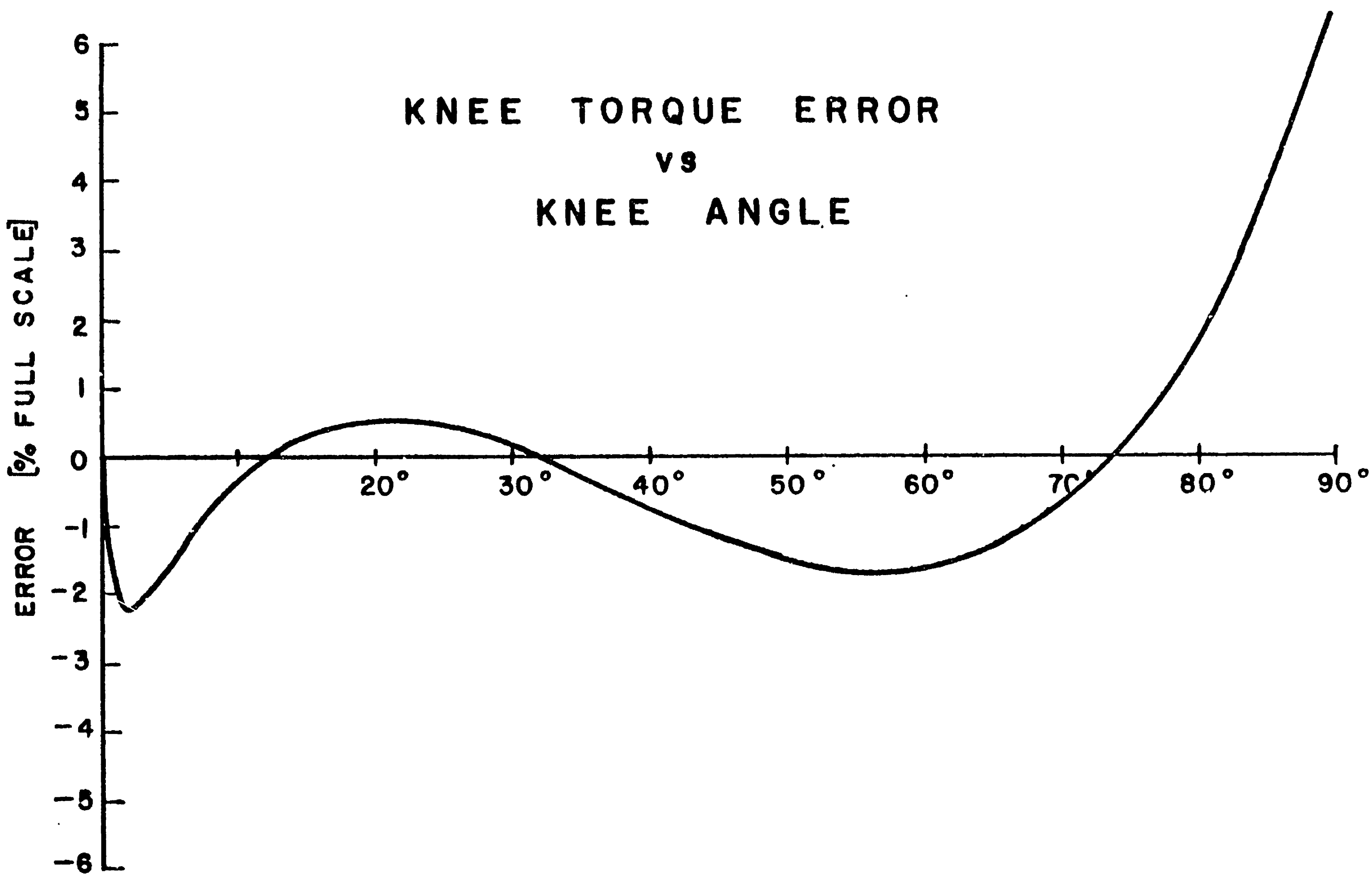

KNEE TORQUE ERROR
vs
KNEE ANGLE
ERROR [% FULL SCALE]
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
20°
30°
40°
50°
60°
70°
80°
90°

Figure 12

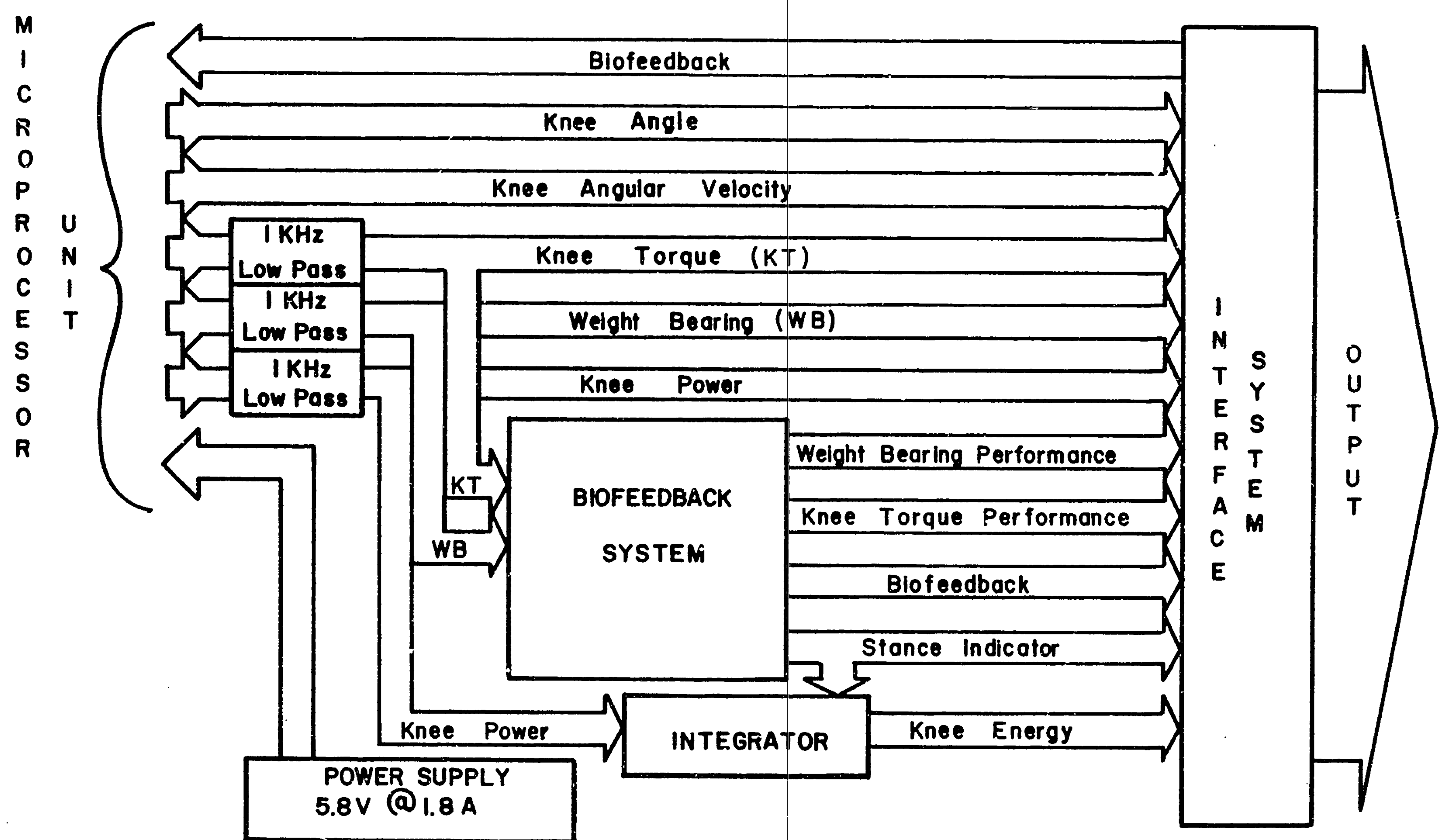
power dissipation signal in addition to the corrected knee torque.

Knowledge of the error of the approximation as a function of angle is important in the consideration of the errors incurred in the knee dissipated power and energy signals, since these usually occur in well defined ranges of swing. Finally, D is also an unknown but its effect is purely linear and under 5%. This was compensated by a simple gain adjustment. The accuracy of the completed transducer was ±3% up to 40 foot pounds, and in the range of -3 to +80 degrees. The instrumentation amplifier and the strain gage bridge are shown in Appendix A. The amplifier is identical in form to that of the load cell and was mounted on the base of the lever arm.

With this system, it was possible to measure the prosthesis weight bearing, knee torque, and knee power as well as knee angular velocity and position. These are the five signals used as input to the MIT Knee Interface/Biofeedback System (IBS), which was built to address some of the other potential problems of the immediate post-operative amputee.

2.2.3 The MIT Knee Interface/Biofeedback System

The function of the Interface/Biofeedback System (IBS) is to relay gait information to external devices while providing biofeedback to the amputee. The system is illustrated in figures 13 and 14. Appendix C contains the schematics of the electronics.



BLOCK DIAGRAM OF THE MIT KNEE INTERFACE-BIOFEEDBACK SYSTEM

Figure 13

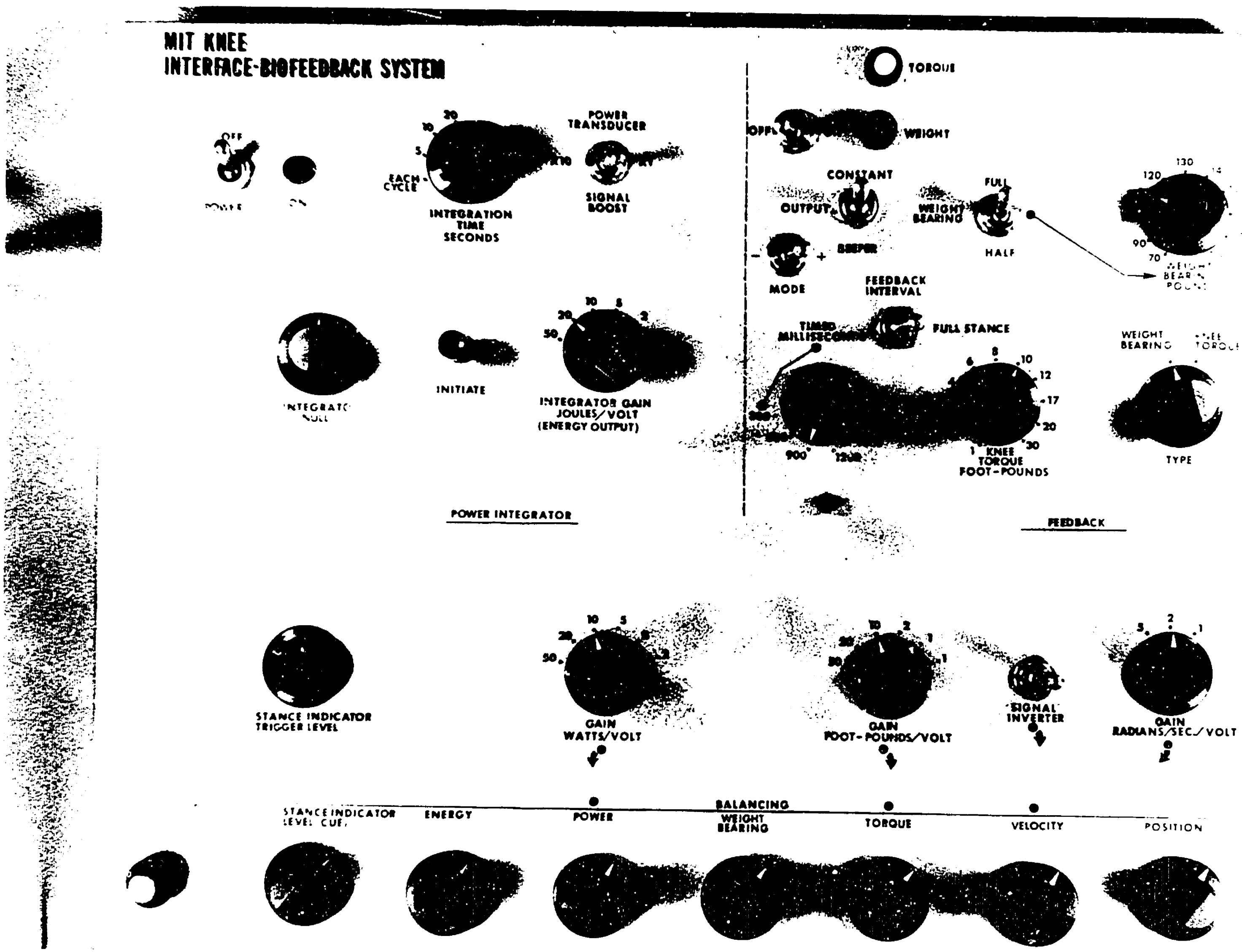


Figure 14. The MIT Knee Interface/Biofeedback System.

It has ten outputs, six of which are for analog signals and four are for logic signals. The analog outputs are for knee angular velocity and position, knee torque, prosthesis weight bearing, and the power and energy dissipated at the knee. The logic outputs are for a stance indicator, knee torque and weight bearing performance signals, and the biofeedback output; these are generated by the biofeedback system, as indicated in figure 13. The performance signals are high (+15V) when the levels of knee torque or prosthesis weight bearing are above the levels determined by the feedback system (figure 14, upper right). The stance indicator is high when more than one pound is applied to the load cell. The biofeedback output is controlled by the feedback mode controls (figure 14, upper right).

The knee energy output is derived from a power integrator circuit in the IBS. This circuit is designed for a wide range of input levels, and is controlled by a timing circuit which zeros it at heal strike. The integrator timing system can be set to indicate the energy dissipated per cycle or per unit time, as shown in figure 14, upper left. Also shown are the manual initiate or rezero button, a null dial, and a 10X input signal booster switch. For amputees who dissipate very little energy, the boost switch is used to obtain greater accuracy of the integrator. When it is on, all integrator output gains are multiplied by 10.0 (i.e., 2W/V to .2W/V). Figure 15 shows four of the ten outputs for the IBS, which demonstrates the operation of the integrator while in the "per cycle" mode.

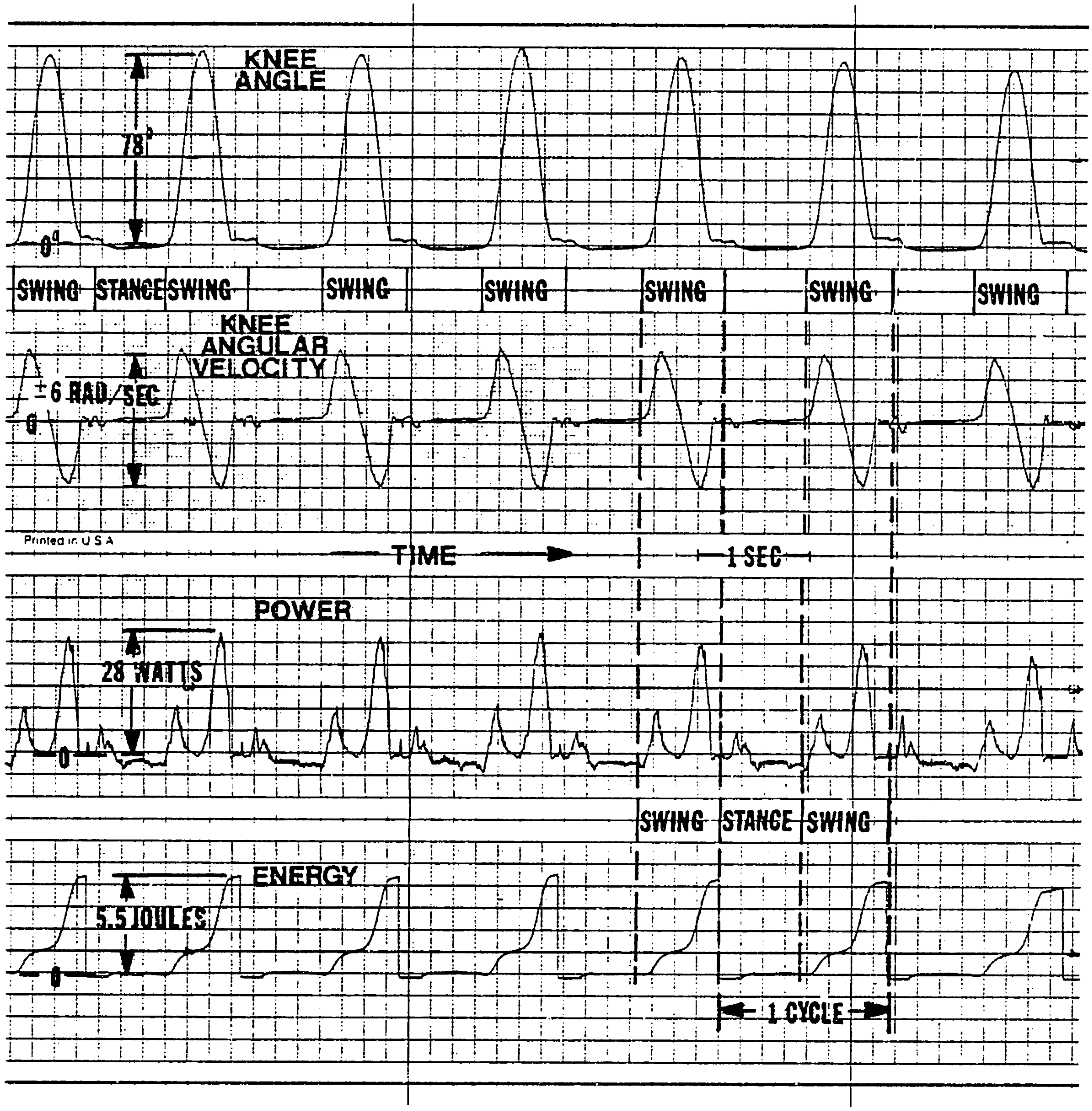


Figure 15. Operation of the Knee Power Integrator.

The power signal, for this experienced amputee, shows dissipative peaks in flexion and extension, corresponding to swing phase damping. The energy signal is observed to return to zero at heal strike and increases again during the next gait cycle. Due to an undetected equipment failure, after this data was obtained estimations of knee power and energy dissipation are not available for the immediate post-operative amputees. Figure 16 shows the two other analog outputs, knee torque and prosthesis weight bearing for the same amputee. Note the large knee torque and full prosthesis weight bearing which this 120 pound subject applies.

Figure 17 shows an example of the logic outputs during knee torque feedback. The stance indicator is high from heal strike to toe off ($\pm$5 milliseconds); and the feedback signal is high when the amputee exceeds 20 foot-pounds. Since the feedback mode was set to positive/full stance, the knee torque performance signal (not shown) is identical to the feedback signal.

The feedback mode options are designed to provide versatility for the physical therapist with a minimum of controls. Shown in the upper right of figure 14 is the feedback system. The "beeper" option allows use of a 100 millisecond beep at the feedback level rather than a constant output as shown in figure 17. This may be useful if the constant feedback becomes annoying. The "mode sign" option allows use of positive or negative feedback, as immediate post-operative amputees may get frustrated if the feedback is always negative for a

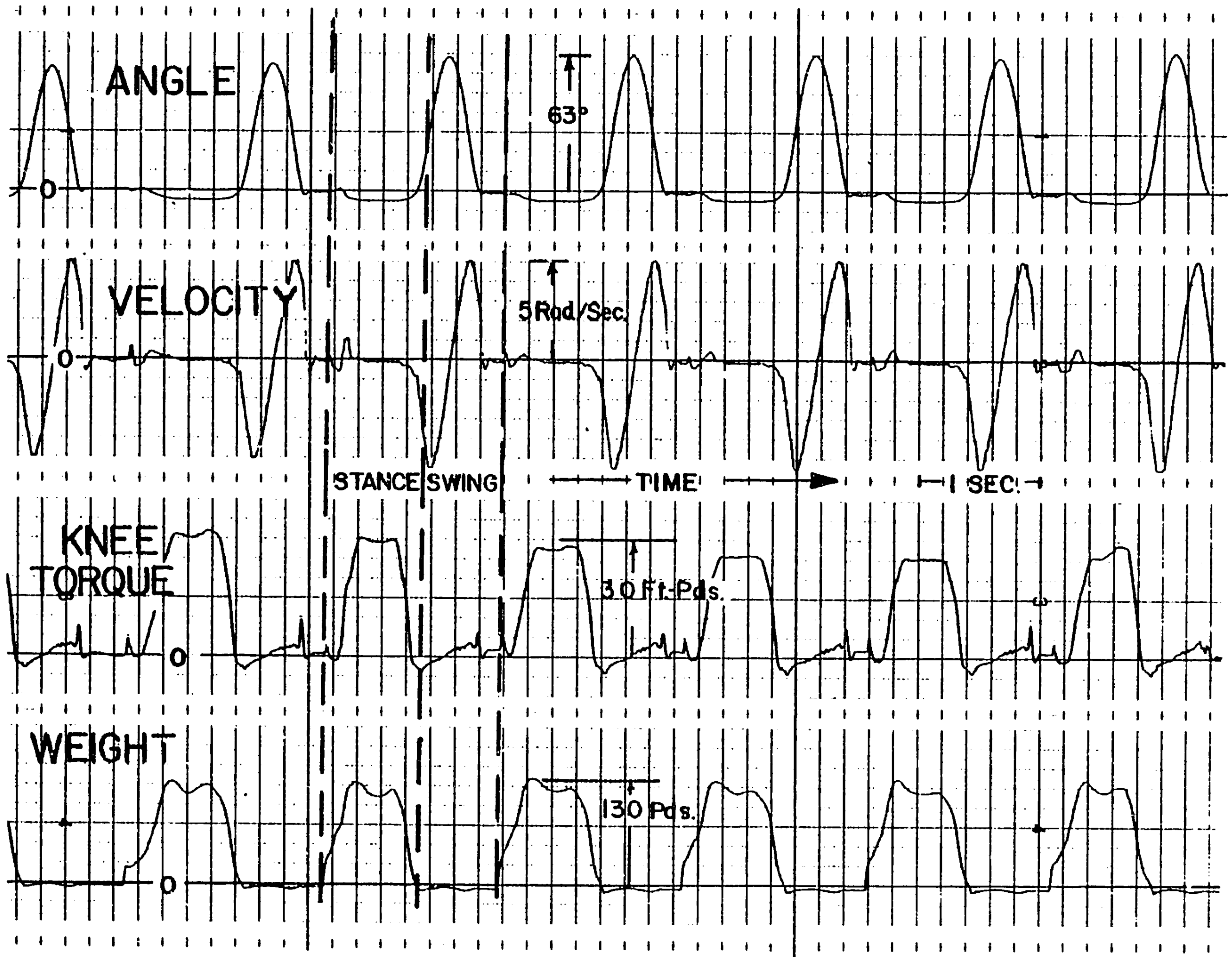


Figure 16. Recordings of the Gait of an Experienced Amputee.

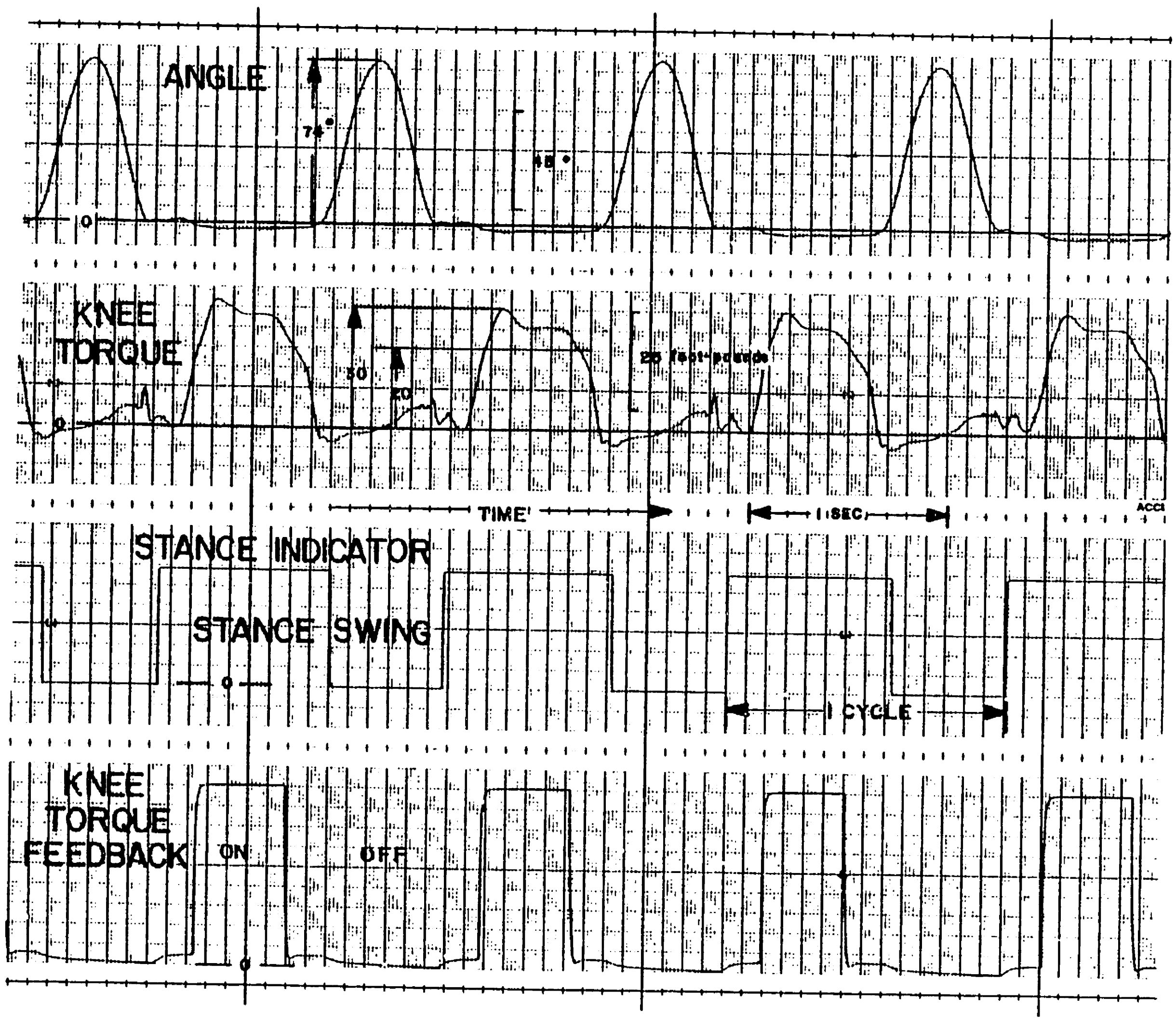
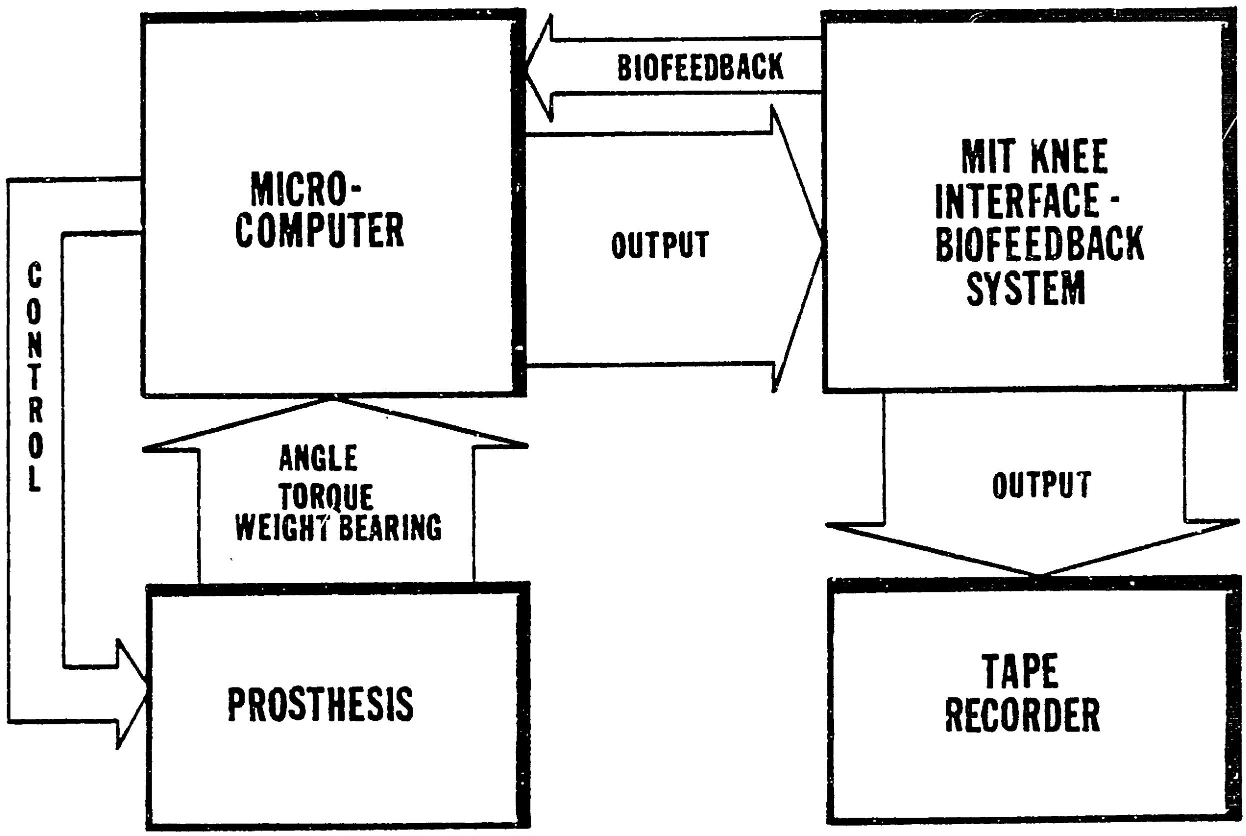


Figure 17. The Use of Knee Torque Biofeedback.

difficult task. Timed feedback allows manipulation of the feedback interval. When selected, a specified amount of time beginning at heal strike is used as the feedback interval. This option was included to provide a means of bringing about prompt initiation of locking knee torque and prosthesis weight bearing in stance. The last option allows one to select half of the weight level set by the system as feedback. In early weight bearing training, a physical therapist may wish to have the patient apply half of their weight to the prosthesis. This option also extends the lower range of possible feedback levels. Auditory feedback was chosen for its simplicity. A constant tone 5KHz sonalert was used. As indicated in figure 17, the amputee heard a 5KHz tone whenever the biofeedback output was high. This output, however, was made to drive a variety of transducers with 5VDC at 100 ma.

The physical therapist is also provided with an estimate of patient performance, regardless of whether the feedback system is turned on. This is done by the two indicator lights on the IBS. They constantly indicate the status of the knee torque and weight bearing performance signals. In this way the therapist knows whether the patient is above or below the levels she/he selected.

This modified training system was designed to help approach some of the problems in the rehabilitation process which occur in both swing and stance phases. The overall signal flow diagram is shown in figure 18. The biofeedback output goes to both an external device and the microcomputer, which is closest to the patient. The IBS connects to the microcomputer



THE MIT KNEE GAIT TRAINING SYSTEM

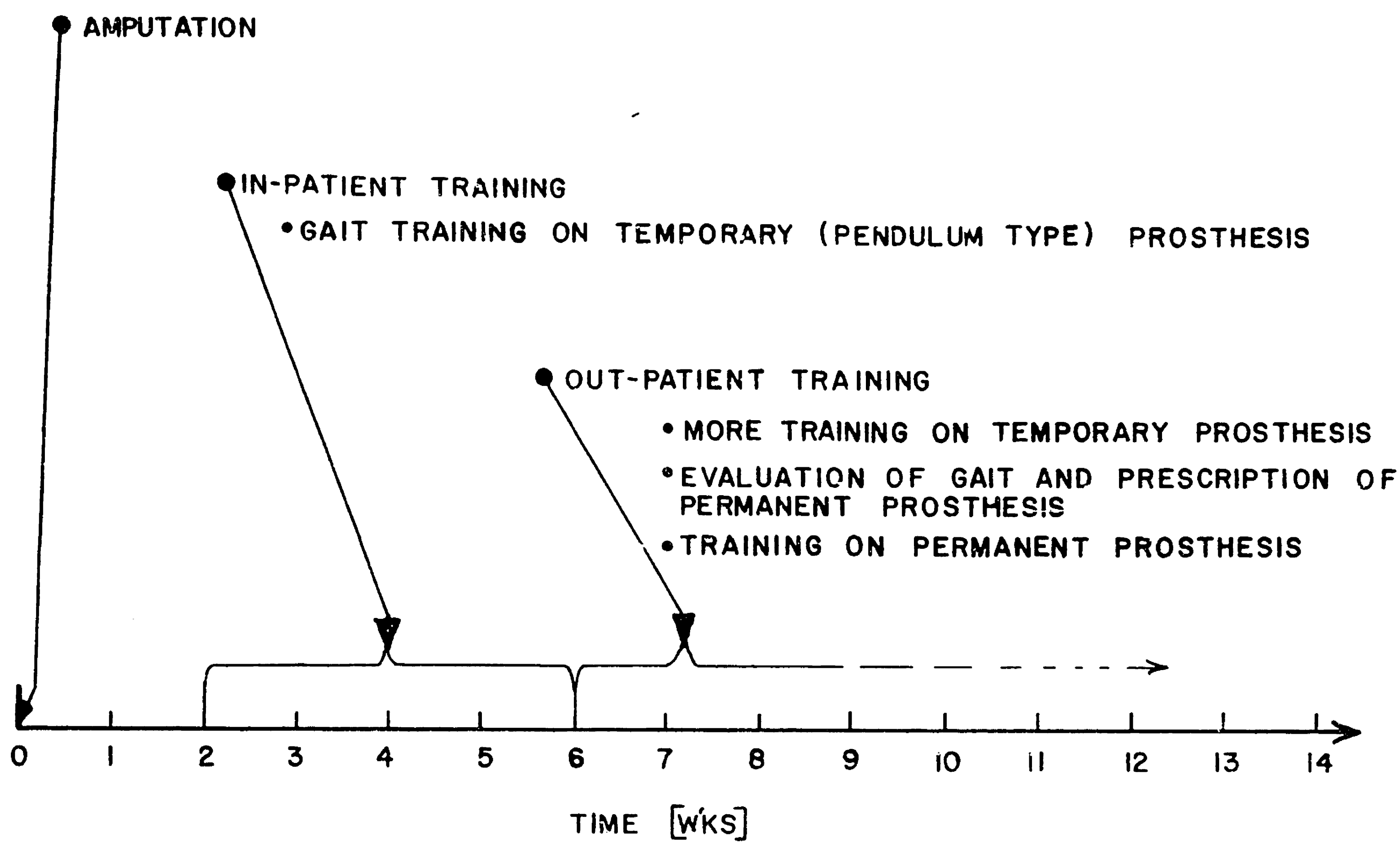
Figure 18

via a lightweight 35 foot umbilical cord which can be disconnected when no feedback or gait analysis is needed. The output device shown here is a 14 channel tape recorder which could be replaced by a minicomputer capable of on-line gait analysis.

3.0 Methods

It is important to try to design an experimental protocol to fit the conventional protocol for early gait training. An approximate time table for conventional training is shown in figure 19. The time spent in each stage is somewhat a function of age. Figure 19 shows approximate times for geriatric amputees which can still vary considerably.

Immediately after amputation, a plaster cast with a prosthetic coupling is placed around the stump. This protects it and facilitates limited weight bearing via a rigid pylon. About ten days after amputation, the cast is removed and a theroplastic temporary socket is made. It is ready to be used in two or three days. Within the first few weeks, the amputee undergoes very little gait training besides possibly bearing some weight on the pylon with the aid of crutches. For geriatric patients, actual inpatient gait training begins after this two-week period and lasts roughly four weeks. It can, however, be as short as one week or longer than six weeks. The amputee is initially placed between parallel bars with a locked pylon. They then practice shifting weight to the locked prosthesis under the direction of the physical therapist. Weight is shifted in a medial-lateral fashion and later in an anterior-posterior direction. Eventually, the therapist begins to coach the patient to place much of her/his weight on the pylon. After this, the amputee is told to "walk" on the locked pylon while shifting weight to the prosthesis in stance. Eventually, the pylon is unlocked and learning control



CONVENTIONAL REHABILITATION OF A/K AMPUTEES

Figure 19

of an articulated prosthesis begins. The amputee must now learn to control an undamped pendulum with a natural frequency which makes it operate best at only one walking speed.

During this learning process, the stump undergoes dimensional changes which affects the socket fit. The reduction in stump size is continually compensated by addition of stump "socks" or socket modification. At this time the patient is seen about twice a day for training in level walking between the parallel bars and soon outside the bars on crutches. At this point the patients may become nervous but usually overcome their fear.

When and if the patient is considered stable enough for unsupervised walking, the therapist encourages them to be more mobile on the hospital floor. This adds 1/2 to 3 hours of ambulation to the 1 to 2 hours of training daily. At some point the patient is considered able to leave the hospital after which she/he is seen as an outpatient twice a week for gait training.

During this period, the physical therapist tries to reinforce good habits of gait while continually assessing the amputee's readiness for prescription of their permanent prosthesis. Usually the patient is seen twice a week for 2 to 6 weeks after which the frequency of visits decline in accordance with progress. Prescription of the permanent prosthesis occurs during this period.

There are a number of prosthetic devices available with a variety of characteristics. Some provide mainly swing phase control while others are designed specifically for promoting stance stability. The factors taken into account in the conventional assessment process are:

1. Age.
2. Present mobility on the temporary prosthesis, potential for future mobility, and the presence of disease processes effecting either.
3. Economic factors.

The older a patient is, the more likely they are to receive a "safety" knee unit rather than a hydraulically damped one. The trade off in many cases is added stance phase stability for less appropriate swing phase control. The major emphasis is on stance phase stability for those who are unstable and have little potential for active ambulation. In contrast, amputees who show signs of activity or potential activity and have learned to control a prosthesis in stance and swing phases, are likely to receive a hydraulically or pneumatically damped swing phase controller.

The question of mobility is partly taken into account with age. However, other factors such as multiple injuries, disease processes or treatments may affect gait permanently or transiently.

Finally, economics play a role in the selection process, as the most equitable solution is sought. Coupled with the limited information available regarding future performance, this at times may result in the prescription of a knee unit which will later be replaced by a more appropriate swing phase controller.

Note that this entire evaluation process conventionally involves assessment of the patient's mobility on a pendulum type prosthesis with characteristics, most often completely unlike their future permanent prosthesis.

The research protocols were designed to fit into the process described. A two-phase approach was considered best.

3.1 The Phase One Protocol

The objectives in this initial fourteen-month period were to use the original MIT Knee to train inpatients in order to:

1. understand whether versatile swing phase dynamics control provides advantages over the use of the conventional pylon and specifically whether the MIT Knee facilitates a more gradual transition between locked and articulated prosthesis;
2. define the major problems of the immediate post-operative above-knee amputee, and assess the ability of the conventional and experimental training programs to address them;
3. acquire a knowledge of conventional inpatient and outpatient gait training protocol in order to propose training methods and design criteria for the next generation MIT Knee;
4. design and build equipment to address the major problems associated with early training.

3.2 The Phase Two Protocol

The emphasis here was on assessing the effects of biofeedback and quantitative gait analysis on the rehabilitation of the patient. Further, more emphasis was placed on stance phase control. Patients entered the program as before, about two weeks after the amputation of their leg. Before the training program began, consideration was given to the type and level of feedback to be initially used. Later, changes were made in response to the progress of the patient.

The objectives of this second, four-month phase were to:

1. assess the effect of feedback upon the performance of the patient;
2. determine whether the present form of feedback provides the physical therapist as well as the patient with useful information, and to provide insight into the development of more user transparent forms of feedback;
3. demonstrate the use of quantitative gait analysis during the early training of the amputee;
4. provide information regarding design criteria and a training protocol for future biofeedback/gait analysis systems.

The basic protocol for the initial training session involved using hyperextensive (locking) knee torque feedback at low levels. This was done to bring about prosthetic knee stability before ·eight was applied to the prosthesis. The patient, then, gains confidence in her/his ability to lock the knee before prosthesis weight bearing begins.

Progress, an understanding of goals, and other practical circumstances determined which type and what level of feedback was used in future sessions. An example of other circumstances would be poor healing of the stump, which makes prosthesis weight bearing difficult.

In the task of gait assessment, the therapist is aided by the feedback signal, indicator lights, and IBS outputs. Further, she/he uses the feedback signal to aid in instruction of the patient as to the proper way in which to walk. The therapist uses the patient's ability to perform given tasks in response to feedback as an additional criteria for progress.

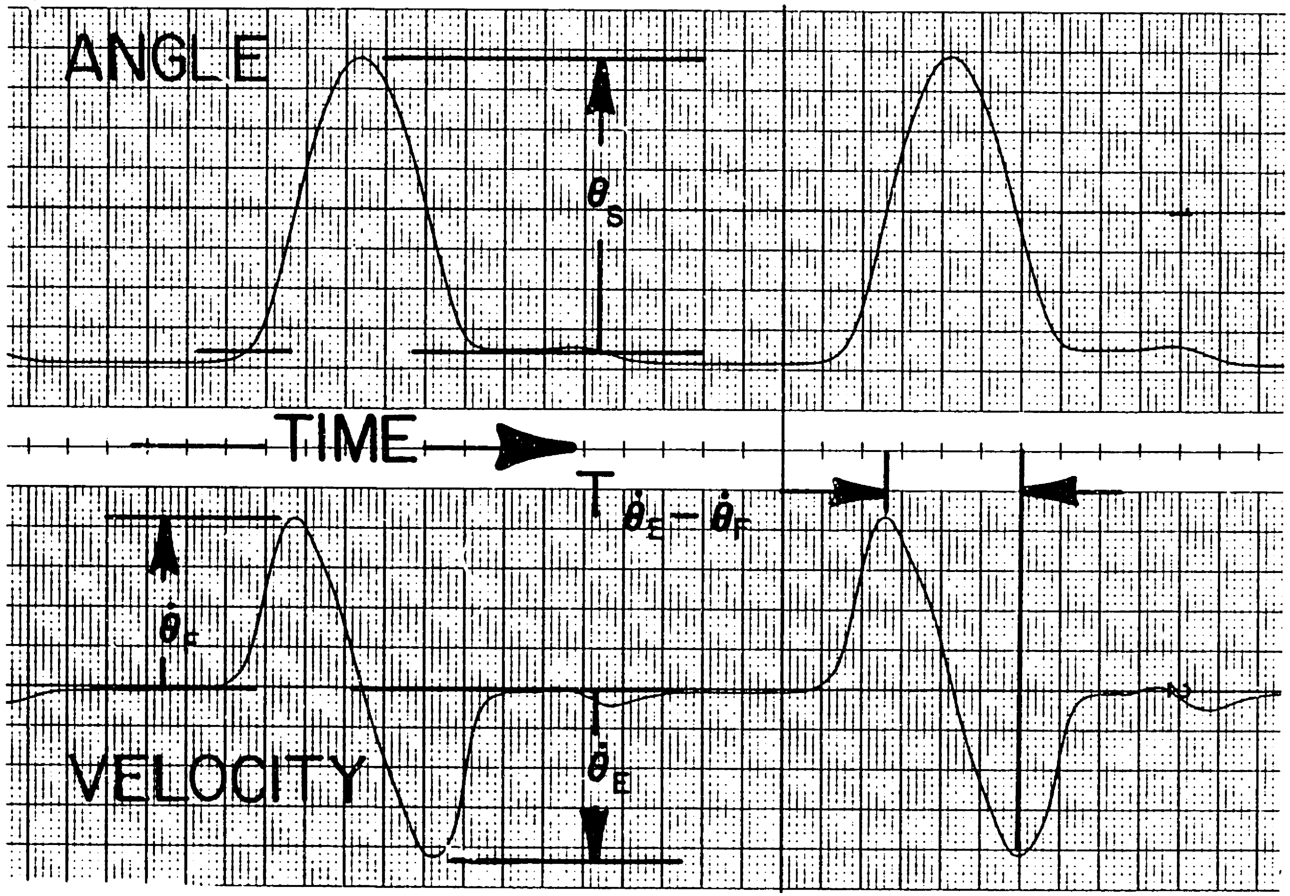
Near the time when the patient is ready to leave the hospital, the conventional pylon is used to ensure its proper use at home. The patients were followed in order to assess their progress, continue training and aid in prescription of their permanent prosthesis.

3.3 Gait Parameters

In both phases of the study, gait parameters were designed. Those used in phase one were also used in phase two. These parameters were the percent of gait cycles in which errors occurred, mean maximum swing angle, mean step frequency and the swing phase repeatability parameter (SWPRP). SWPRP is a measure of the repeatability of swing phase. It has the form:

$$\mathrm{SWPRP} = \frac{1}{\dfrac{\sigma_{\dot\theta_E}}{\overline{X}_{\dot\theta_E}} + \dfrac{\sigma_{\dot\theta_F}}{\overline{X}_{\dot\theta_F}} + \dfrac{\sigma_{\theta_S}}{\overline{X}_{\theta_S}} + \dfrac{\sigma_{T_{\dot\theta_E - \dot\theta_F}}}{\overline{X}_{T_{\dot\theta_E - \dot\theta_F}}}} \qquad (1)$$

where $\dot\theta_E$, θ_S, $\dot\theta_F$, and $T_{\dot\theta_E - \dot\theta_F}$ are defined as shown in figure 20, while σ and $\overline{X}$ are the standard deviation and mean,



DEFINITION OF QUANTITIES USED TO CALCULATE SWPRP

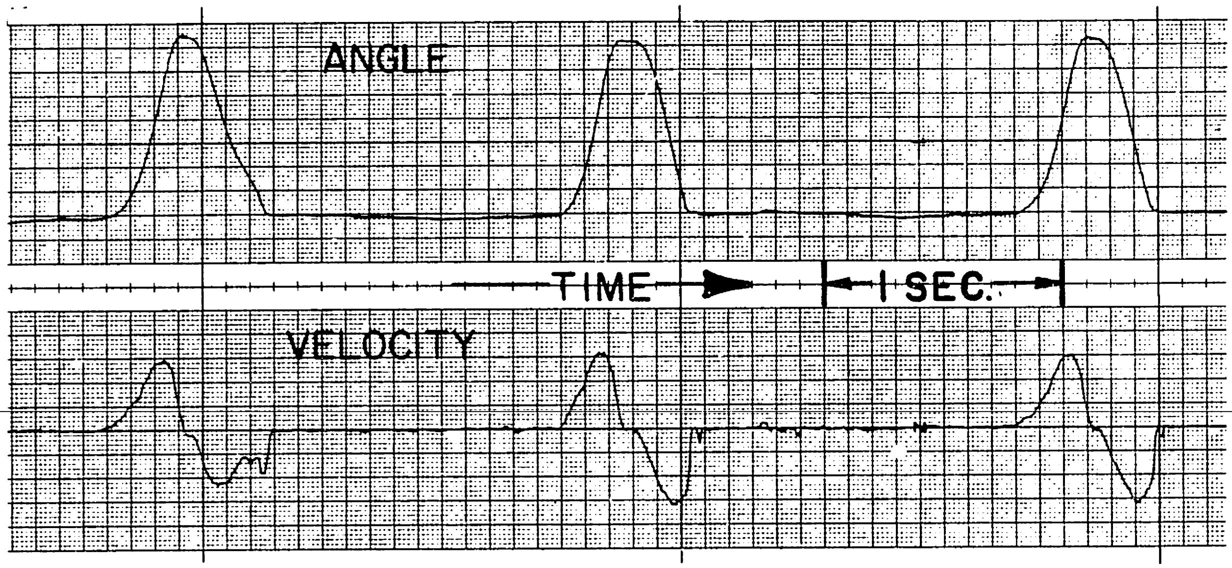
Figure 20

respectively. If the swing phases of successively observed steps are not very repeatable, the standard deviations will increase, and SWPRP will be small. If the reverse is true, SWPRP will become larger and eventually approach a level consistant with experienced amputees. For the experienced subject studied here, this parameter was about 6, while only about 2 to 3 for immediate postoperative amputees in early training. Figure 21 shows knee angular position and velocities traces comparing the two. Note the increased step frequency of the experienced amputee. Since SWPRP may have some sensitivity to changes in step frequency, measurements were made at roughly constant speed. The minimum number of steps used to calculate all of the parameters was fifty.

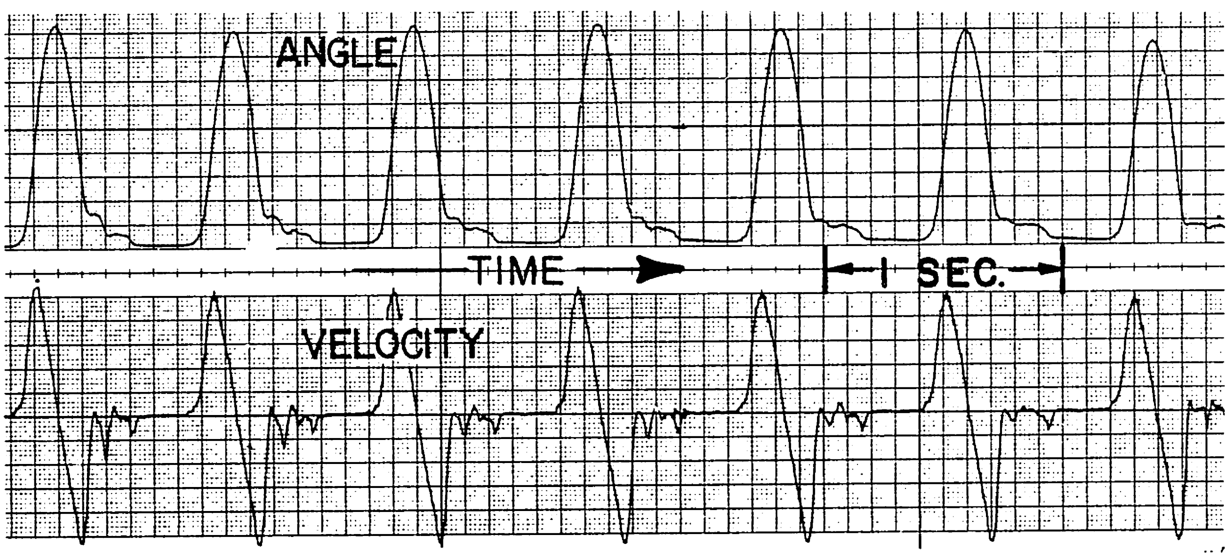
The error parameter indicates the percent gait cycles in which errors occurred in the total number observed. It has the expression:

$$\%E = \frac{\text{number of gait cycles with errors}}{\text{Total cycles observed}} \times 100\%$$

There were two types of errors defined, one for swing phase and one for stance. Either or both types occurring in a gait cycle meant it would be counted as an error. The stance error, being the most common, was defined as greater than zero knee angle during stance. This would cause buckling of the prosthetic knee. The swing phase error was defined as very low angular velocity of the knee at any point in swing phase other than at full extension or the maximum swing phase



IMMEDIATE POST-OPERATIVE AMPUTEE



EXPERIENCED AMPUTEE

COMPARATIVE KNEE ANGLE AND VELOCITY PROFILES OF IMMEDIATE POST-OPERATIVE AND EXPERIENCED AMPUTEES

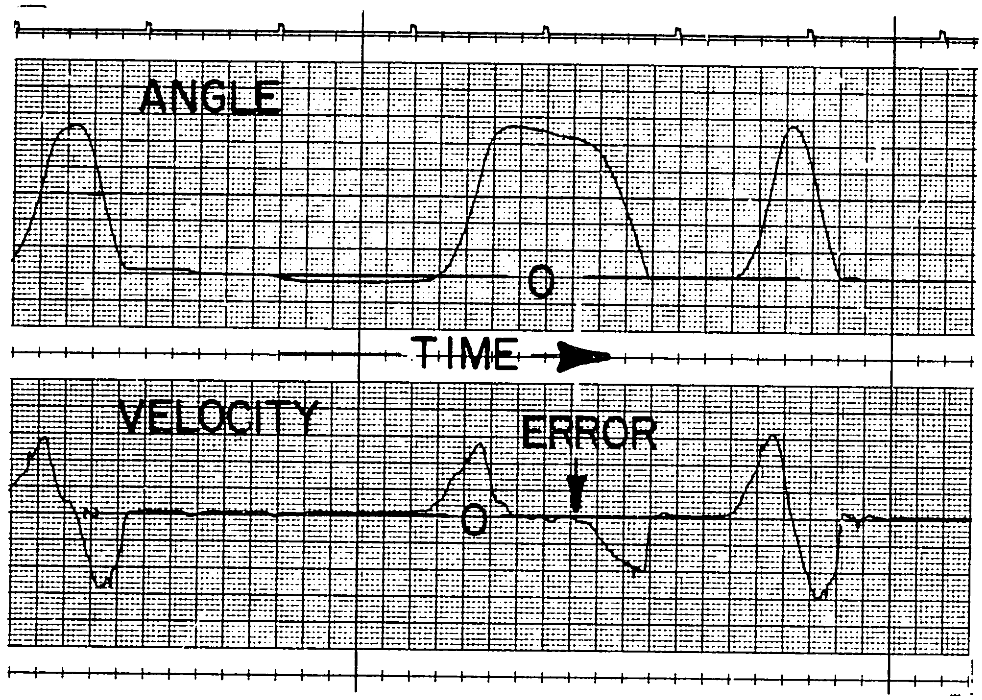
Figure 21

angle. This was due to prosthetic toe stubbing or failure to initiate swing phase. Figure 22 shows examples of these errors.

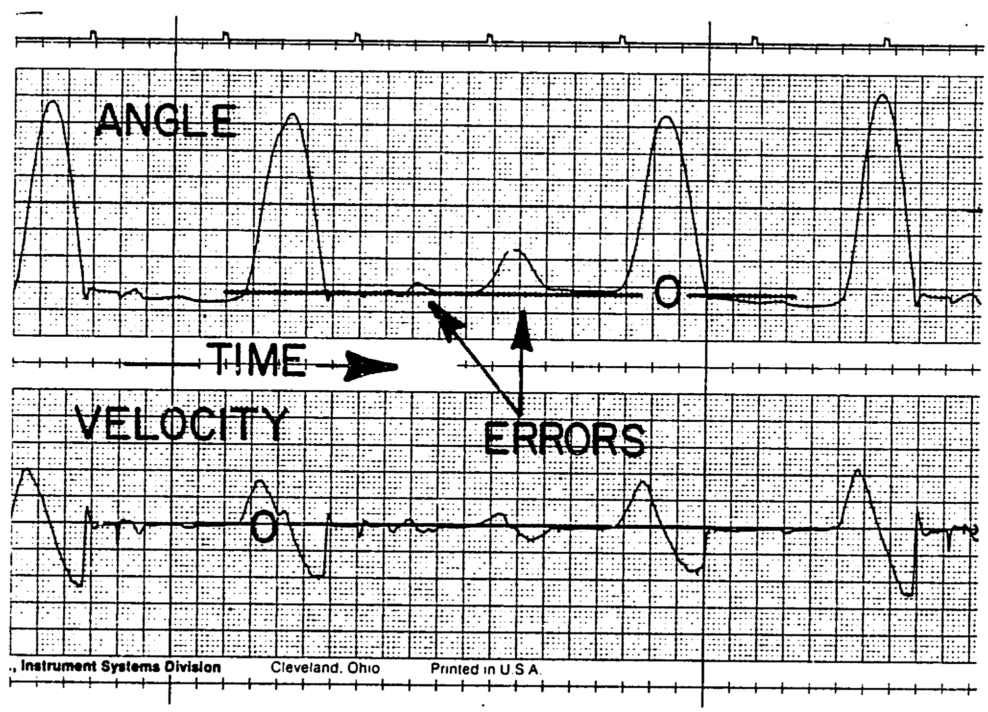
In Phase Two, additional parameters were constructed with the added signals generated by the Interface/Biofeedback System. These were a stance phase repeatability parameter (STPRP), swing/stance ratio (time), mean maximum prosthesis weight bearing, and mean maximum hyperextensive (locking) knee torque. STPRP has the following form:

$$\text{STPRP} = \frac{1}{\dfrac{\sigma_{MT}}{\bar{X}_{MT}} + \dfrac{\sigma_{MW}}{\bar{X}_{MW}}}$$

where $\bar{X}_{MT}$ and $\bar{X}_{MW}$ are the mean maximum knee torque and prosthesis weight bearing, respectively. σ_{MT} and σ_{MW} are the corresponding standard deviations. The more repeatable the application of knee torque and weight is from step to step, the higher STPRP becomes. For an experienced amputee, STPRP was about 13.5 while only 2 to 4 for an immediate post-operative amputee in early training. Figures 16 and 23 show recordings of gait comparing the two. This parameter has apparently very little sensitivity to changes in the step frequency, and was calculated from the same steps used for SWPRP. Consequently, one can observe the trends occurring in either phase of gait simultaneously. No value judgements were made in regard to these parameters, since it seemed possible to have poor but repeatable gait. STPRP and SWPRP should be thought



SWING PHASE ERROR



STANCE PHASE ERRORS

EXAMPLES OF GAIT ERRORS

Figure 22

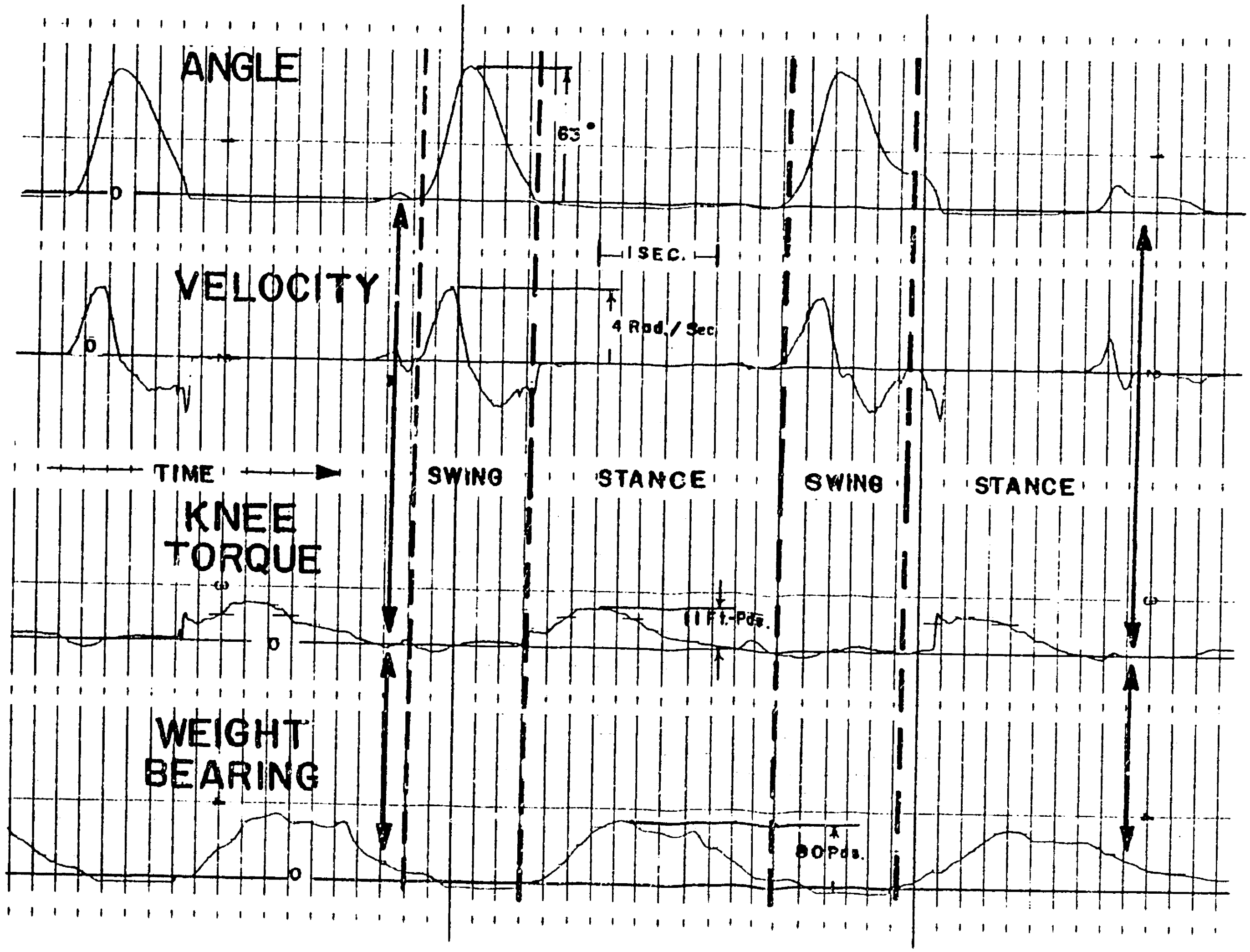


Figure 23. Recordings of the Gait of an Immediate Post-Operative Amputee.

of as indicators of the amputees relative ability to control her/his gait.

4.0 Results: Case Studies

4.1 Phase One: Use of the Swing Phase Controller

During this time, four inpatients were trained. JC was studied without the aid of recording equipment. In later studies, such equipment was available. This 21 year old male, who lost his leg due to bone cancer, had a very short stump. It was therefore difficult for him to control his prosthesis. He also underwent chemotherapy, which caused much nausia. Use of the MIT Knee improved his gait by providing customized swing phase damping, which made heal strike occur almost immediately after full extension. The conventional pylon with its inappropriately high natural frequency causes full extension to occur much earlier than heal strike. This benefit provided by the MIT Knee allowed JC to progress more rapidly though only temporarily, as the nausia caused by chemotherapy became his greatest obstacle. He was discharged from the hospital and returned to his out-of-state home. An attempt to follow him and provide more training was made, but was unsuccessful. JC used, in place of the MIT Knee, a conventional pylon shown in figure 2. He had no trouble using it since he had progressed using the MIT Knee. This lightweight pylon was particularly effective for JC because it minimized the degree to which his short, continuously shrinking stump caused the total contact socket to be ineffective.

The most important service provided to him by the MIT Knee was added ease in walking via an empirically determined damping profile of the prosthesis. This was most useful at the time when the prosthesis was initially unlocked.

When the prosthesis was unlocked, a basic damping profile was immediately used to which modifications were later made. The damping profile which was the most useful as a starting point, was that determined by Tanquary's (19) test subject, Cornell. Changes were made to this profile not only to accommodate progress, but to adapt to setbacks as well. The net effect was to "tune" the prosthesis to the rapidly varying physical ability of the patient. Figure 24a shows the damping profile used during his last inpatient session on the MIT Knee. The positions of the data points represent the slide pot positions as seen on the front of the microcomputer unit. These will be the only profiles shown, as many changes were made during inpatient training.

SY, who was 44 years old at the time of his amputation, lost his leg due to peripheral vascular disease (PVD). He also had peripheral blindness from unrelated causes. This sight deficiency often caused insecurity and anxiety, since he could not usually see the ground in front of him.

SY progressed well, as an inpatient, but it was uncertain as to whether the MIT Knee helped him since his major difficulty seemed to be his sight and nervousness. He did comment however that the noise of the knee mechanism signaled him as to when the prosthesis came to full extension. This patient was also able to go home intermittantly, making it necessary to begin training on the conventional pylon earlier than originally expected. He used the pylon very well; there was

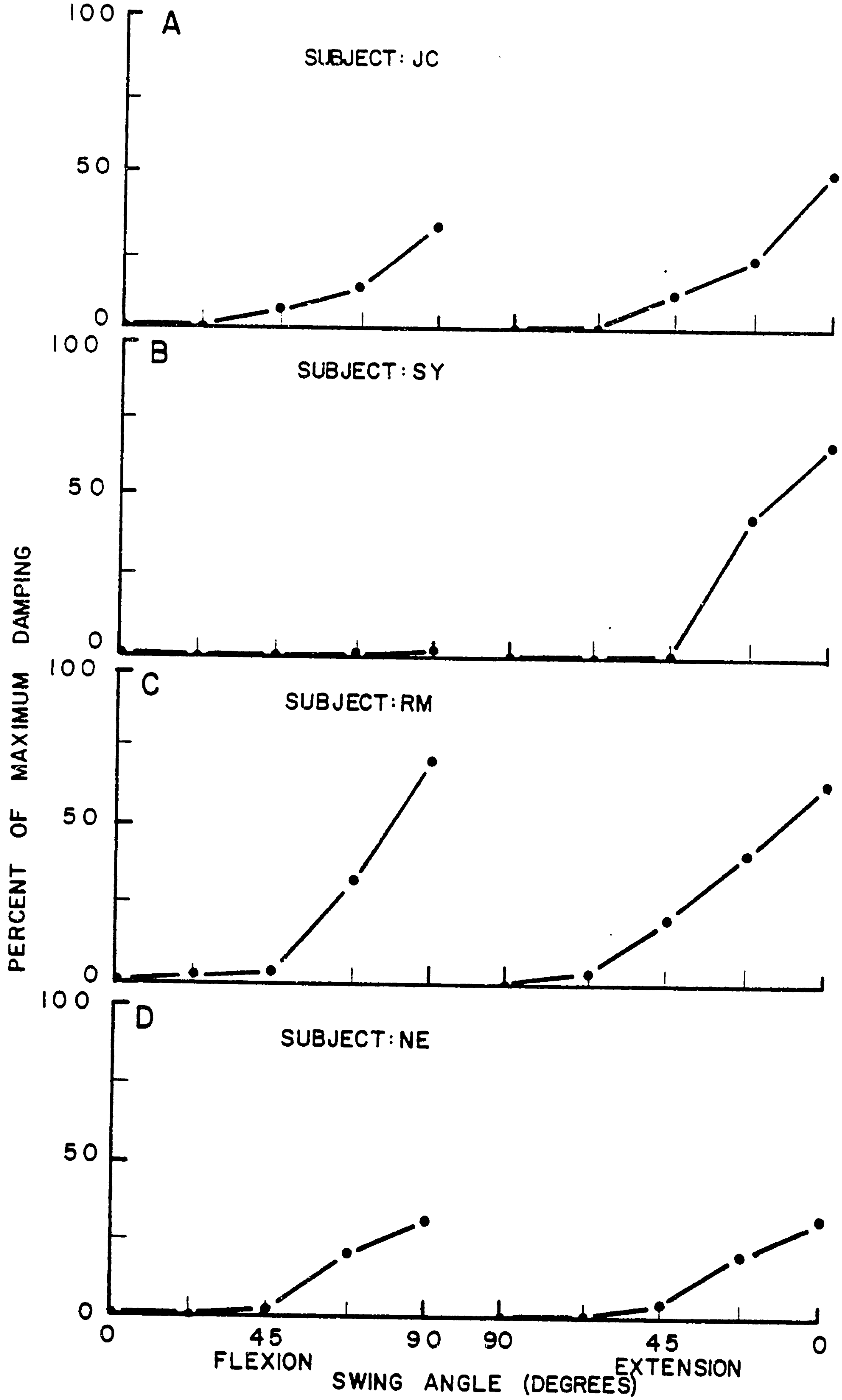
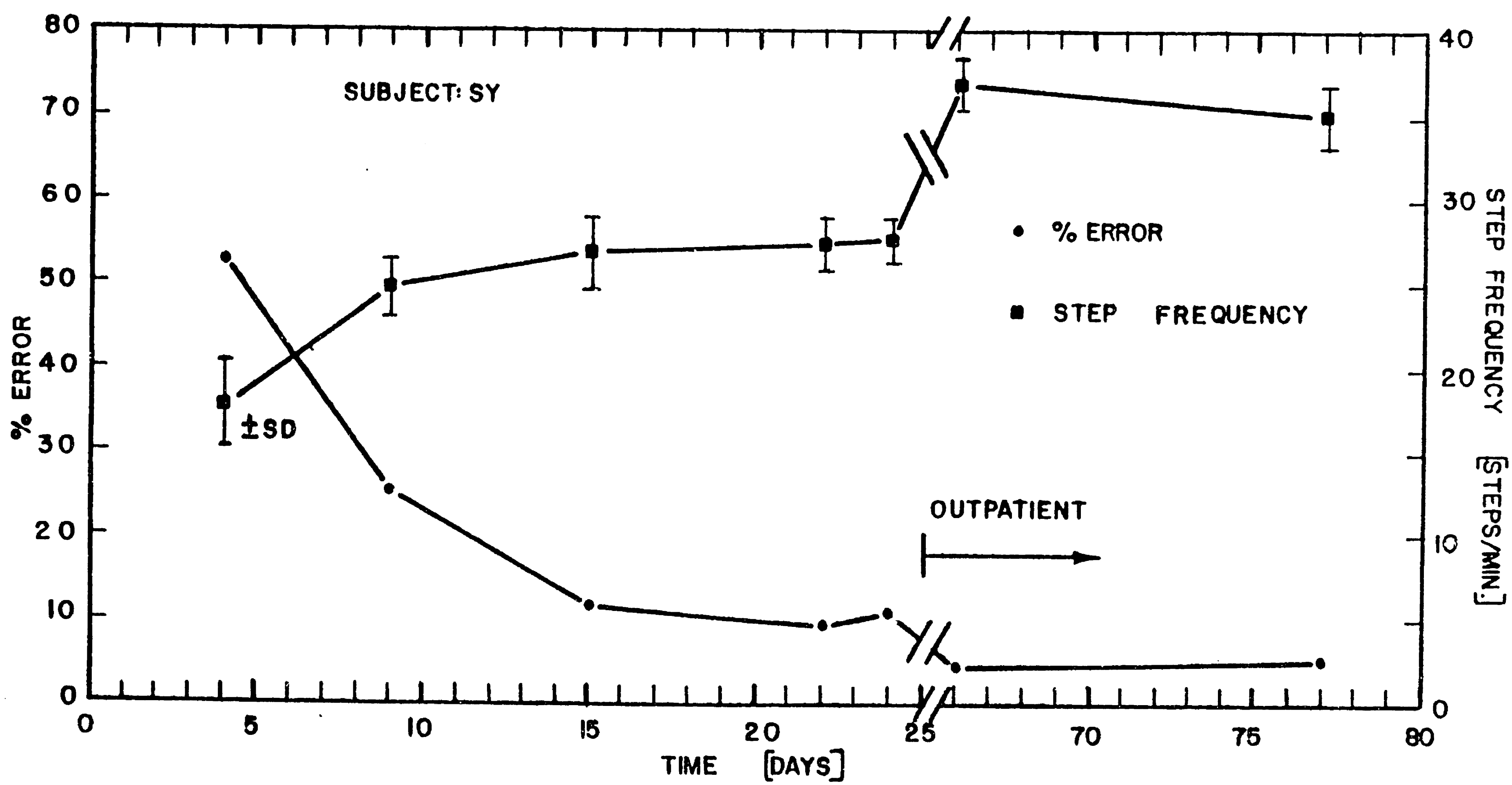


Figure 24. FINAL DAMPING PROFILES

no clear evidence to suggest that the MIT Knee helped in this respect.

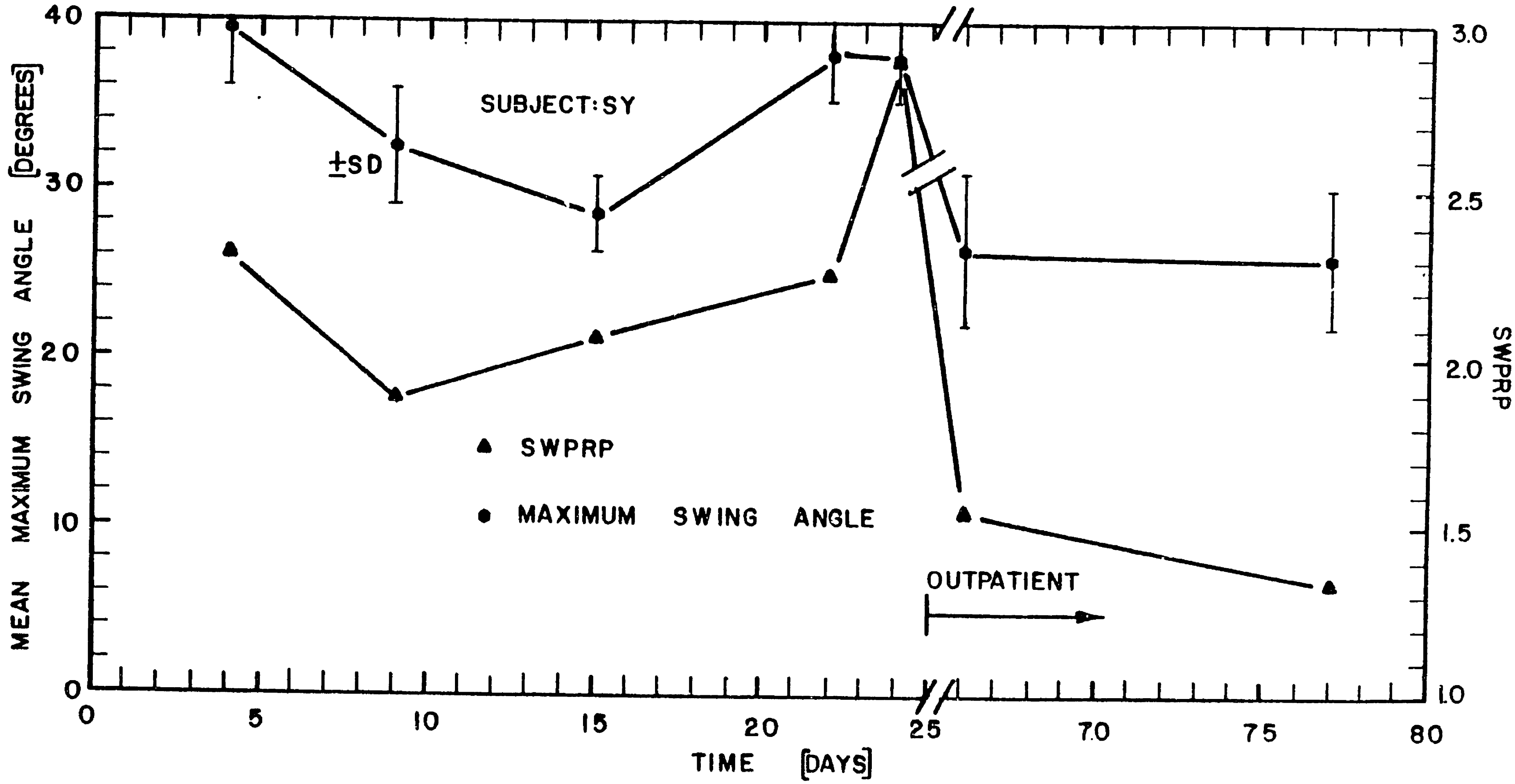
As shown in figure 25, SY steadily improved his ability to walk without errors while his step frequency steadily increased. His ability to control the swing phase portion of gait, however, always seemed to suffer from his nervousness and sight deficiency. Figure 26 shows his mean maximum swing phase angle and SWPRP versus training time. The initial decrease in SWPRP is believed to be due to his increased anxiety when taken outside of the parallel bars. During the last two inpatient sessions, an electronic goniometer was used to record SY's gait as he walked using the conventional pylon. When SY left the hospital, SWPRP decreased again, as did the maximum swing phase angle. During the two outpatient sessions shown, he wore his hydraulically damped permanent prosthesis which he had recently received.

In general, SY progressed slowly but steadily. Figure 27 shows comparitive recordings of his gait on the third and twelfth days of training while figure 24b shows his final inpatient damping profile. Whether the swing phase controller aided him in early inpatient training is unclear, as there were other factors effecting his progress. It was encouraging, however, to hear him comment that he felt more secure on his permanent prosthesis since he had training on the MIT Knee which had similar damping characteristics. The decrease in the repeatability of steps and maximum swing angle during his first few outpatient sessions correlated with the fact



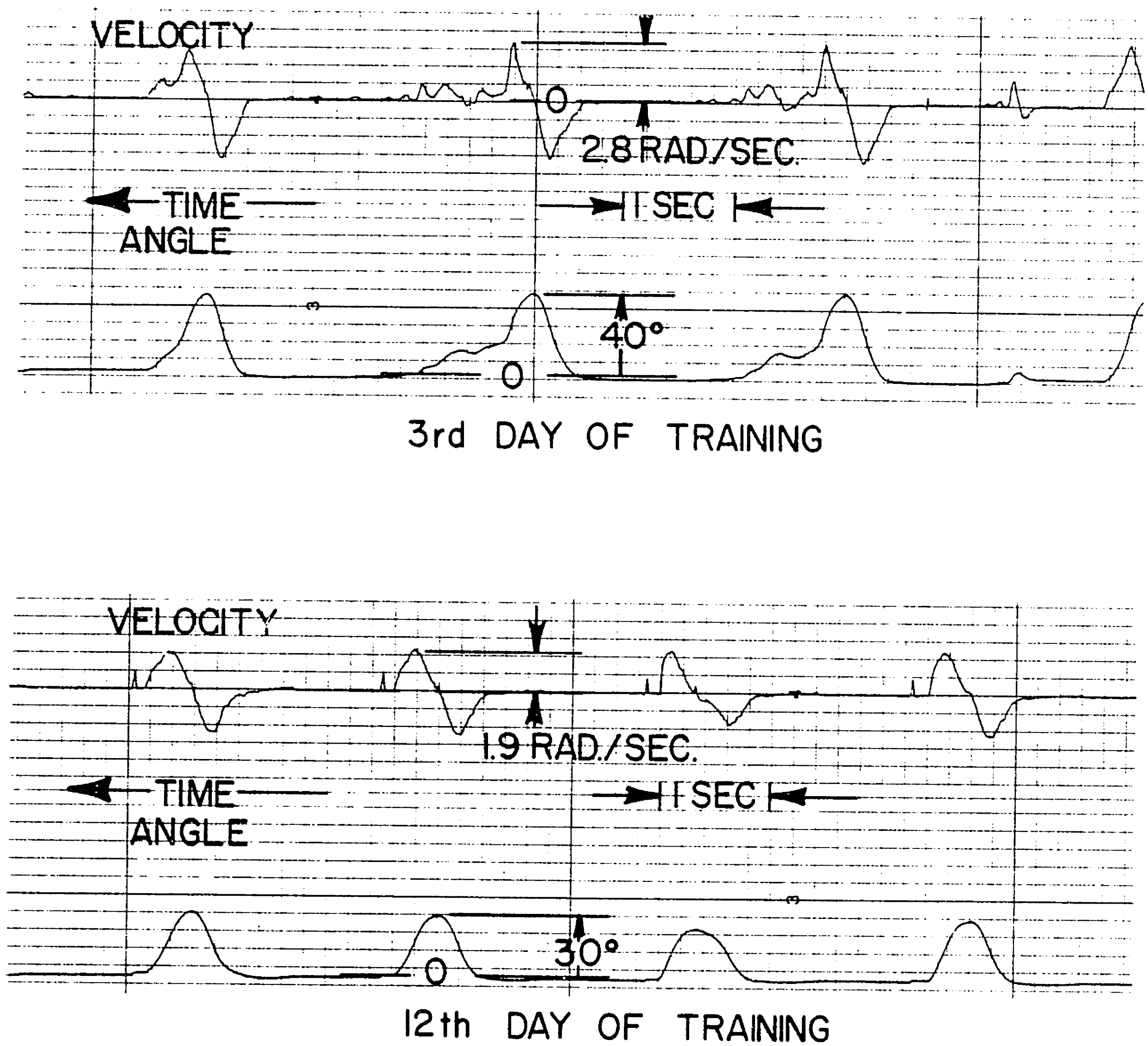
STEP FREQUENCY AND % ERROR VS TRAINING TIME

Figure 25



MEAN MAXIMUM SWING ANGLE AND SWPRP VS TRAINING TIME

Figure 26



SUBJECT: SY

Figure 27. Comparative Gait Recordings.

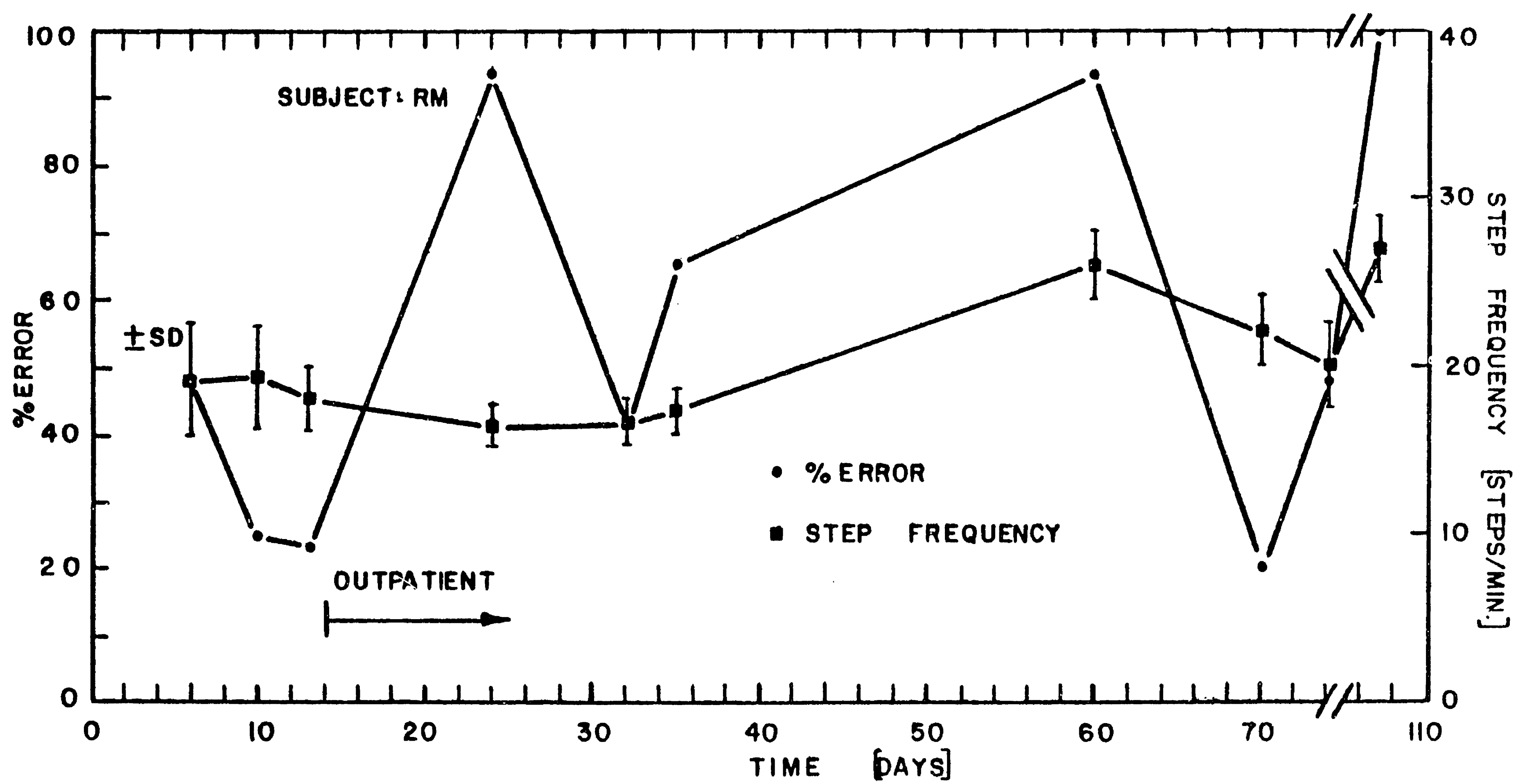
that he had just received his permanent prosthesis. This type of permanent prosthesis was chosen by the medical staff after considering SY's comments about how he liked the "feel" of the MIT Knee which was programmed to behave somewhat like a hydraulic damping unit.

The most significant services provided to SY by the swing phase controller were (a) to give him added confidence and (b) to aid in the prescription of his permanent prosthesis. The latter was significant since the staff was concerned that SY's sight deficiency might not allow him to be active enough to use a hydraulic damping unit. The added input concerning his performance while using the MIT Knee indicated that he would probably walk better using a hydraulically damped prosthesis.

RM was 68 years old when he lost his leg due to peripheral vascular disease. With RM, communication was sometimes difficult and he had a significant hip flexor contraction. His stump was of average length. He later developed circulatory problems in his other leg which eventually caused him to become a bilateral amputee.

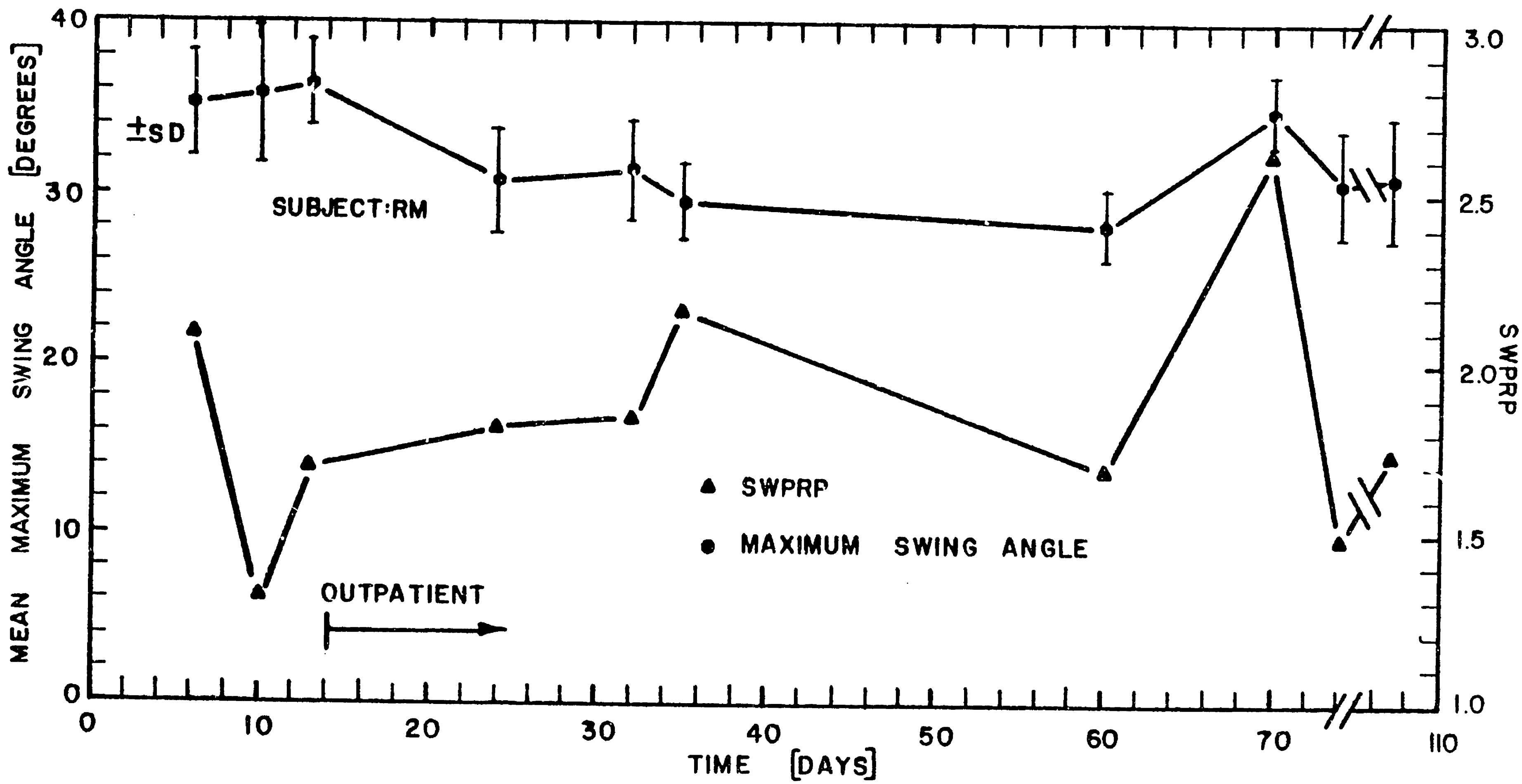
After two days of training, the MIT Knee was unlocked. During his two-week inpatient training period, the MIT Knee was continually programmed to achieve the best comfort and performance. The use of the swing phase controller definitely provided more ease in walking, as RM commented that the difference between the conventional pylon and the MIT Knee was like "the difference between a Ford and a Cadilac." Again this was apparently due to providing an optimum swing phase damping profile to match his physical ability. His gait errors almost exclusively occurred in stance. As an inpatient, then, he showed signs of intermittent knee instability. During the inpatient stay, these errors rapidly disappeared as shown in figure 28. SWPRP, however, was inconsistant, as shown in figure 29. Records of RM's gait appear in figure 30; these are from training sessions occurring toward the middle and end of his inpatient stay. His final inpatient damping profile is shown in figure 24c. Before being discharged he was given a conventional pylon, which he used very well. As an inpatient, RM progressed well considering his age and hip flexor contraction.

Soon after being discharged, however, he fell while not wearing his pylon. This prevented him from coming into the hospital for gait training for twelve days and consequently his hip flexor contraction increased. When he was able to return to the clinic, he walked poorly putting all of his weight on the crutches rather than the prosthesis. An attempt was made to help him achieve his inpatient performance again by increasing his gait training and exercise, and continuing the use of the MIT Knee since with it he walked well. As seen in figures 28 and 29, his performance remained inconsistant. The fact that the hip flexor contraction made full hip extension difficult and the lack of training while at home were major obstacles. The error rate during outpatient sessions



STEP FREQUENCY AND % ERROR VS TRAINING TIME

Figure 28



MEAN MAXIMUM SWING ANGLE AND SWPRP VS TRAINING TIME

Figure 29

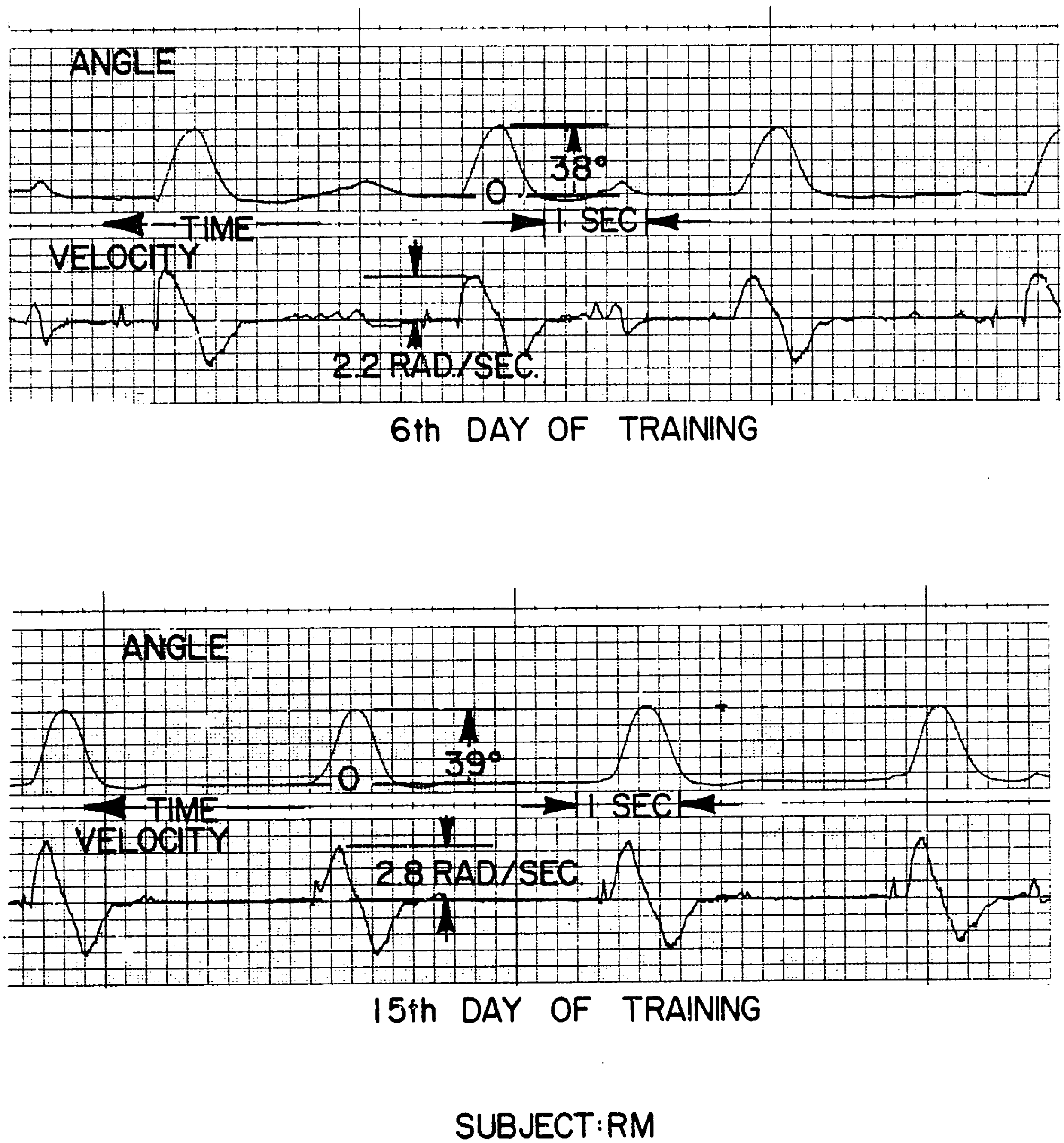


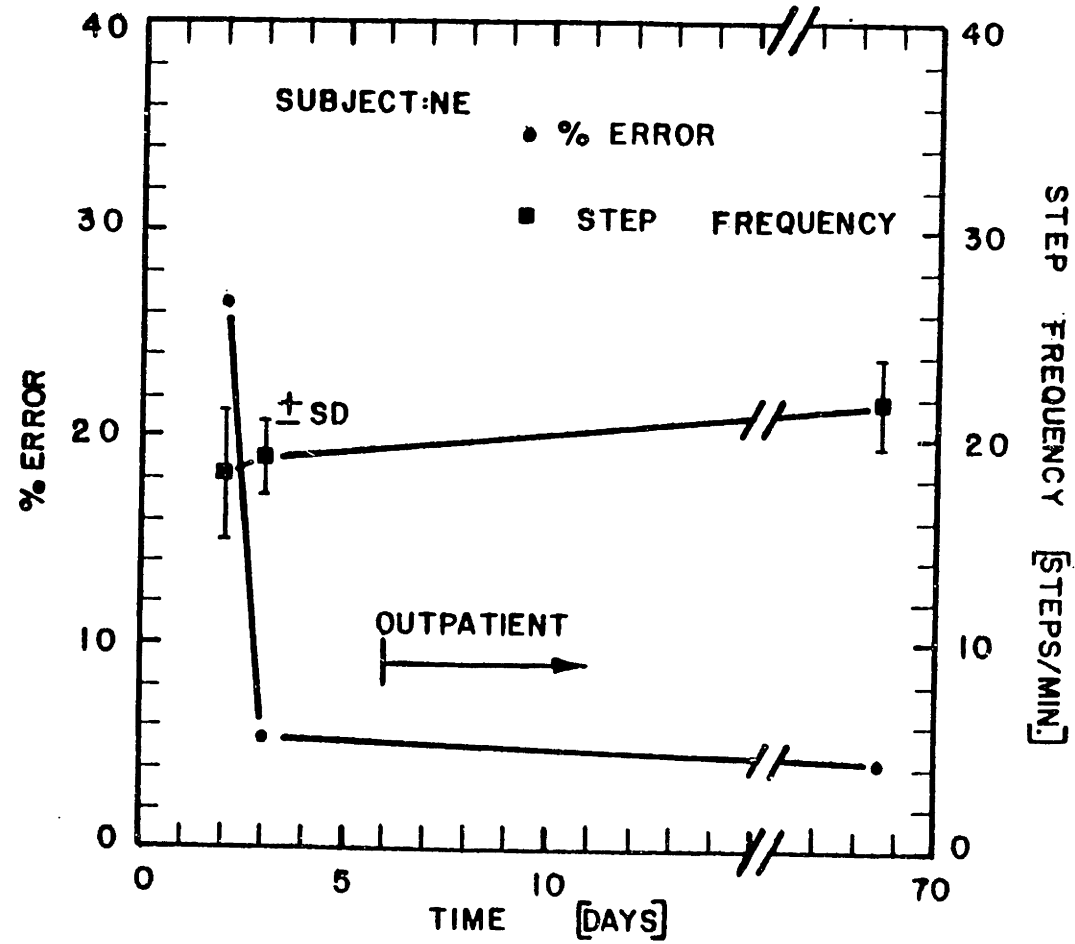
Figure 30. Comparative Gait Recordings.

was due almost exclusively to stance phase errors caused by the flexor contraction of the stump.

A safety knee was prescribed to this patient to help promote knee stability during stance. The last data points in figures 28 and 29 were recorded with an electronic goniometer while RM walked on his permanent prosthesis. As can be seen from the 100% error rate, this prosthesis did not remedy the situation.

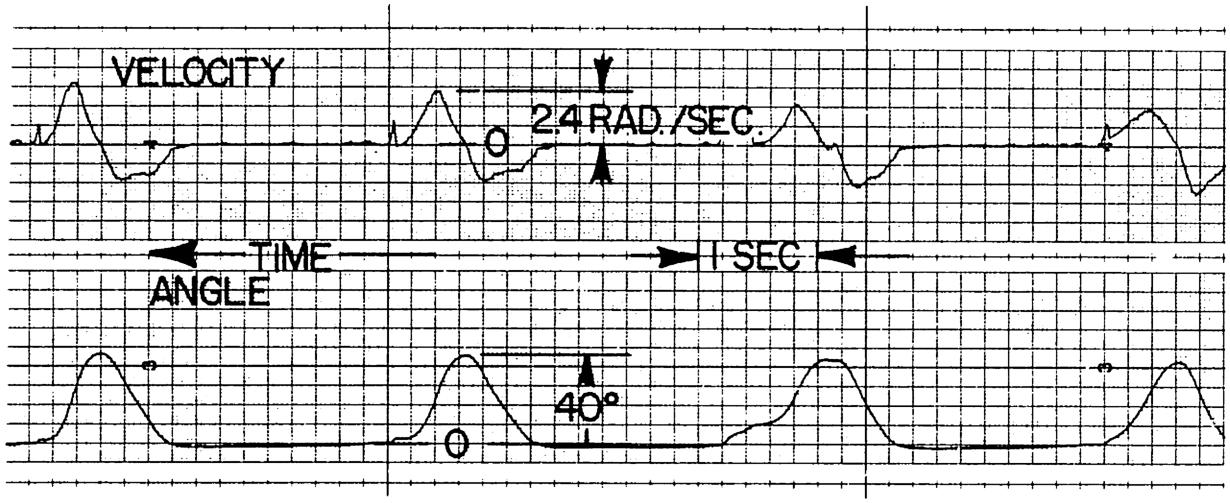
In contrast, NE, who was 55 years old at the time of her amputation, did very well. She had lost her leg due to a chronic tumor and had no other apparent complications. She weighed approximately 200 pounds. The programmable swing phase controller proved quite useful during her very short inpatient training period. NE progressed so rapidly that she was discharged one week after gait training began and was seldom seen for outpatient training.

She was very active while an inpatient and consequently the use of customized swing phase damping was particularly helpful. In four days of inpatient training, her error rate was only 5%, as shown in figure 31. Comfort was achieved by continually programming the prosthesis in response to NE's comments and the physical therapist's suggestions. Increased comfort was associated with the occurrence of heal strike just after full extension. Figure 32 shows comparative records of her gait during the second and third days of training. The heal strike artifact is seen as a small peak in the velocity

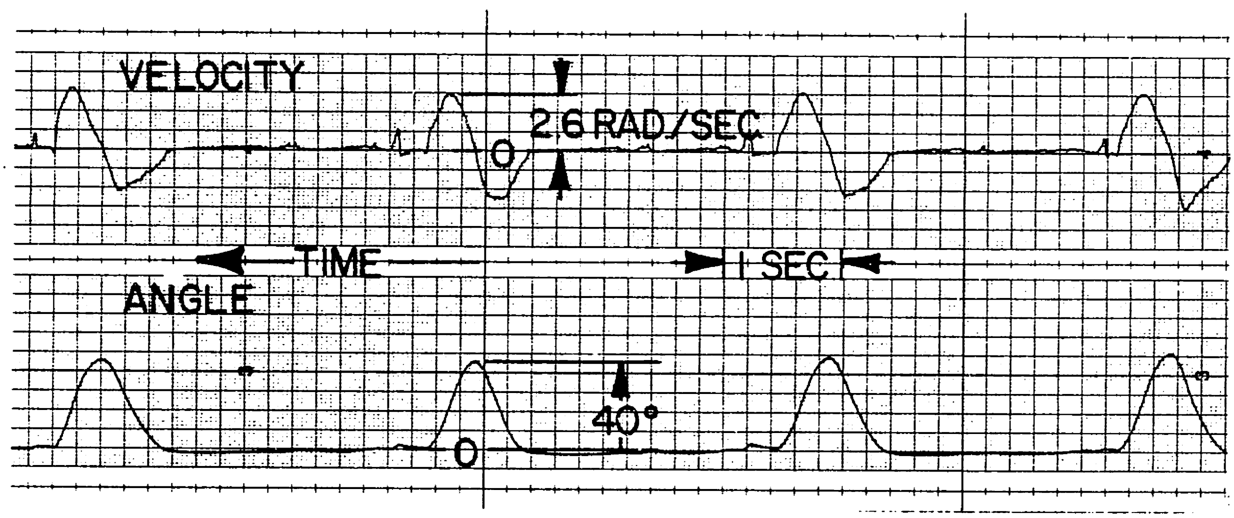


STEP FREQUENCY AND % ERROR VS TRAINING TIME

Figure 31



2nd DAY OF TRAINING



3rd DAY OF TRAINING

SUBJECT: NE

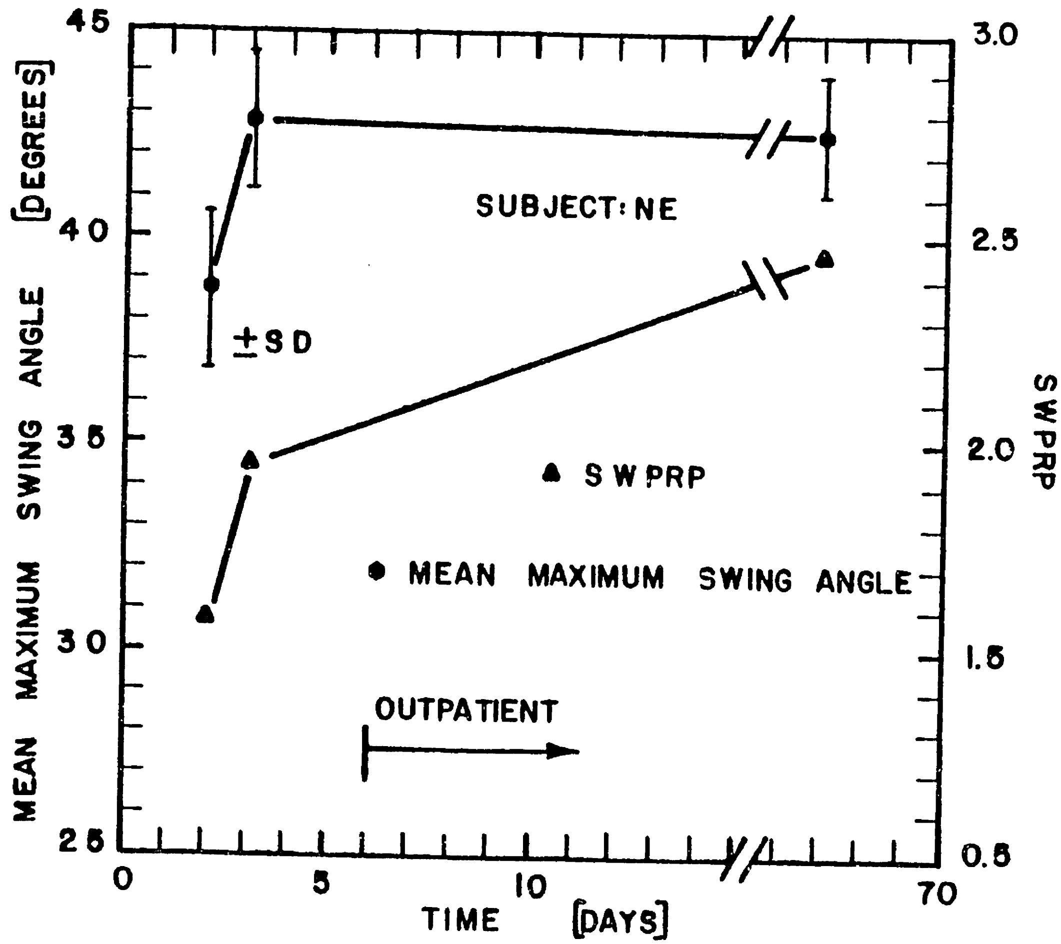
Figure 32. Comparative Gait Recordings.

trace occurring just after the prosthesis reaches full extension. In contrast, the conventional pylon had an inappropriately high natural swing frequency causing full extension to occur much earlier than heal strike.

At the end of her inpatient training she was given the conventional pylon which she used well. The pylon was always given to the patients a few sessions before they were discharged so that the staff could observe them using it.

During one of the few times NE came back to the clinic, the MIT Knee was used and the profile was adjusted for maximum comfort and performance. This was done in order to gain insight into the type of permanent prosthesis NE should receive. Her performance while using the MIT Knee during this session was far superior to that with the conventional pylon. The last data points in figures 31 and 33 are from this session. No great change occurred in her outpatient performance on the MIT Knee. There was, however, a dramatic increase in her walking speed when she used the MIT Knee instead of the pylon. The damping profile used during this final session is shown in figure 24d. This profile made the damping of the MIT Knee similar to that of a hydraulic knee unit.

With this information and NE's comments, the staff recommended prescription of a Dynaplex knee unit for her permanent prosthesis. During this time, the major benefits provided to her by the MIT Knee were added comfort and control, compensation for extremely rapid progress via continually



MEAN MAXIMUM SWING ANGLE AND SWPRP VS TRAINING TIME

Figure 33

reprogramming the controller, and aiding in the prescription of her permanent prosthesis. As the staff pointed out, NE was an exceptional case in that her short stay in the hospital was to be expected with or without the use of the MIT Knee. The swing phase controller, however, improved her performance and gave her experience in the use of a damped prosthesis similar to her permanent prosthesis.

4.2 Phase Two: The Use of Biofeedback

During this four-month period, two patients were trained using the modified system described earlier.

TG, who was 64 years old when he lost his leg due to PVD, had difficulty walking short distances without pain for two years prior to his amputation. Before training began with the new system, consideration was given to the relative difficulties that he might have with prosthesis weight bearing and knee stability.

Weight bearing feedback seemed to be the most promising of the two types available since for the past two years TG probably placed much less weight onto his now amputated leg. As a precaution, however, hyperextensive knee torque feedback was used initially to ensure adequate knee stability. Consequently, knee torque feedback was used to a lesser degree throughout his training program.

At the discretion of the physical therapist, the feedback type was changed as needed. As seen in figures 34 and 35, both types were used in some of the sessions. Both did not, however, occur simultaneously. During these sessions, data was collected only after both forms of feedback were used.

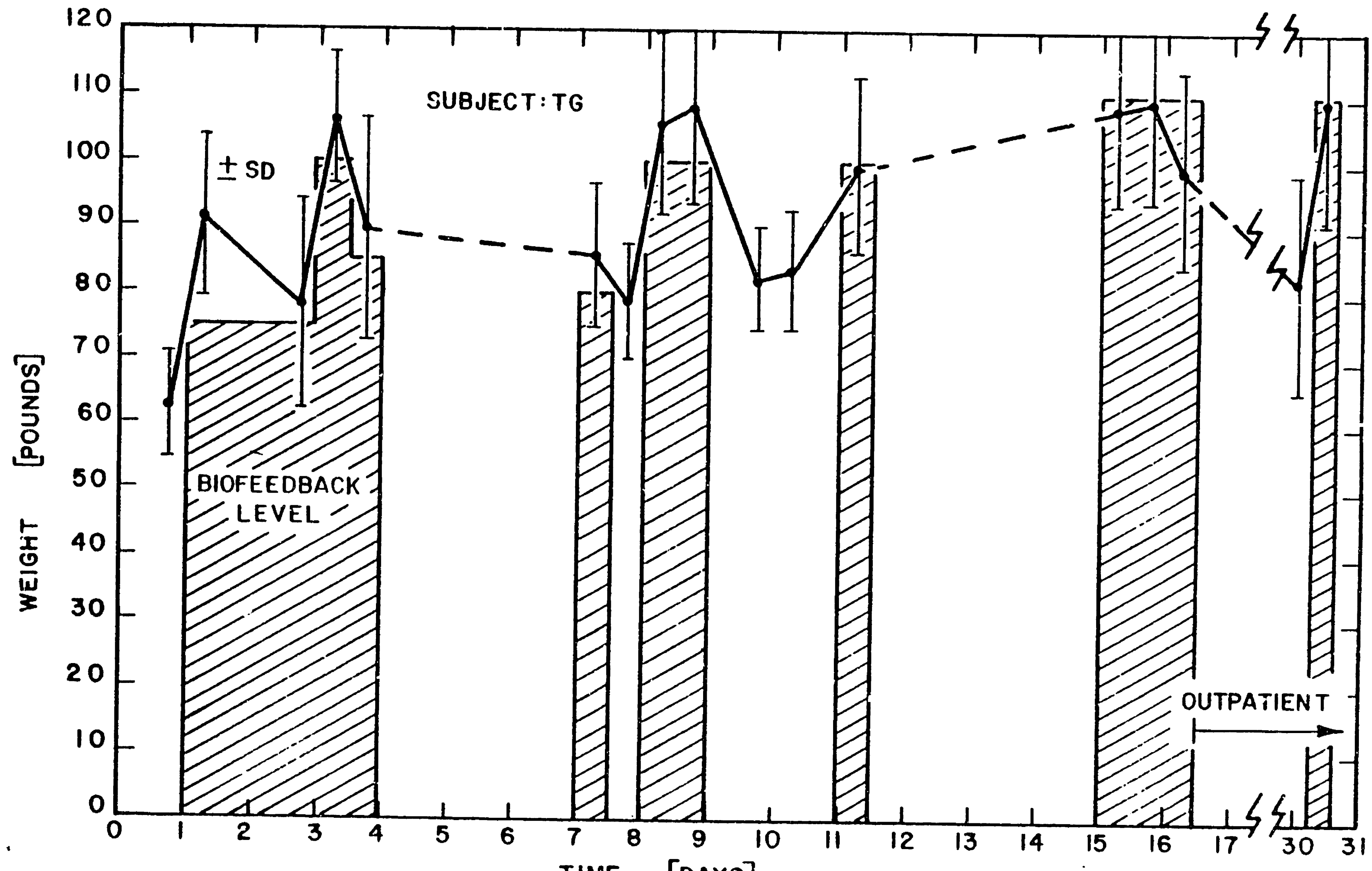


Figure 34. THE EFFECT OF WEIGHT BEARING BIOFEEDBACK

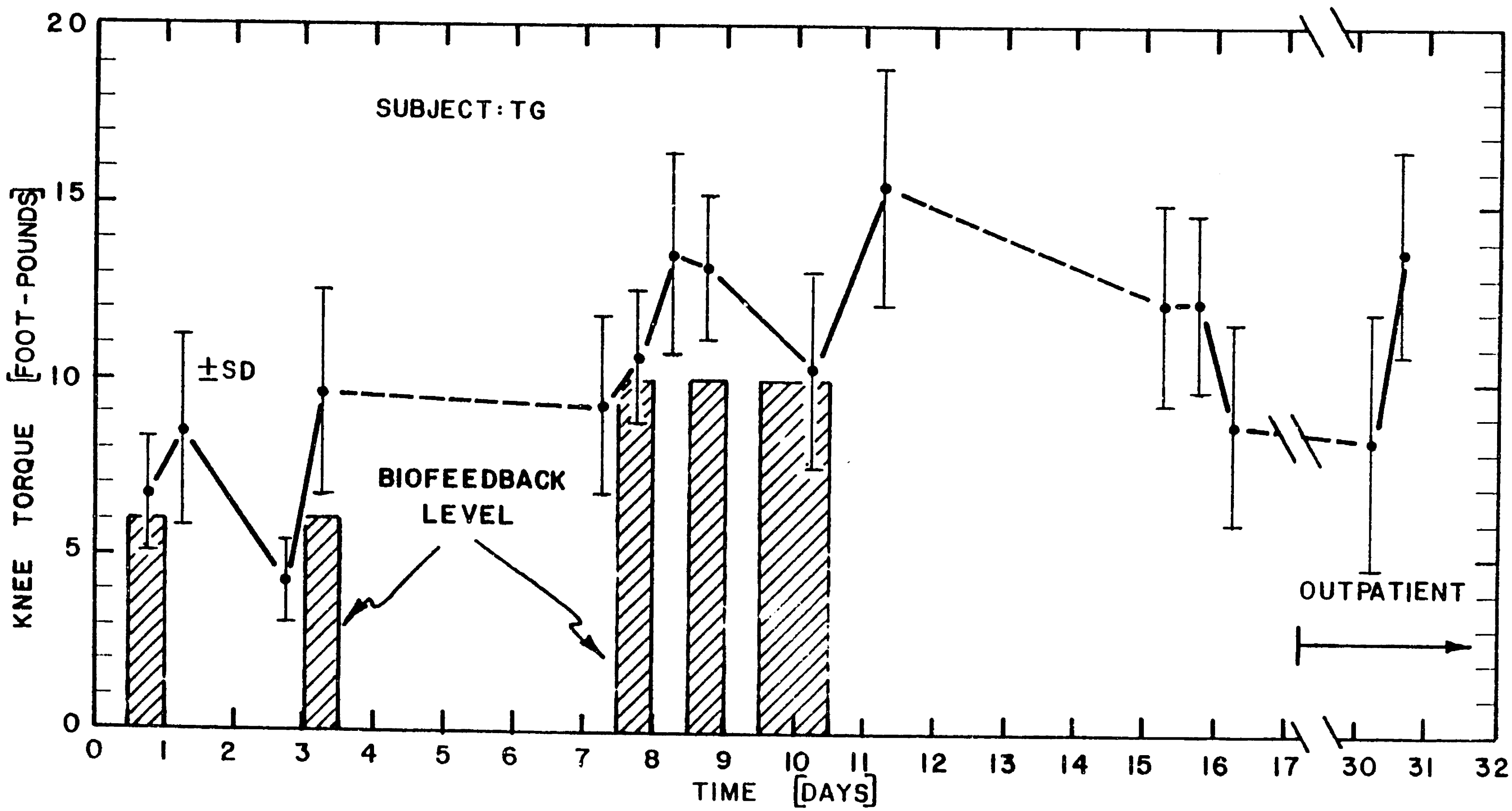


Figure 35. THE EFFECT OF KNEE TORQUE BIOFEEDBACK

The swing phase controller was initially used but was discontinued, as TG showed no preference for additional swing phase damping. Apparently, he walked so slowly that the friction of the knee mechanism provided adequate damping.

Figures 34 and 35 show some of the effects of feedback on TG's performance. The origin of the time axis on these graphs, as in all graphs of the data, corresponds to the beginning of gait training. Training was interrupted during weekends when TG left the hospital with his conventional pylon. These times are indicated by the dashed lines in figures 34 and 35. As seen in figure 35, knee torque feedback was used first to ensure prosthetic knee stability. It was used again only intermittently to ensure continued knee stability. Weight bearing feedback was used in fourteen sessions. As shown in figure 34, TG's mean peak load to the prosthesis increased 50% during his first training session with this form of feedback. This graph shows that weight bearing feedback had a significant positive effect on TG's performance. TG could apply much of his weight to the prosthesis and used the feedback to help understand how much effort was required to attain the level specified. When the feedback level was initially set to 100 pounds TG seemed to fatigue easily, but soon became proficient in applying this level of weight repeatedly. In the opinion of his physical therapist, who was experienced in the training of A/K's his progress in this task was 25-50% faster than that of equivalent patients whom she had trained in the past.

Figure 36 shows comparative gait recordings from sessions toward the beginning and end of his inpatient training. Note that the velocity traces have been inverted. These recordings further indicate his progress, as does his decreased error rate shown in figure 37.

The repeatability of his gait also improved with inpatient training, as indicated by STPRP and SWPRP. As seen in figure 38, SWPRP and the maximum swing angle increased during inpatient training but decreased during outpatient training. The stance phase repeatability parameter, STPRP, increased during inpatient training and showed large but transient increases when the feedback training was most frequent (day 8 - 9), as shown in figure 39. Again STPRP decreased when TG became an outpatient but increased significantly in response to the feedback, as did SWPRP. Figure 40 shows his swing/ stance ratio (time) versus training time. The initial decrease was due to his going outside the parallel bars which caused increased double support and consequently a decreased swing/ stance ratio. No significant changes, however, occurred to this parameter when TG became an outpatient.

During his first outpatient session, on the 31st day of gait training, TG was feeling well. The MIT Knee was used to observe his performance, as before, without using the swing phase controller. After letting him walk to ensure that he was accustomed to the MIT Knee, a test was made regarding the immediate effect of feedback. He was told to place as much weight as he could onto the prosthesis. His gait was recorded

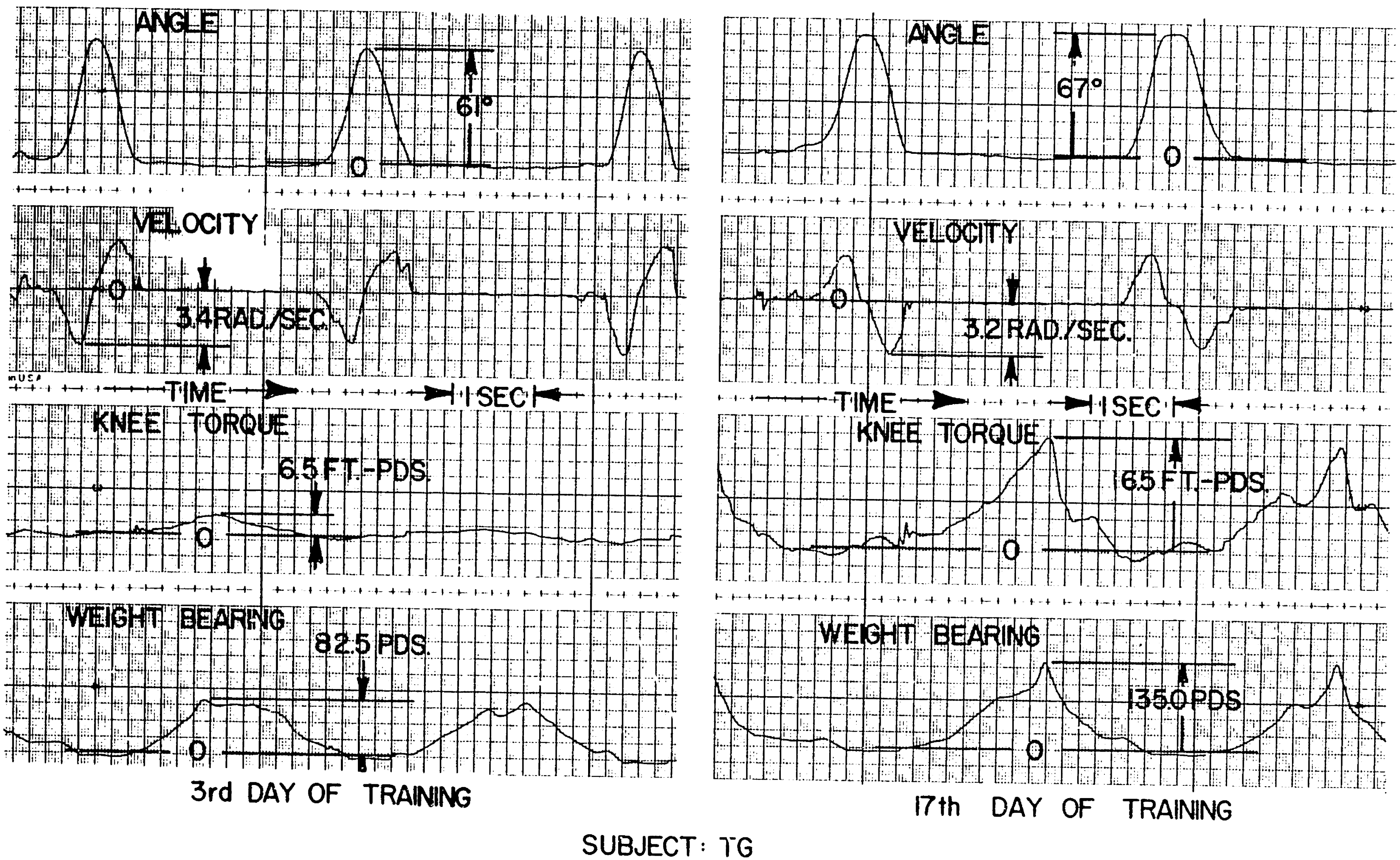


Figure 36. Comparative Gait Recordings.

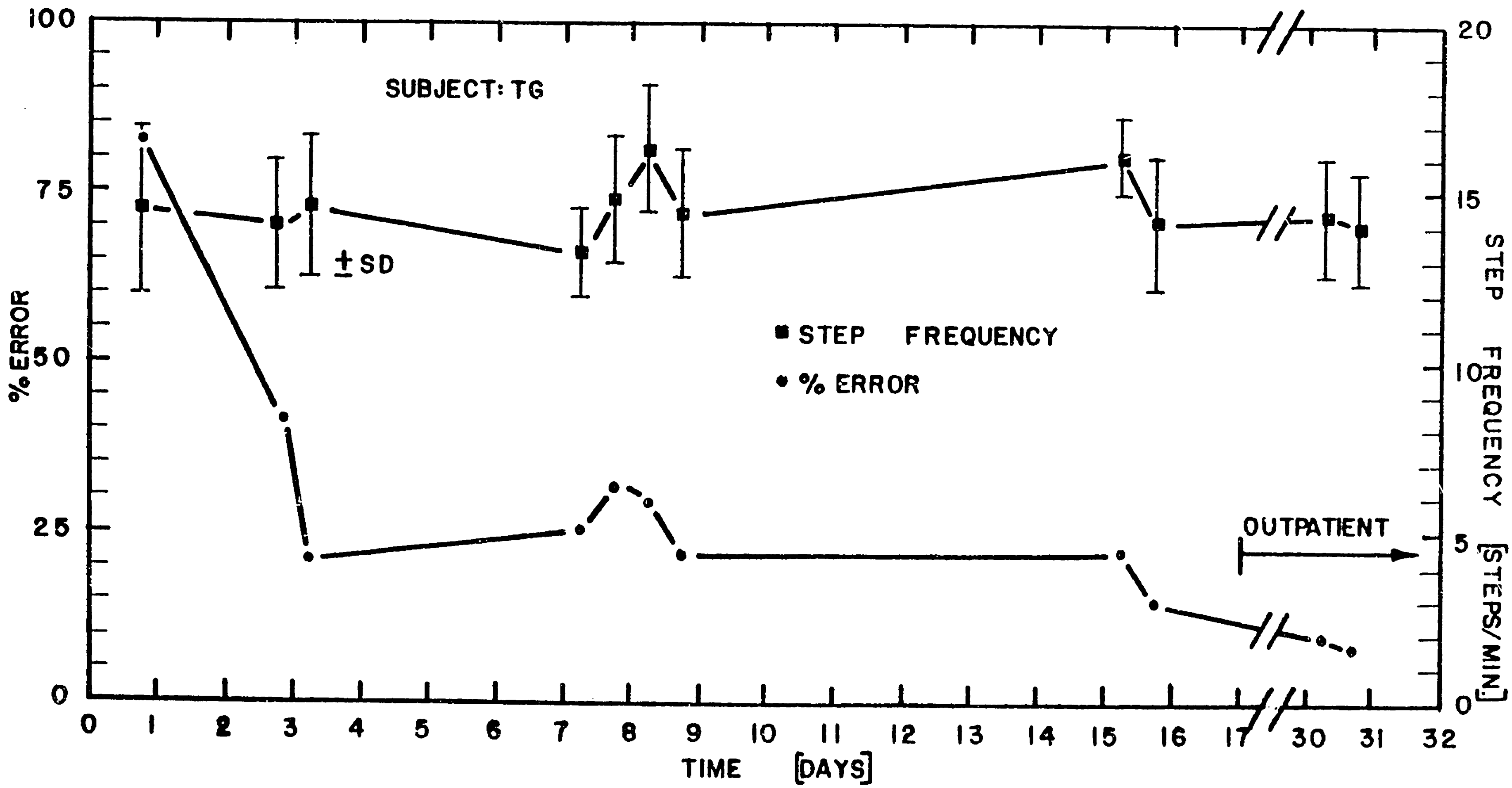


Figure 37. STEP FREQUENCY AND % ERROR VS TRAINING TIME

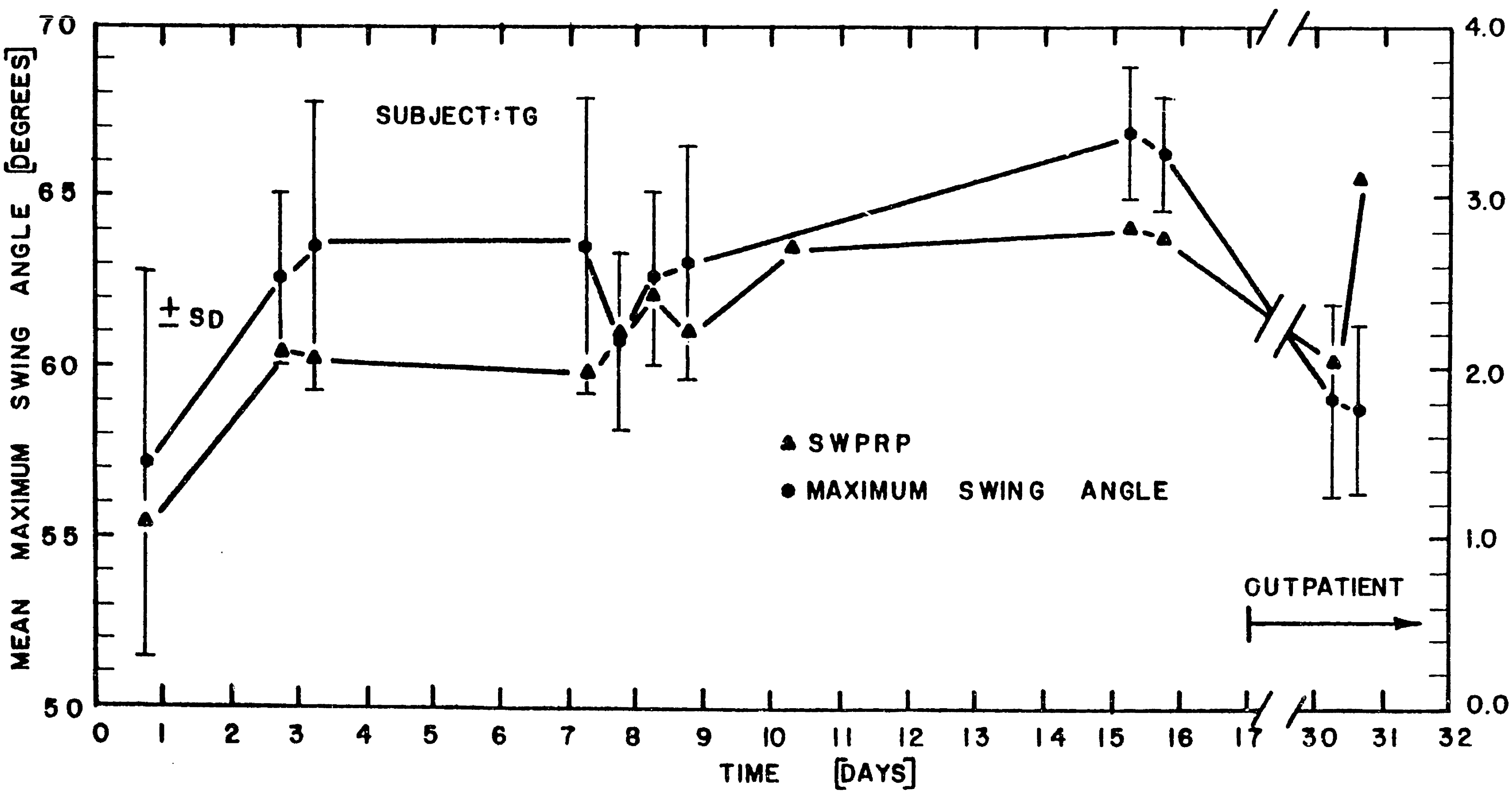


Figure 38. SWPRP AND MEAN MAXIMUM SWING ANGLE VS TRAINING TIME

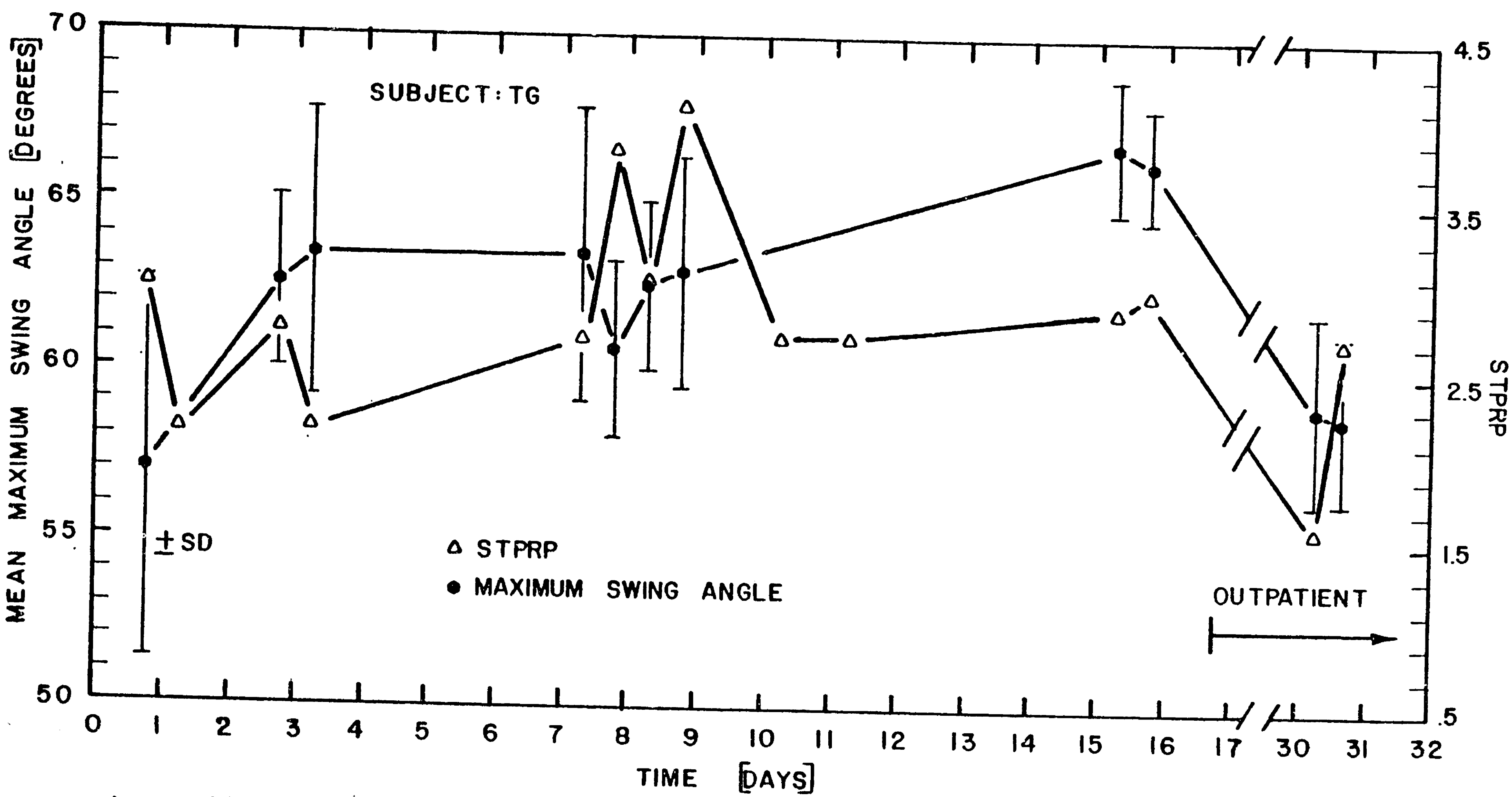


Figure 39. MEAN MAXIMUM SWING ANGLE AND STPRP VS TRAINING TIME

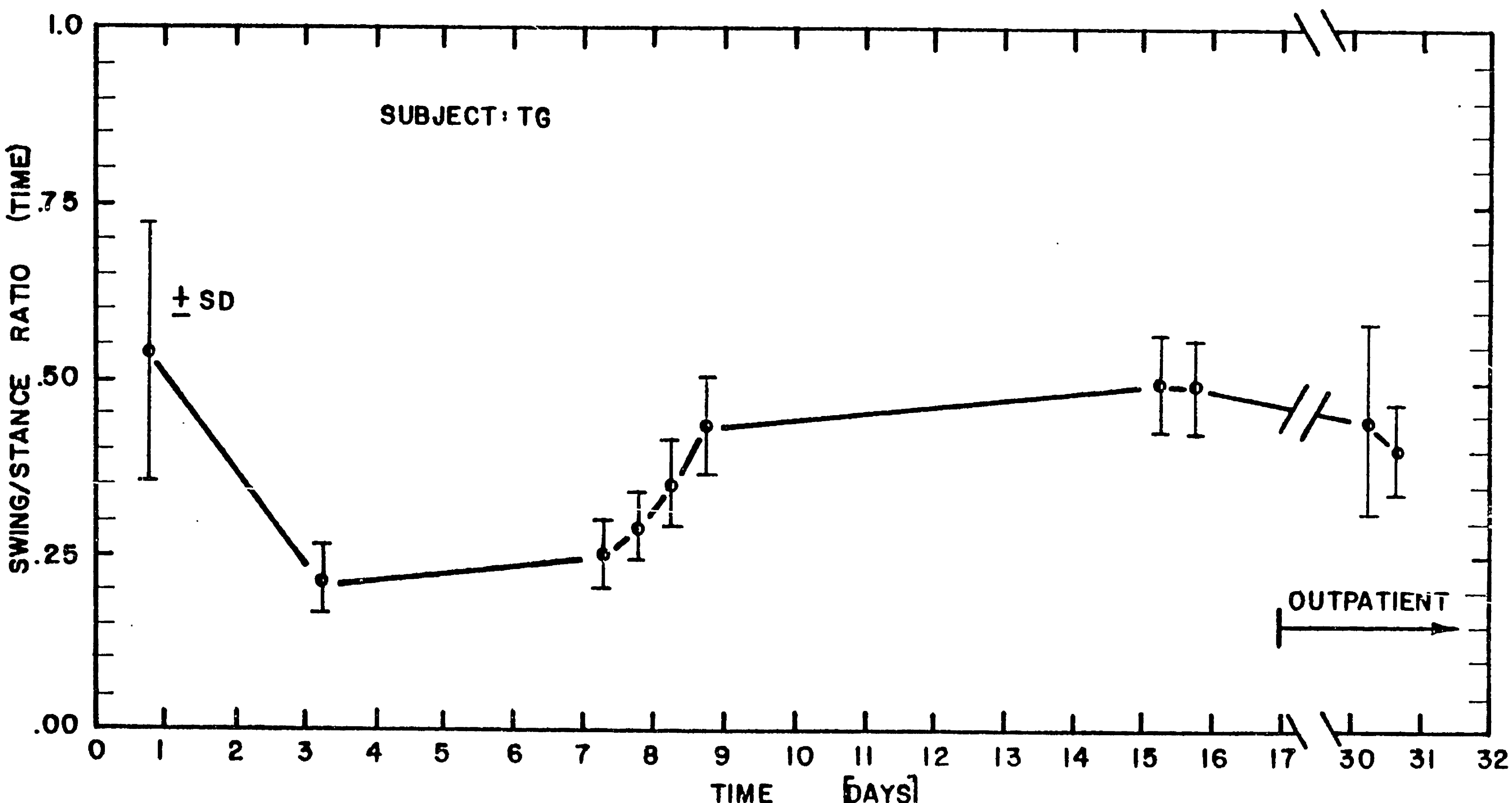


Figure 40. SWING/STANCE RATIO (TIME) VS TRAINING TIME

during this activity. Next the feedback threshold was set for 110 pounds. His gait was again recorded. The last two data points in figure 34 show the mean peak load applied to the prosthesis for the fifty steps immediately before and after the feedback was turned on. There was a 34% immediate increase in his weight bearing performance. He expressed disappointment, however, since he was surprised by the effort required to achieve what he had previously done easily.

The weight bearing feedback during this session affected other aspects of TG's gait as well. In addition to the immediate increases in STPRP and SWPRP, his mean hyperextensive knee torque increased by 62%. As shown in figure 41, a relation between peak knee torque and peak weight bearing appears throughout the inpatient training period as well. These peak loads and knee torques, illustrated in figure 36, occurred simultaneously and in the latter half of stance. The stance phase gait errors caused by inadequate locking knee torque occurred mainly in the first half of stance.

CH was seventeen when she lost her leg due to bone cancer. This previously active patient was subjected to chemotherapy which caused nausia. This nausia increased during her inpatient stay, and hence became her greatest difficulty. Additionally, the treatment caused slowing of the healing process. Consequently, no weight bearing feedback was used, as it would have put stress on her stitches. CH also left the hospital often using a conventional pylon. For this reason the swing phase controller of the MIT Knee was not used,

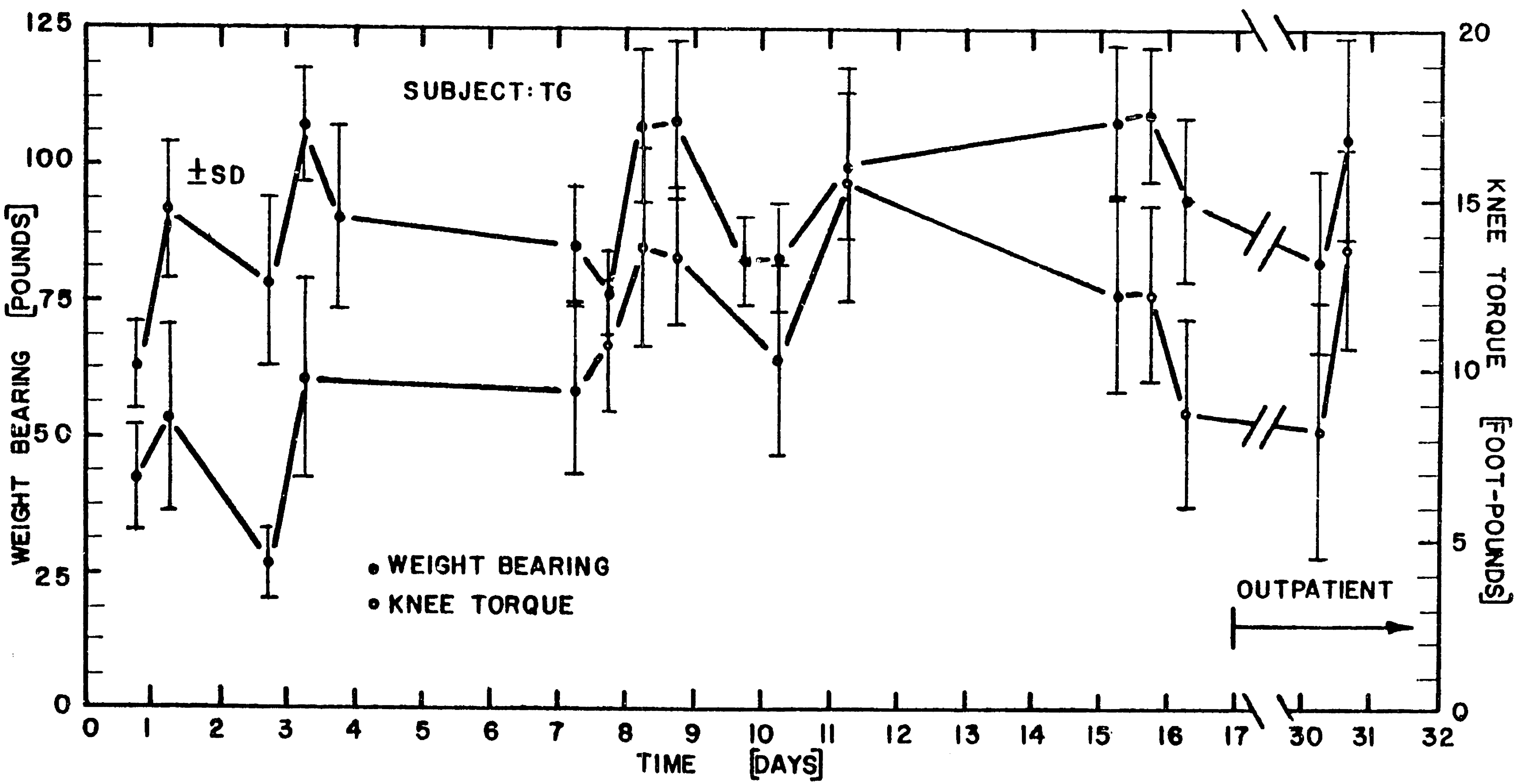


Figure 41. KNEE TORQUE AND WEIGHT BEARING VS TRAINING TIME

as CH would not have benefited from intermittent use of it.

Her response to knee torque feedback is shown in figure 42. She was, in general, capable of applying the level of knee torque desired, regardless of the effects of chemotherapy. She showed the same pattern of immediate response to feedback as TG. During the last inpatient session, the knee torque was measured with and without the feedback system on. First, an attempt was made to induce her to apply at least 17 foot-pounds of knee torque by monitoring the torque and coaching her to meet the desired level. Next she was told that the feedback level would be set to 17 foot-pounds and that she would use only the beeper as feedback. The last two data points in figure 42 were derived from the fifty steps immediately before and after the feedback was turned on. No significant change was seen. CH's response to constant coaching, however, was somewhat negative. At times, when she was told to try harder, she would snap, "I am." No such reaction was observed when she used the now familiar beeper as feedback.

As seen in figure 43, SWPRP remained approximately the same while the maximum swing angle generally increased. STPRP, shown in figure 44, increased during training. Its greatest increase occurred when the feedback system was used in the last session.

Perhaps the parameter most sensitive to CH's increasing nausia was the error rate. Figure 45 shows that while her mean step frequency increased, the error rate varied. In the region of the dash lines, CH either received chemotherapy

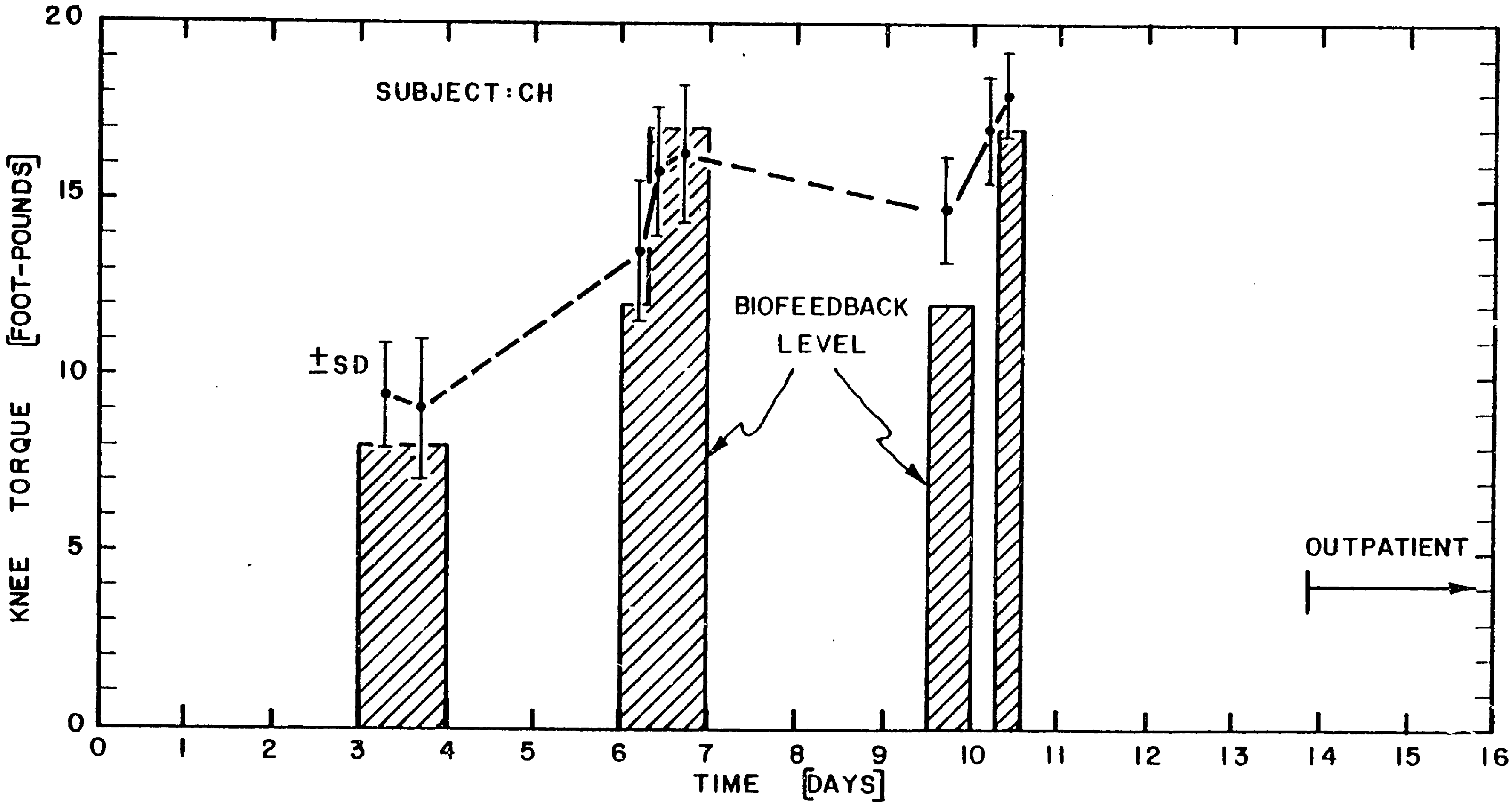


Figure 42. THE EFFECT OF KNEE TORQUE BIOFEEDBACK

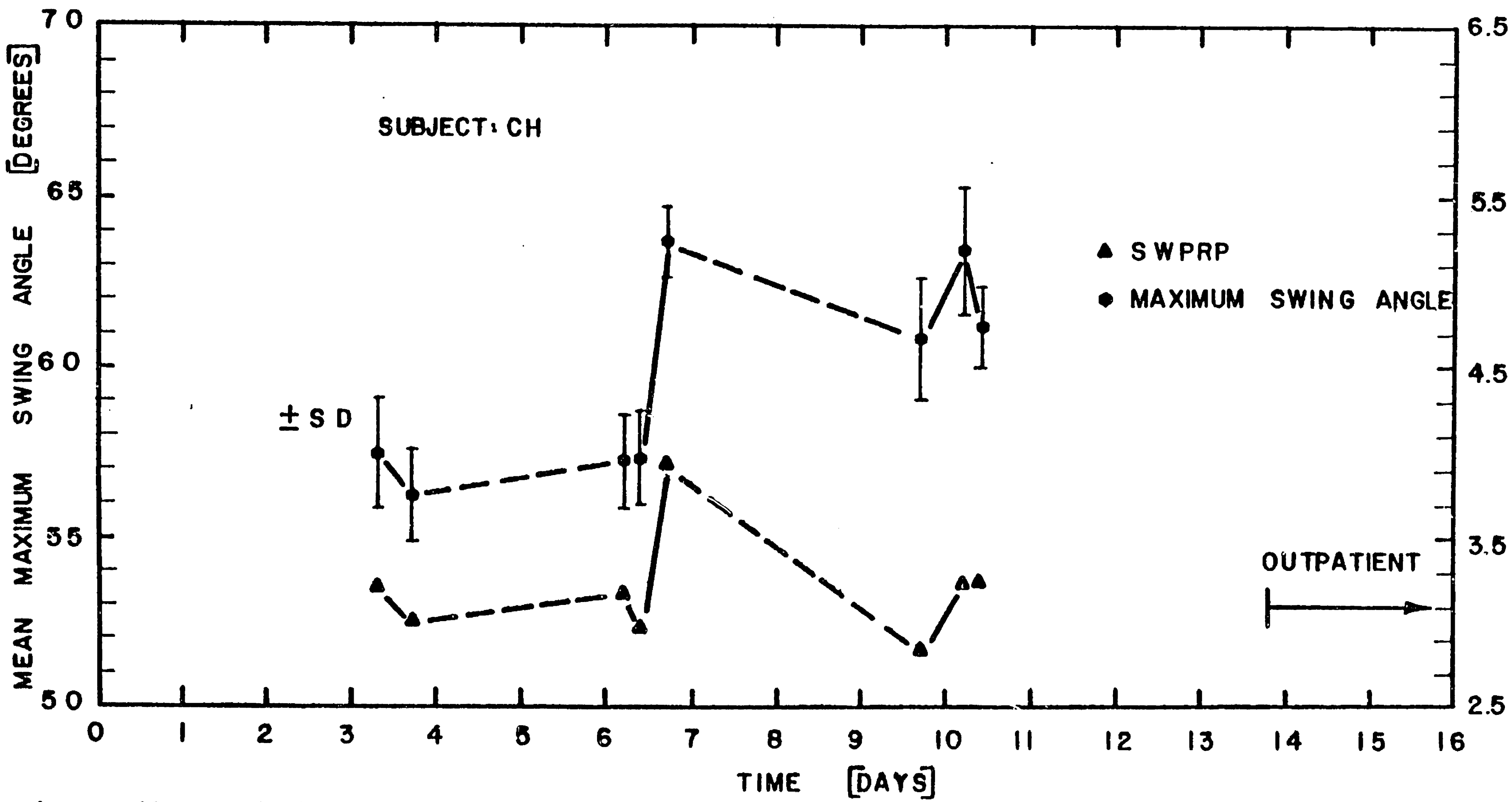


Figure 43. MEAN MAXIMUM SWING ANGLE AND SWPRP VS TRAINING TIME

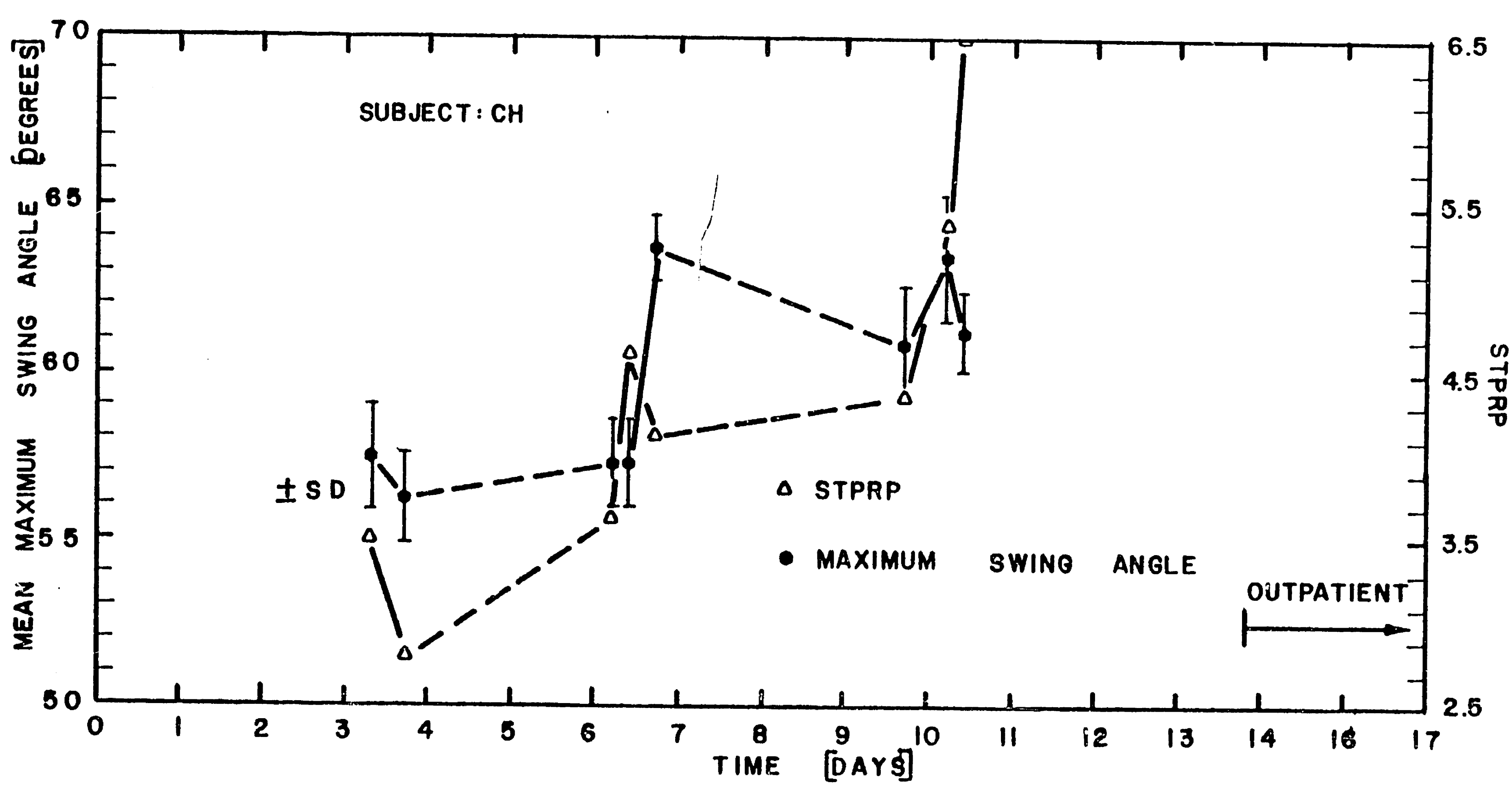


Figure 44. MEAN MAXIMUM SWING ANGLE AND STPRP VS TRAINING TIME

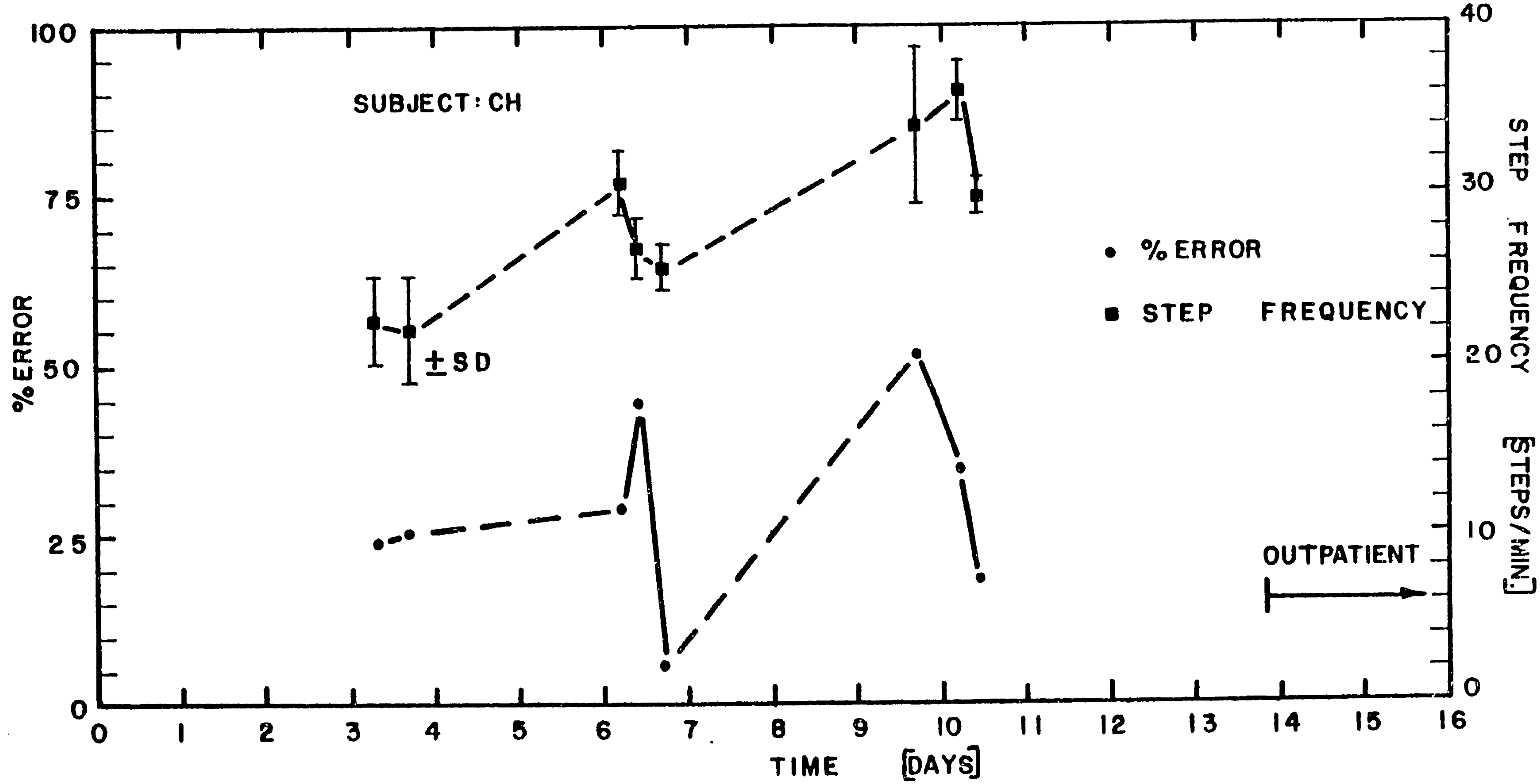


Figure 45. STEP FREQUENCY AND % ERROR VS TRAINING TIME

or had significant side effects from it. The pattern of increased errors at the beginning of a one or two day training session correlated with her increased discomfort at the beginning of these sessions. She improved, however, during the sessions.

The plots of peak knee torque and prosthesis weight bearing versus training time were similar as seen in figure 46. The amount of prosthesis weight bearing indicated in this graph was not excessive. In time, CH could place more weight on her stump. Figure 47 shows comparative recordings of her gait from sessions toward the beginning and end of her inpatient stay.

When CH left the hospital, she found little trouble using the conventional pylon accept for fitting problems with her socket. She became active again and was successful at avoiding gait errors. The staff recommended prescription of a hydraulic knee unit since there was little doubt that she would be quite active in the future.

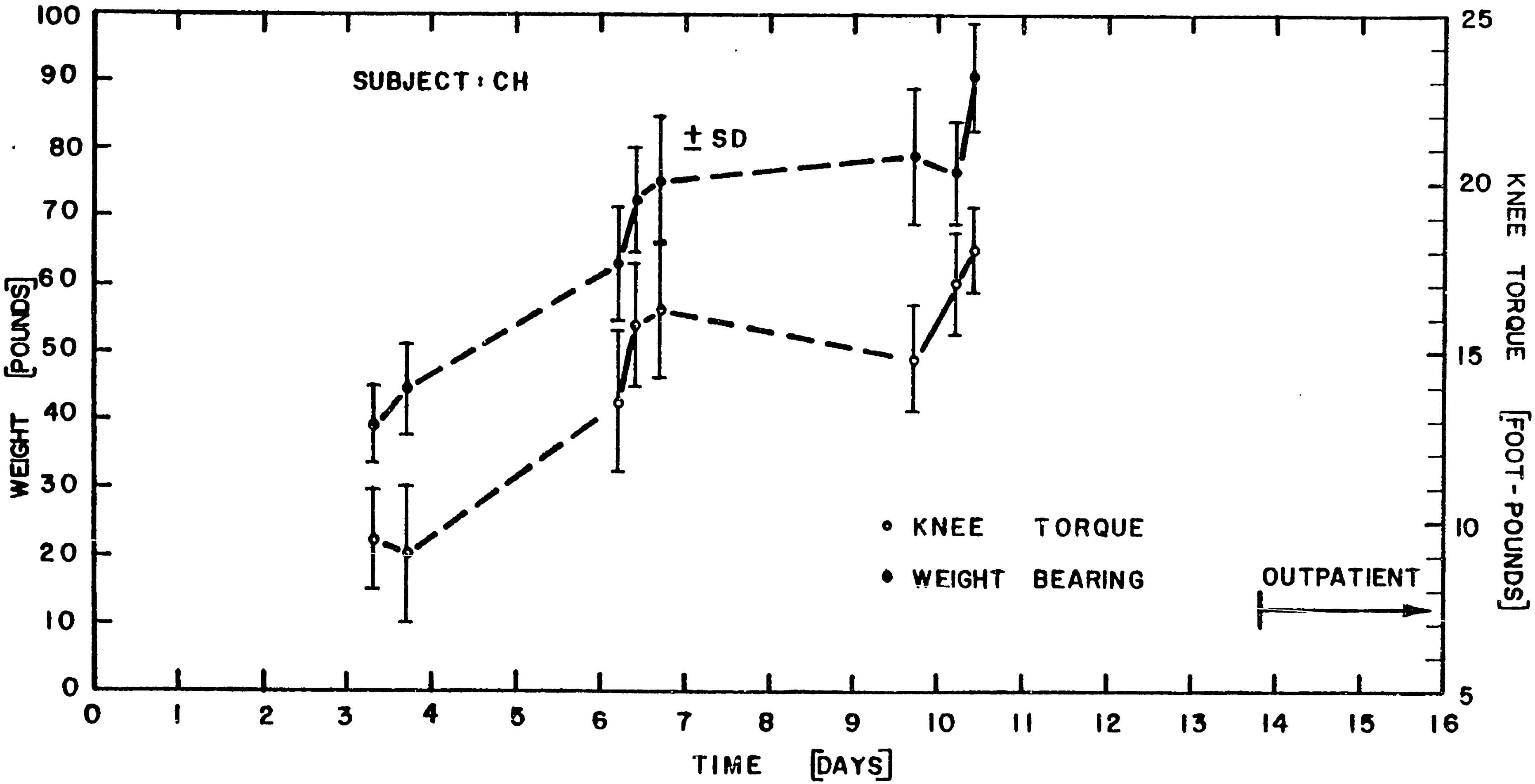
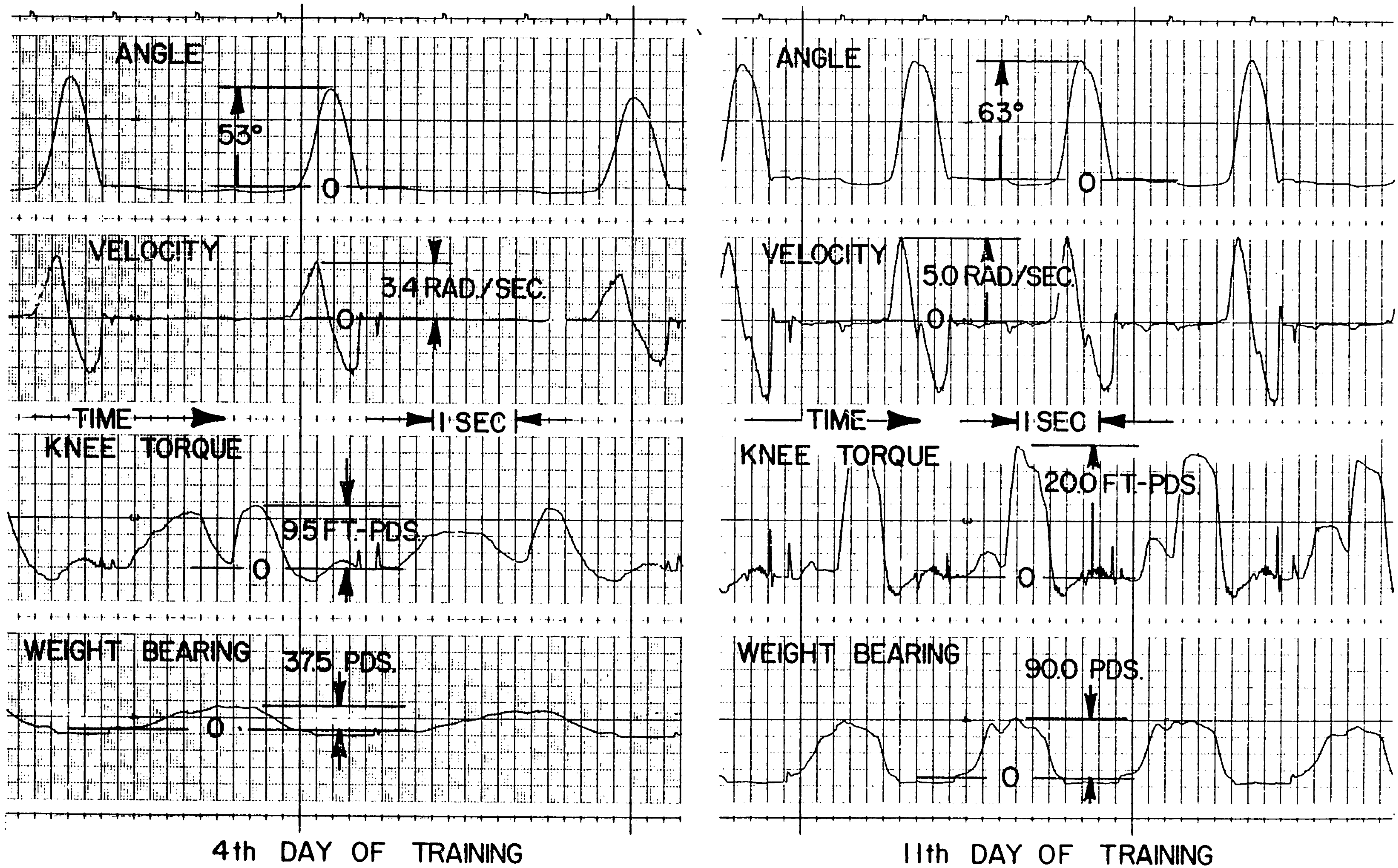


Figure 46. KNEE TORQUE AND WEIGHT BEARING VS TRAINING TIME



SUBJECT:CH

Figure 47. Comparative Gait Recordings.

5.0 Conclusions and Observations

5.1 The Gait Parameters Used

The percent error rate, maximum swing angle, step frequency and SWPRP were calculated for the patients in both phases of the research. STPRP and the peak hyperextensive knee torque and prosthesis weight bearing were available only for the patients in phase two.

The percent error parameter seemed to be the most sensitive to progress and correlated well with the clinical observations. NE, SY, and TG all showed initially rapid declines in error rates which continued to drop more slowly with time. RM's and CH's error rate showed oscilation corresponding to either specific events such as CH's chemotherapy or a general inability to progress.

The mean step frequency in general increased, accept for TG for whom it was relatively constant. This parameter by itself seems to be of moderate significance since it did not directly indicate walking speed. It also showed little sensitivity to progress accept for SY, for whom it initially rose quickly and proportional to the inverse of the error rate.

STPRP and SWPRP, in general showed fair sensitivity to progress and the use of feedback training. For CH, a young active amputee, STPRP shows a rapid increase especially during her last training session. For TG, STPRP exhibited transient but large increases during the time of the most frequent feedback training.

SWPRP, however, shows no such rapid increase for either patient suggesting that the two parameters are independent of each other. Note that there was essentially no use of the swing phase controller with these people. SWPRP, in general, increased in NE's and SY's case, but decreased for SY when he received his new, permanent prosthesis. Erratic behavior as expected, was seen in the case of RM.

Consideration of all of these parameters, as a whole, gives a fair idea of the performance of a patient. They, however, are no substitute for clinical observation. Consideration of any parameter alone is unwise, as can be pointed out in SY's case. In spite of a sharp decrease in SWPRP and the maximum swing angle when he got his permanent prosthesis, there was no significant change in his error rate and step frequency. The data presented here, however, indicates that it may be possible to describe performance quantitatively. Much continued research is needed perhaps using the methods established by Donath (4).

5.2 The Swing Phase Controller

Of the four patients who used the swing phase controller, it was quite useful for two, while only marginally helpful for the others. The more highly motivated, active amputees found the swing phase controller most helpful. For the others, however, versatile damping control was of little use, as their major difficulties were not related to swing phase control. For these patients, stance phase stability and prosthesis weight bearing were among the more difficult tasks.

The major benefits of using the present MIT Knee controller during inpatient training were:

1. its ability to "fine tune" the damping of the knee to make heal strike occur immediately after full extension.
2. its ability to accommodate rapid progress or set backs in performance via reprogramming the controller.
3. its use as a prescription aid.

Making heal strike occur immediately after full extension was always associated with added comfort during gait. Though, this was the major benefit provided to inpatients, there were other problems affecting progress which were remedied by the controller. In early training some patients showed difficulty initially swinging the prosthesis through to heal strike. By using very little damping in the flexion part of swing phase, these patients were able to progress faster. In time, the damping in flexion was increased as needed.

The resulting prosthetic characteristics and patient performance were useful parameters for aiding in the prescription of the patients permanent prosthesis. The present MIT Knee could simulate the behavior of hydraulically damped or free swinging knee units. Hence as a prescription aid, it was crude but useful. The possibility exists however, for future MIT Knees to have a greater role in this important function by being able to behave more closely like a larger number of commercially available prostheses.

The present programming scheme, though versatile, was at times confusing. While a high degree of versatility was necessary, a "starting point" profile was needed. For this study the profile used was that determined by Tanquary's (19) test subject, Cornell.

The greatest disadvantage of using the MIT Knee was that it was restricted to clinical use only. There was a need for versatile swing phase control during outpatient training as well as in early inpatient training. Future prostheses should be able to be used outside the hospital.

5.3 The Use of Biofeedback

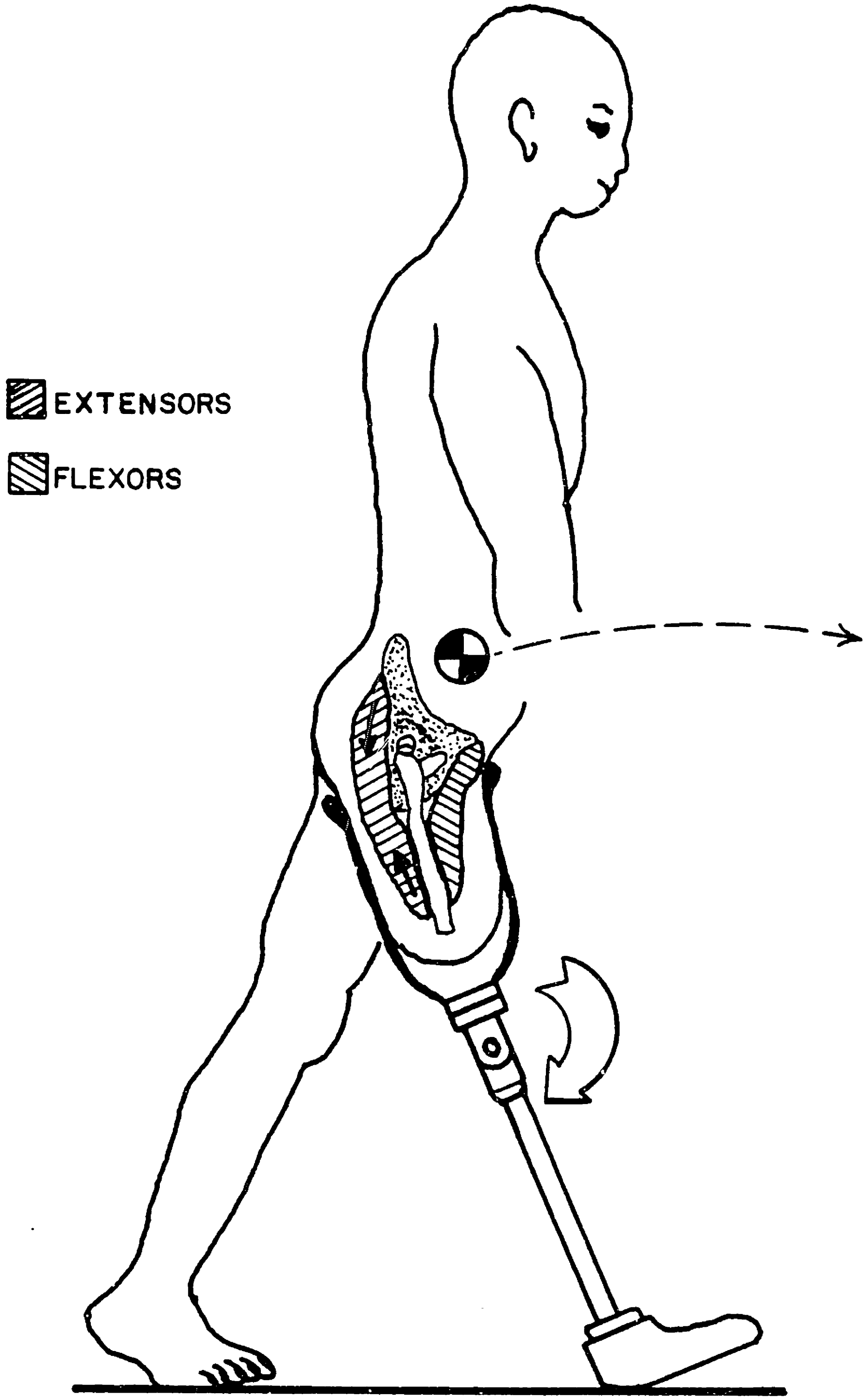
The type of feedback used most frequently with each of the two patients had significant, positive effects on their performance. The effectiveness of each type of feedback was a function of the complexity of the task it was designed to teach. Weight bearing feedback was the least complicated since correct application of weight to the prosthesis was easier than the correct application of hyperextensive knee torque. Further, the point in stance, at which the maximum load occurred was not critical for TG, as he would eventually walk without crutches and apply most of his weight equally throughout stance, as shown for an experienced amputee in figure 16. Binary feedback, however, may be inadequate for some patients, as it did not always provide enough information. TG, at times was frustrated when he was unable to get a response from the feedback system. During these moments he was, in fact, close to the desired level, but still below it. CH, on one occasion, showed similar behavior with the knee torque feedback. Also, as would be useful for patients like CH, a weight limiting signal should be a future option.

However, caution should be exercised in increasing the complexity of the feedback signal, as Fernie (6) suggested that this may confuse the patient.

The use of hyperextensive knee torque feedback was more complicated. Patients could generate knee torque in three distinct ways, one of which was inappropriate. Prompt generation of locking knee torque, as soon as stance began, was extremely important, as the knee would buckle otherwise.

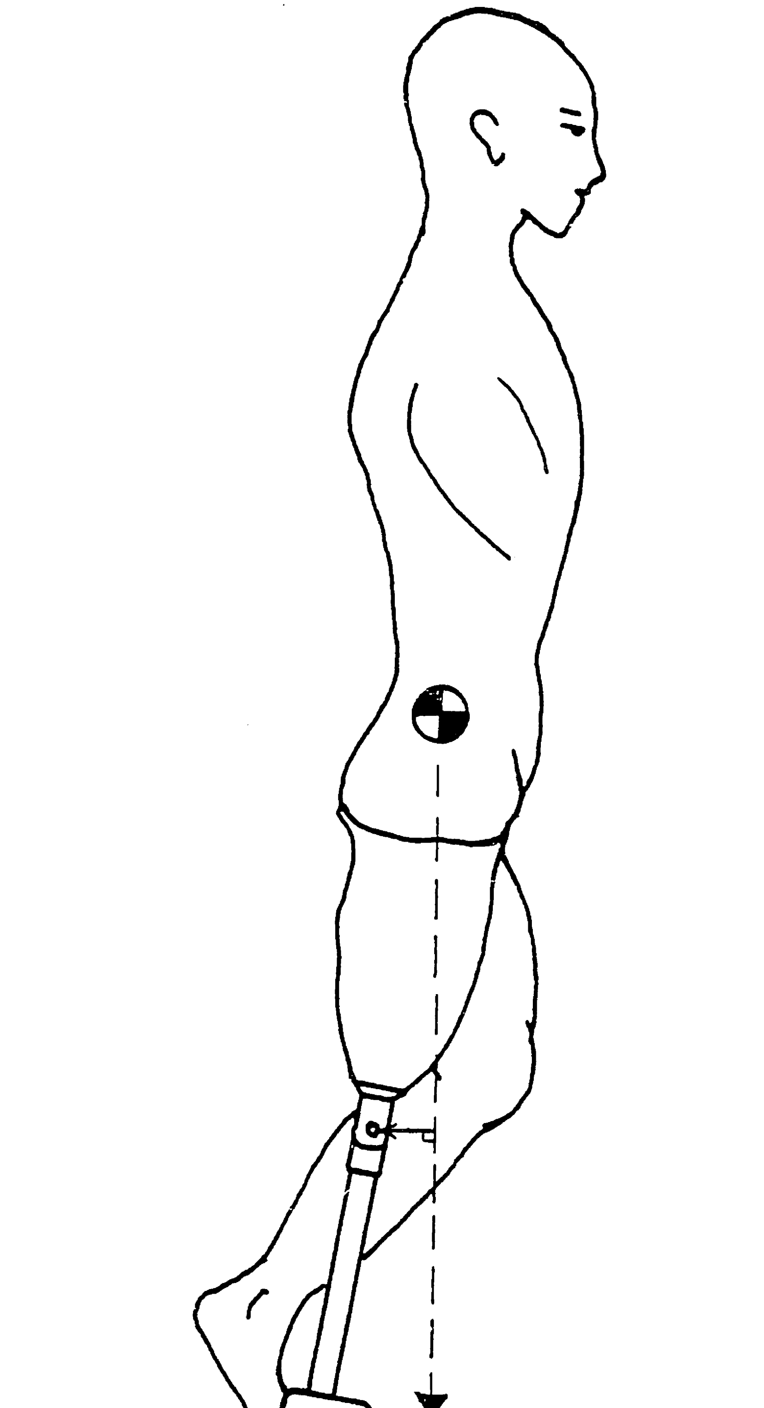
Using the hip extensors of the stump to lock the prosthetic knee was the mechanism used in early stance; the torso should be upright as shown in figure 48. In late stance, however, the geometry of the prosthesis allows the patients weight to create significant knee torque since the weight vector passes through the prosthetic toe, as shown in figure 49. The exact amount generated in this manner is unknown, but it is probably a major portion in late stance. This seems to be a reasonable conclusion since, for immediate post-operative amputees 95% of all peak knee torque and peak weight bearing occurred simultaneously in the latter half stance, as illustrated in figure 36.

The incorrect manner in which knee torque can be generated is shown in figure 50. The amputee leans over the prosthesis in order to place his/her center of gravity anterior to the knee axis, creating a lever arm which provides hyperextensive torque. The stump does not come to full extension when it should because in midstance the amputee must still lean forward to lock the knee. Both TG and CH



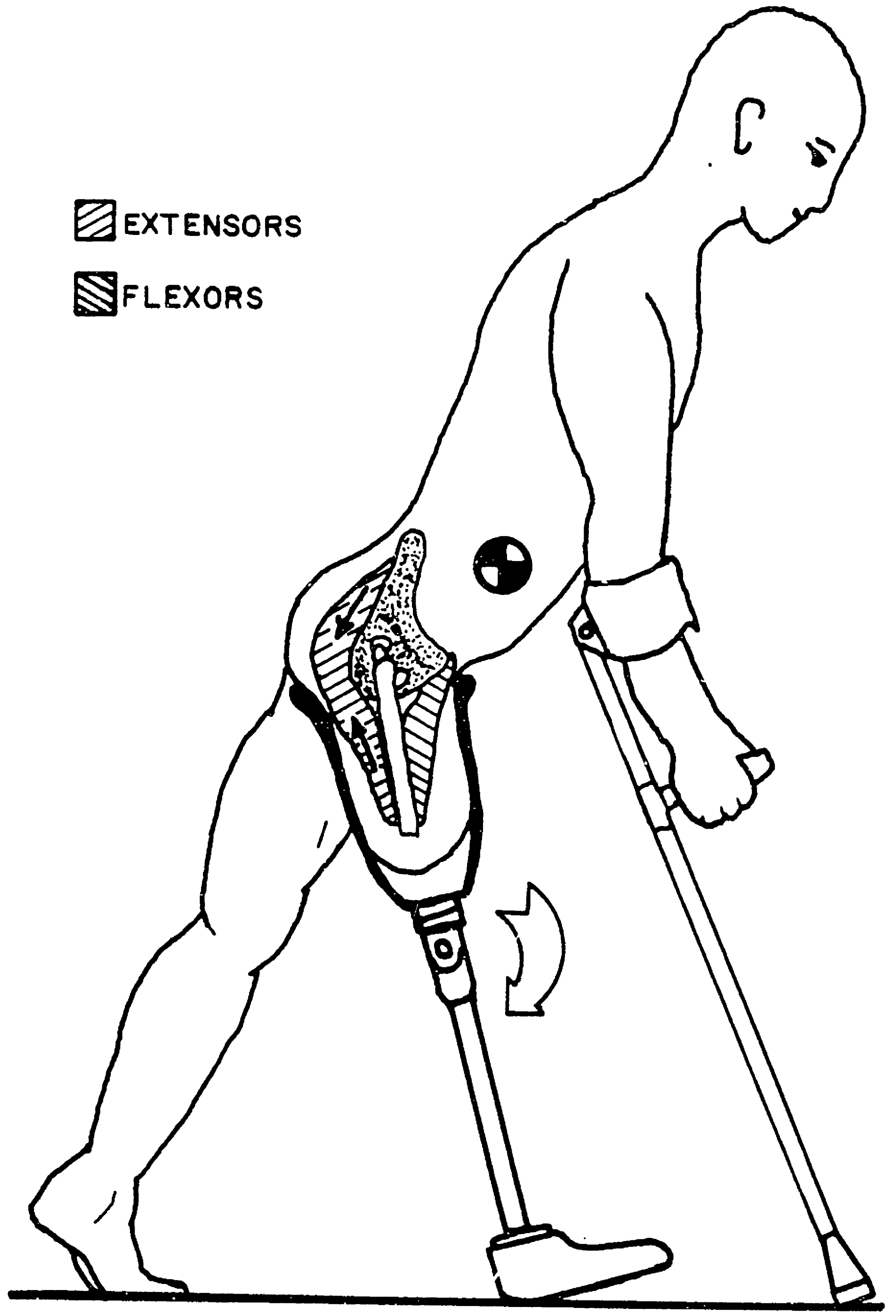
USE OF HIP EXTENSORS TO CREATE HYPEREXTENSIVE KNEE TORQUE

Figure 48



BODY WEIGHT BEING USED TO CREATE HYPEREXTENSIVE KNEE TORQUE

Figure 49



INCORRECT WAY TO CREATE HYPEREXTENSIVE KNEE TORQUE

Figure 50

discovered this method but were immediately corrected by the therapists. Consequently, this type of feedback must be refined, as it requires a great ideal of supervision.

In addition, the feedback did not necessarily teach the patients to apply knee torque as soon as stance phase began, as is important for knee stability. Hyperextensive knee torque was easier to generate in the latter half of stance phase, since the patients could use both their hip extensors and their weight, as described earlier. Consequently, it was easier to sound the feedback beeper in late stance. This is supported by the following observations:

1. 95% of all peak torque and peak prosthesis weight bearing occurred simultaneously and in the latter half of stance;
2. The knee torque levels seen in early stance were not significantly affected by feedback.

These points coupled with the fact that most of TG's and CH's stance errors occurred in the earlier half of stance, suggests that the torque feedback timing needs to be refined. The fact that the mode of feedback used did not discriminate between the first or last halves to stance, was the problem. The IBS, as recalled, has an option for timed feedback. This was not used because the staff thought that it would be too complicated for the patients. In retrospect this may have been an error. The mode of feedback used, however, did induce the generation of high levels of knee torque in, at least, the latter half of stance phase.

6.0 Recommendations

6.1 The Gait Parameters

The effectiveness of gait analysis in this type of rehabilitation depends heavily upon its ability to be used diagnostically. Gait analysis should be able to indicate where, in gait, the subject has the greatest deficiency, swing phase or stance phase. The analysis should also indicate the cause or nature of the deficiency. Refinement of gait analysis for early training and diagnosis should be a major goal of future research. Modification of some of the parameters used in this study is also recommended.

The error rate parameter should be divided into stance and swing phase error rates. This dicotomy would further emphasize the distinction between the relative task difficulties of the swing and stance phases of gait. In addition having an indication of where in stance the majority of errors occur may help the clinician determine which form of knee torque feedback would be most effective in maintaining prosthetic knee stability. Use of the knee torque performance signal generated by the IBS was the first attempt to locate where in stance torques were high enough to maintain knee stability.

Comparing the stance signal to the knee torque performance signal, which is high (+15V) whenever the hyperextensive knee torque is above the feedback level, gives an indication of where in stance the task was achieved. Continually changing the feedback level, however, made day to day comparisons of performance by this method quite difficult. This was true for the weight bearing performance signal as well. A refinement which may facilitate more meaningful, long term assessment of knee torque and weight bearing performance, would be to set the performance signal trigger levels independent of the feedback levels. For prosthesis weight bearing, two suggested levels of interest are half and almost full body weight. The latter is not full weight, as allowance should be made for the continued minimal use of crutches. The former would give an indication of performance in initially placing weight on the prosthesis, while the latter would indicate progress toward unaided ambulation.

From clinical observation, it appears that while experienced amputees generate 20 - 35 foot-pounds of knee torque, only about 5 foot-pounds are needed for knee stability. Thus this level should be considered as criterion for a knee torque performance indicator.

The knee power dissipation signal may also play a role in the analysis of swing phase performance. The use of this parameter should be studied.

6.2 Biofeedback

The use of feedback has much potential. The results of this study suggest that the manner in which auditory feedback is presented to the patient should be modified. The two tasks, prosthesis weight bearing and the application of knee torque, do not necessarily require the same form of auditory feedback.

The weight bearing auditory feedback should have a gradual increase in amplitude, starting about 5 - 15 pounds below the desired level with a sudden increase in amplitude at the desired level. An option should also exist for a weight limiting signal, as some patients require restricted stump loading.

The results indicate that the knee torque feedback should discriminate between different regions of stance, as locking knee torque is most difficult to generate in early to mid stance. Thus, emphasis should be placed on providing knee torque feedback in early stance, as this would bring about prompt application of stabilizing torque. The easiest and already developed method of doing this is by timing the feedback interval from heal strike, as was designed into the IBS.

6.3 Future Operating Modes of the Microcomputer

Future microcomputer-prosthesis systems will operate both at and away from the hospital. Consequently, two operating modes should exist, an "in clinic" mode and an "out of clinic" mode.

a) The "In Clinic" Mode

The microcomputer should be a highly user-interactive device, allowing the clinician to change any aspect of the biofeedback or swing phase damping functions.

Since data could be stored by external devices, the microcomputer could be converted to a high speed data acquisition system, transmitting information externally, for on-line gait analysis. The speed of transmission would be high enough to simultaneously monitor, prosthesis weight bearing, knee torque, knee angular position and velocity, and knee power dissipation.

b) The "Out of Clinic" Mode

One of the more difficult objectives for the clinician is to maintain outpatient performance. The microcomputer must now aid the clinician by "observing and training" the outpatient while she/he is away from the hospital.

While implementing the swing phase damping profile determined at the clinic, the microcomputer should calculate running averages on parameters of interest. These parameters must be designed to use very little memory space. A reasonable compromise for memory space versus information content, would be to design outpatient gait parameters which give an indication of the level of performance or degree of deficiency in particular tasks. The clinician could then use this information to help decide which of the more accurate inpatient, gait analysis techniques would aid in the diagnosis and correction of the problem.

6.4 Design Criteria for the Next Generation MIT Knee

Future MIT Knees should have a coupling designed to allow the socket orientation to be changed ± 20 degrees in both the sagital and coronal planes, as it is difficult to construct a socket without having to make subsequent adjustments in its orientation to the knee unit. In addition the knee mechanism should have a manual lock which can be operated by the patient.

The torque transducer used in the present MIT Knee was too compliant, since when large torques were applied the knee hyperextended as much as 5 degrees. This is undesireable since angular displacements of 5 degrees in stance can be mistaken for knee instability.

Guarding against stumbling due to the instability of the inexperienced amputee is particularly important. The knee mechanism should lock in response to stumbling. The lock should, however, only prevent further flexion of the knee. In this way, the amputee can extend the knee and use it in the locked state. This locking mode should also occur automatically in the case of a microcomputer failure.

6.5 Advantages of Load Cells and Knee Torque Transducers in Prostheses

The expense of instrumented walkways is prohibitive to use in most clinics, and confines the patient to a restricted area which alone modifies her/his gait. The use of relatively inexpensive bathroom scales on the other hand, is restricted to stationary weight shifting.

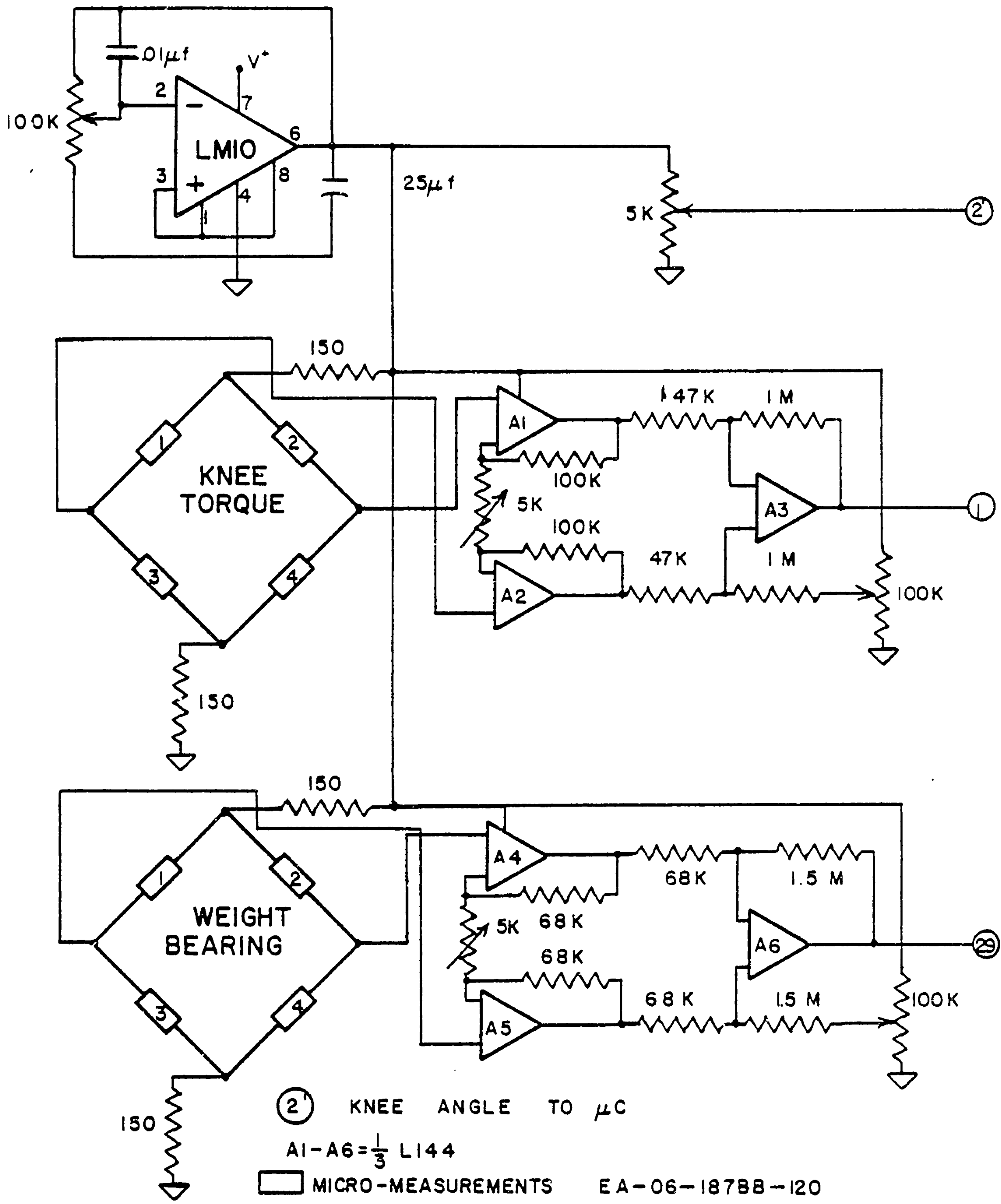
The load cell shown in figures 5 and 6 weighs 6 ounces and has very good performance in the tested range of 200 pounds. Its power consumption is 32 milliwatts. Present technology allows the construction of a similar priced transducer which dissipates a fraction of a milliwatt. There are many advantages to using this relatively inexpensive load cell for training below knee and above knee amputees. A number of amputees can undergo feedback training and quantitative assessments simultaneously. Further this load cell can be used to observe prosthesis loading throughout stance phase.

With a similar transducer knee torque feedback could be provided for A/K amputees as well. Another full strain gage bridge could be placed on the same transducer element to independently measure moments. Consequently, the same load/moment cell can be used for both above-knee and below-knee amputees.

For the cost of an instrumented walkway, many of these load/moment cells could be utilized making it possible to train and assess many patients simultaneously.

Appendix A

Schematic Drawings of Prosthesis Circuitry

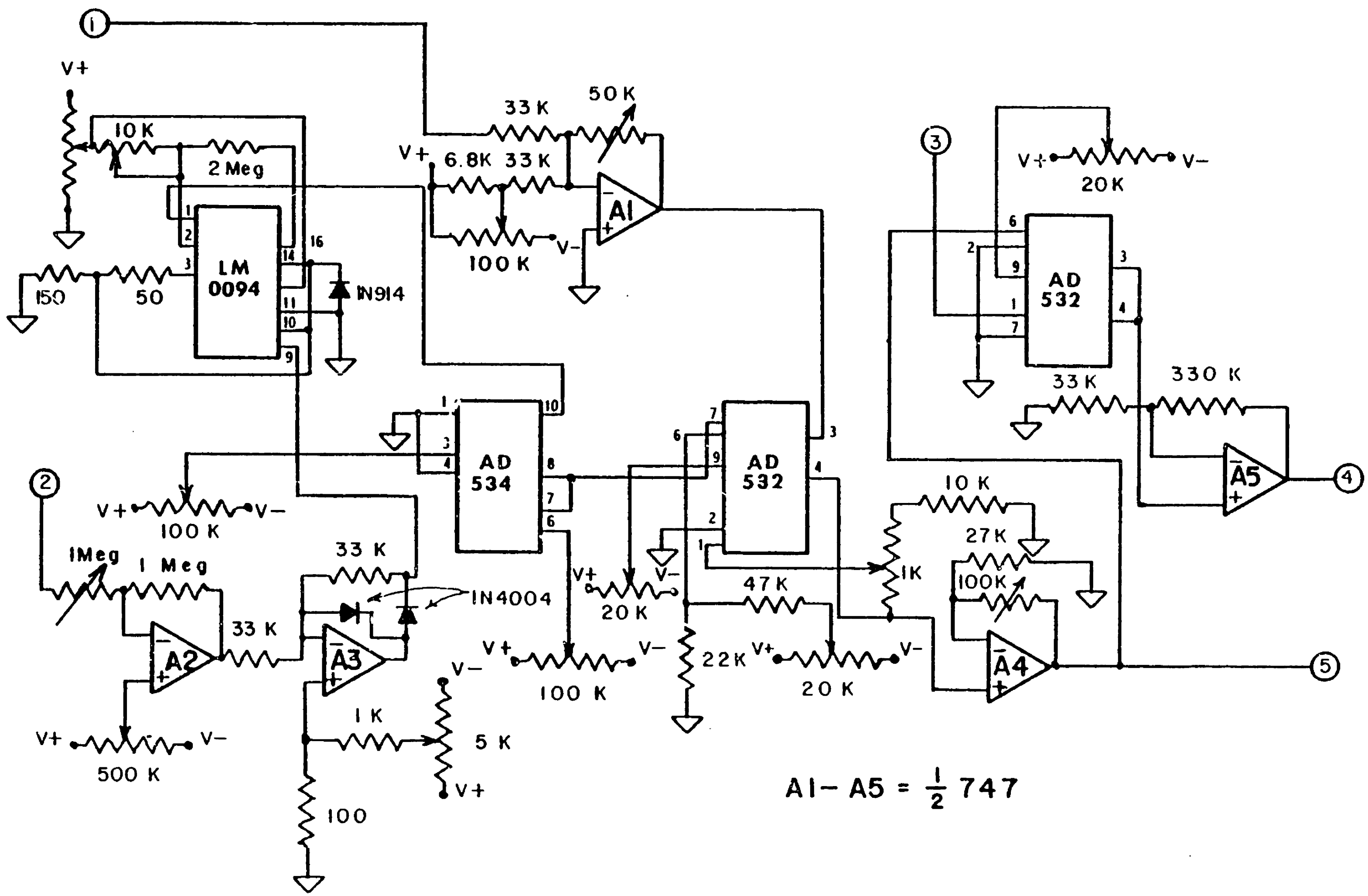


PROSTHESIS CIRCUITRY

Appendix B

Schematic Drawings for

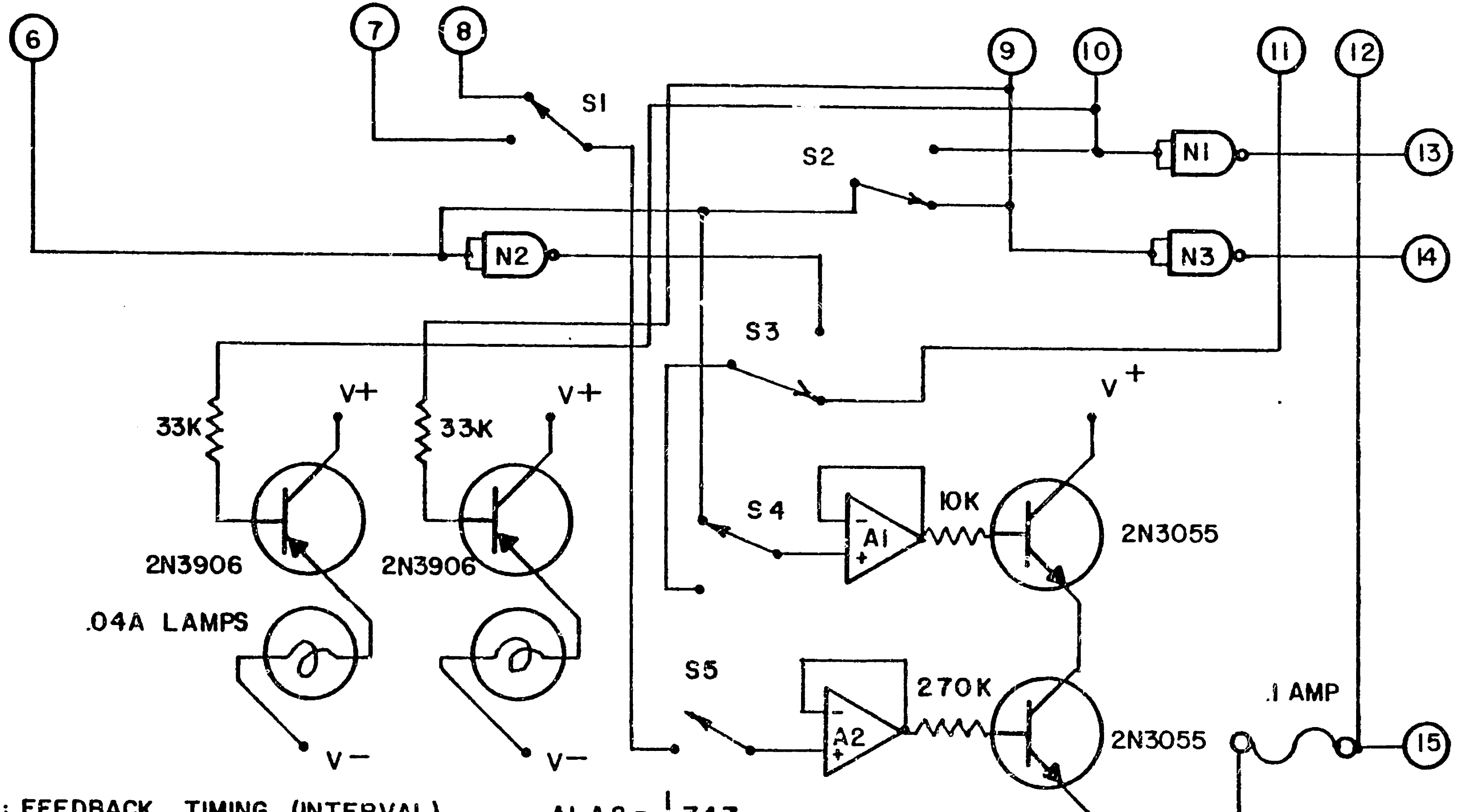
Torque Correction/Power Signal Circuitry



TORQUE SIGNAL CORRECTION CIRCUITRY

Appendix C

Schematic Drawings of the Circuitry for the MIT Knee Interface/Biofeedback System



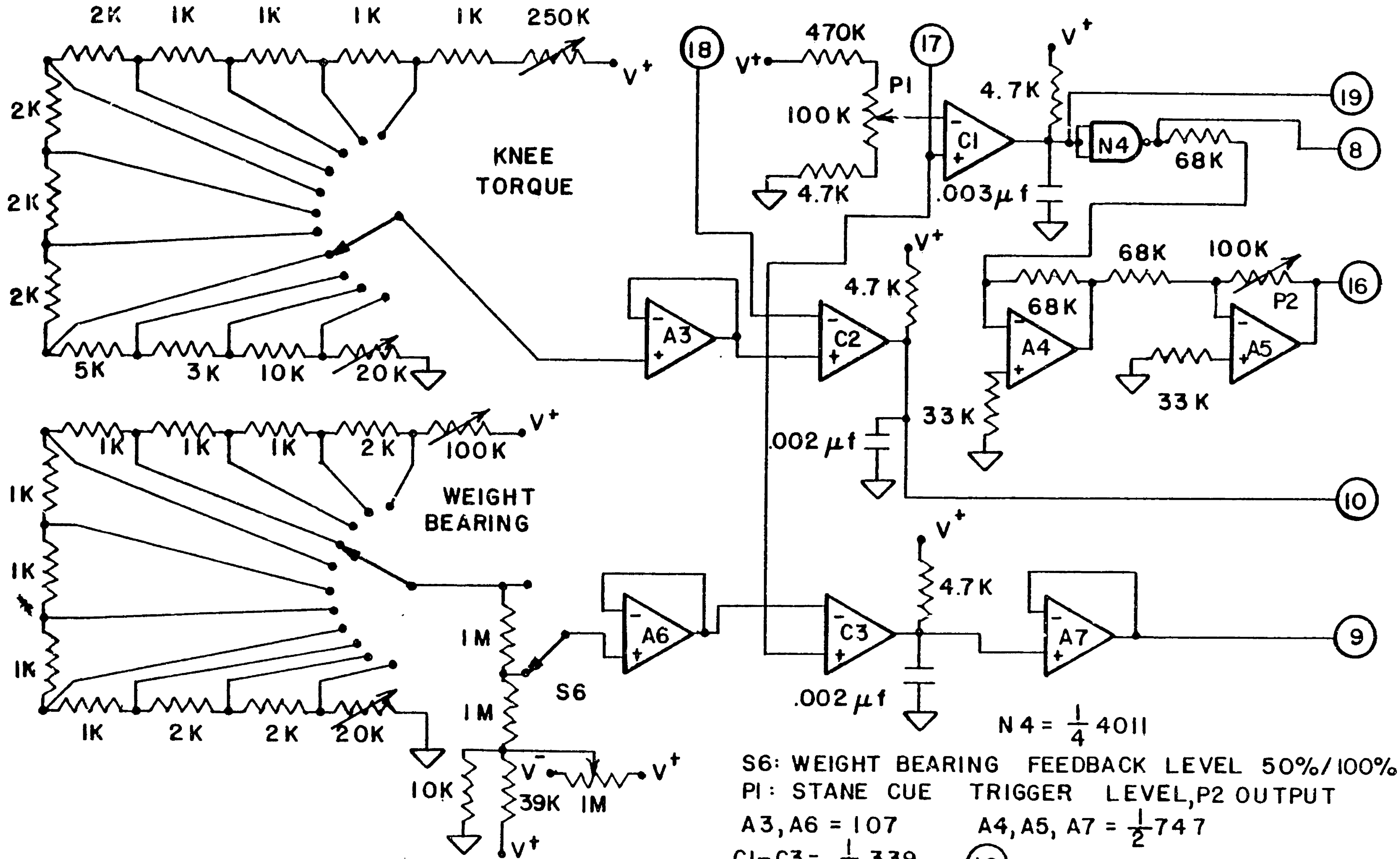
S1 : FEEDBACK TIMING (INTERVAL)
S2: FEEDBACK TYPE
S3: FEEDBACK BEEPER/CONTINUOUS
S4: FEEDBACK SIGN
S5: FEEDBACK ON / OFF

A1, A2 = $\frac{1}{2}$ 747

N1 − N3 = $\frac{1}{4}$ 4011

(13) KNEE TORQUE PERFORMANCE SIGNAL
(14) WEIGHT BEARING PERFORMANCE SIGNAL
(12) BIOFEEDBACK SIGNAL TO μC (15) BIOFEEDBACK OUTPUT

IBS: BIOFEEDBACK INTERFACE / MODE CIRCUIT



N4 = $\frac{1}{4}$ 4011

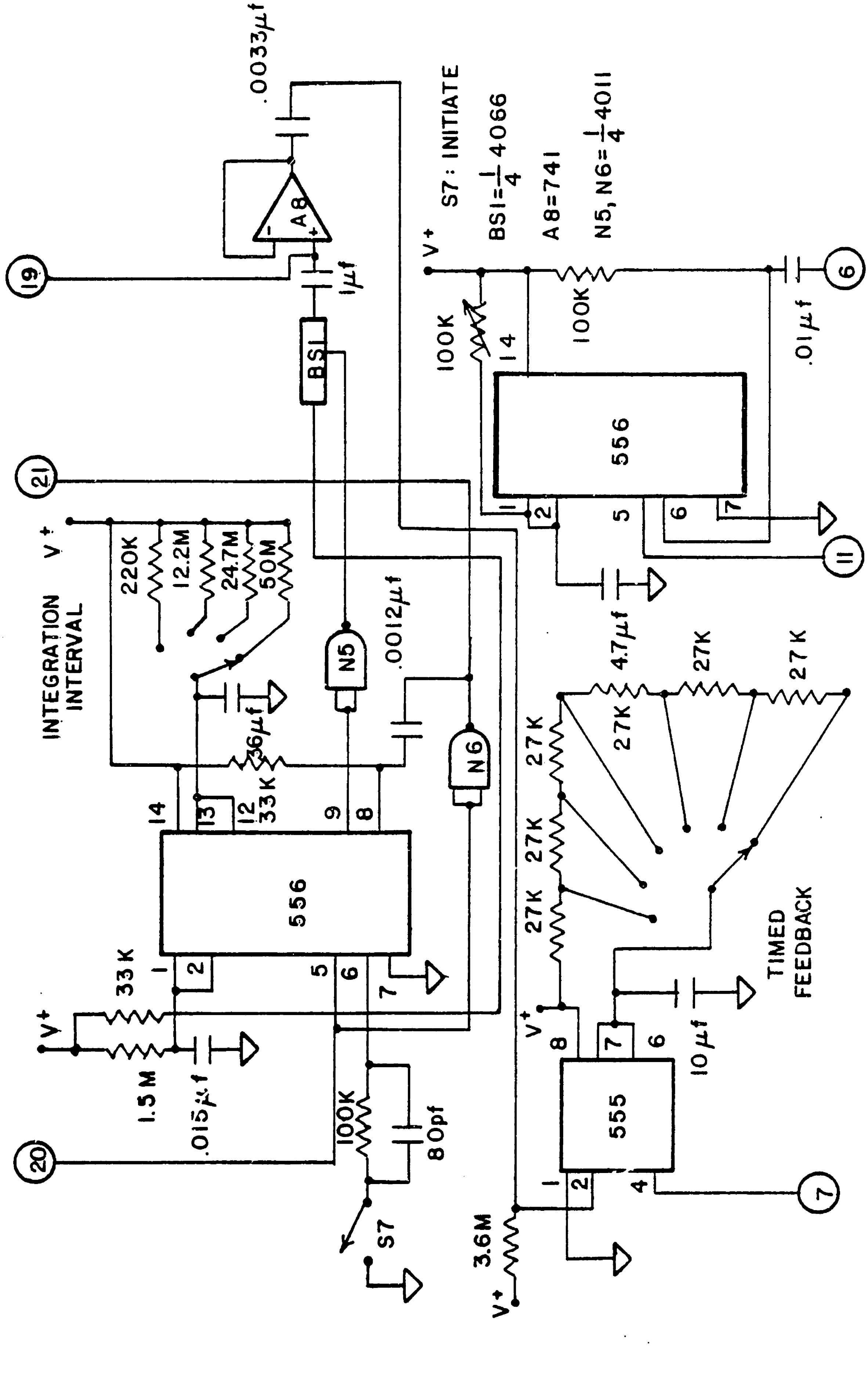
S6: WEIGHT BEARING FEEDBACK LEVEL 50%/100%

PI : STANE CUE TRIGGER LEVEL, P2 OUTPUT

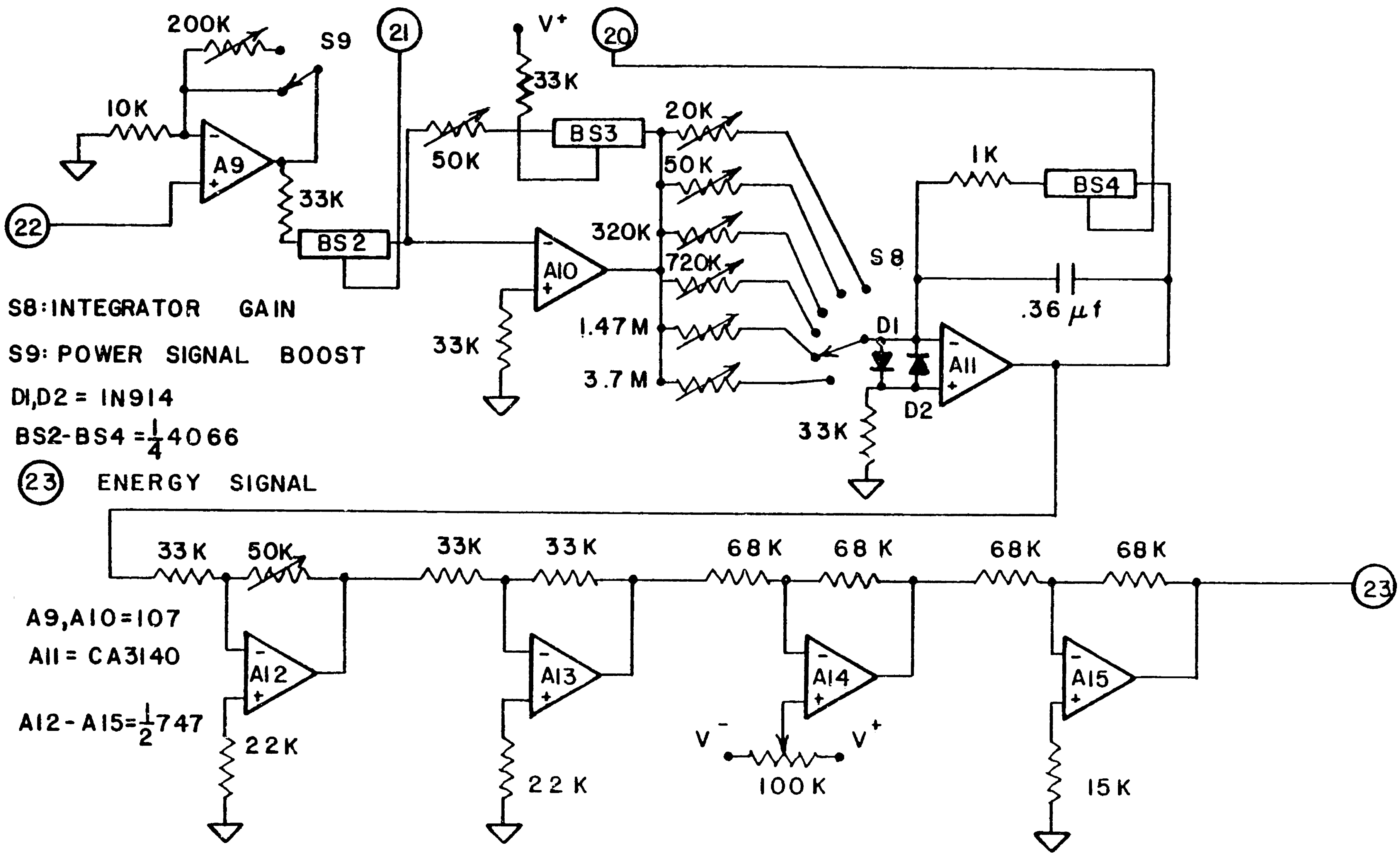
A3, A6 = 107 A4, A5, A7 = $\frac{1}{2}$ 747

CI−C3 = $\frac{1}{4}$ 339 (16) STANCE INDICATOR

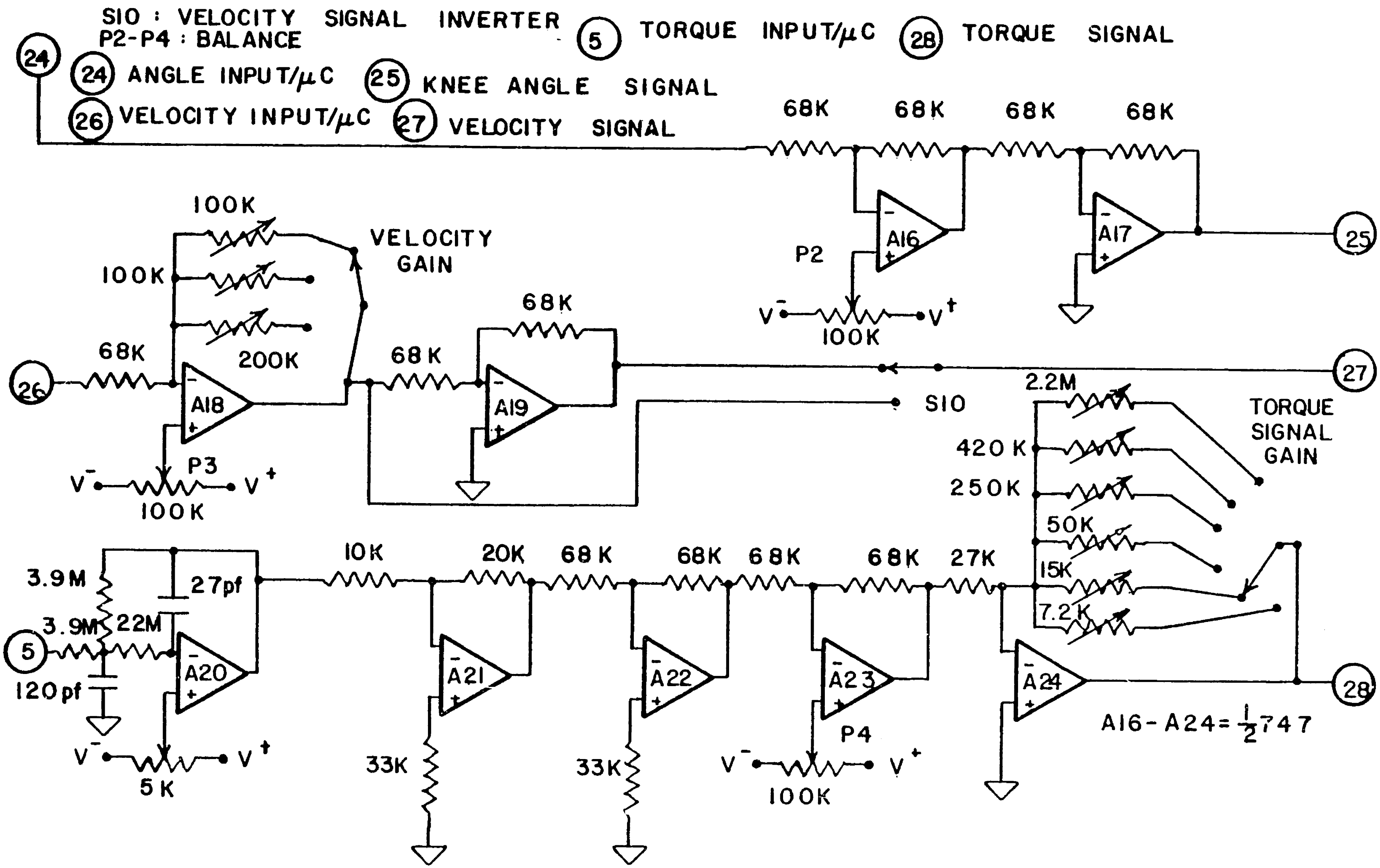
IBS: BIOFEEDBACK LEVEL AND STANCE CUE CIRCUIT



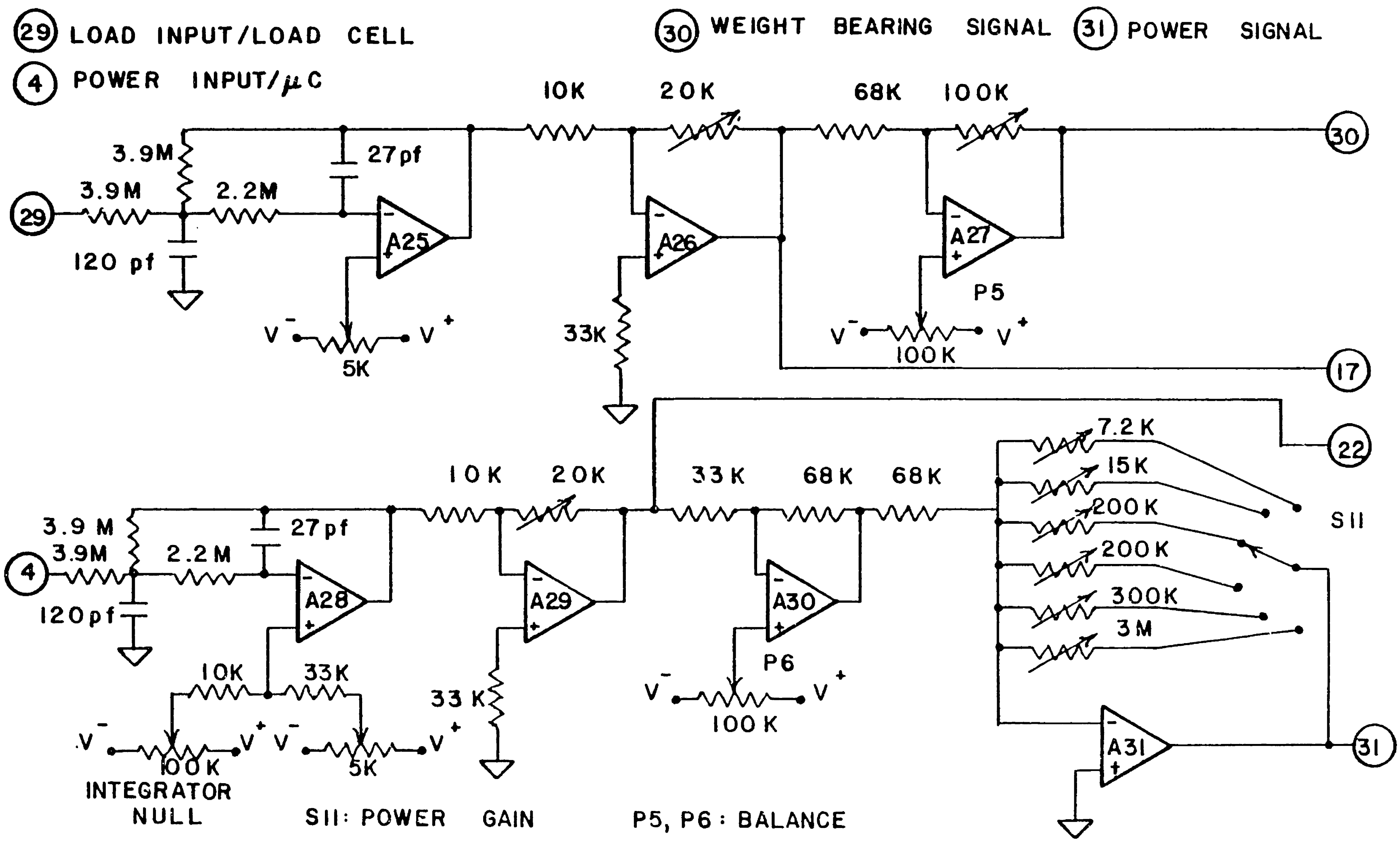
IBS: TIMING CIRCUITS



IBS: INTEGRATOR CIRCUIT



IBS: INTERFACE CIRCUITRY



S11: POWER GAIN

P5, P6 : BALANCE

A25 - A31 = $\frac{1}{2}$747

IBS : INTERFACE CIRCUITRY

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