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PARAPLEGIC STANDING AND RECIPROCAL GAIT USING A FLOOR REACTION HYBRID F.E.S. ORTHOSIS

by

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ABSTRACT

The work presented in this thesis has two main themes. Firstly, it follows the development and initial evaluation of a new, hybrid FES orthosis for paraplegics. Secondly, it describes investigations which were intended to optimize the stimulus parameters used with the orthosis.

One of the major limitations with pure FES standing and walking systems is rapid muscle fatigue. During quiet stance, chronic stimulation of support muscles is required which induces fatigue and significantly reduces their useful contraction time. Mechanical bracing provides safety, strength and protection of delicate joints but it lacks some of the features of FES. The "hybrid" orthosis, considered in this thesis, combines these two techniques so that the disadvantages of either technique alone are reduced.

In the following chapters, the development of the mechanical braces, the sensors, the electrical stimulator and the controlling software are considered. Several preliminary investigations are reported which demonstrate the feasibility of the orthosis with regard to fatigue reduction and stability.

In addition, tests are described which were designed to improve the characteristics of muscle and reflex activity for use with the system. The results of these tests showed that muscle dynamics could be improved by the addition of a single pulse to a regular stimulus pattern. Improvements were also obtained in reflex activity but to a less significant degree.

ABBREVIATIONS

The following is a list of abbreviations and their meanings which are used in this thesis:

AP	-	anterior-posterior
AtoD	-	analogue to digital
CNS	-	central nervous system
CofG	-	centre of gravity
CofP	-	centre of pressure
EMG	-	electromyogram
FES	-	functional electrical stimulation
FFT	-	fast fourier transform
FIR	-	finite impulse response
FNS	-	functional neuromuscular stimulation
FRO	-	floor reaction orthosis
FSR	-	force sensing resistor
GRV	-	ground reaction vector
HER	-	hip extension reflex
HGO	-	hip guidance orthosis
HKAFO	-	hip-knee-ankle-foot orthosis
I/O	-	input/output
IPI	-	interpulse interval
KAFO	-	knee-ankle-foot-orthosis
KER	-	knee extension reflex
ML	-	medio-lateral
pps	-	pulses per second
PW	-	pulsewidth
RGO	-	reciprocation gait orthosis
RMS	-	root mean square
SCI	-	spinal cord injury
SKAFO	-	supracondylar knee-ankle-foot orthosis
sps	-	samples per second
TTL	-	transistor-transistor logic

CHAPTER 1. INTRODUCTION AND LITERATURE REVIEW

CHAPTER 1. INTRODUCTION AND LITERATURE REVIEW

1.1. INTRODUCTION

Throughout the past century, society has become increasingly aware of the special needs of people with spinal cord injury (SCI). With modern rehabilitation techniques, a paraplegic or tetraplegic person can expect to live for a normal life-span and play a useful role in the community. However, despite advancements in medical technology, a severely paralysed individual still cannot expect to live a "normal" life-style. Paraplegics must become consciously aware of routine body functions which were once completely automatic. For example, relief of pressure, temperature control, bowel and bladder management, all become the responsibility of the paralysed patient. Other problems associated with SCI are loss of sensation, loss of normal sexual function, disuse osteoporosis and muscle atrophy (Guttman, 1976).

Although the obstacles faced by SCI patients are many and varied, the most obvious disability, to society in general, is impaired motor function. Indeed, the inability to stand and walk seems to be the greatest factor separating the paralysed person from the community in which he or she lives. Consequently, intense research has been conducted into the restoration of these functions.

The most direct approach is to repair the damage done to the spinal cord. Research into this has been conducted in several centres around the world with some encouraging results (Bjorklund & Stenevi, 1979). It is not realistic, however, to assume that it will be available to SCI patients in the near future so alternative approaches are important.

The purpose of this review is to consider various techniques that have been used to restore stance and walking functions of paralysed patients which are relevant to the aims of this thesis. As well as functional applications, there will also be some consideration of neurophysiological studies of the mechanisms of muscle contraction and reflex activity which may be helpful in understanding their response to certain stimuli.

1.2. MUSCLE FUNCTION

Traditionally, normal human gait has been divided into two stages: Stance phase and swing phase (Murray et al, 1964). Considering one leg only, stance phase is when the leg is relied upon to support a progressively higher loading (up to and over full body weight) as the contralateral leg unloads and makes a step forward. Swing phase, in its simplest form, is the forward placing of the foot in preparation to support the centre of gravity of the body as it progresses. Although normal walking is automatic for most, its detailed biomechanics is very complex and subject to significant interference when pain or paralysis in the leg musculature affects normal function (Saunders et al, 1953).

Normal muscular contraction is achieved by neural activation of motoneurones in the spinal cord which, in turn, innervate muscle fibres (Basmajian, 1978). This activation is an integral function of excitatory and inhibitory signals from spinal reflex activity and higher levels of the central nervous system (CNS). A spinal cord injury will block the signals from higher levels but usually leave intact peripheral nerves and reflex arcs below the level of the lesion (Sunderland, 1968). This leads to what is called "spastic paralysis" of the affected limbs where muscles will readily contract under the influence of a mechanical or electrical stimulus. The location of muscles affected by paralysis depends on the level of the spinal cord lesion and also the severity of the injury (Guttman, 1976).

Severity of a spinal cord injury is loosely divided into two subgroups: Complete and incomplete. The functional condition of a muscle, affected by SCI, may vary continuously from completely paralysed to almost normal. The consequence of this is that voluntary muscle dysfunction can vary from one muscle to another below the level of injury. There is no clear cut distinction between complete and incomplete SCI but it is sufficient, for this project, to say that an injury defined as "complete" will render all limbs and muscles below the injury level incapable of useful motor function under voluntary control (even though sensory innervation may be preserved). An incomplete SCI, therefore, will allow the patient some useful voluntary control of some muscles.

An evaluation of preserved neuromuscular function can be obtained by muscle strength testing. Daniels & Worthingham (1986) describe a manual muscle test by which muscles are graded according to the levels 0 to 5. Zero means no response; five means normal response. Instrumented muscle strength tests have also been described which allow more objective measurements to be made such as maximum rate of contraction and relaxation (Merton, 1954; Edwards et al, 1977b; Zeiderman et al, 1984). Other factors, such as muscle fatigue and endurance, can also be measured (McLaughlin et al, 1987). One important point, which should be noted here, is that paralysed muscle can be tested by electrically evoking a contraction and measuring the corresponding parameters. This technique measures the excitability and function of muscle independently of the amount of voluntary control.

1.3. REHABILITATION TECHNIQUES

At present, the most common means of mobility for patients with serious muscle dysfunction is the wheelchair. This device still offers a form of ambulation which is more convenient and efficient, with respect to time and energy, than most other orthotic alternatives (Clinkingbeard et al, 1964; Cerny et al, 1980; Merritt et al, 1983).

However, the wheelchair does not offer any direct therapeutic benefit to the affected limbs. A number of reciprocating braces have been designed which lock the ankle and knee joints and support the trunk whilst allowing flexion at the hips (Major et al, 1981; Douglas et al, 1983). These devices are very suitable for high thoracic level paraplegics. Ambulation can be achieved by using a walking aid such as a rollator or crutches and shifting weight to allow the effects of gravity and inertia to swing the leg through.

Alternatively, recent advances in the application of functional electrical stimulation (FES) have allowed a selection of complete and incomplete SCI subjects to stand and walk without the aid of external mechanical bracing (Kralj et al, 1981; Bajd et al, 1983b).

Both of these techniques have a number of advantages and disadvantages when applied to paralysed subjects. In this thesis, a third approach called "hybrid" orthotics, which consists of a combination of mechanical bracing with FES, is adopted. The design philosophy behind any hybrid orthosis should be to combine the techniques such that the advantages remain and the disadvantages cancel (Tomovic et al, 1972). This will now be considered in more detail.

1.4. FUNCTIONAL ELECTRICAL STIMULATION

As the name implies, functional electrical stimulation (FES) is the application of electrical neuromuscular stimulation for some functional purpose. These purposes are many and varied but the specific functions dealt with in this study are standing and reciprocal walking for SCI patients.

The most attractive feature of FES is the fact that active mechanical power is generated by the subject's own paralysed muscles. This power can be channeled into positive functions such as locomotion, weight bearing and exercise. The benefits derived can be psychological as well as therapeutic. Useful work produced by paralysed musculature means less work required from the able limbs (Cliquet, 1988). One of the earliest practical successes in the application of FES was the development of the peroneal brace reported by Liberson et al (1961). This used electrical stimulation of the common peroneal nerve to prevent footdrop, during the swing phase of gait, in hemiplegic patients.

Further development of techniques lead to a proposal by Kralj & Grobelnik (1973) to stand complete paraplegics with FES alone. This technique used bilateral stimulation of hip and knee extensors and ankle plantar flexors. Bajd et al (1981) succeeded in standing paraplegic patients using bilateral stimulation of the quadriceps muscles with extra support from the arms. The action of the arms eliminated the need for extra stimulus channels and considerably reduced the knee moment required to stand up (Bajd et al, 1982).

FES assisted reciprocal gait was shown to be possible for SCI patients with incomplete lesions (Kralj et al, 1981) and complete lesions (Bajd et al, 1983b). No external bracing was used but the subject was required to have sufficient balance and upper limb musculature to control crutches or a walking frame.

This technique used stimulation of the quadriceps muscles to brace the legs either bilaterally, during double support, or unilaterally during the single support phase of gait. Lifting of the leg, during swing phase, was achieved by switching the stimulus to an appropriate afferent nerve to elicit a flexion withdrawal reflex. Switching of the stimulus site was achieved using hand switches which were controlled by the subject when he or she had built up the necessary level of skill.

The therapeutic benefits of FES assisted activities, for SCI patients, are considerable from both a clinical and psychological point of view. Problems associated with the following conditions can all be reduced: Pressure sores (Levine et al, 1987); bone mineral loss (Lew, 1987); urinary tract infections (Brindley et al, 1982); muscle atrophy (Fournier et al, 1984); joint contractures (Phillips et al, 1984) and spasticity (Bajd, 1986; Rebersek et al, 1986).

1.4.1. Stimulus Parameters

The stimulus waveform which is used in most FES applications consists of a train of monophasic current pulses. These pulses can vary in duration from 50 to 500μs and in frequency from 10 to 100 pulses per second (pps) according to the application. The task of each stimulus pulse is to excite an action potential in a number of nerve fibres. To achieve this, the pulses must produce sufficient ion flow in the vicinity of the nerve axons to cause membrane depolarization and consequent excitation (Benton et al, 1981). The action potentials then go on to trigger muscle contractions in the normal way (Basmajian, 1978).

The flow of ions in the interstitial fluid surrounding the nerve axons is directly related to the charge delivered by a current pulse. Consequently, the effectiveness of each stimulus pulse depends not only on the current intensity but also on the pulse duration. Variation in the charge delivered by each pulse produces proportional variation in ion flow. Thus, an increase in current pulse intensity or duration usually causes more nerve fibres to be stimulated. This extra recruitment of nerve fibres (and ultimately muscle fibres) leads to a stronger muscle contraction (Benton et al, 1981).

In FES applications, a typical muscle contraction involves the stimulation of a large number of parallel nerve axons which innervate still more parallel muscle fibres. This number is large enough to justify the assumption that the control of pulse intensity, over the strength of the muscle contractions, is effectively continuous.

Another important control over muscle contraction is the number of stimulus pulses delivered per unit time. The stimulus frequency controls not only the force of contraction but also the characteristics of contraction (Edwards, 1981). Usually, a frequency of 20pps or more is sufficient to produce a fused, tetanic contraction. However, frequencies between 40 and 100pps are reported to produce maximum muscle activity (Edwards et al, 1977a).

1.4.2. Electrodes

Most muscles which are useful for standing and ambulation can be stimulated transcutaneously using strategically placed surface electrodes. This type of stimulation is quite effective and has the advantage of being completely non-invasive. Because of the relatively high impedance of the skin, high voltage pulses are required to generate sufficient internal current levels to excite nerve action potentials. Typically, 80 to 100 volts, at the skin surface, will produce muscle contractions which are strong enough for weight bearing.

Devices which use intramuscular electrodes do not have to deal with these high impedance skin layers. Thus, they can operate at much lower power ratings. This has significant implications regarding their relative size. In general, intramuscular stimulators are less bulky and require considerably less battery power than transcutaneous stimulators.

Recent advances in circuit miniaturization have allowed the development of fully implantable, multi-channel stimulation systems (Donaldson, 1986). These devices are designed to receive radio control signals from a transmitter which is placed over the skin surface. The power consumption is so low that the energy contained in the radio carrier signal is sufficient to operate the stimulator. Thus, the compromise between battery size and useful lifetime is eliminated. The system is ready to use at any time so preparation for a stimulation session simply involves applying the transmitter to the skin surface. Intramuscular electrodes provide a more effective muscle contraction than surface techniques and allow greater selectivity of specific muscle groups. However, implanted stimulation systems are invasive and susceptible to infection. Surgery is required to implant the devices which is costly and time consuming. If an infection occurs at any of the electrodes, it can spread to the entire implanted system which must then be surgically removed. Even simple faults, such as component failure or electrode movements, cannot easily be rectified with this type of system.

Percutaneous electrodes provide many of the features of fully implanted devices and do not require the same extent of surgery. Each electrode is introduced through the skin, to the desired stimulus site, with a hypodermic needle. Stimulation is applied to find the optimum electrode position and the needle is withdrawn, leaving the electrode in place. The result of this procedure is a network of intramuscular electrodes that enter the body at specific junction sites and allow simple connection to an external stimulator (Marsolais & Kobetic, 1986). The price paid for electrode failure is significantly less with this type of system. Additionally, if infection occurs at one of the electrodes, it cannot spread to the entire implanted system because each electrode is separate. Finally, a failed or infected electrode can be removed with relative ease.

Marsolais & Kobetic (1983) describe a complex walking system, for paraplegics, which controls many channels of percutaneous muscle stimulation in the lower limbs. The gait pattern produced is faster and more natural looking than the simple FES walking system described above. Despite the advantages offered by intramuscular stimulation, however, it still suffers from the same fundamental problems as surface techniques which will now be considered.

1.4.3. Muscle Fatigue

Pure FES systems, in their present form, suffer from a number of practical limitations. (The most important of these limitations, relevant to the aims of this thesis) is rapid muscle fatigue which occurs during chronic stimulation; particularly if the muscles are being used to support weight. Under normal circumstances, individual muscle fibres receive relatively low frequency excitation. Action potential pulse frequencies in the range of 10 to 20pps, for sustained voluntary contractions, are typical (Edwards et al, 1977a). Muscle contractions which are apparently smooth are achieved because of the asynchronous firing of a large number of muscle fibres. These relatively low firing frequencies are found to be optimum with regard to fatigue resistance (Bigland-Ritchie et al, 1979). Additionally, individual muscle fibres are called upon to contract only in short bursts. This low active duty cycle allows a recovery period for the individual fibres and thus delays the onset of fatigue. The whole process is under the control of the CNS which ensures that a smooth contraction is maintained whilst the load is shared between different muscle fibres at different times.

In most FES applications, neither of the above criteria are fulfilled. Due to the synchronous firing pattern, stimulus frequencies of more than 20pps are required to produce fused, tetanic contractions. At lower frequencies, the muscles cannot produce contractions which are appropriate for supporting weight. High stimulus frequencies, however, have been shown to greatly accelerate the onset of muscle fatigue (Benton et al, 1981; Bajd et al, 1983a; Baker et al, 1986). Rapid muscle fatigue has also been shown to occur when stimulation is applied continuously to the same muscles (Peckham et al, 1976). One mechanism for this is constriction of blood vessels, during a continuous contraction, which causes neuromuscular transmission failure or "ischemic fatigue" (Edwards et al, 1982).

1.4.4. Methods to Overcome Fatigue

Edwards (1981) outlined a difference in fatigue mechanisms which were induced by different stimulus frequencies. High frequency FES caused fatigue which was induced by impairment of neuromuscular transmission or sarcolemmal excitation and low frequency FES produced impaired excitation-contraction coupling. The low frequency fatigue mechanism has been observed to proceed much more slowly than with high frequencies. On the other hand, fatigue induced by high frequency FES recovers more quickly. Edwards et al (1977a) observed that complete recovery from muscle fatigue induced by low frequency stimulation can take several hours.

Stokes & Edwards (1986) attempted to prolong fatigue resistance of muscle by characterizing the composition of muscle fibre types being stimulated, evaluating the fatigue characteristics and determining an optimum stimulus frequency. This does not provide a practical solution because chronic stimulation is still involved and fatigue will inevitably result. Bajd et al (1983a) demonstrated that cyclic stimulation of a muscle will greatly improve its fatigue characteristics because it allows time for muscle recovery. In pure FES applications, however, if support muscles are not constantly being stimulated then safe support is not being provided.

Various attempts have been made to utilize cyclic stimulation of different muscle fibre groups whilst maintaining a constant load. This can be done either sequentially (Peckham et al, 1969; Brindley et al, 1978; Petrofsky, 1979; Pournezam et al, 1988) or according to the posture at any particular time (Kralj et al, 1986). These techniques involve complex and expensive equipment and may not be practical for paraplegic walking systems. The hybrid orthosis is a simple alternative which utilizes the fatigue resisting features of cyclically stimulated muscle. This technique incorporates the use of mechanical bracing to provide long term support of the body weight while FES provides forward propulsion. This will be considered later in more detail.

1.5. MECHANICAL BRACING

Another problem with pure FES systems is the possibility of abnormal joint loading; particularly at the ankle and knee joints. This is important for subjects with no sensory innervation. For example, a turned ankle, without the subject's knowledge, may injure the joint or cause a fall. Orthotic bracing provides strength, reliability and safety. It does not suffer from the time limitations imposed by muscle fatigue and it prevents damage to joints by limiting their range of motion.

Orthoses, such as full length calipers and reciprocal walkers, have been shown to be effective in stance and locomotion functions for paraplegic subjects. Major et al (1981) describe a Hip Guidance Orthosis (HGO) which provides stability at the hip, knee and ankle joints. A high thoracic level paraplegic can walk in this device, with crutches, by laterally shifting weight. This clears the contralateral leg from the ground and allows it to swing through under the influence of gravity and inertia. A similar device, with various biomechanical differences, is the Reciprocation Gait Orthosis (RGO) described by Douglas et al (1983). These devices provide therapeutic loading of the lower limbs and allow the patient to exercise in an upright position. However, some of the direct therapeutic benefits of FES cannot be provided by mechanical orthoses.

1.5.1. Hybrid Orthoses

A hybrid orthosis uses passive mechanical bracing to provide long term support while FES provides the overall system with active power. Tomovic et al (1972) proposed an additional component which derives active mechanical power from an external source. In the interests of practicality, however, this approach has not been adopted in this thesis. Schwirlitch & Popovic (1984) developed a hybrid system based on a modular orthosis which fitted like an external skeleton. FES was used to supply a "biological actuator". Other methods have used various standard orthotic braces, in conjunction with FES, to aid in standing, foot clearance and crutch assisted ambulation (Andrews & Bajd, 1984; Petrofsky et al, 1985; Cliquet et al, 1986). The FES component of these hybrid applications is reported to reduce the upper limb effort and energy associated with ambulation (Patrick & McClelland, 1985; Nene & Andrews, 1986; Cliquet, 1988; Marsolais & Edwards, 1988).

The hybrid system which is specifically dealt with in this thesis is based on a floor reaction orthosis (FRO) (Saltiel, 1969; Yang et al, 1986). This device can brace the knee, under certain conditions, without any activity required from the quadriceps muscles. In some positions, however, the quadriceps must be stimulated to properly support a paralysed leg. The fact that the device allows free flexion of the knee gives it certain advantages over braces that lock the knee. In general, the main function of the FRO in this hybrid system is to provide enough passive mechanical support, during quiet standing or the stance phase of gait, to reduce the duty cycle of efferent muscle stimulation (Andrews, 1986; Andrews et al, 1988). The implications of this will be considered in chapter two.

1.5.2. Cosmesis and Convenience

Cosmesis and convenience are important aspects in the design of any orthotic system. Although they have no direct bearing on function and biomechanics, they determine whether or not an orthosis is accepted by the patient. None of the benefits mentioned above can be gained if the patient does not use the orthosis on a regular basis. This will, almost certainly, be the case if the device constitutes a nuisance to daily living or is overly conspicuous.

The most cosmetically acceptable orthotic systems are those that look natural. For the severely disabled, mechanical bracing does not meet this criterion very satisfactorily. Although devices such as calipers can be concealed under clothing, they are still bulky and obvious to the observer. Reciprocal walking braces are effective for stance and gait but they are far from natural in appearance. To support the weight of a paralysed patient, a brace must also be strong. This often means that mechanical orthoses are heavy, difficult to apply and remove and a hindrance to routine activities such as transfer. FES shows a distinct advantage here because the equipment required is lightweight and relatively easy to apply. If surface stimulation electrodes are being used, they conceal easily under clothing. If the patient has had intramuscular electrodes implanted then the system is optimal with regard to cosmetic appeal and ease of application.

The Hybrid Orthosis considered in this thesis does not provide a complete solution to any particular aspect of the above criteria but it does help to reduce many of the problems associated with mechanical orthoses or FES applied individually.

1.6. POSTURAL STABILITY

Normal postural stability has been the subject of considerable investigation. It is easy to under-estimate the complexity of postural control but a closer look at the biomechanics of stance reveals that it is not a simple matter. In general, normal stance involves co-contraction of antagonistic muscles in the lower limbs, plus the effect of corrective reflexes. These reflexes are part of a complex control network which stabilizes what would otherwise be an unstable system.

The simplest analogy for upright posture is that of an inverted pendulum which is hinged only at the ankles. However, postural corrections against perturbations in the anterior-posterior (AP) plane have been shown to involve rotations about the ankle, knee and hip joints (Nashner & McCollum, 1985). Electromyogram (EMG) studies of the muscles controlling these joints have also indicated that the reaction against an AP perturbation starts at the ankle joint and then proceeds proximally from the support base (Nashner, 1977; Cordo & Nashner, 1982). In these experiments, the initial latency between the perturbation and the reaction at the ankle joint measured about 100-120ms. Each subsequent proximal progression to the next joint was separated by 10-20ms which is too rapid to be an independent spinal reflex reaction. These responses were also adaptable to the magnitude and direction of the perturbation which suggests the influence of preprogrammed muscle patterns controlled by the CNS.

Further complications to the analysis of postural control are introduced by perturbations in the medio-lateral (ML) plane and the effect of the head and upper limbs on the centre of gravity. The afferent signals available to the CNS are from visual, vestibular and proprioceptive sensors. The CNS then has the extensive task of processing this information and coordinating appropriate muscular activity, in sufficiently short time, to prevent the system from becoming unstable.

1.6.1. Sway Measurement

The measurement of postural sway appears to be the most widely accepted means of quantifying postural stability. It has long been known that variations in sway patterns are an indication of neurological disorders (Romberg, 1853; Fearing, 1924). The methods used to measure sway, however, are the subject of some controversy. Sway, during quiet stance, is defined by movements of the centre of gravity (CofG) in a plane which is approximately horizontal and parallel to the supporting base. These movements are due to small deviations of the CofG line from the vertical ground reaction vector (GRV) and their subsequent correction by reflexive muscular action. Since the system is marginally stable, these corrections must be made constantly and the CofG is never actually co-linear with the GRV for more than an instant.

Many researchers have studied sway by measuring the centre of pressure (CofP) on a force platform (Murray et al, 1975; Cybulski & Jaeger, 1986). This amounts to measuring the base position of the GRV which does not necessarily correspond to movement of the CofG. Stevens & Tomlinson (1971) recognized this and called the CofP a "secondary consequence of swaying movements". They further suggested that it may not be effective in measuring all the characteristics of sway. The method that they used recorded "true sway" in the AP plane by directly measuring the displacement of the body at the approximate level of the CofG. A displacement transducer was also placed over the upper thoracic region to detect any bending of the body during stance.

The measurement of displacement, at various sites on the body, has been used by several researchers to study sway. Boman & Jalavisto (1953) employed a photographic technique to measure movement at the head. Sheldon (1963) used a special framework which recorded displacement at the shoulder level. Fernie & Holliday (1978) measured displacement in the AP and ML planes using potentiometric transducers placed at the sacral level of the body. Other methods have employed optical and magnetometry techniques to measure displacement (Koles & Castelein, 1980; Dean et al, 1986).

Koles & Castelein (1980) measured the CofP simultaneously with displacements in the AP plane at the hips, shoulders and head. This data was then used to examine the relationship between the CofP and joint rotations at the ankle, hip and shoulder levels during normal standing. The knees were assumed to be constantly extended, so a three-segment stick model was used for the calculations. The results showed that the CofP was most sensitive to rotations at the ankle joint and least sensitive to rotations at the shoulder level.

CofP was chosen as the method of stability analysis, in this thesis, for the following reasons:

Firstly, in paraplegic standing, no postural corrections are made by muscle action at the ankles or hip joints. All adjustments must be made at the level of the shoulders. Under these circumstances, the body is more closely approximated by a simple, inverted pendulum model and the CofP movement is closer to true sway than with normal stance.

Secondly, although CofP is not a direct measure of sway, it can still be used as a valid measure of relative postural stability (Maki et al, 1987).

Finally, measuring CofP with a force platform is a quick and convenient method for stability analysis. Measurement of true sway requires more complicated techniques and is not necessarily better than CofP for stability analysis; especially with paraplegic standing.

1.6.2. Sway Parameters

For convenience, the word "sway" will now be used, in this thesis, to describe CofP as well as CofG displacements. It should be remembered, however, that these quantities differ in their basic definitions.

As well as variety in measuring techniques, there also exists a large variety of sway parameters. Earlier sway studies usually concentrated on the effective area covered by the sway path and the maximum range in the AP and ML directions (Hellebrandt & Braun, 1939; Boman & Jalavisto, 1953; Sheldon, 1963). The data available, to these researchers, was usually a two dimensional trace of the total sway path. Thus, the information content was limited to the above parameters. Murray et al (1975) took the analysis a step further by resolving sway into the AP and ML planes using polygraph recordings. For normal standing, they found that the average excursion from the mean position, in either direction, was relatively small. The total cumulative excursion from the mean position was found to be surprisingly large.

Later studies have utilized techniques to digitally store sway data and subsequently analyse it with a computer. This allows the extraction of much more useful information. The sway parameters which are now most commonly calculated are: Total sway path length, average speed, effective area, AP and ML components, average radius of rotation and average frequency of rotation. Another common calculation is the ratio of any sway parameter, obtained with eyes open, to that obtained with eyes closed. This is sometimes known as Romberg's coefficient (Dean et al, 1986).

Due to the large variety of parameters and techniques, it would not be sensible to compare data obtained from different sway studies. Sway should not be considered as a strict definition of postural stability but, rather, as a means of comparing the stability of different subject categories. For example, sway has been shown to significantly increase when the subjects are elderly or have their eyes closed (Sheldon, 1963; Dean et al, 1986).

Cybulski & Jaeger (1986) used sway measurement to compare the standing performance of normal subjects with paraplegics wearing knee-ankle-foot orthoses (KAFO). The sway parameters calculated were: Total sway path, average radius of rotation and average frequency of rotation. No attempt was made to compare AP and ML components. Tests of twenty seconds duration were performed with eyes open and closed and with hands on and off a supporting frame. The results showed that postural stability in normal stance was generally superior to paraplegic stance with KAFO's. With eyes open, however, KAFO stance compared more favourably with normal stance. A further comparison was made with paraplegic stance using bilateral FES of the quadriceps muscles to brace the legs. This proved to be less stable than KAFO standing. Cybulski & Jaeger (1986) suggested that an orthosis must show stability characteristics which are comparable to KAFO's before it can be considered as a viable alternative for paraplegic standing. For the work presented in this thesis, a similar but more detailed analysis was used to compare the stability of the hybrid FRO system with other paraplegic standing aids.

1.7. MUSCLE RESPONSE TO VARYING STIMULI

High stimulus frequencies produce increased muscle activity at the expense of rapidly induced fatigue (Edwards et al, 1977a; Edwards, 1981). Baker et al (1986) studied the fatiguability of healthy muscle stimulated at 100pps. This was prompted by the finding that higher frequencies were preferred by subjects who could feel the stimulus (McNeal et al, 1986). The study showed that in order to avoid significant fatigue, a stimulus duty cycle of less than 10% was required. Such a low duty cycle cannot be considered practical for muscle building exercises or most FES based walking systems. A hybrid orthosis requires only intermittent bursts of stimulation for correct operation.

In the selection of stimulus parameters used for the hybrid orthosis, in this thesis, more emphasis was placed upon speed and strength of contraction than upon fatigue reduction. Although fatigue reduction was not disregarded completely, it was assumed that the majority of long term support would be provided by the mechanical bracing. Because of the compromising effect of muscle fatigue, most FES applications use stimulus frequencies which are just high enough to produce fused, tetanic contractions. Thus, the majority of literature confines the study of muscle responses to these relatively low frequencies.

1.7.1. Fibre Type Transformation

A notable exception to this is the study of muscle fibre transformation. A number of experiments have indicated that exercise programmes based on intermittent high frequency stimulation transform slow-twitch skeletal muscle fibres into fast-twitch types. The opposite effect is observed with low frequency stimulation. This has been demonstrated in both denervated muscle (Lomo et al, 1980) and innervated muscle (Salmons & Sreter, 1976; Heilig & Pette, 1980; Salmons & Henriksson, 1981; Stefanovska & Vodovnik, 1985). Although the transformation of muscle fibre types would, almost certainly, have a long term effect on the application of hybrid orthoses, it has not been given detailed consideration in this thesis. Instead, all comparative tests were performed on paralysed muscle conditioned with standard exercises based on low frequency stimulation.

1.7.2. Catch Mechanism

The observation that prompted the muscle response tests, outlined in this thesis, is known as the "catch" mechanism. Wilson & Larimer (1968) clearly demonstrated this property using stimulation of crayfish claw muscles. High frequency stimulation (100pps) caused a rapid increase in the strength of contraction. Similarly, halting the stimulus caused a rapid decrease. However, an intermediate stimulus frequency (20pps), following a period of either of the above extremes, was observed to "catch" the instantaneous strength of contraction and maintain it at a constant level. In actual fact, the contraction strength was not constant but the rate of decay, at the intermediate frequency, was so low that the contraction appeared to be constant over the period of a few seconds.

The catch property is, of course, far less pronounced in mammalian skeletal muscle but still observable (Burke et al, 1970). Whether the similarities observed between invertebrate and mammalian muscle are due to the same mechanisms is not known. In fact, the precise mechanism is still not clearly understood for any type of muscle. Wilson & Larimer (1968) suggested that the property may reside in calcium binding mechanisms but this does not appear to have been established in subsequent literature.

The most useful aspect of the catch property, relevant to the aims of this thesis, is the fact that a short, high frequency burst, superimposed on a low frequency stimulus, can dramatically improve the transient behaviour of skeletal muscle. This opens up the possibility of improving muscle response times without unduly accelerating fatigue mechanisms.

1.8. FLEXION WITHDRAWAL REFLEX

The flexion withdrawal reflex is a polysynaptic, spinal reflex which is usually elicited by a noxious stimulus in the region of the foot. This stimulus may be mechanical or electrical in nature. Afferent signals, from the stimulus site, excite contractions in joint flexor muscles of the ipsilateral leg and extensor muscles in the contralateral leg. Similarly, inhibition of the ipsilateral extensors and contralateral flexors can be observed. In normal individuals, afferent signals also flow through the spinal cord to the cortex where the stimulus is consciously recognized.

1.8.1. Early Investigations

Sherrington (1910) observed the receptive field for stimulation of this reflex over the surface of the leg and described the participating muscles. A number of detailed investigations have taken place to identify the neural mechanisms involved with this reflex; some of which will now be considered.

From the results of early EMG studies, measuring the latency of muscles involved in the flexion reflex, it was generally accepted that the reflex consisted of two components labelled "early" and "late" responses (Lloyd, 1943; Kugelberg, 1948; Hagbarth & Finer, 1963).

Kugelberg (1948) attempted to separate A-type and C-type afferent nerve fibre activity by studying pathological flexion reflexes in humans. He attributed the early response to myelinated A fibres and the late response to unmyelinated C fibres. A double pain sensation was reported where the early response produced "sharp pain" and the late response produced "burning pain". He proposed that the wide range of conduction velocities in the afferent pathways was a major contributing factor in the slowness observed in the flexion response. Hagbarth (1960) observed reductions in the EMG latencies of inhibitory responses of the gluteus maximus and vastus medialis muscles as the stimulus source was moved proximally along the leg. From this he estimated the average conduction velocity in the afferent fibres to be 33-40 m/s and concluded that sensory fibres of the delta group must be involved in the early reflex.

In a later study by Hagbarth & Finer (1963), it was concluded that the late reflex response was a "conditioned cerebral reaction" because it showed learning capability and was adaptable to both the magnitude and direction of a noxious stimulus as well as to the position of the leg. The early component did not show such directional adaptability but did show signs of supraspinal intensity control such as habituation and dependence on the state of attention of the subjects. This component was considered to be a spinal reflex mechanism.

For this reason, several studies of the flexion withdrawal reflex were concentrated only on the early component with minimal latency (Hagbarth, 1960; Dimitrijevic & Nathan, 1968). However, Shahani & Young (1971) observed that patients with chronic spinal cord lesions had a very pronounced late reflex component with normal latency and that the early response was absent or reduced. This observation was also made for normal subjects whilst asleep. They suggested that the early component may somehow regulate inhibition of the late component such that when the early component is absent, the late component is not controlled.

An apparent exception to this observation was that patients with Friedreich's ataxia displayed normal early responses but exaggerated late responses; again with normal latencies. Shahani & Young (1971) attributed this to higher CNS mechanisms. The explanation offered by Horstink et al (1975) is that inhibition of the late response depends on large afferent alpha fibres which are lost in Friedreich's ataxia and that the early response depends on smaller afferent delta fibres which are preserved. This agrees with the original observations made by Kugelberg (1948) and Hagbarth (1960) and casts doubt on the proposal that the late response is under complete cerebral control.

1.8.2. Use of the Reflex for Gait

Stimulation of the peroneal nerve to correct footdrop in hemiplegic patients has been well reported (Liberson et al, 1961; Takebe et al, 1975; Waters et al, 1975). This is an example of the application of direct efferent stimulation of the dorsiflexors of the foot. More recent applications have utilized the flexion withdrawal reflex to aid in the swing phase of gait for hemiplegic patients (Lee & Johnston, 1976) and paraplegic patients (Kralj et al, 1981; Bajd et al, 1983b). These studies investigated several alternative sites to stimulate the reflex but the peroneal nerve was most commonly used. The induction of the withdrawal reflex, by stimulation at a single motor point, is a convenient alternative to directly stimulating a large number of muscles in the leg, in correct sequence, in order to take a step. However, the complexity of the reflex leads to a number of drawbacks.

1.8.3. Problems with the Reflex

One problem with using this reflex is variability. The responsiveness of the reflex, to stimulation, can differ significantly from one subject to another and even with the same subject on different occasions. Another problem with the reflex, when using it for practical walking, is speed. Some patients exhibit very long latencies between the onset of stimulation and limb withdrawal; the reflex can also take time to die away after the removal of the stimulus. Again, a great deal of variability exists for this.

Problems introduced by habituation of the flexion response have been well investigated (Dimitrijevic & Nathan, 1970; Fuhrer, 1976; Kralj et al, 1981). Dishabituation of the reflex has also been shown to occur when a sudden change in the stimulus is introduced (Hagbarth & Finer, 1963; Dimitrijevic & Nathan, 1971; Fuhrer, 1973). With electrical stimulation this could be a single, high intensity pulse or a high frequency burst.

In general, it appears that characterization of the flexion reflex in humans, with respect to its response to various stimulus parameters and controllability, has not been investigated very thoroughly in the literature. Lee & Johnston (1976) applied several variations of pulse intensity, frequency and train duration and observed the time for which the foot was clear of the floor. They found that an increase in any of these parameters produced a corresponding increase in stepping time. No information, however, was derived about the latency of the response or the kinematics of the leg. One of the aims of this thesis is to study this aspect of the flexion reflex and explore the possibility of using variable stimulus parameters to improve the speed and reliability of flexion for paraplegic gait.

1.9. PROJECT AIMS

The remainder of this thesis will be centred around the following hypotheses and associated project aims:

1) Can the floor reaction orthosis form a basis for a feasible, laboratory based system for stance and reciprocal stepping in paraplegics?

Aims: a) Develop a closed loop, hybrid FES walking system which incorporates artificial extension reflexes, feedback of hip angle to control swing phase and use of crutch and foot pressure information to detect stepping intention.

2) Does the hybrid FRO system offer any advantages over other stance and walking aids?

Aims: a) Evaluate the system with respect to stability and fatigue resistance.

3) Can muscle dynamics be improved for standing with the hybrid FRO system?

Aims: a) Characterize muscle dynamics according to stimulation parameters.
b) Determine an optimum stimulus pattern for use with the artificial knee extension reflex.

4) Can the control of flexion withdrawal be improved during the swing phase of gait with the hybrid FRO system?

Aims: a) Characterize the flexion withdrawal reflex according to stimulation parameters.
b) Determine an optimum stimulus pattern for control of reciprocal stepping.

CHAPTER 2. SYSTEM DEVELOPMENT

2.1 Introduction

2.2 Floor Reaction Orthosis

2.2.1 Brace Component

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CHAPTER 2. SYSTEM DEVELOPMENT

2.1. INTRODUCTION

The work for this project involved a considerable amount of hardware and software development. This chapter will outline the design and development of the following system components:

a) Floor reaction orthosis
b) Sensors
c) Computer controlled stimulator
d) Control system software
e) Postural evaluation system

Additionally, during the development stages of the project, a number of preliminary tests were conducted. The results of these tests played a significant role in the progressive design of the orthosis. Thus, it was considered appropriate to include some of them in this chapter.

2.2. FLOOR REACTION ORTHOSIS

In chapter one, it was specified that the combination of FES with mechanical bracing should reduce some of the problems associated with the application of either technique alone. This will now be considered in detail for the hybrid FRO system.

Paraplegics, when using FES to walk, expend more energy, per unit time and distance, than able bodied individuals walking normally. In fact, FES walking is quite a strenuous exercise (Marsolais & Edwards, 1988). Much of this exertion comes from the use of the upper limbs to stabilize the body and carry some of its weight during ambulation. Another source of energy consumption is FES induced activity in the paralysed, lower limb musculature.

Consequently, during prolonged use, it is to be expected that the subject will need to stop periodically and rest. With a pure FES walking system, the subject must sit down and switch off the stimulation if he wishes to recover from the physical exertion and allow the stimulated muscles to recover from fatigue.

If mechanical bracing can be used to support the weight of the subject without the aid of FES then recovery can be achieved whilst maintaining an upright posture. This offers a significant practical advantage because it reduces the subject's dependence on a wheelchair (or an equivalent device) being nearby. The hybrid FRO system not only allows the subject to stand quietly with no stimulation, it also delays the onset of fatigue, during ambulation, by reducing the effective duty cycle of efferent stimulation. Another advantage offered by the brace component is protection of the knee and ankle joints. If the subject has lost sensory innervation at these joints then it is important that they be constrained. This helps to avoid injuries which could be incurred if a leg was improperly positioned whilst attempting to bear weight on it.

On the other hand, the presence of FES in the system offers a number of advantages over the use of conventional mechanical bracing on its own. Apart from the direct therapeutic and psychological benefits, described in chapter one, significant improvements are obtained in cosmetic appeal and practicality.

Firstly, instead of using the upper limbs to shift weight and progress each leg, FES can be used to actively flex the leg and take a step forward. This is not only cosmetically acceptable but also reduces upper limb exertion. Secondly, although reduced in duty cycle, stimulation of support muscles is still sufficient to eliminate the need for mechanical knee locks on the FRO brace component. The free knee facility allows for a more natural looking gait pattern and simplifies standing and sitting procedures.

2.2.1. Brace Component

The initial brace design, illustrated in figure 2.1, is based on a concept introduced by Saltiel (1969). The main functional component is a rigid ankle joint and foot plate which extends the ground reaction vector (GRV) to the end of the foot when the subject leans slightly forward (ie. $\Theta > 0$). When the direction of the GRV lies anterior to the centre of the knee joint, it has the effect of passively stabilizing the joint by creating an extending moment. This has been used successfully with patients suffering from quadriceps weakness (Yang et al, 1986). It has not, however, been previously considered for use with total leg paralysis because it requires a finite amount of quadriceps activity. In the hybrid FRO system, this activity is provided by the FES component.

The vector diagram in figure 2.1 illustrates the effective forces which are exerted on the brace. Namely, the GRV, the load borne through the leg (L) and the resultant of the pressure exerted below the patella tendon (P). This assumes that the system is in steady state and that the GRV is vertical. In the initial FRO system, the quantity "P" was used as an indicator for passive knee stability.

This brace functioned well in the majority of circumstances and was used to obtain some of the preliminary results in this thesis. However, two significant problems were identified:

1) Due to the increased anterior position of the GRV, the brace exerts a greater than normal extending moment at the knee joint and thus increases stress on the knee ligaments. If applied regularly, over a long period of time, the risk of genu recurvatum is present.

2) The patellar pressure is not a direct measure of knee extending moment and cannot be considered reliable in all cases. The importance of accurately measuring the knee extension moment will be detailed later.

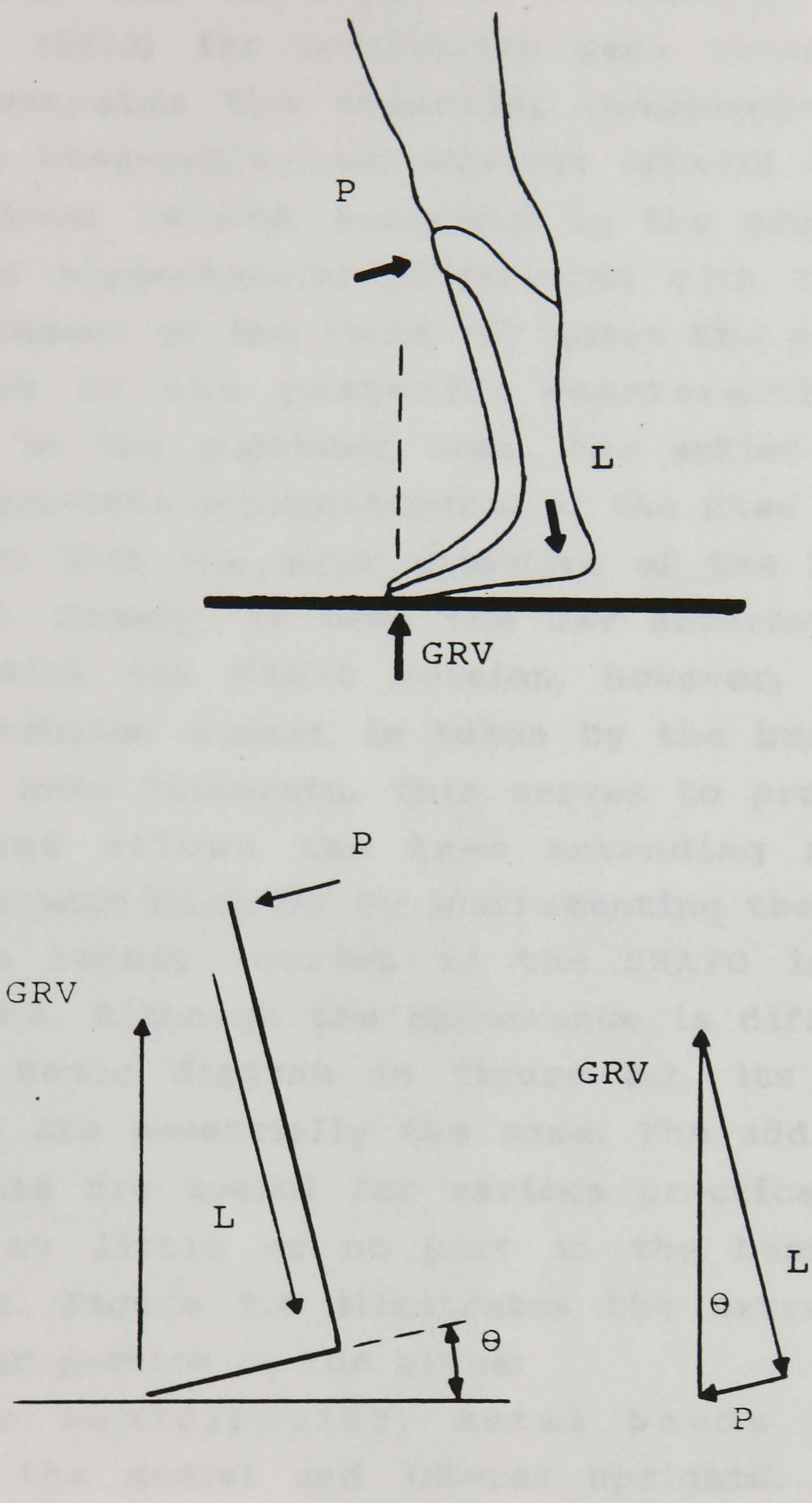


Figure 2.1

Initial FRO design. The vector diagram illustrates the effective forces on the brace.

2.2.2. Supracondylar Component

The problems identified in the previous section can be solved by extending the brace slightly above the knee. This idea is based on an orthosis developed by Lehneis (1972) for controlling genu recurvatum. Figure 2.2 illustrates the essential components of a supracondylar knee-ankle-foot orthosis (SKAFO) which replaces the original version described in the previous section. The main biomechanical differences with this brace are the placement of the force "P" above the patella and the presence of the posterior counteracting force (F) applied in the popliteal area. The action of these two forces prevents hyperextension of the knee joint.

Note that the main objective of the brace is still achieved. Namely, to keep the GRV anterior to the knee joint. With the SKAFO version, however, the resulting knee extension moment is taken by the brace itself and not the knee ligaments. This serves to protect the knee joint and allows the knee extending moment to be measured more directly by instrumenting the brace.

The latest version of the SKAFO is pictured in figure 2.3. Although the appearance is different to that of the basic diagram in figure 2.2, its biomechanical features are essentially the same. The additional straps and joints are useful for various practical reasons but they play little or no part in the basic theoretical function. Figure 2.4 illustrates the extra features on the upper portion of the brace:

Two semicircular, metal bands (B_1 and B_2) connect the medial and lateral uprights. These do not come in contact with the leg; their function is simply to provide the brace with rigidity about the knee. The dotted lines represent elastic straps which are designed to keep the brace in alignment with the leg and prevent relative movement. During stable stance, the forces exerted by these straps, on the leg, are minimal compared with the forces over the suprapatellar and

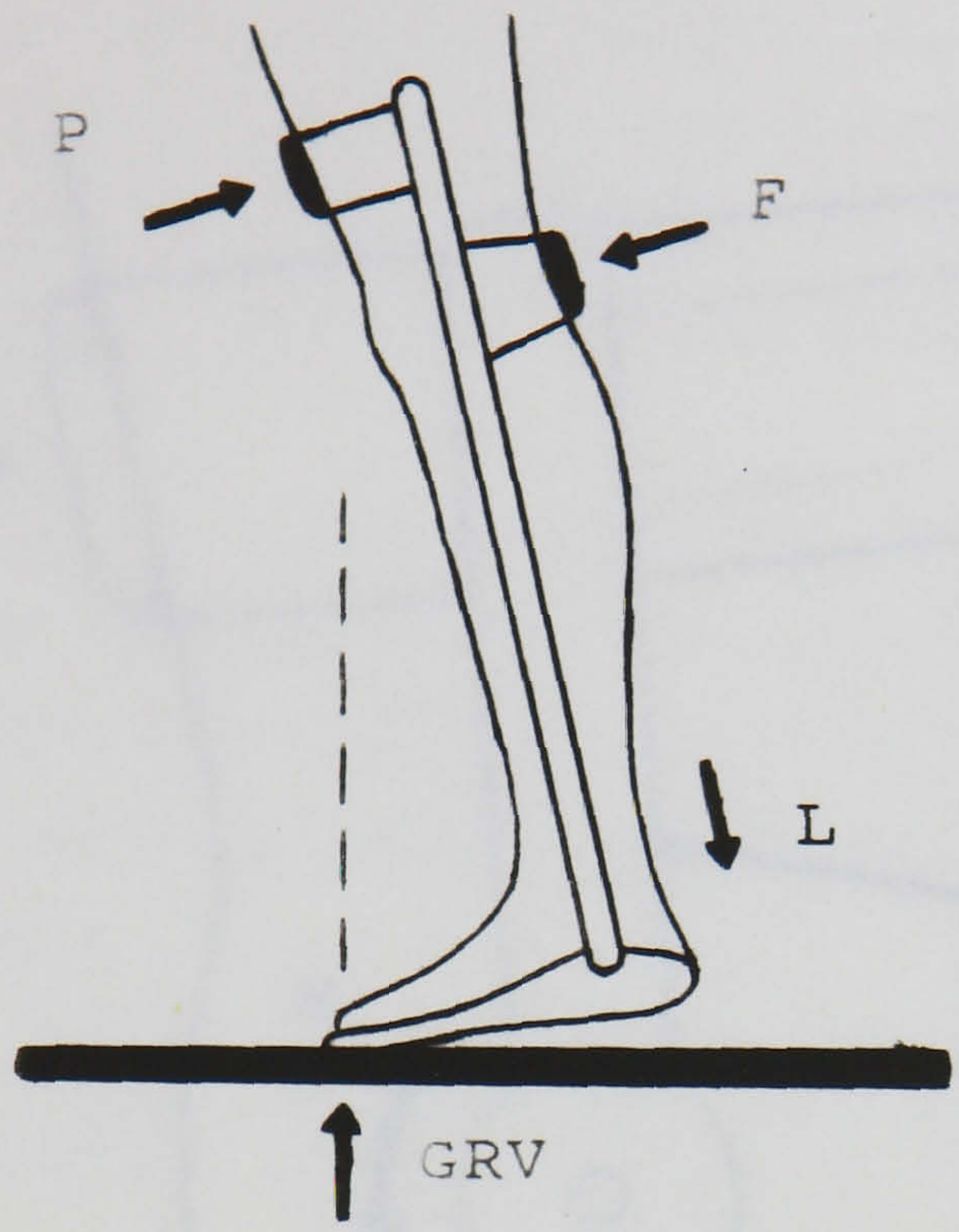


Figure 2.2

Basic SKAFO design.

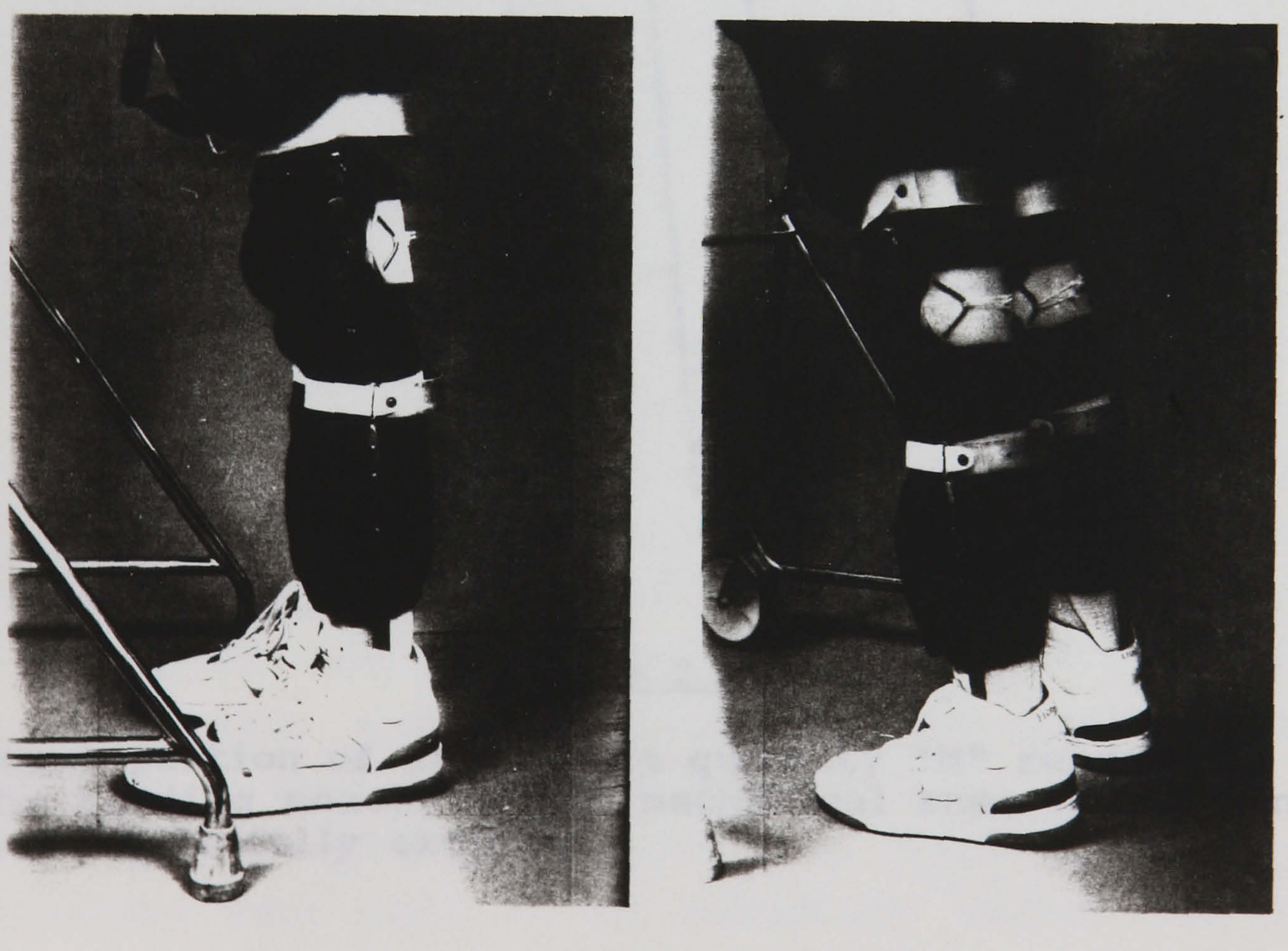


Figure 2.3

Latest version of SKAFO.

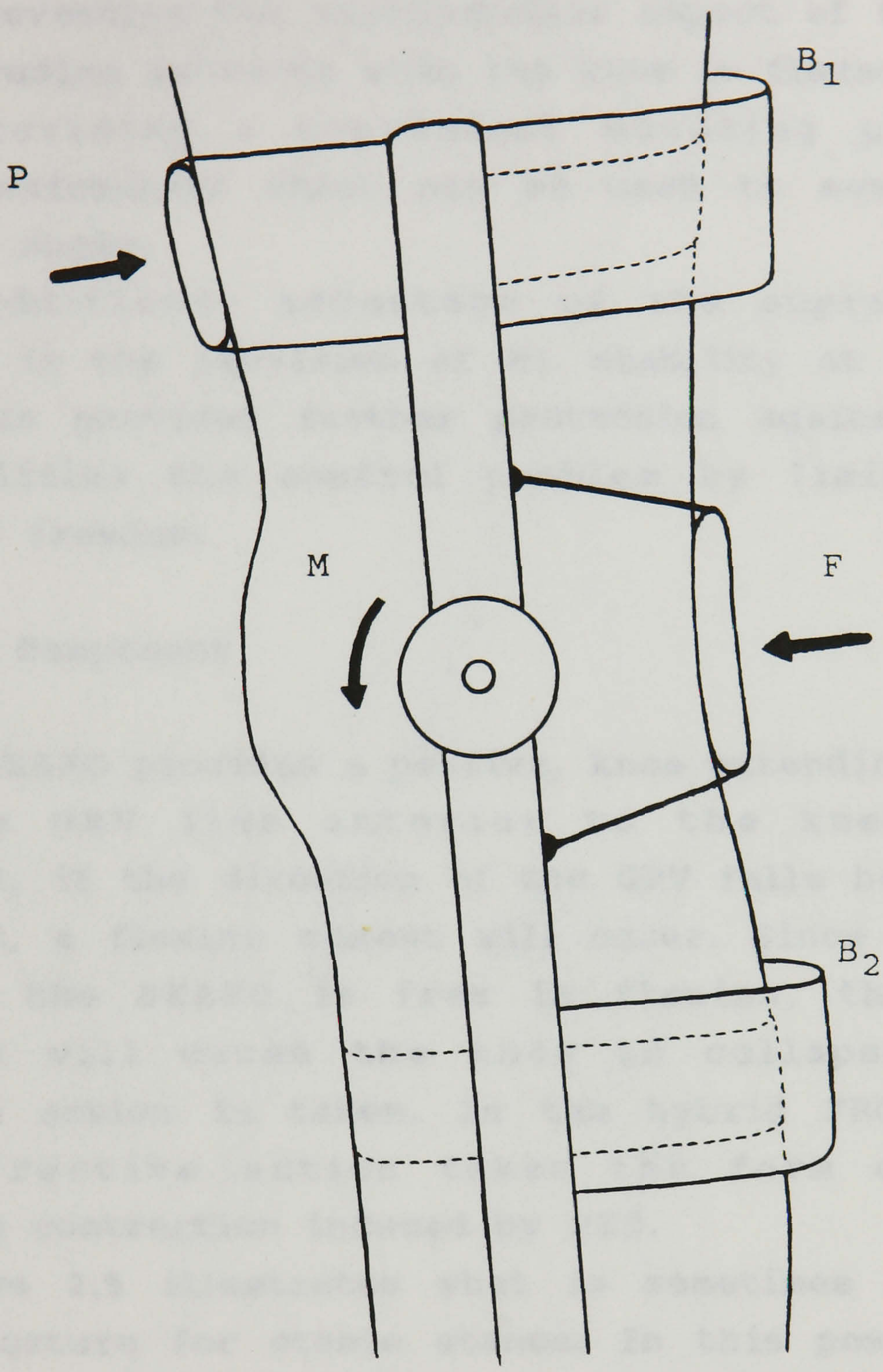


Figure 2.4

Upper portion of SKAFO. The quantity "M" represents the bending moment at the mechanical knee joint when the leg is fully extended.

popliteal areas (P and F). Both uprights are fitted with standard knee joints which allow free flexion and stop extension. Although these are not essential to the basic operation of the brace, they serve two useful purposes:

1) Preventing the suprapatellar aspect of the brace from protruding outwards when the knee is flexed.

2) Providing a convenient mounting point for electro-goniometers which can be used to measure the knee joint angle.

An additional advantage of the supracondylar component is the provision of ML stability at the knee joint. This provides further protection against injury and simplifies the control problem by limiting the degrees of freedom.

2.2.3. FES Component

The SKAFO provides a passive, knee extending moment when the GRV lies anterior to the knee joint. Conversely, if the direction of the GRV falls behind the knee joint, a flexing moment will occur. Since the knee joint of the SKAFO is free in flexion, the latter condition will cause the knee to collapse unless corrective action is taken. In the hybrid FRO system, this corrective action takes the form of rapid quadriceps contraction induced by FES.

Figure 2.5 illustrates what is sometimes known as the "C" posture for stable stance. In this posture, the subject leans slightly forward to utilize the floor reaction function of the SKAFO. The GRV lies in front of the knee joint and behind the hip joint such that both remain in full extension. This is the ideal "rest" posture which requires no FES input.

It is tempting to conclude that quadriceps stimulation acts only as an emergency backup for the brace to prevent the leg from collapsing. However, this is not really the case. It is a common and indeed natural occurrence for the GRV to shift behind the knee

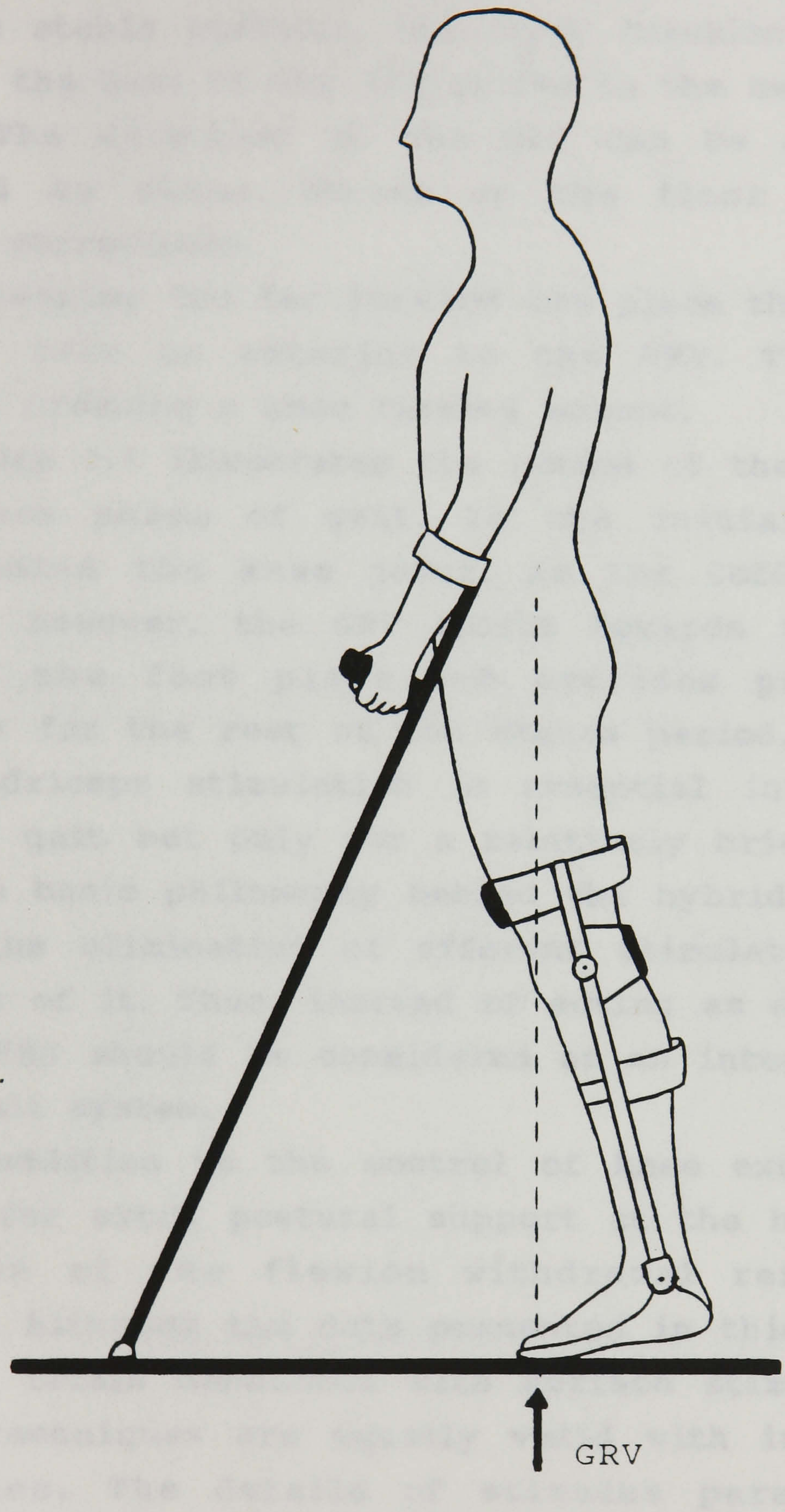


Figure 2.5

The "C" posture for stable stance.

joint during stance and gait. Figure 2.6 illustrates three basic mechanisms which can cause the GRV to shift during quiet stance:

a) If the subject leans backwards by a few degrees from the stable position, the floor reaction function is lost and the base of the GRV shifts to the heel.

b) The direction of the GRV can be significantly affected by shear forces on the floor induced by postural corrections.

c) Leaning too far forward can place the knee joint directly over or anterior to the GRV. This has the effect of creating a knee flexing moment.

Figure 2.7 illustrates the action of the GRV during the stance phase of gait. In the initial stages, it falls behind the knee joint. As the CofG progresses forward, however, the GRV shifts towards the anterior edge of the foot plate and provides passive knee extension for the rest of the stance period. This means that quadriceps stimulation is essential in the stance phase of gait but only for a relatively brief period of time. The basic philosophy behind the hybrid FRO system is not the elimination of efferent stimulation but the reduction of it. Thus, instead of acting as an emergency backup, FES should be considered as an integral part of the overall system.

In addition to the control of knee extension, FES is used for extra postural support at the hips and the induction of the flexion withdrawal reflex during stepping. Although the data presented in this thesis are based on trials conducted with surface stimulation, the control techniques are equally valid with intramuscular electrodes. The details of stimulus parameters and control will be considered in later sections.

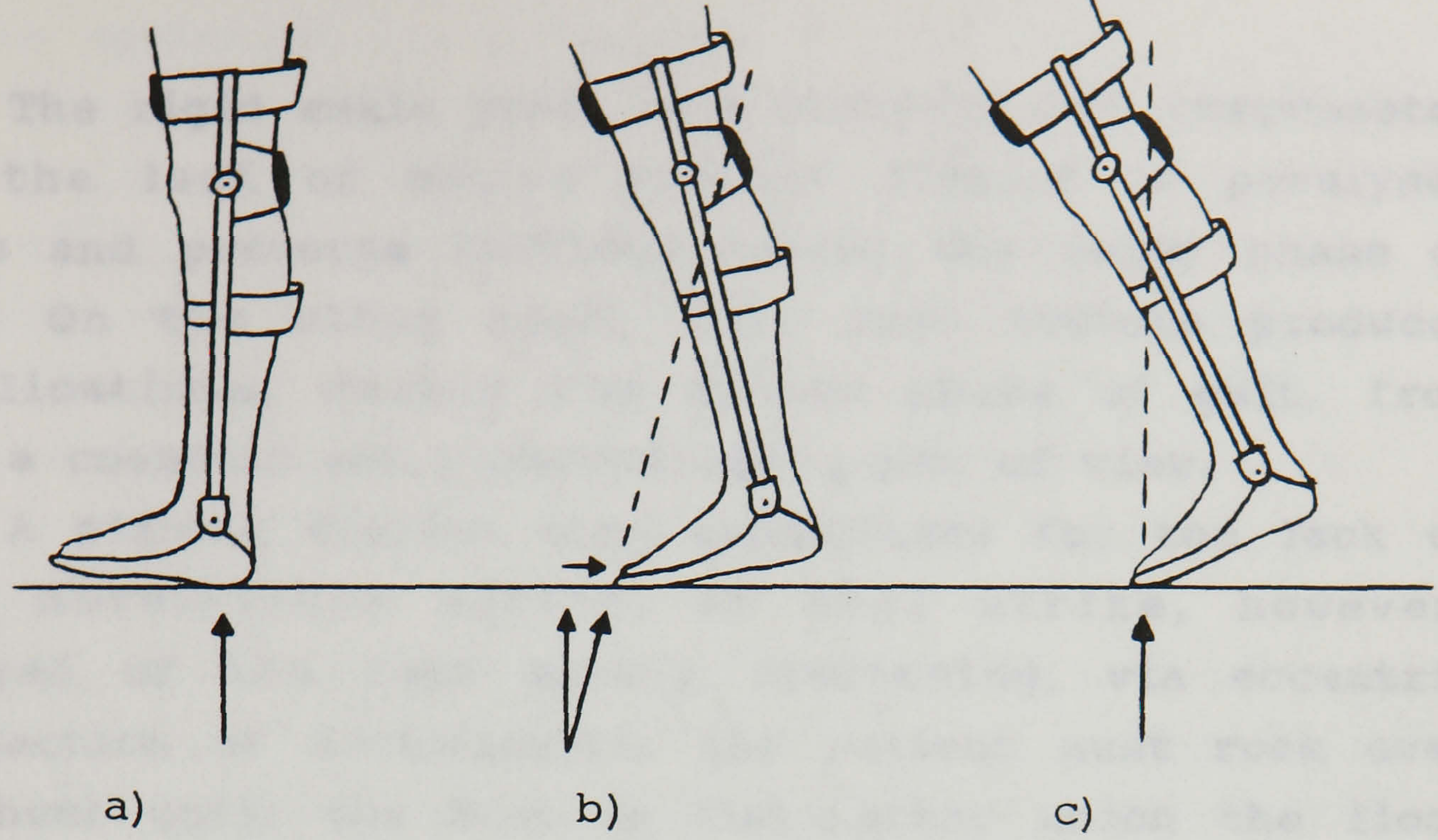


Figure 2.6

Basic mechanisms for movement of the GRV behind the knee joint. a) Leaning backwards b) Shear forces c) Overreaching.

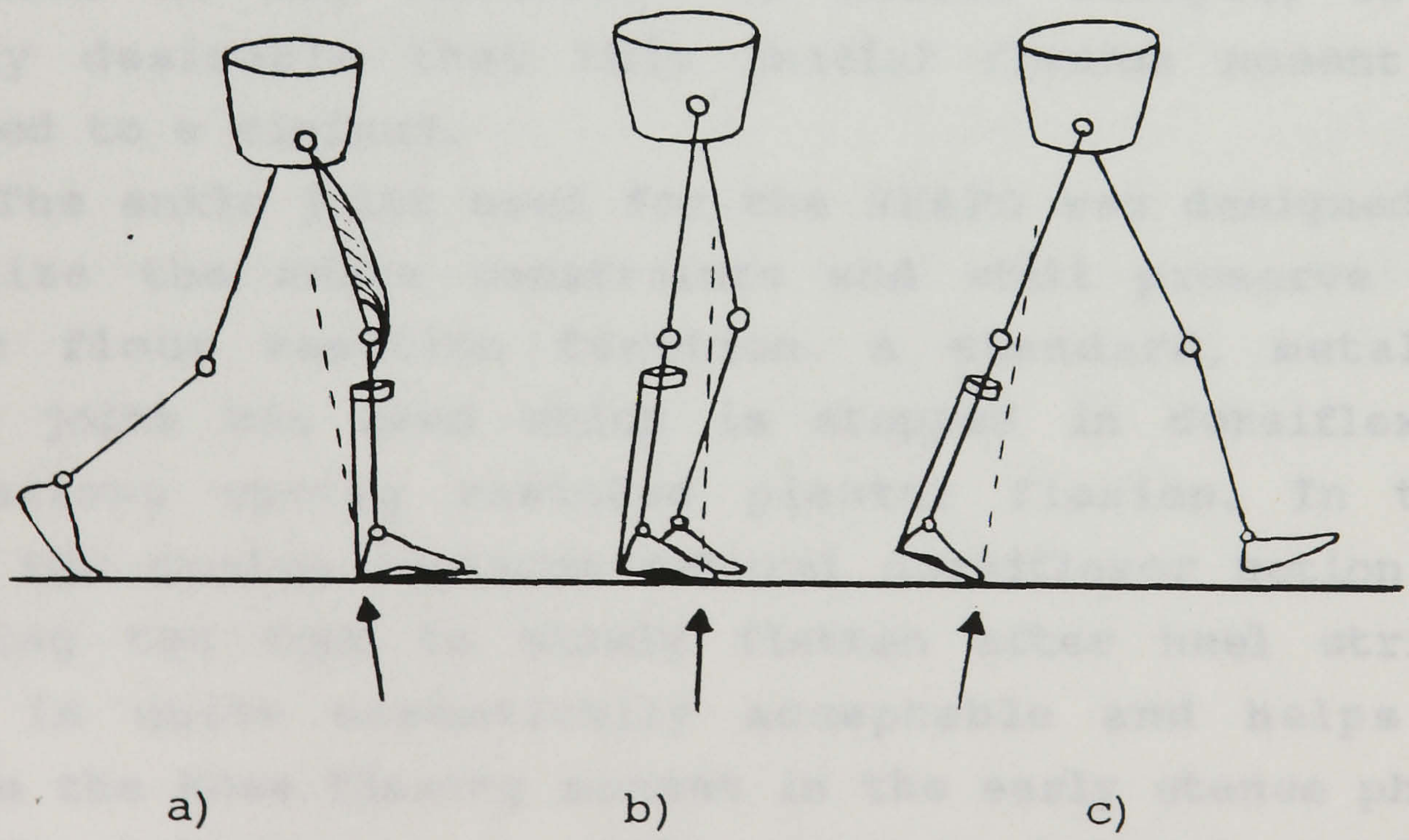


Figure 2.7

Motion of GRV during the stance phase of gait.
a) Early stance with an overall knee flexing moment and eccentric contraction of quadriceps. b) Mid stance and c) Late stance with overall knee extension moment.

2.2.4. Ankle Joint

The rigid ankle joint in a standard FRO compensates for the lack of active plantar flexion in paralysed limbs and prevents footdrop during the swing phase of gait. On the other hand, this same feature produces complications, during the stance phase of gait, from both a cosmetic and biomechanical point of view.

A plantar flexion stop substitutes for the lack of foot dorsiflexor action. At heel strike, however, instead of the foot slowly flattening, via eccentric contraction of dorsiflexors, the patient must rock over the heel until the foot is flat; after which the floor reaction function takes over. Additionally, as mentioned previously, a flexing moment occurs at the knee in the early stance phase of gait which must be overcome by quadriceps action (figure 2.7). Lehmann et al (1982) found that this initial flexing moment was greater with a plantar flexion stop than with normal dorsiflexor action. Since the primary objective of the hybrid orthosis is the reduction of muscle fatigue, it is highly desirable that this initial flexion moment be reduced to a minimum.

The ankle joint used for the SKAFO was designed to optimize the above constraints and still preserve the basic floor reaction function. A standard, metallic ankle joint was used which is stopped in dorsiflexion and allows spring resisted plantar flexion. In this case, the spring replaces natural dorsiflexor action by allowing the foot to slowly flatten after heel strike. This is quite cosmetically acceptable and helps to reduce the knee flexing moment in the early stance phase of gait (Lehmann et al, 1982). Another feature provided by the spring is the prevention of footdrop when the leg is lifted from the ground.

The dorsiflexion stop angle and plantar flexion spring stiffness are adjustable. Since these parameters can make a significant difference to the gait pattern, it is important that this facility exists so that they can be optimized for individual subjects. The version of the SKAFO considered in this thesis was constructed chiefly from standard, metallic components. This allowed for easy modification during the developmental stages of design. For future generations of this device, more emphasis could be placed on weight optimization and cosmetic appeal. The work for this thesis, however, is more concerned with the development of function and control.

One means of reducing weight in the present design was to remove the lower portion of the medial upright. The foot plate was fabricated from carbon fibre, composite plastic which proved to be rigid enough to support a single, lateral upright. Extra care was needed to provide rigidity at the knee and ankle joints but, in general, the single upright brace proved to be lighter and less bulky than the double upright version.

2.3. SENSORS

The control systems associated with the hybrid FRO require the measurement of a number of analogue quantities. The purpose of this section is to outline some of the techniques used to make these measurements.

Throughout the course of this thesis, reference will be made to the following quantities:

- Knee extension moment
- Patellar pressure
- Crutch loading
- Foot loading
- Inclination
- Knee angle
- Hip angle

These can be subdivided into two broad categories: Force measurement and Angle measurement.

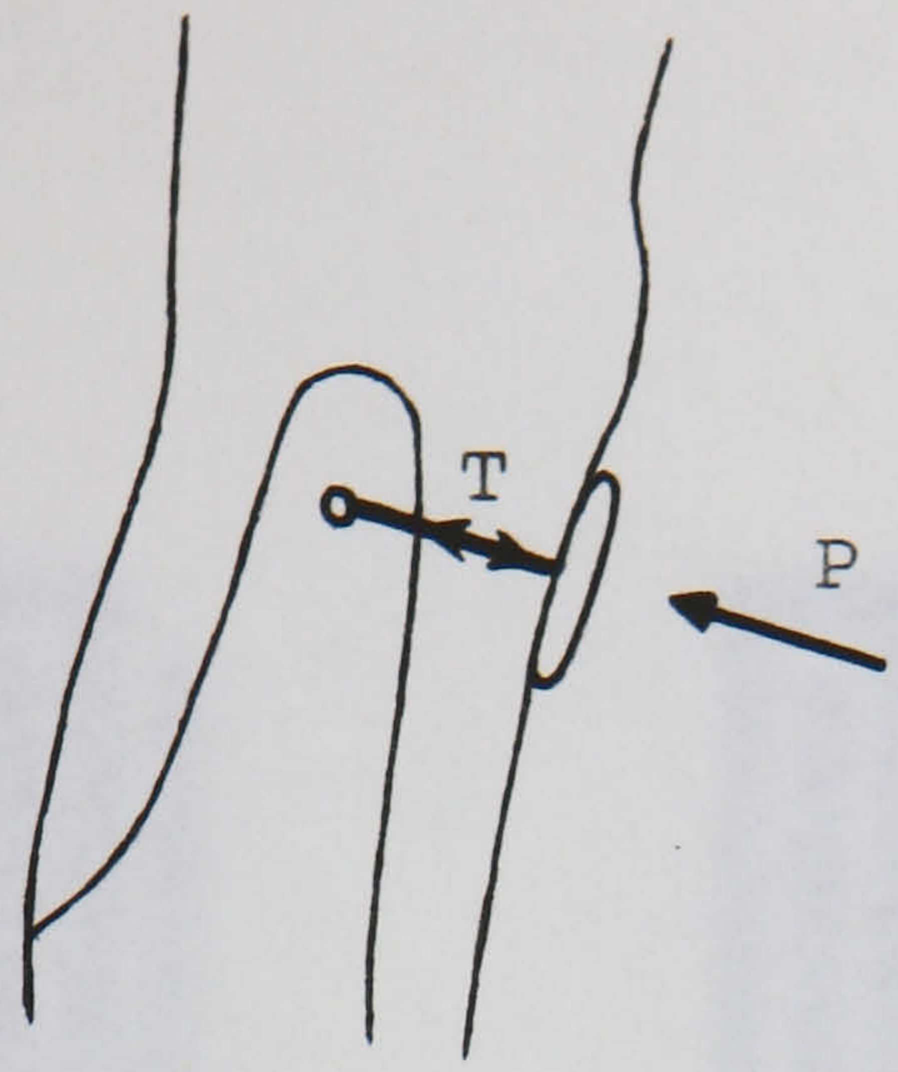
2.3.1. Force Measurement

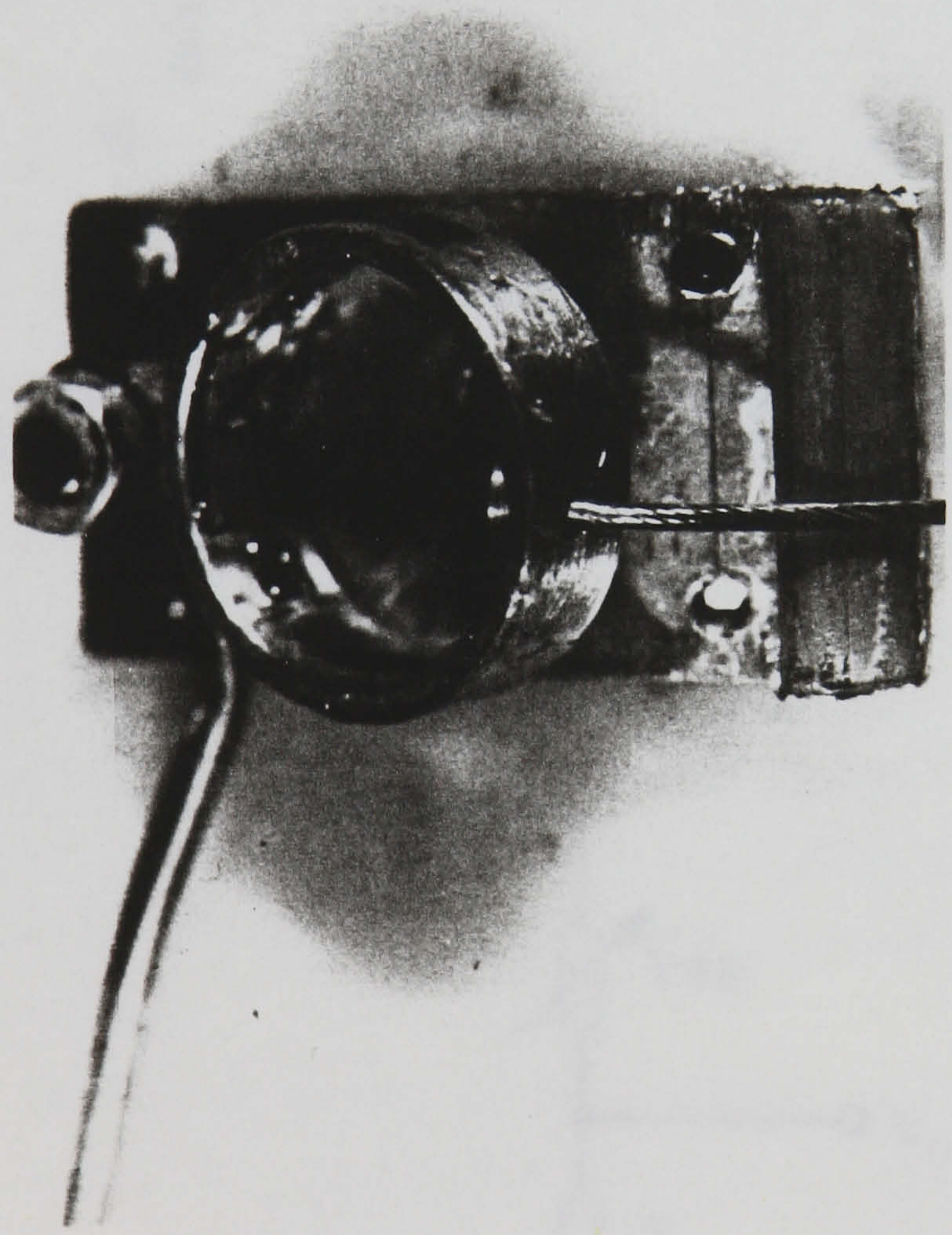
The resultant force exerted below the patella tendon was used as an indicator of stance stability in the original FRO design described in section 2.2.1. The tension (T), developed in the cable connecting the patellar pad to the brace uprights, was proportional to the localized patellar pressure. In the preliminary tests, described in this thesis, in-line ring dynamometers were used to measure this tension (figure 2.8). More detail about these dynamometers and their associated amplifiers can be found in appendix A.

Although dynamometers can provide accurate force measurements, the necessity for power amplification tends to reduce their practicality. Consequently, it was decided that a simpler means of force estimation should be used.

The best alternative was found to be force sensing resistors (FSR); manufactured by Interlink Electronics Inc., USA. These consist of two layers of conductive material which contact each other over a specific surface area (figure 2.9). One layer contains two interleaving, low-impedance conductors which are printed onto a thin, flexible substrate. This contacts another thin layer of resistive material which creates a current path between the low-impedance conductors. The effective resistance bears a non-linear, inverse relationship to the pressure forcing the layers together. The circuit in figure 2.10 produces an output voltage which varies with force applied to the FSR. This method is highly non-linear and lacks precision but it is easy to implement and requires no amplification.

In the SKAFO, FSR's were used to measure the knee extension moment. In figure 2.4, the forces "P" and "F" represent the reaction forces required to prevent the knee from hyperextending. It can, therefore, be inferred that the extension moment (M) is proportional to these quantities. For the SKAFO trials, reported in this





<u>Figure 2.8</u>

Ring dynamometer used to measure the tension (T) in the patellar pad cable.

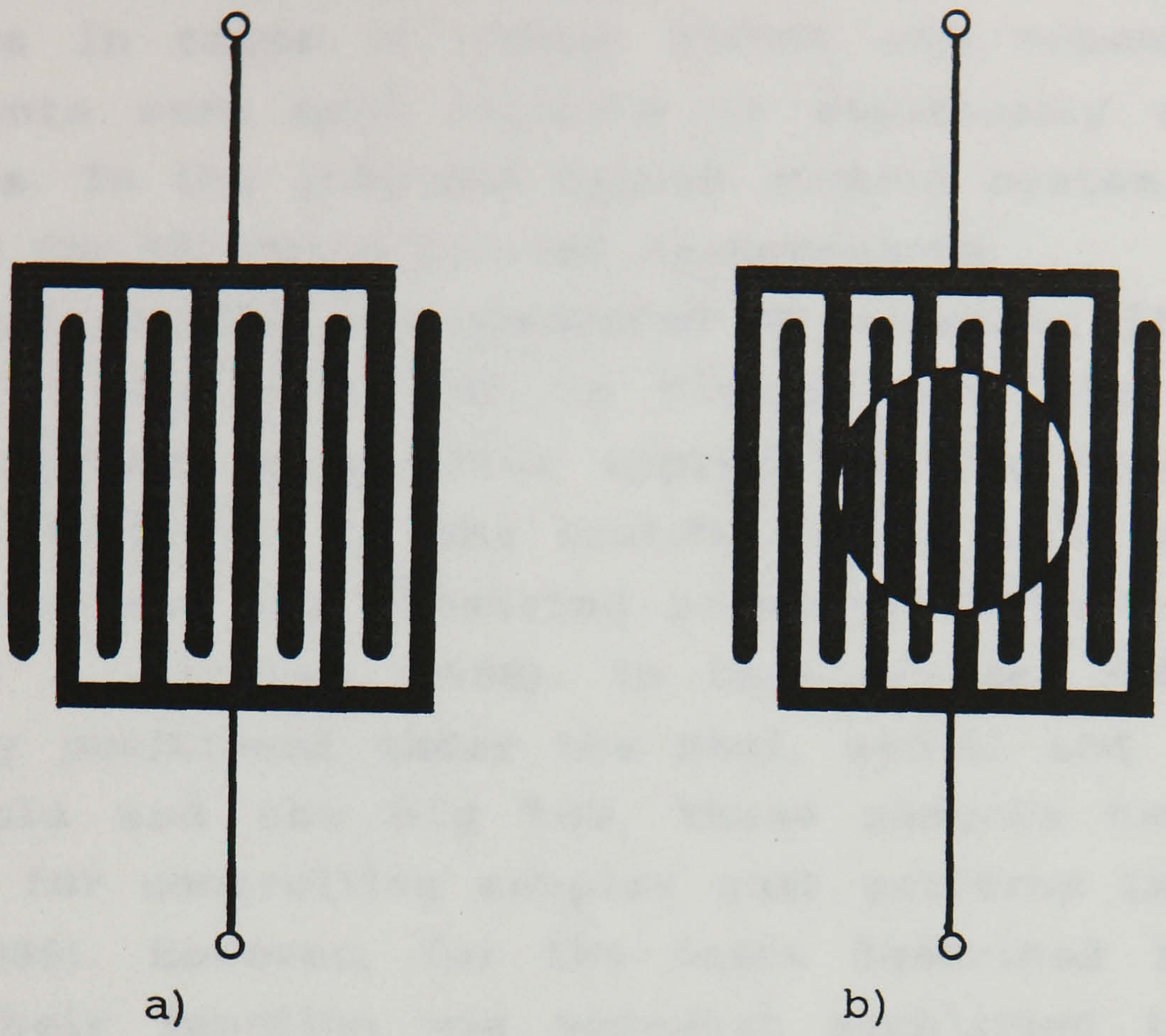


Figure 2.9

Structure of FSR. a) Two interleaving conductors b) A layer of resistive material contacts both conductors.

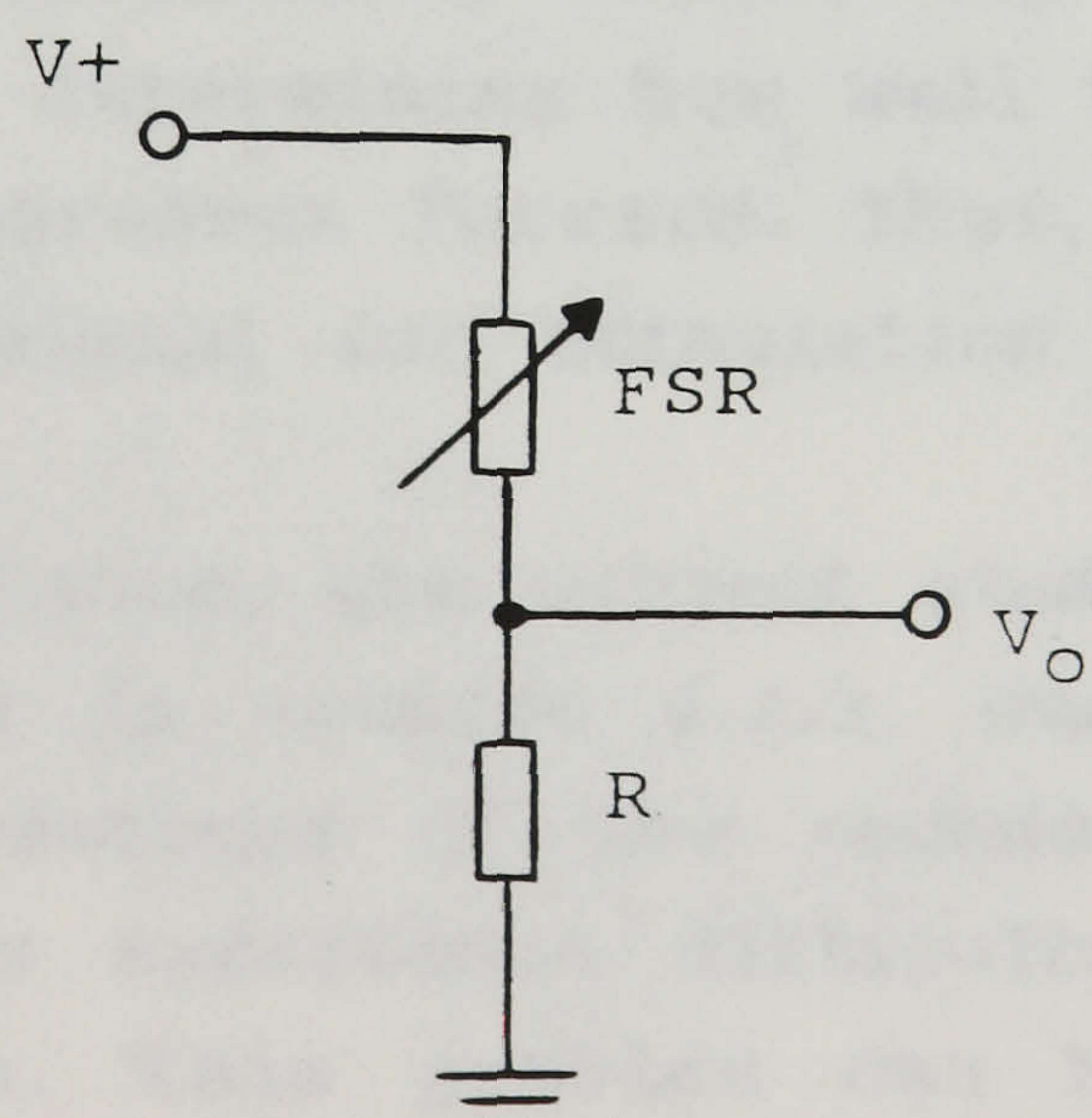


Figure 2.10

Application of FSR. As pressure is increased, resistance of FSR decreases and V_o increases.

thesis, the force "F" was measured by mounting FSR's inside the popliteal pad. Due to their dependence on physical configuration, no attempt was made to calibrate the FSR's in terms of actual forces and moments. All measurements were made relative to empirically derived thresholds. In the complete hybrid control system, FSR's were used for all force related measurements.

Crutch loading was monitored by mounting FSR's on the hand grips as shown in figure 2.11. The output signal responds to pressure applied by the hand when weight is supported by the crutch. Figure 2.12 pictures an insole sensor for measuring pressure under the foot (Kirkwood & Andrews, 1988). In this device, FSR's are separately positioned under the heel, medial and lateral metatarsals and the big toe. These sensors have the potential for controlling complex gait patterns (Andrews et al, 1989). However, for the tests described in this thesis, their function was somewhat simplified to that of a single channel which indicates overall leg loading.

2.3.2. Angle Measurement

Hip angle was used as an indicator for the effectiveness of stepping. Whether induced by reflexive action or direct stimulation, active hip flexion is an important factor in determining how well the foot clears the ground and progresses forward. Thus, hip angle was used as a control signal for stimulation of the flexion withdrawal reflex.

During quiet stance, the subject must adopt the "C" posture as outlined in section 2.2.3. Due to abdominal spasticity or contractions of the rectus femoris, some paraplegic patients experience difficulty in achieving full hip extension. This problem can be overcome by using stimulation of hip extensor and erector spinae muscles. Additionally, measurement of hip angle can be used to monitor hyperextension and control the stimulation accordingly. Special electro-goniometers

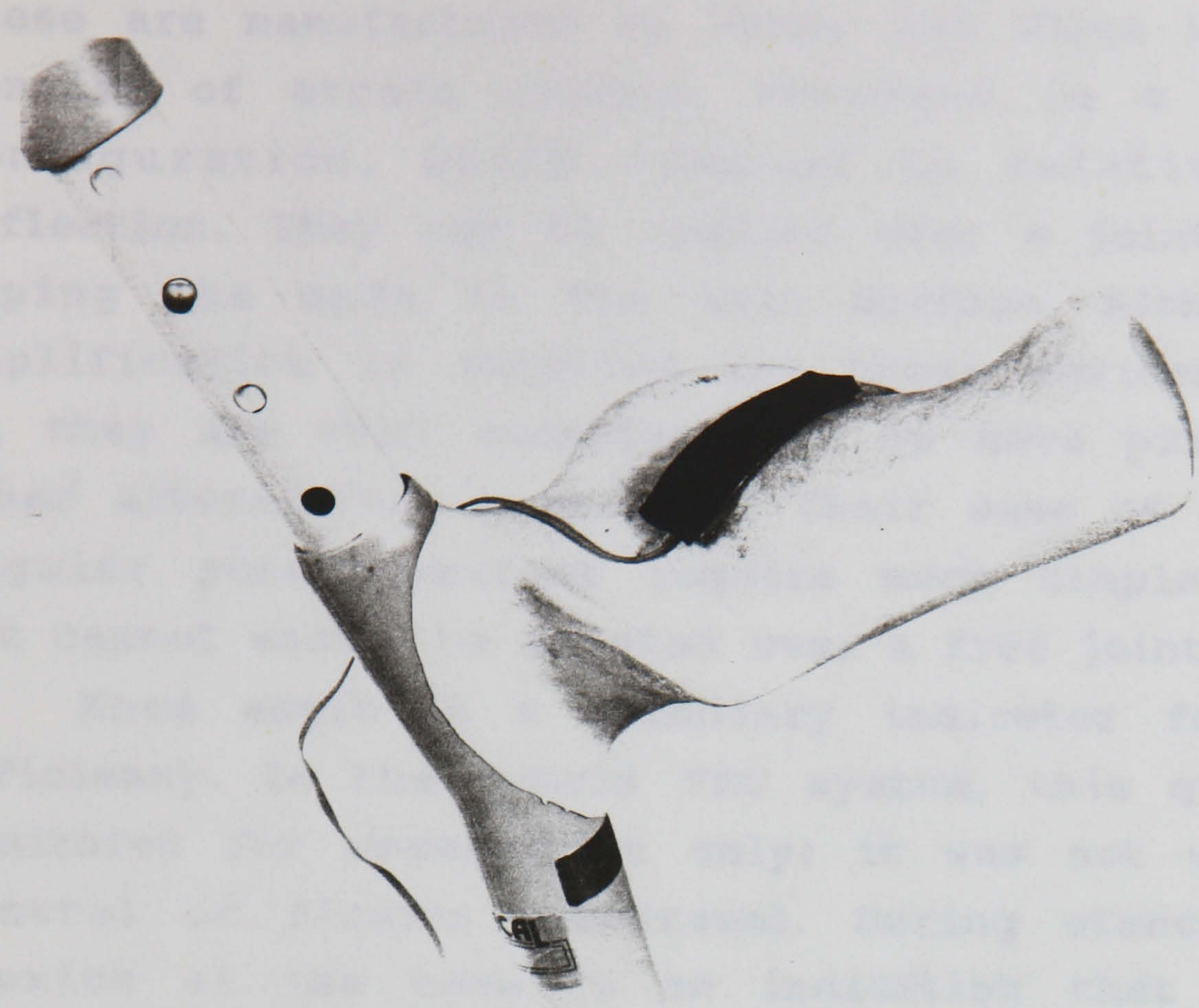


Figure 2.11

FSR configured to measure crutch loading.

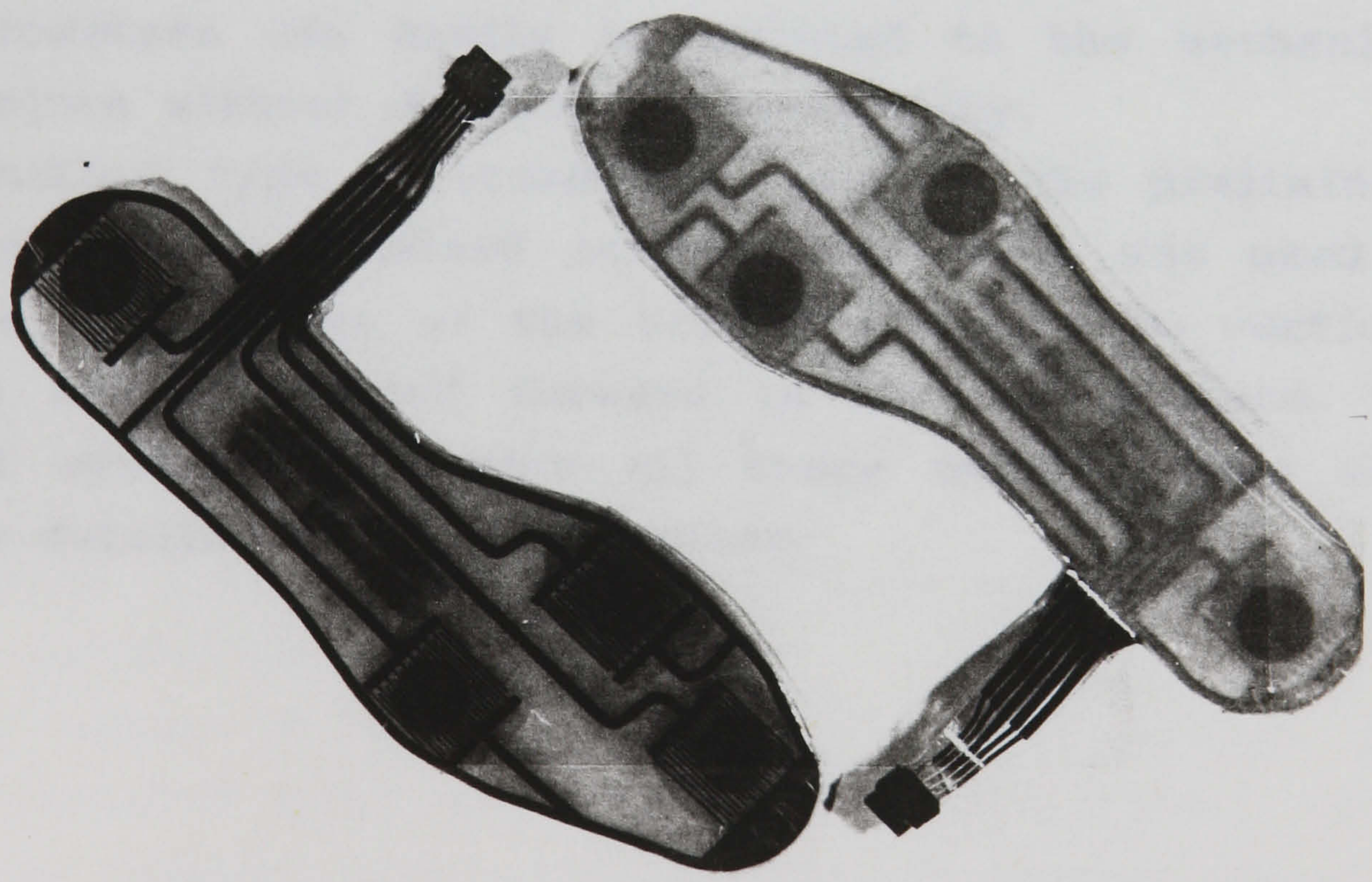


Figure 2.12

Insole sensors featuring four FSR's placed at strategic positions under the foot.

were used to measure hip angle separately for each leg. These are manufactured by Penny and Giles Ltd., UK and consist of strain gauges, arranged in a half-bridge configuration, which respond to relative angular deflection. They can be applied over a joint simply by taping the ends to the skin surface. Although power amplification is required for these devices (appendix A), they are still considered to be more practical than other alternatives because of their ease of application. Angular potentiometers require much simpler circuitry but cannot easily be mounted over a free joint.

Knee angle is a secondary indicator for stepping efficiency. In the hybrid FRO system, this quantity was monitored for observation only; it was not used in the control of flexion withdrawal. During stance, however, flexion at the knee is an indication that instability has occurred and that the leg has started to collapse. A stimulus controller, based on this measure, would initiate quadriceps contraction as soon as this instability was detected. As mentioned previously, the SKAFO provides a simple means of measuring knee angle. Potentiometers can easily be mounted to the mechanical knee joints without degrading practicality.

Another type of transducer used in the preliminary FRO tests is a standard inclinometer. This was used to measure the incline of the braces (relative to vertical) as the subject leaned forward in the "C" posture. The control systems for which all these sensors were used will be detailed in a later section.

2.4. COMPUTER CONTROLLED STIMULATOR

Due to the variety of FES research projects, ongoing at the Bioengineering Unit, it was decided that a general purpose, multi-channel stimulator was required which could meet the demands of any stimulation environment. Such a stimulator would need to be capable of producing a wide range of stimulus parameters with repeatable results. Repeatability is an important factor in laboratory based experiments because, in order to draw reliable conclusions, the researcher must be confident that the test conditions are exactly as specified. The stimulator, which will be described in the following sections, was developed by members of the FES research team with the above criteria in mind.

The initial specification was for 16 independent channels which could produce monophasic, rectangular current pulses suitable for use with surface electrodes. In order to reduce its size and complexity, this was later changed to 8 channels with the capacity to expand if necessary. The repeatability objective could only be realistically achieved with a constant current driver. In section 1.4.1 it was established that electrical charge is the critical factor in artificial stimulation of nervous tissue. Thus, for a particular pulsewidth, a constant current driver is required to ensure that the same amount of charge is delivered in each pulse, despite variations in the load impedance. This means that the stimulus intensity will not be affected by changes in skin or electrode impedance which are common in FES applications.

In order to operate correctly, the stimulator must be interfaced with a computer via a digital, opto-isolating circuit. The computer has complete control of all timing functions, including stimulus pulsewidth and frequency. In this way, very precise specifications can be made about timed events during the period of stimulation. Another excellent feature of computer controlled stimulation is the ability to simultaneously sample analogue data. This has important implications for muscle dynamics tests where the precise timing of the stimulation needs to be known, relative to the data obtained. Alternatively, sampled data can be used as feedback to modify the stimulus parameters in real time. The flexibility of this type of system is limited only by the power of the computer and its software.

2.4.1. Hardware Design

Although most of the stimulus parameters are defined in software, the hardware must be capable of meeting the demands placed upon it. This leads to a number of design objectives.

Firstly, the stimulus should be capable of producing contractions, in weight bearing muscles, which are strong enough to stand heavy paraplegic subjects. Based on general experience, with surface FES, the author and colleagues defined the following maximum values for the stimulus parameters:

Pulsewidth - 500 μs
Frequency - 100 pps
Amplitude - 150 mA

In reality, the stimulator hardware is capable of producing larger pulsewidths and higher frequencies than the values just quoted. Thus, the defined limitations must be implemented in the supporting software. The maximum current amplitude, however, is limited by the hardware and does not need to be considered.

Another important consideration is that of safety. The design which will now be described satisfies the safety regulations required for all equipment used at the Bioengineering Unit. The final design objective involves practicality. Ideally, the stimulator should be light, unobtrusive and easy to use.

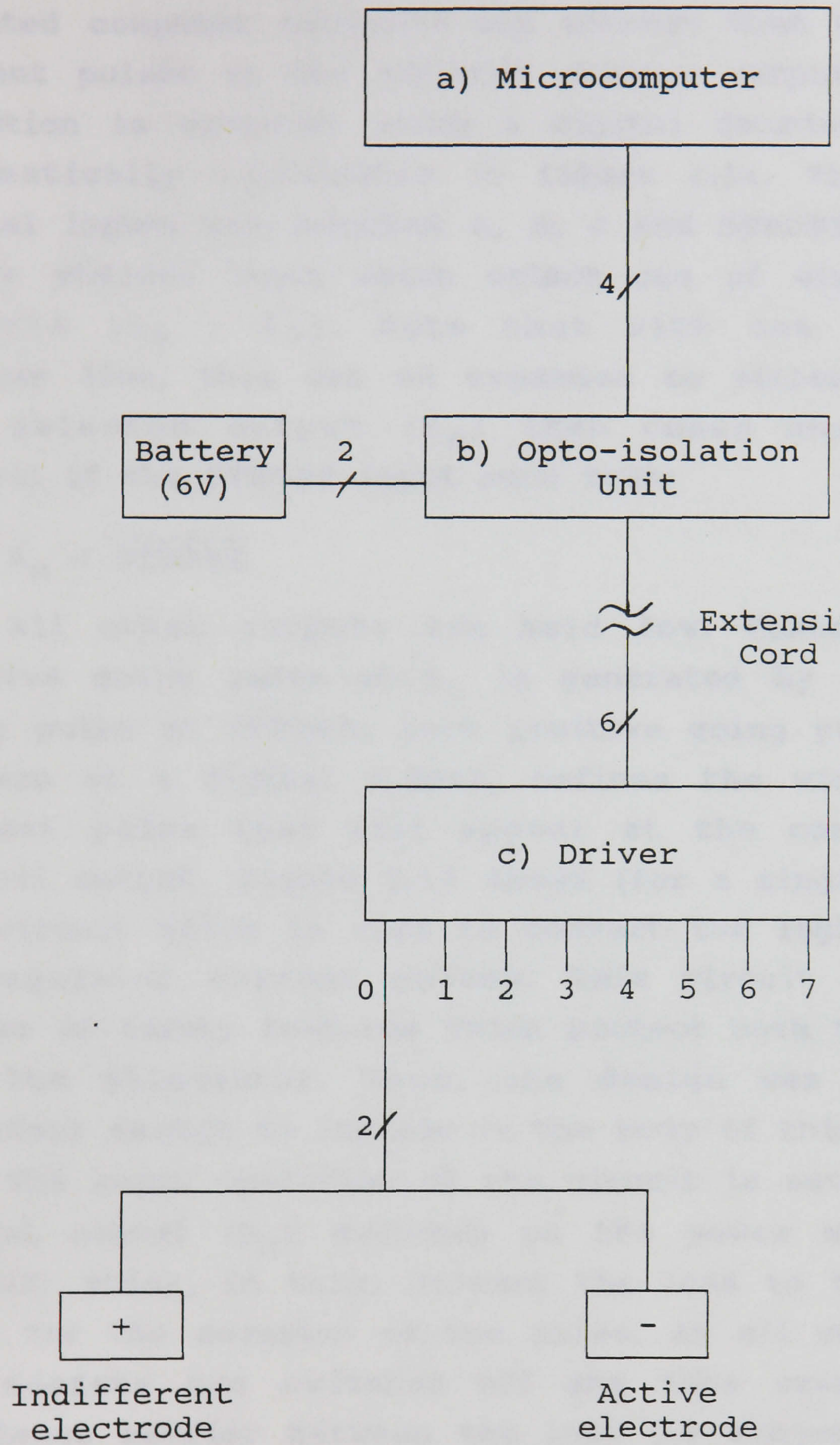
The final design of the stimulator hardware system consists of three basic modules (figure 2.13):

a) Computer
b) Opto-isolation
c) Output driver

Due to the simplicity of the digital commands accepted by the stimulator, control can be implemented by almost any computing device which offers TTL compatible input/output (I/O) facilities. The hardware and associated software used for the tests described in this thesis were developed for the BBC microcomputer and various IBM-AT compatible machines. Amplicon PC-14A boards were used to provide I/O facilities for the IBM equipment.

The task of the opto-isolating unit is simply to convert the TTL signals from the computer to isolated equivalents which are then passed on to the output driver. This, of course, is required to ensure isolation of the subject from the mains power supply. Circuit details of this unit can be found in Appendix A.

The output driver unit provides the actual stimulus and must be placed on or near the subject so that the electrode leads can be connected to it. A cord, containing six conductors, connects this unit to the isolating circuits. Two of these conductors provide the driver with isolated power from a 6V, lead-acid battery. The other four carry the isolated digital signals from the computer. The driver unit acts only as a slave device; it makes no decisions and sends no information back to the computer. Since the extension cord contains only a few conductors, it can be made light, flexible and long. With the addition of a connector at the driver unit, it can also be detached when not being used. Thus, although the computer and battery are not portable, the system, as a whole, can still achieve the design objectives which were outlined above.



<u>Figure 2.13</u>

Block diagram of stimulator hardware system.
a) Computer b) Opto-isolator c) Output driver.

2.4.2. Output Driver Unit

The basic task of this unit is to accept the isolated computer commands and convert them to stimulus current pulses at the selected channel outputs. Channel selection is achieved using a digital decoder which is schematically illustrated in figure 2.14. The isolated digital inputs are labelled A, B, C and STROBE. A, B and C are address lines which select one of eight digital outputs (S_0 - S_7). Note that with one additional address line, this can be expanded to sixteen outputs. The selected output (S_n) then comes under direct control of the STROBE input such that:

$$S_n = \overline{\text{STROBE}}$$

All other outputs are held low. Consequently, a positive going pulse at S_n is generated by a negative going pulse at STROBE. Each positive going pulse, which appears at a digital output, defines the width of the current pulse that will appear at the corresponding channel output. Figure 2.15 shows (for a single channel) the circuit which is used to convert the logical pulses to regulated current pulses. This circuit contains a number of safety features which protect both the subject and the stimulator. Thus, the design was considered important enough to include in the body of this thesis.

The basic operation of the circuit is such that the logical signal (S_n) switches on the power mosfets (M1 and M2) which, in turn, connect the load to the voltage rails for the duration of the pulse. At all other times, the mosfets are switched off and thus create a high impedance barrier between the load (ie subject) and the rest of the stimulator circuitry.

When S_n is asserted (+5V), it provides biasing for M2 at the low voltage rail and indirect biasing for M1 at the high voltage rail. This indirect biasing is achieved by switching on M3 and the optically coupled transistor (T1) which provides the bias for M1.

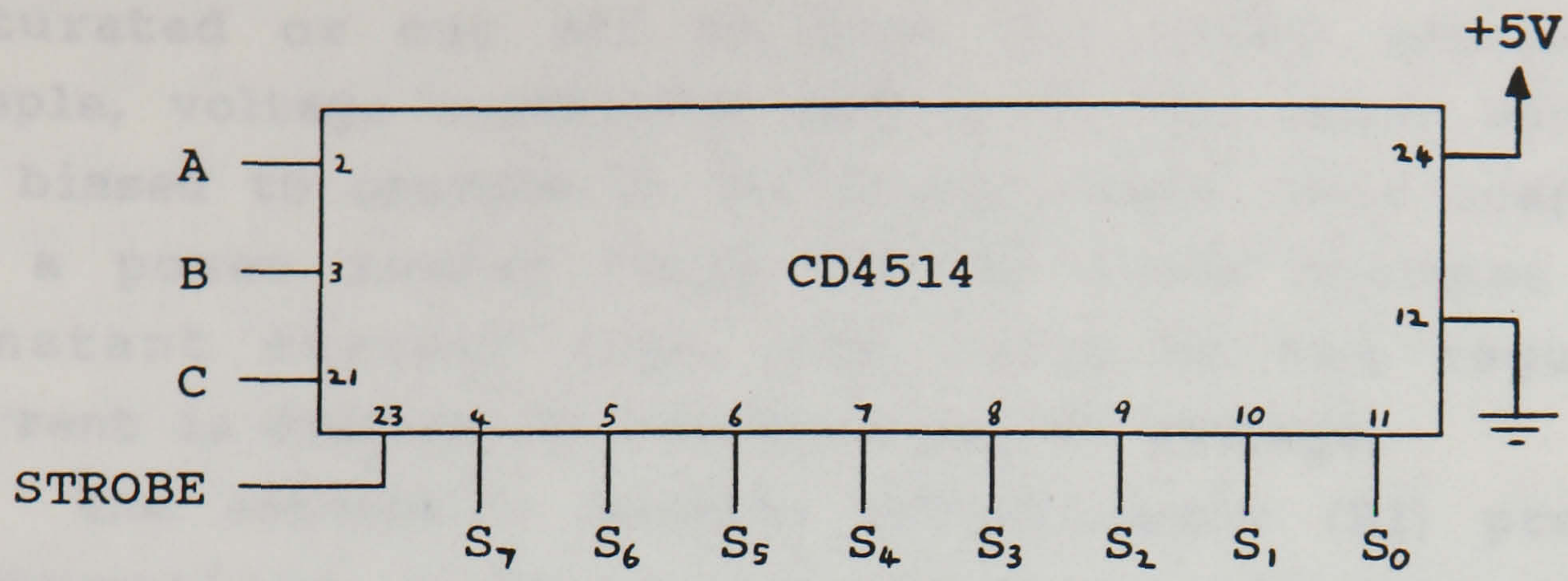


Figure 2.14

The CD4514 digital decoder. In the present stimulator design, only 8 of the 16 available outputs are used.

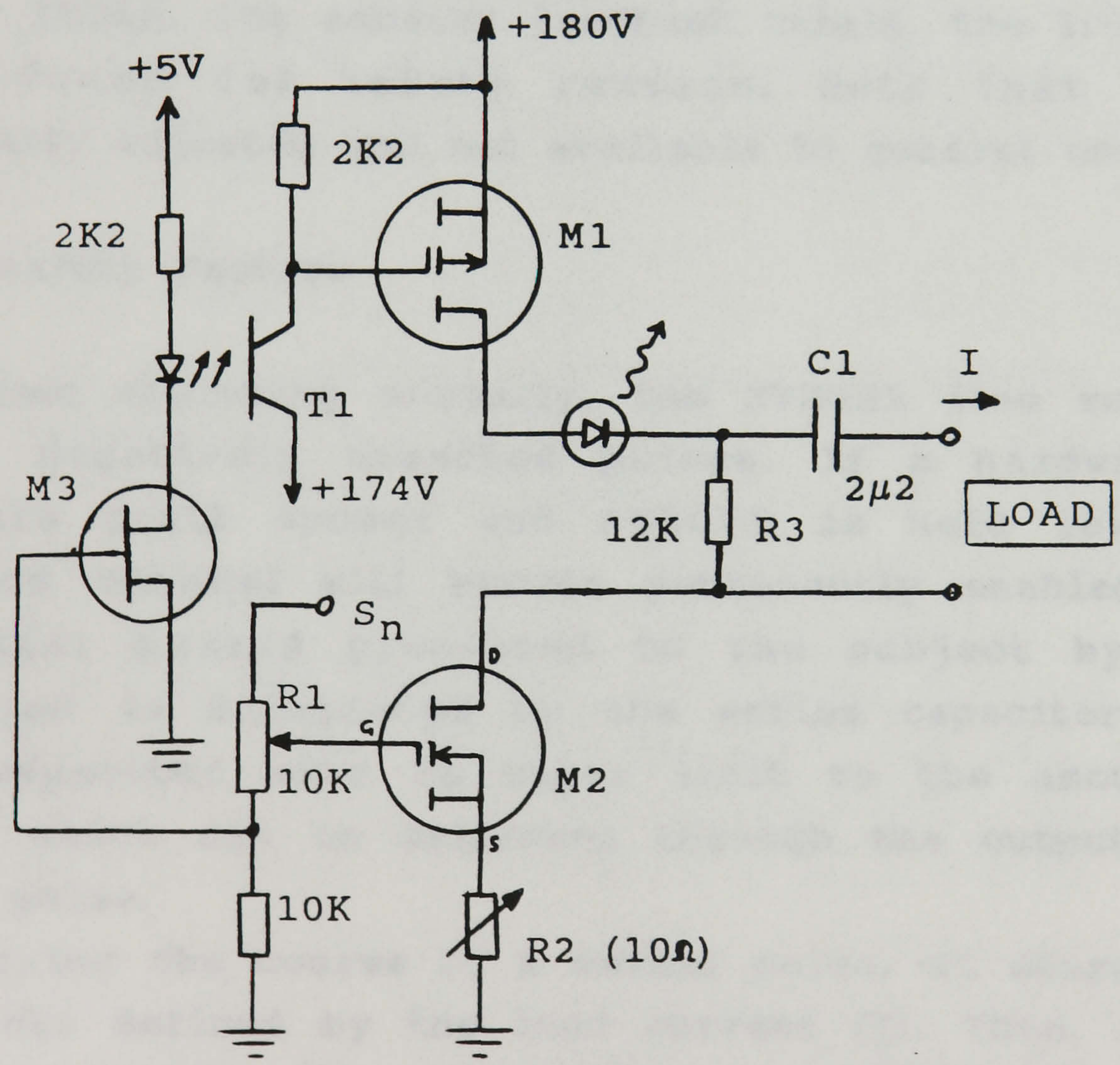


Figure 2.15

Schematic diagram featuring the output stage of a single stimulus channel.

Details of the power supply circuits can be found in Appendix A. M1 is designed to operate either fully saturated or cut off so that its action simulates a simple, voltage controlled switch. On the other hand, M2 is biased to operate in its linear range. This component is a power mosfet (type IRF610) which operates as a constant current sink. The value of the regulated current is defined by the gate-source voltage.

The externally mounted potentiometer (R1) provides appropriate biasing to allow continuous manual adjustment of the regulated output current from zero to maximum. The variable resistor (R2) provides negative feedback at the source of M2 which stabilizes the current regulation and allows the maximum to be trimmed. For general FES applications, this maximum is usually set at 150mA. For sensory feedback trials, the limit can be reduced for safety reasons. Note that R2 is internally adjusted and not available to general users.

2.4.3. Safety Factors

When operating normally, the STROBE line sustains short, negatively asserted pulses. If a hardware or software fault occurs and STROBE is held low, the selected channel will become permanently enabled. The potential hazard presented to the subject by this condition is eliminated by the series capacitor (C1). This capacitor sets an upper limit to the amount of charge which can be delivered through the output in a single pulse.

During the course of a normal pulse, C1 charges up at a rate defined by the load current (I). Then, during the interpulse interval (IPI), C1 discharges again through R3 and the load. The presence of C1 means that the output current waveform is not strictly monophasic, as stated before, but asymmetrically biphasic. However, the time constant defined by R3 and C1 is large enough to ensure a minimal discharge current which is distributed across the IPI. In this way, average DC is eliminated but the characteristics remain essentially monophasic.

If a pulse is abnormally large or long, C1 will charge up to a voltage level which renders the driver incapable of delivering more current through the load. Assuming that C1 is allowed to charge up to 180V, it will store a maximum charge of approximately $400\mu C$. which represents the theoretical upper limit for the amount of charge that the hardware will deliver to the load in a single pulse. In practice, it is probably less. The functional limit, defined in section 2.4.1, is equivalent to $75\mu C$ per pulse which is considerably less than the hardware limit.

If the hardware limit was reduced, the circuit would not be able to provide proper current regulation up to the specified maximum parameters. Additionally, it must be remembered that the hardware limit represents the absolute worst case condition caused by a serious fault which would not occur under normal circumstances. Taking this into consideration, the hardware limit is acceptable since it reduces the potential hazards and is within suggested safety limits (Kralj & Bajd, 1983).

The final safety consideration is that of component failure. The only type of failure which could be hazardous to the subject is one that created a short circuit (SC) at M1, M2 or C1. Any other failures would either have a trivial effect or shut down the circuit completely. A failure in SC at M1 would cause the indifferent electrode of the failed channel to be common with all other active channels. This may create interference between channels but it does not constitute a hazard, unless the interference path nears the heart. The SC failure of C1 would have no direct effect but the charge limiting facility would be lost and the channel would have no safety backup. The SC failure of M2 would mean that the output current pulses are completely unregulated. However, the charge limiting function of C1 would continue to restrain the pulse intensity under these circumstances.

M1, M2 and C1 are all chosen with ratings well above 180V. This reduces the likelihood of component failure and also provides short circuit protection for the stimulator outputs. A serious hazard could be caused by three of the above faults occurring simultaneously. With proper usage of the stimulator, however, this is extremely unlikely.

2.4.4. Software

The purpose of this section is to outline the general principles of the stimulator software. More detailed information can be found in the user manual which accompanies the stimulator.

Software control of the stimulator is at a very low level. Every pulse which comes through any of the output channels must be individually constructed by the computer. Firstly, the channel number must be selected by setting the address lines A, B, and C (figure 2.14). After allowing about 10 microseconds for the decoder to settle, a negative pulse is then sent down the STROBE line which appears as a current pulse at the selected channel output.

The driver unit is incapable of producing pulses simultaneously at two or more outputs. Thus, in order to simulate the effect of multiple stimulation, the pulses must be interleaved. The timing diagram in figure 2.16 illustrates how three channels can be controlled in this way. Note that the technique does not produce timing jitter on individual channels; in fact, the effect is invisible to the user. It would be very tedious to use the stimulator if the programmer had to consider the timing details every time he or she sat down to write a user application programme. Thus, an interrupt service routine which runs in parallel with the user software was developed. This routine accepts high level

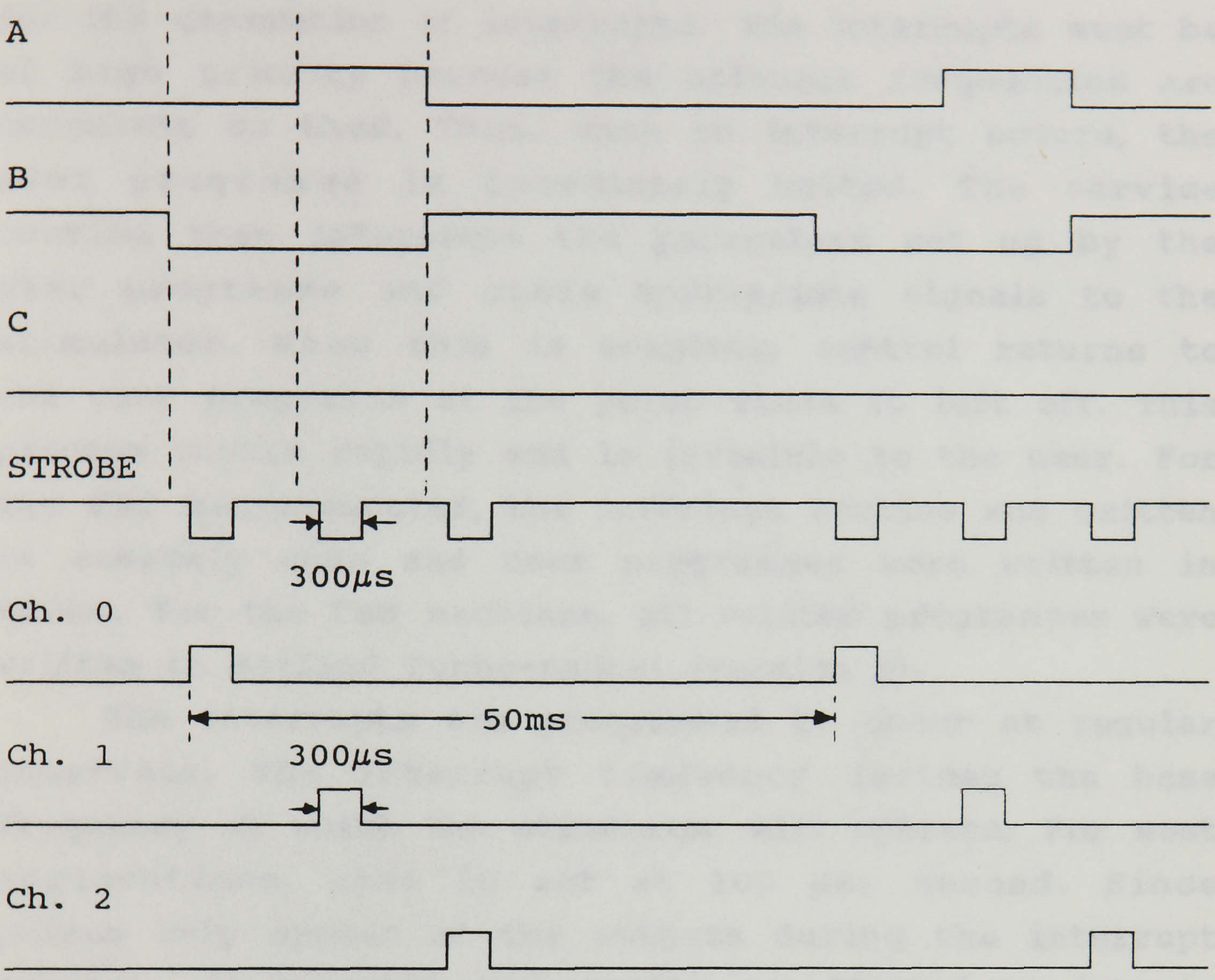


Figure 2.16

Timing diagram for simultaneously generating a 20Hz, 300μs stimulus waveform at three different channels. The channel address ("CBA" in binary) is set shortly before the STROBE signal triggers a pulse at the corresponding channel output.

parameters from the user programme and converts them into low level stimulator control signals.

The BBC and IBM computers, which were used to control the stimulator, have accurate, internal timers for the generation of interrupts. The interrupts must be of high priority because the stimulus frequencies are dependent on them. Thus, when an interrupt occurs, the user programme is immediately halted. The service routine then interprets the parameters set up by the user programme and sends appropriate signals to the stimulator. When this is complete, control returns to the user programme at the point where it left off. This process occurs rapidly and is invisible to the user. For the BBC microcomputer, the interrupt routine was written in assembly code and user programmes were written in BASIC. For the IBM machines, all related programmes were written in Borland Turbo-pascal (version 5).

The interrupts are programmed to occur at regular intervals. The interrupt frequency defines the base frequency at which the stimulator will operate. For most applications, this is set at 100 per second. Since pulses only appear at the outputs during the interrupt service, all stimulus frequencies are limited to integer divisions of the base frequency. This can easily be changed by the user software if unusual stimulus frequencies are required.

Communication between the user programme and the interrupt routine is via a table, reserved in computer memory. The task of the user programme is simply to write the desired stimulus parameters to this table where the interrupt routine implements them. The parameter table is listed in table 2.1. It has a number of useful features which will now be considered.

There are five parameter locations for each channel which can be written to or read from at any time. Note that all entries must be integer values. Each channel runs independently but all transitions are synchronized with the base frequency. The parameter "PW" defines the

Input	Frequency	Driver
	100	Not Active

Parameters

chan	PW	IPI	ENV	FinalPW	Speed
0	300	5	-1	300	5
1	300	2	-1	300	5
2	0	5	-2	300	2
3	300	5	-2	0	-3
4	200	1	120	300	5
5	300	5	0	300	5
6	300	5	0	300	5
7	300	5	0	300	5

<u>Table 2.1</u>

Parameter table for software control of the stimulator.

Features:
Input - Enables data acquisition facility
Frequency - Defines base frequency
Driver - Enable/disable stimulator

Notes:
Channels 0,1 are set for "constant stimulation" mode.
Channels 2,3 are set for "ramp" mode.
Channel 4 is set for "switch-over" mode.

pulsewidth, in microseconds, for the corresponding channel. It can range from 0 (no stimulation) to 500. The interpulse interval is represented by "IPI" which must be a positive integer. The stimulus frequency, actually obtained, equals the base frequency divided by this number. Thus, at a base frequency of 100, IPI=5 would produce a stimulus frequency of 20pps for the corresponding channel.

The envelope parameter "ENV" provides the user software with higher level control functions. When it is loaded with the value -1, the controller maintains constant stimulation at the parameter values defined by PW and IPI. When ENV=0, the channel is switched off. This allows easy implementation of ON/OFF controllers by the user programme. When ENV is set to -2, a ramping facility is enabled. In this mode, the stimulus pulsewidth is progressively ramped from the present value of PW to the value stored in "FinalPW". The stimulus frequency is constant throughout and defined by IPI. The parameter "Speed" defines the increment (in microseconds) which is added to PW, at every interrupt service, until the final value is reached. Thus, the rate of ramping depends on the product of the Speed parameter and the base frequency. Note that Speed can be positive (ramp up) or negative (ramp down).

Another function is enabled when ENV is loaded with a positive integer. In this mode, constant stimulation, defined by PW and IPI, appears at the output. Meanwhile, ENV counts down at a rate defined by the base frequency. When ENV reaches zero, it stops counting and the values in FinalPW and Speed are immediately substituted for PW and IPI respectively. These values then define a new constant stimulus. Ramping and switch-over functions are common in advanced FES applications. Examples of both can be found in the control algorithms described in this thesis. The automatic implementation of these functions by the interrupt service routine relieves the burden of having to control them through the user software.

The final software consideration is that of safety. The interrupt routine automatically imposes restrictions on the stimulus parameters as outlined in section 2.4.1. It also disallows illegal parameter combinations and values. For example, if "Speed" is negative, it should not be used to define a switch-over frequency. Under these circumstances, the interrupt routine defaults the output parameters to a known safe state which is either constantly active or off depending on the application.

2.4.5. Application

The output currents are adjusted manually using potentiometers mounted on the output driver unit. These controls are independent and continuously vary the current pulse amplitude of each channel from 0 to 150mA. With the present design, the controlling computer has no means of automatically recording these pulse amplitudes. Thus, during a typical experiment, current levels should be set and measured at the beginning and left unchanged throughout. This does not reduce the flexibility because stimulus intensity control is still readily available through pulsewidth modulation which is defined in software.

The main disadvantage of a constant current driver is its potential for burning the skin. If the driver encounters a high impedance load, it will attempt to increase its output voltage to a level which is high enough to drive the specified current through the load. The stimulator presented here has a total voltage capacity of 180V. Thus, if an electrode is dry or incorrectly applied, the skin surface could be subjected to the full voltage output during each stimulus pulse. After a prolonged application, this may cause a burn if the effective electrode area is small.

Although a capacity of 180V may seem unnecessarily high, a large voltage is essential for proper current regulation; even though the stimulator may never be called upon to produce its full capacity. Consequently, use of a constant current stimulator should be limited to qualified and experienced personnel. These stimulators are only practical for investigative purposes; they do not offer any advantages over other types for functional training and exercise. Thus, the use of the computer controlled stimulator is strictly limited to controlled, laboratory based applications.

2.5. CONTROL SYSTEM SOFTWARE

The block diagram in figure 2.17 illustrates the generalized hardware setup for the hybrid FRO walking system. This includes all of the components introduced, so far, in this chapter. The task of the microcomputer based controller is to coordinate the sensor and command inputs into a stimulus output sequence which achieves the desired results. The control algorithms used for the components of the overall system are based on empirically derived or "hand crafted" rules. These rules take on the following general form:

IF (a certain set of logical conditions exist)
THEN (follow a predetermined course of action)
ELSE (maintain present state)

This type of "finite state" control is well suited for use with a digital computer. In general, the type of stimulation is ON/OFF in nature. This means that the stimulus parameters are preset and switched either fully ON of OFF by the control system when the appropriate conditions are detected.

A more "classical" approach to the control problem would be to continuously modulate the stimulus parameters using analogue signals from the sensors as feedback. Due to the non-linear and time variant nature of the system, however, this would present a formidable control problem. Instead, the analogue sensor signals are compared with threshold values and converted to boolean variables in the finite state model.

The rules for the finite state model, described in this thesis, were derived mostly from observation and intuition. Techniques are currently being developed to mathematically induce rules using pattern recognition of recorded sensor signals (Andrews et al, 1989). This offers the potential for greatly improved control algorithms which may not be intuitively apparent at first glance. However, machine induction is a future development for the hybrid FRO system and will not be given detailed consideration in this thesis.

2.5.1. Artificial Reflexes

Two localized, artificial control systems have been defined, at the knee and hip joints, during stance. These work independently and have come to be known as the knee extension reflex (KER) and hip extension reflex (HER). Although bearing little similarity to natural stretch reflex mechanisms, the basic objective of the artificial reflex is the same. Namely, to provide an active moment, about a joint, which opposes the joint's tendency to rotate.

The SKAFO provides a simple method for measuring knee angle. Thus, a very simple KER can be implemented by maximally stimulating the quadriceps muscles as soon as flexion at the knee is detected. This can be achieved by setting a signal threshold, in the control software, which is continuously compared to the appropriate input. As soon as the signal representing the knee angle sensor exceeds the threshold value, a logical variable (f) is set which indicates that the knee is flexing (figure 2.18). Thus, quadriceps stimulation is turned ON to straighten the leg. The stimulation is held ON for an appropriate time to allow the subject to regain a stable posture (eg. about 5 seconds) and then switched OFF if the knee has returned to full extension.

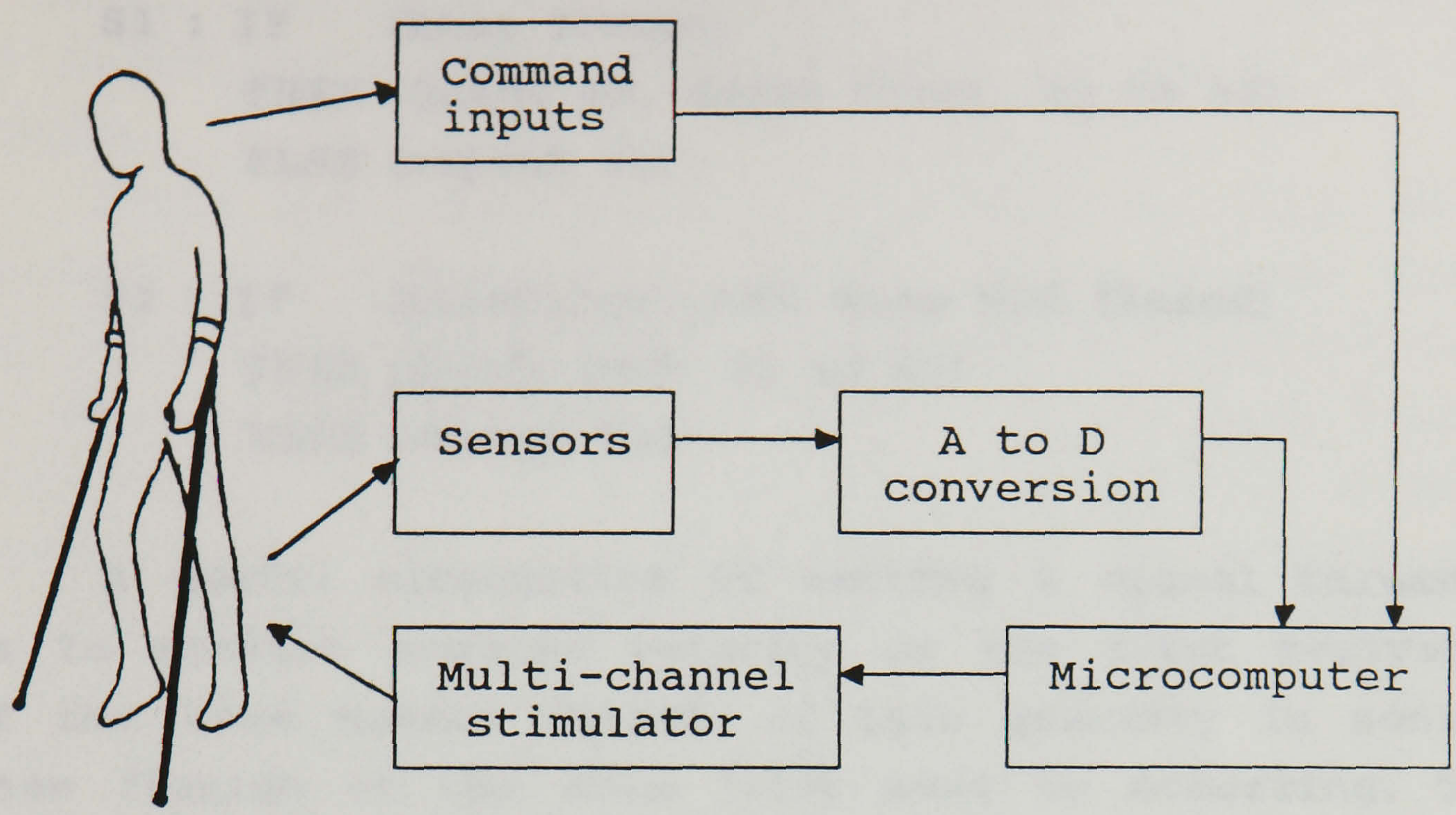
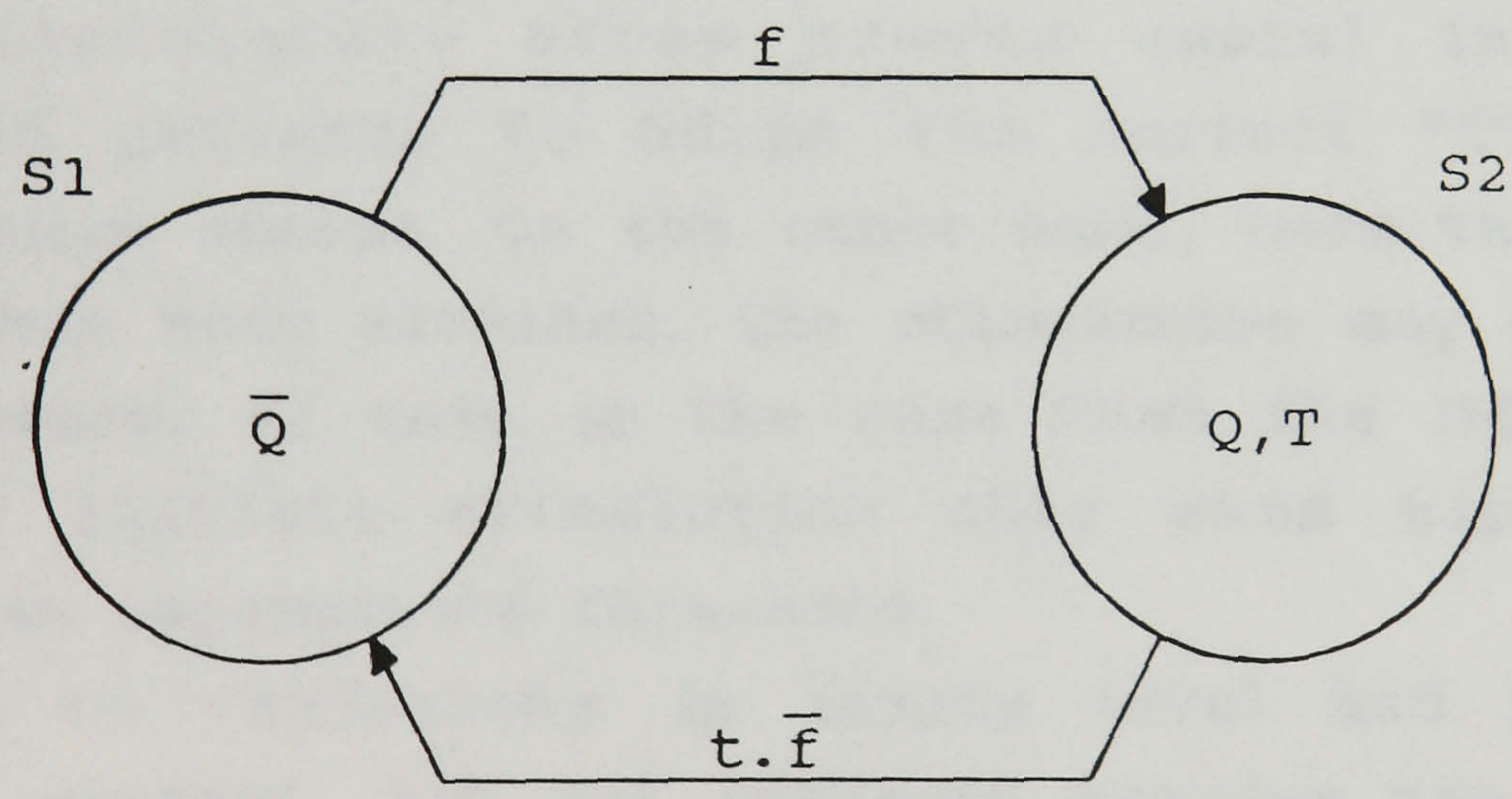


Figure 2.17

Components of the hybrid FRO system.



CONDITIONS
f - knee flexed
t - timer > 5 sec.

ACTIONS
Q - quadriceps ON
T - reset timer

Figure 2.18

State diagram of a simple KER.

This can be summarized in "IF..THEN" format as follows:

```
S1 : IF   (knee flexed)
     THEN (Quads ON, Reset timer, Go to S2)
     ELSE (repeat S1)

S2 : IF   (timer>5sec AND knee NOT flexed)
     THEN (Quads OFF, Go to S1)
     ELSE (repeat S2)
```

A useful alternative to setting a signal threshold is to monitor angular velocity or the first derivative of the knee sensor output. If this quantity is nonzero then flexion at the knee joint must be occurring. This technique is independent of the instantaneous sensor output and thus avoids the need to reset the threshold whenever the sensor characteristics drift or change in any way.

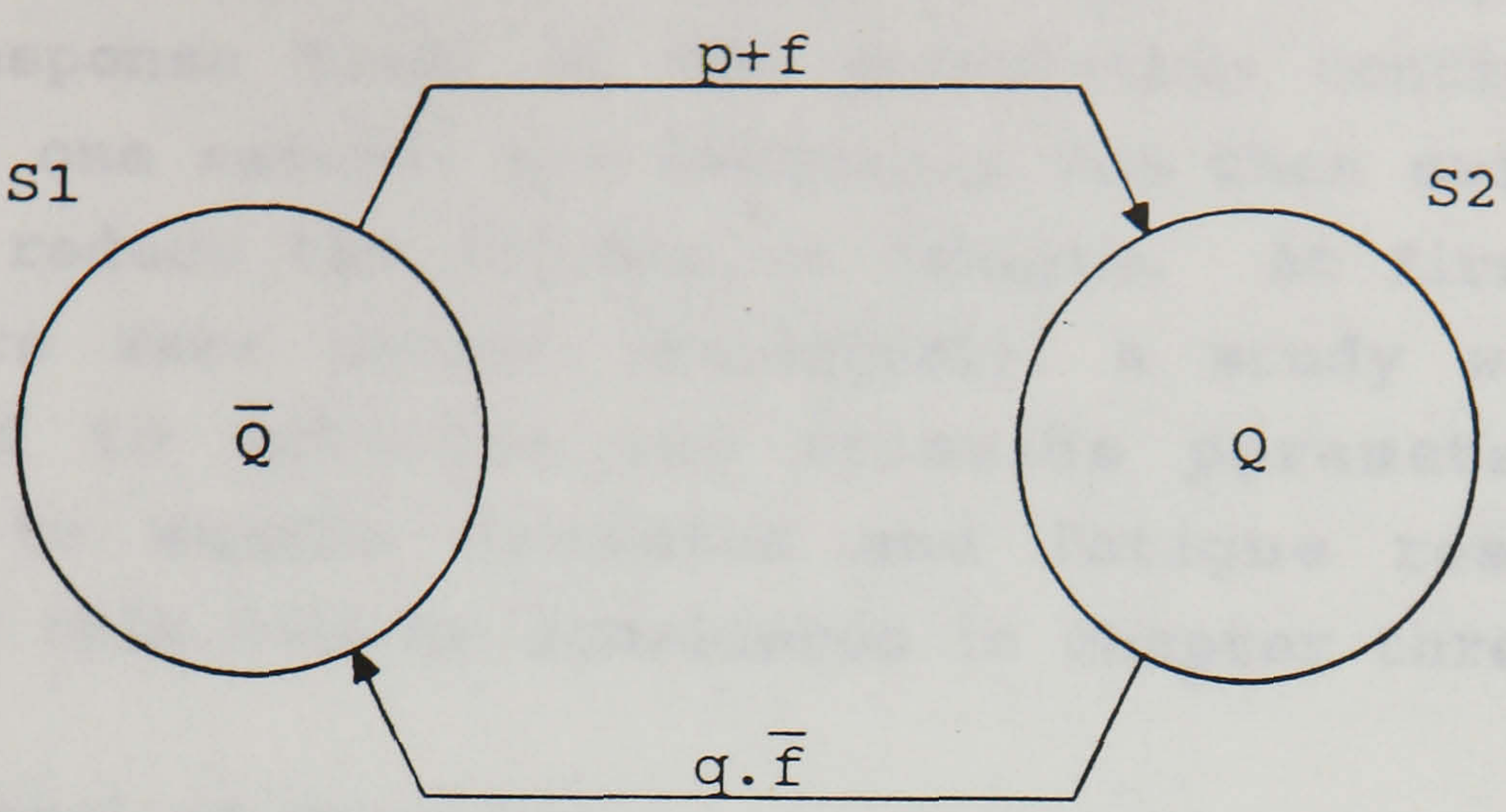
The mechanism for the HER is similar to that described above. Stimulation of the hip extensors and trunk musculature often proves useful in helping paralysed patients to adopt the correct "C" posture during quiet stance. On the other hand, once the correct posture has been attained, the stimulation may no longer be necessary. If this is the case then the HER can be used to initiate stimulation only when hip flexion exceeds an appropriate threshold.

Due to variations in injury level and preserved postural control, not all subjects require the HER for stable stance. The KER, however, is an essential component and one of the central features of the hybrid FRO system. The main problem with using knee angle to control the KER is that corrective action is taken only after instability has been detected and the knee is in the process of collapsing. Thus, any delay in the response brings the subject closer to a potentially dangerous situation. Delays are introduced mostly by the latency of force production in the muscles and the cycle time of the controller. Of course, these delays could be reduced by optimizing the stimulus parameters and using a faster controller but it would be far more appropriate if instability could be prevented before it actually occurs.

This possibility is provided by the force measurements discussed in section 2.3.1. As the forces and moments associated with stable stance approach zero, it can be assumed that the system is tending towards instability. Thus, if thresholds are defined slightly above zero, corrective stimulation can be applied well before the knee collapses. Figure 2.19 illustrates this type of KER which was used for the hybrid FRO system. Note that hysteresis is introduced when threshold (T2) is defined at a value which is greater than T1.

The SKAFO allows the knee extension moment to be realistically estimated during stance. This moment has a passive component, due to the action of the brace, and an active component which is added when the quadriceps contract. Thus, when the knee moment falls below T1, the difference between T2 and T1 must then account for the additional active component which appears when stimulation is applied. This is necessary to prevent the control system from "hunting".

Figure 2.20 shows a representative graph of preliminary tests which were conducted with a paraplegic subject standing quietly in SKAFO's. The subject was asked to periodically lean back to the point of instability and then lean forward again. The purpose of these tests was to determine the appropriate threshold values when using FSR's to measure the knee extension moment. The quantity "δP" represents the active component. Tests were also conducted with the original FRO brace design considered in section 2.2.1. In this case, the patellar pressure was found to be unaffected by quadriceps action. Thus, the KER used for these devices could be based on a single threshold.



CONDITIONS
p - force < T1
q - force > T2
f - knee flexed

ACTIONS
Q - quadriceps ON

Figure 2.19

State diagram of KER based on force measurements.

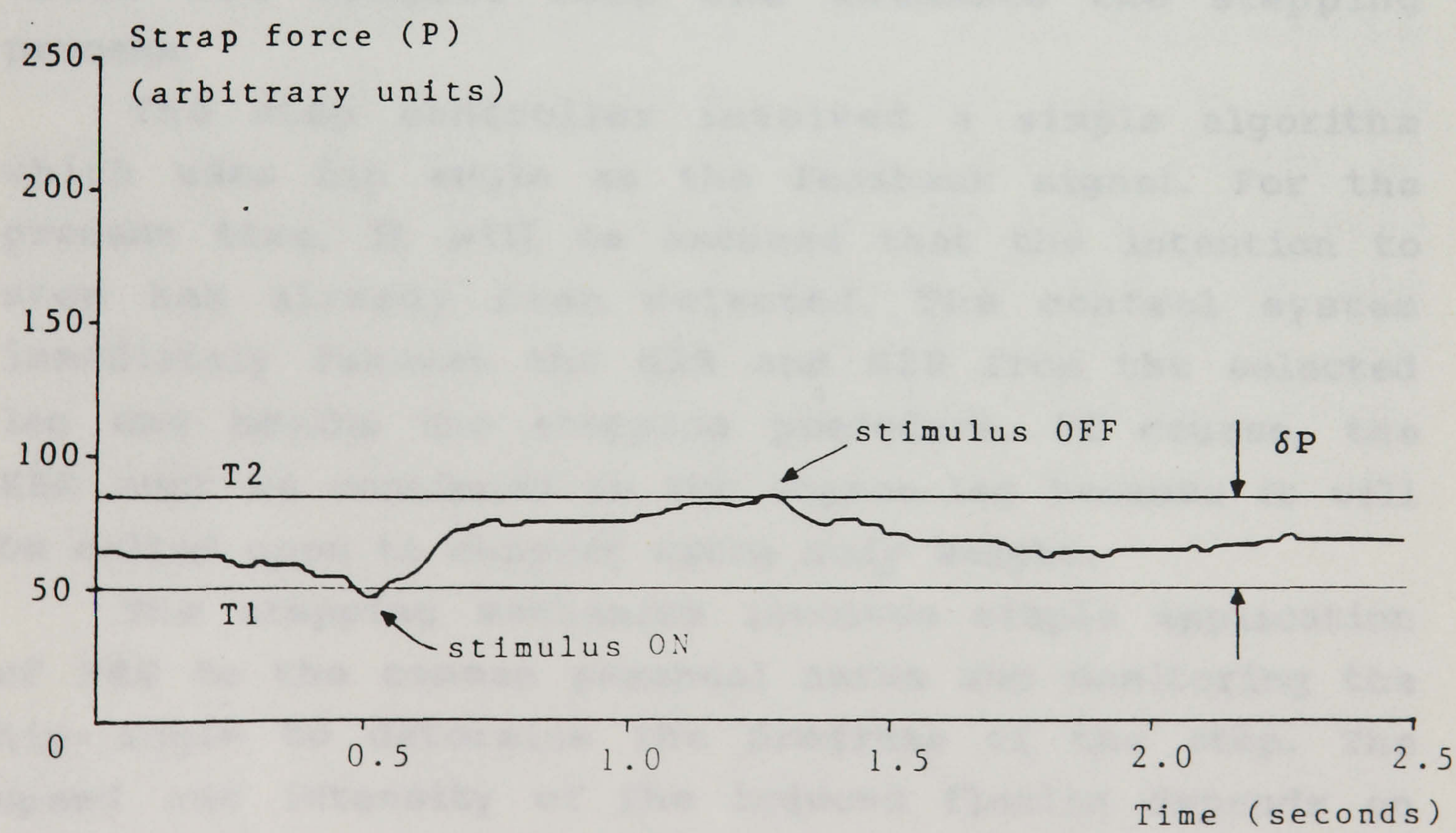


Figure 2.20

Output of FSR during preliminary standing tests with the SKAFO. The quantity "δP" represents the active knee moment caused by quadriceps contraction.

In the preliminary tests, quadriceps stimulation was initially applied at 100pps in order to improve the muscle response time. If the stimulation continued for more than one second, the frequency was then switched to 20pps to reduce the effects of fatigue. At first, these parameters were chosen intuitively. A study was later conducted to optimize the stimulus parameters with respect to muscle dynamics and fatigue resistance. Details of this will be considered in chapter three.

2.5.2. Control of Stepping

Once the intention to step has been detected by the control system it must initiate a stimulus sequence which induces flexion withdrawal of the appropriate leg. In most FES based walking systems which utilize this reflex the stimulus is applied for a time period which is either predetermined or manually controlled by the subject. This type of control is open-loop in nature. In the hybrid FRO walking system, an attempt was made to close the control loop and automate the stepping process.

The step controller involved a simple algorithm which uses hip angle as the feedback signal. For the present time, it will be assumed that the intention to step has already been detected. The control system immediately removes the KER and HER from the selected leg and begins the stepping procedure. Of course, the KER must be continued on the stance leg because it will be called upon to support extra body weight.

The stepping mechanism involves simple application of FES to the common peroneal nerve and monitoring the hip angle to determine the progress of the step. The speed and intensity of the induced flexion depends on the stimulus parameters used. In the preliminary tests, standard 300μs pulses were applied at a frequency of 25pps. The pulse intensity was determined empirically at the time of the tests. Chapter three will consider some techniques which were used to optimize these parameters.

The rules determining the end of the swing phase are centred around the hip angle of the swinging leg. When the hip has achieved a certain level of flexion, the quadriceps are activated shortly before the flexion stimulus is released. The momentary overlap of quadriceps and peroneal stimulation tends to extend the knee joint whilst the hip is maintained in flexion. This aids in the forward placement of the foot and improves the general dynamics of the gait pattern.

The threshold levels for hip flexion are defined in the controller software and compared with the sampled inputs from the hip goniometers. If, for any reason, the hip angle does not reach its defined threshold level, the controller looks for alternate conditions which can also define the end of the swing phase. The first of these is a simple time-out. If the hip has not reached the defined threshold level after two seconds of peroneal stimulation then something must be wrong and the swing phase should be terminated. Another condition for the premature termination of the swing phase is foot contact. If the foot sensor indicates that it is not clear of the floor then flexion must no longer be effective. These backup conditions are useful to ensure that the flexion phase is transitory and that the controller does not get stuck in the swing state. The KER is not active in this state and continued stance would not be safe for the subject.

2.5.3. Finite State Model

In the previous two sections, the most fundamental aspects of the finite state model were introduced. These correspond to the two basic phases of gait; stance and swing. Another important function of the finite state model is coordination of all the local controllers and the processing of command signals.

The command interface, for the system described here, takes the form of simple, push-button hand switches. Using these, the subject can alter the mode of operation of the system or indicate the intention to take a step. In the initial "Ready" mode, all stimulation is inhibited and the control system waits for a command input from the mode switch. When the subject is ready to stand, he must position himself appropriately by sitting near the edge of the seat and placing both feet on the floor directly underneath. The hands are placed in position on the supporting frame. When the mode switch is pressed, the controller enters "Stance" mode and stimulation is progressively applied to the quadriceps from zero to a preset maximum level. This is achieved by linearly ramping the pulsewidth over a period of 2 seconds. As the stimulus increases, the subject rises to a standing posture at a rate which can be regulated by the amount of weight taken through the upper limbs.

Once the standing posture has been attained, the control system enables the artificial reflexes described previously. The subject can then choose either "Sit" mode or "Walk" mode. When the Sit mode is selected, the controller waits for about 4 seconds and then ramps the stimulus pulsewidth down to zero over a period of 5 seconds. Once seated, the controller returns to the Ready mode. In the Walk mode, the controller waits for a logical signal indicating the intention to step. When this signal has been received, the stimulus sequence described in section 2.5.2 is executed.

In the preliminary tests, for the hybrid FRO system, two control strategies for stepping were investigated. In the first case, the subject indicated the intention to step by pushing hand switches. The gait cadence was, therefore, manually controlled by the subject. In the second case, step intention was deduced by the controller from specific combinations of sensor information. Thus, instead of deliberately pushing a switch, the subject adopted a particular posture and shifted weight (as if about to step normally) in order to initiate stepping. Once walking had commenced, the control system could then automatically maintain the gait pattern until the subject consciously halted the sequence.

The rules defined to detect step intention were based on signals from the crutch load and limb load sensors. Figure 2.21 illustrates the state transition algorithm for both manual and automatic stepping. When each state is entered, a number of actions are performed by the control system which are represented by the list of symbols under the state names. Any action, not included in this list, is assumed to be disabled in that particular state. Note that figure 2.21 represents the step controller for one leg only. The other leg is assumed to be in stance phase throughout the cycle.

The following is a brief description of the automatic stepping algorithm which starts at double support (ie. "Stance" state). The left leg has been arbitrarily chosen as the swing leg:

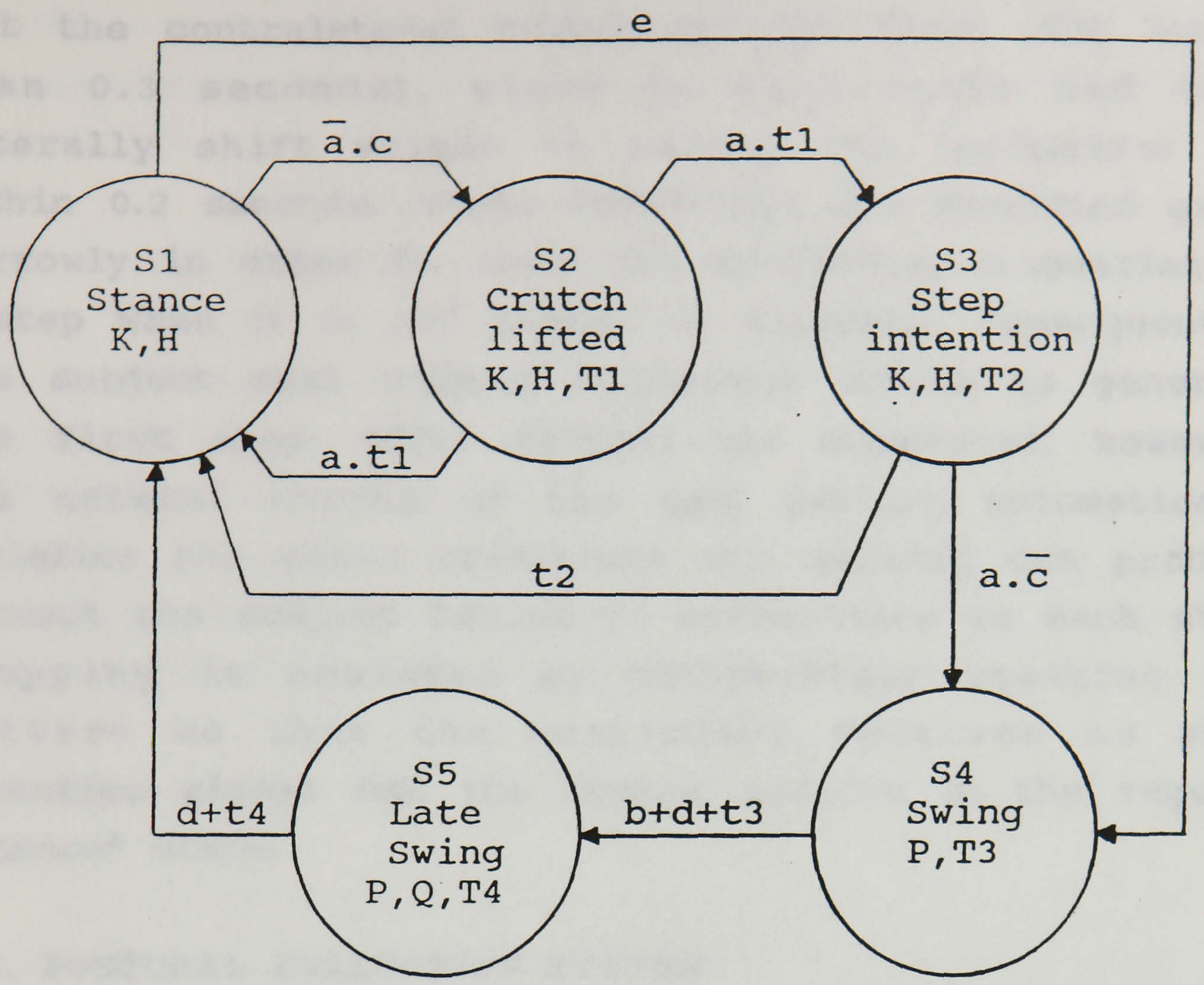
S1: IF the left leg is loaded AND the right crutch is unloaded, THEN go from S1 (Stance) to S2 (Crutch Lifted).

S2: IF the right crutch is loaded again, after the time-out period (eg. 0.3 seconds), THEN go to S3 (Step Intention) ELSE return to S1.

S3: IF the right crutch remains loaded AND the left leg is unloaded, within the time-out period (eg. 0.2 seconds), THEN go to S4 (Swing) ELSE return to S1.

S4: (Step intention has now been detected)
IF maximum hip flexion is attained OR foot contact is detected OR flexion time-out occurs (eg. 2 seconds), THEN go to S5 (Late Swing).

S5: IF foot contact is detected OR overlap time-out occurs (eg. 0.1 seconds), THEN return to S1.



<u>CONDITIONS</u>

a - crutch load > threshold (loaded)
b - hip angle > threshold (hip flexed)
c - limb load > threshold 1 (loaded)
d - limb load > threshold 2 (foot contact)
e - step intention from hand switch
t1 - crutch lift timer > timeout
t2 - step intention timer > timeout
t3 - swing phase timer > timeout
t4 - late swing timer > timeout

Note: (for limb load sensor)
threshold 1 > threshold 2

<u>ACTIONS</u>

K - maintain KER
H - maintain HER
P - peroneal stimulation
Q - unconditional quadriceps stimulation
Tx - reset corresponding timer
(ie. x = 1, 2, 3 or 4)

<u>Figure 2.21</u>

State diagram of manual
and automatic stepping.

In order to initiate stepping, the subject must lift the contralateral crutch off the floor (for longer than 0.3 seconds), place it down again and then laterally shift weight to unload the ipsilateral leg within 0.2 seconds. These conditions are specified quite narrowly in order to avoid the accidental triggering of a step when it is not wanted or expected. Consequently, the subject must make a deliberate effort to generate the first step. After walking has commenced, however, the natural rhythm of the gait pattern automatically satisfies the above conditions and walking can proceed without the subject having to concentrate on each step. Stopping is achieved by deliberately breaking the pattern so that the controller receives no step intention signal and the system remains in the regular "Stance" state.

2.6. POSTURAL EVALUATION SYSTEM

Sway has been chosen, in this thesis, to be the main measure of postural stability. This section considers the technical and mathematical aspects of the analysis; the clinical consequences will be considered in chapter three.

The following sway parameters were calculated:

- Total sway path length
- Average speed of excursion
- Mean radius of rotation
- Mean frequency of rotation
- AP and ML excursions
- RMS maximum and minimum axes
- Direction of maximum axis

All of these parameters are referred to the mean position or the centroid of the sway path.

Most of the sway parameters are based on those used by other researchers. The directional analysis, however, was developed by the author and will be considered in more detail.

2.6.1. Data Collection

A Kistler force platform, instrumented with piezoelectric force transducers, was used to measure CofP which is considered to be a suitable approximation to sway (section 1.6.1). The force platform and its associated charge amplifiers produce six voltage outputs which represent the following mechanical inputs:

F_x, F_y, F_z, M_x, M_y and M_z

These are the forces and moments exerted on the platform in the directions shown in figure 2.22. The output voltages were sampled and stored using an Amplicon PC-26, 16-channel, analogue to digital (AtoD) board interfaced with a Compaq Portable-II, IBM-AT compatible microcomputer. Each channel was sampled, to 12-bits resolution, at the rate of 50 samples per second (sps) for a total of 15 seconds. Thus, 750 data samples were produced for each of the six channels.

Given the force plate calibration factors, the computer software was then used to calculate the sway coordinates in millimetres. The calibration factors convert the sampled data words into units of Newtons (force) and Newton-metres (moment) referred to the cartesian coordinate system illustrated in figure 2.22. Complete calibration of the force plate involves the use of a 6x6 matrix which relates the electrical outputs to the mechanical inputs. The elements of this matrix, which do not lie on the main diagonal, represent slight corrections for mechanical cross-talk between the inputs. These corrections are minor and for most applications the six diagonal elements are sufficient.

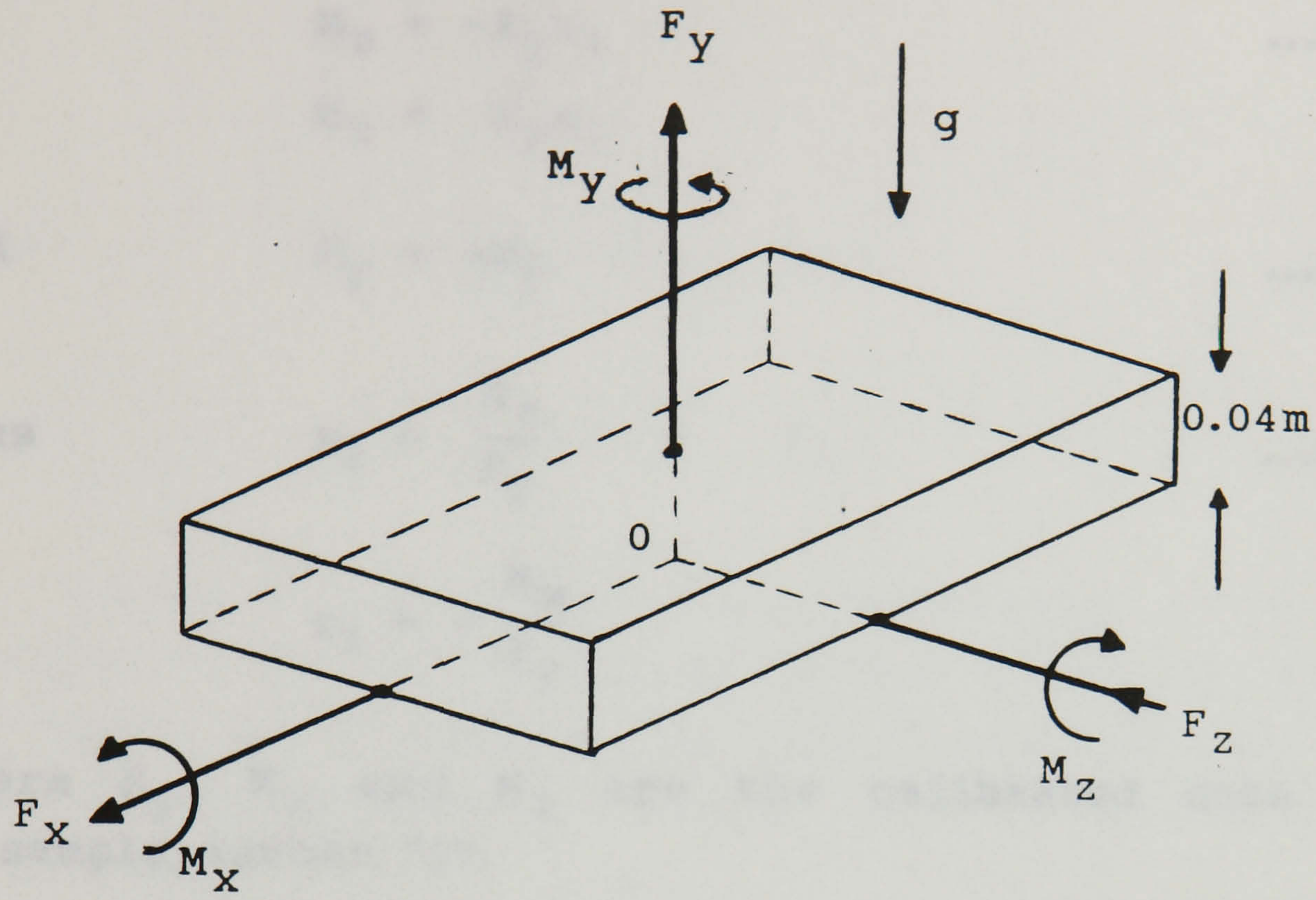


Figure 2.22

Force plate reference axes. The origin lies 4cm below the upper surface.

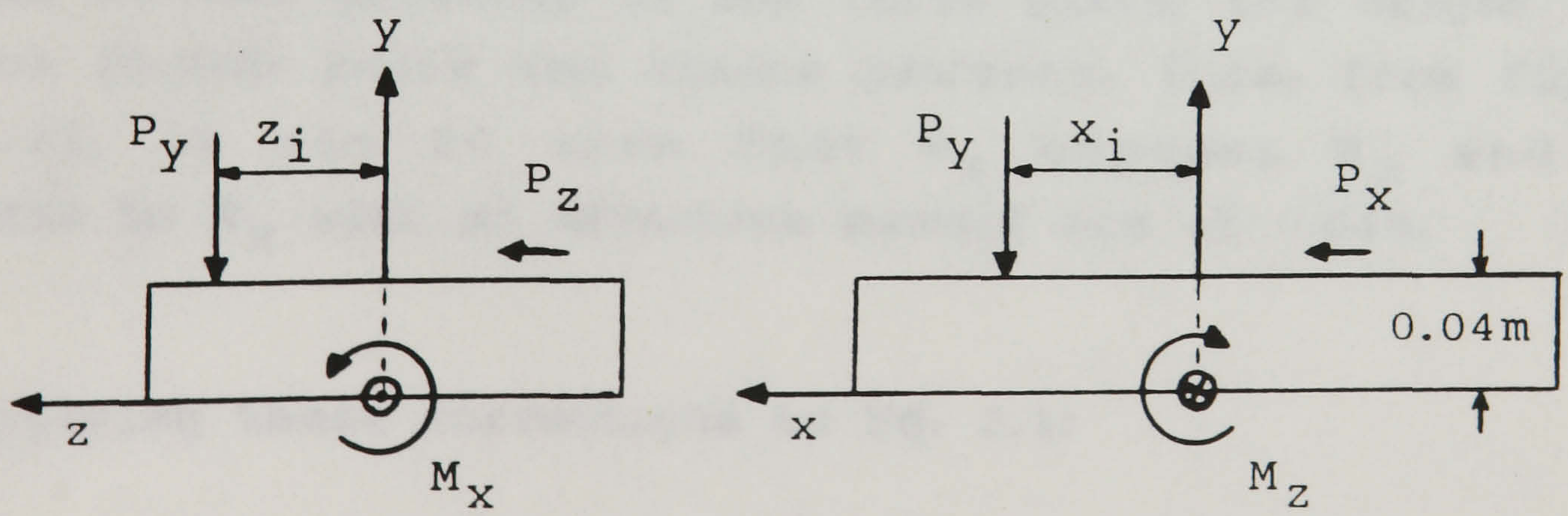


Figure 2.23

Front and lateral view of force plate.

Figure 2.23 shows how the instantaneous position of a vertical point force (P_y), in the x,z-plane, can be calculated:

ie $$M_z = -P_y x_i \qquad \text{...Eq. 2.1}$$

$$M_x = P_y z_i$$

and $$F_y = -P_y \qquad \text{...Eq. 2.2}$$

thus $$x_i = \frac{M_z}{F_y} \qquad \text{...Eq. 2.3}$$

$$z_i = -\frac{M_x}{F_y}$$

Where F_y, M_x and M_z are the calibrated data points at sample number "i".

A distributed vertical force, with its CofP at (x_i,z_i) and a total effective value of P_y, will produce the same result. In quiet standing, however, the net force is seldom ever vertical. The effect of postural corrections is to produce small frictional force components on the upper surface of the platform. These are represented by P_x and P_z in figure 2.23. Due to the geometry of the force plate, the origin lies 4cm (0.04m) below the stance platform. Thus, from figure 2.23, it can be seen that P_x opposes M_z and P_z adds to M_x with an effective moment arm of 0.04m.

Applying these corrections to Eq. 2.1:

$$M_z = -P_y x_i - 0.04P_x \qquad \text{...Eq. 2.4}$$

$$M_x = P_y z_i + 0.04P_z$$

Additionally,

$$F_x = P_x \qquad \text{...Eq. 2.5}$$

$$F_z = P_z$$

$$F_y = -P_y$$

thus

$$x_i = \frac{1}{F_y}(0.04F_x + M_z) \qquad \text{...Eq. 2.6}$$

$$z_i = \frac{1}{F_y}(0.04F_z - M_x)$$

Equation 2.6 defines the coordinates of the base position of the GRV, relative to the centre of the force platform's upper surface. The mean sway position can be determined by calculating the centroid of the coordinates:

ie

$$\bar{x} = \frac{1}{N} * \sum_{i=1}^{N} x_i \qquad \text{...Eq. 2.7}$$

$$\bar{z} = \frac{1}{N} * \sum_{i=1}^{N} z_i$$

where N = number of samples

All sway coordinates can then be referred to this mean position:

ie

$$x_i' = x_i - \bar{x} \qquad \text{...Eq. 2.8}$$

$$z_i' = z_i - \bar{z}$$

For the remainder of this thesis, all references to x_i and z_i will be assumed to be relative to the centroid.

2.6.2. Sway Path Length

The total path length is estimated by calculating the cumulative distance between consecutive data points using the following equation:

$$L = \sum_{i=1}^{N-1} \sqrt{(x_{i+1} - x_i)^2 + (z_{i+1} - z_i)^2} \qquad \text{...Eq. 2.9}$$

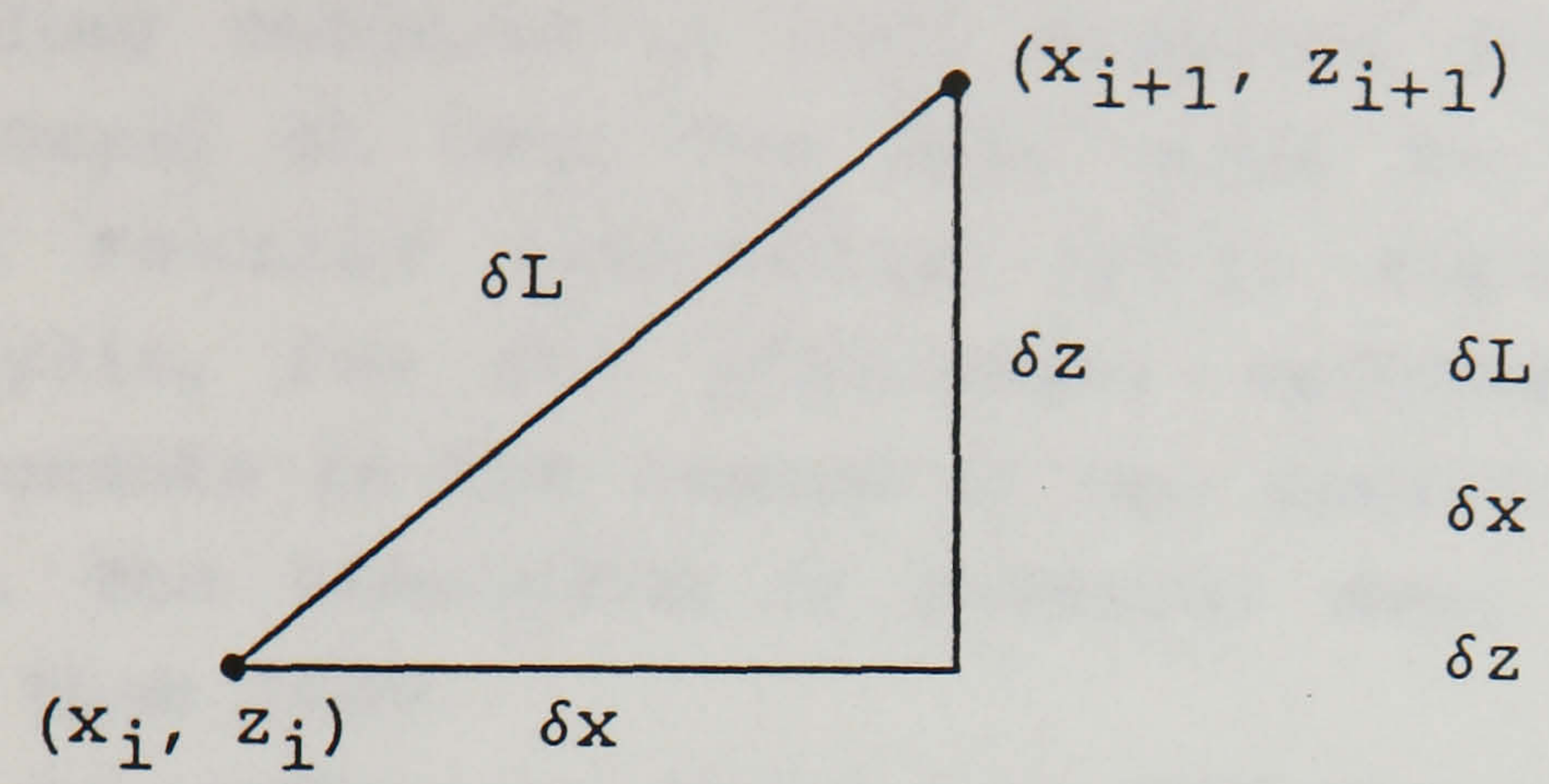
The equation for the average speed of excursion can be expressed as follows:

$$v = L/t \qquad \text{...Eq. 2.10}$$

where t = sample time

The sway path between consecutive data points is assumed to be linear (figure 2.24) which is not strictly true. Figure 2.25a shows that the length of a series of chords, along a curved line, under-estimates the true length of the line. The extent of this error depends on the compromise between the radius of curvature of the line and the number of chords used to approximate it. This, in turn, corresponds to the compromise between the bandwidth of the data and the sampling frequency.

Another potential source of error is the presence of noise in the input data. Figure 2.25b illustrates the effect of a noisy signal superimposed on a smooth sway path. For some calculations, such as the mean radius of rotation, the noise tends to have little effect. The sway path length, however, is a cumulative calculation and added noise can cause gross over-estimation. Errors can, sometimes, be introduced by digital quantization of the data. These have not been considered, in this thesis, because they are relatively insignificant compared with the other sources of error.



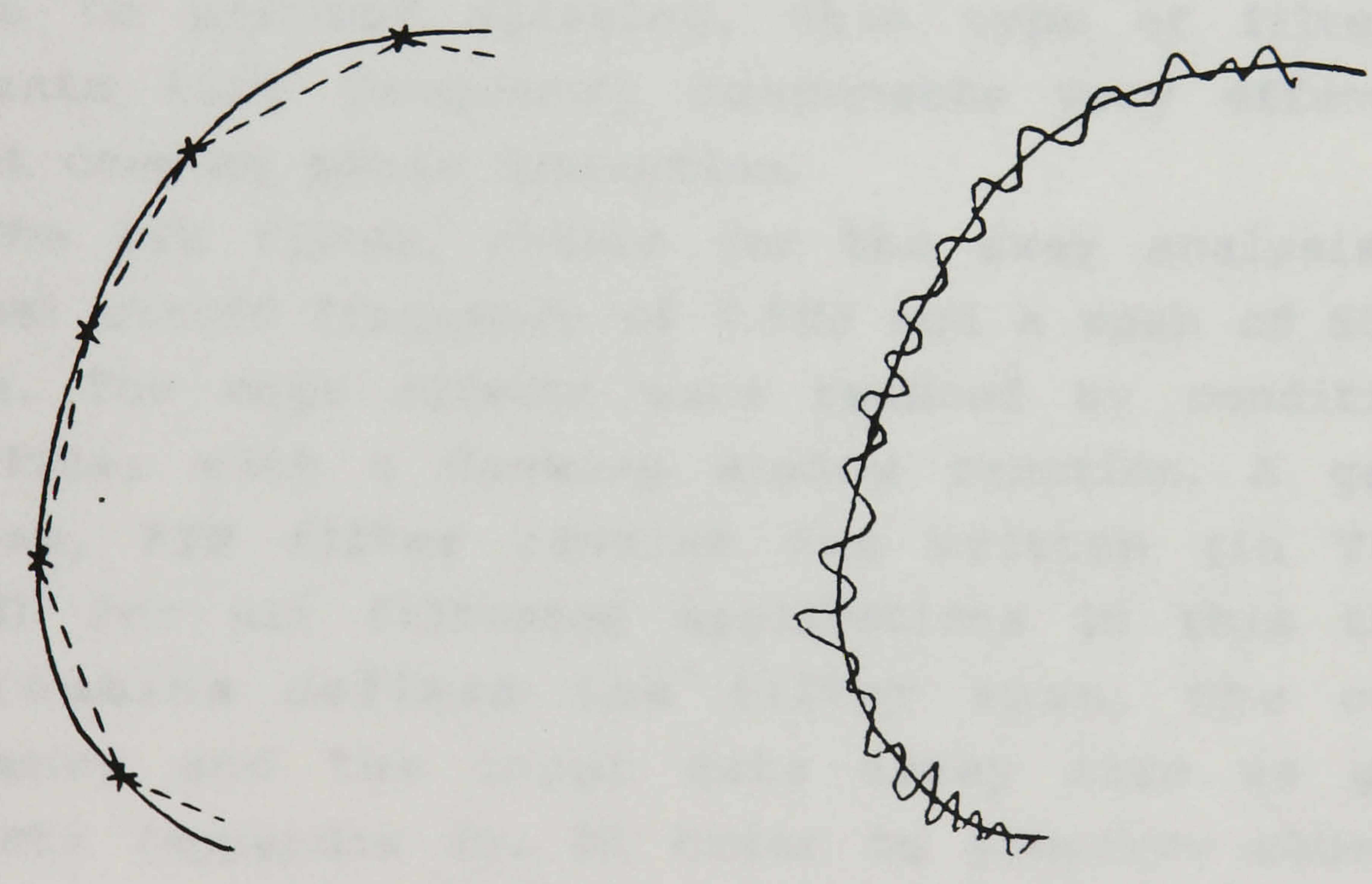
$$\delta L = \sqrt{\delta x^2 + \delta z^2}$$

$$\delta x = x_{i+1} - x_i$$

$$\delta z = z_{i+1} - z_i$$

Figure 2.24

Distance calculation between consecutive points.



a) b)

Figure 2.25

Sources of error in sway path length. a) Smooth curve approximated by a series of chords joining data points. b) Smooth curve with superimposed noise signal.

In order to reduce the above errors to a minimum, the following analyses were performed. Force plate data were obtained using stationary weights and quietly standing subjects. A high sampling frequency was used (1000sps) so that the data could be processed with a fast fourier transform (FFT) algorithm. The FFT analysis, for the stationary weights, revealed noise components in the region of the spectrum between 10 and 20Hz. The bandwidth of postural sway was found to be less than 10Hz.

In order to avoid pre-filtering of all the force plate channels, the data for the postural stability tests were sampled at 50sps. The noise components were then removed using a finite impulse response (FIR), low pass, digital filter. The FIR algorithm is ideal for filtering data which does not have to be processed in real time. Assuming that the sampling frequency is high enough to prevent aliasing, this type of filter can attenuate high frequency components very effectively without causing phase distortion.

The FIR filter, chosen for the sway analysis, had an ideal cutoff frequency of 7.5Hz and a span of 50 data points. The edge effects were reduced by conditioning the filter with a Hamming window function. A general purpose, FIR filter routine was written (in Turbo-pascal) for all filtering applications in this thesis. The routine defines the filter span, the cutoff frequency and the input data array size as global constants (appendix B). In order to preserve causality, a number of points (equal to half the filter span) must be discarded from the beginning and end of the recorded data. Thus, after filtering, 15 seconds of sway data must be reduced to 14 seconds (ie. 2x25 samples are discarded).

Having reduced the errors, equation 2.9 becomes a better estimate of the total sway path length. After filtering, however, the value "N" is reduced to 700 and the divisor in equation 2.10 is reduced to 14.

2.6.3. Radius of Rotation

The results of equations 2.6, 2.7 and 2.8 define the sway data, relative to the centroid, in cartesian coordinates. For the following analyses, these were converted into polar coordinates as follows:

$$r_i = \sqrt{x_i^2 + z_i^2} \qquad \text{...Eq. 2.11}$$

$$\begin{array}{l} \text{IF } x_i = 0 \text{ AND } z_i \geq 0 \text{ THEN } \theta_i = \pi/2 \qquad \text{...Eq. 2.12} \\ \text{IF } x_i = 0 \text{ AND } z_i < 0 \text{ THEN } \theta_i = -\pi/2 \\ \text{IF } x_i > 0 \text{ THEN } \theta_i = \arctan(z_i/x_i) \\ \qquad\qquad \text{ELSE } \theta_i = \arctan(z_i/x_i) + \pi \end{array}$$

The mean radius of rotation then becomes a relatively simple equation:

ie $$\bar{r} = \frac{1}{N} * \sum_{i=1}^{N} r_i \qquad \text{...Eq. 2.13}$$

The frequency of rotation follows on from the average speed of excursion and the mean radius:

ie $$f_r = v/(\,2\pi\bar{r}\,) \qquad \text{...Eq. 2.14}$$

The mean radius and frequency of rotation convert the sway path to an equivalent circular motion. In this way, different data records can be standardized for comparison. More information, however, can be derived from directional analyses.

2.6.4. Directional Analyses

The majority of sway data show different characteristics in the AP and ML directions. The average excursion in the AP plane is usually greater than in the ML plane. The ratio of AP to ML excursions provides additional information about the mechanisms which could be responsible for the sway. Chapter three will consider this in more detail.

The mean AP and ML excursions can be calculated by averaging the magnitudes of the individual x and z cartesian coordinates (referred to the centroid):

ie $$\bar{x}_d = \frac{1}{N} * \sum_{i=1}^{N} |x_i| \qquad \text{...Eq. 2.15}$$

$$\bar{z}_d = \frac{1}{N} * \sum_{i=1}^{N} |z_i|$$

Because of the general asymmetry of sway, in orthogonal directions, an elliptical representation is considered to be more realistic than a circle. Additionally, it is quite likely that the directions of maximum and minimum excursion do not correspond to the AP and ML directions.

Figure 2.26 illustrates an arbitrary point on a typical sway path (P_i), which is defined by the polar coordinates (r_i, θ_i). A new set of cartesian axes (x', z') can be defined by a rotational transformation, about the origin, of "η" radians. The quantity "a_i" is equivalent to the x-coordinate of point P_i in this new frame of reference and thus represents the component of P_i in the direction defined by the angle η.

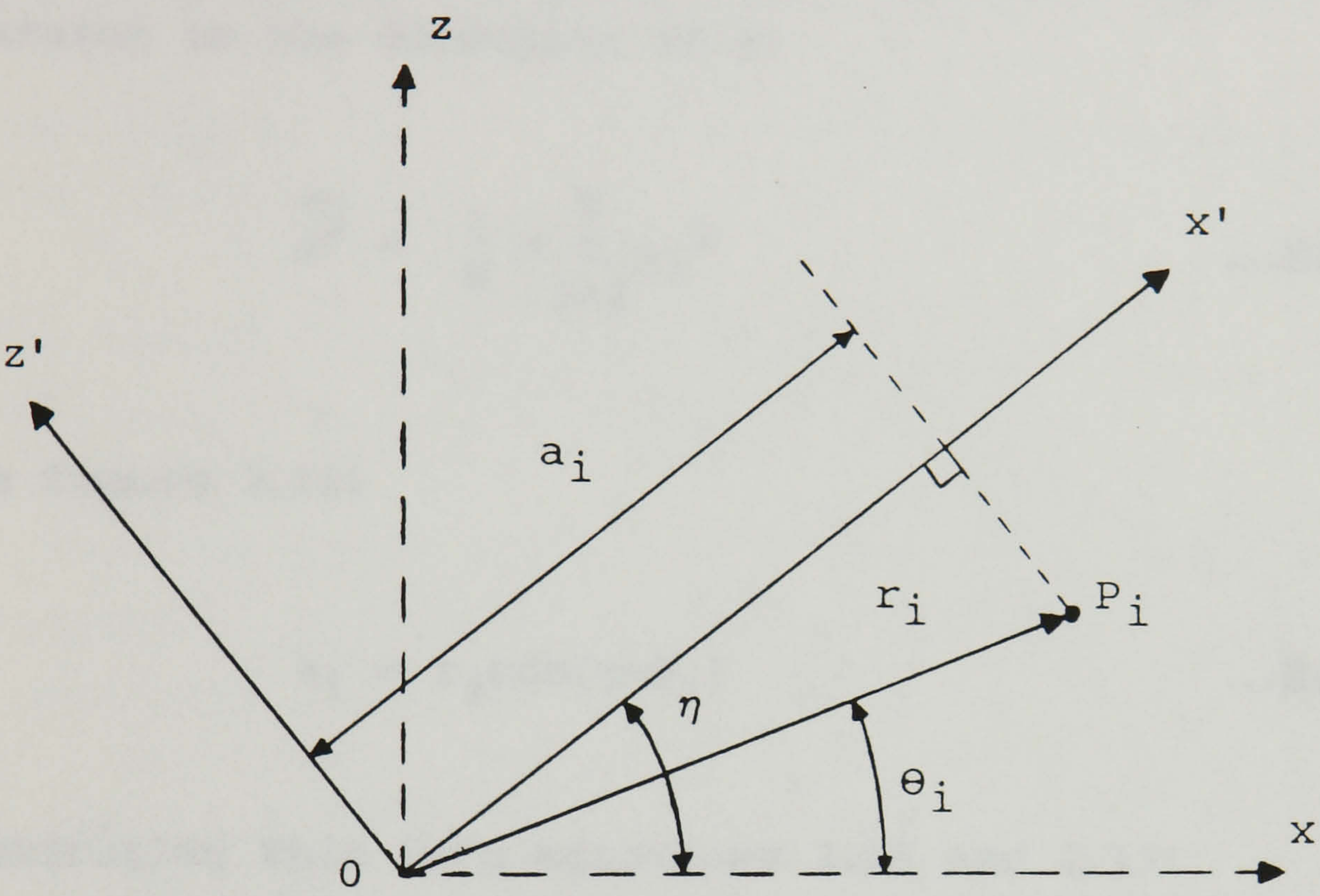


Figure 2.26

Definition of the point P_i in a new frame of reference which is produced by a rotational transformation of "η" radians about the origin.

The mean excursion in this direction can be defined as follows:

$$\overline{a} = \frac{1}{N} * \sum_{i=1}^{N} |a_i| \qquad \text{...Eq. 2.16}$$

Another useful quantity is the root mean square (RMS) excursion in the direction of η:

ie
$$\overline{a^2} = \frac{1}{N} * \sum_{i=1}^{N} a_i^2 \qquad \text{...Eq. 2.17}$$

From figure 2.26:

$$a_i = r_i \cos(\eta - \theta_i) \qquad \text{...Eq. 2.18}$$

Substituting this into equations 2.16 and 2.17:

$$\overline{a} = \frac{1}{N} * \sum_{i=1}^{N} |r_i \cos(\eta - \theta_i)| \qquad \text{...Eq. 2.19}$$

$$= h(\eta)$$

and
$$\overline{a^2} = \frac{1}{N} * \sum_{i=1}^{N} r_i^2 \cos^2(\eta - \theta_i) \qquad \text{...Eq. 2.20}$$

$$= f(\eta)$$

The individual data points, r_i and θ_i, are constant and independent of η. Therefore, $h(\eta)$ and $f(\eta)$ are defined as functions of a single variable.

Figure 2.27 shows polar plots of $h(\eta)$ and $f(\eta)$, which were obtained from a sway data record of normal stance. From these, the following can be inferred:

1) The maximum and minimum axes do not necessarily correspond to the AP and ML directions.

2) The maximum and minimum axes are orthogonal. (This property is also indicated in equation 2.20).

3) The directions of the axes, defined by both $h(\eta)$ and $f(\eta)$, are the same.

4) The plots are, in fact, not elliptical but shaped like two overlapping circles.

The maximum and minimum axes correspond, respectively, to the local maxima and minima in each of the functions $h(\eta)$ and $f(\eta)$. These indicate the points where the first derivative, with respect to η, equals zero. The following is a general outline of the methods used to identify the stationary points of $f(\eta)$ and thus find the direction of the maximum axis. The RMS function was chosen because it is differentiable over all values of η. A stationary point can be defined as follows:

$$f'(\eta) = 0 \qquad \text{...Eq. 2.21}$$

From equation 2.20:

$$f'(\eta) = -\frac{2}{N} * \sum_{i=1}^{N} r_i^2 \cos(\eta-\theta_i)\sin(\eta-\theta_i) \qquad \text{...Eq. 2.22}$$

$$= -\frac{1}{N} * \sum_{i=1}^{N} r_i^2 \sin[2*(\eta-\theta_i)]$$

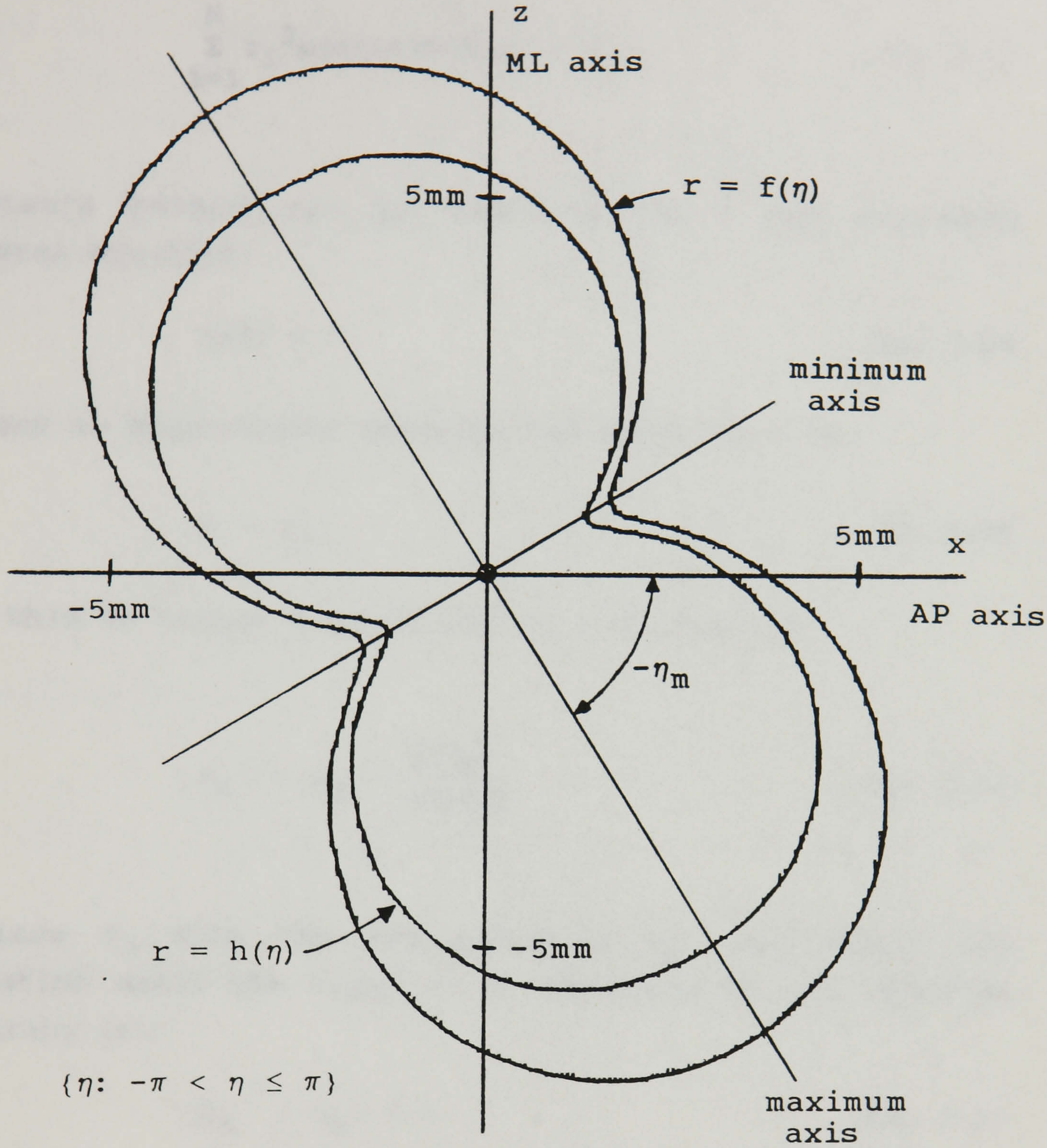


Figure 2.27

Polar plots of h(η) and f(η) for a complete revolution of η. Note that the maximum axis occurs at a negative value of η.

Thus, obtaining a stationary point, for $f(\eta)$, corresponds to solving the following equation for η:

$$\sum_{i=1}^{N} r_i^2 \sin[2*(\eta-\theta_i)] = 0 \qquad \text{...Eq. 2.23}$$

Newton's method can be used to solve the following general equation:

$$g(\eta) = 0 \qquad \text{...Eq. 2.24}$$

Choose an approximate solution for equation 2.24:

ie $$\eta = \eta_a \qquad \text{...Eq. 2.25}$$

Use this to define a new value of η as follows:

$$\eta_a' = \eta_a - \frac{g(\eta_a)}{g'(\eta_a)} \qquad \text{...Eq. 2.26}$$

Replace η_a with the new value of η_a' and repeat the iteration until the value of η converges to the required accuracy (ϵ):

ie $$|\eta_a' - \eta_a| < \epsilon \qquad \text{...Eq. 2.27}$$

From equation 2.23:

let $$g(\eta) = \sum_{i=1}^{N} r_i^2 \sin[2*(\eta-\theta_i)] \qquad \text{...Eq. 2.28}$$

thus $$g'(\eta) = 2 * \sum_{i=1}^{N} r_i^2 \cos[2*(\eta-\theta_i)] \qquad \text{...Eq. 2.29}$$

This method was very effective in finding the angle of either the maximum or the minimum axis. Convergence (to less than $\epsilon = 10^{-4}$ radians) was usually achieved within two or three iterations. Since the axes were known to be orthogonal (from equation 2.20), only one of them needed to be found in this way. The other axis could be defined by adding $\pi/2$ to the solution for η.

The next step is to identify whether the angle obtained corresponds to the maximum or the minimum axis. This information is available from the second derivative of $f(\eta)$.

At a stationary point defined by η_s:

IF $f''(\eta_s) > 0$ THEN $f(\eta_s)$ = local minimum
IF $f''(\eta_s) < 0$ THEN $f(\eta_s)$ = local maximum

From equation 2.22:

$$f''(\eta) = -\frac{2}{N} * \sum_{i=1}^{N} r_i^2 \cos[2*(\eta-\theta_i)] \qquad \text{...Eq. 2.30}$$

Thus, the following condition defines the maximum axis:

$$\sum_{i=1}^{N} r_i^2 \cos[2*(\eta-\theta_i)] > 0 \qquad \text{...Eq. 2.31}$$

The software for the directional analysis is summarized in appendix B. The output value η (eta) is converted to degrees and restricted to the following range:

$$\{\eta: -90° < \eta \le 90°\}$$

This allows the maximum axis to be uniquely defined.

CHAPTER 3. EXPERIMENTAL DESIGN

CHAPTER 3. EXPERIMENTAL DESIGN

3.1. INTRODUCTION

This chapter is concerned with the evaluation of the hybrid FRO system and the optimization of the neuromuscular responses induced by FES. A number of tests will be described which were designed to quantify the following:

a) Postural stability
b) Muscle function
c) Flexion response

The preliminary results, presented in chapter four, clearly demonstrate a significant reduction in the active duty cycle of quadriceps stimulation when walking with the hybrid system. This makes a readily observable contribution to the reduction of fatigue. However, due to the strenuous nature of FES induced walking, relatively little time is spent actually stepping. The majority of time, in an upright posture, is spent recovering from the exertion of walking.

It is difficult to quantify the reduction of fatigue when quietly standing with the FRO system because of the intermittent nature of the stimulus application. In the preliminary standing tests, quadriceps stimulation was usually required when the subject made a deliberate postural shift or the system was disturbed in some way. If the subject was left undisturbed, long periods of quiet standing could be achieved with little or no stimulation. In this type of test, the average duty cycle of stimulation tends to be a rather subjective measure because of its dependence on the experimental conditions.

Sway parameters, which are used to indicate postural stability during quiet stance, constitute a more practical means of evaluating the overall system.

The ability to stand and rest, without any stimulation, is probably the most practical feature of the orthosis. Thus, it was considered appropriate to quantify postural stability under these conditions. The presence of quadriceps stimulation, at any time, indicates that the level of instability has exceeded a certain threshold. Sway parameters, averaged over a given period of time, are an indication of the probability that stimulation will be required; even if the threshold of instability was never actually exceeded during the test.

The second series of tests were intended to characterize the dynamics of muscle in response to various types of stimulation. In the preliminary tests, high frequency stimulation was used to induce a rapid muscle response before the onset of instability. This was applied with little regard for fatigue mechanisms because it was assumed that the fundamental action of the braces would minimize this problem. Despite the reduction in stimulus duty cycle, high frequency stimulation could still induce fatigue in a relatively short time. Thus, tests were designed to determine a stimulus pattern which could minimize the muscle response times without unduly accelerating fatigue mechanisms.

Similar tests were defined to determine an optimum stimulus pattern for induction of the flexion withdrawal reflex. The main objective of these tests was to increase the intensity and reduce the latency of the response. The extra intensity was required to lift the added weight of the SKAFO brace off the ground and the reduced latency served to increase the speed of walking.

3.2. PATIENT PREPARATION

In order to be truly practical, a walking system should be suitable for a wide range of patients and not just a select few. However, for developmental purposes, it is important that the test subjects do not suffer from complications which can impede progress. These complications include the following:

- Excessive spasticity
- Contractures
- Obesity
- Muscle denervation
- Osteoporosis

On the other hand, the following factors are viewed very favourably when selecting subjects:

- High level of motivation
- Strong upper limbs
- Good balance control
- Experience with using calipers

Atrophied muscles are not considered to be a complication because they can be reconditioned with FES. All of the patients who provided the results for this thesis were subject to an extensive training programme before any standing or walking tests were conducted.

Some patients, with incomplete spinal cord lesions, have preserved proprioception in their paralysed limbs. These subjects tend to be in the minority and are not very representative of the SCI population in general. However, they can prove to be very helpful in the development of standing and walking aids because of their ability to sense various effects which may not be apparent from mere observation. Some of the developments in this thesis were obtained from the results of tests performed on a subject with this type of lesion.

In order to expand the generality of the patient population, the orthoses were also evaluated on subjects with complete SCI. These subjects tend to be more representative of the SCI population. For the evaluation tests, however, they were still required to satisfy the criteria outlined above. Although this tended to make application of the system rather selective, it should be remembered that it was only for developmental evaluation that such rigorous screening was applied. General, clinical applications would encompass a much wider population of potential candidates.

3.2.1. Exercise Programme

Before attempting to stand, using FES, each subject was required to undergo a three month exercise plan to restore strength, condition and endurance to atrophied muscles. The main emphasis was centred around building up the quadriceps group. However, other muscles such as the gastrocnemius, hamstrings and gluteal group were also considered.

Patients were instructed to apply the stimulation themselves and to organize their own training schedule at home. The exercises could be performed as often and for as long as desired but the minimum daily exercise time was set at a total of one hour per muscle group. Once fatigue was observed, in a particular group of muscles, further stimulation of these muscles served no useful purpose for exercising. Most of the exercise sessions lasted no more than about 20 minutes per muscle group. Consequently, at least three sessions were required each day to achieve the minimum exercise time. These, in turn, needed to be separated from each other by at least two hours in order to allow time to recover from previously induced fatigue.

The stimulators used for the home exercises are general purpose, two channel devices which produce stimulus voltage pulses, at a rate of 25pps, with an effective pulsewidth of about 300μs. The intensity of each channel is manually adjustable from zero to about 120V. In the "exercise" mode of operation, the stimulus alternates between the two output channels every five seconds. Thus, each channel exhibits a cyclical stimulus pattern with a period of approximately ten seconds.

In the initial stages of the reconditioning programme, the muscles were exercised isometrically. This is a very light form of exercise which is suitable only for muscles with considerable atrophy. Thus, the next progression could usually be achieved quite rapidly. The criterion for progression occurred when 120 stimulus cycles (ie about 20 minutes) could be completed without the muscles showing any appreciable sign of fatigue.

The second set of exercises involved moving joints through their inner range of motion. As the muscles improved, the range of motion was then progressively increased. After about four weeks of daily exercise, the quadriceps muscles were usually strong enough to fully extend the knees whilst the subject was in a seated position. This was still a relatively easy exercise because it involved creating a knee moment only sufficient to lift the weight of the lower leg. More challenging exercises involved the progressive addition of lead weights, attached at the ankles, to increase the resistance to movement and the knee moment required to achieve full extension.

The maximum knee moments were monitored, for each subject, on a weekly basis. These measurements were taken isometrically with the knees fixed in 60 degrees of flexion. The test stimulus, which was generated using the computer controlled stimulator, consisted of regulated current pulses (300μs duration) applied at a rate of 25pps. The current intensity, required to produce maximal contractions, varied between different subjects. For each individual, however, the intensity was kept constant throughout the exercise programme. Details of the equipment used to measure knee moment will be considered in a later section.

When the quadriceps muscles were capable of repeatedly producing knee moments in excess of 40Nm, the subject was considered to be ready for FES assisted standing.

3.2.2. Stance and Gait Training

In order to demonstrate the advantages of the hybrid FRO system, the test subjects were required to be experienced in using FES to stand and walk. Since this is a skill which takes some time to learn, it was necessary to provide a considerable amount of training for each subject. The aim of the gait training programme was to achieve a level of muscle strength and balance control which was suitable for use with FRO's. The walking pattern was based on the simple, four channel system, with hand switch controls, which was described in section 1.4.

During the first attempts at standing, using only quadriceps stimulation, the subjects stood between fixed parallel bars. Initially, these bars were used to support most of the body weight through the action of the upper limbs. As their level of skill and confidence in the system grew, the subjects then learned to rely more on the supporting capability of their own paralysed legs and less on their arms.

With further progression in muscle strength and balance control the subjects could begin to concentrate on improving their stance posture. When capable of standing safely in a portable frame, such as a rollator, the subjects were allowed to stand at home as an additional exercise. If stance could be achieved with bilateral stimulation of the quadriceps only then a single, two-channel, portable home unit could be used.

These stimulators have an additional mode called "sit/stand" which activates both output channels simultaneously. Regular standing was of benefit to the subjects because it served to maintain muscle condition and further increase their confidence and skill.

The next progression in the training programme was learning to take a step. At first, the subject was instructed to remain stationary and practice leaning to one side until most of his body weight could be supported on one leg.

Once this was achieved, a flexion withdrawal reflex was induced in the unloaded leg. When the subject was accustomed to the sensations associated with all the phases of stimulation and familiar with the technique of shifting weight onto one leg, he could then begin to try forward ambulation.

The basic technique for a single step involves moving the rollator forward, shifting weight onto one leg, leaning slightly forward and pushing the appropriate hand switch to trigger a flexion withdrawal reflex. At the end of the step, the leg should have advanced forward so that the process can be repeated for the other leg.

At first, all subjects found this very difficult to master. With practice, however, their timing and coordination improved which resulted in faster walking speeds. Subjects with incomplete lesions and preserved motor control often progressed to using the walking system with crutches. It is conceivable that subjects with complete injuries could also use crutches for walking but, in general, rollators are preferred because of their inherent stability.

3.3. POSTURAL STABILITY TESTS

The equipment and analyses which are used to evaluate postural stability have already been considered in chapter two. In this section, the experimental protocols will be defined and the clinical consequences of the sway parameters will be briefly discussed.

Four separate orthoses were evaluated, during quiet stance, for comparison:

a) FES only
b) KAFO
c) RGO
d) Hybrid FRO

Additionally, various combinations of postural conditions were tested, where possible, with each orthosis. These included the following:

Eyes : open/closed
Hand support : double/single/none

Because of the contrasts in the relative stability of the above orthoses, not all combinations of these conditions could be tested in each case. For example, when standing with FES alone, the subject did not feel safe without his eyes open and the use of both hands for balance. On the other hand, with inherently stable orthoses such as FRO's, the subject could easily stand with eyes closed or with minimal hand support.

3.3.1. Protocol

The subject was required to stand quietly on a force plate with his feet placed approximately 25cm apart. The force plate information, for each trial, was sampled over a period of 15 seconds. With each orthosis, a rollator was used as the supporting frame for the hands. When using single hand support, the subject was asked to place his free hand by his side. For the tests that required no hand support, the subject was allowed to lightly touch the supporting frame with one finger in order to maintain balance. He could not, however, use either hand to support any of his weight.

The stability results presented in this thesis were measured on one patient only. This subject was chosen because he had been fitted with all of the orthoses mentioned above and was capable of standing in each of them. Thus, he presented an ideal opportunity to compare the stability of the hybrid FRO system with a number of other devices.

A total of 110 trials were conducted, over a period of approximately four months, which were divided into weekly sessions. During each session, several trials were conducted, using two different orthoses, under a variety of conditions. Table 3.1 summarizes the combinations of orthoses and conditions which were tested and the number of trials associated with each of them. The entries with null values correspond to conditions under which the subject could not safely stand for an extended period of time. From the table, it can be seen that the majority of data, available for comparison, was obtained from the hybrid FRO system and regular KAFO's. Standing with FES or in the RGO could only be compared when using two hands for support.

No more than two trials, corresponding to each entry in table 3.1, were taken in any one session. The purpose of this was to spread the distribution of similar trials over a period of several weeks. In this way, the effects of changes in the subject's health or state of attention, from week to week, could be reduced.

Eyes	Hand	FRO	KAFO	RGO	FES
EO	2H	8	6	5	4
EO	RH	8	6	-	-
EO	LH	8	6	-	-
EO	NH	6	6	-	-
EC	2H	8	6	5	-
EC	RH	8	6	-	-
EC	LH	8	6	-	-

Abbreviations used for experimental conditions:

EO - Eyes open

EC - Eyes closed

2H - Two handed support

RH - Right hand only

LH - Left hand only

NH - No hand support

Note:
With "NH" support, one finger of each hand could be used for balance control.

Table 3.1

Frequency table showing the number of trials conducted with each orthosis and its associated experimental conditions.

3.3.2. Interpretation of Data

The sway parameters calculated in this thesis provide information on various aspects of the mechanisms involved in postural stability. No single parameter should be considered as a definition of postural stability. Instead, all the parameters must be regarded collectively which can sometimes lead to contradictory conclusions. The following is a brief discussion on the implications of individual sway parameters and how they can be interpreted.

The distance of excursion and average speed of sway indicate the number of postural corrections which occur per unit time. Relatively high values for these parameters are considered to be a positive sign because they indicate healthy vestibular mechanisms and rapid responses to destabilizing movements.

The mean radius of rotation is a reciprocal indicator of the effectiveness of postural corrections. If a small value is obtained for this parameter it usually means that the stance is inherently stable and that the associated postural corrections are minimal. A large value indicates that the system is difficult to stabilize and that overcompensation is occurring during postural corrections.

The frequency of rotation is proportional to the mean velocity and inversely proportional to the mean radius. Thus, it is a convenient combination of the properties mentioned above. A relatively large frequency indicates good postural control over an inherently stable system. On the other hand, a low frequency indicates poor control and a less stable system.

The sway parameters with directional properties can give more specific information about what could be causing instability. For example, in normal standing, with feet apart, the majority of postural corrections are observed in the AP plane. Due to the anatomical structure of the lower limbs, the system tends to be mechanically stable in the ML directions and requires relatively few postural corrections. The mean radius and frequency of rotation are based on a circular model for swaying movements which assumes that the mechanisms causing sway are the same in all directions. Since this is not usually the case, a more realistic approach is to represent the sway path as an ellipse. In this way, sway can be resolved into orthogonal components which, in turn, supply more information about the cause of the instability.

3.4. MUSCLE EVALUATION TESTS

The purpose of the muscle evaluation tests was to determine a stimulus pattern which could rapidly produce strong muscle contractions without accelerating fatigue mechanisms. When standing quietly, with the hybrid FRO system, rapid muscle responses are not usually necessary because the stimulus control system can anticipate the onset of instability and take corrective action well before it occurs. Similarly, if stimulation is applied only occasionally, fatigue should not be a significant problem.

On the other hand, if a sudden destabilizing event was to occur, the system would be expected to respond as quickly as possible in order to prevent a fall. For example, when the subject pulls on a door handle, during stance, the GRV can suddenly move behind the knee joint. A practical system should be able to deal with common situations, like this, which may be encountered. Thus, under these circumstances, rapid muscle responses become very important.

In the preliminary standing and walking tests, described in chapter two, high frequency stimulus parameters were used to speed up the muscle responses. Although the stimulus duty cycle was reduced, muscle fatigue still occurred relatively quickly because the high frequencies tended to accelerate fatigue mechanisms. Consequently, it was decided that an investigation was necessary to determine whether or not both objectives could be met simultaneously.

3.4.1. Equipment

The experimental setup is illustrated in figure 3.1. A Compaq, Portable-II microcomputer was used to control the stimulator and sample the knee moment data. The chair, in which the test subjects were seated, is pictured in figure 3.2. This was designed to enable isometric measurement of the knee extension moment at various angles of knee flexion. When the quadriceps muscles were stimulated, the ankle was restrained by a cable which is shown in figure 3.3. A ring dynamometer, in series with this cable, was used to measure the cable tension and thus the force required to restrain the ankle. The restraining mechanism was configured such that this force was always perpendicular to the leg.

The output of the ring dynamometer, after amplification, was proportional to the knee moment. The constant of proportionality was determined by calibrating the force dynamometer (with known weights) and then multiplying the output with the length of the effective moment arm.

3.4.2. Protocol

The subject was seated in the test chair with his knees fixed in 60 degrees of flexion. The ankle strap was attached to the test leg and the cable was tightened. It was important to ensure that no slack existed in the cable because the period of greatest interest in these tests was the initial buildup of force. Consequently, the cable was adjusted such that a small amount of passive tension was always present. The effective moment arm, for the knee moment calculations,

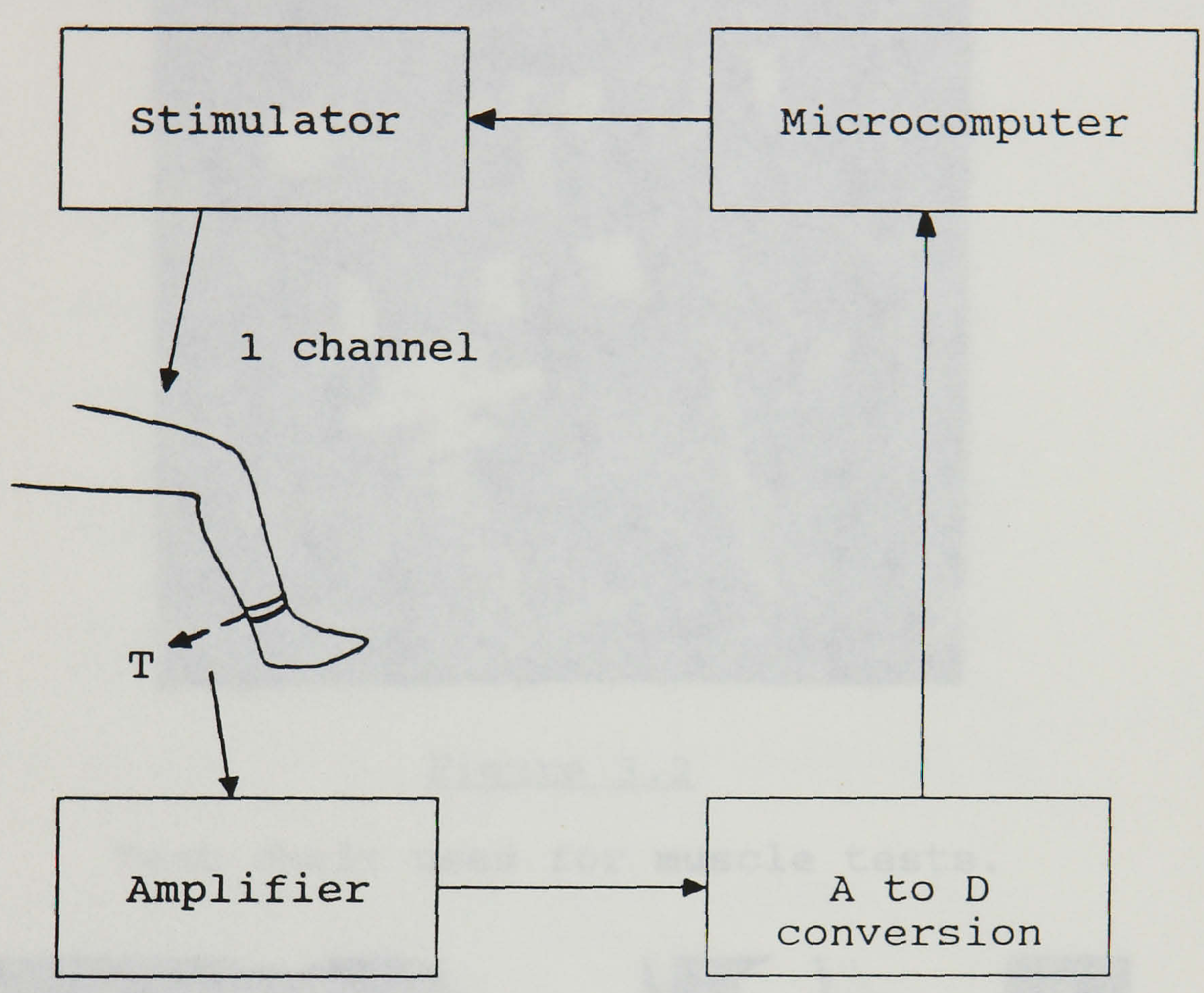


Figure 3.1

Experimental setup for muscle evaluation tests.

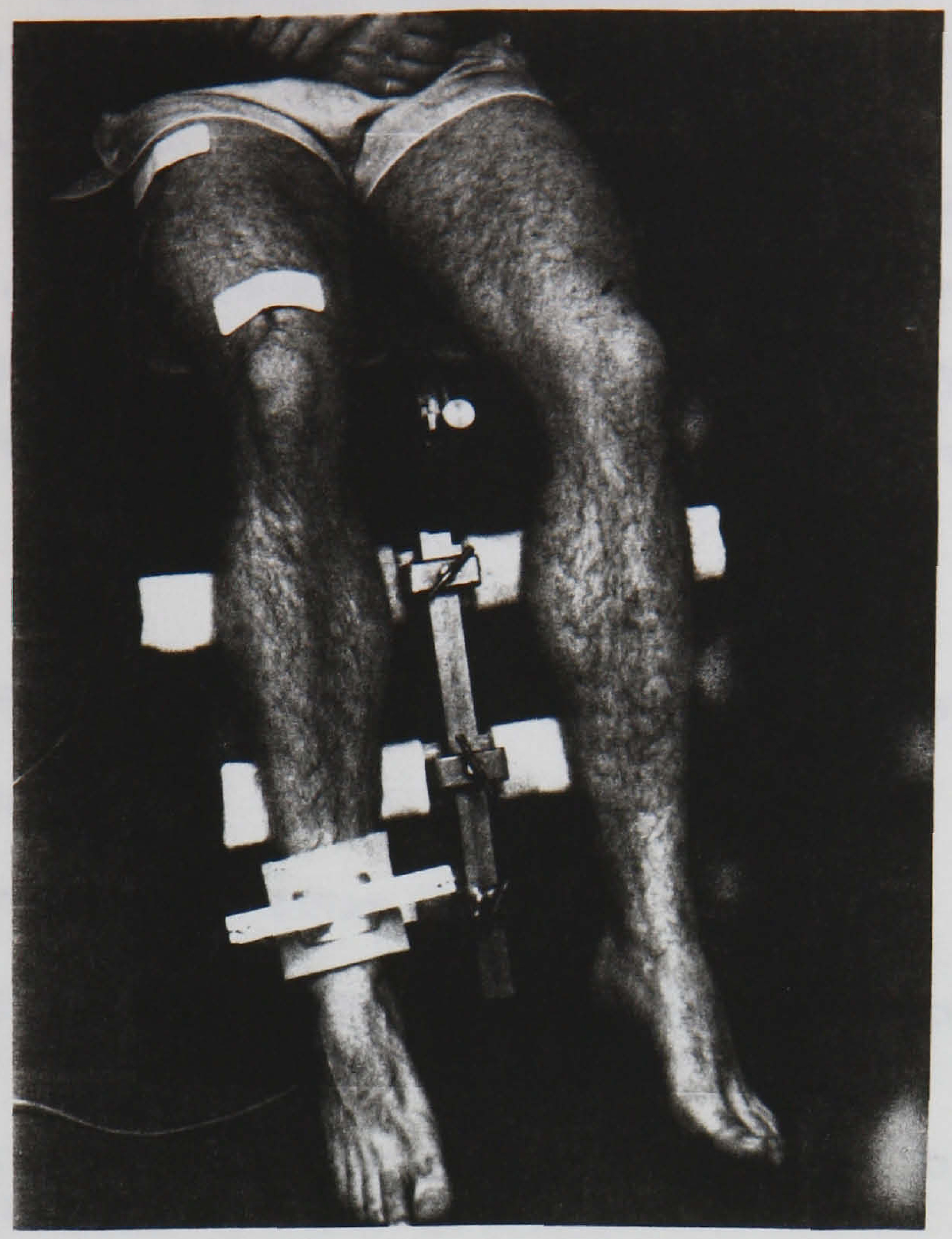


Figure 3.2

Test chair used for muscle tests.

Figure 3.3

Ankle restraint mechanism featuring a ring dynamometer for force measurement.

was measured from the centre of the knee joint to the point where the cable attached to the ankle. This parameter was then typed into the computer for subsequent analysis.

A total of 20 trials were conducted for each leg. Each trial consisted of one second of quadriceps stimulation followed by a 30 second recovery period. Ten stimulus patterns were tested and are summarized as follows:

MC1 - constant @ IPI = 50ms (PW = 300μs)

MC2 - constant @ 20ms (300μs)

MC3 - constant @ 10ms (300μs)

MP1 - 2 pulses @ 10ms (300μs) followed by constant @ 50ms (300μs)

MP2 - 5 pulses @ 10ms (300μs) followed by constant @ 50ms (300μs)

MP3 - 10 pulses @ 10ms (300μs) followed by constant @ 50ms (300μs)

MS1 - 1 second @ 50ms (20μs) followed by constant @ 50ms (300μs)

MS2 - 1 second @ 50ms (50μs) followed by constant @ 50ms (300μs)

MS3 - 1 second @ 50ms (100μs) followed by constant @ 50ms (300μs)

MS4 - 1 second @ 50ms (150μs) followed by constant @ 50ms (300μs)

MC1, MC2 and MC3 are constant, invariant patterns which allow the effects of stimuli with different frequencies to be compared. MP1, MP2 and MP3 utilize the "catch" property by inserting a number of high frequency pulses immediately before a regular, low frequency stimulus (figure 3.4). MS1, MS2, MS3 and MS4 use a sub-threshold, pre-stimulus pattern which is applied for one second before the regular stimulus. The pulsewidths of these pre-stimulus patterns are not large enough to

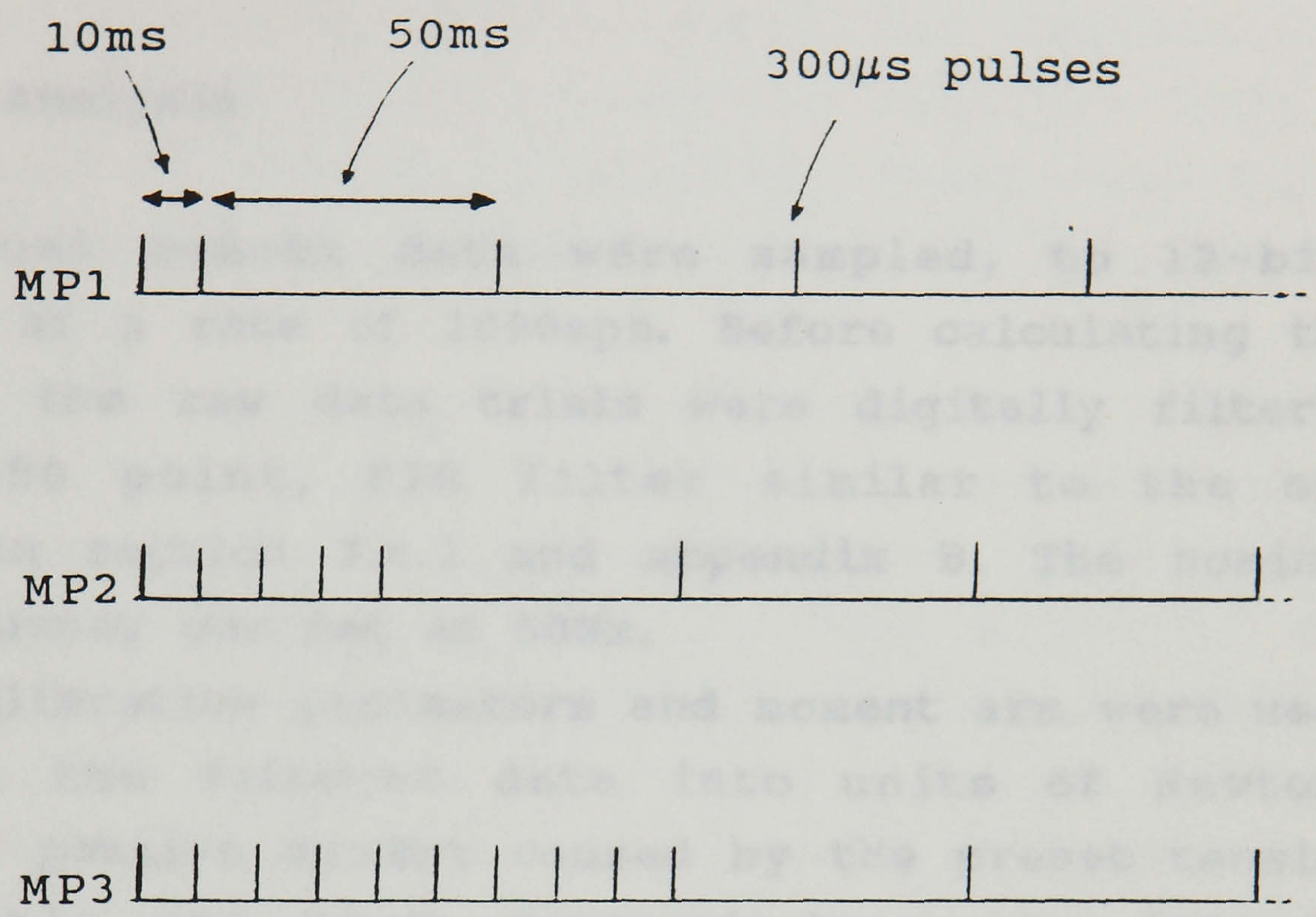


Figure 3.4

Graphical representation of stimulus patterns MP1, MP2 and MP3.

evoke a contraction. However, their effect is to increase the excitability of the motoneurones which, in turn, may improve the latency of the contraction obtained when the regular stimulus is applied. Each of the above stimulus patterns were applied twice, in a randomized order, to each leg.

3.4.3. Data Analysis

The knee moment data were sampled, to 12-bits resolution, at a rate of 1000sps. Before calculating the parameters, the raw data trials were digitally filtered using a 150 point, FIR filter similar to the one described in section 2.6.2 and appendix B. The nominal cutoff frequency was set at 50Hz.

The calibration parameters and moment arm were used to convert the filtered data into units of Newton-metres. The passive moment caused by the preset tension in the cable was then removed from the data by redefining the reference zero value.

The following parameters were calculated:

a) t10
b) t50
c) t90

These represent the time, from the beginning of the stimulus period, to the point where the active knee moment rises to 10%, 50% and 90%, respectively, of its peak value.

The following definitions were also made for comparison:

Latency = t10
Risetime = t90 - t10

3.5. FLEXION EVALUATION TESTS

The inherent slowness in the flexion withdrawal response often makes it less desirable, for use in FES based walking systems, than direct stimulation of flexors. With surface electrodes, however, direct flexor stimulation tends to be difficult and impractical. Induction of the withdrawal reflex requires only a single channel of surface stimulation. Thus, when using this method, a relatively complex action can be produced very efficiently.

During the preliminary walking tests, it was observed that the latency of the flexion response could be altered by different stimulus patterns. Additionally, because of the extra weight of the SKAFO's, the intensity of the stimulation needed to be increased in order to produce responses which were stronger and less prone to habituation. Higher frequencies of stimulation were observed to improve both the latency and strength of flexion. On the other hand, habituation appeared to occur more rapidly. Although differing in mechanism, these observations bore a strong similarity to those which were made for muscle responses. Consequently, a set of experiments, similar to the muscle function tests, were designed in order to optimize the flexion stimulus patterns.

3.5.1. Equipment

The experimental setup was similar to that of the muscle function tests illustrated in figure 3.1. The main differences were that the subject stood between parallel bars and the input signals were obtained from electro-goniometers. These goniometers (described in section 2.3.2) were placed over the knee and hip joints of the test leg. Although capable of defining joint angles in two dimensions, the goniometers were used to measure angles in the sagittal plane only.

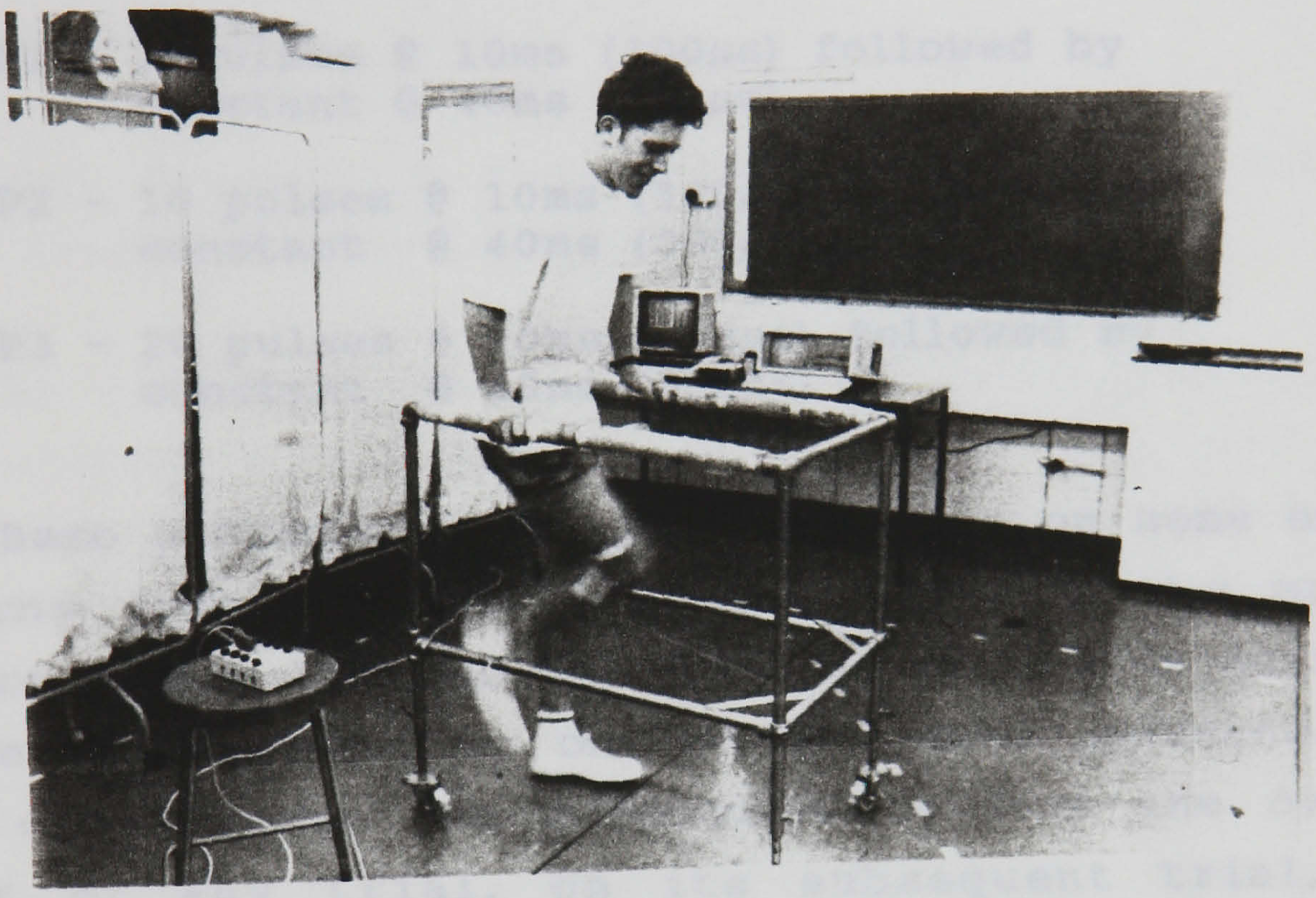
Rotations in the ML plane were considered to be functionally less important for stepping actions. The amplifiers (described in appendix A) were set to an appropriate level for measuring joint angles and then calibrated. The calibration technique involved adjusting the goniometers to a number of known angles over a specific range and recording the digital outputs from the AtoD converter. A least squares analysis was then performed to produce a linear transformation function which converted raw data samples into units of angular displacement.

3.5.2. Protocol

Most subjects stood between parallel bars as shown in figure 3.5. During the tests, stimulation was applied to the peroneal nerve of the test leg in order to induce a flexion reflex. No other stimulus was used because it may have interfered with the response being studied. Consequently, the subject was required to stand without supporting any weight on the test leg. When testing complete paraplegics, one leg was mechanically braced with a caliper and the test leg was allowed to hang freely. If the subject could not stand in this configuration then a tilt table was used to support the trunk vertically whilst both legs hung freely.

Subjects with incomplete SCI are often capable of standing voluntarily on one leg. Several of these subjects were used for the flexion tests because they required a minimum of time and preparation. The results obtained were relevant to their particular category of injury which proved to be very suitable for the hybrid FRO walking system.

In each session, a total of six trials were conducted on each paralysed leg. During a single trial, ten consecutive, identical bursts of stimulation were applied to the test leg. Each of these bursts lasted for 0.5 seconds and were applied every 2 seconds.



<u>Figure 3.5</u>

Experimental setup for flexion tests.

This timing was chosen in order to approximately simulate that of FES based, paraplegic walking. After each trial, the subject was asked to sit quietly for about 5 minutes to allow recovery from the effects of habituation.

The following 6 stimulus patterns were tested:

FC1 - constant @ 40ms (300μs)

FC2 - constant @ 20ms (300μs)

FC3 - constant @ 10ms (300μs)

FP1 - 2 pulses @ 10ms (300μs) followed by constant @ 40ms (300μs)

FP2 - 10 pulses @ 10ms (300μs) followed by constant @ 40ms (300μs)

FP3 - 20 pulses @ 10ms (300μs) followed by constant @ 40ms (300μs)

These patterns are slight variations on some of the patterns (outlined in section 3.4.2) for the muscle function tests. Each of the 6 trials conducted during a session corresponded to one of the above patterns. The order of execution was randomized so that the overall effect of any trial, on its subsequent trial, was minimized.

3.5.3. Data Analysis

From each trial, the result was a set of ten consecutive flexion responses showing the relative angular displacements of the hip and knee joints. Both channels were sampled, to 12-bits resolution, at a rate of 200sps. The raw data were digitally filtered using a 100 point, FIR algorithm with an effective cutoff frequency of 15Hz (section 2.6.2 and appendix B). The calibration parameters were used to convert the filtered data into degrees of joint flexion.

The reference zero value was redefined at the beginning of each flexion response because the joint angles at which the leg came to rest could differ before and after a response had occurred.

The parameters calculated were:

- t10
- t50
- t90
- latency
- risetime

These are defined in exactly the same way as for the muscle function tests (section 3.4.3).

The main indicator for the effectiveness of flexion is considered to be the hip angle. It is also used as a closed-loop control signal, for stepping, in the hybrid FRO system. Consequently, more emphasis was placed on this parameter, in the analysis of the flexion tests, than on the knee angle. The knee angle tended to play a less important role in stepping. It was included in the analysis, however, to support the hip angle data and to indicate the extent to which spasticity was interfering with knee flexion.

CHAPTER 4. RESULTS AND DISCUSSION

CHAPTER 4. RESULTS AND DISCUSSION

4.1. PRELIMINARY TESTS

During the development of the hybrid FRO system a series of preliminary laboratory tests were performed, on SCI subjects, at the Bioengineering Unit. A number of subjects were also tested in collaborative studies with other research units (Barnicle et al, 1988; Andrews et al, 1989). The purpose of this was to expand the application of the system to patients with percutaneous electrodes and implanted stimulators. In this thesis, however, the attention is focussed on two subjects using only surface stimulation.

The initial tests were conducted mostly for developmental purposes. More rigorous testing was reserved for when a final version of the system became available. Although the amount of quantitative data was limited and the results were rather subjective, the preliminary tests were instrumental in the progressive design of the orthosis. The purpose of this section is to discuss some of these results and to demonstrate, in practical terms, some of the the concepts introduced in chapter two.

4.1.1. Standing Tests

Subject :- Male, age 22, mass 57kg, height 1.6m,
lesion T6/7 complete, 2 years post injury

The subject was required to stand quietly, between parallel bars, using the hybrid FRO system. The maximum standing time was set at one hour, during which the quadriceps activation time was monitored. When required, the stimulus was applied at 100pps (300μs). After one second, the frequency was then switched to 20pps in order to reduce fatigue.

Using pure FES, this subject could not stand for more than a few minutes without fatigue setting in. With the hybrid FRO system, he could stand for the full hour without any difficulty. The total quadriceps activation time was calculated to be less than 5% of the stance period. It was also observed that this activation only occurred when the subject consciously changed his posture. In general, the subject found the system to be more comfortable than standing in KAFO's or using FES alone.

Figure 4.1 pictures the subject standing with the hybrid FRO system. The small electrode pairs, attached to the back and shoulders (and a fourth on the chest), formed part of an additional experiment which was designed to test sensory feedback. These electrodes provided slight tingling sensations (50μs and 100pps stimulus) which indicated to the subject the relative position of the CofG. A set-point position was defined where no tingling was felt and the subject was requested to maintain the CofG as close as possible to that position.

If the CofG shifted slightly forward, the electrodes on the chest were activated such that the subject was made aware of the movement. The other three electrode pairs were used in a similar way but in different directions. The strategy adopted by the subject was to move away from any stimulus that was felt. In this way, the mean position of sway could be defined quite accurately. Movement of the CofG, in the AP plane, was detected using an inclinometer mounted on one of the SKAFO's. The signal from this sensor was sampled by the computer which then calculated the corresponding AP displacement of the CofG. Displacements in the ML plane were estimated from the ratio of the signals from the left and right limb load sensors.

These tests were performed whilst monitoring the CofP with a force plate. Figure 4.2 shows two separate traces of the CofP which were recorded at two different

Figure 4.1

Preliminary standing test with sensory feedback.

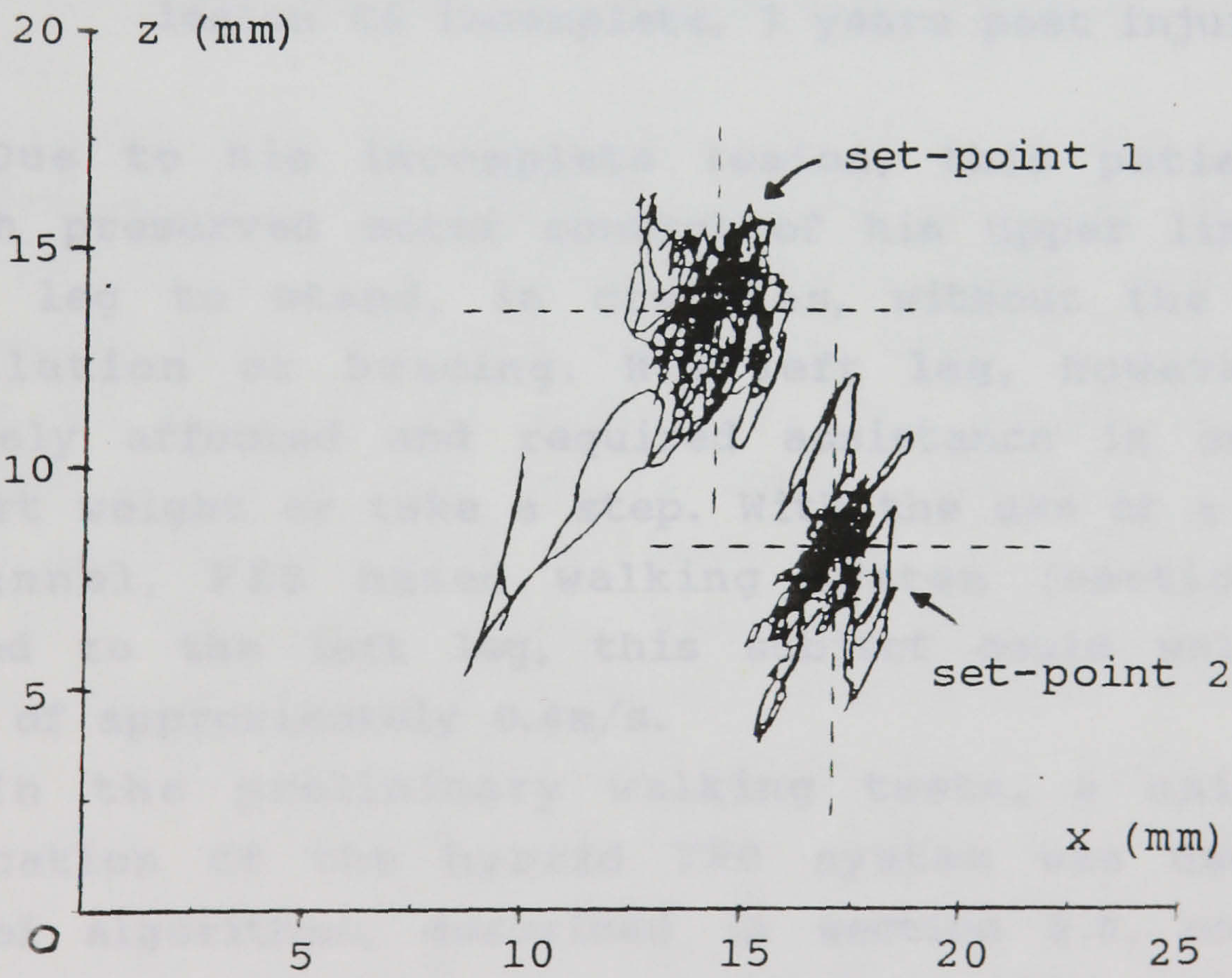


Figure 4.2

CofP traces at two different set-points.

set-points. Each of these traces were taken over a period of 2 minutes. It can be seen that the sensory feedback was effective in defining a mean sway position to which the subject could closely adhere.

The results of the preliminary standing tests indicated that the hybrid FRO system could provide relatively stable stance for paraplegic subjects. The postural evaluation tests, described in section 2.6, were formulated so that a more objective comparison could be made with other stance aids. Sensory feedback is beyond the scope of this thesis and will not be considered in any more detail. However, the preliminary tests have shown that it can be a useful factor in stance stability and should be considered in future developments.

4.1.2. Walking Tests

Subject :- Male, age 24, mass 70kg, height 1.8m,
lesion C6 incomplete, 7 years post injury

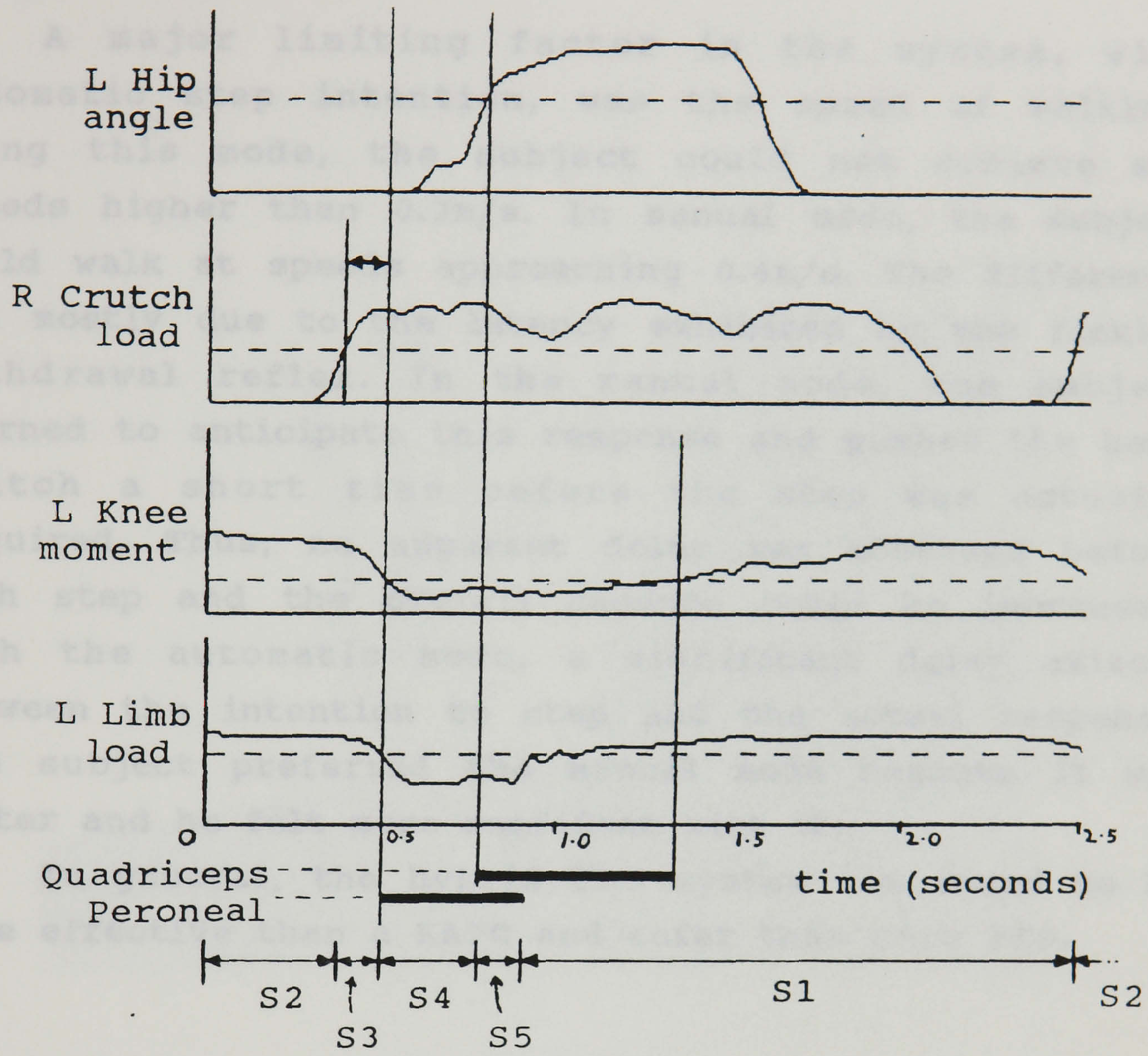
Due to his incomplete lesion, this patient had enough preserved motor control of his upper limbs and right leg to stand, in crutches, without the use of stimulation or bracing. His left leg, however, was severely affected and required assistance in order to support weight or take a step. With the use of a simple, 2-channel, FES based walking system (section 1.4), applied to the left leg, this subject could walk at a speed of approximately 0.4m/s.

In the preliminary walking tests, a unilateral application of the hybrid FRO system was used. The control algorithms, described in section 2.5, contained threshold and time-out parameters which were determined largely by trial and error. Firstly, video recordings of the subject's usual FES controlled gait pattern were used to estimate the parameters. These were then programmed into the computer and used in the control system. The software was written such that the parameters could be altered "on-line".

The primary objective was to achieve a smooth, rapid gait pattern with reliable detection of step intention. The hip angle threshold and overlap time-out parameters were optimized by simply adjusting them until the appearance of the gait was satisfactory and the subject was comfortable with it. Other aspects of the control system, such as the step intention algorithm, required a more detailed analysis. Thus, the controlling computer was also programmed to record the sensor signals for subsequent observation.

The conditions for stepping intention were required to be specified as tightly as possible. This reduced the probability of randomly producing the same sensor combinations and generating a step when it was not expected. On the other hand, the sensor signals revealed that not every step was identical. Variations in the timing of sensor signals meant that certain tolerances had to be added to some parameters in order to make them reliable.

Figure 4.3 shows some of the sensor outputs recorded during one cycle of a gait pattern which was derived using the above method. From these, the strategies used for the automatic control of gait can easily be visualized. Initially, the right crutch is unloaded and the left leg is loaded (ie state S2). The crutch remains unloaded for more than 0.3 seconds (go to state S3). The leg is then unloaded within 0.2 seconds (go to state S4) and peroneal stimulation is applied. The hip flexes to its maximum angle (go to state S5) and quadriceps stimulation is added. After 0.1 seconds of stimulus overlap (go to state S1), peroneal stimulation is switched off and the left leg enters the stance phase. As the leg is progressively loaded, the knee moment exceeds the threshold value and the KER switches off the quadriceps stimulation.



State entry conditions:

S2 - R crutch unloaded AND L limb loaded

S3 - R crutch unloaded > 0.3 seconds

S4 - L limb unloaded < 0.2 seconds

S5 - L hip flexion > threshold

S1 - Flexion timeout > 0.1 seconds

<u>Figure 4.3</u>

Sensor outputs during one cycle
of automatically controlled gait.

With the regular, 2-channel walking system the average duty cycle for quadriceps stimulation was estimated to be about 85%. With the hybrid system, this was reduced to 28%. Figure 4.4 pictures the subject walking with the system during one of the preliminary tests.

A major limiting factor in the system, with automatic step intention, was the speed of walking. Using this mode, the subject could not achieve any speeds higher than 0.3m/s. In manual mode, the subject could walk at speeds approaching 0.4m/s. The difference was mostly due to the latency exhibited by the flexion withdrawal reflex. In the manual mode, the subject learned to anticipate this response and pushed the hand switch a short time before the step was actually required. Thus, no apparent delay was observed before each step and the overall cadence could be increased. With the automatic mode, a significant delay existed between the intention to step and the actual response. The subject preferred the manual mode because it was faster and he felt more confident with it.

In general, the hybrid FRO system was found to be more effective than a KAFO and safer than pure FES.

Figure 4.4

Subject walking with the hybrid FRO system.

4.2. POSTURAL STABILITY

The results presented in this section have been averaged and summarized for simplicity. More specific information can be found in appendix C. Due to the limited amount of available data, these results cannot be considered conclusive. A considerable spread was observed in the data which is reflected in the corresponding standard deviations (appendix C). Although the procedure tends to be complicated and time consuming, a great deal more information needs to be collected before any positive conclusions can be drawn. On the other hand, the results obtained so far show some consistent trends which will now be discussed.

4.2.1. Circular Parameters

Tables 4.1 and 4.2 show the mean values obtained for the average speed and radius of rotation. The number of trials associated with each table entry can be found in table 3.1. An extra column has been added, for comparison, with mean parameters obtained from a quietly standing, able bodied subject. These "normal" data were taken with no hand support and with eyes open and closed. From the tables, two comparisons can be made:

1) Comparison of different orthoses under similar conditions (especially the FRO and KAFO).

2) The effect of different experimental conditions on one orthosis.

The first observation, which can be made from tables 4.1 and 4.2, is that the average speed of sway and radius of rotation, in all the orthoses, are significantly less than in "normal" stance. This is probably due to the fact that postural corrections in paraplegic stance are made at the level of the upper

AVERAGE SPEED OF EXCURSION

Eyes	Hand	FRO	KAFO	RGO	FES
EO	2H	3.0	5.3	4.8	4.4
EO	RH	2.9	5.0	-	-
EO	LH	3.0	4.5	-	-
EO	NH	5.7	3.9	-	-
EC	2H	2.7	3.1	3.2	-
EC	RH	3.9	4.3	-	-
EC	LH	3.3	3.7	-	-

Normal
10.6
16.6

Table 4.1

Averaged results for the average (over 14 seconds) speed of excursion. All entries are in mm/s.

MEAN RADIUS OF ROTATION

Eyes	Hand	FRO	KAFO	RGO	FES
EO	2H	1.2	2.1	1.9	2.1
EO	RH	1.6	2.3	-	-
EO	LH	1.6	1.9	-	-
EO	NH	2.6	1.8	-	-
EC	2H	1.2	1.2	1.6	-
EC	RH	2.0	1.9	-	-
EC	LH	1.5	1.4	-	-

Normal
5.4
4.7

Table 4.2

Averaged results for the mean radius of rotation. All entries are in mm.

limbs. In normal stance, the majority of corrective activity occurs at the ankle joints and thus increases the amount of sway (see section 1.6).

With the exception of the "no hands" condition, the hybrid FRO showed generally lower average speed and radius parameters than the other orthoses. This indicates an inherent mechanical stability which requires a minimum of corrective activity. The stability of the FRO appears to be reduced without the aid of hand support but still compares well with normal stance. Figure 4.5 shows a graphical representation of the mean radius, for each orthosis, obtained with eyes open and with two handed support. The standard deviations have been included to demonstrate the significant spread of the data. Despite this spread, the FRO still appears to show relatively stable characteristics.

The frequency of rotation is a measure of overall controllability during stance. From table 4.3, it can be seen that no orthosis showed a particular advantage in this regard. The highest value was achieved by the FRO but this was only with eyes open and with two handed support.

4.2.2. Directional Parameters

Each entry in table 4.4 represents the ratio of the mean ML excursion to the mean AP excursion. This ratio is a reciprocal measure of the relative stability of the orthosis in the ML plane. A value of 1.0 suggests that the sway is equal in both the ML and AP directions. As discussed in section 3.3.2, the ratio for normal stance is relatively small. This means that normal stance in the ML plane tends to be more stable than in the AP plane. Table 4.4 indicates that the result for FES is comparable to normal stance. The FRO, however, shows consistently higher values than the other orthoses.

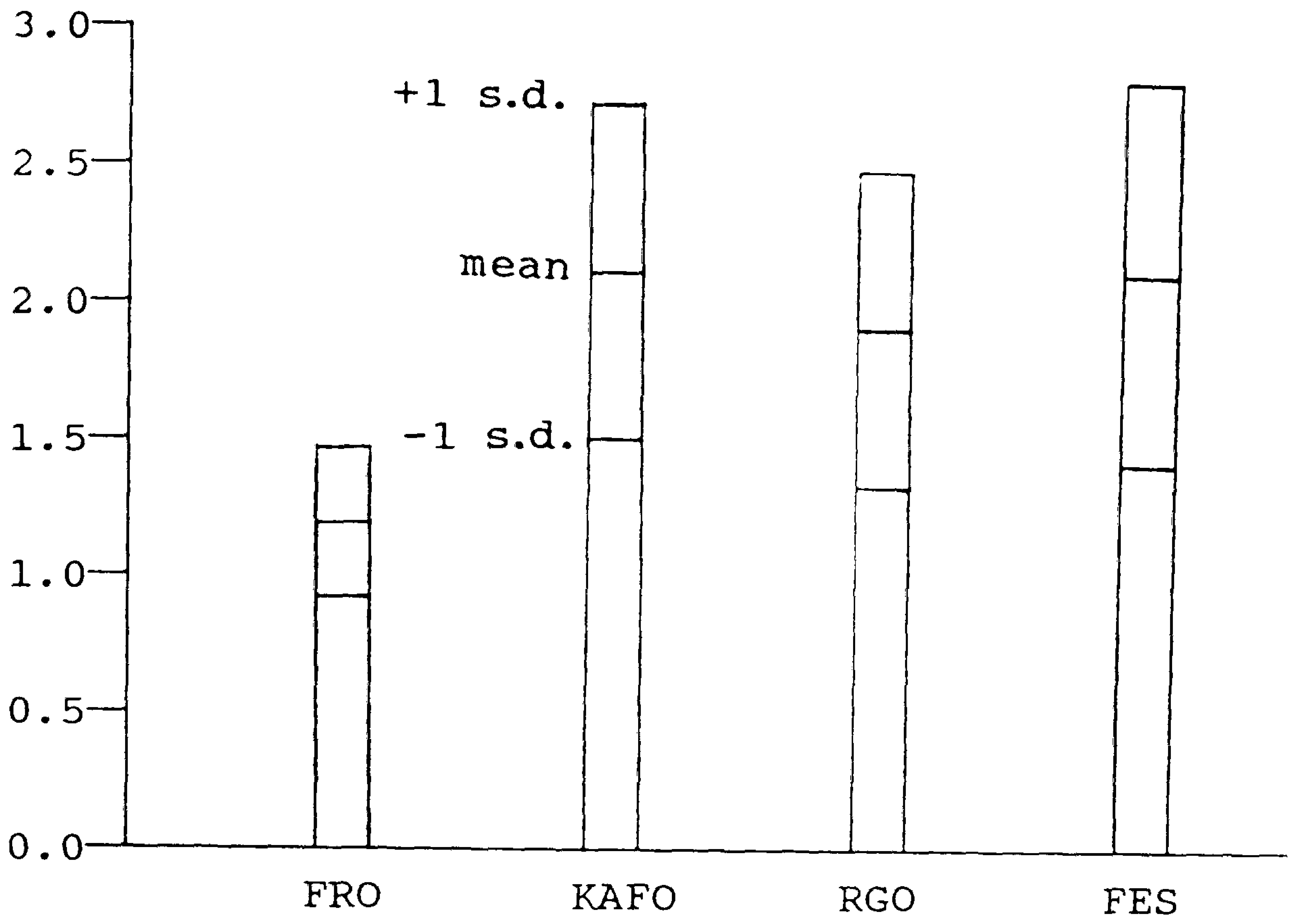


Figure 4.5

Histogram showing the averaged results of the mean radius for each orthosis.

FREQUENCY OF ROTATION

Eyes	Hand	FRO	KAFO	RGO	FES	Normal
EO	2H	0.60	0.47	0.44	0.46	0.32
EO	RH	0.29	0.36	-	-	
EO	LH	0.38	0.41	-	-	
EO	NH	0.35	0.38	-	-	
EC	2H	0.39	0.43	0.46	-	0.58
EC	RH	0.34	0.48	-	-	
EC	LH	0.40	0.42	-	-	

Table 4.3

Averaged results for the frequency of rotation. The units of all entries are cycles/s.

RATIO - MEAN ML/AP EXCURSION

Eyes	Hand	FRO	KAFO	RGO	FES	Normal
EO	2H	0.96	0.60	0.96	0.42	0.44
EO	RH	1.27	0.73	-	-	
EO	LH	1.52	1.02	-	-	
EO	NH	1.17	0.72	-	-	
EC	2H	0.80	1.01	0.46	-	0.41
EC	RH	1.55	1.23	-	-	
EC	LH	1.50	1.29	-	-	

Table 4.4

Ratio of averaged results for the mean ML excursion over the mean AP excursion. A value of 1.0 indicates equal excursions in both directions.

Most of the ratios for the KAFO and FRO are greater than 1.0. This indicates that sway in the ML plane is greater than in the AP plane. It should be remembered, when considering these values, that they are purely relative measures and do not necessarily indicate inferior ML stability compared with other orthoses. On the contrary, the FRO system showed generally smaller absolute values for the mean ML excursion (appendix C).

The ratio of the minimum and maximum axes reveals more information about sway than the previous measure (table 4.5). This is because the maximum axis does not always lie near the AP axis. For example, if the angle of the maximum axis (η) was equal to 45 degrees, the mean excursions in the AP and ML directions would appear to be equal and no asymmetry in the sway pattern would be revealed (see figure 2.27). The entries in table 4.5 indicate the average shape of the sway pattern for each orthosis and its associated conditions. Table 4.6 shows the corresponding orientations of the maximum axes. A small ratio, in table 4.5, indicates a long, flat pattern with a strong tendency to sway in a particular direction. Conversely, a value approaching unity indicates equal tendency to sway in all directions.

The orthosis with the least directional tendency appears to be the KAFO. The other orthoses usually favour a particular direction quite strongly. With normal stance (and possibly FES), this direction is close to the AP axis. With the FRO, however, the direction appears to be very non-specific. The spread of data was relatively large for this parameter (appendix C) which indicates that it may depend on the precise position of the subject's feet and hands at the beginning of each trial.

RATIO - RMS MINIMUM/MAXIMUM AXES

Eyes	Hand	FRO	KAFO	RGO	FES
EO	2H	0.37	0.49	0.34	0.26
EO	RH	0.32	0.58	-	-
EO	LH	0.32	0.74	-	-
EO	NH	0.37	0.62	-	-
EC	2H	0.70	0.63	0.27	-
EC	RH	0.31	0.46	-	-
EC	LH	0.33	0.56	-	-

Normal
0.34
0.40

Table 4.5

Ratio of averaged results for the RMS minimum axis over the RMS maximum axis.

ANGLE OF MAXIMUM AXIS

Eyes	Hand	FRO	KAFO	RGO	FES
EO	2H	22	-17	-38	15
EO	RH	-33	-22	-	-
EO	LH	43	21	-	-
EO	NH	15	6	-	-
EC	2H	-10	3	-16	-
EC	RH	-61	30	-	-
EC	LH	41	60	-	-

Normal
8
4

Table 4.6

Averaged results for the angle of the maximum axis (referred to the x-axis or AP-axis). All entries are in degrees.

4.3. MUSCLE FUNCTION

Table 4.7 shows a representative summary of muscle evaluation data taken from a paraplegic subject. The observations, as stated, were found to be repeatable and common to the four subjects tested. Each line of the table contains the average parameters, rounded to the nearest millisecond, for a particular stimulus pattern. More detailed information can be found in appendix C. The latency represents the time period between the application of the stimulus and the beginning of force production (ie. 10% of the peak force). Once force production has commenced, the risetime represents the time taken to develop maximal force (ie. t90 - t10). Finally, t50 represents the time period from the beginning of stimulation to the point where the developed force reaches 50% of the peak value. This is considered to be an overall indicator of the speed of muscle contraction.

From table 4.7, it can be seen that all three of these parameters are significantly improved with a high frequency stimulus (ie compare MC1, MC2 and MC3). Figure 4.6 shows representative trials which were taken at three different frequencies. From these results, it is obvious that the higher frequencies produce a faster muscle contraction. It can also be seen, in this case, that a stimulus frequency of 20pps fails to produce a fused contraction. The knee moment contains a distinct, 20Hz ripple and the strength of contraction is about 60% of that produced by the 50pps stimulus. This effect was not obvious when viewing the leg directly during the tests.

Despite the improvements offered by high frequency stimulation, its tendency to induce rapid muscle fatigue makes it impractical for use in an FES based system; even when the active duty cycle is relatively small. Consequently, alternative stimulus patterns were derived with a view to combining the speed of high frequency

MUSCLE EVALUATION DATA

Pattern	Latency	t50	Risetime
MC1	61	122	189
MC2	55	98	171
MC3	50	84	102
MP1	46	77	98
MP2	52	78	76
MP3	50	84	80
MS1	63	127	194
MS2	61	125	198
MS3	42	98	186
MS4	39	87	152

Table 4.7

Averaged results for the muscle evaluation tests. All parameters are in ms.

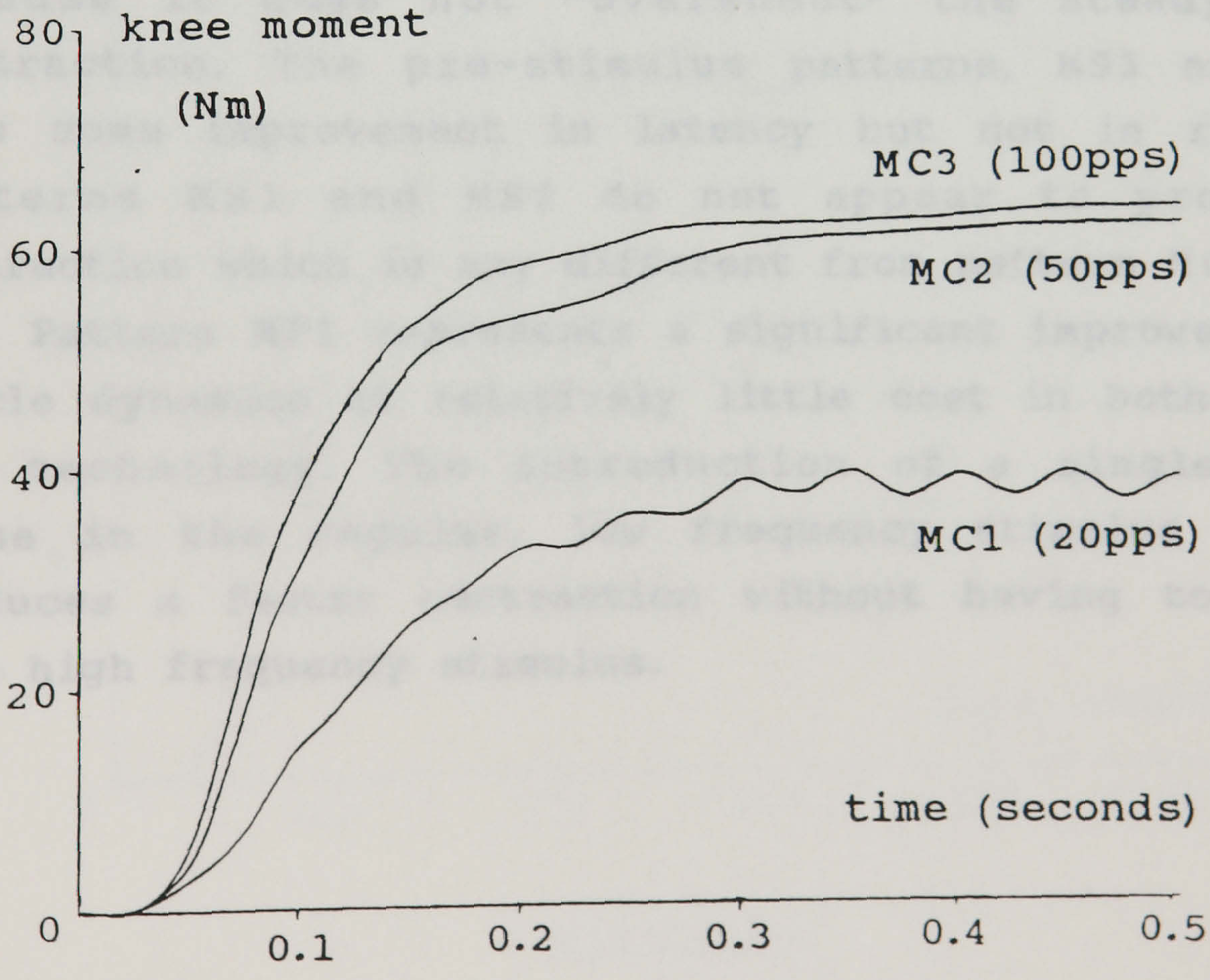


Figure 4.6

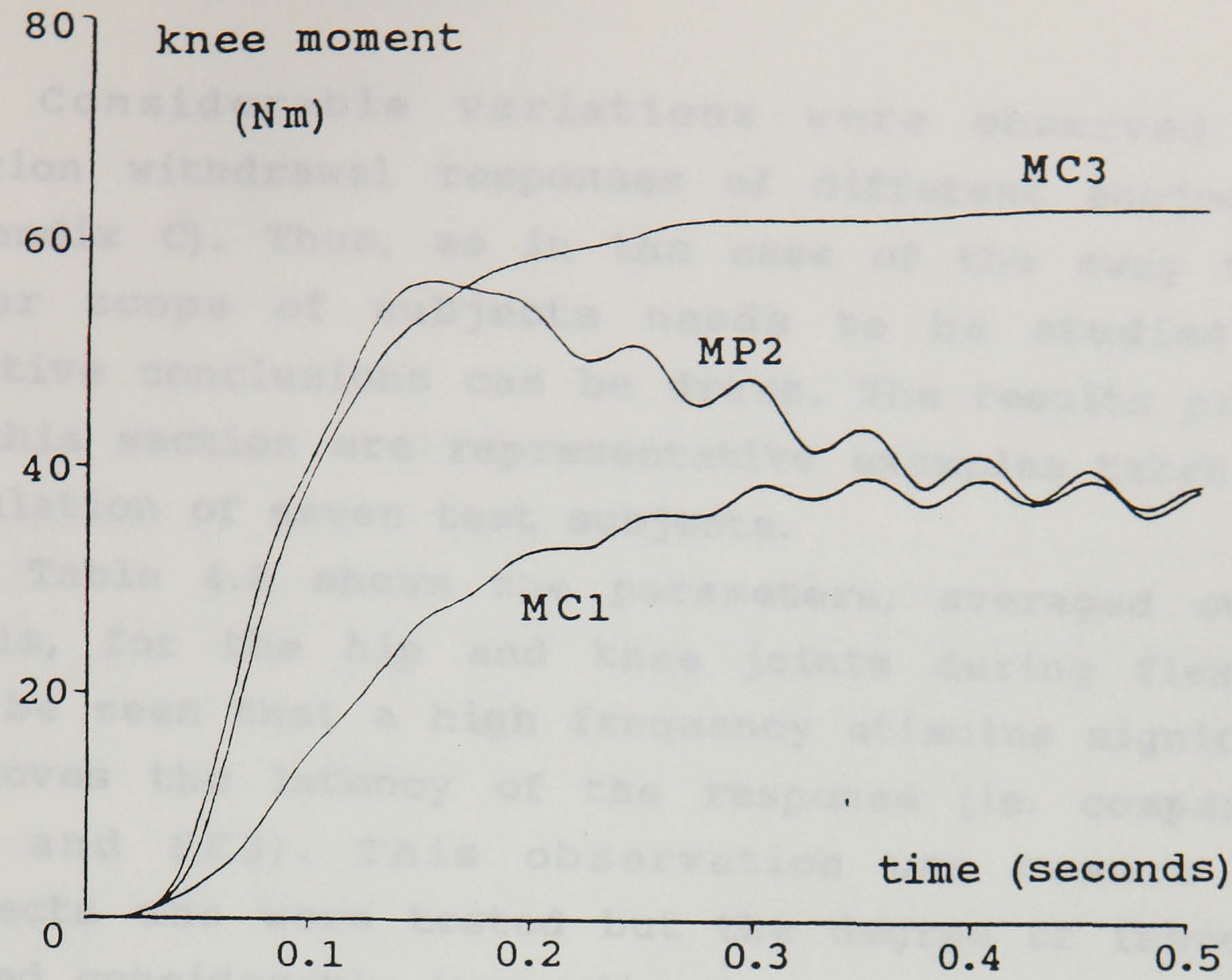
Knee moment trials at different frequencies.

stimulation with the fatigue resisting capabilities of low frequency stimulation.

The stimulus patterns MP1, MP2 and MP3 all show improved latencies over that of pattern MC1. Similarly, the t50 parameters are significantly improved and comparable to that of the high frequency pattern MC3. The risetime in pattern MP1 is comparable to that of MC3 but patterns MP2 and MP3 produce significantly lower risetimes which is a rather unexpected result. This apparent anomaly can be explained by the fact that the parameters are expressed as percentages of the peak moment attained in each trial. Figure 4.7 compares some examples of trials taken using patterns MC1, MC3 and MP2. It can be seen that MP2 initially rises at a rate comparable to MC3 and then decays towards the steady state contraction defined by MC1. Although the literal risetime of MP2 looks similar to that of MC3, the fact that it reaches its peak value sooner than MC3 means that its calculated risetime is faster.

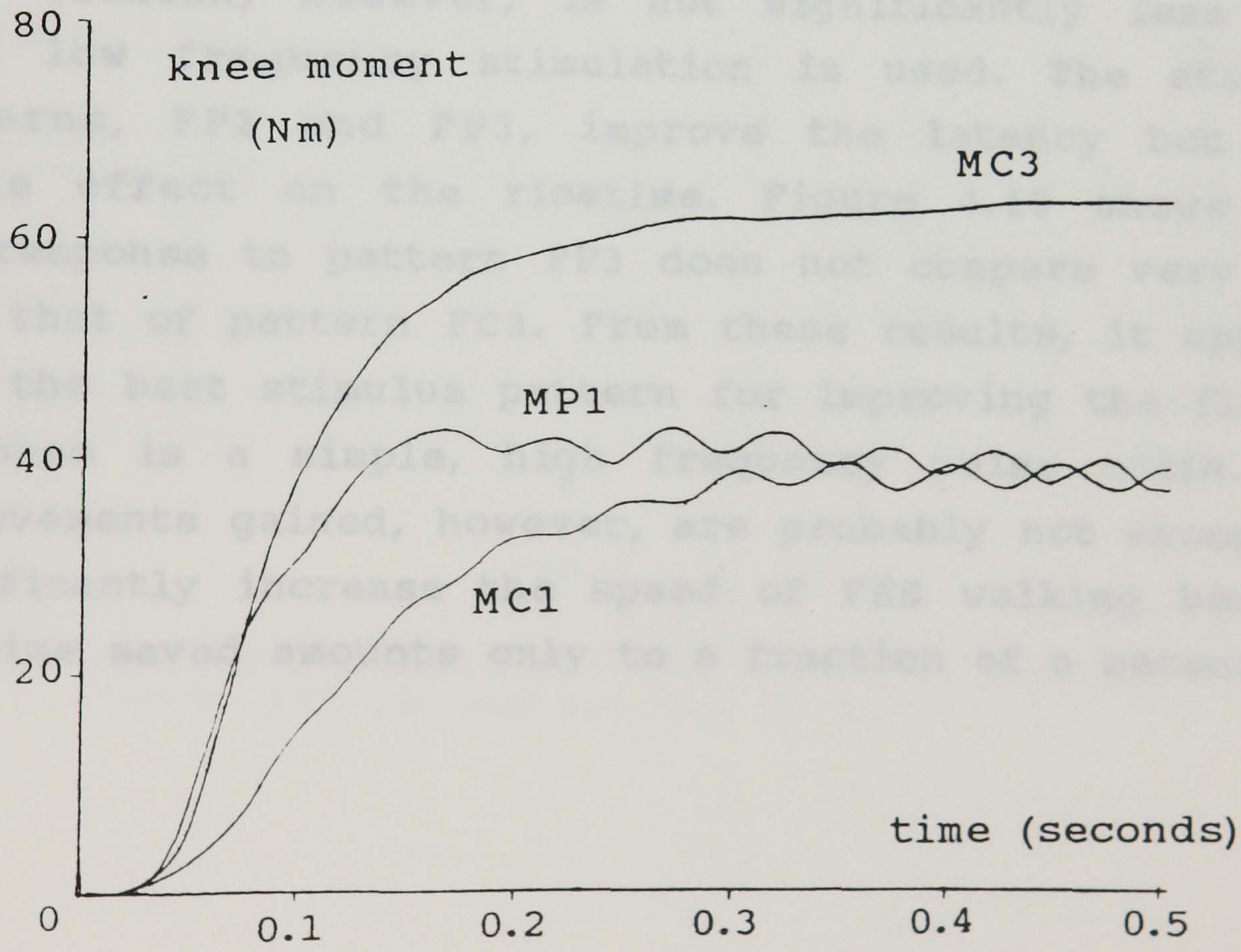
Figure 4.8 compares patterns MC1, MC3 and MP1. Pattern MP1 is considered to be preferable to MP2 because it does not "overshoot" the steady state contraction. The pre-stimulus patterns, MS3 and MS4, show some improvement in latency but not in risetime. Patterns MS1 and MS2 do not appear to produce a contraction which is any different from pattern MC1.

Pattern MP1 represents a significant improvement in muscle dynamics at relatively little cost in both energy and technology. The introduction of a single, extra pulse in the regular, low frequency stimulus pattern produces a faster contraction without having to resort to a high frequency stimulus.



<u>Figure 4.7</u>

Knee moment trials featuring pattern MP2.



<u>Figure 4.8</u>

Knee moment trials featuring pattern MP1.

4.4. FLEXION RESPONSE

Considerable variations were observed in the flexion withdrawal responses of different subjects (see appendix C). Thus, as in the case of the sway tests, a wider scope of subjects needs to be studied before positive conclusions can be drawn. The results presented in this section are representative examples taken from a population of seven test subjects.

Table 4.8 shows the parameters, averaged over ten trials, for the hip and knee joints during flexion. It can be seen that a high frequency stimulus significantly improves the latency of the response (ie. compare FC1, FC2 and FC3). This observation was common to all subjects who were tested but the degree of improvement varied considerably (appendix C).

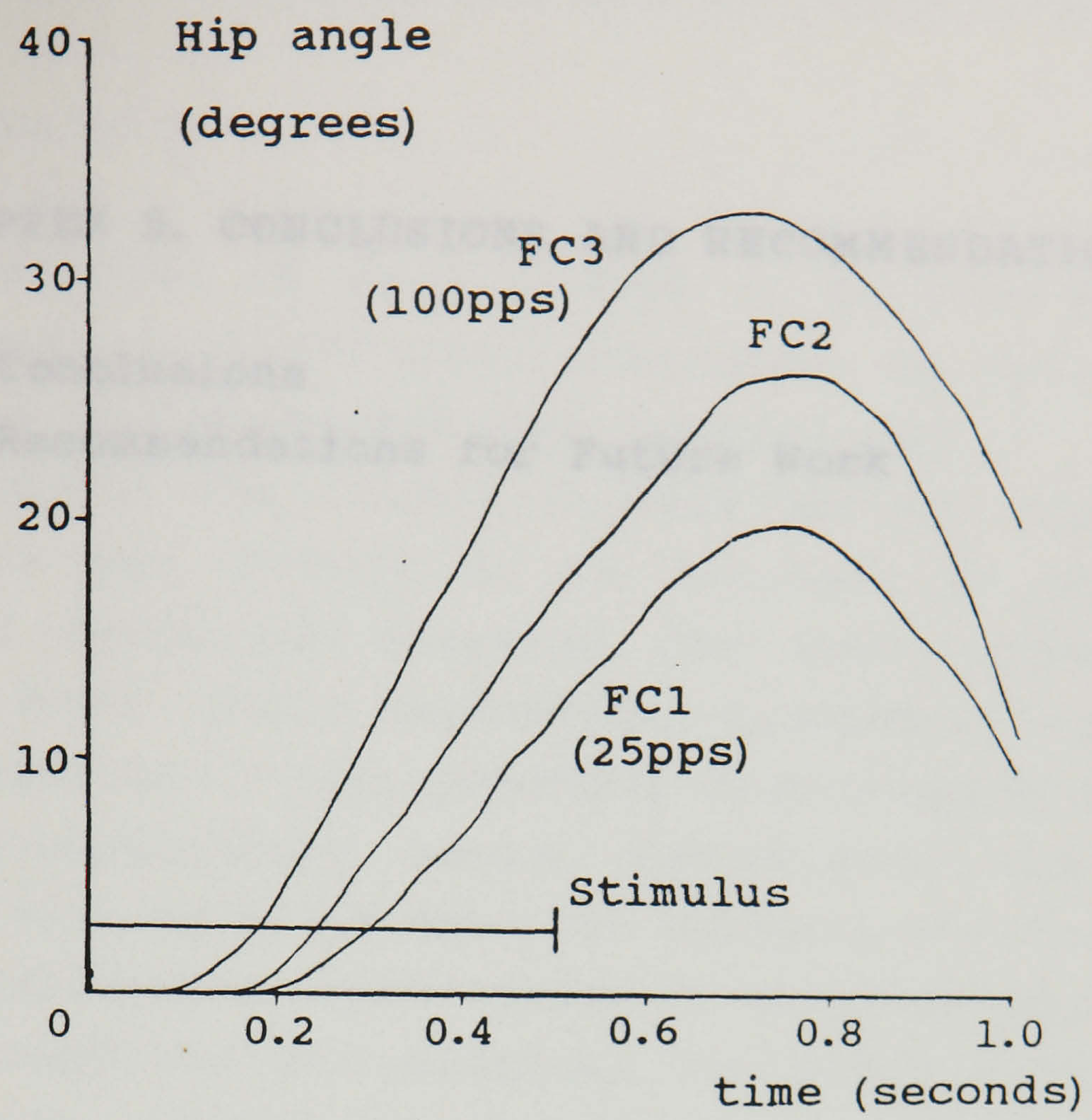
Figure 4.9 clearly demonstrates an improvement in latency and a greater intensity of flexion when high frequency stimulation is used. The total time to the peak flexion, however, is not significantly less than when low frequency stimulation is used. The stimulus patterns, FP2 and FP3, improve the latency but have little effect on the risetime. Figure 4.10 shows that the response to pattern FP3 does not compare very well with that of pattern FC3. From these results, it appears that the best stimulus pattern for improving the flexion response is a simple, high frequency pulse train. The improvements gained, however, are probably not enough to significantly increase the speed of FES walking because the time saved amounts only to a fraction of a second.

FLEXION RESPONSE DATA

Pattern	Latency	t50	t90	Risetime
FC1(H)	316	493	681	365
FC2(H)	254	445	644	390
FC3(H)	202	387	596	393
FP1(H)	290	433	603	313
FP2(H)	204	399	608	403
FP3(H)	202	374	604	402
FC1(K)	305	506	682	377
FC2(K)	268	414	599	331
FC3(K)	187	337	525	338
FP1(K)	313	449	599	286
FP2(K)	256	398	581	324
FP3(K)	252	397	567	315

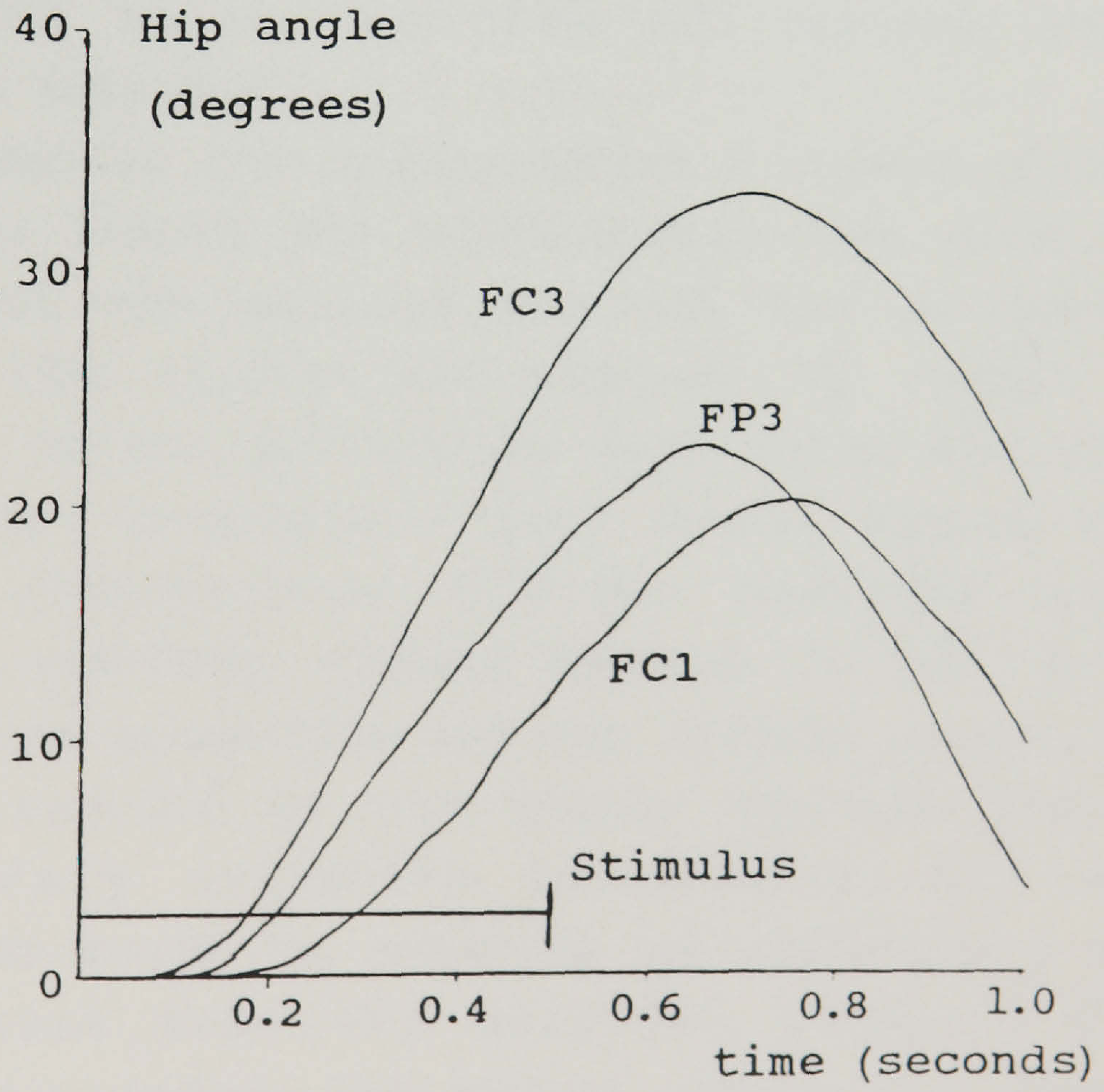
Table 4.8

Averaged results for the flexion response tests. All parameters are in ms.



<u>Figure 4.9</u>

Flexion response at three different frequencies.



<u>Figure 4.10</u>

Flexion responses featuring pattern FP3.

CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

5.1. CONCLUSIONS

The purpose of this section is to briefly review the concepts and results, introduced in this thesis, with regard to the project aims (section 1.9).

Throughout the course of this project, the hybrid FRO system has proved to be feasible in paraplegic stance and reciprocal stepping. The tests conducted so far have been under controlled, laboratory conditions but expansion to a more practical system seems possible. In the preliminary tests, favourable subjective responses were received from the subjects and the system showed considerable improvements in standing times.

For complete paraplegics, the hybrid FRO system provides an effective standing aid which is not cumbersome or limited by muscle fatigue. The automatic walking system has not yet been tested on a complete paraplegic subject. However, with a unilateral application to an incomplete SCI subject, the results have been positive.

The hybrid FRO system offers a number of advantages over other stance and walking aids; the main advantage being that the subject can use the features of FES without the limitations imposed by muscle fatigue. According to the preliminary sway tests, the hybrid FRO system also provides a more stable stance than many orthotic alternatives. This has important implications for quiet standing, without the use of FES, in order to recover from exhaustion and any induced muscle fatigue.

The results of the muscle function tests showed that a very effective increase in the speed of contraction could be achieved by introducing a single, extra pulse into the stimulus pattern. This can significantly reduce the muscle contraction time without unduly accelerating fatigue mechanisms. It also demonstates a practical use for the "catch" property of human muscle tissue. The flexion response tests showed that a high frequency stimulus produced stronger and marginally faster responses. Despite these improvements, the response still proved to be slow and unpredictable. From the results obtained so far, it appears that the flexion response cannot be significantly improved.

5.2. RECOMMENDATIONS FOR FUTURE WORK

As mentioned previously, the subjects using the hybrid FRO system for walking preferred the manual mode for the detection of step intention. This is because the subject felt more in control and could achieve faster speeds of walking. In normal walking, however, an able bodied person does not have to concentrate on each individual step; the process is purely automatic. For this reason, it is worth pursuing the concept of automatic control.

In manual mode, the subject achieved a faster walking speed because he "anticipated" the delay imposed by the flexion withdrawal reflex and pushed the hand switch shortly before preparing for the step. The results presented in this thesis have indicated that the delay in the flexion response cannot be appreciably reduced. Thus, there are two alternative approaches to increasing the speed of automatic gait:

1) Anticipate the delay in the flexion response in much the same way as the subject does in manual mode. It is unlikely that such a control system could be realized with hand crafted rules. However, with the recent availability of pattern recognition and machine induction techniques, such a control system may be feasible.

2) With the use of percutaneous electrodes, stepping can be achieved by direct, efferent stimulation of flexor muscles. In this way, the complications introduced by the flexion response are eliminated.

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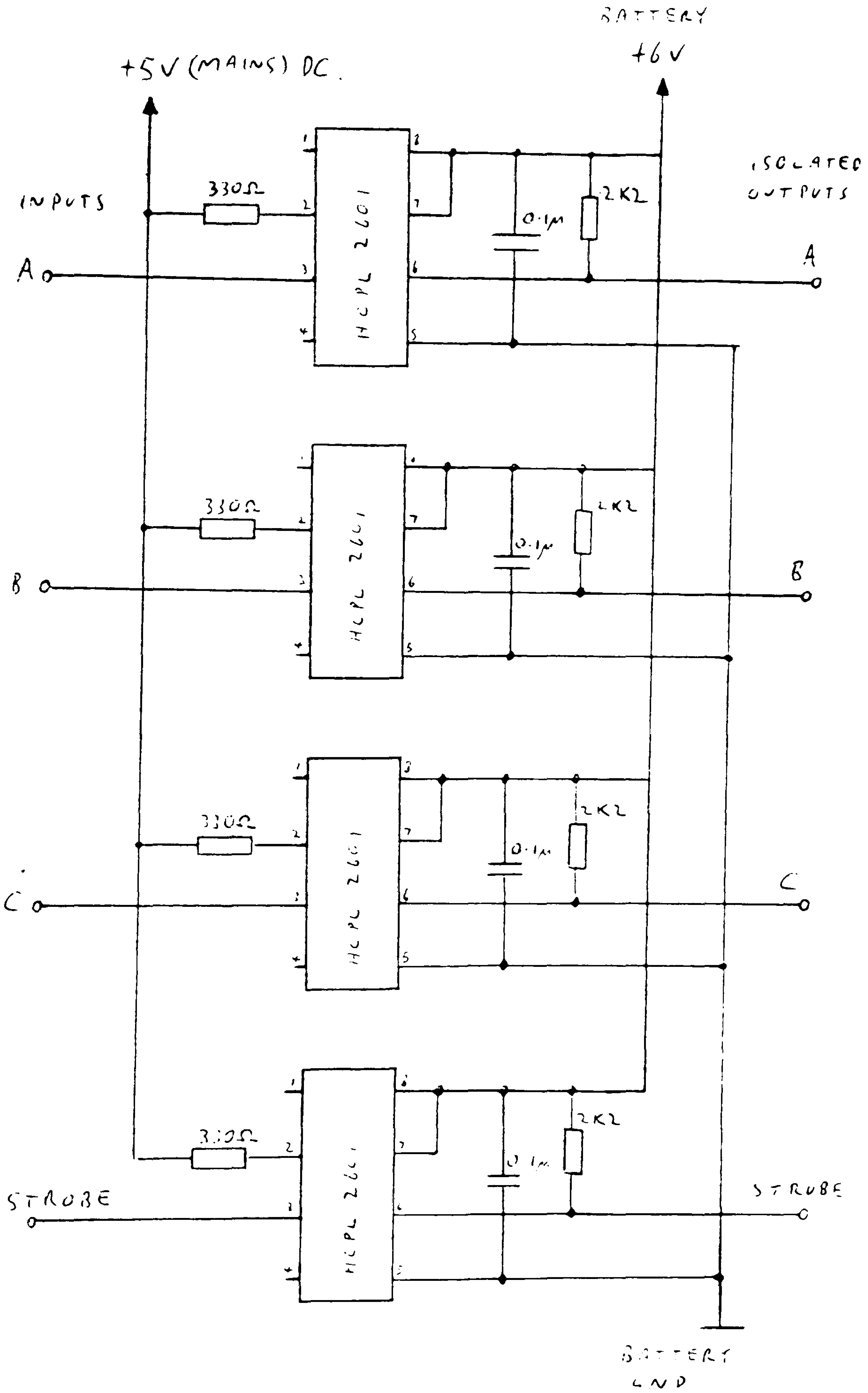
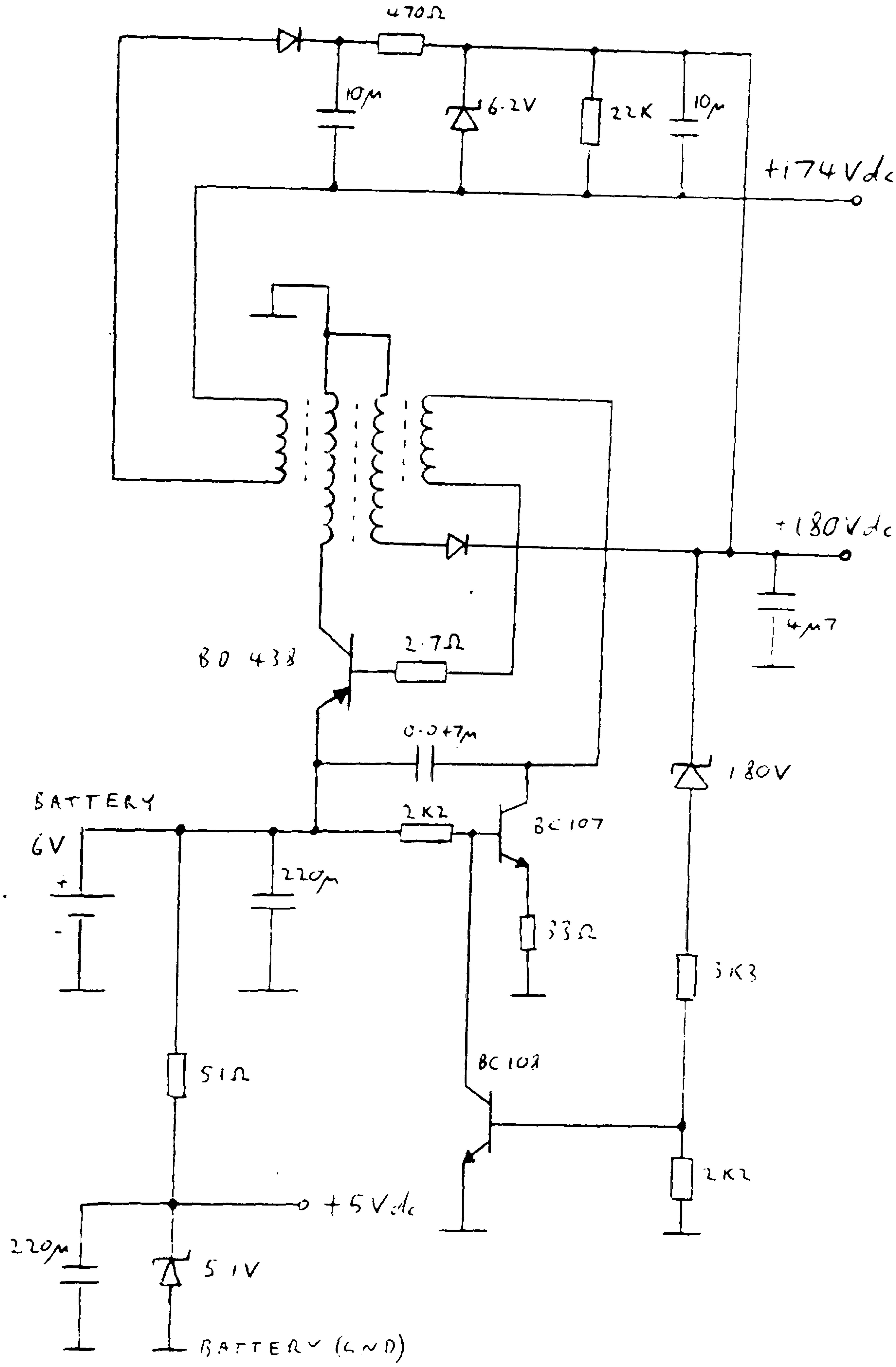
APPENDIX A. HARDWARE

A.1 Signal isolation

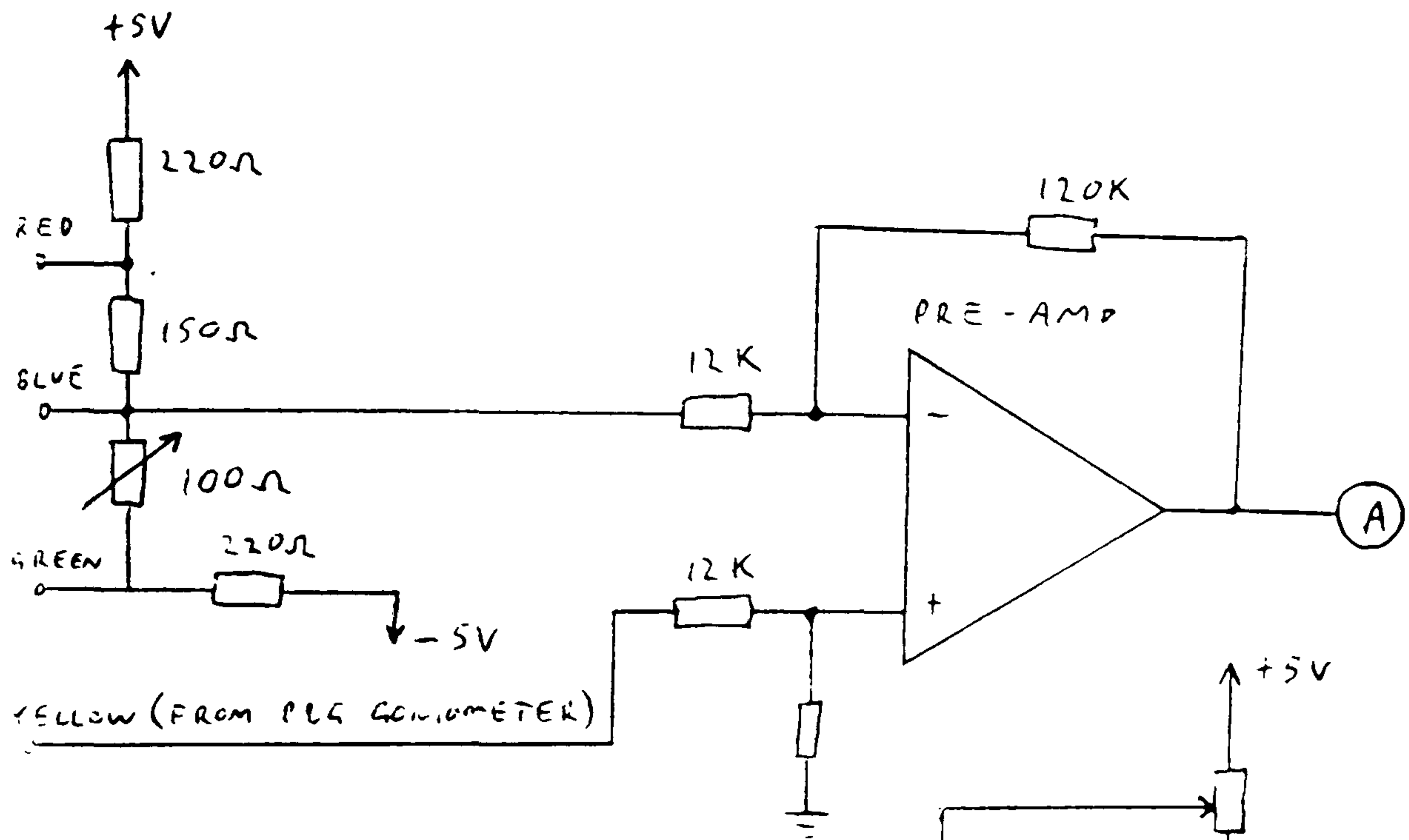


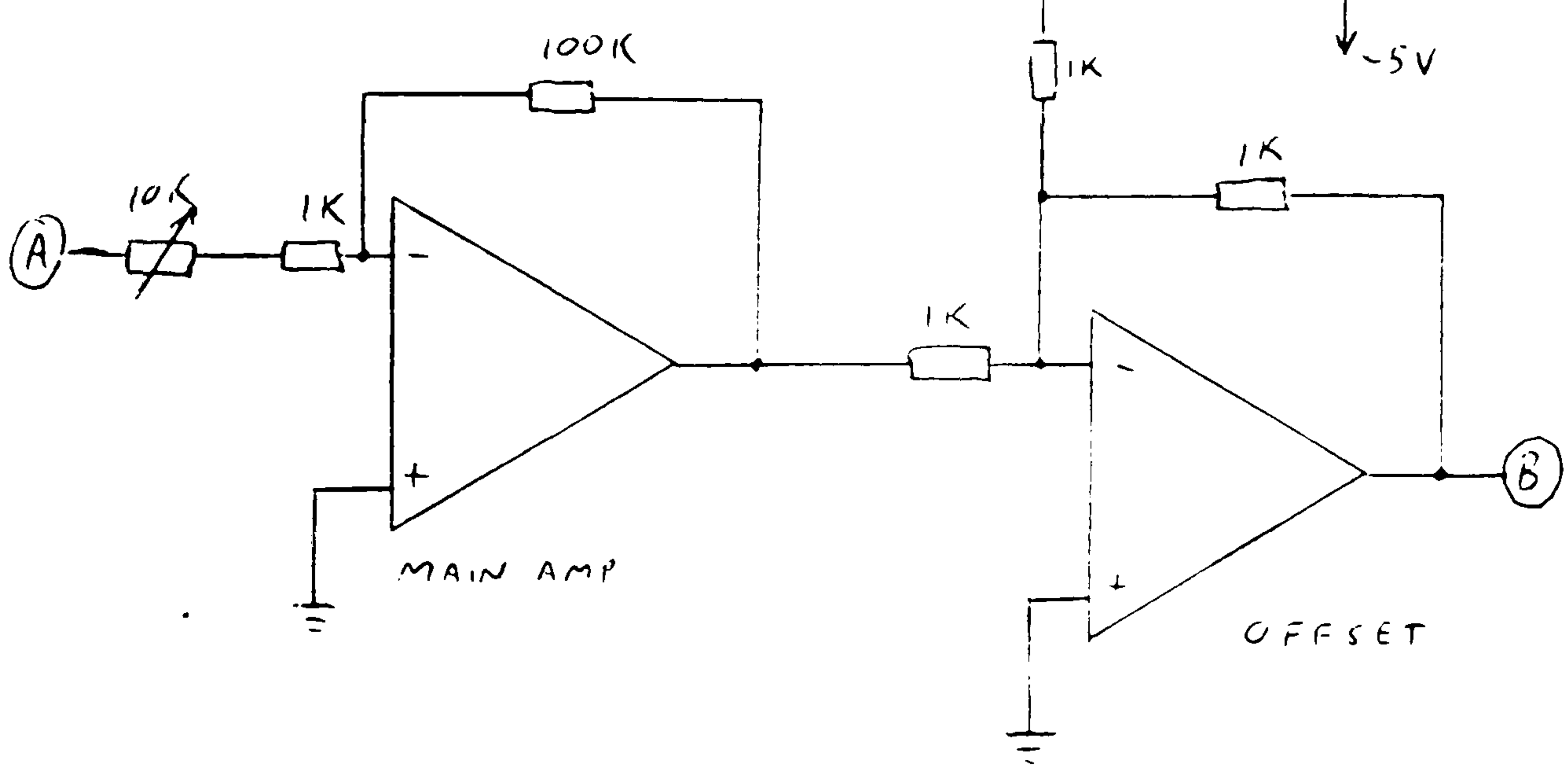
A.2 Stimulator Power supplies

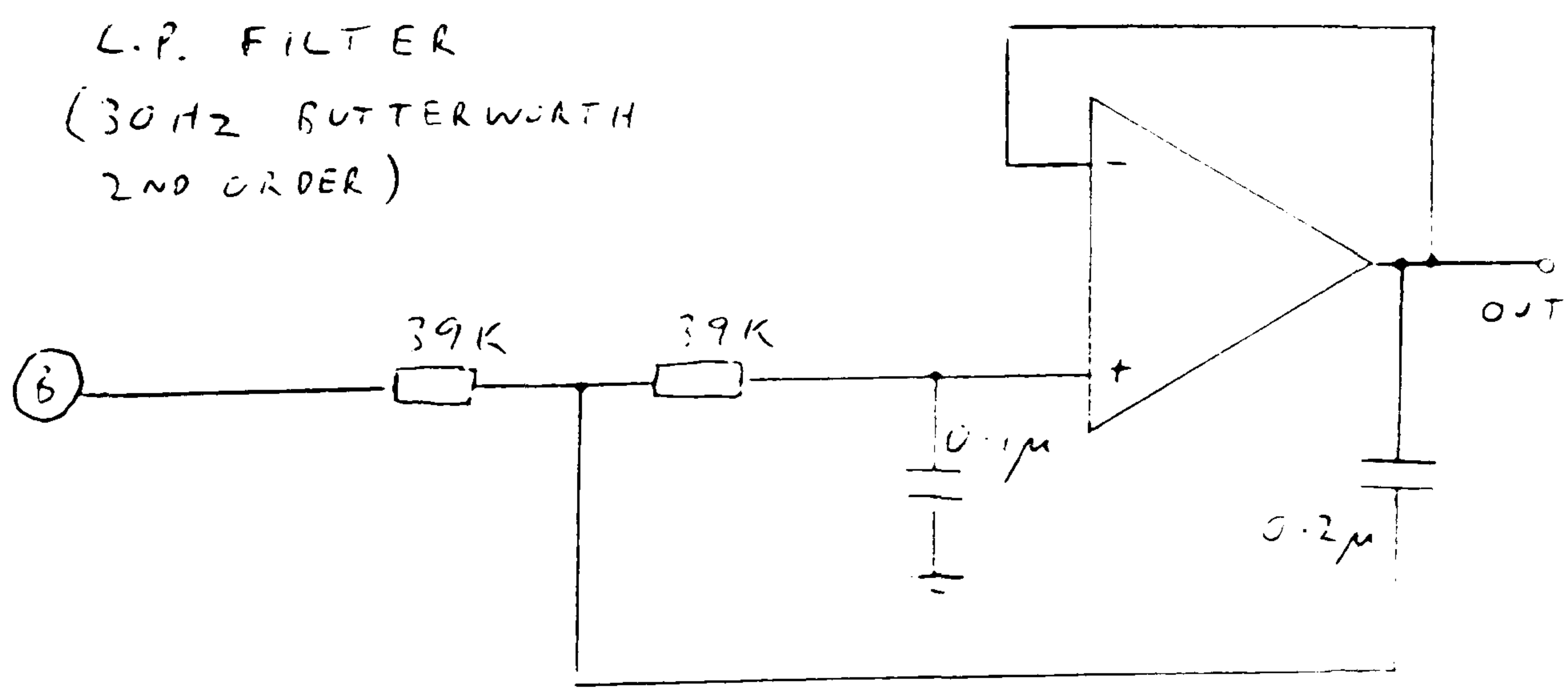


A.3 Goniometer amplifiers

(The resistor circuit before the pre-amp completes a low impedance, wheatstone bridge of which the Penny & Giles goniometer comprises only half)







The following procedures have been adapted from subroutines in larger programmes. They will not compile in their present form.

B.1. Pascal procedures for filtering data

```
const

   pi          = 3.14159;
   nfilter     = half of filter span;
   cut         = cutoff frequency;
   Endrawdata  = array size of raw data;
   Endfiltdata = Endrawdata - nfilter;

{ The cutoff frequency is expressed as a fraction of the
  folding frequency (ie. half the sampling frequency) }


var

   wfilter    : array [0..2*nfilter] of real;
   Filtdata   : array [0..Endfiltdata] of real;
   Rawdata    : array [0..Endrawdata] of real;



procedure filtercoeff;

{calculate filter coefficients}

var

   a : integer;
   window, rfilter : real;

begin
   for a := 0 to 2*nfilter do
    begin
      if a = nfilter then
        rfilter := cut
      else
        rfilter :=
          sin(cut*(a-nfilter)*pi)/((a-nfilter)*pi);
      window := 0.54 + 0.46*cos((a-nfilter)*pi/nfilter);
      wfilter[a] := rfilter * window;
    end;
end;
```

```
procedure filterdata;

{ This procedure fills in "first" values for the
  "nfilter" points preceding Rawdata[0]. If this is not
  true then the first "nfilter" points of Filtdata must
  be discarded }

var

   a, count : integer;
   first, data : real;

begin
   first := 0;
   for count := 0 to 4 do
     first := first + Rawdata[count];
   first := first/5;
   for count := 0 to Endfiltdata do
     begin
       data := 0;
       for a := 0 to 2*nfilter do
         if (count+a) >= nfilter then
           data := data +
             wfilter[a] * Rawdata[count+a-nfilter]
         else
           data := data +
             wfilter[a] * first;
       Filtdata[count] := data;
     end;
end;  {GetMoments}
```

B.2 Pascal procedures for RMS maximum and minimum axes

```
const

   NumberOfPoints = 700; {for filtered sway data}
   pi = 3.14159;

var

   radius : array[1..NumberOfPoints] of real;
   theta : array[1..NumberOfPoints] of real;
   Eta : real; {angle of maximum axis in radians}
   rmsradius: real;
   minrmsrad : real; {minimum axis}
   maxrmsrad : real; {maximum axis}
   maxangle : real;  {angle of maximum axis in degrees}


procedure ReduceEta;

{ reduce Eta such that ( -pi/2 < Eta < pi/2 ) }

begin
  repeat
    if Eta > pi/2 then Eta := Eta - pi;
    if Eta <= -pi/2 then Eta := Eta + pi;
  until abs(Eta) <= pi/2;
end; {reduceEta}


procedure RootMeanSquare;

{Calculate RMS axes and angles}

var

   count : integer;
   sumsqrad,
   meansumsqrad,
   exEta,
   totalcos,
   totalsin : real;
```

```
begin
   sumsqrad := 0;
     for count := 1 to NumberOfPoints do
     sumsqrad := SQR(radius[count]) + sumsqrad;
   meansumsqrad := sumsqrad/NumberOfPoints;
   Eta := 0;
   repeat
     totalsin := 0;
     totalcos := 0;
     for count := 1 to NumberOfPoints do
      begin
       totalsin := totalsin +
         SQR(radius[count])*sin(2*(Eta-theta[count]));
       totalcos := totalcos +
         SQR(radius[count])*cos(2*(Eta-theta[count]));
      end;
     ReduceEta;
     exEta := Eta;
     Eta := Eta-(totalsin*0.5/totalcos); {increment Eta}
     writeln ('eta = ',Eta*180/pi :8:2); {in degrees}
   until abs(exEta-Eta) < 1E-4; {check resolution}
   if (totalcos<0) then Eta:=Eta-pi/2; {local maximum}
   ReduceEta;
   rmsradius := SQRT(meansumsqrad);
   minrmsrad := SQRT(meansumsqrad/2 -
                abs(totalcos)*0.5/NumberOfPoints);
   maxrmsrad := SQRT(meansumsqrad/2 +
                abs(totalcos)*0.5/NumberOfPoints);
   maxangle := Eta*180/pi;
end {RootMeanSquare};
```

C.1 Postural Evaluation Data

The following coding system is used for the sway parameters:

1 - Distance of excursion (mm)
2 - Average speed (mm/s)
3 - Mean radius (mm)
4 - Frequency (cyc./s)
5 - RMS minimum radius (mm)
6 - RMS maximum radius (mm)
7 - Maximum angle (degrees)
8 - Maximum AP excursion (mm)
9 - Maximum ML excursion (mm)
10 - Mean AP excursion (mm)
11 - Mean ML excursion (mm)

2H - Two hands
RH - Right hand
LH - Left hand
NH - No hands
EO - Eyes open
EC - Eyes closed

Table 3.1 indicates the number of trials for each test.
Format of data - Mean value(standard deviation)
eg. 42.4(10.3)

Orth.	FRO(2H,EO)	FRO(RH,EO)	FRO(LH,EO)	FRO(NH,EO)
1 -	42.4(10.3)	41.3(8.48)	46.3(10.8)	79.5(14.7)
2 -	3.03(0.50)	2.95(0.61)	3.04(0.58)	5.68(1.05)
3 -	1.21(0.27)	1.62(0.28)	1.64(0.39)	2.65(0.56)
4 -	0.60(0.11)	0.29(0.05)	0.38(0.07)	0.35(0.06)
5 -	0.48(0.09)	0.59(0.12)	0.53(0.12)	1.05(0.34)
6 -	1.28(0.26)	1.82(0.34)	1.64(0.54)	2.82(0.61)
7 -	21.6(20.7)	-33.0(25.4)	43.1(27.0)	15.2(27.2)
8 -	4.53(0.83)	5.36(1.50)	4.55(0.80)	8.73(1.58)
9 -	3.99(0.65)	5.96(1.03)	6.02(1.92)	9.42(2.74)
10 -	1.71(0.36)	1.83(0.38)	1.66(0.28)	3.20(0.66)
11 -	1.46(0.37)	2.33(0.62)	2.52(0.51)	3.75(0.67)

Orth.	FRO(2H,EC)	FRO(RH,EC)	FRO(LH,EC)	FES(2H,EO)
1 -	37.5(10.5)	54.2(9.20)	46.9(11.5)	61.2(13.0)
2 -	2.68(0.28)	3.87(0.65)	3.35(0.62)	4.37(1.14)
3 -	1.20(0.25)	1.97(0.40)	1.54(0.36)	2.13(0.70)
4 -	0.39(0.09)	0.34(0.08)	0.40(0.09)	0.46(0.10)
5 -	0.92(0.21)	0.74(0.22)	0.56(0.13)	0.73(0.18)
6 -	1.31(0.42)	2.40(0.64)	1.67(0.23)	2.83(0.70)
7 -	-10.2(28.3)	-61.4(20.3)	41.2(26.8)	15.1(9.97)
8 -	4.73(0.49)	6.42(1.20)	4.03(0.88)	12.2(3.41)
9 -	4.00(0.91)	8.95(1.74)	6.14(1.17)	4.83(1.12)
10 -	1.70(0.23)	2.11(0.53)	1.55(0.31)	3.76(0.95)
11 -	1.36(0.21)	3.27(0.61)	2.32(0.55)	1.57(0.35)

Orth.	KAFO(2H,EO)	KAFO(RH,EO)	KAFO(LH,EO)	KAFO(NH,EO)
1 -	74.3(15.7)	69.7(12.8)	62.8(11.3)	54.2(14.4)
2 -	5.31(1.06)	4.98(0.87)	4.48(0.71)	3.87(0.79)
3 -	2.12(0.61)	2.32(0.54)	1.91(0.37)	1.78(0.32)
4 -	0.47(0.10)	0.36(0.07)	0.41(0.09)	0.38(0.05)
5 -	1.05(0.16)	1.32(0.26)	1.26(0.26)	1.03(0.23)
6 -	2.14(0.44)	2.26(0.37)	1.69(0.33)	1.67(0.41)
7 -	-17.4(23.4)	-22.3(29.5)	21.5(25.5)	5.58(20.3)
8 -	8.57(0.97)	8.45(1.74)	7.18(1.24)	6.14(1.32)
9 -	5.67(1.26)	7.01(1.08)	6.09(1.01)	3.55(0.75)
10 -	3.27(0.61)	3.27(0.59)	2.44(0.52)	2.64(0.63)
11 -	1.97(0.39)	2.40(0.38)	2.49(0.42)	1.91(0.28)

Orth.	KAFO(2H,EC)	KAFO(RH,EC)	KAFO(LH,EC)
1 -	44.7(6.58)	60.4(12.2)	51.6(10.5)
2 -	3.07(0.59)	4.32(1.02)	3.69(0.65)
3 -	1.16(0.13)	1.90(0.28)	1.44(0.18)
4 -	0.43(0.08)	0.48(0.10)	0.42(0.12)
5 -	0.62(0.12)	0.98(0.21)	0.84(0.20)
6 -	0.98(0.24)	2.12(0.55)	1.50(0.30)
7 -	2.61(26.9)	29.6(20.9)	59.6(20.7)
8 -	4.31(0.99)	9.29(1.91)	4.83(0.87)
9 -	3.74(0.61)	6.69(1.35)	6.80(1.37)
10 -	1.47(0.46)	2.10(0.53)	1.60(0.32)
11 -	1.49(0.34)	2.58(0.37)	2.07(0.39)

Orth.	RGO(2H,EO)	RGO(RH,EC)	CONTR.(EO)	CONTR.(EC)
1 -	67.3(12.8)	44.2(9.82)	149 (33.3)	252 (53.9)
2 -	4.81(0.66)	3.16(0.27)	10.6(2.38)	16.6(1.41)
3 -	1.92(0.57)	1.61(0.25)	5.37(1.16)	4.75(1.07)
4 -	0.44(0.10)	0.46(0.09)	0.32(0.08)	0.58(0.11)
5 -	0.74(0.12)	0.48(0.11)	1.98(0.19)	2.06(0.23)
6 -	2.15(0.58)	1.80(0.31)	5.82(1.09)	5.21(1.08)
7 -	-38.0(28.5)	-15.8(12.6)	8.03(21.7)	3.64(21.1)
8 -	7.11(1.20)	6.63(1.27)	21.4(3.96)	23.8(4.18)
9 -	6.92(1.13)	3.21(0.53)	11.8(2.78)	12.1(2.13)
10 -	2.48(0.53)	2.81(0.57)	9.44(1.91)	8.20(1.56)
11 -	2.39(0.39)	1.30(0.22)	4.19(0.98)	3.35(0.52)

C.2 Muscle Function Data

Format - Mean(Standard Deviation) in milliseconds
Each entry represents 4 trials (subject A)

Patt.	t10	t50	t90	Risetime
MC1	60.8(6.4)	122(7.3)	249(19.3)	189(16.8)
MC2	55.0(0.8)	98(2.8)	226(27.5)	171(19.2)
MC3	50.5(1.0)	84(2.6)	152(19.7)	102(15.5)
MP1	45.8(2.2)	77(4.9)	144(11.9)	98(6.2)
MP2	52.0(4.1)	78(8.3)	128(18.0)	76(10.7)
MP3	50.0(5.6)	84(10.2)	130(8.7)	80(7.3)
MS1	63.5(4.2)	127(9.9)	257(23.1)	194(24.1)
MS2	60.8(8.4)	125(13.9)	259(22.6)	198(21.9)
MS3	42.5(2.4)	97(7.6)	229(21.6)	186(19.4)
MS4	38.8(1.3)	87(6.5)	191(22.0)	152(17.5)

C.3 Flexion Response Data

Format - Mean(Standard Deviation) in milliseconds
Each entry represents 10 trials (subject A)

Patt.	t10	t50	t90	Risetime
FC1-H	316(32.1)	493(42.4)	681(46.9)	365(35.7)
FC2-H	254(22.5)	445(33.8)	644(35.2)	390(26.2)
FC3-H	202(25.4)	387(29.7)	596(31.0)	393(26.5)
FP1-H	290(42.7)	433(53.6)	603(69.7)	313(49.6)
FP2-H	204(29.0)	399(20.0)	608(26.3)	403(25.1)
FP3-H	202(18.6)	374(15.8)	604(48.3)	402(23.7)
FC1-K	305(30.5)	506(28.6)	682(34.5)	377(37.2)
FC2-K	268(19.0)	414(23.8)	599(27.8)	331(24.5)
FC3-K	187(24.5)	337(35.6)	525(44.0)	338(34.3)
FP1-K	313(33.1)	449(30.0)	599(36.0)	286(29.6)
FP2-K	256(15.6)	398(18.8)	581(26.2)	324(20.2)
FP3-K	252(23.0)	397(25.7)	567(27.7)	315(25.5)

Mean latencies for other subjects (hip only)

Subject	FC1	FC2	FC3
A	316(32)	254(22)	202(25)
B	288(25)	236(22)	163(23)
C	348(45)	187(21)	130(21)
D	264(21)	222(24)	166(14)
E	306(21)	281(20)	246(21)
F	672(63)	536(117)	212(46)
G	220(21)	180(25)	157(31)

C.3 Flexion Response Data

Format - Mean(Standard Deviation) in milliseconds
Each entry represents 10 trials (subject A)

Patt.	t10	t50	t90	Risetime
FC1-H	316(32.1)	493(42.4)	681(46.9)	365(35.7)
FC2-H	254(22.5)	445(33.8)	644(35.2)	390(26.2)
FC3-H	202(25.4)	387(29.7)	596(31.0)	393(26.5)
FP1-H	290(42.7)	433(53.6)	603(69.7)	313(49.6)
FP2-H	204(29.0)	399(20.0)	608(26.3)	403(25.1)
FP3-H	202(18.6)	374(15.8)	604(48.3)	402(23.7)
FC1-K	305(30.5)	506(28.6)	682(34.5)	377(37.2)
FC2-K	268(19.0)	414(23.8)	599(27.8)	331(24.5)
FC3-K	187(24.5)	337(35.6)	525(44.0)	338(34.3)
FP1-K	313(33.1)	449(30.0)	599(36.0)	286(29.6)
FP2-K	256(15.6)	398(18.8)	581(26.2)	324(20.2)
FP3-K	252(23.0)	397(25.7)	567(27.7)	315(25.5)

Mean latencies for other subjects (hip only)

Subject	FC1	FC2	FC3
A	316(32)	254(22)	202(25)
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E	306(21)	281(20)	246(21)
F	672(63)	536(117)	212(46)
G	220(21)	180(25)	157(31)