The Use of Tone Relieving Ankle-Foot Orthoses in the Management of Children with Cerebral Palsy

Victoria Tracy Hall

This thesis is submitted in partial fulfilment

of the requirements for the degree of

Doctor of Philosophy

SALFORD UNIVERSITY

School of Prosthetics & Orthotics

January 1999

CONTENTS

LIST OF FIGURES

EQUIPMENT

METHODS

RESULTS

LIST OF TABLES

Acknowledgements

I would like to express my thanks to my supervisor, Professor Peter Bowker, who made it possible for me to undertake this research. I greatly appreciate his constant support and direction throughout my studentship and over the past year.

I am grateful to the community physiotherapy teams, particularly those based at; Parksfield, Telford, Lancasterian, and Pictor Schools. Without their assistance the identification and recruitment of the subjects would not have been possible.

All the orthoses used in this investigation were cast and manufactured at the North Western Orthotic Unit, Hope Hospital, Salford, and I would like thank all the staff in the Unit for their encouragement and assistance during the study. I am particularly grateful to Mike Gilligan, orthotist, who worked with all the children in the investigation, ensuring that the orthoses were ready on time and manufactured to a very high standard. I would like to thank him for sharing his vision and experience and for the development of the new casting technique.

I would like to thank my family for their constant love and support and who, along with my friends, have shown great patience and understanding, particularly over the last year.

I will be eternally grateful to Paul who has provided continual advice and assistance and repeatedly pestered me to get on with it. His friendship has been endless throughout the most fraught and pressured moments.

Finally, I would like to express my thanks to the children and their parents who volunteered to take part in this study. Their friendship and enthusiasm made this research possible.

Declaration

I declare that this thesis has been composed by myself and embodies the results of my own research, undertaken whilst studying at Salford University from October 1994 to December 1997. All other sources of material are specifically acknowledged. None of the material has been used previously in application for a degree.

Abstract

Tone Relieving Ankle Foot Orthoses (TRAFOs) have been used in the management of neurophysically impaired patients for some years within the United States and during the last few years they have been introduced in the UK. The main difference between a TRAFO and a standard polypropylene ankle foot orthosis (AFO) is that the TRAFO does not have a flat base beneath the foot, but one with various raised and hollowed areas. This unique base is designed to hold the foot in a neutral position and provide support and stability under the dynamic arches of the foot.

The investigation aimed to determine any benefits of using TRAFOs in the management of children with cerebral palsy in comparison with those obtained using standard ankle foot orthoses. Fifteen children were recruited into the investigation and assigned to one of two groups. Group 1 were monitored in standard AFOs for six months and group 2 were monitored in AFOs for three months and then in TRAFOs for a second three month period. The subjects were assessed at regular intervals during the six month period using EMG analysis to establish changes in the pattern of muscular activity during gait. Video analysis and force platform data was also used to determine general gait parameters and record ground reaction vectors.

Results for EMG and the temporal and spatial parameters were unable to highlight any areas in which tone-relieving ankle-foot orthoses produced more favourable results than standard polypropylene ankle-foot orthoses. The results suggest that TRAFOs may not work in the neurological manner previously indicated and may have no greater benefit to a patient than a standard polypropylene AFO.

Section 1

Introduction & Literature Review

1.1 Cerebral Palsy

During the last thirty years there have been dramatic improvements in neonatal special care which has resulted in babies surviving at much younger gestational ages. In all low birth weight babies however, there is an increased risk of an injury to the brain known as cerebral palsy, and for those of less than 2 kg, who nowadays generally survive, the rate rises rapidly (Pharaoh et al, 1987; Pharaoh, 1994). Therefore, as a direct result of the modern technology which has increased the success of special care baby units, there are more low weight babies surviving and the incidence of cerebral palsy in this group is increasing.

The term cerebral palsy is used to cover a group of conditions which result from an injury to the brain or an abnormal development of the central nervous system. The term is only used in cases where the injury occurs in the 'immature' brain and as such, an arbitrary age of onset is usually defined at before 3 years. In some cases, however, this upper limit may be increased to as high as 5 years depending on the view of the clinician (Bedford, 1990). Children affected by cerebral palsy have a lack of neurological control over their movements, although the disorder will establish and develop differently in each individual. Changes can also occur as the child grows with alterations to body size and muscle balance in addition to variations in postural and movement habits.

Children with cerebral palsy do not only have difficulties with their movements. Depending on the severity of the case there can be a whole array of other problems including, epilepsy, and visual, hearing, learning, speech and perceptual problems. In very mild cases there will be difficulties with movements only, but the severity and location of the lesion can result in any number of these additional problems being present. The cause of the injury to the brain is also variable and in many cases it is thought that a combination of factors may be responsible for the damage which occurs. The causes are often classified into one of three groups, determined by the age of the child when the damage occurs, as shown in Figure 1.

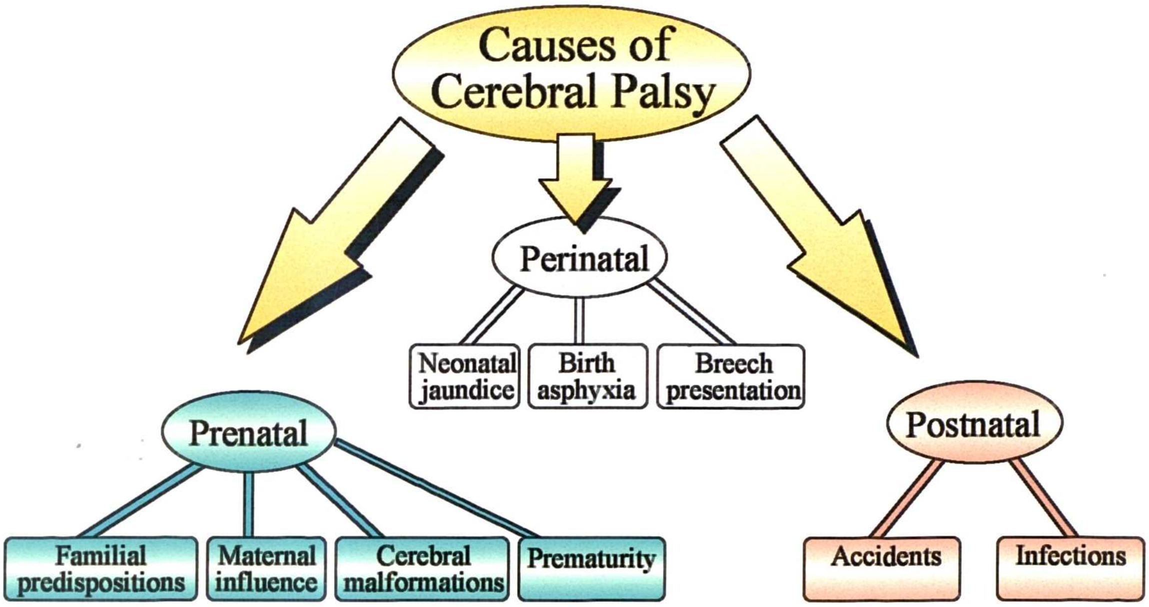


Figure 1
Causes of Cerebral Palsy

As is the case with the causes of cerebral palsy, the characteristics of a cerebral palsied child can also be separated into groups, although, in most cases there are a combination of characteristics present. Many children exhibit problems typical to more than one type of cerebral palsy although often one type will be predominant (Meadows, 1984). This makes categorising children with cerebral palsy a difficult task as there are numerous causes, types, and methods by which it can be assessed and most of these rely on subjective evaluations.

1.1.1 Categories of Cerebral Palsy

As the extent and location of the brain injury resulting in cerebral palsy is different in every case, the condition manifests itself in many different ways. As a result, children with cerebral palsy are categorised using several factors related to their tonal condition. These factors cover: the variations in tonal levels throughout the body, the distribution of tone problems, the severity and the type of cerebral palsy (McDonald & Valmassy, 1987; Bedford, 1990).

<u>Variations in tone</u>

Muscle tone is not easily described and is even less easily measured. The difficulty arises from the fact that the term covers many different properties of the muscle tissue such as elasticity, viscosity and muscle reflexes (Fenn and Garvey, 1934). From a clinical aspect tone is often described as the resistance felt in a limb as it moves or the effort of various muscles to maintain their natural length (Foster, 1890). In some conditions this resistance can be less than normal and the muscle is described as being hypotonic (low tone) and in others the resistance is increased and the muscle is said to be hypertonic (high tone).

Although many scientific methods of measuring muscle tone have been attempted (Walsh, 1992), very few have ever come close to finding a suitable solution which can be used quickly and easily in a clinical environment. Clinicians therefore continue to use a 'hands on' approach to assessing muscle tone by manipulating the limb. One such clinical method which is widely used is the Ashworth scale, see Table 1, which uses a points system to evaluate levels of increased tone.

Score	*Degree of Muscle Tone*
1	No increase of tone
2	Slight increase of tone, giving a 'catch' when the limb was moved in flexion and extension
3	More marked increase in tone, but limb easily flexed
4	Considerable increase in tone - passive movement difficult
5	Limb rigid in flexion or extension

Table 1
The Ashworth Scale (from Ashworth, 1964)

In hypertonic muscles the increased resistance observed can often lessen abruptly and in such cases it is termed spasticity. The term rigidity is also used, and describes those cases where the increase in tone is sustained and occurs in all directions (Bedford, 1990). The nature of tone problems can also vary as children develop, and this is particularly seen in those who exhibit hypotonia early on in life, but then often develop hypertonia and spasticity as they get older.

Distribution of the tone

Three terms are used to describe the distribution of tone problems throughout the body: hemiplegia, diplegia and quadriplegia (tetraplegia). Hemiplegia refers to one side of the body being affected which often includes the trunk and neck in addition to the limbs. Children with hemiplegia generally have spasticity. In children with diplegia both legs are affected although in some cases there may additionally be mild problems in the arms. As with hemiplegia, most have spasticity although some children exhibit a degree of hypotonia. The term quadriplegia is used in those children where all of the limbs are affected and in particular the arms are as severely or more severely affected than the legs.

All of these terms however, are open to variations as they again are based upon the subjective opinion of the clinician involved.

Severity

The severity of the condition is again subjectively graded and is usually termed mild, moderate or severe. In most cases the terms are related to how the extent of the tone problem affects the child's capability to perform everyday tasks and this measure can therefore take a more global view of how the difficulties with particular muscles restrict the child.

Types of Cerebral Palsy

There are three types of cerebral palsy, spasticity, athetosis and ataxia, which describe the manner in which the brain lesion affects the muscles. Those children who have spasticity often have difficulty moving their affected parts, resulting in abnormal patterns of movement and a restriction on the range of movements they are able to perform. In athetosis, children have difficulty maintaining a fixed position and often exhibit involuntary movements. Difficulties often arise in the timing of movements which can be very fast and jerky with the inability to maintain any one position along the way. Finally in ataxia there is an unsteadiness to the movements resulting in difficulties with balance and sometimes an intention tremor is present. Ataxia is the least common of the three types of cerebral palsy.

It is clear that there are no simple mechanisms available to categorise cerebral palsy and that in every case a number of factors have to be considered. Each case is different as the extent and location of the damage to the brain and therefore its effect on the movements of the child can be so varied. The subjective assessment of the clinician involved with a particular child is at present the best method available and this allows a child's condition to be described using a number of key terms relating to the type and severity of problems. In this way children from the very mildest of conditions through to the most severe cases can be covered. The following table (Table 2) summarises some of the key terms which are used to categorise children with cerebral palsy.

Variations	*Distribution*	*Severity*	*Type*
Hypertonicity	Hemiplegic	Severe	Spastic
Hypotonicity	Diplegic	Moderate	Athetosis
Spasticity	Quardriplegic	Mild	Ataxia
Rigidity			

Table 2
Common Descriptions Used to Categorise Cerebral Palsy

1.1.2 Hemiplegic Posture

Often amongst those patients with milder forms of cerebral palsy are the children classed with hemiplegia resulting in spasticity of the upper and lower limb on one side. The manner and extent to which tone is distributed is never consistent between these individuals, however there are some general patterns which are often evident. In the arms spasticity is often strongest in the flexors whereas in the lower limb, it is the extensors which are affected. Hemiplegic posture is therefore most often observed as a flexed elbow, wrist and fingers with equinus of the foot and ankle as illustrated in Figure 2.

Figure 2
Typical Hemiplegic Posture (Bleck, 1987)

1.1.3 Equinus

The equinus position of the foot ankle is particularly relevant to gait patterns and in hemiplegia it becomes more noticeable due to the comparison with the normal side. The equinus position consists of plantarflexion of the foot and can occur with varus or valgus, although varus deformities are most common in hemiplegia (Bennet et al, 1982). During gait, initial contact is made with the forefoot, particularly the lateral border in equinovarus, and the heel often does not make contact with the ground. The pivitol rocker actions at both the heel and ankle are lost resulting in the absence of the normally smooth progression of the body weight along the foot.

1.2 The Nervous System

The nervous system is responsible for the control and communication of systems throughout the body. In general the nervous system has three functions; sensory input, integration and motor output. At input, signals from the sensory receptors are conducted to integration centres such as the brain. Here the information is interpreted and associated with a particular response for the body. Motor output occurs when signals are then conducted via efferent cells to the tissue which will actually perform the response (Campbell, 1990). The nervous system is extremely complex, with its communication occurring via electrical signals allowing a rapid response to sensory input.

Central and Peripheral Nervous System

The nervous system is divided into two parts: the central nervous system (CNS) which consists of the brain and spinal cord, and the peripheral nervous system (PNS) which consists mainly of the nerves from the brain and spinal cord (Williams & Warwick, 1980). The organisation of the nervous system is illustrated in Figure 3. The central nervous system is the link between the sensory and motor functions of the peripheral nervous system. It forms the integration and command centre where it interprets the incoming sensory information and then associates this with a suitable response or motor function depending on experience, reflexes and the current situation.

The peripheral nervous system has spinal nerves which carry signals to and from the spinal cord, and cranial nerves which carry signals to and from the brain. The nerves have two subdivisions with the sensory or afferent nerves carrying information from the sensory receptors to the CNS, and the motor or efferent nerves carrying impulses from the CNS to the effector cells.

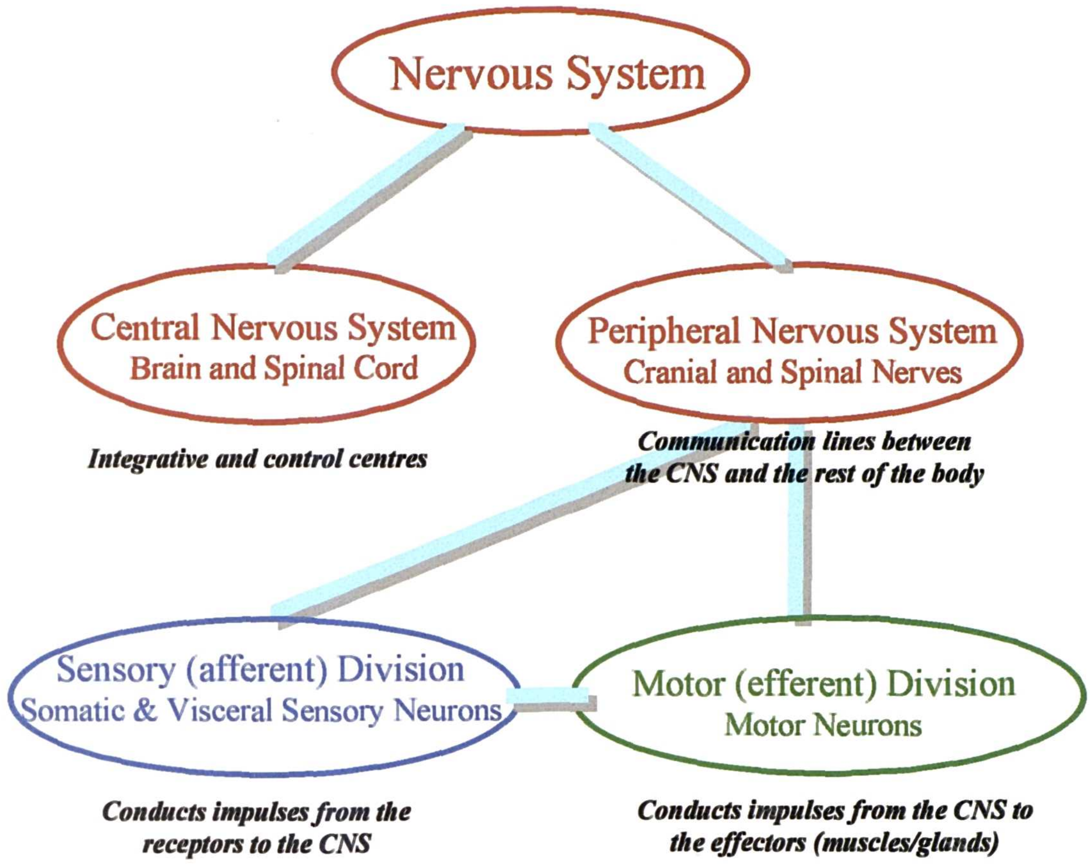


Figure 3
Organization of The Nervous System (adapted from Marieb, 1992)

Inhibitory Pathways & Reflex Arcs

Signals arriving at the CNS via the afferent motor neurons can lead to different types of responses occurring along the efferent pathways. Both excitory and inhibitory pathways of motor neurones exist which allow the CNS to control whether to cause or to inhibit the contraction of a muscle. In this manner the afferent impulses arriving at the spinal cord, can interact with motor neurons to cause the contraction of one muscle, and can also interact with interneurons sending inhibitory signals along other neurons to a second muscle.

The spinal cord is also able to initiate simple but very rapid responses to certain kinds of stimuli. These generally take the form of a reflex action which is an unconscious pre-programmed response to a specific stimulus. Such basic reflexes are unlearned, and involuntary and can be considered to be built into our neural anatomy (Marieb, 1992). In addition to the basic reflexes there are also other reflexes which can be learned or acquired resulting from practice or repetition.

Reflexes occur over specific neural paths known as reflex arcs which have five main components; the receptor, the sensory neuron, the integration centre, the motor neuron and the effector. Many reflexes can occur without any input from the higher brain centres and are thus described as spinal reflexes. Other reflexes however, require the activity of the brain for them to occur and the brain has the control to either facilitate or inhibit the reflex.

Functionally reflexes are classified as being somatic if they activate skeletal muscle, and autonomic when visceral effectors are activated. It is the testing of somatic reflexes which is important clinically and particularly in children with cerebral palsy. By testing such reflexes you can assess the condition of the nervous system and gain an indication of the degeneration or pathology occurring in specific regions (Marieb, 1992).

1.2.1 Primitive Reflexes & the Development of the Nervous System

Primitive reflexes are regularly used when examining an infant for significant motor impairment. The appearance and disappearance of these reflexes is often taken as an indicator of CNS damage, along with the timing of onset which is thought to have specific relevance to the diagnosis of cerebral palsy (Blasco, 1994).

Primitive reflexes are those complex movements which can be observed in the neonate and they are usually clinically evident up to six months of age. Some of the most clinically useful reflexes include the asymmetric tonic neck reflex (ATNR), the Moro tonic labyrinthine, and the positive support reflex, which are described in further detail in Table 3. In general the primitive reflexes have almost all disappeared by the age of six months although the symmetric tonic neck reflex and the Galant reflex persist longer.

In 1978, Capute et al. described the distinction between primitive reflexes and what they termed postural reactions. They described primitive reflexes as being the true reflexes elicited by specific sensory stimuli and being facilitated at a subcortical level in the brain stem. The disappearance of the primitive reflexes is thought to be related to the maturation of the cortical connections which override the brain stem and prevent the reflexes from occurring. In this manner when cortical integration is lost or compromised, either pre or neonatally, the primitive reflexes persist.

Postural mechanisms in contrast are not usually present in the new-born infant and begin to appear at around three months of age. Capute et al. (1978) described the postural mechanisms as being different to primitive reflexes because they are based on multiple input modalities and require cortical integrity. Postural reactions are tested in three main categories described as righting, protection and equilibrium. In children with a brain injury the postural mechanisms appear later than usual, if at all. Table 3 provides an example of four of the many tests available to evaluate primitive reflexes and postural mechanisms.

Reflex	***Action***	***Reaction***
Asymmetric tonic neck reflex (ATNR)	In supine the head is extended to around 45°	Shoulders abduct, elbows flex, lower limbs extend
Moro tonic labyrinthine	In supine the head is turned to one side	The arm and leg extend on the face side and flex on the opposite side
Positive support reflex	The child is suspended vertically then lowered until the feet touch a flat surface	Progressive extension of the lower limbs from feet upwards to hips
Postural Mechanisms	With a child seated and supported around the waist they are tilted to one side.	Movement of head towards midline, protective extension of arm, counter-movements of leg and arm on opposite side

Table 3
Primitive Reflexes and Postural Mechanisms (based on data from Blasco, 1994)

Primitive Reflexes and Postural Mechanisms in the Child with Cerebral Palsy

When cortical integration is lost or compromised the primitive reflex responses often persist beyond their usual age of disappearance and are often somewhat exaggerated (Blasco, 1994). When assessing a child both the inappropriate absence of a reflex at an early age and the inappropriate persistence beyond normal disappearance suggest neurological dysfunction. It is possible to gain indicators about the type and severity of the cerebral palsy by using such markers.

Of greatest use to the clinician during an evaluation however, are the postural mechanism tests. These movements require a complex interplay between cerebral and cerebellar cortical adjustments to many sensory stimuli and are markedly delayed in babies with nervous system damage. A more specific diagnosis can also be facilitated as the quality of the postural mechanisms is altered in a manner specific to different types of cerebral palsy (Blasco, 1994).

The Hierarchical versus Distributed Control Models of the CNS and their Implications to the Treatment of Cerebral Palsy

Current theories regarding the organisation of the CNS and its influence on the appearance and disappearance of primitive reflexes are traditionally based on the view that there is hierarchical organisation (McGraw, 1943; Gesell, 1940). The disappearance of the primitive reflexes is explained by the maturation of the CNS allowing higher centres to inhibit or integrate the movements. In more recent years however, a number of more contemporary theories (Fukuda, 1961; Easton, 1972) have emerged which suggest a distributed control model of the CNS which allows both peripheral and central nervous system factors to participate in the control of movement (Pimentel, 1996). Although much debate still exists, it is important to consider both theories, and their relation to primitive reflexes, if we are to understand the mechanisms by which interventions such as physiotherapy techniques and 'inhibitive' orthotics can aid rehabilitation.

The traditional view assumes that primitive reflexes are independent of voluntary movements and that the reflexes must be suppressed, inhibited or integrated by the higher centres of the CNS in order for voluntary movement to occur. A simplified description of the relationship between primitive reflexes and voluntary movement was put forward by Fiorentino in 1963. The most primitive level of CNS maturation was suggested to be the spinal level which results in total flexion or extension such as prone or supine lying. Fiorentino (1963) then described the progression of maturation of the CNS from brain stem, to mid brain and then cortical control, and linked these to the progression of movements from primitive reflexes, through righting reactions to equilibrium reactions respectively. It was stated that any primitive reflexes which were not inhibited by the maturation of the CNS would interfere with the development of normal voluntary movements because they interfered with the integration of flexor and extensor tone.

The contemporary theories regarding the development of the CNS and its relationship to primitive reflexes have mainly followed the line of two important questions: Do the reflexes have a role in the development of voluntary movements? and do the reflexes actually disappear? (Pimental,1996). Researchers have found evidence to support a number of suggestions including that; reflex behaviour is elicited during voluntary movements (Fukuda, 1961), practising primitive reflexes can prolong their existence and result in the premature appearance of correlated voluntary movements (Zelazo, 1983) and that growth, environmental and cultural factors all influence the progression from primitive reflexes to voluntary movements (Super, 1976; Thelen & Fisher, 1982). The different contemporary theories suggest that information in the CNS flows in all directions and not in a hierarchical manner, allowing distributed control where central, peripheral and environmental factors are integrated.

In terms of clinical interventions, such as physiotherapy and orthoses, it is important to understand the theories behind a particular technique and the proposed effect on reflexes. Based on the hierarchical control system Brunnstrom (1970) advocates the use of primitive reflexes during physiotherapy, whereas Bobath (1978) advocates the inhibition of reflexes in such treatment. If however, the distributed control model of the CNS is more accurate, then orthotists/therapists should not be considering whether to use or inhibit the reflexes, but how to alter the input a patient receives in order to achieve the most functional motor output (Pimentel, 1996).

1.3 The Use of Ankle-Foot Orthoses in Cerebral Palsy

The majority of lower limb orthotic interventions for children with cerebral palsy are directed towards preventing equinus contractures. For those patients who have increased tone in the plantarflexors of the foot, which results in the equinus position, the implications for their gait can be wide ranging and extremely debilitating. These patients generally exhibit a pattern of forefoot contact during the gait cycle, which increases in severity from mild through to high tone patients often resulting in problems at the knee and in some cases, an inability to achieve standing balance. It has therefore been a priority for orthotists working in this area to control the excessive tone and maintain the foot in a more functional position.

The original method of bracing to maintain the foot in the required position was used widely in the 1950s and consisted of two metal posts which ran parallel to the limb. The metal uprights were attached to the heel at either side of a high topped orthopaedic boot and then fastened at an adjustable circular leather cuff secured below the patients knee. These appliances were known as short leg braces, as shown in Figure 4, and were the most popular type of bracing for children with cerebral palsy right into the 1970s. The considerable weight of such a brace is a disadvantage, particularly in children for whom this can be expected to alter walking performance (Brodke et al., 1989). Compliance to wearing such a device has always been a problem, and the fact that short leg braces were bulky and far from cosmetic will no doubt have had a considerable effect on the patients willingness to wear such an appliance. It is clear that a new type of device which could eliminate the problems with the short leg brace, whilst also improving on the support it provided, was desperately needed to alter the whole concept of orthotic support for children with cerebral palsy.

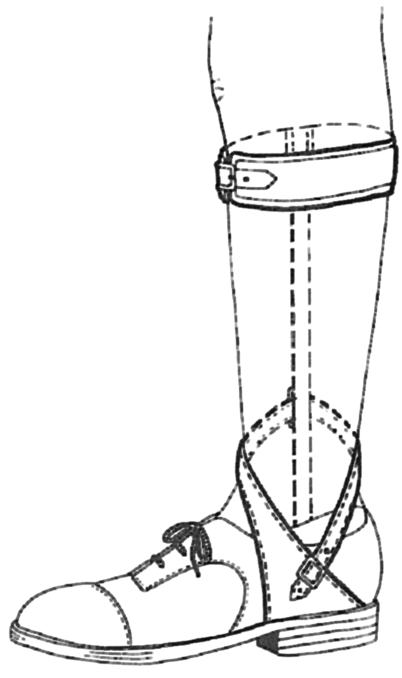


Figure 4
A Short Leg Brace

Major developments in the design and manufacture of ankle-foot orthoses were brought about by the introduction of modern materials such as thermoplastics in the 1960s. Orthoses could now be manufactured which were lighter, cheaper, easier to manufacture and more cosmetically acceptable (Yates, 1968). The use of materials such as polypropylene allowed intimate moulds to be constructed which maximised the contact between limb and orthosis and increased foot stability. Although such orthosis are usually constructed of a polypropylene copolymer, they are generally referred to as polypropylene ankle foot orthoses (AFO) and the remainder of this text will use this convention. A standard polypropylene AFO is illustrated in Figure 5, incorporating double straps to secure the limb in position. A major advantage of such AFOs is that the orthosis can be worn within normal footwear, making it much more acceptable for children and resulting in far greater compliance with the device. Plastic orthoses however, are not suitable where oedema is present. They are also relatively weak and hard to modify for growth which means they need replacing more frequently. By the very nature of their design the orthoses have such a close fit that they can actually create problems if they are not cast and manufactured correctly. An orthotist is therefore essential in the successful orthotic management of children with cerebral palsy.

Early designs of polypropylene AFOs were always rigid which, although providing greater stability, limited the range of motion which had been previously available with the short leg braces. A further development was the introduction of a joint within the orthosis which often improved function in children with cerebral palsy by allowing a degree of passive dorsiflexion whilst resisting plantarflexion (Condie & Meadows, 1993). An example of such an articulated AFO is illustrated in Figure 6. The use of this modification to the standard AFO design has been reported to facilitate a more natural movement of the ankle during the stance phase (Middleton et al., 1988).

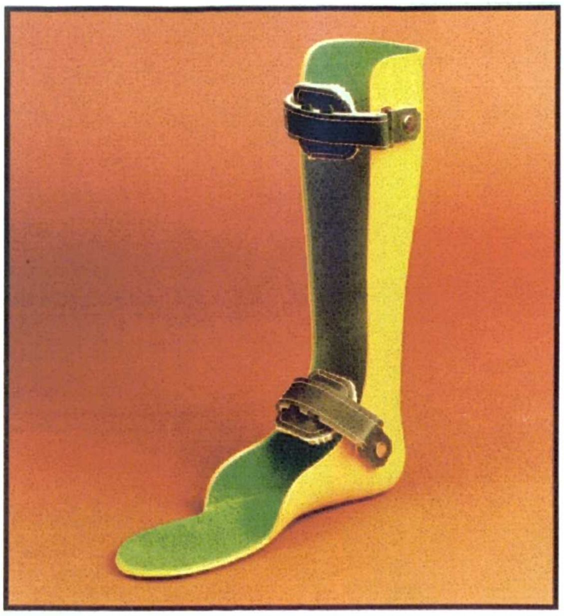


Figure 5
Polypropylene Ankle-Foot Orthosis (AFO)

Figure 6
AFO with Ankle Joint

Ankle-foot orthoses are routinely prescribed for children with cerebral palsy to promote or improve the quality of ambulation and avoid the development of contractures and deformities (Lehmann, 1986; Molnar, 1986). They are only one of several interventions available to the clinician including drug treatment, physiotherapy and surgery, with often a combination of such treatments providing the best results. It is generally accepted clinically that AFOs can be a useful tool to promote standing balance and locomotion in children with such difficulties, and investigations have shown that "...the use of polypropylene ankle-foot orthoses and associated footwear influences markedly the resulting gait patterns" (Meadows, 1984).

There are now a wide range of lower limb orthoses available, from basic foot orthoses, where no support is required around the ankle, through to hip and knee ankle foot orthoses. The different orthotic types cover a range of biomechanical applications and thus can cater for many of the mildest to the most severe cases of cerebral palsy. Modern gait analysis techniques can also measure the detailed kinetics and kinematics of movement, allowing the quantification of changes which occur in posture, balance and locomotion. By using such techniques it is now possible, to examine the effect of small alterations to the whole biomechanical system and fine tune orthoses to an individual's needs, optimising the functional outcome which can be achieved. When orthoses are selected and adapted correctly using a combination of physical examination and gait analysis techniques (Halar & Cardenas, 1987) the result can be profound biomechanical changes and for many children dramatic improvements in ambulation.

1.4 Tonic Reflexes of the Foot

In 1960, Duncan published a report documenting what he described as 'tonic reflexes of the foot and their significance to children with cerebral palsy' and it was this work which in future years provided the theoretical basis to the development of modern splints designed to reduce tone.

In all new born babies there are four tonic reflex movements of the foot which can be elicited through pressure on the corresponding reflex areas. During the first year of life these reflexes gradually disappear as they are suppressed by the maturing cerebral cortex. In children with cerebral palsy, however, the disappearance of one or more of these reflexes is often delayed and it is suggested that the brain injury impairs the suppressive ability of the cortex (Duncan, 1960). This often results in the superficial reflex actions of the foot persisting throughout childhood. The reflexes themselves present as slow movements, which involve the co-contraction of several muscles, and they exhibit a latent period of one to three seconds between the stimulus application and the movement itself.

Duncan (1960) described the four tonic reflexes of the foot as: toe-grasping reflex, inversion reflex, eversion reflex and dorsiflexion reflex. The areas of the foot from which these reflexes can be elicited is illustrated in Figure 7, although the extent of these areas varies for each individual and will diminish with maturation as the reflexes are gradually suppressed.

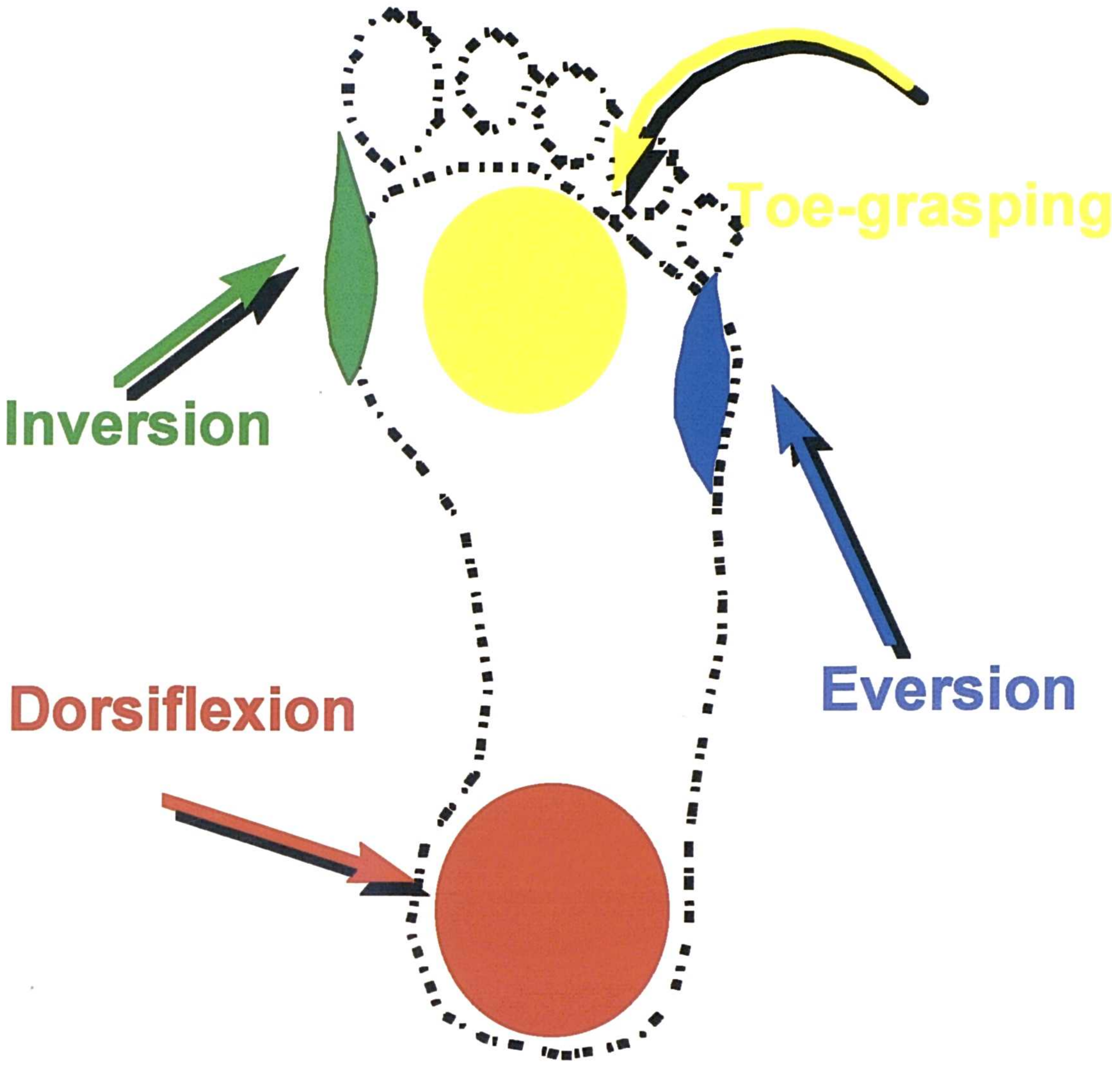


Figure 7
Tonic Reflex Areas of the Foot (Adapted from Duncan, 1960)

Toe-grasping Reflex

Stimulation to the ball of the foot close to the base of the second and third toes results in flexion and adduction of the toes. When a person is displaced forward from the upright standing position this results in the centre of pressure moving forward on to the ball of the foot which will elicit the toe-grasping reflex. This reflex is also associated with the co-contraction of the calf and hamstrings working to return the subject to a balanced position.

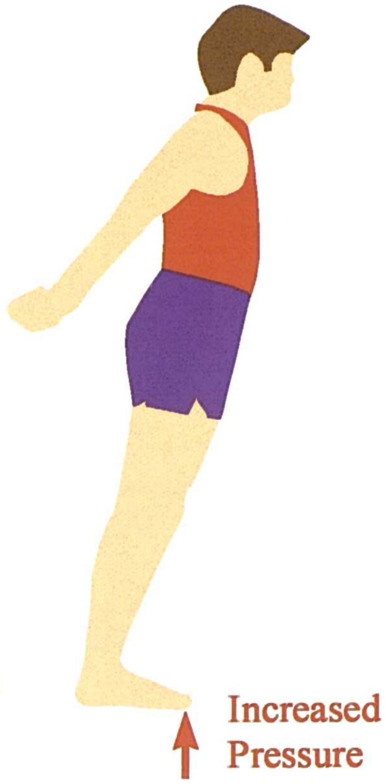


Figure 8
Movement Resulting in the Toe-Grasping Reflex

Inversion Reflex

Stimulation of the medial border of the foot near to the head of the first metatarsal produces a tonic inversion of the foot. The main muscles involved in this movement appear to be the anterior and posterior tibialis with extension of the toes also exhibited in some cases. An upright subject leaning to one side would increase pressure on the medial border of one foot and hence elicit the inversion reflex.

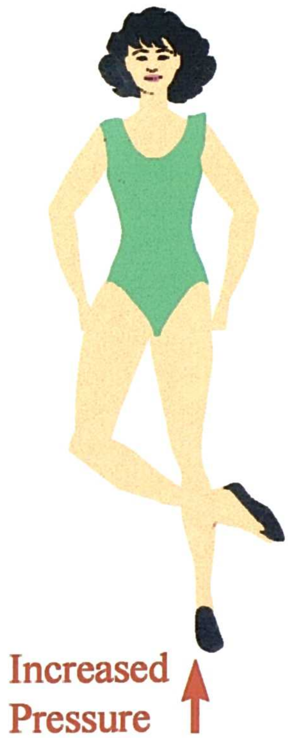


Figure 9
Movement Resulting in the Inversion Reflex

Eversion Reflex

Stimulation of the lateral border of the foot over the head of the fifth metatarsal and the base of the little toe results in eversion of the foot. The main muscle involved in this reflex is the peroneous brevis and flexion or extension of the toes may also occur. An upright subject once again, leaning to one side, would increase pressure on the lateral border of the opposite foot and hence elicit the eversion reflex.

Figure 10
Movement Resulting in the Eversion Reflex

Dorsiflexion Reflex

Stimulation of the central portion of the plantar surface of the heel results in dorsiflexion of the foot and this reflex will occur when an upright subject is displaced backwards. The main muscle involved in this reflex is the tibialis anterior although involvement of the toe extensors is frequently observed.

Figure 11
Movement Resulting in the Dorsiflexion Reflex

The reason babies have these inborn reflexes is thought to be in order to facilitate standing balance and gait. As children begin to attempt upright activities they must learn to interpret plantar sensory input and be able to react to this to maintain balance (Bobath & Bobath, 1962). These early stages of exploration are facilitated by the tonic reflexes which act as righting reactions working to return the child to a balanced position should their centre of gravity be displaced in any direction. It would not be beneficial however for these reflexes to persist as they would interfere with the development of normal voluntary movements. Fiorentino, (1981) suggested that as a child matures primitive reflexes are integrated by inhibitory control which then allows the development of a wider range of voluntary movements.

Duncan (1960) studied the tonic reflexes of the foot in one hundred and fifty children with cerebral palsy and fifty normal subjects of all ages. In the investigation a small electrical vibrator was held against each of the reflexogenous areas of the foot and the duration of the reflex was measured. The results showed that at birth the size of the reflex areas in normal children is extensive but with maturation this diminishes rapidly. In children with cerebral palsy however, the reflex can remain active for many years and the areas can spread resulting in occasional cases where the whole of the foot is involved. Duncan (1960) reported that the persistence of such extensive reflexogenous areas was suggestive of delayed cortical maturation.

1.4.1 Implications for Inhibitive Casting

In 1983, Duncan and Mott reported on the significance of the tonic reflexes of the foot in relation to children with cerebral palsy and the way in which they believed inhibitive casting was able to control these reflexes. The authors described a technique for the manufacture of inhibitive casts which incorporated a 'sculptured' footplate aimed at providing good heel alignment and reducing the pressure in reflexogenous areas of overactive tonic reflexes (Duncan and Mott, 1983). From this early work inhibitive casts and orthoses have developed over many years and maintain the contoured footplate as the most important feature of their design.

The contoured footplate is constructed by creating areas which are elevated in the base of the splint which rise up into the arches of the foot. In addition there are other areas which are hollowed out so that the foot sinks into the base of the splint, the overall result being that of total contact between the foot and the base of the cast or orthosis (Lohman & Goldstein, 1993).

When weight bearing using a traditional cast or orthosis with a flat footplate, only limited areas of the foot are in contact with the footplate and hence take the weight of the subject, as shown in Figure 12. This results in excessive pressure on such areas and in a child with cerebral palsy where reflexes areas persist this would result in a hypertonic reflex action being exhibited. By using a contoured footplate, the whole of the plantar surface of the foot becomes weight bearing. This distributes the pressure more evenly throughout the surface of the foot and most importantly reduces pressure in any reflex areas. In this manner such casts and orthoses are thought to inhibit high levels of tone in the muscles of the lower limb.

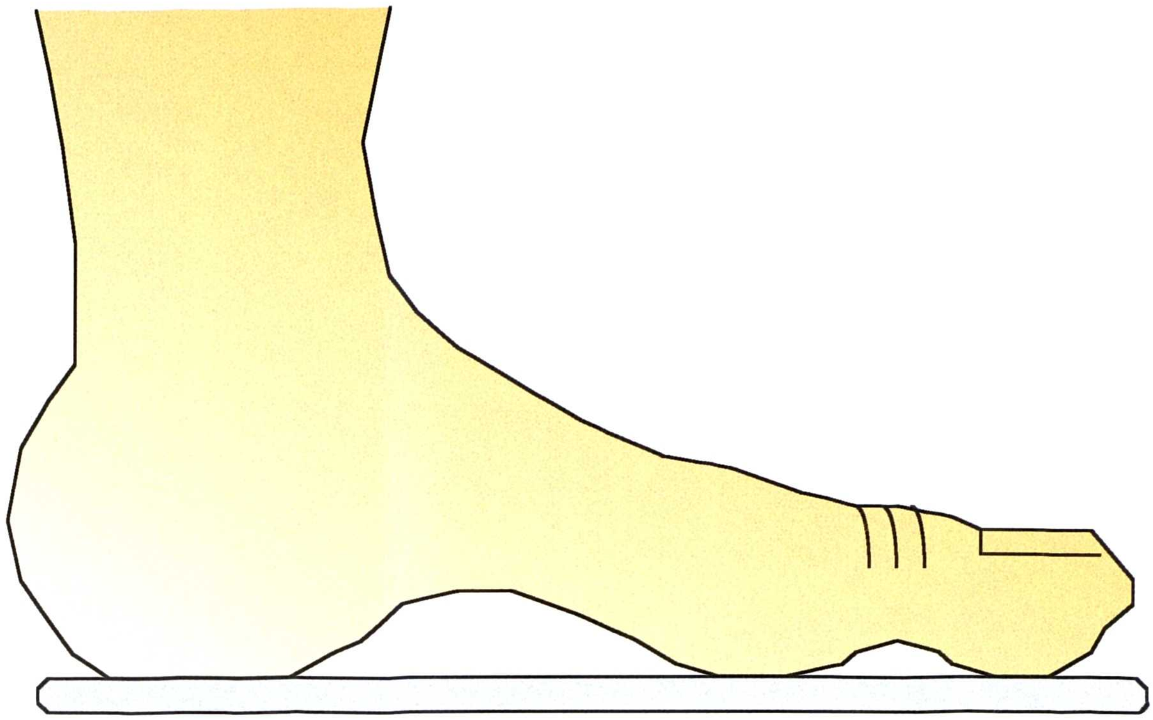


Figure 12
Weight Bearing Areas of the Foot using Traditional Casts and Orthoses

When using a contoured footplate as illustrated in Figure 13, there are two areas which are hollowed out to relieve pressure; under the metatarsal head pads and under the calcaneous. Hylton (1989) described routing to a depth of 1/8" under these areas in order to provide stability and support and maintain neutral alignment of the foot.

The areas which are raised in the footplate, and hence take pressure off the normal weight bearing areas, are the longitudinal arch, peroneal notch and the area proximal to the metatarsal heads as shown in Figure 13. The two built up areas in the longitudinal arch and peroneal notch provide support and stability to the rearfoot and subtalar joint. They hold the foot in subtalar neutral and work to reduce tonic contractions which increase varus or valgus foot deformation.

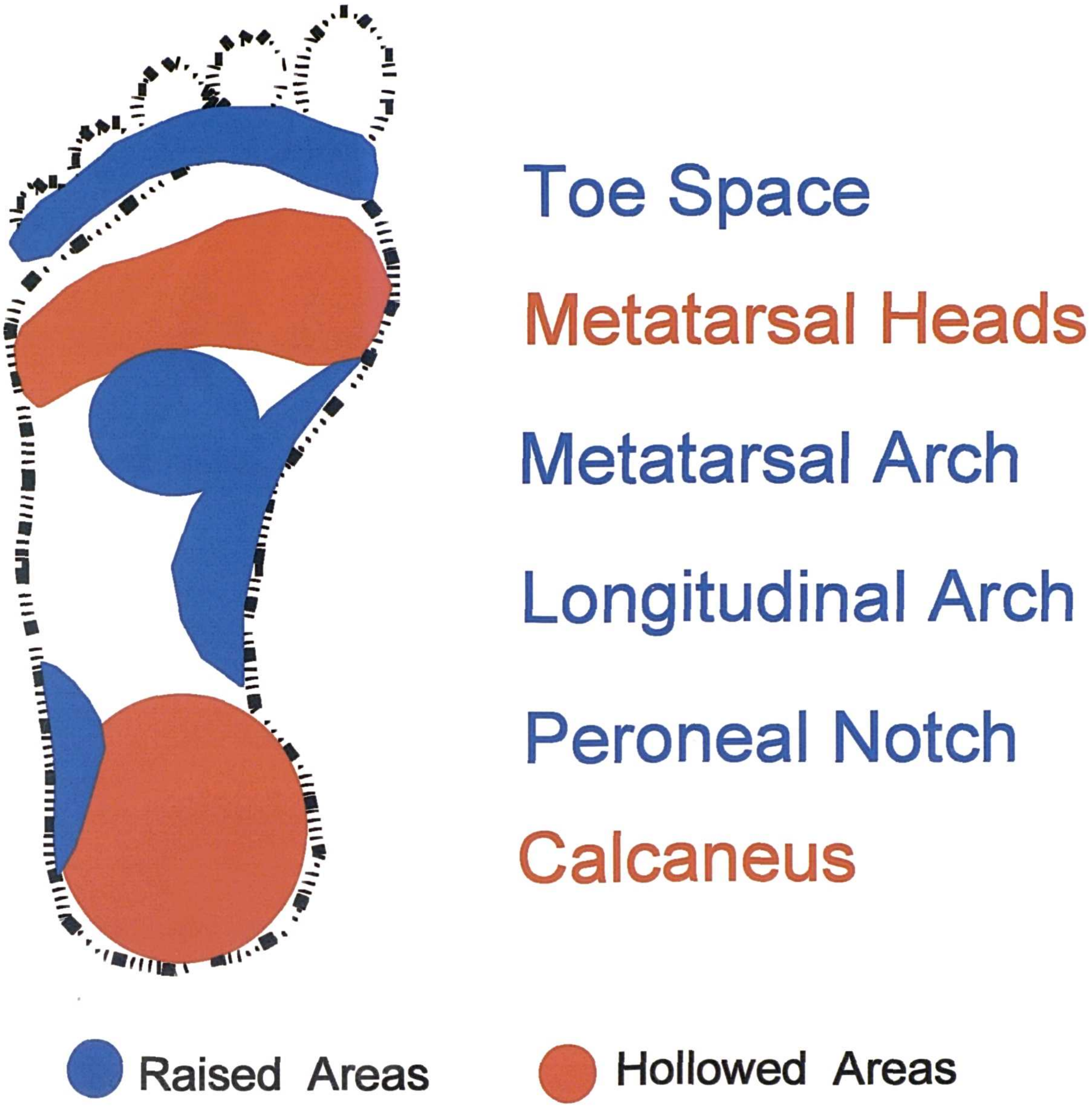


Figure 13
The Contoured Footplate

The area proximal to the metatarsal heads, which is sometimes described as the metatarsal arch, is an area of soft tissue The elevation of the footplate into this area results in improved midline forefoot stability and helps the control of the toes. Improving the positioning of the foot in this way can facilitate better knee, hip and trunk midline alignment.

In addition to these areas, a plaster build up beneath the toes is sometimes used to maintain the toes horizontally in dorsiflexion. This position allows both dorsiflexion and plantarflexion to occur thus promoting active balancing at the metaphalangeal joints.

When considering the aims and benefits of using contoured footplates it is important to remember that children who have cerebral palsy will never have experienced the sensation of normal posture, balance and locomotion. By contouring the footplate it is envisaged that a prolonged and more normal proprioceptive feedback will be provided to the child as they stand or move, thus enabling them to acquire more normal movement patterns.

1.5 The History of Inhibitive Casting

Plaster casts designed specifically for reducing spasticity in children with cerebral palsy have been used in the USA since the early 1970s. Experimentation over a number of years has led to various features being incorporated into the casts including bivalving, hyperextending the toes, and footplate contouring for both long leg and short leg casts. Much of the initial work in contoured footplates has been carried out by Nancy Hylton at the Children's Orthopaedic Hospital in Seattle, USA where the casts eventually became known as inhibitive casts. At this centre many children with different types of cerebral palsy were cast and monitored over several years by Hylton and her colleges. Some of the improvements observed and documented include a reduction in hypertonus, increased freedom to move in all situations, marked reduction in associated reactions and a decrease in fear and increase in confidence (Hylton, 1990).

Once information about this new type of cast had been shared with other physical therapy groups, further centres within the USA were able to begin experimenting with the technique, although at this stage the novel footplate design was still restricted to long leg casts. It was during this time that the term 'inhibitive casting' was first used, and in 1983, Duncan and Mott described their proposed neurophysiological explanation for the results which were being observed. This link between the tonic reflexes of the foot and the contoured footplate in inhibitive casts led to a greater understanding of the techniques and further modifications in the design.

The development of short leg or ankle height casts was again led by the team working in Seattle in the mid 1970s. These splints were initially tried out on those children who exhibited mild tone problems, but were then extended and used as a standard design for all levels of hypertonus. Ankle height casts had sections cut away at the front and the back of the splint which allowed the children some plantar and dorsiflexion, whilst maintaining good medial-lateral control. Such casts were initially used in cases of very mild tone problems, but this was later expanded to become the standard style chosen for even those patients with severe hypertonus.

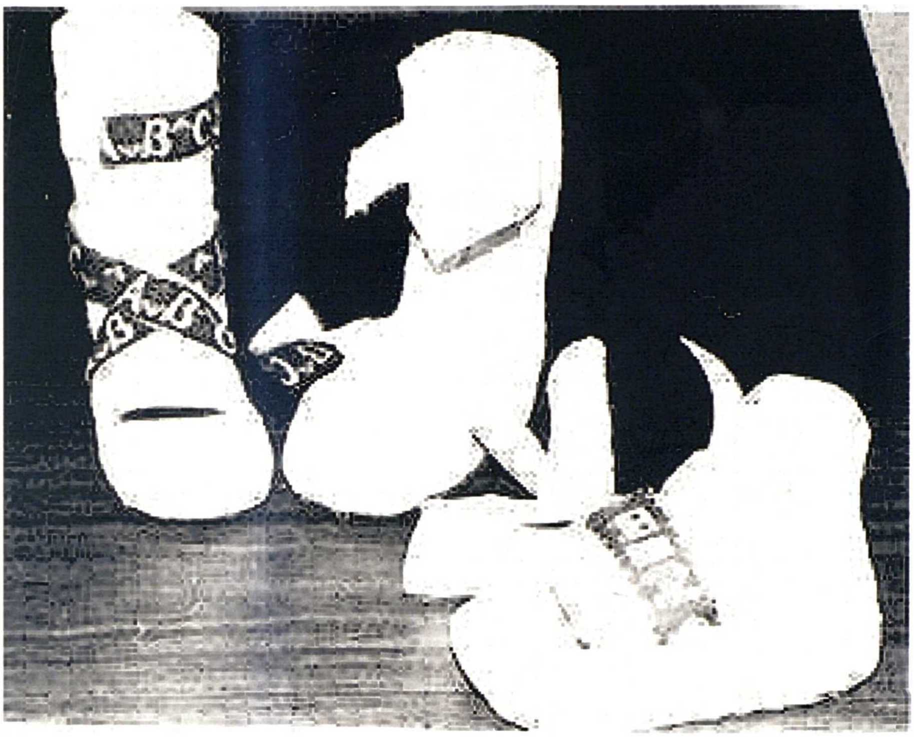


Figure 14
Long Leg and Ankle Height Inhibitive Casts (Duncan & Mott, 1983)

The contouring of the footboard was also refined as the effects of the orthoses in the reduction in tone in more children were monitored. The routed areas were expanded to allow the whole of the metatarsal heads and heel areas to sit completely within the footboard which not only reduced the tone, but was then able to promote the stability of the foot. The toe area which had initially been cast in dorsiflexion at above horizontal, was modified to being cast at horizontal where the toes could then become active in balance control.

Hylton (1990) described how in 1984 the importance of the build up under the peroneal notch was observed, leading to a greater understanding of its relation to midline control of the subtalar joint. It was during this year that there was also a change of name from inhibitive to dynamic casting.

The use of inhibitive casts has diminished during the last decade with the most recent developments being observed in the field of orthotics. In some centres however, dynamic casting techniques continue to be used as an initial phase of intervention before progressing to orthoses (Cusick & Sussman, 1982).

1.6 The Development of Dynamic Ankle Foot Orthoses

During the late 1970s the principles behind the inhibitive splinting techniques were applied to field of orthotics, resulting in the first ankle-foot orthoses being manufactured which incorporated inhibitive contouring. Early work was carried out at the Children's Therapy Unit at the Good Samaritans Medical Centre, and the Children's Therapy Centre, Kent, USA (Hylton, 1990). Here, the first splints produced were not dissimilar to the short leg casts and were effectively short leg AFOs with the contoured footplate built into the base of the orthosis. Gradually the new techniques which had been used on the inhibitive splints filtered through to the orthoses and eventually these too began to take on the ankle-height style allowing some movement through plantar and dorsiflexion. Corresponding to the change in name from inhibitive to dynamic casts, the new ankle-foot orthoses became known as Dynamic Ankle-Foot Orthoses (DAFOs).

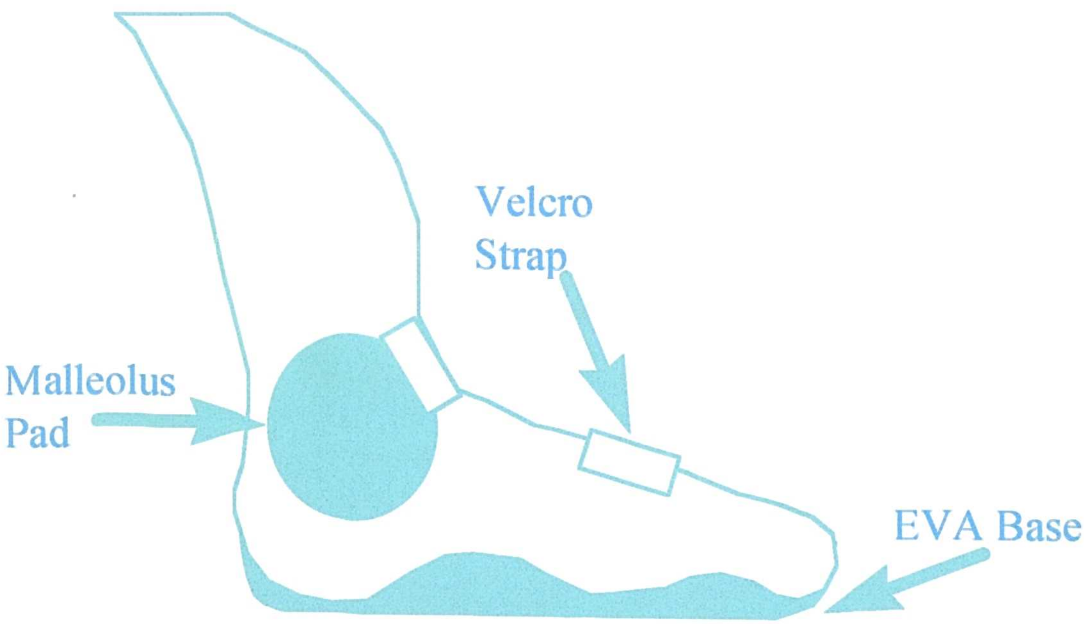


Figure 15
The Early Design of DAFOs

Originally the DAFOs had a solid back extending 2-3 inches above the ankle which allowed dorsiflexion only. Straps were also applied to hold the foot securely in position, and in particular to hold the foot firmly down onto the footplate. Figure 15, illustrates the design of the early DAFOs, made from polypropylene with an EVA base.

During the early 1980s, further modifications were made to the orthoses as centres began experimenting with different trim lines and the thickness of the plastic used in the manufacture. The cut away sections became lower and were also used at the back of the splint allowing some plantarflexion. Additionally the polypropylene was pulled thinner making the splint more tolerable by those children who exhibited severe tonal problems.

By the mid 1980s, a full range of splints were available for children with most levels of tonal problems. In fact those considered to be very mild cases were beginning to be fitted with Dynamic Foot Orthoses (Figure 16) as the trim lines were taken very low when control around the ankle was no longer required. For those patients who were gaining balance and voluntary control this provided them with a smooth transition through the splints towards little or no orthotic support.

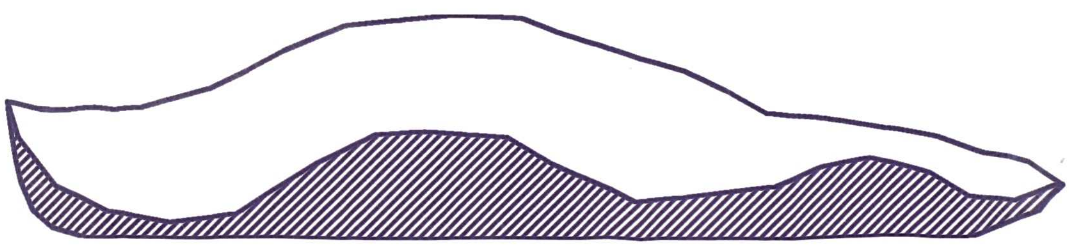


Figure 16
Dynamic Foot Orthosis

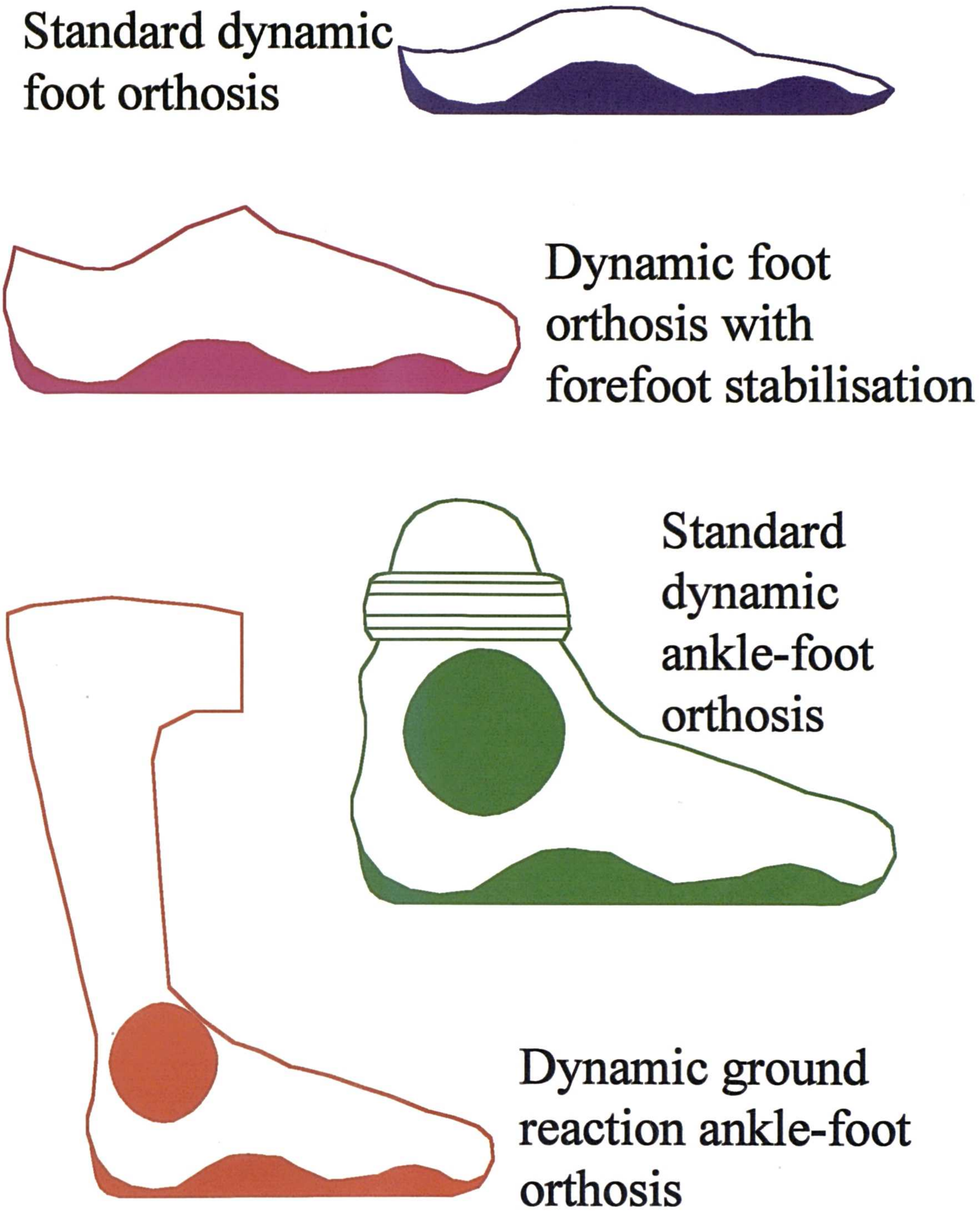


Figure 17
Four Types of Dynamic Orthoses Available

Dynamic Ankle-Foot, and Foot, Orthoses are now available in a wide range of designs and can effectively be purpose made to suit the individual requirements of every child. Figure 17, illustrates some of this range although as every centre/company involved makes orthoses with slightly different characteristics, these illustrations can only act as a guide to the basic types available.

DAFOs are now regularly used throughout the USA and Europe with the orthoses finally being introduced into the UK in the early 1990s. As each centre experiments with and develops the casting techniques and orthosis designs, a whole range of variations on the original DAFOs has emerged. Additionally with alterations to the design, centres have continually renamed the orthoses and there now exist publications describing: neurophysiological, tone inhibiting, tone reducing, tone relieving, functional and dynamic orthoses (Ford et al., 1986; Carlson, 1984; Watt et al., 1986). Although not identical, these splints all have the same origins and work on the same principles, but reflect the variation in techniques across centres.

The most recent development in DAFO manufacture has been the expansion of these orthotics into the commercial sector with orthotic companies now moving into this field. Although this means that more children have the opportunity to be provided with DAFOs, as they can be issued through a school physiotherapist/orthotist, rather than a specialist unit based in a hospital, there is a danger of decreasing the quality of the orthotics by using this avenue. In many cases pre-fabricated 'off the shelf' footboards are used and then incorporated into the cast, to be posted on to the manufacturer for completion. Whilst this may be a quick and easy method of producing the orthoses, one

COMPLETE FAMILY-MED ORTHOTICS

"Complete foot and arch support systems"

TECHNICAL DATA | WHAT PEOPLE SAY | ABOUT C.F.M.O. | ORDER NOW! | E-MAIL US!

www.footandback.com

HOW TO ORDER

How can I order my C.F.M. ORTHOTICS?

1) When you make your order, using our secure online form, you will promptly receive a Complete Order Kit to take your foot measurements. Each Kit consist of: (1) Two impression foam trays (2) Two moisture sensitive print papers (a simple, advanced, extremely effective unit for sizing), (3) Illustrated step by step instructions, (4) A personal Data Sheet.

2) Upon receiving your Kit, simply follow the Step by Step instructions, take an imprint of your feet, answer the questions on your personal Data Sheet and mail them back to Complete Family-Med Orthotics.

3) Our technicians will perform a foot analysis and will send you their recommendations. When you sen us your order, the Orthotics are then **custom fit to your specific requirements** and returned to you on PRIORITY BASIS!

THE SOONER YOU ORDER, THE SOONER YOU WILL BE ENJOYING YOUR CUSTOM ORTHOTICS WITH EVERY STEP!

12 YEAR GUARANTEE!
COMPLETE FAMILY-MED ORTHOTICS
CARRY A 12 YEAR GUARANTEE
This covers full replacement of orthotics at no extra charge if original pair loses form or flexibility with normal use

CLICK HERE TO ORDER NOW!

Technical Details | What Customers say | Order C.F.M. Orthotics | About C.F.M.O. INC. | E-Mail us

Never look at tolerance tables again!
This high quality plastic pocket guide is all you need!
(www.tolerances.com)

FREEDOM FABRICATION

Tone Reducing Ankle Foot Orthoses

Over the past five years the field of orthotics has seen a marked increase in the acceptance and use of tone reducing orthoses. We at Freedom Fabrication have worked hard to put together a group of designs which meet the needs of the majority of patients encountered, and have made available to you an array of standard designs. However, we know the only person who can best judge your patients' needs is you. Therefore, we do our best to fabricate whatever you require.

All of our tone reducing orthoses can be fabricated from your mold using your custom foot plates or from conventional circumferential casts. Nevertheless, accuracy is imperative due to the precise nature of these devices. For this reason, please feel free to contact us for measurement forms and additional information on casting procedures when necessary.

We have found that through the use of colored foams, fasteners, and other decorative accents you often can increase patient acceptability and compliance. Please ask for a current color sample when considering these options.

Send E-mail to Freedom Fabrication

Return to the Freedom Fabrication Home Page

Figure 18
Orthotics Over the Internet

must be cautious of moving in such a direction when the great benefit of these orthoses is their intimate mould with the foot.

The ultimate step in taking advantage of the popularity of such orthoses is the emergence of DIY orthotics which are now available over the Internet. At particular sites you are invited to take your own impression using a DIY kit (Figure 18) and post that on to the manufacturers who will make up the necessary orthotics for you. Although DAFOs have not yet reached this stage, alarmingly one company have a standard set of designs available to purchase 'off the shelf' and are openly inviting orthotists to use conventional casts and a measurement form, from which they will be happy to manufacture Tone Reducing AFOs (Figure 18).

If the success of these orthoses truly lies in the intimate fit and intricacy of the design then this is certainly one road which should be avoided. The highest standards should be maintained if we are to ensure that each patient receives the best possible treatment and has the greatest opportunity for success with their orthosis.

1.7 Clinical Observations on Dynamic Casts and Orthoses

Some of the earliest published reports on inhibitive casting began to emerge in the late 1970s, and took the form of clinical observations reported in the main by paediatric physiotherapists in the USA where these techniques were being pioneered. Unfortunately with the spread of use from inhibitive casts to the more popular inhibitive orthoses the published literature very rarely ventured into the scientific realm. Thus most of the information we have today is based on the clinical opinion of a physical therapist, who in many cases has acted not only as therapist, but also as orthotist and gait analyst.

In 1979, Sussman and Cusick reported on a program which had been running at the Children's Rehabilitation Centre of the University of Virgina for the previous two years. There they had recruited almost 100 children with cerebral palsy and placed them into a treatment program which involved the use of inhibitive casts for 42 days, 2 weeks of intensive therapy, family training on handling and management of the child, adaptive seating, standing and mobility aids along with several types of AFOs once the casts had been removed. The authors outlined the gains which were observed in 52 of the children in terms of their ambulatory status and reported improvements in the quality of movement and head and trunk control. However, these changes could not be quantified. In conclusion it was suggested that the casts were a useful part of the full therapy program although the work could not be used to establish whether the casts actually had any direct effect on the ambulatory status of the children.

Zachazewski (1982) followed the design of a tone-inhibiting cast similar to that which had earlier been described by Sussman and Cusick (1979), but used an adult patient who had sustained a head injury as the result of a car accident. The patient wore casts for four weeks, after which time a set of moulded polypropylene AFOs were constructed incorporating the tone-inhibiting characteristics of the casts. Before and after each of the interventions the patient was analysed using observational gait techniques, by a physical therapist. This analysis reported a number of positive changes including the presence of heel-strike and the development of all phases of gait closer to normal patterns. They concluded that such splints and orthoses should be examined further using a greater number of subjects and concentrating on the electromyogram to determine their effect on the muscle groups involved.

The use of inhibitive casting, particularly as an adjunct to physiotherapy, was questioned by Carlson (1984) who reviewed the published literature and the theories behind the design of such casts and orthoses. Amongst some of the theories put forward was the suggestion that more appropriate patterns of muscle co-ordination are achieved by increased mechanical stability and controlled bony alignment resulting in the elimination of compensatory hypertonus to achieve stability. Carlson (1984) concluded that although some of the literature indicated positive effects of casting, there was a need for more objective studies to determine the exact nature of such changes.

The effect of an inhibitive AFO on the standing balance of a 4 years old cerebral palsied child was measured by Harris and Riffle (1986) in a single-subject, alternating treatments designed investigation. The work looked at a child who had worn a number of inhibitive casts over a two year period and had then moved on to inhibitive orthoses which he had been wearing for a year prior to the study. Initially the barefoot standing balance of the child was measured using a stopwatch during five sessions. A new inhibitive orthosis was then provided and standing balance was measured both barefoot and in the device on a further five occasions. The authors reported a definite improvement in the subjects ability to stand independently whilst wearing the orthoses and described the subject's posture as more symmetrical and with an apparently more even distribution of weight between the limbs.

In 1987, Bronkhorst and Lamb reported on another orthosis which had been designed using some of the principles of the tone-inhibitive casting techniques. This orthosis was designed to reduce spasticity and had been used at the West Texas Rehabilitation Centre for some 10 years. Two single case studies were presented, one a two years old cerebral palsied child and the other a 20 years old head injury patient. In the case of the child the authors reported the emergence of a heel-toe gait which had carry over allowing him to walk in this manner without the orthosis. In the adult patient, following a regime of gradually altering the orthosis along with adjusting the number of hours per day it was worn over a four month period, he was able to progress from ambulating with the help of two physical therapists to a condition where he no longer required the orthosis and could cope using only a quad cane.

In 1990, Hylton published a review of dynamic casting and orthotics through which she shared her clinical experiences of these techniques and devices. Having been involved in the some of the earliest work in the 1970s and in the subsequent developments from casts to orthoses, she was able to provide an interesting insight into the variety of patients who had been treated and the manner in which they had benefited. Hylton (1990) also commented on the scepticism she felt existed in relation to the orthoses, particularly from academics within the field, and noted that this would remain whilst there was no significant research to prove clinical changes. The author acknowledged that most published reports were single case studies and called for research to be initiated which would objectively compare different types of orthotic management for different patient populations.

Further single case studies were still being reported into the 1990s despite the continuous calls of researchers for work to be carried out looking at larger numbers of subjects. One such study was undertaken by Diamond and Ottenbach (1990) who looked at the effect of a tone inhibiting dynamic AFO on the stride characteristics of an adult with hemiparesis. The investigation followed an alternating treatment design similar to that reported previously by Harris and Riffle (1986) which studied the subject in three conditions: (1) Barefoot (2) Standard AFO (3) Dynamic AFO. The authors reported that walking velocity and step length were 'significantly superior' with the dynamic orthosis and suggested that it was the greater attention given to the support and alignment of the foot with the DAFO which contributed to the improvement in ambulation.

A further single case study was reported by Mueller et al. (1992) who investigated the foot loading patterns of a hemiplegic adult whilst wearing a tone inhibiting dynamic AFO. The study measured several variables using an EMED-SF Pressure Platform which maps the progression of foot loading using a pressure sensitive mat. The measurements were taken on two separate occasions with the patient walking both barefoot and using the orthosis at each. With the orthosis the investigators reported an increase in both the total foot force and the total foot area and attributed this to a possible reduction in spasticity induced postures which result in a less complete contact of the plantar surface. Another interesting finding was the possibility of carryover effects of the orthoses as the loading patterns were improved in the barefoot condition after wearing the orthosis for a period of 14 days. The authors concluded that despite being a single case study, positive effects had been illustrated and that work involving larger subject groups would be valuable.

Following a period of collaboration with Hylton, a British Physiotherapist Curtis (1995) reported on clinical work and experiences using DAFOs which had been constructed to the design and specifications promoted by Hylton. A number of claims were made regarding the effects of such orthoses including a reduction in associated reactions, falling over less, and in several cases, fisted/hemiplegic hands opened more. Unfortunately despite having reported on clinical observations with twelve children no quantitative measures were made, and the author acknowledged that to gain any real understanding of DAFOs the initiation of a scientific study was necessary.

1.8 Quantitative Research on Dynamic Casts and Orthoses.

Very few studies looking at dynamic casts and orthoses have been based on more than single case studies or clinical observations. This is no doubt a reflection of both the scepticism of many clinicians regarding the value of gait analysis in previous years, combined with the immense difficulty in assessing a treatment which, by its very nature, is individual to each patient.

In 1980, Mott et al. made a presentation to the American Academy of Cerebral Palsy and Developmental Medicine describing their use of inhibitive casts as part of a neurodevelopmental program. Later Duncan and Mott (1983) published results of the program reporting on 111 children who had been treated using inhibitive casting over a period of three years between 1975 and 1978. To evaluate improvement they initially grouped them in terms of ambulatory status pre and post casting and reported how the percentage of children in each group altered. From 68% being non-walkers prior to casting only 14% remained at this status post-casting and the group of independent walkers rose from 28% prior to casting to 64% post-casting. The Locomotor Prognosis System (Bleck, 1975) was also used to evaluate improvement by the authors. For 86 children who had a poor ambulatory prognosis (they scored two points or more), 60% became ambulatory after being treated with the inhibitive casts and being involved in a neurodevelopment program. Although the evaluations used in this investigation could not be described as scientific, the authors produced the first attempt to move away from single case studies and to more quantitative methods of assessment.

Otis et al (1985) published an investigation which examined plantarflexor spasticity whilst subjects were wearing tone-reducing casts. The authors studied eight spastic diplegic children between the ages of 3 and 6 in two pre and two post casting assessment sessions. Resistance to passive dorsiflexion was measured on each occasion using an isokinetic dynamometer modified with a torque sensor at angular velocities of 0, 12, 60 and 120 $°s^{-1}$. The results showed that wearing the casts for 5 weeks did alter the stretch-related aspects of the spastic muscles. The authors acknowledged however that these results do not provide any information on important functional variables, and that to obtain this data more objective gait assessments are required.

A further investigation (Haigh, 1989) evaluated the effects of Dynamic AFOs on gait. For this study 4 children who were diagnosed as having either cerebral palsy or hypertonia had their gait analysed through four phases, the first and third wearing no orthosis and the second and fourth wearing a DAFO. Between each of the phases an adjustment period was allowed. The measurements made included; time spent in single and double limb stance, knee extension and ankle dorsiflexion during initial contact and mid stance, and the type of initial foot contact. The author reported the most striking effect of the DAFO to have been the improvement in initial foot contact (3 out of the 4 subjects), however the results reflect the great variability between patients with some improving on particular variables whilst others became worse or exhibited no change. As a result of the investigation design, Haigh (1989) was able to show that for some variables there may have been a carry over effect once the DAFO was removed and recommended that future studies investigate this further.

The effects of using inhibitory casts and orthoses on the bony alignment of the foot were examined by Ricks and Eilert (1993). By this time both interventions were becoming widely used within the USA and had been well reported (Carlson, 1984; Hylton, 1990) within the literature. The authors compared the bony alignment during weight-bearing of 27 children both in and out of one of three types of device: (1) Inhibitory casts (2) Static AFOs (3) Articulated AFOs. Despite outlining their investigation as a descriptive study, the authors used X-rays taken of the feet whilst weight-bearing and from these measured five angles and then compared the with and without device values using paired t-tests. The results showed that there were no significant differences in the bony alignment of the foot between any of the devices used, suggesting that improved bony alignment was not the manner in which inhibitive casts achieve improvements in gait. The authors state that the question still remains as to how such devices work and that it is "important to identify what aspects of the inhibitory devices make them effective, so that they can be constructed to give optimal benefit to the child" (Ricks and Eilert, 1993).

1.9 The Gait Cycle

Normal walking occurs when the body is propelled forwards by the independent motion of both lower limbs. The human leg comprises three segments; the foot, the shank and the largest, the thigh, with the latter two exhibiting the cyclical motion of a pendulum, one fixed at the hip and the other at the knee (Clark 1995). As the limbs move they follow a reciprocal pattern of foot-floor contact with one limb serving as a support whilst the other limb advances ready to provide the new support. This provides the mechanism for the transfer of the body weight forwards from one limb to another (Perry 1992a).

The cyclical motion of the limbs is the basis through which walking is described and analysed, the initial point of which being to identify one *gait cycle* or the motion of one limb through two sequential identical positions. The term *stride* is often used to describe the same period of motion, and in normal walking this constitutes the period from heel strike to heel strike on the same limb. In comparison a *step*, describes the motion which occurs between the position of one limb to an identical position in the other limb e.g. heel strike on the right foot to heel strike on the left foot. A stride therefore consists of two steps.

Once a single gait cycle has been identified it can then be divided for analysis into two phases; stance and swing. Further evaluation is then usually based on the timing of events in each phase as a percentage of the time taken for the whole gait cycle (Sutherland et al., 1994). The stance phase accounts for 62% of the total gait cycle (GC) and comprises of initial contact, limb loading, mid stance, terminal stance and pre-swing. In contrast the swing phase, which accounts for the remaining 38% of the gait cycle (GC), covers initial swing, mid swing and terminal swing (Figure 19).

Figure 20 shows the timing and movements which occur within each phase and illustrates the relative position of both the lower limbs at each of the key stages during the stance and swing phases (adapted from Perry, 1992a). The exact timings of each phase will alter depending on a number of factors including the walking velocity and the age of the subject. All data reported therefore, should be taken as a guide rather than a definitive value as some variations will exist

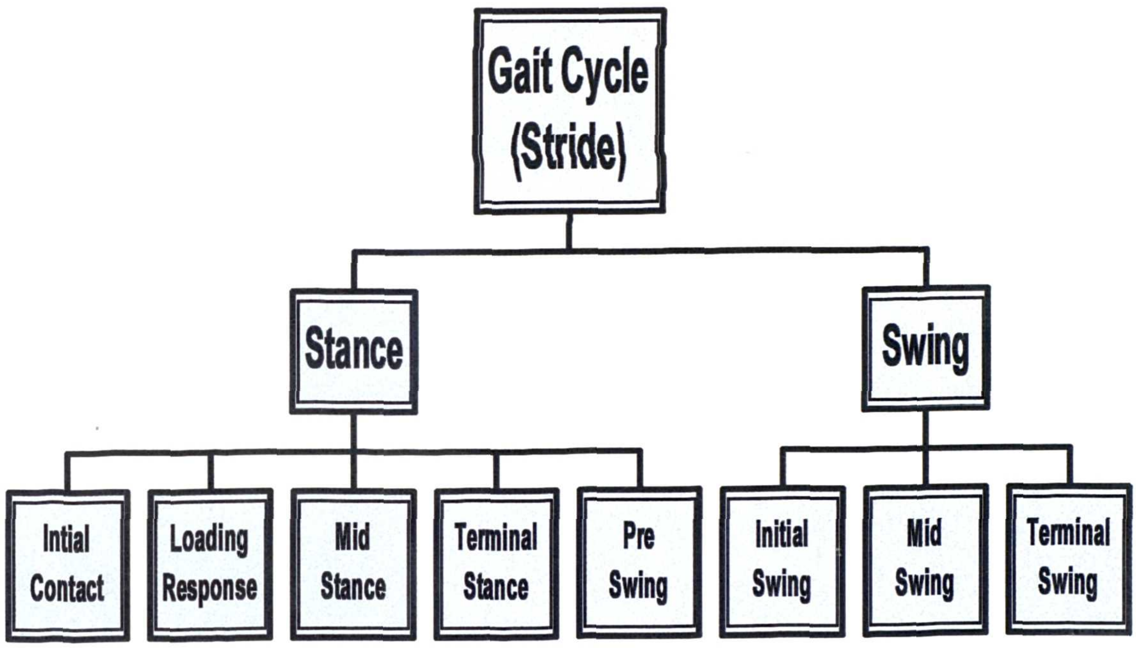


Figure 19
Structure of the Gait Cycle.

Figure 20 **Key Stages in the Gait Cycle**

Stance Phase

Initial Contact **0-2% GC**

Stance phase commences at initial contact where the ankle is at neutral, the knee is extended and the hip is flexed. In normal subjects the contact with the ground is made by the heel and occurs momentarily.

Loading Response **0-10% GC**

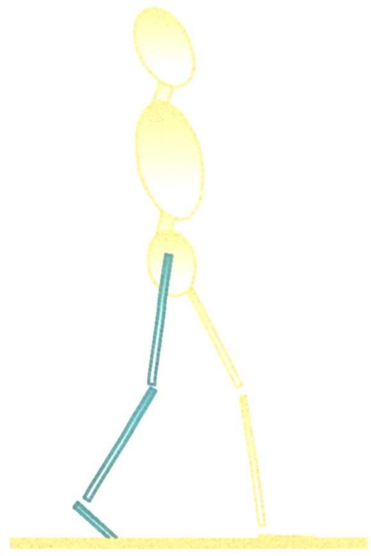
This is the period of double limb support and continues through until the opposite limb is in its pre-swing phase. The heel is used as a rocker for transfer of the body weight to the stance limb and the knee is flexed for shock absorption.

Mid Stance **10-30% GC**

This is the initial period of single limb support, commencing when the opposite limb leaves the ground. The ankle dorsiflexes, while the hip and knee extend, advancing the limb and body weight over the forefoot.

Terminal Stance 30-50% GC

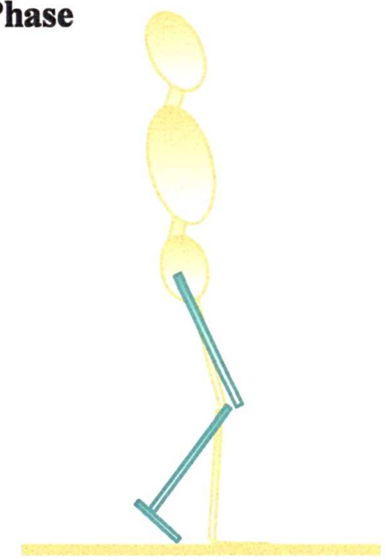
The is the second period of single limb support commencing as the heel begins to rise. The limb and body weight progress over the forefoot with the hip and knee extending to allow forward progression of the trunk.



Pre-Swing 50-62% GC

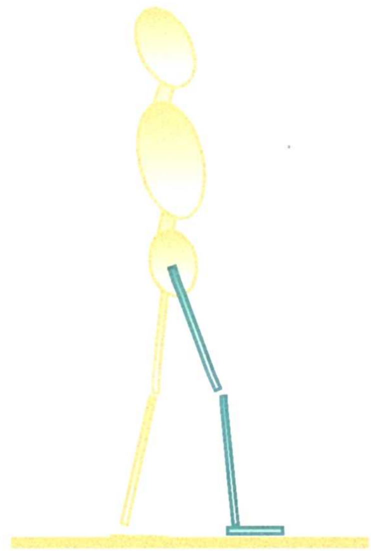
This is the final part of the stance phase and begins as the opposite limb makes contact with the ground (a second double support period). The ankle plantarflexes, and the knee flexes progressing the body weight forwards, loading the opposite limb.

Swing Phase



Initial Swing **62-73% GC**

This period commences when the foot leaves the floor. The limb is advanced as the hip and knee flex and the ankle begins to dorsiflex resulting in foot clearance. The foot swings through and comes opposite the other limb which is in mid stance.



Mid Swing **73-87% GC**

Mid swing continues the limb advancement and foot clearance. The hips flex further moving the limb forward of the centre of gravity. The knee begins to extend whilst the ankle dorsiflexes until the limb is forward with the tibia vertical.

Terminal Swing **87-100% GC**

The final period of the swing phase occurs as the limb is further advanced by knee extension. The hip remains flexed and the ankle dorsiflexed as the limb moves ahead of the thigh in preparation for heel strike.

1.10 Ground Reaction Vector

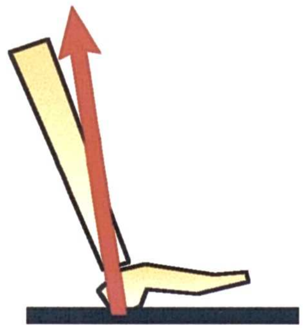
The description and analysis of gait can be greatly enhanced by the use of kinetic information allowing examination of the way both internal and external forces interact during the gait cycle. In the simplest form, the forces between the foot and the ground can be measured by the use of a force plate positioned level to the surface of a walkway over which ambulation occurs. Such plates can be used in a variety of sizes and configurations and determine the magnitude and direction of the ground reaction force in three components: vertical, mediolateral and anterior-posterior.

During normal gait the ground reaction vector changes, in the position of its origin along the length of the foot, in its angle and in its magnitude (Figure 21). In normal subjects the vector passes close to or through the joint centres of the lower limb, thus reducing the moment arm at each joint (Butler & Nene, 1991). Any vector which passes behind the knee joint creates a knee flexing moment and vectors passing in front of the knee create a knee extending moment.

Figure 21 illustrates the position of the ground reaction vector during the stance phase of a normal gait cycle. (Adapted from Perry, 1992a)

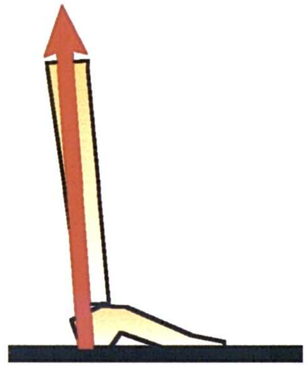
<u>Figure 21</u>
<u>The Position of the Ground Reaction Vector During a Normal Gait Cycle.</u>

Initial Contact



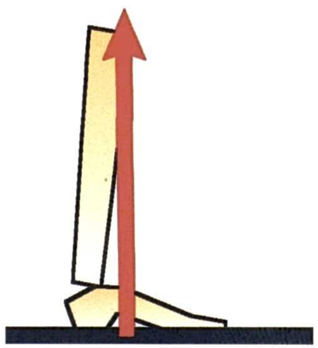
Vector is located posterior to the ankle creating a plantarflexion moment.

Loading Response



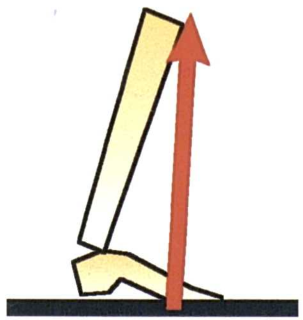
Plantarflexion moment advances the tibia.

Mid Stance



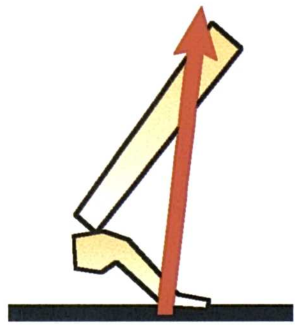
Vector advances forwards through the foot creating dorsiflexion

Terminal Stance



The origin of the vector lies in the forefoot and there is a maximum dorsiflexion torque.

Pre-Swing



Vector lies at the MP joint & passes behind the knee as the tibia advances creating flexion.

A more recent development to the use of force platforms has been the ORLAU Video Vector Generator (Tait and Rose, 1979). Using this, the output of a Kistler force plate can be superimposed on to the monitor picture and video recording of a patient moving along a walkway (Figure 22). This provides a visual representation of the position of the origin of the vector along the foot and illustrates how close to the joint centres of the limb the vector passes.

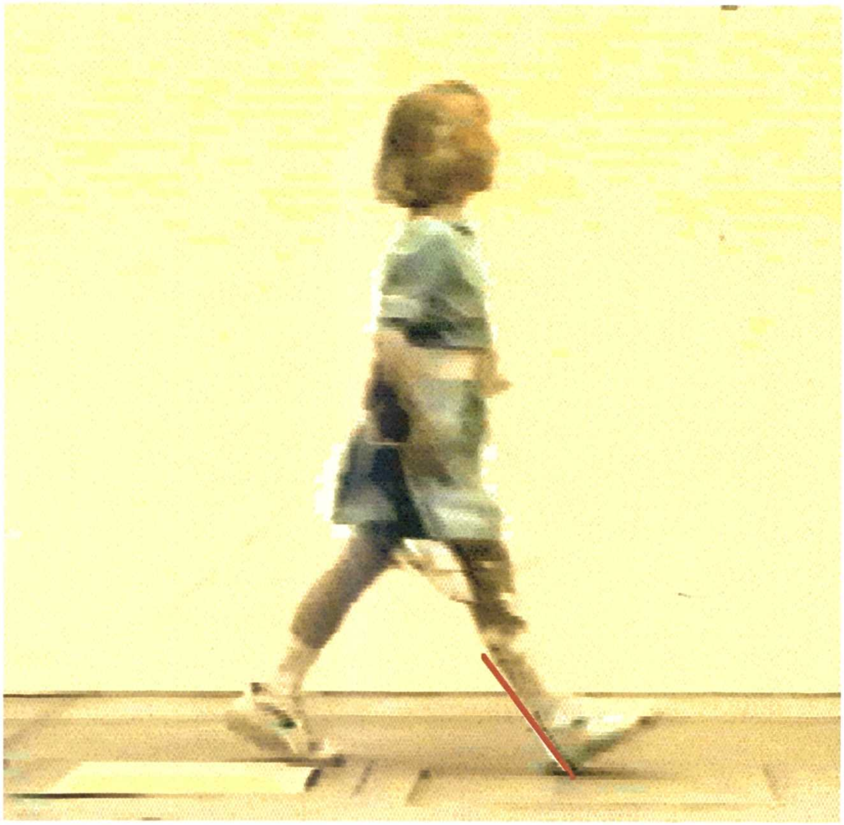


Figure 22
Vector Generator Picture

The Vector Generator is a useful tool for providing visual information on the ground reaction forces during gait. In conjunction with video cameras it can be used to show the ground reaction force in either the sagittal or frontal plane. It is popular in clinical settings where real time information can be provided which is clear and relatively easy to interpret, allowing 'on the spot' adjustments to be made to shoes or orthoses (Stallard, 1987).

1.11 The Electromyogram (EMG)

When a muscle is triggered by an impulse to contract, there are changes in the electrical potential which can be recorded as an electrical signal. An electromyogram is a recording of this electrical signal and is the method by which one can objectively assess when a muscle is active. By using various types of equipment to record an electromyogram it is possible to measure the timing and amplitude of the activity of a muscle. EMG is a valuable tool for the clinician, particularly in neuromuscular disorders where it is advantageous to examine activity during functional tasks. It can aid decision making with regards to treatment programs or surgery and is fundamental in assessing the outcome of such interventions.

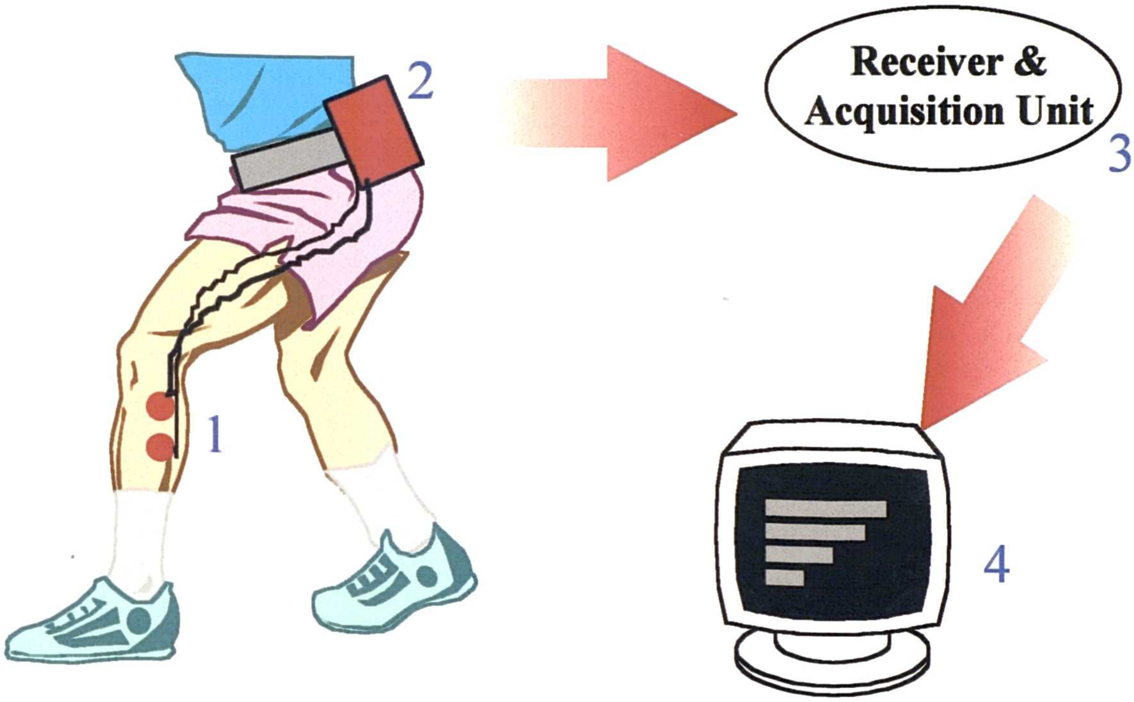
1.11.1 Indwelling Vs Surface Electrodes

There are two methods by which the electrical signals in a muscle can be monitored; via surface or indwelling electrodes. Surface electrodes consist of small metallic discs used with conducting gel placed over the muscle and hence measure the electrical signal through the skin. Indwelling electrodes in comparison can be either needle or wire and are inserted beneath the skin, picking up the signal directly from the muscle. The advantage of using the indwelling technique is that you can access less superficial muscles and there are fewer problems caused by picking up signals from surrounding muscles. However, there are clear disadvantages as a high level of training is required to become proficient at inserting the needle, the procedure can result in pain, the electrodes can displace during walking, and the use of needle electrodes has been shown to alter gait patterns (Young et al., 1989).

The use of surface electrodes has often been criticised as this technique is unable to isolate a single muscle and cannot take measurements from very small or deep muscles. The signal can also suffer from attenuation through the skin surface with factors such as skin thickness, electrode surface area, temperature and cleaning of the skin all having an effect (Winter, 1990). When looking at the magnitude of activity there are also difficulties relating to the position of the electrodes, as changes in the placement can significantly alter the amplitude of the signal recorded. In 1984 Soderberg & Cook reported on the problems with surface EMG and suggested that this technique should only be used to assess the level of muscle activity when a large group of muscles was being studied. For investigations which are involved in the analysis of the temporal characteristics of the EMG signal however, surface electrodes do not pose quite as many problems. Zuniga et al (1969) investigated the effects of different positions of surface electrodes on the EMG signal and found that although the amplitude was altered, the character of the signal remained almost constant. The evidence suggests therefore, that surface EMG is a suitable method for assessing the temporal characteristics of large muscle groups. Despite the criticisms, surface EMG has been used successfully in many investigations, and generally remains the favoured method, as the ethical and moral issues surrounding the use of indwelling electrodes in research often far outweigh the advantages.

1.11.2 Recording an Electromyogram

The recording of an electromyogram is usually made within a hospital or a motion analysis laboratory. Figure 23, shows the equipment and methods by which the EMG is recorded. The illustration shows surface electrodes applied to the subject as this is the most popular method and that used in the present investigation. The signal from the muscle is recorded via the electrodes which are positioned over the muscle belly (1). This signal is then transmitted, via small cables taped to the limb, to the amplifier/transmitter which is a small box fastened to a belt around the subjects waist (2). This box picks up, amplifies and transmits the signals from the electrodes. It incorporates the filtering, offset and gain controls for each of the EMG channels. The modified signals are then transmitted along a 15 m cable to the receiver module and data acquisition unit (3). The receiver module demodulates data and sends it to the data acquisition unit ready for recording, following which it is processed and then displayed on the computer (4).



1 - Electrodes

2 - Amplifier/Transmitter

3 - Receiver module & data acquisition unit

4 - Processing & display device (computer)

Figure 23
Recording an Electromyogram

1.12 Temporal Analysis of the Electromyogram

The simplest method of analysing electromyograms is to look at their temporal characteristics. This is also the most reliable procedure when using surface electrodes as it is relatively unaffected by inconsistency in electrode placement. The EMG recording looks like a series of spikes which vary in size and intensity (see Figure 24) from which the investigator/clinician must aim to establish when the muscle is active and when it is not. The methods used to do this vary greatly depending on the accuracy of the data required although at present no truly objective criteria exist.

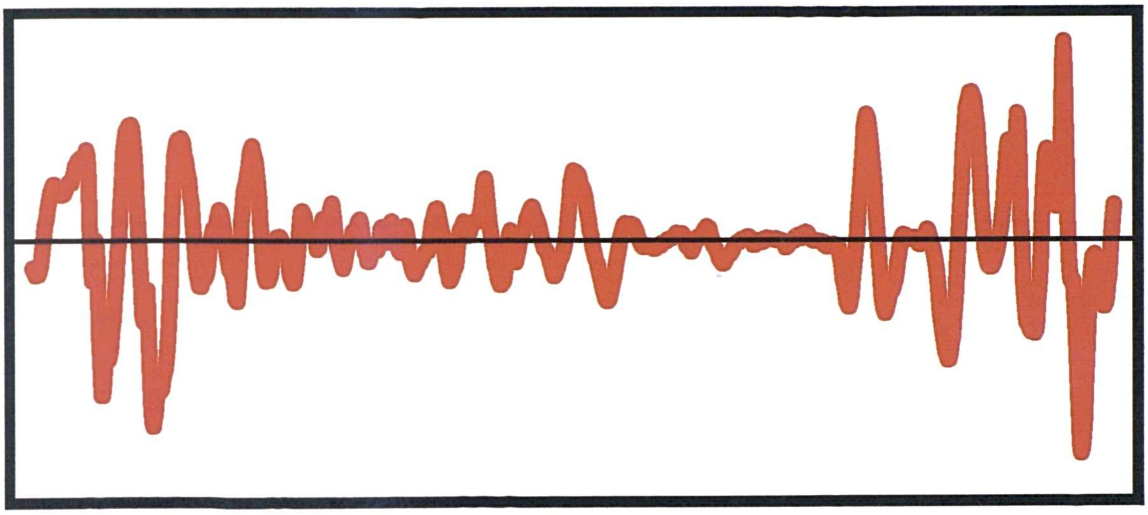


Figure 24
Illustration of an EMG Recording

The simplest technique for analysing the electromyogram is to study it visually and subjectively determine when the muscle is on or off. The activity can then be described in terms of how it deviates from an established normal database. Although descriptive methods are regularly used in clinical settings and can often provide adequate information when studying temporal characteristics, more quantitative methods are often required for scientific investigations and surgical decision making. As every gait cycle will vary in its duration both within and between subjects, the timing of muscle activity must be normalised so that comparisons between subjects or trials can be made. The duration of activity for any one muscle may then be described by reference to one of three intervals; the whole gait cycle, the stance phase or the swing phase. The use of simple foot switches allow investigators to determine all of these intervals and from this information the duration of activity as a percentage of each interval can be established.

In subjects who have pathologic conditions which often result in ambulatory problems, such as children with cerebral palsy, the relative timing of the muscle activity in relation to normal patterns is of paramount importance. A descriptive method for assessing these deviations in activity was reported by Perry (1992b) and is widely used to evaluate timing errors (Table 4).

EMG TIMING ERRORS	
Deviation	**Definition**
Premature	Action begins before normal onset
Prolonged	Action continues beyond the normal cessation time
Continuous	EMG uninterrupted for 90% or more of the gait cycle
Curtailed	Early termination of the EMG
Delayed	Onset later than normal
Absent	EMG of insufficient amplitude or duration
Out of Phase	Swing or stance time reversed

Table 4
EMG Timing Errors

1.12.1 Methods of Interpreting EMG

The are two methods by which the temporal characteristics of an electromyogram can be interpreted. That most often used, and the traditional method, is to use visual interpretation which relies on the experience and judgement of the experimenter/clinician to determine the onset and cessation of activity. The visual method requires the EMG recording of interest to be either displayed on a monitor or printed out as a hard copy. The assessor will then visually determine the onset of activity resulting in very subjective information. This method is that most frequently used in clinical settings when a quick and general impression of the activity provides an adequate understanding.

In more recent years there has been a move away from visual interpretation as the importance of gaining more reliable and scientific methods of analysing data has become an issue. Investigators have recently been involved in the development of computer assisted techniques for determining the onset and cessation of activity. The basis of such techniques, has been to establish a 'threshold' of activity below which the muscle is considered to be inactive. This again leaves the measurements open to subjective influence as there are numerous ways and levels at which to set the threshold. Winter (1984) showed that there were differences in the phasic activity of muscles calculated for 6 subjects, when using 10, 20 and 30 microvolt thresholds to examine the EMGs. Other methods used have been to choose 5% of a maximal contractile effort (Perry, 1992b) or to establish the first set of 25 data points which exceed three standard deviations of the mean baseline values (DiFabio, 1987). As yet objective criteria to determine activation has not been agreed and, with many authors failing to report whether they used even visual or computer analysis, the development of an accurate and reliable system could be many years away.

1.12.2 Normal Temporal Activity

Since the late 1950s many investigations have been carried out which attempted to quantify temporal data on the activity of muscles during walking for normal adults and children (Sutherland et al., 1988, Tata & Peat, 1987). Much of the work was undertaken by Sutherland and other workers at the Shriner's Hospital of San Francisco and eventually led to the creation of a chart defining the active periods of 30 muscles during the gait cycle (Knutson & Soderberg, 1995). This chart still remains in use today and is of great value when studying pathological gait as it is possible to make direct comparisons between patients and normal data. The normal temporal patterns of activity for four muscles relevant to this investigation are illustrated in Figure 25.

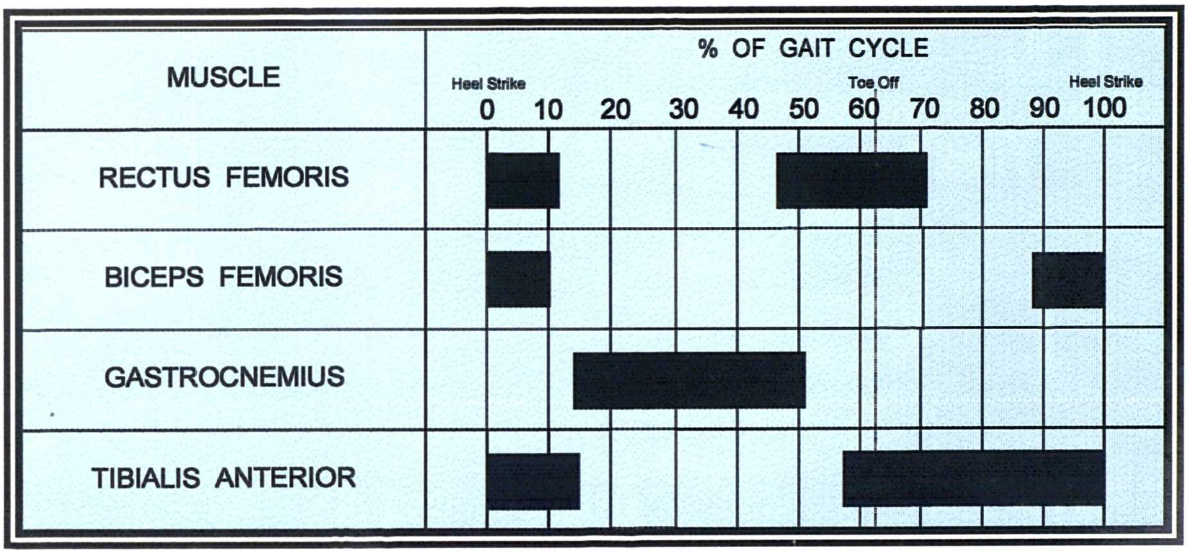


Figure 25
Normal Temporal Activity (Adapted from Knutson & Soderberg, 1995)

1.13 EMG Analysis used with CP Children and Orthoses

Although there is a substantial body of data relating to the EMG patterns of muscles during normal walking, there are relatively few investigations which assess how these differ in children with cerebral palsy (Winter & Yack, 1987; Winter, 1984). Furthermore, studies which examine ankle-foot orthoses and the way these alter the EMG are even more scarce. In particular for tone inhibiting/dynamic casts and orthoses, this kind of analysis would be crucial in determining whether the casts and orthoses work in the neurophysiological manner proposed.

An early study reported by Csongradi, Bleck and Ford (1979) compared 26 normal volunteer children with 32 children who had cerebral palsy. The subjects had EMGs of the quadriceps femoris and medial hamstrings analysed over 10 to 20 gait cycles using a telemetric system and foot switches. The results showed that for the rectus femoris and vastus medialis the children with cerebral palsy had double the normal activity levels. In the medial hamstrings the authors were also able to show an increase in activity well above that of the normal subjects.

Woltering, Guth and Abbink (1979) also looked at EMG patterns in cerebral palsied children and studied the adductors, gluteus medius, quadriceps femoris, semimembranosus, tibialis anterior, and gastrocnemius. The investigation highlighted prolonged activity in the adductor muscles and a substantial amount of cocontraction for the tibialis anterior and gastrocnemius muscles. The authors concluded that the duration of activity in all the muscles was generally prolonged, resulting in the pathological cocontraction of groups which are antagonist to each other (Woltering, Guth and Abbink, 1979).

A further study in this area was published by Brunt and Scarborough in 1988, who reported the findings of an investigation in which they looked at ankle muscle activity in children with cerebral palsy. They assessed thirteen children who were either diplegic or hemiplegic and compared their results with those for normal gait. The authors reported a reduction in tibialis anterior activity during the swing phase of the gait cycle and an increase in the medial hamstring activity during the stance phase. They concluded that such an assessment provides an indispensable contribution when making treatment decisions (Brunt & Scarborough, 1988).

One study which did examine the effects of inhibitive splinting on EMG was reported by Mills (1984). In this investigation 10 limbs were analysed from a patient group of eight brain injured adults, both prior to and whilst wearing an inhibitive splint made of orthoplast or plaster. In addition to EMG recordings, goniometric measurements were also taken of the limb position. The limb postures examined were ankle plantar flexion, elbow flexion and wrist flexion. The results showed that although the limb position altered when wearing the splint, reflecting an elongation of the spastic muscles, there was no change in the activity levels of the muscles. Mills (1984) concluded that although splinting could control postural defects it did not significantly change muscle tone.

In 1990, Lough completed her PhD thesis which investigated the effects of fixed and hinged AFOs on EMG in children with cerebral palsy. Fifteen children were recruited into the investigation and tested under a repeated measures design using Shoes (no

AFOs), Fixed AFOs and Hinged AFOs. Each subject was analysed in a motion analysis laboratory using video analysis, EMG and footswitches. The muscles tested were the vastus lateralis, medial hamstrings, anterior tibialis and lateral gastrocnemius. For each of the test conditions four trials were collected, with all the test conditions being recorded in one session. The EMG data when compared to those reported for normal subjects by Sutherland et al. (1988) showed that in cerebral palsied children the myoelectric activity is higher. The results also illustrated a reciprocal pattern of anterior tibialis and gastrocnemius firing. In relation to the different types of splints however, limited changes in muscle activity were observed despite using a device which had been promoted as inhibiting foot reflexes. The author concluded that, if tone reduction did take place, then it could not be demonstrated by the electromyographic procedures used in the investigation (Lough, 1990).

Electromyographic investigations of casting and orthotic techniques are severely limited at present and the few published do not show favourable results in terms of EMG activity being altered. Despite the request of Mills (1984), for the effects of splinting to be further investigated to aid the understanding of how splinting affects posture, tone and function, it is evident that there is still much work to be done.

Section 2

Research Design

2.1 The Need For Quantitative Research

As discussed in the previous section, Tone Relieving Ankle-Foot Orthoses (TRAFOs) have been used for over 20 years, with their use mainly concentrated within the USA, although this has filtered through to Europe in the past few years. With this considerable record of utilisation one would expect that numerous scientific studies would have been carried out to verify their continued application and quantify any benefits. As the literature has shown however, the majority of published work in this field consists of anecdotal evidence and single subject studies, which although useful, do not provide any scientific evidence to support the use of such orthoses.

Despite the fact that there is little hard evidence to support their use, over the past five years TRAFOs have been readily adopted as a new orthotic technique for the treatment of children with CP in many centres around the UK. Inevitably this soon spread to the commercial sector with TRAFOs / DAFOs becoming one of the most popular orthotic techniques presently used for children with ambulatory problems. This reflects the somewhat non-scientific and more fashion orientated approach to orthotic prescription, which still predominates in the UK.

There is a pressing need to establish primarily whether or not we are providing the best possible treatment for patients, but additionally if the orthoses are not working then other solutions to the problems of hypertonicity need to be investigated. To move forwards in this field there must be quantitative analyses undertaken to investigate what, if any, parameters associated with ambulation are affected by the orthoses and how modifications to the orthoses can affect the outcome. Only once such information is available will it be possible to explore how to optimise orthotic interventions on an individual basis and therefore maximise the benefits of such a treatment regime.

2.1.1 Selecting a Relevant Subject Population.

The North Western Orthotic Unit at Hope Hospital, Salford, was a suitable centre in which to base this investigation as it was one of the first Units in the country to use TRAFOs and both the orthotists and manufacturing technicians were experienced in such techniques. At the time the investigation was being planned and the study designed, over 100 patients had been fitted with TRAFOs from the North Western Orthotic Unit. Based on anecdotal evidence, the staff believed that the splints were successful in relieving tone and improving ambulation in the majority of patients

Although TRAFOs have been used in other patients such as stroke and head injuries, as their main use has been in children with cerebral palsy, this appeared to be the most logical group from which to select subjects for a scientific investigation. At the time the investigation was undertaken, the majority of patients being issued with TRAFOs by the North Western Orthotic Unit were children with hemiplegic cerebral palsy and therefore this was the group chosen from which subjects were selected.

2.1.2 Selecting Parameters for Analysis.

Previous investigations on TRAFOs / DAFOs (Zachazewski, 1982; Bronkhorst & Lamb, 1987) have studied their influence on basic gait parameters and functional activities and used improvements in these as an indicator of the success of the orthoses. If however, the theory proposed by Duncan and Mott (1983) that the unique nature in which these splints work is by reducing muscle tone, is to be believed then it would seem logical that the clearest measure of the success of such orthoses would be their effect on muscle tone. No previous studies have attempted to measure changes in muscle tone whilst using TRAFOs from either a clinical or a mechanical approach.

The difficulties of defining and measuring muscle tone were highlighted in Section 1, along with a summary of the different approaches used. At present a 'hands on' approach is that most commonly used by clinicians, although this clearly is an approach which is unsuitable for a scientific investigation. Also problems exist with more objective measures in which a limb is generally fixed and moved through a specific range, a situation which is not relevant to an ambulatory situation. In general both these approaches are unsuitable for use in this study, as it is considered essential to obtain a realistic measure of muscle tone whilst wearing the orthosis, weight bearing and walking.

It was considered that the best way forward was to measure the muscle activity in the form of an electromyogram during ambulation and use this as an *indicator* of muscle tone. In this manner it would be possible to establish whether a muscle exhibited a normal pattern of activity during gait, and whether the use of a TRAFO alters that muscles activity patterns.

Although the electromyograms were the most important parameters to be studied in the investigation, it was considered beneficial to study the corresponding changes on the overall gait of an individual. Further parameters were therefore measured to provide a complete picture of each subject's gait. The temporal and spatial parameters chosen were velocity, stride length, and cadence plus the durations of stance and swing phases expressed as a percentage of the total gait cycle. These parameters were relatively easy to measure during an assessment and would provide simple indicators of changes in the gait cycle. A final set of pictorial information was also collected using a video vector generator. Whilst this did not provide any scientific data, it gave a valuable visual indication of changes in the position of the ground reaction vector at key points in the gait cycle.

2.2 Objectives

Standard polypropylene ankle-foot orthoses have been used for many years, particularly to aid ambulation in children with cerebral palsy. Before the introduction of TRAFOs, the majority of children showing hypertonicity at the foot and ankle would have been issued with an AFO. In establishing the value of the introduction of TRAFOs into the orthotic care of such children, it is therefore important to consider any benefits observed relative to those obtained with the previous treatment. The success of the TRAFO should be measured against that of an AFO, not only to establish whether it works, but whether it is better than what we already have available.

The objectives of this investigation were therefore:

To perform a comparison between standard polypropylene ankle-foot orthoses and tone relieving ankle-foot orthoses, to determine their effect on patterns of muscle activity, ground reaction vectors, temporal and spatial parameters, during ambulation in children with cerebral palsy.

2.3 Investigation Design

To compare the influence of an orthosis on ambulation a research design was required which would allow measures to be taken before and after orthotic intervention. It was also considered important that there should be a control group in the investigation to take into account any changes which might naturally occur over time in the subjects. Such changes might be a general improvement in ambulation as children grow and/or gain experience and confidence in walking. A minimum of two groups would therefore be required to provide a control group whose conditions remained consistent throughout the investigation.

In this investigation the objectives were for two orthoses to be tested and then compared which led to the possibility of a three group design using one control and two experimental groups. However restrictions on time, the relatively limited availability of subjects and finances resulted in the selection of a two group design, which used one of the orthotic interventions as the control (see Figure 26).

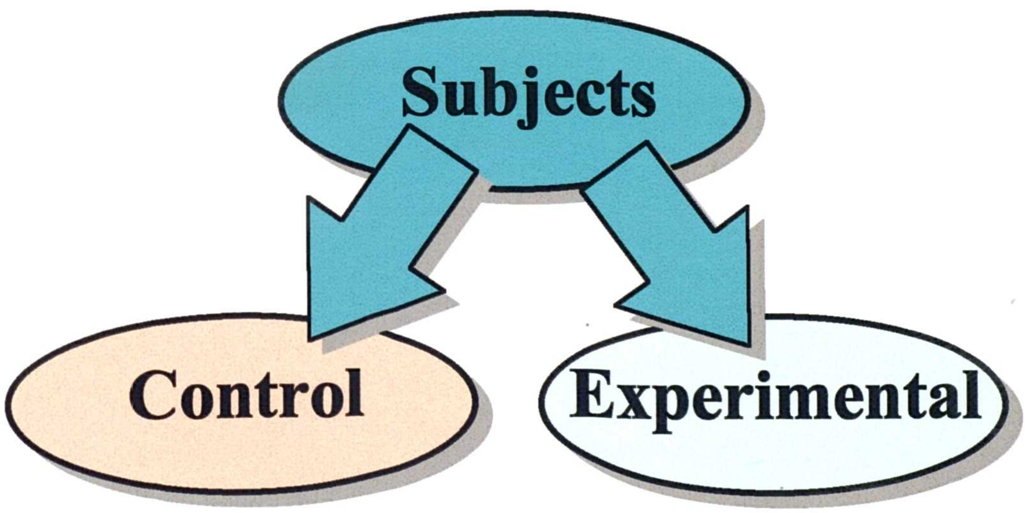


Figure 26
Two Group Design

As children with cerebral palsy all have very different gait patterns absolute measures cannot be compared before and after the intervention. The solution chosen was to measure how much each parameter changed as a result of the intervention and to compare the groups on this basis. The change was measured from baseline data recorded with both groups wearing the same orthosis (AFO) in the first part of the investigation. This was then followed by the second part of the investigation where the control group received a second AFO whilst the experimental group received a TRAFO. This two group repeated measures design allowed the performance of the TRAFO to be measured relative to that of an AFO where changes in the parameters were compared rather than absolute values.

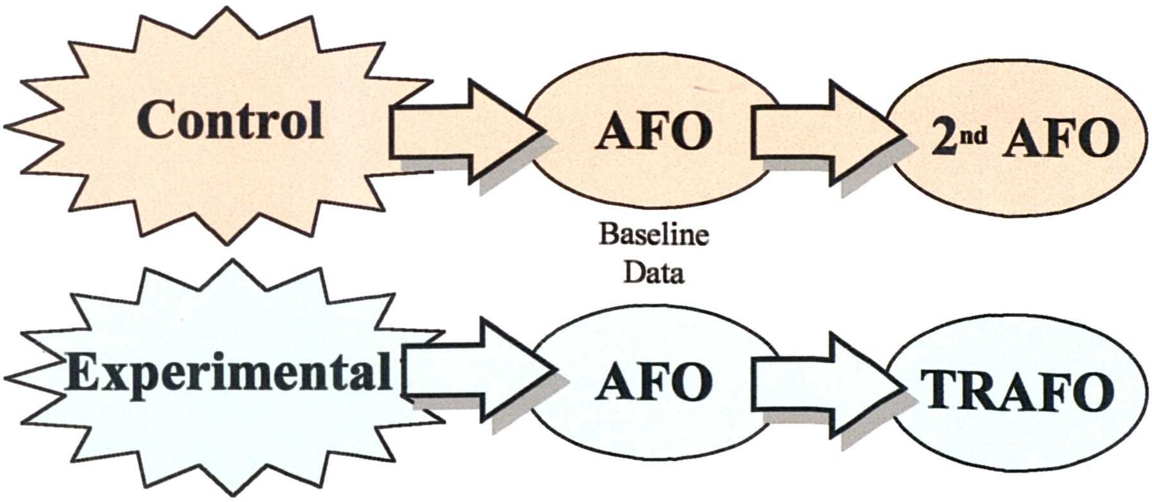


Figure 27
Repeated Measures to Provide Baseline Data

Ideally the experimenters and subjects would have been blind as to which type of intervention they were receiving. Clearly this was not possible for the experimenter and for the subjects it was again difficult as many went to the same schools and were friends with other subjects in the investigation and so could see that there were different types of splints being used. For those in the control group however, a second AFO was cast and fitted for the second part of the investigation in an attempt to convince them that they had been issued with a new and different orthosis and were therefore part of an experimental group.

In summary therefore, the design chosen for this investigation was an experimental, prospective and longitudinal study using two groups with repeated measures on those groups. The subjects were alternately allocated to the two groups as they were recruited and an attempt was made to establish a single-blind investigation.

2.4 Hypotheses

In general terms the aim of the research was to make a comparison of AFOs and TRAFOs when used for children with cerebral palsy. For statistical analyses, it was also important to formulate a Null Hypothesis (H_o) which must then be disproved to establish if any differences exist between the measured variables. The general Null Hypothesis for this investigation was therefore:

There will be no difference between the changes to gait parameters for the children wearing TRAFOs and those for the children wearing AFOs.

The following section lists in detail each of the null hypotheses for the parameters measured in this investigation and for the statistical tests outlined in Section 6.

2.4.1 Gait Parameters

When comparing the children wearing TRAFOs with those wearing AFOs, there will be no differences between;

a) The increase/decrease in velocity

b) The increase/decrease in stride length

c) The increase/decrease in cadence

When comparing the children wearing TRAFOs with those from a published normal population, there will be no differences between;

d) The duration of stance phase as a percentage of the total gait cycle

e) The duration of swing phase as a percentage of the total gait cycle

When comparing the children wearing AFOs with those from a published normal population, there will be no differences between;

f) The duration of stance phase as a percentage of the total gait cycle

g) The duration of swing phase as a percentage of the total gait cycle

2.4.2 Electromyography

When comparing the children wearing TRAFOs with those from a published normal population, there will be no differences between;

h) The duration of activity exhibited by the tibialis anterior during the stance phase

i) The duration of activity exhibited by the tibialis anterior during the swing phase

j) The duration of activity exhibited by the gastrocnemius during the stance phase

k) The duration of activity exhibited by the gastrocnemius during the swing phase

l) The duration of activity exhibited by the rectus femoris during the stance phase

m) The duration of activity exhibited by the rectus femoris during the swing phase

n) The duration of activity exhibited by the biceps femoris during the stance phase

o) The duration of activity exhibited by the biceps femoris during the swing phase

When comparing the children wearing AFOs with those from a published normal population, there will be no differences between;

p) The duration of activity exhibited by the tibialis anterior during the stance phase

q) The duration of activity exhibited by the tibialis anterior during the swing phase

r) The duration of activity exhibited by the gastrocnemius during the stance phase

s) The duration of activity exhibited by the gastrocnemius during the swing phase

t) The duration of activity exhibited by the rectus femoris during the stance phase

u) The duration of activity exhibited by the rectus femoris during the swing phase

v) The duration of activity exhibited by the biceps femoris during the stance phase

w) The duration of activity exhibited by the biceps femoris during the swing phase

Section 3

Casting & Manufacture of Orthoses

3.1 Casting Procedure

The orthoses used in the investigation were all cast and manufactured at the North Western Orthotic Unit, Hope Hospital, Salford. The same orthotist took all the casts and fitted all the orthoses. The following information summarises the procedures undertaken to produce the orthoses. A more detailed description of the casting and manufacturing techniques can be found in Appendix 3.

3.1.1 Traditional DAFO Casts

The traditional methods of casting for Dynamic Ankle Foot Orthoses (DAFOs) have been previously published (Hylton, 1989, 1990) and demonstrated at training courses and orthotic workshops throughout the US and Europe. The traditional method which was developed in the United States has been described in a number of stages:

i) **A draft of the foot outline is made on paper;**

ii) **The paper draft is then transferred on to a footboard;**

iii) **The footboard is hollowed out under the metatarsal and heel areas;**

iv) **Plaster is placed onto the footboard to fill the arched areas of the foot;**

v) **The board is taped on to the foot;**

vi) **The foot and board are cast together.**

Although this method has been reported to have given very favourable results in the US and at centres across Europe (Hylton, 1989; Diamond & Ottenbach, 1990; Curtis, 1995) several difficulties appear to be inherent in the procedure. The main problem lies in the fact that the casting is very time consuming with obvious difficulties when, as in most cases, the patient is a young child. Those with tonal problems will no doubt be affected by the lengthy procedure and the constant manipulation of the affected limb. The draft of the foot along with the insertion of the plaster are also both techniques which are prone to error exacerbated when dealing with an uncooperative child.

With such fragile casts there are obvious problems in both the removal and transportation. Being constructed from plaster of Paris, the resultant cast is very brittle and prone to damage. Areas frequently fracture resulting in untidy casts which need much repair, thus introducing further errors. This is particularly a problem for those orthotists who do not work at dedicated centres and frequently transport casts from schools/hospitals to manufacturing workshops.

This method of casting and manufacture has also been open to abuse from orthotic companies, where 'off the shelf' foot boards are used as part of the casting procedure. The footboards are selected based on the approximate size of a child's foot, but this no doubt detracts from the custom made design of the splints and lessens their individuality.

Figure 28
American Style DAFO

3.1.2 The Salford Casting Technique

Having been introduced into the UK, the traditional casting procedures have been practised and modified at numerous centres where experimental work on DAFOs has been carried out. Initial work at the North Western Orthotic Unit (NWOU) has highlighted the problems with the traditional casting procedures and adaptations to these methods were sought. Care was taken to ensure that the splints met the same criteria as those produced using the traditional technique, i.e. off-loading the trigger areas, holding the calcaneous in a neutral position, positively loading the arches and preventing toe contractions. A modified technique introduced by Mr M Gilligan, an orthotist at the NWOU, has been in place since July 1994, and was the method used to produce the orthoses for this investigation. The resultant orthoses were named Tone Relieving Ankle-Foot Orthoses (TRAFOs) and are now used widely for children with cerebral palsy in and around the Manchester and Salford areas.

The casting procedure follows a number of clear stages:

i) **The patient sits sideways on a couch with the feet flat on a box.**

ii) **The heel and metatarsal bar pads are fixed to the foot.**

iii) **The foot and lower calf are covered with two layers of stockinette.**

iv) **A roll of water-activated polyurethane bandage (WAPB) is used to envelop the foot and lower calf.**

v) **The domed metatarsal pad is positioned.**

vi) **A wet crepe bandage is then applied over the WAPB.**

vii) **The cast is left to set**

viii) **The cast is removed.**

3.1.3 Casting for an AFO

The method used to cast the standard polypropylene AFOs in this investigation is that which is widely used by orthotists. The basic stages are described below;

i) The patient sits on the couch with the feet flat on a box.

ii) The foot and calf are covered with stockinette and plastic channelling.

iii) Rolls of plaster of Paris (POP) bandage are used to envelop the foot and calf.

iv) The foot is held at 90° ankle flexion and the cast is left to set.

v) The cast is removed using scissors or a plaster saw.

3.2 Manufacture

3.2.1 TRAFO Manufacture

The manufacture of the TRAFO follows a similar procedure for that used with AFOs, creating a positive cast from plaster of Paris and then moulding polypropylene around this. The manufacture is described in detail in the following stages:

1. **The WAPB cast is sealed**
2. **The WAPB cast is filled with plaster of Paris**
3. **The negative WAPB cast is removed**
4. **Toe Section is extended**
5. **Rectification of the cast**
6. **Preparation for vacuum forming**

7. **Vacuum forming**

8. **Construction of the sole**

9. **The splint is removed from the POP cast.**

Figure 29
Completed TRAFO

3.2.2. AFO Manufacture

The manufacture of the AFOs followed a simple procedure entailing the production of a positive cast from plaster of Paris and then moulding the thermoplastic around this. The manufacture is described in the following stages:

1) **The POP cast is sealed using a further roll of POP.**

2) **The negative cast is filled with plaster of Paris.**

3) **The negative POP cast is removed.**

4) **The positive POP cast is rectified.**

5) **A stockinette is applied in preparation for vacuum forming.**

6) **The splint is Vacuum formed using 3.5 mm thick thermoplastic.**

7) **The splint is removed from the POP cast trimmed and smoothed.**

8) **Calf and ankle straps are attached.**

Figure 30
Completed AFO

3.3 Orthotic Design

3.3.1 TRAFO Design

The base of a TRAFO is designed to have a contoured footplate which intimately fits to the underside of the foot rather than a flat footplate as seen in standard polypropylene AFOs. The body of the orthosis is substantial, almost completely encircling the foot and ankle with a small section missing anteriorly allowing access to flex and part the splint for application.

As explained in Section 1, TRAFOs can be made in a number of different designs depending on the severity of the patient's tonal and mechanical problems. The TRAFOs used in this investigation however, were all of the standard style and subjects requiring different levels of orthotic intervention were excluded from the research. In this style the top trim line is approximately 5cm above the malleoli and has an adjustable ankle strap circling the top of the orthosis. The orthosis also has a rear section cut away providing more flexibility in the TRAFO (see Figure 32). This area combined with the adjustable strap makes it possible to allow some plantar/dorsi flexion whilst wearing the orthosis. Restriction can be placed on either or both of these movements by tightening the strap accordingly. All the TRAFOs were worn with flat ankle boots or trainers which were securely fastened, reducing the need for additional straps within the shoe.

A diagram of a standard style TRAFO as used in this investigation is shown in Figure 31.

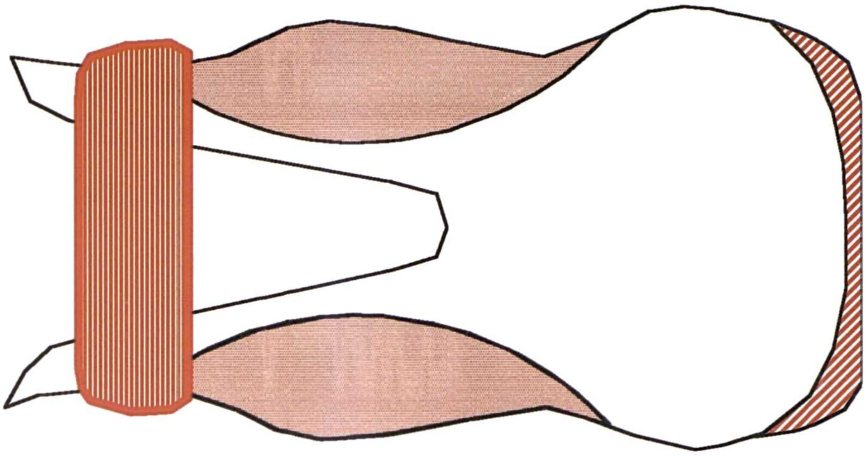


Figure 32
Rear Section Cut Away

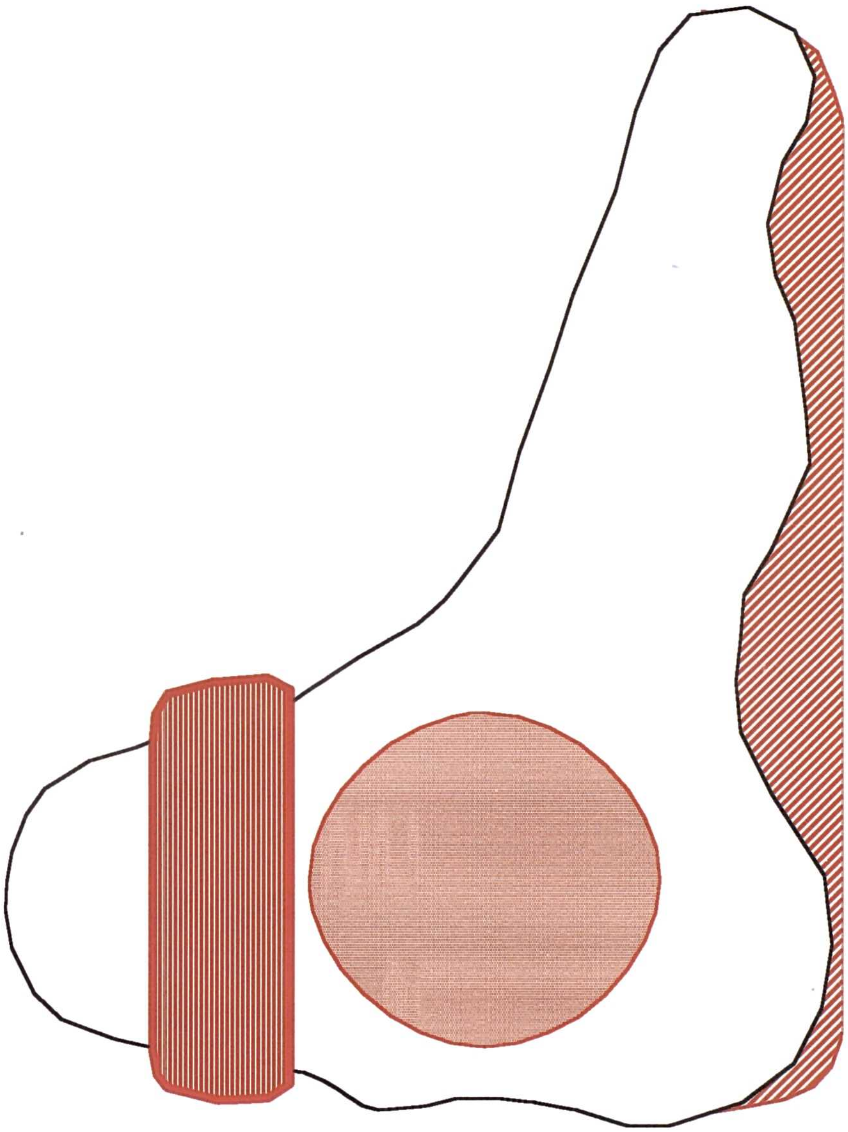
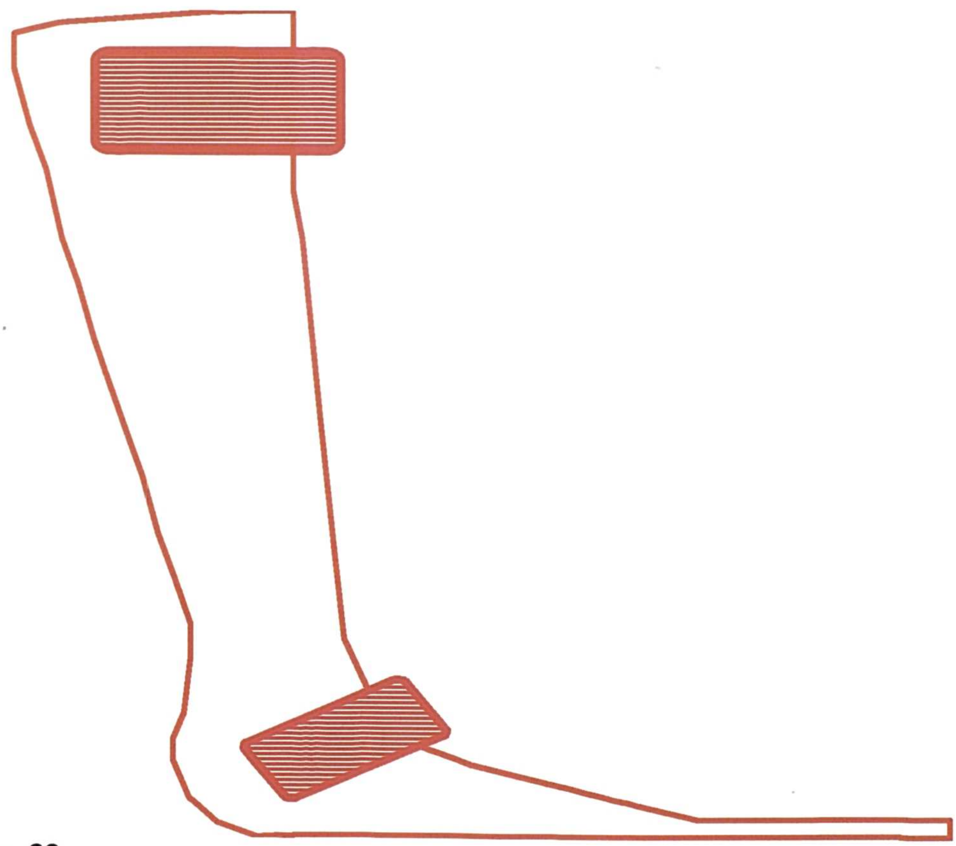


Figure 31
Standard Length TRAFO

3.3.2 AFO Design

A standard polypropylene AFO is designed to have a flat sole plate reaching beneath the patients foot and placed within the footwear. The polypropylene then goes up the back of the leg encircling the calf. The front of the leg and the top of the foot are not covered with the splint, but the limb is held in place by the use of straps.

The AFOs used in this investigation were manufactured to this standard design. The top trim line for the orthosis was around the upper calf region and a Velcro strap was attached at the top to secure the splint to the leg. A second strap was attached at 45° to the calf and foot sections. This strap maintains the foot at 90° and holds it in the splint when the muscles are trying to plantarflex. As with the TRAFOs, the AFOs were all worn within flat ankle boots/trainers and the orthoses were trimmed to fit in these correctly.



<u>Figure 33</u>
<u>Standard Polypropylene AFO</u>

Section 4

Equipment

4.1 Introduction

The location for the assessments was the Gait Analysis Laboratory, School of Prosthetics and Orthotics, University of Salford. Most of the equipment required was readily available and had been installed within the Laboratory prior to the investigation. It was necessary to purchase several additional items during the planning stages of the investigation and these were then integrated with the existing equipment.

The following section discusses the equipment used for each of the main areas of assessment; video and vector generator, footswitch and general gait parameters, and EMG. It then moves on to describe the arrangement of the Gait Laboratory and how the equipment was integrated during the experimental work.

4.2 Video and Vector Generator

4.2.1 Video

The video equipment in this investigation was required to observe the position of the lower limb during gait, in particular during foot contact with the force platform. One camera was chosen to view the movement in the sagittal plane.

The camera system used was a Panasonic HSF15 video camera linked to a Sony SLVE40 video cassette recorder. The camera was situated 4 m away from the centre of the force platform and at right angles to the subjects direction of motion. It was fixed to an adjustable mount with the lens 0.7 m above the floor.

In each assessment the camera had a field of view which covered the force platform and the full height of the subject vertically, and two steps at either side of the platform horizontally. The field of view was adjusted for each individual with the lens being zoomed in to provide the largest possible image size and the shutter speed set to 1/500 second.

4.2.2 Force Platform

The force platform used was a Kistler 9281B multicomponent measuring platform as shown in Figure 34. The unit was a piezo-electric transducer which could measure forces in the vertical, anterior-posterior and medial lateral directions. It could also determine the point of the force application on the platforms surface. The force platform was housed within the floor of the gait laboratory, at the centre of the walkway, providing a rigid and level surface over which the subjects moved. The platform had dimensions of 0.5 x 0.4 m and was positioned so that its long axis lay along the subjects direction of motion.

Figure 34
Kistler 9281B Force Platform

The force platform was connected directly to its Kistler 9865B Charge Amplifier (see Figure 35). This converted the charge signals from the force plate into proportional voltages which normally were then integrated into a computer system for analysis. In this investigation however, the force platform information was to be used for visual appraisal of the gait rather than a quantitative analysis, therefore the output from the charge amplifier was connected directly to the video vector generator unit.

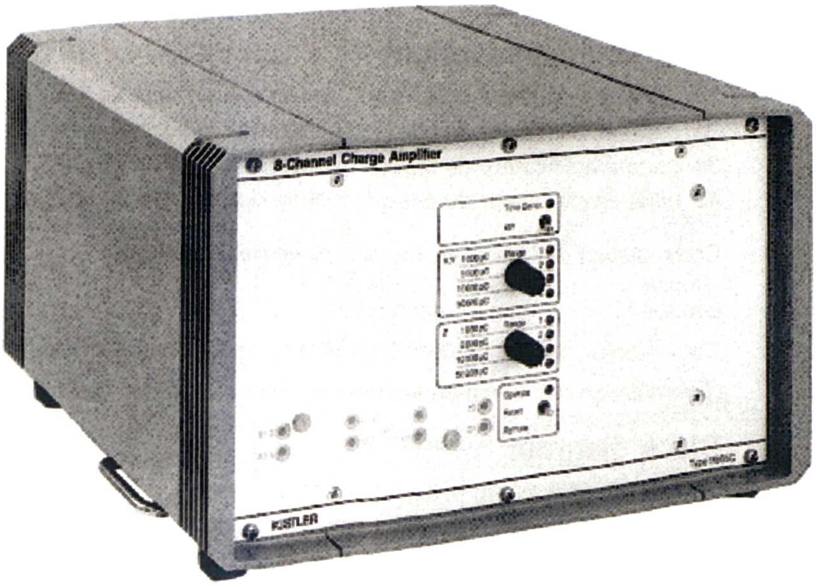


Figure 35
Kistler 9865B Charge Amplifier

4.2.3 Vector Generator

The vector generator used was an MIE/ORLAU Video Vector Generator which combines inputs from the video camera and the force platform to provide an output of a video picture with a line overlaid indicating the point of application of the direction and magnitude of the ground reaction vector. The combined video and force vector image was displayed on a monitor and recorded on the video cassette recorder to be analysed later.

The vector generator had a gain or vector height scale to allow account to be taken of the mass of each subject. By increasing/decreasing the scale with the subject standing on the force platform, the gain was adjusted to ensure that the vector was as large as possible without going out of frame at any point during the gait cycle. This value of gain used was noted at the first assessment for each individual and kept constant throughout their remaining trials to ensure that the data could not be falsely interpreted.

The vector generator had a number of parameters associated with the force platform which were set when it was originally installed. Prior to each subjects assessments however, the view setting procedure was followed to account for alterations to the field of view between trials and therefore the location of the force platform in the field of view.

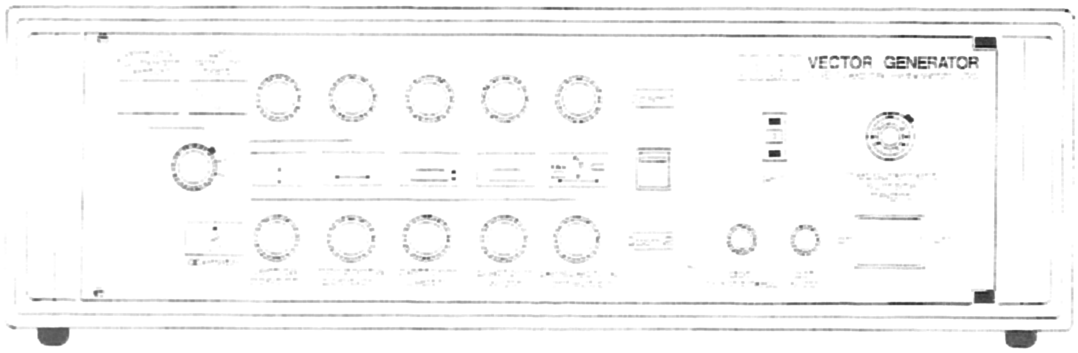


Figure 36
MIE/ORLAU Video Vector Generator

4.3 Foot Switches & General Gait Parameters

4.3.1 Foot Switches

Information on the time of the heel strike and the point of toe off was acquired using footswitches taped to the sole of the subjects shoes. Two switches were used for each subject, one on the heel and one under the toes.

The footswitches were supplied by MIE Medical Research Ltd. The design incorporated a flexible printed circuit board and membrane switches in a thin strip which could be attached to the underside of the shoe with adhesive tape. The switches had two surfaces, one smooth for use with adhesive tape and the other textured to allow grip when walking. The switches used in this investigation were specially constructed with a length of 5 cm (normal sizes 12 and 7 cm) to make them suitable for the smaller foot sizes of some of the younger subjects.

The two switches plugged into a cable which was taped along the outside of the subjects limb and into a transmitter box clipped to a belt around the subject's waist. The transmitter box contained a voltage driver which produced a positive step when the switches were compressed. For a two foot switch system there were four voltage levels which corresponded to the four foot switch permutations: switch 1 & 2 open, switch 1 only closed, switch 2 only closed, switches 1 & 2 closed.

This signal was carried from the transmitter box to the analogue input of the EMG amplifier via a 15 m cable. The foot switch data was then viewed in real time alongside the four channels of EMG data using AcqKnowledge™ software on a Macintosh computer.

4.3.2. General Gait Parameters

The general gait parameters were calculated using the foot switch and temporal information. A digital stopwatch was used during each trial to record the time taken for the subject to travel between two red lines marked on the walkway 5 m apart. Time was measured to the nearest one hundredth of a second.

4.4 EMG

EMG measures were obtained using a Biopac MP100 system. The data acquisition system consisted of a TEL100M portable transmitter which was worn on a belt attached to the subjects waist. Electrodes were attached to the subjects limb and these were connected to the TEL100M via 4 sets of wires. The transmitter picks up the signals from the electrodes and amplifies the four channels of data before transmitting them down a single 15 m cable to the receiver module. Figure 37, shows the portable transmitter worn by the subjects and the receiver module.

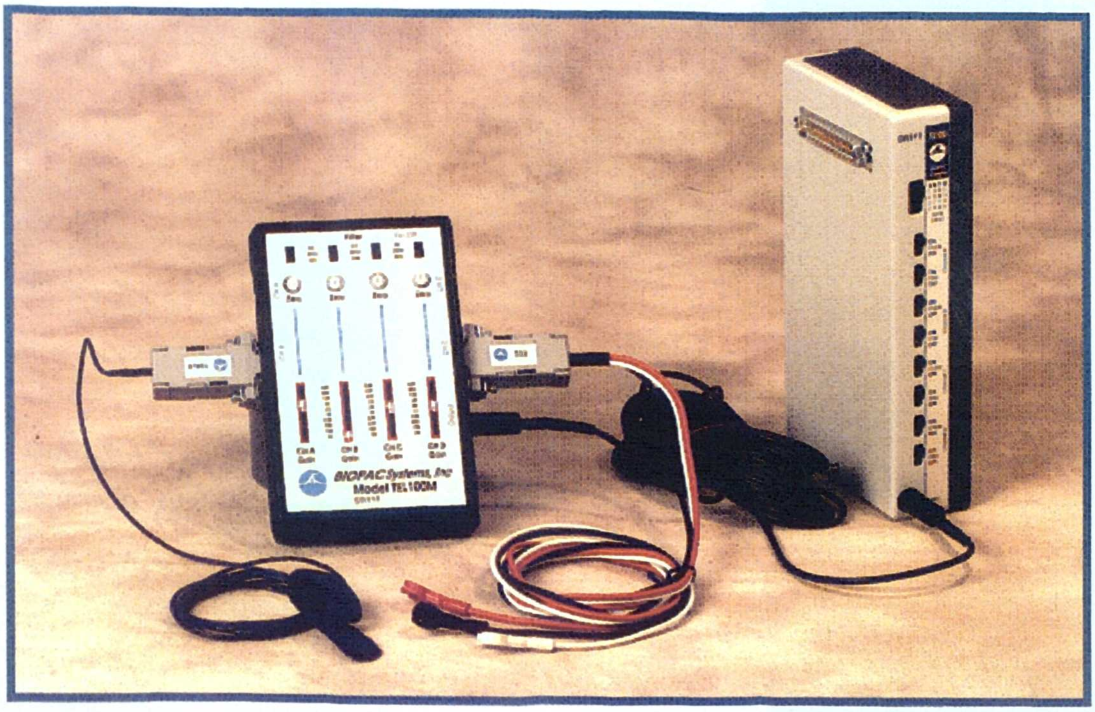
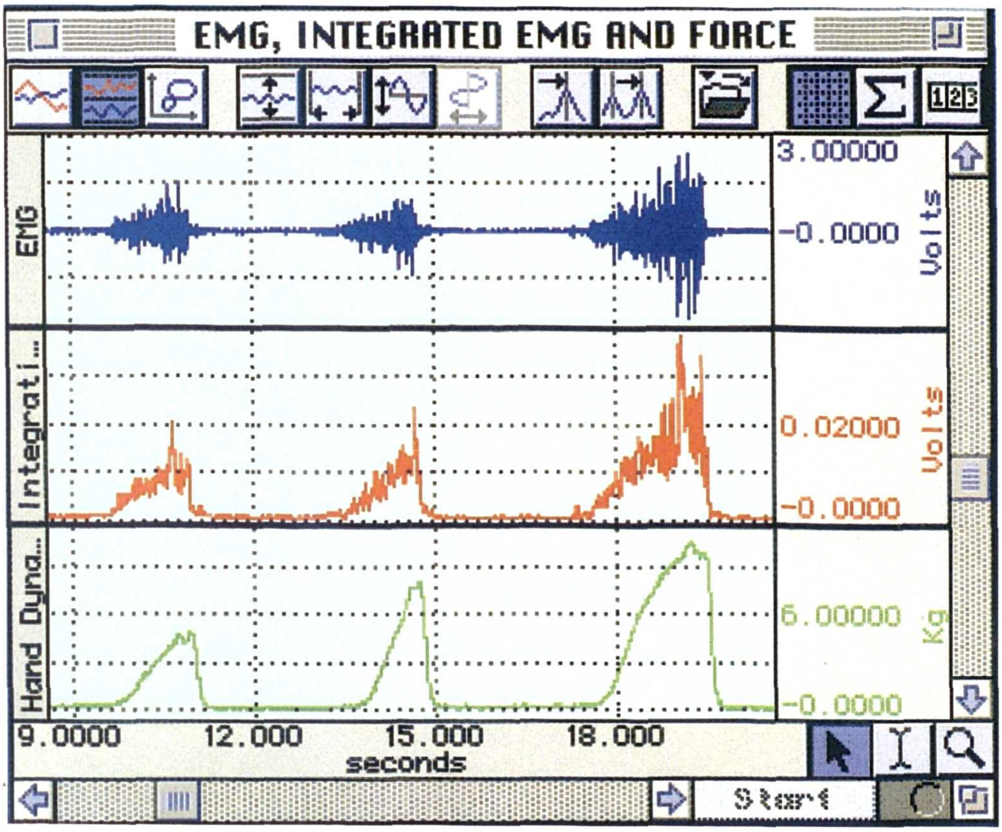


Figure 37
TEL 100M Transmitter and TEL 110D Receiver Units.

The TEL 110D receiver module connected directly to the MP100A data acquisition unit with an input impedance of 1.0 MΩ and a signal/noise ratio of > 90 dB. The voltage resolution was 300 μVolts/bit. The data from the acquisition unit was transmitted to the computer for display and analysis. The Biopac systems data collection and analysis was controlled by AcqKnowledge™ software (See Figure 38) which ran on a Macintosh computer, allowing both on-line and off-line analysis.



<u>Figure 38</u>
<u>Example of AcqKnowledge™ Software used for Data Analysis.</u>

The electrodes used were disposable 3M paediatric monitoring electrodes. They consisted of a small metal disc covered with a conductive gel filled foam pad and surrounded by an adhesive tape ring. On the back of each electrode was a small press-stud to which wires from the pre-amplifier were attached.

4.5 Experimental Conditions

The physical layout of the gait analysis laboratory is shown in Figure 39. The walkway consisted of a 10 x 1 m section of the laboratory floor in the centre of which the force platform was located. At a distance of 2.5 m from each end of the walkway red lines were placed to mark the central 5 m which was used in the calculation of temporal and spatial parameters.

The video camera was positioned at the opposite side of the laboratory, with the axis of the lens perpendicular to the walkway. The force plate was at the centre of the field of view and subjects were filmed in the sagittal plane. Each subject was filmed walking between the two ends of the walkway in one direction only. This was chosen so that the affected limb was always closest to the camera.

The force platform amplifier, vector generator, video recorder, monitor and EMG station were all situated on a bank of desks down one side of the laboratory. The equipment was linked to the video camera and force platform and the EMG station was connected to the subject via a 15 m cable.

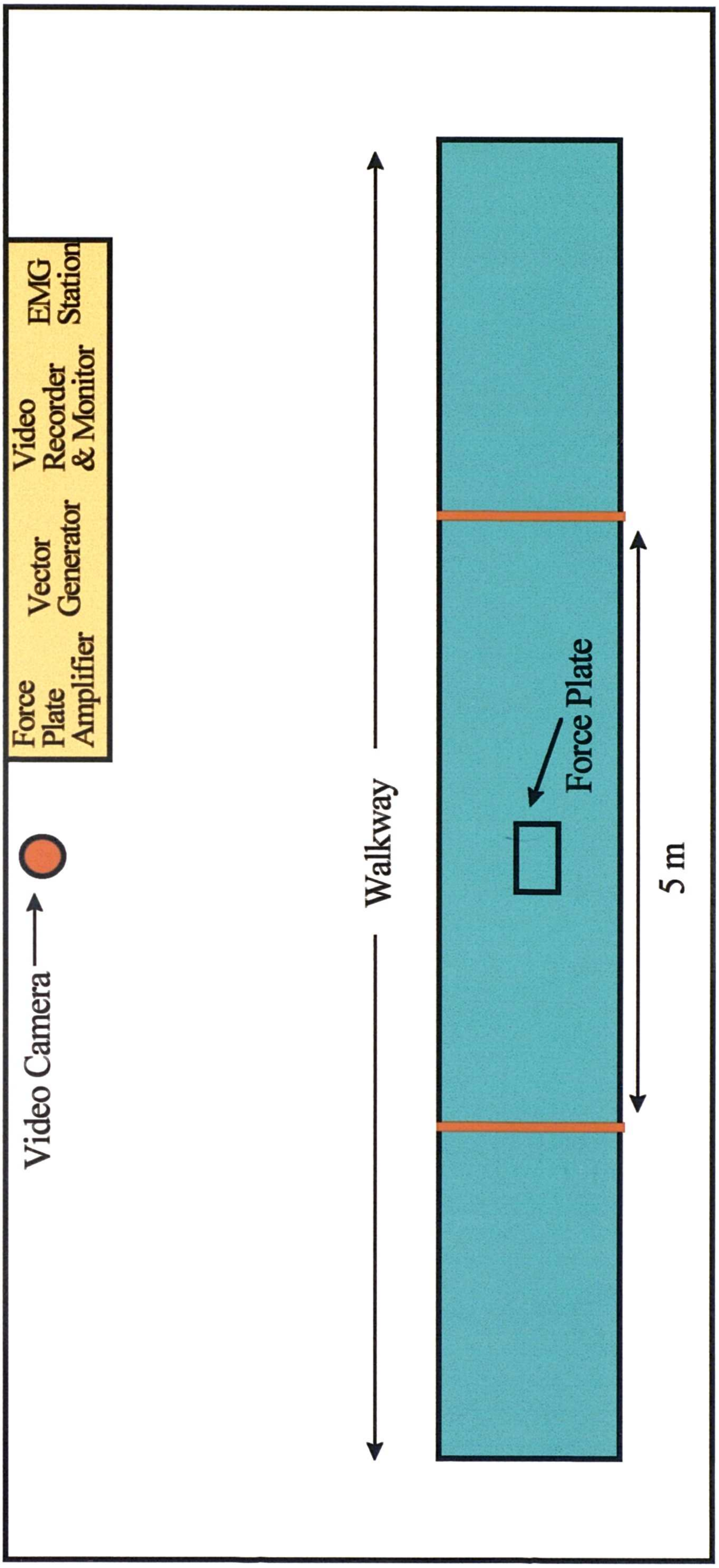


Figure 39
The Layout of the Gait Analysis Laboratory

Section 5

Methods

5.1 Subject Recruitment

The children recruited to this investigation were targeted from the Manchester and Salford areas in an attempt to maximise adherence to both the clinical and assessment programmes which would be carried out at two locations in Salford. Initially a number of letters were sent to paediatric and orthopaedic consultants in the two areas explaining the study and selection criteria for subjects, and inviting their support by highlighting any patients who might be suitable. Little response was received from these letters and it became clear than an alternative method of recruitment would be necessary.

Approaches were made to a number of physiotherapy managers working in the community in the Salford and Manchester areas. The physiotherapy units were based in schools and acted as a base from where the staff treated children in the surrounding community and therefore had access to large number of potential subjects. Educational sessions were held for the physiotherapists in these centres where the experimenter visited to provide information on the types of splints being used and how the proposed investigation intended to evaluate the benefits of such treatments. The staff in these centres were then invited to discuss the investigation with the parents of any children they felt would be suitable and then refer them to the experimenter should they be interested in taking part.

The parents of each of the children put forward by the community physiotherapists were invited to meet with the experimenter where a verbal explanation of the study was given. Written information was also provided (see Appendix 1) which outlined the provision of orthoses, assessment procedures and the number of clinical and assessment sessions which they would need to attend. Parents were then asked to respond to the experimenter if they wished their child to be involved in the study and consent forms (see Appendix 1) were then distributed and signed. The consent forms along with the written information emphasised the subjects and parents right to withdraw from the investigation at any time.

The children used in this investigation were recruited via the community physiotherapists at the following schools in Salford and Manchester:

8 - Parksfield School

1 - Telford School

2 - Lancasterian School

9 - Pictor School

2 - Royal Manchester School for the Deaf

In total 22 children were initially considered, two of which were excluded after visits from the experimenter as they had previously worn or were presently wearing a TRAFO. Twenty children were recruited into the investigation although five of these dropped out during the study for the following reasons.

1 - moved away from the area.

3 - parents were unable to fulfil commitment to assessment sessions.

1 - unable to attend assessment sessions through illness.

Ethical approval for this investigation was granted by the Salford Research Ethics Committee on the 12 of July 1995, with a written update being provided for the committee by the experimenter in September 1996.

5.2 Selection Criteria

The children recruited into this investigation were selected on the following criteria:

- Diagnosed with hemiplegic cerebral palsy.
- Mild to moderately affected with hypertonicity of the foot/ankle.
- Aged between 3 and 16 years at the time the splint was prescribed.
- Ambulatory (with/without walking aids).
- Recommended by the community physiotherapist as a candidate who would benefit from wearing an ankle-foot orthosis.
- Within normal learning limits or having moderate learning difficulties (capable of following simple instructions).

Of the fifteen children who completed the assessments in the investigation, all were either wearing or had previously worn a standard polypropylene ankle-foot orthosis. None of the children had previously had any orthopaedic surgery. Each of the children had the assessments explained to them and a demonstration of the equipment involved prior to the trials.

The fifteen children consisted of ten male and five female subjects who had an age range of 3 - 11 years with a mean age of 6.6 years (6.3 group A, 7 group B) when they were recruited into the investigation. One subject (B1) walked with a rollator and one subject (A2) walked whilst holding the hand of their parent at the beginning of the study. All other subjects were independently ambulating. Table 5, shows the subjects data in more detail.

Subject ID	*Age (yrs)*	*Sex*	*Degree of involvement*	*Additional Complications*	*Orthoses used in investigation* wks 1 -12	wks 13 - 25
A1	7	M	Mild	Hearing & sight problems	AFO	TRAFO
A2	3	M	Moderate		AFO	TRAFO
A3	7	F	Mild		AFO	TRAFO
A4	3	M	Moderate		AFO	TRAFO
A5	11	F	Mild		AFO	TRAFO
A6	8	M	Mild		AFO	TRAFO
A8	3	F	Mild		AFO	TRAFO
A9	8	M	Mild		AFO	TRAFO
B1	4	F	Moderate	Hearing & sight problems, moderate learning difficulties, epilepsy, used rollator.	AFO	AFO
B3	7	M	Mild		AFO	AFO
B4	8	F	Mild		AFO	AFO
B5	8	M	Mild		AFO	AFO
B6	8	M	Mild		AFO	AFO
B7	6	M	Mild		AFO	AFO
B8	8	M	Mild		AFO	AFO

Table 5
Subject Data for the Fifteen Subjects Studied in the Investigation.

5.3 Orthotic Protocol

Once the subjects had been recruited into the investigation and the parents had signed the consent forms, each of the children were invited to the Orthotic Unit, at Hope Hospital, Salford, where the casting and manufacture of the orthoses used in the investigation was to take place. The children were assessed by the orthotist to confirm that they were suitable candidates for the investigation and arrangements for the timings of their casting sessions were made.

At the first session, a cast was made for a standard polypropylene ankle-foot orthosis and then each subject returned two weeks later, when the orthosis had been manufactured, to have the device fitted and for any necessary modifications to be made. No restrictions were made on footwear other than to use lace up shoes which had no heel and fastened adequately. In most cases the child's ordinary school shoes or trainers were suitable.

The parents were advised to build up gradually the number of hours each child wore the orthosis over the first few days and to keep a check for any potential problem areas. They were also provided with instructions to contact either the Orthotic Unit or the experimenter immediately should there be any problems with the orthosis.

Each of the children then entered into the assessment schedule based at the University of Salford and would return to the Orthotic Unit ten weeks later for the same process to be carried out for the casting and manufacture of the second orthosis.

5.4 Experimental Protocol

As each of the subjects were recruited into the investigation, they were alternately allocated to one of two groups, the experimental group (A) or the control group (B). Each of the subjects were also numbered in order as they entered a group providing each with a unique identity i.e. A1 - Group A, Subject1. Each group was evaluated in two different orthoses, each of which they wore for a period of three months. Thus the subjects in this investigation were required to participate for a period of six months in total. The orthoses worn by each of the two groups are shown in Table 6.

Group	*Orthosis Type*	
Control (B)	AFO	2^{nd} AFO
Experimental (A)	AFO	TRAFO

Table 6
Orthoses Worn by the Control and Experimental Groups.

Each of the subjects were tested six times during the six months they were involved in the investigation, three times whilst wearing each of the orthoses. The testing sessions were arranged on the weeks shown in Table 7. This arrangement meant that the subjects were tested during the first week, last week and middle week of wearing each orthosis.

	Week No					
	1	7	12	13	19	24
Orthosis	AFO	AFO	AFO	2nd AFO or TRAFO	2nd AFO or TRAFO	2nd AFO or TRAFO

Table 7
Arrangement of Assessment Sessions for Each Orthosis.

The casting and manufacture of each of the orthoses had to be timed so that the assessments could take place on the required days. It was therefore necessary to have the first orthosis cast and ready to be fitted prior to the first week of the assessment schedule. The second orthosis was then cast and fitted during weeks ten and twelve respectively, (the final two weeks of wearing the first orthosis) so that a direct swap could be made on the required date.

As it would be impossible to deal with all the subjects at the same time, at both the Orthotic Unit and the Gait Analysis Laboratory, the subjects were recruited on a gradual basis at the rate of approximately two per month. This allowed casting, fitting and assessments to be staggered, covering a total period of 18 months. Due to problems with the orthotic provision mid-way through the study however, the total period for assessments actually covered 22 months. The pattern of recruitment and participation for each subject is illustrated in Figure 40.

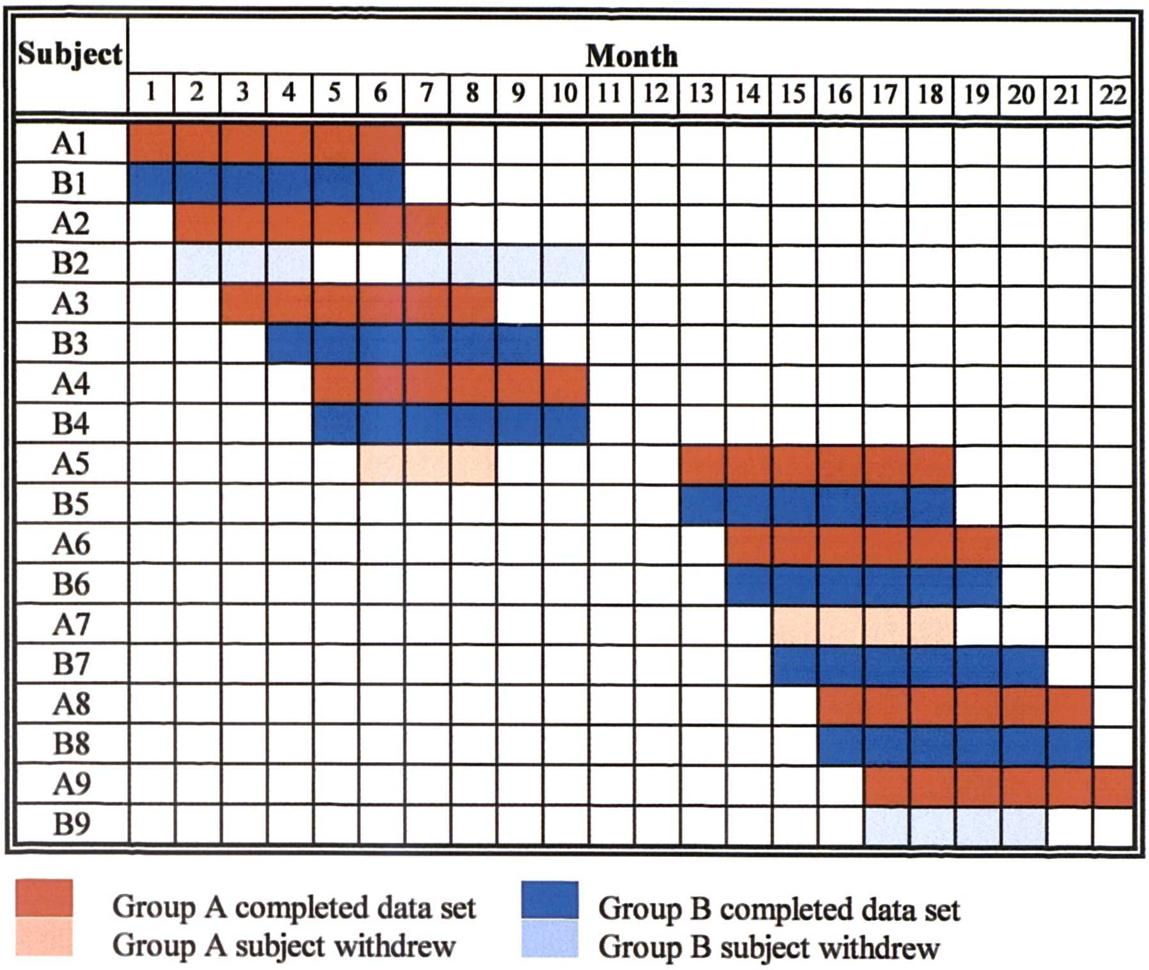


Figure 40
The Timing of Subject Recruitment and Participation

5.5 Assessment Sessions

The gait assessments were carried out in the Gait Analysis Laboratory, School of Prosthetics and Orthotics, University of Salford. On arrival at the School the subjects and their parents were shown around the Gait Laboratory and all the equipment which would be used in their tests was explained and demonstrated to them. The force platform was the only piece of equipment not to be demonstrated to the children in an attempt to avoid them 'stomping' on the plate during the trials. The experimenter then explained to the subjects that electrodes and footswitches would be attached to them and then they would be asked to walk up and down the walkway in a straight line. Both the parents and subjects were invited to ask any questions they might have before the experimenter began the assessment. The trials were conducted with the subject wearing limited clothing, which usually consisted of shorts and a T-shirt, allowing access to the lower limb for electrode placement. The subjects also wore their orthosis on the affected limb and their normal footwear.

Electrodes were placed over four muscles which were selected for EMG measurements. These are listed along with the movement each produces in Table 8 and illustrated in Figure 41.

Muscle	***Movement***	
Rectus Femoris	Prime mover	Knee Extension
Biceps Femoris	Prime mover	Knee Flexion (also PM Hip Extension)
Gastrocnemius	Prime mover	Plantar Flexion (also Knee Flexion)
Tibialis Anterior	Prime mover	Dorsiflexion (also inversion)

Table 8
Muscles Selected for EMG Analysis and their Actions at the Knee and Ankle.

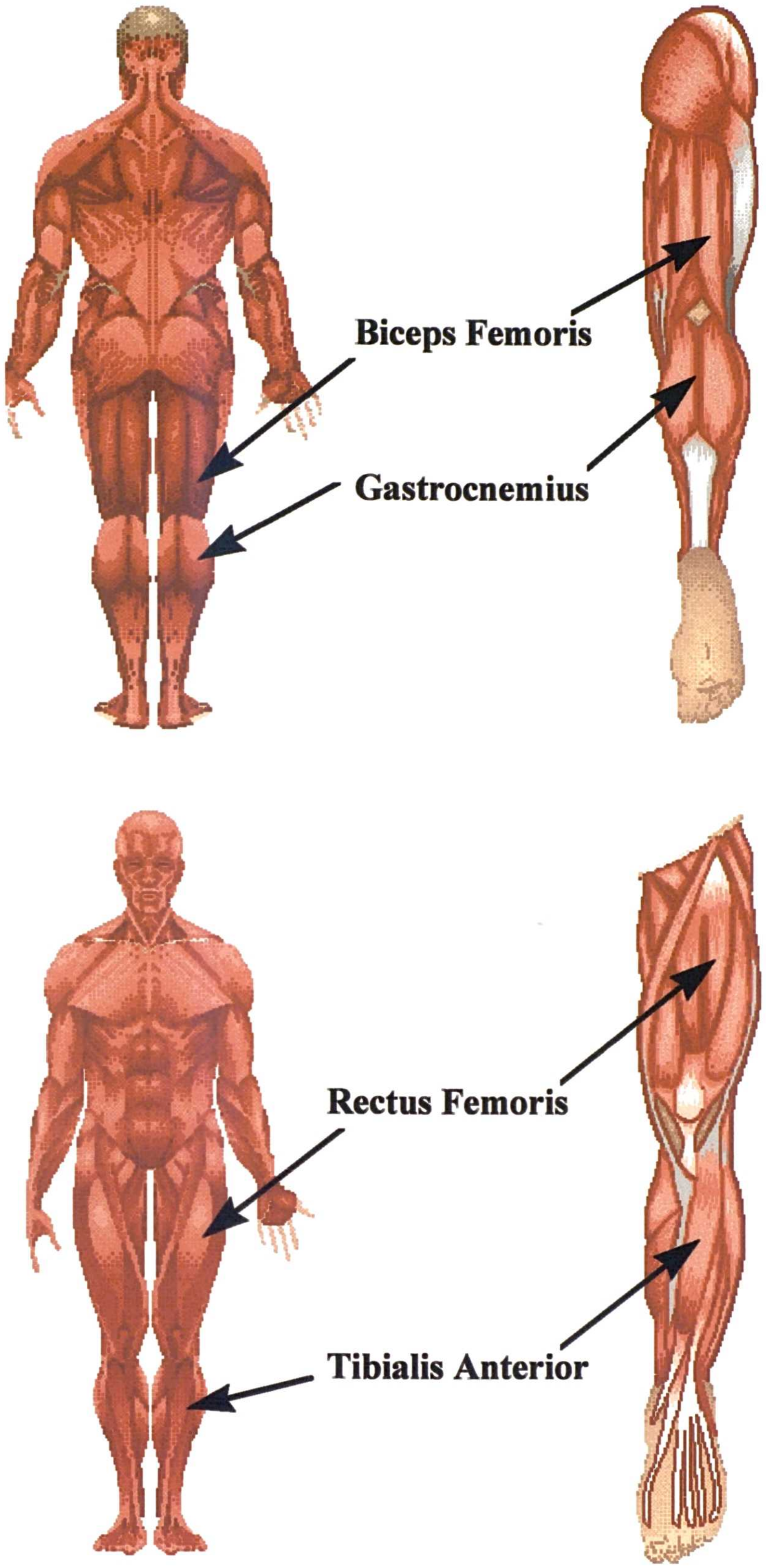


Figure 41
The Four Muscles Selected for EMG Analysis.

Each of the muscles were selected on the following:

- They are representative of the main muscle groups which control the movements of the ankle and knee to be observed in this investigation.
- They are all prime movers in their particular movement.
- They are all superficial and therefore suitable for surface EMG.
- They have been monitored previously by other investigators, hence established patterns of activity exist for normal subjects.

Although the biceps femoris and rectus femoris were specifically targeted for electrode placement, the results from these two muscles were generalised to the hamstrings and quadriceps muscle groups based on the limitations and difficulties associated with surface EMG as described in Section 1.

The areas of skin where the electrodes were to be placed were prepared using cleansing wipes. Nine electrodes were then placed on the affected limb of the subject, two on the muscle belly of each of the muscles being tested and 1 reference electrode was placed on the tibial tuberosity which was chosen as this is a relatively inactive sight. The electrodes were positioned over the muscles based on the recommendations of Zipp (1982). The electrodes were placed in pairs in a direction parallel to the fibres of the muscles and over the muscle bellies which were determined by visual inspection and palpating the muscle during voluntary contractions.

The EMG apparatus was arranged as previously illustrated in Figure 23 (Section 1). An adjustable belt was secured around the waist of the subject to which a pre-amplifier box was attached at the small of the back. Connecting leads from the pre-amplifier were then clipped on to the electrodes, each corresponding to one of four channels being measured (one for each muscle). The lengths of the leads was then adjusted to take account of the subject's limb length. It was necessary to ensure that the leads were not too loose that there was a danger of tripping or snagging, but not too tight as to restrict movement. A 15 m cable was then used to link the pre-amplifier box around the subjects waist to the EMG amplifier at the workstation. This provided ample length for the subject to walk along the walkway and back again.

Figure 42
Subject Moving Along the Walkway with Electrodes, Cables and Belt Attached.

The shoe from the subjects affected limb was then removed and two small footswitches were attached to the sole using adhesive tape. One switch was attached beneath the toes and the other beneath the heel. The shoe was replaced and wires from the footswitches taped along the side of the shoe and then these ran along the limb to a second amplifier box attached to the belt. A further 15 m cable was then used to carry the footswitch data to the EMG amplifier at the workstation.

Once the workstation and pre-amplifiers had been switched on the equipment was ready to record the trials. The subjects were first asked to do some short walks around the laboratory which enabled them to become accustomed to walking with all the equipment attached and also enabled the experimenter to check that all the equipment was working correctly.

At the start of each trial the subject was asked to stand at the end of the 10 m walkway from where they would walk in a straight line which would take them over the force platform. The force plate was reset by the experimenter, the EMG and vector generator recordings were triggered and the subject was then asked to start moving. An assistant (usually a parent) walked either alongside or behind the subject during the trials to manage the cables. Video recordings were made by the camera which was positioned at right angles to the walkway, filming the subject in the sagittal plane (Arrangement of the Gait Laboratory and equipment is illustrated in Figure 39, Section 4.) The video camera was zoomed in to capture three, or preferably four strides as the subject crossed the platform.

This procedure was repeated several times (making sure that the affected limb was always nearest the camera) until three trials had been recorded in which a clear foot placement was made on the force plate. This was particularly difficult for the smaller subjects who had very short step lengths. Trials were also repeated if the experimenter or parents felt that the child's walking significantly deviated from their normal pattern. A manual record was also kept of the video sequence to be analysed, along with the stride number corresponding to the impact on the force plate. A stop watch was additionally used to time the subjects moving between two red lines which were 5 m apart and marked on the centre section of the walkway. This enabled the temporal and spatial parameters to be calculated later.

Once three satisfactory sequences had been captured, the subject was asked to stand still for several seconds whilst a final EMG recording was made. This was used to provide information on the subjects baseline EMG.

At the end of the session the wires were detached, the electrodes were removed and the subjects and parents were asked about any problems they might be having with the orthoses. Home questionnaires were also completed and returned before leaving, providing vital information about each subjects adherence to wearing the orthoses.

5.6 Home Questionnaires

Each of the subjects had their general level of activity and adherence to wearing the splints assessed at weekly intervals by the use of a home questionnaire. A number of questions were presented, covering areas which might additionally result in alterations in each child's gait. Of particular interest were; each child's general level of activity and whether they participated in sports and exercise on a regular basis, any physiotherapy or other therapies they might be receiving and also the parental involvement and encouragement for physiotherapy at home. The area of main interest, however, was to check that there were no problems with the orthoses between assessments. Having questionnaires completed regularly ensured that any problems could be picked up early and the orthoses could be modified, minimising any periods when the orthoses could not be worn and the possible loss of subjects from the investigation. A copy of the questionnaire is reproduced in Figure 43.

The questionnaires were designed and illustrated in colourful folders personalised for each subject. The questions were placed on 'pull out' sheets to be completed weekly and returned in prepaid envelopes which were also contained within the folder. Unfortunately, however, compliance to this part of the study was very low and few of the questionnaires were returned. As a result this procedure was altered after the first four subjects had been through the investigation so that the questionnaires were completed by the parents at each of the testing sessions. This meant that fewer questionnaires (6) were used per subject and this therefore limited the available information, but it ensured that all questionnaires were returned and the data recorded was consistent for all subjects.

HOME QUESTIONNAIRE

Week Number 1

Approximately how many hours each day have you worn your ankle-foot orthosis?

________ hours

If the amount varies greatly between days, please give the maximum and minimum number of hours you have worn your ankle-foot orthosis during the day.

Maximum ____ hours Minimum ____ hours

Have you worn you ankle-foot orthosis to school/nursery?

☐ Always ☐ Sometimes ☐ Never

Have you worn your ankle-foot orthosis after school/nursery and at the weekend?

☐ Always ☐ Sometimes ☐ Never

Have you used a walking aid?

☐ Always ☐ Sometimes ☐ Never

If always/sometimes, which type?

☐ Crutches ☐ Cane

☐ Frame ☐ Rollator

Have you done any physiotherapy exercises?

☐ Yes ☐ No

If yes, how many hours of exercises have you done this week?

_______ hours

What activities have you done whilst wearing your ankle-foot orthosis?

☐ Walking ☐ Running ☐ Jumping

☐ Riding a bike ☐ Football ☐ Netball

Any other activities ____________________

____

____

Can you walk as far as you would like?

☐ Yes ☐ No

If not, how far can you walk before you become too tired? (please give examples such as to the end of the street, to school etc.) ___________

____

____

Have you had any problems or discomfort with your ankle foot orthosis?

☐ Yes ☐ No

If yes, please give details ________________

____

____

Any other comments you wish to make? _____

____

____

When you have completed the questions please remove this sheet from the file and return it to the School of Prosthetics & Orthotics in the envelope provided.

Thank you.

Figure 43
Questionnaire Completed at Assessments by Subject and/or Parent.

5.7 Single Subject Assessments

During the investigation questions arose as to whether any effects which might be observed as a result of wearing the orthoses would be instantaneous, or whether there was a necessary period of adjustment before changes occurred. The design of the investigation meant that there were six week gaps between assessments and therefore if there was a crucial point at which changes occurred this could easily be missed. As the subjects recruited were already being tested at the maximum number of assessments possible, with the available time and resources, the possibility of undertaking a more in depth study on just one subject was considered. The investigation already required a substantial commitment from each of the subjects and their parents and therefore a decision was made to try and recruit one subject who would have an increased number of assessments during the 12 weeks they were wearing their TRAFO.

One subject (A5) was selected as a potential candidate based on the following factors:

- She lived in a close proximity (3 miles) to the gait laboratory where the assessments were carried out.
- She was older (11 years) than most subjects and therefore co-operated readily making assessments sessions fairly simple.
- Her parents had their own transport.
- Her parents were supportive and enthusiastic about her involvement in the investigation.

The subject and her parents were approached with the proposal to increase the number of assessments and agreed to attend sessions every week whilst wearing the TRAFO.

Although on the whole this was carried out, in practice there were some weeks where it was not possible to attend an assessment as the subject was on holiday or had other commitments with school and sports. In total, subject A5 attended 9 assessments whilst wearing her TRAFO and these were distributed across the twelve week period as shown in Table 9.

Assessments

(pink) = Regular (green) = Additional

Week No	13	14	15	16	17	18	19	20	21	22	23	24
Assessment	Regular	Additional	Additional	Additional		Additional	Regular			Additional	Additional	Regular

Table 9
Distribution of Gait Assessments for Subject A5 During the Period of Twelve Weeks Spent Wearing a TRAFO

At each of the assessments the same data was collected as during the regular sessions and this was later analysed to establish whether there might be any sudden or gradual alterations to the subjects ambulation.

5.8 Analysis of Temporal and Spatial Parameters

Temporal and spatial data recorded at the assessments included the time taken to walk a distance of 5m and the time taken for one stride or gait cycle, which was calculated from the foot switch data. From this information the following parameters were calculated:

Velocity (metres. $second^{-1}$) Cadence (strides. $second^{-1}$)

Stride length (metres)

The foot switch traces were analysed to determine the time at foot contact and toe off and this information was used to calculate the total time for the gait cycle. Figure 44, illustrates a typical foot switch trace and the information obtained from this. Further analysis was finally used to determine the duration of the stance and swing phases as a percentage of the total gait cycle.

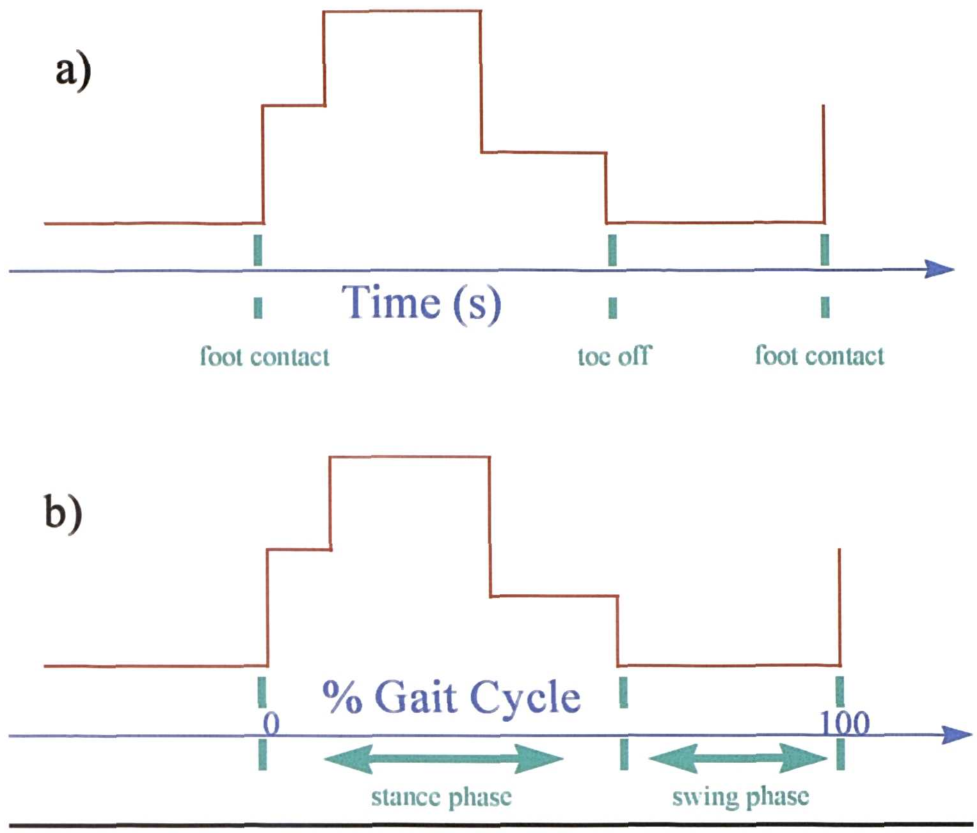


Figure 44
a) Foot Switch Temporal Information
b) Foot Switch Phasic Information

Data sheets were completed for each of the subjects showing not only the raw data from the six trials, but also the % increase or decrease in values between the two orthoses. This was done by taking an average for the three values obtained with the first orthosis and comparing this to the average of the three values from the trials with the second orthosis.

For the stance/swing phase split, values were compared to those previously published as exhibited by 'normal' subjects i.e. Stance phase - 62% of the total gait cycle and Swing phase - 38% of the total gait cycle. An example of the raw data and general gait parameters for one subject is shown in Table 10.

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.64	0.71	0.65	0.67	0.83	0.95	1.06	0.94	42
Stride Length (m)	0.51	0.69	0.52	0.57	0.91	0.97	0.99	0.96	68
Cadence (steps. s^{-1})	1.27	1.03	1.25	1.18	0.91	0.97	1.07	0.98	-17
Stance Phase (%TGC)	68	61	65	65	64	69	62	65	Norm=62
Swing Phase (%TGC)	32	39	35	35	36	31	38	35	Norm=38

Table 10
Example Data for the General Gait Parameters of One Subject Across the Six Trials in the Investigation.

5.9 EMG Processing Techniques

The EMG data collected in this investigation was obtained in the form of the raw signals for each of the four muscles tested. Three sets of data were collected from each assessment session corresponding to each of the three good steps on the force plate which were recorded in combination with the video film. The raw emg signals were then edited so that the only data remaining was for the stride which corresponded to the contact with the force platform. The data in the form of a text file was then exported from the Bipoac system so that it could be edited and graphically presented using a conventional spread sheet.

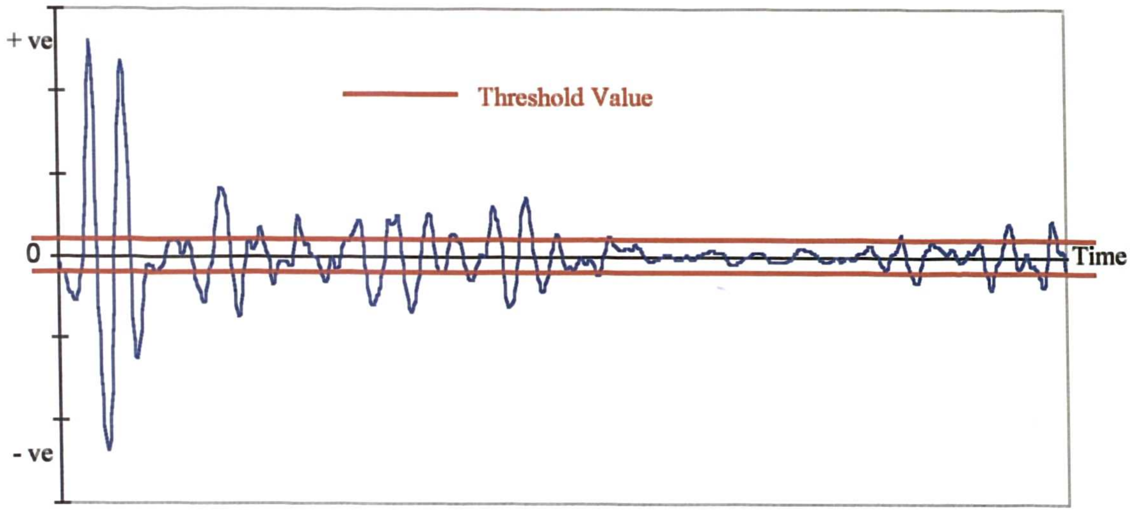
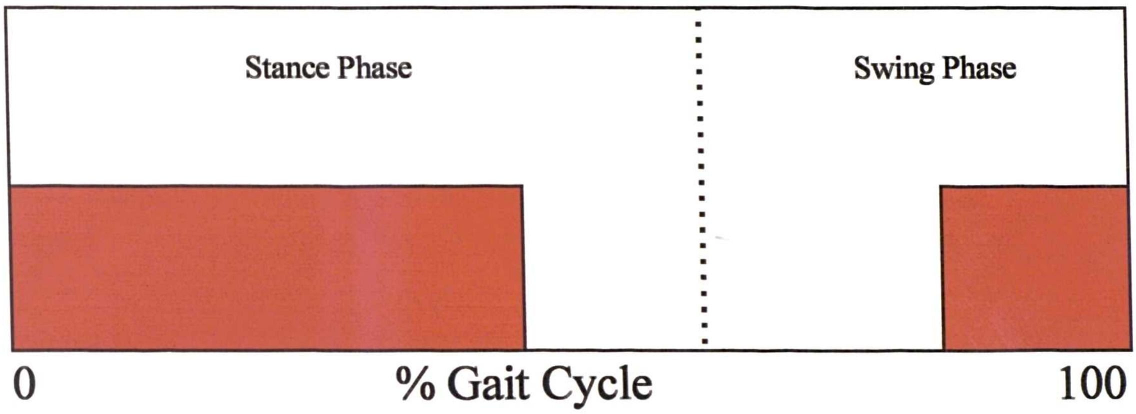


Figure 45
Example of a Raw EMG Trace with Threshold Values for Data Analysis.

As the information required was the temporal patterning of each muscles activity, it was necessary to convert each raw trace into a form where there were definite boundaries between the sections in which the muscle was active and the sections in which the muscle was inactive. As visual interpretation produces very subjective results, as discussed previously, the computer assisted methods described in Section 1 were considered. A cut off value was required, as shown in Figure 45, above which the muscle would be regarded as active and below which, passive.

The method used in this investigation was similar to that described by DiFabio (1987) in which the threshold was set at $\pm$ 3 standard deviations of the mean baseline value. The mean baseline value for each trial was calculated by averaging the 10 s readings that were taken at the end of each session whilst the subject was standing still. The threshold values of $\pm$ 3 standard deviations from this mean were then established. The raw EMG data from the trials was filtered according to the threshold values to provide on/off blocks for the total period of the gait cycle.



Muscle active for 75% of the stance phase and 47% of the swing phase.

Figure 46
Block Diagram of EMG Trace Showing Active and Inactive Periods.

If the signal remained below the threshold level the muscle was considered to be inactive and when the signal went above the threshold the muscle was considered to be active. To remove any erroneous data points from the EMG traces where there were single or small crossings of the threshold line, blocks of data which were smaller than 2% of the total gait cycle were discounted. The resultant trace was a block diagram of activity for each of the muscles which was plotted against time as a percentage of the total gait cycle (see Figure 46).

Block diagrams were produced for each of the subjects at each of their six trials. For each muscle, the blocks of activity were summed over the stance phase and this provided a figure for the total amount of activity recorded as a percentage of that phase. The same procedure was carried out to calculate the total activity of each muscle in the swing phase. This data was then tabulated for each subject, an example of which is shown in Table 11.

Trial	*Phase*	*Tibialis Anterior*	*Gastrocnemius*	*Rectus Femoris*	*Biceps Femoris*
1	Stance	30	43	44	24
	Swing	19	16	13	5
2	Stance	17	23	46	5
	Swing	0	34	48	5
3	Stance	52	58	75	50
	Swing	55	12	59	31
4	Stance	56	69	47	64
	Swing	22	0	27	34
5	Stance	27	82	65	28
	Swing	0	0	56	91
6	Stance	30	78	64	62
	Swing	10	0	68	31

Table 11
Example Data of Summed Activity Blocks for One Subject Across the Six Trials in the Investigation.

5.10 Questionnaire Analysis

Six questionnaires were analysed for each of the subjects in the investigation, three from each of the assessments in both orthotic conditions. The values for individual subjects were then averaged across the three assessments resulting in two sets of data per subject, one for each of the orthoses.

As there were two groups of subjects and two orthoses tested, the data were separated into four categories: group A orthosis 1, group A orthosis 2, group B orthosis 1, and group B orthosis 2. Group averages were then calculated for the number of hours the orthoses were worn each day, the number of hours of physiotherapy the subjects had each day and the number of activities the subjects participated in whilst wearing the orthoses. These values were tabulated and then represented using bar charts.

Further graphs were produced to show the type and number of activities the subjects participated in and additional information on whether the orthoses were worn at school or at home in the evenings and weekends was also presented in this manner.

5.11 Statistical Analysis

5.11.1 Temporal and Spatial Parameters

Descriptive.

For each subject, the percentage increase or decrease in velocity, step length and cadence was calculated when moving from the first orthosis to the second (see 6.1). These values were then plotted on bar charts showing the range, mean and standard deviation for each of the two groups (A & B).

For the split between stance and swing phase as a percentage of the total gait cycle, norm values were taken from the literature and compared with the subject data in this investigation. Bar charts were plotted showing the group mean, range, and standard deviation for each group in both orthotic conditions and the deviation of these values from the published norms.

Inferential.

Following visual analysis of the graphical data for the gait parameters it was clear that there were relatively low sample sizes, and the variances of the two groups were different. The groups had however, been randomly sampled and were thought to be representative of normally distributed populations. Parametric statistics were chosen for the data as they are more powerful than their non-parametric equivalents and a series of two-sample t-tests were performed to compare the change in parameters (velocity, step length, cadence) between the two groups. Such procedures compare the means of two independent samples and work out the probability of getting the observed difference if the null hypothesis were true. When using the t-test for independent samples with separate variance the following assumptions are made:

(i) the groups are independent and have been randomly sampled,

(ii) the population variances are unequal or heterogeneous, and

(iii) the population distributions are normal

The statistical analysis was performed using SPSS computer software and the H_0 was rejected at the 5% significance level. Confidence intervals were also calculated to provide information on the magnitude of the difference between the means from the two groups.

As established normal values are available for the split between stance and swing phases as a percentage of the total gait cycle, one sample t-tests were performed. Such calculations measure the difference between the group mean and a specific hypothesised mean, which in this case would be the population norm value taken from the literature. The formula used is as follows:

$$t = \frac{\text{Sample Mean} - \text{Hypothesised Mean}}{\text{Standard error of the sample mean}}$$

Tests were again measured at the 5% significance level and confidence intervals reported.

5.11.2 EMG

Descriptive.

For each individual a mean level of activity was calculated for each muscle in the stance and swing phases and in both of the orthoses, thus resulting in four values of activity per muscle as shown in Table 12.

ORTHOSIS	*PHASE*	
	Stance	*Swing*
1	Mean Trials 1-3	Mean Trials 1-3
2	Mean Trials 4-6	Mean Trials 4-6

Table 12
Four Values of Activity Calculated for Each Subject.

The data for each of the subjects was plotted on bar charts showing the range, mean and standard deviation. The data from each of the individual subjects were then combined and group means calculated as above for each of the muscles. The group data was then plotted on a further set of bar charts.

Inferential.

The group means calculated as described above, were compared with norm values taken from the literature, by using one sample t-tests as used for the split between swing and stance phase. These tests measured the difference in the levels of muscular activity exhibited by the subjects in this investigation with those reported in a normal population. Tests were again measured at the 5% significance level and confidence intervals reported.

5.11.3 Single Subject Assessments

Descriptive.

For all parameters line graphs were produced to illustrate the variations in the measurements across time i.e. over the nine assessments whilst wearing the second orthosis. Absolute values were presented for the general gait parameters for each trial along with group means, range, and standard deviations for the two orthoses.

Section 6

Results

6.1 Temporal & Spatial Parameters & Vector Analysis

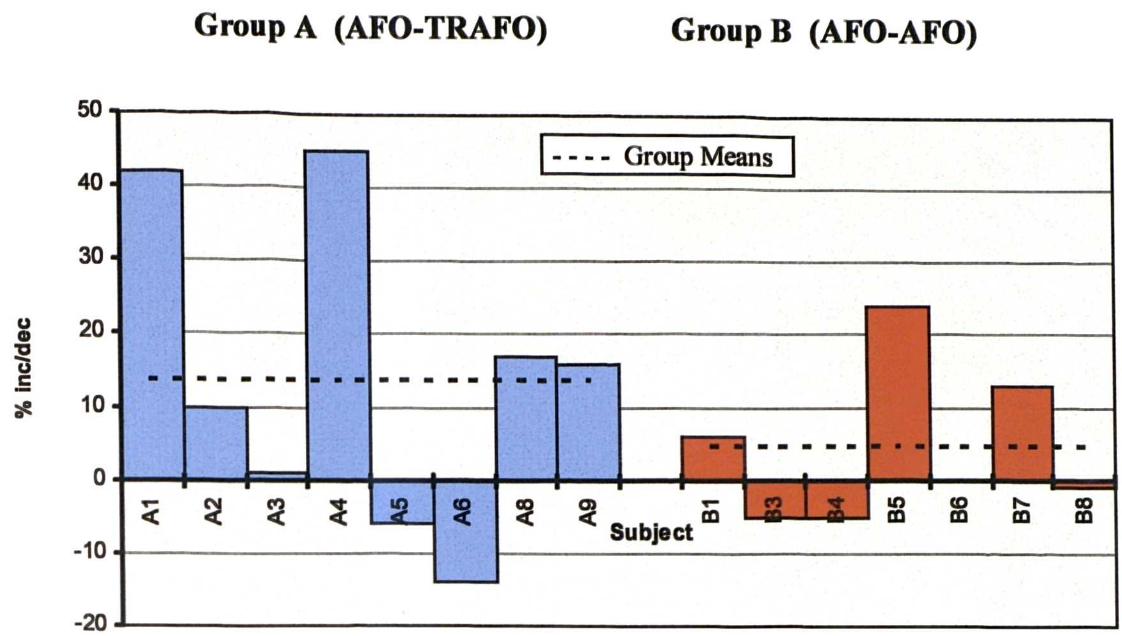
6.1.1 Introduction to Velocity, Cadence, and Stride Length Data

Individual velocity, cadence, and stride length data are presented in Figures 47, 48 and 49 respectively, along with group means, standard deviations and ranges. Each subject's individual data shows the percentage change of the measured variable recorded when the subject transferred from the first to the second orthosis. The parameter plotted was calculated as:

$$\% \text{ inc/dec} = \frac{\text{mean (trials 4-6) - mean trials (1-3)}}{\text{mean trials (1-3)}} \times 100$$

6.1.2 Velocity

There was a large variability in the velocity results between subjects, particularly in group A, in which one subject exhibited a 14% decrease whilst another showed a 45% increase when changing from a conventional AFO to a TRAFO. Variability in the data was also present in group B although to a much smaller extent. The group mean values show group A having a greater increase in velocity between the two orthoses than group B. However, because of the large variability of the data, statistical analysis using a t-test (Appendix 1) did not indicate this difference to be significant (P=0.133).



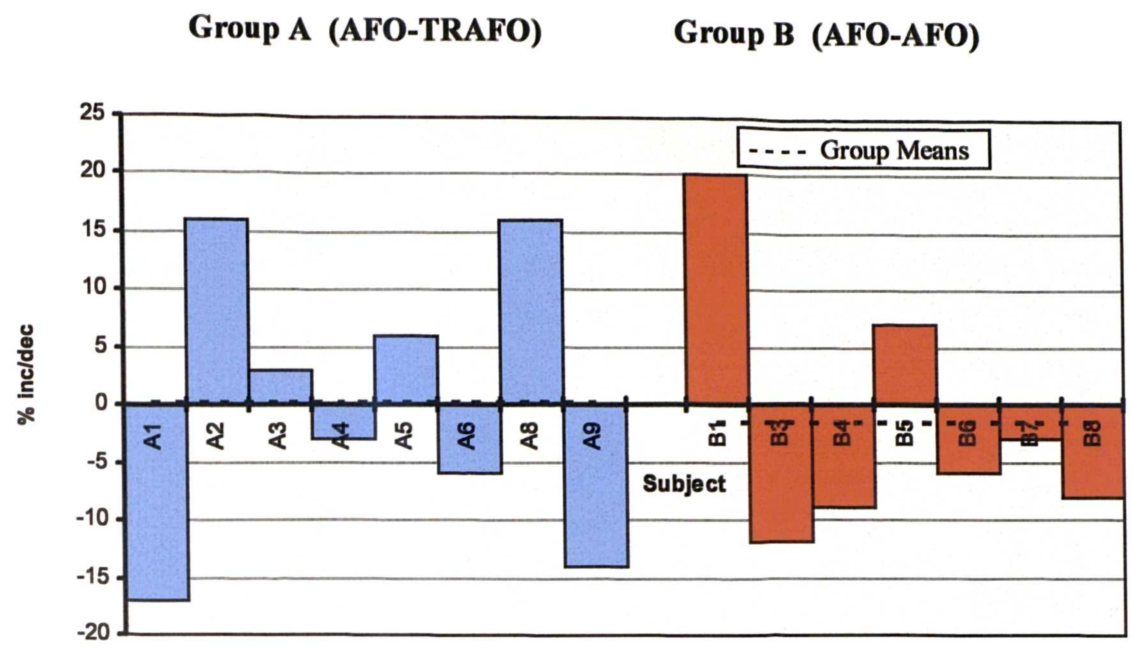
Group A
Mean 13.875
Range -14 to 45
SD 21.484

Group B
Mean 4.429
Range -5 to 23
SD 10.390

Figure 47
The Increase or Decrease in Velocity Observed for Individual Subjects Within Groups A & B when Changing from the First to the Second Orthosis.

6.1.3 Cadence

The individual cadence data are shown in Figure 48, along with the group means, standard deviations and ranges. In both groups there was much variability in the data with an almost even split between those subjects who showed an increase in cadence and those who showed a decrease. The mean group values reflects this even spread in the data with a resultant of almost no overall increase or decrease in both groups. Statistical analysis confirmed that there was no significant differences between the two groups (P=0.702).



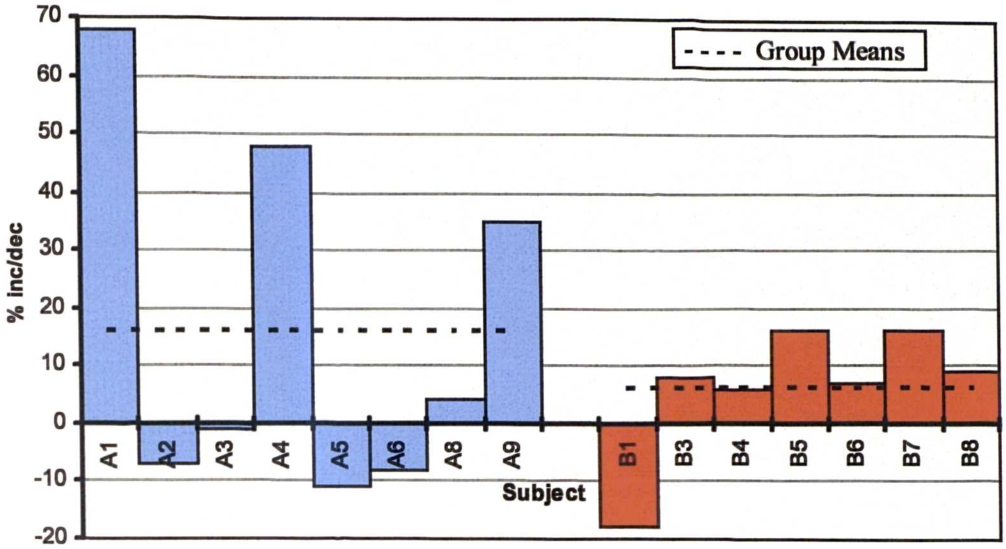
Group A		Group B	
Mean	0.250	Mean	-1.714
Range	-17 to 16	Range	-13 to 20
SD	12.430	SD	11.456

Figure 48
The Increase or Decrease in Cadence Observed for Individual Subjects Within Groups A & B when Changing from the First to the Second Orthosis.

6.1.4 Stride Length

Individual data for stride length are shown in Figure 49 along with group means, standard deviations and ranges. In group B all except one subject exhibited an increase in stride length when changing from the first orthosis to the second. These data are reflected in the group mean which shows a 6% increase in stride length. In group A there was much variability in the data ranging from an 11% decrease in one subject to a 68% increase in another. The group mean value of a 16% increase is clearly influenced by subjects A1, A4 and A9 who all exhibited large increases in stride length. Statistical analysis showed that the differences between the two groups were significant (at the 0.01 level) with a P value of 0.006.

Group A (AFO-TRAFO) **Group B (AFO-AFO)**



Group A		Group B	
Mean	15.875	Mean	6.143
Range	-11 to 68	Range	-18 to 16
SD	29.744	SD	11.481

Figure 49
The Increase or Decrease in Stride Length Observed for Individual Subjects Within Groups A & B when Changing from the First to the Second Orthosis.

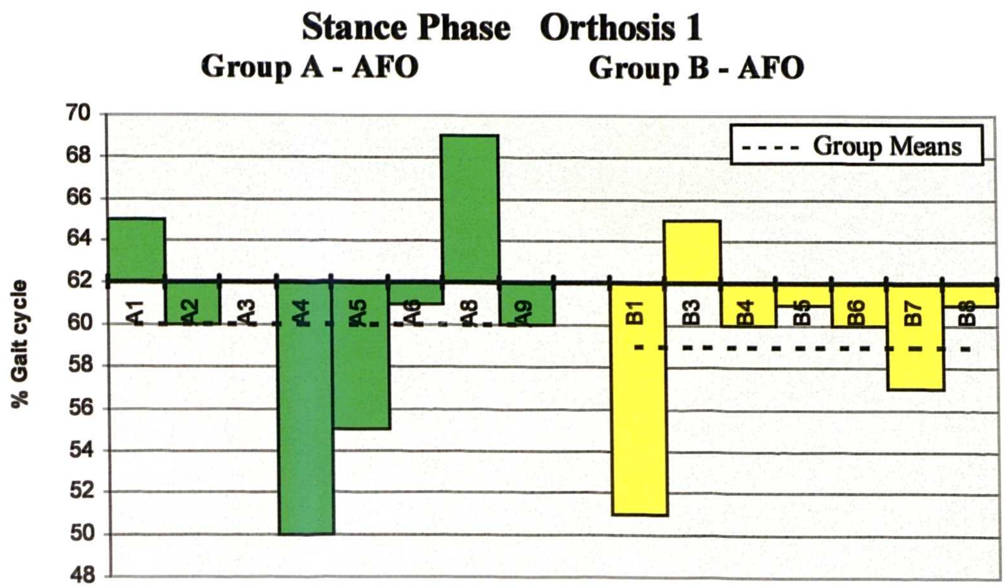
6.1.5 Introduction to Data on Stance and Swing Phase Durations

The data showing the duration of the stance and swing phases as a percentage of the gait cycle time are shown in Figures 50, 51, 52 and 53. Two figures are shown for each phase, one for each of the orthoses used in the investigation. In each figure the individual data bars represent the mean of each subject's data for the three trials for which the orthosis was worn, and the position of the x axis represents the values for normal gait (Knutson & Soderberg, 1995). Thus each of the individual bars in the figures represents the extent to which the observed results for each subject differ from the expected norm.

6.1.6 Stance Phase

The durations of the stance phase as a percentage of the total gait cycle times is shown in Figure 50 for orthosis 1 and in Figure 51 for orthosis 2. Again, the data were varied with some subjects showing more normal patterns in the first orthosis whilst others improved in the second orthosis. Looking at the mean group values, group A moved further away from normal data in changing from AFOs to TRAFOs, although the observed change of 2% was only small. In group B, the mean value moved closer to normal data in the second AFO although again the change was small (1%).

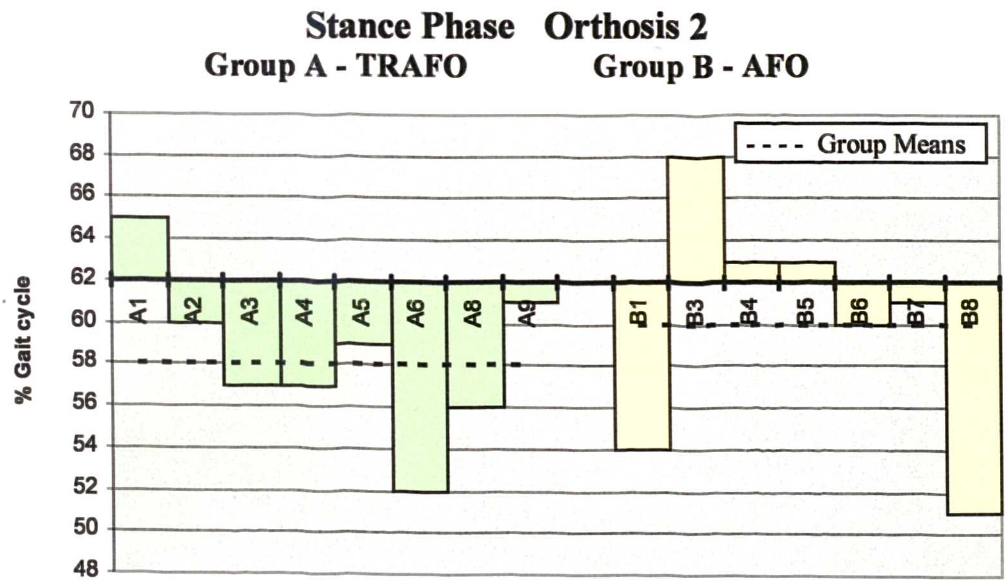
The statistical analysis compared each of the group means to the duration observed in the normal population (62% total gait cycle). The results of the statistical analysis, Table 13, showed that the data for group A wearing the TRAFOs was just significantly different from that of the normal population at the 0.05 level. The data for all the other groups were not significantly different to those for a normal population.



Group A
Mean 60.250
Range 50 to 69
SD 5.800

Group B
Mean 59.286
Range 51 to 65
SD 4.348

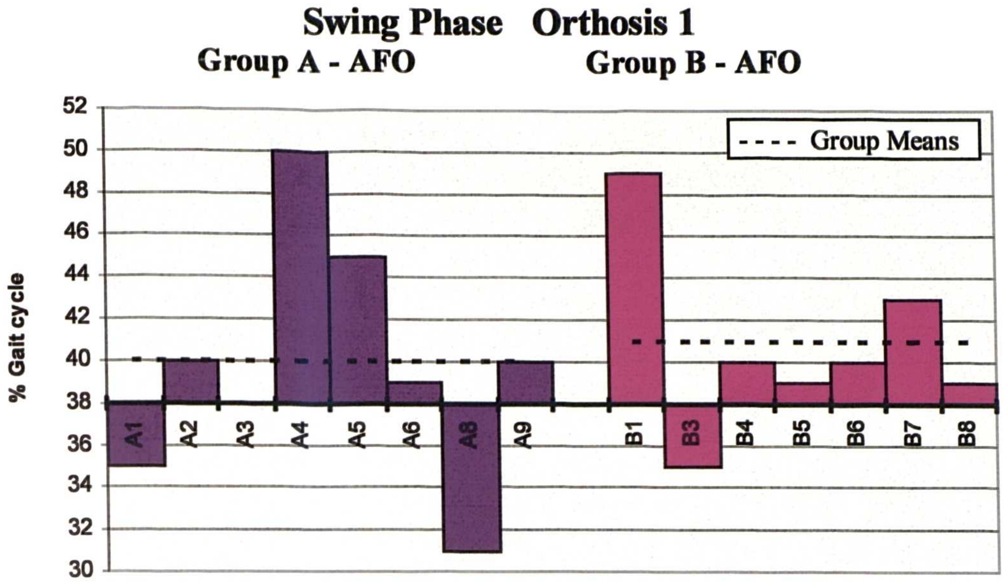
Figure 50
Duration of the Stance Phase for Individual Subjects within Groups A & B, Whilst Wearing the First Orthosis, in Comparison to Data for a Normal Population.



Group A
Mean 58.375
Range 52 to 65
SD 3.852

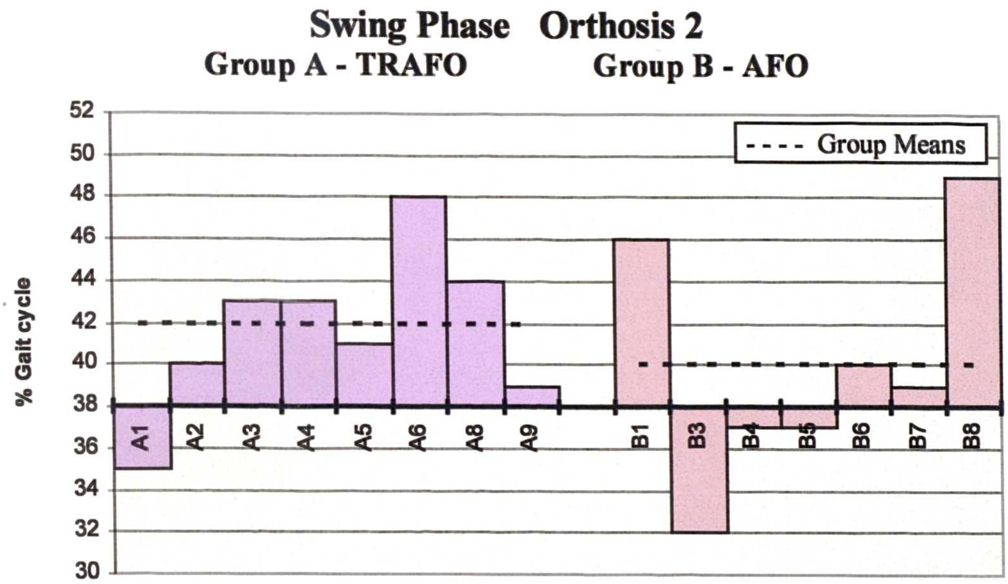
Group B
Mean 60.000
Range 51 to 68
SD 5.774

Figure 51
Duration of the Stance Phase for Individual Subjects within Groups A & B, Whilst Wearing the Second Orthosis, in Comparison to Data for a Normal Population.



Group A		Group B	
Mean	39.750	Mean	40.714
Range	31 to 50	Range	35 to 49
SD	5.800	SD	4.348

Figure 52
Duration of the Swing Phase for Individual Subjects within Groups A & B, Whilst Wearing the First Orthosis, in Comparison to Data for a Normal Population.



Group A		Group B	
Mean	41.625	Mean	40.000
Range	35 to 48	Range	32 to 49
SD	3.852	SD	5.774

Figure 53
Duration of the Swing Phase for Individual Subjects within Groups A & B, Whilst Wearing the Second Orthosis, in Comparison to Data for a Normal Population.

GROUP	ORTHOSIS	
	1	2
A	0.422	0.032*
B	0.150	0.395

*Significant at the 0.05 level

Table 13
Statistical Results (P Values) for the Comparison of Stance Phase Duration Across Groups and Orthoses with that Observed in a Normal Population.

6.1.7 Swing Phase

The data for the duration of the swing phase as a percentage of the total gait cycle are shown in figure 52 for orthosis 1 and figure 53 for orthosis 2. As the total gait cycle is split directly between the stance and swing phases the individual data in these figures is the complement of that observed in the stance phase. The results of the statistical analysis are shown in Table 14 and as for the stance phase, group A wearing TRAFOs had a swing phase significantly different to that reported for a normal population at the 0.05 level, but none of the other group mean values in the swing phase were significantly different.

GROUP	ORTHOSIS	
	1	2
A	0.422	0.032*
B	0.150	0.395

*Significant at the 0.05 level

Table 14
Statistical Results (P Values) for the Comparison of Swing Phase Duration Across Groups and Orthoses with that Observed in a Normal Population.

6.1.8 Vector Generator

Information on the magnitude and direction of ground reaction vectors was provided from the video images. For each subject at every trial, three video images were captured: foot/ground contact, mid-stance and toe-off. The three trials from each splint were then displayed together so that a visual comparison could be made.

Individual subject data showed no clear patterns in the position of the vector at any of the three key stages. There were variations in the characteristics of the foot/ground contact at the beginning of the trials with some subjects exhibiting a clear heel strike whilst for others initial contact was made with the toes.

A number of individuals appeared to have made improvements and moved towards a pattern of flat foot contact or even heel strike as the trials progressed. Other subjects exhibited no changes with almost identical ground reaction vectors throughout the trials despite the change in splints.

The ground reaction vector information was collected to provide a visual assessment of the gait cycle to support the EMG data being collected. No quantitative data could be obtained from the video images but they did provide the means of making subjective assessments of any changes.

Figures 54, 55, 56, and 57 show examples of the ground reaction vector images obtained for two subjects in this investigation. They form a general illustration of the pictorial information obtained for one of the subjects in each of the two groups.

Figure 54 **The Video Vector Images for Subject A8 at Key Stages During Trials 1-3 whilst Wearing an AFO.**

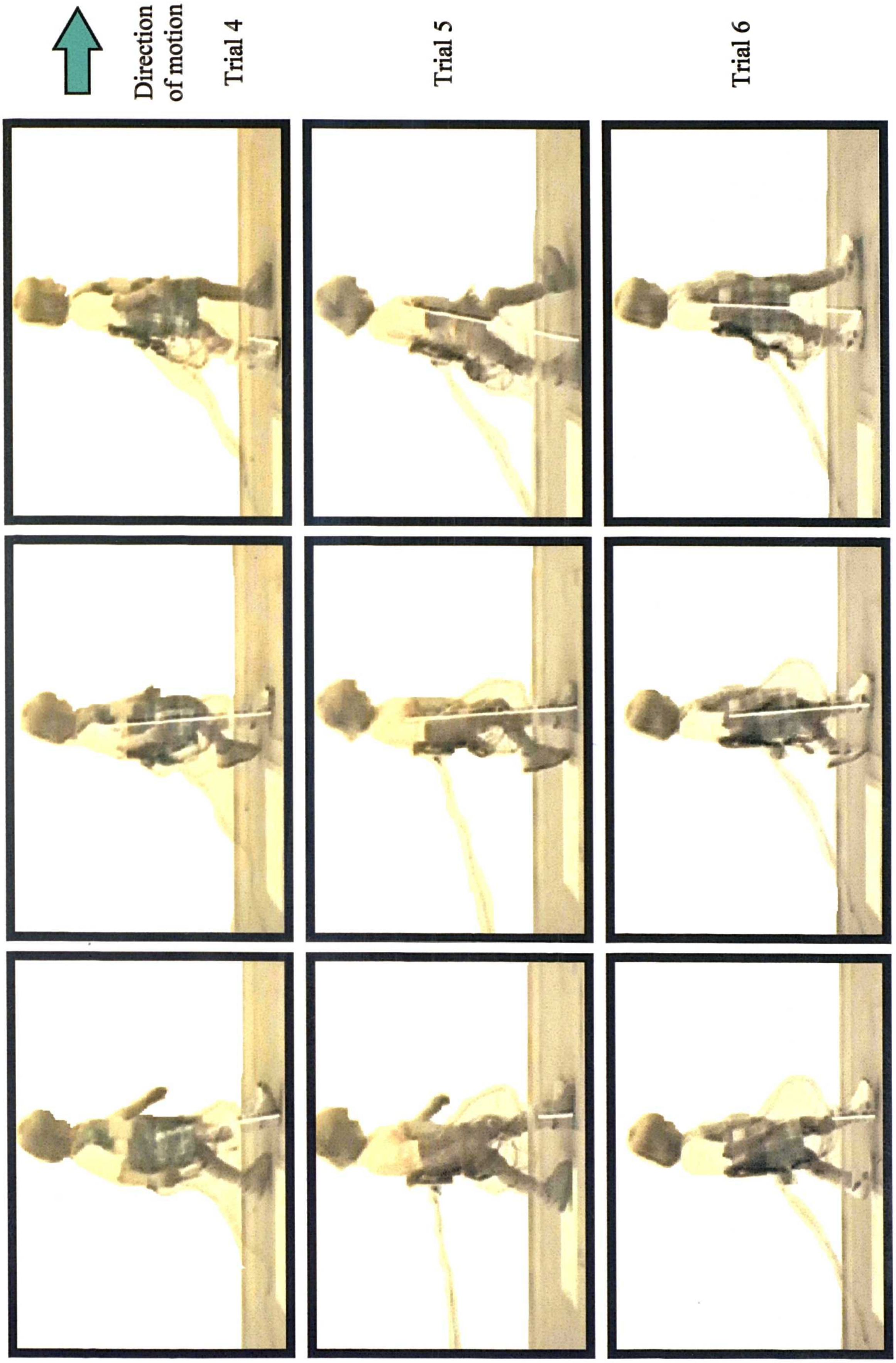


Figure 55 **The Video Vector Images for Subject A8 at Key Stages During Trials 4-6 whilst Wearing a TRAFO.**

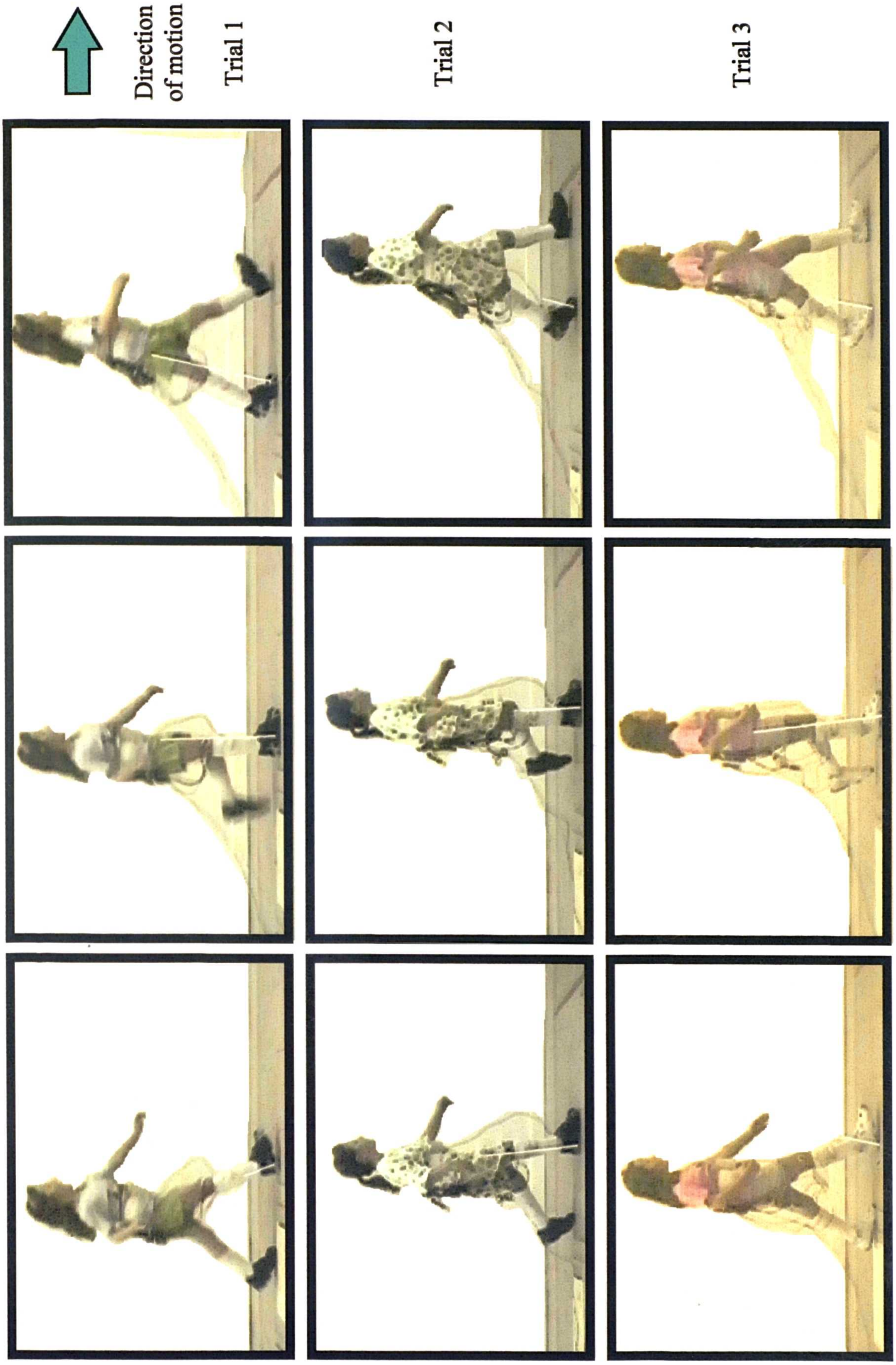


Figure 56 **The Video Vector Images for Subject B4 at Key Stages During Trials 1-3 whilst Wearing an AFO.**

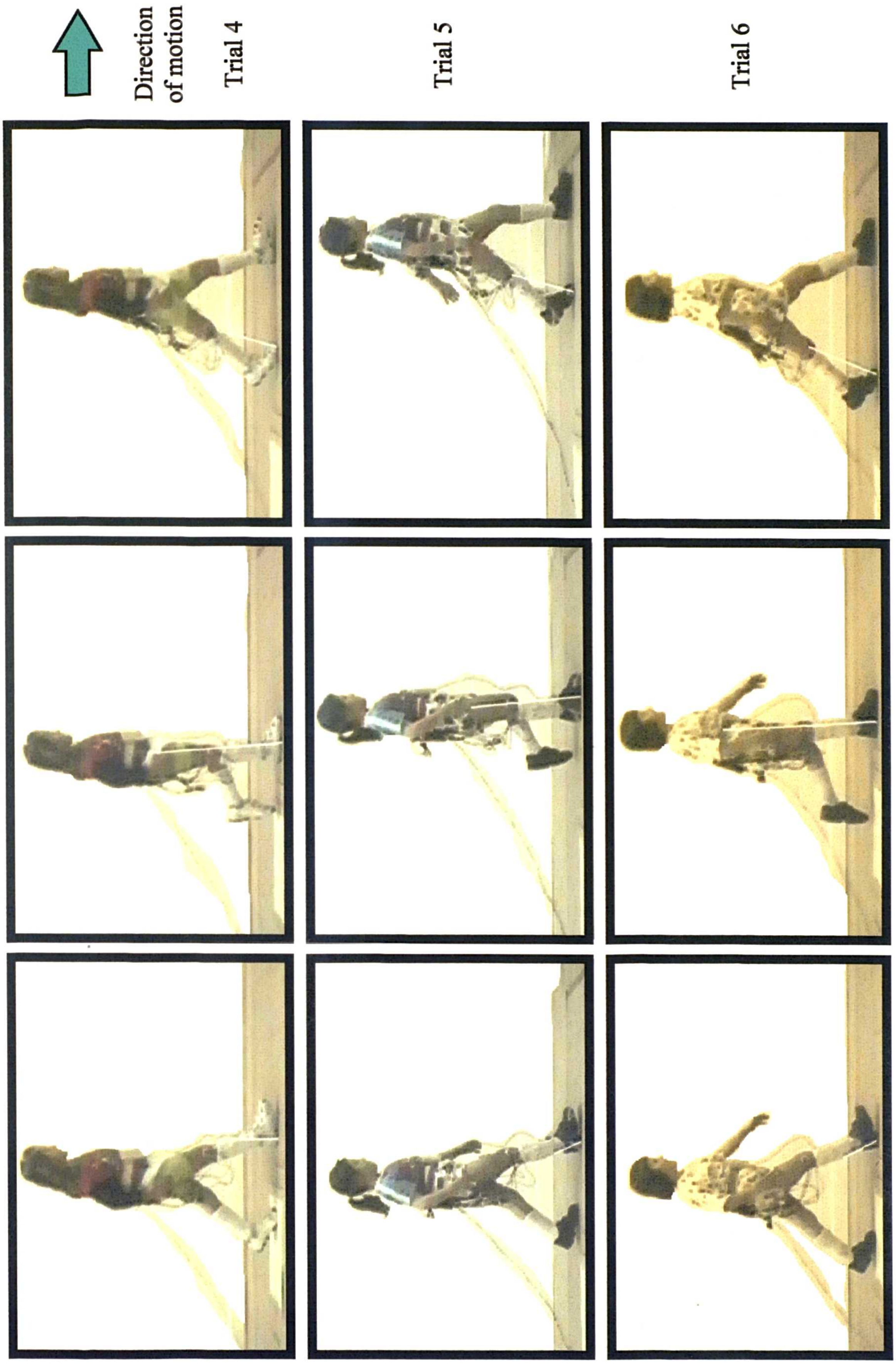


Figure 57 **The Video Vector Images for Subject B4 at Key Stages During Trials 4-6 whilst Wearing an AFO**

6.2 EMG Data

6.2.1 Combined Group Data

Group data for the electromyography results are shown in Figures 58, 59, 60, and 61. Figures 58 and 59 relate to the stance phase of the gait cycle with the first and second orthoses respectively. Similarly Figures 60 and 61 relate to the swing phase with the first and second orthoses. Each block of data represents the group mean value of the total duration of activity as a percentage of the corresponding phase of the gait cycle for the three trials carried out whilst wearing that particular orthosis. The level of activity in the normal population is denoted on the bar charts by a black square for each of the muscles/muscle groups analysed.

In the stance phase results for both groups were similar across the two orthoses. The most notable result from the stance phase data was that regardless of group or orthosis, subjects in this investigation exhibited much higher levels of activity in the hamstrings than the level reported for a normal population. In the swing phase again, results for the two groups were the same across both orthoses. The most notable findings from the swing phase were that regardless of group or orthosis, the subjects in this investigation had a significantly higher activity in the gastrocnemius and a lower activity in the tibialis anterior than that reported for normal subjects.

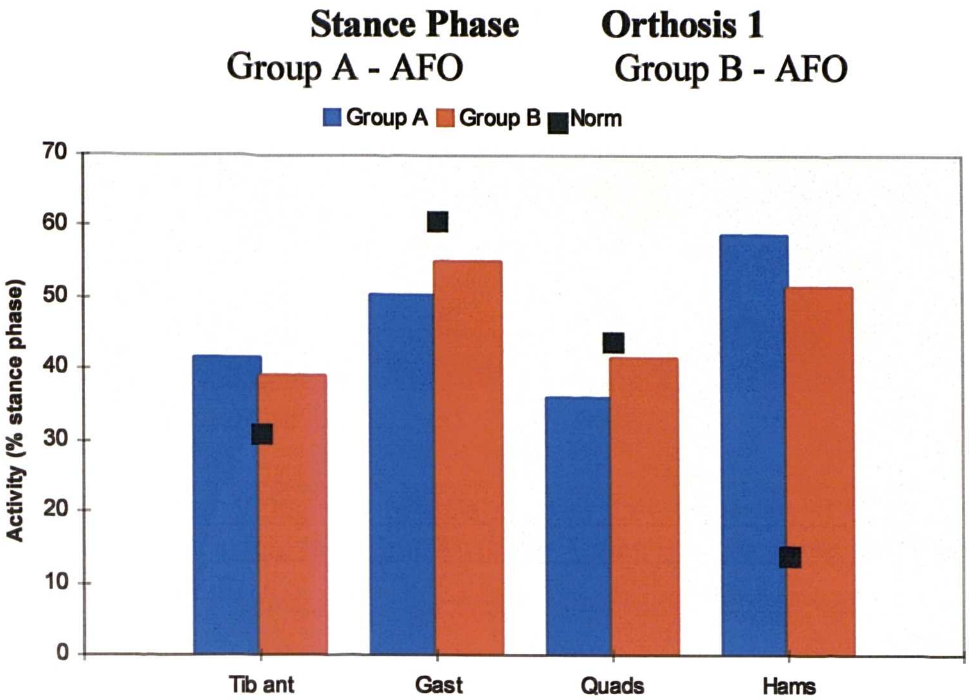


Figure 58
The Group Mean Values for Muscle Activity Levels Observed During the Stance Phase whilst Wearing the First Orthosis Compared to those Reported for the Normal Population.

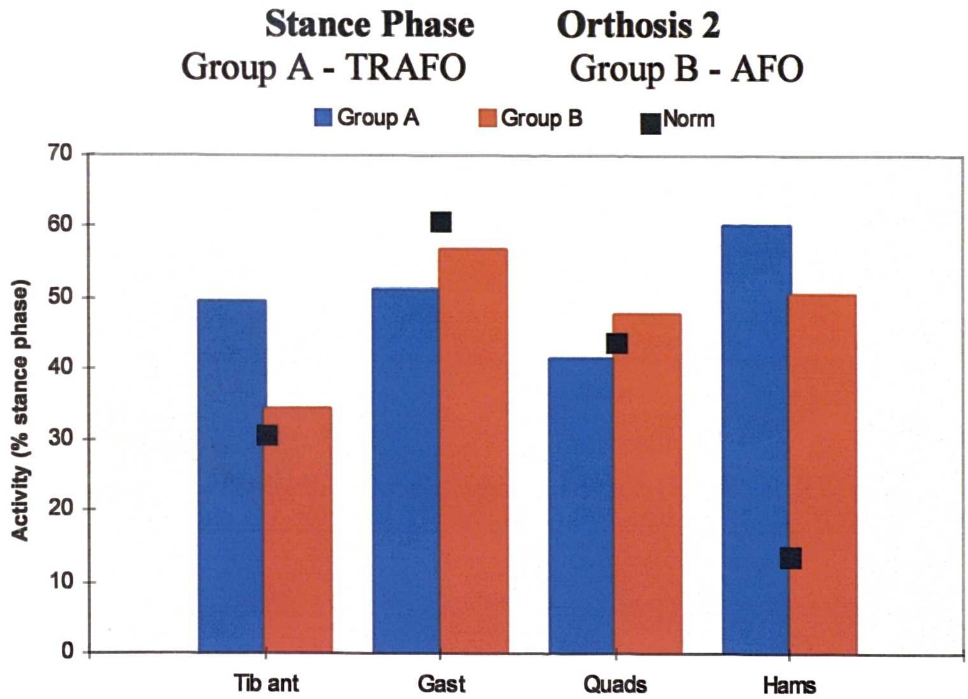


Figure 59
The Group Mean Values for Muscle Activity Levels Observed During the Stance Phase whilst Wearing the Second Orthosis Compared to those Reported for the Normal Population.

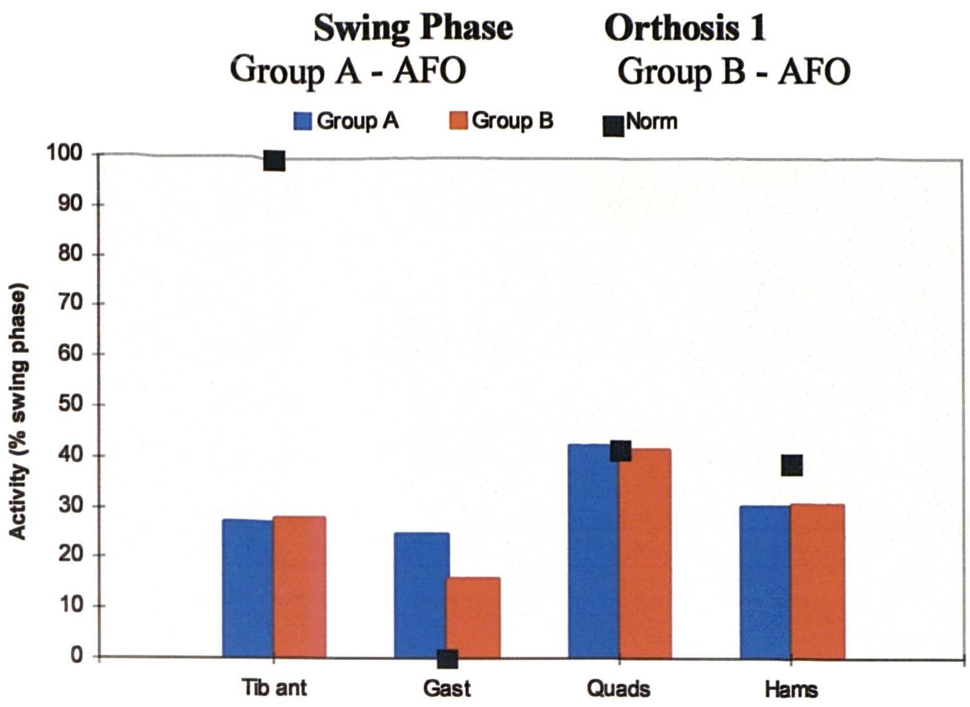


Figure 60
The Group Mean Values for Muscle Activity Levels Observed During the Swing Phase whilst Wearing the First Orthosis Compared to those Reported for the Normal Population

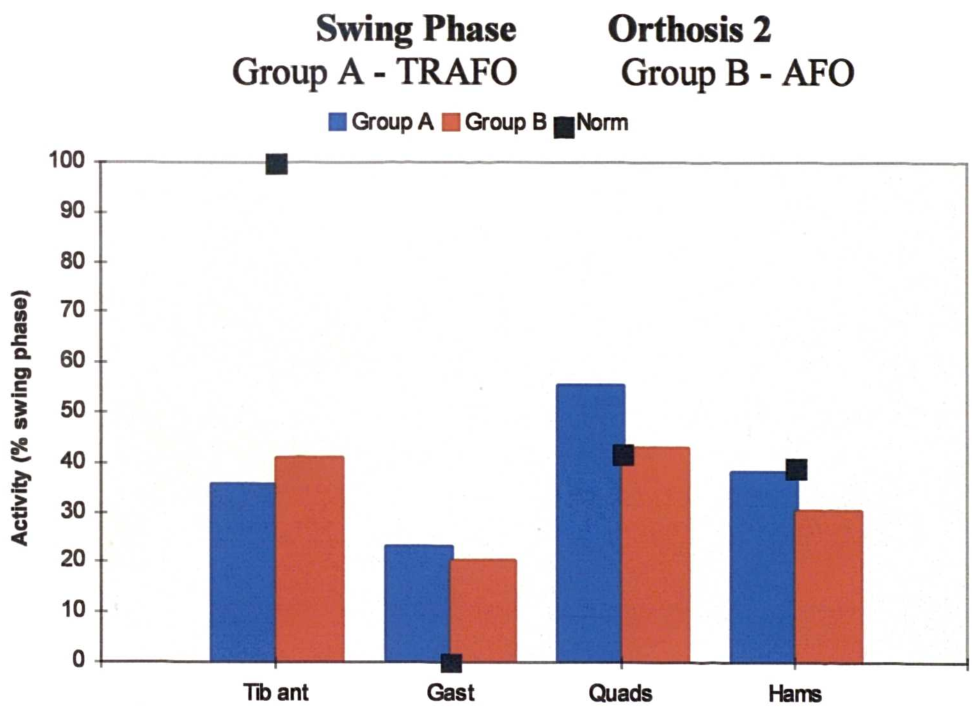


Figure 61
The Group Mean Values for Muscle Activity Levels Observed During the Swing Phase whilst Wearing the Second Orthosis Compared to those Reported for the Normal Population

6.2.2 Individual Muscle Data

Individual subject data for the electromyography results are shown in Figures 62 to 77 where the x axis is displaced to represent the duration of muscle activity reported for a normal population as a percentage of the phase. The results for each muscle/muscle group are shown in four figures corresponding to the two phases of the gait cycle and the two orthoses used in the assessments.

Tibialis Anterior

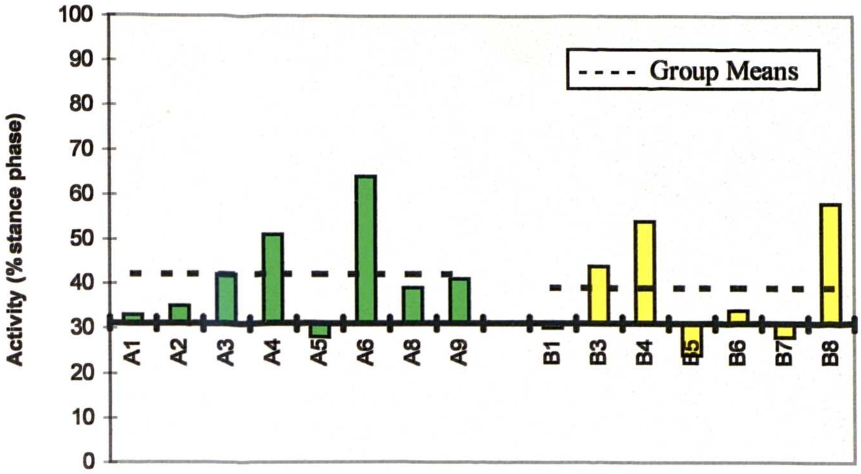
The individual data for the tibialis anterior in the stance phase shows that group B exhibited a spread of results around the normal population value (31% stance phase). Group A in both orthoses however, had all but one subject exhibiting higher levels of activity than the normal population value. Statistical analysis is shown in Table 15, and shows that during the stance phase subjects in group B had activity levels in the tibialis anterior which were not significantly different to those observed in a normal population. Group A however, did have significantly higher activity in both orthoses at the 0.05 level.

GROUP	*ORTHOSIS*	
	1	2
A	0.033*	0.011*
B	0.169	0.483

*Significant at the 0.05 level **Significant at the 0.01 level

Table 15
Statistical Results (P Values) for the Comparison of Tibialis Anterior Activity Across Groups and Orthoses with that Observed in a Normal Population During the Stance Phase of the Gait Cycle.

Tibialis Anterior
Stance Phase - Orthosis 1
Group A - AFO Group B - AFO

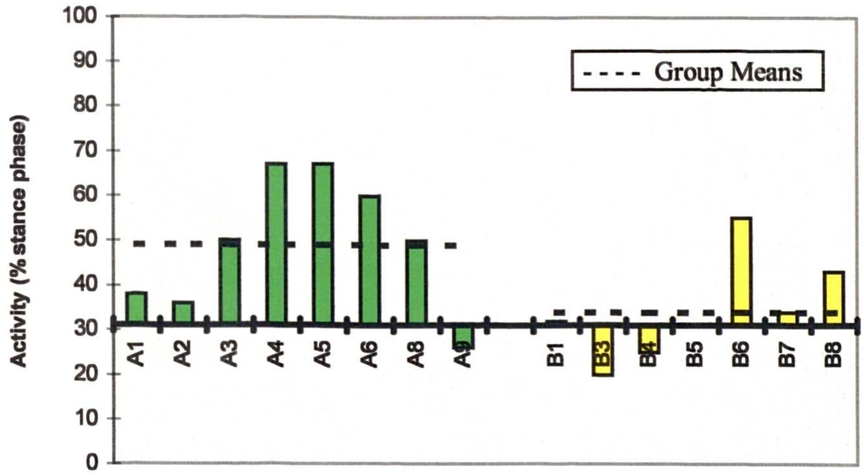


Group A
Mean 41.625
Range 28 to 64
SD 11.338

Group B
Mean 38.857
Range 24 to 58
SD 13.310

Figure 62
Individual and Group Activity Levels for the Tibialis Anterior During the Stance Phase whilst Wearing the First Orthosis.

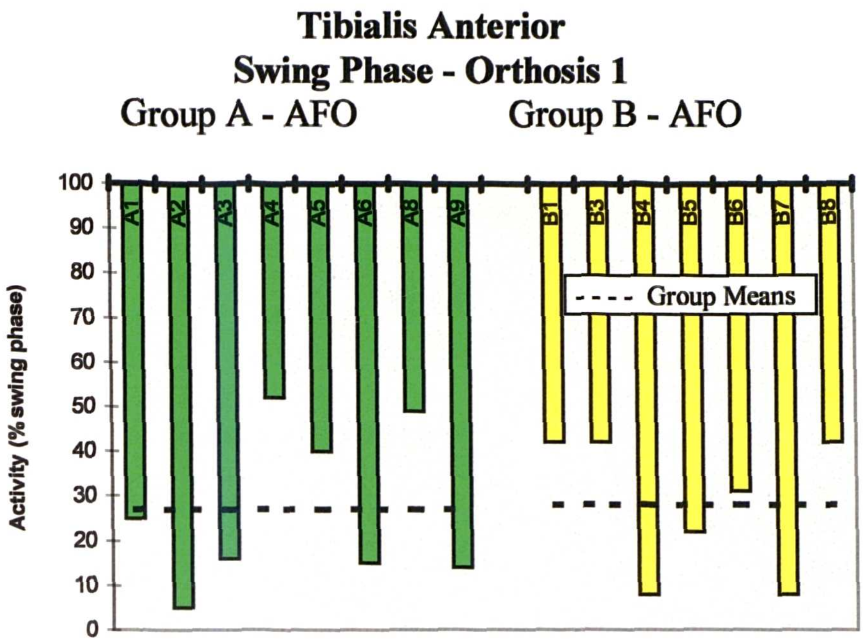
Tibialis Anterior
Stance Phase - Orthosis 2
Group A - TRAFO Group B - AFO



Group A
Mean 49.250
Range 26 to 67
SD 15.069

Group B
Mean 34.286
Range 20 to 55
SD 11.629

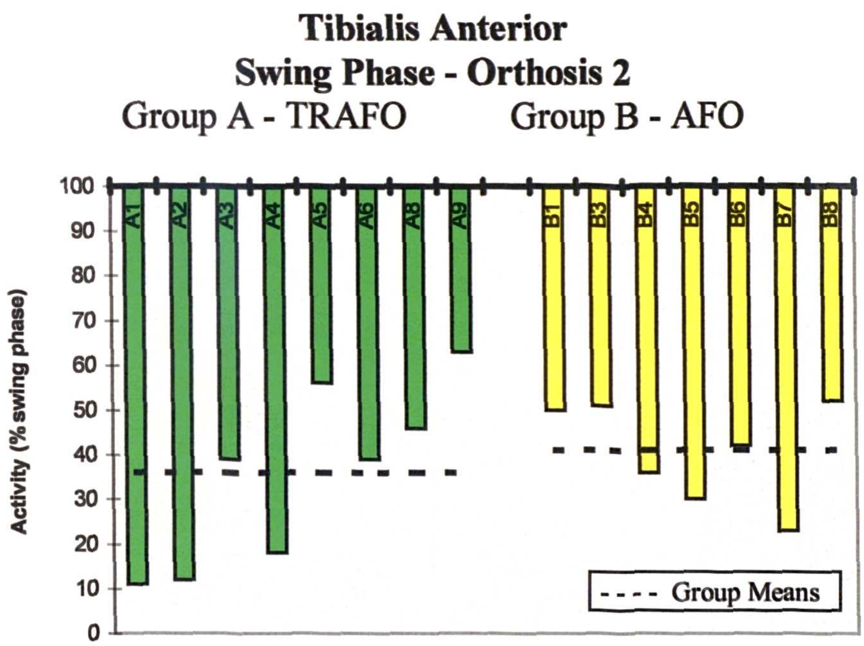
Figure 63
Individual and Group Activity Levels for the Tibialis Anterior During the Stance Phase whilst Wearing the Second Orthosis.



Group A
Mean 27.000
Range 5 to 52
SD 17.728

Group B
Mean 27.857
Range 8 to 42
SD 15.453

Figure 64
Individual and Group Activity Levels for the Tibialis Anterior During the Swing Phase whilst Wearing the First Orthosis.



Group A
Mean 35.500
Range 11 to 63
SD 19.893

Group B
Mean 40.571
Range 23 to 52
SD 11.341

Figure 65
Individual and Group Activity Levels for the Tibialis Anterior During the Swing Phase whilst Wearing the Second Orthosis.

In the swing phase, the level of activity exhibited in all subjects was considerably lower than that for the normal population with group mean values around the 27-40% level in comparison to 100% activity reported for normal subjects. The statistical analysis, table 16, for the swing phase data shows that all groups had activity levels in the tibialis anterior which were significantly different at the 0.01 level to those found in a normal population. The uniformity in the reduced activity levels across the groups would suggest that it is not affected by the orthosis type, but by the underlying pathology common to all subjects in the investigation.

GROUP	*ORTHOSIS*	
	1	**2**
A	0.000**	0.000**
B	0.000**	0.000**

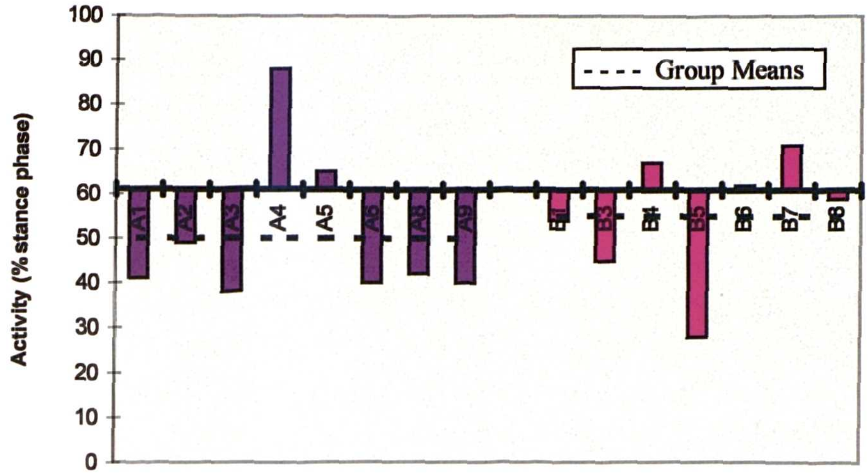
*Significant at the 0.05 level **Significant at the 0.01 level

Table 16
Statistical Results (P Values) for the Comparison of Tibialis Anterior Activity Across Groups and Orthoses with that Observed in a Normal Population During the Swing Phase of the Gait Cycle.

Gastrocnemius

The individual data for the gastrocnemius activity levels in the stance phase show that in the majority of subjects (10/15 orthosis 1 and 12/15 orthosis 2) a reduction in activity was observed in comparison to the value of 61% reported for a normal population. The mean group data reflects these values with activity levels being reduced by between 6 and 12%. The biggest reductions were observed in group A in both splint types.

Gastrocnemius
Stance Phase - Orthosis 1
Group A - AFO   Group B - AFO

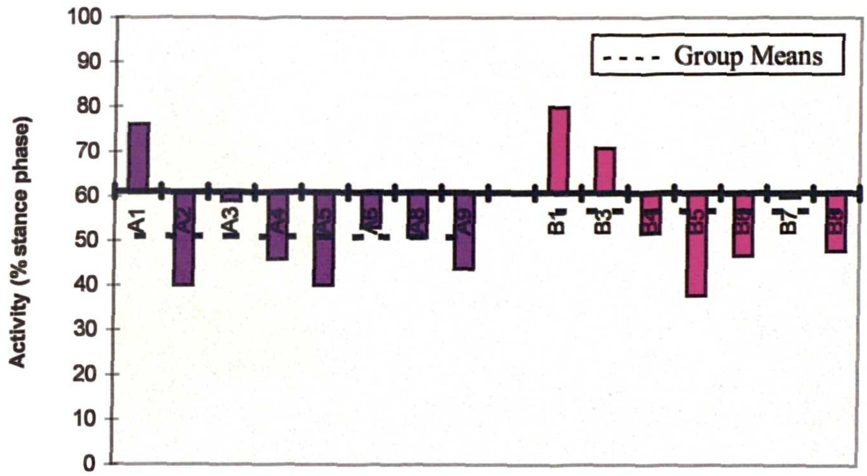


Group A
Mean 50.375
Range 38 to 88
SD 17.558

Group B
Mean 55.143
Range 28 to 71
SD 14.690

Figure 66
Individual and Group Activity Levels for the Gastrocnemius During the Stance Phase whilst Wearing the First Orthosis.

Gastrocnemius
Stance Phase - Orthosis 2
Group A - TRAFO   Group B - AFO

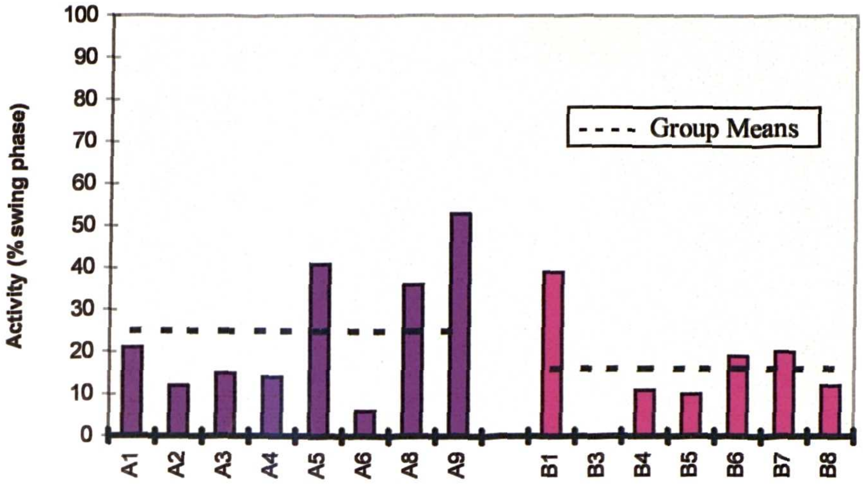


Group A
Mean 51.125
Range 40 to 76
SD 12.005

Group B
Mean 56.571
Range 38 to 80
SD 14.718

Figure 67
Individual and Group Activity Levels for the Gastrocnemius During the Stance Phase whilst Wearing the Second Orthosis.

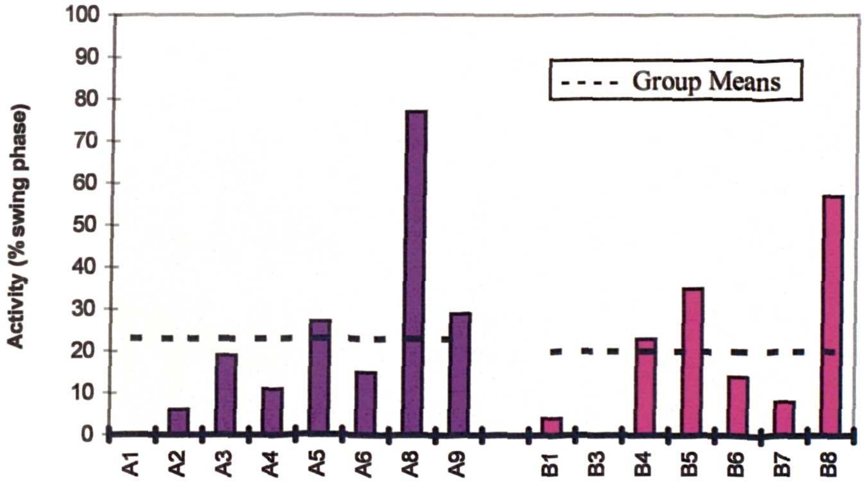
Gastrocnemius
Swing Phase - Orthosis 1
Group A - AFO Group B - AFO



Group A		**Group B**	
Mean	24.750	Mean	15.857
Range	6 to 53	Range	0 to 39
SD	16.594	SD	12.158

Figure 68
Individual and Group Activity Levels for the Gastrocnemius During the Swing Phase whilst Wearing the First Orthosis.

Gastrocnemius
Swing Phase - Orthosis 2
Group A - TRAFO Group B - AFO



Group A		**Group B**	
Mean	23.000	Mean	20.143
Range	0 to 77	Range	0 to 57
SD	23.934	SD	20.161

Figure 69
Individual and Group Activity Levels for the Gastrocnemius During the Swing Phase whilst Wearing the Second Orthosis.

Results of the statistical analysis on the gastrocnemius data for the stance phase are shown in Table 17. Despite an observed reduction in activity, these differences were not found to be significant.

GROUP	*ORTHOSIS*	
	1	2
A	0.131	0.053
B	0.332	0.456

*Significant at the 0.05 level **Significant at the 0.01 level

Table 17
Statistical Results (P Values) for the Comparison of Gastrocnemius Activity Across Groups and Orthoses with that Observed in a Normal Population During the Stance Phase of the Gait Cycle.

In the swing phase there was far greater variability in the data with several individuals showing high levels of activity (A8 77% and B8 57%) compared to 0% reported for a normal population. The group means were clearly affected by a number of such extreme data points and show mean increases in activity of between 15 and 24%. Results of the statistical analysis on the gastrocnemius data for the swing phase are shown in Table 18. Significant differences were found between all the subjects in this investigation and data from a normal population.

GROUP	*ORTHOSIS*	
	1	2
A	0.004**	0.030*
B	0.014*	0.038*

*Significant at the 0.05 level **Significant at the 0.01 level

Table 18
Statistical Results (P Values) for the Comparison of Gastrocnemius Activity Across Groups and Orthoses with that Observed in a Normal Population During the Swing Phase of the Gait Cycle.

Quadriceps

Individual data for the quadriceps muscle group during the stance phase show for both groups a small spread of results around the normal population value of 44%. In the first orthosis the group means highlight that both groups showed a lower level of activity than the norm, however this difference was only small. In the second orthosis group A continued to exhibit a decrease whilst group B exhibited an increase, although again these differences were small.

Results of the statistical analysis on the quadriceps data for the stance phase are shown in Table 19. No significant differences were found between the subjects in either groups or orthoses and the data for the normal population.

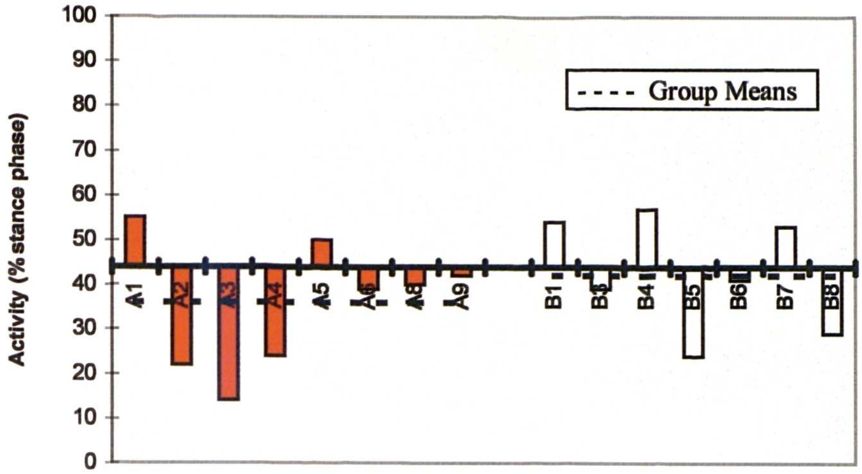
GROUP	*ORTHOSIS*	
	1	2
A	0.148	0.626
B	0.757	0.189

*Significant at the 0.05 level **Significant at the 0.01 level

Table 19
Statistical Results (P Values) for the Comparison of Quadriceps Activity Across Groups and Orthoses with that Observed in a Normal Population During the Stance Phase of the Gait Cycle.

During the swing phase similar results were observed with a small spread around the normal population value of 42%. In the first orthosis the mean activity values for both groups were almost identical with those exhibited in a normal population. In the second orthosis, group A exhibited an increase in activity compared with normal levels whilst group B showed no change.

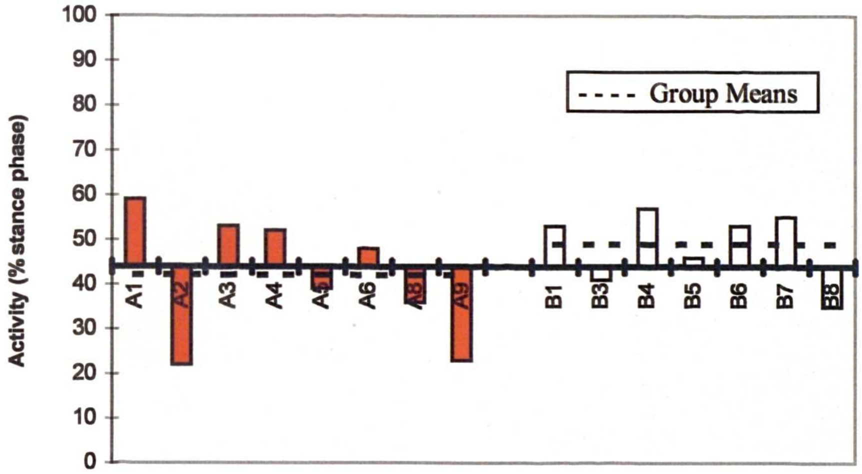
Quadriceps
Stance Phase - Orthosis 1
Group A - AFO Group B - AFO



Group A		**Group B**	
Mean	35.750	Mean	42.429
Range	14 to 55	Range	24 to 57
SD	14.350	SD	12.856

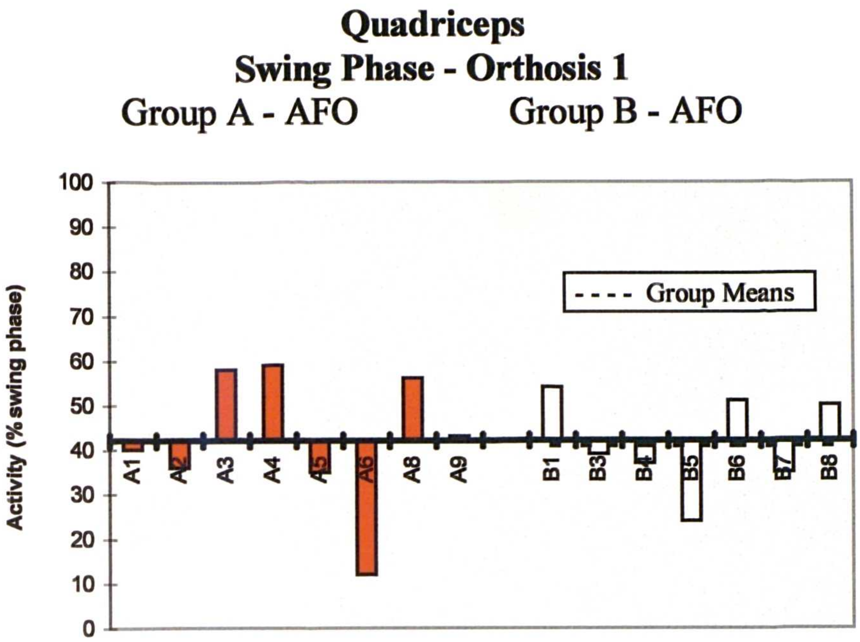
Figure 70
Individual and Group Activity Levels for the Quadriceps Muscle Group During the Stance Phase whilst Wearing the First Orthosis.

Quadriceps
Stance Phase - Orthosis 2
Group A - TRAFO Group B - AFO



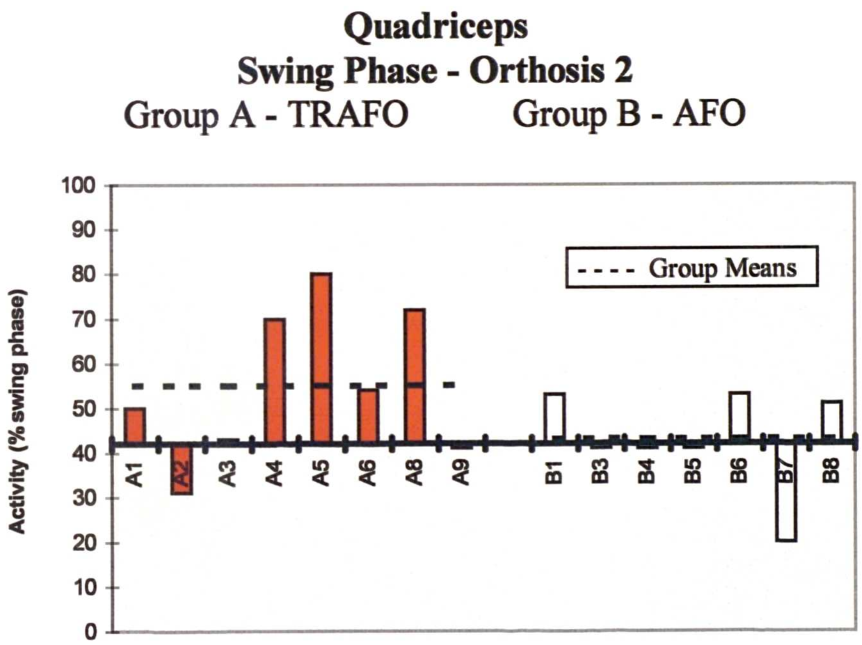
Group A		**Group B**	
Mean	41.500	Mean	48.571
Range	22 to 59	Range	41 to 57
SD	13.887	SD	8.162

Figure 71
Individual and Group Activity Levels for the Quadriceps Muscle Group During the Stance Phase whilst Wearing the Second Orthosis.



Group A		Group B	
Mean	42.375	Mean	41.429
Range	12 to 59	Range	24 to 54
SD	15.720	SD	10.753

Figure 72
Individual and Group Activity Levels for the Quadriceps Muscle Group During the Swing Phase whilst Wearing the First Orthosis.



Group A		Group B	
Mean	55.125	Mean	42.857
Range	31 to 80	Range	20 to 53
SD	17.241	SD	11.582

Figure 73
Individual and Group Activity Levels for the Quadriceps Muscle Group During the Swing Phase whilst Wearing the Second Orthosis.

Results of the statistical analysis on the quadriceps data for the swing phase are shown in Table 20. No significant differences were found between the subjects, in either groups or orthoses, and the data for the normal population.

GROUP	*ORTHOSIS*	
	1	2
A	0.948	0.068
B	0.893	0.851

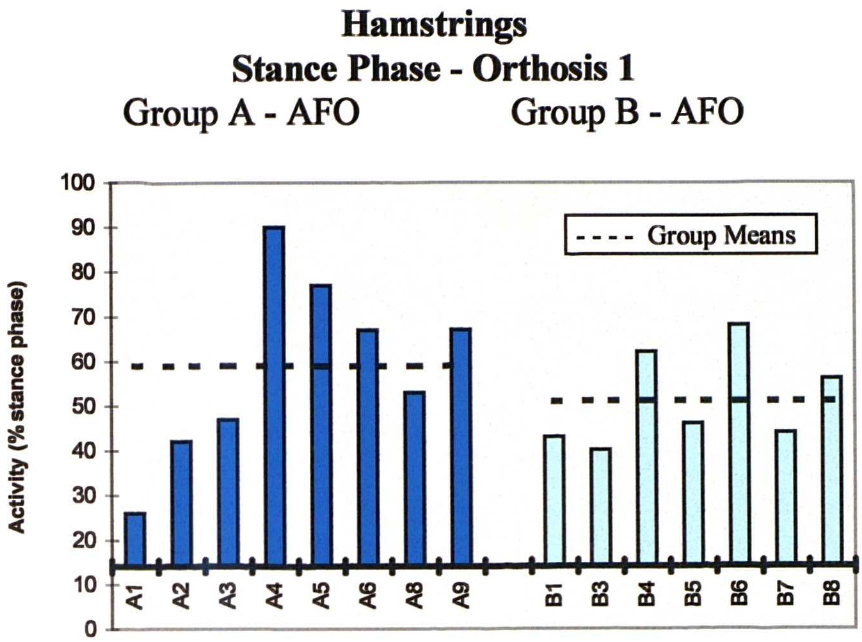
*Significant at the 0.05 level **Significant at the 0.01 level

Table 20
Statistical Results (P Values) for the Comparison of Quadriceps Activity Across Groups and Orthoses with that Observed in a Normal Population During the Swing Phase of the Gait Cycle.

Hamstrings

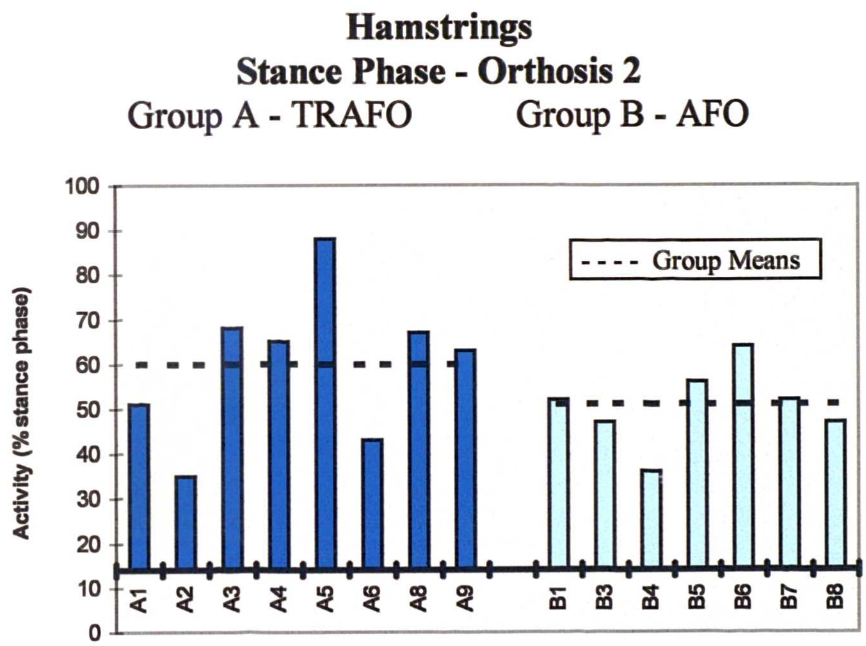
Individual data for the hamstring muscle group activity levels in the stance phase show that all subjects exhibited higher levels of activity with values ranging from 26 to 90% in comparison to 14% reported for normal data. In both the first and second orthoses visual inspection of the group means indicates a considerable increase in activity levels across both groups.

Results of the statistical analysis on the hamstring data for the stance phase are shown in Table 21. All groups had activity levels which were significantly higher than those reported for normal subjects. The uniformity in the increased activity levels across the groups would again suggest that this is not affected by the orthosis type, but by the underlying pathology common to all subjects in the investigation.



Group A		Group B	
Mean	58.625	Mean	51.286
Range	26 to 9	Range	40 to 68
SD	20.598	SD	10.750

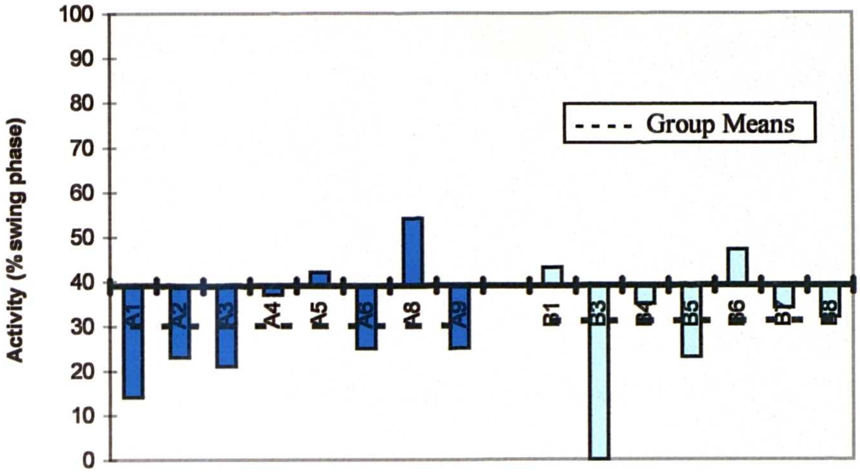
Figure 74
Individual and Group Activity Levels for the Hamstring Muscle Group During the Stance Phase whilst Wearing the First Orthosis.



Group A		Group B	
Mean	60.000	Mean	50.571
Range	35 to 88	Range	36 to 64
SD	16.587	SD	8.677

Figure 75
Individual and Group Activity Levels for the Hamstring Muscle Group During the Stance Phase whilst Wearing the Second Orthosis.

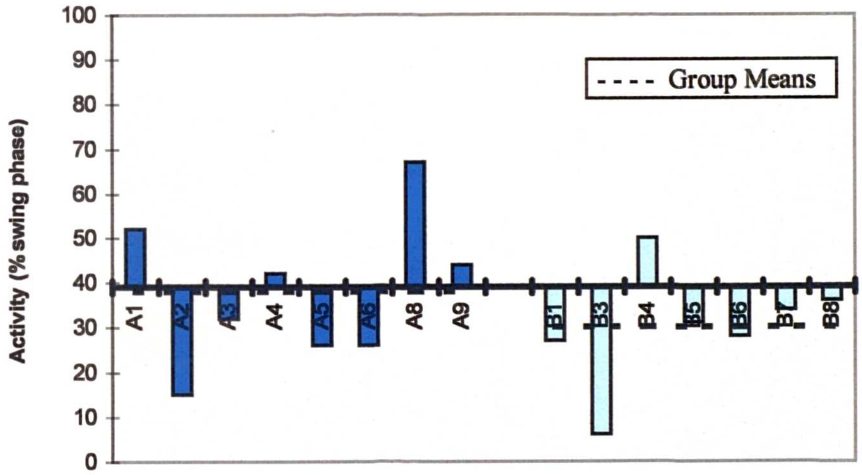
Hamstrings
Swing Phase - Orthosis 1
Group A - AFO Group B - AFO



Group A		Group B	
Mean	30.125	Mean	30.571
Range	14 to 5	Range	0 to 47
SD	13.120	SD	15.544

Figure 76
Individual and Group Activity Levels for the Hamstring Muscle Group During the Swing Phase whilst Wearing the First Orthosis.

Hamstrings
Swing Phase - Orthosis 2
Group A - TRAFO Group B - AFO



Group A		Group B	
Mean	38.000	Mean	30.286
Range	15 to 6	Range	6 to 50
SD	16.656	SD	13.175

Figure 77
Individual and Group Activity Levels for the Hamstring Muscle Group During the Swing Phase whilst Wearing the Second Orthosis.

GROUP	***ORTHOSIS***	
	1	**2**
A	0.000**	0.000**
B	0.000**	0.000**

*Significant at the 0.05 level **Significant at the 0.01 level

Table 21
Statistical Results (P Values) for the Comparison of Hamstring Activity Across Groups and Orthoses with that Observed in a Normal Population During the Stance Phase of the Gait Cycle.

In the swing phase the data shows a small spread of activity levels around the general population norm of 39% activity. In both groups and orthoses the group mean values reflect an overall decrease in activity although these reductions are only small (1-9% lower than norm).

Results of the statistical analysis on the hamstring data are shown in Table 22. In both groups and orthoses no significant differences were found between the subjects in this investigation and data from a normal population.

GROUP	***ORTHOSIS***	
	1	**2**
A	0.097	0.870
B	0.201	0.131

*Significant at the 0.05 level **Significant at the 0.01 level

Table 22
Statistical Results (P Values) for the Comparison of Hamstring Activity Across Groups and Orthoses with that Observed in a Normal Population During the Swing Phase of the Gait Cycle

6.3 Home Questionnaires

Results from the home questionnaire data relating to the number of hours the orthoses were worn, the amount of physiotherapy received and the activities participated in whilst wearing the orthoses, are illustrated in Figures 78 to 83. In each figure individual data is illustrated along with group mean values in each of the orthotic conditions. More detailed information on whether the subjects wore their orthoses at home or at school and the type of activities participated in whilst wearing the orthoses is provided in Figures 84 to 87 section 6.3.2.

6.3.1 Numerical Data

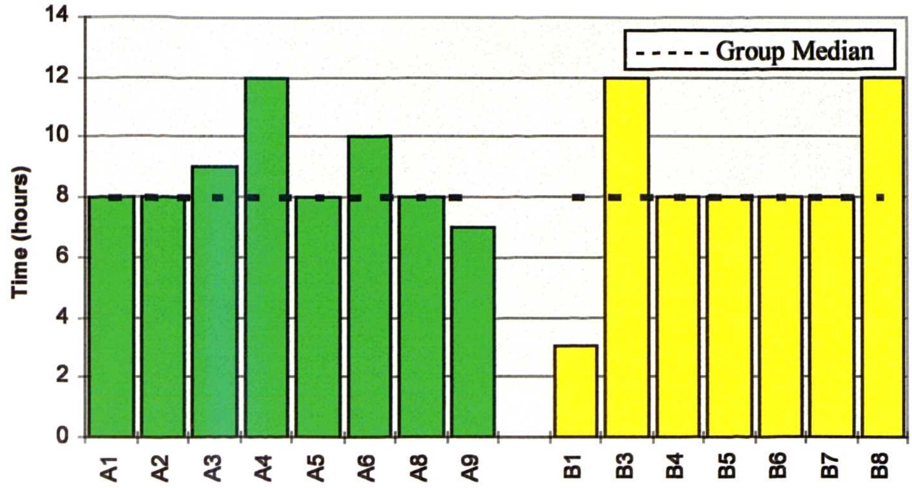
The individual data for the number of hours the orthoses were worn each day are shown in Figures 78 and 79 along with the group means. Mean group values are identical for the two orthotic conditions with group B subjects wearing their orthoses for 1 hour less per day than group A subjects throughout the duration of the investigation. With the exception of subject B1, all the children in the investigation wore their orthoses for between 7 and 12 hours per day, which supports anecdotal information from parents reporting that the orthoses were worn during the day whilst the children were at school and occasionally during the evening. Further information on when and where the orthoses were worn is provided in section 6.3.2.

The individual data for the number of hours of physiotherapy each child received during the week are shown in Figures 80 and 81 along with the group mean values. The mean values for group A were identical in the two orthoses. For group B, identical results were found between the two orthotic conditions, although throughout the investigation subjects in this group received an average of 2 hours physiotherapy more than their counterparts in group A. Physiotherapy was counted as any treatment received by the children whether at home or at school and included exercises and general stretching through to hydrotherapy sessions. There were large variations in the levels of physiotherapy received by the subjects in both groups ranging from 0 to 14 hours per week in some cases. In both groups there were one or two subjects who received very high levels of physiotherapy resulting in the mean group values of 3 and 5 hours being higher than those actually received by the vast majority of subjects. This again supported the anecdotal information from parents, some of whom were extremely dedicated and ensured that they participated in stretching and exercises with their child every day whilst others made no input into the physiotherapy regime.

The individual data for the number of activities in which each child participated whilst wearing their orthoses are represented in Figures 82 and 83 along with the group mean values. Mean group values are again very similar between the two groups and across the orthotic conditions. Subjects from group A participated in 4 types of activity whilst wearing their orthoses and those in group B participated in 3 types of activity. Individual data ranged from 1 to 6 activities and again in many cases reflected parental influences and encouragement. For some subjects however, this data was clearly linked to the severity of the subjects cerebral palsy as in the case of subject B1 who had great difficulty walking and was therefore unable to run, cycle, etc. Further information on the type of activities the subjects participated in is provided in section 6.3.2.

Orthosis 1

Group A - AFO Group B - AFO



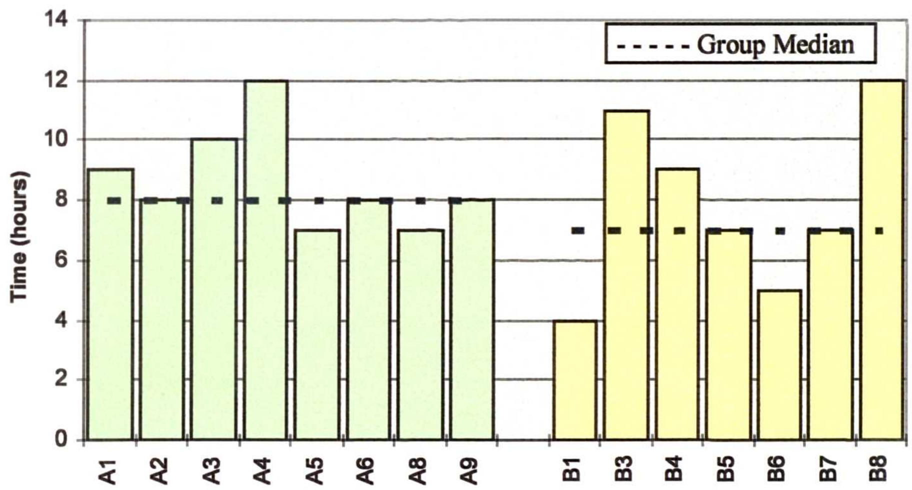
Group A
Median 8
Range 7 to 12

Group B
Median 8
Range 3 to 12

Figure 78
Individual and Group Data Showing the Number of Hours Per Day the First Orthoses were Worn.

Orthosis 2

Group A - TRAFO Group B - AFO



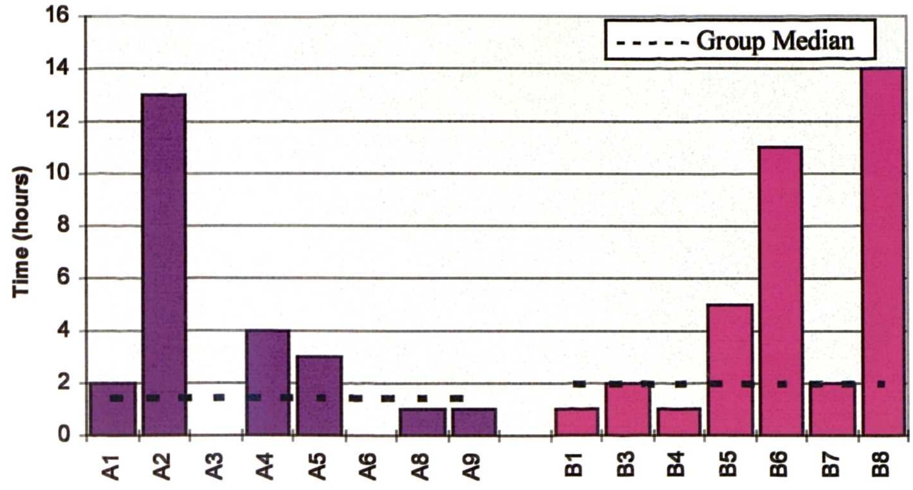
Group A
Median 8
Range 7 to 12

Group B
Median 7
Range 4 to 12

Figure 79
Individual and Group Data Showing the Number of Hours Per Day the Second Orthoses were Worn.

Orthosis 1

Group A - AFO Group B - AFO



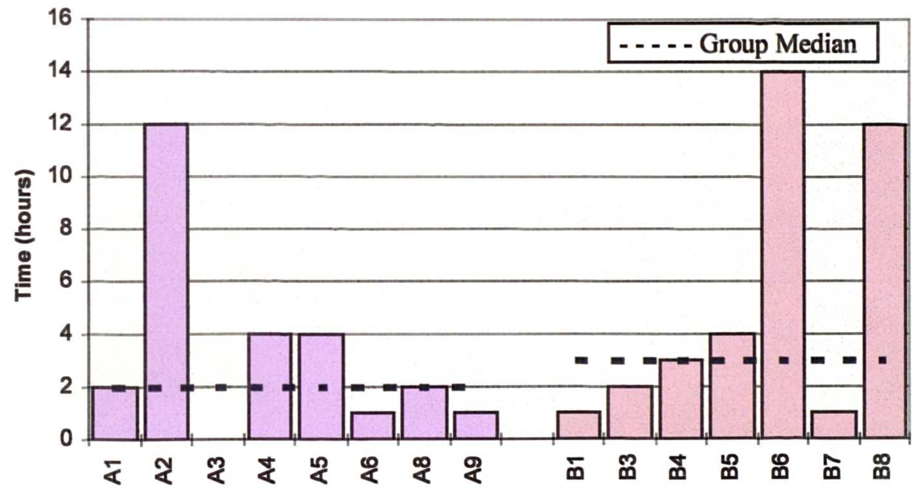
Group A
Median 1.5
Range 0 to 13

Group B
Median 2
Range 1 to 14

Figure 80
Individual and Group Data Showing the Number of Hours of Physiotherapy Received Per Week whilst Wearing the First Orthoses.

Orthosis 2

Group A - TRAFO Group B - AFO



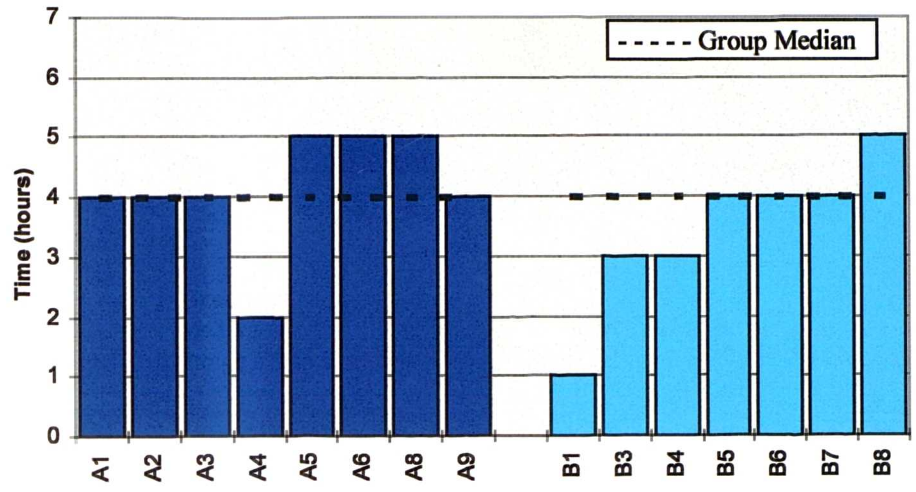
Group A
Median 2
Range 0 to 12

Group B
Median 3
Range 1 to 14

Figure 81
Individual and Group Data Showing the Number of Hours of Physiotherapy Received Per Week whilst Wearing the Second Orthoses.

Orthosis 1

Group A - AFO   Group B - AFO



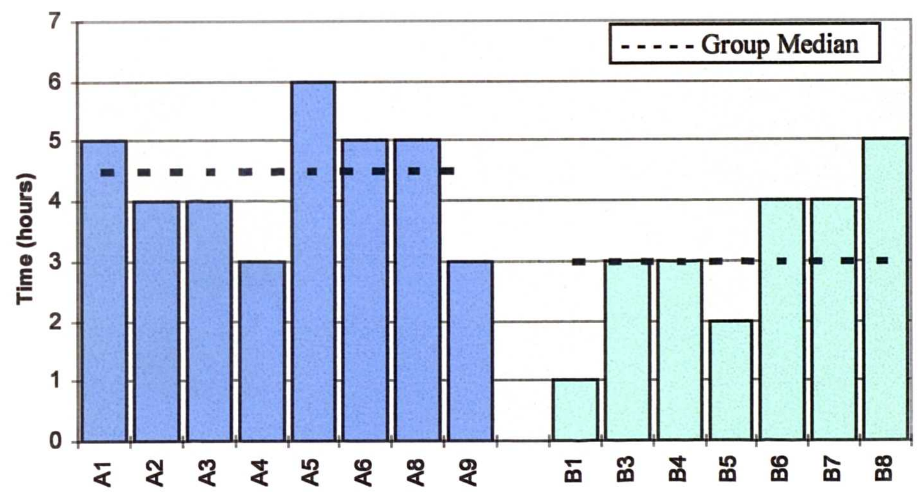
Group A
Median 4
Range 2 to 5

Group B
Median 4
Range 1 to 5

Figure 82
Individual and Group Data Showing the Number of Activities Participated in whilst Wearing the First Orthoses.

Orthosis 2

Group A - TRAFO   Group B - AFO



Group A
Median 4.5
Range 3 to 6

Group B
Median 3
Range 1 to 5

Figure 83
Individual and Group Data Showing the Number of Activities Participated in whilst Wearing the Second Orthoses.

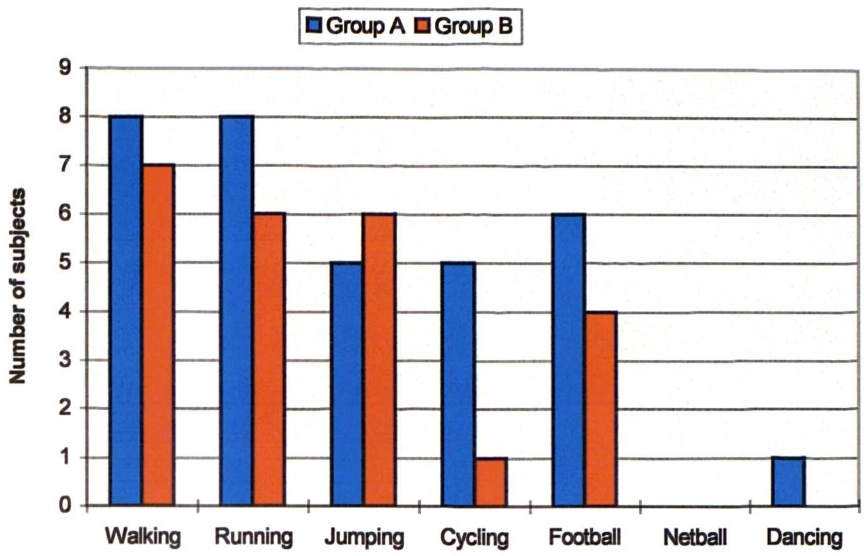
6.3.2 Descriptive Data

Data relating to the activities in which the subjects reported participating whilst wearing each of their orthoses are shown in Figures 84 and 85. A total of 7 activities were reported by the subjects and the y axis of the graphs represents the number of subjects in each group who participated in that activity, with a maximum of 8 for group A and 7 for group B. Data for the two orthotic conditions are very similar with few of the subjects altering the number or type of activities in which they took part. Throughout the investigation most of the children were able to walk, run and jump whilst wearing their orthoses and many also rode a bicycle and played football.

Data relating to whether the subjects wore their orthoses at school and/or at home during the evenings and weekends were separated into responses of always, sometimes and never. None of the subjects responded to these questions with 'never' during the investigation. Figures 86 and 87 show the data for the two groups whilst wearing the first and second orthoses respectively. In both orthotic conditions the majority of subjects in both groups reported always wearing their orthoses at school/nursery. The main difference between the two groups was that in group B none of the subjects reported always wearing their orthosis at home, whereas for group A there was an even split between those who reported that they always and those who reported that they sometimes wore their orthosis at home.

Orthosis 1

Group A - AFO Group B - AFO

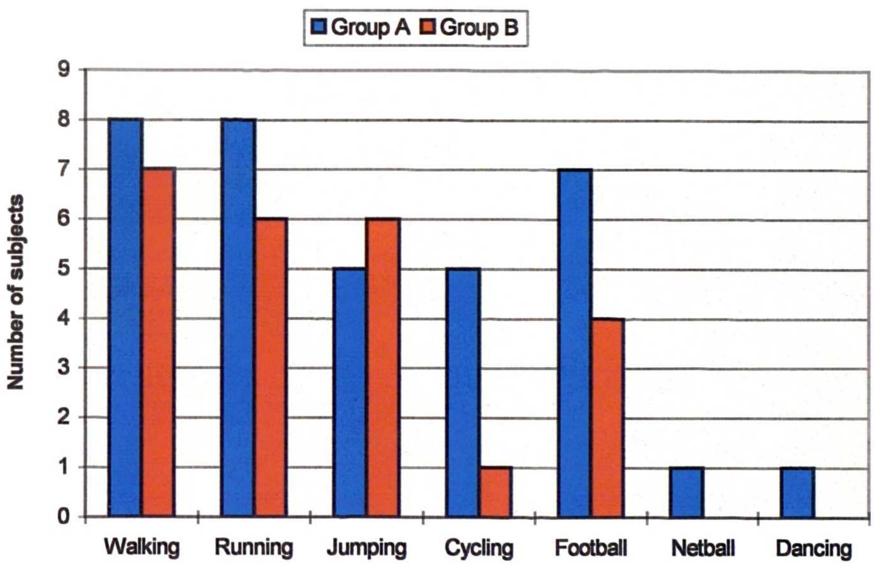


<u>Figure 84</u>

<u>The Number of Subjects from Both Groups Participating in Each of Seven Activities whilst Wearing the First Orthoses.</u>

Orthosis 2

Group A - TRAFO Group B - AFO



<u>Figure 85</u>

<u>The Number of Subjects from Both Groups Participating in Each of Seven Activities whilst Wearing the Second Orthoses.</u>

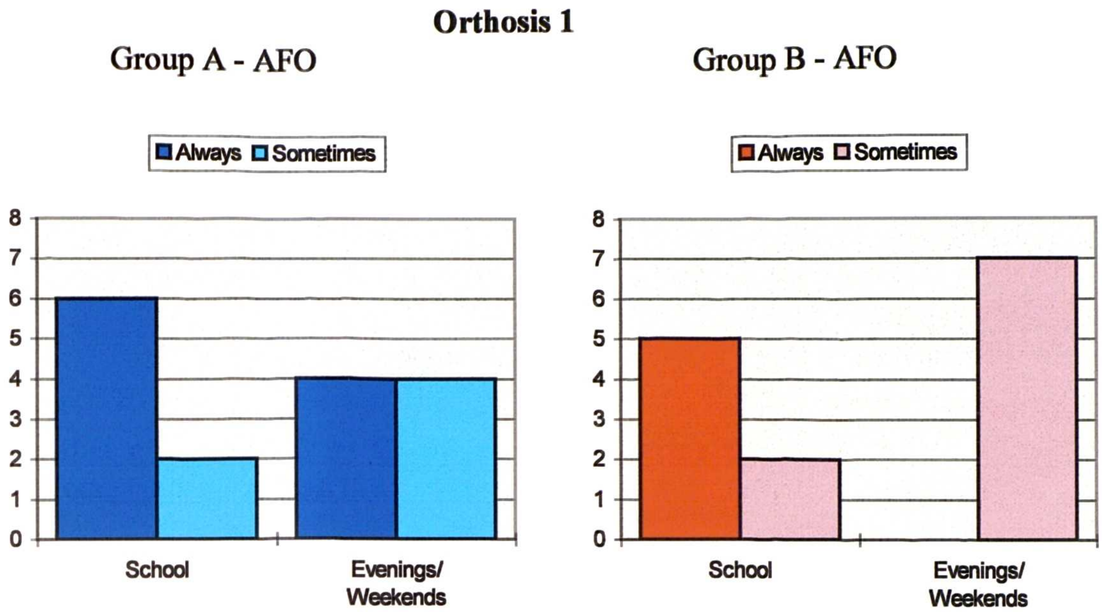


Figure 86
The Number of Subjects from Groups A & B Wearing their Orthoses at School and/or Home whilst Wearing the First Orthoses.

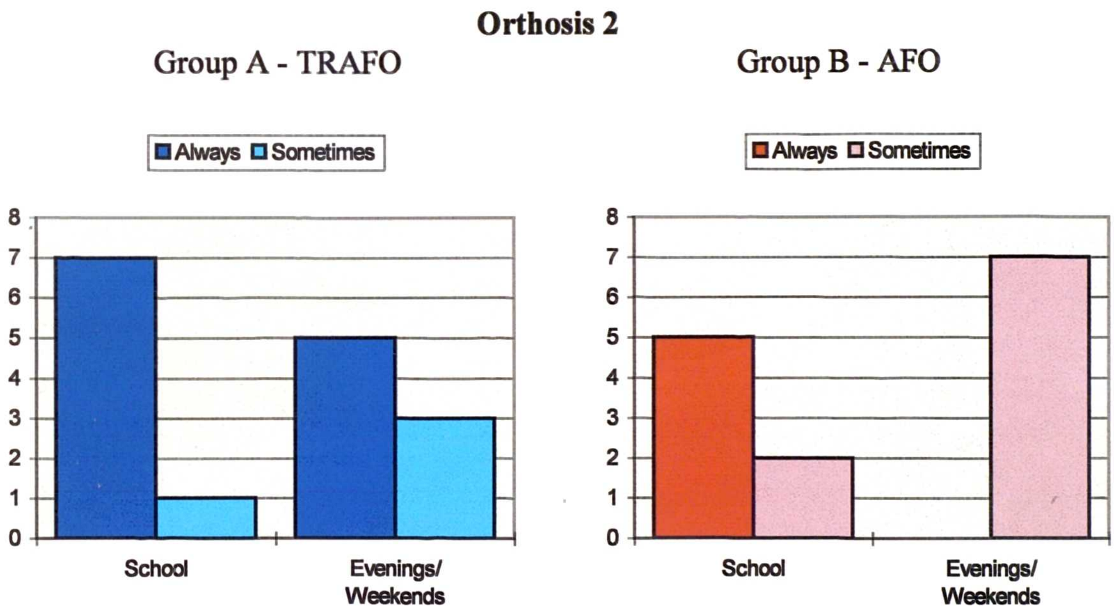


Figure 87
The Number of Subjects from Groups A & B Wearing their Orthoses at School and/or Home whilst Wearing the Second Orthoses.

6.4 Single Subject Assessments

6.4.1 Introduction to Temporal and Spatial Parameters.

Velocity, cadence and stride length data for subject A5 are shown in Figures 88 to 90. In each figure data from 12 trials are shown, 3 in the first orthosis (AFO) and 9 in the second (TRAFO). The trials are labelled 1-6 for the standard assessments that all subjects attended and a-f for the additional 6 assessments that subject A5 completed whilst wearing the TRAFO. For each of the orthoses, the mean value for this subject was calculated and illustrated on each figure.

6.4.2 Velocity, Cadence and Stride Length

Velocity, cadence and stride length data for subject A5 are shown in Figures 88 to 90 respectively along with the means for the two orthoses. In both orthotic conditions there were large variations in the data recorded between trials and this was observed in all of the above parameters. The mean values for each parameter illustrate that there were very little differences in the mean data between the orthoses. For the velocity and stride length the mean values for the AFO were slightly higher than those recorded for the TRAFO trials. For the cadence data the AFO trials had a slightly lower mean value as would be expected considering the relationship between the parameters. In all the parameters no pattern was observed to the TRAFO data to suggest that any changes occurred as a result of time.

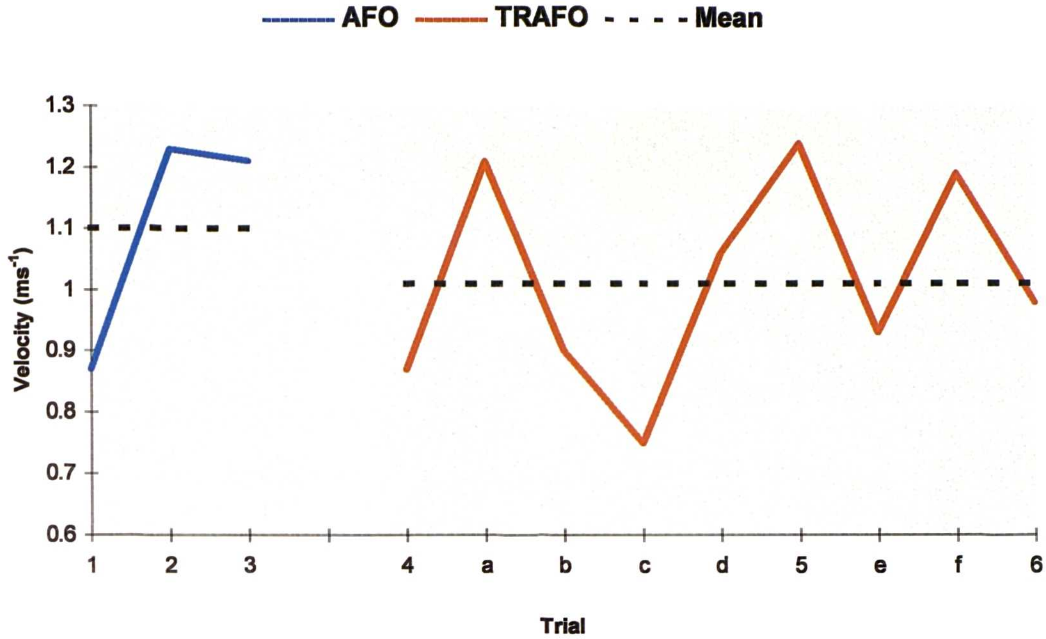


Figure 88
Velocity Data for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn.

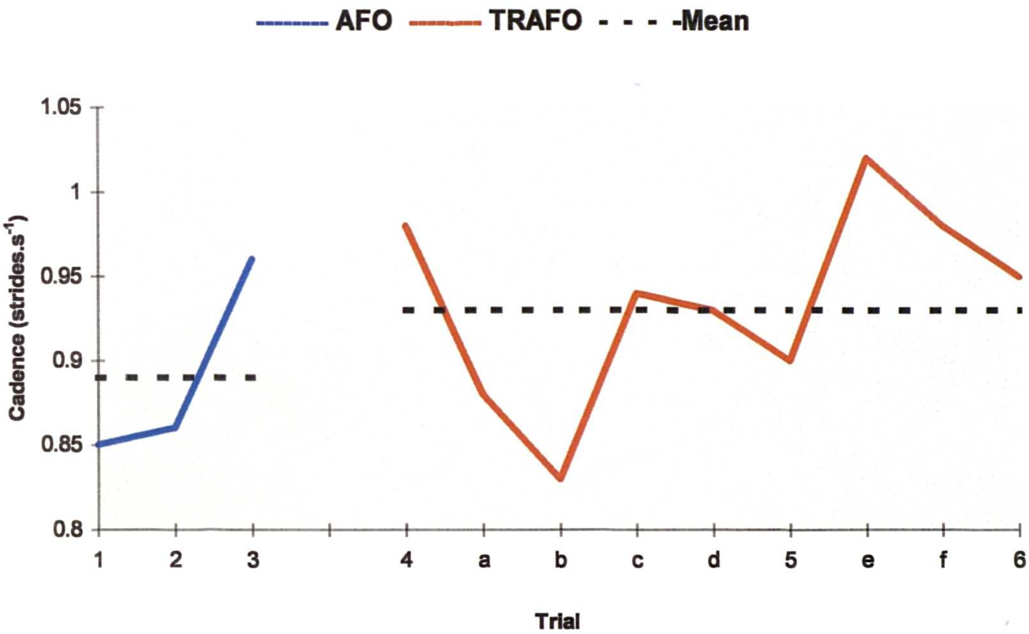


Figure 89
Cadence Data for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn.

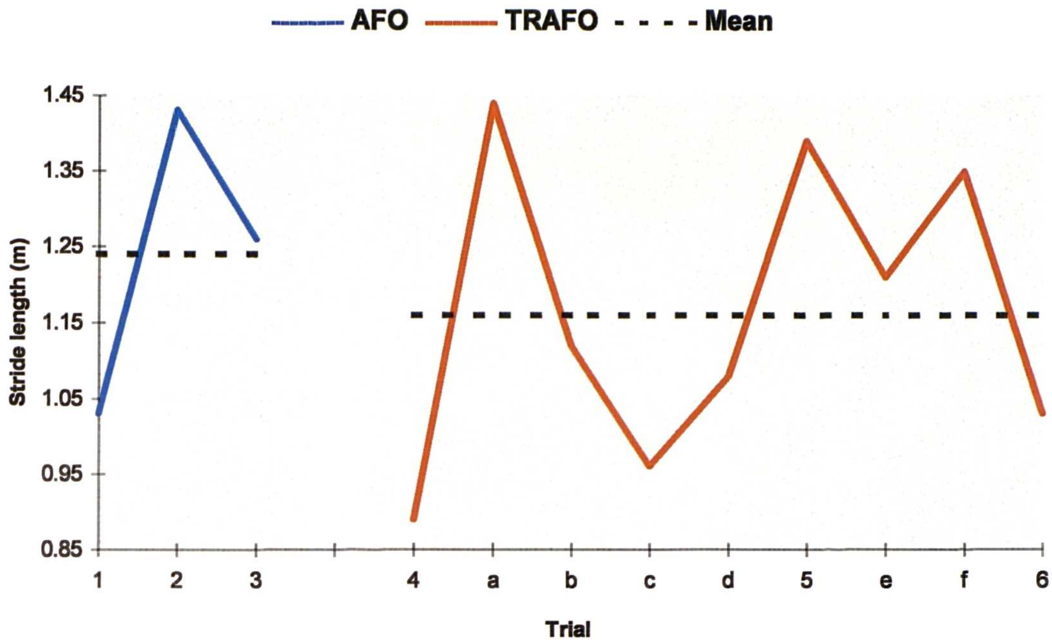


Figure 90
Stride Length Data for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn.

6.4.3 Stance and Swing Phase

Stance and swing phase duration data for subject A5 are shown in Figures 91 and 92 respectively where the duration is calculated as a percentage of the total gait cycle. Means are also represented for the two orthoses. In the stance phase there were fluctuations in the data between trials, the range of these fluctuations was much smaller for the TRAFO than for the AFO. With only three data points for the AFO condition it is possible that the mean could have been distorted by the extreme result of trial two. There is no overall pattern to the TRAFO data to suggest any changes occurred over time and there is an even spread of data above and below the mean throughout the trials. The group value for the TRAFO data is higher than that for the data from the AFO condition and approaches the value reported for a normal population.

Data for the swing phase is as would be expected complementary to that for the stance phase. In this case the mean swing phase duration is reduced in the TRAFO condition when compared to the AFO and again brought closer to that reported for a normal population. It is difficult to decide as to whether the TRAFO produced a positive change in the stance/swing phase split of the gait cycle mainly due to the limited data points in the first condition. Without the data from trial 2 which may be an uncharacteristic result the mean for the AFO condition would have been almost identical to that observed with the TRAFO.

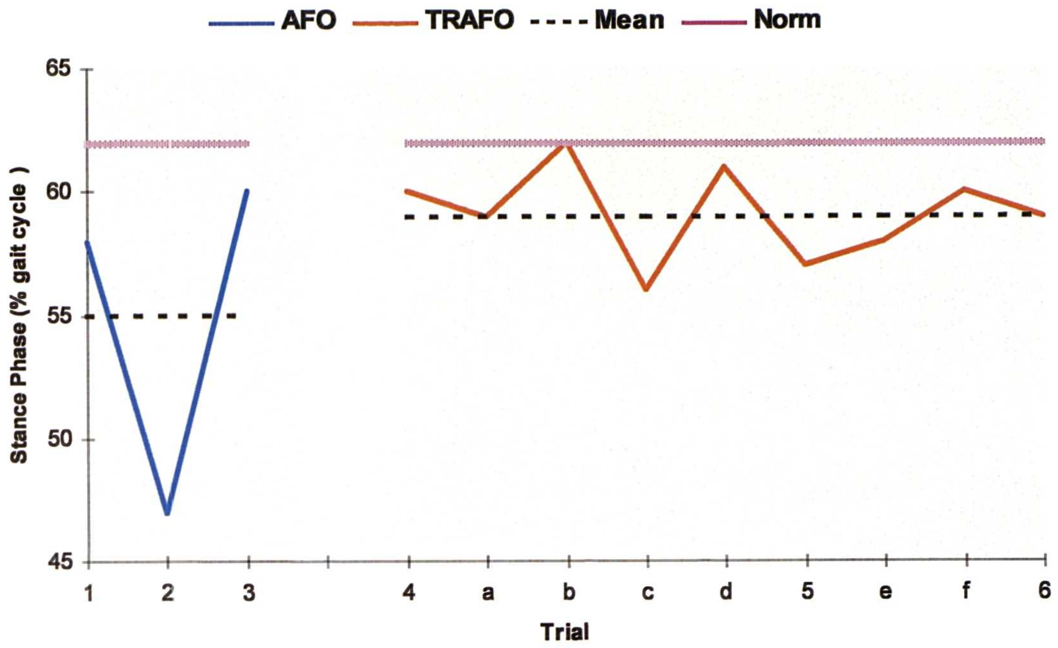


Figure 91
Duration of the Stance Phase for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn.

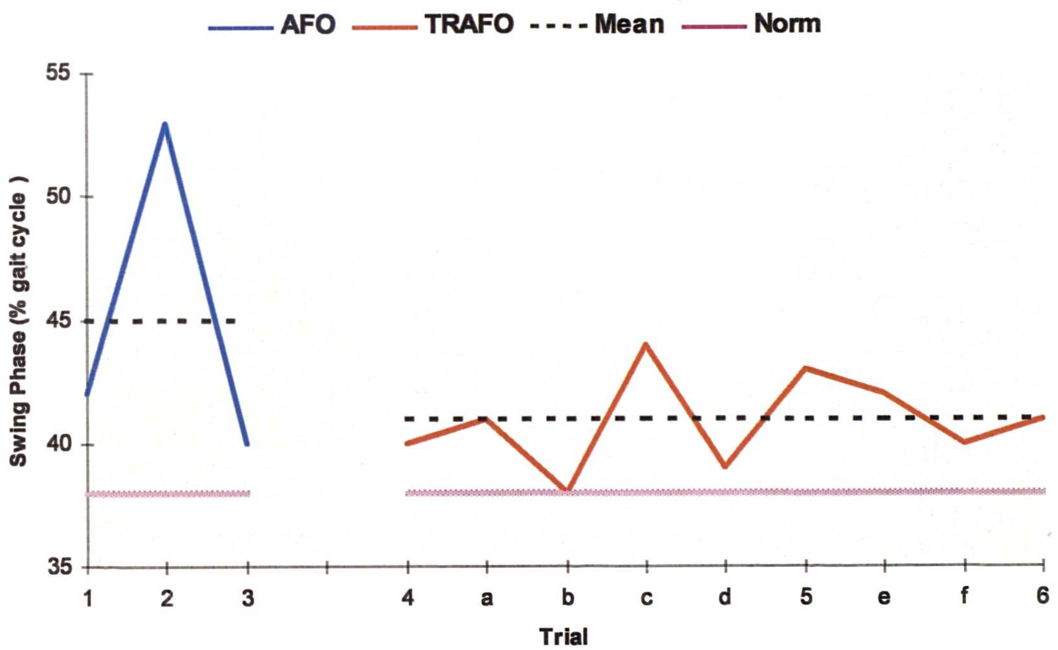


Figure 92
Duration of the Swing Phase for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn.

6.4.4 EMG

Tibialis anterior

Results of the EMG analysis for subject A5 are shown in Figures 93 and 94 corresponding to the stance and swing phases of the gait cycle respectively. The figures illustrate the activity recorded in the tibialis anterior during each of the trials along with the means for the two orthotic conditions and the level of activity reported for a normal population.

The stance phase data from the AFO trials has a small variability and the mean value lies very close to that reported for a normal population. The data from the TRAFO trials shows greater variability, but at all assessments, the values recorded were much higher than those observed previously. The mean group value from the TRAFO condition was almost 40% higher than the normal population value and this reflects the change which was observed in group A subjects as a whole (see section 6.2.2), although this result is far more pronounced in subject A5.

In the swing phase there was an almost equal range of muscle activity levels recorded across the two orthotic conditions. This resulted in the mean values for the AFO and TRAFO conditions being similar at 40 and 46% activity. Both orthotic conditions had levels of tibialis anterior activity considerably lower than that reported for a normal population (100%) and this agrees with the group data presented in section 6.2.2

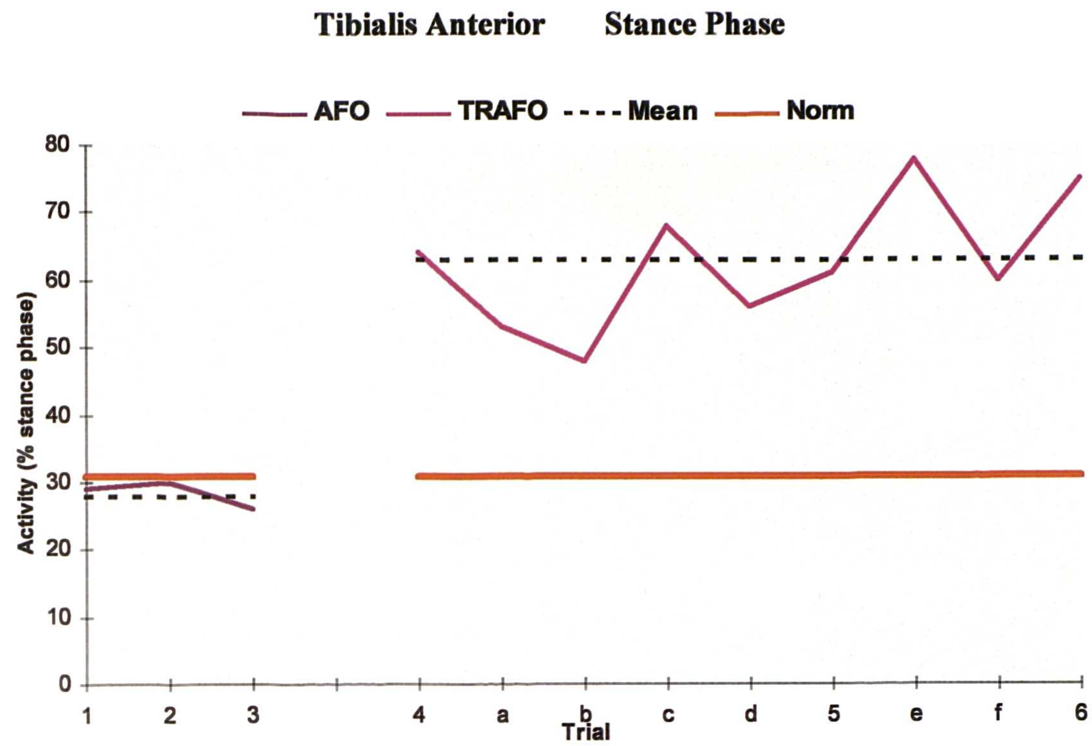


Figure 93
Tibialis Anterior Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Stance Phase.

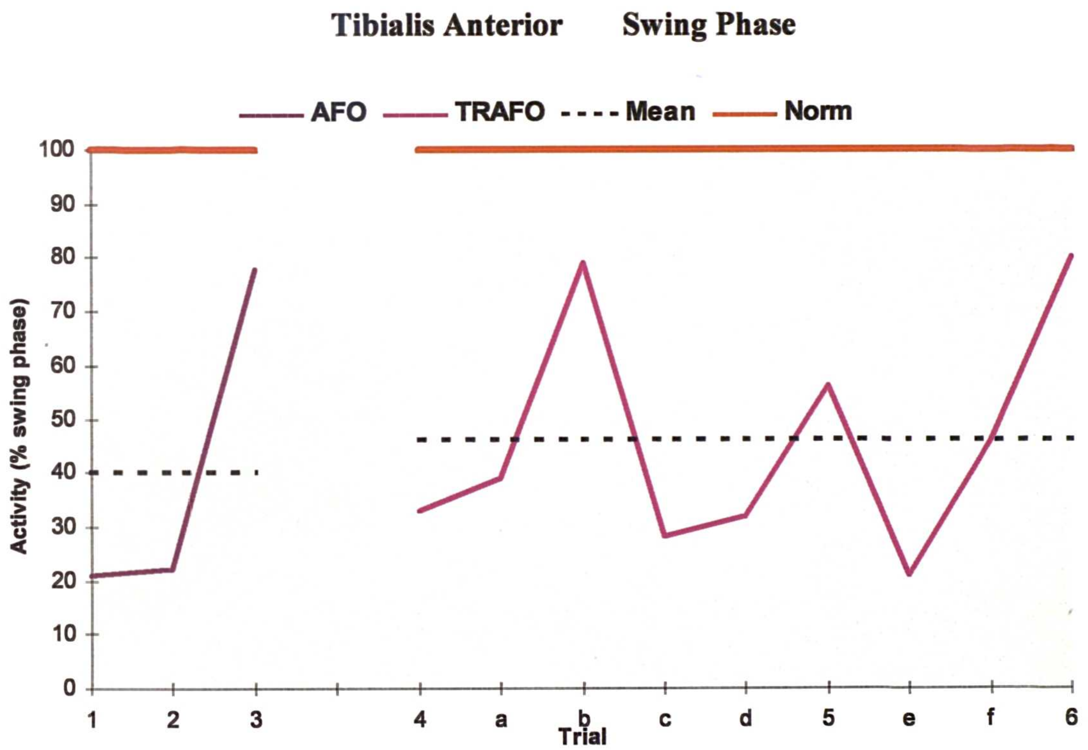


Figure 94

Tibialis Anterior Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Swing Phase.

Gastrocnemius

Gastrocnemius activity levels for subject A5 are shown in Figures 95 and 96. The two figures correspond to the stance and swing phases of the gait cycle respectively and show data from each trial, means values for the two orthotic conditions and also the level of activity reported for a normal population.

In the stance phase, the data for both orthotic conditions showed a small spread of results over ranges of 15-20%. The data from the trials whilst the subject was wearing a TRAFO exhibited no clear patterns, suggesting that changes did not occur over time whilst using this orthosis. The mean value from the data in the AFO condition is very similar to that reported for a normal population, whereas that for the TRAFO trials is considerably lower than the normal population value. This again reflects the data recorded in the main investigation although the reduction in gastrocnemius activity is far more pronounced in this subject.

In the swing phase there was much greater variability in the data from both orthotic conditions covering ranges of 30-60%. In the TRAFO trials this was more notable. The mean group values for the activity of the gastrocnemius were much higher than that reported for a normal population, although in the TRAFO condition this was slightly closer to the norm than that shown for the AFO trials. In this phase the data for subject A5 does not agree with that reported in the main investigation as in group A as a whole the activity levels recorded were lower and remained consistent across the two orthotic conditions.

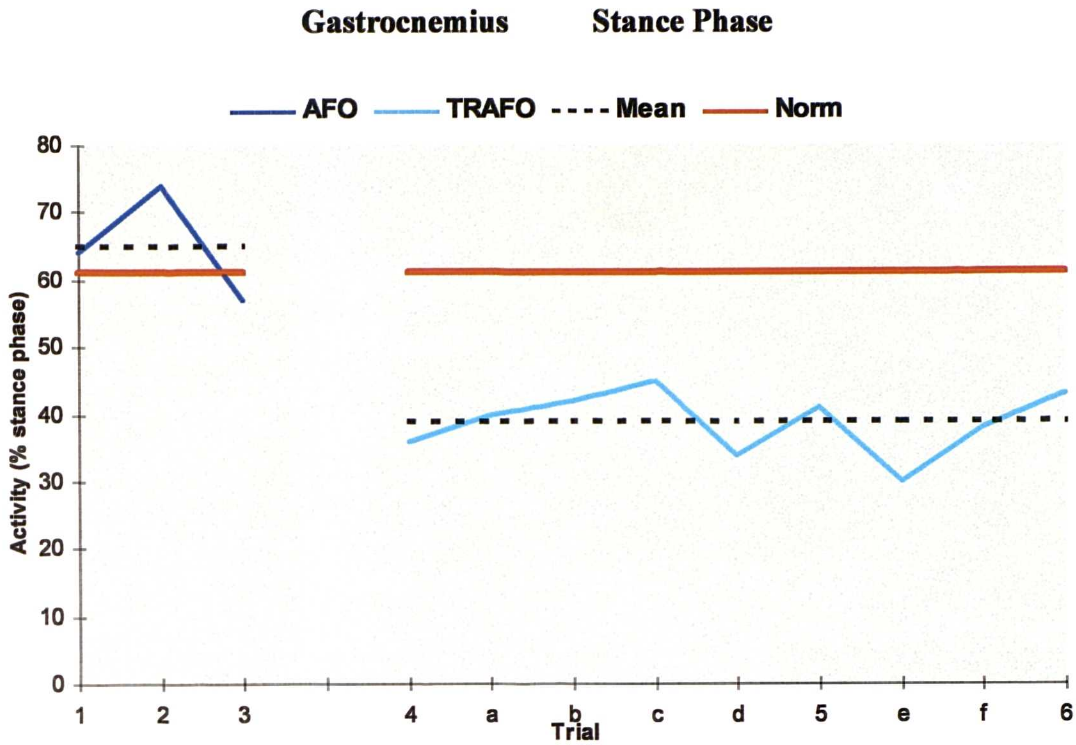


Figure 95
Gastrocnemius Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Stance Phase.

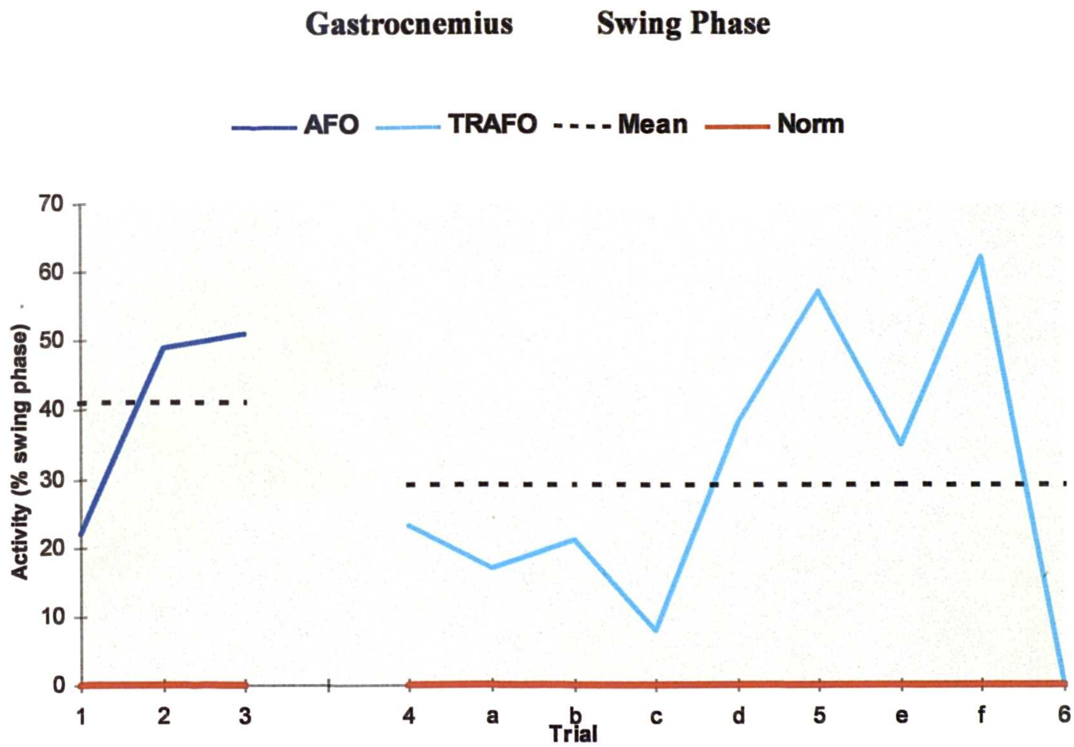


Figure 96
Gastrocnemius Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Swing Phase.

Quadriceps

Results of the EMG analysis for subject A5 are shown in Figures 97 and 98 corresponding to the stance and swing phases of the gait cycle respectively. The figures illustrate the activity recorded in the quadriceps muscle group during each of the trials along with the means for the two orthotic conditions and the level of activity reported for a normal population.

In the stance phase there were large fluctuations in the data between trials particularly in the TRAFO condition where a range of 70% of the stance phase was covered. The data in both conditions however were spread fairly evenly around the value of 44% reported for a normal population. As a result, the mean values were close to the norm values, with the AFO condition having a slightly higher and the TRAFO condition a slightly lower value. These results again reflect those reported for the main investigation where in both orthoses subjects demonstrated normal levels of gastrocnemius activity during the stance phase.

In the swing phase there was again variability in the data recorded between trials which for the AFO condition resulted in the mean group value being close to that reported for the normal population. Whilst wearing the TRAFO however, the mean group value was over 20% greater than the norm value which reflects the data from the main investigation where a rise in activity was recorded when moving from the AFO to the TRAFO although this increase was not found to be statistically significant.

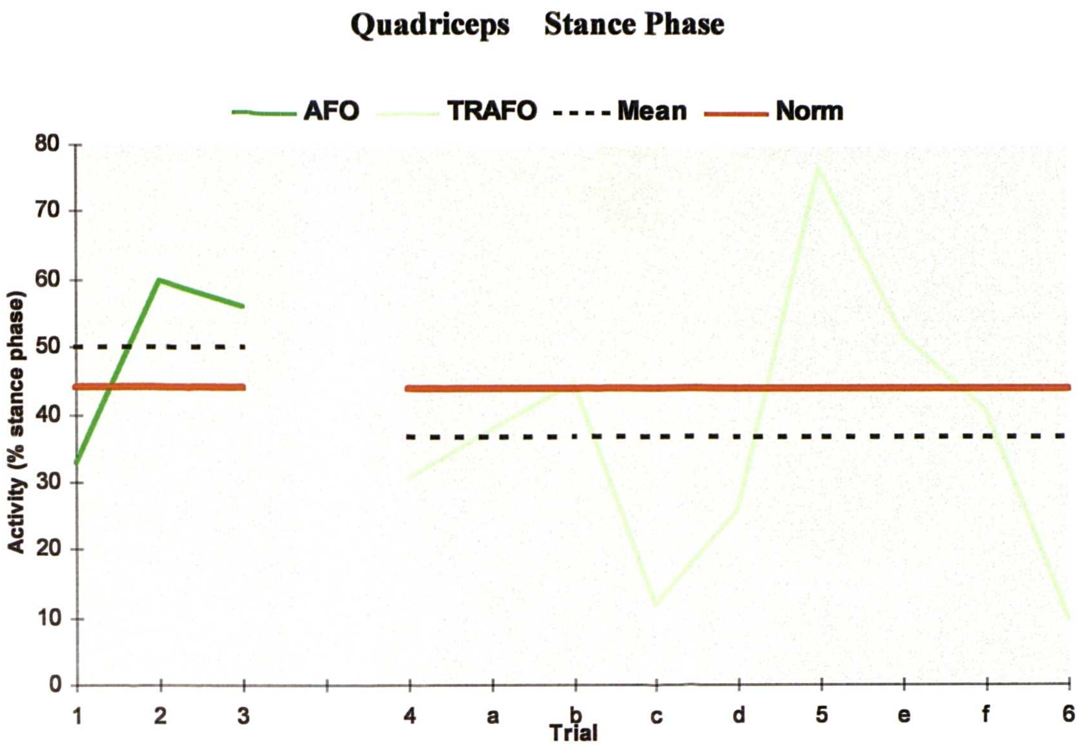


Figure 97
Quadriceps Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Stance Phase.

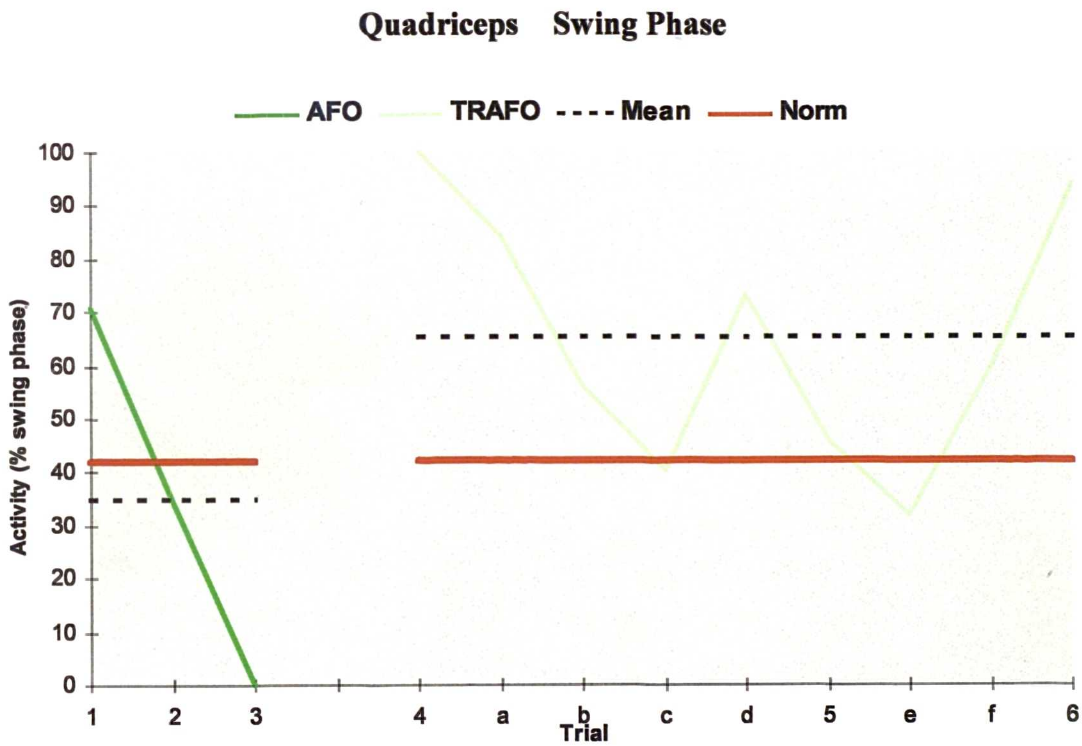


Figure 98
Quadriceps Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Swing Phase.

Hamstrings

Hamstring muscle group activity levels for subject A5 are shown in Figures 99 and 100. The two figures correspond to the stance and swing phases of the gait cycle respectively and show data from each trial, mean values for the two orthotic conditions and also the level of activity reported for a normal population.

In the stance phase the data from both orthotic conditions show small fluctuations across the trials. The mean values for both the AFO and TRAFO conditions are also similar. Both groups have hamstring activity levels much higher than those reported for a normal population during the stance phase. This supports the results from the main investigation which found that subjects in both groups had higher levels of activity in the hamstrings during the stance phase.

During the swing phase the data across trials again shows little variability with a spread of values between 20 and 30%. The mean values from both orthotic conditions were close to that reported for a normal population with the AFO group slightly higher and the TRAFO group lower. The results from the TRAFO group show no clear pattern to suggest any changes in activity occurred over time or that the orthosis had to be worn for a particular amount of time before benefits were observed. The data recorded for subject A5 follow the results of the main investigation where no differences were found between activity levels in the hamstrings during the swing phase and those reported for a normal population.

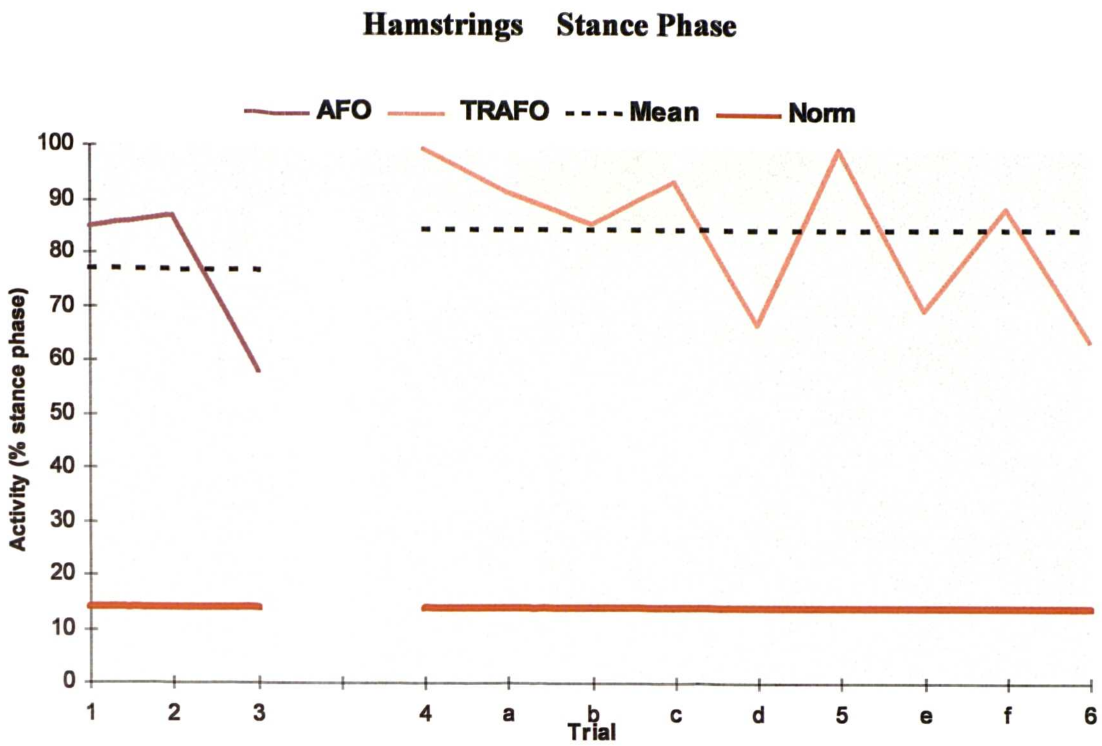


Figure 99
Hamstring Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Stance Phase.

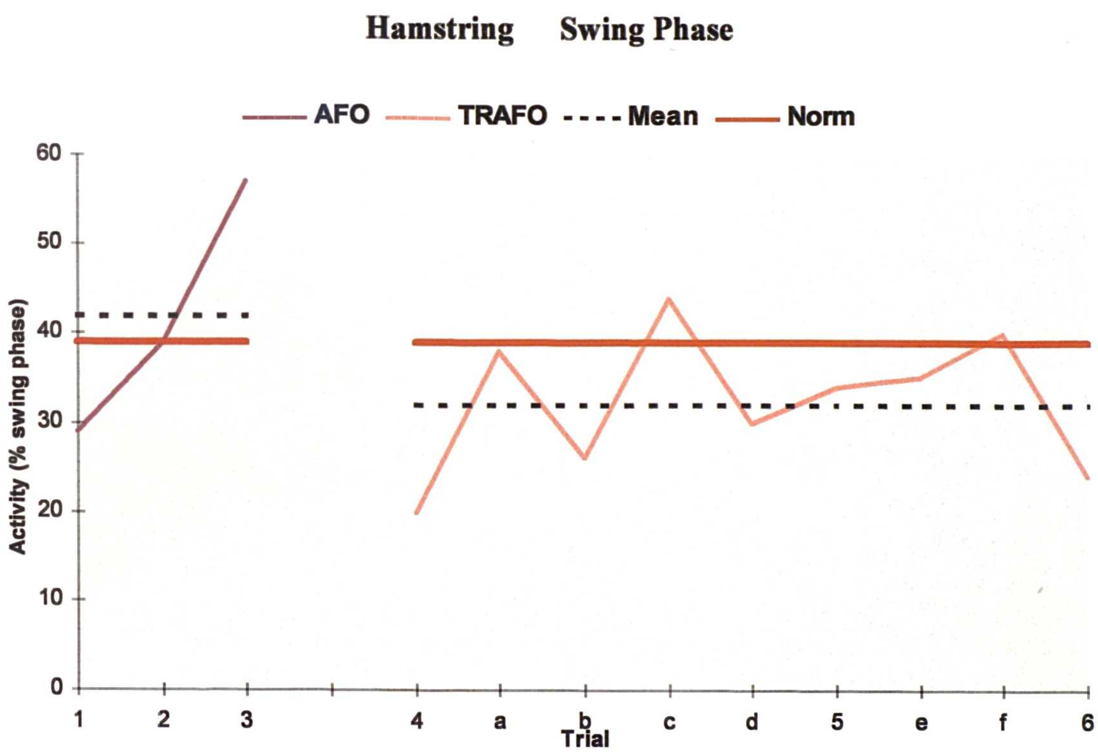


Figure 100
Hamstring Activity for Subject A5 During 12 Trials and Mean Data for the Two Orthoses Worn During the Swing Phase.

Section 7

Discussion and Conclusions

7.1 Investigation Overview

This investigation was undertaken in an attempt to establish whether the use of TRAFOs in the management of children with cerebral palsy is effective in reducing tone in the lower limb. It was based on the indications of previous work and proposed theories which suggested that the unique contouring on the base of the TRAFO facilitates the redistribution of pressure during weight bearing away from the tonic reflex areas beneath the foot. One of the most important factors during the investigation was to move away from clinical to more scientific measures of tone and to record data during ambulation to assess the impact of any changes in tone levels on the subject's gait.

Previous investigators have evaluated TRAFOs by measuring a number of parameters including walking velocity, symmetry and stride length, standing balance, and joint angles (Hinderer et al., 1988; Overby et al., 1991; Embrey et al., 1990). In contrast to this, the current investigation aimed to establish whether the orthoses were able to reduce muscle tone in the lower limb, as had been proposed in seeking to explain improvements observed in the above parameters. Initially a scientific method of measuring muscle tone was pursued. However having been unable to find any satisfactory measures of muscle tone which could be made during ambulation, electromyography was chosen as the main technique through which data would be collected. The use of muscle activity levels as an indicator of tone was taken as a first step towards objectively measuring the effect of wearing the orthoses. The investigation looked, in particular, at electromyographic activity recorded in four muscles of the lower limb which control the main movements at the knee and ankle during the gait cycle.

To complement the electromyographic data, a number of measures of temporal and spatial parameters, including walking velocity and stride length, were also recorded. This allowed the investigator to assess the effect any changes in muscle activity might have had on the subjects' gait in general and to use as a comparison with other investigations using both normal and neurologically impaired children. The use of the video vector generator, although not providing any quantitative data, provided a clear pictorial representation of changes to the gait which is often useful for the biomechanist when explaining results of assessments to therapists and clinicians. Finally, in an attempt to gain an insight into some of the socio-economic and other factors which may determine the outcome of the management programme, home questionnaires were used along with a record of anecdotal information from the subjects, parents and therapists. By using these tools, the investigation attempted to answer the fundamental question relating to the manner in which TRAFOs work whilst also acquiring a more global picture of each subjects ambulatory progress and the factors which may influence this.

In clinical terms the central question posed by the investigation was whether the use of TRAFOs is more advantageous in children with hypertonicity, than that of standard polypropylene AFOs which are currently accepted as the normal treatment. The initial wave of interest regarding TRAFOs on their introduction into the UK indicated that they were likely to replace standard AFOs as the most popular form of treatment in such children. The importance of this investigation for clinicians, therapists and orthotists, was therefore to establish whether TRAFOs were able to reduce tone levels or provide any other benefits beyond those observed when using standard polypropylene AFOs.

7.2 Investigation Design

The need for a scientific approach to evaluate the effectiveness of TRAFOs used in the management of children with cerebral palsy was clear from the existing literature at the start of the investigation. It was acknowledged at an early stage in the study however that carrying out a fully controlled and ideally designed study with neurologically impaired individuals would not be possible. Many of the most commonly used research designs were inappropriate for this research as the differences between individual subjects with cerebral palsy meant that it was impossible to match an experimental group exactly with controls. Likewise, because each child had a unique pathology, it was impossible to recruit a truly uniform group of subjects. Even most careful attempts to filter children out using detailed selection criteria, left the investigator with a group of subjects who were all very much individuals. Consideration also had to be given to the unpredictable manner in which these children progress and therefore to the possibility that changes might occur unpredictably during the investigation as a result of developments in the maturation of the locomotor processes. The variable development of cerebral palsy meant that it was probable that each of the children recruited would progress differently despite receiving identical medical intervention.

Natural developments in the children's locomotion may have also occurred as a result of factors such as maturation and increasing familiarity with the experimental environment, in addition to changes resulting from the underlying pathology. It was therefore considered necessary to maintain one group of subjects in the baseline condition throughout the investigation to assess what natural variation might occur.

As a comparison between two types of orthosis was desired, the use of a baseline in which no orthosis was worn (the preferable choice) would have resulted in the need for either three subject groups or three sets of conditions in which groups were tested. Restrictions on both the time available and the number of subjects which could be recruited made both of these an unrealistic option. The final design chosen, which had two groups and used one of the orthotic conditions as the baseline, allowed the investigator to assess the natural progression of the children, calculate improvements relative to a baseline and compare the two orthoses whilst minimising the number of subject groups and the number of assessments required.

The overriding desire to move away from case study designs to using larger groups of subjects was the main influence in selecting the two group design used in the investigation. With hindsight however, greater consideration should have been given to other qualitative measures which may have provided more useful information about the orthoses and their acceptance by the children/therapists. The investigation provided some interesting and unexpected information mainly from the questionnaires and anecdotal evidence. These methods however, were only used to supplement the main data collection and the information from them could not be analysed or quantified in any detail. Although qualitative methodology is more widely used for research in the social and behavioural sciences it has the potential to enhance and facilitate medical research which has traditionally followed strictly quantitative data collection. Qualitative methods are ideal for the study of long term outcomes, particularly where patient outcome is likely to be influenced by social or psychological factors (Shakespeare & Postle, 1999) and this investigation would most certainly have benefited from the use of such techniques.

7.3 Subject Recruitment

The investigation encountered several difficulties in the recruitment of subjects and as a result the total number of children involved in the study was not as high as originally planned. Initially recruitment was to be done via the orthotic clinic and direct approaches to orthopaedic consultants in the area. This approach however had to be changed in the early stages of the investigation due to poor response, and subsequently help was sought from the community physiotherapy teams. This approach was more successful in making children accessible to the investigator, but it did bring its own problems. The community physiotherapy teams were based in schools and therefore recruitment could only take place during term time and thus there was a long break over the summer holidays. Also the community physiotherapy teams covered large areas around the Manchester/Salford region and often the geographical location of subjects was some distance away from the Hospital and University where treatments and assessments were undertaken. This made it more difficult for the parents to meet the attendance requirements and no doubt increased the drop out rate significantly. During the investigation none of the subjects/parents who were approached by the investigator declined to take part although there was a 25% drop out rate during the investigation.

All the children involved in the study were diagnosed from their medical records as having hemiplegic cerebral palsy, resulting in hypertonicity of the foot and ankle. The subjects were all assessed by their physiotherapist and the orthotist involved in the investigation to confirm that they were suitable candidates for treatment with an ankle-foot orthosis. The subjects selected were all categorised as having mild to moderate cerebral palsy in an attempt to recruit subjects who had similar walking abilities. In reality however the severity of the cerebral palsy varied significantly between subjects and resulted in a large range of walking abilities throughout the investigation. The spread in the severity of the cerebral palsy reflected the condition as a whole and the subjects selected were believed to be representative of the children in the category targeted. It did however present difficulties when attempting to evaluate the effects of orthoses as it was possible that they may only have been effective for a small range of subjects and they may have had no beneficial effects for many others. Anecdotally there did not appear to be any pattern linking the severity of the cerebral palsy to the effectiveness of the orthoses in this investigation, although a detailed clinical assessment pre and post intervention would be necessary to look at this in more detail. It would certainly have been advantageous to this investigation to have recruited subjects who were more closely matched in their severity and ensuing problems although the geographically boundaries of the recruitment process made this impossible.

The age range used in the recruitment of the subjects (3 - 16 years) was fairly wide and was set with these limits purely in an attempt to ensure sufficient numbers could be recruited. No children under the age of three were targeted as it was considered that there would be difficulty getting them to co-operate in the gait analysis assessments and that their gait may not yet have matured sufficiently. In reality most of the children recruited were at the lower end of this range and had a mean age of 6.6 years. This was the result of two main factors; the first being that the community physiotherapists were based in primary and junior schools, and secondly that the younger children were less likely to have had any surgery performed on their lower limbs.

Although the recruitment criteria were highly controlled, although broad, in relation to the children's physical condition. It was impractical to include social or psychological factors within the criteria. Thus it is possible that the children involved in the study may have parents who were exceptionally enthusiastic and dedicated or that there were particular socio-economic factors involved which may all have their own particular influence on the progress of the child and the success of the orthotic regime (see section 7.7). In terms of the statistical analysis the small number of subjects studied means that care should be taken in extending the results of this investigation to the general population of cerebral palsied children.

7.4 Data Analysis

The use of EMG in gait analysis is often fraught with errors and is regularly criticised for the subjective methods of interpreting data, particularly those corresponding to the timing of muscle activity. In recent years however, clinicians and researchers have approached EMG in a far more scientific manner making a clear effort to move away from visual interpretation of traces to computer based methods using thresholds to determine the onset and cessation of activity. Currently most work in this area uses such techniques although there still remain numerous ways of establishing the threshold. As yet no objective criteria have been agreed, which make it very difficult to compare temporal data from different EMG studies.

In the current investigation, one such technique for establishing a threshold was chosen and applied to all the data recorded. The results showed that no changes to the temporal data occurred when changing orthoses. This might suggest that the method chosen was not sensitive enough to pick up subtle differences between the two conditions. However, the data obtained in this investigation differed to that reported previously for normal populations in a number of areas, and the differences observed were consistent with the known differences between normal and cerebral palsied children. It is thought therefore that the techniques for establishing the onset and cessation of muscle activity employed in this investigation were adequate and would have successfully identified any changes in muscle tone between the orthoses had such changes been present.

7.5 Quantitative Results

Temporal and Spatial Parameters

Early in the investigation it was acknowledged that no direct comparison of absolute values of velocity, stride length or cadence could be made between the groups and orthotic conditions, as these parameters were age and height related. In the group of children studied in this investigation a substantial age range from 3 to 12 years was covered, and it was important to consider that an increase in stride length of 0.1m may not have been significant in a 12 year old subject, but would have been a highly significant increase if observed in a 3 year old. For this reason all data recorded in this section of the investigation was presented as a percentage increase/decrease from the first set of trials for comparisons between groups and orthoses. Temporal and spatial data from this investigation cannot therefore be compared to published values for a normal population such as those reported by Sutherland et al. (1988), as these are always given in an age related format and show significant changes in parameters between the ages of 3 and 7 as gait matures.

Velocity data from this investigation showed no significant change between the groups, despite subjects wearing different orthoses in the second condition. This result is comparable to that reported by Knutson (1990) who studied 15 subjects and showed that velocity data for standard polypropylene AFOs was not significantly different to that measured for the subjects whilst wearing hinged AFOs. Knutson did however report a trend in the data with small increases in velocity towards more 'normal' walking speeds when the subjects wore orthoses. This again was evident in the current investigation; both groups showed small increases in velocity which may have reached significance had subjects numbers been larger. The importance of using large groups of subjects is highlighted when comparing the results reported here to those of Diamond and Ottenbach (1990). These authors carried out a single case study and reported walking velocities 'significantly superior' when using a dynamic AFO. It is clear that the current investigation may have drawn the same conclusions had it been based solely on subject A4 who exhibited a 45% increase in velocity when wearing a TRAFO.

Cadence data for the two groups were unchanged when the subjects moved into the second orthoses. This suggests that TRAFOs have no clear advantages over AFOs in terms of their effects on this parameter. In normal populations of children cadence again changes with age and so direct comparisons between such data and that recorded in this investigation could not be made. Cadence is generally higher (20-30%) in children than in adults (Sutherland et al., 1988) and decreases as velocity increases.

The stride length data from this investigation is the only temporal/spatial parameter in which significant differences between the two groups were observed. The subjects in group A exhibited a mean increase in stride length of 15.9% in comparison to the 6.1% increase observed in group B subjects. This would suggest that the TRAFOs were more effective in increasing stride length than the standard polypropylene AFOs. These results were comparable to those reported by Diamond and Ottenbach (1990) in a single case study which highlighted increased step length when using dynamic AFOs. Note should be taken however of the three extreme data points observed in group A in the current investigation. In subjects A1, A4, and A9, 35-68% increases in stride length were measured, when for all other subjects in both groups changes of around 15% and less were recorded. It is probable that without group A having these three extreme results, the increase in stride length would not have been significantly greater than that of group B. In fact, as walking velocity, cadence and stride length are all inter-related, if, as the data suggests, the first two of these parameters did not change, then stride length must have remained unchanged also.

Temporal & spatial parameters are often thought of as a primary measure of gait and a source of easily collected information which can provide an indication of improvement in ambulation. This investigation has highlighted however, that in children such measures are strongly influenced by age and height and in studies where there are small numbers of children with mixed ages and heights, direct comparisons are difficult to make. What should always be considered in such investigations is that to walk faster does not necessarily mean to walk better, and that a shift in data towards a more normal age related value is the best indicator of improvement.

EMG Data

The EMG data from the investigation provided interesting results both in terms of the comparisons between orthoses and those with published data for normal populations. If tone relieving ankle-foot orthoses work in the manner which has been suggested, then a decrease in periods of emg activity would have been expected for group A subjects whilst wearing the TRAFO. Such changes were not however evident; indeed the two groups behaved almost identically for all the parameters measured.

The tibialis anterior was the only muscle in which a difference between groups A and B was observed. In the stance phase, group A subjects wearing both orthoses exhibited muscle activity greater than that reported for a normal population. This however does not suggest that either of the orthoses had an effect on muscle activity, but rather that a high level of activity in the tibialis anterior was a characteristic of group A subjects in general.

In the swing phase, both subject groups wearing both types of orthoses exhibited tibialis activity levels dramatically lower than those reported for a normal population. The consistency in results, regardless of the orthosis type, again suggests that low levels of activity are common to the subjects studied in this investigation. This reduction in activity in the tibialis anterior during the swing phase would diminish ability to dorsiflex the foot, making it more difficult to achieve clearance of the foot during swing.

In the gastrocnemius, the results of the statistical analysis on the activity levels for groups A and B were identical, suggesting that neither of the orthoses had a greater effect than the other on muscle tone. In the stance phase across groups and orthoses the muscle activity levels were no different to those observed in a normal population. The swing phase however provided very different results, and here across both groups and orthoses, activity levels in the gastrocnemius were significantly higher than those reported in a normal population.

The results from the gastrocnemius are interesting as they do not support the findings of Knutson Lough (1990) who reported that for children with cerebral palsy wearing both fixed and hinged AFOs no increase in gastrocnemius emg was observed during the stance phase. The results of the current investigation however are consistent with the finding of Sutherland et al. (1988) for normal children, that gastrocnemius activity during the swing phase was indicative of an immature gait pattern. The activity of the gastrocnemius during the swing phase for the children in this investigation would encourage the foot to plantarflex, making it difficult to achieve foot clearance.

In the quadriceps muscles across groups and orthoses in both the stance and swing phases of the gait cycle, no differences were observed between the data obtained in this investigation and that reported for a normal population. This indicated that the children in this investigation all exhibited normal quadriceps activity throughout the gait cycle and that neither of the orthoses used had any effect on the activity levels.

The data recorded for hamstring activity again showed no differences between the groups regardless of which orthosis they were wearing. In the stance phase, hamstring activity was significantly higher across groups and orthoses than that reported for a normal population. Increased activity of the hamstrings was also observed by Sutherland et al. (1988) in children who had immature gait patterns. In the swing phase, the two groups once again had the same results, demonstrating hamstring activity levels which were not significantly different from normal population values.

The EMG results as a whole were very interesting demonstrating that no differences were evident between the two groups, despite wearing two types of orthosis. They did however highlight a number of areas in which the children in this investigation, in general, differed from their normal population counterparts. The most interesting result seems to be that the children in this study exhibited low levels of tibialis anterior activity during swing and when this was combined with higher than normal gastrocnemius activity during this phase, it was not difficult to understand why so many of these children toe walked and needed orthotic intervention to prevent excessive plantarflexion.

It is important to stress that care must be taken in comparing the results of this investigation with those previously published by other researchers. As discussed earlier, children with cerebral palsy can fall anywhere within a wide spectrum from those very mildly to those very severely affected. The attributes of subjects selected in any two separate investigations described as using 'children with cerebral palsy' are therefore likely to be very different and comparisons between the two studies may not be valid. Also, there are also numerous ways of measuring and presenting EMG data which means that the measurement techniques and quantification of EMG data in any two studies are unlikely to be the same. Until scientists working in this area agree upon a standard protocol for such investigations, the comparison of data between trials will remain difficult.

Single Subject Assessments

The protocol employed in the main investigation required assessment sessions to be carried out at approximately six weekly intervals during the six month period over which each child was monitored. Questions arose early in the investigation however as to whether when changing to the TRAFO instant alterations to muscle tone might occur, or if any changes observed would take place gradually over a period of weeks. It appeared possible that with six week gaps between assessment sessions, important events or changes might be missed. As data for the orthoses were averaged over the three assessments it was also possible that changes occurring towards the end of the three month period could be masked by the data from the two previous assessments. In order to examine these factors in more detail, a single subject study was included within the main investigation in order to observe one child in more detail and monitor changes on a weekly basis.

As for the main investigation, in the single subject study no changes in muscle activity were observed between the two orthotic conditions, suggesting that the TRAFOs did not reduce muscle tone as had previously been suggested. For both the temporal/spatial parameters and EMG data, fluctuations were evident between individual trials, but there were no overall trends across time for any of the parameters to increase or decrease. Rather than highlighting, as intended, a point or time period over which changes in muscle activity occurred, the single subject assessment results suggest that neither orthosis had any effect on muscle tone.

7.6 Anecdotal Information

Important information relating to the success of orthoses in such an investigation often comes from talking to parents, physiotherapists and the children themselves. All reports about the orthoses were favourable both for the standard polypropylene ankle-foot orthoses and the tone relieving ankle-foot orthoses. Parents reported high quality orthoses which required little or no adjustment, suggesting that they had been cast accurately and manufactured to a very high standard. It is however disturbing to find that this was an unusual experience for the group and that, on the whole, the subjects were used to receiving orthoses which often didn't fit and were of poor quality. Consideration must be given to the whole process by which orthoses are prescribed and provided to children with cerebral palsy, which at present can occur via a number of different routes with almost no controls over the quality and suitability of orthoses. The most important factor in the success of the orthotic management of a child must be that the correct orthosis is selected and that it is cast and manufactured to the highest possible standards. The current haphazard approach, often using limited expertise and governed by financial constraints, may well account for the large number of children for whom orthotic intervention has been unsuccessful.

In terms of the TRAFOs, anecdotal evidence from parents and physiotherapists suggested that they were generally pleased with the orthoses and felt that the children were walking better when wearing them. The children themselves were also happier with the orthoses and all preferred them to the standard polypropylene AFOs. This information is in stark contrast to the results of the quantitative section of this investigation which suggested that the effects of wearing the TRAFO's in no way differed from the AFO's. The results of the gait analysis are counter-intuative and do not support the observations and opinions of the therapists, parents or children themselves.

Of the eight subjects in group A, who received AFOs followed by TRAFOs, all of the children except subject A4 continue to wear TRAFOs. Anecdotally both the parents and physiotherapists were pleased with the TRAFOs and felt improvements in ambulation had occurred despite the fact that this investigation has failed to show any such differences between the two orthoses. For subject A4, following some discussion this child returned to wearing a standard polypropylene AFO on the recommendation of his orthopaedic consultant. The investigator, his physiotherapist and his parents all felt however, that neither of the orthotic interventions improved his gait.

In group B, there were seven subjects all of whom received two standard polypropylene AFOs. As would be expected, no improvements in ambulation were reported when moving from one orthosis to the other, although generally the reports from parents expressed pleasure based on the quality of the orthoses rather than their functional outcome. All subjects from group B continue to wear AFOs except for subjects B5 who moved to wearing a hinged AFO shortly after the investigation and continues to wear this orthosis.

Supporting previous reports regarding the standard of orthoses used in the investigation, it was also noted that many of the parents and therapists specifically requested that the children continued to be supplied orthoses from the North Western Orthotic Unit following the study, rather than returning to the suppliers used previously. This certainly indicates that quality of orthoses is very important in influencing the benefits received and the satisfaction of the patients regarding their appliance.

7.7 Other Influences

Orthotic management

The subjects in the study all attended the same unit for treatment and received the same standard of care and quality of orthoses. Orthoses were cast and manufactured by the same orthotist and the same technician.

Of the thirty orthoses which were manufactured in this investigation, all were fitted by the orthotist at special sessions so that any problem areas could be identified and minor alterations made before the subjects were allowed home with their orthoses. All of the children's parents received information on how to gradually introduce the orthosis into their child's daily routine and the signs to look for if there were any problems emerging. Other than minor areas of rubbing during the first few days, no problems were reported for any of the orthoses, and anecdotal reports from parents and therapists suggested that the orthoses provided were of a superior quality to those normally supplied to the children from other sources.

Orthotic provision to children with cerebral palsy in the Manchester and Salford areas can be made from a number of sources which can include hospital based centres or commercial companies. The exact source from which a child receives their orthosis will be influenced by a number of factors such as where they live, the school they attend, the referring consultant/therapist, and financial constraints of the provider. Consequently, even in a small geographical area such as Manchester and Salford the levels of treatment and the quality of orthoses received by children with cerebral palsy can vary immensely. It is therefore difficult to evaluate particular orthotic designs as their success may well depend on the skill of the orthotist and the quality of the workmanship involved.

The integration of dynamic/tone relieving ankle-foot orthoses into the management of children with cerebral palsy in the UK has been fragmented and inconsistent. Each centre/company has incorporated its own features into the design, and the process and techniques used in casting and manufacture vary immensely. The effect has been that anecdotally some centres favour the use of TRAFOs whilst others report numerous problems with casting and manufacture and have stopped prescribing them.

It is clear that to receive any benefits from using TRAFOs the casting and manufacture must be carried out by experienced orthotists and technicians who ideally work on the same site. Anecdotal information from physiotherapists who have experimented with TRAFOs show that many centres have found them generally ineffective and problematic, with many of the orthoses being returned several times before the correct fit was achieved. It appears that care must be taken when selecting suppliers as often the cheaper and more convenient options result in unsatisfactory appliances and most likely account for the unfavourable reports on the use of this type of orthosis.

Parental Influences

Parental involvement in the investigation as a whole was generally high. This was essential as it was necessary for the subjects to attend all the casting and fitting sessions at the assigned times. The requirements were made clear to the parents at the initial interviews at which detailed information was provided on the number and the timing of appointments necessary during the six month period. As mentioned in section 7.3, a number of children dropped out during the investigation, the majority withdrawing because the parents could not meet the attendance requirements. It is possible therefore, that the nature of the investigation may mean that the subject group was biased towards children whose parents were the more enthusiastic and dedicated, and thus provided the best possible opportunities for their children to progress.

It is impossible to know for certain the amount of parental involvement with physiotherapy at home. The home questionnaires were designed to address some of these problems. As the results have highlighted, the difference in the amount of physiotherapy received by the children in this investigation was large and these variations were random across the two groups and orthosis types. Some of the subjects had physiotherapy at school and home each day, whilst at the other extreme some children had none or as little as ½ hour of hydrotherapy each week. One can only guess at the effect parental involvement has on long term prognosis, but the parents and family environment are factors of considerable importance with regards the progress of such children (Pollock, 1975).

In addition to the amount of physiotherapy received, anecdotal evidence also suggests that the parents had considerable influence on such factors as the length of time the orthoses were worn each day and the amount and type of physical activities that the children participated in whilst wearing the orthoses. Again much variation was observed between the subjects in the investigation with some parents clearly taking an active part in encouraging their child to wear the orthosis at home and at school and liaising with teachers and therapists to maximise the benefits. One of the most noticeable factors affecting the level of activity was that it was often sibling encouragement and/or rivalry which resulted in an overwhelming desire for the subjects to join in, whether this be to recover 'stolen' toys or to take part in a game of football. Parental involvement, along with the benefit of brothers and sisters clearly played a large part in the level of physical activity of the children.

It is likely that those children who not only receive adequate professional care, but additionally have other encouraging influences at home from siblings and parents will progress far better in the long term. Such factors could not however be controlled in this investigation, although the home questionnaires allowed the parental influence to be considered.

Social/Psychological Influences

As mentioned previously, the anecdotal evidence from the investigation showed that the TRAFO's were far more popular with the therapists, parents and children alike. What is not clear is whether this preference for the tone relieving orthoses stems from their ability to actually physically alter the gait of the children or whether it is the result of some other social or psychological factors.

It is clear that the physical design of the TRAFO's means that they are far less obtrusive than standard AFO's and can be easily hidden beneath socks and ankle boots or trainers. In school age children it is understandable that they may well prefer an orthosis which can be easily hidden regardless of how it actually effects their ambulation. In this way the social effects of being able to 'fit in' with the rest of a class at school and not in anyway be visibly different from other children could certainly influence their opinion of the orthoses.

It is also more than possible that the children in this investigation were so keen to keep their orthoses that they actually made an extra effort to walk 'correctly' in the TRAFO's, particularly when being viewed by the therapists and investigator. This in addition to the psychological effects of the more cosmetic appearance could go some considerable way to explaining the favourable reports made by the parents and therapists.

It is clear that the progress of any child is dependant on a large number of factors which include orthotic provision, physiotherapy, parental influences and social and psychological factors, and for each child the effect of these factors will vary and influence outcome to a greater or lesser extent. Altering the orthotic intervention alone, as in this investigation, whilst being unable to optimise the other factors, results in each child receiving a very different regime of treatment. An appreciation of all such influences and their respective roles in the global treatment of a child, is necessary when relating the results of any investigation to the general population of cerebral palsied children.

7.8 Key Issues and Investigation Limitations

The discussion has covered in depth the practicalities of undertaking this type of investigation and the results which were attained, giving consideration to the many factors which could have influenced outcome. As a summary there are a number of key issue which should be highlighted:

- The data collected provided no evidence in terms of the gait analysis to suggest that the TRAFO's were any more effective than standard polypropylene AFO's.

- The investigation would have benefited greatly from the integration of some qualitative methods of data collection to support the gait analysis.

- There was a considerable amount of anecdotal information which suggested that the therapists, parents and children all felt the TRAFO's were the superior orthoses.

- It may be possible that TRAFOs do not work by inhibiting tone, but may have some biomechanical advantage over a standard AFO.

- Much care needs to be taken when designing this type of research project as there are many factors which can influence outcome and every child needs to be viewed as an individual.

When considering the results of this investigation there are a number of limitations which need to be taken into account and which might hopefully serve as a guide for those researchers planning to follow on a similar course of study. The greatest problem encountered was the variation between subjects in terms of the severity of cerebral palsy, and the environmental and parental influences on their treatment programmes. During the investigation it became apparent that a diagnosis of moderate/mild cerebral palsy actually covered a wide spectrum of children who were not at all similar in their ambulatory capabilities. Alternative inclusion criteria may have been available which could have provided a more uniform group of subjects.

The investigation also had relatively small group sizes (8 and 7) which meant that results could easily be swayed by the disproportionate effects of one subject. This was noted on several occasions where group means were clearly not a true reflection of the results for the majority of subjects. The small sample sizes used in this investigation clearly limit the generalisations which can be made from the results.

One of the most important limitations of this type of investigation, and one which will be familiar to all who work in gait analysis laboratories, is the variation in gait patterns observed outside and within laboratories. It is clear that children do not walk in the same manner crossing the car-park on their way into the building, in comparison to when they are observed walking down the centre of a gait laboratory. This highlights the importance of the information from parents, teachers and therapists as what is observed in the laboratory is often not a true representation of what occurs in everyday life.

7.9 Implication of Results and Future Directions

This investigation has provided some interesting results in terms of the TRAFOs ability to change hypertonicity in the lower limb and has led to a number of important questions which need to be addressed if we are to establish with any certainty whether TRAFOs can improve gait in children with cerebral palsy and the methods by which this is accomplished. In general terms the data from this investigation suggests that no reduction in the levels of muscular activity occurred whilst subjects wore TRAFOs and therefore no reduction in tone took place. There are several reasons why these results might have been observed, each having very different implications for how this information should be reflected back into the orthotic management of children with cerebral palsy and used to model future research.

The first explanation of the results is that TRAFOs do not actually reduce muscle tone. This suggestion leads to the question as to whether TRAFOs have a significant biomechanical effect rather than working in a neurological manner. Documentation already exists highlighting the biomechanical advantages to gait of using standard AFOs

(Rosenthal et al, 1975; Condie & Meadows, 1993; Mann, 1983) in children with cerebral palsy and it would seem probable that TRAFOs would have a similar effect. The posterior section of a TRAFO does not reach as high up the leg as an AFO and so may be less biomechanically advantageous in this manner, however the TRAFO has the foot fully enclosed and tightly secured into the orthosis, which may result in greater support and better alignment of the foot thus providing its own benefits to ambulation. It would be interesting to explore kinetic and kinematic parameters in relation to TRAFOs and standard polypropylene AFOs in a similar manner to this investigation to establish if biomechanical differences between the two orthoses can be detected.

The results of this investigation could alternatively be explained by a failure in the recruitment criteria to target the 'correct child'. If this were the case then TRAFOs may reduce tone, but only in a particular sub-group of children exhibiting specific attributes. The selection of a varied population of children in which some orthoses work and others fail would mask the positive data when the mean of the whole group was taken resulting in the orthoses appearing to have no overall effect.

When working with a subject group such as children with cerebral palsy, no matter how many restrictions are placed on the selection criteria the subjects recruited will always vary immensely in both physical and mental traits. It is therefore difficult to determine whether such orthoses work for all children with a particular diagnosis or if in only some cases they form the appropriate treatment. It is possible that we need to re-examine the criteria used to determine which children are suitable to wear TRAFOs and how they are selected via community physiotherapy teams, consultants or orthotists. Questions must be addressed to examine whether there are important factors in a child's physical condition which can predetermine the success of TRAFOs and whether these are currently being missed, resulting in the inappropriate use of such orthoses.

A third possibility is that the orthoses do reduce tone, but only if particular critical features are built in to them. If this were the case, it is conceivable that in some children the critical features may have been optimised, leading to successful results, and in others the critical features were missing or inappropriately employed leading to a failure to either reduce tone or improve ambulation. If this were the case, then the next step would be to discover the role, if any, of particular areas of the contoured sole plate. It is possible that some of the raised and hollowed areas may provide no benefit whatsoever. At present it is difficult to interpret reports in the literature because of the inconsistency which exists in the design, materials, trimlines and the contouring of the footplate (Supan, 1995). An investigation into a TRAFO 'style' orthosis, but with alterations to the contoured base, would provide important information relating to key features which may exist. The current investigation also looked specifically at one type, the standard design TRAFO. This is the form of this orthosis which is most often used and on which almost all reports and research have to date been based. It would also be useful to evaluate some of the other styles of the orthosis, in particular the tone relieving foot orthoses whose use is becoming more frequent, particularly in children with mild hypertonicity. The role of the trimline, its position, and the methods by which these are chosen for each child would also all be interesting areas to investigate to establish the advantages of various techniques and the type of child for which each is suitable.

The use of TRAFOs in other subjects groups, such as diplegic cerebral palsied children, head injury patients or stroke victims is also an area of great interest at present. With the use of tone relieving orthoses expanding into these areas in recent years, a number of investigations are currently underway and warrant further investigation to examine the role of the TRAFO.

In relation to the present investigation, the study would obviously have benefited greatly from increased subject numbers, although the expansion to a larger geographical area may be necessary to accomplish this. One way to achieve increased participation may be to run a multi-centre study which would also account for variations in orthotists and the manufacturing techniques. Although potentially very difficult, with adequate funding and support from a number of centres this may be the way to obtain results which can then be extended to the population of cerebral palsied children as a whole.

7.10 Conclusions

The results of this investigation were unable to highlight any areas in which tone relieving ankle-foot orthoses produced more favourable results in the measured parameters than the standard polypropylene ankle-foot orthoses. In contrast to previous work, which suggests that tone relieving/dynamic AFOs are successful at reducing muscle tone in children with cerebral palsy, no evidence was found to support such claims.

It is impossible to say that TRAFOs do not work, or that they are less successful than AFOs and certainly the anecdotal information collected during the investigation suggests that there are some advantages to using these orthoses. What the evidence from this study suggests is that TRAFOs do not work neurologically as previously indicated, but may have biomechanical benefits which make them a successful orthotic technique for such children. It is possible that the physical design of the orthoses alone provides greater support and stability around the ankle altering parameters and improving ambulation in a manner which was not measured in this investigation.

The method of using electromyographic (EMG) recordings to determine levels of muscle activity as an indicator of tone was successful and in several muscles showed the children in this investigation had normal levels of muscle activity when compared to previous studies. In some areas differences in muscle activity were observed relative to those reported for normal populations and these were uniform across the groups and could be explained by the subjects underlying pathology rather than by the orthoses.

The primary objective of this investigation was to establish whether wearing a TRAFO would result in reduced levels of muscle tone, hence supporting the suggestions of earlier investigators that the orthoses work in a neurological rather than a biomechanical manner. The results showed that subjects in both groups performed equally in almost all parameters and there were no differences between the tone relieving ankle-foot orthoses and standard polypropylene ankle-foot orthoses in terms of their ability to reduce levels of muscle tone.

Anecdotal evidence from the physiotherapists, parents and children themselves suggested that there were advantages to wearing TRAFOs and that they were the preferred orthosis. It is impossible to tell however, whether such comments are influenced by the cosmetic appearance and/or other psychological factors rather than actual improvements in ambulation.

Section 8

References & Appendices

8.1 References

Ashworth B. (1964)
Preliminary Trial of Carispodal in Multiple sclerosis.
Practitioner. 192:540-542.

Bedford S. (1990)
Cerebral Palsy
In: *Elements of Paediatric Physiotherapy*. Ed. Eckersley M.
Churchill Livingstone : Edinburgh

Bennet G.C, Rang M., and Jones D. (1982)
Varus and Valgus Deformities of the Foot in Cerebral Palsy.
Developmental Medicine and Child Neurology. 24: 499-503.

Bleck E.E. (1975)
Locomotor Prognosis in Cerebral Palsy.
Developmental Medicine and Child Neurology. 17: 18-25.

Bleck E.E. (1987)
Orthopaedic Management in Cerebral Palsy. *Clinics in Developmental Medicine no. 99/100*
Mac Keith Press, Oxford: Blackwell Scientific Publications Ltd, Philadelphia: J.B. Lippincott Co.

Bobath K. and Bobath B. (1962)
An Analysis of the Development of Standing and Walking Patterns in Patients with Cerebral Palsy.
Physiotherapy. 48: 144-153.

Bobath B. (1978)
Adult Hemiplegia: Evaluation and Treatment. 2nd ed.
William Heinemann : London.

Blasco P.A. (1994)
Primitive Reflexes: Their Contribution to the Early detection of Cerebral Palsy.
Clinical Pediatrics. July: 388-397.

Brodke D.S., Skinner S.R., Lamoreux L.W., Johanson M.E., St. Helen R., Moran S.A. and Ashley R.K. (1989)
Effects of Ankle-Foot Orthoses on the Gait of Children.
Journal of Pediatric Orthopaedics. 9: 702-708.

Bronkhorst A.J. and Lamb G.A. (1987)
An Orthosis to Aid in Reduction of Lower Limb Spasticity.
Orthotics and Prosthetics. 41 (2): 23-28.

Brunnstrom S. (1970)
Movement Therapy in Hemiplegia: A Neurophysiological Approach.
Harper and Row : New York.

Brunt D. and Scarborough N. (1988)
Ankle Muscle Activity During Gait in Children with Cerebral Palsy and Equinovarus Deformity.
Archives of Physical Medicine and Rehabilitation. 69: 115-117.

Butler P.B. and Nene A.V. (1991)
The Biomechanics of Fixed Ankle Foot Orthoses and their Potential in the Management of Cerebral Palsied Children.
Physiotherapy. 77 (2): 81-88.

Butler P.B., Thompson N. and Major R.E. (1992)
Improvement in Walking Performance of Children with Cerebral Palsy: Preliminary Results.
Developmental Medicine and Child Neurology. 34: 567-576.

Campbell N.A. (1990)
Nervous System.
In: *Biology.*
Benjamin/Cummings : Redwood City

Capute A., Accardo P., Vining E., Rubenstein J., Harryman S. (1978)
In: *Primitive Reflex Profile.*
University Park Press : Baltimore

Carlson S.J. (1984)
A Neurophysical Analysis of Inhibitive Casting.
Physical & Occupational Therapy in Pediatrics. 4 (4): 31-42.

Clark J.E. (1995)
Dynamical Systems Perspective on Gait.
In *Gait Analysis: Theory and Application.* Eds. Craik R.L and Oatis C.A.
Mosby : St Louis.

Condie D.N. and Meadows C.B. (1993)
Ankle-Foot Orthoses.
In: *Biomechanical Basis of Orthotic Management.* Eds. Bowker P., Condie D.N., Bader D.L., Pratt D.J.
Butterworth-Heinemann : Oxford.

Csongradi J., Bleck E. and Ford W.F. (1979)
Gait Electromyography in Normal and Spastic Children, with Special Reference to Quadriceps Femoris and Hamstring Muscles.
Developmental Medicine and Child Neurology. 21: 738-748.

Curtis E. (1995)
Dynamic Ankle Foot Orthosis - Tone Inhibiting.
B.A.P.O. Newsletter. 2: 22-26.

Cusick B. and Sussman M.D. (1982)
Short Leg Casts: Their Role in the Management of Cerebral Palsy.
Physical and Occupational Therapy in Pediatrics. 2: 93-115.

Diamond M.F. and Ottenbach K.J. (1990)
Effect of a Tone-Inhibiting Dynamic Ankle-Foot Orthosis on Stride Characteristics of an Adult with Hemiparesis.
Physical Therapy. 70 (7): 423-430.

Di Fabio R.P. (1987)
Reliability of Computerized Surface Electromyography for Determining the Onset of Muscle Activity.
Physical Therapy. 67 (1): 43-48.

Duncan W. R. (1960)
Tonic Reflexes of the Foot - Their Orthopaedic Significance in Normal Children and in Children with Cerebral Palsy.
Journal of Bone and Joint Surgery. 42a (5): 859-868.

Duncan W.R. and Mott D.H. (1983)
Foot Reflexes and the Use of the Inhibitive Cast.
Foot and Ankle. 4: 145-148.

Easton T. (1972)
On the Normal Use of Reflexes.
American Scientist. 60 : 591-599.

Embrey D.G., Yates L. and Mott D.H. (1990)
Effects of Neuro-develpomental Treatment and Orthoses on Knee Flexion During Gait: a Single-Subject Design.
Physical Therapy. 70: 626-636.

Fenn W. O., Garvey P. H. (1934)
The Measurement of the Elasticity and Viscosity of Skeletal Muscle in Normal & Pathological Cases: a Study of So-Called "Muscle Tonus".
Journal of Clinical Investigation. 13: 383-397.

Fiorentino M.R. (1973)
Reflex Testing Methods for Evaluating CNS Develpoment.
C.C Thomas : Illinois.

Ford C., Grotz R.C. and Shamp J.K. (1986)
The Neurophysiological Ankle-Foot Orthosis.
Clinical Prosthetics and Orthotics. 10 (1); 15-23.

Foster M. (1890)
A Textbook of Physiology : Part 3.
Macmillan : London.

Fukuda T. (1961)
Studies on Human Dynamic Postures from the Viewpoint of Postural Reflexes.
Acta Oto-Laryngol Supplement. 161 : 8-15.

Gessel A. (1940)
In: *The First Five Years of Life*.
Harper and Bros : New York.

Haigh K. (1989)
Effects of Dynamic Ankle-Foot Orthoses on Gait in Children with Hypertonia.
Masters Thesis: University of Washington.

Halar E. and Cardenas D.D. (1987)
Ankle-Foot Orthoses: Clinical Implications.
Physical Medicine and Rehabilitation. 1(1): 45-66.

Harris S. R. and Riffle K. (1986)
Effects of Inhibitive Ankle-Foot Orthoses on Standing Balance in a Child with Cerebral Palsy.
Physical Therapy. 66 (5): 663-667.

Hinderer K.A., Harris S.R., Purdy A.H., Chew D.E., Staheli L.T., McLaughlin J.F. and Jaffe K.M. (1988)
Effects of "Tone-Reducing" vs. Standard Plaster-Casts on Gait Improvement of Children with Cerebral Palsy.
Developmental Medicine and Child Neurology. 30: 370-377.

Hylton N. M. (1989)
Postural and Functional Impact of Dynamic AFOs and FOs in a Pediatric Population.
Journal of Prosthetics and Orthotics. 2 (1): 40-53

Hylton N.M. (1990)
Dynamic Casting and Orthotics.
In : *The Practical Management of Spasticity in Children and Adults*. Eds. Glenn M. B. & Whyte J.
Lea & Febiger : Philadelphia.

Knutson L.M. and Soderberg G.L. (1995)
EMG: Use and Interpretation in Gait.
In : *Gait Analysis - Theory and Application*. Eds. Craik R.L. & Oatis C.A.
Mosby : St. Louis.

Lehmann J.F. (1986)
Lower Limb Orthotics.
In : *Orthotics Etcetera*. Ed. Redford J.B.
Williams & Wilkins : Baltimore.

Lohman M. and Goldstein H. (1993)
Alternative Strategies in Tone-Reducing AFO Design.
Journal of Prosthetics and Orthotics. 5 (1): 21-24.

Lough L.K. (1990)
The Effects of Fixed and Hinged Ankle-Foot Orthoses on Gait Myoelectric Activity and Standing Joint Alignment in Children with Cerebral Palsy.
Doctoral Dissertation : University of Iowa.

McDonald K.C. and Valmassy R.L. (1987)
Cerebral Palsy - A Literature Review.
Journal of the American Podiatric Medical Association. 77 (9): 471-483.

McGraw M. (1943)
In: *The Neuromuscular Maturation of the Human Infant*.
Hafner Publishing : New York.

Mann R. (1983)
Biomechanics in Cerebral Palsy.
Foot and Ankle. 4: 114.

Marieb E.N. (1992)
The Peripheral Nervous System and Reflex Activity.
In: *Human Anatomy and Physiology*.
Benjamin/Cummings : Redwood City

Meadows C.B. (1984)
The Use of Polypropylene Ankle-Foot Orthoses in the Management of the Young Cerebral Palsied Child.
Ph. D. Thesis : University of Strathclyde.

Middleton E.A., Hurley G.R.B and McIlwain J.S. (1988)
The Role of Rigid and Hinged Polypropylene Ankle-Foot Orthoses in the Management of Cerebral Palsy: a Case Study.
Prosthetics and Orthotics International. 12: 129-135.

Mills V.M. (1984)
Electromyographic Results of Inhibitory Splinting.
Physical Therapy. 64 (2): 190-193.

Molnar G.E. (1986)
Orthotic Management of Children.
In : *Orthotics Etcetera*. Ed. Redford J.B.
Williams & Wilkins : Baltimore.

Mott D.H., Yates L. and Chapman J. (1980)
Inhibitive Casting to Control Hypertonicity in the Cerebral Palsy Child.
Paper presented at the Annual Meeting of the American Academy of Cerebral Palsy and Developmental Medicine: Boston.

Mueller K., Cornwall M., McPoil T., Mueller D. and Barnwell J. (1992)
Effect of a Tone-Inhibiting Dynamic Ankle-Foot Orthosis on the Foot-Loading Pattern of a Hemiplegic Adult: A Preliminary Study.
Journal of Prosthetics and Orthotics. 4 (2): 86-92.

Otis J.C., Root L. and Kroll M.A. (1985)
Measurment of Plantar Flexor Spasticity During Treatment with Tone-Reducing Casts.
Journal of Pediatric Orthopaedics. 5: 682-686

Overby A.S., Lubin L., Goudelach C. and Scarborough N. (1991)
Single Case Study on Tone Inhibiting AFO in Adult Hemiplegic Subject.
Physical Therapy. 71 (6): S96.

Perry J. (1992a)
Section One : Fundamentals.
In: *Gait Analysis: Normal and Pathological Function.* Ed. Perry J.
McGraw-Hill : New York.

Perry J. (1992b)
Chapter 18 : Dynamic Electromyography.
In: *Gait Analysis: Normal and Pathological Function.* Ed. Perry J.
McGraw-Hill : New York.

Pharaoh P. (1994)
The Changing Face of Cerebral Palsy.
A.P.C.P. Journal. Aug: 13-15.

Pharaoh P., Cooke T., Rosenbloom L. and Cooke R.W.I. (1987)
Trends in Birth Prevalence of Cerebral Palsy.
Archives of the Disabled Child. 62: 379-384.

Pimentel E.D. (1996)
The Disappearing Reflex: A Reevaluation of Its Role in Normal and Abnormal Development.
Physical and Occupational Therapy in Pediatrics. 16(4) : 19-41

Pollock G. (1975)
Assessment of the Results of Surgery in Cerebral Palsy.
In: *Orthopaedic Aspects of Cerebral Palsy.* Ed. Samilson R.L.
J.B. Lippincott Co : Philadelphia.

Ricks N. R. and Eilert R. E. (1993)
Effects of Inhibitory Casts and Orthoses on Bony Alignment of Foot and Ankle During Weight-Bearing in Children with Spasticity.
Developmental Medicine and Child Neurology. 35: 11-16.

Rosenthal R.K., Deutsch S.D., Miller W., Schumann W. and Hall J.E. (1975)
A Fixed-Ankle Below-the-Knee Orthosis for the Management of Genu Recurvatum in Spastic Cerebral Palsy.
Journal of Bone and Joint Surgery. 57a: 545-547.

Shakespeare V. and Postle K. (1999)
A Qualitative Study of Patients Views on the Effects of Breast-Reduction Surgery: a 2-Year Follow-Up Survey.
British Journal of Plastic Surgery. 52 : 198-204.

Soderberg G.L. and Cook T.M. (1984)
Electromyography in Biomechanics.
Physical Therapy. 64 (12): 1813-1820.

Stallard J. (1987)
Assessment of the Mechanical Function of Orthoses by Force Vector Visualisation.
Physiotherapy. 73: 398-402.

Supan T.J. (1995)
The Use of Orthotics to Improve the Dynamic Efficiency of Gait.
In: *Report of a Consensus Conference on the Lower Limb Orthotic Management of Cerebral Palsy*. Eds. Condie D.N. and Meadows C.B.
International Society for Prosthetics and Orthotics.

Super C.M. (1976)
Environmental Effects on Motor Development: the Case of African Infant Precocity.
Developmental Medicine and Child Neurology. 18 : 561-567.

Sussman M.D. and Cusick B. (1979)
Preliminary Report: The Role of Short-Leg, Tone-Reducing Casts as an Adjunct to Physical Therapy of Patients with Cerebral Palsy.
The Johns Hopkins Medical Journal. 145: 112-114.

Sutherland D.H., Olshen R.A., Biden E.N. and Wyatt M.P. (1988)
The Development of Mature Walking. *Clinics in Developmental Medicine no. 104/105*
Mac Keith Press, Oxford: Blackwell Scientific Publications Ltd, Philadelphia: J.B. Lippincott Co.

Sutherland D.H., Kaufman K.R. and Moitoza J.R. (1994)
Kinematics of Normal Human Walking.
In : *Human Walking* (Second Edition). Eds. Rose J. & Gamble J.G.
Williams & Wilkins : Baltimore.

Tait J, Rose, G.K (1979)
The Real Time Video Vector Display of Ground Reaction Forces During Ambulation.
Journal of Medical Engineering and Technology. 3 (5): 252 -255.

Tata G.E. and Peat M. (1987)
Electromyographic Characteristics of Locomotion in Normal Children.
Physiotherapy Canada. 39 (3): 167-175.

Thelan E. and Fisher D.M. (1982)
Newborn Stepping: an Explanation for a 'Disappearing' Reflex.
Developmental Psychology. 18 : 760-755.

Walsh E.G. (1992)
Muscles, Masses and Motion. The Physiology of Normality, Hypertonicity, Spasticity and Rigidity. *Clinics in Developmental Medicine no. 125*
Mac Keith Press, Oxford: Blackwell Scientific Publications Ltd, Philadelphia: J.B. Lippincott Co.

Watt J., Sims D., Harckham F., Schmidt L., McMillan A. and Hamilton J. (1986)
A Prospective Study of Inhibitive Casting as an Adjunct to Physiotherapy for Cerebral Palsied Children.
Developmental Medicine and Child Neurology. 28; 480-488.

Williams P.L. and Warwick R. (1980)
Neurology. *In Gray's Anatomy*.
Churchill Livingstone : Edinburgh

Winter D.A. (1984)
Pathological Gait Diagnosis With Computer-Averaged Electromyographic Profiles.
Archives of Physical Medicine and Rehabilitation. 65: 393-398.

Winter D.A. and Yack H.J. (1987)
EMG Profiles During Normal Human Walking: Stride-to-Stride and Inter-Subject Variability.
Electroencephalography and Clinical Neurophysiology. 67: 402-411.

Winter (1990)
Kinesiological Electromyography
In: *Biomechanics of Motor Control and Human Movement.*
John Wiley : New York.

Woltering H., Guth V. and Abbink F. (1979)
Electromyographic Investigation of Gait in Cerebral Palsied Children.
Electromyography and Clinical Neurophysiology. 19: 519-533.

Yates G. (1968)
A Method for the Provision of Lightweight Aesthetic Orthopaedic Appliances.
Orthopaedics. 1: 153-162.

Young C.C., Rose S.E., Biden E.N., Wyatt M.P. and Sutherland D.H. (1989)
The Effect of Surface and Internal Electrodes on the Gait of Children with Cerebral Palsy, Spastic Diplegic Type.
Journal of Orthopaedic Research. 7: 732-737.

Zachazewski J.E., Eberle E.D. and Jefferies M. (1982)
Effect of Tone-Inhibiting Casts and Orthoses on Gait.
Physical Therapy. 62 (4): 453-455.

Zelazo P. (1983)
The development of Walking: New Findings and Old Assumptions.
Journal of Motor Behaviour. 15 : 99-137.

Zipp P. (1982)
Recommendations for the Standardization of Lead Positions in Surface Electromyography.
European Journal of Applied Physiology. 50: 41-54.

Zuniga E.M., Truong X.T. and Simons D.G. (1969)
Effects of Skin Electrode Position on Averaged Electromyographic Potentials.
Archives of Physical Medicine and Rehabilitation. 50: 264-271.

8.2 Appendix 1

- Patient Information Sheet
- Assessment Protocol
- Consent Form
- Model Release Form
- Assessment Sheet (Gait Data)

Patient Information Sheet

Dear Parent/Guardian

We would like to offer your child the opportunity to take part in a research study run jointly at the North Western Orthotic Unit, Hope Hospital and the School of Prosthetics & Orthotics, University College Salford. The study is aimed at evaluating the use of different orthoses in the treatment of lower limb spasticity for children with cerebral palsy. The orthoses to be tested are designed to reduce muscle tone in the affected leg and hence improve the quality of gait.

The research involves the use of two groups of subjects, all of whom will be fitted with an ankle-foot orthosis for a period of twelve weeks during which they will have gait analysis to follow their progress. A second different orthosis will then be issued to both groups for a further twelve weeks and gait analysis will again be performed. The analysis will require you to attend the School of Prosthetics & Orthotics six times in approximately six months each session lasting about 1 hour. You will also need to visit the Orthotic Unit at Hope Hospital for the casting and fitting of each orthosis.

Please do not hesitate to ask if you have any questions regarding the testing procedures or any other part of the research. If you are happy with the information and agree to your child participating in the research we will ask you to sign a consent form. At any point you will be free to withdraw your child from the research, without having to give a reason and without affecting any future medical care.

We thank you for your co-operation.

Victoria Hall, Professor Peter Bowker.

Assessment Protocol

- On arrival the subject will be asked to wear shorts and their AFO/TRAFO in the footwear of the affected foot.
- Electrodes will then be positioned over the belly of rectus femoris, biceps femoris, gastrocnemius and tibialis anterior muscles.
- The electrodes will be connected to a BIOPAC TEL 100M four channel portable amplifier which can be attached to the waist of the subject.
- The subject will then be asked to stand still for one minute during which time base line EMG is measured using a BIOPAC MP 100 data acquisition system and AcqKnowledge software.
- Finally the subject will be asked to walk along a 10 m walkway whilst they are filmed by video in the sagittal plane and EMG data is collected via electrodes.

Each subjects will have six gait recordings over a total time period of approximately six months as follows:

	Week No					
	1	7	12	13	19	24
Orthosis	AFO	AFO	AFO	2nd AFO or TRAFO	2nd AFO or TRAFO	2nd AFO or TRAFO

SALFORD RESEARCH CONSENT FORM

Project No:

Title: The Use of Tone Relieving Ankle-Foot Orthoses in the Management of Children with Cerebral Palsy.

The patient should complete the following part of this sheet himself/herself

PLEASE DELETE AS NECESSARY

Have you read the Patient Information Sheet? YES/NO

Have you had an opportunity to ask questions and discuss this study? YES/NO

Have you received satisfactory answers to all your questions? YES/NO

Have you received enough information about the study? YES/NO

To whom have you spoken? Dr / Mr / Ms

....

Do you understand that you do not need to take part in the study and if you do enter you are free to withdraw -

* at any time
* without having to give a reason for withdrawing
* and without affecting your future medical care? YES/NO

Do you agree to take part in this study? YES/NO

Signed ....

Date ....

....

(Name in block letters)

Model Release Form

Photographer ____________________________

Subject's name and address ____________________________

____

____

____

Date __________________

With reference to the photographs or video recordings taken of me/my child on the above date. I hereby permit the use of these photographs, video recordings or drawings therefrom and any other reproductions or adaptations thereof, either complete or in part, for the illustration of lectures or of scientific journals or of other professional material produced to illustrate the work of the School of Prosthetics & Orthotics, University of Salford. Photographs may not however, be published in non-scientific magazines or other media without my prior consent.

I understand that I do not own the copyright of any of the photographs taken on the above date, and that I may not publish any which I receive as a present without the consent of the photographer.

Signature __________________________

Date __________________________

Signature of witness __________________________

GAIT DATA

Subject number ________

Trail number ________

Distance ________ m

Time ________ s

Velocity ________ $m.s^{-1}$

Heel Strike ________ s ________ % of total gait cycle

Toe Down ________ s ________ % of total gait cycle

Heel Off ________ s ________ % of total gait cycle

Toe Off ________ s ________ % of total gait cycle

Heel Strike ________ s ________ % of total gait cycle

Duration of gait cycle ________ s

Stance Phase ________ s ________ % of total gait cycle

Single Stance phase ________ s ________ % of total gait cycle

Step Length ________ m

Cadence ________ $steps.s^{-1}$

8.3 Appendix 2

- Individual Summary Data Sheets
- Statistical Analysis

Subject A1 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.64	0.71	0.65	0.67	0.83	0.95	1.06	0.94	42
Stride Length (m)	0.51	0.69	0.52	0.57	0.91	0.97	0.99	0.96	68
Cadence (strides. s^{-1})	1.27	1.03	1.25	1.18	0.91	0.97	1.07	0.98	-17
Stance Phase (%TGC)	68	61	65	65	64	69	62	65	Norm=62
Swing Phase (%TGC)	32	39	35	35	36	31	38	35	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	30	17	52	33	56	27	30	38	31
Gastrocnemius	43	23	58	41	69	82	78	76	61
Quadriceps	44	46	75	55	47	65	64	59	44
Hamstrings	24	5	50	26	64	28	62	51	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	19	0	55	25	22	0	10	11	100
Gastrocnemius	16	34	12	21	0	0	0	0	0
Quadriceps	13	48	59	40	27	56	68	50	42
Hamstrings	5	5	31	14	34	91	31	52	39

Subject A2 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.75	0.91	0.91	0.86	0.83	1.05	0.94	0.94	10
Stride Length (m)	0.59	0.82	0.90	0.77	0.66	0.82	0.67	0.72	-7
Cadence (strides. s^{-1})	1.26	1.11	1.02	1.13	1.25	1.29	1.40	1.32	16
Stance Phase (%TGC)	62	57	62	60	60	61	58	60	Norm=62
Swing Phase (%TGC)	38	43	38	40	40	39	42	40	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	40	36	30	35	53	25	30	36	31
Gastrocnemius	59	60	27	49	41	51	29	40	61
Quadriceps	21	36	8	22	27	39	0	22	44
Hamstrings	38	45	43	42	37	49	19	35	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	0	0	14	5	0	36	0	12	100
Gastrocnemius	18	0	18	12	0	0	19	6	0
Quadriceps	44	17	46	36	13	41	40	31	42
Hamstrings	41	0	28	23	24	22	0	15	39

Subject A3 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	1.12	1.24	0.90	1.09	1.11	1.00	1.18	1.10	1
Stride Length (m)	0.96	1.12	0.81	0.96	0.94	0.81	1.11	0.95	-1
Cadence (strides. s^{-1})	1.17	1.11	1.11	1.13	1.18	1.25	1.06	1.16	3
Stance Phase (%TGC)	67	60	59	62	58	57	57	57	Norm=62
Swing Phase (%TGC)	33	40	41	38	42	43	43	43	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	56	44	26	42	81	9	59	50	31
Gastrocnemius	23	55	36	38	47	64	67	59	61
Quadriceps	17	17	9	14	32	54	73	53	44
Hamstrings	30	66	45	47	54	77	74	68	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	0	0	48	16	47	15	54	39	100
Gastrocnemius	35	11	0	15	0	0	57	19	0
Quadriceps	79	51	45	58	66	41	23	43	42
Hamstrings	0	32	32	21	32	31	33	32	39

Subject A4 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.52	0.60	0.43	0.52	0.87	0.54	0.85	0.75	45
Stride Length (m)	0.53	0.63	0.40	0.52	0.87	0.55	0.98	0.77	48
Cadence (strides. s^{-1})	0.97	0.96	1.08	1.00	1.00	0.99	0.95	0.98	-3
Stance Phase (%TGC)	45	55	51	50	56	57	58	57	Norm=62
Swing Phase (%TGC)	55	45	49	50	44	43	42	43	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	83	40	30	51	100	40	60	67	31
Gastrocnemius	100	100	65	88	100	7	31	46	61
Quadriceps	35	38	0	24	100	22	35	52	44
Hamstrings	75	96	100	90	51	86	59	65	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	67	0	88	52	33	22	0	18	100
Gastrocnemius	9	16	18	14	30	2	0	11	0
Quadriceps	33	54	90	59	53	57	100	70	42
Hamstrings	12	33	66	37	25	50	52	42	39

Subject A5 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.87	1.23	1.21	1.10	0.87	1.24	0.98	1.03	-6
Stride Length (m)	1.03	1.43	1.26	1.24	0.89	1.39	1.03	1.10	-11
Cadence (strides. s^{-1})	0.85	0.86	0.96	0.89	0.98	0.90	0.95	0.94	6
Stance Phase (%TGC)	58	47	60	55	60	57	59	59	Norm=62
Swing Phase (%TGC)	42	53	40	45	40	43	41	41	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	29	30	26	28	64	61	75	67	31
Gastrocnemius	64	74	57	65	36	41	43	40	61
Quadriceps	33	60	56	50	31	77	10	39	44
Hamstrings	85	87	58	77	100	100	64	88	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	21	22	78	40	33	56	80	56	100
Gastrocnemius	22	49	51	41	23	57	0	27	0
Quadriceps	71	34	0	35	100	46	94	80	42
Hamstrings	29	39	57	42	20	34	24	26	39

Subject A6 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.94	0.95	1.05	0.98	0.88	0.79	0.86	0.84	-14
Stride Length (m)	0.93	1.00	1.04	0.99	1.03	0.86	0.85	0.91	-8
Cadence (strides. s^{-1})	1.01	0.95	1.02	0.99	0.86	0.92	1.01	0.93	-6
Stance Phase (%TGC)	61	60	62	61	50	43	62	52	Norm=62
Swing Phase (%TGC)	39	40	38	39	50	57	38	48	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	74	55	64	64	54	79	48	60	31
Gastrocnemius	26	42	53	40	91	9	58	53	61
Quadriceps	44	36	36	39	62	59	24	48	44
Hamstrings	54	73	73	67	48	47	34	43	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	12	10	22	15	45	28	45	39	100
Gastrocnemius	0	2	17	6	20	18	6	15	0
Quadriceps	15	0	22	12	37	100	26	54	42
Hamstrings	30	27	18	25	19	19	40	26	39

Subject A8 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.50	0.52	0.53	0.52	0.45	0.63	0.74	0.61	17
Stride Length (m)	0.50	0.50	0.63	0.55	0.37	0.52	0.82	0.57	4
Cadence (strides. s^{-1})	0.99	1.04	0.84	0.96	1.21	1.23	0.90	1.11	16
Stance Phase (%TGC)	66	65	76	69	47	47	74	56	Norm=62
Swing Phase (%TGC)	34	35	24	31	53	53	26	44	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	17	41	58	39	44	39	66	50	31
Gastrocnemius	48	54	25	42	34	64	55	51	61
Quadriceps	16	64	41	40	45	29	34	36	44
Hamstrings	82	4	74	53	37	100	63	67	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	20	26	100	49	24	29	86	46	100
Gastrocnemius	24	45	40	36	56	74	100	77	0
Quadriceps	34	100	33	56	67	87	62	72	42
Hamstrings	35	46	82	54	76	31	94	67	39

Subject A9 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.71	0.63	0.80	0.71	0.67	0.98	0.84	0.83	16
Stride Length (m)	0.66	0.73	0.79	0.72	0.81	1.19	0.92	0.98	35
Cadence (strides. s^{-1})	1.09	0.87	1.01	0.99	0.82	0.83	0.91	0.85	-14
Stance Phase (%TGC)	69	57	55	60	64	62	57	61	Norm=62
Swing Phase (%TGC)	31	43	45	40	36	38	43	39	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	31	29	62	41	18	17	42	26	31
Gastrocnemius	8	60	53	40	52	24	55	44	61
Quadriceps	16	37	72	42	24	26	20	23	44
Hamstrings	74	78	49	67	30	100	29	63	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	41	0	2	14	59	83	46	63	100
Gastrocnemius	58	0	100	53	0	69	18	29	0
Quadriceps	38	68	23	43	38	23	63	41	42
Hamstrings	15	14	47	25	51	29	52	44	39

Subject B1 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.71	0.52	0.80	0.68	0.79	0.65	0.71	0.72	6
Stride Length (m)	0.64	0.67	1.40	0.90	0.73	0.67	0.82	0.74	-18
Cadence (strides. s^{-1})	1.10	0.78	0.57	0.82	1.09	0.98	0.87	0.98	20
Stance Phase (%TGC)	49	51	52	51	57	55	50	54	Norm=62
Swing Phase (%TGC)	51	49	48	49	43	45	50	46	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	0	45	44	30	24	48	23	32	31
Gastrocnemius	66	13	83	54	79	91	70	80	61
Quadriceps	5	40	58	34	45	51	31	42	44
Hamstrings	39	6	83	43	50	45	62	52	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	20	64	42	42	40	87	23	50	100
Gastrocnemius	18	98	0	39	12	0	0	4	0
Quadriceps	57	45	59	54	30	100	29	53	42
Hamstrings	29	100	0	43	31	45	6	27	39

Subject B3 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.87	0.83	1.00	0.90	0.73	0.94	0.89	0.85	-5
Stride Length (m)	0.74	0.79	0.78	0.77	0.74	0.86	0.89	0.83	8
Cadence (strides. s^{-1})	1.17	1.05	1.28	1.17	0.99	1.08	0.99	1.02	-12
Stance Phase (%TGC)	67	65	64	65	67	68	68	68	Norm=62
Swing Phase (%TGC)	33	35	36	35	33	32	32	32	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	44	38	51	44	27	15	17	20	31
Gastrocnemius	41	37	58	45	70	76	68	71	61
Quadriceps	54	48	27	43	46	48	42	45	44
Hamstrings	38	51	31	40	52	22	66	47	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	55	26	44	42	18	68	68	51	100
Gastrocnemius	0	0	0	0	0	0	0	0	0
Quadriceps	37	18	62	39	42	28	52	41	42
Hamstrings	0	0	0	0	0	0	19	6	39

Subject B4 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	1.27	1.12	0.83	1.07	0.87	1.02	1.17	1.02	-5
Stride Length (m)	1.12	1.13	0.90	1.05	0.90	1.11	1.31	1.11	6
Cadence (strides. s^{-1})	1.13	0.99	0.92	1.02	0.96	0.92	0.89	0.92	-9
Stance Phase (%TGC)	60	60	59	60	67	60	62	63	Norm=62
Swing Phase (%TGC)	40	40	41	40	33	40	38	37	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	68	32	62	54	27	23	24	25	31
Gastrocnemius	69	75	57	67	58	61	37	52	61
Quadriceps	41	63	66	57	61	50	61	57	44
Hamstrings	52	73	61	62	29	17	63	36	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	13	0	10	8	0	73	35	36	100
Gastrocnemius	0	23	11	11	20	0	48	23	0
Quadriceps	51	0	60	37	49	39	35	41	42
Hamstrings	0	71	34	35	33	77	40	50	39

Subject B5 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.97	0.96	0.86	0.93	1.13	1.15	1.16	1.15	24
Stride Length (m)	1.03	1.05	0.89	0.99	1.19	1.08	1.19	1.15	16
Cadence (strides. s^{-1})	0.93	0.91	0.96	0.94	0.95	1.06	0.98	1.00	7
Stance Phase (%TGC)	57	66	60	61	66	61	62	63	Norm=62
Swing Phase (%TGC)	43	34	40	39	34	39	38	37	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	8	20	45	24	18	41	35	31	31
Gastrocnemius	24	36	23	28	41	10	62	38	61
Quadriceps	6	22	74	34	36	52	50	46	44
Hamstrings	41	41	57	46	54	35	80	56	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	25	34	8	22	26	21	44	30	100
Gastrocnemius	10	0	19	10	0	55	49	35	0
Quadriceps	21	9	42	24	14	57	51	41	42
Hamstrings	24	12	34	23	22	35	36	31	39

Subject B6 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.90	1.23	0.86	1.00	1.08	0.78	1.13	1.00	0
Stride Length (m)	0.92	1.20	0.89	1.00	1.13	0.84	1.26	1.08	7
Cadence (strides. s^{-1})	0.98	1.02	0.97	0.99	0.96	0.93	0.90	0.93	-6
Stance Phase (%TGC)	61	59	59	60	58	60	62	60	Norm=62
Swing Phase (%TGC)	39	41	41	40	42	40	38	40	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	25	29	48	34	58	46	61	55	31
Gastrocnemius	68	59	58	62	42	40	58	47	61
Quadriceps	21	22	79	41	26	64	68	53	44
Hamstrings	96	50	57	68	78	47	66	64	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	49	34	9	31	54	64	9	42	100
Gastrocnemius	18	38	0	19	20	10	13	14	0
Quadriceps	53	70	29	51	45	63	52	53	42
Hamstrings	33	46	62	47	56	16	13	28	39

Subject B7 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	1.05	0.94	0.71	0.90	1.01	1.21	0.82	1.01	13
Stride Length (m)	0.96	0.89	0.74	0.86	1.02	1.16	0.83	1.00	16
Cadence (strides. s^{-1})	1.09	1.06	0.96	1.04	1.00	1.04	0.99	1.01	-3
Stance Phase (%TGC)	54	57	60	57	57	63	62	61	Norm=62
Swing Phase (%TGC)	46	43	40	43	43	37	38	39	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	30	42	12	28	38	48	16	34	31
Gastrocnemius	79	76	57	71	55	43	82	60	61
Quadriceps	49	49	61	53	48	83	33	55	44
Hamstrings	35	60	38	44	31	42	82	52	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	23	0	0	8	68	0	0	23	100
Gastrocnemius	12	6	43	20	10	14	0	8	0
Quadriceps	45	5	56	35	14	9	36	20	42
Hamstrings	10	60	32	34	0	63	40	34	39

Subject B8 - Summary Data Sheet

Temporal & Spatial Parameters

Parameter	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*% Inc/Dec*
Velocity (m.s^{-1})	0.91	0.97	0.95	0.94	0.86	0.84	1.10	0.93	-1
Stride Length (m)	0.92	1.04	1.02	0.99	0.97	0.92	1.35	1.08	9
Cadence (strides. s^{-1})	0.99	0.93	0.93	0.95	0.88	0.92	0.82	0.87	-8
Stance Phase (%TGC)	62	62	59	61	61	45	46	51	Norm=62
Swing Phase (%TGC)	38	38	41	39	39	55	54	49	Norm=38

Stance Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	54	51	69	58	53	57	19	43	31
Gastrocnemius	61	56	60	59	75	54	15	48	61
Quadriceps	56	21	10	29	53	12	39	35	44
Hamstrings	83	25	59	56	49	17	76	47	14

Swing Phase EMG

Muscle/Group Activity (% Phase)	*Trial 1*	*Trial 2*	*Trial 3*	*Mean*	*Trial 4*	*Trial 5*	*Trial 6*	*Mean*	*Norm*
Tibialis Anterior	64	54	7	42	72	27	56	52	100
Gastrocnemius	29	0	8	12	50	29	92	57	0
Quadriceps	46	58	46	50	63	34	56	51	42
Hamstrings	34	29	34	32	36	39	32	36	39

Statistical Analysis

Velocity Data % inc/dec

t-tests for Independent Samples of GROUP

Variable	Number of Cases	Mean	SD	SE of Mean
VELOCITY				
GROUP 1	8	13.8750	21.484	7.596
GROUP 2	7	4.4286	10.390	3.927

Mean Difference = 9.4464

Levene's Test for Equality of Variances: F= 2.567 P= .133

t-test for Equality of Means

Variances	t-value	df	2-Tail Sig	SE of Diff	95% CI for Diff
Equal	1.06	13	.310	8.940	(-9.866, 28.759)
Unequal	1.10	10.38	.294	8.551	(-9.512, 28.405)

Stride Length Data % inc/dec

t-tests for Independent Samples of GROUP

Variable	Number of Cases	Mean	SD	SE of Mean
STRDLNGTH				
GROUP 1	8	15.8750	29.744	10.516
GROUP 2	7	6.1429	11.481	4.339

Mean Difference = 9.7321

Levene's Test for Equality of Variances: F= 10.767 P= .006

t-test for Equality of Means

Variances	t-value	df	2-Tail Sig	SE of Diff	95% CI for Diff
Equal	.81	13	.432	11.996	(-16.183, 35.647)
Unequal	.86	9.27	.414	11.376	(-15.887, 35.352)

Cadence Data % Inc/Dec

t-tests for Independent Samples of GROUP

Variable	Number of Cases	Mean	SD	SE of Mean
CADENCE				
GROUP 1	8	.2500	12.430	4.395
GROUP 2	7	-1.7143	11.456	4.330

Mean Difference = 1.9643

Levene's Test for Equality of Variances: F= .153 P= .702

t-test for Equality of Means

Variances	t-value	df	2-Tail Sig	SE of Diff	95% CI for Diff
Equal	.32	13	.757	6.205	(-11.442, 15.370)
Unequal	.32	12.95	.755	6.169	(-11.369, 15.298)

Stance Phase Duration

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	60.2500	5.800	2.051

Test Value = 62

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-1.75	-6.599	3.099	-.85	7	.422

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	58.3750	3.852	1.362

Test Value = 62

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-3.63	-6.846	-.404	-2.66	7	.032

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	59.2857	4.348	1.643

Test Value = 62

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-2.71	-6.735	1.307	-1.65	6	.150

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	60.0000	5.774	2.182

Test Value = 62

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-2.00	-7.340	3.340	-.92	6	.395

Swing Phase Duration

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	39.7500	5.800	2.051

Test Value = 38

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
1.75	-3.099	6.599	.85	7	.422

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	41.6250	3.852	1.362

Test Value = 38

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
3.63	.404	6.846	2.66	7	.032

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	40.7143	4.348	1.643

Test Value = 38

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
2.71	-1.307	6.735	1.65	6	.150

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	40.0000	5.774	2.182

Test Value = 38

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
2.00	-3.340	7.340	.92	6	.395

Tibialis Anterior - Stance Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	41.6250	11.338	4.009

Test Value = 31

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
10.63	1.146	20.104	2.65	7	.033

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	49.2500	15.069	5.328

Test Value = 31

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
18.25	5.652	30.848	3.43	7	.011

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	38.8571	13.310	5.031

Test Value = 31

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
7.86	-4.452	20.166	1.56	6	.169

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	34.2857	11.629	4.395

Test Value = 31

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
3.29	-7.469	14.041	.75	6	.483

Tibialis Anterior - Swing Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	27.0000	17.728	6.268

Test Value = 100

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-73.00	-87.821	-58.179	-11.65	7	.000

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	35.5000	19.893	7.033

Test Value = 100

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-64.50	-81.131	-47.869	-9.17	7	.000

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	27.8571	15.453	5.841

Test Value = 100

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-72.14	-86.435	-57.851	-12.35	6	.000

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	40.5714	11.341	4.287

Test Value = 100

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-59.43	-69.917	-48.940	-13.86	6	.000

Gastrocnemius - Stance Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	50.3750	17.558	6.208

Test Value = 61

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-10.63	-25.303	4.053	-1.71	7	.131

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	51.1250	12.005	4.244

Test Value = 61

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-9.88	-19.912	.162	-2.33	7	.053

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	55.1429	14.690	5.552

Test Value = 61

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-5.86	-19.444	7.729	-1.05	6	.332

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	56.5714	14.718	5.563

Test Value = 61

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-4.43	-18.040	9.183	-.80	6	.456

Gastrocnemius - Swing Phase

One Sample t-tests

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	24.7500	16.594	5.867

Test Value = 0

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
24.75	10.877	38.623	4.22	7	.004

One Sample t-tests

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	23.0000	23.934	8.462

Test Value = 0

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
23.00	2.990	43.010	2.72	7	.030

One Sample t-tests

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	15.8571	12.158	4.595

Test Value = 0

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
15.86	4.613	27.101	3.45	6	.014

One Sample t-tests

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	20.1429	20.161	7.620

Test Value = 0

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
20.14	1.497	38.789	2.64	6	.038

Quadriceps - Stance Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	35.7500	14.350	5.074

Test Value = 44

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-8.25	-20.247	3.747	-1.63	7	.148

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	41.5000	13.887	4.910

Test Value = 44

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-2.50	-14.110	9.110	-.51	7	.626

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	42.4286	12.856	4.859

Test Value = 44

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-1.57	-13.462	10.319	-.32	6	.757

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	48.5714	8.162	3.085

Test Value = 44

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
4.57	-2.977	12.120	1.48	6	.189

Quadriceps - Swing Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	42.3750	15.720	5.558

Test Value = 42

Mean Difference	95% CI Lower	95% CI Upper	t-value	df	2-Tail Sig
.38	-12.767	13.517	.07	7	.948

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	55.1250	17.241	6.096

Test Value = 42

Mean Difference	95% CI Lower	95% CI Upper	t-value	df	2-Tail Sig
13.13	-1.289	27.539	2.15	7	.068

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	41.4286	10.753	4.064

Test Value = 42

Mean Difference	95% CI Lower	95% CI Upper	t-value	df	2-Tail Sig
-.57	-10.516	9.373	-.14	6	.893

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	42.8571	11.582	4.378

Test Value = 42

Mean Difference	95% CI Lower	95% CI Upper	t-value	df	2-Tail Sig
.86	-9.854	11.569	.20	6	.851

Hamstrings - Stance Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	58.6250	20.598	7.282

Test Value = 14

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
44.63	27.405	61.845	6.13	7	.000

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	60.0000	16.587	5.865

Test Value = 14

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
46.00	32.133	59.867	7.84	7	.000

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	51.2857	10.750	4.063

Test Value = 14

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
37.29	27.343	47.228	9.18	6	.000

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	50.5714	8.677	3.279

Test Value = 14

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
36.57	28.547	44.596	11.15	6	.000

Hamstrings - Swing Phase

Variable	Number of Cases	Mean	SD	SE of Mean
A1	8	30.1250	13.120	4.638

Test Value = 39

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-8.88	-19.843	2.093	-1.91	7	.097

Variable	Number of Cases	Mean	SD	SE of Mean
A2	8	38.0000	16.656	5.889

Test Value = 39

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-1.00	-14.925	12.925	-.17	7	.870

Variable	Number of Cases	Mean	SD	SE of Mean
B1	7	30.5714	15.544	5.875

Test Value = 39

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-8.43	-22.804	5.947	-1.43	6	.201

Variable	Number of Cases	Mean	SD	SE of Mean
B2	7	30.2857	13.175	4.980

Test Value = 39

Mean Difference	95% CI Lower	Upper	t-value	df	2-Tail Sig
-8.71	-20.899	3.470	-1.75	6	.131

8.4 Appendix 3

Casting Procedure

8.4.1 Traditional DAFO Casts

8.4.2 The Salford Casting Technique

8.4.3 Casting for an AFO

Manufacture

8.4.4 TRAFO Manufacture

8.4.5 AFO Manufacture

Casting Procedure

The orthoses used in the investigation were all cast and manufactured at the North Western Orthotic Unit, Hope Hospital, Salford. The same orthotist took all the casts and fitted all the orthoses. The following section describes in detail the procedures undertaken to produce the orthoses.

8.4.1 Traditional DAFO Casts

The traditional methods of casting for Dynamic Ankle Foot Orthoses (DAFOs) have been previously published (Hylton, 1989, 1990) and demonstrated at training courses and orthotic workshops throughout the US and Europe. The traditional method which was developed in the United States has been described in a number of stages:

i) A draft of the foot outline is made on paper;

ii) The paper draft is then transferred on to a footboard;

iii) The footboard is hollowed out under the metatarsal and heel areas;

iv) Plaster build ups are placed onto the footboard to fill the arched areas of the foot;

v) The board is taped on to the foot;

vi) The foot and board are cast together.

Although this method has been reported to have given very favourable results in the US and at centres using it across Europe (Hylton, 1989; Diamond & Ottenbach, 1990; Curtis, 1995) several difficulties appear to be inherent in the procedure. The main problem lies in the fact that the casting is very time consuming with obvious difficulties when, as in most cases, the patient is a young child. Those with tonal problems will no doubt be affected by the lengthy procedure and the constant manipulation of the affected limb. The draft of the foot along with the insertion of the plaster are also both techniques which are prone to error exacerbated when dealing with an uncooperative child.

With such fragile casts there are obvious problems in both the removal and transportation. Being constructed from plaster of Paris, the resultant cast is very brittle and prone to damage. Areas frequently fracture resulting in untidy casts which need much repair, thus introducing further errors. This is particularly a problem for those orthotists who do not work at dedicated centres and frequently transport casts from schools/hospitals to manufacturing workshops.

This method of casting and manufacture has also been open to abuse from orthotic companies, where 'off the shelf' foot boards are used as part of the casting procedure. The footboards are selected based on the approximate size of a child's foot, but this no doubt detracts from the custom made design of the splints and lessens their individuality.

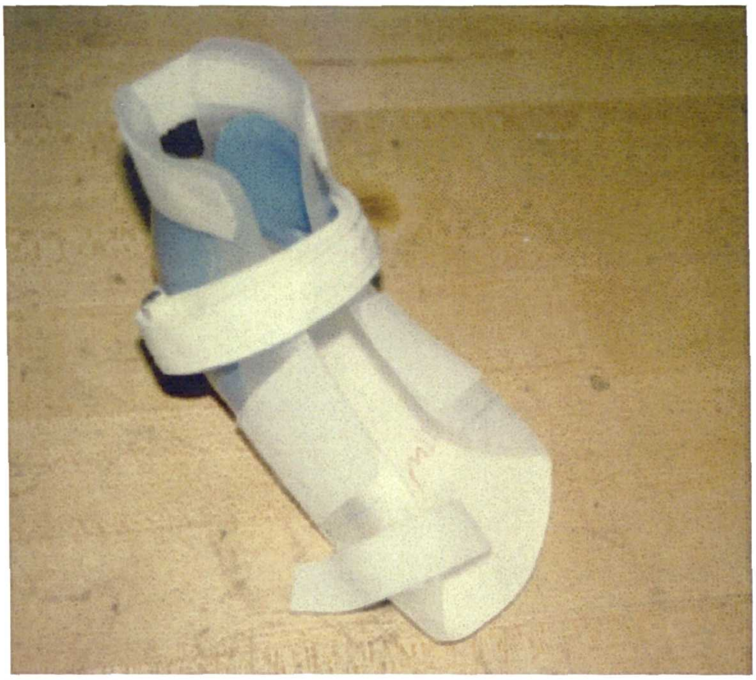


Figure a
American Style DAFO

8.4.2 The Salford Casting Technique

Having been introduced into the UK, the traditional casting procedures have been practised and modified at numerous centres where experimental work on DAFOs has been carried out. Initial work at the North Western Orthotic Unit (NWOU) has highlighted the problems with the traditional casting procedures and adaptations to these methods were sought. Care was taken to ensure that the splints met the same criteria as those produced using the traditional technique, i.e. off-loading the trigger areas, holding the calcaneous in a neutral position, positively loading the arches and preventing toe contractions. A modified technique introduced by Mike Gilligan, an orthotist at the NWOU, has been in place since July 1994, and was the method used to produce the orthoses for this investigation. The resultant orthoses were named Tone Relieving Ankle-Foot Orthoses (TRAFOs) and are now used widely for children with cerebral palsy in and around the Manchester and Salford areas.

Figure b
Materials Required to Cast a TRAFO
Micro-pore tape, crepe bandage, chinograph pencil, stockinette, scissors, plastic channelling, WAPB, metatarsal and heel pads, arch dome, rubber gloves.

The casting procedure follows a number of clear stages as described in the following section. The materials required are shown in Figure b.

Procedure

1) **The patient sits sideways on a couch with the feet flat on a box.**

The patient sits in a relaxed position for the casting with the feet in a semi-weight bearing condition, hips and knees at 90° flexion.

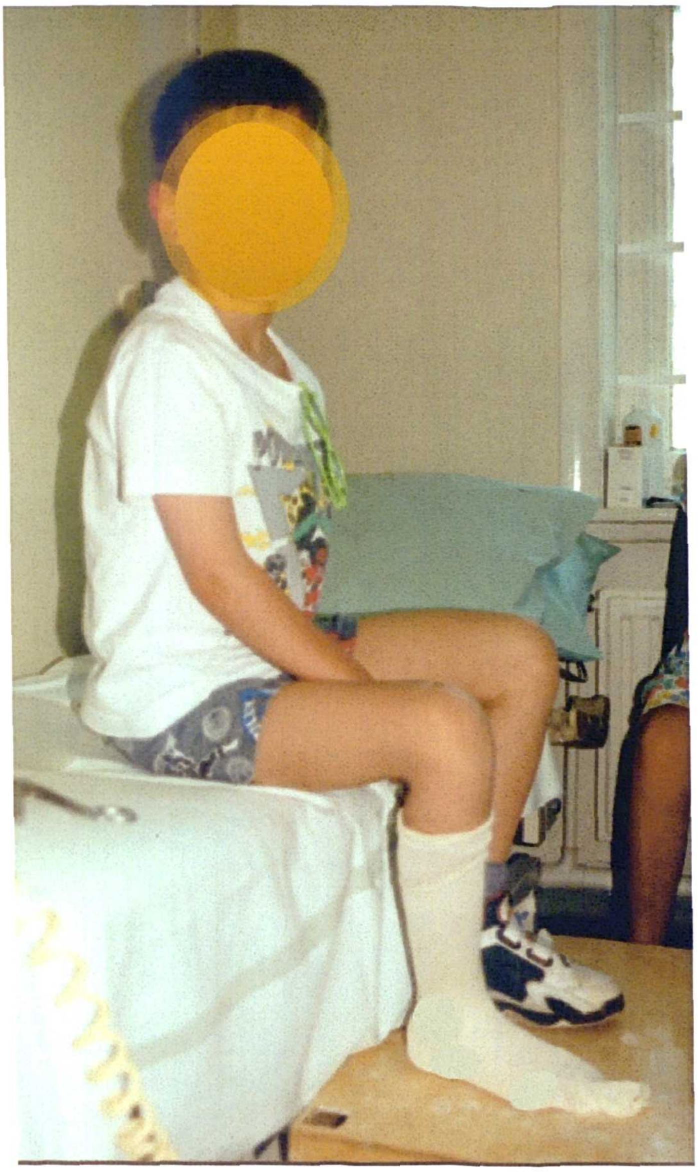


Figure c
Patient Positioning in Preparation for Casting

2) The heel and metatarsal bar pads are fixed to the foot.

Two pads are used for the cast, a circular one for the heel, and the second shaped to cover the metatarsal heads. The pads are pre-fabricated from an adhesive-backed medium density poron, all have feathered edges, and are made in a range of sizes, selected to correspond to each patients foot.

Figure d
Heel and Metatarsal Pads are attached to the foot

3. The foot and lower calf are covered with two layers of stockinette.

Plastic channelling is applied over the stockinette and taped to the dorsal aspect of the foot in order to aid removal of the cast. The upper trim lines, malleoli, peroneal notch, metatarsal heads and bony prominences are then marked on to the stockinette using a chinograph pencil.

Figure e
Stockinette and Plastic Channelling are Applied to the Leg

4. A roll of WAPB is used to envelop the foot and lower calf.

The bandage used is a 7.5 cm wide roll of water-activated polyurethane bandage (WAPB), Dynacast Pro, Smith & Nephew Medical Limited, Hull, UK. This is soaked in water for 1-2 minutes before being applied to the foot two layers thick. The cast is smoothed by hand to ensure accurate moulding into the arches and areas around the heel and pads. All work using the WAPB is carried out wearing rubber gloves.

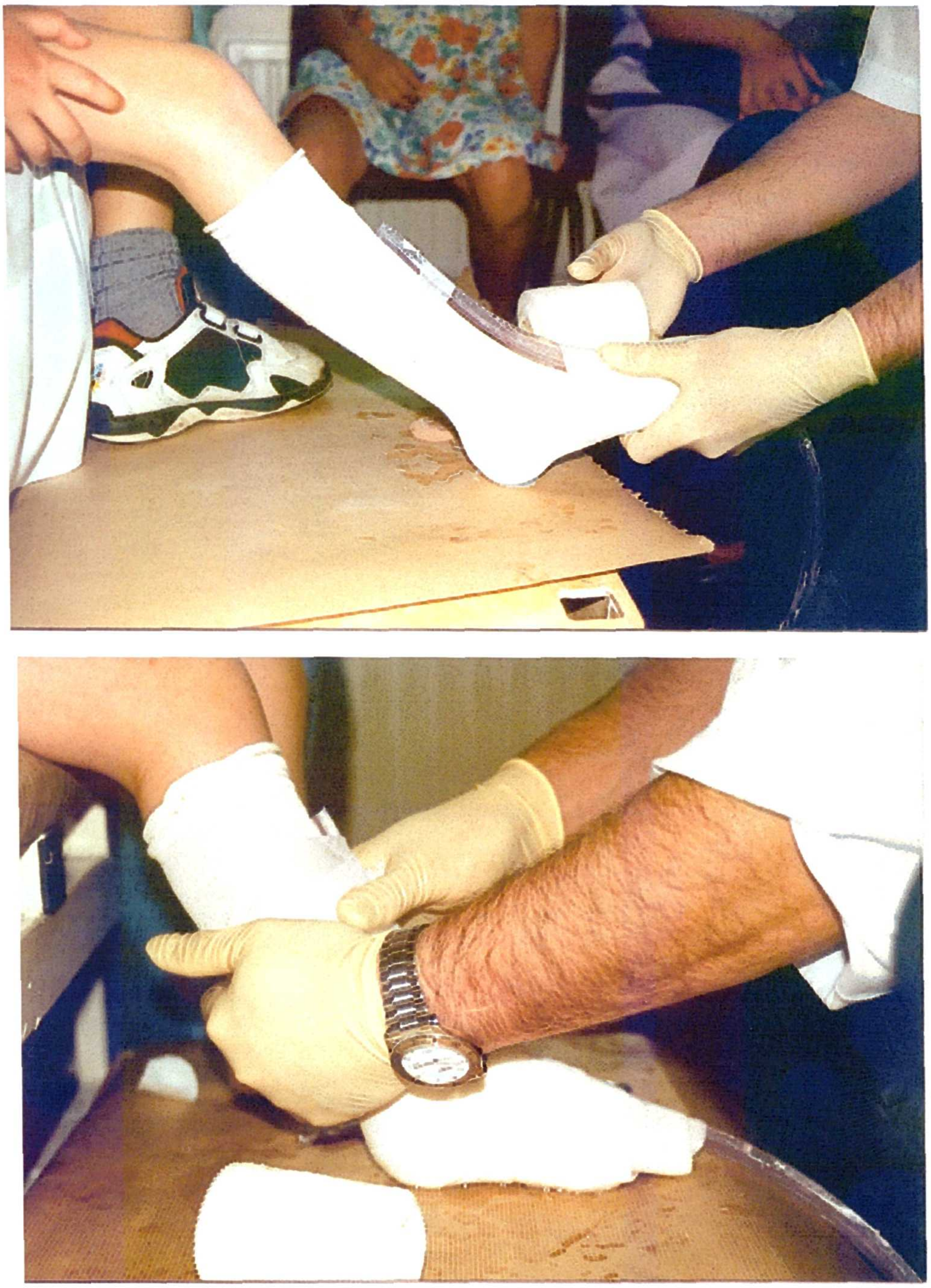


Figure f
The Dynacast Pro Bandage is Applied

5. The domed metatarsal pad is positioned.

The domed metatarsal pads (Algeo Ltd, Liverpool, UK) can be purchased in a number of sizes and are therefore selected to correspond to the patients foot size. The dome is positioned by placing it proximal to the metatarsal heads. The domed surface is held uppermost and in contact with the stockinette and moved gently into position, in which the patients foot remains relaxed and the dome is cushioned behind the metatarsal heads.

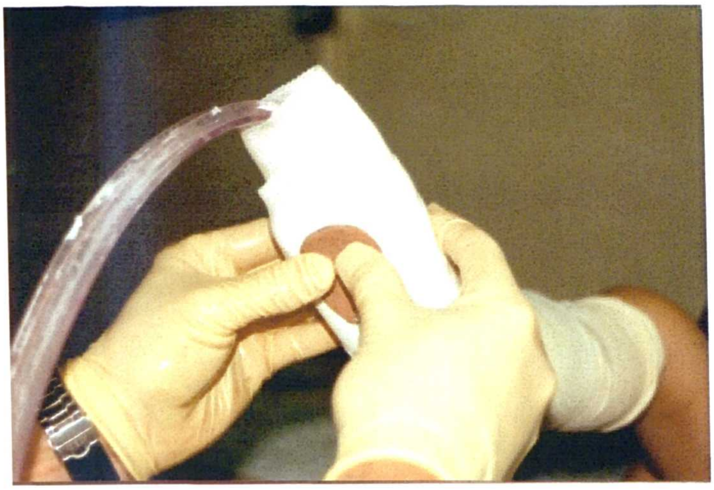


Figure g
Placement of the Dome

6. A wet crepe bandage is then applied over the WAPB.

This helps to maintain the intimate moulding of the cast especially around the peroneal notch, it holds in place the domed pad and also prevents delamination of the WAPB cast.

Figure h
A Crepe Bandage is Applied

7. The cast is left to set

Whilst the cast sets (approximately 3 minutes) the foot is held in 90° ankle flexion with the heel neutral, and pressure is applied to the knee producing a semi-weight bearing condition to allow for foot spread which occurs on standing.

Figure i
Patient Positioning whilst the Cast Sets

8. The cast is removed.

The crepe bandage is removed and the cast is cut away from the foot. The plastic channelling is used as a guide for a single dorsal cut which is made using either scissors or an oscillating plaster saw.

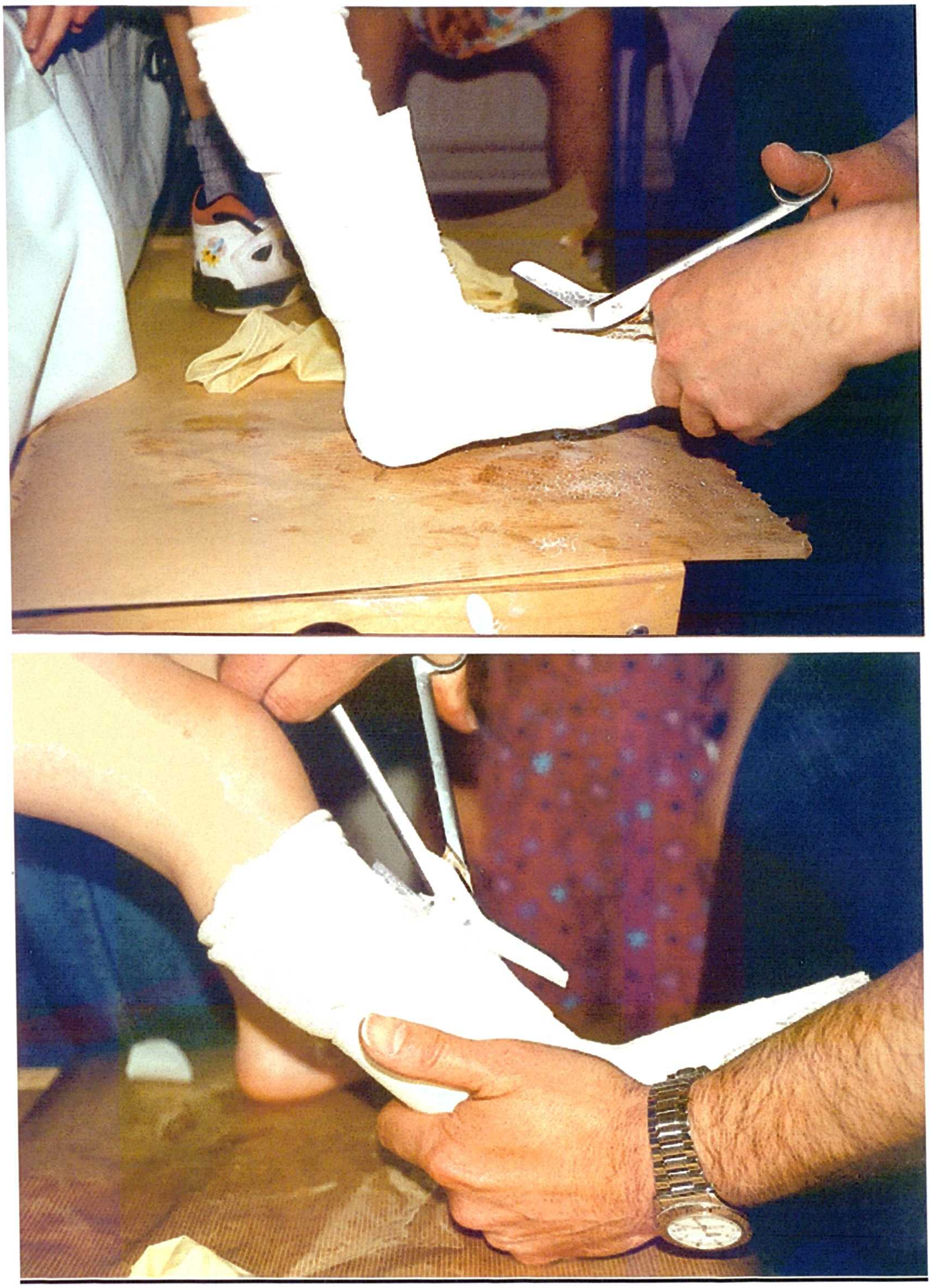


Figure j
Removal of the Cast

The resultant cast should have incorporated a close fit to the contours of the foot, including the hollowed sections at the heel and metatarsal heads. The stockinette is removed from within the cast and the areas marked on this should have been transferred to the inside of the cast and be clearly visible.

Figure k
Resultant Cast for a TRAFO

8.4.3 Casting for an AFO

The method used to cast the conventional polypropylene AFOs in this investigation is that which is widely used by orthotists. The basic stages are described below;

i) The patient sits on the couch with the feet flat on a box.

ii) The foot and calf are covered with stockinette and plastic channelling.

iii) Rolls of POP bandage are used to envelop the foot and calf.

iv) The foot is held at 90° ankle flexion and the cast is left to set.

v) The cast is removed using scissors or a plaster saw.

Figure k
Application of the POP Bandage

Figure l
Removal of the Cast

Manufacture

8.4.4 TRAFO Manufacture

The manufacture of the TRAFO follows a similar procedure for that used with AFOs, creating a positive cast from plaster of Paris and then moulding polypropylene around this. The manufacture is described in detail in the following stages:

1. The WAPB cast is sealed

The WAPB cast which has been removed from the patient is sealed along the cut line and around the toe area using a roll of plaster of Paris.

Figure m
Cast is Sealed Using Plaster of Paris

2. The WAPB cast is filled with plaster of Paris

Once sealed, the cast is filled with plaster of Paris (POP). A metal bar is inserted whilst the POP sets and is used to handle the cast during manufacture.

Figure n
The Cast is Filled with POP and a Metal Bar Inserted

3. The negative WAPB cast is removed

When the POP has set, the WAPB cast is removed using a plaster saw. This reveals the positive POP cast from within.

Figure o
The WAPB Cast is Removed

4. Toe Section is extended

Using a POP mixture the toe end of the cast is extended which means that the plastic in the completed orthosis will extend beyond the foot. At the fitting stage the surplus can then be trimmed so that it matches exactly to the foot and shoe.

Figure p
The Toe Section is Extended

5. Rectification of the cast

Using a further POP mixture, the saw cuts are filled and rectification of the cast is performed. Rectification is necessary to smooth the surface of the cast and hence the resultant orthosis.

Care is taken during this procedure not to lose any of the definition around the depressions and prominences. Minimal rectification maintains the intimate mould of the cast, reduces errors in the process and produces orthoses which are accurate and comfortable.

Figure q
Rectification of the POP Cast

Figure r
POP Cast Following Rectification

6. Preparation for vacuum forming

Following rectification, the cast is covered with stockinette providing a route for the air to escape during vacuum forming. The stockinette also results in a smooth high quality finish which further improves the surface of the orthosis.

Two circular pads, made from 6mm thick low density plastizote, are then fixed over the malleolar regions on the cast. The pads have feathered edges which prevent ridges forming in the plastic.

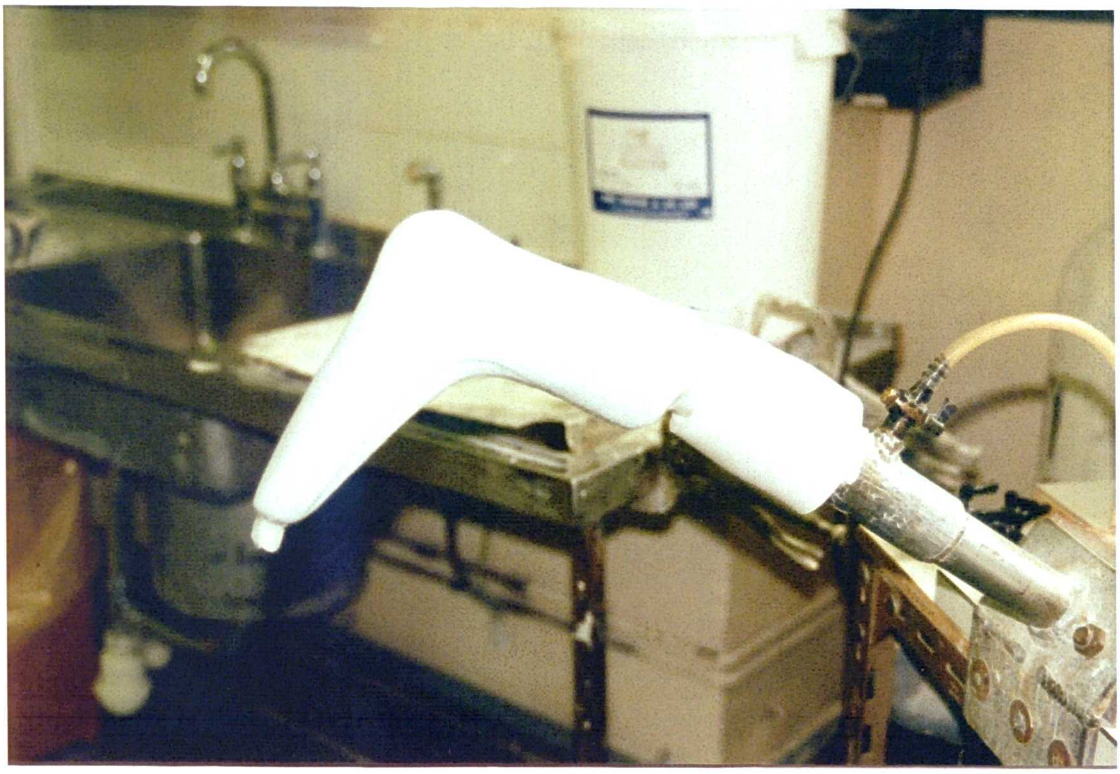


Figure s
Stockinette is Placed Over the POP Cast and Prepared for Vacuum Forming

7. Vacuum forming

A sheet of 2mm thick thermoplastic (polypropylene copolymer) is preheated in an oven at 180 °C. This is then placed over and around the cast, sealed, and a vacuum made to produce an accurate mould. The heat from this process secured the pads to the inside of the splint protecting the malleoli from any abrasions.

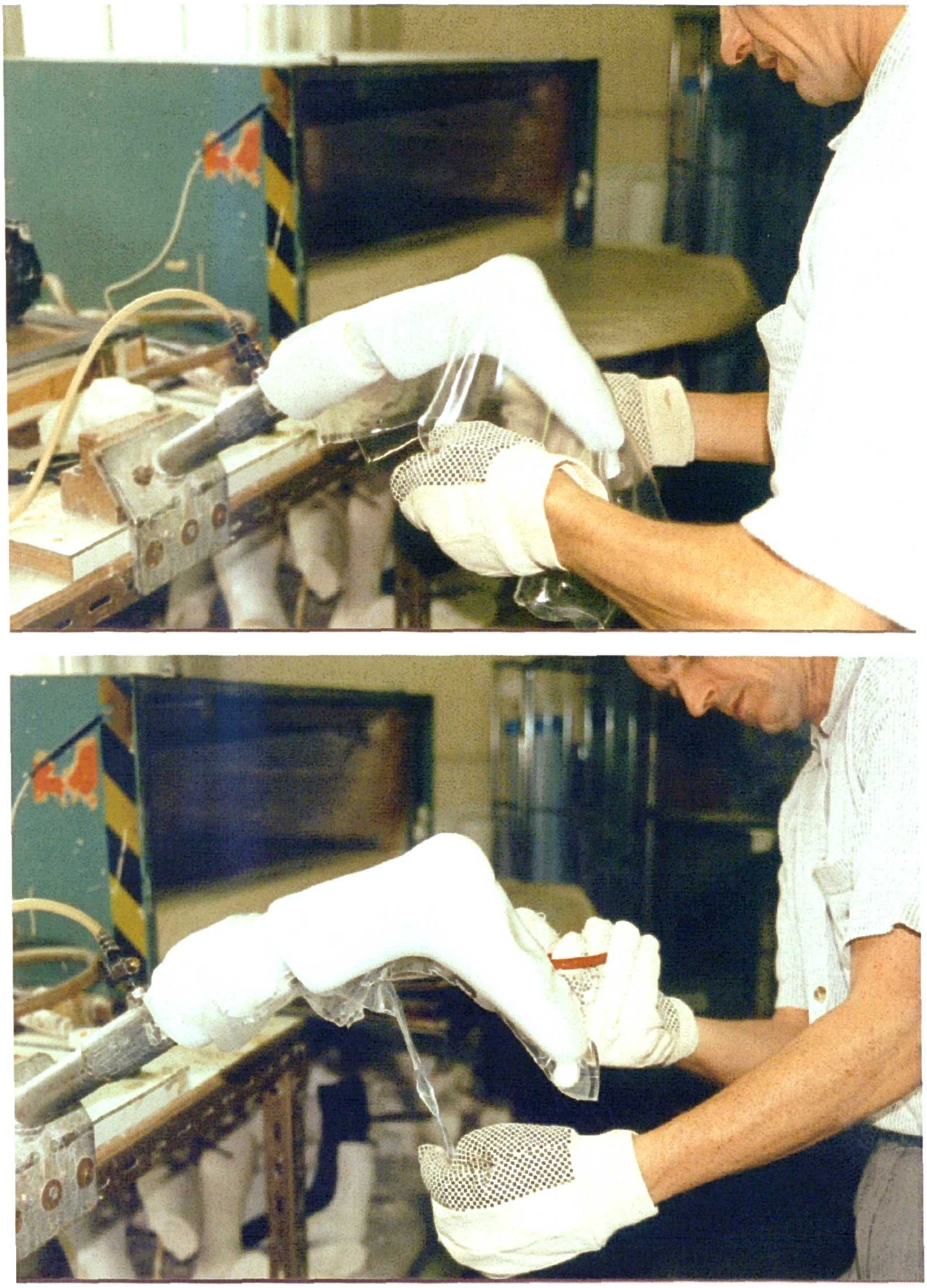


Figure t
The Heated Polypropylene is Placed Around the Cast and Sealed

8. Construction of the sole

A sheet of 10mm thick ethylene vinyl acetate (EVA) is vacuum formed over the sole area of the polypropylene. Once cooled, it is removed and trimmed to the outer contour of the sole and then glued back into position.

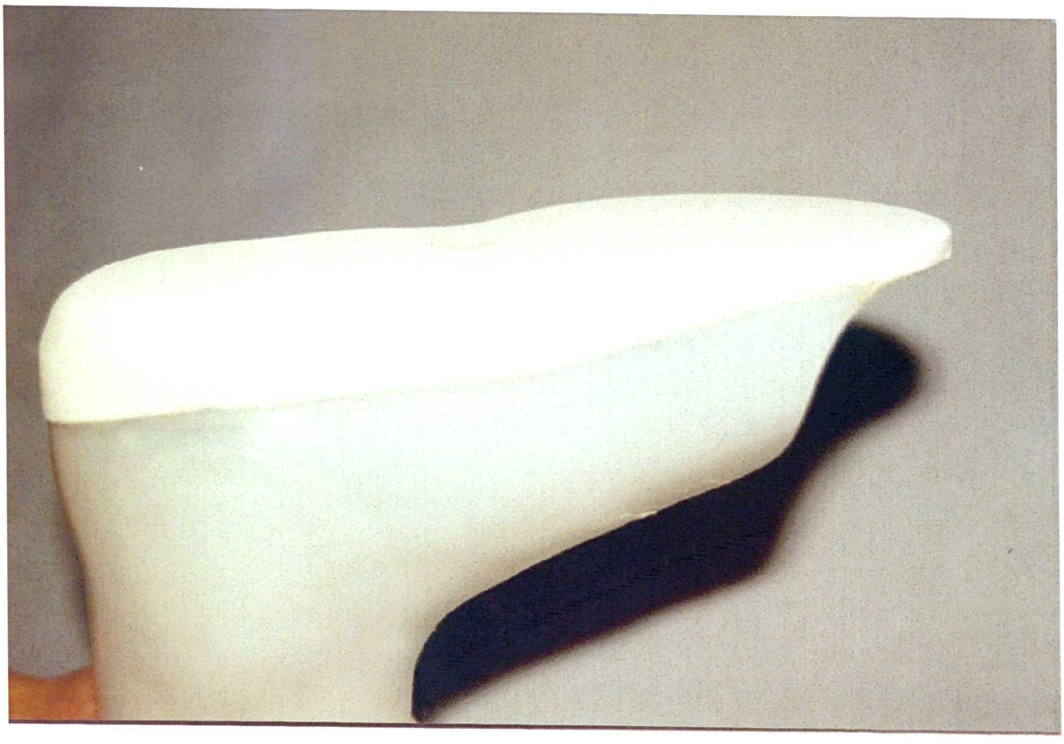


Figure u
EVA Used for the Sole

9. The splint is removed from the POP cast.

The polypropylene splint is cut away from the POP cast and trimmed and smoothed into the required shape. The EVA is machined flat to prevent movement of the TRAFO within the shoe and the required straps are attached.

The EVA can be machined in a number of ways depending on the needs of each patient. This allows the orthosis to be tilted in the anterior posterior direction as well as the medial lateral. Compensation can be made for patients who have a tight TA and cannot quite reach 90° or for those who exhibit a lateral angle of the tibia.

Figure v
Completed TRAFO

8.4.5. AFO Manufacture

The manufacture of the AFOs followed a simple procedure entailing the production of a positive cast from paster of Paris and then moulding the thermoplastic around this. The manufacture is described in the following stages:

1) **The POP cast is sealed using a further roll of POP.**
2) **The negative cast is filled with plaster of Paris.**
3) **The negative POP cast is removed.**
4) **The positive POP cast is rectified.**
5) **A stockinette is applied in preparation for vacuum forming.**
6) **The splint is Vacuum formed using 3.5 mm thick thermoplastic.**
7) **The splint is removed from the POP cast trimmed and smoothed.**
8) **Calf and ankle straps are attached.**

Figure w
Completed AFO