The direct effects of variations in AFO stiffness on the kinematics and kinetics of gait

By

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"Aim for the stars. The sky is not the limit!"

Allen hartelijk dank!

Judith Hagenbeek

Abstract

Weakness of the lower limb on one side of the body is common after stroke and affects the everyday lives of stroke survivors. Various therapies may be prescribed for the management of various lower extremity impairments and disabilities. One of the possibilities that can be of great value is an orthotic treatment, when used in combination with physical therapy. Briefly, orthoses, and in particular ankle-foot orthoses (AFOs), are externally applied devices designed to maintain the foot in a desirable position with respect to the shank. Currently, the prescription and design of orthoses is still based on the expertise of orthotists instead of based on evidence from scientific research. This is partly due to the lack of studies on:

1. Mechanical AFO characteristics.
2. The effects of different types of AFOs on gait.

Performing gait analysis and quantifying the stiffness of different orthoses could lead to more knowledge about the stiffness of AFOs and a better understanding of their effects on gait. In turn, this could lead, with the aid of further study, to better matching up between AFO properties and gait deficits of stroke patients.

In this study the following four custom-made orthoses were tested using three different instruments:

1. A solid AFO made of copolymer polypropylene & reinforced with carbon fibre inserts.
2. Posterior leaf spring (PLS) made of copolymer polypropylene.
3. SWIFT Cast with a six-layer Scotch back slab.
4. SWIFT Cast with an eight-layer Scotch back slab.

The Instron test machine and a custom-made apparatus were used to quantify the stiffness of each type of orthosis in the sagittal plane.
The Vicon motion capture system and four Kistler force plates were used to determine the immediate effects of the AFOs on kinematic and kinetic gait characteristics in the sagittal plane. To carry out the gait analysis, one able-bodied subject was recruited and asked to walk six meters in a straight line with conventional shoes and without orthosis and with shoes and each of the AFOs on the left leg.

Table of Contents

List of Figures

List of Tables

List of Acronyms

Abbreviation:	Definition:
AFO	According to ISO 8549, an orthosis, and thus also an ankle-foot orthosis, is "an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems."
AFOFC	Ankle-foot orthosis footwear combination (AFOFC) refers to the footwear worn with an AFO.
FAC	Foot-ankle complex (FAC)
GRF	The ground reaction force (GRF) is the most prominent external force in human locomotion. These reaction forces act upwards from the ground on the foot of the body and are the result of forces exerted by the body on the ground.
SAF	Shank angle to floor (SAF) of the AFOFC is the position of the lower leg relative to a vertical to the ground and the angle of the ankle in the AFO.
Vicon	Video converter or simply Vicon was the first commercially available television-based system. Nowadays, Vicon camera-based motion systems are mainly sold, by Oxford Metrics Group, Oxford, United Kingdom, for the collection of motion data.

Chapter 1 Introduction

A detailed description of the aim of the pilot study is inter alia given in this chapter.

1.1 Background and aims

The reason for performing this research and writing this thesis emanates from conversations with research fellow Andrew Kerr and Professor Philip Rowe. Both were involved in a controlled evaluation of the clinical efficacy of an ankle-foot cast, called SWIFT Cast, after stroke. The main outcome measures of the study were spatiotemporal parameters and joint kinematics. An element that was missing in their study, according to both researchers, was the mechanical characteristics of the cast. It was not surprising that the mechanical AFO properties, such as the stiffness and neutral angle around the ankle joint, were not objectively quantified because it is known this is rarely done (Bregman et al., 2009; Bregman, 2011). The fact that it is rarely done is surprising knowing that (Bregman et al., 2009):

1. Mechanical AFO characteristics determine the function of ankle-foot orthoses in pathological gait and thus are an important factor in the prescription of orthoses.
2. A good match between mechanical AFO properties and the patient's impairment can lead to a positive impact on the patient's gait.

Given the mechanical characteristics of the SWIFT Cast are unknown and the quantification of these casts or other orthoses could contribute to: better matches and a better prescription of ankle-foot orthoses, one of the aims of this research was to quantify the stiffness of a six- and an eight-layer SWIFT Cast and two other types of custom-made ankle-foot orthoses in the sagittal plane. These four orthoses were similar to orthoses prescribed to stroke survivors.

The aim set was achieved by the use the two measurement systems, the Instron ElectroPuls™ E10000 material testing machine and a custom-made testing device.

The second aim of this pilot study was to determine the influence of these orthoses on kinematic and kinetic gait characteristics of the ankle, knee and hip joint of a male able-bodied subject in the sagittal plane during walking. This aim was achieved through performing instrumented gait analysis and set because combining the results of gait analysis and the results obtained through mechanical testing of the AFOs allowed the study of the mechanical contribution of the different orthoses on gait.

This pilot study should primarily be seen as an important first step towards optimal matching of AFO properties to the individual needs of stroke patients. It should contribute to more knowledge about the stiffness of four different orthotic devices and their effects on able-bodied gait.

This small contribution might have a positive effect in the area of orthotics, knowing that most orthotists in todays practice still make sole use of their expertise to adapt the stiffness of orthoses to the patient’s needs, instead of selecting AFO designs, materials and material thicknesses based on (biomechanical) research studies.

1.2 Ankle-foot orthoses

An ankle-foot orthosis can be defined as an orthopedic device “which encompasses the ankle joint and the whole or part of the foot and is externally applied in order to modify the structural and functional characteristics of the neuromuscular and skeletal systems” (Bowers et al., 2009). They are often considered and used when people with neurological disorders are having problems in terms of (Bregman et al., 2009):

1. Limited ankle dorsiflexion in swing.
2. Reduced stability in stance.
3. Abnormal foot placement at initial contact.

Ankle-foot orthoses aim to enhance (early) recovery and independence of post-stroke patients by (Bowker et al., 1993):

- Supporting, controlling or totally limiting rotational movements of their lower limb joints in both the stance and swing phase of gait.
- Modifying the point of application and the line of action of ground reaction forces, for example by changing the alignment of the foot-ankle complex (FAC).

These aims seem to be achieved in clinical practice because studies have shown that the use of AFOs will immediately lead to the reduction of the risk of tripping, increase in functional independency and improve in spatiotemporal parameters of the stride (Bregman, 2011; Franceschini et al., 2003; Pavlik, 2008).

In contrast to the immediate effects, the long-term effect of AFO usage are less well documented in studies through which they are still debated (Papi, 2012).

Ankle-foot devices aim to affect body segments and joints via direct and indirect biomechanical effects. Direct biomechanical effects of AFOs concern the influence of the movement of the foot and ankle joint. For example, it is known that AFOs can improve ankle kinematics and solid AFOs can help to increase the second peak of the vertical ground reaction force in gait (Carlson et al., 1997). Indirect biomechanical effects concern the influence on the knee and hip joint in both swing and stance phase (Desloovere et al., 2006).

Ankle-foot orthoses are prescribed by medical specialists and cast or scanned, fitted and aligned by qualified orthotists. In the early days, they were made of metal and leather, but this changed by the advent of plastics and other materials. From that moment on, new orthotic designs became available that allowed for the production of lighter and more cosmetic orthoses. Today, ankle-foot orthoses may be individually custom-made or prefabricated and can be made from different types of material, such as polypropylene, polyethylene, silicone elastomer or carbon-fiber composites (Hsu et al., 2008). Polypropylene is the most commonly used material from this list.
In stroke rehabilitation, prefabricated ankle-foot orthoses are of limited value, because they are only applicable for temporary use and can't be individualized (Bowers et al., 2009). Therefore, they fit less intimately and are often not sufficiently stiff to control deformities of the FAC compared to custom-made AFOs (Bowers, 2004). As a result, only custom-made AFOs are used in this study and further discussed in this Chapter.

Custom-made AFOs are available in different forms and sizes and can be categorized into four groups based on their shape (Bowers et al., 2009):

1. Articulated, joined or hinged AFO (HAFO)
2. Ground reaction AFO (GRAFO) or floor reaction AFO (FRAFO)
3. Posterior leaf spring (PLS) AFO
4. Solid or rigid AFO

Joined AFOs incorporate mechanical articulations which assists or allows movement of the ankle within limits in the sagittal plane, while restricting movements in the transverse and frontal plane. This type of design is often indicated when patients are dealing with subtalar joint or mediolateral instability.
Ground reaction AFOs create external knee extension moments and are indicated when maximal control of knee flexion during stance is required.

A PLS ankle-foot orthosis was used in the pilot study. This flexible type of orthosis is often indicated for mild stroke patients with flaccid paralyses. They are able to assist dorsiflexion during swing phase, but are limited in providing mediolateral control.

The last of the four orthotic designs is the solid AFO. This type of AFO was also used in the study. Solid AFOs are usually made from moulded thermoplastic. They are the most commonly used designs in the treatment of conditions and pathologies such as spasticity in plantarflexors and gastrocnemius contracture, due to the fact that they can block any movement about the ankle and foot (Bowker et al., 1993). The presence of this blocking effect makes them suitable for patients who display: mediolateral instability of the foot, moderate to severe spasticity in the plantarflexor and dorsiflexor muscles, weakness or absence of the ankle dorsi- and plantarflexors, and quadriceps muscle weakness. Solid AFOs often require tuning for the optimization of their effects on joint and segment kinematics and kinetics. Tuning can be done by adding (and removing) wedges in the shoe or under the heel of the shoe during stance until the optimum angle of tibial inclination is found. Solid AFOs allow the addition of corrugations or reinforcements such as carbon fibre inserts around the malleolar aspect of the AFO. The incorporation of these inserts or corrugations is mainly interesting when additional AFO stiffness is necessary.

1.3 Ankle-foot cast

Soft scotch ankle-foot (SWIFT) Casts or semi-rigid casts are training devices made of lightweight materials and components, such as Soft Cast, Scotch and a plaster shoe. Depending on the patients weight and the presence of knee hyperextension, the casts are provided with a six-layer or an eight-layer back slab, which determines the stiffness of the cast. The ankle-foot casts are temporary devices used before more expensive custom-made orthoses are being considered and after stroke for early mobilization.

It offers stroke survivors with walking difficulties the opportunity to practice walking as soon as possible.

The use of the SWIFT Cast is interesting for three reasons (Pomeroy et al., 2012):

1. Its use is related to a low risk of adverse events, such as red pressure areas due to rubbing or the experience of pain and fatigue of the affected lower limb.
2. It is inexpensive device in contrast to the solid AFO.
3. It can be made within 24 hours by orthotists, therapists and even by nurses.
4. They are clinically more accepted than prefabricated AFOs.

1.4 Layout of thesis

The work conducted in order to complete the Master's project is described in different chapters:

Chapter 2 presents a literature review. It includes research findings related to dynamic analysis, stroke and stiffness testing.

Chapter 3 describes the materials and methods used in this study.

Chapter 4 presents the results obtained by the use of the Vicon motion analysis system, four Kistler force plates and the Instron ElectroPuls™ E10000.

The research findings reported in Chapter 4 are analyzed and discussed in Chapter 5.

Finally, Chapter 6 concludes the thesis with comments on the methods used and results found, summarizes what was done and makes recommendations for future research.

Chapter 2 Literature review

2.1 Introduction

In the literature review, journal articles and dissertations are reviewed and summarized to provide the reader with relevant background information and to make the reader familiar with the most commonly used research techniques that are relevant for this pilot study.

The first paragraph details the classification of stroke, stroke statistics and stroke symptoms. This is followed by an section on the most common treatments for stroke patients to improve gait. For example, the use of orthotic devices in stroke rehabilitation is highlighted. The last paragraphs of this chapter presents an overview of basic kinematic and kinetic gait characteristics of both able-bodied people and hemiplegic patients.

2.2 Medical aspects of stroke

Stroke or cerebral vascular accident (C.V.A.) is a long-term condition that can be defined as "an acute neurologic dysfunction of vascular origin with sudden or at least rapid occurrence of symptoms and signs corresponding to the involvement of focal areas in the brain" (American Heart Association, 1989). It is a worldwide problem that is expected to grow due to population ageing, being overweight, smoking, high blood pressure, inactivity and other factors. Annually, about 15 million people worldwide suffer a stroke according to Hsu et al. (2008) and Mackay and Mensah (2004). Approximately 20% to 50% of the stroke patients die within the first month after the event, depending on factors: such as type, age, comorbidity and severity. Approximately 1.1 million stroke survivors are living in the United Kingdom. This number annually increases by 152,000 strokes (Townsend et al., 2012). In 2010, stroke caused approximately 50,000 deaths (Townsend et al., 2012) in the United Kingdom. Approximately 36% of the stroke survivors are left with a mild to moderate disability and 22% with a severe to very severe disability each year (The Intercollegiate Stroke Working Party, 2011). Stroke care, the loss of productivity and disability and nursing family care arising from stroke, costs the wider economy of the United Kingdom and the NHS already £7.0 billion each year.

Strokes can be divided into two major categories according to the American Stroke Association (ASA). One of the categories includes ischemic stroke (infarct). This is the most common form of stroke and accounts for approximately 85 percent of all strokes (Department for Work & Pensions, 2013; Hudson et al., 2005). This type of stroke occurs when a vascular structure that supplies blood to the brain becomes blocked, for example due to occlusion or embolism of a clot. In turn, the blockage causes an abrupt interruption or reduced blood supply to parts of the brain, which ultimately could lead to dysfunction of brain tissues in that area.

The other category comprises haemorrhagic strokes (haemorrhages) and accounts for the remaining 15 percent. This type of stroke occurs when a damaged or weakened blood vessel ruptures within the brain or between the brain and skull. As soon as the blood starts to spill into the surrounding spaces of the brain tissue, due to vascular malformation, diet or arteriolar hypertensive disease, it accumulates and compresses parts of the brain (American Stroke Association, 2013). The latter causes brain cells to get damaged and die. This may be reflected in the sudden onset of one or more typical symptoms, such as severe headache, dizziness, inability to speak, high blood pressure, nausea and loss of consciousness. These and other signs such as sudden weakness of an arm or a leg can also be seen in (an acute) ischemic stroke.

The clinical manifestations of a stroke in the long term varies from person to person depending on several factors, such as the type of stroke, location of the obstruction and the amount of brain tissue affected. Depending on these and other factors, strokes can be lethal or cause (Chowaniec, 1983):

- Balance and coordination problems. These problems often result in standing and walking difficulties.
- Hemiparesis and hemiplegia. These are common side effects of a stroke, but may also result from diseases such as meningitis or epileptic fits.
  Hemiplegia refers to paralysis of one side of the body. This develops in a very early phase of stroke and befalls about 80 percent of the stroke survivors.
  Hemiparesis is less severe than hemiplegia and refers to weakness of one side of the body.

Both often cause trouble in performing activities such as eating and walking, which explains why stroke survivors suffering from hemiplegia or hemiparesis form one of the most frequently seen groups requiring rehabilitation.

- Speech problems and language disorders. Two specific examples are aphasia and dysarthria. Patients with aphasia have a reduced ability to understand a language and patients with dysarthria have a reduced ability to pronounce words.
- Sensorimotor deficits. This happens in the minority of the stroke patients. In case it does occur, then often the superficial sensation is only disturbed.
- Other effects such as urinary and/or faecal incontinence (FI) or cognitive problems.

In the long term these impairments can significantly reduce the ability to walk, to write and many other activities. Fortunately, literature suggests that the majority of post-stroke neurological and functional recovery, occurs within 3 months (Teasell and McClure). For example, the majority of stroke survivors (approximately 50-80%) regain their ability to walk independently within three weeks, followed by a smaller group stroke survivors that brings the total to 85 per cent after 6 months (Wade et al., 1987).
Further improvement is limited after this period.

2.3 Treatments in the initial stage of stroke

In the next paragraphs, it is explained what happens when a person is affected by stroke.
In the following section, the choice of a treatment for acute stroke patients, which mainly depends on many variables such as: the site and size of the brain affected, severity of stroke and the overall health of the stroke survivor, is explained in more detail.

As soon as possible after symptom onset, the decision must to be made to call for ambulance assistance. After calling and arrival at the hospital, patients with (a suspected) ischemic or haemorrhagic stroke are treated as a medical emergency and receive their initial treatment as soon as possible to prevent further complications. In order to be able to select an appropriate treatment, the acute (stroke) patient is evaluated and diagnosed first using blood tests, an electrocardiogram (ECG) and imaging techniques such as computed tomography or magnetic resonance imaging. Computed tomography or CT scans are sensitive for detecting hemorrhage stroke and therefore useful for differentiating between the two types of stroke.

If the results of the scans show a hemorrhagic stroke, then thrombolytic therapy is avoided and medical staff will try to control the bleeding and brain swelling.
Controlling the bleeding and brain swelling is often accomplished by the use of surgery, therapy and medications.
Other acts will follow when the scans show evidence of an ischemic stroke. For example, it is possible that blocked arteries are opened or the use of thrombolytics is started within three hours of symptom onset. The latter is a clot-busting treatment which is given by injection into a blood vessel with the purpose to dissolve the relevant blood clots.
After the most acute phase is over, the stroke patient will be assessed by an interdisciplinary team. Based on this assessment can be established:

- If blood thinners should be prescribed in order to prevent the formation of new blood clots.
- If the patient should be recommended to change his or her lifestyle, for example by losing weight if overweight or quitting smoking, to reduce the risk of a recurrent stroke.
- How the rehabilitation process must proceed.

Unlike before, stroke survivors are currently advised to avoid prolonged bed rest and start rehabilitation as soon as possible, preferably within five to seven days after stroke (Asberg et al., 1991). This is because early mobilization could lead to better functional improvements, the prevention of impending complications and regaining maximum strength on the affected side of the body again. Neglecting rehabilitation will result in unilateral stiffness and spasticity and eventually lead to the development of painful spams and abnormal body posture.
The influence of stroke rehabilitation on the recovery of stroke patients is related to the state of the central nervous system. Immediate stroke rehabilitation stimulates the ability of the patient's central nervous system to reorganize its nerve networks in the CNS and may therefore lead to a faster recovery of the motor function. According Teasell and McClure, maximal neurological reorganization and thus also the motor recovery generally occurs in the first one to three months after stroke.

According to the Intercollegiate Stroke Working Party (2004), the most effective method in stroke rehabilitation and care is to deliver care through a multidisciplinary team of professionals. One of the disciplines involved with the team is the physiatrist or rehabilitation physician. Physiatrists are medical doctors who primarily focus on the coordination of the rehabilitation process.

Other healthcare professionals involved with the team are the physical therapists. They come as soon as possible after stroke into view for the treatment of motor problems and have the ultimately goal to improve the walking pattern of stroke survivors. Physical therapists treat motor problems by assisting stroke patients in repetitively performing exercises which are focused on the improvement of their strength, range of motion and balance.

The multidisciplinary team should also include an occupational therapist with special knowledge in neurological rehabilitation, when the patient is having difficulties in activities of daily living. The role of an occupational therapist within the team is to assess and treat the patient so that his or her functional ability to perform everyday activities improves.

Also a certified orthotist is often part of the team. The role of the orthotist within the team is to participate in the patient's evaluation and orthotic prescription, and fabricate an orthosis for the stroke so that the patient's walking pattern comes as close to a biomechanically "normal" pattern again.

In the past, resistance was provided to orthotists and the use of orthotic devices in rehabilitation by the other therapy professionals. This was partly due to the lack of research evidence and their belief that orthoses would inhibit muscle power recovery. Since several years is its use more accepted and the orthotic treatment seen as an adjunction to conventional physical therapy and other pharmacological interventions and therapies (Bowers et al., 2009). This positive development partly emanated from the consensus conference of the International Society of Prosthetics and Orthotics, wherein unanimously was decided that the clinical use of orthoses should also be considered within an appropriate timescale early after stroke, because its use can contribute to the prevention or minimization of further development of deformities, contractures and gait deviations (Bowers, 2004).

2.4 Research findings on the use of AFOs after stroke

Multiple studies have been conducted to explore the immediate and long-term effects AFOs have on the gait of stroke patients. These studies are discussed below.

Miyazaki et al. (1997) had found that two types of ankle-foot orthoses, the double metal upright AFO and plastic AFO, are commonly used in patients with hemiparesis. Out of these two types of orthoses, the plastic custom-made AFO is the most popular with this target group. They have been used for over forty years and regarded as the 'gold standard' for stroke patients who are dealing with deformities or gait abnormalities as a result of ankle and knee instability (Burdett et al., 1988; Franceschini et al., 2002; Bowers et al., 2009).

People who are eligible for AFOs often receive one AFO which is adapted to their specific needs. For example in stroke patients, AFOs often need to be able to compensate for excessive ankle plantarflexion in stance and swing phase and other times they should be able to correct for foot abnormality and/or reduce knee extension during stance (Bowers, 2004; Bowers et al., 2009; Bowker et al., 1993). In case where they are indicated for patients with severe (plantarflexor) spasticity, then AFOs should be able to provide high (plantarflexion) resistance. In case they are indicated for post-stroke patients with mild to moderate plantarflexor spasticity, then orthoses need to be more flexible and thus provide less resistance (Lehmann et al., 1983). Fixed rules for selecting the rigidity, which are commonly accepted, do not exist yet (Miyazaki et al., 1997). For this reason and the reason that trimming is an irreversible process, it is often seen in clinical practice that AFOs too stiff as a result of overbracing (Yamamoto et al., 1993).

Now that the main functions of AFOs in stroke patients are known, scientific findings with respect to the effects of ankle-foot orthoses on hemiplegic gait are discussed.
Walking speed appeared to be the most commonly reported parameter. The study of Burdett et al. (1988) demonstrated that the use of plastic AFOs and Air-Stirrup braces does not significantly change the gait velocity in hemiplegic patients. Similarly to this study, the study of Tyson and Rogerson (2009) also found no significant improvement in walking speed when nonambulant patients with chronic stroke walked with a plastic posterior leaf spring orthosis instead of walking with no device.

Controversially, other studies as for example the study of Franceschini et al. (2001 & 2003) and Pavlik (2008) did found a statistically significant improvement in walking velocity when hemiparetic patients walked with either custom-made solid ankle polypropylene or articulated polypropylene AFOs.
Alongside walking speed, several studies also measured step length, stride length and other spatio-temporal parameters of gait.
Significant improvements in step and stride lengths on the paretic side in favor of different types of plastic AFOs, and prefabricated Air-Stirrup braces were reported by Pavlik (2008) and Burdett et al. (1988). The study of Tyson and Mosely (2003) contradicted these findings. They had found no significant differences between walking with and without individually fitted plastic PLS AFOs. According to Papi (2012), who had reviewed more studies on the effect of AFOs in walking parameters of stroke survivors, the majority of studies had reported an improve in stride length and cadence.

The effects AFOs have on lower extremity joint kinematics and kinetics during level walking are also evaluated but only in a limited number of studies. Bregman et al. (2010) found a positively altered ankle kinematics when chronic stroke and Multiple Sclerosis patients walked with the plastic posterior leaf spring AFO, but found no differences between in knee and hip kinematics when they walked with and without the plastic AFO.
Miyazaki et al. (1997) had investigated the effect of plantar and dorsiflexion rigidity and the initial angle of an experimental AFO with double Klenzak joints on the active ankle moment during gait in hemiparetic patients. They showed that the experimental AFO assisted weak dorsiflexors after initial contact and did not assisted the plantarflexors from mid- to late stance.

2.5 Dynamic analysis of gait

The study of the first observations and experiments of human movement dates back to the time of the ancient Greeks and Egyptians, followed by Giovanni Alfonso Borelli, also known as “Father of Biomechanics”, who wrote the first textbook on the mechanics of human movement. After the invention of photography in the nineteenth century the number of studies on both normal and abnormal gait increased rapidly. Think for example of the classic study of Eberhart et al. (1947) that focused on ground reaction and joint forces in normal gait or the study of Saunders et al. (1953) in which the “six determinants of gait” were proposed. Research findings on characteristics of normal and pathological gait are presented in the next sections.

2.5.1 Characteristics of normal gait

In this pilot study, kinematic and kinetic data were collected on an able-bodied subject during walking with and without orthoses. This was done using a three-dimensional motion analysis system and four Kistler force plates. To interpret the collected data, first there had to be sufficient basis knowledge about normal locomotion.

To start with, bipedal locomotion or human gait can be described as a neuro-biomechanical activity or functional task requiring coordination and complex interactions among the major joints of the lower extremity of the human body (Nordin et al., 2001).
Normal human gait is almost symmetrical with regard to load bearing of the lower extremities and angular motions of the major joints. Only small differences between the left and right side of the human body can be seen.
Gait is a cyclic activity consisting of two phases, stance and swing. Stance phase encompasses 62% and swing phase 38% of the gait cycle or a stride (Nordin et al., 2001). Stance phase typically begins with initial contact or heel strike and terminates with pre-swing or toe-off. The swing phase starts with initial swing and terminates again with initial contact.

Several forces are acting on both feet during walking. These forces are called ground reaction forces and can be split up into a vertical component and two different horizontal components. The vertical component of the ground reaction force provides important information about the overall functioning of the lower extremity. This force component exhibits two peaks and one dip which is located between the peaks (Chowaniec, 1983; Perry et al., 2010). The peaks approximate 1.2 times the person's body weight and the force valley 0.8 times body weight. The first peak (F1) occurs just after heel strike and is related to the load the person is putting onto the front foot. The second peak (F3) occurs just before toe-off and is related to the amount of vertical propulsive force. The valley (F2) which occurs during mid-stance is related to the movement of the person's body over their stance limb. The horizontal (shear force) components are called the progressional or anterior-posterior (AP) shear force and the medial-lateral shear force. Both shear forces have a small magnitude. The anterior-posterior component exhibits three peaks. The first peak is a small anterior-directed force (of less than 0.05 times body weight). This peak is related to a phenomenon called "claw back", which arises from the swinging limb that hits the ground with a posterior-directed velocity at heel strike. After claw back follows a posterior-directed shear force (F4) with a magnitude of 0.2 times the person's body weight. The third and last peak (F5) is an anterior-directed force with the same magnitude as F4. This force can be seen in late stance when someone propels its body forwards. The medial-lateral shear force does not show a very consistent pattern during walking (Chowaniec, 1983) and is not further considered, since the interest is only in joint movements in the sagittal plane.

Moments (Nm) at the various joints of the leg are produced by ground reaction forces during normal walking. These moments tend to rotate the ankle, knee and hip joint, and can be calculated when knowing the point of application of the ground reaction force and the position of the joint (Robertson et al., 2004). Joint moments have many typical features during normal walking (Robertson et al., 2004). For example, the ankle joint normally shows a slight dorsiflexor moment of approximately 15 N∗m immediately after heel strike (or initial contact) during normal level walking (Figure 1a). This moment is required to prevent the foot from moving downwards too quickly and rapidly reverses to a large plantarflexor moment of 160 N∗m at 40% or 45% of the gait cycle to effectuate push-off. The peak decreases to zero as the weight swifts onto the other leg and swing phase commences. Third peak ankle moment seen is a slight dorsiflexion moment of 10 N∗m at 60% of the gait cycle (Figure 1a). This relatively small moment is essential in lifting the forefoot and often absent by mild stroke survivors with dorsiflexor muscle weakness or foot drop and no spasticity.
An important moment that can be seen at the level of the knee joint is an extensor moment of 100 N∗m. This moment occurs at 20% of the gait cycle, or mid-stance, and prevents the stance leg from collapsing (Figure 1b).

In Figure 1c, there are three distinct peaks of the hip moment. The first one is an extensor moment of 80 N∗m which occurs at initial contact, or 10% of the stride. This moment persists until early mid-stance, after which it turns into a flexion moment that reaches 40 N∗m at toe-off (Figure 1c). As terminal swing occurs, an extension moment of about 40 N∗m can be seen.

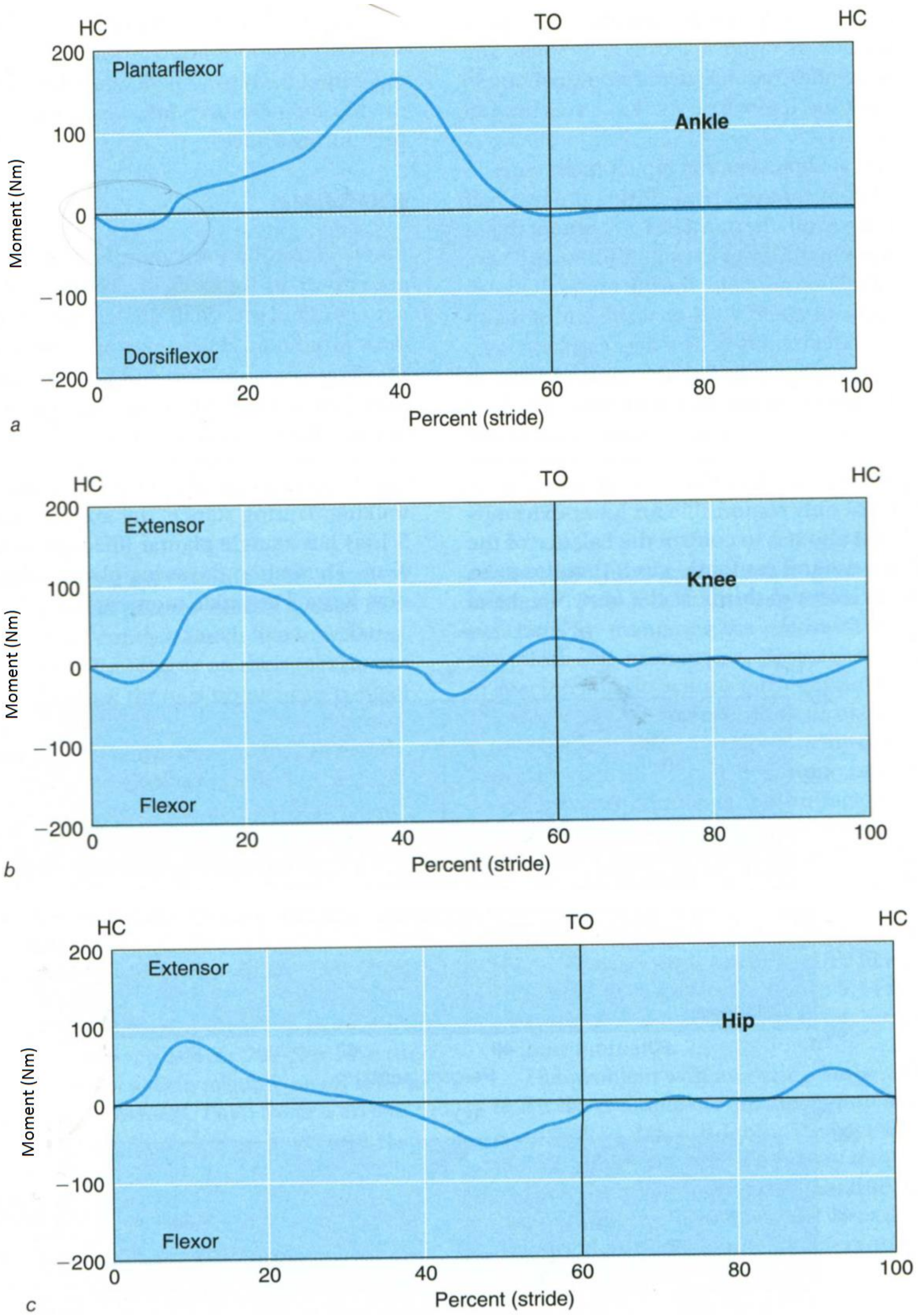


Figure 1: Internal moments generated by the muscles about the (a) ankle, (b) knee, and (c) hip during normal gait. HC stance for heel contact and TO for toe-off (Robertson et al., 2004).

2.5.2 Characteristics of hemiplegic gait

No subjects with a hemiplegic gait participated in the pilot study. Therefore, the effects different AFOs have on hemiplegic gait could not directly be determined. Alternatively, general information and research evidence related to (the characteristics of) hemiplegic gait and the biomechanical effects of AFOs on hemiplegic gait are discussed.

A stroke often results in an acute loss of function on the first day. By the second day, the body is overresponsive to reflexes. Within a month, the resistance to plantarflexion increases and early spasticity develops in the adductor and extensor muscles of the knee and hip while the plantarflexor muscles shows ankle clonus (Perry and Burnfield, 2010).

In the period thereafter, spasticity continues to increase and a typical hemiplegic posture develops. This resting posture is characterized by the upper limb that tends to be: internally rotated and adducted at the shoulder and flexed at the elbow, wrist and fingers. In contrast to the upper limb, the lower limb tends to be extended (Chowaniec, 1983) and shows postural patterns characterized by: adduction and flexion at the hip joint, knee extension and plantarflexion and inversion at the ankle and subtalar joint (talocalcaneal joint) (Ozcakir and Sivrioglu, 2007).

According to Winters et al. (1987), hemiplegic gait can be divided into four types of gait patterns:

Type 1 hemiplegia concerns hemiplegic patients with a 'foot drop'. Foot drop or drop foot is a medical condition often caused by weakness of the dorsiflexor muscles (primarily the tibialis anterior muscle) and/or the loss of motor control on the affected side (Churchill et al., 2003; Pavlik, 2008). It leads to the reduced ability to lift the front part of the foot, which is most clearly visible in the swing phase of the affected leg and disappears during stance phase. This condition is often treated with a posterior leaf spring orthosis or a joined ankle type of AFO.

Type 2 hemiplegia is the most common type of hemiplegia in clinical practice. This type is characterized by spasticity in the three-headed calf muscle and weakness of the tibialis anterior muscle, which results in an equinovarus deformity in both stance and swing and sometimes genu recurvatum in the late stance phase.

The spasticity can be managed by botulinum toxin (botox) injections in the calf muscle, when it concerns a younger child. The problems caused by weakness of the dorsiflexor muscle can partly be tackled by the use of a posterior leaf spring or joined AFO.

Type 3 hemiplegia is characterized by spasticity or contracture of both the gastrocnemius and soleus muscle, and by impaired talocrural dorsiflexion in swing.

Similar treatments as in type 2 hemiplegia can be used. Spasticity can be treated with botox injections. The foot and ankle joint complex can be supported by a solid or articulated AFO.

Type 4 hemiplegia involves patients with increased hip flexion, ankle equinus and reduced mobility of the knee and hip joint in the sagittal plane. Again, spasticity can be treated with botox injections. The ankle and knee problems can be treated with ground reaction, solid or articulated AFOs (Rodda et al., 2001).

Hemiplegic gait differ from able-bodied people and is typified as stiff and slow. For example, post-stroke patients can only walk at 0.55 ms-1 at discharge from rehabilitation, while the normal range for walking is between 1.2-1.4 ms-1 (Pomeroy et al., 2012). Hemiplegic gait is also defined as an asymmetric gait. These gait asymmetries are often caused by two things:

1. Unilateral leg instability which forces the stroke survivor to shift the weight as soon as possible to the unaffected leg.
2. The presence of an extended knee at the affected side which results in a longer swing phase (Pavlik, 2008).

Other striking features are the increase amount of time the hemiplegic leg spent in double limb support and the increase amount of time the unaffected limb spent in stance phase (Churchill et al., 2003; Franceschini et al., 2003; Von Schroeder et al., 1995).

When taking a closer look at different gait cycle phases, it can be seen that in hemiplegic gait:

- Initial contact on the affected side is usually made with:
    - The lateral border of the forefoot when an equinovarus deformity is present.
    - The heel and metatarsal regions at the same time (foot flat). This prevents weight bearing through the heel.
- Knee flexion is missing during stance as a result of persistent and excessive ankle plantarflexion in stance. Instead, knee hyperextension on the affected side of the body is often present at mid- to late stance, through which the vertical displacement

of the centre of gravity cannot be minimized and the energy expenditure is higher than in normal gait.

- Hip extension is often reduced and sometimes replaced by hip flexion and retraction during mid to late stance (Hsu et al., 2008).
- Late stance phase is shortened (Lehmann et al., 1983).

2.6 Mechanical characteristics of AFOs

Forty years ago, the prescription of ankle-foot orthoses mainly relied on qualitative assessments. In due course, the prescription of AFOs shifted to a more quantitative process because studies started to focus on measuring the stiffness of different AFO designs by means of self-fabricated testing apparatuses (Singerman et al., 1999). Through these studies, it was discovered that two design considerations could be used to describe the mechanical behavior of AFOs. One of the two consideration is the AFO stiffness and the other the axis of rotation (Singerman et al., 1999). It was also discovered that making comparisons between ankle-foot orthoses is very difficult, because lots of variations between orthoses are present. For example, the wide range of AFO designs available mutually differ in material thickness, geometric configuration, material selection and the manufacturing process used (Yamamoto et al., 1993; Kobayashi et al., 2011). This finding did not stop the researchers to venture attempts to determine the stiffness of AFOs. In contrast, the number of biomechanical studies that studied mechanical AFO characteristics and applied their results in clinical practice did remained limited through which the design and the prescription of ankle-foot orthoses remain based on experimental techniques (Papi, 2012).

2.6.1 Stiffness

An ankle-foot orthosis can be characterized by various mechanical properties. One of these properties is stiffness. AFO ankle stiffness can be defined as "the moment around the ankle joint exerted by the AFO per degree of ankle joint rotation" (Kobayashi et al., 2011).
This property is often evaluated in studies by the use of custom-made testing apparatus. Methods used and the findings of these studies are discussed below.

Ross et al. (1999) had studied the effect of pigmentation on the bending stiffness of copolymer polypropylene specimens because the researchers had experienced that the orthotists main concern was about the ability of AFOs to resist bending in the sagittal plane

and at that time, there was no certainty about the consistency of their mechanical characteristics between colours at that time, while assessing this variable could lead to the design of more successful AFOs.
To find out the influence of pigmentation, specimens were placed horizontally, clamped at one end and subjected to load. Through these test it was found that the effect of pigmentation on the bending stiffness of ankle-foot orthoses was inconclusive.
Since the effect of pigmentation is not yet know, the colours of both plastic PLS and solid AFO are mentioned in this study.

Until 1997, no recommendations were given on methods for determining rigidity (Miyazaki et al., 1997). This changed by the study of Kobayashi et al. (2011), in which the strengths and weaknesses of mechanical and functional analysis techniques were compared, in order to find out how AFOs rigidity can be effectively be measured.
In this study it was found that the investigation of AFO stiffness can be approached in two ways:

1. Functional analyses
2. Mechanical testing analyses

In functional analyses, measurements are taken while a subject is walking with an AFO. This has the possible advantage over mechanical analyses that functional analysis could more accurately reflect the load applied to the AFO by a person during functional ambulation.
In mechanical testing analyses, AFOs are attached to a testing device and exposed to bending moments or forces while its resistance is measured in one or more planes.
The latter method was and is the most commonly used in industry and very interesting for various reasons. For example, this type of analysis allows an effective, reliable and accurate way to repeatedly measure the stiffness of AFOs, and enables more control of experimental conditions such as velocity or range of motion. However, this method is not commonly used for testing the stiffness of AFOs in clinical practice due to its cost.
Further, it was indicated in the study of Kobayashi et al. (2011) that it is important to continue with the quantification of the stiffness of AFOs because it could lead to the use of plastic AFOs, which possess adequate stiffness in the relation to the patients' needs. In other words, this could lead to more adequately solving of temporarily common problems such as (excessive) plantarflexion of the foot in swing phase and an knee instability as a result of limited plantarflexion from heel strike to foot flat (Lehmann et al., 1983; Yamamoto et al.,

1993). However, matching the stiffness (to gait related problems of the patient) is easier said than done, because AFO stiffness depends on several factors, such as the use of materials, the thickness of the material and trim lines of an orthosis (Novacheck et al., 2007; Lehmann et al., 1983).

In addition to the previous suggestion, it was also recommended to:

- Measure the stiffness of AFOs in the sagittal plane because here the largest movements and the most common problems occur.
- Use the physiological range of motion of the ankle joint in testing that covers the range of the target group.

  Since one able-bodied subjects would take part in the pilot study, it had to be considered to use the average physiological range of motion of able-bodied people in testing. Since Perry and Burnfield (2010) had found that this range varies from 10^{o} of dorsiflexion to 15^{o} of plantarflexion and Nordin et al. (2001) had found that this range varies from 10.2^{o} dorsiflexion to 14.2^{o} plantarflexion, these numbers were taken into account in devising the mechanic test method.

The first researchers that introduced the idea of matching orthotic designs to disabilities and gait abnormalities of patients with an appropriate biomechanical system were Lehneis et al. (1973). Sumiya et al. (1996a, 1996b) were one of the first who actually started to investigate the stiffness of AFOs in the hope to find matches between their mechanical properties and the impairment of patients.

To measure the plantar- and dorsiflexion moments of 30 standard grade polypropylene AFOs when deflected, Sumiya and others had developed a simple device which was independent of motion capture equipment and inter alia consisted of metal bars, a tensiometer and a protractor. Through the use of device, it was found that:

- Stiffness in posterior leaf spring (PLS) AFOs largely depend on the trim lines around the ankle (Sumiya et al., 1996b). The further the width of the orthosis posterior upright reduced by trimming the AFO around the ankle, the more the resistance of the AFO to plantar- and dorsiflexion movement reduced.

  This finding is confirmed by Lehmann et al. (1983) and Singerman et al. (1999).
- The 3 mm thick PLS AFOs generated a maximum resistive moment of 27.5 Nm (±7.2 Nm) when the AFO was 15^{o} plantarflexed and 10.5 Nm (±2.7 Nm) when the AFO was 15^{o} dorsiflexed. According to Sumiya et al. (1996b), the moment produced by the

AFO to resist plantarflexion should be sufficient to assist dorsiflexion in patients with severe spasticity. This doesn't apply for the moment produced by the AFO to resist dorsiflexion. This moment would not be strong enough to stabilize the ankle in patients having reduced plantarflexion strength.

The study of Yamamoto et al. (1993a) was the first study in which a clinically relevant test apparatus was used. Both an electronically controlled muscle-training apparatus and normal human limbs were used in this study to determine the plantar- and dorsiflexion and inversion- and eversion bending stiffness of different types of plastic AFOs (Figure 2).
The flexibility of four different types of AFOs were measured in a range of 20^{o} plantar- to 15^{o} dorsiflexion and 15^{o} inversion to 10^{o} eversion while it was fitted to a patient's limb. The AFOs used were posterior- and anterior-spring types, side stay and spiral AFOs, all made from 4 mm thick polypropylene. Similar to Sumiya et al. (1996b), the researchers found that the width of orthosis at the level of the ankle joint influences its flexibility in plantarflexion. It was also found that the angular velocities at which forces are applied have no significant effect on the stiffness or deflection of plastic AFOs. The study of Yamamoto et al. (1993b) and Novacheck et al. (2007) confirm this latter finding.

[redacted]

Figure 2: Device used for the determination of the relationship between the ankle joint angle of a limb fitted with an plastic AFO and the ankle moment (Yamamoto et al., 1993a).

In another study by Yamamoto et al. (1993b), an experimental AFO, which consisted of a plastic shoes, a potentiometer attached to one of the double-Klenzak joints and two aluminum bars, was used to simultaneously measure: corrective total moments generated by the AFO, ankle-joint moments due to GRF and ankle and knee angles in the sagittal plane.

It was found that the corrective moment produced by the AFO is very small compared with the dorsiflexion corrective moment and the net muscle moment significantly changed when the hemiplegic patient walked with the AFO.
One comment must be made on the study. The AFO used in this study is not an accurate representation of any AFO prescribed and used in clinical practice. Therefore, the results only apply to the experimental orthosis and no other orthosis.

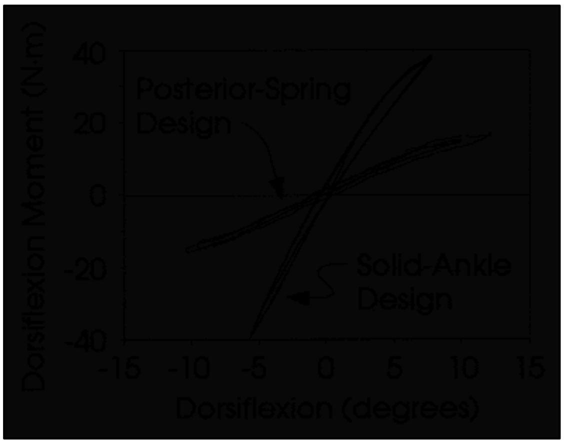
Singerman et al. (1999) used an apparatus consisting of metal T-shaped frame and pipe clamps to measure the moments and to determine whether kinematics of four different AFOs are dependent on design changes made to alter stiffness.
In this study, all AFOs were mounted in this frame and tested between 10^o plantar flexion and 10^o dorsiflexion while the plantar- and dorsiflexion moments were recorded.
Again, this study demonstrated that when the amount of trim increased the stiffness of (solid) AFOs to plantar- and dorsiflexion reduced. In addition, it was found that the stiffness of solid AFOs decreased from a maximum at 6 degrees of plantarflexion to a minimum at 8 degrees of dorsiflexion.
It was also found that the stiffness of the solid AFO tested was:

- 7.2 Nm/^{o} at maximal plantarflexion
- 5.9 Nm/^{o} at the neutral position, where the dorsiflexion moment equals to zero
- 3.6 Nm/^{o} at maximum dorsiflexion

In comparison with the solid AFO, the stiffness of the posterior lead spring was found to be more constant and less stiff (Figure 3a):

- 1.3 Nm/^{o} at maximal plantarflexion
- 1.6 Nm/^{o} at the neutral position, where the dorsiflexion moment equals to zero
- 1.2 Nm/^{o} at maximum dorsiflexion

The solid-ankle design orthosis showed the highest stiffness of the four orthoses tested at maximum plantarflexion (Figure 3b). This can be explained by the tension developed at the ankle trimlines, resulting in a small increase in AFO stiffness.
Also one comment must be made on the study. No information was given about the thickness of the orthoses tested through which the above results could not be used in comparing results with other studies.



	Stiffness (Nm/deg)		
	Plantar Flexion	Neutral	Dorsi-Flexion
Solid-Ankle Design	7.2	5.9	3.6
Locked-Hinge Design	9.0	2.8	7.0
Posterior-Spring Design	1.3	1.6	1.2

Figure 3: (a) Moment-angle curves of the posterior leaf spring and solid AFO, (b) the stiffness of three orthoses tested (Singerman et al., 1999).

In study of the Major et al. (2004), the resistance of three different ankle-foot orthoses to 0-14^{o} dorsiflexion were determined and compared with forward trimlines. Two ankle-foot orthoses reinforced with carbon fibre inserts and an AFO with forward trimlines were tested using the Instron 1185 material testing machine. Each orthosis was tested ten times. Only the data of the last six tests were used, because Major and others had discovered that AFOs show a more consistent loading pattern after four loading cycles.
It was found that the AFO with carbon fibre inserts produced a moment of 62 Nm and the same AFO with the strap produced a moment of 65 Nm at a dorsiflexion angle of 13^{o}.
It should be noted that the values measured are large in comparison to values found by Yamamoto et al. (1993) and Sumiya, et al. (1996).

In the study of Lunsford et al. (1994) a dynamic AFO cycling testing apparatus was used to measure the stiffness and investigate the viscoelastic behavior of pediatric-sized polypropylene ankle-foot orthoses (Figure 4). The device flexed the surrogate limb with ankle-foot orthosis attached between 0^{o} up to 10^{o} of dorsiflexion during a three 24-hour periods of cyclic loading while force measurements were taken, both before, during and after cyclic loading. Through this study it was discovered that the ability of the AFOs to resist dorsiflexion significantly reduced over time. For example, the stiffness of the ankle-foot orthosis decreased more than 30 percent after the first 24 hour.
In addition, it was found that when AFOs were allowed to rest, they spontaneously started to recover within minutes after cycling and even fully recovered to its initial viscoelastic properties.

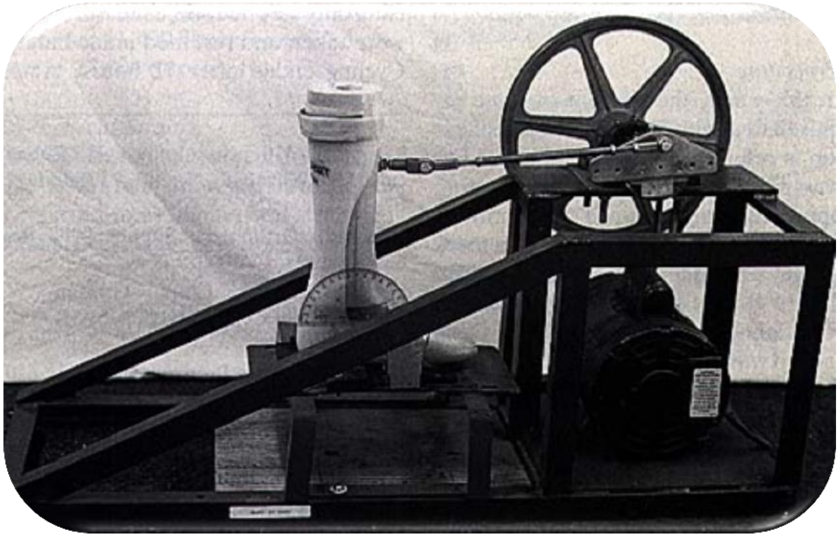


Figure 4: Dynamic ankle-foot orthosis testing device (Lunsford et al., 1994).

Bregman et al. (2009) decided to develop a new mechanical testing device after they had discovered that AFO characteristics, such as the neutral angle and stiffness, are seldom measured, while it is expected that these properties have a strong influence on the function of AFOs in pathological gait. For example, Miyazaki et al. (1997) indicated in their study that the neutral angle of AFOs may also have influence on the patient's gait.

The final device called the Bi-articular Reciprocating Universal Compliance Estimator or simply BRUCE (Figure 5), consisting of a dummy leg with anatomically base joint centers, enabled the researchers to measure the two above-mentioned characteristics both around the ankle and metatarsophalangeal (MTP) joint region.

In the study, the following four orthoses were tested in the BRUCE device: a solid custom-made polypropylene AFO, a prefabricated PLS AFO and two custom-made carbon composite PLS AFOs. From the tests conducted it was found that BRUCE can reliably measure the AFO stiffness around the MTP and ankle joints and that the solid AFO behaves nonlinearly.

It was also found that the solid AFO has an average ankle stiffness of 1.56 Nm/^{o} and the posterior leaf spring an average ankle stiffness of 0.16 Nm/^{o}. The MTP stiffness turned out to be considerably lower. Both AFOs showed a MTP stiffness of 0.09 Nm/^{o}.

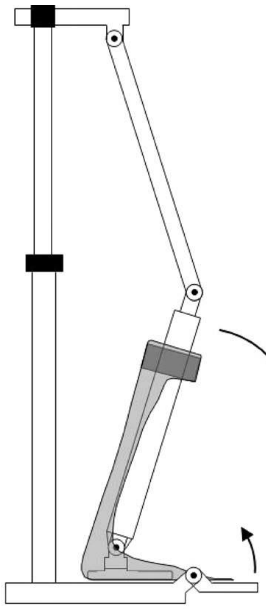


Figure 5: A schematic overview of the mechanical testing device BRUCE (Bregman et al., 2009).

Bregman et al. (2010) had also investigated the fraction of ankle joint powers and moments, and the functional effect of the posterior leaf spring AFO on the gait of MS and chronic Stroke patients. In the study, the AFO mechanical characteristics, stiffness and neutral angle, were measured within a range of 20^{o} dorsiflexion to 10^{o} plantarflexion using the BRUCE device. Also three-dimensional kinematics and kinetics were recorded using an AMTI force plate and the Optotrak system while the patients walked with shoes only and with shoes and AFO.

From the tests conducted it was found that PLS AFOs have mean stiffness 0.19 (0.04) Nm/^{o}. It was also found that the ankle moment during stance is mainly provided by the patient instead of the AFO. The mechanical contribution of the PLS AFO appeared to account for only 13.7% (±1.9%) of the total ankle joint moment, which was sufficient to keep the foot in neutral position during the swing phase.

Further, a relation between mechanical effects and energetic functional effects of AFOs was discovered. Based on all these findings, the researchers concluded that, research on the relationship between the mechanical function of AFOs, properties of AFOs, and the resulting functional effects are required to gain insights into the effectiveness of ankle-foot orthoses at the individual level.

Chapter 3 Materials and methods

3.1 Introduction

This chapter has been written with the intention of providing the reader knowledge about the methods and materials used during the pilot study.

Three measuring devices were used in this study. The motion analysis system (Vicon Nexus MX, Oxford Metrics Ltd, UK) and its associated method are discussed first. Subsequently, the Instron E10000 and a self-fabricated testing device and their associated procedures are extensively discussed.

3.2 Gait analysis

In this study, the Vicon motion capture system was used in conjunction with four Kistler force plates to acquire three-dimensional motion data. Tests were performed on two separate days in the biomechanics lab of the Biomedical Engineering Department, after the ethics were approved by Biomedical Engineering departmental ethics committee and the informed consent form was read and signed prior to the participation.

3.2.1 Subject

One healthy adult (n = 1) was recruited from the Biomedical Engineering Unit community. The screened and voluntarily recruited subject met all the inclusion criteria and agreed to participate in the research by giving informed consent. The participant was an 80-year old male who was 1.65 m tall, had a body mass of 79 kg and had no recent or long-term experience in wearing ankle-foot orthoses before this study began. Prior to the study, a six and an eight layer custom-made SWIFT Cast, a custom-made solid polypropylene AFO with carbon fibre reinforcement and custom-made posterior leaf spring AFO were made for the left leg of the subject. A detailed description on the manufacture of these AFOs is given later on in this chapter.

The criteria on which the selection of the participant was based are listed below.

Inclusion criteria

- Able-bodied male or female
- Aged between 18 and 85 years
- Able to give informed consent

- Able to ambulate independently, without human assistance or the use of assistive devices, for at least six times five minutes with intermediate breaks of 5 minutes
- Sufficient cognitive ability to understand and follow simple instructions
- Skin integrity should be adequate

Exclusion criteria

- Unable to give informed consent
- Communication problems
- Significant structural length discrepancy, musculoskeletal or neurological abnormalities of the lower extremity.
- Symptoms indicating a cardiopulmonary disorder, such as lower extremity peripheral vascular disease.
- People who have recently or for a long-term had experience with wearing an ankle-foot orthosis.
- Known skin allergy to fiberglass or Plaster of Paris.

3.2.2 Instrumentation and measurement procedure

The motion of body segments and joints and for this study in particular, the response of the human body to lower limb devices during walking, can be measured by biomechanical investigation. Biomechanical investigation or biomechanics is a branch that involves all sorts of living structures and their movement performance. This type of investigation can be performed without application of magnetic fields and often expresses the findings in the kinematics and kinetics of human body segments.

It was chosen to carry out the biomechanical investigation using a system called the Vicon MX T-Series motion capture system. This motion analysis system was located at the Department of Biomedical Engineering, University of Strathclyde, United Kingdom, and enabled the researchers to collect three-dimensional motion data of a single subject (Appendix 3). The system consisted of several components. Only the components used in this study are listed below:

- A host personal computer which was equipped with a Vicon Ethernet and network Ethernet card and installed with Vicon Nexus software 1.8.2. to analyze the data.

- Two MX Giganet smart boxes were used. These boxes provided power to cameras and other apparatuses, while they were synchronizing the force plates, cameras and other measurement equipment at the same time.
- Twelve Vicon MX T-Series cameras (Figure 6), whereof six T40 with a resolution of 4 megapixels and six T160 cameras with a resolution of 16 megapixels, simultaneously captured the kinematic and kinetic data of the able-bodied subject during each trial at a sampling frequency of 100 Hz.
- Four Kistler piezoelectric force plates were connected to the Vicon system via the Giganet box. These plates were embedded in the floor and registered forces exerted by the human body during each walking trial at a sampling frequency of 1000 Hz.

Figure 6: A Vicon Nexus MX T-series camera placed on a rail.

The basic principles of both the Vicon system and force plates work are described below.

The Vicon MX system is an optical motion measurement system which can follow and record motion of (moving) objects. Data collection is primarily done by the use of cameras, which track the three-dimensional positions of retro-reflective surface markers that are tactically positioned on the subject. At least two cameras are needed to see and calculate the position of a marker at any given time in three dimensions.

A Kistler force platform is a sensitive, relative expensive and important measuring system used for the indirect measurement of ground reaction forces and moments. The system is able to perform measurements by making use of piezoelectric quartz crystals. These crystals exhibit an effect called “the piezoelectric effect”. This is effect is achieved when forces are acting on the sensor elements, because they deform the lattice structure of the crystals.

As a result of the deformation, the highly sensitive crystals start to produce a signal in the form of an electric dipole moment, which in turn generates an electric charge. This signal is then amplified by a charge amplifier and related to the magnitude of the force applied.

Now that the basic principles of both systems are known, it is time to go into detail about performing the gait analysis.

Many steps were undertaken prior to gait analysis. To start, the subject was instructed in time to bring a conventional pair of shoes with a medium to hard heel stiffness and a heel height of 1.5 to 2.0 centimeters on the day of casting and the day of research. Both shoes were worn during the walking with and without the plastic AFOs. Only one conventional shoe was worn during the trials with the SWIFT Casts, because the SWIFT Cast was fixed to a plaster shoe. The participant was also instructed to wear a tight Lycra suit on the day of research for two reasons:

1. To limit the propagation of measurement errors due to clothing movement as much as possible .
2. So that the majority of the 14.0 mm diameter markers could be attached to the human skin.

As soon as the above-mentioned preparations were undertaken, the cameras and capture volume were calibrated and anthropometric data acquired.

Prior to both test sessions, the Vicon system was calibrated in two stages. The first stage was called the static stage or static calibration. Herein, the global origin of the three-dimensional capture volume and the orientations of the axes in space were determined by placing the L-shaped calibration wand within the force platform location.

This was followed by the second stage called the dynamic stage or dynamic calibration. Herein, the physical position and orientation of each camera was automatically calculated by dynamically moving the same calibration wand through the capture volume. The anthropometric data of the subject were taken by making use of a weighing scale, a mechanical measuring rod and a anthropometer (Figure 7). The measured values taken from the participant were averaged and entered at the bottom of the Vicon Nexus resources pane (Table 1).

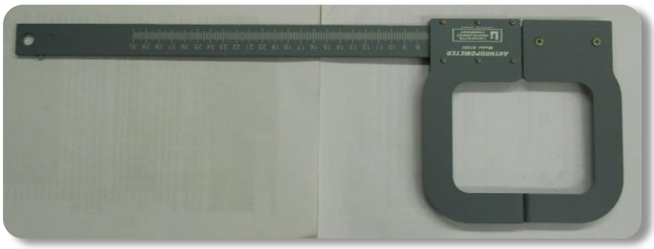


Figure 7: Small anthropometer model 01291 (Lafayette Instrument)

Measurements (unit)	Measurement results
Marker diameter (mm)	14
Body mass (kg)	79
Body height (mm)	1650

Measurements (unit)	Measurement results left side	Measurement results right side
Elbow width (mm)	73	72
Hand thickness (mm)	22	25
Shoulder offset (mm)	40	40
Wrist width (mm)	56	57

Table 1: Subject measurements

Once the subjects measurements were entered a comprehensive marker set was attached to the subject's skin and clothing so that both anatomical landmarks and segments could be identified. The set comprised a total of 38 markers, whereof 18 single markers and 5 rigid cluster of markers, each consisting of 4 individual markers. Only passive markers as illustrated in Figure 8a were used in this study and attached to the subject with hypoallergenic double-sided type.

This custom-designed full body marker set was previously used in the SWIFT Cast study of Pomeroy et al. (2012) and re-used in the pilot study because it allowed for comparing data across studies and because it was suggested by an investigator involved.

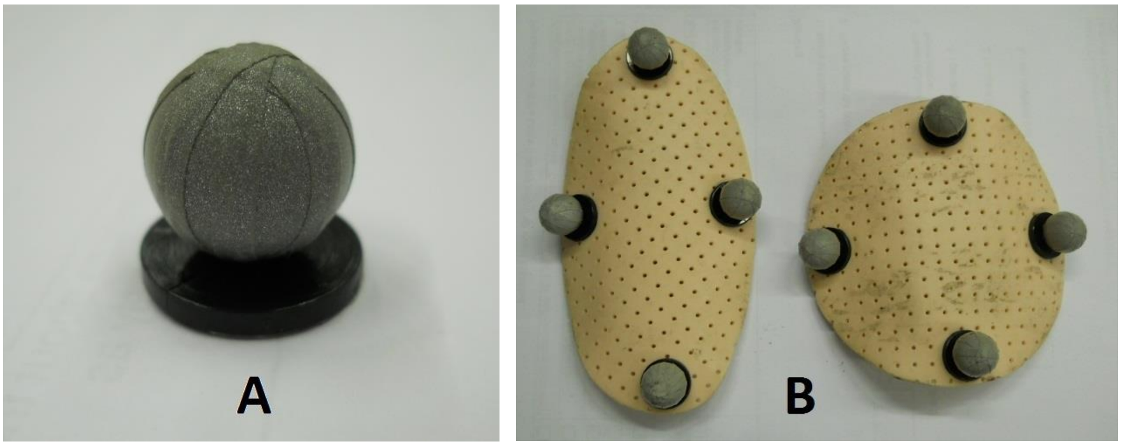


Figure 8: (a) Individual 14 millimetre retro-reflective marker, (b) Cluster marker for shank and thigh segments

The positioning of the markers started at placing a headband on the participants head. Four loose markers were positioned on the headband:

- Left and right back of the head
- Left and right side of the head (temple) behind the eyes

Six individual markers were placed on the subject's torso over:

- Acromioclavicular (ac) joint of the left and right shoulder
- Manubrium sterni
- Xiphoid process of the sternum
- Spinous process of the tenth thoracic vertrebra (T10)
- Spinous process of the vertrebra prominens (C7)

Twelve loose markers were positioned on the following places of subject's upper limb:

- Upper lateral one third surface of the left and lower lateral one third surface of the right upper arm
- Lateral epicondyle of the left and right humerus
- Lower lateral one third surface of the left and upper one third surface of the right forearm
- Over the dorsal aspect of the styloid process of the radii, as close to the radio-carpal joint centre as possible
- Over the dorsal aspect of the distal head of the ulnas, as close to the wrist joint centre as possible
- Over the dorsal aspect of the third metacarpal bones

A rigid cluster of markers, consisting of a set of four individual markers mounted on a curved thermoplastic mould (Figure 8b), was positioned on the back at the level of the lumbar spine between the two PSIS markers to identify this bone segment.

Twelve calibration markers, which were identical to the other markers, were placed on the subjects' skin or clothes over the:

- Left and right anterior superior iliac spine (ASIS)
- Left and right posterior superior iliac spine (PSIS)
- Medial and lateral epicondyle of the left femur
- Medial and lateral epicondyle of the right femur
- Left and right medial malleolus
- Left and right lateral malleolus

These extra markers were used to estimate the location of the ankle, knee and hip joint centers during static calibrations trials and removed prior to capturing dynamic trials. Apart from the calibration markers, it was tried to prevent repositioning of markers to avoid additional variability.

In addition to the waist cluster marker, four more cluster markers were placed on the subjects' skin over the:

- Lower lateral one third surface of the left and right thigh
- Lower lateral one third surface of the left and upper one third surface of the right shank

Six single markers were placed on both shoes of the subject at the level of:

- Posterior tuberosity of the calcaneus (or simply heel)
- First and fifth metatarsal head

These markers were used to identify the foot segments.

Figure 9 graphically represents where the single markers and the clusters of markers were attached to the subject.

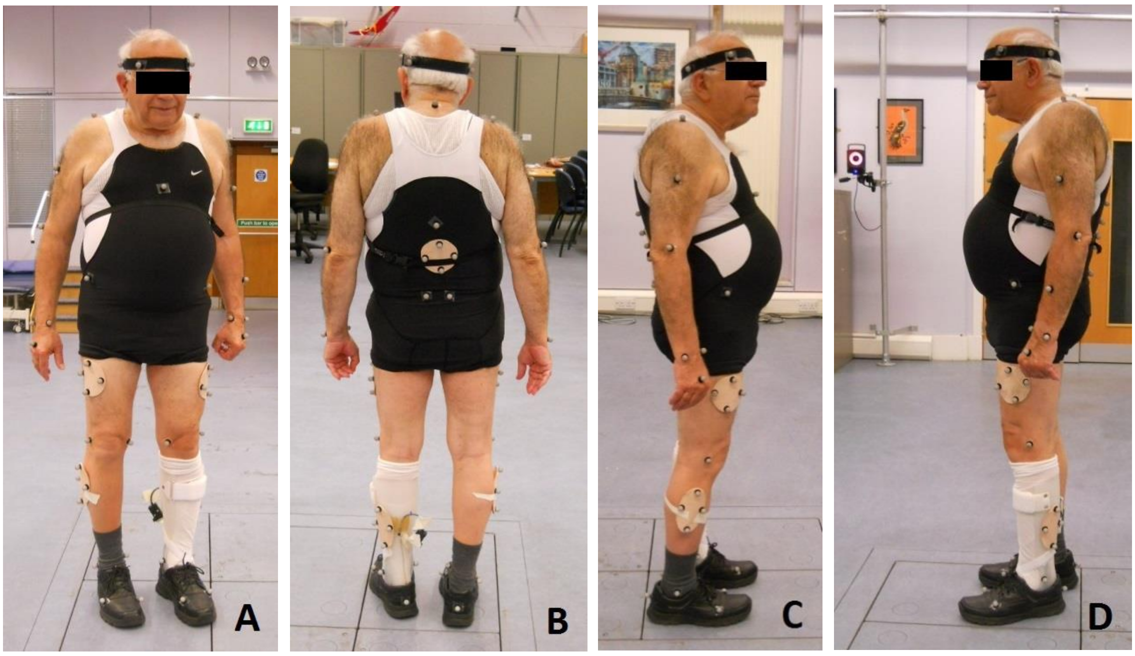


Figure 9: (a) Anterior view, (b) posterior view, (c) right side view, (d) left side view of marker placement.

Prior to each walking condition, in which the participant was asked to wear another type of orthosis, a washout period was offered to the participant. This gave the participant time to get accustomed to walking in each of the devices before data collection started. In addition, this phase gave the orthotist the opportunity to make the necessary adjustments for an appropriate fitting. The try-out phase was stopped when the participant indicated being comfortable to wear the device and being able to consistently and naturally contact one of the force plates without targeting.

Once the first try-out phase was completed, motion data could be captured. Both kinematic and kinetic data were collected during static and dynamic trials.
The static trials were required to detect the position and determine the orientation of anatomical landmarks in cluster technical frames. For the static trials, the participant was instructed to stand sideways on the force plates with its face in the direction of progression, or as shown in Figure 10.

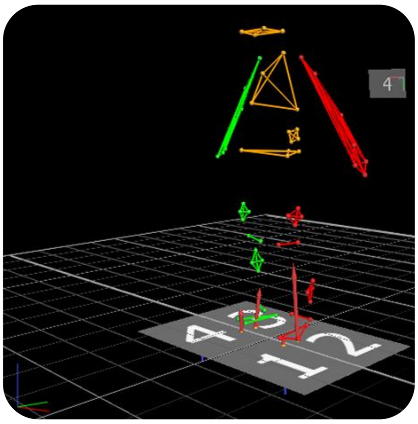


Figure 10: Illustration of the participant standing sideways during a static trial.

For the dynamic recordings, the subject was asked to walk six meter in a straight line at self-selected and comfortable walking speed. These level walking trials had to be performed at least four times, both forwards and back, for each walking condition, while data from both legs were recorded for data analysis.

In total, there were five walking conditions which were performed in random order.

One of the walking conditions was walking with conventional shoes only. This was the control condition. The other four walking conditions involved different types of orthoses:

- Walking with conventional shoes and a custom-made solid AFO with carbon fibre reinforcement.
- Walking with conventional shoes and a custom-made posterior leaf spring AFO made of 3.0 mm thick copolymer polypropylene.
- Walking with one conventional shoe and an SWIFT Cast with a six-layer Scotch back slab and a strong plaster shoe.
- Walking with one conventional shoe and an SWIFT Cast with an eight-layer Scotch back slab and a strong plaster shoe.

Directly after gait analysis in the gait laboratory, the questions listed below were asked in order to obtain information about the participants' experiences.

- How did you experience the research?
- Did you prefer a certain type of orthosis?
- If so, which type of orthosis did you prefer? Why?
- Do you have any comments regarding the research?

3.2.3 Output variables gait analysis

Two separate groups of data were acquired when the able-bodied subject walked with and without different types of AFOs. One of two groups was kinematics and the other kinetics of gait. These outcome measures were chosen because they allow the identification of abnormal motion patterns. Combining both three-dimensional kinematic and kinetic data made it possible to calculate forces and moments at joint centres, which in turn helped in understanding the biomechanical aspects of orthotic management of the lower limb. Three-dimensional kinematics was selected as primary outcome measure and kinetics as secondary outcome measures. Kinematic data can be described as a branch of mechanics which involves the displacements of human or animal body segments and joints with respect to a datum without considering the cause of motion (Chowaniec, 1983).
Kinematics describes relative motion of segments through physical quantities such as: (angular) displacement, (angular) velocity and (angular) acceleration. Kinetics is a branch of mechanics that studies the causes of motion and the effects it has on the motion of a body (Hsu et al., 2008). Herein, forces and moments (or torques) are especially important.

The parameters that were obtained by using the Kistler forces plates and the Vicon system and were used for the analysis are reported in Table 2.

	Ankle joint angles		Knee joint angles		Hip joint angles
A1	Max. plantarflexion in loading response	K1	Max. flexion in early stance	H1	Max. flexion in loading response
A2	Max. dorsiflexion in late stance	K2	Min. flexion in terminal stance	H2	Max. extension in late stance
	Ankle joint moments		**Knee joint moments**		**Hip joint moments**
A3	Max. dorsiflexor moment in early stance	K3	Max. extensor moment in mid-stance	H3	Max. extensor moment in early stance
A4	Max. plantarflexor moment in late stance	K4	Max. extensor moment in late stance	H4	Max. flexor moment in late stance

Table 2: Joint angle and moment parameters.

All the values of these parameters were simultaneously recorded during the five walking conditions and later on averaged and expressed as a percentage (%) of the gait cycle.

3.2.4 Data processing

The data was processed after data collection by selecting a number of pipeline operations in the Nexus software and running the pipeline.

Of each above-mentioned condition, two static trials and at least four dynamic trials were recorded, directly transferred to the hard disk of the host computer and saved as an C3D file. In some studies, it is seen the initial and last recordings are omitted. Since a try-out phase was included in this study and the able-bodied subject had not intimated to be weary after the recordings, there was no reason to neglect any.

After saving the data, all trials were cropped to remove frames that didn't contain marker data. The markers were then manually labeled through the static trials using a custom written marker set file. After labeling, the static trials were post processed by running a "Static Subject Calibration" operation and performing a "static BodyLanguage modeling". Then, the trial was ready for use.

After splitting all the dynamic trials in trials where the subject walked either towards or away from the wall, all markers were also manually labeled through the dynamic trials using the custom written marker set file. In the post process of the dynamic trials, more workstation operations had to be run than in the post process of the static trials. First of all, the gait cycle events "foot strike" and "foot off" were manually identified and marked for both legs, all the way through the dynamic trials (Figure 11). Secondly, gaps in markers' trajectories were filled by running the pipeline operation "Fill gaps (Woltring)". Thirdly, unlabeled trajectories were deleted by selecting and running the "Delete Unlabeled Trajectories" operation. Subsequently, the dynamic trial data was filtered using the Woltring filter. In Vicon Nexus, this operation was called "Apply Woltring filtering routine" and set at a predicted mean squared error value of 15 mm. In the penultimate operation, a BodyLanguage model was used to define segments, generate kinematic angles and seamlessly process the motion data. After saving the data, the data export function was used and the following types of data were selected for ASCII export: kinematics and moments from the model. These outcomes were then imported and opened in Microsoft Excel.

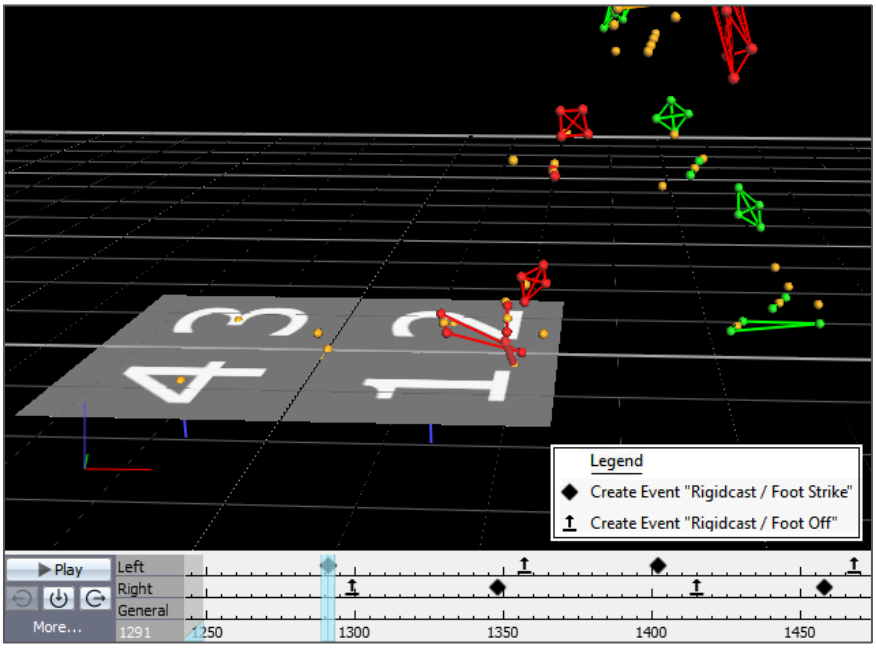


Figure 11: Creating gait cycle events for both legs

3.2.5 Data analysis

In Microsoft Excel, five walking trials of each walking condition were selected and transferred from the Excel worksheet with all data in it to an empty worksheet for further analysis. In this worksheet the data was split up into six variables: ankle, knee and hip joint angles (deg) and ankle, knee and hip joint moments (Nm) for the left leg of the able-bodied subject.
The range of frames of each walking trial was cropped into one complete gait cycle on basis of the gait cycle events created in the Nexus software. Each walking trail ranged from heel strike of the left foot to the next heel strike of the same foot after the data was cropped. Subsequently, spline interpolation was used in Matlab to normalize the data from 0% to 100% of a gait cycle. This was an important step in the process because normalizing allowed to average trials of gait data .
As last, the standard deviation and the mean of each data set were calculated in Microsoft Excel, using the Excel STDEV and AVERAGE functions, to evaluate variability of the measurements. Once all the operations mentioned were performed in Excel, the desired data points of all walking trials were selected and imported into Minitab 16 to perform statistical analyses. It was decided to perform non-parametric analyses after the motion data was tested in Minitab for normal distribution. The Wilcoxon signed rank test was repeatedly performed to identify statistically significant differences ($p < 0.05$) between the maximum joint angles and moments found in the control condition and in the other four walking conditions.

3.3 Mechanical testing

In mechanical testing, a material testing machine and a custom-made testing apparatus were used to determine the mechanical characteristics of three different types of AFOs.

The following AFOs were tested:

1. A flesh coloured 3.0 mm PLS AFO (Figure 12a).
2. A white coloured solid AFO reinforced with carbon fibre inserts and made of 4.6 mm thick copolymer polypropylene (Figure 12b). This is most commonly prescribed to stroke survivors.
3. A six-layer (Figure 12c) and an eight-layer SWIFT Cast (Figure 12d).

Both plastic AFOs were moulded and fitted for the left leg of the able-bodied subject by an experienced and certified orthotist. It was deliberately chosen to leave this to a trained orthotist, because orthotists are considered to be responsible in clinical practice for the design, fitting, alignment, delivery and initial review of (custom-made) AFOs.

SWIFT Casts may also be made by physiotherapists or other medical trained staff. Therefore, a physical therapist who had acquired several years of experience in making SWIFT Casts made both casts for the left leg of the subject.

A more detailed description on the production method used and both AFO designs is given in paragraph 3.3.1 and 3.3.2.

(a) (b) (c) (d)

Figure 12: Set of orthopaedic AFOs, consisting of (a) 3.0 mm thick flesh coloured posterior leaf spring AFO, (b) white coloured solid AFO with carbon fibre reinforcement at the ankle section, (c) six layer SWIFT Cast, (d) eight layer SWIFT Cast, used in mechanical testing.

3.3.1 Manufacture of the plastic AFOs

In short, two different types of ankle-foot orthoses, a posterior leaf spring and a solid AFO with carbon fibre reinforcement, were produced in the National Centre of Prosthetics. Below is a detailed description on the production of both plastic AFOs.

One of the first steps in making an AFO was the casting process. A qualified orthotist took both times a cast of the left lower limb of the subject by molding a plaster of Paris bandage around this body segment. Before the plaster hardened and the cast saw could be used to remove the mold, the orthotist made sure that the shank was forward inclined in an angle of 10 degrees from the vertical, in order to prevent knee extension during walking.
After removing the negative impression, it was filled with liquid molding plaster to produce a three-dimensional positive model. Once the liquid mold plaster was hardened the plaster model was modified. For example, the plantar surface of the model was flattened off to facilitate the attachment to the mechanical testing machine. Thereafter, the plaster model was smoothed for an intimate and comfortable fitting. After a stockinette was added to the model, the plaster model was ready to be used for the production of the PLS AFO.
An additional adjustment had to be made to the plaster model of the solid AFO before it was ready to be used. Two carbon fibre inserts and corrugations (7 mm Ethylene Vinyl Acetate) had the be placed over malleoli.

Once the plaster models were ready for use, the infrared oven was switched on and set to the temperature of 180^{o}C (or 350^{o}F) according to the manufacturer's technical specifications. Under this high temperature, a single sheet of 4.6 mm and 3.0 mm thick thermoplastic polypropylene started to absorb the heat slowly whereby secondary or Van der Waals bonds between the molecules dissociated. This allowed the polymer molecules to slide past and over each other. As a result, the material became transparent, soft and auto adhesive through which the polypropylene could be draped over the positive mold. Subsequently, a technique called vacuum forming was applied to remove the air between the positive model and the plastic. After vacuum forming, the material slowly cooled and solidified so that the Van der Waals bonds could recombine again.
To prevent the casts of distortion or springing they were left for at least 24 hours to cool before it was cut off the positive model. Once the twenty-four hours had passed, the polypropylene casts were cut off and trimmed.

After trimming, the trimlines of the PLS extended:

- Posteriorly 3.5 cm to the medial and lateral malleoli
- Proximally to 9.0 cm below the head of the fibula
- Distally to 10.0 cm before the tips of the toes

After trimming, the trimlines of the solid AFO extended:

- Up to the centre of both of the malleoli
- Proximally to 5.0 cm below the head of the fibula
- Exactly up to the tips of the toes to stop the toes from curling over the edge and to restrict the motion in the toe joint

Once the plastic AFOs were finished, the wall thickness of both plastic AFOs were measured by a micrometer around the malleoli of the ankle section and the sole plate. This was done because Ross et al. (1999) had indicated in their study that manually draping is the most likely reason for non-uniform wall thicknesses which may have an effect on AFO deflection. As last, rings made of EVA were attached around the proximal attachment points so that forces could be transmitted directly through the AFO.

3.3.2 Manufacture of the SWIFT Casts

A physical therapist made and fitted two SWIFT casts without assistance for the left foot of the subject within one week. Making and fitting of both casts was done approximately two weeks before the start of the study.

The following is a description of the steps the physiotherapist had taken in the production process of the SWIFT casts.
The first steps preceding the casting process were arranging a room with sufficient floor space and informing the participant that the process will take up to one hour.
The participant was advised to wear:

- Loose, short or elastic clothing, which enabled the lower leg to be easily exposed.
- Conventional shoes with a heel height of 1.5 to 2.0 cm on the day of casting.

The following stuff were set out on the floor for casting one orthosis on the day itself:

- A pair of gloves
- A pair of plaster shoes
- Apron
- Bandage scissors
- Basin filled with lukewarm water
- Cutting spacer or tube
- Ground sheet of paper
- Marker pen
- One roll of Mircofoam, Micropore and Leukotape
- Three inch Stockinet
- Towel
- Two rolls of crepe bandage
- Two rolls of four inch Soft Cast and Scotch Cast

After the therapist had put on the apron and gloves, the subject was asked to sit on a chair and keep the hips, knees and ankles in a 90 degrees flexed position. Subsequently, one trouser leg was rolled up and the lower limb exposed above the knee, so that two stockinet layers could be fitted. These layers ran from just below the head of the fibula to beyond the toes. A cutting spacer was inserted between both layers at the anterior side of the lower leg. Then, one roll of soft cast bandage was wrapped around the lower leg and extended as far as the stockinet layers.

The next step was to apply the portion that mainly provided the stiffness of the device. This part is called the back slab and consisted of six-layer or eight-layer 3M Scotchcast™. In clinical practice, the numbers of layers were selected based on the size of the patient and degree of knee hyperextension. In this study it was decided to make all available SWIFT Casts versions to quantify and evaluate the characteristics of SWIFT both versions.

The back slab was applied to the back of the lower leg, extending from the head of the fibula, via the plantar aspect of the foot, to just beyond the end of the toes.

Thereafter, the polyurethane resin of the casting tape was activated with water by applying a second roll of soft cast and two wet crepes around the whole cast.

The whole was moulded to the shape of the participant's leg and the foot and the ankle joint manipulated and placed into the desired position. The most important was that the ankle

and foot were positioned in a plantigrade position and the shank inclined forward by an angle of 0 to 10 degrees from the vertical, to prevent knee extension during walking.
After molding, the wet bandages were removed and the cast left to dry for a few minutes. Thereafter, the spacer was pulled out and the material cut off from the subject along the slot that was left behind. The front of the whole was then removed and the remaining part, the cast, symmetrically cut out in such way that its trimlines extended up the posterior side of the shank and under the foot to beyond the metatarsal heads, without covering the malleoli. Leukotape (BFN Medical Ltd., Hull, UK) was directly used after cutting to cover all edges to make sure the layers didn't fell apart. The cast was left to set for at least one day, after which it was fixed to the plaster shoe (Darco Multifit Surgical Trauma Shoe rounded toe, Markell Shoe Co., Yonkers, New York) and two Velcro straps were applied on the tibia. Once the cast was ready, it was fitted and the design, fitting and alignment checked (Pomeroy et al., 2012).

3.3.3 Measuring instruments

From the literature review can be deduced that different devices can be used to determine the mechanical characteristics of ankle-foot orthoses. In this study, two test apparatuses were chosen for the determination of the stiffness of different types of AFOs. The Instron ElectroPuls™ E10000 (Figure 13) was used for the determination of the stiffness of a solid AFO with carbon fibre reinforcement.

A self-fabricated testing device was used for the determination of the stiffness of a posterior leaf spring AFO, a six layer SWIFT Cast, an eight layer SWIFT Cast and the re-determination of the stiffness of the solid AFO with carbon fibre reinforcement.

3.3.3.1 Instron ElectroPuls™ E10000

The reason for selecting this electric dynamic material testing system was based on its high load weighing accuracy of ±0.5% of indicated load and the years of experience the University of Strathclyde has with material testing devices manufactured by Instron, especially when it comes to stiffness measurements.

The standard version of the Instron E10000 system consists of an load frame and base unit, a controller and a computer running Console software. The load frame and base unit contain a cooling system, power amplifiers and an electric linear and/or rotary motor. This part of the system can produce both compressive and tensile forces at low and high velocities, depending on the power level selected, whereby both dorsi- and plantarflexion stiffness can be tested. Another component present is the load cell. This component mounted on the base and used to monitor the force experienced by the orthoses during testing. Not to mention the actuator, located in the upper crosshead, which can monitor displacements and apply loads on the orthoses by making use of electromagnetic forces and magnets.

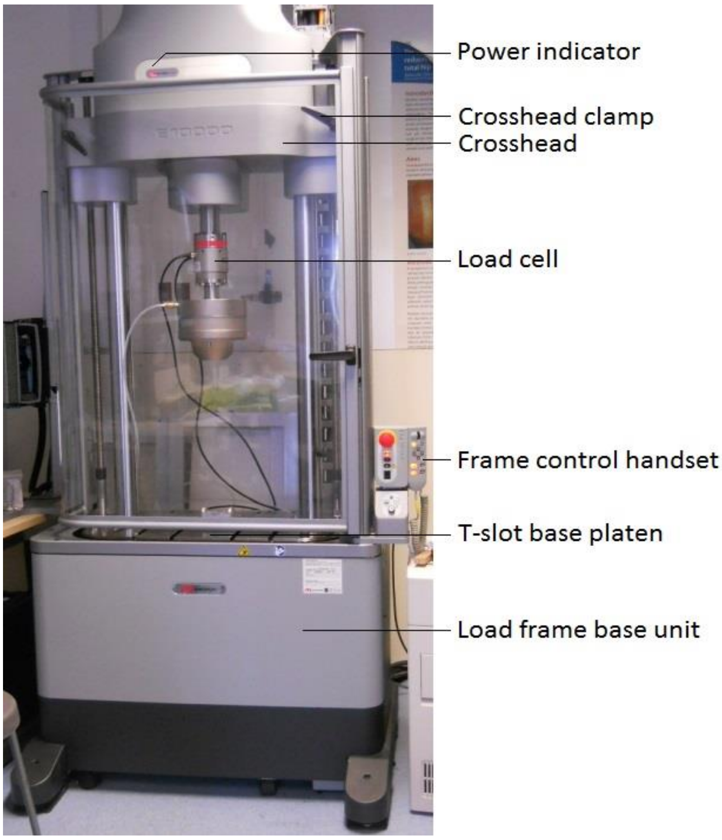


Figure 13: The Instron ElectroPuls™ E10000 linear-torsion floor test instrument.

3.3.3.2 Custom-made testing apparatus

The decision to use a custom-made testing apparatus in addition to the Instron was based on the expectation that the stiffness of the PLS AFO, six layer SWIFT Cast and eight layer SWIFT Cast in the sagittal plane would be so low that the Instron machine would be too powerful and damage the AFOs. The use of the self-fabricated testing apparatus allows the addition of very small forces, which would prevent the AFOs from rupturing (Figure 14), but has the disadvantage that it doesn't offer accurate speed control, which is a pity as visco-elastic materials are being tested.


Figure 14: A representation of an orthosis mounted in a rigid metal frame with G-clamps for testing.

The following tools were needed to perform the mechanical tests in the self-fabricated testing apparatus:

- A metal wire or sling with a small and large loop at the ends (Figure 15a)
- Clock gauge (Figure 15a)
- Cast iron block (Figure 15a)
- Two G-clamps (Figure 15a)
- A rigid metal frame (Figure 14)
- Two small circular and two squared metal pieces with a diameter or width of maximum 3 cm (Figure 15b)
- A small and a large carrier (Figure 15c)
- Fourteen weights ranging from 50 g to 2 kg (Figure 15c)

(a) (b) (c)

Figure 15: (a) Clock gauge, cast iron block, two G-clamps and a sling, (b) four metal pieces, (c) weights and carriers used.

3.3.4 Test procedure

Two different devices were used to measure the stiffness of four AFOs and therefore two different test procedures were used.

3.3.4.1 Instron test procedure

Testing the solid AFO with carbon fibre reinforcement took place in the electronics laboratory of the Biomedical Engineering Department. Here, the mechanical test was performed in one day by use of the Instron E10000 and a single trained person who handled the system.

Prior to testing, two mounting jigs were attached to the solid AFO with bolts. The lower jig or steel plate was secured with four bolts to support the sole of the AFO. The upper jig was secured with three bolts, nuts and washers on both proximal medial and lateral side of the AFO. After completion, the solid AFO was taken to the electronics lab where upon arrival all attendants had put on a lab coat to reduce hazards.

The testing process with the Instron machine started by switching on the mains power of the system, frame and controller. As a result of this action, the system started to run self-test routines. Subsequently, the computer and console were also turned on.
Once these apparatuses were turned on, the fixed crosshead was removed from T-slot base platen and a metal plate designed for AFO testing secured in position on the table. After manually twisting the lever clamps, the upper crosshead was electrically raised and lowered using the frame control handset to accommodate the AFO length. As soon as the crosshead had reached the desired position, then both clamp levers were rotated again to secure the crosshead and an the solid AFO was mounted in a toe off position to the Instron as displayed in Figure 16. Mounting the orthosis was done by clamping the upper jig to the upper crosshead and using a central bolt to mount the footplate to the metal plate (Figure 16).
The system itself automatically selected a gripping force and exerted it on the upper jig in such way, that it could not slip in the grips during testing.
After clamping the orthosis, the frame status and crosshead clamp indicator were checked after which the focus of the operator switched from the Instron machine to the computer. This computer was connected to the Instron and mainly used for controlling the Instron and carrying out the test.

During testing, the computer ran a test procedure, which was entered and saved in the Instron WaveMatrix™ material testing software under the heading "Method". This test procedure is described in detail below.

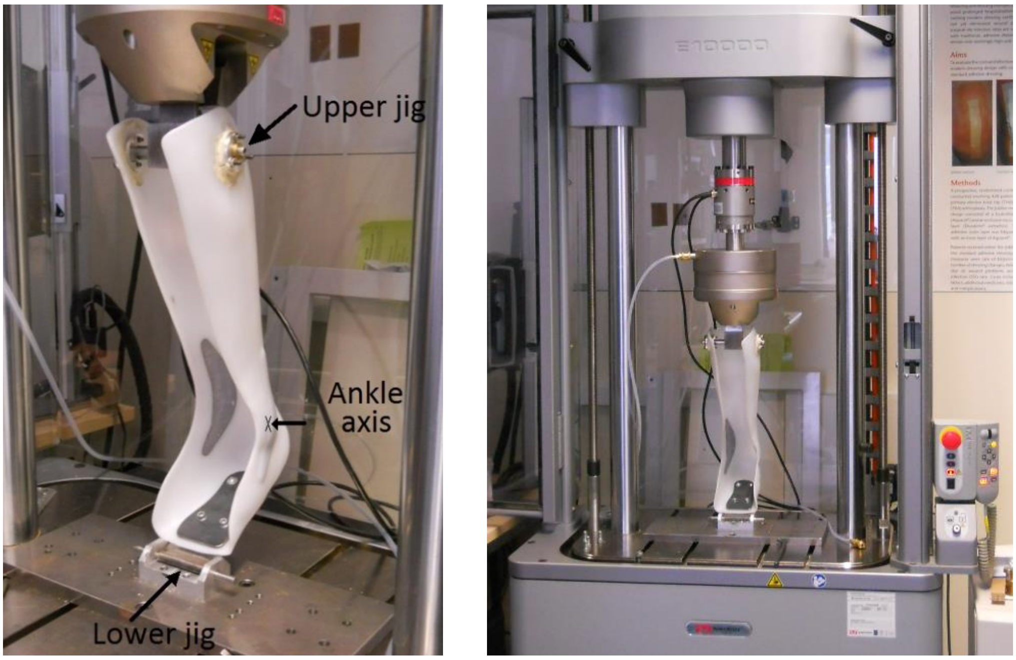


Figure 16: The 4.6 mm solid AFO reinforced with carbon fibre inserts mounted in the Instron testing machine.

Prior to testing the solid AFO, the Instron machine was set to zero and the high power button on the frame control handset pressed. This was followed by calibrating, balancing and setting the load and digital position of channel 1, which is the channel that allows uniaxial testing, to zero. Thereafter, the operating limits of this channel were set to following values in order to reduce hazards to the user and risks of damage or overloading to the orthopedic device:

- The upper limit of displacement of the crosshead was set at 15.0 mm and the lower limit at -15.5 mm.
- The upper limit of load was set at 1.0 kN and the lower limit at -1.0 kN.

At the start of the test, the clamps were held at zero for 5 seconds after which the solid ankle-foot orthosis was put through three tensile loading cycles followed by three compression loading cycles. During these cycles, the AFO was tested at a rate of 200 N/min (3.33 N/s), whereby the force (N) applied to the AFO and crosshead displacement (mm) were recorded at given time with a sample rate of 10 samples per seconds. An uniaxial compressive load of 300 Newton was applied by the Instron machine to dorsiflex the AFO.

An uniaxial tensile load of 300 N was put on the orthosis to plantarflex the AFO. These forces were chosen with the knowledge that they correspond to realistic loads and ensure the researchers that the AFO would only be stressed within the linear region (Papi, 2012).

As soon as a tensile loading cycle was completed, the load automatically went back to 0 Newton and the position of the crosshead was held for 3 seconds, after which the next loading cycle tensile started. After all three tension loading cycles were completed, the AFO was tested in compression. After also all three compression loading cycles were completed, the system automatically stopped so that the orthosis could be removed.

3.3.4.1 Rigid frame test procedure

Also the mechanical tests with the self-fabricated device had to reproduce plantar- and dorsiflexion movements at the ankle and were performed to determine the stiffness of four AFOs.

Once the tools were collected, see Chapter 3.3.3.2, the weights were weighed on a weighing scale and the values found written down on paper. Subsequently, the foot section of the AFO was fixed to the rigid frame with two G-clamps. During securely fixing of the AFO, it was taken into account that the stiffness to deformation of the orthosis in the ankle region would not be altered. In other words, the G-clamps were not allowed to tough the edges of the orthosis and only allowed apply force to the footplate.

After clamping, the large loop of the strong metal wire was placed around the proximal part of the orthosis near the upper jig and the clock gauge set up. The latter was a precise job. The clock gauge was put on a metal block when compression tests had to be performed (Figure 17) and put on a large metal plate when tensile tests had to be performed. The magnet present in the base stand was turned on to grip the clock gauge to one of the two metal surfaces. The cross arm of the gauge was adjusted so that the measuring pin was perpendicular to the surface on which it rested. The metal measuring pin rested on the proximal calf section of the AFO during compressive testing (Figure 17) and on the middle portion of the upper jig during tensile testing.

Figure 17: The surface area on which the measuring pen rested in compression testing.

Once the measuring pin was correctly positioned the test was started.

The first increase in displacement was recorded when the weight carrier was hanged on the small loop of the metal wire. The subsequent displacements were recorded when single slotted weights of 50 to 2000 g were gradually added onto the weight holder and when they were removed one by one.

3.3.5 Data processing

The data recorded using two different devices were processed in two different ways. Both ways are described in the following two sections.

3.3.5.1 Data processing Instron

The data recorded from the Instron machine was saved and at a later moment opened in Microsoft Excel (Appendix 1). The operations performed in the excel spread sheet for calculating the angle and moment are reported below.

To calculate the angle of the solid AFO under load firstly the three columns that contained the displacement data had to be added together and averaged. Thereafter, the original angle could be calculated by using the following trigonometry equation (Figure 18):

$$D^2 = (S)^2 + (F)^2 - (2 * S * F * \cos(\emptyset_0))$$

However, the equation had to be rearranged first to calculate the original angle:

$$\emptyset_o\ (rad) = \cos^{-1}\left[\frac{(-(D^2)) + (F^2) + (S^2)}{(2 * F * S)}\right]$$

After calculating the original angle, another angle had to be calculated. Calculating this angle was done by using the trigonometry equation again and substituting original length D (D0) for distance (D1), which is equivalent to the sum of the average displacement (mm) and length D (mm) (Figure 18).

$$\emptyset_1\ (rad) = \cos^{-1}\left[\frac{(-((Average\ displacement + D)^2) + (F^2) + (S^2))}{(2 * F * S)}\right]$$

Or

$$\emptyset_1\ (rad) = \cos^{-1}\left[\frac{(-((D1)^2)) + (F^2) + (S^2)}{(2 * F * S)}\right]$$

These angles had to be subtracted from each other in order to be able to find the deflection angle in radians.

$$\emptyset\ (rad) = \emptyset_1 - \emptyset_0$$

The final step in the calculation of the angle was the conversion of the angle unit from radians to degrees by multiplying the angle values by $\frac{180}{\pi}$.

The moment applied (Nm) was calculated by averaging the load data and multiplying it by lever arm x (mm). This lever arm was equivalent to the multiplication of length F (mm) with length S (mm) and the sine of an angle (rad), and dividing the whole by distance D (Table 3).

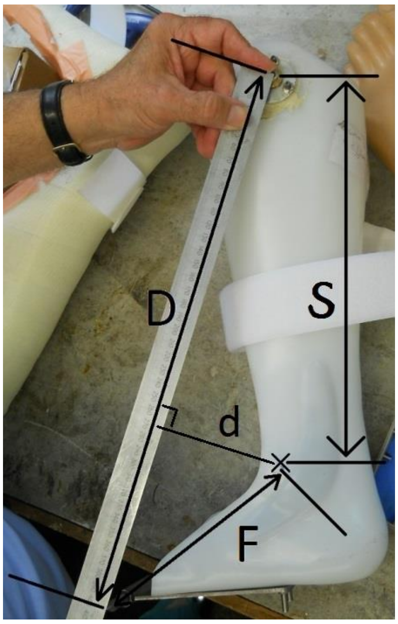


Figure 18: Dimensions relating to the AFO analysis.

$$x\ (mm) = \left[\frac{F * S * (\sin(\emptyset))}{D}\right]$$

Type of AFO	Side	D (mm)	F (mm)	S (mm)
Solid AFO with carbon fibre reinforcement	Lateral	401	161	280

Table 3: Initial values of length D,F and S.

D = distance between the fixation points

F = distance from the ankle axis to lower fixation point

S = distance from the ankle axis to upper fixation point

3.3.5.2 Data processing rigid metal frame

Once the measurements were taken and recorded, the data was manually entered and stored in a Excel spreadsheet and several functions were used to obtain the moment and angle (Appendix 2).

To calculate the moment (Nm) applied to the orthosis firstly the total weight (kg) per slotted weight added had to be calculated. This was done by adding the weights (g) used one by one together and divided each resulting value by 1000. The total weights were then converted from kilograms to newtons by multiplying the number of kilograms by 9,81.

The final step in calculating the moment was the multiplication of the forces (N) by the lever arm. All lever arms were found by measuring the distance between the metal wire and the marking of the lateral malleolus on the outside of the orthosis.

To calculate the deflection angle of the orthoses under load firstly the deflections measured had to be divided by 1000 to convert the small unit (1/1000 inch) to a larger distance unit (inch). Subsequently, inches were converted into millimeters by multiplying the number of inches by 25.4. The number of millimeters were then converted into the SI base unit for length, or meters, by dividing the deflection in millimeters by 1000. To calculate the angle in radians the deflection in meters was divided by the same lever arm (r) used to calculate the moment (Figure 19).

$$Arc\ length = s = \emptyset \times r$$

The final step in calculating the deflection angle was the conversion from radians to degrees by multiplying the angles in radians by 57.2958.

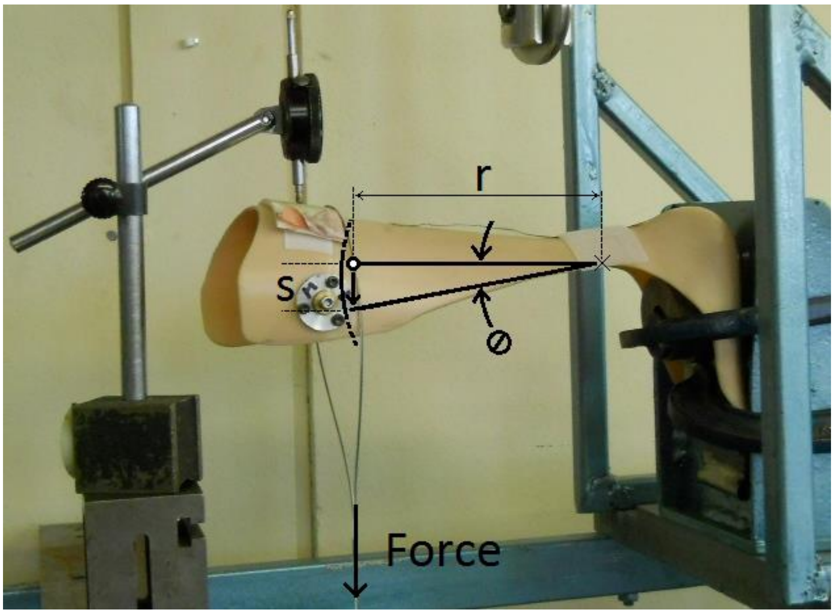


Figure 19: The radius of a circle (r) rotated through an angle (Ø) when a weight was added.

Chapter 4 Results

This Chapter presents the results acquired with the methodology reported in Chapter 3. First results obtained during the mechanical tests with the Instron and the self-fabricated device are presented. In the following section results obtained during gait analysis are given.

4.1 Test results Instron

The Instron machine acquired displacement of the most proximal attachment point and force applied to the AFO at a given time. Once the tests were completed, the data collected was exported to Microsoft Excel spread sheets for further calculations and creating graphs as shown in Figure 20.

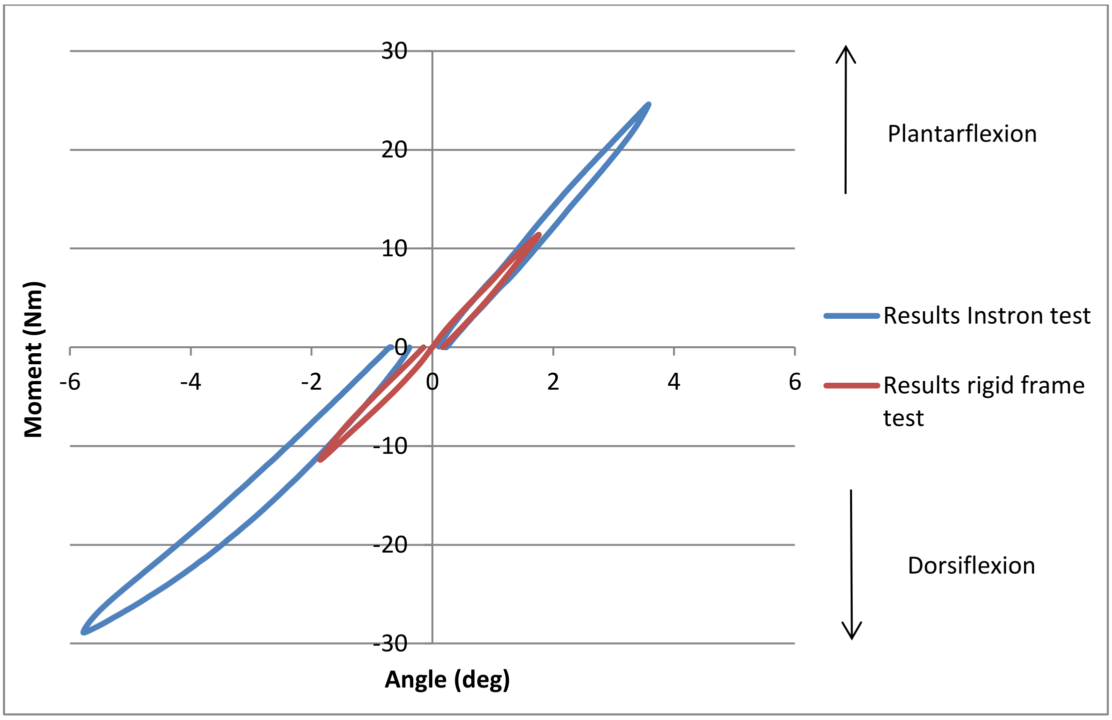


Figure 20: Test results solid AFO reinforced with carbon fibre inserts.

The blue lines in Figure 20 show the experimental results obtained by the Instron apparatus. It presents a moment-angle curve of three cycles in which the load (N) and displacement are averaged over three cycles. The red line in Figure 20 presents the test results produced by means of the rigid metal frame. Also this line shows the relationship between deflection angle and moment applied to the solid AFO, but this time over one test cycle. The x-axis or horizontal axis represents the ankle angle (deg) and the y-axis or vertical axis the moment applied (Nm). A steeper curve indicates higher stiffness.

In both curves viscoelastic property of the thermoplastic polymer called hysteresis is noticeable. This can be recognized to the hysteresis loops or the lines which show a difference between the loading and unloading paths. The Instron and rigid frame test results showed reasonable agreement between the compression tests and poor agreement in tensile testing among the slopes in the equations for the line of best fit (Table 4).

Type of test	**Apparatus**	**Instron**	**Rigid frame**	**Difference (%)**
Compression	Load path	7.018 Nm/deg	6.447 Nm/deg	8.857
	Unload path	7.114 Nm/deg	7.161 Nm/deg	0.656
Tensile	Load path	5.483 Nm/deg	6.071 Nm/deg	9.685
	Unload path	5.555 Nm/deg	6.553 Nm/deg	15.230

Table 4: Slopes best-fit straight trendline in compressive and tensile testing.

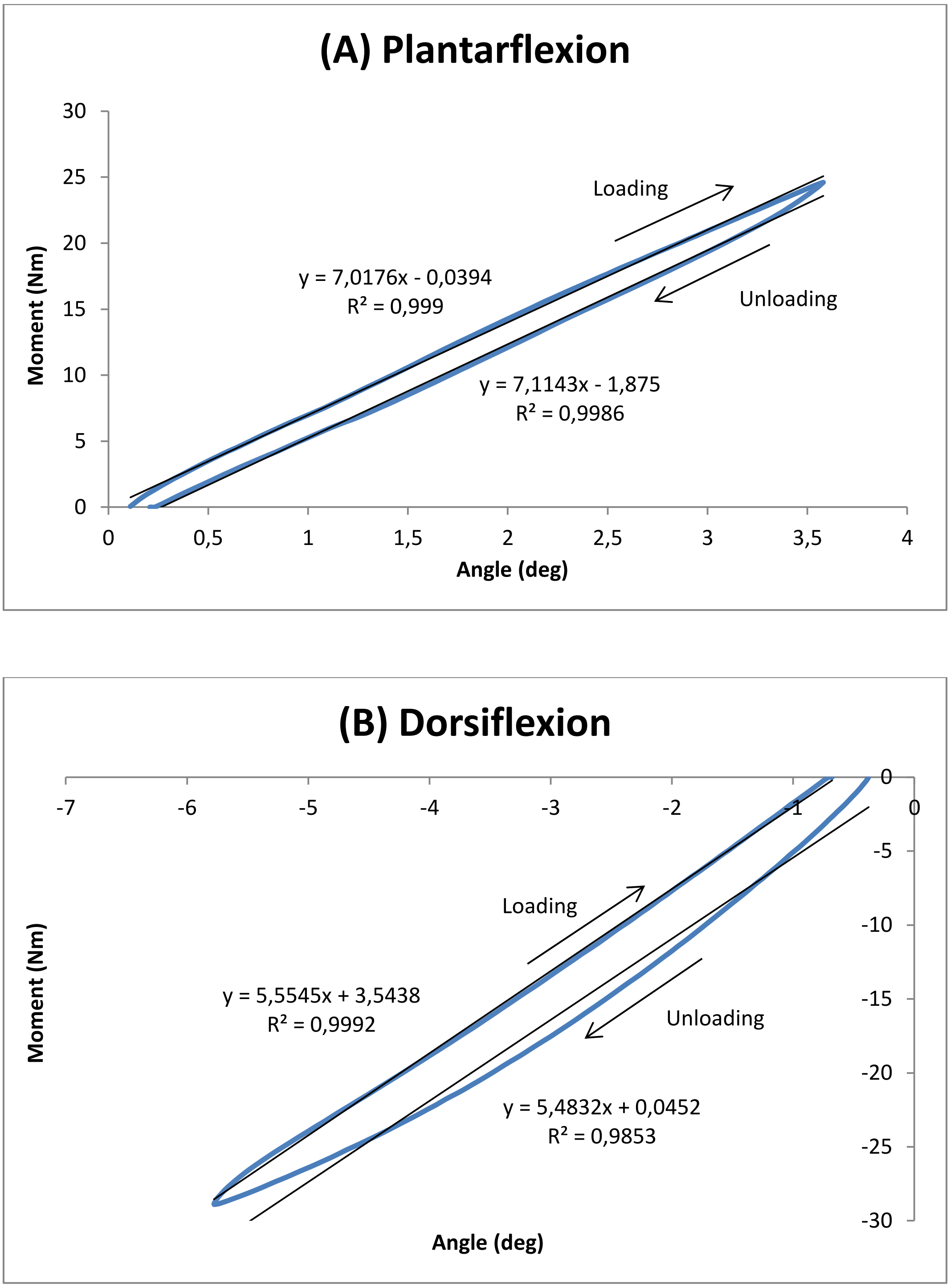


Figure 21: Moment-angle curve A & B of the solid AFO made of 4.6mm copolymer thermoplastic polypropylene.

Both loading and unloading part of the compression and tensile cycle are near coincident with the best-fit trendline by means of moment-angle relation, which is also confirmed by the high R^2 values of 0.9853 or higher (Figure 21).

The load and unload trendlines are parallel as confirmed by almost the same gradients in the equations of the best fitted straight line. Therefore, it can be stated that the hysteresis is low.

4.2 Test results custom-made test apparatus

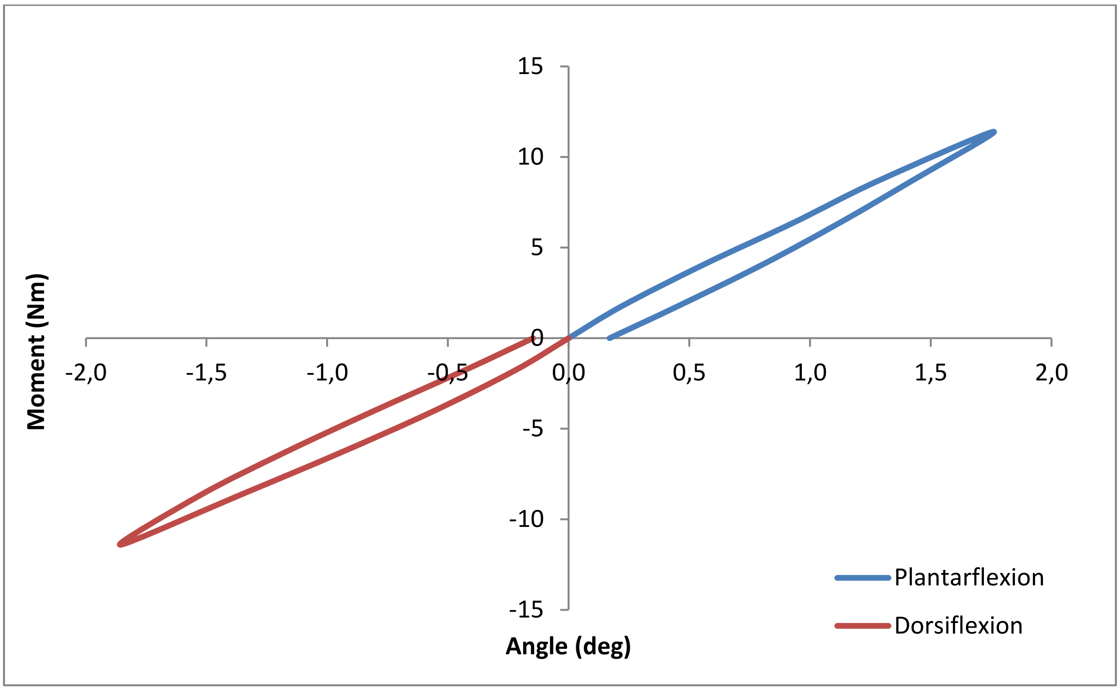


Figure 22: Solid AFO with carbon fibre reinforcement.

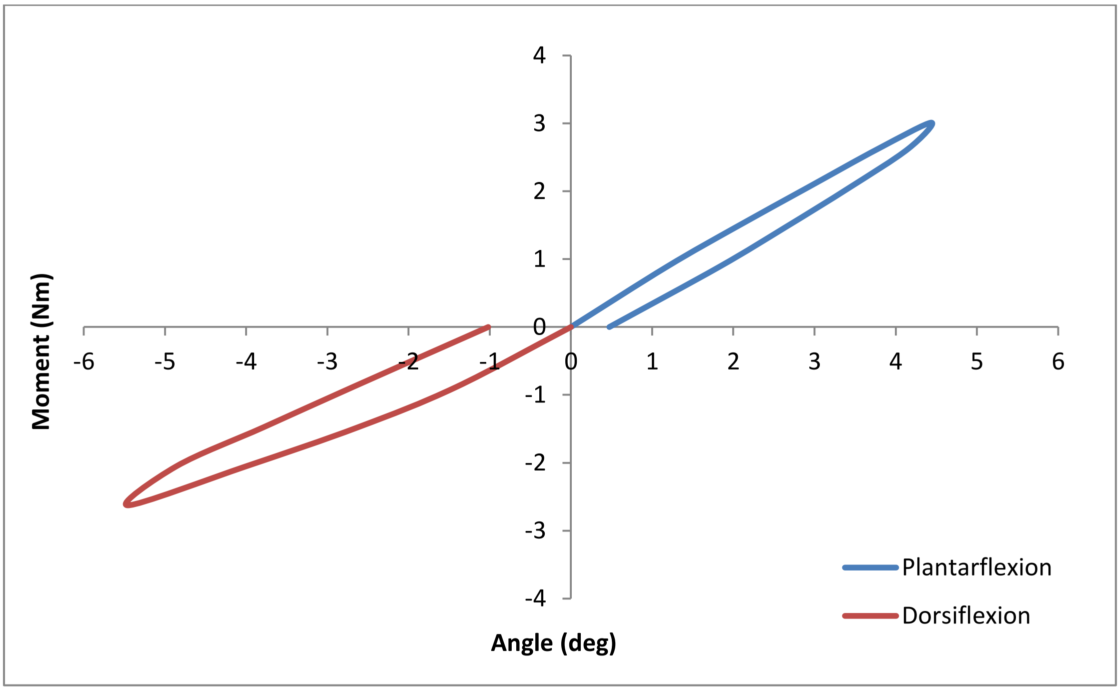


Figure 23: Posterior leaf spring AFO.

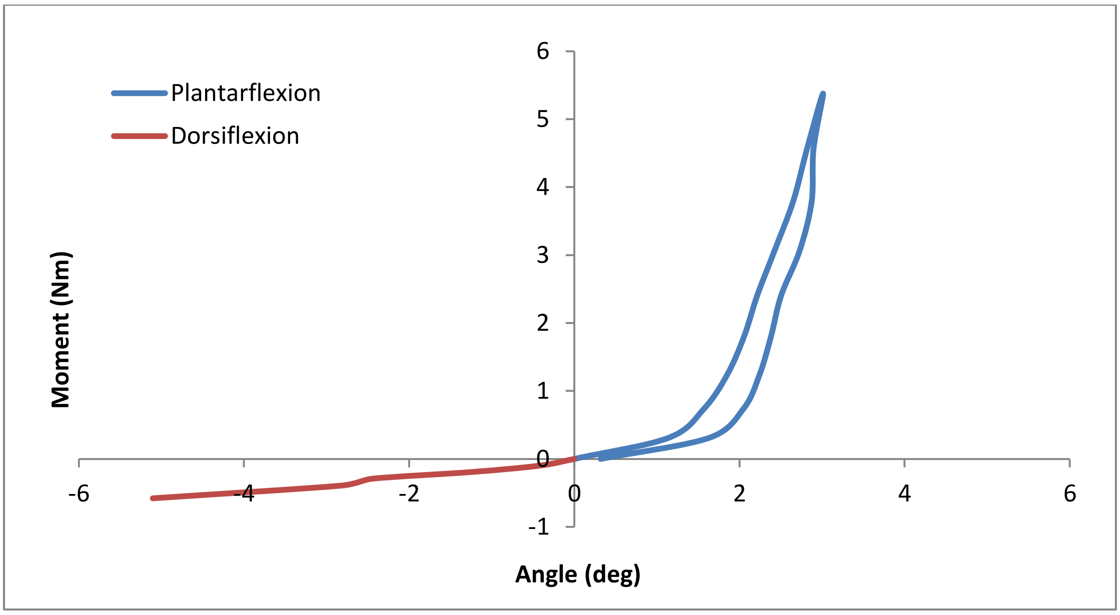


Figure 24: Six-layer SWIFT Cast.

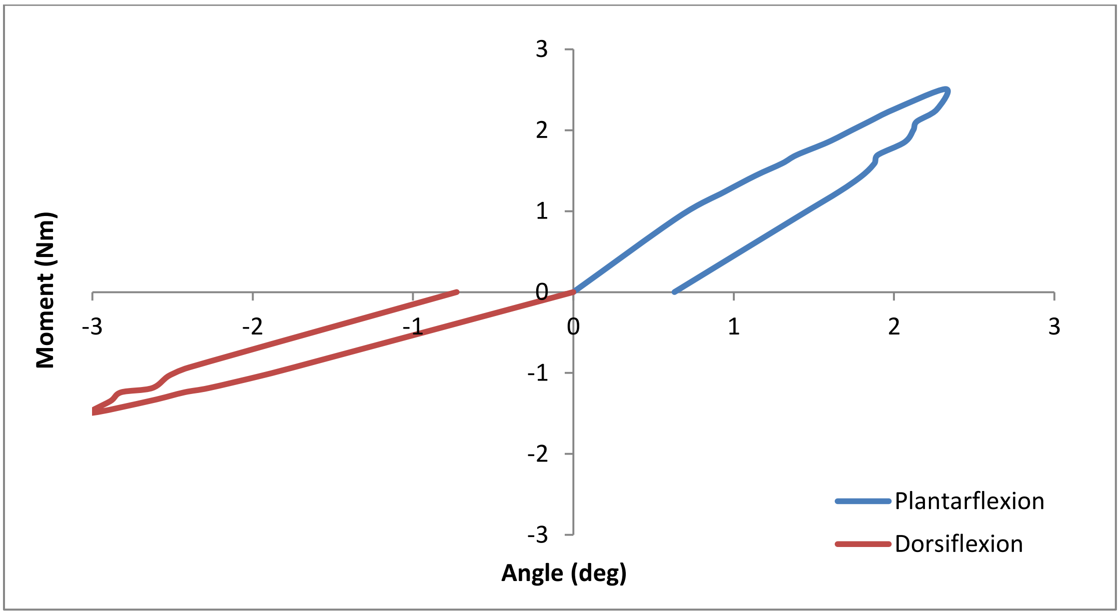


Figure 25: Eight-layer SWIFT Cast.

Figure 22 to 25 show the relationship between the angular deflection around the ankle section of the AFOs and the moment applied to the AFOs. The x-axis or horizontal axis represents the deflection angle of the footplate with respect to the calf section of the orthosis in degrees and the y-axis or vertical axis the moment of the force applied in newton meter.

The sign convention is such that a positive value represents a plantarflexor moment and a negative value corresponds to a dorsiflexor moment around the ankle section of the AFO.

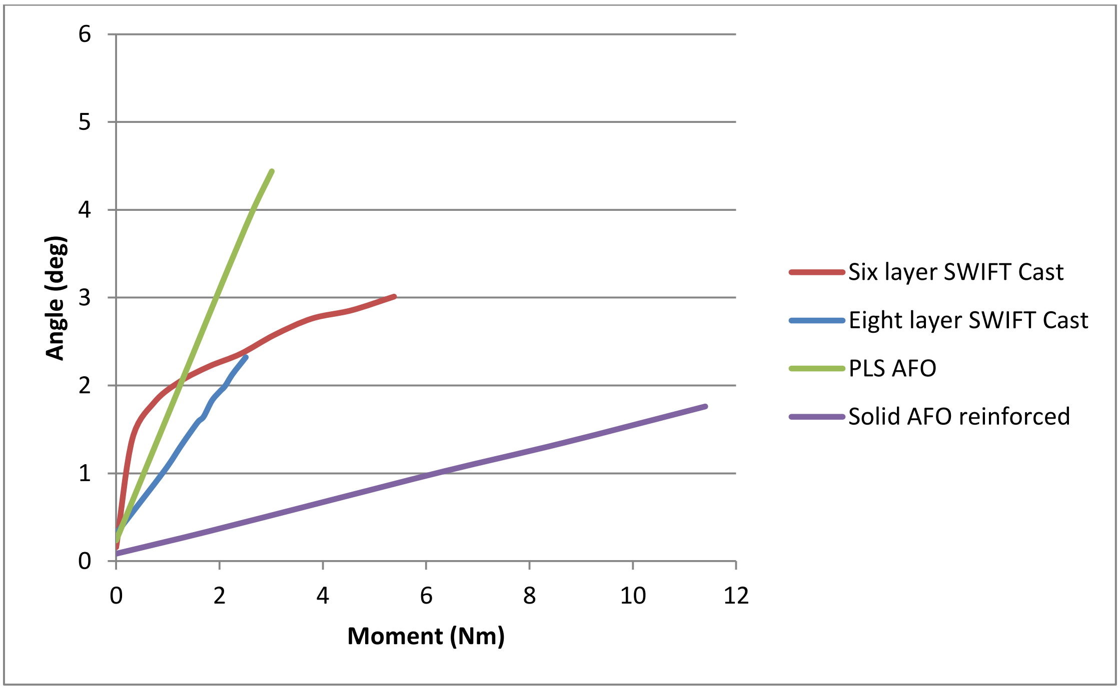


Figure 26: Plantarflexion results. Moment-average deflection angle curve

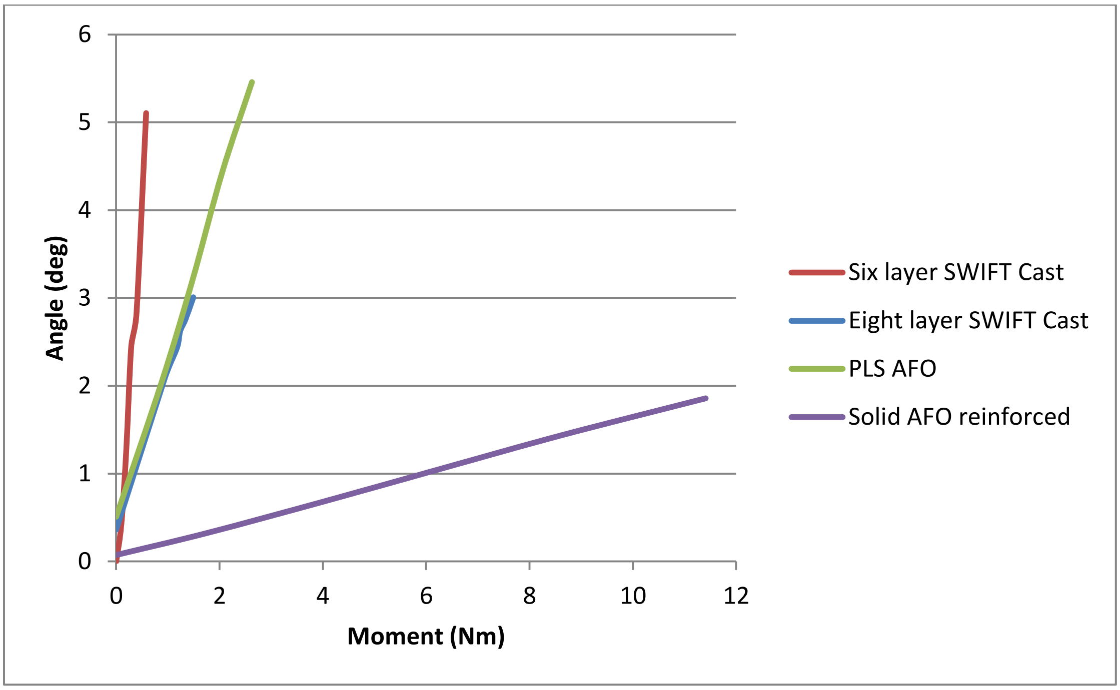


Figure 27: Dorsiflexion results. Moment-average deflection angle curve

In contrast to Figure 22 to 25, the horizontal axis of Figure 26 and 27 represent the moment of the force in newton meter and the vertical axis the angle in degrees. Here applies, the steeper the line or curve the higher the flexibility or lower the stiffness of the orthosis.

The results show that:

Six-layer SWIFT Cast

- The six-layer SWIFT Cast is the most flexible orthosis in both plantar and dorsiflexion of the four AFOs (Figure 26 & 27).
- The six-layer SWIFT cast doesn't show a linear relationship between moment applied to the orthosis and the associated deflection angle from 0.5 degrees.
- The six-layer SWIFT Cast is more flexible in dorsiflexion and less flexible, thus more stiff, in plantarflexion. The latter only applies to the linear part of the graph.
- The curve of the six-layer SWIFT Cast shows an irregular pattern. In other words, a non-linear relation between angle and moment was observed (Figure 24).
- There was no compressive test conducted in which the six-layer SWIFT Cast was gradually unloaded.

Eight-layer SWIFT Cast

- The eight-layer SWIFT Cast is stiffer than the six-layer SWIFT Cast in both dorsi- and plantarflexion.
- The stiffness of the eight-layer SWIFT Cast both in plantar- and dorsiflexion is fairly similar to the stiffness of the PLS AFO. The SWIFT Cast seems slightly stiffer in tensile testing (Figure 26).
- The eight-layer SWIFT Cast deflects more under compressive than tensile forces.
- The loading and unloading paths of the six-layer SWIFT Cast show a less irregular pattern and look a bit like the curves of the solid and posterior leaf spring AFO.

PLS AFO

- The PLS AFO has a higher flexibility and thus a lower stiffness in dorsiflexion than in plantarflexion. In other words, the PLS AFO deflects more under compressive than under tensile forces (Figure 23).

Solid AFO with carbon fibre reinforcement

- The solid AFO reinforced with carbon fibre inserts has clearly the most rigid properties in both compressive and tensile testing (Figure 26 & 27).
- The solid AFO deflects more under compressive than tensile forces (Figure 22).

4.3 Results thickness testing

The wall thickness of all four AFOs were measured at four locations in order to be able to calculate the mean wall thickness. All measurements, at the medial malleoli, lateral malleoli, footplate and the proximal aspect of the calf section, were performed by a single person using a thickness gauge as shown in Figure 28. The measured values are reported in Table 5.

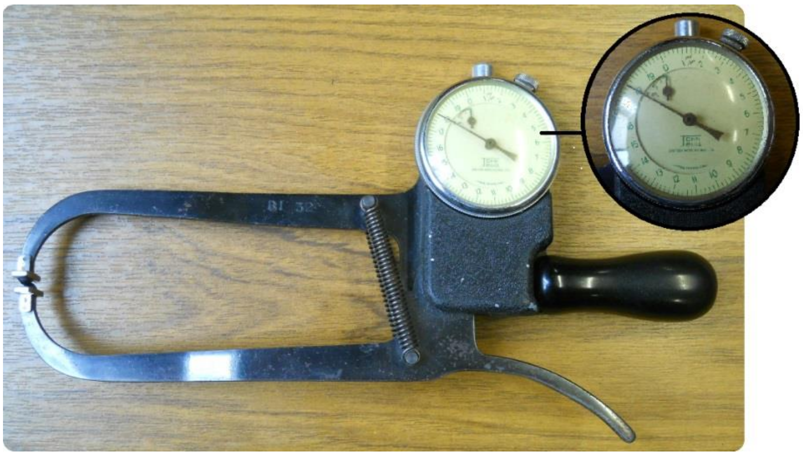


Figure 28: Thickness gauge used to measure the wall thickness of all four AFOs.

	Wall thickness of four AFOs measured at four points (1/10 mm)				
Type of AFO	Medial malleolus	Lateral malleolus	Foot-plate	Proximal aspect of calf section	**Mean (1/10 mm)**
Six-layer SWIFT Cast	25	10	52	60	36.80
Eight-layer SWIFT Cast	26	26	63	82	49.30
3.0 mm PLS AFO	22	18	19	22	20.25
4.6 mm reinforced solid AFO	36	40	33	34	35.75

Table 5: The results of thickness tests on four different types of AFOs

None of the AFOs were trimmed to the same landmarks and therefore no direct comparisons between the four AFOs could be made.

The thickness measurements conducted revealed that the walls of the SWIFT Casts were on average the thickest. The walls of the both plastics were clearly thinner and seemed over the entire AFO length to remain the same. The eight-layer SWIFT Cast had on average the thickest and the posterior leaf spring the thinnest walls.

4.4 Test results gait analysis

The moments were considered as positive when the ground reaction force tended to rotate the distal segment of the joint anticlockwise in relation to the proximal joint segment and negative when the GRF tended to rotate the distal segment clockwise (Figure 29). The ankle joint angle was considered as a positive when the forefoot rotated upwards. The knee and hip joint angles were considered as a positive angle when the these joints flexed. Sample kinematic and kinetic data for the ankle, knee and hip joint are reported in Table 6.

Variables		Walking conditions				
		Control condition (Mean)	Walking with a six-layer SWIFT Cast (Mean)	Walking with an eight-layer SWIFT Cast (Mean)	Walking with a PLS AFO (Mean)	Walking with a reinforced AFO (Mean)
Angles (^{o})						
Max. ankle plantarflexion in early stance	A1	-3.944	-3.197	-3.731	-0.186	5.747
Max. ankle dorsiflexion in late stance	A2	23.471	16.808	17.156	19.742	17.200
Max. knee flexion in early stance	K1	36.217	39.176	39.256	41.422	41.177
Min. knee flexion in late stance	K2	4.010	5.341	3.655	3.252	9.481
Max. hip flexion in early stance	H1	44.784	47.568	46.626	45.529	50.375
Max. hip extension in late stance	H2	-10.445	-6.954	-9.606	-11.791	-10.091

Moments (Nm)						
Max. ankle dorsiflexor moment in early stance	A3	-25.670	-30.820	-28.939	-22.533	-27.82
Max. ankle plantarflexor moment in late stance	A4	115.029	114.290	127.417	105.112	128.940
Max. knee extensor moment in mid-stance	K3	73.501	88.745	93.671	88.845	90.816
Max. knee extensor moment in late stance	K4	24.002	28.164	24.891	22.960	21.699
Max. hip extensor moment in early stance	H3	69.045	81.608	71.560	67.676	74.880
Max. hip flexor moment in late stance	H4	-77.432	-72.933	-75.250	-78.795	-78.280

Table 6: Joint angle and moment parameters for the left leg of the able-bodied subject as mean over five walking cycles.

The ankle joint exhibited a reduced peak ankle plantarflexion in early stance when the six-layer SWIFT Cast, eight-layer SWIFT Cast, posterior leaf spring or the solid AFO was worn on the left leg. The use of the carbon-fibre reinforced AFO even resulted in a dorsiflexed ankle position during early stance.

Walking with the four different orthoses also resulted in: a reduction in peak ankle dorsiflexion in late stance, an increase in peak knee flexion during early stance and an increase in peak hip flexion during early stance for the left leg.

Walking with the four different orthoses resulted in a remarkable increase in peak knee extensor moments in mid-stance for the left leg. The use of the six-layer SWIFT Cast, eight-layer SWIFT Cast and solid AFO resulted in increased peak ankle dorsiflexor moments in early stance and increased peak hip extensor moments in early stance.

The use of the six- and eight-layer SWIFT Cast resulted in a decrease in hip flexor moments in late stance and in an increase in knee extensor moments in late stance, while walking with a posterior leaf spring or a solid AFO resulted in an increase in peak hip flexor moments in late stance and an decrease in knee extensor moments in late stance.

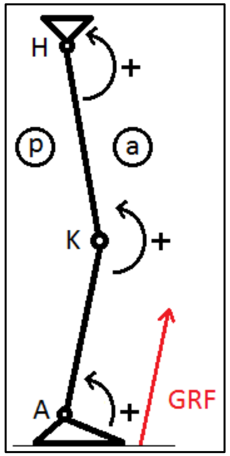


Figure 29: Convention moments at the (A) ankle, (K) knee and (H) hip joint caused by the GRF.

	Wilcoxon Signed Rank Test			
Joint parameters	Walking without AFO vs. walking with a 6-layer SWIFT Cast	Walking without AFO vs. walking with an 8-layer SWIFT Cast	Walking without AFO vs. walking with a PLS AFO	Walking without AFO vs. walking with a reinforced solid AFO
Angles (°)	p-value	p-value	p-value	p-value
A1	0.281	0.590	**0.059**	**0.059**
A2	**0.059**	**0.059**	**0.059**	**0.059**
K1	**0.059**	**0.059**	**0.059**	**0.059**
K2	0.106	0.787	0.281	**0.059**
H1	0.106	0.106	0.418	**0.059**
H2	**0.059**	0.418	0.281	1.000
Moments (Nm)				
A3	**0.059**	0.281	0.281	0.590
A4	0.787	0.481	0.106	**0.059**
K3	**0.059**	**0.059**	**0.059**	**0.059**
K4	0.178	0.787	0.787	0.590
H3	**0.059**	0.590	1.000	0.418
H4	0.178	0.787	0.787	0.590

Table 7: Comparison of the kinematics and kinetics of four walking conditions to the control condition. In the second to the last column p-values deduced from conducted Wilcoxon signed-rank tests are reported.

None of the p-values were less than 0.05. Therefore, it can be suggested that none of the four orthoses seem to have significantly affected the ankle, knee and hip joint moments nor the ankle, knee and hip joint angles of the left leg during gait.

However, p-values near 0.05 and less than 0.1 were found, through which it can be suggested that the orthoses had the potential to significantly influence the joint parameters. It can be suggested that the orthoses had the most influence on the ankle and knee joint angles because these joint parameters are related to the smallest p-values.

The orthoses had the least influence on all the joint moments because most of them are related to high p-values. It seems that the stiffest orthosis or the solid AFO reinforced with carbon fibre inserts had the most influence on the joint angles, followed by the most flexible orthosis or the six-layer SWIFT Cast. The second stiffest orthosis, the eight-layer SWIFT Cast, seem to have the least influence on the joint angles and moments, followed by the PLS AFO.

Chapter 5 Discussion

The aim of the pilot study was to quantify the stiffness of four different orthoses and to evaluate their direct effects on gait characteristics of an able-bodied subject.

5.1 Mechanical testing

The results obtained in the mechanical tests with the Instron E10000 and the self-fabricated device are applicable to todays practice because mechanical AFO characteristics are seldom quantified while they determine the function of ankle-foot orthoses in gait.

The behaviour of two polypropylene and two Scotchcast™ orthoses were investigated under compressive and tensile loading and unloading conditions.

The viscoelastic nature or the time dependent behaviour of the plastic PLS AFO and solid AFO were revealed showing:

1. Nearly a linear moment-angle relation at small loads and a decrease in the linear relation when the load subjected to the orthoses increased.
2. No full recovery to its original length, directly after the applied loads were removed.

The following explanation underlie both findings. Initially both plastic AFOs showed a linear relation because small loads only led to stretching of the atomic bonds. When the load increased, polypropylene started to flow and intermolecular or secondary bonds broke which resulted in energy dissipation and hence hysteresis. Rearranging the bonds takes time, more time than the one allowed during the mechanical tests. As a result, no full recovery was measured. When students consider to continue the pilot study or repeat the measurements, then performing the measurements over a longer time period can be recommended.

Reasonable agreement was found between the *compression* tests carried out with the Instron E10000 and the self-fabricated testing device with respect to the measured values. The values measured were less consistent across the Instron machine and the self-fabricated device when the solid AFO was tested under *tensile* loads.

There is no direct explanation for these findings. However, it is given that the solid AFO was only tested once on the self-fabricated device and three times on the Instron. Further research, in which multiple orthoses of each type of orthosis are repeatedly tested, is required to evaluate whether these findings are correct and to draw further conclusions.

The six-layer SWIFT Cast was found to be the most flexible orthosis in both plantar- and dorsiflexion. This wasn't a surprise and can be explained in various ways. Firstly the materials used for the SWIFT Casts were less able to provide resistance to plantar- and dorsiflexion movements in the sagittal plane. Secondly the stiffness of the cast remained limited because the ankle trimlines only extended posteriorly to the malleoli. Thirdly the material present at the level of the ankle was a flexible bandage called soft cast. Bandages already start to elongate under low forces.

It was also found that the deformation of the six-layer SWIFT Cast was not recorded during unloading in dorsiflexion. This had to do with ankle section of the cast, which was found to be so weak that the cast already could not return to its original length once the cast was securely fixed.

Initially, the moment and angle of the six-layer SWIFT Cast showed a linear relationship. However, after 0.5 degree the straight line made a curve, which means that the stiffness of the cast increased from that point. This can be explained by the G-clamps which possibly came into contact with the trimlines of the cast and restricted the cast in the ability to continue to deflect.

It was expected that the eight-layer SWIFT Cast would:

1. Be stiffer than the six-layer SWIFT because its back slab consisted of eight layers.
2. Deflect more under compressive than tensile forces due to its shape.

It was not expected that the eight-layer SWIFT Cast and the posterior leaf spring almost would be equally stiff in both compressive and tensile testing.

This led the researchers to the question of whether the cheap and easy to manufacture SWIFT Cast could replace the PLS AFO, as soon as the cast is further developed, or could be used for the same target group as the PLS is used for.

It also led to the question of whether it should be considered to transfer the knowledge about the cast to third world countries, so that orthotists there also get the opportunity to try this relatively inexpensive device on acute stroke patients. But first, further research with acute stroke patients is required to answer these questions.

The 4.6 mm solid AFO showed as expected the highest resistance to plantar- and dorsiflexion movements. This could be explained by the location of the ankle trimlines. In contrast to other three orthosis, these extended to the apex of the subjects' malleoli.

It can also be explained by the type of material the orthosis was made of, namely a single polypropylene sheet with a thickness of 4.6 mm. The posterior leaf spring was only made from a 3.0 mm polypropylene sheet and the SWIFT Casts of soft materials. A third factor that most likely had contributed to a high AFO stiffness were the carbon fibre inserts at the malleoli level. Carbon fibre inserts were not incorporated at the ankle section of the other three orthoses.

All four orthoses tested deflected more under compressive than under tensile loads due to their shape. This finding was no surprise with respect to the plastic AFOs, but with respect to the SWIFT Casts it was because no studies were conducted on the mechanical characteristics of SWIFT Casts.

The Instron machine was initially chosen to perform the mechanical tests because of its high reliability. However, an alternative test method had to be sought after realizing the Instron machine would probably rupture three of the four orthoses. It was decided to use a self-fabricated testing device in addition to the Instron E10000. A disadvantage of the self-fabricated testing device was its unknown reliability and accuracy. Since it is a simple and manually operated device, its reliability can be described as questionable.
Further research, in which the mechanical properties of different AFOs are repeatedly measured, is needed to find the reliability of the device.

5.2 Wall thickness orthoses

It was not possible to make direct comparisons between the stiffness of the four orthoses and their wall thickness since none of the AFOs were trimmed to the same trimlines, manufactured in the same thickness nor were made of the same materials.

The walls of the eight-layer SWIFT Cast were on average the thickest compared to the other three orthoses, whereby the wall thickness over its length seemed to vary the most as well. The walls of the plastic orthoses and in particular the walls of the posterior leaf spring were on average the thinnest, whereby the wall thickness over its length seemed to vary the least. The findings can be attributed to the material use. The plastics orthoses were only made from single polypropylene sheets, while SWIFT Casts were made of various materials such as 3M™ soft cast and casting tapes which were wrapped over each other.

5.3 Gait analysis

The male able-bodied subject was able to successfully complete all five walking trials.
The use of the Vicon system with an able-bodied person did not directly provide an insight into the effects AFOs have on the kinematics and kinetics of stroke patients, but did gave an indication of what the four orthoses could do with respect to a human body.

None of the p-values were less than 0.05 through which there was not enough evidence to conclude that there were significant differences between walking with shoes only and walking with shoes and an orthosis as regard to the lower extremity joint moments and angles of the left leg. However, p-values near 0.05 and less than 0.1 were found, through which there seem to be enough evidence to conclude that the orthoses had the potential to significantly influence the lower extremity joint moments and angles of the left leg during walking.

The AFOs seem to have influenced the ankle joint angles the most. This was no surprise because the orthoses used encompassed the ankle joint during walking. It was a surprise that all four AFOs had an considerable influence on the knee joint angle because:

1. They did not encompassed the knee joint.
2. Able-bodied subjects are normally able to compensate for limitations.
3. The SWIFT Casts seemed to provide little resistance to the weights during the mechanical tests through which certainly no changes were expected at the level of the knee due to walking with a six- or eight-layer SWIFT Cast.

The solid orthosis reinforced with carbon fibre inserts seems to have the most influence on joint angles. This can be explained by the stiffness of this orthoses which was found to be highest. Based on the p-values, it can also be suggested that the six-layer SWIFT Cast has the second largest impact on joint angles. This was not expected and is difficult to explain because the test results had revealed that this cast is the most flexible of the four orthoses in the sagittal plane.
The eight-layer SWIFT Cast seems to have the least influence on the joint angles and moments, followed by the PLS AFO. This was also unexpected because research had shown that these two orthoses possessed the second and third highest stiffness. Further research is required to confirm and explain the unexpected findings.

All four orthoses seemed to have little or no influence on the joint moments. Therefore, it can be suggested that wearing these orthoses have little to no influence on the magnitude of ground reaction force and its perpendicular distance from the joint.

Several interesting findings were discovered when comparing the averaged peak joint angle and moment parameters of the four walking conditions with the control trial by visual inspection (Table 6).

The ankle joint exhibited a reduced peak ankle plantarflexion in early stance when the orthoses were worn on the left leg, probably because the casting angle, the overall shape and the stiffness of the orthoses restricted ankle plantarflexion. This is a positive finding because it confirms that the main function of an orthosis in stroke patients with dorsiflexor weakness, namely to assist dorsiflexion in swing and immediately at heel strike, has the potential to be reflected in practice.

It was found that the use of all four different orthoses resulted in:

- A reduction in peak ankle dorsiflexion in late stance. Reductions in ankle dorsiflexion movements could be expected based on the findings in the mechanical tests.
  This effect produced by the ankle-foot orthoses is desirable in hemiplegic patients because they often do not have an adequate gastrocnemius length. Blocking ankle dorsiflexion is a way to meet the gastrocnemius shortening and ensure the alignment of the GRF is in front of the knee joint, through which an external knee extensor moment in mid- to late stance is generated and in turn addition knee stability obtained.
- A remarkable increase in peak knee extensor moments in mid-stance were found for the left leg. This confirms that blocking ankle dorsiflexion actually results in the obtaining more knee stability.
- An increase in peak knee flexion during early stance.
  It was positive to see that all four AFOs showed this effect because the majority of the hemiplegic patients have difficulties in controlling knee recurvatum. The use of the orthoses seems to enhance knee flexion by opposing knee extensor activity.
  In clinical practice, this could lead to the reduction of the vertical displacement of the centre of gravity of the patient’s body and hence the reduction of the patient’s energy cost.

The use of the six-layer SWIFT Cast, eight-layer SWIFT Cast and solid AFO resulted in an increase in peak ankle dorsiflexor moments after heel contact. This is also a positive finding in relation to stroke patients because it indicates that both orthoses help in preventing the left foot from rotating too quickly from initial contact to foot-flat, which is desirable when stroke patients suffer from weakness of dorsiflexor muscles.
Since the posterior leaf spring did not produce this beneficial effect, it might be interesting to find out what it precisely does and doesn't do in stroke patients. This requires further research with stroke patients.

In contrast to posterior leaf spring and the solid AFO, the use of the SWIFT Casts resulted in a decrease in hip flexor moments in late stance and in an increase in knee extensor moments in late stance. Stroke patients could benefit from this latter because it helps to prevent the affected leg from collapsing. It is a pity that the use of the PLS and solid AFO results in an decrease in knee extensor moments, because it could make the patients leg less stable and/or force them to compensate even more.

Good repeatability in joint kinematic and joint kinetic data was observed among the five walking trials of each walking condition throughout a gait cycle (Appendix 3).
Repeatable results in joint kinematics and joint kinetics were also found, when comparing the control condition with the other walking conditions for each joint parameter, except for the ankle joint angle (Appendix 4).

Besides the findings, also positive and negative comments on the use of the various instruments can be made.
The strength of the pilot study lay in the use of three devices, because this enabled the researchers to combine the test results of the mechanical tests and gait analysis. The solely use of the Vicon system, the Instron machine or the self-fabricated test apparatus would have led to the reduced release of knowledge about the mechanical contribution of four different orthoses on gait characteristics.

One of the key advantages of using gait analysis or functional testing over mechanically testing of orthoses was the lower leg of the subject which provided internal support, and the footwear which provided external support to the orthosis during the performance of the walking trials just as in practice. Applying loads to an orthosis through a mechanical test device does not fully correspond to physiological forces applied to AFOs by the human body during gait.

Gait analysis was concluded by an oral questionnaire. The able-bodied subject had indicated in this questionnaire that:

- Both SWIFT Casts were “the most comfortable orthoses”, because they “doesn’t harm you at all.”
- The posterior leaf spring seemed “more flexible” than the solid AFO.
- To “not particularly like” the posterior leaf spring because it provided medial arch support.

It is likely that when stroke patients would fit the SWIFT Cast, they would have said the same as the able-bodied subject, because SWIFT Casts are made out of comfortable and soft materials which have flexible edges and not of the usual hard plastic materials.
In other words, it seems there is still a considerable potential in the area of comfort. This should be taken into account in the further development of orthoses.
This latter problem concerning the medial arch support became apparent too late and probably could have been solved by the orthotist prior to gait analysis. Depending on the extent to which the subject had suffered from the medial arch support, one should keep in mind that this inconvenience could have affected the results.

5.4 Limitations

Several limitations to this pilot are acknowledged and suggestions of how to improve the study given in this section.

5.4.1 Mechanical testing

A limitation of the mechanical tests is only one ankle-foot orthosis of each type was tested and put through one up to three test cycles.

Testing multiple ankle-foot orthoses of the same type prior to data collection:

1. Would have avoided misleading test results.
2. Would have made the results more credible and accurate.
3. Would have led to a better simulation of situations in which stroke patients walked with an orthosis.

In particular, this applies to the posterior leaf spring and solid AFO because they are made of plastic or viscoelastic materials. According to the study of Major et al. (2004), their loading pattern becomes more consistent after approximately four loading cycles.

It could have been interesting to put the orthoses through lots of test cycles. This had enabled the researchers to determine whether walking over a certain period of time would have influenced the AFO stiffness and to which extent.

A second limitation concerns the upper and lower jig. Despite the proximal attachment points were flattened by the use of circular EVA foam and the attachment points aligned relative to each other using a laser, it was found that the jigs were not exactly parallel to each other. As a result, a part of the load applied might be absorbed in other areas of the orthosis due to rotation, instead of being fully absorbed in the sagittal plane. To avoid this problem in the future, it would be interesting to develop a simple device which would be able to alignment the attachments points perfectly parallel to each other.

Another limitation concerning the mechanical tests had to do with temperature. This variable was not controlled when the mechanical tests were performed in both testing environments. Although no marked changes were noticed by the student nor the operator, temperature could have affected the test results of the plastic AFOs.
The presence and the use of an accurate thermometer and an air conditioning control unit in both environments could have minimized the influence of this variable.

One of the aims of this pilot study was to quantify the stiffness of the AFOs in the sagittal plane, because in this plane motion primarily occurs. However, ankle-foot orthoses deflect in all three anatomical planes when they are worn by patients. Therefore, it can be stated that the testing method used was limited.

Initially, there were no markings on the PLS AFO to indicate the apex of the medial and lateral malleoli. These were added were added after the discovery on basis of markings that were present on the other orthoses. As a result, a small systematic error could be present in the test results of the PLS AFO.

The last limitation of the mechanical tests has to do with creep. One should have paid more attention to this phenomenon during testing. However, because it was not expected that the SWIFT Casts would also show creep during the measurement periods, it was done too little. Although it should be noted that one could have been foreseen the presence creep, given the polyurethane resin present in the casting tape of casts.
As a result of the misjudgment , the researchers did not comply with fixed measurement periods through which one allowed that one orthosis could deform more in the measurements periods than the other.

5.4.2 Gait analysis

The main limitation of gait analysis was the small sample size of one *male able-bodied* subject. No stroke patient nor more male and female able-bodied subjects were recruited to participate in the pilot study due to the lack of time and the shortage of AFO materials.
As a result of the small sample size, data points between trials were not normally distributed and the results found through gait analysis could not be generalized to the general population or a stroke population. Further research is required to explain the possible benefits from AFOs on gait characteristics in hemiplegic (stroke) patients.

Due to the constrains of time, it was chosen to focus on:

1. The leg on which the orthosis was worn and thus to ignore the data for the right leg.
2. Kinematic and kinetic parameters and thus to leave spatiotemporal measures to one side. The latter was also decided for reason that it was expected that the AFOs would not significantly influence the spatiotemporal parameters. The AFOs would indeed be worn by an able-bodied subject, which could easily compensate the restrictions that AFOs would impose on the left leg.

Chapter 6 Conclusions and recommendations

6.1 Conclusions

The aims of this pilot study was to:

1. Quantify the stiffness of four different ankle-foot orthoses in the sagittal plane.
2. Determine the influence of these orthoses on kinematic and kinetic gait characteristics of the ankle, knee and hip joint of a male able-bodied subject in the sagittal plane during walking.

The reliability of the self-fabricated device was not known through which all the results found by the use of this device should be seen as an indicative.

The mechanical tests results revealed the time dependent behaviour of all four AFOs.
The six-layer SWIFT Cast was found to be the most flexible orthosis in both plantar- and dorsiflexion. Initially, the cast showed a linear moment-angle relationship in plantarflexion testing. However, after 0.5 degree the cast showed a more nonlinear relation and a strong increase in stiffness. This was not expected and could be ascribed to an error in the measurement setup. In other words, the results found in plantarflexion testing are probably incorrect.
The eight-layer SWIFT Cast and the posterior leaf spring were found to be equally stiff in both compressive and tensile testing. Therefore, It could be considered to use the eight-layer SWIFT cast for the same target group as the PLS is used for. The 4.6 mm solid AFO showed as expected the highest resistance to plantar- and dorsiflexion movements.
Further, it was found that all four orthoses tested deflected more under compressive than under tensile loads due to their shape.

Only p-values near 0.05 and less than 0.1 were found, through which there seem to be enough evidence to conclude that the orthoses had the potential to significantly influence the lower extremity joint moments and angles of the left leg during walking.
All four AFOs seem to influence the ankle joint angles the most and seem to have little or no influence on the joint moments.

The stiffest orthosis, solid orthosis reinforced with carbon fibre inserts, seems to have the most influence on joint angles, followed by the most flexible orthosis, six-layer SWIFT Cast. The second and third stiffest orthosis, the eight-layer SWIFT Cast and PLS AFO, seem to have the least influence on the joint angles and moments.

6.2 Recommendations for further study

There are many recommendations conceivable that can take further studies to a higher level.

Gait analysis

One able-bodied person was recruited for the pilot study. However, it would have been more interesting if stroke survivors were recruited to investigate the mechanical contribution of orthoses to hemiplegic gait.

It is strongly recommended to leave the manufacture of orthoses, the decision in which angle the lower leg should be positioned relative to the vertical and how far the trimlines should extend to a single qualified orthotist. Making these choices on beforehand lead to a strong reduction of variables.

Prior to the pilot study, qualified orthotist Robert Bowers had indicated that it would be beneficial for stroke patients to play with the inclination of the Shank Angle to Floor (SAF) in the cast in order to discover how this variable affects the stiffness of AFOs and within which angle range the patient the most benefits from the orthosis during walking. Due to time constraints, this could not be investigated. However, studying this subject, also known as tuning, would provide clinicians valuable information and make a big difference to stroke survivors.

In the pilot study, the movements of the left ankle, knee and hip were studied in the sagittal plane for the left leg. However, movements occur in three planes during walking. Therefore it should be considered to study the motion of *both legs* in *three planes*.

Moreover, it might be interesting not only to analyse the kinematic and kinetic data but also to analyse spatio-temporal parameters of gait, since orthoses also affect these.

The participant indicated after the gait analysis to find the SWIFT Cast the most comfortable orthosis. It is likely that other subjects would have said the same, since the orthosis is made of soft materials and has flexible edges.
This point should be taken into account in the further development of orthoses. Apparently there is still a considerable potential in the area of comfort.

Mechanical testing

No surrogate limb or other objects were fitted within the orthoses during mechanical testing. As a result, the orthoses could freely rotate and bend in all planes. However, in clinical practice the leg of a patient and the shoes worn does influence the movements of an orthosis. Therefore, it can be stated that the mechanical tests did not realistically simulated walking with an orthosis. When one would have fitted a surrogate human limb model within the AFO and forces would have been applied via this limb, than the results had matched to a greater extent with clinical practice. The use of a human limb in mechanical testing would have been the most ideal, because the viscoelastic properties of the human leg, which the surrogate limb does not exhibit, affect the stiffness of orthoses. Unfortunately, there were and are currently no devices available that can reliably measure AFO characteristics while an AFO is applied to the patients leg.

Three different types of ankle-foot orthoses were tested in the pilot study. Since also other AFO designs in other seizes are prescribed to stroke survivors, it could be interesting to measure their mechanical characteristics in the future.

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Appendix 1

Mechanical test data produced by Instron machine

Results of mechanically testing the 4.6 mm solid AFO with carbon fibre reinforcement in the Instron machine.

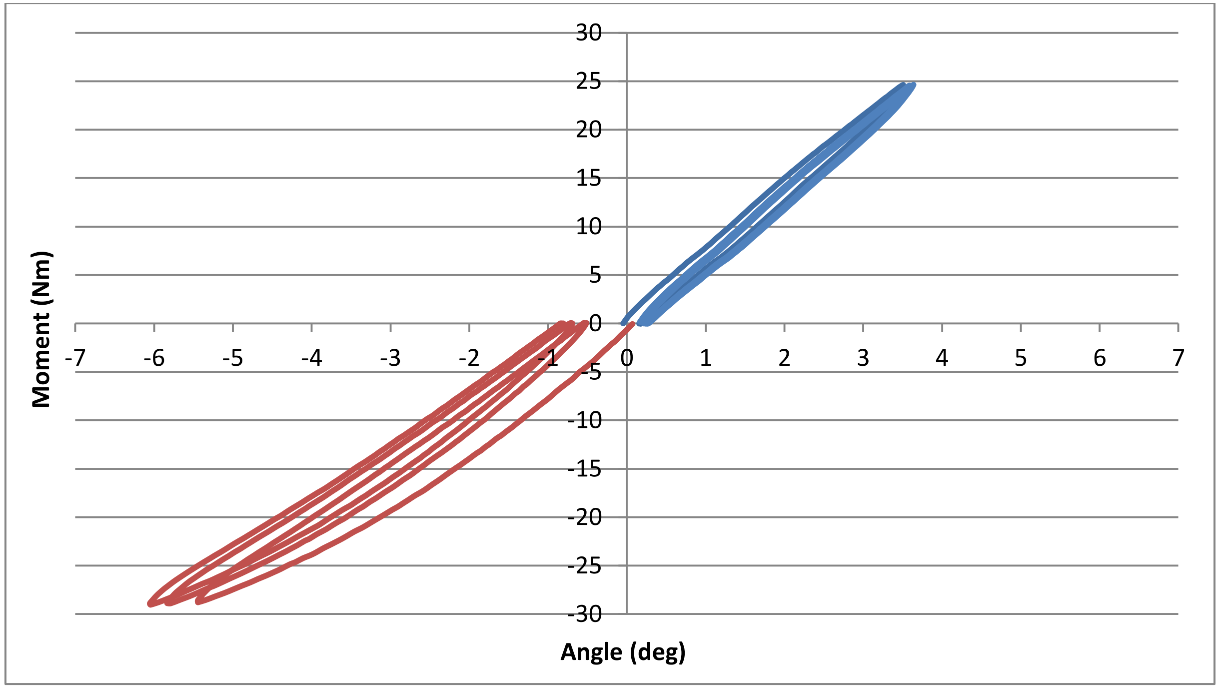


Figure 30: Test results obtained by the Instron E10000 when the solid AFO was put through three compressive (red lines) and three tensile (blue lines) cycles.

AVG Load (N)	AVG Displacement (mm)	Distance (mm) (D1)	Angle (D1) (rads)	Angle (rads)	Angle (deg)	Moment (Nm)
0,640172511	0,168199945	401,1681999	2,249697701	0,001921387	0,110087337	0,055986181
0,640172511	0,168199945	401,1681999	2,249697701	0,001921387	0,110087337	0,055986181
5,000031864	0,216981242	401,2169812	2,250255649	0,002479334	0,142055402	0,437026898
8,204138527	0,255295573	401,2552956	2,250694103	0,002917788	0,167176935	0,716758789
11,73782162	0,302655448	401,3026554	2,251236342	0,003460028	0,198244985	1,024910146
14,55433356	0,345354371	401,3453544	2,251725476	0,003949162	0,226270291	1,270200798
18,5463236	0,403926476	401,4039265	2,252396844	0,00462053	0,264736843	1,617477027
21,41192555	0,448427992	401,448428	2,252907242	0,005130927	0,293980466	1,866413796
25,06087534	0,504782468	401,5047825	2,253553968	0,005777654	0,331035176	2,18302759
28,00287989	0,556258473	401,5562585	2,254145086	0,006368772	0,364903737	2,437817056
31,14495426	0,607126938	401,6071269	2,254729582	0,006953267	0,398392857	2,709719224
34,4297414	0,661644605	401,6616446	2,255356399	0,007580085	0,434306856	2,99356953
37,9189911	0,720073118	401,7200731	2,256028633	0,008252318	0,472822988	3,294660974
41,62161301	0,783479774	401,7834798	2,256758669	0,008982355	0,51465102	3,613640847
44,46423923	0,835215543	401,8352155	2,257354742	0,009578427	0,548803434	3,858060152
48,59323303	0,907412114	401,9074121	2,258187168	0,010410853	0,596497935	4,212688644
51,40475618	0,963934062	401,9639341	2,258839367	0,011063052	0,633866208	4,453414409
54,86545463	1,02642249	402,0264225	2,259560927	0,011784612	0,675208547	4,749670519

57,96982596	1,082357126	402,0823571	2,260207269	0,012430954	0,712241194	5,015045002
61,75217529	1,147176151	402,1471762	2,260956816	0,013180501	0,755187076	5,338098004
65,09915305	1,207959849	402,2079598	2,261660231	0,013883916	0,795489805	5,623304333
68,49138687	1,271957243	402,2719572	2,262401394	0,014625079	0,837955315	5,911759832
71,86912621	1,33317531	402,3331753	2,263110905	0,015334591	0,878607332	6,198716397
74,84814773	1,389669932	402,3896699	2,263766139	0,015989824	0,916149457	6,451242294
78,04729976	1,453934876	402,4539349	2,26451204	0,016735725	0,958886425	6,721738887
81,56740417	1,522611645	402,5226116	2,265309791	0,017533476	1,004594182	7,019043654
84,8104277	1,58564363	402,5856436	2,266042558	0,018266244	1,046578675	7,292514138
87,93309641	1,64548617	402,6454862	2,266738769	0,018962454	1,086468586	7,55550393
91,75732421	1,710972898	402,7109729	2,267501227	0,019724912	1,13015421	7,877789064
94,97165369	1,76688753	402,7668875	2,268152721	0,020376406	1,167482067	8,148176493
97,88471585	1,819053812	402,8190538	2,268760943	0,020984628	1,202330632	8,392737336
101,3192224	1,876307573	402,8763076	2,26942893	0,021652615	1,240603455	8,681112096
104,9793263	1,937746326	402,9377463	2,270146266	0,022369951	1,281703805	8,987920178
108,4663036	1,998220676	402,9982207	2,270852872	0,023076558	1,322189362	9,279546836
111,5120482	2,051164538	403,0511645	2,271471922	0,023695607	1,357658296	9,533888128
114,9298064	2,109234958	403,109235	2,27215138	0,024375065	1,39658836	9,819046296
118,3728315	2,167817009	403,167817	2,272837319	0,025061004	1,435889757	10,1058716
121,6163145	2,22120921	403,2212092	2,273462923	0,025686608	1,471734247	10,37590831
124,7847298	2,273583586	403,2735836	2,274077004	0,026300689	1,506918504	10,63930679

128,1299287	2,328146944	403,3281469	2,274717176	0,026940861	1,543597642	10,91711349
131,4625423	2,380816512	403,3808165	2,275335541	0,027559226	1,579027349	11,19371925
134,9520062	2,438278592	403,4382786	2,276010635	0,028234321	1,617707414	11,48260599
138,3157043	2,492415478	403,4924155	2,276647107	0,028870792	1,654174546	11,76085479
141,6242061	2,546263729	403,5462637	2,277280613	0,029504298	1,690471745	12,03406285
144,6900796	2,598118875	403,5981189	2,277891074	0,030114759	1,725448602	12,2865892
148,3377287	2,658050822	403,6580508	2,278597114	0,030820799	1,765901696	12,58686351
151,6228945	2,714481295	403,7144813	2,279262389	0,031486075	1,804019199	12,8564945
154,9867323	2,77091147	403,7709115	2,279928134	0,03215182	1,842163576	13,13238768
158,5381354	2,829899727	403,8298997	2,280624565	0,03284825	1,882066117	13,42331495
161,7535762	2,884343204	403,8843432	2,281267799	0,033491485	1,918920724	13,6861468
164,8224518	2,935509097	403,9355091	2,281872714	0,034096399	1,953579758	13,93678166
168,443049	2,996882955	403,996883	2,28259883	0,034822515	1,995183156	14,2318513
171,7629346	3,053496265	404,0534963	2,283269125	0,035492811	2,033588257	14,50192326
175,0692042	3,108964495	404,1089645	2,283926331	0,036150016	2,071243368	14,7706488
178,1873219	3,163409314	404,1634093	2,284571862	0,036795548	2,108229586	15,0233038
181,6048908	3,218648662	404,2186487	2,285227272	0,037450957	2,145781798	15,30065916
185,3777903	3,281445805	404,2814458	2,285972916	0,038196601	2,188504049	15,60600641
188,2945249	3,333337458	404,3333375	2,286589522	0,038813207	2,223832962	15,84102552
191,7066425	3,391742037	404,391742	2,287284008	0,039507694	2,263624113	16,11601094
195,0202137	3,450046256	404,4500463	2,287977821	0,040201506	2,303376644	16,38229775

198,2622532	3,507822974	404,507823	2,28866587	0,040889555	2,342798919	16,64226421
201,5107746	3,564731774	404,5647318	2,289344083	0,041567768	2,381657676	16,90254688
204,8774684	3,623927679	404,6239277	2,290050081	0,042273766	2,422108401	17,17181541
208,1306527	3,680817256	404,6808173	2,290729082	0,042952767	2,461012291	17,43165325
211,1578609	3,737127998	404,737128	2,291401667	0,043625352	2,499548563	17,67229807
215,190916	3,80387678	404,8038768	2,292199562	0,044423247	2,545264564	17,9942418
218,3028311	3,86003322	404,8600332	2,292871375	0,04509506	2,583756616	18,24113871
221,5492663	3,919149701	404,9191497	2,29357913	0,045802815	2,624308007	18,49816175
224,4411719	3,972440723	404,9724407	2,294217609	0,046441294	2,660890166	18,72659872
228,1792834	4,036290558	405,0362906	2,294983178	0,047206864	2,704754057	19,0226171
231,7023029	4,098551632	405,0985516	2,295730314	0,047953999	2,74756178	19,30058329
234,7619583	4,154359012	405,154359	2,296400523	0,048624209	2,785961943	19,5411433
237,9298334	4,211381732	405,2113817	2,297085835	0,049309521	2,825227425	19,79000207
241,471349	4,275907185	405,2759072	2,297861937	0,050085622	2,86969476	20,06752298
244,9114	4,33344921	405,3334492	2,298554599	0,050778285	2,909381398	20,33797429
247,7935453	4,386536235	405,3865362	2,299194101	0,051417787	2,946022162	20,56289313
251,4838179	4,449114256	405,4491143	2,299948511	0,052172196	2,989246659	20,85185775
254,821678	4,506898872	405,5068989	2,300645689	0,052869375	3,029192025	21,11244333
258,0683058	4,564469805	405,5644698	2,301340821	0,053564506	3,069020135	21,36509692
261,3691613	4,622209866	405,6222099	2,302038529	0,054262214	3,108995863	21,62176075
264,7978999	4,681972015	405,681972	2,302761236	0,054984921	3,150403931	21,88796947

268,2500767	4,739892529	405,7398925	2,303462222	0,055685907	3,190567466	22,15618975
271,380761	4,79625766	405,7962577	2,304144905	0,05636859	3,229682303	22,39788494
274,766963	4,85436131	405,8543613	2,304849183	0,057072868	3,270034486	22,65971893
278,1369537	4,912489844	405,9124898	2,305554312	0,057777998	3,31043541	22,91975697
281,8281576	4,974514734	405,9745147	2,306307313	0,058530999	3,353579202	23,20457624
284,6974755	5,026661049	406,026661	2,306940872	0,059164557	3,389879435	23,42437196
288,1777597	5,086188802	406,0861888	2,307664657	0,059888342	3,431349249	23,69169448
291,6961163	5,146912076	406,1469121	2,308403577	0,060627263	3,473686267	23,96127789
295,1652184	5,204359776	406,2043598	2,309103197	0,061326882	3,513771534	24,22739869
298,0478977	5,256694292	406,2566943	2,309741021	0,061964706	3,550316141	24,44665747
300,0887856	5,298225914	406,2982259	2,310247507	0,062471193	3,579335682	24,60017922
300,0887856	5,298225914	406,2982259	2,310247507	0,062471193	3,579335682	24,60017922
296,019682	5,264368837	406,2643688	2,309834592	0,062058277	3,555677371	24,27776916
292,5148544	5,230539477	406,2305395	2,309422204	0,061645889	3,532049284	24,00133669
289,0921136	5,196282453	406,1962825	2,309004796	0,061228481	3,508133538	23,73150993
285,8215384	5,161482729	406,1614827	2,308580973	0,060804658	3,483850278	23,47408538
282,5194101	5,126326867	406,1263269	2,308153015	0,0603767	3,459330112	23,21392041
279,3055214	5,090795645	406,0907956	2,307720695	0,05994438	3,434559979	22,9608612
275,9543372	5,052332322	406,0523323	2,307252932	0,059476617	3,40775916	22,69714725
272,5450632	5,013536553	406,0135366	2,306781372	0,059005058	3,380740775	22,42845972
269,6461541	4,976869267	405,9768693	2,306335911	0,058559596	3,355217696	22,20085668

265,5761379	4,925598544	405,9255985	2,305713404	0,057937089	3,319550673	21,88083564
262,5510531	4,884700818	405,8847008	2,305217148	0,057440834	3,291117345	21,64347889
258,9690561	4,837050333	405,8370503	2,304639298	0,056862984	3,258008967	21,36183849
255,6629293	4,790533081	405,7905331	2,304075546	0,056299232	3,225708361	21,10226038
252,3956572	4,744005547	405,7440055	2,303512021	0,055735706	3,193420717	20,84554417
249,1508983	4,698192226	405,6981922	2,302957487	0,055181173	3,161648303	20,59014664
245,9219967	4,650900561	405,6509006	2,302385415	0,054609101	3,128870992	20,33612334
242,5641753	4,603310873	405,6033109	2,301810102	0,054033787	3,095907963	20,0711654
239,1755146	4,552491656	405,5524917	2,301196149	0,053419834	3,060731031	19,80414156
235,6852964	4,500584207	405,5005842	2,300569476	0,052793161	3,024825332	19,52859449
232,4095865	4,450414382	405,4504144	2,299964191	0,052187877	2,990145074	19,26998027
229,2672172	4,401448423	405,4014484	2,299373819	0,051597504	2,956319206	19,02175472
225,8703609	4,350031073	405,3500311	2,298754301	0,050977986	2,920823472	18,75266049
222,4838858	4,297328945	405,2973289	2,29811974	0,050343425	2,884465794	18,4843479
219,4082364	4,248683659	405,2486837	2,297534416	0,049758102	2,850929222	18,24050102
215,5514931	4,189152329	405,1891523	2,296818616	0,049042302	2,809916901	17,93390464
212,2363945	4,135843873	405,1358439	2,296178115	0,0484018	2,773218857	17,67045012
208,9608957	4,083263488	405,0832635	2,295546799	0,047770485	2,737047154	17,40973189
205,7116479	4,030453177	405,0304532	2,294913161	0,047136846	2,700742342	17,15086746
202,4454499	3,977649275	404,9776493	2,294280037	0,046503722	2,664466994	16,89020288
199,252634	3,925368552	404,9253686	2,293653615	0,0458773	2,62857569	16,63516543

195,9634386	3,871014481	404,8710145	2,293002804	0,045226489	2,591286934	16,37214459
192,548496	3,813720039	404,81372	2,292317283	0,044540969	2,552009529	16,09882632
189,0169146	3,756110363	404,7561104	2,291628506	0,043852191	2,512545488	15,8153769
185,4667937	3,697000513	404,6970005	2,290922327	0,043146013	2,47208443	15,53022388
182,2421638	3,642727207	404,6427272	2,290274406	0,042498091	2,434961277	15,27092557
179,0835957	3,588291701	404,5882917	2,289625005	0,04184869	2,397753333	15,01680944
175,5710132	3,529352022	404,529352	2,288922384	0,04114607	2,357496143	14,73346049
172,1437958	3,472842275	404,4728423	2,288249232	0,040472917	2,31892735	14,45637019
169,0054933	3,420223892	404,4202239	2,287622874	0,039846559	2,283039672	14,20242219
165,8831475	3,370216118	404,3702161	2,287027984	0,039251669	2,248954996	13,94898429
162,587855	3,316789868	404,3167899	2,28639285	0,038616535	2,212564471	13,68124886
159,0549511	3,261880059	404,2618801	2,285740531	0,037964216	2,175189373	13,39337195
155,5612839	3,206411158	404,2064112	2,285082035	0,037305721	2,137460349	13,10846874
152,1731044	3,150811947	404,1508119	2,28442246	0,036646146	2,099669485	12,83205686
148,7613314	3,095579527	404,0955795	2,283767699	0,035991384	2,06215443	12,55318236
145,6600397	3,043299922	404,0432999	2,283148366	0,035372052	2,026669266	12,29965226
142,1683033	2,985617603	403,9856176	2,282465507	0,034689192	1,987544304	12,01359916
138,7301895	2,928681385	403,9286814	2,28179197	0,034015655	1,948953467	11,73152987
135,6125778	2,875693006	403,875693	2,28116557	0,033389256	1,913063422	11,47558328
132,4386988	2,822495191	403,8224952	2,280537117	0,032760802	1,877055697	11,21454174
129,1016613	2,766127526	403,7661275	2,279871677	0,032095362	1,838928783	10,93974469

125,7498997	2,709827662	403,7098277	2,279207509	0,031431194	1,800874753	10,66328116
122,6991725	2,65680665	403,6568066	2,278582451	0,030806136	1,765061591	10,41152436
119,1198671	2,597892973	403,597893	2,277888414	0,030112099	1,72529618	10,11528242
115,6625617	2,538360153	403,5383602	2,277187603	0,029411288	1,685142693	9,82902795
112,0565552	2,478249243	403,4782492	2,276480517	0,028704202	1,644629649	9,529751289
108,9409894	2,423756517	403,4237565	2,275839977	0,028063662	1,607929395	9,271097439
105,6545662	2,366113462	403,3661135	2,275162879	0,027386565	1,569134579	8,997880431
102,1616906	2,306399817	403,3063998	2,274461973	0,026685658	1,528975584	8,70688491
99,10426723	2,251492243	403,2514922	2,273817938	0,026041623	1,492075108	8,452076318
95,90684747	2,196844322	403,1968443	2,273177385	0,02540107	1,455374102	8,184933068
92,42706932	2,13550943	403,1355094	2,272458967	0,024682652	1,414211795	7,893955033
89,21937086	2,075314402	403,0753144	2,27175443	0,023978116	1,373844829	7,62566778
85,68228843	2,009693415	403,0096934	2,270986984	0,023210669	1,329873383	7,329284015
82,55916958	1,95042144	402,9504214	2,270294324	0,022518009	1,290186873	7,067291157
78,70782477	1,87446389	402,8744639	2,269407412	0,021631097	1,239370576	6,74390219
75,61108718	1,80516023	402,8051602	2,268598915	0,020822601	1,193047146	6,484077914
72,53143936	1,738313734	402,7383137	2,267819735	0,02004342	1,148403394	6,225075861
69,33654038	1,672293247	402,6722932	2,267050808	0,019274493	1,104347128	5,955676242
65,78515905	1,604375916	402,6043759	2,266260436	0,018484121	1,059062135	5,655314956
62,47496543	1,5409077	402,5409077	2,265522431	0,017746116	1,016777543	5,374903216
58,99293659	1,474426729	402,4744267	2,264750004	0,016973689	0,972520766	5,079438361

55,58992426	1,408288709	402,4082887	2,263982181	0,016205866	0,928527743	4,790274041
51,88069306	1,338780493	402,3387805	2,263175895	0,015399581	0,882330972	4,474409357
48,57941531	1,276794011	402,276794	2,262457432	0,014681118	0,841166089	4,192834598
45,7269419	1,21770465	402,2177046	2,26177305	0,013996735	0,801953857	3,949456829
42,53358891	1,153428828	402,1534288	2,261029151	0,013252836	0,759331562	3,676491963
38,91411548	1,081098891	402,0810989	2,260192725	0,01241641	0,711407881	3,366561614
35,51221453	1,012655065	402,0126551	2,259401907	0,011625592	0,66609736	3,074779498
31,62123884	0,939650478	401,9396505	2,258559108	0,010782793	0,617808541	2,740280068
28,71870374	0,88324299	401,883243	2,257908418	0,010132103	0,580526747	2,490427337
25,30607084	0,820506514	401,8205065	2,257185234	0,00940892	0,539091396	2,196135176
21,65169766	0,753376058	401,7533761	2,256412	0,008635685	0,494788297	1,880501882
18,65191696	0,696918148	401,6969181	2,255762174	0,007985859	0,45755601	1,62105229
15,83260484	0,643333723	401,6433337	2,255145824	0,00736951	0,422241808	1,376899968
12,73684514	0,585349748	401,5853497	2,254479312	0,006702997	0,38405343	1,108435929
9,137019515	0,519748636	401,5197486	2,253725793	0,005949479	0,340880017	0,795775669
5,274787545	0,453029656	401,4530297	2,252960035	0,00518372	0,297005269	0,45976254
1,774616539	0,389616909	401,3896169	2,252232782	0,004456467	0,25533675	0,154795415
-0,212254624	0,348335199	401,3483352	2,251759632	0,003983317	0,228227275	-0,018523454
-0,133030117	0,345095072	401,3450951	2,251722505	0,00394619	0,226100059	-0,011609977
-0,030435622	0,339078337	401,3390783	2,251653566	0,003877252	0,222150153	-0,002656405
-0,019324943	0,33160777	401,3316078	2,251567976	0,003791662	0,217246215	-0,001686819

0,06666407	0,325079069	401,3250791	2,251493184	0,003716869	0,212960904	0,005819364
-0,020734345	0,316821404	401,3168214	2,251398592	0,003622277	0,207541206	-0,001810157

Table 8: Test results produced by the Instron E10000 when the 4.6 mm solid AFO was put through a total of six loading cycles.

Additional information:

- Distance (D0) is a constant of 401 mm.
- Foot is a constant value of 161 mm.
- Shank is a constant value of 280 mm.
- Angle (D0) is a constant value of 2.247776315 radians.

Appendix 2

Mechanical test data produced by custom-made test apparatus

Results of mechanically testing the solid AFO in the custom-made test apparatus.

Eight layer SWIFT Cast									
Plantarflexion (tension)									
Lever arm from wire to ankle (m)	0,210								
Loading path									
Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
452,000	0,452	4,434	**0,931**	95,000	0,095	2,413	0,002	0,011	**0,658**
149,000	0,601	5,896	**1,238**	136,000	0,136	3,454	0,003	0,016	**0,942**
97,420	0,698	6,852	**1,439**	164,000	0,164	4,166	0,004	0,020	**1,137**
73,416	0,772	7,572	**1,590**	188,000	0,188	4,775	0,005	0,023	**1,303**

50,040	0,822	8,063	**1,693**	201,000	0,201	5,105	0,005	0,024	**1,393**
76,636	0,899	8,814	**1,851**	229,000	0,229	5,817	0,006	0,028	**1,587**
73,416	0,972	9,535	**2,002**	251,000	0,251	6,375	0,006	0,030	**1,739**
50,040	1,022	10,026	**2,105**	266,000	0,266	6,756	0,007	0,032	**1,843**
72,054	1,094	10,732	**2,254**	288,000	0,288	7,315	0,007	0,035	**1,996**
123,456	1,217	11,943	**2,508**	335,000	0,335	8,509	0,009	0,041	**2,322**

Table 9: Angles and moments found for the eight-layer SWIFT Cast, when it was put through a tensile loading cycle.

Eight layer SWIFT Cast								
Plantarflexion (tension)								
Unloading path								
Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
1,217	11,943	**2,508**	335,000	0,335	8,509	0,009	0,041	**2,322**
1,094	10,732	**2,254**	327,000	0,327	8,306	0,008	0,040	**2,266**
1,022	10,026	**2,105**	309,000	0,309	7,849	0,008	0,037	**2,141**
0,972	9,535	**2,002**	306,000	0,306	7,772	0,008	0,037	**2,121**
0,899	8,814	**1,851**	298,000	0,298	7,569	0,008	0,036	**2,065**
0,822	8,063	**1,693**	274,000	0,274	6,960	0,007	0,033	**1,899**
0,772	7,572	**1,590**	271,000	0,271	6,883	0,007	0,033	**1,878**
0,698	6,852	**1,439**	260,000	0,260	6,604	0,007	0,031	**1,802**
0,601	5,896	**1,238**	239,000	0,239	6,071	0,006	0,029	**1,656**
0,452	4,434	**0,931**	202,000	0,202	5,131	0,005	0,024	**1,400**
0,000	0,000	**0,000**	91,000	0,091	2,311	0,002	0,011	**0,631**

Table 10: Angles and moments found for the eight-layer SWIFT Cast, when it was put through a tensile unloading cycle.

Eight layer SWIFT Cast

Dorsiflexion (compression)

Lever arm from wire to ankle (m) 0,210

Loading path

Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
452,000	0,452	4,434	**0,931**	252,000	0,252	6,401	0,006	0,030	**1,746**
50,040	0,50204	4,925	**1,034**	281,000	0,281	7,137	0,007	0,034	**1,947**
73,416	0,575456	5,645	**1,185**	328,000	0,328	8,331	0,008	0,040	**2,273**
25,544	0,601	5,896	**1,238**	350,000	0,350	8,890	0,009	0,042	**2,426**
50,040	0,65104	6,387	**1,341**	380,000	0,380	9,652	0,010	0,046	**2,633**
73,416	0,724456	7,107	**1,492**	434,000	0,434	11,024	0,011	0,052	**3,008**

Unloading path

Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,724456	7,107	**1,492**	434,000	0,434	11,024	0,011	0,052	**3,008**
0,65104	6,387	**1,341**	416,000	0,416	10,566	0,011	0,050	**2,883**
0,601	5,896	**1,238**	407,000	0,407	10,338	0,010	0,049	**2,821**
0,575456	5,645	**1,185**	379,000	0,379	9,627	0,010	0,046	**2,626**
0,50204	4,925	**1,034**	364,000	0,364	9,246	0,009	0,044	**2,523**
0,452	4,434	**0,931**	346,000	0,346	8,788	0,009	0,042	**2,398**
0	0,000	**0,000**	105,000	0,105	2,667	0,003	0,013	**0,728**

Table 11: Values measured for the eight-layer SWIFT Cast, when it was put through a compressive loading and unloading cycle.

Six layer SWIFT Cast

Plantarflexion (tension)

Lever arm from wire to ankle (m) 0,201

Loading path

Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
158,000	0,158	1,550	**0,312**	158,000	0,158	4,013	0,004	0,020	**1,144**
217,000	0,375	3,679	**0,739**	217,000	0,217	5,512	0,006	0,027	**1,571**
256,000	0,631	6,190	**1,244**	256,000	0,256	6,502	0,007	0,032	**1,854**
284,000	0,915	8,976	**1,804**	284,000	0,284	7,214	0,007	0,036	**2,056**
306,000	1,221	11,978	**2,408**	306,000	0,306	7,772	0,008	0,039	**2,216**
335,000	1,556	15,264	**3,068**	335,000	0,335	8,509	0,009	0,042	**2,426**
366,000	1,922	18,855	**3,790**	366,000	0,366	9,296	0,009	0,046	**2,650**
389,000	2,311	22,671	**4,557**	389,000	0,389	9,881	0,010	0,049	**2,817**
416,000	2,727	26,752	**5,377**	416,000	0,416	10,566	0,011	0,053	**3,012**

Table 12: Angles and moments measured for the six-layer SWIFT Cast, when it was put through one tensile loading cycle.

Six layer SWIFT Cast									
Unloading path									
	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
	2,727	26,752	**5,377**	416,000	0,416	10,566	0,011	0,053	**3,012**
	2,311	22,671	**4,557**	400,000	0,400	10,160	0,010	0,051	**2,896**
	1,922	18,855	**3,790**	397,000	0,397	10,084	0,010	0,050	**2,874**
	1,556	15,264	**3,068**	377,000	0,377	9,576	0,010	0,048	**2,730**
	1,221	11,978	**2,408**	346,000	0,346	8,788	0,009	0,044	**2,505**
	0,915	8,976	**1,804**	329,000	0,329	8,357	0,008	0,042	**2,382**
	0,631	6,190	**1,244**	310,000	0,310	7,874	0,008	0,039	**2,245**
	0,375	3,679	**0,739**	283,000	0,283	7,188	0,007	0,036	**2,049**
	0,158	1,550	**0,312**	226,000	0,226	5,740	0,006	0,029	**1,636**
	0,000	0,000	**0,000**	44,000	0,044	1,118	0,001	0,006	**0,319**

Table 13: Angles and moments measured for the six-layer SWIFT Cast, when it was put through one tensile unloading cycle.

Six layer SWIFT Cast									
Dorsiflexion (compression)									
Lever arm from wire to ankle (m) 0,201									
Loading path									
Loose weights (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
50,040	0,050	0,491	**0,099**	58,000	0,058	1,473	0,001	0,007	**0,420**
97,420	0,097	0,956	**0,192**	171,000	0,171	4,343	0,004	0,022	**1,238**
147,460	0,147	1,447	**0,291**	338,000	0,338	8,585	0,009	0,043	**2,447**
199,040	0,199	1,953	**0,392**	390,000	0,390	9,906	0,010	0,049	**2,824**
293,880	0,294	2,883	**0,579**	705,000	0,705	17,907	0,018	0,089	**5,104**

Table 14: Representation of values obtained when the six-layer SWIFT Cast was put through a compressive loading cycle.

PLS AFO	
Plantarflexion (tension)	
Lever arm from wire to ankle (m)	0,200

Loading path

Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
0,452	0,452	4,434	**0,887**	162,000	0,162	4,115	0,004	0,021	**1,179**
0,300	0,752	7,377	**1,475**	280,000	0,280	7,112	0,007	0,036	**2,037**
0,294	1,046	10,261	**2,052**	400,000	0,400	10,160	0,010	0,051	**2,911**
0,293	1,339	13,136	**2,627**	520,000	0,520	13,208	0,013	0,066	**3,784**
0,196	1,535	15,058	**3,012**	610,000	0,610	15,494	0,015	0,077	**4,439**

Unloading path

	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
	1,535	15,058	**3,012**	610,000	0,610	15,494	0,015	0,077	**4,439**
	1,339	13,136	**2,627**	571,000	0,571	14,503	0,015	0,073	**4,155**

	1,046	10,261	**2,052**	471,000	0,471	11,963	0,012	0,060	**3,427**
	0,752	7,377	**1,475**	364,000	0,364	9,246	0,009	0,046	**2,649**
	0,452	4,434	**0,887**	251,000	0,251	6,375	0,006	0,032	**1,826**
	0,000	0,000	**0,000**	65,000	0,065	1,651	0,002	0,008	**0,473**

Table 15: Representation of values obtained when the 3.0 mm posterior leaf spring was put through a tensile loading and unloading cycle.

PLS AFO

Dorsiflexion (compression)

Lever arm from wire to ankle (m) 0,200

Loading path

Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
452,000	0,452	4,434	**0,887**	195,000	0,195	4,953	0,005	0,025	**1,419**
300,000	0,752	7,377	**1,475**	360,000	0,360	9,144	0,009	0,046	**2,620**
294,000	1,046	10,261	**2,052**	550,000	0,550	13,970	0,014	0,070	**4,002**
293,000	1,339	13,136	**2,627**	750,000	0,750	19,050	0,019	0,095	**5,457**

Unloading path

	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
	1,339	13,136	**2,627**	750,000	0,750	19,050	0,019	0,095	**5,457**
	1,046	10,261	**2,052**	668,000	0,668	16,967	0,017	0,085	**4,861**
	0,752	7,377	**1,475**	520,000	0,520	13,208	0,013	0,066	**3,784**
	0,452	4,434	**0,887**	370,000	0,370	9,398	0,009	0,047	**2,692**
	0,000	0,000	**0,000**	140,000	0,140	3,556	0,004	0,018	**1,019**

Table 16: Representation of values obtained when the 3.0 mm posterior leaf spring was put through a compressive loading and unloading cycle.

Solid AFO reinforced with carbon fibre inserts

Plantarflexion (tension)

Lever arm from wire to ankle (m) 0,257

Loading path

Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
702,000	0,702	6,887	**1,770**	39,000	0,039	0,991	0,001	0,004	**0,221**
912,000	1,614	15,833	**4,069**	99,000	0,099	2,515	0,003	0,010	**0,561**
908,000	2,522	24,741	**6,358**	164,000	0,164	4,166	0,004	0,016	**0,929**
905,000	3,427	33,619	**8,640**	225,000	0,225	5,715	0,006	0,022	**1,274**
1095,000	4,522	44,361	**11,401**	311,000	0,311	7,899	0,008	0,031	**1,761**

Unloading path

Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
4,522	44,361	**11,401**	311,000	0,311	7,899	0,008	0,031	**1,761**
3,427	33,619	**8,640**	250,000	0,250	6,350	0,006	0,025	**1,416**
2,522	24,741	**6,358**	198,000	0,198	5,029	0,005	0,020	**1,121**
1,614	15,833	**4,069**	142,000	0,142	3,607	0,004	0,014	**0,804**
0,702	6,887	**1,770**	80,000	0,080	2,032	0,002	0,008	**0,453**
0,000	0,000	**0,000**	30,000	0,030	0,762	0,001	0,003	**0,170**

Table 17: Representation of values obtained when the 4.6 mm solid AFO was put through a tensile loading and unloading cycle.

Solid AFO reinforced with carbon fibre inserts

Dorsiflexion (compression)

Lever arm from wire to ankle (m) 0,257

Loading path

Weights added (g)	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
0,000	0,000	0,000	**0,000**	0,000	0,000	0,000	0,000	0,000	**0,000**
702,000	0,702	6,887	**1,770**	39,000	0,039	0,991	0,001	0,004	**0,221**
912,000	1,614	15,833	**4,069**	100,000	0,100	2,540	0,003	0,010	**0,566**
908,000	2,522	24,741	**6,358**	168,000	0,168	4,267	0,004	0,017	**0,951**
908,000	3,430	33,648	**8,648**	240,000	0,240	6,096	0,006	0,024	**1,359**
1095,500	4,526	44,395	**11,410**	328,000	0,328	8,331	0,008	0,032	**1,857**

Unloading path

	Total weight (kg)	Force (N)	**Moment (Nm)**	Deflection (1/1000 inch)	Deflection (inch)	Deflection (mm)	Deflection (m)	Angle (rad)	**Angle (deg)**
	4,526	44,395	**11,410**	328,000	0,328	8,331	0,008	0,032	**1,857**
	3,430	33,648	**8,648**	269,000	0,269	6,833	0,007	0,027	**1,523**
	2,522	24,741	**6,358**	209,000	0,209	5,309	0,005	0,021	**1,184**
	1,614	15,833	**4,069**	144,000	0,144	3,658	0,004	0,014	**0,815**
	0,702	6,887	**1,770**	76,000	0,076	1,930	0,002	0,008	**0,430**
	0,000	0,000	**0,000**	26,000	0,026	0,660	0,001	0,003	**0,147**

Table 18: Representation of values obtained when the white coloured solid AFO was put through a compressive loading and unloading cycle.

Appendix 3

Gait analysis data

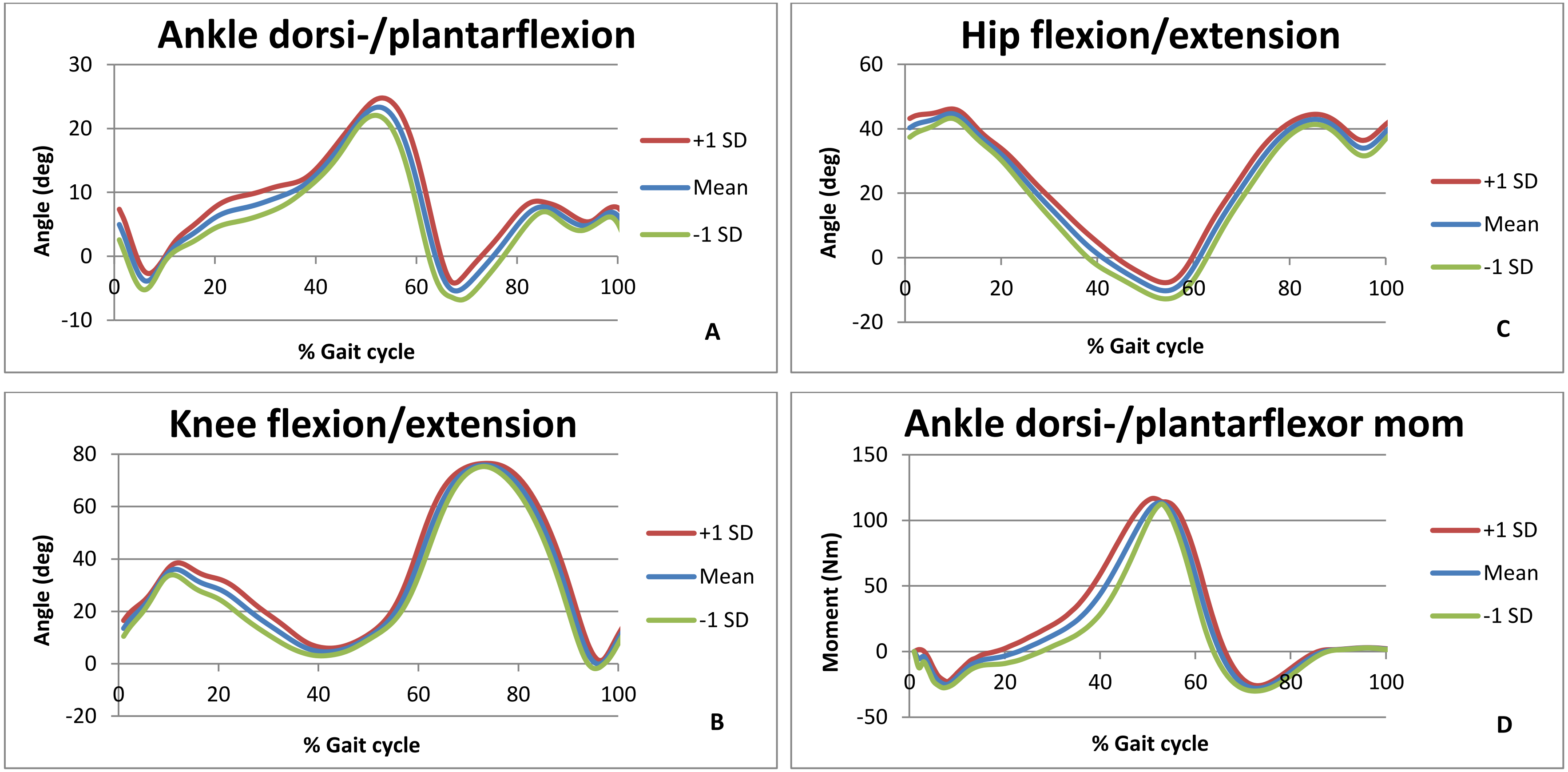


Figure 31: Walking condition 1 - walking with conventional shoes only. The total (a) ankle, (b) knee and (c) hip angles and, (d) ankle moment of one able-bodied subject. Mean (±SD) over five gait cycles for the left leg.

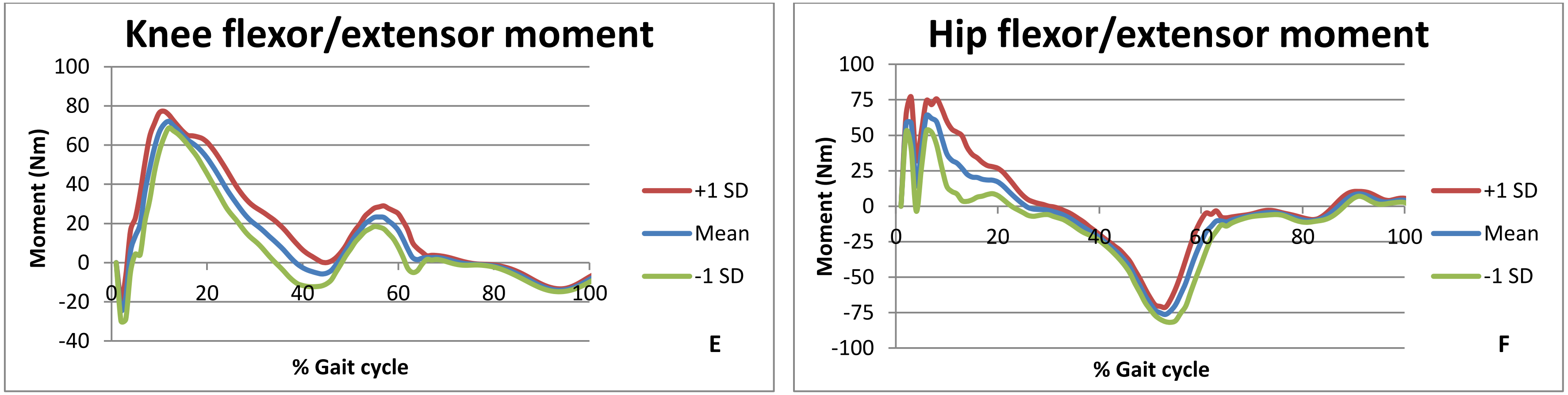


Figure 32: Walking condition 1 - walking with conventional shoes only. The total (e) knee and (f) hip moments for the left leg of one able-bodied subject. Mean (±SD) over five gait cycles.

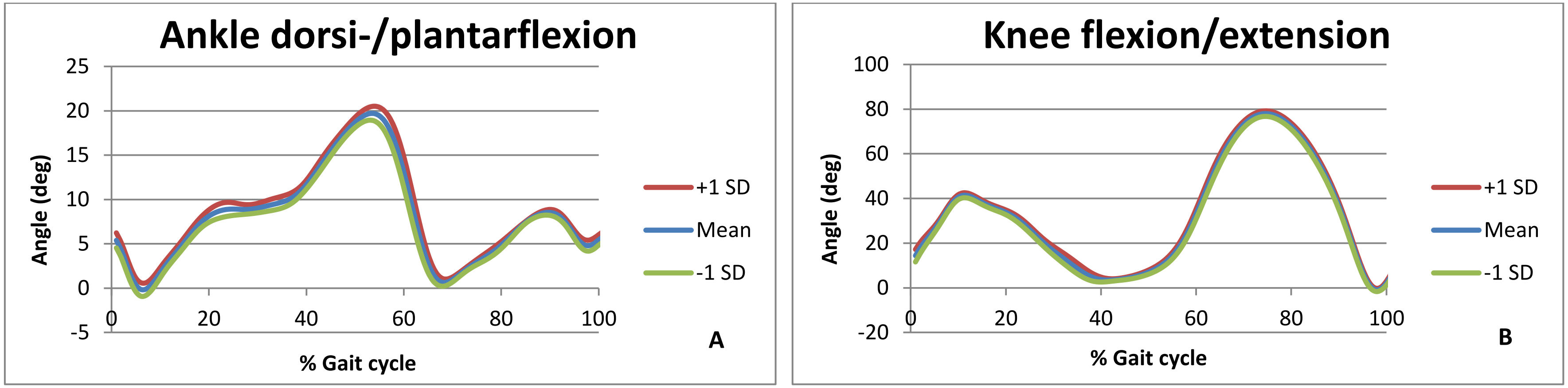


Figure 33: Walking condition 2 - walking with one conventional shoe and a six-layer SWIFT Cast. The total (a) ankle and (b) knee joint angles for the left leg with cast plotted against the percentage (%) of one gait cycle.

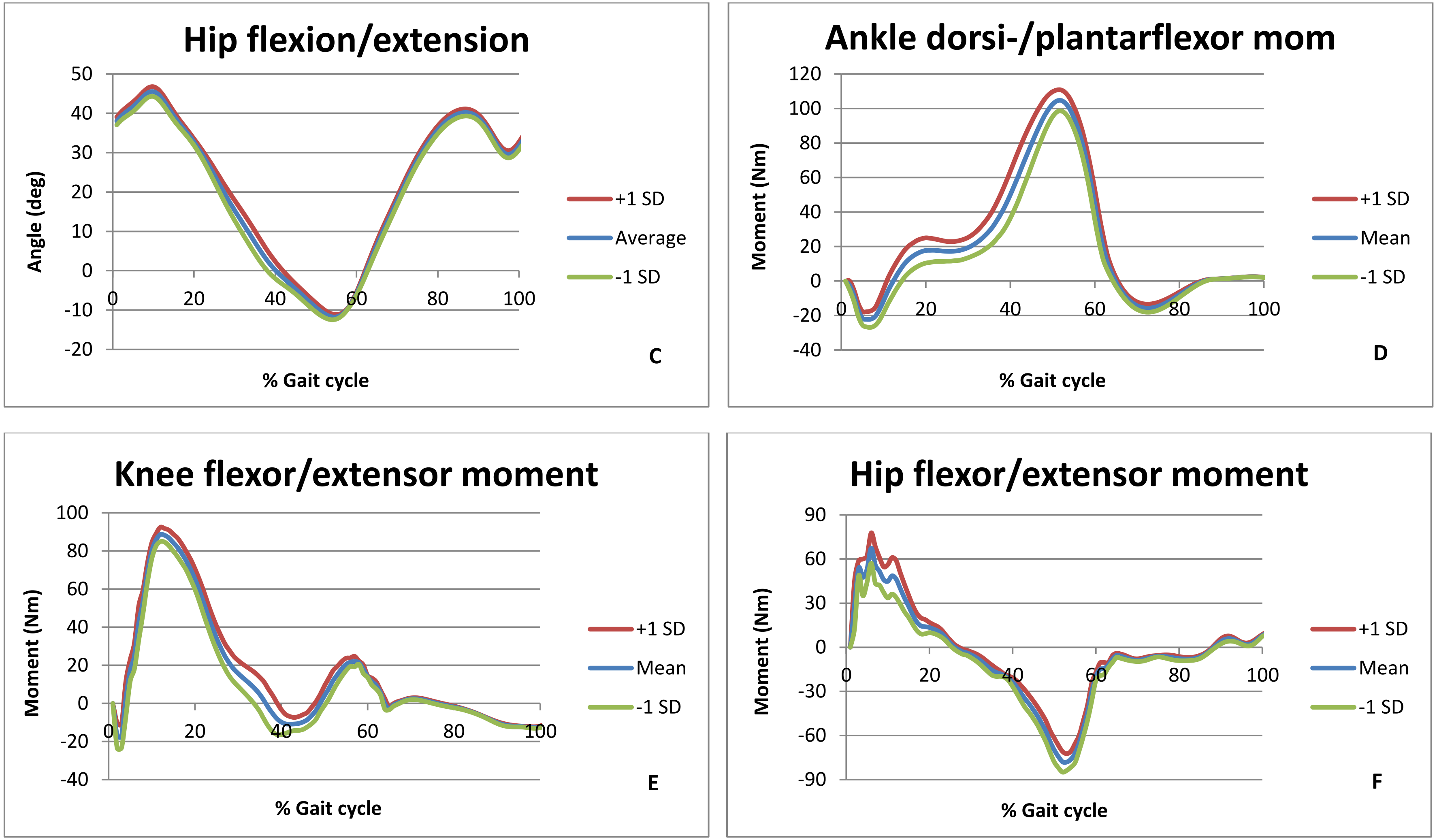


Figure 34: Walking condition 2 – walking with one conventional shoe and a six-layer SWIFT Cast. The total (c) hip joint angle and, (d) ankle, (e) knee and (f) hip joint moments for the left leg with cast. Mean (±SD) over five gait cycles.

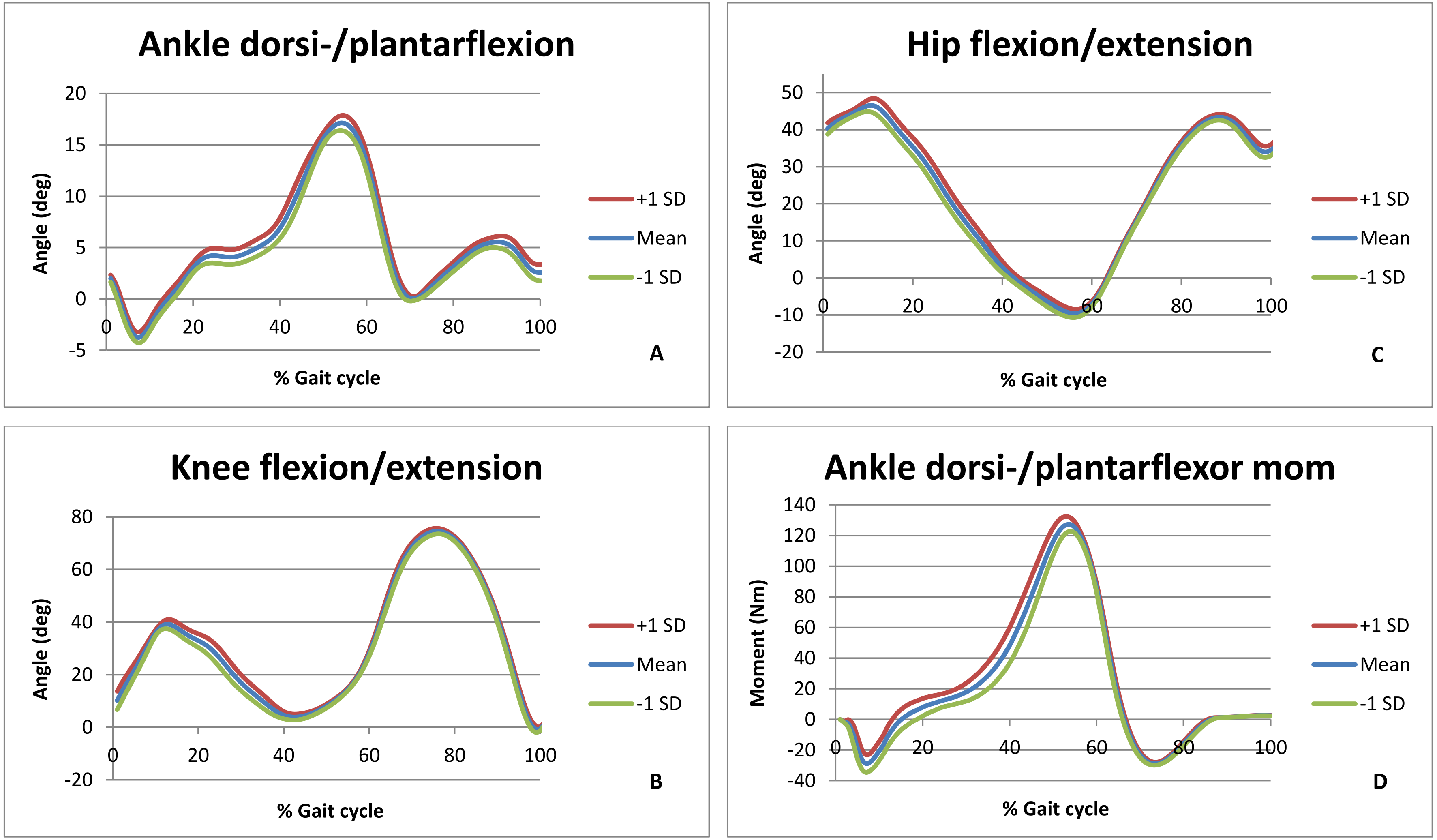
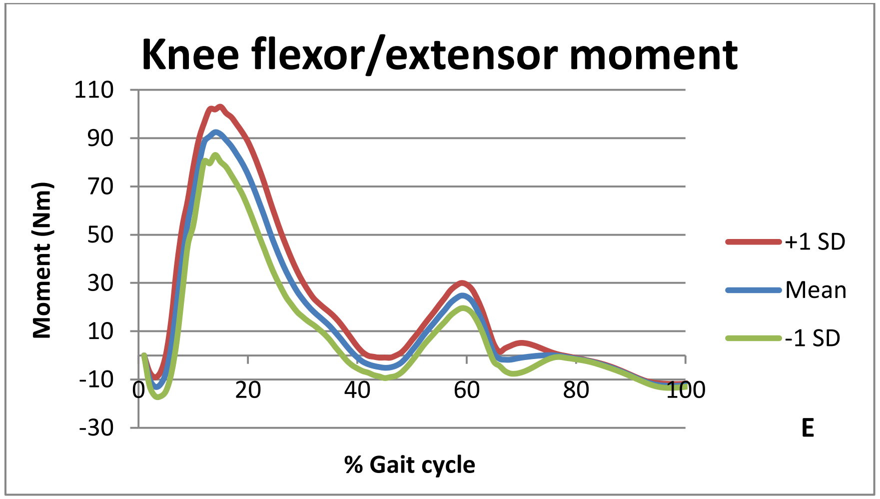


Figure 35: Walking condition 3 - walking with a conventional shoe and an eight-layer SWIFT Cast. Mean (±SD) total angle at the (a) ankle, (b) knee and (c) hip and mean (±SD) total moment at the hip for the left leg with cast.



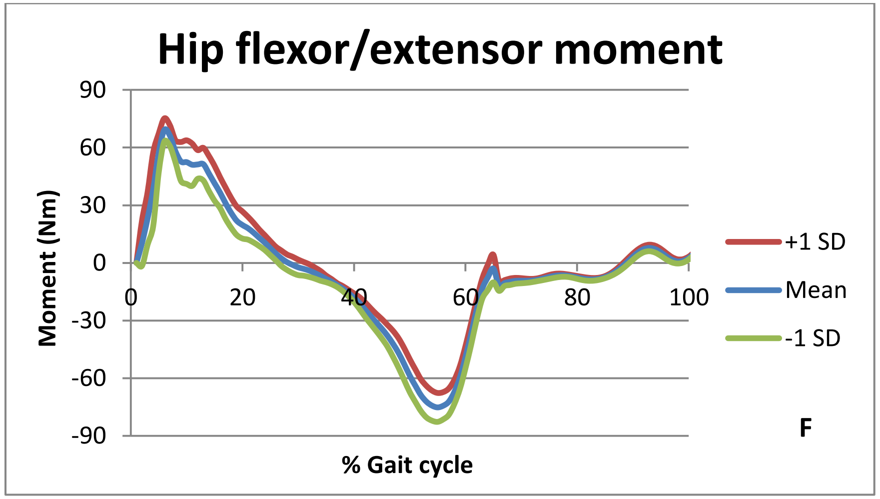
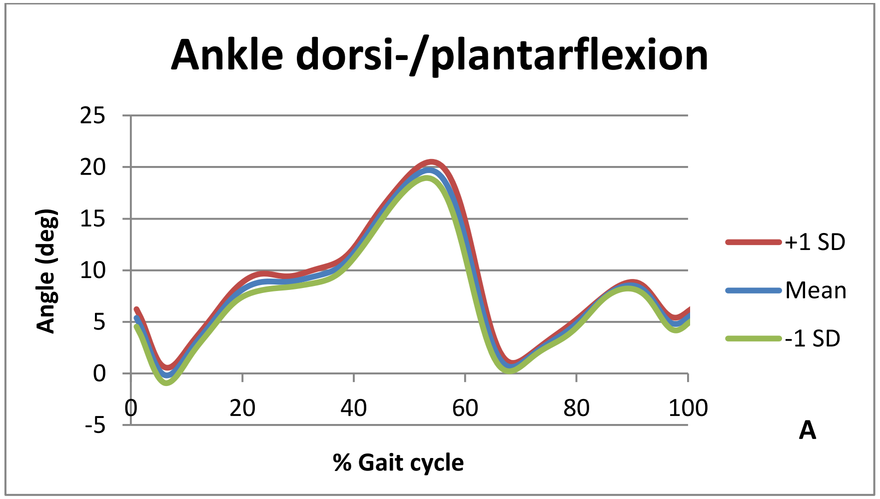


Figure 36: Walking condition 3 - walking with a conventional shoe and an eight-layer SWIFT Cast. Mean (±SD) total moments at the (e) knee and (f) hip for the left leg with cast.



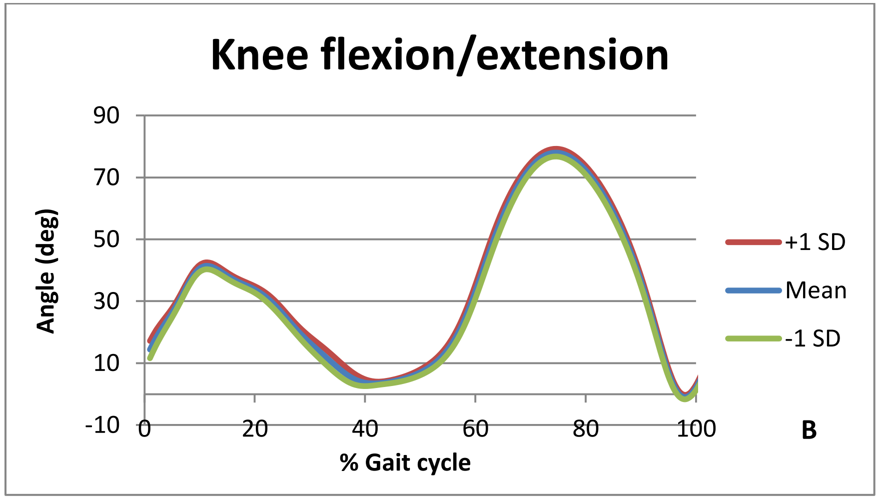


Figure 37: Walking condition 4 - walking with shoes and an posterior leaf spring. Mean (±SD) total moments at the (a) ankle and (b) knee for the left leg over 5 gait cycles.

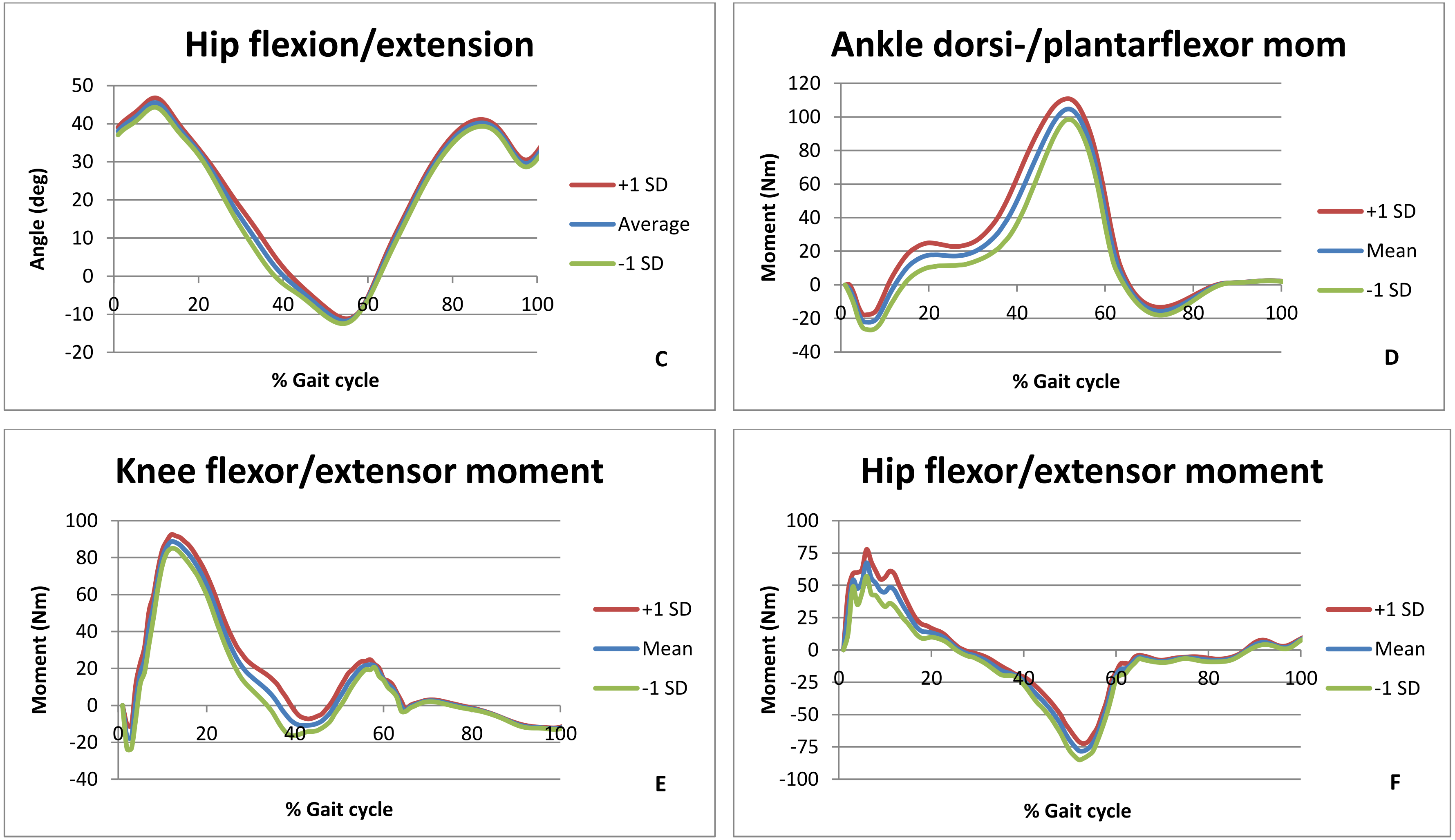


Figure 38: Walking condition 4. Mean (±SD) total angle at the (c) hip joint and mean total moments at the (d) ankle, (e) knee and (f) hip for the left leg with posterior leaf spring AFO.

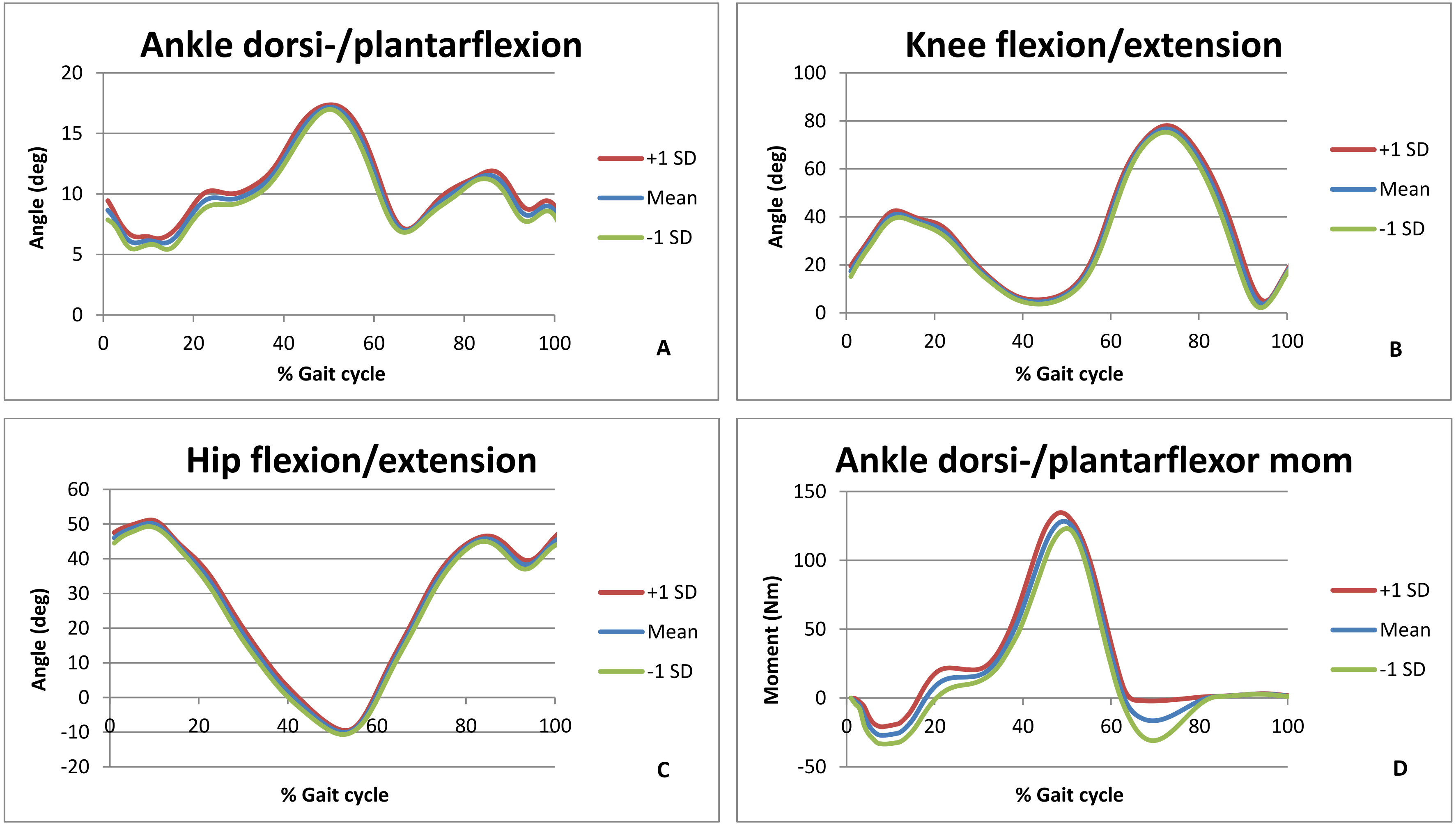


Figure 39: Walking condition 5 – walking with shoes and an 4.6 mm solid AFO with carbon fibre reinforcement at the malleoli level. Mean (±SD) total angles at the (a) ankle, (b) knee and (c) hip joint and mean (±SD) total moment at the (d) ankle for the left leg with solid AFO.

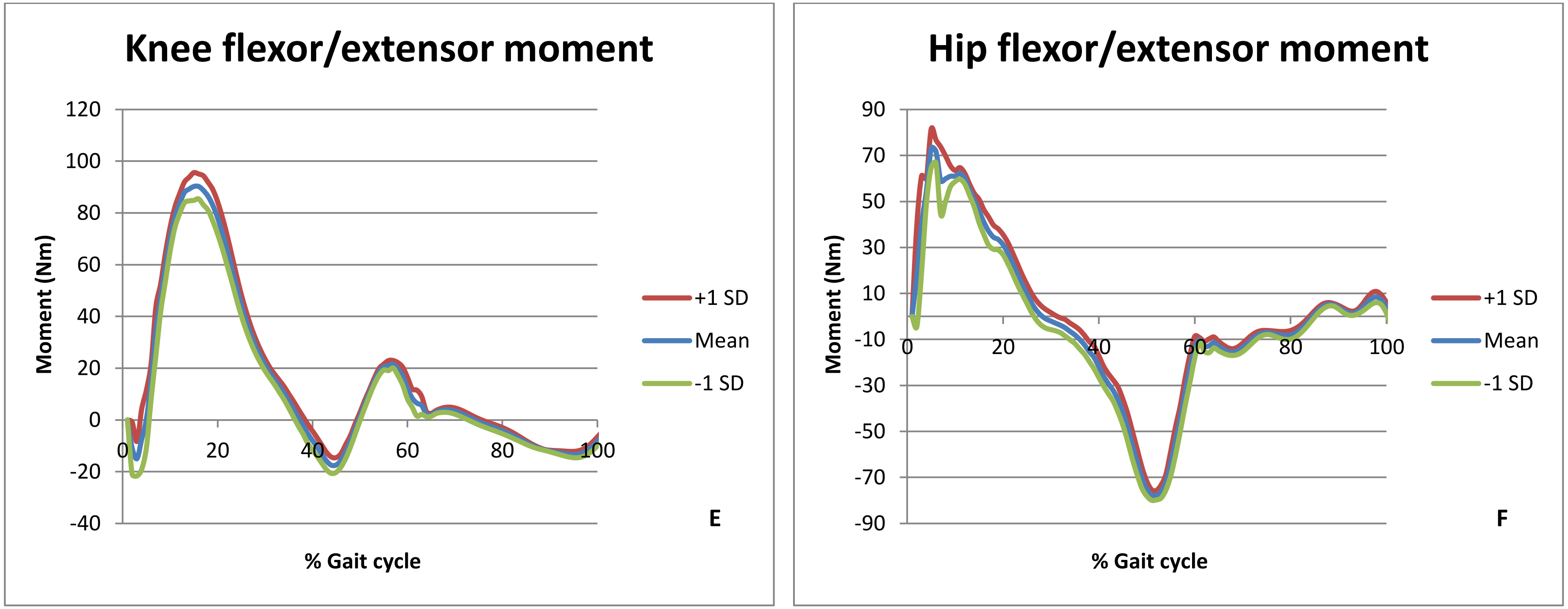


Figure 40: Mean (±SD) total flexor/extensor moments at the (e) knee and (f) hip for the left leg with reinforced solid AFO.

Appendix 4

Comparison between the five walking conditions for the left leg.

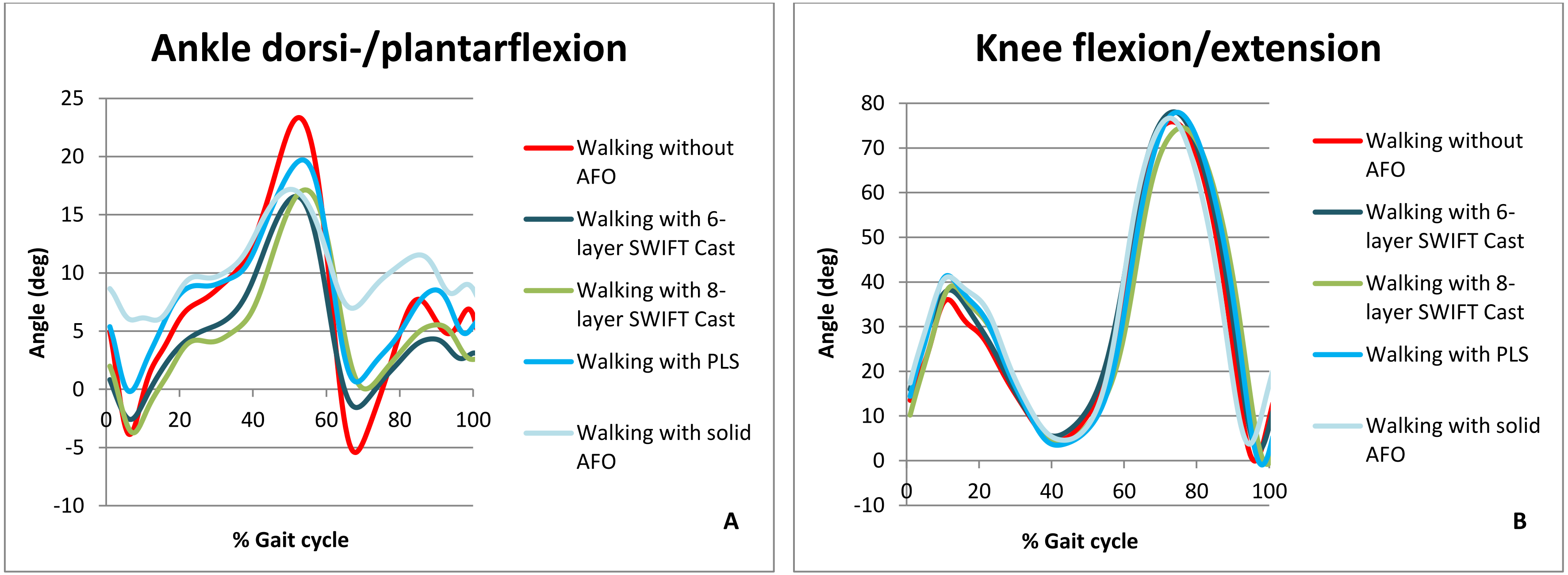


Figure 41: (a) Ankle and (b) knee joint angles in the sagittal plane are shown for the left leg for all 5 walking conditions tested over 5 gait cycles.

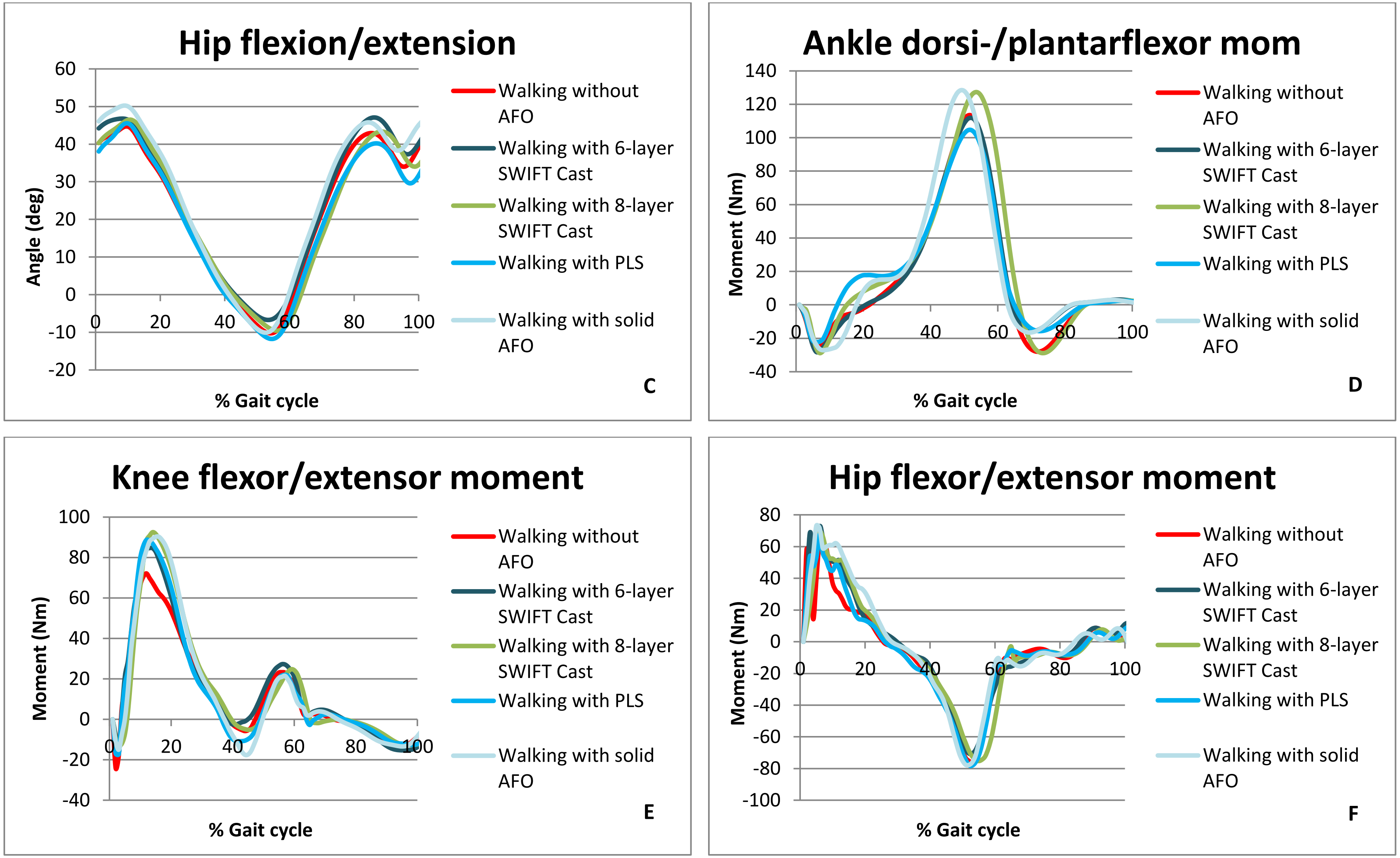


Figure 42: (c) Hip joint angle and (d) ankle, (e) knee and (f) hip joint moments in the sagittal plane are shown for the left leg for all 5 walking conditions tested over 5 gait cycles.