Force-Controllable Ankle Foot Orthosis (AFO) to Assist Drop Foot Gait

by

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University of Miami, 2000

Submitted to the Department of Mechanical Engineering
in partial fulfillment of the requirements for the degree of

Master of Science in Mechanical Engineering
at the
MASSACHUSETTS INSTITUTE OF TECHNOLOGY

February 2003

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Abstract

Drop foot, a loss of use of the muscles that lift the foot, can be caused by stroke, cerebral palsy (CP), multiple sclerosis (MS), or neurological trauma. The two major complications of drop foot are slapping of the foot after heel strike (foot slap) and dragging of the toe during swing (toe drag). The current assistive device is the Ankle Foot Orthosis (AFO), which though offering some biomechanical benefits, is non-adaptive and fails to eliminate significant gait complications.

An Active Ankle Foot Orthosis (AAFO) is presented where the impedance of the orthotic joint is modulated throughout the walking cycle to treat drop foot gait. To prevent foot slap, a biomimetic torsional spring control is applied where orthotic joint stiffness is actively adjusted to minimize forefoot collisions with the ground. Throughout late stance, joint impedance is minimized so as not to impede powered plantar flexion movements, and during the swing phase, a torsional spring-damper (PD) control lifts the foot to provide toe clearance. To assess the clinical effects of variable-impedance control, kinetic and kinematic gait data were collected on two drop foot participants wearing the AAFO. For each participant, zero, constant and variable impedance control strategies were evaluated, and the results were compared to the mechanics of three age, weight and height matched normals.

It was found that actively adjusting joint impedance significantly reduces the occurrence of slap foot, allows greater powered plantar flexion, and provides for greater biological realism in swing phase ankle dynamics. These results indicate that a variable-impedance orthosis may have certain clinical benefits for the treatment of drop foot gait compared to conventional AFO having zero or constant stiffness joint behaviors.

Thesis Supervisor: Dava J. Newman
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Acknowledgements

And now, after these incredible two and a half years, I get to sit down and reflect on those that have made all of these experiences possible.

Dava, for your unconditional help and support. I could not have asked for a better advisor. I will always be in awe of the passion you put in everything you do. I still haven't found it, but I'm getting there.

Hugh, this project would not have existed without you. And like I said in National Geographic, you have allowed me to start my dream of using my gifts to help those in need. We still have to go to Chile sometime.

Woodie Flowers, thank you for the amazing insights and suggestions. I will always remember our first meeting; with just one question you revolutionized my project and my view of it.

Joe Coughlin and the Age Lab for sponsoring this research, showing me all of Cincinnati (that's all there was, right?) and giving me hope that my project may actually become a reality for those in need.

To the Leg Labbers. Mike, for always being the steady shoulder to rely on. Greg for proof reading, football and the Chargers. Andreas, Max and Dan for putting up with the flood of questions. Bruce for the uplifting cynicism.

To the Gait Lab, specifically Jen and Meaghan for putting up with me during the human trials (both Saturday and Sunday!) and to Pat for the barrage of questions that I asked. And yes, Jen, you can back up my data now.

Bob and Wayne of Hanger Prosthetics, for donating your time and all the AFO's used. If I'm as good at my job as you guys are at yours, we're going to help so many people to walk better.

A great thank you to both my subjects and their families. Your commitment of time and effort was beyond any of my expectations and yep, I'm still thinking about how to make this device so you can take it home.

To the MVLers, who I saw a lot less than I wanted. Erika, I'll always remember your engagement phone call when I was in New York sitting at a corner of Barnes & Noble. Chris, all of our long talks when we "shared" the same office. I've probably never mentioned it before, but I've always been so impressed with the dedication and passion that both of you have for your work. Jess, ves, a mi también me tomó mas de dos años, tiene que ser por que los latinos se divierten mas.

My family and friends who saw me through this entire process.

Aaron, I guess it does look like a tissue box, a little bit. Roxanna, do I get an extra batch of cookies for this? Peter, we need to start having lunches again. Meli, you can't read mine either :-P and Jenny, now we can truly start thinking about ending our sabbaticals.

Erisa and Marianne, two IA tappings, one 510k and MIT acceptance and a lot of cell phone minutes later... You've seen me through my ups and downs and have been there and will always be there through it all, what can you call that but true friendship.

Mark, for all the free advice (yeah, I know, you get what you pay for), keeping my head on straight (despite other intentions sometimes) and for just being part of my life despite the distance. What a pair we make.

Sanjit, the artist in my life, thank you for always having a different perspective (and a great meal) for me. Time to travel…

Christian, my sobering "room" mate and dance partner extraordinaire. I finally got to see Montreal, big guy… How about staying in each other's handful.

Eduardo, compañero de frustraciones academicas y crisis de la vida. A pesar de nunca llamarte devuelta, tu sigues siendo mi amigo y mi mejor forma de hablar español.

Sneha, see I can finish my thesis too ☺

Cyndi, my guide through my toughest spiritual times. May my life be a constant prayer.

BB, Martin and Tomas, nunca lo he dicho, pero los quiero.

Mami y Papi, gracias por el amor nunca pronunciado pero siempre presente. Solamente ahora empiezo a reconocer mi suerte en haberlos tenidos como padres. Ustedes mas que cualquier otra cosa me han formado como soy.

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Chapter 1

Introduction

There are millions of individuals with gait disabilities, requiring either rehabilitation or permanent assistance. In the US alone, approximately 866,000 people use an orthosis on a lower extremity (US DoC, 1994). Current assistive methods are usually labor intensive, highly variable, or require constant tuning. Applying robotic technology to gait could provide a means to quantify lower body kinematics and kinetics, improve and monitor locomotion during normal and clinic uses and help reduce the high-energy cost of disabled locomotion (Nene et al., 1996; Bernardi et al., 1995. Further, a robotic assistive device could adapt to human gait, which is consistently changing in both speed and form. In initial work, adaptive hip and knee orthoses have been able to provide more natural gait for the disabled (Goldfarb, 1994; Irby et al., 1999; Suga et al., 1998).

Specifically, this thesis investigates the ankle joint and how drop foot gait affects it. Drop foot, which afflicts over 300,000 people in the US alone (Nat'l Stroke Assoc., 1993), is caused by a weakness in the dorsiflexor muscles that lift the foot. This pathology is caused by stroke, cerebral palsy (CP), multiple sclerosis (MS) (Taylor et al., 1999), and neurological trauma, such as accidents or surgical complications. Current technologies for rehabilitation or permanent assistance rely on a professional's qualitative judgment and trial-and-error to find the appropriate assistive method. The main contribution of this thesis is to apply ankle biomechanics, engineering principles and current robotic technology to develop an improved, adaptive and autonomous system to assist drop foot gait.

1.1 Motivation

The major motivation behind this research effort is to assist those individuals with gait disabilities. The goal is to build an adaptive assistive device for any walking disability. This "bio-suit" would be able to detect and assist any abnormal gait from a spastic ankle to paraplegia. It would also be able to provide the proper rehabilitation or permanent assistance depending on the need of the user.

Initially, the ankle was chosen to be a good starting point and drop foot was selected as the pathology to analyze to make an immediate contribution. The current assistive technology for drop foot is a mechanical brace called an Ankle Foot Orthosis (AFO), which has been gaining increased usage over the last few years (Brown, 1995). Although AFOs offer some biomechanical benefits, there are many disadvantages that can be improved on (Carlson et al., 1997).

Another motivating factor is the better understanding of gait. Though gait has been studied for many years, there is still much to be learned, especially regarding pathological gaits. One new method of analysis is perturbed gait experiments, where a subject walks normally and is then given a sudden disturbance. Current methods for providing this disturbance are large moving platforms capable of high accelerations (Oddsson et al., 1999). However, a wearable or unilateral perturbation system has not been developed. A powered orthosis would provide the means to design these controlled motor learning studies on human locomotion.

1.2 Contribution

This thesis focuses on analyzing the ankle joint, specifically its function due to the drop foot pathology. Drop foot consists of the inability to properly lift the foot due to weakness or non-functioning dorsiflexor muscles. A control algorithm was developed to compensate for this pathology and a new device, the Active Ankle Foot Orthosis (AAFO), built to implement it. This controller adapts to each user's physical ability and to their gait speed.

The device built to implement this controller, the Actuated Ankle Foot Orthosis (AAFO), can also be used as a tool to study the mechanics of normal and pathological human gait. Disturbed gait experiments with the AAFO can elucidate more about the mechanics and stability of human gait. Another use for the AAFO is to prescribe and analyze the effect of different Ankle Foot Orthosis (AFO). A certified orthotist could simulate different prescriptions using the AAFO and then fabricate the AFO with best results.

Finally, this was the initial work in developing an overall mobility suit for paraplegics and other walking pathologies. Starting from the ground up, this is the beginning stage for the use of force controllable actuator in parallel with humans to augment the individual's capacity. The hypotheses guiding this research effort follow.

1.3 Hypotheses

The following are the specific hypotheses of this research effort:

1. Slapping of the foot during controlled plantar flexion (CP) can be eliminated by implementing a variable-stiffness torsional spring at the ankle to resist foot rotation.
2. The appropriate stiffness of the CP spring can be defined by the gait speed of the user and the force the forefoot exerts on the ground at foot flat.
3. Toe drag during swing can be eliminated by implementing a torsional spring-damper system to lift the foot after toe off.
4. The appropriate stiffness and damping parameters for swing can be defined by the gait speed of the user.

1.4 Thesis Outline

Chapter 2 provides a detailed background and a literature review of topics relevant to this thesis. Chapter 3 describes the design of the Active Ankle Foot Orthosis (AAFO) and the control algorithm to assist individuals with drop foot. Chapter 4 describes the experimental methods and data analysis. Chapter 5 details the results, while Chapter 6 discusses the results, summarizes the conclusions of this work and provides recommendations for future work.

Chapter 2

Background

This chapter provides the background on the major experimental topics and theories for this thesis including: kinetics, kinematics and energetics of gait, description of the three major joints in motion, description of the drop foot pathology and current technology used to help individuals with drop foot. Section 2.1, Human Gait, will cover all of the relevant details of human gait as well as the effects of drop foot. Section 2.2, Current Technologies, describes the current measures used to rehabilitate or permanently assist those individuals with gait disabilities, specifically drop foot.

2.1 Human Gait

2.1.1 Definitions

To begin a description of gait, a few terms must be defined, including: reference planes, stride cycle and plantar/dorsiflexion.

Reference planes: The anatomical planes used to analyze human movement. The three reference planes can be seen in Figure 2.1 (Rose and Gamble, 1994).

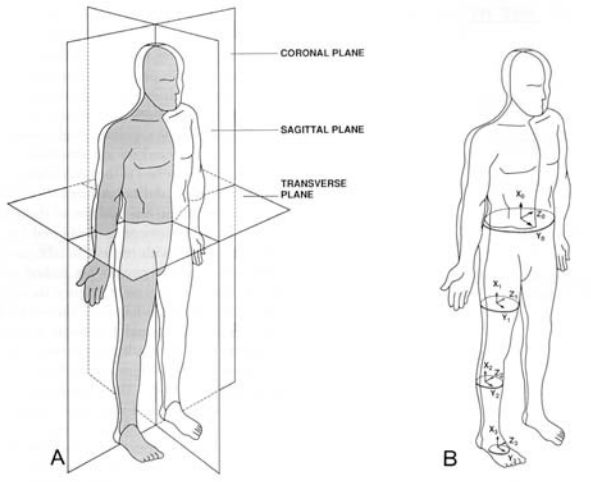

Figure 2.1 (a) Reference planes of body in standard anatomic position (b) coordinate system for lower limb (Rose and Gamble, 1994).

Stride cycle: the period of time between two successive occurrences of one of the repetitive events of walking. It is usually measured from an initial heel contact (HC) of one foot to the subsequent HC of the same foot. In order to compare the stride characteristics of different strides within the same subject or across different subjects, the stride cycle is usually expressed as 0 to 100% (Winter, 1996).

Dorsiflexion/Plantar Flexion: the rotation of the ankle in the sagittal plane towards or away from the body, respectively.

2.1.2 Definition of Gait and Walking

Gait is the "manner of moving the body from one place to another by alternately and repetitively changing the location of the feet" (Smidt, 1990) or "a translatory progression of the body as a while produced by coordinated rotary movements of body segments. Normal gait is rhythmic and characterized by alternating propulsive and restraining motions of the lower extremities" (Norkin and Levangie, 1983). There are many types of gait including walking, running (Novacheck, 1998), skipping (Minetti, 1998), and many pathological gaits. The focus of this thesis, however, is specifically on walking.

The gait cycle is the time interval between two successive occurrences of one of the repetitive events of locomotion (Novacheck, 1998). The beginning of the gait cycle is represented as initial contact of one foot with the gait surface, usually termed heel strike (HS) (Bowker and Hall, 1975; Gage, 1991; Perry, 1992; Smidt, 1990; Whittle, 1991). The gait cycle consists of the stance and swing periods. Swing designates the time the foot is in the air for limb advancement. Stance is the period where the foot is in contact with the ground.

Walking can be further defined as being comprised of initial double stance, single limb support, terminal double stance and swing. Stance comprises sixty percent of the walk cycle, where each double stance interval is ten percent and single limb support is forty percent (Gage, 1991). Swing is the remaining forty per cent. Single limb support of one limb equals swing of the other, as they are occurring at the same time (Perry, 1992).

For the purposes of this thesis, gait and walking will be used interchangeably.

2.1.3 Phases of Gait

The gait cycle can be divided into eight phases, which enable the limb to accomplish three basic tasks: weight acceptance (WA), single limb support (SLS) and limb advancement (LA) as shown in Figure 2.2 (Perry 1992).

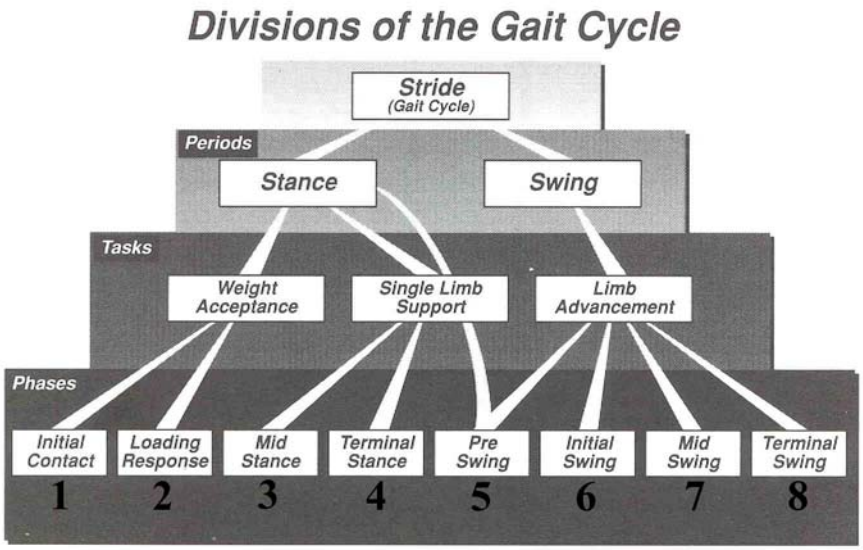

Figure 2.2 Divisions of the gait cycle (Perry 1992).

Weight acceptance (WA) is the most demanding task in the walk cycle since it requires shock absorption of the free-falling body, initial stabilization of the stance limb and preservation of forward momentum. This task comprises the first two walk phases, initial contact and loading response. Stance continues with single limb support (SLS), comprising the mid-stance and terminal stance phases. During this task, the stance limb has total responsibility for supporting body weight while the other limb is in swing. Limb advancement (LA) begins in the final phase of stance, pre-swing, and continues through the three phases of swing: initial swing, mid-swing and terminal swing (Perry, 1992).

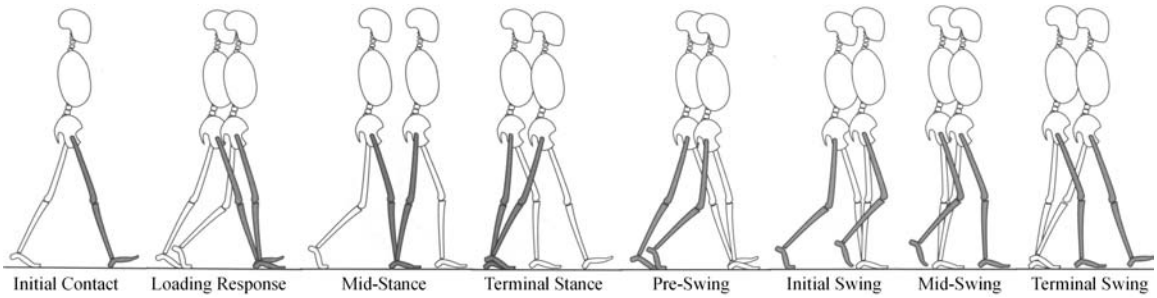

Figure 2.3 Phases of the gait cycle (Perry, 1992).

2.1.4 Kinematics of Gait

Kinematics is the term used to describe the spatial movement of the body, without considering the forces that cause the movement (Winter, 1996). The variables of kinematic data include linear and angular displacement, velocities, and accelerations. It is important to differentiate absolute and relative measurements when talking about kinematic data. Absolute measurements describe the true spatial orientation and position of the object of interest in space. It is made relative to a fixed, or immovable, reference frame. A relative measurement is made to a reference frame that is moving relative to a global fixed reference frame.

For the purposes of this work, joint angles are the main kinematic measurement. By definition, joint angles are relative and therefore tell us nothing about the absolute angle of each of the adjacent segments in space. The kinematics of each of the three major joints: hip, knee and ankle will be discussed further.

2.1.5 Kinetics of Gait

Kinetics pertains to the relationship between force and mass that produces motion. The main measurements of the kinetics of gait include the joint torques and powers. To calculate these variables, an inverse dynamics analysis must be performed using the kinematic data, explained above, and the ground reaction force (GRF).

Ground reaction force (GRF) is a measure of the impact that occurs when the foot makes contact with the ground. When a person walks, a reaction force is generated that is equal to the sum of the person's weight and the acceleration of the center of mass (CM). This reaction force can be decomposed into three components: vertical, lateral shear, and progressional shear GRF. The latter two are small compared to the vertical GRF and result from any non-perpendicular components of the GRF (Wu, 1999). Herein, only the vertical GRF is investigated, therefore, the two shear components are not discussed.

The timing of heel contact, mid stance, and toe off can be identified by inspecting the vertical GRF profile associated with each step. Figure 2.4 shows a typical GRF profile of a single step. The GRF has two peaks separated by a valley. As described earlier, a step consists of two periods: stance and swing. The major phases of stance represented by the GRF are heel contact

(HC), mid stance and push off. The first peak (GRF1) occurs during the HC phase in response to the loading response when the CM of the body drops drastically. This peak is generally more than one body weight (BW) and increases with higher speeds. The minimum occurs during mid stance when the body rolls forward over the stationary foot. It is less than one BW since the CM rises during mid stance. The second peak (GRF2) occurs during the push off phase and has a value greater than one BW, again indicating downward acceleration and lowering of the CM as the body falls forward over the forefoot. Therefore, the magnitude of the GRF is directly related to the acceleration of the CM and can be described by equation UU

$$GRF = M (g + a)$$

Where GRF is the ground reaction force, M is the mass of the person,
g is gravity, and a is the center of mass' (CM) vertical acceleration.

Since M and g are constants, the changes in the magnitude of GRF depend only on the changes in the vertical acceleration.

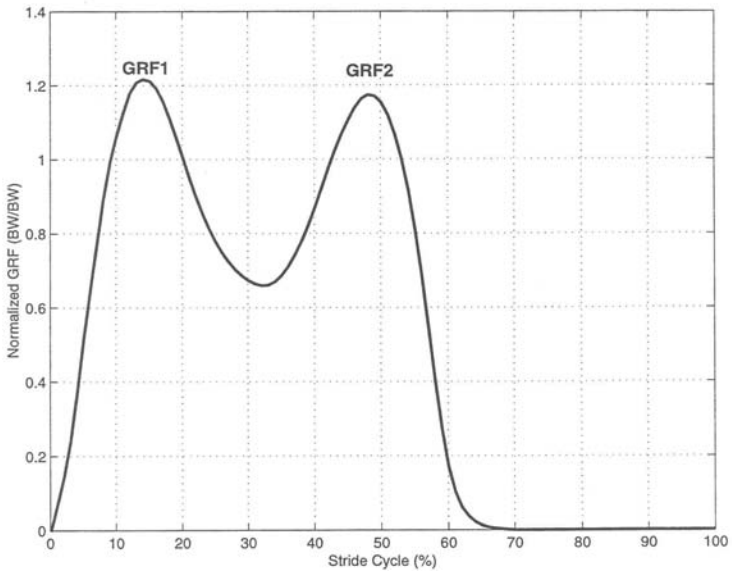

Figure 2.4 Vertical ground reaction force (GRF) of a stride.

2.1.6 Determinants of Gait

The purpose of locomotion is to transport the body over a distance with minimal disturbance to the center of mass (CM). Human gait has six determinants to minimize energy expenditure: compass gait, pelvic rotation, pelvic tilt, stance knee flexion, plantar flexion and lateral displacement (McMahon, 1984).

The first determinant of gait is compass gait, seen in Figure 2.5 (a), which only permits flexion and extension of the hip. Since there is no bending of the knee, the pelvis moves through a series of arcs centered at the ground contact and with a radius equal to the leg's length. Pelvic rotation, the second determinant, flattens the arc to decrease the amount of vertical displacement of the CM. As shown in Figure 2.5 (b), the amplitude of this rotation is approximately $\pm 3^{o}$ in gait at normal speed and increases with higher speeds (McMahon, 1984). The leg length is extended due to the pelvis rotation, making it an effectively larger traveling arc, therefore stabilizing the trajectory of the CM. The third determinant, shown in Figure 2.5 (c), is pelvic tilt, which occurs during the swing phase. The pelvis is tilted down to about 5^{o} relative to the horizontal plane to further flatten the arc traveled by the CM. Figure 2.5 (d) shows the fourth determinant, which is stance knee flexion. By bending the knee slightly, the peak in the pelvic trajectory is lowered. The fifth determinant, shown in Figure 2.5 (e), is plantar flexion of the stance ankle just before toe-off. This reduces the amplitude of the transition from the double-support phase to the swing phase. Plantar flexion also plays an important role in establishing the initial velocities of the shank and thigh limb for the subsequent swinging motion (McMahon 1984). The final determinant of gait is lateral displacement of the pelvis shown in Figure 2.5 (f). Since weight bearing is transferred alternately from one limb to the other, the pelvis shifts about 2 cm towards the stance phase limb to keep the CM aligned with the stance foot so that falling over occur does not occur.

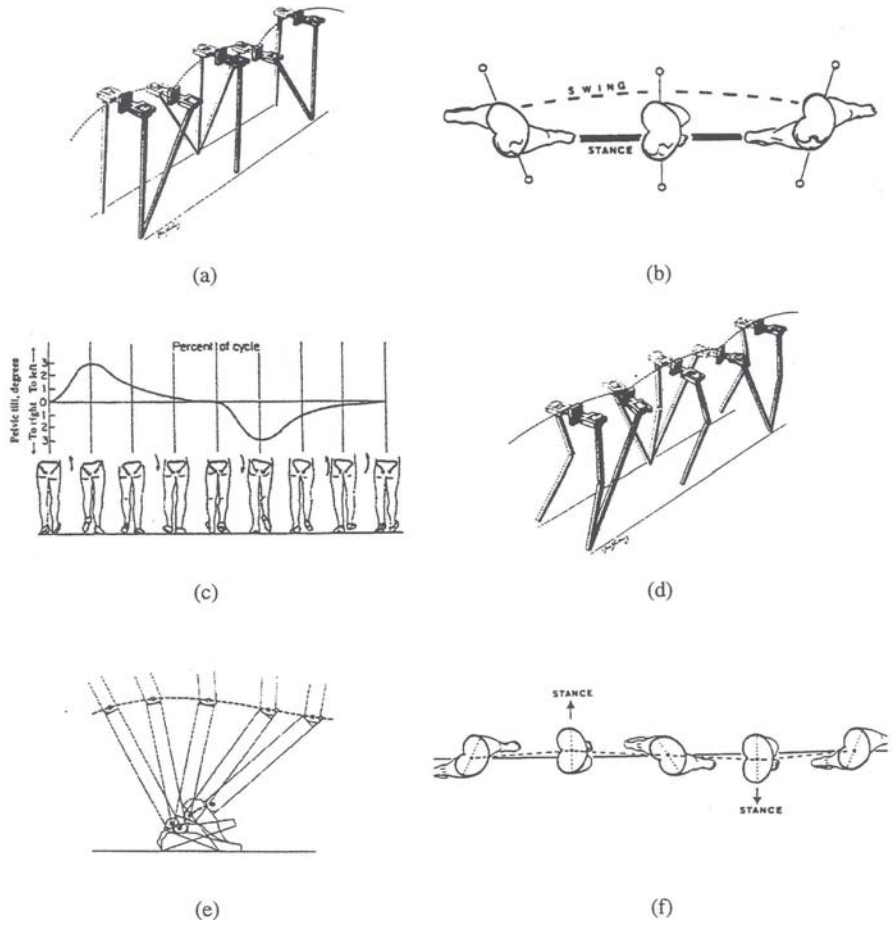

Figure 2.5 Determinants of gait (a) Compass gait (b) pelvic rotation (c) pelvic tilt (d) stance knee flexion (e) plantar flexion and (f) lateral displacement (McMahon, 1984).

2.1.7 Energetics of Gait

Mechanically, gait efficiency is increased due to the constant transfer of energy between potential to kinetic sources. This energy conversation mechanism is analogous to an inverted swinging pendulum (Blickhan and Full, 1987; Cavagna et al., 1977; Heglund et al., 1982). In human gait, as much as 60-70 % of the mechanical energy required to lift and accelerate the center of mass is conserved by this energy transfer mechanism (Cavagna et al., 1976). Mechanical energy savings are maximized at moderate gait speeds, and fall toward zero at very low and very high gait speeds (Cavagna et al., 1976). The potential energy of gait can be defined as the energy in moving the center of mass in the vertical direction and can be written as:

$$PE = mgy$$

where PE is the gravitational potential energy, m is the mass of the body, g is the acceleration of gravity and y is the vertical displacement of the center of gravity of the body

When the leg is vertical, the maximum PE is reached, while the maximum horizontal speed is attained when the center of gravity of the body is at its lowest point. The kinetic energy (KE) is given by:

$$KE = \frac{1}{2} m v^2$$

where KE is the kinetic energy, m is the mass of the body, and v is the velocity

Therefore, an oscillation between maximum PE and KE analogous to an inverted pendulum model is seen.

Vaulting over a stiff leg, as in compass gait, conservers up to 70 % of the mechanical energy required for progression (Full, 1991). In gait, the muscular force generation at step initiation is mainly directed vertically to raise the body and attain maximum gravitational PE. In the second phase of the stride cycle when KE reaches a maximum the falling forward of the body is assisted by the skeletal system and muscles in order to accelerate and decelerate the center of gravity as the alternate foot strikes the ground.

In Figure 2.6, S_V is the vertical displacement of the center of gravity, which is parallel to the changes in the potential energy W_V. The total mechanical energy W_{EXT} is the sum of the potential (W_V) and kinetic (W_F) energy changes. As can be seen, the potential and kinetic energy changes during gait are substantially out of phase. This suggests that energy is conserved during a step by transferring the changes in potential energy to kinetic energy and vice versa. There is work added to the system corresponding to (a) and (b) in Figure 2.6. The work done at (a) is due to the forward and upward push of the foot as it is leaving the ground, sometimes called push-off. The work performed at (b) is necessary to complete the lift of the center of gravity to reach its maximum point directly above the center of pressure (Cavagna and Margaria, 1966).

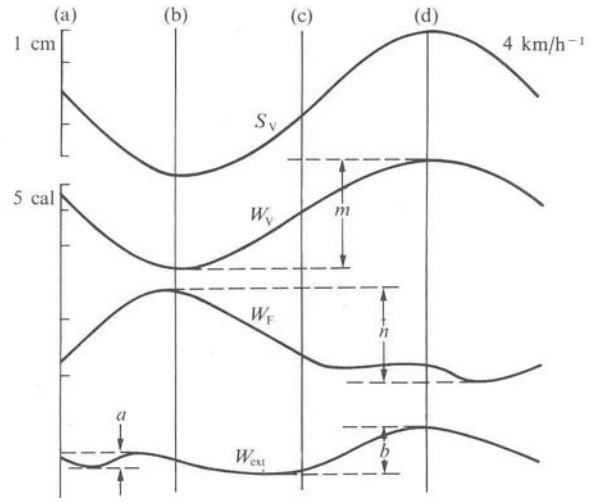

Figure 2.6 Potential (W_V) and kinetic (W_F) energy changes during a step, gait at 4.0 km h^{-1}. m is the anti-gravitational work, n, the work due to frontal acceleration; a+b is the total external work (Cavagna et al., 1963).

2.1.8 Physiology of gait

Trying to develop orthotic devices requires analysis of each functional joint that is being assisted. Thus, the easiest method of looking at gait is to analyze each joint individually in the sagittal plane.

Hip

The hip provides the connection between the dynamic lower body and the almost stationary upper body. The hip moves through only two arcs of motion during a normal stride: extension during stance and flexion in swing. During stance, the primary role is stabilization of the trunk; while during swing, it's control of the limb (Perry, 1992).

The hip is in approximately 25 degrees of flexion at initial contact. All five hip extensors (biceps femoris, semimembranosis, semitendinosis, adductor magnus, gluteus maximus) contract to resist the flexor moment created by the vertical ground reaction force (GRF) and keep thigh position relatively stable. This can be seen in the first three frames of Figure 2.7 (a), below, where the active muscles are darkened (Inman, 1981)

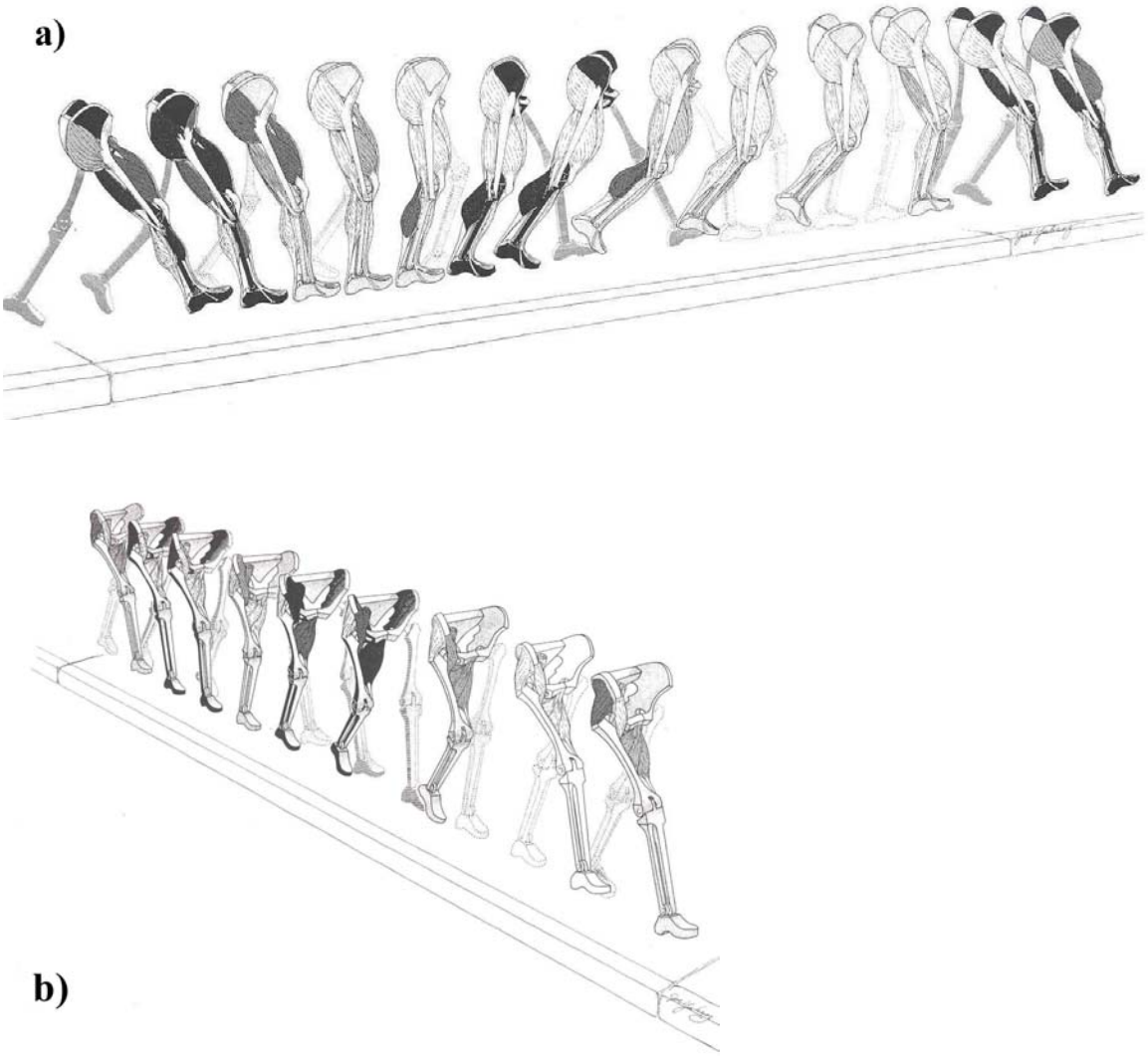

Figure 2.7 (a) and (b) Muscle activation pattern of gait (Inman, 1981).

The abductor muscle group stabilizes the pelvis, which lost its contra lateral support with the transfer of body weight to the forward limb (Perry, 1997). Internal rotation in the transverse plane is the third action initiated due to the change in support from the trailing limb to the forward foot and the subtalar joint reaction to heel loading. In mid and terminal stance, the hip progressively extends, reaching neutral position at 38% of the gait cycle (GC). In terminal stance the erect pelvis and trunk roll forward over the forefoot rocker causing the body weight to move posterior to the hip joint and the thigh to be pulled into hyperextension. The anterior portion of the tensor fascia lata (TFL) responds to restrain passive hip extension and to provide a low level of abduction force (Perry, 1992).

Hip flexion to neutral position during pre and initial swing results from two events. First, contraction of the iliopsoas aided by gravity, the rectus femoris and the adductors (Gage, 1991). This can be seen during the fifth drawing in Figure 2.7 (b). The second event is the ankle mechanics that advance the tibia, induce knee flexion and carry the thigh forward. The contraction of the gastrocnemius is a major part of this event, as can be seen in Figure 2.7 (a). When tibial inertia causes excessive knee flexion, the rectus femoris preserves accelerated hip flexion while correcting knee motion. Minimal hip flexion and partial knee extension continue to advance the limb during mid swing. During terminal swing, strong action by the hamstring muscles prepare the limb for stance by stopping further flexion. The reduction of hamstring muscle activity and accompanying onset of the gluteus maximus and adductor magnus provide hip extension. Because of these actions, the limb is positioned for initial contact (Perry, 1992). The entire range of motion of the hip for normal gait can be seen in Figure 2.8.

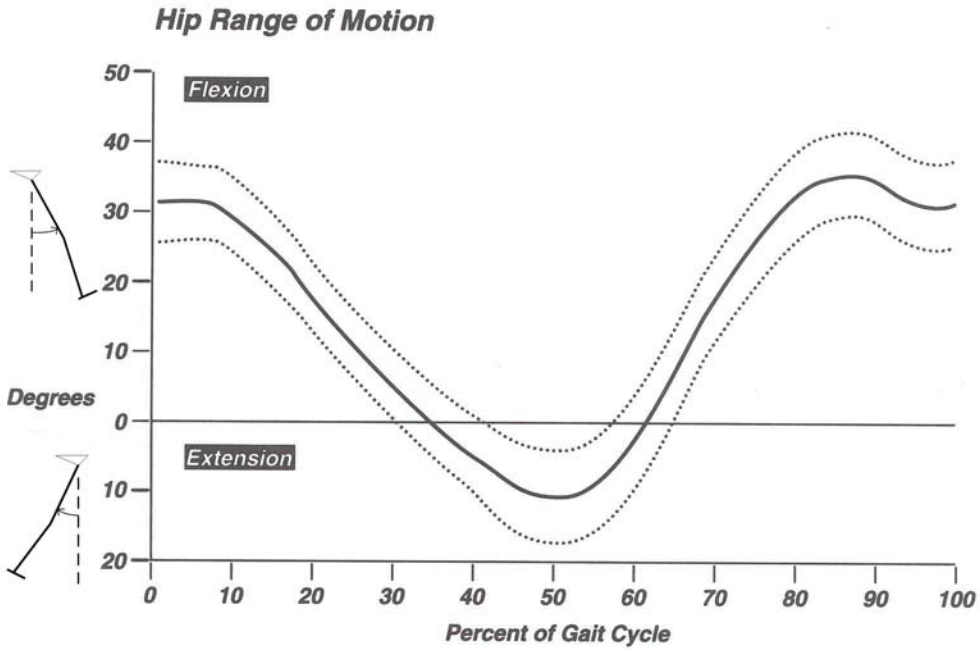

Figure 2.8 Hip range of motion versus percent of gait cycle (Perry, 1992).

Knee

During stance, the knee is the basic determinant of limb stability. In swing, knee flexibility is the primary factor in the limb's freedom to advance (Perry, 1992).

At initial contact, the knee is extended approximately two to five degrees of flexion, as can be seen in Figure 2.9. During loading, body weight is accepted with the knee flexed and the GRF falls behind the knee to produce an external flexion moment. This moment is counteracted by contraction of the quadriceps, including the vastus laterialis, medialis, and intermedius, to prevent the knee from buckling and places the knee under maximum weight-bearing load (Gage, 1991). The activation of these muscles can be seen in the first four drawings of Figure 2.7 (a). At mid stance, total body weight is transferred onto the flexed knee, resulting in an additional five degrees of flexion. The quadriceps react to inhibit further flexion and is then assisted by the tibial stability gained through the combined action of the soleus and the forward motion of the body weight. Three mechanisms contribute to knee extension stability during terminal stance. The first is strong plantar flexion that provides a stable tibia over which the femur advances. Limb momentum and the forefoot rocker that facilitates the forward fall of the body weight over the leg also assist in stabilizing the knee. To avoid knee hyperextension, the popliteus and gastrocnemius provide a flexor action posteriorly. The knee begins to flex at the end of terminal stance from the rolling of the leg. Tibial stability is then lost and the posterior muscles become free to initiate knee flexion.

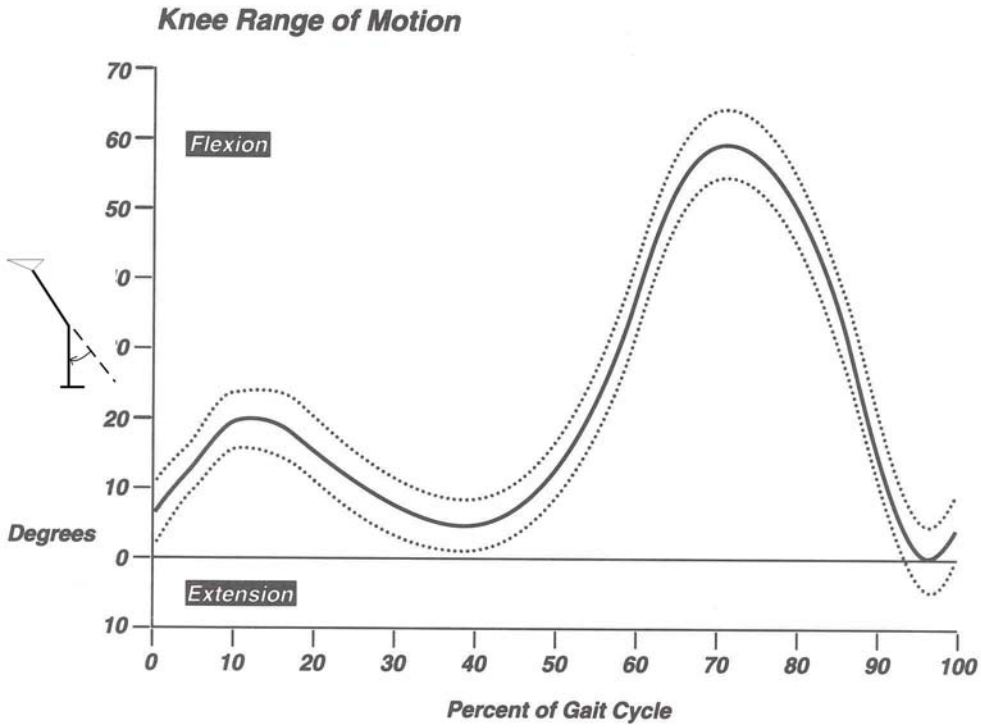

Figure 2.9 Knee range of motion for a normal gait cycle (Perry, 1992).

Body weight is transferred to the opposite limb and as the trailing limb reduces its floor contact, the lower leg is free to roll forward. This is accelerated by the release of the tension stored in the stretched soleus, gastrocnemius, and hip flexors. This force and that from the adductor longus initiate early hip flexion and assist knee flexion. The critical event for initial swing is knee flexion sufficient for the toe clearance as the thigh advances (Perry, 1997). Attainment of full knee flexion largely depends on the imbalance between the forward momentum of the femur generated by hip flexion and inertia of the tibia and the active knee flexion by the biceps femoris, as can be seen on the last drawings of Figure 2.7 (a). Only gravitation forces and the momentum generated by hip flexion are required during mid swing. All four vasti are involved in terminal knee extension to lift the weight of the lower leg. These counteracted by the hamstrings, which prevent knee hyperextension and decelerate the hip (Perry, 1992).

Ankle

The arcs of motion of the ankle are not large, but they are critical for progression and shock absorption during stance. Momentum is preserved by creation of pivotal system in the heel, ankle and forefoot that allow the body to advance while the knee maintains an extended posture, as shown in Figure 2.10 (Perry, 1992). In swing, ankle motion contributes to limb advancement. The range of motion for the ankle can be seen in Figure 2.11.

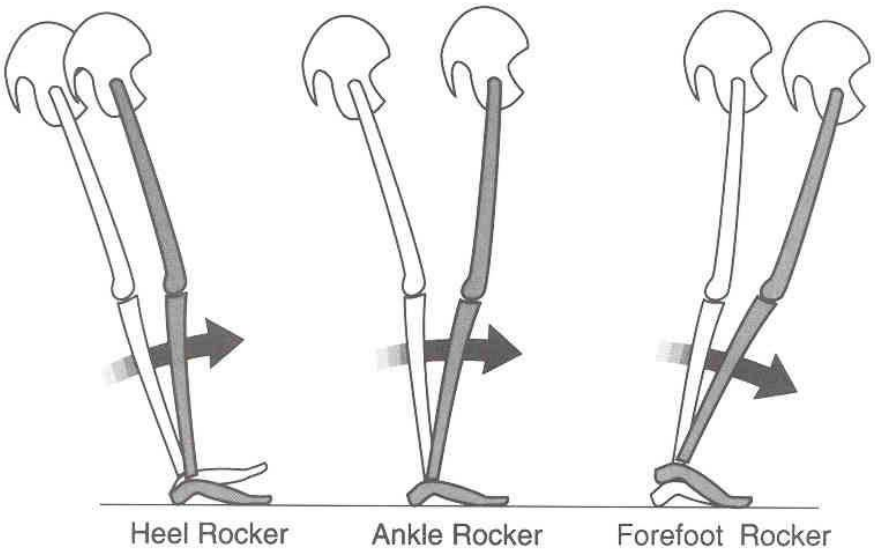

Figure 2.10 Heel, ankle and forefoot rockers used for body advancement (Perry, 1992).

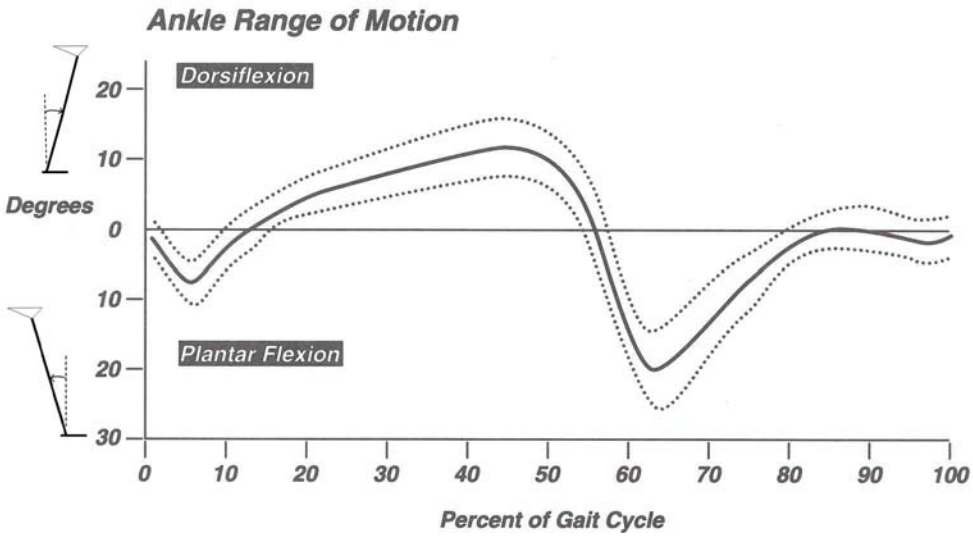

Figure 2.11 Ankle Range of Motion versus a normal gait cycle (Perry, 1992).

Initial contact occurs as the heel contacts the floor with the ankle in neutral position pulled by the tibialis anterior. To keep the body moving forward without interruption, a heel rocker is used. Rapid loading of the limb generates a plantar flexion moment that drives the foot toward the floor. The external plantar flexion moment is resisted by the internal dorsiflexion moment of the pretibial muscles (tibialis anterior, extensor digitorum longus, and peroneus tertius) as they

provide for a controlled, eccentric contraction (Gage, 1991). This extends the heel support period, draws the tibia forward, and roll the body weight forward on the heel. This also provides shock absorption for the brief period when the body weight free falls before heel strike.

Ankle motion during mid stance serves as an ankle rocker to continue progression. The displacement of the body over the foot creates an increasing dorsiflexion moment that rolls the tibia forward from an initial eight degrees of plantar flexion to five degrees dorsiflexion, while the foot remains in contact with the floor (Perry, 1992). The gastrocnemius and soleus muscles slow the rate of tibial advancement until the end of midstance to restrain the forward movement of the tibia on the foot (Whittle, 1991). Soleus activity is the dominant decelerating force because of its larger size and its direct attachment between the tibia and calcaneus, as shown in Figure 2.7 (a).

By the end of midstance, the ankle is locked by the gastrocnemius and soleus, and the heel rises due to continued tibial advancement. This makes the forefoot the sole source of foot support and creates a forefoot rocker to allow for forward progression. During terminal stance, a combination of limited ankle dorsiflexion and heel rise places the ground reaction force (GRF) anterior to the source of foot support. As the GRF moves more anterior to the metatarsal head axis, the foot rolls with the body, leading to a greater heel rise and an increasing dorsiflexion moment. This creates a free forward fall situation that passively generates the major progression force used in gait. The ground reaction force created is greater than body weight and varies with gait velocity. By the end of terminal stance, there is no stabilizing force within the foot, so it is free to plantar flex in response to the triceps surae muscle, commonly called push off (Perry, 1992).

Following the onset of double limb support, the body weight is transferred to the other limb in preparation for pre-swing. Peak soleus and gastrocnemius activity only support a heel rise and accelerate advancement of the unloaded limb. The tibia moves forward as the toe is stabilized by floor contact and the knee flexes in preparation for swing.

During toe-off, the ankle is plantar flexed approximately 20 degrees. The pretibial muscles increase their intensity in initial swing to dorsiflex the foot to neutral by the time the swing foot is opposite the stance limb. The dorsiflexion moment decreases in mid swing since only an isometric force to support the foot at neutral or slightly plantar flexed is required. During terminal swing, pretibial muscle activity increases to assure the ankle is at neutral position for

optimal heel contact and in preparation for the increased force requirement of initial contact (Gage, 1991).

2.1.9 Ankle Pathologies

Two of the most common forms of ankle deviations are excessive dorsiflexion and excessive plantar flexion. The main focus will be placed on drop foot or pretibial muscle weakness since that is the pathology that the device will be assisting. The most common causes of drop foot are stroke, spinal cord injuries, cerebral palsy, multiple sclerosis and trauma.

2.1.9.1 Excessive Dorsiflexion

There are two common conditions for excessive ankle dorsiflexion: soleus weakness and fixation of the ankle. The common causes of inadequate triceps surae action are primary muscle weakness due to disuse or paralysis and excessive surgical lengthening of a tight Achilles tendon. The reasons for an ankle locked at neutral position can be either fusion of the ankle and subtalar joints (subtalar fusion) or an orthosis with a locked ankle joint, as shown in Figure 2.12. In both of these cases, excessive dorsiflexion has more functional significance in stance than swing.

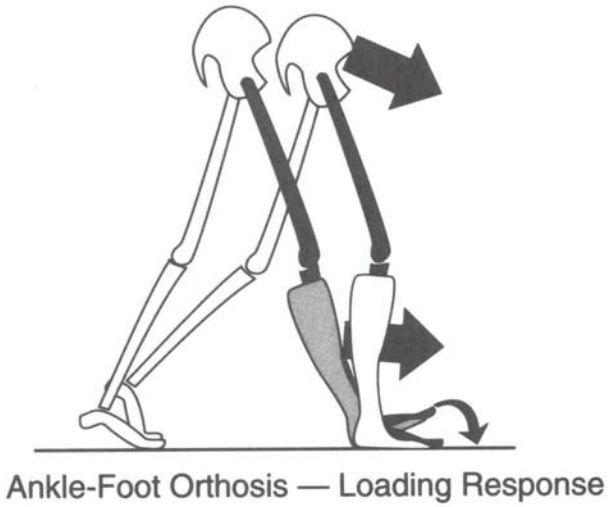

Figure 2.12 Excessive ankle dorsiflexion due to a rigid ankle-foot orthosis (AFO) or ankle fusion (Perry, 1992).

Excessive dorsiflexion during initial contact is infrequent, but when it occurs it places the leg in a position of instability and excessive heel rocker. Continuing through the loading response, this will cause accelerated tibial advancement and a corresponding increase in quadriceps demand. During mid stance, two situations can occur. First, there is insufficient impedance to the forward momentum of the limb over the ankle rocker. Though the final position of the ankle may not the normal passive ranges of the individual, there is stance instability at the onset of single limb support. The second situation is a larger angle between the tibia and foot that has detrimental effects in terminal stance. Both of these situations create an unstable base for the quadriceps and increase its demand (Perry, 1992). During terminal stance, two deviations are seen: prolonged heel contact and excessive knee flexion with a heel rise that tends to mask the additional tibial advancement. Prolonged heel contact during pre-swing is the only abnormality seen during swing, except for the incorrect placement of the ankle before initial contact (Shumway-Cook and Woolacott, 1995).

2.1.9.2 Excessive Plantar Flexion

There are four basic causes for excessive plantar flexion: drop foot (pretibial muscle weakness), plantar flexion contractures, triceps surae over activity, and voluntary posturing for a weak quadriceps. Failure of the pretibial muscles, primarily the tibialis anterior, to produce an adequate dorsiflexion force allows the foot to fall in an uncontrolled manner, sometimes called foot slap. Plantar flexion contractures are affected by both the magnitude of dorsiflexion lost as well as the rigidity of the tissues. Plantar flexion contractures of 15 or 30 degrees are seen, with the former being the most common. The rigidity of the contractures is created by the increased stiffness of the fibrous tissues in the ankle, thus a contracture can be elastic or rigid. The triceps surae may be continuously active if severe spasticity is present. This affects the gait pattern in a fashion similar to a plantar flexion contracture of similar magnitude. Finally, if an individual with normal control has weak quadriceps, they tend to reduce their heel rocker to protect their quadriceps from the usual knee flexion thrust of the loading response (Perry, 1992).

There are two abnormal modes of initial contact due to excessive plantar flexion: low heel contact and forefoot contact. Low heel contact occurs when the foot strikes the floor with the ankle in 15 degrees of plantar flexion and the knee fully extended, as shown in Figure 2.14 (a). In drop foot, the foot will then fall uncontrollably to the ground, producing a distinctive noise

and added stress on the ankle joint. Forefoot contact occurs when both excessive plantar flexion and knee flexion exceed 20 degrees and place the forefoot lower than the heel. Three different loading response patterns can occur from this, as shown in Figure 2.13. If there is good ankle mobility, the foot will rapidly drop onto the heel while the tibia stays vertical. Otherwise, the heel off posture may continue or the tibia is driven backward as the heel drops to the floor (Perry, 1992).

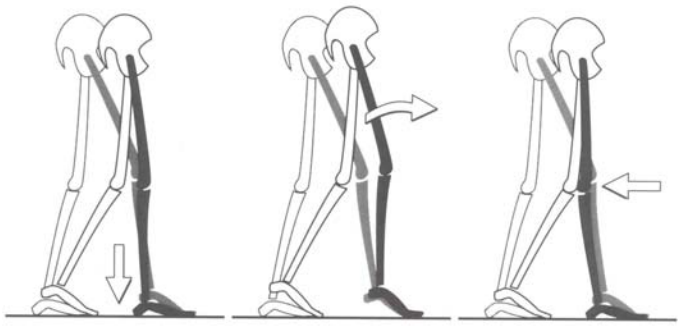

Figure 2.13 Loading response deviations due to excessive plantar flexion (Perry, 1992).

During mid stance, the loss of the ankle rocker limits the progression and lead to a short step length by the other limb. Three substitutions have been characterized in response: premature heel-off, knee hyperextension or forward trunk lean. In premature heel-off, the heel rise occurs in mid rather than terminal stance and the added effort results in a reduction of gait speed. This mechanism is used by active walkers with no other major disabilities. Knee hyperextension occurs when the femur follows body momentum and rolls over the immobile tibia. This is common with stroke hemiplegia, incomplete spinal cord injury, and cerebral palsy. Forward trunk lean is used to maintain balance over the rigid ankle and is used by less mobile persons. Body weight advances as the patient rolls across the forefoot and the patient proceeds immediately into terminal stance. In most cases, terminal stance will have a normal pattern. However, if there is no heel rise, the advancement of the body is limited to the extent that knee hyperextension and trunk lean improve the forward reach of the opposite limb (Perry, 1992).

Unless there is extensive plantar flexion contracture, there will be normal movements during both pre-swing and initial swing. Both of these phases require plantar flexion and can thus hide the pathology. During mid swing, the most common effect is toe drag, which prevents proper limb advancement, as shown in Figure 2.14 (b). Without substitution, this would cause swing to

end prematurely. The most direct substitution is increased hip flexion to lift the limb. As the thigh is lifted, the knee flexes with gravity and lifts the foot to attain ground clearance. Other substitutions use inadequate hip flexion and include circumduction, lateral trunk lean and contra lateral vaulting (Scribner and Dealy, 1989). Most toe drag should be corrected by terminal swing and thus there is usually no significant deviation during this phase unless the individual is not able to substitute for excessive plantar flexion.

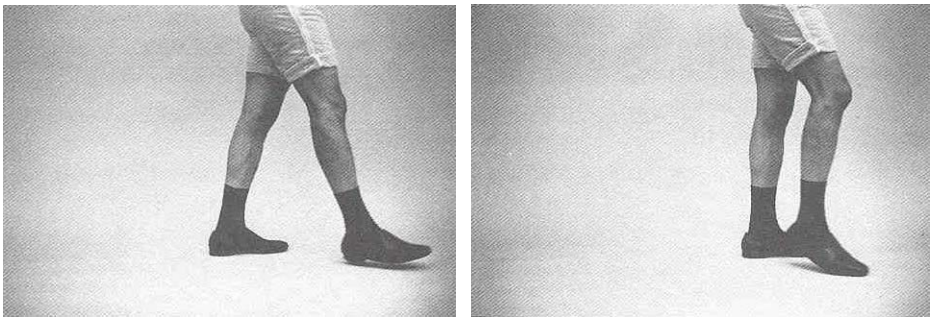

Figure 2.14 Effects of excessive plantar flexion (a) slap foot after HS and (b) toe drag during swing (Perry, 1992).

2.2 Current Technologies

The current medical technologies currently available are ankle foot orthoses (AFO) or functional electrical stimulation (FES) of the peroneal nerve. Both of these technologies have helped hundreds of clinical users in the United States and around the world.

2.2.1 Ankle-Foot Orthosis (AFO)

Wu (1990) defines an ankle foot orthosis (AFO) as "a medical mechanical device to support and align the ankle and foot, to suppress spastic and overpowering ankle and foot muscles, to assist weak and paralyzed muscles of the ankle and foot, to prevent or correct ankle and foot deformities, and to improve the functions of the ankle and foot."

Traditional ankle foot orthosis were double-metal upright braces with leather bands that attached to a pair of shoes. They are still utilized in cases of fluctuating peripheral edema or in situations where patients prefer the metal braces usually because they have worn the braces for years and are accustomed to them. However, they have virtually been replaced by plastic, or polypropylene, braces, shown in Figure 2.15. The major advantages of polypropylene AFOs are that they distribute pressure over a larger surface area of the limb resulting in less discomfort, are lighter than metal braces, more cosmetically appealing, and can be worn with a variety of shoe

types (Good and Supan, 1989). They are also stable and resistant to damage by water or solvents.

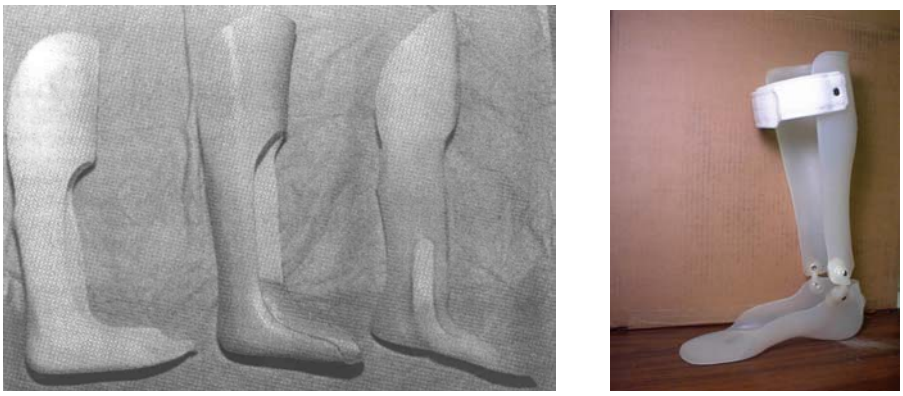

Figure 2.15 (a) Polypropylene ankle-foot orthosis (AFO) (b) Tamarack Flexure™ joint AFO.

Polypropylene AFOs are fabricated by making a cast of the patient's leg below the knee, then molding the polypropylene over it. This ensures a close fit for improved pressure distribution. The AFOs are divided into rigid and flexible types. Rigid AFOs, seen in Figure 2.15 (a), are utilized when more control is needed such as with poor ankle control, spasticity or clonus (Rossi, 1989). Flexible AFOs, seen in Figure 2.15 (b), are utilized to assist the patient who may need dorsiflexion assistance. Two major types of flexible AFO joints are shown in Figure UU, the Tamarack Flexure Joint™ and the Scotty™ hinge joint. They both provide limited mobility in the sagittal plane and restrict all motion in the frontal and transverse planes.

AFOs are prescribed to protect the extremity from injury, to correct abnormal posturing, and to aid in the development of efficient and safe gait. The type of AFO is dependent on the pathology of the user and their physical ability. Numerous studies have shown that AFOs improve ambulation in hemiplegic patients (Lehmann et al., 1970; Lehmann et al., 1982; Burdettt et al., 1988; Corcoran et al., 1970).

2.2.2 Functional Electrical Stimulation (FES)

Functional electrical stimulation (FES) is a methodology that uses shorts bursts of electrical pulses to generate muscle contraction (Bajd et al., 1999; Guyton, 1996). These pulses generate action potentials in motor neurons attached to a muscle, which cause that muscle to contract. For the muscle to contract its motor neurons must be intact i.e., the muscle should not be "denervated" (Popovic, 2001). Also, in order to achieve a continuous muscle contraction, also

called tetanization, the FES system must produce pulses at a minimum of 20 Hz (Bajd et al., 1999; Guyton, 1996). Otherwise, the muscle twitches continuously and does not generate a steady output force. Both monophasic and biphasic current or voltage pulses can be used to stimulate motor neurons. The common belief, however, is that the injected charge should be removed from the body and not allowed to accumulate. Most surface electrodes use biphasic current pulses, which changes the positions of the anode and cathode during stimulation.

There are currently three types of stimulators: surface (transcutaneous), needle (percutaneous), or implanted electrodes (Bajd et al., 1999). Transcutaneous stimulation consists of self-adhesive or nonadhesive electrodes placed on the subject's skin, as shown in Figure 2.16. Percutaneous stimulation uses wire electrodes introduced into muscle with an epidermal needle (Bukett et al., 1998; Hoshimiya and Handa, 1989). Implanted electrodes are attached to the motor neurons or the muscles close to the motor neurons (Cameron et al., 1997; Hoshimiya and Handa, 1989).

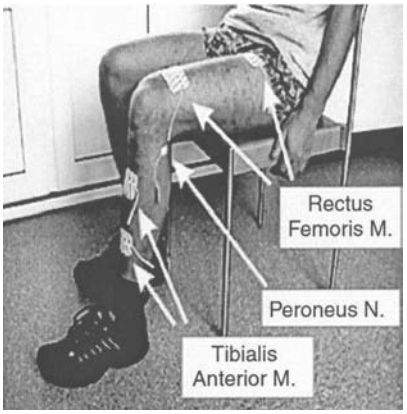

Figure 2.16 ETHZ-Paracare surface electrodes (Popovic, 2001).

The first walking FES neuroprosthesis was proposed by Liberson to help drop-foot subjects. The prosthesis stimulates the peroneal nerve causing a flexion reflex of the hip, knee and ankle that allows the user to move the disabled leg (Liberson et al., 1961). Another system was developed in the Ljubljana Rehabilitation Institute that included a wireless link between the heel switch and stimulator and a small implantable radio receiver for the electrodes (Vodovnik et al., 1978). Since then, several FES systems have been developed to help drop foot subjects. Among them are the Fepa, MikroFES , WalkAid (Neuromotion, Inc. Edmonton, AB), Odstock 2 (http://www.mpbe-sdh.demon.co.uk/index.htm), and ETHZ-Paracare. All these systems use surface stimulation triggered by a push button, foot switch or gait phase recognition sensor. The

push button, attached to a walker, is pressed by the subject and initiates the walking stimulation sequence. The system used on the ETHZ-Paracare is shown in Figure 2.17. The foot switch control, located in the shoe sole under the heel of the subject, automatically triggers the sequence on heel-strike (Taylor et al., 1999). The disadvantage is false triggering from foot sliding or weight shifting (Popovic et al., 1998).

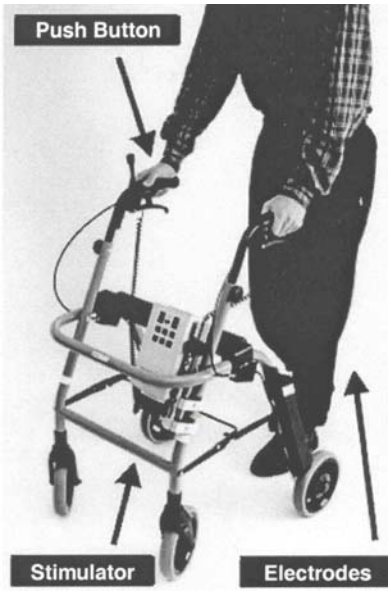

Figure 2.17 ETHZ-Paracare push button drop foot system (Popovic, 2001).

The gait phase recognition sensor consists of three force-sensitive resistors (FSR), a gyroscope, and a rule-based observer. This system is able to identify four gait phases of walking: heel-off, swing phase, heel-strike, and mid stance (Popovic et al., 2001). Most of these devices are used for short-term rehabilitation in a clinical environment, though they have been used as permanent orthosis (Bajd et al., 1999). Though some of these systems have been fitted to hundreds of subjects, only the WalkAid has FDA approval.

Chapter 3

Controller and AAFO Design

The following sections detail the design process of the drop foot controller and the experimental apparatus, the Active Ankle Foot Orthosis (AAFO). Section 3.1, Physical Components of the AAFO, describes he apparatus developed that can be used to test multiple control ideas for different ankle pathologies. Section 3.2, State Controller for AAFO, details the drop foot controller and its method of assisting drop foot by implementing a series of spring and damper systems at the ankle. This device and specifically the drop foot control algorithm serve as one of the major contributions of this thesis.

3.1 Physical Components of the AAFO

The Active Ankle Foot Orthosis (AAFO) that was developed can be seen in Figure 3.1. Each of the five major components is described further.

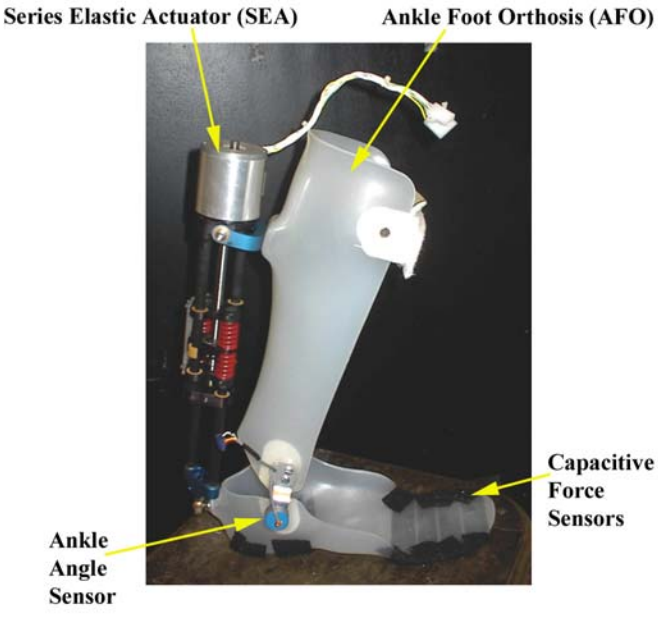

Figure 3.1 The Active Ankle Foot Orthosis (AAFO).

3.1.1 Series Elastic Actuator

A Series Elastic Actuator (SEA) developed at the MIT Leg Laboratory was used to control the motion of the ankle in the sagittal plane. The SEA consists of a brushless DC motor in series with a set of springs to provide series elasticity (Pratt and Williamson, 1995). By measuring the deflection of the springs, the SEA provides force control through a position sensor. Figure 3.2 shows a drawing of the SEA used. The deflection of the springs is measured by a linear potentiometer sampled at 1000 Hz. This measurement is passed through a first order filter with a cutoff frequency of 50 Hz. It is then numerically differentiated and passed through another first order filter with a cutoff frequency of 8 Hz. The SEA is controlled through an internal feedback loop with a Proportional-Derivative (PD) controller with gains of 10 and 15, respectively.

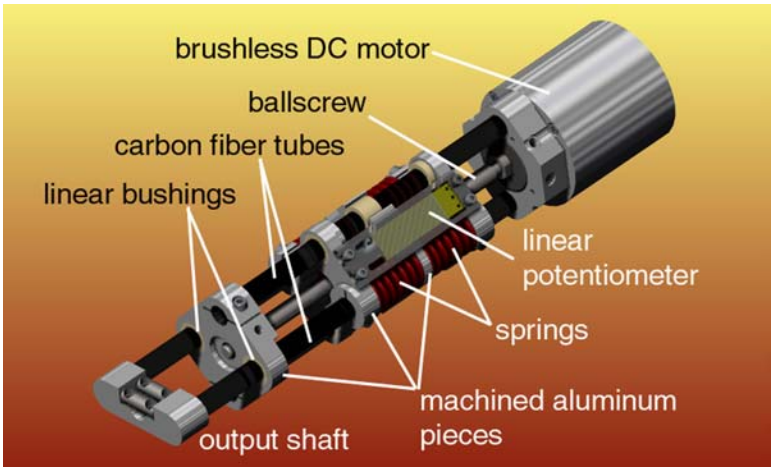

Figure 3.2 Series Elastic Actuator (Paluska, 2000).

The advantages of the SEA are that it has low impedance, motor is isolated from shock loads, and the effects of backlash, torque ripple and friction are filtered by the spring. A further advantage is that the SEA exhibits stable behavior while in contact with all environments, including in parallel with a human. The SEA allows the implementation of any virtual, torsion mechanical element around the ankle. Specifically, the AAFO will implement a virtual linear torsion spring or spring-damper system with varying values of stiffness and damping to accommodate the user.

3.1.2 Ankle Foot Orthosis (AFO)

The final AFO used was a standard polypropylene AFO with a metallic hinge (Scotty ©) ankle joint. This joint allowed free motion in the sagittal plane and was rigid all other directions. The AFO was modified by drilling several holes to place the SEA behind the calf as shown in Figure 3.1. Three 6.3 mm (¼ in.) holes were made at the top indentation and a single 12.6 mm (½ in.) hole was made at the heel. All AFOs were made at Hanger Prosthetics and Orthotics (Woburn, MA).

3.1.3 Ankle Angle Sensor

A Bourns 6637S-1-502 5 kΩ rotary potentiometer was used at the ankle to determine the angle between the shank and the foot. A connector was built to place the potentiometer on the hinge joint at the ankle. The angle signal, sampled at 1000 Hz, is passed through a first order low pass filter with a cutoff frequency of 50 Hz. The ankle velocity is found by differentiating the pot signal and then passing it through a second order Butterworth filter with a cutoff frequency of 8 Hz (Winter, 1990).

3.1.4 Ground Reaction Force (GRF) sensors

Initially, it was thought that an appropriate control scheme would need to measure the ankle spring stiffness, defined as the linear regression of the ankle torque versus angle curve (Palmer, 2002). To measure the ankle spring stiffness an accurate measurement of the ankle torque is required. The most commonly used method to calculate the ankle torque is to use inverse dynamics knowing the total ground reaction force (GRF) and the center of pressure (COP) at the bottom of the foot (Ramakrishnan, 1984). For simplified calculations, the inertial terms can be neglected. The further complication is that the system needs to be on the AFO being worn by the subject.

3.1.4.1 System Requirements

The system requirements for this specific application include: lightweight, thickness of sensor, accuracy and range, and speed

Lightweight

The entire system is placed on the ankle of the subject. As such, the weight of the system must be kept to a minimum to not disturb the gait of the subject. This system is being developed for individuals who have trouble walking. Thus, any further disturbance on their gait may not allow them to walk at all.

Thickness of sensor

The current ankle foot orthosis (AFO) is made to fit within the shoe being worn by the user. The force sensors are placed on the sole of the AFO and increase the height of the entire device. This increase should be small enough that the entire device fits within the user's shoe. The thickness of current AFO is approximately 4 mm (0.15") at the sole. This thickness could be increased to approximately 7 mm (0.275"), allowing for sensors of maximum thickness of 3 mm (0.12").

Accuracy and Range

During walking, humans at heel strike can exert forces up to one and a half times their body weight (Perry 1997). For an average person weighing 800 N (180 lbs), this could be up to 1200 N (270 lbs). Also, for accurate calculations of the ankle torque, the accuracy of the system must be ± 10 N (2.25 lbs).

Speed

In normal walking, the amount of time for one stride is typically less than one second. Controlled plantar flexion (CP), the phase of gait where drop foot users are most affected, lasts approximately 0.1 seconds. Thus, the system must collect data at a rate greater than 100 Hz. For comparison, AMTI force plates, used in many clinical research gait labs, have a collection rate of 1080 Hz.

3.1.4.2 Possible Force Sensing Systems

Several methods of measuring the GRF and center of pressure were investigated:

1) Load Cells.

   A minimum of three load cells could be attached to the bottom of the orthoses to determine both the GRF and COP. However, the load cells would have to be sandwiched between two

hard surfaces to ensure correct force measurements. Thus, a hard plate under the load cells would be required to ensure that the load cells were the only surface touching the ground. The main disadvantage is that the minimum thickness for a load cell is 9.6 mm (0.375 in), which does not allow this system to be worn within a sneaker. A rubber pad could be placed under the metal plate to act as a sole. This, however, would make the system cumbersome.

2) Force Sensitive Resistors (FSR)

Force sensitive resistors (FSR) are polymer thick film devices that exhibit a decrease in resistance with an increase in the force applied to the active surface. This technology allows for extremely thin and flexible sensors, however, they lack accuracy and repeatability. Tekscan (www.tekscan.com) uses a matrix array for an in-shoe insole sensor system called F-scan. Their sensor, seen in Figure 3.3 (a), contains 960 sensing points. This system requires that the sensor be connected to a "handle", a breakout box with a cable attached to a computer to transmit the sensor data. The data are then processed by a PC program developed by Tekscan.

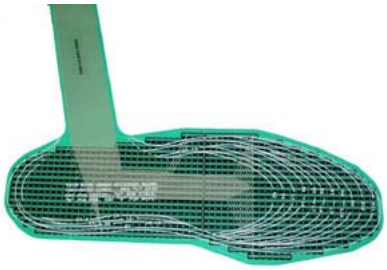

Figure 3.3 (a) Tekscan F-scan insole foot pressure sensing system

(b) Novel Pedar insole pressure sensing system.

3) Capacitance Force Transducers

These sensors are more accurate and durable than FSR's, but are also larger in size. Novel Electronics (www.novel.de) uses a matrix of multiple capacitance transducers in their Pedar insole system, seen in Figure 3.3 (b), with up to 256 sensors in each foot. Like Tekscan, these sensors require a "handle" to translate the sensor data to a format usable by a PC. A PC program developed by Novel then processes this data.

3.1.4.3 Force System Chosen for AAFO Design

The system used is the Computer DynoGraphy (CDG) from Infotronic, Inc. (www.infotronic.nl). This system, called Ultraflex and shown below, uses eight capacitive force transducers 25 mm square placed on the bottom of the foot. Each sensor can detect up to 1000 N (224.8 lb) and has a scanning frequency of 125 Hz. The signal from each sensor was passed through a first-order filter with a cut-off frequency of 5 Hz. The resolution of each sensor is 2.5 Newton (0.562 lb). This system was developed to be a replacement for force platform in clinical gait labs. Therefore, this system is lightweight at 0.9 N (0.2 lbs), is less than 3 mm thick and has the required accuracy, range and speed. The system can be seen below in Figure 3.4.

Two experimental complications arose from this system. First, because the sensors were placed between the AFO and the shoe, there was significant noise due to the shifting of the foot within the sneaker. For example, if wrinkling the toes puts pressure on the AFO against the shoe, which would apply force on the sensors. The second problem was the length of the cables used to connect the system to the DAQ card. Since the change in capacitance of the sensors is small, there is a pre-amplifier, seen in blue in Figure 3.4, to amplify the signal. However, since our system required approximately 10 m (33 ft) of cable, large variance was introduced into the system. The final result was that this system was used as two footswitches for the heel and forefoot to determine timing data and as a qualitative measure of how hard the forefoot was striking the ground. This method will be explained in the Controller section.

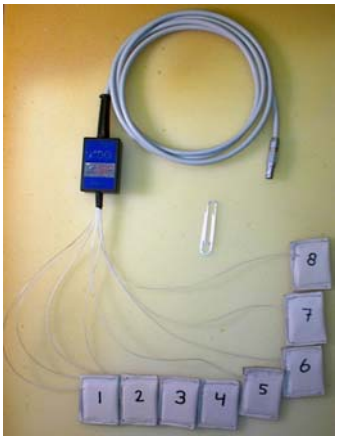

Figure 3.4 Infotronic's Ultraflex force sensors with a paperclip for size comparison.

3.1.4.4 Placement of Sensors

To ensure proper placement of the Ultraflex force sensors at the bottom of the AFO, the pressure distribution of the AFO was found using the Tekscan F-scan system. The AFO was placed inside a sneaker and the pressure distribution for quiet standing on a hard surface and for one full gait cycle was found. For quiet standing, seen in Figure 3.5 (a), the pressure is mostly concentrated at the heel of the AFO and at the lower part of the forefoot. For the complete gait cycle, Figure 3.5 (b) shows the individual maximum of each of the 960 sensors on the F-scan sensor. Here the pressure distribution is more spread out over both the heel and the forefoot. The main conclusion from these experiments is that force sensors do not have to be placed on the middle of the AFO. This is because the form of the AFO is made to fit the arch of the foot. Since the AFO is rigid, it maintains the arch of the foot above the sole of the sneaker.

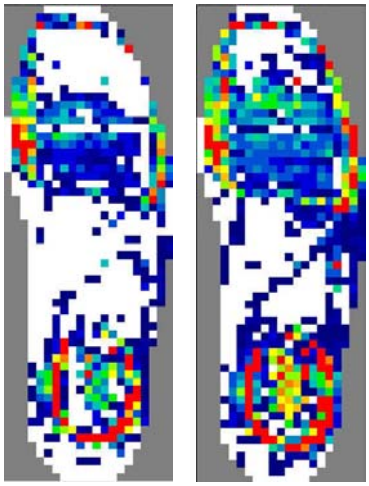

Figure 3.5 Pressure distribution of the AFO (a) during quiet standing (b) during maximum force exertion during gait.

3.1.4.5 Foot Switch

A single foot switch, model MA-153 (Motion Lab Systems Baton Rouge, LA) shown in Figure 3.6, was placed in the heel of the sneaker. An incision was made through the plastic heel of the sneaker, the foot switch placed inside and the heel glued back together. The foot switch has a large resistance when unloaded and a resistance of 12 Ω when loaded more than 50 g. The foot switch was used to detect heel strike with less of a delay than the Ultraflex force sensors. On average, heel strike was detected 30 ms earlier by the heel switch.

Figure 3.6 30 mm foot switch (Motion Lab Systems Baton Rouge, LA).

3.1.5 Electronics

The CIO-DAS08/JR-AO analog and digital I/O card was used in a PC running Debian Linux. The sensors were connected to a breadboard, where they were connected to the I/O card. These signals were processed by code written in C and then output to the amplifier of the SEA. The sampling rate was set at 1 kHz, the fastest rate possible.

3.1.6 Device Weight

Table 3.1 shows each of the components worn by the user and their respective weight. The amplifier and wiring are attached at the hip using a belt. The other components are placed on the AFO and worn at the distal end of the leg.

Table 3.1 List of AAFO parts and their respective weight

Part of AAFO	**Weight**
Series Elastic Actuator (SEA)	11.6 N (2.6 lb)
Amplifier and wiring	8 N (1.8 lb)
AFO and ankle potentiometer	5.3 N (1.2 lb)
Sneaker	4.4 N (1 lb)
Capacitive Force Sensors	.9 N (.2 lb)
Total	30.2 N (6.8 lb)

3.1.7 Safety Mechanisms

Several safety mechanisms were implemented in both hardware and software to ensure the safety of the user. In hardware, a resistor-programmable current limit was set on the amplifier output. The current limit correlates to an actuator force output of 900 N or an ankle torque of 81 N m. For comparison, normal ankle torque during walking can exceed 100 N m. Also, an enable signal to the amplifier must be high at all times for the actuator to work. If the system were

disabled, the Series Elastic Actuator (SEA) would turn off and the AAFO would behave like a rigid AFO. Finally, the stroke of the SEA is within the normal ankle range of motion.
In software, a voltage limit was placed on the control output. This voltage limit corresponds to an actuator force output of 850 N or an ankle torque of 76.5 N m. Also, if either the ankle angle or GRF sensors were out of a safe range, the system would go to a Safe State, which is described in the next section.

3.2 State Controller of AAFO

State controllers are usually used in locomotion assistive devices because gait is repetitive between strides and, within a stride, can be characterized into distinct phases. For the state controller used in the AAFO, the ankle angle and the ground reaction force (GRF) will be the triggers, used to change between states.

3.2.1 States and Triggers

A state controller was implemented to address each of the complications of drop foot separately. Three states were used: Contact 1 for foot slap, Contact 2 where the user's gait should not be disturbed and Swing to deal with toe drag. As seen in Figure 3.7, Contact 1 goes from initial heel strike until the middle of mid-stance at the neutral position i.e. when the shank become perpendicular to the foot. Contact 1 begins when the total vertical ground reaction force (GRF) is above a constant, On Ground, which was set at 60 N, as can be seen in Figure 3.8. This was the minimum value that that would reliably discern ground contact from noise during swing. Also, to eliminate some trigger problems, the force felt at the heel must be greater than On Ground1, which was set to 40 N. This level was the minimum value for which the GRF sensors could reliably detect ground contact. To transition into Contact 2, the GRF must be maintained above 60 N and the ankle must be in dorsiflexion i.e. the angle must be smaller than neutral. If the ankle goes into plantar flexion i.e. the angle is greater than neutral, the controller goes back to Contact 1. Contact 2 ends when the GRF is lower than On Ground. In fact, Swing always starts when the GRF is lower than On Ground.
Finally, a Safe State was created which would shut off the device in any unexpected circumstance. The Safe State is implemented when any of the force or angle sensors went out of a specified range. For the force sensors, it was a force greater than 1000 N. This value is the

maximum force that any one sensor should experience during the normal gait of a 90 kg person. The range for the ankle angle was between ±45 degrees, which is approximately the normal ankle range of motion.

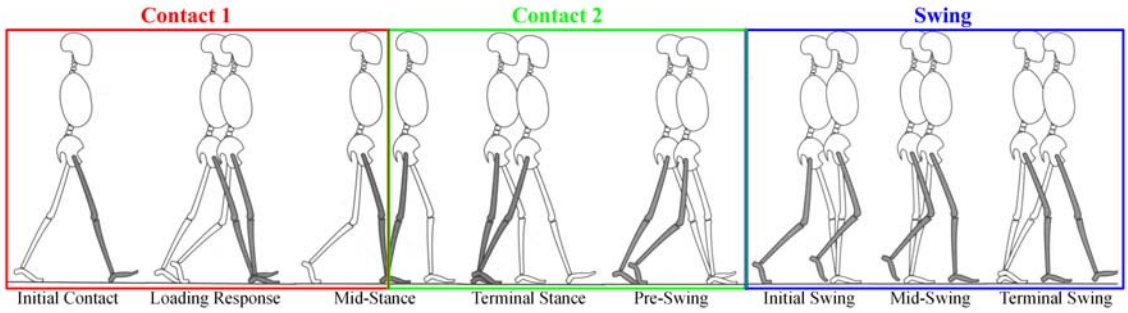

Figure 3.7 Controller states for a complete gait cycle.

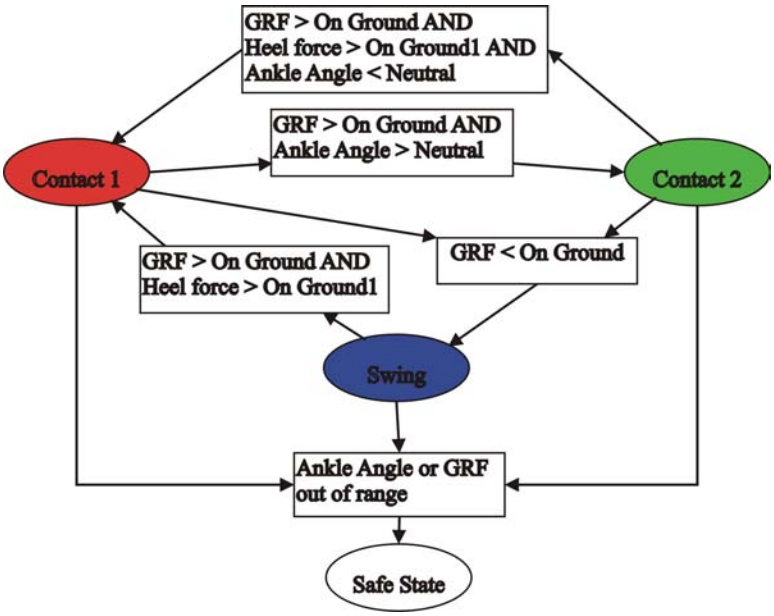

Figure 3.8 Triggers to switch between states for the state controller. GRF is the ground reaction force, On Ground and On Ground 1 are constants and the ankle angle is at neutral when the foot is perpendicular to the shank.

3.2.2 Control Algorithm

One of the main variables that the device should adapt to is gait speed. However the device cannot measure gait speed directly. A correlation has been found between the amount of time one foot is on the ground, called stance time, and the gait speed (Wilkenfeld, 2000; Kram and Taylor, 1990). For normal walking, Figure 3.9 shows the correlation between stance time and

the gait speed (n=30). These data were collected as part of an independent study (Riley et al., 2001) using the system and procedures explained in the Experimental Methods, Section 4.3.2. This method will be used to change the controller parameters according to gait speed. The AAFO will measure the contact time of the previous step and then look up the current gait speed in a table.

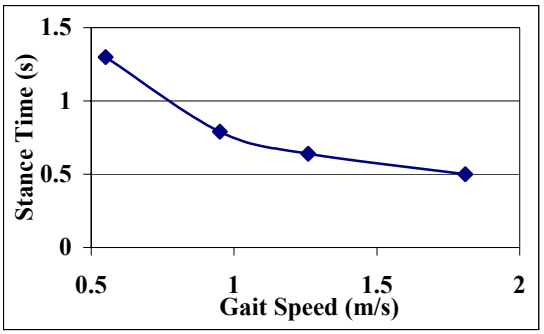

Figure 3.9 Stance time versus gait speed for normal walking (n=30).

Following is the description of each of the three states (Contact 1, Contact 2, and Swing) implemented in the state controller.

Contact 1

The goal of the state Contact 1 is to eliminate slap foot. As such, normal and drop foot ankle function were studied to find the method to compensate for the disability. Here only the results relevant to the development of the controller will be discussed. Further results can be found in Appendix C.

During controlled plantar flexion (CP), Palmer and Herr found that the ankle spring stiffness, defined as the slope of the regression line fit to the ankle torque versus ankle angular position curves, was linear (2002). Thus, ankle function could be characterized by a linear, torsional spring during CP.

The control method consists of simulating a linear, rotary spring at the ankle with variable stiffness across steps. The spring stiffness should adapt to the gait speed of the user as well as their physical ability. To adapt to gait speed, a spring stiffness look up table was created for varying gait speed. To implement this, the AAFO measures the contact time and then finds one of the three stiffnesses that is appropriate. To adapt to the physical ability of the user, kinetic and

kinematic measurements from unimpaired and drop foot gait during CP were analyzed to find a quantifiable difference. This measurement would then be used to increment or decrement the spring stiffness.

Two control methods were developed to adapt the stiffness of the virtual spring. The first was based on the difference in ankle velocities from the unimpaired to the impaired side. However, after analyzing the gait of two drop foot subjects, it was found that the variance in ankle velocities was large enough that a clear distinction between normal and slap foot gait could not be made.

The second was based on the force pattern when the forefoot struck the ground. If a person is slapping their foot after heel strike, then a higher force on the forefoot is expected. To test this hypothesis, two drop foot users wore the AAFO when the SEA was at zero force i.e. minimizing its impedance. Figure 3.10 (a) shows a sample of the forefoot force for three steps of one of the users. Using a digital camera, it was confirmed that on the first and third steps the user did not exhibit slap foot and there was a smooth transition during forefoot contact. Slap foot did occur on the second step and there was a spike in the forefoot force as is seen in the dual peak pattern of the second step. To discern the dual peak, the forefoot force is numerically differentiated and then filtered using a second order Butterworth filter with a cutoff frequency of 0.6 Hz. Figure 3.10 (b) shows the differential of the forefoot force, after filtering, seen in Figure 3.10 (a). As is shown by the arrows, during the period of stance, if slap foot occurs, the differential of the forefoot force will be negative.

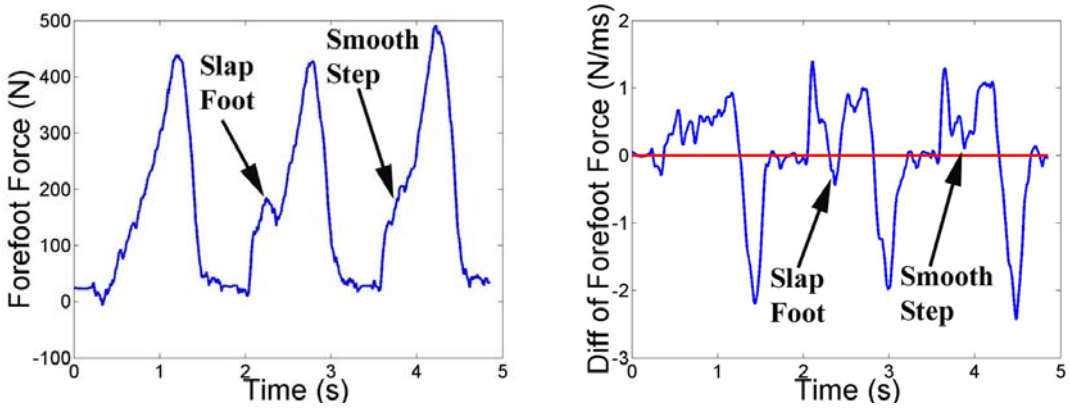

Figure 3.10 Comparison of (a) forefoot force and (b) the filtered differential of the forefoot force.

The control algorithm consists of setting an initial stiffness that would be low enough not to prevent slap foot. This was set to 0.25 of the ankle stiffness of an unimpaired individual with the same height and weight as the drop foot subject, which was approximately 29 Nm/rad (0.5 Nm/deg). The stiffness was then incremented by the rules shown in Table 3.2, where the incremental stiffness ($\Delta\Gamma$) was 5.7 Nm/rad (0.1 Nm/deg).

Table 3.2 Rules for changing the ankle stiffness where $\Delta\Gamma$ is the increment in stiffness (5.7 Nm/rad), n is the number of occurrences of slap foot in the last 5 steps

Number of slaps in last 5 steps (n)	Change in Ankle Stiffness
0	$-\Delta\Gamma$
1	0
2-5	$(n-1) * \Delta\Gamma$

Contact 2

Drop foot does not affect the rest of stance. Therefore, the objective of Contact 2 is to not disturb the gait of the user. During this state, the Series Elastic Actuator (SEA) is set to zero force i.e. it minimizes its impedance.

Swing

The goal of the state Swing is to lift the foot of the drop foot user to clear the toe. To find the most biological method to do this, normal ankle function was analyzed using a second-order model. From this model, it was found that a spring-damper system could be used. Initial values for the stiffness and damping were estimated and final values were found by testing on two individuals with drop foot.

The data for 30 subjects were collected as part of the independent study (Riley et al., 2001) for four different gait speeds: very slow, slow, normal, and fast. Figure 3.11 shows the ankle angle versus percent gait cycle for the fast gait. During swing, the ankle angle was modeled as a linear rotary, second order, under-damped system with an initial position offset. The average moment of inertia used was 0.04 kg m^2 and was calculated using the weight and height of the subjects and looking at anthropomorphic tables (Winters 1990).

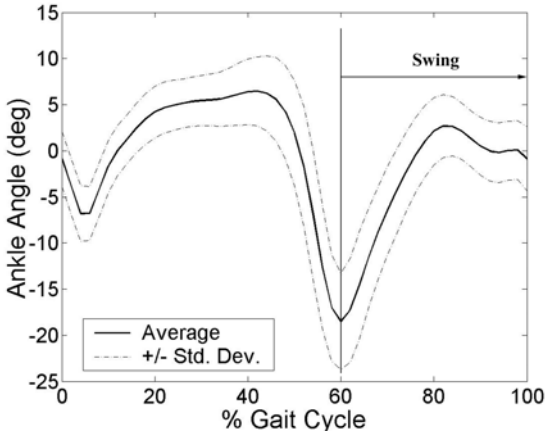

Figure 3.11 Averaged ankle angle (solid line) ± 1 standard deviation (dashed lines) for fast gait speed (n=30).

For each of the four gait speeds, the peak time and percent overshoot were calculated. Peak time is defined as the time required for an under-damped step response to reach the first, or maximum, peak. Percent overshoot is defined as the amount that an under-damped step response overshoots the steady-state, or final, value at the peak time, expressed as a percentage of the steady-state value (Nise, 2000). The damping ratio and natural frequency for each gait speed were found using Equations (3-1) and (3-2):

$$\zeta = \frac{-\ln(\%OS/100)}{\sqrt{\pi^2 + \ln^2(\%OS/100)}} \tag{3-1}$$

where ζ is the damping ratio, %OS is the percent overshoot

$$\omega_n = \frac{\pi}{T_p\sqrt{1-\zeta^2}} \tag{3-2}$$

where ω_n is the natural frequency, T_p the peak time and ζ the damping ratio.

Figure 3.12 shows the collected human data against the second-order model for the normal gait speed.

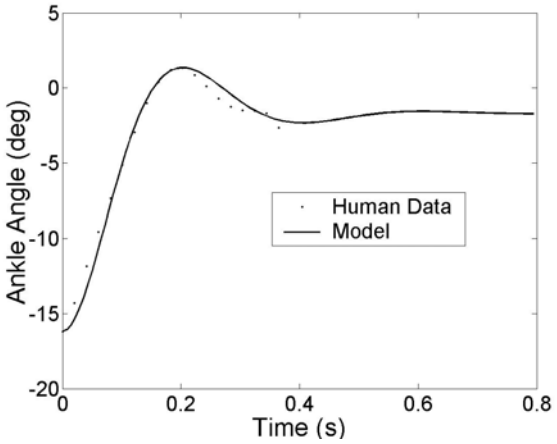

Figure 3.12 Human ankle angle data (dotted line) (n=30) and second-order model (solid line) for normal gait speed (1.26 m/s).

Using the average moment of inertia, the appropriate rotational stiffness and damping were calculated using Equations 3-3 and 3-4:

$$K = \omega_n^2 * J \tag{3-3}$$

where K is the spring stiffness, ω_n the natural frequency, and J the rotational moment of inertia.

$$B = 2 * \zeta * \omega_n * J \tag{3-4}$$

where B is the rotational damping, ζ the damping ratio, ω_n the natural frequency, and J the rotational moment of inertia.

The values can be found in Table 3.3, below. These were the initial values implemented in the AAFO.

Table 3.3 Calculated ankle stiffness and damping from second-order model.

Gait Speed	K (Nm/rad)	B (Nms/rad)
Very Slow (0.55 m/s)	4.30	0.10
Slow (0.95 m/s)	11.20	0.35
Normal (1.26 m/s)	12.00	0.62
Fast (1.81 m/s)	16.30	0.85

These values were tested on two individuals with drop foot gait. Using the MIT data collection described in the Experimental Method, the ankle angle was collected over all four gait speeds. The stiffness values were increased until the slope of the ankle angle of the affected side matched

those of the unaffected side for three different gait speeds. The damping values were the minimum that would not produce unwanted oscillations. The final values of the stiffness and damping used can be found in Table 3.4, below.

Table 3.4 Actual ankle stiffness and damping values used in AAFO.

Gait Speed	K (Nm/rad)	B (Nms/rad)
Slow	28.65	0.57
Normal	37.24	1.03
Fast	45.84	1.15

Chapter 4

Experimental Methods

This chapter describes the detailed methodology of the human experiments. Section 4.1, Experimental Subjects, describes the subjects who participated in the experiments. Section 4.2, Data Collection Methods, outlines the experimental equipment employed during the gait experiments. Section 4.3, Experimental Protocol, describes the experimental protocol. Section 4.4, Data Processing, describes the data analysis used.

4.1 Experimental Subjects

Two drop foot subjects were recruited and compared to three normal subjects to evaluate the AAFO design. Their relevant anthropometric measurements can be found in Table 4.1.

Table 4.1 The subjects' gender, age and anthropometric data

Subject	Gender	Age (yr)	Mass (kg)	Height (m)	Self-Selected Gait Speed (m/s)
LS (D)	M	62	79.1	1.79	1.22
OM (D)	M	62	95.4	1.77	1.07
SMF (N)	M	66	76.6	1.70	1.39
HL (N)	M	67	86.1	1.75	1.01
FJO (N)	M	67	73.2	1.70	1.22

4.2 Data Collection Methods

Two methods of data collection were used. For the experiments at MIT, the AAFO and a digital video camera were used. At the Gait Laboratory in Spaulding Rehabilitation Hospital, the AAFO, VICON motion capture system and AMTI force plates were used. A description of each of the devices is provided below.

4.2.1 Active Ankle Foot Orthosis (AAFO)

The wearable part of the AAFO, as described in Chapter 3, consists of a polypropylene Ankle Foot Orthosis (AFO), a Series Elastic Actuator (SEA), a rotary potentiometer at the ankle and 6 force sensors at the sole of the AFO. The subject wears the AAFO connected to a desktop computer through 7 cables approximately 10 m (33 ft) long. The measurements from the AAFO are: the force at the output of the SEA, the ankle angle, and the heel and forefoot reaction forces. The ankle angle is passed through a first order filter with a cutoff frequency of 50 Hz. The ankle velocity is found by differentiating the pot signal and then passing it through a second order Butterworth filter with a cutoff frequency of 8 Hz. The force at the output of the SEA is measured by a linear potentiometer sampled at 1000 Hz. This measurement is passed through a first order filter with a cutoff frequency of 50 Hz. Each of the reaction forces is scanned at a frequency of 125 Hz. The signal was passed through a first-order filter with a cut-off frequency of 5 Hz. The resolution for the heel reaction force is 5.0 N (1.12 lbf) and 10.0 N (2.24 lbf) for the forefoot reaction force.

4.2.2 Digital Camera

A digital camera (SONY DCR-TRV820) was also used to record the entire experimental process for each subject. Video footage is used for qualitatively comparing the unassisted versus assisted gait of each of the subjects.

4.2.3 Spaulding Rehabilitation Hospital Gait Laboratory

Kinematic and kinetic data were acquired for both the left and right lower limbs using a eight-camera VICON 512 system (Oxford Metrics, Oxford, UK) and two AMTI force plates (AMTI, Newton, MA). The data were processed at 120 Hz with VICON BodyBuilder (Oxford Metrics, Oxford, UK) using the standard model of the lower limbs included with the software (Ramakrishnan et al., 1987; Kadaba et al., 1990; Davis et al., 1991). The data derived using the standard BodyBuilder model, including ankle angular position and ankle torque, were then analyzed using MATLAB (MathWorks, Natick, MA).

The following sign conventions were used: positive ankle position for dorsiflexion and positive ankle torque for dorsiflexor torque. Zero ankle position was arbitrarily assigned to be the

position at which the segment representing the foot was perpendicular to the segment representing the shank.

Ankle angular velocity was calculated by first filtering the ankle position data and then numerically differentiating. The position was filtered using a zero-lag, fourth-order, low-pass Butterworth filter with a cutoff frequency of 6 Hz (Winter, 1990). Numerical differentiation of the filtered position to get the velocity was done using high-accuracy, divided-difference formulas (Chapra and Canale, 1998).

4.3 Experimental Protocol

Initial experiments were performed at Massachusetts Institute of Technology (MIT) at the Leg Laboratory to test the AAFO and to optimize the control algorithm. Here only the two drop foot subjects were tested. All four subjects were then tested at the Gait Laboratory in Spaulding Rehabilitation Hospital (SRH) to analyze the effects of the AAFO on gait.

4.3.1 Human Use Approval

The AAFO experiments were approved by both MIT's Committee on the Use of Human as Experimental Subjects (COUHES) and the Internal Review Board (IRB) at SRH. All subjects are volunteers and permitted to withdraw from the study at any time for any reason. Before participating in the study, each subject reads and signs a statement acknowledging informed consent. Appendix A includes a copy of the subject consent form for both the MIT and SRH sessions.

4.3.2 Subject Preparation

All subjects wore T-shirts, athletic shorts and sneakers with socks. Since the AFOs require sneakers, to eliminate variability, they will also be worn during the non-brace trials.

4.3.2.1 MIT

Initially, the subject donned the AAFO by placing their foot in the brace and sneaker, tying the sneaker and a Velcro strap around the shin. The subject then straps the amplifier for the SEA around their waist using a Velcro belt.

4.3.2.2 Spaulding Rehabilitation Hospital

Initially, like the MIT experiments, the subject donned the AAFO by placing their foot in the brace and sneaker, tying the sneaker and a Velcro strap around the shin. The subject then straps the amplifier for the SEA around their waist using a Velcro belt. Then a number of anthropometric data are measured and recorded. They include height, weight, leg length, knee width and ankle width. The leg length is calculated from the Anterior Superior Iliac Spine (ASIS) to the medial malleolus using a flexible tape measure. The individual then donned the respective AFO for that condition. Next, retro-reflective markers were placed in six locations on both legs: (1) second metatarsophalangeal joint, (2) lateral malleolus, (3) heel, (4) lateral aspect knee joint line, (5) Anterior Superior Iliac Spine (ASIS), (6) mid point between the Posterior Superior Iliac Spines (PSIS). The subject then walks on a platform approximately 10 m in length and 2 m in width.

4.3.3 Test Procedure

The test procedures for each of the two testing sites were planned according to different objectives. The objective for the experiments at MIT was to test the AAFO and to optimize the control algorithm. Those performed at the Gait Laboratory in SRH were to analyze the effects of the AAFO with the control algorithm on the gait of normal and drop foot subjects.

4.3.3.1 MIT

At the beginning of the session, the subject was asked to walk without any assistive device several times along the walkway. This was to capture their unassisted gait on film and for the researchers to qualitatively analyze it.

The subjects were asked to do all conditions at three different gait speeds: slow, self-selected, and fast. The subjects first walked at their self-selected normal speed on a 10 m walkway. The subjects first walked at their self-selected speed using the constant impedance control scheme. The amount of time required to cover the specified distance was measured using a stopwatch. Subjects were then asked to reduce their time by 25% for the fast gait speed and increase their time by 25% for the slow gait speed. These times were then matched when testing the remaining two control conditions.

There were four conditions of the AAFO

1. Mechanically disconnected
2. Zero force
3. Swing controller implemented
4. Swing and Contact 1 controllers implemented

Condition 1 Mechanically Disconnected

In this condition, the Series Elastic Actuator (SEA) was mechanically disconnected from the brace, such that the foot is allowed to move freely in the sagittal plane. The hinges in the AFO limit rotations out of the plane. This condition had two objectives: to test whether the subject could walk with the additional mass of the AAFO and to take measurements of the unassisted gait of the subject. For each of the gait speeds, the subject was asked to walk two lengths of the walkway.

Condition 2 Zero Force

In this condition, the Series Elastic Actuator (SEA) was mechanically re-connected to the AFO and the desired force was set to zero for the entire gait cycle. The two objectives for this condition were: to have the subject become accustomed to walking with the functioning AAFO and to further measure the unassisted gait of the subject. For each of the gait speeds, the subject was asked to walk two lengths of the walkway. During this condition several measurements were checked for accuracy.

1. The Ultraflex force sensors were zeroed and the zeroed values were verified
2. The state controller was checked to make sure it was triggering between states properly.
3. The SEA was calibrated and ensured to be outputting zero force
4.

The data for conditions 1 and 2 were then analyzed.

1. The range of contact times for each of the three bins were set to match the slow, self-selected and fast gait speeds.
2. The average and standard deviation of the ankle velocity during controlled plantar flexion (CP) for each step was obtained and compared to unimpaired values. This was done to check

if the difference in average ankle velocities could be used to change the stiffness (see Chapter 3).

3. The forefoot force was analyzed to find the spike in force corresponding to slap foot. This was also done to look for a method of changing the ankle stiffness (see Chapter 3).

Condition 3 Swing Controller Implemented

As described in Chapter 3, the Swing controller was implemented to lift the foot of the subject after toe off. The main objective for this condition was to determine if the stiffness and damping values that had been calculated from normal data would lift the foot so that the ankle angle would be similar. For each of the gait speeds, the subject was asked to walk four lengths of the walkway. After every time the subject walked one length of the walkway, the ankle angle was compared to a normal trajectory. The stiffness and damping values were then incremented to make the drop foot and normal ankle angles as similar as possible.

Condition 4 Swing and Contact 1 Controllers Implemented

As described in Chapter 3, the Swing and Contact 1 controllers were implemented to lift the foot of the subject after toe off and to slow it down after heel strike to prevent slap foot. The main objective of this condition was to test control algorithm to increment the stiffness according to the pattern of the forefoot force. For each of the gait speeds, the subject was asked to walk until the value of the ankle stiffness for that speed was constant for 5 steps or they had done 8 lengths of the walkway, whichever was first.

4.3.3.2 Spaulding Rehabilitation Hospital (SRH)

The subjects were asked to do all conditions at three different gait speeds: slow, self-selected, and fast. The subjects first walked at their self-selected normal speed on a 10 m walkway. The amount of time to cover a specified distance was measured using a stopwatch. The subject was then asked to reduce their time by 25 % for the fast gait speed and increase their time by 25 % for the slow gait speed. For each gait speed, data for 10 good trials were collected. A good trial had several requirements:

1. None of the markers were lost from the view of the cameras
2. Both right and left heel strikes were on the force plate

3. The gait speed did not vary by more than 10 % from the desired gait speed

There were four conditions tested at SRH:

1. Using the AAFO at zero force
2. Using the AAFO with a constant stiffness
3. Using the AAFO with the Swing and Contact 1 controllers implemented

4.4 Data Processing

This section describes the data processing methods used for these experiments at both the MIT and SRH facilities. Section 4.4.1 outlines the processing of the ground reaction force data. Section 4.4.2 describes the analysis of the kinematic data.

4.4.1 Vertical Ground Reaction Force (GRF)

The AAFO sampled the vertical ground reaction force (GRF) at 125 Hz. This data was then passed through a first order filter with a cutoff frequency of 50 Hz. At SRH, the two AMTI force plates are sampled at 1080 Hz. This data are then resampled to the kinematic sample rate of 120 Hz. It is then passed through a 5^{th} order Woltring spline filter, both forwards and backwards to eliminate any phase lag.

Stride Cycle Determination

This is the most important step of the analysis procedures since all other data are based on the beginning of the stride cycle. A stride cycle is defined as the period of time for two steps, and it is measured from the initial heel contact of one foot to the next initial heel contact of the same foot. To determine the stride cycle in the AAFO, either the foot switch was loaded or the total sum of the Ultraflex force sensors went above 70 N for longer than 4 ms. At this point, the state controller would switch from Swing state to Contact 1. At SRH, the force threshold for the AMTI force plates is 10 N. The point at which the force is higher is considered heel strike.

Normalization

Humans do not walk the same way. A single person performs his or her walking pattern in a fairly repeatable and characteristic way, sufficiently unique that it is possible to recognize a

person at a distance by their gait. The variability o that pattern on a stride-to-stride and day-to-day basis is defined as intra-subject variability. Across any group of normal subjects, there is a greater but not excessive variability, defined as inter-subject variability (Winter, 1996). The differences in height, body mass, age, cadence and sex are the main contributors to the above-mentioned variabilities.

Normalization to Subject's Body Mass

In order to minimize the intra- and inter-subject variability, the joint torques data taken from SRH are all normalized to the subject's body mass. Thus, all joint torques will be presented in the units of N m / kg.

Normalization to Stride Cycle

In order to minimize the stride-to-stride variability, all data are time normalized to 100% of the stride cycle. In the AAFO, two consecutive heel strikes were considered a full gait cycle. The data were then fit by a cubic spline and then resampled to 200 samples. Thus, each point is 0.5 % of the stride. At SRH, the first heel strike is known and the second is approximated using an autocorrelation of the ankle marker. The VICON program records the elevation of the ankle marker from the first heel strike. The second heel strike is marked when the ankle marker is at that same elevation. The result is then manually checked for accuracy. The data were then fit by a cubic spline and then resampled to 50 samples. Thus, each point is 2 % of the gait cycle.

4.4.2 Kinematics

The AAFO (see Section 4.2.1, Ankle Foot Orthosis) measures the relative ankle angle between the shank and the foot at a rate of 1000 Hz. The ankle angle is then passed through a first order filter with a cutoff frequency of 50 Hz.

At SRH, the VICON 512 system tracks the 3-D positions of the retro-reflective markers in the global reference frame using eight high-speed cameras. All data are sampled at 120 Hz. The kinematic data is passed through a fifth order Woltring spline filter, both forwards and backwards to remove any phase lag. A third order polynomial algorithm in VICON BodyBuilder interpolates missing kinematic data.

4.5 Data Analysis

To compare the gait patterns of the drop foot subjects for the different conditions to the normal gait patterns several different parameters were analyzed. In the following section, the parameters and their calculations are described.

4.5.1 Gait Speed

The gait speed for each trial was taken to be the slope of the line given by

$$x = v\,t + x_o \qquad (4.1)$$

where v is the slope, t is time, x is the absolute position of a point fixed in the pelvis along an axis parallel to the direction of forward motion, and x_0 is the initial position of that point. The slope was calculated from the data by simple linear regression.

4.5.2 Quantification of Slap Foot

The slapping of the foot after heel strike, also known as slap foot, is one of two major complications of drop foot. To be able to measure the effectiveness of the AAFO, slap foot was said to occur if the following three conditions were met:

1. The forefoot force was greater than 70 N
2. The filtered differential of the forefoot force was negative
3. The controller was in the state Contact 1

Overall this states that when the user first begins to load the forefoot, if there is a spike in force at the forefoot, slap foot has occurred. Condition 1 ensures that the force reading is not due to sensor noise or internal forces. If there is a spike in the forefoot force due to slap foot, then the differential of the force will be negative, meeting Condition 2. Finally, that controller should be in the state Contact 1 because that is when only loading of the forefoot should be occurring.

4.5.3 Powered Plantar Flexion and Swing Dorsiflexion angles

Powered plantar flexion (PP) occurs during the late stance phase of gait. Immediately after, during swing, the ankle dorsiflexes to provide toe clearance. Figure 4.1 shows the averaged ankle angle vs. percent gait cycle for three normal individuals. The change in ankle angles during powered plantar flexion and swing dorsiflexion are shown in Figure 4.1.

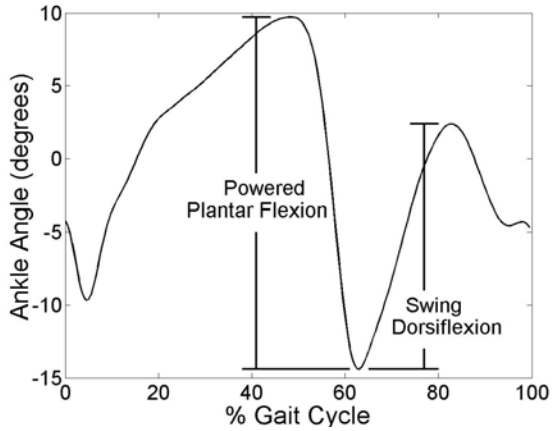

Figure 4.1 The averaged ankle angle vs. % gait cycle for normal subjects showing the powered plantar flexion and swing dorsiflexion angles

4.5.4 Gait Symmetry

We assumed that normal gait is symmetrical and that deviation from a reference pattern is a sign of disability. To analyze spatial asymmetry, the step length of the affected side ($L_{affected}$) was subtracted from the unaffected side ($L_{unaffected}$). The difference in stride lengths (L_{sym}) should be zero for symmetric gait (4-2):

$$L_{sym} = L_{affected} - L_{unaffected} \tag{4-2}$$

To analyze temporal asymmetry, the step time of the affected side ($T_{affected}$) was subtracted from the unaffected side ($T_{unaffected}$). The difference in stride lengths (T_{sym}) should be zero for symmetric gait (4-3):

$$T_{sym} = T_{affected} - T_{unaffected} \tag{4-3}$$

4.5.5 Elevation Angles and Principal Components Analysis

The elevation angle is defined as the angle between the body segment and the vertical direction. For the purposes of gait analysis, the elevation angles for the thigh, shank and foot were calculated, as shown in Figure 4.2.

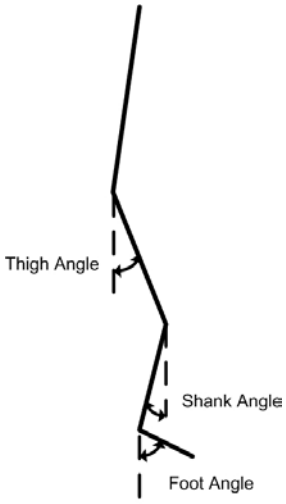

Figure 4.2 Elevation angles for gait analysis in the sagittal plane

To identify the statistical structure underlying the distribution of the geometrical configurations associated with the observed changes of the elevation angles, the principal components were computed by pooling together the sample of time-varying angles after subtraction of the mean value. The *j*th principal component (pc) of the sample is the linear combination of the variates α whose coefficients are the elements of the eigenvector u_j of the sample covariance matrix A corresponding to the *j*th largest eigenvalue λ_j,

$$pc_j = u_j^T \alpha \qquad (4\text{-}4)$$

A 3 x 3 matrix was computed using the thigh, shank and foot elevation angles (Borghese et. al., 1996).

4.5.6 Statistical Analysis

To determine the significance of any parameter, a multiple comparison using one-way analysis of variance (ANOVA) was performed using Matlab. P-values of less than 0.05 are reported as a statistically significant result.

Chapter 5

Results

This chapter describes the results of the implementation of the Active Ankle Foot Orthosis (AAFO) and drop foot controller. Section 5.1, Improving the Slap Foot Condition, explains the method of decreasing the occurrences of slap foot, one of the major complications of drop foot, on one drop foot subject. Section 5.2, Decreasing Toe Drag, describes the method of providing sufficient toe clearance during swing, thus reducing the second complication, toe drag, on both drop foot subjects. Section 5.3, Gait Improvements, describes other specific improvements of the drop foot subjects donning the AAFO as compared to the normal subjects.

5.1 Improving the Slap Foot Condition

Only one of the two drop foot subjects exhibited slap foot after heel strike, thus, only his data are shown in this section. The first test of the drop foot controller was to converge to an optimal controlled plantar flexion (CP) stiffness to prevent slap foot for each gait speed. The algorithm used to find this optimal stiffness is described in section 3.2.2, Control Algorithm. For each of the three gait speeds, the controller was able to find an optimal stiffness within 32 strides, as shown in Figure 5.1. As defined in Section 2.1.1, Definitions, a stride is the period of time between two successive occurrences of one of the repetitive events of walking, usually measured from an initial heel contact (HC) of one foot to the subsequent HC of the same foot. The controller convergence stiffnesses, shown in Figure 5.1, were 137.5, 194.8, and 332.3 Nm/rad for the slow, self-selected, and fast gait speeds, respectively. The gait speeds were measured by the AAFO using a range of stance times: the fast gait speed had a stance time less than 0.9 s, self-selected was 0.9-1.1 s, and slow was greater than 1.1 s. The ankle stiffness for unaffected individuals in dorsiflexion has been found to vary between 25 and 500 Nm/rad for varying amount of muscle contraction (Weiss et. al., 1988; Weiss et. al., 1986), therefore, these controller values are within the range of human capability.

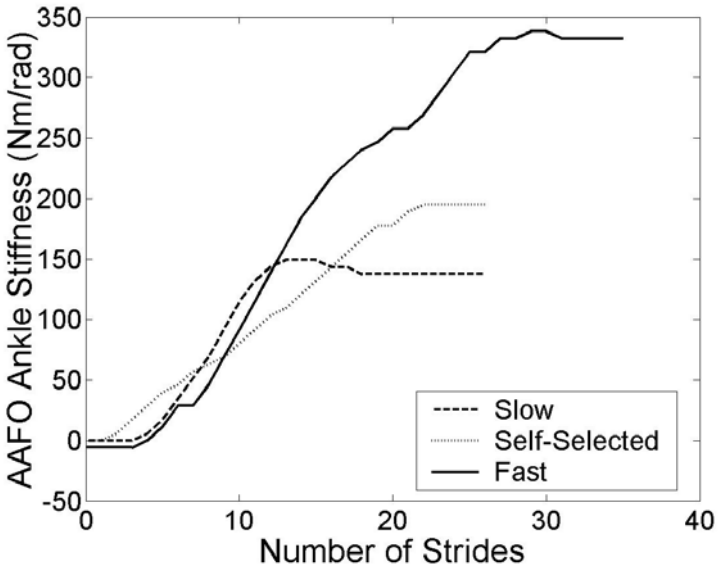

Figure 5.1 AAFO stiffness vs. number of steps showing convergence of the stiffness for three different gait speeds after 25-35 strides.

The final stiffness values decreased with increasing stance time, as shown in Figure 5.2. The shaded regions are the range of stance times corresponding to a single bin in the stiffness look-up table. As described in Section 3.2.2, Control Algorithm, the stance time decreases with increasing gait speed. Thus, the AAFO stiffness is correlated with the gait speed of the user.

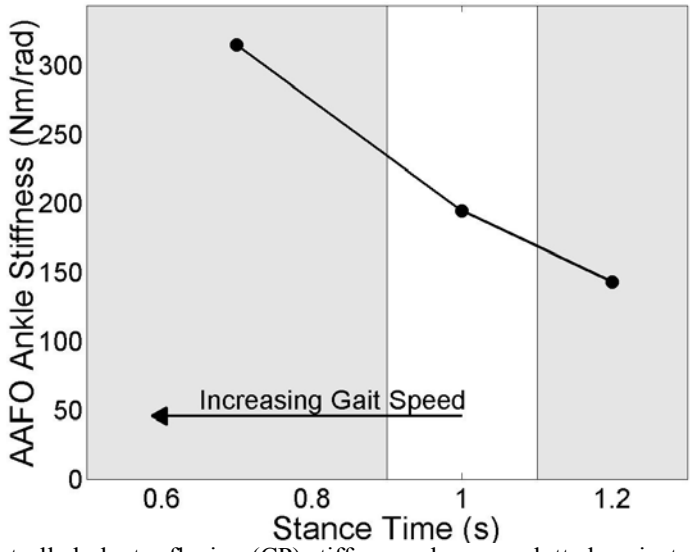

Figure 5.2 The final controlled plantar flexion (CP) stiffness values are plotted against stance time, showing that CP stiffness increases with increasing walking speed.

Figure 5.3 shows the number of occurrences of slap foot versus gait speed in 5 step trials (n = 5) for zero, constant and variable impedance conditions. The subject was unable to walk at the fast

gait speed at the zero force condition because it was deemed unsafe, thus only the slow and self-selected speeds are shown. It is seen that both the constant and variable impedance conditions significantly reduced the number of occurrences of slap foot for the slow and self-selected gait speeds ($p < 0.01$). However, there was a large increase for the constant stiffness condition at the fast gait speed. By increasing the CP stiffness with gait speed, the variable impedance controller significantly reduced the occurrences of slap foot compared to the constant impedance condition ($p < 0.001$), as seen in Figure 5.3.

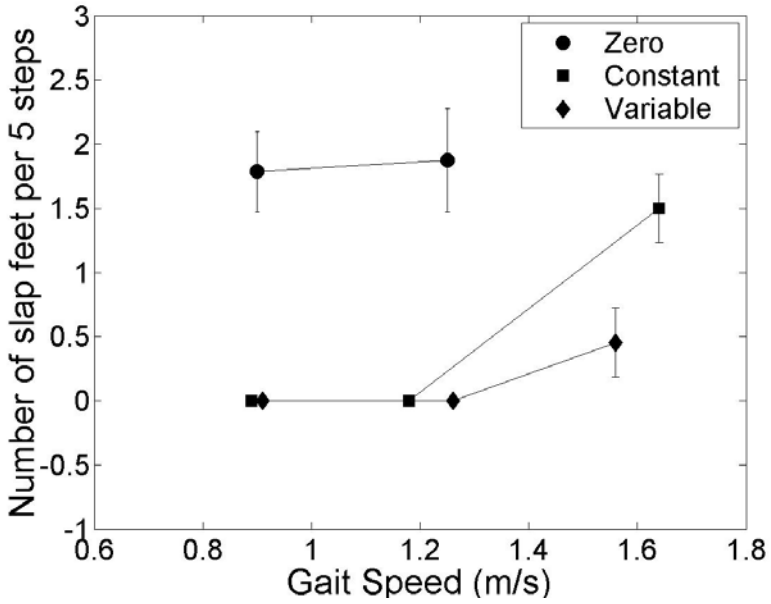

Figure 5.3 The mean and standard error of the number of occurrences of slap foot during a 5 step trial (n = 5) for one subject donning the AAFO. Both the constant and variable impedance were significantly different than zero impedance of the slow and self-selected gait speeds ($p < 0.01$). The number of slap foot occurrences for the variable impedance was also significantly lower than the constant impedance condition ($p < 0.001$).

This section detailed the results of the first state of the controller in alleviating the slap foot gait complication. The next section explores the second major complication of drop foot, dragging the toe during swing.

5.2 Decreasing Toe Drag

To quantify the reduction of the second major complication of drop foot, toe drag, the swing dorsiflexion angle of the ankle was analyzed. The swing dorsiflexion (DF) angle was defined in Section 4.5.3, Powered Plantar Flexion and Swing Dorsiflexion angles. The average and standard error for both subjects are plotted in Figure 5.4. There is a significant difference in

swing dorsiflexion angle across all conditions ($p < 0.01$), except for the zero force and constant stiffness conditions at the slow gait speed.

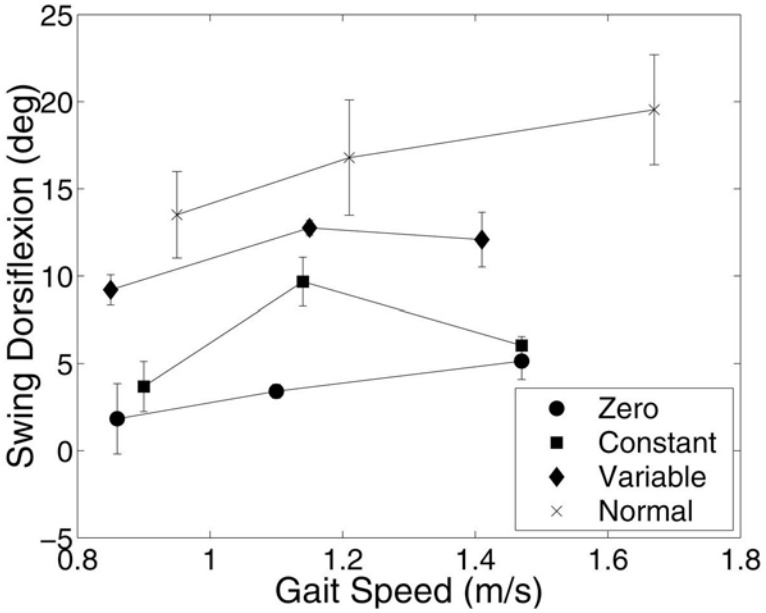

Figure 5.4 The means and standard error of the swing dorsiflexion angle for normal (n = 3) and drop foot (n = 2) subjects. Normal subjects' data are averaged over 9 trials, whereas for the drop foot subjects the average is over 20 trials.

As seen in Figure 5.4, the zero force condition has the lowest amount of swing dorsiflexion, as would be expected due to drop foot. The constant stiffness condition is the next lowest since the AAFO is opposing powered plantar flexion (PP), which is usually unaffected in drop foot. The variable impedance drop foot controller has the closest amount of swing dorsiflexion to the normal participants, since it does not impede PP and lifts the foot during swing. The last sections have dealt with the main two complications of drop foot. The next section outlines the overall gait improvements of the subjects using the drop foot controller.

5.3 Gait Improvements

This section describes the gait improvements of the drop foot subjects using the drop foot controller as compared to the other two conditions (zero force and constant stiffness) and the normal subjects. Specifically, Section 5.3.1, Powered Plantar Flexion Angle, looks at the powered plantar flexion angle, which occurs at the end of stance. Section 5.3.2, Spatial and Temporal Gait Symmetry, details the differences between the affected and unaffected sides. Section 5.3.3, Elevation Angles and Principal Components Analysis, looks at the intersegmental coordination between the ankle, knee and hip.

5.3.1 Powered Plantar Flexion Angle

A constant stiffness brace applies a dorsiflexion moment at the ankle and therefore hinders powered plantar flexion (PP). PP occurs at the end of stance and is used to propel the body forward. To quantify this effect, the PP angle was calculated as described in Section 4.5.3, Powered Plantar Flexion and Swing Dorsiflexion angles. The means and standard errors for the PP angles averaged over both drop foot subjects can be seen in Figure 5.5. As expected, the constant stiffness condition significantly reduced the PP angle as compared to the zero force condition and the normals ($p<0.0005$). Except for the self-selected gait speed, the variable impedance controller had a significantly higher PP angle than the constant stiffness condition ($p < 0.001$). The zero force condition is not different from the normal participants because the calf muscles (gastrocnemius and soleus), which produce PP, are not affected by drop foot. The variable impedance controller in the Swing state should be identical to the zero force condition. The hypotheses for the dissimilarity will be explained in the Discussion, Section 6.3.1 Powered Plantar Flexion Angle.

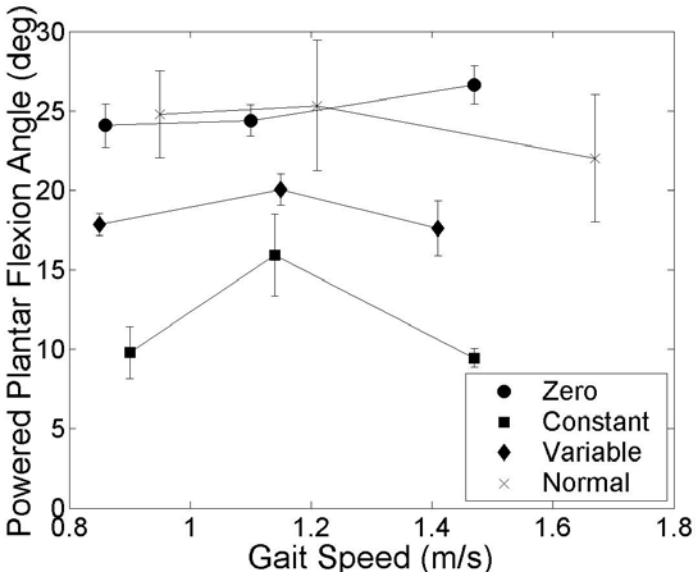

Figure 5.5. The means and standard errors of the powered plantar flexion angle for normal (n = 3) and drop foot (n = 2) subjects. Normal subjects' data are averaged over 9 trials, whereas for the drop foot subjects the average is over 20 trials.

5.3.2 Spatial and Temporal Gait Symmetry

To look at spatial gait symmetry, the differences in step lengths from the affected to the unaffected side (L_{sym}) (cm) were compared for the three different brace conditions. This

measure was described in Section 4.5.4, Gait Symmetry. The results can be found in Table 5.1. L_{sym} for the drop foot controller was significantly smaller than the zero force for both the self-selected ($p < 0.015$) and the slow ($p < 0.003$) gait speeds. The zero force and constant stiffness condition were significantly different for the slow gait speed ($p < 0.003$).

Table 5.1 Difference in step lengths (L_{sym}) (cm) between the affected and unaffected sides[1].

	Gait Speed	
Condition	Self-selected	Slow
Zero Impedance	8.2 ± 6.9	8.7 ± 8.8
Constant Impedance	4.0 ± 6.2	1.5 ± 8.4
Variable Impedance	2.1 ± 7.1	0.1 ± 6.9

To look at temporal gait symmetry, the differences in step times from the affected to the unaffected side (T_{sym}) (ms) were compared for the three different conditions. This measure was described in Section 4.5.4, Gait Symmetry. The results can be found in Table 5.2. T_{sym} for the drop foot controller was significantly smaller than the zero force for both the self-selected ($p < 0.01$) and the slow ($p < 0.003$) gait speeds. The zero force and constant stiffness condition were significantly different for the slow gait speed ($p < 0.011$).

Table 5.2 Difference in step times (T_{sym}) (ms) between the affected and unaffected sides[2].

	Gait Speed	
Condition	Self-selected	Slow
Zero Impedance	86 ± 71	146 ± 155
Constant Impedance	73 ± 52	36 ± 120
Variable Impedance	21 ± 87	14 ± 156

5.3.3 Elevation Angles and Principal Components Analysis

As described in Borghese et. al. there was a large covariation between the three sagittal plane angles. Figure 5.6 shows the averaged gait path for the left leg during the AAFO condition at the self-selected gait speed. The gait path is plotted in the 3D space of the elevation angles. Paths progress in time in the counter-clockwise direction, heel strike and toe-off phases corresponding to the top and bottom of the loop, respectively. The mesh in Figure 5.6 (a) and (b) corresponds to the least-squares best-fitting plane for one brace condition at a single gait speed. The best-fitting plane is identified by the eigenvectors of the covariance matrix. Eigenvectors u_1 and u_2 lie

1 For the fast condition a comparison was not possible because the step length for both sides could not be calculated for one cycle

2 For the fast condition a comparison was not possible because the step time for both sides could not be calculated for one cycle

on the plane and u_3 is orthogonal to the plane. The residual variance that was not accounted for by the planar regression was less than 2 % of the total variance, as shown in Table 5.3. The orientation of the plane of covariation of each side (affected vs. unaffected) was highly consistent across gait conditions for both subjects. The maximum angle between any two planes of the same side for either subject was 4.89 deg. All of the angles between planes can be found in Table 5.4. Finally, the root mean square (rms) error was calculated between each time point of the averaged gait path and the best-fit plane. Those results can be found on Table 5.5.

To compare the three different brace conditions, a multi-comparison (see Section 4.5.6 Statistical Analysis) was performed on the angles between the planes of the affected and unaffected leg for the same brace conditions and the rms error. No statistical difference between the brace conditions was found for either measurement ($p < 0.05$).

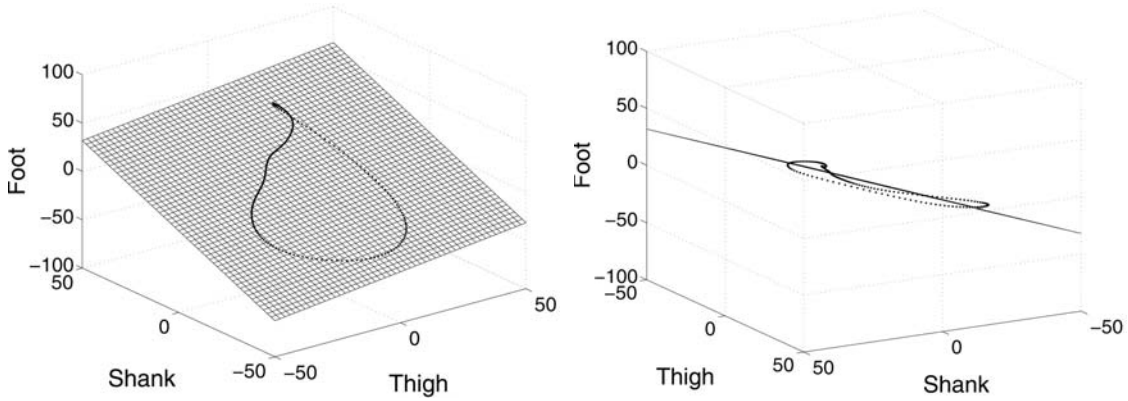

Figure 5.6 Planar covariation of elevation angles (a) isometric view and (b) along the best-fit plane

Table 5.3 The percentage of variance accounted for by each eigenvector of the covariance matrix

	Affected Side (A)			Unaffected side (U)		
Subject 1	zero	constant	AAFO	Zero	constant	AAFO
u1	83.52	84.74	84.35	81.15	84.81	82.21
u2	16.20	14.58	15.01	17.86	14.06	16.66
u3	0.28	0.68	0.64	0.99	1.14	1.13
Subject 2						
u1	81.53	84.83	82.33	76.53	80.34	82.38
u2	17.86	14.41	16.55	21.94	18.62	16.36
u3	0.61	0.76	1.12	1.52	1.04	1.26

Table 5.4 Angles between the best-fit planes

	Affected Side (A)			Unaffected Side (U)		
Subject 1	zero	constant	AAFO	zero	constant	AAFO
zero (A)	0.00					

constant (A)	4.89	0.00				
AAFO (A)	4.87	0.58	0.00			
zero (U)	7.66	2.78	2.85	0.00		
constant (U)	10.31	6.01	6.42	4.34	0.00	
AAFO (U)	12.19	7.72	8.07	5.62	1.95	0.00
Subject 2						
zero (A)	0.00					
constant (A)	4.06	0.00				
AAFO (A)	3.90	0.55	0.00			
zero (U)	19.62	20.62	21.05	0.00		
constant (U)	18.90	19.96	20.38	0.73	0.00	
AAFO (U)	17.36	18.38	18.81	2.26	1.57	0.00

Table 5.5 Root mean square (RMS) error of the averaged gait path with the best-fit plane

	Subject 1	Subject 2
Zero (A)	37.02	40.06
Constant (A)	35.11	39.35
AAFO (A)	35.61	39.38
Zero (U)	31.17	28.55
Constant (U)	32.67	29.36
AAFO (U)	31.48	29.87

Chapter 6

Discussion and Conclusions

This chapter discusses and summarizes the results found in the previous chapter. The Active Ankle Foot Orthosis (AAFO) with the variable impedance controller was found to help improve both major complications of drop foot gait. Further, it did not disturb the unaffected phases of gait. The following sections will explain these findings and put them into perspective. Section 6.1, Inter cycle impedance variations, describes the benefits of variable stiffness during controlled plantar flexion (CP) to improve slap foot and during swing to reduce toe drag. Section 6.2, Intra cycle impedance variations, . Section 6.3, Gait Improvements, summarizes improvements in the overall gait of the drop foot users. Section 6.4, Drop Foot Participants' Feedback, depicts the positive opinions that both drop foot participants had about the AAFO. Section 6.5, Future Work, recommends improvements and extensions of the current project. Finally, Section 6.6, Summary, concludes the contributions of this work.

6.1 Inter cycle Impedance Variations

The CP stiffness was optimized within each gait speed range, or time of contact bin. After the variable-impedance controller adapted CP stiffness across walking speed, the final stiffness at the slow speed was 36% less, and at the fast speed, 57% greater than at the self-selected speed. Thus, from slow to fast gait speeds, stiffness increased more than two-fold. A constant stiffness spring tuned only to the self-selected gait speed allowed slap foot to occur at fast walking speeds (Figure 5.3). It also made the ankle too stiff during slow walking, reducing the angular rotation of the ankle during controlled plantar flexion movements in early stance.

During Swing, the primary concern for both the drop foot participants in the study was catching their toe and loosing their balance. With constant swing phase impedance, both users caught their toe at the fast gait speed. This was not surprising given the fact that, for normal gait, the amount of time to lift the foot and achieve toe clearance was found to decrease by a factor of two from slow to fast speeds. To achieve this time decrease with the AAFO, a four-fold increase in swing joint stiffness was necessary (see Table 3.4). Thus, changing orthotic joint impedance

with gait speed, in order to lift the toe during swing, appears to be an essential control feature of the variable-impedance AAFO.

6.2 Intra cycle impedance variations

Normal ankle function has been modeled as a linear spring during controlled plantar flexion, and as a non-linear, stiffening spring during controlled dorsiflexion (Palmer 2002). Throughout the swing phase, the ankle was modeled as a linear torsional spring and damper in Section 3.2.2, Control Algorithm. Given these differences in ankle function within a single gait cycle, an assistive ankle device, acting in parallel with the human ankle-foot complex, should ideally change its impedance in response to walking phase. To this end, a state controller was used in the AAFO, and joint impedance was modulated in response to walking phase. During the controlled plantar flexion phase of walking, or Contact 1, a linear torsional spring control was employed where the stiffness was adjusted to prevent foot slap. From mid-stance to pre-swing, or the Contact 2 state, a zero impedance control was implemented so as not to impede normal powered plantar flexion movements. Finally, during the Swing state, a spring-damper PD control was implemented to provide toe clearance. These impedance changes reduced the difference in ankle kinematics between drop foot and unaffected individuals. The swing dorsiflexion angle and the powered plantar flexion (PP) angle of the ankle were significantly increased towards unaffected values by the variable impedance controller, as compared to the constant impedance controller.

6.3 Gait Improvements

This section will quantify the overall gait improvements of the drop foot participants by looking at powered plantar flexion, the differences between the affected and unaffected leg and the coordination between the three leg joints (ankle, knee and hip).

6.3.1 Powered Plantar Flexion Angle

The variable-impedance controller should have a similar maximum powered plantar flexion angle as the zero impedance condition since both controllers were designed to *not* impede late stance powered plantar flexion movements. However in this study, this behavior was not observed (see Figure 5.5). It was discovered that the variable-impedance controller transitioned into the Swing state too early, before the foot actually left the ground, due to a lack of resolution

in the forefoot force sensors. Consequently, the Swing spring-damper controller was activated too early, impeding powered plantar flexion movements during late stance. As a resolution to this difficulty in future investigations, we feel a foot switch might have to be positioned in the forefoot region to more accurately detect the event of toe-off.

6.3.2 Spatial and Temporal Gait Symmetry

We hypothesized that changing orthotic joint impedance will result in a more symmetric gait between affected and unaffected legs in unilateral drop foot gait. To test the hypothesis, we evaluated spatial and temporal gait symmetry according to the difference in step lengths and step times between affected and unaffected sides. When using the variable-impedance control, the difference in step time and step length was not significantly different from that measured with the constant impedance control condition. However, for both gait speeds analyzed, the variable-impedance controller did improve spatial and temporal gait symmetry compared to the zero impedance control condition, whereas the constant impedance control did not.

Thus, though the variable impedance controller significantly improved gait symmetry over unassisted gait and the constant impedance brace did not, the two were not significantly different from each other.

6.3.3 Intersegmental Coordination

The results found for the coordination of the elevation angles closely match the observed results of several studies (Borghese et.al., 1996; Mah et. al., 1994), where the temporal changes of the foot, shank and thigh angles described a cyclic loop during each gait cycle whose residual variance around the best-fitting plane was less than 2 % of the total experimental variance. Further, for each leg of the drop foot patients, the angle between the best-fit planes was less than 5 degrees, as has also been previously shown. However, there are large angles between the best-fit planes of the affected to the unaffected legs, as seen in Table 5.4. This is expected due to the unilateral nature of drop foot gait.

One surprising result was the intersegmental coordination of the affected side during the zero impedance condition. Of all of the conditions for either leg, the zero impedance condition was the best described by the first two eigenvectors. This is counter-intuitive since the zero

impedance condition should be a pathological gait. These results show that this method of analysis is not able to differentiate between the brace conditions.

6.4 Drop Foot Participants' Feedback

In the development of any rehabilitation device, including AFOs and FES systems, feedback from the user is always an important consideration. Despite the large weight of the AAFO and its current bulkiness, both drop foot participants preferred the device over any AFO they had ever used. They expressed a desire to use the AAFO at home and wanted to be informed of any commercialization plans. One participant remarked that the AAFO made walking "almost subconscious, like normal walking."

6.5 Future Work

Before the variable-impedance AAFO can have broad utility for individuals suffering from drop foot gait, system hardware and software must be advanced. The series-elastic actuator used in this investigation is too heavy and power intensive to be practical in a commercially available active ankle foot system, and would therefore have to be redesigned. Further, control strategies and sensing architectures specifically suited for the ascent and descent of stairs and ramps would be necessary. The biomechanics of gait change sufficiently where separate states could be created to explicitly help the user in these conditions (McVay and Redfern, 1994; Redfern and DiPasqale, 1997).

In addition to these improvements, different variable-impedance AAFO controllers might be developed for therapy purposes. In this study, the drop foot controller allowed one slap foot for every 5 steps taken by the user, and reduced the stiffness when no occurrence of slap foot occurred. For someone requiring permanent assistance, like the drop foot participants in the study, the final stiffness provided sufficient support to where the participants could not discern foot slap. However, the drop foot controller could also be used as a therapy tool to promote improvements in muscle function and control. In this case the controller might be adjusted to allow more than one slap foot per 5 steps, thus providing the minimal support for gait and promoting the development of muscle dorsiflexors.

The AAFO could be used for research purposes as a system identification tool to measure the dynamics of the foot, ankle or leg while walking by using small perturbations. Also, the current

system can be used by orthotists to prescribe AFO's. The AAFO could be used to simulate current AFO's on a user to specify an optimal design, rather than the current method of trial and error to find a suitable AFO for the user.

6.6 Summary

Drop foot gait is caused by stroke, cerebral palsy, multiple sclerosis and neurological trauma from accident or surgical complication (Taylor et. al., 1999). Although drop foot is a common pathology, with over 250,000 cases in the U.S. from stroke alone (NSA, 1997), current ankle foot orthoses are non-adaptive and fail to eliminate significant gait complications (Carlson et. al., 1997; Lehmann et. al., 1986). The Active Ankle Foot Orthosis (AAFO) was built to test a biomimetic variable-impedance control algorithm to assist with this pathological gait.

Zero, constant and variable-impedance control strategies were evaluated on persons suffering from unilateral drop foot gait. We demonstrate that the variable-impedance control applied to the AAFO reduces the two dominant complications of drop foot gait: slap foot and toe drag. Recalling the hypotheses set out in Chapter 1, the first hypothesis, that a variable-stiffness torsional spring at the ankle would reduce the occurrence of slap foot, was proven. The stiffness of this spring, as described in the second hypothesis, adapted to the gait speed of the user and the pattern of the force that the forefoot exerted on the ground at foot flat. Further, the swing phase ankle dynamics were more biologically realistic when compared to zero and constant impedance control conditions. These results were able to confirm the last two hypotheses that toe drag could be eliminated by a torsional spring-damper system, whose values were defined by the gait speed of the user.

In summary, this work details the construction of the Active Ankle Foot Orthosis (AAFO), a novel actuated ankle system placed in parallel with a human ankle. The AAFO can effectively simulate various assistive and therapeutic tools for different ankle pathologies. Further, the development of a biomimetic control to treat drop foot gait, shows that modulating orthotic joint impedance in response to walking phase and gait variation is an important design goal.

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Appendix A: Subject Consent Forms

Massachusetts Institute of Technology
Leg Laboratory
Artificial Intelligence Laboratory
COUHES Protocol Number 2805

Active Ankle Foot Orthosis (AAFO)

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time. In addition, the investigator in charge of this study may decide to end your participation in this study at any time after he/she has explained the reasons for doing so.

PURPOSE
We would like permission to enroll you as a participant in a research study**.** The purpose of the study is to develop a new active ankle-foot orthosis (AAFO) for people with drop foot. A standard ankle-foot orthosis (AFO) is two plastic shells connected at the ankle with different types of joints. One shell is fitted to the back of the calf and the second to the bottom of the foot. AFO's help people to stand and walk better by assisting or resisting ankle motion. All currentAFO's, however, do not change for different walking speeds. This new ankle foot orthosis (AFO) will adapt to your ankle motion and walking speed to try to improve the way you walk. This is a new device that has never been tested before, but has the potential for reducing the effects of drop foot.

STUDY CONTACTS
The scientist in charge of this study is Dr. Hugh Herr who can be reached at the Massachusetts Institute of Technology (MIT) at (617) 253-8047. You may also contact Mr. Joaquin Blaya at the Massachusetts Institute of Technology (MIT) for questions regarding the orthosis. He can be reached at (617) 258-5794.

PROCEDURES
A professional orthotist will then make you a customized ankle foot orthosis (AFO). Both sessions should take one hour each. The actuated AFO, the device being studied, will then be made from this standard AFO.
You will be scheduled to visit the Leg Laboratory at the Massachusetts Institute of Technology (MIT) for two sessions approximately six weeks apart. Each of these sessions will be identical except for the amount and type of walking you will be doing.
You will be asked to walk along a 30 foot level walkway. During both sessions, you will be asked to walk at slow, normal and fast paces for different conditions. For each walking condition and speed, approximately 10-15 trials should be done. You will be accompanied by a member of the laboratory staff in case you lose your balance. You may ask to rest or stop the study at any time.
For the first session, you will be tested for two conditions:

1. Without any assistive device
2. Using your current assistive device, if you use one

This means that you will be walking on the platform 60-90 times for the entire first session, which should take 2 hours.
For the second session you will be tested on four conditions:

1. Without any assistive device
2. Using your current assistive device, if you use one
4. Using the AAFO turned off
5. Using the AAFO with the walking program.

This means that you will be walking on the platform 120-180 times for the entire second session, which should take about 3 hours. We will also take measurements to determine the size of your limbs and your body weight. You may be asked to return for optional sessions at the Leg Laboratory identical to the second. This session would be in case more data is needed to evaluate the orthosis that we are building. You will receive a stipend of $100 to compensate for your time, effort and travel expenses. We will assist in arranging your transportation but cannot pay transportation cost beyond those covered by the $100 stipend.

COSTS

The device, the actuated ankle foot orthosis (AAFO), will be paid for by the researchers with no cost to you. There will be no cost to you for the gait laboratory evaluations or for any treatment specific to the study.

RISKS AND DISCOMFORTS

1. As with any orthotic walking, there is a small risk of falling during the trials. This will be minimized by having an assistant walk beside you, if necessary.
2. If you become too fatigued you may ask to rest or stop the study at any time.
3. As with any orthotic device, there is also potential physical discomfort from wearing the orthosis. This will be minimized by having a professional orthotist design and modify a customized orthotic for your use.
4. Since the AAFO is an active device, there is a risk of malfunction. The developers will make every effort to reduce this risk, but if a malfunction occurs, the AAFO will default to a inactive state where it will become rigid, like a standard ankle foot orthotic.
5. This device is investigational and there may be risks and side effects that are currently unknown and/or unanticipated.
6. Your participation in this study may be terminated by the investigator if they feel there are excessive risks or insufficient rehabilitation from the device being tested. Your rehabilitation will not be affected by the termination of this study.

BENEFITS

1. Development of an actuated ankle foot orthotic that may help remedy drop foot and other lower leg pathologies.
2. There are no known direct benefits for participating in this experiment. The orthotic being developed is a prototype and will not be immediately available.

ALTERNATIVES

The alternative to participating in this study is to continue with your regular treatment under the direction of your primary care physician.

In the unlikely event of physical injury resulting from participation in this research, I understand that medical treatment will be available from the MIT Medical Department, including first aid emergency treatment and follow-up care as needed, and that my insurance carrier may be billed for the cost of such treatment. However, no compensation can be provided for medical care apart from the foregoing. I further understand that making such medical treatment available, or providing it, does not imply that such injury is the investigator's fault. I also understand that by my participation in this study I am not waiving any of my legal rights.

I understand that I may also contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, MIT 253-6787, if I feel I have been treated unfairly as a subject.

_____
Subject Name

_____ _____
Subject Signature Date

_____ _____
Witness Signature Date

Spaulding Rehabilitation Hospital

Protocol Title: Actuated Ankle Foot Orthotic (AAFO)

Principal/Overall Investigator: Patrick Riley, Ph.D.

Site-Responsible Investigator(s)/Institution: Patrick Riley, Ph.D. / Spaulding Rehabilitation Hospital

Co-Investigator(s)/Study Staff: Hugh Herr, Ph.D., Dava Newman, Ph.D., Joaquin Blaya, B.S.

Description of Subject Population: Two subjects without foot drop gait (normal)

The Spaulding Rehabilitation Hospital Human Studies Committee has approved this study and the recruitment of subjects to participate in this study.

PURPOSE

We would like permission to enroll you as a participant in a research study**.** The purpose of the study is to develop a new active ankle-foot orthoses (AFO) for people with drop foot. A standard ankle-foot orthoses (AFO) is two plastic shells connected at the ankle with different types of joints. One shell is fitted to the back of the calf and the second to the bottom of the foot. AFO's help people to stand and walk better by assisting or resisting ankle motion. All currentAFO's, however, do not change for different walking speeds. This new active ankle foot orthoses (AAFO) will adapt to the user's ankle motion and walking speed to try to improve the way they walk. The AAFO will sense the angle and amount of force of the ankle. It will then resist or assist your ankle motion to lift your toes while you are walking This is a new device that has never been tested before, but has the potential for reducing the effects of drop foot. Your participation would allow us to study the effects of the orthoses on users without a drop foot gait and also to compare this to subjects who have drop foot gait.

STUDY CONTACTS

The scientist in charge of this study is Patrick Riley, Ph.D. who can be reached at the Spaulding Center for Rehabilitation Science (CRS) at (617) 573-2731. You may also contact Mr. Joaquin Blaya at the Massachusetts Institute of Technology (MIT) for questions regarding the orthoses. He can be reached at (617) 258-5794.

PROCEDURES

A professional orthotist will make you a customized ankle foot orthoses (AFO). This session should take one hour. The active AFO (AAFO), the device being studied, will then be made from this standard AFO. You will be scheduled to visit the Gait Analysis Lab at Spaulding Rehabilitation Hospital. After a physical examination, you will undergo a computerized gait evaluation in the gait laboratory (CRS) at the Spaulding Rehabilitation Hospital, which will involve the measurement of the movements of your legs. Reflective markers will be secured with tape to the skin of your legs and to the back of your pelvis. These markers will be recorded by cameras that see only light reflected off the markers. The Human Studies Committee approved this equipment as presenting no significant risk to you. The Partners Health Care System Biomedical Engineering Department has certified that this equipment complies with all safety codes for hospital-based equipment. After being prepared, you will be asked to walk along a 30-foot level walkway. The walkway will sense how your weight is being carried by your legs. In addition to the data collected by computer from the marker tracking cameras and walkway sensors, we will also record your walking using regular video cameras. You will be asked to walk at slow, normal and fast paces for different conditions. For each walking condition and speed, approximately 10-15 trials should be done.

You will be accompanied by a member of the laboratory staff in case you lose your balance. You may ask to rest or stop the study at any time.
For this session, you will be tested for three conditions:

1. Without any assistive device
2. Using the AAFO turned off
3. Using the AAFO with the walking program.

This means that you will be walking on the platform 90-120 times for the entire first session, which should take 3 hours. We will also take measurements to determine the size of your limbs and where your joints are relative to the reflective markers. You may be asked to return for an optional second session at the Gait Laboratory identical to the first. This session would be in case more data is needed to evaluate the orthoses that we are building.
You will receive a stipend of $40 to compensate for your time, effort and travel expenses. We will assist in arranging your transportation but cannot pay transportation cost beyond those covered by the $40 stipend.

COSTS
The device, the active ankle foot orthotic (AAFO), will be paid for by the researchers with no cost to you. There will be no cost to you for the gait laboratory evaluations or for any treatment specific to the study. There will be no charge for parking at the Spaulding Rehabilitation Hospital parking lot.

RISKS AND DISCOMFORTS

7. As with any orthotic walking, there is a small risk of falling during the trials. This will be minimized by having an assistant walk beside you, if necessary.
8. If you become too fatigued you may ask to rest or stop the study at any time.
9. As with any orthotic device, there is also potential physical discomfort from wearing the orthosis. This will be minimized by having a professional orthotist design and modify a customized orthotic for your use.
10. Since the AAFO is an active device, there is a risk of malfunction. The developers will make every effort to reduce this risk, but if a malfunction occurs, the AAFO will default to a inactive state where it will become rigid, like a standard ankle foot orthotic.
11. This device is investigational and there may be risks and side effects that are currently unknown and/or unanticipated.
12. You should inform the investigator if you are or have ever participated in any other research study pertaining to this disability.
13. Your participation in this study may be terminated by the investigator if they feel there are excessive risks or insufficient rehabilitation from the device being tested. Your rehabilitation will not be affected by the termination of this study.

BENEFITS

1. There are no known direct benefits for participating in this experiment. The orthotic being developed is a prototype and will not be immediately available. You will not be able to keep the device at the end of the study.
2. Development of an actuated ankle foot orthotic that may help remedy drop foot and other lower leg pathologies.

ALTERNATIVES
The alternative is not to participate in this study.

THE FOLLOWING PARAGRAPHS CONTAIN STANDARD INFORMATION WHICH GENERALLY APPLIES TO PERSONS INVOLVED IN A RESEARCH STUDY AND ARE REQUIRED ON ALL CONSENT FORMS.

CONFIDENTIALITY

Medical information produced by this study will become part of your hospital medical record, unless specifically stated otherwise in this consent form. Information that does not become part of your medical record will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Your medical record is available to health care professionals at Spaulding Rehabilitation Hospital (SRH), and may be reviewed by appropriate Hospital staff members in the course of carrying out their duties; however, they are required to maintain confidentiality in accordance with applicable laws and the policies of SRH. Information contained in your records may not be given to anyone unaffiliated with SRH in a form that could identify you without your written consent, except as described in this consent form or as required by law.

It is possible that your medical and research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, SRH will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifiers will not be used in any publication or teaching materials without your specific permission. In addition, if photographs, audiotapes or videotapes were taken during the study that could identify you, then you must give special written permission for their use. In that case, you will be given the opportunity to view or listen, as applicable, to the photographs, audiotapes or videotapes before you give your permission for their use if you so request.

REQUEST FOR MORE INFORMATION

You may ask more questions about the study at any time. The investigator(s) will provide their telephone number so that they are available to answer your questions or concerns about the study. You will be informed of any significant new findings discovered during the course of this study that might influence your continued participation.

If during the study or later, you wish to discuss your rights as a research subject, your participation in the study and/or concerns about the study, a research-related injury with someone not directly involved in the study, or if you feel under any pressure to enroll in this study or to continue to participate in this study, you are asked to contact the Department of Research and Training, SRH at (617) 573-2366. A copy of this consent form will be given to you to keep.

REFUSAL OR WITHDRAWAL OF PARTICIPATION

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care at SRH. In addition, the doctor in charge of this study may decide to end your participation in this study at any time after he/she has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

INJURY STATEMENT

If you are injured during the course of the study and as a direct result of this study, you should contact the investigator at the number provided. You will be offered the necessary care to treat that injury. This care does not imply any fault or wrong-doing on the part of SRH or the doctor(s) involved. Where applicable, SRH reserves the right to bill third party payers for services you receive for the injury. The SRH will not provide you with any additional compensation for such injuries.

SIGNATURE

I confirm that the purpose of the research, the study procedures and the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. All my questions have been answered. I have read this consent form. My signature below indicates my willingness to participate in this study.

_____ _____

Subject/Patient Date

_____ _____

Witness/Advocate/Minor/Legal Guardian (if required) Date

_____ _____

Additional Signature (if required)(identify relationship to subject) Date

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered any questions regarding the study to the best of my ability.

_____ _____

Study Representative Date

Appendix B: Additional Controller Design Data

During controlled plantar flexion (CP), Palmer and Herr found that the ankle spring stiffness, defined as the slope of the regression line fit to the ankle torque versus ankle angular position curves, was linear (2002). Thus, ankle function could be characterized by a linear, torsional spring during CP. They also found that the work done by the spring increases with gait speed, and while gait speed is constant, the work is kept constant by modulating the stiffness from stride to stride. The results for one subject can be seen in Figure B.1(b). Finally, the ankle angular velocity immediately before foot flat was found to be a constant close to zero across gait speeds, as seen in Figure B.1(a). Physically, this makes sense since the ankle changes direction at foot flat, from plantar flexion to dorsiflexion.

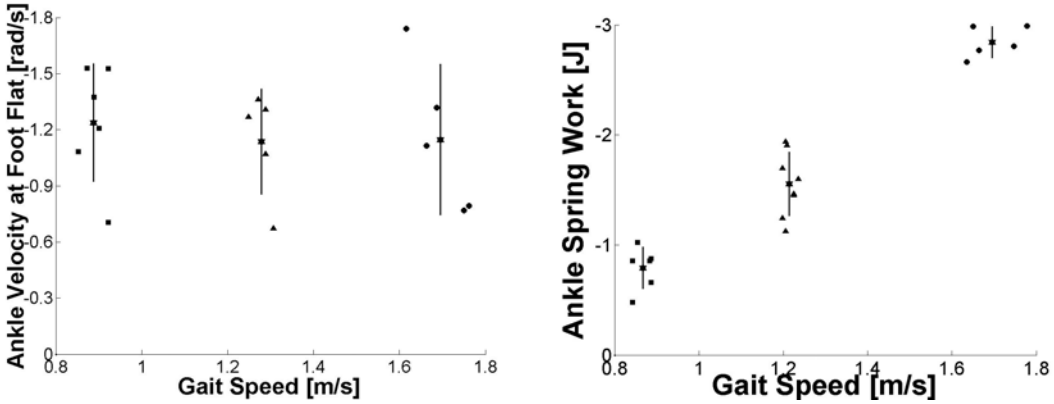

Figure B.1 (a) Ankle velocity before foot flat (b) the work done by the ankle spring during controlled plantar flexion (CP)

However, because of foot slap, a higher angular velocity at foot flat would be expected. Also, an increased plantar flexed position should occur. Preliminary experiments were performed at Spaulding Rehabilitation Hospital using the data collection described in the Experimental Methods section. Two unimpaired subjects walked at their self-selected speed in a normal fashion and imitating foot slap. As seen in Figure B.2, both the angular velocity and the amount of plantar flexion are higher than the unimpaired gait.

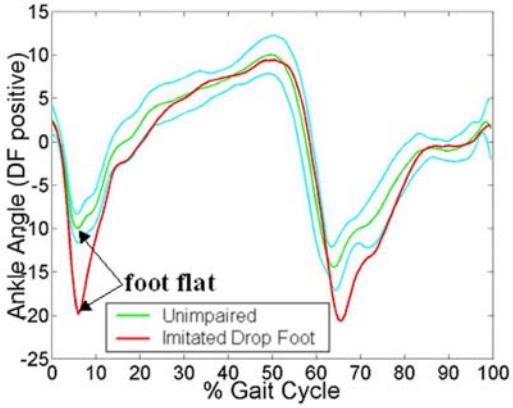

Figure B.2 Ankle angle versus percentage of the gait cycle for one of the subjects

The control method will consist of simulating a linear, rotary spring at the ankle with variable stiffness across steps. The spring stiffness should adapt to the gait speed of the user as well as their physical ability. To adapt to gait speed, three bins were made for varying contact times. To adapt to the physical ability of the user, kinetic and kinematic measurements from unimpaired and drop foot gait during CP were analyzed to find a quantifiable difference. This measurement would then be used to increment or decrement the spring stiffness.

Two control methods were developed to adapt the stiffness of the virtual spring. The one that was not chosen was based on the difference in ankle velocities from the unimpaired to the impaired side. However, after analyzing the gait of two drop foot subjects, it was found that the variance in ankle velocities was large enough that a clear distinction between normal and slap foot gait could not be made.

I can't believe I wrote this much…