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entitled

Towards a Shape Memory Alloy Based Variable Stiffness
Ankle Foot Orthosis

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Submitted to the Graduate Faculty as partial fulfillment of the requirements for
The Doctor of Philosophy Degree in Engineering

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An Abstract of

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Drop foot is a neuromuscular disorder causing a loss of use of the muscles that lift the foot.
Drop foot can primarily be caused by stroke, cerebral palsy, multiple sclerosis, 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 treatment options like Ankle Foot Orthosis (AFO) and Functional Electrical Stimulation, while offering some biomechanical benefits, do not adapt to different walking conditions and fail to eliminate significant gait complications. This study proposes a novel Active Ankle Foot Orthosis design which combines an AFO and combinations of shape memory alloy (SMA) wires. The key feature of SMA is its ability to undergo seemingly large plastic strains and subsequently recover these strains when a load is removed or the material is heated. Because of this distinct thermomechanical behavior, SMA can potentially resolve some of the gait complications associated with use of an AFO.

To provide a basis for the design of an AAFO, gait analysis is performed on healthy subjects along with drop foot patients to establish the deficiency in ankle stiffness
characteristics. The initial verification of the thermomechanical behavior of SMA in the form of stiffness variation is carried out by testing SMA wire combinations. Based on these experiments a COMSOL model is verified which is used for simulating the combinations of SMA wires. Through simulations and experiments it has been shown that changing the combination of SMA wires result in variable stiffness pattern. The performance of different types and combinations of SMA wires are tested successfully on an AFO. The preliminary results demonstrate that SMA wires provide controlled plantarflexion during stance phase, and active dorsiflexion in the swing phase by using stiffness variations of shape memory alloy wires. In particular, the AAFO helps to avoid major complications of drop foot gait. Thus, with the development of a control strategy, and using the inherent stiffness variation of SMA wires it is possible to produce close-to-normal stiffness profiles in the ankle motion of drop-foot patients who are wearing the AAFO.
This dissertation is dedicated to my family members, who have been always supportive of me, guiding and encouraging me through my endeavors.
Acknowledgments

Foremost, I would like to thank my husband. He was my inspiration to follow this path and without him I would never have been able to finish this research. I would also like to thank my parents for being so wonderfully supportive to me all the time. Without their strong support, I would have not reached this step in my education.

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List of Symbols

\( F_{zz} \)  The component of the transformation strain in the axial (\( z \)) direction
\( \zeta \)  Martensitic volume fraction
\( \zeta_s \)  Volume fraction of stress induced martensite
\( \zeta_T \)  Volume fraction of temperature induced martensite
\( \zeta_d \)  Volumetric fraction of detwinned (or temperature-induced) Martensite
\( \zeta_{sn} \)  Volumetric fraction of stress-induced Martensite in the negative direction
\( \zeta_{sp} \)  Volumetric fraction of stress-induced Martensite in the positive direction
\( \sigma_{Ms} \)  Martensite start transformation stress
\( \sigma_{Mf} \)  Martensite finish transformation stress
\( \sigma_{As} \)  Austenite start transformation stress
\( \sigma_{Af} \)  Austenite finish transformation stress
\( \sigma_{SMA} \)  Stress in SMA wire
\( \tau_{sma} \)  Torque of SMA wire
\( \sigma \)  Second Piola-Kirchoff stress
\( \Omega \)  Transformation coefficient
\( \theta \)  Thermal coefficient
\( \mu \)  Lagrange multiplier
\( \epsilon \)  Green-Lagrange strain
\( \epsilon_l \)  Residual strain
\( \varepsilon_{lp} \)  Maximum transformation strains in tension
\( \varepsilon_{ln} \)  Maximum transformation strains in

\( A \)  Matrix of derivatives of martensite phases
\( A_f \)  Temperature for the finish of martensite transformation
\( A_s \)  Temperature for the finish of austenite transformation
\( A_s \)  Temperature for the start of austenite transformation

\( C^d \)  Vector of transformation conditions
\( C \)  Center of mass

\( D \)  Modulus of elasticity
\( D_A \)  Modulus of elasticity for the fully austenitic material
\( D_M \)  Modulus of elasticity for the fully martensitic material

\( E_A \)  Elastic modulus of austenite
$E_M$ Elastic modulus of martensite

$F$ Force

$f_{sp}$ Spring pretention force

$F_{SMA}$ Force exerted by SMA wire

$K$ Stiffness

$k_s$ Spring coefficient

$l_s$ Bias spring length

$M$ Moment

$M_d$ Detwinned martensite

$M_f$ Temperature for the finish of Martensite transformation

$M_s$ Temperature for the start of Martensite transformation

$Mt$ Twinned martensite

$R$ Moment arm

$r_a$ Arm center of gravity

$r_g$ Gripper center of gravity

$S$ Second Piola-Kirchoff stress in the axial direction

$T$ Temperature

$W$ Weight
## List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAFO</td>
<td>Active ankle foot orthosis</td>
</tr>
<tr>
<td>AFO</td>
<td>Ankle foot orthosis</td>
</tr>
<tr>
<td>DOF</td>
<td>Degree of freedom</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyogram</td>
</tr>
<tr>
<td>FES</td>
<td>Functional electric simulation</td>
</tr>
<tr>
<td>FSR</td>
<td>Force sensing resistor</td>
</tr>
<tr>
<td>GRF</td>
<td>Ground reaction force</td>
</tr>
<tr>
<td>HS</td>
<td>Heel strike</td>
</tr>
<tr>
<td>LSSVM</td>
<td>Least squares support vector machine</td>
</tr>
<tr>
<td>LVDT</td>
<td>Linear variable differential transformer</td>
</tr>
<tr>
<td>NiTi</td>
<td>Nitinol/ Nickel Titanium</td>
</tr>
<tr>
<td>PDE</td>
<td>Partial differential equation</td>
</tr>
<tr>
<td>PID</td>
<td>Proportional–integral–derivative</td>
</tr>
<tr>
<td>PP</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>SE</td>
<td>Superelasticity (Pseudo-elasticity)</td>
</tr>
<tr>
<td>SEA</td>
<td>Series elastic actuator</td>
</tr>
<tr>
<td>SM</td>
<td>Shape memory</td>
</tr>
<tr>
<td>SME</td>
<td>Shape memory effect</td>
</tr>
<tr>
<td>TO</td>
<td>Toe off</td>
</tr>
</tbody>
</table>
Chapter 1

Introduction

Drop foot is described as the inability of the patient to raise the front portion of the foot due to weakness or paralysis of the muscles that lift the foot (Figure 1-1). During walking, the major complications of drop-foot are 1) slapping of the forefoot after heel strike and 2) dragging of the toes at the beginning of each swing phase. At heel strike, the foot in these patients falls uncontrolled to the ground, producing a distinctive slapping noise (foot slap) [1]. During the mid swing phase of gait cycle, toe drag prevents proper limb advancement and increases the risk of tripping. As a result, individuals with foot drop scuff their toes along the ground or bend their knees to lift their foot higher than usual to avoid the scuffing, which causes what is called a “steppage” gait.

Drop-foot forces the patient to flex the hip joint to a larger degree during the swing phase to avoid collision between the ground and the toes and to meet the ground with the forefoot first [2]. Affected people tend to have a labored and unsafe gait, and suffer from fatigue which further reduces their speed and the distance they can walk. Foot drop is a symptom of an underlying problem and is either temporary or permanent, depending on the cause.
Figure 1-1 Drop foot anatomy: the inability of the neuromuscular system to produce and control dorsiflexion [3].

Drop foot as a motor deficiency is caused by total or partial central paralysis of the muscles innervated by the common peroneal nerve, or paralysis of the anterior tibial muscle and the peroneal group. Other causes include: neurodegenerative disorders of the brain that cause muscular problems, such as multiple sclerosis, stroke, and cerebral palsy; motor neuron disorders such as polio, some forms of spinal muscular atrophy and amyotrophic lateral sclerosis; injury to the nerve roots, such as in spinal stenosis; peripheral nerve disorders. Combat related trauma can also lead to drop foot condition as major limb injuries are among the most debilitating wounds sustained by those who survive a combat injury, and these injuries leave a lasting impression with the public [4]. Approximately 70 % of war wounds are musculoskeletal injuries, and 55 % are extremity wounds [5]. Many nerve injuries occur directly from blunt trauma, while others are secondary complications due to fractures [6].
Foot drop can be unilateral or bilateral. With most cases of drop foot, the muscles would still function if they were capable of receiving signals from the nerve junctions [1].

1.1 Treatment options

Regardless of the cause, if left untreated foot drop can cause progressive weakness in the affected limb, loss of joint motion and the inability to walk normally. Treatment is individualized and based on symptoms. It can include a conservative "wait and see" approach, therapy, orthotics or surgery. This section summarizes the ways to treat the condition and regain partial or full mobility:

**Orthotics:** Orthotics or braces are considered as the most common treatment option for foot drop. Braces can be as simple as a lightweight shoe insert or as complicated as specialized hinged units. Orthoses are often the first line of foot drop treatment by providing stabilization of the ankle and the foot.

**Functional Electrical Stimulation:** FES uses low levels of electrical current to stimulate physical or bodily functions lost through nervous system impairment. Electrical stimulation is appropriate for a small number of patients who have an intact peroneal nerve. Devices provide stimulation to the nerve either on the surface of the foot or by implantation into the foot. They are shown to provide active correction of foot drop by stimulating the flexor muscles during walking [7].

**Physical Therapy:** Physical therapy may be prescribed to strengthen the weakened muscles and to maintain normal joint motion. Physical therapy is for those whose drop foot is not severe enough for surgery or can be used as assisting technique in situations where foot drop has caused a significant gait disturbance. Specialized physical therapy
for foot drop may include gait training that essentially teaches the patient how to walk all over again.

**Surgery:** Surgery may be an option to correct or alleviate the underlying problem causing drop foot. Options for drop foot surgery include nerve releases, nerve repair, tendon lengthening, tendon transfers and fusion of joints of the foot and ankle. The appropriate treatment is based on advanced diagnostic testing. For example, if drop foot is caused by nerve compression from a lumbar herniated disc, then a spinal surgical procedure called discectomy (disc removal) may be required to relieve or 'decompress' the nerve.

### 1.1.1 Ankle Foot Orthosis

The most commonly used treatment option for drop foot patients is ankle foot orthosis. An ankle foot orthosis (AFO) is defined as a 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 [8]. These orthoses are designed to assist human motions and to rehabilitate and correct the position of ankle (Figure 1-2).

An AFO is generally constructed of lightweight polypropylene-based plastic in the shape of an "L", with the upright portion behind the calf and the lower portion running under the foot. They are attached to the calf with a strap, and are made to fit inside accommodative shoes. These AFOs mostly do not have articulated ankle joints and instead are dependent upon the material properties and geometry which determine motion control characteristics.
Figure 1-2 (a) Polypropylene ankle foot orthosis limits the motion of the ankle [9]

(b) Hinged ankle foot orthosis allows dorsiflexion but limits plantarflexion.

The passive AFO assists the swing phase of the gait cycle by maintaining the ankle in a neutral position, controlling plantar flexion immediately after heel contact to absorb the impact of body weight, and supporting forward propulsion of the body by stabilizing the ankle during terminal stance. It also controls eversion and inversion to provide adequate mediolateral stability. Some AFOs such as shown in figure 1-2(b) allow for limited dorsiflexion.

The type of AFO that is recommended for a patient is dependent on the pathology of the user and their physical ability. The following are the main reasons for choosing an AFO for treating drop-foot patients:

- Improves the ability to support body weight during initial stance
- Improves the progression of foot contact during stance
- Improves the ability to generate push-off in late stance
- Guides the limb and reduces the number of degrees of freedom in order to simplify control problem
- Protects joint and ligaments
Although an AFO offers some biomechanical benefits, there are several areas that can be improved on. Thomson et al. studied the effect of an AFO on patients with myelomeningocele (partial or complete paralysis of the legs) and found that an AFO caused reduction in motion at the ankle joint [10]. Many current AFO designs used for foot-drop treatment are effective at controlling the undesirable plantarflexion during swing, but do not permit free ankle motion during the stance phase of gait. This restriction of movement leads to following shortcomings [11]:

- Gait pattern is different from that of a normal person
- Disuse atrophy of the ankle flexor muscles
- Influences other parts like knee and hip joint and also motion of unaffected leg
- High energy consumption and altered proprioception

1.1.2 Functional Electrical Stimulation

Functional electrical stimulation has been described as the electrical stimulation of a muscle deprived of nervous control for providing muscular contraction and thereby producing a functionally useful movement. Functional electrical stimulation is a technique that uses electrical currents to activate nerves innervating extremities affected by paralysis resulting from spinal cord injury, head injury, stroke and other neurological disorders. In this methodology short bursts of electrical pulses are used to generate muscle contraction. If muscles are stimulated in the right order, a walking-like motion can be attained by paraplegic subjects. The first electrical stimulator for drop foot problems was created in 1961 by Liberson et al. [12]. Since then many researchers have worked on it and developed several prototypes. So far two products are commercially available, which are Bioness and WalkAide as shown in figure 1-3. The Bioness NESS
L300 is an advanced foot drop system designed to provide mild stimulation to lift the foot to help patients walk more safely and easily. WalkAide is a neuroprosthetic device that channels electrical stimulation to the leg and foot in order to restore typical nerve-to-muscle signals, effectively lifting the foot at the appropriate time.

Figure 1-3 Two examples of functional electric stimulation for correcting drop foot condition (a) Bioness L300 [13] (b) WalkAide Bi-Flex Cuff [14].

As shown in figure 1-3 FES comes in a small unit that attaches to the leg below the knee. It stimulates peroneal nerve so that the patient can walk without any support. FES provides the following advantages for the drop foot patient [12]:

• Does not require orthopedic or special shoes
• Increased strength and endurance
• Decreased energy expenditure
• Prevention, retardation, and/or reversal of muscle atrophy

FES has shown some promise as a permanent assistance device, but the technology must be customized to the individual using trial-and-error methods and qualitative measurements. In most cases, a trained professional or clinician is necessary to qualitatively evaluate a subject’s gait and incrementally change device settings [15].
Research on FES systems has shown that constant muscle activation leads to many problems which are as follows:

- Rapid muscle fatigue as muscle gets activated regardless of the need
- Inadequate control of joint torques for reliable and repeatable limb motion and body support
- Patients cannot walk for a long duration

### 1.1.3 Active Ankle Foot Orthosis

Neither AFO nor conventional FES systems adapt to the gait of the user, neither step-to-step changes in gait pattern due to speed or terrain, nor long-term gait changes due to changes in muscle function. An AFO provides excessive resistance to plantarflexion, ankle motion gets inhibited throughout loading response and, as a result, the normal shock absorbing mechanism is disrupted and knee stability is reduced. This limitation is primarily because of the constant stiffness of the device. An effective orthosis should only provide the biomechanical controls necessary to improve the functional deficit without a perturbing effect to other normal movements and functions. As the plantarflexors are frequently not affected, the ideal foot-drop AFO should permit free ankle plantarflexion (with mild resistance) and dorsiflexion during stance phase and block plantarflexion during swing, i.e., prevent foot-drop. The challenge therefore is to apply sufficient resistance to eliminate the gait pathology without introducing additional aberrations.

Researchers developed Active AFOs (AAFO) in which the impedance of the orthotic joint can be modulated throughout the walking cycle to treat drop foot gait. Blaya et al., at MIT media lab have developed a powered ankle-foot orthosis based on a Series Elastic
Actuators (SEA) [15] (Figure 1-4(a)). The basic idea of this AAFO is to change the orthosis impedance (stiffness) actively, which eliminates the slap foot. As a result, the AAFO minimizes the walking kinematic difference from normal people. The MIT group developed a Series Elastic Actuator for the AAFO to realize variable stiffness. This actuator is comprised of a DC motor, mechanical links and springs. A control algorithm was developed to create proper stiffness for each part of the walking (gait) cycle. Although this AAFO shows promising results in a lab environment, the actuator weighs 2.6 kg and requires bulky batteries and electronics for operation. In addition, the patient may not be able to sit while wearing this AAFO because the size of actuators is too large. Another AAFO which uses pneumatically powered lower limb exoskeleton was developed in the Human Neuromechanics Laboratory at the University of Michigan [16]. This AAFO is actuated by McKibben Muscles which are pneumatic actuators. One pneumatic actuator provides plantar flexion torque and a second actuator provides dorsiflexion torque. A control algorithm adjusts air pressure in each actuator independently. The study has shown promising results in gait rehabilitation, human motor adaptation and muscle activations [16] (Figure 1-4(b)). However the applicability of these orthoses is limited to laboratory studies since on board power supplies and computers are required for their operation.

In order for an AAFO to be functional at a level that would allow it to be commercially viable, it must be light-weight, adaptable to a wide range of patients who vary in age, size, and type of disability, reliable and relatively simple. The need of light weight and flexible actuation with a high power to mass ratio brings the idea of using novel actuators
such as Shape Memory Alloys (SMA). SMAs have been used in a variety of actuation, energy absorbing, and sensing applications.

Figure 1-4 Examples of Active AFO: (a) Series Elastic Actuators by MIT [15] (b) McKibben pneumatic actuators by UM [16].

A group from Italy developed orthotic devices using the shape memory and pseudoelastic behaviors of SMA alloys [17-19]. A prototype of Shape memory activated device promoting ankle dorsiflexion (SHADE) was assembled with two thermoplastic shells hinged together at the ankle and strapped on the shin and foot (Figure 1-5 (a)). Two actuators were fixed on the upper shell while an inextensible thread connected each SMA wire to the foot shell [17]. Actuators mount a 250 cm long 250 µm diameter wire which were activated with a current injection of 0.7 A for 7 seconds, followed by cooling and reset by natural convection in 30 seconds. In a clinical setting, they provided sufficient propulsion to elicit dorsiflexion up to almost 20 degrees. With good stability, given the expected forces and displacements, such a device could be beneficial particularly in the early phases of post-stroke care. The main problem reported was dealing with lengthy and hardly controllable cooling of the SMA.
In the second device Lower limb exerciser with intelligent alloys (Liea) orthosis (Figure 1-5 (b)), they monitored tibialis anterior muscle activity to control generation of torque and rotary stroke. Leia is an orthosis mounting a pair of solid state motors based on SMA, allowing electromechanical energy conversion and direct generation of torque and rotary stroke. A computer routine was developed that analyzed the electromyographic (sEMG) signal from TA muscle was used to control the orthosis and trigger its activation. Tests on the orthosis proved that it can produce strokes up to 36 degrees against resisting torques exceeding 180 Ncm. This device was tested only on healthy subjects, and needs further improvement in body orthoses interface.

Figure 1-5 (a) SHADE orthosis [17] (b) EMG based Liea orthosis [19].

The results of this study are still insufficient to fully prove the clinical efficacy of these concepts. However they showed that NiTi SMA has very large deformability, coupled with sufficient strength and a desirable non-linear mechanical behaviour, thus it may provide for a more physiologic correction of gait pattern in patient.
1.2 Problem Statement

Drop foot patients currently can walk with an AFO and/or FES but, as these two systems both have inherent problems, the resulting walking pattern is less than ideal. A typical ankle foot orthosis being a passive device; restricts ankle movement which may lead to many problems such as muscle disuse atrophy, and restriction of ankle movement. Regardless of the need, FES technique activates muscle continuously which leads to early fatigue. This shows that both of these technologies are not ideal. The advantages of the active AFOs over the passive AFOs include the possibility of adjusting stiffness during walking and preventing the disuse atrophy. Previous researchers have built AAFO’s that may be useful in rehabilitation, but due to their design, are limited in their practical assistive applicability. SMA based device promotes sufficient ankle dorsiflexion but lengthy cooling rate limits its applicability in rehabilitation purposes. Current AAFOs need improvement in their esthetics, size, and weight along with its applicability for day to day use.

The aim of this research is to improve performance of the SMA based AAFOs, for the drop foot patient. Evaluate effect of different parameters such as combination of wires, and temperature, which can allow for faster actuation of the AFO. This AAFO is expected to provide an ankle range of motion close to that of a normal person by overcoming disadvantages of the passive systems. Specifically, we anticipate that the major complications of drop-foot gait namely foot slap and toe drag, can be reduced by actively controlling orthotic joint stiffness in response to walking phase.


1.3 Objectives

The primary objective of this study is to achieve stiffness variation of an Active AFO by modifying parameters of Shape memory alloys. Specifically, the goals are:

- Determining normal ankle motion patterns during gait through motion analysis on healthy subjects for different walking speeds, and to establish the stiffness variation in the joint.
- Determining the ankle motion patterns in drop foot patients to quantify the effects of this condition on the gait.
- Characterize and model the effect of combinations of shape memory and superelastic wires on stiffness modulation.
- Develop an algorithm to determine the combination of SMA wires that can be used in an AFO in order to achieve the desired stiffness profile at the joint.
- Design a preliminary prototype to avoid major complications of drop foot conditions by embedding SMA wires.
- Testing an AFO by embedding SMA wires on a mechanical testing device to verify the combination of SMA wires necessary to achieve the desired stiffness profile.
- Performing motion analysis on drop foot patients wearing Active AFO prototype to find out effectiveness of the SMA elements.

1.4 Outline

We conclude chapter one with the proposed approach of this study. Chapter 2 presents the backgrounds on the behavior of shape memory alloy and gait analysis techniques. In particular, section 2.3 reviews ankle behavior while walking. Some information on AFO fabrication and testing is given in the later sections.
In Chapter 3 an SMA-actuated robotic arm is modeled in order to further investigate the stiffness control. Section 3.1 summarizes modeling of SMA wires to simulate different combinations of SMA wires. Section 3.2 and 3.3 introduces experimental procedure to test SMA wires properties.

Chapter 4 explains how SMA wires can be embedded in an ankle foot orthosis along with testing of an Active AFO. Details of the motion analysis testing are described in section 4.1. An algorithm to identify combination of wires to achieve a particular profile is explained in the next section. Section 4.3 and 4.4 gives details of the prototype design and test methods.

Chapter 5 presents the results of gait analysis done on healthy individuals and drop foot patient. Results concerning the stiffness modification of SMA wires are discussed in later sections. Section 5.7 describes the final prototype results.

Chapter 6 concludes the dissertation by highlighting the conclusions and future steps in order to successfully achieve the objectives of this research. Chapter 7 has the detailed business plan for a final product to be developed from this research work.

1.5 Contributions

The main contributions of this dissertation are the following:

- Simulation and experimental characterization of stiffness variation of different combinations of SMA wires.
- Evaluation and modeling of effect of temperature on SMA wire stiffness variation
- Development of a search algorithm by using LSSVM technique to predict the combination of the wire from desired stiffness variation.
- Gait analysis of healthy subjects walking with various speeds
• Gait analysis of drop foot patient with and without AFO to quantify the effect of the condition on walking
• Design and development of an active ankle-foot orthosis prototype that assists ankle joint movement during swing phase of gait cycle
• Testing various types of SMA wires on the prototype using mechanical assembly and bench test setup
• Assess the most efficient the SMA wire combination for AAFO that helps patient dorsiflex foot in swing phase

In the overall, this dissertation presents the design, step by step, of an active ankle-foot orthosis prototype that was built to test stiffness modulation capacity of the SMA wires.

1.6 Publications

Up to date, the publications having been resulted from this research includes:


4. Bhadane, M. Elahinia, M. Armstrong C., and Hefzy, M. “A variable stiffness ankle foot orthosis based on SMA wires,” Biomedical Engineering Society Annual Meeting, October-6–9, 2010; Austin, Texas, Poster presentation.


Chapter 2

Background

2.1 Shape Memory Alloy

Shape memory alloys are a group of metallic materials that demonstrate the ability to return to some previously defined shape or size when subjected to the appropriate thermomechanical procedures. Some examples of these alloys are AgCd, AuCd, CuAlNi, CuSn, CuZn(X). Of all the Shape Memory Alloys that have been discovered to date, Nickel-Titanium (NiTi) has proven to be the most flexible and beneficial in engineering applications. Ming H. Wu et al. discussed industrial applications of SMA such as automotive devices, airplanes, cellular phone antennas, eyeglass frames [20]. Among smart materials suitable for actuator development, SMAs are known for their capabilities in applying both large forces (stress of 600 MPa) and large displacements (strain of 10%). A simple SMA wire can replace an electromagnetic motor, enabling cost savings and design simplicity, especially when simple mechanical movements are required. Mauro Dolce et al. used properties of SMAs in seismic devices [21]. SMAs are extremely corrosion resistant, no frictional parts, demonstrate excellent biocompatibility, and can be fabricated into very small sizes. These properties make these materials a natural candidate for biomedical applications such as stents, guide wires, orthodontic
wires, osteosynthesis etc [22]. The characteristics of SMA that make it stand out from
the other SMAs are: greater ductility, more recoverable motion, stable transformation
temperatures, high force to mass ratio, and the ability to be electrically heated for shape
recovery [23]. S. Pittaccio et al. utilized these characteristics to develop rehabilitative
orthotics devices [17-19]. The pseudoelastic property of shape memory alloys has been
used in a number of commercially available products. An example is an eyeglass frame
that is made of SMA. The shape memory alloy can undergo large deformations without
damaging the frame. SMAs also have disadvantages such as low frequency, large cooling
rates; which must be considered prior to application.

Shape memory alloys are materials that have the unique ability to recover their shape
after undergoing large deformations through either heating (known as shape memory
effect) or removal of load (known as the superelastic effect). The unique property is made
possible by a martensitic phase transformation between a crystallographic high-symmetry
(cubic crystal structure) austenitic phases to a low-symmetry (monoclinic crystal
structure) martensitic phase. The assembly of martensitic variants can exist in two forms:
*twinned* martensite (*Mt*), which is formed by a combination of “self-accommodated”
martensitic variants, and *detwinned* or reoriented martensite in which a specific variant is
dominant (*Md*).

If a straight bar of some SMA in its austenitic (high temperature) phase is allowed to cool
below the phase transition temperature, the crystalline structure will change to martensite
(Figure 2-1). If the bar is subsequently plastically deformed, by say bending, and then
reheated above the phase transition temperature, it will return to its original straight
configuration.
Figure 2-1 (a) Shape memory alloy crystal transformation (b) SMA shape recovery mechanism [24] (b).

The mechanical behavior as a function of temperature, strain, and stress is shown in Figure 2-2. At a temperature above $A_f$, the SMA is in its parent phase, austenite. Upon loading, stress-induced martensite is formed. Below the martensite finish temperature $M_f$, the SMA exhibits the shape memory effect.

Figure 2-2 Three-dimensional stress–strain temperature diagram showing superelastic deformation and shape memory behavior of NiTi shape memory alloy [25].
Deformations due to an applied stress are recovered by heating the material above the austenite finish temperature, $A_f$. That specific temperature level of $A_f$ can be manipulated via changing the composition of the material or thermo-mechanical treatment to get a value around body temperature (Figure 2-2). In other words, apparent plastic deformation and subsequent full recovery is the shape memory effect (SME); also called one-way shape memory effect.

In two-way shape memory effect, a properly processed sample can exhibit one shape when cold, change to a second shape when heated, and return to its original shape when cooled again; all without mechanical intervention. Shape change occurs in two directions, during both heating and cooling, although no appreciable force in the SMA structure is developed during the transition from a high to a low-temperature shape.

Superelasticity (or pseudoelasticity) allows the formation of an elastic behavior but under a level of values more significant than those of the classic metals or alloys (the recoverable strain for a mono crystalline sample of SMA can reach 10% [26]). Superelasticity describes the nonlinear recoverable deformation behavior of SMA alloys at temperatures above the $A_f$ temperature, which arises from the stress-induced martensitic transformation on loading and the spontaneous reversion of the transformation upon unloading. Superelastic applications are isothermal in nature and involve the storage of potential energy.

### 2.1.1 SMA Stiffness Variation

This section will review the SMA thermomechanical response to describe how stiffness of the SMA changes. In pseudoeelastic material, transformation can be induced by applying a sufficiently high mechanical load to the material in the austenitic phase
The stress levels at which the martensite transformation initiates and completes are denoted by $\sigma_{M_s}$ and $\sigma_{M_f}$, respectively. Similarly, as the SMA is unloaded, the stress levels at which the material initiates and completes its reverse transformation to austenite are denoted by $\sigma_{A_s}$ and $\sigma_{A_f}$, respectively. If the material in the austenitic phase is tested above the $M_s$ temperature, but below the $A_f$ temperature, only partial shape recovery is observed.

Stiffness of the SMA depends on elastic modulus of each phase ($E_A, E_M$), and total martensitic volume fraction ($\zeta$) that leads to hysteresis curve. During loading, the initial response shows linear stiffness. At some stress level ($\sigma_{M_s}$) the stiffness changes and a behavior similar to plastic yielding is observed; i.e. a ‘plateau’ is formed. As stress increases to a second level ($\sigma_{M_f}$), the plateau ends and the response stiffens. A nearly linear response with stiffness usually different from the first linear elastic section is observed.

![Figure 2-3 Schematic of stress strain diagram for pseudoelastic material.](image)
During unloading the initial response is nearly linear. A plateau with the same strain length as the one observed during loading is formed at a lower stress level ($\sigma_{Af}$). At the end of the plateau ($\sigma_{Af}$), the response stiffens and becomes nearly linear, with slope equal to modulus of elasticity of the phase. The forward and reverse phase transformation during a complete pseudoelastic cycle results in a hysteretic stiffness profile.

### 2.1.2 Phenomenological Models

In order to successfully predict and utilize the stiffness behavior of SMA, the thermomechanical transformation is modeled in many different ways. A reversible solid state displacive crystalline phase transformation dominated by shear between a high symmetry parent phase (Austenite in the form of ordered body-centered cubic) and a low symmetry product phase (Martensite in the form of monoclinic distortion of a B19 lattice) underpins both SE and SM effects which occurs due to the application of both stress and temperature [27]. Fundamental and complex nature of the SE and SM owing to their connection with the crystallographic phase of the material and the thermomechanics of their transformation lead to various modeling approaches for SMAs [28]. Micromechanical models consider the elastic, thermal and chemical free energies of thermodynamics from a microscopic stand point and then average or homogenize the local relations to obtain the stress-strain and transformation behavior [29]. Mesoscopic or lattice models develop energy relations for a representative lattice and homogenize that control volume to reach to macroscopic constitutive behavior [30]. Models describing the macro-scale behavior of SMAs, also known as the phenomenological models, are developed based on the assumption that the state of each point of the material can be represented as a mixture of phases rather than segregated
distinct ones. The macromechanical models cover a range of theory from irreversible thermodynamics principles [31] to Preisach models [32]. The differences among these models come from the internal variables selected, type of the kinetic transformation equations, energy relations, and the level of thermodynamic consistency through using the energy conservation principle and the Clausius Duham inequality. The influential parameters and state variables in phenomenological models are of engineering nature and easy to measure; therefore, along with their simplicity, they offer good choices for implementation into numerical computations.

One of the first models in the group of phenomenological models was presented by Tanaka and Nagaki [33]. In this model, the second law of thermodynamics was written in terms of the Helmholtz free energy. It was assumed that unidirectional strain, temperature and martensite volume fraction are the only state variables and phase fraction of Martensite, was employed as the internal variable. The state variables were meant to be time/space averaged on a sub-macro scale level with a length scale at least an order of magnitude larger than the average grain diameter. Liang and Rogers formulated a model based on the rate form of the constitutive equation developed by Tanaka. The main disadvantage of this model is that they only describe phase transformation from austenite to martensite, without considering detwinning [34].

Tanaka [35] model was also extended by Brinson, which incorporated phase fractions of twinned and detwinned Martensite as internal variables to capture SE and SM effects based on the loading path of an experimentally defined stress-temperature phase diagram. Gao et al. [36] provided an extension to the previous work by Brinson where the authors described a nonlinear 1D finite element procedure for truss elements to analyze the
behavior of shape memory alloys. In the extended model, the kinetics law developed by Bekker and Brinson [37] was utilized and modified to cover the entire phase diagram. Boyd and Lagoudas developed a model where the total specific Gibbs free energy is determined by summing the free energy of each phase of the shape memory materials plus the free energy of mixing. A constitutive relation satisfying the second law of thermodynamics is used [38]. Leclercq and Lexcellent developed one of the basic works in modeling of the thermomechanical behavior of shape memory alloys. Based on the framework of thermodynamics of irreversible processes, a model is developed whose different parameters were derived from comparison with experimental results. The model showed good compatibility with experiments except for the case of non-proportional loading [39]. Elahinia and Ahmadia developed a unified approach for determining phase transformation starting points [40-43]. Gillet et al. modeled SMA behavior considering the nonsymmetrical behavior of these alloys in tension and compression. This model was included in the framework of the beam theory. The material properties of the model were derived from tension and compression tests conducted [44].

Many groups have compared all these phenomenological models to find out which one gives best results. Schroeder et al. compared the Landau–Devonshire theory formulation with the Graesser and Cozzarelli, Brinson and Boyd and Lagoudas models in terms of their capabilities and computational effort. Another study comparing the phenomenological model of Grasser and Cozzarelli model with the Brinson model showed that while the phenomenological approach was more suitable for repeated mechanical cycling under isothermal conditions, it could not handle more complex situations involving thermal cycling. A comparison between the thermodynamic model of
Boyd and Lagoudas and Tanaka-based models lead to the unification of these approaches under the same broad assumptions, and highlighted some differences in the simulations based on these different approaches [45]. A comparison of these models leads to the observation that most of the constitutive models yielded similar results for most simple simulations.

2.1.3 Effect of Temperature on SMA Stiffness Variation

Stress strain characteristics of SMA can change due to temperature variation and loading region. Thermomechanical behaviors were investigated under monotonic or cyclic loading by Sung Ho Yoon et al. [46]. Shape memory alloy wire was loaded to 6% strain and held for 5 seconds at the reverse point of loading cycles and then unloaded. Environmental temperatures were 17, 25, 32, 33, and 36°C based on the martensitic start temperature of 22.8°C and the austenitic start temperature of 17.9°C (Figure 2-4 (a)). Transformation stress upon loading and reverse transformation stress upon unloading were increased as environmental temperature was increased. This phenomenon agrees well with that transformation stress and reverse transformation stress would be increased as increase in environmental temperature higher than martensitic start temperature.

Qiang pan et al. performed testing to investigate the effect of temperature on the behavior of SMA wires [47]. They concluded that the increase of temperature causes the rise of transformation stress from austenite to martensite phase. Observed from figure 2-4 (b), the area surrounded by hysteresis loop is not significantly changed with temperature, meaningfully denoting the dissipated energy may be considered as temperature independent during this temperature range. This phenomenon is considered to ascribe to the small size of the wire. Due to the thin diameter of wire, the heat generated by the
applied loads may be dissipated very quickly; therefore the influence of temperature on energy dissipation is negligible. They found however that the stiffness is changed with different temperatures and strain rates.

![Stress vs. strain curves](image)

Figure 2-4 Stress vs. strain curves for various temperatures under cyclic loading by (a) Sung Ho Yoon et al. [46] (b) Qiang pan et al. [47].

Similar experimental investigation on Ni–Ti SMA elements was carried out by Mauro Dolce et al., in order to find the best way to exploit the particular properties of SMAs in seismic devices [21]. Stress strain characteristics were recorded during loading–unloading tests at about 7% strain amplitude. A total of six tests were carried out on the same sample and were preceded by ten “training” cycles at 7%, aimed at stabilizing the material behavior. By examination of the experimental results (Figure 2-4) they found that the real effect of an increase in temperature is an upward translation of the hysteresis loops. All these results show that there is a change in hysteretic curve of the SMA wire with temperature variation, which can be utilized to achieve ankle stiffness variation.
2.2 Biomechanics of Human Walking

Understanding the biomechanics of human walking is crucial in the design of active orthoses for the lower limbs. Therefore, this section gives a brief background of the most relevant concepts.

2.2.1 Gait Cycle and its Phases

Walking is a cyclic pattern of body movements which is repeated over and over, step after step to advance an individual’s position. The gait cycle is defined as the time interval between two successive occurrences of one of the repetitive events of locomotion [48]. In general, human walking consists of several sequential steps. Each of these steps is broadly composed of two phases: the stance phase and the swing phase. The stance phase is one of two major phases of the gait cycle and begins when the reference foot contacts the ground (IC) and ends when the reference foot lifts off the ground (TO). It typically consists of 60% to 65% of the normal adult gait cycle. The swing phase is the second of the two major phases of the gait cycle and represents the period when the limb is in the air and moving forward. It begins when the reference foot comes off the ground and ends when the reference foot contacts the ground. The swing phase for one limb typically constitutes 35% to 40% of the normal adult gait cycle [49]. Single limb support (single stance) is the period during which one limb is the only point of contact with the ground, while double limb support (double stance) is the overlapping period of time when the stance phase of one limb occurs concurrently with the stance phase of the opposite limb, so that both limbs are in contact with the ground.
The phases of gait are further divided as shown in figure 2-5:

1. **Initial contact**: This phase represents the instant when the foot first contacts the ground and is the beginning of the stance phase. Contact normally occurs on the lateral aspect of the plantar surface of the heel. This marks the beginning of the first period of double limb support.

![Gait cycle phases](image)

Figure 2-5 Gait cycle phases [50].

2. **Loading response**: In this phase, weight is rapidly transferred onto the outstretched leg, which reacts to absorb the impact of body weight by flattening the foot. This period lasts until the opposite foot has left the ground, ending the first period of double limb support.

3. **Midstance**: During this phase, the body weight progresses directly over a single, stable limb and concludes when the center of gravity is directly over the foot. Normally, the body weight would be evenly distributed across the foot on the supporting surface.
4. **Terminal stance:** In this phase, there is a continuation of body progression over the stance limb. The body moves ahead of the supporting limb and weight is transferred onto the forefoot (metatarsal heads). This phase ends just prior to the contra lateral (opposite) limb making IC with the ground.

5. **Preswing:** This is the final period of the stance phase in which a rapid unloading of the limb occurs in preparation for the swing phase as weight is transferred to the contra lateral limb. This is the second period of double limb support in the normal gait cycle.

6. **Initial swing:** During this phase, the thigh begins to advance as the foot comes up off the floor.

7. **Midswing:** In this phase, the thigh continues to advance as the knee begins to extend; the foot clears the ground.

8. **Terminal swing:** During this last phase of gait, the knee extends, preparing the limb to contact the ground for the next foot contact [51].

### 2.2.2 Gait Parameters

Commonly used gait parameters are defined below (Figure 2-6):

*Step length* is the distance between the point of initial contact of one foot and the point of initial contact of the opposite foot.

*Stride length* is the distance between successive points of initial contact of the same foot.

*Cadence* or walking rate is calculated in steps per minute.

*Velocity* is the product of cadence and step length, expressed in units of distance per time.
2.1 Gait Analysis Technique

Gait analysis is the systematic study of human locomotion, augmented by instrumentation for measuring body movements, body mechanics, and the activity of the muscles.

Figure 2-6 Gait cycle parameters [52].

Gait analysis is used to assess, plan and treat individuals with conditions affecting their ability to walk [53]. To detect and correct gait abnormalities, one must first know what comprises the normal gait pattern. Gait analysis commonly involves the measurement of:

- Temporal /Spatial - velocity, cadence, step length, etc.
- Kinematics - the movement of the body in space without any reference to forces.
- Kinetics - the forces involved in producing these movements.
- Electromyography - the study of muscular activity patterns during walking.

2.1.1 Kinematics

To understand the kinematics of human walking, it is necessary to track human movement during walking. There are different types of human movement tracking systems including non-vision based tracking systems and vision based tracking systems with and without markers [54].
Non-vision based tracking systems:

In non-vision based tracking systems, sensors are attached to the human body to collect movement information. These sensors are commonly classified as mechanical, acoustic and magnetic sensing. The most commonly used sensors are goniometers and accelerometers. Each one of these sensors has certain advantages and limitations. The main advantage of these devices is they are small and compact. The limitations include modality specific, measurement-specific and circumstance specific limitations that accordingly affect the use of the sensor in different environments [40].

Vision based tracking systems:

This is a technique that uses optical sensors e.g. cameras, to track human movements, which are captured by placing visible markers on the body to designate individual body segments. As the human skeleton is a highly articulated structure, twists and rotations make the movement of the body fully three dimensional. Through the use of multiple camera systems the three-dimensional trajectories of the markers can be tracked, allowing for assessment of the movement of any segment in any plane. This has made marker-based vision systems attractive to researchers in medical science, sports science and engineering [41]. In contemporary marker based tracking systems, a digital camera is used to collect the raw data in a sampling process. Based on sampling theory in processing of any time varying data, the processed signal must be sampled at a frequency at least twice as high as the highest frequency present in the signal itself. It has been shown that kinetic and energy analysis can be done with negligible error using a standard 24-frame per second movie camera [42]. However, to add more detail and accuracy, it is better to use higher speed recording cameras.
2.1.2 Kinetics

Kinetics in human gait represents the forces and torques that cause the motion of the body. The reaction force supplied by the ground is specifically called the ground reaction force (GRF), which is basically the reaction to the force the body exerts on the ground. The ground reaction force is an important external force which constantly affects the human motion. Typical GRF curve for walking is shown in figure 2-7 [38].

![Figure 2-7 The change in vertical ground reaction force for one gait cycle [38].](image)

**Force plates:**

Force plates are the instruments that measure the ground reaction forces generated by a body standing on or moving across them, to quantify balance, gait and other parameters of biomechanics (Figure 2-8). Center of pressure
Thus, force plates are used for gait analysis in hospitals, laboratories, clinics, universities, and research facilities around the world.

Typical force plate contains four force transducers, each at one corner, which produce electric signals proportional to the applied load. They are converted to analog DC voltages which are then recorded and processed.

The force plate is used for measuring the following variables:

- 3 components Fx, Fy, and Fz of a force F acting on the platform
- 3 components Mx, My, and Mz of the resulting moment vector M related to the origin of the coordinate system

Units of parameters measured by force plates in the metric system are: ground reaction forces (N), moments (N-mm) and the center of pressure (mm). Normalization of data is typically done by dividing by body weight so that data from different subjects can be compared effectively.
2.1.3 Electromyography

The Electromyogram (EMG) is a measure of the electrical activity of the muscles. EMG is measured using similar techniques to that used for measuring EKG, EEG or other electrophysiological signals. When EMG is acquired from electrodes mounted directly on the skin, the signal is a composite of all the muscle fiber action potentials occurring in the muscle(s) underlying the skin. These action potentials occur at somewhat random intervals so at any one moment, the EMG signal may be either positive or negative voltage. Individual muscle fiber action potentials are sometimes acquired using wire or needle electrodes placed directly in the muscle [44]. EMG provides a representation of the levels of muscle activation during walking, as well as time instance when in the walking cycle which muscle is activated.

Information from all of these systems including video, force plates and EMG, is essential if the goal is to design orthotic devices which can truly mimic human motions very closely.

2.1.4 Gait Phase Detection

In analyzing human walking it is essential to be able to accurately identify the individual phases on the gait cycle. This is particular essential in developing active orthoses that must provide controlled movement at specific times during a gait cycle. The following is a description of sensor technologies that have been used to detect the phases of the gait cycle:

1. **Force based measurement sensors**: Foot switches are force based sensors that convert the mechanical force of the foot contacting the ground into an electrical output signal. While foot switches are the widely used in gait analysis, they actually
have poor detection reliability. One problem of this design is the necessity to wear shoes in order to keep the switch in position, as well as the associated problems of the switch moving out of position. This system is also limited to heel off and heel strike detection on flat surface, which limits their usefulness for broader locomotor applications. [49]. **Force Sensing Resistors** (FSRs) are sensors that change their resistive value, depending on how much they are compressed. They are often used in place of traditional foot switches. Pressure Measuring **Insoles** are paper-thin sensors that measure the contact pressure between virtually any two mating surfaces. When used as insoles, they are inserted in the shoe between the plantar surface of the foot and the inside of the shoe. Catalfamo, Paola et al., and others, have used this method for gait phase detection [50]. **Torque sensors**: Reaction (non-rotation) and rotary torque sensors utilizing, bonded strain gauge technology has been used for gait phase detection. A torque sensor is a transducer that converts a torsional mechanical input into an electrical output signal.

2. **Incline/ tilt sensors**: Tilt sensors allow you to detect orientation or inclination. They are usually made by a cavity of some sort (cylindrical is popular, although not always) and a conductive free mass inside, such as a blob of mercury or rolling ball. One end of the cavity has two conductive elements (poles). When the sensor is oriented so that that end is downwards, the mass rolls onto the poles and shorts them, acting as a switch throw. Depending upon the inclination of the body segment on which they are attached, angle change can be measured during gait analysis.

3. **Angular rate measurement sensors**: These sensors are chiefly classified into a mechanical type (utilizing the precession of a rotary body), an optical type (utilizes
change in the timing of light reception due to the rotation of laser light that is rotated in an enclosure), a fluid type (sensing a hot wire temperature, representing an injection amount of a sensing gas) [49]. **Accelerometer** measures locomotion based on remote sensing. Accelerometers can be used in gait analysis to measure the acceleration of a body segment, which may reflect the start or end of a phase of the gait cycle. Mansfield Avril et al. used accelerometry to detect heel contact events for use as a sensor in FES assisted walking [51]. A **gyroscope** is a device for measuring or maintaining orientation, based on the principles of conservation of angular momentum. Gyroscopes have been used to measure the position and movement of body segments during locomotion. A mechanical gyroscope is essentially a spinning wheel or disk whose axle is free to take any orientation. This orientation changes much less in response to a given external torque than it would without the large angular momentum associated with the gyroscope's high rate of spin. Since external torque is minimized by mounting the device in gimbals, its orientation remains nearly fixed, regardless of any motion of the platform on which it is mounted. Ion P. I. Pappas, Thierry Keller et al. developed a reliable and compact gyroscope based gait phase detection sensor embedded in a shoe sole [52].

4. **Laser range sensor**: The laser range sensors are based on optical principles which allow medium range walking displacements comprising several strides. External markers attached to the human body are needed. The main advantage of a laser range sensor to register gait is that, only one laser sensor placed with the scan plane parallel to the ground is needed to register the displacement of the legs. The system can be used in indoor and outdoor measurements, depending on the laser sensor. The system
can be used on any ground surface without any visual references. The system does not require initial calibration or reference scales. The main disadvantage of the basic measurement system is that only planar information of the position of the legs at a fixed height will be obtained, although multiple laser range sensors at different heights could be used to obtain additional body motion parameters. Tomàs Pallejà et al. developed and tested this technique on six subjects walking on the ground and found promising results [53].

5. **Natural Sensors:** These sensors use recordings from a cuff electrode, on the sural nerve. The sural nerve is purely sensory, whose inputs are touch sensors on the lateral part of the foot which is monitored to find out whether or not the affected foot was supporting weight. This information then can be used to control the application of electrical stimulus to the muscles as is necessary in FES techniques. Hansen Morten et al. performed real time foot drop correction using machine learning and natural sensors to control the application of stimulus to the common peroneal nerve [54].

Rather than relying on a single sensor, combinations of these sensors can be used to enhance the accuracy of gait phase detection. Such a system was designed by M. R. Popovic et al. to detect, in real-time, the following gait phases: stance, heel-off, swing, and heel-strike. The gait phase detection system employed a gyroscope to measure the angular velocity of the foot and three force sensitive resistors to assess the forces exerted by the foot on the shoe sole during walking (Figure 2-9a). Gait events were divided into seven different parts considering all possible situations during walking [55]. Detection algorithms were based on the logic shown in figure 2-9(b). Results have shown a great accuracy while detecting all the phases of the gait during walking.
2.2 Ankle Behavior

Drop foot, the condition for which an active AFO would appear to be ideal, involves an alteration in normal sagittal plane ankle kinematics. Drop foot is commonly described as an inability to dorsiflex the foot during swing as a result of weakness of the dorsiflexor muscle of the lower leg. The tibialis anterior is the main dorsiflexor muscle of the foot, and is innervated by the peroneal nerve. The peroneal nerve is a branch of the sciatic nerve that wraps around the fibular head near knee (Figure 2-10). Dorsiflexion and Plantarflexion are defined as the rotation of the ankle in the sagittal plane upward towards or downward away from the body, respectively. Under normal conditions, initial contact of foot 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 a controlled, eccentric contraction [45].

This extends the heel support period, draws the tibia forward, and rolls 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 forward 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 [46].

(Figure 2-11)

The gastrocnemius and soleus muscles slow the rate of tibial advancement until the end of mid stance to restrain the forward movement of the tibia on the foot [57]. Soleus activity is the dominant decelerating force because of its larger size and its direct attachment between the tibia and calcaneus. By the end of mid stance, 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 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 peak vertical ground reaction force created during normal walking is slightly 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 [46]. Following the onset of double limb support, the body weight is transferred to the other limb in preparation for preswing. 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 intensity in initial swing to dorsiflex the foot to neutral by the time the swing foot is opposite the stance limb (Figure 2-12).

Figure 2-12 Plot of ankle angle, moment, and power for level-ground walking are plotted versus percent gait cycle for a normal healthy individual walking at a self-selected speed [75].
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 [45]. Collectively, ankle stiffness is a reflection of the phasic activation of the muscles surrounding the ankle.

**Ankle Stiffness:**

Drop foot is a result of an inability of the individual to produce the requisite amplitudes and timing of ankle stiffness. There is evidence indicating that an optimal match should exist between a patient’s unique gait related problems and the ankle stiffness of their AFO. [97] Controlling ankle joint stiffness is necessary for creating a functional gait cycle with any orthotic devices. Dynamic joint stiffness can be defined as the resistance that a joint (i.e. the muscles and other soft tissue structures that cross the joint) offers during gait in response to an applied angular displacement. It should be noted however, as Latash and Zatsiorsky argue that joint stiffness does not necessarily imply that the tissue around the joint behaves as a physical spring, storing and releasing energy. Latash and Zatsiorsky therefore defined this behavior of the joint as ‘quasi-stiffness’ [58]. The stiffness of a single joint depends on several variables, including muscle activation level, joint angle, range of motion and angular velocity. A relatively simple method for estimating joint quasi-stiffness is to examine the relation between the net moment at the ankle joint versus the angular displacement of the ankle [59] (Figure 2-13).
In 2004 Hansel et al. ran a series of experiments to evaluate ankle stiffness characteristics. The results show that with normal self-selected walking speed, the quasi stiffness of the ankle changes in hysterical manner as shown in figure 2-14 (a) [60].

Figure 2-13 Ankle stiffness defined as the ratio of moment over angular displacement.

This ankle stiffness behavior is similar to hysteretic behavior of the shape memory alloys being examined in this study, as shown in figure 2-14(b). As explained in section 2.1.1 stiffness of the SMA element depends on the young’s modulus of each phase and total martensitic fraction which changes with stress and temperature.

Figure 2-14 (a) Ankle stiffness plot for a subject walking with normal speed of 1.5 m/s [73] (b) Typical SMA pseudoelastic stress-strain behavior [74].
By manipulating these factors a stiffness variation for the SMA, similar to that of ankle stiffness variation, can be achieved. Hence we used this concept to evaluate variation in stiffness characteristics, which is discussed in the next chapter.

2.3 Fabrication of Custom Fit AFOs

Early AFOs were made from a combination of leather and steel, but nowadays most AFOs are made from thermoplastics, such as polypropylene. 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. Detailed procedure of fabrication of these AFO’s is described below.

To start off, patient assessment is performed in accordance with prosthetic and orthotic (P&O) standards.

AFO casting:

At first stockinet’s and plaster of paris bandages are applied on the lower leg with the ankle in a neutral position, in order to make a cast. The cast is then removed with a saw as shown in the figure 2-15 to form a negative cast of the leg.

Figure 2-15 Making negative cast of lower leg for AFO fabrication.
The cast is then taped or stapled shut to prepare for the next step. Pouring plaster into the negative cast makes a replica of the leg for forming the positive mold of the leg. After the plaster hardens, the outer shell is removed with a cutting knife. A solid plaster replica of the human leg is now formed (Figure 2-16). Any imperfections can be modified by filing off with a metal rasp and smoothing the plaster so it is clean and void of any imperfections.

**Preparation of the polypropylene shell:**

The positive mold is then fixed on the rod which is connected to a suction mechanism. Nylon stocking is applied over it.

![Negative casting and positive mold/plaster model](image)

Figure 2-16 Negative casting and positive mold/plaster model [75].

The polypropylene sheet is heated in oven at 180° for 20 to 25 minutes. This heated sheet is then draped around the plaster positive mold by sticking it together at the anterior side. Polypropylene (PP) is then vacuum molded by starting the suction pump. While it is still hot the excess PP is removed with a pair of scissors as shown in Figure 2-17.
Trim lines are drawn to cut the orthosis with an oscillating saw. The plastic shell is removed from the plaster model. Then the stocking is removed from inside of the AFO. Using a grinder, the AFO is shaped so that it is the proper shoe size for the individual for whom it was molded and the edges are polished so that they are clean and smooth. Velcro strap are added to the brace so it can be secured to the leg. This procedure has been well established as the standard method followed to fabricate AFOs, and typically, an expert technician can do this job within a day.

### 2.4 Test Apparatus to Evaluate Stiffness Characteristics of AFO

In recent times AFOs are no longer considered a simple foot support but also are considered complex dynamic elements that influence the biomechanics of walking of the patient [77]. Plastic AFOs correct abnormal ankle motion by virtue of their stiffness, which defines their orthotic characteristics. In research, the mechanical characteristics of an AFO can be used in combination with the results of instrumented gait analysis in order to study the mechanical contribution of various types of AFOs to pathological gait, as proposed by Stanhope et al. [78]. The mechanical properties of AFOs have been
recognized as relevant parameters to succeed in rehabilitation treatment and were examined both numerically and experimentally.

To date, several testing devices and procedures have been developed to assess the stiffness characteristics of AFOs. Although there is no definite method established, there is a general consensus that sagittal plane stiffness is of particular clinical importance [79]. Stiffness is characterized as the ratio of externally applied moment versus the angular deflection of the brace [80]. Most of the test devices have been manually driven, and typically do not exactly replicate human leg motions. Using such devices, the flexibility of various AFO’s was initially examined to determine the number of flexion cycles likely to cause failure due to the effect of fatigue. Other studies were devoted to the experimental validation of the state of stress obtained numerically, and the results generally confirmed both the findings from FEA and the observed failures in clinical practice [81]. Most of the literature generally focused on the experimental evaluation of the stiffness of AFOs carried out by means of simple mechanical devices [77-92].

One of the earliest apparatuses designed to quantify AFO stiffness was built by Rubin and Dixon (1973) to measure the stiffness using a tensiometer [82] (Figure 2-18 (a)). Their tensiometer measured the applied load and quantified AFO rigidity by directly applying force to a specific area of the AFO [70]. The footplate of the AFO was bolted to a table, and the tensiometer was attached at the proximal edge of the AFO to assess the load-versus-deflection or the load-versus angular properties at the ankle joint by applying a force parallel to the AFO footplate.

DeToro (2001) et al. developed a leg model by taking negative impression from human subject to test eighteen different AFOs [79] (Figure 2-18 (b)). The shank of the
articulated leg model was mounted rigidly to the back of the test stand so that the foot segment could move freely.

Figure 2-18 Bench testing of the AFO stiffness by using tensiometer by (a) Ruboin et al. [82] (b) DeToro et al [79].

A digital force gauge was connected from the steel band to a screw drive, which was used to apply a distraction force that would cause the model to plantarflex. A liquid-filled angle measurement device was attached solidly to the plantar surface of the foot segment for angle measurement. In these studies the force/torque and angle information was converted into a chart to allow easy comparison of different AFO designs. Most of the test apparatuses used in the above studies fixed the footplate of the AFO to a solid base plate and then loaded, rotated, and/or pulled on the shank of the AFO. The loading was applied either directly to the AFO or through an interface with a dummy leg. Studies involving experimental bench testing suggested that the stiffness can be influenced by the way in which the footplate of the brace was constrained.
Further improvements were made when Yamamota et al. (Figure 2-19) introduced an apparatus that involved the use of a human subject; the subject wore an AFO during the assessment procedure [87]. Also, because medial and lateral forces were applied to the AFO, inversion and eversion characteristics could be measured. Their analysis allowed for isolation of physiological ankle stiffness and AFO stiffness by finding difference between the two trials. However the design may not be the most practical solution for clinical and research purposes.

![Figure 2-19](image)

**Figure 2-19** (a) AFO testing setup involving human subject (b) Stiffness characteristics of posterior leaf type polypropylene AFO [87].

Other researchers have developed original testing devices that emulated the actions of an anatomical limb with metal blocks to represent the ankle joint. Bregman et al. designed a test setup to measure neutral angle at the ankle joint, by applying angular motion manually from the top [83] (Figure 2-20 (a)). Force sensors at the bottom of the foot plate provided a means to measure the moment. Figure 2-20 (b) shows the ankle stiffness results obtained by using this setup. A similar setup was developed at Clemson
University using 80-20 blocks, where the foot base plate could be moved manually to apply a moment at the ankle joint (Figure 2-20 (c)) [93]. Although these methods show high precision, repeatability and clinical applicability, with manual cycling they do not fully replicate the loading conditions that typically occur during gait.

![AFO testing setups using metal parts and manual loading technique: (a) BRUCE [83] (b) AFO stiffness characteristics measured with BRUCE setup [83] (c) setup by Clemson University [93].](image)

Singerman et al. developed a setup using a dummy leg and metallic rotary assembly [89]. The lever arm used to apply and measure the moments is attached to the plantar surface of the foot section of the orthosis by means of a rigid bracket (Figure 2-22 (a)).

They compared four types of AFOs; results of the tests are shown in the table 2.1. Stiffness characteristics for two typical designs are shown in Figure 2-21.
Figure 2-21 Angle-moment characteristics of two different AFO designs by Singerman et al. [89].

Table 2.1 Stiffness (Nm/degree) values published by Singerman et al. [89].

<table>
<thead>
<tr>
<th>AFO type</th>
<th>Plantar flexion</th>
<th>neutral</th>
<th>dorsiflexion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid ankle design</td>
<td>7.2</td>
<td>5.9</td>
<td>3.6</td>
</tr>
<tr>
<td>Locked hinge design</td>
<td>9</td>
<td>2.8</td>
<td>7</td>
</tr>
<tr>
<td>Posterior spring</td>
<td>1.3</td>
<td>1.6</td>
<td>1.2</td>
</tr>
<tr>
<td>Flexible hinge</td>
<td>.9</td>
<td>.9</td>
<td>2</td>
</tr>
</tbody>
</table>

P. Cappa et al. (2005) developed a setup for evaluation of a fully automatic apparatus to test AFOs in three dimensions [77]. Figure 2-22 (b) shows the test setup along which uses rotary encoders and 6-DOF load cell for measuring parameters.

As with the earlier devices, the footplate was fixed to a secure surface, but the shank that was placed into the AFO to simulate the lower limb was securely mounted and could be moved along all three axes. In this setup automatic displacement change was implemented, they just focused on stance phase characteristics.
Even though these methods give quantitative measure of the AFO stiffness, the loading profiles do not follow actual walking patterns, and hence, the AFO does not deform in a similar fashion while a person wears the brace during walking. In order to address this issue Polliack et al. developed a wooden leg and applied loading that matches walking conditions manually using pulley mechanism [86]. A force plate was placed below the foot to get close to the method used for clinical gait evaluation (Figure 2-23 (a)). The test protocol required adding weights incrementally, which is cumbersome and time-consuming and poses a small safety risk during the setup procedures. To avoid these manual procedures, a group from Taiwan developed a walking robot by using metallic parts which mimics gait cycle accurately and is fully automated [92] (Figure 2-23 (b)).
The force plate provided the vertical ground reaction forces of the robot to verify its kinetics, as compared to the target gait data. This setup not only had capacity of simulating a patient’s gait, but also their abnormal muscle tone. However, complex mechanism and their control system limited the clinical applicability of this device.

In summary, although there have been numerous attempts at developing an accurate and reliable AFO experimental testing apparatus, that simulates walking gait there seems to be no definitive method for valid estimates of AFO stiffness. In fact the exact constraints that an anatomical lower limb place on an AFO may not be entirely reproducible [80]. Understanding the strengths and weaknesses of each method is crucial to establish an analysis method practical for clinical use in the development of a patient-centered AFO prescription system and for AFO quality assurance in the industry [70].
Chapter 3

SMA Stiffness Behaviour

This chapter is about assessing and evaluating stiffness variation with shape memory alloys. To this end three methods have been used. The first section is about finite element modeling of the thermomechanical behavior of shape memory and superelastic wires. The result of modeling establishes possibility of achieving different stiffness patterns with these materials. The second section is about experimental evaluation of the behavior of these alloys. To this end a mechanical testing machine along with an environmental chamber for controlling the temperature has been used. The third section is about a rotary actuator in which stiffness has been experimentally controlled.

3.1 Simulation of Stiffness Behavior of Wire Combinations

This section is focused on how stiffness of the SMA wires can be changed by making different combinations. In order to characterize the behavior of the shape memory alloys, a modified constitutive model based on Laing and Rogers was developed by Tabesh using COMSOL Multiphysics [94, 95]. In Tanaka model, the second law of thermodynamics is written in terms of the Helmholtz free energy. It is assumed that unidirectional strain, temperature, and martensite volume fraction are the only state
variables, and the stress is calculated as a function of these variables. It may be noted that
the martensitic volume fraction is a function of the stress and temperature, making a
recursive numerical solution necessary in order to determine both stress and volume
fraction simultaneously. The transformation kinetics is described by trigonometric
expression to describe the martensite volume fraction as a function of stress and
temperature. The model considers strain and temperature as field variable and volume
fraction of martensite induced by stress or temperature in the material as internal
variables. The martensite transformation can be triggered with either change of
temperature or application of stress.

The one-dimensional constitutive equation relating the second Piola-Kirchoff stress $\sigma$ to
the thermomechanical variables Green-Lagrange strain $\epsilon$, volume fraction of stress
induced martensite $\zeta_s$, and temperature $T$ is:

$$\sigma - \sigma_0 = D (\epsilon - \epsilon_0) + \Omega (\zeta_s - \zeta_{s0}) + \theta (T - T_0)$$  \hspace{1cm} (2)

where $\Omega$ is the transformation coefficient and $(\sigma_0, T_0, \zeta_{s0}, \epsilon_0)$ represent the initial state of
the material. $D$ is the modulus of the SMA and $\theta$ is the thermal coefficient. It is assumed
that the overall modulus of the SMA structure, according to the rule of mixture, depends
on the total volume fraction of martensite, $\zeta$ as below:

$$D = D_A + \zeta (D_M - D_A)$$  \hspace{1cm} (3)

where $D_A$ and $D_M$ respectively is the modulus value of the fully austenitic and fully
martensitic SMA material $\Omega$, the transformation coefficient from Equation 1, is obtained
from the following equation:

$$\Omega = -\epsilon_l D.$$  \hspace{1cm} (4)

The maximum residual strain $\epsilon_l$ is considered to be constant.
Martensite fraction is divided into stress induced ($\zeta_s$) and temperature induced variants ($\zeta_T$). Furthermore, the stress induced martensite is then separated into positive $\zeta_{sp}$ and negative $\zeta_{sn}$ corresponding to their respective directions of the stress:

$$\zeta = \zeta_s + \zeta_T$$

$$\zeta_s = \zeta_{sp} + \zeta_{sn}.$$  \hspace{1cm} (5)

The transformation kinetics relationships for the aforementioned thermo-mechanical paths in the rate and matrix form are shown to be:

$$\dot{\zeta} = \left[ \dot{\zeta}_{sp} \dot{\zeta}_{sn} \dot{\zeta}_d \right]^T = A \cdot C^d$$ \hspace{1cm} (6)

where $C^d$ is the vector of transformation conditions and matrix $A$ contains the derivatives of martensite phases with respect to time.

Since wire is a 1-D element there is only one component of the transformation strain $E_{zz}^{tr}$, which is shown in the following:

$$E_{zz}^{tr} = \varepsilon_L p \zeta_{sp} + \varepsilon_L n \zeta_{sn}.$$ \hspace{1cm} (7)

where $\varepsilon_L p$ and $\varepsilon_L n$ are the maximum transformation strains in tension and compression respectively. Since the stress along the length of wire is constant the following is true:

$$\frac{\partial \sigma}{\partial x} = 0.$$

And the input into the PDE Module of COMSOL therefore is formulated by Tabesh as \cite{95}:

$$\begin{cases} d_{li} \frac{\partial \chi_i}{\partial t} + \frac{\partial F_{i}}{\partial x_j} = F_{i} \text{ in } V \\ -n_{ij} \Gamma_{ij} = G_{i} + \frac{\partial R_{m}}{\partial u_l} \mu_{m} \text{ on } S \\ 0 = R_{m} \text{ on } S \end{cases}$$ \hspace{1cm} (8)

The first equation is the PDE Module which is solved over $V$ (Domain). The second and third equations are Neumann and Dirichlet boundary conditions defined on $S$ domain.
boundary where $\Gamma$, $F$, $G$, and $R$ are coefficient vectors and $\chi$ is the solution. $\mu$ is a dependant variable, called the Lagrange multiplier, and represents the reaction forces in the structural mechanics problems. Finally, $n$ is the outward unit vector normal to $S$.

These variables are defined as follows:

$\chi = \begin{bmatrix} u & \xi_{sp} & \xi_{sn} & \xi_{sd} \end{bmatrix}$

$\Gamma = [\sigma \ 0 \ 0 \ 0]$

$F = \begin{bmatrix} 0 \ A_1^d \ C_j^d \ A_2^d \ C_j^d \ A_3^d \ C_j^d \end{bmatrix}$

$R = [u \ 0 \ 0 \ 0]^T$

$G = [\text{forceinc} \ 0 \ 0 \ 0]^T$

The problem is then solved via COMSOL using the following matrix inputs:

$\begin{bmatrix} 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \ 0 & 1 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \ 0 & 0 & 1 & 0 & 0 & 0 & 0 & 0 & 0 \ 0 & 0 & 0 & 1 & 0 & 0 & 0 & 0 & 0 \ \end{bmatrix} \begin{bmatrix} \dot{u} \\ \dot{\xi}_{sp} \\ \dot{\xi}_{sn} \\ \dot{\xi}_{T} \end{bmatrix} + \frac{\partial}{\partial x} \begin{bmatrix} \sigma \\ 0 \\ 0 \\ 0 \end{bmatrix} = \begin{bmatrix} 0 \\ A_1^d \ C_j^d \\ A_2^d \ C_j^d \\ A_3^d \ C_j^d \end{bmatrix}$

(10)

Within the PDE module, $R$ and $G$ are the boundary conditions for the fixed and the loaded ends of the sample respectively. They are defined as follows:

$R = \begin{bmatrix} u \\ 0 \\ 0 \\ 0 \end{bmatrix} = \emptyset$

$-n_x \begin{bmatrix} \sigma \\ 0 \\ 0 \\ 0 \end{bmatrix} = \begin{bmatrix} \text{forceinc} \\ 0 \\ 0 \\ 0 \end{bmatrix}$

where $\text{forceinc}$ represents the applied force function of pseudo-time that defines the applied external force (for more details of the model refer [95]). Figure 3-1 shows the
force and temperature profile applied to shape memory wire model for simulating the thermomechanical behavior.

Figure 3-1: Force and temperature profiles for SM wire model.

These profiles are chosen such that the SMA element(s) undergo consecutive mechanical and thermal loadings, which are essential to characterize the thermomechanical behavior of the material.

Table 3.1 summarizes the 10 cases that are investigated using the simulation framework described in this section. These cases represent the combinations that are simulated with three equal-length, equal-diameter SMA wires. These simulations are chosen to assess and establish the envelope for stiffness variation. The envelop can further be modified by combining elements with different geometrical parameters, by proper thermal activation of the elements, and by switching the thermomechanical loading profiles before completion of each cycle.
Table 3.1 SM and SE wire cases simulated using COMSOL model.

<table>
<thead>
<tr>
<th>Case no.</th>
<th>Graphical representation</th>
<th>Wire combination details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td><img src="image" alt="SE" /></td>
<td>Superelastic (SE) wire</td>
</tr>
<tr>
<td>Case 2</td>
<td><img src="image" alt="SM" /></td>
<td>Shape memory (SM) wire</td>
</tr>
<tr>
<td>Case 3</td>
<td><img src="image" alt="SE SM" /></td>
<td>Series SM and SE</td>
</tr>
<tr>
<td>Case 4</td>
<td><img src="image" alt="SE SM" /></td>
<td>Parallel SM and SE</td>
</tr>
<tr>
<td>Case 5</td>
<td><img src="image" alt="SE1 SE2 SM" /></td>
<td>Number 4 (SE1 in parallel with SM) in series with SE2</td>
</tr>
<tr>
<td>Case 6</td>
<td><img src="image" alt="SE SM1 SM2" /></td>
<td>Number 4 (SE in parallel with SM1) in series with SM2</td>
</tr>
<tr>
<td>Case 7</td>
<td><img src="image" alt="SM1 SE SM2" /></td>
<td>Number 4 (SE in parallel with SM1) in parallel with SE2</td>
</tr>
<tr>
<td>Case 8</td>
<td><img src="image" alt="SE1 SM SE2" /></td>
<td>Number 4 (SE in parallel with SM1) in parallel with SM2</td>
</tr>
<tr>
<td>Case 9</td>
<td><img src="image" alt="SM1 SE SM2" /></td>
<td>Number 4 (SE1 in parallel with SM) in parallel with SE2</td>
</tr>
<tr>
<td>Case 10</td>
<td><img src="image" alt="SE1 SM SE2" /></td>
<td>Number 4 (SE in parallel with SM1) in parallel with SM2</td>
</tr>
</tbody>
</table>
3.2 Tensile Testing to Obtain Wire Properties

The COMSOL model employs several experimental parameters in order to accommodate variations in the material properties of each particular alloy. In the current work, these parameters are obtained from standard tensile testing of the SMA wires, defined by the American Society for Testing and Materials (ASTM F2005/F2516) [96, 97]. The parameters are then applied to the constitutive model in order to predict the stiffness characteristics for the combinations. A BOSE ElectroForce 3330 tensile test machine is used for the extensional tests. Temperature is controlled in thermal chamber using WinTest software package. Figure 3-2 shows the experimental setup used for tensile testing. Force is measured at the lower end by a load cell, while displacement is measured at the upper end using the connected linear variable differential transformer (LVDT). Force and displacement both are controlled through WinTest software package.

The tensile tests are carried out on both SM (chemical composition: 55.33% by weight of Ni) and SE (chemical composition: 55.92% by weight of Ni) samples of diameter 0.010 inch obtained from Fort Wayne Metals.

The test gauge length for both samples tested in extension is about 3.75 inches. In this study, SMA wires that are trained to be in a stable state are used. Before the formal test, the SMA wires are trained by cyclic preloading in order to minimize the accumulation of residual strain and stabilize the hysteretic behavior. Displacement control mode is used for the uniaxial tension test of SMA wires. Force, displacement parameters of SMA wire at different temperature levels are then measured.

Once the uniaxial stress–strain tension data at different temperatures is obtained, the parameters for the model are determined. The process of determining these parameters, as
well as a description of each of these parameters, has been described previously by Lagoudas [74].

![ElectroForce® 3330 test instrument by BOSE for testing stiffness characteristics of SMA wires at different temperatures.](image)

Figure 3-2 ElectroForce® 3330 test instrument by BOSE for testing stiffness characteristics of SMA wires at different temperatures.

### 3.3 Experimental Evaluation of Stiffness Characteristics

#### 3.3.1 Effect of Combinations of SMA Wires

To establish the accuracy of the COMSOL model predictions, few combinations were experimentally tested on the BOSE machine shown in figure 3-3. Before the test, both
wires are trained by cycling 15 times. For series combination fixture was developed for keeping wires tight. Figure 3-3 shows the test setup for series and parallel combination of SM and SE wires.

![Figure 3-3](image)

Figure 3-3 Experimental setup for testing (a) series combination (b) parallel combination of SM and SE wires.

### 3.3.2 Effect of Temperature

To determine the effect of factors other than the combination of SMA wires we conducted several experiments. Change in stiffness characteristic with respect to change in temperature was evaluated by experimental testing on ElectroForce® 3330 test instrument. SMA wire of diameter: 0.012”, Length: 140 mm with austenite start temperature of 70° C was used for all the test conditions. SMA wire was loaded and unloaded using WinTest program. Sinusoidal cyclic loading for about 15 cycles was carried out for each condition on shape memory wire. Using environmental chamber synchronized with WinTest, SMA wires were tested for five different temperatures such
as 25 ° C, 40 ° C, 50 ° C, 55 ° C, and 65 ° C. Load – displacement data collected and processed in MATLAB for further analysis.

### 3.4 Stiffness Control of SMA Actuator

The Stiffness variation of SMA wire is evaluated in order to apply the wires in an AFO design to make it an active component. A single degree-of-freedom (1-dof) SMA actuated arm is used for designing stiffness control algorithm and for evaluating the algorithm experimentally. This simple system provides an experimental base for evaluating the possibility of controlling stiffness in rotary systems using shape memory alloys.

The system shown in Figure 3-4 is a one-degree-of-freedom shape memory alloy actuator. The arm is actuated by a bias type actuator constructed with SMA wire, pulleys and a linear spring. Diameter of the SMA wire used is 150 µm which is actuated by electrical heating. Heating the SMA wire induces a negative strain in the material creating a positive torque and rotating the arm in counterclockwise direction. Conversely cooling the wire induces positive strain causing the arm to rotate in clockwise direction.

The stiffness control model of the arm including spring and payload effect is:

\[
\tau_{sma} = k \theta
\]

where \( \tau_{sma} \) is torque of SMA wire, \( K \) is stiffness and \( \theta \) is the angular position of the arm.

Torque resulting from SMA wire can be simplified as

\[
\tau_{sma}(\theta) = \tau_s(\theta) + \tau_g(\theta)
\]

where \( \tau_s(\theta) \) and \( \tau_g(\theta) \) are the resulting torques from bias spring and gravitational loads.
Resulting torques are calculated as follows

\[ \tau_a(\theta) = -(B \times r_a)' \times g_v \times m_p - (B \times r_g)' \times g_v \times m_p \]  
\[ \tau_g(\theta) = (B \times r_g)' \times d_i \times f_s / l_s \] 

Where \( r_a \) is arm center of gravity relative position vector to the joint, \( r_g \) is the gripper center of gravity position vector relative to joint, \( g_v \) is the gravitational acceleration, and \( m_p \) is the payload mass. All the parameters used in modeling are listed in Table 3.2.

Spring force \( f_s \) is given by

\[ f_s = k_s \times (l_s - l_{sb}) + f_{sp} \] 

here \( k_s \) is the spring coefficient, \( f_{sp} \) is spring pretention force and \( l_s \) is bias spring length calculated as

\[ l_s = \sqrt{(d_j \times d_g)} \] 
\[ d_{ij} = r_j + A \times r_s - s_g \] 

where \( r_j \) is joint global location vector, \( r_s \) is arm spring connection relative to joint vector, \( s_g \) is ground spring connection vector

\[ A = [\cos \theta - \sin \theta ; \sin \theta \cos \theta] \]
\[ B = \begin{bmatrix} -\sin \theta & -\cos \theta \\ \cos \theta & -\sin \theta \end{bmatrix} \]  \hspace{1cm} (19)

where \( A \) and \( B \) are the rotation transformation matrices.

Using equations (11) to (19) depending upon the arm link position SMA stiffness can be calculated.

Table 3.2 Modeling parameters and their numerical value (SI units) [99].

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>( m )</td>
<td>SMA wire’s mass per unit length</td>
<td>1.14( e^{-4} )</td>
</tr>
<tr>
<td>( A )</td>
<td>SMA wire’s circumferential area per unit length</td>
<td>4.712( e^{-4} )</td>
</tr>
<tr>
<td>( R )</td>
<td>SMA wire’s resistance per unit length</td>
<td>50.8</td>
</tr>
<tr>
<td>( T_\infty )</td>
<td>Ambient temperature</td>
<td>20</td>
</tr>
<tr>
<td>( r )</td>
<td>Radius of pulley</td>
<td>8.25( e^{-3} )</td>
</tr>
<tr>
<td>( m_p )</td>
<td>Payload mass</td>
<td>0.0572</td>
</tr>
<tr>
<td>( m_a )</td>
<td>Moving link mass</td>
<td>0.0187</td>
</tr>
<tr>
<td>( k )</td>
<td>Bias spring stiffness</td>
<td>3.871</td>
</tr>
<tr>
<td>( l_0 )</td>
<td>Initial length of SMA</td>
<td>0.9</td>
</tr>
<tr>
<td>( f_{sp} )</td>
<td>spring pretention</td>
<td>170.6</td>
</tr>
<tr>
<td>( l_{s0} )</td>
<td>Bias spring initial length</td>
<td>0.03015</td>
</tr>
<tr>
<td>( k_s )</td>
<td>Spring coefficient</td>
<td>37.97</td>
</tr>
<tr>
<td>( r_j )</td>
<td>joint global location vector</td>
<td>[0; 0.12192]</td>
</tr>
<tr>
<td>( r_a )</td>
<td>arm center of gravity relative to joint vector</td>
<td>[0.02985; 0]</td>
</tr>
<tr>
<td>( r_g )</td>
<td>gripper center of gravity relative to joint vector</td>
<td>[0.060; -0.03636];</td>
</tr>
<tr>
<td>( r_s )</td>
<td>arm spring connection relative to joint vector</td>
<td>[0.030; -0.00254]</td>
</tr>
<tr>
<td>( s_g )</td>
<td>ground spring connection vector</td>
<td>[0.00254; 0.062]</td>
</tr>
<tr>
<td>( g_v )</td>
<td>Gravitational acceleration vector</td>
<td>[0; 9.806]</td>
</tr>
</tbody>
</table>
A proper control algorithm enables the SMA actuator to provide suitable action. To investigate the control algorithms for stiffness control, this system uses the angle measurement feedback provided by an encoder and adjusts the voltage of SMA wire to create the required level of force and torque for the stiffness control. In this process, the response time of the controller should be fast enough to address the inherent slow response of the SMA element. The model is constructed from several related blocks, each representing an element of the physical systems behavior. For numerical simulations, the model was built in Simulink. Simulink® is an environment for multi domain simulation and Model-Based Design in MATLAB. The block diagram of the control system is shown in Figure 3-5.

In this application, a PID controller is designed to regulate the applied voltage to the SMA wire. This is done in order to obtain the desired stiffness. The instantaneous stiffness of the SMA wire is calculated according to the stiffness model of the system. The desired stiffness is then compared with the instantaneous stiffness of the wire, which generates an error signal. The PID controller calculates the applied voltage to the wire based on this error signal. By changing the reference signal and with this control logic it is possible to position the actuator to match the desired stiffness or to track desired stiffness profile.

Figure 3-5 Stiffness control algorithm for the 1-dof SMA actuated arm [99].
For all the experiments, dSPACE hardware-in-the-loop solution is used (Figure 3-6). This solution allows for experimental evaluation of the control system. As the system (1-DOF SMA manipulator) is part of the control/data acquisition loop, real time data can be collected and also system parameters can be changed through its graphical interface.

Figure 3-6 dSPACE hardware-in-the-loop solution used for testing the control method experimentally [99].

An optical encoder on SMA arm is used to measure angular position of the 1-dof arm. Depending upon this angle the simulink model calculates the control output voltage on dSPACE processor. As this output voltage range is smaller to move SMA arm assembly, output of dSPACE processor is connected to power supply unit. Power supply amplifies the voltage and changes the arm position.

These experiments shows that utilizing SMA wires and feedback measurements of the angular displacement of the arm, the stiffness of the SMA wires can be adjusted and
controlled to the desired level. It is expected that using a more comprehensive SMA model for simulations will result in closer match of the simulations with experimental studies albeit adding complexity to simulations and control systems design.
Chapter 4

Prototype Development and Testing

Analysis and experiments of chapter 3 shows the possibility of controlling stiffness of shape memory wires. This is the basis for developing the AAFO with SMA wires focusing on stiffness modulation. In this chapter the design and test methodology for the AAFO is presented. The ultimate goal was to create a desired stiffness variation profile to achieve close-to-normal behavior in the ankle joint of the patients. Figure 4-1 shows the conceptual design of the AAFO with SMA wires attached for actuation to achieve ankle stiffness variation.

Figure 4-1 Embedding SMA wire to achieve stiffness variation in an AFO.
4.1 Gait Analysis Test Method to Understand Ankle Behavior

Controlling an ankle joint stiffness is necessary for creating an accurate gait cycle with orthotic devices. To understand the deficiency in ankle stiffness characteristics of a drop foot patient compared to healthy person, gait analysis techniques were used.

4.1.1 Gait Analysis of Healthy Subjects

Subjects:
Gait analysis was performed on 10 young nondisabled subjects (7 male, 3 female) with an age range between 21–26 years. Prior to data collection, age, height, and weight were recorded (Table 4.1). Subject’s wearing soft shoes (tennis/jogging) were asked to walk on a pathway that included a force plate. Prior to the data collection, all subjects provided informed consent according to the rules and regulations of the University of Toledo.

Instrumentation:
Gait evaluation included simultaneous recording using a 3D motion capture system (Motion Analysis Corporation, Santa Rosa, CA, USA) and three-dimensional ground reaction forces using force plate system (Advanced Mechanical Technology, Incorporated, Watertown, MA, USA). Twelve Eagle cameras were used to capture the positions of the markers placed on the subject. Kinematic data was recorded at 100 Hz frequency in Cortex software. Kinetic data was collected at 1000 Hz using force plates embedded in the walkway.
Table 4.1 Subject specific data for study participants

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age</th>
<th>Weight (Kg)</th>
<th>Height(m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZK</td>
<td>F</td>
<td>25</td>
<td>53</td>
<td>1.57</td>
</tr>
<tr>
<td>AE</td>
<td>M</td>
<td>25</td>
<td>87</td>
<td>1.82</td>
</tr>
<tr>
<td>WA</td>
<td>M</td>
<td>26</td>
<td>73</td>
<td>1.77</td>
</tr>
<tr>
<td>LB</td>
<td>F</td>
<td>23</td>
<td>56.69</td>
<td>1.654</td>
</tr>
<tr>
<td>CC</td>
<td>M</td>
<td>25</td>
<td>95.25</td>
<td>1.75</td>
</tr>
<tr>
<td>TR</td>
<td>M</td>
<td>21</td>
<td>102.05</td>
<td>1.93</td>
</tr>
<tr>
<td>JW</td>
<td>M</td>
<td>25</td>
<td>68.18</td>
<td>1.774</td>
</tr>
<tr>
<td>AP</td>
<td>M</td>
<td>24</td>
<td>84.82</td>
<td>1.792</td>
</tr>
<tr>
<td>RD</td>
<td>F</td>
<td>26</td>
<td>60</td>
<td>1.62</td>
</tr>
<tr>
<td>RP</td>
<td>M</td>
<td>26</td>
<td>70.76</td>
<td>1.68</td>
</tr>
</tbody>
</table>

Protocol:

The entire testing was conducted during a single session. A total 37 markers were placed according to a modified Helen Hayes Marker Set protocol on each subject for a static trial, which was used to create a model in Visual3D (Figure 4-2). Medial markers were used to create a template and removed while collecting motion data.

A total of seven different conditions with at least five trials for each condition were collected for each subject (Table 4.2). Subjects were initially instructed to walk for a set of trials at their normal walking speed, then at a slower than normal walking speed, and lastly at a faster than normal walking speed with 2% tolerance.
Figure 4-2 Marker set for static trials (a) on patient (b) on model.

Table 4.2 Walking speed conditions tested.

<table>
<thead>
<tr>
<th>No</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Self selected (normal) speed</td>
</tr>
<tr>
<td>2</td>
<td>10 % faster than normal speed</td>
</tr>
<tr>
<td>3</td>
<td>20 % faster than normal speed</td>
</tr>
<tr>
<td>4</td>
<td>30 % faster than normal speed</td>
</tr>
<tr>
<td>5</td>
<td>10 % slower than normal speed</td>
</tr>
<tr>
<td>6</td>
<td>20 % slower than normal speed</td>
</tr>
<tr>
<td>7</td>
<td>30 % slower than normal speed</td>
</tr>
</tbody>
</table>

For accurate speed management a photocell and timer assembly was used (Figure 4-3). Two photocells were placed at fixed locations; timer was started when subject walked in
front of the first photocell and stopped after crossing second photocell. From the fixed
distance between photocells and the time required to cover that distance, speed for each
trial was calculated and subjects were guided either to increase or decrease the speed to
follow the conditions.

Figure 4-3 Photocell - Timer assembly for speed management.

### 4.1.2 Gait Analysis of Drop Foot Patient

Once the healthy ankle behavior was understood, a drop foot patient walking pattern was
analyzed. The deficiency due to inactive muscles at the ankle joint was evaluated using
gait analysis techniques. The protocol for gait testing was kept similar as that of the
healthy subjects for accurate comparison.

**Subject:**

One patient, male, 80 year age, (weight 94.3 kg, height 1.96 m) with a drop foot
condition was enrolled for this study. The patient was diagnosed with a drop foot
condition on his left leg, with the symptom of frequent falling. The patient was then
prescribed to wear a passive AFO, which he used for walking and jogging.
Protocol:

Similar to healthy subjects 37 makers were placed on the patient as shown in figure 4-4. The subject, while not wearing an AFO, walked across the pathway at a self selected speed. Five trials were collected for the normal walking condition representing zero impedance control scheme. The patient was then asked to walk with his passive AFO representing constant impedance control scheme.

Figure 4-4 Drop foot patient with markers.

A new hinged AFO was custom made to fit the patient for evaluating the effect of the SMA wires (Figure 4-5). To establish inherent stiffness characteristics of the hinged AFO without wires, patient was tested while wearing it for five trials.
Data processing:

For both healthy subjects and drop foot patient, kinematic and kinetic data was collected and initially processed in Cortex. The Visual 3D software program was used to analyze the recorded data in order to deliver the final ankle stiffness plots.

The following processes were carried out using Cortex

1. Static and motion trials data collection
2. Creating template for motion data collection
3. Trimming a trial for one gait cycle
4. Smoothing and joining missing points on motion trials
5. Making c3d files for further processing in visual 3D

The following processes were carried out using Visual 3D

1. Model was created using static data.
2. Using pipeline, the coordinates of the markers were filtered with a Butterworth 4th-order low-pass filter. Force data was filtered by using Low pass filter.
3. Ankle angle, moment, power and ground reaction force parameters were generated using computer based model module.
4. Following events were identified:
   - Initial foot strike
   - Foot flat
   - Maximum plantarflexion moment
   - Toe off
   - Maximum dorsiflexion angle
   - Terminal foot strike

5. Metric module was used to calculate time frame between the events.

6. Ankle parameter plots were generated using reporting module for each walking condition.

This motion data collected on healthy subject and the drop foot patient was further used to find optimal wire combination, and in designing of the AAFO.

### 4.2 Finding a Combination of SMA Wires to Achieve Stiffness Variation

From the gait analysis procedures described in the section 4.1, the deficiency in the walking pattern of the drop foot patient was assessed. The ultimate aim was to reduce this difference in ankle stiffness characteristics by using SMA wire stiffness variability. This section describes an algorithm development process to find out the optimum combination of the SMA wires to achieve any defined stiffness profile.

Ankle stiffness and SMA behavior is represented by a hysteresis curve. In order to find the solution for these complex nonlinear systems, we started with simplified general problem. At first, a linear algorithm was developed by assuming that both the systems are simple and represented by linear element such as a spring. The next step was taken to
capture the nonlinearity using a technique called least squares support vector machine (LSSVM). From the required ankle stiffness curves, SMA stress-strain relation was estimated and given as an input to the nonlinear algorithm to find the optimal combination of SMA wires.

4.2.1 Linear Search Algorithm for Spring Element

As SMA wires have highly nonlinear characteristics, the development of the algorithm was initiated by using linear elements such as linear springs. The aim of this linear element algorithm is to determine the combination of springs, if we know the stiffness value. Mathematical modeling of a configuration of series and parallel wires can be achieved with modeling the wires in a matrix and the connectors in another matrix. As we can see in figure 4-6 there is a net of nodes, between each two nodes in horizontal direction a wire, and in vertical direction a rigid connector can be placed. For both the matrices if there is an element between two nodes, the array element will be equal to 1 and if there is no element, it will be equal to 0.

![Figure 4-6 Configuration of combination of linear elements.](image)

Figure 4-6 Configuration of combination of linear elements.
For example consider a system with the configuration of wires shown in figure 4-6, we can write the wire and connector matrix as:

\[
W = \begin{bmatrix}
1 & 0 & 0 \\
1 & 1 & 0 \\
0 & 0 & 1 \\
1 & 1 & 0
\end{bmatrix}
\quad C = \begin{bmatrix}
1 & 1 & 1 \\
1 & 0 & 0 \\
0 & 1 & 1 \\
1 & 1 & 1
\end{bmatrix}
\]

Wire matrix row represents horizontal progression in configuration while connector matrix row represents vertical progression in configuration. Depending upon elements and connectors present at each node we can find out the combination and stiffness respectively. We developed an algorithm based on this logic shown in figure 4-7 using MATLAB, where if the user gives a stiffness value, the program can output a combination for the same.

For example in first column two wires and two connectors are present making a parallel combination. So stiffness for that particular combination will be \( k + \frac{k}{k} \). If two wires are in series stiffness for that node becomes \( \frac{k \cdot k}{k + k} \).

The stiffness matrix for this combination will be:

\[
K = \begin{bmatrix}
2k & 0 & k_2 \\
2k & k_1 & k_2 \\
0 & k_1 & k_2 \\
k & k_1 & k_2
\end{bmatrix}
\]

where \( K_1, K_2 \) are stiffness’s in second and third column formulated as:

\[
k_1 = \frac{2k \cdot k}{2k + k} + 0 + \frac{k \cdot k}{k + k}
\]  (20)

\[
k_2 = 0 + 0 + \frac{k_1 \cdot k}{k_1 + k}
\]  (21)
Figure 4-7 Flowchart of linear algorithm logic for finding a combination of elements.

The last element of this matrix gives the resultant stiffness of the combination. So from these two matrices we can find out the whole configuration and vice versa. This algorithm was a starting point which helped to understand and develop regression search strategy.

### 4.2.2 Developing a Search Algorithm Using LSSVM Technique

After successful working of the linear algorithm next step was to capture the non linearity of SMA wires. Least Squares Support Vector Machines (LSSVM) is a powerful
methodology for solving problems in nonlinear classification, function estimation and density estimation [127-132]. The SVM uses non-linear mapping based on an internal integral function to transform an input space to a high dimension space and then looks for a non-linear relationship between inputs and outputs in that space. The SVM not only has theoretical support but also can find global optimum solutions for problems with small training samples, high dimensions, non-linear and local optima. The technique has already been successfully used for a wide area of applications: image classification, speech recognition, cancer diagnosis, survival analysis, forecasting, and bio-informatics.

In this method a system model is developed from previous experience which is called supervised learning, to forecast the output value by reducing error. In the case of supervised learning, the learning methods are adopted based on the training data, which include output values [133-138].

Function estimation type was used for this SMA based application by following the logic shown in figure 4-8. Stress strain values from the COMSOL simulations for different combinations acts as an input of the training data set. The configuration as described in linear algorithm in terms of zero and one acts as an output of the training data set. All the data was then divided into training and testing data sets. The training data set was used to build the LSSVM model, and the testing data set verifies the LSSVM model performance. The implementation of LSSVM requires the specification of only two hyper parameters $\gamma$ i.e. regularization parameter and $\sigma$ i.e. kernel parameters. Assuming the hyper parameters and giving known combination and its corresponding configuration was trained.
Figure 4-8 Flowchart of nonlinear algorithm developed using LSSVM.
The optimal parameter combination \((σ, γ)\) selection is the most significant topic when establishing the LSSVM estimation model, because it can significantly affect performance. Calculating the root mean square error between the known test data and the output of the model, gave new hyper parameters. The new parameter combination then replaced in the code and the process was repeated until it approaches the stopping criteria. Finally, we obtained the optimal parameter combination \((σ, γ)\) with minimized error. These parameters were adopted to build the optimum model, which was then tested for prediction performance using the known test data. Search process continued until the combination of the test case matched with the model prediction.

This way if the user gives a stiffness profile, the algorithm predicts the combination of SM and SE wires that can be used to achieve it. With the fairly accurate performance this algorithm can be used in various fields to improve the system by finding optimum stiffness of SMA wires.

4.2.3 Ankle Stiffness Deficiency in Drop Foot Patient

To find out which combination of SMA wires will provide the necessary stiffness variation, the angle and moment curves of healthy subjects and drop foot patient were compared. As the drop foot patient has weak muscles, the main problem of lifting the foot up in swing phase results in toe drag. Therefore large angle differences were observed during the mid to late swing phase of the gait cycle (Figure 5-5). Muscle deficiency also reduces ability to generate push off during late stance. As a result ankle moment differences were detected in the late stance phase (Figure 5-6). Early stance and mid swing phases require increase in stiffness. Initial stiffness can be achieved by wires passively, just by providing resistance to plantarflexion. But the swing phase needs
accurate modulation of stiffness; therefore we decided to focus on SMA actuation in swing phase, to help the drop foot patient lift the foot segment towards dorsiflexion.

4.3 Prototype Design

A polypropylene AFO without the spring at the hinge joint was custom made to fit the drop foot patient. In order to add SMA wires, a freely rotating pulley arrangement was designed for this hinged AFO in order to minimize both friction and unwanted wire hardening, carrying along fragility and loss of shape memory properties. (Figure 4-9).

A total of fourteen plastic pulleys were fixed on the AFO by using screws and spacers making parallel combination of eight wires. The length of the SMA wire was calculated such that complete strain recovery could be achieved in one cycle. Considering total angular variation of about 25 degrees, and constraining 4% strain recovery, the minimum length of the wire needed was about 90 inches.

Figure 4-9 Pulley arrangement on hinged AFO to attach SMA wires.

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The SMA wires need to overcome just weight of the foot segment as there is no other force acting on the ankle during swing phase. The foot segment weighs approximately 1.3 % of the total body weight $W$, which for our subject was about 15 N, and the center of mass $C$ is at about 0.14 meter from the proximal end. Resulting in following moment $M$ at ankle joint:

$$M_{\text{ankle}} = W \times C = 2.1 Nm$$  \hspace{1cm} (22)

The force needed to overcome this moment was:

$$M_{\text{required}} = F_{\text{SMA}} \times R$$  \hspace{1cm} (23)

where $R$ is moment arm and $F_{\text{SMA}}$ represents force exerted by SMA wires. $R$ is the perpendicular distance between point of rotation (center of the hinge) and point where wire is connected at the foot segment.

$$F_{\text{SMA}} = \frac{2.1Nm}{0.03048m} = 70N$$  \hspace{1cm} (24)

From this force stress was calculated for wire of radius $r$ of about 0.005 inch as follows:

$$\sigma_{\text{SMA}} = \frac{F_{\text{SMA}}}{\pi r^2} = 1400 MPa$$  \hspace{1cm} (25)

Considering these maximum stress-strain values, and understanding the loading-unloading path the wires will undergo in one gait cycle, desired stiffness profile was predicted. This profile then was fed to the algorithm as input, which predicted the parallel combination of eight SM wires (0.01 inch diameter). This combination was then tested on the prototype by using the bench test method described in the next section.
4.4 Prototype Testing

4.4.1 Bench Test

To test the wire combination predicted by the algorithm, a bench test setup shown in figure 4-10 was developed. As the focus of design development was in swing phase, the metallic leg mimicking human leg, with a freely rotating foot segment was developed using 80/20 parts. Wires were added onto the AFO and strapped on to the leg which was held suspended using brackets on the table. A digital protractor was mounted on the foot segment to measure the angular variation achieved. For stiffness modulation temperature activation was used for SM wires using a power supply (I=1 A V=35 volts). The aim was to start from a maximum plantarflexion angle and then observe the maximum dorsiflexion angle achieved either actively by SE wires or by activation of SM wires.

Figure 4-10 Bench test setup for AFO with SMA wires.
At first a parallel combination of SM wire (diameter 0.01 inch and length of 130 inch), as predicted by the algorithm, was tested. Even though the pulleys were freely rotating, there was friction occurring at every wire transition, which resulted in smaller rotation at the ankle joint. The simulation output was the training data for the algorithm. Design factors such as friction were not considered in the simulation model, it affected the algorithm model and thus the predictions. As a result, the predicted combination could not achieve expected actuation. Due to these issues, the need of more force to overcome friction was compensated by means of thicker diameter wires and new combinations which are explained in the next section.

4.4.2 Mechanical Assembly for Testing Stiffness Change of an AFO

As described in an earlier section, because of the friction between the pulley and wires, the combination predicted by the algorithm did not actuate the AFO as expected. Hence there was a need to measure the forces exerted by the wires through pulleys on the AFO. As described in section 2.6, several testing devices and procedures have been developed to assess the stiffness characteristics of AFOs. In this project some of these approaches were used for evaluating the stiffness characteristics with a standard ElectroForce, Bose machine for better reliability in an automated way. This assembly was designed to simulate the human leg motion comprised of the foot, ankle joint and lower leg. The objective of this test fixture for the Active ankle foot orthosis was to establish force – displacement relationship for the AFO with the SMA wires.

A key element of the design was to keep the angle at the knee joint less than ninety degrees so that the slider at the knee would not lock-up. The constraint of the Bose machine’s actuator displacement of ±12.5mm was used with motion studies in
SolidWorks software. Iterations were made by altering the fixed height of the pivot-slider and horizontal distances between the actuator pivot, ankle pivot and pivot-slider until the desired range of angular rotation was achieved. This robust design was composed of the 80/20 Inc. parts, so that it would be durable and produce minimal vibration during testing.

A schematic overview of the test setup is shown in figure 4-11 was designed by senior design group [100]. The test fixture was constructed with aluminum T-slotted profiles, single flange linear bearings, and living hinges from 80/20 Inc. A passive hinged polypropylene AFO with metallic hinges was used for the testing. Sufficient material was removed from the AFO so that assembly could move freely from 15 degrees of dorsiflexion to 18 degrees of plantarflexion, thus emulating normal sagittal plane ankle range of motion.

Figure 4-11 AFO testing assembly design [100].
The AFO was fitted on the shank segment with the foam padding at the calf to simulate the behavior of the soft tissues. The foot section was rigidly bolted to the wooden wedge which is mounted on the load cell.

Angle measurement was done by mounting a PRO 3600 Digital Protractor on the shank segment. The whole assembly was mounted on BOSE ElectroForce 3330 machine as shown in figure 4-12. This mechanical testing machine controlled vertical motion of the actuator through the WinTest software package to generate angular motion at an ankle joint. A DSPACE hardware-in-the-loop solution was used for real time data capture of force and angle sensor output. The measured data was displayed real time in the control desk software package and was captured using MATLAB/Simulink.

Two types of test procedures were performed; the first procedure was quasi-static ramping of an angle, while the second involved automated sinusoidal angular displacements (Figure 4-13). Both test procedures were carried out on the AFO and data was captured/processed in MATLAB.

A quasi-static method was mainly used to test the effect of shape memory wire by allowing strain recovery after heating for each angular change. Change in vertical position of an actuator is directly proportional to the change in angle at ankle joint. Hence by changing displacement of an actuator using WinTest software, angular variations were achieved. Many studies have shown that AFO stiffness is insensitive to loading velocity, so an adequate operating frequency was chosen.
Figure 4-12  BOSE machine with AFO testing assembly and data acquisition module [101].

Figure 4-13 (a) Quasi-static, (b) Sinusoidal angular variation at ankle joint.
Tests were conducted first to evaluate stiffness characteristics of the AFO on the metallic leg. Once the inherent characteristics of an AFO were established, Superelastic (SE) wire of diameter 0.01 inch and length of 130 inches was applied and tested on the AFO (Figure 4-14).

![Figure 4-14 SMA wire application on AFO.](image)

The following cases of wires were then tested on the AFO:

- 2 SM: Shapememory (SM) wire of diameter 0.02 inch and length of 130 inches
- 3 SM: Shapememory (SM) wire of diameter 0.03 inch and length of 130 inches
- Thick SM: Shapememory (SM) wire of diameter 0.045 inch and length of 130 inches
- Combination: Shapememory (SM) wire of diameter 0.01 inch and length of 80 inches in parallel with Superelastic (SE) wire of diameter 0.01 inch and length of 50 inches
Force-displacement curves from these cases were compared and efficiency was determined. To follow the test protocol similar to actual on patient testing, these cases were tested on the bench test setup described in section 4.4.1. Performance comparison of different set of wires and by changing the pulley arrangement, helped to develop an optimum design of the AAFO.

4.4.3 Prototype Testing on Drop Foot Patient

From the results obtained by bench testing, a final design was tested on a drop foot patient. As the prototype cannot be used as shoe insert, it was difficult to place the foot inside the AFO while patient walks on the floor. To avoid this problem, the patient was asked to sit on the table while keeping his foot hanging in air during testing (Figure 4-15, 4-16). Reflective markers were applied in a similar way as that of walking trials as shown in figure 4-4. For motion analysis, a template was created from static sitting trail, for capturing the data in Cortex.

Figure 4-15 Drop foot patient test setup for AFO with SMA wires.
To begin the testing, patient was directed to go to a maximum plantarflexion position by actually moving the foot segment. Once the foot reached maximum plantarflexion, the patient gave a signal to start activation of SMA wires. Increasing temperature of the SM wire using the power supply resulted in foot moving into a dorsiflexion position. Activation of the wire was stopped if the angle remained constant for some time. The same procedure was repeated three times to validate repeatability for all cases of SMA wires.

Figure 4-16 Hinged AFO with SMA wires placed on patient for gait data collection.

Even though this patient’s testing protocol did not involve actual walking with the AFO, this procedure helped to simulate the swing phase, which was the main focus of this project. These preliminary results will help in the design of an improved prototype and in the development of a control strategy, which then can be used for evaluating a complete gait cycle.
Chapter 5

Results and Discussion

The first section of this chapter is dedicated to show the gait analysis results. The second part of the chapter presents simulation results from finite element analysis for evaluating stiffness of different combinations of the SMA wires. Experimental results of testing SMA wires at different temperature and evaluating stiffness of a rotary actuator are described in the following sections.

5.1 Gait Analysis of Healthy Subjects

Understanding moment and angular changes of the ankle joint is an important factor in the designing of an Active AFO. There are many groups involved in studying effect of the walking speed on the gait parameters [102-112]. Even though test method for most of these studies is similar each group focused on different aspect of the gait cycle. Details of gait test protocol followed for this testing are discussed in chapter four. Data for ten subjects was collected while walking at different speeds.

Figure 5-1 shows angular variation for each condition considering the mean value of all the subjects. To define the control strategy which will actuate the SM wires accurately with change in speed, the focus was on time aspect of angular variation. A positive angle here is dorsiflexion a while negative angle is a plantarflexion angle. Angular variation at normal speed matches with previously published data (figure 2-12) [48, 68, 69, 113]. As
the speed increases we can see that the peak dorsiflexion angle decreases while the peak plantarflexion angle increases. Even though no group has compared angle change this way, this is exactly as expected, because it represents the increase in stride length associated with faster speeds [108].

Figure 5-1 Ankle angle variation for all conditions for one gait cycle.

Figure 5-2 shows the change in the plantar/dorsiflexion moment for each condition based on the mean value of all the subjects. As the speed increases we can see that the peak amplitudes increase. Similarly with decrease in the speed, peak amplitudes decrease. This is particularly evident for the fastest speed, which had the largest dorsiflex moment in an early stance and the greatest plantarflexion moment in late stance. These results agree with statistical analysis performed by Lelas et al [107], indicating to us the accuracy of the analysis done based on these results.
Figure 5-2 Ankle moment variation for all conditions for one gait cycle.

Figure 5-3 shows a hysteretic curve of the ankle stiffness characteristics which represents the mean value of all conditions for all subjects. For better understanding, the gait phases of a person walking on the ground are also shown below the figure. The interaction of the angular motion of the ankle, and the associated ankle moment, is represented by the concept of ankle stiffness. This reflects the resistance to motion that is due to the presence of soft tissue surrounding the joint, friction within the joint, and the actions of muscles that cross the joint. This hysteretic behaviour of the ankle joint matches with the published data (figure 2-14 (a)) [72, 73, 114, 115] and gives the baseline for evaluation of stiffness variation with change in speed.

This graph illustrates that ankle stiffness was lowest early and late in the gait cycle, and was greatest in the middle of the stance phase. This ankle stiffness curve represents the aim to be achieved, and helps to explain the deficiency that is seen in drop foot patients.
Figure 5-3 Ankle stiffness profile for a normal person walking (mean of all conditions).

The effect of the change in walking speed on the characteristics of stiffness is depicted in figure 5-4. At slower speeds the stiffness hysteretic loop gets divided in three smaller loop patterns. As the speed increases two loop hysteretic curves with one broader loop can be seen in figure 5-4. Interestingly, these graphs illustrate that at slower walking speeds stiffness during midstance is diminished. These results show how stiffness variation changes with respect to changes in walking speed. This is particularly important information, as functionally, patients do walk with different velocities.
Figure 5-4 Stiffness variation of an ankle joint for different walking speeds.

Given the fact that the presence of an AFO alters ankle stiffness, it is essential to know the extent to which this must be accommodated in the design of an AAFO. Also this can be taken into consideration while developing an automatic control strategy to activate the SMA wires in order to change the stiffness with speed variation.

5.2 Gait Analysis of Drop Foot Patient

In order to understand the deficiency in ankle characteristics, gait analysis was performed on a drop foot patient walking without an AFO, with a non-hinged and with a hinged AFO. Figure 5-5 shows the angular variation of the drop foot patient for both the healthy and affected leg. The patient was asked to walk without the AFO, with non hinged passive AFO and with a hinged AFO. Drop foot patients lack control over the foot segment and cannot dorsiflex it in swing phase. Hence it is seen in the graph that while the patient walks without any AFO on the affected leg, the angle remains in plantarflexion and does not come back to dorsiflexion for the next heel strike. Even though a hinged AFO allows the same flexibility of movement, it does not help much in
terms of assisting the foot to dorsiflex. Non-hinged AFO’s help to assist the ankle in the swing phase, but only to a limited extend.

![Ankle angle: Drop foot patient](image)

Figure 5-5 Ankle angle variation of drop foot patient with and without AFO.

Compared to the healthy leg ankle angle variation, large deficiency is observed in early stance and again in the mid swing phase. In early stance an initial difference in the angles was observed, which is described as slap foot. To avoid that, controlled plantar plantarflexion is required. Similarly toe drag implies a deficiency in mid to late swing phases, which requires lifting up the entire foot segment. Potentially adding SM wires on a hinged AFO to actuate the foot towards dorsiflexion, it is possible to reduce toe drag. Similarly the same wires can exert resistive force toward plantarflexion in the stance phase, allowing controlled plantarflexion to avoid slap foot. Overall this plot shows that the SMA wires need to move the foot segment from 14 degree plantarflexion to 2 degree dorsiflexion.
Romkes et al. performed similar analysis for the comparison of a dynamic and a hinged ankle–foot orthosis by gait analysis in patients with hemiplegic cerebral palsy shown in figure 5.6 [166]. These results are comparable to that shown in figure 5.5 carried on drop foot patient along with other literature [18,177].

![Figure 5-6 Ankle angle variation for different AFOS [189].](image)

Angle moment variation for the drop foot patient is shown in figure 5-7. There was not much variation observed for this patient between the affected and unaffected leg, as compared to the angle change. Maximum deficiency in the produced moment is observed in late stance, as the muscles cannot generate the push off. Non- hinged AFO’s restrict the ankle joint movement and increase the difference in the moment. Hinged AFO’s, by allowing movement, help push off and reduced the difference in the moment values. These results are equivalent to the results published by groups, who have performed gait analysis on patients to evaluate the effect of different AFOs [117-119].
Figure 5-7 Ankle moment variation of drop foot patient with and without AFO.

A comparison between ankle stiffness profiles of the drop foot patient across various conditions is shown in figure 5-8.

Figure 5-8 Ankle stiffness variation of drop foot patient with and without AFO.
The hinged AFO gives stiffness variation close to that of the healthy leg, while the non-hinged AFO makes the stiffness loop smaller. If stiffness characteristics of the patient’s healthy leg are compared with those of the healthy subject, large variation can be seen. The reason behind this could be the patient’s age. It is widely known that age itself changes the stiffness characteristics of muscle. Hence while considering the stiffness requirements to be achieved by the SMA wires, we focused on the differences between a patient’s healthy and affected characteristics. Early stance and mid swing phases, require increase in stiffness. Initial stiffness can be achieved by wires passively, just by providing resistance to plantarflexion. But the swing phase needs modulation of stiffness; therefore we decided to focus on SMA actuation in swing phase to help the drop foot patient to lift the foot segment towards dorsiflexion.

5.3 Tensile Testing to Obtain Wire Properties

In this study, SMA wire behavior was simulated using a COMSOL model. In order to create an accurate model we used properties of the wires that were applied on AFO. Before the formal test, the SMA wires were trained by cyclic preloading in order to minimize the accumulation of residual strain and stabilize the hysteretic behavior as described in literature [26]. Force-displacement curve in figure 5-9, shows the progress of stabilization. Displacement control mode is used for the uniaxial tension test of SMA wires.

After that stress, strain values for SMA wire at different temperature levels were measured. The typical stress-strain response at five different constant temperatures is shown in Figure 5-10. The shift in the hysteretic curve with the change in temperature is comparable to the literature (figure 2-4) [46, 47].
Figure 5-9 Stress strain curves for mechanical Training of SM and SE wire.

Figure 5-10 Stiffness variation of SM and SE wires at different temperatures.

Once the uniaxial stress–strain tension data at different temperatures is obtained, the parameters for the model are determined (Figure 5-11). The process of determining these parameters, as well as a description of each of these parameters, has been described previously by Lagoudas [74]. Table 5.1 shows the parameter values used to simulate the model.
Figure 5-11 SMA wire parameters: \( M_f \), \( M_s \), \( A_s \), \( A_f \).

Table 5.1 Parameters obtained from tensile testing.

<table>
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<th>Parameter</th>
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<th>SE wire</th>
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<td>( M_f )</td>
<td>27.39</td>
<td>-51.86</td>
<td>°C</td>
</tr>
<tr>
<td>( M_s )</td>
<td>35.52</td>
<td>-48.7</td>
<td>°C</td>
</tr>
<tr>
<td>( A_s )</td>
<td>47.65</td>
<td>7.5</td>
<td>°C</td>
</tr>
<tr>
<td>( A_f )</td>
<td>54.19</td>
<td>19.4</td>
<td>°C</td>
</tr>
<tr>
<td>( D_A )</td>
<td>( 27 \times 10^3 )</td>
<td>( 36 \times 10^3 )</td>
<td>MPa</td>
</tr>
<tr>
<td>( D_M )</td>
<td>( 20 \times 10^3 )</td>
<td>( 19 \times 10^3 )</td>
<td>MPa</td>
</tr>
<tr>
<td>( C_A )</td>
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<td>4.4</td>
<td>MPa/°C</td>
</tr>
<tr>
<td>( C_M )</td>
<td>8.0</td>
<td>7.0</td>
<td>MPa/°C</td>
</tr>
<tr>
<td>( \varepsilon_L )</td>
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<td>5.2</td>
<td>%</td>
</tr>
</tbody>
</table>
5.4 Simulation of Combinations of SMA Wires

Ten combinations of SMA wires of shape memory (SM) and superelastic (SE) effects were simulated in COMSOL using Tanaka based constitutive model, described in section 3.1. Comparative results of these simulations are shown case by case.

Using parameters from Table 5.1, uniaxial tensile tests are simulated at room temperature for Case 1 and Case 2 SE wire is experimentally tested on the BOSE machine under displacement control mode. SM wire is tested under force control mode and after completion of loading-unloading, voltage is applied to the ends of the wire using power supply for strain recovery. Comparison of simulation and tensile test data are shown in figure 5-12, these curves represent typical behaviour of SMA wires as shown in figure 2-2 [20, 21, 25, 74].

![Stress Strain of SE wire at 25 C](image1)

![Stress Strain of SM wire at room temperature](image2)

Figure 5-12 Comparison experimental and simulated stress strain characteristics of (a) Superelastic wire (b) Shape memory wire.

As this is the first study focused on understanding effect of the combinations on stiffness characteristics, there was no data available in literature for comparison, hence accuracy of
the prediction of the simulations were compared to the experimental data. For series combination of the shape memory and superelastic wires, equal stress needs to be applied to both the wires. To simulate this case, periodic boundary conditions are modified by giving pre-constraints. Addition of individual strain gives the resultant strain which is calculated by defining integration coupling boundary variables in the COMSOL model. For experimental evaluation of stiffness characteristics a fixture is used which holds wire together. The experimental stress-strain response shows a good match to the simulated results. Resultant stiffness of series combination gives a two loop profile as shown in the figure 5-13.

For simulating parallel combination both wires are considered to undergo similar strain variation. This combination is simulated at room temperature and strain is recovered from the SM wire with high temperature profile (figure 5-14). Even though the shape of the curve looks similar to SE wire, this combination has bigger hysteresis loop.

![Series combination of SE and SM wire](image)

**Figure 5-13** Comparison of experimental and simulation results of stiffness characteristics of series combination of SE and SM wire.
Figure 5-14 Comparison of experimental and simulation results of stiffness characteristics of parallel combination of SE and SM wire.

Figure 5-15 Comparison of experimental and simulation results of (a) Case 5 (b) Case 6. The resultant stress strain curve for case 5 is a one loop curve similar but smaller than parallel combination. For case 6 a curve similar to series combination is achieved but with smaller loops.
Figure 5-16 Comparison of experimental and simulation results of (a) Case 7 (b) Case 8. Loading part of stress strain curve for case 7 is similar to case 2 while unloading has unique characteristics. Case 8 is similar to the series combination but has smaller loops compared to case 6.

Figure 5-17 Comparison of experimental and simulation results of (a) Case 9 (b) Case 10. Stiffness characteristics of both case 9 and 10 look similar to SE wire, but has larger hysteresis loop. Figure 5-18 depicts the overall range of maximum stress and strain that can be achieved through the combinations discussed so far.
Figure 5-18 Range of stiffness variation achieved through combinations of SMA wire.

**Parametric study:**

With the confidence of match between experimental and simulated results, few more conditions to modulate stiffness are simulated. Effect of change of geometrical parameter such as length is evaluated on series combination. At first SM wire length is doubled than that of SE wire and later SE wire length is doubled than that of SM wire. Figure 5-19 shows the effect of change in length on stiffness characteristics compared to that of series combination with equal-length wires. Longer SE wire gives a wider upper loop compared to other cases. This drastic change in shape of the hysteresis loops signifies the use of geometrical parameters in further modulation of stiffness characteristics.
Figure 5-19 Effect of change in length of wires in series combination on stiffness characteristics.

A thermal test is introduced in this section in order to demonstrate the ability of the current model in capturing the variation in stiffness with activation (Figure 5-120).

Figure 5-20 (a) Thermomechanical loading (b) Effect of change in thermal activation on parallel combination.

Time in this study is the pseudo-time and defines the evolution of the dependant variables. Temperature profile applied to SM wire in parallel combination is shifted by
0.5 sec for each of the two simulation cycles. Transition of lower plateau in stiffness profile exemplifies that change in thermal activation of wire varies stiffness.

**Effect of cyclic loading**

This test manifests the cyclic loading-unloading behavior in shape memory alloys. The cyclic loading path with partial loading-unloading is shown in Figure 5-21(a), stress-strain curve of SM and SE wire is illustrated in Figure 5-21 (b), and Figure 5-22 shows the resultant of series combination. The cyclic loading results in stress plateaus in the wire that shift up or down during the loading and unloading that follow an incomplete transformation. As it can be seen from figure 5.22, the internal loops correspond to partial transformation and agree well with the applied loading path.

With the addition of the wires in series changes the shape of typical stress strain curve into tow loops. Addition of superelastic wire increases area of upper loop while addition of shape memory wire increases area of lower loop. Parallel combinations show close resemblance to the shape of superelastic stress strain curve. Two superelastic wires in parallel with shape memory wire have the biggest hysteresis loop.

![Figure 5-21 (a) Cyclic loading stress profile (b) Stress- strain graph of SM and SE wires in series combination.](image)

110
Figure 5-22 Resultant stiffness profile of series combination under cyclic loading.

Rena et al. [120] performed a cyclic loading test on a superelastic NiTi wire of 1 mm diameter. The cyclic loading path with partial loading/unloading and the stress-strain response of the wire is shown in figure 5-23. The cyclic loading results in stress plateaus in the wire that shift up or down during the loading and unloading that follow an incomplete transformation [95,121]. This effect, as foregone in figure 5-22, is qualitatively captured through the current model.

All these results show the prominent trend in stiffness variation. Even though these combinations were not tested on current AFO prototype, by adding the design aspect into the model will help to build accurate data base of stiffness profiles for the algorithm. Modified data base will enhance the accuracy of algorithm predictions and hence can be easily adopted for patient specific requirements. This data can very well be referred for any other application to improve efficiency of the current systems by accurate modulation of stiffness of SMA elements.
Figure 5-23 Cyclic loading/unloading applied to SE wire and the resulting stress-strain response [120].

5.5 **Effect of Temperature on Stiffness of SMA Wires**

Temperature plays an important role in shape memory stiffness behavior. Experiments were conducted on SMA wires to find out effects of change in temperature which can be used for stiffness variation discussed in section 3.2. Detailed analysis was performed on
individual curves resulted from series of experiments giving response comparable to figure 2-4[46]. At first shape memory wire was tested at room temperature. Stiffness variation for this case is shown in figure 5-24. This curve is approximated by three linear parts to observe trend of change in stiffness.

Figure 5-24 Load displacement characteristics SMA wire at room temperature. Stiffness variation at 40 degree Celsius temperature is shown in figure 5-25. Comparing this with stiffness profile at room temperature we can see K1 increased and K2 decreased. Similar behavior can be noticed in stiffness profiles shown in figure 5-26 to 5-28 where tests were conducted at 50, 55, 65 degree Celsius temperature.
Figure 5-25 Load displacement characteristics SMA wire at 40 degree Celsius temperature.

Figure 5-26 Load displacement characteristics SMA wire at 50 degree Celsius temperature.
Figure 5-27 Load displacement characteristics SMA wire at 55 degree Celsius temperature.

Figure 5-28 Load displacement characteristics SMA wire at 65 degree Celsius temperature.
For modeling the behavior relation of K1 and K2 is found out with respect to temperature shown in figure 5-29 to 5-30. Graphs represent that K1 (first linear part of stiffness profile of SMA wire) increases while K2 (second linear part of stiffness profile of SMA wire) decreases with the temperature.

Figure 5-29 Relation of K1 part of the curve with temperature.

Figure 5-30 Relation of K2 part of the curve with temperature.
These results agree with the literature presented in section 2.1.3 [46, 47]. All those groups tested superelastic wires while we tested shape memory effect, this shows that effect of temperature is similar in both the cases. Formulating stiffness variation by diving into linear parts is a unique way to find out effect of temperature on stiffness variation. From the graphs quadratic relation of temperature $T$ and stiffness $K$ of each part is formulated.

$$K_1 = 0.048 \times T^2 - 0.26 \times T + 5.1$$  \hspace{1cm} (25)
$$K_2 = 0.0006 \times T^2 - 0.067 \times T + 2.7$$  \hspace{1cm} (26)

These relations help to understand the actual change in the slopes and model this behavior. From these relations MATLAB code is developed which can predict temperature for achieving certain level of stiffness. To modulate ankle stiffness more accurately appropriate temperatures to the combination of wires can be applied. This information can also be used to design control strategy in order to activate wires at accurate instance to desirable temperatures.

### 5.6 Stiffness Control of SMA Actuator

As discussed in section 3.3 stiffness control of SMA wires was evaluated in order to validate the feasibility of stiffness variation concept on the setup which was previously used for testing different hypothesis [23,122,123]. This section gives the results considering control, strategy shown in Figure 3-3. Results showed in Figures 5-31 to 5-32 show the trajectory tracking results.

The reference stiffness control signal is a sinusoidal which requires the arm to move in a continuous loop up and down shown in figure 5-31. Figure 5-32 is the graph of an encoder output obtained from control desktop. Initial angle of the arm is $50.25^\circ$ and goes up to $53.5^\circ$ i.e. arm is moving downwards. Corresponding stiffness variation obtained
from the model is overlapped in Figure 5-32. As the encoder output is not a smooth sinusoidal waveform we don’t get exact stiffness as expected. Range of stiffness variation is 780 N/m to 860 N/m. These two graphs show that with increase in angle, wire stiffness decreases and arm moves downwards and vice versa.

Figure 5-31 Angular variation output of the SMA arm obtained from control desktop.

Figure 5-32 Actual and desired stiffness variation output of SMA arm obtained for sinusoidal reference signal.
By changing the amplitude of the reference signal we get large difference in the error signal going to PID controller, which gives large output voltage and so the large change in angle and stiffness variation is obtained. But still we cannot exceed some limit due to SMA wire and power supply limitations. These results show that stiffness of SMA wires can be controlled in order to follow given reference signal.

5.7 Prototype Testing

This section is focused on the results obtained from testing the final prototype on the machine, and then testing it on the patient. All the results are discussed along with the limitations of each methodology.

5.7.1 Prototype Bench Testing

A bench test setup was developed to follow the test protocol similar to that of the actual patient testing. As described in section 4.4.1, metallic leg mimicking a human leg was used to test the AFO. At first a single SM wire of 0.01 inch diameter was rapped on pulleys and tested, resulting weak actuation of about 5 degrees. Therefore to increase the stiffness and so the actuation, the cross section of the SM wire was doubled by running two identical wires over pulleys (case 2SM). In this case, 19 degrees of actuation was observed. To further evaluate the effect of adding 3 SM wires, the same procedure was repeated giving approximately similar results of 20 degree rotation (case 3 SM). Even thicker SM wire with 0.45 inch diameter was tested (case thick SM) giving about 22 degree rotation. As the diameter increased, time duration for activation also increased, giving slower response. Even though this setup was not accurate, this testing definitely
helped to understand how the wires will actuate the AFO and modify the pulley arrangement for best performance.

5.7.2 Mechanical Assembly Testing

As described in section 4.4.2, the force capacities of the various types of SMA wires were tested on the AFO using the Bose machine test assembly. Two test protocols were followed to test SE and SM wires. A continuous protocol helped to mimic the leg motion, and capture force – displacement data for SE wires. But as SM wires need temperature activation, while going from plantarflexion to dorsiflexion a quasi-static approach was used to capture activation force.

A smooth sinusoidal angular profile was achieved through WinTest program modes as shown in figure 4-13. This protocol gives an automated way of testing AFOs with high precision. Four types of SMA wires were tested on this setup using a continuous protocol. At first, inherent characteristics of AFO were tested, and then SE wire was applied. As applying SM wire did not help in actuation, to increase the diameter two and three wires were used in parallel. A continuous approach from maximum dorsiflexion position to maximum plantarflexion position signifies how much force wires will apply when they are in inactive state. This approach is important as it depicts the force that helps in controlled plantarflexion during the stance phase. Figure 5-33 shows the force – displacement characteristics of the AFO with and without SMA wires, where positive displacement represents maximum plantarflexion while negative represents maximum dorsiflexion. Due to its composition, addition of an SE wire has considerable influence on the force as it tries to restrict the motion of the shank segment during plantarflexion motion. It can be seen that the thickest SM wire applied high resistive force, while
moving towards the plantarflexion. An SE and two SM wires running in parallel resulted
in approximately similar force. The shape of these curves is comparable to the curves
shown in figure 2-21 and figure 2-22 from the literature [89,124].

Figure 5-33 Force- displacement characteristics of AFO with SMA wires.

Figure 5-34 Quasi-static test results of AFO with SE wire.
Quasi-static tests were performed first on the setup with the AFO and then the AFO with SMA wires attached. Step by step ramping of the angle was achieved by displacement control mode in Wintest. A pause of about 10 sec was added after every two degree interval in angle, starting with maximum dorsiflexion position (figure 5-34).

For SM wires, temperature activation was done for each step while moving from plantarflexion to dorsiflexion. Results from figure 5-35 illustrate the change in force after activation of SM wires moving toward dorsiflexion. We see increase in force towards the maximum plantarflexion of AFO. There is very small change in force at the dorsiflexion angle among all the cases.

Results from both the test protocol establish that SE and SM wires change the stiffness of the AFO and can be successfully implemented in the AFO for better performance. All of the different conditions showed that force displacement characteristics of the AFO can be measured in a reliable manner. A limitation in this study is that only one prototype AFO was tested. As the significant stiffness variation at ankle joint can be found in sagittal plane motion, only that plane was taken into consideration. Objective information on the AFO properties will improve our understanding of the relationship between the design of an AFO and the biomechanical properties. This will lead to better insight into the impact of SMA wires on AFOs stiffness characteristics. Overall, this new device can help us to design an efficient AFO by applying SMA wires to improve walking performance of drop foot patients.
Figure 5-35 Force-displacement curve for AFO with (a) 2 SM case (b) 3 SM case (c) Thick SM case.
5.7.3 Prototype Patient Testing

To evaluate the most efficient stiffness modulation that helps to move the patient’s foot to a dorsiflexion position, tests were conducted in the motion analysis lab. While wearing the AFO, patient forcefully plantarflexed the foot as much as he could and then the SM wires were activated. Results in figure 5-36 shows that, in the beginning the angle was decreased because of the forceful pushing of foot downwards (plantarflexion). SE wires helped the foot to move upwards into a dorsiflexion position without any external power, while the SM wires were activated using power supply.

![Angle variation due to SMA wires on AFO](image)

Figure 5-36 Patient's angle variation data wearing AFO with SMA wires.

As seen in the figure 5-36, SM wires running in parallel on pulleys allowed for about 15 degree angular displacement, which was close to healthy foot range of motion. Ideally with more the thickness, better actuation was expected but as the thickness increased, activation duration was increased resulting in a slow response. Also more thickness
resulted in difficulty in movement of the wire through pulleys and hence lesser dorsiflexion was observed. SE wire showed acceptable performance, but that wire offered more resistive force while moving towards plantarflexion and may not be a practically viable. A combination of SM and SE wires showed quicker response, but as the connection holding the wires was not strong enough, force distribution was not effective, resulting in less dorsiflexion angle. From all these results we can conclude that the overall actuation using 2 SM wire case was optimum with 15 degrees of angular movement of the foot segment in about 8 seconds. The result from SHADE as shown in figure 5-37, where about 15 degrees of angular rotation was observed in more than 20 seconds [17]. As the angle recovery observed in figure 0-36 was faster than SHADE, this shows that with different design and different combinations of wires can definitely improve the performance of AFO. This performance further can be improved with better design and control strategy so that patient can use it during the daily activities.

![Figure 5-37 Results of optoelectronic tracking of ankle motion during dorsiflexion produced by SHADE [17].](image-url)
For rehabilitation purpose, as opposed to the functional gait where slower response is accepted, thicker SM wires can be used with suitable a pulley design. For quick response, SE wire can be added in series with SM wire, but a proper clamping mechanism will be needed. The patient had stiffer ankle joint in comparison to the metallic leg assembly; thus the patient testing showed less rotation compared to bench test results.

Blaya et al. tested SEA carried out motion analysis by using adaptive control strategy and established ankle stiffness variation [15, 125] while Kao et. al tested McKibben pneumatic actuator by comparing ankle, hip and knee angle variation for complete gait cycle [16,126]. Due to lack of the control strategy for activation of SM wires, we couldn’t perform walking trails with this prototype and hence couldn’t compare results with other AAFOs. Complete gait analysis would definitely give more insight on the moment changes and the effect on other aspects of gait. As the aim of this first prototype was focused on actuation in the swing phase to avoid slap foot, this test method has definitely showed promising results which will be useful for future improvements.

5.7.4 Drop Foot Patient’s Feedback

In the development of any rehabilitation device, feedback from the user is always an important consideration. The patient did not experience any discomfort after wearing the AFO and even during the activation. He gave a positive response for this prototype; he was interested to participate in further testing and also willing to use the working prototype.
Chapter 6

Summary and Future Works

In this research, we demonstrated that a variable stiffness SMA wires applied to an AAFO reduces the dominant complications in drop-foot patient. By changing combination and thickness of wire, the swing phase ankle angle more closely resembled normals as compared to the zero and constant impedance control schemes.

Within the scope of this dissertation, stiffness control of SMA actuator is investigated. Experimental assessment of the stiffness characteristics of SMA wires with change in temperature is conducted. Effect of different combinations of wires is examined through simulations and verified experimentally. Algorithm to predict combination of SMA wires to achieve a given stiffness profile is developed. Motion analysis is performed on healthy subjects to evaluate ankle stiffness characteristics at various walking speeds. Gait analysis on drop foot patient provided insight into the deficiency in the walking. From all the results and literature review a preliminary design is proposed and tested on mechanical assembly and also drop foot patient. As the aim of this first prototype was focused on actuation in the swing phase to avoid slap foot, this test method has definitely showed promising results which will be useful for future improvements.
In the development of AFO to treat drop-foot gait, we feel modulating orthotic joint stiffness in response to walking phase and gait variation is an important design goal. Based on that, areas for future work fall into two main categories: simulation and control, AAFO design. The main problem faced in this work was to improve the accuracy of the algorithm which if improved can help change combinations easily for patient specific parameters. In order to do so there is a need to incorporate the design aspects of AAFO in the simulations. AAFO design can be improved so that it can fit in shoe, and allow for walking motion analysis. Still further, control strategies and sensing architectures specifically suited for the different walking conditions would be necessary. An important consideration in the design of an Active AFO that is truly functional is its ability to adapt to the various walking conditions encountered in normal walking. Individuals walk at various speeds, up and down grades and steps, and around corners. Each of these conditions involves unique ankle kinematic and kinetic characteristics that must be considered in the design of an Active AFO. One aspect of this that is of particular importance is that involving the influence of walking speed on the magnitudes and timing of the dorsiflexion moments. Developing control strategy will help to better modulation of stiffness to improve efficiency and performance.
Chapter 7

Business Plan

SMART ORTHOSIS, LLC.

Executive Summary

Drop foot is a neuromuscular disorder causing a loss of the use of the muscles that lift the foot. Drop foot can primarily be caused by stroke, cerebral palsy, multiple sclerosis, or neurological trauma. Common treatment options for drop foot condition are Ankle Foot Orthosis (AFO) or Functional Electrical Simulation (FES). AFO provides too much resistance to plantarflexion, and the ankle motion gets inhibited throughout the loading response. FES has shown some promise as a permanent assistance device, but the technology must be customized to the individual using trial-and-error methods and qualitative measurements. Hence both of these technologies are not effective. Smart AAFO (Smart Orthosis) combines AFO & smart material called shape memory alloys. Shape memory alloys (SMA) are metallic alloys that "remember" their original shapes. Biocompatibility and high force-to-mass-density are the main reasons SMA’s are used in this application for a better stiffness profile during walking.
As a result of this combining technology, there is a unique opportunity to provide drop foot patients a better walking ability and, hence there is the potential to surpass the existing solutions of orthotic devices.

The Smart Orthosis company differentiates itself from its direct competitors like AFO and FES based orthotic devices by overcoming disadvantages in respective technologies and by crucially, having a potential to target both the markets by providing a cost effective and more near to normal function restorable solution. In 2010, the total market size of orthotic devices accounted for a revenue of $700 million [1]. Ankle foot orthoses are the most commonly used orthoses, making up about 26% of all orthoses provided in the United States [2], which makes it about $180 million. The AFO market represents the growth rate of 3.6% and forecast to generate $217.2 million in 2015. The projected sales of Smart Orthosis are 2200 units ($1500 per unit), which will generate a revenue of $750,000 by 2020. The break-even volume is 330 units. Gross margins are 15-20%. The company intends to secure production/administrative facilities in and around the University of Toledo, OH. All the component suppliers’ selection is also complete. Management has done exhaustive research into the industry, the product, and the market. The company is proceeding according to schedule. Smart Orthosis is seeking $300,000 to implement the plans described herein. The 30% of the stock is being offered to the investors.


**Opportunity Rationale**

There are a few main reasons why there exists opportunity for SMART ORTHOSIS:

*Need to restore normal functionality:* Foot drop describes the inability of the patient to raise the front portion of the foot due to weakness or paralysis of the muscles that lift the foot. During walking, the major complications of drop-foot are 1) slapping of the forefoot after heel strike and 2) dragging of the toes at the beginning of each swing phase [1].

Ankle foot orthosis (AFO) is the most common treatment option for drop foot condition, but being a passive device; it restricts the ankle movement and leads to an abnormal gait pattern. Functional Electrical Simulation (FES) is another option to treat drop foot condition that uses a neural activation technique. Regardless of the need, the FES technique activates muscle continuously which leads to early fatigue. Both AFO and conventional FES systems adapt neither step-to step changes in gait pattern due to speed or terrain, nor long-term gait changes due to changes in muscle function. Therefore there is a need of orthotic device that provides the biomechanical controls necessary to improve the functional deficit without a perturbing effect to other normal movements and functions.

*Opportunity for innovation:* The applicability of Active AFOs developed so far is limited to laboratory and clinical-based studies since off-board power supplies and computers are required for their operation.


In order for an AAFO to be functional at a level that would allow it to be commercially viable, it must be lightweight, adaptable to a wide range of patients who vary in age, size, and type of disability, as well as reliable and relatively simple.

The need of light weight and flexible actuation with a high power to mass ratio brings the idea of using novel actuators such as Shape Memory Alloys (SMA). Shape memory alloys have been used in a variety of actuation, energy absorbing, and sensing applications. Incorporating the desirable non-linear mechanical behavior of SMAs will help to modulate the impedance of the orthotic joint throughout the walking cycle to treat the drop foot gait.

*Market Opportunity*: The orthotic market accounts for revenue of a $700 million in 2010 [1]. Ankle foot orthoses are the most commonly used orthoses, making up about 26% of all orthoses provided in the United States [2], which makes it about $180 million. The AFO market represents the growth rate of 3.6 % and is forecasted to generate $217.2 million in 2015. Past yearly sales for Otto Bock Health Care were about $386,000 and for Cascade Dafo Inc. was $76,000 [2]. Annual Sales for FES developing companies such as Bioness Inc was about $2.5 million [3] and WalkAide was $3.2 million in the year 2008. This indicates that while the cost of FES systems is higher than that of AFO, the number of units sold per year are less. But as the Smart Orthosis will be cheaper than the FES technique, we will thus get an ample opportunity to tap both markets.

The Company

SMART ORTHOSIS, LLC. is a company based on several novel and innovative technologies that treat patients suffering from different orthotic conditions. The idea was conceived in September, 2010 and the operations are going to be incepted from June 2014 with the product available in January 2015. Initially, the company intends to sell the products directly with the support of a network of clinicians, and later on expand to retail pharmacy and orthotic stores.

The Product

Smart Active Ankle Foot Orthosis (AAFO) can be used to treat patients with the drop foot condition. Drop foot is a neuromuscular disorder that can be caused by stroke, Multiple Sclerosis, diabetes etc. The aim of this product is to provide drop foot patients with an assistive technology that fits well, is cosmetically appealing and also cost effective. Smart orthosis will help drop foot patients walk like a healthy person by modulating impedance of the orthotic joint throughout the walking cycle (Figure 7-1).

![Figure 7-1 Smart AFO Concept.](image)

Smart Orthosis combines AFO & smart material called shape memory alloys. Shape memory alloys are a group of metallic materials that demonstrate the ability to return to
some previously defined shape or size when subjected to the appropriate thermomechanical procedures. Of all the Shape memory alloys that have been discovered to date, Nickel-Titanium (Ni- Ti) has proven to be the most flexible and beneficial in engineering applications. The characteristics of SMA that make it stand out from the other SMAs are: greater ductility, more recoverable motion, stable transformation temperatures, high biocompatibility, and the ability to be electrically heated for shape recovery.

Controlling ankle joint stiffness is necessary for creating an accurate gait cycle with Ankle foot orthosis (AFO). Ankle joint stiffness can be defined as the resistance that a joint offers during gait in response to an applied angular displacement. Rotational stiffness at the ankle can be measured from ankle moment and ankle angle data during one gait cycle [1]. We have performed gait analysis on healthy persons and discovered the stiffness variation as shown in figure 7-2(a). Achieving ankle stiffness variation is the primary aim of the SMA element in Smart orthosis. Stiffness of the wires can also be changed by making combination of two unique phenomenons of SMA wires. Figure 7-2(b) shows two basic characteristics, along with a series combination of SMA wires. These results confirm that a combination of wires can play a major role to achieve a desired level of stiffness variation. These nonlinear thermomechanical characteristics can be used to modulate the impedance of the orthotic joint throughout the walking cycle to treat drop foot gait.

Figure 7-2 (a) Ankle stiffness profile (b) Typical SMA pseudoelastic stress-strain behavior.

Smart AFO will give drop foot patients a better walking ability and hence has the potential to surpass the existing solutions of orthotic devices.

Industry and Market Analysis

Industry Overview

To understand the structure of the orthotic device industry completely, there is a strong necessity to frame the five competitive forces model (figure 7-3). This particular framework is comprised of the following forces: the threat of new entrants, the threat of substitutes, the bargaining power of suppliers, the bargaining power of buyers and the rivalry among existing firms which determine industry profitability and overall attractiveness [1].

• **Threat of substitutes**: Drop foot condition has been treated till now by AFO and FES techniques. Now, we have introduced the smart technology with the addition of SMA to make the end user’s life more comfortable at an affordable price. There are no other products/services from other industries that can serve as substitutes to this technology. Therefore, the threat of substitutes is low.

• **Threat of new entrants**: Market research through Frost & Sullivan helped to find out the market analysis reports related to orthotics which state that the U.S. ankle supports and braces market is mature, and because of its low barriers to entry, there are a high number of competitors in the market [1].

• **Bargaining power of suppliers**: This device procures products from the suppliers which has only 10% of the total cost of the device itself. The major suppliers for the product of Smart Orthosis are custom fit plastic AFOs, SMA wires and controller board parts for SMA activation.

Their concentration in the industry is good in number. But there are not many substitutes for the products these suppliers offer. Hence, the costs are fixed which makes bargaining power of suppliers low.

- **Bargaining power of buyers**: Even though customers of this product are drop foot patients, clinicians are the ones who will advise them to use this product. Insurance companies will cover the cost of the product therefore; making buyers are less sensitive to product price. Furthermore, the existing products have clinical limitations; the threat of substitution to this product is low. Thus, the bargaining power of buyers is low.

- **Rivalry among existing firms**: As we are entering into an industry that features two different technologies, AFO and FES, the rivalry among these two firms is not much. However, both of them have their own niche markets, which makes the industry very attractive to Smart AAFO (Smart Orthosis), opening the gateways of both the markets.

Overall, the industry attractiveness and profitability is high.

**Market Trends**

The primary users of smart orthosis are the drop foot patients. A few reports give information about customer groups as follows:

- Spinal cord injury patients: 150,000. 8,000 new cases each year
- Nearly 3 million annually suffer a stroke
- 0.9 million suffer from cerebral palsy
- 0.6 million suffer from Multiple Sclerosis
- 24 million suffer from diabetes: 0.62 million new cases annually [1,2,3]
More than 35 million (1 in 8) have disabling conditions that interfere with life activities and 16 percent of those individuals reported an orthopedic impairment. In 1990, more than 3.5 million persons in the U.S. were using some kind of orthosis, more than a 100 percent increase since 1980.

By 2020, research predicts the demand for provider services is expected to increase by 25 percent for orthotic care and 47 % for prosthetic care [4]. So in the year 2010 the total of orthosis users was approximately 10 million among which 26% use AFO making at least 2 million patients those who use AFOs. This shows that Smart Orthosis has a wide and constantly growing market.

**Estimated Market Share and Sales**

Information about leading competitors and their annual reports was found by using market research services such as IBIS World and Mergent Online. Leaders in the orthotic industry with their approximate annual sales in AFO division are: Otto Bock Health Care: $386,000 and Cascade Dafo, Inc.:$76,000. The orthotic market accounts for revenue of $700 million in 2010[5].


[2] US Statistics for Impaired Mobility, including foot drop - From Stroke


Ankle foot orthoses are the most commonly used orthoses, making up about 26% of all orthoses provided in the United States [3]. Hence the AFO market is forecasted to generate $217.2 million in 2015, representing a growth rate of 3.6% (Figure 7-4).

![AFO sales graph](image)

Figure 7-4 Annual Sales Projections till fiscal year 2015.

Annual Sales for FES Bioness Inc were about $2.5 million and for WalkAide were $3.2 million in 2008 [1, 2]. As FES is new technology its annual sales are less than the AFO market but they are growing with approximately 20% per year. Depending upon the design and facilities AFO’s costs are between $50 & $500 [4]. Being very new technology, FES costs about $4500 to $5800 [5].


We are targeting AAFO to cost about $1500. The operations are going to be incepted from June 2014 with products available in January 2015. Starting with selling 250 units the first year with the growth rate of 15% per year, at the end of five years, the revenue should be close to $655,000 (Figure 7-5).

All this data indicate that AAFO has a great market opportunity to help drop foot patients. Currently we are in prototype development stage, after which we will do primary market research.

![Revenue in Dollars](image)

Figure 7-5 Expected revenue of AAFO for five years.

**Competition**

**Ankle Foot Orthosis:**

The most commonly used treatment option for drop foot patients is ankle foot Orthosis. AFOs are externally applied, and are intended to control the position and motion of the ankle, compensate for weakness, or correct deformities. These appliances are designed to assist human motions and to rehabilitate and correct the position of the ankle.
Advantages of AFO:

- Improves ability to support body weight during initial stance
- Improves progression of foot contact during stance
- Improves ability to generate push off in late stance
- Reduces overall energy cost
- Guides the limb and reduces the number of degrees of freedom in order to simplify control problem
- Protects joint and ligaments

Disadvantages of AFO [2]:

- Gait pattern is different from that of a normal person
- does not prevent disuse atrophy of the ankle flexor muscles
- Restricts ankle movement and, in turn affects other parts


**AFO developing companies:**

**Hanger Orthopedic Group:** ([www.hanger.com](http://www.hanger.com)) was founded in Virginia during American Civil War in 1861. It is the world's premier provider of orthotic and prosthetic (O&P) services and products, offering the most advanced technology, clinically differentiated programs and unsurpassed customer service. Owning and operating hundreds of patient care centers nationwide, Hanger’s business also includes distribution centers and the largest O&P network management company in the country.

<table>
<thead>
<tr>
<th><strong>Headquarters</strong></th>
<th>Texas, USA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Products</strong></td>
<td>prosthetic, orthotics, WalkAide</td>
</tr>
<tr>
<td><strong>Revenue</strong></td>
<td>$817.4 million (2010) [1]</td>
</tr>
<tr>
<td><strong>Employees</strong></td>
<td>4300 (2010)</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td>$1,061.48 million (2010) [2]</td>
</tr>
</tbody>
</table>

**Otto Bock Health Care:** ([www.ottobockus.com](http://www.ottobockus.com)) is a German prosthetics company situated in Duderstadt. It was founded in 1919 by its namesake prosthetist, Otto Bock. It was created in response to the large number of injured veterans from World War I. The Otto Bock Corporation has been responsible for several innovations in prosthetics, including the pyramid adapter (a highly adjustable linkage for prosthetic parts) and the C-Leg, a computerized knee that adaptively varies its passive resistance to suit the patients' different walking gaits.

[1] *Hanger orthopedic group annual report 2010*

[2]*http://stockreports.nasdaq.edgar-online.com/HGR.html*
Table 7.2 Otto Bock Health Care Company Details.

<table>
<thead>
<tr>
<th>Headquarters</th>
<th>Duderstadt, Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products</td>
<td>wheelchair, prosthetic, orthotics</td>
</tr>
<tr>
<td>Revenue</td>
<td>€ 529.0 million (2010) [1]</td>
</tr>
<tr>
<td>Employees</td>
<td>4330 (2010)</td>
</tr>
<tr>
<td>Total Assets</td>
<td>$23,169,130 [2]</td>
</tr>
</tbody>
</table>

**Anatomical Concepts: (www.anatomicalconceptsinc.com)**

Anatomical Concepts, Incorporated was founded in 1990 as a manufacturer/supplier of quality custom-fit and custom-made orthoses. The corporation is dedicated to providing medical professionals with custom-fit and custom-made AFO and KAFO that allow for adjustability and patient ambulation. It is headquartered in Poland, Ohio and from this location services accounts throughout the United States and abroad. In 1995, the company began an international business relationship and now has a presence in Australia, Germany, Sweden, Belgium, Italy, Japan and the UK. The company offers 16 different designs of AFO.


Active Ankle Foot Orthosis:

Blaya et al., in the MIT media lab has developed a powered ankle-foot orthosis based on a Series Elastic Actuators. The MIT group developed, Series Elastic Actuator (SEA) for the AAFO to realize variable stiffness (Figure 7-7 a). This actuator is comprised of a DC motor, mechanical links and springs. A control algorithm was developed to create proper stiffness for each part of the walking (gait) cycle [1]. Although this AAFO shows promising results in a lab environment, the actuator weighs 2.6 kg and requires bulky batteries and electronics for operation. In addition, the patient may not be able to sit while wearing this AAFO because the size and shape of the actuators is too large. Another AAFO which uses pneumatically powered lower limb exoskeleton which was developed in the Human Neuromechanics Laboratory at the University of Michigan (Figure 7-7 b). This AAFO is actuated by McKibben Muscles which are pneumatic actuators. One pneumatic actuator provides a plantar flexion torque and a second actuator provides a dorsiflexion torque [2]. The study has shown promising results in gait rehabilitation, human motor adaptation and muscle activations. However, the size and weight of the pneumatic auxiliary components, such as the compressor, is prohibitive for outdoor walking and hence can only be used in rehabilitation purposes.


Figure 7-7 Examples of Active AFO’s: (a) Series Elastic Actuator (b) McKibben pneumatic actuator.

Advantages of AAFO:

- Variable stiffness during walking

Disadvantages of AAFO:

- Can be uncomfortable to wear
- Poor cosmetics
- Bulkier footwear

FES:

Functional electrical stimulation (FES) has been described as the electrical stimulation of a muscle deprived of nervous control for providing muscular contraction and thereby producing a functionally useful movement. The most common treatment is to support the foot with lightweight leg braces and shoe inserts, called ankle-foot orthotics. Functional electrical stimulation (FES) is a technique that uses electrical currents to activate nerves innervating extremities affected by paralysis resulting from spinal cord injury (SCI), head injury, stroke and other neurological disorders.
Advantages of FES [1]:

• Improved gait
• Increased mobility
• Increased strength and endurance
• Decreased energy expenditure
• Prevention, retardation, and/or reversal of muscle atrophy
• Maintained or increased joint range of motion
• Increased confidence walking in crowds, upstairs, or on uneven surfaces

Figure 7-8 (a) Bioness L300 [2] (b) WalkAide Bi-Flex Cuff [3].

Disadvantages of FES:

• Rapid muscle fatigue
• Patients cannot walk for a long duration.
• Inadequate control of joint torques for reliable and repeatable limb motion and body support

FES companies:

Bioness Inc: (http://www.bioness.com)

In 2004, a group of visionary leaders established Bioness Inc. to help individuals with neurological impairments regain their independence. With the support of entrepreneur and philanthropist Alfred E. Mann, Bioness was formed to develop and distribute neuromodulation devices into the field of rehabilitation. Bioness partnered with NESS Ltd. to launch two devices in the United States: the NESS H200 Hand Rehabilitation System to help those with upper limb impairments and the NESS L300 Foot Drop System to assist those with foot drop regain a more normal gait. In January 2008, Bioness took this partnership a step further by acquiring NESS Ltd., enabling Bioness to bring together its new products undergoing development with the NESS commercial products.

Innovative Neurotronics, Inc: (http://www.walkaide.com)

Innovative Neurotronics, Inc. provides neuromuscular products. It offers WalkAide, a medical device that is used for improving the walking ability of people suffering from drop foot, as well as helps to restore mobility and functionality for people with paralysis due to multiple sclerosis, stroke, spinal cord injury, traumatic brain injury, and cerebral palsy. Innovative Neurotronics, Inc. offers its products through a network of distributors and trained facilities in the United States, Canada, Australia, Europe, Israel, Korea, Puerto Rico, and South America. The company was founded in 2004 and is based in Austin, Texas. Innovative Neurotronics, Inc. operates as a subsidiary of Hanger Orthopedic Group, Inc.
Uniqueness of Smart AAFO:

Active ankle foot orthosis (AAFO) is a smart orthotic device designed for gait improvement in drop foot patients. In this product features of the current AFO are modified in order to get more efficiency by embedding smart materials. Using an inherent stiffness variation of SMA in an AFO, the impedance of the orthotic joint can be modulated throughout the walking cycle to treat drop foot gait, making it an Active AFO. Mainly two dimensions will be changed which are features and technology. These changes in turn will also increase the price of the product to some extent. Newness will be by changing the performance capabilities of the product, as SMA applications will help patients walk with a better gait pattern. Hence Smart Orthosis has the potential to surpass the existing solutions of orthotic devices.

Regulatory Issues

This device is classified as a Class II medical device requiring a Premarket Notification (510 k) Application submission to the US FDA and such FDA clearance is required prior to market this product in the US. The establishment registration and listing of products generic category or classification name is required prior to marketing in the United States. Compliance to device labeling requirements is also needed. The applicable functional verification testing of output and operational characteristics need to be performed as per FDA consensus standards.


Management Team and Organizational Structure

Smart AAFO is the brainchild of Dr. Mohammad H. Elahinia, PhD in Mechanical Engineering, who is an expert on shape memory alloy material and its applications in orthopedics, and will take charge as President.

Minal Y Bhadane & Vivek Palepu, who are pursuing doctorate of philosophy in biomedical engineering conceived this idea of Smart AAFO and will take charge of Smart Orthosis, Inc. as Vice Presidents (Development and support).

Other members in the organizational team include:

- Mr. P.V.S. Rao - Chief Financial Officer (CFO), who is a chartered accountant (CA) and has an industry experience of more than 20 years.
- Mr. Naresh Kumar Pagidimarry - Regulatory Affairs Specialist (RA).
- Dr. John Jaigley – Manufacturing Manager.
- Board of directors includes Dr. Vijay K Goel, Dr. Sameer Hefzy, Dr. Padanilam.
- Boards of Advisors include Dr. Sonny Ariss, Dr. Armstrong.
- Attorney – Aditya Pawar

Marketing Plan

Smart orthosis is a new concept for treating drop foot patients. Convincing the medical community that this device is a better solution compared to AFO and FES may need more efforts. Publishing technical data along with motion analysis results could be a good start connecting with the industry:

We will publish the research papers in related journals such as:

- Journal of Biomechanics
• ASME Journal of Biomechanics
• IEEE transactions of biomedical engineering
• Journal of rehabilitation research and development
• ASME Journal of Medical Devices
• Journal of Prosthetics and Orthotics

We will give presentations in technical conferences held every year:
• Design medical devices conference (Minneapolis, MN)
• The International Conference on Shape Memory and Superelastic Technologies (SMST™)
• Annual meeting of “American Academy of Orthotists & Prosthetists”
• The Biomedical Engineering Society annual meeting

Trade shows are the prime area where orthotic devices can be launched. Modified products will be launched in a couple of trade shows which are held once a year such as:
• The American Orthotic & Prosthetic Association National Assembly and Exposition
  (http://www.aopanet.org/index.php?option=com_content&view=article&id=70&Itemid=87),
• Midwest Podiatry Conference (http://midwestpodconf.org/).

We can display our product and find out the reaction of the buyers. Even though the end users are drop foot patients, doctors are the main targets who will suggest our patients to wear our AFO. Hence this will be a very good opportunity to get in touch with doctors, experts in this field and get their feedback.
Advertising on websites and in trade shows will increase the sales. Hiring experienced staff will keep the device technologically updated and hence it will have a steady market growth.

Passive AFO’s cost varies from $30 to $500, while FES systems for home use costs around $4500-$5800. We are targeting the selling price of smart AAFOs around $1500. Detailed components cost breakdown will be as follows:

Table 7.3 Components costs breakdown for smart orthosis.

<table>
<thead>
<tr>
<th>components</th>
<th>price per unit ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base AFO</td>
<td>350</td>
</tr>
<tr>
<td>Sensors</td>
<td>10</td>
</tr>
<tr>
<td>activation mechanism</td>
<td>50</td>
</tr>
<tr>
<td>SMA wire</td>
<td>5</td>
</tr>
<tr>
<td>Connector</td>
<td>10</td>
</tr>
</tbody>
</table>

The cost specified above is greater than the AFO device, but is less than the FES device which enables customers to choose a better option at a more competitive price.

**Patents and Proprietary Issues**

Currently we are in the phase of applying a provisional patent. Once the prototype is developed and tested on patients we will modify the product and apply for a patent. With this patent we will form a partnership with existing leaders in the orthotic field.

To monitor current technology patents, a search was performed using the following websites: uspto.gov, google search, www.freepatentsonline.com.
- Active control of AFOs is already proposed in the US patent: 7,650,204 (Active control of an ankle-foot orthosis January 19, 2010)

- Applications of smart materials such as shape memory alloy has been started from the last couple of decades e.g. US patent: 5,103,807 (Shape memory alloy orthotic device, April 14, 1992), US patent: 6,379,393 (Prosthetic, orthotic, and other rehabilitative robotic assistive devices actuated by smart materials April 30, 2002).

- Many designs of AFO are available today in the market, few patents with the great designs were found, which can be modified by applying shape memory alloy wire e.g., US patent no: 5088479 (Ankle & foot orthosis) 4289122 (Ankle foot orthosis).

Product Design and Development Plans

From the research done so far we are expected to finish prototype development within one year. Once the prototype is ready, we will file an application for a patent to protect the technology. With the prototype we will go for product use tests in order to gain more feedback. Experience of group of patients will give insight to different virtues of the product. This feedback will be used for product improvement in phase two development. With the improved product we will attend trade shows for product launch.

Cash of about $300,000 will be raised either from business angels or venture capitalists in order to start the production. Considering the long term growth & increasing R&D expenditure in orthotic industry, [1] to become leaders in the industry we will continue to focus on R&D.
Figure 7-9 Milestones and funding source.

**First year – Prototype development & Evaluation**

Employing the latest technology such as smart material in the field of orthotics makes AAFO development a technological product innovation. This is an improvement in current AFOs in order to help drop foot patients walk like a normal person.

[1] Icelandic Ossur hf Lends its Support to Neuroprosthetics Market, by David Pope, editorial director

http://www.neurotechreports.com/pages/Ossur_profile_bionics_neuroprosthetics_Victhom.html
Figure 7-10 shows a flowchart that will be followed in this process. The first step will be to find out the optimum combination of wires, which then will be tested on the current design. From the results of the testing, changes will be made in the design. The corrected design will be tested on normal person and on drop foot patients. From the feedback of the gait analysis revisions will be made in the design in order to meet the requirements. All the test procedures will be repeated after changes are made giving the optimum prototype. As this project is funded by the National Science foundation along with UTIE prize money, all the expenses till prototype development will be covered under this.

Figure 7-10 Steps for prototype development.

**Underlying Technology:**

AAFO is mainly composed of basic AFOs with SMA wires, along with control mechanism.

Components of the system are shown in figure 7-11:

- Plastic hinged AFO as a basic structure which will be custom fitted to each patient.
• Shape memory wire combinations running over pulley systems
• Gyroscope and three force resistive sensors (FSR) and for gait detection
• A controller box holding a programmed chip for precise actuation of SMA wires.

The gait cycle begins when one foot contacts the ground and ends when that foot contacts the ground again. For drop foot patients to walk like a healthy person we need external assistance in two phases of the gait cycle. To determine at what stage the activation is needed sensors are used. FSRs and gyroscopes help to detect events in the gait cycle. At heel strike, SMA will provide controlled dorsiflexion to avoid drop foot which will be deactivated at flat foot. At heel off, SMA wires will be turned on till the next heel strike. This way we get the stiffness pattern at an ankle joint that is similar to stiffness in a healthy person.

Currently we are in prototype development stage. We have finished preliminary testing of individual components. We have done motion analysis on five healthy persons to find out ankle stiffness characteristics which needs to be achieved by AAFO, shown in figure 7-2.
Ten combinations of SMA wires of shape memory (SM) and superelastic (SE) effects were simulated in COMSOL using the Tanaka based constitutive model figure 7-12. An algorithm to predict which combination of wires is best suited for this design was developed using MATLAB.

Experiments were conducted on SMA wires to find out the effects of change in temperature which can be used for stiffness variation. By using a mechanical assembly stiffness characteristics of the AFO were established and effect of adding SMA wires was evaluated. First prototype was tested on drop foot patient and primary results showed effectiveness of the SMA wires to modulate the stiffness of the AFO. Developing a control strategy and modifying design will be the next steps of this project.

Figure 7-12 Overall stress strain behavior of different combinations of wires.

A team of four people will perform this entire task together for making the prototype within a six months span (Table 7.4). Material cost for these experiments will go up to $5000 based on the cost of parts required which are planned to get support from the existing National Science Foundation (NSF) grants.
Table 7.4 Prototype development timeline.

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**Second Year – Phase 2 and FDA submission**

Based on the mechanical testing and patient testing, the collected data will be analyzed. The analyzed data will be screened thoroughly in terms of safety and effectiveness. If the data is within the standards of expected output, the FDA submission will be done. The analyzed data is also investigated for further modifications and Phase 2 design and development will be initiated. This loop continues till the satisfactory results are obtained.

The necessary resources will be procured with the help of funding raised from SBIR/Private grants and other bootstrapping techniques like B-Plan competitions.

**Third Year – Production Start-up**

After getting FDA approval, the initial promotion will be done to get the order of sales through the established network of clinicians. To meet the small demand, an incubator space will be procured. The components required for assembling the final products will be ordered. Then, the FES and SMA technology will be embedded by using a fabricating room facility at the University of Toledo’s engineering campus. Finally, all the parts will be assembled in the assembly room. All the facilities are intended to be leased in and around the University of Toledo, OH campus to reduce the cost price of the final product.
Fourth Year & Fifth Year – Expansion, Aggressive Marketing, Research and Development

With the product entry into the market with initial sales through an established network of clinicians, feedback will be sought from end users as well as clinicians. Necessary feedback will be utilized efficiently for R&D. Simultaneously; aggressive marketing will be planned by gaining access to several other networks of physicians and distributors of orthotic devices in the local markets.

Technical service:

Once the AAFO is in production, it will need to be customized for each drop foot. Patients will be asked to come to the facility for the measurements. After the AAFO is ready, patients will be fitted and given some training. If some problems persist, the AAFO will be modified for better performance of the patient.

Manufacturing and Operations Plan

Smart Orthosis’s intention is to establish the main facilities in and around the University of Toledo campus due to three main reasons: 1) cost 2) location 3) expandability. The facilities include incubator space to carryout office requirements, seeking permission for usage of fabricating facility to embed the SMA, and finally an assembling facility to assemble all the components.

Knowledge of the technology and IP are the important aspects needed for this product. Other inputs will include expert recourses in research, marketing, finance, etc.
**Pattern of consumption:**

There will be no negative change in the current pattern of consumption of AFOs. Once the patient is diagnosed with drop foot and recommended for an AAFO, leg measurement will be taken. After about a week the patient will be fitted with an AAFO and given some training. If some problems persist, modifications will be done for better performance of the patient.

**Operations Cycle**

Figure 7-13 shows the overall manufacturing process along with marketing strategies. Starting from the prototype design, patient & doctor feedback will help us to develop an efficient product. Patient specific products will then be produced using the Just In Time (JIT) strategy. Marketing will focus on trade shows and conferences for gaining more market and also to get feedback on products, which will be used for total quality management. The cycle shown below clearly depicts the operations carried out within the company.
Financial Plan

Detailed financial forecasts for the first several years of operation have been created utilizing figures from projected sales forecasts, pricing strategies, detailed cost estimates, and budgets. Prototype development is supported by NSF funding and phase two development can be funded through SBIR grants of about $300,000.

Break-even Analysis

We expect the break-even point for the company to be in three years with initial funding of $300,000. The break-even analysis is summarized in Table 7.5. Beyond the projected
financials presented here, it is expected that Smart Orthosis begin to be extremely profitable once a strong brand is established.

Table 7.5 Break-even analysis.

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Pro Forma Monthly Cash Flow statement:

Equity capital raised before the production start up should be enough to finance company’s operations. The company sales forecast predicts the increase up to 330 units generating profit of $300,000 in 2017. First year net profit will be around $80,000. This figure is expected to climb steadily over next five years.

Table 7.6 Monthly ProForma cash Flow Statement: first year.

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Pro Forma Yearly Income Statement:

Table 7.9 Yearly ProForma Income Statements over a 5 year period.

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Critical Risks

The U.S. ankle supports and braces market is mature, and because of its low barriers to entry, there are a high number of competitors in the market.

- The primary users of ankle braces and supports are the patients themselves, but professionals involved in the recommendation, prescription, and resale of the devices include orthopedic surgeons, physical therapists, athletic trainers, rheumatologists, podiatrists, general practitioners, orthotists and prosthetists (O&Ps), and DME/HME dealers [1].

- One of the barriers could be convincing the medical community that this device is a better solution compared to AFO and FES. This might take some time but could be resolved by going to trade shows, and publishing research papers.

- Important barriers relating to medical devices is getting insurance coverage. But as per the research AFO [1] and FES [2] systems are covered by insurance hence the possibility of getting insured increases. This issue of advanced devises is addressed in [3].

- Technology might not work as expected and might need revisions or change in concept.

- Getting FDA approval might take some time but FES and AFOs are already under the approval category [4].

**Proposed Company Offering**

The company Smart Orthosis requires the major funding of $1,000,000 at the beginning of the third year. Out of the total funding sought, a quarter million will be used for R&D, the second quarter million will be used for the facility procurement, the following quarter million will be used for aggressive marketing of the product and the last quarter million will be utilized for the operations during the long production cycle of the products. The company will start getting ROI from the end of the 4th year.

The company will give about 30% of the stock of the company to outside investors.


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