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**THE MODIFICATION, SYSTEM SOFTWARE DEVELOPMENT,  
VALIDATION, AND CLINICAL TRIAL OF A NOVEL ANKLE STIFFNESS  
TESTING DEVICE**

A Thesis  
Submitted to the Graduate Faculty of the  
Louisiana State University and  
Agricultural and Mechanical College  
in partial fulfillment of the  
requirements for the degree of  
Master of Science in Biological and Agricultural Engineering  
  
in  
  
The Department of Biological and Agricultural Engineering

by  
T. Tyler Clement  
B.S., Louisiana State University, 2006  
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## **ABSTRACT**

The purpose of this project is to modify, validate, and gather preliminary clinical data on a novel ankle stiffness device that measures stiffness (torque / degree) and range of motion (ROM) of the ankle joint complex (AJC). The initial device was designed by a mechanical engineering design group at Louisiana State University in 2006, but had not been tested on human participants. Clinical evaluation of the ankle joint is important in patients afflicted with diabetes mellitus, Hansen's disease, or peripheral neuropathies. The combination of peripheral neuropathies, decreased ankle range of motion, and increased stiffness pose a threat to these patients, and often plays a significant role in ulcerations and other pathologies of the foot.

Using instrumentation, the data gathered from the device was validated to ensure accurate ankle parameter measurements. Testing of normal participants and participants with one previously injured ankle was then undertaken. Injured participants had normal sensation with one non-injured and one previously injured ankle and were used as their own control. Testing (typically 45-60 minutes) involved securing the participant's ankle in the device, and measuring the torque as the ankle was passively rotated through the participant's ROM, in both plantarflexion and dorsiflexion.

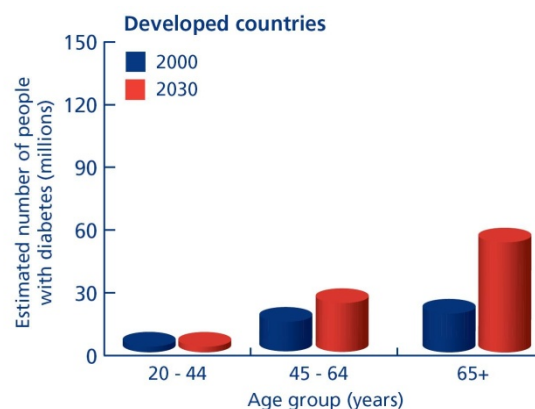
Torque versus Range of Motion (TROM) curves were mathematically fit using regression analysis and analyzed to assess differences between injured and uninjured ankles. TROM curves were compared based on the average torque, angular velocity, dorsiflexion and plantarflexion slopes, and the hysteresis in the functional range of motion of ankle rotation.

Significant difference, at a  $\alpha = 0.05$ , was not found in these parameters across all ankles including healthy, injured (normal), and injured. However, significance was found between the unstretched and stretched treatment across the all groups at an  $\alpha = 0.05$  in average torque (unstretched:  $148.13 \pm 4.78$  in\*lb and stretched:  $143.73 \pm 4.78$  in\*lb,  $p = 0.0442$ ) and dorsiflexion slope (unstretched:  $3.18 \pm 0.21$  in\*lb/deg and stretched:  $2.70 \pm 0.21$  in\*lb/deg,  $p = 0.0006$ ). The result of this study validate that the device can determine biomechanical properties of the AJC, and could be utilized in a clinical environment.

## CHAPTER 1. INTRODUCTION

### 1.1 Diabetes Mellitus, Hansen's Disease, and Peripheral Neuropathy

Diabetes mellitus (DM), the most common of the endocrine diseases, is estimated to affect 180 million people worldwide with this figure forecasted to double by 2030 (see Figure 1) (Organization 2006). DM Type II is a metabolic condition in which the pancreas fails to produce sufficient insulin, which is a peptide normally secreted in an effort to regulate elevated blood glucose levels. Insulin is the hormone responsible for increased glucose storage, synthesis of proteins, as well as the inhibition of lipolysis and gluconeogenesis. In individuals afflicted with the Type II or adult-onset form of diabetes, a lack of insulin is typically accompanied with hyperglycemia, elevated blood sugar, which is a central trait to DM. On the other hand, Type I or juvenile-onset, occurs when the body cannot utilize the insulin produced effectively (Bynum 1993). In addition to Type I and II diabetes, gestational diabetes, a transitory form of the illness, which is present only during pregnancy, can occur; however, it is irrelevant in the development of foot ulceration as it is only a temporary manifestation (Organization 2006). The uncontrolled glycemic levels present in these conditions have a number of repercussions and are especially detrimental to nerves and blood vessels as well as the body's organs and systems (Bynum 1993).



**Figure 1: Diabetes Mellitus Forecast in Developed Countries (Organization 2006)**

Risk factors for Type II DM include obesity, age, sedentary lifestyle, family history, ethnicity, high blood pressure, and high cholesterol (Control 2008). However, these differ for Type I DM where the primary cause is the autoimmune destruction of the islets of Langerhans, the insulin-producing cells located in the pancreas (Bynum 1993). Individuals with DM are plagued with a myriad of health related problems including retinopathy, neuropathy, decreased blood flow, kidney failure, dental disease, high blood pressure, heart disease, and stroke (CDC 2008). Diabetic retinopathy is a condition where hyperglycemia results in compounded damage to the blood vessels found throughout the eye, culminating with visual impairment or blindness. Diabetic neuropathy is another condition of DM where hyperglycemia causes nerve damage resulting in decreased sensation, especially in distal members, such as the hands and feet. Diabetic neuropathy and decreased blood flow (Organization 2006) work in concert with increased stiffness and decreased range of motion (ROM) (Birke, Franks et al. 1995; Trevino, Buford et al. 2004; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006) to significantly increase the chance of foot ulceration in the affected population (Organization 2006). Foot ulceration is of primary concern with DM patients, being the most common cause for hospital admission in many countries (Boulton 1992), as these ulcerations provide an ideal environment for infection by aerobic and anaerobic bacteria (Gadepalli 2006). Of patients presenting to the hospital with diabetic foot ulcers, 66% have a past medical history of one or more similar lesions (Boulton, Betts et al. 1987). If left untreated, these infections can eventually lead to irreparable damage and subsequent amputation (Organization 2006). Diabetic amputations comprise 50% of all non-traumatic amputations in the United States with the DM patients having a 15 times higher

risk than normal (Boulton, Betts et al. 1987). The mitigation of this circumstance is one of the major end goals of this project.

In the United States in 2007 alone, direct medical costs secondary to DM exceeded \$116 billion while indirect costs, including disability and work loss, exceeded \$58 billion, resulting in a net cost of \$174 billion dollars (CDC 2008). With a projected increase in the mortality rate of 50% over the next 10 years, China alone faces an economic loss in excess of \$558 billion dollars due to diabetes and secondary complications (Organization 2006). In addition to the staggering economic cost, the decrease in the quality of life of those affected is a growing social concern in the case of this illness. In 2005, the death toll related to DM reached a staggering 1.1 million people worldwide (Organization 2006).

Peripheral Neuropathy (PN), a disease closely related to DM, refers to any condition that affects the nerves outside of the central nervous system (CNS). Generally, patients experience symptoms of either a near total lack of or excessive sensation. While DM is the most common cause of this condition, there exists a plethora of causative factors including nutritional deficiencies, gastrointestinal disorders, and autoimmune conditions, genetic disposition, infectious diseases, toxins, and drugs. In addition to these factors, the most common cause of PN in the undeveloped world is leprosy, also known as Hansen's disease (HD) (Latov 2007). Hansen's disease is the result of an infection of bacterium *Mycobacterium leprae*, which affects nerve cells (Hays and NetLibrary Inc. 1998). This bacterium is transmitted through mucosa, however it is not highly infectious and certain genetic factors offer resistance. HD is now curable by multidrug therapy (MDT) in as little as six months and following the initial dose, are no longer infectious. However, the consequences of HD are permanent as a result the damage done to neural tissue which typically does not heal (Organization 2009).

## **1.2 Ankle Anatomy**

The ankle joint complex (AJC) consists of talocalcaneal and talocrural joints which are constrained by the articulating surfaces, numerous ligaments surrounding the joints, and musculo-tendon forces. The distal ends of the tibia and fibula form the ankle joint, an idealized hinge joint. The ankle joint is composed of several main ligaments; the deltoid or internal lateral, external lateral, anterior, and posterior ligaments (Gray, Pick et al. 1987). In addition to the ligamentous tissues which help to constrain the ankle, there is musculature which also serves as limiting factors to joint motion. In PF or extension, the limiting factors are the anterior joint capsule, anterior portion of the deltoid, anterior talofibular ligaments, and the tibialis anterior. In DF or flexion, the limiting factors are the posterior joint capsule, deltoid, calcaneofibular, posterior talofibular ligaments, gastrocnemius, and soleus muscles (Clarkson 2005). According to Johns and Wright (1962) the contribution of musculature is not the sole factor that determines joint stiffness. The joint capsule, tendons, and skin are also contributing factors to total joint stiffness (Johns and Wright 1962).

## **1.3 Rheological and Muscular Characteristics of Biological Systems**

Rheology, defined as the study of the flow of matter, has been utilized in a variety of disciplines to define core properties of materials. Many materials utilized in engineering applications exhibit a linear relationship between stress and strain, behaving linear elastically. This characteristic is important in design and can be described by Hooke's Law (see Equation 1) (Gere and Timoshenko 1997).

$$\sigma = E \times \varepsilon \quad [Eqn.1]$$

Where  $\sigma$  is axial stress,  $E$  is the modulus of elasticity, and  $\varepsilon$  is axial strain.

A crucial concern that had to be accounted for in this study is that viscoelastic properties of biological materials do not behave in a Hookean manner, the AJC being no exception. Viscoelasticity is the ability of a material to exhibit both elastic and viscous behavior. This property of biological systems allows for resiliency and low hysteresis, but resulting in energy loss through cyclic repetition. As a result of this property, under conditions of loading and unloading cycles, hysteresis or energy loss occurs and is rate dependent. While crystalline materials and ideal rubbers are described by stress and strain at a given temperature, viscoelastic biological materials require an additional component for evaluation, time. Viscosity is defined as the ratio of shear stress to velocity gradient (see Equation 2) (Vincent 1981).

$$G = \frac{\tau}{y} = \frac{F/A}{dx/dy} \quad [Eqn.2]$$

Given the time dependent behavior of the AJC, it is important to consider possible musculature activity. The myotatic stretch reflex is a mechanism which prevents muscles from being overextended resulting from quick motion. Proprioceptors, or muscle spindles, are responsible for this monosynaptic stretch reflex (McAtee and NetLibrary Inc. 1999).

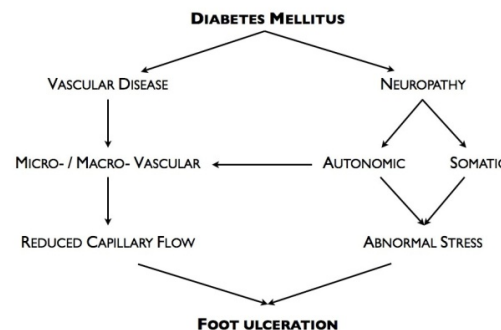
Joint stiffness is directly related to temperature in the joint. Wright, et al. (1971) found, relative to 33°C, at 18°C there was a 10% to 20% increase in joint stiffness and at 45°C there was a 20% decrease in stiffness. Additionally, there was no significant decrease in joint stiffness following muscle heating, suggesting these changes are due to alterations in the structural properties of the joint (Wright 1971).

#### **1.4 Foot Ulceration and Limited Joint Mobility**

Approximately 50% of DM patients are also affected with peripheral neuropathy (PN), a condition characterized by sensation loss in the limbs (Organization 2006). Neural, mechanical,



and vascular abnormalities are factors having primary roles in ulceration formation (Thomson 1991). These abnormalities are not mutually exclusive and often work in concert to cause ulceration (See Figure 2). PN is solely a permissive factor in the formation of ulcers in extremities where ischemia is not present (Boulton 1992; Birke, Franks et al. 1995). While changes in mechanical properties affect the structure and function of the ankle complex as a whole, the causative agent in the formation of ulceration is the presence of neuropathy and subsequent lack of protective threshold (Boulton 1992).



**Figure 2: Diabetic Foot Ulceration Model - Adapted from Thomson, 1991 (Thomson 1991)**

Changes in mechanical properties of the foot and ankle have long been associated with DM, HD, and PN (Wright and Johns 1961; Ctercteko, Dhanendran et al. 1981; Boulton, Betts et al. 1987; Birke 1988; Delbridge, Perry et al. 1988; Fernando 1991; Thomson 1991; Veves, Murray et al. 1992; Young, Cavanagh et al. 1992; Lin, Lee et al. 1996; Salsich, Mueller et al. 2000; Trevino, Buford et al. 2004; Hajrasouliha, Tavakoli et al. 2005; Nube, Molyneaux et al. 2006; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006). Decreased ankle ROM and increased stiffness are the biomechanical properties that are most commonly connected with these diseases. Limited joint mobility (LJM), deformity, callus formation, motor neuropathy, weight, and height have been shown to be related to foot pressure and may contribute to plantar ulceration (Birke, Franks et al. 1995).

Diabetic neurotrophic ulcers are confined almost exclusively to plantar surfaces of the first metatarsal head (MTH) and toes, suggesting that abnormal pressure of the diabetic foot may contribute to the etiology of foot ulcers (Boulton, Betts et al. 1987). In fact, Fernando (1991) demonstrated a strong association between LJM and elevated plantar foot pressure in the diabetic foot (Fernando 1991). The first MTH is one of the most common sites of ulceration in diabetic patients (See Figure 3) (Ctercteko, Dhanendran et al. 1981; Birke and Sims 1986; Birke, Franks et al. 1995). However, while these strong correlations exist, abnormal plantar foot pressures alone do not lead to foot ulceration (Fernando 1991).

Foot ulceration is the result of a combination of factors, including increased stiffness and decreased ROM, and is not a mere causal result of DM or PN. It is important to note that a mere change in ankle parameters does not definitively culminate in ulceration and subsequent amputation (Boulton 1992). While the etiology of LJM is unknown, current evidence favors a relationship with collagen abnormalities, specifically non-enzymatic glycosylation of protein that occur in diabetes. These connective tissue abnormalities are recognized as a widespread phenomenon in diabetes (Delbridge, Perry et al. 1988).



**Figure 3: First MTH Ucleration (Hupp)**

Patients with any degree of PN are at potential risk for development of ulceration due to a lack of protective threshold (see Figure 4). The combination of neuropathy, decreased ankle range of motion (ROM), and increased stiffness pose a formidable threat to patients with DM, as the development of ulcerations is the result of repeated damage to the soft tissue of the foot. Due to the decrease in the flexibility of the ankle joint, higher than normal pressures are exerted on metatarsals. This can lead to tissue damage complicated by the lack of sensation and poor circulation, creating injuries that are unable to repair and can culminate in ulceration. Without proper wound care, the ulceration provides a hospitable environment for bacterial growth, which can then lead to amputation.



**Figure 4: Neurotrophic Ulceration (Hupp)**

### **1.5 Joint Stiffness and Range of Motion: Current State of the Field**

There have been relatively few studies dedicated to the exploration of the relationship between ankle stiffness and diseases such as DM, HD, or PN, below are several which are related.

#### **1.5.1 Siegler (1988)**

Siegler, et al. (1988) had several main goals; to investigate including the ROM of the foot-shank complex (FSC), kinematic coupling characteristics of the FSC, and lastly to relate

ankle and sub-talar joints to the motion of the FSC. Using 15 fresh cadaver leg limbs, 4 sonic emitters were used to track the position of the FSC and pneumatic actuators were utilized to apply controlled moments to the calcaneus during non-axially loaded movement. The actuators were engaged and driven until no further motion was observed. Dorsiflexion ROM had a mean of  $24.68^{\circ}$  and SD of  $3.25^{\circ}$  while plantarflexion ROM had a mean of  $40.92^{\circ}$  with a SD of  $4.32^{\circ}$ . (Siegler, Chen et al. 1988)

### **1.5.2 Lundberg (1989)**

Lundberg, et al (1989) proposed to study the ankle axis of the talocrural joint by roentgen stereophotogrammetry in eight healthy volunteers through flexion in pronation and supination of the foot through medial and lateral rotation of the leg. One of the most noteworthy finding of this study is that the axis of rotation in PF and DF, both in supination and pronation, changes throughout the ROM. Furthermore, these changes in axes of rotation intersect, in coronal and sagittal plane projections, on a small area in the trochlea of the talus. Unfortunately, statistical values of these variables are not reported, but a range is presented of rotation about the helical axes between  $3^{\circ}$  and  $18^{\circ}$  per  $10^{\circ}$  interval. (Lundberg, Svensson et al. 1989)

### **1.5.3 Inman (1976) and Johnson (1991)**

Inman (1976) set to investigate the empirical axis of rotation of the AJC. He used 107 cadaver leg limbs for the study and measured the angle between the midline of the tibia and the plane of the plafond of the tibia. The angle between this and the empirical axis differed by  $11.3^{\circ} \pm 4.1^{\circ}$ , meaning that the actual axis of rotation of the ankle and the lower facet of the tibia were not collinear (Inman 1976). A noteworthy finding of the study was that the empirical axis passes distally to the tibia-fibula malleoli and can be located for clinical purposes through palpation (see Figure 5) (Stiehl and Inman 1991).

#### **1.5.4 Vandervoort, et al. (1992)**

Vandervoort, et al. (1992) set out to determine a method to quantify passive ankle stiffness. A custom designed machine was utilized for this study that consisted of a potentiometer and strain gauge. Exact device specifications or images are not provided in the study's published paper. However, the premise of the device is a torque versus position measurement. The passive ROM for this study was defined as the maximum deflection before muscle contraction, participant discomfort, or heel lift was seen. A total of 179 individuals, 94 males and 85 females, were divided into 5-year age groupings from 55 to 85. The study found a significant difference in DF ROM between 55-60 and 81-85 year old females ( $19.3 \pm 3.2$  and  $12.1 \pm 5.5$ ,  $p = 0.001$ ) and males ( $15.4 \pm 4.3$  and  $13.1 \pm 3.5$ ,  $p = 0.001$ ), respectively. Vandervoort, et al. concluded that dorsiflexion ROM decreased as a function of age in both populations (Vandervoort, Chesworth et al. 1992).



**Figure 5: Ankle Axis Malleoli Palpation**

#### **1.5.5 Salsich, et al. (2000)**

Salsich, et al. (2000) proposed to determine the relationship between DM and PN patients and ankle joint stiffness and ROM. The purpose of the study was to quantify dorsiflexion ROM and passive ankle stiffness with an experimental group containing patients with DM and PN and

an age-matched control group. A total of 34 participants, 17 in each group, with 10 male and 7 female in the experimental group, were tested using a Kin Com dynamometer at 60° per second. Data gathered included maximal dorsiflexion angle, plantar flexor muscle excursion, and plantar flexor torque curve. The plantar flexor torque curve was bisected and two stiffness values were calculated. The study found that patients with DM and PN had a smaller maximal dorsiflexion angle ( $10.8 \pm 5.2$  and  $17.6 \pm 4.0$  degrees,  $p < 0.001$ ) and less plantar flexor muscle excursion ( $43.8 \pm 9.7$  and  $53.4 \pm 5.7$  degrees,  $p < 0.001$ ) than the control group, respectively. However, initial angle and both stiffness measurements showed no significant difference between the two groups. Salsich, et al. stated that the results of their study implied that DM and PN patients had shortened, not stiffened, plantar flexor muscles (Salsich, Mueller et al. 2000).

#### **1.5.6 Trevino, et al. (2004)**

Trevino, et al. (2004) proposed that the passive mechanical properties of the ankle in a diabetic group, derived from torque versus range of motion (TROM) curves, would be significantly different from a non-diabetic control. Utilizing a novel single-degree-of-freedom TROM device consisting of a single strain gauge and precision single-turn potentiometer previously validated by this group, data was gathered on 41 diabetic and 42 non-diabetic age-matched feet. Unlike previous studies, the dorsiflexion and plantarflexion ROM, hysteresis, and stiffness values were all calculated. Additionally, this device approximately aligns near the tibio-talar joint axis to preserve natural ankle rotation, the axis of rotation of the ankle according to Inman (Inman 1976). Also noteworthy, this study calculated a third order polynomial to determine ankle parameters. The study found a significant difference between the DM and control group in hysteresis area ( $161.7 \pm 65.7$  and  $91.1 \pm 46.9$  Nm\*degree,  $p < 0.0001$ ), dorsiflexion stiffness ( $0.9 \pm 0.3$  and  $0.4 \pm 0.1$  Nm/degree,  $p < 0.0001$ ), and plantarflexion

stiffness ( $0.7 \pm 0.3$  and  $0.3 \pm 0.1$  Nm/degree,  $p < 0.0001$ ). When normalized to the units used for this study these values become: hysteresis area ( $1433.9 \pm 584.2$  and  $806.2 \pm 416.0$  in\*lb/degree,  $p < 0.0001$ ), dorsiflexion stiffness ( $7.966 \pm 2.655$  and  $3.540 \pm 0.885$  in\*lb/degree,  $p < 0.0001$ ), and plantarflexion stiffness ( $6.196 \pm 2.655$  and  $2.655 \pm 0.885$  in\*lb/degree,  $p < 0.0001$ ). However, ankle ROM was not significantly different between the two groups (Trevino, Buford et al. 2004).

#### **1.5.7 Rao, et al. (2005)**

Rao, et al. (2005) proposed to determine the relationship between ankle joint stiffness and dorsiflexion ROM in patients with DM and PN and those without. Similarly to Salsich, et al. (2000), dorsiflexion ROM and passive ankle stiffness was determined. In addition, this study included plantar loading during gait. A total of 20 participants, 10 in each group, were age and gender matched and tested with an Iowa ankle ROM device. The study found that individuals with DM and PN have less passive ankle dorsiflexion ROM ( $6.4 \pm 6.9$  and  $19.3 \pm 3.9$  degrees,  $p < 0.001$ ) and increased stiffness ( $1.5 \pm 0.49$  and  $1.042 \pm 0.56$  Nm/degree,  $p < 0.001$ ) relative to their matched controls. While loaded under gait, ROM, stiffness, and plantar pressures were similar to their counterparts. Rao, et al. (2005) stated that their findings suggested individuals with DM and PN utilize shortened stride length and reduced push-off to normalize their plantar loading (Rao, Saltzman et al. 2006).

#### **1.5.8 Rao, et al. (2006)**

Rao, et al. (2006) compared the relationship of ankle ROM and stiffness in a DM and normal group. A total of 89 participants, 25 diabetic and 64 non-diabetic, were age and gender matched and tested using an Iowa ankle ROM device. The study found that the DM group had a decreased dorsiflexion ROM ( $5.1 \pm 8.2$  and  $11.5 \pm 5.4$  degrees,  $p < 0.001$ ) and increased passive

ankle stiffness ( $1.505 \pm 0.388$  and  $1.012 \pm 0.138$  Nm/degree,  $p < 0.001$ ) than the non-diabetic control group, respectively.

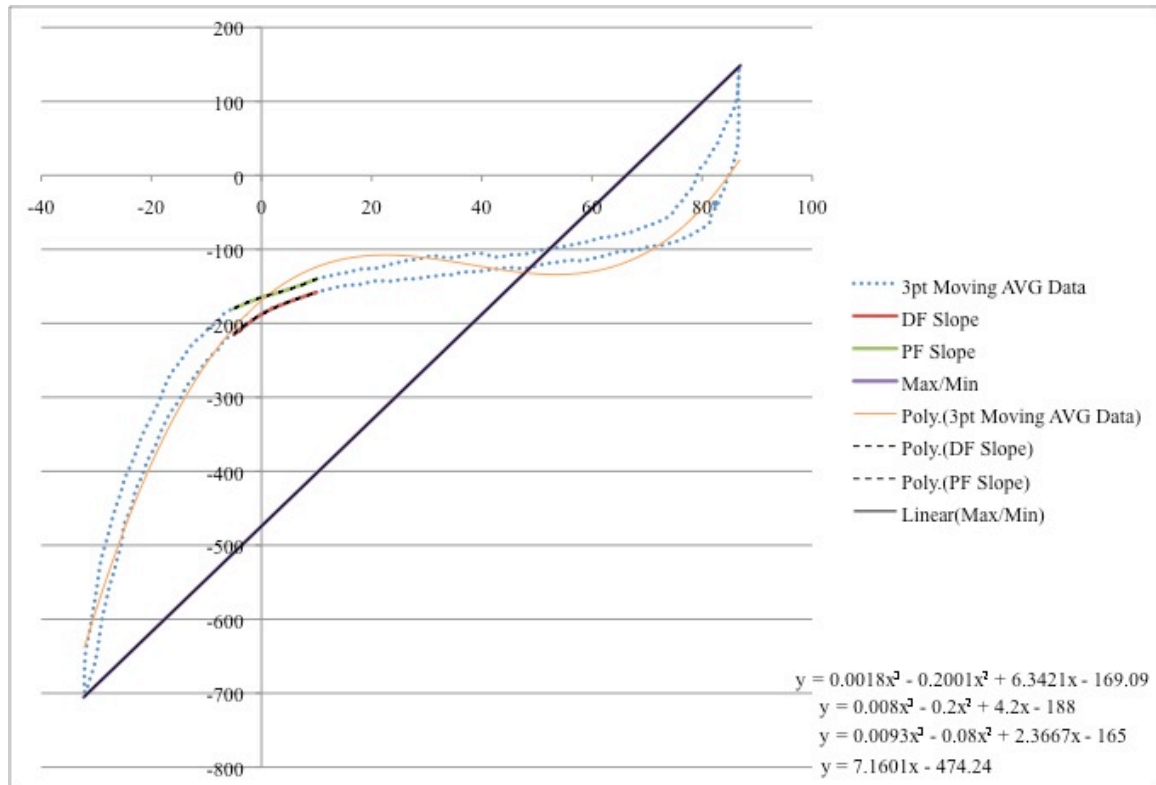
### **1.5.9 Active or Loaded Range of Motion Studies**

Other studies including Nigg, et al. (1992), Allinger and Engsberg (1993), and Nubé, et al. (2006) measure active ROM, a parameter not assessed in this study (Nigg, Fisher et al. 1992; Allinger and Engsberg 1993; Nube, Molyneaux et al. 2006). Although Allinger (1993) did study ankle ROM, the study did not provide DF/PF values; only a polyhedron with average and statistical values of the volume enclosed by the entire ROM (Allinger and Engsberg 1993).

### **1.6 Limitations in Existing Studies**

Several of the aforementioned studies utilized a device where the leg and foot were secured to provide feedback on the ROM and the application of force required to move the ankle through that ROM. However, these devices do not adequately constrain the ankle to provide for only one degree-of-freedom oriented about the ankle's axis of rotation or in the case of Trevino, et al. (2004), non-perpendicular forces are not measured. Furthermore, those devices, which do constrain the ankle, do so on an axis that is not co-linear with the axis of rotation of the ankle or do not make accommodations for its movement through the entire ROM. This limits the measurements, as they do not provide information with respect to a specific reference point, namely the trochlea of the talus. Shortcomings of previous devices include: (1) nonsystematic variation of loading, (2) subjective definition of the neutral position and axis of rotation, and (3) variability among device operators. In addition to these inadequacies, some studies provide only maximum torque and ROM values without relating the two in a torque versus ROM curve. This TROM curve information is important in fully describing the ankle axis and its parameters, including hysteresis and intermediate TROM values.





**Figure 6: Graph of Data with Superimposed Stiffness Slopes**

Furthermore, the means of stiffness calculation in previous studies assumes a single value of stiffness across the entire ROM or portions which are not accurately defined (Trevino, Buford et al. 2004; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006). The assumption that stiffness can be described by a single variable across the entire ROM is a simplistic and rudimentary characterization of the AJC. Should a single variable be utilized to describe the stiffness of the AJC, it should be done so in a well defined region of linearity so that the assessment is a reliable means of specification, independent of force application. For instance, Figure 6 shows the means of stiffness calculation for several studies and for this study. As shown, the other studies utilize either linear or cubic functions to characterize the cycle. For example, Trevino, et al. (2004) (Trevino, Buford et al. 2004) utilized a 3<sup>rd</sup> order polynomial to describe both the PF and DF cycles by a single curve, separating the curve into 3 separate linear regions. While this is

certainly better than a single value, it still over simplifies the complexity of the system by both compiling the PF and DF slopes and including the maximum and minimum ROM and torque in the slope calculations. One aspect of Trevino, et al. (2004) that is worthy of attention is the calculation of the slope in a linear region in the ROM, which does not include the maximum and minimum values. These maxima should be given consideration if they fall within the persons active ROM, otherwise the values offer little substance. This is exceedingly important to the characterization of the biomechanical properties of the ankle and safety of the participant for one main reason; these extreme values do not in fact represent the properties of the ankle, they instead represent the consistency and capability of the operator to exert force and to the degree the operator is willing to so before harming the participant.

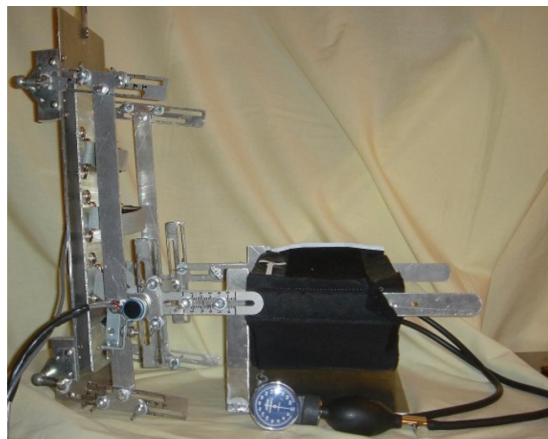
## **CHAPTER 2. TORQUE VERSUS RANGE OF MOTION DEVICE**

### **2.1 Project Rationale**

This study differs from previous studies in that a novel device was used to rotate the AJC about the ankle axis of rotation, thereby assuring that the force and ROM measured was primarily that of only the ankle and not an artifact of the device. The preliminary goal of the project was directed to test the initial version of the prototype as manufactured by an LSU Mechanical Engineering (ME) group in a clinical setting to gather data on injured and uninjured populations following the verification of device performance. However, following the verification process, it was clear that certain portions of the device were insufficiently designed or nonoperational. Several modifications to the design and accompanying programming were carried out to ensure that the data collected would be valid and the testing process and procedure would be simplified in a research or clinical setting. These modifications were carried out and instrumentation was calibrated and cross-referenced to standards.

### **2.2 Initial Device Description**

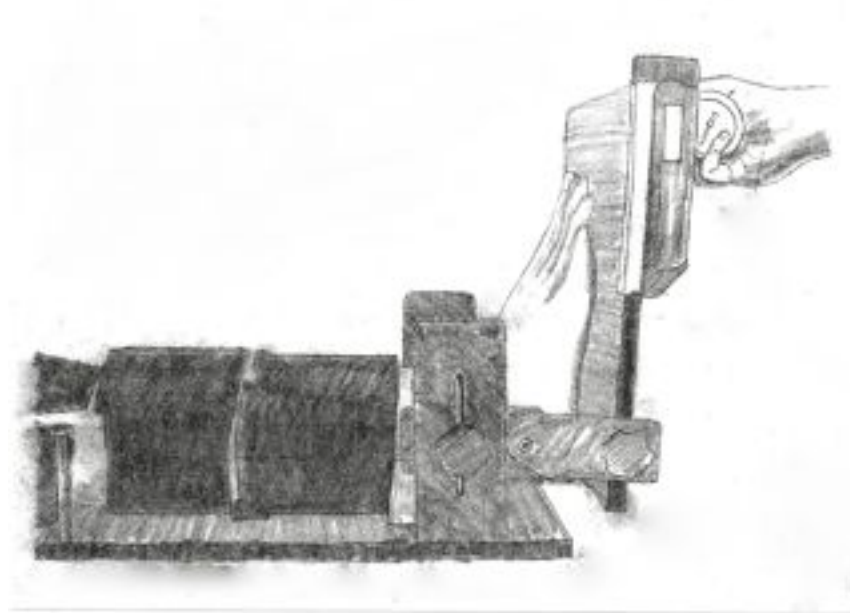
Please see Appendix F for hardware specifications. The following section describes the initial form of the device.



**Figure 7: Preliminary ME Group Device**

A novel ankle stiffness device (see Figure 7) was designed and manufactured by a mechanical engineering group (Higgins 2006) at Louisiana State University in conjunction with the National Hansen's Disease Program (NHDP) in Baton Rouge, LA. The goal of the project was to design and construct a device capable of measuring torque versus ROM, through plantarflexion and dorsiflexion, for DM, HD, or PN patients.

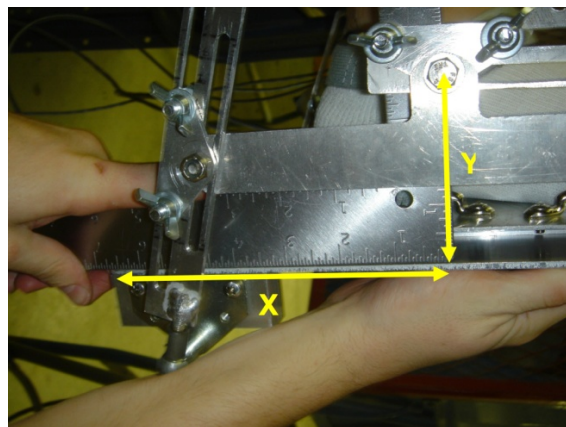
The apparatus (see Figure 8) is conceptually similar to the devices used in other studies, in that it constrains the leg and foot, and utilizes force gauges and a potentiometer or goniometer to gather force and ROM data, respectively (Trevino, Buford et al. 2004; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006).



**Figure 8: Previous device – Adapted from Rao (Rao, Saltzman et al. 2006)**

The structural components of the device were manufactured of aluminum for strength and non-ferrous properties, while fasteners and high stress components were constructed with stainless steel bolts and fasteners. The only structural components not manufactured of

aluminum were the leg linkages that were made of stainless steel, to accommodate the higher forces expected on that component. Velcro® straps were used to constrain the foot and a sphygmomometer was used to constrain the leg. A four-bar linkage with ball joint connections was utilized to attach the base plate to the footplate in order to minimize any contribution to the force from the binding of the device. A strain gauge was attached to the top of the footplate, to which a handle was connected to move the footplate through the range of motion. In order to calculate proper torque values, a relative measurement was taken on either side of the device to determine the axis of rotation (see Figure 9).



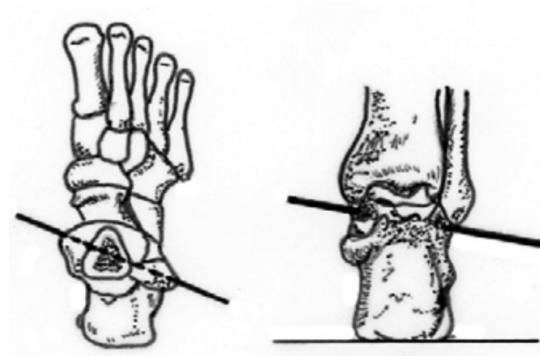
**Figure 9: Axis of Rotation Determination**

A potentiometer was attached to the device joint axis that intersected the approximate axis of rotation of the ankle. A novel aspect of this device is the axis of rotation coincides with the actual axis of rotation of the ankle unlike the devices used in other studies. LabVIEW was used to gather the data from the load cell and the potentiometer and then calculate a moment arm and display a Torque versus ROM (TROM) curve.

The initial instrumentation setup of the device included a National Instruments NI USB-6008 Multifunction DAQ system for acquisition from the potentiometer and single load cell in addition to a custom manufactured amplifier and signal conditioner.

### 2.3 Device Standards

It is imperative for the device to be aligned with the axis of rotation of the ankle in order for accurate torque and ROM to be calculated. The axis of rotation of the ankle for the purposes of this study will be considered to be the line that intersects the lateral and medial malleoli. For 14 normal males, this line is  $6.8^{\circ} \pm 8.1^{\circ}$  and  $7.0^{\circ} \pm 5.4^{\circ}$  in the horizontal and vertical plane, respectively (see Figure 10) (van den Bogert, Smith et al. 1994). The standing ROM for females, 95<sup>th</sup> percentile, is  $17.4^{\circ}$  DF and  $91.1^{\circ}$  PF (Thornton 1979-1980).



**Figure 10: Ankle Axis of Rotation (Higgins 2006)**

### 2.4 Device Validation

One of the goals of the proposed study was to determine the viability of the ankle flexibility tester in a clinical environment and test the device with patients having one injured ankle. The purpose of testing injured versus uninjured was to experimentally show that the device was capable of distinguishing differing ankle mechanical properties across a single patient. To achieve this, several software and hardware modifications of the device were made. The verification of this novel ankle flexibility tester will give physical therapists and physicians a tool that can provide consistent, objective data on patients. The validation of this device will allow us to make conclusions on the relationship between ankle stiffness and ulceration or other pathology.

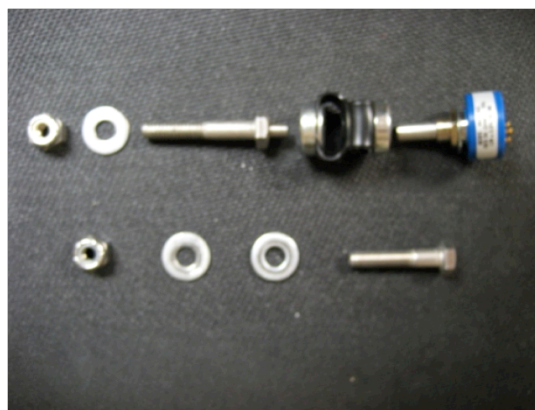
## 2.5 Device Modifications

In order to proceed to later phases of this study, several modifications were necessary to ensure valid data. Several changes were made in response to device malfunction, to prevent future complications in testing, and facilitate testing and data analysis.

### 2.5.1 Structural Modifications

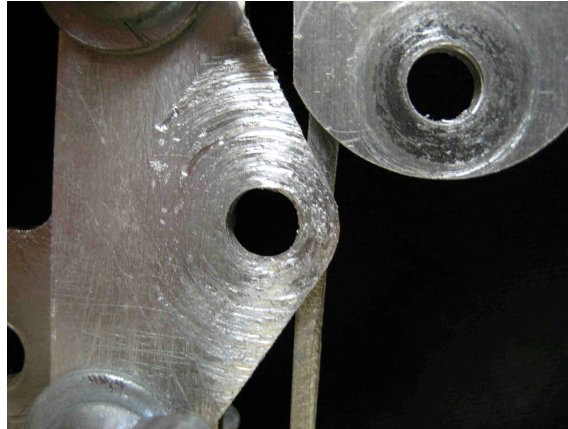
Structural modifications of this device were relatively limited; however, there were many nonstructural device modifications which were made to proactively to facilitate ease of acquisition and valid data.

Initial setup of the potentiometer consisted of the shaft of the potentiometer directly attached to the shoulder bolt, which served at the axis of rotation on the left side of the device, from the participant perspective. Following preliminary testing of the device in trials, adjustment of the participant resulted in the shaft of the potentiometer sweeper being sheared within the housing. In order to prevent this occurrence in future tests, a coupling between the potentiometer and the axis shoulder bolt was incorporated to minimize off axis binding which is seen at the maximum DF and PF ROM and to prevent binding during the adjustment of the footplate (see Figure 11).



**Figure 11: Potentiometer Setup**

Following the installation of the coupling, there was significant marring of the internal facets of the device. This marring (see Figure 12) not only caused wear of the device, it also increased friction, thereby increasing the error of the systems torque measurements. Previously, these components were not buffered and were affixed using a threaded bolt. To reduce friction between moving device components, nylon washers were inserted in addition to shoulder bolts.



**Figure 12: Device Wear at Axis of Rotation**

The utilization of the sphygmomanometer was for leg constraint was mildly effective at preventing movement of the leg; however, the repercussions in a clinical environment, where patients with poor peripheral circulation would eventually be tested, could be detrimental.



**Figure 13: Foam Leg Bed Replaced Sphygmomanometer**



In order to reduce the possibility of causing a further decrease or total stoppage during testing trials, and to better constrain the leg, as well as improve participant comfort during testing, the sphygmomanometer was removed and in its place, a foam leg bed with Velcro® straps was utilized (see Figure 13).



**Figure 14: Angular Support Bracket**

One shortcoming of the initial device was that the foot plate was not held orthogonal to the four bar linkages and parallel with the support bars, thereby invalidating the torque arm calculations performed before testing. In order to hold the four bar linkages perpendicular, four small rectangular aluminum supports were placed on all four bar linkage arms to prevent rotation, ensure proper torque arm calculation, and facilitate adjustment (see Figure 14).

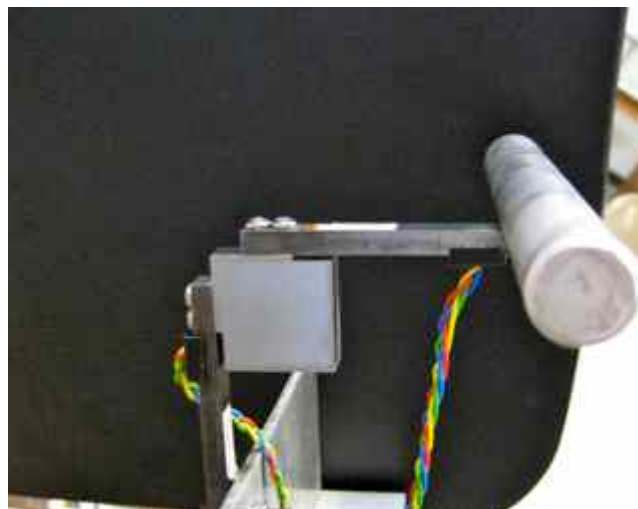


**Figure 15: Modified T-Bar for Axis Orientation**

The axis orientation bars that connect the footplate to the base plate were also modified to accommodate for 95% of the male and female population by remanufacturing the component to align with the axis of rotation instead of the subjective orthogonal ankle neutral position. In addition, the component was constructed of 2024 Aluminum in order to increase the resiliency of this high stress component (see Figure 15).

### **2.5.2 Instrumentation Modifications**

Of the instrumentation modifications, most noteworthy was the addition of a secondary load cell. Previously, the device measured force only perpendicularly to the footplate. While this served to give approximate data, forces applied non-perpendicularly were unaccounted for, leading to inaccurate and invalid data. In order to account for all forces applied by the operator perpendicular to the axis of rotation, the second load cell was oriented orthogonally (see Figure 16).

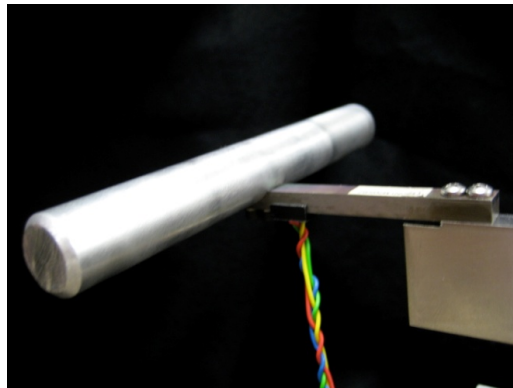


**Figure 16: Load Cell Joint with Chamfer for Deflection**

A necessary addition to the instrumentation setup following the installation of a secondary load cell was the incorporation of a full bridge modular signal conditioner capable of handling two signals. The previous system consisted of a combined amplifier and signal

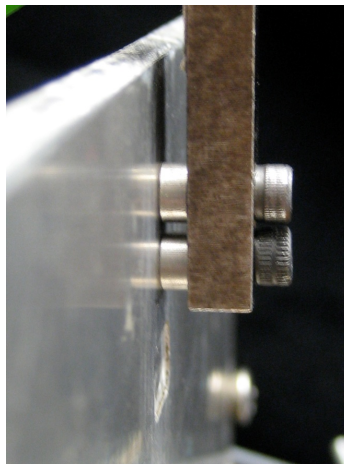
conditioner capable of handling only one strain gauge. The Omega Engineering OM5-WBS-2-C signal conditioner was utilized because of its low cost and availability.

Further modification of the power supply included the removal of the custom system which was replaced by a power supply capable of providing stable, sufficient power to the system. Similar to the signal conditioner, this Omega Engineering OMX-955 power supply was selected for its low cost and availability.



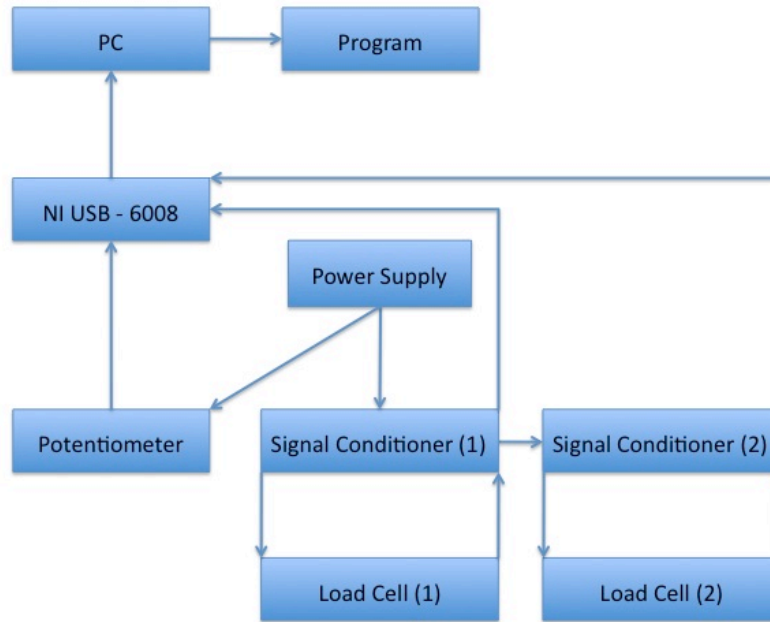
**Figure 17: Load Cell Handle**

In order to improve force application consistency and operator comfort, a handle was incorporated into the load cell component (see Figure 17). The previous force application handle was both difficult to grasp and apply sufficient force because of its size.



**Figure 18: Load Cell Attachment to Footplate – Spacers for Deflection**

Additionally, a load cell offset on both the attachment to the footplate and load cell to load cell was incorporated to allow for full load cell deformation in both DF and PF (see Figure 18).



**Figure 19: Wiring Diagram for DAQ System**

## **2.6 Results**

### **2.6.1 Torque Accuracy and Calibration**

In order to validate the torque values, both the calculated torque arm and the load cells were calibrated with known standards. For the torque arm, a line was connected from the axis bolts, and measurements were taken from the midpoint of that line to the base of the vertical load cell and cross-referenced to the values calculated by the LabVIEW programming. This was repeated in several orientations of the linkages. In order to calibrate the LCs, the testing setup of the system was securely affixed with the vertical LC in its normal orientation, then in a

horizontal orientation. This setup was utilized because it maintained instrumentation geometry on the device and because calibration took into account deflection of the LC beams (see Appendix G). Following this calibration, the LCs were then calibrated through the entire ROM to verify that gravitational contribution was zeroed. This ensured that the force contribution from the mass of the footplate was minimized. Following these calibrations, the device was run at maximum DF and PF to both verify the calibration curve and determine inherent system noise at those values. With respect to typical maximum values of torque, the resulting error is both consistent and negligible, typically less than 0.1% of maximal range (see Tables 1 and 2).

**Table 1: DF Maximum Torque Statistics (in\*lb)**

DF Maximum	Torque
Mean	0.11
Standard Error	0.02
Standard Deviation	0.61
Sample Variance	0.37

**Table 2: PF Maximum Torque Statistics (in\*lb)**

PF Maximum	Torque
Mean	1.28
Standard Error	0.02
Standard Deviation	0.61
Sample Variance	0.37

### 2.6.2 Angle Accuracy and Calibration

Angle calculations were validated by calibrating the device potentiometer with a protractor across the entire range of motion every 5° and a regression was found. The values calculated, run through the programming, and were then re-verified with the protractor. Similar to the torque values, the resulting error is consistent across both maxima and negligible with respect to ROM (see Tables 3 and 4).

**Table 3: DF Maximum Angle Statistics (Deg)**

DF Maximum	Angle
Mean	-59.21
Standard Error	0.003
Standard Deviation	0.090
Sample Variance	0.008

**Table 4: PF Maximum Angle Statistics (Deg)**

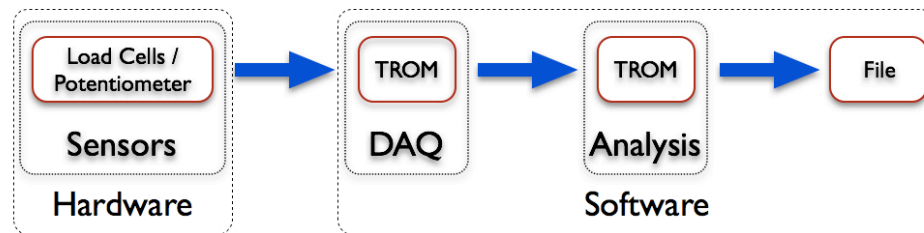
PF Maximum	Angle
Mean	90.54
Standard Error	0.01
Standard Deviation	0.14
Sample Variance	0.02

## CHAPTER 3. PROGRAMMING AND DATA ANALYSIS

### 3.1 Data Flow

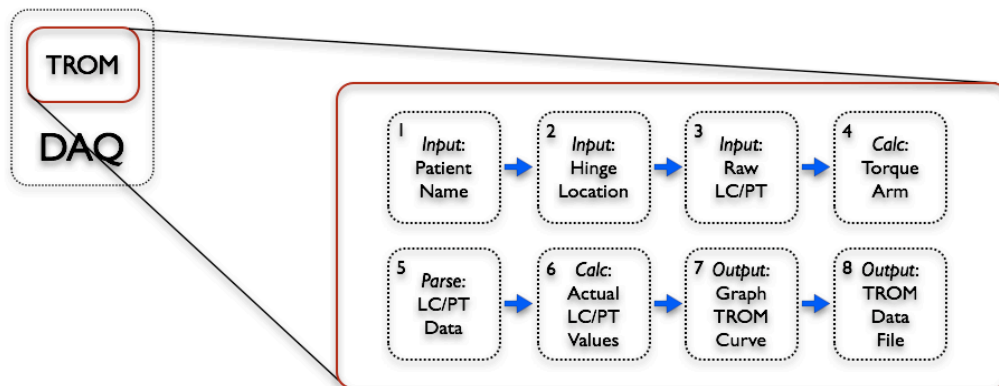
The following figures in this chapter represent data flow from acquisition to analysis and finally file output. For actual graphical programming images, please see Appendix E.

The overall data flow from raw to processed data and file output can be seen in Figure 20 below.



**Figure 20: Entire Program Data Flow**

Data for the load cells and potentiometer was acquired using a National Instruments USB 6008 Multifunction DAQ module. Upon *Tier 1* program execution, a user dialogue window (Phase 1) queries the operator for participant data and axis location measurements. Torque arm calculations are then executed and load cell and potentiometer data is acquired. In real time the data is converted to actual values and displayed graphically on the user interface (UI).



**Figure 21: TROM DAQ – Data Flow**

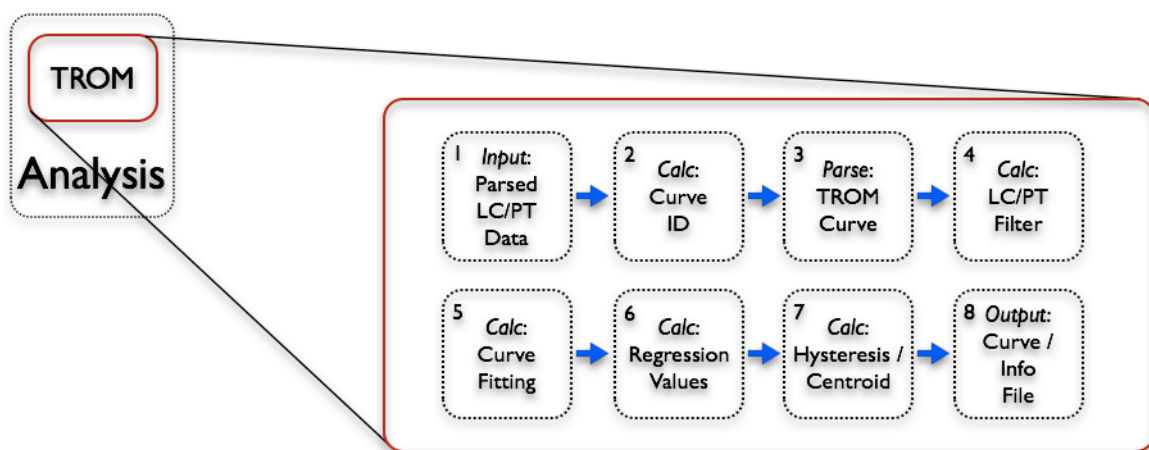
Following each data acquisition cycle, an unparsed data file is written to preserve initial data should original raw data be needed for further analysis and parsing of the DF and PF curves are executed and written to file (see Figure 21).

### 3.2 Automated Data Parsing

Given the extent of the data gathered over the course of testing a single participant, 80 TROM curves, the automatic parsing of data cycles for both later review and slope calculations, was required to perform subsequent automated calculations. This allowed for stiffness calculations, at any angle(s) through the ROM, to be determined for both DF and PF.

### 3.3 Automated Data Analysis

See Curve Parsing and Hysteresis/Integral/Centroid VIs in Section 3.4. See Figure 22 for analysis data flow.



**Figure 22: TROM Analysis – Data Flow**

### 3.4 Pseudo-Code

The following section is intended to more completely explain the programming written for this project. The architecture of this program follows a reentrant, launched occurrence, and launched daemon methodology and the following explanation will also use this methodology.

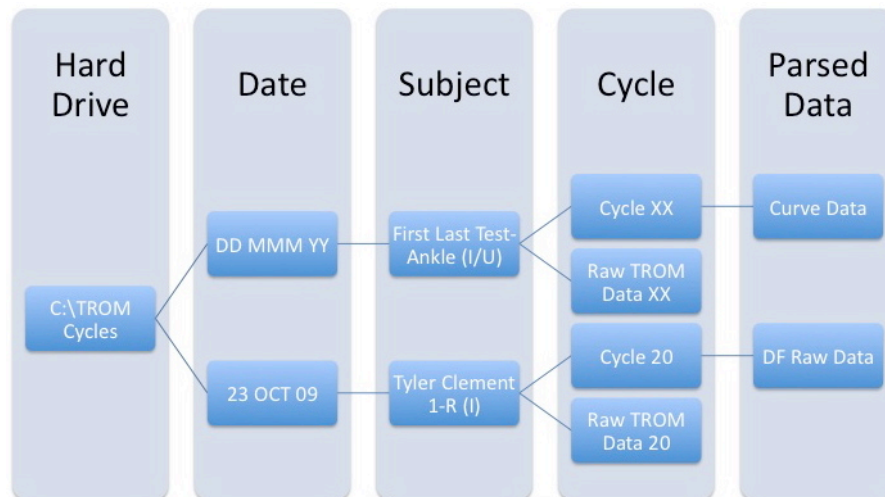


Tier 1: This is the highest level of the program, which encompasses all major aspects of TROM DAQ and analysis.

- TROM DAQ VI: In addition to block diagram programming, this VI contains the following Sub-VIs: Patient Name, Input Hinge, and Torque Arm, which are explained in further detail below. Following the completion of Patient Name VI and Input Hinge VI, a loop is initiated to allow for uninterrupted continuous data acquisition for potentiometer and load cell data. Data is acquired at a default setting of 60 Hz and is easily adjusted by the user. Data from both load cells is then converted to calibrated values, multiplied by the torque arm, and summed. Data from the potentiometer is also converted to calibrated values. In order to correct for gravitational force, potentiometer values are utilized to calculate location of the device and subsequent gravitational force, which is subtracted from the load cell summation. These values are then compiled for each subsequent iteration of the loop and upon stoppage of the loop are sent out to a raw data file, utilizing file information from the Patient Name VI, and to Curve ID VI. Proceed to Curve ID VI.
  - Patient Name VI: (First Sub-VI in TROM DAQ VI) Upon running, queries the user for the patient's first and last name. The remainder of the programming is held for input of this information. Once this information is acquired, a string is written for output to file name for several write to file commands. Proceed to Input Hinge VI.
  - Input Hinge VI: (Second Sub-VI in TROM DAQ VI) Following completion of Patient Name VI, the user is queried for hinge data manually acquired from the device orientation. Axis location from either side of the footplate is input. Proceed to Torque Arm VI.

- Torque Arm VI: (Within block diagram programming) Receives data from Input Hinge VI to calculate the torque arm for stiffness calculations. Values are averaged and output into the block diagram.
- Curve ID VI: Following completion of the TROM DAQ VI, data is received and parsed to determine inflection points. A derivative with respect to time is taken of the waveform. This information is then fed to a conditional that removes all zero derivatives and sends an indicator values to an array for all non-zero derivatives. Using these indicator values, the potentiometer data is re-indexed and then derivative is taken with all zero values removed. A condition is then set to output an indicator where a change in derivative is found. Cases where the derivatives are zero or signal noise would cause a false positive are removed by a conditional following the previous. These indicator values are then output to the next VI, Curve Parsing VI. Proceed to Curve Parsing VI.
- Curve Parsing VI: Following completion of the Curve ID VI, data is received from the previous VI in addition to the TROM DAQ VI. The rate of collection is utilized to remove inflection points that are separated by less than 15% of the rate. This ensures that signal noise or non-uniform motion does not result in a false positive for curve identification. Utilizing the indicator values from the previous VI, the raw data is indexed and information corresponding to the maximum/minimum torque and ROM are sent to an array. Concurrently, all load cell and potentiometer data is smoothed by means of a 3 point moving average. Following averaging, the Hysteresis/Integral/Centroid VI is run. Following completion of Hysteresis/Integral/Centroid VI, output data, torque, and ROM data are written to file for later reference.

- Hysteresis/Integral/Centroid VI: Following the 3 point moving averages, data is received and fitted using a cubic regression. Using this regression and averaged potentiometer data, regression values are calculated. These regression values are then utilized to calculate the integral, X centroid, and Y centroid. These values are output and received by the block diagram.
- Average Velocity/Stiffness/Average Torque/Hysteresis: Utilizing a modified Hysteresis/Integral/Centroid Sub-VI, Curve Fitting VI, and Statistical Express VI, average velocity, stiffness, average torque, and hysteresis are calculated and written to separate files for the active ROM from -5° DF to 10° PF. This range was chosen for its linearity and inclusion in the ankle functional ROM from 23° flexion (DF) and 10° extension (PF) (Sammarco 1977).



**Figure 23: File Hierarchy for Program Across all Participants**

- Program and Mined Max Min VI: This VI serves as the main data mining function of the programming system. Following running of the Tier 1 VI (or solo run where the user is prompted for a source file), this VI opens either Raw TROM files or parsed files in order to extract data or perform minor calculations. Following all mining and calculations,

files are written into the source directory from which they were drawn from, thereby maintaining a homogeneous file hierarchy (see Figure 23) across all participant folders.

- **Compiling Entire Data Set VI:** This VI serves as the main file preparation for SAS analysis of the programming system. Data is read from multiple files (Angular Velocity (-5 to 10), Average Torque (-5 to 10), Centroids INT (-5 to 10), and DF and PF Slopes (-5 to 10)), the user is prompted for information pertaining to the participant (injury, injured ankle, stretching phase, side tested) and all information is compiled into a single appending file for all test participants and cycles. For all trials, the first cycle was removed as it served as a buffer clearing function of the program. This file serves as input data for statistical analysis programs.

## **CHAPTER 4. METHODS**

### **4.1 Participants**

Two groups of 15 injured and 13 uninjured participants each took part in this study. Criterion of injury was based on the participant's disclosure of past medical history with respect to ankle injury. Individuals with injury were not further classified based on the severity of injury or date of injury. The uninjured group served to demonstrate both the difference between ankles unstretched and stretched in addition to a control for the injured group's uninjured ankles. The uninjured ankle of the injured group participants served as an internal control for each participant, under the assumption that the injury did not influence ankle parameters on the uninjured side. Both the control (uninjured) and experimental (injured) groups were age and gender-matched, consisting of females, aged 18-25 years, with no previous medical history of DM, PN, HD, ulceration, or sensory loss.

### **4.2 Procedure**

Torque versus Range of Motion (TROM) for passive ROM of the AJC was performed on all participants. Each of the participants was placed seated with both legs extended outward. The leg, first uninjured ankle if from the injured population, was placed on the foam leg bed and securely affixed using 2 Velcro® straps. The foot was then affixed to the footplate by Velcro® straps. With the foot and leg secured, the 4-bar linkages and axis linkages were adjusted so that the device's axis of rotation would coincide with the ankle axis of rotation. The alignment of the device was supervised by a physical therapist to ensure proper alignment over the lateral and medial malleoli. The participant was instructed to relax all musculature in the leg and several cycles, at a rate below 60° per second per cycle, through the ROM were performed to acclimatize the participant and minimize resistive torque as reported by Lamontagne, et al. (Lamontagne,

Malouin et al. 1997). The data acquisition began once the participant's ankle had been rotated through several cycles of dorsiflexion and plantarflexion. The operator applied a force, perpendicular to the footplate through 20 cycles. This was repeated following a stretching procedure where the participant would actively stretch in dorsiflexion and plantarflexion for 10 cycles, 10 seconds per cycle (Society 2008). Following stretching, the participant would be resealed and aligned in the device for a second set of cycles. This was repeated on the opposing ankle. Each set of 20 cycles required approximately 4 minutes of acquisition for a total of 4 minutes and 40 seconds per test, 18 minutes and 40 seconds for both ankles, stretched and unstretched.

### **4.3 Analysis**

The statistical analysis performed on the participant groups was a one-way ANOVA with three levels. The factors being analyzed were angular velocity, average torque, hysteresis, PF slope, and DF slope. The levels for the ANOVA of all data were uninjured, injured (normal, uninjured), and injured ankles. One of the assumptions of the study is that the left and right ankle of an uninjured participant had similar biomechanical properties. In order to verify this assumption, the groups were separated and the uninjured group was run through the SAS program. Following verification of the assumption, all groups were pooled and tested utilizing the same methods. In order to serve as a partitioning mechanism, all negative slopes, negative hysteresis values, and hysteresis values over 3000 in\*lb\*deg were removed from the analysis pool. This was done as negative slopes and hysteresis were seen rarely as a suspected result of muscle activity. Hysteresis values over 3000 in\*lb\*deg were also rarely observed and were also a suspected product of muscle activity and were subsequently removed as they exceeded the theoretical values of the area calculated. Less than 6% of the total curves were not considered as

a result of negative or excessive values. The number of and detail on these different parameters removed can be seen in Appendix I.

## CHAPTER 5. RESULTS

### 5.1 Injured and Control Groups

Throughout Chapter 5, references to specific subjects are shown to illustrate changes in parameters across ankles, cycles, or both. Initially, the control (uninjured) group was analyzed separately in order to verify the assumption that in uninjured participants, there was no significant difference between the left and right ankles. First, a one-way ANOVA was run for angular velocity, average torque, hysteresis, PF slope, and DF slope across a portion of the active ROM. The results of this ANOVA for the left versus right ankle and stretched versus unstretched uninjured group can be seen in Tables 5 and 6, respectively.

**Table 5: Uninjured Group - Ankle Treatment**

Variable	Left	Right	SEM	P-value
Angular Velocity	35.341	35.415	1.8805	0.9463
Average Torque	146.13	138.44	7.023	0.1766
Hysteresis	449.35	490.48	44.617	0.3618
PF Slope	2.2622	2.0446	0.2141	0.1795
DF Slope	3.2421	2.8828	0.3064	0.105

The results of this ANOVA suggest that the assumption that the left versus right ankle have similar biomechanical properties was valid, as there was no significant difference observed across each of the parameters. The results of this ANOVA suggest that there are significant differences between the unstretched and stretched ankle with respect to hysteresis and DF slope.

**Table 6: Uninjured Group - Stretched Treatment**

Variable	Stretched	Unstretched	SEM	P-value
Angular Velocity	35.6437	35.1122	1.8805	0.5278
Average Torque	139.95	144.61	6.734	0.1714
Hysteresis	430.69	509.14	43.1593	0.0328
PF Slope	2.1484	2.1584	0.2169	0.9509
DF Slope	2.8016	3.3233	0.31	0.0235



Following verification of this model assumption, a second one-way ANOVA across each of the parameters was performed, this time including all groups. For simplification of the model, based on the previous assumption, all uninjured ankles were grouped, resulting in uninjured, injured, and injured normal groups. The results of this ANOVA for the entire population can be seen in Table 6.

**Table 7: All Groups – Ankle Treatment**

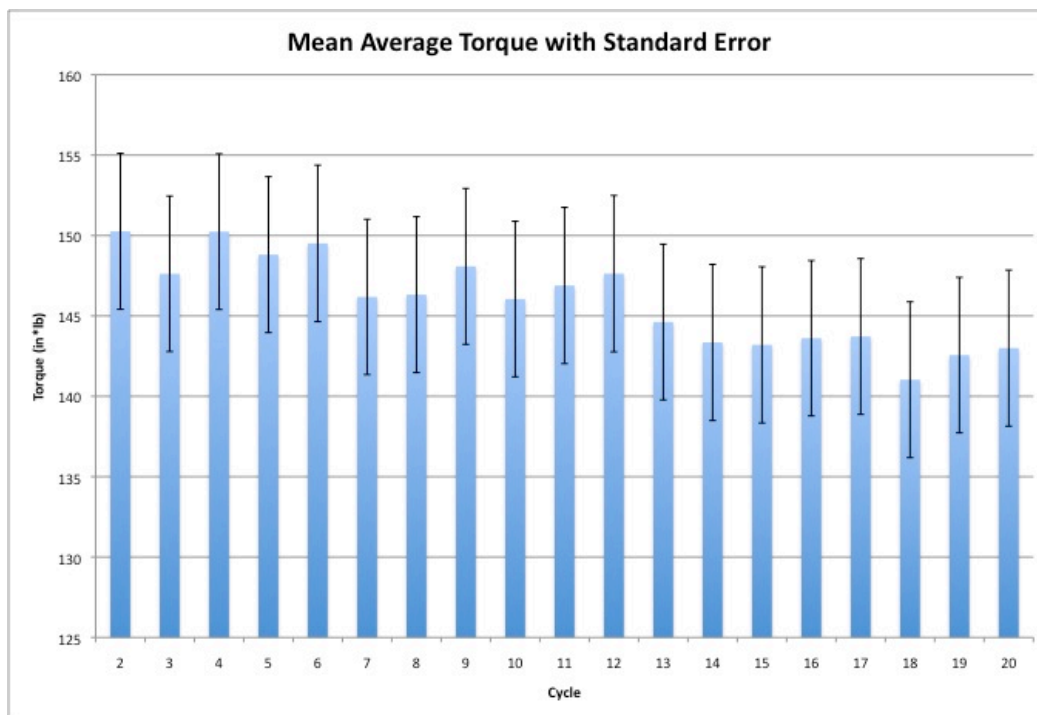
Variable	Uninjured	SEM	Injured Normal	SEM	Injured	SEM	P-value
Angular Velocity	35.3544	1.431	34.3667	1.392	33.998	1.398	0.7472
Average Torque	142.31	6.658	146.48	6.593	149	6.611	0.736
Hysteresis	470.17	54.2	479.72	54.5	474.54	54.73	0.9888
PF Slope	2.1599	0.2	1.799	0.193	1.8693	0.194	0.4225
DF Slope	3.0785	0.284	2.8438	0.285	2.8926	0.286	0.8461

Similar to the previous results, these suggest that there is no significant difference between uninjured, injured normal, and injured ankles in any of the measured parameters. While the results of the statistical analysis did not show significance between the ankles of injured versus uninjured, they did show significance ( $\alpha = 0.05$ ) across two treatments: stretching, and some variables across cycles. The ANOVA results across all the entire population of stretching treatment can be seen in Table 7.

**Table 8: All Groups - Stretching Treatment**

Variable	Stretched	Unstretched	SEM	P-value
Angular Velocity	34.87	34.3426	1.0448	0.3802
Average Torque	143.73	148.13	4.7828	0.0442
Hysteresis	454.84	494.79	39.632	0.0872
PF Slope	1.9435	1.942	0.1472	0.9879
DF Slope	2.6988	3.1777	0.2093	0.0006

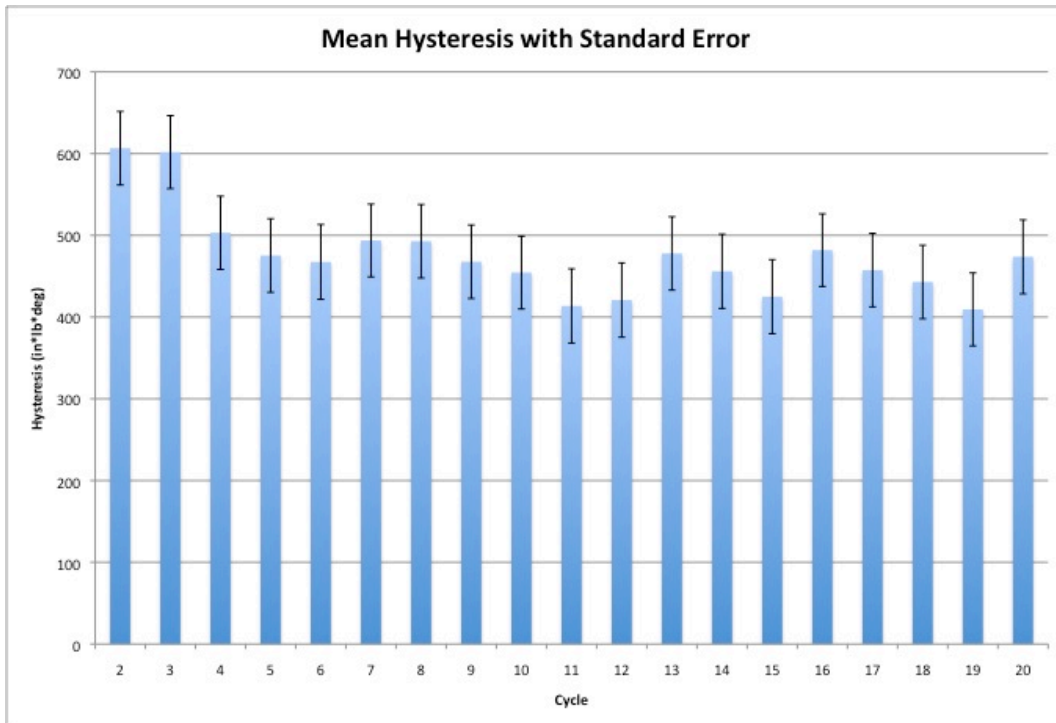
These results show significant difference across all ankle groups between unstretched and stretched for average torque and DF slope. They also suggest some level of significance for hysteresis across the same treatment. While hysteresis does not show significance at  $\alpha = 0.05$ , there is a difference ( $p = 0.0872$ ) between the means before and after stretching. Below are graphs of each of these parameters across each of the cycles (see Figures 24 through 26). The associated p-value shows a significant difference between, not all, but at least two cycles. While this difference is not shown between which cycles, there are noticeable trends across cycles of an overall decrease in average torque, DF stiffness, and hysteresis.



**Figure 24: Trend of Data for Mean of Average Torque Across all Groups ( $p = <0.0001$ )**



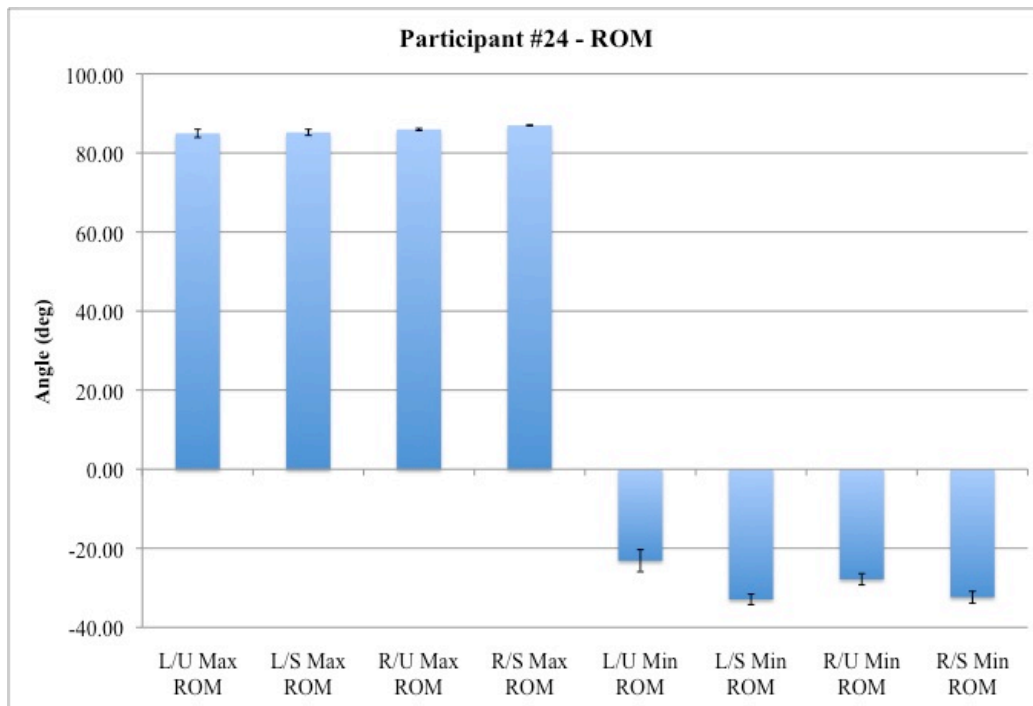
**Figure 25: Trend of Data for Mean of DF Slope Across all Groups ( $p = <0.0001$ )**



**Figure 26: Trend of Data for Mean of Hysteresis Across all Groups ( $p = <0.0001$ )**

## 5.2 Range of Motion Variable

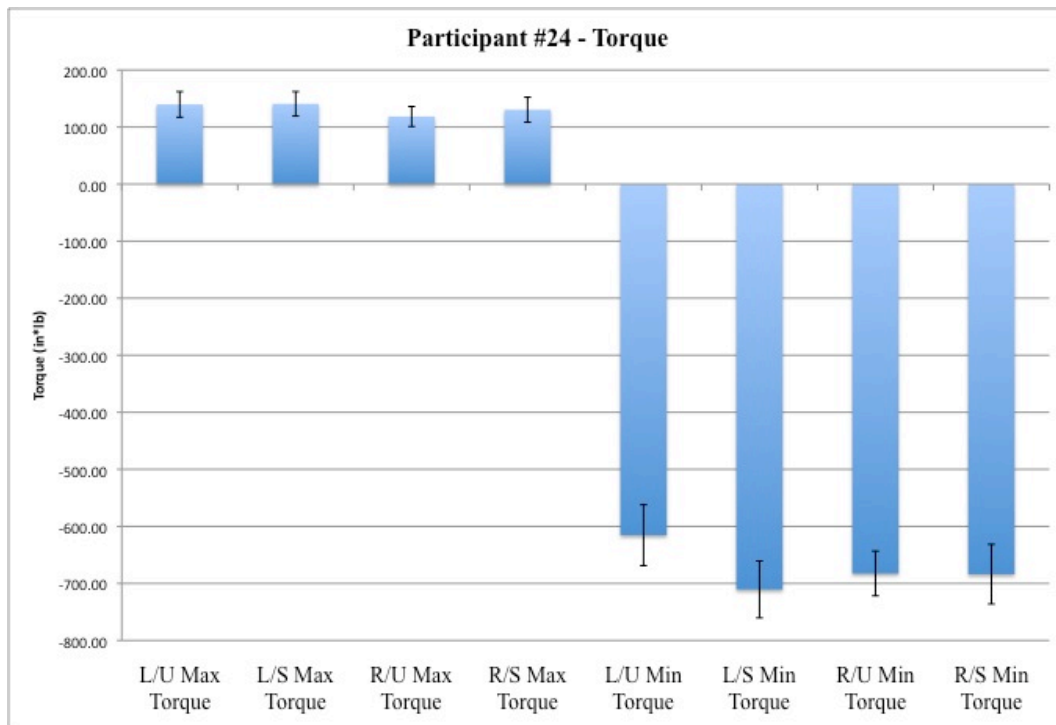
Total range of motion has long been utilized as a descriptive property of the AJC (Inman 1976). In order to address its legitimacy and accuracy we must first review the results of a sample participant. In figure 27, maximum (PF) and minimum (DF) values are displayed as averages across all cycles and several characteristics are apparent. First, there is little change across all PF values, which is indicative of the ankle reaching the end ROM due to a hard stop of bones or ligaments. Second, it is evident that from unstretched to stretched trials in DF, there are significant trends of increasing ROM. Also noteworthy is the larger error in DF than PF, a result suggesting musculature as the stoppage in DF. However, while these seem similar, they are dependent upon the consistency of the force and velocity application, which could be unintentionally altered by the device operator.



**Figure 27: Participant #24 – Average Range of Motion (Degrees) Across all Cycles with Error Bars (Ex: Left/Unstretched Dorsiflexion = L/U DF)**

### 5.3 Average Torque Variable

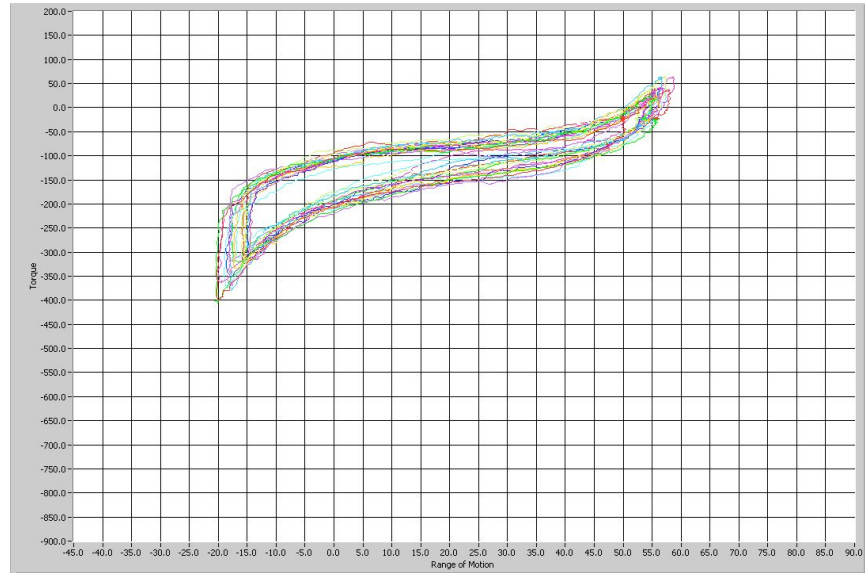
Much like ROM, torque variables have been utilized to describe ankle properties in recent studies including Rao, et al. (2006) and Trevino, et al. (2004). Similar to ROM, there appears to be consistent values across each test; however, maximum torque values are not as consistent in this study (see Figure 28).



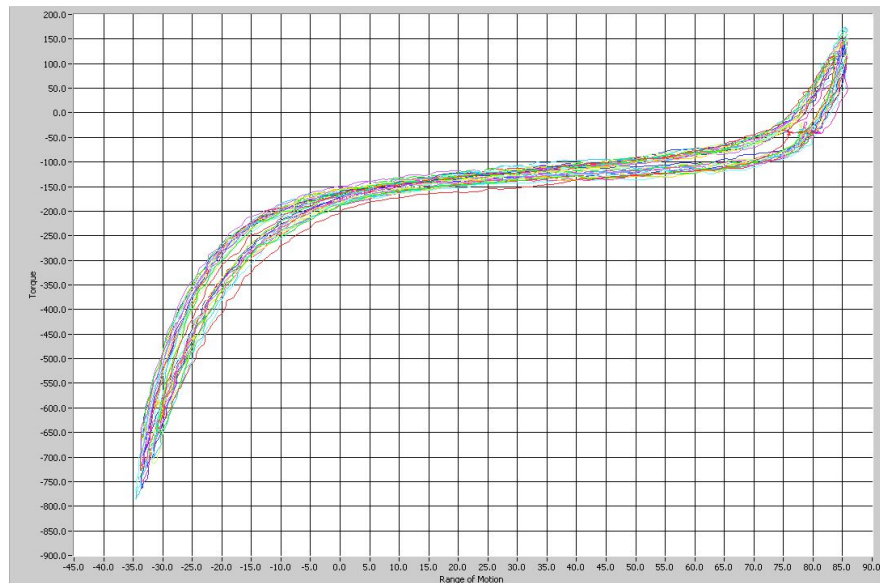
**Figure 28: Participant #24 – Average Torque (in\*lb) Across all Cycles with Error Bars (Ex: Left/Unstretched Dorsiflexion = L/U DF)**

While this would suggest inconsistencies in the AJC, in fact it is insignificant because torque is dependent upon the force applied by the operator. This can be illustrated by comparing participant #2's trial (see Figure 29) where the maxima are approximately -400 in\*lb (DF) to 50 in\*lb (PF) to participant #24's trial on the same stretched ankle (see Figure 30) where the maxima are approximately -750 in\*lb (DF) to 150 in\*lb (PF). While there are other differences

worth pointing out, such as slope and hysteresis, the forces exerted by the operator can vary significantly between each of the trials and subsequently affect maximum and minimum ROM, torque, hysteresis, and slopes fitted.



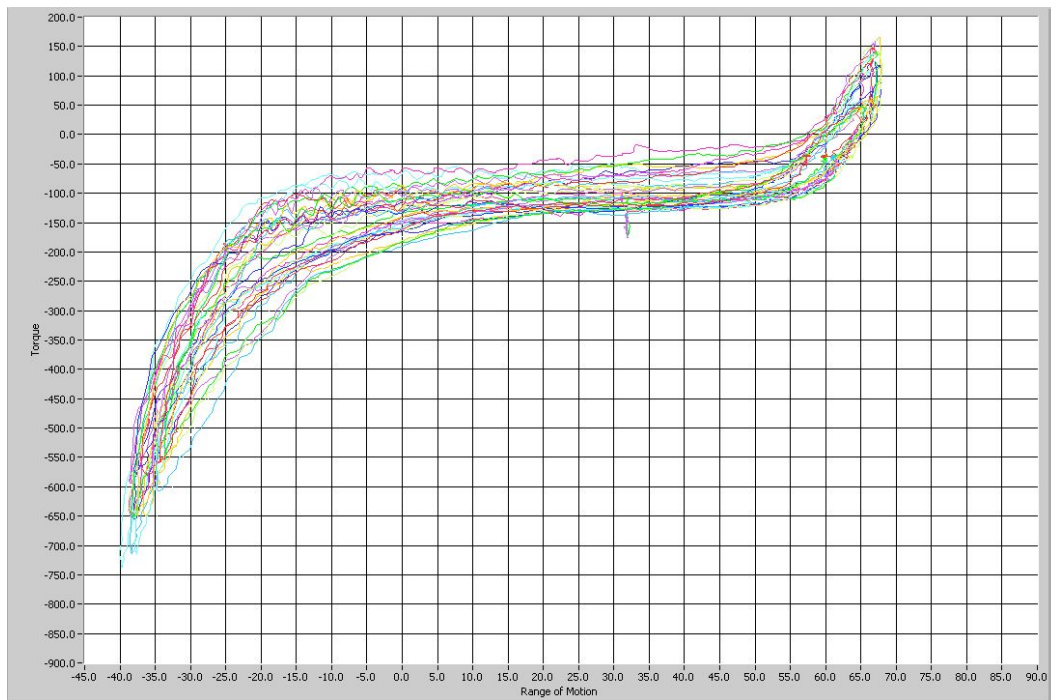
**Figure 29: Participant #2 - Right, Stretched: Limited ROM and Torque Resulting from Lower Applied Force**



**Figure 30: Participant #24 - Right, Stretched: Extended ROM and Torque Resulting from Higher Applied Force**

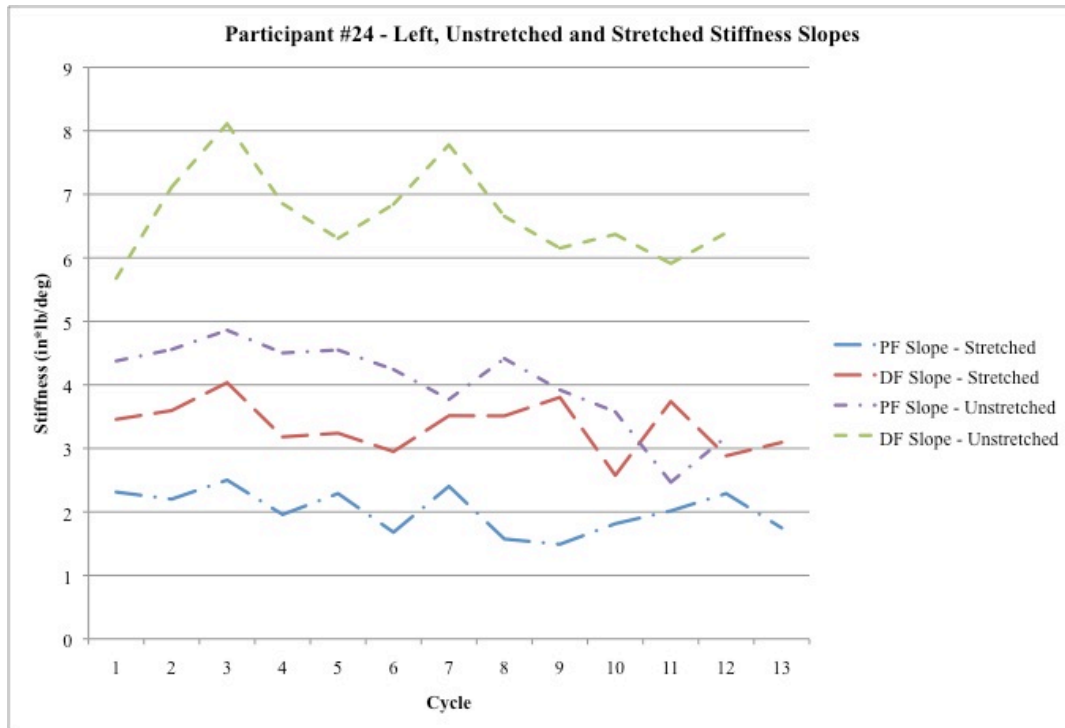
## 5.4 Stiffness Variable within Active Range of Motion

Unlike the maximum and minimum ROM and torque, DF and PF stiffness have not been characterized as a quasi-linear region of the active ROM. The slopes described are the stiffness through an active region of the ROM while average torque is indicative of the torque where that stiffness occurred; that is, it's the vertical shift of the linear equation. Across some of the trials, there existed significant noise resulting from suspected muscular activity resulting in poor linear regression fit (see Figure 31).

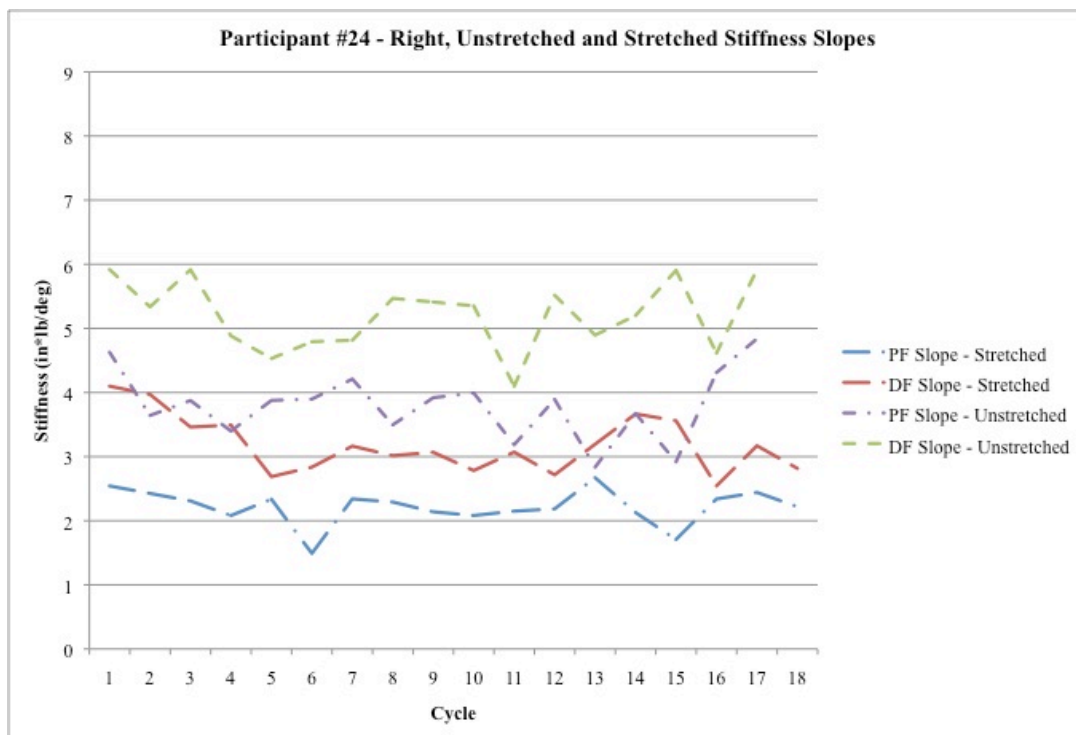


**Figure 31: Participant #19 - Left, Unstretched Suspected Muscule Activity**

Figures 32 through 34 show changes in both DF and PF stiffness within the range across cycles having high linear correlation coefficients ( $R^2 \geq 0.90$ ). As seen in the statistical analysis, there is a definite change across the unstretched and stretched treatment (see Figures 32 through 34). This implies that, with all other device parameters maintained, the device is capable of detecting differences in ankle stiffness before and after stretching.

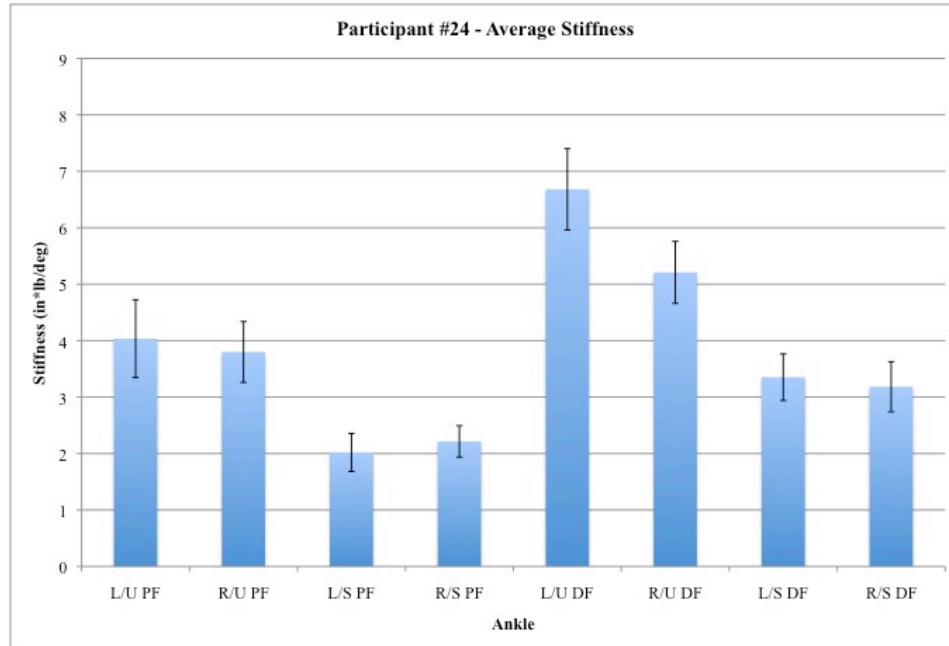


**Figure 32: Participant #24 - Left, Unstretched and Stretched Stiffness Across all Cycles**



**Figure 33: Participant #24 – Right, Unstretched and Stretched Stiffness Across all Cycles**

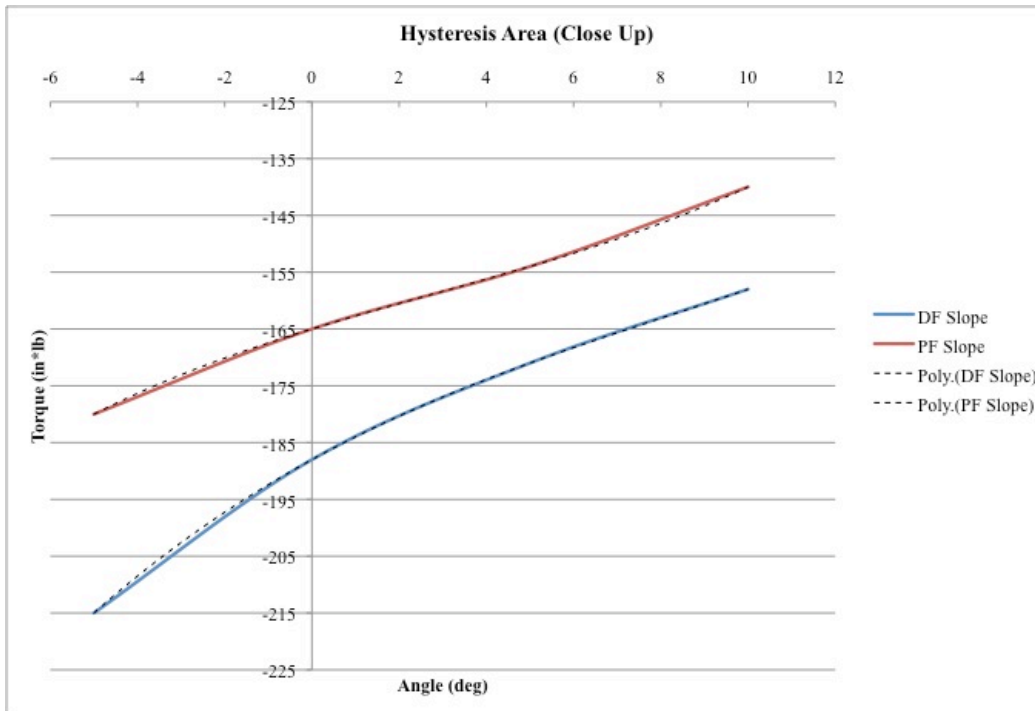




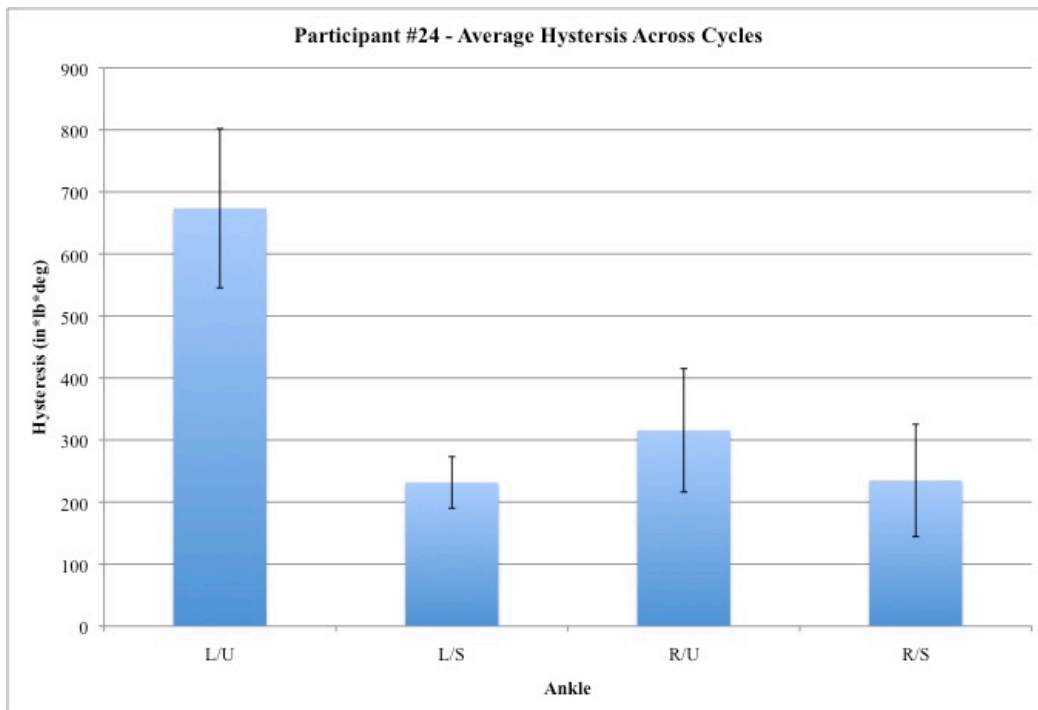
**Figure 34: Participant #24 - Average Stiffness Across all Cycles and Ankles (Ex: Left/Unstretched Dorsiflexion = L/U DF)**

### 5.5 Hysteresis Variable within Active Range of Motion

Similarly to maximum and minimum ROM and torque, hysteresis across the entire ROM is not a new concept. The unaddressed problem with this parameter is that it is calculated from ROM and torque values and should these maximum and minimum values not be a function of the ankle, and instead the operator, the resulting calculations would be the product of a dependent system comprised of the operator and participant. However, if the ankle were still moved near these maxima, but only the values within a portion of the active ROM considered, more consistent, representative values would be produced (see Figure 35). For the same participant, significant difference in hysteresis between unstretched and stretched can be seen for the left ankle. While the right ankle's mean hysteresis is different, the values fall within standard deviation for this participant (see Figure 36).



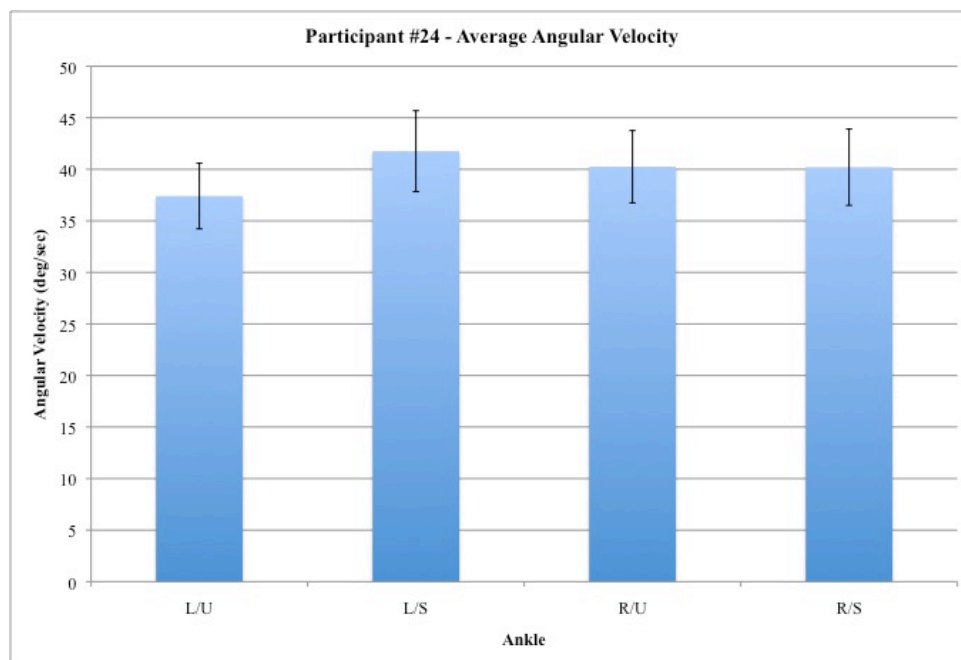
**Figure 35: Participant #24 - Hysteresis Area for Single Cycle from -5° to 10°: Region in between Upper and Lower Curves**



**Figure 36: Participant #24 - Average Hysteresis Across all Cycles and Ankles (Ex: Left/Unstretched Dorsiflexion = L/U DF)**

## 5.6 Angular Velocity Variable within Active Range of Motion

Angular velocity in the active ROM was included in statistical variables for this study in order to determine if there was a cycle dependency across each of the participants tests. The results across each ankle test of participant #24 (see Figure 37) coincide with the results of the statistical analysis (uninjured:  $p = 0.9463$ , all groups:  $p = 0.3802$ ) illustrating that there is no significant difference across the cycles of angular velocity. All of these means fell well below the  $60^\circ$  per second threshold as previously stated and below still the  $40^\circ/\text{sec}$  threshold recommended by Dr. Smita Rao (Rao 2009). This analysis was performed to ensure that there was no significant difference across the cycles with angular velocity.



**Figure 37: Participant #24 - Average Angular Velocity Across all Cycles and Ankles (Ex: Left/Unstretched Dorsiflexion = L/U DF)**

## CHAPTER 6. DISCUSSION

### 6.1 Scientific Contribution

Through both quantitative and qualitative methods, several parameters have been either shown to be neither practical nor viable indicators of biomechanical ankle properties in this type of test. Maximum ROM and torque values were two of the parameters used as significant indicators in previous studies but were shown not to be consistent means of ankle description in this study (Siegler, Chen et al. 1988; Lundberg, Svensson et al. 1989; Vandervoort, Chesworth et al. 1992; Salsich, Mueller et al. 2000; Trevino, Buford et al. 2004; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006). Through the course of testing both injured and non-injured groups, it was found that maximum ROM and torque values differed across subjects. This difference can be seen in Figures 29 and 30. It is easily seen that the ROM of these two curves differ in addition to the maximum torques. Also, differences of the slope of the curve at these end points are apparent at the maxima. This problem is complicated by the lack of a threshold to indicate where the ‘end’ ROM exists; as there is no definition for these maxima, nor can there be. For example, if a given torque threshold was set to be the end ROM, that threshold might suffice for some participants where in other participants the threshold could cause permanent damage to the AJC. Similar issues arise with each independent parameter, where a static value is set, which complicates the definition of the location of the end ROM. However, other variables within the midrange of motion such as average torque, hysteresis, and DF Slope are suspected to be more consistent indicators of ankle properties based on variability and could be defined for different patients and possibly populations. These variables are more indicative of ankle properties because they are more readily defined and therefore can be isolated to the participant, not the operator unlike parameters used in previous studies.

One possible shortcoming of the set of assumptions of the study is that significant differences were not observed between the uninjured and injured ankles within the injured groups. This result has two primary implications: first, the assumption that ankle parameters would be significantly different. Secondly, it is possible that the device is not capable of detecting these differences. The first implication is thought to be more likely as the injured population was grouped regardless of the severity or specificity of injury, meaning that previously broken ankles and ligament injuries were grouped together under the assumption that both would have led to the development of scar tissue and a subsequent stiffening of the AJC. Without a quantifiable method to describe the degree of ankle injury, there is a lack of clinical means to further partition the injured group on the basis of the severity of injury. The second implication is thought to be less likely as a difference in average torque, hysteresis, and DF stiffness was observed between the stretched and unstretched ankle. Care was taken to rule out changes in device alignment and orientation in these tests. The subject was initially evaluated unstretched, then subsequently tested after stretching with the device alignment and orientation remaining in its original conformation.

It is important to note that hysteresis calculations, while expressing some level of significance, are based on both the DF and PF full range of values. Considering that PF values are suspected of being affected significantly by muscle activity, it is reasonable to conclude that with a mechanism, for example EMG and an activity threshold, that separates the muscularly active from the inactive, the significance of PF slopes and hysteresis might be observed.

Considering the viscoelastic properties of the ankle, there are several parameters measured by the device that would be expected to have high correlations. Average torque and hysteresis through a region of the functional ROM with average velocity would hypothetically

have a strong positive correlation while hysteresis and slope would have a strong negative correlation. These correlations would suggest that the ankle would be acting more viscously than elastically. For example, if the AJC was found to have increased hysteresis, increased torque, and decreased stiffness at an increased velocity, viscous behavior of the ankle would be expected rather than elastic. The implications of a more viscous behavior of the ankle than elastic would greatly affect the treatment of many injuries and diseases in medicine and physical therapy.

## **6.2 Clinical Contribution**

The results of this study have several significant clinical implications. Due to the manual nature of a majority of the ankle TROM devices currently in scientific use, DF and PF ankle stiffness, hysteresis, torque, and angular velocity in an active ROM are keynote variables for ankle characterization. Several closely related studies have focused on the total ROM, torque, stiffness, or hysteresis across the entire ROM (Siegler, Chen et al. 1988; Lundberg, Svensson et al. 1989; Vandervoort, Chesworth et al. 1992; Salsich, Mueller et al. 2000; Trevino, Buford et al. 2004; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006). While this would seem logical to review, these variables do not serve as ideal clinical indicators in all cases. To use an analogy to a standard combustion engine, while the engine is capable of operating at both extremes of engine revolutions, it is most capable and efficient at midrange. So too is the AJC in that while it is capable of operating at maximum DF, PF, and torques, the stiffness indicative of the ankle during the midrange of motion, where it functions during gait, is at its lowest (see Figure 39). In this midrange, these variables of interest are less influenced by the maximum forces exerted by the operator and are therefore indicative of the participant's ankle properties, rather than the operator's applied force. This approach is better than determining the stiffness at a single point

within the ROM or at a maximum, as determining stiffness at a single point greatly over simplifies the complexity of the AJC. In this sense, this study is transformative to the field of ankle stiffness testing because the findings suggest that some previous studies pursued non-optimal biomechanical parameters.

The capability of the device developed in this study to consistently align with a patient's ankle axis of rotation is a significant development in the ability of physicians and physical therapists to characterize ankle parameters. In previous devices, there is a lack of means to adjust the devices to align consistently with some unvarying parameter. A novel aspect of the device is that it is capable of replicating alignment about the axis of rotation, a criteria based off of boney landmarks, permitting consistency across multiple trials over a period of time and especially the assessment of treatment efficacy. This would serve as an important feedback mechanism for physicians in helping to decrease morbidity secondary to DM, PN, and HD.

The importance of device axis alignment to the ankle's axis of rotation should not be downplayed as misalignment can lead to inaccurate measurements of the ankle. Specifically, if the situation where the foot is forced away from the footplate due to initial or progressive shifting of the ankle across cycles, the forces required to move the AJC through the ROM will most likely vary as the component of the force perpendicular to the ankle's axis will decrease. This could also pose additional risk to the patient, as forces applied to the ankle will be about a non-collinear axis. Unlike previous devices, which only take into account forces perpendicular to the footplate, this device also measures the forces applied axially to the footplate. Given that the device rotates about a single axis, the addition of this second load cell accounts for all forces, which contribute to torque values about the axis of rotation of the device. This permits even an

inexperienced operator to utilize the device and capture forces, which might be applied non-perpendicularly to the footplate throughout the arc of rotation.

### **6.3 Physiological Relevance**

The midrange of motion as defined in this study is  $-5^{\circ}$  in DF to  $10^{\circ}$  in PF and is within the functional ROM of the ankle during gait (Sammarco 1977). While this does not represent the entire ROM through gait, it represents a quasi-linear region of ankle stiffness through the neutral position of the ankle whereby a model could be created to identify parameters for the purposes of developing a diagnostic tool for healthy and diseased or injured ankles. The importance of this quasi-linear region of ankle stiffness is that it allows for consistency of description of the ankle across trials of the participant and across different participants allowing for development of representative characteristics of the ankle within normal and diseased populations. However, the model does not extend into the region where ulceration could occur due to pressures, as ulceration is the result of a chain of events, not solely high MTH forces or repetition of forces (Thomson 1991). From the patient care perspective, the device should not exert repetitive forces where the foot could experience pressures that could lead to ulceration.

### **6.4 Previous Studies versus Present Study**

Previous studies have gathered biomechanical properties of various diseased and normal populations across many different variables. These variables differ across studies and are generally inconsistent; this lack of well-defined variables hinders the ability of researchers to relate findings (Vandervoort, Chesworth et al. 1992; Salsich, Mueller et al. 2000; Trevino, Buford et al. 2004; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006). This is the result of progression and further definition of the ankle biomechanical properties and should not be construed as a lack of thought or effort on the behalf of these studies to adequately define the



variables of interest. However, in fully defining variables of hysteresis and DF and PF stiffness within a quasi-linear region of the ROM, this study removes effects, which were not controlled in previous studies such as device orientation, operator force application, and non-systematic variations of the system. Subsequently, the resulting variation in definition of ankle parameters does not allow for meaningful numeric comparisons.

Similar to this study, there have been several that have utilized custom designed devices consisting of a potentiometer and load cell to measure biomechanical properties of the AJC (Vandervoort, Chesworth et al. 1992; Trevino, Buford et al. 2004). Other studies (Salsich, Mueller et al. 2000; Rao, Saltzman et al. 2006; Rao, Saltzman et al. 2006) utilized commercially available devices such as the Kin-Com® dynamometer and Iowa ankle testing device, respectively. As with all of these devices, the device design or capabilities were not fully detailed in their clinically-focused reports. However, it is clear in these reports that the ankle axis of rotation was not addressed in these studies with respect to device design or capabilities aside from an adjustment perpendicular to the ankle axis at the lateral malleoli in a few studies (Vandervoort, Chesworth et al. 1992; Trevino, Buford et al. 2004). The device in this study isolated torque and ROM data about the ankle axis of rotation and included forces exerted non-orthogonally with the addition of a second load cell to account for the total moment about the axis. These advancements in the design of ankle torque versus range of motion measurement devices allow for a more reproducible assessment of the AJC.

## **6.5 Programming Suite**

Development of a fully functional tiered data acquisition and analysis suite for assessment of ankle biomechanical parameters from a novel device is one of the major contributions of this study. The architectural approach to this program was that of reentrant,

launched occurrence, and launched daemon versus state-machine. Reentrant refers to a VI which has allocated data space and is capable of executing without interfering with another instance of that VI. Launched occurrence refers to a VI which will not run unless specified by some data or user input. Launched daemon refers to a VI which runs in the background and is generally unseen by the user. This methodology is closely related to the architecture utilized in the programming developed for this study. The importance of this approach is that subsequent deployments of this program with other ankle devices or even other instrumentation can be accomplished with little to no modification to the existing structure. Furthermore, incorporation of additional instrumentation, for example electromyography (EMG) or linear potentiometers for torque arm calculations, can be accomplished by the introduction of an appropriate VI at the highest tier.

Inherent to the programming suite are several VIs, which operate as calibration, normalization, global, compellation, compression and deletion, self-testing and diagnostic functions. Because of the architecture of the program, these VIs are capable of running within the tiered system or separately as a single VI. This highlights the adaptability of the suite; for instance, should this be employed on a system not capable of high rates of acquisition or different information is desired, sub-VIs can be removed or added to the tier.

Regarding the utilization of LabVIEW for the project's operating environment, it is superior with respect to ease of widespread deployment of the device in a clinical environment on a multitude of systems. The tiered approach allows for the top tier to be written as an executable with an included launched occurrence run-time engine.

The simplicity of use is another novel aspect of the program operation; the program was designed for an operator who is inexperienced in both programming and the LabVIEW

environment itself. In order to operate the entire program from start to completion, a single button is depressed beginning acquisition of individual cycles, analysis of individual cycles, and recording of raw and calculated data for later review. This allows the operator to operate gathering significant amounts of data without regard to the time consuming tasks of manual post-acquisition data manipulation or macro usage, a norm in many studies.

## **6.6 Future Considerations**

As a result of the wide scope of this project, there are several avenues for further investigation including programming and instrumentation, the device itself, and incorporation of EMG data and analysis. The perceived muscular activity observed during testing is suspected of contributing significantly to ankle stiffness throughout the ROM, especially in returning to maximum PF from maximum DF. Addition of EMG could serve as a threshold parsing mechanism to attenuate data where a high level of muscular activity or hypertonicity is present or serve to identify those curves where the ankle is operating in a non-Hookean manner or is unable to regulate itself. Poor muscular control is of interest in PN ankle where there is decreased neuro-muscular interaction, which could lead to changing ankle parameters.

For implementation of the system in a clinical environment, there are several additions to the programming system, which could be made to allow the system to function remotely and dynamically. Considering the difficulties of dispatching even a single modification of any aspect of the program, the development of real-time distribution by means of a server through the internet would allow for testing at several sites without requiring the operator to maintain the program. Following the development of this remote dispatch of programming, the next step would be to consolidate data storage on a central server where it can be post-processed. This would not only remove the necessity for operator to install program updates, as well as freeing

the operator from database management and processing. Furthermore, if the data were post-processed at the server level instead of the acquisition level, it would allow for less expensive systems to run the acquisition, an important factor in promoting implementation of the device in clinics where monetary funds are a concern. Necessary to this type of implementation, a streamlining of several resource intensive functions for CPU optimization would be ideal as this was not a factor during initial programming design. Concurrent with a large distribution, the development of a secure study participant appending server file where participant information would be input, subject number assigned, and system information, date, and time recorded. This would allow for a comprehensive, secure means of protecting participant information and consistency through the data set.

In order to simplify the initial setup, a set of linear potentiometers could be incorporated in parallel with the four bar linkages to provide measurements for torque arm calculations. Of course, some minimal additional programming would be required to determine the actual value of the torque arm, which would then be inserted into the existing program. Second, the existing power supply, signal conditioners, and NI USB – 6008 could be incorporated into a single enclosure to ready the system for field deployment. Lastly, the introduction of a push button control for the programming at the device force bar to initiate data acquisition would further simplify use.

In preparation for long-term use in a clinical or research environment, the device would require several major structural changes. Increasing the robustness of the device's structural members, with square tubular aluminum for example to reduce lateral motion of the footplate through the ROM at increased PF and DF forces, would facilitate testing and potentially help to decrease device flexion at increased force application. This could help to minimize off-axis

binding of the parallel bars and ease adjustment of the device. The addition of a full leg constraint to prevent flexion of the leg at the knee would help to reduce variability in ankle placement in the device across the patient population, providing for more consistent measurements of the ROM about the neutral position. Concerning the axis of rotation, the device currently rotates about two shoulder bolts on the medial and lateral malleoli. While this is sufficient for the preliminary testing, incorporation of ball bearings would reduce friction and wear over the device's clinical lifespan and allow the connection at the axis of rotation of the footplate to the base plate to be held rigid.

## **6.7 Conclusions**

Previous efforts with ankle biomechanical characterizations viewed clinical differences rather than device design and validation. There exists an absence of scrutiny of the parameters studied, leading to a patchwork of conclusions and statistical results from diseased populations, which offer little to advance this field in terms of fully cataloging the ankle. The contributions of this study help to more completely define ankle parameters and provide a means to determine them, which can now be applied to the previous studies mentioned to test DM, PN, and HD patients.

The novel ankle device designed has been evaluated in preliminary trials and has performed as designed. The development of a robust data acquisition and analysis system has further simplified the process of acquiring meaningful, accurate data from the device. The study found that the device is capable of acquiring data that can determine biomechanical properties of the ankle joint. The device could be utilized a research or clinical environment to track changes in the biomechanical properties of a patient or characterize these properties in different disease populations.

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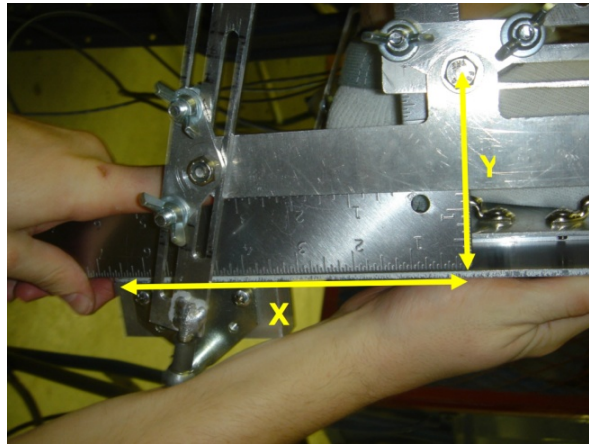
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## APPENDIX A: TESTING PROCEDURE

1. Ensure that the TROM device is **placed flat on the test table** with something supporting the device (i.e. a stool) in the upright position. Also, ensure that all wing nuts are loosened.
2. **Connect the Data Acquisition Card (DAQ)** to the computer. Then open the Measurement & Automation Explorer (MAX) and click OK on the screen that pops up. Next left click “Data Neighborhood” and then right click on potentiometer and then “Test”.
3. When the Virtual Channel Test Panels is opened rotate the device slightly to make sure the green line will move up and down with the rotation. Then, on the Virtual Channel Test Panel, left click Strain Gauge and first check that the green line is approximately on zero (due to noise it is not possible for the output voltage to remain zero). Then apply some force to the strain gauge on the device and make sure that the green line moves up with force towards the patient and down with force away from the patient. Finally, if everything is working, close the MAX screen and continue.
4. Carefully attach the subject’s leg to the foam support. It is recommended that the patient wear a sock for increased comfort when being strapped into place. If he or she is wearing long pants, the pants should be rolled up to avoid interference.
5. Check to see if the medial and lateral malleolus of the tibia-fibula are close to the axis of rotation. If not, have the patient move their leg in or out of the device to bring the malleolus of the ankle in the desired position.
6. **Secure the foot into the footplate** with the Velcro® straps.
7. **Adjust the footplate** so that the foot is allowed to sit in its neutral position. Loosen the

four wing nuts at the bottom of the base plate, slide the footplate in the desired position, and tighten the wing nuts back down.

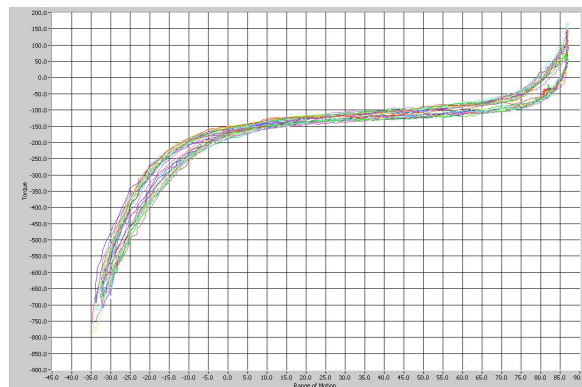
8. **Align the axis of rotation** on top of the malleolus of the ankle. This can be done in two coordinates, x and y. Carefully slide the hinge into the desired position and tighten the wing nuts down.



9. Verify that the axis is aligned on the malleolus of the ankle from both a side and a top perspective. Also, **check the scale reading at the top portion** of the device on each side. Each small hash mark is two millimeters (mm) and each large hash mark is one centimeter (cm).
10. **Set the side links at the lower portion** of the device. Using the top of the locking plate as a reference, set the higher side first (the side that is lower at the top portion of the device) to where the footplate is flush against the foot allowing it to remain in contact from heel to toe. Ensure that the side link is parallel with the base plate. Then, set the opposite side “x” cm lower to compensate for the loss at the top. The base plate should be perpendicular to the patient’s leg.
11. The assembly of the hardware is complete. Check that all the **wing nuts are tightened**,

that the **axis of rotation is aligned on the balls of the ankle**, that the **side links are parallel to the base plate**, and that the **footplate is perpendicular to the patient's leg**.

12. **Open the LabVIEW program named *Tier 1*** from the computer and click run. Enter the patient's last and first name in the dialogue boxes. Click continue.
13. The second frame enables the operator to **input the hinge coordinates**: X1, Y1, X2, and Y2. The x-coordinate is the distance from the back of the base plate to the x-coordinate of the center of the hinge point. The y-coordinate is the distance from the top of the base plate to the center of the hinge point. It does not matter which side is one or two. Take these measurements with a square ruler.
14. Once the hinge coordinates are entered, press continue. **Force can now be applied** in the dorsiflexion range of motion until the ankle reaches its maximum angular rotation. Make sure that the force is applied on the handle, which is at the tip of the strain gauge. The plot on the screen will begin to spike up, this is when the operator should reverse the force into plantarflexion. The cycle can be repeated as many times as desired. A typical **torque versus range of motion curve set** can be viewed below, where the x-coordinate is the range of motion of the ankle in degrees (positive x is dorsiflexion and negative x is plantarflexion) and the y-coordinate is the torque in inch-pounds.



15. Once the operator is finished acquiring data, click on the “Stop” tab to the right of the graph. The data will automatically be processed and a file written with the patient’s name along with the date and time of testing. To access the spreadsheet, search the Local Disk (C:) for the folder named TROM and file with automatically generated date.

## APPENDIX B: INSTRUMENTATION ACCURACY

Potentiometer Uncertainty	Value
Linearity	±2.0%
Uncertainty	2.0%
Actual	0.52%

Signal Conditioner	Accuracy	Non-Linearity
OM5-WBS-2-C	± 0.08%	0.02%

Strain Gauge Uncertainty	
Hysteresis	± 0.03%
Linearity	0.05%
Repeatability	0.05%
Creep Recovery	0.05%
Uncertainty per LC	0.0917%
Both LCs	0.1297%
Theoretical Error (Sig. Cond. And Two LC)	0.369%
Actual Error from #24 (% of Maximum)	0.751%

$$\text{Load Cell and Signal Conditioner Uncertainty} = (0.03^2 + 0.05^2 + 0.05^2 + 0.05^2 + 0.03^2 + 0.05^2 + 0.05^2 + 0.05^2 + 0.08^2 + 0.02^2)^{1/2} = 0.1536\%$$

## APPENDIX C: CONSENT FORM

### Consent Form

**1. Study Title:**

Use of a novel ankle stiffness tester to quantify stiffness in peripheral neuropathy patients

**2. Performance Sites:**

Data collection sites will depend on subject group and can include: National Hansen's Disease Program (NHDP), 1770 Physicians Park Dr., Baton Rouge LA 70816; LSU Bio. & Ag. Engineering Biomechanics Lab: 140 EB Doran Bldg., LSU Campus; LSU Kinesiology Labs: Rooms 137 and 54 HP Long Fieldhouse, Room 2B in the Cox Communication Bldg., LSU Campus

**3. Contacts:**

Dr. Todd Monroe	phone: 225-578-1059	e-mail: tmonroe@lsu.edu
Dr. Mike Mailander	phone: 225-578-1058	e-mail: mmailander@agcenter.lsu.edu
Dr. Li Li	phone: 225-578-2036	e-mail: lli3@lsu.edu
CAPT David Giurintano	phone: 225-756-3740	e-mail: dgiurintano@hrsa.gov
Tyler Clement	phone: 225-578-1097	e-mail: tcleme4@lsu.edu

**4. Purpose of the Study:**

The purpose of this study is to carry out clinical trials using a novel ankle stiffness tester to measure ankle torque versus range of motion (TROM). Clinical evaluation of the ankle joint is important in patients afflicted with diabetes, Hansen's disease or peripheral neuropathies. The combination of peripheral neuropathies, decreased ankle Range-of-Motion (ROM), and increased stiffness pose a threat to patients with diabetes mellitus, often resulting in ulcerations. The hypothesis of this study is that the mechanical parameters of the injured ankle will be significantly different from controls. Study outcomes could suggest that this small and inexpensive device could be used in the clinic to test ankle stiffness and potentially serve as an early indicator of foot complications.

**5. Subjects:**

**A. Inclusion Criteria**

History of previous ankle injury to only one ankle. Absence of diabetes mellitus (DM) diagnosis, Hansen's disease (HD), or peripheral neuropathy (PN).

**B. Exclusion Criteria**

Current or history of previous ipsilateral foot ulcer, great toe or transmetatarsal amputation, Presence of ipsilateral or contralateral Charcot neuroarthropathy. Diagnosis of DM, Hansen's disease or undetermined peripheral neuropathy. Presence of neuropathy will be documented using 5.07 Semmes-Weinstein monofilaments.

**C. Maximum number of subjects: 60**

**6. Study Procedures:**

As the subject in this study, you will insert your lower leg and foot into the device. The sphygmomanometer (blood pressure) cuff will then be inflated to 30mmHg and the device footplate

will be adjusted to align with the ankle axis of rotation. The footplate will then be rotated through several cycles through plantarflexion and dorsiflexion to the maximal angular rotation. During these cycles, torque and range of motion parameters are recorded by a laptop computer attached to the device. Testing is not expected to exceed 15 minutes.

**7. Risks/Discomforts:**

The minimal risks and discomforts associated with this study are as follows:

The test will consist of rotating the ankle through the participant's range of motion, very similar to what is done during a routine foot exam in a physician's or physical therapists' office.

- a. Because the base of the foot is in contact with a metal plate, there could be some discomfort if the participant has difficulty in maintaining the foot completely flat on a surface.
- b. The metal hardware of which the prototype device is fabricated could have some edges that may present risk if the skin of the foot were to strike them aggressively. Thus at the beginning of the test prior to securing the participant's foot, the investigator and/or physical therapist will assist in guiding the participant's foot into the device.
- c. The electrical sensors for torque and range-of-motion on the device are electrically insulated and operate at a low (<12V) voltage and minimal current and thus do not present any shock hazard to the participant.

**8. Right to Refuse:**

You may withdraw from the study at any time without penalty or loss of any benefit to which you are otherwise entitled.

**9. Privacy:**

The results of the study may be published, but no names or identifying information will be included in the publication. Your identity will remain confidential unless disclosure is required by law.

**10. Financial Information:**

Participation in this study is voluntary with no financial compensation. Any adverse responses that occur during participate the project resulting in medical treatment are your financial responsibility. No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from LSU A&M College.

**11. Withdrawal:**

There are no consequences if you choose to withdraw from participation at any time during this study.

**12. Removal:**

The investigators may remove you from the study for any number of reasons, including, but not limited to, the detection of adverse responses, the appraisal of health status, and technical difficulties in obtaining information during the testing session. If the investigators elect to remove you from the study they will provide you with the justification for doing so, and you will be given an opportunity to ask questions regarding your removal.



**13. Unforeseeable Risks:**

The risk of the project is minimal and various precautions are in place to avoid any possible unforeseeable risks.

**14. Study-associated injury or illness:**

Every effort will be made to avoid any study related injury or illness. However, in the unlikely event of injury and illness, there will be no compensation or medical care provided by the investigators or LSU.

**15. Study-related illness or injury:**

You should inform your primary physician and seek medical care in a timely manner in the event of an unlikely study-related illness or injury.

**16. Participant Signatures:**

The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigators. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, Chairman, LSU Institutional Review Board, (225) 578-8692. I agree to participate in the study described above and acknowledge the researchers' obligation to provide me with a copy of this consent form if signed by me.

Subject Signature \_\_\_\_\_ Date \_\_\_\_\_

**Illiterate subjects:**

The study subject has indicated to me that he/she is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above, the subject has agreed to participate.

Signature of Reader \_\_\_\_\_ Date \_\_\_\_\_

## **VITA**

T. Tyler Clement was born in Lafayette, Louisiana, in March of 1984. He attended Episcopal School of Acadiana High School. He received his Bachelor of Science in Biological Engineering in August 2006 from Louisiana State University. He serves as a commissioned officer in the United States Army. His technical interests are systems automation and instrumentation.