

**DEVELOPMENT OF A COMPUTER-CONTROLLED DEVICE
TO QUANTITATIVELY MEASURE THE DEGREE OF
SPASTICITY AT A SUBJECT'S ANKLE**

by

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ABSTRACT

The objective of this thesis project was to develop a device to quantitatively measure the degree of spasticity at a subject's ankle, and to use this device to find a means to determine a quantified measure of spasticity. The device imposes a controlled passive rotation of a subject's ankle joint, while simultaneously recording the resulting resistive torque and associated electromyographic (EMG) muscle activity. Comparative analysis of Data from subjects with and without spasticity were compared to identify response characteristics and parameters which could be associated with the presence and/or severity of spasticity. These differences were evaluated by modeling the data with a mathematical equation representing spasticity response. Parameters of the equation were then analyzed, and two of the four parameters deemed to be robust, reliable indicators of spasticity, were plotted to create a diagnostic model and curve for distinguishing between test subjects with and without spasticity. The perpendicular distance of the data points from the model curve can then be utilized as a quantified measure of spasticity. This quantified measure of spasticity was found to correlate with clinical evaluations. The analysis of variance test determined a 7.8% probability that the sets of data, from subjects with and without spasticity, were from the same population, indicating that there was a significant difference between the two data sets . Thus it is concluded that a diagnostic model has been developed which shows potential as a means to quantify spasticity.

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CHAPTER 1: INTRODUCTION

Spasticity is a debilitating condition which limits the abilities and daily activities of millions of people, young and old. Individuals with spasticity are restricted in their movement by the uncontrolled reflex actions of their own muscles. Essentially someone with spasticity has their own muscles working against them as they try to move their limbs. Spasticity is often associated with head and spinal cord injuries, stroke, multiple sclerosis, and cerebral palsy. Individuals with the aforementioned conditions are often very debilitated and, what should be noted is that the impairment associated with these conditions is often due to spasticity. Numerous treatments for spasticity do exist, ranging from exercise to drugs and surgery, but they are all limited to clinical trials and conjecture. None of the treatments are universally successful nor is there a known cure and, as a result, effective treatments for spasticity are needed to alleviate this condition. In order to determine whether the treatments and therapies are successful, one must be able to monitor day-to-day changes and this requires the ability to accurately and reliably measure the progress of the condition. The mechanisms causing spasticity are not fully understood and as a result, there is no general agreement on the most suitable way to measure spasticity. Generally, the evaluation of spasticity is based on qualitative or semi-qualitative clinical observations which are of limited usefulness. Spasticity is currently measured clinically by subjective, manual methods which are unsuited to quantifying incremental day-to-day changes in severity required to evaluate new treatments. The most common clinical method of assessing spasticity involves manually manipulating the

joint and subjectively assessing the degree of resistance to this passive stretch based on an ordinal scale of 0 (no spasticity) to 4 (severe spasticity). This generally accepted method of evaluating spasticity is entirely unsuitable as it is both subjective and uses much too gross a scale. In order to effectively study spasticity, it is essential to have an objective, quantitative method of measuring spasticity. At this point it would be useful to review the characteristics of spasticity.

1.1 Definition of Spasticity

Spasticity can be defined as a velocity and position dependent reflex resistance to passive stretching of the involved muscles. One of the more commonly accepted definitions of spasticity from the literature was put forward by Lance [1], who described spasticity as “a motor disorder characterized by velocity-dependent increases in tonic stretch reflexes (‘muscle tone’) with exaggerated tendon jerks resulting from hyper-excitability of the stretch reflex as one component of the upper motor neuron syndrome”.

Motion of our limbs is accomplished when electric signals from the brain reach the agonist muscles via motor neurons. In normal circumstances, the agonist muscles contract (see Figure 1.1-1) causing movement while the antagonist muscles are inhibited and provide no resistance to the movement. On the other hand, a person with spasticity will also have impulses sent to the antagonist muscles, making them active, resulting in increased muscle tone and resistance to voluntary movement and passive stretch.

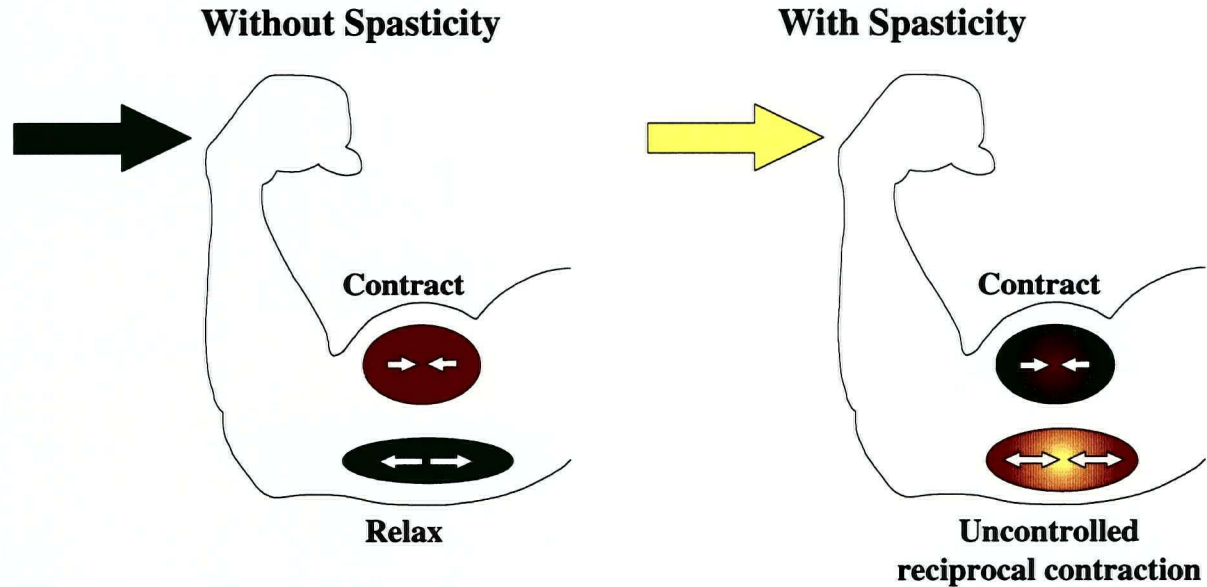


Figure 1.1-1 Schematic representation of the effects of spasticity

When a healthy person moves their arm, as shown in Figure 1.1, their agonist muscle (in this case the biceps) contracts and at the same time their antagonist muscle (the triceps) will relax allowing smooth and uninhibited movement. On the other hand, if someone with spasticity were to try to do the same thing, the biceps muscle will contract to try and initiate movement but the triceps muscle might also contract, rather than staying relaxed, thus inhibiting the arm's movement. This symptom also occurs when the arm is passively moved (i.e. the individual is trying to relax) by someone else. In cases where an individual suffers from severe spasticity, their muscle contractions can be so uncontrollable that they can be completely debilitated and unable to move themselves. Other characteristics which are occasionally observed in conjunction with spasticity are clonus, which is a series of repetitive muscle contractions elicited by a rapidly applied, but maintained stretch, and the Clasp Knife

phenomenon, which is a sudden relaxation of the involved muscle following a strong reflex resistance to a maintained stretch [2, 3].

1.2 Measurement of Spasticity

Measurement of spasticity has been a troublesome issue for many years. Because so little is known about the causes and mechanisms of spasticity, there is no general agreement as to the most appropriate way to measure spasticity. However, no-one disagrees that some means of quantifying spasticity in an accepted and dependable manner is necessary to determine suitable treatments and therapies for the disease.

The most common forms of spasticity measurement in use today are based on qualitative or semi-qualitative clinical observation. One of the more commonly employed tests to evaluate spasticity is the Modified Ashworth test which involves manually manipulating the joint and qualitatively assessing the degree of passive resistance based on an ordinal scale ranging between low and severe. Unfortunately, these recognized methods for evaluating spasticity are unsuited to quantifying incremental day-to-day changes in severity which would be required to evaluate new treatments and therapeutic intervention. In order to study the effectiveness of therapeutic intervention for spasticity, it is essential to have an objective, quantitative method of measuring spasticity.

Devices developed with the intent of quantifying spasticity do exist, but none of them have been entirely successful in providing an acceptable measurement of spasticity. Some of the

tests using these devices are subjective and do not provide therapists with the ability to distinguish and record small changes in a patient's condition. In many cases devices developed to measure spasticity have relied upon manual manipulations which limits the objectivity and repeatability of the test. Several motor driven, computer-controlled systems to measure spasticity exist, but they are limited either by design or application such that they have not been accepted as a suitable protocol for quantifying spasticity.

The ankle is particularly troublesome to test for spasticity due to its geometry. Determining resistance is more difficult while testing at the ankle because its range of movement (ROM) is typically less than half of that of the elbow. Also, since the lever arm available to the tester is shorter at the ankle than the elbow, subtle differences in encountered resistance may be more difficult to detect [4]. However, because the ankle plays an important role in gait [5, 6], posture [7], and activities of daily living, it is an important joint to evaluate for spasticity even though it may be more difficult to test clinically. For these very reasons the ankle joint was chosen as the joint of interest for this research project. Since testing will be accomplished using a computer-controlled device, some or all of the difficulties encountered by manual manipulation of the joint should be eliminated.

1.3 Research Objectives

The ultimate goal of this project is to provide the ability to suitably measure the degree of spasticity of an individual, in a quantifiable manner, which would allow the results of therapeutic intervention and treatment to be evaluated. This, in turn, would result in the

development of better treatments for spasticity and potentially a better understanding of the nature of spasticity. More immediate objectives were set for this project, which were to be achieved at different stages throughout the course of the research. Objectives to be met in the design phase of the project are outlined below.

- The short term objective was to develop and validate a computer-controlled device to quantitatively measure the degree of spasticity at the ankle in a clinical application.
- The device had to perform the testing in a safe manner and required redundant safety features to protect the test subjects.
- This device had to be flexible enough to accommodate testing based on various measurement protocols (e.g. load controlled rotation, displacement/velocity controlled rotation etc.) so that a method chosen as most suitable for measuring spasticity could be accommodated.
- The device had to be portable so that it could be taken to the patients to be tested in the event that they were bed bound or unable to travel to a clinic.
- The device had to be able to test subjects in different positions such as standing, sitting, and prone.
- The device had to have the ability to test subjects while simulating the effects of the subject's weight on the joint being tested. In this manner, the effect of the muscles balancing response on spasticity could be investigated.
- The device had to be flexible enough to be able to test different limbs so that it could be used to test knees and elbows as well as the ankle.

Throughout the testing phase of the research a number of milestones were to be achieved to establish the capabilities and effectiveness of the testing system. The following were required or desired:

- The device had to reliably measure the resistive torque at the ankle.
- The device had to distinguish between joints with and without spasticity.
- The device had to be able to distinguish different levels of spasticity.
- The device should be able to observe and record clonus and other phenomena associated with spasticity.
- These measurements should be repeatable on a trial-to-trial and day-to-day basis within a statistically acceptable envelope.
- By evaluating the data collected using the device, be able to establish a means of quantifying spasticity and be able to effectively use this technique to differentiate spasticity severity.

Ultimately the testing phase of the project lead us to the current long term objective which is to use this device to determine a reliable method for the evaluation and measurement of spasticity to aid in the diagnosis and treatment of spasticity. The importance of this long term objective is evidenced by the lack of understanding of the mechanisms of spasticity and the inability of current measurement techniques to provide a suitable measurement which would significantly aid in the diagnosis and treatment of this debilitating condition.

We propose that this device will be able to diagnose, assess, and help rehabilitate people who are suffering from spasticity. This device will aid the health care provider in performing these tasks by doing much of the work previously done by the care provider and then by subsequently acting as a home exercise device to help rehabilitate the patient. This will reduce the cost associated with diagnosing and evaluating spasticity while at the same time providing a more accurate and quantifiable evaluation of the condition. Similarly the cost of rehabilitating the patient can be significantly reduced by allowing the patient to self rehabilitate at home or in the clinic thereby reducing the workload of physical therapists and other health care professionals. The end result of these objectives is the ability to suitably measure the results of therapeutic intervention and treatment, and, through the better understanding of the mechanisms of spasticity, to develop superior treatments for this condition.

1.4 Thesis Overview

In the following chapters the entire research project is reviewed and discussed. Chapter 2 reviews the literature and includes more detailed background information on the current understanding of spasticity and its effects, as well as how spasticity is currently measured clinically. Also included in Chapter 2 is a critique of other researcher's attempts to quantify spasticity, including a prototype of the current device, and how their work relates to the current research project. Chapter 3 covers all aspects of the experimental procedure including design of the device, safety concerns, control of the device, data acquisition, and testing protocol. Chapter 4 discusses the data obtained using the device and includes an in

depth analysis of the results as well as a thorough discussion of the significance of the data and results. Chapter 4 also includes a suggested means to quantify spasticity based on the collected data. Chapter 5 evaluates the research project with respect to the original objectives and suggests future work which would contribute to the work undertaken for this project.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

The information in this chapter expands on the motivation for the project and reviews information vital to developments discussed in the following chapters. This review includes, but is not limited to information relevant to the understanding of spasticity, current clinical measurement of spasticity, and attempts to quantify spasticity. Not all measurement systems reviewed were designed to measure spasticity at the ankle, but because of the limited amount of research reported in this area, it was found useful to review the literature where measurement of spasticity or joint stiffness in general was the focus.

This literature review covers a number of important areas regarding spasticity and its measurement. Firstly, the current understanding of spasticity and how it affects people who suffer from it is discussed to help explain why this project was undertaken and why there is so much difficulty associated with spasticity measurement. In order to understand spasticity measurement, one must first understand the physical aspects of spasticity such as stiffness and reflex response. From this understanding, a model of the spasticity phenomenon can be determined. Clinical measurement of spasticity is currently performed and these techniques are discussed in some detail. The shortcomings of clinical measurements of spasticity led to early

attempts to quantify spasticity, which were largely unsuccessful, and to more recent computer-controlled measurement techniques. The current literature review highlights earlier problems with spasticity measurement which can hopefully be avoided and reveals some of the more useful measurement techniques. These techniques were used by the Rehabilitation Engineering and Clinical Technology (REACT) research group to develop a prototype device to measure spasticity, which is also discussed.

2.2 Current understanding of spasticity

There are many schools of thought as to the best way to measure spasticity and much disagreement exists over the suitability of various measurement techniques [8]. This follows from the lack of understanding of the nature of spasticity. Panizza et al [9] recognizes this situation and states; "Currently, physicians usually have very little difficulty in the diagnosis of spasticity in most of their patients, but the problem arises when quantitative considerations must be added, probably because spasticity is not a simple entity but a syndrome originating from a variety of disorders ...". The literature does not adequately address these issues as is confirmed by Levin [10] who writes; "As yet there is no literature addressing the reproducibility of the existing barrage of clinical evaluations of spasticity and reflex measurement. Also not clear is whether or not a systematic relationship might exist between these multiple indices of spasticity." As a result, the exact pathophysiological mechanisms underlying spasticity still remain obscure [11].

2.2.1 Stretch reflex

A stretch reflex is a monosynaptic reflex evoked by a sudden increase in muscle length, resulting in a contraction of the stretched muscle. The reflex is controlled by stretch receptors called muscle spindle organs, located in the muscle. The muscle spindles respond to both the velocity of lengthening (dynamic stretch, or angular velocity), and to the actual length of the muscle (static stretch, or angular position) [12]. The response of the muscle spindles to dynamic and static stretch means that the stretch reflex consists of two components, the phasic and tonic stretch reflex. The phasic component of the stretch reflex responds to rapid stretching of the muscle, whereas the tonic component of the stretch reflex is the response to a slower stretch of the muscle [11]. The tonic stretch reflex is also modulated by the size of stretch and the length of the muscle at which the stretch occurs [13, 14, 15].

In the presence of spasticity, the sensitivity of the stretch reflex is exaggerated and the subject is unable to control the reflex which responds to the stretching of muscle, whether appropriate or not [11]. There are two measurable parameters which can be altered in the stretch reflex which could account for the reflex mediated increase in resistance associated with spasticity [16]. The reflex threshold is the angular threshold at which the stretch reflex occurs. This threshold is manifested clinically as the 'catch point' at which the resistance to a manual stretch abruptly increases. If this reflex threshold was reduced, a smaller and/or slower motion would be sufficient to reach the reflex threshold at which point the reflex torque or force of the muscle increases in proportion to the increasing muscle length. Another possible disturbance of the stretch reflex is the reflex gain, which is characterized by an abnormal increase in reflex force

with increasing rotation of the joint without significant change in the reflex threshold angle. In quantitative terms, the angular stiffness, which is a measure of stretch reflex gain, is increased above normal at the point where the reflex response occurs. It has been found that the stretch reflex activity varies with ankle position [12].

2.2.2 Muscle stiffness

“Stiffness” is broadly defined as the incremental force evoked by a unit displacement. In terms of spasticity measurement, it is often considered torque over angular displacement, obtained by simply dividing the incremental change in force or moment by the corresponding displacement as if the curve was linear. The spring-like properties of muscles are believed to play an important role in maintaining human vertical posture, both during locomotion, and in control of muscular activity. In order to describe and study these properties, researchers in the field of biomechanics frequently use the well established physical notion of stiffness described above. The applicability of this term for describing such complex objects as muscles, tendons, and joints is not obvious although measurement of mechanical properties (stiffness, viscosity, impedance etc.) of passive joints, albeit not easy, does not meet with conceptual difficulties [17]. A basic understanding and definitions of the terms that are being measured, as well as an understanding of the limitations of the definitions, are required to ensure that meaningful results, which can be compared with other research, are obtained.

Stiffness, defined as the total mechanical resistance to an externally imposed change in joint angle, is the result of the combined contributions of passive tissues and active contractile

properties of the involved muscles and tendons, so the presence of increased stiffness cannot be automatically contributed to an enhanced stretch reflex [18, 19, 20]. One has to consider the model of the muscles and reflex mechanism to help understand what occurs when a joint rotation takes place. When the length of a passive muscle exceeds the resting length, increased resistance is provided by the connective tissue known as the parallel elastic components (PEC) according to the well known Hill model [21]. By definition, PEC are responsible for muscle stiffness when contractile components do not generate force. The stiffness of the whole activated muscle is determined by its PEC as well as the series elastic components (SEC). A common three element muscle model is shown in Figure 2.2.2-1 (including the contractile components (CC)). A viscous element is also assumed in the model.

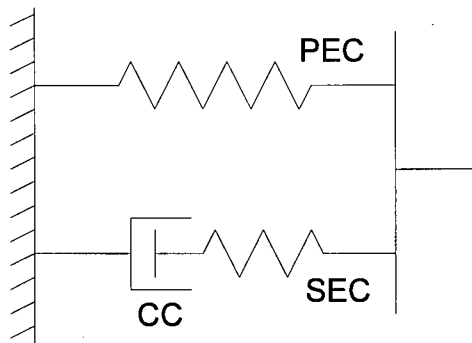


Figure 2.2.2-1 Three element muscle model [21]

When a joint is rotated to a given angle at varying angular velocities, the slope of the curve relating muscle force to angle of joint displacement (muscle length), commonly referred to as the stiffness, is contributed to by both the intrinsic stiffness of the muscles as well as the reflex response. This response is similar to a simple spring which generates a restoring force that is

proportional to its change in length. It has been considered that an increase in the intrinsic mechanical stiffness of the muscle is responsible for the increased resistance noted in spasticity. However this hypothesis, involving a change in intrinsic muscle properties, does not easily account for many established findings such as enhanced phasic muscle stretch reflexes which indicate that motoneuron excitability is increased [16]. This type of response would have to be caused by a latent reflex loop, which is taken into consideration in the following models.

Kearney described ankle mechanics in terms of a model having a linear passive pathway in parallel with a non-linear, velocity dependent reflex pathway as shown below [22].

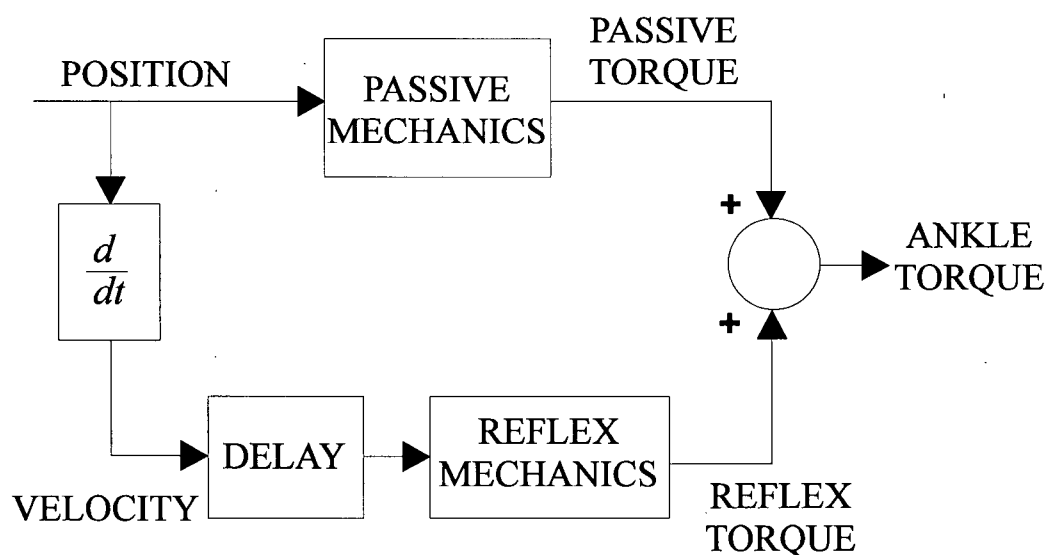


Figure 2.2.2-2 *Passive and reflex stiffness mechanisms [22]*

In this case the phasic stretch reflex response, dependent on velocity, is delayed, roughly 40 milliseconds, behind the intrinsic stiffness of the muscle-tendon complex.

The figure below shows another model of the stiffness properties of muscles [20]. This model incorporates the linear visco-elastic properties of the muscle and tendon and includes a latent reflex loop. The active components of this model, i.e., the reflex loop, influence the behavior of the model through five parameters; gain, latency, phase shift, natural frequency, and damping ratio. The active component is mathematically represented by a second order, low pass system function. It is this contribution of the active component which is exaggerated in spasticity [20]

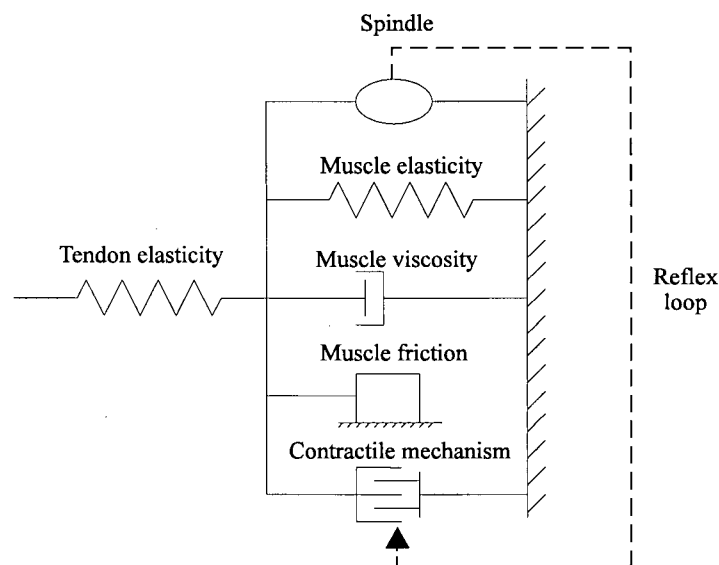


Figure 2.2.2-3 Model basic to visco-elastic properties of muscle and tendon [20]

“Dynamic stiffness”; a term adopted by Kirsch et al [23] is used to describe the overall relationship between the dynamic, nonlinear force and an imposed displacement. This term was adopted because an external displacement imposed on a muscle or limb elicits a force or moment that generally has both static (intrinsic muscle stiffness) and dynamic (reflex response stiffness) components which results in a nonlinear response. The term was introduced in an attempt to clear up the confusion created by the casual use of “joint

stiffness". The nonlinear nature of the neuromuscular system results in estimates of dynamic stiffness that are heavily dependent upon the definition used and the type of experimental data obtained [23]. The functional significance of different measures of muscle stiffness can be usefully evaluated by recognizing the limits of each type of measure and the mechanisms giving rise to the observed behavior.

There are a number of proposed models to describe the stiffness of a human joint, whether suffering from spasticity or not. Each of the models attempts to accurately model what is an impossibly complicated system full of nonlinearities. The model developed by Kearney [22] is clearly expressed in Figure 2.2.2-2 as a function of the input position. In this case the output torque is a function of both the input position and the input velocity subject to a delay. This model fits well with the commonly accepted definition of spasticity. From the perspective of this project, the most relevant stiffness model is the Kearney model. Adopting this model for this project would require some means to mathematically express this non-linear system. The non-linearity of the model arises from the delayed velocity contribution which was found to be lagging approximately 40 milliseconds behind the initial position input [22, 23]. This short delay is significant in the research done by Kearney as the testing perturbations were less than 40 milliseconds, and data gathering was only half a second long at 200 Hz. However, the testing proposed for the current project is of much longer duration so the 40 ms delay may be ignored. This allows the model to be approximated with a second order system. The mathematical equation for this approximation will be a second order linear differential equation of the form,

$$\frac{d^2T}{dt^2} + 2\zeta\omega_n \frac{dT}{dt} + \omega_n^2 T = K\omega_n^2 \theta + V \frac{d\theta}{dt} + A \frac{d^2\theta}{dt^2}$$

where θ is the input angle or position, T is the output torque, and t is time.

In this case, the resistive torque will depend upon four parameters related to the joint. The gain parameter, K , will be dependent on the intrinsic stiffness of the joint. The response parameter, ω_n , will be related to the rapidness of the output torque curve matching the input position and the damping parameter, ζ , will be related to the viscous elements within the joint. The velocity component, V , will be related to reflex response due to the speed of the test and is indicative of the velocity dependence of spasticity. The fifth parameter, A , is the acceleration gain, and is assumed to be zero.

2.2.3 Effects of spasticity

Spasticity represents one of the most crucial impairments for individuals with central nervous system disease [16] and it affects over six million people each year [24]. The main concern of people with spasticity is usually their loss of strength and dexterity, plus increased muscle stiffness which obstructs movement. The weakness brought on by spasticity is due to a loss of voluntary muscle strength or a depression of motor function. This degree of weakness may differ for different muscle groups and for different diseases associated with spasticity. The loss of dexterity associated with spasticity [25] is most significant during fine movements and results in an inability to make independent movements as well as a slowing

of the rate of voluntary muscle contraction [11]. This lack of coordination and muscle weakness ultimately reduces the subject's quality of life.

Spasticity results in impairment of postural control, mobility and function [26]. Spasticity interferes with voluntary movements causing them to be performed clumsily with the limb adopting abnormal or awkward posture. Involuntary, often painful spasms may also occur [27]. The level of spasticity is known to be affected by a number of factors including anxiety, depression, fatigue, ambient temperature, the use of drugs, body position, as well as by the comfort of the subject [28]. Spasticity disrupts activities of daily living for those affected and limits the efficacy of physical therapy by resisting therapeutic movement [29, 30]. The reduction of spastic hypertonia is mandatory to improve the individual's level of function [31]. Rehabilitation for individuals suffering from spasticity is very difficult without a reduction in the severity of the spasticity.

2.3 Clinical measurement of spasticity

Although caregivers have little difficulty in diagnosing spasticity due to its well established characterization, its measurement by a reliable, well accepted means has challenged both clinicians and researchers, and quantification remains elusive. One of the most obvious and consistent characteristics of spasticity is an increased resistance to passive stretch. As a result, clinicians often evaluate the severity of spasticity by applying a manual passive stretch to a muscle group and observing the encountered resistance. In the past, spasticity was popularly assessed using an ordinal scale of Mild, Moderate, or Severe.

The most common method for clinically assessing spasticity in use today, is the Ashworth Scale or the Modified Ashworth Scale [32, 33]. Almost all studies monitoring the effectiveness of therapeutic or drug treatment for spasticity monitor their progress using this scale [32, 33, 34], sometimes in conjunction with electromyography (EMG) which measures the activity of a muscle. The Ashworth scale, named after its creator in 1964 [35], uses a five point ordinal scale for grading the resistance encountered while passively stretching the muscle (Table 2.3-1). The scale is a nonlinear method of qualitatively assessing the severity of a subject's spasticity, and because of this, results are usually clustered in the middle of the scale.

Grade	Description
0	No increase in muscle tone.
1	Slight increase in muscle tone, giving a "catch" when the affected part(s) is moved in flexion or extension
2	More marked increase in muscle tone but affected part(s) easily flexed.
3	Considerable increase in muscle tone: Passive movement difficult.
4	Affected part(s) rigid in flexion or extension.

Table 2.3-1 Ashworth scale for grading spasticity [35]

In 1987 Bohannon and Smith presented a modified version of the Ashworth scale appropriately called the Modified Ashworth Scale (MAS) [36]. This version of the Ashworth Scale had an additional grading (1+) and slightly altered definitions (see Table 2.3-2). Their study supported the reliability between testers of a manual test of elbow flexor muscle

spasticity using the MAS. Although this finding contrasts with the idea that subjective methods for assessing spasticity are unreliable, the results of such testing are far too gross to detect incremental changes in the disease, nor are they suitable for comparison with other clinician's results. Indeed, Bohannon and Smith write: "We believe that the reliability we obtained can be attributed, in part, to our experience and extensive mutual testing and discussion. Without such collaboration, different results might have been obtained." [36]

Grade	Description
0	No increase in muscle tone.
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM.
2	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved.
3	Considerable increase in muscle tone, passive movement difficult.
4	Affected part(s) rigid in flexion or extension.

Table 2.3-2 Modified Ashworth scale for grading spasticity [36]

Sloan et al performed an independent study of the MAS and found that it provides a satisfactory clinical measure of spasticity in the upper limb [37]. The results were not as good for lower limb spasticity and thus Sloan et al concluded that the MAS does appear useful for testing spasticity of the upper limbs but questioned its validity for testing lower limb spasticity.

A further study by Allison et al testing spasticity at the ankle plantarflexors (as they were cited by Bohannon and Smith as one muscle group which may be more difficult to assess lent some qualified support to the continued use of the MAS) [4, 33]. However they felt that the reliability of the test for spastic plantarflexors may be less than optimal due to mixed results for intrarater reliability and poor interrater reliability. They concluded: "Although marginal reliability has been demonstrated in this study, a larger question which has not been addressed is whether a qualitative ordinal scale is an acceptable measure, regardless of its reliability." [33].

There is a certain amount of discomfort associated with the use of an ordinal scale to assess spasticity. Terminology used in the MAS table contribute to poor interrater reliability. Adjectives such as 'slight', 'minimal', 'considerable', and 'difficult' are ambiguous and invite varied interpretations. Even deliberate attempts to address these ambiguities by testers failed to alleviate tester's discomfort with the level of subjectivity inherent in the scale [33]. It has been found that manual scales, such as the MAS, suffer from a clustering effect with most patients in the middle grades [16]. However, the modified Ashworth scale remains the main method of evaluation of spasticity in routine practice.

2.4 Quantification of spasticity

The importance of quantifying spasticity has never been greater than it is today. Numerous treatments, therapies and drugs are undergoing testing to determine their suitability to alleviate spasticity. These treatments require reliable, quantitative means to assess day-to-day

incremental improvements or increases in the severity of spasticity. At the same time there are increasing demands on therapists to document clinical treatment outcomes for reimbursement by third party payers such as insurance companies and government health providers [4, 38]. This required treatment outcome documentation depends on measures with demonstrated reliability [4] such as a means to quantitatively measure spasticity. The literature offers a variety of alternatives for measuring spasticity but no single method seems to be widely used [39,40]. This has been confirmed by a recent survey [38] which indicates that health care professionals did not measure spasticity although it was regarded as an important issue.

In a review of the available literature, the device controlled quantitative methods for the measurement of spasticity can be divided into two groups; 1) those methods of measurement which have some non-automated component, which could introduce variation between measurements, and 2) those which were entirely automated and therefore more reproducible. Those in the first category are generally superior to the qualitative and semi-qualitative methods currently used to clinically evaluate spasticity, but they still introduce unnecessary variability into the measurement. While those in the second category provide a higher level of repeatability, unfortunately none have been entirely successful in providing an accepted measurement of spasticity, nor do they meet the criterion for this research project.

The various quantitative measurements of spasticity are divided into several different categories. Non-automated methods of measurement such as dynamometers and goniometers are discussed in Section 2.4.1, while fully automated methods of quantifying spasticity are discussed in Section 2.4.2.

2.4.1 Device assisted methods of measurement

Perhaps the most basic means of 'quantifying' spasticity is the use of electromyography (EMG) to record the relative activation of the involved muscles which is then correlated to the degree of spasticity. A number of researchers [39, 41, 42, 43, 44] have used EMG analysis as a means to objectively quantify spasticity with some measure of success. However, the repeatability of EMG is generally poor due to the use of surface/skin electrodes which can never be applied with precision to the same location [38]. Another shortcoming of EMG lies in its inability to distinguish between voluntary muscle activity and spontaneous, involuntary muscle activity due to spasticity [39]. Other limitations of EMG measurement to determine muscle activity around a joint include the inability to include all of the involved muscles around complex joints such as the ankle, and the fact that muscle activity alone does not constitute a measure of the degree of spasticity. EMG does contribute to the understanding of the muscle behavior associated with spasticity and, correlated with other measures, can be a powerful tool, but on its own it simply has too many limitations.

Another method of quantifying spasticity, which has been in use for many years is the pendulum test [45, 46]. The leg is dropped from full extension and allowed to swing freely with the patient lying in a supine position. The swings are recorded, occasionally with EMG measurements, and the position vs. time data is used to determine the degree of spasticity. The recorded knee movement is usually a sinusoidal pattern of angular motion which can be modeled mathematically to differentiate between a limb with spasticity and one without. This mathematical model questionably assumes that the mechanical properties of the knee

extensor and flexor muscles are equal and that the model can be treated as a simple linear second order system. However, muscle stiffness and viscosity vary with the degree of muscle excitation and muscle length. [16]. Despite these flaws Katz found the pendulum test to be a practical and reproducible measure of spasticity [40]. Other research also found that consecutive trials of the pendulum have quite good reliability's ($r=0.96$) [47]. However, some concern over the transferability of the pendulum test has been expressed. Undefined definitions needed to perform the pendulum test have led to incorrect interpretation of results and lack of repeatability over time [48]. Another shortcoming is that this test is only used to test the quadriceps muscle and is unsuited for measuring other muscle groups [38].

Hand held dynamometers have often been used to measure spasticity [49,50,51]. Typically they are used to measure the resistance of a voluntary muscle contraction (recording the maximum value) and are therefore more suited to measuring strength or weakness. In one case a hand held dynamometer was used to push the subject's passive limb about its joint at approximate speeds, while the device recorded the maximum resistive torque [50]. The use of hand held dynamometers provides only approximate angular velocity and only a single measure of the maximum resistive torque and therefore obviously cannot meet the requirements for objectivity demanded by this research project.

Another technique makes use of the isokinetic dynamometer to restrict joint motion to a constant velocity. Some commercially available units such as the KINCOM Dynamometer [32, 50, 52, 53, 54] and the Cybex II [42, 55, 56, 57, 58] have been used in attempts to

measure spasticity. However, dynamometers are used to restrict velocity rather than controlling it and therefore are not as consistent as a computer-controlled motor driven device. In the event that the velocity is too low, the dynamometer will not increase the velocity, nor will it maintain a constant velocity with 100% accuracy. The KINCOM [54] is typically used for strength measurements and has a passive mode which allows the measurement of spasticity. However, a severe limitation is that it is not portable. The work done by Ensberg [32] correlated the slope (work done) results of a computer-controlled KINCOM with a clinical assessment using the Ashworth scale with little success ($r = 0.28$). Other researchers used only the end values of the torque curves [50], ignoring most of the data, or manually rotated the joint, relying on the dynamometer to restrict movement [52] resulting in velocities of unknown accuracy. The Cybex II requires the subject to lie on their back on a table with the subject's knee at the edge of the table and the lower portion of the leg in the device. Movement of the knee joint is then used to elicit spasticity. This device is often used in conjunction with the pendulum test [47, 55]. In other research using the Cybex II, the subject was required to perform a voluntary movement which was restricted by the dynamometer [59]. In this research, the voluntary movement cannot be considered objective, or repeatable.

After a review of the device assisted methods of measurement it is obvious that all of these available techniques for quantifying spasticity cannot meet the objectivity requirements demanded by this project because none are fully governed by the devices used. In addition several of the techniques only provide one measurable point of data from which spasticity is

quantified which results in the loss of potentially important data. Finally, some of the devices require a voluntary contraction which is sometimes not possible and cannot be considered entirely objective.

2.4.2 Motor controlled measurement

In order to have a completely objective and entirely reproducible test for the measurement of spasticity, controlled displacement must be applied to the limb. One of the easiest and most effective methods to provide controlled passive manipulation of the ankle is to use a motor. Several motorized devices to measure spasticity have been developed and are discussed below.

There are two main methods used for testing for spasticity using a computer-controlled motorized device. The first method rotates the joint through a sinusoidal velocity profile while recording the response. The second more common method (and subsequently adopted for this project) rotates the joint through a fixed rotation at a constant velocity while recording the response. This latter method is known as the ramp and hold method, referring to the velocity profile generated by the joint rotation. This method closely duplicates the motion used in common clinical testing discussed in Section 2.3. Both of these methods have been implemented with varying success and are reviewed, along with some less common techniques, within this section.

Several researchers have attempted to measure the severity of spasticity using a computer-controlled, servo-motor driven device to impose a sinusoidal oscillating movement to the joint

at different frequencies, which is met by a corresponding cyclically changing force from the joint [19, 29, 59, 60]. The reasoning behind adopting this method of measuring spasticity is that sinusoidal oscillations produce more readily repeatable and consistent stimuli than the ramp method. However, in order to effectively isolate the torque due to the reflex response, the inertia of the limb, inertia and drag of the measurement system, and the contribution of the passive properties of the tissues have to be considered. While a concern, these contributions can be roughly approximated and removed from the final results thus providing a measured spasticity response of reasonable accuracy.

One device, using sinusoidal movement, was used to quantify spasticity based on frequency dependent changes in viscous and elastic stiffness [19]. Torque values representing ankle resistance as a function of ankle displacement were reduced to two components; 1) the in phase resistance due to elastic stiffness and 2) the 90° out of phase resistance due to viscosity. These two components of the resistive torque were determined by using a Fourier analysis to decompose the combined torque response into their sinusoidal components. The vector sum of these components was considered to be the total ankle stiffness and the final path length of the total stiffness values was used to represent the overall degree of ankle spasticity. This path length was determined by plotting the total stiffness vectors for all frequencies tested, and then adding together the distance between each consecutive vector apex. Longer path lengths resulted from frequency dependent variations in the ankle stiffness which were attributed to the velocity dependence of spasticity and were considered to be related to the degree of spasticity. Test-retest reliability was shown to be good for subjects with spasticity at high frequencies (11

Hz). However lower frequencies, especially below 7 Hz, showed either lower stiffness due to viscosity for the subjects with spasticity, or inconclusive results. At higher frequencies (11 Hz) it was concluded that spasticity could be quantified, but some of the earlier conclusions at lower frequencies lend a measure of doubt. A drug evaluation study [29] which employed the device produced results which showed that, for the same subject, day-to-day variations in the degree of quantified spasticity ranged from as little as 0% to as high as 56% for the 9 subjects, with an average day-to-day variation of 22%. Variations of this magnitude cannot be representative of a reliable and repeatable method for the measurement of spasticity.

Other studies, using similar techniques, have been undertaken, but the objective of the research was to simply investigate the properties [60] or the stretch reflex [59] of ankle joints with and without spasticity rather than determine a means to quantitatively measure the degree of spasticity. The results of Rack et al [59] were somewhat inconclusive as they concluded; "Spastic subjects showed relatively stereotyped responses, with evidence of a vigorous spinal stretch reflex. The responses of limbs without spasticity were variable; there was little reflex response to the first cycles, but as the movement continued the reflex responses increased and often came to resemble the responses of spastic limbs." Patterns of stretch reflex activity provoked by sinusoidal oscillations of the ankle joint were studied by Reberšek et al [60]. Their device consisted of an electrohydraulic position controlled servo-system. The intent of their research was not to develop a clinical tool for the evaluation of spasticity, but rather to determine the muscle length dependence of a spastic reflex response. They found that in the case of carefully controlled experimental conditions, an acceptable repeatability of results can

be achieved using the sinusoidal oscillation technique. They concluded that the resistance to passive movement was highly dependent on the muscle length at which it was tested. This is commonly acknowledged to be the case. In either study, no attempt was made to quantify the results.

Problems associated with using a sinusoidal movement are numerous. It is not clear whether such an unnatural movement could be considered as an effective means of assessing spasticity, nor can it be directly compared to current clinical methods of testing such as the modified Ashworth scale. Using a sinusoidal movement also necessitates the use of servo-motors rather than stepper motors which could also result in some discrepancies in the repeatability of the movement, as servo-motors use feedback controlled positioning. Similarly, sustained repeated movements for a period of time, over a number of test frequencies, could result in fatigue of the subject which could cause unforeseeable effects on the degree of spasticity. The repeated movement could also result in training effects over time.

Inertia is another problem associated with using sinusoidal oscillations of a joint to measure spasticity. The forces generated by inertia are proportional to the acceleration of the limb. Therefore, sinusoidal motion forces are related to the square of the frequency of the oscillations so for large oscillations, the motion must be restricted to quite slow movements, and as a result, the effects of rapid stretching cannot be discerned. On the other hand, for rapid movement, the oscillations must be quite small, and the motion restricted to a few degrees, providing limited information [61]. In addition, research has suggested that the reflex response is strongly

nonlinear and that on-going movements inhibit the reflex action in proportion to their average velocity [22, 62, 63] thus constant oscillations may actually inhibit the reflex response which is being measured.

In contrast, the ramp and hold technique closely duplicates common clinical testing. Several groups of researchers have made use of this technique by implementing a computer-controlled motor driven device to quantitatively measure stiffness about a joint. Some have simply been used on healthy subjects to measure passive stiffness properties [64, 65] while others have been used to evaluate spasticity [16, 18, 19, 40, 66, 67, 68]. The work done by Sinkjær's group [19,66] used a unique approach in which the subject's ankle was subjected to a perturbation (or small movement) of between one and seven degrees for periods of 450 ms followed by a 450 ms release period, then repeated. This is similar in practice to the sinusoidal motion discussed earlier because it subjects the joint to oscillations at a frequency of approximately 67 Hz, but in principal is quite different. In fact the perturbations are essentially a ramp and hold technique since the velocity of the joint returns to zero after approximately 50 ms and is held at that position for the remaining 400 ms of each cycle. The technique could be accurately described as using ramp and hold oscillations. However, because a servo-motor was used, there was a considerable acceleration and deceleration phase such that the velocity profile was not a true ramp and could be best described as 'step-like'. In addition, the tests were performed to investigate reflex response during a voluntary contraction (i.e. the subjects were asked to match a torque level preset on an oscilloscope and were asked not to attempt to adjust the torque

during the stretch and release periods) rather than during a passive stretch which more closely conforms to the definition of spasticity. The research came up with a single stiffness value representing the degree of spasticity. Some of the results were contradictory. Intrinsic stiffness increased for the subjects with spasticity, but the reflex stiffness was zero for the patients and increased up to 50% for the subjects without spasticity. Although this type of measurement is quite useful for investigating properties of the stretch reflex, the very small and brief perturbations require very accurate measurements which might not be typically used in a clinical setting. Also not all subjects are able to perform a voluntary contraction as many would have no control over the limb being tested. Voluntary contractions also introduce unnecessary variability to the measurements and produce an increased non-reflex resistance and torque. The relationship between the degree of voluntary contraction, increase in reflex response and change in passive properties is not known so results of this testing are subject to even further unknowns.

A group of researchers led by Katz [16, 40] have developed a device most closely related to the device used for this project. The device utilized a computer-controlled servo-motor to rotate the subject's elbow joint through a ramp and hold velocity profile while recording the resulting resistive torque and EMG activity. The device was developed to study stretch reflex dynamics in spastic elbow muscles [67, 68] and used ramp and hold rotations of the forearm in the horizontal plane. This research tested both passive and voluntary stretch of the involved muscles and found that, contrary to earlier studies, stretch evoked torque displays a relatively

weak dependence on stretch velocity. The research concluded that increased tone in subjects with spasticity was likely due to a decrease in reflex threshold rather than a velocity dependent increase in stretch reflex responsiveness.

Further work by the same group used the device to quantitatively measure the degree of spasticity at the elbow [16, 40]. The results from the spasticity measurement device were correlated with clinical measures of spasticity. The use of the device to measure reflex threshold angles at speeds of 30°/s and 60°/s significantly correlated with clinical estimates of spasticity using the Ashworth scale. However, they acknowledged that there were some unresolved difficulties with the measurement of reflex threshold. Estimating the onset angle of muscle activity from low levels of EMG is technically difficult, and different muscles will show different reflex responses so that identical muscles need to be measured each time, which is in itself difficult. The researchers conceded that occasional EMG tracings were eliminated due to uncertainty. These problems make this type of analysis difficult and undesirable for clinical use. In order to avoid these difficulties they chose to use a more practical approach by measuring the torque at some specified joint angle just before the end of the constant velocity ramp stretch. This was done because stiffness was not considered to be a significant variable thus the torque measured at a predetermined angle should be closely dependent on the reflex threshold. However, correlation between this method of quantifying spasticity and clinical testing was shown to be not statistically significant. In conclusion, they suggested that torque measures would be more useful as a means of measuring spasticity.

Later work done by Given [17] was very similar to this project. Subjects with spasticity were tested at both the ankle and the elbow at speeds between 20°/s and 60°/s. The research was interested exclusively in 'passive' stiffness of the joints which, by their definition, excluded any results which showed any EMG activity of the muscles. The research had some success in quantifying spasticity using the slope of the torque vs. time curve, representing stiffness, at the elbow, but had some difficulty at the ankle because of curvilinear nature of the torque vs. time curves from the ankle. Unfortunately, ignoring results showing EMG activity precludes the proper measurement of the reflex response which manifests itself as uncontrolled muscle activity and can be monitored by observing changes in EMG. The current research project is interested in reflex response of the muscles and would include these results.

One of the most unusual attempts to objectively measure spasticity, developed by Walsh, is based on the theory that the best way to measure spasticity is to measure the motion of the limb induced by varying the force applied to it [61, 69]. The theory is based on the idea that the limb exhibits a resonance and it is this resonant frequency that reflects the degree of muscle tone or spasticity according to the equation:

$$f = \frac{1}{2\pi} \sqrt{\frac{K}{J}}$$

where: f is the resonant frequency

K is the muscle stiffness

J is the inertia

The device used by Walsh, accomplishes the testing by applying a sinusoidal torque to the passive joint at a continuously changing frequency, while the position and velocity of the joint are also recorded. The resonant frequency for the limb (i.e. the point at which the peak to peak oscillations of the position and velocity of the limb are greatest) is then used to find muscle stiffness. This method was developed to provide a simple means of evaluating spasticity without having to deal with the effects of inertia of the limb and to easily evaluate the spasticity at varying inputs (in this case the level of torque). This method for the measurement of spasticity has been successfully correlated with electromyography (EMG) of the affected muscles which determines the firing of the motor units in the muscle (i.e.: the activity of the muscle). However, the method of measurement does not follow from the current understanding of the mechanisms of spasticity and as a result it has not received much support. Similarly, the quantification provides only one number (the resonant frequency) from which to determine the degree of spasticity.

Some additional work has been done by a group of researchers [22, 23, 62, 63, 70, 71, 72] who have expanded on the theories put forward by Walsh. Although their research has not been used to measure spasticity at the ankle, they have contributed to the pool of knowledge in the measurement of stiffness about the human ankle. Their research compared mechanical and reflex response evoked by a standardized pulse displacement with and without superimposed stochastic perturbations. The results demonstrated that, under certain conditions, passive joint movement alters stretch reflex gain. Even healthy stretch reflexes can generate substantial torque (approaching 10 Nm). Stretch reflex gain was significantly

modulated during changes in voluntary contraction, increasing with level of contraction and decreasing as the subject relaxed. The magnitude of response was shown to depend non-linearly on a number of factors (amplitude and duration of pulse, angle of the ankle joint, and the level of voluntary contraction). Similar results were found by another research group in Germany [73] using similar techniques and the results were corroborated by Sinkjær [19, 66] who, using slightly different techniques, concluded that the similarities between their work indicated that stiffness is relatively independent of the type of perturbation, whether it is a consistent step-like perturbation or the pseudo-random stretch as was Kearney's.

2.5 Initial Prototype Development

In order to quantitatively measure spasticity at the ankles of patients in several positions, at variable angular speeds, and to obtain a plot of torque versus time for each of these speeds, a prototype computer-controlled spasticity measurement device was developed. The prototype system was built prior to this thesis project and initial testing showed that successful quantitative measurements of an applied resistive torque could be obtained.

The prototype device was developed by the REACT research group over a period of several years [74]. The device was able to effectively record resistive torque data to passive stretch about the ankle [74]. To achieve these measurements, test subjects inserted their foot into a special foot pedal designed to securely hold the foot in place. The foot pedal was designed so that it was adjustable to allow the subject's ankle to line up with the axis of rotation of the device. A computer-controlled stepper motor provided torque, increased via a worm gear

reducer, engaged through an electric clutch and a torque transducer shaft, to rotate the subject's foot in a controlled manner. In doing so, the subject's ankle was rotated through a predetermined rotation and velocity profile while resistive torque measurements were recorded.

The initial prototype spasticity testing was planned in order to avoid extraneous reflex muscle activity, in which case the stiffness of the ankle joint would be measured at velocities less than $20^\circ/\text{s}$. This meant that the maximum angular velocity of the rotation was to be $\omega_{\text{max}} = 0.35 \text{ rad/s}$. The testing protocol was developed to passively rotate the subject's ankle joint through a series of repeated trapezoidal position vs. time profiles while recording the resultant resistive torque. An example of one of the trapezoidal position vs. time profiles is shown in Figure 2.6-1.

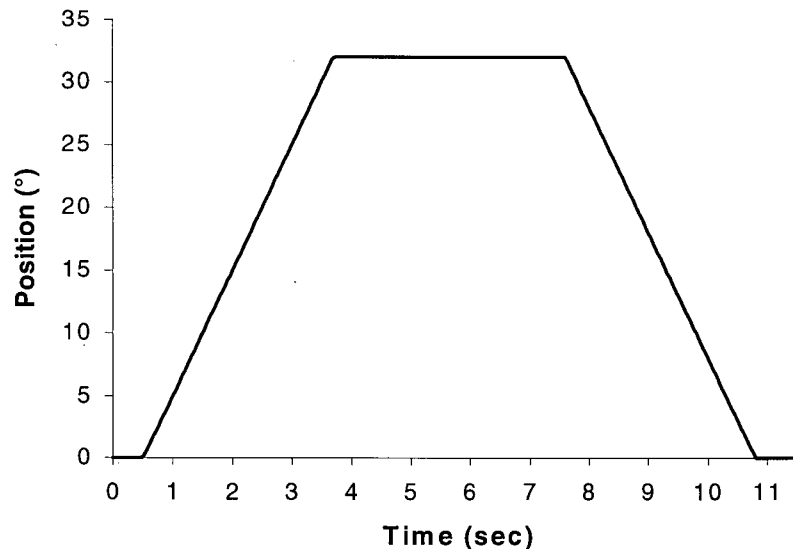


Figure 2.6-1 Example of Trapezoidal Position vs. Time Profiles

In order to accurately manipulate the joint through a desired velocity profile while being subjected to a constantly varying resistive torque, a sufficiently powerful stepper motor was desired. According to the information available at the time, a torque of 11 Nm had been recorded at the ankle of a patient with severe spasticity. Since there was much uncertainty associated with spasticity measurement values, it was decided to use a design factor of two so the torque required to overcome the spastic response was approximately 22 Nm. The loading effects of the system measured at no load were approximately 2 Nm. This accounted for the friction in the system as well as the gravity effects of the foot pedal at maximum extension. The gravity effects of the foot are already taken into account in the torque to overcome the passive resistance. In addition the torque of the stepper motor was geared down by 30:1 using a worm gear reducer with a conservatively estimated 50% efficiency. Using these specifications, the maximum torque required from the motor was determined to be 1.68 Nm at 10.5 rad/s. The calculations are shown in Appendix A. A Pacific Scientific motor/driver/indexer package was selected to power the system. This motor met the power requirements to drive the system at the maximum angular velocity of 10.5 rad/s. With 1.8 °/step the motor would have to run at:

$$\omega_{\max} = \frac{10.5 \text{ rads} / \text{s}}{1.8^\circ / \text{step}} * \frac{360^\circ}{2\pi} = 334 \text{ steps} / \text{s}$$

At this maximum velocity, the motor provides approximately 1.94 Nm of torque which was more than sufficient to power the system. The package included an integrated programmable indexer/high efficiency bipolar MOSFET driver combination. The specifications for the stepper motor package far exceeded those required for the system.

Although the prototype device existed, it lacked certain features that made it unsuitable for the defined application. Substantial modifications to the prototype were therefore necessary to meet the specifications for the current project. In order to determine the exact nature of the changes required, specifications for the current device needed to be defined and corresponding design changes needed to be completed.

2.6 Conclusions and Summary

Spasticity is little understood and a means to measure the effects of spasticity would greatly aid in its understanding. The physical aspects of spasticity such as stiffness and reflex response are easily grasped and understood but have been troublesome to model accurately. A number of complicated models exist which attempt to describe the torque response of spasticity. One of the existing models was chosen for this project and was approximated with a second order system.

Clinical measurements have proven to be unsuitable for accurate measurement of spasticity. This has lead to a number of attempts to quantify spasticity using device assisted techniques. Use of EMG measurements to quantify spasticity has proven troublesome and difficult. Repeatability of EMG is generally poor and EMG activity is unable to distinguish between voluntary muscle activity and activity due to spasticity. In addition it is unable to include all of the involved muscles, nor does muscle activity alone constitute a measure of the degree of spasticity. The pendulum test has proven reliable but only measures the quadriceps muscle and is unsuited for measuring other muscle groups. There has also been some concern over

the transferability of the pendulum testing protocol. Hand held dynamometers provide only approximate angular velocity and only a single measure of the maximum resistive torque. This is partly addressed by isokinetic dynamometers such as the Cybex II and the KINCOM. However, the isokinetic dynamometer is used to restrict velocity rather than controlling it. In some cases the systems rely on voluntary movement which is too variable for a truly objective test. Motor controlled measurement techniques identified into two categories; those which employed sinusoidal oscillations, and those which employed ramp and hold position profiles. Sustained sinusoidal movement is both an unnatural movement and is not analogous to current clinical testing. Using a sinusoidal movement also necessitates the use of servo-motors rather than stepper motors which could also result in some discrepancies in the repeatability of the movement. Another problem associated with sinusoidal movements is the constant inertia of the limb. The use of the ramp and hold technique closely models current clinical practices which are the benchmark against which quantified tests will be measured. By using a ramp and hold technique, inertia effects are eliminated during the constant velocity stretch. Several researchers have used ramp and hold techniques to investigate spasticity. In some cases voluntary contractions of the subjects were required. It is felt that voluntary contractions introduce too much of an unknown into the testing process. The relationship between the degree of voluntary contraction, increase in reflex response and change in passive properties is not known. Two research groups employed a device very similar to the current project device. Only one of the groups made an effort to quantify spasticity. Their device was used to measure reflex threshold angles which were correlated with the degree of spasticity. However, because of difficulties associated with the measurement of reflex threshold the

correlation between their quantifying spasticity and clinical testing was shown to be not statistically significant. In conclusion, this group suggested that torque measures were a more useful means of measuring spasticity. In keeping with that advice, the current project uses a stepper motor controlled, ramp and hold technique to collect resistive torque data in response to a passive rotation of the ankle joint. It was decided that a stepper motor should be used for the movement control as it provides exact movement control rather than feedback control. The analysis of the experimental data will also be a significant factor in successfully determining a quantitative measure of spasticity. Attempts to measure spasticity in this manner have already been attempted by the REACT research group using a prototype device which measured the resistive torque due to a passive stretch by a computer-controlled stepper motor and the ramp and hold technique.

CHAPTER 3: DEVICE AND PROTOCOL DEVELOPMENT

3.1 Overview

This chapter covers the current project's design, and method of operation, of the device developed to quantitatively measure spasticity at the ankle. An initial prototype design [74] of a device created prior to the current work was found to be insufficient for the testing to be done for this project. As a result, portions of the device were redesigned to meet the specifications of the new device and a testing protocol was developed for use with the new device. Safety concerns were also addressed in the redesign and corresponding safety procedures were included in the testing protocol. Once the design and protocol were completed, the control system and data acquisition system were developed along with a routine for data formatting and processing.

3.2 Limitations of the Prototype Device

The prototype device lacked a number of features which made it unsuitable for the current project. The original testing was to be done at much slower speeds than required by the current project, which meant a more powerful motor would be required. Safety for test

subjects, which is a serious concern, was not properly addressed by the prototype device. The prototype driveline was improperly supported and suffered from poor tolerances making accurate measurements impossible. The control system of the prototype had a poor user interface, had reliability problems, and was not comprehensive enough to meet the newer protocol requirements. More specifically, the prototype control system was very rudimentary and merely controlled the device to perform one of a few very specific tests which were determined to be unsuitable for the current project. In addition, simultaneous EMG measurements were not previously considered, and the device was not equipped for position measurement.

In order to properly redesign the device to meet the current project objectives, a set of design specifications were identified as provided below.

- A torque output of at least 2.04 Nm at 31.5 rad/s.
- A variable maximum applied resistive torque which could be adjusted for each test subject (by the use of a variable slippage clutch, for example).
- Maximum safe torque limits monitored by the control software which must have the capability to stop testing if the limits are met or exceeded.
- A mechanical 'last resort' safety mechanism (such as a shear pin or a ball détente).
- A precise and reliable driveline.
- A means to record angular position measurements of the ankle.

- A means to obtain and record EMG activity of the involved muscles.
- A user-friendly, and reliable control system.
- A control system which can properly accommodate the new testing protocol.

Based on these specifications, the current project requires a motor to overcome resistive torque as high as 2.04 Nm at speeds of up to 31.5 rad/s. This requires an upgraded stepper motor, and perhaps a new controller/indexer for the new motor. More stringent safety standards are also required for the new device in order to meet university ethics requirements for human testing and to ensure the safety of the test subjects. In order to obtain meaningful data, the new device requires a precise driveline arrangement and must be able to collect and store position data as well as EMG activity data to correlate with the spastic reflex torque response. An upgraded control system capable of accommodating the more rigorous testing protocol of the current project will also be necessary. Finally, in order for clinicians and therapists to use the device, a more user-friendly interface software program will also need to be developed.

3.3 System Development

After substantial design and development work, a measurement system to meet the objectives of this project has been constructed; a schematic of this system is shown in Figure 3.3-1.

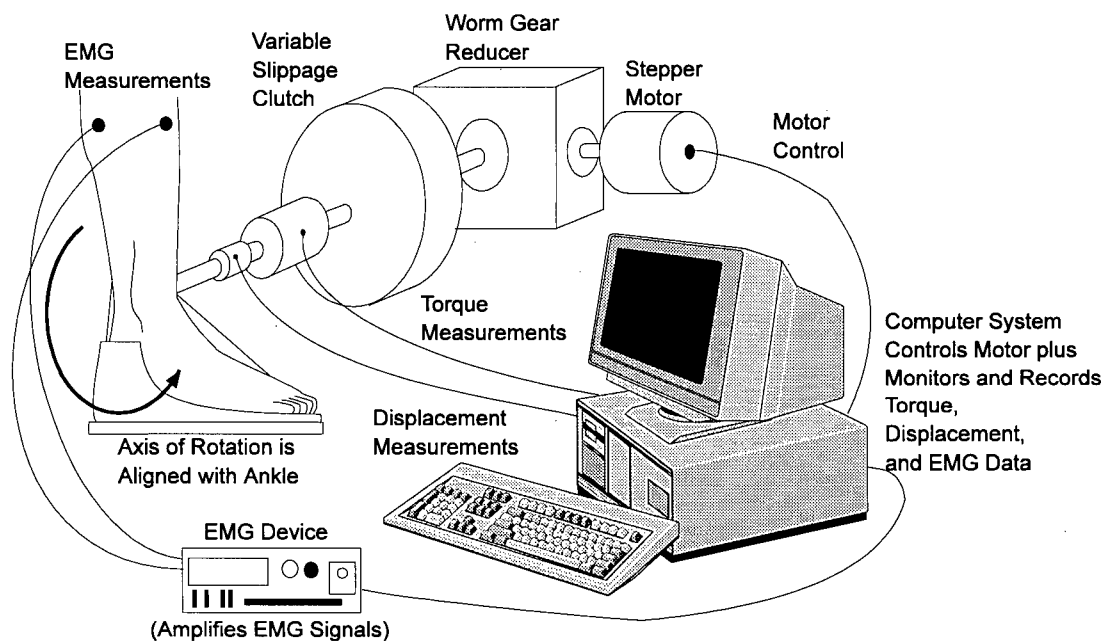


Figure 3.3-1 *Schematic diagram of the computer-controlled system to quantitatively measure spasticity*

In a similar manner as the prototype system, but with substantial improvements, this measurement system has been designed such that the motor-powered, computer-controlled apparatus can be used to simultaneously measure the resistive torque, ankle position, and muscle activity due to a passive stretch about the ankle joint. To accomplish this, subjects would insert their foot into a molded plastic and foam form mounted to a pedal-type platform specially designed to hold the foot securely in place without exposing the subject's foot to any cold metal. The pedal is adjustable, both vertically and horizontally, so that the axis of rotation of the ankle can be properly aligned with the axis of rotation of the device. The maximum angular range of motion (ROM) and allowable torque for each individual subject, measured prior to initial testing, will be stored by the computer for future control system comparisons to be used as a safety shutdown if required. Ankle joint rotation is provided via

a computer-controlled stepper motor, with its torque increased via a worm gear reducer, and engaged through an electric clutch. This system will move the ankle through a predetermined rotation and velocity profile while both resistive torque and position measurements are simultaneously recorded. At the same time, electromyography (EMG) measurements can be taken of the relevant muscle (gastroc soleus) to determine the extent of electrical activity associated with activity of the muscle, for correlation with spastic response. The computer control of the device allows testing to be undertaken at different velocities and duplicate tests to be performed to assess test-to-test and day-to-day reproducibility.

While the basic prototype device concept was used as the basis for the device used in the current project, the inherent limitations of the prototype device necessitated a number of substantial design changes. These changes to the prototype were performed in five areas; motor changes, driveline changes, safety component changes, control software changes, and data acquisition system changes.

3.3.1 Required Design Modifications to the Motor

A stepper motor, as opposed to a servo-motor, was chosen as the best means to power the device because a stepper motor provides accurate position and velocity control without the necessity of a feedback loop. A stepper motor will provide identical velocity profiles every rotation. If a servo-motor were chosen, it might not provide consistent velocity profiles under a varying resistive torque. A servo-motor would perform the rotation but might provide an

improper velocity profile due to insufficient power or poor feedback control, a condition which could be difficult to identify.

Because of a number of reasons the chosen prototype stepper motor did not provide sufficient power to properly rotate the ankle. Reasons included the higher than expected resistive torque due to spasticity, which was as high as 25 Nm rather than 11 Nm as originally measured, and the fact that tests were now required to be performed at speeds as high as 60°/s rather than 20°/s. At higher speeds the power provided by a stepper motor reduces dramatically. Because of budgetary constraints it was impractical to purchase another stepper motor/controller combination. Pacific Scientific provided a range of stepper motors which operated using the same controller/indexer combination, so the most powerful stepper motor which operated using the current indexer was purchased. The system response using this new stepper motor was found to be superior to that provided by the original stepper motor (see Figure 3.3.1-1).

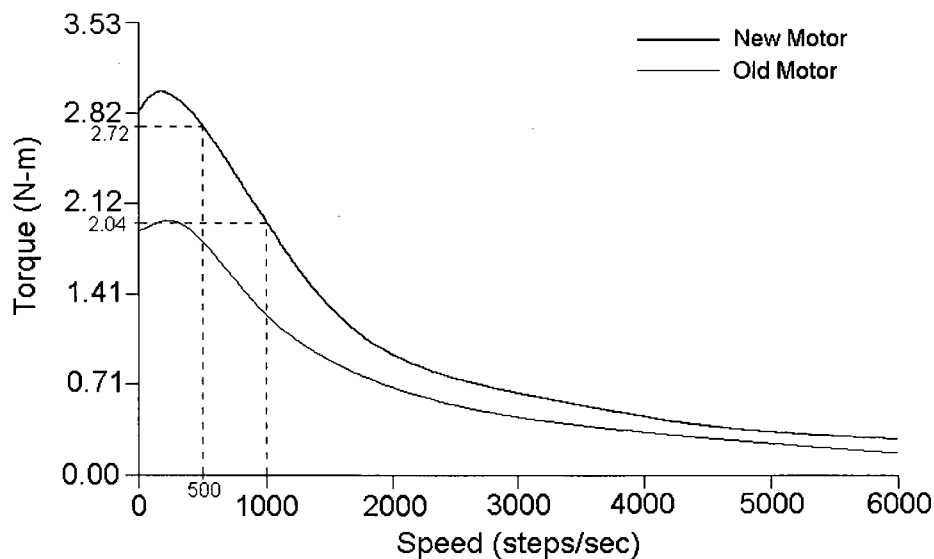


Figure 3.3.1-1 System response comparison of the two stepper motors

Most of the testing was done at a maximum velocity of $30^\circ/\text{s}$ (500 steps/s or 15.75 rad/s) and maximum torques were approximately 25 Nm. At this velocity the stepper motor was required to provide a minimum torque of 1.99 Nm to overcome a 25 Nm resistive torque at the ankle. According to Figure 3.3.1-1 the stepper motor provides approximately 2.72 Nm of torque at this velocity which was deemed sufficient for the research testing. At test velocities of up to $60^\circ/\text{s}$ the motor must provide at very least 2.04 Nm of torque (calculated in Appendix A) and in fact, provides exactly 2.04 Nm of torque which was deemed marginally suitable for the application. However, in cases where the passive resistance was quite high, testing at speeds as high as $60^\circ/\text{s}$ was impossible.

The new stepper motor was selected such that it would be sufficiently powerful to accurately follow the desired velocity profile against the expected varying resistive torque. The total range of motion of the device had to be capable of meeting the available range of motion for a human ankle joint. The mean values of ankle rotation for the general population are 35° flexion and 38° extension for a total range of motion of 72° . It was decided that a minimum range of motion for the system was 90° . However, given that the device had to accommodate testing of different joints, with a subject in a variety of positions, it was deemed appropriate for the device to have a range of motion of a full 360° .

The stepper motor torque was geared down using a 30:1 worm gear reducer. This allowed the use of a cheaper and lighter stepper motor which provides smoother rotation at the foot pedal, while the choice of gearing avoids the problems associated with resonance at the desired

driving speeds. Typically the natural frequency of a stepper motor is in the range of 90 to 160 steps/s. The device currently operates between 330 and 1000 steps/s (which translates to 20°/s to 60 °/s at the ankle).

3.3.2 Required Design Modifications to the Driveline

Several components of the driveline needed to be redesigned. The couplings were poorly designed in the prototype between the stepper motor and the worm gear reducer, the electric clutch and the torque transducer shaft, and the torque transducer shaft and the foot pedal shaft. The poorly designed couplings of the prototype device were held with only a set screw to transmit torque. The set screw often slipped when subjected to applied torque. For example, the foot pedal shaft was only 12.5 mm in diameter and so, with only a set screw to couple it to the torque transducer shaft, the transmitted torque values were large enough to cause the set screw to score the foot pedal shaft. In addition, the couplings were poorly fit and of low tolerance so the driveline suffered from 10-20 degrees of backlash. The redesigned couplings all used keyed shafts with proper tolerances. This eliminated driveline slippage and considerably reduced the backlash problem. The prototype device bearing supports were all single bearing supports which did not adequately support the driveline under load and required the driveline to carry a bending moment in certain regions, especially with the subject's foot loading the foot pedal. To correct this problem the driveline was redesigned with dual bearing supports allowing each bearing support to independently carry the load.

3.3.3 Safety Components

Safety was a major concern during the design and implementation of the device. Since the subject's foot was to be securely strapped into a device driven by a motor, numerous safety measures were deemed necessary in order to ensure the subject's safety. Computer control of the device provided the first level of safety. Before testing began, the device was used to record the subject's maximum voluntary contraction. A percentage of this value was then used as a limit for the recorded torque during the testing. The control software included a feedback loop from the torque transducer and if the maximum pre-set torque levels were exceeded, the control software would immediately shut down the stepper motor to prevent possible injury to the subject. Similarly there were 'panic' switches provided which either the subject or the tester could use to terminate a test at anytime if they felt uncomfortable. In the initial prototype, the electric clutch was intended to be employed as a safety device as it would slip if the transmitted torque exceeded a maximum value. The prototype's clutch was designed to slip at approximately 30 Nm which may be sufficiently low to test individuals with sturdy ankles, but for many individuals this slippage torque was too high to ensure safety. In addition, in some cases where resistive torque values higher than 30 Nm might be encountered, the slippage torque could be too low to allow proper testing. The solution to these problems was to replace the clutch with a variable slippage electric clutch. The new clutch would slip proportionally to the supply voltage which could be varied by the user. The new clutch offered a selectable slippage torque from 0 to 50 Nm, allowing the slippage torque to be reset for each new test subject as required. If the amount of resistive torque exceeded a pre-set safe level, the clutch would slip preventing excessive torque from reaching the subject's

ankle. Since the clutch is an entirely separate system from the computer control of the device and is set by the tester for each individual prior to testing, it provides an additional fail-safe unaffected by a potential failure of the computer-control.

The variable slippage of the clutch is set by the tester by modulating the power supplied to the clutch. This is accomplished by choosing the supply voltage based on ordinal settings, from 1 to 10, on the power supply. These ordinal settings are correlated with torque values in Newton meters as shown in Table 3.3.3-1. The correlated values were obtained by comparing the torque levels recorded by the device during slippage at a given level on the clutch, averaged over five recordings, each recording being at least 20 measurements.

Setting on clutch	Recorded torque at slip (Nm)	Extrapolated torque for common settings (Nm)
1	0.0	(0.0)
2	2.1	2.1
2.5		7.4
2.75		10.0
3	12.3	12.7
3.25		15.3
3.5		18.0
3.75		20.6
4	23.2	23.2
4.25		25.9
4.5		28.5
4.75		31.2
5	33.8	33.9

Table 3.3.3-1: Variable slippage clutch testing results

The calibration curve for presetting torque values was found to be;

$$T = 10.56C - 19$$

where T represents the ensuing torque (Nm) and C represents the equivalent ordinal settings on the clutch power supply. A graph of the results is shown in Figure 3.3.3-1.

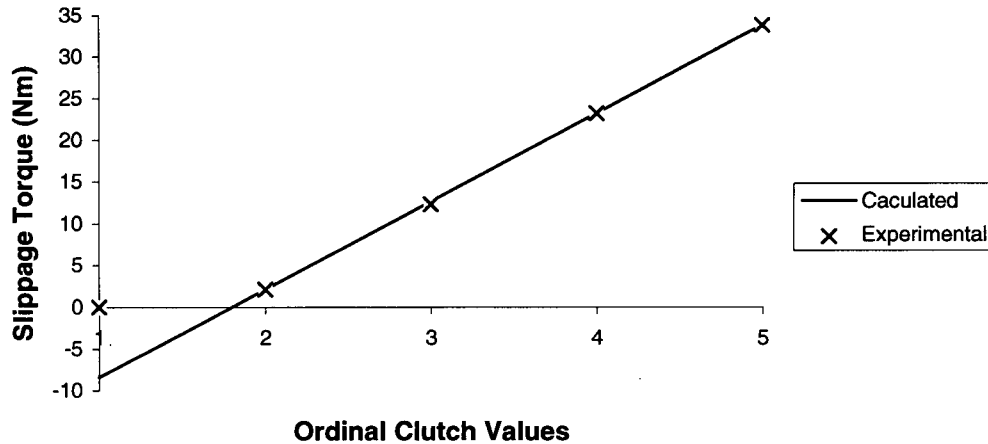


Figure 3.3.3-1 Relationship between the ordinal scale on the variable slippage clutch and actual torque values

In the worst case scenario, if a control and electrical failure should occur, a mechanical torque limit is ensured by the use of a shear pin which will break thereby ensuring the safety of the subject and providing a fail-safe system. The coupling between the torque transducer and the foot pedal shaft is secured with a pin linking overlapping shafts. This pin is sized so that it can serve as a mechanical "fuse". If an "absolute" safe torque limit is exceeded (assuming all other safety mechanisms fail) this mechanical "fuse" will break thus halting the device. Making the device operational again is a simple matter of replacing the pin. The

'strength' of this mechanical fuse can be modulated by the use of different size shear pins in order to accommodate the different ankle strengths of various subjects.

The torque required to shear the shear pins was determined by experimental testing using a jig identical to the coupling between the torque transducer and the foot pedal shaft. Shear pins, made of 1/4 inch 6061-T6 aluminum rod were radially grooved to varying inner diameters at the point where the couplings joined using a 1/16 inch radius tool. Figure 3.3.3-2 shows a schematic of the jig used to test the shear pins and a depiction of a shear pin.

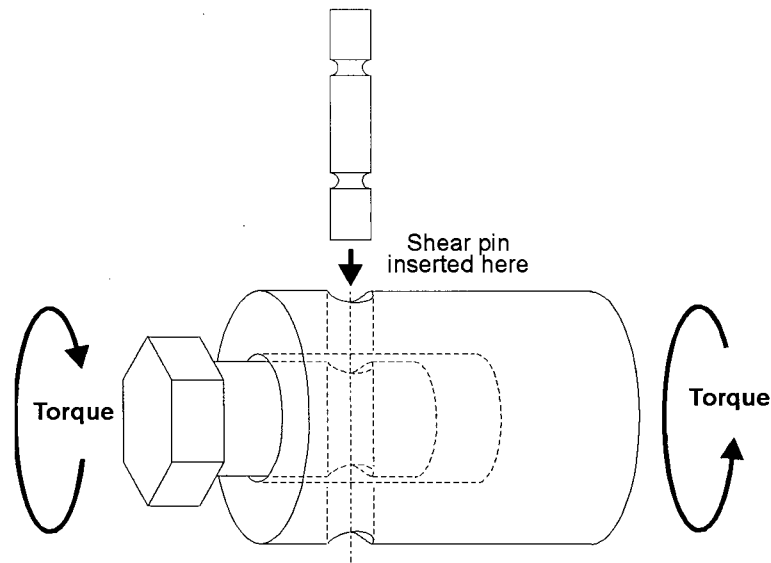


Figure 3.3.3-2 Schematic of testing jig used to measure torque to failure of shear pins

The tests were conducted using an Aries Model 200-DBB-U 200 lb. S-Beam tension load cell and recorded using a Houston Instruments Series 2000 Omnigraph X-Y recorder while applying torque manually using a large wrench. The averages of the measured results were found to be exponential and fit a curve of;

$$T=3.2D^{2.95}$$

where T represents torque (Nm) required to shear the shear pin and D represents the equivalent diameter (mm) at the radial groove of the shear pin. A graph of the results is shown in Figure 3.3.3-3.

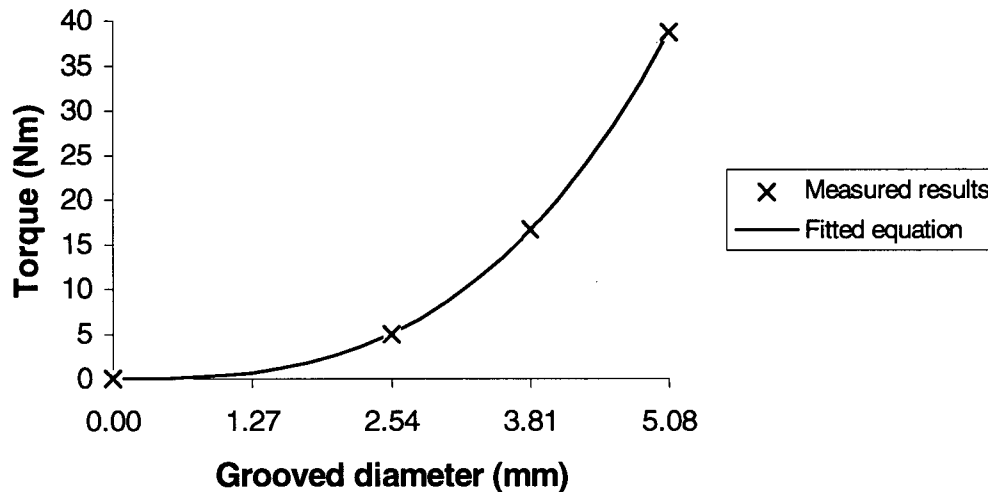


Figure 3.3.3-3 Torque to failure results compared to fitted equation

It was expected that the relationship between the diameter at the radial groove of the shear pin and the torque required to shear the pin would be exponentially related to the diameter cubed. Because of the radial groove at the interface of the coupling, the forces on the shear pin would be, strictly speaking, an applied moment rather than a shear force. In this case, the torque required to 'shear' the pin should be related to bending of a short beam [75, 76] affected by the stress concentration factor, due to the decreasing radial groove diameter. In fact, the relationship was proportional to $D^{2.95}$. Table 3.3.3-2 shows the results of shear pin testing averaged from five measurements.

Diameter of shear pin (mm) (6061-T6 Al)	Grooved diameter (mm)	Average torque required to shear (Nm)	Extrapolated torque required to shear (Nm)
6.35	2.54	5.0	5.0
6.35	3.81	16.7	16.6
6.35	4.06		20.0
6.35	4.32		24.0
6.35	4.57		28.3
6.35	4.83		33.3
6.35	5.08	38.7	38.7

Table 3.3.3-2: Shear pin testing results

The results were interpolated to determine the torque required to shear pins of differing radial groove depths in order to determine the size of shear pin required for any individual test subject. A selection of shear pins was available before the testing took place so that the appropriately sized pin could be selected for each subject. Conservatively sized shear pins were to be used when the exact size was not available.

The final safety aspect of the design was to provide mechanical stops on the device which can be set manually by the tester based on the subject's joint limits. These mechanical stops prevent the device from exceeding the joint limits as determined in the pretest subject joint limit test.

3.3.4 Control Software Design

The control software provides an interface for the physician or other user of the device to conduct testing and data acquisition. The control software guides the user through the testing protocol, and when required, initiates data acquisition, and automatically determines and initiates a program which activates the stepper motor. Control software changes required a completely new control system utilizing a Microsoft® Windows environment for ease of use. The Windows-based event-oriented programming graphically allows the user to choose a selection of options resulting from previous decisions. The new stepper motor controller required a new communication protocol as did the new data acquisition board. A more rigorous testing protocol was also programmed into the new software including stepper motor control options, stepper motor programming, more flexible data acquisition, and better file management. The new software also included a feedback loop from the torque transducer to a comparator function in the control software which ensures the test is terminated if maximum torque levels are exceeded. If the maximum torque levels are exceeded, the control software would immediately shut down the stepper motor to prevent possible injury to the subject.

The control software for the device was initially written in 'C' and Pascal and was subsequently rewritten in Visual Basic 3.0 in order to run the software in the Microsoft® Windows environment. A number of issues regarding programming in a Microsoft® Windows environment needed to be addressed. The control software makes use of several second party packages including those which run the data acquisition board (discussed in

Section 3.3.5) and two Visual Basic VBX's (a Visual Basic 'custom control' which provides a number of built in features to assist programming) to facilitate the control of the stepper motor and the data acquisition system. The public domain communication Visual Basic control, VBCOMM.VBX Version 2.0 for Visual Basic 3.0, by Mark Gamber (August 1992), was used to set up RS-232 serial port communication with the stepper motor controller, send commands to the controller, receive replies from the controller and perform additional similar functions. Since Microsoft® Windows uses a 57 millisecond internal clock, Visual Basic timers can only be activated every $1000 \text{ ms} / 57 \text{ ms} \cong 16 \text{ Hz}$ and therefore could not reliably control timing of the data acquisition and motor control. As a result, the high speed timer control, HITIME.VBX, from Mabry software was substituted to control the timing of the data acquisition and motor control. The Hitime control allowed timing to take place at one millisecond intervals so the timing of the data acquisition would have no more than 2.5% error.

The event-oriented nature of Microsoft® Windows programming makes the software self explanatory. Each time an event takes place, the software responds by presenting the user with new choices resulting from the previous decision. Each of the users choices is graphically represented as a push button, text box, or option button selection. By simply selecting the next appropriate choice, a new set of choices is presented. More detailed information on the program can be found in Appendix B which contains the source code for the device control software.

Data files are recorded and stored by the computer as TAB delimited ANSI files (text files where the data is divided by the TAB character; HEX 0x09). Separate files are recorded for position (degrees), resistive torque (Nm), and EMG activity (percentage of maximum output) for each test. Each of the files includes the measured data recorded every 40 milliseconds as well as important header information such as the total range of the test and the maximum allowable torque. Velocity of the test and the order of the tests, along with the initials of the individual tested and the type of data are indicated by the title of the data file. For example, file names ending in e, p, t indicate electromyography, position, and resistive torque data respectively. The second last digit in the name indicates the order of the test (starting at zero) while the preceding two characters indicate the speed of the test in degrees per second. Any preceding characters (up to three) are input by the tester to identify the subject. The data files all have the extension *.dat (for example jra301t.dat). The data files are post-processed by importing them into either Microsoft® Excel or Matlab® depending on the type of processing required.

3.3.5 Design Modification to the Data Acquisition System

Data acquisition drivers are used to initialize, and control the data acquisition board. The control of the data acquisition board entails initiating each data acquisition cycle to collect the raw torque, position, and EMG data which is passed on to the control software for filtering and storage. Data acquisition refinements required replacing the prototype data acquisition board with a faster board which had a driver usable within a Microsoft® Windows operating environment. The device had to be modified to include angular position and EMG

measurements, and amplifiers for the torque transducer and EMG signals were required. Data acquisition is done using a CIO-AD08 (Computer Boards Inc.) data acquisition board. The board offers eight 12 bit A/D channels (a bit underrated for this application because of the resolution - a 16 bit board would be more suitable), 3 digital inputs, 4 digital outputs, and three 16 bit down counters. Input frequencies up to 2.5 MHz can be handled by the board. A/D conversion time is typically 25 microseconds and using the supplied software driver, throughputs of up to 4000 samples/sec can be attained operating under BASIC. The control software receives three channels, sampling at 2000 samples per second. The 12 bit analogue inputs offer full scale ± 5 V, with a resolution of 2.44 millivolts. The Computer Boards Inc. Universal Data Acquisition and Control Library Revision 3.0 is used to acquire the data and control the A/D board. The Universal Library provides a Microsoft® Windows dynamic link library file (cbw.dll) which is used by calling functions from the Visual Basic application to initialize the board and to collect data from the board. Once the data has been received from the data acquisition board, the computer sends the data to user written comparator functions to determine if the resistive torque data is within the safe limits established earlier, and then stores the data to file.

The data acquisition system records the following data (refer to Figure 3.3-1):

- One analogue signal from the strain gauge bridge located on the torque transducer shaft
- One analogue signal from the potentiometer integrated into the coupling between the foot pedal and the torque transducer shaft

- One analogue signal from the EMG amplifier collected from electrodes attached to the subject's lower leg

Torque is measured by strain gauges on the torque transducer shaft. The strain gauge signal processing and design is discussed in Appendix A. The torque measurements are amplified, converted to digital and sent to the computer to be recorded. The amplified signal is converted to torque (Nm) in the control software using a predetermined calibration constant. The torque data is then reduced to the resistive torque by subtracting the inertial and frictional torque due to the driveline and foot pedal, adjusted for velocity and angular position. The bandwidth of the strain gauge was designed to be sufficiently large so that feedback from the gauge can be used to immediately stop the stepper motor in the event the resistive torque approaches an unsafe level. Assuming a common 200 steps/rev stepper motor operating at 5 rev/s, the stepper would be performing 1000 steps/s in order to rotate the ankle joint at the specified 60°/s. The strain gauge would have to operate at a minimum of 2000 Hz to stop the stepper before the next pulse. A suitable bandwidth for the strain gauge was determined to be at least 2000 Hz.

At the same time as resistive torque measurements take place, the potentiometer measures the angular displacement of the joint. These measurements are also sent to the computer via the same A/D board. The signal from the potentiometer is simply converted in the control software to degrees of rotation using a pre-calibrated correction constant.

EMG Electrodes affixed to the test subject's lower leg passively register small electrical impulses (voltages) which indicate activity of the muscle being monitored. The EMG signal

passes through a GRASS P5 Series A.C. Pre-Amplifier to the control computer where it is calibrated to a zero mean, rectified, and converted to a percentage of the maximum voluntary contraction EMG.

3.4 Testing Procedures

An important aspect of the testing is the protocol used to acquire measurements. Initial testing of the device was to be done on subjects without spasticity to assess the repeatability of the device and its suitability as a clinical measurement device, as well as to provide data on a control group for future comparison with a group with spasticity. Subjects with spasticity were then to be tested to assess spastic response to ankle rotational velocity. Electromyography was to be utilized to detect muscle firing patterns for correlation with spastic response, resistive torque data. This was to be used to identify increases in stretch reflex resistance associated with extraneous muscle activity. This information was to be gathered on a variety of subjects exhibiting spasticity and correlated with both day-to-day, person-to-person, and possibly within disease groups. The goal is to better understand the effect of these factors on spastic response and to provide recommendations for minimizing and/or treating spasticity in a hospital environment.

Testing procedures or protocols for using the device as a measurement tool are reviewed below. All subjects provided informed consent before testing took place. The consent forms and information provided to each subject are shown in Appendix C. Initially the subject should be made as comfortable and relaxed as possible. They should be seated comfortably, at the proper

height with the foot pedal in the horizontal position. Before any testing takes place, EMG electrodes will be placed on the relevant muscles (of the shin and calf) according to testing protocols established for the electromyography.

The testing protocol for this device is currently established as follows:

1. The subject is to be in one of two or three positions;
 - i) Seated with the upper leg horizontal and the knee joint at 90° .
 - ii) Lying prone with the leg straight.
 - iii) Standing with the testing foot resting on the device, and with the subject's weight equally distributed between each leg, in order to simulate the effects of the subject's weight on spasticity.
2. Position the foot pedal so that the subject's ankle joint coincides with the axis of rotation of the foot pedal and strap the subject's foot firmly in place. Ensure that the foot pedal is level.
3. Determine the maximum safe torque for the subject's ankle. This is done by the subject applying a maximum force voluntary contraction to the foot pedal while the computer records the torque output. The maximum safe torque limit is then set to 90% of the maximum level. This maximum safe torque limit is then entered into a control software routine which monitors the torque at the ankle and disengages the motor if the

maximum torque limit is met or exceeded. This value is also used to select the appropriate shear pin and variable clutch safety settings to ensure the subject's safety.

4. Determine the range of motion for the subject's ankle. The computer-controlled stepper motor rotates the subject's ankle until some discomfort occurs or until the maximum safe torque limit for that subject is reached while the computer records the angles corresponding to the joint limits. This stage must be repeated for each position of the subject. Once the joint limits are established and recorded by the computer for each subject position, they can be used to construct the testing velocity profiles for subsequent testing. Physical stops on the foot pedal can also be set to limit the range of motion of the device within the safe joint limits to ensure the subject's safety.
5. To begin the testing procedure, the tester is simply asked to choose one of seven velocities for the ramp and hold testing. The seven velocity options are 5°/s, 10°/s, 20°/s, 30°/s, 40°/s, 50°/s, or 60°/s. The computer automatically designs a velocity profile for each chosen velocity defined by the established joint limits. The control software configures, downloads, and launches a program in the stepper motor controller and initiates data acquisition to collect the data from the torque transducer, the potentiometer, and the EMG transducer. Data is recorded and stored in the computers memory for post processing.
6. The actual manipulation of the ankle by the device will start at 0° (with the ankle joint at 90° to the subject's lower leg) and proceed through the ankle's dorsi-flexion range to

the maximum joint limit as illustrated in Figure 3.4-1. The testing performs a ramp and hold test which means that the ankle joint is rotated at a constant velocity through the viable range of motion. At the end of the range of motion, the joint is held at the extent of its range for four seconds in order to detect any beats of clonus and to determine the steady state resistive torque. If clonus is present the ankle will rhythmically spasm and the torque and frequency will be recorded by the computer. The joint is then slowly returned to the starting position in preparation for the next test. This procedure is likely to be the primary function of the device as it fulfills the requirements conceived for the project. This test would be used to establish how spasticity can be defined using the data collected by the device.

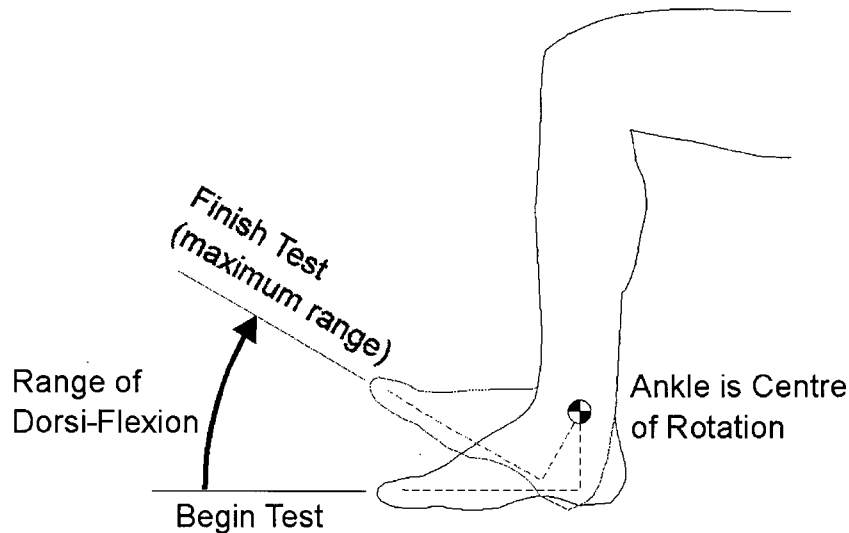


Figure 3.4-1 *Depiction of the rotation of the ankle joint during testing*

It should be noted that, for the purposes of this project, any future reference to range of test refers to a testing rotation as shown in Figure 3.4-1. Also, references to maximum range refer

to the subject's maximum range in dorsi-flexion as depicted in Figure 3.4-1. Starting position, or neutral position refers to the subject's ankle joint being 90° to the lower leg, as it is labeled as 'Begin Test' in the figure.

Ideally clonus testing would determine the torque level at which clonus occurs, measure the length of time the clonus continues, measure the spasm torque from the clonus, and the frequency of the spasms. The device should be able to perform all these tests at different patient positions considering effects of the subject's weight and so forth. This would require an in-depth study which goes beyond the scope of the current project. In the future, a simple test for clonus could be incorporated into the device to test the feasibility of further clonus testing.

Data could also be collected for variations of the above test using different knee joint angles to investigate the position dependence of spasticity, and with the subject standing to study the effect of the subject's weight on spasticity of the ankle. Continued clinical testing of the spasticity measurement device will be directed towards developing a family of resistive torque versus time curves which reflect the characteristics of spasticity and to provide proof of the clinical usefulness of the device.

CHAPTER 4: DATA ANALYSIS, RESULTS AND DISCUSSION

4.1 Overview

The device has been utilized to collect data from groups of people with and without spasticity. Initial testing on subjects without spasticity was used to assess the suitability and repeatability of the device, as well as provide data as a control group for future comparison. Subjects with spasticity were then tested to assess variations in spastic response. This data was carefully analyzed to determine any relevant trends indicating spasticity. The data within subjects having spasticity was also examined to determine variations of those trends with the degree of spasticity. By exploiting indications of spasticity which varied with degree of spasticity, a means to model the observed variations of the data was determined and used to quantify the degree of spasticity. A statistical analysis of the data collected by the device was performed to assess the potential of this measure as a reliable, quantifiable, statistical indicator for spasticity.

4.2 Data Analysis

The chosen protocol for testing of the device involves two stages. In the first stage, the subject's ankle is rotated through a predetermined arc, corresponding to the subject's joint limit

in dorsi-flexion, at a specified number of selected velocities. During the second stage, the subject's ankle is held stationary at the maximum extent of the arc for four seconds. The first part of the testing is done to evaluate the velocity dependence of spasticity and elicit a resistive torque to the movement. The second portion of the testing is used to observe the reaction of the joint when held at the limit of dorsi-flexion which allows the determination of the steady state gain with respect to the position and velocity input. In addition, the second stage of the test may induce clonus which manifests itself as regular oscillations of the joint. The severity of the clonus response is often used as an indicator of the degree of spasticity.

The resistive torque, position, and EMG data retrieved from the testing was transferred to a Microsoft® Excel spreadsheet for analysis. Curves of resistive torque versus time, and EMG response vs. time were plotted. The torque data curves within a testing session were averaged and plotted. In addition, the time for each test was normalized so that the ramp time was one second for any velocity and for any range of ankle rotation. This allowed for a visual comparison of results from tests at different velocities in order to determine if there was a significant velocity dependence in the results. Data was also plotted against position, and EMG activity in order to correlate the results with angular motion of the joint and activity of the muscle.

The data from Microsoft® Excel was ported to Matlab® in order to fit an equation relating the input position with the output (resistive torque) over time. Parameters of this equation were then analyzed for use as indicators of the severity of spasticity. The parameter data was then

compared to a curve separating data from subjects with and without spasticity using Maple®.

The results of the comparison were used as a quantitative indicator of the degree of spasticity.

The following sections explain in detail the procedures leading up to and including the analysis of the data and the determination of a quantitative measure of spasticity. Also included is a statistical analysis of the results reviewing the reliability of the testing data and the results.

4.3 Evaluation of Results

Torque versus time curves are the most obvious method of analyzing the test data. A typical resistive torque versus time curve of a subject without spasticity is shown in Figure 4.3-1.

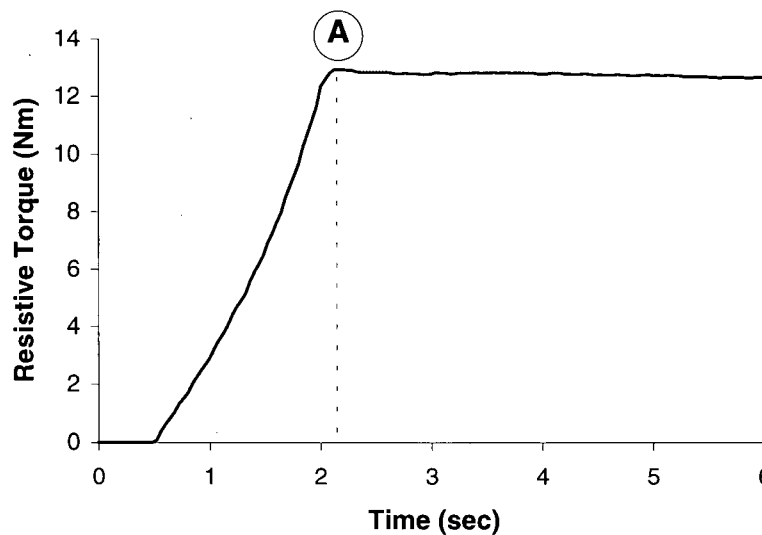


Figure 4.3-1 Typical resistive torque versus time curve of a subject without spasticity at 20°/s

The two stages in the testing process, the velocity dependent section and the hold period at the extent of the range section, (divided at point A) can be considered separately or together in the analysis of the data. Of potential interest in the resistive torque versus time curves are a number of salient features which have, in the past, been considered as an indicator or measure of spasticity. These features include the maximum resistive torque, the slope of the velocity dependent curve, the area under the two portions of the curve (Torque vs. Position - total energy expended), the reflex threshold, reflex gain, onset and amplitude of the EMG response, and inconsistencies in the smooth torque profile such as uncontrolled oscillations, or the number and strength of clonus beats. Considerations of the EMG data which can indicate the degree of spasticity include the bandwidth of the EMG results, deviations and number of excursions from the average bandwidth, and the maximum bandwidth. Correlation of the EMG data with the resistive torque data can also be done to try to differentiate between the spastic response and the intrinsic stiffness of the ankle joint. If significant EMG activity is observed during a passive stretch, then a spastic reflex response must be present. However, if little or no EMG activity takes place, the observed resistance is due solely to the intrinsic stiffness of the ankle joint.

The most obvious and commonly used parameter among the traditional measures of spasticity is the maximum torque value obtained during the test. The maximum torque value is considered a large influencing factor in common clinical scales such as the Modified Ashworth Scale (MAS). Clinical testing provides a more general feel for the resistance that is then translated into a qualitative feel for the behavior of the joint. In the current test results, the maximum torque was affected by the range of angular motion of the test, and possibly by other

more esoteric factors such as comfort, or fatigue of the subject. Moreover, there did not appear to be any correlation of maximum torque values with the degree of spasticity, and in fact, maximum torque values were, in some cases, higher for subjects without than with spasticity. As a result, maximum torque values cannot be used as a realistic indicator of spasticity.

The gradient of the increasing torque vs. time curve was analyzed to determine if it could be indicative of the resistance to movement with respect to the velocity and extent of the angular motion. However, this requires that the increase in the resistive torque with movement be linear, the data collected showed this area of the curves to be quite non-linear. In addition, the value of the slope is subject to the vagaries of range of motion and the velocity of the test. Finally, to use slope to describe spasticity demands that, at a certain velocity, the maximum torque value must be related to the degree of spasticity, which has not proven to be the case. As a result, the slope does not appear to be a useful means of quantifying spasticity.

Reflex threshold is defined as the angular threshold at which the stretch reflex occurs and is identified as the point where the resistance to manual stretch abruptly increases. If the reflex threshold is reduced, a smaller and/or slower motion would be sufficient to reach the reflex threshold at which point the reflex torque or force of the muscle shows a marked increase with increasing muscle length. The onset of an abrupt increase in torque can prove very difficult to determine given the somewhat inconsistent nature of the torque curves. Moreover, it is not clear whether people with little or no spasticity even have a reflex threshold (except for one which may activate to prevent over-rotation of the joint). Research work in the past had used EMG to determine the onset of the reflex muscle firing which defines the reflex threshold

because resistive torque curves themselves cannot accurately provide a measure of the reflex threshold. However, using EMG requires very precise and accurate measurement. Because of the complications and inconsistencies associated with the use of surface EMG, this is not a practical measure of spasticity. Similarly using the severity of the EMG response as a measure of spasticity only provides a qualitative measure of the degree of spasticity, as the EMG response can vary significantly (an order of magnitude) depending on the placement of the electrodes. In order to get a (semi-) qualitative measure of EMG, a baseline is required. In the initial testing using this device, a baseline was achieved by asking the control test subjects to provide a maximum voluntary contraction and the subsequent EMG results were compared to this maximum amount. This technique seemed to work quite well in subjects without spasticity, however, subjects with spasticity had difficulty eliciting a maximum voluntary contraction or could not provide one at all.

Reflex gain is characterized by an abnormal increase in reflex force with increasing rotation of the joint. During a passive angular rotation of a joint, the intrinsic stiffness of the joint provides a degree of resistive torque. If reflex activity of the involved muscles occurs (as may be the case with spasticity) the corresponding reflex action of the muscles contributes to the total stiffness of the joint. This additional stiffness is referred to as the reflex gain. However, reflex gain is difficult to measure directly as it requires some fore knowledge of the reflex curve *without* reflex gain. Reflex gain has proven troublesome to measure in the past and, in addition, can be largely influenced by input velocity and angle of rotation. A more appropriate and more informative measure of spasticity might be the steady state gain, K , with respect to the input position profile. Steady state gain refers to the ratio of the output of a system after it has

stabilized, with respect to its input. In the case of the current project, the input is the angular position and the output is the resistive torque. Steady state is achieved after the system has settled, and, in the case of the current project, is considered to occur four seconds after the motion stops. In this manner the resistive torque gain could be relative to the range of the test. This gain, K , as a measure of spasticity, might be more suitable for comparisons over a variety of testing ranges.

A thorough analysis of the data generated by the device is needed to reveal the most valuable indices of spasticity. The traditional measures mentioned above (i.e. maximum torque, slope of the torque vs. time curve, reflex gain, and reflex threshold) are either too difficult to measure or are not suitable as a measure of spasticity. By comparing several sets of data from subjects with spasticity with data from the control group, it is hoped to be able to isolate the most useful indications of spasticity. An in-depth analysis of the control data compared to the data from subjects with spasticity is required to define a pattern suitable to distinguish between the two groups.

4.3.1 Evaluation of Data from Subjects Without Spasticity

Test data was plotted in a number of ways to help graphically analyze the data. Curves were generated of torque vs. time, averaged torque vs. time, averaged torque vs. normalized time, plus torque and position vs. time. EMG activity was also correlated with the torque data by including the EMG results in some of the graphs.

Within a test session (i.e. in a single day) up to ten tests were performed at each velocity. Correlation between these tests was found to be good (covariances were as high as 40). However, in order to more accurately analyze the data, averaged torque curves were used because they provide a more accurate description of the general behavior. Figure 4.3.1-1 shows a family of torque curves from a single test session. The tests were all performed within an hour of each other and while the subject remained connected to the device.

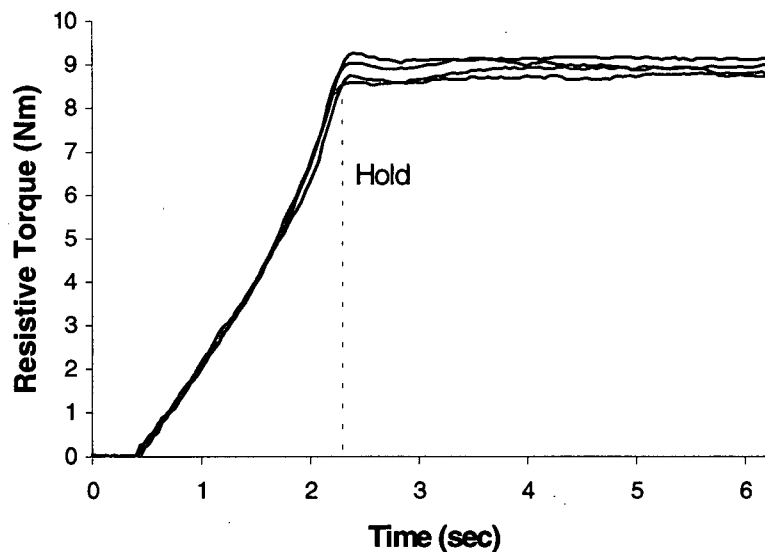


Figure 4.3.1-1 *Resistive torque responses of a subject without spasticity to passive rotation about the ankle joint within a test session (20°/s)*

By comparison, the same group of data is shown as an averaged torque vs. time curve including position in Figure 4.3.1-2.

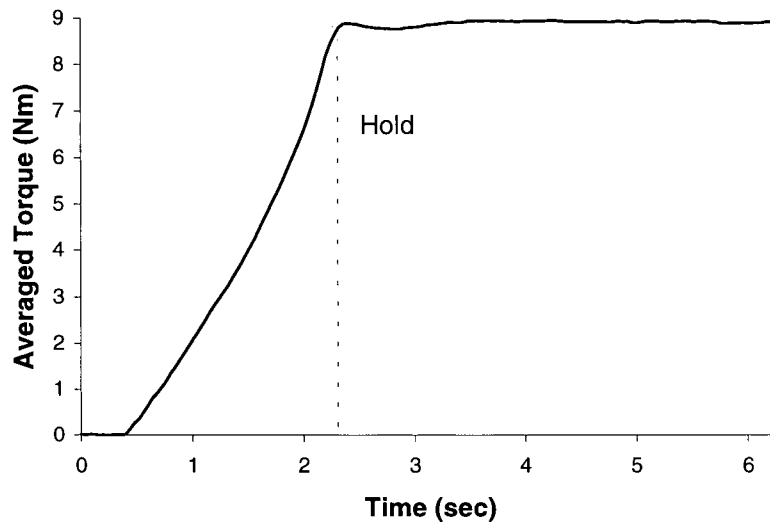


Figure 4.3.1-2 *Averaged torque response of a subject without spasticity to a passive rotation about the ankle joint at 20°/s*

This curve illustrates the typical behavior observed in the data from subjects without spasticity. The curve exhibits a generally linear ramp of increasing torque in the velocity dependent portion of the testing. As the motion stops, the torque abruptly stops increasing and retains its level throughout the four second position 'hold' portion of the test. Occasionally a slight overshoot is observed at the transition between the velocity and holding portions of the curve, most likely due to the momentum of the foot. Using this data for subjects without spasticity, a number of traditional parameters, such as slope, maximum torque, and area under the curve could be determined. However, without corresponding data from subjects with spasticity, no sound conclusions can be drawn.

To determine if any velocity dependence exists between the various test results, a number of averaged torque versus normalized time curves were generated. The time component was normalized so that the curves could be directly compared. Figure 4.3.1-3 compares averaged torque vs. time curves of different velocities without normalized time.

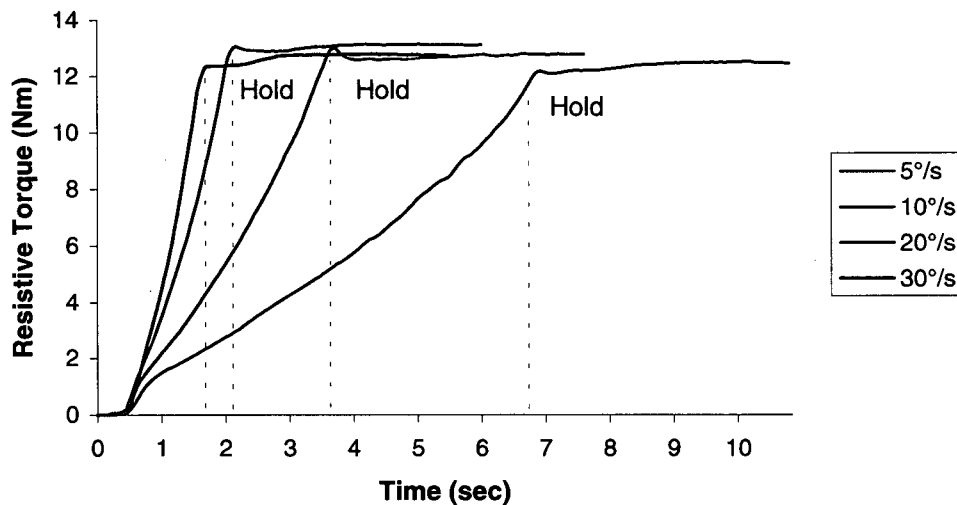


Figure 4.3.1-3 Comparison of averaged torque vs. time curves of different velocities

It is obviously difficult to objectively analyze these curves because of their differing slopes. The solution to this problem is to normalize the curves. By normalizing the time during the position ramp to a unit value (in this case one second) resistive torque curves at differing velocities can be directly compared to establish any velocity dependence. A comparison of averaged, resistive torque curves of different test velocities plotted against normalized time, from a subject without spasticity, is shown in Figure 4.3.1-4.

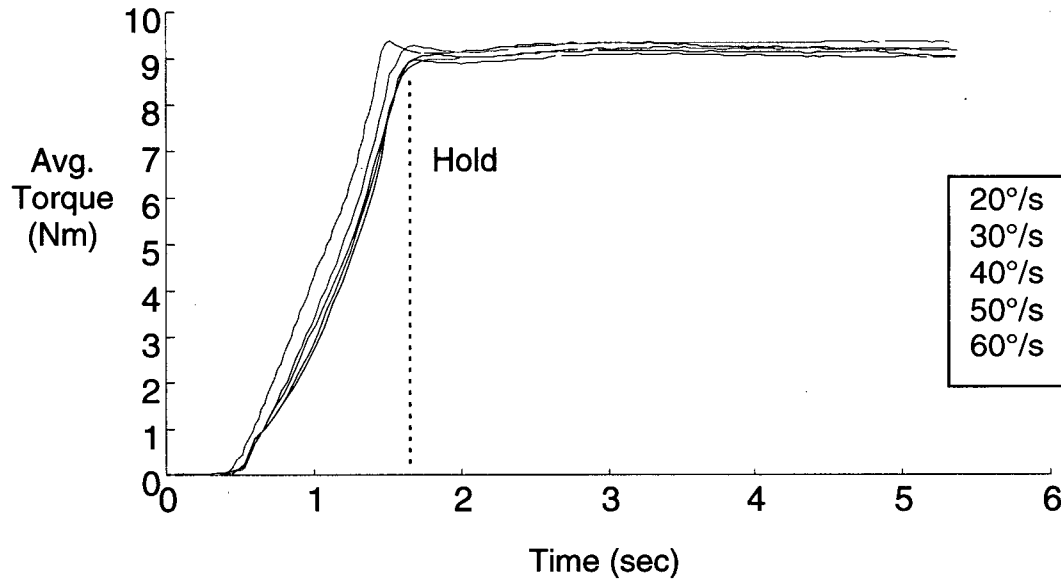


Figure 4.3.1-4 Averaged torque vs. normalized time curves of different velocities

In this case it is clear that the torque curves from different test velocities can be visually compared in an easy manner. It is clear that for subjects without spasticity there does not appear to be any significant velocity dependence of the torque response at velocities as high as 60°/s. Although there may be velocity dependence of the torque response of subjects without spasticity to a passive rotation of the ankle at higher velocities, none was observed in the control test data from this project.

The control group of subjects without spasticity showed little or no EMG response during tests at any velocity. The control group EMG response during tests was compared to EMG values obtained during a maximum voluntary contraction. In this manner the EMG response was quantified as a percentage of the maximal contraction level. Figure 4.3.1-5 shows a typical EMG response during a test of a subject without spasticity.

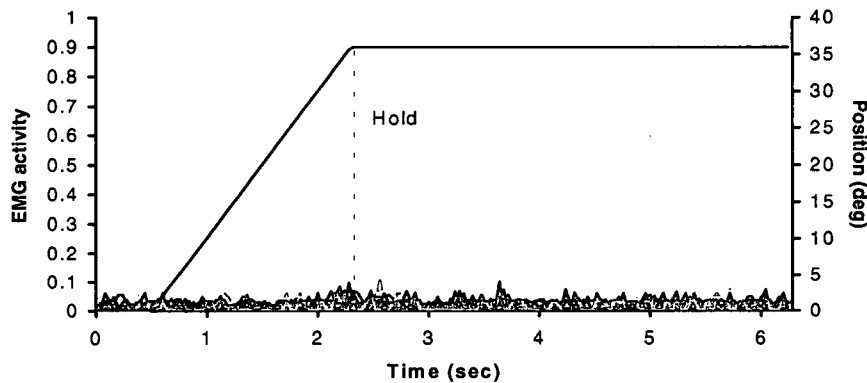


Figure 4.3.1-5 Control EMG response (20°/s), including position of the test (in green)

There was little or no EMG correlation with torque increases for the control group. It is clear that normal behavior of the joint during a test is largely due to the intrinsic stiffness of the joint, muscles, and connective tissue and that no significant reflex action of the involved muscles takes place.

In order to determine the most valuable indicator of spasticity, the control group data must be compared to data obtained from individuals with varying degrees of spasticity. In doing this the most salient differences between the two groups of data can be exploited to establish a means to quantify spasticity. This requires a similar analysis of test data from subjects with spasticity.

4.3.2 Evaluation of Data from Subjects With Spasticity

Comparison of data from subjects with spasticity and the control group data is an obvious method to determine differences between the data which ought to be indicators of spasticity.

However, in order to determine differences in the data related to the *degree* of spasticity, data within the groups of people with spasticity should also be compared. In this manner, differences which indicate the severity of spasticity can be established and corroborated against the control data. A number of issues traditionally related to spasticity were also investigated, such as EMG activity correlation with increased resistive torque, velocity dependence of spasticity, occurrence of clonus, and the clasp knife phenomenon.

Data from the subjects with spasticity were also subjected to a similar analysis as was the control data. Initially two subjects with mild degrees of spasticity were tested and evaluated. Due to the tiring effects of testing, only five tests were performed at each velocity. Figure 4.3.2-1 shows resistive torque responses of a subject with mild spasticity to passive rotation about the ankle joint within a test session.

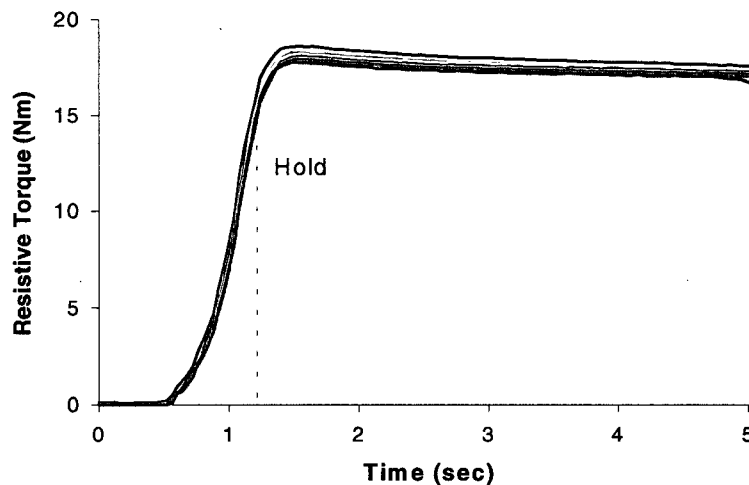


Figure 4.3.2-1 Resistive torque responses of a subject with spasticity to passive rotation about the ankle joint within a test session ($40^{\circ}/s$)

There were a number of minor differences between the curves of subjects with and without spasticity but it was not clear whether they were significant or coincidental. Primarily the variances were the transition between increasing torque and steady torque, which was not as sharp, the increasing torque curve, which was slightly less linear, and a more significant overshoot of the steady state torque value at four seconds. However, the differences were very subtle and not the exaggerated differences, which might be expected from an individual with severe spasticity. In order to determine whether the small noted differences were significant, a third subject with severe spasticity was tested. The averaged resistive torque responses to passive rotation about the ankle joint of the three subjects is shown in Figure 4.3.2-2.

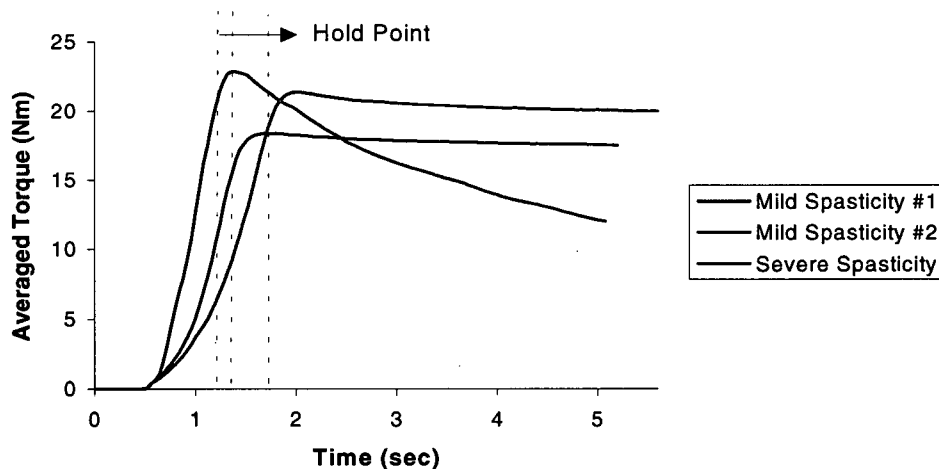


Figure 4.3.2-2 Average torque vs. time curves of three subjects with varying degrees of spasticity at 30°/s

With the addition of the third subject with severe spasticity, it was observed that some of the characteristics of the curves of the two subjects with mild degrees of spasticity became more pronounced in the case of the subject with severe spasticity. One of the more obvious

differences was the amount of overshoot with respect to the steady state gain. For the subject with severe spasticity, after the angular velocity ceased (at $t = 1.18$ sec), the curve kept rising and then slowly diminished. Also noted in the case of severe spasticity was a smoothed transition from the velocity dependent section to the holding section. These same features were also noted in the data from the subjects with mild spasticity, but to a lesser extent. An exaggerated curvature of the resistive torque curves which was more pronounced in the data from subjects with mild spasticity was less obvious in the subject with severe spasticity. This curvature was still evident in data from the subject with severe spasticity but the curvature took place at the very beginning of the test over a very short period of time, so it was less obvious. As these features (over shoot and subsequent decreasing resistive torque, exaggerated curvature, and smooth transition from the velocity dependent section to the holding section) were consistent in subjects with spasticity, and appear proportional to the degree of spasticity, they appear to be potential parameters to quantify spasticity.

Electromyographic activity of the involved muscles, indicating firing or activity of the muscles, was correlated with increases in resistive torque and with position. It was found that the subjects with spasticity had significantly more muscle activity taking place during the tests, particularly at the end of the range of motion. This observation lends some support to the theory of reflex threshold. As the subjects were asked to relax and the rotation of the joint was passive, the increase in muscle activity is probably attributed to reflex reaction of the involved muscles. EMG activity of a subject with mild spasticity correlated with position of the test is shown in Figure 4.3.2-3. The rotation of the joint occurs in the increasing section of the blue curve in the figure.

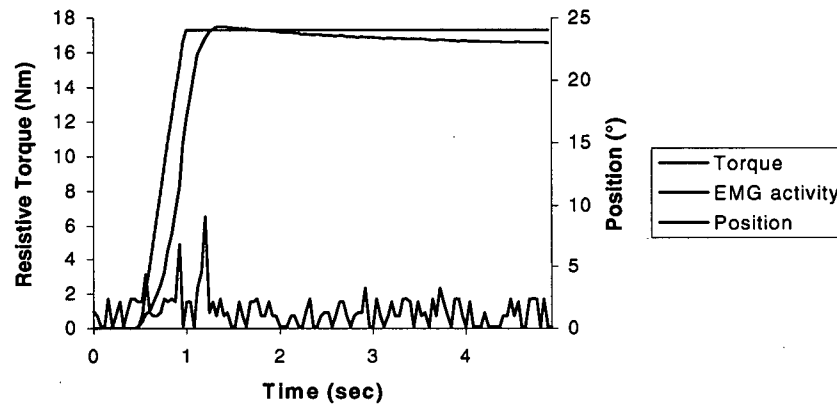


Figure 4.3.2-3 Mild spasticity EMG activity correlated with position of test (50°/s)

It is clear that the reflex response of the involved muscles initiated as the rotation began, increased throughout the rotation, and slowly dissipated after the position remained constant at the end of the range taking roughly half a second. Figure 4.3.2-4 shows the same relationship, but of the subject with severe spasticity.

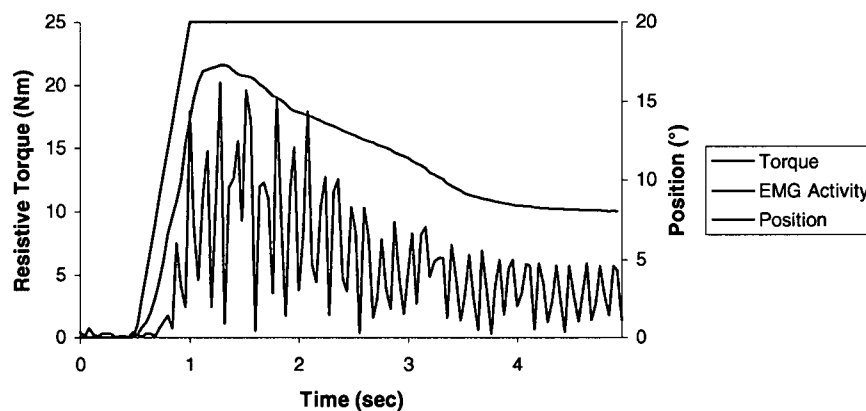


Figure 4.3.2-4 Severe spasticity EMG activity correlated with position of test (50°/s)

In this case, a similar pattern of EMG is seen except that the EMG activity at the end of the velocity portion of the curve takes much longer to disperse. This accounts for the much higher peak torque values with respect to the steady state torque and the much slower decrease of the torque curve. In practical terms, this increase in reflex activity starting after the rotation begins and increasing as the rotation progresses is manifested as a more rapid increase in the velocity dependent torque curve and a very subtle exponential curvature at the very beginning of the resistive torque curve. One can speculate that the subject's intrinsic joint stiffness provides a relatively linear resistive torque to a passive movement similar to that of subjects without spasticity. Then if an increasing torque with position (such as the reflex response indicated by the EMG activity) is added to this linear curve, the result is increased torque and possibly some exponential curvature like that observed in the data from subjects with spasticity, more obvious in the data from the subjects with mild spasticity. This may result from a slower, more moderate reflex response in the cases of mild spasticity.

The velocity dependence of spasticity was investigated by comparing averaged torque data of different velocities against normalized time in a similar manner to that of the control data. A typical set of curves for one individual with spasticity, at velocities of 5°/s, 10°/s, 20°/s, 30°/s, 40°/s, 50°/s, and 60°/s is shown in Figure 4.3.2-5.

It is clear from these results that for up to 60°/s there is little or no velocity dependence of the spastic torque response to a passive rotation of the ankle. However, the black curve at 60°/s trends away from the rest of the group. The velocity dependent portion of this curve is significantly more non-linear than that of the rest of the group of curves. This type of non-

linear response was rarely seen in subjects without spasticity but was noted as a characteristic of torque response due to spasticity. This leads to the conclusion that the spasticity is more pronounced at the 60°/s velocity. Given that this is the case, it suggests that there may be a velocity dependence to spasticity starting at or near 60°/s for subjects with spasticity.

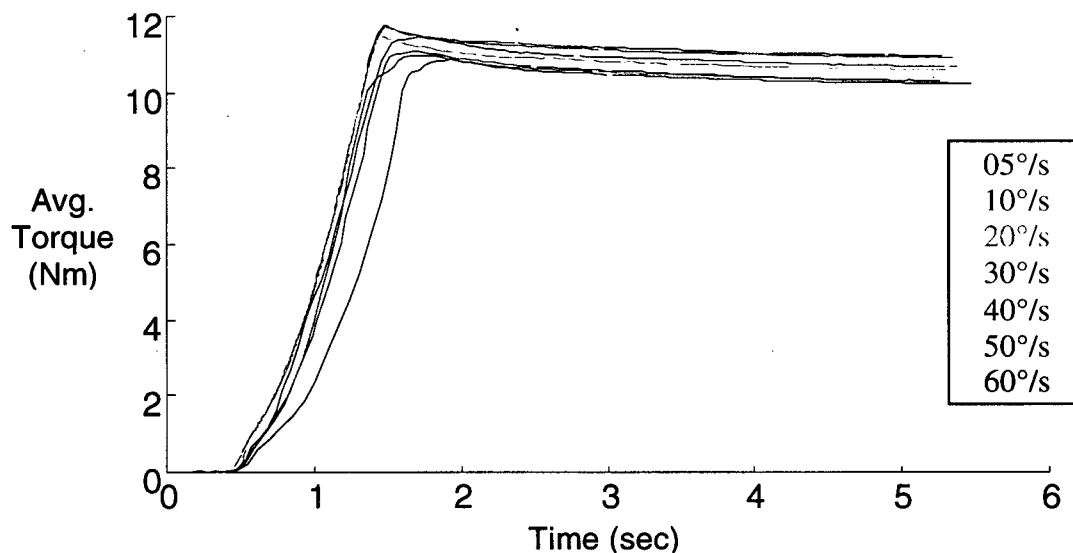


Figure 4.3.2-5 *Velocity dependence of spasticity*

Although clonus was found in the subjects during clinical evaluation, the device never induced sustained clonus during testing. In part, this may be due to the method by which the subject's foot is rotated. In a clinical setting, the ball of the foot is grasped and is forced up as far as is 'reasonable' whereas the device simply rotates a flat foot plate about the subject's ankle joint while the subject's foot remains flat and evenly rotated. On the other hand, in a clinical setting the foot would be bent and the point of contact is on the ball of the foot. In addition, in the clinical setting the range of motion can be more fully realized as the clinician has a better 'feel' for the range than the device does (the device will always err on the side of caution for obvious

safety reasons). These differences between clinical testing and testing with the device may be responsible for the lack of clonus during testing. One of the subjects did, however, self induce clonus for the benefit of science. A graph of the self induced clonus is shown in Figure 4.3.2-6. In this case the subject's ankle and knee were at 90° and no movement of the device took place. The variation of the torque up to the point at which clonus began (approximately 1.4 seconds) was due to the subject's leg movement while trying to induce the clonus response.

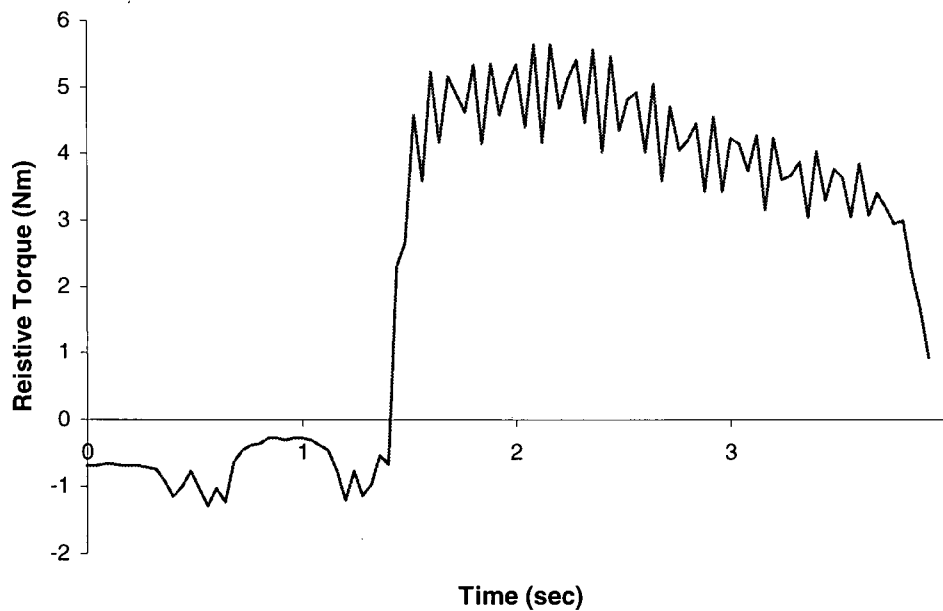


Figure 4.3.2-6 Self induced clonus

Two interesting observations were made regarding the clonus data. First, the initial torque before the clonus begins is approximately zero, but after the clonus is induced, the mean torque rises to approximately 5 Nm and then fluctuates about the mean at approximately 10 Hz. Second, during the course of the clonus, the mean torque value slowly decreases although the

fluctuations remain relatively constant. This pattern was repeated a number of times with surprising repeatability.

The subject with severe spasticity suffered from a brain injury which had severely affected the subject's left side while the right side had only been mildly affected, but which suffered from spasms. The right leg was tested and some of the resulting data is shown in Figure 4.3.2-7.

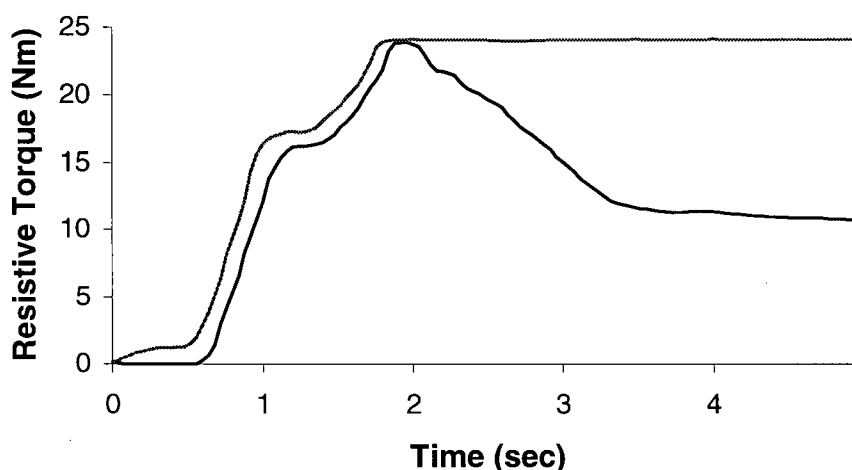


Figure 4.3.2-7 *Spasms occurring during testing*

Because of the spasms of the ankle joint it is difficult to compare the data from this leg to the side suffering from spasticity. The spasms might be considered as a form of clonus because they meet the most basic definition of clonus (i.e. muscle contractions elicited by a rapidly applied, but maintained stretch). However, of more interest is the possible clasp knife phenomenon in the curve where one of the curves abruptly drops off after a certain point.

After examining the data from both the control population and the group with spasticity, it is clear that there are a number of distinct differences which appear to be related to the degree of spasticity. A careful comparison between parameters related to these differences is required to clearly distinguish between the two groups. In order to do this, some means to mathematically represent the parameters related to spasticity, must be chosen to describe the curve. This is accomplished in Section 4.3.3.

4.3.3 Comparison of Data from Subjects With and Without Spasticity

To establish this device as a clinical diagnostic tool, data needed to be compared between the groups of subjects with and without spasticity with respect to the variances between groups, and between degrees of spasticity. To accomplish this, parameters describing the variances had to be determined. This was done by fitting a curve, based on the chosen model for spasticity, through the resistive torque data at the various velocities. By modeling the torque response to a position input as a second order system, four parameters are obtained describing the fitted curve. In order to determine the four parameters which described the curves, each curve was fitted to a second order differential equation of the form: (Transfer function of a second order system)

$$\frac{d^2T}{dt^2} + 2\zeta\omega_n \frac{dT}{dt} + \omega_n^2 T = K\omega_n^2 \theta + V \frac{d\theta}{dt} + A \frac{d^2\theta}{dt^2}$$

where T is the output torque

θ is the input angle or position

t is time

ζ is the damping parameter which corresponds to the damping ratio

ω_n is the response parameter which corresponds to undamped natural frequency

K is the gain parameter which corresponds to the steady state gain with respect to the input position

V is the velocity dependent gain

A is the acceleration dependent gain

As the tests occurred at a constant velocity, the acceleration dependent gain, A , is assumed to be zero. This equation left four parameters which (with the input and output curves known) describes a curve which most closely fits the output curve (Torque vs. time). The input curve used was the position (ramp and hold curve) which allowed some significance to the gain parameter, K . Thus K relates the amount of torque output with respect to the angular rotation (range) of the test. What is also of interest is the smooth transition between the increasing torque and the steady state torque (described in part by the damping factor ζ). As well, the response parameter, ω_n , describes the speed of response of the torque increase to the position input. Finally, the velocity dependent gain, V , is representative of the reflex response subject to a slight delay (ignored in this model), dependent on the velocity of the rotation. This parameter is of some significance with respect to the amount of overshoot

By using this second order differential equation to model the resistive torque data, the four parameters can distinguish differences in the data that are not obvious to the human eye.

However, in order to determine values of the equation parameters, a curve needs to be fitted to the experimental data. This was done in the frequency domain where the equation takes the form:

$$\frac{T(s)}{\theta(s)} = \frac{Vs + K\omega_n^2}{s^2 + 2\zeta\omega_n s + \omega_n^2}$$

Using the dynamic model parameter identification in Matlab®, a least squares regression fit of the data was used to determine the equation parameters. The Matlab® code used to do this is shown in Appendix D. The parameters provide the relationship between the input position data and the output torque data. A sample of the averaged torque and position vs. time input data for analysis in Matlab® is shown in Figure 4.3.3-1. The green curve represents the position input while the red curve is the torque output. The torque data within test sessions was averaged to provide more generally applicable results.

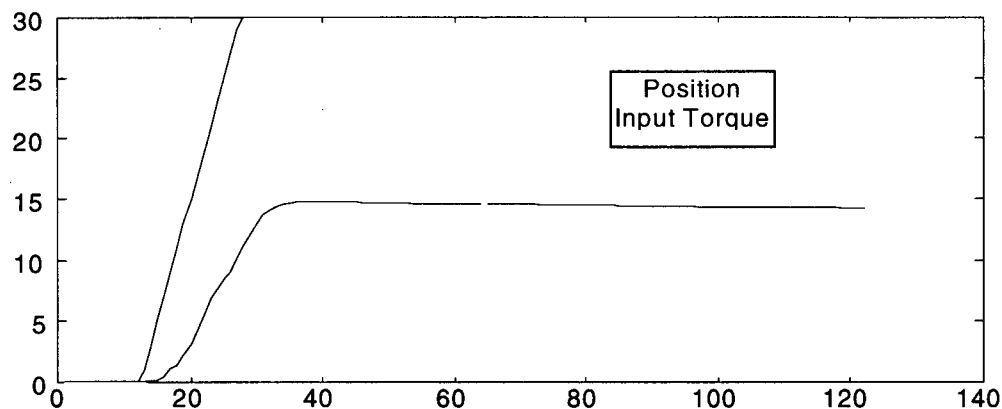


Figure 4.3.3-1 Data input to Matlab®

The Matlab® program provides a curve from the model which most closely fits the data. In general, fit of the equation curves to the experimental data was excellent. Figures 4.3.3-2 and 4.3.3-3 show typical fitted curves to data from subjects without and with spasticity respectively. In each case the green curve is the position input, the red curve is the torque output and the blue curve is the fitted curve based on the equation of the model. Fit of the two curves is so close that it is often difficult to distinguish them.

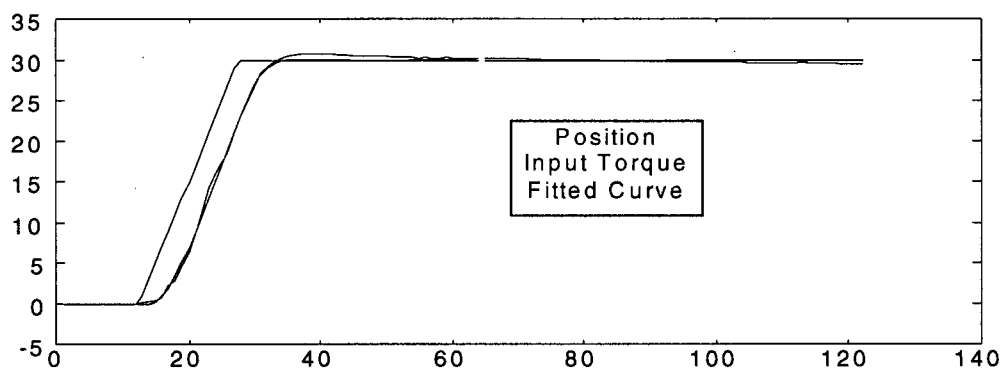


Figure 4.3.3-2 Typical equation curve fitted to resistive torque data from a subject without spasticity ($40^{\circ}/s$)

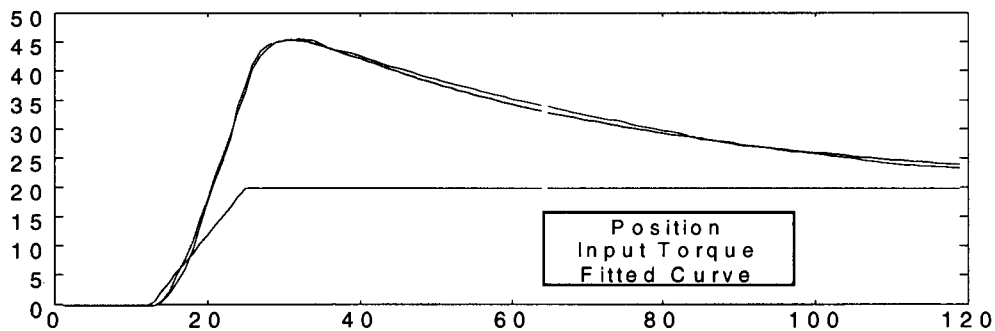


Figure 4.3.3-3 Typical equation curve fitted to resistive torque data from a subject with spasticity ($60^{\circ}/s$)

With curves fit to the data, the four parameters for each curve were evaluated. Parameters were determined for each velocity, for each individual, and for each test session. The calculated values of the model parameters are listed in Table 4.3.3-1. In the table ω_n is linearized at 30°/s in order to compare the data at different velocities. This was done by varying the time constant of the equation fitting inversely proportionally to the velocity of the test. As a result, ω_n is proportionally changed while the other parameters remain constant.

	10°/s	20°/s	30°/s	40°/s	50°/s	60°/s
Control #1						
ω	7.5	6.26 6.86	5.11 6.83	6.44	6.01	5.4
ζ	2.49	0.93 0.93	0.95 0.88	0.83	0.97	0.99
K	0.24	0.26 0.26	0.2 0.26	0.25	0.26	0.25
V	1.72	1.39 1.16	0.64 -0.42	-0.70	-1.07	-1.37
Control #2						
ω	6.42	5.81 6.11	6.19 6.05	5.57	5.83	5.35
ζ	0.85	0.95 0.87	0.88 0.99	0.82	0.86	1.02
K	0.58	0.57 0.54	0.54 0.57	0.53	0.57	0.53
V	1.34	1.32 1.24	-0.67 0.11	0.67	-0.78	-1.28
Control #3						
ω	9.24	6.5	6.44 6.37	5.61	4.84	5.23
ζ	1.21	1.15	1.12 0.99	0.97	0.96	0.83
K	0.39	0.41	0.39 0.49	0.49	0.49	0.48
V	1.58	1.86	1.70 -0.63	-1.49	-1.34	-2.52
Control #4						
ω	20.1 14.94	11.45 10.67	8.52 7.17 7.7	6.89	6.71	6.34
ζ	0.97 0.85	1.06 1.14	0.8 0.94			

			0.87	0.98	1.02	0.85
K	0.18	0.18	0.2			
	0.19	0.2	0.21			
			0.2	0.2	0.19	0.21
V	1.08	1.08	0.59			
	1.53	1.87	1.11			
			0.86	0.34	-0.03	-0.42

Mild spasticity #1

ω		5.4	4.5			
		5.54	4.13	4.16	5.08	4.49
		4.58	4.19			
			4.12			
(right leg)	4.89	3.41	3.3			
ζ		0.54	0.63			
		0.7	0.9	0.91	0.56	0.76
		0.6	0.59			
			0.65			
(right leg)	0.75	0.99	0.78			
K		0.33	0.33			
		0.34	0.34	0.35	0.34	0.34
		0.57	0.57			
			0.57			
(right leg)	0.37	0.37	0.37			
V		1.51	2.09	2.97	1.11	-1.78
		0.99	-0.10			
(right leg)	0.61	1.43	1.20			

Mild Spasticity #2

ω		5.48	5.24	4.97	4.36	3.83
						3.54
ζ		0.65	0.59	0.68	0.7	0.69
						0.83
K		0.75	0.74	0.73	0.7	0.71
						0.68
V		1.75	-0.28	-0.17	-3.27	-2.25
						5.57

Severe Spasticity

ω		3.47	2.27	1.86	1.54	N/A
				1.67		
				1.85		
ζ		1.48	2.67	2.4	2.21	N/A
				2.18		
				2.4		
K		0.67	0.48	0.44	0.64	N/A
				0.47		
				0.41		
V		7.96	14.97	13.38	12.38	N/A
				11.30		
				12.46		

Table 4.3.3-1 Equation parameters for each test subject at various velocities

By examining the values of the parameters in Table 4.3.3-1, a number of trends in the data can be noted. In particular, as the severity of spasticity increases, the response parameter, ω_n , decreases while the damping parameter, ζ , increases. In practical terms, this means that the curves tend to take longer to respond to the initial movement, have a smoother transition from the velocity curve to the holding curve, and take longer to return to the steady state gain. It also indicates that the curves tend to take longer to respond to the position input which would be manifested by more of an initial delay or a slower increase in the torque response. This behavior well describes the characteristics which were associated with the curves from subjects with spasticity. The gain, K , along with the velocity gain, V , seem loosely related to the degree of spasticity but are not reliable indicators. While the velocity gain is considerably higher in the test data from the subject with severe spasticity, it does not follow an obvious trend when employing the other data. A larger steady state gain, K , means a larger torque increase with respect to a smaller movement (i.e. it relates range with torque). Gain has a tendency to be slightly higher for subjects with spasticity but it is not conclusive. This trend is to be expected as, in general, we expect higher torques from a subject with spasticity for the same rotations. The gain, K , is also largely dependent on the maximum range for the subjects with spasticity which can vary day-to-day and with mood (either in an emotional context or in a physical sense as well). The range of gain for subjects without spasticity seems more constant. This variation in maximum range of the subjects with spasticity does not affect the other parameters (ω_n and ζ) as much so they are more stable indicators of spasticity. The

observed trends in ω_n and ζ are also generally applicable to the control data and thus some combination of these two parameters may provide a useful indicator of spasticity.

By plotting the two most reliable indicators (ω_n and ζ) of spasticity against each other the following plot in Figure 4.3.3-4 is obtained for all velocities tested. Data from subjects with and without spasticity are plotted.

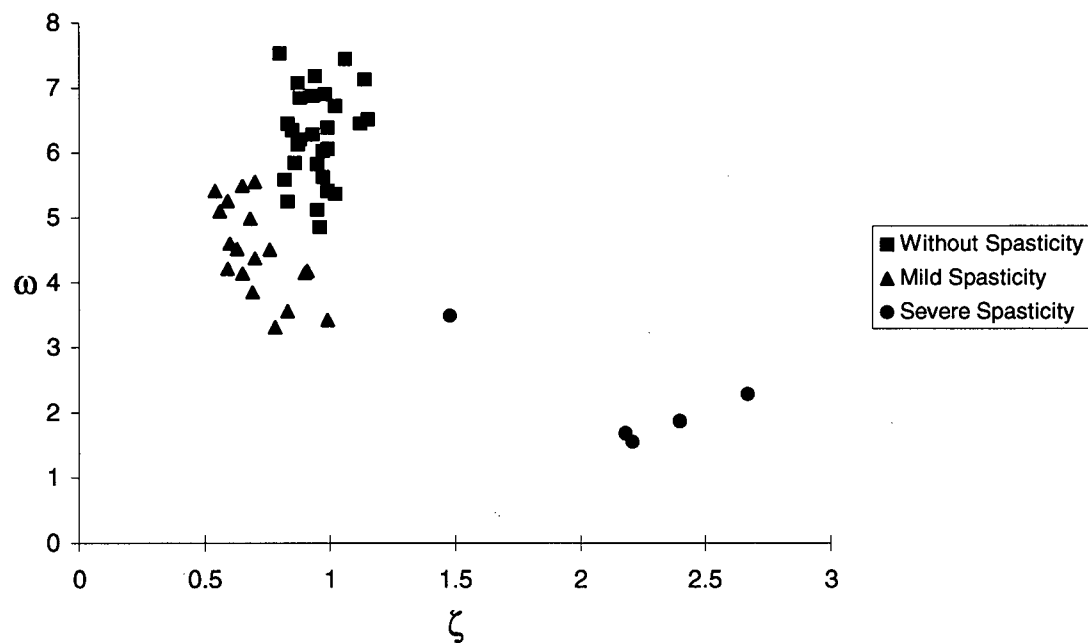


Figure 4.3.3-4 Response parameter versus damping parameter for all velocities tested

Although there is some overlap of the two parameters individually, when they are plotted together there is a clear difference between the data from subjects with and without spasticity. Given that the data from subjects with and without spasticity can clearly be distinguished from each other in this plane, some quantitative measure of the degree of spasticity can be estimated.

4.3.4 Quantification of Results

By plotting the response parameter and the damping parameter together, the data from subjects with and without spasticity can clearly be distinguished. By making use of this relationship, the degree of spasticity can be quantified. From Figure 4.3.3-4 it can be seen that the more severe cases of spasticity are also differentiated from the mild cases. This can be taken advantage of by delineating a curve between the two sets of data.

To separate the data from subjects with and without spasticity, an equation was determined which describes a curve between the two sets of data. The distance of the data *outside* this curve, measured perpendicular to the curve, was used to determine a quantitative number related to the degree of spasticity. Inside the curve, or on the curve, the data indicates no evidence of spasticity. The equation determined below was arbitrarily chosen to have the best fit between the two sets of data:

$$\omega = \frac{\zeta^2}{\sqrt{\zeta - 0.73}} + 2.7$$

This equation was chosen, rather than a straight x^n type equation, in an attempt to linearize the data from subjects with spasticity with respect to the degree of spasticity. Figure 4.3.4-1 shows the response parameter, ω_n , versus damping parameter, ζ , for all velocities tested separated by the delineating curve.

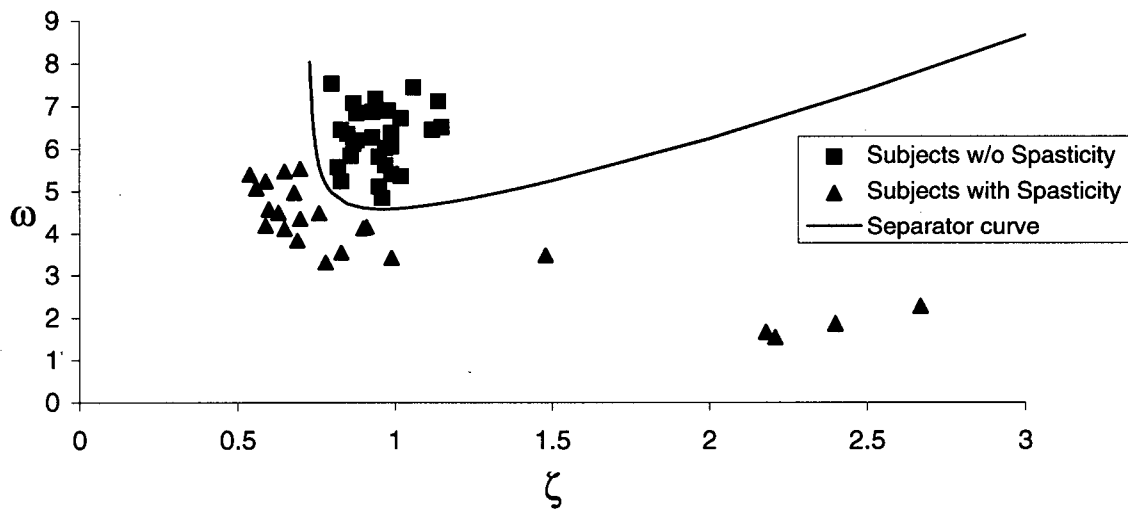


Figure 4.3.4-1 Response parameter versus damping parameter for all velocities tested separated by delineating curve

The points on the graph are then compared to the delineating equation to determine their perpendicular distance outside the curve. If they are inside, or on the curve they are assumed to be free of spasticity. To determine if the points are inside the curve or outside the curve each data point is simply inserted into the following equation of the curve:

$$\frac{\zeta^2}{\sqrt{\zeta - 0.73}} + 2.7 - \omega = \text{Solution}$$

If the solution to the equation is zero or negative the test indicates non-spastic behavior. If the solution to the equation is positive or an error occurs ($\zeta < 0.73$) the test indicates evidence of spasticity and the corresponding distance outside the curve must be determined to quantify the

degree of spasticity. The distance of any given point outside the curve can be determined by minimizing the square of the distance between the two points:

$$D = (x - \zeta)^2 + (y - \omega)^2$$

Where the equation is constrained by:

$$y = \frac{x^2}{\sqrt{x - 0.73}} + 2.7$$

Then:

$$D(x) = (x - \zeta)^2 + \left(\frac{x^2}{\sqrt{x - 0.73}} + 2.7 - \omega \right)^2$$

To minimize this equation set:

$$\frac{dD(x)}{dx} = 0$$

Using Maple® (code shown in Appendix D) this function is minimized for any given value of ω or ζ to determine the value of x corresponding to the shortest distance from the curve to the data point. This value of x is then used to determine y which can be used to determine the distance equation, $\sqrt{D}$, to get the shortest distance to the curve. This value of the distance of the data point from the separator curve is then used as a quantified measure of spasticity. After analyzing all the data points, the degree of spasticity for each subject was tabulated in Table 4.3.4-1.

Subject	Calculated Spasticity Measurement Parameter ($\sqrt{D}$)				
	20°/s	30°/s	40°/s	50°/s	60°/s
Control Group	0	0	0	0	0
Mild spasticity #1	0.24	0.32	0.46	0.24	0.22
	0.07	0.50			
	0.30	0.56			
		0.58			
Mild spasticity #2	0.13	0.14	0.13	0.36	0.83
					1.09
Severe spasticity	1.25	2.88	3.10	3.31	N/A
			3.18		
			3.11		

Table 4.3.4-1 *Quantified measurements of spasticity for all subjects.*

With the exception of the case of 'Mild Spasticity #1' it was noted that there did appear to be a clear velocity dependence of the quantified spasticity measure. As the velocity of the rotation increases, so too does the quantified spasticity measure. In the case of 'Mild Spasticity #1' the quantified spasticity measure increased from 20°/s to 30°/s and then remained relatively constant through 40°/s. At 50°/s and 60°/s the measure decreases with increasing velocity. However, this observation results from only one testing session and may be attributed to experimental error. In the case of 'Mild Spasticity #2' the spasticity measure remains relatively constant up to test velocities of 40°/s, and above this test velocity it increases rapidly. It was observed that 'Severe Spasticity' showed a distinct trend of increasing quantified spasticity measure with increasing test velocity. Initially, from 20°/s to 30°/s the measure increases quite rapidly and then increases more slowly from 30°/s to 50°/s. In each case the quantified

spasticity measure began increasing at different velocities and behaved slightly differently (increasing along different slopes, leveling off etc.). It could be theorized that the differing velocity dependence of each subject may be related to the associated disease. The subject of 'Mild Spasticity #1' suffered from a stroke, the subject of 'Mild Spasticity #2' had a spinal cord injury, and the subject of 'Severe spasticity' had a brain injury. It is possible that individuals with similar associated diseases might exhibit similar velocity dependence of the quantified spasticity measure. In this case it is difficult to compare the results of each individual test subject or to speculate on the relevance of the velocity dependence. Suffice to say, there does appear to be a velocity dependence and the quantified spasticity measure does correlate with increasing clinical degree of spasticity.

In order to have clinically validated results, the subjects should be tested for spasticity by an experienced physician using one of the commonly accepted techniques, such as the Ashworth scale. The subject designated 'Mild Spasticity #1' was clinically evaluated and was found to have mild spasticity which was slightly worse in the subject's left leg than the right. The subject with severe spasticity was also clinically evaluated, and was found to have an extremely severe spastic response in the subject's left leg, while the right leg was not as severe. The subject designated 'Mild Spasticity #2' was not clinically evaluated in the course of this project, but was able to self induce persistent clonus consistent with the clinical confirmation of spasticity. In addition, this subject had been evaluated for spasticity prior to this project and reported having mild evidence of spasticity. The quantified results of this research project

concur with the clinical evaluation of spasticity, although, at present, it is not clear exactly how the quantified measurement of spasticity will relate to clinical evaluations.

Although the delineation curve effectively separates all the data points at all velocities, it may be more practical to quantify the degree of spasticity using one standardized velocity, or to relate numbers from the same velocities. In addition, the exact curve to separate data from subjects with and without spasticity should be determined by statistical analysis of further test data from both groups. As more data for the control group (and subjects with spasticity of varying degrees) is obtained this equation can be refined to provide a more accurate differentiation between subjects with and without spasticity.

4.4 Statistical Significance of the Test Results

By comparing data sets within a test session, the covariance between the sets of data can be determined, indicating a measure of the relationship between the two ranges of data. If there is a weak relationship between the two sets of data, the covariance tends toward zero. Covariance of experimental data within test sessions for data from subjects with and without spasticity was calculated. The covariance between the sets of experimental data was found to be very good for both test groups. The values of covariance for subjects without spasticity ranged from a low of 6 to as high as 36, indicating good to excellent correlation. The covariance for the data from subjects with spasticity was slightly better.

It is impossible to obtain an accurate measure of the reliability of the test data on a day-to-day basis because of the limited day-to-day sampling during this project. In order to check the day-to-day reliability of the test data or the results, requires a larger sample of day-to-day tests. This was difficult to obtain because of the time constraints of the test subjects. It appears that day-to-day reliability was not as good as within testing sessions (test-to-test). This may be due, in part, to inconsistencies of the device. As well, testing took place over a period of several months while the testing protocol was being continuously changed to optimize the testing procedure.

The analysis of variance test (ANOVA), which expands on the test for two means, was used to evaluate the hypothesis that the two data sets, repeated over a number of months on a variety of subjects with, and without spasticity, are drawn from populations with the same mean. The specific test used was the two-factor ANOVA test with replication, meaning that more than one sample for each group of data (i.e. ω and ζ) was included in the analysis. The results of the test demonstrated a significant difference between the two data sets.

ANOVA between the data samples from subjects with and without spasticity for ω and ζ yields:

$$SS = 33.26$$

$$P = 0.078$$

This indicates that the probability that the two groups are from the same population samples is only 7.8%. This indicates that a reasonably reliable indicator for spasticity has been developed.

Although the quantified results of the testing did agree with the clinical measure of spasticity, further testing is needed to correlate it as a measure of the degree of spasticity. In order to determine the reliability of day-to-day tests, a larger population sample is required.

4.5 Comparisons with Previous Work

Previous research has often attempted to quantify spasticity with varying degrees of success. The results have often been a single number related only to one parameter of spasticity such as peak torque of the test. In addition, the parameters chosen for measuring spasticity have only been questionably shown to relate to spasticity. In this research, one of the most common methods utilized to measure spasticity, the peak torque has been shown not to relate to spasticity at all. Another common measure of spasticity, reflex gain, is both difficult to determine and related more to other factors, such as the input position, rather than to spasticity. By relating the torque response gain to the input position, as in this research, some loose correlation has been established between gain and spasticity. The measure developed by this project takes into account a variety of factors which were seen to be indicators of both the existence of spasticity, and the severity of spasticity. These factors were carefully chosen because of their relative robustness and clear correlation. Other loosely related factors, often chosen by other researchers, were ignored because of poor correlation or inconsistent results. By carefully choosing the factors related to spasticity and its severity, and intelligently presenting this data, a single, relevant measure of spasticity has been developed.

4.6 Summary

Initially subjects without spasticity were tested to determine the behavior of the ankle joint. Resistive torque data from the tests were plotted against time. The curves exhibited a generally linear ramp of increasing torque in the velocity dependent portion of the test followed by a steady torque level after the motion had stopped. There was little or no EMG activity evident during the testing, indicating no reflex muscle activity. Nor was there any obvious velocity dependence up to $60^\circ/\text{s}$ rotations of the ankle. This data was compared with data from people with spasticity. Subjects with spasticity were tested to assess variations in spastic response. The data was analyzed to determine variations between data of subjects with and without spasticity. Noted variations included a smoother transition between increasing torque and steady torque, an increasing torque curve which was slightly less linear, and an overshoot and subsequently decreasing resistive torque. These variations were confirmed, in an exaggerated form, in data from a subject with severe spasticity. In addition, EMG activity was found to have increased during the tests of the subjects with spasticity indicating active reflex response. It was also noted that there might be velocity dependence of spasticity starting at or about $60^\circ/\text{s}$.

A number of traditional measures for spasticity were investigated using the collected data. Maximum resistive torque, slope of the velocity dependent curve, reflex threshold, gain, and severity of EMG response were all considered. None of the traditional measures of spasticity was deemed suitable as a reliable measure of spasticity. Instead an equation, based on the chosen model for spasticity, was used to fit a curve to the resistive torque vs. time data. Parameters of this equation were correlated with the degree of spasticity. It was noted that, as

the severity of spasticity increased, the response parameter, ω_n , decreased while the damping parameter, ζ , increased. These two parameters were plotted against each other and a delineating equation was drawn between the data from subjects with and without spasticity. The perpendicular distance of the data points from this delineating curve was used as a quantitative measure of spasticity. This quantified measure of spasticity correlated with the clinical evaluation of the subjects. The ANOVA test was used to analyze the two sets of data and showed that the probability that the two groups were from the same population was only 7.8%. This demonstrates that a reasonably reliable indicator for spasticity has been developed.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS FOR FUTURE WORK

5.1 Conclusions

The general purpose of this investigation, as mentioned in Chapter 1, was to develop an objective, quantitative means of measuring the degree of spasticity. To this end, a number of objectives were set for the development and testing stages of the project. For the development stage of the device the following objectives were met.

- The short term objective to develop and validate a computer-controlled device to quantitatively measure the degree of spasticity at the ankle in a clinical application has been achieved.
- This device performs the testing in a safe manner and has built in redundant safety features to protect the test subjects from any possible failure of the device. These safety features include torque limited computer control, a variable slippage clutch, physical stops for the foot pedal, and mechanical shear pins designed to shear at unsafe levels of torque.
- This device was designed to be flexible enough to accommodate testing of various measurement protocols. The displacement/velocity controlled rotation method was

chosen as the best method to measure spasticity and the device was able to accommodate this method of measurement.

- Although no test data was generated, during laboratory testing, the device was able to test subjects in different sitting positions with the subject's knee joint and ankle joint in a variety of positions. In the course of this project subjects were seated with their knees and ankle joints at 90°.

Throughout the testing phase of the research the following objectives were met:

- The device was able to reliably measure the resistive torque at the ankle of individuals with and without spasticity.
- Using data acquired using the device, a diagnostic model has been developed which indicates the ability to distinguish between joints with and without spasticity. This was done by parameterizing the chosen model and applying that model to the experimental data. The parameter data was examined for trends in spasticity and plotted accordingly. A separator equation between the two sets of data was used to quantify the results and clearly distinguished between the data sets.
- The developed model, which utilizes resistive torque data, was able to distinguish between degrees of severity of spasticity for the tested subjects and provides a parameter to quantify degrees of spasticity severity. By determining the minimum distance of the plotted spasticity parameters outside the separator curve, experimental data from the device was used to quantify different spasticity severity. By modifying the separator

equation one could attempt to linearize the quantified results with respect to clinical scales.

- The device was able to record self induced clonus in one subject. Other phenomenon associated with spasticity such as spasms, and perhaps a clasp knife reaction, were also recorded.
- On a trial-by-trial basis, the repeatability of the device was excellent. Covariance values between 6 to as high as 50 were achieved between data from the same testing sessions.
- Using the analysis of variance test in order to test the hypothesis that the control data and the data from subjects with spasticity were different, a value of the probability factor, P , was determined to be 0.078 indicating that the parameters separating the data sets were able to reasonably differentiated people with spasticity from people without spasticity.

5.2 Recommendations for Future Work

Throughout the course of this research project a number of recommendations for improvements and future work became apparent. These were related to both the use and design of the device, and the confirmation of the testing protocol and analysis of the data.

- Increased testing of both subjects without spasticity and, more specifically , subjects with spasticity should be undertaken in order to more accurately determine the limits of normal spasticity. This additional data should be analyzed and plotted against the control data. This would more accurately show the ranges of the model parameters for people with and without spasticity and would allow a more accurate delineation equation to be developed.

- More testing of subjects with spasticity, correlated with clinical trials should be performed to further refine the delineation equation. This data should be used to linearize the quantified data with clinical measures.
- Results should be correlated within disease groups (such as head and spinal cord injuries, stroke, multiple sclerosis, and cerebral palsy) to determine if the model parameters are affected more by one disease group than another.
- Results should be correlated against a variety of testing conditions to help understand how results are affected by uncontrolled factors (such as comfort, fatigue, mood, ambient temperature, and so forth).
- A more accurate method for determining the maximum range of motion should be developed. This was found to be troublesome using the current protocol.
- The testing protocol should be made more rigorous to better control the testing environment and improve day-to-day variations of test data.
- The device should be made more concise to more exacting tolerances so that the quality of the device does not cause day-to-day variations of the data.
- The stepper motor of the device is not strong enough to reliably test subjects above 50°/s. The motor should be replaced with a stronger motor. This is of some importance if the apparent velocity dependence of spasticity above 60°/s is to be investigated.
- The data acquisition system is only capable of collecting data at 25 Hz. This is mostly due to running the control software through Microsoft® Windows. However, if the AD board were replaced with one with a buffer, the present system could be retained.

Movement of a joint is very important in the maintenance of that joint and, as mentioned in Chapter 1, the device has potential as an exercise device to help rehabilitate people with spasticity. This was not investigated during the course of this project, but would be of interest for further study. Theoretically, once a suitable evaluation of spasticity has been established, the device could be used to determine conditions under which a particular patient will be least affected by spasticity. There are instances where, under certain circumstances, spasticity is not apparent in the muscles of people with spasticity. In certain positions, at particular velocities, and through various paths, an individual might have their joints manipulated without a spastic response. By moving the ankle joint through various positions at varying velocities, while recording the muscle activity, the conditions where movement occurs without a spastic response could be determined by the device. This information could then be programmed into the device so that those conditions could be reproduced as an exercise routine or stretching program to help rehabilitate an individual. There is also a possibility that by moving the joint without eliciting spasticity, the subject may learn to move in a like manner, without evoking a spastic response.

The device could be modified to accommodate a number of therapeutic and exercise applications. Some of the potential uses of the device as an exercise tool which would be of interest for further study are:

- i) Stretching of the ankle joint - The device could be modified to rotate a subject's ankle from one joint limit to the other for a given number of cycles (beginning and ending at

the ankle's neutral position) thereby stretching the spastic muscles. Alternatively, the ankle could be rotated from torque limit to torque limit.

- ii) Movement control exercise - By setting the clutch resistance to a chosen level, a subject could attempt to move their ankle at a given velocity, over a given range, with a fixed resistance. The computer could use the data acquisition system to monitor the subject's response, so the subject could monitor their own progress in real time by matching it against the desired values displayed on the screen.
- iii) Torque control exercise - The motor could manipulate the subject's ankle through a chosen velocity profile for a number of cycles while the user attempts to match a given level of resistance. The subject could monitor their progress in real time in a similar manner as in (ii) above.

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APPENDIX A - DESIGN CALCULATIONS

The prototype stepper motor was sized according to the following calculations. Recall that initially the maximum angular velocity of the ankle joint was to be 0.35 rad/s. The selected motor therefore had to provide at least $T_{\max} = 24 \text{ Nm}$ at $\omega_{\max} = 0.35 \text{ rad/s}$ at the foot pedal in order to overcome the resistive forces in the system. Assuming this angular velocity should be achieved in 0.05 s, then the maximum angular acceleration would be:

$$\alpha_{\max} = \omega_{\max} / 0.05 \text{ s} = 7.0 \text{ rad/s}^2$$

The inertia of the system (J_{system}) is estimated to be 0.172 kgm^2 at the foot pedal. Thus the torque required to overcome the inertial forces in the system is:

$$T_{\text{inertial}} = J_{\text{system}} \alpha_{\max}$$

$$T_{\text{inertial}} = 0.172 \text{ kgm}^2 * 7.0 \text{ rad/s} = 1.2 \text{ Nm}$$

Thus the total torque required at the motor is:

$$T_{\text{motor}} = (T_{\text{inertial}} + T_{\max}) / (e * n)$$

Where e = efficiency of reducer = 0.50

n = gear ratio of worm gear = 30

$$T_{\text{motor}} = (25.2 \text{ Nm}) / (0.50 * 30) = 1.68 \text{ Nm}$$

This torque had to be available with the motor running at:

$$\omega_{\text{motor}} = 0.35 \text{ rad/s} * 30 = 10.5 \text{ rad/s}$$

Minimum specifications the new motor were determined according to the following calculations. The minimum required torque at the foot pedal is 25 Nm at 1.05 rad/s (60°/s). Losses in the driveline are approximately 2 Nm. . The new motor therefore had to provide at least $T_{\max} = 27 \text{ Nm}$ at $\omega_{\max} = 0.35 \text{ rad/s}$ at the foot pedal in order to overcome the resistive forces in the system.

$$\alpha_{\max} = \omega_{\max} / 0.05 \text{ s} = 21.0 \text{ rad/s}^2$$

$$T_{\text{inertial}} = 0.172 \text{ kgm}^2 * 21.0 \text{ rad/s} = 3.6 \text{ Nm}$$

$$T_{\text{new motor}} = (30.6 \text{ Nm}) / (0.50 * 30) = 2.04 \text{ Nm}$$

The transducer shaft was designed as follows. Using St. Venant's principle governing stresses, a transducer shaft 2-3 diameters long at a uniform thickness was selected to ensure reliable results from the strain gauges. The transducer shaft was constructed of 17-4 PH stainless steel. Two rosette strain gauges were acquired to measure the torque in the shaft connecting the drive system to the foot pedal. Each rosette consisted of three strain gauges but only the outer two were required for measuring torque. The strain gauges were mounted exactly opposite each other in the center of the transducer shaft to evaluate accurate torque measurements. The strain gauges were connected in a wheatstone bridge arrangement which limits the effects of lateral bending of the shaft. Temperature effects should cancel out because of this, as well. The gauges were composed of Constantan foil of 0.125 in. thickness, mounted on a polyamide backing and were temperature compensated.

The output from the resistive bridge is given by the equation:

$$V_b = \epsilon * 2.04 * n * E / 4$$

Where: ϵ = strain

2.04 = gauge factor

n = number of active arms = 4

E = potential across input = 5 V

To design the shaft, the following analysis was done:

Where: $T_{\max} \gg 25 \text{ Nm}$

d_i = inner diameter of shaft = 12.7 mm

d_o = outer diameter of shaft

J = moment of inertia

G = Modulus of Rigidity = 75.5 GPa

$E_{\max}$ = maximum strain $\gg 1500 \text{ mm/m}$

$$t_{\max} = T_{\max} d_o / J = G E_{\max}$$

$$J = p(d_o^4 - d_i^4)/32$$

$$\text{Then: } T_{\max} d_o / G E_{\max} = p(d_o^4 - d_i^4)/32$$

Solving for $d_o \gg 15.2 \text{ mm}$

And from St. Venant's principle, the length of the uniform section of the shaft was selected to be 50.8 mm.

APPENDIX B - COMPUTER CODE

The following is the main computer code used for control of the device to measure spasticity at the ankle developed for this project. The code was printed from a Visual Basic Professional Edition 3.0 application. Some of the global declarations were removed for space reasons.

MODULE1.BAS - 1

```
'Prog2.MAK=====
' File:          Prog2.MAK
' Purpose:       Scans a range of A/D Input Channels and stores
'               the sample data in an array.
' Other Library Calls:  cbErrHandling%()
'=====

Global Const BoardNum = 0      ' Board number
Global Const NumPoints& = 3    ' Number of data points to collect
Global Const FirstPoint& = 0   ' set first element in buffer to transfer to array
Global ADDData%(NumPoints&)    ' dimension an array to hold the input values
Global MemHandle%              ' define a variable to contain the handle for
                                ' memory allocated by Windows through cbWinBufAlloc%()
Dim FName, Msg, TestString     ' Declare variables.
Global Offset@(3)              ' Calibration constant array to zero each channel
Global selection As Variant
Global motor%
Global ULimit As Variant
Global toggle%
Global TorLim As Variant      ' Safe Torque limit
Global MaxEMG As Variant

Sub Wait ()
    N = 0
    Screen.MousePointer = 11
    Do While N < 14000
        N = N + 1
    Loop
    Screen.MousePointer = 0
    N = 1
End Sub
```

```
Sub OpenData ()
```

```
' Open data files:
```

```
Open "c:\data\" & FileTxt.Text & "0p.dat" For Output As #1 ' Angular position data
Open "c:\data\" & FileTxt.Text & "0t.dat" For Output As #2 ' Resistive torque data
Open "c:\data\" & FileTxt.Text & "0e.dat" For Output As #3 ' EMG activity data
Open "c:\data\" & FileTxt.Text & "1p.dat" For Output As #4 ' Angular position data
Open "c:\data\" & FileTxt.Text & "1t.dat" For Output As #5 ' Resistive torque data
Open "c:\data\" & FileTxt.Text & "1e.dat" For Output As #6 ' EMG activity data
Open "c:\data\" & FileTxt.Text & "2p.dat" For Output As #7 ' Angular position data
Open "c:\data\" & FileTxt.Text & "2t.dat" For Output As #8 ' Resistive torque data
Open "c:\data\" & FileTxt.Text & "2e.dat" For Output As #9 ' EMG activity data
Open "c:\data\" & FileTxt.Text & "3p.dat" For Output As #10 ' Angular position data
Open "c:\data\" & FileTxt.Text & "3t.dat" For Output As #11 ' Resistive torque data
Open "c:\data\" & FileTxt.Text & "3e.dat" For Output As #12 ' EMG activity data
Open "c:\data\" & FileTxt.Text & "4p.dat" For Output As #13 ' Angular position data
Open "c:\data\" & FileTxt.Text & "4t.dat" For Output As #14 ' Resistive torque data
Open "c:\data\" & FileTxt.Text & "4e.dat" For Output As #15 ' EMG activity data
Open "c:\data\" & FileTxt.Text & "5p.dat" For Output As #16 ' Angular position data
Open "c:\data\" & FileTxt.Text & "5t.dat" For Output As #17 ' Resistive torque data
Open "c:\data\" & FileTxt.Text & "5e.dat" For Output As #18 ' EMG activity data
```

```
End Sub
```

```
Sub GetData ()
```

```
' Collect the values with cbAInScan%()
```

```
' Parameters:
```

```
' BoardNum :the number used by CB.CFG to describe this board
```

```
' LowChan% :the first channel of the scan
```

```
' HighChan% :the last channel of the scan
```

```
' CBCount& :the total number of A/D samples to collect
```

```
' CBRate& :sample rate
```

```
' Gain% :the gain for the board
```

```
' AddData% :the array for the collected data values
```

```
' Options% :data collection options
```

```
LowChan% = 0 ' first channel to acquire
```

```
HighChan% = 2 ' last channel to acquire
```

```
CBCount& = NumPoints& ' total number of data points to collect
```

```
CBRate& = 2000 ' sampling rate (samples per second)
```

```
Options% = NOCONVERTDATA
```

```
Gain% = BIP5VOLTS ' set the gain
```

```
If MemHandle% = 0 Then Stop ' check that a handle to a memory buffer exists
```

```
ULStat% = cbAInScan%(BoardNum%, LowChan%, HighChan%, CBCount&, CBRate&, Gain%,  
MemHandle%, Options%)
```

```
If ULStat% = 84 Then
```

```
MsgBox "The CONVERT option cannot be used with 16 bit convertors. Set Options% to  
NOCONVERTDATA."
```

```
Stop 'Change Options% above to NOCONVERTDATA (Options%= 0)
```

```
End If
```

```
If ULStat% <> 0 Then Stop
```

```
' Transfer the data from the memory buffer set up by Windows to an array for use by Visual Basic
```

```
ULStat% = cbWinBufToArray%(MemHandle%, ADDData%(0), FirstPoint&, CBCount&)
```

```
If ULStat% <> 0 Then Stop
```

```
For I% = 0 To NumPoints& - 1
```

```
If ADDData%(I%) >= 0 Then
```

```
ADDData%(I%) = ADDData%(I%) - 32768
```

```
Else
  ADDData%(I%) = ADDData%(I%) + 32768
End If
'Store the data to a 2 dimensional array in memory:
dataArray@(I%, temp) = ADDData%(I%)
Next I%
End Sub
```

DAS8.BAS - 1

' This file contains the Visual BASIC declarations for all Computer
' Boards library commands. This file should be imported via Visual
' BASIC's Load Text command (from the code menu). It should be
' imported into either a form or the Global section of the program.

FRMEMG.FRM - 1

```
Dim temp
Dim MaxVal@
```

```
Sub CmndCancel_Click ()
  TmrEMG.Enabled = 0
  Unload FrmEMG
End Sub
```

```
Sub CmndOK_Click ()
  MaxEMG = Text1.Text
  Form2.Show
  Unload FrmEMG
End Sub
```

```
Sub CmndStart_Click ()
  CmndCancel.SetFocus
  RunTotal@ = 0
  TmrEMG.Enabled = True
End Sub
```

```
Sub Form_Load ()
  MaxVal@ = 0
  temp = 0
End Sub
```

```
Sub Form_Unload (Cancel As Integer)
  Form1.CmndClose.Enabled = 1
  Form1.CmndDA.Enabled = 1
  Form1.CmndProg.Enabled = 1
  Form1.CmndLim.Enabled = 1
End Sub
```

```
Sub Text1_Change ()
  Text1.BackColor = &HFFFFFF
  MaxEMG = Text1.Text
End Sub
```

```
Sub Text1_GotFocus ()
    Text1.Text = ""
End Sub

Sub Text1_KeyPress (KeyAscii As Integer)
    If KeyAscii = 13 Then
        MaxEMG = Text1.Text
        Form2.Show
        Unload FrmEMG
    End If
End Sub

Sub TmrEMG_Timer ()
    On Error Resume Next
    Call GetData
    Limdata@ = ADDData%(0) - Offset@(2)
    Limdata@ = Abs(Limdata@)
    Limdata@ = Limdata@ + RunTotal@
    RunTotal@ = Limdata@
    Text1.Text = Format$(Limdata@, "0.0")
    If temp >= 100 Then
        MaxEMG = Limdata@ / temp
        Text1.Text = Format$(MaxEMG, "0.0")
        TmrEMG.Enabled = False
        temp = 0
    End If
    temp = temp + 1
End Sub

FRMFILES.FRM - 1

Sub CmndCancel_Click ()
    Unload FrmFileSave
End Sub

Sub CmndOK_Click ()
    On Error Resume Next
    Call OpenData
    frmDataDisplay.Show
    Unload FrmFileSave
End Sub

Sub FileTxt_KeyPress (KeyAscii As Integer)
    If KeyAscii = 13 Then Call OpenData
    frmDataDisplay.Show
    Unload FrmFileSave
End Sub

Sub Label2_Click ()
    toggle% = 1
End Sub

PROG.FRM - 1

Dim temp
```

```

Dim total@(3)
Dim DataArray@(3, 51)      ' Array to hold data for calibration
Dim run As Variant

Sub CmndClose_Click ()
    Comm1.Enable = 0        ' Disable port
    CmndClose.Enabled = 0
    CmndLim.Enabled = 0     ' Enable Initialize and
    CmndInit.Enabled = 1    ' Exit buttons
    CmndExit.Enabled = 1
    CmndTest.Enabled = 0
    CmndStart.Enabled = 0
    CmndDA.Enabled = 0
    CmndProg.Enabled = 0
    CmndExit.SetFocus
End Sub

Sub CmndDA_Click ()
    FrmFileSave.Show
    CmndLim.Enabled = 0
    CmndDA.Enabled = 0
    CmndProg.Enabled = 0
End Sub

Sub CmndExit_Click ()
    End
End Sub

Sub CmndInit_Click ()
    CmndInit.Enabled = 0
    Form1.Comm1.Parity = 0
    Form1.Comm1.Comport = 1
    Form1.Comm1.Baud = 3
    Form1.Comm1.Stop = 0
    Form1.Comm1.Enable = 1
    If Comm1.Enable = 0 Then Exit Sub    ' If not enabled, exit
    Picture1.Cls                        ' Clear the picture
    'Zero the data channels:
    Screen.MousePointer = 11
    tmrConvert.Enabled = True
End Sub

Sub CmndLim_Click ()
    CmndLim.Enabled = 0
    CmndDA.Enabled = 0
    CmndProg.Enabled = 0
    FrmEMG.Show
End Sub

Sub CmndProg_Click ()
    If Comm1.Enable = 0 Then    ' If not enabled...
        CmndInit.Enabled = 1  ' Enable Initialize and
        CmndExit.Enabled = 1  ' Exit buttons and exit
        CmndProg.Enabled = 0
    Exit Sub

```

```

End If
CmdnClose.Enabled = 1
' Determine the extent of programming in the device
' already. We must assume that the users knows what they are doing.
' In this case we might be able to inform them (warning box)
' and warn them at what point they could safely start
' programming again.
Title = "Entering Programming Mode"
Msg = "Programming may render device inactive!" + Chr(13) + Chr(10)
Msg = Msg & "Do you want to continue?"
Beep
response = MsgBox(Msg, 3 + 48, Title)
If response <> 6 Then Exit Sub
CmdnLim.Enabled = 0
CmdnProg.Enabled = 0
CmdnDA.Enabled = 0
Form4.Show
End Sub

Sub CmdnStart_Click ()
    motor% = 1
    FrmFileSave.Show
End Sub

Sub CmdnTest_Click ()
    CmdnLim.Enabled = 0
    CmdnProg.Enabled = 0
    CmdnDA.Enabled = 0
    Form3.Show 1
End Sub

Sub Comm1_InQueue (Queued As Integer)
    s$ = Comm1.DataStr          ' Put characters in a string
    Picture1.Print s$;          ' Print the string to picture
End Sub

Sub Form_Load ()
    temp = 0
    motor% = 0
    toggle% = 0
    ' Initiate error handling
    ' activating error handling will trap errors like
    ' bad channel numbers and non-configured conditions.
    ' Parameters:
    '   PRINTALL   :all warnings and errors encountered will be printed
    '   DONTSTOP   :if an error is encountered, the program will not stop,
    '               errors must be handled locally
    ULStat% = cbErrHandling%(PRINTALL, DONTSTOP)
    If ULStat% <> 0 Then Stop
    ' If cbErrHandling% is set for STOPALL or STOPFATAL during the program
    ' design stage, Visual Basic will be unloaded when an error is encountered.
    ' Suggest trapping errors locally until the program is ready for compiling
    ' to avoid losing unsaved data during program design. This can be done by
    ' setting cbErrHandling options as above and checking the value of ULStat%
    ' after a call to the library. If it is not equal to 0, an error has occurred.

```

```

MemHandle% = cbWinBufAlloc%(NumPoints&) ' set aside memory to hold data
If MemHandle% = 0 Then Stop
End Sub

Sub Form_Unload (Cancel As Integer)
ULStat% = cbWinBufFree%(MemHandle%) ' Free up memory for use by other programs
If ULStat% <> 0 Then Stop
Unload Form2
Unload Form3
Unload Form4
Unload frmDataDisplay
End Sub

Sub Label1_Click (Index As Integer)
If Label1(1) = "" Then
For I% = 0 To 2
Label1(I%) = Offset(I%)
Next
Else
For I% = 0 To 2
Label1(I%) = ""
Next
End If
End Sub

Sub tmrConvert_Timer ()
On Error Resume Next
Call GetData
If temp >= 50 Then
tmrConvert.Enabled = False
For J% = 0 To NumPoints& - 1
total(J%) = 0
Next J%
For I% = 1 To temp - 1
total@ (0) = total@ (0) + DataArray@ (0, I%)
total@ (1) = total@ (1) + DataArray@ (1, I%)
total@ (2) = total@ (2) + DataArray@ (2, I%)
Next I%
Offset@ (0) = total@ (0) / (temp - 1)
Offset@ (1) = total@ (1) / (temp - 1)
Offset@ (2) = total@ (2) / (temp - 1)
Screen.MousePointer = 0
CmdnLim.Enabled = 1 ' Enable Begin button
CmdnClose.Enabled = 1
CmdnExit.Enabled = 0
CmdnTest.Enabled = 0
CmdnProg.Enabled = 1
CmdnDA.Enabled = 1
Comm1.DataStr = " " + Chr$(10) + Chr$(13) ' Send ATZ to modem
CmdnLim.SetFocus
temp = 0
End If
temp = temp + 1
End Sub

```

```
Sub TmrStart_Timer ()
    CmndStart.SetFocus
    TmrStart.Enabled = 0
End Sub

Dim Calim@(2)          ' Calibration constant
Dim Plim As Variant
Dim Nlim As Variant
Dim Torque@
Dim LimData@
Dim temp3

Sub CmndAbort_Click ()
    Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
    Plim = 0
    TmrPos.Enabled = False
    TmrNeg.Enabled = False
    CmndStop.Enabled = 0
    CmndQuit.Enabled = 1
    CmndPos.Enabled = 1
    'CmndNeg.Enabled = 1
End Sub

Sub CmndNeg_Click ()
    CmndQuit.Enabled = 0
    CmndAbort.Enabled = 1
    CmndPos.Enabled = 0
    CmndNeg.Enabled = 0
    Torque@ = 0
    temp3 = 0
    Nlim = 0
    TmrNeg.Enabled = True
End Sub

Sub CmndPos_Click ()
    Text2.BackColor = &HFFFFFF
    CmndQuit.Enabled = 0
    CmndAbort.Enabled = 1
    CmndStop.Enabled = 1
    CmndPos.Enabled = 0
    CmndNeg.Enabled = 0
    CmndStop.SetFocus
    Torque@ = 0
    temp3 = 0
    Plim = 0
    TmrPos.Enabled = True
End Sub

Sub CmndQuit_Click ()
    Unload Form2
End Sub

Sub CmndStop_Click ()
    Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
    ULimit = Plim
```

```
TmrPos.Enabled = False
TmrNeg.Enabled = False
CmndStop.Enabled = False
CmndQuit.Enabled = 1
CmndPos.Enabled = 1
CmndQuit.SetFocus
TmrHold.Enabled = True
End Sub

Sub Form_Load ()
    CmndAbort.Cancel = True
    TorLim = 35
    ULimit = 0
    Calim(0) = .0063           ' Calibration multiplier for angular position
    Calim(1) = .00080826      ' Calibration multiplier for resistive torque
    Form1.Comm1.DataStr = "\20" + Chr$(10) + Chr$(13)
    Call Wait
    Form1.Comm1.DataStr = "V1000" + Chr$(10) + Chr$(13)
    Call Wait
    Form1.Comm1.DataStr = "m3" + Chr$(10) + Chr$(13)
    Call Wait
    Form1.Comm1.DataStr = "f300" + Chr$(10) + Chr$(13)
End Sub

Sub Form_Unload (Cancel As Integer)
    On Error Resume Next
    ' Make sure timers are off:
    TmrNeg.Enabled = False
    TmrPos.Enabled = False
    TmrHold.Enabled = False
    Form1.CmndClose.Enabled = 1
    Form1.CmndDA.Enabled = 1
    Form1.CmndProg.Enabled = 1
    Form1.CmndLim.Enabled = 1
    If ULimit Then
        ULimit = Fix(ULimit * 1) ' Fix the testing extents to XX% of the comfort limits
        Form1.CmndTest.Enabled = 1
        Form1.CmndTest.SetFocus
    End If
    If Form1.CmndTest.Enabled Then Form1.CmndTest.SetFocus
End Sub

Sub Text1_Change ()
    TorLim = Text1.Text
End Sub

Sub Text1_KeyPress (KeyAscii As Integer)
    If KeyAscii = 13 Then
        CmndPos.SetFocus
    End If
End Sub

Sub Text2_Change ()
    Text2.BackColor = &HFFFFFF
    ULimit = Text2.Text
```

End Sub

Sub Text2_GotFocus ()

Text2.Text = ""

End Sub

Sub Text2_KeyPress (KeyAscii As Integer)

If KeyAscii = 13 Then

Unload Form2

End If

End Sub

Sub TmrHold_Timer ()

Form1.Comm1.DataStr = "-" + Plim + Chr\$(10) + Chr\$(13)

CmndQuit.Enabled = 1

CmndAbort.Enabled = 0

CmndPos.Enabled = 1

'CmndNeg.enabled = 1

TmrHold.Enabled = 0

End Sub

Sub TmrNeg_Timer ()

On Error Resume Next

' Move motor approximately one third of a degree (11 steps):

Form1.Picture1.Cls

Form1.Comm1.DataStr = "-11" + Chr\$(10) + Chr\$(13)

' Collect and compare data:

Call GetData

If -Torque@ >= TorLim Then

TmrNeg.Enabled = False

TmrHold.Enabled = True

End If

Nlim = Nlim + 11

End Sub

Sub TmrPos_Timer ()

On Error Resume Next

' Move motor approximately one third of a degree (11 steps):

Form1.Picture1.Cls

Form1.Comm1.DataStr = "+11" + Chr\$(10) + Chr\$(13)

Plim = Plim + 11

' Collect and compare data:

Call GetData

If Torque@ >= TorLim Then

TmrPos.Enabled = False

TmrHold.Enabled = True

ULimit = Plim

End If

End Sub

Sub CmndCancel_Click ()

Unload Form3

End Sub

Sub CmndOK_Click ()

```

On Error Resume Next
If Option1(0).Value <> 0 Then selection = 0
If Option1(1).Value <> 0 Then selection = 1
If Option1(2).Value <> 0 Then selection = 2
If Option1(3).Value <> 0 Then selection = 3
If Option1(4).Value <> 0 Then selection = 4
If Option1(5).Value <> 0 Then selection = 5
If Option1(6).Value <> 0 Then selection = 6
Form1.CmndStart.Enabled = True
Unload Form3
End Sub

Sub Form_Load ()
    CmndCancel.Cancel = True
End Sub

Sub Form_Unload (Cancel As Integer)
    Form1.CmndLim.Enabled = 1
    Form1.CmndProg.Enabled = 1
    Form1.CmndDA.Enabled = 1
    Form1.TmrStart.Enabled = 1
End Sub

Sub Command1_Click ()
    Form1.Picture1.Cls
    Form1.Comm1.DataStr = Text1.Text + Chr$(10) + Chr$(13)
    Text1.Text = ""
End Sub

Sub Command2_Click ()
    Unload Form4
End Sub

Sub Command3_Click ()
    Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
    Text1.SetFocus
End Sub

Sub Form_Unload (cancel As Integer)
    Command3.cancel = True
    Form1.CmndClose.Enabled = 1
    Form1.CmndProg.Enabled = 1
    Form1.CmndLim.Enabled = 1
    Form1.CmndDA.Enabled = 1
    Form1.CmndInit.Enabled = 0
    Form1.CmndExit.Enabled = 0
End Sub

Dim DataCal@(3, 1000)           ' Calibrated data array
Dim Dta@                        ' Data calibrated with zeroing constant
Dim temp2
Dim Calib@(3)                   ' Calibration Constant
Dim N As Variant
Dim TestVel%(5)
Dim UnifVel%(5)

```

```

Dim NorVel%(5)
Dim HiVel%(5)
Dim LoVel%(5)
Dim LoVel2%(5)
Dim LoVel3%(5)
Dim LoVel4%(5)
Dim ADLimit%(5)

Sub CmndAbort_Click ()
    Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
    TmrData.Enabled = False
    CmndAbort.Enabled = False
    CmndStop.Caption = "Pause A/D"
    CmndStop.Enabled = False
    CmndStart.Enabled = True
    CmndQuit.Enabled = True
End Sub

Sub CmndQuit_Click ()
    Unload frmDataDisplay
End Sub

Sub CmndStart_Click ()
    On Error Resume Next
    temp2 = 0
    CmndStop.Enabled = True
    CmndQuit.Enabled = False
    CmndAbort.Enabled = True
    CmndAbort.SetFocus
    CmndStart.Enabled = False
    Label1.Caption = "      Test #" + N + " in progress"
    Label1.BackColor = &H80000005
    TmrData.Interval = 100
    If motor% Then•
        TmrData.Interval = 40
        Form1.Comm1.DataStr = "e7" + Chr$(10) + Chr$(13)
        Call Wait
        Form1.Comm1.DataStr = "v" + CStr(TestVel%(N - 1)) + Chr$(10) + Chr$(13)
        Call Wait
        Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
        Call Wait
        Call Wait
        Form1.Comm1.DataStr = "g0" + Chr$(10) + Chr$(13)
    End If
    TmrWait.Enabled = True
End Sub

Sub CmndStop_Click ()
    If TmrData.Enabled Then
        CmndStop.Caption = "Restart"
        TmrData.Enabled = False
    Else
        CmndStop.Caption = "Pause D/A"
        TmrData.Enabled = True
    End If

```

End Sub

Sub Form_Load ()

On Error Resume Next

CmndAbort.Cancel = True

Calib@(0) = .0062 ' Calibration multiplier for angular position

Calib@(1) = .0015857 ' Calibration multiplier for resistive torque

Calib@(2) = 1

N = 1

For n = 0 to 5

UnifVel%(n) = 990

NorVel%(n) = 330

HiVel%(n) = 660

LoVel%(n) = 165

LoVel2%(n) = 1320

LoVel3%(n) = 1650

LoVel4%(n) = 1980

Next n

Select Case selection

Case 0

For I% = 0 To 5

TestVel%(I%) = LoVel%(I%)

Next I%

Case 1

For I% = 0 To 5

TestVel%(I%) = NorVel%(I%)

Next I%

Case 2

For I% = 0 To 5

TestVel%(I%) = HiVel%(I%)

Next I%

Case 3

For I% = 0 To 5

TestVel%(I%) = UnifVel%(I%)

Next I%

Case 4

For I% = 0 To 5

TestVel%(I%) = LoVel2%(I%)

Next I%

Case 5

For I% = 0 To 5

TestVel%(I%) = LoVel3%(I%)

Next I%

Case 6

For I% = 0 To 5

TestVel%(I%) = LoVel4%(I%)

Next I%

End Select

If toggle% Then

For I% = 0 To 5

ADLimit%(I%) = (ULimit / TestVel%(I%) + 20.5) * 25

Next I%

Else

For I% = 0 To 5

ADLimit%(I%) = (ULimit / TestVel%(I%) + 4.5) * 25

```

    Next I%
End If
If (motor% = 0) Then
    For I% = 0 To 5
        ADLimit%(I%) = 100
    Next I%
End If
Form1.Comm1.DataStr = "e13" + Chr$(10) + Chr$(13)
Call Wait
Form1.Comm1.DataStr = "+" + ULimit + Chr$(10) + Chr$(13)
Call Wait
Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
Call Wait
Form1.Comm1.DataStr = "e22" + Chr$(10) + Chr$(13)
Call Wait
Form1.Comm1.DataStr = "-" + ULimit + Chr$(10) + Chr$(13)
Call Wait
Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
End Sub

Sub Form_Unload (Cancel As Integer)
    motor% = 0
    Form1.CmndClose.Enabled = 1
    Form1.CmndDA.Enabled = 1
    Form1.CmndProg.Enabled = 1
    Form1.CmndLim.Enabled = 1
    Form1.CmndClose.SetFocus
    Close 'Close all files
End Sub

Sub TmrData_Timer ()
    On Error Resume Next
    If temp2 < ADLimit%(N - 1) Then
        temp2 = temp2 + 1
    End If
    Call GetData
    For I% = 0 To NumPoints& - 1
        Dta@ = ADData%(I%) - Offset@(I%)
        ' Multilply Data by calibration constant:
        Dta@ = Dta@ * Calib@(I%)
        If motor% And I% = 1 Then
            If Dta@ >= TorLim Then
                Form1.Comm1.DataStr = Chr$(27) + Chr$(10) + Chr$(13)
                TmrData.Enabled = False
                CmndAbort.Enabled = False
                CmndStop.Caption = "Pause A/D"
                CmndStop.Enabled = False
                CmndStart.Enabled = True
                CmndQuit.Enabled = True
            End If
        End If
        ' Store the data to a 2 dimensional array in memory:
        DataCal@(I%, temp2) = Dta@
        ' Print data to screen:
        If Not motor% Then

```

```

        lblADData(I%).Caption = Format$(Dta@, "0.00")
    End If
    Next I%
Else
    ' Process EMG data and store the test data:
    For I% = 0 To 2
        Print # (I% + N + 2 * (N - 1)), "Range is: " + Ulimit + " steps"
        Print # (I% + N + 2 * (N - 1)), "Max EMG is: " + MaxEMG
    Next I%
    average@ = 0
    For J% = 0 To (temp2 - 1)
        average@ = average@ + DataCal@(2, J%)
    Next J%
    average@ = average@ / temp2
    For I% = 0 To NumPoints& - 1
        For J% = 0 To (temp2 - 1)
            If I% = 2 Then
                DataCal@(2, J%) = DataCal@(2, J%) - average@
                DataCal@(2, J%) = Abs(DataCal@(2, J%))
                DataCal@(2, J%) = DataCal@(2, J%) / MaxEMG
            End If
            Print # (I% + N + 2 * (N - 1)), DataCal@(I%, J%)
        Next J%
    Next I%
    temp2 = 0
    TmrData.Enabled = False
    CmndStop.Enabled = False
    CmndQuit.Enabled = True
    CmndAbort.Enabled = True
    TmrReturn.Enabled = True
    Label1.Caption = "    Press 'Start' to begin data collection"
    Label1.BackColor = &HFFFF&
    If motor% Then
        N = N + 1
        If N > 6 Then
            Label1.Caption = ""
            N = 6
        Else
            If N = 6 Then
                CmndQuit.SetFocus
                CmndStart.Enabled = 0
                N = 1
            End If
        End If
        Label1.Caption = "    Test velocity #" + N + " Press 'Start' to continue"
    End If
End Sub

Sub TmrReturn_Timer ()
    CmndStart.Enabled = True
    CmndStart.SetFocus
    TmrReturn.Enabled = False
End Sub

```

```
Sub TmrWait_Timer ()  
    TmrData.Enabled = True  
    TmrWait.Enabled = False  
End Sub
```

SPASTICITY MEASUREMENT STUDY

Principal Investigator: Dr. Cecil Hershler

I agree to participate in a study which is designed to test a machine to measure spasticity. At present spasticity is commonly measured manually which provides only qualitative information and which makes it difficult to record small changes. If we can measure spasticity more effectively we will have a better method for evaluating treatment and intervention for patients suffering from spasticity. This measurement of spasticity is completely harmless and painless. There are no known side effects.

I understand that the resistance to passive stretch of my ankle will be measured using the device. In conjunction with this measurement, the underlying motor unit firing pattern of the active muscle at my ankle will also be recorded. This is a passive measurement which is totally harmless and painless with no known side effects. The entire procedure would require approximately 60 minutes. The procedure for the spasticity measurement study will consist of:

- 1. Your foot will be placed in a foot pedal specially designed to hold your foot and ankle firmly in place.**
- 2. An electrode will be placed on your skin above the active muscle of your ankle.**
- 3. With you attempting to relax your ankle, the spasticity measuring device will manipulate your ankle through a range of motion within your ankle's range.**
- 4. The resistive torque to the passive stretch of your ankle will be recorded.**
- 5. The electrode will passively record the motor unit firing pattern of the muscle in your ankle. This is an indication of the underlying activity of the muscle during the procedure.**
- 6. Steps 2-5 will be repeated using different manipulation velocities and with you sitting down and lying down.**

This study is being carried out at the research laboratory of Dr. Doug Romilly in room 031 of the CICSIR building. All procedures will be carried out in collaboration with Dr. Cecil Hershler and Dr. Doug Romilly of the UBC Mechanical Engineering program.

APPENDIX D - DATA ANALYSIS CODE

The data analysis was performed using a custom made Matlab® program which fitted a least squares regression curve to the data. This code is shown below:

```
% determines the best fit of a second order differential system to a set of data
% sampling rate of data collection system
Ts=.04 ;
% load data file
load c.dat -ascii
% displacement
u=c(:,1)';
% torque
y=c(:,2)';
% plot original response
subplot(2,1,1);
plot([u;y]');
% order
order=2;
% minimum delay
delay_min=0;
% maximum delay
delay_max=0;
% least square fit
theta=ide(y,u,delay_min,delay_max,order);
% z-domain coefficients of ODE
```

```
b=[0,theta(3:4)];
a=[1,theta(1:2)];
% measure of quality of fit (the smaller the better)
J=theta(5)
% s-domain coefficients of ODE
[bc,ac]=tfd2tfc(b,a,Ts);
k=ac(1);
ac=1/k*ac;
bc=1/k*bc;
% steady state gain
K=bc(3)/ac(3)
% natural frequency
wn=sqrt(ac(3))
% damping ratio
zeta=ac(2)/2/wn
% Velocity gain
V = bc(2)
% determine fitted response
y1=filter(b,a,u);
% plot fitted and measured responses
subplot(2,1,2);
%plot([u;y/K;y1/K]');
plot([u;y/K;y1/K]');
% transfer a continuous transfer function to a discrete one
function [NUM,DEN]=tfc2tfd(num,den,Ts);
[a,b,c,d]=tf2ss(num,den);
[P,G]=c2d(a,b,Ts);
[NUM,DEN]=ss2tf(P,G,c,d,1);
% transfer a discrete transfer function to a continuous one
function [num,den]=tfd2tfc(NUM,DEN,Ts);
```

```
[a,b,c,d]=tf2ss(NUM,DEN);  
[P,G]=d2c(a,b,Ts);  
[num,den]=ss2tf(P,G,c,d,1);
```

The distance of the data from subjects with spasticity from the interface curve was determined by minimizing the distance from an unknown point on the curve to a known data point. The equation to be minimized was differentiated and set to zero. The equation was solved using the following Maple® code:

```
> y:=x^2/sqrt(x-0.73)+2.7;  
> F:=(x-zeta)^2+(y-omega)^2;  
> fd:=diff(F,x);  
> fdd:=diff(fd,x);  
> zeta:=2.4;  
> omega:=1.85;  
> z:=solve(fd,x);  
# First Solution  
> evalf(subs(x=z[1],sqrt(F)));  
> evalf(subs(x=z[1],fd));  
> evalf(subs(x=z[1],fdd));  
# Second Solution  
> evalf(subs(x=z[2],sqrt(F)));  
> evalf(subs(x=z[2],fd));  
> evalf(subs(x=z[2],fdd));  
# Possible Third Solution  
> evalf(subs(x=z[3],sqrt(F)));  
> evalf(subs(x=z[3],fd));  
> evalf(subs(x=z[3],fdd));
```

Possible Fourth Solution

> evalf(subs(x=z[4],sqrt(F)));

> evalf(subs(x=z[4],fd));

> evalf(subs(x=z[4],fdd));