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VALIDITY OF THE PENDULUM TEST TO MEASURE QUADRICEPS SPASTICITY IN CHILDREN DIAGNOSED WITH CEREBRAL PALSY

Henry Dulin White II University of Kentucky, hwhite@shrinenet.org

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ABSTRACT OF DISSERTATION

Henry Dulin White, II

The Graduate School University of Kentucky 2007

VALIDITY OF THE PENDULUM TEST TO MEASURE QUADRICEPS SPASTICITY IN CHILDREN DIAGNOSED WITH CEREBRAL PALSY

ABSTRACT OF DISSERTATION

A dissertation submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in the College of Health Sciences at the University of Kentucky

By

Henry Dulin White, II

Co-Directors: Dr. Tim Uhl, Professor of Rehabilitation Sciences, and Dr. Gilson J. Capilouto, Assistant Professor of Rehabilitation Sciences

Lexington, Kentucky

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ABSTRACT OF DISSERTATION

VALIDITY OF THE PENDULUM TEST TO MEASURE QUADRICEPS SPASTICITY IN CHILDREN DIAGNOSED WITH CEREBRAL PALSY

The stiff-knee gait pattern of children diagnosed with cerebral palsy (CP) is assumed to be caused by spasticity of the quadriceps which interferes with knee flexion normally occurring during the swing phase of walking. In current clinical practice, the ability to assess quadriceps spasticity is limited by the lack of an objective and reliable test that discriminates the role spasticity plays in functional limitations.

 The primary purpose of this series of studies was to assess the pendulum test as an objective measure of quadriceps spasticity. The first study assessed the reliability of the pendulum test. Moderate to very high between day reliability for all thirteen measures of the pendulum test were found. The second study assessed the discriminant ability of the pendulum test to correctly identify a stiff-knee gait pattern. Because most clinicians do not have access to a three dimensional motion analysis system, the third study assessed the reliability and accuracy of visual observation of the pendulum test.

Sixty-eight children with a primary diagnosis of cerebral palsy participated. A three-dimensional motion analysis system was used to measure the subjects' knee motion while walking, and performing the pendulum test. Spasticity of the quadriceps was also assessed using traditional clinical measures i.e., the modified Ashworth scale (MAS), and the Ely tests.

Forty-seven percent of the variance in the stiff-knee gait pattern was explained by a regression model using the pendulum test and traditional clinical measures. The only significant measure in the regression model was the magnitude of knee motion occurring during the first swing of the pendulum test (A1). Discriminant analysis revealed the A1 measure correctly classified 77% of the subjects' knee-gait pattern.

Four observers demonstrated moderate accuracy and repeatability in estimating A1 value. The visual assessment of A1 correctly classified 72-76% of the subjects' kneegait pattern with no prior knowledge of the subject's gait.

 This series of studies demonstrated the pendulum test is an objective, repeatable measure of quadriceps spasticity. A negative pendulum test (indicated by an A1 value greater than 45 degrees) is more useful for ruling out a stiff-knee gait pattern compared to the traditional clinical measures.

KEYWORDS: Cerebral Palsy, quadriceps muscle, spasticity, measurement, pendulum

Multimedia Elements Used: MPEG (mpg)

Henry D. White, II

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VALIDITY OF THE PENDULUM TEST TO MEASURE QUADRICEPS SPASTICITY IN CHILDREN DIAGNOSED WITH CEREBRAL PALSY

By Henry Dulin White, II

> Tim L. Uhl Co-Director of Dissertation

> Gilson J. Capilouto Co-Director of Dissertation

Jodelle F. Deem Director of Graduate Studies

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DISSERTATION

Henry Dulin White, II

The Graduate School

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This dissertation is dedicated to my mentor and benefactor, Elizabeth (Libby) Lane, PhD. Because of her interest in my well being, her support and encouragement I was motivated to demonstrate the responsibility and commitment necessary to become a physical therapist and later in life pursue this doctoral degree.

This dissertation is also dedicated to my parents for their love and support throughout my life. The work ethic and moral values they instilled in me continue to support me to this day.

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CHAPTER ONE - Spasticity and Gait

Introduction

Cerebral Palsy (CP) is a clinical syndrome characterized by some type of insult to the brain during development, birth, or in the first two years of life.¹ The incidence of Cerebral Palsy (CP) is approximately 2 children per 1000 births.² The clinical presentation of CP includes a broad spectrum of impairments of the neuromusculoskeletal system.¹ Among these impairments are decreases in motor control and increases in muscle spasticity. These impairments can result in activity limitations such as a decreased ability to walk and perform transfers safely.³ Activity limitations can result in participation restrictions in the home, school and community.

The impetus for this series of studies grew from my clinical interest in the gait pattern of children diagnosed with CP. There are many sources of information available to clinicians when diagnosing an abnormal gait pattern including: physical examination, visual analysis of the gait pattern, electromyographic data, and kinematic data generated from a three-dimensional motion analysis system. Three-dimensional motion analysis systems are designed to accurately measure human motions. Clinical measures of body structure and function impairments (range of motion, strength, and spasticity assessments) are routinely performed as part of the motion study. Ideally, if a patient demonstrates a certain gait pattern, we (physicians and therapists) hope to relate the clinical examination with the kinematic data and electromyographic data collected with three-dimensional motion analysis system in order to identify the cause of the gait abnormality. However, the expected relationships between clinical measures and gait pattern are not always present. Therefore, clinicians are required to rely on their clinical experience to decide which abnormal measures are most important in identifying the abnormal gait pattern. This series of studies was designed to improve the understanding of the relationship between different measures of quadriceps spasticity and the stiff-knee gait pattern in children diagnosed with CP.

Stiff-knee Gait Pattern

In typical human walking the knee rapidly bends and straightens when the leg is swinging in the air. The rapid knee flexion during the first half of swing, is required to prevent the foot from dragging on the ground.⁴⁻⁷ A retrospective review of three-

dimensional gait studies of 492 children with the primary diagnosis of cerebral palsy reported the stiff-knee gait pattern was the most common gait abnormality noted (present in 80% of the children). $8A$ stiff-knee gait pattern is characterized by a decreased amount of total knee motion throughout the gait cycle, a decreased magnitude and/or delay in timing of maximum knee flexion during the swing phase of the gait cycle, and inappropriate activity of the rectus femoris during the swing phase as documented by dynamic electromyography (EMG) .^{3, 9, 10} The results of these gait abnormalities can include difficulty clearing the foot during swing, resulting in a trip or fall.³ Different combinations of the previously described criteria have been reported in the literature to categorize a stiff-knee gait pattern.

A large number of published studies have collected three-dimensional gait analysis data from subjects with a stiff-knee gait pattern, before and after surgical interventions. The outcomes of these interventions have been variable for children diagnosed with CP.^{2, 10-12} This high level of variability in outcomes has lead some authors to propose that more objective criteria are needed to define the spasticity of the quadriceps to refine the decision making process for subjects with CP and other neuromuscular impairments.^{2, 6} The primary muscle group believed to be the cause of a stiff-knee gait pattern is the inappropriate activity of the rectus femoris during late stance or early swing phase $12-14$ resulting from spasticity of the quadriceps.¹³

Etiology of Muscle Spasticity

 One of the most common definitions of spasticity is " a motor disorder characterized by a velocity dependent increase in the tonic stretch reflex (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome."15 One conclusion from a European network called 'SPASM' (Support Programme for Assembly of database for Spasticity Management)¹⁶⁻¹⁸ was that this often cited definition of spasticity is too restrictive, and proposed a new definition based on research evidence. Spasticity was redefined as 'disordered sensori-motor control, resulting from an upper motor neurone lesion, presenting as intermittent or sustained involuntary activations of muscles."¹⁶

The pathophysiology that results in muscle spasticity is not known and continues to be investigated.^{19, 20} There are numerous potential mechanisms of pathophysiology for

spasticity including but not limited to: fusimotor hyperactivity, hyperexcitability of motor neurons, abnormal excitability of spinal segmental and intersegmental interneurnons from loss of supraspinal inhibitory or excitatory influences, presynaptic Ia inhibition, reciprocal inhibition, recurrent Renshaw cell inhibition and changes in muscle properties.^{19, 20} In general it is believed that changes in the previously described excitatory and inhibitory descending motor pathways from the cortical centers result in changes in the intensity of the stretch response of a muscle.¹⁹

Recent studies using an animal model for spinal cord injury-induced spasticity demonstrated that spasticity was due in part to changes at the spinal level connections between interneurons and motor neurons rather than from changes in the number of afferent inputs.^{21, 22} Results from these animal model studies suggest that increases in excitation, not decreases in inhibition, of the spinal circuitry result in increases in spasticity. The increase in spasticity presents as an increased stretch response, increased noxious stimulus response, and increased hypersensitivity. Decreases in the noxious stimulus response, stretch response and hypersensitivity were noted in rats who were administered Neurontin®, which blocks the release of Glutamate (an excitatory neurotransmitter), compared to those rats administered no mediation.²²

 For children diagnosed with CP, muscle spasticity is proposed to be due to damage to the motor cortex which results in decreased cortical input to the corticospinal tract.³ A decrease in descending input to spinal interneuron pool is proposed to result in an increased activity of the gamma and alpha motor neurons.³⁻⁵ The end result is muscle spasticity. Input to the spinal interneuron pool via the afferent nerves in the dorsal roots have a net excitatory effect on the efferent nerves output via the alpha motor neuron.⁴ Therefore when a dorsal rhizotomy is performed (cutting 50-70 % of dorsal sensory roots [L1-S2]) the result is a decrease in the excitability of alpha motor neuron and decrease in muscle spasticity.⁴

One result of muscle spasticity can be an exaggerated stretch response.¹⁹ A stretch response is the contraction of a muscle when it is lengthened. For example, a reflex hammer strikes the patellar tendon, which causes a quick stretch of the quadriceps tendon, the result is a contraction of the quadriceps.¹⁹ An exaggerated stretch response of the quadriceps during the first half of the swing phase has been proposed to cause the

stiff-knee gait pattern in children diagnosed with CP.¹⁰ However, the assumption that impairments (spasticity) cause limitations in functional activities has not been demonstrated in the literature.¹⁶ One reason the relationship between quadriceps spasticity and the stiff-knee gait pattern has not been established may be due the methods used to assess quadriceps spasticity.

Measuring spasticity

The SPASM review of clinical spasticity measures reported most clinical scales used in spasticity assessment are prone to subjectivity and the reliability and validity of many scales have not been thoroughly evaluated.17Biomechanical instrumentation techniques have the potential to provide greater reliability and precision in measuring spasticity if standardized methods are implemented.²³ Ultimately, the result could be more reliable clinical monitoring of a patient's progress and improvements in spasticity management.²³ It has been recommended that futures studies should assess spasticity with more than one method, and that correlation between clinical measures of spasticity and functional activities are needed.²⁴ One purpose of this series of studies was to assess the relationship between four clinical measures of quadriceps spasticity and the stiff-knee gait pattern of children diagnosed with CP. The four measures of quadriceps spasticity were: the modified Ashworth scale, the Ely tests (two versions), and the pendulum test.

The Modified Ashworth Scale

The Ashworth scale and modified Ashworth scale (MAS) are the most widely used clinical tests to assess muscle spasticity.¹ Consequently, new spasticity measures are typically compared to the MAS.²⁵ The MAS is a subjective measure of the resistance to passive movement across a relaxed extremity joint. The resistance perceived is reported using an ordinal scale of 0 to 4, with a 0 indicating no resistance and a 4 indicating the joint is rigid.²⁶ Poor inter-tester reliability and tendency to cluster results are two limitations of the MAS.^{20, 25} To date, only moderate repeatability (ICC[3,1] = 0.67) has been reported in assessments of quadriceps spasticity in children diagnosed with $CP²⁶$ A nonsignificant relationship between the MAS and the knee angular velocity during walking has been reported for children diagnosed with $CP²⁷$.

Ely Test

Depending on how the Ely test is performed it can be an assessment of quadriceps flexibility (if assessing knee angle and pelvic rotation) or an assessment of quadriceps spasticity (if assessing resistance with rapid passive knee flexion).^{3, 14} Marks et al. reported specificity of 67 % for the Ely test (assessment quadriceps spasticity) as a measure of time to peak knee flexion, and for the dynamic knee ROM in swing (specificity 64 %).²⁸ The authors concluded if the Ely test was positive, there was a good chance quadriceps dysfunction may exist, as evidenced by decreased knee ROM and abnormal EMG during gait. 28 Kay et al. suggested the Ely test (assessment of quadriceps flexibility) is useful in predicting surgical outcome (rectus femoris transfer) because improved timing of maximum knee flexion during swing phase of the gait cycle was noted for subjects who demonstrated a positive Ely-test pre-operatively.³ However, the reliability of the Ely test has not been reported in the literature.

Pendulum Test

In 1951, Dr. Wartenberg described a simple clinical test for quantifying lower limb hypertonia in Parkinson's disease.²⁹ During the pendulum test, the lower leg was allowed to fall freely from a fully extended position.³⁰ The knee motion demonstrated was damped by the viscoelastic properties of the limb. This damping was dramatically altered in the spastic limb.^{29, 30} From this simple test, numerous measures have been calculated and reported as measures of quadriceps spasticity.³¹ Results of the pendulum test have been reported in the literature for over 50 years for subjects with different upper motor neuron impairments (multiple sclerosis, 3^2 status post cerebral vascular accidents, 3^3 status post spinal cord injuries, 31 and cerebral palsy (34) ; yet, the pendulum test is not routinely used clinically. This is likely because the pendulum test requires knee motions to be quantitatively measured using electrogoniemeters, 31 two-dimensional video analysis,³⁵ magnetic tracking system³⁶or a three-dimensional motion analysis system.³⁷ Because of the cost and time required to instrument a subject, these quantitative tools are not routinely used by most clinicians. To date, the relationship between the pendulum test (a measure of quadriceps spasticity) and the stiff-knee gait pattern (proposed to be caused by quadriceps spasticity) has not been reported. Potentially, the pendulum test is a more objective, reliable, and sensitive measure of quadriceps spasticity compared to the MAS

 $\overline{5}$

and Ely tests. If a significant relationship between the pendulum test and the stiff-knee gait pattern in children diagnosed with CP is found, then eventual improvements in the assessment process of the stiff-knee gait pattern for children diagnosed with CP could occur.

Purpose

The primary purpose of this series of studies was to investigate the pendulum test as a measure of quadriceps spasticity to identify the stiff-knee gait pattern in children diagnosed with CP. The secondary purpose was to investigate the repeatability of the pendulum test. The tertiary purpose was to assess the accuracy and repeatability of observers' visual estimate of the knee motion occurring during the pendulum test. This series of studies was designed to answer the following questions:

- 1. Is the pendulum test, measured with a three-dimensional motion analysis system, a reliable measure of quadriceps spasticity for children diagnosed with CP?
- 2. Are the values for the pendulum test for children diagnosed with CP significantly different from the values for able-bodied children?
- 3. Do the clinical measures of quadriceps spasticity (MAS, Ely tests, pendulum test) correlate with the gait pattern measured with a three-dimensional motion analysis system?
- 4. What combination of the spasticity measures (MAS, Ely tests, pendulum test) discriminate between a stiff-knee and a not-stiff-knee gait pattern as measured by a three-dimensional motion analysis system?
- 5. Can visual analysis of pendulum test accurately estimate the knee motion occurring during the pendulum test?
- 6. What is the inter-rater reliability of visual analysis of the pendulum test?
- 7. Can results from visual analysis of the pendulum test discriminate between a stiffknee and a not-stiff-knee gait pattern as measured by a three-dimensional motion analysis system for children diagnosed with CP?

Overview

Information specific to each question will be presented in the following sequence. The information in chapter 2 describes the repeatability of the pendulum test, and the ability of the pendulum test to differentiate between able-bodied children and children

diagnosed with CP. Chapter 3 data examines the relationship between clinical measures of spasticity and the knee-gait pattern by using regression and discriminant analysis statistics. Chapter 4 was designed to provide an assessment of the accuracy, repeatability and discriminatory ability of a visual analysis of pendulum test and chapter 5 provides a summary of all aspects of this series of studies.

Operational Definitions

Stiff-knee gait

For this series of studies a child will be classified as having a stiff-knee gait pattern if he/she demonstrates at least four of the six following characteristics of a stiffknee gait pattern:

- 1. A delay in timing of maximum knee flexion in swing phase. This is defined as two or more standard deviations above the normal value (as a percent of the swing phase of the gait cycle). 38
- 2. A diminished magnitude of knee flexion during swing phase of gait. This is defined as two or more standard deviations below the average normal value of maximum knee flexion occurring during swing phase.³⁸
- 3. Diminished total knee motion, defined as two or more standard deviations below the average normal value of total sagittal plane knee motion occurring throughout the gait cycle.³⁸
- 4. Diminished knee angular velocity, defined by two or more standard deviations below the average normal value of knee angular velocity at toe-off.³⁸
- 5. Impaired foot clearance is considered present if the toe/foot is noted to drag on the ground (based on visual observation) during the swing phase of the gait cycle.
- 6. Inappropriate quadriceps activity during the swing phase of the gait cycle.³⁹

Subject Inclusion Criteria

For this series of studies, subjects were recruited from children referred to the Lexington Shriners Hospital for Children's motion analysis laboratory for a clinical gait analysis study. Only subjects with the primary diagnosis of cerebral palsy, spastic diplegia, or hemiplegia were included. The subjects were to be between the ages of 8

years to 21 years and classified as a level I, II, III or IV of the Gross Motor Function Classification System (GMFCS).40

Subject Exclusion Criteria

Subjects were excluded from participation if they had undergone: 1) orthopaedic surgery in the past twelve months to the lower extremities, 2) Botox® injections in the past 6 months to the lower extremities, or 3) a rectus femoris transfer surgery.

Kinematic and Electromyographic Data for Walking (Three-dimensional gait analysis)

Surface reflective markers and surface electrodes were placed on each of the subject's legs following the standard gait analysis protocol.⁴¹ The surface reflective markers are used to measure the movement of the subject's arms and legs when walking and when performing the pendulum test. Using the Motion Analysis Corporation Real Time System (EVaRT 4.4.4) and with eight Eagle digital cameras, a video was recorded showing only the markers on the subject's body (Figure1.1). This video can be replayed to observe the subject's movements when walking and performing the pendulum test. OrthoTrak 6.24 software was used for precise measurements of the leg movements occurring while walking and while performing the pendulum test. After placement of the surface electrodes and surface reflective markers, each individual was allowed a period of time (up to 5 minutes) to become comfortable walking while wearing the testing apparatus. Each individual walked several times along a 30'walkway in the motion laboratory for data collection (a minimum of three strides of data was collected). The subject then participated in the pendulum test.

The Pendulum Test

For this test, each subject was positioned laying comfortably on his/her back on a large bench. The examiner then positioned the subject's leg in maximum knee extension. To control the starting position of the test the distance from the heel of the foot to the floor was measured for the first trial, and the same distance was used for all trials. Prior to each trial, the subject was instructed to let the leg swing freely once it was released by the examiner. One to three practice trials were performed prior to data collection. Data collection with the motion analysis system was initiated approximately one second before the examiner released the subject's foot. After the subject's leg came to rest, at least

thirty seconds passed before the next trial was performed (to prevent reflex inhibition of the quadriceps). During data collection, the test was repeated if excessive quadriceps activity was noted or if it appeared to the examiner the subject was assisting or resisting the knee motions. The procedures were repeated until three trials (without interference) of each leg were obtained for each subject. The surface EMG and reflective markers were then removed, and the subject then participated in standard physical examination including assessment of quadriceps spasticity using the MAS and Ely tests.

Assumptions

The assumptions made for this series of studies were:

- 1. Each subject would demonstrate his/her typical walking pattern.
- 2. Control subjects do not have orthopaedic or neurological impairments.
- 3. Subjects have been previously diagnosed with cerebral palsy, spastic diplegia or hemiplegia.

4. Subjects did not assist or resist the knee motions occurring during the pendulum test. Limitations

The following were limiting factors of this series of studies:

- 1. Subjects were a convenience but representative sample of patients seen by the facility.
- 2. Each subject may not have demonstrated his/her typical walking pattern.
- 3. Subject may have assisted or resisted the knee motion during the pendulum test and it was not detected during data collection.
- 4. The primary investigator was not blinded to data collection or analyses.
- 5. Observers of the pendulum test using the EVaRT video may have observed each trial in a manner different from the instructions provided.
- 6. The subject selection was biased toward subjects who could correctly follow the instructions provided by the examiner.

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Figure 1.1 Sagittal view of 'Stick person' at the beginning of the pendulum test generated from EVaRT software video. The subject's left knee is straight and he is lying on his back. The cluster within the box represents the subject's left foot and shank. The clusters within the circle represent the subject's knee and thighs. The clusters on the right represent the subject's pelvis, trunk and arms.

CHAPTER TWO - Reliability of the three-dimensional pendulum test for able-bodied children and children diagnosed with cerebral palsy

Introduction

Children with the primary diagnosis of cerebral palsy (CP) often present with gross motor limitations resulting in decreased ability to walk and transfer.³⁶ Increased tone/spasticity of the rectus femoris, hamstrings and gastrocsoleus muscle groups are often associated with causing impaired walking and transfer abilities for children diagnosed with CP.^{34, 36, 42} Numerous potential interventions can be used to treat spasticity in children with CP. Determining the appropriate intervention and its effectiveness requires an objective, repeatable assessment of the spasticity impairment. Spasticity of the rectus femoris has been proposed as one potential cause for a stiff knee gait pattern (decreased knee flexion during swing) for children diagnosed with cerebral palsy.43 This stiff knee gait pattern can result in a child tripping/falling when walking. Currently, a clinical test that is standardized, objective and repeatable to assess quadriceps spasticity is not used routinely.

The modified Ashworth scale is often used clinically and in research to assess spasticity, however it is only performed at a single speed.⁴⁴ It is an ordinal scale based on subjective evaluation of passive resistance perceived by the examiner and to date neither the reliability nor validity of the MAS has been reported in children with $CP⁴²$ The MAS may not be sensitive enough to detect small changes in spasticity.^{25, 44}

In 1951 Dr. Robert Wartenberg, published "Pendulousness of the Legs as a Diagnostic Test".²⁹ The pendulum test was performed on subjects sitting with both knees passively placed in full extension. The subject was instructed not to assist or to resist the swinging knee motions. The subject's legs were quickly pushed backwards and then allowed to swing freely. If no upper motor neuron involvement was present; the knee would demonstrate six or seven oscillations of flexion and extension; each oscillation demonstrating a smaller arc of motion. A sign of upper motor neuron involvement was reported to be a decrease in the length of time the knee would swing, or a decrease in the number of knee oscillations occurring during the test. A prolonged swinging of the knee would indicate a sign of lower motor neuron involvement. Wartenberg reported one

limitation of the pendulum test involved getting the subjects to completely relax so not to affect the knee motions observed.

Since Wartenberg's publication, different versions of the pendulum test have been reported in the literature. The knee motions occurring during the pendulum test have been quantitatively measured using electrogoniometers, $31 \text{ two-dimensional video analysis}$, 35 s magnetic tracking system,³⁶ and three-dimensional motion analysis system.³⁷ The main focus of these three studies was to present the methodology of measuring the knee motions using each technology. $31, 35, 37$

Two studies have reported on the repeatability of the pendulum test for ablebodied subjects.^{42, 45} In a test-retest (7-14 days apart) reliability of the pendulum test performed on able-bodied children 3-8 years old reported coefficient of variance ranging from 3 % to 47 % for variables calculated from the pendulum test.⁴² An inter-day reliability study on able bodied adults revealed a large range in reliability with ICC ranging from $0.08 - 0.88$ on 10 variables recorded using an electrogoniometer.⁴⁵ To date, no studies have reported the test-retest reliability of the pendulum test for subjects diagnosed with CP.

If spasticity is a velocity-dependent resistance to passive motion, then the maximum knee angular velocity during the pendulum test could be considered a measure of quadriceps spasticity. A number studies have assessed the changes in the pendulum variables after spasticity reducing interventions such as medications, 46 anesthesia, 36 and rhizotomy.42 Six months after undergoing selective dorsal rhizotomy, the mean maximum knee angular velocity during the pendulum test was significantly increased postoperatively from preoperative values in subjects diagnosed with CP.⁴² Nance et al. assessed the affects of Tizanidine, a spasticity reducing medication that binds at the spinal and supraspinal levels, on quadriceps spasticity of 78 subjects with spinal cord injuries.47 One of the reported results of the study was the subjects treated with Tizanidine demonstrated more normal pendulum results.⁴⁷

If muscle tone is the muscle's resistance to passive stretch representing the mechanical-elastic characteristic of the muscle, then the different ratios calculated from the magnitude of the first swing of the pendulum test and the resting angle of the knee following the pendulum test could be considered measures of quadriceps tone. Three

ratios are calculated from the pendulum test. These ratios are based on the amount of knee motion occurring during the first swing and the resting angle of the knee at the end of the pendulum test. Nordmark and Anderson report an increase in these ratios for subjects diagnosed with CP after undergoing rhizotomy.⁴² Nance et al. reported an increase first swing excursion in subjects with spinal cord injuries treated with Tizanidine, and no change for subjects treated with placebos.⁴⁷ Another study reported a similar response for patients diagnosed with multiple sclerosis treated with Tizanidine.⁴⁵ Fee and Miller compared the results of the pendulum test of eight able-bodied children and ten children with a primary diagnosis of cerebral palsy awake and under anesthesia.³⁶ The phase plane plots of subjects with CP when awake were abnormal. Under anesthesia, the phase plane plots of the subjects diagnosed with CP were almost identical to the ablebodied subject's phase plane plot.³⁶ However, because differences in the pendulum test were noted awake and under anesthesia for both groups, the author's concluded the pendulum test is a measure of an active component of spasticity (reflex), chronic changes in musculotendonous tissues, and the 'rest state' of muscle tone.

A reliability study examining the multiple variables calculated from the pendulum test is needed before the pendulum test can be used as a clinical measure of quadriceps spasticity to: determine the effectiveness of interventions, or discriminate different levels of spasticity of children diagnosed with CP. Therefore, the primary purpose of this study was to assess the test-retest reliability of thirteen kinematic variables calculated from the pendulum test in able-bodied children compared to those of children diagnosed with cerebral palsy with at least a one-month interval between assessments. The second purpose of this study was to determine if the variables calculated are different between able-bodied children and children diagnosed with CP.

Materials and methods

Participants

All procedures were approved by the institutional review boards. After obtaining informed consent a convenience sample of 10 healthy children and 10 children with a primary diagnosis of cerebral palsy (CP) spastic diplegia participated in the study. The mean age of the able-bodied children was 14 years $(+/- 2.2)$ and 12 years $(+/- 2.4)$ of the children diagnosed with CP. The mean height was 160.7cm (+/- 13.7) for the able-

bodied children and 143.4 cm (+/-16.4) for the children diagnosed with CP. Data were collected on two separate occasions; the average length of time between testing was 73 days (+/- 28 days) for the able-bodied subjects and 72 days (+/- 27 days) for the subjects diagnosed with CP. The Gross Motor Function Classification System, (GMFCS) is a classification system for children diagnosed with CP based on self-initiated movements. Five of the children were a GMFCS Level I, four of the children were a Level II and one subject was classified as a GMFCS level III. For subjects diagnosed with CP the Modified Ashworth scores for quadriceps tone were 0s for both legs of 8 subjects. One subject demonstrated 1 MAS for one leg and 0 MAS for the other. The other subject demonstrated 2 MAS for one leg, and 0 MAS for the other leg.

Data processing and data analysis

 Kinematic data were collected at 60 Hz for 15 seconds using a Motion Analysis Corporation Real Time System (EVaRT 4.4.4) with eight Eagle digital cameras. OrthoTrak 6.24 software was used to reduce and plot kinematic data (Motion Analysis Corporation, Santa Rosa, CA). The raw data were filtered using a Butterworth filter at 6 Hz. Electromyographic data were collected at 1000 Hz using Noraxon's TeleMyo 900 system **(**Noraxon U.S.A. Inc., Scottsdale, AZ) with surface silver-silver chloride electrodes (ConMed Corporation, Utica, NY). Study variables derived from the measured knee motions were calculated in Microsoft Excel. The average and standard deviation of the knee angle for the first 10 frames of data were defined as movement baseline. Movement onset and offset were defined as more than one standard deviation above this average knee angle. When calculated, the average movement onset/offset was 0.5 degrees change in the knee angle in $1/60th$ of a second.

Because the subject lies supine to perform the pendulum test, the Cleveland clinic marker set was modified so the OrthoTrak software could be used to calculate the knee motions during the pendulum test. The "ASIS markers" were placed on the mid-point of iliac crest directly above the greater trochanter. The "PSIS marker" was placed over the umbilicus. The thigh marker triads were decreased in size to 8 cm in length and width to minimize interference of the mat with the triad, and were held in place with Co-flex®. The remaining markers were placed using the standard Cleveland Clinic protocol.

Surface electromyography of the vastus medialis oblique, rectus femoris and the semitendinosus were collected to confirmed that the muscles were not active prior to the test. To assist the subject in relaxing his/her muscles the electromyography system was connected to a speaker to provide audio feedback of the muscle activity. The trial was initiated when no audio feedback (representing quadriceps activity) was subjectively heard by examiner and subject.

Each subject was positioned lying comfortably on a bench (seat to floor height 30 inches) so the posterior calf did not contact the bench when the knee was in maximum flexion. This was performed to ensure that the mat did not impede maximum knee flexion. To allow for consistent positioning of each subject, the distance from the popliteal fossa to the edge of the mat was measured and used for both data collection days. If excessive hip rotation was noted during the practice trials, a small towel was placed under the distal third of the femur to decrease hip rotation. The examiner positioned the subject's leg in maximum knee extension. To control the starting position of the test, the distance from the heel of the foot to the floor was measured for the first trial, and the same was used for all trials on both data collection days. Prior to each trial, the subject was instructed to let the leg swing freely once it is released by the examiner. One to three practice trials were performed prior to data collection. Data collection with the motion analysis system was initiated approximately one second before the examiner released the subject's foot. After the subject's leg came to rest, at least thirty seconds passed before the next trial was performed. During data collection, the test was repeated if it appeared to the examiner the subject was assisting or resisting the knee motions. The procedures were repeated until three trials (without interference) of each leg were obtained for each subject. At least 4 weeks later the subjects returned for a repeat study. The order for data collection (right leg versus left) was randomized.

Data Reduction

The variables calculated from the knee kinematic data during the pendulum test can be subdivided into three groups based on: the knee angular velocity, the knee oscillations, and the magnitude of knee motions in each plane. The following variables were calculated from the knee motions measured (Figure 2.1):

Knee angular velocity variables

Maximum knee flexion angular velocity (degrees/sec) – The maximum knee flexion angular velocity occurring.⁴²

Time to knee flexion angular velocity (sec) – The amount of time from initiation of movement to maximum knee angular velocity.³⁷

Knee Oscillations variables

Number of Oscillations – The number of complete sine waves produced by the swinging \log^{31}

Duration of oscillations (seconds) - The duration of time from the onset of knee flexion until the cessation of knee movement. 30

Oscillation frequency (Hz) - The number of oscillations (from one peak of knee flexion to the next peak of knee flexion) per second. 37

Magnitude of knee motion variables

AO **-** The knee angle difference measured from the pre-release position to the final resting position. 31

A1 **-** The maximal knee angle difference measured during the first swing from the prerelease position. 31

A2 **-** The number of degrees difference between the first maximum knee flexion angle and the first minimum knee flexion angle. 31

 $R_1 = A_1 / (A_1 - A_2)^{31}$

R2 (relaxation index) = A_1/A_0^{31}

R2n (Normalized relaxation index) = $A1 / 1.6A₀$.³¹

Previous study reported for able-bodied subjects, R2 was 1.6 or more. Therefore by dividing the R2 ratio by 1.6 would result in a quantification of spasticity, R2N. A limb with spasticity would have a R2N value of less than one, and a limb without quadriceps spasticity would have an R2N value greater than one.³¹

If the knee does not demonstrate oscillations, then the calculations from the previous described ratios (R1, R2, etc) may not be meaningful, therefore the integrals were calculated. The integrals of sagittal, frontal, and rotational plane motions (deg*sec) are defined as the area under the kinematic curve of in each plane as a sum of degrees of knee motion by time component. 37

SPSS software version 13.0 was used to perform statistical analysis. A one-way ANOVA based intra class correlation coefficients (ICC) with day 1 and day 2 was used to assess the between days reliability of the pendulum test variables. Because only one examiner performed the test with each subject; a one-way mixed model ANOVA of absolute agreement was used. The ICC is an estimate of a measure's reliability, but it does not provide information regarding the precision of a measurement. Therefore, the 95 % confidence interval of the mean was also calculated to provide an estimate of the precision of each variable reported.⁴⁸ The intra class correlation coefficient mixes random and systematic error, therefore the 95 % limits of agreement was calculated for each variable (Tables 2.1 & 2.2). This is reported to be a measure of sampling error.⁴⁹ Because of the small sample size, nonparametric t-tests (Wilcoxon W) were used to compare the means of the variables between the two groups.

Results

Nonparametric t-test revealed no statistical difference between the right and left legs of the able-bodied children for all variables. However, the duration of oscillations and number of oscillations were statistically different between the right and left of the children diagnosed with CP ($p < .05$). Therefore, the results of each lower extremity are presented separately in Tables 2.3 and 2.4. For clarity, the results of the right lower extremity are described in the result section.

Knee angular velocity variables

The maximum knee flexion angular velocity was significantly less in children with CP (202 deg/sec) compared to able-bodied children (293 deg/sec) ($p<.01$). The time to maximum knee flexion angular velocity was significantly less in children with CP (0.23 sec) compared to able-bodied children (0.34 sec) (p<.01). The time to maximum knee angular velocity for both groups of subjects (able-bodied and CP) demonstrated moderate ICC scores (0.60 for subjects with CP; ICC 0.72 for able-bodied subjects) (2.3 $& 2.4.$

Knee oscillations variables

On average, subjects diagnosed with CP demonstrated two fewer oscillations compared to the able-bodied subjects $(p<.01)$. The number of knee oscillations demonstrated high to very high reliability (0.85 for subjects with CP; 0.93 for able-

bodied subjects). The duration of time for knee oscillations was almost half as long for subjects diagnosed with CP (2.60 sec) compared to the able-bodied subjects (6.60 sec) (p< .001), with very high reliability (0.94 for subjects with CP; 0.97 for able-bodied subjects). The oscillations frequency was defined as the amount of time between each peak knee flexion. Subjects diagnosed with CP demonstrated larger oscillation frequency (1.89 Hz) compared to the able-bodied subjects (1.05 Hz) (p<.001). Oscillations frequencies demonstrated high and very high repeatability with 0.88 for subjects with CP, and 0.94 for able-bodied subjects.

Magnitude of knee motion variables

The remaining variables were calculated from the knee motions occurring during the pendulum test (Figure 2.1). The majority of these variables (A1, R1, R2 and R2n) are based on the amount of knee flexion that occurred during the first oscillation of the pendulum test. For the children diagnosed with CP these variables were all significantly smaller compared to those of able-bodied children $(p<.001)$. The between day ICC scores for these five variables were high to very high for the children diagnosed with CP (0.88 to 0.97) and for the able-bodied children (0.89 to 0.97). The variable A0 (starting angle minus resting angle) was significantly less for children with CP compared to able-bodied children $(p<.01)$.

For both groups (able-bodied and CP) the largest integrals (85 deg*sec for ablebodied subjects; 25 deg*sec for subjects diagnosed with CP) were in the sagittal plane (knee flexion/extension). The smallest integrals (12 deg*sec for able-bodied subjects; 6 deg*sec for subjects diagnosed with CP) were in the transverse plane (knee rotation). In the frontal plane, the able-bodied children demonstrated integrals significantly larger than the subjects diagnosed with CP (25 deg*sec versus 8 deg*sec; $p < 01$). The between day ICC scores for the integrals were high to very high ranged from for the children diagnosed with CP (0.85 to 0.98) and for the able-bodied children (0.79 to 0.96).

Modified Ashworth score

The modified Ashworth scale was not obtained for one of the ten subjects on the second data collection session. For the nine subjects with diagnosed with CP, the modified Ashworth scale demonstrated high reliability for the right leg (ICC 0.78) and low reliability for the left leg (ICC 0.29).

Discussion

The purpose of this study was to examine the reliability of the pendulum test in able-bodied children and children diagnosed with CP. The data demonstrate high to very high between day test-retest reliability of the thirteen variables calculated from the pendulum test in able-bodied children and children diagnosed with cerebral palsy. The pendulum test has been shown to be a quantifiable measure of quadriceps spasticity, as evident by a more normal pendulum motion in subjects with upper motor neuron disorders after undergoing spasticity reducing interventions.^{36, 42, 46, 47}

Only one previously published study has reported the inter day repeatability of the pendulum test over time in subjects with a upper motor neuron impairment (following a cerebral vascular event).⁵⁰ The intra-subject variability (using the coefficient of variance) was reported to range from 1 to 31.5 % for the R2n variable (A1/1.6A0). In regards to the variability between sequential testing sessions the authors reported: "we failed to demonstrate significant variations between values obtained" ($p.343-344$).⁵⁰ Unfortunately no other statistical correlations or analysis were provided. In comparison, for our subjects diagnosed with CP, the between day coefficient of variance for the R2n ratio range was 24 % for the right leg and 28 % for the left leg. For the able bodied subjects the coefficient of variance for the R2n ratio was 7 % for the left leg and 8 % for the right.

Because of the small sample size and small variance, the time to peak angular velocity was the only variable not to demonstrate high repeatability. For the right leg the ICC was 0.60 for children with CP and 0.72 for able-bodied children. For the left leg the time to peak angular velocity demonstrated an ICC of 0.90 for children with CP. The interclass correlation coefficient is a ratio of the variance of a measurement over the sum of the variance and error of the measurement; because the variance was 0.00 for the ablebodied subjects the ICC could not be calculated, resulting in the ICC reported of -0.06. However, a nonparametric t-test for the time to peak angular velocity was not statistically significantly different between the right and left leg for both groups of subjects ($p>0.05$). The increased variability for the children diagnosed with CP may be due to variability within the subjects. Considering the time to peak angular velocity was 0.34 sec for ablebodied children and 0.23 seconds for children diagnosed with CP; a larger sample size may better assess the repeatability of this variable calculated from the pendulum test.
Able-bodied subjects demonstrated a decreasing magnitude of knee motion with each oscillation. For the children with CP, some of the children demonstrated knee oscillations of decreasing magnitude (Figure 2.2) and others did not demonstrate any knee oscillations (Figure 2.3). Previous authors have suggested that an integral of the sagittal plane knee motions may be a more sensitive measure.³¹ This is because the sagittal plane integral of knee motion is not dependent on the knee demonstrating decreasing magnitude of oscillations. The sagittal plane integral for children diagnosed with CP was one third as large as the sagittal integral for the able-bodied children. For both groups, the sagittal plane integral demonstrated high repeatability. Therefore the sagittal plane integral may be a better variable to measure knee motion than previously reported ratios (R1, R2n, and R2) which are dependent on multiple oscillations.

Previous literature reported that motions other than knee flexion/extension may be an indicator of spasticity, however these studies used visual or two dimensional assessments of knee motion.^{29-31, 45} By using a three dimensional motion analysis system, the knee motions in all three planes (sagittal, frontal and transverse) were measured. For all subjects, the sagittal plane integrals were three and seven times greater than the frontal and transverse plane integrals, respectively. Because of the relatively small magnitude of frontal and transverse plane motions, three-dimensional motion analysis may not be required to perform the pendulum test, and using an electrogoniometer may be an acceptable alternative.

The clinician performing data collection in this study has 11 years experience using the modified Ashworth scale and 10 years experience applying the motion analysis system markers. The large variability in repeatability of the modified Ashworth scale (ICC 0.78 right leg and ICC 0.29 left leg) is a limitation of the Ashworth scale which has been previously alluded to by Nordmark $\&$ Anderson.⁴² For the ten children diagnosed with CP, 17 of the 20 limbs on the first visit of and 14 of the 18 limbs on the second visit were graded a zero, no increase in tone, using the modified Ashworth scale. The relatively high reliability of the pendulum test illustrates the sensitivity differences in these two measures. The results of this study suggest that the pendulum test provides an objective and reproducible measure of quadriceps spasticity in children diagnosed with

CP; however future studies to assess if the pendulum test can discriminate different levels of spasticity are needed.

One limitation of the pendulum test is that the amount of influence due to muscle spasticity, tone and/or changes in musculotendonous tissues can not be differentiated clinically. Because of the large number of variables that have been calculated from the pendulum test future studies to decrease the number of variables calculated from the pendulum test would be beneficial. I propose the maximum angular knee velocity and the time to maximum angular knee velocity variables could be used as measures of the active component of quadriceps spasticity. The AO variable (resting knee angle – start knee angle) could be used as a measure to assess the resting state of quadriceps tone and quadriceps tightness due to the chronic changes in the quadriceps musculotendonous tissues. The sagittal integral calculated could be used as a measure of overall quadriceps interference due to spasticity, tone and tightness of the quadriceps.

From the findings of this study I believe implementing the pendulum test (using motion analysis or an electrogoniometer) to better objectively quantify quadriceps spasticity in clinical care and future research assessing quadriceps spasticity is warranted. Future studies to assess the relationship between quadriceps spasticity (measured with the pendulum test) to functional measures of mobility (GMFM, walking velocity, and knee kinematic data) are also needed.

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AB-able-bodied subjects

CP- subjects diagnosed with CP

Table 2.1 (Continued)

AB-able-bodied subjects CP- subjects diagnosed with CP

AB- able-bodied subjects

CP- subjects diagnosed with CP

Table 2.2 (Continued)

Variables (left leg)	Mean	Standard	95 %	95%	95 % Confidence		95 % Confidence	
	Difference	Deviation	Lower	Upper	Interval for the		Interval for the	
		of Mean	Limits of	Limits of		Lower Limit of	Upper Limit of	
		Difference	Agreement	Agreement		Agreement		Agreement
Transverse plane integral (deg*sec) AB	-2.01	7.35	-16.42	12.40	-39.82	-21.83	17.82	35.80
Transverse plane integral (deg*sec) CP	-2.01	3.65	-9.18	5.15	-20.81	-11.87	7.84	16.78
Frontal plane integral (deg*sec) AB	-9.04	11.95	-32.46	14.39	-70.51	-41.27	23.20	52.43
Frontal plane integral (deg*sec) CP	-2.53	5.48	-13.26	8.21	-30.69	-17.29	12.24	25.64
A0 [rest knee angle-start knee angle] (deg) AB	0.00	2.99	-5.85	5.86	-15.36	-8.05	8.06	15.37
A0 [rest knee angle-start knee angle] (deg) CP	-4.23	6.79	-17.54	9.08	-39.16	-22.54	14.08	30.70
A1 [max knee angle $-$ start knee angle] (deg) AB	-1.40	5.41	-12.01	9.21	-29.24	-16.00	13.20	26.45
A1 [max knee angle – start knee angle] (deg) CP	-9.49	19.42	-47.56	28.58	-109.40	-61.88	42.90	90.42
R1 [relaxation index] AB	-0.62	0.97	-2.52	1.28	-5.60	-3.23	1.99	4.36
R1 [relaxation index] CP	-0.46	0.59	-1.62	0.71	-3.51	-2.06	1.15	2.60
$R2$ [A1/A0] AB	-0.02	0.09	-0.20	0.15	-0.48	-0.27	0.22	0.43
$R2$ [A1/A0] CP	-0.07	0.29	-0.63	0.49	-1.55	-0.85	0.70	1.41
R2n $[A1/(1.6*A0)]$ AB	-0.02	0.06	-0.12	0.09	-0.30	-0.16	0.13	0.27
R2n [A1/ $(1.6*A0)$] CP	-0.04	0.16	-0.34	0.26	-0.84	-0.46	0.38	0.76

AB- able-bodied subjects

CP- subjects diagnosed with CP

Table 2.3 Variables calculated from the pendulum test

AB- able-bodied subjects *** significant difference (p< .001) between CP and able-bodied subjects

CP- subjects diagnosed with CP $*$ significant difference $(p<.01)$ between CP and able-bodied subjects

Table 2.3 (Continued)

Variables (right leg)	Mean	Standard Deviation	ICC	95 % Confidence Interval for Mean		
				Lower Limit	Upper Limit	
Transverse plane integral (deg*sec) AB	$12.25*$	7.69	.79	6.75	17.74	
Transverse plane integral (deg*sec) CP	5.75	3.75	.92	3.06	8.43	
Frontal plane integral (deg*sec) AB	24.95*	9.55	.94	18.12	31.78	
Frontal plane integral (deg*sec) CP	8.39	9.54	.98	1.56	15.21	
A0 [rest knee angle-start knee angle] (deg) AB	$61.14*$	5.56	.95	57.16	65.12	
A0 [rest knee angle-start knee angle] (deg) CP	44.00	12.72	.97	34.91	53.10	
A1 [max knee angle – start knee angle] (deg) AB	$105.14**$	10.33	.96	97.75	112.53	
A1 [max knee angle – start knee angle] (deg) CP	49.78	25.58	.96	31.49	68.08	
R1 [relaxation index] AB	$4.16*$	0.95	.91	3.48	4.84	
R1 [relaxation index] CP	1.93	0.77	.92	1.38	2.48	
$R2$ [A1/A0] AB	$1.73*$	0.14	.92	1.62	1.83	
$R2$ [A1/A0] CP	1.08	0.31	.92	0.86	1.30	
R2n $[A1/(1.6*A0)]$ AB	$1.08*$	0.09	.93	1.02	1.14	
R2n [A1/ $(1.6*A0)$] CP	0.68	0.19	.92	0.54	0.81	

AB- able-bodied subjects *** significant difference (p< .001) between CP and able-bodied subjects

CP- subjects diagnosed with CP \bullet * significant difference (p<.01) between CP and able-bodied subjects

Table 2.4 Variables calculated from the pendulum test

AB- able-bodied subjects *** significant difference (p< .001) between CP and able-bodied subjects

CP- subjects diagnosed with CP $*$ significant difference $(p<.01)$ between CP and able-bodied subjects

Table 2.4 (Continued)

Variables (left leg)	Mean	Standard Deviation	ICC		95 % Confidence Interval for Mean
				Lower Limit	Upper Limit
Transverse plane integral (deg*sec) AB	$11.40*$	6.20	.92	6.96	15.84
Transverse plane integral (deg*sec) CP	5.50	3.00	.85	3.36	7.65
Frontal plane integral (deg*sec) AB	25.46*	10.54		17.93	33.00
Frontal plane integral (deg*sec) CP	9.94	9.26	.96	3.31	16.57
A0 [rest knee angle-start knee angle] (deg) AB	$61.35*$	5.55	.97	57.38	65.32
A0 [rest knee angle-start knee angle] (deg) CP	46.53	13.60	.97	36.80	56.26
A1 [max knee angle – start knee angle] (deg) AB	104.98**	11.49	.97	96.76	113.20
A1 [max knee angle – start knee angle] (deg) CP	52.42	24.76	.96	34.70	70.13
R1 [relaxation index] AB	$4.15*$	0.94	.89	3.47	4.83
R1 [relaxation index] CP	1.78	0.61	.88	1.34	2.21
$R2$ [A1/A0] AB	$1.71*$	0.12	.92	1.63	1.80
$R2$ [A1/A0] CP	1.05	0.30	.93	0.84	1.27
R2n $[A1/(1.6*A0)]$ AB	$1.07*$	0.08	.92	1.02	1.12
R2n [A1/ $(1.6*A0)$] CP	0.68	0.16	.93	0.56	0.79

AB- able-bodied subjects *** significant difference (p< .001) between CP and able-bodied subjects

CP- subjects diagnosed with CP \bullet * significant difference (p<.01) between CP and able-bodied subjects

Figure 2.2 Kinematic data of a subject's knee which demonstrates oscillations of decreasing magnitude

Figure 2.3 Kinematic data of a subject's knee which does not demonstrates oscillations of decreasing magnitude

CHAPTER THREE - An objective measurement of quadriceps spasticity to identify the stiff-knee gait pattern of children diagnosed with CP

Introduction

The clinical presentation of cerebral palsy (CP) includes a broad spectrum of motor impairments of the neuromusculoskeletal systems such as joint contractures, decreased motor control and muscle spasticity.¹ These impairments often result in activity limitations such as decreased ability to perform transfers, or walk and poor balance leading to participation restrictions in a child's home, school and community.³ A series of review articles published in 2005 as part of a European network called 'SPASM' (Support Programme for Assembly of database for Spasticity Management) concluded that links between spasticity and other impairments (contractures) with limitation in activity and restrictions in participation need to be demonstrated in future research.^{16-18, 23} Furthermore, futures studies assessing spasticity with more than one method and correlations between clinical measures of spasticity and functional activities are needed.

For some children diagnosed with CP, the knee does not flex during weight release and early swing phase of the gait cycle. Clinically, this type of walking is described as a 'stiff-knee gait pattern'. The stiff-knee gait pattern has been reported to be the most common gait abnormality of children with a primary diagnosis of CP.⁸ Spasticity of the quadriceps during late stance or early swing phase of the gait cycle has been proposed as the cause of stiff-knee gait pattern.^{12, 13}

Presently, the most frequently cited criteria for identifying the quadriceps as the cause of a stiff-knee gait pattern are different combinations of the following measures: a positive Ely test, $3, 28$ dynamic electromyography (EMG) data of inappropriate activity of the quadriceps during swing, 10 a decreased magnitude of total knee motion throughout the gait cycle, 10 a decreased magnitude of maximum knee flexion in swing, 38 a delayed timing of maximum knee flexion in swing, 38 resulting in a decreased knee flexion velocity at toe off ³⁸ and impaired foot clearance in swing.⁵¹

Impaired foot clearance, the Ely test and the modified Ashworth scale (MAS) are subjective measures used to classify a stiff-knee gait pattern. Impaired swing phase foot clearance is often cited as the primary concern for a stiff-knee gait pattern because this can result in a child tripping or falling. However the frequency of impaired foot

clearance during swing has never been reported. To date, the usefulness of the Ely test to predict rectus spasticity is uncertain. Two studies have reported that the Ely test (as a measure of spasticity²⁸ and as a measure of flexibility³) is a useful predictor of rectus spasticity, yet a third study reported a positive Ely test pre-operatively did not influence post-operative results.³⁸ The most commonly used clinical measure of spasticity in children diagnosed with CP is the Modified Ashworth scale $(MAS)^{1}$. However, poor reliability of the MAS to assess quadriceps spasticity in children diagnosed with CP has been reported. 26

Sagittal plane knee kinematic data and EMG data are objective data commonly used to classify a stiff-knee gait pattern. However, EMG data have limited usefulness because inappropriate EMG activity of the quadriceps is commonly present in the stiffknee gait pattern of children diagnosed with $CP¹⁰$. Also, activity of the rectus femoris has recently been reported to occur from 50-85 % of the gait cycle in able-bodied children.³⁹ Previously, activity during this portion of the gait cycle was proposed to be inappropriate activity of the rectus femoris due to spasticity.¹³ Despite the large volume of studies reporting pre- and post-operative knee kinematic data from children with a stiff-knee gait pattern, the results of surgical interventions have been mixed.^{10, 12}

Because of the limitations of these subjective and objective measures, it has been proposed that more objective criteria are needed to help discriminate the stiff-knee gait pattern of children diagnosed with $CP⁶$ One test that has been reported to objectively quantify quadriceps spasticity is the pendulum test.²⁹ During the pendulum test the subject's knee is passively extended by the examiner and then the leg is allowed to fall freely into flexion. If no upper motor neuron involvement is present; the knee typically demonstrates six or seven oscillations of flexion and extension; with each oscillation demonstrating a smaller arc of motion. If upper motor neuron involvement is present the knee motion is dramatically altered.⁴²

After undergoing a selective dorsal rhizotomy to reduce spasticity all pendulum values for the children diagnosed with CP were closer to the pendulum values of ablebodied children.⁴² In a study comparing the pendulum test under awake and anesthesia conditions for able-bodied children and children diagnosed with CP, fewer differences

were noted between the two groups while under anesthesia.³⁶ However, differences were still present between the two groups (able-bodied vs. CP). The authors proposed that the differences present under anesthesia were due to chronic changes in soft tissues. These two studies provided support that the pendulum test measures the neural or active response to stretch along with the associated non-neural changes of soft-tissue due to chronic adaptations of the quadriceps.

The pendulum test could potentially better distinguish the stiff-knee gait pattern of children diagnosed with CP compared to the previously described subjective measures (MAS, and Ely test). To date, the relationship of the pendulum test to the stiff-knee gait pattern of children with CP which is proposed to be due to quadriceps spasticity has not been established. The purpose of this study was to examine the relationship of the pendulum test, MAS, and Ely tests as measures of quadriceps spasticity to the presence of a stiff-knee gait pattern a common functional limitation. Furthermore, to examine the ability of the clinical test(s) to discriminate the presence or absence of stiff-knee gait in children diagnosed with CP.

Methods

Participants

Subjects referred to the Shriners Hospital for Children for a clinical gait analysis study were recruited for this prospective study. All procedures were approved by the institutional review boards. Informed consent was obtained prior to participation in the study. Criteria for study participation were: primary diagnosis of CP, aged 8 to 21 years, and classified as a level 1, 2, 3 or 4 of the Gross Motor Function Classification System⁴⁰ (Table 3.1). Excluded were any subjects who had undergone orthopaedic surgery in the twelve months prior to being seen in the motion analysis laboratory, subjects who had previously undergone a rectus femoris transfer or if in the parent's opinion the child could not correctly follow the necessary directions. A convenience sample of 68 subjects (39 boys, 29 girls) with a mean age of 11(2) years participated in the study. The mean height and weight were 141 (13) cm and 42 (15) kg, respectively. Six of the subjects had previously undergone a dorsal rhizotomy and two subjects had Baclofen pumps in place. **Procedures**

Data were collected in the same order for all subjects. Surface reflective

markers and surface electrodes were first placed on each of the subject's legs following the standard gait analysis protocol (Cleveland clinic marker set) per methods previously $described.⁵²$

After the walking trials, each subject participated in the pendulum test. Multiple measures can be calculated from the pendulum test.⁵² For this study the following measures were assessed: the final resting position of the knee (degrees), 31 the magnitude of knee flexion occurring during the first swing of the pendulum test (degrees) $(A1)$ [max knee angle – start knee angle], $3¹$ the duration of time from the onset of knee flexion until the cessation of knee movement, 30 and the maximum knee flexion angular velocity (degrees/sec).⁴² Because different types of knee motions were noted during the pendulum test, the area under the sagittal plane kinematic curve was calculated as the sum of degrees of knee motion by time component (deg*sec) and reported as a measure of total knee motion occurring during the pendulum test. 37

The Pendulum Test

To perform the pendulum test the subject was first positioned supine on a bench and then the examiner placed the subject's leg in maximum knee extension. Prior to each trial, the subject was instructed to let the leg swing freely once it was released by the examiner. One to three practice trials were performed prior to data collection. Motion analysis data collection was initiated approximately one-half second before the examiner released the subject's leg. After the leg came to rest, at least thirty seconds passed before the next trial was performed to prevent reflex inhibition of the quadriceps. The procedures were repeated until three trials of each leg were obtained. After surface electrodes and reflective markers were removed, a standard clinical examination including assessment of bilateral lower extremity spasticity was performed using the modified Ashworth scale, and two Ely tests (Table 3.2).

The MAS

The MAS was performed with each subject positioned in supine. The hip was flexed to less than 45-degrees and the knee was passively flexed and extended by the examiner at a rate of approximately 1 cycle per second.²⁶ The examiner subjectively assessed the resistance felt during passive knee flexion. For this study the MAS is reported using an ordinal scale 0, 1, 1.5, 2, 3, and 4 as a measure of quadriceps spasticity.⁵³

The Ely tests

The Ely test has been reported as a measure of rectus femoris tightness and spasticity, depending on how it is performed.^{3, 28} The Ely-S test (an assessment of quadriceps spasticity) was performed with the subject positioned in prone while the examiner rapidly flexed the knee. For this study, a positive Ely-S test was reported as the presence of resistance experienced by the examiner when performing prone knee flexion rapidly.²⁸ The Ely-F test (an assessment of quadriceps flexibility) was also performed in the prone position. The examiner stabilized the subject's pelvis by placing one hand on the sacrum, and then he slowly flexed the subject's knee. For this study, a positive Ely-F test was reported if the magnitude of knee flexion at which the pelvis began to rotate anteriorly was 90-degrees or less.³

Stiff-knee criteria

For the purposes of this study a subject was classified as having a stiff-knee gait pattern if he/she demonstrated at least four of the six following characteristics of a stiffknee gait pattern:

- 1. A delay in timing of maximum knee flexion in swing phase defined as two or more standard deviations above the normal value (as a percent of the swing phase of the gait cycle).³⁸
- 2. Two or more standard deviations below the average normal value of maximum knee flexion occurring during swing phase.³⁸
- 3. Two or more standard deviations below the average normal value of total sagittal plane knee motion occurring throughout the gait cycle.³⁸
- 4. Two or more standard deviations below the average normal value of knee angular velocity at toe-off. 38
- 5. Impaired foot clearance considered present if the toe/foot was noted to drag on the ground (based on visual observation) during the swing phase of the gait cycle.
- 6. Inappropriate quadriceps activity during the swing phase of the gait cycle.³⁹

It should be noted, inappropriate quadriceps activity in swing phase was classified as dynamic EMG activity two or more standard deviations above the minimum dynamic activity during gait, as recently proposed.³⁹ Inappropriate quadriceps activity was confirmed by visual analysis of two independent raters.³⁹ Raters had over 10

years experience performing visual analysis of EMG data and were blinded to knee kinematic data and the computer classification of EMG activity. If discrepancies between computer method and visual analysis were noted, then the visual analysis assessment of the clinician with the most experience was used for categorizing the EMG activity as inappropriate in swing phase. Eight-five percent of the time inappropriate quadriceps activity in swing phase was identified with the criteria of dynamic EMG activity two or more standard deviations above the minimum dynamic activity during gait

Data preparation/reduction

Study measures derived from the knee motions during the pendulum test were calculated in Microsoft Excel using methods previously described.⁵² See Figure 3.1 for an example of the kinematic output from the knee motions occurring during the pendulum test for a subject diagnosed with CP.

Subjects diagnosed with CP can demonstrate asymmetry between each lower extremity. However, student's t-test demonstrated no statistical differences between the right and left leg for the dependent measures. Therefore the results of data for the left leg (arbitrarily chosen) of the subjects diagnosed with spastic diplegia were reported. If a child was diagnosed with hemiplegia, then data from the involved side were reported.

All pendulum measures were highly correlated (Table3.3). Significant multicollinearity was noted for the sagittal integral measure (Pearson correlation 0.93 and tolerance value was (0.1) ⁵². This measure was removed from the regression analysis to allow for a more stable prediction equation, leaving seven measures in the regression analysis.

Results

Statistical analyses were conducted using SPSS, V13.0. All dependent and predictor measures were normally distributed (skewness $\lt +/2$). None of the 68 subjects demonstrated significant multiple measure outliers.

A hierarchical stepwise regression was used to assess the amount of variance (of the stiff-knee gait classification criteria) explained by the pendulum test above and including the traditional clinical measures of spasticity. The measures in the first step of the hierarchical model were the MAS and the Ely-F and Ely-S test. The first step of the hierarchical model was significant F $(3, 64) = 9.8$, p <.001 (Table 3.4). The first step

explained 28 % of the variance of the knee gait patterns. The Ely-S test demonstrated the largest standardized Beta coefficient of 0.34 (p=.01). The Ely-F test demonstrated a Beta coefficient of -0.23 (p=.05). The MAS was not a significant measure in the model (Beta coefficient of 0.14 ($p=.24$). The second step of the hierarchical model (addition of the four remaining pendulum measures) was significant $F(7, 60) = 9.50 \text{ p} \le 0.001 \text{(Table 3.4)}$. The second step explained 19 % of the variance of the knee gait patterns above the first step for a total of 47 % variance was explained by the model. However, the only significant measure in the second step of the regression equation was the A1 measure of the pendulum test (Beta= -0.45 , p= $.04$). The Ely-F and Ely-S demonstrated large decreases in standardized Beta values and large increases in p-value. The MAS remained nonsignificant, regardless of model (Table 3.4).

Significant multivariate main effects between the stiff-knee classification groups for the pendulum measures were noted F $(8, 59) = 4.20$, p= .001. Table 3.2 contains the means and standard deviations for the different measures calculated from the pendulum test for the stiff-knee and not-stiff-knee groups. A multivariate main effect between the stiff-knee classification groups for the dependent variables was also significant, F (4, 63) $= 14.95$, p<.001. Table 3.2 contains the means and standard deviations for the dependent measures for the stiff-knee and not-stiff-knee groups.

A stiff-knee gait pattern was identified for those subjects with four or more of the stiff-knee gait classification criteria. Thirty-one of the 68 (46 %) subjects demonstrated a stiff-knee gait pattern. A discriminant analysis function using the A1 measure was used to predict group membership (stiff-knee, not stiff-knee gait pattern) of subjects diagnosed with CP. The discriminant analysis function revealed an overall accuracy of 77 % in correctly classifying the original groups as having a stiff- or not-stiff-knee gait pattern (Chi-square[1df] =19.27; Wilk's Lambda = 0.75, p \lt .001) For an A1 of 45 degrees, the sensitivity of the measure was 87 % (95 %CI 75 %-99%) and the specificity was 68 % (95% CI 53%-83%).

Discussion

The stiff-knee gait pattern in subjects diagnosed with CP is thought to be caused by spasticity of the quadriceps muscle which restricts knee flexion from weight release through the mid-swing phase of gait.¹³ A series of review articles published in 2005

concluded that future studies should assess spasticity using more than one method and correlate passive movement measures of spasticity (i.e. MAS, ELY and pendulum test) with a functional activity (i.e. gait).^{16-18, 23} For this study, the nature of association between the gait pattern and the clinical measures of spasticity was assessed using multiple regression models. The A1 measure of pendulum test demonstrated a higher correlation ($r = -0.68$) with the stiff-knee gait pattern compared to the MAS ($r = 0.37$), Ely-F test ($r = -0.41$) and Ely-S test ($r = 0.49$). This study is the first to report high correlation between a clinical measure of spasticity (the pendulum test A1 measure) and the dynamic knee gait pattern of subjects diagnosed with CP. Many clinicians acknowledge that subjective clinical measures of spasticity (MAS, Ely tests) often demonstrate poor correlations to functional activities. Still, most clinicians are unwilling to abandon the use of these subjective measures in the absence of a reasonable alternative. Only through continuing research involving clinical implementation of other measurement protocols, including the pendulum test, will we learn if the more accurate data obtained through objective measurements of impairments will contribute to the development of treatment plans that result in improved functional activities.

The amounts of variance in knee gait patterns explained by each individual clinical measure of spasticity (MAS, Ely-F, Ely-S and A1) were assessed. The A1 measure explained 46% of the variability of the stiff-knee gait patterns calculated from a simple linear regression which exceeded the other measures (MAS 12 %, Ely-F 23 %, and Ely-S 16 %). There are a number of possible explanations for the discrepancy in the amount of variance explained by these measures. For all test situations (walking, pendulum, MAS, and Ely) the magnitude and velocity of knee flexion are resisted by the passive (chronic changes in musclotendonous tissues) and the active (stretch reflex) components of quadriceps spasticity. During the MAS, a less consistent force is applied by the examiner who subjectively reports the resistance perceived. During the Ely test, the examiner subjectively defines the point at which the pelvis begins to rotate and then measures the knee motion with a goniometer, or subjectively reports if resistance was experienced during rapid knee flexion. During the pendulum test, a constant force (gravity) is applied, and the knee motions are objectively measured by the motion analysis system. This combination of a consistent application of force with a more

objective measurement of knee motion are two likely reasons why the pendulum test explained more of the variances in knee patterns while walking compared to the more subjective assessments of quadriceps spasticity (MAS and Ely tests). The A1 of the pendulum test is a measure of the displacement of the knee during the first swing of the pendulum test. It is proposed the reason the A1 explained more of the variance in knee pattern compared to the other pendulum test measures was that four of the six criteria of a stiff-knee gait pattern were also measures of displacement of knee motion occurring during the gait cycle.

The regression analysis identified those measures most related to the target problem (stiff-knee gait pattern). From the regression analysis, the greatest amount of variance of the knee gait patterns was explained by the A1 measure of the pendulum test. However, from a clinical perspective, this information is not very applicable. Clinically, it is more important to know the discriminant ability of a test, or how well a test can identify the target problem. Therefore discriminant analysis was performed to assess the ability of the clinical measure to correctly identify stiff-knee gait pattern. The A1 measure demonstrated a higher overall accuracy to correctly classifying the original groups as having a stiff- or not-stiff-knee gait pattern 77 % compared to the other measures (MAS 69%, Ely-F 62% and the Ely-S 71%).

However, the overall accuracy of a test does not provide information regarding false positive and the false negative rate of a test.⁵⁴ Therefore the sensitivity and specificity of a test are often reported as measures of the usefulness of a diagnostic test. The specificity of a test indicates the test's ability to correctly identify the presence of the target problem, and the sensitivity represents the correct identification of absence of the target problem.⁵⁴ In our study, the A1 measure calculated from the pendulum test demonstrated the highest sensitivity (87%) compared to the other measures (MAS 48 %, Ely-F 52 %, and Ely-S 61%). The A1 measure demonstrated the lowest specificity (68 %) compared to the other measures (MAS 87%, Ely-F 70 %, and Ely-S 78 %) (Table 3.5). Rarely a test demonstrates both high specificity and high sensitivity.⁵⁴ A test with high sensitivity indicates few false negative results occurred, while a test with high specificity indicated few false positive test results. When the test is negative, a test with high sensitivity is used to rule out the presence of the target problem. However, this does

not provide information regarding if the test results are positive.⁵⁴ A test with high specificity is a test with few false positive results. When a test with high specificity is positive, that test is used to rule in the presence of the target problem.⁵⁴ Therefore, a negative pendulum test (indicated by a large A1 value [greater than 45 degrees]) is potentially more useful for ruling out a stiff-knee gait pattern compared to the other measures.

A limitation of sensitivity and specificity is that one has to know if the target problem is truly present to calculate the sensitivity or specificity of a test. Sensitivity and specificity only indicate the probability of a correct test result (true positive, false positive, false negative and true negative).⁵⁴ The sensitivity and specificity measures are not easily translated to an individual. Positive and negative likelihood ratios are ratios calculated from the specificity and sensitivity of a measure and can be easily translated to an individual.⁵⁵ The positive likelihood ratio equals sensitivity/ $(1$ -specificity). The negative likelihood ratio equals (1-sensitivity)/ specificity.⁵⁶ There are several benefits to positive and negative likelihood ratios. These measures: are less affected by the prevalence of the target problem, can be used with continuous measures, can be applied to individuals, and can refine clinical judegement.⁵⁶

By multiplying the pre-test probability of a target problem by the likelihood ratio gives the post-tests odds of the target problem.⁵⁶ The A1 measure demonstrated a moderate negative likelihood ratio of 0.19 compared to the other measures small likelihood ratios (MAS 0.60, Ely-F 0.70, and Ely-S 0.50). Hypothetically, if a clinician were .50 (50%) confident a child did have a stiff-knee gait pattern, then the post-test probability of having a stiff-knee gait pattern for a negative result for each measure would be: MAS $(.5*,6) = 0.30$ (30%), Ely-F $(.5*,7) = 0.35(35%)$, Ely-S $(.5*,5) = 0.25$ $(25%)$ and for A1 $(.5*.19) = 0.10(10%).$ These results indicate that a negative pendulum test would decrease the probability of a stiff knee gait pattern more than a negative result for the other clinic measures. Therefore, a negative pendulum test (as evident by an increased magnitude of A1), decreased the pretest probability from 50 % to the post-test probability of 10 % that the child has a stiff knee gait pattern. The positive likelihood ratio of the A1 measure (2.7) was similar to the other measures (MAS 3.6, Ely-F 1.7, and Ely-S 2.8); indicating each measure demonstrates a similar increase in the post-

test probability of identifying the target problem (stiff-knee gait) when a positive test is present.

One of the most frequently cited definitions of spasticity is "a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome." 15 However, the European network 'SPASM' proposed an evidenced-based definition of spasticity as 'disordered sensorimotor control, resulting from an upper motor neurone lesion, presenting as intermittent or sustained involuntary activations of muscles." $(p.5)^{16}$ Nordmark & Anderson reported all pendulum measures for subjects with CP were closer to those of able-bodied subjects after undergoing a rhizotomy (a spasticity reducing intervention).⁴² These results provide face validity that the pendulum test is a measure of quadriceps spasticity. In our study, the concurrent validity of the A1 measure pendulum test has been established as evident by the high correlation between the A1 measure and the knee gait pattern and by the ability of the measure to correctly classifying 77 % the original groups as having a stiffor not-stiff-knee gait pattern.

One limitation of this study involved the collection of dynamic EMG data (these were collected but not reported). A cursory visual analysis of the quadriceps EMG data revealed 55 of 68 (81%) of the subjects demonstrated a burst of activity during the first swing of the pendulum test. In a future study I plan to analyze the EMG data collected during this study in a formal manner and combine it with existing data. If future studies demonstrate a significant relationship between quadriceps EMG activity and knee motion during the pendulum it would provide construct validity that the pendulum test is a measure of both the neural component of spasticity(stretch reflex) and the non-neural component (chronic changes in musculotendonous tissues) of quadriceps spasticity in subjects diagnosed with CP.

Another limitation of this study is that three-dimensional motion analysis systems are not routinely available to clinicians. An electronic goniometer is a more affordable alternative to objectively measure the knee motion. However, most clinicians believe they possess accurate visual assessment skills and therefore prefer observational assessments of motions because these do not require the use of equipment. Future

studies assessing the accuracy and reliability of clinicians using visual observation to estimate the A1 measure are needed to determine if the pendulum test can be implemented without the use of equipment.

Conclusions

All of the subjects demonstrated some degree of a spasticity impairment (measured from the pendulum test) but depending on the severity of the impairment it did not always result in a functional limitation (a stiff-knee gait pattern). Forty-eight of the 68 subjects (71%) demonstrated a zero score with the MAS. Indicating the pendulum test is a more sensitive measure of quadriceps spasticity compared to the MAS. This study has demonstrated a significant relationship between quadriceps spasticity measured by the A1 of the pendulum test, with a limitation in activity (stiff-knee gait pattern) for subjects diagnosed with CP.

By using multiple regression analysis I have demonstrated the A1 explained more of the variance in knee gait patterns compared to the other clinical measures (MAS, Ely-S, and Ely-F). By using discriminant analysis, the magnitude of knee flexion occurring during the first swing of the pendulum test (A1) correctly assigned 77% of the subject into the two categories (stiff-knee or not-stiff-knee gait pattern). The A1 measure demonstrated a moderate negative likelihood ratio and high sensitivity, indicating the test is helpful in ruling out spasticity of the quadriceps. Therefore, consideration should be given to implementing the pendulum test clinically as a more objective and reliable measure of quadriceps spasticity for children diagnosed with CP.

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Table 3.1 Characteristics of subjects (n=68)

Cerebral Palsy	N	%
Diagnosis		
Spastic Diplegia	55	81
Right Hemiplegia	5	7
Left Hemiplegia	8	12
GMFCS level		
I	29	43
H	24	35
Ш	12	21
IV	1	1
Assistive device		
None	53	78
Walker	9	15
Loftstrand crutches	6	

Table 3.2 Dependent and independent measures means (standard deviations)						
Measures	Stiff-knee		Not-stiff-knee $(n=37)$		Control	
(*p<.05 **p<.01 ***p<.001 p-values between stiff- and not-stiff-knee groups)	$(n=31)$				$(n=30)$	
Criteria of knee gait pattern						
Knee flexion angular velocity at toe off (degrees/sec), mean (SD)	120	(80) ***	263	(95)	348	(49)
Time to maximum knee flexion in swing (percent of swing phase), mean (SD)	55	(18) ***	43	(11)	36	(4)
Maximum swing phase knee flexion (degrees), mean, (SD)	56	(13)	60	(6)	63	(3)
Total knee motion (degrees), mean, (SD)	38	(14) ***	50	(13)	64	(5)
Inappropriate quadriceps EMG activity, n, (%)	25	(81)	24	(65)	NA	
Toe drag, n , $(\%)$	11	(36)	1	(3)	NA	
Pendulum test						
A1 [max knee angle – start knee angle = amount of knee flexion occurring	34	(15) ***	57	(23)	ND	
during first swing] (degrees) mean, (SD)						
Maximum knee angular velocity (degrees/seconds) mean, (SD)	166	(48) ***	219	(51)	ND	
Duration of knee motion from onset of movement to cessation of						
moment(seconds) mean, (SD)	2.2	(0.8) *	3.0	(1.4)	ND	
Integral of motion (Numerical integration/trapezoidal method						
where: $A = \frac{1}{2}(a + b) h$ (degrees*seconds) mean, (SD)	18	(9) **	27	(16)	ND	
Final resting position of knee (degrees) mean, (SD)	56	(14)	59	(13)	ND	
Modified Ashworth Score n, (%)						
$\boldsymbol{0}$	16	(52)	32	(87)	NA	
	10	(32)	5	(13)		
1.5	3	(10)				
$\overline{2}$	2	(6)				
Ely-S (quadriceps spasticity) $n, (\%)$						
Yes	12	(39)	29	(78)	NA	
N _o	19	(61)	8	(22)		
Ely-F (quadriceps flexibility) n , $(\%)$						
90 degrees or less	23	(74)	15	(40)	NA	
Greater than 90 degrees	8	(26)	22	(60)		
MD (no dote) MA (not evaluable)						

Table 3.2 Dependent and independent measures means (standard deviations)

Table 3.3 Pearson correlations of measures

Measure	$\mathbf{1}$	$\overline{2}$	3	$\overline{4}$	5	6	7	8	9
1. Summary of Stiff-knee criteria	1.00								
2. Ely-F test (quadriceps flexibility)	$-.41$	1.00							
3. Ely-S test (quadriceps spasticity)	.49	$-.39$	1.00						
4. Modified Ashworth Score	.37	$-.35$.44	1.00					
5. A1-(knee flexion during first swing of pendulum test)	$-.68$.41	$-.61$	$-.47$	1.00				
6. Maximum knee angular velocity during pendulum test	$-.60$.31	$-.55$	-42	.88	1.00			
7. Duration of motion during pendulum test	$-.56$.24	$-.31$	$-.22$.70	.68	1.00		
8. Integral of motion during pendulum test	$-.56$.26	$-.31$	$-.22$.74	.67	.93	1.00	
9. Final resting position of knee during pendulum test	$-.37$.31	$-.35$	$-.53$.60	.57	.52	.56	1.00

Shaded area represents high correlations between pendulum measures.

Table 3.4 Hierarchical Regression Model

*indicates significant measure in regression model (p<.05)

Spasticity Measure	Sensitivity	Specificity	Positive	Negative
	$(95\% \text{ CI})$	$(95\% \text{ CI})$	Likelihood	Likelihood
			Ratio	Ratio
			$(95\% \text{ CI})$	$(95\% \text{ CI})$
A1 of pendulum test 0.87(0.75-0.99) 0.68(0.53-0.83) 2.69(1.66-4.37)				$0.19(0.07-0.49)$
MAS			$0.48(0.31-0.66)$ $0.87(0.76-0.98)$ $3.59(1.47-8.76)$	$0.60(0.42 - 0.86)$
$Ely-F$	$0.52(0.34-0.69)$		$0.70(0.55-0.85)$ $1.74(0.95-3.17)$	$0.69(0.45-1.05)$
$Ely-S$	$0.61(0.44-0.78)$	$0.78(0.65-0.91)$	$2.84(1.45-5.57)$	$0.50(0.31-0.80)$

Table 3.5 Sensitivity, Specificity, positive and negative likelihood ratios for clinical measures of spasticity (n=68 subjects)

Figure 3.1 Example of sagittal plane knee kinematic data from pendulum test

CHAPTER FOUR - Visual analysis of the pendulum test; Spasticity, do we know it when we see it? Introduction

 Damage to the central nervous system can result in spasticity. Spasticity is defined as "a disordered sensori-motor control, resulting from an upper motor neurone lesion, presenting as intermittent or sustained involuntary activations of muscles." $(p.5)^{16}$ Children diagnosed with cerebral palsy often demonstrate increased muscle spasticity.¹

When asked to define what is perceived as muscle spasticity interfering with a patient's gait pattern, experienced therapists and physicians have been reported to say; "I know it when I see it". Similar statements have been reported by other professionals when attempting to objectively define a vague and subjective concept.⁵⁷

Cerebral palsy (CP) is a chronic neuromotor disability resulting from brain damage or malformation in perinatal life or early childhood and characterized by abnormal control of movement that is not progressive in nature.⁵⁸ Cerebral palsy may result in motor and sensory abnormalities. The prevalence of CP is estimated to be 1.2 to 2.5/1000 births.² The typical presentation of CP is an increase in muscle spasticity and/or a decrease in control of skeletal muscles.⁵⁸ These impairments may cause gross motor limitations that can result in a decreased ability to walk and transfer.³⁶ Specifically, spasticity of the quadriceps has been reported to cause swing phase interference (toe drag) of children diagnosed with CP when walking.¹³ The stiff-knee gait pattern, has been proposed to be caused by quadriceps spasticity and has been reported to be the most common gait deviation for children diagnosed with CP^8 . To date, an objective, reliable and accurate test to assess quadriceps spasticity is not routinely available to most clinicians.

A recent review of the literature reported different versions of the Ashworth scale were the most frequently cited measure of assessing spasticity.¹ However, the modified Ashworth scale (MAS) is an ordinal scale based on subjective evaluation of passive resistance perceived by the examiner.⁴⁴ The MAS may not be sensitive enough to detect small changes in spasticity.⁴⁴ Clopton et al. recently reported moderate test-retest reliability (ICC = 0.67) of the MAS to assess quadriceps spasticity in children diagnosed with $CP²⁶$

An alternative, objective clinical measure of quadriceps spasticity is the pendulum test.⁴² The pendulum test is performed with the subject lying in supine or sitting. The subject's leg is positioned in maximum knee extension by the examiner and then released. If an able-bodied subject does not assist or resist the knee motions, the knee will demonstrates six to eight oscillations of flexion and extension.³⁴ However, if upper motor neuron involvement is present, the knee will demonstrate a dramatically altered knee motions compared to able-bodied subjects.³⁶

 High test-retest reliability of the pendulum test has been reported for able-bodied children and children diagnosed with CP when measured with a three-dimensional motion analysis system.⁵² The between day reliability ICC scores of thirteen variables calculated from the pendulum test were moderate to very high (0.60 to 0.98) for children with CP and high to very high (0.71 to 0.98) for able-bodied children. The between day reliability for the magnitude of knee flexion occurring during the first swing of the pendulum test (A1) was very high (0.96) for both able-bodied children and children diagnosed with $CP⁵²$ Recently, it has been reported the magnitude of knee flexion occurring during the first swing of the pendulum test (A1) measured with a threedimensional motion analysis system correctly identified the knee gait pattern as stiff-knee or not-stiff-knee for 52 of 68 (77%) of the children.⁵⁹

The knee motions occurring during the pendulum test have also been measured using magnetic tracking system, 36 electrogoniometer, 31 and two-dimensional video analysis system.35 However, many clinicians believe instrumented motion analysis systems are unnecessary because they possess accurate visual assessment skills.⁶⁰ Some clinicians, prefer to video tape an activity of interest because this allows multiple viewing of the same task and can allow for blinded observation of the activity of interest.⁶¹ High test-retest reliability (ICC range 0.76-0.96) has been reported for observers using a visual analog scale to assess the upper extremity movements of subjects who have suffered a cerebral vascular accident.⁶⁰ Because the upper extremity motions were measured simultaneously by a Peak motion measurement system each observer's accuracy was also assessed. The therapists demonstrated high accuracy $(0.87 < r < 0.96)$ in assessing speed of movement and moderate accuracy $(0.68 < r < 0.93)$ in assessing the smoothness of upper extremity movements.⁶⁰

Since visual observation appears to have reasonable accuracy in upper extremity movements, and a three-dimensional (3-D) motion analysis system yielded reliable and discriminating results of the pendulum test (but is not available to all clinicians) this study was performed to determine if visual observation of the pendulum test is adequate for clinicians to evaluate quadriceps spasticity without requiring instrumentation of the subject. Therefore the purposes of this study were: 1) to compare the inter- and intra-rater reliability of four independent observers of the A1 measure of the pendulum test, 2) to compare the accuracy of these observers to the 3-D kinematic data in order to determine if visual observation was able to discriminate stiff-knee gate pattern and 3) to assess the sensitivity of the visual observation of the A1 measure of the pendulum test in identifying a stiff-knee gait pattern with no prior knowledge of the actual gait pattern demonstrated.

Methods

Participants

Data for this study were collected as a part of a larger prospective study using a three-dimensional motion analysis system. Sixty-eight children with a primary diagnosis of CP were involved with gait analysis and the pendulum test. Data for 50 subjects with the primary diagnosis of spastic diplegia (86%) or left hemiplegia (14%) were randomly selected for use in this study. For the 50 subjects, 29 were boys and 21 were girls. Average age was 11(2) years, and average height and weight were 141(13) cm and 42(15) kg, respectively. The Gross Motor Function Classification System (GMFCS) was used to classify subjects. Twenty-one (42%) of the participants were classified as GMFCS Level I, 17 (34%) Level II, 11 (22%) Level III, and one (2%) subject was classified as a GMFCS level IV. The modified Ashworth scale was used to assess quadriceps tone.²⁶ Thirty-seven (74%) participants were scored 0, nine (18%) participants scored 1, two (4%) participants scored 1+, and two (4%) scored 2, with the modified Ashworth scale. One trial of the pendulum test for the left leg of 50 participants was used for visual analysis.

Four observers participated in the study. Two observers (#1 and 2) had significant experience evaluating the output from three-dimensional motion analysis systems. The other two observers had limited experience (observer #3) or no previous experience (observer #4) assessing the 'stickperson' output from the motion analysis system.

All observers worked in patient care settings. Three observers (# 1, 3 and 4) were physical therapists and the fourth observer (#2) was a biomechanical engineer with 18 years experience working in motion analysis laboratory settings.

Procedures

Data for this study were collected using a Motion Analysis Corporation Real Time System (EVaRT V4.4.4) with eight Eagle digital cameras to measure the knee motions occurring during walking and the pendulum test (Motion Analysis Corporation, Santa Rosa, CA). OrthoTrak V6.24 software was used to reduce and plot knee kinematic data during gait and the pendulum test as previously described.⁵² The EVaRT video files were used for visual analysis of the pendulum test. The EVaRT video files are a threedimensional digital video recording of a person represented as a 'stickperson' performing the activity of interest (Figure 4.1). Typically, 'stick person' video files are processed with other software to measure the motions occurring during the activity of interest. Videos can also be played on a computer monitor to visually assess the activity the 'stickperson' is performing.

As part of the larger study incorporating all 68 subjects, the cut-off value of the A1 was calculated using a receiver operator characteristic curve.⁵⁹ The knee of the receiver operator characteristic curve represents the cut-off point for the magnitude of knee flexion during the pendulum test $(A1)$ with the highest sensitivity and highest specificity.⁶² An A1 value of 45 degrees demonstrated 87 % sensitivity and 68 % specificity to correctly identify the presence of the stiff-knee gait pattern.⁵⁹ Therefore, each observer was instructed to assess each trial and report the tests was positive if the knee flexed less than 45-degrees and negative if greater than 45-degrees of knee flexion occurred during the first swing of the pendulum test.

Each observer familiarized him/herself with the EVaRT software using standard written instructions. Instructions were designed to ensure consistent observation. A standard video and an EVaRT 'stick person' video of the same pendulum trial of an ablebodied person and a person diagnosed with CP were included in the instructions to help familiarize observers with the 'stick person' videos. By using the 'stick person' data for this study, observers were blinded to the age, and gender of each subject. This allowed the observers to assess the change in knee angle during the pendulum test without

being distracted by extraneous (aesthetic) information derived from the human form.

Observers were instructed to watch each EVaRT video a maximum of two times and not pause or rewind the video file while it was playing. Once each observer felt they were competent using the software, he/she participated in a pre-test. The pre-test consisted of five EVaRT video files. Each observer was required to correctly identify four out of the five pre-test trials. Observers were given the opportunity to take the pretest up to three times. Only one observer required a single repeat test to successfully complete the pre-test.

Following the pre-test, observers viewed up to two repetitions of one trial for each of the 50 subjects performing the pendulum test. To prevent fatigue, observers were allowed to observe 25 subjects in one session. At least 30 minutes later observers could continue observing the other 25 subjects. One week later, each observer reviewed the data of 20 randomly selected subjects to assess intra-rater reliability of identifying less than or more than 45° of knee flexion for the A1 of the pendulum test. Accuracy of the observers' results for the 50 trials was also compared to the three-dimensional motion analysis system's measured knee motions of the same trial. Throughout the study the four observers had no knowledge of each subject's gait pattern. All data were analyzed by the primary investigator who was not one of the four observers.

Data Preparation/Reduction

OrthoTrak software V6.24 was used to measure the magnitude of knee flexion (A1) occurring during the first swing of the pendulum test. These data were used to represent the reference standard to which the observers were compared in statistical analysis of the data. The three-dimensional (3-D) knee kinematic data were recoded as a 1 if less than 45° and a 0 if greater than 45° of knee motion occurred. The four observers' assessments were recorded in the same manner.

Statistical analyses were conducted using SPSS, V15.0 (Chicago, IL). Because dichotomous data were used the percent agreement and Kappa values are reported as a measure of inter- and intra-rater observer agreement.⁶³ To determine the agreement between observer and the three-dimensional (3-D) motion analysis system, the observer's results were recoded as 1 when the observer was in agreement with the 3-D results and a
0 when disagreement between the observer and the 3-D results were reported. Repeated measures logistic regression analysis was used to obtain the estimated probability agreement between each observer and the knee motion measured with the 3-D motion analysis system. Pairwise comparisons of each observer with the 3-D calculation were performed to assess the validity of each observer's estimate of knee motion occurring during the first swing of the pendulum test (A1). Using each observer's estimation of A1 (0 if greater than 45° , or a 1 if less than 45° of knee motion occurred); a discriminant analysis function was used to predict group membership (stiff-knee, not stiff-knee gait pattern) of subjects diagnosed with CP.

Results

Reference standard

As determined by 3-D kinematic analysis, the mean A1 value of the pendulum test was 47 (23) degrees (range 8-101 degrees) for the 50 subjects. Twenty-eight (56%) of the subjects demonstrated an A1 value of less than 45-degrees. The discriminant analysis using the A1 of the pendulum test (measured with the 3-D system) resulted in correctly categorizing 80 % of the 50 subject's gait pattern (as stiff-knee or not-stiffknee).

Subjects were categorized as stiff-knee if at least 4 of the 6 criteria were noted: 1) two or more standard deviations below the normal value of knee angular velocity at toe-off, 2) at least two standard deviations below the normal value of maximum knee flexion during swing, 3) at least two standard deviations below the normal value of total knee motion throughout the gait cycle, 4) at least two standard deviations above the normal value of delayed timing of maximum knee flexion in swing, 5) inappropriate swing phase activity of the quadriceps and 6) toe-drag.⁵⁹ Based on these criteria, twentysix (52%) of the subjects demonstrated a stiff-knee gait pattern measured by the threedimensional motion analysis system.

Inter-rater reliability

Fair to moderate inter-rater agreement was noted between the four observers, with Kappa values ranging from 0.32 to 0.56. However, the pairwise comparison of each observer's ability to correctly classify the knee motions demonstrated no statistical difference between observers (p>.05) (Table 4.1).

Intra-rater reliability

The four observers demonstrated moderate to excellent test-retest repeatability to estimate A1 value. The average Kappa value for the four observers was 0.77 (95% CI 0.50-1.0). The average percent agreement for the two sessions for the four observers was 89 % (95%CI 76-100%) (Table 4.2). Two observers demonstrated perfect agreement between the two sessions.

Observers' accuracy as compared to 3-D kinematics

Moderate accuracy was noted for all observers. The average estimated probability of agreement between the observers' visually identifying less than or more than 45° of knee flexion for the A1 of the pendulum test with the 3-D system was 75% (95 % CI 70- 80%) (Table 4.3). A pairwise comparison of each rater with the 3-D data demonstrated that the observers' assessments were not statistically significantly different $(p>0.05)$.

Discriminant analysis

The discriminant analysis function using the observers' visual assessment of less than or more than 45° of knee flexion for the A1 of the pendulum test correctly identified 72-76% of the subjects' gait pattern (stiff-knee, not-stiff-knee) (Table 4.4). The observers' sensitivity to identify a stiff-knee gait pattern from visual analysis of the A1 ranged from 0.63 to 1.00. The observers' specificity to identify a stiff-knee gait pattern from visual analysis of the A1 ranged from 0.46 to 0.85 (Table 4.4).

Discussion

The purposes of this study were to assess the inter- and intra-rater reliability and accuracy (compared to 3-D kinematic data) of four observers to visually assess less than or more than 45° of knee flexion for the A1 of the pendulum test. This study was also designed to assess the sensitivity and specificity of the visual observation of the A1 of the pendulum test in identifying a stiff-knee gait pattern with no prior knowledge of the actual gait pattern demonstrated.

Fair to moderate inter-rater agreement was noted between the four observers. These levels of agreement are similar to those previously reported for observational gait analysis.⁶⁴ The inter-rater reliability for our study was higher than previous studies in which therapists visually assessed shoulder flexion angles,⁶⁵ and visual assessment of

passive ankle range of motion.⁶⁶ Therefore, if visual assessment of A1 was used, the same observer would be required to evaluate the same subject at each assessment.

On average, the four observers demonstrated moderate to excellent intra-rater repeatability in identifying the A1 measure as less than or more than 45 degrees. This is consistent with previous studies that reported high test-retest reliability for observers using a visual analog scale for upper extremity movement and ankle power generation during gait. $60, 67$

All four observers demonstrated moderate accuracy (mean Kappa 0.49 95% [CI 0.41-0.57]) to identify a threshold of 45-degrees of knee flexion during the A1 phase of the pendulum test. However, the accuracy of the observers was not a high as that previously reported for estimating the speed and smoothness of upper extremity movements.^{60, 67} Knudson reported observers were unable to estimate the absolute angle of knee flexion and trunk flexion compared to these motions measured by the Peak system.⁶⁸ However, when the observers used a visual analog scale to identify too little or too much motion when jumping, significant correlations $(r = .62)$ were reported between the criterion measure and observers estimates.⁶⁸ The author concluded human vision does not take 'snapshots' of discrete events. Instead, humans accomplish visual assessments by gathering information about motions occurring over brief periods of time.⁶⁸ Other authors have also proposed that studies assessing the ability of human observers to accurately estimate motions should focus on complete motions and not estimating an angle at a certain point in time.⁶⁹ In our study, the accuracy of visual assessment of A1 could have been affected by the methodology which required the observers to assess the absolute knee angle at an instant in time. Accordingly, future studies to improve observer accuracy could have the observers assess the A1 of the pendulum test with a visual analog scale instead of trying to assess the angle with a yes/no response.

Another factor that could have caused a decrease in accuracy was the range of knee motion occurring during the pendulum test. The A1 of eleven (22%) subjects was between 40-50 degrees. For this range of knee motion, the percent error for the observers was the highest (between 36 and 55 %). This was higher than the total percent error for the four observers for all 50 pendulum trials which ranged from 20 to 30 %. The accuracy between the four observers was not statistically different. Therefore the previous

experience of two observers looking at 'stickpersons' did not significantly affect observers' ability to identify less than or more than 45° of knee flexion for the A1 measure. This is consistent with previous studies of visual analysis of human motions which reported the experience of the examiner did not affect the accuracy of estimating the movements of interest. $67, 70$

Potentially, the pendulum test could be used to assist in identifying a stiff-knee gait pattern for clinicians without access to a three-dimensional motion analysis laboratory. Therefore, an assessment of the sensitivity and specificity of visual analysis of the A1 measure to correctly identify stiff-knee gait pattern was performed. The discriminant analysis function using the observers' estimation of A1 correctly identified 72-76% of the subjects that were classified with a stiff-knee gait pattern (Table 4.4). The observers' sensitivity to identify a stiff-knee gait pattern from visual analysis of the A1 ranged from 0.63 to 1.00. The observers' specificity to identify a stiff-knee gait pattern from visual analysis of the A1 ranged from 0.46 to 0.85. These sensitivity and specificity values for visual assessment of A1 to identify a stiff-knee gait pattern based on stringent criteria (4 or more criteria of a stiff-knee gait pattern) are greater than those previously reported by Marks et al. who assesses the sensitivity and specificity of the Ely-S test to identify only two criteria of a stiff-knee gait pattern.²⁸

A test with high sensitivity, and a negative result for a subject, assists in ruling out the target problem.⁵⁴ The observers' sensitivity ranged from $0.63 - 1.0$, compared to the three-dimensional motion analysis system's sensitivity of 0.92 (95%CI 0.81-1.00) (Table 4.4). This high sensitivity indicates the pendulum test is a useful measure to rule out stiffknee gait pattern if three-dimensional motion analysis data are not available. However, the sensitivity and specificity measures are not easily translated to an individual.

Calculated from the specificity and sensitivity of a measure are the positive and negative likelihood ratios are ratios which can be better translated to an individual.⁵⁵ Both positive and negative likelihood ratios refer to the likelihood of the target problem being present. Tests with high sensitivity demonstrate more meaningful negative likelihood ratios. The negative likelihood ratio for the observers ranged from 0.00 to 0.44 (Table 4.4). One observer (#2) demonstrated perfect sensitivity, resulting in a zero negative

likelihood ratio. However, the other observers negatively likelihood ratios were considered to demonstrate only small changes in post-test results. While the threedimensional motion analysis system's negative likelihood ratio of 0.12 (95% CI 0.03- 0.46) is considered to demonstrate a moderate change in post-test results.

The A1 is a continuous measure; therefore different cut-off values from the receiver operator characteristic curve of A1 can be assigned to obtain different positive and negative likelihood ratios (Table 4.5). The result of increasing the positive and negatively likelihood ratios is an increase in the odds of ruling in or ruling out quadriceps spasticity and the stiff-knee gait pattern. From the pendulum data of the 50 subjects, increasing the cut-off value of A1 to 59-degrees would result in a negative likelihood ratio of 0.00 (95% CI 0.00-Infinity). Conversely, if the cut-off value of A1 is decreased to 26-degrees, the result is a positive likelihood ratio of infinity (95% CI 0.00-Infinity). By manipulating the A1 value you can improve the post-test likelihood of correctly identifying the stiff-knee gait pattern. If the value of A1 for a subject is greater than 59 degrees then that subject has a 0 % post-test chance of having a stiff-knee gait pattern. While if the value of A1 for a subject is less than 26-degrees then that subject has a 100 % post-test chance of having a stiff-knee gait pattern.

A limitation of this study was that the observers watched a video of an EVaRT software stickperson performing the pendulum test. Although studies have shown that human motion can be readily identified without seeing the human form, $⁷¹$ one could</sup> argue that the absence of the human form could have affected the observer's judgment. The converse could also be argued, the methodology used in this study assessed observers' ability to visual estimate an angle without interference of the human form. Therefore, future studies accessing the accuracy of visual observation of the pendulum test in a more traditional clinical scenario are needed.

The observer's visual perspective when watching the EVaRT stickperson would be similar to one's visual perspective when positioned perpendicular to the subject's lateral knee (for a sagittal plane view) with a 4-5 foot distance separating the subject and observer. This view of the EVaRT video was chosen based on the premise that accurate assessment of planar motion requires the optical axis to be placed perpendicular to the plane of motion of interest.⁷² For one clinician to place the subject's leg in

maximum knee extension and be able to accurately observe the knee flexion from the side (perpendicular to the lateral knee) the clinician would be positioned near the floor so the subject's leg could be held with one hand (Figure 4.2). The clinician's visual perspective of maximum swing flexion during the first swing of the pendulum test would be similar to that seen in Figure 4.3. Some clinicians may not want to assume this posture and instead try to estimate the knee motion from a standing position (Figure 4.4). The clinician's perspective of maximum knee flexion during the pendulum test (A1) would be similar to that seen in Figure 4.5. From this view, a perspective error would occur and this would potentially result in a less accurate estimation of the A1 measure and was not used in this study. To see a video clip of the pendulum test from these two visual perspectives go to [MPEG1.MPG.](#page-137-0)

Instrumented gait analysis is the gold standard for assessing gait.⁷³ Most clinicians accept that instrumented methods of measuring human motion are more accurate than observational assessments. However, clinicians often do not have access to a motion analysis laboratory. For clinicians without access to a motion analysis laboratory, a large value for the A1 (greater than 45 degrees) will assist in ruling out a stiff-knee gait pattern for a subject diagnosed with CP. Because the accurate assessment of movements varies for each person,⁶⁷ clinicians should first assess their own reliability and accuracy of visually assessing of the A1 measure of the pendulum test prior to implementing the pendulum test without instrumentation. This could be performed by having clinicians compare their assessment of knee motion with a more objective measure. A more objective measure of the knee motion occurring during the pendulum test could be performed with a video camera placed perpendicular to the subject's lateral knee as previously described.35 The maximum knee flexion occurring during the first swing of the pendulum test could be measured with a goniometer placed on the monitor or the angle can be calculated using free ware Image J from the National Institute of Health.

Despite the moderate accuracy for visual analysis of the pendulum test, objective measurement of the knee motions occurring during the pendulum test is recommended for three reasons. First, the objective measurement would provide a more accurate estimate of small changes in knee motion that could potentially be missed by visual assessment. Secondly, the motions occurring during the pendulum test occur

very rapidly, with the A1 occurring at approximately 0.5 seconds or less, making it difficult to visually estimate the magnitude of A1 with accuracy of less than 10 degrees. Third, an objective measurement of spasticity is consistent with reviews of the literature that suggest to improve best clinical practices, spasticity measures should be quantitative in nature, easy to implement with results that are readily and easily interpreted.^{23, 24} It was also recommended that the spasticity measures should be performed using standardized, repeatable methods to develop more reliable measures of spasticity for clinicians and researchers.²³ The pendulum test performed with a single video camera or other instrumentation methods will meet these criteria as a more objective assessment of quadriceps spasticity.

Conclusions

The four observers demonstrated fair to moderate inter-rater reliability and moderate to perfect intra-rater reliability to identify less than or more than 45° of knee flexion for the A1 measure A1 measure of the pendulum test. The visual assessment of the pendulum test correctly classified 72-76 % of the subjects' knee-gait patterns with no prior knowledge of the subjects' gait. These findings indicate that clinicians without access to motion analysis laboratory can use visual analysis of the A1 of the pendulum test to assess quadriceps spasticity for children diagnosed with CP. The larger the magnitude of knee flexion during the first swing of the pendulum test (A1), the more likely the subject will not demonstrate a stiff-knee gait pattern.

Three important methodological procedures should be maintained to obtain similar results. First, a consistent starting position of maximum knee extension must occur. A yardstick attached to a small block of wood was used to consistently measure the heel to floor distance prior to initiating the pendulum test. Second, measurement of the knee motion should occur in the sagittal plane to prevent perspective error of the visual assessment (or with a single video camera) or with some type of instrumentation. Third, if more than one trial is to be performed, then at least 30 seconds should pass to allow sufficient recovery of the stretch reflex.³⁵

Visual assessment of the A1 of the pendulum test will assist in identifying a stiffknee gait pattern for those clinicians without access to some type of instrumentation system. However, if clinicians are to use the pendulum test to assess changes in

quadriceps spasticity pre- and post-spasticity reducing intervention (including: oral medications, Botox®, selective dorsal rhizotomy, intrathecal Baclofen, and orthopedic surgeries), then consideration should be given to using some type of instrumentation (electrogoniometer, two-dimensional video analysis, magnetic tracking system or other three-dimensional motion analysis systems) to more accurately and objectively measure the magnitude of knee flexion during the first swing of the pendulum test (A1).

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Table 4.1 Inter-rater reliability and estimated probability agreement between observers

	Kappa	
Observer	(95 % CI)	Percent agreement
1	0.56	80
	$(0.18 - 0.95)$	
2	1.00	100
	$(1.00-1.00)$	
3	0.50	75
	$0.12 - 0.88$	
	1.00	100
	$(1.00-1.00)$	
Average	0.77	89

Table 4.2 Intra-rater reliability for repeatability of four observers

Table 4.3 Estimated probability of agreement comparison of observer's estimation of A1 compared to three-dimensional motion analysis system's measurement of A1

Table 4.4 Sensitivity, Specificity, positive and negative likelihood ratios for a three-dimensional (3-D) motion analysis system and four observers (n=50 subjects) to identify stiff-knee gait

	Observer Percent of subjects	Sensitivity	Negative	Specificity	Positive
	correctly classified	$(95\% \text{ CI})$	Likelihood	$(95\% \text{ CI})$	Likelihood
			Ratio		Ratio
			$(95\% \text{ CI})$		$(95\% \text{ CI})$
$3-D$	80 %	$0.92(0.81-1.00)$	$0.12(0.03-0.46)$	$0.69(0.51-0.87)$	$2.98(1.65-5.36)$
	74 %	$0.79(0.63-0.95)$	$0.30(0.13-0.68)$	$0.69(0.51-0.87)$	$2.57(1.40-4.74)$
2	72 %	$1.00(1.00-1.00)$	$0.00(0.00-0.00)$	$0.46(0.27-0.65)$	$1.86(1.30-2.65)$
3	76 %	$0.63(0.43-0.82)$	$0.44(0.26-0.76)$	$0.85(0.71-0.98)$	4.06 (1.57-10.52)
$\overline{4}$	74 %	$0.83(0.68-0.98)$	$0.24(0.10-0.61)$	$0.69(0.51-0.87)$	$2.70(1.48-4.94)$

A1 in degrees	Sensitivity	Negative	Specificity	Positive
(Number subjects at or	$(95\% \text{ CI})$	Likelihood	$(95\% \text{ CI})$	Likelihood
below threshold value of A1)		Ratio		Ratio
		(95% CI)		$(95\% \text{ CI})$
26	0.25	0.75	1.00	Infinity
(6)	$(0.08 - 0.42)$	$(0.60 - 0.94)$	$(1.00-1.00)$	$(0.00$ -Infinity $)$
36	0.67	0.54	0.62	1.76
(17)	$(0.48-86)$	$(0.28 - 1.02)$	$(0.43 - 0.81)$	$(1.00-3.09)$
46	0.92	0.12	0.69	2.98
(30)	$(0.81 - 1.03)$	$(0.03 - 0.46)$	$(0.51 - 0.87)$	$(1.65 - 5.36)$
59	1.00	Infinity	0.46	1.86
(38)	$(1.00-1.00)$	$(0.00\text{-}Infinity)$	$(0.27 - 0.65)$	$(1.30-2.65)$
79	1.00	Infinity	0.23	1.30
(44)	$(1.00-1.00)$	$(0.00\text{-}Infinity)$	$(0.07 - 0.39)$	$(1.05-1.61)$
102	1.00	Infinity	0.00	1.00
(50)	$(1.00-1.00)$	$(0.00\text{-}Infinity)$	$(0.00-0.00)$	$(1.00-1.00)$

Table 4.5 Sensitivity, Specificity, positive and negative likelihood ratios of the three-dimensional motion analysis for different Cut-off values of A1 (n=50 subjects)

Figure 4.1 Sagittal view of 'Stick person' at the beginning of the pendulum test generated from EVaRT software video. The subject's left knee is straight and he is lying on his back. The cluster within the box represents the subject's left foot and shank. The clusters within the circle represent the subject's knee and thighs. The clusters on the right represent the subject's pelvis, trunk and arms.

Figure 4.2 Appropriate posture of clinician for observing knee flexion during pendulum test

Figure 4.3 Visual perspective of knee flexion during pendulum test from appropriate posture

Figure 4.4 Inappropriate posture of clinician for observing knee flexion during pendulum test

Figure 4.5 Visual perspective of knee flexion during pendulum test from standing posture

CHAPTER FIVE - So What?

During the course of these studies, I would often present my primary advisor with what I believed were significant findings. Each time, I was asked the simple, but always pertinent question: "So what?" In other words, what is the clinical relevance of these findings?

This series of studies was performed to determine if the pendulum test is a more objective test to assess quadriceps spasticity in children diagnosed with CP as compared to commonly used clinical measures, i.e., the MAS, and Ely tests. If the pendulum test is a more objective test, then improvements in treatment decisions could lead to improved functional outcomes for children diagnosed with CP. As clinicians we believe that a clinical test should be related to an individual impairment and limitation in function; unfortunately there are more tests than scientific evidence to support their use. These studies were implemented to assess the pendulum test as a viable measure for improving the clinical decision process, and to identify the stiff-knee gait pattern in children diagnosed with cerebral palsy.

Studies were designed to answer the following questions:

- 1. Is the pendulum test, measured with a three-dimensional motion analysis system, a reliable measure of quadriceps spasticity for children diagnosed with CP?
- 2. Are the values for the pendulum test for children diagnosed with CP significantly different from the values for able-bodied children?
- 3. Do the clinical measures of quadriceps spasticity (MAS, Ely tests, pendulum test) correlate with the gait pattern measured with a three-dimensional motion analysis system?
- 4. What combination of the spasticity measures (MAS, Ely tests, pendulum test) discriminate between a stiff-knee and a not-stiff-knee gait pattern as measured by a three-dimensional motion analysis system?
- 5. Can visual analysis of pendulum test accurately estimate the knee motion occurring during the pendulum test?
- 6. What is the inter-rater reliability of visual analysis of the pendulum test?
- 7. Can results from visual analysis of the pendulum test discriminate between a stiff-

knee and a not-stiff-knee gait pattern as measured by a three-dimensional motion analysis system for children diagnosed with CP?

The preferred study design for assessment of a diagnostic test is one in which blind comparisons are made between the test of interest and a reference test from a relevant population.⁵⁴ The level of involvement of subjects in this study represents typical levels of impairments of children assessed at our facility for determination of interventions to improve walking. The validity of the pendulum test as a measure of quadriceps spasticity has been previously discussed and is reasonably supported based on post- rhizotomy and anesthesia interventions.^{36, 42} Before a relationship between impairments and functional activities can be established the reliability and validity of the tests used to measure such impairments must be determined.

Prior to this series of studies, the reliability of the pendulum test had not yet been established for children diagnosed with CP. The pendulum test, measured with a threedimensional motion analysis system was found to be reliable for ten able-bodied subjects and ten subjects diagnosed with CP. The between-day reliability ICC scores of thirteen variables calculated from the pendulum test were moderate to very high for children with CP and high to very high for able-bodied children. Specifically, the between-day reliability for the magnitude of knee flexion occurring during the first swing of the pendulum test (A1) was very high (0.96) for both able-bodied children and children diagnosed with CP. These high reliability values would be meaningless if there were not significant differences between able-bodied children and children diagnosed with CP. The magnitude of knee flexion occurring during the first swing of the pendulum test (A1) was significantly less in the children with CP (50 degrees) when compared to the ablebodied children (105 degrees) (p<.001). Therefore, the pendulum test demonstrated very good reliability and has clinical potential to differentiate levels of spasticity in children diagnosed with CP.

These data are reassuring since published reports of limitations in objective measures of spasticity including the variability of spasticity from day to day and within the same day.²⁰ Moreover, these results provide evidence that objective differences exist between able-bodied children and children diagnosed with CP, and these differences can be reliably measured. However, this information does not address a deficit

previously identified in the literature, that a relationship between impairments and function limitations must be identified.¹⁷ If these relationships exist, then improvements in assessments and interventions can potentially be realized.

Although the pendulum test was found to be reliable and able to discriminate between children with and without CP, a more important clinical finding would be relating the pendulum test to a functional limitation for patients with CP. Therefore, the relationship between clinical measures of quadriceps spasticity and the stiff-knee gait pattern of children diagnosed with CP was assessed. The next question was: Do the clinical measures of quadriceps spasticity (MAS, Ely tests, pendulum test) correlate with the gait pattern measured with a three-dimensional motion analysis system?

In this study, a subject was classified as having a stiff-knee gait pattern if he/she demonstrated four or more of six characteristics reported in the literature.^{38, 39} The largest correlation $(r = -0.68)$ to the stiff-knee gait pattern criteria was the magnitude of knee flexion occurring during the first swing of the pendulum test (A1). This information is important because the measures that demonstrate a high correlation with stiff-knee gait pattern criteria are potentially the measures that can be used to explain the variance in the stiff-knee gait patterns and more importantly, to discriminate the stiff-knee gait pattern for children diagnosed with CP.

I sought to determine if a combination of clinical measures of quadriceps spasticity predicted the stiff-knee gait pattern in children diagnosed with CP. A hierarchical regression model was used to assess what combination of spasticity measures i.e., MAS, Ely-S, Ely-F, and pendulum test, explained the most variance of the stiff-knee gait pattern criteria. The traditional measures (MAS, Ely-S and Ely-F) explained 28 % of the variance of the stiff-knee gait pattern criteria. Four measures from the pendulum test were entered into the model were: the magnitude of knee flexion occurring during the first swing of the pendulum test (A1), the duration of time knee movement occurred, the maximum knee flexion angular velocity, and the final resting position of the knee. These measures explained 47 % variance of the stiff-knee gait pattern; 19 % more of the variance above the first step. However, the only significant measure in the regression model was the A1 of the pendulum test. With the addition of the A1 measure, large decreases were demonstrated in the standardized Beta values and large

increases in p-value for the Ely-F test and Ely-S test indicating these measures were no longer significant in the model.

These results suggest a significant relationship between the clinical impairment measure (A1 measure of the pendulum test) and the stiff-knee gait pattern. The combination of a consistent application of force with a more objective measurement of knee motion by the three-dimensional motion analysis system are two likely reasons why the pendulum test explained more of the variance in knee patterns while walking compared to the more subjective assessments of quadriceps spasticity (MAS and Ely tests). The A1 of the pendulum test is a measure of the displacement of the knee during the first swing of the pendulum test. It is proposed the reason the A1 explained more of the variance in knee pattern compared to the other pendulum test measures was that four of the six criteria of a stiff-knee gait pattern were also measures of displacement of knee motion occurring during the gait cycle.

Although the above findings are interesting, they have limited clinical relevance. It is more important to know what combination of spasticity measures i.e., MAS, Ely-S, Ely-F, and the pendulum test, discriminate between a stiff-knee and a not-stiff-knee gait pattern of children diagnosed with CP.

Discriminant analysis functions were performed for each individual clinical measure of spasticity (MAS, Ely-S test, Ely-F test and the A1 measure from the pendulum test) to assess which could best predict group membership (stiff-knee, not stiffknee gait pattern) of subjects diagnosed with CP. The discriminant analysis function of the A1 demonstrated the highest accuracy (77 %) in correct classification of the original group as having a stiff-knee gait pattern. Therefore, the A1 measure of the pendulum test can provide clinicians a measure that can discriminate subjects with specific quadriceps spasticity resulting in stiff-knee gait pattern from those that may have a stiff-knee gait pattern due to other impairments. The A1 measure of the pendulum test was more sensitive than specific; indicating the A1 is better at ruling out the presence of quadriceps spasticity. If a clinician observes a stiff-knee gait pattern but a negative pendulum test as evident by more than 45-degrees of knee flexion during the first swing of the pendulum test, then the probability of quadriceps spasticity causing the stiff-knee gait pattern is not

greater than 10 %, and other causes for the stiff-knee gait pattern should be considered. It should also be noted that if the threshold value of A1 is increased, then the measure is more sensitive, and if the threshold value of A1 is decreased, then it is more specific. Therefore, the more an individual's knee flexes during the first swing of the pendulum test the less likely that individual will have a stiff-knee gait pattern

A three-dimensional (3-D) motion analysis system yielded reliable and discriminating results for the pendulum test. However, this technology is not available to all clinicians. Therefore, the third study was performed to determine if visual observation of the pendulum test is sufficient for clinicians to evaluate quadriceps spasticity when instrumentation is not available.

Because standard video data were not collected during the previous study, the EVaRT data were used for visual analysis of the pendulum test. The EVaRT data are a three-dimensional digital video recording of an individual performing the pendulum test represented as a 'stickperson'. On average, the four observers demonstrated good testretest repeatability for identifying less than or more than 45° of knee flexion for the A1 of the pendulum test suggesting that visual analysis of A1 may be acceptable.

For a repeatable test to be useful, it must also be accurate. Since the knee motions were also measured by the three-dimensional motion analysis system the observers' accuracy was also assessed. The average estimated probability of agreement between observers and the three-dimensional motion analysis system was 75 %. Because this moderate accuracy was noted for the four observers' visual assessment of the A1 measure could potentially be used to identify quadriceps spasticity and a stiff-knee gait pattern with minimal instrumentation of the subject.

Since the observers' demonstrated moderate accuracy and repeatability the discriminant analysis function was applied to each observer's assessment of A1. The four observers correctly identified 72-76% of the subject's gait pattern (stiff-knee, not-stiffknee), which is similar to the 80 % correctly classified with the motion analysis system. These results suggest that for those clinicians without access to a motion analysis system, visual assessment of the A1 measure of the pendulum test may be useful in identifying quadriceps spasticity. However, if the pendulum test is to be used to assess

changes in quadriceps spasticity before and after spasticity reducing interventions, then some type of equipment (video camera, electronic goniometer, electromagnetic or optical motion analysis system) is recommended to more accurately and objectively measure changes in the A1 of the pendulum test.

Nordmark & Anderson reported all pendulum measures for subjects with CP were closer to those of able-bodied subjects after undergoing a rhizotomy (a spasticity reducing intervention).⁴² That study provided face validity that the pendulum test is a measure of quadriceps spasticity. A three-dimensional motion analysis study is a functional analysis of a subject's ability to walk. The A1 of the pendulum test differentiated the degree of involvement of a stiff-knee gait pattern, a functional limitation of children diagnosed with CP. Therefore the results of these studies provide concurrent validity that the A1 measure pendulum test can correctly classify a stiff-knee gait pattern 77 % of the time. If clinical observation reveals characteristics of a stiff-knee gait pattern, then the pendulum test should be performed. The data from these studies support the idea that if a patient demonstrates an A1 of the pendulum test greater than 45 degrees, then spasticity of the quadriceps is not the cause of the stiff-knee gait pattern and other impairments should be assessed.

A cursory visual analysis of the quadriceps EMG data revealed 55 of 68 (81%) of the subjects demonstrated a burst of activity during the first swing of the pendulum test. To demonstrate construct validity that the pendulum test is a measure of both the neural component of spasticity (stretch reflex) and the non-neural component (chronic changes in musculotendonous tissues) of quadriceps spasticity these EMG data must be studied in a formal manner and combine with existing data.

Despite the moderate accuracy for visual analysis of the pendulum test, an objective measurement of the knee motions occurring during the pendulum test is recommended for confirmation. This would be consistent with reviews of the literature that suggest to improve best clinical practices, spasticity measures should be quantitative in nature, easy to implement with results that are readily and easily interpreted.^{23, 24} The pendulum test performed with a single video camera or other instrumentation methods will meet these criteria as a more objective assessment of quadriceps spasticity.

It has also been recommended that spasticity measures should be performed

using standardized, repeatable methods to develop more reliable measures of spasticity for clinicians and researchers.²³ Three important methodological procedures should be maintained to obtain similar results of these studies. First, a consistent starting position of maximum knee extension must occur. A yardstick attached to a small block of wood was used in these studies to consistently measure the heel to floor distance prior to initiating the pendulum test. Second, measurement of the knee flexion/extension should occur with some type of instrumentation. At minimum a single video camera should be placed perpendicular to the lateral knee to prevent perspective error. Third, if more than one trial is to be performed, then at least 30 seconds should pass to allow sufficient recovery of the stretch reflex. 35

Future research

There is controversy within the pendulum test literature regarding what the test measures. Some authors report the pendulum test to be a measure of quadriceps tightness,⁷⁴ while others report it is a measure of quadriceps spasticity.^{34, 42} More recently it has been proposed that the pendulum test assesses the dynamic component (quadriceps spasticity), the passive components (quadriceps elasticity) and input from the neuromuscular system (quadriceps tone) and is therefore an assessment of all three.^{36, 75}

Numerous articles from the biomechanical literature have reported using the pendulum test and computer modeling to better understand the hypothesized mechanisms causing the differences in pendulum test results between able-bodied subject and subjects with upper motor neuron disorders.⁷⁵⁻⁷⁹ A detailed description of these studies is beyond the scope of this manuscript. In general, to replicate the pendulum test results for subjects with upper motor neuron disorders, computer modeling required the addition of components that simulate the stretch reflex response of the quadriceps. When these active components of the quadriceps were added to the computer models, the models accurately simulated the pendulum test results of subjects with diagnosis of multiple sclerosis, cerebral palsy, status post cerebral vascular accidents and spinal cord injuries.^{75, 76, 78, 79} Therefore, future studies assessing the amplitude and onset of the quadriceps muscle activity will be required to provide construct validity that the pendulum test is a measure of both the neural component of spasticity (stretch reflex) and the non-neural component

(chronic changes in musculotendonous tissues) of quadriceps spasticity in subjects diagnosed with CP.

For most clinicians it is difficult to let go of a traditional measure, especially in the absence of a more reliable measure. However, this series of studies has assessed in detail a clinical measure that was first proposed over 50 years ago, but for reasons unknown has not been routinely implemented.

This series of studies results provide support that the A1 of the pendulum test is a valid, reliable, and objective measure of the stiff-knee gait pattern (a limitation of activity) for children diagnosed with CP. However, this is a nature of association between the gait pattern and the clinical measures of spasticity. Future studies to assess the results of the pendulum test and the outcomes pre- and post- spasticity reducing interventions (pharmaceutical, therapeutic and surgical) will be required before a cause and effect relationship can be established between the pendulum test and the knee gait pattern of children diagnosed with CP. The ultimate goal is to develop better prediction methods for interventions resulting in improved outcomes for children diagnosed with CP.

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APPENDICES

__ Consent Form

SHRINERS HOSPITALS FOR CHILDREN

LEXINGTON HOSPITAL

INFORMED CONSENT TO PARTICIPATE IN RESEARCH PROJECT OR STUDY

Participant:

Principal Investigator*:* Chester M. Tylkowski, MD

Co-Investigators*:* Hank White, Sam Augsburger, Tim Uhl, Donna Oeffinger, Christin Minter, Bobbie Edester and Dwana Knapp

Title of Project or Study: Three-Dimensional Motion Analysis of Two Pendulum Tests Used to Quantify Spasticity in Children with and without Cerebral Palsy

If you are acting on behalf of a child or adolescent, the words "you" and "your" as used in this explanation mean that child or adolescent.

You have been invited to participate in this research study.

Before you agree to participate, it is important that you read and understand the following information. It tells how and why the study will be done. It also tells about the benefits that could be learned from the study. Possible risks or things that may hurt or be uncomfortable are described and the different kinds of medical treatment that may also help you are explained.

It is important to know that no promises can be made about the results of the study. You can drop out of the study at any time and no one will be upset. Please ask questions about anything that you do not understand before deciding whether or not to participate.

1. PURPOSE:

I agree to the participation of __________________________________ in this study being conducted by Dr. Chester Tylkowski, and certain of his assistants. This study involves research and the investigators hope to:

- Learn about spasticity (stiffness) of leg muscles (quadriceps and hamstrings) in children with and without cerebral palsy by using two tests that measure how your legs swing when you are laying down on a bench, and one test will measure how your leg moves when someone bends and straightens your knee.
- Compare the information from these two tests to other regular measurements taken such as how far your legs move from one side to the other, how strong your legs are, how you walk and how much energy you use to walk.
- Learn whether the tests give the same results when you do them twice. For this part of the study, we will ask you to come back a second time and do these tests again.

You are being invited to take part in a research study about ways to measure spasticity in muscles. You are being invited to take part in this research study because:

You have muscle spasticity due to cerebral palsy.

 \Box You have no physical disability and you have volunteered to be part of a contrast group.

2. PROCEDURE:

If you agree to participate and you are being treated for cerebral palsy:

1. You will be asked to come to the Motion Lab at Shriners Hospital in Lexington one or two times. (These visits may be the same day as you come to see the doctor or it may be another day).

2. You will be asked to wear reflective markers to measure how your legs move. You will be asked to wear electrodes to measure your muscle activity. You will be asked to have special digital computer images taken of you lying down on a bench. The pictures they take will not look like normal photographs. Instead, the pictures will look similar to

"stick people" and are created from the reflective markers. This way, the pictures do not identify you.

You may also have pictures taken of you walking, standing and sitting, but these pictures are not part of the research study. We may use the other pictures that are taken for your regular clinical care to compare to the pictures we take for the research study.

3. The researcher will use two tests to measure your spasticity for this research study. For the first test, you will lie on your back and the researcher will hold your leg stretched out and then they will let go and see how your leg swings freely. For the second test, you will lie on your stomach and the researcher will hold your leg up and then let go to see how it swings freely.

4. You will be asked to come back to Shriners Hospital on another day and do the same tests again. This second visit will occur 4 to 12 weeks after your first visit. Each visit will take about 2 to 3 hours.

If you agree to participate as part of a contrast group:

1. You will be asked to come to the Motion Lab at Shriners Hospital in Lexington one or two times.

2. You will be asked to wear reflective markers to measure how your legs move. You will be asked to wear electrodes to measure your muscle activity. You will be asked to have special digital computer images taken of you lying down on a bench. The pictures they take will not look like normal photographs. Instead, the pictures will look similar to "stick people" and are created from the reflective markers. This way, the pictures do not identify you.

3. The researcher will use two tests to measure your spasticity for this research study. For the first test, you will lie on your back and the researcher will hold your leg stretched out and then they will let go and see how your leg swings freely. For the second test, you will lie on your stomach and the researcher will hold your leg up and then let go to see how it swings freely.

4. You will be asked to come back to Shriners Hospital on another day and do the same

tests again. This second visit will occur 4 to 12 weeks after your first visit. Each visit will take about 1 hour.

3. EXPERIMENTAL PROCEDURES:

Some of the procedures used in this study are used regularly to diagnose or treat the medical condition of cerebral palsy. Other procedures are not usually used for these reasons and they are considered to be experimental. The experimental procedures in this study are doing two tests to measure spasticity in the thigh muscles of children with and without cerebral palsy.

4. RISKS:

The risks or discomforts that we know about that you might experience as a result of participating in this research study are:

The risks of the study are minimal, no more than risks experienced in everyday walking and activities. There is the potential for slight skin irritation from the adhesive backing on the reflective markers (similar to risks from band-aids). In addition to the risks mentioned, you may experience a previously unknown risk or side effect.

5. DURATION:

If you are in the cerebral palsy group, the duration of your participation will last for approximately 4 to 12 weeks but you will only need to come to Shriners Hospital twice and each visit will take approximately 2 to 3 hours. If you are in the contrast group, the duration of your participation will last approximately 4 to 12 weeks but you will only need to come to Shriners Hospital twice and each visit will take approximately 1 hour.

6. ALTERNATIVES:

The following alternative procedures or courses of treatment are available that might be helpful to you:

For those in the cerebral palsy group, the spasticity tests are in addition to regular

standard gait analyses performed in the motion lab. Continued regular orthopaedic and medical treatment for cerebral palsy will be given whether you take part in the study or not. If you are in the contrast group, there is no alternative except not to participate in the study.

7. BENEFITS:

No promises are being made that you personally will benefit from this study. Possible benefits to you or to others that might result from this research are:

- An improved understanding of spasticity in cerebral palsy
- An improved understanding of how these 2 tests compare with other regular tests done in the motion lab for regular clinical care
- An improved understanding of the repeatability of doing these 2 tests over time

8. CONFIDENTIALITY:

Your participation in this study and your medical records will be kept confidential in accordance with applicable state and federal laws. Someone from the University of Kentucky, Kosair Charities, Inc. or Shriners Hospital for Children may look at or copy records that identify you. Anyone who looks at your records is required to keep them confidential. Otherwise, no information identifying you will be released without your permission unless it is subject to a subpoena or court order.

A statistical report of this research project or study, which may include slides or photographs that do not identify you, may be presented t a scientific conference or printed in a scientific paper.

9. QUESTIONS:

If you have any questions now, please ask us. If you have any questions later, please call Dr. Tylkowski or one of the other investigators listed at the beginning of this form at (859) 266-2101 or 1-800-668-4634.

You can contact the Office of Research Integrity at the University of Kentucky at (859) 257-9428 or 1-800-400-9428 for answers to questions you might have about research

and about your rights as a research participant.

10. STUDY RELATED INJURIES:

In the event of injury or undesirable reaction from participation in research-related activities, Shriners Hospitals for Children can only provide those medical services available at this Hospital. Shriners Hospitals will pay no financial compensation for children for a research-related injury or an undesirable reaction.

If you believe you are hurt or if you get sick because of something that is done during the study, you should call Dr. Tylkowski at Shriners Hospital for Children immediately (859- 266-2101). It is important for you to understand that the University of Kentucky and Kosair Charities will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study.

11. COMPENSATION:

Neither you nor your parents will receive any cash, gifts or other financial compensation for taking part in this study.

In the event of injury or undesirable reaction from participation in research-related activities, Shriners Hospitals for Children can only provide those medical services available at this Hospital. No financial compensation will be paid by Shriners Hospitals for Children for a research-related injury or an undesirable reaction.

You understand that in the event of injury resulting from the research procedures, no form of compensation (i.e. payment) is available from the University of Kentucky or Kosair Charities. Medical treatment may be provided at your own expense or at the expense of your health care insurer, which may or may not provide coverage. If you have questions, you should contact your or your child's insurer.

12. WITHDRAWAL FROM THE STUDY:

Your participation in this research study is voluntary. If you decide not to participate, there will be no penalty and you will not lose any benefits you would otherwise receive. If you change your mind after you volunteer for this study, you may withdraw from this study and stop participating at any time without penalty or loss of benefits you would otherwise receive. No one will be upset if you end your participation in this study. You will continue to receive your usual treatment at Shriners Hospitals for Children, Lexington Hospital.

There are no consequences to you if you decide to withdraw from this research study.

If you wish to withdraw from this study, please contact Dr. Tylkowski at (859) 266-2101.

13. GENERAL INFORMATION:

If the investigator feels that this study is not appropriate for you or that you have not followed directions for hospital tests or outpatient follow-up visits, you will be excluded from the study.

14. NEW FINDINGS

You will be informed of any new findings that develop during this study that may affect your willingness to participate or to continue to participate.

15. There will be approximately 250 participants involved in this study.

Your signature, below, will indicate that you have decided to volunteer as a research participant, that you have had an opportunity to ask questions and all of your questions have been answered, and that you have read and understood the information provided above. You will be given a signed copy of this informed consent form, which is yours to keep.

Assent Form

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SHRINERS HOSPITALS FOR CHILDREN LEXINGTON HOSPITAL

ASSENT TO PARTICIPATE IN A RESEARCH PROJECT OR STUDY

Participant: Principal Investigator: Chester M. Tylkowski, MD

Co-Investigators: Hank White, Sam Augsburger, Tim Uhl, Donna Oeffinger, Christin Minter, Bobbie Edester, Dwana Knapp

Title of Study: Three-Dimensional Motion Analysis of Two Pendulum Tests Used to Quantify Spasticity in Children with and without Cerebral Palsy

I, ______________________________, agree to participate in a study by Dr. Tylkowski and certain of his assistants to learn more about spasticity, or stiffness, of leg muscles in children with and without cerebral palsy. I understand that the researchers will use two tests that measure how my legs swing when I am lying down on a bench, and one test will measure how your leg moves when someone bends and straightens your knee. I also understand that the researchers would like to compare these tests to other clinical measurements taken in the motion lab. I also understand that the researchers want to see whether the tests give the same results when they are done twice which is why I will be asked to come back another time and repeat these tests. I understand that this information might help doctors in the future when treating other children with my same condition because they will have more information about spasticity in leg muscles of children with and without cerebral palsy.

For the study I will be asked to come to the Motion Lab and a researcher will place markers on my legs and hips. There will be cameras in the room that will take picture of my legs while I am lying on a bench. The pictures will not identify me and they will look similar to "stick people". The researcher will hold my leg up and let it fall freely. This should take about 1 to 3 hours on two separate days.

I understand that I can quit the study any time I want by telling any of the doctors or researchers.

I volunteer to participate in this study and am not being paid or given anything to sign this paper. I understand that if I do have any question about this study I can contact Dr. Tylkowski or one of the other investigators listed at the beginning of this form at (859) 266-2101 or 1-800-668-4634.

I will be given a copy of this paper.

Kinematic and Electromyographic data

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Electromyographic data was collected at 1000 Hz using Noraxon's TeleMyo 900 system **(**Noraxon U.S.A. Inc., Scottsdale, AZ) with surface silver-silver chloride electrodes (ConMed Corporation, Utica, NY). The muscle groups assessed were: the gluteus maximus, gluteus medius, medial hamstrings (biceps femoris), adductor longus, vastus medialis oblique, rectus femoris, anterior tibialis and gastrocsoleus.⁸⁰ Surface electromyography of the vastus medialis oblique, rectus femoris and the semitendinosis were collected to confirmed that the muscles were not active prior to each trial of the pendulum test. To assist the subject in relaxing his/her muscles the electromyography system was connected to a speaker to provide audio feedback of the muscle activity to each subject prior to performing the pendulum test.

Kinematic data collection

Surface reflective markers were placed on each subject following the standard gait analysis protocol (Cleveland clinic marker set). This marker set consists of 14 individual surface reflective markers and four marker triads. The individual surface reflective markers are placed directly on the subject's skin and are secured with $3MTM$ double stick discs. These markers were placed on the following boney landmarks: anterior superior iliac spine, posterior superior iliac spine, left posterior thorax, dorsum of the foot (at the third metatarsal head), posterior calcaneous, lateral epicondyle of the humerus, ulnar styloid of the writs, acromion of the shoulder. The four marker triads were secured with Coflex® to the distal third of the lateral thigh and the distal lateral shank of each leg. The surface reflective markers allowed us to measure the movement of the subjects' limbs when walking and performing the pendulum test. Based on the link segment model, kinematic data of the pelvis, hips, knees and ankles were calculated while walking. Two of the key assumptions of the link segment model are: the body segments are rigid, and linked to one another through a joint whose rotation is assumed to take place about a fixed point in the proximal segment.

After placement of the surface electrodes and surface reflective markers, each individual was allowed up to five minutes to adjusting to walking while wearing the

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surface electrodes and reflective markers. Each subject then walked several times along a 30'walkway in the motion laboratory for data collection (a minimum of three strides of data were collected).

Each subject participated in the pendulum test. Because the subject lies supine to perform the pendulum test, the Cleveland clinic marker set was modified so the OrthoTrak software could calculate the knee motions during the pendulum test. The subject stands while the two ASIS markers were placed on the mid-point of each respective iliac crest directly above the greater trochanter. The PSIS marker was then placed over the umbilicus. The distance from the reflective marker on the iliac crest to the greater trochanter and from the right iliac crest marker to the left iliac crest marker were recorded. These measurements were later used to calculate the new hip joint centers(see kinematic data processing).

To perform the pendulum test for this series of studies, each subject was positioned lying comfortably on a bench (seat to floor height 30 inches) so the posterior calf did not contact the bench when the knee was in maximum knee flexion. This was performed to ensure that the mat did not impede maximum knee flexion. To allow for consistent positioning of each subject the distance from the popliteal fossa to the edge of the mat was measured and used for both data collection days. If excessive hip rotation was noted during the practice trials, a small towel was placed under the distal third of the femur to decrease hip rotation. The examiner positioned the subject's leg in maximum knee flexion. To control the starting position of the test the distance from the heel of the foot to the floor was measured for the first trial, and the same was used for all trials on both data collection days. Prior to each trial, the subject was instructed to let the leg swing freely once it is released by the examiner. One to three practice trials were performed prior to data collection. Data collection with the motion analysis system was initiated approximately one second before the examiner released the subject's foot. After the subject's leg came to rest, at least thirty seconds passed before the next trial was performed. During data collection, the test was repeated if excessive quadriceps activity was noted or if it appeared to the examiner the subject was assisting or resisting the knee motions. The procedures were repeated until three trials (without interference) of each leg were obtained for each subject.³⁷ At least 4 weeks later the subjects returned for a

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repeat study. The order for data collection (right leg versus left) was randomized.

Kinematic data while walking and performing the pendulum test were collected at 60 Hz during walking trials using a Motion Analysis Corporation Real Time System (EVaRT 4.4.4) with eight Eagle digital cameras and OrthoTrak 6.24 software is used to reduce and plot kinematic data (Motion Analysis Corporation, Santa Rosa, CA).

Kinematic data processing

The raw kinematic data were filtered using a Butterworth filter at 6 Hz using the EVaRT 4.4.4 software. The data were then processed using OrthoTrak 6.24 software was used to reduce and plot kinematic data. The segmental angles of the thigh and shank (relative to the horizontal) were calculated using the law of cosines. The relative knee joint angles were calculated by subtracting the angle of the proximal segment (thigh) from the angle of the distal segment (shank).

OrthoTrak 6.24 is a software package used for gait analysis. For the OrthoTrak software to calculate the joint angles of each body segment at least one gait cycle (right heel strike to right heel strike) must identified. Because the data for the pendulum test were collected for a standard length, the five events were artificially applied so these data could be averaged across time. The knee kinematic data of the pendulum test generated from the OrthoTrak software were then exported as an ASCII file. Each ASCII file was then converted to an excel file. Each excel file was used to calculate and plot the knee joint motions as kinematic graphs for the pendulum tests.

The knee kinematic data while walking and while performing the pendulum test were plotted on graphs for visual analysis. For the walking trials, the horizontal axis was the gait cycle and the magnitude of knee flexion and extension was plotted on the vertical axis. For the pendulum trials, the horizontal axis was time and the magnitude of knee flexion extension was plotted on the vertical axis.

The Cleveland clinic marker system uses standard percentages to calculate hip joint center from ASIS markers. The standard hip joint centers were calculated using 21 % in the X- posterior direction, 32% in the Y- lateral direction, and -34 % in the Zvertical direction from the mid-point between the ASIS markers. ⁴¹ Typically, these percentages are not adjusted in gait studies, unless there is a lot of adipose tissue resulting in the ASIS markers not being near the ASIS. In these situations, the distance from

one ASIS marker to the other is measured. The vertical distance from each ASIS marker to the greater trochanter is also measured. From these measurements, a new calculation is made to estimate the location of the hip joint center relative to the ASIS markers.⁴¹ The distance from the left "ASIS marker" (which was actually on the left iliac crest) to the right "ASIS marker" (which was actually on the right iliac crest), and the vertical distance from each "ASIS marker" to the ipsilateral greater trochanter were used to calculate the new hip joint centers during the pendulum test. The hip joint centers were calculated based on the averages of the ASIS measurements of 20 subjects. The new hip joint centers calculated and used for the pendulum data were: 1 % in the X- anterior direction, 22.8 % in the Y- medial direction, and - 50.2 % in the Z- vertical direction from the "ASIS markers".

Appendix D

Observer's instructions for performing visual analysis of the pendulum test using EVaRT5.O.3 Introduction

The stiff-knee gait pattern has been reported to be the most common gait abnormality for children diagnosed with cerebral palsy (CP). By using 3-D motion analysis system to measure knee motions that occur during the pendulum test we have successfully explained forty-six percent of the variance of the stiff-knee gait patterns of 68 children diagnosed with CP. The magnitude of knee flexion occurring during the first swing of the pendulum test revealed an overall accuracy of 77% to correctly classifying the participants as having a stiff- or not-stiff-knee gait pattern. The sensitivity (if a person has a disease, how often will the test be positive [true positive rate]) of the measure was 87 % and the specificity (if a person does not have the disease how often will the test be negative [true negative rate]) was 68 %. I believe that therapists in clinical practice might be able to detect these restrictions in the knee motion without the 3-D motion devices. The purpose of this study is to determine if clinicians can identify from video those with and those without restricted knee motion during the pendulum test.

During the pendulum test the knee is passively extended by the examiner and then the leg is released and allowed to freely swing. If no upper motor neuron involvement is present; the knee typically demonstrates six or seven oscillations of flexion and extension; with each oscillation demonstrating a smaller arc of motion. To see a video of an able-bodied child performing the pendulum test go to **MPEG2.MPG**. If upper motor neuron involvement is present the knee motion is dramatically altered. To see a video of a child diagnosed with CP performing the pendulum test, go to [MPEG3.MPG.](#page-138-0)

By using our standard set up and software the motion analysis system generates a three-dimensional video of each child performing the pendulum test. These videos can be further processed with other software to measure the knee motion occurring during these activities. These videos can also be played back on a computer monitor at real time speeds to visually assess the knee motions occurring during the pendulum test. To see a video of a 'stick person' of an able-bodied child performing the pendulum test go to [MPEG4.MPG.](#page-138-0) To see a video of a 'stickperson' of a child diagnosed with CP

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performing the pendulum test, go to [MPEG5.MPG.](#page-139-0)

The purpose of this study is to see if clinicians can visually estimate the amount of knee flexion occurring during the first swing during the pendulum test. Two persons who are familiar with 3-D motion analysis software and 2 persons who are not familiar with 3- D motion analysis software will observe the collected data of children performing the pendulum test. You will be asked to determine if the knee flexes less than or greater than 45° during the first drop.

To visually analysis pendulum data

Double click on "EVaRT5.O.3" icon on desktop.

(At the top left corner of the computer screen) Select 'File'

Load project

Look in: P:\Hank\ **examples (folder)** Select **RTgait4p.prj <open>**

Select 'File'

Load calibration

Look in: P:\Hank**examples (folder)**

Select **RT5calibration.prj** <open>

Select 'File'

Load tracks file

Use the pull-down menu

Look in: P:\Hank**examples (folder)**

Select **NORMAL.trb <open>**

The first time you open Evart the stick man will look something like this:

You will be required to adjust the view each trial before you analyze the knee motion occurring during the pendulum test.

To familiarize yourself with how to adjust the view:

Adjust view by placing mouse curser anywhere in the screen near the stickman:

First, Make the stick man turn around 180 degrees so the left leg (green leg) is closest to you (feet are on left hand side of computer screen).

- 1) Place mouse curser on any purple square.
- 2) Select Control+Alt+Left mouse buttons, Hold all three buttons down at once
- 3) Move the curser/Mouse to the left and the view should rotate until the green leg is closer to you.

Next, make adjust the view so you are looking at the stickman directly from the side. This is done by lining up stickman so the top ball of the left thigh/knee covers the top ball of the right thigh.(Therefore, the right thigh top ball can not be seen.)

To adjust the tilt of the view:

- 1) Place mouse curser on the right side of the screen on any purple square.
- 2) Select Control+Alt+Left mouse buttons, Hold all three buttons down at once
- 3) If you move the curser/mouse straight down, then the view should tilt so it looks like you are over top of stickman. If you move the curser/mouse straight up, then the view should tilt so it looks like you are under the stickman.

Adjust how far away stick man is so you can see 2 - 2 1/2 white squares past xyz coordinate. The xyz coordinate looks like this:

To make the stickman bigger/smaller

- 1) Place mouse curers on any square near the stickman.
- 2) Select Control+Alt+Left+Center mouse buttons, Hold all four buttons down at once
- 3) If you move the curser/mouse straight down, then the view should change so the stickman gets closer. If you move the curser/mouse straight up, then the view should get smaller, so the stickman looks further away from you.

Last, you can adjust the view so the Stickman is in center of screen.

To move the stickman to the center of the screen:

1) Place mouse curers on any square near the stickman.

- 2) Select Control+Alt+Center mouse buttons. Hold all three buttons down at once.
- 3) If you move the curse/mouse straight up, then the view should change so the stickman moves straight up. If you move the curser/mouse straight down, then the view should change so the stickman moves straight down. If you move the curser/mouse to the left, then the view should change so the stickman moves to the left. If you move the curser/mouse to the right, then the view should change so the stickman moves to the right.

Before beginning each trial the stickman should look very much like this:

To orient you to the stick person, starting from the bottom left the markers are placed on the following surface land marks:

1 lateral foot at the $5th$ metatarsal

2 lateral heel

3 three markers on the lateral shank

4 three markers on the lateral thigh

5 lateral crests of the pelvis, the umbilicus, an extra marker identifying the left side of the trunk

6 shoulder, elbow, wrist

(FYI, when watching a video play, the knee appears to be at one of the markers attached to the thigh.) To assess the knee motion, you should focus on the #3 marker set and on the person's lower leg, or the change in the knee angle at the #4 marker set. Note: You may accidentally identify a marker while adjusting the view of the stick person. When this occurs, the marker will have a box around it and as the marker

moves a trail will follow the marker. You will also notice in the right window the marker name is highlighted in color. At the top of the right window it says "Click: All/None". By clicking on these words the marker box and trail should disappear.

Familiarize yourself with how to start and stop video

 Use the mouse curser to "Click on" black arrow (play forward) at bottom of screen. The video will continuously run and each trial is 15 seconds in length. The same trial will be repeated each time.

To stop the video "click on" the same location. However, now the button looks like this square:

Children with CP can demonstrate many different knee patterns and motions.

However, we are going to focus on assessing one thing:

1) Does the leg falls less than 45 degrees during the first swing of the pendulum test?

Play each of the following examples to see how the leg can move differently for children with CP.

In the folder entitled **'examples'** are example files to view using the EVaRT5.O.3 software:

Select 'File'

Load tracks file:

Less 45.trb is an example of a leg that falls less than 45 degrees. Therefore, you would record "Y" on answer sheet.

More45.trb is an example of a leg that falls 45 degrees or more during the first swing of the pendulum test. Therefore, you would record "N" on answer sheet.

Difficult.trb is a leg that is difficult to call. However, the leg does fall more than 45 degrees, therefore the answer recorded would be "N'.

Once you have familiarized yourself with the EVART software you may take the pre-test.

To visually analysis pendulum data

Double click on "EVaRT5.O.3" icon on desktop

Select 'File'

 Load project Look in: P:\Hank\ **reviewer test (folder)** Select **RTgait4p.prj <open>**

Select 'File'

 Load calibration Look in: P:\Hank**reviewer test (folder)** Select **RT5calibration.prj** <open>

'File'

Load tracks file

Look in: P:\Hank**reviewer test (folder)**

Select the first subject in the folder **4367392Lquad2.trb <open>**

You may let the video play a maximum of two times. You can not stop/pause the video until you have completed your assessment of that subject.

Note the red line moving across the screen above the arrow (insert picture) You should begin preparing for the trial to repeat when this line is at 800-850.

Remember, you are trying to assess the amount of knee motion occurring during the test. Therefore, the markers you should focus on are the three triad markers (#3 marker set) on the subject's shank, or the change in the knee angle at the #4 marker set.

DO NOT focus on the foot/ankle makers because the foot may move after the leg has stopped moving.

From the first or second time the video loop plays, answer the following question on your answer sheet

If the leg **falls less than 45 degrees** during the first swing, then mark **"Y"** on answer sheet.

If the leg **falls 45 degrees or more** during the first swing, then mark **"N"** on the answer sheet.

Remember: The red line moving across the screen above the arrow (insert picture) You should begin preparing for the trial to repeat when this line is at 800-850.

Stop the video after the trial has played a maximum of two times by "clicking on" the square:

Write the day the data was reviewed.

Please write comments as needed: I.e., not certain of answer, very certain of answer, or anything unusual noted during the trial.

Remember: **Stop the video before loading the next subject.**

To load next subject:

Select 'File'

 Load tracks file **4370861Lquad2.trb <open>**

NOTE: **You may need to make minor adjusts to re-center the stickman in the middle of the screen, and the top green ball of the left leg covers the top red ball of the right leg.**

Answer the question on your answer sheet *Remember:* **You can play each trial a maximum of two times.**

Remember: **To stop the video before selecting the next subjects**

Repeat with each subject

TO close EVaRT5.O.3 program

Click black X in top right hand corner of computer screen A Confirm exit window will open Select "yes, exit the program"

You must correctly answer each question for 4 of the 5 subjects. If you do not, you may re-take the test up to 3 times.

Once you have successfully passed the training examination you will review 50 subjects for the study.

You may do up to 25 subjects in one session.

To prevent fatigue, you must wait at least 30 minutes before beginning the next session.

To open the data:

Select 'File'

 Load project Look in: P:\Hank\ **Left2 (folder)** Select **RTgait4p.prj <open>**

Select 'File'

 Load calibration Look in: P:\Hank**Left2 (folder)** Select **RT5calibration.prj <open>**

'File'

 Load tracks file Look in: P:\Hank**Left2 (folder) 4150263Lquad2.trb <open>**

At least 1 week later and no later than three weeks later, you will review 20 subjects to assess your repeatability of observing the pendulum test.

To open the data

Select 'File'

 Load project Look in: P:\Hank**Repeat (folder)** Select **RTgait4p.prj <open>**

Select 'File'

 Load calibration Look in: P:\Hank\ **Repeat (folder)** Select **RT5calibration.prj <open>**

'File'

Load tracks file

Look in: P:\Hank**Repeat (folder)** Select **4150263Lquad2.trb <open>**

Cheat sheet for adjusting view of the stickman:

 $Control+Alt+Left$ mouse \Rightarrow adjust tilt and rotates the view

Control+Alt+Leftmouse+center mouse => adjust how far or close stickman is

Contrl+Alt+Center mouse \Rightarrow adjust view up/down or left/right

Appendix E

Data collection Sheets

Name __________________ Study number _____________________

Date __________________

__

Measurements for Spasticity study

Quantify Spasticity Data Collection/Reduction Sheet

Data collected by:

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VITA

Henry Dulin White II, MSPT

Date of birth: April, 1965 Place of birth: Lexington, Kentucky

Education

Washington University School of Medicine, St. Louis, Missouri. Masters of Science of Physical Therapy, August 1991- December 1993.

University of Kentucky, Lexington, Kentucky. Bachelor of Science in Animal Science, August 1983 - December 1987.

Professional Positions

Shriners Hospitals for Children, Physical therapist, June 1994 – present

Shriners Hospitals for Children, 1999, Senior physical therapist

Central Baptist Hospital (employer Lexington Physical Therapy), Physical therapist January 1994 - June of 1994

Scholastic and Professional Honors

2004 Recipient of University of Kentucky Department of Physical Medicine and Rehabilitation 16th Annual Research Day "Best Student Research" Award and "Best Poster" Award

Publications - Manuscripts

White H, Uhl T, Augsburger S, Tylkowski C: "Reliability of the three-dimensional pendulum test for able-bodied children and children diagnosed with cerebral palsy," Gait and Posture, 26(1): 97-105, 2007.

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Henry D. White, II

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