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UNIVERSITY OF CALIFORNIA, SAN DIEGO

Augmenting Subjective Assessments with Objective Metrics for Neuromuscular

Disorders

A Thesis submitted in partial satisfaction of the requirements

for the degree Master of Science

in

Electrical Engineering (Communication Theory and Systems)

by

Saisri Padmaja Jonnalagedda

Committee in charge:

Truong Nguyen, Chair

Harinath Garudadri

Tse Nga Ng

Ramesh Rao

2017

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Chair

University of California, San Diego

2017

DEDICATION

I dedicate this work to –

My family, who supported my every endeavor unconditionally;

To my gurus, who made me what I am;

**To the energy of the universe that we call God, whose support I had through thick
and thin;**

And to science, in hopes that this work would be of use to many.

EPIGRAPH

Learn how to see. Realize that everything connects to everything else.

-Leonardo da Vinci

Everything should be made as simple as possible, but not simpler.

-Albert Einstein

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LIST OF ABBREVIATIONS

CP.....	Cerebral Palsy
MS.....	Multiple Sclerosis
TBI.....	Traumatic Brain Injury
SCI.....	Spinal Cord Injury
MAS.....	Modified Ashworth Scale
MTS.....	Modified Tardieu Scale
HAT.....	Hypertonia Assessment Tool
GMFCS – E&R.....	Gross Motor Classification System Expanded and Revised
EMG.....	Electromyography
H-Reflex.....	Hoffman reflex of the Soleus muscle
BTA.....	Botulinum Toxin (Botox)
ITB.....	Intrathecal Baclofen
SDR.....	Selective Dorsal Rhizotomy
COTS.....	Commercial, Off The Shelf
IMU.....	Inertial Measurement Unit
FFT.....	Fast Fourier Transform
LPC.....	Linear Predictive Coding

DWT.....Discrete Wavelet Transform

DTW.....Dynamic Time Warping

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Chapter 2, in full, is a reprint of the material as it appears in the Healthcare Innovation Point-Of-Care Technologies Conference (HI-POCT), 2016 IEEE titled “An instrumented glove for improving spasticity assessment”; Jonnalagedda, Padmaja, Fei Deng, Kyle Douglas, Leanne Chukoskie, Michael Yip, Tse Nga Ng, Truong Nguyen, Andrew Skalsky, and Harinath Garudadri. The Thesis author was the first author of this paper.

Chapter 4, in part is being prepared for submission for publication. The Thesis author and Fei Deng are among the authors for the same.

ABSTRACT OF THE THESIS

Augmenting Subjective Assessments with Objective Metrics for Neuromuscular
Disorders

by

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Master of Science in Electrical Engineering (Communication Theory and Systems)

University of California, San Diego, 2017

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Spasticity is a debilitating neuro-muscular disorder which is characterized by involuntary muscle movements and stretch reflexes. There is a large population of the world who suffers with spasticity due to various diseases like Cerebral Palsy, Multiple Sclerosis, Spinal Cord Injury, Traumatic Brain Injury etc. The diagnosis standards of spasticity for treatment prescription are highly subjective, most of them either heavily

based on the clinicians' "feel", on voluntary movements by patients or mounting sensors on patients with no defined correlation to the assessment standards. Hence, they have high inter- and intra-rater variability. Spasticity is diagnosed every few weeks whereas extent of spasticity can vary more frequently. Thus, a subjective assessment which does not account for the dynamic nature of spasticity is not a good measure for treatment. Moreover, the account of patients and their family affect the treatment as well. Treatment effectiveness and costs can vary highly based on inaccurate assessment. This calls for a dire need of an objective, consistent and repeatable scale for spasticity assessment. For this purpose, we have developed an instrumented glove in hopes that it will give such an assessment. The research of this Thesis describes the development of this glove, the algorithms to obtain an assessment measure and techniques to validate said glove.

We also intend to make this glove so it instruments the clinicians or raters rather than the patients. This comes out of a consideration of both convenience to the patients and their finances.

1. INTRODUCTION

This chapter discusses what spasticity is, its symptoms, causes, diagnosis and reasons/developments that lead to the research in this Thesis. At the end of the chapter, I discuss the organization of the Thesis.

1.1 What is spasticity?

Spasticity is a neuro-muscular disorder characterized by an increase in muscle-tone or stiffness of the limbs. It often occurs in patients with problems like Cerebral Palsy (CP), Multiple Sclerosis (MS), Traumatic Brain Injury (TBI), Stroke, Spinal Cord Injury (SCI), Paralysis etc. It is typically caused by damage in the part of brain and/or spinal cord which is responsible for motor control. It affects 764,000 people and is diagnosed in two to three live births out of every 1,000 in the United States [2]. The pharmaceutical industry spends billions of dollars developing drugs to relieve spasticity, but these efforts are stymied by the lack of repeatable, objective metrics to quantify the outcomes; excessive dosage of drugs to treat spasticity can cause severe side effects such as such as seizures, blurred vision, and severe rashes, while inadequate dosage is ineffective at treating spasticity [1].

It is estimated that spasticity affects more than 12 million people around the world. About 80 percent of people with CP and MS have spasticity (of varying degree). Since an estimated 500,000 people in the United States suffer with a form of CP, this means about 400,000 people suffer from some degree of spasticity. Similar statistics for MS show an estimated 400,000 people in the United States with MS and hence 320,000 people with some degree of MS-related spasticity [4]. Paresis and signs like increased stretch reflexes that occur with spasticity are collectively

referred to as upper motor neuron syndrome. Paresis particularly affects distal muscles, with reduced ability to perform fractionated movements.

Damage to the motor pathways at cortical, brainstem and spinal cord levels cause the upper motor neuron syndrome, justifying the neurophysiological aspect of spasticity. The interval between injury and the appearance of spasticity varies from days to months according to the level of the injury.

Pathophysiology

The pathophysiologic basis of spasticity is incompletely understood. Polysynaptic responses may be involved in spinal cord-mediated spasticity, while enhanced excitability of monosynaptic pathways is involved in cortically mediated spasticity [3].

As discussed, the damage in cortical and spinal cord levels alters the balance of inputs from the descending pathways of motor control and spinal cord neurons. This causes the change and involuntary behavior of muscle tone. Subsequently, the muscles develop physical changes like shortening and contribute further to stiffness.

1.2 Symptoms of spasticity

Spasticity often has the following symptoms: [3], [4]

- Increased muscle tone
- Overactive reflexes
- Involuntary movements, which may include spasms (brisk and/or sustained involuntary muscle contraction) and clonus (series of fast involuntary contractions)
- Pain
- Decreased functional abilities and delayed motor development
- Difficulty with care and hygiene

- Abnormal posture
- Contractures (permanent contraction of the muscle and tendon due to severe persistent stiffness and spasms)
- Bone and joint deformities
- Clonus
- Weakness
- Clasp-knife phenomenon
- Hyperreflexia
- Babinski sign
- Flexor reflexes
- Flexor spasms

Loss of descending tonic or phasic excitatory and inhibitory inputs to the spinal motor apparatus, alterations in the segmental balance of excitatory and inhibitory control, denervation supersensitivity, and neuronal sprouting may be observed. [3]

1.3 Diagnosis

There are many methods to diagnose spasticity. There are clinical scales, which basically are based on a doctor's "feel" of the patients' stiffness. Therefore, these methods are very subjective. Clinical methods of assessment include:

1. Ashworth and Modified Ashworth Scale
2. Tardieu and Modified Tardieu Scales
3. Hypertonia Assessment Tool
4. Composite Spasticity Scale
5. Gross Motor Function Classification System - Expanded & Revised (GMFCS - E&R)
6. King's Hypertonicity Scale

Secondly, there are neuro-physiological assessment tools which are inclusive of the neurological aspect of spasticity. These methods don't always correlate to the actual level of spasticity even though the measurement correlation is usually high. These methods also often rely on voluntary motion by patients which is an undesirable property in assessment as the patients may or may not move to their full extent and this might cause them inconvenience. Some neurophysiological assessment tools are as follows:

1. Electromyography
2. Tonic stretch reflex testing
3. H-reflex

The third type of assessment tools are biomechanical tools. These are machines or use some mechanical tools to assess spasticity. Some of these methods are:

1. Myotonometer
2. Wartenberg Pendulum Test
3. Three-dimensional pendulum test
4. Dynamometry
5. Measures using goniometry
6. Inertial sensors
7. Stiffness tool with robotic-assisted gait orthosis

These methods are described and analyzed in detail in the following section.

1.4 Prior work

Spasticity is a velocity dependent neuro-muscular disorder characterized by muscle tone [17]. There are many assessment tools for spasticity assessment. Broadly, they are divided as (i)

Clinical assessment tools (ii) Neurophysiological assessment tools and (iii) Biomechanical assessment tools. Each of these methods is described and analyzed in the following text.

Among the clinical assessment tools, the following have been proposed. The common problem with these are their subjective nature as they depend on feel and not hard measurements.

a) Ashworth and Modified Ashworth Scales:

Description: The Ashworth scale (AS) is a 5-point scale and the Modified (MAS) scale is a 6-point scale to account for catch-no catch (1 and 1+) [7]. Both AS and MAS assessments are done by moving the limb of the patient and the resistance “felt” by the doctor is reported as rating.

Pros: MAS is the most widely used metric on account of its simplicity.

Cons: MAS is a highly subjective rating [8-10]. It has high inter- and intra-rater variability [16, 26]. It has also been claimed that MAS does not consider the velocity aspect and only captures resistance to passive movement [11, 12]. It does not distinguish between neural and non-neural causes of resistance [11]. Considerable research has been put into understanding spastic models [13, 14], yet none address developing an objective metric.

b) Modified Tardieu Scale (MTS):

Description: The MTS scale measures spasticity over three speeds on a 6-point scale. MTS considers the strength and duration of the stretch reflex; the angle at which the stretch reflex is activated; the speed necessary to trigger the stretch reflex. The angle for catch (using goniometers) at high velocity stretch and the angle for full passive range at slow velocity stretch responses are measured [15]. Thus, it considers the velocity aspect of spasticity. It is suggested as the more appropriate metric over MAS because of this [11, 15].

Pros: The MTS performs better in case of intra and inter-rater reliability than MAS [16].

Cons: It's inter-rater reliability is still not very good [16, 25]. Even though it is closer to actual description of spasticity given by Lance [17], the MTS is still subjective in nature. This is proven by change in variability (both) before and after training of raters [18]. It is less popular than MAS because MAS is simpler.

c) Hypertonia Assessment Tool (HAT):

Description: The HAT is a 7-item assessment tool: for spasticity (2 items), dystonia (3 items) and rigidity (2 items).

Pros: HAT has intermediate variability (less than MTS and in some cases, less than MAS).

Cons: It is basically a binary rating confirming presence or absence of that subtype. The procedure is fairly more complicated than the above two tools [19]. The variability comparison (in pros) doesn't make much sense because the HAT only gives binary assessment unlike MAS and MTS.

Note: "Spasticity" is defined as hypertonia in which 1 or both the following signs are present: 1) resistance to externally imposed movement increases with increasing speed of stretch and varies with the direction of joint movement, and/or 2) resistance to externally imposed movement rises rapidly above a threshold speed or joint angle. "Dystonia" is defined as a movement disorder in which involuntary sustained or intermittent muscle contractions cause twisting and repetitive movements, abnormal postures, or both. "Rigidity" is defined as hypertonia in which all of the following are true: 1) the resistance to externally imposed joint movement is present at very low speeds of movement, does not depend on imposed speed, and does not exhibit a speed or angle threshold; 2) simultaneous co-contraction of agonists and antagonists may occur, and this is reflected in an immediate

resistance to a reversal of the direction of movement about a joint; 3) the limb does not tend to return toward a particular fixed posture or extreme joint angle; and 4) voluntary activity in distant muscle groups does not lead to involuntary movements about the rigid joints, although rigidity may worsen. [23]

d) Composite Spasticity Scale (CSS):

Description: It is a mixture of 3 measures: i) A 5-point scale to measure Achilles tendon jerk; ii) A doubly weighted 8-point MAS for full scale passive stretch reflex and iii) A 4-point scale to measure clonus. The final assessment is the sum of all three measures. Thus, CSS ranges from 0-16.

Cons: There have been no studies on inter and intra rater variabilities of this scale [20] and its occurrence in literature isn't as prominent as other scales. It is not actively used clinically. There is nothing specific about speed variations.

e) Gross Motor Function Classification System - Expanded & Revised (GMFCS - E&R) [24]:

Description: The Gross Motor Function Classification System - Expanded & Revised (GMFCS - E&R) is a 5-level classification system that describes the gross motor function of children and youth with cerebral palsy based on their self-initiated movement with particular emphasis on sitting, walking, and wheeled mobility.

Cons: It is a highly descriptive measure based on a self-report questionnaire which adds a high amount of bias. The focus of the GMFCS - E&R is on determining which level best represents the child's or youth's present abilities and limitations in gross motor function. Emphasis is on usual performance in home, school, and community settings. There is no

provision to include judgement about quality of movements or scope of improvement. This method also focuses only on the age group of 12-18 years.

The neuro-physiological tests use some sensors to get measurements. There is some consistent disadvantage that all these tools display. They instrument the patient and they do not have a defined translation to *extent* of spasticity. All the neurophysiological tools and their variants are not commonly used since literature does not back these methods up with a direct correlation to level of spasticity [21, 22]. None of these methods correlate to spasticity levels and merely give measurements of passive reflex threshold, velocities and stretch angles

The following are the neuro-physiological tools:

a) Electromyography (EMG):

Description: In EMG, recordings are obtained at joints like ankles. Patients are made to perform maximal isometric voluntary contractions and the measurements, co-contraction ratios and mean torque are measured.

Pros: For the above measurements, results show less variability [21].

Cons: The biggest disadvantage of this method is that the patient is instrumented with sensors like loadcell etc., and the patients are asked to perform voluntary motions. Sensors on their bodies become cumbersome and inconvenient for the patients. At the same time, asking patients to perform voluntary motion while they suffer from muscle stiffness may cause pain or difficulty to the patients and in addition, may cause less accurate readings.

b) Tonic stretch reflex testing:

Description: This method uses motors at various joints of the patients. Then, the torque and additional EMG measures are taken.

Cons: Even this method requires voluntary motion by the patient and patient is instrumented.

c) Hoffman reflex of the Soleus muscle (H-reflex):

Description: The H-reflex is basically the electrical analog of a stretch reflex. It essentially stimulates the soleus fibers (calf muscles). Low and high intensity of stimulus activates the motoneurons to generate a reflex response (H-wave) and direct activation (M-wave) of the soleus respectively. Ratio of max amplitudes of H and M gives level of spinal excitability.

Pros: The variability is low.

Cons: No defined correlation to spasticity.

Many biomechanical assessment tools were proposed in order to measure or quantize the level of spasticity.

a) Myotonometer:

Description: Myotonometer is a portable electronic device capable of measuring the amount of muscle-tissue displacement per unit force applied using a linear array of transducers [27-29].

Cons: It requires a voluntary motion from the patient which would have variance between different patients. Moreover, patients with serious injury or disable may not able to produce such voluntary motion. [35]

Some studies claim correlation to be significant but are a maximum of -60% (significant negative correlation) [34] [36] or are not in the spasticity range [37].

b) Wartenberg pendulum test:

Description: It can record the activity of the leg during swing [30]. It initially started as a qualitative measurement with doctor simply observing the swing of patient's foot. Now, it is improved by use of electric goniometers (angle measurement sensors) or 3D motion analysis systems. The doctor holds the foot of the patient at full extension of leg, then drops the leg and the computer records motion and vibration [38].

Pros: In the trials it has been tested, it showed high inter-rater correlation and shows promise that it can differentiate between some levels of spasticity [39].

Cons: Despite the promise, the current correlation to various levels of spasticity is weak [40] and the application of this method to the target population is debatable [38]. In addition, it can only work for the leg, and it is not suitable for other part of the body.

- c) **Dynamometry:** It can record the force and velocity during passively stretched motion. There is an experiment tries to correlate the torque during motion with the slope of work methods of spasticity [31]. Inertial sensor can record the angular position and angular velocity during the muscle flexion and extension [32].

Cons: There are not enough experiments that show how the measurements correlate to standards of spasticity. The amount of force used to perform such motion is an important aspect for spasticity assessment, and such sensor is not recording it.

- d) **Robotic-assisted gait orthosis:** It is implemented for measure the stiffness by produce torque to knee and hip [33]. The same study refers to this method as “not sensitive enough” for spasticity assessment. It also is not financially feasible just for assessment.

1.5 Treatment

Treatment types are evaluated on a case to case basis. This evaluation depends on the underlying cause and severity of spasticity as well as the age of patient [4]. The common goals of treatment are:

1. Relieving the signs and symptoms of spasticity
2. Reducing the pain and frequency of muscle contractions
3. Improving gait, hygiene, activities of daily living and ease of care
4. Reducing caregiver challenges such as dressing, feeding, transport and bathing
5. Improving voluntary motor functions involving objects such as reaching for, grasping, moving and releasing
6. Enabling more normal muscle growth in children

There are many different methods of treatment:

Physical and Occupational Therapy

Physical and occupational therapy for spasticity is designed to reduce muscle tone, improve mobility and alleviate pain. It comprises of stretching and strengthening exercises, casts, braces, cold pack applications or electric stimulations.

Oral Medications

When effects of spasticity affect day to day activities, oral medications are prescribed. For these to be effective, they can be suggested in combination with some other forms of treatment. It is essential that the patient or their family work closely with their clinician to devise a personalized treatment plan. If not, the side effects may be huge.

Medications include:

1. Baclofen
2. Benzodiazepines
3. Dantrolene sodium
4. Imidazolines
5. Gabapentin

Botulinum Toxin (BTA) Injections

BTA, also known as Botox injections, when used in tiny amounts, have proven effective in paralyzing spastic muscles. Injection sites are carefully determined based on the pattern of spasticity.

Surgery

The primary neurosurgical procedures to treat spasticity are intrathecal baclofen (ITB) pumps and selective dorsal rhizotomy (SDR).

Intrathecal Baclofen (ITB)

In severe cases of spasticity, ITB is administered. This is done by implanting a pump under the skin that pumps dosage into the spine. Due to direct administering of medication, the relief is faster and has less side effects on the patient. Thus, ITB has been found to be extremely effective in treating spasticity.

Selective Dorsal Rhizotomy (SDR)

In SDR, the neurosurgeon cuts selective nerve roots (rhizotomy), the nerve fibers located just outside the back bone (spinal column) that send sensory messages from the muscles to the spinal cord. SDR is used to treat severe spasticity of the legs that obstructs simple or every day motions or activities.

1.6 Research of this Thesis

As seen in the previous section, treatment of spasticity is a critical concern and thus it is equally critical to have accurate assessment tool. This is the basis for the research of this Thesis. A lot of research has been done in this area addressing the lack of quantitative metrics in spasticity assessment. This has been discussed in detail in Chapters 2 and 4. As part of this Thesis, we have developed an instrumented glove (hereby referred to as ‘the glove’) to obtain a repeatable and objective metric for spasticity assessment. This glove is mounted with force sensitive elements and a motion measurement unit to account for the force to move the arm during assessment and the speed during motion respectively (as spasticity is velocity dependent stretch reflex). The intention is to make the glove as consistent, repeatable and objective as possible. To assess the repeatability, we have developed a “mock patient”, which is a spasticity simulating mechanical arm. This serves as the ground truth for the glove measurements as obtaining repetitive measurements from actual patients with same levels of spasticity is not possible.

In one of the clinical experiments conducted with 6 clinicians from Rady Children’s hospital and California Children Services, some personal communication revealed the effect of the methods of spasticity assessment on the medication. The clinicians were of the opinion that for the most part, assessment tools like MAS do not impact their dosage of medication. This is because they test the patients once every 6 weeks or so and spasticity can change in a matter of few hours. They must highly rely on the account of the patient and/or their family members to decide the state of the patient. This introduces a high amount of variation for medication which may prove either ineffective or lethal to the patient. The per annum healthcare cost for a patient with CP-spasticity is \$46K as compared to \$8K for a normal person. Thus, it is vital that the dosage prove effective to the patient from a healthcare as well as financial perspective. The clinicians also stated that the assessment is highly variable when they do testing and it would be immensely beneficial to have a

device that would not require high medical expertise to assess the patient. This is where the glove proves to be useful. This device can enable us to come up with an objective and consistent metric. By being able to assess the patient more often, this glove can also help in understanding spasticity better than ever before.

1.7 Organization of this Thesis

The Thesis is organized as follows:

Chapter 2 is the paper [1] detailing the initial work and results that went into the development of the glove and the first mock patient. Chapter 3 details all the algorithms that have been implemented throughout the course of this Thesis and their results. Chapter 4 is the detail of the latest algorithms, validation and results of the project and the same draft has been submitted to the IEEE transactions in Biomedical Engineering. Finally, Chapter 5 is Conclusions and Future Scope of this project. This is followed by references and appendix.

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2. AN INSTRUMENTED GLOVE FOR IMPROVING SPASTICITY ASSESSMENT

2.1 Abstract

An instrumented glove worn by caregivers that can augment subjective assessments of spasticity with an objective, repeatable metric with reduced inter- and intra- rater variability and improved resolution over existing standards is highly desirable. We present the design and preliminary results of such a system using commercial, off the shelf (COTS) components. The glove includes spatially-resolved, force-dependent resistive sensor elements and an inertial measurement unit. We developed a mock patient that is equipped with a mechanism to adjust the arm stiffness, a load-cell and a potentiometer to measure the work done to move the arm. The mock patient provides ground truth to validate the proposed concept. We report the power measured by the sensors in the mock patient to move the arm and the power estimated by the glove in moving the arm and show Pearson correlation coefficient of 0.64. We observe that raw sensor data and instrumentation errors contributed to significant outliers in these experiments. Initial assessments by clinician show promise of the proposed approach to improve spasticity assessment. Future work includes improvements to instrumentation and further clinical evaluations.

2.2 Introduction

Spasticity is a debilitating condition and the most common physical symptom of acquired brain injury, stroke, or other neuro-muscular disorders such as cerebral palsy, which affects 764,000 people and is diagnosed in two to three live births out of every 1,000 in the United States. Patients with spasticity are unable to produce smooth and fluid limb movements due to the imbalance of signals from the brain and spinal cord to the muscles. The pharmaceutical industry spends billions of dollars developing drugs to relieve spasticity, but these efforts are stymied by the lack of repeatable, objective metrics to quantify the outcomes [1-3]; excessive dosage of drugs to treat

spasticity can cause severe side effects such as seizures, blurred vision, and severe rashes, while inadequate dosage is ineffective at treating spasticity.

The current benchmark for assessing spasticity is the 6- point modified Ashworth score (MAS) shown in Figure 2.1 [4,5]. There are several limitations to this MAS, including poor interrater reliability and poor sensitivity to changes in spasticity [6- 8]. An approach that allows reproducible assessment with improved resolution is urgently needed to monitor patient progress under medication and eliminate negative reactions.

This research is aimed at improving spasticity assessment by augmenting MAS with an objective, repeatable measure that shows finer level of details than MAS and has reduced variability in intra-rater and inter-rater scores. In Section II, we present prior efforts to improve spasticity assessment. In Section III, we present the development of an instrumented glove that senses pressure and hand motion during spasticity assessment. Since MAS is a highly subjective rating, we initially lacked a reliable criterion measure for verifying the glove measurements. To overcome repeatability issues, we present in Section IV the development of a mock-patient that was used to generate a “ground truth” criterion metric for validating objective scores from the glove. We present experimental results in Section V. In Section VI, we discuss sources of errors in the instrumentation, present future work and conclusions.

Score	Modified Ashworth Scale [28]
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion (ROM) when the affected part(s) is moved in flexion or extension
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part(s) rigid in flexion or extension

Figure 2.1: The Modified Ashworth Scale

2.3 Prior work

Many researchers have taken different approaches to address the lack of quantitative assessment of spasticity. Wearable devices [17, 18, 20] and EMG sensors [19] have been deployed on patients to detect spasticity symptoms, but the drawback is that such devices can be inconvenient and uncomfortable for the patient. Studies using electromyography (EMG) sensors [9, 19, 21] were carried out on patients with spasticity to characterize the patients' muscle tones under flexion and extension. Wu et al. [9] measured the catch angle reliably by determining the instantaneous velocity and the time derivative of torque. Research by Park et al. [10] also targeted measurement of catch angle and elbow range of motion. Both of the above studies were focused on identifying the presence/absence of a catch phase for correlation to a MAS score between 1 and 2, but these studies did not provide a continuous scale to quantify the different levels of severity. The lack of a quantitative scale for spasticity was addressed by development of musculoskeletal models [11] or haptic simulations [12] to determine key physical parameters that contribute to spasticity. One of the most common models is the Haptic Elbow Spasticity Simulator (HESS) [12], [13], [14], in which the properties of spasticity are simulated with the muscle resistance as torque and the catch phase as an impulse. Development of the HESS simulator mainly benefits the doctors as they can

practice MAS assessments without requiring actual patients. Their research focused on modeling of spasticity and emphasized on the factors that characterized each MAS level. Alternatively, a mathematical model by Zakaria et al. [16] formulated the resistance as torque and accounted for additional parameters such as the angular velocity, modulus of elasticity etc. The above models have yet to be translated into physical tests that can be implemented on patients to track the spectrum of spasticity conditions.

2.4 Instrumented Glove

Our approach to improve spasticity assessment is an instrumented glove worn by the doctor during patient evaluation. We integrated a spatially-resolved, force dependent resistive sensor array (by Tekscan, [22]) and an inertial measurement unit (IMU) consisting an accelerometer, gyroscope and a magnetometer [23]. The force sensor on the glove measures the contact force being applied to move a patient's limb. The level of muscular resistance to motion indicates severity of spasticity. Figure 2.2 (left) shows the force sensor integrated on to a golf glove. It has 18 sensing regions, with a total of 349 sensing elements that output a voltage proportional to the applied force. The raw output is a spatial map of 8-bit values for each sensing element. The data was collected at 20Hz. For our analysis, we used the sum of the output of all the sensing elements. During the experiment, the researchers wore the glove and performed cycles of movement with the patient, such as elbow flexion and extension, and the sensor recorded the force F (Newtons) versus time as shown in Fig.



Figure 2.2: The instrumented glove with pressure sensors (left) and IMU (right)

2.3 (A). The IMU is attached to the back of the glove as shown in Figure 2.2 (right). It is used to characterize the hand maneuvers during clinical assessment of spasticity. In this work, we use only the gyroscope data to estimate the power needed to manipulate a limb. The IMU data is collected at 20 Hz. The angular velocity ν from gyroscope is converted to linear velocity at the location of the grip in the mock patient. The gyroscope data in a typical maneuver is shown in Figure 2.3 (B). We estimate the power to move the patient's limb as $F \cdot \nu$. In our initial study, five individuals with cerebral palsy volunteered to participate in this study. Participants and/or their parents provided informed consent as per the UCSD Human Subjects Internal Review Board regulations. Participants engaged in a modified Ashworth scale assessment with two physicians well-trained in this methodology (AS and his colleague) and then again by the same two physicians while wearing the spasticity measurement device. These data were collected in UCSD's Research on Autism and Development Laboratory. In this experiment, there was substantial inter-rater variability resulting in only 27% agreement in MAS values. Consequently, we were not able to use these data to validate the estimates from the glove sensors. To mitigate this, we created a mock patient capable of generating criterion metric (ground truth) that can be used to validate the objective numbers estimated from the glove sensors.

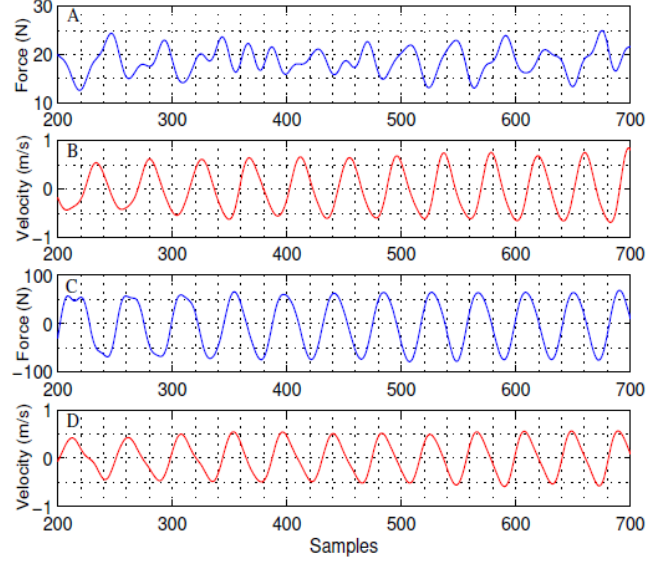


Figure 2.3: Low pass filtered raw sensor data. A. Total pressure from glove sensors over time. B. Linear velocity from gyroscope data. C. Force from load cell data. D. Linear velocity from differentiated potentiometer data. The positive half cycle corresponds to flexion and negative half to extension

2.5 Mock Patient's Arm Structure

The mock patient has an arm structure as shown in Fig. 2.4. The arm has a lever connected to a disc clamped by a 5" clamp with stationary-bike brake pads, such that the resistance can be changed manually. The arm has an embedded load cell (model HX711 [24]) that senses the dead weight m due to the resistance set by the clamp. We compute the force to overcome this resistance as $F = m \cdot a$, where a is standard gravity, 9.8 m/s^2 . We use the term “preset resistance on the mock patient” to denote the force required to move the arm. The units are Newtons. The mock patient also has a potentiometer [25] to sense the angular velocity v during flexion and extension. We use this to measure the power as $F \cdot v$, in N-m/s. In our experiments, we measure the power from the mock patient sensors and use it compare with the power estimated from the sensors in the glove worn by the rater.

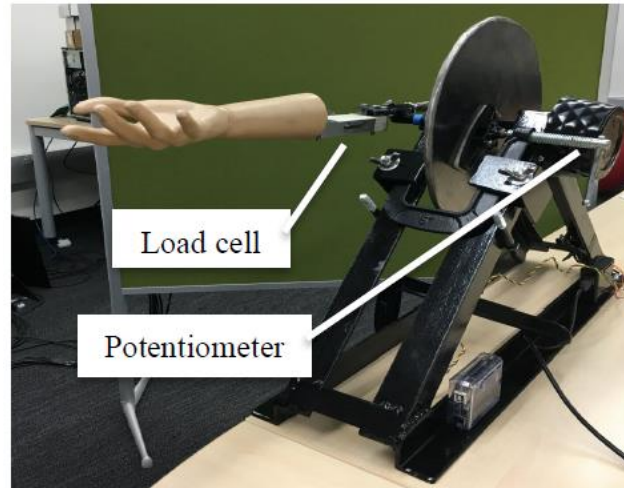


Figure 2.4: Model of the mock patient

2.6 Results

We investigated the agreement between measured power from the mock patient and estimated power from the glove. We focused on MAS values of 1+, 2 and 3 in this study. The values of 0 and 4 are easy to assess since they correspond to normal tone and rigid limbs, respectively. Similarly, a value of 1 is also easy to assess since it is characterized by catch and release. A well-trained physician in spasticity assessment (AS) tested the mock patient and identified the range of to be 20-90 Newtons for MAS values of 1+, 2 and 3.

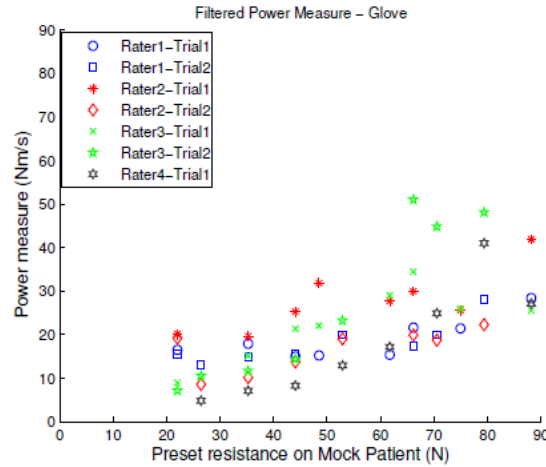


Figure 2.5: Power measurement for the instrumented glove

Spasticity is a highly velocity driven response [1], [2], [8], [14]. For both glove and mock patient, we converted the angular velocity to linear velocity and estimate the power to move the patient's limb as $F \cdot v$. Here, we present experimental results for two trials by 4 researchers. Figures 2.5 and 2.6 show the power measured from the glove sensors and mock patient sensors, respectively, for different preset resistances on the mock patient. Note that while there are outliers in both cases, the mock patient data shows better agreement with the preset resistances, compared to that of the glove. From Figure 2.2, it can be seen that the force data from glove does not follow

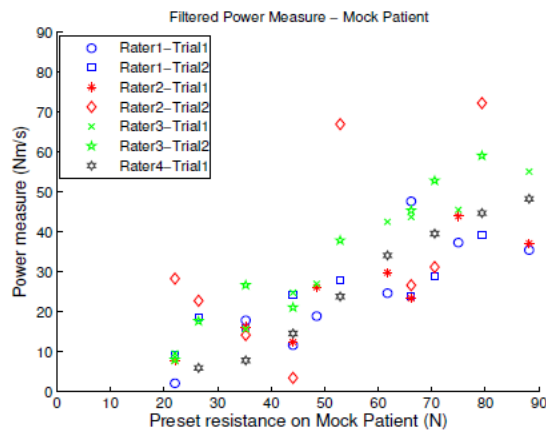


Figure 2.6: Power measurement for the mock patient

the cyclical nature of other sensors. Figure 2.7 shows the power measured from the mock patient sensors versus power measured from the glove sensors. We note that there are bias and variability issues in all these experiments. The Pearson correlation coefficient between the mock patient and the glove was 0.64. When we compute the agreement between the mock patient and glove for flexion and extension independently, the Pearson coefficients were 0.64 and 0.57 respectively. The experimenters gripped the mock patient at the wrist – flexion involved in pushing the mock patient arm, while extension involved pulling it. We performed another experiment with a physician (AS) performing MAS assessment for various resistance settings of the mock patient, as shown in Figure 2.8. The physician did not know the resistance setting so that he could provide an unbiased assessment. This shows the promise of improving MAS ratings resolution with the instrumented glove.

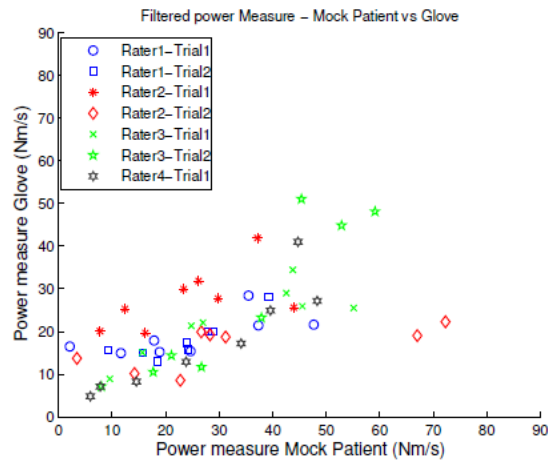


Figure 2.7: Instrumented glove versus mock patient

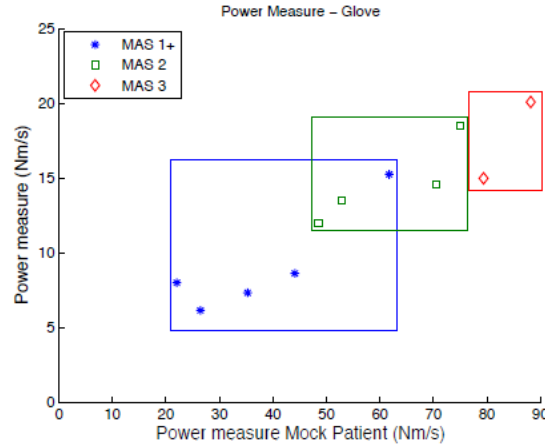


Figure 2.8: Power estimates for MAS values

2.7 Discussions and Future Work

There are some sources of error such as grip variation, posture, etc. that could introduce certain bias and also result in outliers in the measurements. In addition, we observed certain errors in the pressure sensor, similar to other researchers ([29] reported up to 34% errors). Further, our COTS instrumentation used different clock domains for the potentiometer, load cell, pressure sensor and the gyroscope. This resulted in significant drift in the alignment between pressure and gyroscope data; load cell and potentiometer data during each experiment. Future work must address (i) improvements in sensor reliability (ii) custom hardware to acquire glove sensor data with a common clock and mock patient sensor data with a common clock (iii) further testing by doctors to understand the statistical validity of results shown in Figure 2.7.

2.8 Conclusions

Spasticity is a debilitating neurological, musculo-skeletal condition, affecting people with CP, TBI, stroke, etc. This research addresses development of an instrumented glove to be worn by doctors while performing MAS assessment, a gold standard in current standard of care for diagnosis and treatment of spasticity. We presented a design of the glove based on COTS components. In

order to develop an objective metric from the glove measurements, we presented the development of a mock-patient arm with adjustable resistance to motion and sensors to report the load and angular displacement. We presented power (N-m/s) measured at the mock patient and estimated by the glove for various stiffness values that correspond to MAS values of 1+, 2 and 3. Our results demonstrate that the instrumented glove has a correlation of 0.64 with the mock patient. Preliminary assessment by a physician demonstrates that an objective metric based on measured power has improved resolution over MAS. Future work will include improvements to sensors, custom hardware to mitigate clock issues and additional characterization in clinical settings.

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3. DESCRIPTION OF ALGORITHMS

The objective of this research is to obtain a repeatable, objective metric that is consistent over inter- and intra-rater variabilities. This chapter describes all the algorithms and data processing performed considered and applied to obtain that metric.

Four sets of data are obtained from the experimental setup (glove and mock patient). These are:

- (i) Poundage data from the glove (referred henceforth as *glove data*)
- (ii) Poundage data from the loadcell (referred henceforth as *loadcell data*)
- (iii) Angular speed data from IMU on the glove (referred henceforth as *glove gyro*)
- (iv) Angular speed data from the loadcell (referred henceforth initially as *arm potentiometer* and subsequently as *arm gyro*)

The loadcell and glove data are “force-sensitive” sensors. However, their output is proportional to the pound-force applied to them and not actual force. We later multiple this data with acceleration (differential of gyroscope data) to obtain force.

3.1 Initial Steps

One of the initial steps of data processing was noise removal. The initial analysis included some rudimentary low pass filtering to observe the general trend of the data. This filtering was done with the knowledge that the doctors’ maneuvers are typically at 2Hz or less (2 maneuvers in one second). The term “maneuver” here refers to the action of moving the patient’s limb into flexion and extension. Thus, the stop band frequency was slightly higher than 2Hz. Additionally, considering the factor that spasticity is a velocity dependent phenomenon, it made intuitive sense that the power expended on the patient’s arm should increase as extent of spasticity increases. After considering almost 12 physical quantities like momentum, drag, power, kinetic energy etc., to

compare with our intuition, it was verified that power/work done showed a positive trend as the extent of spasticity increased.

The following text describes the issues faced and steps undertaken to obtain denoised and reliable data:

Data filtering:

Of all the four data streams, the glove data was the most unreliable. Thus, to make the filtering more sophisticated, LPC, FFT based filtering and DWT denoising were attempted.

For LPC based filtering: An LPC filter of order 2 was chosen. The LPC coefficients were found using the gyroscope data.

For FFT based filtering: From FFT, the first 2 peak frequencies of data were found. This was used to find the cutoff frequency for a Butterworth filter.

For DWT denoising: DWT was found using a Haar wavelet. From the detail and approximate coefficients, two approaches were considered: (i) reconstruct signal from only approximate coefficients (ii) reconstruct signal from most significant detail and approximate coefficients.

The loadcell data was a relatively much less noisy data and hence was filtered using a Butterworth low pass filter (LPF).

For the glove gyro and loadcell potentiometer data, LP filtering was initially performed. Subsequently, the potentiometer started displaying high impulse spike noise. For this reason, median filtering was implemented for the potentiometer.

This issue with the potentiometer was later attributed to connection issues. After analysis, it was revealed that the potentiometer tended to disconnect from the mock patient, thus rendering

chunks of data gibberish. After assessing some solutions like 3D printed fixtures for fixing the potentiometer, we decided to replace the potentiometer with a gyroscope breakout board. This made it less prone to connection errors and made it easier to mount and replace it.

Thus, at this point, the loadcell and both gyroscopes had the same filtering process and the glove needed something more sophisticated. All final filtered data are in the Results chapter.

The correlation method:

As described above, the glove data had the most noise. As can be seen in Figure 3.1, some parts of the glove are not covered and some not used during motion. This paved way for a new method.



Figure 3.1: Glove sensel matrix

Until the previous step, the data obtained was the raw sum of every pixel element. In this approach, data from every pixel was used. Thus, initially a data from a matrix of 25×30 force sensing elements (sensels) is obtained. Out of these 750 data streams, only 25×38 (700 sensels) are filled with sensors and the rest are zeros. This is illustrated in Figure 3.2.

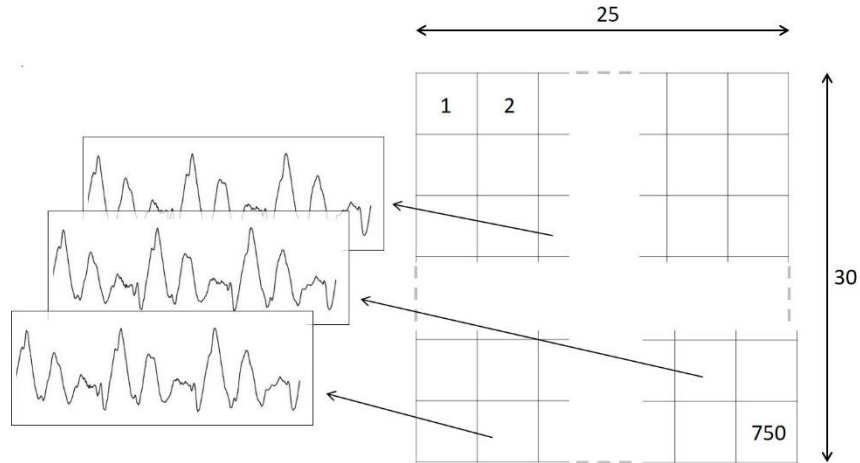


Figure 3.2: Frame by frame data from every glove sensel

Each of these 700 data streams is passed from an LPC filter. The gyroscope data correlates to the glove data as they are collected during the same maneuver on the same instrument. Thus, the glove data is correlated with each of the 700 waveforms. The sensels with highest correlation with the gyroscope data were used to obtain the final glove data waveform (by raw sum). The figure 3.3 shows the bar graph showing correlation of each sensel with gyroscope data. This data was later used to find the force in power calculation.

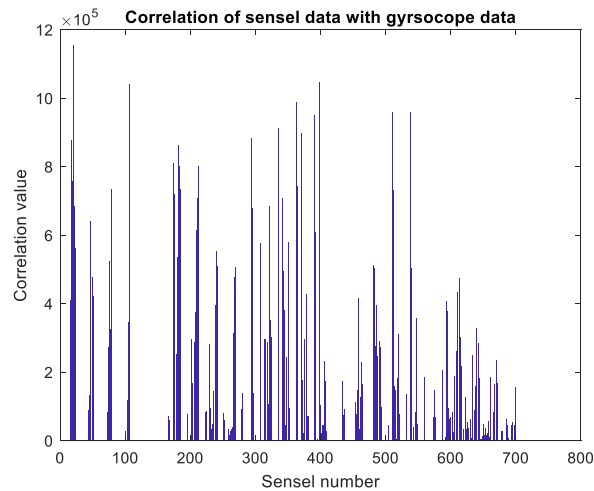


Figure 3.3: Maximum correlation of every sensel data with glove gyroscope data

Later during experimentation, it was found the instead of eliminating the data with least correlation, it was better to find the weighted mean of data stream of each sensel with respect to its correlation value. This essentially boosted the energy of the more relevant sensels and suppressed the non-relevant ones. The reasoning behind boosting method over elimination method was that the former retained the bias offered by some noisy or non-relevant sensels which in turn helped preserve the properties of glove data as a whole whereas the latter eliminated them altogether. The method is revisited later in this chapter. The waveforms of the glove data before and after processing:

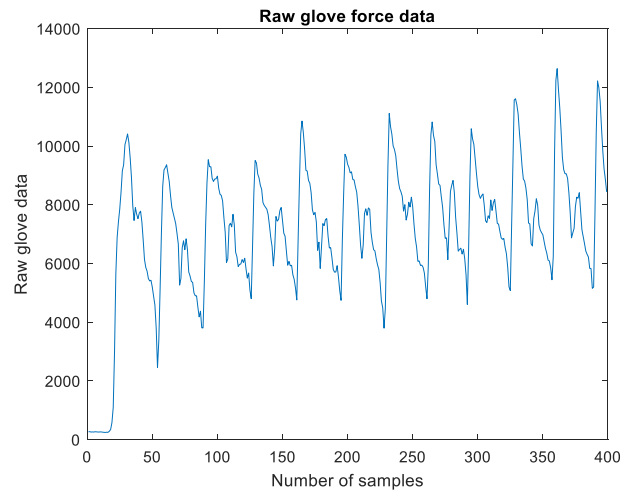


Figure 3.4: Raw glove data

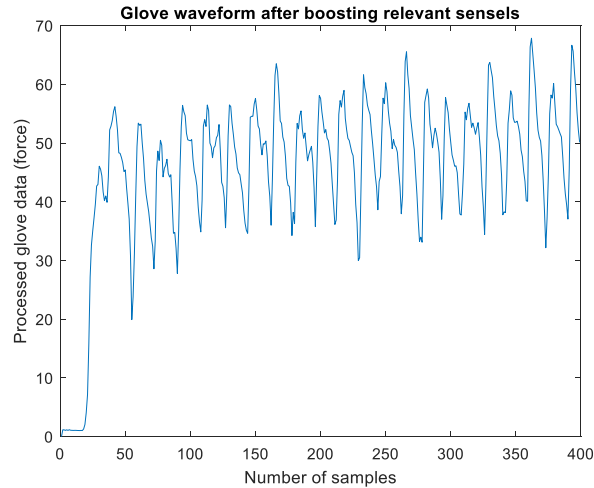


Figure 3.5: Glove data after sensel boosting

The problem of drift:

Even though the data from the gyroscopes was less noisy, it had a different issue: drift. The gyroscope data noticeably drifts from the glove and loadcell data. The analysis initially started with a point by point analysis of the time series and hence this became a problem. The following solutions were employed to mitigate the issue.

Dynamic Time Warping: DTW is a method that only looks at trend of data and stretches/shrinks the signal as depicted in Figure 3.6:

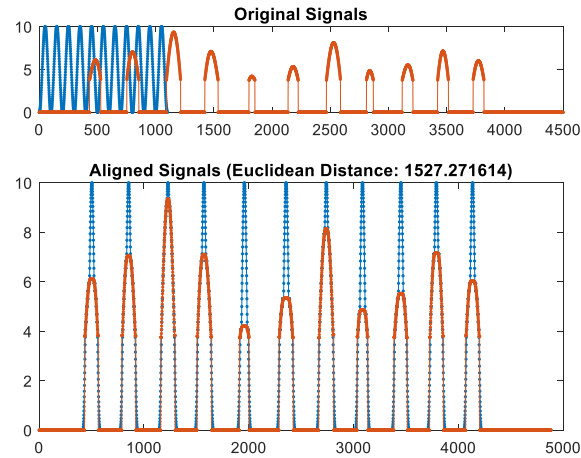


Figure 3.6: Illustration of Dynamic Time Warping

However, this method was highly susceptible to variations in amplitude and frequency from a coding perspective (which varies highly among all doctors). Thus, the following method was used instead.

Peak detection: In this case, the extremities of the waveform were considered as opposed to the entire waveform. This is depicted in Figure 3.7:

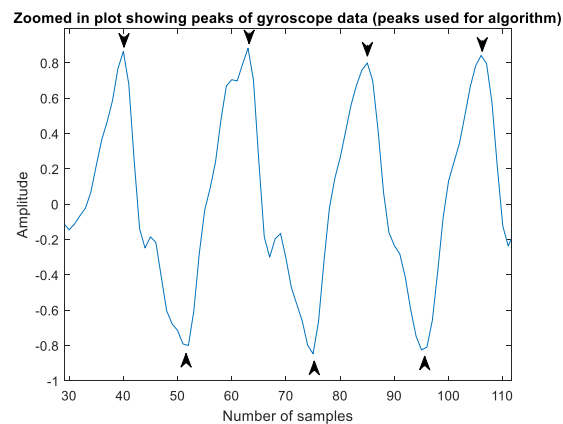


Figure 3.7: Peaks of gyro data used for power calculation in arm and glove

During the flexion and extension, the maximum speed occurs mid motion (just like SHM). The processing for flexion and extension is explained later in this chapter. This is the intuition behind choosing the peak speed in the waveform.

The following approaches were used succeeding the method in chapter 2.

3.2 Approaches Attempted

3.2.1 Processing on selected sensels:

In this method, the glove data is obtained by boosting relevant sensels and LPC filtering. The loadcell data and both gyroscopes' data are filtered with the common low pass filter. The power on the glove is calculated by multiplying the median of peak values of the glove data obtained and the median of peak values of glove gyro data (to eliminate outliers in peaks). Loadcell power is found by the same method.

The result obtained by this method as compared to the method in Chapter 2 is detailed in the results chapter.

The flow chart for the method is shown in Figure 3.8.

3.2.2 Model based approaches:

In order to obtain more accurate glove data, some model based approaches have been tried. Among the methods tried, the two most tried methods were SVM and linear regression. The aim was to get better correlation between loadcell and glove data. Thus, I attempted to apply the loadcell data to model and obtain hyperplane for SVM classification. However, the two issues as to why this approach did not work were: (i) Each of the sensel was assumed independent while classifying which is not true. (ii) The SVM model was an overly complicated model for this data.

Thus, the second approach: linear regression was considered. This turned out to be an over simplification of the problem. Thus, in both these cases, the results obtained were worse than those obtained in Chapter 2. The plots are shown in the Results chapter.

During this attempt, Fei Deng [1] modeled a neural network that does non-linear regression and thus fits the data well. The structure of and results from neural network are described in the next chapter.

3.2.3 Aggregation method:

This method is the latest development in this research and described in detail in the next chapter.

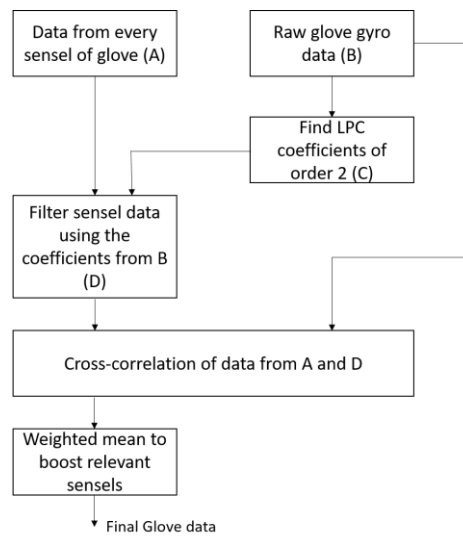


Figure 3.8: Flow chart to boost relevant sensels of glove using glove gyro data

3.3 For Flexion and Extension

For flexion and extension, the same algorithms can be applied with segmentation at some point of the algorithm. Preferably, the segmentation is done when the final glove waveform is

obtained after filtering. The motion of flexion and extension is very similar to a Simple Harmonic Motion. Thus, the segmentation is done as show below:

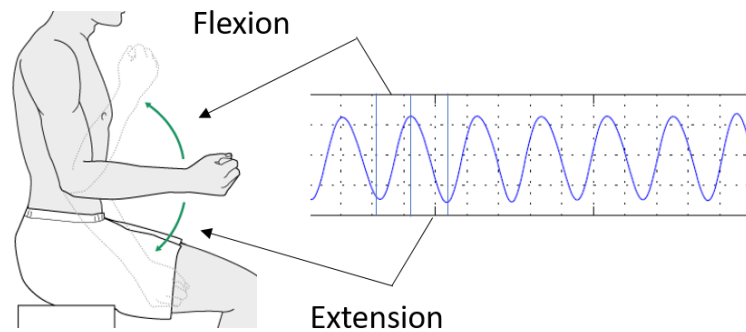


Figure 3.9: Force data in flexion and extension

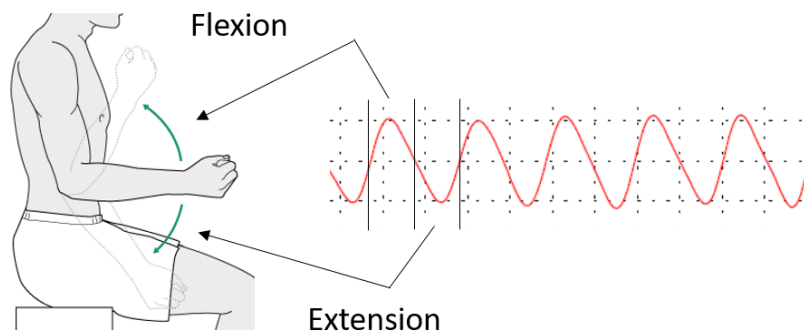


Figure 3.10: Gyroscope data in flexion and extension

Once this segmentation is done, any of the above described algorithms can be applied to find the flexion and extension spasticity values.

REFERENCES

- [1] “*Validating objective metrics for improving assessment of spasticity*” – Fei Deng (Master’s thesis - unpublished)

4. AN INSTRUMENTED GLOVE FOR AUGMENTING SPASTICITY ASSESSMENT WITH OBJECTIVE METRICS

4.1 Abstract

In this contribution, we propose an instrumented glove worn by experts to augment subjective assessments of spasticity with an objective, repeatable metric with reduced inter- and intra- rater variability and improved resolution over current best practices. We present the system design and validation using commercial, off the shelf (COTS) components. The glove includes spatially-resolved, force-dependent resistive sensor elements and an inertial measurement unit (IMU). We describe development of a mock patient equipped with a mechanism to adjust the arm stiffness, a load-cell and an IMU to measure the work done to move the arm. The mock patient provides ground truth to validate the proposed concept. We report the power measured by the sensors in the mock patient to move the arm and the power estimated by the glove in moving the arm and show Pearson correlation coefficient of 0.9 with untrained users. With experts trained in spasticity assessment, the correlation was 0.7 and 0.8 with and without outliers, respectively. We identify the sources of errors during expert assessment trails and the limitations of the COTS realization of the glove and the mock patient. We conclude with recommendations for improving the glove electronics, mock patient realization and guidelines for experts to incorporate limitations of electronics in the proposed system to improve spasticity assessment and patient care.

4.2 Introduction

Spasticity is a neuro-muscular disorder characterized by an increase in muscle-tone or stiffness of the limbs. It often occurs in patients with problems like Cerebral Palsy (CP), Multiple Sclerosis (MS), Traumatic Brain Injury (TBI), Stroke, Spinal Cord Injury (SCI), Paralysis etc. It is typically caused by damage in the part of brain and/or spinal cord which is responsible for motor control. It is estimated that spasticity affects more than 12 million people around the world. About

80 percent of people with cerebral palsy (CP) and Multiple Sclerosis (MS) have spasticity (of varying degree). Since an estimated 500,000 people in the United States suffer with a form of CP, this means about 400,000 people suffer from some degree of spasticity. Similar statistics for MS show an estimated 400,000 people in the United States with MS and hence 320,000 people with some degree of MS-related spasticity [1]. The pharmaceutical industry spends billions of dollars developing drugs to relieve spasticity, but these efforts are stymied by the lack of repeatable, objective metrics to quantify the outcomes [2-4]; excessive dosage of drugs to treat spasticity can cause severe side effects such as such as seizures, blurred vision, and severe rashes, while inadequate dosage is ineffective at treating spasticity.

Multiple methods have been proposed to assess spasticity, the most commonly used being a subjective scale called the Modified Ashworth Scale (MAS) [5-6]. The methods and scales for spasticity assessment lacks repeatability, consistency, or objectiveness [7-8]. This results in inaccurate prescription of treatment which is either inadequate or copious to the patients resulting in either no relief or seizures. Some of the methods proposed for spasticity management are described in the next section.

The current best practice of spasticity assessment requires a high level of medical training and yet result in inconsistent numbers with high inter- and intra- rater variability. Typically, spasticity assessments are done weeks and months apart. Given the subjective nature and poor resolution of the MAS scale, it becomes difficult to incorporate long-term assessments in patient care. Consequently, accounts from patients and their family members are also factored in treatment options.

Due to the above reasons, this research focused on a repeatable, objective and consistent metric that can be employed easily across clinicians or raters of varied medical expertise. We developed an instrumented glove with an array of sensors to sense force and arm motion and

compute an objective rating reflecting the amount of work done to move the limb. We also built a “mock patient” to serve as the “ground truth” and aid the development of this instrumented glove

The paper is organized as follows: Section II describes the currently present metrics for spasticity assessment and prior research to address the lack of repeatable assessment metrics. Section III describes the development of the instrumented glove and the mock patient. Section IV details the experimental protocol for data collection, description of clinical trials and algorithms that go into calculating the metric. Section V presents the results from the experimental data and the algorithms from Section IV. Section VI is the conclusion and the future scope.

4.3 Prior Work

There are many methods to diagnose spasticity. There are clinical scales, which basically are based on a doctor’s “feel” of the patients’ stiffness. Therefore, these methods are very subjective. Clinical methods of assessment include:

1. Ashworth and Modified Ashworth Scale: MAS is the most widely used metric on account of its simplicity. MAS is a highly subjective rating [7, 9-10]. It has high inter- and intra-rater variability [11-12]. It has also been claimed that MAS does not consider the velocity aspect and only captures resistance to passive movement [13-14]. It does not distinguish between neural and non-neural causes of resistance [13]. Considerable research has been put into understanding spastic models, yet none address developing an objective metric.
2. Tardieu and Modified Tardieu Scales: In MTS, the angle for catch (using goniometers) at high velocity stretch and the angle for full passive range at slow velocity stretch responses are measured [15]. Thus, it considers the velocity aspect of spasticity. It is suggested as the more appropriate metric over MAS because of this [15]. The MTS performs better in case of intra and inter-rater reliability than MAS [16]. It’s inter-rater reliability is still not very good [16] [17]. Even though it is closer to actual description of spasticity given by Lance [18], the MTS

is still subjective in nature. This is proven by change in variability (both) before and after training of raters. It is less popular than MAS because MAS is simpler.

3. Hypertonia Assessment Tool [19]
4. Composite Spasticity Scale [20]
5. Gross Motor Function Classification System - Expanded & Revised (GMFCS - E&R) [21]
6. King's Hypertonicity Scale

Secondly, there are neuro-physiological assessment tools which are inclusive of the neurological aspect of spasticity. These methods don't always correlate to the actual level of spasticity even though the measurement correlation is usually high. These methods also often rely on voluntary motion by patients which is an undesirable property in assessment as the patients may or may not move to their full extent and this might cause them inconvenience. Some neurophysiological assessment tools are as follows:

1. Electromyography
2. Tonic stretch reflex testing
3. H-reflex

The neuro-physiological tests use some sensors to get measurements. There is some consistent disadvantage that all these tools display. They instrument the patient and they do not have a defined translation to extent of spasticity. All the neurophysiological tools and their variants are not commonly used since literature does not back these methods up with a direct correlation to level of spasticity [22-23]. None of these methods correlate to spasticity levels and merely give measurements of passive reflex threshold, velocities and stretch angles

The third type of assessment tools are biomechanical tools. These are machines or use some mechanical tools to assess spasticity. Some of these methods are:

1. Myotonometer

2. Wartenberg Pendulum Test
3. Three-dimensional pendulum test
4. Dynamometry
5. Measures using goniometry
6. Inertial sensors
7. Stiffness tool with robotic-assisted gait orthosis

These methods either get too bulky for the patient or rely on the voluntary motion of the patients which is not reliable [24]. Some studies also mention a not so significant correlation with clinical scales [25-27].

Many researchers have taken different approaches to address the lack of quantitative assessment of spasticity. Wearable devices [28-30] and EMG sensors [31] have been deployed on patients to detect spasticity symptoms, but the drawback is that such devices can be inconvenient and uncomfortable for the patient. Studies using electromyography (EMG) sensors [31, 32] were carried out on patients with spasticity to characterize the patients' muscle tones under flexion and extension. Wu et al. [33] measured the catch angle reliably by determining the instantaneous velocity and the time derivative of torque. Research by Park et al. [34] also targeted measurement of catch angle and elbow range of motion. Both the above studies were focused on identifying the presence/absence of a catch phase for correlation to a MAS score between 1 and 2, but these studies did not provide a continuous scale to quantify the different levels of severity. The lack of a quantitative scale for spasticity was addressed by development of musculoskeletal models [35] or haptic simulations [36] to determine key physical parameters that contribute to spasticity. One of the most common models is the Haptic Elbow Spasticity Simulator (HESS) [37-39], in which the properties of spasticity are simulated with the muscle resistance as torque and the catch phase as an impulse. Development of the HESS simulator mainly benefits the doctors as they can practice MAS assessments without requiring actual patients. Their research focused on modeling of

spasticity and emphasized on the factors that characterized each MAS level. Alternatively, a mathematical model by Zakaria et al. [40] formulated the resistance as torque and accounted for additional parameters such as the angular velocity, modulus of elasticity etc. The above models have yet to be translated into physical tests that can be implemented on patients to track the spectrum of spasticity conditions.

4.4 Experimental Setup

The experimental setup consists of two parts: a) the instrumented glove and the b) mock patient. The instrumented glove is intended to be worn by the raters/clinicians who assess the patients. The sensors on the glove would then give an estimate of the extent of spasticity. We have decided to instrument the raters instead of the patients for the following reasons:

1. It is more convenient for the patients to not wear instruments or sensors as seen from previous studies in section II
2. Considering the doctor-patient ratio, it makes more financial sense to instrument the doctors

The mock patient is a validating ground truth for the glove. This is used to simulate consistent conditions for the glove to test.

A. Instrumented Glove:

Our approach to improve spasticity assessment is an instrumented glove worn by the doctor during patient evaluation. We integrated a spatially-resolved, force dependent resistive sensor array (by Tekscan, [41]) and an inertial measurement unit (IMU) consisting an accelerometer, gyroscope and a magnetometer [42]. The force sensor on the glove measures the contact force being applied to move a patient's limb. The level of muscular resistance to motion indicates severity of spasticity. Figure 4.1 (right) shows the force sensor integrated on to a golf glove. It has 18 sensing regions, with a total of 349 sensing elements that output a voltage proportional to the applied force. The raw output is a spatial map of 8-bit values for each sensing element. The data was collected at 20Hz.

For our analysis, we used the sum of the output of all the sensing elements. During the experiment, the researchers wore the glove and performed cycles of movement with the patient, such as elbow flexion and extension. The IMU is attached to the back of the glove as shown in Figure 4.1 (left). It is used to characterize the hand maneuvers during clinical assessment of spasticity. In this work, we use only the gyroscope data to estimate the power needed to manipulate a limb. The IMU data is collected at 20 Hz. The angular velocity v from gyroscope is converted to linear velocity at the location of the grip in the mock patient. We estimate the power to move the patient's limb as $F \cdot v$. In our initial study, five individuals with cerebral palsy volunteered to participate in this study. Participants and/or their parents provided informed consent as per the UCSD Human Subjects Internal Review Board regulations. Participants engaged in a modified Ashworth scale assessment with two physicians well-trained in this methodology (AS and his colleague) and then again by the same two physicians while wearing the spasticity measurement device. These data were collected in UCSD's Research on Autism and Development Laboratory. In this experiment, there was substantial inter-rater variability resulting in only 27% agreement in MAS values. Consequently, we were not able to use these data to validate the estimates from the glove sensors. To mitigate this, we created a mock patient capable of generating criterion metric (ground truth) that can be used to validate the objective numbers estimated from the glove sensors.



Figure 4.1: Instrumented glove and IMU

B. Mock Patient:

The mock patient has an arm structure as shown in Fig. 4.2. The arm has a lever connected to a disc clamped by a 5”C-clamp with stationary-bike brake pads, such that the resistance can be changed manually. The arm has an embedded load cell (model HX711 [43]) that senses the dead weight m due to the resistance set by the clamp. We compute the force to overcome this resistance as $F = m \cdot a$, where a is the differential of the velocity found by gyroscope data. We use the term “preset resistance on the mock patient” to denote the force required to move the arm. The units are Newtons. The mock patient also has a gyroscope [44] to sense the angular velocity v during flexion and extension. We use this to measure the power as $F \cdot v$, in N-m/s. In our experiments, we measure the power from the mock patient sensors and use it compare with the power estimated from the sensors in the glove worn by the rater.

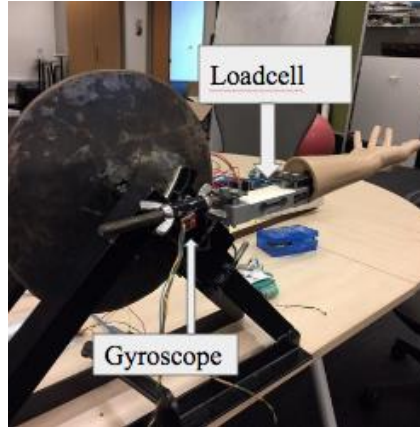


Figure 4.2: Mock patient with loadcell and gyroscope

4.5 Experiments and Algorithms

Two sets of data collection were done. One has 15 datasets from 8 non-clinician raters from a MAS range of 1+ to 3 (the MAS range settings we suggested by an expert - AS). The second data collection was done among 6 clinicians from various affiliations [47].

A. Experimental protocol

The raters should hold the mock patient arm parallel to the wrist with thumb on the top side of their arm. In that position, they should do multiple flexion and extension maneuvers for a 20 second duration. This counts as one trial. The raters do this for multiple weight settings. In this experiment, there are 6 weight settings at 3 pound increments from 5 to 20 pounds. All 6 trials count as one set. All the clinician and non-clinician raters did these sets for the purpose of this experiment.

For each of the trials, there are four data streams collected from 4 sensors: glove pressure sensors, loadcell, gyroscope on the glove and gyroscope on the mock patient.

B. Algorithm

We get 4 sets of data from the entire setup. Force data and gyroscope data from both the mock patient and the glove. The consistent metric, as mentioned above, is power. However, certain

pre-processing steps need to be followed to obtain meaningful data information. The block diagram in Fig 4.3 explains the algorithm in use.

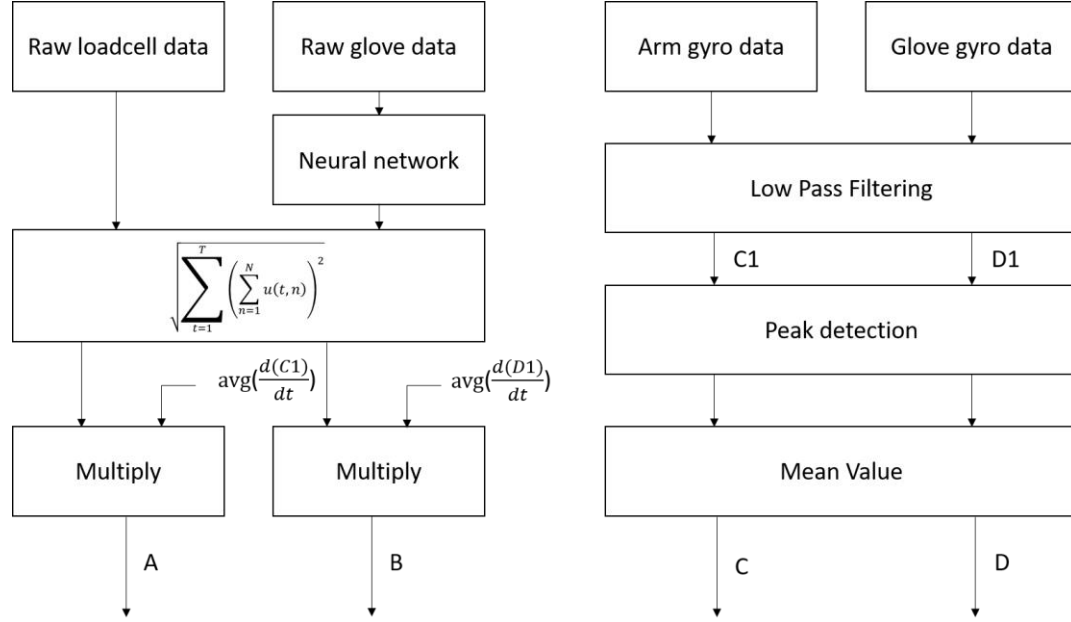


Figure 4.3: Block diagram of algorithm. $u(t,n)$ is data signal for n th sensel

The data from glove pressure sensors has the highest amount of error among the four sensors. A neural network has been employed to remodel this data without the error terms using data from loadcell. The description of neural network is mentioned in the next section. The square root of sum of squared of the data is found for both glove and loadcell data. This assess the frequency content of the signal. Alternate intuition is to find the square root of sum of data FFT squared. This intuition is also due to assessment of energy content of the data. Both these yield the same result owing to the Parseval's theorem. For the gyroscope data from both the mock patient and glove, we do FFT based low pass filtering and find the peak values. The median of these peaks is considered as the value of speed in computing power. Thus, finally, the product $A \cdot C$ for glove and $B \cdot D$ for mock patient give the power expended in the maneuvers (since $F = m \cdot a$ and $a = dv/dt$).

The analysis in [46] mentioned drift in signals as a major source of error. This algorithm aggregates the effect of drift and thus gives better result.

Figure 4.4 shows the glove force vs loadcell force measure data. Similarly, figure 4.5 shows the glove and mock patient gyroscope data waveforms. The actual force in Newtons is found by multiplying the glove (or loadcell) data with its corresponding acceleration found using gyroscope data.

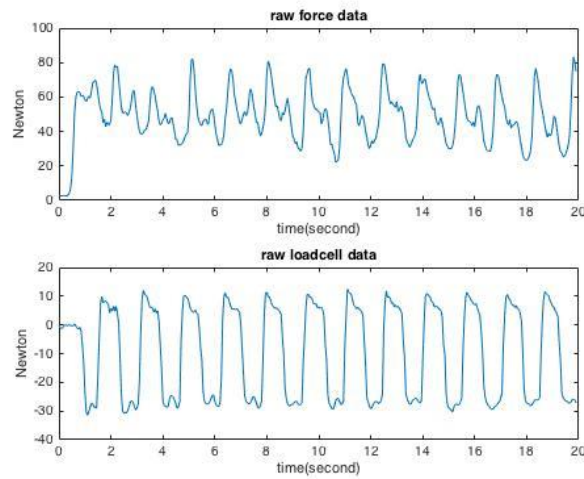


Figure 4.4: Glove and loadcell force data

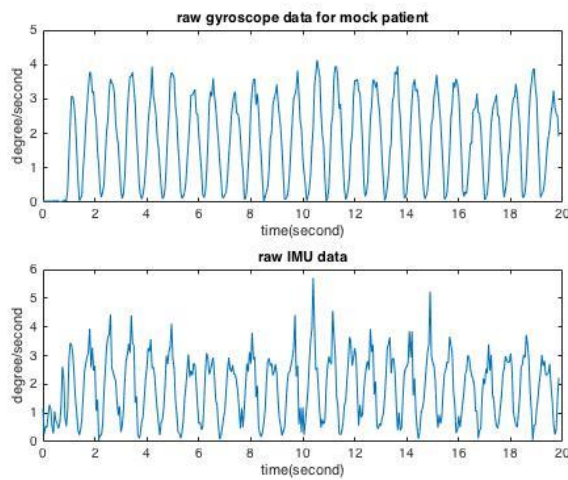


Figure 4.5: Mock patient gyroscope data (top) and glove gyroscope data (bottom)

C. The Neural Network

The instrumented glove contains a total of 349 sensing elements and records data at 20Hz. Thus, there are 349 dimensions for each sample. However, since each rater has different gripping and hand size, simply take the sum of the output of all the sensing elements will not match the loadcell reading in the mock patient. Even with same rate, there are disturbance can come from changing of gripping during the trial. Thus, it requires a robust approach to map the glove data to the loadcell reading. Since the dimension of the glove data is much larger than the dimension of the loadcell reading, the mapping can be solved using a neural network.

The neural network contains an input layer, one hidden layer, and one output layer, and there are 100 neurons in the hidden layer, and 1 neuron in the output layer. The forward pass of the neural network is as follows:

For the batch of training set, $X=[x_1, x_2, \dots, x_n]$, where each x_i is a sample of glove data and n is the total number of samples in the training set. The output of the hidden layer $Y(X)$ can be compute as:

$$Y = \tanh(WX)$$

W is the weighting matrix corresponding to the input layer and hidden layer, where W_{ji} corresponding to the i th neuron in the input layer, and j th neuron in hidden layer. Then, the output of the output layer can be computed as:

$$Z = \tanh(UY)$$

U is the weighting matrix corresponding to the hidden layer and output layer, where U_j corresponding to j th neuron in hidden layer and output layer. Finally, $Z=[z_1, z_2, \dots, z_n]^T$ is the predicted value given n samples of glove data.

Since the mapping is basically a regression problem, the loss function used in this problem is least square loss function.

$$L(U, W) = \|T - Z\|^2$$

Which $T = [t_1, t_2, \dots, t_n]$; T is the target of the prediction, and it is the loadcell reading from the mock patient.

With the forward pass and the loss function, the weighting matrix of the neural network can be updated using gradient descent. For each weighting matrix:

$$W_{t+1} = W_t - \eta \nabla L(W_t)$$

$$U_{t+1} = U_t - \eta \nabla L(U_t)$$

The derivate of the loss function with respect to each weighting matrix can be compute using the backpropagation algorithm.

$$\partial L / \partial U = -2(T - Z) * (1 - \tanh^2(UY))Y$$

$$\partial L / \partial U = \delta Y$$

Where

$$\delta = -2(T - Z) * (1 - \tanh^2(UY))$$

$$\partial L / \partial W = \delta (1 - \tanh^2(WX)) * X$$

The results for the neural network performance are as follows:

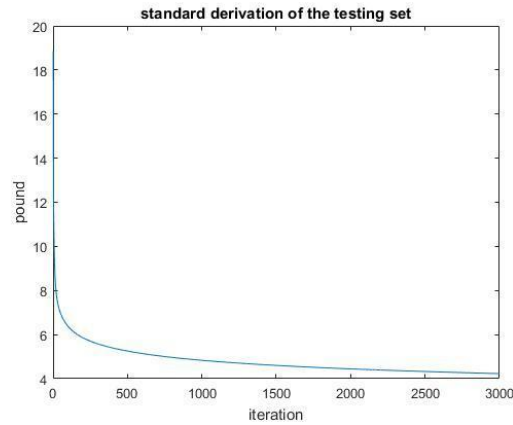


Figure 4.6: Error in NN

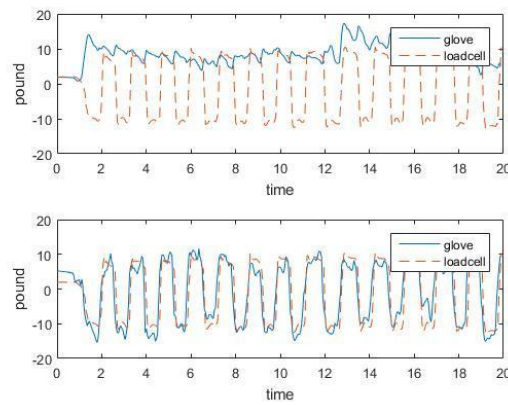


Figure 4.7: Glove vs loadcell before and after NN

The dataset contains trials from 18 raters, and each rater performed 6 trials from 5 pounds to 20 pounds with 3 pound increments. Each trial has 20 seconds, thus there are around 42000 samples from glove and loadcell. The training set contains 80 percent of the dataset, and the testing set has 20 percent of the dataset. Figure 4.6 is the standard deviation of the testing set. It is trained using batch learning with learning rate of 10^{-6} .

In the first plot of Figure 4.7, the glove data is simply generated by taking the sum of the output of the sensing elements. The glove data in the second plot is processed using the neural network. The glove data in the second plot is more correlated with the loadcell reading.

4.6 Results

For the data collected from clinicians and non-clinicians, power expended is calculated as explained in section IV.B. This section shows the results thus obtained.

For the non-clinician data, the correlation between glove and loadcell force (A vs B on Figure 3) is shown in Figure 4.8. The Pearson correlation coefficient obtained is 88%.

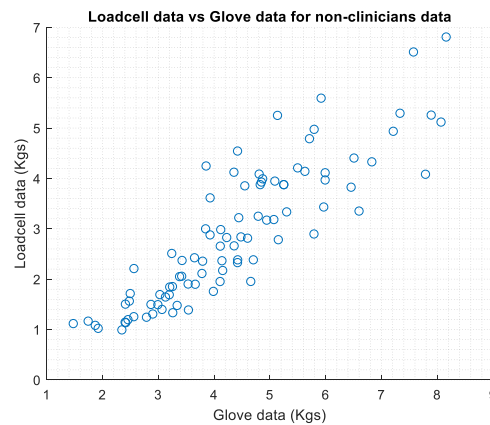


Figure 4.8: Loadcell data vs final glove data for non-clinicians' data. The correlation obtained is 88%

The correlation between mock patient and glove gyroscope data (C vs D on Figure 3) is give in Figure 4.9. The Pearson correlation coefficient obtained is 83%.

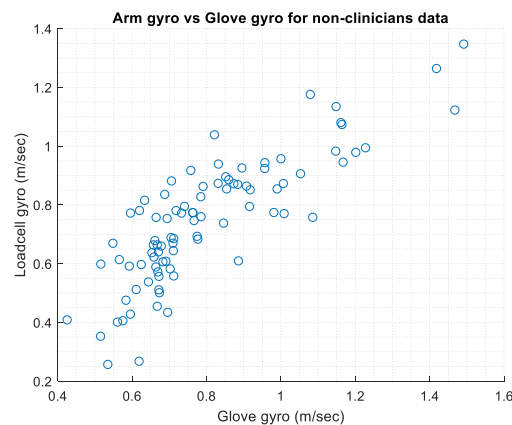


Figure 4.9: Arm gyro data vs glove gyro data for non-clinicians' data. The correlation obtained is 83%

The result (A*C vs B*D in Figure 3) for the non-clinicians' data is given below in Figure 4.10. The result and Pearson correlation coefficient obtained is 90%.

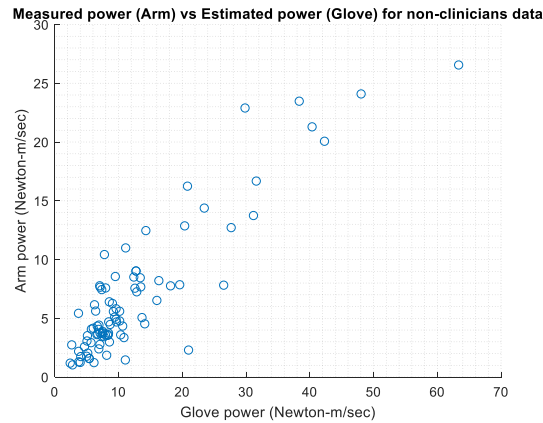


Figure 4.10: Final measure power (Arm) vs estimated power (Glove) in non-clinicians' data. The correlation coefficient obtained is 90%

To further evaluate how the algorithm performs across different raters, the variation of final correlation between mock patient (measured) power and glove (estimated) power across raters is shown in Figure 4.11.

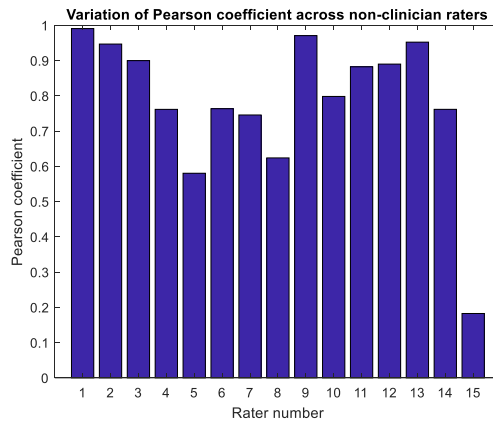


Figure 4.11: Variation of Pearson correlation coefficient (between final measured arm and estimated glove power) across non-clinicians

Similarly, to investigate how the algorithm performs with varying weight settings across all raters, the said correlation is plotted for different weights across all raters in Figure 4.12.

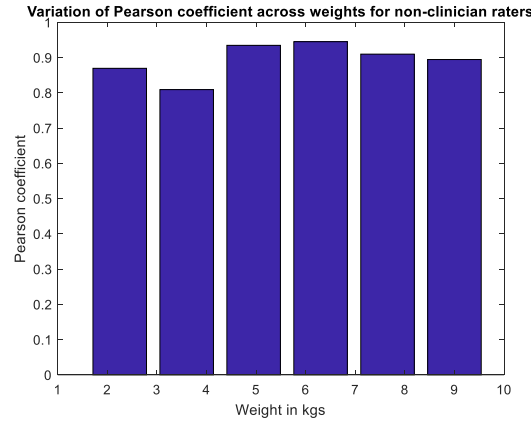


Figure 4.12: Variation of Pearson correlation coefficient (between final measured arm and estimated glove power) among all non-clinicians across different weight settings

The similar results are shown in the following figures for the clinician datasets. It is noteworthy that with the non-clinician data, the experiment protocol was followed as instructed to the non-clinician raters. Thus, the results for non-clinician raters is under more controlled environment as compared to the clinicians' data where some bias was introduced due to highly varying grip (as compared to what was mentioned in section IV.A) and left-handed doctors using a right handed-glove.

The correlation between loadcell data and glove data is shown in Figure 4.13. The correlation coefficient is found to be 89%.

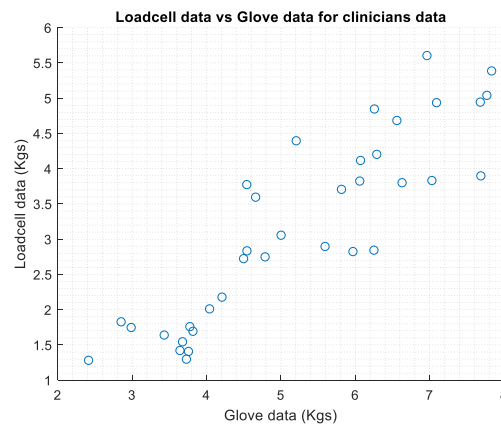


Figure 4.13: Loadcell data vs final glove data for clinicians' data. The correlation obtained is 89%

The correlation between mock patient gyro data and glove gyro data is shown in Figure 4.14. The correlation coefficient is found to be 71%.

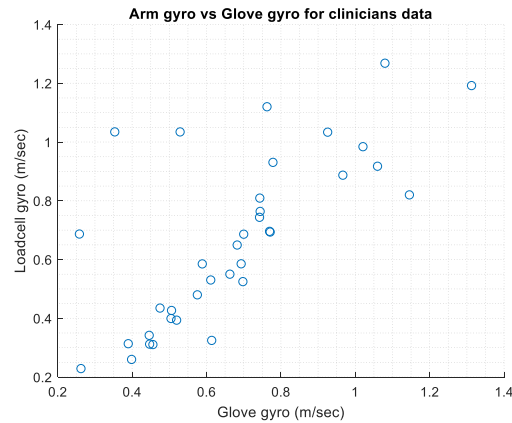


Figure 4.14: Arm gyro data vs glove gyro data for clinicians' data. The correlation obtained is 71%

The correlation between final measured power and estimated power is shown in Figure 4.15. The correlation coefficient is found to be 74%.

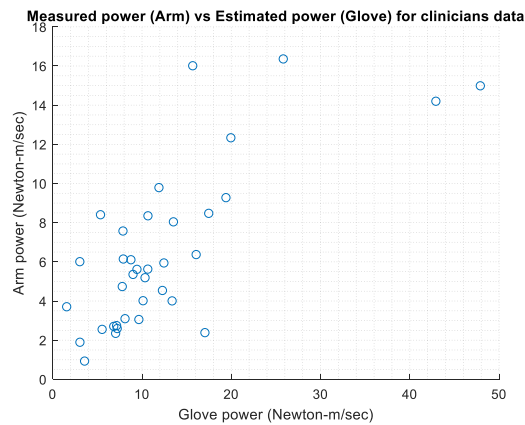


Figure 4.15: Final measure power (Arm) vs estimated power (Glove) in clinicians' data. The correlation coefficient obtained is 74%

The variations of correlation between measured and estimated power across different raters and different weights are shown in Figure 4.16 and Figure 4.17 respectively.

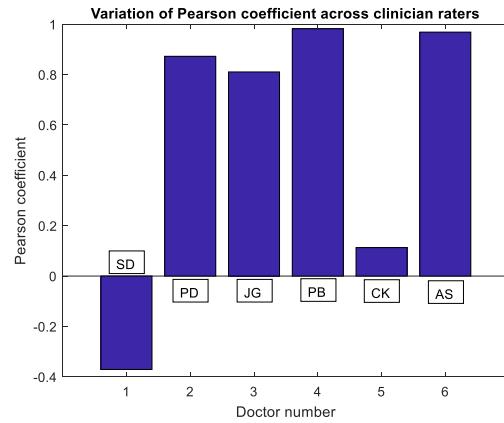


Figure 4.16: Variation of Pearson correlation coefficient (between final measured arm and estimated glove power) across clinicians in descending order

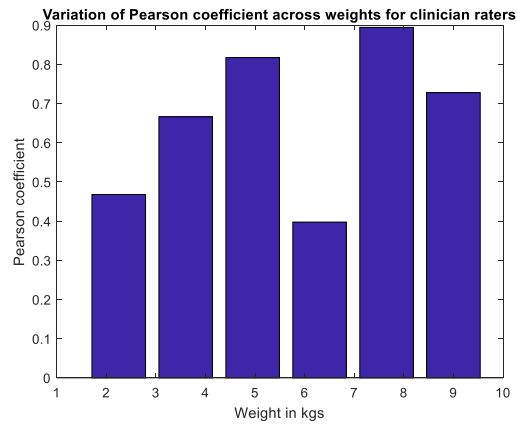


Figure 4.17: Variation of Pearson correlation coefficient (between final measured arm and estimated glove power) among all clinicians across different weight settings

For various weight settings, the MAS value as assigned by the clinicians for various weight settings is shown below.

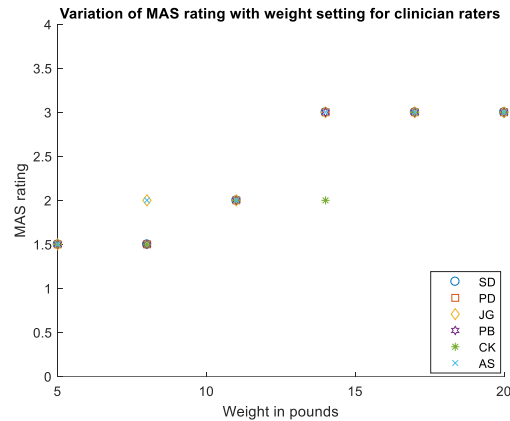


Figure 4.18: Variation of MAS rating by clinicians for varying weight settings

4.7 Conclusions and Future Scope:

In conclusion, we see that the glove gives very reliable variation and correlates to the ground truth. In cases where the correlation falls, the raters are either left handed (PD, PB and JG) or had high grip variations. As can be seen in Figure 4.11, the correlation is very stable across various raters, thus showing very positive signs for mitigation of inter-rater variability which is a huge concern in the other subjective metrics. By comparing Figures 4.10, 4.15 and 4.18; we see that there is a definite correlation between the estimated power and the MAS rating. Thus, we conclude that this estimate shows positive signs of being consistent unlike clinical tools in Section II. It also shows that it can correlate to MAS unlike the neurophysiological tools. By the consistency across weights in Figure 4.12, we can also conclude that it has the potential to be a repeatable metric. Thus, with some more improvement, this can be a repeatable, consistent and objective metric with a definitive mapping to standard spasticity measures. This glove needs to be only worn for assessment and thus does not require any clinical expertise on the rater's part.

For the future developments in this research, we aim to make the glove robust against grip variations. We also aim to improve the current mock patient to include high variety of spasticity profiles based on real patient data. As can be seen in Figure 4.18, the mock patient is repeatable for

weight settings and thus can be used to train inexperienced clinicians in spasticity assessment. We are experimenting with the resolution of the glove sensors in order to print our own flexible force sensors instead of the COTS sensors which have been established to have considerable variance [45] (up to 34%). Even though current algorithms mitigate drift effects, to allow for higher flexibility with sampling and processing, we would like to get all the sensors on a common clock. All these steps are essentially to improve sensor reliability and to mitigate grip issues.

Chapter 4, in part is being prepared for submission for publication. The Thesis author and Fei Deng are among the authors for the same.

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5. RESULTS

This chapter details the results of approaches after Chapter 2. The scatter plots are arranged similar to the format of Chapter 4.

Results for processing on boosted sensels' data:

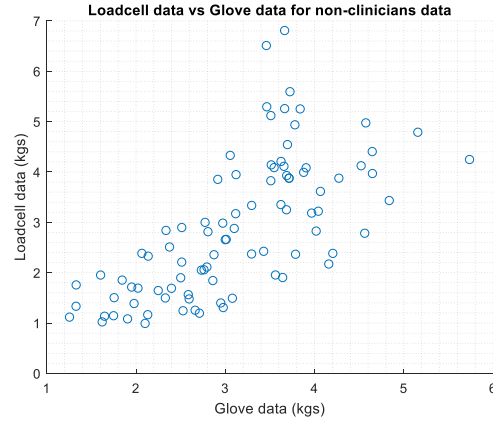


Figure 5.1: Loadcell data vs Glove data for non-clinicians' data for sensel boosting algorithm. The correlation coefficient found was 68%

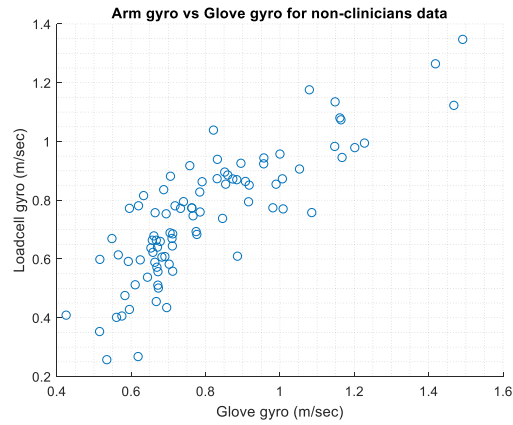


Figure 5.2: Arm gyro vs Glove gyro for non-clinicians' data for sensel boosting algorithm. The correlation coefficient found was 83%

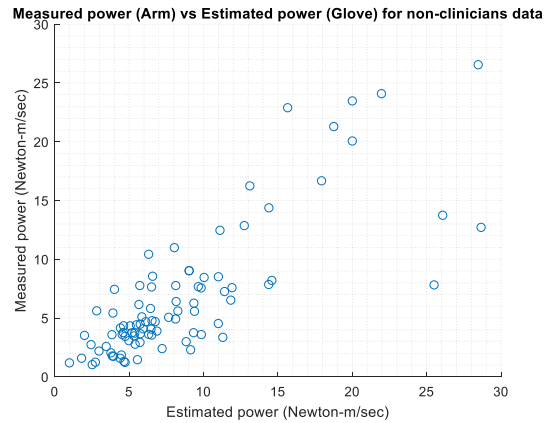


Figure 5.3: Arm power vs Glove power for non-clinicians' data for sensel boosting algorithm. The correlation coefficient found was 80%

These results are on the new data sets. This data collection is described in Chapter 4. Data in Chapter 2 has not been used since. The same algorithm yielded the following results for clinicians' data:

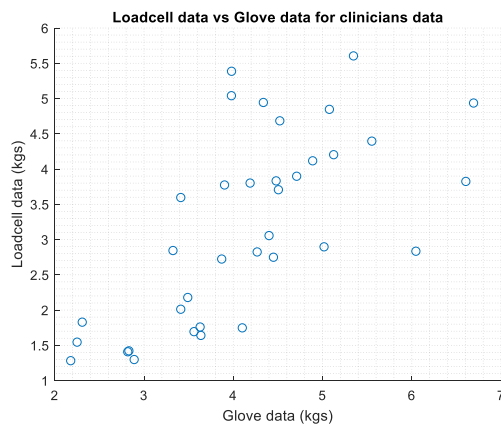


Figure 5.4: Loadcell data vs Glove data for clinicians' data for sensel boosting algorithm. The correlation coefficient found was 67%

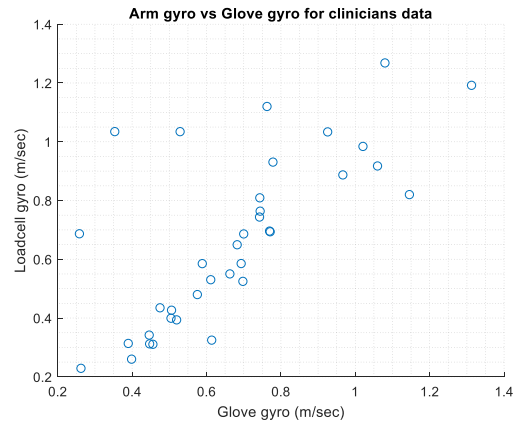


Figure 5.5: Arm gyro vs Glove gyro for clinicians' data for sensel boosting algorithm. The correlation coefficient found was 71%

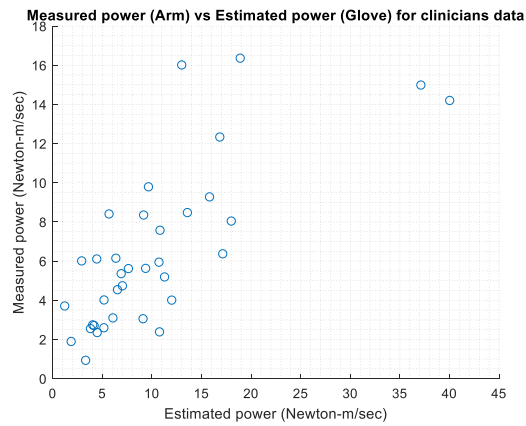


Figure 5.6: Arm power vs Glove power for clinicians' data for sensel boosting algorithm. The correlation coefficient found was 74%

Results for approach in Chapter 4 (final algorithm) before Neural Network was applied –

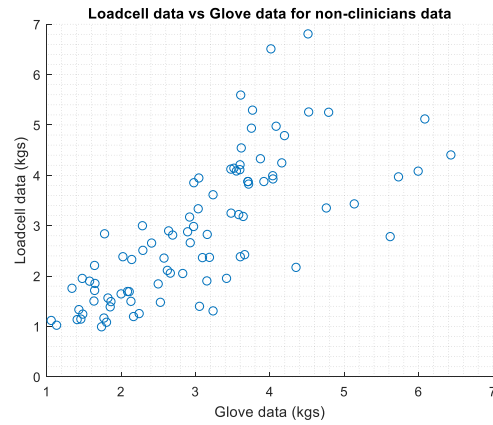


Figure 5.7: Loadcell data vs Glove data for non-clinicians' data for final algorithm. The correlation coefficient found was 74%

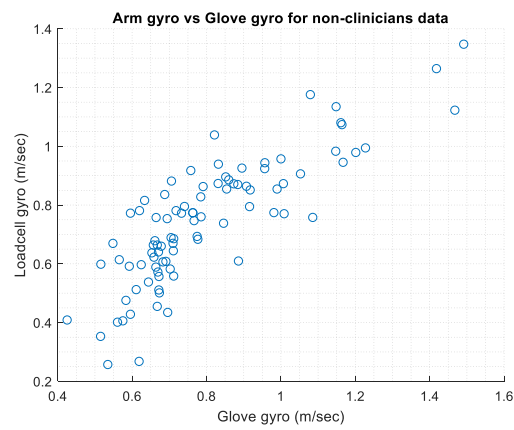


Figure 5.8: Arm gyro vs Glove gyro for non-clinicians' data for final algorithm. The correlation coefficient found was 83%

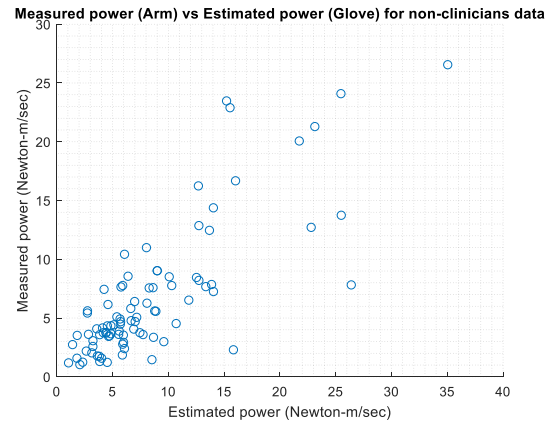


Figure 5.9: Arm power vs Glove power for non-clinicians' data for final algorithm. The correlation coefficient found was 80%

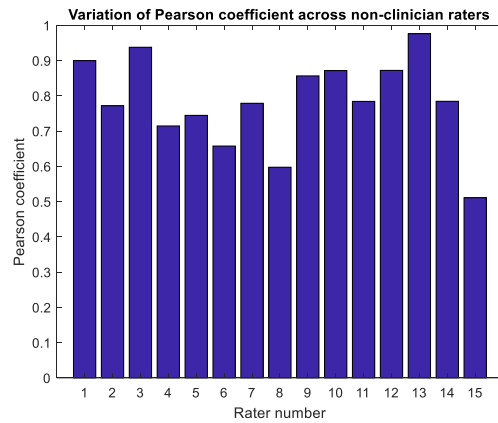


Figure 5.10: Variation of Pearson coefficient (between final measured arm and estimated glove power) across non-clinician raters

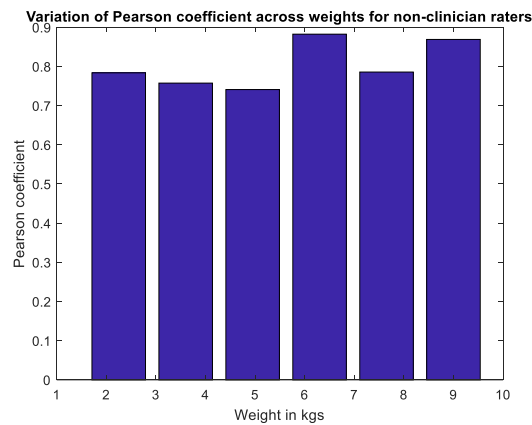


Figure 5.11: Variation of Pearson coefficient (between final measured arm and estimated glove power) across different weights for all non-clinician raters

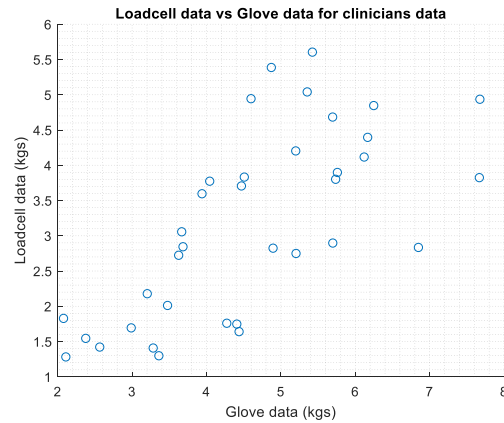


Figure 5.12: Loadcell data vs Glove data for clinicians' data for final algorithm. The correlation coefficient found was 69%

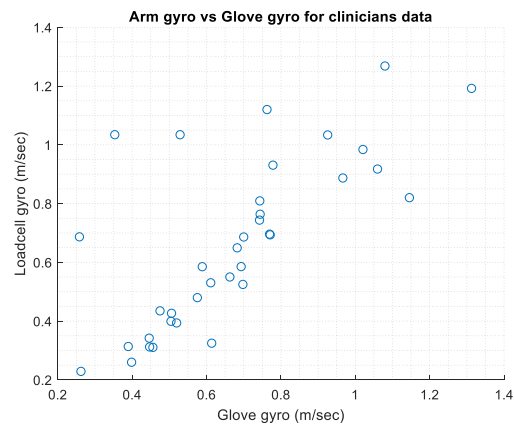


Figure 5.13: Arm gyro vs Glove gyro for clinicians' data for final algorithm. The correlation coefficient found was 71%

It is noteworthy that the high error in some clinicians is because they were left-handed doctors assessing with a right-handed glove. Apart from that, the bar charts show clear indications of a low inter-rater variability.

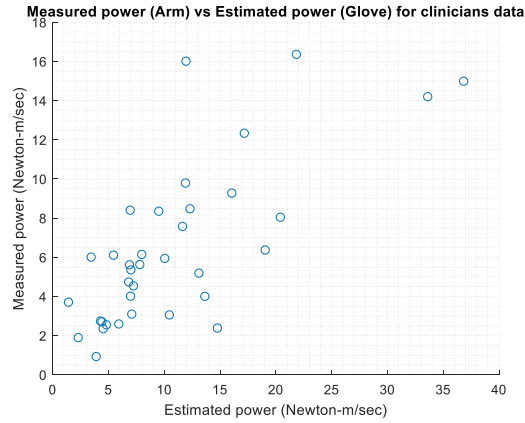


Figure 5.14: Arm power vs Glove power for clinicians' data for final algorithm. The correlation coefficient found was 73%

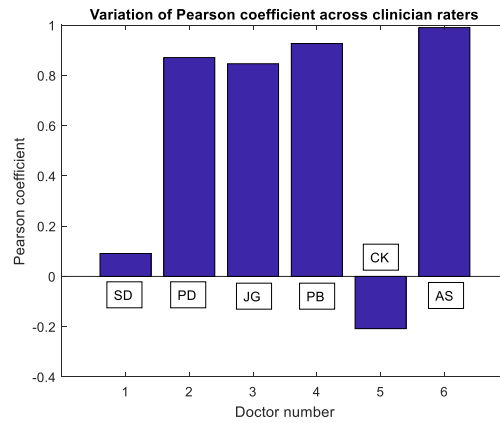


Figure 5.15: Variation of Pearson coefficient (between final measured arm and estimated glove power) across clinician raters

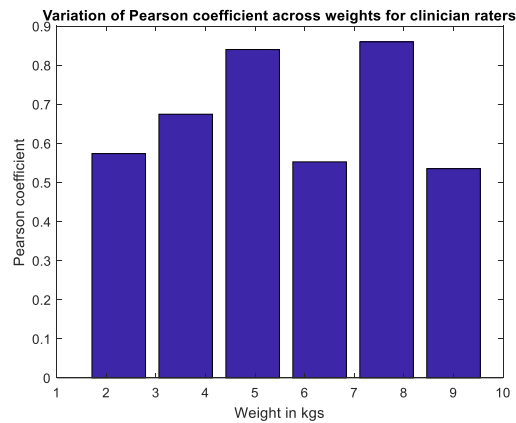


Figure 5.16: Variation of Pearson coefficient (between final measured arm and estimated glove power) across different weights for all clinician raters

After using the Neural Network: These results are detailed in Chapter 4. A comparison of the results from Aggregation method, Sensel boosting algorithm and aggregation with Neural Network are as follows:

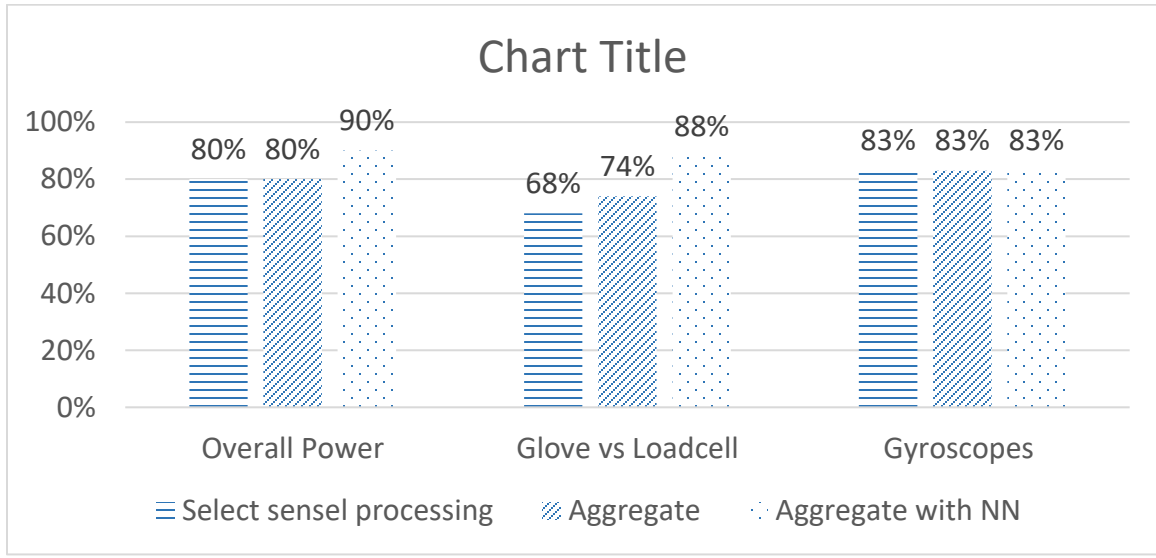


Figure 5.17: Comparison between methods for non-clinician data

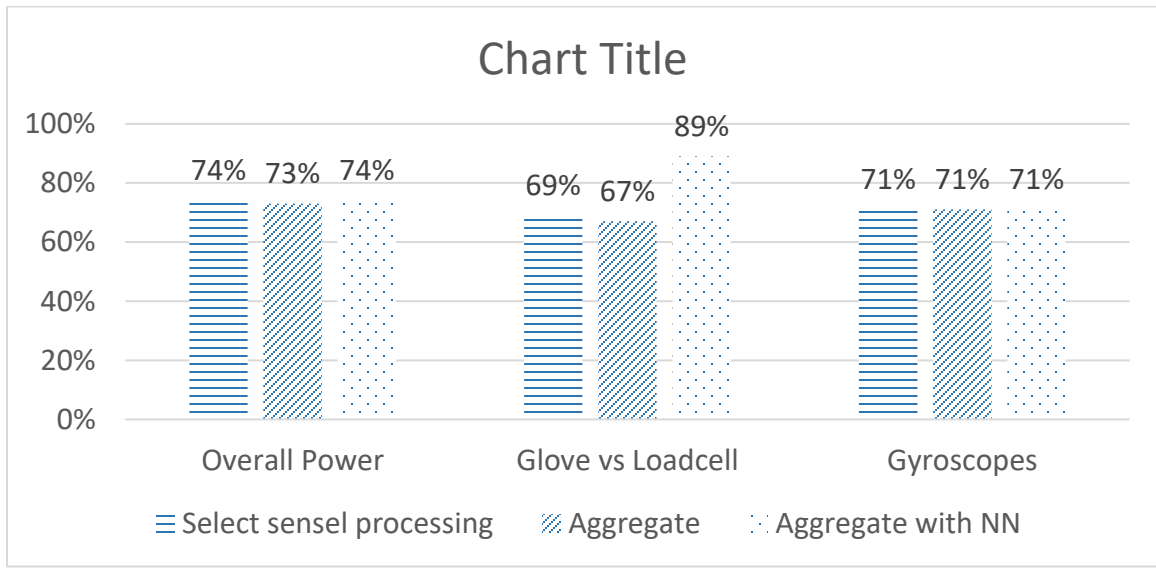


Figure 5.18: Comparison between methods for clinician data

6. CONCLUSIONS AND FUTURE SCOPE

Thus, from the research of this Thesis, we see that the Instrumented Glove shows definite promise of being a consistent, repeatable and objective measure for spasticity assessment. We see from Chapter 2 and 4 that it also correlates to the MAS whilst being more granular than MAS. We also see that the sensel boosting algorithm and the final (energy based) approach are effective methods of analyzing the glove data. The glove also shows a low rate of inter-rater variability. The glove is, however, sensitive to grip issues which need to be addressed. One of the key takeaway messages is that looking at inter-rater variabilities (bar charts showing variations), we see that it is significantly reduced. Thus, we have a trend depicting consistency and objectivity.

In the future, it would be highly beneficial if all the data is collected from a single system. In this way, all data streams would be on a common clock and there will also be an ease of data collection. Once this is achieved, the next goal would be to make the glove processing real time and wireless. In this way, a rater could use a computer or phone after wearing the glove to test the patient and the result would be readily available. The development of the new mock patient [1] would highly benefit the validation of glove and also be used for training of new doctors. The functionality to download and recreate actual patient data would immensely help in improving the glove. As discussed in the previous chapters, the glove has close to 34% errors and for this reason, research is being done in printing our own glove with required resolution and much less errors. This will also fit the glove better and thus remove issues like sensor coverage etc.

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