Setting the Tone for Virtual Spasticity Assessment: Planning Development and Testing of the Telerehabilitation-Objective-Neuromuscular- Evaluation (TONE) Device

by

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Abstract of Thesis

Background: Telehealth provides the ability to connect specialist healthcare providers with patients regardless of their geographical location or other limitations restricting in-person care. Spasticity is a common complication affecting individuals with neurological conditions requiring specialist management. In current in-person practice, challenges remain in objectively identifying the neural and non-neural components of spasticity, as no gold standard assessment exists. In telehealth and spasticity assessment practices, the inability to use routine hands-on approaches is a significant barrier to care. Quantitative measures relating to range of motion, muscle activity, and force are essential for advancing in-person and telehealth spasticity assessment practices. The Telerehabilitation-Objective-Neuromuscular-Evaluation (TONE) device is a novel device and software application capable of measuring and transmitting quantitative spasticity assessment information, including range of motion, surface electromyography, and force data within telehealth contexts.

Objectives: The main objective of this doctoral research was to develop, construct, and evaluate a device and software application for obtaining biomechanical and neurophysiological measurements of spasticity compatible with telehealth settings.

Methods: A series of three complementary studies were conducted to achieve the primary objective of this research. Study 1 utilized an online survey and focus group interviews to gather information about how spasticity clinicians across Canada are currently performing telehealth spasticity assessments. This study also aimed to identify challenges and advantages associated with telehealth spasticity assessment delivery. Plan-Do-Study-Act methodology was used to guide development of the Telerehabilitation-Objective-Neuromuscular-Evaluation (TONE)

device and software application as outlined in chapter 3. Device development was completed between the completion of Study 1 and prior to the validation testing of the device in Study 2. Study 2 involved validating the TONE device against reference standards in a population without neurological impairment. Proof of concept testing was completed in study 3, involving preliminary testing of the TONE device within a group of five participants with known post-stroke and traumatic brain injury-related spasticity of the upper extremity.

Results: Survey findings from study 1 indicated that most respondents felt the ability to perform telehealth spasticity assessments would benefit their clinical practice. However, most respondents also reported not being satisfied with current telehealth spasticity assessment practices. Qualitative analysis revealed telehealth spasticity assessment success to be highly variable and dependent on several personal and environmental factors. Participants identified the inability to perform hands-on clinical assessments of spasticity in telehealth environments as a significant limitation. Another theme emerging from qualitative interviews was uncertainty among spasticity clinicians regarding adopting quantitative measures of spasticity within clinical practice. Development of the first iteration of the TONE device and software application commenced in January 2021 and was completed in December 2021. Successful wireless transmission and recording of range of motion, force, and muscle activity measures were achieved prior to validation testing.

Study 2 demonstrated a moderate to strong relationship between elbow joint kinematic measures assessed between the TONE device and reference standard optical motion tracking measures. Good agreement was found between the TONE device's surface electromyography (sEMG) sensor and Delsys's sEMG reference standard measure for measures of muscle contraction duration time. Timing of the duration of muscle contraction and average force

analysis demonstrated good agreement between the developed TONE device and the commercially available handheld dynamometer (KForce®) reference device. Results from proof-of-concept testing in study 3 demonstrated that the TONE device was successfully able to measure and transmit quantitative spasticity assessment data from patient to specialist within a simulated telehealth environment. In five individuals, differences between the spastic and non-spastic limbs were detected during passive elbow extension in the measures of range of motion, joint angular velocity, force, and EMG signal response.

Conclusions: This thesis has outlined a collaboration between healthcare providers, biomedical engineers, researchers, and patients to develop a device and software application for obtaining biomechanical and neurophysiological measurements of spasticity compatible with telehealth settings. This thesis has also demonstrated that biomechanical and neurophysiological measures related to spasticity can be obtained within telehealth environments. Preliminary evidence has been presented that the TONE device is capable of differentiating between spastic and non-spastic upper limbs in individuals with post-stroke spasticity. Future work should aim to enhance the precision of the sEMG sensor data by preserving the raw signal, allowing for post-signal processing methods to determine if the catch angle can be visualized. Additionally, strategies for assessing spasticity in other body regions should be explored. Further investigation is needed into the feasibility and effectiveness of adopting quantitative measures of spasticity within clinical practice.

Preface

This thesis represents the original work completed by Daniel Gillespie. The research projects, of which this thesis are a part, received research ethics approval from the University of Alberta Research Ethics Board

- Study 1: Provider Prospectives on Remote Spasticity Assessment, No. Pro00101753, approved July 29th, 2021.
- Study 2: Setting the TONE for Virtual Spasticity Assessment: Validation of the Telerehabilitation Objective Neuromuscular Evaluation (TONE) Device and Software Application, No. pro00112935, approved February 7th, 2022.
- Study 3: Virtual Spasticity Assessment Using the TONE Device: Proof of Concept, No. pro00127061, approved February 28th, 2023.

This thesis is an original work by Daniel Gillespie. No part of this thesis has been previously published.

Dedication

To Emily, Alyssa, Breanna, and Terri

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List of Abbreviations

AS – Ashworth Scale

BoNT – Botulinum Toxin

BoNTA – Botulinum Toxin Type A

DSRT – Dynamic Stretch Reflex Threshold

EMG - Electromyography

ES – Electrical Stimulation

FSR – Force Sensitive Resistor

ICC – Intraclass Correlation Coefficient

ICT – Information Communications Technology

IMU – Inertial Measurement Unit

MAS – Modified Ashworth Scale

MOCAP – Motion Analysis Capture

MTS – Modified Tardieu Scale

MUAP – Motor Unit Action Potential

MVC – Maximal Voluntary Contraction

PDSA – Plan-Do-Study-Act (Development Process)

R1 – Slow Passive Range of Motion as measured during the Modified Tardieu Scale.

R2 – Fast Passive Range of Motion as measured during the Modified Tardieu Scale.

ROM – Range of Motion

sEMG – Surface electromyography

SENIAM – Surface Electromyography for the Non-Invasive Assessment of Muscles

SPASM – Support Programme for Assembly of a database for Spasticity Measurement

TONE – Telerehabilitation Objective Neuromuscular Evaluation

TSRT – Tonic Stretch Reflex Threshold

UMN – Upper Motor Neuron

UMNS – Upper Motor Neuron Syndrome

Chapter 1. Introduction

1.1 Post Stroke Spasticity Background

Spasticity is a common neurological impairment affecting sensory-motor control arising from lesions of the central nervous system (Dressler et al., 2018; Raghavan, 2022; Zorowitz, Gillard, & Brainin, 2013). Stroke, in particular, is a leading cause of neurological impairment, spasticity, and, consequently, disability within developed countries (Katan & Luft, 2018). In the United States, 795 000 new or recurrent strokes occur annually, with an estimated 9.4 million American adults (≥20 years of age) self-report having had a stroke (Benjamin et al., 2019; Tsao et al., 2023; Zeng Chen Guo, & Tan, 2020). In Canada, 62,000 new cases of stroke occur each year, with an estimated 405,000 individuals living with stroke-related impairments (Heart and Stroke Heart Canada, 2018; Krueger et al., 2015). Spasticity is also commonly experienced by individuals with multiple sclerosis, traumatic brain injury, spinal cord injury, and cerebral palsy (Hundza et al., 2016; Pandyan, Conway, Hermens, & Johnson, 2017; A. D Pandyan et al., 2005).

Spasticity presents within the first few weeks after stroke and has been estimated to affect between 20 to 40% of stroke survivors (Katoozian, Tahan, Zoghi, & Bakhshayesh, 2018; Opheim, Danielsson, Alt Murphy, Persson, & Sunnerhagen, 2014). Disabling or more severe presentations of spasticity after stroke occur in between 2 to 13% of stroke survivors (Opheim et al., 2014; J. Wissel, MD, Manack, A., & Brainin, M., 2013; Zorowitz et al., 2013). The large variability in spasticity prevalence estimates can be explained by the absence of a universally accepted definition and the several methods used for measuring and diagnosing spasticity (Brashear & Elovic, 2015; Opheim et al., 2014). Individuals who develop post-stroke spasticity are more likely to experience challenges performing voluntary movements necessary for

completing activities of daily living (Katoozian et al., 2018; Milinis, Young, & Trajectories of Outcome in Neurological Conditions, 2016). Features commonly associated with post-stroke spasticity include the presence of pain, restricted range of motion, paresis, muscle shortening, soft tissue contracture, abnormal posture, and functional impairment (Chang et al., 2013; Katoozian et al., 2018; Kuo & Hu, 2018). Functional impairment associated with spasticity has also been demonstrated to increase the burden of care placed on caregivers (Alberto Esquenazi, 2011).

Despite the high occurrence and associated negative consequences of spasticity reported in the literature, spasticity is often unrecognized and, as a result, undertreated (Tamburin, Filippetti, Mantovani, Smania, & Picelli, 2022). A retrospective study by Cox et al. (2016) examined a primary care database of over 35,000 stroke cases in the United Kingdom over five years between January 1, 2007, and December 31, 2011. Their study revealed a reported prevalence of post-stroke spasticity of only 2%, revealing a value much lower than even the lowest estimates of post-stroke spasticity in the literature (Cox et al., 2016). The findings by Cox et al. (2016) provide objective evidence that post-stroke spasticity is likely underdiagnosed and under-reported. Living with undiagnosed spasticity places patients at risk for deferred treatment only after secondary complications arise and likely results in a number of patients with spasticity-related functional problems who do not receive treatment at all (Christofi et al., 2018).

1.2 Defining Spasticity

One of the challenges in identifying spasticity is that no universally accepted definition of spasticity exists (Malhotra, 2009). Spasticity is most commonly defined as “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" (Lance, 1980; Malhotra, 2009). The upper motor neuron syndrome (UMNS), referred to in Lance's definition, represents a variety of sensory-motor control abnormalities that can occur due to central nervous system pathology. Symptoms of the UMNS are classified into positive and negative features. Positive features include muscle overactivity, while contrasting negative features result in muscle underactivity (Segal, 2018). Positive features of the UMNS include co-contraction, clonus, spastic dystonia, positive primitive reflexes, for example, positive Babinski or Hoffman reflex, flexor and extensor spasms, hyperreflexia, and spasticity. Negative features of the UMNS include muscle weakness, fatigue, and overall difficulty with controlling and regulating voluntary muscle movements (Alberto Esquenazi, 2011; Segal, 2018). Although representing one of many UMNS symptoms, within clinical practice, 'spasticity' has become an umbrella term under which many of the positive features of the UMN syndrome fall (Segal, 2018).

In 2005, the Support Programme for Assembly of a Database for Spasticity Measurement (SPASM) project proposed a spasticity definition based on needs highlighted in research and clinical settings. The SPASM project defines spasticity as "a disordered sensory-motor control resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles" (Burridge et al., 2005). This broader definition of spasticity goes beyond the main focus of changes to passive stretch reflexes – as found in Lance's (1980) definition – capturing more of the commonly described clinical features occurring with active movements, such as clonus and spastic co-contraction (Burridge et al., 2005).

Although not widely cited in the literature, Li et al. (2021) have proposed a more encompassing definition of spasticity that captures recent advances in understanding the pathophysiology of post-stroke spasticity. Their definition of spasticity related to stroke states

that “spasticity is manifested as velocity and muscle length-dependent increase in resistance to externally imposed muscle stretch; it results from hyperexcitable descending excitatory brainstem pathways and the resultant exaggerated stretch reflex responses; other related motor impairments, including abnormal synergies, inappropriate muscle activation, and anomalous muscle coactivation, coexist with spasticity and share similar pathophysiological origins (Li, Francisco, & Rymer, 2021). The authors argue that their updated definition reflects both the recent changes in our understanding of the pathophysiology of spasticity along with describing more of the commonly associated motor impairments resulting from abnormal neuroplasticity after stroke.

The Lance (1980), SPASM project (2005), and Li et al. (2021) definitions highlight different and vital aspects of spasticity. The Lance definition describes the ‘velocity dependent’ nature of spasticity, while the broader SPASM definition includes more features of the UMNS aligning more closely with the clinical use of the term spasticity. The Li et al. (2021) definition describes anatomical structures involved in post-stroke spasticity and commonly coexisting features of the UMNS that present with spasticity. Regardless of the definition, a common theme of ‘exaggerated tendon jerks,’ ‘stretch-reflex hyper-excitability,’ and ‘intermittent or sustained involuntary muscle contraction’ all point to non-voluntary muscle hyperactivity that can occur during passive and active movement. The term ‘spasticity’ in this thesis project will refer to the definition provided by Lance (1980).

1.3 Spasticity Pathophysiology

As mentioned in the definition by Lance (1980), spasticity represents one component of the upper motor neuron UMNS. An understanding of the UMNS is essential to understanding how spasticity manifests. The UMNS can be divided into *active* and *passive* components, producing changes in muscle tone and motor control. Active components (spastic dystonia, spastic co-contraction, and spasticity) refer to alterations in motoneuronal hyperexcitability within the spinal cord resulting in changes to motor control. In contrast, passive components refer to plastic changes observed within the muscle and connective tissues (Baude, Nielsen, & Gracies, 2018). The plastic muscle and connective tissue changes related to the UMNS, referred to as "spastic myopathy" by (Baude et al., 2018), result in changes to viscosity, length, and elasticity observed within the muscle and connective tissues. This phenomenon is believed to result from hypo-mobilization of the limb, commonly occurring after central nervous system lesions affecting sensory-motor function. Due to this hypo-mobilization, the muscle is often left in a shortened position. This prolonged period of muscle shortening is associated with increased collagen and fat accumulation, loss of sarcomeres, loss of skeletal muscle mass, and bone mineralization (Baude et al., 2018; Thibaut et al., 2013). It should be noted that although the passive component of the UMNS is not directly related to the pathophysiology of spasticity, spastic myopathy could have indirect effects as it is thought to facilitate muscle spindle sensitivity in the contracted muscles (Baude et al., 2018).

Regarding post-stroke spasticity, the work by (Li, Chen, Francisco, Zhou, & Rymer, 2019) gives a theoretical framework highlighting several important physiological structures and processes to help illuminate how spasticity manifests post-stroke. This work resulted in the updated definition of post-stroke spasticity by Li et al. (2021). Within this framework, cortical

lesions affecting the primary motor cortex and, subsequently, the reticulospinal system are believed to result in changes to spinal motoneuron excitability. The reticulospinal tract is known to assist in postural control during ambulation; it has also been demonstrated to recruit upper extremity distal and proximal muscles, including the muscles acting on the fingers, as cited by (Li et al., 2019). The authors propose that spasticity is likely to occur due to an imbalance between inhibitory and excitatory inputs from the reticulospinal system, creating an environment for spasticity to arise. Due to the close anatomical proximity of the corticoreticular tract, corticospinal tract, and primary motor area, lesions to the primary motor cortex can result in damage to the corticoreticular tract. Damage to this region results in less activation of the medullar reticular formation and inhibitory dorsal reticulospinal tract to spinal motoneurons.

Additionally, the contralesional primary and supplementary motor areas project descending fibres to the pontine reticular formation that produce excitatory descending inputs to spinal motoneurons. The descending medial reticulospinal tract releases serotonin and norepinephrine, facilitating persistent inward currents in spinal motor neurons. These unopposed excitatory inputs result in sustained firing and hyperexcitability of spinal motor neurons. Therefore, the commonly observed clinical features of spasticity, including increased tendon jerks, muscle overactivity, and hyperreflexia, are a result of the unopposed *excitatory* influence of the contralesional primary motor cortex and supplementary motor areas, along with decreased inhibitory input from the primary motor cortex on spinal motoneurons (Li et al., 2019).

Motoneuron hyperexcitability and plastic changes at the spinal level are also believed to be altered by afferent input changes to spinal motoneurons. These changes are also likely affected by a *decrease* in homosynaptic depression (Burke, Wissel, & Donnan, 2013). In the absence of pathology, repetitive stimulation of type Ia afferent fibres arising from intrafusal

muscle spindles results in the depression of the release of excitatory transmitter acting on the alpha motoneuron (Burke et al., 2013). The elicited depression is not solely restricted to the afferent Ia fibre and motoneuron; this mechanism also depresses the excitation of reflex pathways resulting in "habituation" of reflexes that are evoked repeatedly (Burke et al., 2013). In the presence of spasticity, a decrease in homosynaptic depression has been a key finding and has been demonstrated to correlate with the degree of spasticity (Burke et al., 2013).

1.4 Clinical Spasticity Management

Within clinical practice, the assessment and management of spasticity is complex, requiring specialized services for accurate diagnosis and effective management. Challenges remain in correctly identifying and measuring spasticity – a condition that has no universally agreed-upon definition and lacks a gold-standard method of assessment (Sunnerhagen, 2013). Clinicians must navigate these challenges while providing optimal and individualized treatment recommendations to patients presenting for spasticity assessment. Multidisciplinary teams are often involved and include physicians, physical, occupational, and speech therapists, and nurses, with the patient playing a vital role in evaluating and managing their condition (Reeves & Lambeth, 2016). Knowledge surrounding spasticity pathophysiology, along with rehabilitation assessment and treatment options, is vital in assisting patients in achieving the greatest level of independence possible (Sunnerhagen, 2013). The following sections will provide an overview of in-person and virtual approaches to spasticity assessment and treatment.

1.5 In-Person Spasticity Assessment

Traditional in-person spasticity assessment starts with a detailed patient history to aid in determining the presence or absence of spasticity and the impact of spasticity on the patient's

life. As spasticity is a symptom of central nervous system pathology, the patient's medical history must be reviewed to establish the presence of a neurological condition known to give rise to the UMNS. Without an associated diagnosis leading to central nervous system pathology, spasticity is highly unlikely unless an unknown underlying neurological condition is present. The patient history should also explore the timing and onset of symptoms, along with the frequency and severity of muscle tightness and spasms experienced by the patient. Other areas of interest within the patient's history include asking the patient about medications taken, the muscle group(s) affected, and whether or not pain is present (Balci, 2018). History taking should also examine for any known factors causing the worsening of symptoms identified by the patient, such as cold temperature, infection, pain, and stress (Balci, 2018; Phadke, Balasubramanian, Ismail, & Boulias, 2013). Lastly, it is also necessary for the clinician to investigate whether the patient feels their increase in muscle tone is helpful or harmful regarding performing functional activities.

After completion of the patient history, a thorough physical examination of the patient should be completed. Three important spasticity evaluation areas of focus have been mentioned in the literature and include: 1) identifying the clinical pattern of motor dysfunction; for example, the clinical pattern most commonly affecting individuals with spasticity in the upper limb is a combination of internal rotation and adduction of the shoulder, along with flexion at the elbow, wrist, and the fingers; 2) identifying the patient's abilities in performing movements within the clinical pattern(s) restricting movement; 3) differentiating the role of muscle stiffness and contracture (Thibaut et al., 2013). The most commonly used clinical assessments of spasticity involve moving the affected limb or joint through a series of passive movements to grade the degree of resistance to passive stretch or muscle tone (Reeves & Lambeth, 2016). The Ashworth

Scale (AS) and Modified Ashworth Scale (MAS) are the most frequently used clinical evaluations of spasticity (Kaya, Karatepe, Gunaydin, Koc, & Altundal Ercan, 2011). The AS was the first proposed clinical scale developed to measure spasticity in individuals with multiple sclerosis by Ashworth (1964) (as cited in Johnson, 2002). The AS uses a five-point ordinal scale to classify a muscle group's resistance to passive stretch (see Table 1). The MAS was later proposed by Bohannon & Smith (1987) to add a '1 +' rating to distinguish further the resistance felt in the presence of a catch' (see Table 1) (Johnson, 2002). A systematic review by (Platz, Eickhof, Nuyens, & Vuadens, 2005) examining clinical scales used in spasticity assessment found the AS and MAS demonstrated good interrater reliability, but not in all circumstances (Platz et al., 2005). Another limitation of the AS and MAS is that these scales do not distinguish between neural (reflex hyperexcitability) and non-neural (muscle contracture and tissue shortening) causes of increased resistance to passive movement (Luo, Lo, Bian, Wong, & Li, 2019).

Table 1. Ashworth and Modified Ashworth Scales

Clinical Scale	Grade	Description
Ashworth Scale	0	No increase in tone.
	1	Slight increase in tone giving a 'catch' when the limb is moved in flexion or extension.
	2	More marked increase in tone, but limb easily flexed.
	3	Considerable increase in tone, passive movement difficult.
	4	Limb rigid in flexion or extension.

Table 1. *(Continued)* Ashworth and Modified Ashworth Scales

Clinical Scale	Grade	Description
Modified Ashworth Scale	0	No increase in tone.
	1	Slight increase in tone – a catch and release at the end of the range of motion.
	1+	Slight increase in tone – a catch, followed by minimal resistance in remainder of range.
	2	More marked increase in muscle tone through most of range.
	3	Considerable increase in tone, passive movement difficult.
	4	Limb rigid in flexion or extension.

The Modified Tardieu Scale (MTS) is another widely used scale in the assessment of spasticity. The MTS incorporates varying speeds of passive movement into the evaluation of spasticity, aligning more closely with the 'velocity dependent' aspect of the spasticity definition by Lance (1987) (Thibaut et al., 2013). Evaluation of the MTS includes four components: 1) R1, which is the angle of catch measured during a fast velocity passive stretch; 2) R2, the passive range of motion following a slow velocity stretch; 3) R2-R1, indicating the dynamic component of spasticity within the muscle, and 4) quality ratings of fast velocity, passive movement (see table 2) (Naghdi et al., 2014; Sonvane & Kumar, 2019). Larger differences between R1 and R2 reflect greater available dynamic range, whereas smaller differences represent a larger muscle contracture component (Naghdi et al., 2014; Sonvane & Kumar, 2019). Incorporating fast and slow passive movement velocity within the assessment makes the MTS superior to the MAS in detecting the neurological component of stiffness, as the MAS does not explicitly control for the speed of passive movement performed during evaluation (Sunnerhagen, 2013). The validity and reliability of the MTS has been primarily examined in children with cerebral palsy and not

specifically in the context of adult stroke (Thibaut et al., 2013). There is a need for further evaluation of the validity and reliability of this scale in various muscle groups and conditions (Sunnerhagen, 2013).

Table 2. Modified Tardieu Scale

Clinical Scale	Grade	Description
Modified Tardieu Scale	0	No resistance throughout the course of the passive movement.
	1	Slight resistance throughout the course of the passive movement, with no clear catch at precise angle.
	2	Clear catch at precise angle, interrupting the passive movement, followed by release.
	3	Fatigable clonus (<10 s when maintaining pressure) occurring at precise angle.
	4	Infatigable clonus (>10 s when maintaining pressure) occurring at precise angle.

1.6 In-Person Spasticity Treatment

Decision-making surrounding the treatment of spasticity is highly complex and requires specialist consultation for effective management (Christofi et al., 2018). Specialist multidisciplinary teams are often involved, typically including physiatrists, physicians, physiotherapists, occupational therapists, and nurses (Turner-Stokes et al., 2018). Treatment decisions should be patient-centered, focusing on the goals of patients and their caregivers (Brashear & Elovic, 2015). Treatment must be tailored specifically to the individual, as no single approach is suitable for all individuals experiencing spasticity. Spasticity is not always

problematic and can even be beneficial to patients, further complicating treatment recommendations.

The increase in muscle tone, often accompanying spasticity, has been reported to assist with functional transfers, walking, and other functional movements (Rekand, 2010). In these cases, spasticity treatment recommendations may be very different than for a patient with problematic or disabling spasticity, where the goal of reducing muscle tone in the overactive muscle may be desired. In this way, treatment decisions should not focus solely on reducing muscle tone but should aim to improve patient function and well-being (Francisco & McGuire, 2012). Several treatment options exist for spasticity management, which can be grouped into two categories: pharmacological and non-pharmacological (Hashemi, Sturbois-Nachef, Keenan, & Winston, 2021).

1.6.1 Pharmacological Management of Spasticity

Pharmacological management includes oral anti-spasmodic medication, injectable chemical neurolytic agents, and intrathecal baclofen pumps. Although these medications have different mechanisms of action, they all modulate the response of the central nervous system or peripheral muscles to reduce spasticity (Kuo & Hu, 2018). For this reason, correctly diagnosing spasticity becomes imperative, as there must be a neurological component to the patient's movement restriction for pharmacological treatments to be effective. Under these approaches, reducing involuntary muscle over-activity is assumed to help restore the mobility of the patient's joints and limbs, leading to improvements in active and passive movement. In patients with joint stiffness and limited range of motion unrelated to spasticity – for example, paresis leading to immobility and subsequent contracture – the prescription of these same nervous system modifying agents would be ineffective. Therefore, the prescription of medications to further

decrease nervous system activity in patients without spasticity would have no effect on mobility and may even lead to further weakness and movement problems.

Oral Spasticity Medications

Baclofen and tizanidine are two of the most commonly prescribed oral anti-spasmodic medications for spasticity (Bethoux, 2015). Baclofen acts by crossing the blood-brain barrier where it binds to gamma-aminobutyric acid – B receptors (Chang et al., 2013; Kuo & Hu, 2018). This causes membrane hyperpolarization at the synaptic terminals, resulting in restricted calcium influx, which restricts endogenous excitatory neurotransmitter release, and inhibits mono- and polysynaptic spinal reflexes (Chang et al., 2013). While baclofen is commonly prescribed, its use is not without risk. Adverse effects of baclofen can include systemic muscle relaxation, sedation, and fatigue (Bethoux, 2015). There is also a risk of hepatotoxicity which requires monitoring of liver function when taking baclofen (Brashear & Elovic, 2015). It is not recommended for use in elderly patients due to its tendency to cause excessive drowsiness in this population (Hulme, MacLennan, Ritchie, John, & Shotton, 1985). There is also some evidence from animal studies that baclofen may limit neuroplasticity and is not recommended in the early stages of recovery after stroke (Simon & Yelnik, 2010).

Tizanidine is an alpha 2-adrenergic agonist which increases presynaptic inhibition of motoneurons by a reduction in the release of excitatory amino acids from spinal interneurons, resulting in muscle tone reduction (Chang et al., 2013; Kuo & Hu, 2018; Simon & Yelnik, 2010). Tizanidine is a short acting medication less likely to cause persistent muscle weakness and is often prescribed in combination with baclofen for additional effects (Chang et al., 2013; Kuo & Hu, 2018). Tizanidine has a half-life of 2.5 hours, due to its quick absorption rate, it is usually taken regularly every 4-6 hours (Simon & Yelnik, 2010). Common side effects of tizanidine are

sedation, hypotension, xerostomia, muscle weakness, and hallucinations (Simon & Yelnik, 2010).

Chemical Neurolysis: Phenol & Alcohol

Chemical neurolysis represents a more targeted approach to treating muscle overactivity associated with spasticity. Interventions using neurolysis involve the injection of chemical agents directly into a nerve or motor point with the goal of impairing muscle activation by the nervous system (Brashear & Elovic, 2015). Phenol and alcohol were commonly used for chemical neurolysis between the 1950's and 1990's. Phenol is a carbolic acid, prepared for injection by dissolving in water and other mediums such as glycerine. When injected into tissues at concentrations of 5% or greater, phenol denatures proteins causing tissue necrosis (Brashear & Elovic, 2015). Concentrations between 3-5% applied to peripheral nerves, can cause axonal degeneration and motor fiber demyelination (Kuo & Hu, 2018). The mechanism of action of alcohol injection is very similar to phenol resulting in the non-selective denaturization of proteins affecting axons, myoneural junctions, muscle fibres, and interstitial tissue (Brashear & Elovic, 2015). Adverse effects of phenol and alcohol include pain and swelling at the injection site and dysesthesia (Kuo & Hu, 2018; Teasell, Foley, Pereira, Sequeira, & Miller, 2012). The use of these agents can also result in irreversible damage to the nerve supplying the spastic muscle. Overall the use of phenol and alcohol injections are in decline, but can be effective under special circumstances where motor and sensory neurolysis is desired (Brashear & Elovic, 2015).

Botulinum Toxin Injection

Chemical neurolysis using botulinum toxin (BoNT) injection represents the gold standard for treating focal spasticity in post-stroke patients (Baricich et al., 2023; Ojardias et al., 2022;

Ward et al., 2003). Strong evidence supporting the effectiveness and safety of BoNT use for the treatment of upper and lower limb post-stroke spasticity has been extensively reported in the literature (Dong, Wu, Hu, & Wang, 2017; Esquenazi et al., 2013; Intiso, Santamato, & Di Rienzo, 2017; Kaku & Simpson, 2016; Lamb & Scott, 2016). The use of BoNT injection has been demonstrated to be effective for reducing pain, improving walking ability, mobility, patient care procedures, activities of daily living, and quality of life (Baricich et al., 2023). A review by Esquenazi et al. (2013) concluded that BoNT type A injection was generally associated with reductions in muscle tone as compared to placebo injection for upper limb spasticity post stroke within 2 weeks of injection with beneficial effects lasting 3-4 months (Esquenazi et al., 2013).

BoNT is one of the most poisonous biological substances known to humans (Münchau & Bhatia, 2000). It is a potent neurotoxin that works by inhibiting the release of acetylcholine into the synaptic cleft by binding to one or more of the transport protein chains at the presynaptic terminals (Brashear & Elovic, 2015; Ozcakir & Sivrioglu, 2007). Compared to phenol and alcohol neurolysis, BoNT neurolysis specifically inhibits muscle nerves without causing skin sensory loss or dysesthesia (Suputtitada & Suwanwela, 2005). The effects of BoNT are reversible, giving this treatment a significant advantage over phenol and alcohol injections. BoNT has also been reported to result in less reported adverse systemic effects that more commonly occur with oral spasmodic medications (Walker, Lee, Bahroo, Hedera, & Charles, 2015). A systematic review by Dong et al. (2017) examining the efficacy and safety of BoNT type A (BoNTA) injection in adults with upper limb spasticity, found no statistically significant difference in the number of adverse events reported between BoNTA and placebo injection (Dong et al., 2017). Despite being relatively safe, adverse events or reactions can occur with use of BoNT injection such as systemic absorption when administered in large doses, muscle

atrophy, dysphagia, and immunological reactions (Guzman-Venegas, Araneda, & Silvestre, 2014; Yiannakopoulou, 2015).

Seven distinct serotypes of BoNT have been identified (labelled A through G), of these, types A and B have been approved for spasticity treatment. The most commonly used neurotoxin for the treatment of upper and lower limb post stroke spasticity BoNT-A. The three leading BoNT-A products commercially available for spasticity treatment include onabotulinumtoxinA (Botox®, Allergan, Inc., Irvine, CA), bobotulinumtoxinA (Dysport®, Ipsen Ltd., Berkshire, UK), and incobotulinumtoxinA (Xeomin®, Merz Pharma Ltd., Frankfurt, DE) (Ozcakir & Sivrioglu, 2007; Teasell et al., 2012). Botulinum toxin (type B) is commercially available as rimabotulinumtoxinB (Myobloc® in the United States and NeuroBloc® in Europe (Elan Pharmaceuticals, San Diego, CA). BoNT type b injection is less commonly used in clinical practice with few studies examining its effectiveness in the literature (Ozcakir & Sivrioglu, 2007; Sheean, 2006).

Botulinum Toxin Injection Guidance Techniques

The efficacy of BoNT injection is enhanced by accurate needle placement and application of the correct neurotoxin dosage in close proximity to the neuromuscular junction of the targeted muscle (Guzman-Venegas et al., 2014). Units of each product are not equivalent necessitating the clinician administering the injection to be familiar with the recommended dose depending on the toxin used. No perfect method of injection into the neuromuscular junction exists; however, guided techniques are strongly recommended over the use of anatomical landmarking alone (Walker et al., 2015; J. Wissel et al., 2009).

Guided techniques involve the use of anatomical localization in combination with electromyography, electrical stimulation, or ultrasound guided injection (Walker et al., 2015). Clinicians must have extensive anatomical knowledge while also accounting for unique anatomical features of each individual. If using electromyography or electrical stimulation guided BoNT injection, a 25-gauge hollow insulated monopolar needle with an electrically conductive inner core is used (Walker et al., 2015). The stimulating needle can be used to record electromyography signals or identify motor points using electrical stimulation to assist with identifying correct needle placement. Once the stimulating needle is within satisfactory position, BoNT injection can be administered with the same needle left in place. Ultrasound guided injection can also be used to visually identify anatomical structures in real time including muscle, nerve, and bone tissue (Kaymak et al., 2018). This technique is useful in determining correct needle placement prior to injection of the targeted muscle tissue. Electromyography, electrical stimulation, and ultrasound guided techniques have been shown to be superior to anatomical localization alone in respect to accuracy and BoNT treatment effectiveness (Walker et al., 2015; J. Wissel et al., 2009).

Intrathecal Baclofen

Although not commonly used in the treatment of post-stroke spasticity, intrathecal baclofen can be indicated in the presence of severe lower limb and generalized spastic hypertonia within this population (Bakheit, 2012; Creamer et al., 2018). Intrathecal baclofen has also been demonstrated to help with individuals experiencing pain after stroke (Bakheit, 2012; Taira & Hori, 2007). Unlike oral baclofen, intrathecal baclofen therapy is administered using an externally programmable pump surgically implanted into the patient. The pump administers baclofen directly into the cerebrospinal fluid through a small flexible catheter inserted into the

intrathecal space (Meythaler, Guin-Renfroe, Brunner, & Hadley, 2001). Due to the close proximity of the deployment and uptake of the medication directly within the spinal neurons, only a small amount of medication is required to be effective. This reduced dosage results in less undesirable side effects such as the sedation and drowsiness commonly occurring with oral baclofen (Francisco et al., 2006; Meythaler et al., 2001).

1.6.2 Non- Pharmacological Management of Spasticity

The prescription and use of non-pharmacological management includes rehabilitation techniques often employing stretching and strengthening exercises, bracing, and surgery. Rehabilitation techniques performed with physical and occupational therapists along with bracing represent the first line of spasticity treatment with surgical management reserved for patients with severe spasticity not amendable to other non-pharmacological and pharmacological treatment (Hashemi et al., 2021). A combination of non-pharmacological and pharmacological interventions is most often recommended. Therapy employs a number of treatment techniques and modalities often administered by physical and occupational therapists.

Stretching Interventions

Stretching is the most commonly prescribed intervention for the management of spasticity (Harvey et al., 2017; Salazar et al., 2019). Stretching programs are prescribed for a number of reasons including maintaining or increasing soft-tissue length, reducing muscle tone, reducing pain, preventing contractures, and improving function (Bovend'Eerdt et al., 2008). Stretching accomplishes these goals by improving the viscoelastic structure of the muscle tendon unit and depressing stretch reflex activity of muscle spindle afferents (Gracies, 2001). While muscle is often the intended target of stretching interventions, several other structures are also

placed under tension during the application of stretch, including tendon, connective, vascular, dermal, and neural tissue (Bovend'Eerdt et al., 2008).

Stretching interventions can be applied manually, or with external devices such as splints, orthoses, and plaster casts and are often performed as an adjunct treatment (Bovend'Eerdt et al., 2008; Gomez-Cuaresma et al., 2021). Manual stretching is usually performed by rehabilitation professionals or caregivers who apply passive movements of the affected limb(s). If able, patients may also be instructed to perform stretching exercises independently. The effects of stretching are transient often requiring multiple sessions to be performed on a regular basis. The use of external devices for the application of more frequent and longer duration stretching interventions can greatly assist when manual stretching is not feasible.

Despite the widespread use of stretching programs, there remains inconclusive evidence in the research regarding the effectiveness of stretching for improving range of motion and function for individuals with post-stroke spasticity (Gomez-Cuaresma et al., 2021; Harvey et al., 2017). There is also no consensus on the optimal frequency, intensity, velocity, and duration of stretching interventions for individuals with spasticity. The lack of conclusive evidence surrounding the effect of stretching effectiveness on spasticity improvement is likely due to both the large variability in prescribed stretching regimens and how spasticity improvements are measured. Regardless of the lack of clear evidence, the use of stretching interventions play an important role in lessening the known detrimental affects of limb immobilization and continue to be an important intervention for individuals with spasticity.

Strengthening Exercise

In the past, strengthening activities were believed to worsen spasticity and as a result avoided in this population (Pak & Patten, 2008). Research has refuted this traditionally held belief providing support for the inclusion of strengthening exercises for individuals with spasticity (Abal del Blanco & Taboada-Iglesias, 2021; Ada, Dorsch, & Canning, 2006; Miller & Light, 1997; Pak & Patten, 2008). Graded resistance exercises work by repetitively overloading specific muscle groups resulting in improved motor unit recruitment and muscle hypertrophy leading to improvements in strength and endurance.

Hemiparesis is estimated to affect between 73-88% of individuals after stroke, with many of these patients developing concurrent spasticity impairing functional tasks (Winstein et al., 2004). Resistance training has been shown to increase strength, gait speed, and functional outcomes resulting in improved quality for individuals post-stroke without exacerbation of spasticity (Pak & Patten, 2008). A systematic review by Ada et al. (2006) concluded that 'interventions to increase strength after stroke can improve strength and activity and do not necessarily increase spasticity'. Another systematic review of 10 randomized control trials by Abal del Blanco and Toboada-Iglesias (2021), supports the inclusion of strengthening exercises for individuals with spasticity. In their review, functional improvements were found to be associated with resistance based exercise, with no associated worsening of spasticity symptoms (Abal del Blanco & Taboada-Iglesias, 2021). Although there is no clear evidence showing that strength training reduces spasticity, resistance training should be prescribed for individuals post stroke given the strong evidence that strength training can improve functional tasks and quality of life without exacerbating spasticity symptoms.

Electrical Stimulation

Electrical stimulation (ES) has been widely reported to reduce spasticity and improve range of motion in persons with stroke (Chasiotis et al., 2022; Stein, Fritsch, Robinson, Sbruzzi, & Plentz, 2015). ES works by stimulating the axons of intact lower motor neurons causing contraction of the targeted muscle (Brashear & Elovic, 2015). ES can be used to elicit passive muscle contraction in completely paralyzed muscle groups, or, in combination with voluntary movements such as opening and closing of the hand (Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2003). Repetitive ES has not only been shown to reduce muscle tone, but has also been found to strengthen antagonist muscles in individuals with post stroke spasticity (Sahin, Ugurlu, & Albayrak, 2012). ES has also been advocated to work synergistically with BoNTA and has been demonstrated to increase the effectiveness and latency of uptake of the neurotoxin (Hesse, Jahnke, Luecke, & Mauritz, 1995; Hesse, Reiter, Konrad, & Jahnke, 1998).

Surgery

Surgical procedures for spasticity can be used to address common limb and joint deformities resulting from post stroke spasticity including elbow flexion, forearm pronation, wrist and finger flexion, and spastic equinovarus foot (Tranchida & Van Heest, 2020). A number of surgical options are available that typically involve soft tissue lengthening, tendon transfer, joint stabilization procedures and neurectomy (Tranchida & Van Heest, 2020). Surgical interventions are performed with the same goals as other interventions for spasticity including optimizing limb positioning, improving range of motion, and improving ease of personal care. Surgical treatment for post stroke spasticity is mainly used for severe cases, or for cases non amenable to other interventions (Kuo & Hu, 2018).

1.7 Telehealth and Spasticity Management

Telehealth has long been promoted as an essential strategy for improving accessibility to healthcare services (Blacquiere et al., 2017; Brennan, Mawson, & Brownsell, 2009; Field, 1996; Kairy, Lehoux, Vincent, & Visintin, 2009). Telehealth care – once mainly thought of as a strategy for improved healthcare access for individuals living in rural and remote regions – became a widely promoted solution of continuing healthcare services amid access restrictions experienced by patients and providers during the recent COVID-19 pandemic (Werneke et al., 2021). The pandemic placed telehealth in the spotlight and highlighted the detrimental effects on individual and societal health when healthcare services are not accessible. With the increase in telehealth adoption worldwide, healthcare providers need to consider telehealth's role in the future beyond the pandemic (Thomas et al., 2022).

In the area of spasticity assessment and management, efforts were made to leverage telehealth as a means of continuing care during in-person access restrictions. Recent publications aimed at guiding clinicians involved in outpatient telehealth spasticity assessment emerged during the COVID-19 pandemic (Reebye et al., 2020; Verduzco-Gutierrez et al., 2020). Despite the promotion of telehealth during the pandemic, an Italian survey of 151 patients with spasticity related to stroke and traumatic brain injury found that only 7.3% of patients reported receiving care via telerehabilitation with professionals during pandemic-related outpatient clinic closures (Santamato et al., 2021). The same study revealed a worsening in perceived spasticity, functional independence, and quality of life following treatment interruptions during the pandemic (Santamato et al., 2021).

The low percentage of individuals with spasticity receiving telehealth care during the pandemic, as reported by Santamato et al. (2021), is likely more related to clinician capacity and

training rather than patient willingness to participate in telehealth care. In a survey of 1,441 outpatients seen at the University of Arkansas general neurology clinics, over 52% of patients stated they would be interested in telemedicine appointments for follow-up care, with higher interest among patients with physical disabilities or geographical barriers (travel > 1 h) (Bashiri, Greenfield, & Oliveto, 2015).

A study by Gumussu and Erhan (2023) investigated the effects of disruptions to spasticity management experienced by individuals with spinal cord injury during the COVID-19 pandemic. In their phone-based survey of 24 individuals with spasticity, 87.5% of participants reported a moderate or severe increase in their spasticity symptoms during the pandemic restrictions (Gumussu & Erhan, 2023). Additionally, only 50% of survey participants reported completing home based exercises regularly, of these, only 12.5% reported being able to access physiotherapist or occupational therapist appointments during the pandemic restrictions. The authors highlight that telemedicine and telerehabilitation may help solve this issue by allowing for exercise treatment monitoring and home-based therapy when in-person care is unavailable (Gumussu & Erhan, 2023).

1.8 Telehealth Spasticity Assessment

Spasticity teleassessment has great potential in reaching patients experiencing barriers to in-person consultation. The use of telehealth can assist with identifying individuals with spasticity who would benefit from a referral for in-person treatment (Harper et al., 2020). Despite the many potential benefits of telehealth use for spasticity assessment, few publications exist. The earliest mention of telehealth spasticity assessment in the literature is by Park, Peng, and Zhang (2008). In their study, the authors describe the testing of a portable haptic system for

evaluating spasticity and neurologically related elbow impairment. Amazingly, the authors developed a system enabling the clinician and patient to remotely feel each other's movements. The system allowed for the remote assessment of passive ROM, active ROM, muscle strength, velocity-dependent spasticity, and catch angle. However, the authors reported challenges with movement tasks performed at high speeds and highlighted potential issues with bandwidth and network latency(Park, Peng, & Zhang, 2008). Although the authors report the system was 'designed to be low cost,' the components used in their design would cost several thousand dollars. This cost would be a financial barrier for the vast majority of patients and healthcare agencies, making the widespread uptake of this system into clinical practice impractical.

A cross-sectional study by Harper et al. (2020) evaluated the performance of a telehealth screening tool for identifying spasticity. Spasticity assessments were completed by two teleneurologists and compared with in-person neurological examination to determine the presence or absence of spasticity. The study found that both teleassessment ratings of spasticity showed high specificity ≥80% and ≥65% sensitivity in identifying the presence of spasticity compared to the in-person assessment reference standard. The authors also found 94% agreement in identifying spasticity presence among the two teleneurologists (Harper et al., 2020). This study provides evidence that a simple telehealth screening procedure may be suitable for identifying individuals in need of spasticity treatment. This approach avoids complex approaches to telehealth spasticity assessment without involving additional equipment other than videoconferencing while still directing patients to appropriate care.

While limited options exist about the physical examination of spasticity in telehealth environments, essential conversation-based elements of the spasticity assessment included within the traditional assessment are amenable to telehealth environments.

1.9 Telehealth Spasticity Treatment

Research describing spasticity-specific treatment interventions using telehealth is virtually nonexistent. A review of the literature by Bascunana-Ambros et al. (2021) found no publications related to gaming or exercise applications explicitly designed for telehealth spasticity treatment (Bascunana-Ambros et al., 2021). Despite the limited evidence, telehealth has the potential to enhance access to spasticity treatment for many individuals not currently receiving treatment. Telehealth is well suited to deliver treatment, including patient and caregiver education, treatment options, and rehabilitation techniques (Verduzco-Gutierrez et al., 2020). Prescription for oral anti-spasmodic medications and patient monitoring could be completed by telephone or videoconferencing. In cases where procedures necessitating primary in-person care are required, such as for BoNT-A injections and surgery, telehealth could provide an important role in patient follow-up and in delivering adjunctive rehabilitation interventions for individuals experiencing barriers to attending in-person care.

Although not specific to spasticity, support for strengthening and stretching interventions targeting sensory-motor function in individuals post-stroke using telehealth has been documented in the literature. Sarfo et al. (2018) conducted a systematic review of the use of telerehabilitation interventions in stroke aimed at treating motor impairment, higher cortical dysfunction, and post-stroke depression. The author has found no significant outcome differences between in-person vs. telehealth interventions. In 8 of 22 studies, the authors found more favorable outcomes in individuals completing telerehabilitation interventions related to motor recovery (Sarfo, Ulasavets, Opare-Sem, & Ovbiagele, 2018). While not specific to spasticity, this review does provide evidence that non-pharmacological interventions targeting sensorimotor impairment after stroke can be effectively delivered using telehealth.

1.10 The Need for Objective Spasticity Assessment

Accurate diagnosis and measurement of spasticity is essential for prescribing appropriate treatment. The administration of specific pharmacological treatments targeting the central nervous system may be detrimental when mistakenly given to patients with joint stiffness unrelated to spasticity. The results obtained from clinical spasticity assessments primarily depend on subjective measurement information gathered by the clinical evaluator. They cannot accurately distinguish neural from non-neural causes of resistance to passive motion (Wang et al., 2017). Furthermore, the hands-on requirement necessitated by the examiner in conducting the MAS and MTS evaluations is incompatible with telerehabilitation approaches to spasticity assessment. Additional challenges related to the use of these scales in assessing spasticity include 1) non-standardized durations of passive joint movement during testing, 2) repetitive passive joint movements have been found to reduce resistance and affect scoring, 3) differing estimates of inter and intra-rater reliability that are dependant on the region assessed, and 4) discrimination between neural and non-neural causes of resistance to passive movement during testing is impossible (Luo et al., 2019; Meseguer-Henarejos, Sanchez-Meca, Lopez-Pina, & Carles-Hernandez, 2018).

The use of electrophysiologic measurements, including the use of surface electromyography, has demonstrated the ability to assess stretch reflex thresholds. This ability provides a method of quantifying neural and non-neural components of spasticity within the clinical setting (Zhang et al., 2019). Recent studies by Zhang et al. (2019) and Yu et al. (2020) have described an assessment device and procedure using sEMG and inertial measurement unit (IMU) sensor data to provide a measure of the dynamic stretch reflex threshold (DSRT) and tonic stretch reflex threshold (TSRT). These measures can be biomarkers quantifying the stretch-

reflex sensitivity (neural component) of spasticity. The authors concluded that their procedure provides "a convenient solution to spasticity assessment, suitable for clinical, community, and home-based rehabilitation" (Yu et al., 2020; Zhang et al., 2019). Biomechanical assessments examining kinematic data such as muscle torque, range of motion, and angular velocity can also indirectly assess muscle stiffness. In a study by Lorentzen et al. (2012), a portable device designed to measure ankle stiffness was tested in individuals with spinal cord injury and multiple sclerosis. The authors compared measures obtained by their device against a control population without spasticity and reference standard torque motor. The results provided evidence that the device was useful in distinguishing between stiff and control ankle joints and strongly correlated with torque motor measures. The authors reported challenges with accurately assessing rapid movements. Despite this limitation, this work demonstrated the usefulness of biomechanical data as a diagnostic tool to obtain reliable information related to stiffness for the ankle joint (Lorentzen, Grey, Geertsen, Biering-Sørensen, Brunton, Gorassini, & Nielsen, (2012).

The combination of biomechanical and electrophysiological measures might be considered a 'gold standard' for spasticity evaluation (Biering-Sorensen, Nielsen, & Klinge, 2006; Sunnerhagen, 2013). The limited uptake of these quantitative measures may be related to a lack of expertise and technology required to perform these evaluations within clinical settings (Campanini, Disselhorst-Klug, Rymer, & Merletti, 2020). There is "a clear need to develop more easy-to-use devices that can help the clinician in the routine clinical diagnosis [of spasticity]" (Nielsen et al., 2014).

The use of sEMG has additionally been reported as a non-invasive, convenient, and low-cost method of measuring muscle activity with the potential for clinical use in individuals with post-stroke spasticity (Luo et al., 2019). Recent advances in the development of quantifiable and

objective measures of spasticity using sEMG and IMU sensors have great potential in enhancing virtual spasticity assessment procedures. Data obtained through these methods can be collected and transmitted from the patient's location to centralized spasticity specialists, improving access to care and decreasing the need for the specialist to be physically present with the patient. Quantitative measures of spasticity also have the potential for use in traditional in-person care settings as an important adjunct to the observer-based ordinal spasticity assessment scales discussed previously.

sEMG has the potential to provide answers to critical clinical questions such as: Is the muscle active or not at a given time? When does the muscle turn on and off during a task? Is muscle activity triggered by lengthening and by the velocity of the stretch? Is co-activation of muscles present during a task? (Campanini et al., 2020). Answers to these questions can identify and distinguish between neural and non-neural factors contributing to spasticity. Quantitative measures can objectively make these distinctions (Campanini et al., 2020). Appropriate identification of neural and non-neural factors of spasticity can significantly assist with clinical decisions regarding management, which may include focal muscle blockages, non-pharmacological treatments, and neuro-orthopedic or functional surgery (Campanini et al., 2020).

Quantitative assessment methods and devices have been developed and examined mainly in research settings and are not commonly used in clinical practice. No clinically usable device provides quantitative assessment data for post-stroke spasticity, and even less is known regarding the usability of these measures by clinicians in telehealth environments.

1.11 Thesis Objectives & Research Questions

The primary objective of this doctoral research was to develop, construct, and evaluate an initial prototype of a device and software application for obtaining biomechanical and neurophysiological measurements of spasticity compatible with telehealth settings. The following research questions were formulated to address this objective:

1) What are the current successes and challenges experienced by front-line clinicians when performing telehealth spasticity assessments?
2) What are the perceptions of front-line clinicians of incorporating biomechanical and neurophysiological measures of spasticity into clinical practice?
3) Can a low-cost portable device and software program be developed to wirelessly measure and transmit quantitative measures of spasticity compatible with telehealth environments?
4) What is the agreement of biomechanical and neurophysiological measures between the developed device and reference standards?
5) Can the newly developed device be successfully used to assess and detect the presence of spasticity within a telehealth setting?

1.12 Structure of the Thesis

A series of three studies, along with a description of the TONE device's initial development process, are included in the thesis designed to address the research questions. Chapter 2 (Study 1) explored the perspectives of frontline clinicians experienced in telehealth spasticity assessment. A mixed methods study, including administering an online survey, focus group interviews, and email communication with spasticity specialists, was used to gather

information surrounding their experiences and thoughts about incorporating quantitative measures of spasticity within clinical practice. The results from the survey and qualitative analysis are presented in Chapter 2. Chapter 3 gives a detailed description of the development of the TONE device and software application. The development chapter includes a description of the iterative Plan-Do-Study-Act process guiding the development of the TONE device prior to validation testing in Chapter 4 (Study 2). Initial validation testing of the TONE device in a population without spasticity is provided in Chapter 4 (Study 2). A validation study assessed the relationship and level of agreement between the TONE device and chosen reference standards. Levels of agreement assessed between the TONE and reference standards include passive ROM of the elbow, muscle contraction on time as measured by surface electromyography and force versus time measures, and average force measured during isometric elbow flexion contraction. Results from this study are presented in Chapter 4. Chapter 5 (Study 3) uses a proof-of-concept study to determine if the TONE device and software application can measure and transmit quantitative spasticity assessment measures in a simulated telehealth environment. Measures obtained relating to spasticity include elbow joint ROM, elbow joint angular velocity, average and peak force measures of resistance to passive elbow extension, and lastly, muscle activity (average rectified sEMG signal) during passive elbow extension in individuals with known upper limb spasticity.

1.13 Contributors to the Thesis

Chapter 1 includes a summary of background research relating to current concepts in spasticity assessment and management. I was responsible for the original writing and organization of this chapter and received suggestions and editorial input from my supervisor Dr. Patricia J. Manns and committee members Dr. Jaynie F. Yang, and Dr. Martin Ferguson-Pell.

In Chapter 2, entitled, 'Study 1: Provider Prospectives on Virtual Spasticity Assessment' I was responsible for completing the ethics application, study design including online survey and focus group question development. Feedback and suggestions for survey development related to Study 1, was also provided by my supervisor Dr. Patricia J. Manns, Dr. Sean Dukelow, and Dr. Lalith Satkunam. I led the focus group interviews with assistance from my primary supervisor Dr. Patricia J. Manns and was responsible for data collection, data analysis and manuscript preparation for this study with guidance from my supervisor.

I was responsible for outlining the desired functions of the initial prototype of the TONE device and software application as outlined in Chapter 3. Dr. Martin Ferguson-Pell provided guidance surrounding which technology and sensors would be most appropriate to achieve the desired device functions. Dr. Martin Ferguson-Pell created the firmware for the TONE device including development board with attached electronic sensors, battery power supply, and wireless transmission component. Khilesh Jairamdas (engineer) was hired to create a software application to receive output from the TONE device and display the sensor information graphically in real-time along with the ability to save data for further analysis. Weekly meetings between myself and Khilesh Jairamdas were held over 6 months to provide input and discuss progress and challenges related to software development. Feedback relating to device development was also sought from two physiatrists specializing in spasticity management Dr. Lalith Satkunam and Dr. Sean Dukelow.

In Chapter 4, entitled 'Study 2: Validation of the Telerehabilitation-Objective-Neuromuscular- Evaluation (TONE) Device for Spasticity Assessment' I was responsible for ethics approval, study design, data collection, data analysis, and manuscript writing with assistance from my supervisor Dr. Patricia J. Manns. I also received assistance with study design

from Dr. Martin Ferguson-Pell and Dr. Jaynie F. Yang. I received assistance with data collection from Palak Jhingan for this study.

In Chapter 5, entitled 'Study 3: Virtual Spasticity Assessment Using the Telerehabilitation-Objective-Neuromuscular-Evaluation Device: Proof of Concept' I was responsible for completing the ethics application, study design, data collection, data analysis, and manuscript writing with assistance from my supervisor Dr. Patricia J. Manns. Palak Jhingan, Caitlin Hurd, and Dr. Lalith Satkunam all assisted with data collection.

Chapter 2. Study 1. Provider Perspectives on Virtual Spasticity Assessment

2.1 Abstract

Background: Specialist consultation is recommended for the management of spasticity. Telehealth has been promoted to expand specialized services to individuals living in rural and remote areas experiencing healthcare access disparities. Telehealth for spasticity assessment and management increased during in-person care restrictions during the COVID-19 pandemic. Currently, no standardized telehealth spasticity assessment procedure exists. Little is known regarding the experiences of frontline clinicians using telehealth to perform spasticity assessments.

Objectives: 1) To investigate current satisfaction levels with performing virtual spasticity assessments. 2) To investigate how spasticity assessment information is being captured and used in virtual environments to inform spasticity management decisions and identify current successes and challenges associated with virtual assessment processes. 3) To explore perspectives from frontline clinicians regarding the need and usefulness of quantitative measures of spasticity within both in-person and telehealth clinical practice.

Methods: A mixed-methods study involving the administration of an online survey and focus group interviews was conducted to achieve the study objectives. Additional information was gathered by email correspondence with two physiatrists specializing in spasticity care. Descriptive statistics were used to summarize survey responses. Audio recordings obtained from focus group interviews were transcribed verbatim. Descriptive qualitative analysis was used to summarize focus group interview transcriptions and categorize responses in relation to the research objectives.

Results: Survey Results: 24 participants managing spasticity across Canada completed the online survey. 88% of participants reported that the ability to perform spasticity assessments virtually would be beneficial within their practice. Commercial-grade videoconferencing was the most commonly used technology for performing telehealth spasticity assessments. Range of motion (ROM), functional mobility, and muscle tone (resistance to passive movement) were rated as clinicians' top three essential items directing spasticity intervention and treatment planning.

Interview Results: 7 participants completed the focus group interview sessions. Successes related to virtual spasticity assessments included: 1) Improvements in the efficiency of spasticity service delivery, 2) The ability to assess clients within their natural environment, and 3) The avoidance of unnecessary travel for patients. Challenges associated with telehealth spasticity assessments included 1) The inability to perform hands-on physical assessments, 2) Technology-related challenges, and 3) Physical and cognitive impairment affecting the ability to participate in virtual spasticity assessment evaluations. Uncertainty surrounding the use of electronic sensors to measure ROM, resistance to passive movement (force), and muscle activity (EMG) was found among the participants interviewed.

Conclusion: The results of this study provide new insights into clinicians' experiences performing virtual spasticity assessments. Telehealth spasticity assessments enabled the continuation of essential appointments for individuals with spasticity during the COVID-19 pandemic. Technology availability and familiarity challenges resulted in a wide variety of experiences related to telehealth spasticity assessment among clinicians. Future work is needed to determine better the usefulness of quantitative sensor-based spasticity measures in telehealth and in-person clinical practice.

2.2 Introduction

Restrictions to in-person healthcare due to the COVID-19 pandemic resulted in an acute accelerated uptake of telehealth services as never before (Wosik et al., 2020). Telehealth technology was leveraged by healthcare providers, demonstrating the potential to enhance access to specialized healthcare services during and beyond the pandemic. Spasticity management is an example of a healthcare service requiring specialized care. Spasticity is most commonly defined as "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" (Lance, 1980). It occurs in people with neurological conditions affecting the central nervous system, such as stroke or spinal cord injury. While not always problematic, spasticity can result in abnormal posture, pain, restricted range of motion, paresis, changes in muscle composition, and functional impairment (Hundza et al., 2016; Zorowitz et al., 2013). Complications related to spasticity can lead to challenges in performing daily living activities and negatively impact health-related quality of life for individuals living with spasticity and their caregivers (Ganapathy et al., 2015; Zorowitz et al., 2013).

The Canadian Stroke Best Practices recommend "timely and appropriate assessment and management of upper and lower extremity spasticity" (Teasell et al., 2020). Telehealth has been promoted to overcome access restrictions to outpatient spasticity services for both initial and follow-up patient visits (Park et al., 2008; Reebye et al., 2020; Verduzco-Gutierrez et al., 2020). The recent shift toward telehealthcare has expanded options for accessing specialized spasticity services, even addressing challenges to accessing care existing prior to the global pandemic. According to the Canada Health Act, all Canadians are entitled to equitable access to health

services, regardless of where they live in Canada (McDonald & Conde, 2010). Individuals with spasticity living in rural and remote regions experience challenges in attending in-person care (Canning, Phadke, Ismail, & Boulias, 2013). Many individuals with spasticity experience mobility impairments, making the attendance of in-person specialist appointments challenging (Verduzco-Gutierrez et al., 2020). Despite telehealth's ability to enhance access to care, challenges remain, as no consensus exists on delivering spasticity care within virtual environments.

Experts in the United States and Canada have published initial guidelines and practical advice for clinicians delivering outpatient spasticity services during the COVID-19 pandemic (Reebye et al., 2020) (Verduzco-Gutierrez et al., 2020). Reebye et al. (2020) provide a framework to identify and prioritize urgent and semi-urgent patients requiring a combination of in-person and telehealth care, compared with non-urgent patients who can likely be managed using a telehealth approach alone. The work by Verduzco-Gutierrez et al. (2020) discusses practical considerations and tips for conducting spasticity assessments within a virtual context. While these guidelines form a helpful starting point for clinicians, research needs to be more comprehensive in understanding the perceptions and experiences of spasticity care providers who have had to adjust from in-person to virtual practices.

Accurate assessment and diagnosis of spasticity by clinical specialists is crucial in planning effective interventions and monitoring patient responses to treatment. As part of the spasticity evaluation, specialists must differentiate neural and non-neural causes of the presenting muscle stiffness (Thibaut et al., 2013). Neural causes relate to spasticity and represent increased excitability of the muscle stretch reflex, resulting in undesired muscle activation in response to passive stretch. Non-neural factors relate to muscle stiffness and refer to the plastic changes

observed within the muscle and connective tissues, such as changes in viscosity, length, and elasticity (Baude et al., 2018). Pharmacological interventions such as botulinum neurotoxin (BoNT) injections are used when there are neural changes. If muscle stiffness is found to have a non-neural origin (i.e., connective tissue changes), the treatment focus will not be pharmacological but will focus on passive stretching, serial casting, and surgical interventions, all with the goal of decreasing muscle and joint contracture (Campanini et al., 2020).

Challenges remain in objectively diagnosing spasticity even within in-person practice, as no gold standard assessment exists. Hands-on assessment procedures using clinical scales such as the Modified Ashworth Scale (MAS) and Modified Tardieu Scale (MTS) are the most widely used method of determining the presence of spasticity in clinical practice (Guo et al., 2022; Kaya et al., 2011). These measures provide observer-based ordinal information regarding spasticity presence and severity. In the context of telehealth and spasticity assessment, a significant barrier to assessment is the inability to use routine hands-on approaches such as the MAS and MTS outcome measures. This barrier is also an opportunity to promote quantitative spasticity measures that can objectively assess spasticity in both remote and in-person settings. Collecting and transmitting quantitative spasticity assessment data from electronic sensors can improve the accuracy of telehealth spasticity assessment approaches.

Surface electromyography (sEMG) and biomechanical data obtained from electronic goniometers and load sensors can provide quantitative information on muscle activity during passive stretch and subsequently be transmitted to spasticity specialists using information communications technology (ICT). Electrophysiologic measurements have demonstrated the ability to assess stretch reflex thresholds altered by spasticity. This ability provides a method of quantifying neural and non-neural components of spasticity within the clinical setting (Yu et al.,

2020; Zhang et al., 2019). Biomechanical assessments examining kinematic data such as muscle torque, range of motion, and angular velocity can also indirectly assess muscle stiffness (Sunnerhagen, 2013). The expertise and technology required to perform these evaluations within clinical settings are lacking (Campanini et al., 2020).

While recent research points to the need for quantitative spasticity assessment methods, these measures have yet to be adopted into widespread clinical practice. The reasons for the lack of quantitative spasticity measures used in clinical practice have yet to be entirely understood. For these measures to be adopted into clinical practice, barriers to the widespread adoption of quantitative measures of spasticity must be identified. Quantitative measures are highly compatible with telehealth practice and may represent a solution to accurately diagnosis spasticity within virtual settings.

Objectives

Objective 1) To investigate current satisfaction levels with performing virtual spasticity assessments.

Objective 2) To investigate how spasticity assessment information is currently being captured and used in virtual environments to inform spasticity management decisions and to identify current successes and challenges associated with virtual assessment processes.

Objective 3) To explore perspectives from frontline clinicians regarding the need and usefulness of quantitative measures of spasticity within both in-person and telehealth clinical practice.Data analysis from the online survey relates to objective 1. Qualitative descriptive analysis from the focus group interviews and specialist consultation relates to objectives 2 and 3.

2.3 Methods

Research Design

This study was approved by the Human Research Ethics Board at the University of Alberta (Pro00101753) prior to data collection. A mixed-methods study design, including an online survey with subsequent follow-up virtual focus group interviews, was used to gather information related to the study objectives. An 11-item online survey entitled "Virtual Spasticity Assessment Process" was advertised to healthcare professionals across Canada involved in assessing and treating individuals with spasticity (see Appendix A) between September 2020 and February 2021. The following organizations assisted with advertising the survey: Canadian Physiotherapy Association Neurosciences Division, Canadian Association of Occupational Therapists, Society of Occupational Therapists of Alberta, and Alberta Health Services. Questions within the online survey pertained to the first study objective.

Respondents completing the online survey were given the option to participate in a one-hour virtual focus group using ZOOM videoconferencing. Three focus group interview sessions were completed between February 2021 and April 2021. Focus group sessions were audio and video recorded and subsequently transcribed. A series of pre-planned questions relating to the second and third study objectives were presented during the virtual focus group sessions to guide the discussion (see Appendix B). Email communication between the researchers and two physiatrists specializing in spasticity management sought additional input regarding the third study objective. Specialists were emailed a short six-minute video demonstrating a proposed quantitative spasticity assessment device and were given a series of questions to guide their feedback (see Appendix C).

Data Analysis

Quantitative data obtained from the online survey was transferred from Google Forms into a database using Microsoft Excel 2016. Descriptive statistics including percentages, frequencies, and median values were calculated using Microsoft Excel 2016. Differences in median satisfaction levels between initial and follow-up virtual spasticity assessments were described using descriptive statistics. Qualitative descriptive analysis was used to analyze verbatim transcriptions of the virtual focus group sessions and email communication from specialists to identify and explore important themes relating to the study objectives. Participant responses were categorized in relation to the questions asked during each interview session. The primary researcher examined all participants' responses in relation to the interview questions and identified similarities and differences among participant responses. The interview questions were then categorized and summarized in relation to the study objectives.

2.4 Results:

Online Survey:

A total of 24 (N=24) participants involved in managing spasticity across Canada completed the online survey. Most participants were from Alberta, Canada (n =18), with the remainder practicing in 5 other provinces. Fifty percent of participants indicated they had experience performing an initial or follow-up virtual spasticity assessment. The mean percentage of clinical time associated with spasticity management reported by participants was 30% (SD +/- 18 %, Range = 10-70%). Eighty-eight percent of participants reported that the ability to perform spasticity assessments virtually would be moderately to extremely beneficial within their practice (see Figure 1). Satisfaction scores of performing initial virtual spasticity assessments demonstrated less than moderate satisfaction levels among clinicians (*Median = 3/10)*.

Satisfaction scores for follow-up virtual spasticity assessments were slightly higher (*Median = 5/10),* indicating moderate clinician satisfaction levels. (see figure 2). Commercial-grade videoconferencing was the most commonly reported technology for performing telehealth spasticity assessments, as reported by 92% of respondents. Lastly, a summary of participant rankings of spasticity assessment information gathered within in-person settings ranked between 'least' to 'most essential' can be found in Figure 3. Range of motion (ROM), functional mobility, and muscle tone (resistance to passive movement) were rated as clinicians' top three essential items directing spasticity intervention and treatment planning.

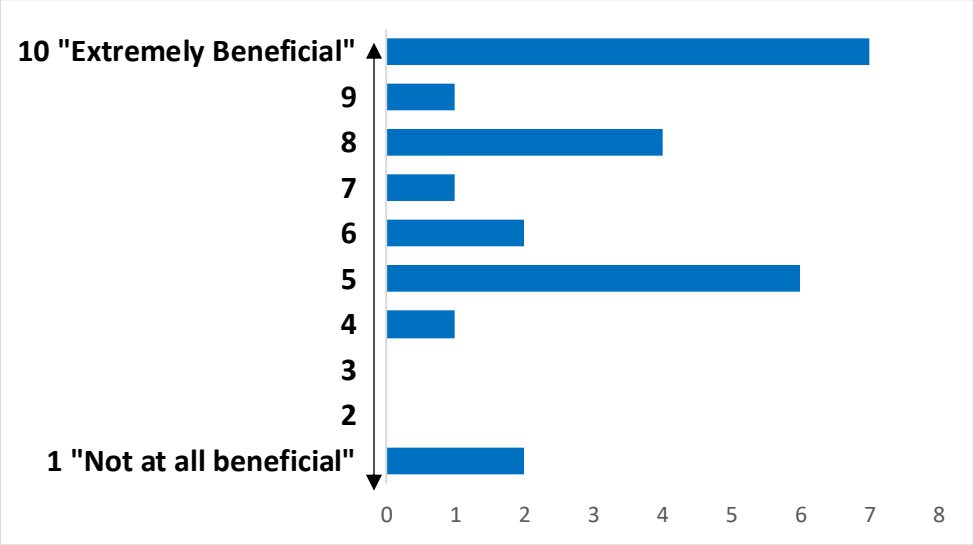


Figure 1. Participants' responses to survey question 3. "Do you believe the ability to offer spasticity assessment at a distance would be beneficial to your practice?"

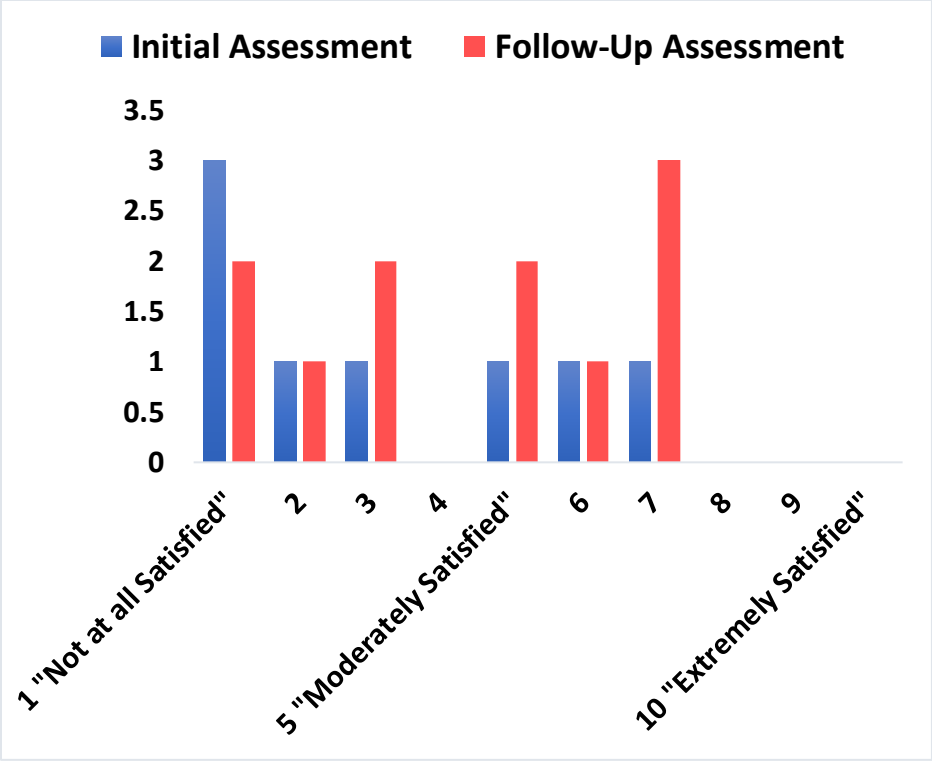


Figure 2. Participants' responses to survey questions 5 and 6. "If you answered 'Yes' to performing an initial virtual spasticity assessment, how satisfied were you with the experience?" and "If you answered 'Yes' to performing a follow up virtual spasticity assessment, how satisfied were you with the experience?"

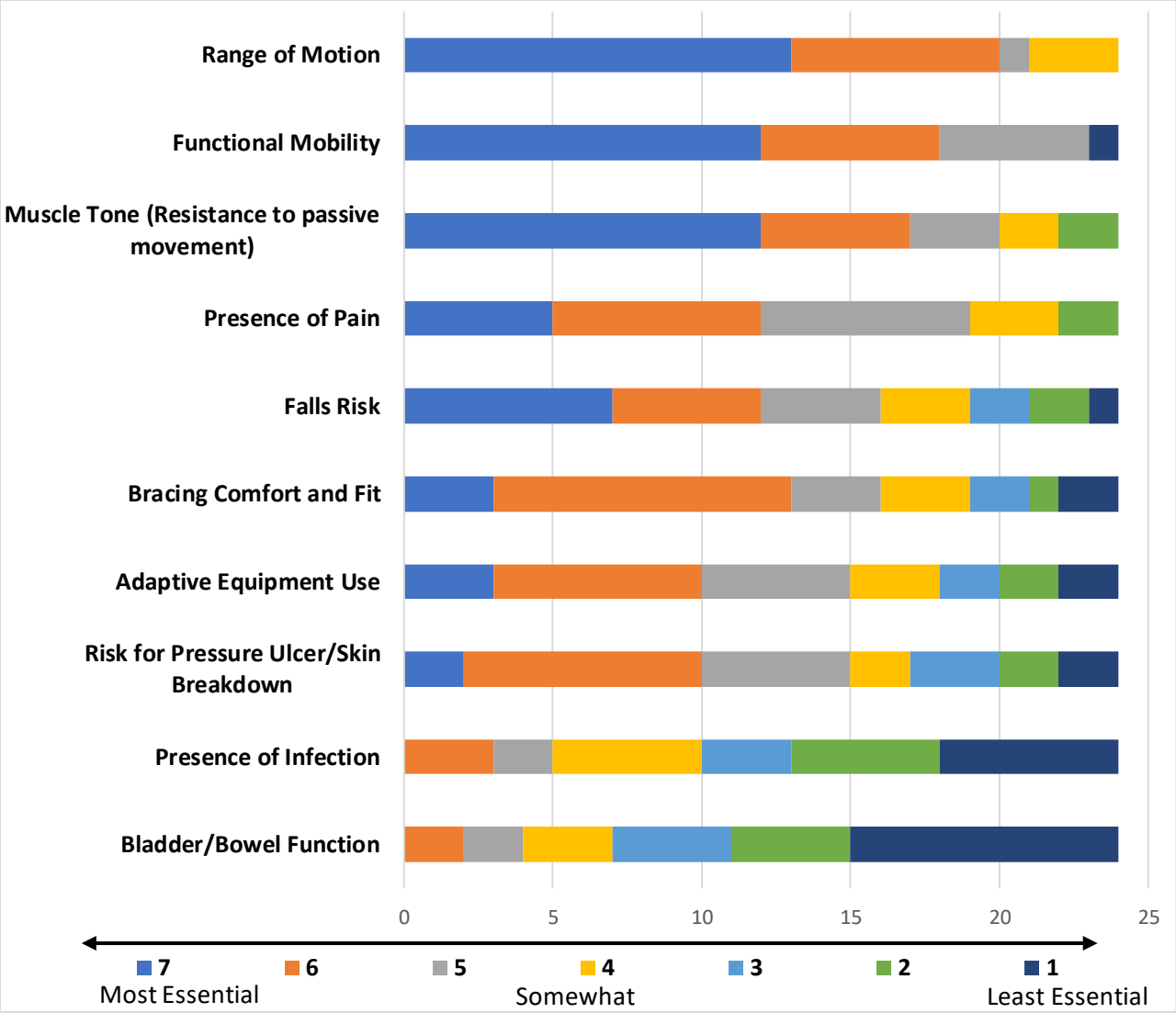


Figure 3. Participants' responses to survey question 10. "In completing your usual in person spasticity assessment please rate the usefulness of the following assessment items from "most essential" to "least essential" in regards to how these items inform your intervention/treatment planning".

Qualitative Results

Two virtual focus groups, and one virtual individual interview with a total of seven participants (n=7) were held between February and April of 2021 (see Figure 4).

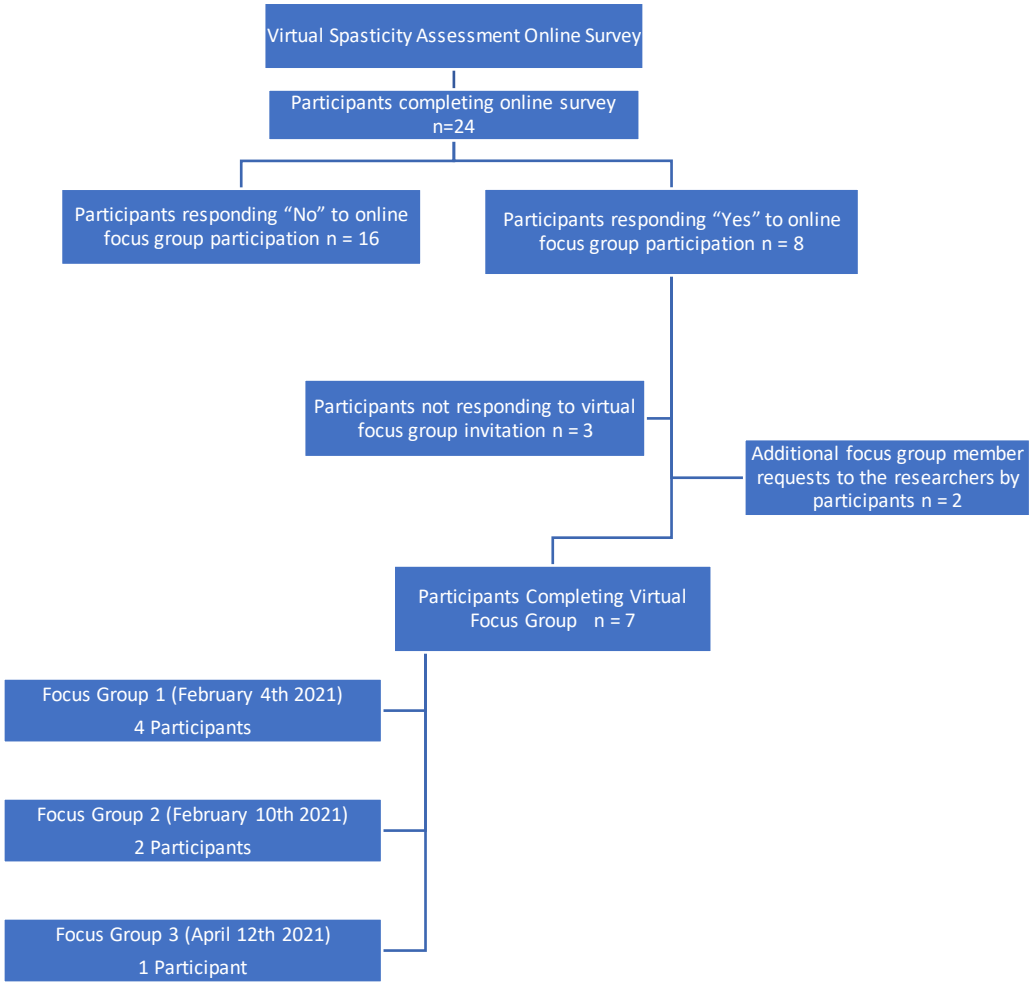


Figure 4. Diagram of online virtual spasticity assessment survey and follow up virtual focus groups session participation.

Information regarding virtual focus group participants (n=7) is summarized in Table 1. Qualitative information relating to the three main study objectives is summarized with examples of participant responses below.

Table 1. Virtual Focus Group Participant Information. (n=7)

Participant ID	Professional Designation	Province of Practice	Clinical Time Associated with Spasticity (%)
P01	Occupational Therapist	Alberta	20
P02	Physiatrist	Alberta	40
P03	Physiotherapist	Newfoundland	20
P04	Family Physician	Newfoundland	unknown
P05	Physiotherapist	Alberta	50
P06	Physiotherapist	British Columbia	70
P07	Physiotherapist	Prince Edward Island	20

Objective 2) To investigate how spasticity assessment information is being captured and used in virtual environments to inform spasticity management decisions, and to identify current successes and challenges associated with virtual assessment processes.

Current Telehealth Spasticity Assessment Practices

Transitioning from in-person to telehealth visits requires a change in how spasticity assessment information is gathered by the clinician. Virtual spasticity assessments rely on clinicians' interpretation of audio and visual information as a function of current technology. Most participants reported using videoconferencing as their preferred virtual appointment method, maximizing their ability to send and receive auditory and visual information. A participant shared their experiences using videoconferencing:

> P07 “Having video, telehealth... makes the world of difference for patients and it's way-way-way better than nothing... or the phone.”

Focused history taking and goal setting were reported as being obtainable in virtual settings as shared by participant P02 and participant P06:

> P02 “we're able to do the initial detailed history…”

> P06 “Doing that initial history, some problem solving, some of that pre-work in advance is great…”

In addition to history taking, participants also shared their experiences of performing observation-based spasticity assessments in virtual environments. Participants discussed various information sources they used to assess and diagnose spasticity in telehealth environments. Clinician participants referred to the ability to observe clonus, a clinical feature of spasticity, during virtual assessments:

> P02 “[The patient] put the laptop on the hallway floor and we just watched him go and his complaint on his history was a lot of severe clonus that was impacting his standing transfers and his gait and we could see that come out.”

> P07 “So, you're doing a lot of [virtual spasticity assessment] visually and trying to… at least just get a visual, like is there any clonus? Does it look like it's rigid?”

In addition to observing for clonus during particular movements, participants also reported on observing functional tasks within the patient’s own environment as part of the virtual spasticity assessment:

> P04 “You get to see how they get in and out of their chair, how they get in and out of the kitchen. It adds a lot of insight into how they are functioning and it can help

you appreciate the goals that they're trying to achieve or the goals they don't really care about."

Telehealth Spasticity Assessment Successes:

Participants shared their thoughts on the successes associated with performing virtual spasticity assessments. Successes related to virtual spasticity assessments were identified as relating to three main areas: 1) Improvements in the efficiency of spasticity service delivery; 2) The ability to assess clients within their natural environment; and 3) The avoidance of unnecessary travel for patients.

Successes of telehealth use in spasticity care relating to improvements in efficiency as compared to usual care were summarized well by participants P02 and P06.

> P02 "[telehealth appointments] did cut down timing for us because we're able to do the initial detailed history…it allowed us to pre-plan what we wanted to do for treatment and get processing of special authorization and drug applications etc. done so by the time they arrived in clinic it was a much shorter visit and targeted intervention."

> P06 "Doing that initial history, some problem solving, some of that pre-work in advance is great, versus bringing someone all the way down and spending hundreds and sometimes thousands of dollars to get them [to attend in-person], some of that work can happen [ahead of time]." … We realized that certain people were not appropriate fit or they were actually referred to the wrong clinic, or we found out that some people were already seen in a different clinic, and it was a duplication of services…."

The ability to assess clients within their natural or home environment was another theme that commonly emerged among participants in regards to successes experienced when performing virtual spasticity assessments. With one participant summarizing this point well.

> P04 “One of the nice things… is that you get to see them in their own home… Like the clinic is so artificial, you know, we have a nice clean and flat floor and all that sort of jazz… but when you see them in their home and you put that computer on the ground and then they go… it's like a mini home visit to a certain degree. You get to see [their environment] and at the same time that you get to see how they get in and out of their chair, how they get in and out of the kitchen. It adds a lot of insight into how they are functioning and it can help you appreciate the goals that they're trying to achieve or the goals they don't really care about.”

Experiences and successes relating to the elimination of unnecessary travel for patients as a result of using telehealth services were also brought up by focus group participants.

> P04 “overall for the patient experience somebody who doesn't have to fly from Labrador to St John's in order to be assessed, that's a success as far as they're concerned.”
>
> P02 “so I saw one patient who's from Grand Prairie, they're about a five-hour drive north of us… and so that assessment was excellent to see…”
>
> P04 “Somebody takes this poor [person] they put him in a car, they drive him 6 and 1/2 hours… and then you're sitting down there and you're looking at him and your [thinking], he came all the way in here and is looking for [spasticity

treatment], and he really doesn't even need it… So, if you can get to see those people earlier, than that would be extremely helpful…

Telehealth Spasticity Assessment Challenges:

Challenges identified when performing virtual spasticity assessments were shared by participants and found to relate to three main categories: 1) The inability to perform hands-on physical assessments; 2) Technology related challenges; and 3) Physical and cognitive impairment affecting the ability to participate in virtual spasticity assessment evaluations. The inability to perform a physical hands-on assessment of spasticity was mentioned as a challenge by the majority of participants. This resulted in a loss of confidence in the ability to make treatment recommendations based on virtual spasticity assessment findings alone. Several participants reported that often subsequent physical assessments performed in person were required to confirm the patient history and visual observation findings obtained during the virtual assessment.

P02 "When I'm seeing that functional impairment, immobility, is this because of weakness versus tone limitation? So that hands-on assessment [when they later came into the clinic] allowed us to kind of figure that out a bit more."

P05 "I think of you know, someone who has gait issues …through our visual observation in the virtual [assessment] and their story we think ... plantar flexors... toes...maybe inverters [have spasticity]? is it [tibialis anterior]? is it [tibialis posterior]? I don't know? We want to see that; we want to feel it… we kind of know what the problem is but we need to be hands-on to identify the actual area to focus on."

> P04 “the block I run into is [spasticity] requires physical examination… If you want to be able to do an assessment you need hands-on”.
>
> P05 “[In a telehealth follow up appointment] It is very difficult to pick up things like improvement in range of motion, unless it's a very active movement, if it's a passive movement it's hard to fully appreciate that, or if that catch is later and that's better, again its hard to appreciate that... I think it's harder to kind of push for that very objective evidence in follow up within the virtual world versus in-person where they're more discrete things that we can do.”
>
> P07 “we couldn't get hands-on and so most of our assessments are, the Modified Ashworth or the Tardieu, they're hands on assessments so that’s hard to do over a computer... even if you had a competent family member somebody there on the other end… they're not trained to be able to do proper scoring.”

One participant (P01) also highlighted the potential for adverse events in cases of wrongful diagnosis related to the inability to perform traditional in person assessments.

> P01 “Very focal treatments trying to improve efficiency of someone's walk where if you don't have that full assessment of the upper motor neuron syndrome with the spasticity assessments, you could definitely do more harm than good uh they may lose their ability to walk for a few months.”

In addition to the inability to perform hands-on assessments within virtual spasticity assessment interactions, several challenges related to technology were also brought up amongst participants. As stated by one participant “Technology is not equal in everybody's home”. Other

participants also shared their views on challenges related to technology availability and connectivity:

> P06 “There are a few people where, for example, just looking at them you just know a zoom or a telephone call was not going to work well, or if they just tell our booking clerk “I don't have the technology.”
>
> P07 “Some of the challenges are the same as any type of physio assessment, so technology, the connection, a lot of our clients are in rural areas. The age group [related issues] where a lot of our patients need to find family members try to help them, [some patients] didn't even have computers.”
>
> P07 “… urban connections, generally are better than rural. However, I've had some really-really [bad] connections for people that live in the city. And some days its better and some days its [worse]... I've tried connections like internet Wi-Fi we've tried connections via just going on a cell phone service. And it really is dependent on the patient and the patient's location... and the day sometimes.”

Even when patients had access to the required technology and successful internet connections, limited technology experience posed a problem. Issues related to the inability to adequately see the patient due to sub-optimal camera placement were identified:

> P06 “Sometimes patients just cannot figure out where to put the camera. We had one caregiver… just put the phone in front of the patients face [during the telehealth assessment] so that she could see us... but, could not figure out how to get the [phone’s] camera facing other body parts… It turned out to be a big

history taking session versus us seeing her actual body… That was probably the biggest challenge I've encountered."

Physical and cognitive impairment challenges experienced by patients were also brought up by participants:

> P06 "Our patients have neurological injuries, some of them only have one hand, so if they're trying to film themselves doing things that becomes a challenge. Sometimes even placing the phone in the right place, to be able to see something is hard…I think those are the biggest challenges of all."
>
> P05 "Like especially for a non-functional hand… the patient's trying to show [you their hand on the camera] but they can't move and they can't get the screen to show you…

Objective 3) To explore perspectives from frontline clinicians regarding the need and usefulness of quantitative measures of spasticity within both in-person and telehealth clinical practice.

Participants were provided with information on the proposal to develop a device and software application capable of measuring and transmitting quantitative spasticity assessment information. Initial impressions of the perceived need and usefulness of the device were mixed among participants. Some participants indicated that the ability to gather information in addition to audiovisual information obtained using videoconferencing would be useful. For example, one participant shared:

> P02 "I don't think that our clinical acumen is that good, it would be really interesting to know on a more objective basis with engineering and measurement

> if there's a way to distinguish [neural vs. non-neural causes of joint stiffness] better...

Participant 04 shared similar feedback on the proposed device and software application:

> P04 “It might be very useful to be able to confirm...like an EMG type of thing, being able to see some things that might be indicative of spasticity. I think it'd be very cool to test it out and see if it had utility….”

However, the same participant later voiced a counter statement, highlighting the uncertainty of the usefulness of quantitative measures such as sEMG when performing telehealth assessments:

> P04 “But again, if they have a functional issue and you kind of see it, you see the clonus when they're moving. I can look and say well do I really need sEMG to be able to tell me what that is?”

Other participants also questioned the added usefulness of measuring and transmitting quantitative spasticity assessment information:

> P06 “Yeah you know what, I'm not sure, because I have done assessments with another physio on the other end and just by watching and maybe [seeing] so much spasticity, sometimes even as someone else is assessing I can already guess what the Modified Ashworth Scale [score] is. You see the catch, you see the let-go, you see the catch no let go, you see that someone's struggling to range… I'm not sure if it would add a huge amount of value to be honest.”

After receiving mixed reviews on the usefulness of the proposed spasticity device and software application, the research team sought feedback from additional sources. A video outlining a proposal for a spasticity assessment device and software application was emailed to two physiatrists specialists involved in spasticity care (S01 and S02). Questions relating to the usefulness of the device and software application were posed at the end of the video. Responses received from both physiatrists in response to the questions asked are summarized below. Both specialists agreed that measures of joint velocity, range of motion, force, and sEMG measures would be helpful in performing virtual spasticity assessments. The specialists shared:

> S01: "Yes. Fundamentally I think having objective measures will be useful in monitoring and guiding treatment."
>
> S02: "I think all the parameters are helpful for the study purpose… In recent years the pendulum has shifted toward goal attainment management in spasticity, downplaying the need for objective measures. This is compounded by [the modified Ashworth scale] also being variable depending on the rater. So having a device that is easy to use and providing some meaningful data is a win. It certainly would be a great tool for in-person assessments."

While the idea of utilizing quantitative measures was supported, both specialists provided feedback regarding foreseeable challenges and considerations of incorporating the device and software application into clinical practice. As one specialist shares:

> S01: "Instructions will have to be very clear. Getting your device positioned over the right muscles will require anatomical knowledge. Method of attachment

should be secure. Normative values will need to be presented to assist with interpreting the results obtained by the measurement device."

Specialist S02 provided additional considerations specific to each of the proposed measures of spasticity (i.e., sEMG, angular velocity, force, and ROM measures). Specialist 02 shared:

S02: "sEMG - good for study purposes but will be a challenge in practice. sEMG is subject to variability based on movement artifact and amount of subcutaneous tissue. Behind the scenes we can adjust the gain and interpret but in a clinical setting… not practical. Secondly electrodes have to be fastened quite securely to skin to avoid movement artifact. This could pose a problem if you are using a Velcro strap to hold the device. We do experience these problems in the gait lab and interpretation becomes a challenge."

Further feedback shared by S02 in relation to angular velocity, force, and ROM are summarized below:

S02: "Angular velocity and Force are helpful. How I see this evolving in clinical practice - once we have established the utility of the device, we need to collect normative data to show the correlation between angular velocity and force. This will then help us 'define' what we mean by spasticity --> Increase in angular velocity resulting in disproportionate increase in force (i.e., resistance to movement) - maybe even a 'spasticity score'. Range of motion helps to determine what element of range is limited by myogenic contractures."

2.5 Discussion

This is the first study to provide insight into the experiences of frontline clinicians involved in performing virtual spasticity assessments. The primary objective of this study was to investigate how spasticity assessment information is currently being captured and used in virtual environments to inform spasticity management decisions and to identify current successes and challenges associated with virtual assessment processes. Information obtained during telehealth spasticity assessments was found to be classified into two main categories: subjective report and visual observation. Videoconferencing was reported as the most frequently used method of performing virtual spasticity assessments. This finding agrees with previous research that identifies videoconferencing as a preferred method of telehealth interaction (Rodriguez, Betancourt, Sequist, & Ganguli, 2021). Videoconferencing enables the ability to obtain visual and auditory information, whereas telephone consultations were limited to only auditory or verbal report information (Rush, Howlett, Munro, & Burton, 2018).

Focused history-taking and goal-setting were identified as essential information obtained through verbal reports during virtual spasticity assessments by focus group members. However, history-taking and goal-setting were not included as options for online survey item 10, where participants were asked to rate essential sources of spasticity assessment information (see Figure 3). This was done intentionally, as it was assumed that history-taking and goal-setting would be highly essential and easily performed during telehealth interactions. The vast majority of participants confirmed this within the focus group sessions.

The interviews emphasized the importance of obtaining the patient's history and setting goals for clinical decision-making. Patient preferences for treatment, as discovered through goal-setting conversations, were also discussed as having the ability to strongly influence treatment

decisions. In addition to verbal reports, when used effectively, videoconferencing allowed clinicians to observe functional tasks performed by the patient. Specifically, videoconferencing allowed the ability to visually observe gait and standing transfers within the patient's environment. While the patient performed functional tasks, clinician participants reported observing for the presence or absence of clonus, a clinical sign associated with spasticity. Several participants reported observing clonus during activity as a telltale sign of spasticity useful in diagnosing spasticity in online environments.

Successes associated with performing virtual spasticity assessments were found to relate to improved efficiency of service delivery, observation within the natural environment, and reduction in patient travel burden. Reports of improved efficiency of spasticity service delivery were consistent with other research demonstrating that telehealth can 'reduce resource utilization' (Rush et al., 2018). The ability to observe patients outside of clinical settings was an unexpected success associated with telehealth sessions. Being able to see the patient move in their natural environment has great potential for clinicians to better understand specific functional challenges experienced by individuals with spasticity. Reducing patient travel burden is an important and often overlooked success associated with telehealth delivery. In addition to improving access to care, telehealth practice significantly reduces personal and societal loss such as reduction in time away from work and usual activities, along with costs associated with travel for the patient (Snoswell, Smith, Scuffham, & Whitty, 2017).

The focus group sessions mentioned several challenges associated with performing virtual spasticity assessments. These challenges influenced the type and quality of the information obtained during the telehealth spasticity assessment interaction. The inability to perform hands-on physical assessments during virtual spasticity assessments was categorized as

a major limitation, affecting clinical decision-making and the perceived success of the virtual spasticity assessment. Access to the required technology and adequate internet connection for videoconferencing does not always guarantee a successful telehealth spasticity assessment session. For example, the ability or inability to effectively position the camera used for videoconferencing during the telehealth session greatly affected the type and quality of information obtained during the telehealth session.

The final objective of this study was to gather feedback from frontline clinicians on incorporating quantitative spasticity assessment information obtained by a device and software application during telehealth assessments. The ability to measure and transmit objective assessment information related to spasticity is hypothesized to assist in overcoming the inability to perform hands-on assessments within telehealth appointments. Several studies advocate using more objective methods of measuring spasticity within in-person settings (Kim et al., 2020; Park et al., 2008). Participants indicated that the ability to measure and transmit objective spasticity information could enhance telehealth and even in-person spasticity assessment practices. However, questions remained regarding the added benefit of using the proposed device in in-person and telehealth settings. Interestingly, some participants shared that focused history-taking and visual observation obtained in virtual settings provided adequate information to inform clinical decision-making. This finding was surprising given that hands-on procedures related to diagnosing spasticity, including range of motion and the assessment of muscle tone, were rated as the most essential information informing treatment, as found in Figure 3. Overall, physician participants seemed to view the incorporation of quantitative spasticity measures into clinical practice more favorably as compared to the rehabilitation professionals within the focus group interview sessions. A possible reason for this is the different roles each profession plays in

managing spasticity. Physicians are responsible for decision making surrounding the use and appropriate dosage related to the pharmacological management of spasticity; whereas, rehabilitation professionals typically employ exercise-based interventions. In general, the pharmacological management of spasticity is mainly targeted at reducing muscle activity and may therefore be the reason why quantitative measures of muscle tone would be of more interest to physicians as compared to rehabilitation professionals. It should also be acknowledged that quantitative assessment data is not routinely measured in clinical practice which could also explain the uncertainty surrounding the usefulness of these measures.

Limitations

Limitations of this study include limited external validity of the findings due to the relatively small sample size (N=24). Response bias is also considered to be a limitation; however, as a result of survey advertising practices, response rate to the survey is unknown. Not all participants who contributed to the survey and focus group sessions had experience performing virtual spasticity assessments. However, all participants reported spending a minimum of 10% of their clinical time related to the care and management of spasticity. Another limitation is the difference in methods used to seek feedback from clinician participants related to the third objective. Although efforts were made to present the proposed quantitative spasticity device in a similar way, the video emailed to the two specialists was not used in the other three focus groups. This difference in the method of presenting information may have influenced the responses given by the specialist clinicians.

Conclusions

The results of this study provide new insights into clinicians' experiences performing virtual spasticity assessments. Telehealth spasticity assessments enabled the continuation of essential appointments for individuals with spasticity during the COVID-19 pandemic. Successes of telehealth use within the spasticity population include enhanced service delivery efficiency, the ability to observe patients within their natural environments, and a reduction in patient travel burden. The successes of telehealth adoption have also come with challenges. Spasticity telehealth assessment experiences are highly variable and depend on several personal and environmental factors. The benefits of adopting objective spasticity assessment measurement within telehealth practice are currently unknown and highly speculative. The development and testing of a device capable of obtaining and transmitting objective spasticity assessment information is required to determine the usefulness of these measures in clinical practice. Information gathered in relation to the objectives explored in this study was used to guide the development of a remote telerehabilitation assessment device and software application, as outlined in Chapter 3.

Chapter 3. Development Process of The Telerehabilitation-Objective-Neuromuscular-Evaluation (TONE) Device & Software Application

3.1 Development Process Framework (PDSA)

Plan-Do-Study-Act (PDSA) methodology was the framework chosen guiding development of the 'Telerehabilitation Objective Neuromuscular Evaluation' (TONE) device and software application. Edwards Deming, the creator of the PDSA cycle, described the cycle as 'a flow diagram for learning, and for improvement of a product or of a process' (Deming, 1994). PDSA methods have been employed in numerous healthcare quality improvement (QI) initiatives (Knudsen et al., 2019; Nicolay et al., 2012; Taylor et al., 2014). Healthcare QI initiatives using PDSA methodology typically focus on implementing and studying potential solutions to improve processes within smaller trials as a precursor to widespread uptake (Moen, 2009; Taylor et al., 2014). PDSA methodology was chosen as it has been demonstrated to inform product or process improvement while being cost-effective effectively (Taylor et al., 2014).

PDSA methodology involves an iterative, four-stage procedure that begins with the 'plan' stage (see Figure 1). The planning stage is initiated by identifying a process or product in need of improvement and by asking questions such as, "What changes can be made that will result in improvement?" In the planning phase, several ideas for change proposed to result in improvement may be identified. Predicting outcomes in relation to generated ideas can assist in selecting the most pragmatic or promising solution to be tested (Deming, 1994). The 'do' stage involves conducting the selected change or test proposed to result in improvement identified within the planning stage. Next, the 'study' stage examines the test results performed in the do stage, including an analysis of successes and failures encountered during testing. Lastly, the 'act'

stage identifies adaptations and next steps to inform the next iteration of the cycle (Moen, 2009; Taylor et al., 2014).

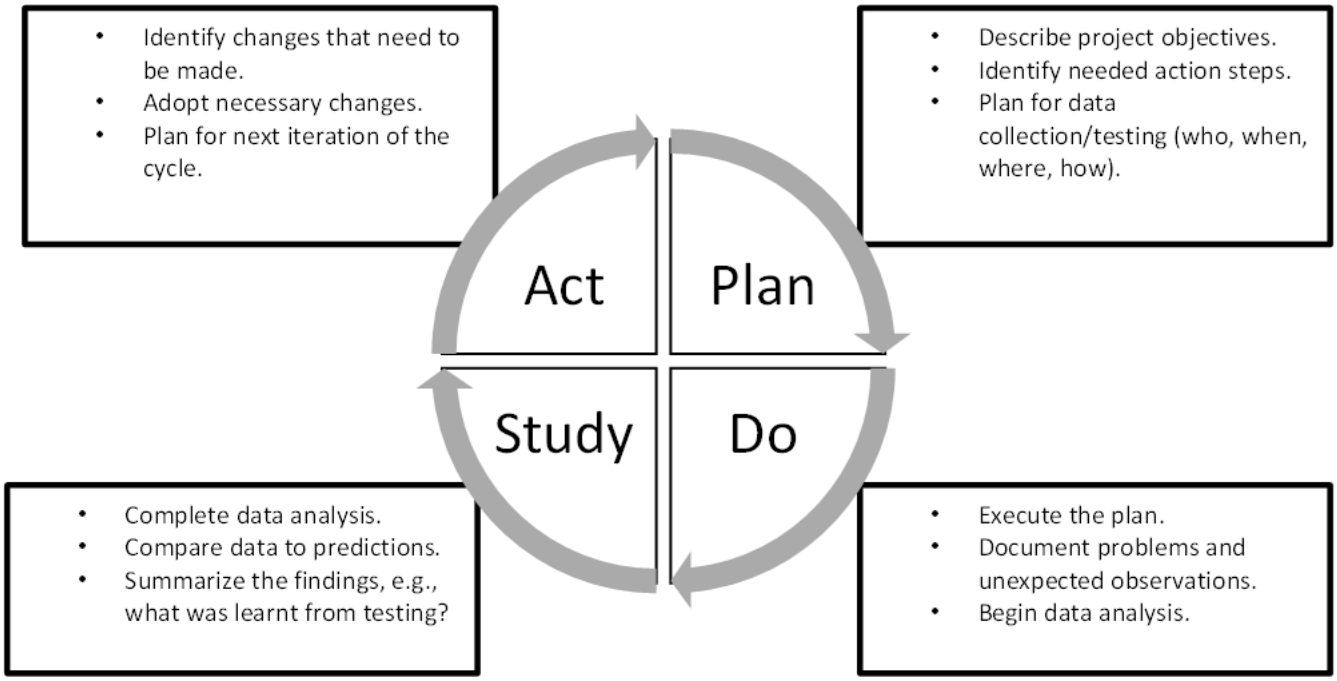


Figure 1. The Plan-Do-Study-Act Cycle, adapted from (Deming, 1994; Taylor et al., 2014)

The development of the TONE device and software application was initiated with the underlying foundational goal of improving the quality of telerehabilitation spasticity evaluations. The inability to perform traditional hands-on spasticity assessment measures within telerehabilitation practice was identified as a problem affecting the quality of telerehabilitation evaluations. The following chapter will outline the 'Plan' phase of the PDSA process relating to the development of the TONE. The planning process and decisions leading to the initial prototype of the TONE device and software application will be discussed. The plan for validation testing of the TONE will also be outlined. The remaining phases of the PDSA cycle (do, study, act) will be described in chapters four and five. Chapter 4 describes validation testing

of the TONE device and software application within a non-patient population. Testing within a non-patient population was used to inform further improvement of the device and software application prior to testing within a patient population in Chapter 5.

3.2 Planning Phase Identifying Objectives

The planning phase was initiated by identifying a need to improve the quality of telerehabilitation spasticity evaluation. This need was confirmed through a literature review, meetings, and formal focus group sessions with providers of spasticity care (findings provided in Chapter 2). A central issue related to telerehabilitation spasticity evaluation, and the practice of telerehabilitation in general, is the inability to perform hands-on procedures that are commonplace within traditional in-person rehabilitation settings (Albahrouh & Buabbas, 2021; Theodoros & Russell, 2008). Objective measures providing quantitative data related to spasticity were of primary interest when planning for the features of the TONE device. Objective measures of spasticity can easily be transmitted between patients and specialists using the internet, making them compatible with telerehabilitation environments. Objective measures were also considered desirable, as even within in-person contexts, they have been proposed to address the need for more consistency and reliability of observer-based ordinal clinical scales such as the MAS and MTS (Cha & Arami, 2020).

The main questions guiding development became: “What alternative options, aside from observer-based ordinal clinical scales, exist for objectively assessing spasticity? And, of these options, “which would best be suited for telerehabilitation?” While virtually no research exists on the use of quantitative telehealth spasticity assessment, several in-person objective approaches to spasticity assessment exist within the literature. Objective methods of spasticity assessment

are commonly categorized into neurophysiological and biomechanical approaches. These methods are often combined to assess spasticity.

Neurophysiological methods involve using electromyography (EMG) and analyzing muscle activity, typically during passive movement. Biomechanical methods involve obtaining kinematic measures, including a range of motion, joint angular velocity, and force or torque (Biering-Sorensen et al., 2006; Cha & Arami, 2020). The following section will describe technology options available for obtaining neurophysiological and biomechanical spasticity data in the literature. A summary of technology hypothesized to be compatible with telerehabilitation will also be provided, guiding initial prototype development of the TONE device and software application. 3.3 Objective Spasticity Assessment Practices

3.3.1 Neurophysiological Measures

Surface electromyography (sEMG) is an important method of quantitatively evaluating and assessing muscle activity within the field of rehabilitation (Becker, von Werder, Lassek, & Disselhorst-Klug, 2019; Brambilla et al., 2021; Campanini et al., 2020). sEMG has been promoted as a useful tool for identifying motor disorders, including spasticity (Brambilla et al., 2021). sEMG has been used to assess spasticity by providing a quantitative method of measuring various muscle reflexes, including the stretch reflex (induced by passive stretching of a muscle), tendon-reflex (tendon tap assessment with a reflex hammer), and H-reflex (induced by stimulating the peripheral nerve supplying the muscle) (Biering-Sorensen et al., 2006).

sEMG is a method commonly used to assess the stretch reflex induced by an examiner's passive stretch. When considering the use of EMG measures as a component of the TONE device, sEMG was seen as advantageous over intramuscular EMG for telehealth use. sEMG

techniques for measuring MUAP are less invasive and require less technical skill than intramuscular EMG measurement. Therefore, the evaluation of muscle activity using sEMG was viewed as a more favorable measure of spasticity for telerehabilitation as compared to intramuscular EMG.

The relative ease of sEMG use does not come without caution, as this commonly cited quotation in the literature shows, "To its detriment, electromyography is too easy to use and consequently too easy to abuse" (De Luca, 1997). Some known factors affecting sEMG responses include electrode placement, skin resistance, subcutaneous fat, muscle atrophy, and electronic noise from other sources (Biering-Sorensen et al., 2006). Despite these limitations, sEMG remains a widely used and cost-effective method of measuring muscle activity in spasticity assessment within research settings. In recent years, inexpensive sEMG sensors and development boards with analogue to digital converters have become widely available. Prior to this, sEMG systems were cost-prohibitive for use outside of research environments.

The widespread use of sEMG for spasticity assessment in the literature and affordable options for sEMG sensors led to the decision to include sEMG as a vital component of the TONE device for assessing muscle activity and diagnosing spasticity. Additionally, using sEMG was considered compatible with telehealth assessment of spasticity as the procedure is non-invasive. Electrode placement and sEMG use were predicted to be achievable by guidance provided by a specialist to a remote assessor and patient using videoconferencing.

3.3.2 Biomechanical Assessment: Range of Motion, Velocity, & Force

Biomechanical measurements of spasticity involve examining responses to passive movement using joint position sensors and torque. These measures are also often accompanied

by simultaneous measures of muscle activity (sEMG measures) (Balci, 2018; Bar-On et al., 2013). Biomechanical measurements used in research settings correlate with clinical measurements and are reliable and objective (Balci, 2018). These measures focus on quantifying resistance to passive movement by obtaining measures of range of motion, angular velocity, and force, sometimes expressed as torque during passive joint movements (Bar-On et al., 2013). Despite their relative absence from clinical practice, it has been argued that quantitative measures of resistance to passive movement are essential for valid and reliable spasticity assessment (Balci, 2018; Burridge et al., 2005; Cha & Arami, 2020; Hameau et al., 2014; Luo et al., 2019). Several different electronic quantitative methods for measuring range of motion, joint angular velocity, and reactive force measurement exist within the literature. The following will describe various methods and technology for obtaining biomechanical spasticity assessment data. The compatibility of these methods with telerehabilitation environments will also be discussed.

Force Measurement

Isokinetic dynamometers represent the gold standard for obtaining biomechanical measures related to muscle force (Stark, Walker, Phillips, Fejer, & Beck, 2011). These large, computerized machines can provide precise measures, including muscle strength, torque, peak torque, and threshold angle (Balci, 2018; Bar-On et al., 2013; Cha & Arami, 2020). Isokinetic dynamometers have been frequently used to assess measures of torque related to spasticity (Biering-Sorensen et al., 2006). In a review of spasticity assessment, Biering-Sorenssen et al. (2006) concluded that isokinetic dynamometers can objectively capture the velocity-dependency of muscle resistance associated with increases in angular velocity in patients with spasticity. Despite being a gold standard, isokinetic dynamometry has not been adopted within clinical

practice due to high cost (roughly $150 000 CDN), large space requirements, and difficulty with applying to patients with spasticity (Balci, 2018; Biering-Sorensen et al., 2006; Cha & Arami, 2020; Lee, Chen, Ju, Lin, & Poon, 2004). Additionally, these devices are not-portable, making them difficult to move between sites and virtually impossible to use within patient home settings (Chen, Wu, Huang, Lee, & Wang, 2005). With the known barriers to adoption within standard clinical practice, isokinetic dynamometers were determined to be incompatible with telerehabilitation environments and, therefore, excluded as a technology of interest for this project. After excluding isokinetic dynamometry for obtaining biomechanical spasticity measures, it became apparent that multiple smaller, more portable sensors would be better suited for development. Next, a review of wearable technology options for measuring range of motion, joint angular velocity, and force was completed.

Range of Motion & Joint Angular Velocity Measurement

More recently, biomechanical measures of range of motion and angular velocity obtained by wearable sensors have become popular (Calota, Feldman, & Levin, 2008; Kim, Park, Lee, & Nam, 2020; Yu et al., 2020; Zhang et al., 2019). Wearable sensors have been promoted as portable and low-cost, providing highly accurate measures of joint angles and angular velocity (Porciuncula et al., 2018). The most common wearable sensors involved in assessing spasticity providing range of motion and angular velocity measures within the literature are inertial measurement unit (IMU) sensors and electronic goniometers. Signals recorded from these sensors are typically analyzed to derive clinically meaningful indexes related to spasticity and are often compared with clinical scales (Kim et al., 2020). Inexpensive and readily available IMU sensors typically include a 3-axis accelerometer, 3-axis gyroscope, and 3-axis

magnetometer data for calculating position and velocity measures (Porciuncula et al., 2018). Due to the high affordability (approximately $10 CDN), wearability, portability, and accuracy of measurement reported in the literature, IMU sensors were of interest to measure joint angle and velocity for initial development.

Electrogoniometers also offer a wearable technology option for joint angle and velocity measurement. Electrogoniometers are electronic versions of the standard goniometers commonly used within clinical settings to measure joint range of motion or angular displacement. Electrogoniometers typically involve one or two potentiometers or strain gauges anatomically aligned in relation to the joint axis of rotation centre. Arms attached to the potentiometer are aligned along anatomical references in relation to the joint being assessed. As the potentiometer moves, a position-dependent voltage output can represent the angle of motion (Bronner, Agraharasamakulam, & Ojofeitimi, 2010). Although electronic goniometers are larger and bulkier than IMU sensors, these devices are significantly more portable than the mechanized approach using isokinetic measures discussed earlier. Additionally, these devices can be pre-calibrated before use within clinical settings, thereby lessening the time required during the clinical assessment. These devices are also cost-effective and capable of obtaining joint angle and velocity measures. Therefore, using a potentiometer-based electronic goniometer was considered a viable option for development.

Force Measurement

Lastly, the task of selecting a feasible measure of force compatible with telerehabilitation was required. It was determined that force measures would need to be obtained during manual passive movements (i.e., a clinician moving the limb), as mechanized motor-driven approaches

were previously excluded. The investigation into the use of small, portable, and inexpensive electronic force sensors used for spasticity assessment revealed several studies adopting this approach (Bar-On et al., 2013; Lee et al., 2004; Lorentzen et al., 2012; Pandyan, Price, Rodgers, Barnes, & Johnson, 2001; Wu et al., 2018; Yamaguchi et al., 2018). Pandyan et al. (2001) developed a non-invasive biomechanical measurement device to measure resistance to passive movement. In their study, they used a force transducer (load cell) to quantify force during manually applied flexion and extension passive movement of the elbow. Another study by Bar-On et al. (2013) assessing spasticity in children with cerebral palsy describes using a force-sensor load cell to measure torque during manually applied passive knee and ankle movements.

Aside from using force transducers, alternative methods for measuring force were found in the literature. In a study by Lee et al. (2004) assessing spasticity in individuals post-stroke, the authors used small pressure-sensing airbags to measure force. Airbags were attached to the dorsal and volar sides of the wrist to measure force using a differential pressure sensor while performing passive elbow flexion and extension (Lee et al., 2004). A recent study by Wu et al. (2018) incorporated a portable dynamic torque sensor mounted to a forearm brace to measure stiffness and joint torque during passive movement. Despite producing high accuracy measures of joint angle, velocity, torque, and torque change rate to characterize catch angle and spasticity quantitatively, dynamic torque sensors were not considered due to the requirement of mounting to a forearm brace, limiting the portability and wearability of this type of sensor.

An alternate approach by Jonnalagedda et al. (2016) used force-sensitive resistor sensors integrated into a glove worn by a clinician for spasticity assessment. Force-sensitive resistors work by outputting a voltage proportional to applied forces. They are simple to use, low-cost, wearable, and come in various sizes. Although the study by Jonnalagedda et al. (2016) did not

directly evaluate patients with spasticity, the instrumented glove's accuracy was tested compared to measures obtained by a Haptic Elbow Spasticity Simulator (HESS).

The HESS consisted of a mannequin arm with a torque motor, potentiometer, and load cell. This device can simulate spasticity by providing artificial muscle resistance and creating a simulated catch phase produced as an impulse. Although the authors found only moderate agreement between the HESS and instrumented glove, FSR sensors were viewed as a potential technology for force measurement due to their low cost.

3.4 Summary of Desired Features Guiding Initial Prototype Development

After reviewing the literature, the initial desired features of the TONE device were established. It was determined that a hybrid approach to quantitative spasticity assessment would be pursued, including electronic sensors obtaining both neurophysiological and biomechanical spasticity measures. The inclusion of both neurophysiological and biomechanical information was seen as essential as both reflex hyperexcitability (neurophysiological) and mechanical stiffness (biomechanical) may contribute to increased resistance to passive movement (Baude et al., 2018; Foran, Steinman, Barash, Chambers, & Lieber, 2005). Identifying reflex-related resistance and mechanical stiffness have been identified in the literature as important for guiding interventions for effective spasticity management (Balci, 2018).

Surface electromyography was selected as the preferred method of obtaining neurophysiological measures. Surface electromyography signals would be useful in determining the timing onset of muscle activation associated with passive movement applied by an examiner during assessment. Inertial measurement units and electrogoniometer sensors were viewed as the most feasible sensors for measuring biomechanical spasticity data relating to a range of motion and joint

angular velocity. Lastly, force transducers and force-sensitive resistor sensors were selected as the most feasible technology for obtaining force measures. Several common characteristics were found in the sensor technology chosen to develop the TONE device. All the sensors chosen were low-cost, highly portable, and easily wearable. These features enable the assessment of spasticity within multiple environments, including within the patient's home and care facilities and remote healthcare hospitals and clinics. All sensors converted analogue into digital signals, allowing for the electronic transfer of quantitative spasticity assessment data using the internet. In summary, the selected sensors, including IMUs, potentiometer-based electro goniometer, load cell, and force-sensitive resistor, were all viewed as compatible with telerehabilitation environments.

3.5 Identifying Action Steps: Initial Firmware Development

After selecting the most pragmatic objective measures of spasticity, the next step was to determine if developing a device capable of obtaining and transmitting the desired measures was possible. It was also essential to assemble a team capable of developing the device. Planning of the initial prototype of the TONE device was held on November 16th, 2020. This meeting involved the primary researcher, a physiotherapist with clinical stroke rehabilitation experience, and Dr. Martin Ferguson-Pell, a biomedical engineer and credentialed clinical scientist of the Rehabilitation Robotics Lab at the University of Alberta. The meeting was held virtually using Zoom videoconferencing and a real presence robot for achieving better camera views during the interaction and various technology demonstrations. During this meeting, the primary researcher presented the technology in the literature review and summarized the goal of producing a measurement device capable of measuring and transmitting muscle activity, ROM, joint angular velocity, and force signals. The primary researcher discussed the sensors used within the

literature initially identified as being compatible with telerehabilitation, including force-sensitive resistor, force transducer, IMU, electrogoniometer, and sEMG sensors.

The meeting involved Dr. Ferguson-Pell sharing valuable insights into the potential advantages and challenges of the sensors presented by the primary researcher. Reservations regarding using force sensitive resistor sensors for force measurement were voiced. Several issues related to force-sensitive resistor sensors were explained to the primary researcher, including nonlinearity of measurement, hysteresis or lag between mechanical force application and mechanical stimulus, and temperature dependency. Force-sensitive resistors are also known to drift or change values under conditions of constant force (Matute, Paredes-Madrid, Moreno, Cárdenas, & Palacio, 2018). Force transducers or load capacitive sensors were reported to be more advantageous for measuring force than force-sensitive resistor sensors. The advantages of load capacitive sensors were discussed in the meeting and included providing a more responsive and accurate linear measure of force. Load capacitive sensors were also promoted as more temperature-independent and reliable than force-sensitive resistors. The benefits of load capacitive sensors compared with force-sensitive resistors were seen as highly advantageous. It was determined that load capacitive sensors would allow for an accurate determination of force while remaining low-cost, wearable, and easily incorporated within the device's design.

Next, the discussion turned to obtaining ROM and joint angular velocity measures. The primary researcher indicated that several studies on quantitative spasticity assessment involved using IMU sensors for ROM and angular velocity measurement (Calota et al., 2008; Luo et al., 2019; Zhang et al., 2019). Issues related to drifting values or changes in position data, even in the absence of movement of IMU sensors, were explained to the primary researcher. Drifting values are a common issue experienced with IMU sensors that have been discussed in the literature.

Various methods exist to correct drifting values, but even with these corrections, drifting values remain an issue. Another potential challenge voiced during the discussion of IMU sensor use was the requirement for calibration procedures prior to individual testing sessions. These sensors orientate about gravity and not body segments; the sensors cannot determine where in space they are relative to one another. This prompted the need for multiple IMU sensors to measure the movable and stationary limbs during assessment. Using multiple IMU sensors also comes with challenges, as the sensors must be aligned within the same plane of movement during measurement to output accurate joint angles. Solutions to this problem have been presented in the literature but remain complex and challenging to integrate.

Despite the challenges associated with measuring static joint angles, IMU sensors are known to provide accurate measures of velocity during movement. Measures of velocity are not as prone to drifting values. Inertial measurement units remained a technology of interest as accurate measures of angular velocity were hypothesized to be easily achievable; however, uncertainties remained regarding how to achieve accurate absolute measures of joint ROM.

After discussing the limitations of IMU sensors, electrogoniometer or potentiometer-based sensors for ROM and angular velocity measurement were brought up. Electrogoniometers do not suffer from drifting values, which is common in IMU sensors; this lack of drift results in more stable and reliable measurements over time. Electrogoniometers can be calibrated before testing, reducing initial setup times during assessment. Limitations of electrogoniometers were discussed, including known challenges of ROM and angular value accuracy being dependent on electrogoniometer placement. The accuracy of electrogoniometers is dependent on the axis of rotation being correctly positioned over the joint center of the axis, along with the stationary and movable arms being in good alignment with anatomical references.

An attractive alternate method for measuring joint kinematics demonstrated by Dr. Ferguson-Pell was a markerless motion capture system developed by Kinetisense Incorporated (Medicine Hat, Alberta, Canada). The Kinetisense markerless motion capture system uses three-dimensional camera technology and artificial intelligence to detect anatomical landmarks automatically and analyze human movement. The Kinetisense system does not require reflective markers to be worn during testing. A limitation of markerless motion capture identified during development planning was the requirement of a specific Microsoft Kinect camera for assessment. Although costs associated with cameras used for markerless motion capture are significantly less than optical motion tracking cameras, the remote setup of the Kinect camera for markerless motion capture was not seen as feasible within the current project. Additionally, no markerless motion capture system currently exists that incorporates sEMG and force measures, which was considered to be important for spasticity assessment.

Marker-based optical motion tracking was also discussed during the meeting as an alternative method of measuring range of motion and joint angular velocity. Optical motion tracking represents the gold standard for kinematic measurement of human movement, including joint angles and angular velocity. This assessment method relies on the placement of reflective markers and infrared cameras to measure joint kinematics. These systems are expensive, requiring specialized equipment and calibration procedures; although highly accurate, it was determined that optical motion tracking would only be feasible in research settings. Despite not being compatible with prototype development, optical motion tracking was endorsed as a technology to keep in mind for validation testing of the initial prototype device.

The final item of discussion covered technology options for receiving, processing, and transmitting information received from the chosen analogue sensors into digital electronic

outputs. The Feather M0 microcontroller (Adafruit, NY) was presented as a capable analogue to digital convertor. The concept of edge computing was also presented to the primary researcher as an efficient data transfer method. Edge computing was described as a process whereby the microcontroller performs calculations before transmitting information to a software program. This was seen as advantageous as a means of decreasing the volume of data transferred and reducing program development requirements for synthesizing raw data. Another feature of the Feather M0 microcontroller discussed during the meeting was the onboard microsecure digital (microSD) removable flash drive, offering an option to store data locally. This was seen as essential as data from the assessment could be saved and reviewed asynchronously in the event of power loss or connection failure.

Next, the primary researcher also indicated that wireless transmission of the signals from the device to a computer would be of benefit, further improving the portability of the device. Bluetooth low energy (BLE) transmission was discussed as a means of wireless transmission of data; however, latency issues were identified as experienced by Dr. Ferguson-Pell in a previous project involving BLE wirelessly transmitted sEMG data. Zig-Bee wireless technology was recommended as a solution to the known latency issues associated with BLE and thought to handle better the data packet output generated by the microcontroller. Wireless capabilities also necessitated battery power options for the microcontroller and attached sensors. Fortunately, small microcontrollers require very low power consumption, typically in the range of 20 milliamps, requiring input voltages typically between 7–12 volts (Ehrmann, Blachowicz, Homburg, & Ehrmann, 2022). Dr. Ferguson-Pell indicated that small lithium-ion polymer batteries were readily available and could provide adequate power to the development board and electronic sensors.

The outcome of this meeting resulted in a plan to develop battery-powered electronic hardware programmed to record and wirelessly transmit the desired objective spasticity information, including a range of motion (ROM), joint angular velocity, muscle force, and muscle activity measures. The initial version of the device was completed in early January 2021 (see Figure 2). The next task identified was to hire a software developer to assist in creating an application capable of receiving and displaying the data obtained and transmitted wirelessly from the firmware.

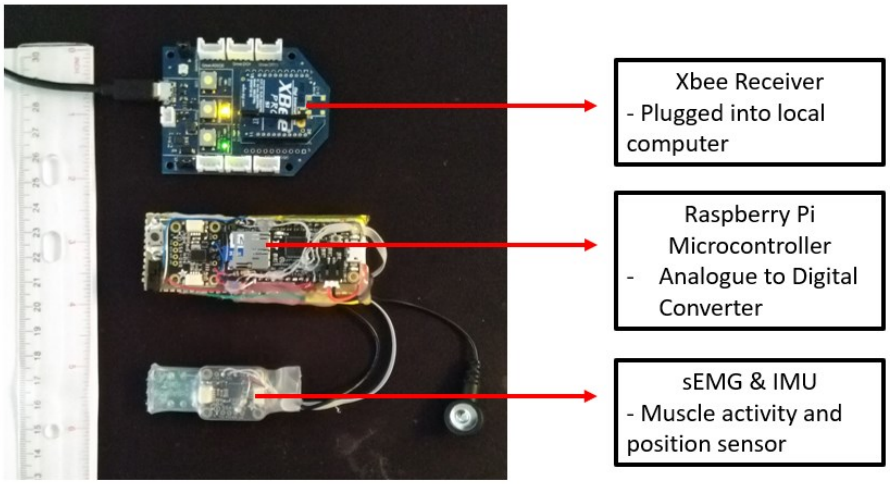


Figure 2. Initial firmware prototype of the TONE spasticity assessment device completed January 5th, 2021.

Software and Firmware Development Process

Twenty-three weekly meetings between the primary researcher and software engineer (Khilesh Jairmdas) were arranged between January 13th, 2021, and June 23rd, 2021. All scheduled meetings took place virtually using Google Meet videoconferencing. The meetings

consisted of weekly updates on the progress of the software application. The Windows Presentation Foundation (WPF) platform was selected as the format for developing the TONE device software application. WPF was chosen as it is compatible with Microsoft Windows, typically used within healthcare settings. The software coding followed the Model-View-Viewmodel (MVVM) architecture, which assists in logically segregating software coding. This software design pattern allows changes to be made in one area of the software without affecting other program areas. The MVVM architecture also assists in project handoff, should the need arise, between one software developer and another; MVVM does this by maintaining the software code in a segregated and easy-to-interpret format. This was an advantage as it was important to have a backup plan should the need to hire another software developer arise.

Once the software development platform was selected, the next task was to create a visual representation of joint angle, angular velocity, force, and surface electromyography (sEMG) measures. The initial version of the TONE device hardware included two inertial measurement units (IMUs) for measuring ROM and joint angular velocity. During early testing, it became apparent that the IMU sensors would require a calibration procedure to provide accurate joint angle estimations. This requirement was considered a limitation as standardized calibration movements may not be possible for individuals with spasticity. Solutions to this problem were explored by examining the literature; however, no pragmatic solution was found. The team decided to switch to a potentiometer-based electrogoniometer for measuring ROM and joint angular velocity instead of IMU sensors. Adaptations to the firmware were made to include input from an electrogoniometer.

After finalizing the choice of sensors, attention was shifted to the three-dimensional printing (3D printing) of a case designed to house the firmware. Discussion between the primary

researcher and Khilesh Jairmdas resulted in a decision to integrate the load cell and microcontroller within a created 3D-printed case. The 3D-printed case would act as a hand-held dynamometer during patient testing while housing the microcontroller development board and power source. Pressure applied through the lid of the 3D printed case would be measured by the load cell and transmitted to the microcontroller. Ports would be required to access the power switch and microSD card, allowing room for the electrogoniometer and sEMG sensor cables. An initial version of the 3D-printed case was completed on June 11th, 2021 (see Figure 3).

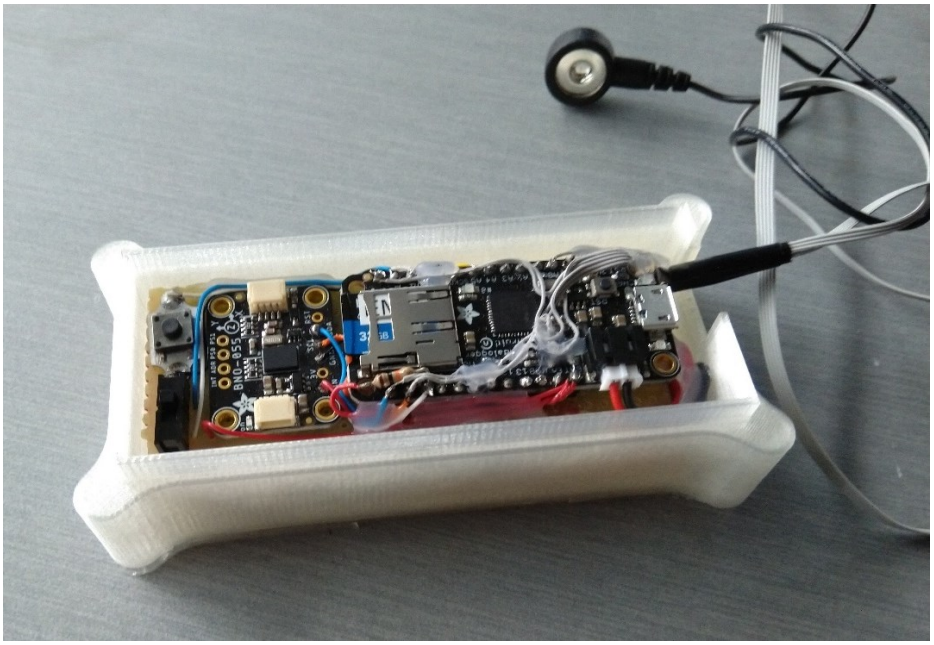


Figure 3. Initial 3D printed case with TONE device firmware, battery installed, completed June 11th, 2021.

The first in-person meeting between the primary researcher and Khilesh Jairmdas occurred on August 11th, 2021, and took place at the Rehabilitation Robotics Lab at the University of Alberta. Initial testing of the device was completed at this meeting and revealed apparent inaccuracies in the output of the device. The first observed problem was that the force

sensor produced negative output values (see Figure 4.) The negative output values occurred even in the absence of pressure applied to the 3D printed case and in instances after applying pressure to the case. During preliminary testing, it was observed that force measure values did not correspond with the estimated force being applied to the case. The situation was summarized in an email communication between the primary researcher and the development team on October 28th, 2021.

> "I noticed that fairly large amounts of pressure had to be exerted on the case before force values register in the data on excel and in the dashboard… I am wondering if the sensor would give more responsive readings if the pressure from the examiner was applied directly to the load cell?"

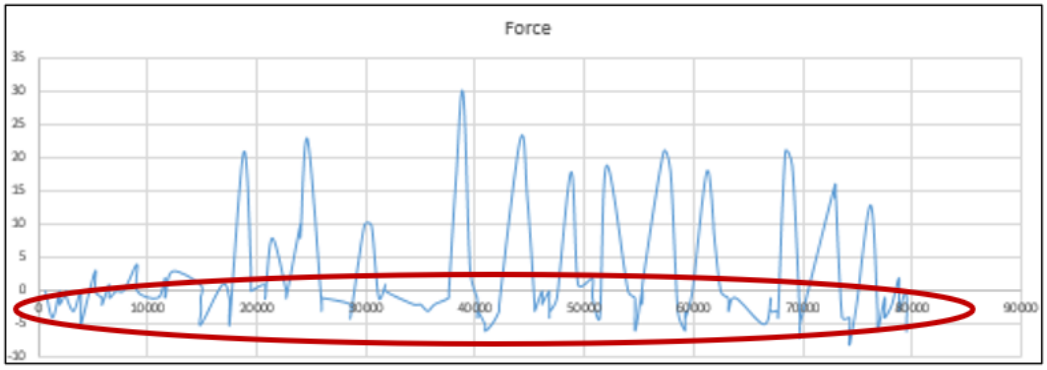


Figure 4. Negative force output values (< 0 Newtons) circled in red obtained from preliminary testing of the TONE device on August 11th 2021.

The negative force values were thought to result from the lid of the 3D-printed case pulling upward on the load cell when decompressed after compression. The negative values were also thought to result from difficulty in calibration due to changes in lid pressure due to plastic material deformation and compressible material between the lid and 3D printed case. As a result,

a piston-style method of applying force from the examiner's thumb to the load cell was designed and printed to allow for a more responsive and accurate force reading (see Figure 5).

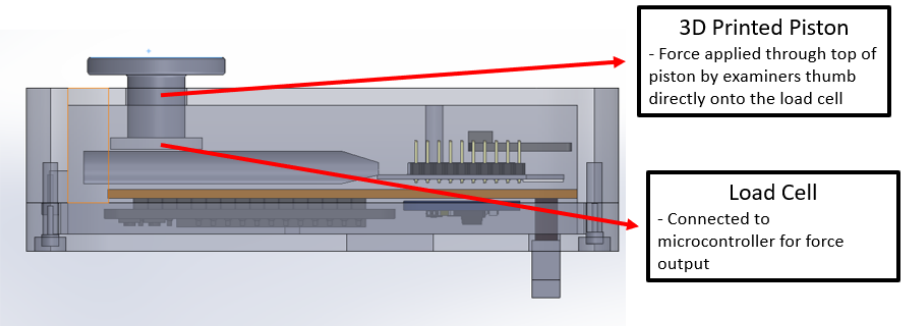


Figure 5. Schematic of second version of the 3D printed case housing TONE device firmware, incorporating piston applying direct force to the load-cell from email communication between Khilesh Jairmdas and the primary researcher November 22nd 2021.

On December 8th, 2021, the second in-person meeting was held to complete further testing with the newly designed 3D printed case, sEMG sensor, and electrogoniometer (see Figure 6). Dr. Patricia Manns, the primary researcher's supervisor, Khilesh Jairmdas, Dr. Martin Ferguson-Pell, and the primary researcher were present at the meeting. The purpose of this meeting was to form impressions from the entire team regarding any noticeable changes that would be required prior to validation testing. This meeting also focused on comparing sEMG measures obtained from a research grade system (Delsys Bagnoli) to the TONE device's sEMG sensors. During this meeting, the TONE device was tested at the elbow joint. Electrodes from both the Delsys Bagnoli and TONE sEMG sensor were applied to the biceps brachii muscle in parallel sequence. A series of 4-5 voluntary muscle contractions of the biceps brachii were completed with sEMG signals recorded from the research grade Delsys Bagnoli system and the TONE device. Although not statistically analyzed, visual analysis of the signals demonstrated

relatively comparable outputs, satisfying the team that the sEMG sensor would be ready for standardized validation testing.

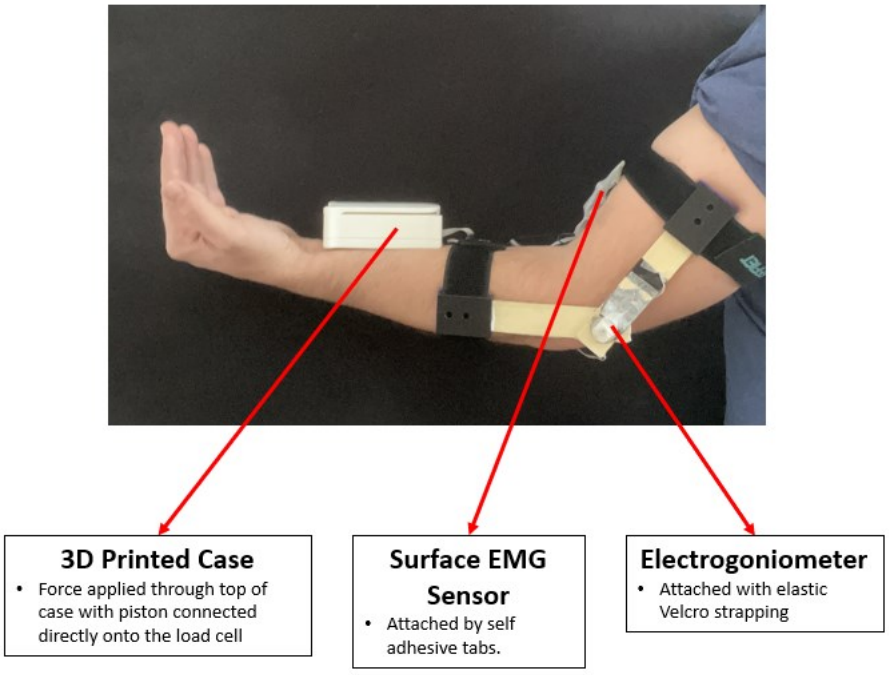


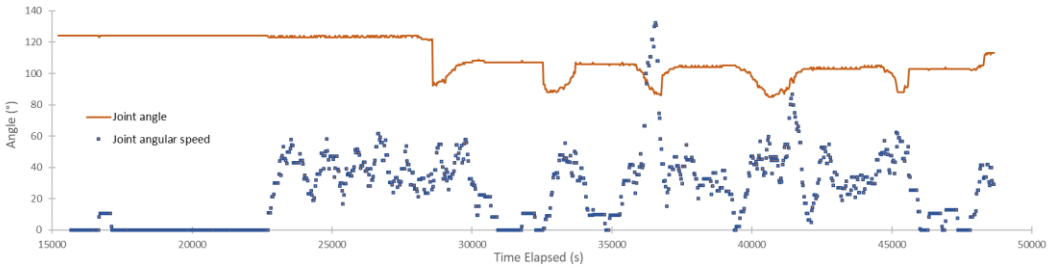
Figure 6. The finalized version of the TONE device including the newly developed 3D printed case with piston, electrogoniometer, and sEMG sensor applied to the elbow joint for demonstration.

Testing of elbow flexion and extension ROM and angular velocity during the meeting identified instability of angular velocity measure outputs. It was decided that averaging a larger sample of angle versus time values would likely solve this issue, resulting in a smoother and more interpretable signal output. This was captured well in an email communication sent from Khilesh Jairmdas on December 10th, 2021:

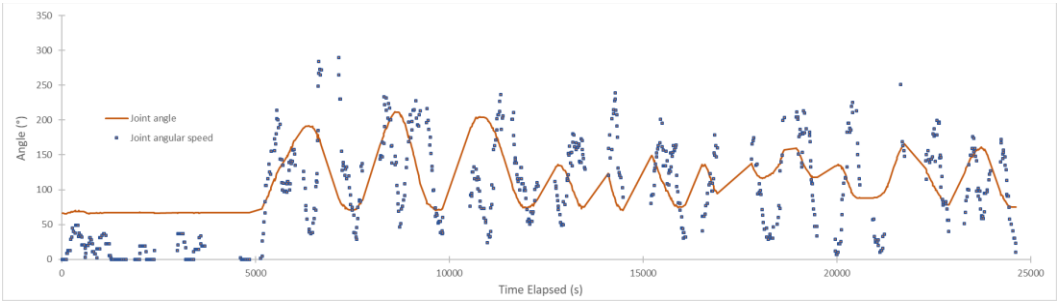
> "I wrote [into the programming code] a better way to calculate angular velocity (moving average of velocity with buffer size of 10 readings or a third of a

second's worth). Here is a before and after picture [including angle (red) and joint angular velocity (blue) versus time]

Before:



After:



You can see that the prior method really amplified signal noise and that the new method is fast and responsive to inflection points in angle."

The meeting also resulted in noticeable improved responsiveness of the force sensor; however, the limitation of only capturing force applied through the thumb of the examiner was seen as a limitation as captured by this email communication dated December 10th, 2021, from Khilesh Jairmdas to the primary researcher:

> "The new piston style contact method works to give stable values. Whereas this was a good prototype to discover that bypassing the case using a piston gives smooth, stable readings, I believe I can do much better… I plan to design a case integrating this contact method with superior ergonomics and structural stability."

Changes to the 3D-printed case design identified at the December 8, 2021, meeting were completed on January 6, 2022. Improvements to the case included a more ergonomic attachment to the piston-style interface with the load sensor (see Figure 7). These changes allow the examiner to apply force using their whole hand rather than the thumb alone, capturing more of the force applied during the assessment. This was also thought to improve the examiner's comfort while applying pressure to the lid of the 3D-printed case during passive motion.

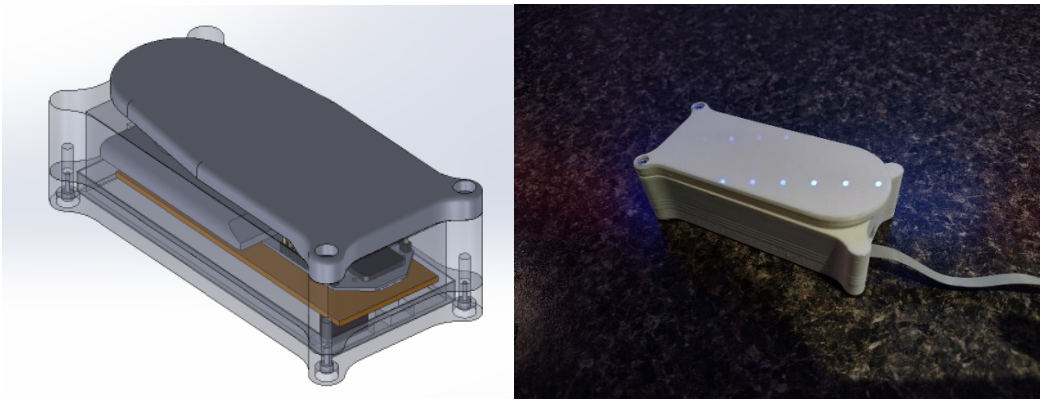


Figure 7. Improved 3D printed case with ergonomic lid interfacing with an embedded load-cell completed January 6th, 2022 by Khilesh Jairmdas.

3.6 Plan for Data Collection and Testing

With the initial development phase finalized, validation testing of the TONE device will be outlined in the next chapter (Chapter 4), describing the completion of the first iteration of the PDSA cycle. The study outlined in the following chapter will include the execution of validation

testing of the TONE device within a healthy population (Do: Phase). Analysis of the TONE device's output will be compared to reference standards to determine the device's accuracy (Study: Phase). Based on the device's agreement with the reference standards and any notable issues encountered during testing, recommendations for changes before patient testing will be summarized and implemented (Act: Phase).

Chapter 4. Study 2. Validation of the Telerehabilitation-Objective-Neuromuscular Evaluation (TONE) Device for Spasticity Assessment

4.1 Abstract

Background: Quantitative measures relating to range of motion (ROM), muscle activity, and muscle force are important for advancing in-person and telehealth spasticity assessment practices. The Telerehabilitation-Objective-Neuromuscular-Evaluation (TONE) is a novel device and software application capable of measuring and transmitting quantitative spasticity assessment information, including range of motion, surface electromyography, and force data.

Objective: The purpose of this study was to determine the level of agreement between the TONE device and reference standards, including optical motion tracking, hand-held dynamometry, and research-grader surface electromyography in a population without neurological deficits.

Methods: An inter-methods comparison study was completed with a convenience sample of individuals without neurological impairment (n=11). Agreement between the TONE device and reference standards was assessed for measures related to passive ROM of the elbow, along with surface electromyography and muscle force assessment of elbow flexion. Descriptive statistics, intraclass correlation coefficients, and Bland-Altman analysis was used to assess the level of agreement between the TONE device and reference standards. Testing was completed in two phases using a plan-do-study-act format. Data collected from phase one was analyzed and interpreted informing necessary changes thought to improve the performance and usability of the TONE device and software application. Phase two was used to confirm whether the updated device and software application improved the agreement between the TONE device and reference standards.

Results: Spearman's correlation coefficient (rho) values demonstrated a moderate to very strong relationship between the TONE device and OptiTrack Trio device angle versus time signal output (Phase 1: rho = 0.482-0.906; *p-value* = ≤ 0.001, Phase 2: rho = 0.593-0.960; *p-value* = ≤ 0.001). Surface electromyography measures of agreement comparing muscle contraction duration of the biceps brachii between the TONE and Delsys Bagnoli devices demonstrated moderate agreement (ICC = 0.5-0.74). The duration of muscle contraction time (seconds) and average force (kilograms) obtained by the TONE and KForce devices demonstrated good agreement (ICC = 0.75-0.9) in both phases of testing. Bland-Altman analysis comparing the duration of muscle contraction on time recorded by the TONE and KForce devices showed an average difference of 0.24 and 0.71 seconds for phases 1 and 2, respectively. Good agreement between measures of muscle force obtained by both devices (ICC = 0.75-0.9) was found in the first phase of testing, with poor agreement (ICC = <0.5) found between measures of force in the second phase of testing.

Conclusion: TONE device measures demonstrated moderate to excellent agreement compared to reference standards for the majority of relationships examined. Changes directed at increasing the transmission rate of the TONE device from 30 Hz in phase I to 50 Hz in phase II of testing resulted in improved performance of the TONE device's angle versus time measures. Increasing the transmission rate of the Tone device's rectified sEMG signal from 30 Hz to 50 Hz did not result in improved muscle contraction duration measurement agreement between the TONE and reference standard Delsys device. Overall, satisfactory levels of agreement were found between the TONE device and reference standards, indicating the device was ready for preliminary testing within a patient population.

4.2 Introduction

Spasticity is a common neurological impairment associated with lesions to the central nervous system that can lead to muscle stiffness and movement problems (Balci, 2018; Hundza et al., 2016; Pandyan et al., 2005; Thibaut et al., 2013; J. Wissel, MD, Manack, A., & Brainin, M., 2013). Spasticity is defined as "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." (Lance, 1980). An estimated 12 million people worldwide are living with spasticity, including individuals with stroke, multiple sclerosis, spinal cord injury, cerebral palsy, and traumatic brain injury (Weiss & Lin, 2007). Complications related to spasticity can cause difficulties in performing activities of daily living and negatively impact health-related quality of life for patients and their caregivers (Ganapathy et al., 2015; Zorowitz et al., 2013). Accurate assessment and diagnosis of spasticity by clinical specialists is crucial in planning effective interventions and monitoring patient responses to treatment (Hara et al., 2017). Without access to timely management, individuals are at a greater risk of losing range of motion within the affected joints, resulting in decreased limb use and quality of life for patients and their caregivers (Teasell et al., 2020). Despite the importance of early diagnosis and monitoring, no universally accepted definition or gold standard approach for spasticity assessment exists, and challenges remain in objectively assessing and diagnosing spasticity within current clinical practice (Banky et al., 2019; Calota et al., 2008; Cha & Arami, 2020).

Telehealth environments further exacerbate assessment challenges by limiting spasticity assessment information primarily to visual observation and subjective reports (Reebye et al., 2020; Verduzco-Gutierrez et al., 2020). Wearable electronic sensors offer the potential to

objectively assess and monitor patients requiring rehabilitation services within and outside clinical environments. Quantitative measures of muscle activity, including force, range of motion (ROM), and joint angular velocity, can provide important information regarding spasticity presence, severity, and patient response to treatment (Cha & Arami, 2020). Despite this, these measures have been mainly explored in research settings only. Accurate spasticity assessment depends on correctly determining the relative contributions of neural and non-neural factors restricting desired movement (Burke et al., 2013). Neural factors refer to the presence of involuntary muscle overactivity along with increases in stretch-reflex sensitivity. Non-neural factors refer to plastic changes observed within the muscle and connective tissues, including changes to viscosity, length, and elasticity (Baude, Nielsen, & Gracies, 2018). The identification of neural factors related to movement restrictions is indicative of spasticity.

The Modified Ashworth Scale (MAS) and Modified Tardieu Scales (MTS) are the most commonly used methods of determining the presence and severity of spasticity within clinical settings. The MAS involves moving the affected limb through a series of passive movements to grade the degree of resistance to passive stretch or muscle tone (Reeves & Lambeth, 2016). This method uses a six-point ordinal scale for classifying resistance to passive stretch. It includes a rating of '1 +' to record the resistance felt in the presence of 'a catch' followed by minimal resistance in the remainder of the passive movement (Johnson, 2002). The presence of a 'catch' is believed to be the abnormal reflex response of the muscle during passive stretch. The MTS also involves moving the affected limb through a series of passive movements but differs from the MAS by incorporating both slow and fast passive movements when evaluating spasticity. Evaluation of the MTS includes four components: 1) R1, which is the angle of catch measured during a fast velocity passive stretch; 2) R2, passive range of motion following a slow velocity

stretch; 3) R2-R1, indicating the dynamic component of spasticity within the muscle, and 4) quality ratings of fast velocity, passive movement (Naghdi et al., 2014; Sonvane & Kumar, 2019). Incorporating fast and slow passive movement velocity within the assessment makes the MTS superior to the MAS in detecting the neurological component of stiffness, as the MAS does not explicitly control for the speed of passive movement performed during evaluation (Sunnerhagen, 2013). Although cost-effective and easy to administer, the MAS and MTS cannot determine how neural and non-neural factors influence the resistance to passive movement (Zhang et al., 2019). Additionally, these clinical measures are incompatible with telehealth assessments due to the requirement of hands-on procedure methods.

The Telerehabilitation-Objective-Neuromuscular-Evaluation (TONE) is a novel device and software application capable of measuring and transmitting quantitative spasticity assessment information. The device can provide measures related to the presence and influence of neural and non-neural factors affecting resistance to passive movement. The device is equipped with sensors to measure ROM (electronic goniometer sensor), muscle force (load cell sensor), and muscle activity (surface electromyography (sEMG) sensor). It is wireless and battery-powered to enhance its portability for use within clinical and telehealth environments.

While an initial prototype of the device and software application has been developed, the device has yet to be validated against a reference standard. It is important to validate the TONE device against reference standards prior to testing within a patient population with neurological conditions.

Purpose & Objectives

The purpose of this study was to determine the agreement between the TONE device and reference standards. The following specific objectives were identified to achieve this purpose:

Objective 1: To assess the level of agreement between the TONE device's electrogoniometer, force sensor, and sEMG sensor in comparison with reference standards including optical motion tracking, hand-held dynamometry, and research grade sEMG respectively.

Objective 2: To identify and implement any modifications required to improve the performance and usability of the TONE device and software application prior to testing within a patient population.

4.3 Methods

Plan-Do-Study-Act Testing Format

This study completed two phases of the Plan-Do-Study-Act (PDSA) cycle (see Figure 1). Data collected in Phase 1 was analyzed and interpreted in the "Do" and "Study" phases of the first cycle. This information was used in the "Act" phase to inform any required changes believed to improve the level of agreement between the TONE device and reference standards before the next iteration of testing. In phase 2, modifications were made to the TONE device and software application in the "Plan" stage of the cycle, with testing repeated using the updated device and software application in the second phase of the PDSA cycle. Data collection and analysis were performed to determine if the changes made - informed by validation testing in phase 1 - resulted in performance improvements of the updated TONE device in phase 2 of the validation testing procedure. Information gathered from the second iteration of the PDSA cycle

will then be used to inform any changes required before testing within a patient population in a subsequent study.

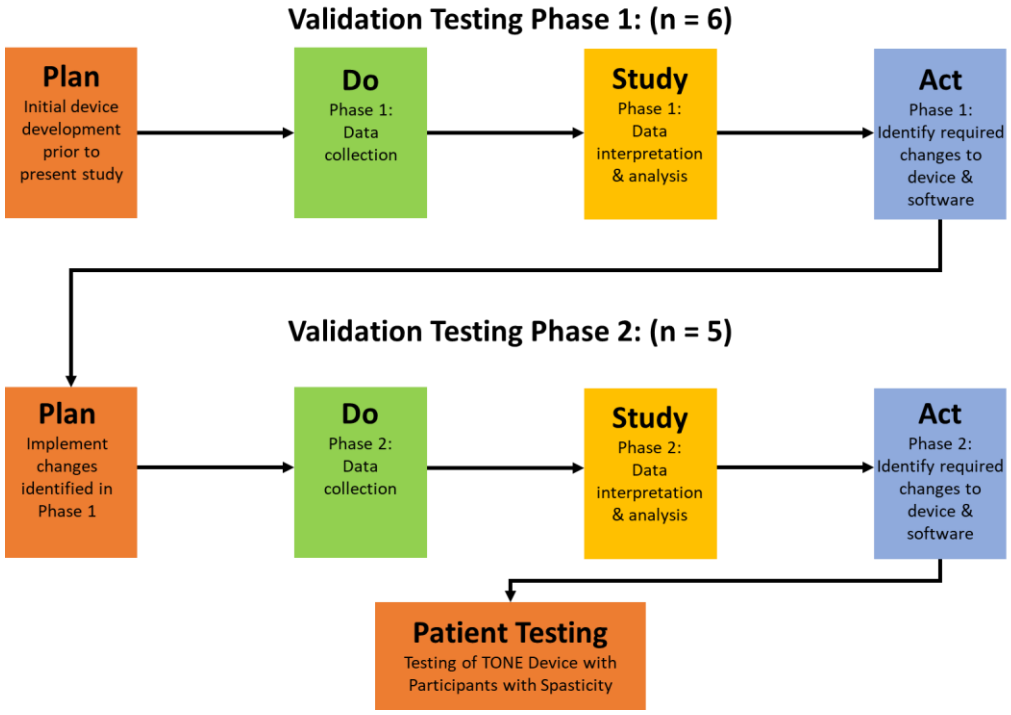


Figure 1. Schematic of two iterations of the Plan-Do-Study-Act cycle Phases 1 and 2 of validation testing with the TONE device and software application.

Participants

Participants included a convenience sample of 11 participants recruited from the Faculty of Rehabilitation Medicine (FRM) at the University of Alberta (UofA). This study was approved by the Human Research Ethics Board at the University of Alberta in January 2022 (Pro00112935). All participants provided informed written consent prior to participation. The following inclusion criteria were used: 1) No previous history of neurologic condition or diagnosis of spasticity, and 2) adult aged 18-65 years. Sample size calculations were based on a predicted moderate to good agreement between angular velocity, ROM, force, and sEMG measures obtained by the TONE device and chosen reference standards. Based on a predicted

intraclass correlation coefficient (ICC) of 0.70 and 95% confidence interval of ≤ 0.54, it was determined that 60 total measurements (10 subjects, 6 repeated measures of each variable of interest) would be required as described by Gwet (2014), (see Appendix D).

Instruments

OptiTrack Trio® optical motion tracking (Natural Point Inc. Corvallis, Oregon), Delsys Bagnoli™ 8 channel amplifier sEMG system with double differential sEMG sensor (Delsys Inc., Natick, Massachusetts), and KForce® wireless hand-held dynamometer (KINVENT Inc., Montpellier, France) were used as the reference standards to assess the TONE's accuracy in measuring kinematic joint data (ROM, angular velocity), duration of muscle contraction time, and muscle force respectively. Optical motion tracking involving the use of reflective markers placed on anatomical landmarks is considered to be the gold standard for measuring human motion (Sfalcin, Ji, Gouw, Potvin, & Cort, 2019). The Delsys Bagnoli sEMG system is a research-grade EMG acquisition device used in over 60 research studies in the past decade alone (Delsys Inc. (2023). The KForce wireless hand-held dynamometer was chosen as the reference standard. It assesses force by having the examiner push against the patient's resistance, consistent with the intended method of assessing force using the TONE device. Additionally, the KForce product specifications indicate that the device's accuracy is rated to be within 100 grams of force with a maximum force rating of 90 kilograms (KINVENT, 2020). Due to funding limitations and equipment accessibility, isokinetic dynamometry – considered the gold standard for measuring force – was not used as the reference standard for force in the present study. Despite this limitation, hand-held dynamometry has been demonstrated to have moderate to good reliability as compared to isokinetic testing, which is considered to be the gold standard for

assessing muscle force and was considered to be a suitable reference standard (de Almeida et al., 2023; Stark et al., 2011)

Kinematic Measurements

Reflective markers were placed at pre-specified anatomical landmarks for measuring elbow flexion and extension. Kinematic measures, including average joint angular velocity, total joint ROM, and start and end joint angle measures, were obtained simultaneously by the OptiTrack V120 Trio system and TONE device. Motive® software version 1.23 was used to capture measures obtained by the OptiTrack V120 Trio and was set to record measurements at a sampling rate of 120Hz. Kinematic measures from the TONE device were obtained from an electronic goniometer (potentiometer) aligned with anatomical landmarks in relation to the elbow joint (see Figure 2). The TONE device was set to record at a sampling rate of 30 Hz in the first phase of testing and 50 Hz in the second phase of testing.

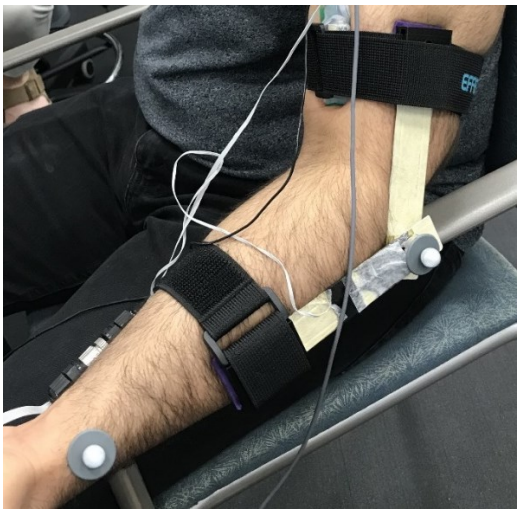


Figure 2. Electronic goniometer aligned with anatomical landmarks for obtaining kinematic measures of elbow flexion and extension. *Note marker placement for joint axis on top of electronic goniometer to enable simultaneous OptiTrack Trio system and TONE device measurements.

Force Measurement Technology

The KForce muscle controller (by Kinvent) is a commercially available hand-held dynamometer that wirelessly transmits force measures obtained by applying manual resistance. The KForce device transmits force data by Bluetooth at 75 Hz. A smartphone or tablet is required to connect the KForce application for real-time and post-assessment visual feedback. Measures of force obtained by the KForce will be compared to measures obtained by the load cell sensor (see Figure 3) component of the TONE device set to transmit data wirelessly at 30 Hz in the first phase and 50 Hz in the second phase of testing.

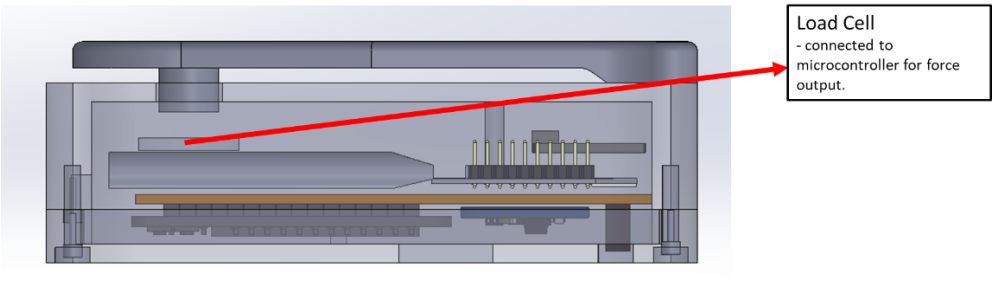


Figure 3. Schematic of TONE device microcontroller highlighting the force senor. Force is applied by an assessor pressing piston through top of 3-D printed case to the load-cell connected to the microcontroller.

Muscle Activity (sEMG) Measurement Technology

The Delsys Bagnoli sEMG system and EMG works software (version 7.4.9) and TONE device and software application were used to simultaneously measure sEMG signal output during the same series of 6 contractions of the biceps brachii muscle performed at 50% of maximal voluntary contraction (MVC). The reference Delsys system sampled the raw sEMG

signal at 1000 Hz. The root mean square was used to smooth the EMG signal. The effective sampling rate of the processed, rectified, and smoothed Delsys was 15.8Hz.

TONE Device sEMG Hardware

A Feather M0 microcontroller (Adafruit, NY) was used to acquire the EMG data using a bespoke program using the Arduino programming language. A 3-bar, differential EMG electrode was developed incorporating a 250 Hz low pass filter to avoid aliasing and a preamplifier with a 1.5-volt offset circuit to ensure that signals transmitted to the microcontroller A-D converter were bi-polar but always positive. This baseline offset was then removed in the firmware, which then rectified the signal and roughly smoothed it, enabling the output data rate to match the TONE device software application dashboard's capabilities.

Rectified Signal from TONE

The program collected the raw sEMG reading each time the loop was executed at 500Hz. The raw EMG signals were averaged to create a circular array of 10 values updated each time the loop was executed. This produced a moving window average of the EMG data, enabling the output to be sent to the wireless transmitter at about 1/10th the sampling rate. This was necessary to ensure the dashboard stayed synchronized with the TONE device and did not introduce a significant lag. The effective sampling rate of the rectified and roughly smoothed data was 33Hz (in phase 1) and later increased to 50Hz (in phase 2) to be sure sudden changes in sEMG signal activity were optimally recorded. (See Figure 4).

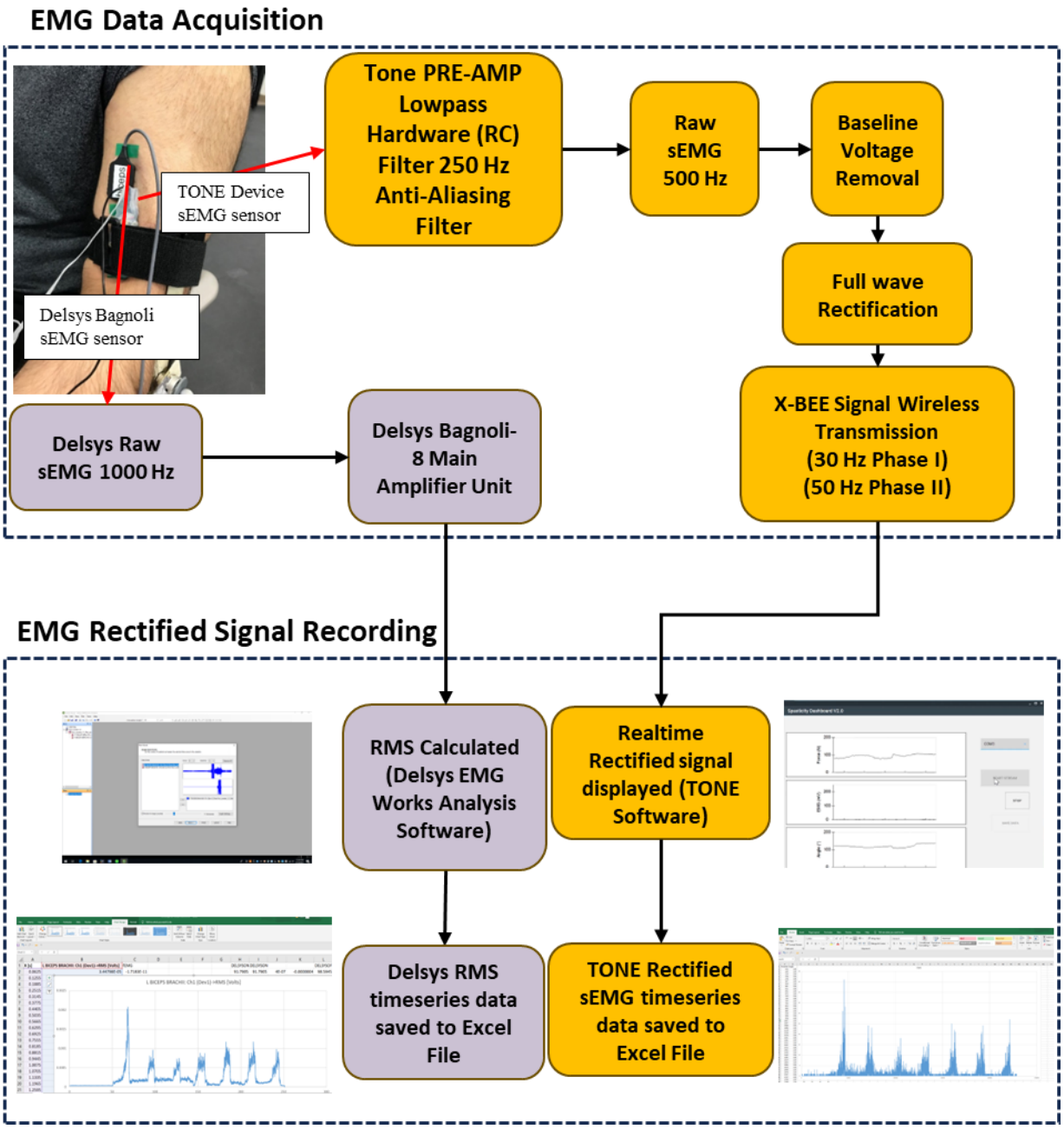


Figure 4. Surface electromyography data acquisition and recording diagram for Delsys and TONE devices for measuring muscle activity of the left biceps brachii muscle during a series of 6 contractions performed at 50% of maximal voluntary contraction.

Calibration Procedure

Calibration of the TONE electronic goniometer was conducted prior to testing. Five different angles representing values found within normal elbow flexion and extension limits were compared. Known angles were drawn on paper using a protractor and pencil. The known angles were then measured by aligning the centre of the TONE device's electronic goniometer arms with the drawn angles and recorded using the TONE device's software application. A strong correlation was found between the known angles and recorded TONE device angle measurements ($r^2 = 0.99$).

Testing Procedure

Kinematic testing was performed on the left elbow joint of each participant. The setup for recording the kinematic measures was completed first. Validation of all three measures (kinematic, sEMG, and force) was not possible as issues related to the OptiTrack system erroneously assigning the Delsys and TONE device's sEMG sensor and TONE and KFORCE hand-held dynamometer devices as optical markers were observed which would have resulted in non-usable angle versus time data. Participants were asked to lie supine with their left upper extremity facing toward the OptiTrack V120 Trio camera system. Next, the research team assisted with donning the TONE device by fastening two elastic straps (one above and one below the elbow joint) to secure the device in place (see Figure 2). Reflective markers were then attached to the anatomical landmarks associated with elbow joint flexion and extension, including the distal radius and, 3 centimeters inferior to the acromion clavicular joint on the lateral shaft of the humerus. The center for the axis of joint rotation was placed on the TONE device's electronic goniometer (axis of joint rotation) to allow for simultaneous kinematic

measures to be recorded by the OptiTrack cameras and TONE device. Once the TONE device and reflective markers were set up, OptiTrack Motive software and the TONE device's software were initiated to begin recording. Next, a series of 6 passive movements alternating between elbow flexion and extension were performed by the examiner (primary researcher). The passive movements were performed at two speeds, including three fast and three slow trials. The speed of each passive movement was performed in random order and chosen by the examiner, ensuring the completion of three fast and three slow movements with each participant. This was done to prevent anticipatory learning or reactions by participants. Fast movements were defined as having the examiner move the participant's limb 'as fast as possible,' with slow movements defined as having the examiner move the participant's limb 'as slow as possible.'

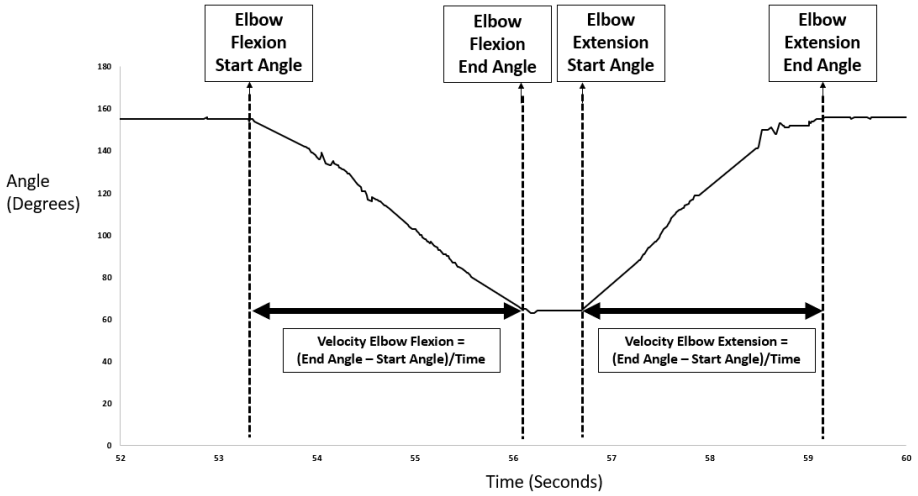
After recording and saving kinematic measures, participants were asked to move to a seated position to collect the muscle force and muscle activity measures. The examiner attached the TONE and Delsys device's sEMG sensors in series and in close proximity to the participants' biceps brachii muscle in accordance with Surface Electromyography for the Non-Invasive Assessment of Muscles (SENIAM) recommendations (see Figure 4). Next, participants were asked to perform a series of 3 MVCs for 5 seconds against manual resistance applied by the examiner holding the KForce hand-held dynamometer only. The TONE device was not used to measure the MVC force to protect the relatively small load cell from damage, as the maximum range of the load cell used was 400 newtons. The three MVC measures obtained by the KForce were then averaged and used to determine the 50% MVC force value for each participant. Afterward, participants were given a 3-minute break. Next, the software for recording force (KINVENT application) and sEMG (EMG Works version 7.4.9) was initiated. Participants performed a series of 6 muscle contractions at 50% of their MVC against manual resistance

applied by the examiner holding the KForce hand-held dynamometer. To allow for near-simultaneous force measures, the examiner applied the KForce hand-held dynamometer indirectly on top of the TONE device placed on the participants' forearms in a supinated position. Using a stopwatch for timing, participants were asked to perform each muscle contraction for 5 seconds and to keep the arm relaxed for 20-30 seconds between muscle contraction to allow for recovery. After the final muscle contraction, force, and sEMG data obtained by the KForce, Delsys sEMG, and TONE devices were recorded and saved. The examiner assisted in removing the sEMG electrodes and TONE device Velcro straps.

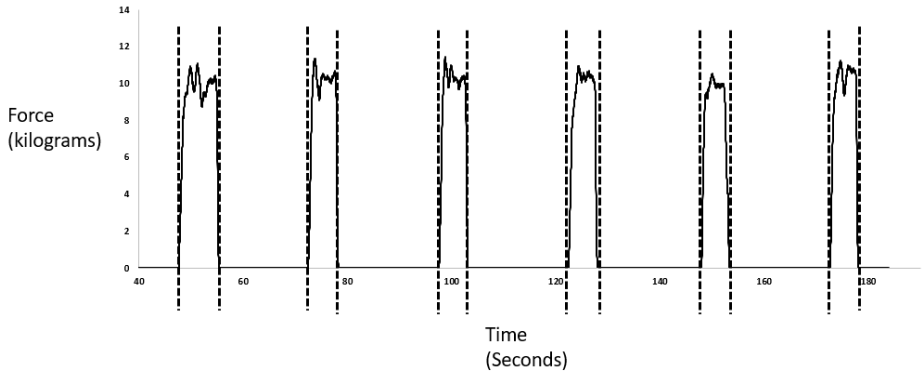
Data Analysis

Kinematic (ROM, start angle, end angle, and average velocity) and kinetic (average muscle force and duration of muscle contraction) data were identified using visual analysis in Microsoft Excel (see Figure 5). Kinematic measures of ROM were interpolated using spline interpolation in MATLAB to adjust for sampling frequency differences between the OptiTrack V120 Trio and the TONE device. The rectified sEMG data obtained by the TONE device's software application was further processed using a third-order low-pass Butterworth filter in MATLAB and smoothed using an asymmetrical moving mean window of 250 milliseconds. The signal was then normalized using z-score normalization in MATLAB. The processed Delsys and TONE sEMG signals were then interpolated and cross-correlated using the XCORR function in MATLAB in order to optimally align the TONE and Delsys sEMG time series data prior to analysis (see Figure 6). Descriptive statistics, including mean and standard deviation for all variables of interest, were calculated in SPSS. Agreement between measures obtained using the reference standards and the Tone device were calculated using Spearman's correlation

coefficients, intraclass correlation coefficients, and Bland-Altman agreement plots in SPSS and Microsoft Excel, respectively.



A)



B)

Figure 5. A) Example visual analysis procedure of kinematic measures obtained by the TONE device's electronic goniometer for start angle, end angle, range of motion, and angular velocity (participant P11). B) Example of visual analysis of force measures obtained by the K-Force for muscle contraction time (seconds) and average force (kilograms) (participant P08).

*Note doted lines represent start and end points in reference to time on the X-axis.

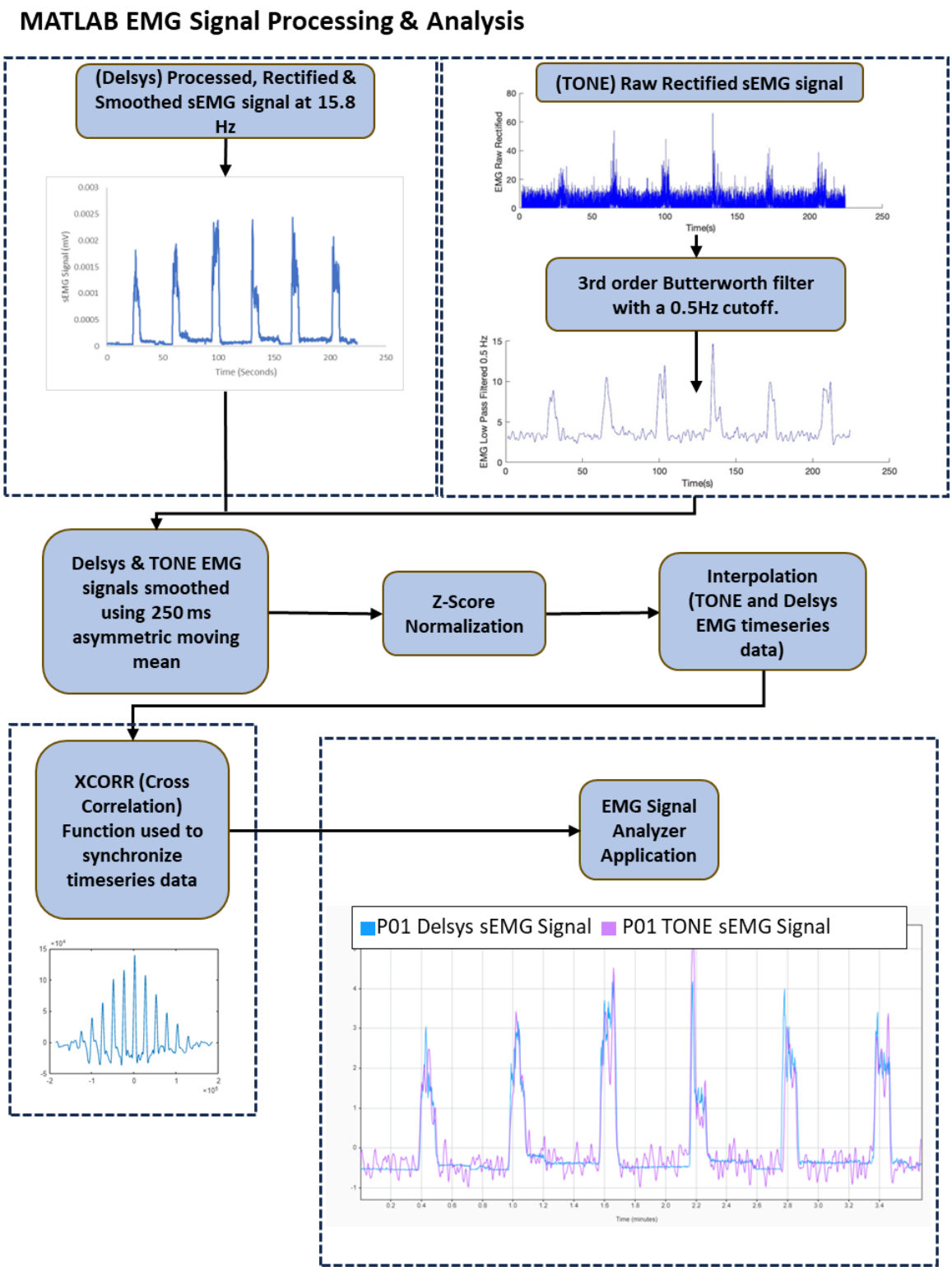


Figure 6. MATLAB surface electromyography signal processing and analysis procedure shown for participant P01. Description of surface electromyography signal processing for both the Delsys Bagnoli and TONE device signal output for the same series of isometric muscle contractions of the biceps brachii muscle performed at 50% of maximal voluntary contraction.

4.4 Results

Eleven adult participants (>18 years of age) without history of neurological impairment completed the study protocol. The first phase of testing was completed with 6 participants (5 female and 1 male). Phase 2 testing was completed with 5 participants (4 female, 1 male). All kinematic and sEMG measures were successfully obtained, recorded, and analyzed for each phase. After phase I testing, it was determined that increasing the sampling rate of the TONE device was required. The wireless transmission rate was increased from 30 Hz to 50 Hz in the second phase of testing. The increase to 50 Hz represented the maximum simultaneous transmission rate of angle, force, and sEMG signal data achievable by the XBee wireless transmitter.

ROM Measures Analysis

The similarity between the TONE and OptiTrack Trio angle versus time signal output was analyzed using two methods. Firstly, Spearman's correlation coefficient was used to compare the strength of the relationship between the TONE and OptiTrack Trio device's ROM versus time-interpolated signal outputs (see Table 1. & Figure 7.). Spearman's correlation coefficient (rho) values ranged between 0.482-0.906 (moderate to strong) and 0.593-0.960 (strong to very strong) (*p-value* = ≤ 0.001) in phases 1 and 2 of testing, respectively.
Next, the TONE and OptiTrack ROM signal output was compared for each repetition of movement. A total of 68 individual movements (n=34 elbow flexion, n=34 elbow extension) were analyzed in the first phase of testing, with 64 individual movements (n=32 elbow flexion, n = 32 elbow extension) analyzed in the second phase of testing. Bland-Altman analysis summarizing agreement for passive elbow extension and flexion start angle, end angle, total

ROM, and average velocity for both fast and slow speeds of movement are summarized for phases 1 and 2 in Table 2 and Appendix E. All measures demonstrated a reduction in the mean difference observed between the TONE device and OptiTrack reference in the second phase of testing except for fast elbow extension end angle and fast elbow flexion start angle (see Table 2). Reductions in the average differences comparing the TONE and OptiTrack system measures of average velocity in degrees per second for each movement were observed between the first and second phases of testing (see Table 2).

Table 1. Spearman's rho correlation coefficient between the TONE and OptiTrack angle versus time tracings.

	Phase 1(n=6)			Phase 2 (n=5)	
Participant Number	Correlation coefficient* (r)	*p*-value	Participant Number	Correlation coefficient* (r)	*p*-value
P01	0.482	<.001	P07	0.965	<.001
P02	0.852	<.001	P08	0.960	<.001
P03	0.518	<.001	P09	0.937	<.001
P04	0.693	<.001	P10	0.954	<.001
P05	0.877	<.001	P11	0.593	<.001
P06	0.906	<.001			

*Spearman's (rho) correlation coefficient

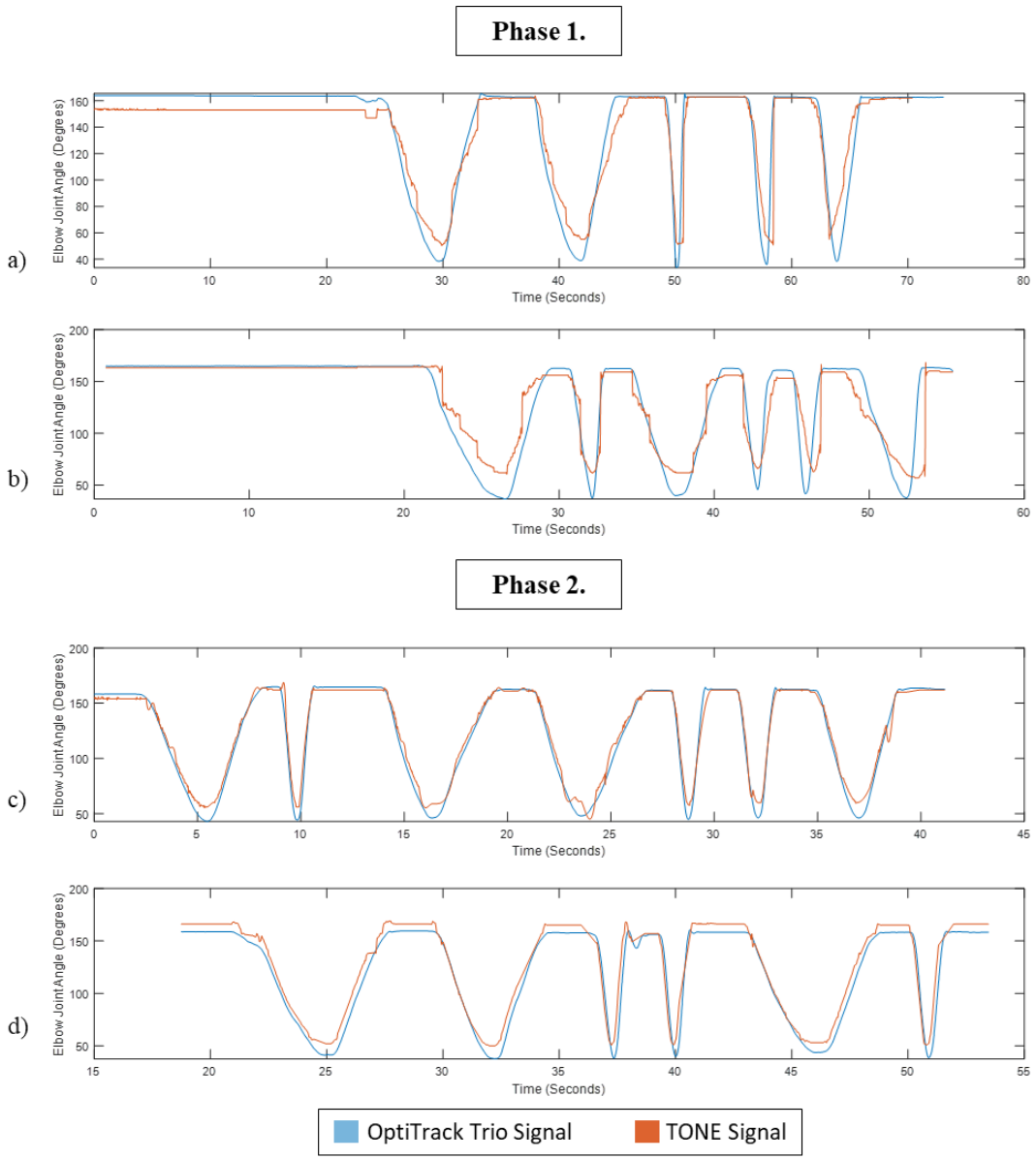


Figure 7. Example elbow angle versus time tracings. Interpolated and synchronized OptiTrack Trio (blue) and TONE (orange) angle versus time signal measures obtained during a series of simultaneous passive movements of elbow flexion and extension (3 fast and 3 slow). a) Phase 1 testing (participant P01), b) Phase 1 testing (participant P05), c) Phase 2 testing (participant P07), & d) Phase 2 testing (participant P10).

Table 2. Measures of agreement between the TONE and OptiTrack Trio devices

Joint and Direction of Movement Measured (Speed of movement)	Variable Measured	Device	Phase 1 Mean (Standard Deviation)	Phase 2 Mean (Standard Deviation)	Phase 1 Bland-Altman Analysis Mean Difference TONE – OptiTrack (lower, upper limit)	Phase 2 Bland-Altman Analysis Mean Difference TONE – OptiTrack (lower, upper limit)
Elbow Extension (Slow)	Start Angle (°)	TONE	57.1 (+/- 5.8)	57.8 (+/- 5.4)	19.5 (8.7, 30.3)	13.0 (0.7, 25.3)
		OptiTrack	37.6 (+/- 6.7)	44.8 (+/- 3.8)		
	End Angle (°)	TONE	156.8 (+/- 6.9)	159.8 (+/- 9.4)	-2.6 (-19.1, 13.0)	-1.8 (-17.5, 14.0)
		OptiTrack	159.4 (+/- 2.9)	161.6 (+/- 3.6)		
	Total ROM (°)	TONE	99.7 (+/- 7.9)	102.1 (+/- 8.7)	-22.1 (-35.3, -9.0)	-14.8 (-32.0, 2.5)
		OptiTrack	121.8 (+/- 6.1)	116.8 (+/- 5.7)		
	Average Velocity (°/sec)	TONE	43.5 (+/- 17.2)	41.2 (+/- 8.2)	-78.3 (-113.0, -43.7)	-2.6 (-14.2, 9.0)
		OptiTrack	56.3 (+/- 34.0)	43.8.3 (+/- 9.4)		
Elbow Extension (Fast)	Start Angle (°)	TONE	58.3 (+/- 13.8)	60.38 (+/- 11.1)	23.9 (1.2, 46.7)	18.6 (-3.9, 41.0)
		OptiTrack	34.4 (+/- 7.4)	41.8. (+/- 3.1)		
	End Angle (°)	TONE	157.6 (+/- 5.4)	159.7 (+/- 10.2)	-2.83 (-14.1, 8.5)	-3.2 (-21.0, 14.6)
		OptiTrack	160.4 (+/- 2.6)	162.9 (+/- 4.0)		
	Total ROM (°)	TONE	99.2 (+/- 15.4)	99.3 (+/- 16.7)	-26.8 (-52.4, -1.1)	-21.8 (-54.9, 11.3)
		OptiTrack	126 (+/- 7.5)	121.1 (+/- 5.2)		
	Average Velocity (°/sec)	TONE	186.4 (+/- 130.0)	117.4 (+/- 37.1)	13.74 (-238.7, 266.2)	-36.9 (-94.9, 21.2)
		OptiTrack	172.6 (+/- 42.9)	154.3 (+/- 30.0)		
Elbow Flexion (Slow)	Start Angle (°)	TONE	156.1 (+/- 7.6)	161.7 (+/- 10.8)	-3.3 (-19.3, 12.6)	-0.1 (-17.2, 17.4)
		OptiTrack	159.4 (+/- 2.4)	161.5 (+/- 4.2)		
	End Angle (°)	TONE	54.9 (+/- 7.0)	57.8 (+/- 5.2)	18.6 (8.0, 29.3)	13.1 (1.7, 24.5)
		OptiTrack	36.2 (+/- 6.7)	44.7 (+/- 3.8)		
	Total ROM (°)	TONE	101.2 (+/- 7.5)	103.8 (+/- 9.5)	-22.0 (-32.1, -12.0)	-13.0 (-28.5, 2.5)
		OptiTrack	123.2 (+/- 6.1)	116.8 (+/- 4.9)		
	Average Velocity (°/sec)	TONE	32.7 (+/- 8.7)	36.0 (+/- 10.7)	-7.28 (-24.5, 9.9)	-3.8 (-21.4, 13.8)
		OptiTrack	40.0 (+/- 12.8)	39.8 (+/- 9.2)		

Table 2. (Continued) Measures of agreement between the TONE and OptiTrack Trio devices

Joint and Direction of Movement Measured (Speed of movement)	Variable Measured	Device	Phase 1 Mean (Standard Deviation)	Phase 2 Mean (Standard Deviation)	Phase 1 Bland-Altman Analysis Mean Difference TONE – OptiTrack (lower, upper limit)	Phase 2 Bland-Altman Analysis Mean Difference TONE – OptiTrack (lower, upper limit)
Elbow Flexion (Fast)	Start Angle (°)	TONE	158.1 (+/- 7.5)	160.0 (+/- 8.6)	-0.17 (-18.6, 18.2)	-1.9 (-16.5, 12.7)
		OptiTrack	158.2 (+/- 3.0)	161.8 (+/- 3.9)		
	End Angle (°)	TONE	59.6 (+/- 13.2)	60.6 (+/- 11.2)	24.7 (2.7, 46.7)	18.5 (-1.2, 38.2)
		OptiTrack	34.9 (+/- 7.9)	41.9 (+/- 3.1)		
	Total ROM (°)	TONE	98.4 (+/- 16.0)	99.4 (+/- 14.8)	-22.9 (-56.0, -10.1)	-20.6 (-51.2, 12.6)
		OptiTrack	123.3 (+/- 6.5)	120.0 (+/- 5.0)		
	Average Velocity (°/sec)	TONE	149.4 (+/- 179.6)	116.0 (+/- 26.1)	35.5 (-294.9, 365.9)	-8.7 (-41.2, 23.7)
		OptiTrack	113.9 (+/- 39.2)	124.7 (+/- 19.1)		

Surface Electromyography Measures Analysis

Surface electromyography measures of agreement comparing the time duration of muscle contraction of the biceps brachii during a series of 6 repetitions performed at 50 percent MVC between the TONE and Delsys Bagnoli devices are summarized in Table 3. The signal processing procedures of the TONE and Delsys sEMG signal are shown in Figure 6. A total of 30 muscle contractions and associated sEMG signals were analyzed for agreement in both the first and second phases of testing. Good (ICC = 0.75-0.9) agreement between measures of the timing of muscle contraction duration obtained by the TONE and Delsys Bagnoli devices in phases 1 and 2 of testing were found. The mean difference in muscle contraction time measured by the TONE and Delsys Bagnoli devices was -0.16 seconds in phase 1 and 0.04 seconds in phase 2 (see Table 3 and Appendix F). An example tracing demonstrating the agreement of the sEMG signal in time series between the TONE device and Delsys system is presented in Figure 8.

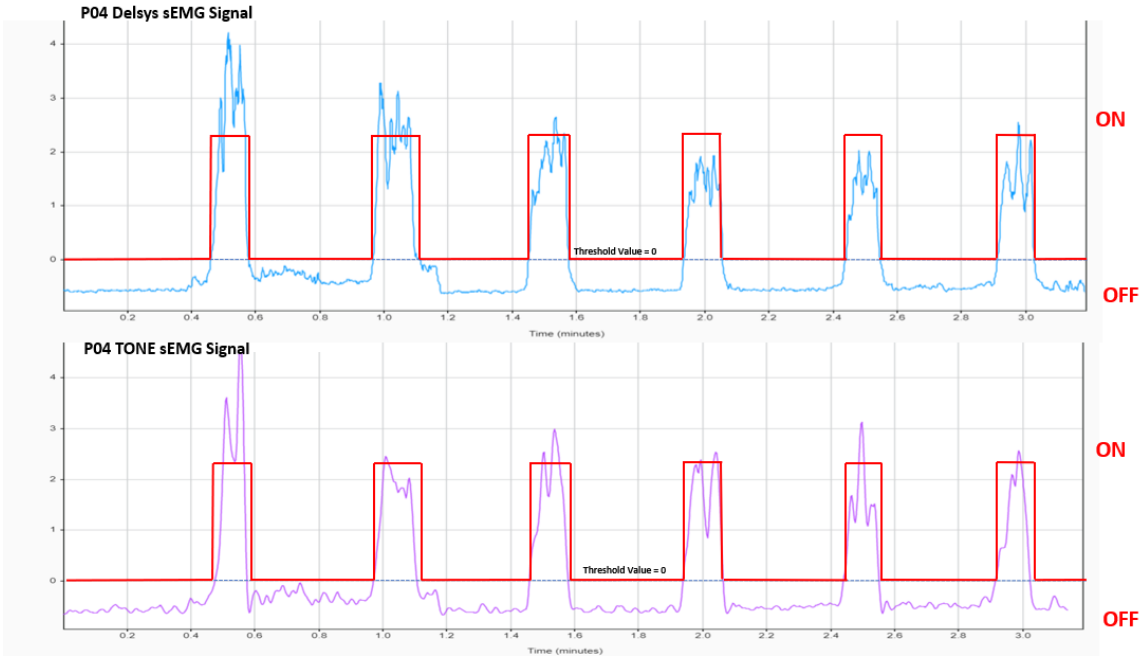


Figure 8. Example sEMG signal output from participant P01 comparing the Delsys (blue tracing) and TONE (purple tracing) device signals measures performed during a series of 6 isometric contractions performed at 50% of maximal voluntary contraction.

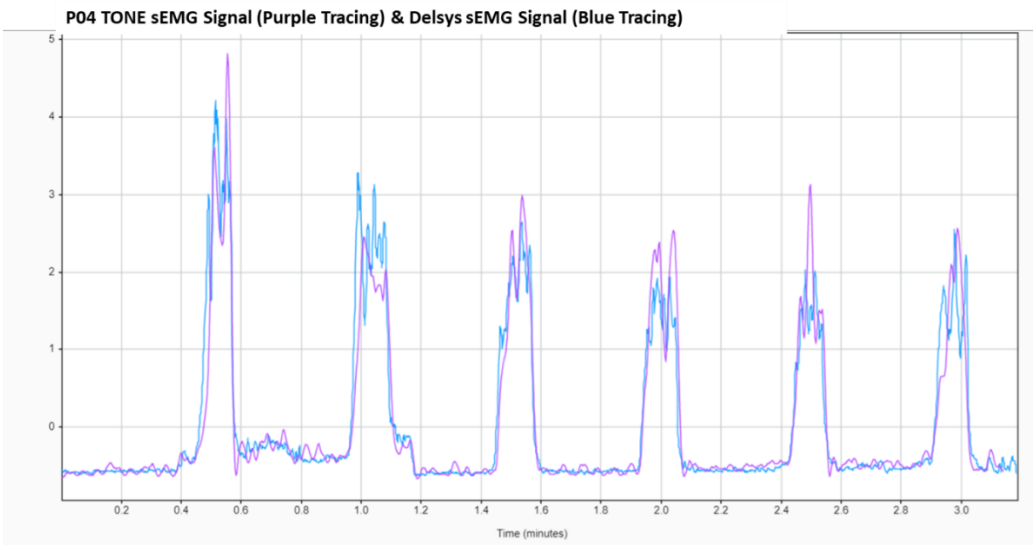


Figure 9. Example sEMG signal output demonstrating synchronized sEMG timetable data from participant P04 comparing the Delsys (blue tracing) and TONE (purple tracing) device signals measures performed during a series of 6 isometric contractions performed at 50% of maximal voluntary contraction.

Force Measures Analysis

The time duration of muscle contraction (seconds) and average force (kilograms) obtained by the TONE and KForce devices during 50 percent MVC are summarized in Table 3. A total of 30 repetitions of elbow flexion were analyzed for agreement in both phases of testing. Good agreement (ICC = 0.75-0.9) between the TONE and Kforce devices was found between measures of the duration of muscle contraction on time. Bland-Altman analysis comparing the duration of muscle contraction on time recorded by the TONE and KForce devices showed an average difference of 0.24 and 0.71 seconds for phases 1 and 2, respectively. Good agreement between measures of muscle force obtained by both devices (ICC = 0.75-0.9) was found in the first phase of testing, with poor agreement (ICC = <0.5) found between measures of force in the second phase of testing. The average measured force difference between the TONE and KForce devices was 6.9 and 2.4 kilograms in the first and second phases of testing, respectively (see Table 3 and Appendix F).

Table 3. [a] **Surface electromyography and** [b] **force measure agreement between the TONE, Delsys Bagnoli, and KForce devices at 50 percent maximal voluntary contraction.**

Muscle Assessed and Action Performed	Variable Measured	Device	Phase 1 Mean (Standard Deviation)	Phase 2 Mean (Standard Deviation)	Phase 1 ICC (95% CI) [α] TONE and Delsys Agreement	Phase 1 Bland-Altman Analysis Mean Difference TONE – Delsys and Kforce (lower, upper limit)	Phase 2 ICC (95% CI) [α] TONE and Delsys Agreement	Phase 2 Bland-Altman Analysis Mean Difference TONE – Delsys and Kforce (lower, upper limit)
[a] Biceps (Elbow Flexion 50% MVC)	Time of Muscle Contraction (Seconds)	TONE Delsys	7.7 (+/- 0.9) 7.8 (+/- 1.0)	6.51 (+/- 0.9) 6.45 (+/- 1.1)	0.83** (0.68, 0.92)	-0.16 (-1.3, 1.0)	0.84** (0.86, 0.97)	0.04 (-1.1, 1.1)
[b] Biceps (Elbow Flexion 50% MVC)	Time of Muscle Contraction (Seconds)	TONE Kforce	7.5 (+/- 1.1) 7.3 (+/- 0.9)	7.5 (+/- 1.1) 7.3 (+/- 0.9)	0.88** (0.74, 0.94)	0.24 (-0.9, 1.4)	0.88** (0.74, 0.94)	0.71 (-0.3, 1.7)
	Average Force (Kilograms)	TONE KForce	12.6 (+/- 1.9) 5.6 (+/- 1.6)	11.5 (+/- 0.9) 9.2 (+/- 2.1)	0.86** (0.70, 0.93)	6.9 (4.5, 9.4)	0.42 (-.21, 0.73)	2.4 (-0.1, 4.9)

ICC (95% CI)[α] = Intraclass Correlation Coefficient (Cronbach's Alpha, absolute agreement) with 95% Confidence Interval, * = Moderate Agreement (0.5-0.74), ** = Good Agreement (0.75-0.9), ≤0.5 = Poor Agreement.

4.4 Discussion

Quantitative measures of ROM, muscle activity, and force that can be recorded and synchronously transmitted are essential for advancing telehealth and in-person spasticity assessment. Quantitative measurement using peripheral electronic sensors allows for creating a digital assessment record that can be shared between patients and specialists and among clinicians and facilities as part of the electronic health record. Currently, many devices used to measure and record this information are cost-prohibitive for use within routine clinical practice (Cha & Arami, 2020). Gold-standard devices such as optical motion tracking and research-grade sEMG systems are not portable and require specialized equipment typically available only within research settings (Banky et al., 2019; Cha & Arami, 2020). The TONE is low-cost, portable (case measurements = 3 X 10 cm), battery-powered, and communicates wirelessly with the host computer. Data from the TONE device can be saved and reviewed for asynchronous evaluation after the real-time specialist-patient encounter. The primary purpose of this study was to compare the level of agreement between the TONE device and chosen reference standards, including optical motion tracking, hand-held dynamometry, and research-grade sEMG in a population without neurological deficits.

A moderate to very strong relationship was found between the OptiTrack and TONE interpolated angle versus time signal outputs, demonstrating satisfactory accuracy of the TONE device as compared to the reference standard. After analyzing the data from Phase 1, it was hypothesized that increasing the transmission rate of the TONE device would improve the sensor data signal resolution, leading to improvements in performance. In the “Plan” stage of Phase 2, a meeting was held to discuss increasing the transmission rate of the TONE device to provide a higher resolution of the angle vs. time curve. This resulted in an update of the TONE device,

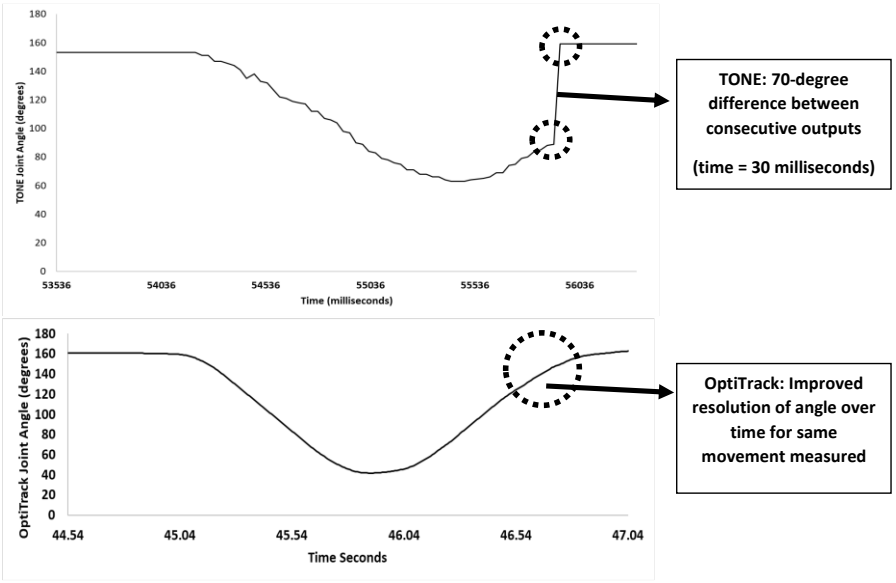
increasing the transmission rate from 30 Hz to 50 Hz. The maximum wireless transmission rate achievable by the TONE device was 50 Hz without causing lag or latency issues in the software application dashboard. After modifications to the TONE device's transmission rate were made, the correlation between the TONE device and reference standard improved, resulting in improved angle versus time signal resolution (see Figure 7).

When analyzing individual movements of passive elbow flexion and extension, mean differences between kinematic measures were observed to be greater with fast velocity movements compared to slow velocity movements in phase 1. This was likely due to the differences in the sampling rates between the TONE (30 Hz) and OptiTrack optical motion tracking system (120 Hz). The four-fold higher sampling rate of the OptiTrack system allows for high-precision representations of the joint angle over time compared to the TONE device. In Phase 1, faster velocity movements recorded by the TONE device often displayed large changes between consecutively measured angles. This resulted in an unclear representation of what was happening to the joint angle data between consecutive readings (see Figure 10 A). The improvement in the transmission rate of the TONE device from 30 Hz to 50 Hz appeared to improve the resolution of passive movements performed at fast velocities in Phase 2 (see Figures 7 & 10 B). This is also reflected in the smaller mean differences in measures of velocity performed in Phase 2 compared to Phase 1 (see Table 2).

Relatively large differences in the start and end angle for elbow flexion compared to elbow extension were observed in Phase 1 and Phase 2 of testing. This also resulted in differences in absolute ROM for both elbow flexion and extension measures obtained between the TONE and OptiTrack systems. These differences were not improved by increasing the transmission rate in the second phase of testing. The differences in absolute ROM observed for

elbow flexion kinematic measures between the TONE and OptiTrack can be attributed to the method of deriving joint angle for each of these technologies. The OptiTrack records three-dimensional position data for each reflective marker over time by using an infrared camera to capture coordinates in the horizontal (X), vertical (Y), and depth (Z) dimensions. This allows for joint angles to be measured in three-dimensional space. This is in contrast to the electronic goniometer used by the TONE device, which is capable of providing measures in only one degree of freedom. Although effort was made to perform passive movements purely in one degree of freedom (flexion and extension of the elbow), avoiding any movement in the Z dimension (for example, forearm supination and pronation) is impossible. Changes in joint angle affected by movement in the Z dimension would, therefore, only be captured by the OptiTrack system and not be represented by the TONE device's electronic goniometer. Additionally, the measurement of joint angles with electronic goniometers relies heavily on accurately identifying the center of rotation, which is known to change with motion (Cha & Amani, 2020). These differences would likely result in greater differences in elbow flexion when the electronic goniometer of the TONE device was moved from its initial position (extension).

A)



B)

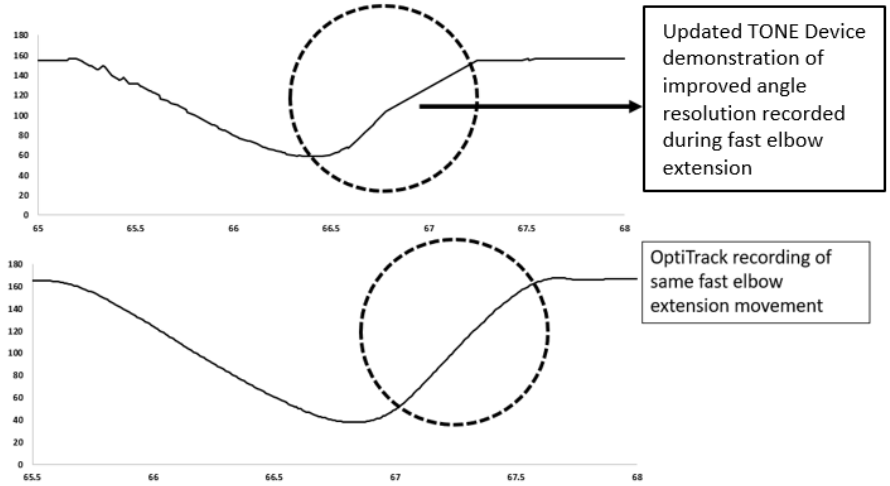


Figure 10. A) Phase 1 joint angle (degrees) vs. time (seconds) (top tracing = TONE device, bottom tracing = OptiTrack) for participant P05 for same repetition of movement with markers highlighting difference in ROM over time resolution. B) Phase 2 joint angle (degrees) vs. time (seconds) (top tracing = TONE device, bottom tracing = OptiTrack) for participant P10 for same repetition of movement with markers highlighting improvement in Phase 2 of the angle vs. time resolution of date obtained by the TONE device with sampling at 50 Hz.

Comparison of the TONE and Delsys Bagnoli sEMG systems to determine the total muscle contraction time between each repetition of manually resisted elbow flexion demonstrated good agreement in Phases 1 and 2 of testing. Bland-Altman analysis comparing muscle contraction time recorded by the TONE and Delsys Bagnoli sEMG sensors showed an average difference of -0.16 and 0.04 seconds in the first and second phases of testing, respectively. This suggests that the average measured duration of each isometric muscle contraction of the biceps brachii was between 0.16 seconds less and 0.04 seconds more when measured using the TONE device compared to the Delsys Bagnoli system. Although good agreement was found between the TONE and Delsys sEMG with respect to voluntary muscle contraction duration, it should be acknowledged that differences of 0.16 and 0.04 seconds are likely large enough to create challenges in detecting and measuring involuntary muscle activity related to the stretch reflex response. Differences observed between these two systems improved slightly after increasing the transmission rate from 30 Hz to 50 Hz of the rectified sEMG signal of the TONE device in Phase 2. Differences between sEMG measures of muscle contraction duration can also be explained by differences between the gain settings of the sEMG sensors and sEMG sensor placement. Although the effort was made to process the TONE and Delsys system sEMG signals similarly, differences in muscle contraction duration observed can also be explained by differences in sEMG signal acquisition and processing. For example, the Delsys sEMG system sampled the raw signal at 1000 Hz compared to the TONE sEMG raw signal sampling rate of 500 Hz.

Accurately determining the onset of muscle contraction time is important in the context of spasticity assessment. The timing of muscle activation as represented by a burst in sEMG activity in relation to varying velocities of passive joint movement is used to assess the

sensitivity of the stretch reflex threshold. If there is a significant delay or missed detection of sEMG activity, the joint angle and velocity measures corresponding with the increase in sEMG activity would be non-informative. Despite the differences in the duration of muscle contraction time, all muscle contractions were easily identifiable for each participant using visual analysis for both the TONE and Delsys sEMG data. It was determined that testing of the TONE device within a patient population with known spasticity would be required to assess the ability of the device to detect muscle activity related to the involuntary stretch reflex response.

Lastly, measures comparing the TONE device's force sensor and KForce hand-held dynamometer demonstrated good agreement between the time duration of muscle contraction and average force measured between devices. Differences in the duration of muscle contraction time were found to be larger than differences observed with sEMG sensor data. The average force measured by the TONE device was 6.9 and 2.4 kilograms higher than the KForce device in phases 1 and 2, respectively. Despite the large average difference in force, the difference was reasonably consistent across measures, suggesting that the TONE device's force sensor can assess changes in force across a wide spectrum.

Limitations

The small sample size used within this study limits the generalization of findings to larger populations. However, given that this was the first time the TONE device had been tested since it was developed, a small sample size was advantageous as we wanted to check for any apparent complications or improvements required before testing on a larger population or with individuals with spasticity or neurological impairment. Another limitation included methods for assessing simultaneous measures of ROM and muscle activity between devices. Simultaneous ROM measures obtained by the TONE and OptiTrack necessitated the placement of the centre of

rotation marker over the centre of axis of the goniometer. This is in contrast to the desired marker placement directly on the skin at the centre of rotation. While effort was made to limit movement in the depth (Z) dimension, this change in marker placement would affect the accuracy of the measured elbow joint angle. For obtaining simultaneous sEMG recordings, placing both sensors within the recommended area was impossible. Instead, sensors were placed in series to one another in an attempt to measure the same group of MUAPs (see Figure 4). This was done in accordance with another study comparing simultaneous sEMG signals between a low-cost device and reference standard of the vastus lateralis muscle (Heywood et al., 2018). It should be noted that effort was made to place the TONE device's sEMG sensor as close to the recommended position as possible to give the sensor the greatest chance of accurately measuring the same group of MUAPs. Another limitation was using the KFORCE handheld dynamometer as the force reference standard. In future studies, more robust gold standard force measures, such as using isokinetic dynamometry, would serve as a gold standard reference. Lastly, a risk of confirmation bias was identified as only one rater was used to assess the timing of the variables assessed, including ROM, sEMG, and Force onset and offset times for each movement assessed. Using multiple raters would have reduced this bias and allowed for the assessment of agreement between raters on the variables of interest.

Conclusions

In conclusion, kinematic angle versus time measures obtained by the TONE device demonstrated a moderate to very strong relationship compared to optical motion tracking. Good agreement was found between the TONE and reference standard sEMG signal when comparing measures of time duration of muscle contraction "on time ." Updates to the transmission rate from 30 to 50 Hz in Phase 2 of testing resulted in improved agreement between kinematic and

sEMG measures obtained by the TONE device and reference standards. The increase in transmission rate did not improve the agreement of the time measure of muscle contraction duration time between the TONE device's force sensor and the KForce reference device.

This low-cost, portable, wireless, and battery power device provides an exciting alternative to equipment traditionally used in research settings for assessing spasticity. The TONE device's ability to provide near-simultaneous measures of ROM, sEMG, and force all from one device and software application is a unique feature of the device. Synchronization of electronic signals across multiple devices is not always possible when using different technologies. For example, in our study, the KForce relied on Bluetooth connection for data transmission between the handheld dynamometer and smartphone, whereas the OptiTrack utilized a wired USB connection between the camera and the computer. These files were then saved and stored in different locations for analysis. Although both the OptiTrack and Kforce can provide kinematic and force measures, respectively, synchronizing these signals after being collected is challenging and time-consuming. Overall, continued improvements directed at increasing the sampling rate of the TONE would be beneficial in further improving kinematic, kinetic, and surface electromyography measurement agreement with reference standards.

Chapter 5. Study 3. Virtual Post Stroke Spasticity Assessment Using the Telerehabilitation-Objective-Neuromuscular-Evaluation Device: Proof of Concept

5.1 Abstract

Background: Quantitative measures relating to range of motion (ROM), muscle activity, and muscle force are important for advancing in-person and telehealth spasticity assessment practices. The Telerehabilitation-Objective-Neuromuscular-Evaluation (TONE) is a novel device and software application developed and tested within a population without neurological impairment. Further testing of the TONE device in a small patient population with known spasticity is required to examine the feasibility of using the device during a telehealth assessment and device performance prior to testing within a larger population.

Objectives:

1) To determine the level of agreement between in-person MTS catch angle and catch angle measured using the TONE device during the R2 passive elbow extension.

2) To determine if TONE device measures obtained during a telehealth assessment can detect differences in ROM, angular velocity, peak force, average force, and average rectified sEMG signal output between the affected and non-affected limbs in individuals with known upper limb spasticity.

3) To determine the level of agreement between TONE measures of ROM, angular velocity, peak force, average force, and average rectified sEMG signal output between the telehealth and in-person assessment of the affected limbs in individuals with known upper limb spasticity.

4) To determine the feasibility of using the TONE device for spasticity assessment within a telehealth encounter.

5) To inform ideas for improvement and future development of the TONE device and software application helpful in promoting quantitative spasticity assessment within telehealth environments.

Methods: A proof-of-concept study including five participants (n=5) with known upper limb spasticity resulting from stroke or acquired brain injury participated in the study. The Modified Tardieu Scale was administered with each participant prior to testing with the TONE device. Testing of each participant's affected limb was completed using the TONE device under two conditions (telehealth and in-person). The TONE device was also used under a third condition involving testing each participant's non-affected limb in an in-person setting. Testing procedures using the TONE device were identical for each condition and involved six passive movements of elbow extension (three slow (R1) and three fast (R2). TONE device measures were collected and analyzed. A survey was administered after the assessment procedures were complete to gather patient participant feedback about their experience.

Results: Catch angle could not be determined from the TONE device measures or assessed for agreement with Modified Tardieu Scale measures. Good agreement (ICC = 0.75-0.9) was found between telehealth and in-person TONE device assessment of the affected limb for R2 ROM and R1 average velocity. Moderate agreement (ICC = 0.50-0.74) was found between telehealth and in-person TONE device assessment of the affected limb for R1 ROM, R1 peak force, and R2 peak force. Poor agreement (ICC = < 0.5) was found between telehealth and in-person TONE device assessment of the affected limb for R2 average velocity, R1 average force, R2 average force, R1 average rectified sEMG signal, and R2 average rectified sEMG signal. The TONE

device successfully captured all measures of ROM, angular velocity, force, and EMG signal output, demonstrating that the procedure was feasible and compatible with telehealth environments. Efforts to preserve the raw sEMG signal for post-assessment processing analysis are recommended, as the precise onset of muscle activity related to the reflex response (catch) was not able to be determined from the transmitted rectified signal.

Conclusion: This study provides an easy-to-perform procedure for assessing muscle tone associated with spasticity of the elbow in telehealth environments. The TONE device successfully measured and recorded differences in passive elbow joint extension ROM and average angular velocity between the affected and non-affected limbs in participants with known spasticity. Efforts to improve sampling frequency are needed to improve EMG and force signal resolution. After addressing the identified modifications for device improvement, future testing within a larger population with spasticity is needed.

5.1 Introduction

Spasticity can lead to muscle stiffness and movement problems that limit daily activities. It is strongly recommended that individuals experiencing symptoms of spasticity be referred to specialized healthcare providers (Reeves & Lambeth, 2016). Spasticity specialists typically operate out of large urban centres due to the necessity of high patient volumes. As a result, many individuals living in rural and remote regions experience access challenges to traditional in-person spasticity care. Information communications technology (ICT) is expanding how people access health care, providing important alternatives to traditional in-person care. Telehealth has been defined as "the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using ICT for diagnosis, treatment, and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interest of advancing the health of individuals and their communities" (Scalvini, 2004). Advancements in ICT have great potential to improve telehealth quality and acceptance among healthcare providers and patients alike, leading to improved health outcomes.

The use of ICT, such as smartphones, tablets, and personal computers for performing spasticity assessment and treatment appointments, increased significantly due to the COVID-19 pandemic (Verduzco-Gutierrez et al., 2020). Videoconferencing and phone-based consultations became a means to connect individuals living with spasticity to specialists who helped guide their care when in-person appointments were limited or not possible. Although many individuals used telehealth to access care during the COVID-19 pandemic, this rapid change in healthcare delivery has not been without challenges. An Italian study by Santomato et al. (2021) found that only 7.3% of patients with spasticity carried out telerehabilitation or home rehabilitation with professionals during the COVID-19 lockdowns (Santomato et al., 2021). In a subsequent study

by DeDonno et al. (2021), the authors list several potential reasons for the limited uptake of telehealth by spasticity clinicians and patients during the pandemic, including limited access to ICT tools, limited familiarity with technology, and potential distrust in these tools held by professionals and patients (DeDonno et al., 2021). Another significant barrier to performing spasticity telehealth assessments described in the literature is the inability to perform traditional hands-on assessments within telehealth environments (Reebye, 2020).

Traditional in-person spasticity assessment is rated by a clinician performing a series of passive movements of a patient's limb and scoring the amount and feel of the resistance encountered during testing (Pizzi, Carlucci, Falsini, Verdesca, & Grippo, 2005). The Modified Tardieu Scale is a commonly used measure of spasticity to rate the resistance to passive movements. Administering the Modified Tardieu Scale involves moving a patient's limb at both fast and slow velocities and recording the joint angle associated with when the examiner feels the onset of muscle activation (Sonvane & Kumar, 2019). Due to the hands-on nature of the Modified Tardieu Scale, it is not compatible with telehealth environments (Reebye et al., 2020).

In recent years, there has been much interest in developing more objective methods for assessing spasticity using biosensors, robotics, medical imaging, and artificial intelligence (He et al., 2023). Quantitative spasticity assessment data can easily be transmitted between patients and specialists using the Internet. Despite the interest in moving to more objective spasticity assessment strategies, no standardized procedure is currently compatible with telehealth environments. Quantitative spasticity assessments have yet to be widely adopted, even within in-person clinical settings. More studies on the validity and reliability of telehealth in spasticity assessment are needed for telehealth to live up to its potential as an effective solution to access

challenges (He et al., 2023). There is a strong need to develop resources to improve the availability and usability of telehealth technology to improve telehealth access to specialists for individuals with spasticity.

The Telerehabilitation Objective Neuromuscular Evaluation (TONE) device is a technology that has been developed to obtain objective measurements of spasticity and send information from patients to specialists using the Internet. The device is low-cost, portable, and can be administered to patients by specialists using videoconferencing technology. The TONE device captures simultaneous electronic measures, including range of motion (ROM), muscle activity measured using surface electromyography (sEMG), and measures of force obtained during passive movement. A software application has been developed to display the TONE device's electronic sensor values which can be recorded from the patient and transmitted to a local computer and onto specialists using the Internet. If sufficiently accurate, the measures obtained by the TONE device can replace hands-on assessment practices that are incompatible with telehealth assessments. Prior testing of the TONE device has been completed within a population without neurological impairment or history of spasticity. Early testing has demonstrated moderate to excellent agreement when comparing the TONE device and reference standard measures of range of motion, with poor to moderate agreement between the TONE device and reference standard measures of muscle activity and force.

Further testing is required to confirm how the device works within a patient population with a known history of spasticity. Testing is also necessary to determine how the device works when used within a telehealth environment. This information will be necessary to see if the

device is successful in measuring and sending valuable information in diagnosing spasticity within a patient population and will inform further device developm

Purpose

The purpose of this study is to determine if the TONE device and software application can identify differences in kinematic, kinetic, and neurophysiological measures between the affected and non-affected upper limb of individuals with known post stroke upper limb spasticity within a virtual environment.

Objectives

1) To determine the level of agreement between in-person MTS catch angle and catch angle measured using the TONE device during the R2 passive elbow extension.
2) To determine if TONE device measures can detect differences in ROM, angular velocity, peak force, average force, and average rectified sEMG signal output between the affected and non-affected limbs in individuals with known upper limb spasticity.
3) To determine the level of agreement between TONE measures of ROM, angular velocity, peak force, average force, and average rectified sEMG signal output between the telehealth and in-person assessment of the affected limbs in individuals with known upper limb spasticity.
4) To determine the feasibility using the TONE device for spasticity assessment within a telehealth encounter.
5) To inform ideas for improvement and future development of the TONE device and software application helpful in promoting quantitative spasticity assessment within telehealth environments.

5.2 Methods

Participants

Five participants with known upper limb spasticity participated in the study. Participants were recruited from the Glenrose Rehabilitation Hospital (n=3) (Edmonton, Alberta) and the Faculty of Rehabilitation Medicine (FRM) (n=2) at the University of Alberta (UofA) (Edmonton, Alberta). This study was reviewed by the Human Research Ethics Board at the University of Alberta and approved in February 2023 (Pro00127061). Written consent was obtained from all participants prior to study participation. Participant inclusion criteria were as follows; 1) community-dwelling adult aged 18 years of age or older), 2) known diagnosis of stroke or acquired brain injury, 3) history of post-stroke spasticity of the upper extremity, 3) Able to speak English and comprehend basic instructions. Participants were excluded if they had an additional diagnosis or injury of the central nervous system or bilateral spasticity affecting both upper extremities.

Instruments

The TONE device – as described in Chapter 3, with improvements made after validation testing described in Chapter 4 – was used to assess spasticity with each participant. The TONE device includes sensors to capture kinematic, kinetic, and muscle activity (sEMG) measures of spasticity. Kinematic measures for passive elbow extension were obtained from an electronic goniometer (potentiometer) aligned with anatomical landmarks in relation to the elbow joint. The TONE device was set to transmit and record angle, force, and sEMG data at 50 Hz. The Logitech™ Bcc950 Video Conferencing Camera was used with Zoom videoconferencing to perform all telehealth assessments. The camera was located on the participant's end of the call within the same physical space. This camera was chosen as it enables remote pan, tilt, and zoom

controls by the remote assessor during the testing procedure. Remote screen control was also used within Zoom videoconferencing sessions, allowing the assessor to remotely control the far-end computer and TONE software application (see Figure 1).

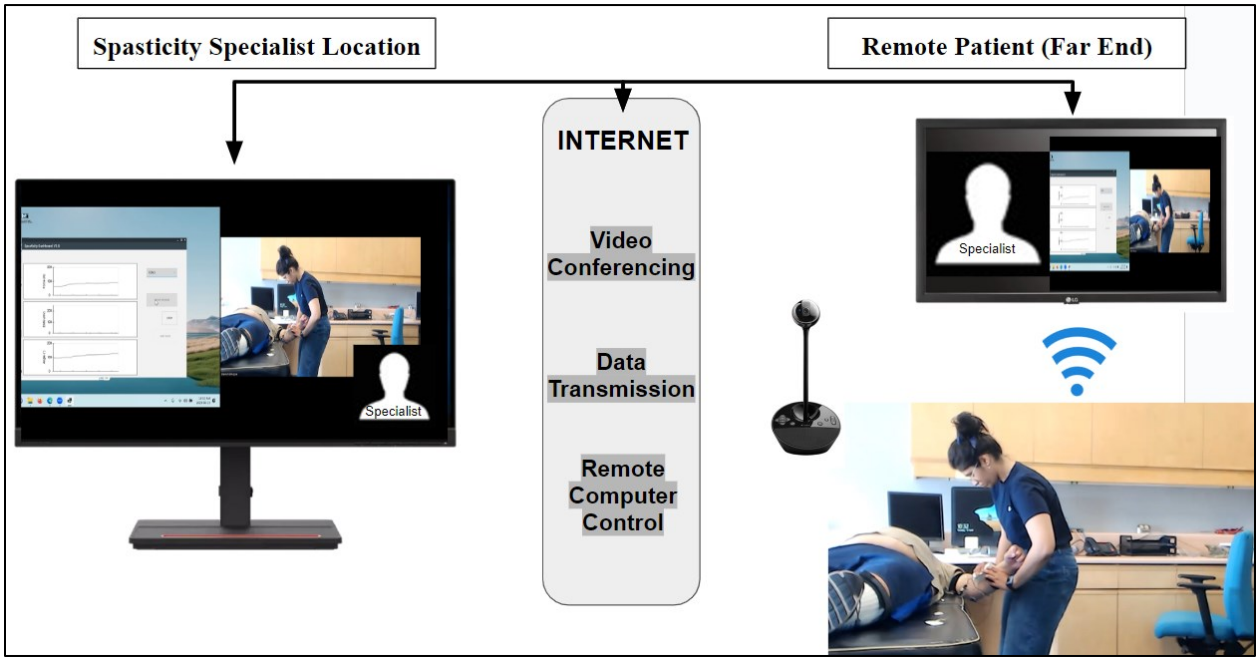


Figure 1. Schematic of experimental set up for telehealth spasticity assessment with research assistant (PJ) located with the patient participant being directed by the acting specialist connected by Zoom™ videoconferencing.

The Modified Tardieu Scale was selected as a clinical comparison measure of spasticity and performed with each participant in person, independent of the telehealth assessment. The MTS is a widely adopted clinical scale that is used to detect the presence of spasticity and grade its severity. The MTS is administered by performing a series of passive movements of the affected limb at different velocities while detecting and grading the quality of movement. The presence of a 'catch' during assessment refers to the sudden increase in resistance to passive movement felt by the examiner. It is thought to occur due to the overactive stretch reflex

associated with spasticity (Morris & Williams, 2018). The administration of the MTS is achieved by measuring four components of the passive movement: 1) R1, which is the angle associated with the catch onset measured during fast velocity passive stretch; 2) R2, which represents the angle of catch during slow velocity passive stretch, 3) R2-R1 (X), indicating the dynamic component of spasticity within the muscle, and 4) quality ratings of fast velocity, passive movement (see table 1) (Naghdi et al., 2014; Sonvane & Kumar, 2019). Additional equipment included a plinth, pillow for patient positioning, and a manual goniometer to perform the in-person MTS assessment.

Table 1. Modified Tardieu Scale Grades

Modified Tardieu Scale	
Grade	**Description**
0	No resistance throughout the course of the passive movement
1	Slight resistance throughout the course of the passive movement, with no clear catch at precise angle
2	Clear catch at precise angle, interrupting the passive movement, followed by release
3	Fatigable clonus (<10 s when maintaining pressure) occurring at precise angle
4	Infatigable clonus (>10 s when maintaining pressure) occurring at precise angle

Calibration Procedure

Calibration of the TONE electronic goniometer was conducted prior to testing. Five different angles representing values found within normal limits of elbow flexion and extension ROM were compared. Known angles were drawn on paper using a protractor and pencil. The known angles were then measured by aligning the centre of the TONE device's electronic goniometer arms with the drawn angles and recorded using the TONE device's software application. A strong correlation was found between the known angles and recorded TONE device angle measurements ($r^2 = 0.99$).

Testing Procedure

The testing procedure was performed in three stages: 1) MTS assessment was performed in person, 2) telehealth assessment of the *affected* limb was performed using the TONE device and software application, 3) in-person assessment of the *affected* and *non-affected* limbs was performed using the TONE device and software application.

Modified Tardieu Scale Testing

MTS evaluations were performed by a research team member (CH) with previous experience using the MTS instrument. The MTS was performed in person, with each participant supine on a plinth. Participants were asked to completely relax their affected limb during the duration of testing. A series of three passive elbow extension movements were performed by the research assistant "as slowly as possible." Measurements, including range of motion and the catch angle – if present – were measured using a standard goniometer and recorded. Next, a series of three passive movements of elbow extension as "fast as possible" were performed by the research assistant. Each participant had a manual goniometer used to record the angle of

catch and range of motion. The research assistant also graded movement quality during the fast passive elbow extension maneuver of the MTS (see Table 1). The MTS was performed with all participants prior to testing with the TONE device. Participants were given a 15-minute break prior to telehealth evaluations.

TONE Device Telehealth Assessment

Telehealth evaluations of each participant's affected limb were directed by two assessors (DG & LS) who guided another member of the research team (PJ) located in person with each participant during testing. The first assessor (DG) – a research team member – guided the telehealth spasticity assessments with four participants (P01-P04). A physician specializing in adult spasticity management (LS) directed the telehealth spasticity assessment with the remaining participant (P05). For the telehealth spasticity assessment, a research assistant was physically present with the participant during testing in a separate room from the remote assessor. The research assistant located with the participants was guided by the remote assessor, who was connected using Zoom videoconferencing software. The remote assessor gave instructions on how to apply the TONE device and perform the spasticity assessment to the research assistant and participant during the telehealth assessment. The research assistant was asked to align the TONE device's electronic goniometer axis of rotation at the lateral epicondyle of the elbow with the stationary arm aligned with the shaft of the humerus and the moveable arm in alignment with the radius. The remote assessor also provided guidance on applying the sEMG sensor. The research assistant was instructed on skin preparation using an alcohol swab, hair removal with a disposable razor (if required), and instructions relating to sEMG sensor placement over the biceps brachii muscle in accordance with Surface Electromyography for the

Non-Invasive Assessment of Muscle (SENIAM) guidelines (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000). After the TONE device was donned, telehealth assessments were performed by having each participant assume a supine position on a plinth. The telehealth assessment procedure consisted of three slow and three fast repetitions of passive elbow extension performed by the research assistant, consistent with the MTS instructions. The remote examiner used Zoom's remote screen control feature to operate the TONE device's software application during the assessment procedure (see Figure 1). Electronic measurements obtained by the TONE device and wirelessly transmitted to the software application were saved as a Microsoft Excel file and emailed to the remote assessor for asynchronous analysis.

TONE Device In-Person Assessment

After completing the telehealth assessment, a 30-minute break was given to participants between testing conditions in an attempt to decrease the effects of post-activation depression known to cause changes in the sensitivity of the stretch reflex induced by preceding conditioning stimuli (e.g., repetitive passive muscle lengthening) (Trompetto et al., 2014; Zurawski et al., 2019). Participants were asked to remain relaxed in a supine position during this period. After the break, an in-person assessment of both the affected and non-affected limbs using the TONE device was performed by DG for participants P01-P04 and by LS for participant P05. Participants were asked to complete a survey about their experience using the TONE device during the telehealth spasticity assessment (see Appendix H).

Data Analysis

Kinematic (ROM and average velocity) and Kinetic (average and peak force) measures during passive elbow extension were identified using visual analysis in Microsoft

Excel prior to analysis (see Figure 2). The rectified sEMG data obtained by the TONE device's software application was further processed using a third-order low-pass Butterworth filter in MATLAB and smoothed using an asymmetrical moving mean window of 250 milliseconds. The average sEMG signal output was averaged throughout each passive movement performed (see Figure 2.).

Measures recorded during passive elbow extension during the telehealth and in-person assessments were analyzed using descriptive statistics to identify differences between spastic and non-spastic limbs. Intraclass correlation coefficients were also used to assess the agreement of the TONE device measures comparing the telehealth to in-person assessment values of the affected limb. Findings will be used to inform and implement necessary changes to improve the usability of the TONE device and software application prior to completing further testing with larger populations.

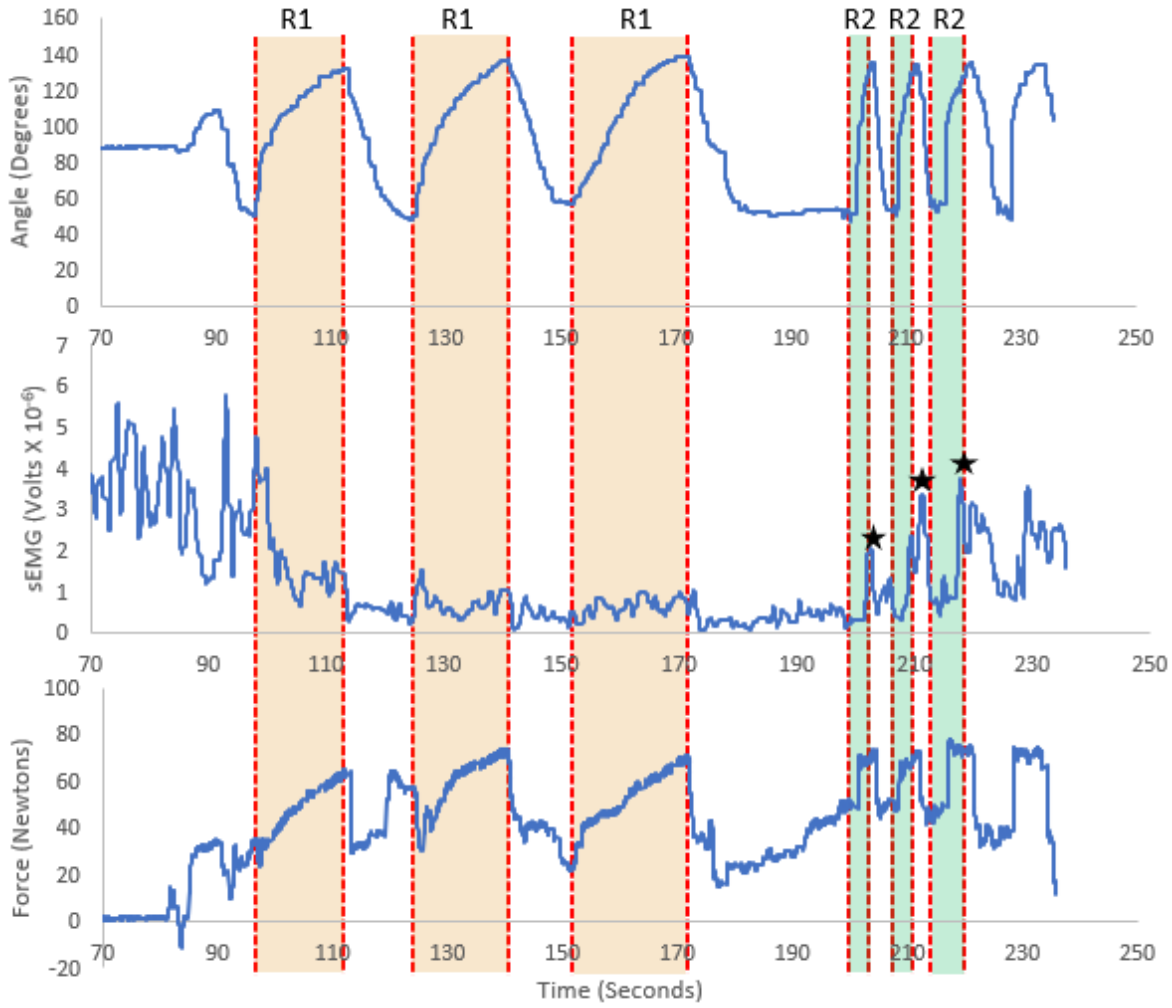


Figure 2. Example of visual analysis for participant P03. Orange and green shaded areas represent measures used to determine ROM, average angular velocity, average force, peak force, and sEMG average rectified signal used for 3 slow (R1) and 3 fast (R2) passive movements of elbow extension.

*Note doted lines represent start and end points in reference to time on X-axis, star symbol (★) highlighting the delay in sEMG signal response during fast passive motion.

5.3 Results

Five persons with upper limb spasticity participated in our study (participant characteristics are listed in Table 2). The mean age of the participants was 55.2 (+/- 15.4) years of age, with an average time from stroke or acquired brain injury diagnosis of 20 (+/- 18.7) years.

The majority of participants reported receiving ongoing treatment for spasticity-related symptoms after stroke and acquired brain injury. Two participants (P01 and P02) were recruited at the University of Alberta and were known to a research team member prior to testing. The remaining participants were recruited from the Adult Spasticity Clinic at the Glenrose Rehabilitation Hospital in Edmonton, Alberta. MTS Scores for all participants are presented in Table 3.

Table 2. Subject Characteristics

Participant ID	Sex (Male /Female)	Age (Years)	Time from stroke Diagnosis (Years)	Affected Side (Right/Left)	Diagnosis	Currently Receiving Spasticity Specific Treatment? (Yes/No) Medications
P01	Male	32	12	Right	Hemorrhagic Stroke	No
P02	Male	49	7	Left	Ischemic Stroke	Yes BoNTA* Last injection 3 months prior to testing.
P03	Female	72	8	Left	Hemorrhagic Stroke	Yes BoNTA Last injection 4 months prior to testing.
P04	Female	63	52	Left	Traumatic Brain Injury	Yes BoNTA Last injection 2 months prior to testing.
P05	Male	60	21	Right	Hemorrhagic Stroke	Yes BoNTA Last injection 1.5 months prior to testing.

*BoNTA = Botulinum Toxin Type A

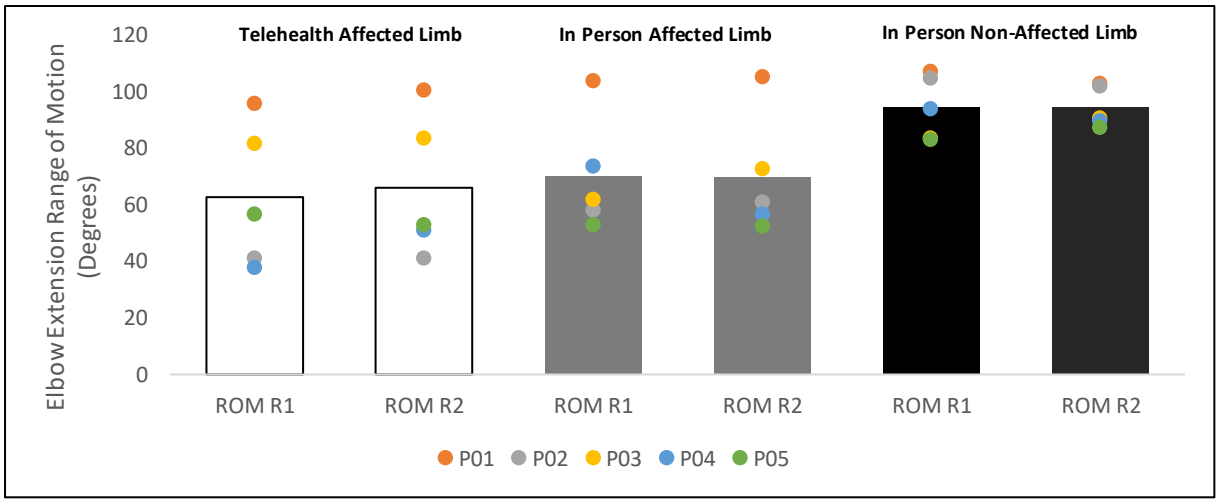
Table 3. Modified Tardieu Scale Measures

Participant ID	MTS* Onset Angle of Muscle Activity Slow Velocity (R1) (°)	MTS* Onset Angle of Muscle Activity Fast Velocity (R2) (°)	MTS X Angle (Difference between R1 & R2 (°))	MTS* Score (0-5)
P01	183	179	4	0
P02	159	126	33	2
P03	168	128	40	2
P04	135	93	42	2
P05	172	138	34	2

*Modified Tardieu Scale

A series of three slow (R1) and fast (R2) passive elbow extension movements were successfully performed with all participants under three separate conditions: 1) Telehealth assessment of the affected limb, 2) In-Person assessment of the affected limb, 3) In person assessment of the non-affected limb. Measures of joint angle (degrees), force (newtons), and sEMG (rectified signal) versus time were successfully recorded for all participants in each condition. Elbow joint ROM scores were defined as the maximum difference between the start (minimum angle) and end (maximum angle) angles measured by the TONE device's electronic goniometer during passive elbow extension. Average velocity was calculated by dividing passive elbow joint ROM by the total elapsed time during each passive movement. Peak force was calculated as the maximum force value recorded during each movement of passive elbow extension. Individual and group mean scores for ROM (degrees) and average joint angular velocity (degrees per second) are displayed in Figure 3. Measures of average force (Newtons), peak force (Newtons), and the average rectified sEMG signal for each condition of passive elbow extension speed (R1 and R2) are displayed in Figure 4.

a)



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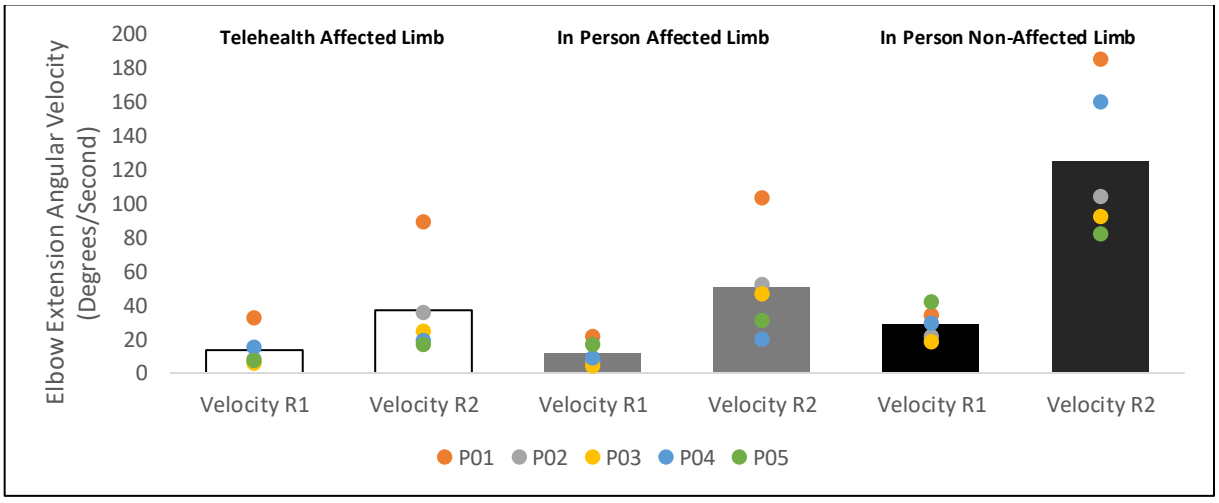
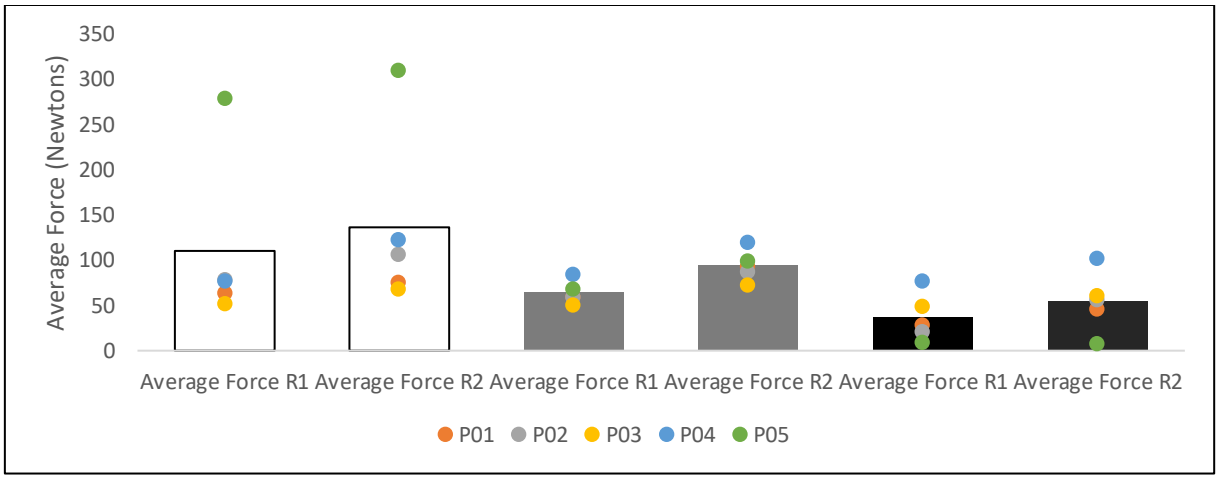


Figure 3. Mean (bar) and individual score (data point) score differences (N=5) for; a) range of motion (degrees) and b) velocity (degrees/second). Differences shown between three conditions (telehealth affected limb, in person affected limb, and in person non-affected limb for slow (R1) and fast (R2) passive elbow extension measured by the TONE device and software application.

a)



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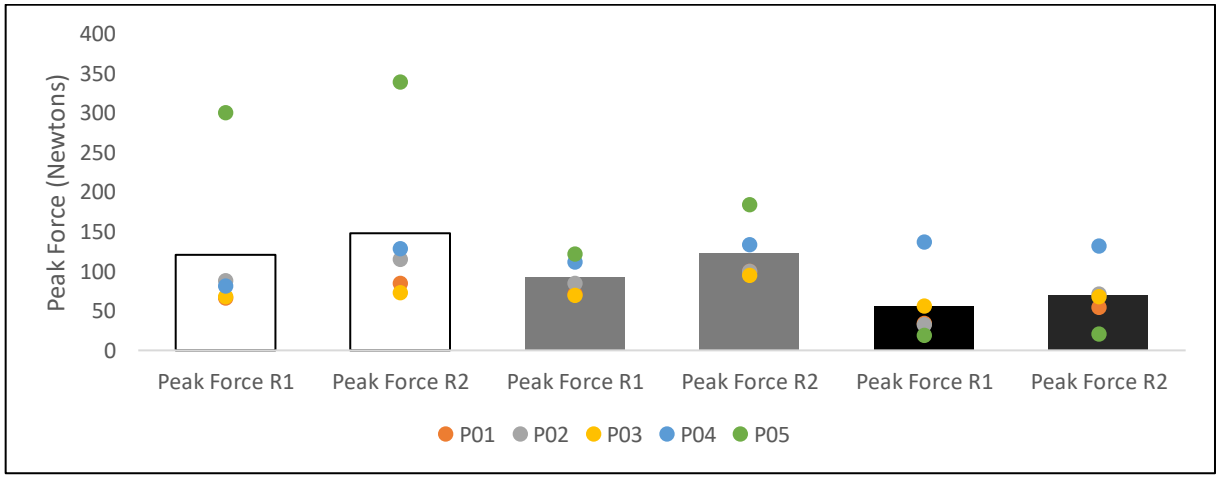

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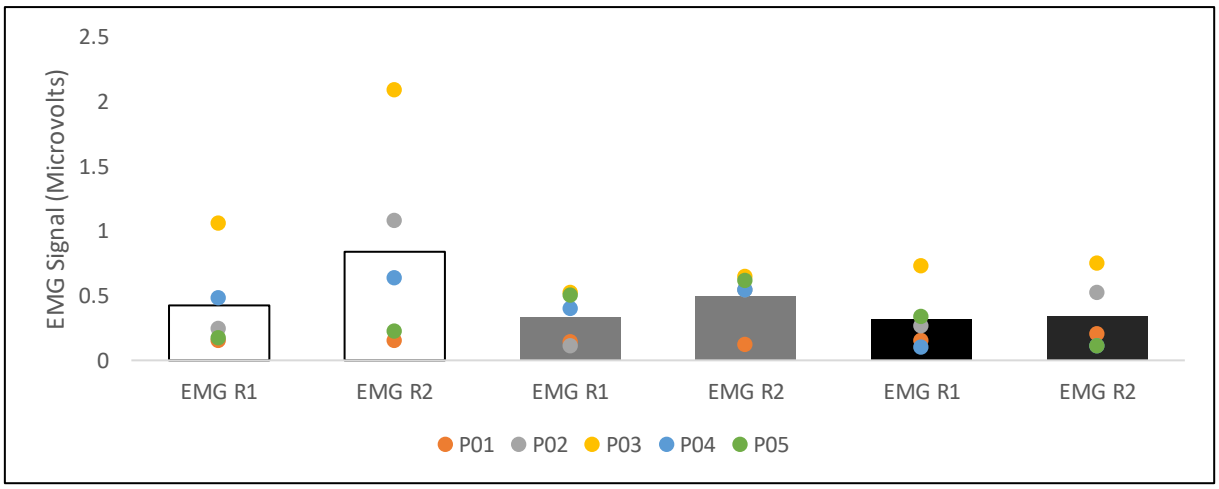

Figure 4. Mean (bar) and individual score (data point) differences (N=5) for; a) average force (Newtons), b) peak force (Newtons), and c) surface electromyography (microvolts). Differences shown between three conditions (telehealth affected limb, in person affected limb, and in person non-affected limb for slow (R1) and fast (R2) passive elbow extension measured by the TONE device and software application.

The level of agreement between TONE measures obtained during the telehealth and in-person assessments of the affected limb were assessed using Cronbach's alpha intraclass correlation coefficients. Moderate to good agreement was found between R1 ROM, R2 ROM, R1 average velocity, and R1 peak force (see Table 4). Feedback from the specialist (LS) performing testing of the TONE device with Participant 05 was to include a strap enabling attachment of the TONE device's hand-held dynamometer directly to the examiner's hand (see Figure 5). No participants reported pain or discomfort during the spasticity assessment using the TONE device. All participants reported they could interact effectively with the examiner. Full survey results related to participant telehealth spasticity assessment experiences are summarized in Figure 6. The telehealth spasticity assessment procedure was completed within under 30 minutes on average, demonstrating that the procedure is feasible within clinical time demands (see Table 5.)

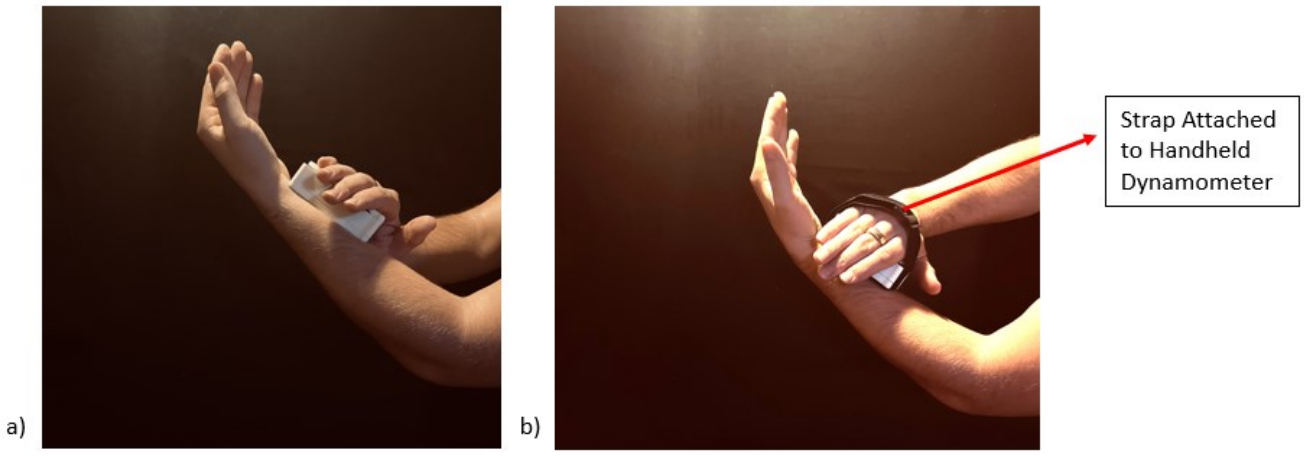

Figure 5. a) Photograph showing handheld dynamometer set up used for testing with participants. b) Photograph showing addition of strap to reduce grip variability recommended by specialist LS.

Table 4. Cronbach's alpha intraclass correlation coefficient between telehealth assessment conducted by the acting specialist and in person assessment conducted by the acting specialist of the affected limb by (n=5).

TONE Measure	Comparison Condition	Mean (SD)	Cronbach's Alpha ICC (95% CI) [α]
R1 ROM (Degrees)	IP Affected Limb TH Affected Limb	70.3 (19.3) 62.7 (23.6)	*0.73 (0.20-0.90)
R2 ROM (Degrees)	IP Affected Limb TH Affected Limb	69.9 (19.9) 66.1 (25.3)	**0.90 (0.70-0.96)
R1 Average Velocity (Degrees/second)	IP Affected Limb TH Affected Limb	11.7 (6.8) 13.5 (9.9)	**0.79 (0.40-0.93)
R2 Average Velocity (Degrees/second)	IP Affected Limb TH Affected Limb	50.4 (38.6) 37 (31.6)	0.46 (-0.54-0.81)
R1 Average Force (Newtons)	IP Affected Limb TH Affected Limb	64.5 (15.0) 110.4 (88.4)	0.145 (-0.97-0.67)
R2 Average Force (Newtons)	IP Affected Limb TH Affected Limb	80.2 (36.2) 136.5 (93.4)	0.30 (-0.35-0.62)
R1 Peak Force (Newtons)	IP Affected Limb TH Affected Limb	92.2 (24.3) 120.8 (93.7)	*0.51 (-0.46-0.84)
R2 Peak Force (Newtons)	IP Affected Limb TH Affected Limb	186.0 (35.1) 347.0 (102.1)	*0.73 (0.20-0.91)
R1 sEMG (microvolts (X 10^{-6} Volts)	IP Affected Limb TH Affected Limb	1.33 (2.48) 0.42 (0.44)	0.16 (-0.36-0.61)
R2sEMG (microvolts (X 10^{-6} Volts)	IP Affected Limb TH Affected Limb	0.50 (0.24) 0.84 (0.91)	0.19 (-0.41-0.57)

ICC (95% CI)[α] = Intraclass Correlation Coefficient Absolute Agreement (Cronbach's Alpha) with 95% Confidence Interval, * = Moderate Reliability (0.5-0.74), ** = Good Reliability (0.75-0.9), No symbol = Poor Reliability (<0.5).

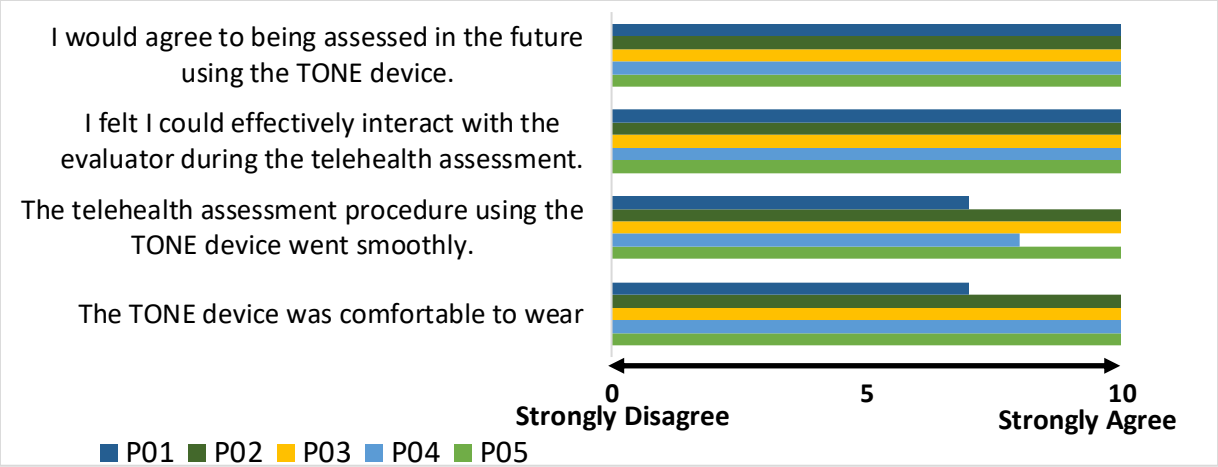

Figure 6. Participant telehealth spasticity feedback survey responses (N=5).

Table 5. Telehealth Spasticity Assessment Set-Up Requirements & Time.

Task	Personnel Involved	Time (minutes)
Far-end laptop and camera set-up.	Research Assistant	10
Zoom® videoconferencing scheduling & remote desktop control set-up.	Research Assistant Acting Specialist	5
Donning of the TONE device.	Research Assistant Patient Participant Acting Specialist	5
Telehealth spasticity assessment procedure.	Research Assistant Patient Participant Acting Specialist	5
Saving Spasticity Assessment Excel Data File.	Acting Specialist	2.5
Removal of the TONE device.	Research Assistant Patient Participant Acting Specialist	2.5
Total Time		**30**

5.4 Discussion

This study provides preliminary evidence that quantitative electronic measures related to spasticity can be collected, recorded, and transmitted between patients and specialists within telehealth environments. The TONE device detected differences in mean ROM, average velocity, average force, peak force, and average sEMG scores between the affected and non-affected limbs in 5 participants with known upper limb spasticity in both in-person and telehealth assessment conditions. The affected limb's Mean ROM measures were less than the non-affected limb's. This was expected as it is known that individuals with spasticity experience ROM loss in affected joints. Mean scores for average and peak force were found to be greater in the affected versus non-affected limb. This was also expected as increased resistance to passive movement is known to occur with spasticity.

No consistent method of determining the angle of catch was found when analyzing the TONE device's signal output. This was unexpected, as it was hypothesized that an apparent burst of EMG activity and associated rapid increase in force measure would appear in unison, indicating a clear catch, as demonstrated by Flueren et al. (2010) (see Figure 7). Visual analysis of the TONE device's force and sEMG signal output revealed a delay between force and sEMG increases in activity. This occurred because the force data was updated each time the loop was executed and the EMG data was averaged and also later smoothed, this introduced a lag between the smoothed EMG data and the Force data. This lag is thought to explain the delay between the spike in the force signal and the EMG response as highlighted by the starred data in Figure 2. Preserving the raw sEMG signal would enable enhanced post-assessment processing techniques to better identify the timing of the catch onset.

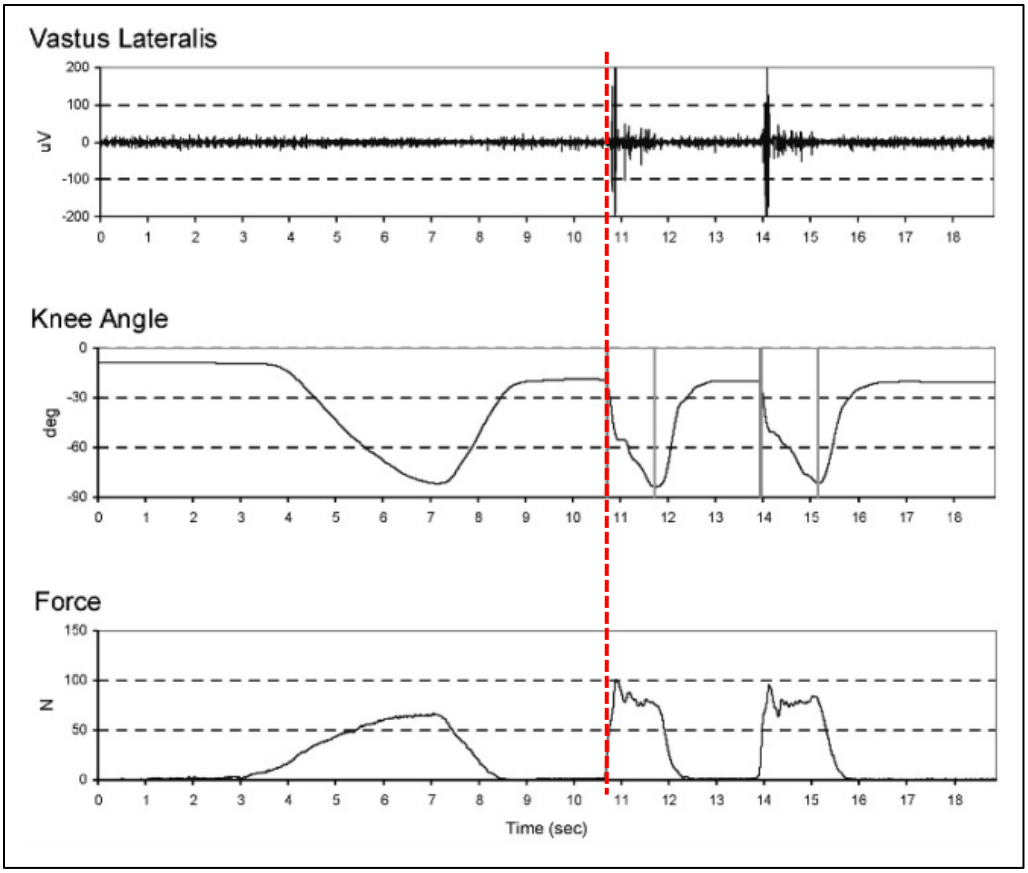

Figure 6. Adaptation of example of surface electromyography, knee angle, and dynamometry output by Fleuren et al., (2010) from their study examing vastus lateralis muscle response to fast passive knee flexion in an individual with heriditary spastic paraparesis. Sample frequency = 512 Hz, bandpass filtered at 15–256 Hz using a second order Butterworth filter.

An alternative to determine the amount of muscle activity in the biceps brachii muscle in response to slow and fast passive elbow extension was the examination of the average rectified sEMG signal obtained throughout the entire passive elbow extension movement. The average rectified sEMG signal analysis showed differences between the non-affected and affected limbs, as shown in Figure 4. However, the average rectified sEMG signal values were extremely low and appeared to differ minimally between affected and non-affected limbs. Differences in sEMG scores were highly variable both within and between subjects. More obvious differences in sEMG values were expected between the affected and non-affected limbs. A surprising finding

was the relatively large difference between the R2 velocity observed between the affected and non-affected limbs of participants. Instructions for R2 were identical in all conditions: “Move the limb as fast as possible.” However, R2 velocities of the affected limb were found to be much slower when compared to the non-affected limb. The increased resistance to passive movement may have increased the time for the affected limb to reach the maximum extension angle. Four participants (P02-P05) scored a grade of 2 on the MTS, indicating a clear catch at a precise angle, interrupting the passive movement, followed by release. However, a high level of variability between participants in all measures obtained by the TONE device was found. This finding highlights the need for continuous measures to detect differences between individuals better, as ordinal ratings are not sensitive enough to demonstrate existing differences in spasticity severity between patients.

Although the TONE device successfully captured and transmitted all measures within the telehealth assessment, several challenges were identified. Challenges were experienced observing passive movements performed in the telehealth assessment. For example, a sagittal view is optimal for viewing elbow flexion and extension ROM movement; however, this view places the assistant performing the passive movement between the camera and the participant. As a compromise, a frontal view was used to view passive elbow extension, as shown in Figure 1. Additionally, it was challenging to ensure that the electrogoniometer’s stationary and moving arms and sEMG sensor electrodes were placed in the correct anatomical position when performing the telehealth assessment. Far-end camera control and remote screen control features in Zoom™ used during the telehealth assessment were beneficial as these features limited the need for the research assistant to operate the computer used for connecting the video conferencing call. This allowed the research assistant to focus on instructions given by the

remote assessor and the patient participants rather than being required to operate the computer and software application used during the assessment.

Limitations and Future Directions

Convenience sampling methods were used to recruit participants for the present study. Convenience sampling is also known to limit the generalisability of findings to larger populations. Patient participant feedback was not used to design the telehealth spasticity assessment procedure used within this study. Future studies should engage with individuals living with spasticity to better understand their needs and expectations related to telehealth assessment. Measurement challenges and variability of limb position in individuals with spasticity can make anatomical landmarks for goniometer use challenging. For example, aligning the goniometer's mobile arm with the patient's distal radius was impractical, forcing the acting examiner in the study to align the goniometer with the center dorsum of the forearm, as shown in Figure 3. Alignment issues are known to occur when using electrogoniometers and goniometers in general, resulting in measurement errors. The force sensor also demonstrated negative drift values over time; a procedure to re-calibrate the force sensor would be helpful to enhance consistency in force values.

While this research represents the first iteration of the TONE device, it is important to note that it is not ready for use in clinical practice. Future development is required prior to testing within a larger population. Future studies are needed to determine the diagnostic accuracy of the TONE device. Studies should also be conducted to determine normative values obtained by the TONE device. Normative values have the potential to serve as a reference to grade spasticity severity.

Conclusion

In conclusion, the TONE device successfully detected mean differences in elbow joint ROM and passive elbow extension average angular velocity between the affected and non-affected limbs of five participants with known spasticity. The procedure used to assess spasticity in telehealth environments was found to be feasible with the total time of assessment taking approximately 30 minutes. The procedure was easy to perform with patient participants all reporting that they were able to interact effectively with the far-end examiner. The TONE device is low-cost, portable, and wireless, allowing objective measures of spasticity to be performed within in-person practice. Efforts to enable the TONE device to save the raw sEMG signal and improve the force and angle sensor's transmission rate would likely enhance the TONE device's ability to detect the angle of catch. Modifications to the TONE device's hand-held dynamometer, including the addition of a strap to attach the device to the examiner's hand, are recommended and may reduce variability in force measures.

Chapter 6. Discussion & Conclusions

6.1 Summary of Findings

The main objective of this doctoral research was to develop, construct, and evaluate a device and software application for obtaining biomechanical and neurophysiological measurements of spasticity compatible with telehealth settings. A review of the background literature relating to spasticity and information gathered from end-users in Study 1 was used to inform the initial development of the TONE device. The development of the first iteration of the TONE device was followed by two studies designed to validate, refine, and test the device. Validation testing and device refinement were performed in a population without spasticity in Study 2. Findings from Study 2 informed changes to improve the performance of the TONE device prior to testing within a patient population. Next, the device was tested within a population with known upper limb spasticity in Study 3. A complete timeline outlining significant dates in relation to the project work completed to meet the main thesis objective is provided in Figure 1.

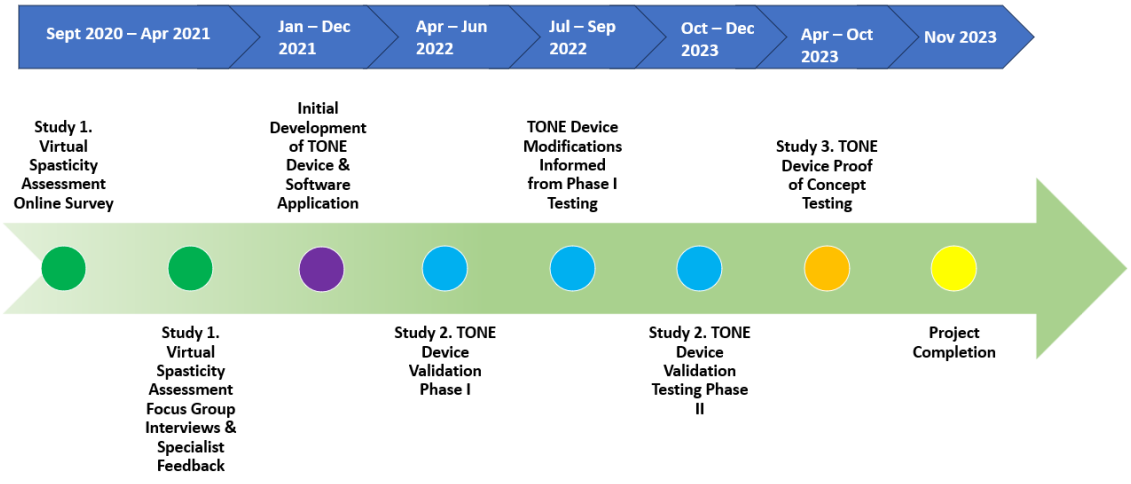

Figure 1. Timeline of doctoral work

Study 1 utilized an online survey and focus group interviews to gather information about how spasticity clinicians across Canada are currently performing telehealth spasticity assessments. The online survey and interview data analysis found that current telehealth practices rely on videoconferencing or phone consultation to gather spasticity assessment data. The information obtained from telehealth spasticity assessment is currently limited to subjective reports and visual observation. Videoconferencing was preferred among clinicians as it allowed for the collection of both subjective and visual observation-based information. Reported advantages of telehealth spasticity assessment include the capacity to evaluate and observe patients in their natural settings, ensuring consistent care even when in-person consultations are not possible, and reducing patient travel time. Telehealth spasticity consultations were also seen as an efficient method of gathering the patient history and patient demographic information. A significant challenge of performing telehealth spasticity evaluations expressed by participants was the inability to perform hands-on assessment techniques routinely administered in person. There was uncertainty among participants as to whether or not quantitative methods of spasticity assessment would be beneficial when performing telehealth spasticity assessments.

The findings from Study 1 highlighted the need for a more standardized approach to telehealth spasticity assessment practices. It was determined that the development of a device capable of accurately measuring quantitative spasticity data was necessary to fully grasp its potential usefulness within telehealth and in-person clinical practice. The TONE device was developed to create a low-cost, portable, and wireless device that records and displays spasticity-related measures, including range of motion, force, and muscle activity. Once the initial prototype was completed, the TONE device was validated in study 2 within a population without neurological impairment.

In Study 2, optical motion tracking (OptiTrack V120 Trio), hand-held dynamometry (Kforce hand-held dynamometer), and laboratory grade sEMG (Delsys Bagnoli) were used as reference standards in comparison to the TONE device's ROM, force, and sEMG sensors respectively. The TONE device measures demonstrated moderate to excellent agreement compared to reference standards for the majority of relationships examined. The sampling rate of the TONE device was identified as problematic within the first half of Study 2 and increased from 30 Hz to 50 Hz. After this change was completed, improvements in the resolution of the joint angle, force, and sEMG vs. time measurements were achieved. After satisfactory levels of agreement between the TONE device and reference standards were demonstrated, further testing within a patient population with known spasticity was initiated.

In Study 3, the TONE device was tested within a group of five participants with known post-stroke and traumatic brain injury-related spasticity of the upper extremity. This study demonstrated that kinematic, kinetic, and neurophysiological measures related to spasticity can be obtained within telehealth environments. These measures were successfully obtained by an individual with limited experience using the TONE device directed by an acting specialist. This study provided preliminary evidence that a low-cost, portable assessment device is capable of diagnosing spasticity by showing increases in average sEMG activity, peak force, and average force measures obtained at differing passive joint angular velocities differentiating between spastic and non-spastic limbs. This study also provided support that measures obtained by electronic sensors are advantageous as they allow for a detailed record saved for future comparison. This study also confirmed challenges in assessing spasticity in telehealth contexts expressed by clinician participants in Study 1. Viewing of passive joint movements using video conferencing was difficult as an examiner must perform these measures and is often between the

patient and the video camera. This makes viewing of the passive movement quality particularly challenging. Instead of monitoring the movement of elbow flexion and extension in the sagittal plane, which would be optimal, a frontal view was needed to view the patient's limb during passive movements. This challenge of a sub-optimal video capture angle was somewhat resolved by capturing the TONE device's angle and time tracing.

6.2 Implication of Findings

The work presented in this thesis advances the knowledge surrounding the use of quantitative spasticity assessment within telehealth and in-person practice. This is important, as quantitative spasticity assessment practices have long been promoted as essential to advancing our understanding of the mechanisms responsible for spasticity and subsequently developing more targeted and effective interventions. Furthermore, several publications have suggested these methods may be advantageous for telehealth use where hands-on assessment is not feasible (He et al., 2023; Kim et al., 2020; Park et al., 2008; Weizman, Tirosh, Fuss, Tan, & Rutz, 2022). Arguments in favor of adopting quantitative measures within clinical practice seem logical. However, our research indicates that clinicians may need more certainty about the practical value of using such measures. Many quantitative spasticity assessment devices and procedures described in the literature are relatively new and are not routinely used within clinical practice. This likely explains some of the uncertainty regarding the usefulness of these measures within telehealth and traditional in-person environments among clinicians. Our research indicates that clinicians are not satisfied with current telehealth spasticity practices, highlighting the need for new techniques and approaches to assessment.

Our work serves as a first step towards gaining a deeper comprehension of the implications and challenges associated with developing and incorporating quantitative spasticity measures within clinical practice. The development and testing of the TONE device described in this thesis represents the successful first iteration of a low-cost, portable, and wireless device and software application capable of obtaining quantitative ROM, force, and EMG measures of upper limb spasticity. We have demonstrated a procedure using the TONE device that can easily be administered by a specialist instructing a remote generalist clinician connected by videoconferencing. Due to the small size of the TONE, the device can easily be mailed from specialists to patients regardless of their location. While the procedure for recording data was feasible, signal analysis was highly time-consuming, presenting challenges for frontline clinicians. Software development is recommended to focus on automated signal processing methods to allow clinicians to focus on signal interpretation rather than signal processing.

The measures obtained by the TONE device detected differences between the affected and non-affected elbow joints in individuals with known spasticity. The TONE device provided information useful with respect to assessing the impact of both neurological and peripheral factors associated with spasticity. Force, sEMG, and ROM measures can greatly assist in quantifying strength by providing numerical values related to resistance to passive motion or even force measures related to active movement. This can assist in creating more standardized assessment procedures compared to clinical measures such as the modified Ashworth and modified Tardieu scales, which have been shown to vary greatly depending on each clinician's subjective interpretation of the forces felt through passive movements.

It is important to note that objective measures of spasticity have limitations. Even objective measures of spasticity, including sEMG, force measures of passive movement, and

ROM values, are known to be highly variable between and within individuals, as confirmed in Study 3. Despite these limitations, quantitative measures provide recorded data of the assessment procedure, which has several advantages over clinical measures that are performed and scored based on subjective feel alone. Assessments are often repeated several months later with no record other than an ordinal level score based on the clinician's interpretation of the resistance they felt during the passive movement. Taking subsequent quantitative assessments gives the advantage of more precise tracking, which could be very important when recommending medication dosages and monitoring changes in ROM, resistance to passive movement, and involuntary muscle activity in response to passive stretch.

Continued advancements in sensor-based technology will make measures previously only available within laboratory settings more affordable and available to within clinical settings. The existence of technology does not automatically guarantee that it will be adopted into clinical practice. Further education must be provided to clinicians on why these measures should be adopted into clinical practice. Education on how to perform and interpret electronic sensor-based measures such as sEMG measures of muscle activity and hand-held dynamometry measures of resistance to passive movement should be developed for clinicians. Lastly, clinicians and patients should be involved in planning and development processes, facilitating collaboration with researchers to create meaningful assessment devices and procedures for clinicians, researchers, and patients alike.

6.3 Future Work

The TONE device and software application developed and tested in this thesis represent the first steps toward creating a clinically usable method of quantitatively assessing spasticity in telehealth and traditional clinical settings. The following is a summary of recommended next steps required to advance the development of the TONE device and other quantitative spasticity measurements compatible with clinical settings.

1. **Multiple Joint Assessment:** Future studies should focus on creating measurement devices capable of examining multiple regions and joints of the body known to have spasticity. Most spasticity assessment devices outlined in the literature are designed to assess the elbow – as in the case of the present work – and ankle (Cha & Arami, 2020; Guo et al., 2022). This is likely due to both the elbow and ankle joints being synovial hinge joints, allowing for movement within only one plane. More complex joints that allow for movement in multiple planes are likely viewed as more challenging to assess and, as a result, avoided. Although the elbow and ankle joints are commonly affected by spasticity and serve as a logical starting point for device development, spasticity affects all body regions. Therefore, future work should involve assessing more complex joints, including the hands, wrist, shoulder, hip, and trunk.
2. **Multiaxial ROM Assessment:** The electronic goniometer used to measure kinematic spasticity data by the TONE device was rigid and uniaxial, allowing for measurement within only one plane of movement. Findings from Study 3 revealed challenges in aligning the electronic goniometer with conventional anatomical landmarks. When performing elbow flexion and extension ROM assessment, the rigid mobile arm of the goniometer was not

always able to be aligned with the styloid process of the radius due to limited available forearm supination. As limb positioning is a significant challenge experienced by individuals with spasticity, future studies should examine using less rigid devices capable of assessing biaxial or triaxial movement when assessing ROM in individuals with spasticity.

3. **Active Movement Assessment:** Much of the research surrounding quantitative spasticity assessment – including the present work – has focused on assessing passive movement. While passive movement can provide important information regarding muscle tone, future work should also aim to quantitatively evaluate the effects of spasticity in relation to active movement. Further investigation into using quantitative spasticity measures involving standardized active tasks should be further explored.
4. **Consensus of Quantitative Spasticity Measures:** Clinicians should also work toward forming a consensus on which biomechanical and neurophysiological measures are most useful and how these measures should be analyzed to detect spasticity treatment responses. This work should also focus on determining if repeated quantitative measures of spasticity can better detect spasticity changes over time compared to standard clinical measures. More sensitive measures of spasticity have the potential to better inform medication dosage and timing of medication administration, such as BoNT injection.
5. **Increase in Signal Resolution**: While the present work was successful in achieving stable wireless transmission of sEMG, force, and joint angle signals, the angle of catch was not able to be identified. The maximum transmission frequency achieved by the X-Bee wireless module connecting the TONE device and software application was 50 Hz. This transmission rate is sufficient for visual feedback to ensure the device records data but insufficient for identifying the reflex response's precise onset timing during passive movement. Preserving the raw sEMG signal and recording the angle and force signal data at a higher sampling rate saved within the device's hardware SD memory would be beneficial for asynchronous

analysis. Further investigation into other wireless methods, such as WiFi data transmission, should also be explored as it has been demonstrated to provide adequate and low-cost sEMG signal transmission rates (Yang, Ruan, Chen, Liu, & Hsueh, 2020).

6. **Automated Output:** Future work should also focus on improving the functionality of the TONE device's software, including incorporating automated techniques to assist with filtering data and identifying and grading spasticity severity. Further software development should make the interpretation of the device's signal output more user-friendly compared to viewing the raw angle, force, and sEMG vs. time signals alone.
7. **Telehealth Spasticity Treatment:** Efforts should also be focused on treating spasticity in telehealth environments. It is known that individuals living in rural and remote regions access specialist services at a lower rate than their urban counterparts. Although a necessary starting point, identifying spasticity alone does nothing to improve the lives of individuals with spasticity. Therefore, efforts should be made to use telehealth to provide remote treatment to individuals with limited access to care to improve the quality of life for individuals with spasticity.

As a guiding principle to all future work, collaboration is needed among researchers, biomedical engineers, spasticity clinicians, and patients to develop a balance of useful and pragmatic approaches. The inclusion of patient participants for informing virtual spasticity assessment procedures is strongly recommended. Very little is known regarding the perceptions of patient need for telehealth spasticity assessment. Engagement with patients could help to design assessment procedures that are aligned with patient values and needs. Future studies should focus on identifying the most suitable methods for quantitatively assessing spasticity in clinical settings. Future studies should also investigate whether using quantitative assessment over the current observer-based ordinal clinical scales can improve patient management and

outcomes for individuals with spasticity. The electronic goniometer used to measure kinematic spasticity data by the TONE device was rigid and uniaxial allowing for measurement within only one plane of movement. Findings from Study 3 revealed challenges aligning the electronic goniometer with conventional anatomical landmarks. When performing elbow flexion and extension ROM assessment, the rigid mobile arm of the goniometer was not always able to be aligned with the styloid process of the radius as a result of limited available forearm supination. As limb positioning is a major challenge experienced by individuals with spasticity, future studies should examine the use of less rigid devices capable of assessing biaxial or triaxial movement when assessing ROM in individuals with spasticity.

6.4 Conclusion

This thesis aimed to develop, construct, and evaluate a device and software application for obtaining biomechanical and neurophysiological measurements of spasticity compatible with telehealth settings. A device capable of obtaining and transmitting objective measures of spasticity was successfully developed. This thesis provided evidence that neurophysiological and biomechanical measures related to spasticity can be successfully obtained and transmitted from patient to specialist using the internet. The TONE device was able to successfully detect spasticity and differentiate between the affected and less affected limb in all participants with known stroke or traumatic brain injury-related spasticity. However, the measures obtained were not sensitive enough to provide information regarding spasticity severity. The findings contrast the assumptions that electrophysiological measures of spasticity cannot be obtained within telehealth environments (Verduzco-Gutierrez et al., 2020). This work provides supporting evidence that quantitative measures of spasticity can be achieved within telehealth and in-person assessment practices.

References

Abal del Blanco, J., & Taboada-Iglesias, Y. (2021). Effects of resistance exercise in patients with spasticity: Systematic review. *Apunts Sports Medicine, 56*(212).

Ada, L., Dorsch, S., & Canning, C. G. (2006). Strengthening interventions increase strength and improve activity after stroke: a systematic review. *Aust J Physiother, 52*(4), 241-248.

Albahrouh, S. I., & Buabbas, A. J. (2021). Physiotherapists' perceptions of and willingness to use telerehabilitation in Kuwait during the COVID-19 pandemic. *BMC Med Inform Decis Mak, 21*(1), 122.

Bakheit, A. M. (2012). The pharmacological management of post-stroke muscle spasticity. *Drugs Aging, 29*(12), 941-947.

Bakhtiary, A. H., & Fatemy, E. (2008). Does electrical stimulation reduce spasticity after stroke? A randomized controlled study. *Clin Rehabil, 22*(5), 418-425.

Balci, B. P. (2018). Spasticity Measurement. *Noro Psikiyatr Ars, 55*(Suppl 1), S49-S53.

Banky, M., Clark, R. A., Mentiplay, B. F., Olver, J. H., Kahn, M. B., & Williams, G. (2019). Toward Accurate Clinical Spasticity Assessment: Validation of Movement Speed and Joint Angle Assessments Using Smartphones and Camera Tracking. *Arch Phys Med Rehabil, 100*(8), 1482-1491.

Bar-On, L., Aertbeliën, E., Wambacq, H., Severijns, D., Lambrecht, K., Dan, B., . . . Desloovere, K. (2013). A Clinical Measurement to Quantify Spasticity in Children with Cerebral Palsy by Integration of Multidimensional Signals *Gait and Posture, 38*(1), 141-147.

Baricich, A., Battaglia, M., Cuneo, D., Cosenza, L., Millevolte, M., Cosma, M., . . . Santamato, A. (2023). Clinical efficacy of botulinum toxin type A in patients with traumatic brain injury, spinal cord injury, or multiple sclerosis: An observational longitudinal study. *Front Neurol, 14*, 1133390.

Bascunana-Ambros, H., Nadal-Castells, M. J., Ramirez-Mirabal, E., Beranuy-Rodriguez, M., Pintor-Ojeda, A., & Perrot-Gonzalez, J. C. (2021). Emerging Concepts and Evidence in Telematics Novel Approaches or Treatments for Spasticity Management After Botulinum Injection. *Front Rehabil Sci, 2*, 720505.

Bashiri, M., Greenfield, L., & Oliveto, A. (2015). Telemedicine Interest for Routine Follow-Up Care Among Neurology Patients in Arkansas. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association, 22*.

Baude, M., Nielsen, J. B., & Gracies, J. M. (2018). The neurophysiology of deforming spastic paresis: A revised taxonomy. *Ann Phys Rehabil Med*.

Becker, S., von Werder, S., Lassek, A. K., & Disselhorst-Klug, C. (2019). Time-frequency coherence of categorized sEMG data during dynamic contractions of biceps, triceps, and brachioradialis as an approach for spasticity detection. *Med Biol Eng Comput, 57*(3), 703-713.

Benjamin, E. J., Muntner, P., Alonso, A., Bittencourt, M. S., Callaway, C. W., Carson, A. P., . . . Stroke Statistics, S. (2019). Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. *Circulation, 139*(10), e56-e528.

Bethoux, F. (2015). Spasticity Management After Stroke. *Phys Med Rehabil Clin N Am, 26*(4), 625-639.

Biering-Sorensen, F., Nielsen, J. B., & Klinge, K. (2006). Spasticity-assessment: a review. *Spinal Cord, 44*(12), 708-722.

Blacquiere, D., Lindsay, M. P., Foley, N., Taralson, C., Alcock, S., Balg, C., . . . Stroke Foundation Canadian Stroke Best Practice, C. (2017). Canadian Stroke Best Practice Recommendations: Telestroke Best Practice Guidelines Update 2017. *Int J Stroke, 12*(8), 886-895.

Bovend'Eerdt, T. J., Newman, M., Barker, K., Dawes, H., Minelli, C., & Wade, D. T. (2008). The effects of stretching in spasticity: a systematic review. *Arch Phys Med Rehabil, 89*(7), 1395-1406.

Brambilla, C., Pirovano, I., Mira, R. M., Rizzo, G., Scano, A., & Mastropietro, A. (2021). Combined Use of EMG and EEG Techniques for Neuromotor Assessment in Rehabilitative Applications: A Systematic Review. *Sensors (Basel), 21*(21).

Brashear, A., & Elovic, E. (2015). *Spasticity : Diagnosis and Management*. New York, UNITED STATES: Springer Publishing Company, Incorporated.

Brennan, D. M., Mawson, S., & Brownsell, S. (2009). Telerehabilitation: Enabling the Remote Delivery of Healthcare, Rehabilitation, and Self Management. *Studies in Health Technology and Informatics*.

Bronner, S., Agraharasamakulam, S., & Ojofeitimi, S. (2010). Reliability and validity of electrogoniometry measurement of lower extremity movement. *J Med Eng Technol, 34*(3), 232-242.

Burke, D., Wissel, J., & Donnan, G. A. (2013). Pathophysiology of spasticity after stroke. *American Acadamey of Neurology, 80* (20-26).

Burridge, J. H., Wood, D. E., Hermens, H. J., Voerman, G. E., Johnson, G. R., van Wijck, F., . . . Pandyan, A. D. (2005). Theoretical and methodological considerations in the measurement of spasticity. *Disabil Rehabil, 27*(1-2), 69-80.

Calota, A., Feldman, A. G., & Levin, M. F. (2008). Spasticity measurement based on tonic stretch reflex threshold in stroke using a portable device. *Clin Neurophysiol, 119*(10), 2329-2337.

Campanini, I., Disselhorst-Klug, C., Rymer, W. Z., & Merletti, R. (2020). Surface EMG in Clinical Assessment and Neurorehabilitation: Barriers Limiting Its Use. *Front Neurol, 11*, 934.

Canning, M., Phadke, P. C., Ismail, F., & Boulias, C. (2013). A Survey of Rural and Urban Family Physicians: Analysis of Spasticity Helath Literacy and Availability of Appropriate Spasticity Care. *University of Toronto Medical Journal, 90*(03), 114-118.

Cha, Y., & Arami, A. (2020). Quantitative Modeling of Spasticity for Clinical Assessment, Treatment and Rehabilitation. *Sensors (Basel), 20*(18).

Chang, E., Ghosh, N., Yanni, D., Lee, S., Alexandru, D., & Mozaffar, T. (2013). A Review of Spasticity Treatments: Pharmacological and Interventional Approaches. *Crit Rev Phys Rehabil Med, 25*(1-2), 11-22.

Chasiotis, A., Giannopapas, V., Papadopoulou, M., Chondrogianni, M., Stasinopoulos, D., Giannopoulos, S., & Bakalidou, D. (2022). The Effect of Neuromuscular Electrical Nerve Stimulation in the Management of Post-stroke Spasticity: A Scoping Review. *Cureus, 14*(11), e32001.

Chen, J. J., Wu, Y. N., Huang, S. C., Lee, H. M., & Wang, Y. L. (2005). The use of a portable muscle tone measurement device to measure the effects of botulinum toxin type a on elbow flexor spasticity. *Arch Phys Med Rehabil, 86*(8), 1655-1660.

Chen, S. C., Chen, Y. L., Chen, C. J., Lai, C. H., Chiang, W. H., & Chen, W. L. (2005). Effects of surface electrical stimulation on the muscle-tendon junction of spastic gastrocnemius in stroke patients. *Disabil Rehabil, 27*(3), 105-110.

Christofi, G., Ashford, S., Birns, J., Dalton, C., Duke, L., Madsen, C., & Salam, S. (2018). Improving the management of post-stroke spasticity: Time for ACTION. *Journal of Rehabilitation Medicine – Clinical Communications, 1*(1).

Cox, A. P., Raluy-Callado, M., Wang, M., Bakheit, A. M., Moore, A. P., & Dinet, J. (2016). Predictive analysis for identifying potentially undiagnosed post-stroke spasticity patients in United Kingdom. *J Biomed Inform, 60*, 328-333.

Creamer, M., Cloud, G., Kossmehl, P., Yochelson, M., Francisco, G. E., Ward, A. B., . . . Saltuari, L. (2018). Effect of Intrathecal Baclofen on Pain and Quality of Life in Poststroke Spasticity. *Stroke, 49*(9), 2129-2137.

de Almeida, M. B., et al. (2023). Intra-Rater and Inter-Rater Reliability of the Kinvent Hand-Held Dynamometer in Young Adults. *Medical Sciences Forum, 22*(1), 12.

Delsys Incorporated. (n.d.). Delsys Bagnoli® EMG System User's Guide. https://www.delsys.com/downloads/USERSGUIDE/bagnoli-emg-system.pdf.

De Luca, C. J. (1997). The Use of Surface Electromyography in Biomechanics. *JOURNAL OF APPLIED BIOMECHANICS*(13), 135-163.

Deming, W. E. (1994). *The new economics for industry, government, education*. Cambridge, MA: Massachusetts Institute of Technology, Center for Advanced Engineering Study.

Dong, Y., Wu, T., Hu, X., & Wang, T. (2017). Efficacy and safety of botulinum toxin type A for upper limb spasticity after stroke or traumatic brain injury: a systematic review with meta-analysis and trial sequential analysis. *Eur J Phys Rehabil Med, 53*(2), 256-267.

Dressler, D., Bhidayasiri, R., Bohlega, S., Chana, P., Chien, H. F., Chung, T. M., . . . Saberi, F. A. (2018). Defining spasticity: a new approach considering current movement disorders terminology and botulinum toxin therapy. *J Neurol, 265*(4), 856-862.

Ehrmann, G., Blachowicz, T., Homburg, S. V., & Ehrmann, A. (2022). Measuring Biosignals with Single Circuit Boards. *Bioengineering (Basel), 9*(2).

Esquenazi, A. (2011). The Human and Economic Burden of Poststroke Spasticity and Muscle Overactivity.

Esquenazi, A., Albanese, A., Chancellor, M. B., Elovic, E., Segal, K. R., Simpson, D. M., . . . Ward, A. B. (2013). Evidence-based review and assessment of botulinum neurotoxin for the treatment of adult spasticity in the upper motor neuron syndrome. *Toxicon, 67*, 115-128.

Field, M. J. (1996). *Telemedicine: A Guide to Assessing Telecommunications in Health Care*. Washington, D.C. : NATIONAL ACADEMY PRESS

Foran, J. R., Steinman, S., Barash, I., Chambers, H. G., & Lieber, R. L. (2005). Structural and mechanical alterations in spastic skeletal muscle. *47*(10), 713-717.

Francisco, G. E., & McGuire, J. R. (2012). Poststroke spasticity management. *Stroke, 43*(11), 3132-3136.

Francisco, G. E., Yablon, S. A., Schiess, M. C., Wiggs, L., Cavalier, S., & Grissom, S. (2006). Consensus panel guidelines for the use of intrathecal baclofen therapy in poststroke spastic hypertonia. *Top Stroke Rehabil, 13*(4), 74-85.

Ganapathy, V., Graham, G. D., DiBonaventura, M. D., Gillard, P. J., Goren, A., & Zorowitz, R. D. (2015). Caregiver burden, productivity loss, and indirect costs associated with caring for patients with poststroke spasticity. *Clin Interv Aging, 10*, 1793-1802.

Gomez-Cuaresma, L., Lucena-Anton, D., Gonzalez-Medina, G., Martin-Vega, F. J., Galan-Mercant, A., & Luque-Moreno, C. (2021). Effectiveness of Stretching in Post-Stroke Spasticity and Range of Motion: Systematic Review and Meta-Analysis. *J Pers Med, 11*(11).

Gracies, J.-M. (2001). Pathophysiology of Impairment in Patients with Spasticity and Use of Stretch as a Treatment of Spastic Hypertonia. *Physical Medicine and Rehabilitation Clinics of North America, 12*(4), 747-768.

Guo, X., Wallace, R., Tan, Y., Oetomo, D., Klaic, M., & Crocher, V. (2022). Technology-assisted assessment of spasticity: a systematic review. *J Neuroeng Rehabil, 19*(1), 138.

Gumussu, K., & Erhan, B. (2023). Management of spasticity in individuals with spinal cord injury in the era of COVID-19 pandemic societal restrictions. *Spinal Cord Ser Cases, 9*(1), 17.

Guzman-Venegas, R. A., Araneda, O. F., & Silvestre, R. A. (2014). Differences between motor point and innervation zone locations in the biceps brachii. An exploratory consideration for the treatment of spasticity with botulinum toxin. *J Electromyogr Kinesiol, 24*(6), 923-927.

Gwet, K. L. (2014). Handbook of Inter-Rater Reliability, 4th Edition. Gaithersburg, MD., Advanced Analystucs, LLC.

Hameau, S., Bensmail, D., Robertson, J., Boudarham, J., Roche, N., & Zory, R. (2014). Isokinetic assessment of the effects of botulinum toxin injection on spasticity and voluntary strength in patients with spastic hemiparesis. *European journal of physical and rehabilitation medicine, 50*(5), 515-523.

Hara, T., Abo, M., Hara, H., Kobayashi, K., Shimamoto, Y., Samizo, Y., . . . Niimi, M. (2017). Effects of botulinum toxin A therapy and multidisciplinary rehabilitation on upper and lower limb spasticity in post-stroke patients. *Int J Neurosci, 127*(6), 469-478.

Harper, K. A., Butler, E. C., Hacker, M. L., Naik, A., Eoff, B. R., Phibbs, F. T., . . . Charles, P. D. (2020). A comparative evaluation of telehealth and direct assessment when screening for spasticity in residents of two long-term care facilities. *Clin Rehabil*, 269215520963845.

Harvey, L. A., Katalinic, O. M., Herbert, R. D., Moseley, A. M., Lannin, N. A., & Schurr, K. (2017). Stretch for the treatment and prevention of contracture: an abridged republication of a Cochrane Systematic Review. *J Physiother, 63*(2), 67-75.

Hashemi, M., Sturbois-Nachef, N., Keenan, M. A., & Winston, P. (2021). Surgical Approaches to Upper Limb Spasticity in Adult Patients: A Literature Review. *Front Rehabil Sci, 2*, 709969.

Hesse, S., Jahnke, M. T., Luecke, D., & Mauritz, K. H. (1995). Short-term electrical stimulation enhances the effectiveness of Botulinium toxin in the treatment of lower limb spasticity in hemiparetic patients. *Neuroscience Letters, 201*, 37-40.

He, J., Luo, A., Yu, J., Qian, C., Liu, D., Hou, M., & Ma, Y. (2023). Quantitative assessment of spasticity: a narrative review of novel approaches and technologies. *Front Neurol, 14*, 1121323.

Hermens, H. J., Freriks, B., Disselhorst-Klug, C., & Rau, G. (2000). Development of recommendations for SEMG sensors and sensor placement procedures. *J Electromyogr Kinesiol, 10*(5), 361-374.

Hesse, S., Reiter, F., Konrad, M., & Jahnke, M. T. (1998). Botulinium toxin type A and short-term electrical stimulation in the treatment of upper limb flexor spasticity after stroke: a randomized, double-blind, placebo-conrolled trial. *Clinical Rehabilitation, 12*, 381-388.

Heywood, S., Pua, Y. H., McClelland, J., Geigle, P., Rahmann, A., Bower, K., & Clark, R. (2018). Low-cost electromyography - Validation against a commercial system using both manual and automated activation timing thresholds. *J Electromyogr Kinesiol, 42*, 74-80.

Hulme, A., MacLennan, W. J., Ritchie, R. T., John, V. A., & Shotton, P. A. (1985). Baclofen in the elderly stroke patient its side-effects and pharmacokinetics. *Eur J Clin Pharmacol, 29*(4), 467-469.

Hundza, S., Quartly, C., Kim, J. M., Dunnett, J., Dobrinsky, J., Loots, I., . . . Temple, V. A. (2016). Similar barriers and facilitators to physical activity across different clinical groups experiencing lower limb spasticity. *Disabil Rehabil, 38*(14), 1370-1381.

Intiso, D., Santamato, A., & Di Rienzo, F. (2017). Effect of electrical stimulation as an adjunct to botulinum toxin type A in the treatment of adult spasticity: a systematic review. *Disabil Rehabil, 39*(21), 2123-2133.

Johnson, G. R. (2002). Outcome measures of spasticity. *European Journal of Neurology, 9*(1), 10-16.

Jonnalagedda, P., Deng, F., Douglas, K., Chukoskie, L., Yip, M. C., Ng, T. N., . . . Garudadri, H. (2016). An Instrumented Glove for Improving Spasticity Assessment. *IEEE Healthcare Innovation Point-Of-Care Technologies Conference* 167-170.

Kairy, D., Lehoux, P., Vincent, C., & Visintin, M. (2009). A systematic review of clinical outcomes, clinical process, healthcare utilization and costs associated with telerehabilitation. *Disabil Rehabil, 31*(6), 427-447.

Kaku, M., & Simpson, D. M. (2016). Spotlight on botulinum toxin and its potential in the treatment of stroke-related spasticity. *Drug Des Devel Ther, 10*, 1085-1099.

Katan, M., & Luft, A. (2018). Global Burden of Stroke. *Semin Neurol, 38*(2), 208-211.

Katoozian, L., Tahan, N., Zoghi, M., & Bakhshayesh, B. (2018). The Onset and Frequency of Spasticity After First Ever Stroke. *J Natl Med Assoc, 110*(6), 547-552.

Kaya, T., Karatepe, A. G., Gunaydin, R., Koc, A., & Altundal Ercan, U. (2011). Inter-rater reliability of the Modified Ashworth Scale and modified Modified Ashworth Scale in assessing poststroke elbow flexor spasticity. *Int J Rehabil Res, 34*(1), 59-64.

Kaymak, B., Kara, M., Tok, F., Ulasli, A. M., Ozturk, G. T., Chang, K. V., . . . Ozcakar, L. (2018). Sonographic guide for botulinum toxin injections of the lower limb: EUROMUSCULUS/USPRM spasticity approach. *Eur J Phys Rehabil Med, 54*(3), 486-498.

Kim, J. Y., Park, G., Lee, S. A., & Nam, Y. (2020). Analysis of Machine Learning-Based Assessment for Elbow Spasticity Using Inertial Sensors. *Sensors (Basel), 20*(6).

KINVENT Incorporated. (2020, July). KFORCE by KINVENT: Technical Characteristics of the KFORCE muscle controller. https://k-invent.com/wp-content/uploads/2020/07/K-FORCE-Features-in-20-pages-en-2.pdf

Knudsen, S. V., Laursen, H. V. B., Johnsen, S. P., Bartels, P. D., Ehlers, L. H., & Mainz, J. (2019). Can quality improvement improve the quality of care? A systematic review of reported effects and methodological rigor in plan-do-study-act projects. *BMC Health Serv Res, 19*(1), 683.

Kuo, C.-L., & Hu, G.-C. (2018). Post-stroke Spasticity: A Review of Epidemiology, Pathophysiology, and Treatments. *International Journal of Gerontology, 12*(4), 280-284.

Lamb, Y. N., & Scott, L. J. (2016). IncobotulinumtoxinA: A Review in Upper Limb Spasticity. *Drugs, 76*(14), 1373-1379.
Lance, J. W. (1980). Symposium synopsis. *Spasticity: Disordered Motor Control, R. G. Feldman, R. R. Young, and W. P. Koella, Eds.*, 485–494.
Lance, J. W. (1990). What is spasticity? *The Lancet, 335*(8689), 606.
Lariviere, C., Delisle, A., & Plamondon, A. (2005). The effect of sampling frequency on EMG measures of occupational mechanical exposure. *J Electromyogr Kinesiol, 15*(2), 200-209.
Lee, H. M., Chen, J. J., Ju, M. S., Lin, C. C., & Poon, P. P. (2004). Validation of portable muscle tone measurement device for quantifying velocity-dependent properties in elbow spasticity. *J Electromyogr Kinesiol, 14*(5), 577-589.
Li, S., Chen, Y. T., Francisco, G. E., Zhou, P., & Rymer, W. Z. (2019). A Unifying Pathophysiological Account for Post-stroke Spasticity and Disordered Motor Control. *Front Neurol, 10*, 468.
Li, S., Francisco, G. E., & Rymer, W. Z. (2021). A New Definition of Poststroke Spasticity and the Interference of Spasticity With Motor Recovery From Acute to Chronic Stages. *Neurorehabil Neural Repair, 35*(7), 601-610.
Lorentzen, J., Grey, M. J., Geertsen, S. S., Biering-Sørensen, F., Brunton, K., Gorassini, M., & Nielsen, J. B. (2012). Assessment of a portable device for the quantitative measurement of ankle joint stiffness in spastic individuals. Clinical neurophysiology : official journal of the International Federation of Clinical Neurophysiology, 123(7), 1371–1382.
Luo, Z., Lo, W. L. A., Bian, R., Wong, S., & Li, L. (2019). Advanced quantitative estimation methods for spasticity: a literature review. *J Int Med Res*, 300060519888425.
Malhotra, S. P., A. (2009). Spasticity, an impairment that is poorly defined and poorly measure. *Clinical Rehabilitation, 23*, 651-658.
Matute, A., Paredes-Madrid, L., Moreno, G., Cárdenas, F., & Palacio, C. A. (2018). A Novel and Inexpensive Approach for Force Sensing Based on FSR Piezocapacitance Aimed at Hysteresis Error Reduction. *Journal of Sensors, 2018*, 1-16.
McDonald, J. T., & Conde, H. (2010). Does geography matter? The health service use and unmet health care needs of older Canadians. *Can J Aging, 29*(1), 23-37.
Meseguer-Henarejos, A. B., Sanchez-Meca, J., Lopez-Pina, J. A., & Carles-Hernandez, R. (2018). Inter- and intra-rater reliability of the Modified Ashworth Scale: a systematic review and meta-analysis. *Eur J Phys Rehabil Med, 54*(4), 576-590.
Meythaler, J. M., Guin-Renfroe, S., Brunner, R. C., & Hadley, M. N. (2001). Intrathecal baclofen for spastic hypertonia from stroke. *Stroke, 32*(9), 2099-2109.
Milinis, K., Young, C. A., & Trajectories of Outcome in Neurological Conditions, s. (2016). Systematic review of the influence of spasticity on quality of life in adults with chronic neurological conditions. *Disabil Rehabil, 38*(15), 1431-1441.
Miller, G. J., & Light, K. E. (1997). Strength training in spastic hemiparesis: should it be avoided? *NeuroRehabilitation, 9*(1), 17-28.
Moen, R. (2009). *Foundation and History of the PDSA Cycle*. Detroit, MI.
Münchau, A., & Bhatia, K. P. (2000). Uses of botulinum toxin injection in medicine today. BMJ (Clinical research ed.), 320(7228), 161–165. https://doi.org/10.1136/bmj.320.7228.161
Musselman, K. E., Manns, P., Dawe, J., Delgado, R., & Yang, J. F. (2018). The Feasibility of Functional Electrical Stimulation to Improve Upper Extremity Function in a Two-year-old Child with Perinatal Stroke: A Case Report. *Phys Occup Ther Pediatr, 38*(1), 97-112.

Morris, S. L., & Williams, G. (2018). A historical review of the evolution of the Tardieu Scale. *Brain Inj, 32*(5), 665-669.
Naghdi, S., Ansari, N. N., Abolhasani, H., Mansouri, K., Ghotbi, N., & Hasson, S. (2014). Electrophysiological evaluation of the Modified Tardieu Scale (MTS) in assessing poststroke wrist flexor spasticity. *NeuroRehabilitation, 34*(1), 177-184.
Nicolay, C. R., Purkayastha, S., Greenhalgh, A., Benn, J., Chaturvedi, S., Phillips, N., & Darzi, A. (2012). Systematic review of the application of quality improvement methodologies from the manufacturing industry to surgical healthcare. *Br J Surg, 99*(3), 324-335.
Olds, M., McLaine, S., & Magni, N. (2023). Validity and Reliability of the Kinvent Handheld Dynamometer in the Athletic Shoulder Test. Journal of sport rehabilitation, 32(7), 764–772.
Ojardias, E., Ollier, E., Lafaie, L., Celarier, T., Giraux, P., & Bertoletti, L. (2022). Time course response after single injection of botulinum toxin to treat spasticity after stroke: Systematic review with pharmacodynamic model-based meta-analysis. *Ann Phys Rehabil Med, 65*(3), 101579.
Opheim, A., Danielsson, A., Alt Murphy, M., Persson, H. C., & Sunnerhagen, K. S. (2014). Upper-limb spasticity during the first year after stroke: stroke arm longitudinal study at the University of Gothenburg. *Am J Phys Med Rehabil, 93*(10), 884-896.
Ozcakir, S., & Sivrioglu, K. (2007). Botulinum toxin in poststroke spasticity. *Clin Med Res, 5*(2), 132-138. doi:10.3121/cmr.2007.716
Pak, S., & Patten, C. (2008). Strengthening to promote functional recovery poststroke: an evidence-based review. *Top Stroke Rehabil, 15*(3), 177-199. doi:10.1310/tsr1503-177
Pandyan, A. D., Conway, B. A., Hermens, H. J., & Johnson, G. R. (2017). Definition and Measurement of Spasticity and Contracture. In *Neurological Rehabilitation: Spasticity and Contractures in Clinical Practice and Research*. New York: Taylor & Francis Group.
Pandyan, A. D., Gregoric, M., Barnes, M. P., Wood, D., Van Wijck, F., Burridge, J., . . . Johnson, G. R. (2005). Spasticity: clinical perceptions, neurological realities and meaningful measurement. *Disabil Rehabil, 27*(1-2), 2-6.
Pandyan, A. D., Price, B. H., Rodgers, H., Barnes, M. P., & Johnson, G. R. (2001). Biomechanical Examination of a Commonly Used Measure of Spasticity. *Clinical Biomechanics, 16*, 859-865.
Park, H. S., Peng, Q., & Zhang, L. Q. (2008). A portable telerehabilitation system for remote evaluations of impaired elbows in neurological disorders. *IEEE Trans Neural Syst Rehabil Eng, 16*(3), 245-254.
Phadke, C. P., Balasubramanian, C. K., Ismail, F., & Boulias, C. (2013). Revisiting physiologic and psychologic triggers that increase spasticity. *Am J Phys Med Rehabil, 92*(4), 357-369.
Pizzi, A., Carlucci, G., Falsini, C., Verdesca, S., & Grippo, A. (2005). Evaluation of upper-limb spasticity after stroke: A clinical and neurophysiologic study. *Arch Phys Med Rehabil, 86*(3), 410-415.
Platz, T., Eickhof, C., Nuyens, G., & Vuadens, P. (2005). Clinical scales for the assessment of spasticity, associated phenomena, and function: a systematic review of the literature. *Disabil Rehabil, 27*(1-2), 7-18.
Popovic, M. B., Popovic, D. B., Sinkjaer, T., Stefanovic, A., & Schwirtlich, L. (2003). Clinical evaluation of Functional Electrical Therapy in acute hemiplegic subjects. *J Rehabil Res Dev, 40*(5), 443-453.

Porciuncula, F., Roto, A. V., Kumar, D., Davis, I., Roy, S., Walsh, C. J., & Awad, L. N. (2018). Wearable Movement Sensors for Rehabilitation: A Focused Review of Technological and Clinical Advances. *PM R, 10*(9 Suppl 2), S220-S232.

Raghavan, P. (2022). Neural Basis of Spasticity. In P. Raghavan (Ed.), *Spasticity and Muscle Stiffness: Restoring Form and Function* (pp. 3-16). Cham: Springer International Publishing.

Reebye, R., Finlayson, H., May, C., Satkunam, L., Wein, T., Miller, T., . . . Winston, P. (2020). Practical Guidance for Outpatient Spasticity Management During the Coronavirus (COVID-19) Pandemic: Canadian Spasticity COVID-19 Task Force. *Can J Neurol Sci, 47*(5), 589-593.

Reeves, S., & Lambeth, K. (2016). *Spasticity: Diagnosis and Management*. In EBSCOHost (Ed.), *The Role of Physical and Occupational Therapy in the Evaluation and Management of Spasticity*.

Rekand, T. (2010). Clinical assessment and management ofspasticity: a review. *Acta Neurologica Scandinavica, 190*, 62-66.

Rodriguez, J. A., Betancourt, J. R., Sequist, T. D., & Ganguli, I. (2021). Differences in the use of telephone and video telemedicine visits during the COVID-19 pandemic. *Am J Manag Care, 27*(1), 21-26.

Rush, K. L., Howlett, L., Munro, A., & Burton, L. (2018). Videoconference compared to telephone in healthcare delivery: A systematic review. *Int J Med Inform, 118*, 44-53.

Sahin, N., Ugurlu, H., & Albayrak, I. (2012). The efficacy of electrical stimulation in reducing the post-stroke spasticity: a randomized controlled study. *Disabil Rehabil, 34*(2), 151-

Salazar, A. P., Pinto, C., Ruschel Mossi, J. V., Figueiro, B., Lukrafka, J. L., & Pagnussat, A. S. (2019). Effectiveness of static stretching positioning on post-stroke upper-limb spasticity and mobility: Systematic review with meta-analysis. *Ann Phys Rehabil Med, 62*(4), 274-282.

Santamato, A., Facciorusso, S., Spina, S., Cinone, N., Avvantaggiato, C., Santoro, L., . . . Fiore, P. (2021). Discontinuation of botulinum neurotoxin type-A treatment during COVID-19 pandemic: an Italian survey in post stroke and traumatic brain injury patients living with spasticity. *Eur J Phys Rehabil Med, 57*(3), 424-433.

Sarfo, F. S., Ulasavets, U., Opare-Sem, O. K., & Ovbiagele, B. (2018). Tele-Rehabilitation after Stroke: An Updated Systematic Review of the Literature. *J Stroke Cerebrovasc Dis, 27*(9), 2306-2318.

Scaglione, F. (2016). Conversion Ratio between Botox(R), Dysport(R), and Xeomin(R) in Clinical Practice. *Toxins (Basel), 8*(3).

Segal, M. (2018). Muscle Overactivity in the Upper Motor Neuron Syndrome: Pathophysiology. *Phys Med Rehabil Clin N Am, 29*(3), 427-436.

Sfalcin, B., Ji, X., Gouw, A. d., Potvin, J., & Cort, J. (2019). Optical and inertial motion capture joint angle comparison using Jack™. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting, 63*(1), 1137-1141.

Simon, O., & Yelnik, A. P. (2010). Managing spasticity with drugs. *Eur J Phys Rehabil Med, 46*(3), 401-410.

Snoswell, C., Smith, A. C., Scuffham, P. A., & Whitty, J. A. (2017). Economic evaluation strategies in telehealth: Obtaining a more holistic valuation of telehealth interventions. *J Telemed Telecare, 23*(9), 792-796.

Sonvane, I., & Kumar, T. S. (2019). Test Retest Reliability of Modified Tardieu Scale to Quantify the Spasticity in Elbow Flexors in Patients with Cerebro Vascular Accident. *Indian Journal of Physiotherapy and Occupational Therapy - An International Journal, 13*(2).

Stark, T., Walker, B., Phillips, J. K., Fejer, R., & Beck, R. (2011). Hand-held dynamometry correlation with the gold standard isokinetic dynamometry: a systematic review. *PM R, 3*(5), 472-479.

Stein, C., Fritsch, C. G., Robinson, C., Sbruzzi, G., & Plentz, R. D. (2015). Effects of Electrical Stimulation in Spastic Muscles After Stroke: Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Stroke, 46*(8), 2197-2205.

Sunnerhagen, K. S., Olver, J., & Francisco, G.E. (2013). Assessing and treating functional impairment in poststroke spasticity. *American Acadamey of Neurology, 80*(2), 35-44.

Suputtitada, A., & Suwanwela, N. C. (2005). The lowest effective dose of botulinum A toxin in adult patients with upper limb spasticity. *Disabil Rehabil, 27*(4), 176-184.

Taira, T., & Hori, T. (2007). Intrathecal baclofen in the treatment of post-stroke central pain, dystonia, and persistent vegetative state. *Acta Neurochir Suppl, 97*(Pt 1), 227-229.

Tamburin, S., Filippetti, M., Mantovani, E., Smania, N., & Picelli, A. (2022). Spasticity following brain and spinal cord injury: assessment and treatment. *Curr Opin Neurol, 35*(6), 728-740.

Taylor, M. J., McNicholas, C., Nicolay, C., Darzi, A., Bell, D., & Reed, J. E. (2014). Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. *BMJ Qual Saf, 23*(4), 290-298.

Teasell, R., Foley, N., Pereira, S., Sequeira, K., & Miller, T. (2012). Evidence to practice: botulinum toxin in the treatment of spasticity post stroke. *Top Stroke Rehabil, 19*(2), 115-121.

Teasell, R., Salbach, N. M., Foley, N., Mountain, A., Cameron, J. I., Jong, A., . . . Lindsay, M. P. (2020). Canadian Stroke Best Practice Recommendations: Rehabilitation, Recovery, and Community Participation following Stroke. Part One: Rehabilitation and Recovery Following Stroke; 6th Edition Update 2019. *Int J Stroke, 15*(7), 763-788.

Theodoros, D., & Russell, T. (2008). Telerehabilitation: Current Perspectives. In *Current Principles and Practices of Telemedicine and E-Health* (Vol. 131, pp. 191-209).

Thibaut, A., Chatelle, C., Ziegler, E., Bruno, M. A., Laureys, S., & Gosseries, O. (2013). Spasticity after stroke: physiology, assessment and treatment. *Brain Inj, 27*(10), 1093-1105.

Thomas, E. E., Haydon, H. M., Mehrotra, A., Caffery, L. J., Snoswell, C. L., Banbury, A., & Smith, A. C. (2022). Building on the momentum: Sustaining telehealth beyond COVID-19. *J Telemed Telecare, 28*(4), 301-308.

Tranchida, G. V., & Van Heest, A. (2020). Preferred options and evidence for upper limb surgery for spasticity in cerebral palsy, stroke, and brain injury. *J Hand Surg Eur Vol, 45*(1), 34-42.

Trompetto, C., Marinelli, L., Mori, L., Canneva, S., Colombano, F., Traverso, E., . . . Abbruzzese, G. (2014). The effect of age on post-activation depression of the upper limb H-reflex. *Eur J Appl Physiol, 114*(2), 359-364.

Tsao, C. W., Aday, A. W., Almarzooq, Z. I., Anderson, C. A. M., Arora, P., Avery, C. L., . . . Stroke Statistics, S. (2023). Heart Disease and Stroke Statistics-2023 Update: A Report From the American Heart Association. *Circulation, 147*(8), e93-e621.

Turner-Stokes, L., Ashford, S., Esquenazi, A., Wissel, J., Ward, A. B., Francisco, G., . . . Simpson, D. M. (2018). A comprehensive person-centered approach to adult spastic paresis: a consensus-based framework. *Eur J Phys Rehabil Med, 54*(4), 605-617.

Verduzco-Gutierrez, M., Romanoski, N. L., Capizzi, A. N., Reebye, R. N., Kotteduwa Jayawarden, S., Ketchum, N. C., & O'Dell, M. (2020). Spasticity Outpatient Evaluation via Telemedicine: A Practical Framework. *Am J Phys Med Rehabil, 99*(12), 1086-1091.

Walker, H. W., Lee, M. Y., Bahroo, L. B., Hedera, P., & Charles, D. (2015). Botulinum toxin injection techniques for the management of adult spasticity. *PM R, 7*(4), 417-427.

Wang, H., Wang, L., Xiang, Y., Zhao, N., Li, X., Chen, S., . . . Li, G. (2017). Assessment of Elbow Spasticity with Surface Electromyography andMechanomyography based on Support Vector Machine. *IEEE Engineering in Medicine and Biology Society.*, 3860–3863.

Ward, A. B., Aguilar, M., De Beyl, Z., Gedin, S., Kanovsky, P., Molteni, F., . . . Yakovleff, A. (2003). Use of botulinum toxin type A in management of adult spasticity--a European consensus statement. *J Rehabil Med, 35*(2), 98-99.

Weiss, E., & Lin, D. (2007). *Spasticity, in Therapeutic uses of Botulinium Toxin*: Human Press.

Weizman, Y., Tirosh, O., Fuss, F. K., Tan, A. M., & Rutz, E. (2022). Recent State of Wearable IMU Sensors Use in People Living with Spasticity: A Systematic Review. *Sensors (Basel), 22*(5).

Werneke, M. W., Deutscher, D., Grigsby, D., Tucker, C. A., Mioduski, J. E., & Hayes, D. (2021). Telerehabilitation During the COVID-19 Pandemic in Outpatient Rehabilitation Settings: A Descriptive Study. *Phys Ther, 101*(7).

Winstein, C. J., Rose, D. K., Tan, S. M., Lewthwaite, R., Chui, H. C., & Azen, S. P. (2004). A randomized controlled comparison of upper-extremity rehabilitation strategies in acute stroke: A pilot study of immediate and long-term outcomes. *Arch Phys Med Rehabil, 85*(4), 620-628.

Wissel, J., MD, Manack, A., & Brainin, M. (2013). Toward an epidemiology of poststroke spasticity. *American Acadamey of Neurology, 80*(2), 13-19.

Wissel, J., Ward, A. B., Erztgaard, P., Bensmail, D., Hecht, M. J., Lejeune, T. M., . . . Tieranta, N. (2009). European consensus table on the use of botulinum toxin type A in adult spasticity. *J Rehabil Med, 41*(1), 13-25.

Wosik, J., Fudim, M., Cameron, B., Gellad, Z. F., Cho, A., Phinney, D., . . . Tcheng, J. (2020). Telehealth transformation: COVID-19 and the rise of virtual care. *J Am Med Inform Assoc, 27*(6), 957-962.

Wu, Y. N., Park, H. S., Chen, J. J., Ren, Y., Roth, E. J., & Zhang, L. Q. (2018). Position as Well as Velocity Dependence of Spasticity-Four-Dimensional Characterizations of Catch Angle. *Front Neurol, 9*, 863.

Wu, Y. N., Park, H. S., Chen, J. J., Ren, Y., Roth, E. J., & Zhang, L. Q. (2018). Position as Well as Velocity Dependence of Spasticity-Four-Dimensional Characterizations of Catch Angle. *Front Neurol, 9*, 863.

Weiss, E., & Lin, D. (2007). *Spasticity, in Therapeutic uses of Botulinium Toxin*: Human Press.

Wissel, J., MD, Manack, A., & Brainin, M. (2013). Toward an epidemiology of poststroke spasticity. *American Acadamey of Neurology, 80*(2), 13-19.

Yiannakopoulou E. (2015). Serious and long-term adverse events associated with the therapeutic and cosmetic use of botulinum toxin. *Pharmacology*, *95*(1-2), 65–69. https://doi.org/10.1159/000370245

Yang, Y.-H., Ruan, S.-J., Chen, P.-C., Liu, Y.-T., & Hsueh, Y.-H. (2020). A Low-Cost Wireless Multichannel Surface EMG Acquisition System. *IEEE Consumer Electronics Magazine, 9*(5), 14-19.

Yamaguchi, T., Hvass Petersen, T., Kirk, H., Forman, C., Svane, C., Kofoed-Hansen, M., Boesen, F., & Lorentzen, J. (2018). Spasticity in adults with cerebral palsy and multiple sclerosis measured by objective clinically applicable technique. Clinical neurophysiology : official journal of the International Federation of Clinical Neurophysiology, 129(9), 2010–2021.

Yassin, M. M., Saber, A. M., Saad, M. N., Said, A. M., & Khalifa, A. M. (2021). Developing a Low-cost, smart, handheld electromyography biofeedback system for telerehabilitation with Clinical Evaluation. *Medicine in Novel Technology and Devices, 10*.

Yu, S., Chen, Y., Cai, Q., Ma, K., Zheng, H., & Xie, L. (2020). A Novel Quantitative Spasticity Evaluation Method Based on Surface Electromyogram Signals and Adaptive Neuro Fuzzy Inference System. *Front Neurosci, 14*, 462.

Zeng, H., Chen, J., Guo, Y., & Tan, S. (2020). Prevalence and Risk Factors for Spasticity After Stroke: A Systematic Review and Meta-Analysis. *Front Neurol, 11*, 616097.

Zhang, X., Tang, X., Zhu, X., Gao, X., Chen, X., & Chen, X. (2019). A Regression-Based Framework for Quantitative Assessment of Muscle Spasticity Using Combined EMG and Inertial Data From Wearable Sensors. *Front Neurosci, 13*, 398.

Zorowitz, R. D., Gillard, P. J., & Brainin, M. (2013). Poststroke spasticity Sequelae and burden on stroke survivors and caregivers. *American Acadamey of Neurology, 80*(2), 45-52.

Zurawski, E., Behm, K., Dunlap, C., Koo, J., Ismail, F., Boulias, C., . . . Phadke, C. P. (2019). Interrater Reliability of the Modified Ashworth Scale with Standardized Movement Speeds: A Pilot Study. *Physiother Can, 71*(4), 348-354.

Appendices

Appendix A: Virtual Spasticity Assessment Online Survey

Virtual Spasticity Assessment Process

A Survey from the University of Alberta Faculty of Rehabilitation Medicine

Principal Investigator:
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780-563-0068
dan.gillespie@ualberta.ca

Before beginning the survey, please read the following to provide your informed consent.

Invitation to participate
You are invited to participate in a 5-8 minute survey about your experiences and perspectives on the assessment of spasticity within your practice.

What is the purpose of this research?
The information gathered within this research will assist in developing an optimal virtual procedure to assess spasticity remotely.

Who are we?
Dan Gillespie is a PhD candidate in the Faculty of Rehabilitation Medicine who is interested in spasticity assessment using information communications technology. Dan is currently teaching an introduction to telerehabilitation professional development course with the University of Alberta Linked Here:
https://www.ualberta.ca/rehabilitation/professional-development/introduction-to-telerehabilitation.html

Dr. Trish Manns is the Dan's PhD supervisor, and a researcher in the Faculty of Rehabilitation Medicine at the University of Alberta. Her research interests focus on strategies to maintain or improve health and function in individuals with stroke.

Dr. Sean Dukelow is a clinician-scientist at the University of Calgary and Foothills Medical Centre. He is a practicing physiatrist in Calgary, Alberta who is part of Dan's doctoral committee. Dr. Dukelow has extensive experience in assessing and treating individuals with spasticity.

What is involved?
Your participation is entirely voluntary. If you choose to participate you will complete a short (5-8 minute) online survey that asks about your perceptions and experience in the assessment of spasticity both from a traditional in-person and virtual or remote assessment perspective.

Benefits & Risks
While there are no direct personal benefits to participation, there are no anticipated risks.

Confidentiality and Anonymity
The information that you will share will remain strictly confidential and will be used solely for the purposes of this research. The only people who will have access to the research data are Dan Gillespie, Dr. Trish Manns, and the Research Ethics Board as well as University of Alberta auditors. No personal or identifying information will be required for this survey. Should you wish to participate in an optional spasticity focus group you will be required to provide your email within the survey.

Data Storage
Electronic copies of the survey will be encrypted and stored on a password- protected computer in the Faculty of Rehabilitation Medicine at the University of Alberta. Data will be stored for 5 years prior to being deleted.

Voluntary Participation
You are under no obligation to participate and if you choose to participate, you may refuse to answer questions that you do not want to answer. Should you choose to withdraw midway through the electronic survey simply close the link and no responses will be included. Given the anonymous nature of the survey, once you have submitted your responses it will no longer be possible to withdraw them from the study. At the end of the survey you will be asked to participate in an optional subsequent online zoom focus group.

Contact Information
If you have any questions or require more information about the study itself, you may contact the researcher at the following email address: dan.gillespie@ualberta.ca

This study has been approved by the Research Ethics Board at the University of Alberta Pro00101753 . If you have any questions regarding your rights as a research participant or how the research is being conducted you may contact the Research Ethics Office at 780-492-2615.

Thank you for considering taking part in this research.

What if I have other questions?
If you have any questions please contact us:
Dan Gillespie
dan.gillespie@ualberta.ca

University of Alberta Research Ethics Board: Pro00101753
* Required

1. Do you agree to participate in this study? *

Mark only one oval.

- ◯ Yes
- ◯ No *Skip to section 3 (Thank you for Visiting)*

Virtual Spasticity Assessment Process

Thank you for agreeing to fill out this survey, please answer the following questions to the best of your knowledge. The survey should take between 5-8 minutes of your time. At the end of this survey you will be asked to participate in an optional follow-up focus group using zoom to discuss the survey results along with sharing your views on the formation of an effective remote spasticity assessment procedure.

2. Please select your location of practice by province/territory *

Mark only one oval.

- ◯ Alberta
- ◯ British Columbia
- ◯ Manitoba
- ◯ New Brunswick
- ◯ Newfoundland & Labrador
- ◯ North West Territories
- ◯ Nova Scotia
- ◯ Nunavut
- ◯ Ontario
- ◯ Prince Edward Island
- ◯ Quebec
- ◯ Saskachewan
- ◯ Yukon

3. Please provide an estimate of the percentage of your clinical time associated with the management of spasticity *

Mark only one oval per row.

	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	1
Spasticity % of Clinical Time	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	(

4. Do you believe the ability to offer spasticity assessment at a distance would be beneficial to your practice? *

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Not at all Beneficial	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	Extremely Beneficial

5. Have you performed an initial or follow up spasticity assessments virtually? (eg. using telephone, videoconferencing, other technology) Please select all options that apply. *

Check all that apply.

- [ ] Yes (Initial Assessment)
- [ ] Yes (Follow-Up Assessment)
- [ ] No
- [ ] Other: _____

6. If you answered "Yes" to performing an "initial" virtual spasticity assessment previously, how satisfied were you with the experience?

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Not at all satisfied	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	Extremely satisfied

7. If you answered "Yes" to performing a "follow up" virtual spasticity assessment previously, how satisfied were you with the experience?

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Not at all satisfied	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	Extremely Satisfied

8. If you responded "Yes" to performing a virtual spasticity assessment, please indicate the type and percentage of use of technology in providing your virtual spasticity assessments.

Mark only one oval per row.

	Not Used	<20%	20-40%	40-60%	60-80%	80-100%
Telephone	◯	◯	◯	◯	◯	◯
Commercial Videoconferencing (eg. FaceTime, Zoom, Skype etc.)	◯	◯	◯	◯	◯	◯
Medical Grade Videoconferencing (eg. Provinical telehealth systems	◯	◯	◯	◯	◯	◯
Email/Fax correspondence	◯	◯	◯	◯	◯	◯
Other	◯	◯	◯	◯	◯	◯

9. Please indicate the approximate percentage of each condition typically seen in your spasticity caseload? (*note: % does not have to equal 100%)

Mark only one oval per row.

	<20%	20-40%	40-60%	60-80%	>80%
Stroke	◯	◯	◯	◯	◯
Complete Spinal Cord Injury	◯	◯	◯	◯	◯
Incomplete Spinal Cord Injury	◯	◯	◯	◯	◯
Cerebral Palsy	◯	◯	◯	◯	◯
Traumatic Brain Injury	◯	◯	◯	◯	◯
Multiple Sclerosis	◯	◯	◯	◯	◯
Other Conditions	◯	◯	◯	◯	◯

10. Please indicate the approximate percentage of clients presenting with spasticity related to the following regions. (*note % do not have to equal 100%)

Mark only one oval per row.

	<20%	20-40%	40-60%	60-80%	>80%
Neck Region	◯	◯	◯	◯	◯
Shoulder	◯	◯	◯	◯	◯
Elbow	◯	◯	◯	◯	◯
Wrist/Hand	◯	◯	◯	◯	◯
Trunk	◯	◯	◯	◯	◯
Hip	◯	◯	◯	◯	◯
Knee	◯	◯	◯	◯	◯
Foot/Ankle	◯	◯	◯	◯	◯

11. In completing your usual in person spasticity assessment please rate the usefulness of the following assessment items from "most essential" to "least essential" in regards to how these items inform your intervention/treatment planning. *

Mark only one oval per row.

	1 Least Essential	2	3	4 Somewhat Essential	5	6	7 Most Essential
Presence of Pain	◯	◯	◯	◯	◯	◯	◯
Muscle Tone (Resistance to passive movement)	◯	◯	◯	◯	◯	◯	◯
Bladder/Bowel Function	◯	◯	◯	◯	◯	◯	◯
Presence of Infection	◯	◯	◯	◯	◯	◯	◯
Range of Motion	◯	◯	◯	◯	◯	◯	◯
Functional Mobility	◯	◯	◯	◯	◯	◯	◯
Falls Risk	◯	◯	◯	◯	◯	◯	◯
Risk for Pressure Ulcer/Skin Breakdown	◯	◯	◯	◯	◯	◯	◯
Bracing Comfort and Fit	◯	◯	◯	◯	◯	◯	◯
Adaptive Equipment Use	◯	◯	◯	◯	◯	◯	◯
Other	◯	◯	◯	◯	◯	◯	◯

12. Please add any other assessment information not listed above, that is pertinent to the assessment of spasticity.

_____

Thank you for your responses. Please click this link: https://forms.gle/wTA9GwJqF5JsSbrPA if you would like to participate in an upcoming ZOOM focus group where we will present the survey results and discuss the topic of virtual spasticity assessment. Please contact us with any questions related to this survey.

Our contact information: Dan Gillespie dan.gillespie@ualberta.ca or Trish Manns trish.manns@ualberta.ca

Appendix B: Spasticity Assessment Focus Group Interview Questions.

Spasticity Assessment Focus Group Questions

1. What are the essential elements required for the assessment of spasticity?
2. How are treatment decision made in the management of spasticity?
3. What treatments in the management of spasticity would be appropriate for remote delivery?
4. What have been some of the challenges experienced in performing spasticity assessments remotely?
5. What have been some of the successes experienced in performing spasticity assessments remotely?
6. Where would remote spasticity assessments best take place for the patient? For example, In the patient's own home, within their family physicians' office, or telehealth site at local hospital.
7. With the potential to offer remote spasticity assessments are there concerns about changes in workload or workload management?
8. Would an objective measure of muscle tone (e.g., force measure or surface electromyography) responses during passive movement be beneficial to either remote and in-person practice?
9. Would a wearable device worn by a patient for example an accelerometer or surface electromyography sensor be useful in determining treatment recommendations?
10. How are follow up assessments arranged with patients?

Appendix C: Email correspondence questions directed to spasticity specialists.

Questions emailed to physiatrists requesting their responses to the 6:00 min video presented on the proposed development of a spasticity assessment device and software application.

1. Would transmitting measures of joint velocity, ROM, Force, and sEMG be helpful in performing initial or follow up virtual spasticity assessments?
2. What problems do you foresee with using a device like this?
3. Would this device be useful for in-person consultations as well?
4. Could this device be useful in training other clinicians on how to assess spasticity?
5. Do you need more clarification on this device at this time?

Appendix D: Sample Size Calculation for Predicted ICC (ICC = 0.7) and desired 95% confidence interval (0.54).

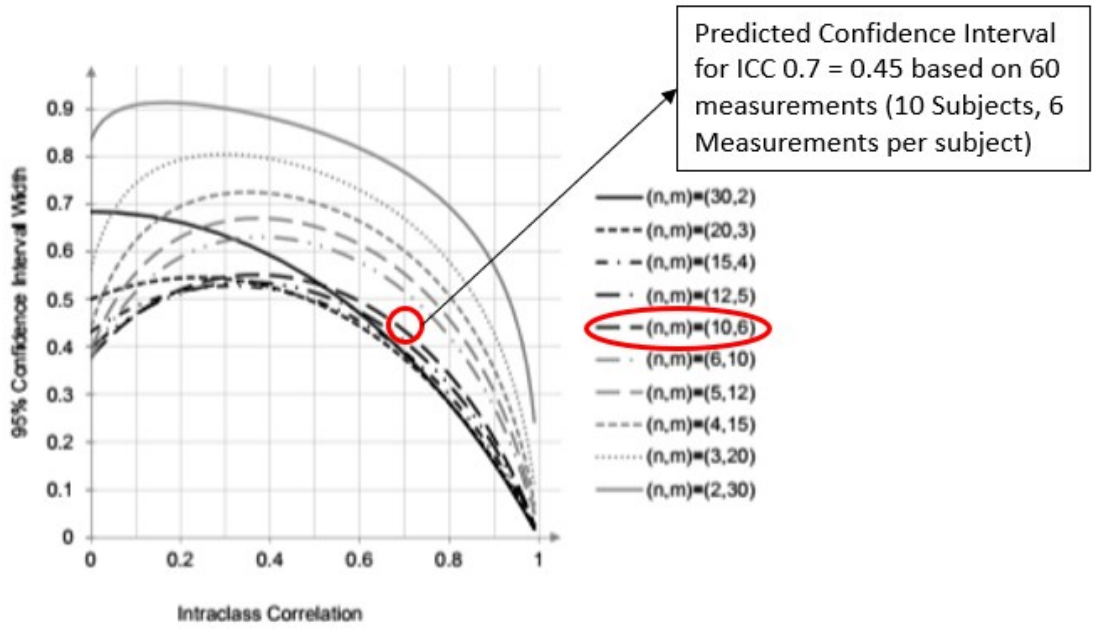


Figure 8.3.3: Expected width of the 95% confidence interval as a function of ICC for $n \times m = 60$ measurements.

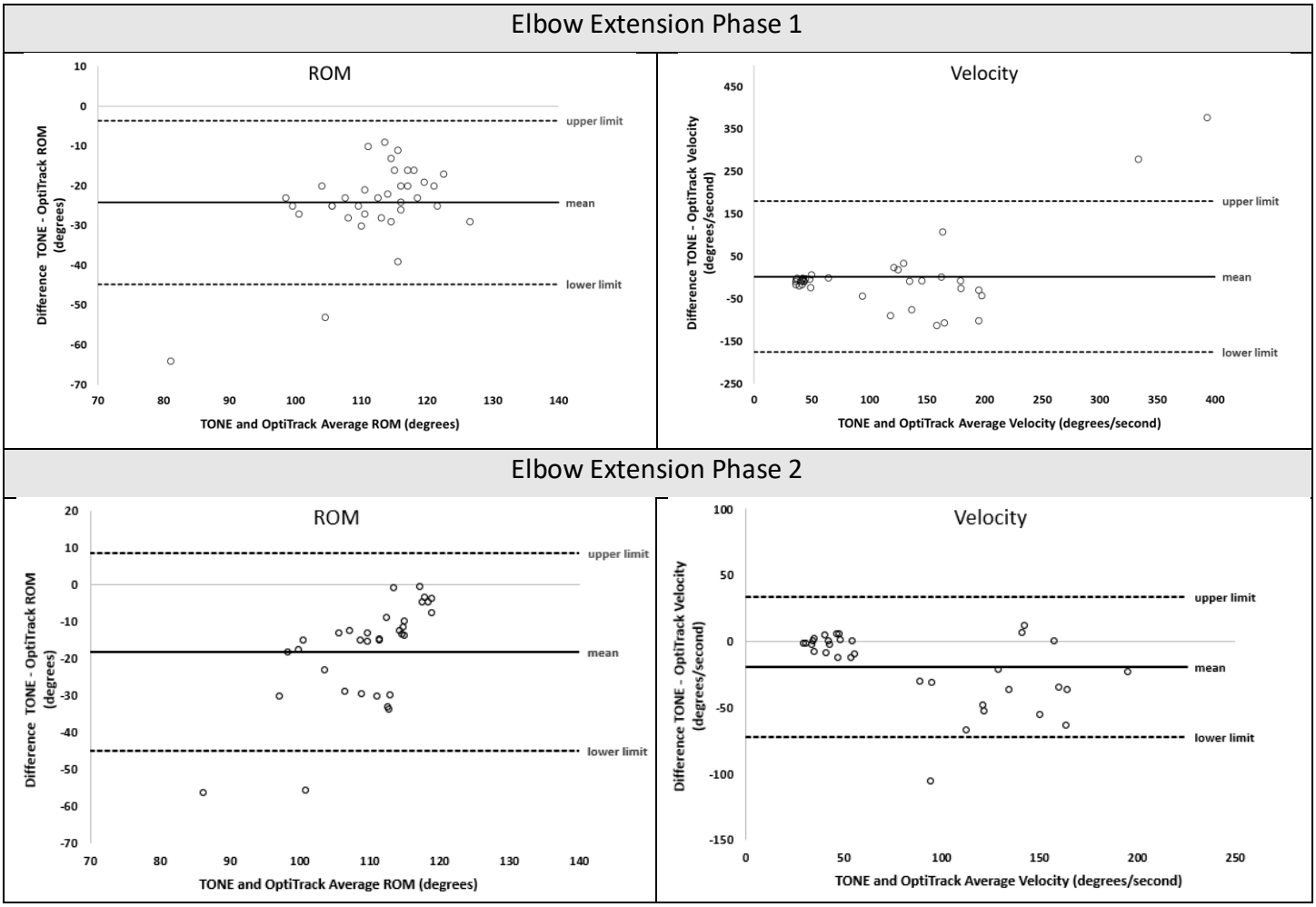
Predicted ICC = 0.7

Desired Confidence Interval = Predicted ICC X 0.8

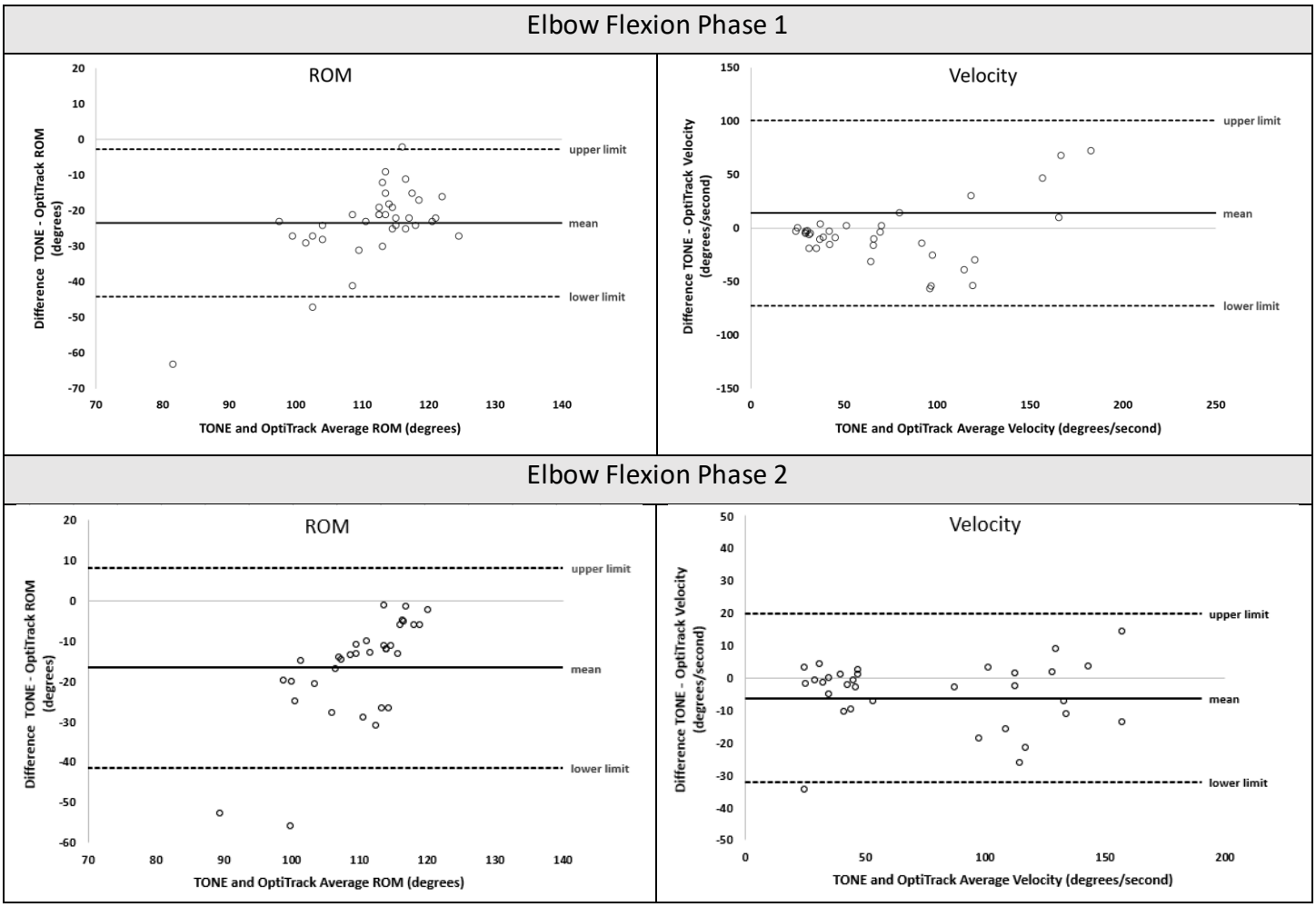
Desired Confidence Interval = 0.54

Figure adapted from Gwet, (2014).

Appendix E: Bland-Altman Plots comparing ROM and average velocity measures between TONE & OptiTrack



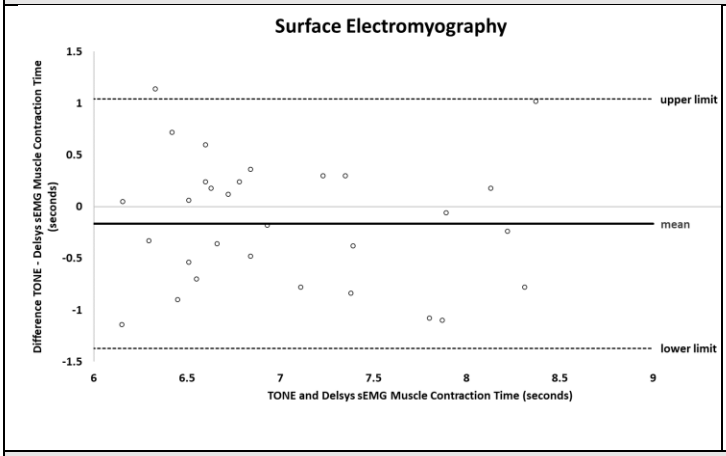
Bland-Altman Plots comparing ROM and average velocity measures for elbow extension Phase 1 (n=34) and elbow extension Phase 2 (n=32).

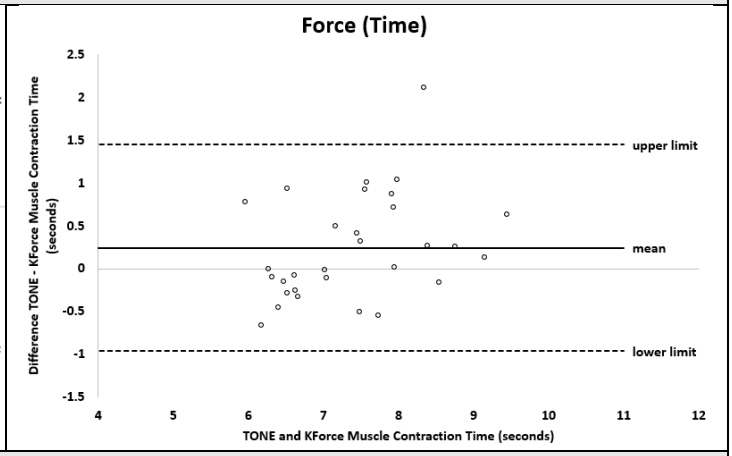


Bland-Altman Plots comparing ROM and average velocity measures for elbow flexion Phase 1 (n=34) and elbow extension Phase 2 (n=32).

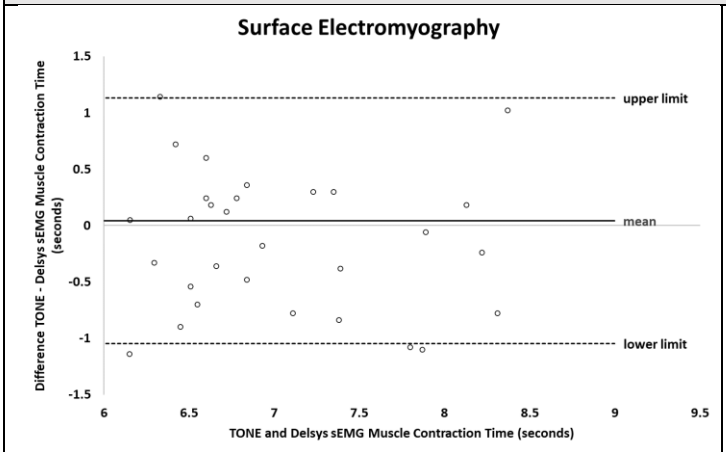
Appendix F: Bland-Altman Plots comparing muscle contraction on time and average force between TONE and reference standards.

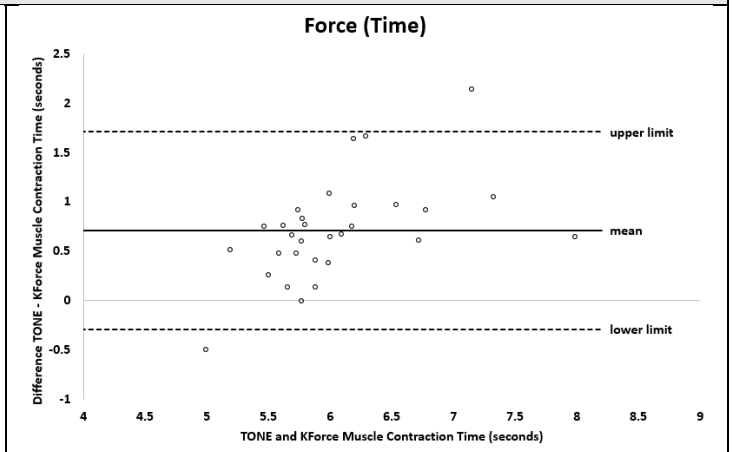
Biceps Muscle Contraction "On-Time" Phase 1



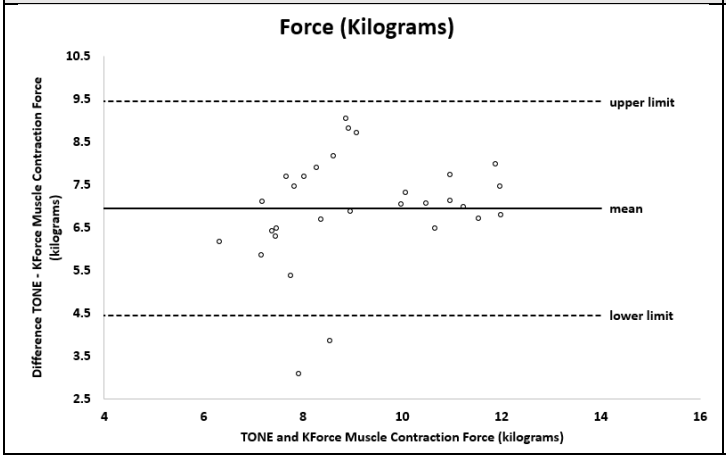


Biceps Muscle Contraction "On-Time" Time Phase 2

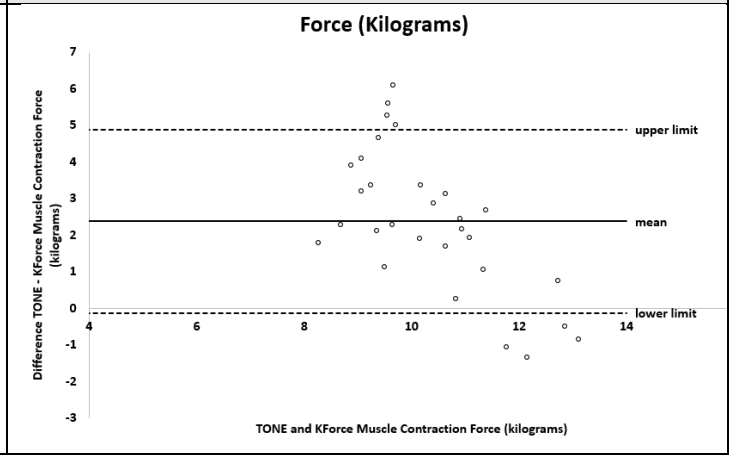




Biceps Muscle Contraction Force Phase 1



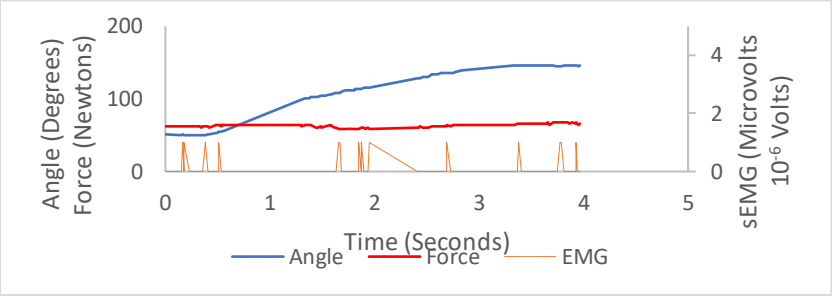
Biceps Muscle Contraction Force Phase 2



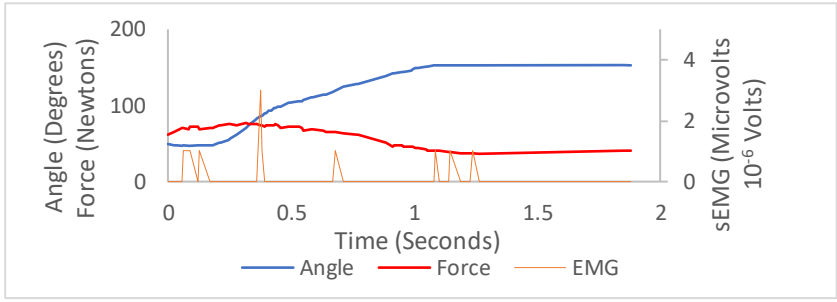
Bland-Altman Plots comparing muscle contraction time at 50 percent of maximal voluntary contraction and average force measures for elbow flexion (n=30) measures for Phase 1 & Phase 2 of testing.

Appendix G: Example Angle, Force, EMG versus time tracings for individual participants.

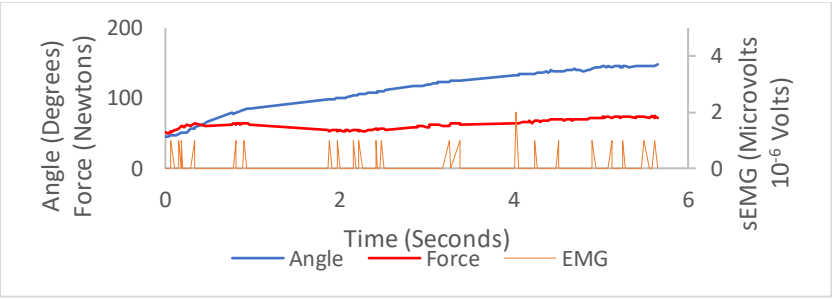
P01 Telehealth Affected Limb Slow



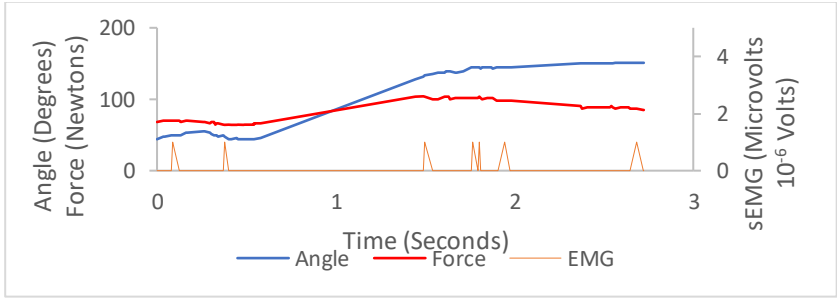
P01 Telehealth Affected Limb Fast Extension



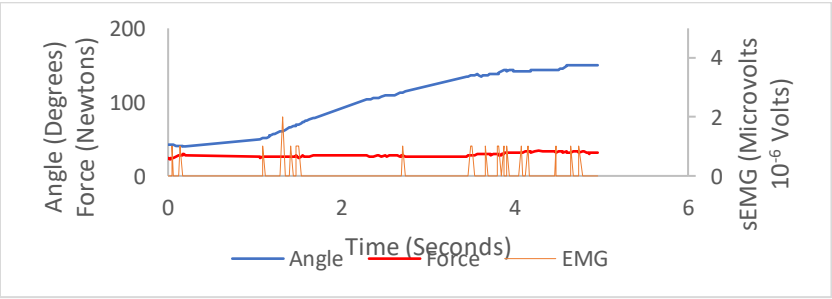
P01 In Person Affected Limb Slow Extension



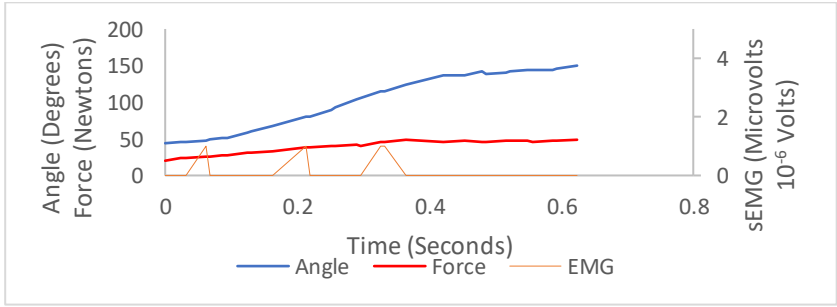
P01 In Person Affected Limb Fast Extension



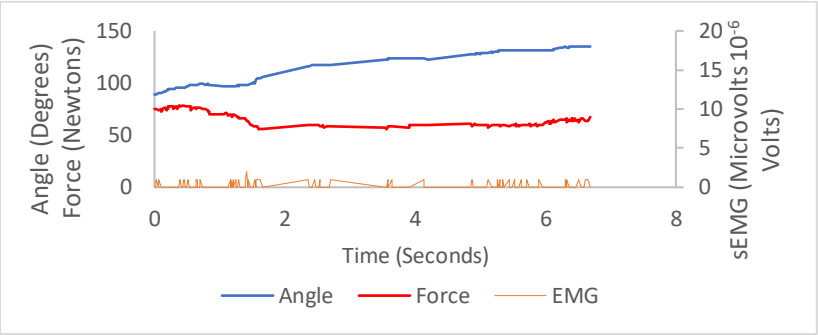
P01 In Person Non- Affected Limb Slow Extension



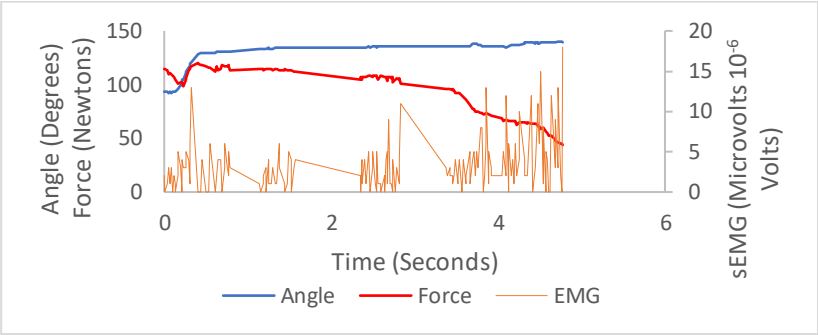
P01 In Person Non-Affected Limb Fast Extension



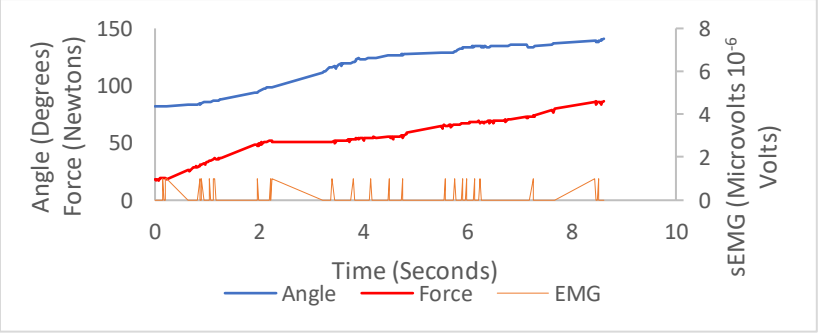
P02 Telehealth Affected Limb Slow



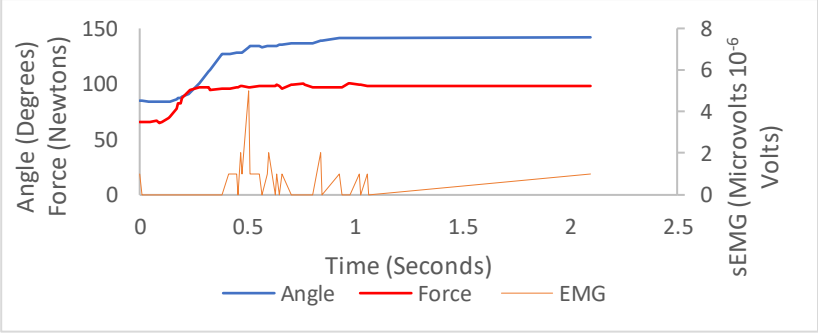
P02 Telehealth Affected Limb Fast Extension



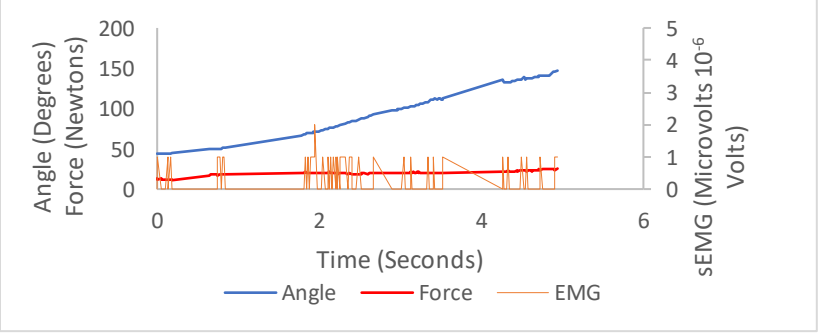
P02 In Person Affected Limb Slow Extension



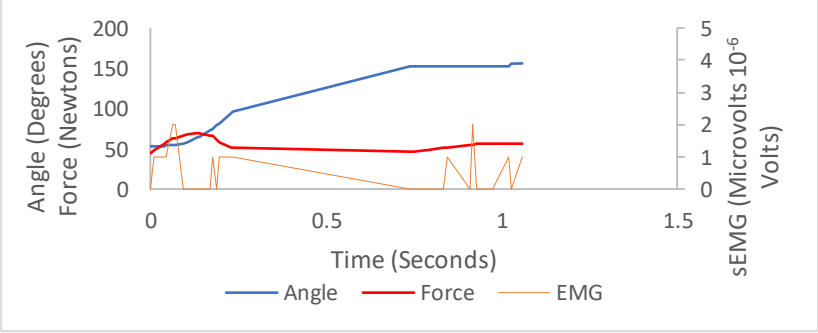
P02 In Person Affected Limb Fast Extension



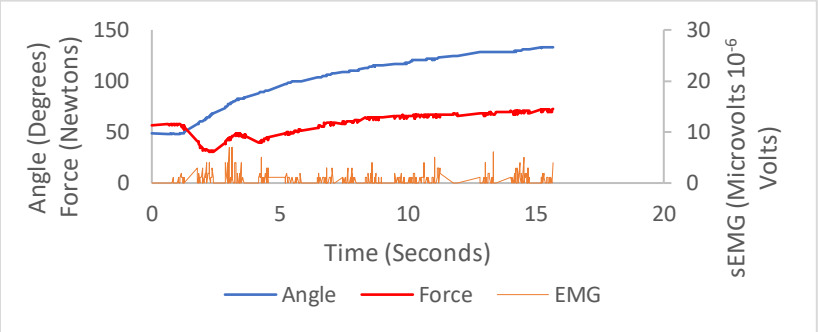
P02 In Person Non- Affected Limb Slow Extension



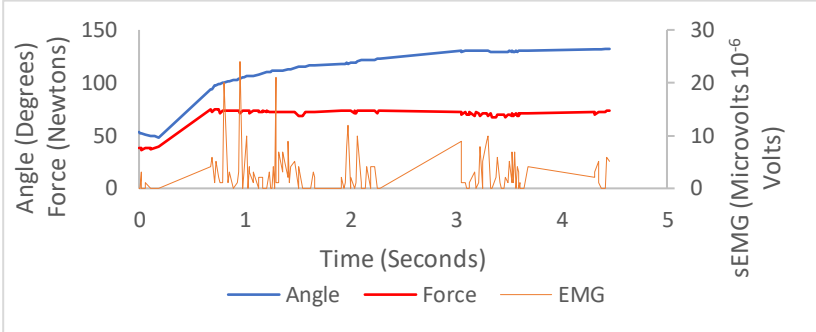
P02 In Person Non-Affected Limb Fast Extension



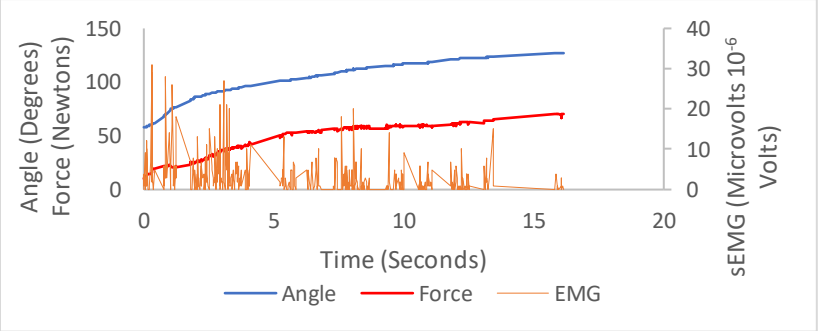
P03 Telehealth Affected Limb Slow



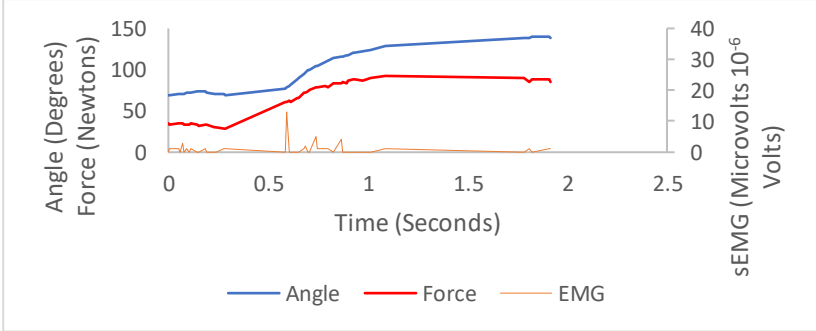
P03 Telehealth Affected Limb Fast Extension



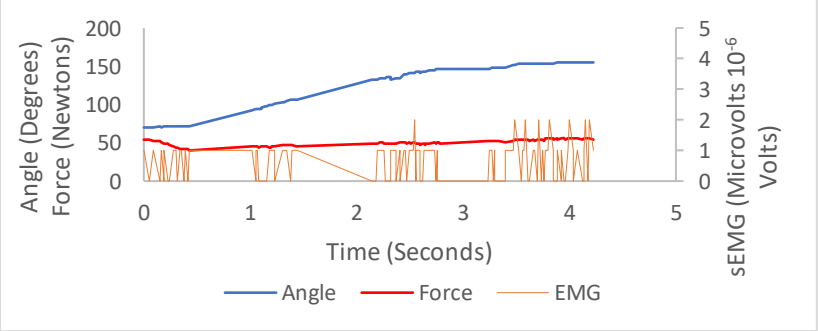
P03 In Person Affected Limb Slow Extension



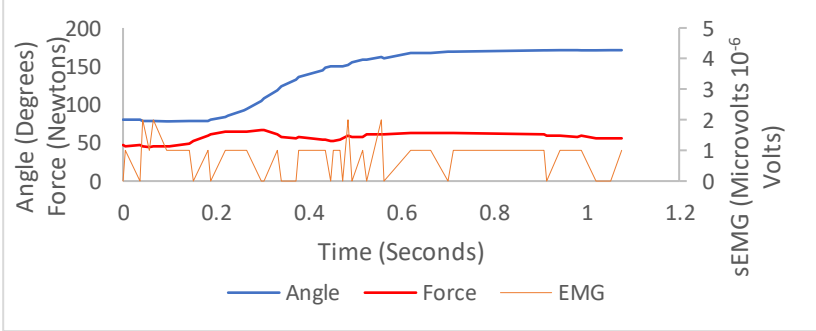
P03 In Person Affected Limb Fast Extension



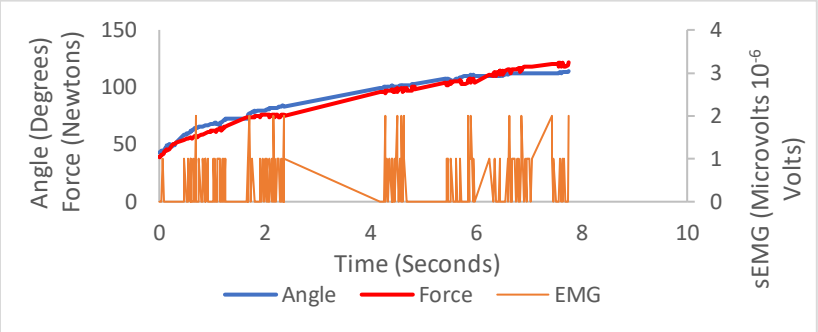
P03 In Person Non- Affected Limb Slow Extension



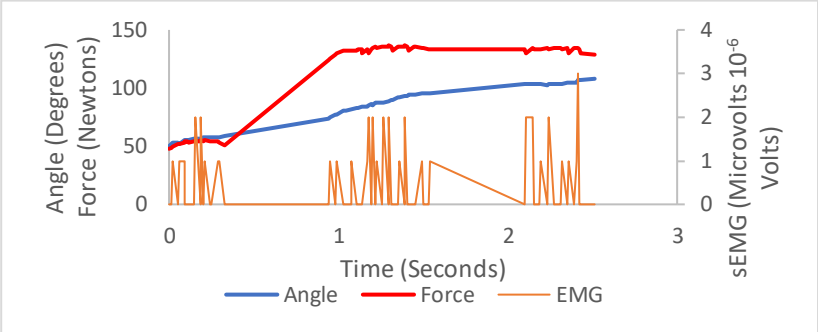
P03 In Person Non-Affected Limb Fast Extension



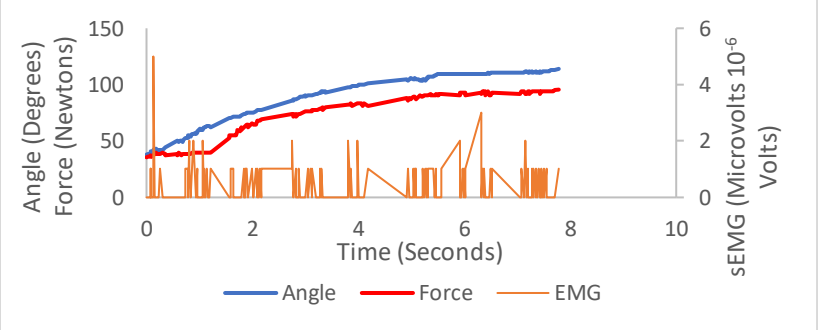
P04 Telehealth Affected Limb Slow



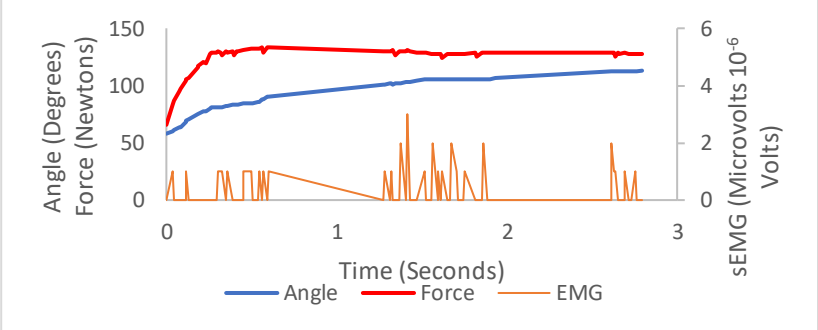
P04 Telehealth Affected Limb Fast Extension



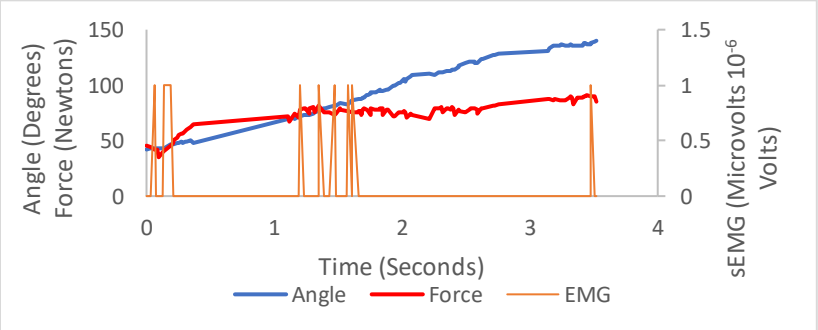
P04 In Person Affected Limb Slow Extension



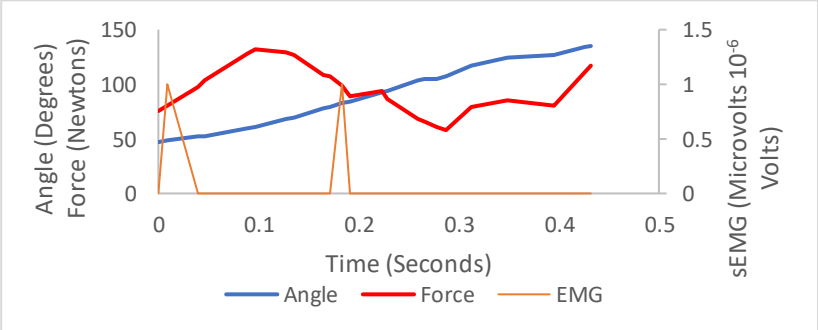
P04 In Person Affected Limb Fast Extension



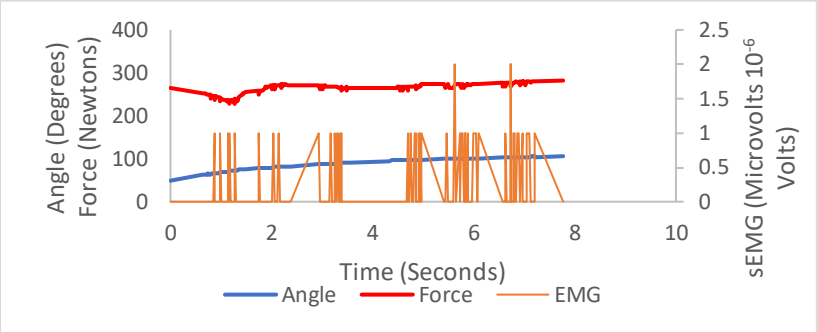
P04 In Person Non-Affected Limb Slow Extension



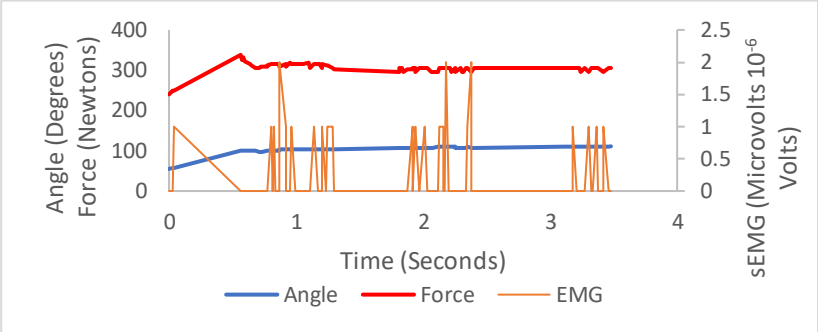
P04 In Person Non-Affected Limb Fast Extension



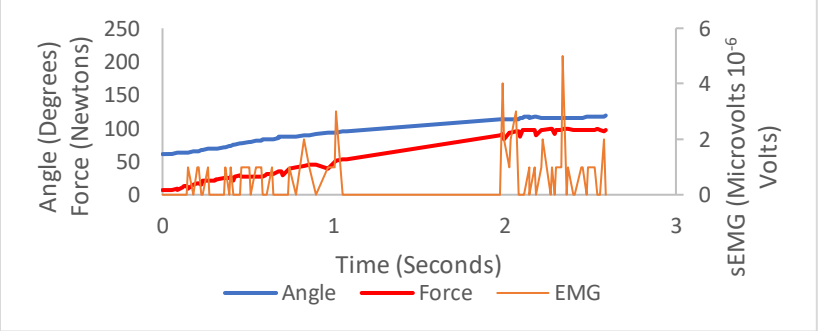
P05 Telehealth Affected Limb Slow



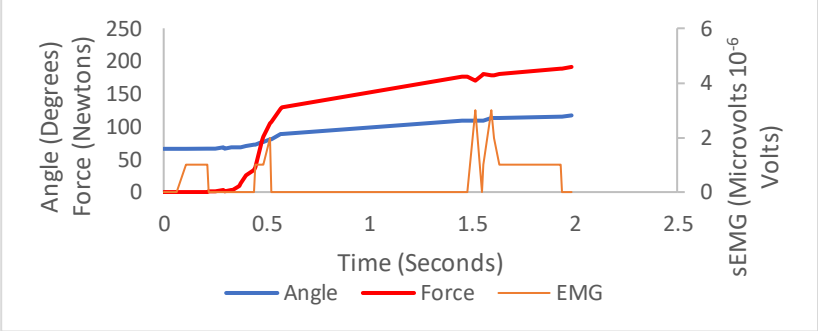
P05 Telehealth Affected Limb Fast Extension



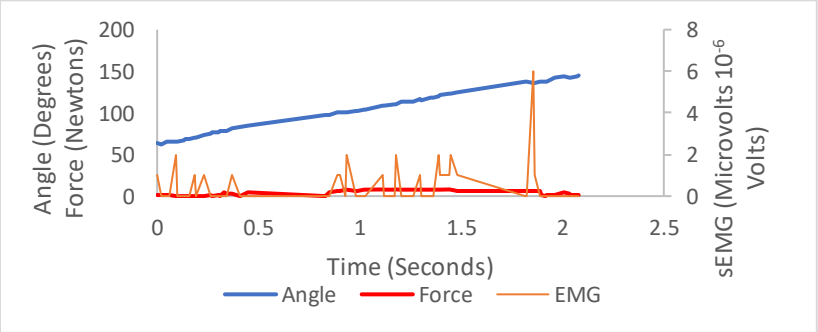
P05 In Person Affected Limb Slow Extension



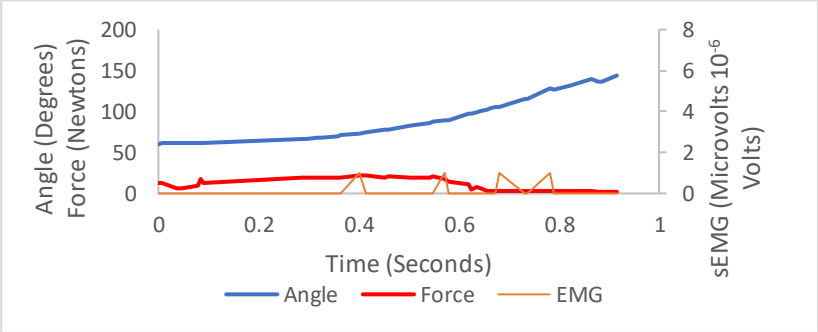
P05 In Person Affected Limb Fast Extension



P05 In Person Non- Affected Limb Slow Extension



P05 In Person Non-Affected Limb Fast Extension



Appendix H: Tone Device Participant Feedback Survey.

Tone Device Participant Feedback Survey

Survey Item No.	Survey Text
1	The TONE device was comfortable to wear. Rating: Strongly Disagree (0) to Strongly Agree (10)
2	The virtual assessment procedure using the TONE device went smoothly. Rating: Strongly Disagree (0) to Strongly Agree (10)
3	I felt I could effectively interact with the evaluator during the virtual assessment. Rating: Strongly Disagree (0) to Strongly Agree (10)
4	I would be happy to be assessed using the TONE device in the future. Rating: Strongly Disagree (0) to Strongly Agree (10)
5	Did you experience any pain or discomfort during the assessment using the Tone device? Rating: Yes/No
6	What changes would you make to the TONE device? (Open ended question)
7	What changes would you recommend to improve the virtual assessment experience? (Open ended question)