Design of an Upper-Limb Exoskeleton for Functional Assistance of Bimanual Activities of Daily Living

By

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DEDICATION

To Family

To Gloria, my wife, for keeping me anchored through the hardest parts of life and for walking through this graduate school adventure with me

To my children, Joseph and Annie, who will probably forever be slightly confused about the distinction between school and work.

To my Grandmother, Marjorie Gasser, through whom I received much encouragement and funding to embark on many learning adventures – a piece of her love of life, science, and learning forever lives on in her children, grandchildren, and the many lives she touched.

To my parents, Jim and Marie Gasser, who took responsibility to give me an excellent foundation in faith, education, and love as mentors and home school parents.

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No man is an island,
Entire of itself,
Every man is a piece of the continent,
A part of the main.
If a clod be washed away by the sea,
Europe is the less.
As well as if a promontory were.
As well as if a manor of thy friend's
Or of thine own were:
Any man's death diminishes me,
Because I am involved in mankind,
And therefore never send to know for whom the bell tolls;
It tolls for thee.

~John Donne, 1624

We are like dwarfs sitting on the shoulders of giants. We see more, and things that are more distant, than they did, not because our sight is superior or because we are taller than they, but because they raise us up, and by their great stature add to ours.

~John of Salisbury, 1159

During this endeavor, it has been my pleasure to work under and alongside many great individuals. I have been inspired, challenged, mentored, and humbled many times by those who have gone before, walked in the path alongside, and followed behind me – each adding clarity, light, and direction to this meandering path of assistive technology that has been my privilege to walk. To mention and pay proper due to each individual would consume excessive space and words to allow for it to be written here, but it is my hope that those whom I have had opportunity to know have also experienced in some measure my thanks and my respect.

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CHAPTER I

INTRODUCTION

Loss of voluntary upper-limb mobility greatly impacts the ability of an individual to interact with even basic activities of life. This dissertation describes the research and design efforts performed at the Center for Rehabilitation Engineering and Assistive Technology (CREATE) at Vanderbilt University on the development of an upper-limb exoskeleton intended to enable individuals with hemiparesis of the hand and arm to regain the ability to perform some bimanual activities of daily living. The introduction contains a background on some of the causes and populations statistics of those affected by upper extremity hemiparesis, a review of the current state of the art in hand and arm assistive devices, and a summary of the existing needs that motivated this research. Chapter II describes the mechanical design of the structure of the upper-limb exoskeleton, the actuator units, and discusses some fatigue life testing to ensure the viability of the system to translate from a research prototype to a production medical device. Chapter III covers the development of the control methodology, necessary electronics, and the control software. Chapter IV summarizes the results of a clinical study of the efficacy of the developed exoskeleton for four research subjects having varying degrees of chronic right arm motor loss following stroke. Finally, Chapter V is a concluding discussion of the overall research project and includes the future work from which the research with this device would benefit.

1. Demographics and Needs of Individuals with Upper Extremity Hemiparesis

Functional motor loss of the upper-limb can occur following any trauma resulting in brain or nervous system damage. Direct spinal cord injury at a level sufficiently high to affect arm mobility will most likely affect all limbs in a bilateral manner, leaving the individual with complete or partial tetraplegia. In contrast, a stroke typically affects one half of the body due to its localized occurrence in either the right or left-brain hemisphere, and because of the many brain structures that might be damaged, create a wide range of upper-limb motor and sensory deficits as well as various cognitive challenges. Other traumatic injuries, such as nerve damage or brachial plexus injury, create disabilities that are localized and affect only that portion of the limb that is distal to

the injury. While technology developed for daily upper-limb assistance may apply to any of these broad categories, focus for this research was given to individuals with hemiparesis following stroke because it is the largest global contributor to hemiparetic motor loss.

Approximately 795,000 individuals per year suffer a stroke in the US [1], of whom roughly 660,000 survive [2], yielding a prevalence of this population in the US of approximately 6.8 million [1]. Of the 660,000 stroke survivors per year, approximately 77.4% experience upper limb motor deficit [3] following the stroke. A study of the long-term outcomes of stroke (i.e., 4-years post-stroke) found that 57% had recovered “fair to good" arm function in the affected arm [4] based on a score of at least 20 out of 66 possible points in the Fugl-Meyer motor assessment [5]. As such, 43% were left with an essentially non-functional arm. The same study further found that 67% of chronic post-stroke individuals felt that loss of arm function was a major problem. Thus, based on a Fugl-Meyer score of less than 20, one can estimate a prevalence of 2.25 million individuals (i.e., 43% of 77.4% of 6.8 million) in the US with a non-functional arm due to stroke. Alternatively, from the perspective of the patient, 3.5 million (i.e., 67% of 77.4% of 6.8 million) consider their loss of arm function to be a “major problem” four years after the stroke. If similar trends hold internationally, the world prevalence of individuals with a non-functional arm due to stroke would be approximately 20 times that of the US prevalence. As such, there is a significant need to restore hand and arm function in these individuals.

2. Overview of the Current State of the Art

The field of upper-limb assistive orthoses has seen a considerable amount of attention in recent years. Prior to 2010 nearly all devices were focused toward therapy, tetraplegic assistance, or augmentation of the healthy human hand in extreme tasks. More recently, a lot of attention has been given to the design of devices intended for therapy and assistance of impaired hands and arms for the intent of aiding the user in basic activities of daily living (ADLs).

In order to help address this need, several researchers have developed hand and arm exoskeletons to improve or restore function for this population. A recent review paper by Bos et al. presents a thorough survey of such upper-limb devices [6]. Such devices can roughly be classified as having one of two functional objectives – therapy or functional assistance. The objective of a therapeutic device is to facilitate functional recovery, while the objective of an

assistive device is to directly augment function. The former are more likely to be used while in a clinical setting, while the latter are intended for use in ADLs, and thus must be a wearable device portable enough to accompany the user.

A therapeutic device is intended to indirectly enhance hand and arm function by providing recovery through limb retraining and neural plasticity. Recent examples of therapeutic devices for recovery of hand and arm function are well summarized and described in several recent review papers [6]–[9]. Such devices offer the potential to remove a portion of the time and physical burden from a therapist by performing exercises in a precise and consistent manner over long periods of time with increased dosage for the patient. Additionally, they can provide a variety of directly reported measurements to assist with assessment of the therapeutic progression of an individual, and as such may offer insight into the stroke recovery process [10].

In contrast to a therapeutic device, the intent of an assistive device is to enhance function directly (i.e., while the device is being worn). The two devices are complementary in a clinical context, but the design objectives and requirements are substantially different. Specifically, unlike a therapeutic device, an assistive device must be lightweight and portable; should provide useful levels of force and speed relative to ADLs; and must respond to volitional movement commands from the user. A thorough survey of such devices is given in [6], [9] and [11]. Most of the proposed hand devices for assistance fall into two major design categories: passive orthotic devices, and active exoskeletons.

The passive devices typically consist of an elastic member designed to assist with the opening of the hand for individuals with voluntary hand flexion but limited voluntary hand extension. A few examples of such passive devices are the SaeboFlex [12], SaeboGlove [13], and the HandSOME device [14]. These systems are lightweight, robust, and relatively inexpensive, but they all require that the user have good volitional flexion control and adequate hand strength to overcome the extensile force imposed by the orthotic. These passive devices are not indicated for use by individuals have significant hand tone or spasticity because the extensile force required in those situations would negate the ability to voluntarily close the hand.

Active exoskeletons can overcome the drawbacks of the passive systems because they can inject power into the system to enable increased grasp strength, hand opening, or a combination of the two. Because of this added power, active systems have the potential to be applicable to a wider user population with more diverse functional hand impairments including weakness of grasp,

inability to open the hand due to high levels of spasticity, and complete loss of motor function. Proposed active exoskeletons found in the literature can generally classed in one of three design categories: rigid robotic systems composed of joints and linkages with discrete centers of motion, soft robotic systems with distributed deformation guided by the user's skeletal structure, and flexure-based finger actuators.

Most rigid exoskeleton devices are composed of rigid finger linkages with electromechanical drive units with one actuation unit per aided finger. Other primary movers include pneumatics, Bowden cables, and shape memory alloys. A few examples of the rigid style of devices can be found in [15]–[21]. These devices can provide effective movement assistance, but entail several design challenges, including transmitting biomechanical levels of grasp or release assistance to the remote center of the finger joints without interfering with grasp or finger movement. Design solutions for doing so often require a high profile over the posterior aspect of the hand, which can interfere with ADLs performed in confined workspaces.

Soft exoskeletons, formed of fabric or polymer gloves that use either pneumatic actuation [22]–[30] or cable tendons (e.g. Bowden cables) [31]–[40], provide a structural impedance that is well-matched to the surface of the human body. Because of the inherently flexible nature of soft systems, they often conform well to variations in hand size, shape, and joint placement. Soft robotic approaches, however, entail design challenges associated with providing bidirectional actuation, and many employ off-board drive units associated with their pneumatic or cable drive systems. Such off-board drive units reduce the device mass imposed on the hand, which is desirable, but when used as an assistive device, the associated tether may interfere with performing ADLs, and the use of distributed apparatus may hinder adoption.

Another category of hand exoskeletons found in the literature is the sliding flexure design [41], [42]. Using sliding flexures has some of the benefits of both the rigid systems (bidirectional actuation, reduced modeling complexity, etc.) and some of the adaptability of the soft exoskeletons. However, generating adequate output forces and torques for ADLs entails some difficulty with this arrangement of actuator, so it has not seen widespread use.

Hand functionality in ADLs is strongly dependent upon the ability of the hand to be positioned and oriented in space by the arm. For people with significant hand hemiparesis following stroke, it is likely that the wrist and elbow will also have associated motor deficits. Despite the large number of assistive hand exoskeletons found in the published literature, few have

been combined with a wrist and/or elbow supporting orthotic device. A few notable exceptions are the MyoPro device by Myomo, Inc. [35], the SCRIPT orthoses [36], [37], and the system by Nycz et al. [29]. These devices are a combination of powered joints and passively repositionable systems to achieve support and orientation. However, to enable the loads required in ADL, these devices require relatively large drive systems having a mass that would not be consistent with a significant portion of the goal stroke population considered in this work. Additionally, an active exoskeleton requires a good control signal to cooperatively move with the arm but, as discussed later, a clear signal likely is not present.

Many ADL tasks could be accomplished using a simpler passive, repositionable orthotic support device like those commercially available for joint support following injury or surgery. If combined with a hand exoskeleton, the correct poses could potentially be achieved, but the ease of changing the joint settings is often not simple, and the combination would lack a consistent user control experience that could be inconvenient or confusing. These devices are generally meant to limit joint range of motion and therapy and are not specifically designed for load bearing activities consistent with ADLs.

This research proposes that an adequate solution to the ADL arm positioning and load challenge is a semi-passive orthosis (i.e., between powered exoskeleton and passive orthosis). An orthosis that can be readily repositioned by the user's unaffected hand and offers load support for the affected will be able to engage with the necessary bimanual ADLs without the mass associated with an active exoskeleton system.

Finally, powered exoskeleton control is a considerable challenge with the exoskeleton ideally having a fluid motion that follows, and augments, the user's natural motion and grasp. That becomes difficult following stroke because many of the physiologic hand and arm motor signals are absent or confused. Surface electromyography (sEMG) is a common control input strategy for prosthetics and exoskeletons for individuals with adequate volitional motion. However, for individuals with a high degree of hand and arm motor affectation, causing paresis, the signal is likely too weak to be useable. Additionally, the natural signal from the brain to the arm is confused following stroke and residual tone and spasticity further complicate the signal and may preclude use of sEMG as a control strategy even for patients with higher levels of strength. Other technologically advanced (e.g. EEG) or clinically invasive (implants) user inputs are beyond the

scope of this study and do not fit with the goals targeting the average individual living with chronic motor deficits following stroke.

3. Summary of Needs and Research Motivation

Many people experience a stroke each year and often lose hand and arm dexterity and strength as a result. Many of those thus affected have a sufficient degree of mobility and cognitive function to engage in typical daily actions, but they lack hand and arm strength on one side of the body, which greatly interferes with the ability to perform typical ADLs that are inherently bimanual in nature. Many of those thus affected also have moderate to strong hand tone and little voluntary hand motion, so donning of any device is necessarily an assisted or one-handed operation.

While most of the assistance devices discussed earlier are wearable and offer the necessary output forces required to perform basic ADLs, most also require a large power unit (motor/battery pack, pneumatic system, etc.) that greatly reduces the overall portability of the total system. The need for an offboard power unit may be acceptable in a non-ambulatory population that makes regular use a wheelchair for mobility, but it greatly impedes the potential for adoption by those having good ambulation but limited ability to carry objects of moderate mass. An offboard power unit also necessitates long transmission lines (Bowden cables, pneumatic hoses, etc.) that are cumbersome and create an undesirable risk of snagging on objects, and they further contribute to the overall personal impact (e.g. visual aesthetic) and effective volume of the device. A majority of the devices presented also have no clearly defined method of user control input, or they use a method of control (e.g. electromyography) that is not well suited to the stroke population of interest due to the inherently weak and/or confused signal coming from the brain to the involved hand and arm muscles.

Additionally, many devices incorporate high levels of complexity to enable individual actuation of each finger, and sometimes joints thereof, which results in a significant increase of mass upon the hand, complicated control strategies, and difficulty donning. High complexity also tends to equate with a high cost and increased failure modes, which in turn will contribute to the inability of many devices to translate into the medical device space outside of the academic research laboratory.

In summary, most existing devices cannot simultaneously: handle high loads created by elevated hand spasticity unless they are too massive or cumbersome for use by individuals with significant hand affectation; offer effective bidirectional (flexion and extension) actuation; or assist users with no volitional motion in the affected limb. Further, there is a lack of combined systems offering functional support for the hand, wrist, and elbow in a unified device with a mass consistent with the proposed stroke population. These limitations exclude most individuals with profound upper-extremity motor loss complicated by significant hand spasticity.

The remainder of this work presents the mechanical design (Chapter II) and user control interface (Chapter III) of a hand, wrist, and elbow exoskeleton for use by individuals with hemiparesis following stroke. The exoskeleton is a stand-alone wearable device with an active hand section and semi-passive locking wrist and elbow joints that provide static support but can be repositioned through the press of a button. Several individuals with hemiparesis following stroke were recruited for an exploratory protocol to investigate the level of upper-limb affectation for which the exoskeleton is an adequate intervention, results are shown in Chapter IV.

4. Design Objectives

When this work began in the spring of 2013, many design objectives were identified and others were subsequently added as increased knowledge was obtained directly from the designed device and indirectly from the concurrent work of others. The primary design considerations were as follows:

4.1 Foundational

While many devices have been designed that can produce appropriate motion in the hand, they are generally too complex, bulky, or the design simply cannot be translated into the home environment. Therefore, one objective of this research was to design a functional device that is foundational (a system that lacks unnecessary complexity in the current design but would fundamentally allow for adaptation later) in nature.

4.2 Modular

Since this is an exoskeleton for the upper-limb, and humans come in a variety of sizes, a certain level of modularity of components is beneficial as it allows smaller subsystems to be swapped for a more adaptable unit, while simultaneously allowing for a reduced number of parts/subsystems for production. This in turn leads to a preference for actuation units located as near to the point of actuation (e.g. drive units proximal to the driven joint) as possible so that a minimal number of components (wires, tendons, pneumatic lines, etc.) are needed to span moving joints and/or points of separation.

4.3 Minimal

There is a temptation to make new devices collect as much information about themselves and the user as possible. Sometimes this has great value as it can lead to new and interesting insights into the actual needs of the population under consideration. However, it also has a tendency to make devices bulky, increases the failure modes, increases overall cost, and generally limits the ability of the device to translate from the laboratory space and into general use. Therefore, this research adopted the goal of minimalism upon its outset; only the sensors and systems absolutely necessary to create the foundational device would be included, and all other possibilities noted for future potential.

4.4 Maintain Existing Sensation

As mentioned earlier, while 77.4% of individuals who have experienced a stroke have chronic upper-limb motor deficit, only 30.3% experience sensory deficit [3]. Therefore, it is clear that many individuals having decreased functional capability may still be able to engage tactilely in activities. Since this is the case, it is highly desirable to maintain the palmar aspect of the hand in as natural a state as possible (minimize structure, straps, etc.).

4.5 Minimize Impact, Maximize Portability

The intent of this device is to augment the existing hand, so it is desirable to produce a system that minimizes added mass and device volume. While this goal is intuitively obvious, it is

important given that many of the individuals who might benefit from a device like this also have significantly weakened joint structures (particularly subluxation of the shoulder joint). Since a maximal mass that would be tolerated by the wearer is difficult to clearly define, a hand exoskeleton mass target of less than or equal to the mass of the natural hand was adopted, which according to Clauser et al. [43] is approximately 400 g for a 50th percentile male. Total mass for the entire upper-limb exoskeleton should not exceed 1500 g which is all inclusive of drive units, structure, batteries, and electronics.

4.6 Goal ADLs and Required Grasps

Although the stroke population is highly heterogeneous in nature, a significant portion of the population is composed of individuals affected on only one side of the body. Therefore, it is expected that most fine motor tasks can be accomplished with the unaffected limb. The underlying functional objective of the hand exoskeleton described here is to provide the support function for performing bimanual ADL. As such, the device should enable the paretic hand to grasp and hold objectives, but once held, does not require dexterity or power for movement. Examples of such bimanual daily tasks include opening large jars, carrying two-handed baskets and trays (laundry baskets, food trays, etc.), restraining items to a surface with one hand while performing work on the item with the other hand (e.g. cutting of fruits and vegetables), and carrying smaller objects (grocery bags, water bottle, phone, etc.) in order to leave the unaffected limb free to perform fine motor tasks (e.g. unlocking a door, dialing a cell phone).

These activity types show that many bimanual activities of daily living are characterized by asymmetric hand function. Specifically, one hand will require power and dexterity, while the other hand will primarily provide a support function. This asymmetry of function has been well noted by a couple of recent design studies [44], [45]. As shown in [46], the majority of support grasps can be accomplished using the cylindrical, spherical, and platform power grasps. These grasps do not require a significant degree of independent finger motion. Therefore, the fingers can be actuated in unison as if the user were wearing a mitten instead of a glove.

4.7 Hand Forces and Speed

For the design of this exoskeleton, there are two types of force expectations that must be satisfied. The first is the ability to assist the weakened hand with adequate grasp force to accomplish a given task. Various grasp force requirements have been described in [47]–[50] and summarized for the purpose of hand prosthesis design by [51] and [52]. Of the tasks enumerated above, opening of jars is likely to require the highest contact forces, with an estimated combined fingertip force of 20-30 N as reported by [48]. With an assumed finger length of 100 mm, this indicates a required torque of 2-3 Nm at the metacarpophalangeal (MCP) joint. In addition to providing a sufficient grasp force, the exoskeleton must also be able to overcome the presence of involuntary hand flexion, resulting from the larger relative size of the forearm flexor muscles versus the extensors, when opening the hand. It is assumed that these forces will be lower than those required for grasp in a majority of individuals having muscle contractures. Therefore, assuming the actuation forces are bi-directionally symmetric, the magnitude of grasp forces should be sufficient for hand opening. These assumptions are consistent the results of a couple of published studies [53], [54] measuring small populations of individuals having involuntary hand flexion. Another important design factor for an exoskeleton of this nature is the ability to provide appropriate joint velocities, and specifically to move at a speed representative of those used during ADLs. Based on studies described in [51], [52] a half-ROM bandwidth of approximately 1.5 Hz is generally adequate for ADLs.

CHAPTER II

MECHANICAL DESIGN

Described in this chapter is the design of the mechanical systems for the Vanderbilt Upper-Limb Exoskeleton. The hand exoskeleton concept was first described at the 2105 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society in Milan, Italy [55], and a further expansion of the hand design and first study subject results can be found in a paper presented at the 2017 IEEE International Conference on Rehabilitation Robotics hosted in London, United Kingdom [56]. Material from those works is included in the first section of this chapter. In addition, the first section details various results from a cycle loading test performed to ensure the ability of the design to meet a minimum operating lifespan, and a preliminary exploration of the quantity of production sizes required to accommodate a functional fit of 80-90% of a standard population. The second section discusses the design process and considerations of the semi-passive upper-limb wrist and elbow orthosis. Finally, the whole exoskeleton system is considered and summarized in the third section of this chapter.

1. Hand Design

An essential design object for the hand exoskeleton is to enable the performance of bimanual activities of daily living. Because the projected user population retains dexterity in one hand, it is not necessary for the exoskeleton to provide the precision grasps (e.g. tip, tripod, and lateral pinch) used primarily for single-handed, dexterous object manipulation. For bimanual ADL, the support hand only requires the conformal power grasps to achieve most tasks [44]–[46]. The final hand design is shown in Figure II-1 and the design decisions that resulted in that design are discussed at length in the subsections that follow.

Figure II-1: Hand exoskeleton shown fitted to an approximately 50th percentile male hand.

1.1 Hand exoskeleton structure and joint location

A functional hand exoskeleton must provide a sufficient range of motion and degrees of freedom (DOF) to facilitate ADL, but accommodating native DOF is made difficult by the relative inaccessibility of the centers of rotation of the finger joints. Some hand exoskeleton designs have employed linkages on the dorsal aspect of the hand in order to accommodate the remote centers of rotation associated with the joints of the hand. In the early conceptualization phase of this project one such linkage device was explored. Although such designs can provide individual finger motion, and user surveys have indicated a preference to have individual finger articulation, pursuing such a design creates a highly complex system with numerous actuators and a large associated volume, mass, and a complex control system. These aspects in turn restrict portability and ease of use, which may ultimately restrict the user's ability to engage in ADL rather than enabling their performance.

A design, see Figure II-2, wherein the four fingers are actuated together creates the most minimal system required to produce the primary power grasps for support of bimanual ADL. Given this approach, it is possible to capture the metacarpophalangeal (MCP) joint center of rotation by using a simple revolute joint, located on the medial and lateral aspects of the hand, which shares

its axis of rotation with the MCP. Similarly, the proximal interphalangeal (PIP) joint axis of rotation can be accommodated by incorporating two revolute joints located on either side of the hand. Locating the exoskeleton joints on the side of hand produces a minimal device structure: small volume on back of hand, minimal mass required. The distal interphalangeal (DIP) finger joint was omitted because it contributed minimal associated functional gain (relative to the desired grasps), and omitting it also minimized complexity in the design and excessive bulk on the distal portion of the fingers,.

Some inexactness in alignment of the shared MCP and PIP joint centers is to be expected due to variation in the length of the four captured fingers. However, if the fingers are not overly constrained within the device, this misalignment was found to be acceptable and comfortable for use. Furthermore, this tolerance for joint misalignment presents benefit in terms of the ability of the device to fit a larger variation in hand size

Figure II-2: Rigid hand exoskeleton structure showing simultaneous finger motion at the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints

The main structure of the exoskeleton is comprised of Nylon 11 produced using a selective laser sintering (SLS) additive manufacturing process. This method of production was chosen for its ability to produce fine details in a material with good mechanical properties. The material properties are: tensile strength of 48 MPa, tensile modulus of 1700 MPa, and a flexural modulus of 1500 MPa. Additionally, the impact strength is relatively high at 440 J/m (IZOD - Unnotched) and 220 J/m (IZOD - Notched). Because of this high strength, it was possible to create a hand structure that is only 3-4 mm thick over the majority of the surface while still removing nearly all of the material on the dorsal aspect of the hand (note the open space shown in Figure II-1 and Figure II-2). In addition to minimizing mass, this open space provides visual continuity for the user, facilitates improved ventilation for comfort and skin health, and enables visual inspection of the skin within the device.

1.2 Finger attachment cups

In the earliest prototype, published in [55], the fingers were intended to be affixed to the device via either hook-and-loop (Velcro®) straps or by means of a rigid bar snapped across all four fingers. These methods were prototyped and found to be functionally deficient. The rigid snap bars impaired the overall quality of grasp, and thus were determined to be infeasible for the application. The hook-and-loop straps did not adequately restrain the most distal portion of the fingertips, such that flexor tone in the hand resulted in flexion at the anatomical DIP joints. Additionally, the loops were difficult to don and were uncomfortable. In order to affix the fingers to the exoskeleton in a more effective and comfortable manner, a set of finger cups was implemented, which retains the distal portion of each finger in a small neoprene cup, each of which are rigidly attached to the structure of the exoskeleton, as shown in Figure II-1.

To facilitate donning, as well as various finger sizes, the cups snap into the rigid shell of the exoskeleton. This snap system allows the user to attach one finger at a time, which is convenient for hands having high degrees of spasticity or contracture. Because the snap can translate along the axis of the finger (see Figure II-3), it also supports an increased range in finger length variability. The use of finger cups makes the exoskeleton relatively easy to don and enables the fingers to be comfortably restrained without need for additional straps.

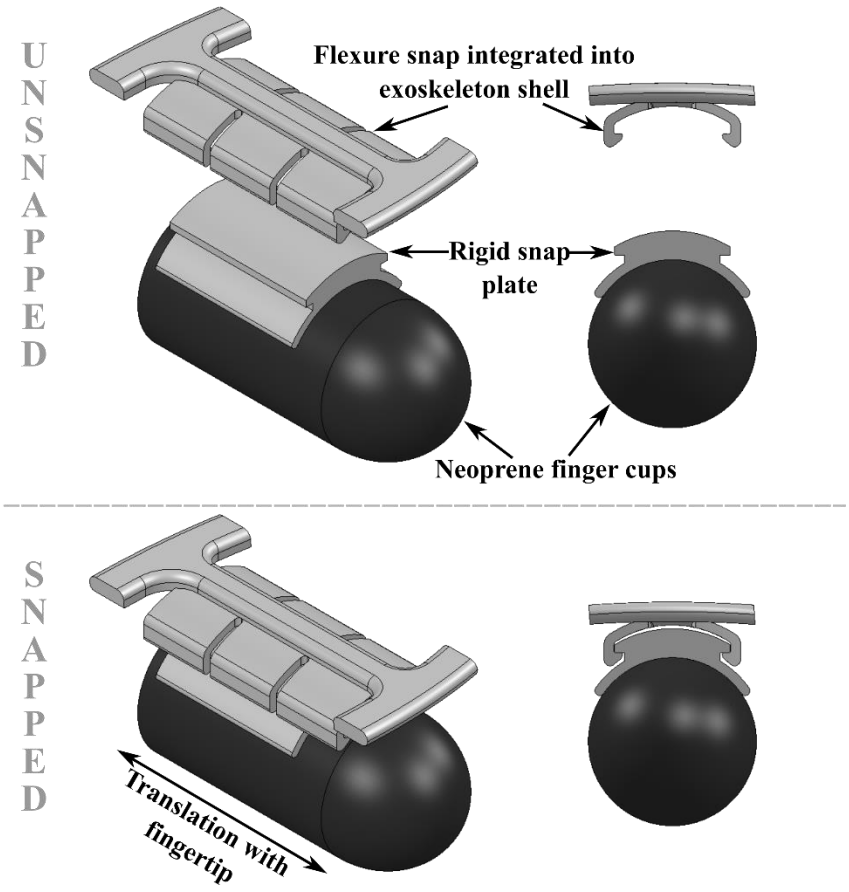

Figure II-3: Finger cup snap system. The female flexure snaps are integrated into the hand shell structure as a single component while the male catch is attached to the back of the neoprene finger cups. Once snapped, the finger cup can translate along the axis of the finger to facilitate anatomical and exoskeleton joint alignment.

1.3 Adjustable thumb

As seen in Figure II-2, the thumb is supported in opposition to the middle finger to create a stable tripod grasp. The design decision to utilize a fixed, but adjustable, thumb support was made in conformance with the objective to include only the most foundational features needed to achieve the required grasps for bimanual ADL. The thumb design, shown in detail in Figure II-4, includes four readily adjustable degrees of freedom (DOF) (two rotation, two translation) with a fifth DOF achieved through bending of the metal support rod. Functional range of adjustments is limited somewhat by the structure of the user's hand within the device and the inability to capture

all the joint centers associated with the thumb. Proper fit of the thumb proved to be among the most difficult part of the design, and some additional development of a more generalized, and user adjustable, thumb system would be of benefit to the overall utility of the device. Through testing with users, it was found that an actuated thumb may be appreciated, but likely would not offer enough added utility to justify the required additional drive units, control complexity, and mass.

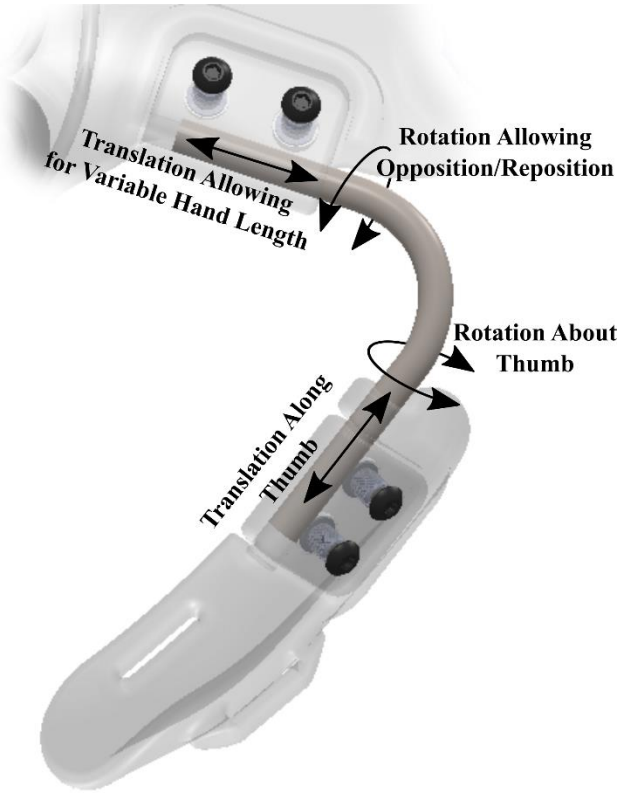

Figure II-4: Close-up of the fixed thumb mechanism showing the four primary degrees of adjustment freedom

1.4 Tendon drive system

Use of revolute joints facilitates a tendon driven actuation system. Tendons offer excellent power transmission over the full range of motion of the actuated joints. For simple revolute joint pulleys, this means that the output flexion and extension MCP and PIP joint torques are consistent throughout the entire grasping range. Because of their flexible nature, tendons are also easily routed to almost any desired location, which allows great flexibility in motor/pulley location. Use

of tendons also provides flexibility in selecting the motor mounting locations, due to the ease of routing tendons through small channels. The ease of routing and variable drive unit location also allows increased adaptability for variable hand size and shape.

This exoskeleton is configured with a pair of agonist/antagonist tendons, on each of its medial and lateral aspects, for a total of four tendons. Each tendon is comprised of a braided Spectra® filament chosen for its high strength, natural lubricity, and ability to tolerate tight bends. The medial and lateral components of the flexion and extension tendon channels of the orthosis are shown in Figure II-5.

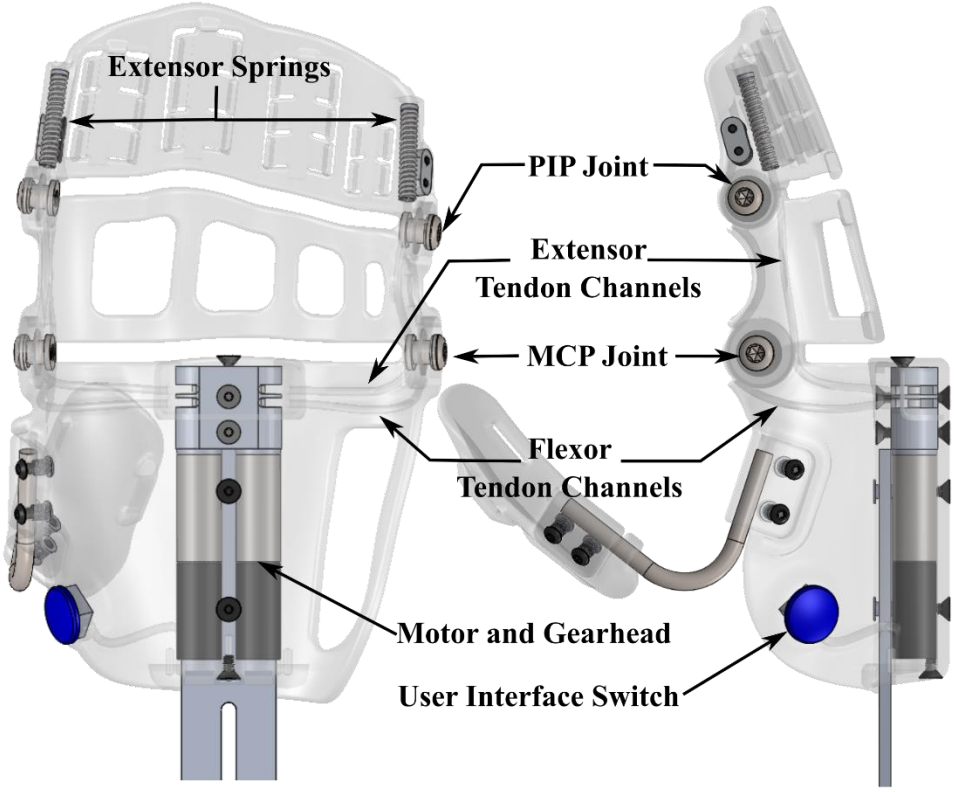

Figure II-5: Transparent view of the hand exoskeleton showing tendon passageways and interior components.

Although the orthosis contains two motors and two actuated joints, the system is an underactuated single control DOF design with the two motors acting in parallel (to increase joint torque), and with the MCP and PIP joints collectively underactuated by this motor pair (i.e., both sets of tendons actuate both the MCP and PIP joints). The under-actuation is designed such that the MCP joint will actuate first (due to the larger 19 mm versus 15.8 mm tendon pulley radius), and after the hand contacts an object, producing a resistive torque, the PIP will subsequently actuate, causing the hand to wrap naturally about the object being grasped.

1.5 Drive units

Actuation of the orthosis is produced by a pair of Faulhaber 1226A012B brushless DC motors paired with Faulhaber 12/4 256:1 gearheads. The motors are electronically coupled to act in unison with each motor driving a bidirectional, overrunning clutched tendon spool as described in [52] and shown in Figure II-6. Use of a bidirectional clutch enables passive holding, which allows the motor to be run briefly into a high torque regime and then turned off, which in turn allows a strong static hold with minimal continuous power requirements.

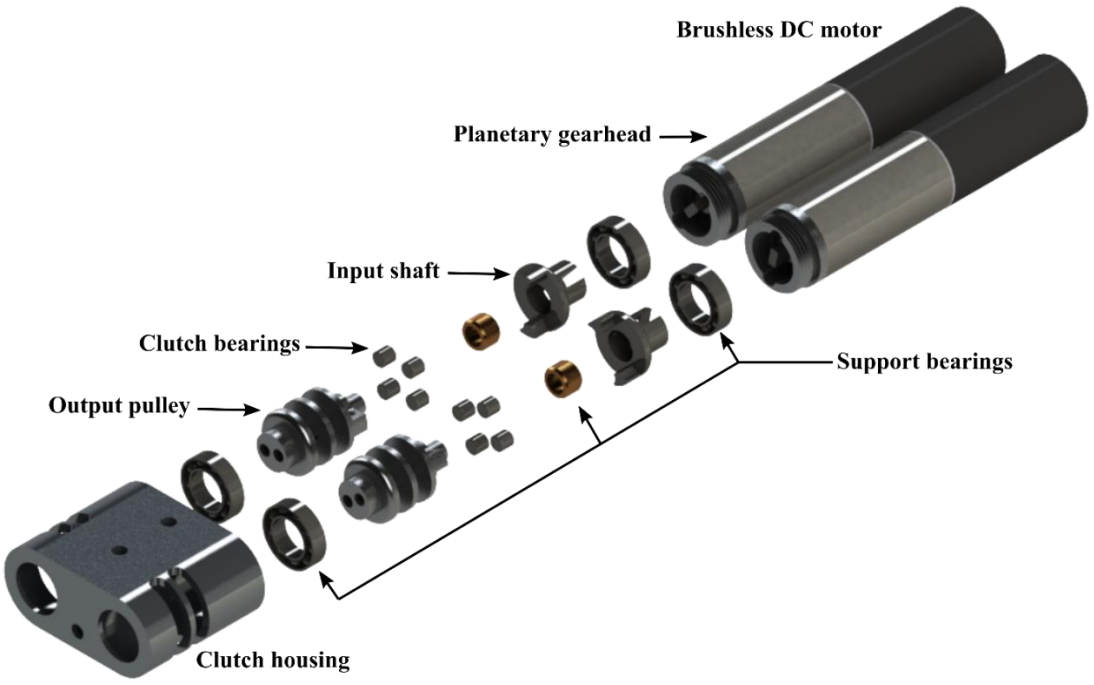

Figure II-6: Expanded view of motor assembly and bidirectional clutch.

The tendon spools used in this design have an effective tendon spooling radius of approximately 1.9 mm (approximate due to the diameter of the chosen tendon and spooling efficiency). With this motor, gearhead, and pulley arrangement, the theoretical maximum tendon tension is 450 N using 1.5 A of current to drive the motor. In practice, the empirical results have indicated an efficiency of about 60-70 percent resulting from spooling inefficiency, and friction within the clutch, tendon channels, and revolute joints. Because both tendons drive each joint, this results in an MCP joint torque of approximately 5 Nm and a fingertip force of 50 N (100 mm finger length assumed), which is well in excess of the 2-3 Nm and 30 N, respectively, set forth in the Design Objectives in Chapter I. In practice, the motor current is typically limited to no more than 1 A for user comfort and reduction of strain on the drive unit to promote system longevity.

Using the electronics and 7.4 V battery described in Chapter III, this drive system achieved a half range of motion bandwidth speed of approximately 1.9 Hz, which is satisfactory given the identified goal of 1.5 Hz. Earlier prototypes used control electronics with a higher 20 V input, which promoted the selection of the 12 V winding used in the Faulhaber 1226A012B motor. Better performance in both torque and higher bandwidth capability could be achieved using the Faulhaber 1226A006B motor with its 6 V winding, due to the more favorable terminal resistance and back-EMF characteristics for use with the lower voltage system. Additionally, a 64:1 gearhead could be used to further improve system bandwidth and efficiency, but that would come at the cost of reduced Hall effect sensor counts which would limit the ability to implement good speed control algorithms without the addition of a dedicated encoder. Testing with subjects did not indicate any need for either higher speed or force, so neither change was implemented.

1.6 Summary of mass, performance, and dimensional characteristics

Due to the limited amount of material required for the structure, and the use of high torque-density actuators combined with two-way clutches, the overall mass of the hand (not including the battery) is 360 g. The selected battery has a mass of 40 g, so the total hand system mass is 400 g.

The design was targeted to fit a 50th percentile male hand, which resulted in a measured length (wrist to fingertips) of 184 mm and breadth (measured at MCP) of 115 mm. As such, both the mass and size are consistent with the originally desired mass and size design targets.

Use of only the MCP and PIP joints in the chosen underactuated scheme produced a very effective cylindrical grasp. Also, because of the flexibility of the Nylon plastic used in the

structure, the hand can conform during grasp which yields some of the useful attributes of the spherical grasp. Since the system is powerful enough to extend fingers having moderate to strong tone into the fully open position, it is possible to achieve the platform pose as well with a caveat that there is not currently a simple way to adduct the thumb into the same plane as the palm.

A tabular summary of the relevant design specifications and achievements is exhibited in Table II-1.

Table II-1: Summary of important hand design characteristics and achieved results

Characteristic	**Objective**	**Achieved**
Mass	<400 g	400 g (with battery)
Fingertip force	20-30 N	>50 N
Torque at MCP	2-3 Nm	~5 Nm
Speed (half-ROM bandwidth)	1.5 Hz	~1.9 Hz
Grasps	Cylindrical	Cylindrical and attributes of Spherical and Platform

1.7 Mechanical cycle life testing

Total life of the tendons, drivetrain, and support structure is of interest to the development of this work as it directly represents the potential for the mechanical system to translate from the research space into real-world application. Research prototype devices benefit from the luxury of expert assembly, short service times, controlled operating environments, regular maintenance/rebuilds, and the acceptance of failure. Production devices on the other hand must survive widely variable conditions of operation, user expectation of long, uninterrupted service times, and maintenance performed at comparatively long intervals by individuals who may not have a lot of experience/training.

Of primary concern are the tendons because of the vulnerability of synthetic fibers to abrasion induced degradation and tendon sensitivity to tight termination knots which require derating of the tensile load. Also, the drivetrain developed in [52], and modified for this application, had never received a comprehensive evaluation of life expectancy and failure

mechanisms. To evaluate these concerns, and implement mitigating design modifications, a cycle loading test stand was developed, numerous tests were performed, and the life of all major components tracked.

1.7.1 Test stand implementation

To accurately simulate a real-world scenario, a representative duty cycle was gathered during clinical testing with a subject who experienced a stroke and had chronic hand hemiparesis with significant tone. The characteristics of this loading cycle were replicated, see Figure II-7, in a benchtop cycle testing stand which is shown in Figure II-8. The hand was repetitively cycled through one half full range of motion, grasping over a padded cylinder, until a component failure was detected. The failure was evaluated, and design adjustments were made to mitigate the perceived point of failure, and then a new test was performed.

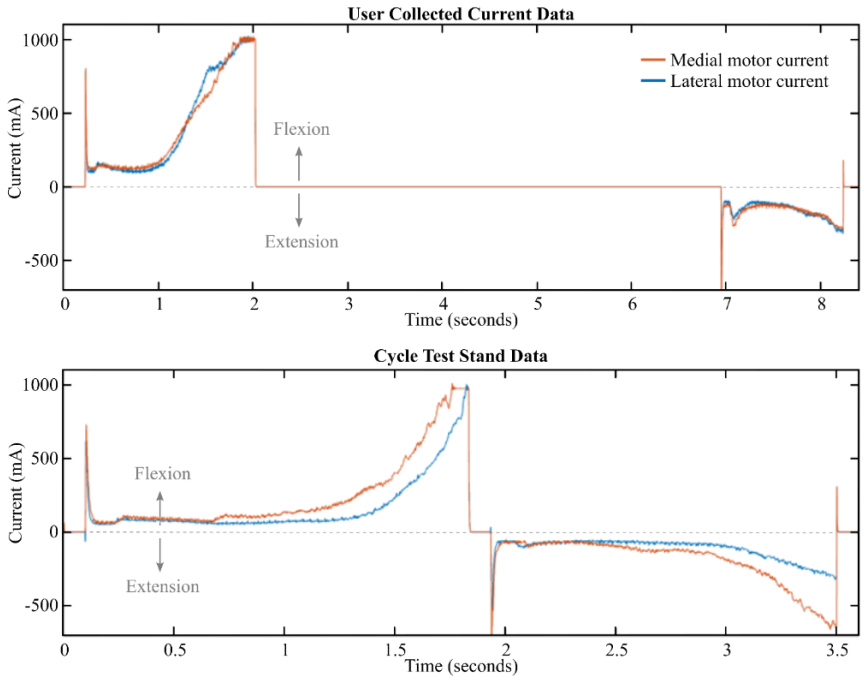

Figure II-7: Plots of motor current during performance of a cylindrical grasping task. The top figure shows data gathered during a clinical session with a human subject having hand hemiparesis with significant muscle tone. In the bottom plot are the motor currents measured during one complete cycle performed on the cycle loading test stand which exhibits all of the peak loading characteristics found in the test with human subject.

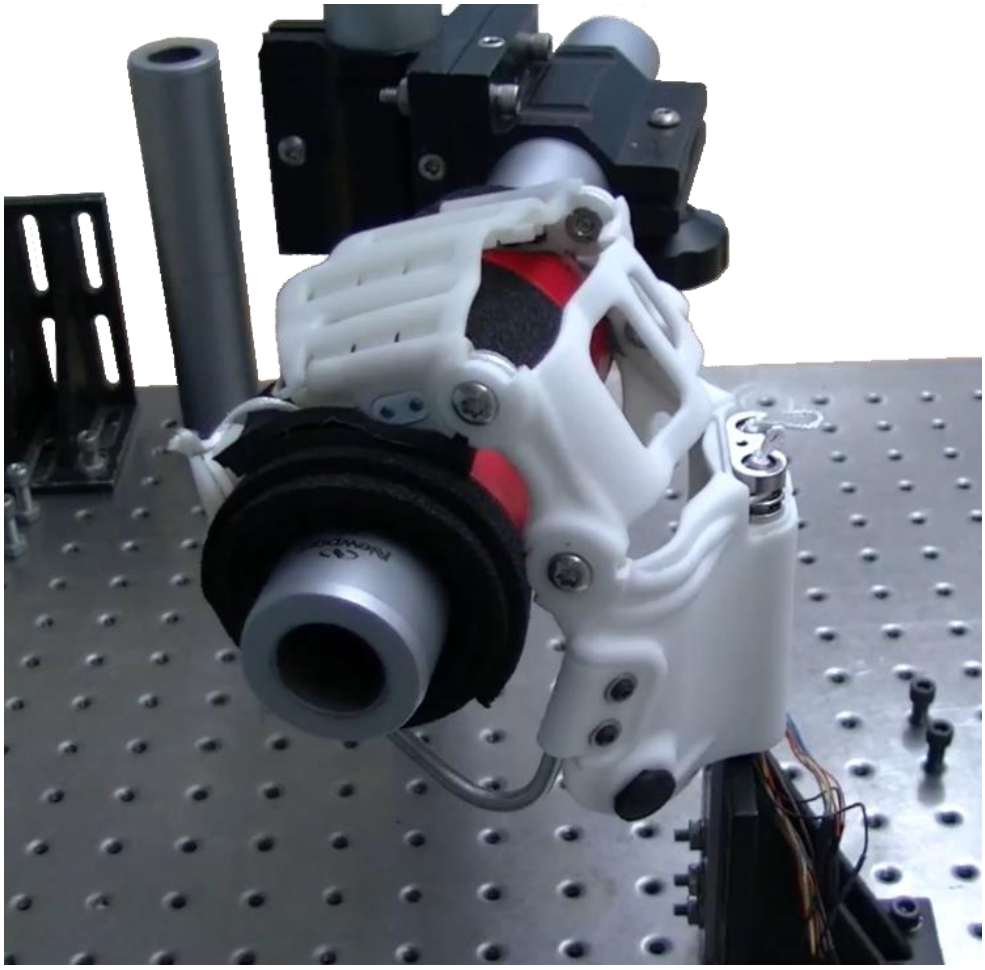

Figure II-8: Cycle test stand

1.7.2 Goal cycles

It is estimated that the average target user of this hand exoskeleton will perform less than fifty grasp cycles per day with the affected hand. Nominally, this device is envisioned to have a service life of three to five years with only minor part replacements during that time period. Therefore, all major components (motors, gearheads, plastic structure, etc.) must be capable of surviving in excess of 54,750 grasp cycles. For inexpensive and relatively easily serviced parts (tendons, springs, etc.), a one-year minimum life of 18,250 cycles is reasonable. To allow for margin, the target three-year and one-year cycle counts were set at 75,000 and 25,000 cycles, respectively.

1.7.3 Results

The results from twenty-four test runs is summarized in Table II-2. Each test commenced with a new tendon set, but all other components experienced multiple testing cycles, so the numbers shown are the cumulative sum of the total cycles experienced. All components demonstrated the ability to perform well in excess of the minimums required with the drivetrain and plastic shells experiencing 5-8x the minimum without failure or significantly degraded performance.

Table II-2: Cycle testing results

Component	**Cycles**	**Functional Life (years*)**
Plastic shell	>590,000	>23.6
Motors: Faulhaber 1226	>622,000	>24.9
Gearheads: Faulhaber 12/4 256:1	>383,000	>15.3
Pulley and clutch	>383,000	>15.3
Tendons: 300 lb. Spectra®	31,776 (median of final configuration) 143,768 (peak)	1.3 (median) 5.8 (peak)

The primary failure mode was tendon abrasion located at the point where it passes through the pulley wall. If the passthrough hole has a very sharp radius or residual edge burr from machining, the tendon will fail within less than ten thousand cycles. With a properly rounded and polished hole, two additional wraps of the tendon about the pulley can be used to mitigate the extra stress concentration at the passthrough to such an extent that the tendon exhibited nearly consistent wear along the full length of the spooled/unspooled portion of the tendon. Also, it was noted that the overwinds reduced the chance of a reversal of the tendon direction upon unwinding which can cause excessive bending of the fibers at the passthrough hole. A representative tendon failure is shown in Figure II-9(a).

Several different tendon fibers with varying load ratings were tested. Among the tendon types tested were 200- and 300-pound rated ultra-high molecular weight polyethylene (UHMWPE) Spectra® kite line acquired from Goodwinds, LLC, 400 Ultra Spectra® sourced from TRS

Prosthetics, and 300-pound braided Technora® with a PTFE coating sourced from Twinline, LLC. Steel rope was also considered but calculations, based on recommended worst case design scenarios, indicated that its use would require a considerable redesign of the drive unit to allow for the required minimum bend radius. Such a design change to accommodate steel rope would have necessarily negated many of the primary design benefits, so no physical testing was performed. The performed cycle tests indicated that the Spectra® group of fibers exhibited the best survival when subjected to the tight bending radiuses required within the hand pulley system.

Among the Spectra® specimens, the 200-pound rated line had inadequate strength to withstand the imposed load with the strength loss associated with the termination knots and was found to fail quite quickly. TRS 400 Ultra Spectra® proved relatively capable of withstanding high cycle counts, but the large diameter of the cord created additional spooling issues which reduced peak output forces and contributed to tendon abrasion as the fibers rubbed over one another on the pulley spool. The 300-pound Spectra® kite line found a good position in the midrange that proved a good combination of strength and size for this dimension of pulley – it was strong enough to allow for knot associated derating, had a small enough tendon diameter to spool well, and withstood the highest cycle counts of all types tested. The final six cycle tests were performed using 300-pound Spectra® line and resulted in a median cycle count of 31,776 with a generally improving trend that resulted in a peak value of 143,768 cycles at the cessation of tests.

Other noted failures included failure of the plastic hand components, fatigue and subsequent fracture of the tendon extension springs, and failure the clutch input shaft at the motor interface.

The first metacarpal hand segment used in testing was manufactured from Accura® Xtreme™ White 200 resin using a stereolithography process (Tensile Strength: 45-50 MPa, Tensile Modulus: 2300-2630 MPa, Flexural Modulus: 2350-2550 MPa) which was selected for its strength, feature accuracy, and smooth surface. Despite its apparent strength, this plastic has a relatively low impact strength (55-66 J/m, IZOD-Notched) which indicates a rather brittle nature. Its brittleness resulted in cracks forming at the tendon entry/exit points and propagating along the tendon channels. This result initiated the change to using Nylon 11 plastic. Nylon 11 prototypes were formed using a selective laser sintering process that produced components with a high impact strength of 220 J/m that provides better system longevity.

Of the metallic components utilized in the hand, only two showed failures throughout the entire set of tests – the tendon extension springs and the clutch input shaft. The springs were commercial of the shelf precision compression springs whose failure can be mitigated by use of springs designed for an infinite fatigue life. The exact number of cycles each spring withstood is not known because no failure detection was built into the system for this component and the overall test setup continued functioning properly (later tests omitted the springs because their presence/absence did not seem to affect the fatigue life of the tendons or other components). Spring failure is shown in Figure II-9(b) The clutch input shaft fractured at a stress concentration formed at the transition from the motor input slot to the clutch drive face. This failure was easily mitigated by changing the machining profile from a straight slot that cut through the entire cylinder into an enclosed slot with radiused corners as shown in Figure II-9(c)

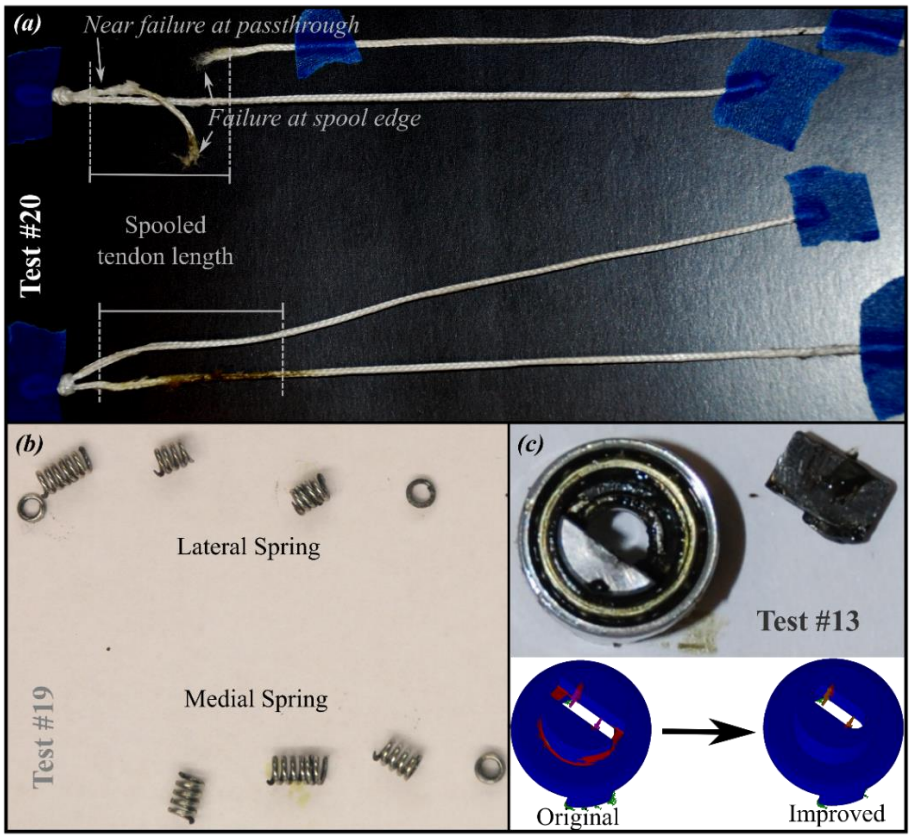

Figure II-9: Representative component failures. Counterclockwise from top: (a) shows a typical tendon failure with most tendon abrasion occurring within the spooled tendon length. (b) exhibits the failure of the commercial off the shelf compression spring used to keep the extension tendons in tension. (c) failure of the clutch input shaft with FEA evaluation of failure (red shows areas with a factor of safety less than 1.5) and the improved design implemented.

1.8 Production considerations and size requirements

All research prototypes of the hand exoskeleton plastic structure were created using additive manufacturing (3D printing) processes. Additive manufacturing is beneficial because of its low up-front costs, nearly unlimited creative design, adaptability from one part to the next, and ability to form complex features (e.g. tendon channels) directly into the structure of the hand. However, the current state of the technology has not reached a speed and per unit cost point that can be widely used for mass production while simultaneously offering a product at a price point consistent with user needs. Also, parts produced using additive manufacturing tend to have reduced material properties compared with more traditional production methods.

For the plastic components forming much of the hand exoskeleton, injection molding is the most likely method of production because it can produce large numbers of excellent parts very quickly with a very low per part costs in a wide range of materials options. While the per part cost can be very low, the initial tooling costs are very high. Therefore, the ideal goal would be to minimize the number of exoskeleton sizes required to fit the largest possible user population. Working hypothesis: two sizes can cover up to ninety percent of the population

1.8.1 Development of hand shells

Two simplified hand exoskeleton shells were developed as shown in Figure II-10. The simplifications included omission of any motor mounting solutions, tendon channels, and geometry not affecting the fit of the exoskeleton to the user's hand. Sizes of the two shells were based on the anthropometric data published in [57] and [58] with the size splits chosen as a large fitting up to a 90^{th} percentile male and a small based on a 95^{th} percentile female hand (using the hand breadth as the most restrictive measure). Since finger lengths, measured from the MCP to the fingertip, were not present in those anthropometric studies, the finger length (based on the middle finger) and MCP to PIP length were estimated at 50 percent and 23 percent, respectively, of the total hand length. These break points resulted in the large having dimensions of 95 mm breadth, 105 mm finger length, and 47.7 mm MCP to PIP joint centers, and the small had an 85 mm breadth, 95 mm length, and 43.1 mm MCP to PIP joint centers. The PIP joint center was angled at five degrees with respect to the MCP joint axis to help improve the capture of all fingers simultaneously. Essentially, these two sizes create a male hand orthosis and a female hand orthosis with some crossover at the extremes of a small male hand and a large female hand.

Figure II-10: Hand fit shells showing Large and Small dimensions. Hand shell dimensions are based on a middle finger length and MCP to PIP distance estimated at 50% and 23%, respectively, of the overall hand length. Large shell is consistent with a 90th percentile male hand and the small with a 95th percentile female (15th percentile male) hand.

1.8.2 Test procedure

At the beginning of each test, the subject's hand joint centers were marked and hand measured. Six different measurements were acquired including hand breadth, hand length, hand circumference, finger length, MCP to PIP length, and DIP joint circumference. The hand measurements were performed using the methods prescribed in [57] and [58]. Finger length measurements were performed using a pair of calipers to measure the distance from the MCP joint

center to the fingertip and MCP joint center to the PIP joint center (DIP joint center for the little finger). DIP circumference was measured using a standard set of jeweler's ring gauges.

Able-bodied volunteers then donned the two (small and large) simplified hand shells and were asked to move his, or her, hand through the full range of motion and grasp three cylinders with diameters of 25 mm, 70 mm, and 89 mm (physical objects used were a wooden dowel, 500 mL Nalgene® water bottle, and 1000 mL Nalgene® water bottle). All grasps were observed and photographed (representative grasps and photos are shown in Figure II-11) to record functionality and any observable issues regarding the ability of the hand exoskeleton shell to fit that subject's hand. Each subject was asked to comment on ability to form the grasp, comfort, and any concerns regarding pinch points or the ability of the exoskeleton to move cooperatively with the hand.

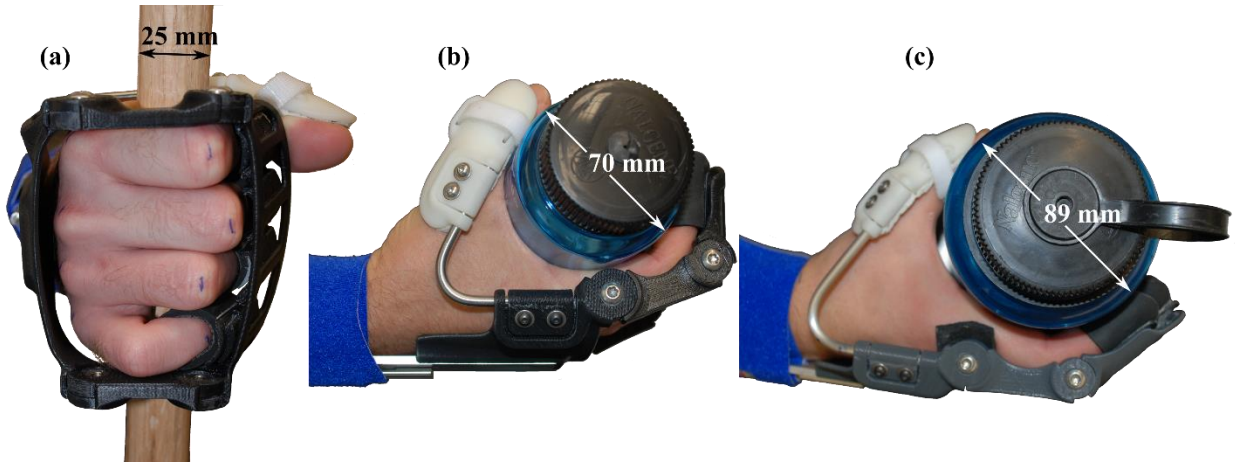

Figure II-11: Hand fit grasp tests using cylinders of various size. (a) is a wooden dowel of 25mm diameter which requires a grasp similar to that needed for a variety of household implement handles (e.g. broom), (b) shows the grasp of a small water bottle (Nalgene® 500 mL), and (c) the grasp of a large water bottle (Nalgene® 1000 mL). These three sizes are consistent with the span of a large number of household items required for ADL.

1.8.3 Results

As seen in Table II-3, two sizes produced a fit that a majority of the population found to be functional. Because of the extra effort required to obtain an acceptable fit and the potential for added user comfort, a third size falling in the intermediate space between the two selected sizes would be beneficial to the overall user experience and would ease clinician size selection. Study participants generally expressed a preference for a fit that was a little tight on the hand over one

that was too loose. This commentary implies that reducing the two orthosis sizes to coincide with an anatomic hand breadth/volume of 80-85th percentile male/female would, somewhat counterintuitively, increase the fit acceptability for a larger population.

Table II-3: Hand fit results.

	Hand Length Percentile	Hand Breadth Percentile	Hand Circumference Percentile	Large Length	Large Width	Small Length	Small Width	Preference (if stated)
M1	96	60	60	**Y**	**Y**	**N**	**N**	Large
M2	75	91	82	**Y**	**Y**	**N**	**N**	Large
M3	75	10	22	**Y**	**Y**	**Y**	**Y**	Small
M4	50	45	47	**Y**	**Y**	**Y**	**N**	Large
M5	49	34	22	**Y**	**Y**	**Y**	**N**	Small
M6	37	48	20	**Y**	**Y**	**Y**	**Y**	
M7	37	10	4	**Y**	**Y**	**Y**	**Y**	Small
F1	56	95	90	**Y**	**Y**	**Y**	**Y**	Small
F2	45	60	55	**Y**	**Y**	**Y**	**Y**	Small
F3	15	30	15	**N**	**N**	**Y**	**Y**	Small

With three hand orthosis sizes, the estimated target percentile sizes (based on hand breadth) would be 55th percentile female, 98th percentile female/18th percentile male, and 88th percentile male for small, medium, and large sizes, respectively. All recommended dimensions are shown in Table II-4 while the hand layout, including five degree PIP joint angle, remains the same as that shown in Figure II-10.

Table II-4: Proposed hand orthosis production sizes

	Breadth cm (approximate percentile)	**Finger Length** cm (approximate percentile)	**MCP to PIP** cm
Small	7.75 (55F)	9 (47F, 3M)	4.1
Medium	8.55 (98F, 18M)	9.75 (90F, 40M)	4.5
Large	9.35(84M)	10.5 (100F, 88M)	4.8

During development of the testing shells, the rigid member over the proximal phalanges seemed to add little value and was not required. Its removal offered greatly increased range of fit, user comfort, improved conformal grasp, and better visual engagement with the hand. Omitting the rigid connecting member reduces the metacarpal segment to two simple link bars located on the lateral and medial aspects of the hand. Having the separated link bars also enables greater freedom to adjust for hand length changes with fewer, and simpler, manufactured components. Separated metacarpal links combined with the three proposed sizes in Table II-4 produces the ability create nine different hand length/breadth combinations.

2. Design of a Repositionable Wrist and Elbow Orthosis

The exoskeleton hand was then integrated with a semi-passive repositionable wrist and elbow orthosis (shown in Figure II-12) to enable the user to position the wrist pronation/supination

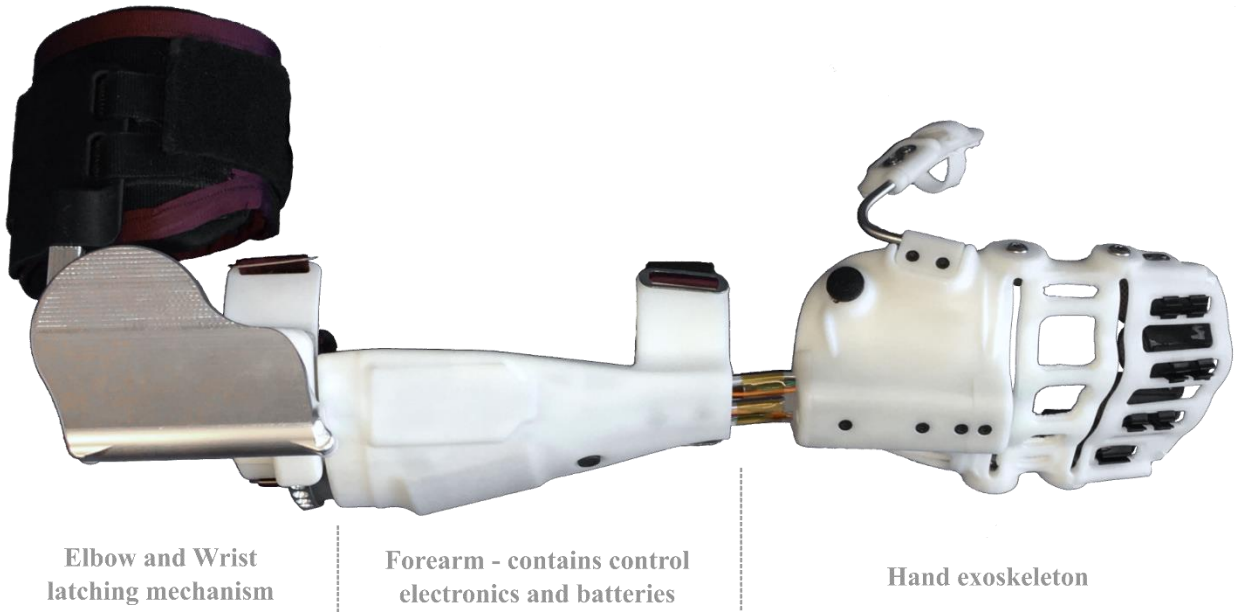

Figure II-12: The Vanderbilt upper-limb exoskeleton. Shown is the integrated hand exoskeleton and semi-passive wrist and elbow orthosis. As indicated, the exoskeleton is composed of three primary segments: the hand exoskeleton; elbow and wrist orthosis latching unit; and the forearm that connects the previous two segments and contains all necessary electronics and batteries.

and elbow flexion/extension for various tasks. Due to considerations regarding user control input, mass, and uncertainty regarding perceived utility, no attempt was made to create a fully active

exoskeleton for the wrist and elbow joints. Instead, a semi-passive orthosis was designed to be reconfigurable by a simple button push so that the user could achieve an almost entire anatomical range of motion and position the arm for various tasks.

A wrist orthosis with repositionable flexion/extension has limited perceived utility compared with the extra complexity and mass of the device, so it was simplified as a rigid joint fixed with approximately twenty degrees of wrist extension for comfort and function. This allowed for a reduced total, and specifically distal, device mass and easier passage of the power and control wiring to the motors located on the dorsal aspect of hand.

Rotation (pronation/supination) of the natural wrist is distributed throughout length of radius and ulna bones, so for design purposes the motion can happen anywhere within that space. Placement of the wrist rotation mechanism proximal to the elbow reduced distal mass, enabled utilization of a single solenoid for both the wrist and the elbow, and eased wire routing by allowing the control electronics to be located mid-forearm with wires passing through only one active joint to reach the elbow. The realized wrist rotation joint has a range of 120 degrees centered about the neutral hand position (palm facing in toward body center) with seventeen discrete locking points evenly distributed over that range. Although not quite the full pronation/supination range of motion allowed by the natural wrist (approximately 180 degrees), this degree of freedom produces adequate motion for most ADL.

The elbow joint has a range of 153 degrees of movement from full extension (straight arm) to near full flexion with eleven discrete locking positions distributed evenly over that range. Although the elbow design accommodates the full extension/flexion range of the natural elbow, the straps necessary to hold the device in place tend to limit the comfortable range of motion to a slightly smaller window operation (approximately 120 degrees of flexion depending upon individuals musculature).

In device testing with study subjects, the available locking positions proved to be somewhat coarse (especially with regard to the elbow joint), so the device would benefit from some continued development with regard to both the quantity of locking positions as well as the precise location of those holding points within the ADL task space. Despite the desire for intermediate arm locations, the orthosis was able to obtain functional positions for all tasks and subjects.

2.1 Method of locking and unlocking wrist and elbow joints

Both the wrist and elbow joints use a solenoid actuated ball detent mechanism, shown in Figure II-13, to lock and unlock. When the solenoid is activated, the cams retract allowing the ball bearing to fall out of the locking slots of the wrist and elbow sprockets. This displacement of the ball bearing allows the wrist and elbow rotation to move freely. When the solenoid is not active, the ball detent cams push (via a small spring placed between the solenoid coil and the detent cam) the ball bearings into the detent pockets and passively hold the wrist and elbow orthosis in the locked state. Because the cam moves fully underneath the bearing and onto parallel portion of the profile, any forces from the bearing into the cam act in a manner that is normal to the cam axis and thereby prevent motion of the arm while under load.

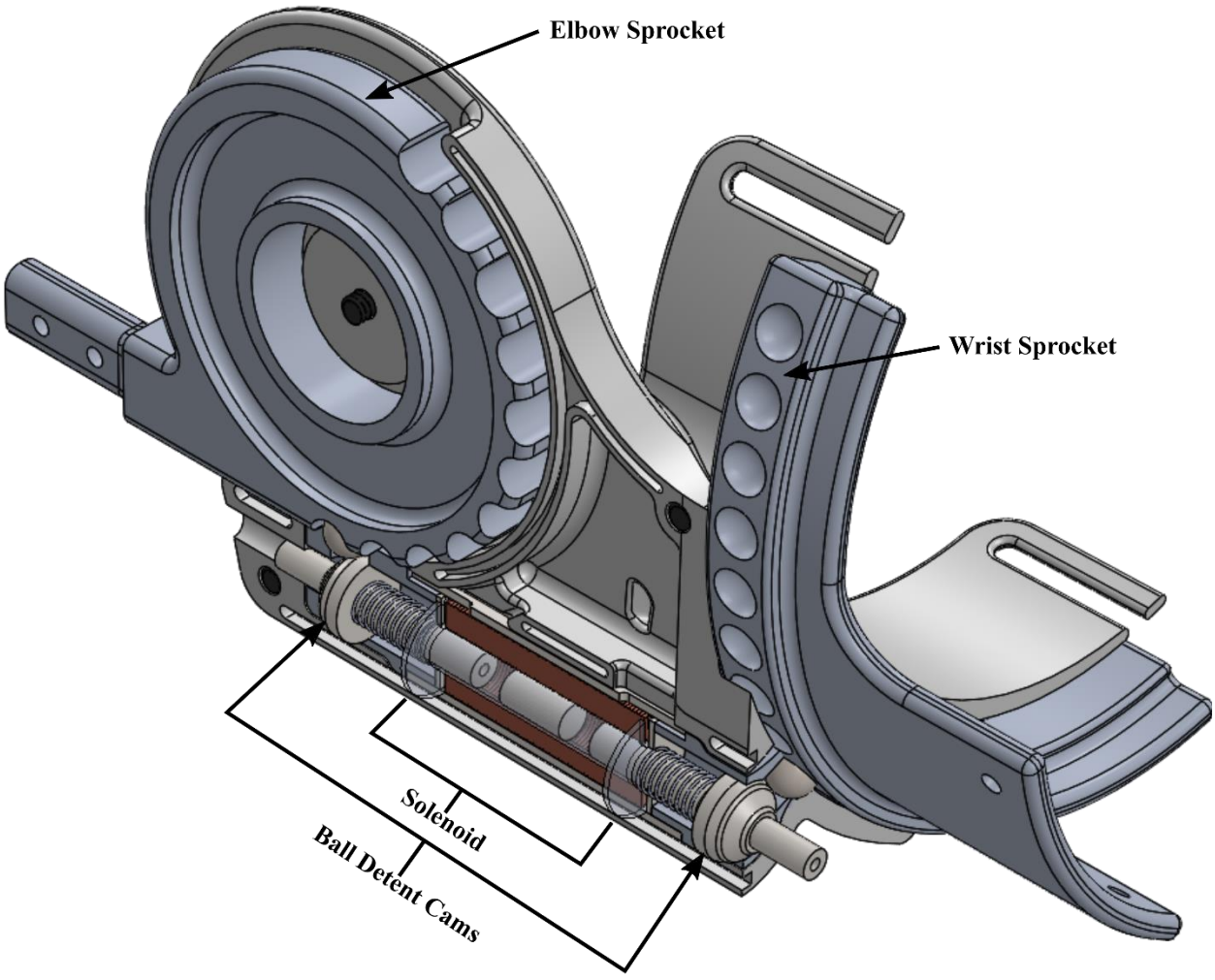

Figure II-13: Elbow and wrist locking mechanism. Cutaway view showing elbow sprocket, wrist sprocket, and solenoid release mechanism.

2.2 Detent sprocket design

Because forces acting on a rotationally unconstrained sphere must be normal to the surface and act through the center, the detent pockets of both the wrist and the elbow are, nominally, half the depth of the detent bearing so that, even under high load, the forces travel through the bearing and are transmitted to the wall of the enclosure. In an ideal case where there is no material deflection, this load path would prevent any extra force acting upon the sliding detent cams and would allow them to release the detent bearing consistently under all loading conditions.

In practice, the wrist pockets were made slightly shallower to ensure good rejection of the bearing from the pocket, when the cam is retracted, regardless of the arms position with respect to gravity. Because the rotational load about the wrist is generally very small, this shallower pocket does not prevent good retraction of the wrist detent cam. The wrist pockets are hemispherical in shape, seen in Figure II-13, so that the portion of the wrist sprocket that protrudes from the housing will have a smooth feel and will not snag, catch, or cause clothing (or other objects) to be pulled in when the sprocket is retracted. Since the pockets are symmetric, they can hold equal load in either direction.

For the elbow, the ball detent mechanism allows bidirectional loading for tasks such as heavy load support that would cause the arm to extend (basket carry, water bottle hold) and restraining of items to surface which would normally cause arm to flex (food preparation, restrain paper to surface, etc.). Initial designs utilized a symmetric ball detent pocket, but it was found that the symmetric pockets present problems with either load carrying capacity (while still enabling unlocking ability) or positive rejection of the bearing from the slot when unlocked. Typical ADL require that the orthosis elbow be able to support higher extensile loads versus those inducing arm flexion. Therefore, the nominal half-depth of the detent pocket was modified slightly with a release angle of 18.3 degrees, illustrated in Figure II-14, on the flexion side of the slot which ensures positive ball detent disengagement when the user lifts (flexes) the arm. The full pocket on the extension side allows for maximum load carrying capacity without extra loading placed on the ball detent cam, but the ball may not fall out of the slot until the loaded condition is removed. Unlike the wrist detent pockets, there was no benefit to a hemispherical pocket design as the elbow sprocket remains within the space enclosed by the housing of the unit. Therefore, the detent pockets were cut as slots to simplify machining and to allow consistent operation even with assembly inaccuracy.

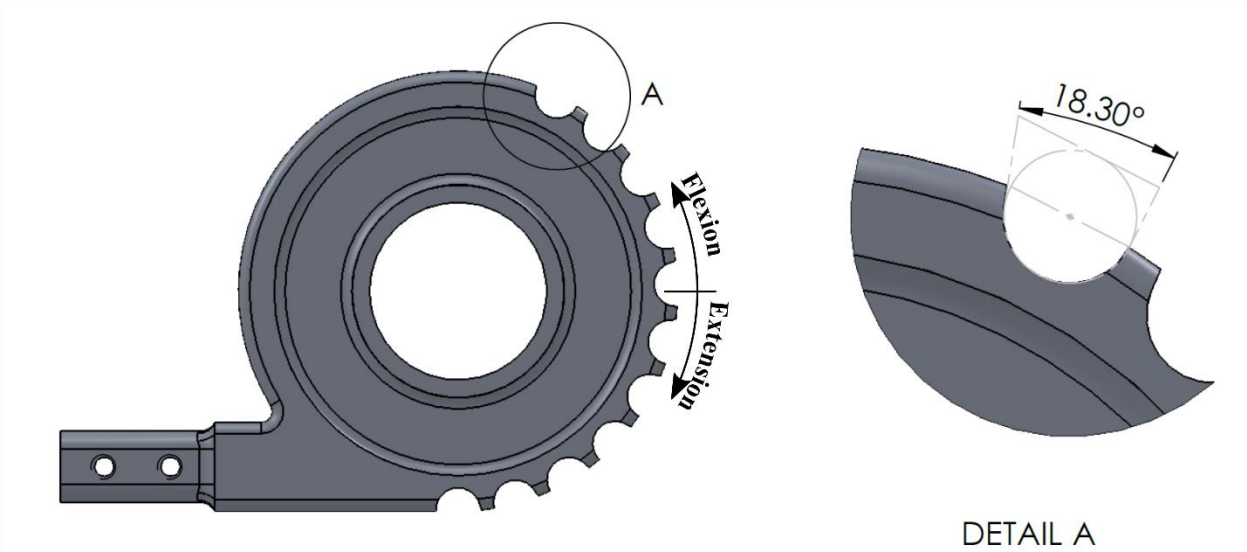

Figure II-14: Elbow sprocket notch design exhibiting asymmetry for different release characteristics in elbow flexion and extension. Load directions indicate the direction of the force applied to the sprocket when the arm experiences a load in the anatomical directions given.

Both the wrist and elbow sprockets were manufactured from Aluminum 7075-T6, chosen for its hard yet lightweight characteristics and ease of machining. This choice proved to be sufficient for a functional prototype, but wear on the elbow sprocket quickly became apparent and would necessitate the use of a material with a hardness approaching that of the detent bearing to avoid premature failure due to the mismatch in material characteristics at the load interface.

2.3 Dual acting solenoid design

To retract the detent cams, a solenoid coil was used. Various commercial options were explored with the Ledex 195203-231 solenoid used in early system prototypes. Ultimately the commercial versions were abandoned in favor of a fully custom actuation unit for the following two reasons: First, the commercially available solenoids were not readily available in a winding optimized for the designed voltage and current, and were therefore not strong enough to effectively actuate the latching mechanism once the necessary springs and expected friction were introduced. Second, use of a single push/pull type solenoid coupled the wrist and elbow locking mechanisms – meaning the actuation force was divided between the two joints, and if one detent cam could not move, both wrist and elbow would remain fixed. Use of two solenoids, one per joint, could remedy

many of these problems, but would necessitate increased mass, device volume, and total power draw.

A custom solenoid actuation unit, shown in expanded format in Figure II-15, was designed using a single coil to retract both, independent wrist and elbow detent cams. The solenoid coil has the characteristics summarized in Table II-5. Each detent cam had a retraction force of 1.1 Newtons at 4.76 millimeter excursion, which was reduced to 0.5 Newtons by the addition of the return spring which had a spring rate of approximately 0.050 Newtons per millimeter. All detent cam guides and housings were integrated into the solenoid system for compactness and consistent alignment.

Table II-5: Wrist and elbow solenoid coil characteristics

Characteristic	Value
Wire Gauge	24 AWG
Number of turns	496
Terminal resistance	1.2 Ohms
Coil dimensions	31.7 L x 13.4 OD (mm)
Pull force @ 4.76mm	1.1N @ 5A
Pull force with springs @ 4.76mm	0.5N @ 5A

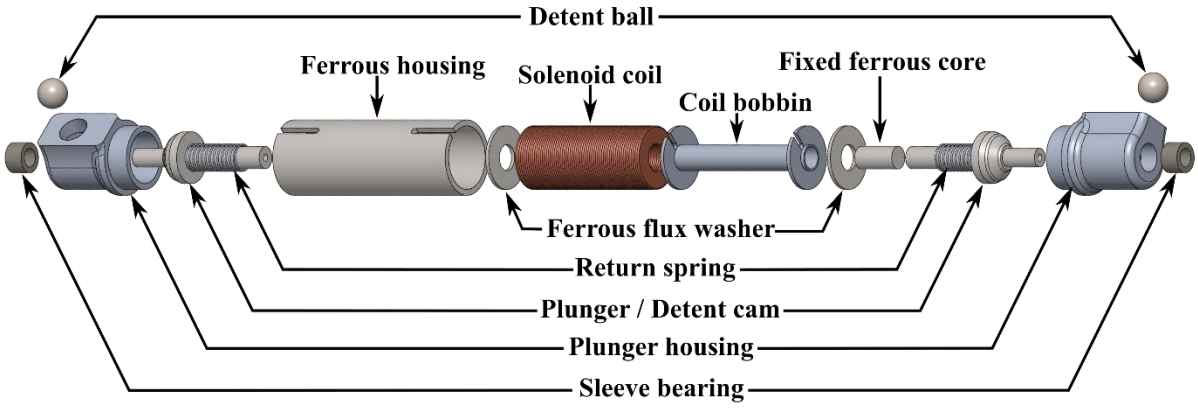

Figure II-15: Expanded view of solenoid actuator with component labels

2.4 Material and mass summary of wrist-elbow orthosis

The designed semi-passive upper-limb wrist and elbow orthosis was primarily constructed of laser sintered Nylon 11 and Aluminum 7075-T6. The Nylon material is the same described for the hand exoskeleton portion, and the reasons for use are the same (e.g. strong, impact resistant, lightweight, ease of prototype manufacture). Several components in the wrist and elbow structure are composed of machined Aluminum 7075-T6 because those components required particularly high strength, stiffness, and durability for the points of engagement with the detent bearings. Half of the elbow shell is also composed of a machined piece of aluminum because it was empirically found that a plastic section allowed overly much flexure which created trouble with the tolerances between the wrist and elbow sprockets and the ball detent cams. Use of aluminum in this position also allow for an excellent heatsink on the solenoid allowing for extended duty cycles without heat buildup next to the user's skin. Final mass of the wrist-elbow orthosis is 520 g.

3. Summary of Integrated Upper-Limb Exoskeleton

As seen in Figure II-12, the hand exoskeleton and upper-limb orthosis integrate to form a single cohesive system. The hand exoskeleton offers powered actuation of the hand, for both flexion and extension of the fingers, using a set of underactuated tendons and pulleys to induce motion in all four fingers simultaneously. An upper-limb orthosis offers passive support of the wrist and elbow joints during ADL, and the wrist supination/pronation and elbow flexion/extension can be rapidly repositioned by engaging the solenoid in the wrist-elbow unit to unlock both joints. Both major exoskeleton systems (powered hand and semi-passive upper-limb orthosis) share a single set of electronics with all systems and batteries contained within the forearm of the upper-limb orthosis. Two tactile buttons are placed on the device to enable user interaction; one on the hand, and one on forearm of the upper limb orthosis.

The structure of the exoskeleton is composed primarily of Nylon plastic, formed using a selective laser sintered rapid prototyping technique, machined Aluminum, and machined stainless steel for various small components where surface durability is important. Total mass of the system is 920 grams with 400 grams and 520 grams of mass associated with the hand exoskeleton and upper-limb orthosis, respectively.

CHAPTER III

ELECTRONICS AND CONTROL SYSTEM

Fitting with the design goals of this device, all electronics and control systems must be fully embedded for portability. Therefore, all systems must be small and of a form factor appropriate for inclusion in a wearable device. This section describes the electronics designed to accomplish the goals of this upper-limb exoskeleton. Additionally, the control processes and states are discussed.

1. User Input Options

Exoskeleton control is a considerable challenge with the exoskeleton ideally having a fluid motion that follows, and augments, the user's natural motion and grasp. That becomes difficult following stroke because many of the physiologic hand and arm motor signals are absent or confused.

Surface electromyography (sEMG) is a popular control input strategy for prosthetics and exoskeletons for individuals with adequate volitional motion. However, for individuals with a high degree of hand and arm motor affectation, causing paresis, the signal is likely too weak to be useable. Additionally, the natural signal from the brain to the arm is confused following stroke and residual tone and spasticity further complicate the signal and may preclude use of sEMG as a control strategy even for patients with higher levels of muscle volume and strength.

Since this exoskeleton device is designed for use by individuals having one hemiparetic arm and one largely dexterous upper limb, an option is to use the unaffected hand to interact with a variety of touch points on the exoskeleton. Because stroke often affects the learning and mental abilities in addition to the physical, these points of interaction should be obvious, easily engaged, and the interactions simple to learn so that they are consistent with use by an individual having cognitive challenges following stroke.

For this exoskeleton there are two primary interactions required: a trigger to open/close the hand, and a method to temporarily unlock the wrist and elbow for repositioning of the arm. These two functions can be achieved using two simple tactile buttons and software state timers.

A hand button is located proximal to the anterior aspect of the thumb which provides visual connection for most hand positions while also creating a visual and tactile engagement throughout all phases of task performance. As discussed in detail in the Control Logic section, when pressed, the hand button toggles the state of the hand, so if the hand is open it closes and vice versa. The hand button also serves as the primary user interface to toggle through the various device mode menus based on time button hold conditions.

The wrist and elbow lock and unlock feature is controlled using a second tactile button located on the distal forearm. When pressed and held, the wrist and elbow joints unlock, allowing the user to reposition his/her limb into the desired configuration, and then the button is released allowing the joint locking mechanism to reengage and passively hold given joint locations. Note that the wrist and elbow control can be programmed such that each button press changes between a locked and unlocked arm configuration, though this feature was not generally used.

2. Embedded Electronics System

An embedded electronics system was developed for the exoskeleton which provides sensing and control of the device, so that the exoskeleton can be operated as a standalone system without need of a power or control tether. The embedded system includes: dsPIC microcontroller for executing the control states, low-level control, and motor commutation; voltage regulation for 3.3, 5, and 12 Volts (as needed to supply the microcontroller, motor hall effect sensors, and servo-amp and solenoid gate drivers, respectively); brushless DC motor drivers for the two Faulhaber 1226 hand exoskeleton motors; circuitry for current sensing in each motor (used to estimate grasp force); circuitry for position sensing in each motor (used for motor commutation, hand position, and hand velocity); a solenoid control circuit for the wrist and elbow locking mechanism; and a Controller Area Network (CAN) communication bus for communicating with an external computer (used for diagnostics, logging, and control prototyping). A block diagram of this functionality is shown in Figure III-1.

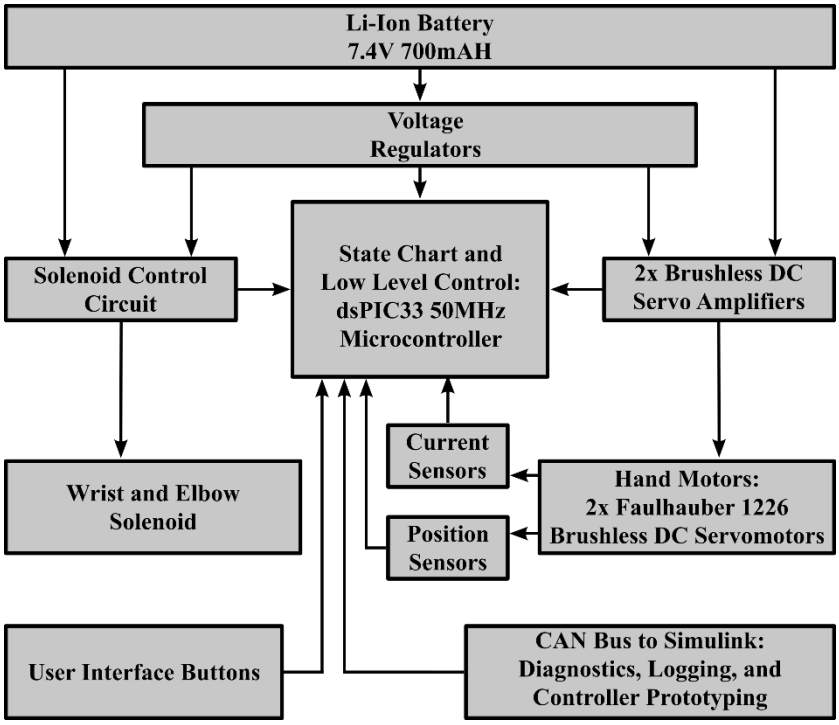

Figure III-1: Block diagram of embedded electronics functionality.

The embedded system consists of a single 4-layer printed circuit board, which is housed in the forearm of the exoskeleton. A picture of the printed circuit board is shown in Figure III-2. Also contained in the forearm is the battery pack which is a nominally a 7.4 Volt system capable of supporting peak current draw greater than, or equal to, 6 Amps to handle the solenoid starting current. A lithium-ion battery pack consisting of four 10440 cells (two placed in series which are then placed in parallel with the second series pair) was used to power the prototype system. This yields a low-profile battery pack that meets the above specifications. This battery pack has a storage capacity of 700 mAh, which is enough for a few hours of use with frequent hand and arm cycling.

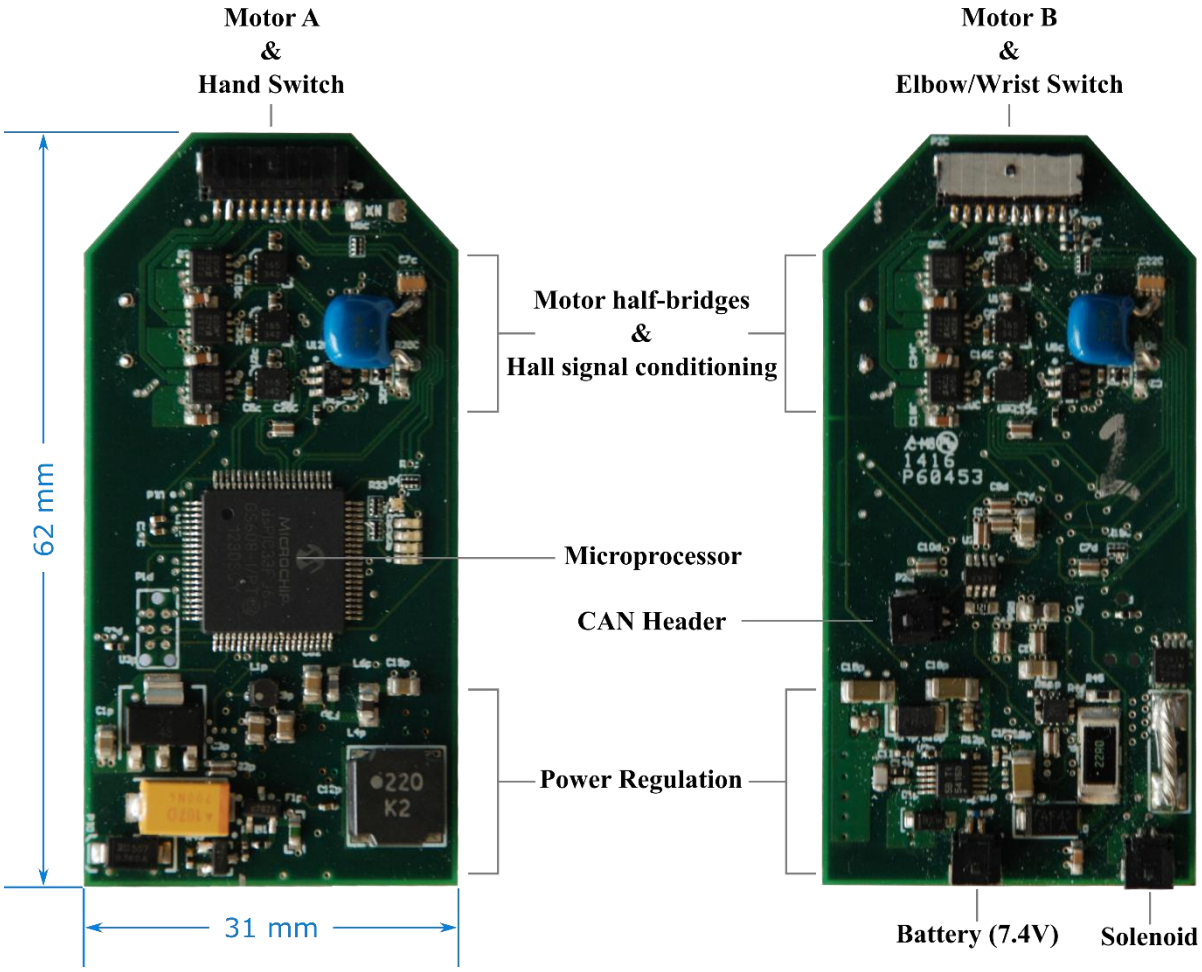

Figure III-2: Upper limb exoskeleton printed circuit board comprised of microprocessor, 2x BLDC motor servo amplifiers, solenoid control circuit, CAN communications interface, and appropriate power conversion.

3. Control Logic

Only two momentary push buttons and state timers are used to interface the user and the exoskeleton to accomplish the necessary state transitions. The intention behind stripping the controls down to the absolute minimum is to present a simple control scheme that is easy to learn and appropriate for a user with cognitive challenges. Figure III-3 shows the global view of the upper-limb exoskeleton control states. To begin, the button located on the hand acts as the primary interface switch and is first used to enter the transient POWER AND CALIBRATION states and then moves into the HAND OPEN/CLOSE super state. Almost all operational time is spent within the hand control states with brief excursions into the ELBOW/WRIST REPOSITION states.

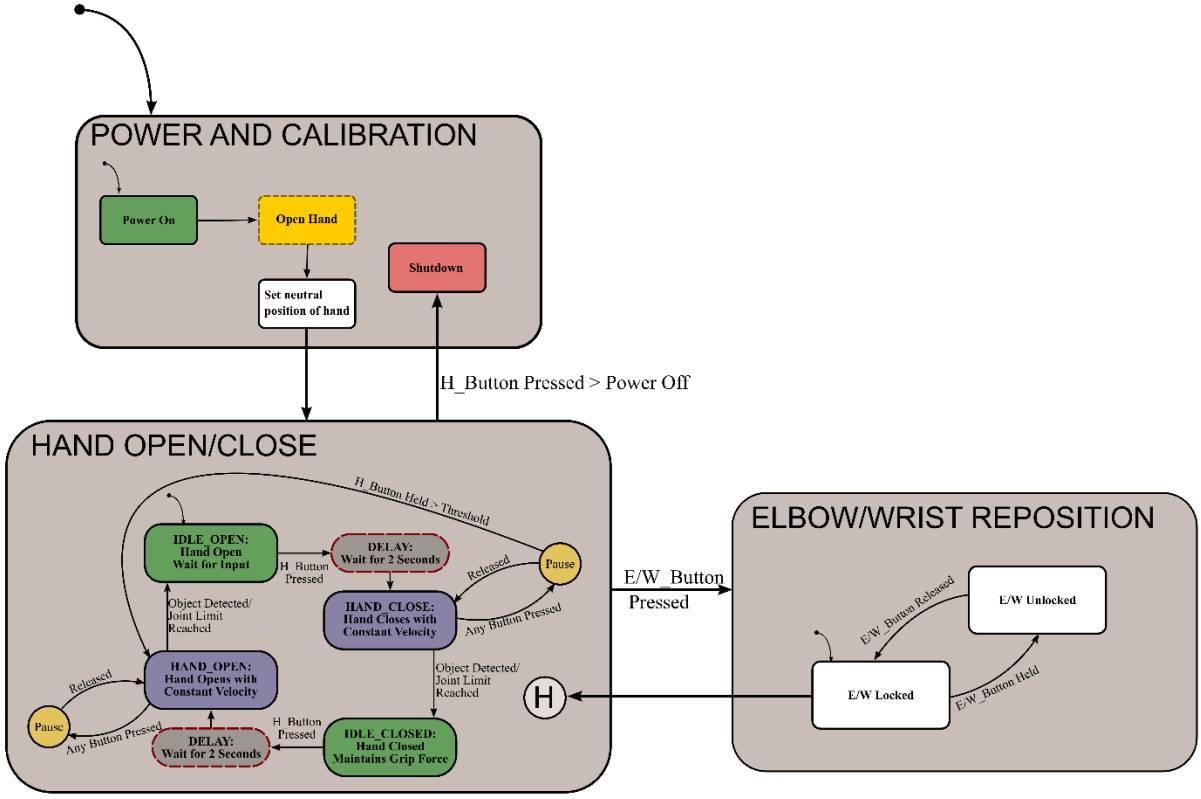

Figure III-3: Exoskeleton control state chart. Shown are the three super states containing the power-on and initialization routines, hand open/close home state, and the transient elbow/wrist reposition state.

At startup, there is a brief hold in the PowerOn state (shown in Figure III-4) during which the microcontroller watches to make sure the power button has been held long enough to initiate the power up sequence, it then watches for stable power and enables the other system components on the board. Once powered on, a hand motor position calibration routine is run. The motor position is based upon the embedded hall effect sensors in the brushless dc motors, so the read position is incremental rather than absolute and does not inform the system of the initial state of the hand (e.g. open vs. closed). To overcome this, the calibration routine runs the hand motors until full extension is achieved (or a reasonable stall torque is achieved in case it was calibrated while donned). This position, at full extension, is then recorded as the motor zero setpoint and used as an absolute reference for the remainder of time the device is powered on.

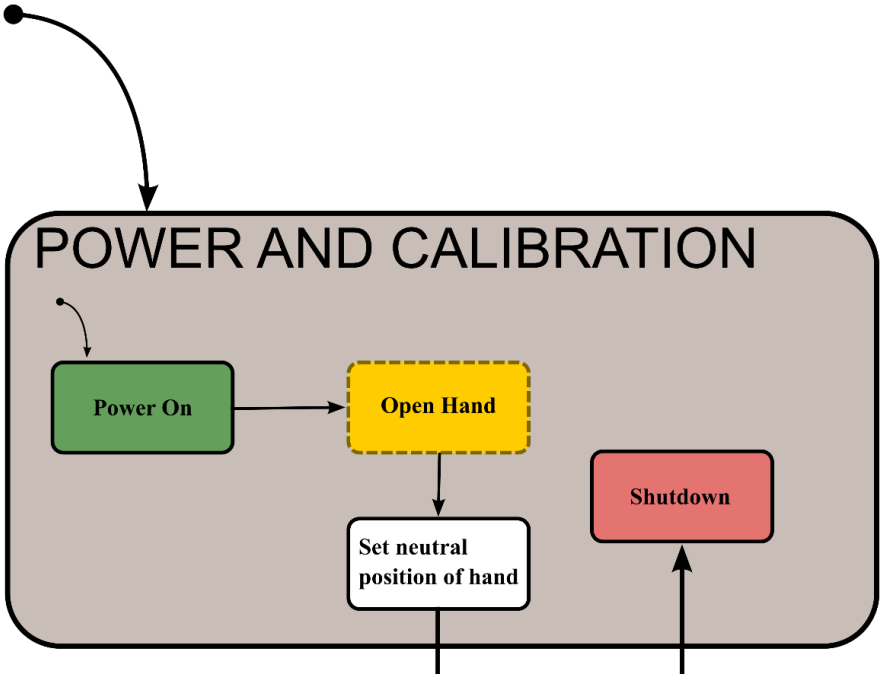

Figure III-4: Control state chart - Power and Calibration states

After calibration, the system transitions directly into the HAND OPEN/CLOSE states (Figure III-5) and first enters the IDLE_OPEN state (note that the hand was in the open position following the position calibration routine). The hand exoskeleton is moved out of the idle states into the open or close states by a press of the momentary pushbutton switch located at the base of the thumb. Specifically, the user momentarily presses this button with his or her unaffected hand to toggle the device from the hand open to hand closed position. Once the button is pressed, the system enters a transient delay state (typically one to three seconds based on user preference). The delay exists to give the user time for placement of an item to be grasped within the hand. Once the delay is satisfied the hand begins to close at a set speed and continues to close until grasp is detected via feedback from increasing motor current. Once the selected grasp force is reached, the motors are turned off to conserve power while the bidirectional clutches maintain the achieved grasp. The system enters the IDLE CLOSED state. Opening of the hand from the closed state follows the same pattern of a single button press followed by a short delay, the hand opens to the zero position, and then the system enters the IDL_OPEN state once again.

For safety, if at any time during a motion state any button is pressed (hand or wrist/elbow), the hand motion is paused for as long as the button is held. Once the button is released, the hand continues its open/close motion. If it was the hand button that was pressed, it is also possible to cancel the closing motion by holding the button for a given timer threshold. If the user cancels a hand close cycle by holding the hand button, the exoskeleton opens the hand and enters once again to the IDLE_OPEN waiting state.

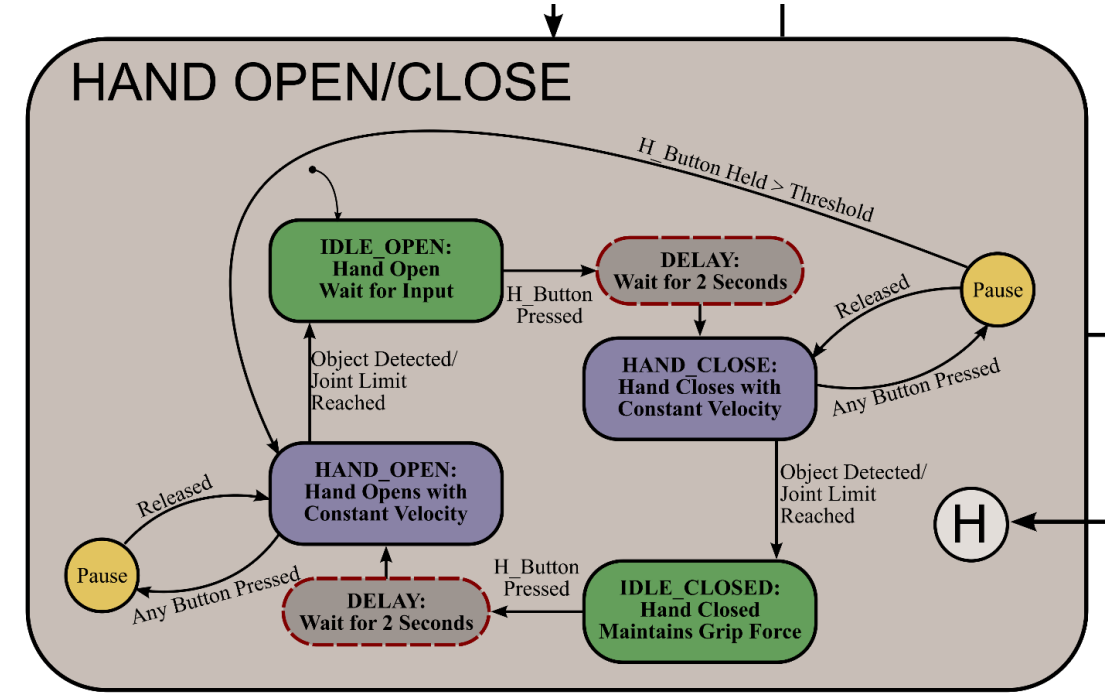

Figure III-5: Control state chart - Hand function states

The elbow and wrist joints are held in deenergized and normally locked state. When the user wishes to change the elbow or wrist pose, he presses the wrist/elbow button located on the forearm of the device. For as long as the button is held, the elbow and wrist joints are placed into the unlocked state which allows the wearer to position the paretic arm with his unaffected hand. Once the arm is in the desired position, the button is released and the system locks in the given pose. This functionality is shown visually in Figure III-6. After the wrist/elbow button is released, the system moves back into the hand states and resumes whatever task was defined at the point that the system was pushed into the elbow/wrist states.

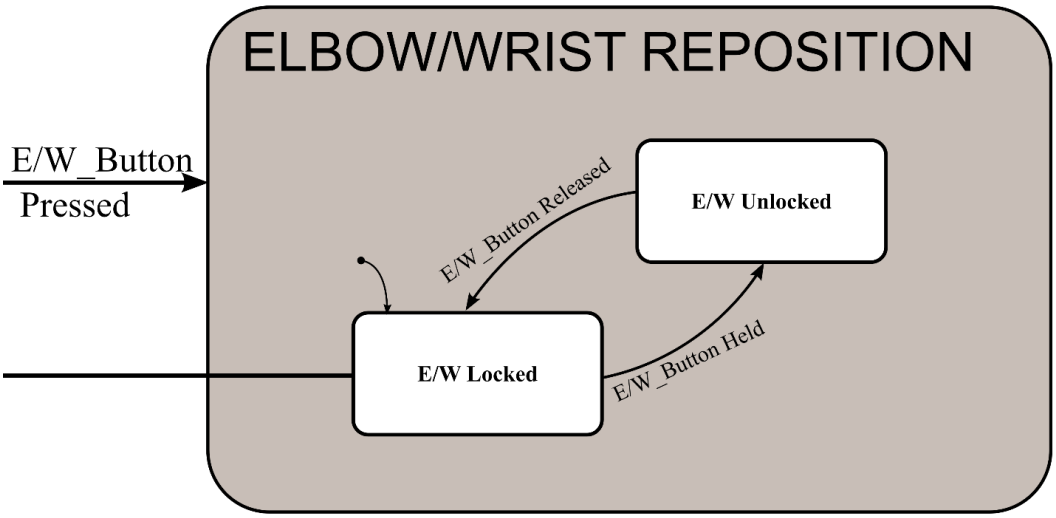

Figure III-6: Control state chart - Wrist and Elbow

4. Summary

The electronics and control methodology used for this exoskeleton fit with the design objectives outlined in Chapter 1. They are the minimum essential set required to operate this exoskeleton while still allowing for control prototyping in programs such as MATLAB/Simulink. Because of low number of components and small processor, the power consumption of the electronics is very low which yields a long device runtime with a minimalist battery pack. In turn, the battery can be housed within the device forearm, so no additional power tethers are necessary.

The presented two-button user interface is a simple method of interacting with the exoskeleton. While it does not allow for the exoskeleton to move fluidly throughout a given task, it performs all the essential functions required to enable performance of many bimanual ADL for an individual with hemiparesis. Also, the interface is very easy to learn and worked well for all study subjects (some of whom presented with significant aphasia and cognitive challenges) after only a brief device introduction. Using tactile buttons also eliminates the need for any extra sensors that the user must don prior to, or in addition to, the exoskeleton, and so removes any extra burden associated with donning/doffing the device.

CHAPTER IV

PRELIMINARY CLINICAL STUDY OF EXOSKELETON EFFICACY

To be accepted a device for human functional augmentation of ADLs must effectively enable greater task performance than experienced without the device. This fourth chapter is a preliminary clinical assessment of the complete Vanderbilt Upper-Limb Exoskeleton with several subjects having chronic, post-stroke hemiparetic upper-limb motor deficits that result in their inability to effectively utilize their hand and arm to accomplish ADL. In total, five subjects were recruited to be involved in this study. Three subjects were found to be ideal candidates for use of the exoskeleton while two subjects exhibited a higher level of natural limb function than would likely warrant adoption of this device in its entirety. The bulk of this chapter focuses on the results from the three subjects for whom the exoskeleton was a useful intervention while the other two subjects results help form the discussion of whom would be an ideal user candidate.

The first part of this chapter presents a brief statement of the goals of the clinical study. Section two contains discussion of the subjects recruited and their clinical presentation regarding limb motor deficits and relevant factors (such as aphasia) that may affect ability to interact with the exoskeleton device. Section three presents a summary of the developed assessment protocol and the descriptions of the most informative tasks. Next the results from the three primary subjects are presented followed by a discussion and interpretation of those results. The chapter concludes with a preliminary analysis of whom the device is most likely to benefit and presents the contraindicators exhibited by the two subjects who did not find the exoskeleton to be of functional benefit.

1. Study Goals and Scope

This preliminary clinical study was conducted with three primary goals: demonstrate the efficacy of the designed upper-limb exoskeleton within typical bimanual ADLs; begin refinement of the target user population by observing the efficacy across a set of study subjects with varied degrees of upper-limb motor affectation; and clarify hardware and control interface changes, potential for new or varied devices, and inform future studies through observation of, and feedback from,

individuals using the exoskeleton and control interface. This study was intended to be preliminary in scope and therefore limited to a small number of subjects.

2. Subject Recruitment

This study was approved by the Vanderbilt University Institutional Review Board under study number 160499 and by the Shepherd Center Institutional Review Board under project number 754. Subjects were recruited by therapist referral and each subject provided informed consent to participate in the study. All study tasks were performed with at least one research personnel and therapist present for the duration of all tasks.

Five subjects with right-sided hemiparesis following stroke were recruited for this study. All subjects presented with impairments of the right upper-limb (required by the study, due to the exclusive availability of right-handed exoskeleton prototype), and all were similarly right-hand dominant prior to their stroke. Three subjects who were a good fit for the study formed a subset group whose results are presented in the remainder of this chapter. Two subjects who had a Manual Muscle Test (MMT) of at least 3 or higher in both shoulder and elbow function helped inform the level of appropriate motor affectation for whom the upper-limb exoskeleton is not an adequate intervention (i.e., they had enough motor function that the full exoskeleton was often a detriment to their arm movements). The data for these two subjects is not presented in this chapter but is available in Appendix B and mention of their performance is given in the final discussion.

2.1 Subject clinical descriptions

Following are the clinical descriptions of the three subject subset. A full description is given in the text with details regarding nature of stroke, chronic physical affectation resulting from the stroke, and relevant medical history. A summary is provided in Table IV-1.

Table IV-1: Study subject demographics

Subject ID	**Gender**	**Age** (yrs.)	**Time Post-stroke** (yrs.)	**Affected limb/Pre-stroke dominant hand**	**Modified Ashworth Scale** (Hand+Wrist /Elbow)	**Manual Muscle Test Grade** (Elbow/Wrist/ Fingers)
S1	Male	58	4	R/R	3/NAT[1]	2F3E/2/1F0E[2]
S2	Male	56	6.8	R/R	3/3	1F2E/0/1F0E[2]
S3	Male	65	1.5	R/R	2/1	0/0/0

1 NAT = not assessed at time of testing. 2 F = flexion, E = extension

2.1.1 Subject 1

Subject 1 (S1) was a 58-year-old male who was 4 years post-stroke at time of testing. His stroke was a left internal carotid artery dissection and middle cerebral artery hemorrhage. His medical history was otherwise unremarkable. His clinical presentation was significant for right hemiparesis, spasticity, and aphasia (expressive greater than receptive).

The subject's volitional arm strength was insufficient to move his right arm through its full range of motion against gravity in all muscle groups except the elbow extensors, and his distal musculature was weaker than proximal. The subject had no active finger extension.

In addition to profound arm and hand weakness, the subject had notable spasticity; specifically, his finger flexors, thumb flexors and adductors, and forearm pronators were graded at 3 out of 4 on the Modified Ashworth Scale (MAS). A grade of 3 is consistent with a "considerable increase in muscle tone" making "passive movement difficult"[59].This strong flexor spasticity enabled the subject to have a functional grasp (thus his ability to perform the bottle-opening tasks without the hand exoskeleton), although extended time and effort were required to stretch his hand into extension, and to place the item to be grasped in it. Hand opening to release items after grasping is also affected, as the he relies on his unaffected left upper extremity to pull the item out of his paretic right hand. These motor impairments render the use of his paretic right arm inefficient and cumbersome, which deters use of the arm in the completion of ADLs.

This subject was recruited early in the development of this exoskeleton, and the design dimensions were partially chosen to accommodate a good fit with his hand and arm dimensions.

2.1.2 Subject 2

Subject 2 (S2) was a 56-year-old male who sustained a left-sided stroke, 6 years and 10 months prior to this study, with resultant right hemiparesis and expressive aphasia. He was very cognitively engaged and could readily understand all instructions and communicate complex suggestions for new ideas or techniques despite his expressive aphasia.

At the time of the study, his elbow extensors and wrist/finger flexors both had spasticity graded at 3 out of 4 on the MAS [59]. He had been receiving Botox injections every three months, for at least the previous three years, to muscles of the right upper extremity, including triceps, pectorals, and flexor digitorum. His last Botox injection was approximately 2 months prior to beginning this study.

The subject had trace to poor (grade 1 to 2) muscle activation of the right elbow, and trace (grade 1) activation of the right finger flexors – measured using the Manual Muscle Test (MMT) [60]. Due to this weakness and the above-mentioned spasticity, he relied heavily on his left upper extremity for ADL. The subject also exhibited some minimal glenohumeral subluxation; heavily weighted tasks were eliminated to minimize risk for increased subluxation. Because of his high cognitive ability, full functioning left upper extremity, and lack of function in the right arm, this subject falls into the projected ideal user population.

This subject had hand measurements of 8.9 centimeters in breadth and 20.0 centimeters in length (45^{th} and 60^{th} percentiles, respectively [58]). As the hand exoskeleton was designed for a 50^{th} percentile male, only minor adjustments of the padding and thumb bar were required for a nearly ideal fit. Similarly, the elbow and wrist exoskeleton was a suitable fit with only minor adjustment to the overall length when assembled with the hand.

2.1.3 Subject 3

Subject 3 (S3) was a 65-year-old male who was 1.5 years post-stroke. After experiencing a ground level fall, he was found to have had an ischemic stroke in the left middle cerebral artery (MCA) with acute infarction of the inferior and posterior left frontal lobes, left parietal lobe, and left temporo-occipital region. He presented with right sided hemiparesis, pain in the right upper

extremity, spasticity, and global aphasia. He attended research sessions with his wife or full-time caregiver.

The subject required minimal to moderate assistance to perform ADLs. Most activities were done primarily, if not exclusively, using his unimpaired left upper extremity. Functional use of the right upper extremity was significantly limited due to spasticity at the elbow, wrist and hand; pain with passive movement; and zero to trace (grade 0 to 1) volitional muscle activation throughout the limb (measured using the MMT). He regularly used a hand and wrist orthosis to support the right hand and wrist. The subject also had moderate glenohumeral subluxation [61]; several tasks were eliminated due to risk for exacerbating shoulder subluxation or pain.

This subject's hand measured 8.5 centimeters in breadth and 19 centimeters in length (15^{th} and 25^{th} percentiles, respectively [58]). With a small amount of padding in the hand portion of the exoskeleton and adjustment of the thumb position, a good fit was achieved. Because of concerns with his easily bruised skin, additional padding and a soft arm sleeve were added to the exoskeleton forearm and upper-arm portions during testing.

3. Assessment Protocol

Many clinical assessment tools have been designed to assess hand, arm, and limb function following stroke or other injury. A great number of the existing options are aggregated at the Shirley Ryan Ability Lab Rehabilitation Measures Database [62] (formerly rehabmeasures.org hosted by the Rehabilitation Institute of Chicago). Following a review of the available assessments, it was found that all were designed for assessment of essentially only the affected limb and could not effectively measure the value-added to a bimanual task by an exoskeleton or other assistive aid. Because this study is specifically focused on the value-added to bimanual ADLs, it became necessary to create an assessment protocol to measure the functional contribution of an assistive aid to the performance of ADLs involving the use of both hands during the task cycle.

Our developed assessment was created using modified tasks drawn from the Chedoke Arm and Hand Activity Inventory (CAHAI) [63], [64], Toronto Rehabilitation Institute Hand Function Test (TRI-HFT) [65], and a collection of ADLs (which require, or benefit from, the use of both hands) deemed representative of a broad spectrum of common bimanual activities. The full protocol can be found in Appendix A. When this protocol was created, a primary goal was to use as many quantitative assessment metrics as possible to remove subjective interpretation or

variation caused by different administering personnel. In addition to the ADL tests, each subject received a questionnaire so that they could provide user perspective on strengths and weaknesses of the device and whether they could foresee wanting a device of this nature. If the subject could not fill out the form personally due to difficulty writing, they were assisted by one of the physical therapists present or by a primary caregiver.

For this study, four of the tasks (Grasp strength test, Bottle opening: sitting and standing, and Bread cutting) were found to be most indicative of the value of the exoskeleton device, while the remainder of the tasks were found to exhibit either a neutral device impact or were eliminated from use with particular subjects because of concerns regarding their shoulder with the mass involved. The tasks presented in the results are briefly summarized as follows:

3.1 Grasp strength

The grasp strength test is a modified palmar grasp torque test adapted from the Toronto Rehabilitation Institute Hand Function Test (TRI-HFT) [65]. The modifications include manufacture of the grasp cylinder from aluminum instead of wood and the inclusion of two cylinder sizes (3 cm and 7 cm). Subjects' ability to grasp an object was evaluated by grasp strength tests where each subject grasped a either the small (3-cm diameter) or large (7-cm diameter) aluminum cylinder using a palmar grasp with his affected hand while torque was applied to the cylinder. Subjects repeated the grasp three times with each cylinder in a clockwise and counterclockwise rotation first in the no exoskeleton condition (hereafter called unassisted condition) and then while wearing the upper-limb exoskeleton (hereafter called assisted condition). Subjects were allowed a minimum 30 seconds rest between each attempt. Figure IV-1(a) shows a subject performing the grasp test while wearing the exoskeleton.

3.2 Bottle opening tasks

Two water bottle opening tests were chosen as representative bimanual tasks. For both tests, subjects were instructed to open five 500 mL wide-mouth water bottles (Nalgene, Nalge Nunc International Corp) placed on the table at an extended arm's length from the subject. The water bottles were partially filled with 400 mL of water and lids were closed with 1.13 Nm (10 in-lb) torque using a precision torque wrench. Participants were instructed to open the five water bottles as quickly as possible without spilling. If a spill occurred, the bottle was considered to have been opened effectively but occurrence of the spill was noted. The task was considered complete

when all five bottles were open and the bottles and respective lids were placed on the table surface. In order to account for learning effects, the bottle-opening test was repeated until the total time for two consecutive tests were within 10% of each other, indicating that task completion time had effectively plateaued.

Performance of the test was recorded using a video camera and post processed to parse out the primary phases involved in bottle-opening. The bottle opening tasks were divided into three parts: grasp, lid removal, and release. The grasp time is defined as the time from when the subject first touched the bottle until the time when the subject achieves a stable grasp and the unaffected hand touches the lid to begin the lid removal process, lid removal was the time from the end of the grasp phase until the lid was set on the table, and release was measured from the initiation of removal of the bottle from the affected hand until it was placed back on the table.

3.2.1 Sitting bottle opening task

During the sitting bottle opening test, subjects were permitted to use the table to aid with stabilizing the water bottle during the task. The table was set at a comfortable sitting desk height, nominally 70-75 cm, and subjects sat on a chair during the tasks. Figure IV-1(b) shows a subject performing the sitting bottle-opening test while wearing the exoskeleton.

3.2.2 Standing bottle opening task

The standing bottle test consisted of subjects standing near a counter height table with the five bottles placed on that surface. Subjects were instructed to not use the table to help stabilize the water bottle during the standing task. Figure IV-1(c) shows a subject performing the standing bottle opening test while wearing the exoskeleton.

3.3 Bread cutting task

An additional assessment task, cutting successive slices of bread using a bread knife, was included in the original protocol. Due to a combination of lack of motor skills, receptive aphasia, and potential for injury, however, only one of the three subjects could complete this task without assistance from the attending therapist. As such, this task provided no usable data across subjects, but did provide data for S2, who completed the task unassisted. As such, results from S2 are presented in the results section.

The bread cutting task was performed while standing at a table 86.5 cm high. A baguette, a cutting board, and a bread knife were placed on the table, and the subject was instructed to

stabilize the baguette with his affected hand and cut eight slices from the end of the baguette, each 1-2 cm thick. The task was conducted two times in each condition (i.e., with and without the exoskeleton). If needed, the subject was allowed to lean on the table for balance while performing the task. The quality of cutting was graded as follows: a good cut was a slice with little to no deformation and uniform cut edges; a moderate cut included some deformation of the bread slice and at least some tear at an edge; and a poor cut was one with substantial deformation and substantial tearing at the edges. Note that for the bread cutting task, the exoskeleton hand grasp strength was reduced to prevent the hand from crushing the bread. Figure IV-1(d) shows a subject performing the bread cutting test while wearing the exoskeleton.

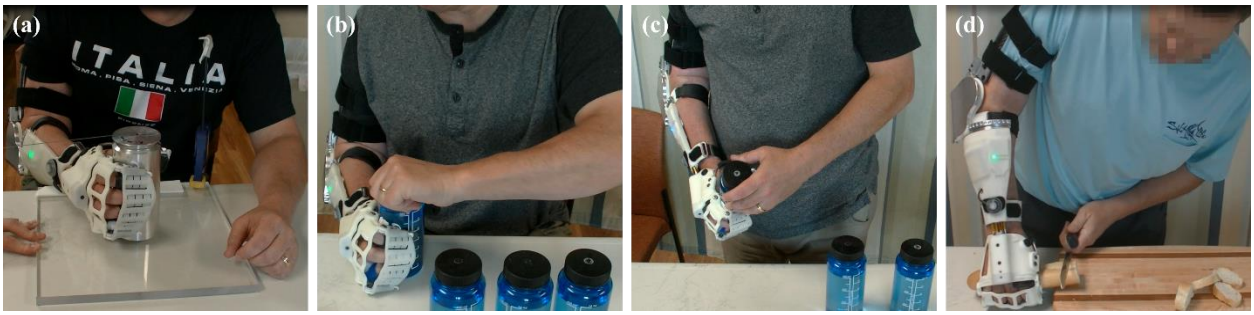

Figure IV-1: Images showing performance of study tasks. (a) shows a subject engaged in the grasp strength test with the large grasp cylinder, (b) is the sitting bottle opening test, (c) standing bottle opening test exhibiting no use of the table or other support, (d) shows a subject cutting bread while using the exoskeleton.

4. Results

The results for each test, performed both with and without the exoskeleton, are plotted separately for each subject in Figure IV-2 through Figure IV-4. The results are plotted separately for two reasons. First, a high degree of functional heterogeneity existed between the subjects, and as such, averaging performance together would obfuscate or wash out the effect on each subject. Second, in both the seated and standing bottle-opening task, S3 was unable to perform the tasks without the exoskeleton. Since time to complete is the performance metric for both tasks, and S3 could not complete these tasks, S3's performance could not be quantitatively characterized, and therefore could not be averaged with that of S1 and S2. As such, the authors felt the assessment results would be clearer if considered separately for each subject.

Statistical analysis of the data sets was performed using a Lilliefors test for normality and the data set pairs (unassisted versus assisted) were subsequently tested using either a Paired Student T-test or the Wilcoxon Rank Sum test (depending on the normality results) against the null hypothesis that both the unassisted and assisted data sets are samples from continuous distributions with equal means/medians. The calculated probability (p-value) is shown on the figures or described in brief in the figure captions.

4.1 Grasp strength test

Figure IV-2 shows the results for the grasp strength testing. Specifically, Figure IV-2 exhibits the median grasp torque capability of S1, S2, and S3, respectively, for each of four grasp cases (small and large cylinder diameters, clockwise and counterclockwise directions) while wearing the exoskeleton (blue) and without it (green), along with the range for each measurement. The numbers on the figure represent the median grasp torque associated with each test condition. Across grasp cases, the exoskeleton on average increased grasp strength by a factor of 2.2, 2.2, and 6.5 for subjects S1, S2, and S3, respectively. The extent to which these improvements might be functionally useful is informed to some extent by the bottle-opening tests.

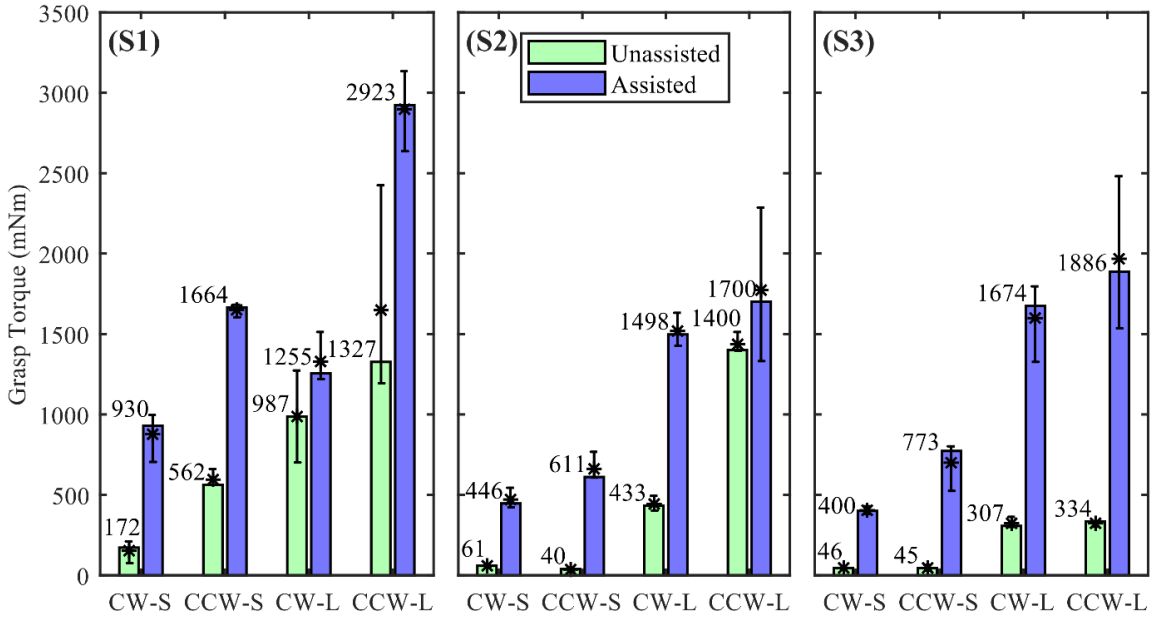

Figure IV-2: Palmar grasp torque values for subjects S1 through S3 from the left, respectively. Displayed values and bars indicate median grasp torque and whiskers indicate the total data range (n=3), the calculated mean for each is indicated by an asterisk (*) symbol. CW stands for clockwise; CCW for counterclockwise; S for the small diameter cylinder; and L for the large diameter cylinder. All data set pairs had a p-value of 0.10 except S1-CW-L and S2-CCW-L with p = 0.40 and p = 0.70, respectively.

4.2 Bottle opening tasks

Figure IV-3 and Figure IV-4 show, respectively, the results of the sitting and standing bottle-opening tests both with and without the exoskeleton. Tabular versions of this same information is contained in Table IV-2 and Table IV-3. Specifically, each figure shows a comparison of two time metrics for the bottle-opening tasks: 1) the Total Time, which is the time required per bottle to complete the task (i.e., the time required to grasp the bottle, remove the lid, and place the lid and bottle on the table); and 2) the Grasp Time, which is the time required for the grasp portion of the task only. The purpose of the grasp time measure is to isolate the role of the exoskeleton since the other portions of the task (removing the lid and placing the lid and bottle on the table) are determined primarily by the unaffected limb. Note that S3 could not open the bottle without the exoskeleton, and therefore no data is shown for the unassisted case. The number of spills for each subject, from the ten bottles opened in each test, is listed in Table IV-4.

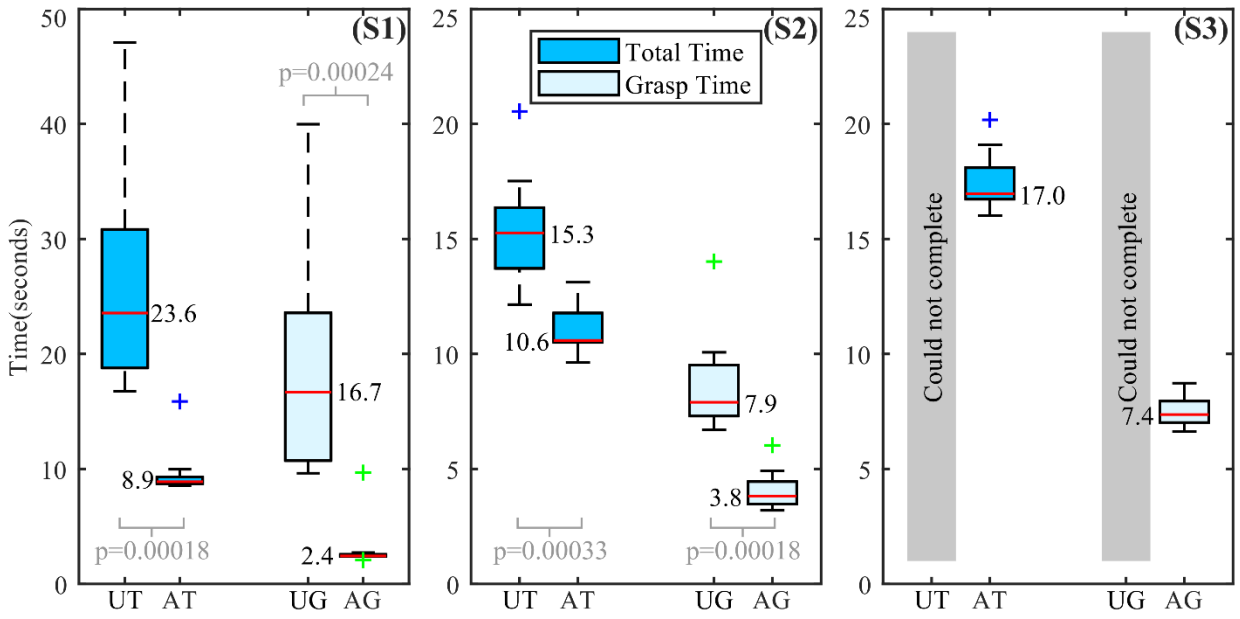

Figure IV-3: Sitting bottle open task performance times. Boxplots show median (n=10) performance times for total time spent opening a single bottle and the time it took to obtain a stable grasp on the bottle (UT = unassisted total, AT = assisted total, UG = unassisted grasp, AG = assisted grasp). Boxes indicate the interquartile range, whiskers indicate total data range, and (+) indicates a datum that fell a distance more than twice the interquartile distance from the median. Plots show subjects S1 through S3 from left to right, respectively.

Table IV-2: Sitting Bottle Open - Median and Interquartile Range Values

	Unassisted				**Assisted**			
	Total Time (seconds)		Grasp Time (seconds)		Total Time (seconds)		Grasp Time (seconds)	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR
S1	23.56	12.05	16.67	12.85	8.89	0.58	2.43	0.19
S2	15.26	2.65	7.90	2.22	10.59	1.28	3.82	0.98
S3	n/a	n/a	n/a	n/a	16.96	1.37	7.36	0.93

For the sitting bottle opening test, the median improvement in time for subjects S1 and S2 while wearing the upper-limb exoskeleton was 14.7 and 4.7 seconds, respectively, which corresponds to factors of 2.7 and 1.4 improvement in the total time. Additionally, the interquartile range (IQR) was reduced to 0.6 and 1.3 seconds, respectively, which corresponds to factors of 20.7 and 2.1 improvement in the time consistency for opening the bottle. Subject S3 was unable to complete the unassisted sitting bottle opening test, so there was no percent mean improvement, but rather a transition from a non-functional to a functional arm. Note that the reduction in time associated with subjects S1 and S2 between the unassisted and assisted conditions was almost entirely due to improvement in grasp time, which accounted for 14.3 and 4.1 second median differences, respectively, corresponding to a factor of 7.0 and 2.1 improvement, respectively. Participants S1 and S2 did not spill water from any bottles while assisted by the upper-limb exoskeleton (Table IV-4), whereas they had one and four spills (of ten bottles opened) while unassisted, respectively. As indicated in Table IV-4, the number of unassisted spills for subject S3 were not applicable as S3 could not open the bottles without the exoskeleton. S3 had one spill (of ten bottles) while using the exoskeleton.

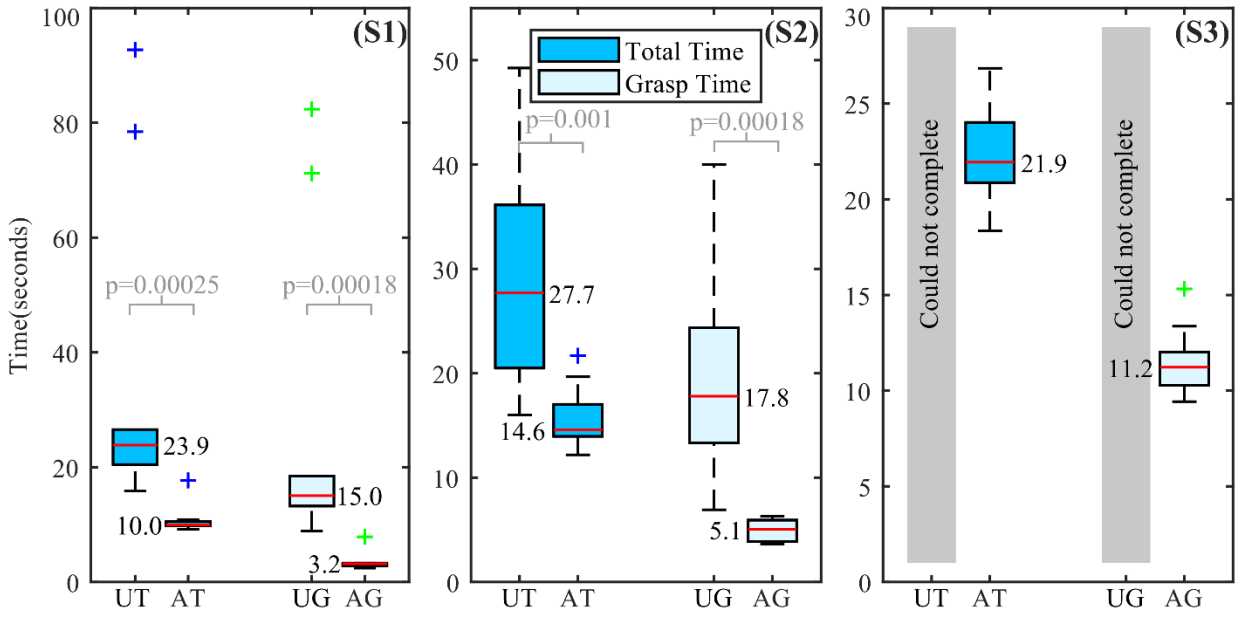

Figure IV-4: Standing bottle open task performance times. Boxplots show median (n=10) performance times for total time spent opening a single bottle and the time taken to obtain a stable grasp on the bottle (UT = unassisted total, AT = assisted total, UG = unassisted grasp, AG = assisted grasp). Boxes indicate the interquartile range, whiskers indicate total data range, and (+) indicates a datum that fell a distance more than twice the interquartile distance from the median. Plots show subjects S1 through S3 from left to right, respectively.

Table IV-3: Standing Bottle Open Median and Interquartile Range Values

	Unassisted				**Assisted**			
	Total Time (seconds)		Grasp Time (seconds)		Total Time (seconds)		Grasp Time (seconds)	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR
S1	23.85	6.12	15.04	5.25	9.97	0.79	3.18	0.45
S2	27.69	15.63	17.80	11.02	14.56	3.07	5.05	2.05
S3	n/a	n/a	n/a	n/a	21.94	3.15	11.22	1.75

For the standing bottle opening task, the subjects employed the arm portion of the exoskeleton to provide postural support for the arm, in order to avoid spilling the contents of the bottle, and the hand portion to grasp the bottle in order to remove the lid. For this task, the median improvement in time for subjects S1 and S2 while wearing the upper-limb exoskeleton was 13.9 and 13.1 sec, respectively, corresponding to factors of 2.4 and 1.9 improvement in total time. The

IQR was reduced to 0.8 and 3.1 seconds showing factors of 7.7 and 5.1 improvement in the time consistency for opening the bottle. Like the seated bottle-opening task, the time saved between the unassisted and assisted conditions was largely a result of the change in grasp time. The median grasp time was 11.8 and 12.7 sec for subjects S1 and S2, respectively, which corresponds to factors of 4.7 and 3.5 improvement. Like the seated task, subject S3 changed from a non-functional to a functional arm when assisted.

Table IV-4: Number of Spills for the Bottle Opening Tasks

	Sitting		**Standing**	
	Unassisted	Assisted	Unassisted	Assisted
S1	1	0	0	0
S2	4	0	1	0
S3	n/a	1	n/a	4

4.3 Bread cutting

All three presented subjects attempted the bread cutting exercise. Subject S1 was not able to develop the skill during the available session time, so no meaningful data was acquired for him. Subject S3 completed the task with the attending therapist aiding in the positioning of his affected hand and the exoskeleton, and a complete understanding of the task was not achieved due to his aphasia and cognitive abilities. In review, the exoskeleton does appear to have aided the subject in the task, but there are so many confounding influences that the results are not shown in this text. Subject S2 completed the task without external aid or significant coaching. His results are shown below and should be regarded as exploratory but point toward the aid that the upper-limb exoskeleton can provide to some users.

The results of the bread-cutting task for S2 are shown in Figure IV-5 through Figure IV-7 where Figure IV-5 shows the median time per slice (for 16 slices in each condition), Figure IV-6: Bread cutting task states. shows the action states during the process, and Figure IV-7 indicates the quality of each produced slice. As shown in Fig. 8, the median time per cut was 20.4 sec per cut unassisted with an IQR of 10.5 sec, whereas the median time per cut was 6.8 sec for the assisted

condition with an IQR of 3.8 sec. Therefore, subject S2 was able to cut bread on average three times faster while assisted than unassisted by the upper-limb exoskeleton.

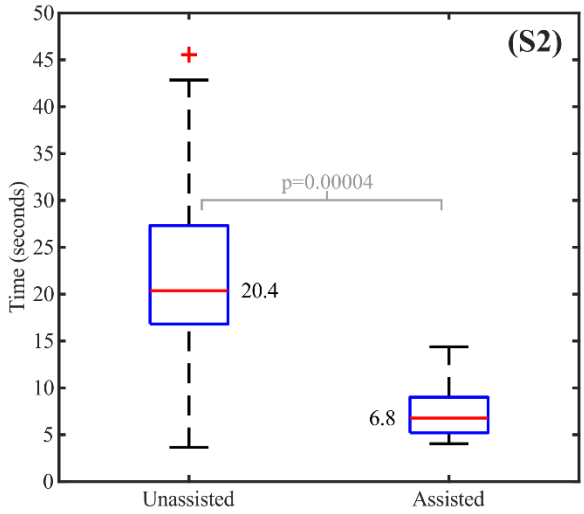

Figure IV-5: Bread Cutting time per slice without and with exoskeleton assistance. n=16 for each category.

In addition to the per slice time improvement, the overall process was condensed and became more consistent and predictable with the use of the exoskeleton. These results can be seen in Figure IV-6 which shows the overall time required to cut sixteen slices of bread as well as the state progression of the subject throughout the bread cutting process. The total time to cut sixteen slices of bread unassisted was 538.3 seconds while the assisted time dropped to 235.8 seconds.

Cut quality for the bread cutting task is shown in Figure IV-7 with cuts categorized into good, moderate, and poor quality. In the unassisted condition, subject S2 executed five good, nine moderate, and two poor cuts; in the assisted condition, all the 16 cuts were good cuts.

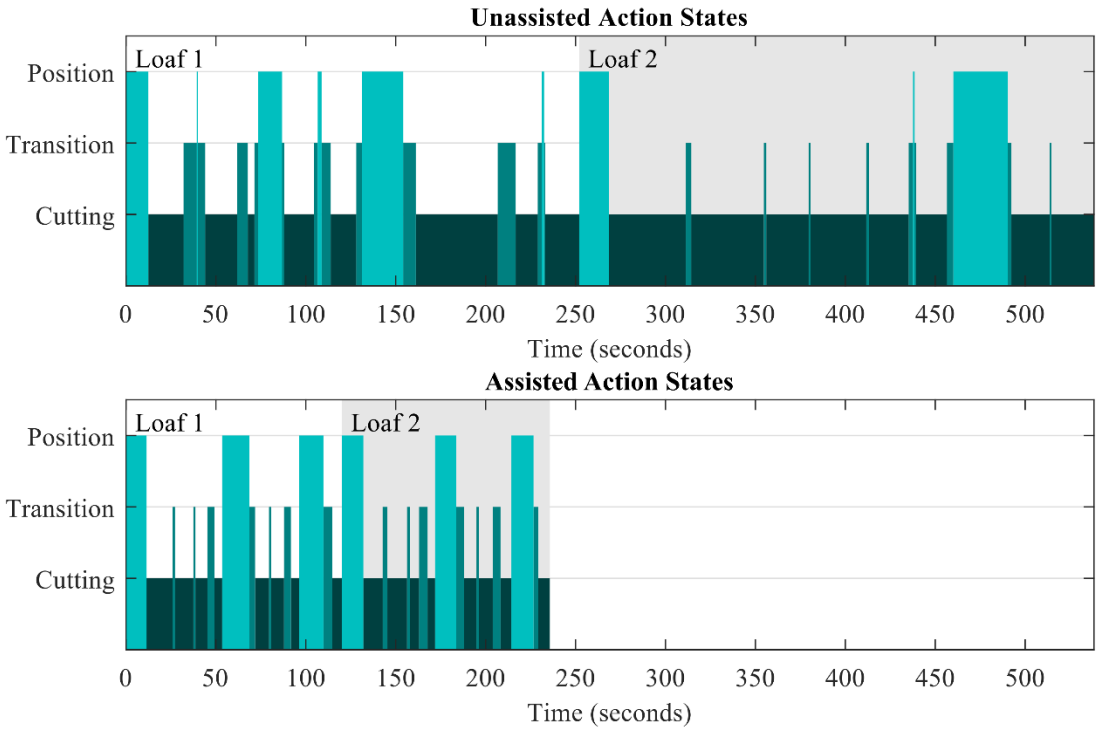

Figure IV-6: Bread cutting task states.

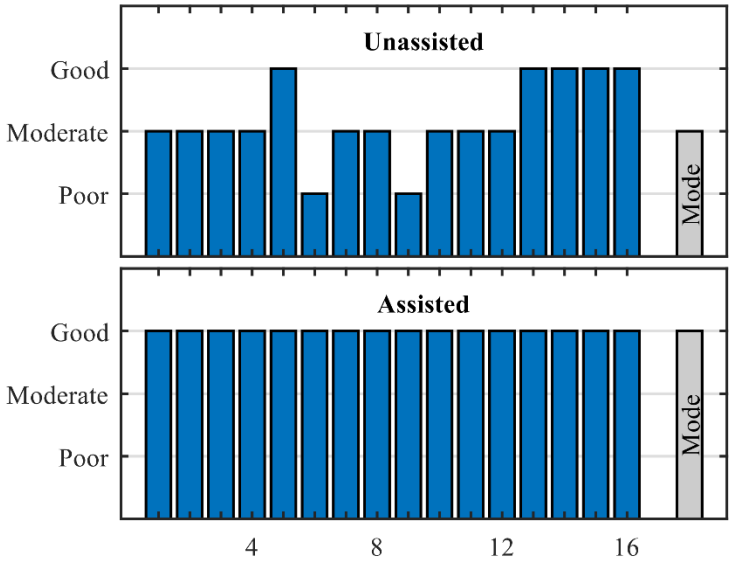

Figure IV-7: Graded quality of slices produced during the Bread Cutting exercise showing an increase in slice usability when performed with exoskeleton assistance.

4.4 Anecdotal experience and questionnaire statements

Throughout the testing and time with the exoskeleton, subject S1's frequently repeated statement was "too cool." He regularly expressed enjoyment of the device and some of the functional abilities it offered him, but he also communicated the times when it was of less assistance to him (such as some of the proposed lifting tasks). There was some debate with his wife regarding whether he would use it regularly with the conclusion being a maybe with continued device development. Certainly the idea of the exoskeleton appealed to him.

Subject S2 stated generally that he would not use this device in daily life because he found it to be too hard to put on, but that he liked how it helped him with two-handed lifting and manipulation tasks. He also proposed that it could be helpful for tasks such as riding a bike because it would allow him to keep his hand on the handlebar.

After completing the bottle opening tasks and removing the upper-limb exoskeleton, subject S3 attempted to grasp bottles with his affected right hand. As noted by the subject's caretaker, this action was something that the subject had never attempted to do after his stroke. This indicates potential that the upper-limb exoskeleton may have residual benefit with re-learning of tasks such as grasping. Because of his aphasia, S3 could not personally complete the questionnaire, but his caretaker provided answers based on her experience and stated that she felt that he would use it and that she appreciated that it was a device that he could control on his own to give him greater autonomy.

5. Discussion

The purpose of the preliminary protocol was to investigate the functionality of the upper-limb exoskeleton and explore the functional benefit from using the device to assist with ADLs. Two criteria were considered a requisite for a subject to benefit from the upper-limb exoskeleton: functional and cognitive ability.

5.1 Improvements to functional ability

Subjects' upper limb functional ability (or their level of muscle affectation) resulting from stroke is the primary indicator of whether an assistive device such as the one detailed in this paper will provide functional benefit. As shown in the results section, the upper-limb exoskeleton is capable of improving the user's grasp strength (as demonstrated in the grasp tests), improving

grasp consistency (bottle opening tests) and providing support at the wrist and elbow joints while manipulating small loads (standing bottle opening task).

The three subjects whose data is included in this paper presented MMT grades of 2 or lower at the wrist and elbow with a 1 or lower at the hand and two had very elevated hand spasticity (MAS of 3) which made unassisted grasp attainment challenging. These subjects' arm function level was appropriate for the upper-limb exoskeleton to improve their ability to consistently grasp and stabilize objects with their affected side for bimanual tasks.

5.1.1 Grasp strength test

The grasp strength task was one of the primary indicators whether an individual would benefit from the upper-limb exoskeleton intervention. Results indicated that the subjects went from a low-functioning (subjects 1 and 2) or non-functioning (subject 3) grasp to a functioning grasp. Further, the two excluded subjects in this protocol presented unassisted grasp strengths of over 1 Nm torque grasp strength. Individuals with similar grasp strength would not benefit from the upper-limb exoskeleton's grasp assist.

5.1.2 Bottle open tasks

The upper-limb exoskeleton benefitted subjects by enabling the ability to extend their fingers to create an open, grasping hand posture on command. Subjects S1 and S2 received notably improved finger extension function while assisted. Grasp time was considerably improved because subjects were able to quickly and consistently grasp the bottle in their hand. Subject S3 was able to complete the bottle opening task due to the improvement in finger flexion assistance. Additionally, the decrease in number of spills for the bottle opening tasks while assisted indicate improved wrist stability for all subjects.

The standing bottle opening task further confirms grasp improvements to the user while assessing the utility of the wrist and elbow support of the upper-limb orthosis. Recall that subjects were instructed to not use the table, except perhaps to lean against for support, and had to depend on their arm and exoskeleton's combined stability to open a water bottle without spilling. Because of his hand spasticity, S1, when unassisted, often had to make use of the table to obtain a grasp on the bottle while stretching out his affected fingers with his unaffected hand. Subject S2 had to use his torso to support the base of the bottle to obtain grasp when unassisted. The upper-limb orthosis added stability to subjects' arm and reduced reliance on supporting the bottle with the subjects' torso while obtaining grasp. Benefits like those in the sitting bottle open were observed related to

opening and closing of the hand for subjects in this task while the wrist and elbow components allowed performance of the task in open space.

5.1.3 Bread cutting

The bread cutting task investigated the effect of using the upper-limb exoskeleton on a task requiring repeated repositioning of the upper limb and opening and closing the hand portion on a different type of grip. Additionally, this task required a steady elbow and wrist support. The improved cutting speed and cut quality while assisted demonstrates added grasp and position stability for a task requiring more fine motor skills than the bottle opening task.

5.2 Importance of cognitive ability when using the upper-limb exoskeleton

Recall the upper-limb exoskeleton was designed with two buttons for its use: one for opening and closing the hand; another for locking and unlocking the wrist and elbow support functions. This simple interface was designed to minimize complexity for a population (stroke) who typically have a reduced range of cognitive abilities in addition to the relevant limb motor loss. Subjects who would benefit from the upper-limb exoskeleton intervention must have a baseline cognitive engagement to understand and learn the functionality of the device, irrespective of their limb's MMT scores. In this study, S3 had the lowest cognitive ability. Despite this, subject S3 was able to understand the device's functionality and cognitively engage with the device after some practice. However, further complexities to the upper-limb exoskeleton's interface would have prevented the subject from using the device. For individuals similar to subject S3, increased interface complexity would decrease the likelihood of device adoption for daily use.

5.3 Other preliminary assessments

Subjects S1 and S2 conducted other preliminary assessments: two bimanual basket lifts with baskets weighing 8 kg; and an affected-hand weighted bag hold with 2 kg and 5 kg. Subject 1 was able to complete all the aforementioned tests while unassisted, whereas subject S2 had difficulty with the 2 kg bag hold unassisted (the 5 kg bag hold was eliminated because of shoulder subluxation). It is important to note that, while S2 was able to complete the weighted bag hold while wearing the upper-limb exoskeleton, the limiting factor for the 5 kg test was the shoulder joint rather than hand, elbow, or wrist. S2's performance in weight-bearing tasks could have been improved through the addition of a shoulder sling coupled to the exoskeleton to improve shoulder support to offload the pressure at the shoulder joint.

6. A few comments on mass

Throughout the exoskeleton design cycle, total device mass was of significant concern with uncertainty regarding an allowable upper bound. At a mass of 920 grams, this exoskeleton device is among the lightest systems presented in the literature. Additionally, that mass is inclusive of all batteries, drive units, and control electronics, which is not the case for most systems claiming lower values. In working with the individuals who participated in this preliminary clinical study, it was observed that the mass of this exoskeleton, while tolerable for all five subjects, is on the upper edge of allowable without additional support at the shoulder.

7. Conclusion

The exoskeleton improved grasp strength in all subjects; enabled or facilitated bottle opening in all subjects; and enhanced bread-cutting ability in the subject who was able to safely perform that task. An important factor in the extent to which the exoskeleton might enhance hand and arm function is related to the extent of residual function in the paretic hand and arm. Specifically, as a user's arm becomes increasingly functional, the device serves diminishing purpose, and at some level of user ability the exoskeleton will inhibit or slow overall performance. As shown in Table IV-1, the subjects included in this functional assessment were characterized by an MMT grade of 2 or less. The MMT scale varies from 0 to 5, where 0 indicates no muscle movement (i.e., complete paralysis), and 5 indicates normal arm strength. In preliminary exploratory testing with two additional subjects having a higher degree of arm motor function, the authors determined that a MMT grade of 3 or greater (where a grade of 3 indicates the ability to move against gravity) is a nominal indicator that the user has sufficient arm function that he or she is unlikely to benefit from this arm exoskeleton assistance at the corresponding joint. As such, the arm exoskeleton is expected to be of potential functional benefit to individuals with a MMT grade of 2 or lower at the elbow, wrist, and hand.

The presence of a high degree of spasticity did not appear to inhibit the device from operation. As indicated in Table IV-1, two of the three subjects where characterized by a MAS grade of 3 in the hand and wrist (where 0 indicates no spasticity and 4 indicates full rigidity). The exoskeleton was able to substantially increase grasp strength and decrease bottle opening time for both subjects. As such, a MAS score of 3 does not appear to be a contraindication for use of the exoskeleton prototype.

Therefore, based on the combination of preliminary exploratory testing with two subjects with MMT of 3 or greater at the assisted joints, and on the testing of the three subjects with MMT of 2 or lower at the same joints who conducted the protocol described herein, indications for potential efficacy include an MMT grade of 2 or lower in the assisted joints, with an MAS score of 3 or lower in the same joints . Additionally, prospective users should have sufficient cognitive ability to operate the exoskeleton in the manner intended.

7.1 Limitations

This testing provided a preliminary assessment of potential utility, but entailed a number of substantial limitations. Among these, the results presented here represents potential utility for only three subjects. The population of individuals with hemiparesis from stroke is highly heterogeneous, and as such, a much larger sample size would be required to provide more confidence in the potential for functional utility. The inclusion of subjects for this study was limited in part by the existence of a single exoskeleton prototype, which required eligible subjects to be right-hand affected, and have a specific hand size (i.e., approximately male 50th percentile).

In addition to more subjects, a larger variety of tasks would better inform potential utility. As described in this paper, the original protocol included a bread-cutting task, although only one of the three subjects was able to complete this task without aid from an assistant. In addition to bread cutting, the original protocol also included measuring the maximum weight that a subject could hold, in both one-handed and two-handed holding. These tasks were excluded, however, due to concerns of shoulder subluxation. As such, it is likely that an arm exoskeleton without shoulder support would be limited to relatively low-load ADLs. Alternatively, a more active user may be able to engage in higher-load ADLs with the use of a shoulder support orthosis or sling.

Finally, the tasks performed in this preliminary assessment were all supervised. A key aspect of the potential utility of arm exoskeletons for this population is the extent to which users would employ the exoskeleton in unsupervised ADLs. This preliminary assessment did not specifically address this issue. The true potential utility of an arm exoskeleton for this population would be best informed with an arm orthosis that could be taken home by the subjects, to assess not only the extent to which the device provides functional benefit, but the extent to which they might employ the device in non-supervised ADLs.

CHAPTER V

CONCLUSION

1. Contribution

This text has presented the motivation, goals, design, and evaluation of an upper-limb exoskeleton intended for use to aid functional performance of bimanual activities of daily living. Work on this exoskeleton has been multidisciplinary involving mechanical design, electronics and control design, and clinical assessment. The mechanical design work presented has yielded a complete upper-limb exoskeleton including a powered hand to aid in opening and closing the user's hand in the necessary power grasp; and a semi-passive, user repositionable wrist and elbow orthosis offering support of the natural limb. Electronics and control design produced a minimalist set of embedded electronics that allows a lightweight exoskeleton device with low power needs. Specifically, this work has produced the following:

- An active hand exoskeleton offering the cylindrical power grasp necessary for a majority of bimanual ADL. This hand exoskeleton has been tested both clinically and in design analysis. The preliminary clinical testing evaluated the potential for the exoskeleton to provide meaningful function for individuals presented with challenges caused by hemiparetic upper-limb motor deficit. The design analysis studies evaluated the ability of the tendon and pulley drivetrain to perform an adequate

- A semi-passive upper-limb orthosis that can be easily reconfigured by the user to aid in arm and hand pose as well as structural support during the performance of ADL.

- A two-button control methodology that is appropriate for use by individuals whose motor affectation would prevent adoption of other sensor-based operation. Further, during clinical testing this technique was easily learned and understood even by individuals with notable cognitive deficits following stroke.

2. Future Work

There is probably some famous saying or proverb to the effect of 'no labor is truly finished because there is no limit to ideas and the creativity of man,' and such is certainly the case in this work. I would count this project to be just the beginnings of a device that can bring ability back to individuals having hemiparetic motor loss and there are many paths yet to wander in this exploration. The current device is merely a good foundation presenting a minimalist attempt at adding functional benefit and much can be added. There are three primary categories of future work stemming from the knowledge gained in this project. First, continued clinical testing of the existing device. Second, modification and expansion of the hardware framework. And finally, development of novel control methodologies for users with severely affected upper-limb motor function.

2.1 Continued clinical testing

For the existing device, the most immediate future work is increased clinical testing. The users who participated in the discussed study appear to be appropriate candidates for an intervention of this nature, and as such their results should be representative, but it is important to note that it is a small sampling of individuals of a very heterogeneous group of potential users and should be regarded more as a set of case studies rather than a clear answer regarding applicability of the device across a wider population. Additional testing should also branch to include variations of the device – one branch for added trials of the existing structure and another for just the hand exoskeleton involving participants with adequate elbow mobility. As a final note on clinical testing, only right-hand affected individuals of a certain hand size could be included in this study because of limitations preventing the creation of multiple exoskeletons in various sized right- and left-hand variants, which necessarily excludes a significant population of potential users (likely with different cognitive affectations due to the shift in stroke location within the brain from a left hemisphere to right hemisphere).

2.2 Hardware and sensing development

Hardware developed in this work has proven to be capable of providing the desired grasps and is able to significantly assist a user in bimanual ADL, but there are many additions or

modifications which may be valuable to improved functionality and user experience. Among the most likely are a repositionable thumb, automated closing of the hand, more flexible elbow, and introduction of additional compliant or soft elements.

The current thumb fixture allows for good stability of the thumb and a reasonable ability to fit a user, but it cannot be moved for alternate grasps. Addition of a repositionable thumb was discussed during the development of the hand exoskeleton but was ultimately not pursued because its development became beyond the scope of the project. The thumb poses of particular interest are a lateral pinch (allowing for a true platform hand) and variable degrees of hand openness with the thumb placed in opposition to the index and middle fingers (variable cylindrical grasp size).

Presently the user must push the hand button to initiate a grasping motion of the hand. This need to push the button first was often observed to be the most confusing feature of the control methodology for the study subjects. Often the user would attempt to place an item within the hand prior to pressing the button, which in turn led to a somewhat awkward positioning of the unaffected hand to press the button whilst also holding the object of interest. A possible solution would be the placement of a pressure or tactile sensor within either the palm or the web of the hand between the thumb and index finger to augment the two-button control system with an ability to detect object placement within the hand and initiate an automated hand closure.

Elbow performance in ADL may benefit from free motion in flexion. The current hardware effectively locks the user's arm into position in both extension and flexion, as was intended. However, during testing it was observed that all users struggled with finding the ideal arm position for picking objects, such as baskets, up off of the floor because if the arm was elevated (flexed) enough to allow for easy placement of the object on a table, then the user would have to bend or stoop very far to retrieve the object initially. Also, as a rule, it was not observed that the users gained any significant functional benefit from the locked elbow flexion. Therefore, it is proposed that introducing freedom of the elbow to move in flexion at any time, while still locking in extension for load support, may offer valuable function for lifting of two-handed items.

The rigid frame of the hand exoskeleton is very efficient at transmitting the motor forces to the user's hand, but it also increases the difficulty of achieving a good fit and can create uncomfortable pressure points. It is suggested that a hybrid structure of rigid sides with a compliant mid-structure across the hand may create a more comfortable and user-friendly arrangement without sacrificing much in terms of force transmission. Additionally, flexibility across the hand

would allow the exoskeleton to achieve more conformal grasps that may improve function through a broader range of tasks.

Finally, sensation is overrated. As described in the goals of this project, a strong emphasis was placed on maintaining the user's natural hand sensation when grasping objects. This resulted in minimal placement of any items on the palmar side of the hand. This device-hand interaction, coupled with the passive holding of the clutches, creates a couple of interesting unintended consequences. First, the user's fingers are trapped between the grasped object and the exoskeleton which may cause unnecessary discomfort as the exoskeleton imposes grasping forces. Indeed, the grasping force had to be reduced for certain subjects due to inability to tolerate the pressure imposed on the back of the fingers. Additionally, were the user to inappropriately grasp a non-suitable object (e.g. a hot pan), the hand would necessarily be held in contact in such a way that injury may be unavoidable. To alleviate these issues, it is proposed that user tactile sensation be relegated to a tertiary goal allowing the hand exoskeleton structure to be inverted with the primary structure placed within the user's palm. Placing the device within the palm will also likely ease the donning effort for individuals with spasticity as well as reduce the structures necessary to correctly locate the fingers within the exoskeleton hand.

2.3 Control methodologies

At the present time, the upper-limb exoskeleton field lacks control methodologies consistent with hemiparesis. This work has presented a simple two-button approach to device interaction. While this method is simple and easy to learn, it does not allow for fluid multi-joint interaction with ADL tasks. A major benefit could be derived from intuitive device interactions that allow for unguided, multi-joint ADL performance. The author does not currently see a clear path for this work to take and simply places the idea here in the abstract as one of the grand challenges that could revolutionize this human motion space.

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APPENDIX A: CLINICAL ASSESSMENT PROTOCOL

UPPER-LIMB EXOSKELETON TESTING

Outline of testing procedure for use with subjects experiencing upper-limb hemiparesis following stroke.

List of Abbreviations:

CAHAI: Chedoke Arm and Hand Activity Inventory

TRI-HFT: Toronto Rehabilitation Institute Hand Function Test

PROJECTED SESSIONS

Introduction/ Session I

- Introduction (5 minutes)
- Description of device (10-15 minutes)
- Goals of study (5 minutes)
- Sign consent forms (10 minutes)
- Fit Upper-Limb Exoskeleton and record fit details (15 minutes)
- Allow subject to learn exoskeleton controls and 'play' with system (10 minutes)
- Perform*: Modified Palmar Grasp Torque* and *Hold Increasing Mass* tests (15 minutes)
- Wrap-up (5 minutes)

Total Time: 1.25-1.5 hours

Session II

- Ensure proper fit of exoskeleton (5-10 minutes)
- Allow subject to reacquaint with exoskeleton controls (10 minutes)
- Perform: *Open Sets of Water Bottles* and *Basket Lift with Mass Sweep* tests (70 minutes)

Total Time: 1.5 hours

Session III

- Ensure proper fit of exoskeleton (5-10 minutes)
- Allow subject to reacquaint with exoskeleton controls (10 minutes)
- Perform: *Cut Bread* and *Shopping Cart Walk* (45 minutes)
- Debrief with subject (10 minutes)
- Give copy of Questionnaire

Total Time: 1.5 hours

INCLUSION CRITERIA

Right-sided upper-extremity paresis

Dexterous left hand to engage with exoskeleton

Adult (defined for this study as 21 years or older)

Greater than 3 months post-stroke (>6 months preferred)

Full range of motion in affected hand

Adequate sensation – must be able to alert research personnel to pain/discomfort

Ambulatory (capable of standing and walking – may use stability aid)

Absence of complicating physical or mental conditions

EXCLUSION CRITERIA

Inability to follow verbal directions

Compromised bone, joint, or skin health (e.g. severe arthritic conditions causing joint pain or limited joint mobility, tendency for shoulder subluxation)

History of multiple strokes

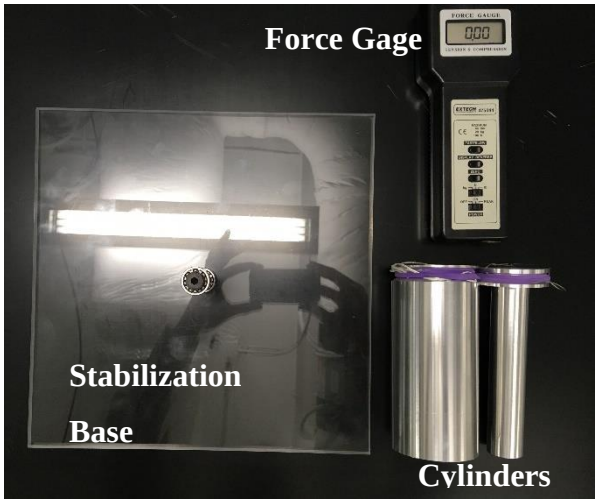
Other compromising health factors

SEQUENCING OF TESTING CONDITION

Tests are to be performed first with no exoskeleton assistance, and then subsequently repeated with exoskeleton assistance.

A completely randomized trial arrangement would require the subject to don/doff the exoskeleton device many times during a single session and was deemed to be too much of a burden with minimal expected gain in either accuracy or richness of results. By performing all tasks first without assistance, it is expected that the subject will be the least fatigued, and therefore most capable, during the unassisted portion of the exercise. Little or no learning influence is expected as the tasks chosen are ones that are common in daily life (i.e. the subject is likely to already know the process well and could have performed the task with ease prior to arm/hand paresis).

Modified Palmar Grasp Torque



Source: TRI-HFT (Note: TRI-HFT uses a 3 cm cylinder made of wood)

Summary: A numerical measurement of the maximum torque generated by a palmar grip on a 3 cm (representative of handles on utensils and household tools) and 7 cm (representative of a medium sized water bottle) diameter cylinders.

Metric: Torque

Treatment of Data: Subject specific delta of grasp torque between unassisted grasp and exoskeleton assisted grasp.

Estimated Time: 15 seconds per test, 30 second rest between tests. Total time: 9-10 minutes

Description: Subject grasps cylinder (smooth, machined aluminum surface) using a palmar grasp and the person conducting the study uses a force gauge on a moment arm to cause a torque about the cylinder. Value to be recorded is the maximum resistive torque the subject could impose upon the cylinder. For each cylinder, repeat three times clockwise and counterclockwise (rotation of cylinder in hand) unassisted and then three times clockwise and counterclockwise with exoskeleton assistance.

Weighted Bag Transfer

Summary: A test of ability to transfer and hold a weighted object

Metric: Mass, Time of hold (must meet minimum of 10 seconds to count)

Treatment of Data: This a timed test with the total time required to perform the task the metric of interest.

Estimated Time: 15 seconds per mass increment, repeated at least three times. Total Time: 5-7 minutes

Description: Subject should stand with arms at sides. He or she will then pick up a weighted bag from a chair/therapy mat, using his/her unaffected hand, and transfer the bag to the affected hand and then maintain a 10 second hold. Record the time it takes for the subject to pick up the bag, transfer to the affected hand, and maintain a 10 second hold. Subjects may not use the unaffected arm to assist with the holding phase. Repeat at least three time unassisted, and then at least three times with exoskeleton assistance, until the performance time is within 10% of the mean of the previous two attempts.

Open Sets of Water Bottles

Summary: Five 500 ml Nalgene type water bottles are opened in a single sequence. All bottles lids are torqued to the same value with the chosen tightness of the lid being moderately difficult.

Metric: Primary - Time. Task is filmed and then post-processed into task phases involving grasp, lid removal, and bottle release. Secondary – Subjective assessment of subject's level of control.

Treatment of Data: Time required to open each bottle, will be averaged across the unassisted and then assisted data sets for each subject. These average times will then be used to create subject specific delta comparisons of task/task phase time between the unassisted and assisted trials.

Estimated Time: 30-40 minutes

Sitting

Description: The bottles are filled to 80% with water and are placed on a table. Subject is seated at the table with bottles placed at extended arm length. When cued to begin, he/she proceeds to open all five bottles (one at a time) as quickly as possible. The task is complete when the last bottle and lid are returned to the table surface. The subject may use the table to help stabilize the bottle during the task. The task is to be performed a minimum of

four times (twice unassisted, and twice with exoskeleton assistance). The task may additionally be performed until the time between the previous trial time converges to within 10%.

Standing

Description: The bottles are filled to 80% with water (or free flowing simulant such as fine sand) and are placed on a standing height counter (~36 inches in height). Subject stands at the counter and, upon verbal cue, begins opening the bottles in sequence as in the sitting arrangement. Task is complete when the last bottle and lid are set back on the counter. Subject may not use the counter to assist with stabilizing the bottle while opening. The task is to be performed a minimum of four times (twice unassisted, and twice with exoskeleton assistance). The task may additionally be performed until the time between the previous trial time converges to within 10%.

Basket Lift with Mass Sweep

Summary: Lift a weighted plastic bin from the floor and place it upon an elevated surface (e.g. bed height, table height). (Note: this test is similar to the CAHAI Place Container on Table test except that the CAHAI does not use a changing mass and allows for fewer repetitions).

Metric: Mass. Potentially body position as taken from video recordings.

Treatment of Data: Subject specific delta of total container mass for unassisted versus assisted repetitions.

Estimated Time: 30-40 minutes

Large Container (e.g. Laundry Basket)

Description: Subject stands facing toward table. Large container is filled with 4 kg of mass and placed on the floor in front of subject. Subject reaches down, lifts the container, and places container on the table. This cycle is to be repeated with 8 kg of mass and then, if not possible for subject to manage 8 kg, again with 6 kg. If subject can handle 4 kg and 8 kg, it is assumed that he/she will also be able to perform basket lift with 6 kg. The task is to be performed a minimum of four times (twice unassisted, and twice with exoskeleton assistance).

Small/Medium Container (e.g. Box or Milk Crate)

Description: Subject stands facing toward table. Small container is filled with 4 kg of mass and placed on the floor in front of subject. Subject reaches down, lifts the container, and places container on the table. This cycle is to be repeated with 8 kg of mass and then, if not possible for subject to manage 8 kg, again with 6 kg. If subject can handle 4 kg and 8 kg, it is assumed that he/she will also be able to perform basket lift with 6 kg. The task is to be performed a minimum of four times (twice unassisted, and twice with exoskeleton assistance).

Cut Bread

Summary: Cut ten slices of baguette

Metric: Time

Treatment of Data: Subject specific delta of total time required for unassisted versus assisted task performance.

Estimated Time: 20-30 minutes

Description: Subject stands at standard height counter (allowable to lean against the counter) with cutting board, baguette, and bread knife placed in front of him/her. Upon being told to begin, he/she restrains the baguette with his/her affected hand and proceeds to cut slices from the end of the baguette with the goal being slices of about 1-2 cm in thickness. Once ten slices have been cut, the task is complete. The task is repeated twice unassisted and twice with exoskeleton assistance.

Shopping Cart Walk

Summary: Push a standard sized shopping cart.

Metric: Time

Treatment of Data: Subject specific delta of total time required for unassisted versus assisted task performance.

Estimated Time: 20-30 minutes

Description: Subject will walk with a shopping cart around a course that requires a few right and left turns and simulates navigating a grocery store. During the course, the subject may be asked to retrieve items from shelves.

FOLLOW-UP QUESTIONNAIRE

a. Would you wear this device at home? Why or why not?

b. Would you wear this device in public, or only at home?

c. What activities do you think this device would be most useful for?

d. What would make the device better?

e. What do you like about this device?

f. What do you dislike about this device?

g. Other – please list any comments, concerns, or ideas you think we should know.

APPENDIX B: HIGHER FUNCTIONING SUBJECTS

This appendix summarizes a two-subject subset of the subjects recruited for this arm exoskeleton study. Both subjects had less significant motor loss in their paretic arm than those found in Chapter IV and found the exoskeleton to be of less functional value in the performance of ADLs. Additionally, both had hand sizes that were not quite consistent with the dimensions of the available exoskeleton device and, as a result, experienced some functional loss. Because of these difficulties and nuances, it was decided that a full presentation of their data in the main text of this dissertation would only create confusion and distract from the most important results. For completion and comparison, their results and a short discussion are provided in this appendix.

1. Subjects 4 and 5

A summary of subject 4 and 5 characteristics is provided in Table B-1 with full descriptions in the following subsections.

Table B-1: Subject characteristics

Subject ID	**Gender**	**Age** (yrs.)	**Time Post-stroke** (yrs.)	**Affected limb/Pre-stroke dominant hand**	**Modified Ashworth Scale** (Hand+Wrist /Elbow)	**Manual Muscle Test Grade** (Elbow/Wrist/ Fingers)
S4	Female	32	2.7	R/R	1F0E/0[1]	4/2F1E/2F0E[1]
S5	Female	37	7.8	R/R	1F0E/1+[1]	3/1F2E/1F0E[1]

1 F = flexion, E = extension

1.1 Subject 4

Subject 4 (S4) was a 32-year-old female who experienced a left stratocapsular intraparenchumal hemorrhage. Her stroke occurred 2.7 years prior to the date of testing. She presented with right hemiparesis, and at the time of the study, was enrolled in graduate school for occupational therapy (indicating clear cognitive abilities and no significant aphasia).

At the time of testing, she had no noticeable increase in muscle tone except in the right wrist/finger flexors where she received a Modified Ashworth Scale score of 1 which is consistent with a "slight increase in muscle tone". In the right elbow joint she had complete range of motion against gravity with moderate resistance (Manual Muscle Test grade of 4), but her wrist and finger flexion strength were poor (grade of 2), trace (score of 1) wrist extension, and zero voluntary motion or muscle contraction in finger extension. The left upper limb was unaffected by the stroke and found to be within normal limits (WNL). The subject noted lack of voluntary motion within her right hand as a significant source of frustration – especially since she was right hand dominant pre-stroke.

Although on the upper female percentile, her hand was significantly below the target percentile for which the available hand exoskeleton was designed. This led to a moderate to poor fit. Padding was added to the exoskeleton to aid joint alignment, and while the fit was deemed adequate for continuation with the study, it is noted that it made proper retention of the fingers within the device difficult, contributed to the overall perceived bulkiness of the exoskeleton device, and created additional difficulties with all the tests involving smaller grasps because the rigid structure of the exoskeleton contacted the grasped objects prior to the user's hand.

1.2 Subject 5

Subject 5 (S5) was a 37-year-old female who experienced an ischemic stroke affecting the left middle and posterior cerebral arteries and the thalamus. Her stroke occurred 7.8 years prior to the date of testing. She presented with right upper-limb hemiparesis and mild receptive and expressive aphasia.

At the time of testing, her hand wrist and elbow present with a slight increase in muscle spasticity (Modified Ashworth Scale score of 1). Her Manual Muscle Test indicated fair (grade of 3) range of motion in the elbow, trace to poor motion at the wrist, and zero to trace motion at the fingers. Her left upper-limb was unaffected and could perform many complex compensatory skills (e.g. tying her shoes with the left hand only).

Her hand size was similar to that of S4 with similar adjustments to fit required and associated challenges with exoskeleton functionality when grasping small diameter objects.

2. Results:

2.1 Grasp strength test

Figure B-Figure IV-21 shows the results for the grasp strength testing. Specifically, Figure B-Figure IV-21 exhibits the median grasp torque capability of S4 and S5, respectively, for each of four grasp cases (small and large cylinder diameters, clockwise and counterclockwise directions) while wearing the exoskeleton (blue) and without it (green), along with the range for each measurement. The numbers on the figure represent the median grasp torque associated with each test condition.

For S4 the exoskeleton prevented the attainment of a strong grasp with the small cylinder because of the device to hand fit discrepancy, causing a large decrease of function in that use case. For the large cylinder, the functional effect of the exoskeleton was largely neutral with the median grasp scores in the assisted versus unassisted cases being similar, and the range of the assisted cases being narrower than that of the unassisted case. Subject S5 experienced a decrease in function for all assisted cases except the small cylinder counterclockwise case.

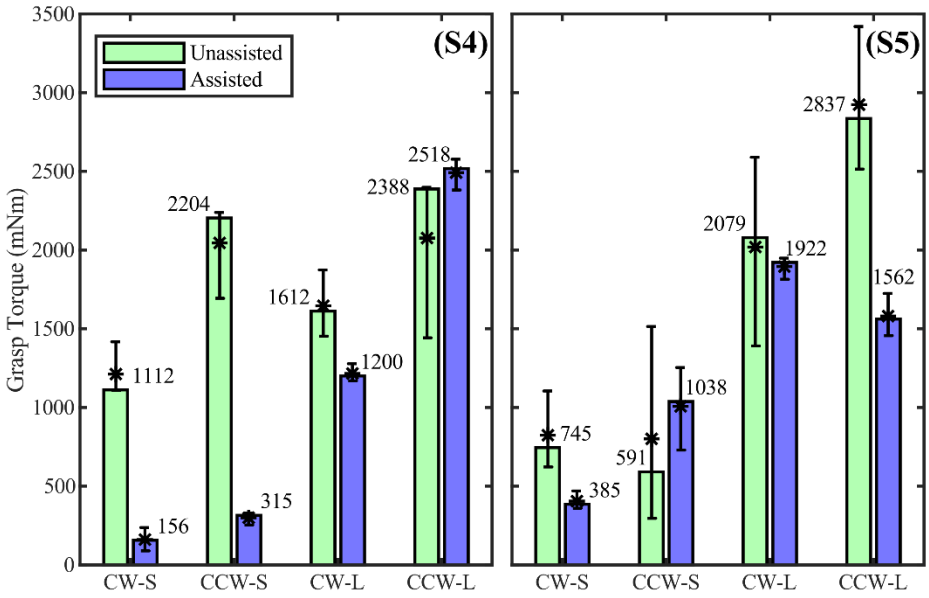


Figure B-1: Palmar grasp torque values for subjects S1 through S3 from the left, respectively. Displayed values and bars indicate median grasp torque and whiskers indicate the total data range (n=3), the calculated mean for each is indicated by an asterisk (*) symbol. CW stands for clockwise; CCW for counterclockwise; S for the small diameter cylinder; and L for the large diameter cylinder.

2.2 Bottle opening tasks

Figure B-Figure IV-22 and Figure B-Figure IV-23 show, respectively, the results of the sitting and standing bottle-opening tests both with and without the exoskeleton. Specifically, each figure shows a comparison of two time metrics for the bottle-opening tasks: 1) the Total Time, which is the time required per bottle to complete the task (i.e., the time required to grasp the bottle, remove the lid, and place the lid and bottle on the table); and 2) the Grasp Time, which is the time required for the grasp portion of the task only. The purpose of the grasp time measure is to isolate the role of the exoskeleton since the other portions of the task (removing the lid and placing the lid and bottle on the table) are determined primarily by the unaffected limb.

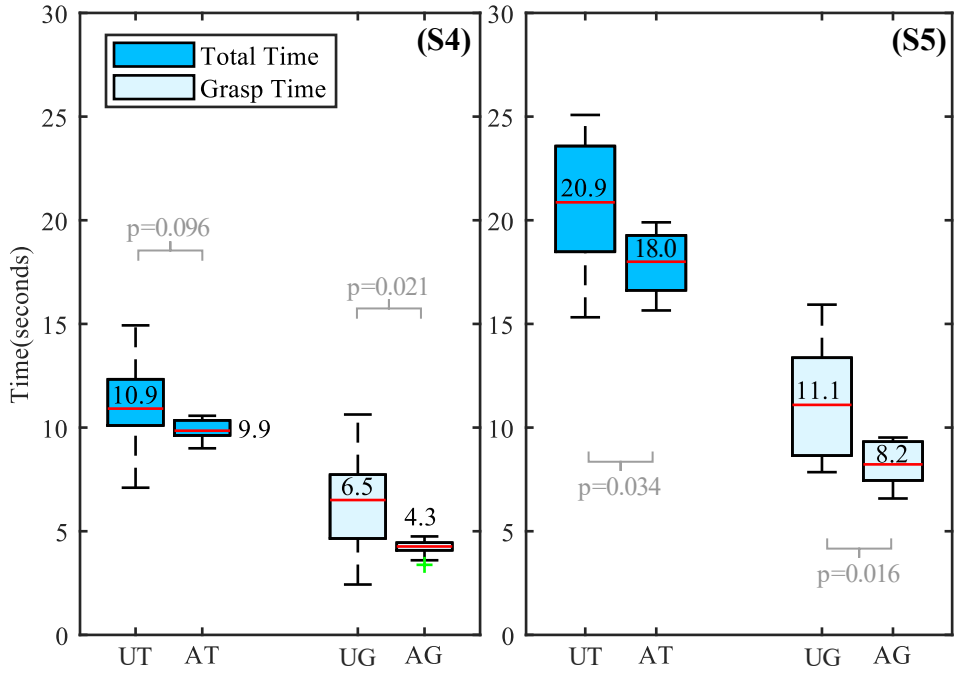


Figure B-2: Sitting bottle open task performance times. Boxplots show median (n=10) performance times for total time spent opening a single bottle and the time it took to obtain a stable grasp on the bottle (UT = unassisted total, AT = assisted total, UG = unassisted grasp, AG = assisted grasp). Boxes indicate the interquartile range, whiskers indicate total data range, and (+) indicates a datum that fell a distance more than twice the interquartile distance from the median. Plots show subjects S4 through S5 from left to right, respectively.

For the sitting bottle opening test, the median improvement in time for subjects S4 and S5 while wearing the upper-limb exoskeleton was 1.0 and 2.9 seconds, respectively, which

corresponds to factors of 1.1 and 1.2 improvement in the total time. Additionally, the interquartile range (IQR) was reduced to 0.73 and 2.65 seconds, respectively, which corresponds to factors of 3.1 and 1.9 improvement in the time consistency for opening the bottle.

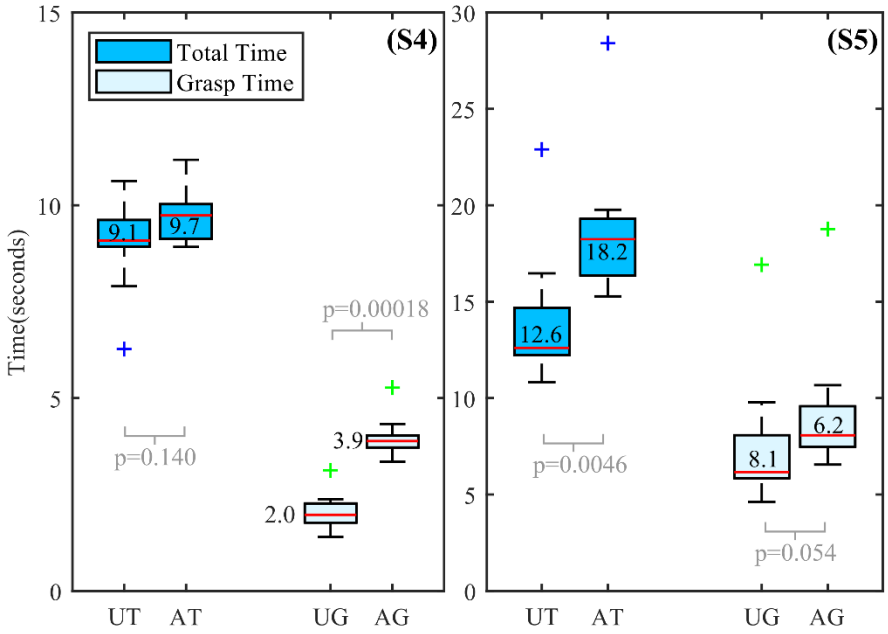


Figure B-3: Standing bottle open task performance times. Boxplots show median (n=10) performance times for total time spent opening a single bottle and the time taken to obtain a stable grasp on the bottle (UT = unassisted total, AT = assisted total, UG = unassisted grasp, AG = assisted grasp). Boxes indicate the interquartile range, whiskers indicate total data range, and (+) indicates a datum that fell a distance more than twice the interquartile distance from the median. Plots show subjects S4 through S5 from left to right, respectively.

For the standing bottle opening task, the subjects employed the arm portion of the exoskeleton to provide postural support for the arm and the hand portion to grasp the bottle in order to remove the lid. For this task, the median time for subjects S4 and S5 increased while wearing the upper-limb exoskeleton by 0.6 and 5.6 sec, respectively.

3. Discussion

3.1 Grasp Strength

Several factors are believed to have contributed to the lack of positive results found in the grasp strength test for these two subjects. The first factor is the appropriateness of the exoskeleton fit. It was observed by the researchers that the rigid exoskeleton frame made contact with the

cylinder prior to the user's hand. Therefore, the grasping force was placed on a relatively small contact patch having poor frictional characteristics. A second factor is that the upper arm strength of these subjects contributed to the grasp cylinder results as the subjects could exert sideways pressure on the cylinder, which was fixed to the table surface. While useful for a fixed object, this ability to use the strength of the upper arm joints would not be possible with a free object, which may explain why these subjects experienced a larger than expected gain when opening water bottles. Finally, subject S5 was, subjectively, observed to not make as strong of an attempt to grasp the cylinder while wearing the exoskeleton and instead allowed the exoskeleton to do all, or the majority, of the grasp.

3.2 Bottle opening

The results of the bottle opening tasks were mixed. Both users experienced a functional gain in the sitting test while both experienced a loss in the standing condition. The gain in the sitting condition is likely attributable to the increased grasp consistency and strength provided by the hand portion of the exoskeleton device. The loss in the standing bottle opening test is a little more difficult to explain but it is believed to be due to the upper exoskeleton joints hindering the motion of the arm, particularly the elbow joint.

4. Concluding Remarks

Both of these subjects had enough arm function to position and stabilize their hand in space and therefore found the wrist and elbow exoskeleton a hindrance to their ability to perform ADLs. As such, this seems to indicate that this nature of a locking, support only arrangement is not suitable for augmentation of joints having a Manual Muscle Test grade of three or better.

While the Manual Muscle Test grades and spasticity scores for both subjects' hands is consistent with the projected user case for the hand exoskeleton, the performance results were complicated by an inadequate fit. After performing the study, subject S4 stated that she may be interested in use of just hand exoskeleton with the appropriate fit.