Designing an Assistive Mobility Device for Geriatric Sit to Stand

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A Major Qualifying Project submitted to the Faculty of Worcester Polytechnic Institute in partial fulfillment of requirements of the Degree of Bachelor Science

BY

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Abstract

Challenges with the sit to stand (STS) transition are one of the chief complaints amongst the nearly 309 million elderly people in the United States. The STS transition is defined as the process of rising from a seated position to a stable standing position. This Major Qualifying project designed a device to augment the forces required for the STS transition. The objectives were to create a safe, reliable, and ergonomic device which reduces energy expenditure at a reasonable cost. The design utilized a moment about the knee providing 25% assistance based on an average moment of 1Nm/kg. Forces were produced using springs, which extend as the user sits down. The design requires the user to wear one brace on each knee. Clinical tests addressed issues of comfort, impact on gait, and assistance with the STS transition. This data were used to determine device effectiveness.

Chapter 1: Introduction

Mobility is a key indicator of health and independence [1]. As humans age, mobility becomes increasingly challenging. Difficulty with the sit-to-stand transition (STS) affects 6% of the community dwelling population, which is defined as older adults who are still capable of living on their own [2]. Approximately 60% of the assisted living population has problems with STS [2]. This is an increasing problem because the American geriatric population, defined as individuals older than sixty-five years, is estimated to grow from approximately 13% of the population to 20% by 2040 [3]. The issues with the STS transition seen in many older adults is rooted in muscle weakness. With each additional year of aging, about 1-3% of muscle strength is lost, and becomes exacerbated by a sedentary lifestyle. The inability for older adults to smoothly transition from sitting to standing has become problematic for individuals who want to live independently and perform tasks efficiently. An assistive device focusing on the sit-to-stand transition would fit a specific and growing need.

Challenges with the sit-to-stand transition are one of the chief complaints amongst the elderly, because it is an instrumental act of daily living [4, 5]. A sedentary lifestyle contributes to the deterioration of muscle groups, and an active lifestyle helps maintain muscle functionality [6]. The typical free-living person completes the sit-to-stand transition sixty times a day [7]. This fundamental occurrence is also mechanically demanding, requiring coordinated work from the quadriceps and abdominal muscles [1].

Weakened quadriceps and abdominal muscles lead to less control of the body's center of mass (COM). As adults age, they tend to have a decreased tactile sensitivity and increased muscle activation latency. This combination of aging factors can lead to incorrect weight shifting patterns during STS [8]. An inability to rise and sit, which is necessary for many daily activities, can lead to an increased chance of becoming immobilized.

During the sit-to-stand transition, there are four identifiable phases.

- Flexion Momentum: The first phase of the sit-to-stand transition is the initiation of the forward lean. This is when the head, arms, and trunk (HAT) body segments rotate forward in preparation for vertical uplift.
- Momentum Transfer: During the second phase, the COM is transferred over the feet, resulting in the anterior translation of the center of pressure (COP). In this phase, the buttocks are lifted from the seat, and the COM has then reached its maximal anterior point. The momentum of the HAT segment generated in this phase contributes to the total upward movement of the body [9].

- Extension: The third phase involves the initiation of vertical displacement, in which the HAT segment begins to rise upward and the knee extends. The knee and hip moments felt during this phase decrease with increased extension.
- Stabilization: The last phase is recovery. In this phase, the trunk moves backwards in order to regain normal oscillatory sway of the COP during quiet stance [9].

Currently, there are several variations of sit-to-stand tests to help measure the functional strength of the lower extremities. Two common methods are the 30-Second Test and the 5-Time Test. During the 30-Second test, the participant is asked to complete as many STS transitions as possible over the course of thirty seconds. The 5-Time test has the participant complete the STS transition five times regardless of speed. Specific variables associated with these tests can be controlled depending on the purpose of the study. Variations of the tests are discussed in 2.4. Both tests assist in establishing the lower extremity strength. When combined with force data obtained during the trial, both tests provide valuable insight regarding the acting forces and moments.

The current market has a variety of products that can help older adults move from a seated position to a standing position. Devices such as canes and lift seats are frequently prescribed as methods for assisting the body into the vertical position from a seated state. However, while reducing internal joint stresses, they do not address the inherent biomechanical adaptations which are a result of the impaired ability to transition from sitting to standing [4]. The state of the art, and most preferred STS interventions are lift cushions and lift chairs which provide additional forces by moving the seated plane vertical as the patient stands [2]. Another widely developed device market is home fixtures, such as grab bars. When installed next to or in front of an adult with remedial upper body strength, the user can pull themselves into a standing position. These fixtures and lift seats are beneficial for the adult who frequently sits in the same location. However, since these devices are not mobile, they have limited impact on the total STS transitions performed per day. This MQP intends to develop a mobile and biomechanically targeted device which is presently unchallenged in the current market. The goal is to design an economical, comfortable, and easy to use assistive mobility device which aids in the sit-to-stand transition and augments muscle force in the thighs of individuals with mobility problems.

In order to accomplish this goal, five primary objectives have been identified: safety, minimal energy expenditure, reliability, cost, and ergonomics. Some initial constraints include weight, cost, durability, lifespan, and energy. On a functional level, the device must facilitate movement, adapt to different body sizes and types, and have improved performance in the sit-to-stand functional test. These are explained in depth in Chapter 3. In order to accomplish these

objectives, a thorough analysis of current STS assistive devices was completed. Each device was analyzed for its strengths and weakness to identify deficiencies in the current market. Once the deficiencies were identified, the design process began, targeting specific intervention points in the STS transition. With this information, our team created several potential designs. The top performing model, was prototyped and iterated to improve performance. The chapters following this introduction document our detailed background research, design methodology, and performance tests of the final design. Associated materials are included in the appendix

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Chapter 2: Literature Review

As the body ages, it makes biomechanical changes in order to compensate for loss of muscle strength and mass. The most visible adaptations are greater forward lean to initiate standing and smaller stride length when walking [4]. While many of these changes are directly related to underlying medical conditions, plenty occur as a result of aging [4, 10]. STS is an important precursor to gait and mobility disorders and on average, is performed 60 ± 22 times per day by free-living adults [7, 9, 11-13]. As of 1987, approximately two million people over the age of sixty-four struggled with STS, which is considered the most performed daily task [14, 15]. This is of increasing concern since the population of Americans older than sixty-five years old is expected to double by 2038 to seventy-two million people [16]. By understanding the underlying mechanics and adaptations relating to STS, it is possible to design a device that aids in geriatric sit-to-stand.

2.1 Sit-to-stand Analysis

The STS transition can be in defined terms of phases. This allows specific movements and their associated kinetic and kinematic components to be isolated and analyzed. This highly dynamic system relies heavily on quadriceps muscle strength. The phases, and associated work, are based off of conclusions from a mass literature analysis.

The most popular model is a four phase model which identifies phases as a result of changes in the center of mass (COM) location. The phases are: flexion momentum, momentum transfer, vertical extension, and stabilization [9, 17, 18]. Figure 1 shows these four phases and their associated key events.

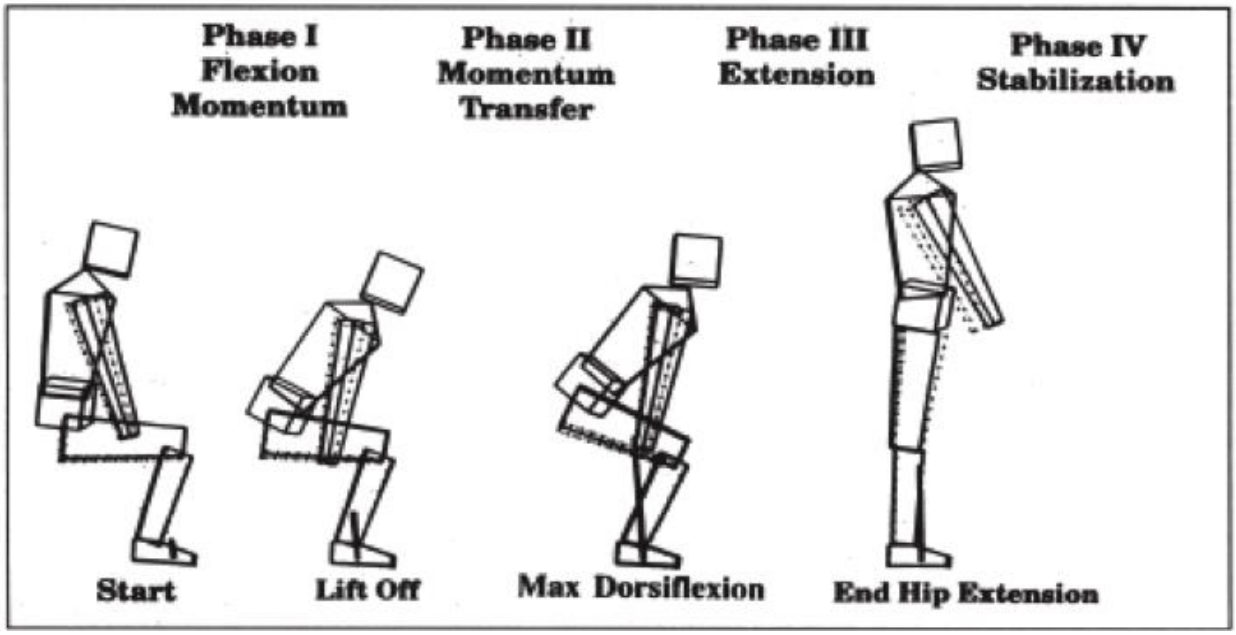

Figure 1: Shows the four phases of STS and their key events as described by the American Physical Therapy Association.

The cycle begins with flexion momentum when the center of mass (COM) is translated forward and downward as the head-arms-trunk (HAT) segment rotates anteriorly around the hips [18]. This generates upper body momentum while the legs remain stationary. This phase does not include the lift off of the buttock from the chair [9].

Next, momentum transfer occurs. This phase occurs immediately after liftoff when hip flexion raises the COM vertically and anteriorly [9, 18]. The momentum is transferred from the HAT segment to the legs, shifting the COM forward to assist in raising the body [9].

Vertical extension is when the COM moves upward until the body is standing. This phase has the highest ankle flexion [9, 18].

Lastly, the stabilization phase occurs which involves regaining standing balance through activation of the hip abductors [18]. The vertical hip velocity has reached zero and minor hip rotation occurs until the individual is balanced [9]. See Appendix A for displacement and angulation vs time graphs.

Kerr et al. determined that each of the four phases have an ascending and descending component. These phases are described as initiation of forward lean (flexion momentum), initiation of vertical displacement (momentum transfer), initiation of knee angular displacement (vertical extension), and recovery (stabilization) [19]. Although these phases do not perfectly coincide with the previous model, it is useful in analyzing STS as well as Stand-to-sit.

2.2 Geriatric Populations: Physical Changes

Older adults were found to take a longer time to execute the STS transition [20]. This is attributed to a loss in muscle mass which occurs naturally as a result of senescence and is exacerbated with a sedentary lifestyle. The importance of the quadriceps and associated knee forces in STS are explain more in Sections 2.2.1 and 2.2.2 respectively.

2.2.1 Quadriceps Muscles

The quadriceps femoris are the largest muscle group located on the anterior side of the thigh. This muscle group works together as knee extensors [21].

As skeletal muscle decreases with age, research has found a correlation with a decrease in strength. Takai et al. examined whether STS can be affected by the knee extensor muscle's force generating capabilities. The purpose of the study was to find the relationship between the power index of STS and time required to complete the ten transitions in relation to the size and strength of knee extensor muscles. In this study, twenty-eight men of age 63 $\pm$ 7.8 years, and twenty-nine women 64.2 $\pm$ 7.5 years were asked to complete ten STS transitions as quickly as possible. The power required for STS was affected by body mass, leg length and transition time. The results showed a direct correlation with the knee extension strength and leg extension power during STS. The power index was determined by Equation 1:

$$PI = \frac{(L - 0.4) * mg * 10}{t} \qquad \text{Eq. 1}$$

Where L is the leg length, t is the time to complete STS, m is mass, and g is the gravitational constant. The experiment indicated that the power index derived from STS could help determine the knee extensor's ability to produce force in older people and therefore their ability to perform STS [22].

While STS is a commonly performed task with a relatively standardized movement, there are variations according to different sub-populations. By age 72, older adults demonstrate a longer rise time during STS and have lost approximately 25% of their lower extremity strength and muscle mass [20]. Lower peak force outputs as a result of a loss of muscle mass increase difficulty with STS. [22]. This difficulty is then seen when analyzing STS times. Older participants have slower results which are exacerbated with lower seat heights, indicating a higher likelihood of falling [9, 16, 23] In these situations, adults will typically increase their trunk flexion in order to increase momentum in the forward direction [9].

2.2.2 Required Knee Forces

Yoshioka et al. studied the relationship between STS time and muscle strength. The experiment was used to determine if there was a correlation present between muscle strength, and the time required to complete STS [24]. It was determined that the peak hip and knee joint moments, when summed together, are an indicator of the strength required to complete STS. Eleven male subjects of ages 25 $\pm$ 2 years were asked to complete STS fifteen times at any speed, and were timed. [24]. Using an inverse dynamic method, the inertial and static components of the joint were calculated which reflected the gravitational forces, and body acceleration, respectively. The study determined that the time to complete STS increased as the joint moment decreased, converging to the static component. The transition required a moment ranging from 1.51-1.54 Nm/kg per knee.

The findings of the study determined that when STS occurred at fast and moderate speeds (less than 2.5 seconds), joint moments increased significantly. Joint moments were found to be relatively constant for times greater than 2.5 seconds. This research helps understand the necessary forces and moments required for STS.

2.3 Market Review

Current market devices for STS are designed for patients struggling with mobility [25]. The target users are older adults of the community dwelling population who need minimal assistance. These individuals are capable of living on their own, however, have started to show longer STS rise times to complete particular tasks. The following sections will detail a variety of assistive mobility devices.

2.3.1 Lift Assists

Users of lift assists must be partially weight bearing and have remedial upper body strength. This class of devices are both passive and active. These devices are designed to be integrated into the routines of the user.

Lift cushions can be mounted on hard surfaces and can be easily moved to other locations. They use lever-activated spring action to accomplish vertical assistance. The non-electric lift cushions cost around $90 while electric versions cost between $180 and $200. Lift chairs are seats (frequently recliners), which have been fitted with motors to tilt the chair itself and have control interfaces to initiate their motor actuation [26]. Lift chairs price around $550 to $800 [27].

The patents existing for the mechanisms associated with lift cushions range from pistons, passive gravity assistance, and powered gas springs [28-30]. All are designed to replicate the

normal rise pattern by providing assistive forces; however, existing designs are not easily moved between locations.

2.3.2 Installed Support Devices

These devices, which include mobile canes and grab bars, are marketed as implements to the natural independent habits of community-dwelling people [4, 26]. For example, the Able Life Universal Stand Assist is a set of handlebars designed to be mounted around the frame of recliner chairs to add more stable leverage points for elders to apply their upper body strength during STS and costs $100 [31].These devices rely on the upper body strength of the user and provide as much assistance as the user can output.

2.3.3 Knee Braces

Knee braces are useful for individuals who experience pain or injury. Braces are typically made from plastic, metal, foam, and elastic and sized to fit individuals of differing sizes. Many times, knee braces are used following a surgery as a rehabilitative device, or when knee pain is experienced. The four main kinds of knee braces are prophylactic, functional, rehabilitative, and unloader/off loader [32].

Compression braces are able to provide moderate support for knees that are weak or experiencing pain. The compression of the brace helps support the muscles and ligaments and surrounding area, while also retaining heat to increase blood circulation, ultimately promoting healing. The brace reduces the amount of force that traverses the patella by improving kneecap movement. This type of knee brace is comprised of dual side knee stabilizers, which are paralleled spiral bone springs, offering medial and lateral support [32].

The hinged knee brace is useful to individuals for reducing pain and instability of the knee. This style offers more lateral support, and hyperextension prevention than compression braces [33]. Hinged braces are commonly used for arthritis, weakness of the knee, knee instability, and work to reduce the pain.

In a study conducted by Abe et al., a supporting device containing spiral bone springs was designed and placed on the knee of young and older adults in order to reduce the physical stress exerted on muscles during STS [33]. Spiral bone springs are able to offer fore-aft and lateral support [34] . With the supporter on, twelve young women and fifteen elderly adults were asked to walk on a treadmill and complete a sit-to-stand test. Electromyography was used to view the right leg during STS, and from this, the root mean square and mean power frequency were calculated [33]. The test results from both populations proved that when the supporter was used, less physical

stress was placed on the quadriceps muscles. This indicates that use of the support device can reduce the risk of losing balance and falling in older adults [33]. Additionally, the physical burden on the quadriceps muscles was reduced. This reduction in physical exertion and energy required for activities could indicate a decrease in sedentary behavior [33].

2.3.4 Patent Review

The most popular, dynamically assistive knee braces documented in academic literature and patent law are externally powered. These devices predominantly rely on DC motors that power mechanisms grounded to the thigh and shank segments, and are controlled by sensor feedback systems. These motors are mostly dominated by linear actuators and hydraulics [35-38].

The passively powered orthoses were more diverse in how they aimed to produce assistive forces. Several devices have been developed which utilize stored elastic energy. The brace seen in Figure 2 was designed by Ota et al. to charge and release energy over normal movements, specifically gait [39].

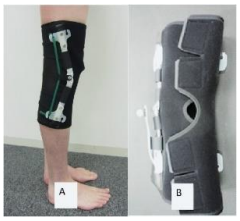

Figure 2: Brace designed by Ota et al which included a charging component about the knee

Alternative devices have been proposed using pneumatic cylinders and other variations of linear actuators to aid in mobility [40, 41]. See Figure 3 for the brace designed by G. Mukherjee [41]. The design used the relationship the frame attached to the thigh and shank to gain mechanical advantage from an extension spring.

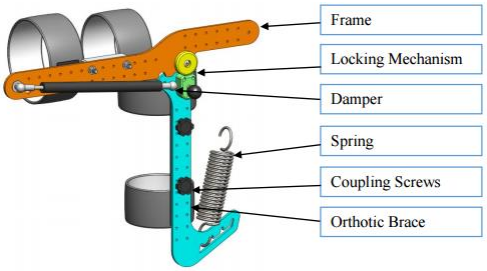

Figure 3: Brace by Mukherjee which used pneumatic cylinders for actuation

A design presented by Alexander Spring in 2011 provides assistive forces from compression springs, which are deformed by a cable attached to a disk that is mounted coaxially with the knee as the rotation center. A pneumatic actuator installed beneath the heel locks the knee disk, or allows it to rotate freely. When locked in place, the cable transmits a force to the compression springs, storing energy. The springs contain this energy when in the seated position through a ratchet fixture within the spring compartment, as seen in Figure 4. This device appeared to provide a moment profile linearly proportional to angular deflection.

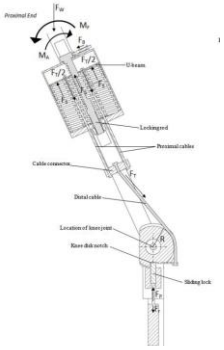

Figure 4: Spring brace with a ratchet spring design

2.4 Testing Methods

A variety of tests are used to understand STS. The STS test is a quantitative tool that controls for specific variables during the transition and analyses when force data is collected. However, many tests are more subjective,

focusing on personal experience as a gauge. One example of useful but subjective tests is Rating of Perceived Exertion.

The Five Times Sit-to-stand Test is primarily used in measuring lower extremity strength and balance. In the test, the participant is asked to fully stand up and sit down as fast as possible five times on "go". Subjects are also instructed not to touch the back of the chair during the exercise [13, 23]. Important variables which are standardized and predefined are chair height, start time, end time, and speed of motion. These variables are typically defined and standardized for the STS test due to their large influence on the motion outputs. Arm use and movement is also highly discouraged, however are still allowed in clinical trials [23].

Variations in the Sit-to-stand Test include:

- controlled rise time [9, 17] vs natural rise speed [12, 17, 19] vs fast as possible [42]
- constant chair height [17, 42] vs custom chair height based on participant's leg length [9, 13, 17] v comfort [11]
- number of trials [11, 13, 42, 43] vs duration of trial [43]
- use of arms [12, 13] vs arms crossed [9, 13, 17]
- thighs supported [12] vs thighs not supported [9]

These variations allow the experiment to be customized for specific needs. Highly controlled tests are advantageous because they obtain clean data sets for easier analysis; however, the restrictions impede the natural STS transition. This may cause the application of results to be questioned in real world settings, casting doubt regarding their validity [17].

2.5 Summary

The review has laid out a platform to further determine the direction of the design. The analysis of the stages of the STS transition determined the force needs during each phase and corresponding intervention points. These forces were quantified with respect to the knee joint and proved useful when designing device components.

A market review was performed to gain a thorough understanding of the state of the art. Popular devices did not have the ability to be fully mobile while providing assistance. This gap in technology limits the range of applications for these devices. As a result, the do little to increase the overall activity of their users.

Chapter 3: Project Strategy

An explicit project strategy guided the design of an assistive device targeting the sit-to-stand and stand-to-sit movements efficiently and effectively. This chapter will discuss design components, specifically the objectives and constraints which define the client statement and creative space. Sections 3.1 and 3.4 identify the initial and revised client statements which were used to focus research. Section 3.2 derives objectives and constraints from the initial client statement. Lastly, the project approach is detailed in Section 3.5, which provides an overview of the timeline and its associated execution.

3.1 Initial Client Statement

Design an economical, wearable, comfortable, and easy to use assistive mobility device which aids in the sit-to-stand transition and augments thigh muscle forces of geriatric individuals. The device will target specific phases of the sit-to-stand transition in order to attain safe vertical momentum, decrease hip and knee moments, control trunk displacement, and not increase perceived energy expenditure. The device is designed for community dwelling people and will not interfere with daily events such as walking, stair climbing, or bathroom use. The device cost must not exceed $300.

3.2 Objectives and Constraints

The objectives and constraints of this device were determined by deconstructing the client statement. These were useful in guiding the design process and ensuring the design goals were met.

3.2.1 Objectives

After a thorough analysis of the client statement, five primary objectives were identified to maintain safety and user satisfaction. These also served as benchmarks to gauge the success of the final design.

3.2.1.1 Safety

Biomechanical changes brought on by senescence result in adaptive strategies to accomplish mobility tasks. These aging-related strategies make falls more likely, which have possibly fatal consequences [4]. The device must not increase the likelihood of accidents and falls nor cause physical trauma to the muscle or skin during use. Considering the required force for STS is directly related to weight, the device will be designed in several sizes to provide 25% $\pm$ 10% to the user.

3.2.1.2 Minimal Energy Expenditure

This device is intended to make the STS transition easier. By augmenting and paralleling the forces associated with STS, the device should decrease the amount of perceived energy exerted. Additionally, the device should not increase the energy needed to perform additional tasks, including but not limited to, walking and stair climbing.

3.2.1.3 Reliability

Since the device is intended to intervene with every STS transition throughout the day, it must be reliable. This includes ensuring it provides the expected amount of force when it engages, as well as, device durability and lifespan of two years. The device should not be at risk of failure as a result of daily use, as long as it is maintained appropriately and within the recommended lifespan. Daily life includes but is not limited to bumping into corners, height drops, perturbed rising/descending transitions, and repeated impact.

3.2.1.4 Cost

The device should be economical for users while not compromising safety or performance. This includes looking at materials and production costs as well as the potential for an insurance company to assist with managing the retail price.

3.2.2 Constraints

Six items were identified as constraints. Success by these metrics grants validity to our device design. These constraints are in no particular order since they will be tested on a pass-fail basis. Any failing components will result in iterating the design.

3.2.2.1 Maximum Weight

The device must not weigh more than five pounds. This weight cap ensures that the device will meet the ergonomics objective and does not become cumbersome over time. The recommended maximum load for adults to carry is one third of their body weight so five pounds is well under that benchmark [44].

3.2.2.2 No Skin Damage

The device is intended to be worn as close to the skin as possible; therefore, it must not cause any skin irritation or pinching. Such irritation can escalate to pressure sores if not managed appropriately [45]. Pressure ulcers were the cause of over 100,000 deaths from 1990 to 2001 and

therefore pose significant risk to users of objects that rely on prolonged skin contact, including wheelchairs and bed rest environments [46].

3.2.2.3 Cost

The device must not exceed $300 dollars. The market price for lift assists ranges from $50 to $2000 depending on the complexity and actuation of the device. By having a price cap of $300, the device is able to maintain the necessary technology while still being kept at a reasonable price point to account for research, prototyping, manufacturing, administrative, and marketing expenses.

3.2.2.4 Product Life

A minimum product life of two years is desired. Most individuals begin experiencing mobility challenges in their late sixties and early seventies. According to the Center of Disease Control, the expected American lifespan for individuals who have reached 65 years is 85 years [47]. A two year product life allows for maximum reliability and use while still being economically manageable.

3.2.2.5 Actuation

Large power sources are frequently associated with unwieldy and indiscrete systems. In order to keep the device discrete and economical, it will have a maximum of two actuators per device. Power sources will be restricted by the weight limit as well as output properties and size.

3.2.2.6 Walking & Stair Climbing Interactions

Since the device is intended to be worn at all times, it cannot interfere with activities of daily living, including but not limited to walking, stair climbing, and bathroom use. The device can neither decrease range of motion nor increase the amount of energy needed to perform tasks. The perceived difficulty and time required to accomplish these tasks can be increased by a maximum of 10% assuming 25% assistance with STS.

3.2.3 Functions

By analyzing the market for comparable products and detailing the client statement, a list of functional requirements were identified.

The functions requirements pertaining to this device are:

- Device will assist in knee extension and vertical displacement.
- Device will minimally interfere with gait and tasks between STS transitions.
- Device will store energy during the descent into the seated position.

- Device will transmit minimal stored energy while seated.
- Device will recognize the completion of the vertical displacement phase and onset of the stability phase.

3.3 Design Requirements

The standards relevant to the success of this device are addressed below. These standards were identified based on their international recognition and scope. These standards address the benchmarks necessary to protect the device users.

- ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes [48]
- ISO IEC 62366:2007 Medical Devices – Application of usability engineering to medical devices
- ISO 9001: Quality Management Systems [49]
- FDA Guidelines [50]
- ADA Guidelines [51]

3.4 Revised Client Statement

Design an economical, wearable, comfortable, and easy to use assistive mobility device which aids in the sit-to-stand transition by augmenting muscle forces in the thighs of individuals with impaired mobility. It will be designed to be worn comfortably for a minimum 8 hours and donned in less than 10 minutes. The device will target the momentum transfer and vertical extension phases of the sit-to-stand transition in order to attain safe vertical momentum, decrease knee moments to accommodate the elderly output of 1Nm/kg per knee [24] , and not increase perceived energy expenditure. The device is designed for community dwelling people and will not interfere with activities of daily living. The device cost must not exceed $300.

3.5 Project Approach

In order to best accomplish the goals of this project, specific plans were made for each term.

3.5.1 A Term

A term was devoted to understanding the project and gaining sufficient knowledge of related concepts in order to be fully prepared for the design phase. During this time a thorough market analysis and literature review was completed. This assisted in determining the scope of the current and potential market and identified functional and design parameters that should be

considered during the design process. The term produced the first three chapters of this report, the client statement, functional requirements, customer constraints, and B term plan. See Table 1: A Term Plan for a week-by-week breakdown of work.

Table 1: A Term Plan

	Week						
A Term	1	2	3	4	5	6	7
Research							
Client Statement							
FRs, CCs							
Chapter 1							
Chapter 2							
Chapter 3							
B Term Plan							

3.5.2 B Term Plan

The primary brainstorming of this project was slotted for B-term. Several designs were modeled in cardboard to gain an understanding of their feasibility. During this term, many different approaches were analyzed for effectiveness and manufacturability. The mechanical and clinical testing procedure were drafted according to common practices. Additionally, the IRB application process began in week five. The results of this term included selecting the final design, written test protocols, initial draft of the IRB application, C Term plan and Chapter 4. See Table 2: B Term Plan for a week-by-week breakdown of B Term events.

Table 2: B Term Plan

	Week						
B Term	1	2	3	4	5	6	7
Research							
Preliminary Designs							
Dynamic Model							
Testing Protocols							

Chapter 4							
C Term Plan							

3.5.3 C Term Plan

The design was finalized in the first two weeks of C term. In the following third and fourth week, iterations to the design were be made as a result of preliminary testing and part availability. Design analysis followed each iteration until the end of the sixth week. Continued design testing began at the start of the fourth week with the validation procedure written by the start of the fifth. This term produced a validation procedure, completed Chapters 5 and 6, test results, an iterated prototype and a detailed D Term plan. See Table 3 for a week by week breakdown of C Term.

Table 3: C Term Plan

	Week						
C Term	1	2	3	4	5	6	7
Research							
Design Selection							
Design Iterations							
Mechanical Testing							
Validation Protocol							
IRB Application							
Chapters 5& 6							
D Term Plan							

3.5.4 D Term Plan

The final revisions from the second round of iterations and testing were manifested into a third and final design prototype during the first two weeks of D-term. All mechanical verifications and clinical trials were performed to confirm device functionality and identify potential improvements.

The final term was dedicated to presenting the success and potential of our final design as well as developing associated materials. See Table 4 for a week by week breakdown of work completed D Term.

Table 4: D Term Plan

	Week						
D Term	1	2	3	4	5	6	7
Research	■	■	■	■	■	■	■
Associated Materials	■	■	■	■			
Device Testing	■	■	■				
Mechanical Verification	■	■	■	■			
Clinical Trials		■	■	■	■		
Preliminary Validation		■	■	■			
Chapter 7 & 8				■	■	■	■

3.5.5 Work Breakdown Structure

A work breakdown structure was created in order to identify the scope and general tasks associated with the problem statement. These broad topics provided enough guidance to productively work throughout the terms while still allowing room for creativity and exploration. The main components of the chart were: understanding the problem, developing a design, selecting the design, design testing and final design. Appendix B shows the complete work breakdown structure.

Chapter 4: Design Process

The following chapter documents the design process used to arrive at the final model. The needs, and means were developed through controlled brainstorming, iterative prototyping, and mathematical verification.

4.1 Needs and Wants Analysis

Considering the device is intended to help make the STS transition easier, the device would provide the user an external force to supplement internal joint forces and thus ease the standing

process. To make it ergonomic and compatible with a community dwelling lifestyle, the device should be wearable. Additionally, the worn device could not impede STS, walking, or stair climbing. Due to the economic limitations of the elderly, we hoped that the combined manufacturing costs would not make the device too expensive and stay under $300.

In addition to these necessary features, we endeavored to make the device as appealing to wear as possible. While some assistive devices are clunky and hold connotations of disability, we wanted our users to be at ease wearing the device due to its subtlety and comfort.

4.2 Functional Needs

Several functional needs were identified to help identify specific device feature.

4.2.1 Help produce the necessary joint moments to perform STS

Yoshioka et.al determined that any healthy individual needed a maximum knee moment of 1 Nm/kg for STS at the beginning of the transition, with the moment decreasing until the standing position is reached [24].

The device should produce a maximum amount of assistive force during the momentum transfer phase of STS. The device should scalable to provide variable levels of assistance.

4.2.2 Adjustable to be compatible for the average sized American

The device needed to be accommodating to users of varying weights and sizes. The designed mechanisms needed to fit within the confines of the average width of the thighs and calves and be customizable for individuals of different weights and sizes. Based on the anthropometric data collected by the Center of Disease Control in 2006 [52], we set approximate limits in device size around the average radii of the midthigh and mid-calf, 8.49 cm and 6.19 cm respectively. For prototyping purposes, we centered our subject weights at 65kg. The design provides the flexibility to be scaled in order to maintain assistance with difference body sizes and weights.

4.3 Design Specifications

Five design specifications were developed to define the design space for the device.

4.3.1 Allow for natural movement

The user must be able to maintain natural range of motion while using the device. Considering healthy adults allow for 0 to 135 degrees of flexion, the device must allow for the same movement [53]. Use of the device must not encourage unhealthy biomechanical adaptations.

4.3.2 Weight limitations

The final design must not weigh more than 2.3kg in order to not further inhibit the user's motion. This weight restriction also reduces fatigue as a result of use.

4.3.3 Safety

At any point in time, the release of the stored energy in the device must not injure the wearer; therefore, the mechanism must never permit the knee to hyperextend and all the mechanism parts must be mounted securely. Additionally, it must not pinch or irritate the skin.

4.3.4 Longevity

The device must be effective for a minimum of two years, while being worn throughout the day while being compatible with an active lifestyle.

4.3.5 Aesthetics

The final design should sleek, compact, and as subtle as possible.

4.4 Conceptual Designs

The final design emerged from intensive dissection of STS and controlled brainstorming of assistive means. Means for actuation, attachment, and engagement were discussed for merit and assessed with regards to the design objectives.

4.4.1 Actuation Means

The instant of STS with the greatest required knee moments was the initial action of raising the buttocks off of the seat, which occurs at the beginning of the momentum transfer phase. From this instant the moment about the knee decrease to a minimum at standing. The healthy moment profile should be paralleled to provide the most assistance when needed, which can be done through a variety of actuation methods.

4.4.1.1 Electrical Energy

We initially considered attaching a motor to a rigid housing to control the applied force. Ideal motor performance would be accomplished by incorporating advantageous gearing. However, requiring a power supply was determined inappropriate for this technology for several reasons. A battery-dependent device demands more maintenance by the user and manufacturer, making it more expensive and less ergonomic. It also risks reliability if it runs out of power and would not be as discrete.

4.3.1.2 Potential Energy

Passive elastic actuators were the most represented method drafted in conceptual designs. As the user would sit, the potential energy from the height change would be stored within an elastic material. The most promising means were torsion springs, extension springs, and bistable spring bands.

Torsion springs were an attractive option because there would be a direct relationship between knee-flexion angles and spring force, though this force would be constantly applied, making prolonged sitting uncomfortable. The bistable springs were a promising actuation alternative due to their to equilibrium states. In principle, the wearer could feel no external moments while they had a straight leg or when they were in the seated position. However, the bistable spring requires a significant input force to release the elastic energy which transitions the spring from one equilibrium state to the other. This could make STS difficult to initiate.

Extension springs would require additional mechanisms to have uniaxial deformation, but were very versatile. Both of the torsion spring and bistable spring alternatives were discarded due to their inability to permit natural and comfortable leg motion outside of the STS transition.

4.4.2 Energy Storage Methods

Several mechanisms were developed to collect the energy from descending into the seated position. In the event the captured potential energy was not enough to significantly assist someone in STS, design alternatives incorporated mechanisms to manually increase the stored energy.
The most effective way to generate energy with minimal input is to design favorable mechanical advantage. This was accomplished by introducing gears to the design space.
Three alternatives were considered feasible at the time.

4.4.2.1 Ratcheting of single spring around a spool

The first was a spool and ratchet mechanism which would wind a cable around a spool attached to an extension spring, as seen in Figure 5. As an individual sat down, a spool would rotate corresponding to the knee's angular deflection. A pawl mounted on the opposite ground would catch on the ratchet mounted coaxially with the spool. This captured rotation caused winding that resulted in spring extension. The user could repeatedly flex and extend their knee to gain additional assistance. The ratchet design would store this additional energy which could be released by the user when they chose to stand.

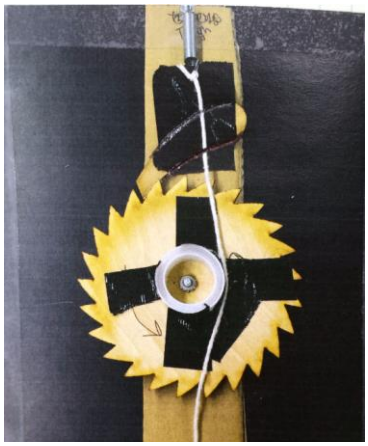

Figure 5: Preliminary iterations of Spring-Ratchet design

This idea was rejected because of the lack of mechanical advantage the system was able to achieve. The user would have to directly charge the device to achieve the desired stored energy. In order to do so, the user would need to supply large amounts of energy and act against the natural movement of the spring. This did not meet the minimal energy expenditure objective and was therefore rejected.

4.4.2.2 Freewheel and pinion

The second ratchet-inspired idea was the application of a freewheel mechanism can be seen in Figure 6Figure 6: Preliminary Iteration of Freewheel and Pinion Design (lacking shank pinion system). While the prior design extended the springs towards the joint center, this design attempted to extend the springs away from the joint. A master gear would rotate and this motion would power independent gear trains on the thigh and shank. Through the use of idlers, the torque would eventually power a rack and pinion attached to the end of the springs. The pinion would be coaxial with the freewheel. Only rotation associated with flexion would provide torque to the pinion shaft and therefore extend the springs.

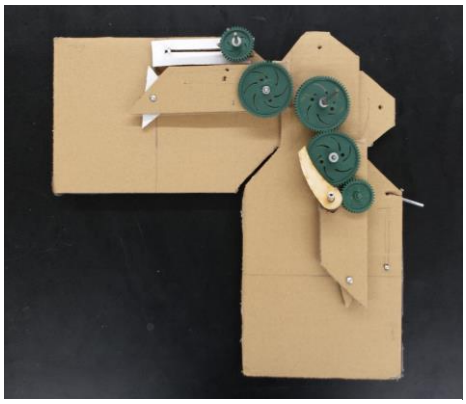

Figure 6: Preliminary Iteration of Freewheel and Pinion Design (lacking shank pinion system)

This design was discarded for being too complex. The number of moving parts increased the risk for failure and pinching. Additionally, a stable housing would prove excessively cumbersome, since it would need to span from the joint center to the furthest end of each segment. This span would need to account for the necessary spring displacement and be covered by consecutive idlers.

Additionally, the incorporation of two freewheels made the simultaneous release of energy from the thigh and shank trains more difficult.

4.4.2.3 Geared Spool

This design captures energy during the stand to sit transition and a cardboard model can be seen in Figure 7. A gear was mounted to the thigh ground and powered a free rotating gear on the shank. These gears were selected to increase mechanical advantage when releasing the stored energy during the rising phase. The shank gear was coaxial with the spool. As the spool rotated while sitting, it wound cables attached to springs, causing extension. These forces caused a couple moment on the spool which was transmitted to the joint center. The offset of the spool from the joint center of rotation allowed for maximum mechanical advantage while staying within the dimensions of the leg. Knee extension would release the energy stored in these springs onto the joint center during STS. The centralization and simplicity of the mechanism made this design alternative a viable option.

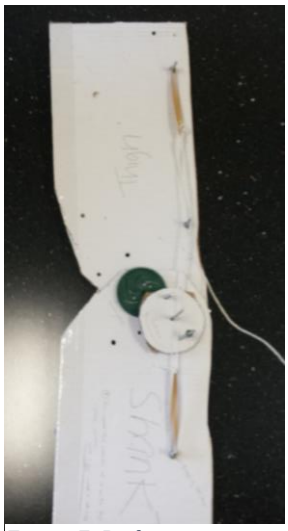

Figure 7: Preliminary Iteration of Geared Spool Design

4.4.3 Attachment Means

The device's kinetic specifications require it to be securely attached to the user. Suggested attachment means were inspired by the current knee brace market.

4.4.3.1 Rigid Housing

A rigid frame provides excellent support and limits variability of force insertion points and slack in a kinematic frame. Mechanism performance on a rigid frame may be more precise. Although this housing risks migration during use, it provides consistent support of the force insertion points. Additionally, forces may become uncomfortably concentrated at attachment points if the rigid frame is not continuously flush with thigh or shank regions.

4.4.3.2 Soft Housing

A compliant housing, like a neoprene sleeve, conforms to the unique shapes of the user. Although this brace offers the advantage of distributing forces to increase comfort, it inhibits the brace's ability to consistently deliver the assistive force at the correct insertion points. The compliant benefit of the brace could distort the force vector's line of action. Additionally, the soft housing provides less overall support to the user.

4.4.3.3 Rigid-Compliant Fusion

A compromise between soft and rigid housing is one where the knee is encased in a compliant sleeve with rigid supports on the medial and lateral sides. The stability of this device ensures the mechanism can operate as designed. This housing offers the benefit of minimal movement of the device while maintaining maximum comfort.

4.4.4 Materials Selection

The device needed to be constructed from a material which was easy to manufacture, inexpensive, attractive and strong enough to withstand expected forces of 70N. Table 5 shows the pertinent parameters for each material considered. The final material was selected by balancing the tradeoff between compressive strength, Young's modulus, and cost.

Table 5: Mechanical Properties of Considered Materials

Material	Ultimate Compressive Strength (MPa)	Young's Modulus (GPa)	Cost ($/ft^2, 0.9" wide)
Wood [54]	50-100	10-14	0.49
Steel [55]	340-1900	190-210	33.00
Aluminum [55]	100-550	70-79	18.05
Acrylic [56]	124	2.90	4.95

4.4.4.1 Plywood

The birch plywood was the least expensive material per square foot. Additionally, it could conveniently be cut by the Washburn Shops laser cutter for easy manufacturing. The lower strength and anisotropic properties of the wood risked unreliability. It allowed full scale modeling and the ability to identify design flaws. It would not be appropriate for a final design, but suitable for developing a proof of concept.

4.4.4.2 Steel & Aluminum

These metals had high material properties, making them most desirable for a final prototype; however, expense and manufacturing turnaround time excluded them from the design space.

4.4.4.3 Acrylic

The stable material properties of continuous cast acrylic made it a versatile material for an early prototype. The modest material properties were deemed suitable for early prototyping applications. Its ability to be used on the laser cutter permitted rapid prototyping and its competitive price made it suitable for realizing final design.

4.4.5 Engagement Means

It was imperative the applied moment corresponded with the natural knee moment profile during STS. Ideally, it would provide zero moments while seated and standing, and provide peak assistance at 6% completion of the STS transition [24].

4.4.5.1 Click-pen cam design

The button used in click-pens to eject or retract the inkwell served as inspiration for a manual engagement button and can be seen in Figure 8Figure 8: Example of the Click-Pen Mechanism, where the engaged version is on the left and disengaged version is on the right.

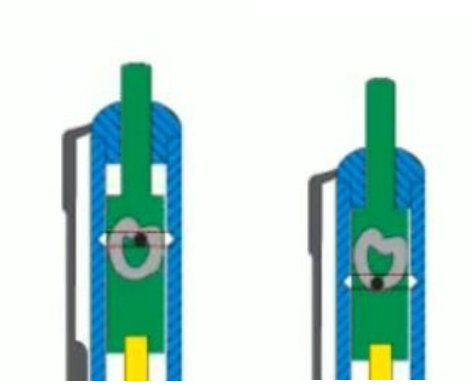

Figure 8: Example of the Click-Pen Mechanism, where the engaged version is on the left and disengaged version is on the right [73]

The cusps in the cam locked the mechanism in the on and off states. In the brace design, the engaged position would contain the stored forces while disengaging the device would release the forces on the joint center. Using a cam to generate an engaged equilibrium position could not accomplish the large required spring displacement. There was also difficulty in converting the linear motion needed to engage the cam with the angular movement experienced with STS.

4.4.5.2 Mechanical stop button

A mechanical stop would have physically locked the thigh and shank components in the seated position. This option would have ensured total stability while seated; however locked the knee at a 90degree angle. It would also have severely limited the leg motion while in the seated position and the user would have to manually engage and disengage the device.

4.4.5.3 Variable Diameter Cam

An engagement method where force is directly proportional to angular deflection would eliminate the need for user input. The design minimizes the experienced moment while seated by reducing the perpendicular distance between the force vector and spool axis.

We originally assumed this would be accomplished by changing the insertion angle of the winding mechanism so the cables tangent to the spool would pass through the joint center. This proved insufficient because it did not account for the moment transmitted through the gear train. The calculation for the force vector to achieve a zero-moment revealed that the spool offset was still subject to a couple moment. Although this proved a zero-moment was not possible, is demonstrated the ideal location for the spool.

This angle is defined between the geared distance vector of 5.08 cm from the joint center to the global vertical. A 30degree insertion angle kept all device components within average leg dimensions and resulted in appropriate force directions. This scenario permits anterior mounting of a shank spring system. Doing so limits the risk of catching clothes and pinching the user.
An alternative method were considered to produce a varying moment which mimicked a zero-moment. A cam was able to minimize experienced forces while seated and was still able to provide a maximum force at 6% completion of the transition. This was accomplished by changing the diameter parameters to generate an optimal moment profile.

4.5 Final Design Selection

This section discusses the design selection based components discussed in previous sections. Each component was judged separately before being combined into a final design. Initial mathematical calculations are also presented to demonstrate the expected functionality of the device. The final design with labeled part names can be seen in Figure 9.

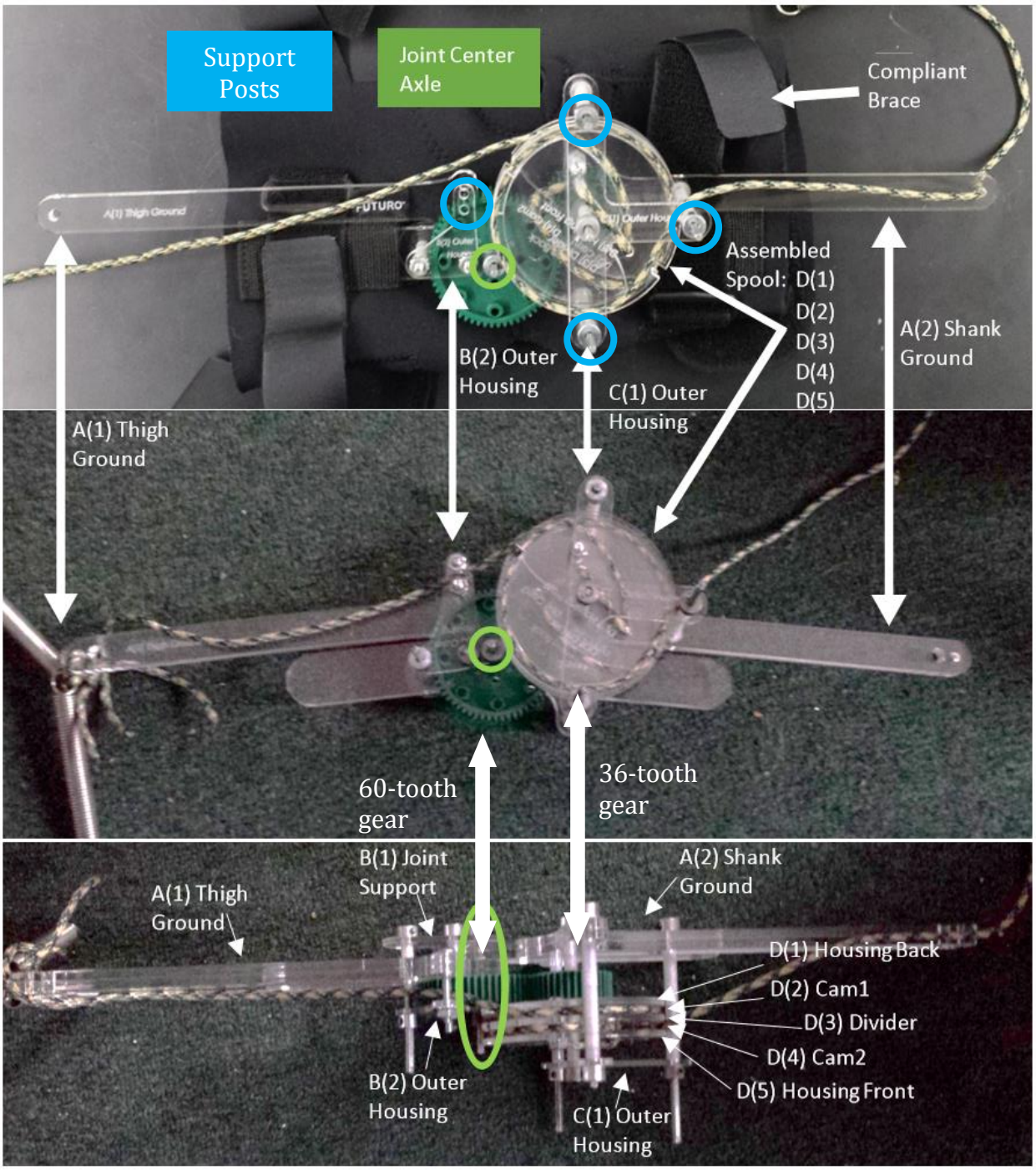

Figure 9: Final Design with Annotations

The thigh and shank grounds served as supports for the mechanism and run parallel to the leg. The spring is attached to the end of the ground to allow spring extension. The springs that are attached to the grounds store the assistive force for the STS transition. These springs have a cord attached to them which is wound around a variable diameter spool. As the spool spins, the cord pulls on the spring to cause extension. Because of the variable diameter of spool, the force changes

with angular rotation. This allows for the maximum force to be applied at the hardest part of the transition. The 60 and 36 tooth gears achieve a mechanical advantage and therefore reduce the energy needed to be exerted for STS. The remained of the components serve as support posts to assist in stabilizing the device.

4.5.1 Design Selection from Conceptual Designs

The final design was a synthesis of the best means per feature from the conceptual designs. Feasibility was determined by testing basic principles with cardboard models. The function and means were compared to each other in several decision matrixes. Each score was given between one and ten. Each design was judged based on natural movement, weight limitations, safety, longevity, and aesthetics. The winning features had the highest total scores and were incorporated into the final design. See Appendix C for the decision matrices for each component.

The final design is actuated by extension springs which are charged by the winding of the spool which is coaxial to a gear. They are attached to a compliant brace, which allows the device to be attached on the lateral side. The rigid supports and mechanisms being prototyped and preliminarily tested are from continuous cast acrylic. The device provides variable levels of assistance during STS by exploiting the position kinematics and spool diameter of the mechanism.

There are two spring insertion points, each attached at the end of the thigh and shank segments. Both springs are connected to cables which wind around the variable-diameter spool. The variability in the spool's diameter permits a peak moment to be produced on the axle but a smaller moment when at sitting and standing. The wound cables cause spring extension and produce a couple moment on this axle. This moment is delivered through advantageous gearing to the joint center of rotation, providing an assistive force during STS.

4.5.2 Design Calculations

Mathematical verifications were performed to justify choices made to the form of the final design confirming functionality. These proofs occurred in two phases. The first strove to compute the ideal values for the geometry of the design and the parameters of the springs. With these ideal parameters, springs were purchased that most closely matched these specifications. The second phase adjusted the design parameters to accommodate the actual springs applied to the design. These calculations were performed by hand and through Matlab. The computation scripts can be found in Appendix D.

4.5.2.1 Target Calculations from Design Parameters

Part Geometry

The final design incorporated gears to achieve mechanical advantage during STS. A positive mechanical advantage during knee extension would allow the target moment to be achieved with weaker springs. By introducing this mechanical advantage, more off the shelf springs with smaller dimensions and parameters became compatible for use in the design. The lower force magnitudes demonstrated the decreased likelihood of failure at stress concentrations. A disadvantage of this design choice was that the user would experience increased resistance while sitting down, since this action back drives the mechanism, resulting in a negative mechanical advantage. The advantage of lower k-constant springs outweighs the inconvenience of greater resistance to while sitting down. The final design incorporated gears to achieve mechanical advantage during STS.

The 60-tooth and 36-tooth VEX gears were selected for their robustness and convenience. They produced a mechanical advantage (MA) of 0.6 during knee extension, which scaled down the required assistive forces. For stability, we used the gears with a diametral pitch of 24, with a pressure angle of 20% and face widths of 1.3cm. The combined pitch diameter of the 60 and 36 tooth gears was 5.1cm, which determined the necessary distance for the spool from the joint center [57].

A line from the axle of the 36 tooth gear (and the spool) to the joint center makes a 30^0 angle from vertical when the brace is in the bent position. This optimized available area to keep components within the confines of the leg.

Length of Spring Displacement without Considering Diameter Change:

Determining the possible amount of spring displacement relied on the amount of cable wound, spool dimensions, and location of support posts. The amount of cable wound was directly proportional to the sum of the angular displacement of the thigh ground relative to the shank ground and spool rotation. This potential energy was directly proportional to the total displacement of the springs.

Spool dimensions were determined by size constraints. The largest allowable spool diameter was 8cm, as any larger would have cause it to extend anteriorly past the shank and become an obstruction. The initial circumference calculations were performed before the design incorporated the spool of variable diameter and therefore did not account for how diameter affected change in cable length.

The location of the support post on the thigh ground influenced spring extensions associated with the rotation of the spool. Considering the device optimizes a couple moment to provide support, this meant that the thigh spring experienced more extension than the shank spring and therefore provided more force. The location of the thigh support post was represented symbolically for the first pass of calculations, then was minimized to balance the couple moment about the spool as much as possible. Figure 10 and Equations 2-11 below illustrate the symbolic representation of the design geometry, from the perspective of analyzing the thigh ground.

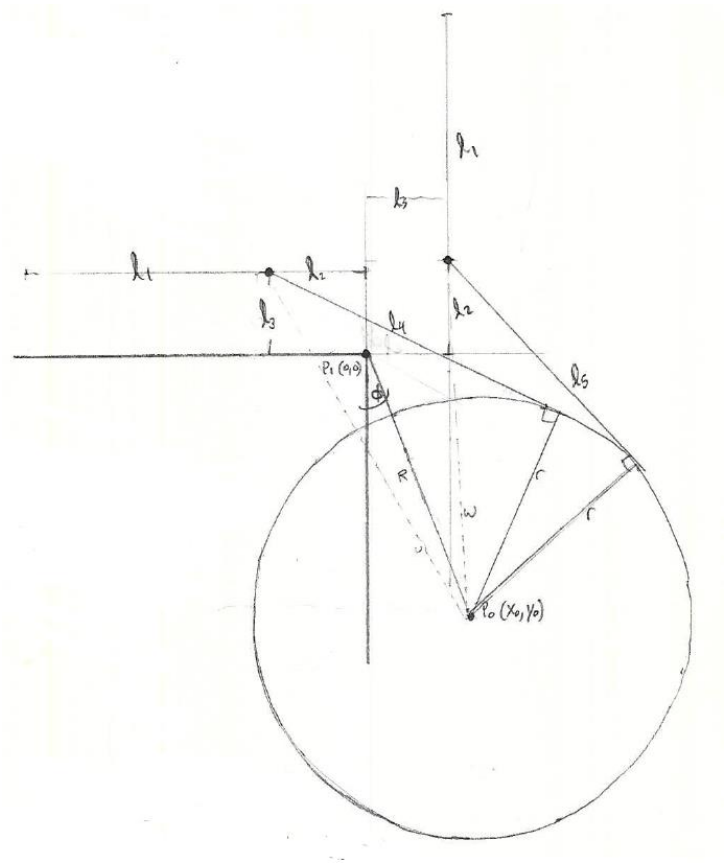

Figure 10: Symbolic representation of additional displacement due to angular thigh movement

R = geared distance from the joint center equal to the sum of gear radii = 5.08cm

r = outer spool radius = 4cm

Φ = spool insertion angle between global vertical and R in the seated position

(x0,y0) = spool axis center

l_1 = Distance from spring insertion point to support post

l_2 = Distance from support post to the joint center, collinear with spring mounting line

l_3 = Distance from support post to the thigh ground, perpendicular post offset

l_4 = Diagonal distance from support post to spool during seated condition

l_5 = Diagonal distance from support post to spool during standing condition

u = the direct line from the support post to the spool axis center while sitting

w = the direct line from the support post to the spool axis center while standing

$$x0 = R * \sin(\Phi) \quad \text{Eq. 2}$$

$$y0 = R * \cos(\Phi) \quad \text{Eq. 3}$$

$$u = \sqrt{(l_3 + y0)^2 + (l_2 + x0)^2} \quad \text{Eq. 4}$$

$$l_4 = \sqrt{u^2 - r^2} \quad \text{Eq. 5}$$

$$w = \sqrt{(l_2 + y0)^2 + (x0 - l_3)^2} \quad \text{Eq. 6}$$

$$l_5 = \sqrt{w^2 - r^2} \quad \text{Eq. 7}$$

$$\Delta cable_{angDisp} = l_4 - l_5 \quad \text{Eq. 8}$$

$$\theta_{spoolRotation} = 90 * \frac{60}{36} = 150 \quad \text{Eq. 9}$$

$$\Delta cable_{winding} = 2\pi r \frac{150}{360} \quad \text{Eq. 10}$$

$$\Delta cable_{total} = \Delta cable_{angDisp} + \Delta cable_{winding} \quad \text{Eq. 11}$$

Cable length displacement is equal to spring displacement. This will be used to determine the ideal moment profile for the assembled brace.

Percent Assistance Moments:

The peak moment during healthy STS was identified to be 65.8 Nm for 65kg individual per knee. The target moment was calculated using Equation 12:

$$M = 6580\ Ncm * \%\ Assistance \qquad \text{Eq. 12}$$

The target moment was calculated at 25%, 30%, and 50% assistance. The mechanical advantage of 0.6 was then considered by multiplying the target moment by 0.6. This data is summarized with the predicted generated moments in Table 6.

Table 6: Target percent assistance values

Percent Assistance	Target Assistance	Max Expected Moment	K-Constant
25%	987Ncm	991.9Ncm	16.74N/cm
35%	1382Ncm	1488Ncm	25.11N/cm
50%	1974Ncm	1984Ncm	33.48N/cm

Necessary k-constant to attain Target Spool Moments:

The forces required to produce the target moment were derived from the maximum spool diameter and the corresponding spring displacement at the critical phase of STS. These calculations assumed the same type of spring on the thigh and shank segments.

Standard healthy knee moment profiles show the maximum moment occurring 6% into the transition. This was accounted for in the designed moment profile with the associated spring extension value. This extension value with the spool diameter enabled us to determine the ideal spring constant required to produce the peak moment. In this section, calculations featuring "d" refer to the perpendicular distance from the tangent cable to the axle. It is assumed that the distance for the perpendicular distance from the tangent cable to the axle is equal on both the thigh and shank grounds. See Equations 13-19 for calculation proofs:

Eq. 13 $$F_{thighSpring} = kx_{thighSpring}$$ $$F_{shankSpring} = kx_{shankSpring}$$ Eq. 14

Eq. 15 $$M = F * d$$ $$d_{thighSpool} = d_{shankSpool}$$ Eq. 16

$$M = kd_{thighSpool}(\theta) * x_{thighSpring}(\theta) + kd_{shankSpool}(\theta)x_{shankSpool}(\theta)$$ Eq. 17

$$M = kd(x_{thighSpring} + x_{shankSpring})$$ Eq. 18

$$k = \frac{M_{peak}}{d(x_{thighSpring}(\theta_{peak}) + x_{shankSpring}(\theta_{peak}))}$$ Eq. 19

Angle of Offset for Spool Mounting:

The spool-cams for the thigh and shank spring systems needed to be angularly offset in order for both to generate their maximum forces at the same time during STS. This angle depended on the support post locations the inner diameters. The thigh winding post location was previously defined, and the shank support post was dual purposed as a housing support to encase the spool itself. The setup and proof determining the offset can be seen below. In this section of calculations, the "d" refers to the perpendicular distance to the center of the axle, and "outer" and "inner" to the diameters of larger and smaller magnitude, relatively. See Figure 11 and 12 Equations 20-23 for calculation proof. These equation yielded values which were used in designing how the spool was mounted onto the axle.

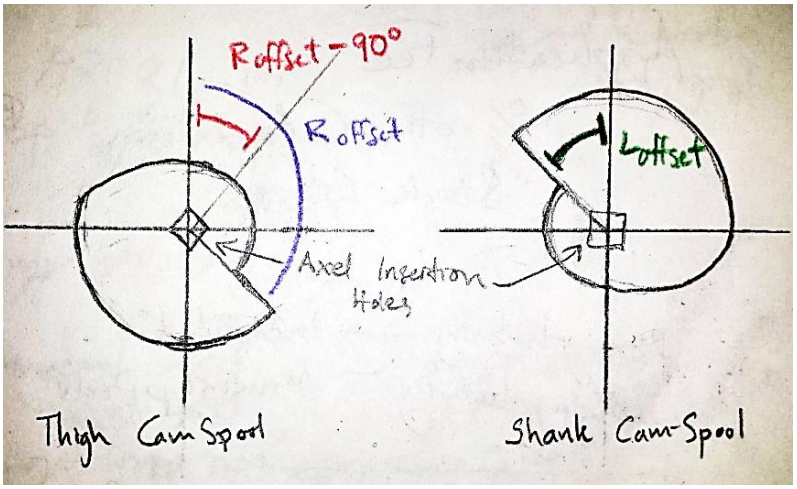

Figure 12: Sketch for visualizing angle of offset

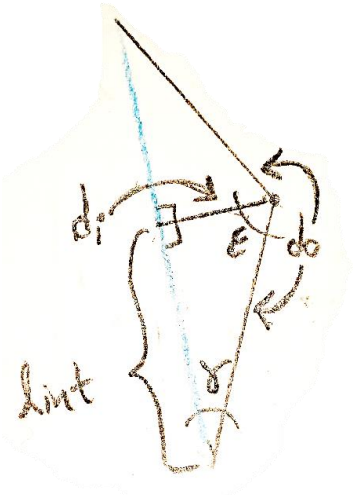

Figure 11: Defines the relationship between gamma and eta which are used to compute the offset angles

$$\frac{\sin(\gamma)}{d_i} = \frac{\sin(90)}{d_o}$$ Eq. 20

$$\sin(\varepsilon) = \frac{l_{int}}{d_o}$$ Eq. 21

$$R_{offset} = \gamma + \varepsilon$$ Eq. 22

$$180 - \angle\varepsilon = \angle_{offset}$$ Eq. 23

4.5.2.2 Parameter Calculations from Spring Specifications

The spring which most closely matched the extension, k-value, and maximum force requirements was Product No. 9065K381 from McMaster-Carr. This is a type 302 stainless steel ultra-precision extension spring with 1.3cm outer diameter, 10cm resting length. A single set of springs on the device would result in approximately 12% assistance. By fixing multiples of this spring to the ends of the device. Its specifications are displayed in the Table 7: Design Specifications for Spring Product No. 9065K381.

Table 7: Design Specifications for Spring Product No. 9065K381[58]

	Imperial Units	Metric Units		Imperial Units	Metric Units
K-value	4.78 lbs./in	8.37 N/cm	Maximum Force	16.34 lbs.	72.68 N
Resting Extension	4.0”	10.16 cm	Extended Length	7.07’	17.96 cm

Part Geometry and Cable Displacement considering Change in Diameter and Max Spring Forces:

With the established spring specifications, we were able to optimize the location of the thigh support post by minimizing the value of the distance from the winding post to the joint center. The maximum allowed spring displacement length was used to redefine the length of the ground and how much slack needed to be permitted to avoid overextending the spring.

Next, we took into account how the change in diameter effected spring displacement. The peak moment in STS occurs at 6% of the STS cycle. The STS cycle can be simplified to occur over 90^0 of knee flexion. The corresponding amount of rotation of the spool is seen in Equations 24-25 will be [59]:

$$MA = Gear\ Ratio = \frac{T_1}{T_2} = \frac{\theta_2}{\theta_1} = -\frac{N_1}{N_2}$$ Eq. 24

$$\theta_{spool} = 150° \quad \theta_{spoolPeak} = 150 * 0.06 = 9$$ Eq. 25

The offset from the initial inner diameter to the larger outer diameter must occur over 9^0. This is conservatively rounded up to 10^0 to offset the peak moment to occur later in the STS cycle.

Therefore, the cable/spring displacement associated with 140^0 of spool rotation will factor into the available force needed for the peak moment.

Figure 13Figure 13 and Equations 26-37 presents the considerations to computing cable displacement with respect to variable cam diameter and maximum spring allowance.

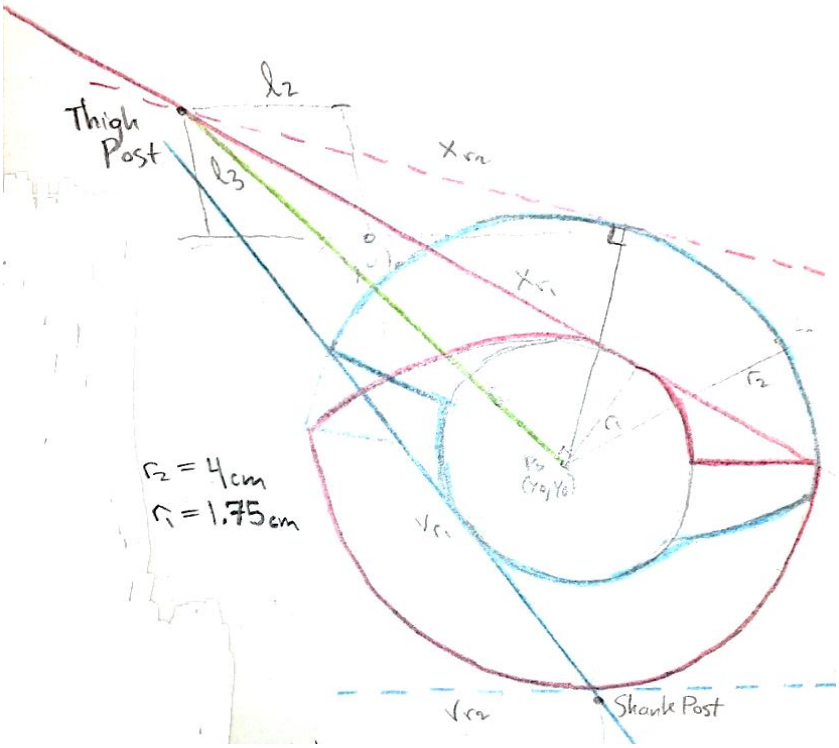

Figure 13: Spool considerations for final design, where red is the cable that attaches to the thigh spring and cam1. Blue is the cable that attaches to the shank spring and cam2. Green is the distance from the center of the spool rotation to the thigh support post.

$$x0 = R * \sin(\Phi) \quad \text{Eq. 26}$$

$$y0 = R * \cos(\Phi) \quad \text{Eq. 27}$$

$$u = \sqrt{(l_3 + y0)^2 + (l_2 + x0)^2} \quad \text{Eq. 28}$$

$$l_4 = \sqrt{u^2 - r^2} \quad \text{Eq. 29}$$

$$w = \sqrt{(l_2 + y0)^2 + (x0 - l_3)^2} \quad \text{Eq. 30}$$

$$l_5 = \sqrt{w^2 - r^2} \quad \text{Eq. 31}$$

$$l_{d\_di} = \sqrt{u^2 + {d_i}^2} \quad \text{Eq. 32}$$

$$l_{int} = \sqrt{r^2 - {d_i}^2} \quad \text{Eq. 33}$$

$$\Delta cable_{angDisp} = l_{4\_di} + l_{int} - l_5 \quad \text{Eq. 34}$$

$$\theta_{spoolRotation} = 90 * \frac{60}{36} = 150 - 10 = 140 \quad \text{Eq. 35}$$

$$\Delta cable_{winding} = 2\pi r \frac{140}{360} \quad \text{Eq. 36}$$

$$\Delta cable_{total} = \Delta cable_{angDisp} + \Delta cable_{winding} \quad \text{Eq. 37}$$

Peak Moments and Percent Assistance:

The inner and outer diameters, their corresponding spring displacements at each point during STS, and the actual spring k-constant were used to calculate the expected moment profile at each assistance level. Increased assistance was provided by attaching multiples of the purchased spring to the grounds. The plots can be seen in Figure 14.

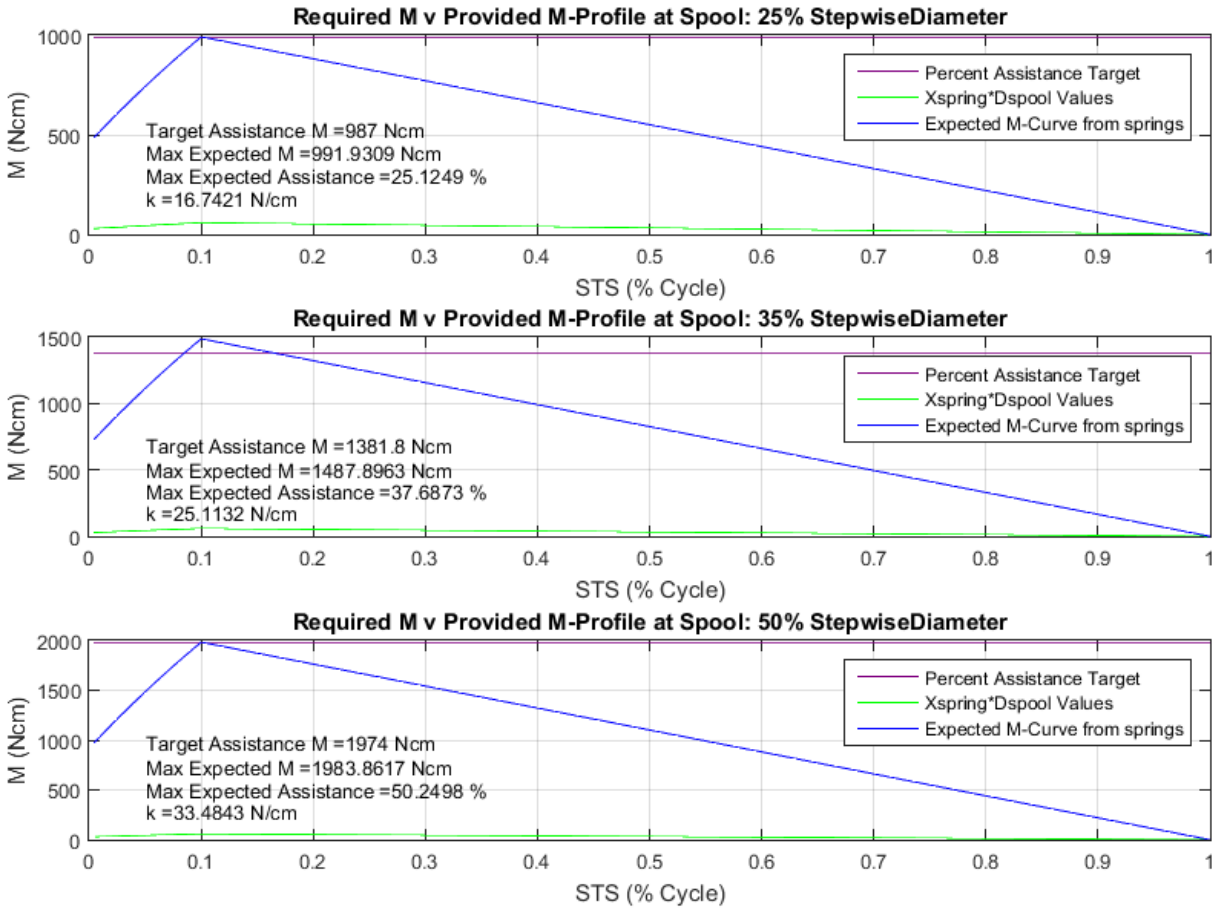

Figure 14: Designed cam moment profile

4.5.3 Design Prototyping and Feasibility Assessment

The selected design was first assembled from cardboard to prove its baseline feasibility. Part and assembly files were created in SolidWorks to visualize the design and were used for laser

cutting. With each prototyping, opportunities for improvement were identified for the next assembly. The use of a cheap prototyping material and standardized VEX parts made rapid customization and correction of errors inexpensive. These proofs of concepts revealed assumptions on the stability of the device housing, which were corrected before the production of the final model.

The final test model was printed in continuous cast acrylic. Assembly instructions, Bill of Materials, and device schematics are be included in Appendix E, F, and G.

Chapter 5: Design Verification and Validation

Verification testing revealed how the device operates in reality compared to theoretical expectations. First, the reliability and efficacy of device components were tested independently and then as an assembly in controlled settings. These mechanical tests assessed the brace's behavior under forces generated during STS. Next, the device went through preliminary clinical testing. These trials illuminated how its use effected healthy users.

5.1 Device Verification

The mechanical tests performed on the springs, cord, and frame strove to verify the reliability of each component. The component testing data were compared to the expected force and deflection values from the design process. The alignment of these values determined whether the brace was safe.

5.1.1 Springs

The verification tests for the device and testing springs were to ensure they generated the required forces and displacements. We needed to prove that the springs were linearly elastic and produced the magnitude of force required to generate our assistive moment.

The springs procured through McMaster-Carr and a Spring Assortment kit from TEKZ had advertised specifications, and we needed to ensure these were reflected in the product's performance. An Instron5544 was used to test the springs. The testing set-up can be seen in the Figure 155.

Due to the limitations of the Instron5544, the springs were not tested over the minimum device lifespan. The average healthy adult performed STS approximately 60 times per day. Assuming a 365 day year, STS is expected to occur 21,900 times in a year [4]. The team set the expectation that the device should function for at minimum one year. The expected rate of spring extension required for our device, approximately 726mm/min, was not possible using the Instron5544. Hypothetically, such a test on the Instron5544 would take approximately five hours to complete at the ideal speed.

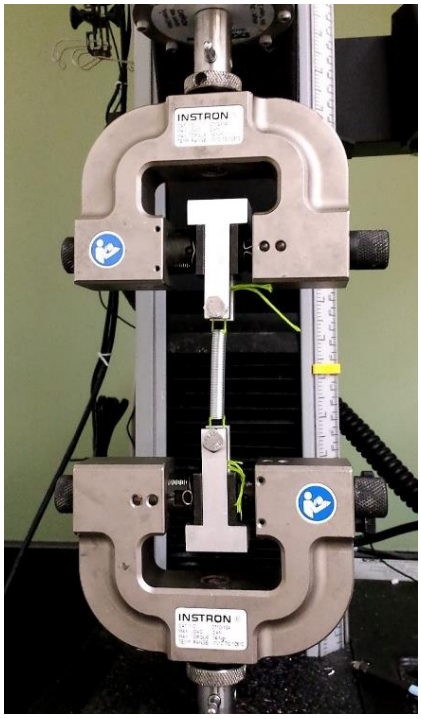

Figure 15: The springs were mounted between the Instron grips and extended controlled amounts while the load data was collected.

5.1.1.2 TEKZ Springs

The TEKZ spring had a resting length of 4.4cm with a diameter of 0.48cm TEKZ did not advertise the spring's k-constant. The spring was installed on the Instron5544 with ring grips. The spring was subjected to a displacement-controlled extension test, where the test would end as soon as there was 2.5cm of extension. Three springs were tested 7 times, yielding 21 sets of extension data. The extension occurred at a rate of 60mm/min and the data was taken every 50ms and 2N intervals.

The load data was plotted against the extension data for all of the trials. Matlab was used to find a polynomial regression. Linear regressions proved highly efficient at accounting for the change in load by extension for each trial. The loads for all the trials were averaged, and this averaged data was also fit with a linear regression. These plots can be seen in the Figure 166. The regression for the average had a coefficient of determination R^2 of 0.99986. The greater the R^2 value, the more variability of the dependent variable is explained by the regression model [60].

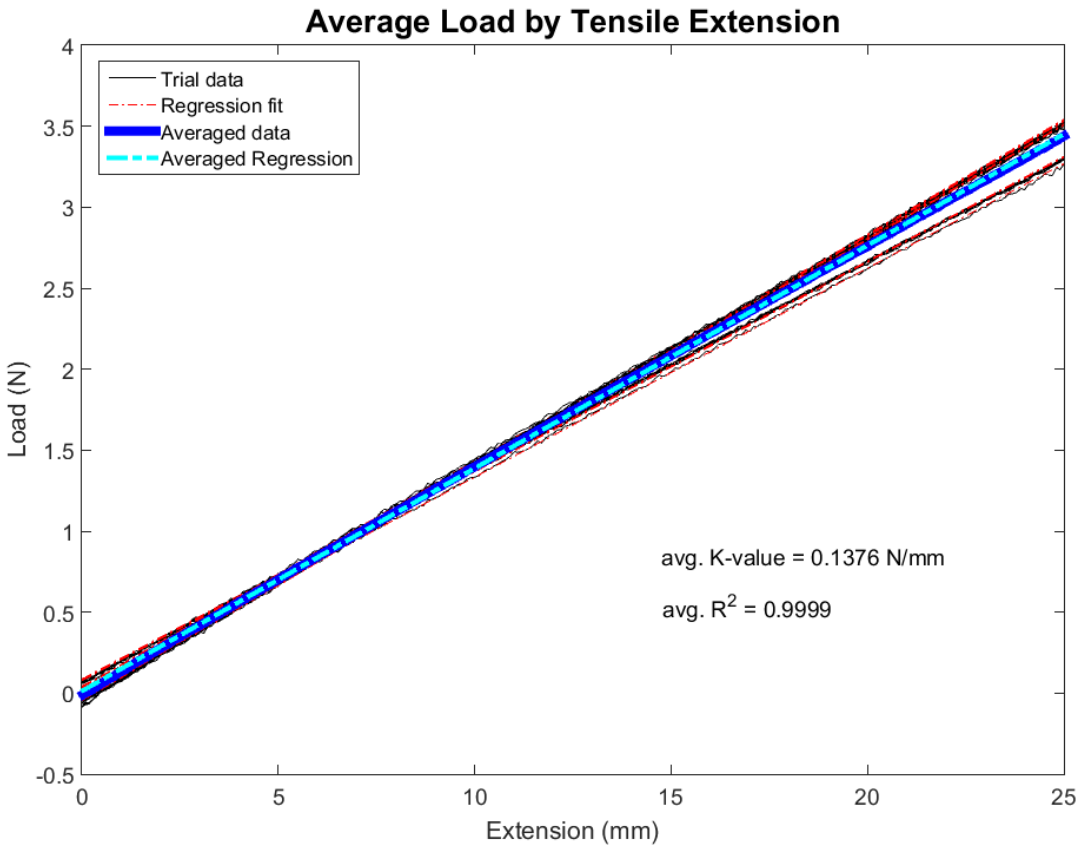

Figure 16: The load by extension trials for the TEKZ springs and averaged load by extension data display linearly elastic behavior.

The high value of R^2 in this case is strong evidence that the TEKZ springs were indeed linearly elastic with a k-value of 1.3756 N/cm, and therefore suitable for our testing purposes.

5.1.1.2 McMaster Spring Product No. 9065K381

The testing occurred on the Instron5544 with ring grips. The spring was subjected to a force-controlled extension test. Each test cycled 20 times with a maximum load of 70N and minimum load of 0N. The test was repeated 5 times, yielding 100 peak force values. The extension occurred at a rate of 500mm/min and the data was taken every 50ms and 2N intervals.

The loading by displacement data for all trials displayed linear elastic behavior for the McMaster springs. As in Section 5.1.1.1, each trial was fit with a linear regression, and all the load data was averaged to be plotted with its own regression. These plots can be seen in Figure 177.

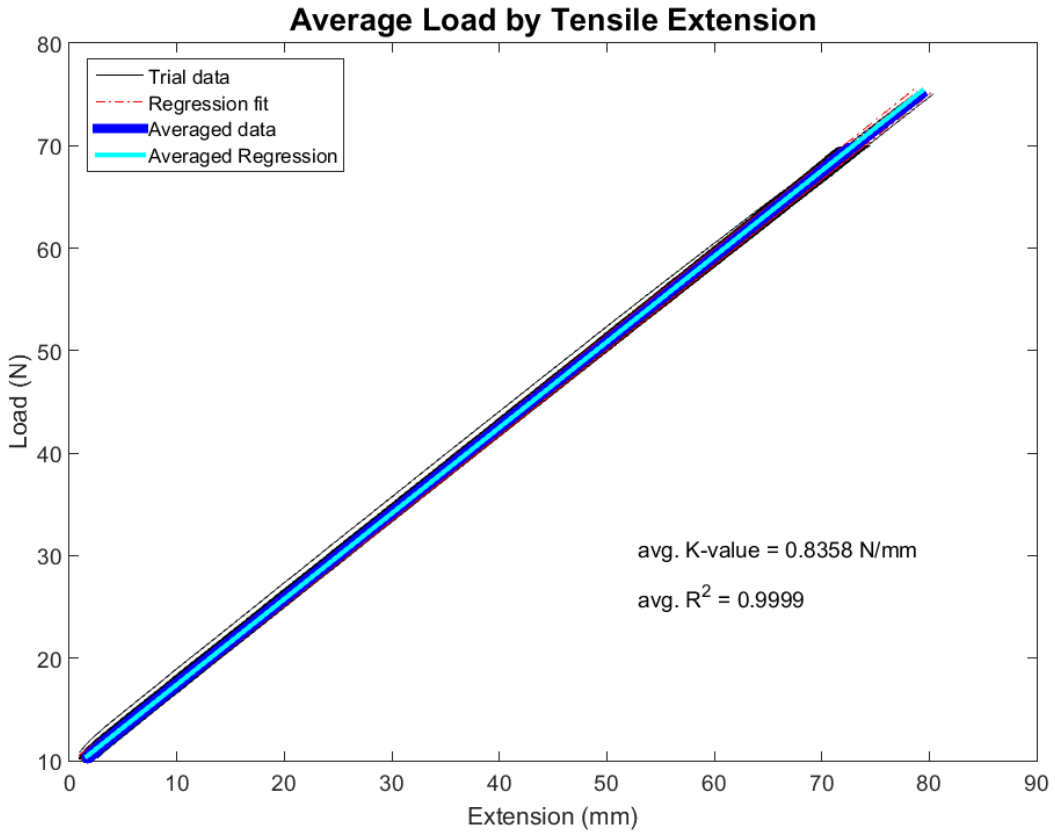

Figure 17: The load by extension trials for the McMaster springs Product No. 9065K381 and averaged load by extension data display linearly elastic behavior.

The regression for the averaged data had a coefficient of determination R^2 of 0.99. The mean squared error (MSE) between the slopes for each linear regression to the advertised k-value of 8.4N/cm. The exceptionally large R^2 value and the small MSE value strongly suggest that the purchased springs are indeed linearly elastic with a k-value quite comparable to the advertised value.

5.1.2 Cord

The cord's performance under repeated tensile loading was analyzed for reliability. The cord experienced tension with every sit to stand transition, and repeated loading could lead to plastic deformation. Testing sought to determine how the cord deformed with use thus predicting how the cord would respond when installed in the device. Unaccounted plastic deformation of the cord would reduce overall spring extension and lower the level of assistive force provided. Any plastic deformation which occurred during testing can be managed through precycling the cord prior to installation in the device.

The cord verification procedure was identical to the spring testing procedure described in Section 5.1.1.2. Two marks were placed 10cm apart on the cord to serve as explicit reference points while measuring. The cable was purchased from Lowe's and has a 3 mm diameter, and is rated to withstand 489N of force. The team assumed that the manufacturer has correctly verified how much force the cable can withstand. The cord was tested to find if it was able to withstand the 70N force that associated with one spring and what type of deformation occurs with repeated use. Data collected from these tests revealed that the cord deformed 0.75cm after one trial (20 cycles) and the subsequent four trials, each with 20 cycles, yielded no plastic deformation. The percent strain experienced was 7.5% and could be managed through precycling.

5.1.3 Initial Moment Profile and Frame Verification

The following protocols were to verify whether the mechanism frame could withstand the forces of a 65±6.8kg individual wearing the brace at 25%, 35, and 50% assistance. This evaluation was crucial in determining safety. Without a reliable and properly working frame, the mechanism would not serve its intended purpose as an assistive device.

The device mechanism is attached to a continuous frame and is grounded onto the lateral sides of a rigid compliant brace. The frame permits the mechanism to generate forces on the knee. We assumed the knee had one center of rotation which did not change position over STS. Given proper donning of the brace, our device's generalized rotation center would cover expected range of motion. Failure to strap the device onto the leg properly would reduce the effectiveness of the assistive forces and compromise device safety. This set up permitted calculations which expressed the moments at the joint as if it was a point location.

The moment profile and frame verification were initially tested concurrently. The device used the ideal McMaster springs which were capable of producing the expected load. Additional holes in the thigh and shank grounds were drilled to allow the design to fit in the Instron5544 using ring grips. This free rotation of the device allowed for flexion angle and the associated moment to be compared.

Figure 18: Brace repair

Figure 19: The location of brace failure.

During the first test, the brace experienced an unexpected shear force, which resulted in the grounds shattering. The failure can be seen in Figure 19. This test showed the frame to be very sensitive to z-directional forces and the acrylic to be especially weak when subjected to bending. The test caused the thigh and shank segments to rotate relative to one another, rotating the spool and causing the springs to elongate. The force resulting from this elongation proved too strong for the frame.

In order to proceed with testing, the grounds were reinforced with LOCTITE, an adhesive and waterproof polyurethane. The ground reinforcement alone was not sufficient in preventing breaking. The spring strength was reduced and the TEKZ springs were used for the remainder of testing. The reinforced brace with weaker springs proved sufficient for the remainder. The repair can be seen in Figure 19.

5.1.3.1 Cam-Spool Output

A reinforced frame with low value k-constant TEKZ springs was repeatedly flexed on the Instron5544 to compare the generated to the designed moment. This test was to identify the generated moment profile from with the extension of linear elastic springs. The desired moment magnitude can be obtained and scaled based on the k-value, the spring constant defined as necessary force to obtain one unit of extension.

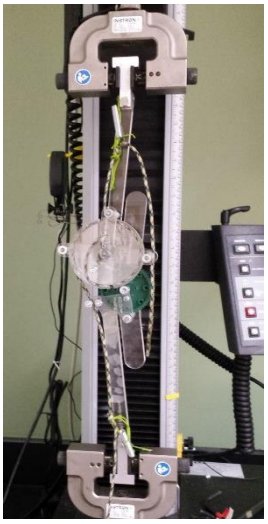

Figure 20: The brace in the fully extension position with relaxed springs.

Figure 21: Brace at full deflection in Instron5544

The testing setup simulated the standing to sitting transition. Due to the kinetic consistency of the cam, the forward and backward motion of the system is identical. The moment profile is reversed with respect to time and extension during STS compared to stand to sit. The Instron5544 would begin in an extended pose, as seen in Figure 20, where the angular deflection between the grounds is approximately zero. Beginning the test with a small flexion angle ensured the brace deflected in the desired direction.

The Instron5544 would push the ground ends together 12.5cm to achieve a deflection angle of 90degrees. The deflection would occur at 600 mm/min, because this speed is comparable to healthy STS times. See Figure 21 for depictions of this end condition. The test was run 10 times, though the first three trials were expunged due to improper cable orientation. Once this set-up error was identified, it was corrected. The remaining seven trials were completed and evaluated.

The Instron5544 would report the resulting vertical load for every 5N and 2seconds. This force was converted to the equivalent perpendicular force exerted on the ground ends, which when combine with the time-dependent cam diameter, generated the experienced moment. The test was run seven times.

The deflection tests generated consistent vertical load profiles, which translated to consistent moment profiles. The representative data can be viewed in Figure 222**Error! Reference source not found.** and Figure 233.

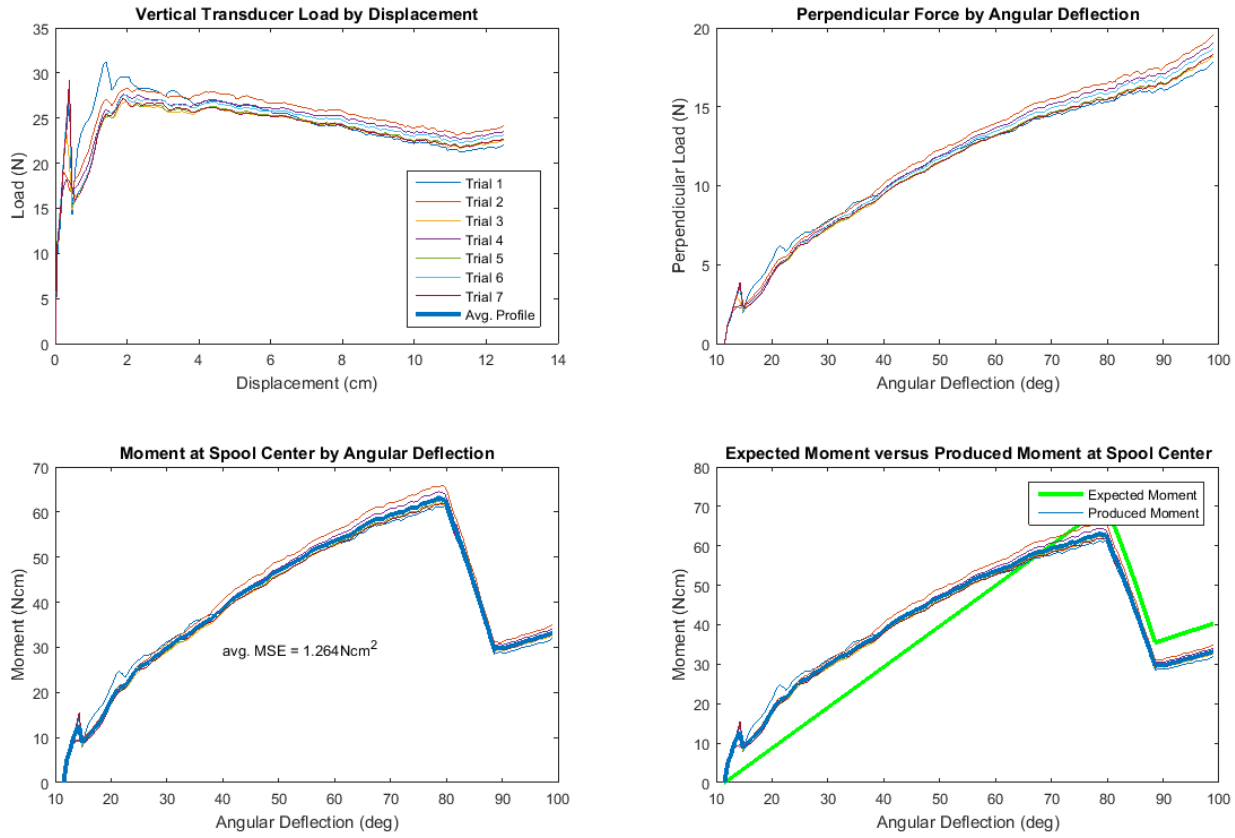

Figure 22: The vertical data from the 7 trials adjusted to produce the equivalent perpendicular force and moment profile at the spool. These moment profiles are compared to our expected moment displayed in green.

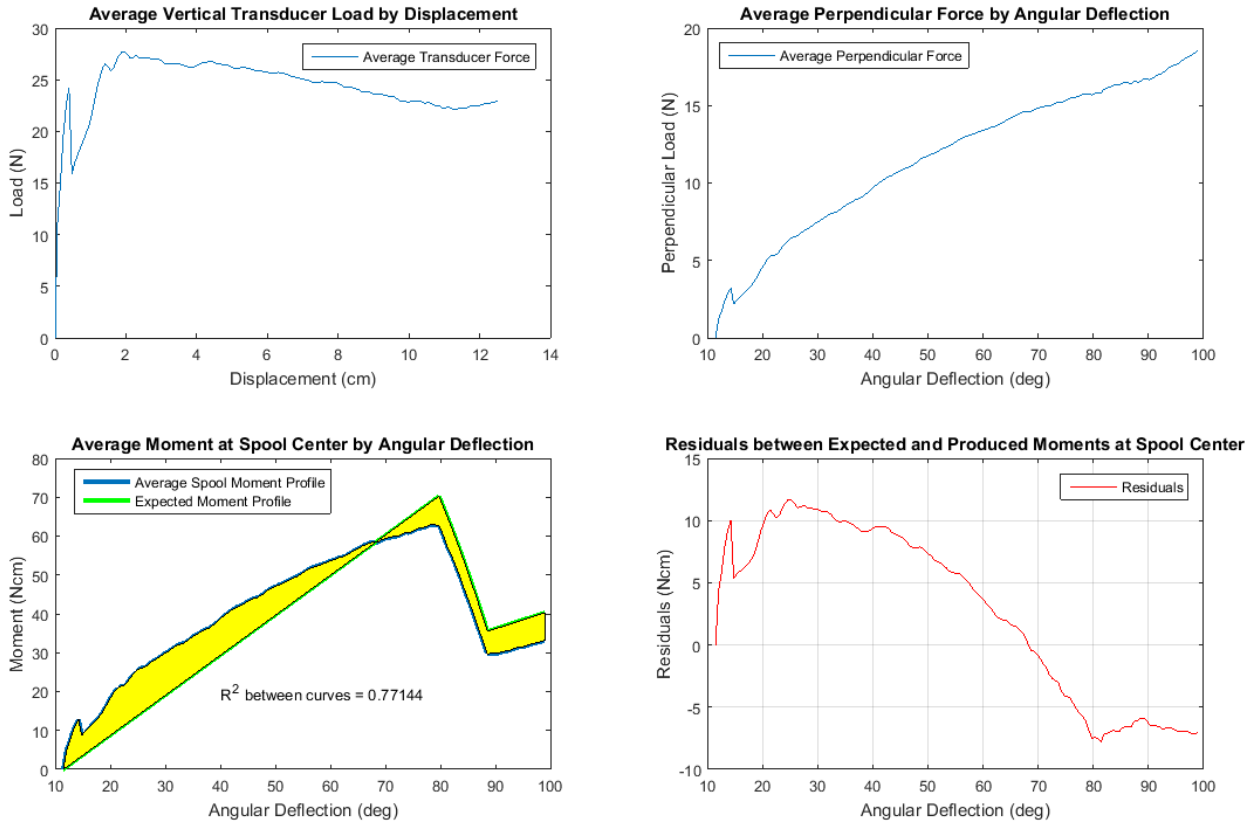

Figure 23: The averaged vertical load profiles were converted into averaged perpendicular load and spool moment. This average moment was compared to the expected moment profile and plotted for residuals. The yellow demonstrates the difference in designed v experienced moment profiles.

The averaged perpendicular moment appeared linear, but had a distinct curve. The averaged moment was not exactly linear up to the peak and instead, dropped off in at a rate resembling the predicted profile. The designed moment profile accounted for 77.14% of the variability from the generated moment profile according to the R^2 value. The generated moment consistently overshot the expected profile before the peak moment, where it undershot for the rest of the cycle. This systematic error accounts for the remaining 22.86% of variability. Although the curves do not match perfectly, the experienced moment profile is sufficient to demonstrate STS assistance without injury.

5.1.3.2 Frame Test

The reinforced brace, which refers to having two layers of acrylic on the thigh and shank grounds, limited overall torqueing and failed along the adhered fault lines. The maximum vertical load experienced in this test was 137.2N at 10.21% completion. This translated into an equivalent perpendicular force of 26.45N and a spool moment of 105.8Ncm. After this failure, all perpendicular

force and moment data was irrelevant since it was calculated under the assumption that the mechanism was still functioning. The failure data can be seen in the Figure 244.

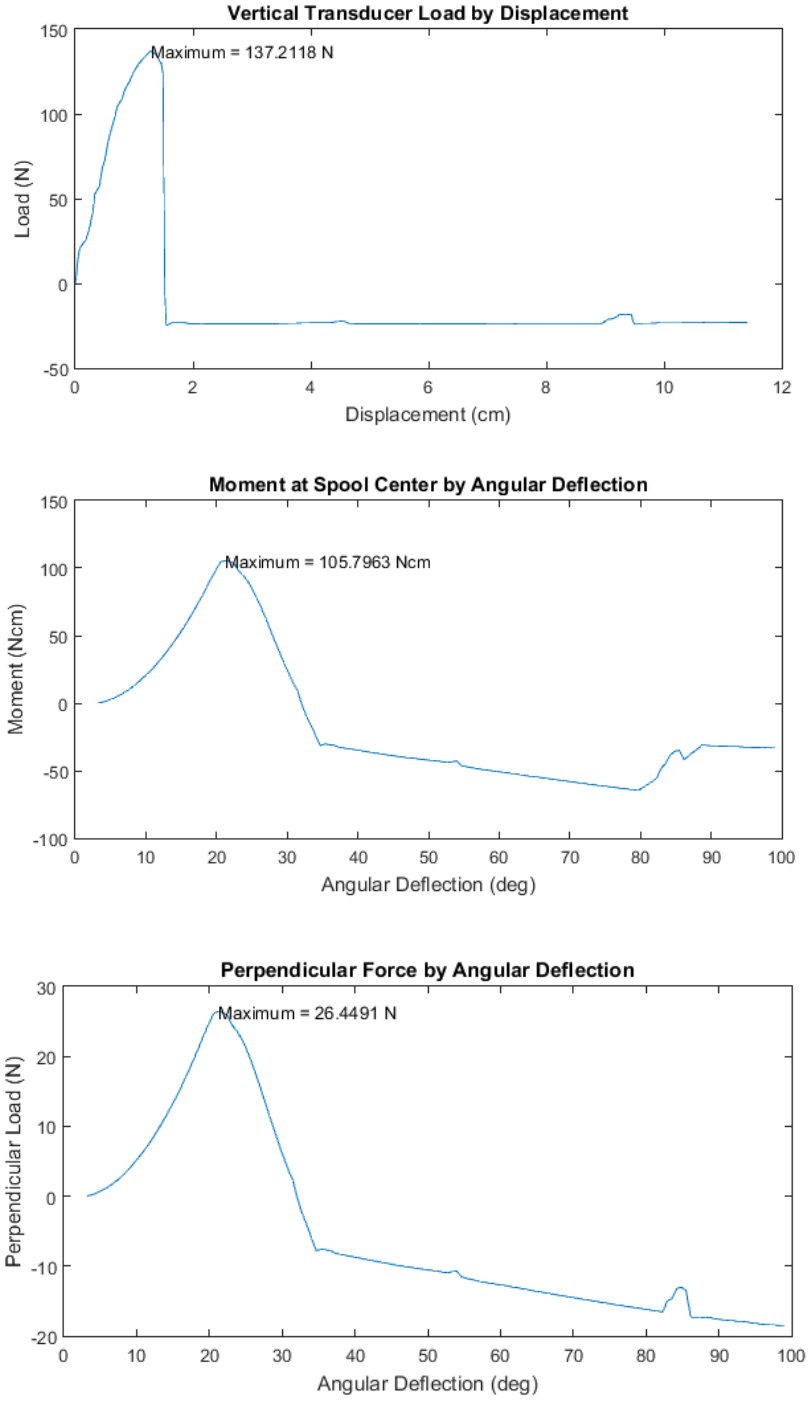

Figure 24: Second frame test failure data

The third execution of this test protocol was identical to the second, except that the reinforced grounds were intact and freshly laser cut. The assembled device with a single McMaster spring on each ground was tested on the Instron5544 and failure data can be seen in Figure 255Figure 25.

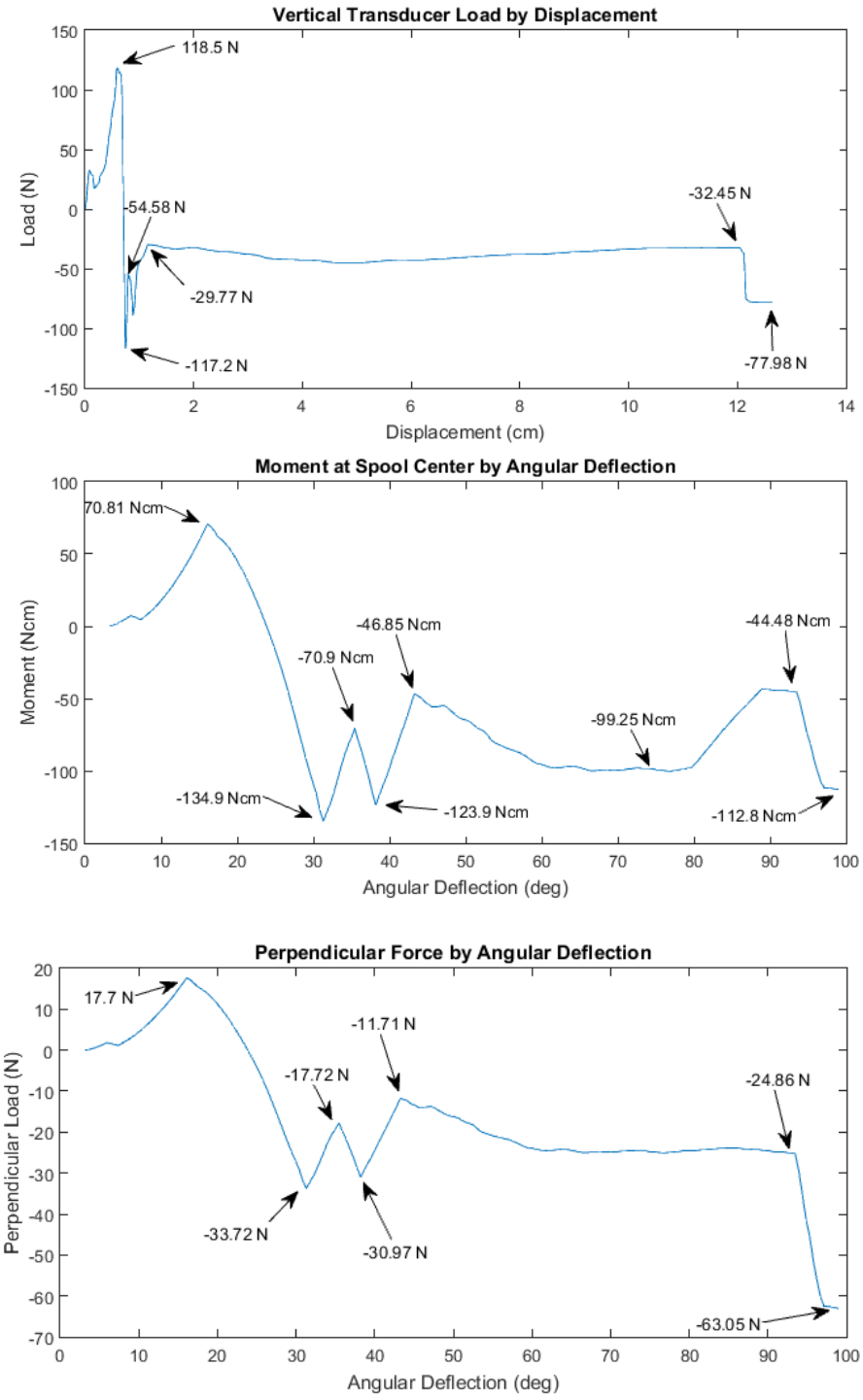

Figure 25: Third frame test failure data

The housing, and reinforced thigh grounds failed in this test, all along the central joint axle. The three failures made the vertical load, perpendicular force, and moment profiles unrecognizable when compared to the shape of the cam-spool data. The failure patterns are most apparent when

examining the vertical load profile. The housing support, B1 as seen in Figure 9, failed first, at the start of the test. The two smaller peaks, which become more pronounced in the force and moment profile, are not failures, and are attributed to device movement to regain stability. The initial failure rendered the zeroed load inaccurate and the absolute minimum load was used to calculate the moment after this point. The grounds, A1 as seen in Figure 9, shattered at the same time at the end of the test. With this timeline in mind, the housing shattered at a maximum equivalent moment of 70.81 Ncm and the grounds shattered at a 90.42 Ncm.

5.2 User Interface Test

The following test evaluated the entire functionality of the frame, cam, and spring components with one McMaster spring per ground on the brace. This condition would have provided approximately 8% assistance to the user in STS and tested several hypothesis regarding the differences in Instron5544 set up and clinical settings. Potential variability existed between the experienced shear forces, considering clinical settings have a larger surface area, and how the natural contour of the leg would impact performance.

These tests revealed the realistic impact of shear forces in addition to the accounted two-dimensional forces. Due to the natural contour of the leg, the gears experienced shear forces, causing them to slip by each other. This effect was exacerbated to the point of failure because the cables were not coplanar to the joint center adding shear on the gears. Considering the gears had a larger width because of their high power function, the full effect of the shear could not be seen without the contour of the leg.

5.3 Clinical Tests

The clinical tests were performed on five healthy people ranging from 20 $\pm$ 2 years and 59-72kg. All tests were approved by the Institutional Review Board at Worcester Polytechnic Institute prior to starting the study. The brace used the weaker TEKZ springs and a single layer of acrylic for the grounds.

5.2.1 Walking Test

The first procedure completed by each of the subjects was the walking test. The walking test was implemented as a way to ensure the brace does not interfere with normal walking ability. This test was performed in Goddard Hall and required study participants to walk five laps of the building with the brace on. The route is as follows:

- start in GH207,

- exit the room, turn left, go to the end of the hall,
- walk up the stairs, walk straight down the hall, turn left,
- walk down one flight of stairs, walk straight, arriving back at GH207.

Following the walk, each subject was asked to answer a survey regarding their experience walking with the brace on compared to walking without the brace. This survey provided insight as to the comfort of the device during daily use. See Table 8: Summary of walking test survey data for a summary of the results where n=5 for all analysis. The data were collected though analyzing the survey data regarding the user's experience with the device. Comfort was calculated with the mean and standard deviation of the reported values. The survey can be included in Appendix H.

Table 8: Summary of walking test survey data, where n=5.

Upstairs Easier	100%
Downstairs Easier	60%
Walking Easier	80%
Comfort	6.9±2.13

5.2.2 Gait Analysis

The gait analysis test was designed and implemented to ensure the device does not interfere with normal gait patterns. The test was set up by using 2 force plates oriented so they had a continuous y axis. Several boards were placed before and after the force plates to have a level surface. The participant was instructed to walk normally across the platform, ensuring one foot steps on each force plate. This was performed for three trials with and without the brace. The goal of this experiment was to yield information on the ground reaction force, stride length, stride speed and center of pressure all of which were measured and analyzed. Braced and unbraced conditions would then be compared to identify whether or not the brace significantly altered the gait pattern. The team expected to see no significant change in gait because the device provides minimal assistance and resistance during knee flexion angles associated with gait.

Due to unfortunate circumstances, force plate data was not able to be obtained. Software issues prevented the force data to be collected and exported appropriately. Stride length was analyzed and was defined as toe off to heel strike of a single leg. The average unbraced stride length was 64 ± 16cm compared to the braced condition of 24 ± 5.6. A paired T-Test revealed a t value of 0.23 indicating no statistical significance.

5.2.3 STS Test

The Sit to Stand Test was designed to ensure the device does not inhibit performance of STS when used. Two force plates were set up, with one under the chair, and one on the floor under the feet of the subject. The chair was held at constant standard height of 46.7cm. The participant repeated this test twice, first without the braces, then with the braces. The participant was asked to sit down, and stand up five times, at a comfortable pace. The arms were crossed over the chest, while the rest of the movement remained natural. The participant rested for one second before returning to the standing position. Once standing, the participant had time to stabilize and remained in the position for a second before returning to a seated position. This was repeated five times.

This test also suffered from the lack of available force data. Following the test, a rate of perceived exertion and ergonomics survey was completed. STS times were analyzed to show an average rise time of 1.61 $\pm$ 0.25 seconds during unbraced conditions and 1.62 $\pm$ 0.32 seconds while braced. A paired T-Test showed no statistical significance with a t value of 0.86. The ground reaction force at the feet and hips, and angular acceleration for the hip and knee would have been measured, evaluated, and compared if force plate data was able to be collected.

Chapter 6: Final Design and Validation

Mechanical and clinical tests were performed to identify how the device met the predetermined objects and constraints. The five primary objectives were identified for design: safe, minimal energy expenditure, cost, reliability and ergonomics. The constraints included device weight, no skin damage, cost, lifespan, actuation and stair climbing interactions.

6.1 Mechanical Testing Analysis

The following mechanical tests confirmed the performance and efficacy of the deconstructed and assembled mechanism components. The spring tests proved linear elastic behavior in all the testing extension springs, while the cord tests proved the device cable would not experience disruptive plastic deformation. The cam-output test illustrated the produced moment at the device joint center. The data suggests that the device will produce a reliable moment profile dependent on knee kinematics.

6.1.1 Spring Testing Analysis

The spring extension test was designed in order to evaluate the amount of force produced by the spring, per centimeter of extension. The test was run on the Instron5544, and BlueHill software was use to generate a force v. displacement graph based on the extension of the spring.

The linear regression of spring extension data was proved accurate, and the springs consistently performed according to this model. The predictable performance of the springs makes them compliant of the reliability objective. They are also safe, since at no point during testing was there an indication of part failure with expected loads. The springs pass each design constraint: there are only two actuator sites per brace, combined account for very little of the total device weight, were inexpensive, and their mounting position keeps them away from any skin contact.

6.1.2 Cord Testing Analysis

The cord extension test was designed to identify how the cord would respond to cyclic loading. The test was run on the Instron5544, and BlueHill software was utilized in order to determine if the cord extended during extension. The data suggested that the cable should be exposed to precycling before being applied to the device. By precycling the device, this will ensure that the team is able to meet the objective of creating a reliable device that will provide the necessary STS forces.

The cyclic force tests on the cord were to prove its reliability and safety if incorporated into the device. The cord itself was purchased at a low cost, thus meeting the cost-effective objective. The results of this test showed that the cord would deform approximately 7.5% of its starting length only during the first 20 cycles. No additional stretching occurred over the following the initial 20 cycles. This performance suggests it meets the reliability and cost objectives. The safety objective is accomplished due to the fact that at no point is the cable in contact with the user.

6.1.3 Cam-Output Analysis

The cam output analysis was designed in order to assess whether the moment profile generated the device closely matches the profile created by the knee. The device was placed inside on an Instron5544, and positioned, so the device could bend as it would on the user. The data from the testing suggested that a stronger material should be used for the frame, after shear forces caused failure. By using a stronger material, this will allow for the use of stronger springs on the device.

6.2 User Interface Analysis

The user interface test was to determine how the entire device would operate on a subject at the upper limit of its force-bearing capabilities. The gears slipped by each other as the shear force grew with increased angular deflection. This failure, however, proves the device meets the safety objective and constraint while failing in reliability. It was determined that the failure of the gears, while inconvenient, did not risk injury to the user. This particular failure poses minimal risk to the user's wellbeing, whereas shattered grounds would bear greater risks.

6.3 Clinical Testing Analysis

The walking test, gait test, and STS test were designed to determine the comfort and effectiveness of the device. The clinical trials determined the assistive device with TEKZ springs does not require additional energy expenditure through a rate of perceived exertion test. This data suggests that the device can be scaled up to provide more assistance without dramatically increasing energy expenditure. The team also designed to meet the ergonomic objective. The neoprene sleeve provided structural support for the device while maintaining flexibility during use. The assistive device is secured on the lateral side of the brace, with the frame of the device lying parallel to the thigh and shank. The team determined that the device met the weight constraint by weighing 3N per leg.

6.3.1 Walking Test Analysis

The walking test was designed to identify the comfort and usability of the device. Subjects identified the brace as being moderately comfortable (6.9 ± 2.13 out of 10). Depending on thigh circumference, the Velcro on the brace was not always able to be fully secured. During this test, users explained that the brace helped with overall walking and stair climbing abilities. One participant voiced concerns regards the device accelerating her while descending stairs. Overall, the device received positive feedback and users believe that they would be able to wear it for a minimum of eight hours if it made mobility easier.

6.3.2 Gait Test Analysis

The gait test was designed to ensure the device does not interfere with normal gait patterns. On average, the device decreased stride length 1.1cm. Upon completing a paired T-Test, this was not considered statistically significant. This information was compared to the survey completed after the test. Subjects reported that use of the device made walking slightly easier and therefore the shortened stride length was not deemed problematic.

6.3.3 STS Test Analysis

The Sit-to-Stand Test was designed to ensure the device does not inhibit performance of STS in healthy participants. On average, the time required to complete STS in the braced condition took longer than the unbraced condition. A paired T-test was completed, and determined that the time difference was not statistically significant. This was compared to the post-test survey, where all of the subjects reported that the brace made it easier to complete STS. Although the data shows that there may be a slight increase in the required time for STS when the user is wear the brace, this was not deemed to be a critical problem.

6.4 Standards

The creation of a medical device would mean that national and global standards have to be met in order to ensure the mechanism is safe for the user. The team researched various standards and organizations that would impact the device's marketability.

6.4.1 International Organization for Standards

The International Organization for Standards, (ISO), is a quality management system that governs management principles of customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships. ISO 9001 acts as a standard for quality management systems. Quality management is the effort to ensure that products satisfy the needs of the customer, and comply with regulations set forth that are applicable to those particular products. This system of management ensures that customer's quality requirements are met, that products comply with regulation, and give requirements for what is organization is required to manage any processes that may impact the environment. The ISO developed the IEC 62366:2007 "Medical Devices- Application of Usability Engineering to Medical Devices" as engineering guidance for design and testing procedures [61].

The standard ISO 13485:2016 gives the requirements for an organization to produce and provide medical devices that will meet the customer quality, and regulatory requirements. The goal of the standard is to harmonize the requirements for medical devices [48]. The standard specifies requirements that a quality management system should demonstrate in order to show how it can provide medical devices and services that meet the requirements of the customer. The standard applies to quality organizations that may be involved in various steps of the product development life cycle. The standard is also able to be used by suppliers that provide the product. These requirements set forth apply to organizations, regardless of type of organization. ISO 13485:2016

also assumes that the processes required by the standard that are applicable to the organization, but are not performed by the organization, are still responsible for those standards, and are to be managed through the organization's quality management system [62].

These standards relate to our team's goal of designing a device that is reliable, and safe. By meeting the standards set forth by the ISO, the device meets quality standards. The team determined that creating a quality device would include designing a device that does not harm the user, and also consistently good in performance and quality. Our device will be affected by this standard if it fails to aid in STS every time it is used within the minimum lifespan of two years. Further testing is required to establish the actual lifespan of the device. Our device would also be affected by the standard if it proves to pose a safety hazard to those who use it.

The importance of manufactured devices to be ISO 9001 certified is that it ensures the quality of the product. Consumers want to have medical devices to be ISO 9001 certified, as this promotes a level of security that helps to ensure that the product came from a quality system [62].

6.4.2 Food and Drug Administration

The FDA is able to manage a large spectrum of medical devices, ranging from complex technologies, such as the artificial heart, to the low risk tongue depressor devices. The FDA is responsible for regulating devices prior to be placed on the market, and also while they are available to consumers. The FDA defines a medical device to be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or component part". A medical device is classified as a medical device if:

- it is recognized in the National Formulary, United States Pharmacopeia, or a branch of them,
- is intended to diagnosis of disease, or is able to cure, mitigate, or treat the disease, or
- intended to affect the structure of bodily function of man or animal, and does not do so through chemical action or metabolic means [50].

Based on the description set forth by the FDA, our medical device meets the criteria of affecting a bodily function without going through chemical action within the body. The device is external to the body, assisting with sit-to-stand, ultimately affecting the function of the quadriceps muscles as STS occurs.

An external knee brace is classified in the FDA database as a Class 1 Device. In most cases, the FDA exempts almost all cases for class 1 devices from premarket notification requirement. Knee braces are good manufacturing practice (GMP) exempt, and exempt from regulation, as long as the device is not sterile [63].

The FDA harmonized its quality system with the ISO standards in order to have a consistent quality system. Many countries rely on ISO standards as well, so it is also easier for an industry to maintain a quality system similar to other countries. Additionally the FDA and other countries' regulatory systems are able to readily rely on each other's inspections and inspection reports when both organizations have harmonized quality management systems [62].

6.4.3 Americans with Disabilities Act

The Americans with Disabilities Act (ADA) prohibits the discrimination of people with disabilities, and ensures that those who are disabled have the same opportunities to participate in American life. In order to be protected by the ADA, an individual must have a physical or mental impairment, which limits major life activities [51]. The group researched the groups who are considered covered under the ADA, and the impairments covered. However, after evaluating the purpose of the ADA, the device created to assist with STS would not be covered by the act. This could be due to the brace being an assistive device for those who are able to perform STS. Those who will use the device would not qualify as disabled, but rather, are using the brace to improve performance of a daily function that is still doable in the absence of the device.

6.5 Economics

The team was allotted a budget of $375.00 in order to prototype, iterate, test, and finalize a design. The budget included the purchase of acrylic, which would be used for the final design. The budget also included the cost for springs and paracord. The materials used in the design are all considered to be inexpensive in terms of manufacturing. The plastic components of the device, including acrylic, and vex parts are inexpensive, and easily obtainable materials. The springs cost approximately $20. The paracord can be found at major hardware stores at an inexpensive price of about $8. No additional costs will have to be put into testing the device. The neoprene knee brace was found to be the most expensive component to the design, costing about $40. However, the brace that was obtained also contained additional lateral supports that run alongside the knee, which could be the reason for the higher cost. Together, the team determined that the manufacturing costs necessary allowed for a feasible design at a minimal cost.

6.6 Environmental impact

As a standard of the ISO 9001, when a device is created or used, activities that could impact the environment must be evaluated and controlled [64]. The team assessed the environmental impact that the device could potentially have on the environment. The four crucial environmental

factors that the team determined could possibly have negative impacts on the environment are air acidification, carbon footprint, total energy consumed, and water eutrophication. The team has made the assumption that the parts needed to manufacture and assemble the device have previously met the requirements for protecting the environment. Because of this, the team has not evaluated the environmental impact for the manufacturing of neoprene, acrylic, metal springs, or the paracord used in the device.

Air acidification is caused by the burning of fossil fuels and other acidic emissions, which could lead to an increase in the acidity of rainwater [65]. The only manufactured process that could lead to this would be the creation of the acrylic, springs, or paracord used in the design, which is outside the control of this team.

Carbon footprint is determined from carbon dioxide and other gases accumulating in the atmosphere. Similar to the air acidification, it would have to be determined whether the production of acrylic would lead to the carbon dioxide emissions into the atmosphere. However, as previously stated, the team assumes that the production of any of the involved components have met the necessary regulations to manage the environmental impact.

The third environmental factor measures the nonrenewable energy sources that is associated with lifecycle of a product [65]. The team has determined that because this factor relies on the total energy consumed from non-renewable resources, this environmental factor could be impacted due to the production of neoprene or acrylic, which are assumed to have met production regulation.

Water eutrophication is due to an abundance of nutrients added to the water in the ecosystem. The added nutrients cause an overabundance of algae, eventually depleting water of oxygen, and killing other plant and animal life [65]. The team predicted that due to the composition of the device, water eutrophication would not be an impacted environmental factor.

Overall, the team determined that there would be minimal impact on the environment, based on the amount of acrylic that would be produced to make the device. As an objective, the team determined that the device should be safe for the user; however, the team also determined that it was important for the device manufacturability to be safe for the environment.

6.7 Societal Influences

A device that is able to assist with STS will be beneficial to those who struggle to complete this basic life task. The device will work to augment the forces of the thigh that are needed for STS to occur. Because this task has become difficult for so many elderly individuals, the device may prove beneficial in not only assisting with STS, but also improving the number of times STS is able

to be completed. The assistive knee brace, because it is helping individuals to complete a basic, yet necessary day-to-day task, will be helping to improve the STS transition, which will help to ultimately improve the quality of life.

The device may become a choice that society chooses to wear, despite that it is a rehabilitative device. Calling upon the example of glasses, a rehabilitative device can become considered "stylish" and "typical" to the average person. Eventually, the assistive knee brace may be seen in this same light, where society opts to wear the device, despite its rehabilitative function.

6.6 Political Ramifications

The team has determined that there are no political ramifications that could arise due to the use of the device. Possible business ramifications would involve the product not meeting quality standards, and thus being recalled. Recalling is a method used to remove and correct a product, which violates the laws set forth by the FDA. Recalling is done by the manufacturer, as it is the responsibility that products given to the public are intended to protect the well-being of the consumer. For medical devices, recalls would occur voluntarily, and would be conducted by the manufacturer under the standard 21 CFR 7[66, 67]. If the manufacturer fails to recall a device that proves to go against the best interest of the consumer, the FDA is able to issue a recall order, 21 CFR 810. Products are typically recalled once injury or disease has resulted from the use of the product, or there is a likelihood of hazard to occur [67].

Recall can be extremely burdensome and detrimental to an organization's business and development. This would also lead to ramifications for the FDA, who initially approved the device. It is critical to our device that it is well tested in order to assess possible problems that could arise, and potentially harm the consumer. Because of this, the team developed and conducted several tests that will ensure the quality of the device before it is placed on the body.

6.8 Ethical Concerns

Ethical concerns for the device may arise, therefore it is important that the testing and use of the device is with a protected population. Considering the target population is the elderly, additional safety and ethical measures need to be taken during testing. The device is expected to cause minimal harm to the subject who uses it during testing therefore as long as appropriate safety measures are taken, the ethical concerns associated with testing should be minimized.

All studies associated with this research have been approved by the Institutional Review Board at Worcester Polytechnic Institute.

6.9 Insurance

This device was designed and intended to assist the elderly in completing STS, which becomes more challenging with the weakening of quadriceps muscles. Medical insurance often will cover necessary durable medical equipment, which is prescribed by the doctor, and is intended for home use. Durable Medical Equipment (DME) is covered if it meets the criteria of being durable, used for a medical reason, has an expected lifespan of 3 years, is used at home, and is not particularly useful for someone who is not sick or injured [68].

STS devices that are considered DME are limited to the patient lift. The knee brace, even with a durable mechanism attached to the frame, may not be eligible to be covered by insurance. Currently, knee brace coverage is determined by individual policies. For many companies, if the brace has been recommended by a physician, or a prescription is given in order to obtain the knee brace, then it may be partially or fully covered [69]. However, because the device would be used for assistance, and may not be necessary, it may not be able to be covered by an insurance policy.

6.10 Manufacturability

The knee brace is very similar to a neoprene sleeve, with the exception that there is Velcro on the back for adjustment. The frame of the device will be attached to the device, with the knee center of rotation corresponding with the center of rotation of the device.

The frame and device are both made from a plain acrylic obtained from United Plastics in Worcester, Ma. The acrylic was able to be laser cut, allowing for easy manufacturing. The laser cutter operates by directing the laser output through optics, and the laser optics paired with the computer numerical control (CNC) direct the laser beam. Acrylic was found to be a durable, strong material for the forces required for the device.

Acrylic comes available as flat sheets, elongated shapes, or as a molding powder. Acrylic sheets were selected by the team, as they worked the best for laser cutting the parts of the design. The sheets are created through bulk polymerization where the monomer that makes up the acrylic composition, and a catalyst are poured into a mold and react, creating the material. Acrylic is composed of toxic materials as it produced [70]. However, the material is able to be laser cut due to its low toxic gas release when cut. Because of this, WPI allowed for the material to be cut using the laser cutting machine.

The assembly of the device requires that the mechanism used to generate the force is attached to the frame of the device. The frame and device are brought together using vex parts,

which have proven to be strong and durable to withstand the forces necessary for the device to work.

6.11 Sustainability

The team determined that the lifespan for the device would be one year. This was determined by finding about how many STS transitions occur daily, and then further determining how many would be expected to occur over a year. Due to the high rate of STS transitions that are likely to occur, the device is expected to last with for a year, without any of the components wearing significantly from use.

Chapter 7: Discussion

The final device developed was designed to meet five objectives in order to be successful for the user.

7.1 Objectives

The first objective was safety. The three main components were identified to achieve maximum safety. They were: prevent pinching and skin abrasion, encased cam to prevent slipping, and cannot allow for hyperextension.

In order to ensure that the device met these objectives, the mechanism was mounted to the lateral side of the brace to avoid pinching and skin abrasion. Creating a housing for the spool would keep mounted parts and Paracord from slipping into the device and out of predetermined tracks. The mounted parts allow for full extension and flexion of the knee within natural ranges of motion.

The next objective was to design for minimal cost. This focused on the affordability of the device. While there is the possibility of the device being covered by insurance, the team did not want to rely on this fact. People from all socio-economic statuses should be able to afford the device regardless of their insurance coverage.

The team determined the need for minimal energy expenditure during use. When the user is in the seated position, passive energy storage occurs. This is due to the extension of the springs; however minimal force is translated to the user because of the shape of the cam. The spool portion of the device creates a moment profile at approximately 10% completion of STS, and is able to provide additional aid to match the healthy moment profile.

The next objective was to provide an ergonomic solution to assist with STS. This objective was broken down into four components including: lifestyle compatibility, comfort, aesthetics, and lightweight.

The brace has to be compatible to the lifestyle of the user. As the user wears the braces, they must also be able to complete natural day-to-day tasks, without limiting their normal functioning. The device must also be comfortable for the user. The brace was intended to be worn for long periods of time, and cannot cause discomfort. The mechanism also attaches to the outside of the knee, helping to keep the user from experiencing any chaffing or any harm to the skin. The knee brace is adjustable, which is able to accommodate adults of various sizes that need assistance. This also accommodates for those older adults who may be more susceptible to weight gain or weight loss as a result of aging. Preliminary results also indicate the device is comfortable and effective. The kinematic design of the device, the moment profile decreases while the user is in a seated position. The device was also designed to be aesthetically pleasing. The design has a generally symmetric appearance, running from the middle of the thigh, to the middle of the calf. The device is made from a clear material, with a neutral colored cord running through, and silver extension springs. The device fits into a sleek black knee brace, which fits snug over the knee.

Lastly, the device accomplished the goal of being reliable. Mechanical testing was completed on the device in order to validate that each of the components completed its intended task. The moment profile was generated by the device during testing, and was found to closely resemble that of the healthy knee. Clinical testing was then completed with the entire device assembled, and attached to the brace, and placed on a subject. The brace did not show any signs of failure upon the completion of the clinical tests.

7.2 Constraints

The team determined that it was crucial that the device not be heavy while on the user, considering a heavy brace would reduce comfort, and eventually decrease usefulness. The team established that the braces are not to weigh over 22N combined. The final prototype was determined to be 3N, subjecting the user to 6N additional pounds from braces on both legs, therefore meeting this constraint.

The second constraint determined by the team was that there should be no skin damaged by the device. In order to ensure that this could be met, the device is placed outside of the neoprene knee brace. This keeps the device from having direct contact with the leg, avoiding chafing, abrasions, bruising, etc. A neoprene sleeve was selected because of its abundant use with existing knee braces.

The device was developed for a maximum of $300. Parts used maintained standard dimensions to decrease purchase price. Quality acrylic was purchased at lower prices from spare sheets. Although the team would like to use a stronger material for future iterations, the use of acrylic was cost-effective for prototyping purposes. The team also did not machine any fine precision parts. By removing fine precision parts and motors, the cost was able to be driven down significantly. Overhead would have included the purchase and maintenance for a laser cutter and other manufacturing equipment in addition to labor costs. These costs were not considered because of the device's current status as a prototype and not final device. The cost to produce one device was $74.77, well within the cost constraint of $300. The estimated part and total costs for the final device can be seen in **Error! Reference source not found.**.

Table 9: Cost analysis

Price of Goods				
Item	Price	Quantity	No. Device Units	Cost per Device
Futuro Sport: Hinged Knee Brace	$36.79	1	1	$36.79
Transparent Acrylic: 12"x12", Thickness 0.250" [71]	$15.46	1	2	$7.73
Transparent Acrylic: 12"x12", Thickness 0.125"	$7.42	1	3	$2.47
McMaster Ultra Precision Extension Springs. Product No. 9065K381	$10.12	3	1	$10.12
Lowes Cable 5 mm	$7.39	50ft	20	$0.37
VEX High Strength Gear Kit [57]	$19.99	60 tooth – 4 each 36 tooth – 4 each	4	$4.99
VEX 2"&3" Shaft Kit [72]	$5.49	2" shafts – 4 each 3" shafts – 4 each	1	$5.49
8-32 x 0.125" set screw pack	$4.99	32	6	$0.83
Plastic spacer, 4.6mm	$2.99	20	1	$2.99
Plastic spacer, 8mm	$2.99	20	1	$2.99
Total Cost per Device				$74.77

Mechanical testing was completed to determine the durability of the device, as well as determine the lifespan of the components. The device had to be able to withstand the forces that would be applied by an individual who is 65 $\pm$ 6.8kg. The device also had to be able to provide 25% of the necessary forces for STS to the user. The device was designed to have a two-year lifespan,

before regular maintenance may be necessary. This takes into account minimal deformation of the springs and cable that may occur form frequent use, and frame shear forces that lead to deformation. Due to testing limitations of the Instron5544, the lifespan constraint was not able to be confirmed.

The team met the maximum of two actuator per brace by using extension springs. Motors were deemed inappropriate due to their higher cost, decreased discreteness, and need for a power supply. The device would most likely have more bulk because of the motor, and there may be some noise associated with use. A combination of springs, plastic vex parts, acrylic, and Paracord were used in order to create a moment about the knee to keep production costs manageable and low.

Lastly, the mechanism would not interfere with stair climbing interactions. The mechanism is placed on laterally on the knee. This keeps the devices separate from one another so that they are unable to affect the performance of either brace and keeps the braces from accidentally hitting one another. Preliminary data demonstrated an unexpected but beneficial result of assisting with stair climbing. A more thorough analysis would need to be completed to identify this effect.

The device would ideally last for a minimum of two years. The components of the device should undergo rigorous cyclic testing to understand fatigue associated with use. Due to Instron5544 testing limitations, the team was unable to perform these tests.

7.3 Mechanical Testing

The spring extension test was completed using an Instron5544. The extension test was designed in order to find the load that the spring could bear, per centimeter of extension. The team's initial objective was to test three different springs, which would provide 25, 35, and 50 percent assistance. However, during frame testing, the device grounds failed. It was then determined that in order to complete testing and device verification, springs with a lesser k-constant (TEKZ springs) were selected.

The cable extension test was also performed on an Instron5544. The cable test was performed in order to assess if the cable would stretch while it is on the device. The cable had to withstand the 70 N force that is associated with the expected STS forces of a 65kg person. The cable, which had a length of 10 cm, was found to stretch 0.75 cm after the first trial. The team recommended that the cable should be pre-cycled before use of the device. The stretching of the cable will lead the device to be less effective, because this will allow for less spring extension. Pre-cycling the cable will allow for the 0.75 cm extension to be accounted for in the length of the cable in the device, rather than stretching occurring with use.

The frame-bending test was completed to find the moment profile when the device flexes. The test also assessed whether or not the frame would fail when a force is applied. The test mimics the user going into a seated position, and then returning to standing. For testing, the team assumed that the frame would have the same moment profile as a healthy knee. The frame was tested in an Instron5544 in order to determine the moment profile when the device flexes, as well as to ensure that the frame will not break under an applied force. When the device frame was tested, shear stresses contributed to the failure of the frame in the z direction. The frame was then reinforced with more acrylic at the grounds in order to avoid failure. The reinforcement of the grounds broke again at the same location as the previous failure. The team determined that the springs should be scaled down on the device. By doing so, the device was able to complete the moment profile test without failure.

The team determined that it would be ideal to have a stronger material to be used for the frame. The laser cutter used to produce the parts of the frame was only able to cut through wood, acrylic, and cloth. Due to the limitations associated with the laser cutter, acrylic was selected because it was determined to be the strongest of the three available materials. Additionally, the clear acrylic was determined to be more aesthetically pleasing of the three materials.

7.4 Clinical Testing

The three clinical tests obtained both expected and unexpected results. This section outlines some of the possible reasons for the performance not matching expectations.

7.4.1 Walking Test

Considering the device is intended to be worn while walking throughout the day, it must be comfortable, and ergonomic. All users believed they would be able to wear the device as expected. They did proved some valuable information regarding the overall comfort of the device and areas of irritation.

The assumptions determined by the team for these trials were that the user does not currently have issues with walking, and is capable of completing the five laps in Goddard. The team concluded, however, that there is a possibility that subjects experienced a “placebo effect”, where they reported the brace made walking easier.

7.4.2 Gait Test

The purpose of the gait analysis was to determine whether or not the brace affected the user's normal gait patterns. The team assumed that all of the subjects were truthful in reporting no gait disorders.

During this test, the team assumed that the subjects exhibited their normal gait patterns during the unbraced condition, which was then used as the control to compare against the braced condition. Based on available resources, the most accurate way to measure the stride length was to compare still images that show the subject during toe off and heel strike. The images of the braced and unbraced subject were compared, and a scale was used to measure stride length. The variation is stride lengths measured between the braced and unbraced condition did not prove to be statistically significant and therefore, the team concluded the brace did not inhibit normal gait patterns.

7.4.3 STS Test

The purpose of completing the STS test was to assess whether or not the brace served its intended purpose. The mechanism was designed to provide an assistive force to the user during the momentum transfer phase of STS. Due to software issues, force data was unable to be collected. The team was able to analyze videos of the sagittal plane.

Following testing, the team determined that the average rising time unbraced was 1.61 $\pm$ .025s, and the braced rise time was 1.62 $\pm$ 0.32s. Although the time appears to be longer, the difference in time is negligible, and is not statistically significant. The post-test survey revealed 100% of users said that the brace required less energy to complete STS. Therefore, it was determined that the brace does not impede the ability to complete STS and the slower rise time was not significant.

Similar to the walking test, the team also took into account that the possibility of a placebo effect.

7.5 Data Integrity

From self-reports and the mechanical validation testing, the team determined that the device was successful in helping users to walk, and complete STS. Mechanical validation testing was able to show how each of the components individually worked, and the forces they were able to withstand. The primary concern with the mechanical testing data is the assumption that the TEKZ and McMaster springs has identical moment profiles when applied to the device. Although

mathematical theory suggests that they maintain the same shape, a mechanical test should be performed to confirm this hypothesis.

All of the subjects were of a healthy adult population. We assume that the population does not have weakening quadriceps and abdominal muscles. Younger populations who are not experiencing this muscle loss may not feel the assistance provided by the device. Additionally, the subjects were then asked to self-report about their experience using the knee brace. The users were asked whether they felt the brace was helpful in completed the tasks in each test. The subjective nature of this data can be room for concern and should be explored on a larger population set with more objective testing methods. Upon further reflection, the post test surveys may have introduced bias based on open ended questions and question phrasing.

Lastly, the cam profile of the device was slightly shifted to provide assistance later in the transition than expected. This was due to cord slack being managed inappropriately. This can suggest that applying larger supplemental force later in the transition may be a useful addition. During this test, the brace was occasionally knocked into walls and door frames. This led to several posts which were inserted for stability to fall out. Due to the low assistive force, this was determined to be a potential improvement.

Chapter 8: Discussion

The success of the device was determined by how well it met the needs of the client statement. Potential features of the design were identified throughout the entire design process to allow for future maximum innovation.

The frame design had two primary purposes: transmit the forces to the user and provide an attachment means to the neoprene sleeve. Although frame broke under several frame verification procedures, the overall design is sound, it is recommended that the material is replaced. As it is designed and assembled now, it does not permit the delivery of the at least 25%, 35% and 50% assistance.

The user interface test highlighted the magnitude of shear that the brace experienced. This can be attributed to the brace being forced to bend in order to conform to leg shape. Future iterations of the design should consider the force vectors associated with leg shape and ensure uniaxial force applications. One particular area of investigation should be multiaxial stress concentrations.

A proof of concept mechanism was developed which stores elastic energy from sitting and returns it to the user with a unique moment profile. The resulting moment profile was ~80% accurate compared to our expected moment profile. However, the profile shape did not appear linear during the rising section, suggesting that one or more variables was not performing as expected. This discrepancy possibly originates from the springs extending at different rates or generated friction along the cord.

During mechanical testing, the device failed at an equivalent joint moment of 71Ncm, when providing approximately 12% assistance for a 65kg individual. The preliminary clinical tests suggest that with a scaled down device, it would be comfortable and not interfere with STS, gait, or stair climbing. However, because the subject sample was only five individuals, true conclusions must be based on a larger population size.

To mature the prototype into a robust assistive device, the diameter of the spool must be analyzed more thoroughly. The cam diameter can be further developed to better match the healthy knee profile. Experiments can be conducted to determine if extending the time at which the peak moment is applied positively impacts the user. The moment at the sitting position can be further minimized through better cam design, and developed to provide an assistive force when standing up from a deep squat. Furthermore, the cam can be redesigned to account for nonlinear changes in generated moment.

There is a potential for future iterations of the device to utilize a nonlinear elastic material for storing energy. This may provide the opportunity to match the healthy moment profile better. This could also have the advantage of interfering less with walking without compromising assistance with STS.

Testing protocols should be created to in order to thoroughly validate the device. The team recommends that a lifespan test be completed to identify appropriate lifetime information. Additional testing phases should be added to the clinical verification and tests should be repeated with geriatric populations.

The application of these tests will hopefully contribute to the development of a robust geriatric assistive mobility device, which will in turn improve the quality of life of its user by enabling greater independence.

Overall, the device demonstrated the potential to become a highly effective assistive mobility device. The preliminary tests indicated success and several areas for improvement have been identified. The recommendations set for in this chapter provide a foundation for future iterations of the device.

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Appendix A: STS Graphs

These figures demonstrate aspects of STS vs time data and are broken down to into the main phases of STS.

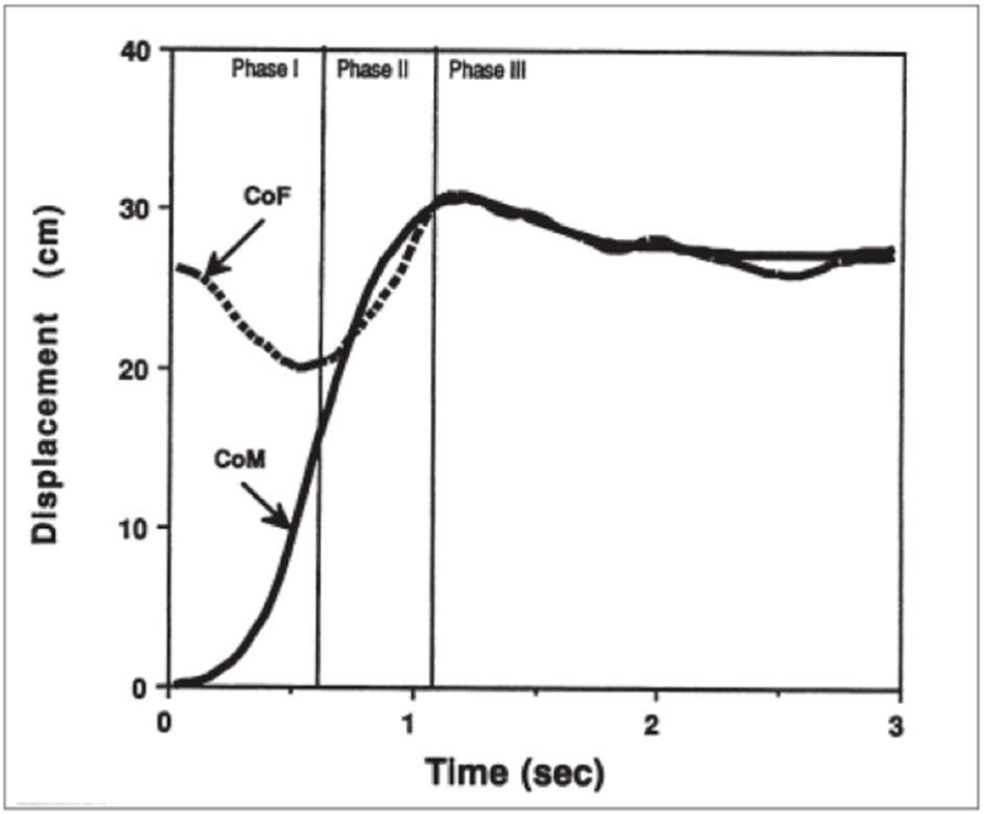


Figure 26: Displacement of Center of Force (COF) and Center of Mass (COM) with respect to time of the STS transition

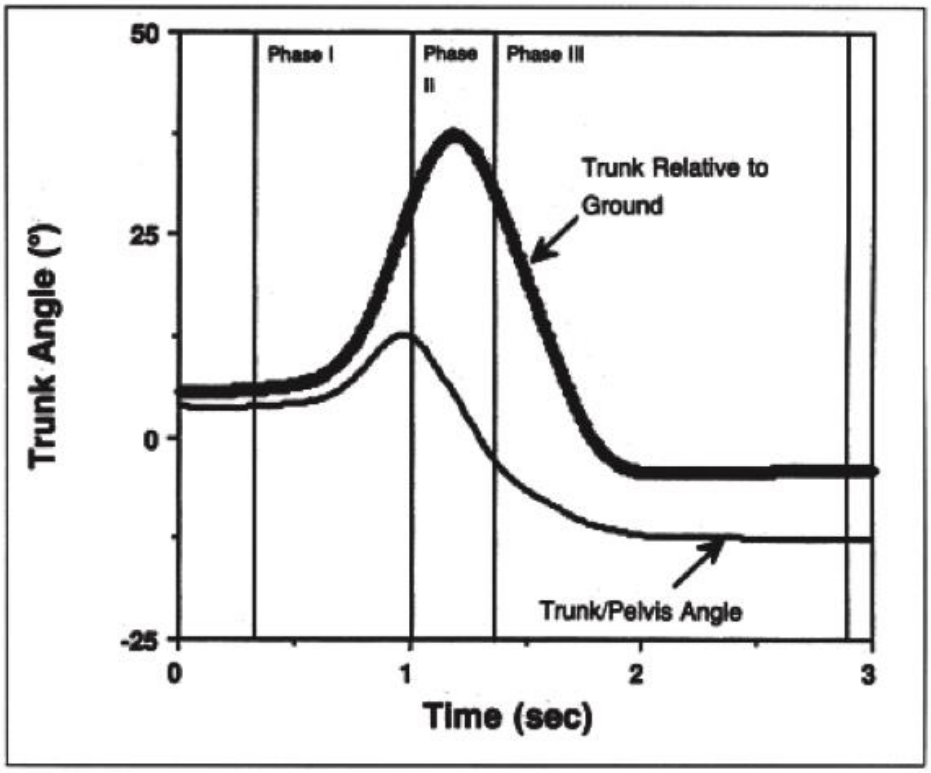


Figure 27: Trunk Angle v time data

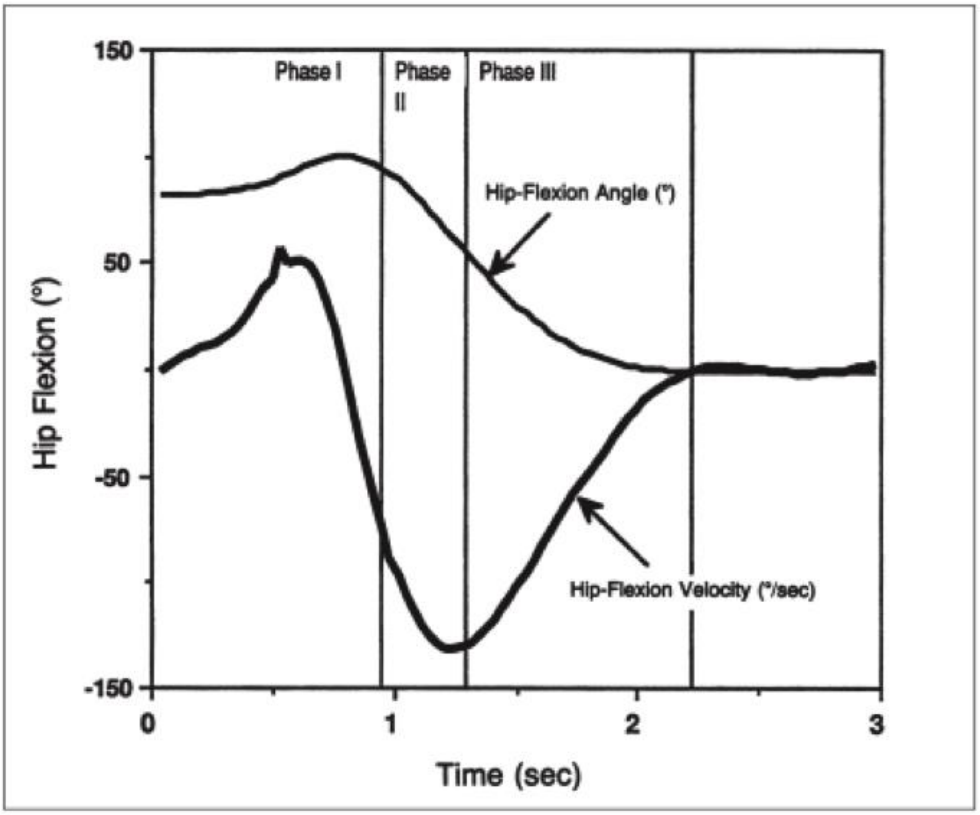


Figure 28: Hip Flexion Angle vs Time data

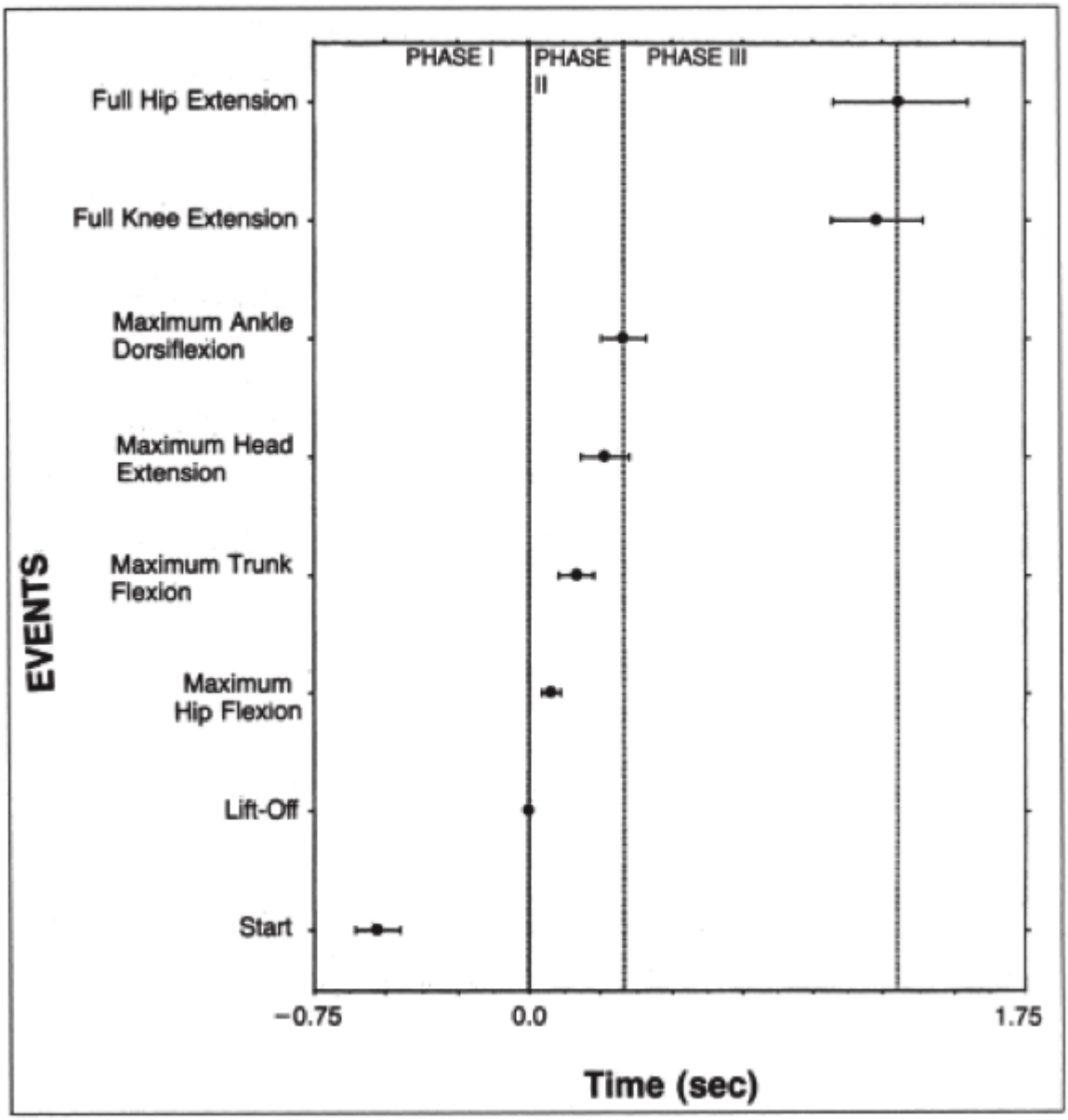
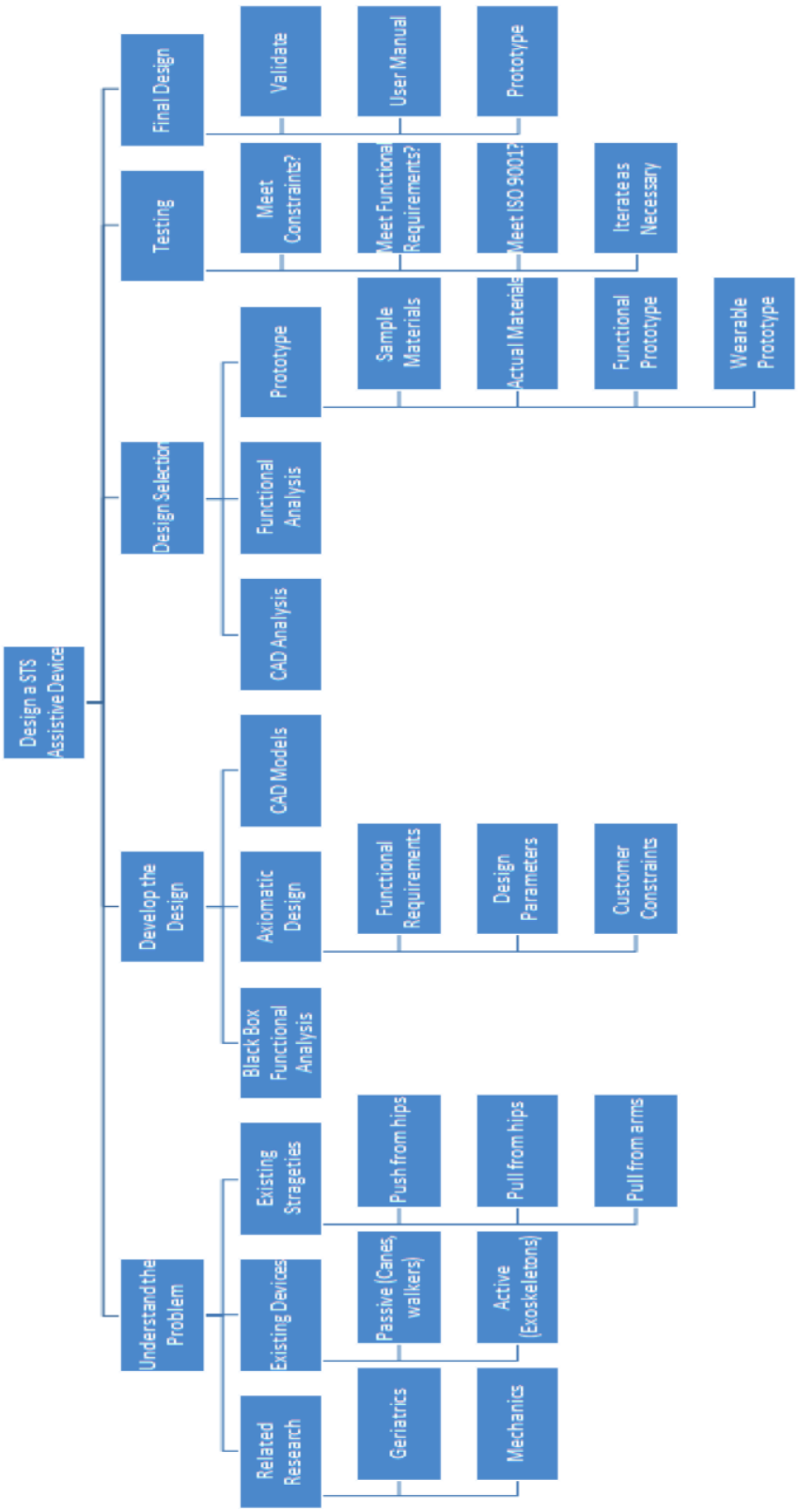


Figure 29: Key points of the STS transition and where they occur with respect to time

Appendix B: Work Breakdown Structure



Appendix C: Decision Matrices for Design Selection

These table present each design component analyzed and potential means of execution.

Table C.1: Actuation Means

	Natural Movement	Weight Limitations	Safety	Longevity	Aesthetics	Total
Electrical Motor	7	5	4	4	3	23
Torsion Springs	7	7	5	7	5	31
Extension Springs	**7**	**7**	**8**	**7**	**5**	**34**
Bistable Spring Bands	4	8	3	6	7	28

Table C.2: Charging Means

	Natural Movement	Weight Limitations	Safety	Longevity	Aesthetics	Total
Spring Ratchet	5	7	5	6	6	29
Freewheel	8	5	4	4	3	24
Geared Spool	**8**	**8**	**6**	**6**	**6**	**34**

Table C.3: Attachment Means

	Natural Movement	Weight Limitations	Safety	Longevity	Aesthetics	Total
Solid Housing	6	6	9	7	4	32
Compliant Housing	9	9	5	6	7	36
Rigid-Compliant Fusion	**8**	**8**	**8**	**7**	**7**	**38**

Table C.4: Materials

	Natural Movement	Weight Limitations	Safety	Longevity	Aesthetics	Total
Wood	7	8	5	4	4	28
Steel	**7**	**6**	**9**	**9**	**6**	**37**
Aluminum	**7**	**7**	**9**	**9**	**6**	**38**
Acrylic	7	8	6	7	9	37

**Acrylic was selected due to availability of time and resources.

Table C.5: Engagement Means

	Natural Movement	Weight Limitations	Safety	Longevity	Aesthetics	Total
Click-pen Mechanism	3	5	8	5	5	26
Mechanical Stop Button	6	5	5	5	5	26
Variable Diameter Cam	**8**	**5**	**8**	**5**	**5**	**31**

Appendix D: Matlab Code for Mathematical Verification

Parameter Proofs

```
clear
syms l1 l2 l3 l4 l5 w u y0 x0 r delt_l45 di l4_di l_int ang_disp SLACK positive

%totally sure these are right, see "all the maths"
w = sqrt((l2+y0)^2 + (x0-l3)^2);
l5 = sqrt(w^2 - r^2); % dist from thigh post to spool edge while
 standing

u = sqrt((l3 + y0)^2+(l2 + x0)^2);
l4 = sqrt(u^2 - r^2);  % dist from thigh post to spool edge while
 sitting

l4_di = sqrt(u^2 + di^2);
l_int = sqrt(r^2 - di^2);

ang_disp = ((l4_di + l_int) - l5); % Spring disp caused by rotating
 GNDS

% Taking into account the change in cam diameter, peak happens at 6%
 of the
% cycle
% x = 90*(60/36) = 150.    150*0.06 = 9 degrees. Round it up to
 10degrees
% dist of winded cable: wound around the outer diameter
%            {(36/60)*360deg}-10deg
spool = 2*pi*r*(140/360);
% shank_D = (spool);


cableDisp = ang_disp + spool;  % maximum disp needed for STS (thigh)
% Is greater than the allowed spring displacement
MCspringDisp = (3.07*1.05*2.54);    % maximum disp allowed by MC
 spring
thigh_D = MCspringDisp;

cableLength = MCspringDisp + SLACK;
% cable must be enough to account for winding around
% spool, with angular displacement, with slack so that the MC spring
 isnt

eqn1 = cableLength; % cableX;
sol_symbSLACK = solve(eqn1==cableDisp,SLACK) % find what SLACK must be
 symbolically
% = (7*pi*r)/9 - ((l3 - x0)^2 + (l2 + y0)^2 - r^2)^(1/2) + (r^2
 - di^2)^(1/2) + ((l2 + x0)^2 + (l3 + y0)^2 + di^2)^(1/2) -
 2304629852064071/281474976710656
% returns solution for cableLength equation with equality limit,
 seeking SLACK
```

DataAnalysis_SpringConstants

This data determines the k-value of the rinkydinky and Standard springs used produce the moment profile. Plugging this k-value into the expected moment-profile formula will give us an expected value from our experimental data. \

```
close all
% springData =
 {SpecimenRawData11,SpecimenRawData12,SpecimenRawData13,...
%     SpecimenRawData14,SpecimenRawData15,SpecimenRawData16,...
%     SpecimenRawData17,SpecimenRawData21,SpecimenRawData22,...
%     SpecimenRawData23,SpecimenRawData24,SpecimenRawData25,...
%     SpecimenRawData26,SpecimenRawData27,SpecimenRawData31,...
%     SpecimenRawData32,SpecimenRawData33,SpecimenRawData34,...
%     SpecimenRawData35,SpecimenRawData36,SpecimenRawData37};

% Spring Data from Standard Spring
springData = {SpecimenRawData1,SpecimenRawData2,SpecimenRawData3,...
    SpecimenRawData4,SpecimenRawData5};

% Only applicable for McMaster Spring
desiredkValue = 8.37106272/10.0; % N/cm originally, convert to mm;
MspringExtension = []; % in mm
MspringLoad = [];
MspringTime = [];
val=cellfun(@(x) numel(x),springData);
out=springData(val==max(val));  % returns the largest matrix
 dimensions
maxN = size(out{1},1);
for i = 1:size(springData,2)

    % eachN = size(filename{i},1);

    trial_time = springData{i}(:,1);
    trial_ext = springData{i}(:,2); %
    trial_load = springData{i}(:,3);

    % Only applicable for McMaster Spring
    % trim tare loads
    Indless10N = find(trial_load<10); % vector of indexes when angle
 is less than 90
    trial_time(Indless10N) = [];
    trial_ext(Indless10N) = [];
    trial_load(Indless10N) = [];


    MspringExtension(:,i) =
 interp1(trial_time,trial_ext,linspace(min(trial_time),max(trial_time),maxN)');
    MspringLoad(:,i) =
 interp1(trial_time,trial_load,linspace(min(trial_time),max(trial_time),maxN)');
    MspringTime(:,i) =
 linspace(min(trial_time),max(trial_time),maxN)';
```

Data Analysis: Profile Verification

This data proves that the cam produces a moment profile that mimics STSmoments for which we designed

```
close all
% How to automate this process:

filename = {SpecimenRawData1,SpecimenRawData2,SpecimenRawData3,...
    SpecimenRawData4,SpecimenRawData5,SpecimenRawData6,...
    SpecimenRawData7,SpecimenRawData8,SpecimenRawData9,...
    SpecimenRawData10};

% Unequal numbers of data points require data to be interpolated:
% Determining the Scaling Value
val=cellfun(@(x) numel(x),filename);
out=filename(val==max(val));  % returns the largest matrix dimensions
maxN = size(out{:,:},1);


% Produces TimeMaster, ExtensionMaster, LoadMaster
MasterTime = []; MasterExtension = []; MasterLoad = [];
% These vectors will grow each iteration: processing time for this
 analysis
% is not a priority
for i = 1:size(filename,2)
    if i == 3
        continue
    end
    % Determining the Individual Scaling Factor vnew = interp1( t, v,
 t/(1+a), 'linear');
    eachN = size(filename{i},1);

    trial_time = filename{i}(:,1);
    trial_ext = filename{i}(:,2); %
    trial_load = filename{i}(:,3);

    MasterExtension(:,i) =
 interp1(trial_time,trial_ext,linspace(min(trial_time),max(trial_time),maxN)');
    MasterLoad(:,i) =
 interp1(trial_time,trial_load,linspace(min(trial_time),max(trial_time),maxN)');
    MasterTime(:,i) = linspace(min(trial_time),max(trial_time),maxN)';
end

% Trial 3 is an outlier, eliminating Trial 1-3 for consistancy
MasterExtension(:,1:3) = [];
MasterLoad(:,1:3) = [];
MasterTime(:,1:3) = [];

% Converting Extension from (mm) to (cm):
MasterExtension = MasterExtension./10; % mm to cm

% Zeroing the Load Data
```

Data Analysis: Failure Data

```
% This is where the failure data is refined, isolated and presented
% Code is borrowed from Data Analysis: Profile Verification

% This data does not have multiples, only 2 tests were run.
% The M-profile will deviate from the expected form previously
 established

% There will be peak forces that will lead to breaks
% This code illustrates what loads were on the device at failure

close all
filename = {SpecimenRawData1,SpecimenRawData2};

glue_time = filename{1}(:,1);
glue_ext = filename{1}(:,2);
glue_load = filename{1}(:,3);

reinf_time = filename{2}(:,1);
reinf_ext = filename{2}(:,2);
reinf_load = filename{2}(:,3);
% Converting Extension from (mm) to (cm):
glue_ext = glue_ext./10; % mm to cm
reinf_ext = reinf_ext./10; % mm to cm
% Zeroing the Load + Extension Data
glue_load = glue_load-glue_load(1);
reinf_load = reinf_load-reinf_load(1);

glue_ext = glue_ext-glue_ext(1);
reinf_ext = reinf_ext-reinf_ext(1);

% Cleaning Data: Extension--> Angular Dispacement
% Triangle of grounds and space between grips - ABC
A = 20.5145; % thigh ground
B = 23.4754; % shank ground
%C = 31.17526; % dist between grips at IDEAL 90deg bend

% Representing the change in angle over time:
% Start of Test Angle: from Starting image, ImageJ
ang_stt = (176.891+176.465+177.057)/3;

% time and original angle data pulled from {mProfile test RinkDink 1}
m_theta = (80.9940-168.4963)/(12.5);
final_theta_glue = size(glue_time,1)*m_theta;
final_theta_reinf = size(reinf_time,1)*m_theta;

% Test Angle changes over time, refered to in Chapter 5 as angC

% Isolate Extension Data:
% dAng{1} = linspace(ang_stt,final_theta_glue,size(glue_time,1));
% dAng{2} = linspace(ang_stt,final_theta_reinf,size(reinf_time,1));
```

Appendix E: Bill of Materials

Bill of Materials			
ITEM NO.	PART NAME	DESCRIPTION	QTY.
1	Gear60	VEX high-strength gear. N = 60, Diameter = 2.58” Mounted on A (1).	1
2	Gear36	VEX high-strength gear. N = 36, Diameter = 1.58” Mounted on A (2).	1
3	Futuro Sport: Hinged Knee Brace	Conforms to user’s leg shape and delivers the mechanism forces to the body segments. A (1) and A (2) are connected through insertion into lateral sleeves.	1
4	A(1) Thigh Ground	Attachment point to compliant brace fixed to thigh. Anchor point to extension spring. Fixed in half joint with A (2). Supports posts that immobilize Gear60 and manage cables.	1
5	A(2) Shank Ground	Attachment point to compliant brace fixed to shank. Anchor point to extension spring. Fixed in half joint with A (1). Supports posts that immobilize cam-spool and manage cables.	1
6	B(1) Joint Support	The most medial part on the thigh section of the brace, sandwiches A (2) with A (1) to reinforce the joint.	1
7	B(2) Outer Housing	The most lateral part on the thigh section of the brace, sandwiches Gear60, A (1), and A (2) between itself and B (1).	1
8	C(1) Outer Housing	The most lateral part on the shank section of the brace, sandwiches D (1-4) and Gear36 between itself and A (2).	1
9	D(1) Housing Back	A circular cover with notches and holes for cable management.	1
10	D(2) Cam1	A spool of variable diameter with holes for cable management.	1
11	D(3) Divider	A circular plate to separate the cams with notches and holes for cable management.	1
12	D(4) Cam2	A spool of variable diameter with holes for cable management.	1
13	D(5) Housing Front	A circular cover with notches and holes for cable management.	1
14	1/8th” Axle	Used to secure parts together or serve as reference points for cable management depending on length.	5
15	Axle lock	To control the compression and hold of incorporated axles.	10
16	8-32 (0.164” diameter) Screw	Used to secure parts together or serve as reference points for cable management.	5
17	8-32 (0.164” diameter) Washer	To control the compression and hold of incorporated screws.	5

Appendix F: Device Assembly Instructions

The device assembly is such that the joint support is the most medial part and the cam-spool is the most lateral. The gears and cam-spool are held in place by housings connected to the segment grounds. The cables are managed by holes in the spool that keep it in place by friction forces. Support posts which anchor the housings double as winding posts that contain the cable tracks. Refer to the schematics of the assembly parts throughout these instructions. All parts are assembled when facing upright—this is when surface showcasing the engraved part name can be read naturally.

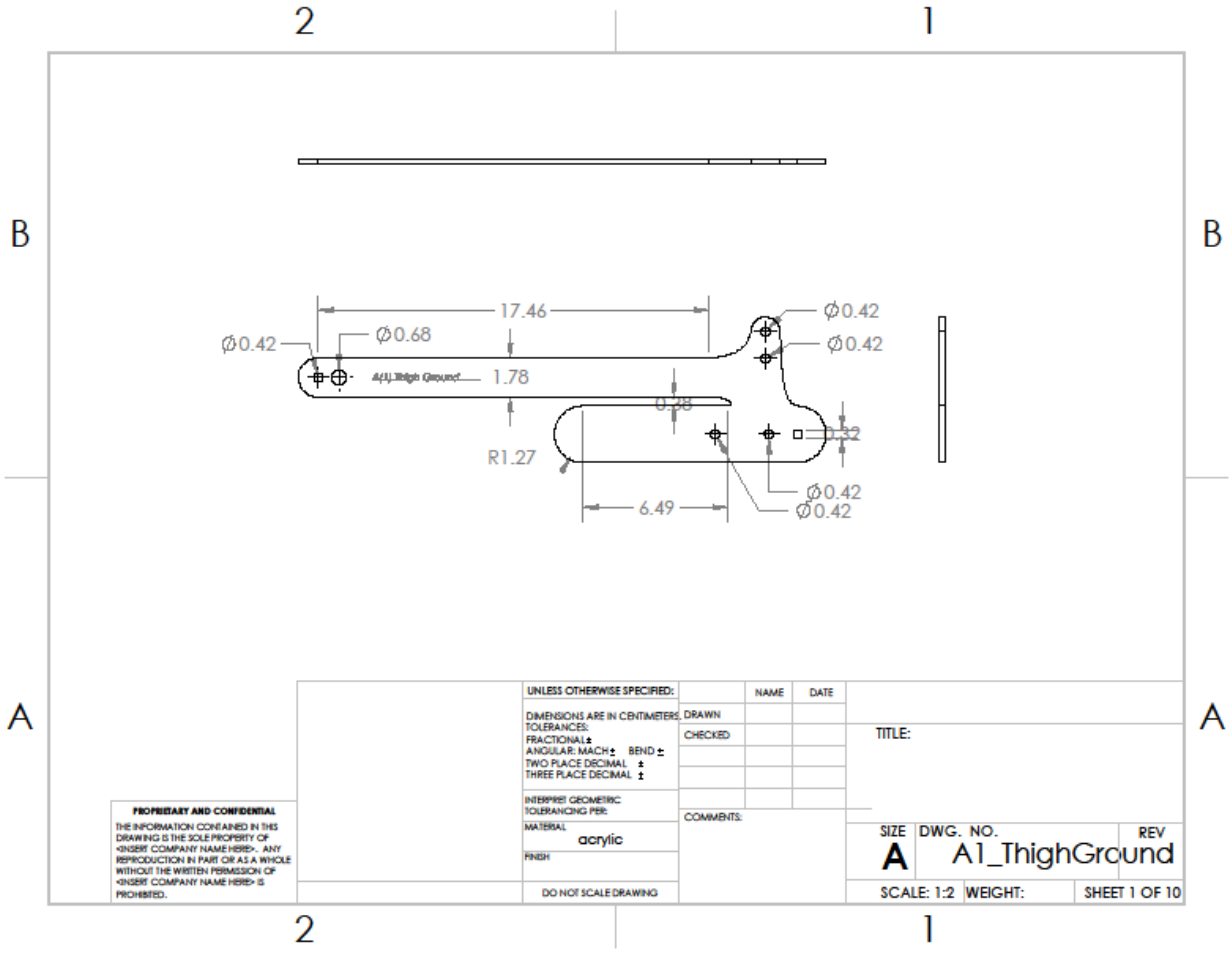
A(2) is held between B(1) and A(1). B(1) is flush with the compliant brace, is the most medial part. These parts are mounted on the joint center axle through the square hole of each piece. The 60 tooth high-power VEX gear is mounted on the joint center axle on top of A(1). B(2) caps the joint center axle by being mounted through its square hole. Two additional axles are mounted as a support posts through B(1), A(1), the 60 tooth gear, and B(2). Two axles span the upper holes in B(2) and A(1). Mechanical stability is maintained by including spacers.

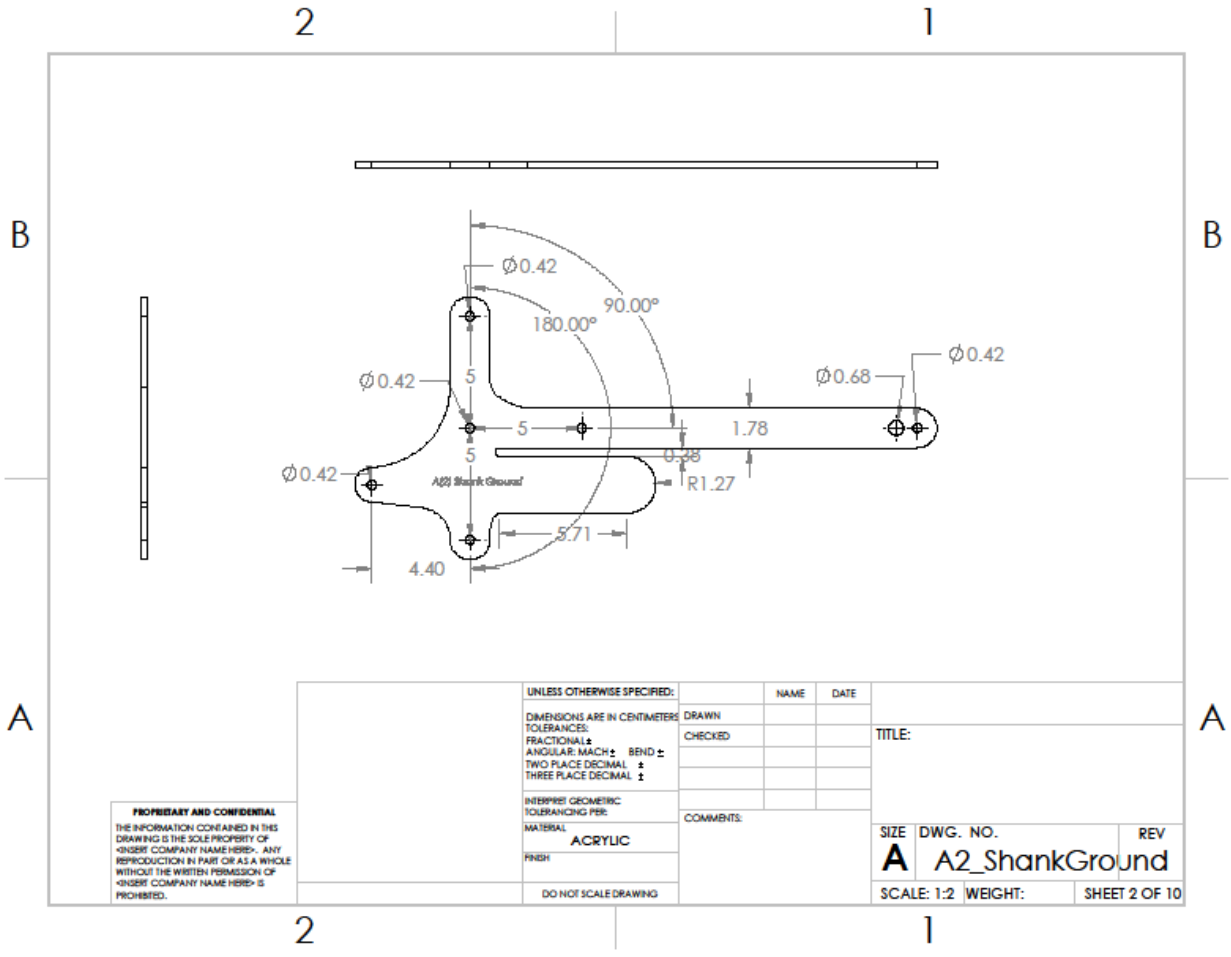
The 36 tooth gear is mounted on top of A(2) over the central hole. The teeth of the 36 tooth gear and 60 tooth gear should be enmeshed. The wound spool is mounted on top of the 36 tooth gear. The spool comprises of D(1)-D(5) mounted on top of one another so that D(5) is furthest from the brace and the two holes near the central axle align for each part. The spool is covered by C(1), and support posts are mounted through each of the holes in C(1) and the corresponding holes in A(2). Each support post is locked in place.

The spool is wound by taking the end of the cable and drawing it through the pass between D(1) and D(3). Draw the end through the hole in D(1) so it is exiting toward the brace. This end will enter the hole closest to the center and span the spool so the end is facing away from the brace. The end passes through the hole in D(5) towards the brace so it is in the space between D(3) and D(5). Pull the cable so the length is equal on either side of the spool. Insert and a secure an 8-32 screw through the remaining free hole through the spool. Wind the cord over each cam surface counter clockwise. The spool is mounted onto the axle so that when the brace is deflected, the cords are tangent to the surface of the inner diameter and the support posts. Once this position is specified, the cords are tied to the ends of the springs when the device is in the extended position.

The assembled parts are attached to the compliant brace by inserting the off-hanging grounds of A(1) and A(2) into the brace sleeves corresponding to the thigh and shank specific regions.

Appendix G: Design Schematics




2
1
B
B
A
A
Ø0.42
90.00°
180.00°
Ø0.42
5
Ø0.68
Ø0.42
5
1.78
5
0.38
Ø0.42
A(2) Shank Ground
R1.27
5.71
4.40
UNLESS OTHERWISE SPECIFIED:
NAME
DATE
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
DRAWN
CHECKED
TITLE:
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
COMMENTS:
SIZE
DWG. NO.
REV
A
A2_ShankGround
DO NOT SCALE DRAWING
SCALE: 1:2
WEIGHT:
SHEET 2 OF 10
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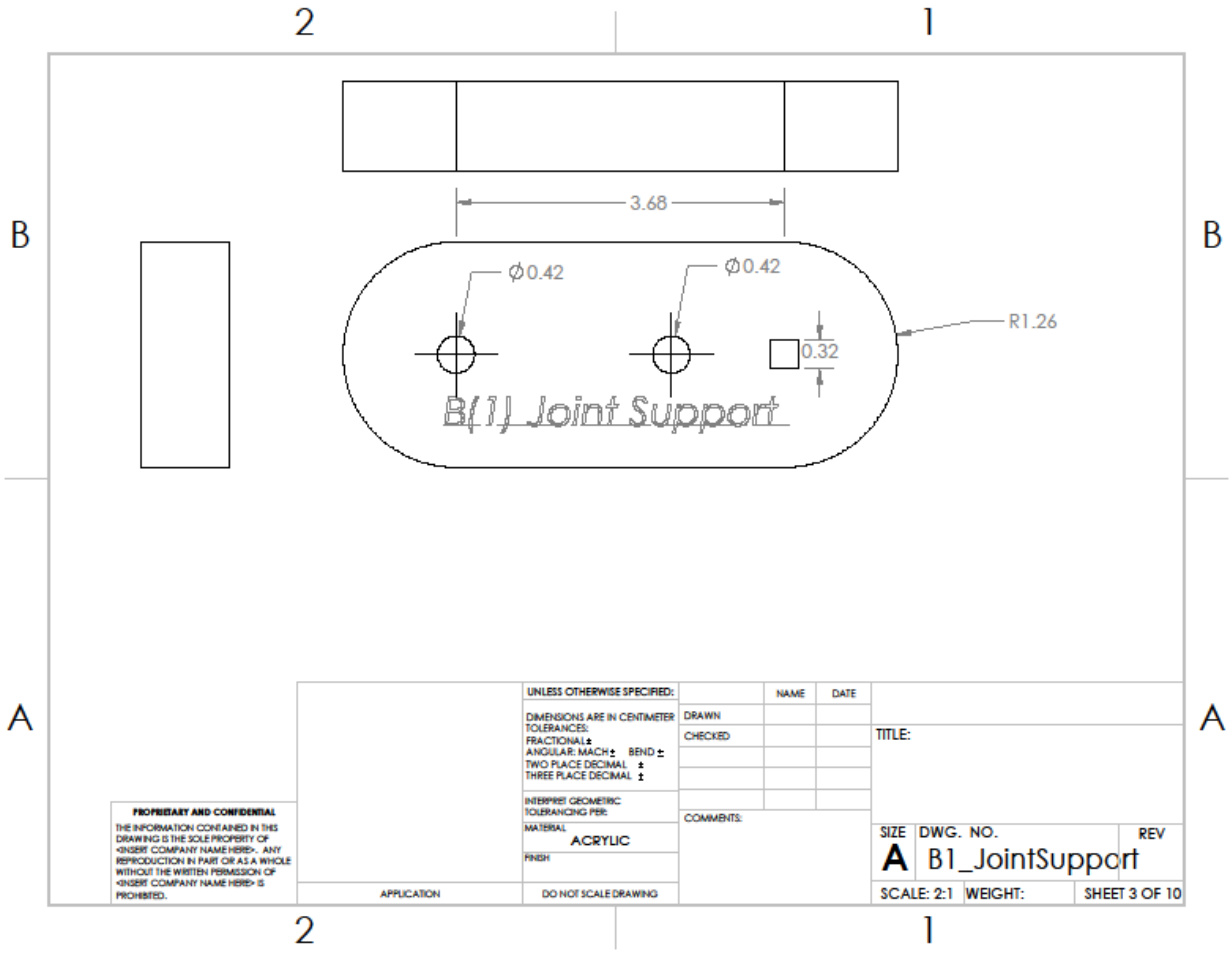
2
1
B
B
3.68
Ø0.42
Ø0.42
R1.26
0.32
B(1) Joint Support
A
A
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN CENTIMETER
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
COMMENTS:
TITLE:
SIZE
A
DWG. NO.
B1_JointSupport
REV
SCALE: 2:1
WEIGHT:
SHEET 3 OF 10
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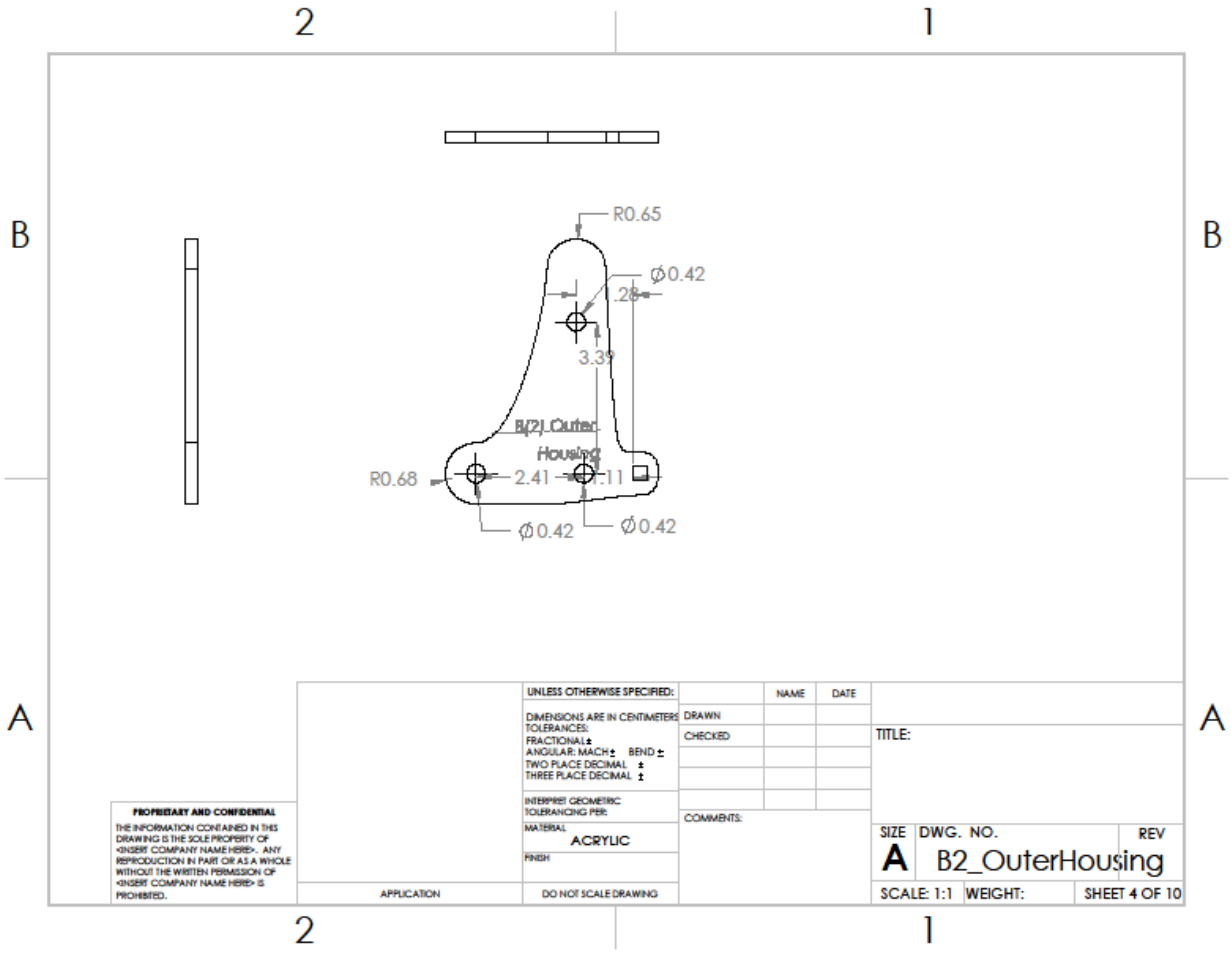
2
1


2
1
B
B
A
A
R0.65
Ø0.42
.28
3.39
B(2) Outer Housing
R0.68
2.41
.11
Ø0.42
Ø0.42
UNLESS OTHERWISE SPECIFIED:
NAME
DATE
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
DRAWN
CHECKED
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
COMMENTS:
TITLE:
PROPRIETARY AND CONFIDENTIAL
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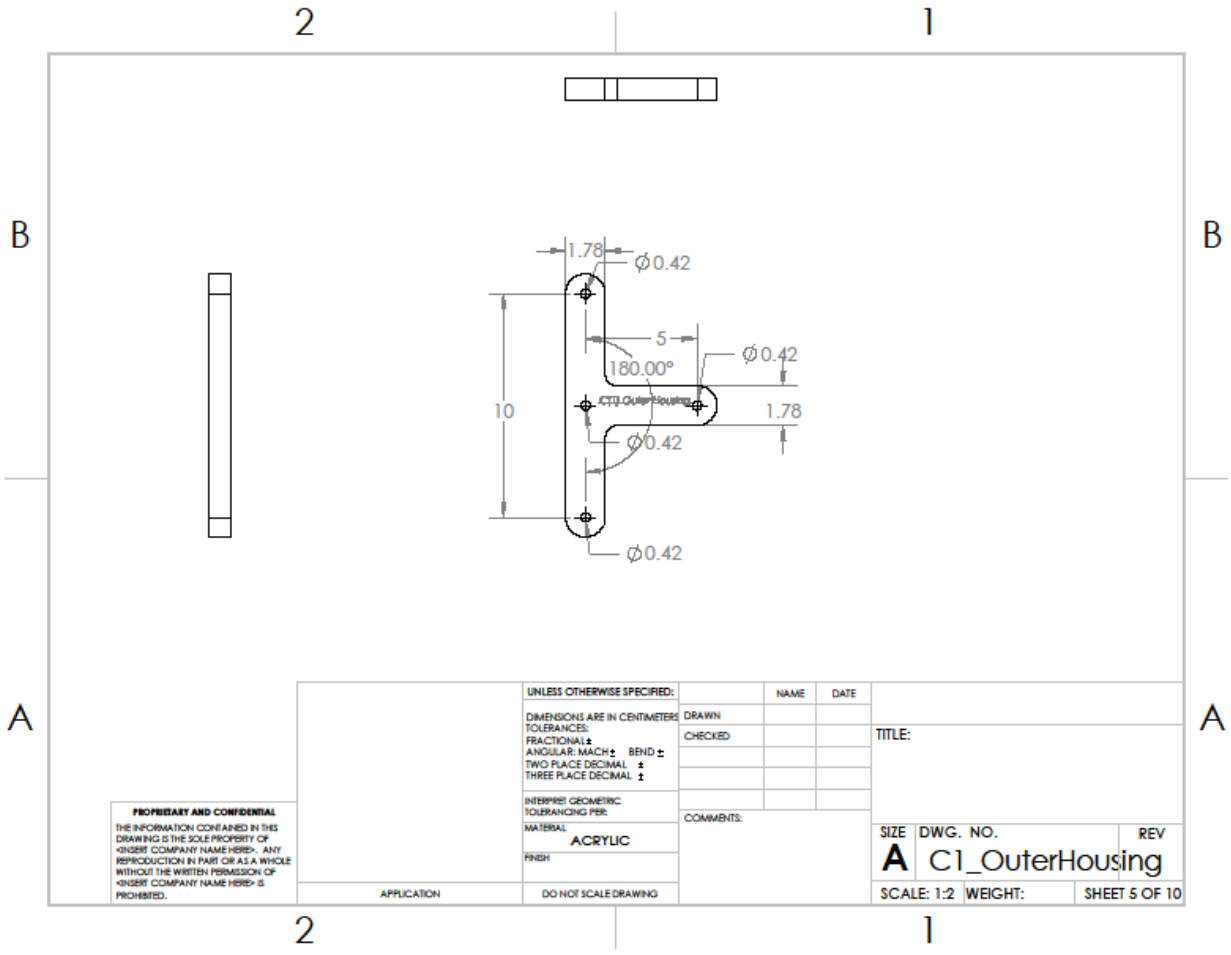
DO NOT SCALE DRAWING
SIZE
A
DWG. NO.
B2_OuterHousing
REV
SCALE: 1:1
WEIGHT:
SHEET 4 OF 10


2
1
B
A
1.78
Ø0.42
5
180.00°
Ø0.42
10
1.78
Ø0.42
Ø0.42
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
NAME
DATE
DRAWN
CHECKED
COMMENTS:
TITLE:
PROPRIETARY AND CONFIDENTIAL
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APPLICATION
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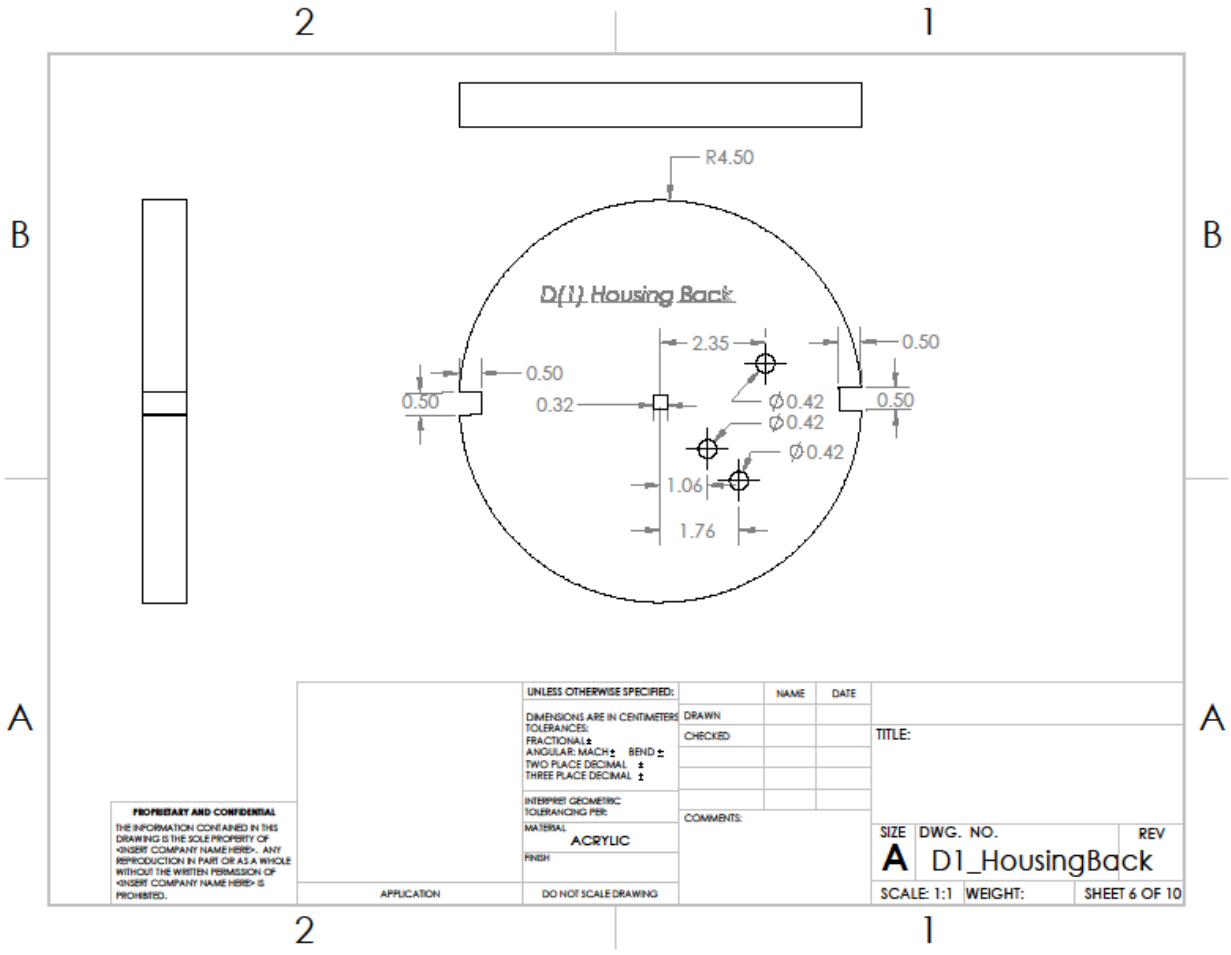
SIZE
A
DWG. NO.
C1_OuterHousing
REV
SCALE: 1:2
WEIGHT:
SHEET 5 OF 10


2
1
B
B
A
A
R4.50
D(1) Housing Back
2.35
0.50
0.50
0.50
0.32
0.50
Ø0.42
Ø0.42
Ø0.42
1.06
1.76
UNLESS OTHERWISE SPECIFIED:
NAME
DATE
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
DRAWN
CHECKED
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
COMMENTS:
TITLE:
PROPRIETARY AND CONFIDENTIAL
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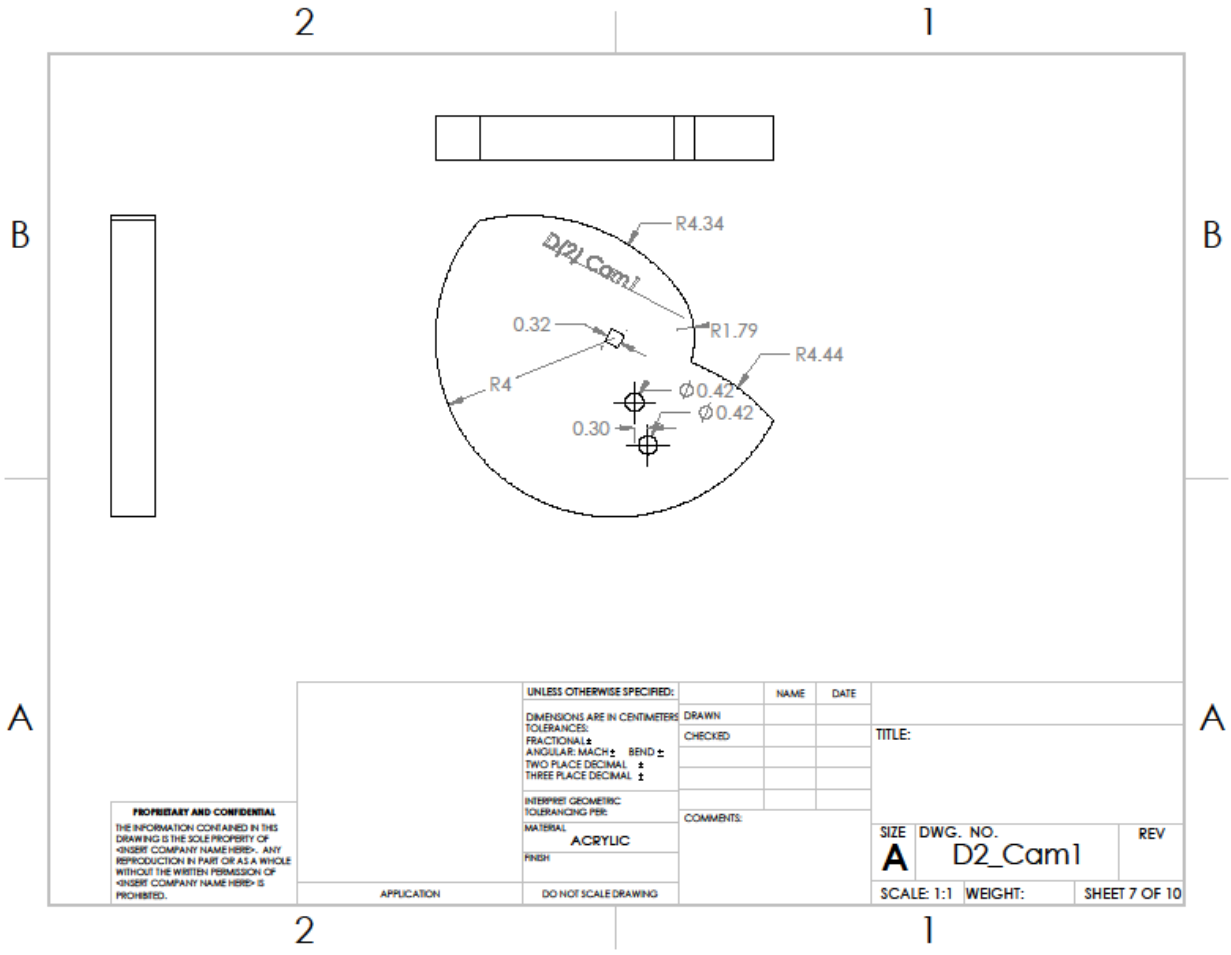
APPLICATION
DO NOT SCALE DRAWING
SIZE
A
DWG. NO.
D1_HousingBack
REV
SCALE: 1:1
WEIGHT:
SHEET 6 OF 10
2
1


2
1
B
B
A
A
R4.34
D2_Cam1
0.32
R1.79
R4.44
R4
Ø0.42
Ø0.42
0.30
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
COMMENTS:
TITLE:
SIZE
A
DWG. NO.
D2_Cam1
REV
SCALE: 1:1
WEIGHT:
SHEET 7 OF 10
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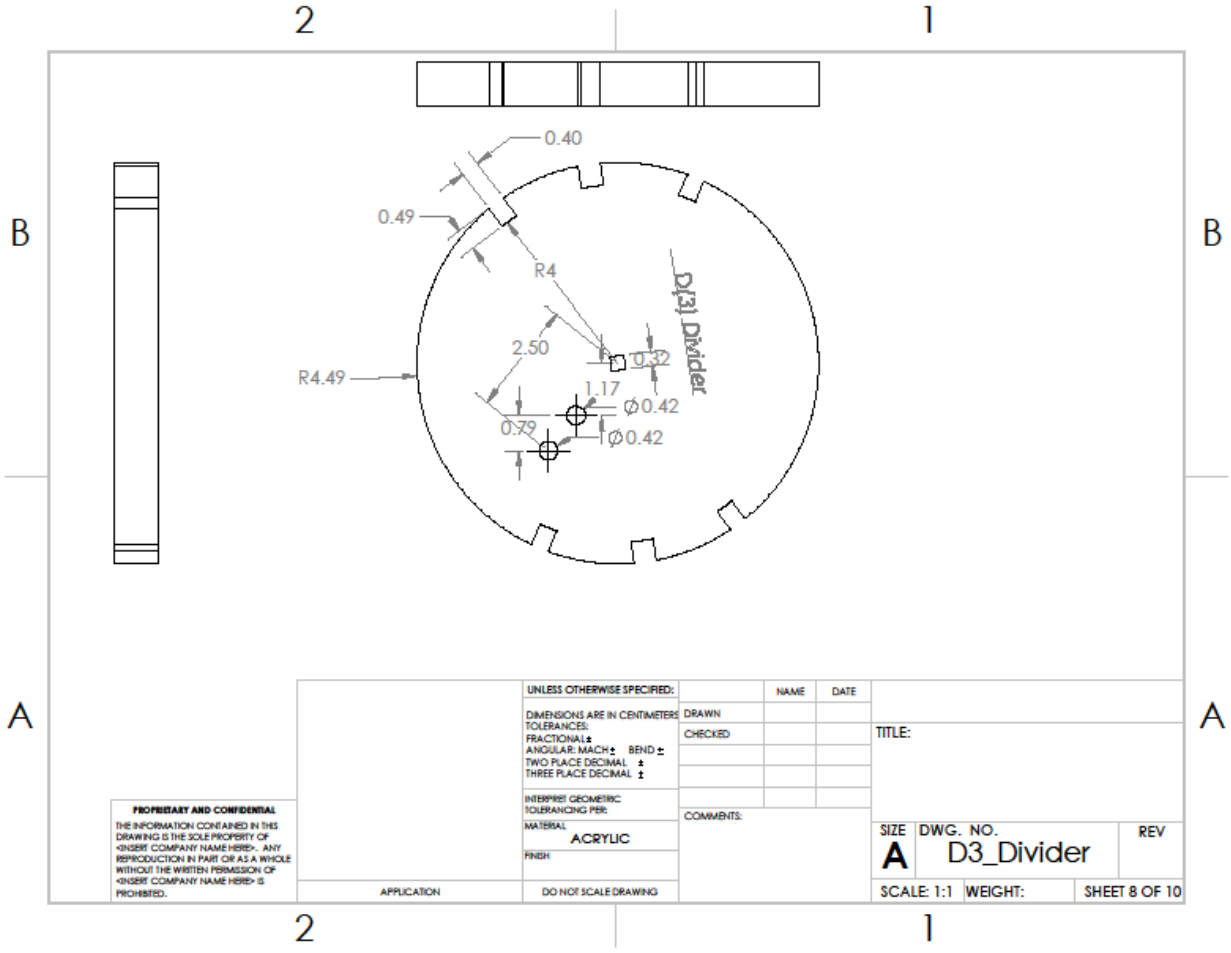
2
1
B
A
0.40
0.49
R4
D[3] Divider
2.50
0.32
R4.49
1.17
Ø0.42
0.79
Ø0.42
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
NAME
DATE
DRAWN
CHECKED
COMMENTS:
TITLE:
SIZE
A
DWG. NO.
D3_Divider
REV
SCALE: 1:1
WEIGHT:
SHEET 8 OF 10
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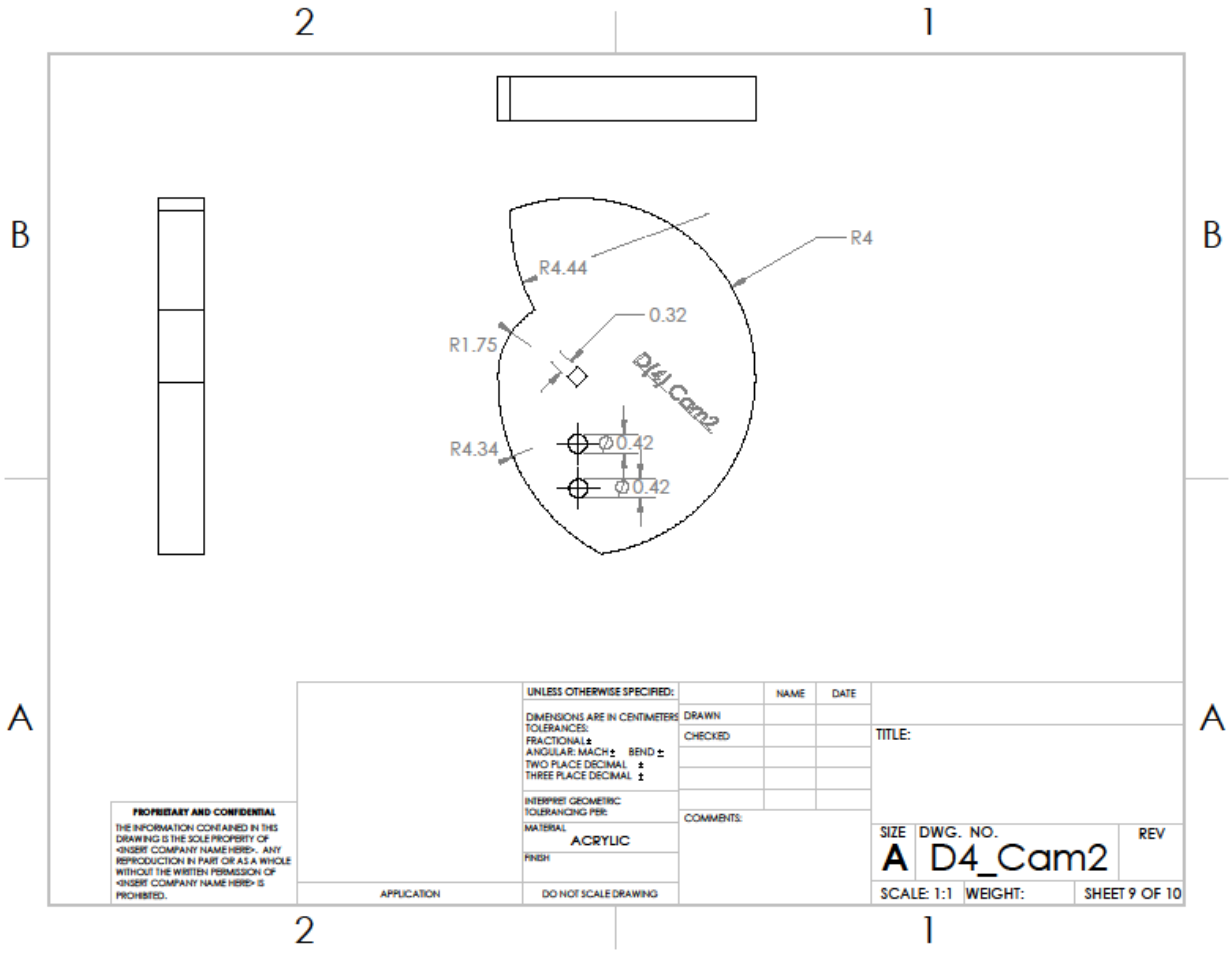
2
1
B
A
R4
R4.44
0.32
R1.75
D4_Cam2
R4.34
∅0.42
∅0.42
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
NAME
DATE
DRAWN
CHECKED
COMMENTS:
TITLE:
SIZE
A
DWG. NO.
D4_Cam2
REV
SCALE: 1:1
WEIGHT:
SHEET 9 OF 10
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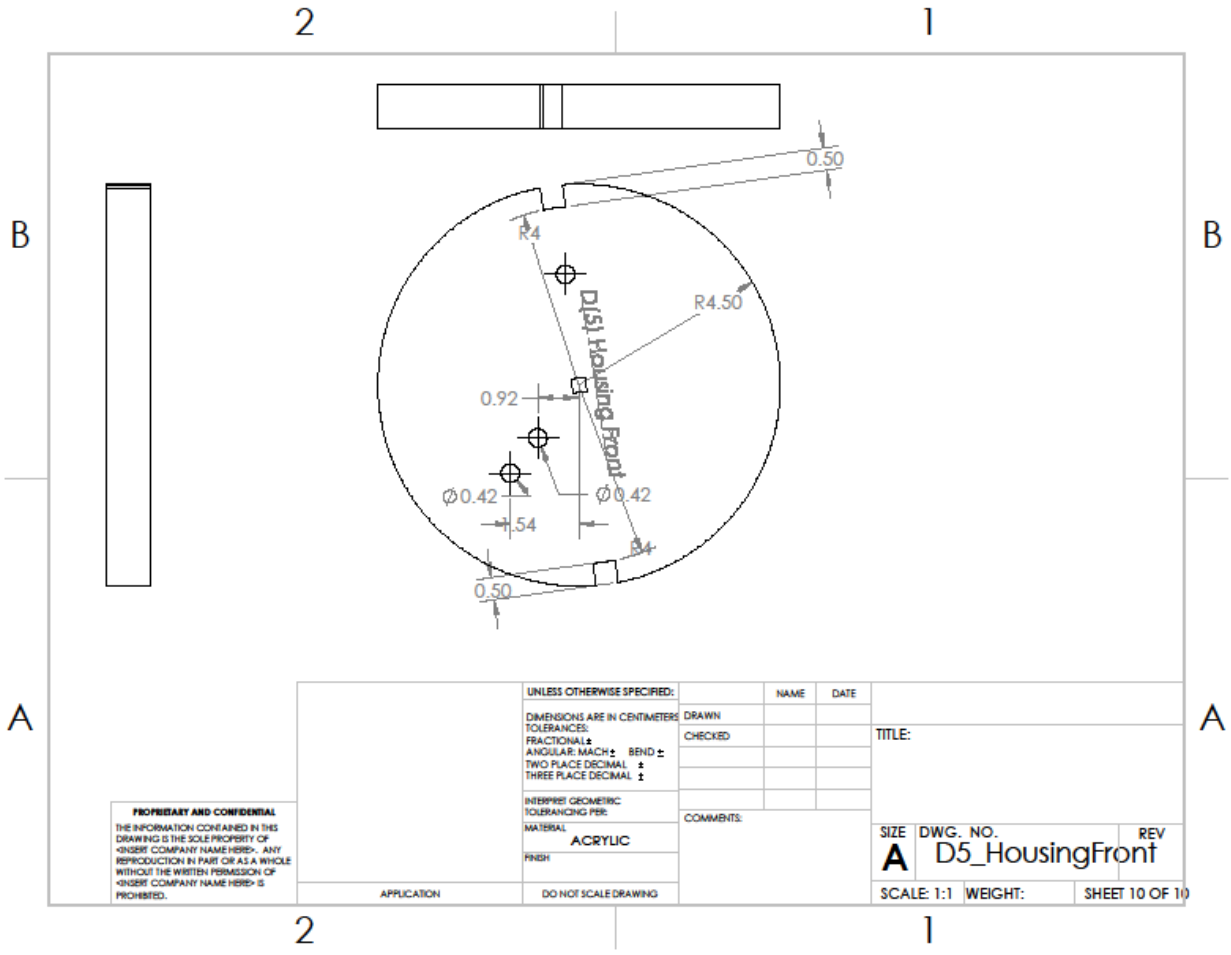
2
1
B
A
0.50
R4
R4.50
D[5] Housing Front
0.92
Ø0.42
Ø0.42
.54
R4
0.50
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN CENTIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
ACRYLIC
FINISH
NAME
DATE
DRAWN
CHECKED
COMMENTS:
TITLE:
SIZE
A
DWG. NO.
D5_HousingFront
REV
SCALE: 1:1
WEIGHT:
SHEET 10 OF 10
PROPRIETARY AND CONFIDENTIAL
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Appendix H: Post Test Survey

Post Testing Survey

For Official Use Only	
Subject ID:	Date:
Administered by:	

Walking Test

Did you notice the brace doing work for you, making it easier for you to go up stairs?

Did you notice the brace doing work for you, making it easier for descend stairs?

Were you able to easily bend your knee while walking?

Did you notice the brace doing work for you, making it easier for you to walk?

Did the brace inhibit normal walking function?

STS Test

STS without brace Borg Rate of Perceived Exertion (6-20): _____
STS with brace Borg Rate of Perceived Exertion (6-20): _____

Did you notice the brace doing work for you, making the sit to stand transition easier?

Did you notice the brace doing work for you, making the sit to stand transition harder?

Overall Experience

Rate of a scale of 1 to 10 how comfortable the brace was. One being painful and ten being extremely comfortable. _____

Where was it least comfortable?

Would you be able to wear it for 8 hours? If not, why?

Did you experience any pain while wearing the brace?