Designing a Preventative Assistive Knee Exoskeleton for The Aging Population Suffering from Degenerative Knee Joint Conditions

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1. Assistive

2. Exoskeleton

3. Osteoarthritis

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Executive Summary

Introduction

The aging population is increasing at high rates, which is over burdening the healthcare system due to frequent doctor and hospital visits. With the healthcare system unable to continue to care for a major influx of patients, medical solutions are beginning to turn to preventative care options. Knee joint damage is common in people over 65 year of age. Osteoarthritis is a joint disease which is described as the wearing away of cartilage between long bones. Years of movement and extensive physical activity cause the cartilage, not only in the knee, to degenerate eventually leaving the bone to rub on each other causing pain. Increasing movement pain with the elderly can inhibit their mobility reducing quality of life. Gait disorders in people aged 60-69 years is around 10% compared to 60% in people aged over 80 years. [3]

External braces, including exoskeletons, can help correct gait disorders and aid in activities of daily living. Unfortunately, effective and affordable exoskeletons are not available to patients who would benefit from their use. Another common and more accessible solution to reducing OA pain is a passive knee brace which unloads the knee. These simple braces reduce the force when walking purely because of their mechanical design and some realign the leg. The reason these are not an encompassing solution is that they do not provide walking assistance. If the user has reduced muscle activity and severe bone mass loss, then a nonpassive brace has many limitations with how much support it can give.

The goal of this project was to develop a low cost, customizable assistive knee exoskeleton for activities of daily living. This device was intended to aid patients with degenerative knee joint conditions. Customization of the assistive device came from analysis of the biomechanics of each patient. The final product took into account aesthetic and user needs. Ideally, this device should cut down on doctor intervention and maintenance, and will turn an exoskeleton from a novelty to an useful assistive device.

Methodology

This device was intended to aid ageing patients with degenerative knee joint conditions. This goal was broken down into 4 objectives which focus on, understanding user needs, customization through software development and hardware, and prototype testing.

1. To apply user centered design principles for the ageing population to increase comfort and independence.

2. To actively facilitate knee flexion and extension.

3. To use image processing and 3D modeling software to generate and manufacture a patient-specific orthotic.

4. To utilize gait analysis for proof of concept, safety needs and functionality requirements to validate the system.

Before designing the device, it was necessary to establish design functions. This included determining that applied forces and torque were needed, having a non motion restrictive design, and gait cycle

correction. The design functions were divided into mechanical and user centered specifications, as well as sensing requirements. These requirements helped to constrain the device to being lightweight, allow for natural range of motion and fit easily under the user's clothing. In addition, the following specifications were created to promote optimal usability of the device.

1. Support the patient's weight at the knee during the gait cycle

2. Fit comfortably to the user's body and not suffer from migration

3. Have each piece of the device be easily customizable in the manufacturing process

4. Cost under $1,000 to be affordable to the target audience

All design functions, constraints, and design specifications were restricted by industry standards during the design process. To ensure user safety, the device followed ISO and FDA standards, as well as established testing procedures. Since the device will be working with patients who have osteoarthritis, the device needs to follow ISO 17966:2016. In addition, the final model produced during this project is considered a Class II device, which means that the device will be working directly with a patient and provides moderate risk to the patient.

Design Process

The goal of this project was to address the needs of the user through effective design and engineering, thus the design phase reflected this expectation. Preliminary testing was performed before the start of designing the brace. Through statics analysis, EMG sensor exploration, motion capture, and gait analysis, a standard was set for performance of the natural gait cycle. These tests helped determine the moment acting upon the knee, the forces acting on it, and the various tests through the motion capture and gait analysis software programs. From these baseline tests, three concept designs were developed. The designs combined different actuation methods and mechanical support structures to accomplish powered assistance at the knee. A pairwise comparison chart was used to determine which components of each design would be used in the final prototyping phase.

Three alternative movement following designs were developed as a result of the pairwise comparison chart. A gear system with non-circular gears were created to generate an outward force at the knee joint while in extension to reduce load but have no force on the knee when it is in flexion. The other design incorporated circular gears aimed at mimicking a modified hinge joint, closely modeling the knee. The third design was a four bar actuation system, which fulfilled the same function as the gears, but was easier to manufacture. After understanding that it was not realistic to push the knee apart as exoskeletons typically shift 10 mm during movement, a bar with gear ends was developed to mechanically support the brace while the motor actively supported the user through the gait cycle. This was developed in unison with the series elastic actuator, and the capstan drive to ensure functionality and safety. The final design of the mechanical elements, was designed to wear over the soft component. In designing the soft element, two miniature prototypes of a garter and pant were created as a proof of concept. The final decision was made to move forward with the garter design as it fulfilled the objectives and specifications more closely. The under lining was sewn from nylon and thread to a pattern made for the model of the brace. Velcro was then sewn in the appropriate places for closure purposes.

The final design was comprised of a three bar linkage, the capstan drive, and the series elastic actuator. The three bar linkage is made from the force unloading bars with gear head ends that are linked together via a small connector piece. The capstan drive is attached to the linkage opposite the small connector piece. The series elastic actuator is used for safety and actuation purposes. All pieces are connected together and anchored to customizable leg blocks. Velcro straps bind the device to the patient. Underneath the whole mechanism is the underlining.

Results

After comparing the preliminary motion capture data with the walking data when the subject had the brace on their leg, the team can conclude that the device does not significantly alter the gait. This is the desired result because the subject is assumed to be healthy and the device should not change their gait cycle. Preliminary testing was performed to obtain the knee moment and knee angle in the x direction. The averages of these data sets were used to validate the design. Paired t-test results, with an alpha value of 0.05, for each leg validated if the device changed the gait cycle. The null hypothesis stated that there would not be a significant change in results which proved that the brace does not affect the gait of a healthy subject. The results show that the ground reaction force comparison have a h value of 0 and p value greater than 0.05, accepting the null hypothesis. For knee angle and knee moment, the h value is 1 with p values less than 0.05 rejecting the null hypothesis and proving there is a significance in the mean difference between the preliminary and testing data. This could be explained by the shift in the data with the brace which slightly decreases the stride length.

Recommendations and Conclusions

The purpose of this project was to create a low cost, customizable, assistive knee exoskeleton aimed at the ageing population. Through gait testing, it was successfully determined that the device allows knee flexion and extension. The device was also demonstrated to effectively provide walking assistance. Customizable pieces not only provide increase comfortability during long term use but the device also corrects the misalignment usually found in OA patients. Using relatively inexpensive parts like PLA and aluminum the team was able to reduce the costs while providing adequate durability. Sensors and other electrical components usually drive up costs in exoskeletons and are not low profile. By only using a potentiometer and decoupling the motor from the knee joint, the device gives successful performance while lowering costs and keeping it low profile. Future studies can help provide better gait detection.

Future work includes further development of the testing and validation of the device. The availability of EMG data would allow the group to see what muscles are working during the gait cycle both with and without the device. The goal of using these sensors would be to target the muscles which are providing the most walking support then reduce their usage. EMGs would also provide additional device validation and safety validation. Also, once the motor control and brace design have been iterated, to where the device works on a normal patient, the next step would be to test on patients with osteoarthritis. This would validate the design as successful in aiding with activities of daily living, therefore increasing quality of life in an affordable manner.

Figure 1: Final Device

Authorship

The report and project was equally prepared by all team members. We confirm that all content presented in this report as well as the mechanical design of the device are our own and do not knowingly violate the intellectual property rights of others. We can also confirm that everyone in our group:

1. Completed the entirety of this project while in candidature for an undergraduate degree at Worcester Polytechnic Institute.
2. Conducted proper research and cited sources where needed
3. Gave full acknowledgements to any department or persons who gave us any support during the project

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Abstract

The increasing aging population frequently suffers from knee joint degeneration, with 6 million people over 65 showing signs of knee OA [1]. This demographic has limited access to preventative injury solutions due to the high costs of medical devices, thus impacting range of motion, independence, and safety [2]. Typically, assistive exoskeletons to combat these problems are designed for a general population and then fit for each patient. In response, this project aimed to develop a low cost, customizable assistive knee exoskeleton for increased quality of life. The device includes a motor which provides assistance in walking. Testing showed that there is a minimal amount of change of gait when a healthy subject walks with the brace. This shows promise for assisting real patients with osteoarthritis.

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Chapter 1: Introduction

Currently, the United States is seeing a rise in its 65+ population. The earliest baby boomers turned 65 in 2011 and by 2050 many of the youngest baby boomers will be 85 [4]. The elderly population already accounts for 26% of physician visits, 47% of hospital outpatient visits, 35% of overnight hospital visits, 34% of prescription services, 38% of EMT calls, and 90% of nursing home residents, making them one of the biggest groups in need of medical support [5]. The health system is at risk of being overburdened as the elderly population continues to rise. With an increase in the over 65 demographic, knee osteoarthritis rates are also climbing. Symptomatic Knee Osteoarthritis causes increased pain in the affected joints, bone damage, and decreased mobility. People with osteoarthritis experience as much as 30 percent more falls and have a 20 percent greater risk of fracture than those without osteoarthritis. [6] As the ageing community increases, so will prevalence of accidents due to knee OA. In addition to increasing knee OA rates, the ageing community is the only demographic to see increased poverty rates [7]. With the ageing community overburdening the healthcare system, the focus must shift from expensive post-accident care to affordable preventative care.

The market gap in assistive technology designed for degenerative knee joint conditions will continue to increase if the needs of the ageing population are not addressed [7]. In addition to a large pool of potential users, the United States also possess a large share of the exoskeleton market across the healthcare, military, and industrial fields. Companies such as Ekso Bionics, ActiveLink, Cyberdyne, Inc., Rewalk Robotics Ltd, Rex Bionics Plc, Lockheed martin Corporation, Suit X, RB3D, and Hocoma are all companies that have produced exoskeletons [7]. Many of the exoskeletons created by these companies address the rehabilitative market and assistive market, but few of the models have been designed for elderly patient use. The assistive and rehabilitative devices are designed for spinal cord injury (SCI), stroke, and other paralyzed patients, to enable them to move freely (e.g.[8]). However, there has been little to no focus on assistive exoskeletons in relation to preventative care for the elderly population.

Most exoskeletons available for purchase whether for rehabilitative or assistive purposes are high in cost. Active exoskeletons for the lower limbs cost between $70,000 and $120,000. This upfront cost does not cover physical therapist appointments, servicing, doctor appointments, etc. [9]. Furthermore, the poor financial status of the rising elderly population lessens the potential for users to buy and maintain a device easily. Stakeholders report that they do not consider an exoskeleton as a solution due to its cost and would only pay up to $20,000 for a device [10]. Currently, as less than 1,000 rehabilitative active exoskeletons sell each year [11]. Few can afford the high price tag on exoskeletons making the technology more of a novelty rather than a realistic option [9]. With exoskeleton model costs soaring, a market gap exists for low cost, powered, lower limb exoskeletons.

The goal of this project is to design, prototype, and test a low cost customizable assistive knee exoskeleton for activities of daily living. The device will aid patients with degenerative knee joint conditions by providing assistance through the gait cycle. The primary users of this project are individuals with aging-related knee pain that are hoping to prevent future cartilage degradation, thus this is an assistive device, not a rehabilitative one. Since this populations typically struggle with mobility due to pain or stiffness in the knees, the device must mobily assist the user by providing extra power. The device should mimic the natural movement pattern of the knee and not provide restriction on movement. Patients

need a device that can help with supporting the leg and adding torque to the knee during an ordinary gait cycle. To accomplish this goal, the following four objectives were created

1. To apply user centered design principles for the ageing population to increase comfort and independence.

2. To actively facilitate knee flexion and extension.

3. To use image processing and 3D modeling software to generate and manufacture a patient-specific orthotic.

4. To utilize gait analysis for proof of concept, safety needs and functionality requirements to validate the system.

These objectives were met by using mechanical, electrical, and user centered design properties. The combination of these three fields would allow for movement mimicry and gait . The final design was tested on the hypothesis that a healthy person's gait would not be greatly affected by the device. This was done by testing biomechanical statics analysis, motion capture, and force plate gait analysis with multiple activities of daily living. These tests were executed both with and without the device. Once all of the data was completed, t-tests aided in making conclusions about whether or not the brace effects a subject's gait in any way. The final prototype proves a safe low cost assistive brace that is effective at not changing a healthy subjects' gait.

Chapter 2: Background

2.1 Project Motivation

The healthcare sector in the United States will be challenged for the foreseeable future due to the increasing ageing population [12]. As a person ages, their body begins to deteriorate. Body parts such as bones become more fragile, and minor accidents can have severe consequences. This deterioration impacts a person's ability to move freely. Without the freedom to exercise, complete household chores, and work, an individual becomes increasingly dependent on external sources for care and basic needs [2].

The lack of mobile independence in the elderly population inhibits their ability to maintain a high quality of life. In a recent study, it was found that patients hope to use an exoskeleton or orthotic device to move freely, whereas the doctors of these patients did not feel as strongly on the topic. Doctors believed that the patients would feel self conscious with an assistive device, whereas the patients were eager and excited to take care of themselves once more [10]. This demonstrates a lack of understanding among doctors of what patients are really seeking. The affected population wishes to improve mobility, but the doctors see their needs differently. As the elderly population rises, accepting more patients in hospitals will be more difficult due to high demand of services. Doctors will rely on preventative care devices to ensure their patients can meet their quality of life requirements.The focus will begin to shift from post accident care to preventative care, especially in the population experiencing knee pain. In order for these preventative care devices to fully allow this population to regain their independence, quality research the following subjects is the first step in designing and developing a successful knee exoskeleton: knee structure, the diseased state of osteoarthritis, knee kinematics, gait analysis, existing market of knee exoskeletons, actuation methods, novel software, sensors, and more.

2.2 Knee Structure

With an increasing ageing population, one must understand how the body functions to maintain mobility. Constant stress and force applied to the knee often results in joint failure. During a normal gait cycle, the knees support 1.5 times one's body weight. Additionally, climbing stairs is about 3-4 times one's body weight and squatting about 8 times [13]. The knee bears enormous weight and pressure loads from carrying body weight the upper extremities, while providing flexible movement.

Knowledge of the knee anatomy is important when developing an understanding of an injury and ways in which to heal or fix the condition. The knee is known as a synovial joint, which connects the femur, the largest bone in the body, to the tibia and fibula, the second longest bones in the body. The two joints of the knee are the tibiofemoral joint, which joins the the tibia to the femur, and the patellofemoral joint, which forms the kneecap and femur. These joints work together to allow the knee to move uniaxially as well as rotate slightly from side to side. This gives the knee the ability to flex and extend.The knee is responsible for multiple functions such as, weight bearing, supporting the body in an upright position without the need of muscles to work, shock absorbing, allow twisting of the leg, propelling the body forward, stabilizing, and efficiency [14]. These responsibilities are due to the articulation of bones, ligaments, cartilage, muscles, and tendons.

THE HUMAN KNEE
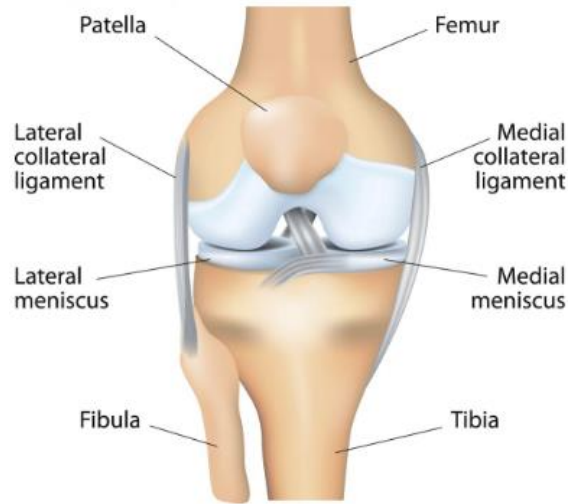
Figure 2: Knee Anatomy [14]

It is important to use anatomical terminology when talking about locations of the body for clarity purposes. If facing the knee, the anterior view is the front of the knee. The posterior view is the back of the knee. The medial view is the side of the knee closest to the other knee. Finally, the lateral view is the side of the knee that is furthest from the other knee [14].

The bones of the knee, tibia, fibula, femur, and patella give the knee strength, stability and flexibility. The tibia is made of two plateaus that have two crescent shaped shock absorbing cartilages called menisci at the top of each plateau. The patella is a triangular bone that relieves friction between bones when the knee is flexing and extending. The kneecap glides along the anterior bottom of the femur between two protuberances called femoral condyles. The femur is the largest and strongest bone of the body. The fibula is the bone that runs alongside the tibia laterally [14].

Collectively, the ligaments of the knee all function as bone to bone attachments and give strength and stability. They are tough bands with little flexibility, which provides support in an unstable joint. If over extended, the ligament may snap, resulting in traumatic injury to knee and the inability to walk.
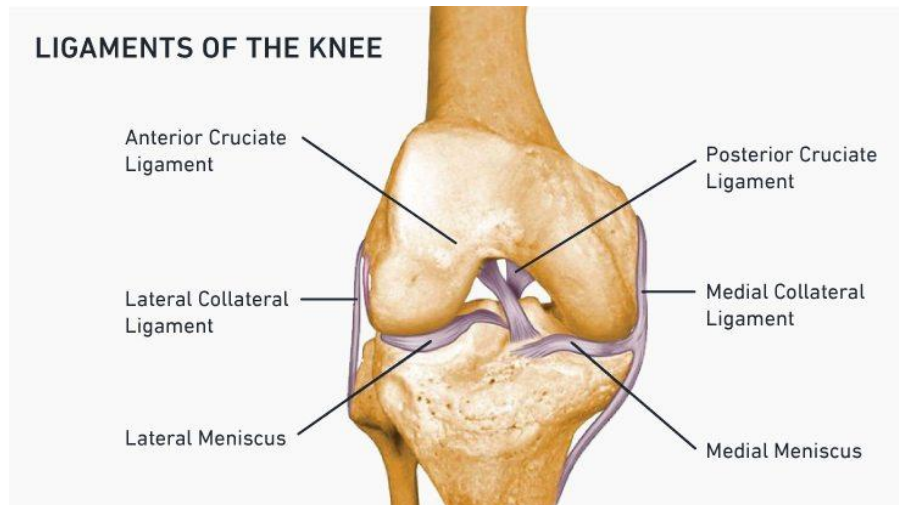
Figure 3: Ligaments of the Knee [15]

The five different ligaments are the Anterior Cruciate, Lateral Collateral, Medial Collateral, Posterior Cruciate, and Patella. The Anterior Cruciate ligament attaches the femur and tibia in the center of the knee. The purpose of this ligament is to limit rotation and forward movement of the tibia [15]. The Lateral Collateral ligament attaches the lateral side of the femur to the lateral side of the fibula.The Medial Collateral ligament attaches the medial side of the femur to the medial side of the femur. Both connections limit sideways movement of the knee. The lateral and medial sides of the knee provide strength and stability to keep the bones aligned. The Posterior Cruciate ligament is the strongest attachment of the femur and tibia limits backward motion of the knee. Finally, the Patellar ligament attaches the kneecap to the tibia [13].

The tendons of the knee are elastic tissue that connects the muscle to the bone. The two major tendons, the Quadriceps and Patellar, stabilize the knee. The main function of the quadricep tendon is to provide the power to straighten the knee. The patellar tendon functions as a connection for the kneecap and tibia [14].

The muscles of the leg work together to flex, extend, and stabilize the knee joint. The femoris quadricep group of muscles run along the anterior surface of the thigh, which are the vastus lateralis, vastus medialis, vastus intermedius, and rectus femoris. Contraction of these muscles aid in the extension of the knee and flexion of the leg at the hip [15].
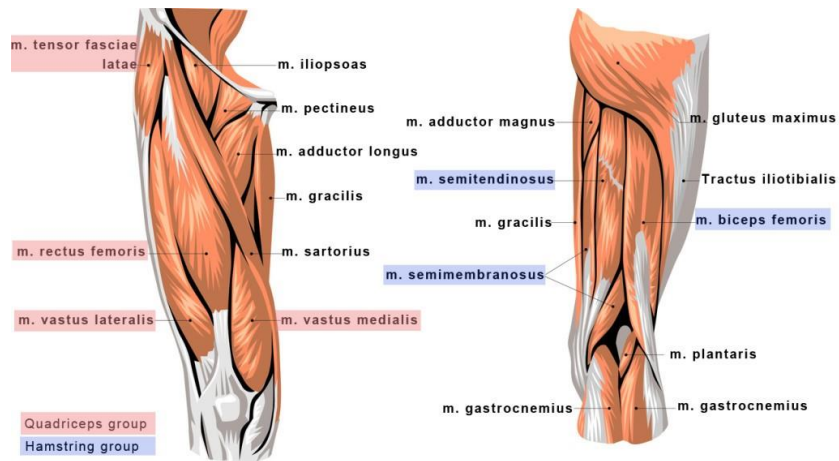
Figure 4: Muscle Groups in Thigh [16]

The hamstring muscle group extends across the posterior surface of the thigh, which include the biceps femoris, semitendinosus, and the semimembranosus. This group of muscles work together to flex the leg at the knee. Then the gastrocnemius muscle is located in the distal end of the femur through the Achilles tendon to the calcaneus of the heel. This calf muscle is a contributing member to flexing the knee and plantar flexion of the foot [16].

In a healthy knee, cartilage is the weight bearing protection of the bones. The articular cartilage covers the ends of the femur, tibia and back of the patella. It is slippery due to the synovial fluid in the knee, which allows for smooth, painless movement of bones. Also the meniscus cartilage plays a role in shock absorption. It is attached to the tibia on the medial and lateral sides of the knee [13].
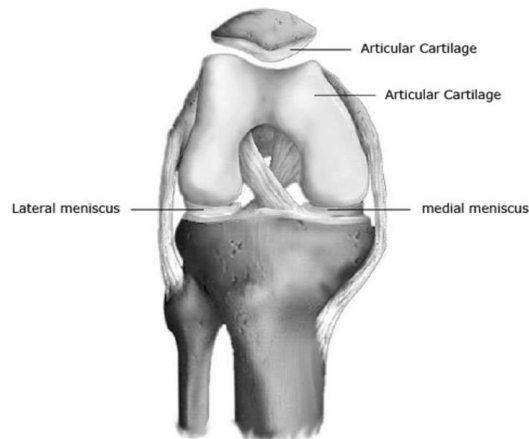
Figure 5: Cartilage Locations [13]

2.3 Osteoarthritis and Cartilage Deficiency

Osteoarthritis refers to the degeneration of cartilage between the joints. Not only can it affect weight bearing joints like the ankles and knees but fingers, hips, and the back can also lose cartilage. Uneven loading and years of multiple repetitions wear away the cartilage between long bones which eventually

causes bone on bone interaction during movements. As a result of osteoarthritis, symptoms include increased pain in the affected joints, bone damage, and decreased mobility. People with osteoarthritis experience as much as 30 percent more falls and have a 20 percent greater risk of fracture than those without osteoarthritis. [15]. There are ways to reduce the chance of developing severe osteoarthritis like reducing body weight through exercise and dieting, take medications which reduce pain, and use braces which reduce the amount of force in weight bearing joints.[17]

Osteoarthritis of the Knee
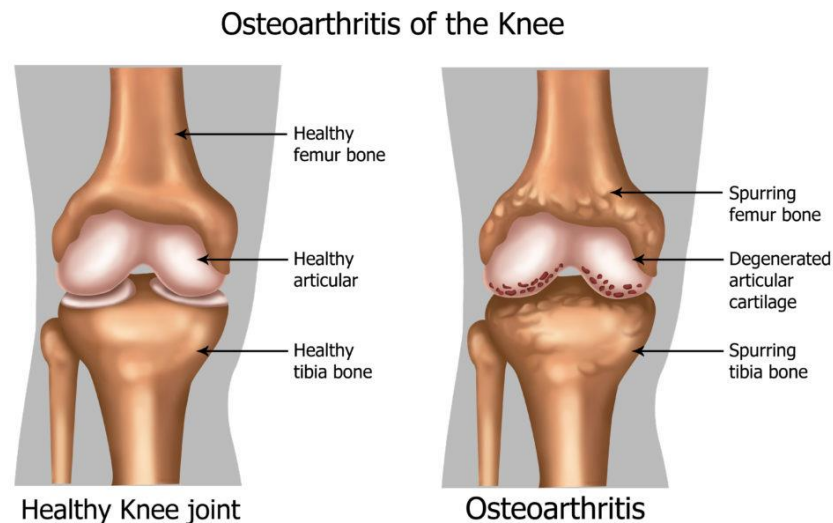
Figure 6: Comparing Healthy Knee to Osteoarthritic Knee [18]

Osteoarthritis pathophysiology can be described as the process of degeneration of articular cartilage, bone deficiencies and changes, and inflammation of the synovial membrane [18]. Cartilage degeneration occurs due to it's vulnerable structure, age, and other factors. Chondrogenesis is the process in which cartilage is created, which is made of a matrix of proteins. This provides a layer of cushion between the interaction points of bone ends. If there is pressure loading to this layer, the chondrocytes produce collagen and protein matrics to replace degenerated layers [19]. This replacement process is slow and if there is excessive loading, the chondrocytes cannot replace at the same rate of degeneration. Also excessive loading causes the activation of enzymes, called metalloproteases that digest the matrix. Once there is damage to the cartilage, the products are engulfed and digested by synovial cells, causing inflammation. Low level synovial inflammation is the most common in people with Osteoarthritis. The degree of inflammation is associated with severity of pain [19].

Osteoarthritis is difficult to prevent because of the constant and unpredictable loading on the joints especially from the weight of the body. There are many pharmaceutical solutions, like anti-inflammatory medications, but they are limited in their effectiveness. Specifically, the most common solution is a steroid injection which is a powerful anti-inflammatory but is temporary and can require constant visits to the doctor for treatment. Non-pharmaceutical solutions include full knee replacements which are expensive and require a lot of recovery time which is unfavorable for most elderly citizens [18]. Since there is constant loading on one point in both legs, a biomechanical solution, such as an assistive device, would ease the pain and reduce loading and redirect it to another area. The result is a reduced amount and severity of symptoms which leads to less falls.

Figure 7: MRI Comparison of Healthy versus an Osteoarthritic Knee [20]

Figure 7 shows the effects of osteoarthritis on the knee. In window A, there is a normal concavity of the femoral head-neck junction. Then in window B, the femoral head is inflamed, the bone ends are spurring, and there is no gap in the tibia and the femoral head-neck junction.

Another risk factor of osteoarthritis is misalignment of the legs. As a person ages and OA progresses, the legs lose muscular strength and bone density causing instability [21]. This instability causes a medial or lateral misalignment usually centered at the knee joints which causes non uniform force dispersion on the cartilage. Realigning the legs would reduce the amount of bone on bone interaction from the part of the cartilage which was worn.

The social implications of this severity include impaired independence of the individual. A patient with osteoarthritis has difficulty performing ordinary tasks at work or at home. Simple acts like tucking in bed sheets, opening a box of food, grasping a computer mouse or driving a car can become nearly impossible. When the lower body joints are affected, activities such as walking, climbing stairs and lifting objects may become difficult [1]. Therefore impacting quality of life as well as a populations confidence.

2.4 Effects of aging on gait

Daily exercise is an important way to maintain health which also reduces the chances of developing severe osteoarthritis. Wolff's Law explains that bone in a person or animal when under different amounts of load will restructure in response to activity [22]. Decreasing exercise decreases load on bones, which has many physiological and physical health effects like a higher chance of developing cancer, dementia, diabetes, and more.

Osteogenesis is the process in which the human body forms bone structure. Collagen is the protein that is constantly broken down and rebuilt. This entire process is completed around the age of 25 which signifies all bones are completely ossified and do not continue to strengthen. In the elderly population, walking in any amount may be painful and with decreasing exercise, there is an increasing chance of developing

brittle bones [23]. To evaluate why walking is painful for the elderly, a comparison to how healthy people walk needs to be made. The joint angles, pressure points on each foot, and weight distribution, among others are important factors which can be compared to provide a better analysis of the differences. This is completed by using the gait cycle.

The gait cycle is a standard classification on how people with full range of motion and no bone deformities walk. The motion from when the right heel contacts the ground, swings, and lands again is broken up into many cycles [24]. Walking is described as a constant fall state where the body constantly realigns the legs and repositions the center of gravity. Gait cycle classification and characteristics are based on the motion of the right leg.
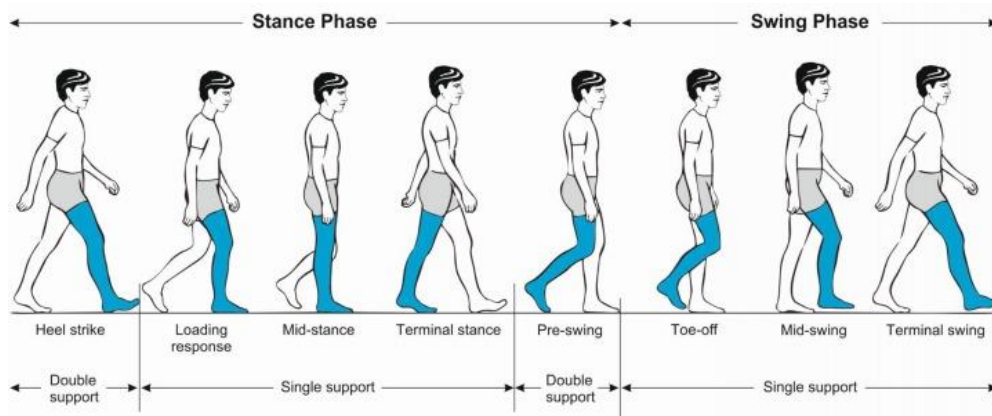
Figure 8: The Gait cycle [25]

Figure 8 shows the breakdown of the entire gait cycle. The stance phase encompases the first part then transitions into the swing phase. In the stance phase, the right heel contacts the ground followed by single-limb support when the foot is planted on the ground. At this same phase, the left foot swings in the air, which counteracts the forward motion of the person. The swing phase begins as the right toe lifts off the ground, then swings in the air as the left leg supports the weight of the body. The gait cycle is completed when the right heel makes contact with the ground.

There are two major methods to analyze gait. The first is using a motion capture system which utilizes reflective markers that are placed on the subject's limbs. This provides coordinates which show the joint angles, moments, ground reaction forces, center of pressure, and other information about how a subject walks. Software then records where the markers are placed which produces a virtual skeletal structure of the subject. Using this data can help provide an accurate model of gait from a wide range of walking abilities. The second method to analyze gait is using force plate data to identify how much force is applied on each foot as well as the distribution of pressure points on the foot during walking. The force plate data can be analyzed using graphs produced from integrated software.

The gait cycle is changed with added weight, change in bone structure, faster motion, and other changes in anatomical structure. Analyzing the gait patterns of the elderly population, due to a decrease in range of motion, will provide crucial information about how to correct an abnormal gait cycle. Gait disorders in people aged 60-69 years is around 10% compared to 60% in people aged over 80 years [3]. External braces, including exoskeletons, can utilize this data by learning the patient's gait pattern to aid mobility.

Unfortunately many manufacturers of these assistive and rehabilitative devices are not profitable and it is due to the current state of the market.

2.5 Market analysis

The market gap in assistive technology designed for degenerative knee joint conditions will continue to increase if the needs of the ageing population are not addressed [7]. In addition to a large pool of potential users, the United States also possess a large share of the exoskeleton market across the healthcare, military, and industrial fields. Companies such as Ekso Bionics, ActiveLink, Cyberdyne, Inc., Rewalk Robotics Ltd, Rex Bionics Plc, Lockheed martin Corporation, Suit X, RB3D, and Hocoma have all produced exoskeletons [7]. Many of the exoskeletons created by these companies address the rehabilitative market and assistive market, but few of the models have been designed for elderly patient use. The assistive and rehabilitative devices are designed for SCI, stroke, and other paralyzed patients, to enable them to move freely (e.g. [8]). However, there has been little to no focus on assistive exoskeletons in relation to preventative care for the elderly population.

Consumer available exoskeletons for lower limb assistance or rehabilitation cost between $70,000 and $120,000. This cost is solely only for the device and excludes servicing costs, doctor visits, and rehabilitation expenses. With such high costs and a poor financial stability of the elderly population, exoskeletons are a highly inaccessible solution for both walking assistance and osteoarthritic pain relief. Stakeholders report that they do not consider an exoskeleton as a solution due to its cost and would only pay up to $20,000 for a device [10]. Not only are consumers unsatisfied with the preventative care options, exoskeleton manufactures are losing profits since there is a minimal amount of products sold per year.

2.6 Existing Exoskeletons on the Market

A lower limb exoskeleton is a general term used to describe a powered device which helps a patient with gait rehabilitation, walking assistance, and increased weight support. There are few exoskeletons on the market that excel in more than one of the areas mentioned above, but high prices for this advanced technology decreases their accessibility. A rehabilitative exoskeleton allows a person to regain mobility by improving muscular strength, gait, and motor skills. Mainly spinal cord injury patients use this type of exoskeleton with the intent to improve mobility. An assistive exoskeleton is meant to be worn constantly by the user who suffer from decreased motor functions, have difficulty performing daily activities, or has pain with simple movements [26]. Weight support exoskeletons are used in the manufacturing industry aimed towards helping workers lift loads which cannot normally be supported by the human body. Also, the military uses these kinds of exoskeletons to help soldiers carry increased amounts of equipment without the use of a vehicle. There are many assistive exoskeletons, powered or passive, on the market but issues with customization, cost, and comfort limit reliability.

The geriatric population would highly benefit from an assistive device because of the lack of strong motor functions and increasing joint pain. A major disconnect between the solution, exoskeletons, and the target population is the cost. One of the major reasons the costs are exorbitant is the technology which allows the device to function safely and reliably. Currently, the market for exoskeletons is slowly growing because of the limited accessibility to customers. With technological advancements developing in the

future, costs will decrease and more patients will have access to exoskeletons. In order to understand the market, comparisons need to be made with existing devices [26].

Figure 9: ReWalk Personal 6.0 [27]

The ReWalk Personal 6.0 is one of the industry's leading standards in walking assistance systems. This particular device allows paraplegics to engage in basic daily activities such as walking, climbing stairs, and standing upright. Patients are able to use this device in a clinical setting as well as in a home setting. The cost of this device is about $70,000 which makes it one of the lowest costs for a device in this category and a major market contender because of it's FDA approval.

Figure 10: Ekso GT [28]

Ekso Bionics is a new company as of 2005 and their FDA approved device, the Ekso GT, allows for the same type of motions as the ReWalk. It is an assistive device which uses hydraulic actuators to provide movement. The list price for the exoskeleton is an estimated $120,000 which is almost double the price of the ReWalk [28]. Ekso is currently pushing towards entering the industry side of exoskeletons by targeting professional healthcare facilities which in turn provides more consumers exposure to their products. Two aspects critical to its actuation is gait training, posture support, and pre-ambulatory assistance.

Figure 11: Cyberdyne's Hybrid Assistive Limb [29]

Cyberdyne's Hybrid Assistive Limb (HAL) is a full body exoskeleton aimed towards providing patients with increased support with carrying objects. This is the first powered exoskeleton to receive global safety certification. This device not only helps the elderly with mobility issues, it gives increased strength to people when carrying increased weighted, mainly in an occupation setting. There are two models with major interest from the market: a full body suit and a legs only model. Currently, the price for model with both legs costs around $1200 a month to rent.

Figure 12: Vanderbilt Exoskeleton [30]

A team at Vanderbilt designed the Indego exoskeleton, another example of an assistive device, used in the spinal cord injury field. The cost is around $140,000 but it is a contender in the market because of its ease of use as well as its FDA approval [31]. Since there are only three main components to assemble, users can attach the device themselves without external help. It is the first device to have integrated software which comes on an iPod Touch. The user and a trained professional are able to control the movements remotely for ease-of-use training.
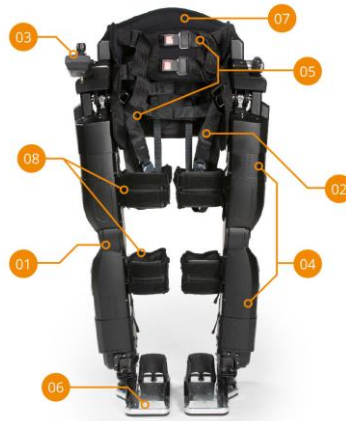
Figure 13: REX Bionics REX Exoskeleton [32]

REX Bionics created the REX exoskeleton which uses brain activity to predict the user's intended gait movements. This is much different from the other actuation methods and provides promising areas of research. Since this device is self supporting, there is no need for any support crutches. The REX uses a joystick to control the entire device. The cost for this device is around $150,000 but most devices within this price range do not have a solution like the REX exoskeleton which makes it stand out in the market.

The above devices are assistive devices which allow users to perform simple movements while not constrained to a healthcare facility, although some require specialists for training. Other exoskeletons, like rehabilitative tend to be stationary devices which help support the patient while they are recovering mobility and provide gait cycle data analysis. An example is the C-ALEX exoskeleton. The purpose is to wear this device on a treadmill for gait rehabilitation.
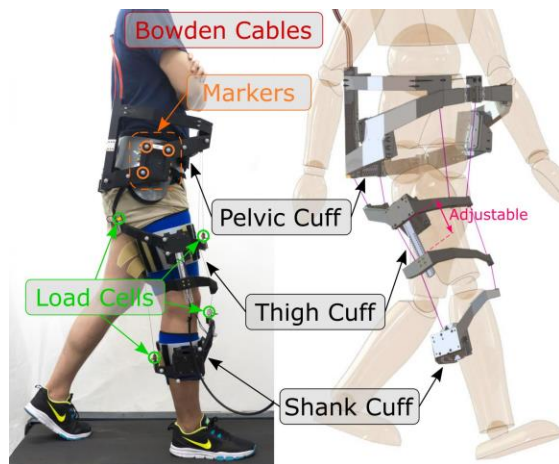
Figure 14: C-ALEX Rehabilitative exoskeleton [33]

The C-ALEX uses a single leg component equipped with reflective markers, load cells, and bowden cables. These are all attached to the legs by adjustable cuffs which prevent migration which the user performs different types of activities. Bowden cables attached to a motor actuate the leg which move the cuffs with the purpose of providing full range of motion. The purpose of the markers are to analyze the gait data then adjust to provide the correct assistance. More data to the machine is given by the load cells.
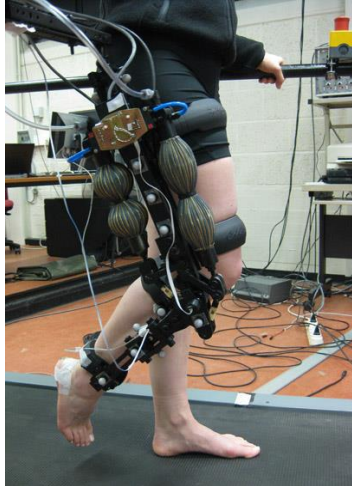
Figure 15: KNEXO [34]

The KNEXO is another example of a device which functions the same. This device uses pleated pneumatic artificial muscles to create external muscles which are air powered to provide support to the patient [34]. Since the device uses an external compressor, it limits the mobility of the device.

	Rewalk Rehabilitation	Ekso Gt	Cyberdyne HAL	Indego	REX Bionics	KNEXO	C-ALEX
Type of Device	Rehabilitation	Gait trainer and rehabilitation [38]	Rehabilitation and assistance [43]	Personal rehabilitation [40]	Rehabilitation and clinical [49]	Rehabilitation and gait training [51]	Gait trainer [33]
Total Weight	51 lbs [35]	50 lbs [39]	30 lbs [40]	26 lbs [46]	88 lbs [40]	N/A	11 lbs [33]
FDA Approved	Yes [35]	Yes [9]	Yes [43]	Yes [47]	No [40]	N/A	N/A
Price	$65,000 - $85,000 [35]	$120,000 [40]	$1200 monthly rental	$70,000 - $100,00 [40]	$100,000 [40]	N/A	N/A
Covered by insurance	Yes but regional [35]	Yes [41]	Yes but regional [44]	No [46]	Limited [50]	N/A	N/A
Wearable duration	N/A	4 hours [40]	1 hour [30]	1.5 hours [40]	1 hour [32]	N/A	N/A
Battery	Rechargeable [36]	2 Lithium ion	Custom [30]	Lithium ion [46]	2 Lithium-polymer [32]	N/A	N/A
Assembly Time	15 minutes [36]	10 minutes [42]	N/A	No assistance [46]	5 minutes [49]	N/A	N/A
Safety	Crutches/Stand mode after idle/alarms/backup batteries [36]	Knee lock at power failure/Fall detection [40]	Weight and height limit/No severe joint disorders [45]	Crutches/Fall detection/knee lock at power failure [40]	Stand at power failure/fall detection [40]	"Zero-torque" mode for unassisted walking [34]	N/A
Motion	Plantarflexion/Dorsiflexion/Sit to stand	First steps/hip flexion	Sit to stand/walking [45]	Sit to stand/Walk/Turn [48]	Squats/lunges/sit to stand/leg swings/stretches [32]	Forward walking [52]	Forward walking [53]

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Speed	5.04 km/hr [37]	1.8 km/hr [40]	N/A	2 km/hr [48]	0.2 km/hr [40]	N/A	4.2 km/hr [53]
Patient Weight Limit	220 lbs [37]	220 lbs [38]	220 lbs [29]	250 lbs [46]	220 lbs [40]	N/A	Customizable[53]
Torque	125 Nm [37]	N/A	N/A	N/A	94.9 Nm [51]	15 - 25 Nm [52]	N/A
Knee flexion	Extension - 2 degrees Flexion - 112 degrees [37]	N/A	Extension - 6 degrees Flexion - 120 degrees [29]	Extension - 10 degrees Flexion - 110 degrees [48]	N/A	Full flexion assistance[52]	Extension ~ 3 degrees Flexion ~ 60 degrees [53]

Table 1: Exoskeleton Comparison

The above table gives comparisons of the leading rehabilitation assistive exoskeletons on the market. Some parameters to note are cost, knee flexion, assembly time, and weight. Since cost is a major limiting factor, the least expensive device is desirable especially with the elderly patients. The gait cycle is inhibited by any increased weight and some of these exoskeletons are heavy, some over 50lbs. It is counter productive to add weight to user while trying to improve gait. These devices should not prohibit mobility and most allow knee flexion of over 110 degrees. The time taken for the user to fully assemble and start the device is a crucial aspect. Rex Bionics' exoskeleton takes less than 5 minutes to fully put on which is the lowest in this comparison. Improving these design challenges can increase accessibility to not only stroke patients but elderly patients as well.

Powered exoskeletons are not the only solution for osteoarthritis of the knee. There are simple knee braces which use elastic materials or metal to give support and shift the weight off of the painful areas. Padding ensures that the brace is comfortable to wear for long lengths of time. There are risks associated with using a brace instead of an exoskeleton. Some include unequal weight shifting which could lead to prolonged damage, skin irritation from long term use, and problem with customizability. An advantage to using knee braces include low cost which results in higher accessibility [54].

Compression sleeves are a common example of entry level knee braces. These are aimed towards people who have minimal amount of knee pain but require support when engaging in high levels of activity. Prices are usually under $50 for this type of solution.

The next tier solution include bulkier compression sleeves which implement metal or composite parts for increased support. These restrict movement to prevent damage to the knee when engaging in exercising. Costs for these devices are under $100. Even though these devices are low cost, they do not provide enough support for a long term solution. They have a high ease of use but lack the components to help with gait assistance. A solution which combines the characteristics of powered exoskeletons with compression sleeves are mainly used for sporting injuries. These devices range from $100-$400 depending on how much support is needed from the device. They are not powered but rely on their mechanical design to restrict movement and redistribute force.

The top market competitors, Ekso Bionics and ReWalk, have taken on more debt just to keep their company from bankruptcy. The reality that these devices are powerful enough to give a paralyzed patient the ability to walk is not enough to keep these companies profitable. High costs for these machines are not met with high profits which unfortunately does not allow for a rapid growth in this market. ReWalk and

Ekso have sold under 500 models [11]. New developments of hardware and more efficient production techniques can reduce costs of exoskeletons and increase accessibility. Stock price changes of dedicated exoskeleton companies have dropped in 2017. The smallest decrease is 8% and the largest is 35% [9]. Since the market is saturated with low profits for the majority of companies, it would be beneficial for these companies to combine and collaborate. Techniques which need to be utilized more is medical imaging to account for differences in people's unique anatomy. This will allow for a streamlined process for the manufacturing phase of production.

2.7 3D Imaging Technologies

In order to create a customizable exoskeleton, it was important to gather information about each patient's anatomy. There are a variety of scanning and imaging technologies that have the potential to provide this useful data about the body. The first of these is Magnetic Resonance Imaging (MRI). An MRI uses strong magnetic fields and radio frequency pulses to image the inside structure of the body. There is no ionizing radiation, but some potential downsides are that this type of scan is very noisy, takes a long time, and can be uncomfortable for the patient because it requires them to be inside a relatively small enclosure while remaining still. Also, since it uses strong magnetic fields, any kind of metal devices can not be near the machine or they can cause extensive damage to the patient, operator, or machine. This scan also needs a specialized radiologist to interpret the results [55].

A Computerized Axial Tomography (CAT) scan uses X-rays to image the body, similar to how a normal X-ray image is taken of bones or teeth. The device moves in an arc around the body and takes a number of images at different angles. A software program will then use these images to create a 3D model of the internal structure of the body. There is a potential for radiation exposure with this type of scanner, however the risk is low as modern CAT scans expose patients to less radiation than a commercial flight. It is also usually more comfortable, less noisy, and faster than an MRI scan [56].

An ultrasound scan uses high frequency sounds waves to create an image of the inside of the body. The images are often of lower quality than some other image types, and are highly subject to environmental noise. These scans are much cheaper and less hazardous than other scan types, because they use sound waves instead of some other methods of propagation. They do also require a lot of post-processing, which can add to system complexity. They can also be used from a distance to find the locations of objects like a sonar [57].

A 3D scanner sweeps over the surface of the body using lasers, measuring the distance to the emitter at each point. This spatial data is then used to construct a 3D depth map of the surface of the object being scanned. These devices are fairly cheap, and often available as a Commercial Off the Shelf (COTS) product, but they it can only show the outer surface of the body as the laser cannot penetrate the surface of an the object [58]. These devices can be used with image reconstruction software to create a full 3D model of the object, similar to how CAT scans are used.

The final type of imaging technology is optical tracking. This is similar to motion capture technology, which tracks the entire body to see the entire gait cycle or a certain body part to see how one limb will bend. This uses external markers on the body to track where the parts of the body are in relation to the

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camera. This technology is also fairly cheap, but can require some special equipment and large spaces depending on the scope of the tracking being done [59].

An MRI is best used to show organs, soft tissues, bones, and other internal structures in the body. It can also better indicate the presence of abnormal tissues than a CAT scan is able to [56]. Doctors can also more clearly see the parts of the nervous – brain and spine – and muscular system – muscles, tendons, and ligaments – than in a CAT scan [60]. A CAT scan is able to show information about the differences in tissue density inside a region of the body, as well as provide data about the head and chest as well as the skeletal, reproductive, urinary, and gastrointestinal systems [56]. An ultrasound, used from close up, can be used to find bones and other structures inside the body, albeit at a lower resolution than MRI and CAT scans. If used from far away it enables doctors to find the rough positions of these structures without the need for external markers on the skin, which can more accurately portray the locations of areas of interest [61]. A 3D scan will only show the outside geometry of the body and not any internal structures. This can tell the users the limitations and constraints of any devices that they need to place on the body, but will not provide information about what is happening internally during movement or other tests. Optical tracking will show the locations of external skin markers, which can be used to extrapolate where bones are, but with slightly less accuracy because the skin is not rigidly attached to the skeleton. This information can be used to find where the joints are and how they are bending at a given point in time [62].

2.8 Novel Software Used in Assistive Devices

2.8.1 Computer Vision

Given the many options for medical imaging available on the market, there are many ways visual information might be used to learn about a patient's unique anatomy. If computers can understand these images, doctors and engineers could save significant time when trying to design solutions that are patient-specific. To accomplish this, computer vision and image processing are two types of algorithms that are used to understand medical scans and customize medical devices to the user. According to the Encyclopedia Britannica, computer vision refers to algorithms capable of "identify[ing] objects represented in digitized images provided by video cameras." This is different from image processing, where the software is designed for "analyzing, enhancing, compressing, and reconstructing images." The primary difference in these definitions is that computer vision extracts information from an image, while image processing does not. However, both are important to creating a custom medical device such as a knee exoskeleton. Image processing techniques can convert medical scans into a more understandable or visually pleasing form. Then, computer vision can automate the process of computing dimensions and locating features of the knee. This information is important for customizing the exoskeleton to the patient's dimensions. In the literature, computer vision is the main focus because medical image processing is not a novel field of research.

Computer vision has been used in several research studies to quickly generate custom Ankle-Foot Orthoses (AFOs). The typical AFO design is simpler than an active knee exoskeleton, but the studies' uses of computer vision are similar to what would be done for the knee. For instance, in 2015, Morshed Alam [63] and colleagues used CT-scans to parameterize the lower leg for customizing and printing a

CAD model of an AFO. They found that this approach was less cumbersome than the traditional method of creating a mold of the foot and ankle to create the orthosis. More importantly, the CT-scan also allowed for observation of the underlying bone structure and location of the joint axis. By using computer vision to extract that information and customize the AFO, they created devices that put less resistance on the patient's motion while walking than commercially available models. Less resistance means a healthier gaitand less energy expenditure, both favorable results that an off-the-shelf device could not provide. Similar results were seen in Milusheva et. al [64] and Mavroidis et. al [65], where both computer vision and 3D printing were used to create AFOs that were more effective than traditional devices.

The use of computer vision in other medical applications is also well-researched and commercialized. One of the best examples is the MIMICS software package, which is capable of turning medical scans into accurate 3D models of the limb with interior and exterior layers [66]. This software was used in several of the studies mentioned above, and offers powerful capabilities such as integrating with popular CAD software packages. The software can be used to virtually test medical devices or procedures before manufacturing a custom brace for a patient. Many applications exist outside of simply modeling. Computer vision is being applied to imaging of the heart, brain, eyes, and more, and is helping researchers learn more about patients' needs and problems in those places [67]. With improvements in imaging technology and processing power, the possibilities are growing and computer vision is gaining a bigger role in understanding medical data.

2.9 Additive Manufacturing

Additive manufacturing technologies, commonly referred to by the term 3D printing, could allow for fast production of inexpensive knee exoskeletons that are unique to each patient. Formally, additive manufacturing is defined as a method for "fabricating three-dimensional objects by layering two-dimensional cross sections sequentially one on top of another [68]." In recent years, it has become tremendously popular because it can quickly and cost-effectively produce components that are impossible to create with traditional manufacturing techniques [69]. In their report on the topic in 2015, Babu and Goodridge anticipated that additive manufacturing would increasingly enable "mass customised hybrid components at low cost" in years to come [69].

This prediction has already been realized in research, especially in the medical field. For instance, in 2017, Sara Santos and colleagues created a 3D printed knee brace for correcting joint misalignment [70]. Their designs were effective because they were customized to the patient, and a large part of the study's motivation was to reduce the cost of this procedure using additive manufacturing. The work is part of a larger trend of using inexpensive custom components in medicine. While few other customized knee devices currently exist, many have been made for the ankle and foot to help with conditions such as drop-foot (e.g., [63], [64], [65]).

Of the many additive manufacturing methods available on the market, only some are known to be effective for wearable assistive devices such as orthoses and prostheses. The most commonly used are Selective Laser Sintering (SLS), Fused Deposition Modeling (FDM), and MultiJet Modeling (MJM) [71]. FDM and MJM fit the standard definition of additive manufacturing given above, because they create an object by depositing material in layers (typically using plastic materials). SLS also produces objects by layers, but instead of depositing molten material in the desired shape, it uses a laser beam to melt and fuse

layers of powdered material into the desired form. The powders could be plastics or metals. These approaches lend themselves best to wearable devices because they can effectively create intricate parts that are reliable under stress and daily use.

2.10 Sensors

In addition to robust manufactured parts, a sensor suite that is capable of measuring any data necessary for modelling and operation is necessary. To get this functionality, there are a number of sensors that have been used on other devices. The first of these is a soft tactile sensor, which is essentially a touch sensor that can tell how hard it is being pressed. The underlying device consists of an LED and photodetector that is partially or completely blocks to work as an analog trigger for the sensor. It uses a silicon half-cylinder that deforms under pressure, and partially or completely blocks the LED as the silicon deforms. This causes a varying amount of light to reach the sensor, and the device is able to tell how hard the silicon is being pressed based on how much light makes it to the sensor [72].

Another type of sensor is the Inclinometer. This sensor is used to measure the overall orientation of the device and operator wearing it, and can be used to find out if the wearer is falling over, and also where they are in the walk cycle. It will tell you the orientation of the sensor relative to the force of gravity along one axis of rotation. This is useful for giving additional information to other sensors on the unit [73].

Encoders allow for measurement of the absolute or relative rotational positions of joints during operation. They can be attached to the points of rotation and work by measuring the rotational movement of the structure they are attached to. Some encoders work by absolute position, which means that the encoder always knows where it is regardless of the initial position of the device. Others work with relative positions, where the encoder knows where it is, but only in relation to the initial position of the device when it is powered on. Using these devices, you can also tell the velocity and acceleration of the joints using the derivatives of the position data [73].

Accelerometers record absolute acceleration in three dimensions. By integrating this data, accelerometers allow for measurement of linear position and movement of the "bones" of the device. However, they measure the linear acceleration of the sensor instead of the position. This means that you can easily know the immediate movements of the device, but figuring out the velocity and position of each sensor requires integration of the acceleration data. Because of this, there is no "absolute position" for an accelerometer, because all data measured is only about changes in position, so the device must start in or measure some initial configuration itself [73].

Myoelectric sensors can detect the electrical impulse that causes movement of muscle fibers. This allows for the device to measure the intent of the operator movement, instead of reacting to the results of it. For example, is the operator trying to move their arm, or is there some weight forcing it down? In the former case, the device may want to generate power to assist the movement, in the latter, the device may want to generate power to oppose it. These sensors could allow for syncing up the movements directly to the muscle movements of the operator. Often, these devices would be placed on the skin to function, but they could be placed anywhere where they would be able to detect the electrical signals from the muscle cells [73].

Load cells can measure the forces exerted on the sensor by some object. In some exoskeletons, these are placed in the feet to help tell where in the walking cycle the user is. There would be a sensor near the ball of the foot and one near the heel, and by measuring the force exerted on each sensor, you can tell if the foot is contacting the ground in front of, underneath, or behind the wearer. This works by measuring the difference in weight between the sensors [73].

Similar to the imaging techniques discussed above, each of these sensor types has some distinct advantages and disadvantages to them. Tactile sensors are fairly comfortable to wear, can be attached almost anywhere, and can be fairly low profile if designed properly. Some designs are vulnerable to movement disturbances if they use mechanical parts, but the ones discussed above use light sensors, which are less sensitive to that effect [72]. Inclinometers are simple devices, and only one of them would be required to measure the orientation of the device, which can give you a good idea of the big picture operation, however they do not provide any lower-level details about the individual joints and limbs. Encoders are able to tell you the absolute position of joints, or the positions relative to the starting condition of the device. This data allows you to use forward kinematics and solve for the positions of the ends of limbs fairly easily. Accelerometers can be useful for measuring the movement of limbs, however they can require accurate models to use, since they do not directly provide position data themselves. They are also subject to disturbances and noise, particularly at high sensitivity. Without additional corrective sensors or costly accelerometers, they are subject to considerable drift. Myoelectric sensors tell the control system exactly what the operator is trying to do, however this only works if the user still has full nerve control of their muscles. They can also require a lot of filtering, but function well in noisy environments with the proper hardware. However, they do need a considerable amount of calibration and setup initially. For smaller non-full body devices, load cells would require additional hardware on the back or feet, which can be cumbersome if you are only working with a single or a few joints. However, if you are dealing with the walking cycle, they do give valuable information on weight distribution [73].

2.11 Actuators

Finally, to take full advantage of sensors and hardware parts, an actuation method that fulfills all the torque, mechanical power, and efficiency requirements of the device is required. There are a number of different types that all serve different purposes and would provide different capabilities to the system as a whole. The first actuator type is electric motors, which create rotational motion through induction in wire coils. These are a fairly standard type of actuator used in many devices, not just exoskeletons, and there are a wide variety of different types that exist, with different power curves, maximum torque, and other behaviors and parameters [73].

The design of air muscles, also known as McKibben actuators, is similar to a Chinese finger trap. When the air is taken out of the bladder, the device contracts radially and expands along its axis. When the air is put into the bladder, the radius expands and pulls inwards along its axis. This creates behavior similar to a real muscle, because the main force comes from the pulling force on the bladder expansion, which means that a second antagonist muscle is required to move in both directions, if that operation is needed [73].

A hydraulic muscle is essentially a piston that operates by filling a chamber with an incompressible fluid like water or oil to push a cylinder in or out along an axis. Because of the nature of a piston, this can push in either direction, and so only one would be required to actuate in both directions [73].

Linear springs are passive actuators that can be placed on the device to store energy when moving in one direction and release it to move in the other direction. Because springs cannot create motion themselves, these can only be used in conjunction with another type of active actuator like a motor or piston. An example of this would be ankle muscle flexion which helps propel the leg forward after being compressed when the foot hits the ground. Storing energy like this would allow for a one-directional actuator to be used without an antagonistic pair to move in the other direction [73].

Bowden cables can be used to transfer movement from one part of the device to another. Like springs, they themselves cannot actuate directly, but they can be used with active actuation devices to move parts of the device. These cables are essentially the same as bicycle brake cables – an internal metal wire surrounded by a plastic sheath. They allow for actuators to be placed in more convenient places than on the joints directly but still allow for moving the joints [73].

Just like imaging devices and sensors, each of these actuators has some inherent advantages and disadvantages that makes each one potentially better for different scenarios. Electric motors have a quick response time and high peak torque, but they can draw a lot of power to sustain that torque. They need to continuously draw power to maintain operation, Air muscles have a somewhat delayed response time due to the fluid dynamics of air, but a higher sustained torque and better power density. They also do not require continuous operation to stay in one position; locking can be achieved by closing a valve, sealing the pressure inside the bladder. However, a serious downside is that the output force scales quadratically with contraction. This means that the devices must be placed strategically to work optimally, which can result in bulky designs. Hydraulic muscles have a high power to weight ratio, high output force, and low input impedance, but they can be difficult to model because of the complexities of fluid dynamics of water and similar substances. Linear springs are useful, however they are a passive actuator, which means they require another type of actuator to be used, even if that is the power of the operator's own muscles. Unfortunately, springs are also subject to stretching over time, which degrades their output force and usefulness over time [73]. Bowden cables, like springs, are not actuators themselves, but can be used to augment other devices in the operation of the exoskeleton. They allow for the actuator to be placed in a more desirable position or orientation than if the actuator was directly attached to the joint. This does mean that such devices might require additional mounting hardware, but this problem could be outweighed by the design improvements that could be made to the rest of the device. Placing the actuators somewhere else could also allow for a better weight distribution, reducing the strain and/or discomfort on the operator's body [74].

The solution to this will directly address the needs of the user through effective design and engineering. Ideally, the active knee brace will be highly customizable, while also being low in cost. Customization should come from analyzing the biomechanics of each patient. Furthermore, the device should cut down on doctor intervention and excessive maintenance after short periods of time. The final product will take into account aesthetic and user needs. It will combine the elements of an exoskeleton and passive knee brace to create a more accessible assistive device.

Chapter 3: Methods

3.1 Initial Client Statement

The initial client statement of this project is to develop a low cost, customizable assistive knee brace for activities of daily living. This device is intended to aid ageing patients with degenerative knee joint conditions. This goal was broken down into 4 objectives which focus on, understanding user needs, customization through software development and hardware, and prototype testing. The full objectives are outlined below.

3.2 Technical Design Requirements

3.2.1 Objectives

The following objectives outline the main tasks that will guide the project to successful completion. These objectives were created to provide constraints on the project within the realms of the goal, while also allowing for iterations and growth opportunities.

1. To apply user centered design principles for the ageing population to increase comfort and independence.
2. To actively facilitate knee flexion and extension.
3. To use image processing and 3D modeling software to generate and manufacture a customized orthotic.
4. To utilize gait analysis for proof of concept, safety needs and functionality requirements to validate the system.

Each of these objectives were further broken down to best accomplish the task. These tasks became vital in understanding how to best serve the initial client statement.

1. In order to apply user centered design principles, it is important to understand the needs of the user. A survey, which can be found in Appendix C outlines a survey created to further understand what the user needs and wants from this device. Furthermore, by speaking to professionals in the field, a clearer idea of this picture was established. These ideas will then be applied to the device via a soft under lining.
2. This objective will require the development of a rigid exoskeleton to lay over the soft under lining. This hard component will control the movement of the patient. This movement is knee flexion and extension, which will be actuated by a motor.
3. Surface mapping data taken from the kinect system will be processed using Skanect and Blender software programs. Together, an output of the leg profile may be produced.
4. Objective 4 will be accomplished by taking force plate test and motion capture data of the patient with and without the device to ensure the device is working, and safety needs are being met.

3.2.2 Design Functions

The group incorporated multiple design requirements for the device and reasons why these requirements were important. The group decided on these design requirements by background research on knee kinematics and commonalities of existing knee exoskeletons. These requirements are shown in the organized table 2 below.

Mechanical and User Centered	
Controlled applied forces and torque	Determine from literature and by experimentation how much force is required to lift the knee and proper acceleration to maintain safety. Reduce pain due to osteoarthritis.
Non-restrictive design	Rigid exoskeleton customized to patient, avoid constricting blood flow
Attaches to body and aligns with joints	Determine biomechanics of the knee to ensure proper modeling of the device and correct joint alignment
Move to support common knee movements (wide range of motion)	Will account for main motion paths of knee during core ADLs
Gait cycle correction	Study the biomechanics and kinematics of the knee and design the device to correct abnormalities in the gait
Weight of device is evenly distributed	Motors, battery, and hardware are mounted in a convenient place that does not negatively impact the gait
Functional in long term daily use	Design the device to be sleek and durable, aesthetically pleasing and long-lasting
Quickly and inexpensively produce the design	To reduce cost to customers as well as manufacturers, while not sacrificing durability.

Table 2: Mechanical Design Requirements

Sensing	
Position sensing	Use IMU or potentiometer sensing to detect knee's location in space
Detect wearer's desired motion	Potentiometer and optical encoder feedback will sense the user intent.

Table 3: Sensor Design Requirements

The design requirements found in table 2 and 3 are expanded upon in the Design Functions table found below. Each requirement was broken down into possible solutions. The solutions were then chosen with a weighted decision matrix.

Controlled Applied Force + Torque	Motors	Spring	Pulley/Cable	Series Elastic Actuator	
Non-restrictive Design	Compression/Elastic Sleeve	Adjustable Padding	Width/Length	Clamps/Velcro	External Support Bars
Attach to Body + Align w/ joint	Pin Joint	Restricted Ball Joint			
Long term Use	Replaceable Battery	Large Battery	Disposable Battery		
Sensor Processing	Arduino	Raspberry Pi	Mbed		
Even Weight Distribution	Fanny pack	Belt Clip	Thigh	Knee	
Cost	Material	Processor Power	Battery Size	Actuators + Sensors	
Position Sensing	IMU	Potentiometer	Force Sensor		
Muscle Sensing	EMG	Force Sensors			
Detect Motion	EMG	Force Sensors			

Table 4: Design Functions

3.2.3 Constraints

The assistive knee device was constrained by both anatomical and logistical specifications. Anatomically, the leg is constrained to its normal gait cycle swing. The device must allow for the natural range of motion of the knee and subsequently, should not cause pain. In addition, the force applied to the knee from the device must not exceed the normal abilities of the knee. The device will also be work under the users' clothing, so it must be able to easily operate underneath pants or a skirt. This project was also limited by its attachment method to the patient. As the elderly have sensitive skin, and have difficulty bending down, the device material and configuration were taken into account. The weight of the device should also be kept to a minimum to reduce the amount of force being exerted on the knee. This will also allow the user to wear the device for longer periods of time bys reducing the shock absorption in the knee during activities of daily living. The elderly population generally has less muscle activity and strength as well, making it important to constrain device weight.

Logistically, the device is also limited by cost and time. The team had a total of $1,250 to spend on parts and other needed resources. The project must be completed in an eight month window. The validation and quality stages were also limited by the speed of approval from the Institutional Review Board (IRB).

3.2.4 Design Specifications

Design specifications were created to further guide the objectives. These specifications are centered around specific design goals, customization needs, and cost requirements. The specifications are as follows:

- Support the patient's weight at the knee during the gait cycle

- Fit comfortably to the user's body and not suffer from migration

- Have each piece of the device be easily customizable in the manufacturing process

- Cost under $1,000 to be affordable to the target audience

The focus of this project is to create a device for people who still have some mobility and support capability from their own body. Thus, the device is only providing partial support, rather than fully replacing the joint function. This necessitates an upper bound on the assistive force that will be required of the motor. There is approximately 45 Nm of torque required at the knee for normal walking on a flat surface. This data was obtained for 90kg individuals that have no muscle power whatsoever [75]. This serves as the absolute maximum value for actuation requirements.

Patients with osteoarthritis will typically have a muscular deficiency of between 10-50% [76]. This range depends on the stage of the disease as well as other factors specific to a single patient. The focus of this project was on early-stage preventative care, because it would decrease the overall requirements and therefore the cost of the device. The project demographic will target patients who have 85-90% muscle capacity, and provide assistance for the additional 10-15%. Using this range,t a torque requirement of 5-7 Nm is required. The other side of this part of the design is looking at the maximum speed of the knee. At a fast walking speed of 1.5±0.1 m/s, the knee normally reaches an angular velocity of around 400 deg/s [77]. This is equivalent to a speed of approximately 67 RPM, which would be the maximum rotational velocity required of the device to comfortably assist with the gait.

A typical range of motion for a patient with OA during walking can vary between approximately 2 degree to 47 degrees [78]. For reference, 0 degrees refers to when the knee is not bent and 90 degrees refers to when the knee is fully bent. The theoretical maximum angles of flexion and extension during knee movement can range between -5 degrees (in hyperextension) and 160 degrees (in flexion). To ensure the device does not prohibit the range of motion and also allows for the user to fully straighten their leg, the device should have a lower bound that is slightly outside of this range. The allowed range of motion will increase from 45 degrees to 70 degrees.

Because the weight should be distributed away from extremities, and heavier components should move as little as possible, the electronics and actuators should not be positioned directly on the leg. This will reduce the moment of inertia of the parts of the device directly attached to the leg. Therefore the device will have less of an unintended impact on the gait cycle during operation. Reducing this weight will create

less of an imbalance between each leg, and also relative to what the user is used to walking around with. This will help assist in reducing the time it takes for someone to become accustomed to the device as well.

3.3 Standards for Design Requirements

The goal of this project is to develop an assistive medical device that will be attached to a patient and work to actively move extremities of the body. It is imperative that all standards related to patient safety, rights, and assistive technology.

The first set of standards that the team considered when developing the device was developed by the International Organization of Standardization (ISO). Since the device will be working with patients who have a disability, such as osteoarthritis, this device needs to follow ISO 17966:2016. This standard specifies requirements and associated testing methods for assistive products related to personal hygiene, that both support users and relieve or compensate for a disability [79]. It also specifies methods of measurement of the forces required to operate as well as identification of all force limits to safely operate the device. This will prove to be useful in the design process and developing device iterations. Although the device does not target hygiene specifically, this standard will help create appropriate testing methods that will provide useful evaluations of the device's effectiveness.

Another set of standards the team incorporated in the device are the FDA regulations. It is important to follow these guidelines because this would be how the device can get distributed to consumers in a safe and regulated manner. The FDA has three classes that a medical device can fall under, Class I, Class II, and Class III. These classes are used to place a degree of control to assure the various types of devices are safe and effective [80]. The main difference between each class is risk, Class I being minimal risk, Class II being moderate risk, and Class III being high risk. The final model that was produced during this project will be considered a Class II device, which means that the device will be working directly with a patient and provides moderate risk to the patient. Other devices in this class include, powered wheelchairs and pregnancy test kits. The FDA has approved lower limb powered exoskeletons, so the team will have advanced prior knowledge of designs that fit the FDA's regulations and use these examples for comparison of the team's device.

Once the team starts testing the prototype, the team will assess the efficiency and safety of the device using a questionnaire and biomechanical method developed by the Privolzhsky Federal Research Medical Center [81]. Although this study focused on lower limb paralysis, the parameters used will be useful for testing the team's lower limb exoskeleton. Some parameters include analyzing kinematics of the knee joint, heart rate, walking speed. The team also can use a test called MWT, which tests how long a user takes to walk 10 meters [81]. The safety of the device will be tested using a 5-point Likert scale, (1) strongly disagree, (2) disagree, (3) neutral, (4) agree, and (5) strongly agree. This assessment will produce quantitative results of people's opinions of the safety, convenience, and efficiency of the prototype.

The team will use ISO and FDA regulations, as well as using previously successful efficiency and safety testing protocols to create a device that could eventually be put into the market. The goal is to improve daily living activities and quality of life and using these methods will be a sufficient stepping stone in creating a device that will achieve this goal.

3.4 Revised Client Statement

Through research, feedback and design iteration, a new client statement was created. This project aims to create an assistive knee device that actively and passively unloads forces, which normally pass through the knee. The device should promote a healthy gait cycle during activities of daily living, specifically for the ageing population. The device is intended to be a preventative care device for the the ageing population that suffers from knee osteoarthritis to avert a worsening condition.

3.5 Management Approach

3.5.1 Gantt Chart

This project was guided by the gantt chart as seen in figures 16, 17, 18, and 19. The chart is guided both by WPI terms in the format of A, B, C, and D as well as the Cornell Cup, a competition focused on the design development of the assistive device. A term was for background research, and design ideation, and paper writing. B term had a large focus on design refinement and the beginning stages of prototyping. C term was split up by paper writing, prototyping, and the start of testing, while D term was for paper writing, presentation creation, and validation.
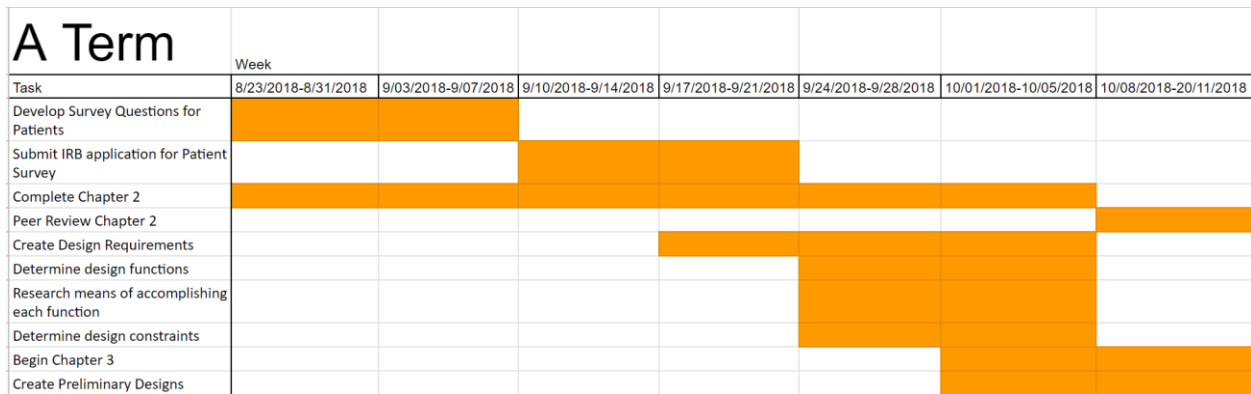
Figure 16: A Term Gantt Chart
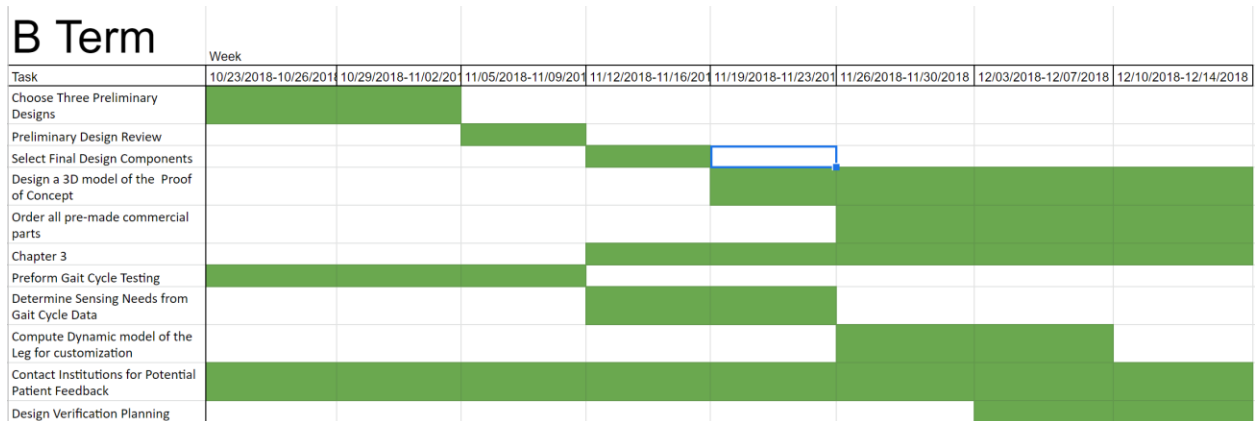
Figure 17: B Term Gantt Chart
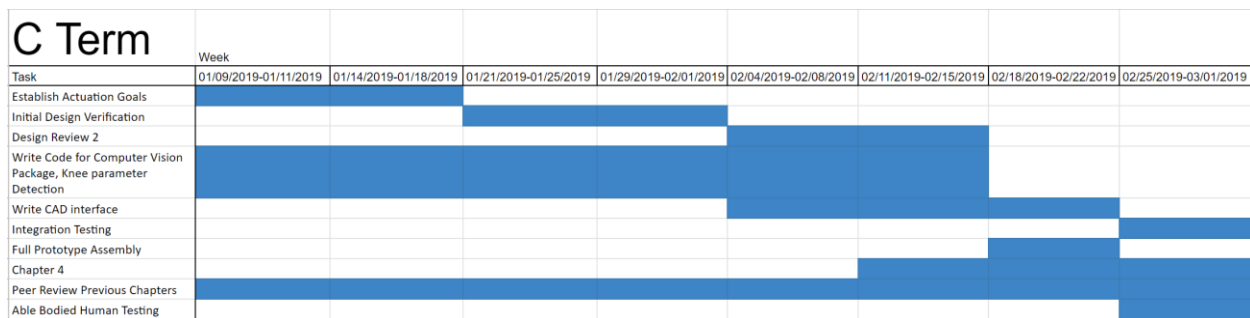
Figure 18: C Term Gantt Chart
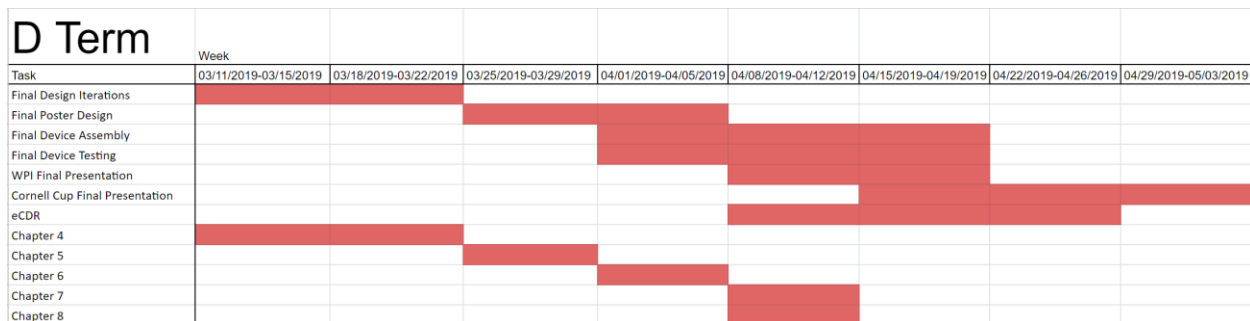
Figure 19: D Term Gantt Chart

3.5.2 Financial Considerations

Going into the project, the team had a total budget of $1,250 for all supplies. Each team member received $250 from their respective departments at WPI. The budget was used on three main categories; Brace Components, Hardware, and Electrical components. Electrical Components was the largest spending category with 50% of the budget and $500 being allocated to it. As sensors, microcontrollers, batteries, and motors tend to cost more, the Electrical components required the largest budget. Hardware was the second largest category at $300 and made up 30% of the spent budget. The $300 was to account for materials such as machined and 3D printed parts. Lastly, Brace Components was the smallest category with a total of $200, being used. Bracing components amounted to 20% of the budget and is being used for materials such as fabric, velcro, and fasteners. The proposed budget, as seen in Figure 20 is to spend only $1,000 out of the available $1,250. This is to give leeway incase an unforeseeable circumstance arises. Additionally, this budget may shift throughout the duration of the project. The final spent budget can be seen in section 7.8.
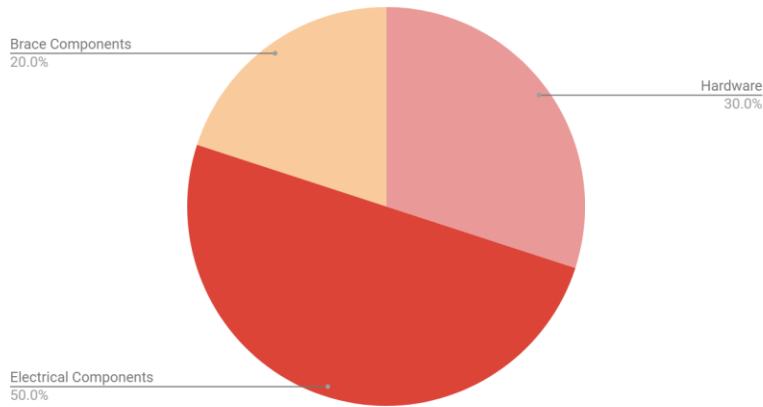
Figure 20: Proposed Budget

Chapter 4: Design Process

4.1 Preliminary testing

In order to develop concept designs for the assistive exoskeleton device, the team first conducted preliminary testing to characterize the knee joint to use as a guide when developing parameters. The testing included biomechanical statics analysis, motion capture, and force plate gait analysis with multiple activities of daily living. These tests provided the team with important information on the precise correctional forces needed, how the knee can be modelled as an ellipsoid to calculate the joint center, the angular velocity of the patient's gait, and ground reaction forces during the patient's gait.

4.1.1 Statics Analysis

Static analysis of the device on the knee is needed to determine the moment on the knee caused by the torque output from the motor for test validation. The proposed model assumes that everything below the knee, the bottom part of the leg and foot, are treated as a singular body. Another assumption that was made is that the motor which is attached to the hip, creates a force around the middle of the leg by the support bars. Below are the Newtonian and Euler equations for motion with the static analysis at the knee.

$$\Sigma F = m * a = F_K + F_{GRF} + \left(m_{Lower\ Leg} + m_{Foot}\right) * g + \left(m_{Upper\ Leg}\right) * g + F_{Upper\ Leg} + F_{Motor}$$
$$\Sigma M = I * \alpha = M_K + M_{GRF} + (r_K * F_K) + (r_{GRF} * F_{GRF}) + r_{Motor} * F_{Motor}$$

Equation 1: Statics Analysis (See diagram for frames in Appendix E)

The unknown variables are the moment around the knee and the force acting on the knee. These unknowns calculated through the static equations, will be validated during the gait testing phase of the project. These unknowns are important to not overpower the natural capabilities of a human body's knee.

4.1.2 Motion Capture

Initial gait analysis and testing validation is completed by two different motion capture software. The data obtained from both systems were used to determine how to approach a brace acutation based off the biomechanical complexities of the knee joint. As the knee joint is not a perfect pin joint, the team used the motion capture to simplify the knee joint model. The team also used the gait data to give a baseline for how the microprocessor should move the motor based off the potentiometer output.

Motion Capture Part 1:

The first software (Motive, Natural Point, Inc., Corvallis Oregon) utilized 8 infrared cameras to record reflective marker positions in 3D space. The team used two separate pieces with three reflective pieces attached, one on the thigh and one on the calf as seen in Figure 21.
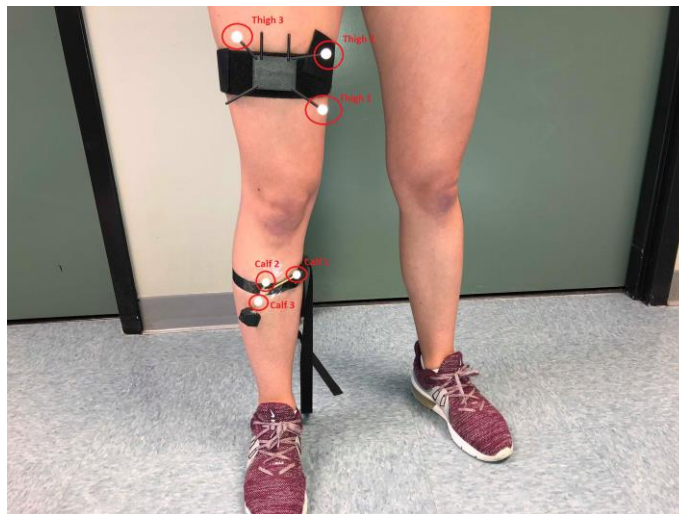
Figure 21: Reflective Marker placement

The subject was asked to perform a series of exercises to test the range of motion of the knee. The first exercise was bending the knee approximately 90 degrees while keeping the thigh in place for 5 iterations. This exercise showed the maximum bending of the knee while walking. The next exercise performed was a leg squat, which would simulate someone bending down to pick an object up. The purpose of these trials was to determine the range of motion and get a baseline of the moment around the knee during different exercises. The results are shown in Figure 35.

4.1.3 Gait Analysis

The team was fortunate enough to use the new Practice Point Motion Capture and Gait Analysis room that was newly built and finished in February 2019. This room featured ten infrared cameras set up around the room as well as two force plates in the center of the room. Four video cameras allow for recording of the motion capture session as well as a graphical overlay which validates that the software is accurately tracking the markers. A lower body modeling plugin was used which allows the system to recognize a subject's gait that outputs the kinematic and kinetic calculations that were required for static analysis. The outputs included are shown below:

Output Kinematics: **Angles**	Description
AbsAnkleAngle	The angle between the AJC to KJC vector and the AJC to TOE vector
AnkelAngles	Relative. The angles between the shank and the foot
FootProgressAngles	Absolute. The angles between the foot and the global coordinate system
HipAngles	Relative. The angles between the pelvis and the thigh
KneeAngles	Relative. The angles between the thigh and the shank
PelvisAngles	Absolute. The angles between the pelvis and the laboratory coordinate system

Table 5: Gait plug-in outputs of angles and descriptions

Output: Kinematics	Description
Forces	
AnkleForce	The force between the shank and the foot
GroundReactionForce	The force exchanged between the foot and te ground while walking
HipForce	The force between the pelvis and the thigh
KneeForce	The force between the thigh and the shank
NormalizedGRF	The ground reaction force expressed as a percentage of the body weight
WaistForce	The force between the pelvis and the thorax

Moments	
AnkleMoment	The moment between the shank and the foot
HipMoment	The moment between the pelvis and the thigh
KneeMoment	The moment between the thigh and the shank
WaistMoment	The moment between the pelvis and the thorax

Table 6: Gait plug-in outputs and descriptions of force and moment

Output: Powers	Description
AnklePower	The power between the shank and the foot
HipPower	The power between the pelvis and the thigh
KneePower	The power between the thigh and the shank
WaistPower	The power between the pelvis and the thorax

Table 7: Vicon output reference for powers and descriptions

The parameters of interest are knee moments, ground reaction forces, and knee angles. With these calculations, the exact location of the biomarkers was important for auto labeling of the left and right side of the body. In order to locate the precise point for placing the knee markers (LKNE, RKNE), the subject was instructed to passively flex and extend the knee. Then identify where the knee joint axis passes through the lateral side of the knee by finding the lateral skin surface that comes closest to remaining fixed in the thigh. This is the point where the lower leg appears to rotate, which is 1.5 cm above the joint line, mid way between the front and back of the joint. This is where the marker should be placed. Figures 22, 23, and 24 below show the exact placement of the markers.
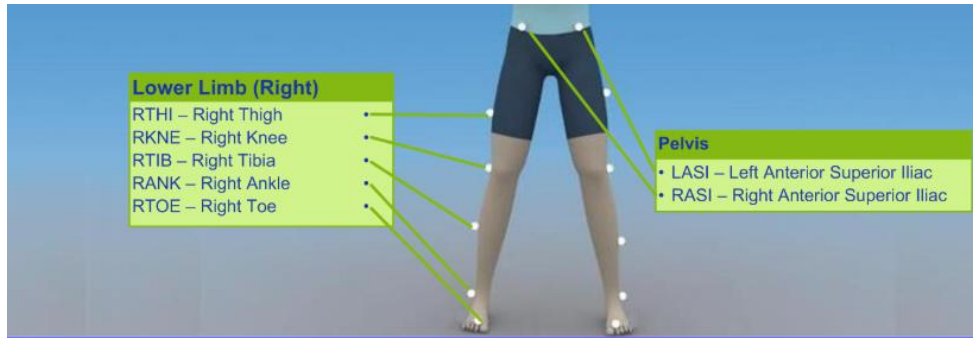
Figure 22: Front view of lower body
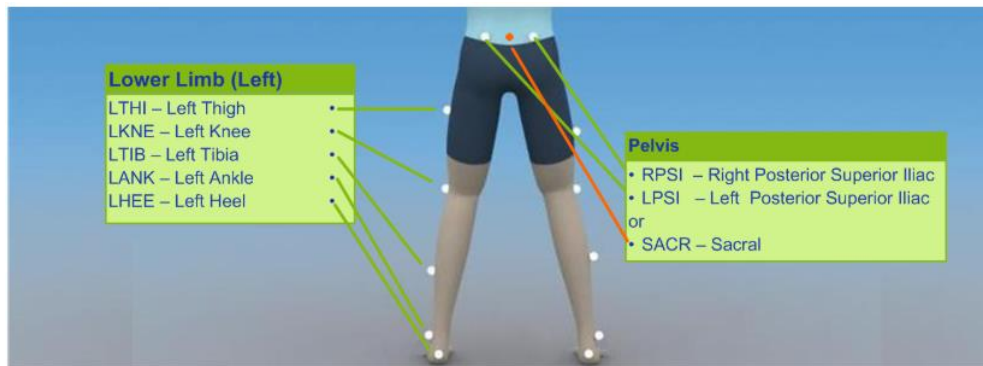
Figure 23: Back view of lower body
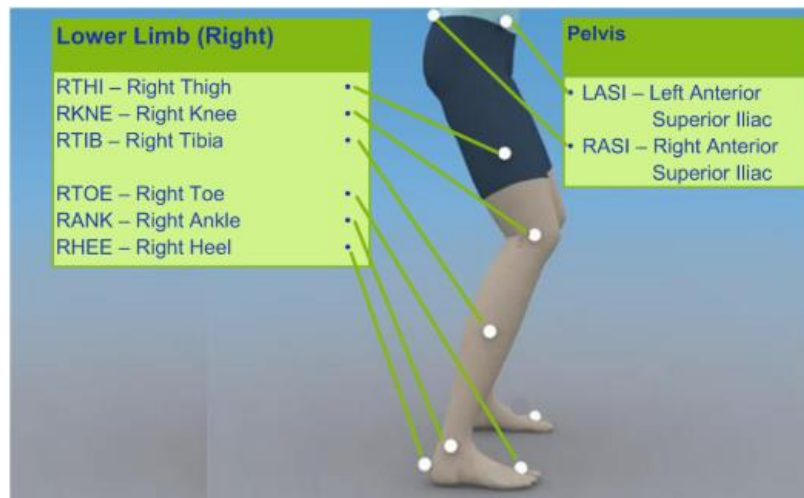
Figure 24: Side view of lower body

The THI and TIB markers anterior-posterior position is critical for identifying the orientation of the knee and ankle flexion axis. The thigh markers (LTHI, RTHI) are used to calculate the knee flexion axis orientation and the tibia markers (LTIB, RTIB) are used to determine the alignment of the ankle flexion axis. Using a subject, the markers were as instructed. This is shown in Figures 25, 26, 27, and 28. The subject was also instructed to raise their arms as if they were riding a motorcycle, which is the

predetermined position that allowed accurate reading of the markers and full visibility. This is shown in Figure 29.

Figure 25 & 26: Preliminary Trial Marker Placement

Figure 27 & 28: Preliminary Trial Marker Placement cont.

Figure 29: Preliminary Trial Calibration Stance

This configuration was the correct marker placement on the subject. Once all markers were placed, and the subject got into the correct position in the middle of the force plates, the system was then calibrated for every trial. This occurred before any testing was performed.
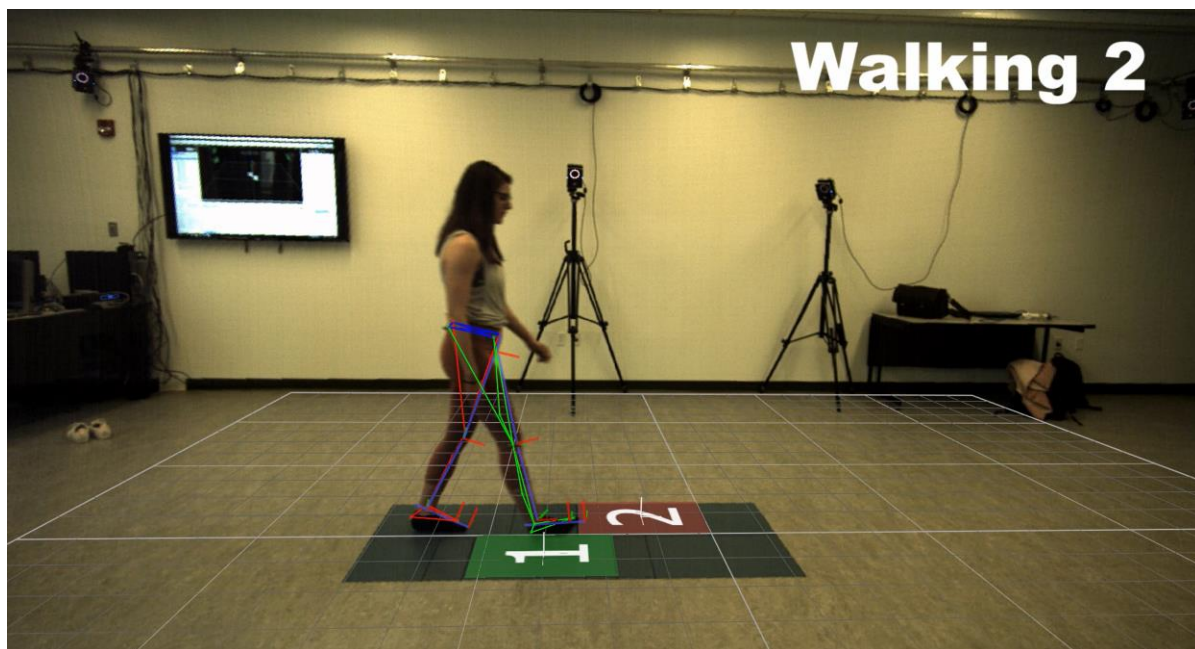
Figure 30: Vicon Software Overlay Toe-on Phase
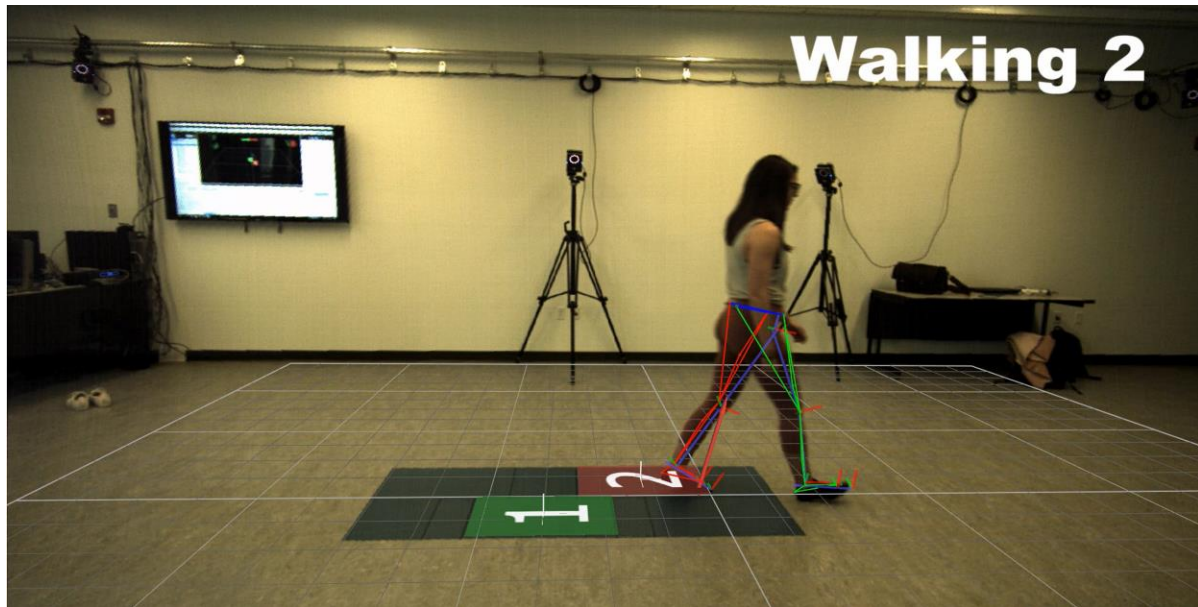
Figure 31: Vicon Software Overall Toe-off Phase

Figures 30 and 31 show screen captures of the gait trials taken from the Vicon system. An overlay shown by the red, green, and blue lines correspond with the marker placement on the subject. This gives validation that the raw data matches with the motion capture footage. Figure 30 shows when the subject is in the heel strike cycle. Figure 31 shows when the subject is in the toe off phase in the gait cycle. Using the different gait cycle phases, the moment and knee angles can be compared throughout the preliminary trials as well as when the device is active on the subject. Force plates, shown by the green and red 1 and 2 give information about any misalignment in the legs as well as where the center of pressure from the feet are during the gait cycle. Even weight distribution is a key aspect that the final design should have. The data can determine if one leg is applying more weight than the other which will have an effect on the overall design.

As a baseline, the group collected preliminary gait data from four iterations to show a normal gait cycle. Throughout all the gait cycles, the subject was instructed to walk in a straight line at their normal walking speed. Also, the subject started at a certain distance away from the force plates to ensure that they started at heel strike with their right leg on the right force plate. Raw data will allow us to compare results from gait trials when the subject has the brace on the leg. The parameters compared were the ground reaction forces in the z-direction, knee angles in x-direction, and knee moment in the x-direction. For reference, the first large peak in the data corresponds to the right foot when it is going through the gait cycle on the right force plate. Then the second large peak corresponds to the left foot at heel strike to toe off.
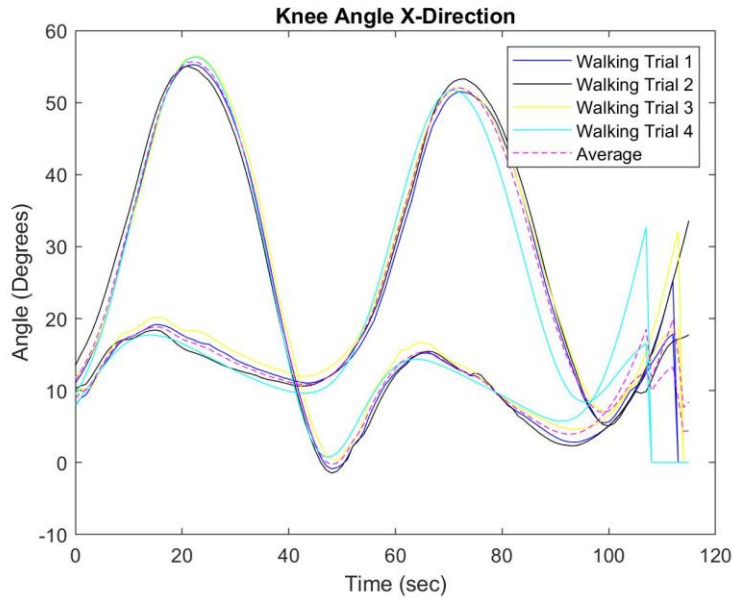
Figure 32: Knee Angle Preliminary Trial Results.

The line with the first peak is the right leg hitting the force plate and the second line with the second peak is the left leg hitting the second force plate.

Preliminary Angle Trials	Max Values Right Leg (degrees)	Max Values Left Leg (degrees)
Walking Trial 1	51.5410	55.2657
Walking Trial 2	53.3074	55.0731
Walking Trial 3	52.0245	56.4347
Walking Trial 4	51.7517	56.3097

Table 8: Knee Angle Preliminary Trial Overall Results

Figure 32 and table 8 show the raw data from four motion capture walking trials. The graph also shows the average data line as a dashed line. This will be the baseline to compare with the knee angles when the brace is on the patient. The table with the max values also provide a range of motion insight. The maximum knee angle is 56.3 degrees which means the device needs to provide a minimum of this amount of degrees of flexion.
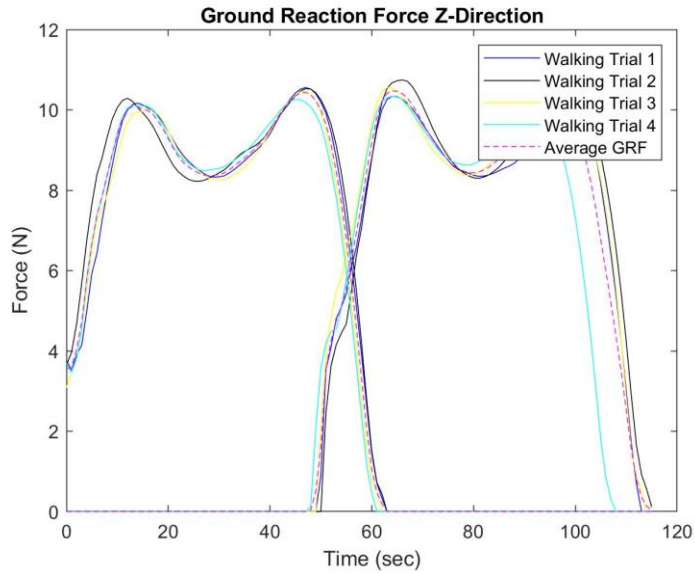
Figure 33: Ground Reaction Force Preliminary Trial.

The first ground reaction force pattern is of the right leg and the second ground reaction force pattern is of the left leg.

Preliminary GRF Trials	Max Values Right Leg (Newtons)	Max Values Left Leg (Newtons)
Walking Trial 1	10.5543	10.5993
Walking Trial 2	10.5290	10.7453
Walking Trial 3	10.4625	10.5534
Walking Trial 4	10.2640	10.3425

Table 9: Ground Reaction Force Preliminary Max Values

Figure 33 and table 9 show the raw ground reaction force data from all trials as well as the average curve. The max values are also noted in the table above. A max ground reaction force of 10.7N provides data used in the static analysis.

Figure 34: Knee Moment Preliminary Trial Results

Preliminary Moment Trials	Max Right Leg Values (Nm)	Max Left Leg Values (Nm)
Walking Trial 1	34.8119	39.0439
Walking Trial 2	43.4541	44.6616
Walking Trial 3	32.9400	40.8517
Walking Trial 4	32.3426	33.7669

Table 10: Knee Moment Preliminary Trial Max Values

Figure 34 and Table 10 show the results from the smoothed moment data from all the trials. The average curve will be used to confirm what was found in previous studies about the torque requirements of flat walking. The max knee moment value is 44.7Nm. These values were calculated by converting millimeters to meters from the raw data as well as multiplying all values by 60kg, which is the subject's weight.

4.1.4 Motion Capture Centroid Plot
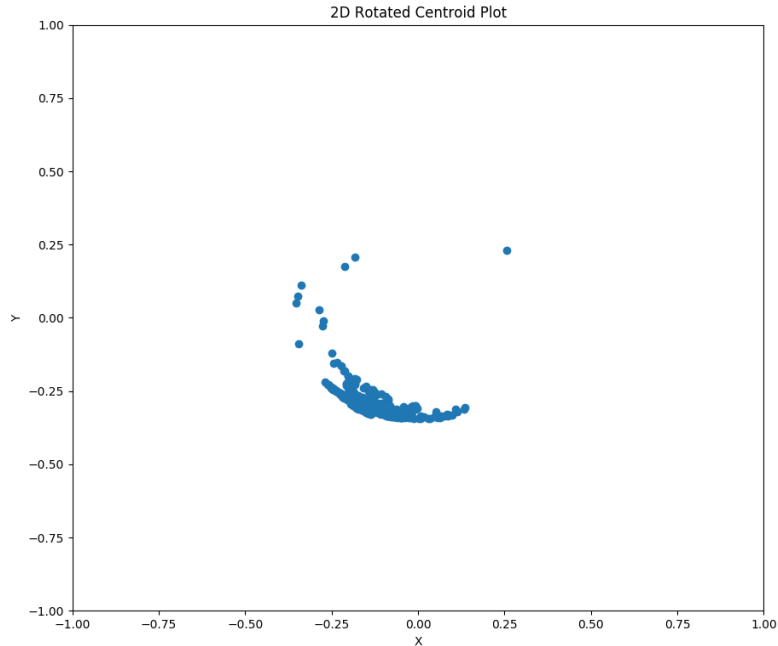
Figure 35: Knee Centroid Plot

Figure 35 shows the centroid plot. This data was generated with motion capture markers while the subject was performing multiple movements, prioritizing the bending motion. Once preliminary testing was completed, designs could be tested to see which would be able to satisfy the parameters found through research and the preliminary testing.

4.2 Concept Designs

The initial concept designs were developed based on the goal of assisting the patient to walk with more ease in their activities of daily living. This was explored in the form of unloading devices, as well as through wearable tech that was powered with faux piezoelectric muscles. A total of three designs were created all with the goal of increasing comfort in the normal gait cycle.

4.2.1 Concept Design One
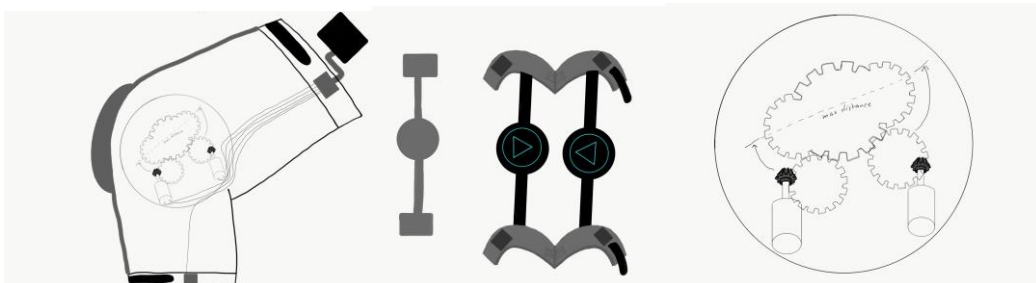
Figure 36: Concept design one
Featuring an oblong gear fixed to the knee with the intent to separate the knee bones during gait

The above concept shows a powered knee device similar to the final concept. A motor box at the hip runs cables down the leg which attaches to two motors. The purpose of these motors are to drive gears inside the gearbox. A unique aspect about this design is the oblong long gearshape, shown in the third picture. As the motor turns, the two small gears, which are connected to metal bars used to assist the leg, rotate about the center gear which will cause a separation in the knee to relieve pain in the joint at a certain angle. The entire brace attaches to the thigh and shank by velcro straps. A major limitation of this design is the inaccuracy of the oblong gear on the joint. Since knee braces shift slightly because of the skin, this would cause a shift in the separation which could hurt the user rather than support them.

4.2.2 Concept Design Two
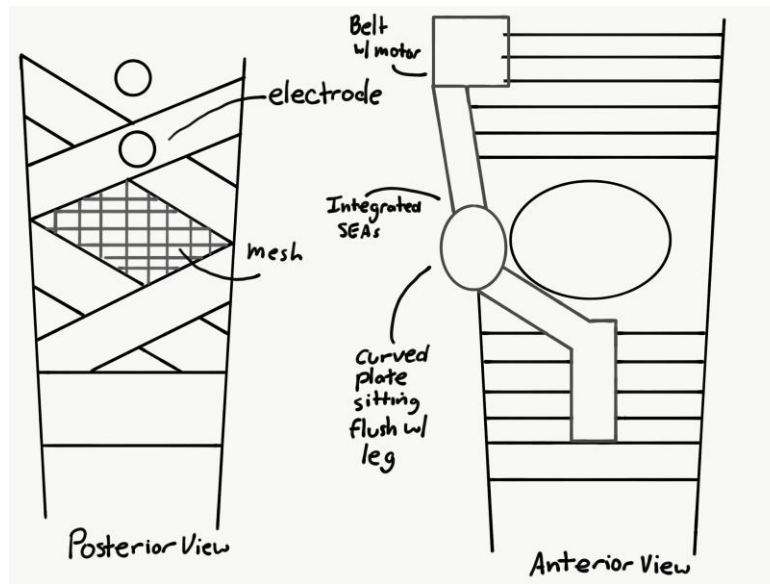
Figure 37: Drawings for Concept Design Two

Figure 37 shows a flexible knee brace with the implementation of electrodes. Similarly to the first design, a motor attached at the hip moves cables which helps assist with knee movement. The flexible brace is easily attached to the leg by velcro straps which weave around the leg to provide maximum support. Electrodes interwoven in the soft brace material will give the motor information about movement intent which provides accurate assistance. A key safety factor is the series elastic actuators which are implemented on the final design. A major limitation to this design is the nonsymmetrical nature of the brace, which could affect the weight distribution. Another limitation would be the complicated attachment to the user, such as the placement of the velcro straps, where the curved plate should sit on the thigh, and the design forces the user to bend over to put it on.

4.2.3 Concept Design Three

The third design was designed into a pair of leggings that would help the patient move based on faux piezo electric muscles. These muscles would be stimulated during activities of daily living by impulses being sent to the patient's muscles. The faux muscles would be sewn into a pair of leggings which could fit underneath the patient's clothes. They would recognize the amount of energy being expended in the

muscles and how much the the to help the patient needed to live a more independent lifestyle. This design is limited by its hard to obtain materials, as well as by its difficulty in creating strong enough impulses to assist in lifting the body during activities of daily living. The piezoelectric faux muscles were also not proven to be sufficient in propelling the body forward, while unloading devices have been.
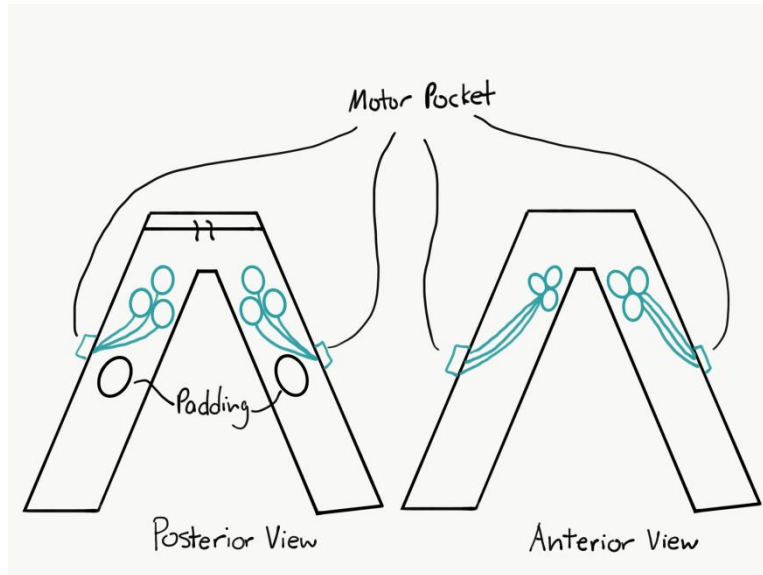
Figure 38: Drawings for Concept Design Three

4.3 Alternative Designs

In using a pairwise comparison and feasibility analyses, the most practical option was to pursue a combination of the first and second concept designs. The separate components of every design were favorable, so the group used a decision matrix based on device qualities rather than the complete designs.

Actuator	Power Transmission	Sensing	Support structure	User Comfort/Interfacing	Knee mechanism
Motor	Direct attachment	EMG	Hip Attachment	Leggings	1 joint
Piezoelectric	Bowden Cables	IMU	Ankle Attachment	Helical Wrap	2 joints
	Series Elastic Actuator	Potentiometer	1 strap per limb	Compression Sleeve with hip Strap	Pin joint
		Bumper	2 straps per limb	Brace straps	Synovial Joint
		Strain gauge			

Table 11: Decision Matrix--Highlighted values were selected

In the decision matrix, the categories were broken up by the main components of the elements that would create an effective assistive device. After discussing the feasibility, comfort, practicality, and cost of each

category, the result of each column is highlighted in yellow. Certain categories were determined to have two favorable categories. In these cases, the were used in combination in the end product.

The ideal device would be able to at least partially support the weight of the user while walking, to reduce stress on the knee cartilage and bones. It would also need to be customizable to fit the specific anatomy (both internal and external) of the user. The team came up with a number of possible alternatives while brainstorming the final idea for the design, and while each of them had some positives, ultimately there were too many issues with each one to choose it for the final design. Because the hard and soft parts of the exoskeleton could be considered separate for brainstorming, ideas for these two parts were evaluated individually at first. Once there were a few ideas that could potentially fit the design criteria, the team examined various combinations between them to see what would work the best overall.

4.3.1 Mechanical Device Structure

4.3.1.1 Actuation Method

There are a few different potential methods for actuation on the device: electric motors, piezoelectric fibers, pneumatic systems, and hydraulic systems. Each of these has its own strengths and drawbacks, which are touched on in section 2.11 above. Due to the complexity, weight, and cost of attempting to implement a pneumatic or hydraulic system, out team was able to rule these options out fairly early on in the design process.

A   B
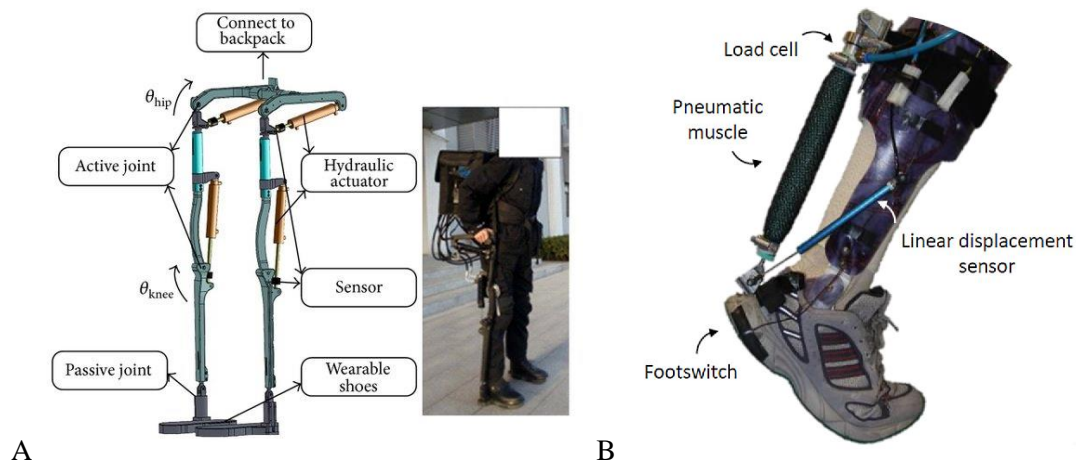
Figure 39: Hydraulic and Pneumatic Actuation Methods

Photo A is a diagram of hydraulic actuation method [82] and Photo B is a pneumatic actuation method [83].

Because the device will be designed to help with walking, the actuator will be in motion most of the time, which eliminates the benefit of pressure-sealing with valves when using fluid-based systems. These systems also require strategic placement of actuators to take full advantage of the force scaling with contraction, which would make the final device more bulky. Pneumatic systems also have a more delayed response time, which would not work well with the proposed model trying to mimic quick body

movements. Hydraulic systems are also more difficult to model due to the need to account for fluid movement and compression, which would increase the complexity of the software system.

Electric motors have a quick response time, which is needed for the control system to make the motion as natural as possible. They do require a continuous draw of power during operation, but because the device is mainly intended for low-impact low-torque actions like walking upright, the group did not believe that this will be an issue. Additionally, power supplies could be changed out fairly easily in a final design. Electric motors are also much easier to model, and combined with their ubiquity in many devices as well as their cost effectiveness, the group believed that this is the ideal solution for the device.

4.3.1.2 Power Transmission

Based on the client statement, the team developed a series of criteria that the device should satisfy to be effective. Then, each idea was examined based on this framework. From most to least important, these seven criteria are:

1. Safety - Likelihood to cause damage to itself or user

2. Cost - Lower price options are better than higher price ones

3. Durability - How long it will last with daily use

4. Structural Integrity - How much does it resist wear caused by daily use

5. Weight Distribution - How much will it change the CoM of the user's limb(s)

6. Synchronization - How well does the desired output correspond to the input

7. Simplicity - How simple will it be to produce

When evaluating each of the three ideas, each category was assigned a value from 1 (worst) to 3 (best) and then multiplied by a weight depending on how important the category was from 1 (least) to 7 (most).

Power Transmission	Category Weight	Direct Attachment	Bowden Cables	Series Elastic Actuator
Safety	7	1	2	3
Simplicity	1	3	2	1
Structural integrity	4	3	2	1
Durability	5	1	2	3
Cost	6	3	2	1
Synchronization	2	1	2	3
Weight distribution	3	1	2	3
Total		50	56	62

Table 12: Pairwise Comparison Chart

In the pairwise comparison chart, each category was assigned a weight to establish importance. It is important to note that all of these categories are significant, however the team needed to focus on which of them were most crucial to having. As the device is being worn on a person, safety was determined to be the most important category. The second highest ranked objective of this project was to create an affordable device, which is why cost was assigned the second highest weight. The durability of the device was given the third highest ranking as it is important to ensure lasting quality for the user. Structural integrity was the fourth highest ranking in order to prioritize support of the patient continuously. Weight distribution was given the the fifth highest as it was important to design a device that does not affect gait. Having an uniformly distributed device promoted ease of use for the patient. All components are expanded upon below.

Direct attachment of the motor to the device was by far the most simple idea to implement. It required no additional hardware than a mounting bracket for the motor. Because of this it also scored highest on structural integrity and cost, because a device with fewer moving parts will be less likely they are to break, and also cheaper to produce and distribute. However, this method is not as safe, as it can extra bulk nearer to extremities, which can result in unintended collisions. Additionally, the motor should not be able to move a limb through an obstruction, as this would result in an injury to the user, which could happen with direct attachment. Because there are no compliant parts in this design, it would also be more likely to break over time. Finally, the extra bulk added by this method would seriously impact the center of mass of the user and throw off their gait cycle, which would not be favorable.

Adding bowden cables removes some of the issues with safety and weight distribution that direct attachment has. Moving the motor away from the limb helps reduce the likelihood of accidents and bumping into objects, and reduces the impact on the center of mass. However, it does little to improve the issues with durability and synchronization. It also reduces the positive impact by reducing the simplicity and structural integrity and increasing the cost due to the additional parts and difficulty of manufacturing.

The final method of power transmission is a Series Elastic Actuator (SEA). The specific layout and functionality of this is discussed more in detail in section 5.1.2. This device is much safer than other methods because it adds a layer of compliance between the actuator and the human interface. The springs also absorb extra force that is exerted when there is an obstacle that reduces the load on inflexible components to increase durability. This also acts as a benefit for synchronization because the expected output when encountering an obstacle is to not try to force the limb through it and instead detect it and stop the actuation. Similarly to the normal bowden cable design, this idea improves weight distribution. However, this device would be too complex, which makes it more costly and decreases structural integrity for the same reasons as just bowden cables.

4.3.1.3 Movement Following

In order to mimic the knee movement, the group decided to use a gear system to force the two bars attached to the upper and lower legs to move synchronously. To achieve this, the group wanted to use either circular or elliptical gears. Originally the design used elliptical gears because they had a different center-to-center distance based on how the gears were aligned and if the major or minor axes were coincident at the point of contact. This would allow us to create an outward force at the knee joint while in extension to reduce load but have no force on the knee when it is in flexion. The group thought it was

possible to apply a small amount of separation at the joint (on the order of a few mm). This small amount of separation would be able to provide the support at the knee without causing the user additional pain.

Unfortunately, the group found through research and testing that this would not work for two main reasons. First, in order to get an amount of separation that was over an order of magnitude smaller than the overall size of this part, the foci of the elliptical gears would need to only have a few mm of distance apart. This would be difficult and more complex to implement because even though mathematically the foci are not intersecting, because the real life components have a thickness, they would intersect each other. Second, based on reviewing literature and other exoskeletons as well as testing, that it was typical for device to move upwards of 10 mm over the skin during operation. Because the skin is not rigidly attached to the skeletal system, it acts as a sort of spring the absorb lateral forces at the surface of the skin. For this reason, an external device that aimed to push apart the knee by only a few mm would not work.

Since there was nota way to implement the original idea, the group decided on a more simple design of circular gears, which are much easier to model and produce. This setup is similar to the actual structure of the knee, and acts as a modified hinge joint while moving. The circular gears still force the two bars to be coupled together during movement, however they do not explicitly try to create a certain amount of separation at the knee joint, which could be taken care of in other parts of the device.

4.3.1.4 Support Structure

There were two main ideas for a support structure. The first was a multi-part linkage based on the four bar design, and the other was a simpler three-part series linkage. The multipart linkage consisted of multiple parallel sets of links that distribute the force through the device and around the users knee. While this allows for each individual component to be smaller, it does result in the overall device footprint to be larger. It also increases the complexity and difficulty of manufacturing the device.

The simpler three part linkage was easy to adapt to the circular gear design, because the two gears could be attached to the ends of two bars and then a smaller bar could connect the two main bars at the centers of the gears. This allowed for the force between the bars to be transferred through the second linkage instead of going through the teeth of the gear, which would cause additional strain on the gears themselves. However, having the gears would force the two bars to move with a single degree of freedom, simplifying the actuator required. This has the added benefit of requiring half as much actuation of the device, because any motion applied to the second link causes the third link to move twice as much. This would also be useful as it would mean that the theoretical maximum required speed of the actuator was cut in half.

4.3.2 Soft Components

For the underneath layer, the group brainstormed four key design considerations the prototype must have.

1. Minimalistic design

2. Antimicrobial

3. Breathability

4. Accessibility

The elderly require a specific set of design requirements due to their ability and health. The cloth lining component of this project plays a vital role in ensuring the design of the exoskeleton meets these needs. For optimal usability, the design needs to be able to fit underneath clothing by fitting to the body's specific measurements and the material cannot be bulky but still be hold structure. The goal was to have the soft exoskeleton be easily integratable with the hard exoskeleton. This can be achieved by designing the pattern to cover just where the hard exoskeleton will be attached to on the body. The design must also be made with material that is antimicrobial, meaning the material inhibits microorganisms from growing inside the material. This key feature protects the user from infection, reduces odor caused by sweating and mildew, and extends the life of the product by limiting the number of washes needed. Alongside having an antimicrobial material, breathability must also be taken into consideration when deciding what materials to use in the regions of the body that naturally accumulate moisture.

Soft Exoskeleton Structure	Pro	Con
Pants	- Less migration - Distribute forces equally	- Complicated design - Expensive (more material needed) - Variability
Garter	- Modular - Ease of producibility - Integratable with hard exoskeleton - Accessible	Force distributed unequally

Table 13: Pant vs. Garter Design

A miniature model of each of design was created made using an arbitrary material. The goal was to create a proof of concept that would demonstrate design challenges and highlight the pros of each design. The pants model has a built in elastic waistband and knee padding, while the garter configuration has padding in the hip pocket to cushion falls in the fragile area. It has a closure system made from dress hooks, which is a fastener ideal for those suffering from hand arthritis. By integrating options that provide ease of the device, the likelihood for use will increase.

Figure 40: Proof of Concept Pant and Garter Models

In deciding between the pants and garter design, the garter proved to be the most effective design. The pants had certain advantages such that due to the fact that forces acting against the legging would produce less migration. Leggings are longer and require more bending over, which is not ideal for the elderly. In addition, if the pants were to be accessible and and could be easily assembled with velcro or snaps, the crotch would require more bending over to ensure it is fastened correctly. Ultimately, due to its higher cost, and its unfriendly user centered design principles, the garter design was chosen. The garter incorporates a high waist band which attaches via a velcro closure. The leg components are also fastened with velcro making it easy for the elderly to put it on without excess bending and is user friendly for those suffering from hand arthritis. The garter design also easily slips under clothes discreetly. In combination with utilizing Nylon for its elastic nature, thickness, and anti-microbial properties, the garter design is both effective and based on universal design.

Figure 41: Final Design Sketches and Finished Product (Front View)

Figure 42: Rotated Views of Lining Component

Chapter 5. Final Design Verification

The final design contained several essential subsystems. The motor is the source of actuation for the device, which is attached to a bowden cable transmission with series elastic elements for compliance. The gear train consists of a capstan drive mechanism and a three-bar linkage. Finally, controlling the device is the electrical subsystem, comprised of a microcontroller and motor driver. These subsystems and components are illustrated in further detail in the figure below, and described in the sections that follow.

High level subsystems

Low level core components

- Electrical and control systems
  - Microcontroller
  - Motor driver
  - Potentiometer
- Motor and power transmission system
  - Maxon motor
  - Bowden cables
  - SEA springs
- Gear train and mechanism system
  - Modified Capstan drive
  - Three-bar linkage
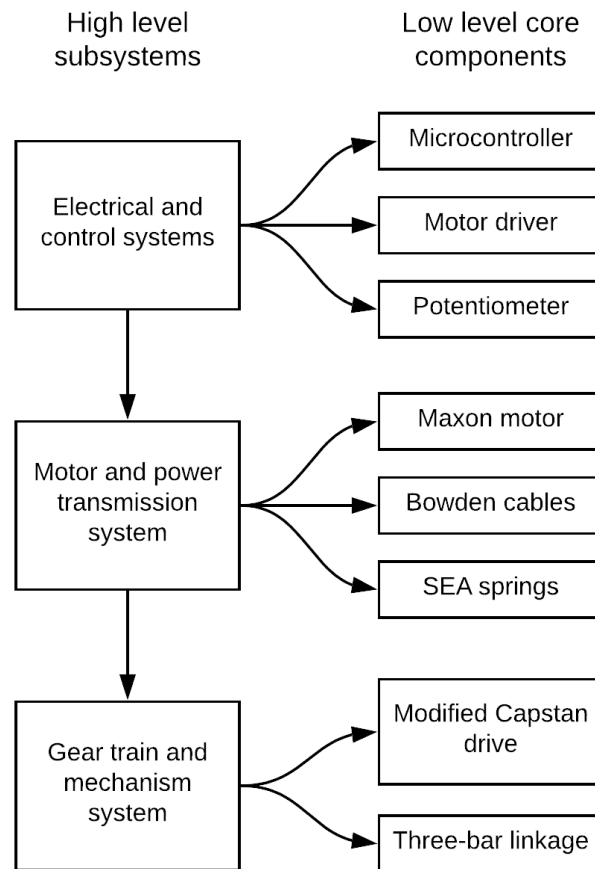
Figure 43: High and Low Level Components

5.1 Mechanical Features

The final mechanical design was a culmination of the most favorable ideas discussed above in Section 4.3. Each of these ideas went through a number of design iterations and manufacturing cycles. For brevity, only the final design will be discussed in this section, however images of each of the main iterations can be found in Appendix D. The final model of the device is included below.
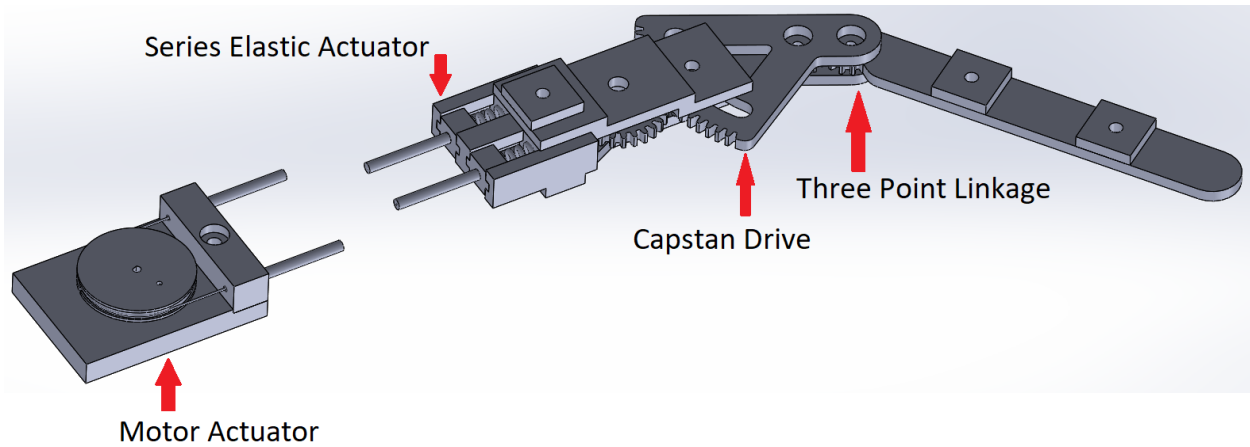
Figure 44: Final Brace Design Iteration

5.1.1 Actuation Method

The actuator section consists of the motor, pulley, mounting plate, and cable tensioner. The selected motor is a Maxon 22mm DC motor. The motor selection process is discussed further in Section 5.3.2 below. The pulley is an aluminum part with a groove cut around the edge, and a hole for the motor shaft and cable to be tightened through. Because the motor chosen had a smaller shaft, 3D printed parts were not strong enough to withstand the force of the motor turning under load. The cable is a 1.5mm steel cable that is wound around the pulley wheel to tension it with the other side. The mounting plate and cable tensioner are both 3D printed parts that are attached together with a 1/4 inch bolt. There are also pneumatic fittings screwed into the other side of the cable tensioner (not seen in figure) with pneumatic tubing then fitted into those fitting for the cables to run through. The mounting plate also has holes for the motor to be screwed into to ensure that it is securely attached.
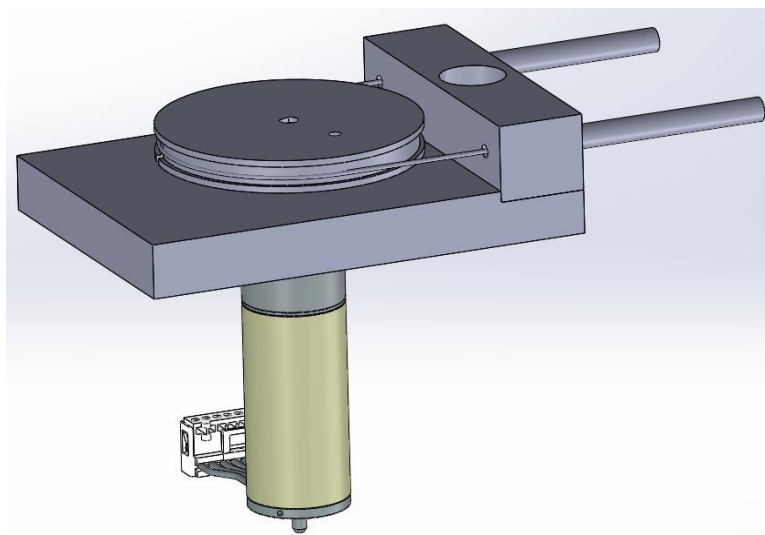
Figure 45: Motor Actuator

5.1.2 Series Elastic Actuator

The Series Elastic Actuator (SEA) consists of two main sections connected by steel cables running through pneumatic tubing. These tubes are attached to pneumatic fittings that are screwed into the tensioner mechanisms on each half of the device. These materials were chosen because they were easily accessible to develop a custom length and stiffness Bowden cable. This section has a gear ratio of 1:2. The motor half of the device is discussed in Section 5.1.1.

The lower half of the device consists of the tensioner mechanism and the pulley gear. The pulley gear functions both as the pulley for the SEA and also as the pinion gear for the Capstan Drive discussed in Section 5.1.3. The springs inside the tensioner mechanism pull on the cables relative to the pneumatic tubing sheath, which allows for the springs to help absorb sharp changes in force and impacts on either side of the device. When working normally, the device acts as a simple pulley system, with the springs only doing significant work when there are undesired forces acting on the system. Each spring acts independently, however they will work opposite each other: when one is in compression the other will be in tension.

The small slider pieces that hold the springs in place with a countersunk hole are fitted into the main tensioner mechanism with two grooves on opposite sides. This prevents them from sliding around, but still allows for movement along the axis of the cable. These pieces also have a hole for the pneumatic fittings to be screwed into, which allows the cable to go into one side and then out the fitting and through the pneumatic tube securely fashioned to the other side.

On both pulleys, there is a groove cut along one of the faces (seen in Figure 46 on the right side) to allow the cable to wrap through. This feature was added to increase the friction force between the pulley and the cable, because originally the cable would slide around the pulley and not turn the Capstan Drive, especially when under load. Adding this meant that the cable was first fitted through this slot on the Capstan pulley and then wrapped around before being pulled through the pneumatic tubing. Except for the motor pulley, springs, and pneumatic parts, all pieces are 3D printed in PLA to reduce weight. The tensioner has a gap in the underside to allow for the pronged bar in the Three Part Linkage in Section 5.1.4 to fit snugly inside. Since none of these parts are load bearing, they do not need to be made of metal or other stronger material like the Three Part Linkage.
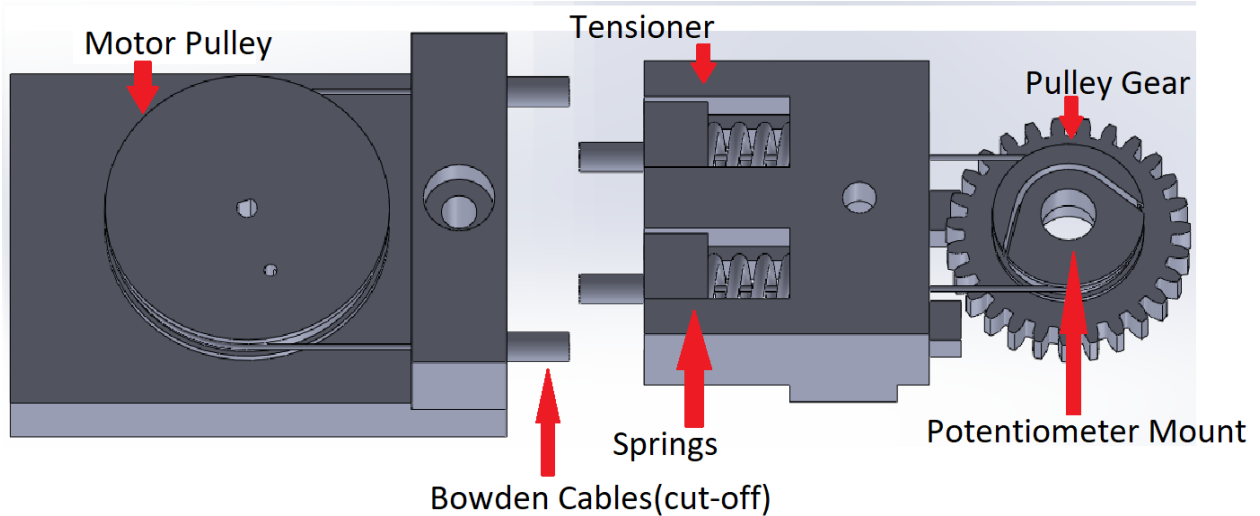
Figure 46: Series Elastic Actuator Model

5.1.3 Capstan Drive

The modified Capstan Drive is based on a design by Brown et al. that used a cable driven system to actuate a larger pulley using a small one immediately adjacent to it [84]. The original part was more similar to this design, however there were a number of issues with slippage of the cables, especially with the 3D printed parts. Even when using the groove in the pulley described in Section 5.1.2 there were still problems with fitting the device together and maintaining structural integrity with the parts. It was also more difficult to have this part be reproducible with planar manufacturing techniques such as laser-cutting. Eventually this cable-based design was replaced with one based on gears instead. This design uses a similar feature to the original Capstan Drive where it has a small part driving an angular section of a much larger one. This allowed the overall footprint of the device to remain small while still achieving a large gear reduction in the device, in this case 3.33:1. The main slider section could be replaced with one that was fully planar, which meant that this structurally important part could be manufactured easily out of metal using laser- or plasma-cutting.

The Capstan Drive slider serves to actuate the second link in the Three Bar Linkage discussed in Section 5.1.4. This allows the angular movement of this part to be doubled by the Linkage system and allows the size of the Capstan slider to be further reduced from 120 degree to 60 degrees. The slider is also attached at to the upper leg bar at the point of rotation on the gear and where the slot is in the slider. The pulley gear is attached to a plate that goes over top of both parts, which is not seen in Figure 47 to show the main working parts of the mechanism.
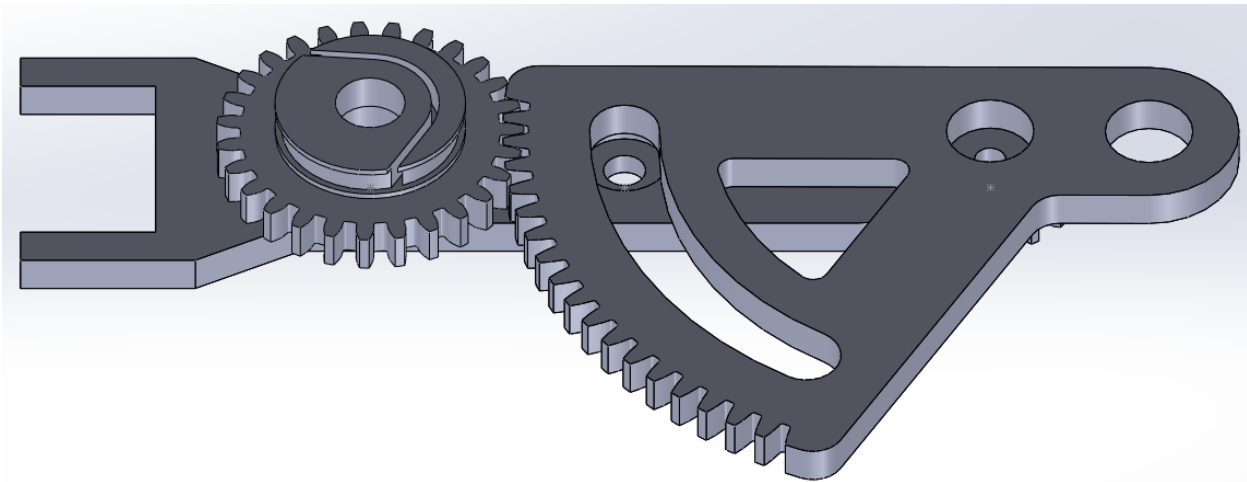
Figure 47: Capstan Drive

5.1.4 Three Part Linkage

The Three Part Linkage is designed to double the actuation of the Capstan Drive discussed in Section 5.1.3. It is composed of two bars with gear teeth on one end and two connector parts, one of which is the slider for the Capstan Drive. The SEA tensioner discussed in section 5.1.2 is also press fit onto the pronged end of the upper leg bar. Separating the tensioner from the main device body allows for the structural parts to be manufactured out of a stronger material. The connector pieces have bearings in the holes for a shaft to run through, which is also press fit into the small holes at the pitch circle center of the gear teeth. This ensures that the pieces will stay together while minimizing the amount of friction between the parts. There are also holes cut into the bars for attaching velcro tensioners to anchor the device to the patient's leg.

This device causes the actuation of the Capstan Drive to double because it actuates the second link in the chain. Because of the gear teeth, the two long bars are forced to turn in relation to each other, and while the upper bar remains fixed, the connector pieces force the lower bar to rotate along the teeth of the upper bar, causing the knee bending motion. This allows for the reduction in motor actuation distance discussed in Section 5.1.3. Since the motor is required to turn less, this allows us to reduce the speed with a higher gear reduction to get more torque out of the system to help the patient walk and stand.
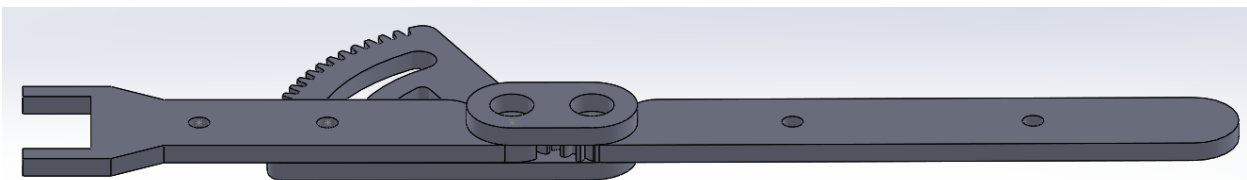
Figure 48: Three Part Linkage

5.2 Customization

5.2.1 Reproducing User Leg Contour

The team utilized a Microsoft Kinect sensor to take a 3D scan of one of the team member's legs. This was utilized alongside the Skanect software package that WPI's lab had a license for. This software allowed us to use the Kinect sensor to construct a 3D Model of a leg, and use some of the built-in features to fill holes in, smooth, and crop the model to be easily usable in the next step. The group also was able to reduce the number of polygons in the model to increase the speed of other software steps and reduce the overall file size. This model was turned into an STL file and then printed using PLA filament. This process is fairly easy and inexpensive to implement and teach other people to use, and also allows for easily creating the customized parts using 3D Printing technology. Although the plastic parts are quite strong, they can also be easily adjusted in the future using heat to soften the plastic to reshape it. This thermoforming process is often used during orthosis manufacturing.
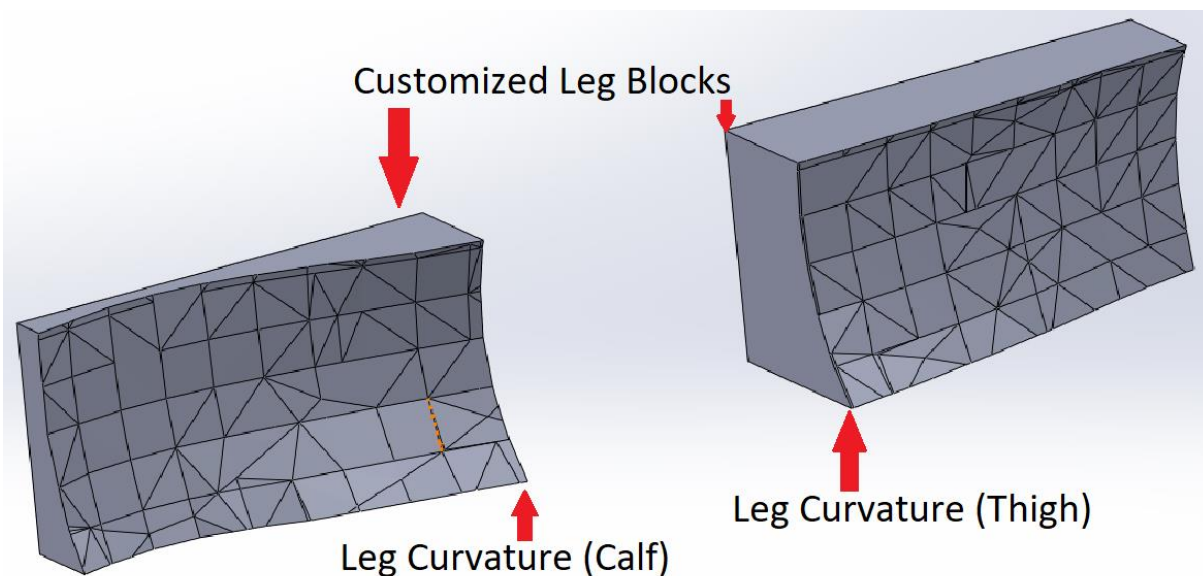
Figure 49: Leg Profile Parts

5.2.2 User Centered Design

The under lining was created to fit each patient. By measuring the hips, thighs, calves, and waist, a sewing pattern was created according to each specification. The bottom of the rear end to the hip is also measured for the supportive strap. The pattern of the knee brace can be found in Appendix A. This pattern is of a legging. The middle point between the knee and the hip and the bottom of the leg was cut to make a section just for the knee. The straps and waist belt were attached using the dimensions of the patient so that the waistband closed in the middle of the user's body. The material for the pattern, nylon, is elastic enough that the body can change as it ages without the risk of the brace not fitting. The brace also has all velcro closures making it highly adjustable and easy to put on. The under lining interacts with each user to ensure the best fit possible.

5.3 Electrical and Sensing Features

The active, powered component of the device required a system of electrical components and sensors to move and respond to the wearer. This section discusses the electrical and sensing needs and the processes used to select components that fit those needs.

5.3.1 High Level Circuit Block Diagram

The first step to understanding the electrical systems on the device is to build a block diagram showing all of the necessary components. The block diagram, shown below in Figure 50, was constructed to include every possible sensing need--even those that were not intended for the original design. In other words, this block diagram shows all possible sensors, but not necessarily everything in the block diagram was included in the design.
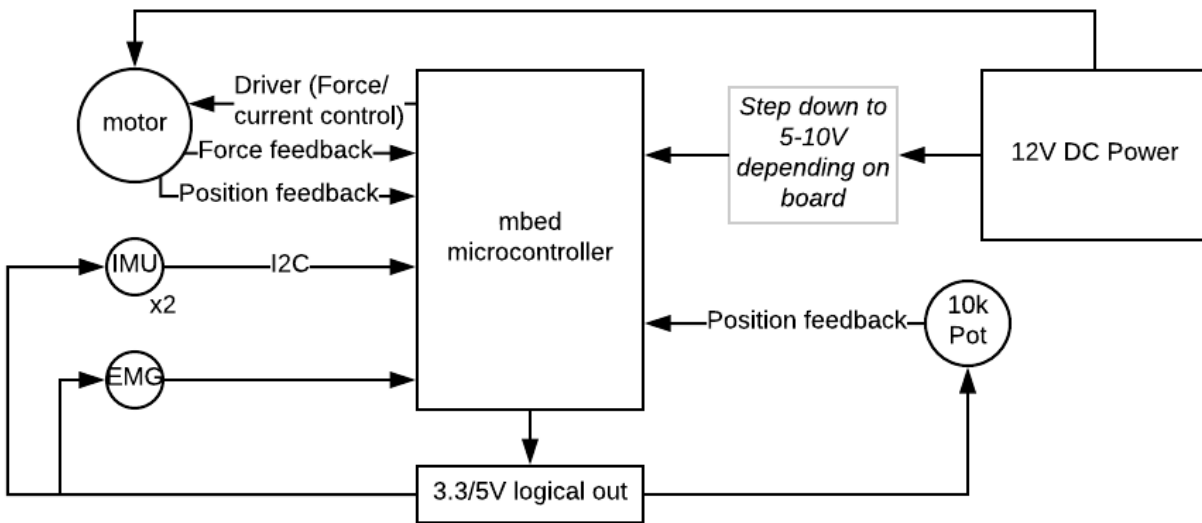
Figure 50: Block Diagram of Electrical and Sensing Needs

Since group members had positive experiences with devices running on the mbed operating system in the past, mbed devices were favored in the selection process. This operating system provides a powerful set of base libraries for microcontroller development and there are many add-on packages available online.

Since 12V is a standard voltage for DC motors that are usually able meet the needs of this device, a 12V DC battery was obtained to provide power for the motor and microcontroller. This means that a voltage step-down circuit would likely be required to provide the correct input voltage for the microcontroller. Then, the microcontroller would be expected to provide 3.3V and 5V of regulated output voltage for the various sensors.

The sensor communication protocols depend on the sensors chosen, but the I^2C protocol is desirable because fewer data lines are needed. However, it is important to have a microcontroller capable of using various serial I/O protocols. Analog sensors need to be processed through ADC inputs that convert input voltage to a digital value. Thus, the microcontroller also needs a sufficient number of analog input pins.

Motor control should be through force (or current, given that they are proportional in less complicated systems) to permit more advanced control algorithms. However, position sensors are also needed such as a rotary shaft encoder at the motor and a potentiometer at the knee to determine ground truth position. Initially, control can be done through position, and as time permits, the force component can be incorporated to make the device more responsive and comfortable for the wearer.

A variety of other sensors could be used to control the motion of the device. Here, Inertial Measurement Units (IMUs) and Electromyography (EMG) sensors are included as possible future expansions of the sensing capabilities. IMUs provide information about linear and rotational motion in space, and could be used to determine knee position and the intended movement of the wearer. EMG sensors detect electrical signals in muscles and would be able to signal different parts of the gait cycle or the beginning and end of a sequence of steps. However, these are not crucial to basic functionality in the way that position feedback is.

5.3.2 Motor Requirements and Selection

In order to choose the right motor for this device, estimates of the torque and speed requirements of gait in patients with osteoarthritis are needed. These estimates were found through a review of the literature on human gait.

Based on a study which conducted a systematic review of the literature, the device should provide about 5 Nm of torque to adequately assist the wearer. About 45 Nm of torque is required for walking on a flat surface. This data was obtained for a 90 kg individual with no muscle power whatsoever [75]. Individuals with osteoarthritis have a muscle ability deficit of about 10-15% on the lower end, and up to 50% on the high end [76]. Considering the aim was to work on preventative care with early stage patients, the group took the low end of patients, who have 85-90% muscle capability, and provide assistance for the additional 10-15%. This yields the final maximum torque requirement of roughly 5 to 7 Nm. Since the capstan mechanism discussed in Section 5.1.3 has a gear reduction of about 12:1, the torque output of the motor only needs to be about 0.5 Nm. To run the motor around peak efficiency, a motor with stall torque around 1 Nm is ideal.

The speed requirement was reached in a similar fashion. The knee reaches a maximum angular velocity during fast walking (that is, walking in a straight line at 1.5 +/- 0.1 m/s) of around 400 deg/s [77]. This is equivalent to about 66 RPM, which would be the maximum rotational velocity required of the motor to comfortably assist with the gait.

Some additional constraints emerge through analysis of the usage of the motor as part of an exoskeleton device. Motors typically have high speed and low torque output relative to the design requirements, so gearing is likely to be necessary. However, back-drivability is also desirable because it means less resistance will be provided to the wearer while trying to move or while wearing the brace if power is lost. Gearing typically reduces the ability to easily back-drive a motor, so having minimal gearing or no gearing at all is important to the design. This is a delicate trade-off because too much gearing could make the device unusable, but not enough gearing would mean a large motor is required, or worse, the device is not effective at assisting the gait.
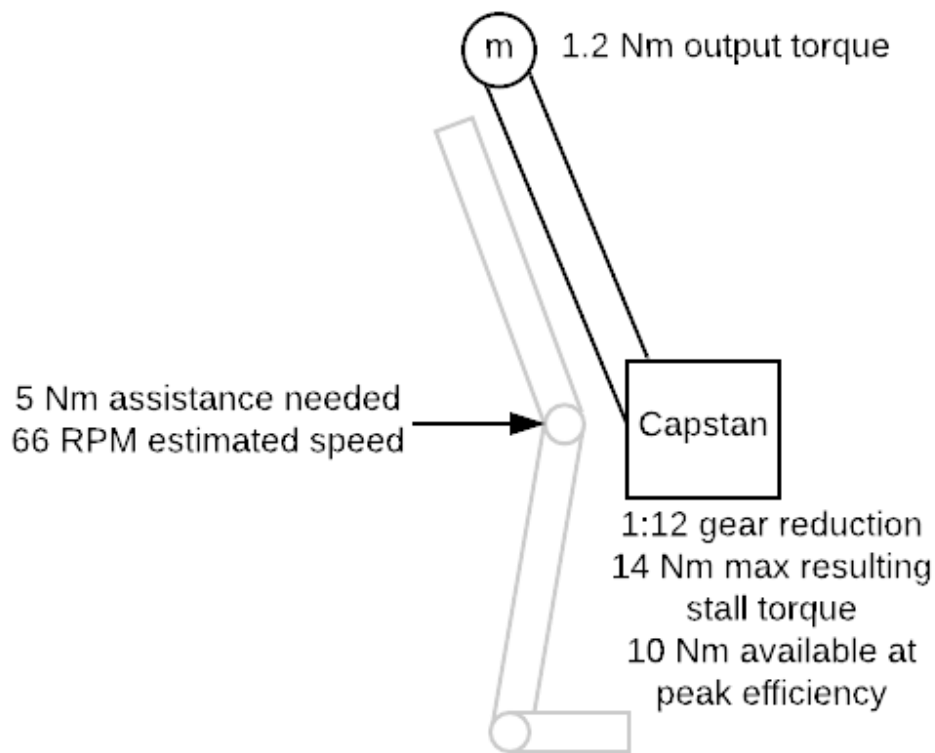
Figure 51: Motor and Capstan Drive Output Parameters

The original motor selected was a Globe brand brushed DC motor. To control the motor, an integrated circuit with an H-bridge was used. The Pololu MC33926 H-bridge was chosen because it was readily available and had a carrier board that easily interfaced with the rest of the circuitry. The H-bridge allowed for easy adjustment of motor speed using pulse-width modulation (PWM) from the microcontroller. The H-bridge carrier board also had other useful features, such as motor current sensing and protection against back-EMF generated by the motor. The carrier board is capable of feeding up to 5A of current at the desired 12V, so it was compatible with the motor needs. However, it was ultimately decided that with a maximum output torque of 0.2 Nm, this motor would not meet the needs of the design and something more powerful was needed.

Maxon motors are known for providing high performance (measured in torque, speed, and precision) while still being compact. The final motor selected to meet the needs outlined above was a Maxon EC-Max motor with a planetary gearbox, capable of providing about 1.2 Nm of torque at 12V. This motor is a brushless DC motor, making it more easily backdrivable, despite the large gear reduction in the gearbox. It also came with a built-in encoder for accurate position sensing, as well as Hall-effect sensors are used to allow a motor control circuit to accurately control speed. This circuit was acquired as a separate breakout board. The breakout board allowed for motor speed control using analog input voltage and direction control with a digital pin. A final diagram showing the motor requirements, selected motor, and output after gear reduction is shown in Figure 51.

5.3.3 Sensor Selections

Sensing the rotation of the knee is crucial to device control, so a rotary position sensor was needed. Rotary potentiometers are a common choice for similar applications since they provide an absolute analog position reading. Potentiometers generally do not provide a full 360 degrees of rotation, but this is not a problem because the knee never rotates more than 180 degrees, at an absolute maximum. The potentiometer chosen for this application is a simple 10 kilo-ohm potentiometer, which was readily available and easily mounted to the device.

Several other sensor types were considered, but not chosen to be included in the first prototypes. One such sensor is the Inertial Measurement Unit, or IMU. IMUs provide data about acceleration and rotational velocity. Position information can be obtained by using this data to compute the numerical derivatives. An IMU would provide extra information about the motion of the device on the wearer's leg. However, IMUs are known for being hard to implement. They are subject to drift in the measurements, which can lead to large accumulated errors. Furthermore, correcting these errors requires a large amount of processing power to filter the data, which is not necessarily available on a small microcontroller. Ultimately, the position information gained from a potentiometer at the knee and an encoder at the motor is ample for the initial prototypes.

The Electromyography (EMG) sensor is another candidate sensor that was not selected for the initial design. EMGs are used for detecting the electrical signals in a patient's muscles that are produced when the patient moves. This capability would be helpful for detecting the intent of the device's wearer, such as when the wearer wishes to start walking from a standstill. An array of EMGs placed across several muscles could also detect more complex intended movements, such as standing up from a sitting position or climbing stairs. Unfortunately, EMG sensors are difficult to use because they are sensitive to oils in the skin and placement. It was also determined that complex movements were outside the scope of this project, and that the first iteration of the device should only focus on walking. Since the beginning and end of a sequence of steps can be detected in other ways using the potentiometer and motor configuration, the EMG was ruled out.

5.3.4 Microcontroller Selection

The microcontroller requirements are outlined in Section 5.3.1 through the electrical block diagram. The mbed LPC1768, shown in Figure 51, was chosen to meet these needs because it was readily available to use and met all of the requirements. For instance, the LPC1768 has I2C, SPI, and UART serial communications pins, five analog input pins, several PWM output pins, and plenty of digital I/O pins. The board also provides regulated 3.3V and 5V outputs and has a built-in voltage step-down circuit, allowing the 12V battery to be connected directly to it. In total, the board has 40 pins and can accomodate all of the device's electronics, but features a small size that will help the circuitry maintain a low profile.
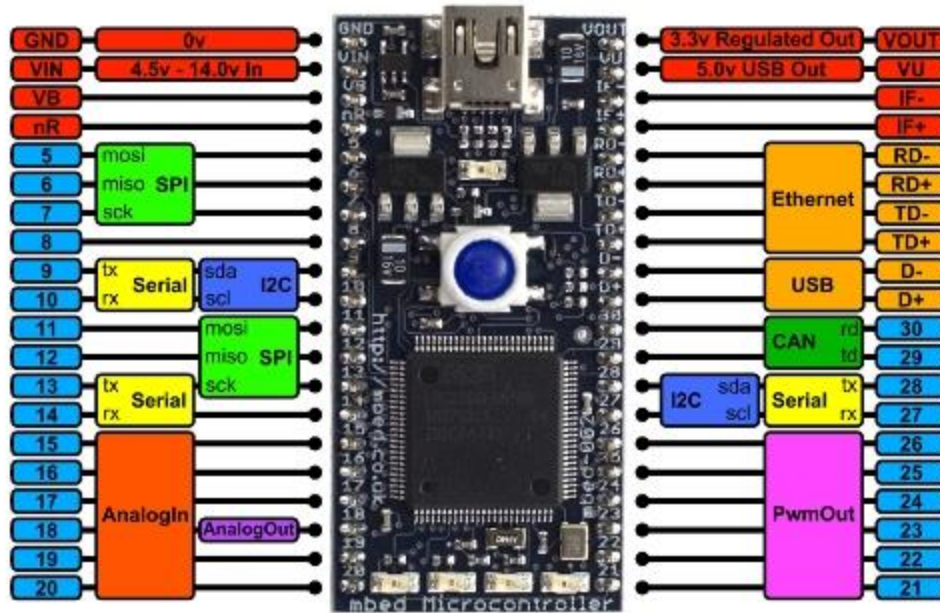
Figure 52: mbed Microcontroller Layout [87]

When verifying the operation of the board, one issue was that the step-down components became very hot during operation. While this did not cause the board to fail, it did raise the concern of providing too much input voltage. Consulting online sources led to the discovery that there was an error in some of the board's documentation; the microcontroller documentation specified a maximum VIN of 9V at some sources, and 14V at others. Thus, an external 9V voltage regulator was obtained which was interfaced via a breadboard to step down the input voltage safely and without danger of overheating and damage to the microcontroller.

5.3.5 Schematic and PCB Design

The electronic systems were built on a breadboard for prototyping, but the final version was made with a custom printed circuit board (PCB) to reduce the size and eliminate loose wires. The PCB design was created with Altium Designer and printed through OSH Park. The original electronic control system was designed to control a brushed DC motor through an H-bridge circuit. Later, it underwent slight modifications to control use a brushless DC motor with a separate motor controller board.

The final schematics of both designs are shown below. The schematics contain all of the preliminary components, and include header pins where additional components can be added later since the design is ever-evolving. These headers are attached directly to the microcontroller pins so that input and output can be accessed directly. The 3.3V, 5V, 12V, and ground rails are also available via header pins so that any new components have access to power.
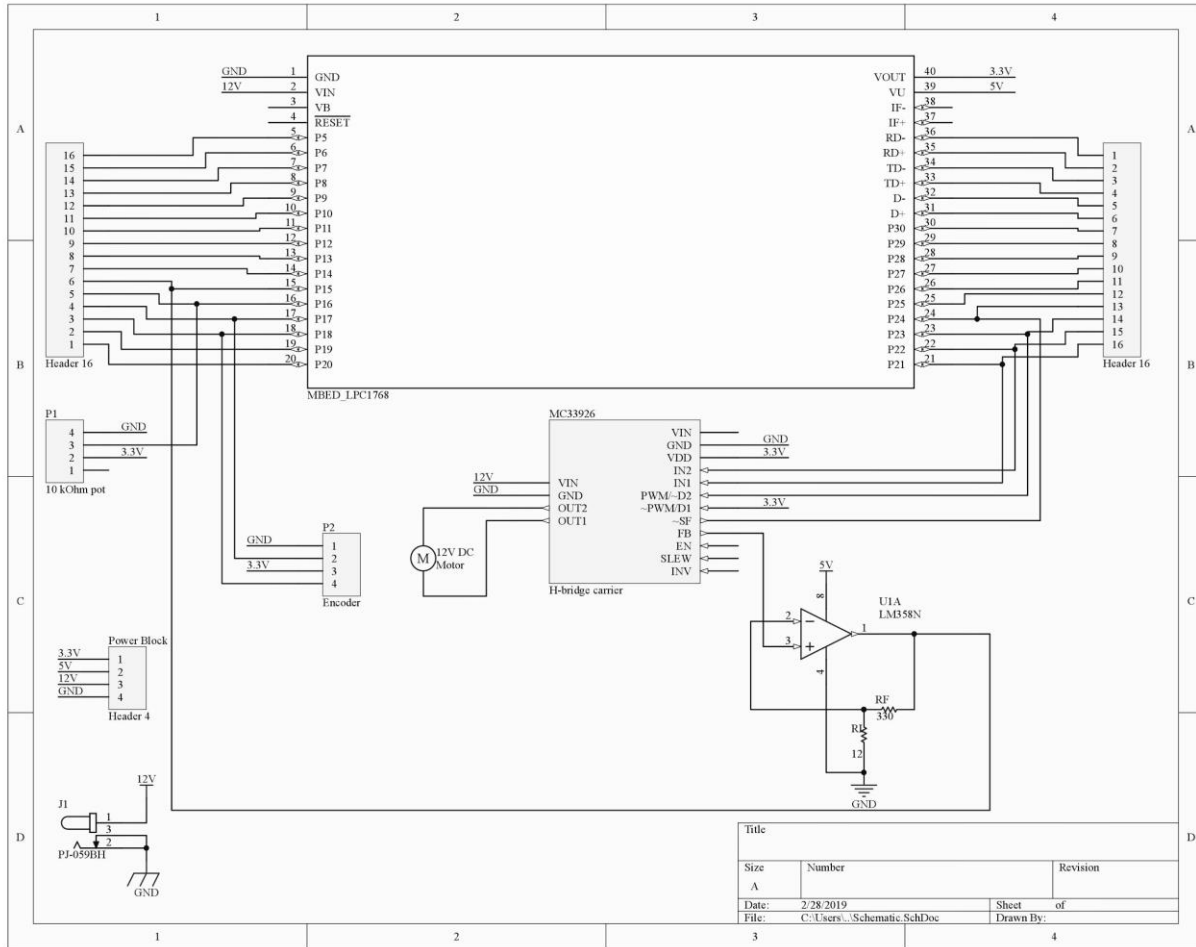
Figure 53: Schematic based on DC Motor Design

5.3.5.1 DC Motor Based Design

Since the original prototype used a traditional DC motor, the first PCB was built to carry an H-bridge motor driver which is a circuit that controls a DC motor. The operational amplifier (op amp) in the circuit serves to amplify the current sense reading from the H-bridge circuit. Based on the datasheet, the current sense from the H-bridge provides 525 mV per amp while the motor is being driven, but the 12V motor has a maximum stall current of 0.11 amps according to the datasheet. At this level of current, the H-bridge output is only 57.75 mV. The LPC1768 microcontroller has a 12-bit 3.3V ADC, meaning the resolution of input voltages is in increments of 0.806 mV per step. This would lead to a maximum ADC output reading of roughly 0.15. Thus, amplification is needed for the signal to be meaningfully measured by the microcontroller. The LM358 op amp was used to achieve this. The op amp circuit is in the inverting configuration and has a gain constant of 27.5 due to the input resistance of 12 Ω and the feedback resistance of 330 Ω. This gain amplifies the maximum current voltage reading to 1.588 V, means more of the operating range of the ADC can be used and a higher degree of precision can be obtained while sensing the current.. This circuitry is shown in a high level diagram in Figure 54.
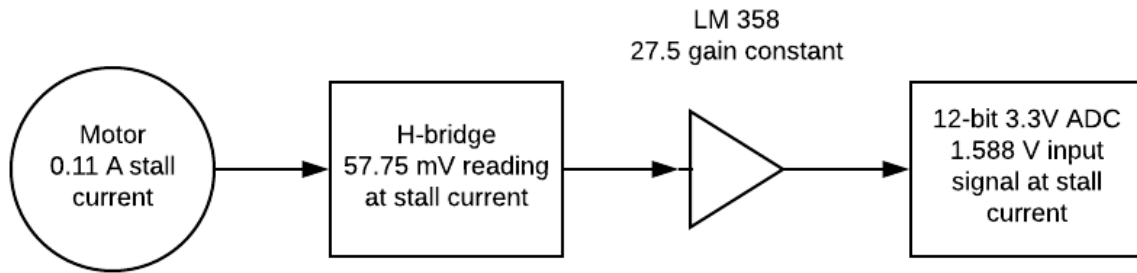
Figure 54: Current Sense Amplifier Circuit

Finally, the schematic includes a pin header for the two channel rotary shaft encoder and a pin for the 10 kΩ potentiometer. These require interrupt pins and an analog input pin, respectively. The final PCB design is illustrated in Figures 55 and 56 below.
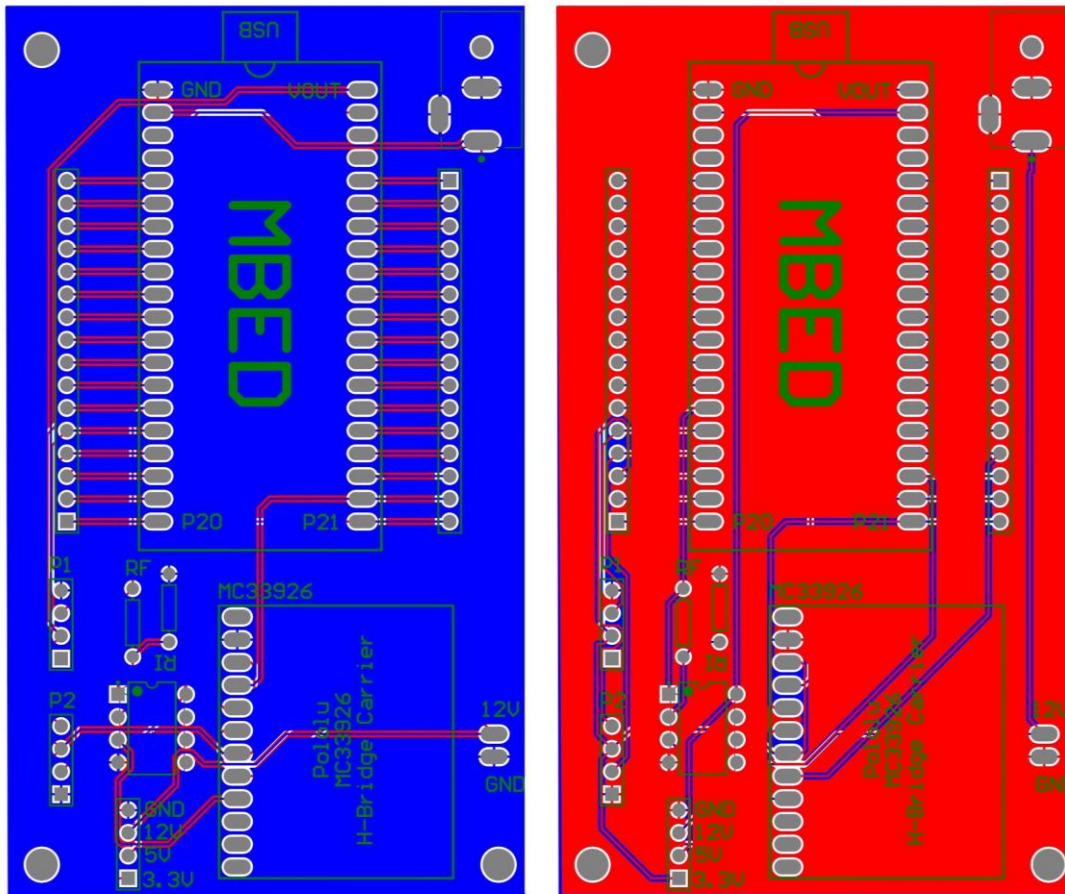
Figure 55: Top and Bottom Views of Custom PCB Design
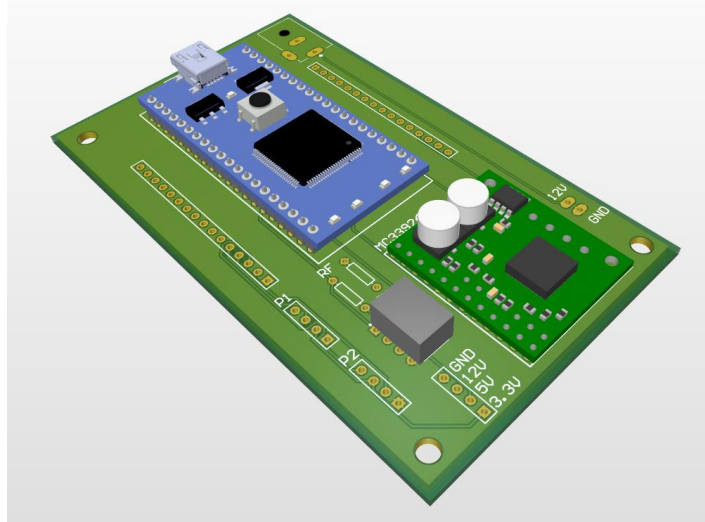
Figure 56: 3D Computer Generated Model of PCB with Essential Components

5.3.5.2 Brushless DC Motor Based Design

In the second iteration of the PCB, the Brushless DC (BLDC) motor discussed in Section 5.3.2 was used, which required a separate BLDC motor driver. This driver is contained in a breakout board which interfaces with the pins on the main PCB but is not mounted directly to it. It utilizes feedback from the Hall-effect sensor in the BLDC motor to control the motor speed based on an analog input setpoint.

The direction of the motor can be changed by altering the state of a digital input pin on the board. This pin was connected directly to a general I/O pin on the microcontroller. Speed was controlled via a Pulse Width Modulation (PWM) signal, where the duty cycle of a digital wave corresponds to the desired speed. The motor control board board came with a mounting card which allowed the control board to interface with the microcontroller without exposing any of the pins. Additionally, utilizing this mounting card meant no modification to the original PCB was required, and the PCB retained a small size that could be easily reverted to brushed DC motor operation if desired. However, an updated schematic was produced to illustrate the difference as shown in Figure 56. The motor is not pictured because it interfaces directly with the driver board, which only requires two data lines from the microcontroller.
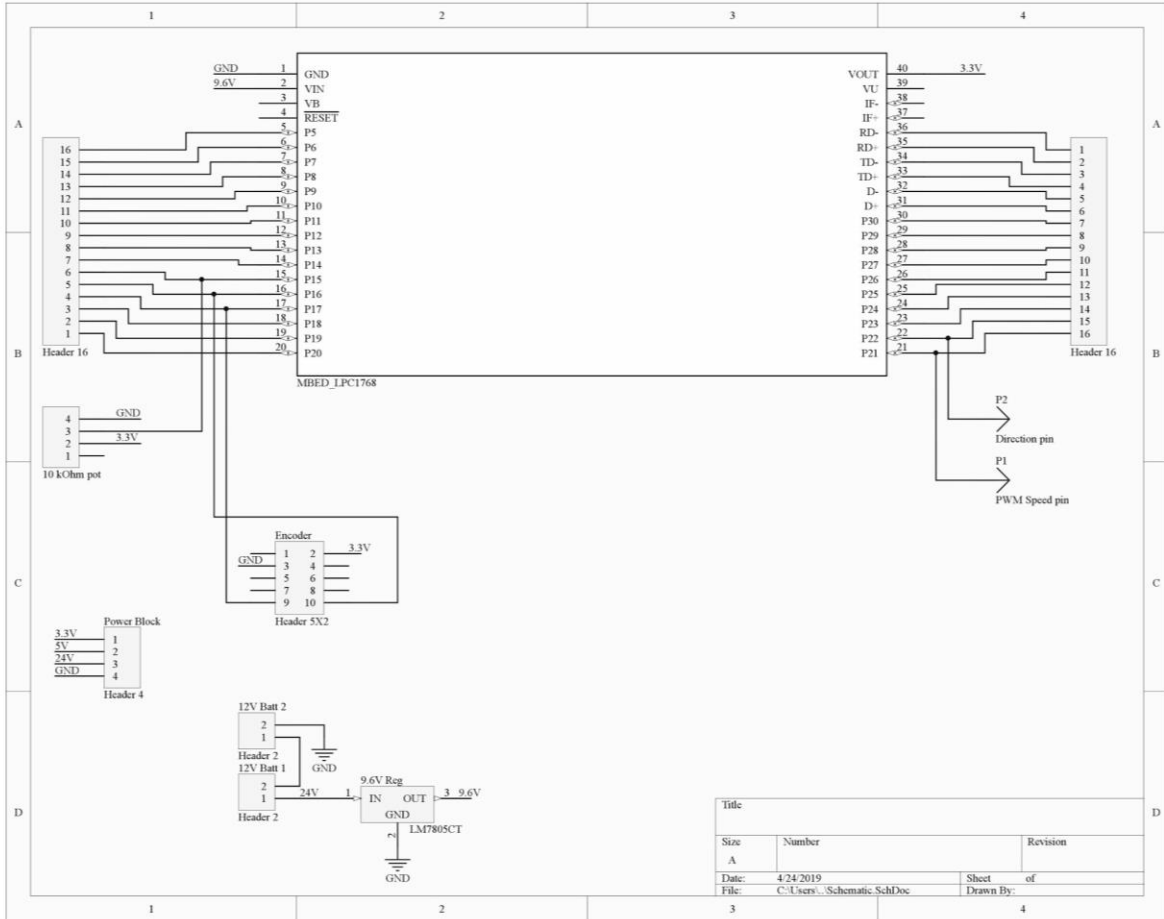
Figure 57: Final Circuit Schematic, Updated for BLDC Motor

5.4 System Controls

5.4.1 System Software Block Diagram

The software that runs on the microcontroller and controls the behavior of the device is referred to as the system software. The basic software needs were outlined in a block diagram to determine how the software would work and how the code should be structured. The block diagram, shown below in Figure 58, depicts a closed-loop process. This is represented by feedback coming from the sensors that affects the behavior of the device.
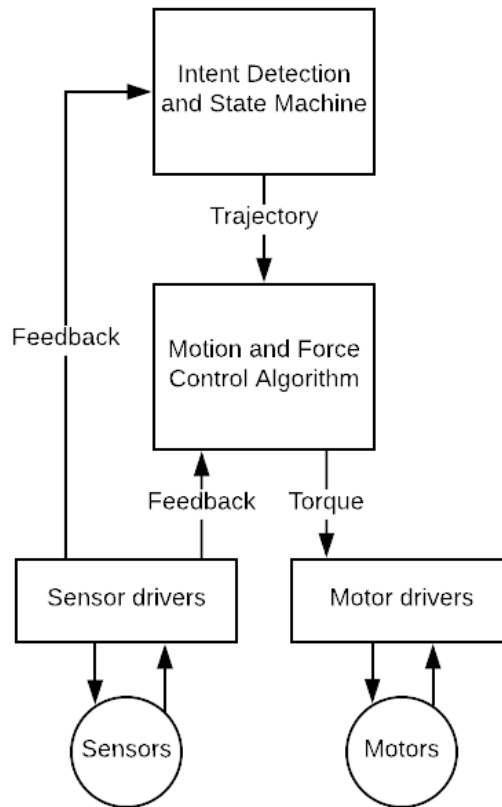
Figure 58: High Level Firmware Block Diagram

At the bottom of the diagram are the sensors and motors, which physically interact with the wearer of the device. Sensor drivers are any components necessary to interact with the sensors, such as amplifiers, ADCs, or the necessary data lines for a specific communication protocol. Many of the sensor drivers are simply features of the microcontroller, but the software still must interact with the driver, rather than the sensor directly, so it is important to represent the sensor separately from the driver. Similarly, the motor driver is the intermediary between the microcontroller and the motor, and holds any circuitry required to power the motor. This allows for a much simpler interface between motor and microcontroller.

The motion and force control algorithm sends motion commands and directs the motion of the device through the gait cycle based on sensor feedback. This is where closed-loop trajectory control takes place. Based on the deviation between the motor's path and the desired trajectory of the knee, the motor will provide more or less force. And while force control is the eventual goal of this block, position control was implemented first since force control is much more complex.

Finally, at the top of the diagram is a state machine where intent detection takes place. This state machine relies on sensor feedback to constantly detect whether the device should start or stop providing assistance. Further capability can also be defined here, such as setting the speed of the gait during ordinary walking, and assisting with more complex knee motions such as sitting and standing. Regardless of the capability, the state machine is responsible for feeding the wearer's intended trajectory into the controller, which then operates the device with the given trajectory.

5.4.1.1 State Machine

The state machine developed for high level operation of the device had two states and relied on potentiometer feedback to transition between them. The states are designated "walking" and "standing", and they provide the functionality for someone to walk normally without worrying about manually starting or stopping the device. More complex movements such as sitting and stair climbing were not implemented in the state machine due to the difficulty of intent detection and time constraints.

Swapping between the walking and standing states was done by detecting whether the user had stopped or started moving. To accomplish this, the state machine continuously monitored the knee angle through potentiometer feedback. A "safe zone" was hard-coded, such that the device would not move if the knee angle was below a certain threshold. This enabled the user to stop the actuation at any time by returning to a straight-legged standing position. In order to start moving again, the user simply needed to bend the knee slightly to trigger controlled actuation once more. These two states and the transitions between them are illustrated in Figure 58 below. The state machine runs in a 10 Hz loop to ensure that the delta is updated frequently enough for the motor to stop or start in sync with the user.
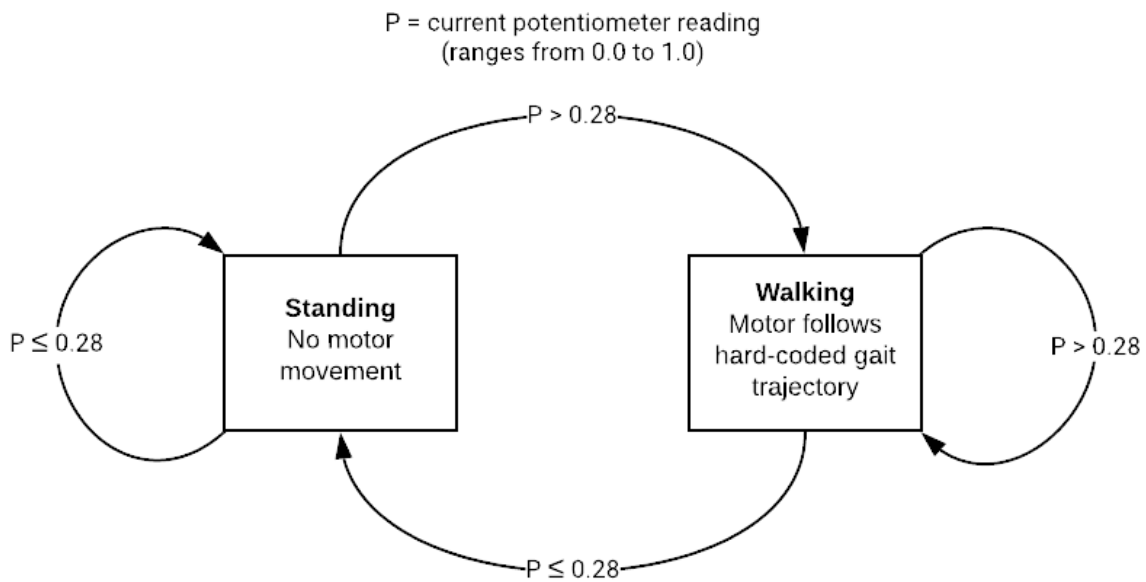
Figure 59: States and Transitions in Firmware State Machine

5.4.1.2 Control Algorithm

A closed-loop trajectory control algorithm was used to actuate the motor through the gait cycle. Proportional and Derivative (PD) gains were used to minimize the error between the position of the motor and the desired trajectory. In a normal gait, the knee joint angle can be modeled by a two-peak sine wave, as shown below in Figure 60.
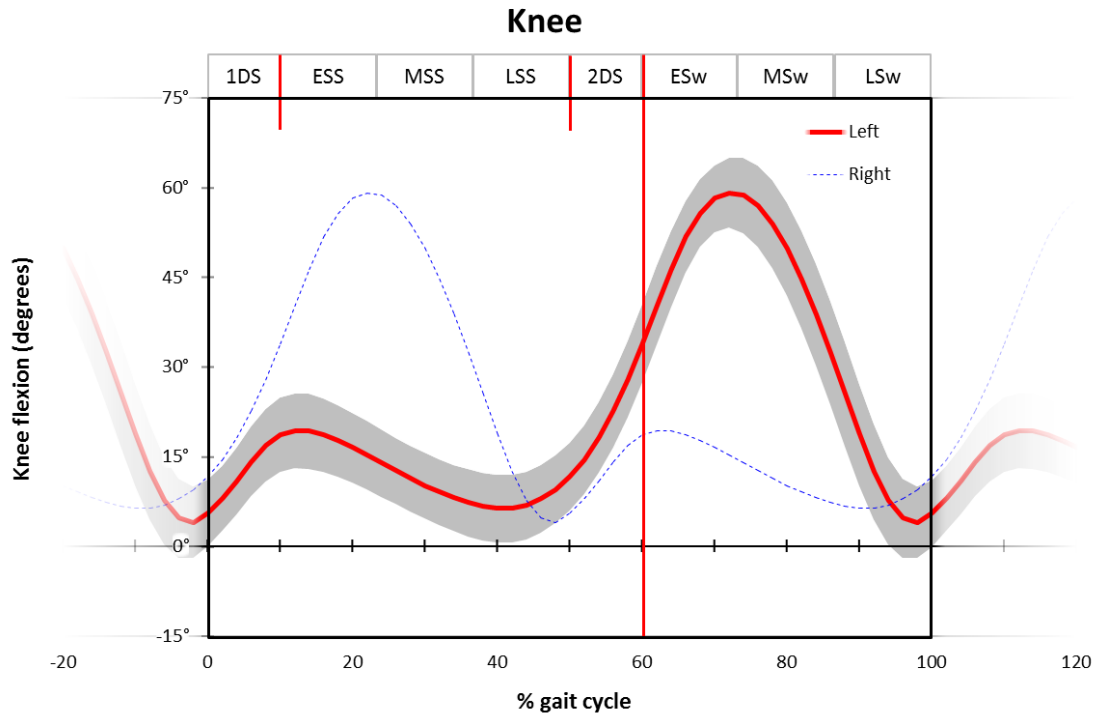
Figure 60: Knee Angles in a Normal Gait Cycle [89]

After collecting knee angle data during gait analysis, a close mathematical approximation of the function that models the knee angle was found. By modeling the desired knee angle as a function of time, it was possible to generate a desired setpoint at any moment in time. Since the microcontroller is limited in terms of its computational speed, this allowed the motor control loop to run on an on-demand basis rather than trying to maintain a fast, reliable control loop with discrete setpoint values. The approximate gait function was hard-coded into the PD control loop, such that the user was assisted with walking at a specific, predetermined speed with normal levels of support for knee flexion and extension. The approximate function used is shown in Figure 61, where the bottom axis is the time in milliseconds and the height of the graph represents the angle of the potentiometer (which turns from 0 to 270 degrees, corresponding to decimal values between 0.0 and 1.0).
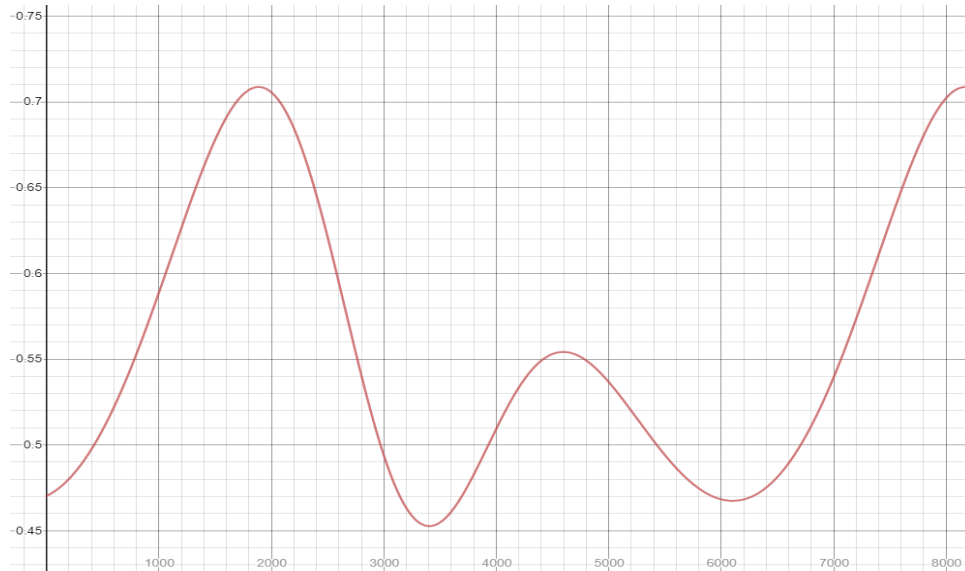
Figure 61: Approximated Gait Function used for PD Control

$$f(t) = 0.08 \cdot \left[sin \left(\frac{t}{1000} - \frac{1}{2} sin \left(\frac{t}{1000} \right) \right) - sin \left(\frac{2t}{1000} - \frac{1}{2} sin \left(\frac{t}{1000} \right) + 1.5 \right) \right] + 0.55$$

5.5 Safety Features

Safety features are of the utmost importance for a robotic device that interacts directly with a human user. The safety features designed for this device are both mechanical and software based to ensure redundancy in case of failure. Mechanically, series elastic actuators allowed for compliance when physical obstacles are encountered in the real world. In the software, potentiometer feedback is used to quickly respond to the user and prevent damage.

5.5.1 Series Elastic Actuators

Series Elastic Actuators (SEAs) are springs in series with a cable driven actuator. An ordinary cable drive has no compliance; in other words, resistance on the end-effector is met with no change in the force applied to the end effector. However, actuator compliance is crucial for safe exoskeletons. If an actuator is not compliant, the wearer can be injured when the device continues to turn despite the limb being stuck against an obstacle. And obstacles are only one scenario where a lack of compliance can be dangerous. The goal of placing a spring in series with the cable drive is to provide compliance and mitigate danger to the user.
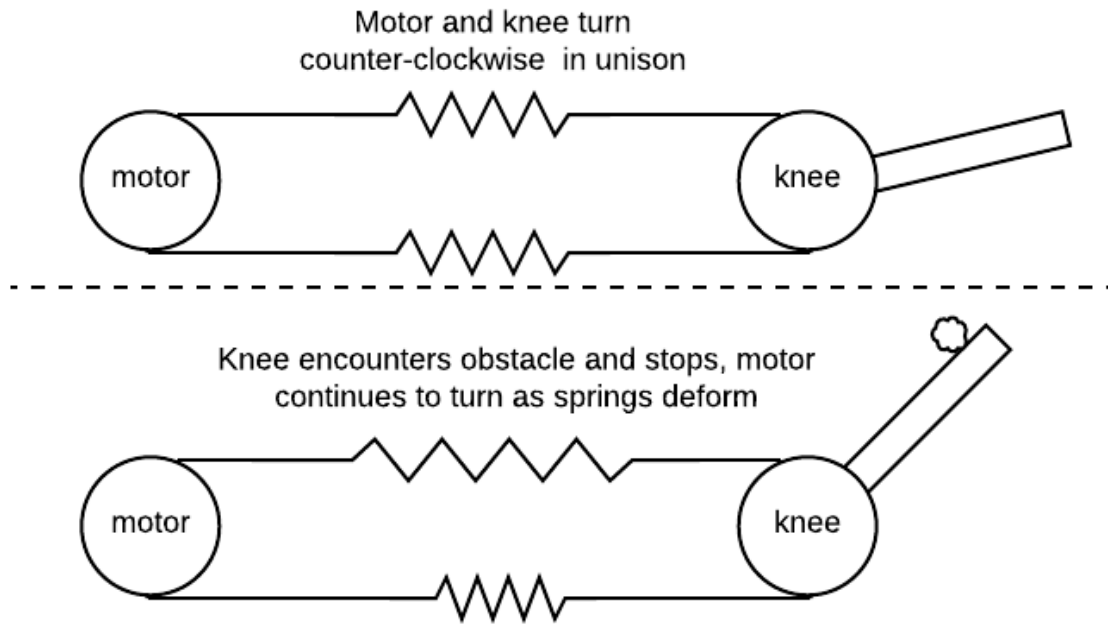
Figure 62: Series Elastic Actuators Allow Device Compliance

Using a spring with known dynamics, the device can ensure that if too much resistance is met at the end-effector, the spring will stretch as the motor continues to turn instead of applying the force to the end effector directly, as seen in Figure 62. Ordinarily, the spring is unstretched, but when obstacles are met, the spring deforms before damage is done to the leg. This important safety feature ensures the device is compliant with the wearer and does not attempt to overpower the wearer when motion is blocked.

5.5.2 Knee Potentiometer Reading

The potentiometer positioned at the knee provides valuable information for the control of the device, but also acts as a safety feature. By checking the difference between the "ground truth" potentiometer reading at the knee and the encoder reading at the motor, the control software can detect when the knee has stopped moving despite continued motor movement. A stoppage in knee movement is a signal that an obstacle was met or the wearer is resisting the device, so the motor should be stopped to prevent damage. Since there may be a slight delay before this signal is registered, the SEA prevents excessive knee torque at the moment of an impact, but ultimately the potentiometer stops the motor from continuing to move.

Chapter 6. Final Design Validation

6.1 Experimental Methods

The team can validate how well the device provides enough assistance and improves the gait of the wearer by using motion capture and force plate data when the subject wears the device and compare that to the preliminary testing. In order to get the most accurate results, the same motions will have to be used with the same parameters to be able to make the comparison. Validating that the device improves

activities of daily living will require heart rate testing. Ideally, heart rate should decrease for patients with the brace on because they are using less energy and are in less pain when in motion, especially for a long period of time. The team will use Matlab to analyze the raw data from the Vicon system and use the output data from a Garmin VivoActive 3 to quantify the heart rate data.

6.1.1 Range of Motion

Walking is the main motion which the group was trying to improve for the user. Restricting range of motion for the user would cause further knee damage and more of misalignment of the leg. To ensure an improvement of gait, the brace on the user must provide the same average knee angles compared to the baseline preliminary data. The team collected data from a healthy teammate with the brace on, which theoretically should produce similar results to the preliminary testing. This data would validate that the brace does not affect range of motion.. This is because the team was unable to find subjects with osteoarthritis.

In the range of motion trials, the subject was asked to put the brace on and walk at a normal walking speed for 15 minutes without data being collected. This allows the body to adjust to the brace and in return the gait will improve. As shown below is the brace on the subject in the Practice Point Lab.

Figure 63: Final Gait Testing Marker Placement

The picture above shows the user with the final brace on and the motor running. The makers were placed in the same position as in the preliminary trial. As in the preliminary testing, the subject started in line with the force plates. Knee moment, knee angle, and ground reaction forces were all found at the same time interval as when the subject stepped on and off the force plates. Using the average curve from the preliminary testing, a visual similarity is shown. The final testing parameter results are shown below.
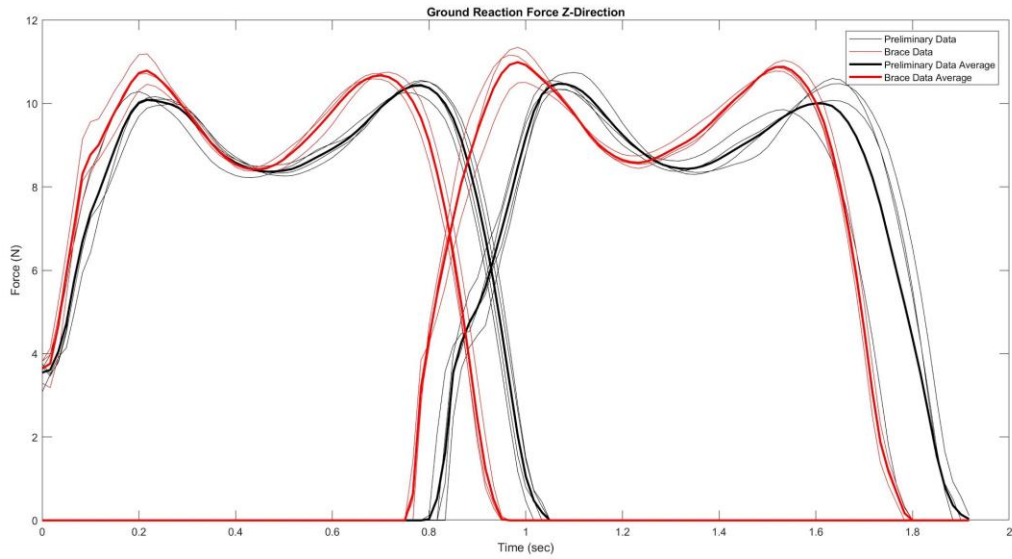
Figure 64: Ground Reaction Force Trial Comparison
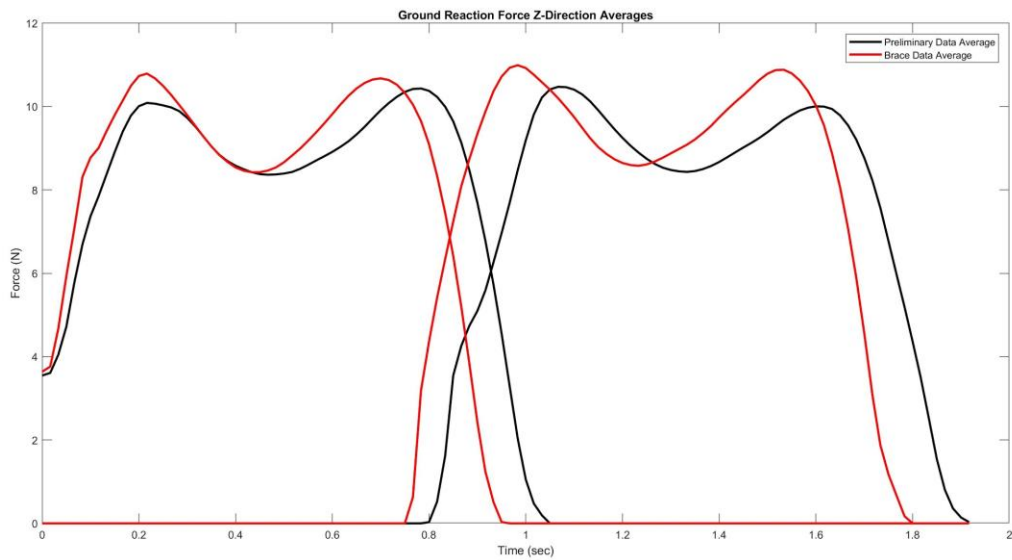
Figure 65: Ground Reaction Force Averages Comparison

Preliminary GRF Trials	Max Values Right Leg (Newtons)	Max Values Left Leg (Newtons)	Brace Testing GRF Trials	Max Values Right Leg (Newtons)	Max Values Left Leg (Newtons)
Walking Trial 1	10.5543	10.5993	Walking Trial 1	10.7175	11.3474
Walking Trial 2	10.5290	10.7453	Walking Trial 2	10.5930	11.1662
Walking Trial 3	10.4625	10.5534	Walking Trial 3	11.1926	10.7813
Walking Trial 4	10.2640	10.3425			
Average	10.45	10.56		10.83	11.1

Table 14: Ground Reaction Force Trial Results

The figures 64 and 65 and table above shows the comparison data between the preliminary data and brace testing data. As shown visually, there is a shift to left and higher force when the subject had the brace on. This could be explained by extra weight added to the leg. This in turn could cause the subject to take shorter steps to make up for the shift in center of pressure. The average max ground reaction force values shows that there are higher averages when the brace is on the patient but the max difference is 0.65N, (11.1N- 10.45N) To put this value in perspective, the brace puts an extra 0.066kg, or 0.15lbs.
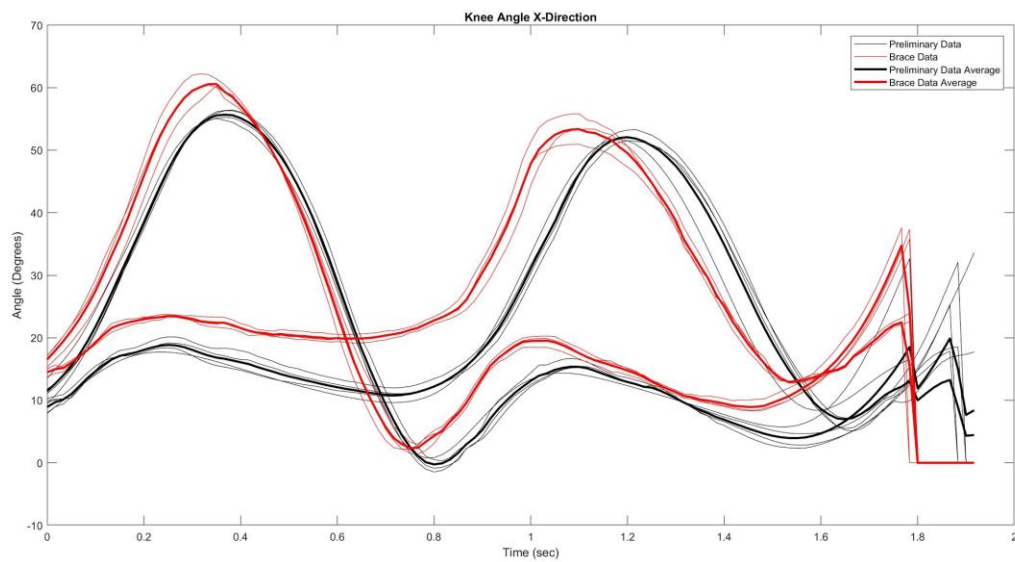
Figure 66: Knee Angle Trial Comparison
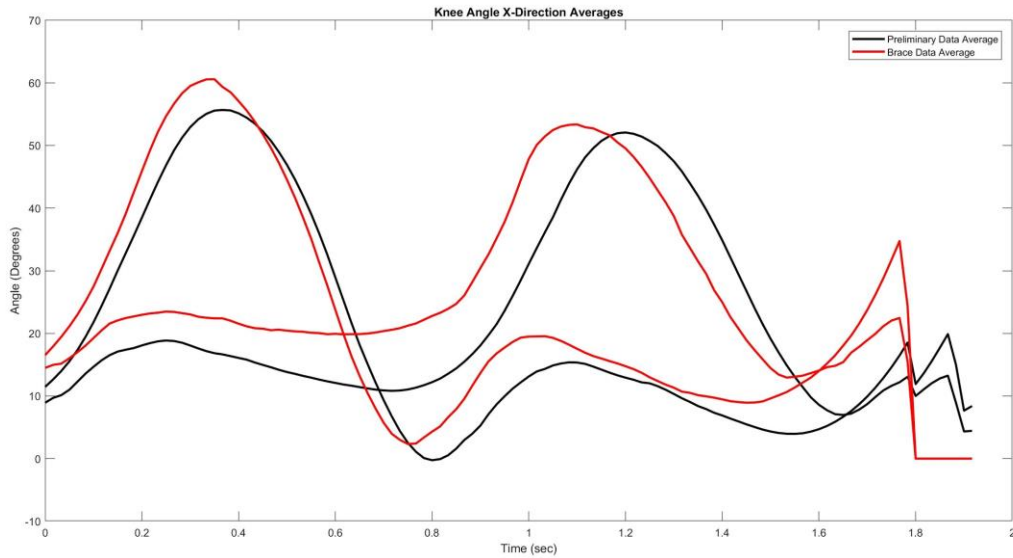
Figure 67: Knee Angle Averages Comparison

Preliminary Angle Trials	Max Values Right Leg (degrees)	Max Values Left Leg (degrees)	Brace Testing Angle Trials	Max Values Right Leg (degrees)	Max Value Left Leg (degrees)
Walking Trial 1	51.5410	55.2657	Walking Trial 1	55.8258	60.4466
Walking Trial 2	53.3074	55.0731	Walking Trial 2	50.9492	60.3099
Walking Trial 3	52.0245	56.4347	Walking Trial 3	53.3961	62.2087
Walking Trial 4	51.7517	56.3097			
Average	52.16	55.77		53.39	60.98

Table 15: Knee Angle Results

Figures 66 and 67 and Table 15 show the results from the angle data between the preliminary and brace testing trials. The graphs show an increase in knee flexion of the right leg when the subject had the brace on. There is also a significantly higher amount of knee flexion of the left leg when the subject is assisted with the brace. A leftward shift, also shown in the ground reaction force data, can be explained by shorter steps taken and a shorter gait cycle. The average max values show that there is an overall increase in knee flexion which validates that the brace does not restrict movement of the leg, rather allows for more knee flexion.
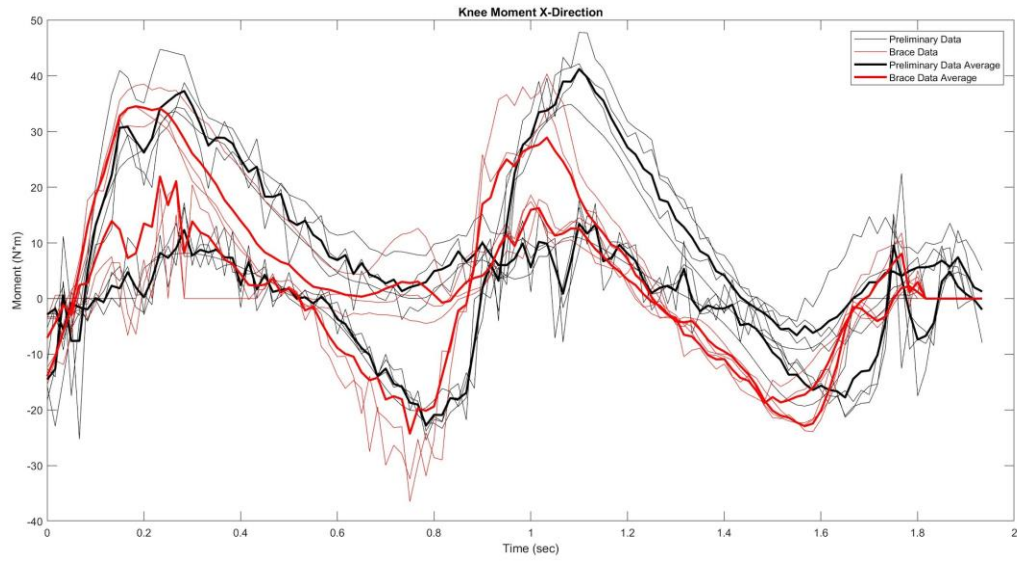
Figure 68: Knee Moment Trial Comparison
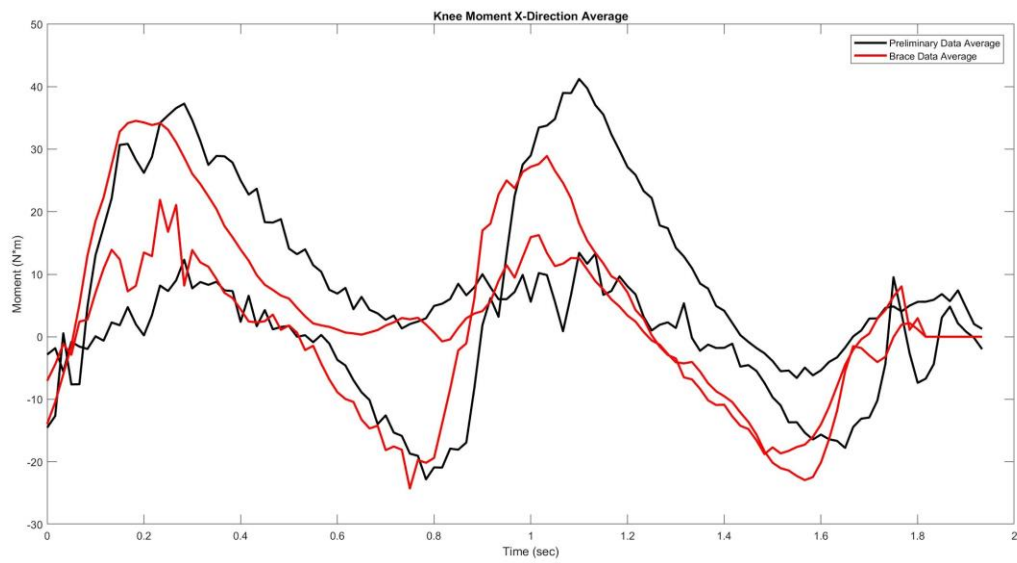
Figure 69: Knee Moment Averages Comparison

Preliminary Moment Trials	Max Right Leg Values (Nm)	Max Left Leg Values (Nm)	Brace Testing Moment Trials	Max Right Leg Values (Nm)	Max Left Leg Values (Nm)
Walking Trial 1	34.8119	39.0439	Walking Trial 1	38.0262	31.6389
Walking Trial 2	43.4541	44.6616	Walking Trial 2	18.8748	37.6443
Walking Trial 3	32.9400	40.8517	Walking Trial 3	37.9233	30.1059
Walking Trial 4	32.3426	33.7669			
Average	35.89	39.58		31.61	33.13

Table 16: Knee Moment Trial Results

The figures 68 and 69 and table 16 show that the maximum moment was 38.0262 Nm and the average moment of the right knee was 31.61 Nm. This result compared to the preliminary data concludes that the maximum knee moment decreased by 15% and the average right knee moment decreased by 12%. This can be explained by the increased knee angle. The moment pattern was also shifted to the left, which can also be attributed to the added mass of the device [85].

6.1.2 Centroid Comparison
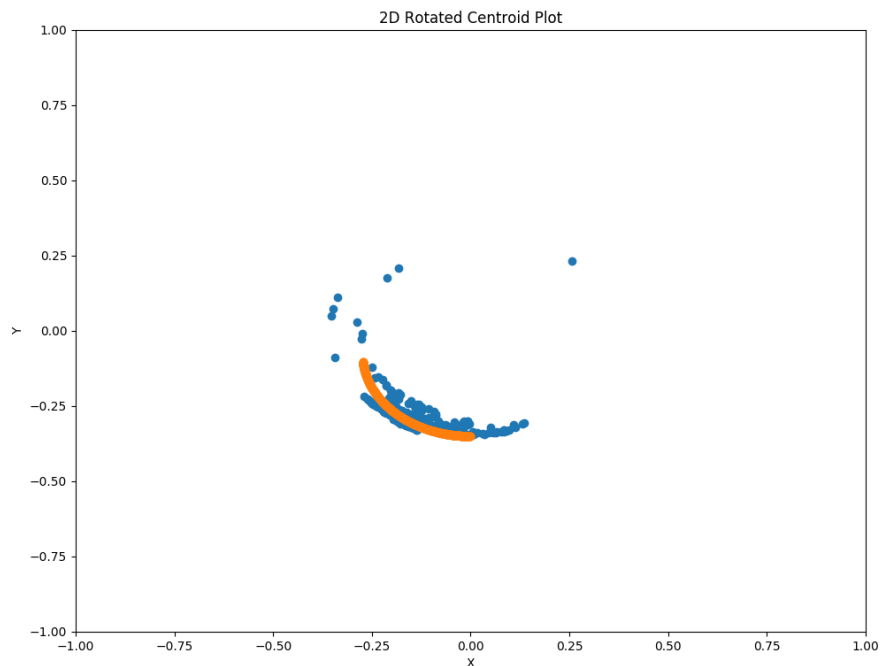
Figure 70: Knee Centroid Plot with Brace Overlay (orange)

Figure 70 shows the original knee centroid generated from preliminary motion capture data with the brace centroid in orange. The overlay validates that the brace follows the knee centroid path accurately which

will not cause additional damage to the user's leg. Since the knee is not a perfect pin joint, a mechanical joint design which closely matches the movement of knee is required for the success of the device.

6.1.3 Heart Rate Monitoring

To test the comfortability of the device the team used a heart rate monitoring system. This experiment provided quantitative results. The group member who was wearing the brace had a Garmin VivoActive 3 device that monitors heart rate in real time. The group member also had an app that shows their updated heart rate. The procedure was:

1. Attach watch to user's left wrist
2. User moves back and forth across the room during testing period ~5 minutes
3. Partner commanding the Vicon system record heart rate every 3 seconds until the testing period is over
4. Plot the user's heart rate versus time

The heart rate versus time graph is shown below.
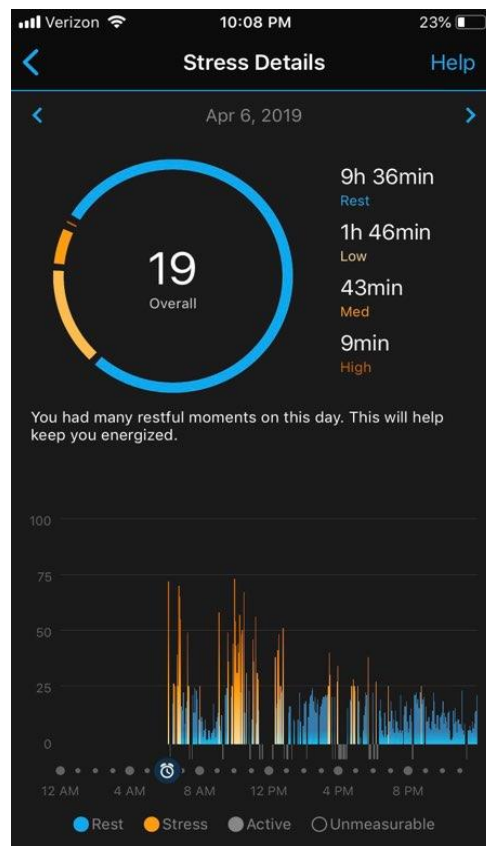
Figure 71: Stress Level During Walking Testing

The average heart rate was 80 bpm. There were a few peaks of stress recorded during the testing period. This can be explained by the user getting stressed about having to walk over the specific force plates.

6.1.4 ADL performance

To validate the team's objective of improving activities of daily living, the data was quantified by having the subject perform multiple ADLs while heart rate is recorded. During this test the subject was asked to bend over simulating picking up an item. The purpose of this test is to see if the brace can allow for that much flexion of the knee. The group also performed a test where the subject was holding two heavy bags, simulating holding groceries, and walking back and forth across the force plates. This test showed another activity of daily living and whether the device was able to withstand. Ideally, with a patient with OA the plot should show a greater difference between resting and motion heart rate because of the amount of effort exerted.

6.1.5 Statistical testing

Accurately providing device validation requires proving that the device does not statistically change the gait cycle of the subject. Since the subject does not have osteoarthritis of the knee, they can be used as an example of a healthy subject. The group utilized the t-test function in Matlab to compare the preliminary testing maximum average of right knee moment, knee angle, and ground reaction force versus the brace testing average maximum right knee moment, angle, and ground reaction force. It is a simpler comparison of two means and gives clear approval of assumptions. The results of the t-test are below.

Data Set	H value - Left Leg	P Value - Left Leg	H value - Right Leg	P Value - Right Leg
Knee Angle	1	8.2313e-06	1	5.9493e-07
Knee Moment	1	3.5781e-05	1	0.0061
Ground Reaction Force	0	0.5714	0	0.1401

Table 17: T-test Results

Table 17 shows the t-test results from the average of preliminary data and testing data comparisons. The paired t-test, with an alpha value of 0.05, will validate if the device changes the gait cycle. The null hypothesis states that there will not be a significant change in results which proves that the brace does not affect the gait of a health subject. In the table only the ground reaction force shows a h value of 0 and a p value of greater than 0.05, accepting the null hypothesis. For knee angle and knee moment, the h value is 1 with p values less than 0.05 rejecting the null hypothesis and indicating there is a significance in the mean difference between the preliminary and testing data. Quantitatively, there were minimal viable trials, there is always variability in a person's normal gait, and only one person was tested using the device. These factors could have skewed the data to one person's "healthy/normal" gait cycle as well as the person's ability to adjust to the brace in a timely manner.

6.2 Reproducibility

The materials below, in Figure 72 were used to construct the device. This list represents both the materials used to make the physical device, and the control system materials.

Item	quanitity
Bearings	4
Rods	1
Velcro Straps	3
Velcro Tape	1
3D Printer Filament	312 grams
Aluminum Parts	1
Pneumatic Tube/Fittings	1
Misc Hardware	1
Circuit Board	1
Motor	1
Motor Driver	1
Microcontroller	1
24 V Battery	1
Misc Electrical Parts	1
Nylon Fabric	1 yard
Velcro	1
thread	1 spool

Figure 72: Brace Materials

6.2.1 Mechanisms and Actuation Components

All the mechanical components were created based on 3D models of the patient's specific leg. The kinect software was used to take the initial scan of the leg. In order to scan the leg, the kinect was pointed at the leg and filmed until a complete scan was taken. From this 3D scan, the model was imported into the Skanect software. This software was used to refine the model of the patient's leg. There are utilities within the Skanect software that allow for smoothing, filling holes, and polygon reduction, that were all used to improve the final leg model. The model was then imported into Blender where the leg profile was extracted. Using the boolean modifier, the leg profile was imprinted onto a block. A visual diagnosis of a patient could tell whether the patient has a varus or valgus force. After identifying which misalignment needs correcting, modifications in Blender can change the support blocks by rotating the pieces towards or away from each other to provide a correction force. This block was then exported as an STL file. The STL file was converted to a gcode in slicing software and then sent to the 3D printer. Between patients, the process of extracting the 3D model is the same. A new model must be constructed for each new user as their leg is shaped differently from the next person. This will ensure optimal fit during use.

The other 3D printed parts are all standardized to be used with any patient's leg. Thus, all of these parts can simply be reprinted for any new device that needs to be made. The laser cut pieces that make up the Three Part Linkage discussed in Section 5.1.4 are also standardized for any leg, and can simply be manufactured using the process of the user's choice. The team chose to use a plasma cutting service for aluminum parts to add additional strength to the device without adding too much weight, but any 1/4 inch

thick material can be used in its place. The motor pulley was turned on a lathe because the plastic pulley was not able to withstand the motor torque. Once all the parts are printed, cut, or otherwise manufactured, the leg component are now ready for full assembly. The 3D models of the parts can be found in Appendix D.

A description of the assembly process of the device is given in the following paragraphs. First, press fit the bearings into the holes in the metal connector piece and the Capstan slider, using a hammer or other force as necessary, but ensure that they are aligned straight with the holes. Fit the axles through the holes in the connector piece bearings with the same technique. The axles are then put through the holes on the geared bars until the pieces are flush together. Then, fit the axles into the bearings on the Capstan slider. Press fit the cable tensioner onto the top of the upper bar where the prongs are, again using extra force when necessary. At this stage, only press fitting is required, no extra assembly hardware.

Next, assemble the potentiometer mount and the lower half of the SEA. Screw the potentiometer into the mounting plate until the threaded section is flush with the inside part and not sticking out. Press fit a nylon spacer into the hole in the Capstan gear, and then thread the cable through the groove cut in the pulley side and bend it around the edges. Then, wrap the cable around in each direction 1.5 times, being careful not to overlap the sections as they are wrapped. Then press fit the pulley side onto the potentiometer knob until it is flush with the surface. This should also help prevent the cable from coming out of the groove. Feed the cable ends through the holes in the tensioner and pull them all the way through, leaving some space for movement of the pulley gear, as it will need to be moved around to fit exactly. Attach the potentiometer mount using the two screw holes in the tensioner mechanism and on top of the SEA slider. Slide the springs over the cable ends and fit them into the countersunk holes in the tensioner. Screw the pneumatic fittings into the small tensioner parts and then thread the cable through the small hole opposite the fitting and run the tensioners down to the tensioner housing. Do not fit them into the grooves in the tensioner housing yet, so that the device can be properly tensioned later.

After this, run the pneumatic tubes over the ends of the cables and push them into the pneumatic fittings until they are secured into them. Another set of fittings are then screwed into the tensioner for the motor board. This piece is then screwed into a mounting plate, which must be as tight as it can be to make sure that the piece does not spin. The motor is then fit into its hole in the mounting plate and secured using three screws through the small holes around the shaft hole. Run the cables through the pneumatic fittings and then fit the tubes into these fittings, pulling the cables through to the other side of the holes. Then, run the cables 1/2 turn around the motor pulley and through to the center of the groove, and pull them through the hole to the other side. Place the pulley onto the motor shaft, making sure to line up the set screw with the flat part of the motor shaft. Tighten the set screw onto the motor shaft, going as tight as possible to make sure that the pulley does not slip on the shaft. Pull the cables through the off-center hole one last time to make sure they are properly tightened, and apply hot glue, or another adhesive, to make sure that the cables stay in place during operation. If you are unsure about the final placement of these cables, make sure to use a temporary adhesive so they can be adjusted later. Finally, put the tensioner mechanisms into their grooves in the lower tensioner. This will require a significant amount of force, because this is how the cables remain under an ideal amount of tension.

To finalize the design, put a 1/4 inch bolt through each of the three remaining holes and put a velcro tensioner square on the outside of them. Two of them are on the lower geared bar, and one of them is on

the cable tensioner. On the other side, first put the velcro straps, and then put the plastic part followed by a washer and nut. Tighten down these parts as much as possible to ensure that they do not move when the device is attached to the patient. Then, line up the leg profile parts with the two geared bars on the leg to find out where they are supposed to line up. Then, heat up the plastic around where the bolts will go to create an area of clearance for them. Then, use a piece of metal to press into the profile piece to create a gap for the bolt. This step may need to be repeated depending on how quickly this is done and how fast the plastic parts cool down. Once the screw head can fit without interfering with the plastic, apply a liberal amount of hot glue or other adhesive to the metal bars and attach the profile parts to secure them. As before, if you are unsure about ht exact placement, use a temporary adhesive to make sure that you can adjust it in the future.

6.2.2 Soft design

The soft design was constructed using the Nylon fabric, thread, and the velcro. To begin, a pattern (seen in Appendix A) was created based on the measurements of the user. This pattern is the cut out of a large piece of paper and pinned to the nylon. With two layers of fabric beneath it, the knee pattern was cut out. The two layers were then sewn together in the middle, with a hem of ½ inch. To create a hem, the fabric was pinned together, with the pins turned horizontally, and only pinning together the intended hem length. Each side of the knee was sewn with a ½ inch of hem. Velcro was subsequently sewn into the sides of the knee for closure and adjustability purposes. On the inside of the knee, the inside to go over the knee was given four horizontal strips of velcro placed 1 inch apart. On the inside to go under the knee, one long vertical strip of velcro was sewn in. This occurred for both knees.

Once the knees were done, the front, back and side straps were also cut from the pattern. All the straps only had a single layer of fabric beneath it. These straps were also given a ½ hem. The waist was cut measuring the users waist and then using the pattern found in Appendix A for the knee sections. The waist was cut out with two layers of fabric underneath it along a side of the overall piece of fabric, so that when it was folded over it was 6 inches in height. This created an automatic edge. The bottom of the waist band was then sewn up. Velcro was place at the two ends. One on the inside of the band and the other on the outside for easy closure.

The straps were sewn onto the waistband first. Their placement is in the middle of each side of the waist band. Equal amounts of fabric should be on both sides of the two front straps. The two side straps were placed along the hips. Again for exact placement. It was ensured that the fabric lay in the middle of both of these sections by measuring the amount of fabric on each side. The straps cupping the rear was similar in that it met up with the side straps in the same place on each side and ended around the same place on each side, but these straps were also tested multiple times to ensure that it provided the proper support. The bottom of the straps were sewn into the knees 10 inches down along the hem lines of the knees for cosmetic purposes. The straps cupping the rear were sewn in place determined by the comfort of tautness.

6.2.3 Electrical Components

The Printed Circuit Board (PCB) discussed in Section 5.3.5 was designed with Altium Designer. This board can be modified and multiple copies can be printed using manufacturers such as OSH Park.

Additionally, the board has header pins which can be used to expand the functionality of the device by adding more input or output devices. This is meant to allow for future iterations of the design.

The LPC1768 runs on firmware that was written in Mbed OS. The source code is available through the private AIM Lab Bitbucket server or by contacting the lab directly. This source code contains the high level state machine and the low level control software that moves the motor through the desired knee trajectory in the gait cycle. To use this firmware with a brushed DC motor, very little modifications are needed, and comments in the code point to where adjustments need to be made.

6.3 Project Considerations and Impact

6.3.1 Economic Impact

There are limited customizable, preventative care device similar to this on the market that targets the osteoarthritic ageing population. The device is unique in that it is actively powered, whereas the only device that can compare is passively actuated. Due to this, the device costs cannot be directly compared to any existing options on the market. The best comparison is to the Osskin Evoke knee brace. This brace is similar except for that it is not actively powered. The Evoke brace has sold over 2,000 units within the first year of production showing the high demand for devices such as this one. Similar knee braces cost upwards of $1,000 and can range to above $75,000. The team suspects that the devices will cost much less than this due to its materials. It is adding to the user's functionalities, more so than many of the passive devices within this price range. The team's expectation is that due to the high demand for customizable devices that are inexpensive. This project would be sought after and influence the assistive device market place which is valued at $24.6 billion by the mid 2020s [86].

6.3.2 Environmental Impact

Two lithium ion batteries are used to power the microprocessor and motor which actuates the brace. Lithium rocks are mined, mainly from South America [87]. This process is harmful to the environment by changing the geography of the area as well as the use of machines which pollute the air. Less than five percent of these kinds of batteries are recycled which shows that there is a lot of waste especially since lithium ion batteries are widely used.

Parts of the brace are constructed out of 3D printed materials, mainly PLA. This is a type of plastic which melts at high temperatures and used to make complex geometries relatively quickly. The more complex the geometry, the more support materials are needed to manufacture the part. Support materials are temporary and serve no other purpose in the final product. Unfortunately this material is not reusable in 3D printers and end up in the trash. In turn, plastics can end up in the oceans which can cause a multitude of problems to sea life and can end up in the food supply. However, PLA is recyclable so choosing to recycle can avoid some negative environmental impacts.

6.3.3 Societal Influence

By the year 2020, the elderly population will increase by 18 million. Additionally, this population includes an increase of 6 million people who are diagnosed with osteoarthritis [1]. From this population,

there will be a significant number of potential users for this preventative knee exoskeleton. This device was designed for day to day life, which allows the the user to perform ADLs that are necessary to live with decreased pain in the knee. Many ADLs required for taking care of one's self are more likely to be completed if the user is able to walk with no pain. Once this device is deployed, it will decrease the need of caregiving and assisted living homes. This decrease in caregiving will give the ageing population potential to spend less money on care as well as the ability to contribute to society for longer.

6.3.4 Ethics

There are two main ethical concerns that surround a class II medical device including human testing as well as the definition of a successful active device that has the ability to detect a person's gait. Testing the device on user's who have fragile bones is especially important to make sure there has been enough preliminary testing on healthy subjects.

6.3.5 Health and Safety Concerns

This assistive knee exoskeleton was intended for patients with osteoarthritis, in their knee, who experience difficulty performing activities of daily living such as walking, bending over, standing up etc. The goal of this device was to improve quality of life of the patient when performing these activities, but there are health and safety concerns when employing a new device that will be put on a human being. A major concern involves how the device will influence a user's walking and other activity's pattern. The device is intended to try and work with the person's movements. So if the person is sitting, the device allows for their knee to be bent at a 90 degree angle.

6.3.6 Manufacturability

The assistive knee exoskeleton has the ability to be manufactured in a large scale environment. For the purpose of this project, every piece was 3D printed and plasma cut with simple CAD files. No molding was necessary for developing and manufacturing every piece. The customized parts including the fanny pack and two leg blocks, did not include the use of molds, but instead the fanny pack was ordered on amazon and the leg blocks were 3D printed from a simple kinect scan of the leg. All parts were created in a streamlined process by which, if this product was manufactured in a large scale setting, it could be produced in a timely and efficient manner with appropriate materials that are required.

6.3.7 Sustainability

The final brace is composed of aluminum and PLA plastic. These parts need to be able to withstand multiple repetitions of movements per day as well as any other external wear and tear caused by the user. Also to be a low cost and low maintenance brace, the user should not be required to repurchase a new brace after a relatively short amount of time. Finding the equilibrium between quality materials, low cost, and replacement time is necessary to develop a widely accessible device. PLA has a tensile strength of 37MPa which is more than enough to withstand the walking force and the force caused by the motor [96]. The support bars, made of aluminum, have the most strain applied. The 6000 series of Aluminum has a tensile strength of around 276MPa, much stronger than PLA [89]. More testing would have to determine where the device is most likely to fail but the device should be able to last at least two year of use.

From an environmental perspective, aluminum and PLA are recyclable, which means that end-of-life parts can be put to new use instead of into the waste stream. The control hardware is entirely reusable and made of robust components that can be transferred from an old device to a new one without loss of functionality. Thus, there is no need for the electronics such as the potentiometer, cables, microcontroller, or motor driver to be thrown away either. The only aspect of the control system that may wear out with time is the Lithium Ion batteries, which can be recycled through safe battery recycling programs to avoid damage to the environment. These batteries are rechargeable, however, eliminating the need for frequent battery replacement and the resulting waste.

Chapter 7. Discussion

7.1 Objective 1: To apply user centered design principles for the ageing population to increase comfort and independence.

The final version of the prototype was created based on user needs by incorporating ageing friendly components. The under lining incorporates an antimicrobial cloth fabric to promote breathability, which is particularly important on fragile skin. The design itself minimizes bending over, and all the closures are made from velcro. Velcro is one of the more optimal closing methods for those with low gripping strength or hand arthritis. The device itself straps on with velcro as well. By utilizing customization techniques for the thigh blocks, the user can easily align their leg with the exoskeleton. The custom fit also promotes higher comfort while wearing the device. Furthermore, as the leg blocks are 3D printed, they are able to be easily reproduced as the body changes to ensure long lasting comfort.

7.2 Objective 2: To actively facilitate knee flexion and extension.

The success of the device is based on its ability to actively predict a gait cycle, change the motor output and safely assist the leg while walking. Mechanically, the device allows for enough flexion for activities of daily living, proven by gait testing. The software integrated in the microprocessor uses a baseline moment graph to take input from an abnormal gait and make adjustments to correct it.

7.3 Objective 3: To use image processing and 3D modeling software to generate and manufacture a customized orthotic.

The device interfaces with the wearer's leg by customized pieces which are contoured to the leg. For the final prototype, these pieces were 3D printed and produced for one team member's specific leg shape. This shape was obtained through 3D modeling using a Microsoft Kinect. The Skanect software package was used to create a CAD-ready model from the Kinect reading. The process of transforming the 3D scan to a custom-contoured mounting surface for the brace was done with modeling and imaging software including Blender and Solidworks. This process of scanning, imaging, and developing customized parts led to the creation of a more comfortable device with a better fit for each potential patient.

7.4 Objective 4: To utilize gait analysis for proof of concept, safety needs and functionality requirements to validate the system.

Objective 4 was accomplished by comparing results from motion capture studies. Comparing a baseline gait with the adjusted gait, when the subject had the brace on, allowed for device and safety validation. Ideally, the gait would not change in the final study because the brace was applied on a healthy subject who was assumed to produce a baseline gait. T-tests, with an alpha value of 0.05, showed that the ground reaction forces were not significantly different but knee angles and moments were significantly different. This can be explained by the added weight of the brace which creates a quicker gait cycle. While wearing the brace the subject did not have any movement restriction and the device did not harm their leg. The series elastic actuators provide increased safety by allowing the user to move against the movement of the brace when the motor is active. Gait analysis and mechanical design provide proof of concept and safety standards to ensure optimal performance.

7.5 Specification 1: Support the patient's weight at the knee during the gait cycle

The device was designed so that the gear bars are a force bearing mechanism. The weight going through the knee is distributed with the device so that the gear bars become the force bearing mechanisms. This allows the knee to not undergo a high amount of loading, which in turn affects the joint's ability to support weight. With less weight being supported by the knee joint, the development of osteoarthritis decreases.

7.6 Specification 2: Fit comfortably to the user's body and not suffer from migration

Typically, knee braces tend to fall down easily making them uncomfortable to wear throughout the day. An under lining was created to support the device and prevent migration.The design of the under lining was inspired by a garter due to its effectiveness in holding up pantyhose. The final design altered the concept to all be one piece of fabric instead of two that were connected by clips. There are two sides of the garter meant to offset the one side weighing down. This will aid in the device's ability to stay in place. Additionally, since the device is customized, it is meant to fit precisely to the user's body. The velcro attachments will aid in the device's ability to stay in place.

7.7 Specification 3: Have the leg blocks of the device be easily customizable in the manufacturing process

To complete this specification, the leg blocks were made by taking a video on the Kinect and manipulating the model in the Skanect software. This data was then converted into an STL file and printed as a gcode. This process worked efficiently and can be easily repeated with another patient. The leg block production allows for a highly customizable print, which increases comfort exponentially.

7.8 Specification 4: Cost under $1,000 to be affordable to the target audience

Item	unit price	quanitity	total cost
Bearings	0.56	4	2.24
Rods	1.8	1	1.8
Velcro Straps	0.72	3	2.16
Velcro Tape	5.28	1	5.28
3D Printer Filament	0.03	312 grams	9.36
Aluminum Parts	90.6	1	90.6
Pneumatic Tube/Fittings	9.99	1	9.99
Misc Hardware	5	1	5
Circuit Board	40	1	40
Motor	100	1	100
Motor Driver	25	1	25
Microcontroller	50	1	50
24 V Battery	50	1	50
Misc Electrical Parts	5	1	5
Nylon Fabric	20	1 yard	20
Velcro	5	1	5
thread	1	1 spool	1
Total Device Cost:			422.43

Figure 73: Cost Breakdown

The overall cost of the brace amounted to $422.43, which is less than the $1000 goal. All components of the device were added to calculate this final number. Labor is not included in this cost, thus if the device were to be produced on a large scale, the price may go up slightly. By having a low priced device, there is a higher likelihood that a larger demographic will be able to purchase the product. This will add to the device's ability to benefit not only the patients, but the healthcare system. With more people using the device, dependency on in and out patient care will hopefully decrease.

Chapter 8. Conclusions and Recommendations

8.1 Conclusion

The purpose of this project was to create a low cost, customizable, assistive knee exoskeleton aimed at the ageing population. Through gait testing the team was able to successfully determine that the device provides enough knee flexion and extension while providing walking assistance. Customizable pieces not only provide increase comfortability during long term use but the device also corrects the misalignment usually found in OA patients. Using relatively cheap parts like PLA and aluminum the team was able to reduce the costs while providing adequate durability. Sensors and other electrical components usually drive up costs in exoskeletons and are not low profile. By only using a potentiometer, the device gives successful performance while lowering costs and keeping it low profile. Future studies can help provide better gait detection and increase the amount of users' needs met.

8.2 Recommendations

The team concluded on several high priority recommendations for future work.

Recommendation 1: Biomedical Analysis

The first recommendation for the future includes more testing of the device, especially using EMG sensors. The goal of the implementation of EMG sensors was to test a wide variety of muscles that are important when a person is walking and performing activities. The EMG signals show when a person is activating a muscle to perform a motion. This would provide a better motion intent actuation by incorporating the moment cycle of the gait with the nerve stimulation of the muscles while in motion. The sole use of the potentiometer integrated in the device reduces costs while providing data on intent detection. EMG sensors could contribute toe better intent detection and with a wider range of motions. The goal of the device was to decrease the load on the knee, which should also translate to less force needed to work the muscles. Testing using EMG sensors would give the group a validation comparison on whether or not the goal was achieved. A protocol was written to start the data collection, but due to time constraints the group was unable to start the EMG testing. The protocol is listed below and the group recommends for the future to use this protocol as a backbone to experimentation.

EMG

1. Placement
    a. On clean shave skin
    b. Check SENIAM for recommended placement
        i. Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles
2. Signals processing
    a. EMG signals were pre-amplified, band-pass filtered (10–700 Hz) at a sampling rate of 2520 Hz, but not processed further.
3. Walking
    a. User presses run on the Delsys program
    b. Subject walk for five consecutive steps
    c. Stop walking
    d. User stops the program
    e. Perform test three times
4. Bending
    a. User presses run on the Delsys program
    b. Subject bend down and grab book then stand back up five times
    c. User stops the program
    d. Perform this three separate trials

Recommendation 2: Testing on OA/Knee injury subjects

Once the motor control and brace design has been iterated, to where the device works on a healthy patient, the next step would be to test on patients with osteoarthritis. This would validate the design as successful in aiding with activities of daily living, therefore increasing quality of life in an affordable manner. In order to test on people outside of the project group an IRB would have to be filled out through WPI and get approved before recruiting patients. The group had difficulty finding patients with OA who were willing to come into the lab to test. A good strategy would be to reach out to the athletic trainers at WPI as well as the student body about potential students that may have OA and are willing to test outside of class time. If there are no candidates, then another good option would be asking the athletic trainers if

they know students with lingering knee injuries that require them to use a brace. Knee injury would be an appropriate alternative to OA patients as it will make the device more universal.

Further testing procedures that the team also can use is a test called MWT, which tests how long a user takes to walk 10 meters [81]. The safety of the device will be tested using a 5-point Likert scale, (1) strongly disagree, (2) disagree, (3) neutral, (4) agree, and (5) strongly agree. This assessment will produce quantitative results of people's opinions of the safety, convenience, and efficiency of the prototype. Also for a more qualitative measurement of the device need can be achieved by an IRB approved survey, which can be seen in Appendix C.

Recommendation 3: Developing the device control system and firmware

The next steps for developing the device control systems and firmware include adding functionality to follow different types of leg motions and incorporating additional sensors. Patients with osteoarthritis struggle with climbing stairs, sitting, and standing, in addition to walking. The device already has the range of motion and power necessary to assist with these movements, but due to the complexity of detecting the user's intent and supporting these movements, implementing them was out of this project's scope. Simple code for these movements could be designed that runs when the user manually triggers it, such as through a button press. Alternatively, adding more sensors could help with automatically detecting the type of motion a user is trying to accomplish. EMGs or IMUs could provide the information necessary to detect the intended motion. The microcontroller and printed circuit board already have the capability to interface with these sensors.

This device has the capability of utilizing machine learning to further the device control system. Machine learning refers to a class of algorithms that improve their performance with experience. In many cases, it is used in situations where there is too much data for a human to analyze by hand, or a phenomenon is too complicated to model with traditional methods. Both of these situations can be problems when creating customized medical devices. Patients differ in their dimensions and physiology, and it would take a lot of effort for each device to be programmed specifically for each patient. A customized exoskeleton would benefit from adapting its software to match the wearer in order to save doctors and engineers the time of doing this by hand. Decreasing the amount of time to customize a brace for each specific anatomy will increase the quality and accessibility.

Gait varies from person to person, even when gait abnormalities are ignored, and programming a device to assist in "proper" gait can therefore be a daunting task. Machine learning has been effectively used to overcome the difficulty of assessing and modeling gait from patient to patient in medical applications. Typically, sensors like the Inertial Measurement Unit (IMU) are used, which can easily be mounted on different parts of the body to detect linear acceleration and rotational velocity. With some sample data gathered in this manner, a classification algorithm can identify which phase of the gait a patient is in while walking. A review of studies demonstrating this technique found that the research is valid and the algorithms are effective [90]. This technique could be useful for an assistive knee brace to learn a specific patient's gait, and apply the correct forces at each phase of the gait.

Although machine learning techniques are becoming more popular, they are not robust, in terms of control theory. This means that while machine learning algorithms are effective, there is no guarantee that they will converge to the correct answer every time. However, an example of a learning algorithm that is

robust is found in Bae and Tomizuka's 2012 research [91]. They used iterative learning control to improve the torque applied by an assistive knee brace based on previous strides. In other words, they determined the correct knee joint trajectory based on a "healthy" gait model, but adjusted the torque to provide more or less assistance where needed. Similar to a machine learning algorithm, the controller improved with experience, but the area of improvement was in the torque applied rather than the desired trajectory for that patient.

An effective solution to the varying needs of patients would incorporate well-known control algorithms in some places and machine learning in others. What matters is whether the desired gait and required torque are known or must be learned ahead of time. This varies depending on the application. For instance, in rehabilitation, both may be known, whereas for assistance in daily walking, both could be unknown. In this case, it is up to the software to adapt to what the patient needs.

Recommendation 4: Improve User Centered Design Components

User centered design can be greatly improved upon in this project. The main changes that can be made are to create a design that is slim enough to fit underneath clothes, further prevent migration and to improve the technique in which the patient utilizes to put the device on. In order to create a thinner design, stronger materials can be used, which would allow for slimmer versions of the force bearing bars, capstan drive and series elastic actuator to be produced. With a slimmer motor and controls, the fanny pack can be eliminated and thus the device will blend in more easily to the user's daily outfits. By promoting refined looking designs, the patient may take a higher interest in using the device regularly as they would not be embarrassed to use the exoskeleton. In addition, with frequent migration, the exoskeleton becomes unattractive if it is more of a hindrance than helping. Although preventing migration with the garter design was successful, further work can be done such as developing thicker straps with frictional properties to prevent sliding down. If the design were to become thinner, the device would potentially weigh less, which would also positively affect migration. Lastly, the exoskeleton was designed to be put on sitting down so that the elderly would not have to bend over and strain themselves. The design does still require bending down while sitting, a future design specification could be to ensure that the back would not have to surpass 45 degrees to fasten the leg components of the underlining and the exoskeleton straps.

Appendices

Appendix A: Pattern of Knee Brace
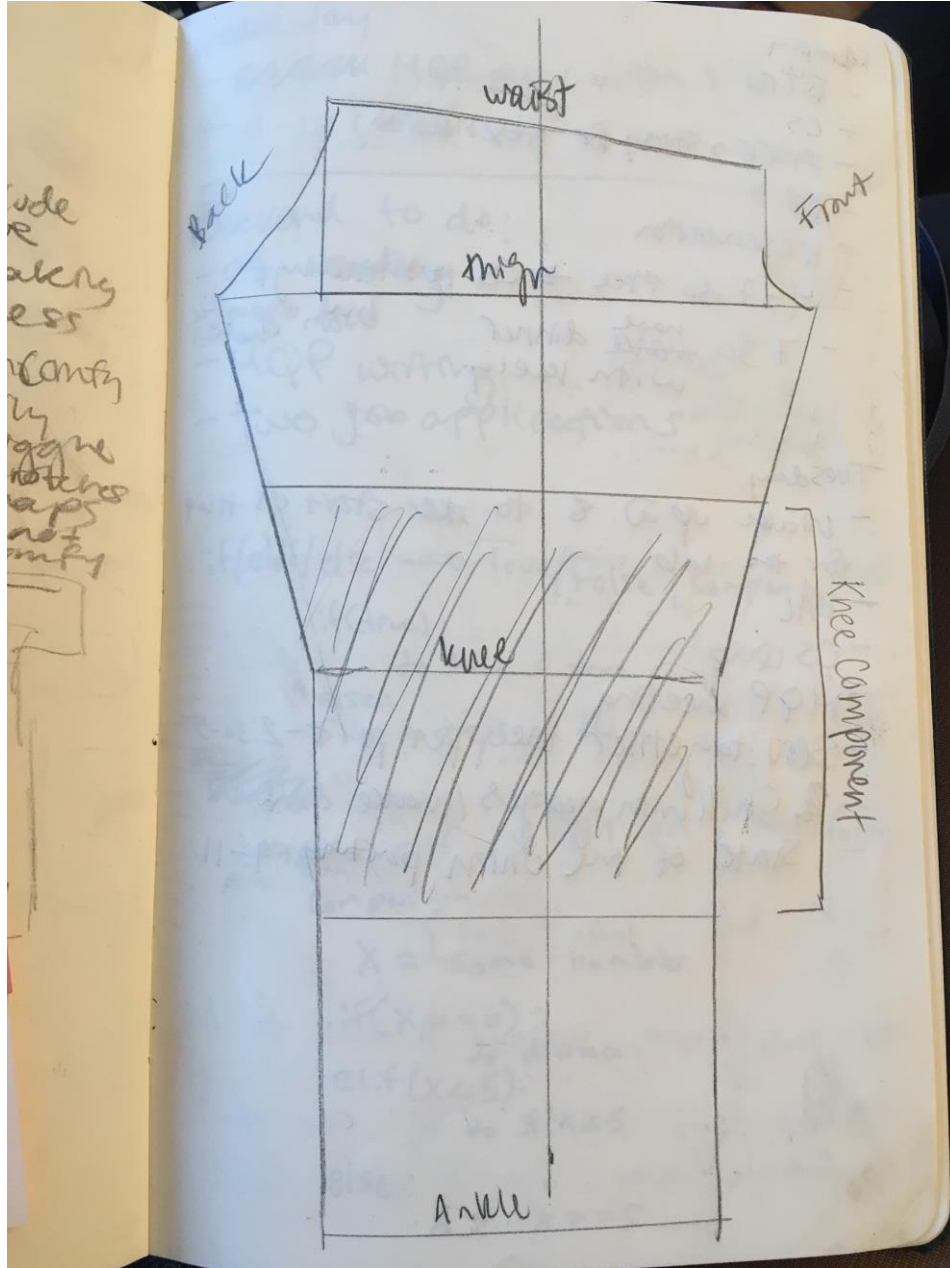
Appendix B: MATLAB Gait Analysis Code

```
%% GRF Code
filename = 'GRF Preliminary.csv';
GRF_Prelim = csvread(filename,4,0);
clearvars filename delimiter startRow formatSpec fileID dataArray ans;
%% Name Variables
LGRF_2 = GRF_Prelim(:,1);
RGRF_2 = GRF_Prelim(:,2);
LGRF_3 = GRF_Prelim(:,3);
RGRF_3 = GRF_Prelim(:,4);
LGRF_4 = GRF_Prelim(:,5);
RGRF_4 = GRF_Prelim(:,6);
LGRF_8 = GRF_Prelim(:,7);
RGRF_8 = GRF_Prelim(:,8);
LGRF_13 = GRF_Prelim(:,9);
RGRF_13 = GRF_Prelim(:,10);
LGRF_15 = GRF_Prelim(:,11);
RGRF_15 = GRF_Prelim(:,12);
LGRF_17 = GRF_Prelim(:,13);
RGRF_17 = GRF_Prelim(:,14);
Time = 0:1/60:1.93;
%% Plot
figure;
LGRF1 = plot(Time, LGRF_2,'k-');
hold on
RGRF1 = plot(Time, RGRF_2,'k-');
hold on
LGRF2 = plot(Time, LGRF_3,'k-');
hold on
RGRF2 = plot(Time, RGRF_3,'k-');
hold on
LGRF3 = plot(Time, LGRF_4,'k-');
hold on
RGRF3 = plot(Time, RGRF_4,'k-');
hold on
LGRF4 = plot(Time, LGRF_8,'k-');
hold on
RGRF4 = plot(Time, RGRF_8,'k-');

hold on
LGRF13 = plot(Time, LGRF_13,'r-');
hold on
RGRF13 = plot(Time, RGRF_13,'r-');
hold on
LGRF15 = plot(Time, LGRF_15,'r-');
hold on
RGRF15 = plot(Time, RGRF_15,'r-');
hold on
LGRF17 = plot(Time, LGRF_17,'r-');
hold on
```

```matlab
RGRF17 = plot(Time, RGRF_17,'r-');
%% Stats
Left_Avg = (LGRF_2+LGRF_3+LGRF_4+LGRF_8)./4;
hold on
LGRF_AVG = plot(Time, Left_Avg,'k-','LineWidth',2);
Right_Avg = (RGRF_2+RGRF_3+RGRF_4+RGRF_8)./4;
hold on
RGRF_Avg = plot(Time, Right_Avg,'k-','LineWidth',2);
Left_Avg_Test = (LGRF_13+LGRF_15+LGRF_17)./3;
hold on
LGRF_AVG_Test = plot(Time, Left_Avg_Test,'r-','LineWidth',2);
Right_Avg_Test = (RGRF_13+RGRF_15+RGRF_17)./3;
hold on
RGRF_Avg_Test = plot(Time, Right_Avg_Test,'r-','LineWidth',2);
xlabel('Time (sec)')
ylabel('Force (N)')
title('Ground Reaction Force Z-Direction')
set(gca,'FontSize',20)
legend([LGRF1 LGRF13 LGRF_AVG LGRF_AVG_Test],{'Preliminary
Data','Brace Data','Preliminary Data Average','Brace Data Average'})
%% Averages
figure;
LGRF_AVG = plot(Time, Left_Avg,'k-','LineWidth',2);
hold on
RGRF_Avg = plot(Time, Right_Avg,'k-','LineWidth',2);
hold on
LGRF_AVG_Test = plot(Time, Left_Avg_Test,'r-','LineWidth',2);
hold on
RGRF_Avg_Test = plot(Time, Right_Avg_Test,'r-','LineWidth',2);
title('Ground Reaction Force Z-Direction Averages')
xlabel('Time (sec)')
ylabel('Force (N)')
set(gca,'FontSize',20)
legend ([LGRF_AVG LGRF_AVG_Test],{'Preliminary Data Average','Brace
Data Average'})


%% paired t-test
[RTest_h,RTest_p] = ttest(Right_Avg,Right_Avg_Test)
[LTest_h,LTest_p] = tttest(Left_Avg_Test,Left_Avg)

%% Knee angle code
filename = 'Knee Angle Prelim.csv';
Knee_angle_Prelim = csvread(filename,4,0);
clearvars filename delimiter startRow formatSpec fileID dataArray ans;
%% Name Variables
LKA_2 = Knee_angle_Prelim(:,1);
RKA_2 = Knee_angle_Prelim(:,2);
LKA_3 = Knee_angle_Prelim(:,3);
RKA_3 = Knee_angle_Prelim(:,4);
LKA_4 = Knee_angle_Prelim(:,5);
```

```
RKA_4 = Knee_angle_Prelim(:,6);
LKA_8 = Knee_angle_Prelim(:,7);
RKA_8 = Knee_angle_Prelim(:,8);
LKA_13 = Knee_angle_Prelim(:,9);
RKA_13 = Knee_angle_Prelim(:,10);
LKA_15 = Knee_angle_Prelim(:,11);
RKA_15 = Knee_angle_Prelim(:,12);
LKA_17 = Knee_angle_Prelim(:,13);
RKA_17 = Knee_angle_Prelim(:,14);
Time = 0:1/60:1.93;
%% Plot
figure;
LKA1 = plot(Time, LKA_2,'k-');
hold on
RKA1 = plot(Time, RKA_2,'k-');
hold on
LKA2 = plot(Time, LKA_3,'k-');
hold on
RKA2 = plot(Time, RKA_3,'k-');
hold on
LKA3 = plot(Time, LKA_4,'k-');
hold on
RKA3 = plot(Time, RKA_4,'k-');
hold on
LKA4 = plot(Time, LKA_8,'k-');
hold on
RKA4 = plot(Time, RKA_8,'k-');
hold on
LKA13 = plot(Time, LKA_13,'r-');
hold on
RKA13 = plot(Time, RKA_13,'r-');
hold on
LKA15 = plot(Time, LKA_15,'r-');
hold on
RKA15 = plot(Time, RKA_15,'r-');
hold on
LKA17 = plot(Time, LKA_17,'r-');
hold on
RKA17 = plot(Time, RKA_17,'r-');
%% Stats
Left_KA = (LKA_2+LKA_3+LKA_4+LKA_8)./4;
hold on
LKA_AVG = plot(Time, Left_KA,'k-','LineWidth',2);
Right_KA = (RKA_2+RKA_3+RKA_4+RKA_8)./4;
hold on
RGRF_Avg = plot(Time, Right_KA,'k-','LineWidth',2);
Left_KA_Test = (LKA_13+LKA_15+LKA_17)./3;
hold on
LKA_AVG_Test = plot(Time, Left_KA_Test,'r-','LineWidth',2);
Right_KA_Test = (RKA_13+RKA_15+RKA_17)./3;
hold on
```

```matlab
RGRF_Avg = plot(Time, Right_KA_Test,'r-','LineWidth',2);
title('Knee Angle X-Direction')
xlabel('Time (sec)')
ylabel('Angle (Degrees)')
set(gca,'FontSize',20)
legend([LKA1 LKA13 LKA_AVG LKA_AVG_Test],{'Preliminary Data','Brace
Data','Preliminary Data Average','Brace Data Average'})
%% Averages
figure;
LKA_AVG = plot(Time, Left_KA,'k-','LineWidth',2);
hold on
RGRF_Avg = plot(Time, Right_KA,'k-','LineWidth',2);
hold on
LKA_AVG_Test = plot(Time, Left_KA_Test,'r-','LineWidth',2);
hold on
RGRF_Avg = plot(Time, Right_KA_Test,'r-','LineWidth',2);
title('Knee Angle X-Direction Averages')
xlabel('Time (sec)')
ylabel('Angle (Degrees)')
set(gca,'FontSize',20)
legend([LKA_AVG LKA_AVG_Test],{'Preliminary Data Average','Brace Data
Average'})
%% T-test
[RTest_h,RTest_p] = ttest(Right_KA,Right_KA_Test)
[LTest_h,LTest_p] = ttest(Left_KA,Left_KA_Test)

%% Knee moment
filename = 'Knee Moment Prelim.csv';
Knee_moment_withBrace = csvread(filename,1,0);
clearvars filename delimiter startRow formatSpec fileID dataArray ans;
%%
LM_2 = Knee_moment_withBrace(:,1);
RM_2 = Knee_moment_withBrace(:,2);
LM_3 = Knee_moment_withBrace(:,3);
RM_3 = Knee_moment_withBrace(:,4);
LM_4 = Knee_moment_withBrace(:,5);
RM_4 = Knee_moment_withBrace(:,6);
LM_8 = Knee_moment_withBrace(:,7);
RM_8 = Knee_moment_withBrace(:,8);
RM_13 = Knee_moment_withBrace(:,10);
LM_13 = Knee_moment_withBrace(:,12);
RM_15 = Knee_moment_withBrace(:,14);
LM_15 = Knee_moment_withBrace(:,16);
RM_17 = Knee_moment_withBrace(:,18);
LM_17 = Knee_moment_withBrace(:,20);
Time = 0:1/60:1.94;
%% Plot
figure;
LM1 = plot(Time, LM_2,'k-');
hold on
RM1 = plot(Time, RM_2,'k-');
```

```
hold on
LM2 = plot(Time, LM_3,'k-');
hold on
RM2 = plot(Time, RM_3,'k-');
hold on
LM3 = plot(Time, LM_4,'k-');
hold on
RM3 = plot(Time, RM_4,'k-');
hold on
LM4 = plot(Time, LM_8,'k-');
hold on
RM4 = plot(Time, RM_8,'k-');
hold on
LM13 = plot(Time, LM_13,'r-');
hold on
RM13 = plot(Time, RM_13,'r-');
hold on
LM15 = plot(Time, LM_15,'r-');
hold on
RM15 = plot(Time, RM_15,'r-');
hold on
LM17 = plot(Time, LM_17,'r-');
hold on
RM17 = plot(Time, RM_17,'r-');
%% Stats
Left_Mom = (LM_2+LM_3+LM_4+LM_8)./4;
Left_Mom_Test = (LM_13+LM_15+LM_17)./3;
Right_Mom = (RM_2+RM_3+RM_4+RM_8)./4;
Right_Mom_Test = (RM_13+RM_15+RM_17)./3;
hold on
Left_Mom_AVG = plot(Time, Left_Mom,'k-','LineWidth',2);
hold on
Right_Mom_AVG = plot(Time, Right_Mom,'k-','LineWidth',2);
hold on
Left_Mom_Test_AVG = plot(Time, Left_Mom_Test,'r-','LineWidth',2);
hold on
Right_Mom_Test_AVG= plot(Time, Right_Mom_Test,'r-','LineWidth',2);
title('Knee Moment X-Direction')
xlabel('Time (sec)')
ylabel('Moment (N*m)')
set(gca,'FontSize',20)
legend([LM1 LM13 Left_Mom_AVG Left_Mom_Test_AVG],{'Preliminary
Data','Brace Data','Preliminary Data Average','Brace Data Average'})
%% Averages
figure;
Left_Mom_AVG = plot(Time, Left_Mom,'k-','LineWidth',2);
hold on
Right_Mom_AVG = plot(Time, Right_Mom,'k-','LineWidth',2);
hold on
Left_Mom_Test_AVG = plot(Time, Left_Mom_Test,'r-','LineWidth',2);
hold on
```

```
Right_Mom_Test_AVG= plot(Time, Right_Mom_Test,'r-','LineWidth',2);
title('Knee Moment X-Direction Average')
xlabel('Time (sec)')
ylabel('Moment (N*m)')
set(gca,'FontSize',20)
legend([Left_Mom_AVG Left_Mom_Test_AVG],{'Preliminary Data
Average','Brace Data Average'})
%% paired t-test
[RTest_h,RTest_p] = ttest(Right_Mom,Right_Mom_Test)
[LTest_h,LTest_p] = ttest(Left_Mom,Left_Mom_Test)
```

Appendix C: IRB Survey Questions

Participant Number: Date:

Location of Survey: Time:

1. Is knee discomfort an issue for you?
    a. Yes
    b. No
    c. Other: _____
2. Do you believe an assistive device would allow you to be more independent?
    a. Yes
    b. No
    c. Other: _____
3. What activity do you have difficulty doing due to your knee pain? (Circle all applicable options)
    a. Sitting/ Standing
    b. Walking up stairs
    c. Bending over
    d. Walking for short periods of time
    e. Walking for long periods of time
    f. Other: _____
4. Do you live alone?
    a. Yes
    b. No
5. Do you have a caretaker?
    a. Yes
    b. No
6. Do you believe your knee pain is one cause that impacts your ability to be fully independent?
    a. Yes
    b. No
    c. Other:_____
7. Are there any activities that you cannot perform due to your knee pain?
    a. Yes (if so, what?_____)
    b. No
8. Do you want to live alone?
    a. Yes
    b. No (if so, why not _____)
9. Have you used any other devices before?
    a. Yes (If so (circle one) a. Brace b. Exoskeleton c. crutches d. Cane e. Other: _____
        i. What did this help you with?
        ii. _____
        iii. Where did you wear this device?

   iv. _____

  b. No

10. Would you prefer the device to have the ability to be worn under clothing?
  a. Yes
  b. No
  c. *Have a conceptual picture to show size here*

11. How would you prefer the device to be placed?
  a. Slip on
  b. Clipped on
  c. Strapped on
  d. Other: _____

12. How many hours each day would you like to use the device, based on your activity level?
  a. 1 hour
  b. 2 hour
  c. >5 hour
  d. >10 hour
  e. Other:_____

13. How much are you willing to pay for an assistive device?
  a. <$500
  b. <$1,000
  c. <$5,000
  d. <$10,000
  e. <$20,000
  f. Other:_____

13. If the aesthetics are pleasing, are you willing to wear a device in public or just within your house?
  a. House
  b. Outside
  c. Other: _____

14. Pictures of different brace designs, ask which one they would prefer to wear, or rate them, etc

15. What are you hoping to gain from an assistive device?

_____

_____

_____

_____

_____

_____

_____

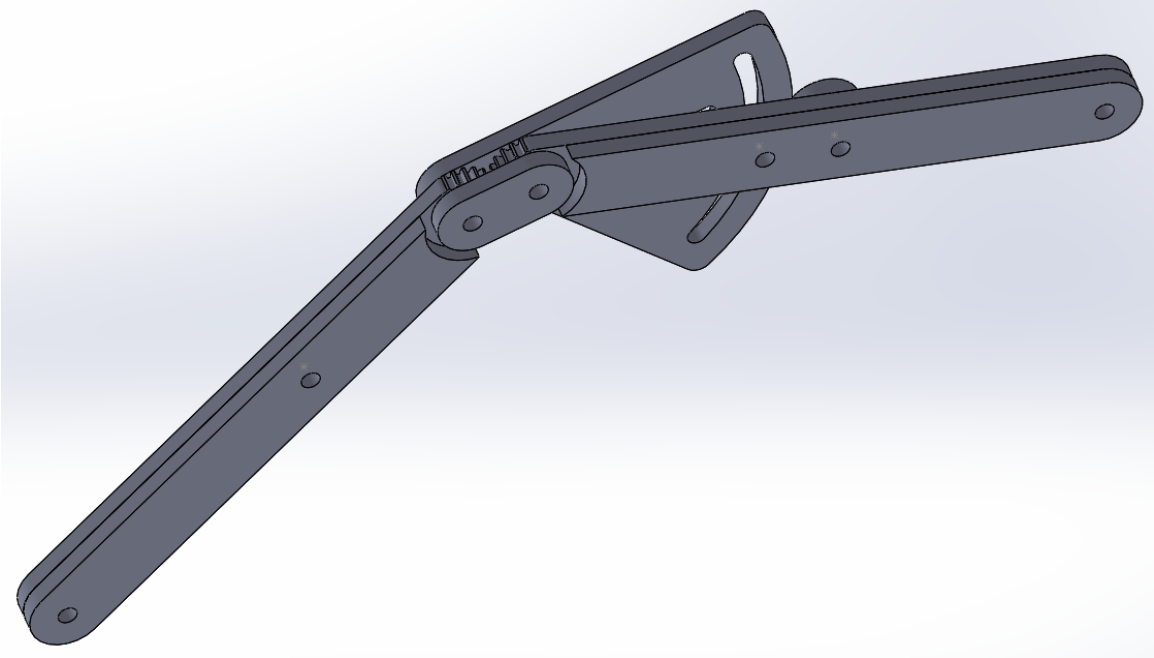# Appendix D: Images of Mechanical Device Iterations
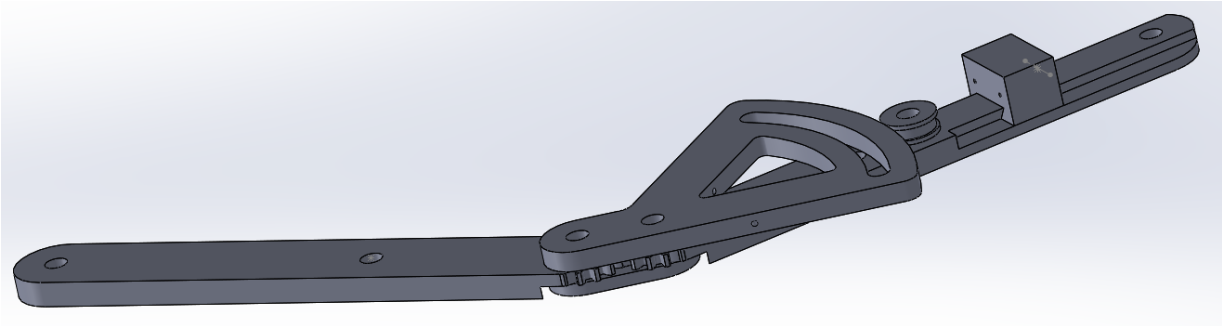
Figure 74: Mechanism Design Iteration 1

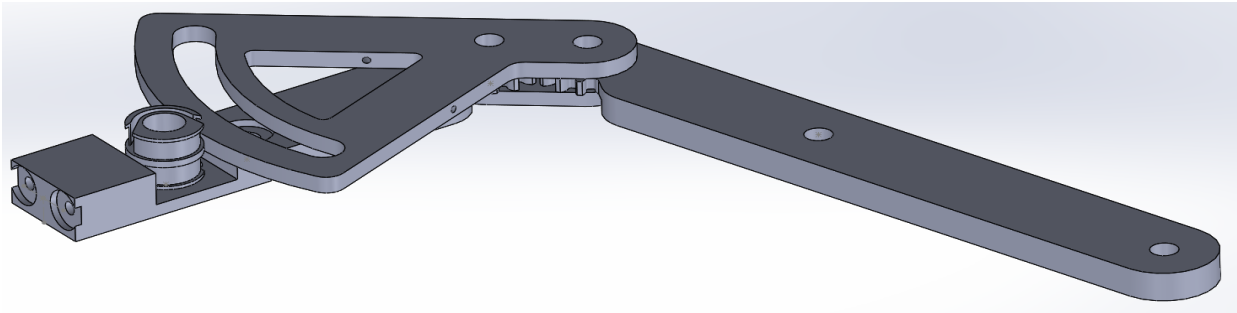Figure 75: Mechanism Design Iteration 2
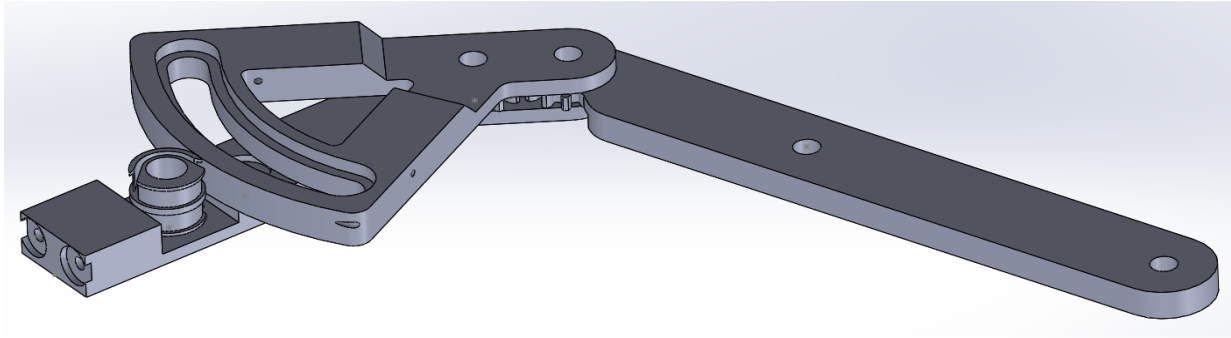
Figure 76: Mechanism Design Iteration 3

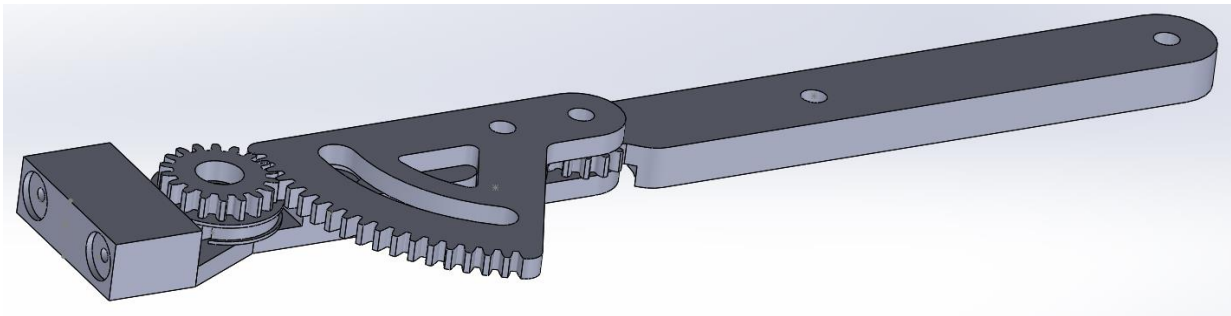Figure 77: Mechanism Design Iteration 4

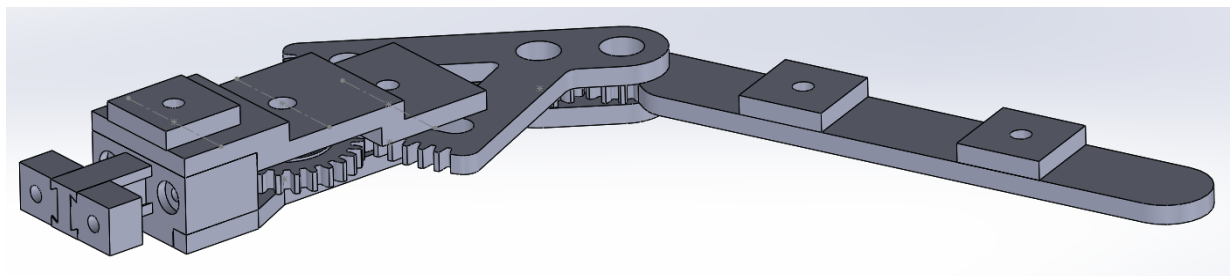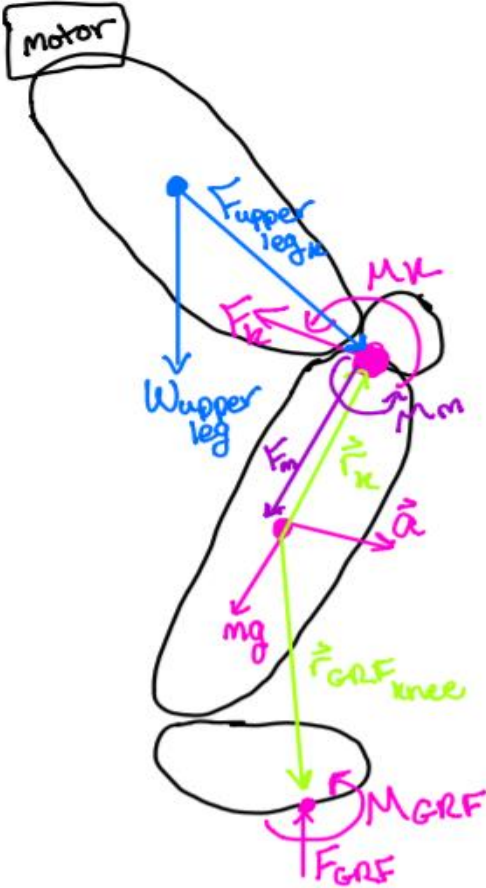Figure 78: Mechanism Design Iteration 5

Figure 79: Mechanism Design Iteration 6

Appendix E: Reference Frames for Equation 1

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