Developing a Knee Prosthesis

A Major Qualifying Project Report Submitted to the Faculty of
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for the Degree of Bachelor of Science

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Abstract

Millions of people need above-the-knee prostheses, yet their designs are not perfected. The goal of this project was to create a knee prosthesis that aids users in traversing stairs with greater ease than current knee prostheses. Our prosthesis utilized a four-bar mechanism to mimic the motion and forces a healthy knee sustains; the prosthesis resulted in an improvement in knee flexion angles while walking and stair traversing compared to current models. Overall, our prosthesis successfully met the necessary design goals.

Executive Summary

Our MQP (Major Qualifying Project) spanned our senior year at WPI. We designed a knee prosthesis with goals of being cost effective and providing the user with a greater range of motion while traversing stairs.

A higher percentage of lower limb amputees utilize prosthesis post amputation in comparison to individuals who receive an upper limb amputation. Lower limb prostheses are divided into two categories – above and below the-knee – where above-the-knee prostheses are more complex due to relying on a knee joint. These knee joints are either single-axis or polycentric, and while there are benefits to both designs, the polycentric knee improves the stability and swing phase issues existing in the single-axis knee during a normal walk. Due to the complex structure of the human knee, researchers classify each prosthesis based on activeness, or K-levels. For example, stair climbing is level 2, while level 3 allows the users to traverse most environmental barriers. Depending on the K-level, engineers attempt to mimic the angles, rotation, and anterior-posterior (AP) displacement of healthy knees in the design of knee prostheses.

While walking and traversing stairs may seem like a trivial matter for most people, these actions are difficult for leg prosthesis users. By comparing the knee flexion angle of ascending and descending stairs for healthy knees to prosthesis users, it is apparent that the general motion is maintained, but the prosthesis fails significantly more to replicate the range of angles or nuances of a healthy knee compared to a normal gait walk. Forces in the knee also differ when climbing stairs compared to horizontal walking. When people climb stairs, the forces they exert are approximately four times their body weight, whereas the forces during the gait cycle is about 1.5 times the body weight. Lower limb amputees find it difficult to ascend and descend stairs with the current prostheses on the market. Therefore, this project was created to improve the design, functionality, and forces acting on above-the-knee prostheses for K3 level users.

In order to accomplish the goal of the project, the following functional constraints and prototype goals were established.

To guarantee the functional constraints, the knee prosthesis must:

1. Apply to a specific section of the United States of America's population between the ages of 20 and 30 years.
2. Match or exceed a K-level of 3 for single leg amputees.
3. Permit a person to walk an extended period without significant additional fatigue.
4. Allow a person to ascend stairs safely and comfortably with minimum trip potential.
5. Maintain or improve the following factors relative to other knee joint prostheses on the market: Compatibility, Lifespan, and Cost

To meet the prototype specifications, the knee prosthesis must:

1. Match knee flexion angles metrics during gait cycle.
2. Match knee flexion angles metrics during stair climbing.
3. Match forces metrics during gait cycle and stair climbing.
4. Be a lightweight, inexpensive knee joint that weighs less than the ones on the market.

The knee joint prosthesis will undergo virtual simulations and physical experiments to determine if it meets these metrics. Testing will be conducted through *Solidworks 2021* for virtual simulations, and physical testing will involve each group member measuring the knee joint prosthesis angles and forces. All results will be compared to existing data of healthy knees from the literature. To create the final knee joint prosthesis design, an iterative process was utilized, which can be seen in Figure 3.1 subsequently. Each iteration was evaluated to determine if the design fulfilled the needs of a knee joint or if changes were required.

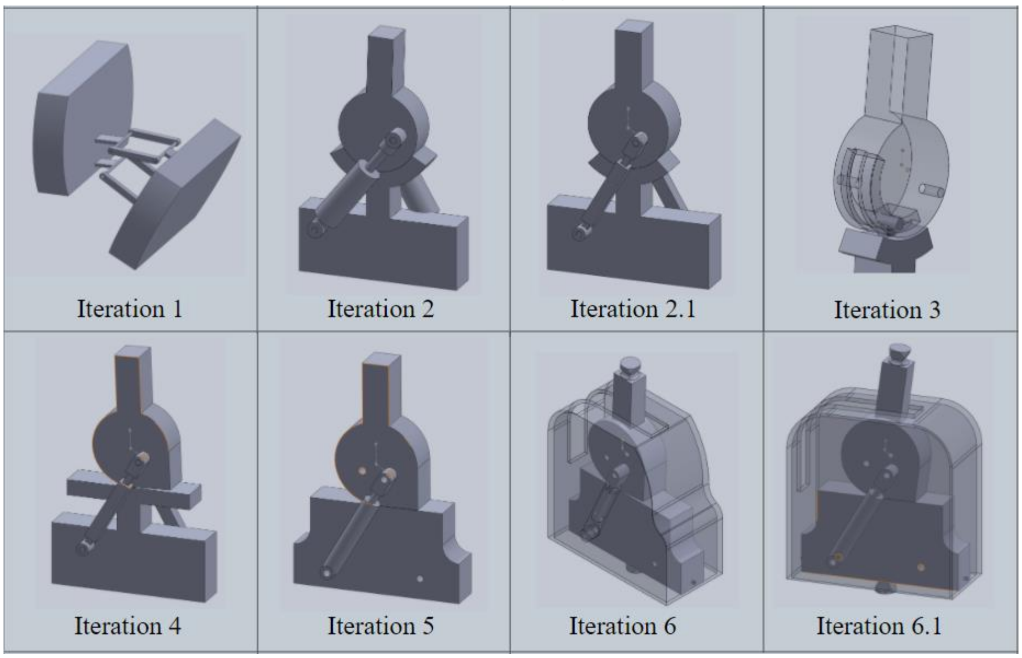

Figure 3.1: Knee Joint Prostheses Iterations

The prototype successfully imitated the motion required for walking and traversing stairs as determined by the prototype simulation, physical testing, prototype specifications, and functional constraints. By applying all three metrics – knee flexion angle, AP motion, and applied forces – to the PLA model, the prototype far exceeded the properties of current knee joint prostheses on the market. However, the forces acting on the PLA prototype had to be scaled down due to having different material strength. Therefore, the proposed clinical trial prototype would be stainless steel for the load-bearing components and a lighter polymer for the prosthetic cover since it could better handle the forces exerted from a 266-pound person. Some of the constraints, such as fatigue testing and prototype lifespan, could not be evaluated due to a lack of resources. The prototype exceeded the goals for imitating the gait cycle flexion angles, stair climbing flexion angles, normalized forces acting on the cycles, and manufacturing of the prototype. Therefore, the goal to create a cost-effective and widely available knee joint prosthesis that improved the user's ability to ascend and descend stairs was achieved.

Acknowledgements

The authors of this report would like to thank the following people who contributed to the success of our project. First off, we would like to thank Tsuiyee Ng and Aidan Kennedy for their assistance in additive manufacturing and troubleshooting the analysis of the prototype in *Solidworks 2021*. Furthermore, we would like to acknowledge the Foisie Prototyping Lab for aiding in the manufacturing process. Lastly, we want to thank our advisor, Professor Sullivan, who provided us with incredible guidance and supported us throughout the entire project.

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Chapter 1 – Introduction

There are many ways an individual can be healthy, from physical to mental to emotional. Living a healthy lifestyle helps prevent chronic diseases and long-term illnesses; it can also raise the self-esteem and image in individuals (Maintaining a Healthy Lifestyle, 2016). Through physical activity, nutrition, and self-care, people can ensure they are on the right path to a healthy lifestyle. One important aspect of staying physically healthy is as simple as being able to walk everywhere you go. Studies have shown that increasing the distance walked by a small amount increases health benefits, such as lowering the risk of cardiovascular diseases (Diehr & Hirsch, 2010). Furthermore, walking is also beneficial as it is a form of exercise that does not require equipment or take a lot of time out of an individual's day. Additionally, chronic disease risk decreases, health care costs are lowered, and few injuries are sustained when people utilize walking for their exercise (Lee & Buchner, 2008).

Despite the many benefits of walking, not everyone has the ability to walk on their own, no matter how healthy they may be otherwise. People with leg amputations, whether through a medical procedure, an accident, or an existing condition, lack the ability to walk without the use of some form of assistance. In the United States of America (USA), over 2 million people have limb amputations and the number continues to rise (BioTech Possibilities, 2019). Some of the limb loss derives from unforeseen accidents with lawn mowers or motor vehicles while others are from birth defects. They are also due to casualty of war, where approximately 40,000 veterans throughout history have received amputations (McGimpsey & Bradford, n.d.). Accidents and war play a significant role in amputation cases; however, the majority of limb loss per year is the result of disease. Every year, there are around 185,000 people requiring limb amputations due to disease (George et al., 2018). The type of diseases include malignancy, trauma, periprosthetic joint infection, and especially to diabetes and peripheral vascular disease.

Assistant devices come in various forms depending on the location of amputation, but arguably one of the best forms for lower limb amputation is a prosthetic leg. However, the market for prosthetic knee joints – which benefit individuals with an above-the-knee amputation – does have its disadvantages that go alongside the advantages. One such disadvantage is that undergoing an amputation can be costly on the individual, not only mentally but also financially. Users need to purchase prostheses to compensate for their missing limb, and as with most items, the better the prosthetic, the more costly it becomes. Therefore, it is imperative that a strong, successful knee prosthetic be created in a cost-efficient manner.

In addition to prostheses being costly, many users of knee prostheses have a difficulty in traversing stairs; therefore, we, a group of students from Worcester Polytechnic Institute (WPI), will endeavor to engineer a new knee prosthesis that will be more cost efficient to the buyer as well as provide the user a greater range of motion while traversing stairs.

Chapter 2 – Background

Limb amputations are divided into two categories: upper limb and lower limb. Upper limbs include the arms, while lower limbs consist of the leg and foot. The frequency of lower limb prosthesis use is nearly double that of upper limb prostheses; therefore, the focus will be on lower limb amputations for the project. This chapter defines key terms used in the anatomy and physiology of the knee, lower limb prosthetics, current components of knee prosthesis as well as the materials and overall cost. This research will aid in understanding what the prosthetic market is lacking and how those gaps could potentially be filled.

2.1 Anatomy and Physiology of a Healthy Knee

The human body is composed of numerous complex systems including the knee. It consists of multiple bones, ligaments, and muscles working together. Each component plays an essential role in providing people with the ability to complete simple, daily tasks, such as walking, carrying items, and sitting. In order to create a successful knee prosthetic, it is important to understand the general anatomy and physiology of the knee and to create working models to replicate such geometries and functions.

2.1.1 Planar Motion and Types of Movement

There are three main anatomical planes that describe the positions on the human body: sagittal, frontal (coronal), and transverse, as depicted in Figure 2.1. The sagittal plane splits the body into left and right sections by appearing vertically from the front to back. The frontal plane cuts the body vertically; however, unlike the sagittal plane, the frontal plane cuts the body from the anterior to posterior sections. Lastly, the transverse plane divides the body horizontally into upper and lower regions, typically at the center of the body.

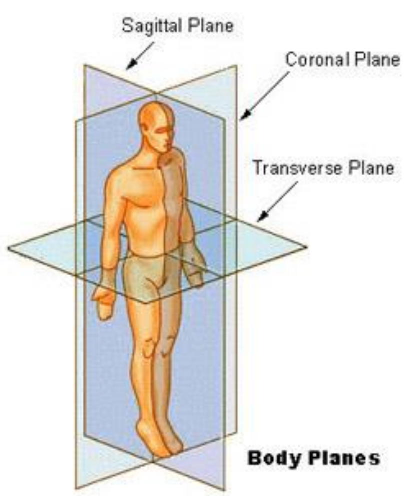


Figure 2. 1: Body Plane (*Anatomical Terminology | SEER Training*, n.d.)

In general, the body can perform over ten types of movements. Some of the most prominent types of movement are flexion and extension as shown in Figure 2.2. Flexion occurs when the angles between two body segments decrease; extension occurs when the angles increase. Another important movement is called abduction. Abduction occurs only when limbs move away from the frontal plane. Reversely, adduction takes place when limbs move towards it. Due to the complexity of the human structure, certain areas of the body can perform multiple types of movement.

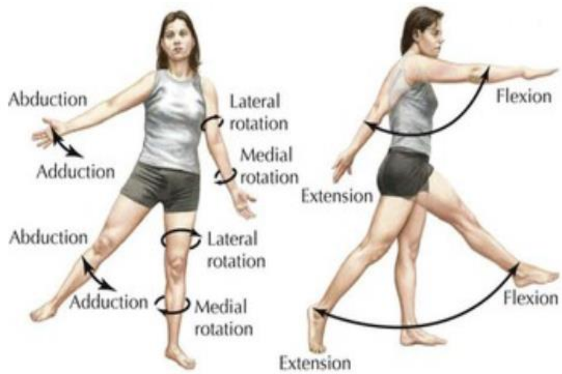


Figure 2. 2: Body Movement (I*ntroduction to Anatomy*, n.d.)

2.1.2 Knee Joint Movement and Components

The human knee joint is a hinge joint, and its scientific name is tibiofemoral joint since it joins the tibia and femur bones. Hinge joints move on one plane and are composed of two or three bones as illustrated in Appendix A. These joints consist of a synovial capsule that is filled with fluid. This reduces the friction between the bones to allow smooth movement. Furthermore, the capsule is surrounded by dense, flexible connective tissue that permits movement without dislocation (Abulhasan & Grey, 2017). The knee's hinge joint also involves the femur and tibia, which permits the knee to move in six degrees of freedom as shown in Figure 2.3. The knee's greatest range of motion takes place about the sagittal plane where it can flex and extend about 145 degrees. The second largest range is on the transverse plane where the knee can rotate internally and externally. The internal rotation can rotate up to 30 degrees, while the external rotation is about 45 degrees. The last range of movement for a flexed knee occurs when the knee abducts (valgus) and adducts (varus) on the frontal plane. For both, it can move up to 30 degrees without strain (Zatsiorsky, 2002).

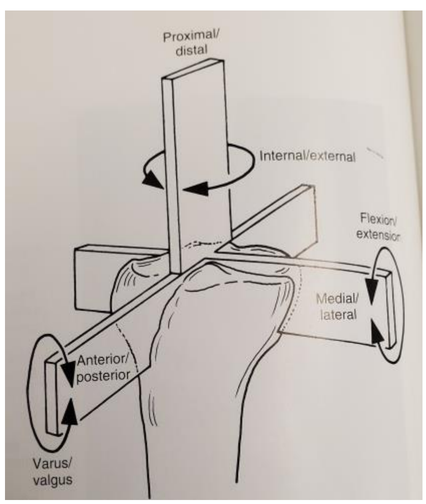


Figure 2. 3: Knee Joint Degrees of Freedom (Nordin & Frankel, 2001)

2.1.3 The Movement of Knees

In order for knees to move, they have two types of stabilizers. The primary stabilizers consist of ligaments and cartilage, while the secondary stabilizers involve muscles. Primary stabilizers consist mainly of two collateral ligaments and two cruciate ligaments as shown in Figure 2.4. These ligaments prevent the displacement of the tibia in the frontal and transverse plane relative to the femur. One key ligament is the anterior cruciate ligament (ACL). It accounts for 85% of knee stabilization, allows flexion, and permits rotation up to 20 to 30 degrees without incurring significant strain (Abulhasan & Grey, 2017). In addition, the articular cartilage helps smooth joint movement and absorbs impact, while the cavities reduce friction by retaining fluid.

The other stabilizer is called a secondary stabilizer, which involves the muscles surrounding the leg, and their main role is to produce motion. These muscles are divided into two categories: anterior and posterior muscles. Anterior muscles predominantly involve the quadriceps muscles; their main function is to extend the knee. On the other hand, posterior muscles' role is to flex the knee by using the hamstrings.

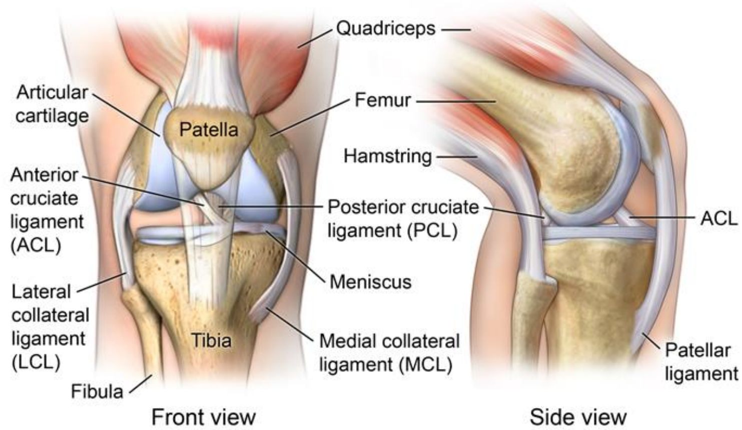


Figure 2. 4: Knee Anatomy (*Anatomy of the Knee*, 2016)

Consequently, anatomical knees are complex systems that comprise various components such as the primary and secondary stabilizers. The ligaments, cartilage, and bone must work synchronously to provide the ability to move. Without all of these parts working together, it would inhibit locomotion.

2.2 Lower Limb Prostheses

Lower limb amputees can undergo two types of amputations: above-the-knee and below-the-knee. Both knee prostheses are complex devices that imitate leg functions, and they consist of a socket, pylon, and foot. However, below-the-knee prostheses rely on the ankle joint, while above-the-knee prostheses depend on both the ankle and knee joint, as shown in Figure 2.5. Above-the-knee prostheses tend to be more complex due to the various components. Additionally, less research has been done on the knee versus foot prosthetics. Therefore, the focus lied with above-knee prosthesis, specifically the knee joint, which will be discussed in the following section.

Figure 2. 5: Above and Below Knee Prosthesis (*Above Knee Leg Prosthetics*, n.d.) and (*Below Knee Leg Prosthetics*, n.d)

In both above- and below-the-knee amputations, users receive a custom-made shrinker that fits around their residual limb. The shrinker helps heal and control any swelling that may occur. Once the user is accustomed to the shrinker, they receive a liner to place over their skin to reduce forces acting upon the limbs. The liners can be personalized to the user's preference such as activity level, skin issues, hand dexterity, and shape. The liners are typically fitted to the user, but there are also less-expensive, off-the-shelf liner options. For first time prosthesis users, a diagnostic socket is used to determine a good suspension method, know where their weight aligns, and check alignment. Finally, once the socket modifications are confirmed, the user will be given a laminated socket made of carbon fiber since it is a durable, lighter, and long-lasting material (Above Knee Leg Prosthetics, n.d.).

Lower limb prostheses are classified by K-level, which are levels given by Medicare to classify prostheses based on activeness (Balk, 2018). These levels define the amount of activity the user is capable of and can perform on a regular basis. K-levels cover a wide range of motion, and Table 2.1 delineates the K-Level classifications.

Level 0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
Level 1	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
Level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Table 2. 1: Medicare Functional Classification Levels (Balk, 2018)

2.3 Types of Knee Prostheses

While there are more than 100 knee mechanisms on the market today, all knee prostheses can be broken into two groups: single-axis knees and polycentric knee prostheses. While single-axis knees mechanically operate as a single hinge, polycentric knees have multiple axes of rotation. All prosthetic knees, whether single-axis or polycentric, require additional mechanisms for stability and motion control (Dupes, 2019). Stability mechanisms typically consist of manual locking systems or weight-activated locking systems, sometimes referred to as stance control. For control of motion, mechanisms used can provide constant or variable friction as well as hydraulic and pneumatic control through fluid dynamics. Researchers have also developed computerized knees that utilize microprocessors and sensors. These knees can detect changes in the user’s surroundings to provide more varied movement and improve the function of current mechanical knees. Images of the types of knee prosthetics can be found in Table 2.2 and 2.3.

Single Axis Knee Joint		Polycentric Knee Joint	
Manual Locking System		Weight-Activated Locking System	

Table 2. 2: Axis and Stability Control Knee Joints (*Above Knee Leg Prosthetics*, n.d.)

<table>
<tr><td>Friction Knee Joint</td><td></td></tr>
<tr><td>Hydraulic and Pneumatic Knee Joint</td><td>

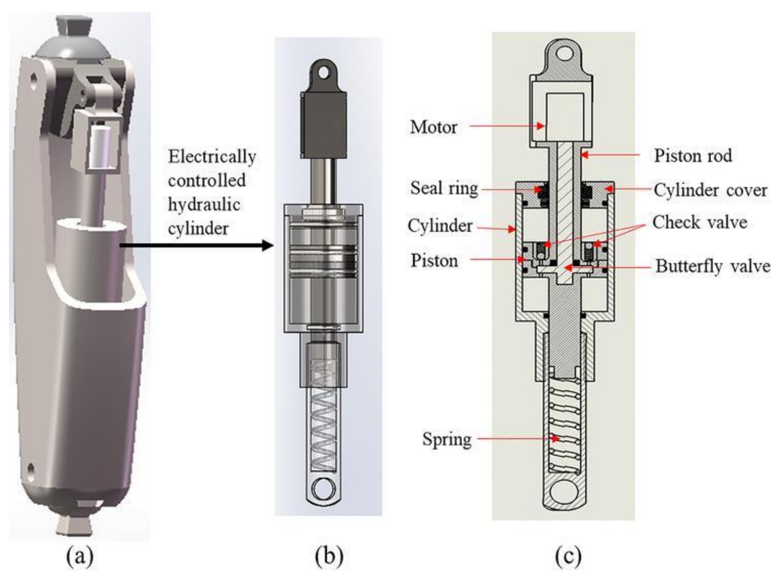

</td></tr>
<tr><td>Microprocessor</td><td>
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Table 2. 3: Motion Control Knee Joints (*Guardian Friction Knee*, n.d.), (*3R80*, n.d.), and (Zhang et al., 2020)

To understand the challenges of certain knee elements, it is imperative to understand the gait cycle, also known as the process the leg undergoes while the user walks. The gait cycle is broken into two phases: stance and swing. The stance phase consists of the initial contact (heel strike), loading response, mid-stance, terminal stance, and pre-swing (toe-off), while the swing phase includes the initial swing, mid-swing, and terminal swing. In addition, at each phase of the gait cycle, the leg experiences a moment (about the hip, knee, and ankle) and a force acting on the foot when it makes contact to the ground. The phases of the gait cycle and the forces about the knee are outlined in Figure 2.6.

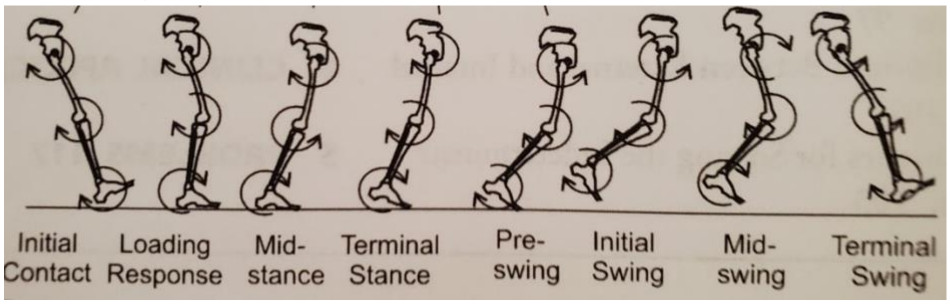


Figure 2. 6: Gait Cycle with Moments and Forces (Mow and Huiskes, 2005)

2.3.1 Axis Design: Single Axis versus Polycentric Knee Joints

Single-axis knee joints are the most basic knee joint and aimed towards older, less active users. With no additional elements, it is a simple hinge that has pure rotation about a single line and a K1 activity level (Monocentric (single axis) knees, n.d.). This knee joint has many advantages: it is cost-effective, lightweight, and durable. In order to increase the capabilities of single-axis knees, they are often combined with stance control to maintain stability when standing, friction to regulate the swing speed, and may feature a manual lock. However, there are some disadvantages such as not adapting to different walking speeds. The user must also use their own muscular strength to keep the knee locked in extension without the help of a locking system. Single-axis knees also fail to imitate the anatomical leg during the gait cycle; the effective length of an anatomical leg naturally shortens to provide floor clearance during the gait cycle. According to Moosabhoy 2006, foot clearance "is not defined by any single joint in the kinematic chain…Rather, it is a product of progressive, coordinated movements of the pelvis and of the hip, knee, and ankle joints of both swing and stance limbs during walking." In an above-the-knee amputee, they can only use their hip joint to contribute to this shortening and typically need assistance from their prosthetic, which a single-axis knee does not provide. In order to achieve this, single-axis legs must be shortened to provide floor clearance during the swing phase of the gait cycle. Furthermore, the knee joint may be noisy or increase risks of stumbling.

The most common structure for a polycentric joint is a four-bar mechanism; however, more complex designs exist that utilize more bars for varied movement. A four-bar mechanism, also known as a four-bar linkage, is a closed-chain linkage that consists of four bars. The four-bar mechanism allows for three types of motion: full rotation, oscillation, and oscillation with full rotation (Four Bar Mechanism, n.d.), which can be seen in Appendix B. Figure 2.7 shows eight snapshots of the four-bar mechanism as the knee flexes and extends where II is approximately toe-off and VII is heel-strike. The four bars are as follows in II: the blue, horizontal link, a, is on the surface of the tibia, link b is at a downwards angle on the femur, link c represents the posterior cruciate ligament (PCL), and link d is the ACL. Even though links a and b are located on the tibia and femur, respectfully, a is fixed, while link b moves with links c and d. In addition, link c rotates about point ac, but link d rotates, extends, and compresses itself during the motion. With all four links working simultaneously in the knee, it produces locomotion.

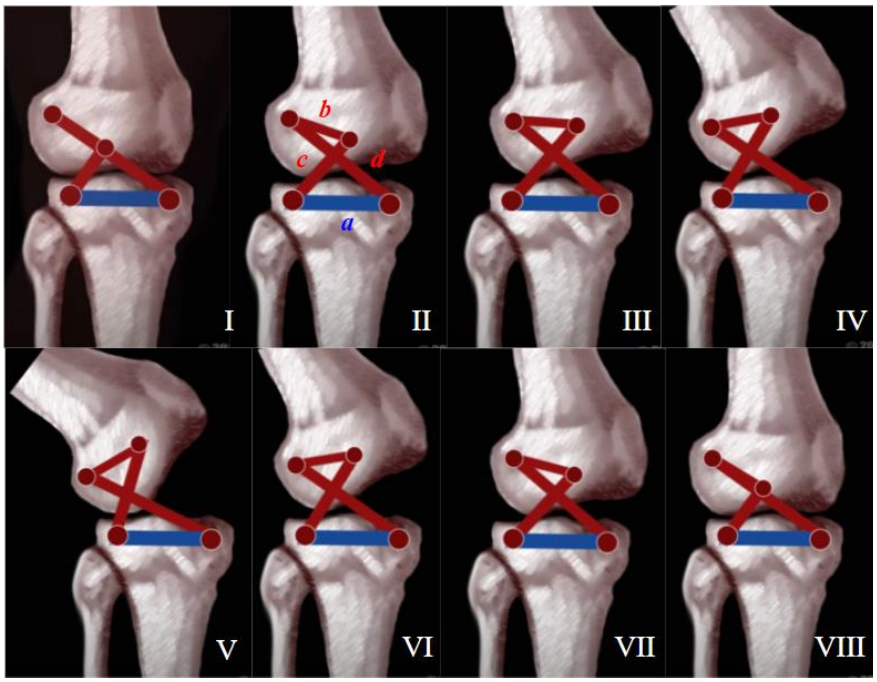


Figure 2. 7: Four-Bar Mechanism of Knee (*Four-Bar Mechanism of the Knee*, n.d)

The complex structure of polycentric knees also allows for the center of rotation of the prosthesis to be located above the knee joint. This not only better replicates the movement of the human knee than a single-axis knee prosthetic, it also adds stability to the knee. With a higher center of rotation compared to a single-axis joint, a polycentric knee adds stability by requiring less muscular energy from the user to keep the knee locked in extension. Another benefit to polycentric knees is their capability to shorten during the swing phase, which is similar to the human knee joint as mentioned above (Greene, 1983). Figure 2.8 shows how the polycentric knee replicates this shortening.

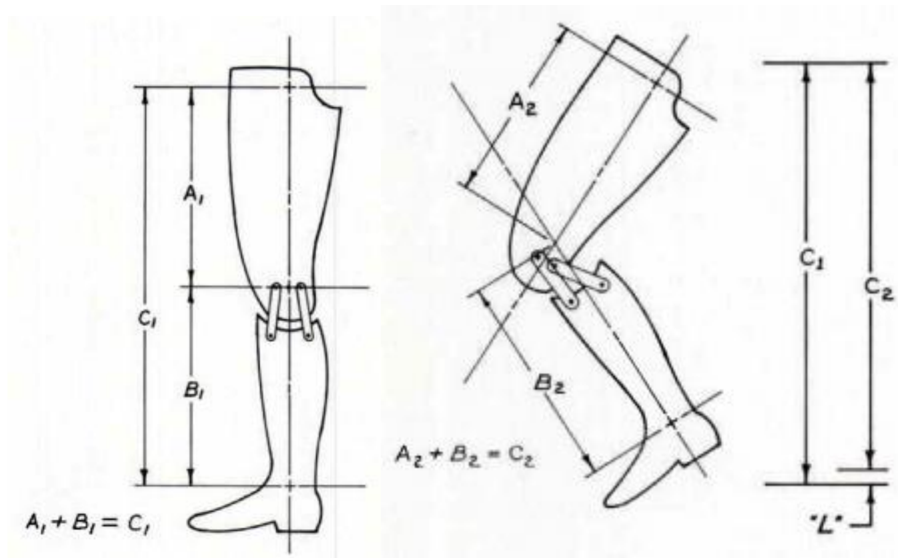


Figure 2. 8: Polycentric Knee Shortening with Swing (Greene, 1983)

Despite the benefits polycentric knees offer, they have limitations. Polycentric knees are heavier and may need to be repaired more often than single-axis knees due to the number of parts they contain. Furthermore, the range of motion of polycentric knees may be more limited, but this is not a significant issue (Dupes, 2019).

In conclusion, there are benefits to both single-axis and polycentric knees. While the polycentric knee improves upon stability and swing phase issues existing in the single-axis knee, its increased complexity makes it more expensive and difficult to repair. Single-axis knees are simpler in design, making them inexpensive and easier to repair, but they rely on locking systems to provide stability and sometimes need to be shortened to allow for swing clearance. Choosing between the two of them depends on the patient's need and lifestyle. In addition, it will depend on additional stability control and motion control elements in the knee.

2.3.2 Stability Control: Manual versus Weight-Activated Locking Systems

In some amputees, locking systems add stability to help prevent knee buckling while the leg is bearing weight in the stance phase. This issue is most prevalent in single-axis knees; therefore, locking systems are most often found in single-axis knee designs but are occasionally incorporated into polycentric knee designs.

Manual locking knees are one of the most stable options for locking systems and consist of an automatic lock that engages when the leg reaches full extension. Furthermore, the user can lock and unlock the knee voluntarily. They can walk with the knee locked, but it causes the user to expend additional energy and to walk awkwardly. Knees with manual locking systems are usually rated at a K1 level and are commonly used in weaker, older users or for active users that need to adapt to different terrains.

Weight activated or stance control knees are another stable option, and they are often someone's first prosthesis. When the leg is in the stance phase and weight is applied, the system locks to prevent buckling or excessive muscle usage. When that weight is lifted, the lock disengages and swings freely. Knees with this element are typically rated at a K-level 1 or 2 (Dupes, 2019).

2.3.3 Motion Control: Friction, Hydraulic and Pneumatic Knee Joints, Microprocessors

Both single-axis and polycentric knee joints fail to replicate the time and speed of the swing of the leg. Consequently, motion control additions such as friction, hydraulic and pneumatic systems, and microprocessors can be added to the knee design to alter the timing of the knee movement.

Many single-axis knee prosthesis joints utilize a constant friction design in order to control the amount of friction being placed on the knee joint (Murray, 1983). The design is inexpensive, provides damping during the motion of the swing phase of walking, and limits the heel rise prior to the heel strike while walking. Due to the simple design, there is little need for servicing, thus making the design even more affordable for users. However, there are limitations to the single-axis prosthesis that have constant friction; one limitation is that the joint only swings correctly when it is at one fixed cadence. Additionally, the user of the single-axis controlled friction knee prosthetic is unable to walk at a different speed or on irregular surfaces. Therefore, this knee prosthetic is most suitable for K1 or K2 levels.

Some polycentric knee prostheses offer friction swing phase controls, which have more advantages than the single-axis constant friction designs. While the polycentric knee design has the same disadvantage of only being suitable for one walking speed, they have a larger toe clearance during the mid-swing stage of walking (Murray, 1983). This benefit is achieved using a four-bar mechanism that allows the prosthetic to move and increase the knee flexion.

Hydraulic and pneumatic knee prostheses have a K-level of three or four and use fluid dynamics to provide variable resistance. This variable resistance controls the knee's speed of motion. While both types of knee prostheses use pistons, pneumatic elements compress air while hydraulic elements compress a liquid. Pistons operate by compressing and storing energy when the knee flexes and releases that energy as the knee extends. Hydraulic knee prostheses are beneficial because they provide stance phase control as well as swing phase control (Keeratihattayakorn, 2019). This additional control that hydraulic knees provide allows them to be classified at a K-level of three or four. However, they are not without their downsides. Some drawbacks to hydraulic knees are that they tend to be heavy, require more maintenance, and have a higher initial cost (Keeratihattayakorn, 2019). Pneumatic knee prosthetics have their own advantages. With the ability to power the joint, the pneumatics provide torque to aid the user in level walking and stair climbing (Wu & Shen, 2017). The disadvantages to pneumatic knee prostheses are similar to those of hydraulic knee prostheses: costly, heavy, and require more maintenance.

Microprocessor knees utilize sensors to detect the user's movement and subsequently adjust elements within the knee to produce a more natural walking movement. These designs are newer, and many are still in development (Dupes, 2019). Despite mainly occupying the developmental stage, microprocessor knee prosthetics already exhibit benefits and drawbacks. Microprocessor knees allow the user to use less energy to walk while simultaneously providing the user with a more natural gait (*Prosthetic Knee*, n.d.). In addition, the user can easily ambulate at varying speeds and assist in helping the user stay upright when they may have otherwise tripped. Despite the copious advantages, the cost of microprocessor knees is a large downside. The prosthesis tends to weigh more than other knee prostheses and has an additional disadvantage of needing to be charged. Finally, the prosthetic requires regular servicing in order to stay in optimal shape.

2.4 Ankle and Foot Prosthesis

An important component of above-the-knee prostheses is the ankle and foot prosthesis. Similar to knee and leg prostheses, ankle and foot prostheses are designed around certain K-levels; therefore, it is imperative that the K-levels of each prosthetic match the user to ensure a certain level of activity range. In addition, the comfort and feel of a prosthetic foot is important; the more comfortable the prosthesis is, the easier it will be for the user to be more active and function as designed. There is an abundance of foot and ankle prostheses on the current market, and each offers its own benefits and drawbacks. However, the ankle and foot prosthesis will not be considered in the scope of the project

2.5 Gait Cycle Analysis Between Healthy, Single Axis, and Polycentric Knees

Due to the complex structure of a human knee, engineers attempt to mimic the angles, rotation, and anterior-posterior (AP) displacement of healthy knees in the design of knee prostheses. Figure 2.9, subsequently, illustrates the origin and reference point on the gait cycle to the knee flexion and extension angles. As mentioned previously, flexion occurs when the angles between two segments decrease, while extension takes place when the body segments increase. With the knee flexion graph, as the value goes above zero degrees, flexion is occurring; when the value goes under zero degrees, it is an extension movement. In the gait cycle, the red line forming the top of the “T” is the transepicondylar axis, defined in Appendix C, while the vertical red line is perpendicular to create the coordinate plane. Furthermore, the blue line is the tibial shaft axis at each stance of the gait cycle. To determine the angles of flexion, the angle between the first and fourth quadrant to the tibial axis was measured by moving in a clockwise direction.

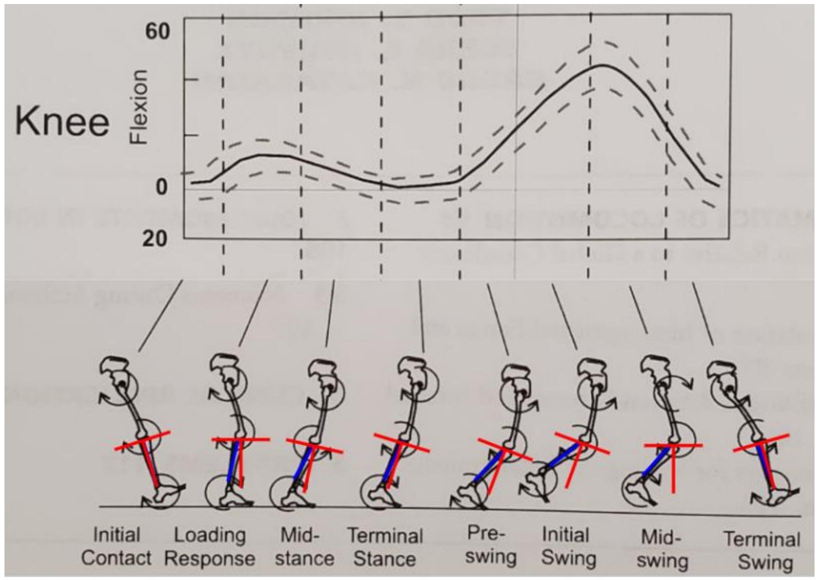
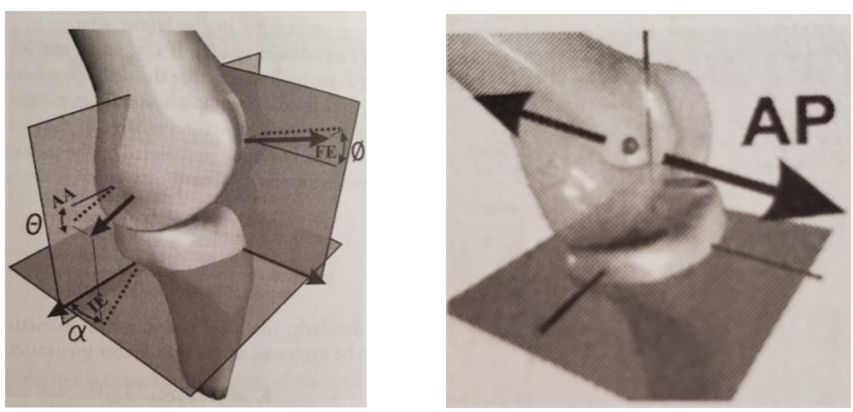


Figure 2. 9: Knee Angles and Gait Cycle (Mow and Huiskes, 2005)

On the other hand, the knee rotation and AP displacement have different origins on the knee. Figure 2.10a defines the location of the knee moment as α; α follows the axis perpendicular to the tibial shaft axis on the frontal plane. In addition, the knee experiences internal (rotated posterior) and external rotation (rotated anterior). Furthermore, Figure 2.10b displays the AP displacement origin. The researchers used the midpoint of the transepicondylar axis as the origin and related that point to the tibial axis. This means, as the femur extends over the tibial axis, the anterior displacement would increase, while the opposite effect would increase the posterior displacement.



a) Moment **b) AP Displacement**

Figure 2. 10: Knee Origin (Mow and Huiskes, 2005)

Consequently, Figure 2.11 depicts the flexion, rotation, and AP displacement of a normal knee during one gait cycle. Based on the flexion images, during the initial contact, the knee starts slightly above 0 degrees, increases to 15 degrees at loading response, decreases to 10 degrees at mid-stance, returns to 0 degrees at terminal stance, and rises to 15 degrees during the pre-swing for the stance phase. On the other hand, the initial swing reaches 30 degrees, the mid-swing increases to 40 degrees, then the angle decreases to 5 degrees at the terminal swing to end the swing phase.

The rotation of the knee starts with an internal rotation of 8 degrees at initial contact, reaches 1 degree at loading response, has a small rise to 3 degrees before having an external rotation of -2 degrees, then down to -3 degrees at the mid-stance. At the toe off, there is an internal rotation of 5 degrees. The swing phase has a rotation of 9 degrees before lowering down to 7 degrees at the terminal swing.

Lastly, for the AP displacement, when the values on the graph is negative, posterior displacement is in effect, while positive values signify anterior displacement. At heel strike, the AP displacement is -1.25 cm, increases to 0 cm during loading response, then stays around 1 cm until the toe-off. Afterwards, there is a slight dip during the initial swing to 0.75 cm, then rises to 1.75 cm at the mid-swing, then returns to -1 cm at the terminal swing.

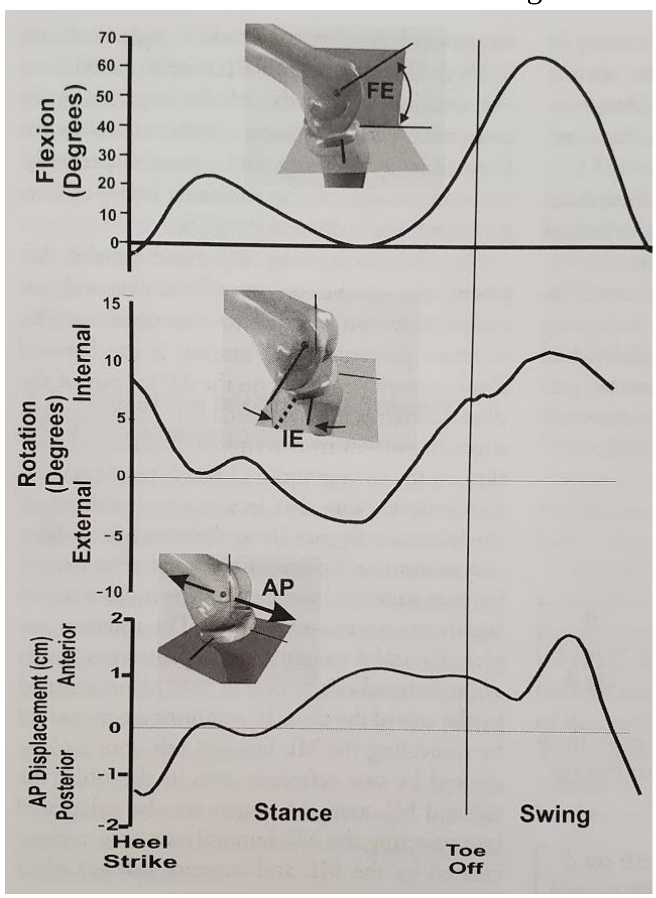


Figure 2. 11: Knee Joint Properties During Gait (Mow and Huiskes, 2005)

The knee angle and knee moment for single-axis and hydraulic knee joint can be found in Figure 2.12. In this experiment, there were three different groups. Group one consisted of experienced single-axis and hydraulic prosthesis knee users with knee–ankle link, group 2 used single-axis and hydraulic knee prosthesis without a knee–ankle link, and group 3 were healthy individuals. During the gate cycle, groups 1 and 2 experienced an asymmetrical gait. Therefore, there is a large variance from 0-25% and 65-85% where the normal individuals' knee angles are higher than the prosthesis users. For the knee moment in the single-axis knee prosthesis, there are drastic differences. From 0-37%, groups 1 and 2 fail to imitate group 3's knee moment, but the values are similar from 56-100% of the gait cycle.

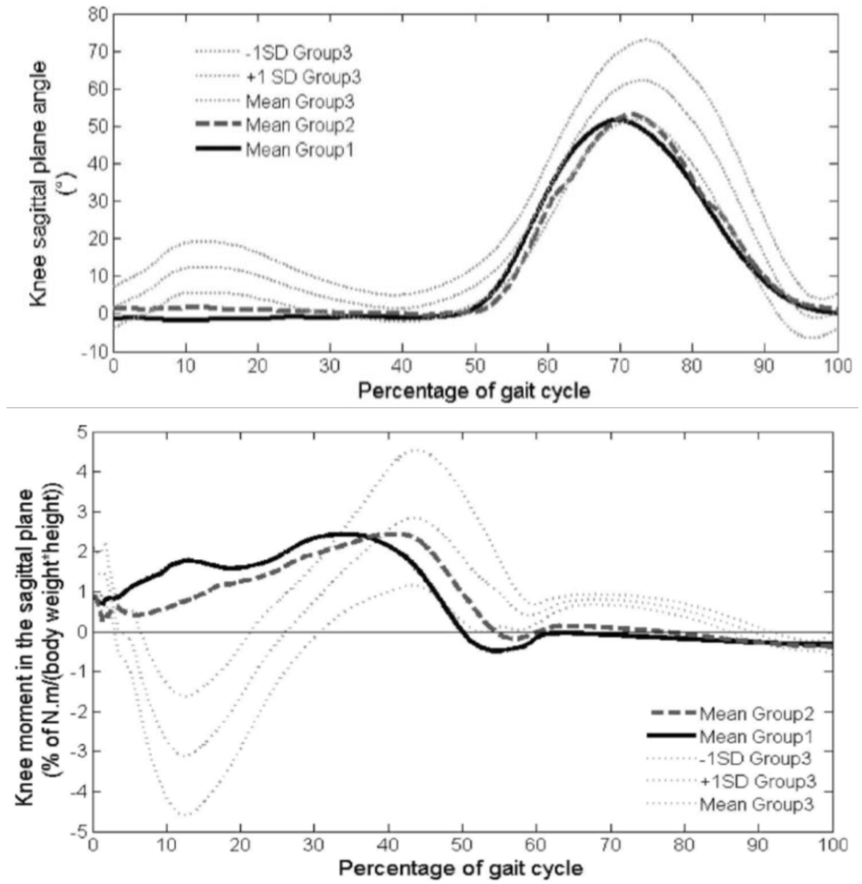


Figure 2. 12: Single-Axis Gait (Sapin, Goujon, de Almeida, Fodé, & Lavaste, 2008)

For polycentric knees, researchers try to emulate anatomical knees more closely. As shown in Figure 2.13, there are two data entries: normal knee and the bolder line is the polycentric knee prostheses. The anatomical and single-axis knee figures subsequently may seem different, but they contain the same data collection methods. The only difference is that the knee angles and moments in the polycentric knee joints start at different reference points.

For the polycentric knee joint, the origin starts at the second quadrant on the gait cycle illustration where the red lines are the axes. The horizontal axis corresponds to the transepicondylar axis, while the vertical axis is perpendicular to establish the coordinate plane. The blue line is the same tibial shaft axis at each stance. Instead of moving clockwise in the other knee flexion graphs, the polycentric knee angles measured counterclockwise from the vertical axis in between the first and second quadrant to the vertical axis between the third and fourth quadrant. Therefore, the orientation of the graph looks different, but the data collected for all three graphs were conducted similarly.

The moments in the polycentric knee were conducted in a similar manner. The stances during the gait cycle are the same, but the graph looks different. This is due to measuring at a different origin.

During the gait cycle, the polycentric knee copies the same shape as the normal knee angle. However, the polycentric knee does not reach the same knee angles during most of the stance phase, especially at the peaks and valleys. There is a slight overlap in between the stance and swing phase though. On the other hand, the polycentric knee does exhibit similar angles at the beginning of the swing phase. For the knee moment, there is a large difference at the beginning of the stance phase around 0-50% of the gait cycle, but they exhibit similar rotation towards the second half.

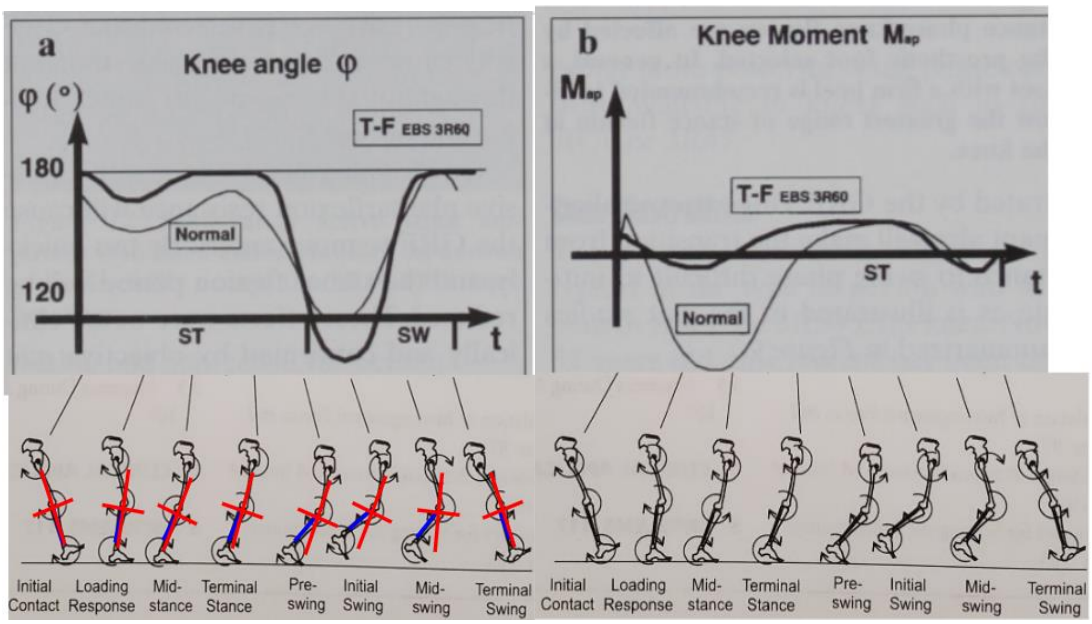


Figure 2. 13: Polycentric Knee Angle and Moment with Gait Cycle (Blumentritt, Scherer, Wellershaus, & Michael, 1997) and (Mow and Huiskes, 2005)

Both single-axis and polycentric knees mimic normal knees, but they ultimately fail to emulate anatomical knees during the gait cycle. The two knee prostheses have similar shapes for the knee angles and rotation; however, there is still much that can be improved.

2.6 Ascending and Descending Stairs

Walking up and down stairs is rather difficult for leg prosthesis users with passive and semi-active knee joints. Users walking on prosthetic knees show an asymmetrical gait, which causes instability on stairs (Windrich, et al, 2016). Another aspect of prosthetic legs that makes ambulating stairs difficult is the foot and ankle are oftentimes set solely at a right angle, unable to change (Kenney Orthopedics, 2020). The set angle not only makes it difficult for the foot and ankle to match the angle needed to walk up stairs but also inhibits the user's balance.

For prosthesis users, ascending and descending stairs is classified as K2 level. The main contributing force is the knee flexion and extension on the sagittal plane. In the free-body diagram in Figure 2.14, the two forces on a lower leg during stair climbing are depicted. The force *W* occurs when the leg pushes against the stairs, and the second force arises in the tibiofemoral (knee) joint, labeled force *P*. The tibiofemoral joint experiences a range from 0°-83° while ascending stairs and 0-90° descending stairs (Nordin & Frankel, 2001).

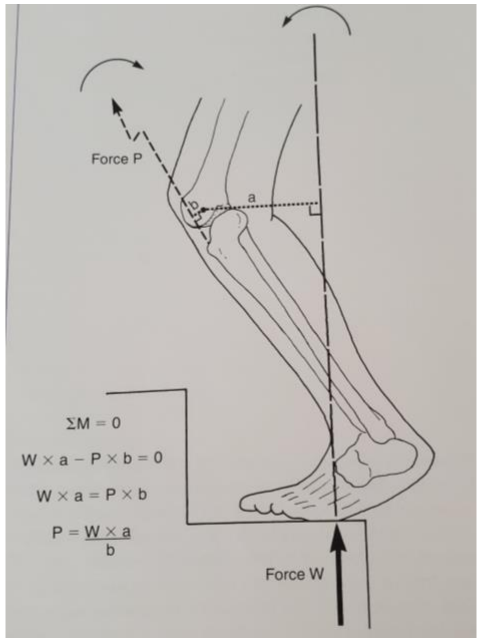


Figure 2. 14: Free-Body Diagram of Leg Climbing Stairs (Nordin & Frankel, 2001)

Despite having numerous studies regarding the knee angles as users ascend and descend stairs, prosthetic knees do not fully imitate the normal knee during the normal walking gait. In Figure 2.15, subsequently, the knee angles of a healthy user's knee as they climb and descend stairs are portrayed, while Figure 2.16 depicts the knee angles of prosthesis users. The subjects in Figure 2.16 were referred to as TF, which signifies above-the-knee amputees; TF1-3 were experienced prosthesis users, while TF4-6 were novice prosthesis users. For both figures, the stride cycle of the data is collected when the foot contacts the second step and ends when the same foot touches the fourth step.

Between these two graphs, the prosthesis knee replicates the shape of the healthy knee angles, but it does not exhibit the minimum or height of the knee angles. In the healthy knee, the data for ascending stairs starts from 50 degrees at the first contact with the second stair, while the powered knee begins at 60 degrees. Furthermore, around 85% of the gait cycle, the healthy knee reaches 90 degrees in between steps, and the prosthesis makes it to 85 degrees. Afterwards, both users return to their starting value. The prosthesis almost achieves the same values as the healthy knee; however, it does not replicate the nuances of the curvature. For example, 20-60% of the gait cycle, the knee angle remains around 0 degrees, which is longer than the healthy knee. Due to these differences, it demonstrates that the prosthetic knee cannot fully replicate the healthy knee's ascension and descension.

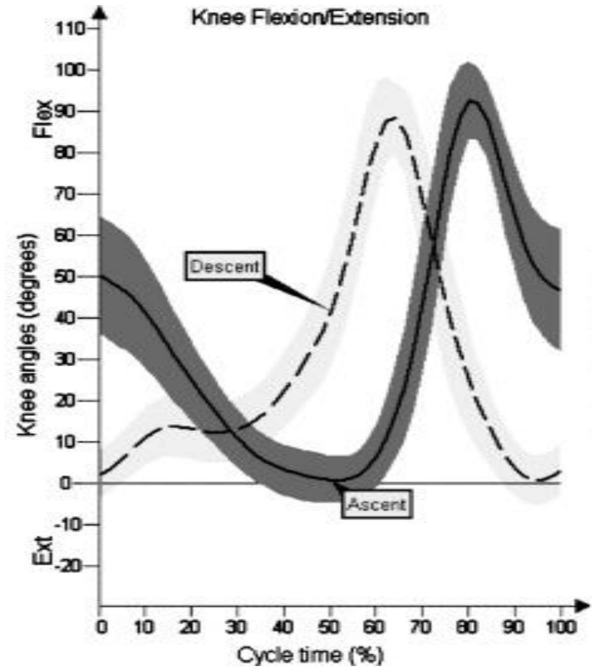


Figure 2. 15: Healthy Knee Angle Ascending and Descending Stairs (Protopapadaki, Drechsler, Cramp, Coutts, & Scott, 2007)

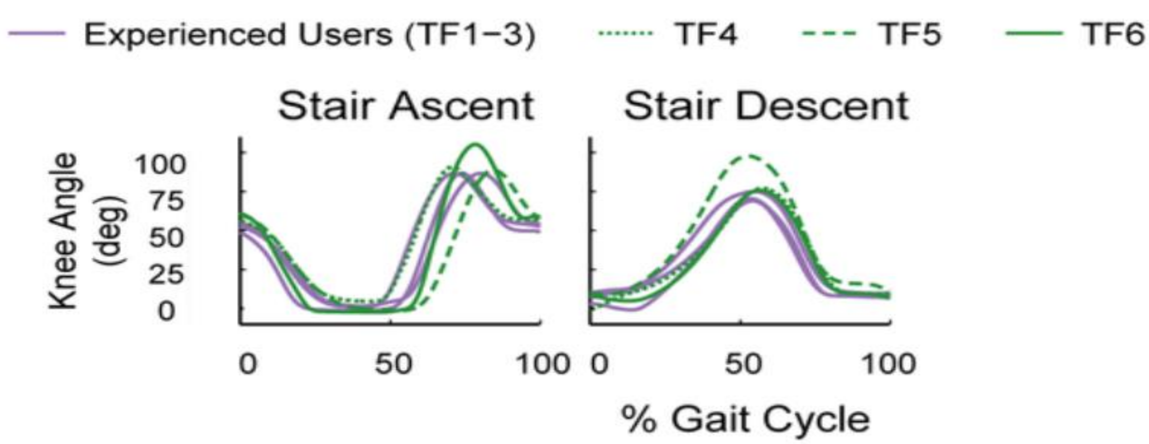


Figure 2. 16: Powered Knee Ascent and Descent Stairs (Simon et al., 2014)

2.7 Forces Acting on Knee During Gait Cycle and Stair Climbing

When people climb stairs, the forces they exert on their knees are approximately four times their body weight, whereas the forces during the gait cycle is about 1.5 times the body weight (Costigan, Deluzio, & Wyss, 2002). One example of the contact forces that are exerted on a knee while ascending stairs can be seen in Figure 2.17, where the 0% of the gate cycle corresponds to the initial leg lift towards the next stair and the 30% of gate cycle corresponds to the onset of one's body load having planted the foot fully on the next stair. Furthermore, the graph depicts the forces on a knee in three positions: posteriorly to anteriorly (PA), laterally to medially (LM), and distally to proximally (DP). The mean is shown by the solid lines, while plus and minus one standard deviation is depicted with the dotted lines (Costigan et al, 2002). The maximum PA force falls at a mean of approximately 4.5 N/kgf while the minimum force is close to -1 N/kgf. The mean maximum LM force is approximately 0.0 N/kgf, and the minimum force is under -2.0 N/kgf. Lastly, the mean maximum DP force is around 1 N/kgf, and the minimum is around -11 N/kgf. The forces on the three graphs are all constant from 0 to 30% of the gait cycle; they fluctuate from 30 to 100% of the gait cycle.

One important aspect while analyzing the forces on a knee is addressing potential differences in males and females. According to Costigan et al (2002), the maximum force males and females exert while stair climbing is of similar percent of body weight. Therefore, since gender does not play a role in load dynamics, one force cycle is sufficient to be inclusive of the entire population regardless of gender.

Understanding the difference forces exert while walking on flat ground and traversing stairs is also important. One difference is the elevation; walking on flat ground has little to no elevation, while the elevation of stair climbing is between 30 – 50 degrees (*Step Sizes*, n.d.). The cycles also start with varying positions; the gait cycle starts at heel strike while the stair climbing begins with lift-off. In addition, the maximum force while ascending stairs occurs at 60% because the foot is planted on the step, while the maximum value on the gait cycle happens around 20%. With these three instances, it is evident that the two cycles are contrasting. However, despite these disparities, the force graph of the stairs can be applied to the gait cycle since the curvature of the forces graph is similar.

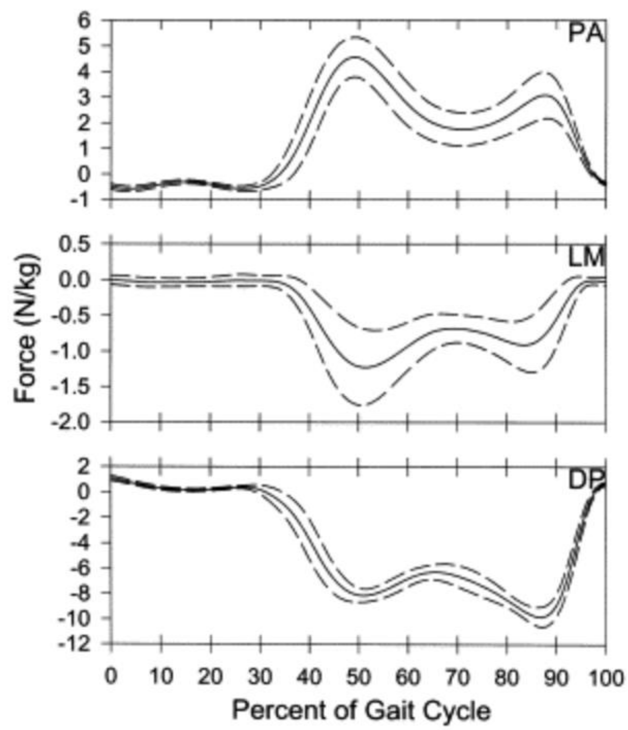


Figure 2. 17: Forces the Knee Experiences During Stair Climbing (Costigan, Deluzio, & Wyss, 2002)

In conclusion, lower limb amputees find it difficult to ascend and descend stairs with the current prostheses on the market. Therefore, for this project, above-the-knee prostheses for K3 level users was chosen to improve. This includes improving the design, functionality, and forces acting on a polycentric knee joint since single-axis knees are geared towards lower K-levels.

2.8 Materials

An important aspect of potential materials for use in prosthetics is the nonlinearity of the material. The nonlinearity is based on the material's current deformation, deformation history, rate of deformation, temperature, pressure, and more. Prostheses rely heavily on the nonlinearity of the material because it allows the prostheses to be moved and manipulated with little to no deformation. Materials that have strong nonlinearity are materials with large strain elastoplasticity and hyper elasticity which reduces the risk of deformation. Two examples of these materials are rubber and plastic. Plastic is a strong contender in prosthetic material due to its light weight which allows for easier wear by the user. Therefore, these two materials are commonly used in prosthetics.

When designing a prosthetic, the nonlinearity of a material is not the only aspect that should be considesred. In addition to nonlinearity, the cost of the materials being utilized is pertinent. While the main reason prosthetics tend to be expensive is due to the fact that instead of being mass produced, they have to be custom made for each individual. Furthermore, using different materials can also greatly impact the overall cost of the prosthetic. Aluminum is one of the most cost-effective options for prosthetics, at $.83 per pound (Aluminum, 2020). Aluminum is also lightweight but not as nonlinear as other choices.

2.9 Cost of Leg Prostheses

Commercially, basic leg prostheses cost around $12,000 to $15,000 for various functions, such as running and mimicking anatomical legs, with K3 or K4 level. For the prostheses that cost more than $15,000, they tend to have more advanced features such as hydraulic systems and polycentric knee joints (McGimpsey & Bradford, n.d.). To help alleviate the cost in the USA, users pay 20% of the Medicare-approved amount. However, there are multiple factors that are taken into consideration such as doctor charges, type of facility, item testing, services, and more (*Prosthetic Coverage*, n.d.). For health insurances, they allow $500 to $3,000 for prosthetic services and a lifetime cap of $10,000 per device. A lifetime cap is the total expense insurance companies will pay for one device and includes the initial cost of the prosthesis as well as any future repairs. Lastly, leg prostheses are expensive because they cannot be mass-produced, and they need to be replaced every several years. Each component of the prosthesis is customized towards the specific user, and there are typically around six to eight pieces (McGimpsey & Bradford, n.d.).

2.10 The Summary

Above-the-knee prostheses tend to be problematic since they are trying to emulate the knee, a complex system, without understanding the various components well. Additionally, the prosthetic used to replace the foot complicates the overall situation. The market currently has different types of knee prostheses, but they are costly or inefficient to perform regular motions. Therefore, the goal of the project is to create a cost-effective above-the-knee prosthesis that improves the user's ability to ascend and descend stairs.

Chapter 3 – Design Process

The overall goal of this project is to create a cost-effective, lightweight knee joint prosthesis that improves above-the-knee amputees' ability to ascend and descend stairs safely and comfortably. In order to accomplish this, functional constraints and prototype goals were established. The functional constraints involve the user's physical conditions and external control, while the prototype goals specify the plans and realization of the model.

3.1 Functional Constraints

The knee prosthesis must:

1. Apply to the United States of America's population between the ages of 20 and 30 years, at a minimum.
2. Match or exceed a K-level of 3 for single leg amputees.
3. Permit a person to walk an extended period without significant additional fatigue.
4. Allow a person to ascend stairs safely and comfortably with minimum trip potential.
5. Maintain or Improve the following factors relative to other knee joint prostheses on the market:
    1. Compatibility
    2. Lifespan
    3. Cost

3.1.1 Functional Constraint 1: User's Definition

The first functional constraint defined the target population of the prosthetic knee joint. The prosthesis prototype was designed for the average young adult, both male and female. Therefore, the target height for the user was between 59 and 73 inches, the weight was between 125 and 266 pounds, and the age was between 20 and 30 years. The weight range and height range were both determined using CDC averages in the USA from 2016 (Fryar et al, 2018) – the calculations can be found in Appendix D. The low end of the weight range was three quarters of a standard deviation less than the average weight of women while the high end of the weight range was three quarters of a standard deviation above the average weight of men. The values were also rounded to the nearest whole number. The height range was found similarly to the weight range but used one standard deviation as opposed to three quarters. These metrics were chosen to accommodate approximately 50% of the limited population to be eligible for the use of the prosthetic. 20 years of age was chosen as the bottom of the range as that is the average age at which bones stopped developing; 30 years of age was chosen as the top of the age range because that is the age at which muscle starts deteriorating. Therefore, by restricting the applicability pool, there is a better viability prior to accommodating other compromising situations, which increases the number of potential candidates.

3.1.2 Functional Constraint 2: K-Level and One Leg Amputees

Since the prosthesis was designed for an active adult, the k-level target of the prosthetic was either three or four. These k-levels allow the user to traverse various terrains and stairs. In addition to the constraints listed, the prosthetic was designed for one leg amputees; specifying one leg amputees allowed the prototype to be designed for a more specific use by eliminating the variable of double leg amputees.

3.1.3 Functional Constraint 3: Fatigue

The third functional constraint stated that the knee prosthesis should have added little additional fatigue to the user while they walked or traversed for an extended period. On average, an American adult walks around 0.7 miles in one walking period, which is about 15 minutes (Yang & Diez-Roux, 2012). With 97% of walking trips lasting less than 2 miles, it was pertinent that the knee prosthesis allowed the user to traverse 2 miles with little additional fatigue caused by the prosthesis. Creating a prosthetic that was lightweight and allowed the user to complete an average stride length commensurate with their body height helped limit the user from experiencing excessive fatigue from the prosthesis. In order to test fatigue caused by the prosthesis, the forces on the prosthetic leg were compared to the ones on a healthy leg. If the prosthesis user exerted 20% or more force than on a healthy leg, it signified that there was too much stress and fatigue.

3.1.4 Functional Constraint 4: Traverse Stairs Safely and Comfortably

The fourth functional constraint defined the ease and safety of the user's ability to ascend and descend stairs. Oftentimes, people trip due to various causes such as not wearing appropriate footwear, walking without using the handrail, or carrying large objects. However, the most prevalent cause of tripping is failing to meet the height clearance (Crist, 2017).

For the project, straight-run staircases were used to test the prototype due to their commonality. The specifications of this staircase type that meet code in the USA are as follows: the width of each stair must be at least 36", the horizontal surface must be 10-11" minimum, the staircase headroom (clearance height for the user's head) must be at least 6' 8", and the height of each step must be below 7.75" (Wallender, 2020). There are approximately 3,000 stair-related injuries per day - or one every thirty seconds - in the USA (Crist, 2017). These values were not inclusive of all tripping, but to ensure the safety of the knee joint prosthesis, the user must be able to meet a height clearance of 8" with their step up. Matching this height clearance was imperative as it permits the ability to overcome stairs and allows the users to walk in control. Therefore, the aim was to match the minimum for most traversing stairs in the knee joint.

3.1.5: Functional Constraint 5: Maintain or Improve Market Prostheses Specifications

The fifth functional constraint was focused on the compatibility, lifespan, and cost of existing knee joint prostheses. As mentioned in Chapter 2, above-the-knee prostheses have four basic components: socket, knee joint, shaft (pylon), and ankle and foot prosthesis. Since the project examined only the knee joint, it was important that the knee joint is compatible with the socket (above the knee joint) and the shaft (below the knee joint). There were common models for both, so the same socket and shaft inputs were used to make the knee joint universal. The last component of above-the-knee prostheses are the ankle and foot. Ankle and foot prostheses play an important role, but this is not included in the scope of the project.

The second factor focused on the maintenance of the prosthesis. Prostheses have varying lifespans due to the environment and the frequency of use. Some break down after two years while others last as long as fifteen years; however, on average a prosthesis is used for three to five years (What to consider, n.d.). Therefore, the target of the knee joint prosthesis was to have a lifespan that exceeds 5 years.

The third factor focused on the cost of the knee prosthesis and its weight. Knee prostheses tend to be costly because every component of the knee prosthesis is customized for each user. For the knee joint specifically, manufacturers use metals such as titanium, stainless steel, or aluminum. In addition to the initial cost of materials, subtractive manufacturing has additional expenses such as material waste, machining and tooling expenses, and time which increases the overall cost. With these costs in mind, the intentions were to match or decrease the weight and cost for an improved knee joint prosthesis.

3.2 Prototype Specifications

Along with the functional constraints, four prototype specifications were created and are outlined subsequently:

1. Match knee flexion angles metrics during gait cycle.
2. Match knee flexion angles metrics during stair climbing.
3. Match forces metrics during gait cycle and stair climbing.
4. Be a lightweight, inexpensive knee joint that weighs less than the ones on the market.

3.2.1 Specification 1: Gait Cycle Metrics

The gait cycle consists of four metrics – knee flexion angles, internal rotation, AP displacement, and forces – which were be taken from the literature for each a healthy knee, a single axis knee, and a polycentric knee. For every model, the data was graphed to quantify the merit of the prototype. Once data collection of the prototype was completed, it was graphed in the same manner as the literature data of the healthy knee. The data from literature and the prototype was then compared through a least squared analysis which was evaluated using the software *MATLAB*. The least squared analysis consisted of taking the difference of one point from one data set and the same point from the second data set, squaring the difference, summing each square in the data set, and then taking the square root. The closer the least squared value was to 0, the less variation there was between the two data sets. If the prototype measurements perfectly matched those from the healthy knee, the least squared value would be 0; however, the farther the measured values strayed from the literature, the higher the value would be. If the prototype matched or exceeded a least squared value of 5 or less from the healthy knee, single axis, and polycentric knee, it would pass the first specification. 5 was chosen as the least squared value as it shows there is only 5% variance between the prototype measurements and those of a healthy knee. If the prototype failed to meet the criteria, it would be redesigned to improve upon its shortcomings. The least squared value is low for the gait cycle as there is extensive research and studies upon this subject; therefore, it is realistic to match a higher criteria. Furthermore, specification one was limited to walking because the gait cycle is a simple locomotion for prosthesis and commonly found in literature. Thus, it was imperative the design can handle walking prior to determining if it was successful in the other specifications.

3.2.2 Specification 2: Stair Climbing Metrics

One aspect of the stair climbing metrics is the knee flexion angles that are necessary in order to ascend and descend stairs. The literature data of a healthy knee, single axis knee, and polycentric knee was plotted and used as the base comparison to the prototype. After the data from the prototype was plotted and analyzed, it was compared to a healthy knee from the literature through a least squared analysis. If the prototype matched a least squared value of 5 or less, when compared to the healthy knee, it passed specification two. Even though stair climbing is more complex than the gait cycle, the least squared values are the same. The entire scope of the project is to improve the properties of traversing stairs for knee prostheses since the ones on the market fail to do so. Utilizing lesser constraints of which to match our prototype to stair climbing metrics would fail to prove our prototype achieved our goal; therefore, if the prototype did not meet the criteria, it was analyzed to determine areas of improvements.

3.2.3 Goal 3: Specification 3: Forces Metrics

The third specification ensured the prototype would be successful under the forces acting on the gait cycle and stair climbing. The literature data of a healthy knee would be plotted from the respective cycles to be used as the target for the prototype. After testing and graphing the forces, the graphs would be compared through a least squared analysis. For the forces acting on the gait cycle, if the prototype met a least squared value of 5 or less when compared to a healthy knee, it completed the third specification. For the forces while traversing stairs, if the prototype exceeded the same least squared value, it too would pass the third specification. The least squared value is the same for the forces as the flexion angles as the forces play an important role.

However, if the prototype failed to meet the specifications, it would be redesigned to fix the shortcomings.

3.2.4 Specification 4: A Lightweight, Cost-effective Prototype

The fourth prototype specification was to create a prototype that is both lightweight and cost-effective. A lightweight knee prosthesis is generally more user-friendly and reduces fatigue. In addition, a cost-effective prototype allows more individuals access to the prototype. The prototype would not exceed 900 grams in order to deem the first part of specification 4 successful; 900 grams is lighter than many current aluminum knee prostheses on the market and allows users to utilize the prosthesis with little added forces due to added weight. Additionally, the prototype would not exceed $50 to manufacture as that value would allow our prototype to be widely available and affordable. Insurance companies will pay a lifetime cap of $10,000, and this value applies to material, tooling, and other operational costs. Since the price of our prototype will not include the additional costs, $10,000 is an inaccurate comparison. Therefore, if the prototype is under 900 grams and costs less than $50 to manufacture, specification 4 will be met.

3.3 Testing Process

The knee joint prosthesis underwent two testing methods – virtual simulations and physical experiments – in order to determine if it met the previous metrics. The first testing was conducted through the software *Solidworks 2021* for prototype simulation testing. This software was chosen as it was utilized to design the prototype and therefore, each design was located in the software. In addition, the Motion Analysis function allowed the model to upload specific inputs such as knee flexion angles and forces. Through this, *Solidworks 2021* could animate the motion and plot the values for each metric. These plots and animations helped determine if the knee joint prosthesis could mimic the properties of a healthy knee. However, the data collection from the simulation only occurs theoretically by idealizing the properties of each component. Due to this unrealistic behavior, a second method of testing the knee joint prosthesis was required.

The second testing method used to collect data involved the group members measuring the knee joint prosthesis angles and forces. After printing and assembling the knee joint prosthesis, the knee flexion angles for the gait cycle, stair ascension, and stair descension were measured two times by each group member. A protractor was used to measure the angles that correspond to at least twenty-one points on the cycle; these values included every 5 percentages of the gait cycle from 0 to 100 percent, as well as the global maximum and global minimum values. To stay consistent with the literature, each group member measured the upper portion of the prototype as 0 degrees when it created a 90-degree angle relative to the base with the stopper to the right. As the upper portion turned towards the stopper, that signified a negative value; as the upper portion rotated away from the stopper, it created positive values. Once that is completed, the averages of all six trials were calculated, plotted, and analyzed in comparison with the previous literature. Six trials were chosen to minimize human error and produce reproducible results that can be compared with confidence to the literature.

In order to test the forces during the gait cycle and stair climbing, the forces were tested one time by each group member for a total of three trials. The trials contained points for the same percentages as the angle measurements. In this test, one group member read the flexion angle and the force that is associated with one point of the gait cycle. The second group member moved the prototype to the correct angle, while the last group member applied the force to the upper portion of the prototype with their hand. A weight plate was utilized, when necessary, to assist in applying higher forces to the prototype. The device that measured the force was a bathroom scale that was calibrated to an accuracy of +/- 0.1 pounds. After the data collection, the data was averaged, plotted, and analyzed to determine if the prototype could withstand the forces that were applied to the knee and at the specific position.

3.4 Iteration Process

An iterative process was utilized to create the final knee joint prosthesis design. After each iteration, the design was evaluated to determine if the design fulfilled the needs of a knee joint or if changes were required. In order to accomplish this, a checklist was created and each element had to be marked as successful before establishing a final product. If one element failed to be checked off, the design of that iteration ceased and moved on to solving the element that was lacking. The elements of the checklist were based on background research and aforementioned functional constraints, which can be found in Table 3.1 subsequently.

The categories on the checklist were divided into three parts: design, action, and production. The two elements of design were if the prototype could achieve at least a maximum angle of 120 degrees and if it displayed AP displacement. Those two parameters were chosen as they ensure that the product would be able to mimic the movement of a healthy knee. Mimicking walking and stair climbing and being able to handle forces were chosen as action elements because without them, the knee prosthesis would fail to be utilized daily by the user and would not fulfill the goal of the project. The action elements were chosen in the order that they were tested, as walking is prioritized over stair climbing and the motion is prioritized over sustaining forces. Finally, printability, cost, and weight were the elements for production. These elements do not impact the effectiveness of the prototype; thus, they were placed lower than the design and action. However, they are all weighted metrics for the design and will allow the prototype more accessible to everyone.

Type of Element	Element	Was it Fulfilled?
Design	120 Degree Angle	
	AP Displacement	
Action	Mimic Walking	
	Mimic Stair Climbing	
	Handle Walking Forces	
	Handle Stair Climbing Forces	
Production	Printability	
	Cost	
	Weight	

Table 3. 1: Iteration Checklist

This section discussed each iteration, the pros and cons, and why another iteration was created where all iterations can be found in Figure 3.1. Furthermore, following the breakdown of each iteration, a completed checklist can be found.

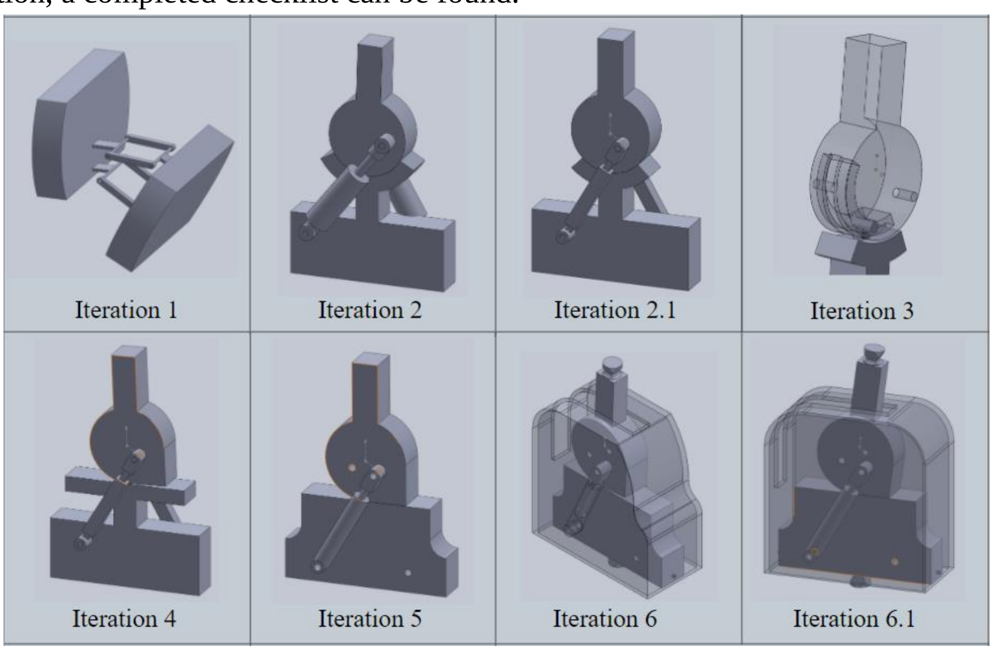


Figure 3. 1: Knee Joint Prostheses Iterations

3.4.1 Iteration 1

The first design iteration was a simple four-bar mechanism that was a first step in understanding how to replicate the movement of a healthy knee in a four-bar linkage. The group designed a basic shape for a thigh in order to know the placement of the knee joint prosthesis and how it moved. However, the knee design was not polycentric and did not allow for AP displacement that can be seen in healthy knees.

3.4.2 Iteration 2

Following the first iteration, the design evolved completely to a four bar linkage consisting of two pistons, a rocker, and a base. The two pistons acted as the ACL and PCL in the prosthesis knee joint to provide a greater range of motion to the user. This helped the movement be more similar to the gait of a healthy knee than the first iteration. However, this design did not consider AP displacement, limiting how accurately the motion mimicked the healthy knee.

3.4.3 Iteration 2.1

Like the previous model, iteration 2.1 had the same rounded piece with a saddle at the top and rectangular base at the bottom, but the shape of the pistons changed. Instead of a cylindrical piston shape, the outer piston shape changed to a square. This switch confined the pistons to a linear acceleration, which limited the rotation. Even with this modification, the prototype had a wide range of bending that was not feasible in normal knees. In addition, the straight leg limit was 0 degrees.

3.4.4 Iteration 3

Iteration 3 had the same features as the previous prototypes, but there was a track added to the upper portion. The track guided the path of the pistons and limited the distance it traveled. However, the track restricted the AP movement and forced the prototype to move on a single axis.

3.4.5 Iteration 4

Iteration 4 reverted back to the basis of iteration 2.1, but it consisted of a couple modifications. Instead of a curved saddle, the group made a flat surface. Furthermore, there was a stop attached to the bottom right side of the upper portion. The stop, once rocked back and forth, prevented the knee from hyper-extending, while it maintained the AP displacement.

3.4.6 Iteration 5

Iteration 5 looked similar to 4, but it exhibited slight modifications to take 3D printing in account. Instead of having the saddle hung over the base, the upper portion rests on top of the base as the empty space did not provide anything. The shape and structure of the piston also changed. Instead of a square shape, the shape of the pistons were once again cylindrical to print easily. Furthermore, the pistons contained a lock-and-key mechanism to permit the inner piston to enter the outer piston without additional attachments. Lastly, the extruded pegs around the upper portion and base were removed for insertable dowels. The reason being the dowels were simpler to buy and reduced any tolerance complications that arose while printing.

3.4.7 Iteration 6

Iteration 6 featured multiple changes. There were pyramid adaptors added to the upper portion and base of the prototype. The reason being, knee joint prostheses on the market use those adaptors to connect to the socket and pylon. The angle of the stop on the upper portion also changed angles to permit hyperextension during the gait cycle. Furthermore, the size of the pistons exhibited slight modifications, which made assembling each piece more efficient. Lastly, the group created a cover for the prototype which screwed into the base. The cover was essential since it protects the user and their clothing from getting caught between the upper portion and base.

3.4.8 Iteration 6.1

The final version of the knee joint prosthesis was iteration 6.1 which contained slight modifications. The cover design had a uniformed rectangular shape and increased in size to allow more room for AP displacement. The other adjustments were made to the outer cylinders of the piston. The cylinder was split into two parts that fit together like a puzzle in the final assembly, which was more efficient to assemble and contain the springs. The internal boundaries for the outer cylinder were also modified to adapt to the length of the available springs and prevent potential collisions detected in *Solidworks2021*.

3.4.9 Iteration Checklist

The subsequent Iteration Checklist Table contained the same criteria for the knee joint prosthesis as Table 3.2 but was filled out after each iteration. On the table, the iteration received a check mark if it passed that element and continued down the column. However, if the iteration failed, it got an ‘X’; with the acquired ‘X’, the group stopped and evaluated the iteration to determine ways to improve upon the design. For the last iteration, 6.1, it passed all criteria that was established at the beginning of the results chapter.

Type of Element	Element	Iteration							
		1	2	2.1	3	4	5	6	6.1
Design	120 Degree Angle	✔	✔	✔	✔	✔	✔	✔	✔
	AP Displacement	X	X	X	X	✔	✔	✔	✔
Action	Mimic Walking					✔	✔	✔	✔
	Mimic Stair Climbing					✔	✔	✔	✔
	Handle Walking Forces					✔	✔	✔	✔
	Handle Stair Climbing Forces					✔	✔	✔	✔
Production	Printability					X	X	X	✔
	Cost								✔
	Weight								✔

Table 3. 2: Outcomes After Each Iteration

3.5 Conclusion

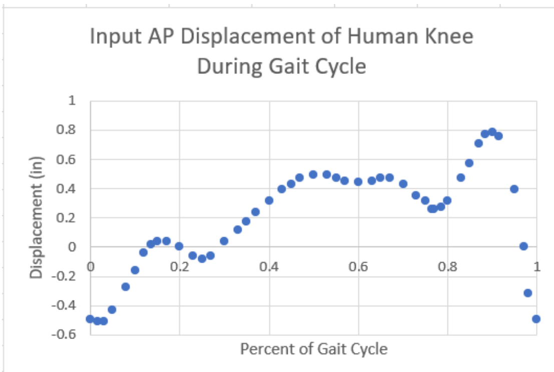
The process outlined above attempted to create an innovative knee joint that improved the existing models on the market. This was done through the functional constraints – creating boundaries for the users and their environments – and the prototype specifications, which included the quantified goals of the design. In addition, the iterative process created the best prosthesis. Therefore, with these aforementioned goals and iteration process, they ensured that the knee prosthesis prototype was cost-effective, lightweight, and functional for users to traverse stairs with ease.

Chapter 4 – Results and Discussion

This chapter evaluates the prototype as measured against the motions and loads experienced by a normal knee during a walking gait and stair traversing, as outlined in Chapter 3

4.1 Prototype Simulation Testing

To test if the prototype mimicked the same AP displacement, knee flexion angles, and forces acting on a healthy knee, the prototype underwent prototype simulation testing. The first test for the prototype was the AP displacement during the gait cycle. The points in Figure 4.1a corresponded to the data interpolated for a healthy knee from the literature. These values were then input into *Solidworks 2021* to generate the motion the prototype exhibits, which can be seen in Figure 4.1b. By having the two graphs side-by-side, it is evident that the points extracted from the literature matched the same path as the one from the prototype. Figure 4.2a illustrated the knee flexion angles taken from literature of a healthy knee. The points on this graph were uploaded into *Solidworks 2021*, which created a best-fit curve of the prototype as displayed in Figure 4.2b. The prototype path also demonstrated the same curve as the healthy knee. Therefore, the simulation tests of the displacement and angles proved that the prototype can imitate the ones from a healthy knee during the gait cycle.



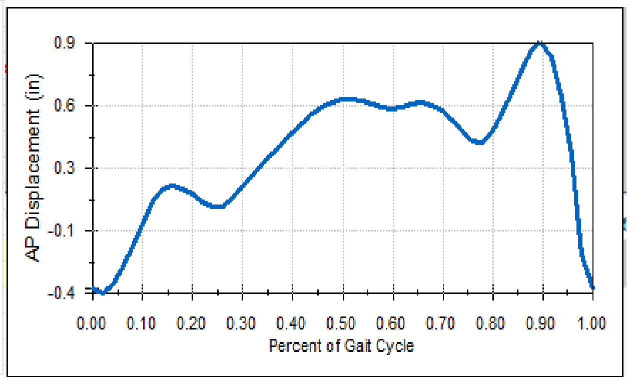
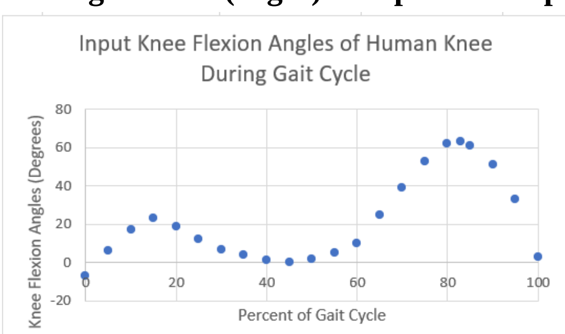


Figure 4. 1a (Left): Input AP Displacement of Human Knee During Gait Cycle

Figure 4.1b (Right): Output AP Displacement of Prototype from *Solidworks 2021*



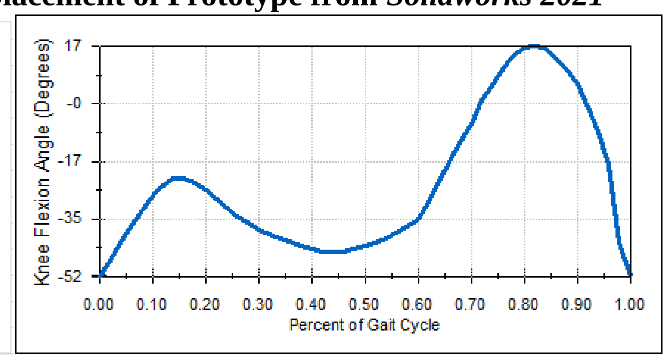
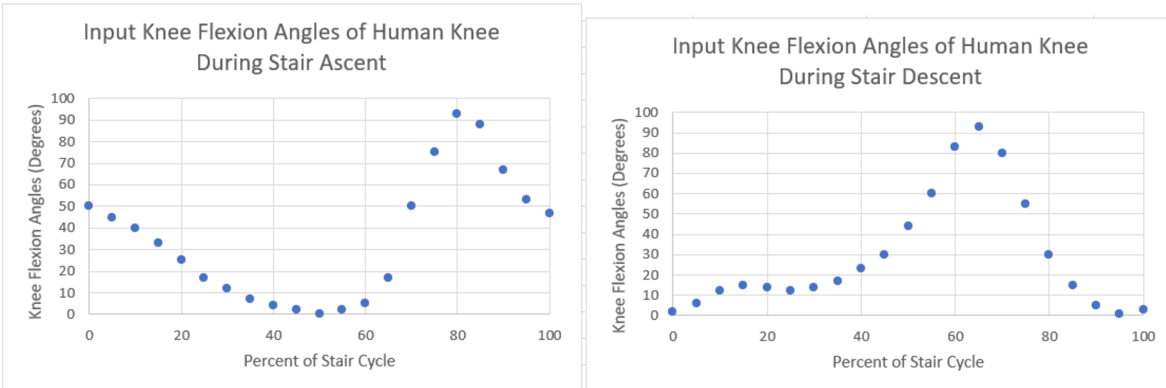


Figure 4. 2a (Left): Input Knee Flexion Angles of Human Knee During Gait Cycle

Figure 4.2b (Right): Output Knee Flexion Angles of Prototype from *Solidworks 2021*

The second prototype simulation tests pertained to stair climbing. Figure 4.3a showed the knee flexion angles of the human knee during stair ascent (left) and descent (right). These interpolated literature graphs were input into *Solidworks 2021* to simulate the prototype. The outcome of both tests can be seen in Figure 4.3b, with the stair ascent data on the left and the stair descent data on the right. The path of the prototype matched the one from a healthy knee, which signified that the prototype successfully simulated the stair ascending and descending properties.



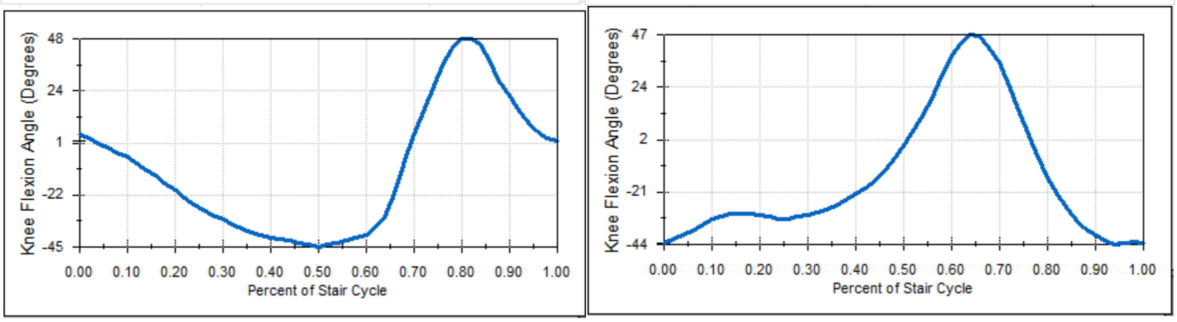
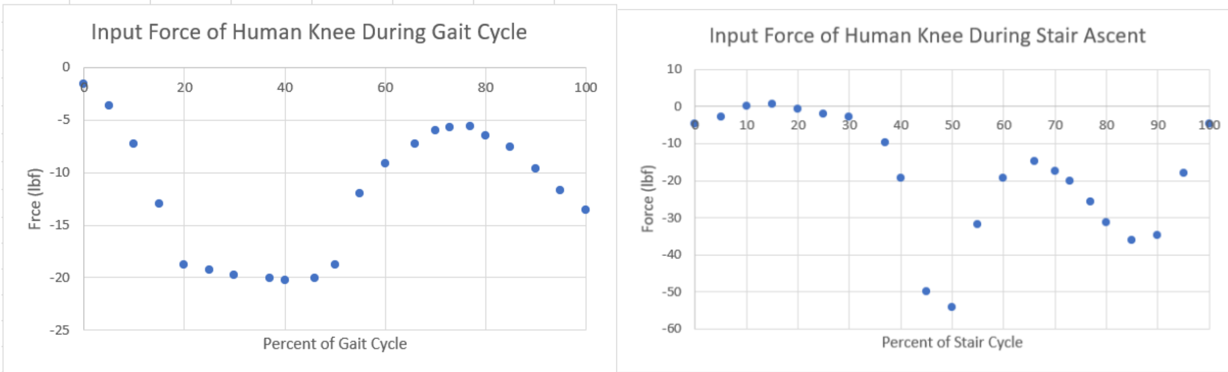


Figure 4. 3a: Input Knee Flexion Angles of Human Knee During Stair Ascent (Top Left) and During Stair Descent (Top Right)

Figure 4.3b: Output Knee Flexion Angles of Prototype from *Solidworks 2021* During Stair Ascent (Bottom Left) and During Stair Descent (Bottom Right)

The last prototype simulation involved the forces during the gait cycle and stair ascension. Figure 4.4a on the left illustrated the force exerted on a healthy knee during the gait cycle, while the right had the forces acting during stair ascent. Furthermore, both graphs were interpolated from the literature to be input into *Solidworks 2021*. The output graphs can be seen in Figure 4.4b, where, unlike the aforementioned figures, the forces graphs did not replicate the same path as the healthy knee. The location of the force exerted on the prototype was at the surface of the pyramid adaptor for the socket where the forces were acting solely on the Y-axis. Once the upper portion of the prototype became perpendicular with the Y-axis, the force was zero as the program could not compute the force to change from the Y to X axis. If the prototype plot during the gait cycle translated to the left, it would have a similar curve to the one of a healthy knee. However, this was not the case; the forces simulated during the gait cycle failed to replicate the forces applied on a knee during the appropriate time of the gait cycle. On the other hand, the prototype simulation test during stair ascension had a similar path to the ones from a healthy knee. The prototype simulation g established that the prototype could successfully imitate the knee flexion angles and AP displacement, but it could not fully mimic the forces. Therefore, it was imperative that the prototype underwent physical testing to determine if the results from the prototype simulation were accurate or had potential shortcomings from simulation testing.



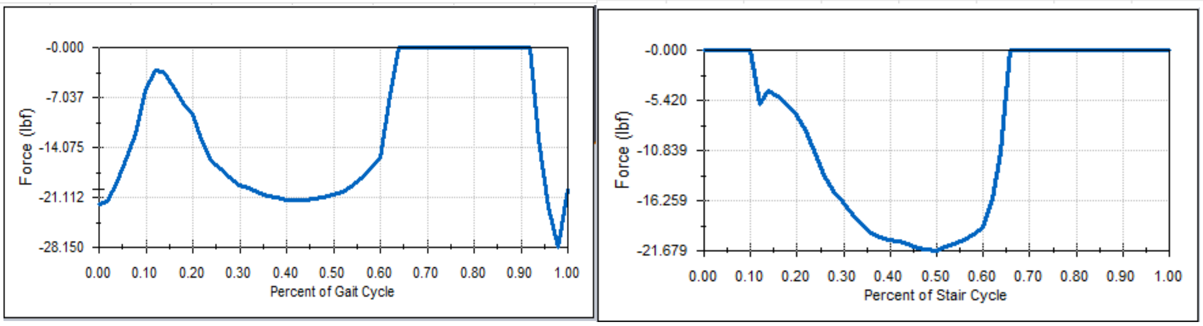


Figure 4. 4a: Input Forces of Human Knee During Gait Cycle (Top Left) and During Stair Ascent (Top Right)

Figure 4.4b: Output Forces of Prototype from *Solidworks 2021* During Gait Cycle (Bottom Left) and During Stair Descent (Bottom Right)

4.2 Prototype Specifications

To test if the prototype was successful, the physical prototype was measured against four prototype specifications:

1. Match knee flexion angles metrics during gait cycle.
2. Match knee flexion angles metrics during stair climbing.
3. Match forces metrics during gait cycle and stair climbing.
4. Be a lightweight, inexpensive knee joint that weighs less than the ones on the market.

Through 3D printing, the prototype was created and assembled. This assembly was then tested in the following manners. The prototype can be found in Figure 4.5 where the prototype with and without the cover, for safety, are shown. Springs are located inside each piston shown.

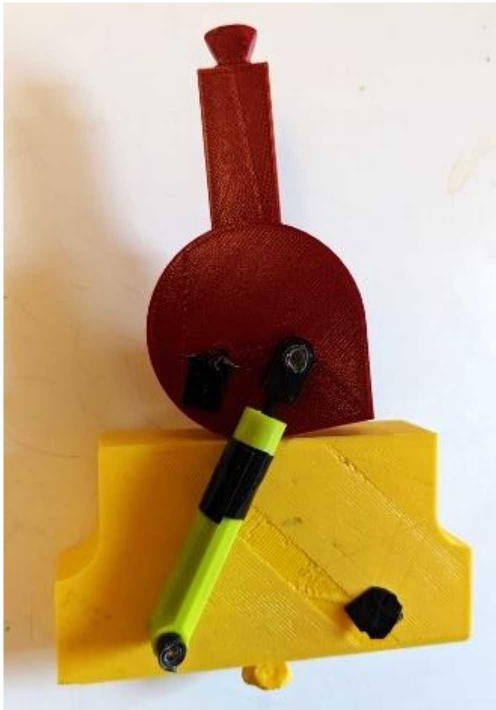


Figure 4. 5: Prototype without Cover (Left) Prototype with Cover (Right)

4.2.1 Specification 1: Gait Cycle Knee Flexion Angles

Following the success of the virtual testing, the prototype underwent physical testing to see if the theoretical results translated to reality. The first step was to measure the knee flexion angles of the gait cycle – as outlined in Chapter 3.3 – and determine if the prototype could achieve the angles needed for the gait cycle. After averaging the six measurements taken of the knee flexion angle throughout the gait cycle, it was determined the maximum knee flexion angle reached 67.3 degrees while the minimum was at -7.3 degrees. Furthermore, the curvature of the graph was similar to the curve from the literature of a healthy knee; a comparison of these two graphs can be seen in Figure 4.6. There was a series of six measurements taken to form the prototype graph to give a greater statistical confidence in the data. Additionally, the measurements were on 22 points throughout the gait cycle.

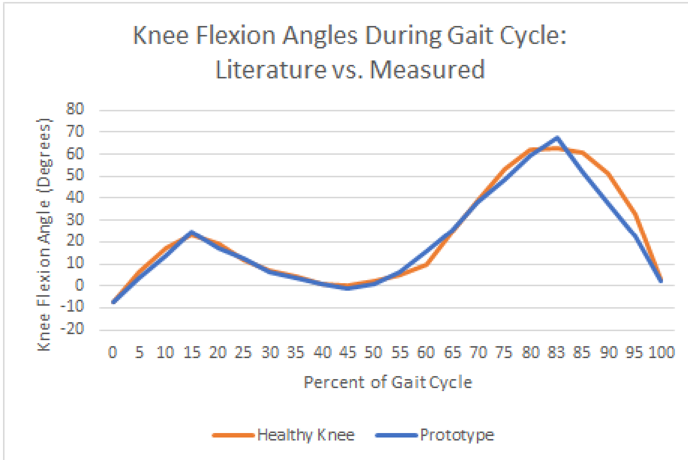


Figure 4. 6: Knee Flexion Angles in a Healthy Knee and the Prototype During the Gait Cycle

As described in Chapter 3, a least squares analysis was used to compare the prototype and literature. The least squares value between the literature and prototype data was 4.6767; these calculations, along with the least squares calculations, can be found in Appendix E. Since this value is less than 5, it signified that the flexion angles between the healthy knee and prototype are extremely similar. To determine if the prototype matched or exceeded current knee joint prostheses, a least squares analysis was also conducted for the gait cycle for two types of prostheses: single axis and polycentric. For both prostheses, the knee flexion angle was compared to the angles from literature of a healthy knee. The least squares value for the former was 9.5877, while the least squares value for the latter was 10.6114. Since the least squares values for both are higher than 4.6767, it can be concluded that the prototype exceeded what is on the market today. Furthermore, a graph comparing the knee flexion angles for a healthy knee, a single axis prosthesis, and a polycentric prosthesis can be found in Figure 4.7, further showing how dissimilar the prostheses are to a healthy knee. Due to the results of this analysis, specification one was met.

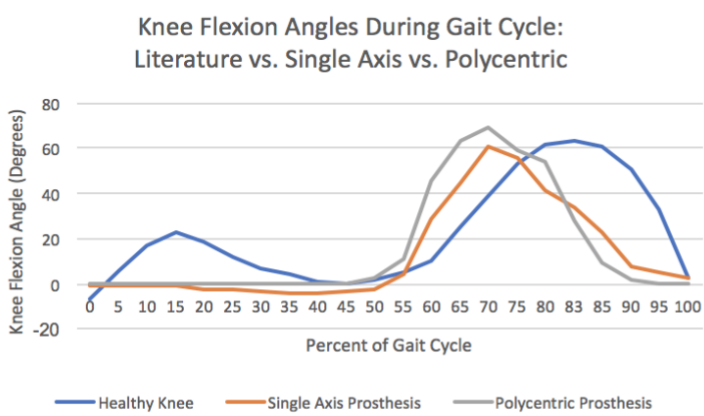


Figure 4. 7: Knee Flexion Angles During Gait Cycle From the Literature, Single Axis Prostheses, and Polycentric Prostheses

4.2.2 Specification 2: Stair-Climbing Knee Angles

The second physical testing step established if the prototype mimicked the knee flexion angles of the gait cycle while ascending and descending stairs. The results of the testing determined the maximum angle of 92.33 degrees can be found at 80 % of the gait cycle, while the minimum angle of -0.17 degrees can be found at 50 % of the gait cycle. The curvature for the hand measured knee flexion angles was similar to those from the literature, thus demonstrating the prototype's ability to mimic stair ascension. The two graphs together can be found in Figure 4.8. Along with the comparison of the two graphs, a least square analysis was completed that computed a value of 3.8941, which is less than the required value of 5 to deem specification 2 successful. Therefore, the first part of specification 2 was successful.

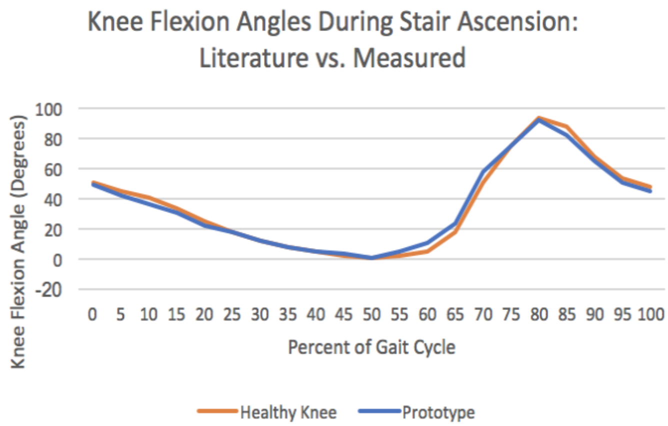


Figure 4. 8: Knee Flexion Angles in a Healthy Knee and the Prototype During Stair Ascension

Figure 4.9 displays the average measured knee flexion angles in comparison to the knee flexion angles in a healthy knee during stair descent. As seen in the graph, the maximum angle from the prototype is 96.17 degrees at 65% of the gait cycle; the minimum angle is 2 degrees at both 0% and 95% of the gait cycle. The knee flexion angles for the physical experiment and the literature also have a similar curvature. Similar to the knee flexion measurements, the data points were chosen and human error was minimized in the same fashion. After a least squares analysis, a value of 4.5178 was calculated. Since stair ascent and descent fall within the parameters of specification 3, specification 3 was successfully completed.

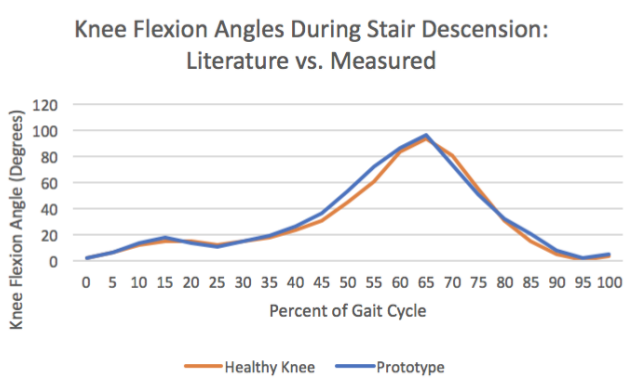


Figure 4. 9: Knee Flexion Angles in a Healthy Knee and the Prototype During Stair Descension

The performance of the literature's polycentric prosthetics was compared to the normal knee motions while ascending and descending stairs. The least squares value for ascending stairs was 8.1424, and the least squares value for descending stairs was 9.9546. Both values are significantly lower than both least squares values for the measured angles of the prototype versus the literature, at 3.8941 and 4.5178 for stair ascension and descension, respectively. Since the prototype can exceed what is on the market today in terms of ascending and descending stairs, it can be concluded that specification 2 is met. In addition to the least squares analysis, two graphs overlaying the knee flexion angles while ascending stairs and while descending stairs between the healthy knee and from polycentric prostheses can be found in Figure 4.10.

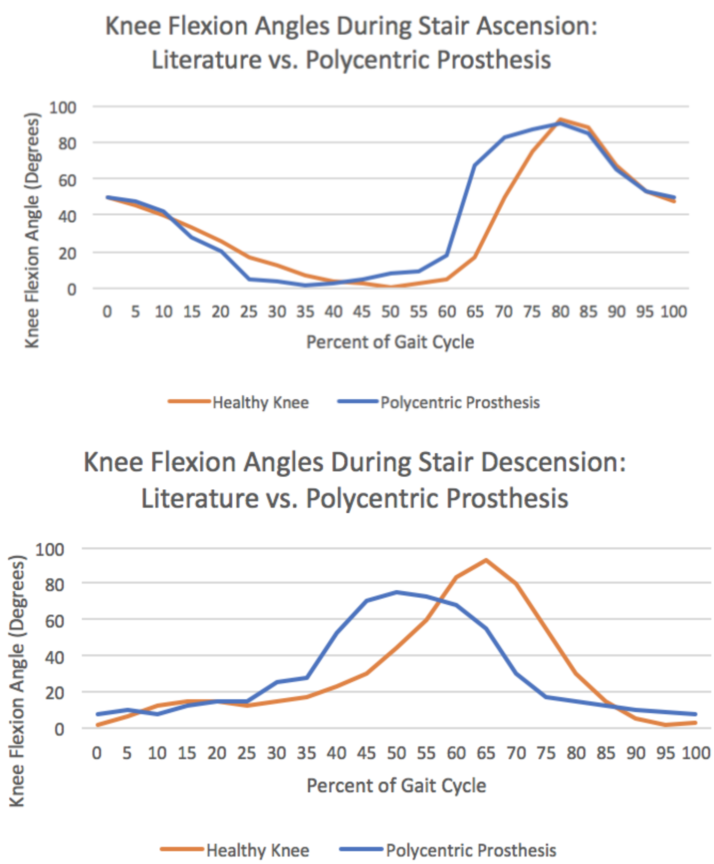


Figure 4. 10: Knee Flexion Angles Between the Literature and Polycentric Prostheses During Stair Ascension (Above) and Stair Descension (Below)

4.2.3 Specification 3: Forces for Gait Cycle and Stairs

The forces applied on the prototype to test both the gait cycle and the stairs were the forces sustained by a healthy knee normalized to the prototype. The maximum weight of an individual for whom the prosthesis was being designed is 266 pounds, and the maximum force that such an individual might exert on their knee while ascending stairs is approximately 1,064 pounds – or four times their body weight. Due to limitations on testing materials available through WPI and time constraints, it was unrealistic for the physical prototype to be tested under a load of this magnitude. Thus, the force calculations for four different materials were done: aluminum, PLA, stainless steel, and titanium. These calculations showed which material would be the most cost-effective option that theoretically would be able to sustain the forces for the gait cycle and traversing stairs. These full calculations and steps can be found in Appendix F. By creating the prototype out of stainless steel, it has the potential to cost less than a titanium or aluminum prototype; therefore, stainless steel was chosen. The strength ratio of PLA to stainless steel is 1:19 so the forces were all divided by 19 where those values were utilized to test the strength of the prototype. The following conclusions drawn are based on the idea that the prototype will be successful if it is made with stainless steel. It cannot be guaranteed PLA would be successful, but this material choice was not ruled out either.

To determine if specification 4 was met, the first step was to test the forces applied to a knee while walking. As seen in Figure 4.11, the maximum force applied to and sustained by the prototype was -22.2 lbf at 40% of the gait cycle, and the minimum force was -1.63 lbf applied at 0% of the gait cycle. The percentages were the same ones measured for the knee flexion angle testing, and the curvature of the graph is also similar to the force graph from the literature. A visual comparison of the two graphs can be found in Figure 4.11. Through a least squares analysis of the literature force data and the measured force data, the value was calculated as 1.9213. Since the least squares value matched the criterion and the curvature of the two data sets in the graph were similar, specification 3 was met for the gait cycle.

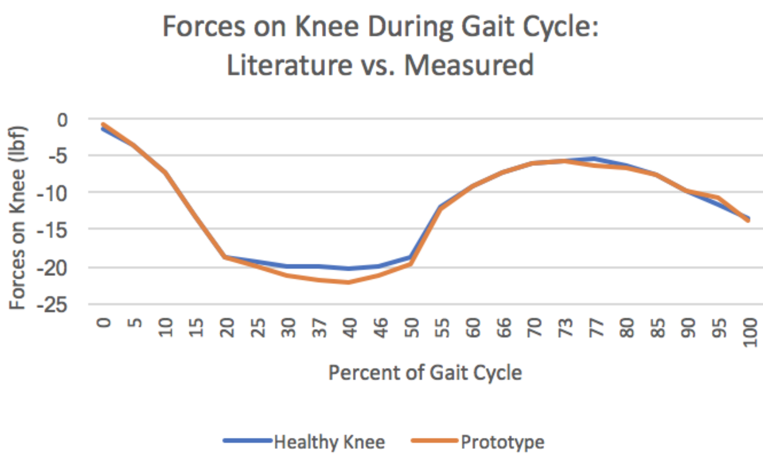


Figure 4. 11: Knee Forces in a Healthy Knee and the Prototype During Gait Cycle

After the prototype successfully managed the normalized forces during the gait cycle, the forces acting while climbing stairs were simulated at each respective angle of the knee flexion. As seen in Figure 4.12, at 50% of the gait cycle, the maximum force applied to the knee joint prosthesis while mimicking climbing stairs was -55.33 lbf, and the minimum force was 0 lbf at 10% of the gait cycle. The curvature of the graph is also similar to the graph of the forces applied on the knee while ascending stairs found in the literature. Through a least squares analysis it was determined that the least squares value was 1.8537; therefore, specification 3 was met for stair ascension and the gait cycle, marking it successful.

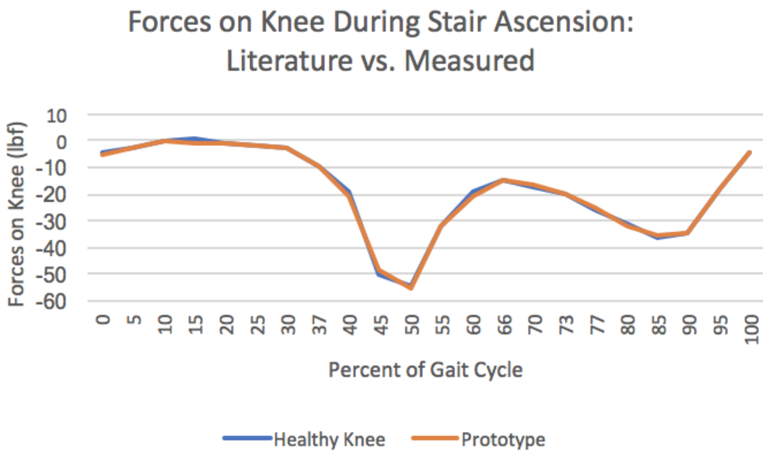


Figure 4. 12: Knee Forces in a Healthy Knee and the Prototype During Stair Ascension

4.2.4 Specification 4: A Lightweight, Cost-effective Prototype

In order to design a prosthesis that was both lightweight and cost-effective, the prototype was produced through additive manufacturing – otherwise known as three-dimensional printing (3D printing). 3D printing offers the opportunity to use different materials of varying costs and weights. Taking into account the cost, weight, and strength of each of these materials, the prosthesis was printed using PLA. Another benefit to 3D printing is the ease at which a piece can be adjusted to fit each individual user, as well as the simplicity to replace a broken part. Pieces can be scaled prior to being sent to the printer in a matter of minutes, benefiting both the engineer and the user. These aspects of 3D printing help make the overall cost of an individual owning a 3D prosthesis overall less expensive and more customizable. Through developing the knee prosthesis with 3D printing, it effectively created a product that is both lightweight and cost effective for the user.

The cost of manufacturing the PLA model and of creating the prototype out of stainless steel are both miniscule in comparison to the amount that the medical industry currently charges for knee prostheses. However, the cost of knee prostheses on the market have more components that increase the cost than just the material. For example, the cost of running machinery, along with other secondary and tertiary operations, help raise the cost. Therefore, it is beyond the scope of this project to provide the full production cost of the prototype. Nonetheless, specification 4 was met since the cost of the prototype is well below $50.

4.3 Functional Constraints

The majority of the functional constraints outlined in Chapter 3 were met. However, a few were unable to be deemed successful due to a lack of testing capabilities, such as ensuring the prosthesis would not provide additional fatigue to the user. The first functional constraint was guaranteed, as the prototype was developed for the height and age range of the population specified. Additionally, the prototype withstood the normalized forces during the gait cycle and stair traversing. Functional constraint two stated that the prototype must be at a K-level 3. Therefore, since the prototype allowed users to traverse stairs, constraint two was also guaranteed. The third functional constraint, discussing the fatigue from utilizing the prototype, failed to be met; nonetheless, further testing could determine if the constraint could be guaranteed. Furthermore, since the prototype assisted users in traversing stairs with more ease than current prostheses, functional constraint four was met. Finally, the prototype maintained the compatibility and improved upon the cost of current prostheses. However, determining the lifespan of the prototype was not guaranteed as it was out of the scope of this project. Therefore, functional constraint five was partly met.

4.4 Conclusion

As previously delineated, the virtual data testing, prototype specifications, and functional constraints determined the knee joint prosthesis improved the functionality of current prostheses and allowed the user to traverse stairs with ease. Despite the prototype not guaranteeing approximately half of the functional constraints, it met the prototype specifications. The prototype exceeded the goals for imitating the gait cycle flexion angles, stair climbing flexion angles, forces acting on the cycles, and manufacturing of the prototype. Therefore, the project was successful in being cost-effective, lightweight, and functional for stair traversing.

Chapter 5 – Conclusion

A knee joint prosthesis that was both cost-effective and improved the motion of traversing stairs in comparison to current market knee prostheses was successfully developed. Functional constraints and prototype specifications were established to achieve our goal of a cost-effective, improved motion prosthetic. The prototype was compared to existing knee prostheses, including the single-axis knee prosthetic and the more advanced polycentric knee prosthetic. The metrics used for analysis were knee flexion angle, anterior-posterior displacement, and applied forces during motion. These metrics used the human knee motions as the target. The metrics were applied to both walking through a gait cycle and through a full stair-ascent sequence as well as a full stair-descent sequence. Additionally, least-squared analyses were applied on our prototype and the literature's data for single-axis and polycentric prostheses against the healthy knee data.

Our prototype simulation and physical prototype far exceeded the prostheses currently on the market in all three metrics applied – knee flexion angle, AP motion, and applied forces – in which the physical forces were applied to the PLA model. However, the proposed clinical trial prototype would be stainless steel for the load-bearing components and a lighter polymer for the prosthetic cover. Therefore, this stainless steel-polymer prototype was determined to be cost effective and lightweight.

Even though the prototype design and the preliminary results of the physical model showed success, they still warrant more analysis. However, since there was a lack of resources, additional assessments of fatigue, lifespan, and comfortability were not performed.

In conclusion, the final prototype could help make knee joint prostheses available for a wide range of users, with enhanced motions that more closely imitate the healthy knee motions. Therefore, the goal to create a cost-effective prototype that improved the user's ability to ascend and descend stairs was achieved.

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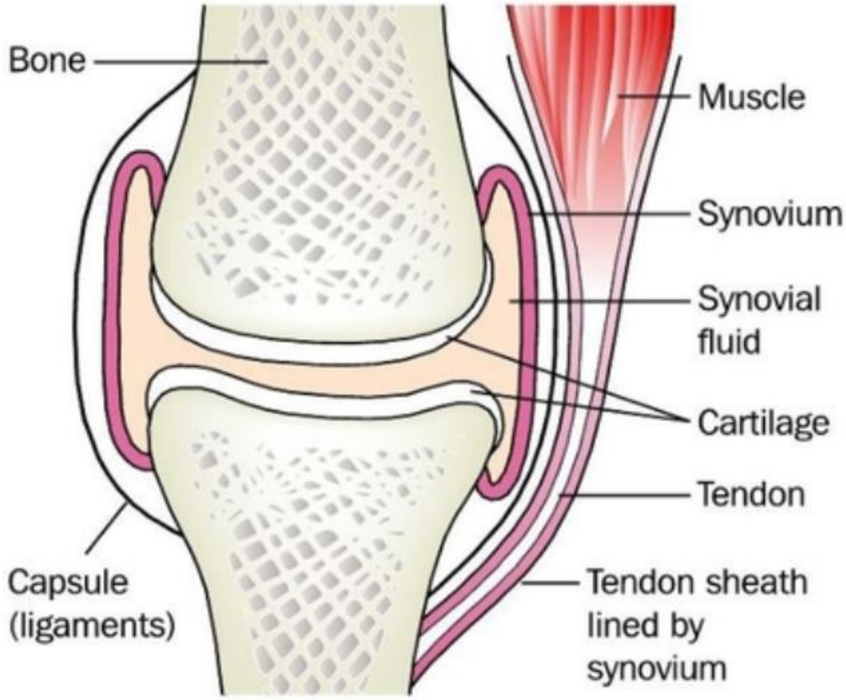
Appendix A

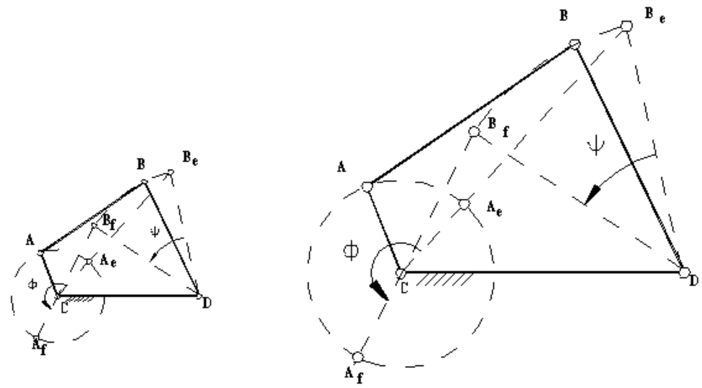
Structure of the Knee (Berlin & Adams, 2017)



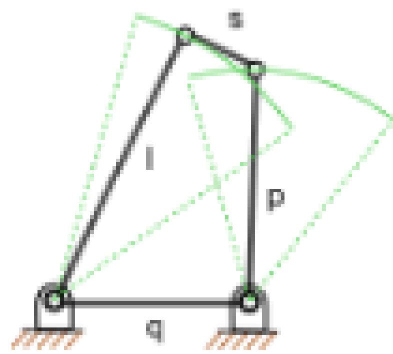
Appendix B

Four bar linkages

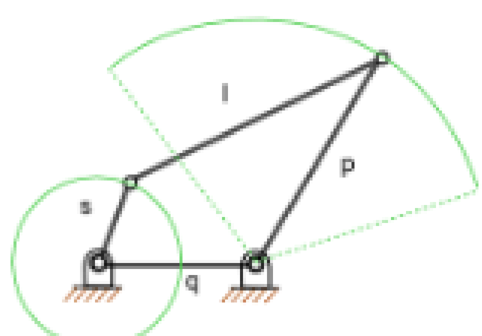
With full rotation (*Four bar Mechanism*, n.d.)



Four bar linkage with oscillation (*Lab Manual*, 2009)



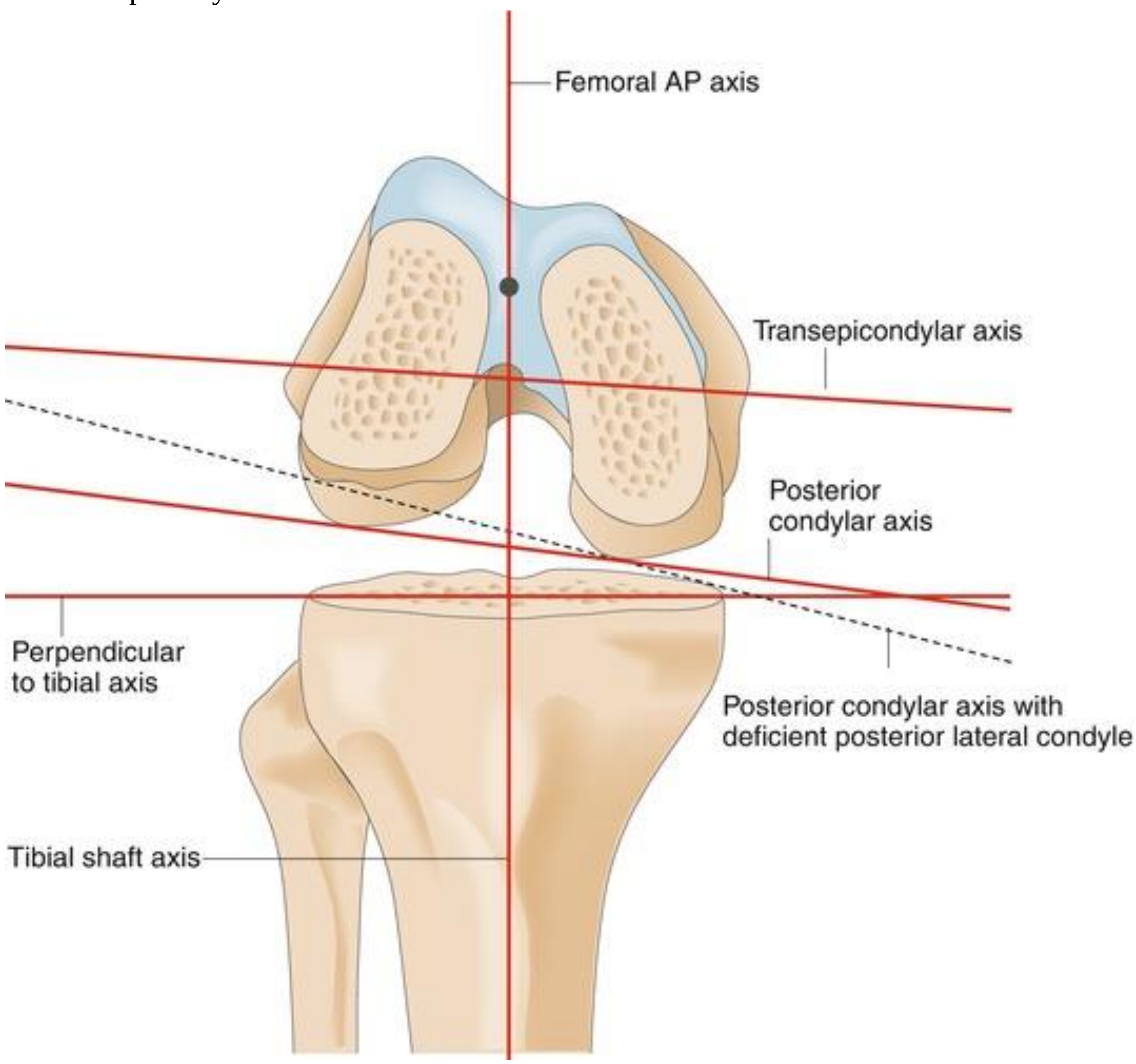
Four bar linkage with oscillation and rotation (*Lab Manual*, 2009)



Appendix C

Sagittal View of Femur and Condyle Axis (Themes, 2016)

The subsequent figure illustrates the major axes of the knee joint such as the transepicondylar axis and tibial shaft axis. The transepicondylar axis is the horizontal line that is located on the condyles of the femur; condyles are protrusions at the end of bones where bones encounter adjacent bones. To create the transepicondylar axis, one must cut horizontally along the condyles of the femur. The tibial shaft axis is the vertical line that runs along the center of the tibia. In addition to the vertical axis, people bisect the tibial shaft axis to create a horizontal axis that is perpendicular to the tibial axis. In Figure 2.9, the top of the “T” may seem to be perpendicular to the tibial axis, but the red line follows the condyles of the femur; therefore, it follows the transepicondylar axis.



Appendix D

Calculations for Height and Weight Ranges

The averages, standard deviation, and sample size were taken from Fryar et al, 2018. The subsequent standard deviations were calculated, where SE is standard error, is standard deviation, and n is sample size. The weight numbers used in range were calculated using ¾ of the standard deviation found.

Height (in)		Average	Standard Error	Standard Deviation	Sample Size	Number used in Range
	Men	69.3	.1	2.97	884	73
	Women	64.0	.2	6.02	907	59
Weight (lbs)						
	Men	196.9	3.1	92.17	884	266
	Women	167.6	2.9	87.34	907	125

Appendix E

Least Squares Calculations

Additional annotations to the calculations have been bolded for clarification.

Output

```
The sum of squared residuals: Gait Angles
ans =
    4.6767

The sum of squared residuals: Healthy v Polycentric Gait
ans =
   10.6114

The sum of squared residuals: Healthy v Single Axis Gait
ans =
    9.5877

The sum of squared residuals: Stairs Ascent Angles
ans =
    3.8941

The sum of squared residuals: Healthy v Polycentric, Stairs Ascent
ans =
    8.1424

The sum of squared residuals: Stairs Descent Angles
ans =
    4.5178

The sum of squared residuals: Healthy v Polycentric, Stairs Descent
ans =
    9.9546

The sum of squared residuals: Gait Cycle Forces
ans =
    1.9213

The sum of squared residuals: Stair Forces
ans =
    1.8537
```

Code

```
% MQP Least Squares evaluation
clear
clc
% for Data sections 1-6, all variables beginning with “k” are literature
values for a healthy knee, “p” are our evaluated prosthetic, “po” is a
standard polycentric knee, “s” is a single axis knee.
%% 1.Stairs Ascent Data:
k1 = [50 45 40 33 25 17 12 7 4 2 0 2 5 17 50 75 93 88 67 53 47]';
```

```
p1 = [48.83333333 42.33333333 36.5 29.83333333 22.16666667 16.83333333
11.83333333 7.5 4.833333333 2.5 -0.1666666667 4.666666667 10.33333333
23.16666667 56.83333333 74.66666667 92.33333333 81.16666667 64.5
50.33333333 44]';
po1 = [50 47.5 42.5 27.5 20 5 3 1 2.5 5 7.5 9 17.5 67.5 82.5 87.5 90 85 65
52.5 50]';
%% 2. Stairs Descent Angles
k2 = [2 6 12 15 14 12 14 17 23 30 44 60 83 93 80 55 30 15 5 1 3]';
p2=[2 6.666666667 12.66666667 17.33333333 13.66666667 11 14.33333333 19
26.33333333 36 53 72.33333333 86.5 96.16666667 73.5 49.83333333
31.33333333 19.66666667 7.833333333 2 4]';
po2=[7.5 10 7.5 12.5 14 15 25 27.5 52.5 70 75 72.5 67.5 55 30 17.5 15 12.5
10 8.5 7]';
%% 3.Gait cycle Forces
k3 =[-1.561421516 -3.643293718 -7.286610588 -13.01177651 -18.73696558 -
19.25743942 -19.77791326 -20.0381386 -20.2983871 -20.0381386 -18.73696558
-11.97085198 -9.108257447 -7.286610588 -5.985414416 -5.725189072 -
5.569053866 -6.505888254 -7.546835931 -9.628731286 -11.71060349 -
13.53225035]';
p3=[-0.834645 -3.746666667 -7.293333333 -13.26666667 -18.73333333 -
20.06666667 -21.2 -21.86666667 -22.2 -21.06666667 -19.53333333 -
12.33333333 -9.066666667 -7.466666667 -6.066666667 -5.933333333 -
6.333333333 -6.6 -7.666666667 -9.666666667 -10.8 -13.73333333]';
%% 4. Stair Forces
k4 = [-4.718986664 -2.775889035 0 0.693966085 -0.6939413895 -2.081885907 -
2.775889035 -9.715549885 -19.43116151 -49.96575568 -54.12958923 -
31.92260043 -19.43116151 -14.85096312 -17.34921386 -20.1251029 -
25.67688097 -31.2285973 -36.08637224 -34.69842772 -18.04321699 -
4.718986664]';
p4 = [-5.333333333 -3.133333333 0 -1.4 -1 -2.133333333 -2.733333333 -
9.733333333 -20.53333333 -48.66666667 -55.33333333 -31.93333333 -20.4 -
14.93333333 -16.86666667 -19.73333333 -25.53333333 -31.8 -35.33333333 -
34.4 -18.4 -4.8]';
%% 5. Gait angles
k5 = [-7 6 17 23 19 12 7 4 1 0 2 5 10 25 39 53 62 63 61 51 33 3]';
p5 = [-7.333333333 3.666666667 13.66666667 24.83333333 17.33333333
12.33333333 6.166666667 3.333333333 1 -1 1.166666667 6.333333333
15.83333333 25.5 38.16666667 48.5 59.33333333 67.33333333 52 37.66666667
22.5 2.166666667]';
%% 6. Polycentric lit, Single Axis lit v Healthy
po6= [0 0 0 0 0 0 0 0 0 0 3 11 46 63 69 59 54 28 9 2 0 0]';
s6= [-1 -1 -1 -1 -2 -2 -3 -4 -4 -3 -2 4 29 45 61 56 41 34 23 8 5 3]';
k6 = [-7 6 17 23 19 12 7 4 1 0 2 5 10 25 39 53 62 63 61 51 33 3]';
```

%In the subtraction step, the difference is evaluated between our baseline healthy knee and the situation we are evaluating for.

```
%% Calculation:
x1 = k1-p1;
x15 = k1-po1;
x2 = k2-p2;
x25 = k2-po2;
x3 = k3-p3;
x4 = k4-p4;
x5 = k5-p5;
```

```
x6 = k6-po6;
x7 = k6-s6;
```

%By evaluating the 2 norm of the matrices formed in the subtraction step and taking the square root of that, we evaluated the sum of squared residuals for that condition.

```
fprintf('The sum of squared residuals: Gait Angles');
norm(x5,2)^.5

fprintf('The sum of squared residuals: Healthy v Polycentric Gait');
norm(x6,2)^.5

fprintf('The sum of squared residuals: Healthy v Single Axis Gait');
norm(x7,2)^.5

fprintf('The sum of squared residuals: Stairs Ascent Angles');
norm(x1,2)^.5

fprintf('The sum of squared residuals: Healthy v Polycentric, Stairs
Ascent');
norm(x15,2)^.5

fprintf('The sum of squared residuals: Stairs Descent Angles');
norm(x2,2)^.5

fprintf('The sum of squared residuals: Healthy v Polycentric, Stairs
Descent');
norm(x25,2)^.5

fprintf('The sum of squared residuals: Gait Cycle Forces');
norm(x3,2)^.5

fprintf('The sum of squared residuals: Stair Forces');
norm(x4,2)^.5
```

Appendix F

Data calculations to determine the percentage of force to place on the prototype

Prototype								
Mass (g)	51	Volume (in^3)	9.3	Surface area (in^2)	54.69	Surface area of base and rocker	2.48	
Mass (lb)	0.34							

	Aluminum		PLA		Stainless Steel		Titanium	
Price ($/lb)	1.08	1.16	1.01	1.7	1.37	1.47	10.3	11.1
Weight/ft^3	168.4931				493.18		283.423	
Density (lb/in^3)	0.0975075810		0.0448		0.2854050926		0.1640179398	
Yield Strength (ksi)	17.1	38.1	7.25	7.98	37.3	165	102	158
Yield Strength (psi)	1710	3810	725	798	3730	16500	10200	15800
Force (lbf) (F)	4240.8	9448.8	1798	1979.04	9250.4	40920	25296	39184
Force based on V (f)	456	1016	193.3333333	212.8	994.6666667	4400	2720	4213.333333
			0.1943699732					
%			19.43699732					

The above calculations determined the percentage of force that once applied to the prototype ensured it could handle the forces of a user going up the stairs when the prototype was made of a material besides PLA. Aluminum, stainless steel, and titanium were chosen as contenders as they are some of the most popular materials prostheses are made of. The forces that each material could handle – based on the volume of material being used – was calculated and compared to the volume of the prototype. Stainless steel was the most cost-effective option whose calculations showed it could handle the maximum forces needed for ascending stairs for a 266 pounds individual. From there, it was determined that PLA can only handle 19% of the forces stainless steel can sustain. Therefore, each force was divided by 19 and those forces were tested under the respective knee flexion angles.